CONTENTS

INSTRUCTIONS

JCA-BM6010/C

AUTOMATIC ANALYZER

ICABM6010/C -4
OCT2011-13110424
Printed in Japan

JEOL
Serving Advanced Technology

CONTENTS

JCA-BM6010/C

AUTOMATIC ANALYZER

Please be sure to read this instruction manual carefully, and fully understand its contents prior to the operation or maintenance for the proper use of the instrument.

JEOL

CONTENTS

NOTICE

- The following actions must be avoided without prior written permission from JEOL Ltd. or its subsidiary company responsible for the subject (hereinafter referred to as "JEOL"): modifying the instrument; attaching products other than those supplied by JEOL; repairing the instrument, components and parts that have failed, such as replacing pipes in the cooling water system, without consulting your JEOL service office; and adjusting the specified parts that only field service technicians employed or authorized by JEOL are allowed to adjust, such as bolts or regulators which need to be tightened with appropriate torque. Doing any of the above might result in instrument failure and/or a serious accident. If any such modification, attachment, replacement or adjustment is made, all the stipulated warranties and preventative maintenances and/or services contracted by JEOL or its affiliated company or authorized representative will be void.
- Replacement parts for maintenance of the instrument functionality and performance are retained and available for seven years from the date of installation. Thereafter, some of those parts may be available for a certain period of time, and in this case, an extra service charge may be applied for servicing with those parts. Please contact your JEOL service office for details before the period of retention has passed.
- In order to ensure safety in the use of this instrument, the customer is advised to attend to daily maintenance and inspection. In addition, JEOL strongly recommends that the customer have the instrument thoroughly checked up by field service technicians employed or authorized by JEOL, on the occasion of replacement of expendable parts, or at the proper time and interval for preventative maintenance of the instrument. Please note that JEOL will not be held responsible for any instrument failure and/or serious accident occurred with the instrument inappropriately controlled or managed for the maintenance.
- After installation or delivery of the instrument, if the instrument is required for the relocation whether it is within the facility, transportation, resale whether it is involved with the relocation, or disposition, please be sure to contact your JEOL service office. If the instrument is disassembled, moved or transported without the supervision of the personnel authorized by JEOL, JEOL will not be held responsible for any loss, damage, accident or problem with the instrument. Operating the improperly installed instrument might cause accidents such as water leakage, fire, and electric shock.
- The information described in this manual, and the specifications and contents of the software described in this manual are subject to change without prior notice due to the ongoing improvements made in the instrument.
- Every effort has been made to ensure that the contents of this instruction manual provide all necessary information on the basic operation of the instrument and are correct. However, if you find any missing information or errors on the information described in this manual, please advise it to your JEOL service office.
- In no event shall JEOL be liable for any direct, indirect, special, incidental or consequential damages, or any other damages of any kind, including but not limited to loss of use, loss of profits, or loss of data arising out of or in any way connected with the use of the information contained in this manual or the software described in this manual. Some countries do not allow the exclusion or limitation of incidental or consequential damages, so the above may not apply to you.
- This manual and the software described in this manual are copyrighted, all rights reserved by JEOL and/or third-party licensors. Except as stated herein, none of the materials may be copied, reproduced, distributed, republished, displayed, posted or transmitted in any form or by any means, including, but not limited to, electronic, mechanical, photocopying, recording, or otherwise, without the prior written permission of JEOL or the respective copyright owner.
- When this manual or the software described in this manual is furnished under a license agreement, it may only be used or copied in accordance with the terms of such license agreement.

- In some cases, this instrument, the software, and the instruction manual are controlled under the “Foreign Exchange and Foreign Trade Control Law” of Japan in compliance with international security export control. If you intend to export any of these items, please consult JEOL. Procedures are required to obtain the export license from Japan’s government.

TRADEMARK

- Windows is a trademark of Microsoft Corporation.
- All other company and product names are trademarks or registered trademarks of their respective companies.

MANUFACTURER

JEOL Ltd. 1-2, Musashino 3-chome, Akishima, Tokyo 196-8558 Japan
Telephone: 81-42-543-1111 Facsimile: 81-42-546-3353 URL: http://www.jeol.co.jp/

Note: For servicing and inquiries, please contact your JEOL service office.

Please be sure to read carefully the following Software License Agreement before using the software supplied by JEOL Ltd. If you do not agree to the terms and conditions of the Agreement, please do not use the software and contact JEOL Ltd.

Software License Agreement

This Software License Agreement is made and entered into by and between you, the end-user customer, and JEOL Ltd. (hereinafter referred to as JEOL) in witness of agreement between both parties upon licensing of the right to use the software (which is hereinafter referred to as the Licensed Software) owned by JEOL.

Article 1. (Right to Use Licensed Software)

"Right to Use the Licensed Software" means your right to use the Licensed Software in the country where the JEOL product you purchased is installed (hereinafter referred to as Country of Installation).

Article 2. (Grant of License)

1. JEOL grants you the non-exclusive and non-assignable right to use the Licensed Software in the Country of Installation.
2. You may install and use the Licensed Software on a single computer limiting the purpose to carrying out of your job.
3. You may not cause any third party to use the Licensed Software by establishing a sublicense or other means, and shall not disclose the Licensed Software to any third party.
4. You may not take the Licensed Software out of the Country of Installation under any circumstances.

Article 3. (Prohibition of Assignment and Other Acts)

1. You may not assign, rent or lease the right to use the Licensed Software, disclose the content of the right, or transfer possession of the Licensed Software to any third party.
2. You may not modify, translate, carry out reverse engineering, decompile, and disassemble the Licensed Software in whole or in part.

Article 4. (Prohibition of Reproduction)

You may not reproduce the whole or any part of the Licensed Software.

Article 5. (Rights to Licensed Software)

All rights related to the Licensed Software including copyrights belong to JEOL.

Article 6. (Warranty)

1. JEOL does not guarantee proper performance of the Licensed Software if it is modified or translated.
2. JEOL does not warrant that the Licensed Software is free from defects or fit and useful for your particular purpose.

Article 7. (Exemption from Liability)

JEOL shall not be liable for any damages or losses incurred by you or any third party or for any claim of a third party against you arising out of or in relation to the use of the Licensed Software.

Article 8. (Confidentiality)

You shall keep confidential the content of the Licensed Software supplied hereunder by JEOL and the terms and conditions of this Agreement, and shall not divulge or disclose them to any third party without the prior written consent of JEOL.

Article 9. (Term of Validity)

1. This Agreement shall become effective as of the day you accept the terms hereof and so remain unless it is terminated pursuant to the next Article.
2. Notwithstanding the item above, the provisions set forth in the Article 8 (Confidentiality) shall remain effective even after the termination hereof.

Article 10. (Termination)

In any of the following event, JEOL may forthwith terminate this Agreement by so notifying you without any prior notification and may claim the damages incurred:

(1) Any breach on your part of any of the provisions hereof,

(2) Occurrence of seizure or provisional seizure or provisional injunction on your property; auctioning of your property; bankruptcy, corporate liquidation, and filing for corporate reorganization on your part; or proceedings taken against you for collection of tax delinquency.

Article 11. (Steps to Be Taken after Termination)

Upon the termination of this Agreement pursuant to the Item 1 of Article 9 and Article 10, you shall destroy the Licensed Software and notify JEOL of such destruction.

Article 12. (Discussion in Good Faith)

Matters not stipulated herein shall be discussed in good faith and settled between you and JEOL.

WARRANTY INFORMATION

1 Limited Warranty

Products manufactured by JEOL Ltd. (hereafter “JEOL products”) that fail under normal use by the customer during the warranty period will be repaired or replaced, at JEOL’s discretion, without charge.
The components, modules and devices that are provided as replacements will be new parts or refurbished parts that provide the same performance as new parts. All components, modules and devices removed under this warranty become the property of JEOL.

1.1 Applicable Products

- This warranty applies only to hardware and software products manufactured by JEOL Ltd.
- For components that are not JEOL products, such as the computer, HDD, memory device, and the like, the warranty provisions of the respective manufacturers shall apply.

1.2 Warranty Period

- In the case of products for which the warranty period is recorded in the contract documentation, the recorded warranty period shall take precedence.
- If not specifically stated elsewhere, the warranty period is 12 months or a separately specified period from the date on which the acceptance test is completed after delivery to the customer.
- For components that are not JEOL products, like the computer, HDD, memory device, and the like, the warranty start date shall be the date on which the acceptance test is completed after delivery to the customer and the warranty periods established by the respective makers shall apply.
- In the event that parts are replaced or repaired free of charge during the warranty period, there is no change to the warranty start date or the warranty period for the product.

1.3 Scope of the Warranty

■ Failure diagnosis

If a problem occurs, contact your JEOL service office and describe the conditions and content of the problem. JEOL will assess the problem based on the situation and content of the problem.

■ Repair method

If it is determined that the problem is caused by a fault or defect of a JEOL product, repair or replacement will be performed free of charge. The choice of whether to repair or replace a component is entirely at the discretion of JEOL.

■ Warranty exclusions

This limited warranty does not extend to products for which any of the following situations apply. Even within the warranty period, in the situations listed below, a fee will be charged to repair the product.

- Product is operated or stored in an environment or under conditions that do not satisfy the specified installation requirements.
- The installation environment has changed (temperature, humidity, magnetic fields, etc.) since the time of installation.
- There is significantly accelerated deterioration of components and/or corrosion of electrical circuitry as a result of exposure to extreme temperature, humidity, or an environment containing highly-corrosive gases or excessive dust.
- The quality of the utilities (including electricity, water, gas, air quality) has worsened.
- The customer has relocated an installed instrument.

- Even in the case of a portable or movable instrument designed to be transported to a remote location or moved around for use by the user, damage or failures caused during the instrument relocation by the customer.
- Product has not been properly maintained.
- Consumable items or parts with the specified replacement period have not been replaced as specified.
- Corrupted operating system or application software, or damaged computer used with the instrument, caused by shutting down the main power to the computer without performing the proper shutdown sequence.
- Products that have been disassembled, modified or repaired by the customer in ways other than those specified in the instruction manuals provided with the instrument.
- Products with damage or failure caused by using them in combination with hardware, software, peripheral devices, and accessories that have not been provided or approved by JEOL.
- Damage or failure resulting from a situation caused by the customer, such as failing to properly manage the instrument, for which JEOL cannot be held responsible.
- Corruption of the operating system or application software, or damage to a computer used with the instrument, caused by fluctuations in the electricity or power failure.
- Product damaged as a result of fire, earthquake, flooding, lightning or other natural disaster, or due to local conflict or war.
- Damage or malfunction of operating system, application software, or the instrument itself as a result of infection by a computer virus.
- Instruments that have been restored after being disposed of or re-sold without prior written notice to and agreement from JEOL.

1.4 Items Not Covered by Warranty

- Regardless of whether a product is still within the warranty period, this warranty does not cover losses or damage to devices made by any other manufacturer at the customer site even if they are damaged by a malfunction of the JEOL product.
- JEOL is not responsible for any loss or damage to data recorded onto storage media, or to storage units. The customer is responsible for making back-up copies of their own data.
- Replacement parts for maintenance of the instrument functionality and performance are retained and available for seven years from the date of installation. Thereafter, some of those parts may be available for a certain period of time. Please contact your JEOL service office for details before the period of retention has passed.
- For items that are frequently updated, remodeled, or disappear from the market, like the computers used with the JEOL products, it may not be possible to obtain an exact replacement.

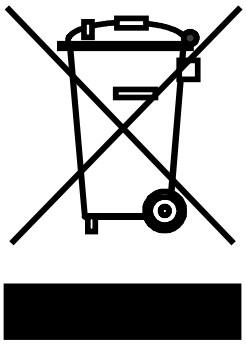
2 Repairs for a Fee

Repairs of JEOL products are available with charges after the end of the warranty period, or at anytime a customer requests. The components, modules and devices that are provided as replacements during the paid repair work will be new parts or refurbished parts that provide the same performance as new parts. All components, modules and devices removed during such repairs will become the property of JEOL.

- The warranty period for parts replaced and the service during paid repair work is a period of 3 months after the completion of the repairs; or, in the case of parts that must be periodically replaced, the warranty period is the length of the specified replacement period.
- In the event that repairs are performed again during the warranty period, there is no change to the warranty start date or the warranty period.

Notes on Disposal for Business Users

Attention:
Your product is marked with this symbol. It means that used electrical and electronic products should not be mixed with general household waste. There is a separate collection system for these products.



■ In the European Union

This symbol means that electrical and electronic equipment, at the end of its life, should be disposed of correctly.

In the European Union there is a separate collection system for used electrical and electronic products. Please help us to conserve the environment we live in!

Electrical and electronic appliances and machines often contain materials which, if handled or disposed of incorrectly, are potentially hazardous to human health and to the environment. They are, however, essential for the correct functioning of your appliance or machine. Therefore, please do not dispose of your old machine or appliance together with your household waste.

Your JEOL product is designed and manufactured with high-quality materials and components which can be recycled and reused. If the product is used for business purposes and you want to discard it, please contact your JEOL dealer, who will advise you about the end-of-life disposal arrangements.

■ Outside the European Union

If you wish to discard this product, please contact your local authorities and ask for the correct method of disposal.

NOTATIONAL CONVENTIONS AND GLOSSARY

■ Examples for general notations

: Important precautions for use, which, if not followed, may result in damage to or problems with the device itself.


: Additional points to remember regarding the operation.


: A reference to another section, chapter or manual.

CONTENTS

SAFETY PRECAUTIONS

Although this instrument is protected with a safety device which prevents the occurrence of accidents that could result in injury, harm, and damage to the users or the instrument itself, the safety feature may not work properly if you use the instrument for a purpose not intended or in an improper manner. For the proper use of the instrument, please be sure to carefully read all of the instructions, descriptions, notices, and precautions contained in this manual to understand them fully prior to the operation or maintenance. This section, "Safety Precautions," contains important information related to safety for using of the instrument.

The safety indications and their meanings are as follows:

⚠ **DANGER:**	An imminently hazardous situation which, if not avoided, will result in death or serious injury.
⚠ **WARNING:**	A potentially hazardous situation which, if not avoided, could result in death or serious injury.
⚠ **CAUTION:**	A potentially hazardous situation which, if not avoided, may result in minor or moderate injury, or a situation that could result in serious damage to facilities or acquired data.

Labels bearing the following symbols are attached to dangerous locations on the instrument. Do not touch any of these locations with your hands or anything else.

Pay extra attention when you work in the area that has "Beware of handling" label. Make sure to refer to the relevant section in the Instruction Manual for more detail.

Examples of symbols

- **Use the instrument properly within the scope of the purpose and usage described in manuals.**

- **Take the course provided by JEOL on the operation and maintenance of the instrument.**

- **Use extracorporeal diagnostic agents as the regents for measurement.**

- **Never open or remove protective parts (exterior panels) and parts that cannot be opened or removed without the use of a tool, or disconnect or connect the cables and connectors that are not described in this manual.**

- **Never attempt to do any disassembling or assembling of the instrument other than what is described in this manual.**

- **Never make modifications that include disassembling the instrument and installing substitute parts.**

- **Never disconnect the grounding wire or move it from the prescribed position. Failure to follow this instruction could result in electric shock.**

- **The AC power cord provided with this system is supplied for the particular device so that never use it for any other equipment.**

- **To avoid falling, do not climb onto the operation table and console during daily operation or during maintenance or inspection.**

- **When you dispose the instrument, liquids, and other wastes, follow all applicable laws and regulations, and dispose them in a proper manner without polluting the environment.**

- **Be sure to read the "Safety Precautions" section of the manuals for the accessories attached to or built into the instrument.**

- **If anything is unclear, please contact your JEOL service office.**

⚠ WARNING for Installation

- **Do not attempt to install the instruments by yourself.**
  Installation work requires professional expertise and JEOL is responsible for the installation of the instruments and related attachments purchased from JEOL.
  Consult your JEOL service office.

⚠ WARNING

- **Never use the equipment in an environment where there is an ignitable gas or an anesthetic gas. This equipment is not built to be explosion-proof.**

- **If you replace the unit with new one for maintenance or other operations, be sure to turn off the power or power breaker of the analyzer.**
  If you continue working while the power is turned on or in the PC CONTROL status, you may get a shock, or the electrical devices or parts may get damaged.

- **Only operators who have received JEOL's maintenance training can carry out dangerous maintenance work such as that performed with the top cover open and by turning on or off the main power of the instrument. Be sure to wear insulating gloves.**

- **To protect yourself against infection, be sure to use protective gloves. If protective gloves are torn or if you injure yourself anyway, please receive a doctor's diagnosis.**

- **If any liquid, including reagents, wash solutions and Cuvette Conditioner EX and Reaction Bath Oil, or effluent solution gets in your eye, you risk a loss of eyesight or an infection. Wash your eyes immediately using pure water (tap water is also acceptable), and receive a doctor's diagnosis.**

- **If water or reagent enters the instrument, immediately turn off the power or the power breaker of the analyzer. Before replacing a unit having a power cable (for example, in order to carry out maintenance), turn the OPERATE/STANDBY switch OFF(◯) or turn OFF the MAIN power switch(◯) on the analyzer unit. If you work with the OPERATE/STANDBY switch ON(⊙) or the MAIN power switch ON (\|), you may receive an electric shock or the printed circuit boards may be damaged.**

- **When you deal with corrosive reagents or infection samples, be sure to wear protective equipment or clothes.**
  Your skin may get damaged or infected.

- **Before you clean the outside panels, be sure to turn off (Ⓞ) the operate/standby switch of the analyzer unit power panel.**
  If you clean them while the operate/standby switch is turned on (⊙), the gauze you are using may be caught in the cooling fan and you may get injured.

- **Before you clean the inside of the MIX wash port, be sure to turn off (Ⓞ) the operate/standby switch of the analyzer unit power panel.**
  If you continue operating the instrument while the power is turned on and you touch it, you may get injured, or you may get infected with a virus or a bacterium in the serum.

- **Before you clean the filter of the cooling part, be sure to turn off (Ⓞ) the operate/standby switch of the analyzer unit power panel.**
  If you continue operating the instrument while the power is turned on and you touch it, you may get injured, or you may get infected with a virus or a bacterium in the serum.

- **Before you clean the waste fluid lines of the probes and Mix wash ports, be sure to turn off (Ⓞ) the operate/standby switch of the analyzer unit power panel.**
  If you continue operating the instrument while the power is turned on and you touch it, you may get injured, or you may get infected with a virus or a bacterium in the serum.

- **If there is a possibility that the unit may start moving suddenly, be sure to turn off (Ⓞ) the operate/standby switch of the analyzer unit power panel.**
  If you continue operating the instrument while the power is turned on, the unit may move, and you may get injured, or it may get damaged.

- **Before you clean the cooling fans, be sure to turn off (Ⓞ) the operate/standby switch of the analyzer unit power panel.**
  If you perform the task while the power is turned on, you may receive an electric shock or may injure yourself with the fans.

- **While you operate the instrument, its probes and the Tray may move. Be careful not to touch these parts.**
  If you touch the instrument while it is being operated, you may get injured or infected by a bacterium or a virus in the serum, or the probes or the Tray may be damaged.

- **When you replace parts or perform maintenance in high places, stand on a step and ensure your safety before starting work.**

- **If you turn off the power while performing any operations including maintenance, probes may droop under their own weight.**
  If you turn on the power while the probes are drooping, they may move, and you may get injured, or the instrument may be damaged.

- **Do not use the equipment in the event that an earthquake warning has been issued. In the event that an earthquake has occurred, be sure to carry out a safety check on the equipment and confirm that there is nothing wrong with it.**
  If you fail to do this, the equipment may malfunction and you may be unable to obtain correct data.

- **When you replace the light source lamp, be sure to turn the power off for 10 minutes before you replace it with a new one.**
- **Right after you turn off the power, the lamp house is really hot and you may get burnt.**

- **Use the equipment while fixing the STT splashing cover with the screw except when performing maintenance. If you touch the moving parts in the STT splashing cover, you may be injured or infected. Close the STT splashing cover except when performing maintenance. Fasten the retainer screw of the STT splashing cover so it cannot be opened except for the person who received maintenance training from JEOL.**

- **Be sure to open and close the top cover correctly. If opening and closing the top cover are not done correctly, the top cover could accidentally fall down.**

- **Ethanol used for system cleaning is a combustible. Please do not use it if there is a possibility of igniting when using it in the high temperature part. Also, be careful, do not pour ethanol into the instrument.**

- **Probe Wash Solution 2 is a class 3,6,1 (Flammable, acute toxicity material) hazardous material. Do not use the material for a purpose other than for BM Chemistry operation/maintenance.**

- **Risk of Biohazard. Strictly follow the instructions by JEOL when transporting or disposing of the analyzer.**

⚠ CAUTION

- **Dispose appropriately any parts, such as sample tubes and stirring rods that have directly touched the sample and parts or units to which the sample may have spread and adhered as medical waste. Also, dispose appropriately any cloth and paper used for cleaning as medical waste.**

- **In maintenance work, if you directly touch the parts and units with your hands, the parts and units may rust or be stained by the dirt on your hands. Moreover, if you directly touch wash solutions, Cuvette Conditioner EX or Reaction Bath Oil with your hands, they may cause a skin inflammation. In maintenance work, be sure to use protective gloves.**

- **Please do not use replacement parts and that are not recommended by JEOL.**
  The performance of the instrument will not be maintained. Also, it may result in the breakdown of the instrument.

- **On holidays and at night when there is no user, make sure that you close the water tap.**
  Water leakage from the connection due to pressure increases can damage the instrument or nearby equipment.

- **Do not expose your eyes to the laser beam.**
  The laser beam is not harmful to the skin. There is, therefore, no danger in exposing your arms or hands to the beam. The only possible health hazard is the exposure of your eyes to the laser beam. Damage to the eyes can occur if the operator stares directly into the beam.

- **Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.**

- **Before operating the equipment, ensure that the top cover is properly closed. Also, be sure to close all the covers.**
  If you operate the equipment with the top cover open, or with a cover removed, you may injure yourself, or the equipment may stop or become damaged.

- **If power fails, for example, due to lightning, or you reset the personal computer, restart the computer according to the procedure described in the instruction manual, as the normal start-up operation will result in the loss of the day's data.**

- **Please use the detergents recommended by JEOL.**
  If you use detergent not recommended by JEOL, the instrument may be damaged, and you may not attain correct data.

- **If you use your keyboard for a long time, your hands or arms may suffer from a nerve disorder. Operate the instrument following the labor safety and health standards established at each institution.**

- **Install the equipment in a place that meets the following requirements:**
  a) A dust-free, well-ventilated place.
  b) A place that is not exposed to direct sunlight.
  c) A place where there is no vibration.
  d) A place where the equipment can be installed on a level surface.
  e) A place that is free of electrical noise.
  f) Do not run the equipment with a power supply to which a machine that emits high-frequency electrical noise (such as a centrifugal separator or discharge equipment) is connected. Also, do not install the equipment near such a machine.

- **Do not put hands or objects on the trays or the conveying belts, and do not remove the rack-feeding tray forcefully, while performing the rack feeding.**
  It is very dangerous, since you may get injured or the instrument may be damaged.

- **Cuvette Wash Solution, Reagent Probe Wash 1 and Reagent Probe Wash 3 are class 8 (Corrosive) hazardous materials.**

- **Different kinds of screws are used in the materials and standards in this instrument depending on their purpose. When assembling the instrument, be sure to use the screws in their original positions. If you lose the screws, please ask for replacements from the JEOL service center.**

- **When you set samples and reagents, make sure that the loader is properly set on STT/RTT and the samples and reagents are firmly set on the loader.**

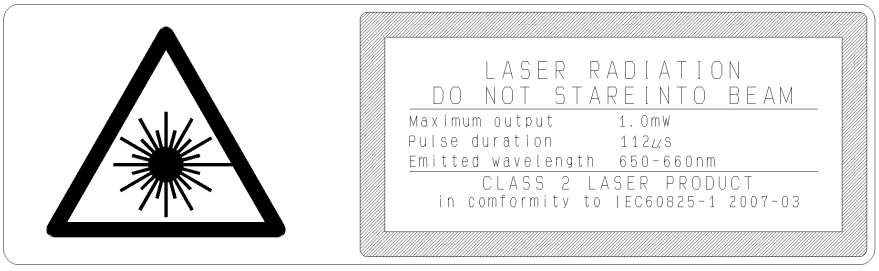
WARNING AND CAUTION LABELS

The warning and caution labels attached to the instrument are explained.

■ Rear panel

- **Laser beam**

Be careful with the laser beam that is inside the panel.
Location: ①RTT1, RTT2 and STT/CTT at analyzer front



- **Electric shock**

Be careful so you do not receive an electric shock caused by the high voltage. Turn off the main breaker before you do any maintenance or repairs on the instrument.
Locations: ③ rear panel

- **Infection**

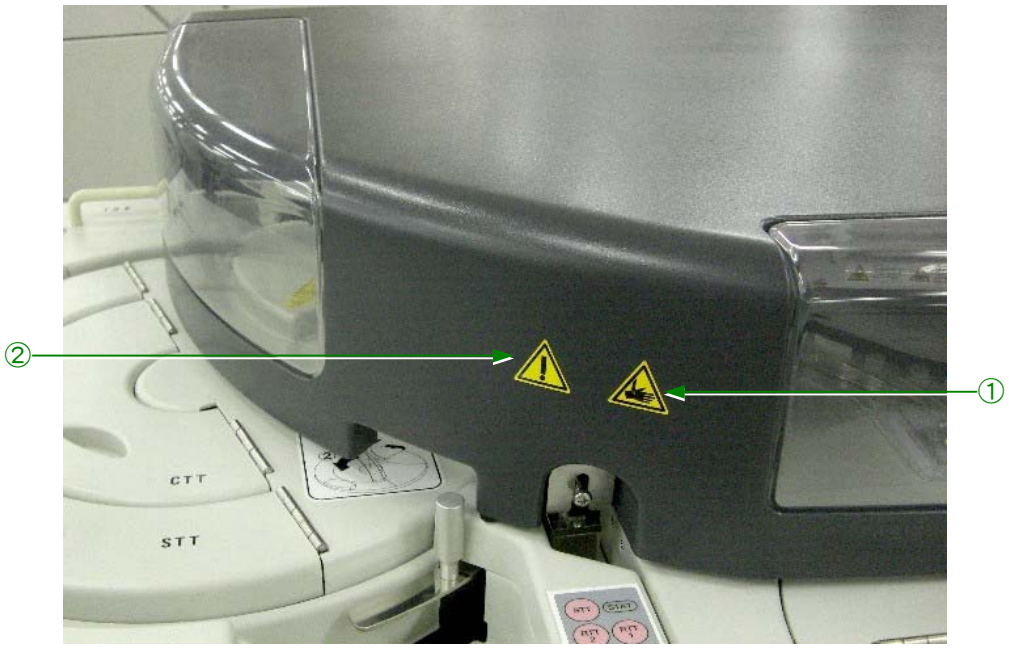
Be careful so you do not receive an infection. The waste fluid might contain infectiious agents.
Locations: ② condensed effluent tube

- **Caution: Outlet Rating**

This analyzer is rated at 100V 7.5A as stated on the label.
Do not use the analyzer with the voltage more than 100V 7.5A..
Location: ④ rear panel

After turning off the power, wait for three minutes or longer before turning on the power again.
Location: ⑤ rear panel

■ Cover on top panel



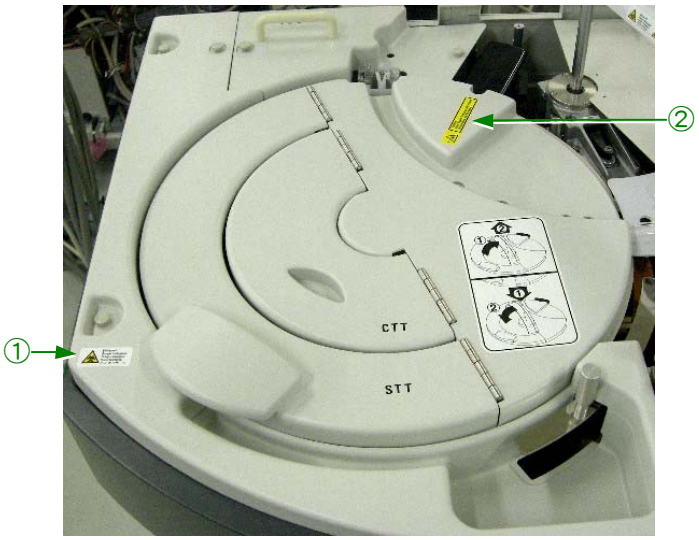
- **Your fingers might be caught**

If the damper of the top cover malfunctions, your fingers might be caught by the cover and be injured.
Location: ① cover on the top panel

- **Caution:**

When opening or closing the top cover, be aware that some unit or part may be in operation and may suddenly move.
Location: ② Analyzer Top Cover

■ Sample tray

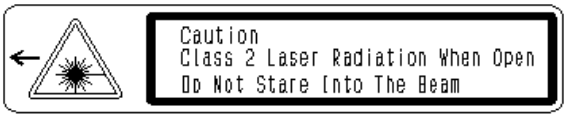


- **Infection**

The instrument might contain infectious agents inside of this cover. Handle the samples with care so that you are not infected.
Location: ① sample tray

- **Laser beam**

Be careful with the laser beam that is inside the cover.
Location: ② Sample Tray

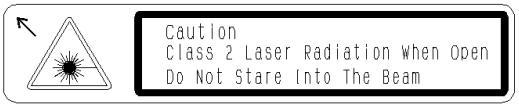


■ Reagent tray cover

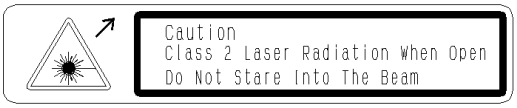
- **Laser beam**

  Be careful with the laser beam that is inside the cover.

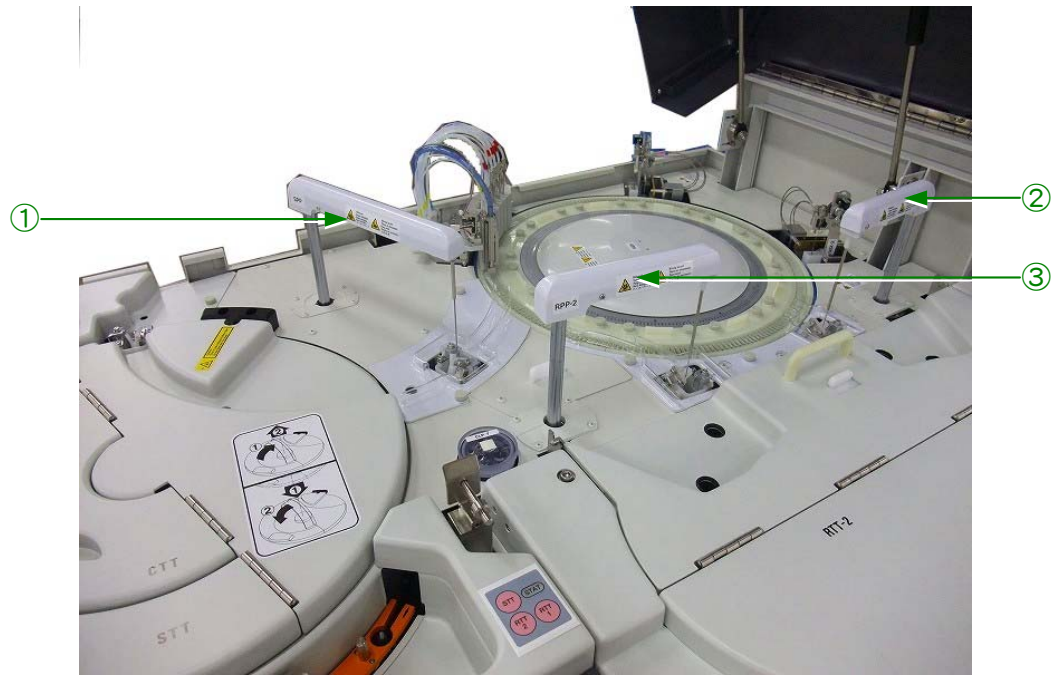
Locations: ① Reagent Tray 1



Locations: ② Reagent Tray 2



■ SPP, RPP 1, RPP 2



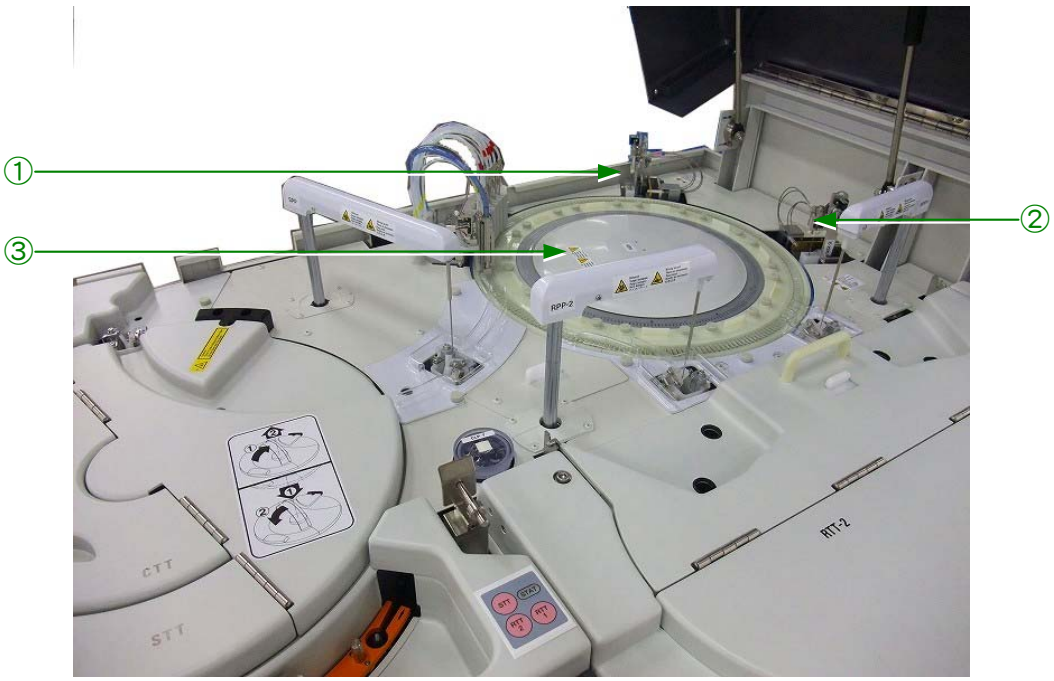
- **Risk of injury**

  Do not touch the probes, sample tubes or cuvettes while the Sample Tray or Reaction Carousel is in operation.

- **Infection caution; unit containing infectious agents moves**

  The unit that might contain infectious agents moves. Refer to the instruction manual when you do any maintenance such as replacement and cleaning.
  Locations: ① SPP probe, ② RPP probe 1, ③ RPP probe 2

■ RRV, MIX 1, MIX 2



- **Risk of Electric Shock**

Do not touch the centre of RRV (③) and Mixing Rods (① and ②) when the analyzer power is on. You may receive an electric shock.

- **Risk of Electric Shock**

Do not touch the metal part under the RRV (③) top cover. You may receive an electric shock.

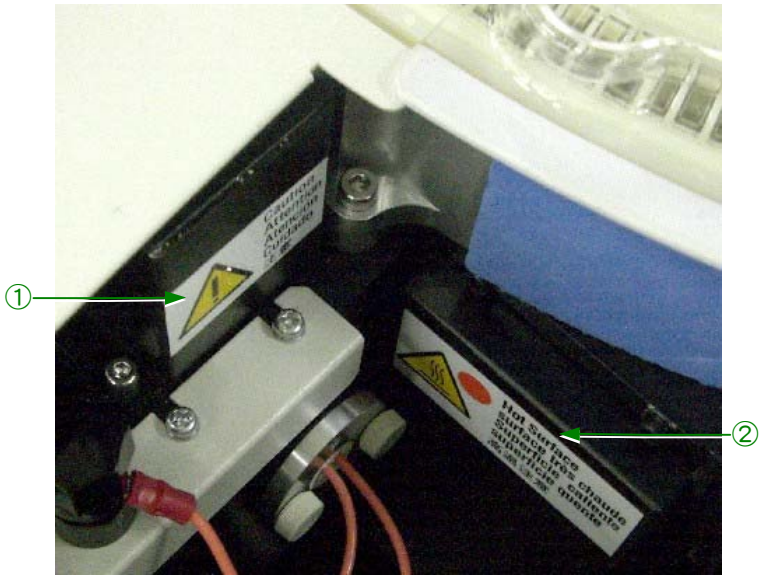
- **Caution: Some Unit may be in operation**

Do not touch the Reaction Carousel while the analyzer is in operation

- **Infection caution; unit containing infectious agents moves**

The unit that might contain infectious agents moves. Refer to the instruction manual when you do any maintenance such as replacement and cleaning.
Locations: ① MIX 1, ② MIX 2, ③ RRV

■ Lamp



- **Caution**

A lamp inside of this cover might be damaged if a strong shock is applied on it. Refer to the instruction manual when you do any maintenance such as replacement of the lamp.
Location: ① lamp housing

- **High temperature**

Be careful not to touch the lamp inside of this cover while it is hot, If you touch, you might get burned.
Location: ② optical unit

PRECAUTIONS FOR USE

Parameters for assays must be entered in this system. Use those values of the parameters, such as sample volumes, reagent volumes, measurement wavelengths, and calibrator that accompany reagents and reference samples. Enter these values correctly according to the procedures in the instruction manual.
Should a failure that is not described in this instruction manual occur, turn off the power immediately and contact JEOL.

■ Precautions for handling samples

- Do not leave samples uncovered for a long time because evaporation could take place. Handling samples improperly may change the composition of samples due to evaporation.
- Confirm that there are no fibrins or dirt in the sample. If the sample contains them, the diluting pipettes (SPP) or dilution tubes will become clogged, preventing correct data from being obtained.
- The SPP or dilution system tubes can become clogged with samples having high viscosity, preventing the acquisition of correct data.
- When blood-collecting tubes containing serum separators are used, the SPP or dilution system tubes can become clogged with separation agents, preventing the acquisition of correct data.
- If you use bar codes on blood-collecting tubes, correctly stick the bar codes that can be read clearly on them. To prevent the bar codes from being read incorrectly, it is recommended that you use barcodes with check digits.
- This system is designed to analyze serum, urine, and spinal fluid. However, some samples cannot be analyzed depending on the assay items or reagents. Consult the reagent manufacturer on this matter.

■ Precautions to be observed when handling measurement reagents

- Use or keep measurement reagents, reference solution, samples used for management correctly according to the instructions of the reagent manufacturers.
- Do not add or replace a measurement reagent during operation.
- When adding or replacing a measurement reagent, make sure to perform calibration again.
- When refilling a measurement reagent, use a clean container exclusively for that reagent.
- When replacing a major component in the sample or reaction system, such as a dilution pump, sampling pump, reagent pump, or light-source lamp, make sure to perform calibration.
- One reagent may interfere with another one depending on the combination of assay items, influencing measurement values, or causing a malfunction of the equipment due

to deposition produced by mixing with the waste liquid. Consult the reagent maker on the interfering items.

- Install the measurement reagents in the correct positions.
  The wrong position produces incorrect data and can cause a malfunction of the equipment.

- Store opened or unopened measurement reagents according to the instructions of reagent makers. If reagents are not stored properly, correct data may not be obtained even within the effective period.

■ Caution for handling solutions

Cuvette Wash Solution 7	For in vitro diagnostic use as a cleaning agent on BioMajesty systems. **Composition and ingredients:** Sodium Hydroxide, 4.0% Wear proper protective equipment to avoid contact with skin or inhalation of the vapor. **Disposal consideration** Residual disposal: Dilute the chemical with a large amount of water and flush in a drain after neutralizing with diluted acid. Or entrust approved waste disposal companies with the disposal. Containers : In case of disposal of empty bottles, dispose bottles after removing the content thoroughly.
Cuvette Conditioner EX	For in vitro diagnostic use as a cleaning agent on BioMajesty systems. **Composition and ingredients:** Surfactant Wear proper protection equipment. Avoid contact with skin and eye. This product may discolor or cause rust on metal. **Disposal consideration** Dispose residual product with plenty of water. If substantial volume needs to be disposed, entrust approved waste disposal companies with the disposal .
Lamp Coolant C	For in vitro diagnostic use as a lamp coolant on BioMajesty systems. **Composition and ingredients:** Organic acid, Organic nitrogen compound, Alcoholic compound Do not inhale mist or spray. Wear proper protection equipment. Avoid contact with skin and eye. **Disposal consideration** Dispose of residual product with plenty of water. If substantial volume needs to be disposed, entrust approved waste disposal companies with the disposal .
Reagent Probe Wash K	For in vitro diagnostic use as a cleaning agent on BioMajesty systems.

Composition and ingredients: Sodium Hydroxide, 2%
Wear proper protective equipment to avoid contact with skin or inhale the vapor.
Disposal consideration
Residual disposal : Dilute the chemical with a large amount of water and flush in a drain after neutralizing with diluted acid. Or entrust approved waste disposal companies with the disposal.
Containers : In case of disposal of empty bottles, dispose bottles after removing the content thoroughly.

Reagent Probe Wash S

For in vitro diagnostic use as a cleaning agent on BioMajesty systems.
Composition and ingredients: Potassium hydroxide 4.5%, Sodium polyacrylic acid 4.0%, Sodium hypochlorite 4.7%, Surfactant
Do not inhale mist or spray.
When handling in a room, make sure that there is adequate ventilation in the room and maintain the concentration under indicative concentration.
Wear proper protection equipment.
Avoid contact with skin and eye.
For normal use, only adequate general ventilation is required.
Handle the product with care.
Do not drop the product.
Disposal consideration
This product is chlorite alkaline solution. Dispose the product with plenty of water or neutralize it with acid after dechlorination with sodium thiosulphate (Hypo), then dispose it with plenty of water. If substantial volume needs to be disposed, entrust approved waste disposal companies with the disposal

Reagent Probe Wash 1

For in vitro diagnostic use as a cleaning agent on BioMajesty systems.
Composition and ingredients: Sodium Hydroxide, 3.6%
Wear proper protection equipment.
Do not inhale mist or spray.
Avoid contact with skin and eye.
For normal use, only adequate general ventilation is required.
Handle the product with care.
Do not drop the product.
Disposal consideration
This product is alkaline. Dispose residual product with plenty of water or antalkaline with acid substance, then dispose of it with plenty of water. If substantial volume needs to be disposed, entrust approved waste disposal companies with the disposal.

Reagent Probe Wash 2	For in vitro diagnostic use as a cleaning agent on BioMajesty systems. **Composition and ingredients:** Oxalic acid 3.0%, Hydroxyacetic acid 20.0%, Methyl alcohol 4.8%, PEG-400 3.0% Do not inhale mist or spray. Wear proper protection equipment. Avoid contact with skin and eye. For normal use, only adequate general ventilation is required. Handle the product with care. Do not drop the product. **Disposal consideration** This product is acid. Dispose the product with plenty of water or neutralize it with alkaline substance, then dispose it with plenty of water. If substantial volume needs to be disposed, entrust approved waste disposal companies with the disposal.
ISE Detergent Solusion	For in vitro diagnostic use in the quantitative determination of certain electrolytes in human serum, plasma and urine on BioMajesty system. **Composition and ingredients:** Sodium hypochlorite 6.0% Wear appropriate protection equipment. Avoid contact with eye and skin. Avoid inhalation of vapor. Ensure that the work area has adequate local ventilation/general ventilation. Avoid spillage. Do not eat and drink or smoke while handling this product. Avoid contact with skin/eye, inhalation or ingestion. Wash hands after handling the product. **Disposal consideration** Dispose residual product in an appropriate method in accordance with the relevant law, rules and regulation.
ISE Buffer (IS)	For in vitro diagnostic use in the quantitative determination of certain electrolytes in human serum, plasma and urine on BioMajesty system. **Composition and ingredients:** Formaldehyde < 1.0%, Phosphate < 1.0%, Triethanolamine < 2.0% Wear appropriate protection equipment. Avoid contact with eye/skin and inhalation of gas. Ensure that the work area has adequate local ventilation/general ventilation. Avoid spillage.

	Avoid contact with skin/eye, inhalation or ingestion. Wash hands after handling the product. **Disposal consideration** Disposal of residual product : Dispose residual product in an appropriate method in accordance with the relevant law, rules and regulation. Contaminated container and wrapping: Dispose any contaminated container and wrapping in accordance with the relevant law and the regulations by local authorities.
Internal Standard Solution	For in vitro diagnostic use in the quantitative determination of certain electrolytes in human serum, plasma and urine on BioMajesty system. **Composition and ingredients:** Formaldehyde < 0.1% Wear appropriate protection equipment. Avoid contact with eye/skin and inhalation of gas. Ensure that the work area has adequate local ventilation/general ventilation. Avoid spillage. Avoid contact with skin/eye, inhalation or ingestion. Wash hands after handling the product. **Disposal consideration** Disposal of residual product : Dispose residual product in an appropriate method in accordance with the relevant law, rules and regulation. Contaminated container and wrapping : Dispose any contaminated container and wrapping in accordance with the relevant law and the regulations by local authorities.
ISE Serum Standard Solutions	For in vitro diagnostic use in the quantitative determination of certain electrolytes in human serum and plasma on BioMajesty system. **ISE Serum High Standard** **Composition and ingredients:** Formaldehyde 0.1%, Na+ 160mmol/L, K+ 6mmol/L, Cl- 120mmol/L, Preservative **ISE Serum Low Standard** **Composition and ingredients:** Formaldehyde 0.1%, Na+ 130mmol/L, K+ 3.5mmol/L, Cl- 85mmol/L, Preservative Wear appropriate protection equipment. Avoid contact with eye/skin and inhalation of vapor. Ensure that the work area has adequate local ventilation/general ventilation. Avoid spillage. Do not eat and drink or smoke while handling this product. Avoid contact with skin/eye, inhalation or ingestion. Wash hands after handling the product. **Disposal consideration**

Residual disposal : Dispose residual product in an appropriate method in accordance with the relevant law, rules and regulation.
Contaminated container and wrapping : Dispose any contaminated container and wrapping in accordance with the relevant law and the regulations by local authorities.

ISE Urine Standard Solutions

For in vitro diagnostic use in the quantitative determination of certain electrolytes in human urine on BioMajesty system.
ISE Urine High Standard
Composition and ingredients: Formaldehyde 0.1%, Na+ 200mmol/L, K+ 100mmol/L, Cl- 180mmol/L, Preservative
ISE Urine Low Standard
Composition and ingredients: Formaldehyde 0.1%, Na+ 50mmol/L, K+ 10mmol/L, Cl- 50mmol/L, Preservative
Wear appropriate protection equipment.
Avoid contact with eye/skin and inhalation of vapor.
Ensure that the work area has adequate local ventilation/general ventilation.
Avoid spillage.
Do not eat and drink or smoke while handling this product.
Avoid contact with skin/eye, inhalation or ingestion. Wash hands after handling the product.
Disposal consideration
Residual disposal : Dispose residual product in an appropriate method in accordance with the relevant law, rules and regulation.
Contaminated container and wrapping : Dispose any contaminated container and wrapping in accordance with the relevant law and the regulations by local authorities.

■ Precautions concerning data

In order to measure a sample with this equipment, measurement reagents, reference solution, samples used for management are required. Make inquiries concerning the use of these reagents and samples to the respective reagent makers.

- Use reagents and reference solutions made exclusively for electrolyte (Na, K, Cl) measurements.
- Follow the instructions of the reagent makers for the timing and frequency of calibration, and the use of reference solutions.
- When measuring a sample, use a management sample to monitor the condition of the equipment in real time at suitable intervals.
- If abnormal color appears during sample testing, pay attention to the possibility of interference or influence on the measurement data.

- Data of a patient who is taking certain medications may show a higher or lower value than the actual value. Access the information from the maker beforehand. If the patient is treated based on the higher or lower value falsely measured, the treatment may result in a critical condition.
- When cleaning the equipment, use the specified detergents.
- If an abnormal value appears in the measurement data, confirm the reaction process and repeat the measurement.
- Samples with abnormal values that are extremely high may have carryover. Please pay attention to the values of the next sample and the one in the dilution container.
- Do not change (delete) the contents of your requests during analysis. It may result in inconsistency between sample numbers.

Precautions concerning water supply and drain

- Handle the demineralizer correctly according to the instruction manual.
  If the purity of the water supplied from the demineralizer to the Analyzer Unit deteriorates, data can be influenced.
- Process waste liquid suitably according to water-pollution prevention ordinances and all related regulations.
  Treat reagents containing substances regulated by pollution-prevention ordinances and drainage standards after consulting the makers.

Precautions concerning loss of data and parameters

- Especially when starting the system, be sure to operate the system correctly.
  Mistakes can cause loss of data.
- Be sure to back up the setting parameters.
  Various types of setting parameters may be lost or irrecoverable due to misoperation or breakdown of the equipment.
- Do not load software on the hard drive other than the software specified by JEOL.
  To do so can cause a malfunction, resulting in loss of data.

Notes on storing the instrument

- If you have not operated the instrument for a long time, wash the lines and reaction tubes well enough. Also, pay attention to any liquid leakage from each part.
- If there is a possibility of frost, drain the water from instrument, and inspect it before operation.
- Be aware of biohazard risk. Wear appropriate protection and operate the analyzer with care.
- If the analyzer is used in a manner not specified by JEOL, the protection provided by the analyzer may be impaired.

■ Precautions concerning the cleaning of the panels

- If a large amount of serum, hazardous materials or water is splashed on the system, stop it and turn off the power at the main breaker. You must use ethanol to remove the contaminant from the system.
- For the purpose of cleaning the analytical console's panels and safety covers, use water or ethanol. Other solutions might peel off the paint, corrode and dissolve some part of the system's panels and safety covers. Contact your service office authorized by JEOL whenever you are unclear about any operation or maintenance.

■ Decontamination and Cleaning

- Appropriate decontamination is carried out if hazardous material is spilt onto or into the equipment.

  ☞ Decontamination is described in the following procedures. To perform decontamination, be sure to wear gloves. First, wipe the dirty surface of a sample well. Next, use a lint free cloth, and wipe the surface where the sample is adhering. Lastly, wipe the same surface well with another lint free cloth impregnated with 5% sodium hypochlorite solution.

- Do not use decontamination or cleaning agents which could cause a HAZARD as a result of a reaction with parts of the equipment or with material contained in it.
- Should you wish to use any solution other than solutions specified by JEOL for wash or decontamination, please contact JEOL.

■ Notes to transport and/or store the system.

- If you transport or store the system by a method other than that recommended by JEOL, then JEOL will not bear any responsibility for erroneous results reported by the system or problems with the units on the system.
- If you have further questions, please contact local service center.
- If the system will be stopped for long period of time, take the necessary actions, like removing water from the system.

■ Correspondence for a breakdown and an abnormality

- If an equipment breakdown or abnormality occurs, please turn off the MAIN power supply. And, contact your service office authorized by JEOL.

■ Precautions concerning the disposal of the device

- Please process it according to the guidelines of the laws, ordinances, and so forth when you dispose the device.
- Contact your service office authorized by JEOL whenever you are unclear about any operation or maintenance.

■ Emergency Procedures

To stop the operation after the analyzer has started

To avoid possible injury and damage to the analyzer, make sure that all probes and mixers can move without any obstruction and that all analyzer covers are in place.

1. At the bottom of the power panel, press the **System Stop** button.

2. Click **INITIALIZE**
3. If reagents were dispensed, you must perform a Weekly Wash2 before resuming operation. Load Reagent Probe Wash-S (5% solution) into, RTT1-49 ,RTT2-49.

To manage an expected power outage

If you know in advance of an upcoming power outage:

1. Turn off the workstation and analyzer power by performing the normal shutdown.
2. If you expect the power supply to be off for a long period of time, remove the reagents in RTT1 and RTT2 and refrigerate them.
3. When the power returns, perform the normal startup operation.

To respond during a power failure-power is still off

While the electrical power is still off:

1. Turn **OFF** the workstation power switch.
2. At the power panel, set the **OPERATE/STANDBY** switch to **STANDBY**.

When the electrical power returns:

1. Turn **ON** the workstation power switch.
2. When the Startup window appears, turn the **OPERATE/STANDBY** switch to **OPERATE.**
3. On the **Startup** window, click **Re-Start**, enter user name and password, then click **OK**.
4. Repeat the task prior to the power failure and verify that the data were stored.
5. If reagents were dispensed, you must perform a Weekly Wash2 before resuming operation. Load Reagent Probe Wash-S (5% solution) into, ,RTT1-49 ,RTT2-49.

To resume after a power failure-power is restored

1. If the **Startup** window is open, click **Shutdown.**
2. When prompted by “It is now safe to turn off your computer,” turn off the workstation power and turn the **OPERATE/STANDBY** switch to **STANDBY.**
3. After approximately 20 seconds, turn on the workstation power.
4. Perform the normal startup operation.
5. If reagents were dispensed, you must perform a Weekly Wash2 before resuming operation. Load Reagent Probe Wash-S (5% solution) into, RTT1-49 ,RTT2-49.
6. If possible, repeat the last task prior to the power failure, and verify that any data generated were stored properly.

■ Notes on Electromagnetic waves

This instrument complies with the emission and immunity requirements described in the IEC61326-2-6：2005.

Warning
This equipment has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference.

Caution
The electromagnetic environment should be evaluated prior to operation of the equipment.

Caution:
Do not use this equipment in close proximity to sources of strong electromagnetic radiation, as these may interfere with the proper operation.

■ When the analyzer remains unused for a long period

When the analyzer remains unused for a long period (more than 3 days), there is a risk that the detergent lines for WUD become dry and may cause clogging.
In order to avoid such damage on the analyzer, please follow the steps before and after leaving the analyzer unused.

● Before turning off the analyzer for a long period

a. Perform WASH2 to complete washing when the routine operations are over.
b. Remove the aspiration line from the cuvette conditioner bottle and the cuvette wash solution bottle in the detergent compartment. Rinse the lines with pure water and then put them in a beaker filled with 500ml of pure water. Cover the bottles if there is some solution left in them.

Note: **IMPROTANT: Do not drain the Reaction Bath Oil.**

c. Perform WASH3 (washing only with water).
d. When WASH3 is completed, fix the aspiration lines back to the bottles where they were originally installed.
e. Cover the top of detergent and reagent bottles set on the reagent trays with some plastic film. (Make sure to remove the plastic film when you restart the analyzer.)
f. Perform Shutdown.

Note: **Do not perform Auto-Startup.**

● Before starting up the analyzer again

a. Check that there are no crystals on the tip of WUD nozzles.
Check the second port/red 2 (cuvette wash solution), and the fourth port/red 4 (cuvette conditioner).

Note: **If there are any crystals or clogging, remove the WUD unit (with one Allen screw) and feed a wire through the nozzle tips from the bottom of the nozzles to remove any crystals or clot. (Do not remove the connection joint.)**

b. Startup the analyzer.

c. Remove the plastic film that has covered the top of the detergent and reagent bottles on RTTs.
d. Perform PRIME1.
e. Perform WASH3. When WASH is started, observe the WUD movement to ensure that no line comes off from WUD and there is no leak from there.
f. Run a routine analysis.

■ Air Bubbles in the Reaction Bath

The analyzer uses dedicated Reaction Bath Oil (inert oil) so that no air bubbles are generated in the Reaction Bath.
However, it is important for the analyzer to have adequate supply of the Reaction Bath Oil to stablize the test result.
Please check the Reaction Bath Oil status in the [System Monitor] window when you start up the analyzer.

Note: Refer to Chapter 1 in 'Basic Operations' for the startup operations.

IMPORTANT INFORMATION RELATED TO USE AND MANAGEMENT

- The customer is responsible for maintaining and managing the delivered equipment.
- Be sure to store important data in a clinical chart, notebook or external memory device.
- Only doctors and legally qualified persons are allowed to use this equipment.
- This equipment is intended to provide doctors with data required for diagnosis.
- Do not modify or change this product (including software).
- The useful life span of this product is seven years from the date when you started to use it (when it was installed).
- Subsequent to the explanation of the warranty period, after-sale service is available for a fee.
  For after-sales service, consult your nearest service center.
- If it is necessary to move or transport this equipment after delivery to your site, we can do this for a fee.
  In order to prevent any problems from occurring when the equipment is being moved or transported, be sure to consult your nearest service center.
- This instruction manual contains warnings concerning dangers that JEOL considers could conceivably arise. However, be very careful of any other dangers that may arise as well.
- Maintenance and operation of the system must be performed by the personnel who have completed JEOL's official training and have sufficient knowledge of the system's dangers.
- Contents of the safety precautions must be observed strictly.
- Do not use any parts other than those recommended by JEOL.
- If the analyzer is used in a manner not specified by JEOL, the protection provided by the analyzer may be impaired.

EXEMPTION CLAUSES

- It is important to maintain the equipment in a very safe and reliable condition.
  From manufacturing to installation, JEOL puts every effort into implementing integrated quality control, to ensure that the equipment can be delivered to the customer in as safe and reliable a condition as possible.
  However, once the equipment has been delivered to the customer, the customer is responsible for maintaining and managing the equipment.
  JEOL can carry out maintenance and inspection of the equipment for a fee subsequent to the expiration of the warranty period.
- When using this equipment for clinical examinations, use it under the supervision of a doctor or clinical technician.
  This instrument aims to provide a doctor with data to be used for diagnosis. JEOL will not bear responsibility for secondary damage due to diagnosis results or data obtained when the equipment is used.
- JEOL will not bear responsibility for any breakdown or damage due to installation, moving, maintenance, or repair carried out by a person other than JEOL's service engineer or designated engineer.
- JEOL will not bear responsibility for loss of data stored in the equipment as a result of misoperation or an unforeseen accident. Store your important data on recording media such as medical records, notes, or floppy disks.
- JEOL will not bear responsibility for any injury or infectious disease caused by transportation or disposal without supervision by a JEOL representative.
- JEOL will not bear responsibility for the equipment breaking down or becoming damaged due to another company's equipment not delivered by JEOL.
- JEOL will not bear responsibility for any breakdown or damage caused by maintenance or repair carried out using spare parts not specified by JEOL.
- JEOL will not bear responsibility for any breakdown or damage caused by use of the equipment in a country not specified by JEOL.
- JEOL will not bear responsibility for any breakdown or loss of data due to failure of the user to observe the safety precautions and operation instructions described in this instruction manual.
- Be careful about receiving an infection with a computer virus via your recording media including USB memory.
  The PC that comes with this instrument has been checked for viruses, and it is not infected with a virus. However, if you use recording media including USB memory, check your PC for viruses using antivirus software or other software, and using it is your responsibility. JEOL will not bear responsibility for the instrument that stopped operating due to the use of recording media infected with a virus.

CONTENTS

Chapter

1 Overview and Main Features of BM6010/C

1.1 Overview

The analyzer system JCA-BM6010/C is a compact and high-performance analyzer of chemistry and electrolyte components of human blood and urine samples. The system comprises two units: the analyzer (left) and the workstation (right). The analyzer can be used standalone or in combination with a third-party laboratory automation system.

BM6010/C System

Main Features

Reagent pickup type

- Single line, full random access

Throughput

- 1200 tests/hour for chemistry and ISE analysis combined.
  (Chemistry tests only: 800 tests/hour, ISE tests only: 600 tests/hour)

Ultra micro reagent volume

- Minimum reagent volume needed for measurement: 80 µl

Flexible capability for analyses

- Up to three-part reagent analysis is possible
- Specialized diluent can be used (i.e. for immunoassay tests)

Data credibility assured

- Number of measurement points: 63 (with reaction time of 15 minutes)
- Mixing by rotation and repeated left-right movement of the rod
- Reaction process monitoring with 14 wavelengths
- Three dimensional reaction monitoring

Enhanced usability

- Automatic calibration
- Automatic startup/shutdown
- Automatic rerun
- Automatic avoidance of using cuvettes with cuvette blank error
- STAT port

High productivity

- Reflex test
- Reagent probe/cuvette contamination avoidance
- Reaction Check Logic function
- Sample carryover avoidance

1.2 Components

The standard BM6010/C system includes the following components.

Standard components

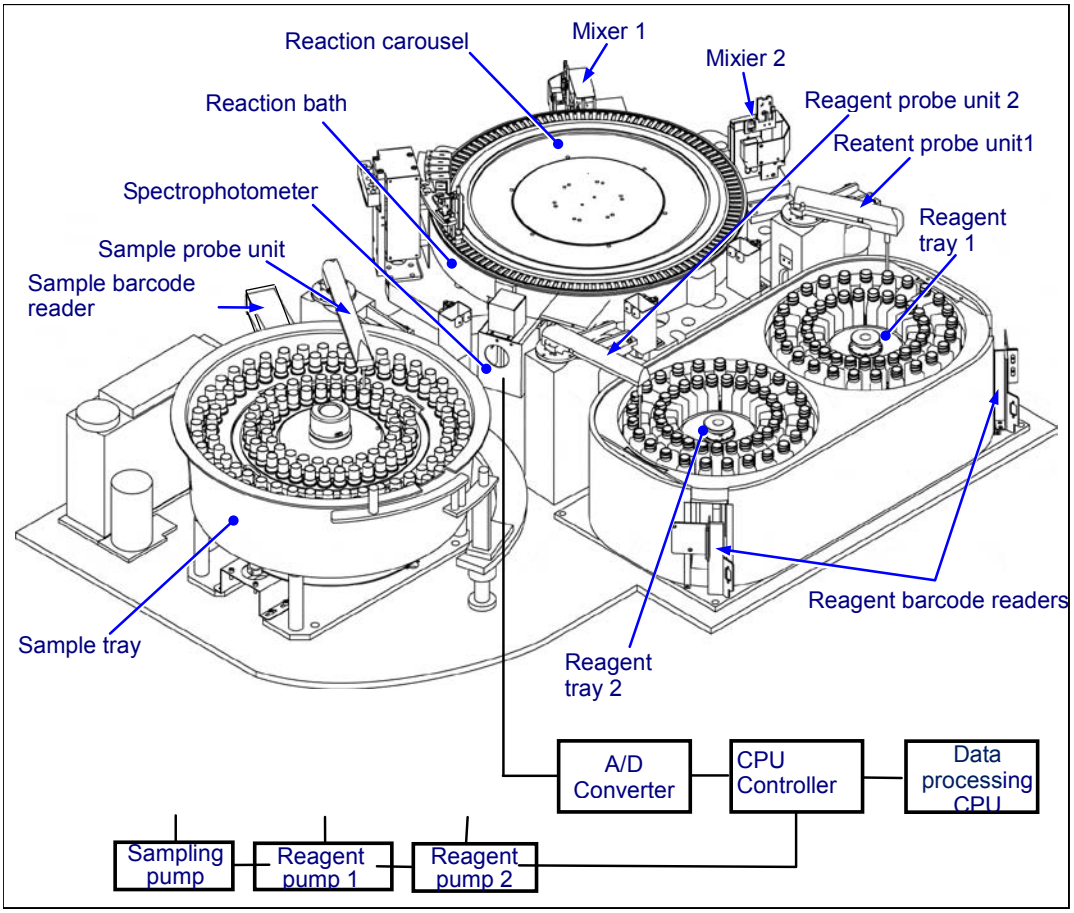
Analyzer

- Analyzer main unit (1)
- Reaction tray (RTT) cover (1)
- Sample tray (STT) and cooling tray (CTT) covers
- Bottles for cuvette detergent, cuvette conditioner, and reaction bath oil.
- Sample tray loader (STT) (1)
- Cooling tray loader (CTT) (1)
- Reagent tray 1 loader (RTT1) (1)
- Reagent tray 2 loader (RTT2) (1)
- Splash cover (1)
- Ion selective electrode (ISE) unit (1)

1 set of Accessories

1.3 Operation Principle

The operation principle of the BM6010/C system is as follows:



Operational schema of BM6010/C

The reagent probe (RPP) dispenses reagent 1 (R1) from reagent tray 1 (RTT1) to a clean reaction cuvette on the reaction carousel (RRV).

The sample probe (SPP) dispenses the sample in the quantity required for the test from the sample tray (STT) into the RRV now containing R1.

Sample dilution is possible if necessary. The diluent is placed in the RTT and dispensed into the reaction cuvette. Next, the sample is dispensed into the same cuvette by the SPP and mixed with the mixing rod. Now the diluted sample is in the reaction cuvette. The SPP dispenses the diluted sample in the reaction cuvette in which R1 required for the test has already been dispensed.

The dispensed sample and R1 are mixed in the reaction cuvette. Next, reagent 2/2e (R2/R2e, see '1.4.2: Three-part Reagents' for details on reagents) is dispensed from the RTT as required. The contents are then mixed for the length of time required by the test. Photometric measurement data is collected by the spectrophotometer every 13.5 minutes to calculate concentration at each measurement point, which are posted to the workstation.

The reaction cuvettes are washed with detergent and tepid water and blank measurement is performed for each wavelength.

1.4 Functional Features

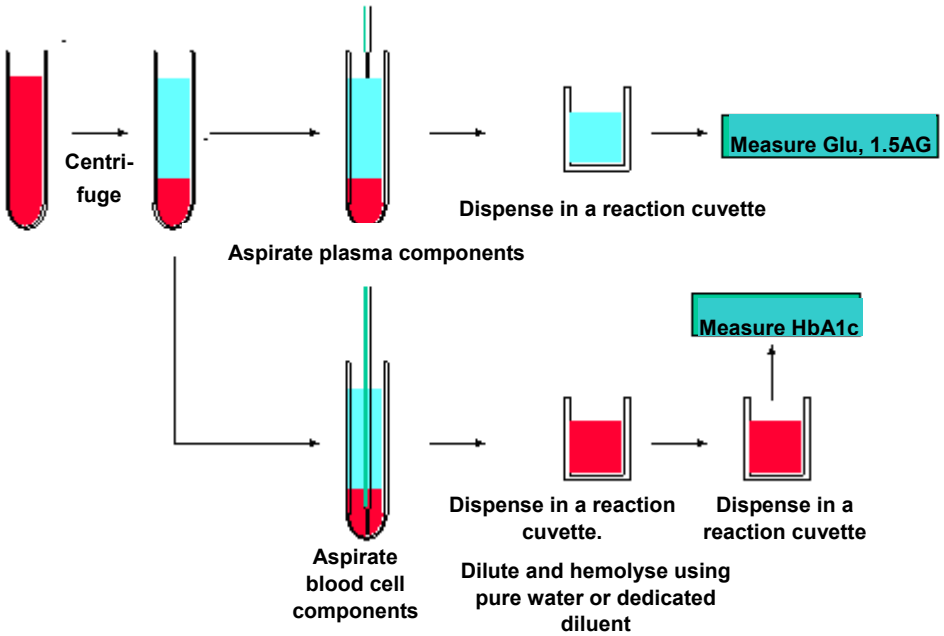
1.4.1 Simultaneous measurement of blood cell components (HbA1c) and plasma components

Hemolysis of the sample is required to measure HbA1c in an automatic chemistry analyzer.

BM6010/C has automatic on-board hemolysis function to enable high-throughput simultaneous measurements of plasma components (glucose, 1.5 AG, etc.) and blood cell components (HbA1c) of the blood sampled from a single tube. This procedure is called "simultaneous measurement" which is a special characteristic of the BM6010/C automatic analyzer.

The blood sample, which is collected in a tube with anti-coagulant, needs to be centrifuged first, then decapped to be loaded on the analyzer. The sample probe (SPP) aspirates the sample in accordance with the settings for the sample and assays to start the tests. The sampling order for simultaneous measurement is illustrated in the following diagram:

Sampling order during simultaneous measurement



1 Serum / plasma component measurement: sampling of the upper phase of the sample tube.

The sample probe (SPP) descends toward the sample surface. When the sensor detects the sample surface, SPP stops descending and aspirates the sample from the surface.

2 Washing the SPP.

The SPP returns to the wash port and descends by 15mm. The outer surface of SP is washed with wash solution in the wash port.

3 Dispensing of the sample into the reaction cuvette

The SPP dispenses the sample in the reaction cuvette, in which reagent 1 (R1) has already been dispensed. The analyzer starts running general chemistry analysis

4 Washing the SPP.

The SPP returns to the wash port and descends by 15mm. The outer surface of SPP is washed with wash solution in the wash port.

5 Blood cell component measurement: sampling of the lower phase of the sample tube.

The SPP descends near the bottom of the tube to aspirate the blood cell component sample.

6 Washing the SPP.

The SPP returns to the wash port and descends by 60mm. The outer surface of SPP is washed with wash solution in the wash port.

7 Hemolysis of the sample.

The SPP dispenses the sample in the reaction cuvette, in which the lysis solution has already been dispensed.

8 Washing the SPP.

The SPP returns to the wash port and descends by 15 mm. The outer surface of SPP is washed with wash solution in the wash port.

9 The hemolysed sample is dispensed into another reaction cuvette to measure HbA1c.

The SPP aspirates the hemolysed sample and dispenses it into a reaction cuvette, in which R1 has already been dispensed. The analyzer starts running HbA1c analysis.

Throughput

Maximum 800 tests / hour

The HbA1c test involves hemolysis of the sample in a reaction cuvette prior to the measurement. The hemolysis procedure requires the time equivalent to that of a serum test (4.5 sec.). Therefore, one HbA1c analysis requires time equivalent to that for 2 tests (4.5 sec. for hemolysis and 4.5 sec. for the actual HbA1c analysis = 9.0 sec.), making the throughput for HbA1c is 400 tests per hour.. When running a combination of a general chemistry test and HbA1c measurement, the throughput becomes 600 test per hour, running 2 tests in the time required for 3 tests.

1.4.2 Three-part reagents

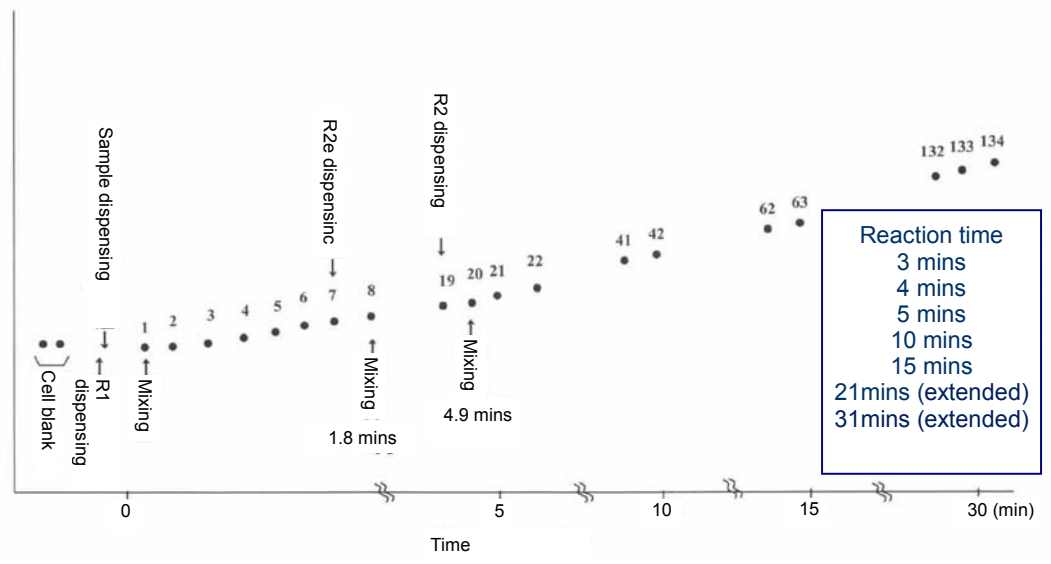
The analyzer can run tests with up to three-part reagents. The reagents are dispensed at the timing of measurement points shown below.

Reagent Probe 1 (RPP1) dispenses Reagent 1 in a reaction carousel (RRV) cuvette from the Reagent Tray 1 (RTT1). Reagent Probe 2 (RPP2) dispenses Reagents 2e and 2 from the Reagent Tray 2 (RTT2) in the RRV cuvette. Reagent 1 is required for any reaction; reagents 2e and 2 are configured as required by each assay.

In order to se up R2e and R2, log on as 'manager' and select [Setup] > [Analytical Parameters (Chemistry)]. ('Manager' can edit user-defined tests.) Enter the required volume for both [R2e Volume], [R2 volume], [R2e diluent volume] and [R2 diluent volume] in the [Analytical conditions] column.

For two-part reagent tests, enter "0" for [R2e volume] and [R2e diluent volume].

The graph below shows an example of a test time course.



Time course of a test with BM6010/C

1.4.3 Diluting the sample

Dilution Steps:

Fill the reagent bottle with diluent and set it on the reagent tray 1 (RTT1).

If the sample does not need to be diluted, the reagent probe 1 (RPP1) dispenses the reagent 1 (R1) in a cuvette in the reaction carousel (RRV); then the sample probe (SPP) dispenses the sample into the cuvette.

If the sample needs to be diluted, diluent, instead of R1, is first dispensed in the cuvette. Then, the sample is added to the cuvette to make a diluted sample. The mixing rod 1 (MIX1) mixes the diluted sample and the cuvette comes again to the sample dispensing position. SPP aspirates the diluted sample and dispenses it in another cuvette, into which R1 has already been dispensed.

Then, MIX1 mixes the mixture again. If the assay requires R2e and R2, they are dispensed and mixed in accordance with the settings.

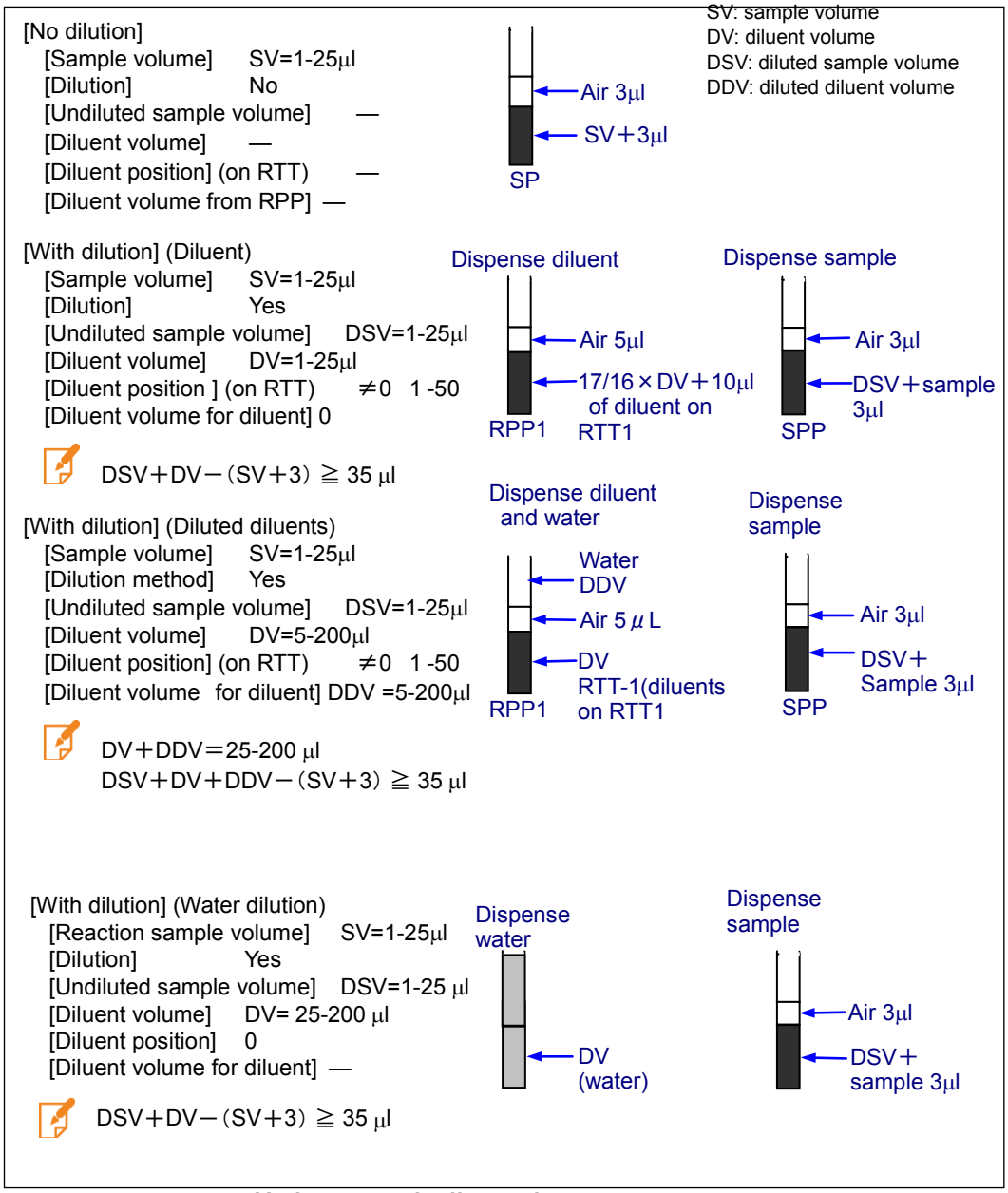
Setting up sample dilution

Open [Setup] > [Analytical Parameters (Chemistry)] to set up the parameters.

Click the [Analysis item condition setting (M)] button or [Rerun conditions] button and select "With dilution" for the [Dilution method] field.

The sample is diluted according to the values set in the [Undiluted sample volume], [Diluent volume], and [Diluent volume from RPP] fields.

Examples of sampling for sample dilution are shown below:



Various sample dispensing patterns

Dilution conditions (M, D1, D2, D3, D4)

Setting "No sample dilution"

The samples are not diluted in most of routine tests. To set "no sample dilution" for a test, select [Analytical Parameters (Chemistry)] > [Analysis test condition setting (M)] button, and select “No dilution” for [Dilution method]. When registering tests for a sample in the [Request] > [Order Entry] window, select “1: M Cond.” for [System Dilution Mode].

Setting "with Dilution" for a test

If a test requires sample dilution for all samples, select [Analytical Parameters (Chemistry)] > [Analysis test condition setting (M)] button, and select "With dilution"

for [Dilution method]. Set appropriate values for [Undiluted sample volume], [Diluent volume], [Diluent position], and [Diluent volume].

When registering this type of test for a sample, select [Request] > [Order Entry], and select "1:M Cond." for [System Dilution Mode].

Setting "with Dilution" only for the samples with high result value for some test

For the samples that are already known to have high values for certain tests, sample dilution can be set up for initial run.

Select [Request] > [Order Entry], then select [With dilution] for [System Dilution Mode] and select an option from [D1 Cond.]-[D4 Cond.].

To set multiple dilution conditions for a sample, click [Multi. Dil.] button in the [Order Entry] window and set the required dilution conditions by clicking [M], [D1], [D2], [D3], and [D4] buttons. When you set multiple dilution conditions for a sample, the sample volume and reagent volume are dispensed for each condition as configured in the setting..

1.5 Specifications

1.5.1 Specifications of the analyzer

The specifications of the analyzer are summarized in the following table.

The installation conditions will be presented separately in section 1.6.

Item	BM6010/C
Size	1220 (W) ×850 (D) ×1108 (H) cm
Weight	450 kg
Power source	AC200, 220, 230 or 240V±10%, 50/60Hz, A ground must be installed near the breaker. 2.6 kVA
Water Consumption	20 L/hour
Measurement method	
Chemistry	Open discrete Single-line, simultaneous, multi-item measurement
ISE	Na, K, Cl ion selective electrolyte assay Dilution measurement method Simultaneous measurement of serum and urine samples
Test throughput	
Simultaneous chemistry and ISE measurement	Maximum 1200 tests / hour
Chemistry alone	Maximum 800 tests / hour
ISE alone	Maximum 600 tests / hour
Sample throughput	
Simultaneous chemistry and ISE measurement	Maximum 800 samples / hour
Chemistry alone	Maximum 800 samples / hour
ISE alone	Maximum 200 samples / hour
Number of test items	
Simultaneous chemistry and ISE measurement	Maximum 103 test items Routine 45 chemistry test items＋3 ISE test items
Sample parameter / processing unit	
Sample types measured	Serum and urine
Tray	Sample tray (STT): 2 rows (42 samples each = 84 total samples) Barcode reader for sample ID Cooling tray (CTT) used for calibrators, controls, and diluents with 61 total available positions. Point-in-space sampling for laboratory automation system (optional)

Item	BM6010/C
Barcode reader	Class 2 laser product Maximum output 1.0mW, pulse duration 112μs, emitted wavelength 650-660nm
Dispensed sample volume	1 - 25μl (0.1 μl increments)
Sample dilution	Reaction cuvette is used for sample dilution
Dilution ratio	1 - 200X
Dilution patterns	Maximum 5 patterns of dilution available for the initial run and rerun Different diluents and different dilution ratio can be used for a primary sample
Rerun	Primary sample in the STT is used for rerun
Liquid level sensor	Incorporated
Reagent parameter / processing unit	
Dispensing system	3-part reagent capability, 2 probes
Trays	Two trays, 45 positions each
Container capacity	20, 40, and 70 mL
Refrigerator	All reagents
Reagent volume per test	5 - 300 μL
Dispensing increments	0.1μL
Reagent remaining volume	Calculated based on the liquid level sensor detection result
Reagent barcode	Standard barcode system for reagent containers of automatic analyzers specified by the Japan Analytical Instrument Manufacturers' Association
Barcode reader	Class 2 laser product Maximum output: 1.0 mW, Pulse duration: 112 μs, Emitted wavelength: 660 nm, Class 2 laser product or Maximum output: 1.5 mW, Pulse duration: 65 μs , Emitted wavelength: 650 nm, Class 2 laser product
Reaction parameter / processing unit	
Reaction tray	Turntable style
Reaction cuvette material	Plastic
Cuvette light path length	10 mm
Reagent volume	80 - 430 μl
Stirring system	Rotation and reciprocation with vibration cleaning Stirring immediately after additions of samples and reagents (R2e、R2)
Reaction time	3, 4, 5, 10, or 15 minutes
Reaction temperature	37°C
Reaction bath	Inert liquid circulation method

Item	BM6010/C
Reagent drain	A drain line available for concentrated waste fluid with the optional dedicated bottle
Measurement parameter / processing unit	
Measurement method	Reaction point measurement
Measurement point	63 measurement points, 1point per 13.5 seconds in 15 minute reaction
Photometer	Concave diffraction grating, rear spectroscopy system
Measurement wavelength	14 fixed wavelengths between 340 - 884 nm; 1 or 2 wavelengths are used for calculation
Light source	Halogen lamp with cooling system
Assay method	Photometric assays • Endpoint assay (EPA) • Reaction rate assay (RRA) • 2-point rate assay (2PA) • Constant rate assay (CRA) • Immunoassay (IMA) • 3-test simultaneous measurement (parameter independent) • Prozone detection • Point forwarding in rate assay • Sample blank correction
Rerun system	Automatic or manual (selectable)
Automatic correction	Blood serum blank, cell blank, measurement point change, sample volume change in rerun
Maintenance (including ISE unit)	
Automatic maintenance	Auto startup and shutdown scheduled by weekly timer
ISE	Na, K, Cl ion selective electrolyte assay Dilution measurement method Simultaneous measurement of serum and urine samples
Analysis	
ISE	Simultaneous measurement of 3 test items
Mode	2 modes, either serum or urine
Data processing	Correction available for serum and urine modes respectively. Other types of result processing are available including “ratio” parameters, flag display, and statistical calculation.
Electrode	
Na:	Crown ether membrane
K	Crown ether membrane
Cl	Super-layer solid molecule orientation membrane
reference	Sealed silver/silver chloride electrode
Sample	
Measurable samples	Serum, Urine
Sample volume	22 µL

Item	BM6010/C
Calibration method	
Upon measurement	Internal standard measurement
Calibration	2-point calibration using low and high concentration calibrators (L-STD and H-STD respectively)
Standard substance for calibration	NIST Standard salt #2201 and #2202 used as reference
Sensitivity	
Standard solution	Changes in potential with L-STD for serum and urine for each measurement are: L-STD for serum L-STD for urine Na 270 to 430 -15 to 385 K 160 to 330 75 to 825 Cl -160 to -40 270 to 400
Accuracy	within ± 5% deviation
Measurement range	Serum Urine Na: 100-200 10-400 K: 2.5-200 2-400 Cl: 50-200 15-400

Reference range for each test:

The reference range for each test is as follows:

Na:	Serum Urine	136 to 145 mEq/L 40 to 220 mEq/day
K	Serum Plasma (male) Plasma (female) Urine	3.5 to 5.1 mEq/L 3.5 to 4.5 mEq/L 3.4 to 4.4 mEq/L 25 to 125 mEq/day (varies with diet)
Cl	Serum Urine	98 to 107 mEq/L 110 to 250 mEq/day

Reference ranges based on Tietz NW, *Clinical Guide for Laboratory Tests* 3rd edition. WB Saunders Company, Philadelphia, PA, pp 610-611 (1995)

1.5.2 Reproducibility and Accuracy

Chemistry Tests Examples (when using reagents approved in Japan)

Test Name/Method	Abbrev.	Reproducibility	Accuracy
Aspartate aminotransferase / JSCC	AST	CV ≤ 5%	CV ≤ 10%
Gamma glutamyl transpeptidase / JSCC	γ-GTP	CV ≤ 5%	CV ≤ 10%
Total protein / Biuret	TP	CV ≤ 5%	CV ≤ 10%
Triglyceride / GPO	TG	CV ≤ 5%	CV ≤ 10%
Calcium / o-CPC	Ca	CV ≤ 5%	CV ≤ 10%

ISE Tests

Test Name/Method	Abbrev.	Reproducibility	Accuracy
Sodium	Na	CV ≤ 3%	CV ≤ 5%
Potassium	K	CV ≤ 3%	CV ≤ 5%
Chloride	Cl	CV ≤ 3%	CV ≤ 5%

1.6 Installation

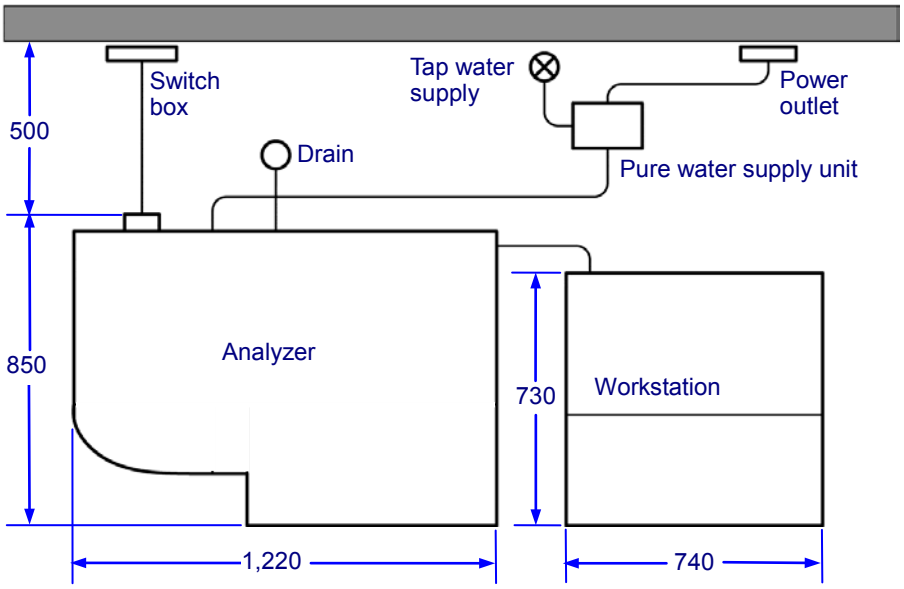
Environment

Item	Condition
Power source	AC200, 220, 230 or 240V±10%, 50/60Hz
Power consumption	Maximum 2.6 kVA
Ambient temperature	18 - 30°C (Variation: ±2°C / 1 hour or less)
Change in temperature after calibration	±5°C
Humidity	40% - 70% with no condensation
Ambiance	Free of corrosive gas and significant vibration Free of electrical disturbances such as electromagnetic and electrostatic induction
Altitude	Up to 2000 meters above sea level
Floor	The system should be placed on a level floor (1/200 gradient or less) that is capable of supporting a load of 450 kg (990 lb)
Pure Water Requirements	Water temperature: 10 °C - 30°C Dissolved oxygen: 8mg O_2/L or less (DO value) Purity of pure water: 1μS/cm or less
Overvoltage Category	II
Pollution degree	2
Drain outlet	Height: up to 200 mm, opening diameter: 50 mm or over
Water supply capacity	40L/ hour or more Direct plumbing deionized water pressure: 1.4-14.2 psi (9.8 – 98 kPa)
Transportation and storage condition	Temperature: -18 °C to +55 °C Fragile. Handle with care. Keep dry. Do not stack, do not overturn.

Precautions for Installation

- The system is for indoor use only. An appropriate ventilation system is required in the installation room.
- Sufficient ventilation space is required around the ventilation grids in the rear side of the system. The system should be installed at least 50 cm (20 inches) from the wall with nothing placed between the system and the wall that might block ventilation.

Examples of installation room

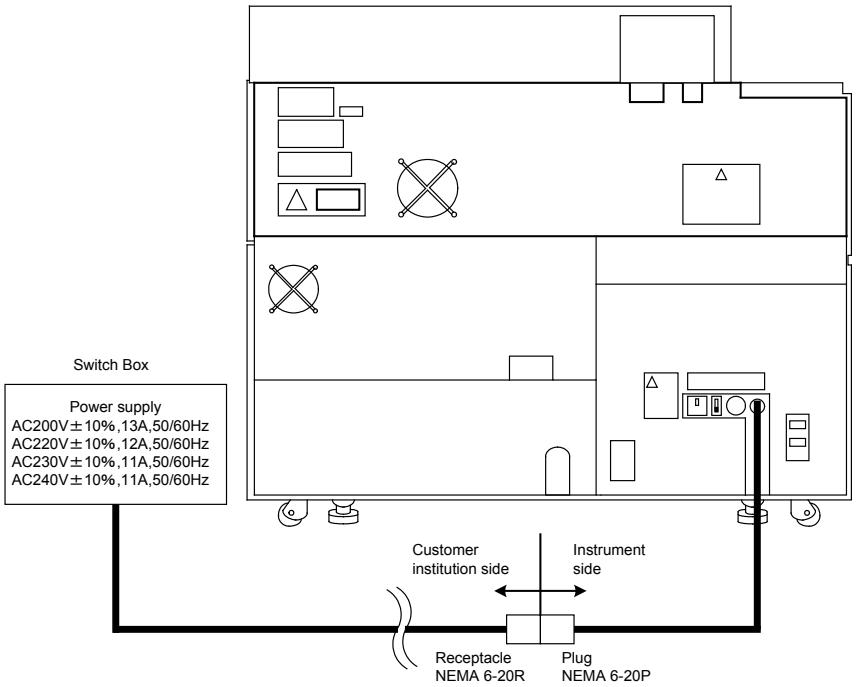


Power supply specifications

Supply wiring requirements:

USA or Canada	UL listed cord for external wiring Must be CSA certified cord in Canada. Rated 600V, 105°C. Size AWG#14.
EU	Electric wire that is approved to a harmonized (HAR) standard Rated 300V or greater, 60°C or greater Size 2mm^2 or more, outside diameter 13 to 18 mm Circuit breaker - 15 or 20 amps.
Other countries	Electric wire that is approved to the national standard of the installation site. Rated 300V or greater, 60°C or greater Size 2mm^2 or greater, outside diameter 13 - 18 mm Circuit breaker: 15 or 20 amps.

Connection specification (US / Canada)



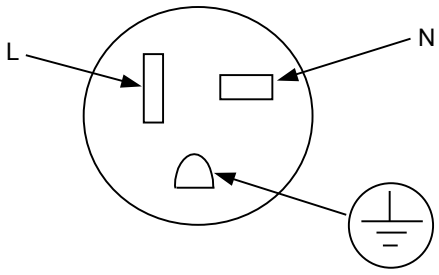
Disconnecting means in US and Canada: Plug.

Make sure to connect the ground wire of power supply to the protective conductor terminal in the switch box. The system should be placed so that the operator can easily access the plug.

Power supply wiring specifications:

USA or Canada: Power is supplied to the system via plug connection.

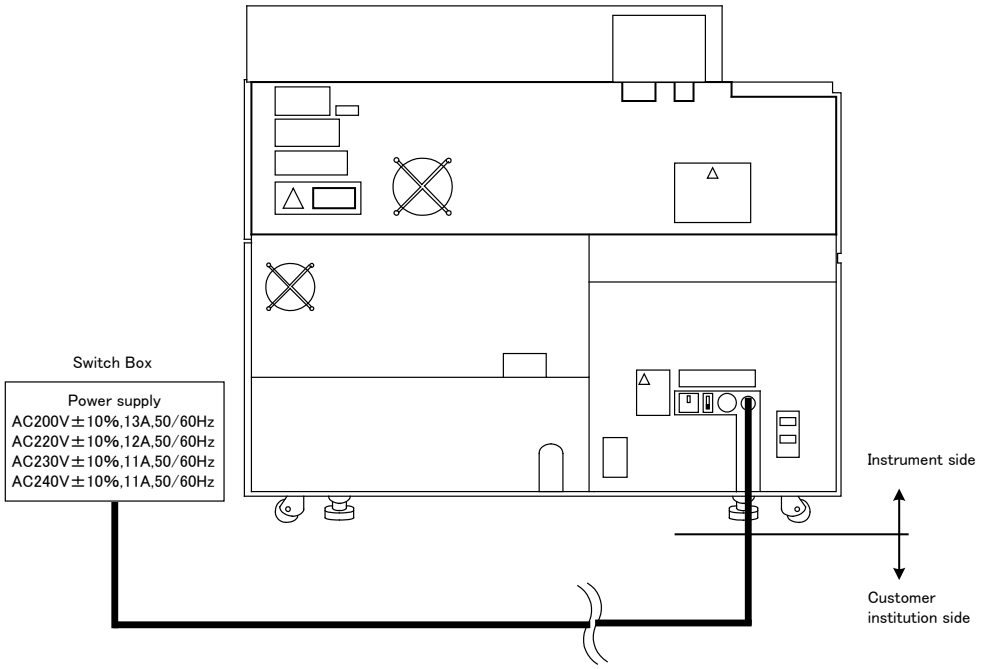
A NEMA 6-20R receptacle is required in the installation room.



NEMA 6-20R Receptacle

3-wire configuration with a protective ground wire covered with green and yellow striped material.

Connection specification (EU and other countries)



Disconnecting means in EU and other countries: breaker installed in the switch box

The system should be placed so that the operator can easily access the connection device.

Make sure to connect the ground wire of the power supply to the protective conductor terminal in the switch box.

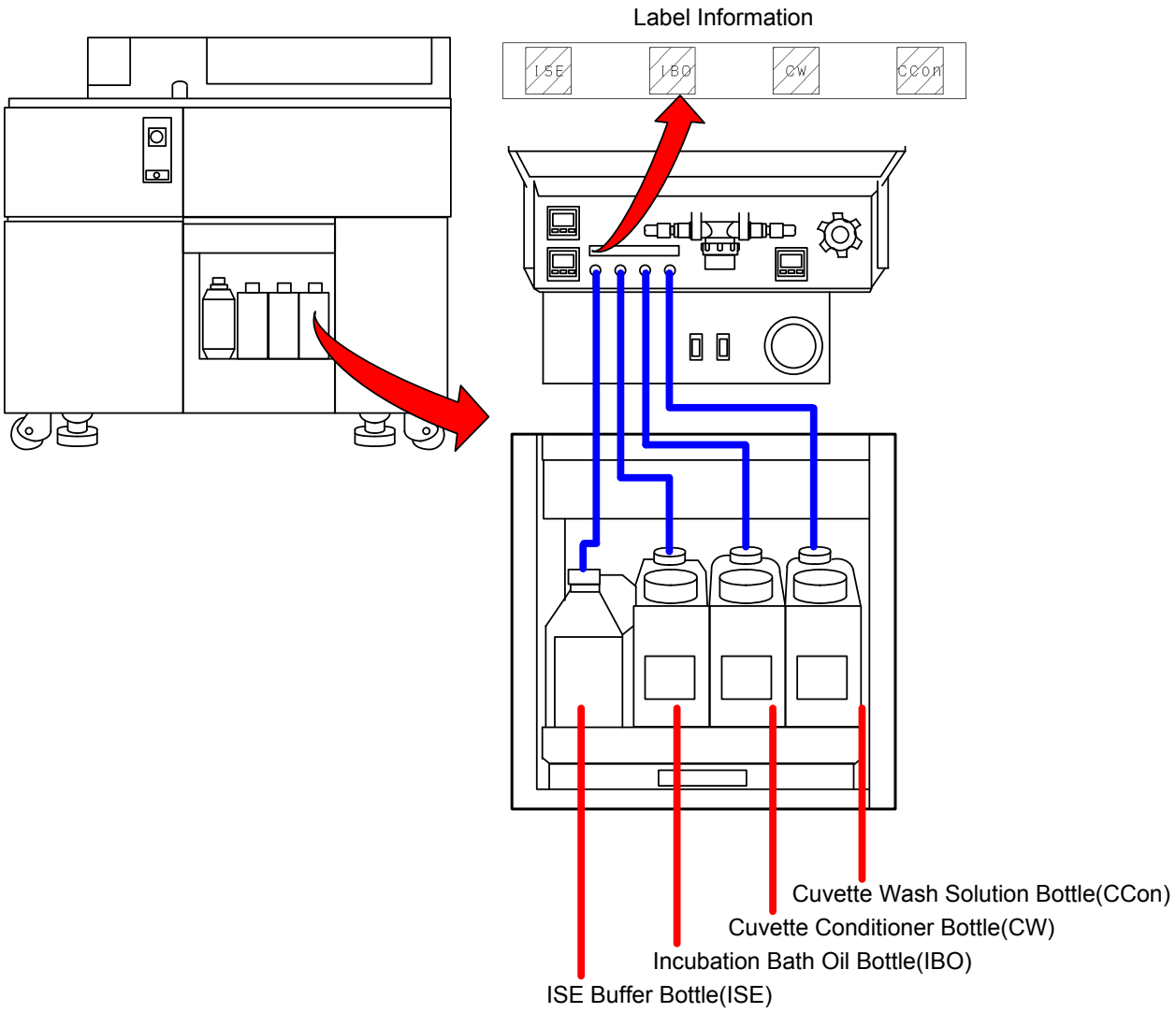
An appropriate external circuit breaker should be available as a connection device at the installation site.

Switch type should be either circuit breaker or knife switch.
The operation room should have sufficient space to accommodate a switch box.

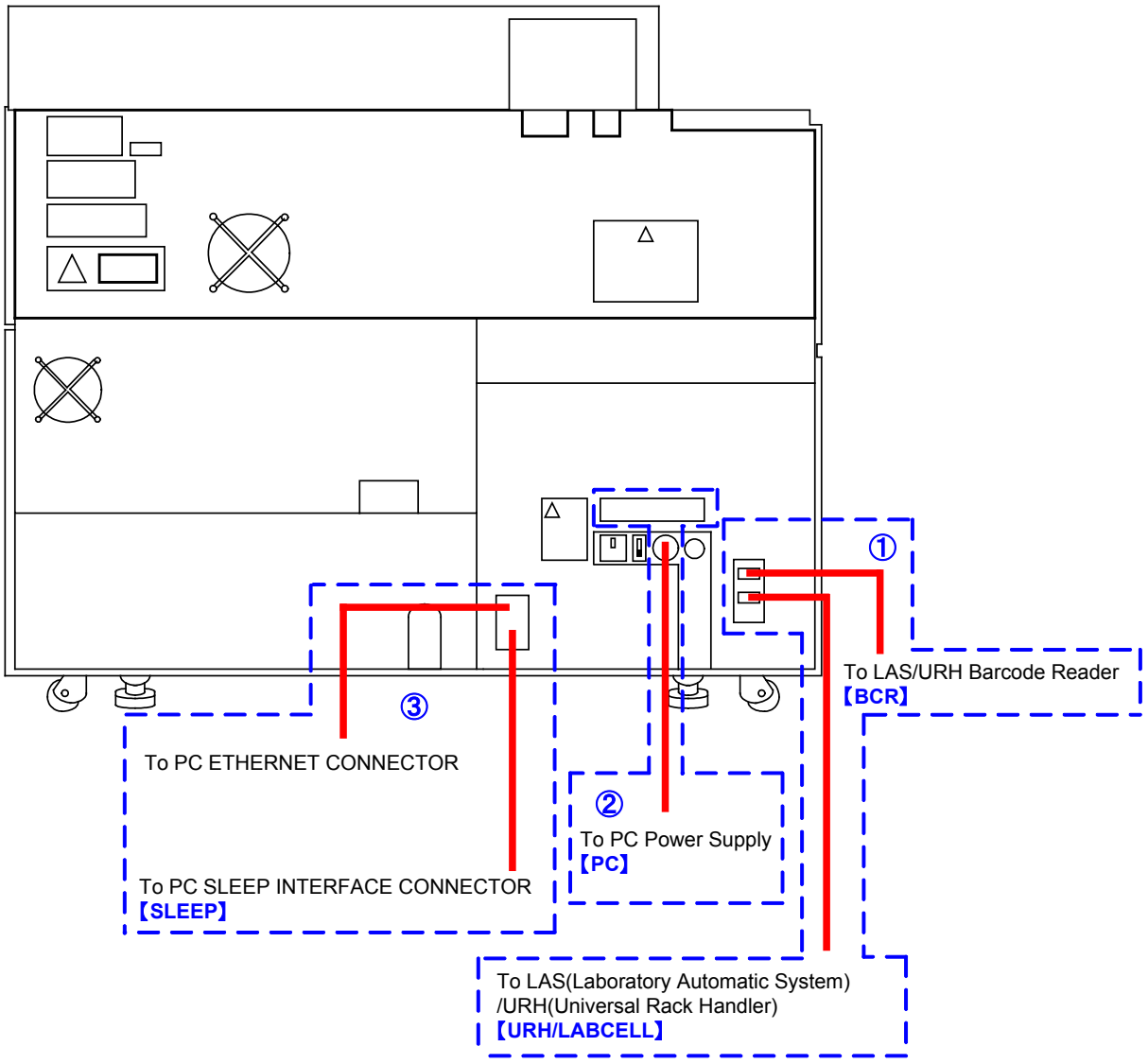
The switch box should be located within 5 meters (15 feet) of the system for good accessibility. Mark the analyzer's particular breaker or knife switch in the switch box to avoid confusion.

Wiring inside the analyzer

Front side



Rear side


①
To LAS/URH Barcode Reader
【BCR】
③
To PC ETHERNET CONNECTOR
②
To PC Power Supply
【PC】
To PC SLEEP INTERFACE CONNECTOR
【SLEEP】
To LAS(Laboratory Automatic System)
/URH(Universal Rack Handler)
【URH/LABCELL】

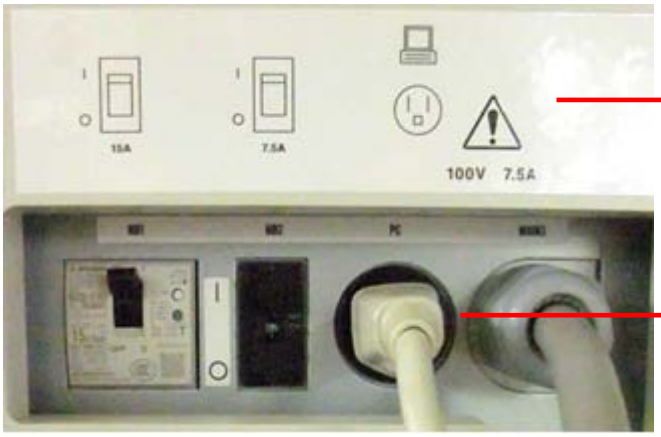
Connector

①

To LAS/URH Barcode Reader
【BCR】

To LAS(Laboratory Automatic System)
/URH(Universal Rack Handler)
【URH/LABCELL】

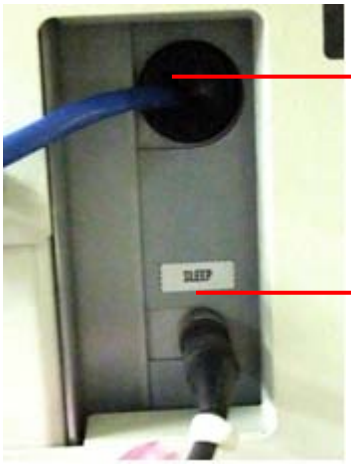
②



Outlet rating information

Power supply to the
workstation
【PC】

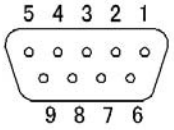
③



To PC ETHERNET
CONNECTOR

To PC SLEEP INTERFACE
CONNECTOR
【SLEEP】

Connector pin layout

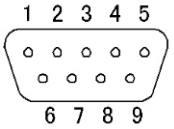


Connector : D-sub 9pin (Mail)
Screw : #4-40

Pin No.	Signal
1	N/A
2	RD
3	SD
4	N/A
5	Signal Ground
6	N/A
7	N/A
8	N/A
9	N/A

- Connection specification of LAS/URH barcode reader

Connector pin layout



Connector : D-sub 9pin (Femail)
Screw : #4-40

Pin No.	Signal
1	TIM
2	RD
3	SD
4	N/A
5	Signal Ground
6	NG
7	RS
8	CS
9	+5V

1.7 Descriptions of Units and Components

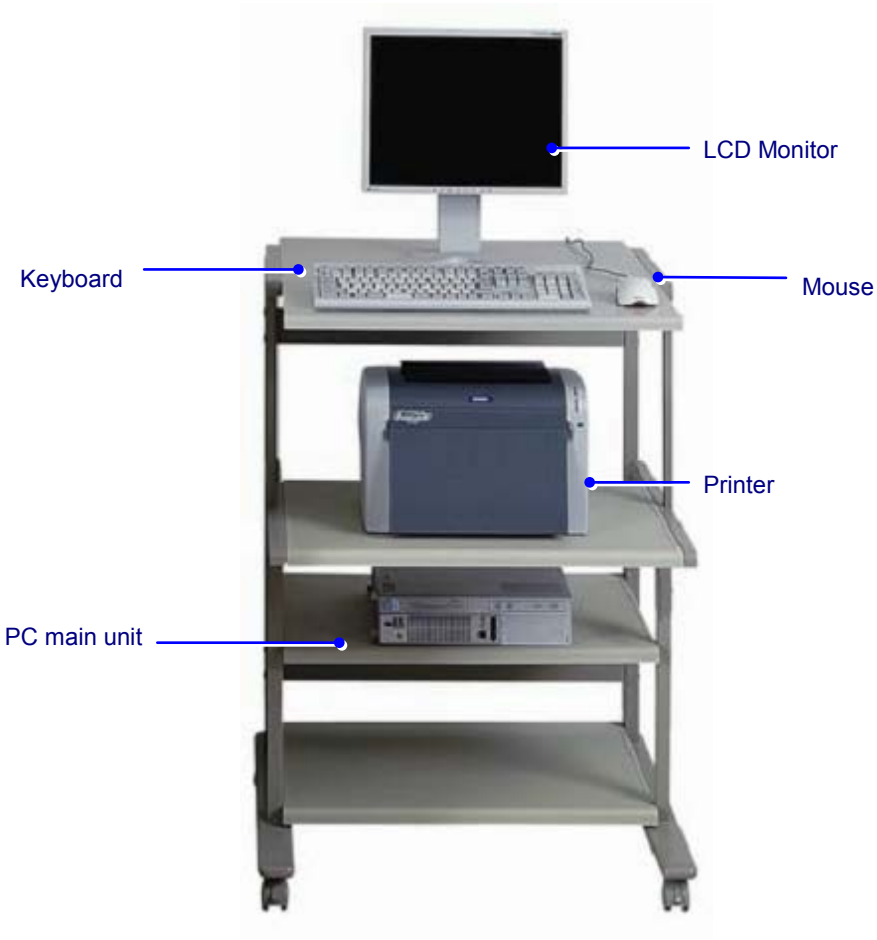
The analyzer system BM6010/C comprises two main units: the analyzer and workstation.

BM6010/C System - whole view

This section describes the names of units and components of the analyzer and workstation.

The details and functions of the units and components used for routine analysis will be described in the section 1.8.

1.7.1 Workstation



The PC, LCD monitor, and printer delivered may be different from those shown in the picture above.

For the details of the PC, monitor, and printer, please refer to the instruction manual attached to each.

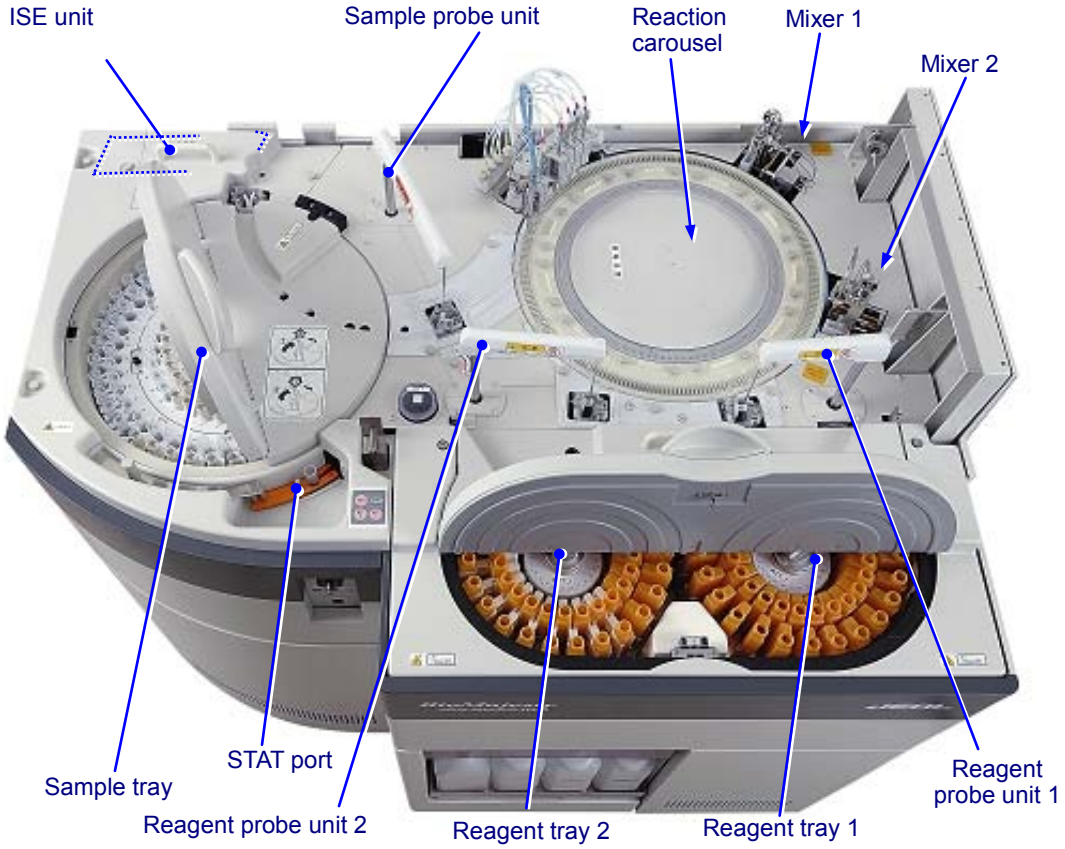
1.7.2 Analyzer

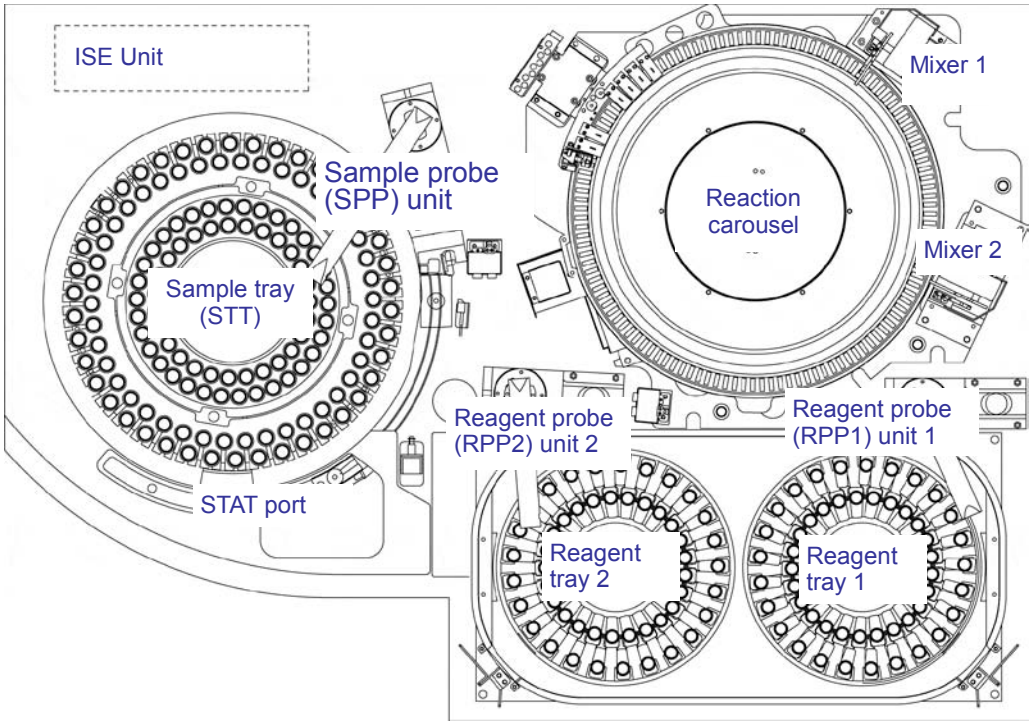
The units and components of the analyzer are shown in front, top, and rear views.

1.7.2a Front view

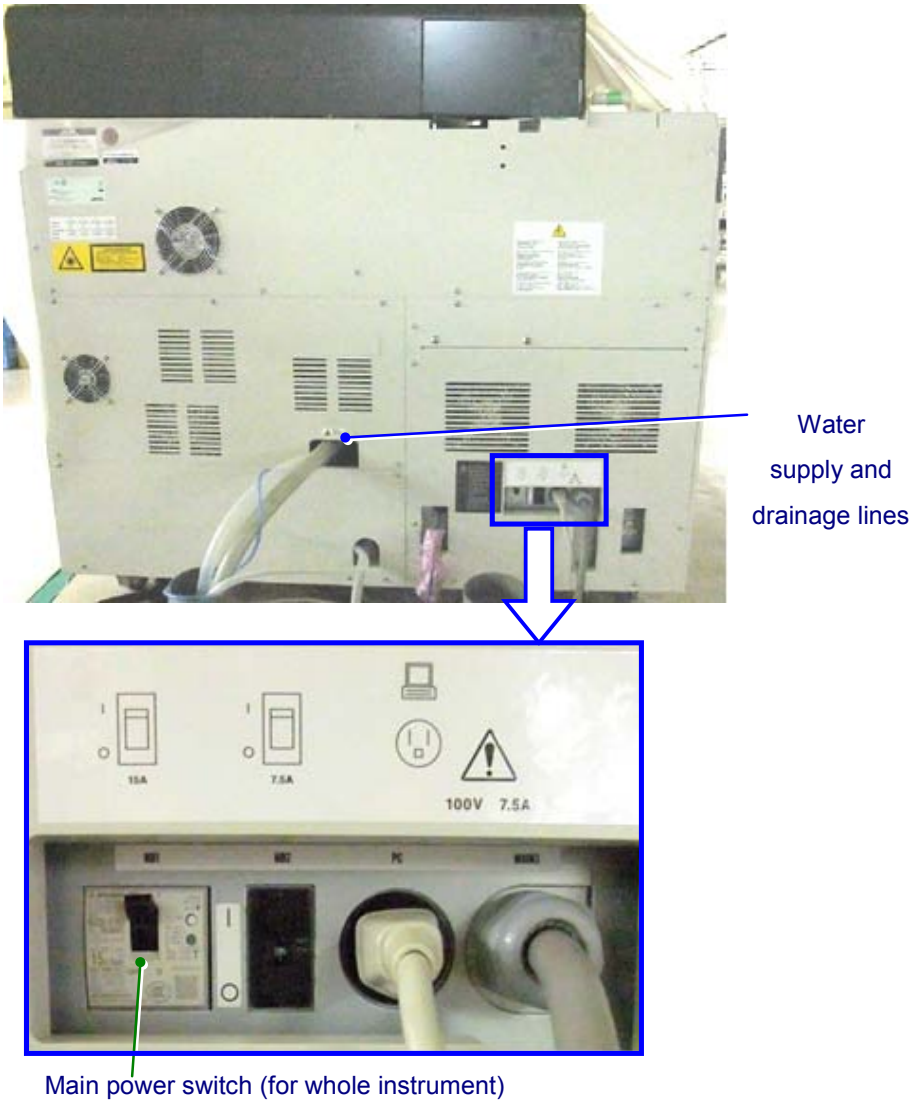
*LWP stands for large water supply pump

1.7.2b Top view





1.7.2c Rear view

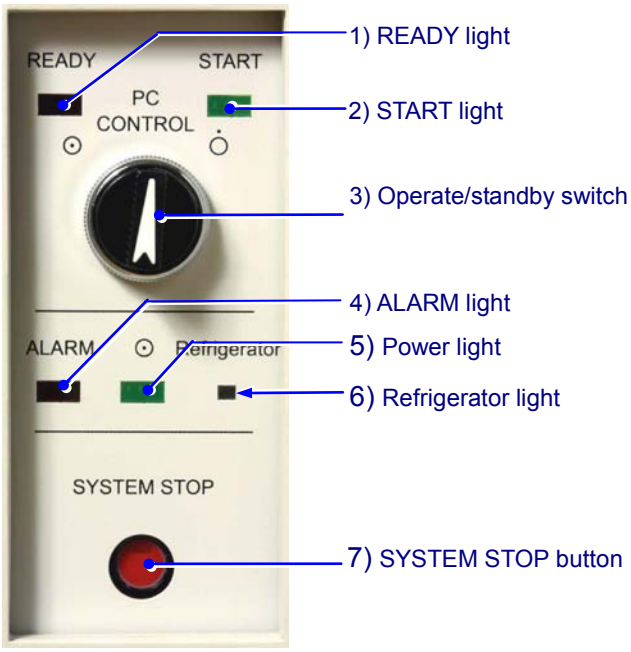


1.8 Functions of the Units and Components of the Analyzer

1.8.1 Units and components on the front side

The only unit on the front side required for routine analysis is the power panel.

1.8.1a Power panel



1) READY light

The READY light is lit when the analyzer is ready to begin analysis.

2) START light

The Start light is lit when the analyzer is in operation.

3) Operate/Standby switch

This switch is used for selecting whether the PC will control the ON/OFF status of the analyzer. Normally the [PC CONTROL] position is selected.

PC CONTROL: The analyzer is turned on/off automatically with the workstation's startup and shutdown.

⊙ ON: The analyzer is turned on.

⏻ OFF: The analyzer is turned off. (Even in the OFF status, the refrigerated reagent compartment is electrically connected.)

4) ALARM light

This light is lit when some error is detected in the analyzer.

5) Power light

This light is lit when the analyzer is turned on.

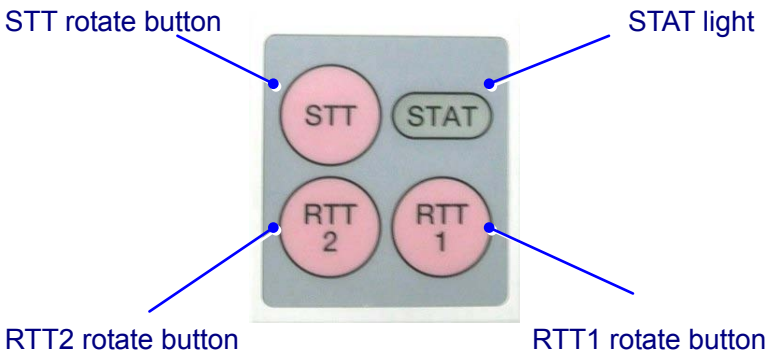
6) Refrigerator light

When green, this light indicates refrigeration is at normal temperature; a continuous yellow light indicates low temperature while a blinking yellow light indicates high temperature.

7) SYSTEM STOP button

This button is used for an emergency suspension of the analyzer's operation.

1.8.1b Button panel



The [STAT] button displays the status of the STAT sample measurement. You can rotate the position of the sample or reagent by pushing the [STT] or [RTT] buttons.

✔ STAT light

Status of the STAT port is indicated by the LED lamp color.

Green: Analysis using the STAT port is available. You may place a new sample in the STAT port.

Orange: STAT sample measurement is in operation. You may not remove the sample placed in the STAT port.

✔ RTT1 rotation button

Pressing this button rotates the reagent tray 1 (RTT1). The button is active when the system is in the READY or Reagent-PAUSE mode.

✔ RTT2 rotation button

Pressing this button rotates the reagent tray 2 (RTT2). The button is active when the system is in the READY or Reagent-PAUSE mode.

✔ STT rotation button

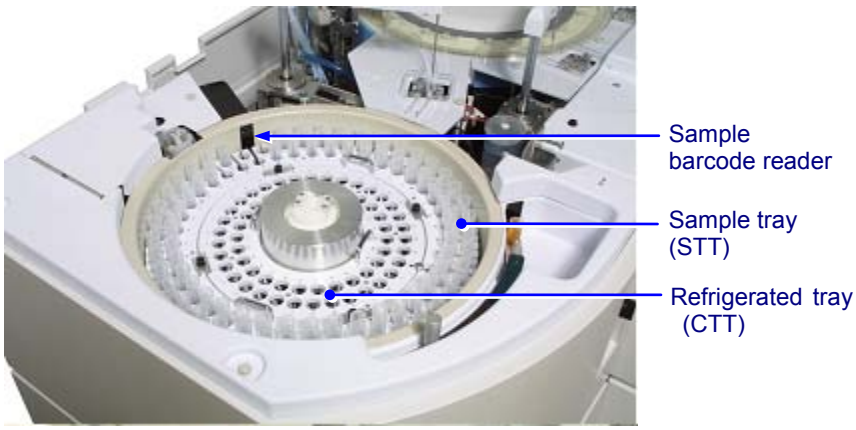
Pressing this button rotates the sample tray (STT). The button is active when the system is in the READY, Processing, or PAUSE mode.

If the STT operation has been specified as the “TT Continuous Mode” in the [Setting System Parameters] window, the STT rotation button is only available in the [READY] mode.

1.8.2 Units and components on the top side

The units accessed from the top of the analyzer which are required for routine measurement are the sample tray (STT) / refrigerated tray (CTT), the reagent tray (RTT), and the sampling probe (SPP).

1.8.2a Units for sampling operation



STT/CTT

Functions

The sampling operation units are used for inserting patient and control samples and calibrators for measurement.

Samples are moved to the aspiration position by the tray rotation.

Specifications

STT Used for routine samples and multipoint calibrators
Comprises two rows to accommodate a total of 84 samples (42 samples in each of the inner and outer rows)
Includes a built-in barcode reader for sample identification

CTT Used for calibrators and control samples
Comprises two rows to accommodate a total of 61 samples (34 samples in the outer row and 27 in the inner row)
Includes a refrigeration control system

Operation

In the [INITIALIZE] mode (see next section for various system modes)

The tray turns clockwise and stops when the STT position 1 comes to the aspiration position.

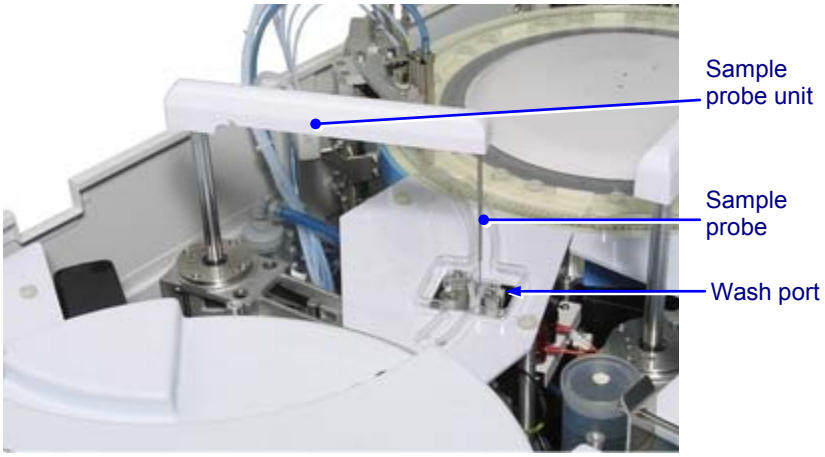
The analyzer performs "initializing operation" at the start of measurement. Next, the STT rotates clockwise or counter-clockwise so that the next sample moves more quickly to the aspiration position.

When the sample barcode is used, STT makes a full turn clockwise for

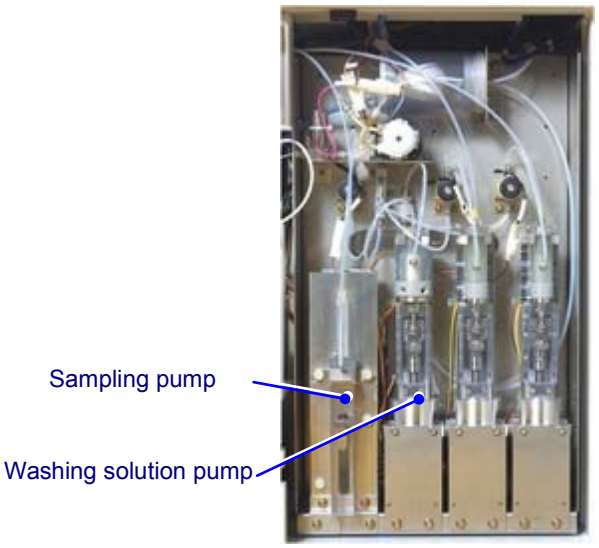
each barcode reading.

In the STT continuous mode, STT rotates clockwise at the shortest possible interval for a sample (4.5 seconds).

1.8.2b Sample probe (SPP) unit



SPP unit



Sampling pump (SP)

Functions

The SPP aspirates a volume of sample from STT and discharges it into a cuvette in the reaction carousel in accordance with the specified test conditions. The SPP unit has a built-in liquid level sensor.

Specifications

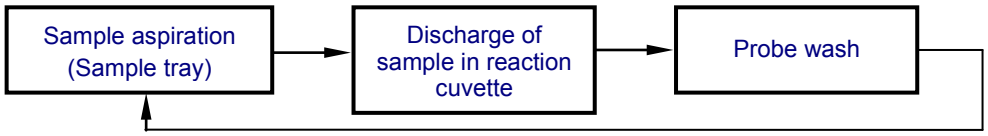
Dispensed sample volume: 1 - 25µL (at a 0.1µL increment)

Operation

In the [INITIALIZE] mode (see next section for operation modes)

The sample probe (SPP) moves to its highest position, rotates over the reaction carousel, and stops above the SPP wash port. The pumps are in stand-by status, which is the same status after the SPP discharged the sample.

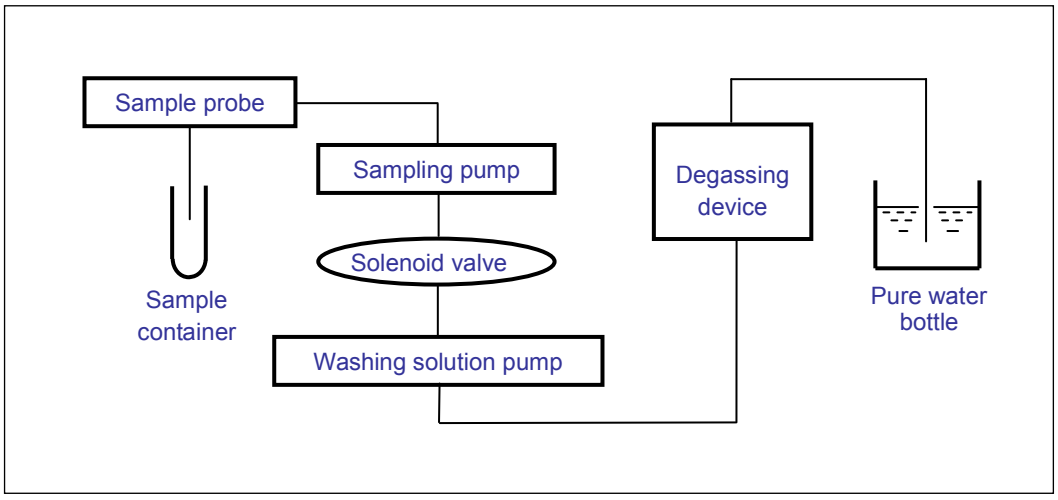
During measurement, after the above initialization operation, the SPP performs the next three steps in the following order.



SPP sequence

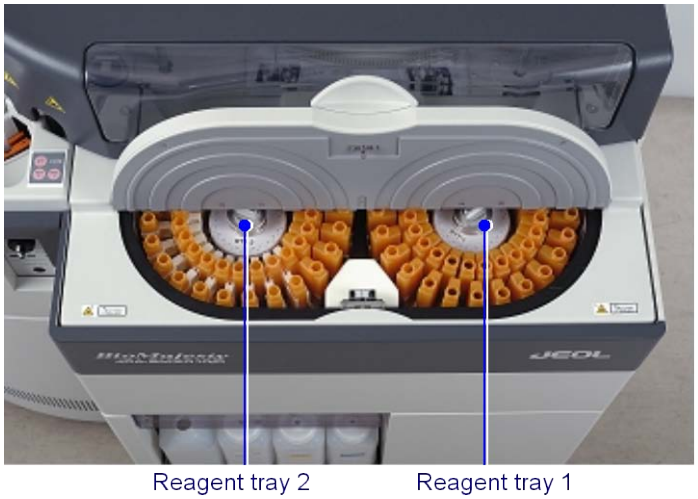
When the liquid level sensor detects a sample shortage before aspiration, SPP does not aspirate the sample but goes directly to the wash port.

Flow diagram

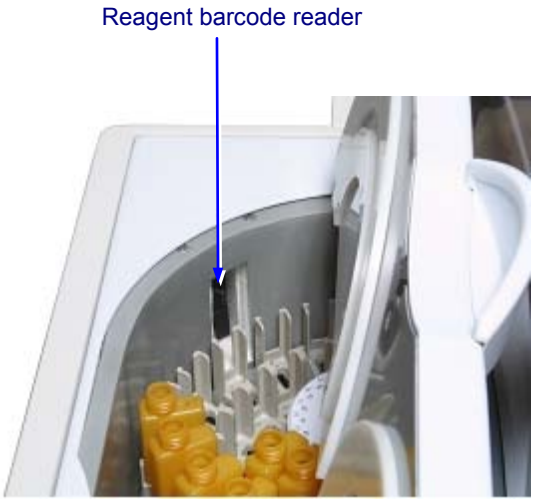


Sampling flow diagram

1.8.2c Reagent tray (RTT)



RTT



Reagent barcode reader

Functions

Used for setting reagents for the test Reagent 1 is set in the reagent tray 1 (RTT1) and Reagents 2 and 2e are in the reagent tray 2 (RTT2). Also used for loading sample diluent, routine detergents, and reagent probe washes.

The reagent trays rotate to the reagent aspiration position in accordance with the test condition.

Specifications

Number of reagent bottles loaded: 45 each

20 mL, 40 mL, or 70 mL bottles can be loaded

One bottle can be used for multiple tests; likewise, multiple bottles can be used for a single test.

Includes a built-in barcode reader for reagent identification

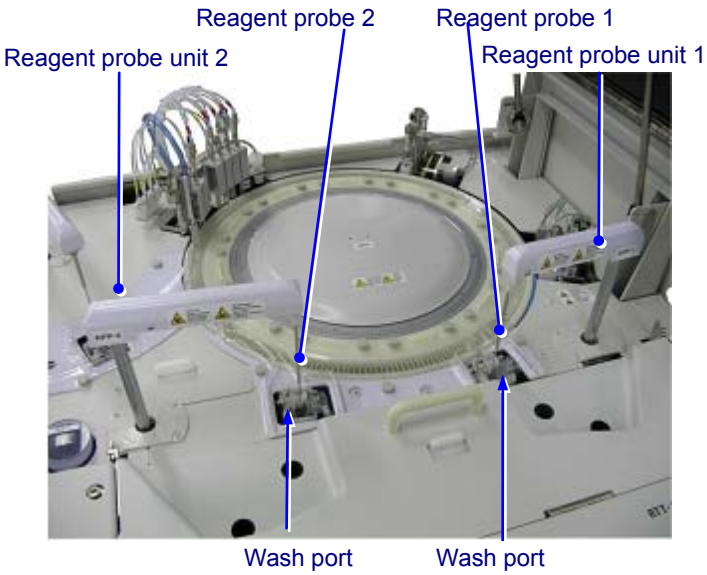
Includes a refrigeration control system

Operation

In the [INITIALIZE] mode, the reagent tray turns clockwise and stops when the first bottle comes to the aspiration position.

During measurement, the reagent tray (RTT) rotates so that the next reagent quickly to the aspiration position.

1.8.2d Reagent probe (RPP) unit



RPP unit

Functions

The RPP aspirates a volume of reagent on the RTT and discharges it into the cuvette in the reaction carousel in accordance with the specified test condition. The RPP unit includes a liquid level sensor.

Specifications

Capable of dispensing up to three reagents

Dispensed volume of Reagent 1: 25 - 300 µL (in 0.1µl increments)

Dispensed volume of Reagents 2 and 2e: 5 - 300 µL (in 0.1µl increments)

Dilution of condensed reagent with pure water is available. The reagent is diluted upon dispensing.

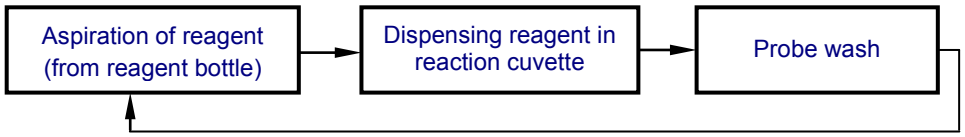
Dispensed volume of diluted reagent 1: 5 - 300 µL (in 0.1µl increments)

The maximum volume that a reaction cuvette can accommodate is 430µl w hich includes the sample volume.

Operation

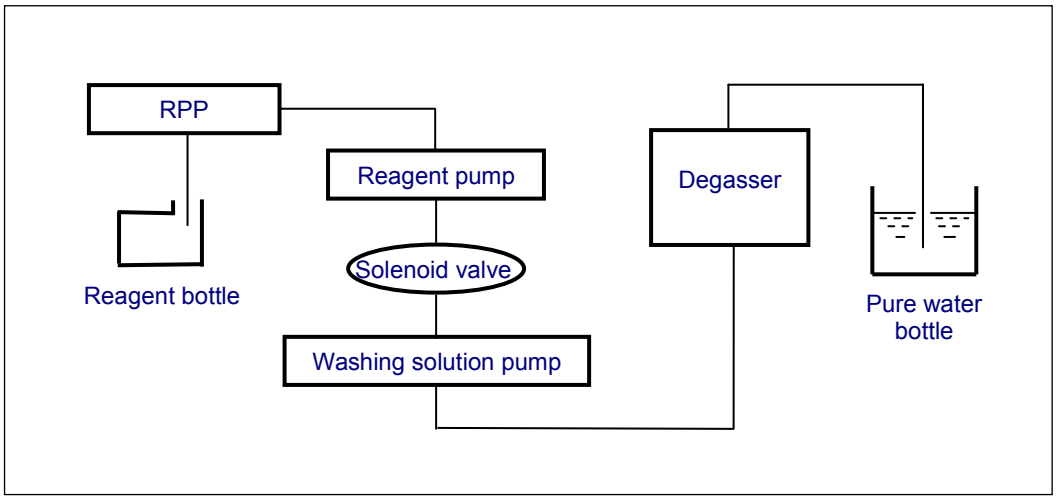
In the [INITIALIZE] mode, the reagent probe (RPP) moves to its highest position, rotates over the reaction carousel, and stops above the RPP wash port. The pumps are in stand-by status, which is the same status after the RPP discharged the sample

During measurement, after the above initialization operation, the RPP performs the next three steps in the following order.



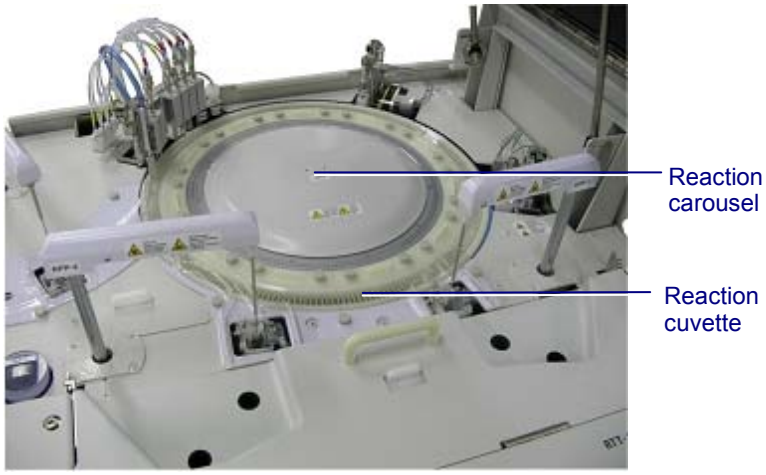
RPP sequence

Flow diagram



RPP-related flow diagram

1.8.2e Reaction carousel (RRV)



RRV

Functions

Holds reaction cuvettes and provides a temperature controlled environment for the reaction. Temperature is maintained by a reaction bath which is kept at 37°C.

Each reaction cuvette passes in front of the spectrophotometer by the RRV rotation. As the reaction cuvette is suitable for both the reaction and optical measurement, the absorbance of the reaction solution in the cuvette can be directly measured.

Specifications

Number of cuvettes: 231 (11 cuvette holders with 21 cuvettes per holder)

Cuvette light path length: 10 mm

Operation

In the [INITIALIZE} mode, RRV rotates counterclockwise up to two rotations until the reaction cuvette #1 comes to the reagent 1 dispensing position.

During measurement, the analyzer does not perform the initialization operation when it starts measurement.

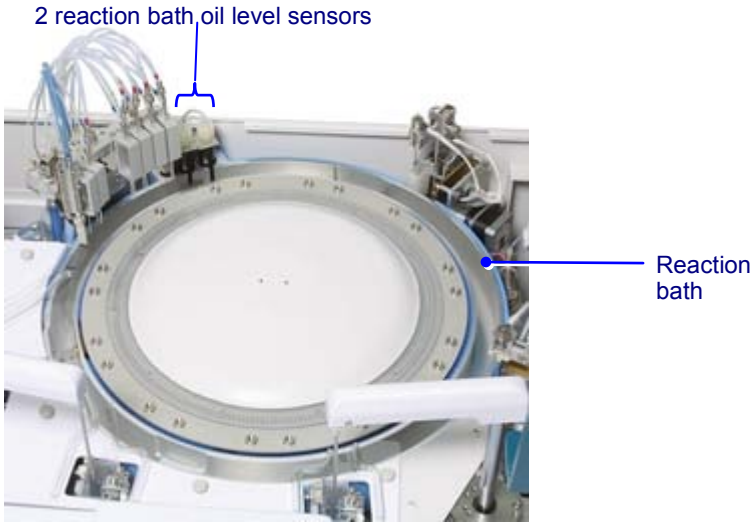
The carousel rotates as follows:

1. Clockwise rotation for 42 cuvettes.
2. Clockwise rotation for 37 cuvettes.
3. Counterclockwise for 3 cuvettes.

It takes 4.5 seconds to complete all three steps; each movement of 4.5 seconds is called 1 motion which corresponds to a rotation of 76 cuvettes.

This rotation pattern supports sample dilution.

1.8.2f Reaction bath



Reaction bath

Function

Maintains a constant temperature for the reaction solution in the reaction cuvette.

Specifications

Temperature 37°C (Analyzer ambient temperature 18-30°C)

Reaction temperature deviation ±0.1°C

An inert oil is used as the reaction bath oil.

Reaction bath oil bottle contains two sensors:

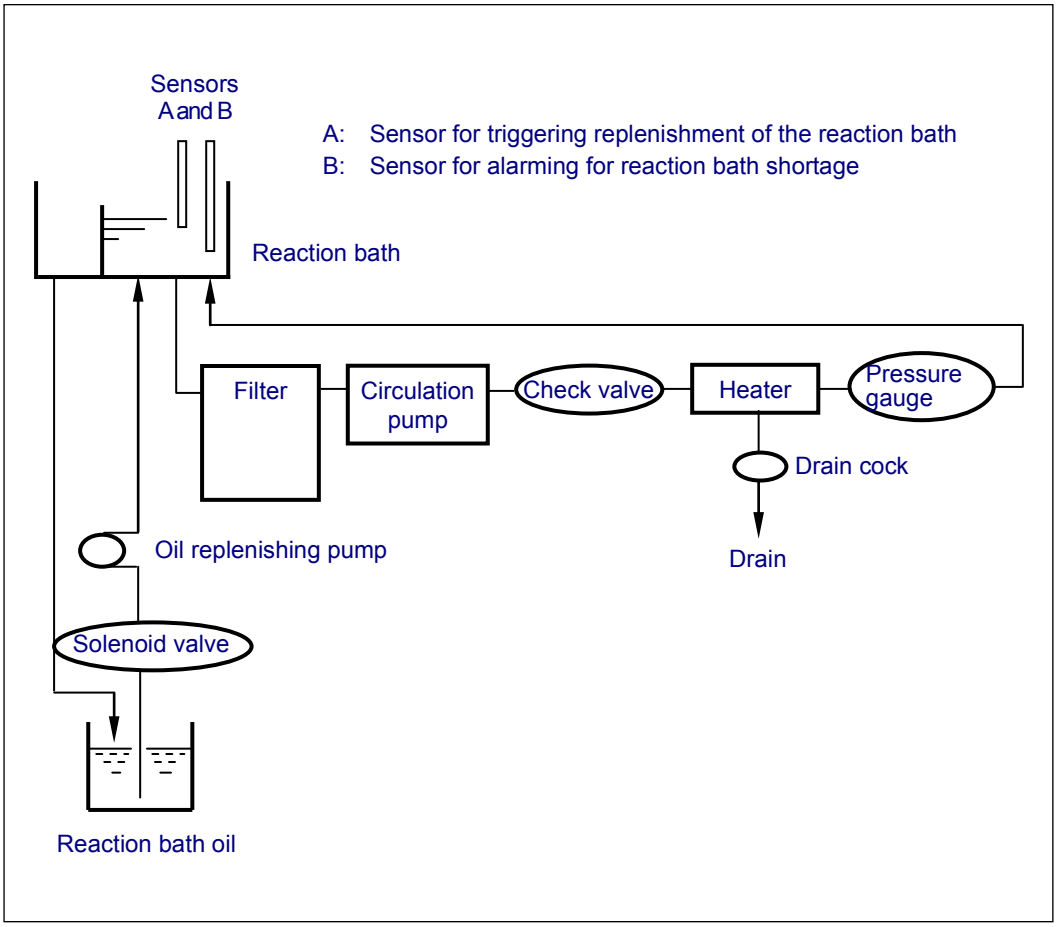
One for triggering replenishment of the reaction bath oil

One for alerting for the reaction bath oil shortage

Integrated automatic oil replenishing function

Integrated oil shortage alarm function

Flow diagram

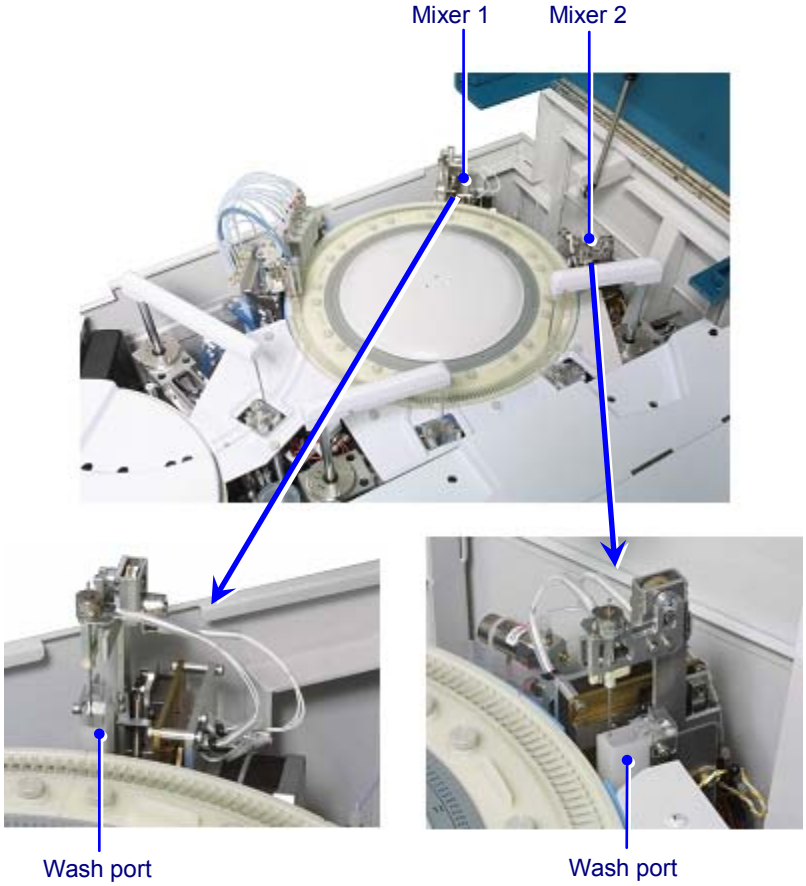


Bath oil temperature controlling diagram

Operation

If the oil surface level becomes lower than the sensor A, the oil replenishing pump is activated for a certain period of time to replenish the reaction bath oil. If the oil surface level is lower than sensor B level, an “Empty” error occurs.

1.8.2g Mixing units



Mixing units

Function

The mixing units stir the reaction solution dispensed in the reaction cuvette.

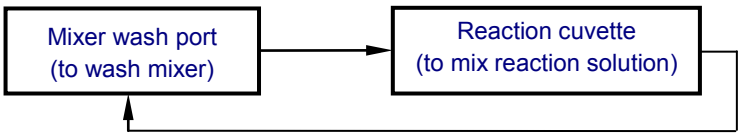
Specifications

Mixing	Back-and-forth / rotation mixing the reaction solution directly with a rod Strong and weak mixing options are available.
Mixer 1 (MIX1):	Stirs Reagent 1 and diluted sample
Mixer 2 (MIX2):	Stirs Reagent 2e and 2

Operation

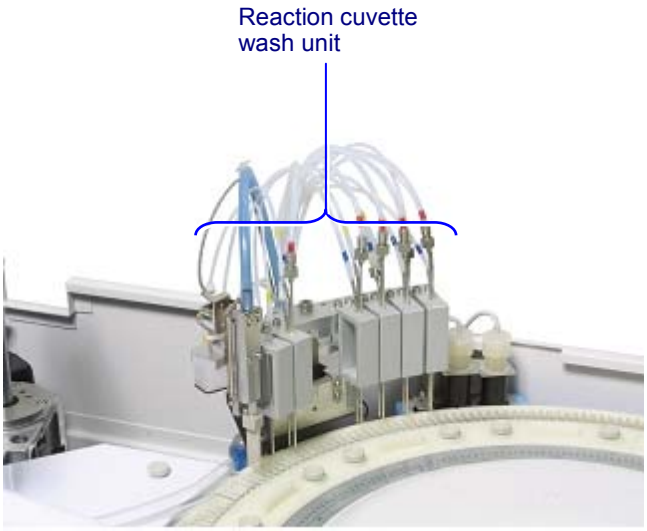
In the [INITIALIZE] mode, the mixers move to their wash ports. It a mixer is already at the wash port position, it is raised, then lowered. Finally, both MIX1 and MIX2 are raised from the wash ports.

During measurement — The analyzer performs "initializing operation" at the start of measurement. However, they are not raised from the wash ports. The sequence that follows is as below:



Mixer sequence

1.8.2h Reaction cuvette wash unit (WUD)



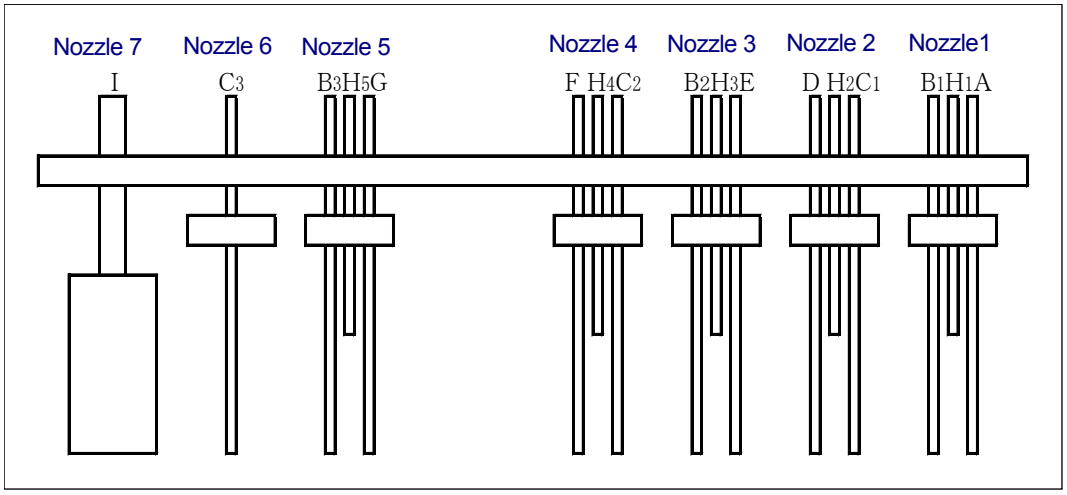
WUD

Function

The WUD washes the reaction cuvettes after measurement and drains the wash solution.

Specifications

Washing nozzles used are as follows:



Wash Nozzle layout

A	for draining reaction solution
B_1-B_3	for discharging wash solution
C_1-C_3	for draining wash solution
D	for discharging detergent
E	for draining detergent
F	for discharging Cuvette Conditioner-EX
F	for draining Cuvette Conditioner-EX
H_1-H_5	for aspirating overflow liquid
I	for vacuuming remaining liquid from cuvette

The cuvette detergent and JEOL provided "Conditioner-EX" are first diluted with pure water from the pure water bottle located in the lower front compartment of the analyzer. (See Section 1.7.2 of this chapter) before dispensed in the cuvette. The dilution rate is as follows:

Cuvette wash solution 7 x 10

Cuvette Conditioner-EX x 40

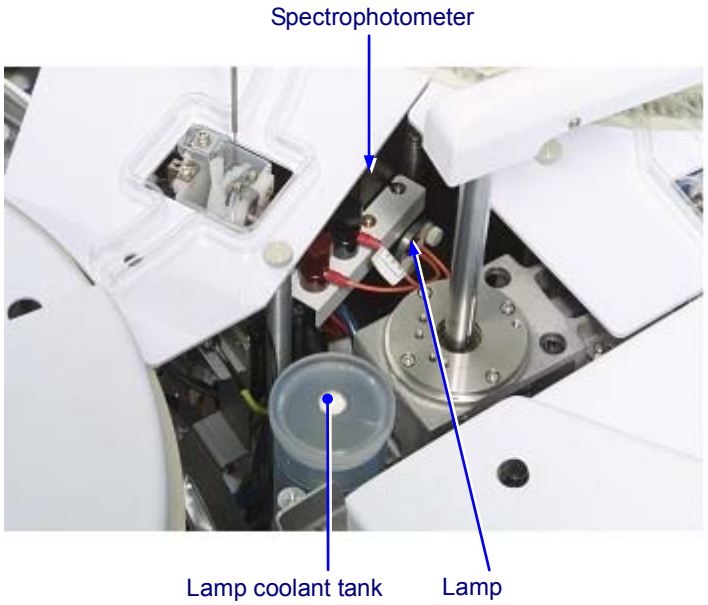
Operation

In the [INITIALIZE] mode, the wash nozzles are raised to the highest position and then suspended. When a nozzle is already in the top position, it is lowered first and then is raised again.

During measurement, the cuvette is washed and dried via ports 1 to 7 as follows:

Step	Wash solution	Port
1	Pure water	1
2	Cuvette wash solution 7 (10%)	2
3	Tepid pure water	3
4	Cuvette conditioner EX (2.5%)	4
5	Tepid pure water	5
6	- (Draining)	6
7	- (Drying)	7

1.8.2i Spectrophotometer



Spectrophotometer

Function

The spectrophotometer measures the light absorption of the liquid contained in the reaction cuvette.

Specifications

Spectrophotometer: Concave diffraction grating, rear spectroscopy system

Spectra available: One or two wavelengths can be used per test

340, 410, 451, 478, 505, 545, 571, 596, 658, 694, 751, 805, 845, or 884 nm.

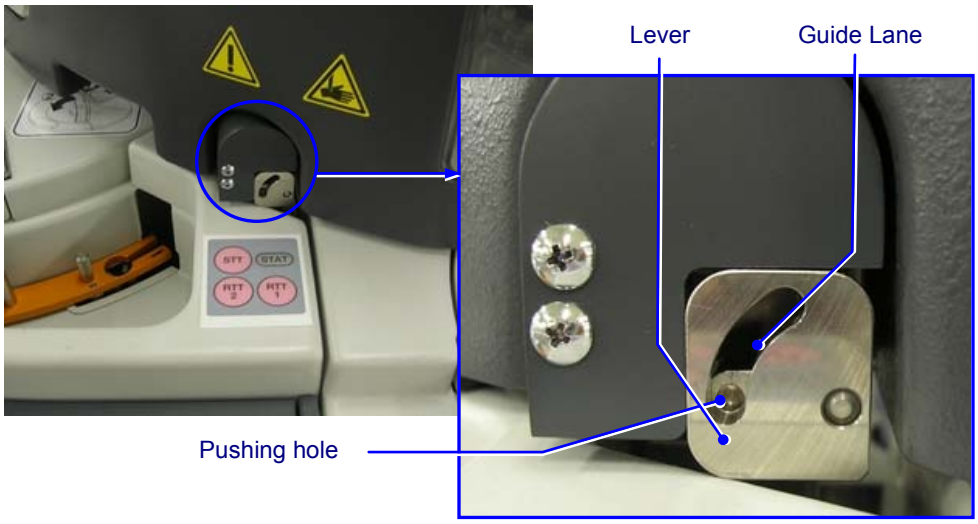
Lamp: 12V, 50W halogen lamp with forced cooling system

1.8.2j Top cover

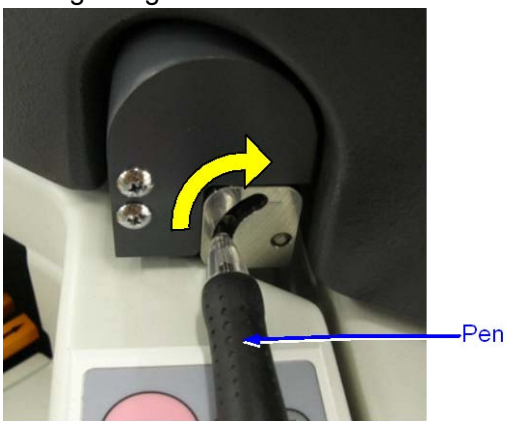
The top cover remains locked during operation; it must be unlocked to be opened for routine maintenance services. Steps for unlocking are as follows:

Steps to unlock the top cover

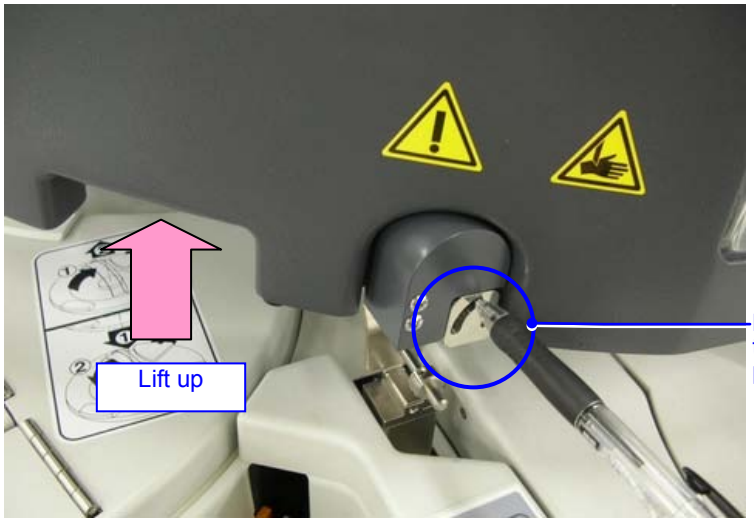
1. Prepare a ball-point pen or mechanical pencil.
2. The locking device is located as shown below.



3. Push out the pen point and insert the tip in the pushing hole of the lever.
4. Raise the lever toward upper right along the guide lane.



5. Keeping the lever in the raised position, insert your hand under the top cover to raise it up.

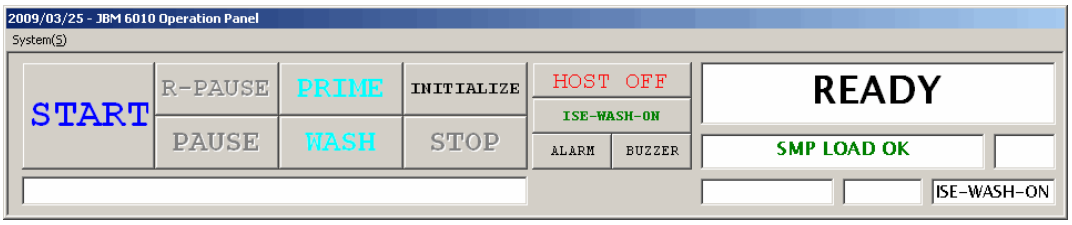


Steps to close the top cover

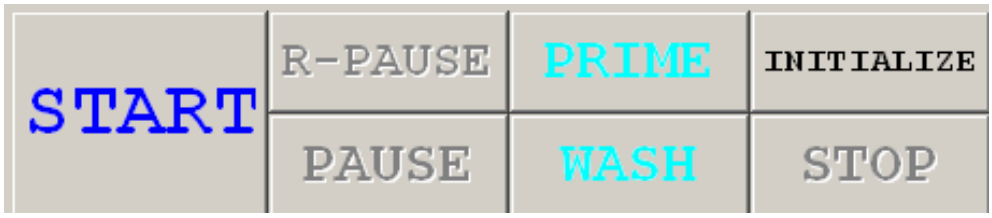
1. Lower the top cover slowly until the locking device locks.
2. Make sure that the cover will not come open even when you try to.

1.9 System mode and operation buttons

In the [Startup] window of BM6010/C displayed on the workstation screen, click the [OK] button in the lower middle of the window to display the following Operation Panel which will appear in the upper right. The system mode is shown in the upper right box in the Operation Panel.



Operation buttons



Buttons in the Operation Panel

Analyzer Modes

The table below summarizes each mode and the operation button(s) available in the mode. The [System Stop] button in the lower part of the power panel shown in the section 1.8.1a can be used to immediately stop the operation of the system in any mode.

System Mode	Status of the Analyzer	Available Button
[WAIT]	The analyzer has not been initialized yet.	[INITIALIZE]
[INITIALIZE]	The analyzer is being initialized.	
[READY]	The analyzer has finished initialization.	Any operation can be started.
[START]	The analyzer is in operation.	[PAUSE] [R-PAUSE] [STOP]
[PAUSE]	The analyzer is in operation but has temporarily suspended dispensing the sample.	[START] [STOP]
[Smart PAUSE]	The analyzer is in operation but has temporarily suspended dispensing the sample. Opening the sample tray cover triggers this mode.	[START] [STOP]
[Reagent PAUSE]	The analyzer is in operation but has temporarily suspended dispensing the sample. The reagents are already dispensed.	
[PROCESSING]	The analyzer is in operation and the sample has already been dispensed.	[START]
[PAUSE SHIFT]	The system is shifting to [PAUSE] mode.	[START] [STOP]
[R-PAUSE SHIFT]	The system is shifting to [Reagent PAUSE] mode.	[START] [STOP]
[Proces.SHIFT]	The system is shifting to the [PROCESSING] mode.	[START] [PAUSE] [R-PAUSE]
[END]	The analyzer is still in operation but is ready to stop because all samples have been processed.	
[WASH]	Washing is in progress.	[STOP]
[PRIME]	Priming is in progress.	[STOP]
[STAT START]	The analyzer is running a STAT (emergency) sample.	[STOP]

Function of each operation button and the system mode

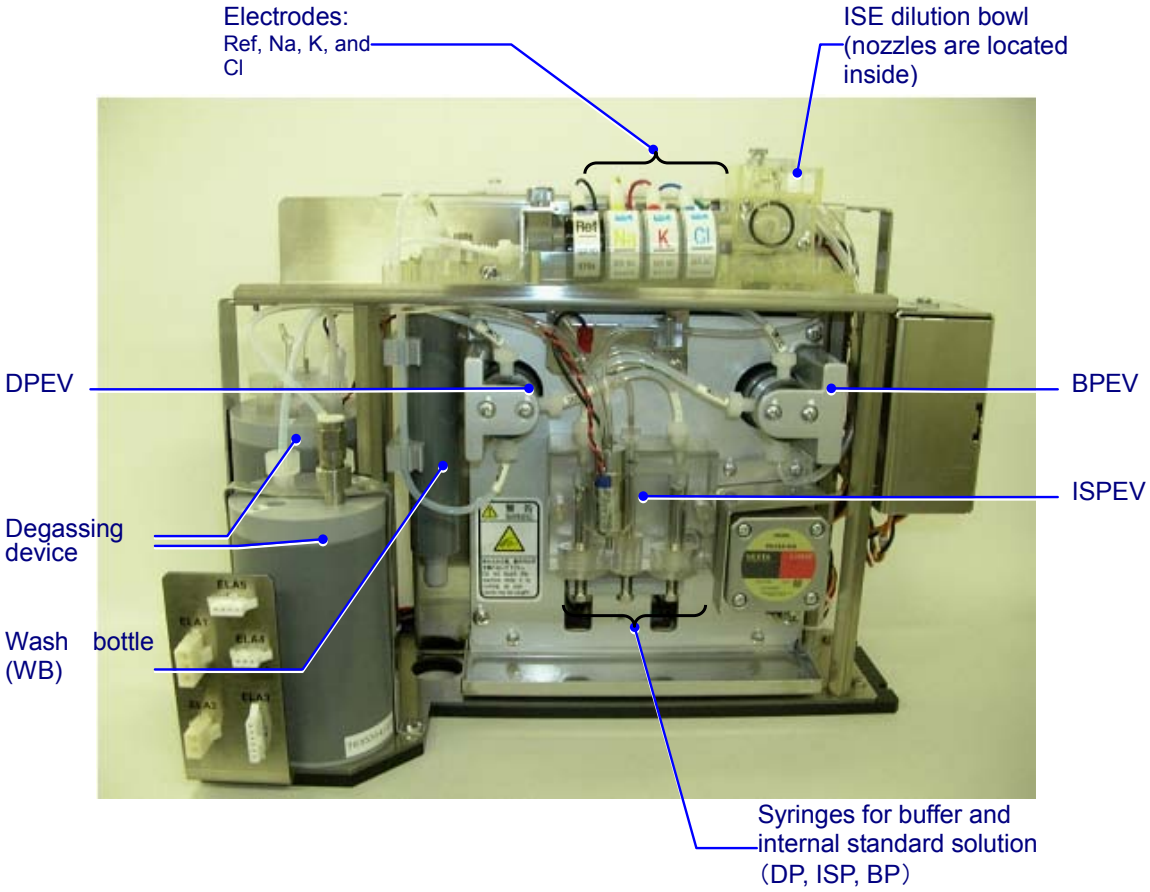
The functions of the SYSTEM STOP (emergency stop) button on the Power Panel and the six buttons in the left side of Operation Panel are summarized in the table below together with the system mode after using the button.

Button	Modes in which the button is used	Function	Mode after the button is used
[SYSTEM STOP]	All modes	All operations are immediately stopped.	[WAIT]
[INITIALIZE]	[WAIT] [READY]	The units of the analyzer are initialized.	[INITIALIZE]
[START]	[READY]	The analyzer starts operation in accordance with the settings configured in the [Start Condition] window.	[START]
	[PAUSE]	The analyzer releases the temporary pause of sample dispensing in accordance with the settings configured in the [Start Condition] window.	
	[PROCESSING]	The analyzer starts sample dispensing in accordance with the settings configured in the [Start Condition] window.	
	[PAUSE SHIFT]	The analyzer returns to the system mode before the [PAUSE] button was pressed.	
	[R-PAUSE SHIFT]	The analyzer returns to the system mode before the [R-PAUSE] button was pressed.	
	[Proces.SHIFT]	The analyzer returns to the system mode before the [PROCESSING] button was pressed.	
[PRIME]	[START] [Proces.SHIFT]	The analyzer shifts to the temporary suspension of the sample dispensing.	[PAUSE SHIFT]
[R-PAUSE]	[START] [Proces.SHIFT]	The analyzer starts to shift to temporary suspension of sample dispensing, but completes reagent dispensing.	[R-PAUSE SHIFT]
[PROCESSING]	[START] [PAUSE] [PAUSE SHIFT] [R-PAUSE SHIFT]	The analyzer shifts to the system mode for sampling completion.	[Proces.SHIFT]
[WASH]	[READY]	The analyzer begins washing.	[WASH]
[INITIALIZE]	[READY]	The analyzer begins priming.	[PRIME]

1.10 ISE (ion-selective electrode analyzer) unit

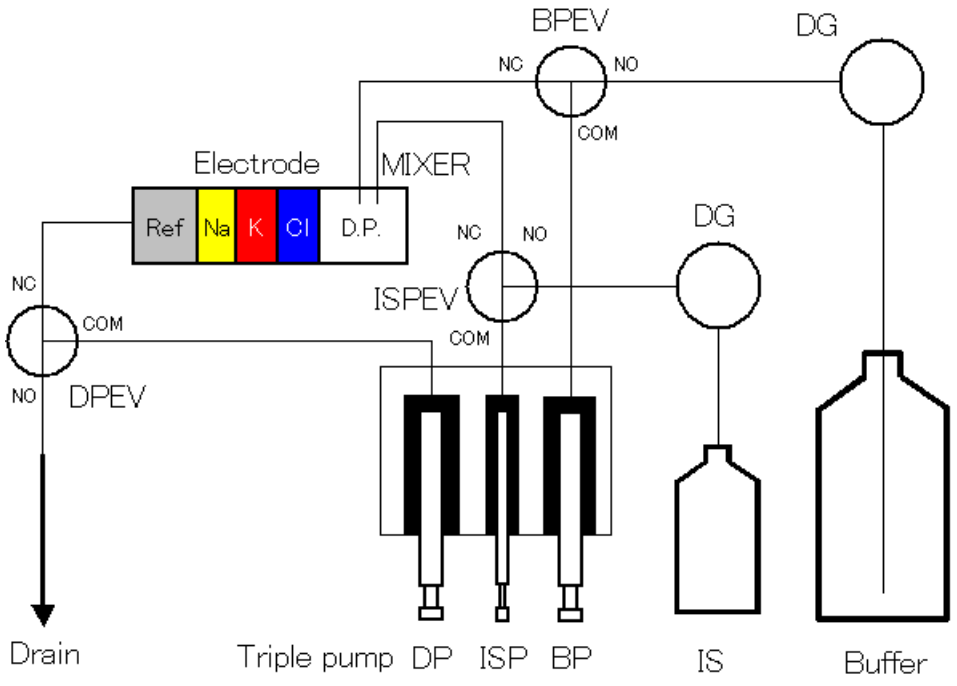
This section describes the ISE unit integrated in the system for sodium (Na), potassium (K), and chloride (Cl) measurement.

Components of the ISE unit



Side view of the ISE unit

Flow diagram



Flow diagram

Measurement

- An ISE measurement is selected in the same way as a chemistry measurement. Ordering measurement of Na, K, or Cl will activate the analyzer to perform only the test ordered.
- Undiluted sample is required for ISE measurements, therefore sampling for an ISE measurement must always come before that of chemistry measurement. When selecting an ISE measurement only, the results are displayed in the [RealTime Monitor] window after the measurement is finished. The results can also be printed in batch.

Calibration

- Calibration should be performed at least once a day.
- Calibration is available in two modes: serum and urine. Both modes can utilize either type of calibrator, the high-density calibrator (H-STD) or the low-density calibrator (L-STD), for measurement.
- When a buffer, electrode, or consumable (except printing paper) is exchanged or maintenance service is performed, be sure to perform calibration before subsequent operation.
- After measurement, the slope value and dilution factor are displayed in t he [Realtime Monitor] window. These values are also displayed in the [ISE Monitor] window.
- Calibration can be selected from the [ISE Operation] window accessed from [Maint.] button or from the [Start Conditions] window accessed from [START]

button in the Operation Panel.

When calibration is executed from the [ISE Operation] window, the ISE unit is independently activated for calibration. When calibration is selected from the [Start Conditions] window, the analyzer as a whole starts its preparatory movement; calibration is performed at the same time. The settings for calibration started from the [Start Conditions] window are defined in the [ISE Parameters Settings], [CTT Set], [CTT/STT set], [Test Select], and [Sample Select] windows.

The settings for calibration are not linked between those activated from [ISE Operation] window and those from [Start Conditions] window. Therefore the parameters, including calibrator position, should be defined separately.

Reagent

The reagents used in the ISE unit are as follows:

- Buffer
- Internal Standard (IS) solution
- Standard (Calibrator) Set (Serum, Urine)

Warning

If the buffer, IS solution, or calibrator comes in contact with skin, wash thoroughly with soap and water. In case of accidental eye contact, wash the eye with running water and seek medical assistance. In case of accidental ingestion, seek medical assistance immediately.

- When serum, plasma, or urine is measured in the unit, be sure to use the buffer, IS solution, and calibrator specified by JEOL. If a reagent or calibrator not specified by JEOL is used, the measurement result may be incorrect, the analyzer's interior flow system may become deteriorated, and the life of the electrode may be shortened significantly.
- Preservatives are added to the buffer, IS solution, and calibrator to prevent deteriorated. However, it is advised to use the liquid reagents as soon as possible after opening.
- The opened buffer and calibrator can be stored in a sealed bottle at the room temperature.
- Improper storage of the buffer and calibrator (eg. left unsealed) may cause performance degradation which will result in inaccurate measurements even before the expiration date.
- Please make sure that the calibrator does not become concentrated when using a cup as container. The degradation degree may depend on the cup type, temperature, and

humidity, but generally do not use the calibratort that has been left for over 20 minutes after dispensed in the cup.

- Be sure to set the buffer in the specified position. If loaded in a wrong position, it can result in incorrect measurements and damage to the analyzer.

CONTENTS

Chapter

2 Measurement Settings

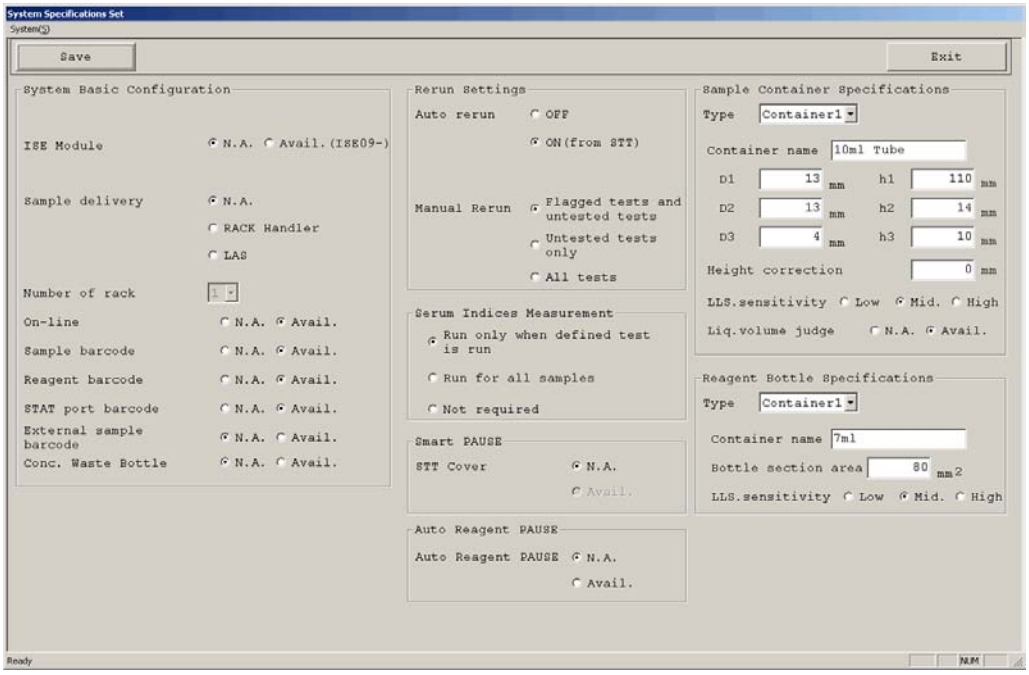
2.1 Basic Settings

This section describes the settings to be made prior to measurement.

2.1.1 System specification settings

Configure the settings for system operation.

Select [Setup] > [System Specification Settings]. The [System Specification Set] window is displayed.



If you change settings in the [System Basic Configuration], [Rerun Settings], [Serum Indices Measurement], [Smart PAUSE], and [Auto Reagent PAUSE] columns in this window, the new settings will be effective after shutting down the system and restarting with "New Start" selected in the “Bio Majesty” starting window. The new settings selected in the other columns will be effective after starting the analyzer from the [READY] mode.

Setting items in the [System Basic Configuration] column

[ISE Module] — This item selects whether the system includes the Ion Selective Electrode (ISE) unit. The default value is “Avail. (ISE09-)”.

[Sample delivery] — Select "N.A." when you use the sample tray.
Select "RACK Handler" when you use an optional rack handler.
Select "LAS" when you use an optional laboratory automation system.

[Number of rack] — Indicate the number of samples placed on a rack when you selected "RACK Handler" for [Sample delivery].

[On-line]	This item selects whether the system is connected to LIS or not.
[Sample barcode]	Select "Avail." when you use the barcode pasted on the sample container for sample identification.
[Reagent barcode]	Select "Avail" when the barcode label is pasted on the reagent bottle. When using a reagent barcode, the barcode reader reads the label on the bottle anywhere on the RTT, eliminating the need to select the bottle position on the display of the workstation.
[STAT port barcode]	Select "Avail." when you use the barcode pasted on the sample container placed in the STAT port for sample identification.
[External sample barcode]	Select "Avail." when you selected “LAS” for above [Sample delivery] and use the barcode pasted on the sample container for sample identification.

Barcode identification serves to confirm the sample arrival at the analyzer. This is an optional function.

[Conc. Waste Bottle]	This item selects the availability of the optional concentrated waste bottle.

Setting items in the [Rerun Settings] column

[Auto rerun]	Select whether to use the automatic rerun function or not.
[OFF]	Select this option if you do not use the automatic rerun function.
[ON (from STT)]	Select this option to use the sample from the sample tray (STT) for rerun. When you have selected "On (from STT)", you cannot remove the sample from the tray until sampling is completed for the rerun.

[Manual Rerun]

[Flagged Tests and Untested Tests]	Select this option to run the tests not completed in the previous run and those that were completed but should be rerun.
[Untested Tests Only]	Select this option to run the tests that were not completed the last time.
[All Tests]	Select this option to run all the tests again at rerun.

Setting items in the [Serum Indices Measurement] column

Select how the serum index is measured.

[Run only when defined test is run]
Select this option to perform the serum index measurement when the tests ordered in the [Order Entry] window for the sample include the serum index measurement.

[Run for all samples]
If the tests ordered in the [Order Entry] window for the sample do not include the serum index measurement, select this option. The top-priority test selected as test #1 in the [Analytical Parameter (Serum)] is automatically run.

[Not required]
Select this option when you do not wish to perform the serum index measurement.

Setting [Smart PAUSE]

[STT Cover]
Opening the sample tray (STT) cover triggers the [Smart PAUSE] function in which the analyzer enters [PAUSE] mode; closing the STT cover returns the analyzer to the [START] mode and resumes operation. Select "Avail." to use this function.

Setting for [Auto Reagent PAUSE]

[Auto Reagent PAUSE]
This function allows the replacement of reagent bottles during measurement.
With this function, the analyzer pauses automatically when a reagent shortage is detected during measurement.
Select "Avail." to use this function.

Additional settings are required for the "Auto Reagent PAUSE" option.
Refer to “Section 4.12 R-PAUSE” as required.

Setting the values in the [Sample Container Specifications] column

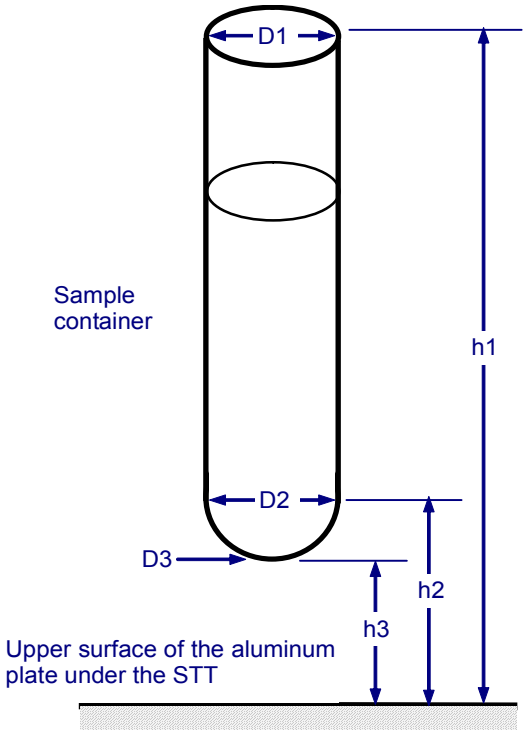
The analyzer controls the probe movement and judges the sample volume based on the sample container type indicated here. The sample probe may be damaged if the values entered are incorrect.

[Type] Select a container number (Container 1 – Container 9). Enter the following values for the selected container number.

[Container name] Enter a name for the container.

[D1][D2][D3] Enter the diameter of each dimension as indicated below (unit: mm).

[h1][h2][h3] Enter the height of each dimension as indicated below (unit: mm).
Remove the sample tray and measure the height of the container from the aluminum plate beneath the tray.



[Height Correction] Adjust the aspiration height in 0.1 mm increments when the rack handler or LAS is used for sample delivery.

[LLS.sensitivity] Select the sensitivity of the liquid level sensor. The default value is "Med."

[Liq.volume judge] Select whether to judge the liquid level with the liquid level sensor. "Avail" is the default value. Select "N.A." for a small quantity sample such as a pediatric sample whose liquid level might be low and undetectable.
When you select "N.A.", be sure that the container has sufficient volume of sample so that the measurement data will be correct.

Setting the values in the [Reagent Bottle Specifications] column

The analyzer controls the movement of the reagent bottle and judges the reagent volume on the basis of the reagent bottle type selected here. An incorrect setting will cause erroneous measurement results.

[Type] Select a container number (Container1 to Container 9). Enter the following values for the selected container number.

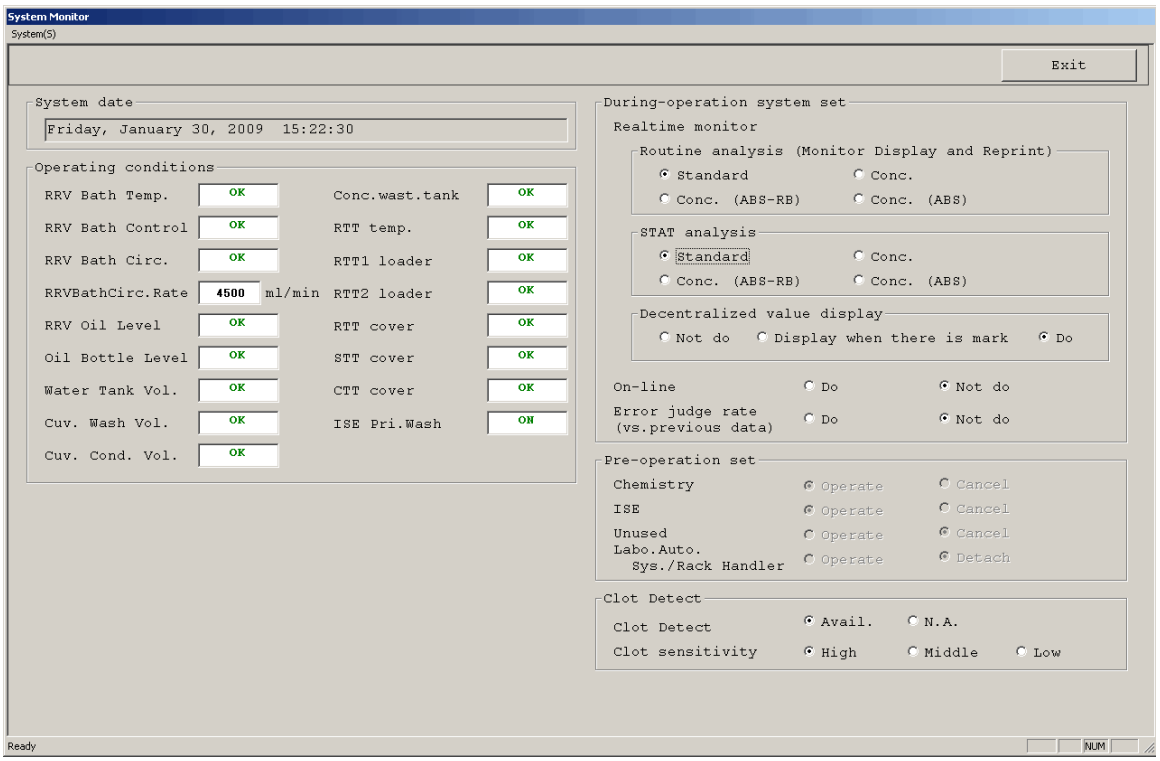
- [Container Name] Enter a name for the container.
- [Bottle Section Area] Enter the capacity of the bottle. Four options are available:
  7mL — 80mm^2
  20mL — 300mm^2
  40mL — 470mm^2
  70mL — 850mm^2

[LLS. sensitivity] Define the sensitivity of the liquid level sensor. "Med." is the default value.

2.1.2 Settings for [System Monitor]

The [System Monitor] window is used to view the status of analyzer and also to select some functional options.

Select [Maint.] > [System Monitor]. The [System Monitor] window is displayed.



[During-operation system set] column

The options changed in this column are immediately effective even when the analyzer is operating.

[Realtime monitor] Indicates the display type of the [Realtime monitor] window.

- [Routine analysis] Selects how data is displayed in the [Realtime monitor] window after completion of sample measurement.
- [STAT analysis] Selects how data is displayed in the [Realtime monitor] window after completion of STAT sample measurement.

[Variance value display] Selects whether to display the variance value on the [Realtime monitor] which allows continuous monitoring for abnormalities in the reaction process.

- [Not Do] Hides the variance value.
- [Display when there is flag] Displays the variance value only when a flag is posted (See Section 11.1 for further information about flags).

[Do] Displays the variance value regardless of the flag status.

<Example of display>

Test Name	Conc.	flag	ABS-RB	ABS	E1	E2 ···
Fe	98.65		0.0132	-0.0148	0.0228	-0.0062 ···
		0.12670	0.14629	0.00399	0.09974	
Ca	8.85		0.1908	0.3906	·····	

The second line of each test shows the following values: (in order, left to right) main wavelength for reagent 1, sub wavelength for the reagent 1, main, sub for the reagent 2e, main and sub for the reagent 2.

In the above example, the main wavelength for reagent 1 is 0.12670, the sub-wavelength for reagent 1 is 0.14629, the main wavelength for reagent 2 is 0.0039, and the sub-wavelength for reagent 2 is 0.09974.

[On-line] Selects whether to activate communication between the analyzer and a laboratory information system (LIS) if one is connected. When "Not do" is selected, the analyzer will be used as a stand-alone device. A laboratory automation system (LAS) can be used with the analyzer even when "Not do" is selected.

[Error judge rate (vs. previous data)] This is a function which determines whether an error has occurred on the basis of the difference between the present and previous result values. The options are "Do" and "Not do". When "Do" is selected, the values entered in the [Error judge rate (vs. previous data)] are used for the error judgment. Select [Analytical Parameters (Chemistry)] > [Error judge rate (vs. previous data)] button to open the window.

[Pre-operation set] column

Selections made in this column are immediately effective.

[Chemistry] Selects whether chemistry tests are performed.

[ISE] Selects whether ISE tests are performed.

[Rack Handler/LAS] Selects whether to connect to the optional external rack handler or the LAS.

[Clot Detect]

[Clot Detect] Selects whether to use the clot detection function.

[Clot Sensitivity] Selects the sensitivity of the clot sensor.

2.2 Registering New Tests

This section describes the steps to register a new test to the analyzer.

Following steps can be also performed in [Setup] > [New Test Registration] window. Sub-windows for the test registration can be opened directly from the [New Test Registration] window.

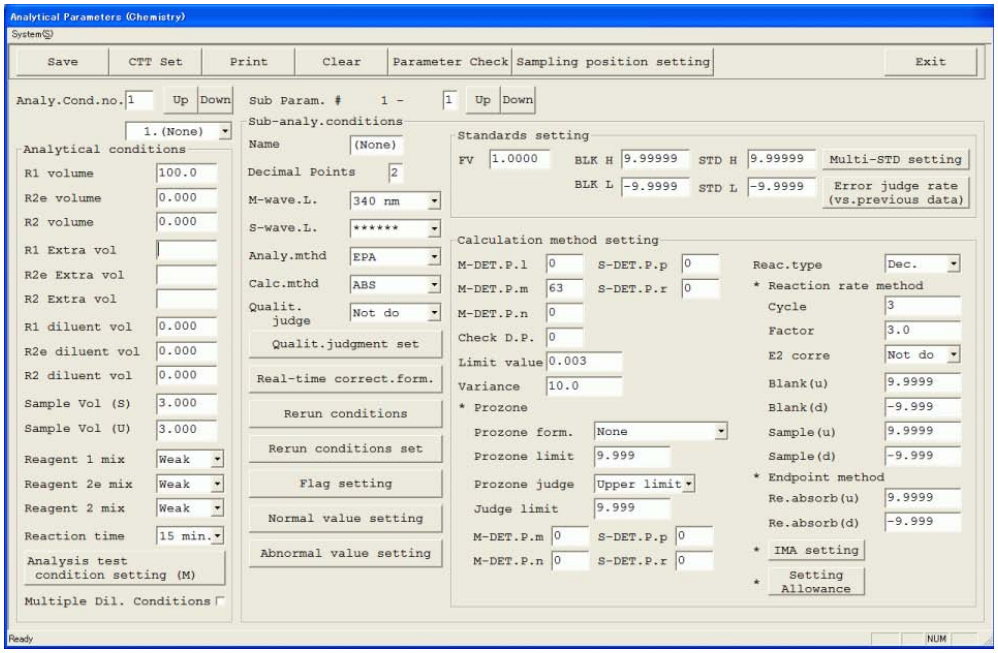
2.2.1 Setting analytical conditions

New parameter settings must be entered for each test.

2.2.1a Basic settings

Select [Setup] > [Analytical Parameters (Chemistry)] to display the window below.

If 1 - 90 is selected for [Analy.cond.no.], some parameters are grayed out and unchangeable as they have been automatically selected. If 91 - 100 is selected, the [Analytical Parameters (Chemistry)] window is displayed as below and all the parameters can be changed.



[Analy.cond.no.] field

Enter a number (1 - 100) for the analytical condition you wish to define.

Use the [Up] and [Down] buttons to change the number. Alternatively, select a test name from the drop-down menu of the field below the [Up] and [Down] buttons.

[Analytical conditions] column

[R1 Volume] Enter a value between 25 -300 µL in 0.1 µL increments.

If the volume of reagent 1 + the volume of diluent for reagent 1 is ≥ 25 µL, a value between 5 and 300µL can be entered for [R1 volume].

[R2e volume][R2 volume] Enter a value between 0.5 -300 µL in 0.1 µL increments. The value "0" means that no reagent is used.

[R1 Extra vol][R2e Extra vol][R2 Extra vol] Enter a value only when you want to change the supplementary reagent volume that the reagent probe (RPP) aspirates. Normally, no value is entered.

[R1 diluent vol][R2e diluent vol][R2 diluent vol] Enter a value between 0.5 and 300 (µL) in 0.1 µL increments.

The total reaction solution volume (sample volume + reagent volume + reagent diluent volume) should be between 80 and 430 (µL).

The total volume of the reagent and reagent diluent should be between 25 and 300 µL.

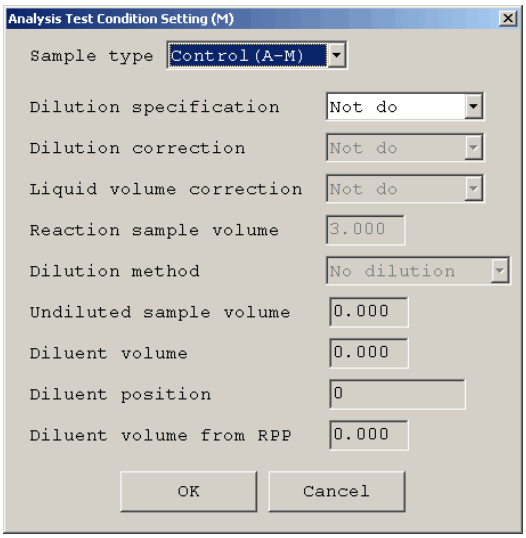
[Sample vol (S)][Sample vol (U)] Enter the sample volume to be used for measurement.
Enter a value between 1 and 25 (µL) in 0.1 µL increments.
This value will be automatically shown in the [Reaction sample volume] of serum and urine in the [Analysis test condition setting (M)] window.

[Reagent 1 mix][Reagent 2e mix] [Reagent 2 mix] Select "Weak" or "Strong" to define the force of the mixer that stirs the respective reagent.

[Reaction Time] Select "3 min.", "4 min.", "5 min.", "10 min.", "15 min.", "21 min." or "31 min."

[Analysis Test condition setting (M)] button

Click this button to display the window below.



[Sample type] Select a sample type. Options are "Serum", "Urine", "STAT/Priority", "Control (A-M)", "Control (N-Z)", "BLK" and "STD".

[Dilution specification] Options are "Do" and "Not do".
If "Not do" is selected, the analytical condition for serum or urine is automatically applied to run the sample selected in the above [Sample type].
If "Do" is selected, you can define a new analytical condition in this window to run the sample selected in the above [Sample type]. Define the new condition by filling the following fields. However, defining a new analytical condition in this window is not available when “Serum” or “Urine” is selected for the above [Sample type].

[Dilution correction], [Liquid volume correction] "Do" or "Not do" can be selected depending on the selected sample type and dilution method. The default value is "Do". If "Not do" is selected, no corrective calculation is applied to the analysis result based on the dilution factor and reaction solution volume.

[Reaction sample volume] Enter 1 - 25 (µL) in 0.1 increments for the sample volume used in analysis.
The values entered here will be automatically displayed in the [Sample Vol (S/U)] field in the [Analytical Parameters (Chemistry)] window.

[Dilution method] Select either "No dilution" or "With Dilution". "With Dilution" is a setting to dilute a sample in a reaction cuvette. Following fields also need to be filled when “With Dilution” is selected; [Undiluted sample volume], [Diluent volume], [Diluent position], and [Diluent volume from RPP].

[Undiluted sample volume] Enter a value between 1 and 25 (µL) in 0.1 increments for the volume of undiluted sample before being dispensed in the cuvette.

[Diluent volume] Enter a value between 25 and 200 (µL) in 0.1 increments for the volume of diluent dispensed in the cuvette for sample dilution.

Enter a value between 5 and 200 (µL) in 0.1 increments if the diluent is to be diluted.
However, the total volume of the diluent volume plus the diluent (pure water) volume from RPP should be between 25 and 200 (µL).

The total of [Undiluted sample volume] + [Diluent volume] - ([Reaction sample volume] + 3µL) should be ≥ 35µL.

[Diluent position] Enter the position number on the reaction tray 1 (RTT1) in which the diluent is placed. Enter "0" when the pure water is dispensed from the RPP directly through the RPP line as diluent.
Two or more diluent bottles can be placed on RTT1. For example, when you have placed the bottles in positions #43, 44, and 45, enter "43-45".

[Diluent volume from RPP] This field is available only when a value is entered in the [Diluent position] field. The aspirated diluent is dispensed with the pure water by the pump.

[Diluent volume]+[Diluent volume from RPP]=25 - 200µL

[Undiluted sample volume]+ [Diluent volume]+[Diluent volume from RPP]-([Reaction sample volume] + 3µL) should be ≥ 35 µL.

See Section 1.4.3 Diluting the Sample for more details on the steps for sample dilution.

[Multiple Dil. Conditions] option

When this option is selected, multiple dilution conditions are applied to the test. Therefore, when the test is ordered, two or more dilution conditions can be selected in the [MultiDil.] column in the [Order Entry] window. When "Sub-analy. Conditions" are selected for a sample, different dilution conditions can be set for each condition.

When this option is not selected, multiple dilution conditions cannot be applied to the test. Even if the sub-analysis conditions have been defined for that test, the test is always run under the same dilution condition.

Deselect this option for a "Ratio" test where a ratio is calculated between the values of tests with same analytical conditions but with different sub-analysis conditions. In this case, the dilution condition should be the same for all tests. By deselecting this option, the same dilution condition is automatically applied for all tests.

[Sub Param.#] field

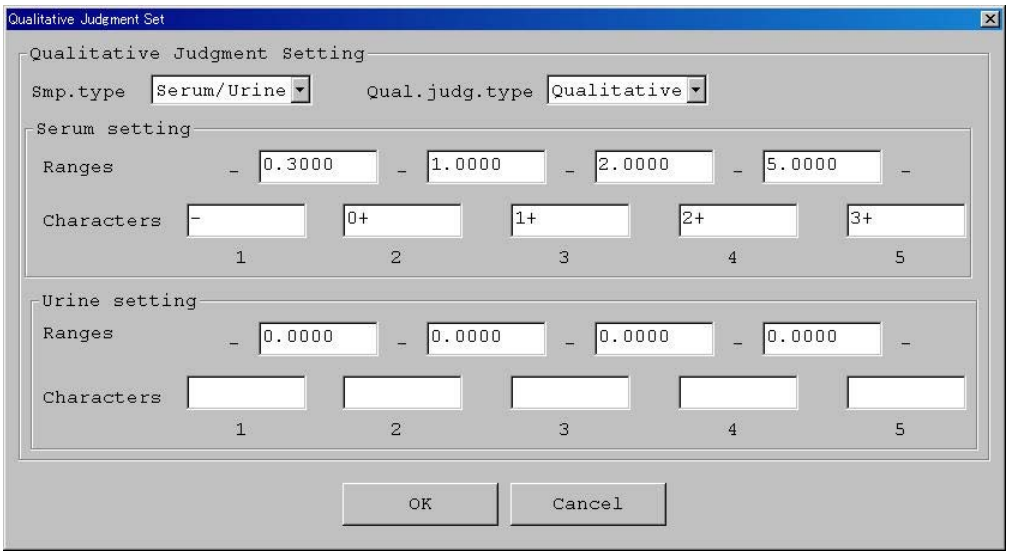
The sub-parameter number is the number of measurement values obtained from the reaction in one cuvette. Click the [UP] or [DOWN] button to choose from one, two, or three results per reaction.

[Sub-analy.conditions] column

[Name]	Enter a name in up to 6 alphanumeric characters.
[Digits]	Enter 0 - 4 to define the number of decimal places.
[M-wave.L.], [S-wave.L.]	Select a wavelength from 14 options: "340nm", "410nm", "451nm", "478nm", "505nm", "545nm", "571nm", "596nm" "658nm", "694nm", "751nm", "805nm", "845nm", and "884nm". Select " *****" if you do not wish to select a sub-wavelength.
[Analy. mthd]	Select an analysis method from the options: "EPA (end point assay)", "RRA (reaction rate assay)","2PA (2-point assay)", “CRA (constant rate assay)”, and “IMA (immunoassay)".
[Calc.mthd]	Select a calculation method for calibration: "ABS (absolute)", "STD (standard)", and "MSTD (multi-standard).
[Qualit.judge]	Options are "Do" and "Not do". When "Do" is selected, click the [Qualit. judgment set] button to enter the values necessary to perform the qualitative judgment.

[Qualitative Judgment Set] button

Click this button to display the window below.



[Smp.type] Select "Serum/Urine", "Serum" or "Urine".

[Qual.judg.type] Select "Qualitative" or "Critical".

When “Critical” is selected, upper and lower limit values are used for defining a target range. Measurement values between limit values are displayed as a numerical value; measurement values above and below the limits are displayed as less than or greater than the limit, i.e. "<0.3" will be displayed for all the values below 0.3. Enter a very large value for the upper limit value if you do not wish to judge the upper limit.

[Ranges] Enter the value ranges for qualitative and critical judgment.

For qualitative judgment: Define the threshold value for displaying flags such as "-" and "+".

For critical judgment: Only the left-most and right-most values are valid.

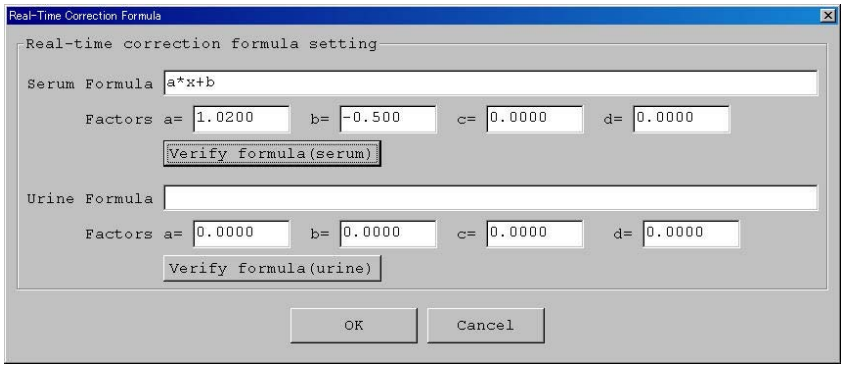
[Disp. Characters] Enter a mark or character to indicate the value is within the limits defined in the [Ranges] field. In critical judgment, only the left-most and right-most marks or characters are valid.

[Real-Time Correction Formula] button

Click this button to display the window below.

Use this window to enter the correction formula for serum and urine samples.

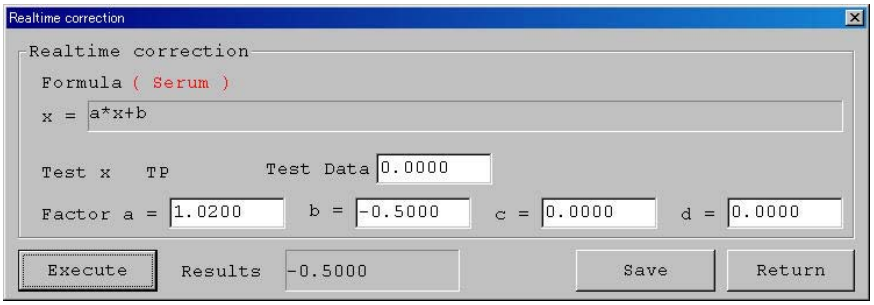
The correction formula is applied to all the measurement values then the results are displayed.



[Formula] Enter the correction formula for serum and urine respectively.
Use the following symbols in entering the formula (e.g. "x*10/aˆb".)
x: raw measurement data (concentration)
a, b, c, d: factors (defined in the "Factors" fields)
*, /, +, -: four arithmetic operations
1～9, ". (a period)" : Fixed value
R( ) : root
L( ): log
ˆ( ) : power
(,): parentheses

[Factors a-d] Factors used in the formula

[Verify formula] button Click this button to display the [Realtime correction] window below.



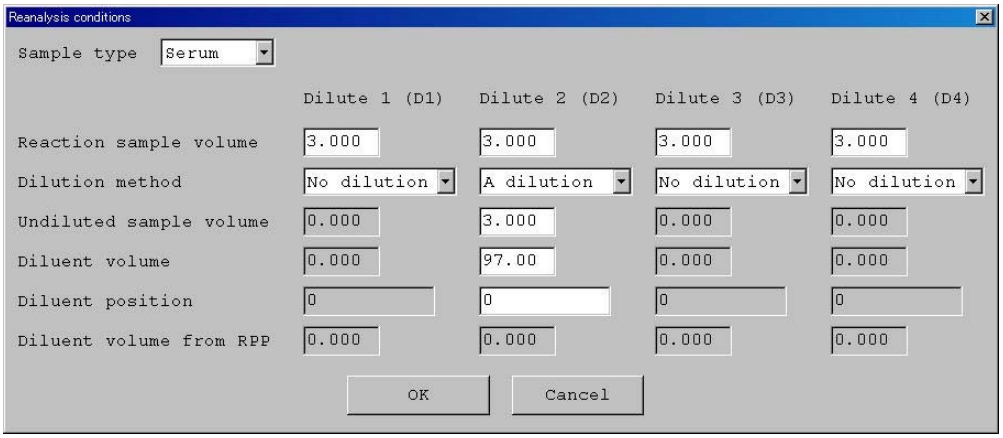
Enter a tentative value in the [Test Data] field and click [Execute] to display the result value in the [Results] field. From the value displayed, the validity of the

formula can be judged. Click [Save] to save the factors entered in this window.

[Rerun conditions] button

Click this button to display the [Rerun conditions] window below.

Four rerun conditions from [Dilute 1 (D1)] to [Dilute 4 (D4)] can be defined as "Rerun conditions" in this window

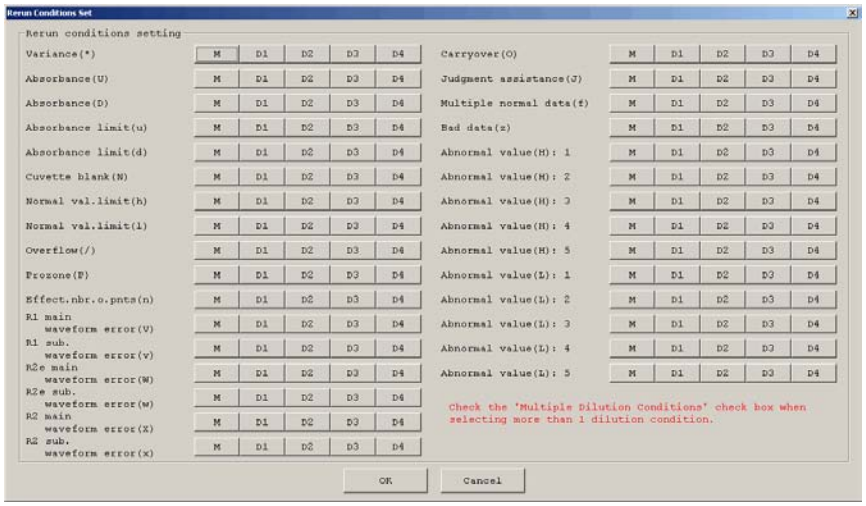


See “Section [Analysis Test Condition Setting (M)]” in “Section 2.2.1a: Basic Settings” in this chapter.

Conditions for [Dilute 2] and [Dilute 3] in the [Rerun conditions] window are automatically set to the conditions entered for [Dilute 1], but they can be edited.

[Rerun Conditions Set] button

Click this button to display the [Rerun Conditions Set] window below.



Select whether to rerun the tests for the items listed in this window. When selecting a rerun, one condition can be chosen from the conditions [M], [D1], D2], [D3], and [D4]. The rerun conditions [M], [D1], [D2], [D3], and [D4] are defined as follows:

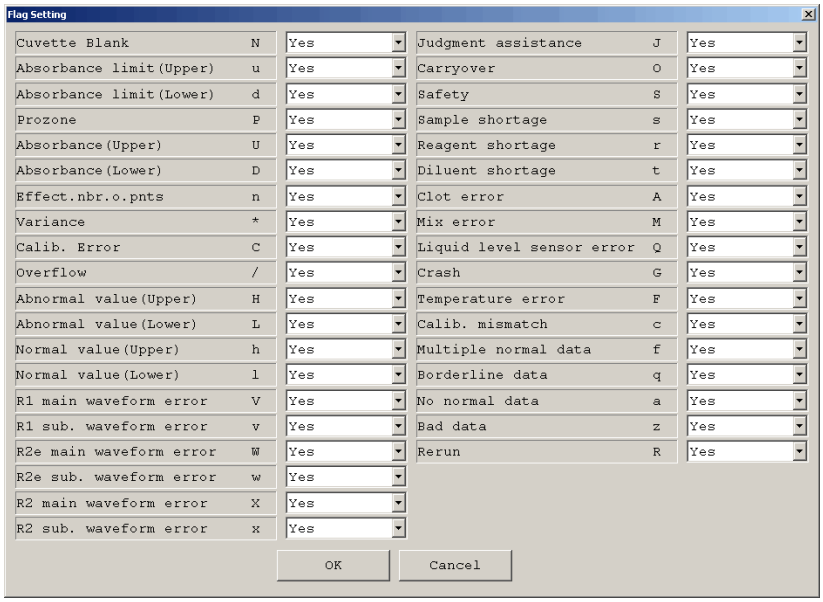
[M]	The conditions as defined in the [Analysis test condition setting (M)] window.
[D1], [D2], [D3], [D4]	The conditions defined respectively in the [Rerun conditions] window for [Dilute 1], [Dilute 2], [Dilute 3], and [Dilute 4]. .

ATTENTION

To perform a ratio calculation between the results of a test with three different sub-analytical parameters (sub-parameter #1, 2, or 3), a same dilution condition must be set for the three sub-parameters in [Rerun Conditions Set] window. If different dilution conditions are set for the three sub-parameters, the result of a ratio calculation may be an abnormal value.

[Flag Setting] button

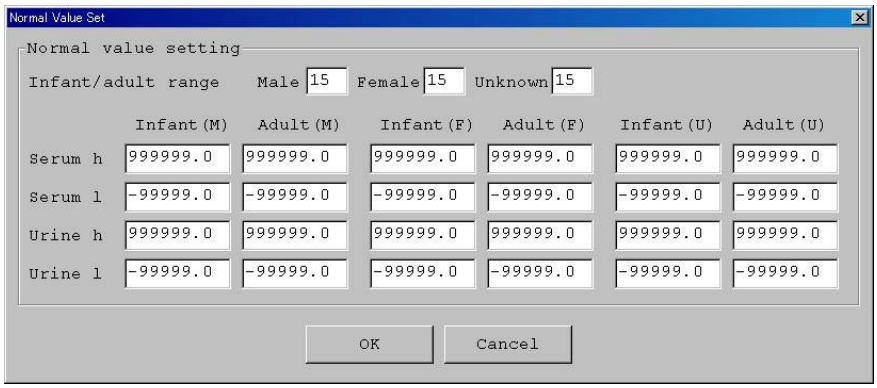
Click this button to display the [Flag Setting] window below.



Select "Yes" to post a flag with the abnormal result of the relevant item, or "No" to not to post a flag, when displaying or printing the result.

[Normal value setting] button

Click this button to display the [Normal Value Set] window below.

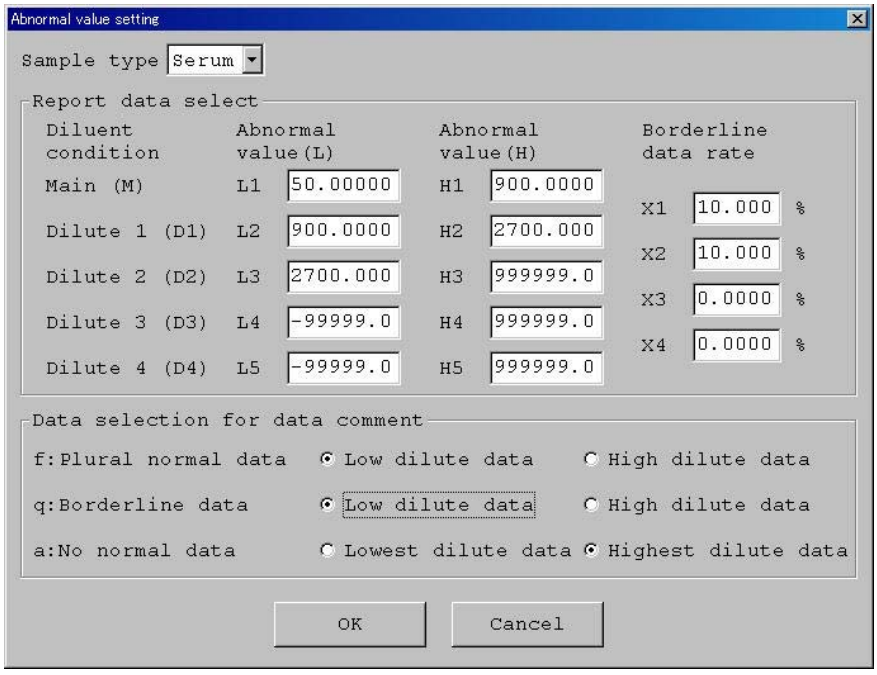


[Infant/Adult Range] Enter the age limit respectively for [Male], [Female], and [Unknown]. The patient is regarded as adult if his/her age is the same or older than the entered age.

[Serum h], [Serum l] Enter the upper limit of the normal serum value in the [Serum h] fields and the lower limit in the [Serum l] fields.

[Abnormal value setting] button

Click this button to display the [Abnormal value setting] window below.



[Sample type] Select "Serum" or "Urine".

[Report data select] column

[Abnormal value (L) or (H)] Enter the values beyond which a measurement is considered outside the normal range (abnormal).

[Borderline data rate] If all the measurement values are abnormal and the value with low dilution is judged "H" and that with high dilution "L", a “difference rate” is calculated. The “difference rate” is defined as the difference between the two values divided by the value obtained with the higher dilution. If this difference rate is lower than the value set here, the above two values are judged to be borderline measurements. "Data (X)" indicates the measurement value with the dilution condition "X". "x1" indicates the difference between the "Data(M)" and "Data(D1)", "x2" indicates the difference between "Data(D1)" and "Data(D2)", etc.

[Data selection for Data Comment] Flag "f", "q" or "a" is posted for the selected item of the following.

[f: Plural normal data] When two or more normal values are obtained, select which value to report: [Low dilute data] or [High dilute data].

[q: Borderline data] When no normal value is obtained, yet both "L" and "H" values exist and borderline data exist, select which value to report, [Low dilute data] or [High dilute data].

In the [Abnormal value] fields, enter the values that satisfy the following conditions.
L1<H1, L2<H2, L3<H3, L4<H4, L5<H5

[a: No normal data] When no normal value is obtained, select which value to report: the [Lowest dilute data] or the [Highest dilute data] for all the measured values.

See Section 6.1.3e and Section 11.2 for details.

[Standard setting] column

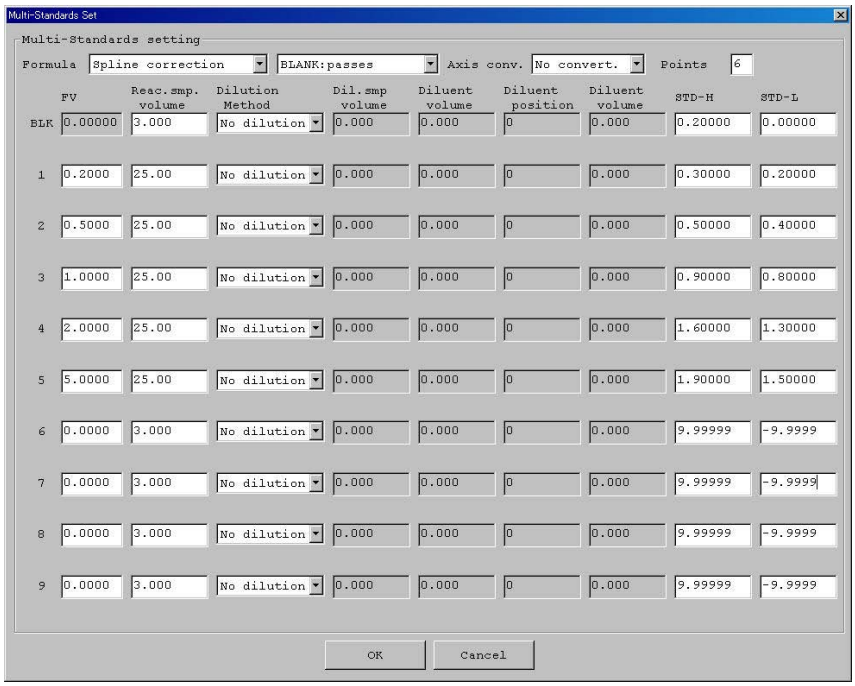
Select the standard to be used in the [Standard setting] column located in the upper right section of the [Analytical Parameters (Chemistry)] window. The parameters are as follows:

[FV] Define the concentration of the calibrator when "STD (standard)" calculation method is selected, or the factor value when "ABS (absolute)" calculation method is selected.

[BLK H], [BLK L], [STD H], [STD L]
Define the ranges of absorbance for the blank and the standard calibration.

[Multi-STD Setting] button

Click this button to display the [Multi-Standards Set] window below.



Use this window when "MSTD" is selected for [Calc. mthd] in the [Sub-analy.conditions] column.

You can prepare a series of calibrators with several concentrations automatically by diluting a calibrator using various dilution factors. This series of diluted calibrator is then used to generate the calibration curve for multi-point calibration.

Use this window to define the dilution condition for each point of the calibration curve.

[Formula] Select an approximation formula to generate the calibration curve. Select either [BLANK: passes] or [BLANK: not pass.] when defining the formula. Selecting [BLANK: not pass.], you can enter a value in the [FV] field for BLK.

[Axis. conv.] Select an axis conversion method to use in generating the calibration curve after measurement.

[Points] Define the number of data points used to generate the calibration curve (up to ten points are possible including the blank).

[FV] Define the concentration of each calibrator.

[Reaction sample volume] Enter a value between 1 and 25 (µL) in 0.1 increments for the sample volume used in calibration.

To set conditions for [Dilution method], [Undiluted sample volume], [Diluent volume], [Diluent position], and [Diluent volume from RPP]:

See [Analysis Test Condition Setting (M)] in “Section 2.2.1a: Basic Settings” in this chapter.

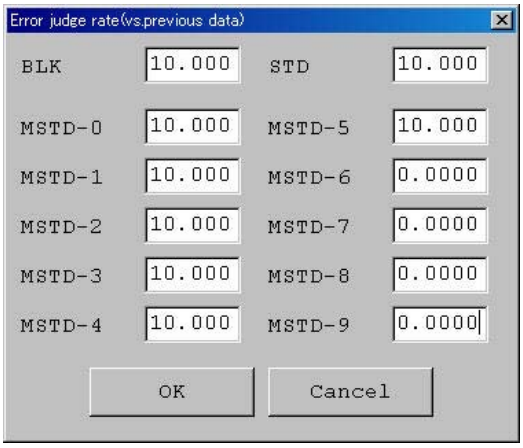
[STD-H], [STD-L] Define the upper and lower allowance limits of absorbance measured.

When the volume and dilution condition of the calibrator is different from those for serum measurement, the "FV" value should be edited.

See “Section 2.3.2 Multi-standard” as required.

[Error judge rate (vs. previous data)] button

Click this button to display the [Error judge rate (vs. previous data)] window below.



Enter the allowance in this window to judge if the difference in absorbance between the current and previous measurements is within the allowable range.

The difference rate is calculated using the following formula:

$$\frac{\left|\text{previous calibration value} - \text{current calibration value}\right|}{\text{previous calibration value}} \times 100(\%)$$

If this rate is higher than the allowance range, the value is judged as abnormal and flag "z" is posted to the result. The new calibration result will not be used and the previous calibration result is maintained.

The "Error judge rate (vs.previous data)" function is not available unless "Do" is selected for [Error judge rate (vs.previous data)] in the [System Monitor] window.

[BLK], [STD], [MSTD0-9] Enter the allowance rate (%) for each field.

[Calculation method setting] column

The parameters in the [Calculation method setting] column are different depending on the analytical method.

See “Chapter 6 Data Processing” for details.

2.2.1b Settings for measuring urine samples

Serum and urine

When selecting tests to perform on a sample, specify the sample type "serum" or "urine". The tests are performed on the sample according to the analytical conditions specified for each type. See the "[Analytical test condition setting (M)] window section below for instructions for defining the sample type.

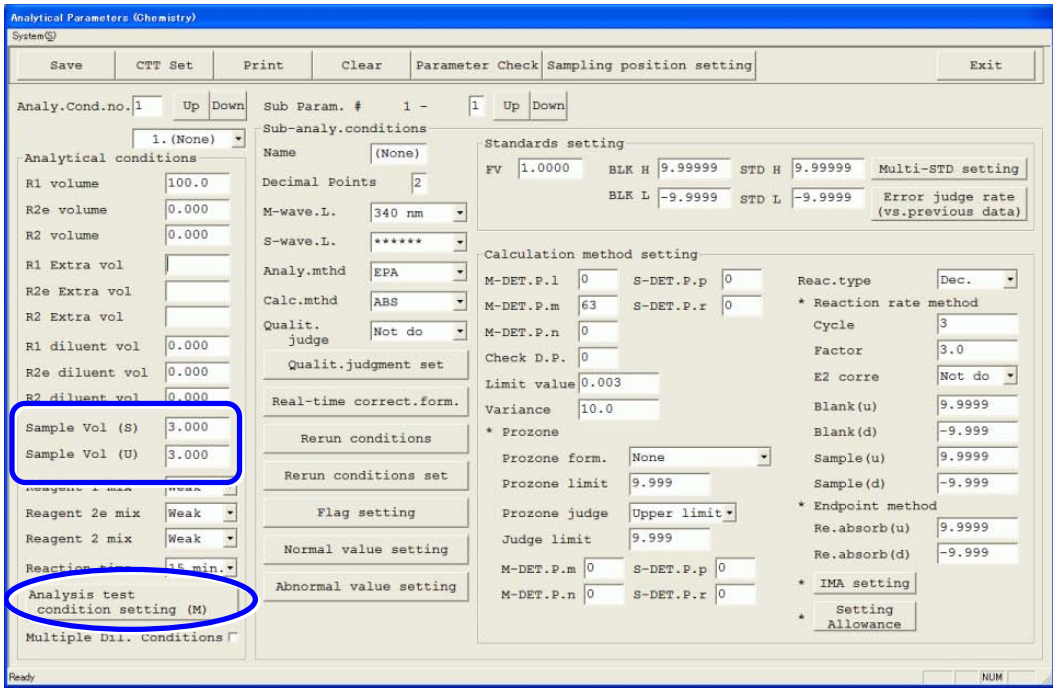
You can enter different values depending on the serum or urine sample type for the following analytical parameters; the [Sample Vol.] fields in the [Analytical conditions] column and for the [Analysis test condition setting (M)] and [Rerun conditions] windows. Common parameters include reagents, mixer force, detected wavelength, calculation-related settings, and calibration-related settings.

Parameters concerning the measurement results can also be defined by sample type in the [Qualitative Setting], [Real-time Correction Formula], [Normal value setting] and [Abnormal value settings] windows which are accessed by using the respective buttons in the [Analytical Parameters (Chemistry)] window.

(The basic settings for the serum sample were described in Section 2.2.1a; therefore, the settings for the urine are described here.)

Setting the analytical conditions

Select [Setup] > [Analytical Parameters (Chemistry)]. The [Analytical Parameter (Chemistry)] window is displayed.



[Analytical conditions] column

[Sample Vol (U)] Enter the urine sample volume to be dispensed into the reaction carousel (RVV) cuvette. Enter a value between 1 and 25 µL in 0.1µL increments.

[Analysis test condition setting (M)] window

Click the [Analysis test condition setting (M)] button located in the lower left of the [Analytical Parameters (Chemistry] window to display the [Analysis test condition setting (M)] window. Select "Urine" for the [Sample type] field on top of the page.

Set the other parameters in the same way as described in "Section 2.2.1a: Basic Settings."

[Rerun conditions] window

Click [Rerun conditions] button in the [Sub-analy.conditions] column to display the [Rerun conditions] window.

Select "Urine" for the [Sample type] field.

Set the other parameters in the same way as described in "Section 2.2.1a: Basic Settings."

Defining the data processing and flag conditions

Click the [Qualit. judgment set], [Real-time correct.form.], [Normal value setting], and [Abnormal value setting] buttons respectively to display the corresponding window. Define the parameters separately for serum and urine sample type in these windows.

Set the other parameters as described in "Section 2.2.1a: Basic Settings."

Defining the ratio parameters

Select [Setup] > [Ratio Parameters]. The [Ratio Parameters] window is displayed.

See Section 2.3.4 for details.

Defining QC samples

Select [QC] > [QC Sample Definition]. The [QC Sample Definition] window is displayed.

Select "Urine" for the [samp. type] field in the [Control Sample Definition] column.

This defines the control sample to be run using the analytical conditions for urine and used exclusively for urine measurement.

2.2.1c Settings for measuring HbA1c

The following settings are required for measuring HbA1c.

[Sampling Position Setting] window

Select [Setup] > [Analytical Parameters (Chemistry)]. The [Analytical Parameter (Chemistry)] window is displayed. Click the [Sampling Position Setting] button to display the [Sampling Position Setting] window.

Select the sample aspiration position. You can define the position by both test and sample category such as patient sample, control sample, calibrators, etc.

Click the arrow in each field to select either "Top" or "Bottom" from the drop-down menu.

[Top] The sample probe (SPP) aspirates the sample from the liquid surface.

[Bottom] SPP aspirates the sample near the bottom of the sample container.

[Sampling Position Setting] window

[No. Name1 Name2 Name3] The test # and names defined in the [Process Sequence] window are displayed.

[Patient/STAT/Pri.] In this column, the sampling positions of the patient, STAT, and priority samples are selected. The upper field selects the sampling position of the patient and STAT samples.
The lower field selects the sampling position of the priority samples.

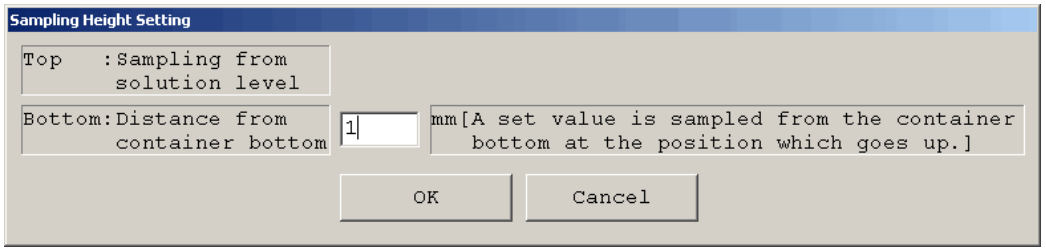
[Control （A-M/N-Z）] In this column, the sampling positions of control samples are selected. The upper field selects the sampling positions of the control samples A - M.
The lower field selects the sampling positions of the control samples N - Z.

[Calibrator] In this column, the sampling positions of calibrators are selected. The upper field selects the sampling position for the reagent blank.
The lower field defines the sampling position of the standards.

[Multi-Standard] In this column, the sampling positions of standards used for multi-standard measurement are defined. The sampling position of the reagent blank and calibrators (STD1 – STD9) are defined respectively.

[Next Page]/[Prev Page] buttons Click [Next Page] to proceed to the next page and [Prev Page] to go back to the previous page.

[Height Setting] button Click this button to display the window below. This window is used to specify the height of the sampling position from the bottom when "Bottom" is selected. Enter "1" mm for measuring HbA1c. The default value is "1".



[Sampling Height Setting] window

Buttons in [Sampling Height Setting] window

[OK] button in Click this button to save the current setting values and close the [Sampling Height Setting] window.

[Cancel] button Click this button to close the window without saving the entered settings.

Buttons in [Sampling Position Setting] window

[Clear] button Click this button to reset all sampling positions to "Top".

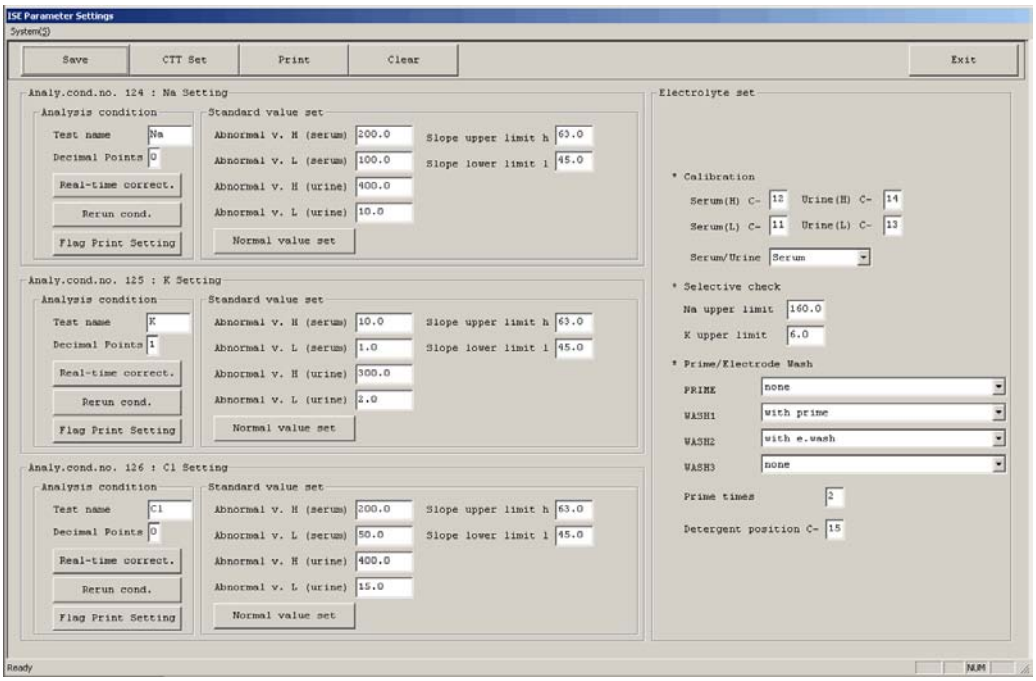
[Print] button Click this button to print all the sampling position and height settings.

[Cancel] button Click this button to quit the [Sample Position Setting] window without saving the entered settings.

[OK] button Click this button to save the current settings and close the [Sampling Position Setting] window.

2.2.1d Settings for ion selective electrode (ISE) measurement

Select [Setup] > [ISE Parameter Settings] to display the [ISE Parameter Settings] window. Use this window to set parameters for the data acquisition and processing of ISE measurements.



[ISE Parameter Settings] window

Data processing settings for Na, K, and Cl measurements

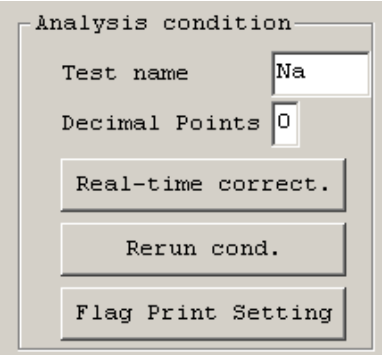
This window is used to enter settings for processing measurement values for Na, K, and Cl respectively.

Setting items are the test name, number of decimal places, real-time data correction formula, display of flags for abnormal values, rerun, range of abnormal values, range of normal values, concentration of calibrators (H-STD/L-STD), limit value of the slope, and the upper limit value of selectivity check.

[Analy.cond. no.] column

In each [Analy.cond.no.] field, the number corresponding to Na, K, and Cl is automatically displayed.

[Analysis condition] column

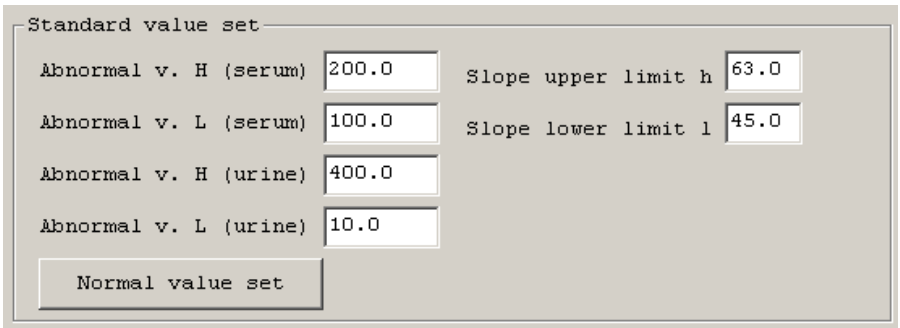


The following table gives an explanation of the analytical condition parameters.

Parameter	Explanation
Test nam e	Enter up to 6 one-byte characters (alphanumerical) or 3 two-byte characters (Japanese, Chinese, etc.) However, the test name will be automatically entered as Na, K, or Cl when the CV check, interval check, calibration, or selectivity check is performed.
Digits	Enter 0 - 2 to define the number of decimal places used when displaying the measurement data. However, the number of decimal places is always "1" for Na and Cl, and "2" for K when displaying/printing the values from the CV check, Interval check, and Selectivity check.
Real-time correct.	Click this button to select a formula for correcting the measured concentration. Enter a separate formula for serum and urine. See "Section 2.2.1a: Basic Settings" for details. • The formulas are not applied to the values from CV check, interval check, and selectivity check because they are values for maintenance.
Rerun cond., Flag Print Setting	Select "To be rerun" or "No rerun" for each rerun condition. When "To be rerun" is selected, an automatic rerun is performed for a patient sample with flagged data. Flags for rerun can be defined for each test.

[Standard value set] column

The following table summarizes the parameters in the [Standard value set] column in the [ISE Parameters Setting] window.

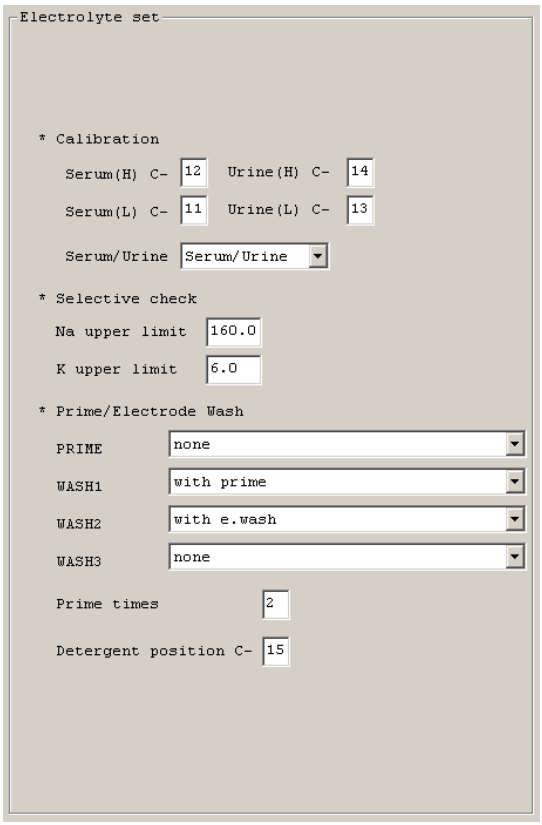


Parameter	Explanation
Abnormal v. (serum)	The threshold of abnormal values for serum measurement. The upper limit is indicated with "H" and the lower with "L". The default value is the limit concentration with which the measured potential of each test and the concentration value keeps the linearity (limit of linearity). • If "No flag" is selected for [Limit of abnormal value], the flag "H" or "L" will not be posted even when the measurement value is out of the normal range.
Abnormal v. (urine)	The threshold of abnormal values for urine measurement. The upper limit is indicated with "H" and the lower with "L". The default value is the limit of linearity value for each test. • If "No flag" is selected for [Limit of abnormal value], the flag "H" or "L" will not be posted even when the measurement value is out of the range.
[Normal value set] button	Click this button to display the [Normal Value Set] window where the age ranges and threshold values are entered respectively for serum and urine. The upper limit is indicated with "h" and the lower with "l". • If "No flag" is selected for [Limit of abnormal value], the flag "h" or "l" will not be posted even when the measurement value is out of the range.
Slope upper limit (h), Slope lower limit (l)	The slope of the calibration curve is out of the range set by the upper and lower limits, the flag "h" or "l" is posted as an alert. Analysis can continue in either "h" or "l" status. The slope value for Cl will be negative, however, it is converted to positive value when judging slope validity. Therefore, enter positive values for Cl in this window as for Na and K. The upper limit (h) and lower limit (l) are common with serum and urine. The default values are 63 for the upper limit and 45 for the lower limit, which are common with Na, K, and Cl • The threshold slope values are 65 for the upper limit and 38 for the lower limit. They are default values and automatically entered in [ISE Parameter Settings] window. When the value reaches these thresholds, it is posted with "H" or "L" flag and judged to be a slope error. When this error occurs, the ISE calibration data for both serum and urine samples are deleted. Therefore, repeat the calibration and obtain a new normal calibration values; alternatively, transfer existing values by selecting [ISE Monitor] > [Data transf.]

Measurement settings common to all Na, K, and Cl measurements

Some settings are common for all Na, K, and Cl measurements. These settings include the sampling volume, the number of calibration curve data points, whether to combine priming and washing of the ISE unit with those of the chemistry unit, the number of priming times, positions on the refrigerated sample tray (CTT) of calibrators and the pure water for washing electrodes.

The table below summarizes the contents of the [Electrolyte Set] column located at the right side of the [ISE Parameter Settings] window.

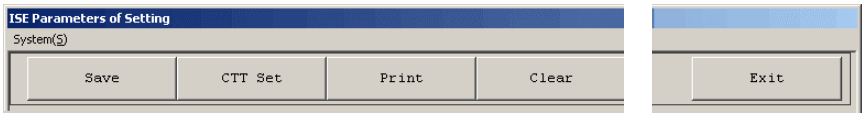


Item	Description
Calibration	The calibration setting is used when the calibration is started by clicking the [START] button in the Operation Panel.
CTT positions of calibrators	The CTT positions of the high concentration calibrator (H) and the low concentration calibrator (L) are defined separately for serum and urine. Default positions are C-12 for Serum (H), C-11 for Serum (L), C-14 for Urine (H) and C-13 for Urine (L). When you change the CTT position or container type, click the [CTT Set] button in the top bar to open the [CTT Setting] window for confirmation.
[Serum/Urine] field	Select a calibration mode from "Serum", "Urine", or "Serum/Urine". The default value is "Serum/Urine".

Item	Description
Selectivity check	Enter a value to evaluate electrodes when they are checked with the selectivity check solution. If the concentration is greater than the set value, the reading is flagged with "u".
• Na upper limit	Enter the upper limit of normal electrode sensitivity for Na. The default value is "160".
• K upper limit	Enter the upper limit of normal electrode sensitivity for K. The default value is "6.0".
Prime/Electrode Wash	Enter values when performing the "priming" and "electrode wash" of the ISE unit in combination with [PRIME], [WASH1], [WASH2], and [WASH3] of the Chemistry unit. When you change the CTT position or container type of the detergents, click the [CTT Set] button in the top bar to open the [CTT Setting] window for confirmation.
• PRIME	Select "**with prime**" to prime the ISE unit simultaneously with the chemistry unit. When "**none**" is selected, priming of the ISE unit must be started independently.
• WASH1, WASH2, WASH3	Select "**with prime**" to prime the ISE unit when one of the WASH is being performed at the chemistry unit. Select "**with e. wash**" to wash the ISE unit when one of the WASH is being performed at the chemistry unit. When "**none**" is selected, washing and/or priming of the ISE unit must be started independently.
• Prime times	Enter the number of priming sequences in the [INITIALIZE], [PRIME], and [WASH] procedures respectively. The default value is "2". The value range is 0 - 3.
• Detergent position	Enter the CTT position number of the ISE detergent solution used for electrode washing during the [WASH] procedure. The default value is "C-15".

Command buttons

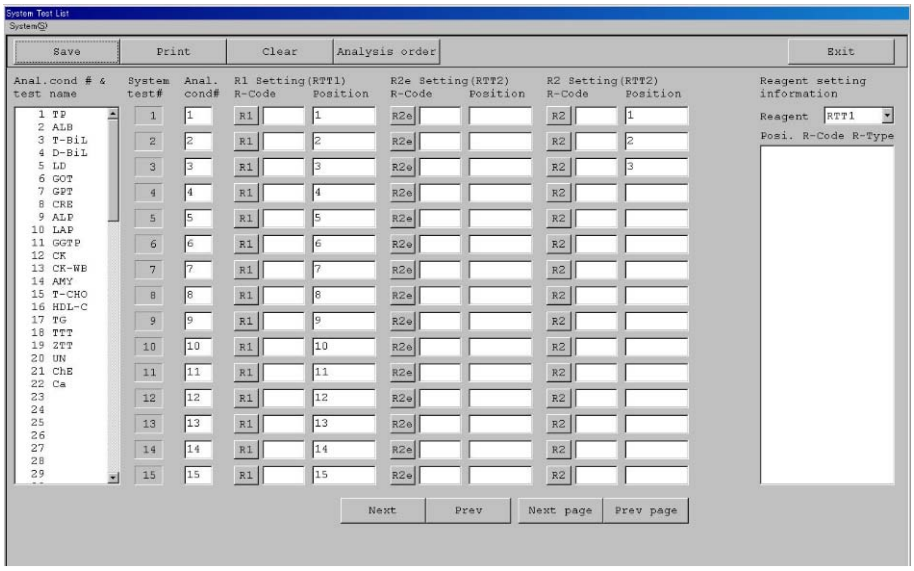
The table below summarizes the functions of buttons on the top bar in the [ISE Parameters Setting] window.



Item	Description
Save	Click this button to save the changes made in the [ISE Parameters Setting] window.
CTT Set	Click this button to display the [CTT Setting] window. Check that the CTT positions of the calibrators for the current test and the ISE detergent solution do not overlap with those of the calibrators and control solutions for other tests.
Cup/Tube Type	Click the arrow to select the container type to place on the CTT. The container types and names must be entered in the [System Specifications Set] window beforehand. Be sure to select an appropriate container.
Print	Click this button to print the settings entered in the [ISE Parameters Setting] window with the current date. Be sure to print the window for record of the defined settings in case of power outage or system failure.
Clear	Click this button to reset the values in the [ISE Parameter Setting] window to default.
Exit	Click this button to close the [ISE Parameter Setting] window.

2.2.2 [System Test List] window

Select [Setup] > [System Test List] to display the [System Test List] window. Select the reagent bottle positions for each test in this window.



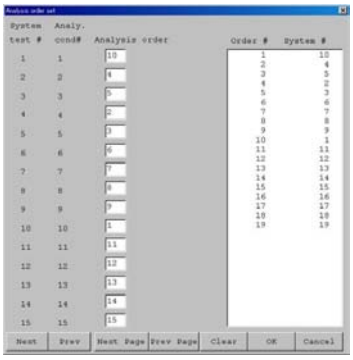
Items in the window

The system test list is organized by the [System test #] on the basis of which the corresponding [Anal.cond. #] and reagent tray (RTT) position number of each reagent are defined. Use the [Anal.cond. #] that has already been selected in the [Analytical Parameters] window.

When you use the barcode of the reagent bottle, enter a 5-digit code (manufacturer code for the first 3 digits and test code for the last 2 digits) in the field to the right of the [R1], [R2e], or [R2] button.

Select the test order

Click the [Analysis Order] button on the top bar to display the window below.



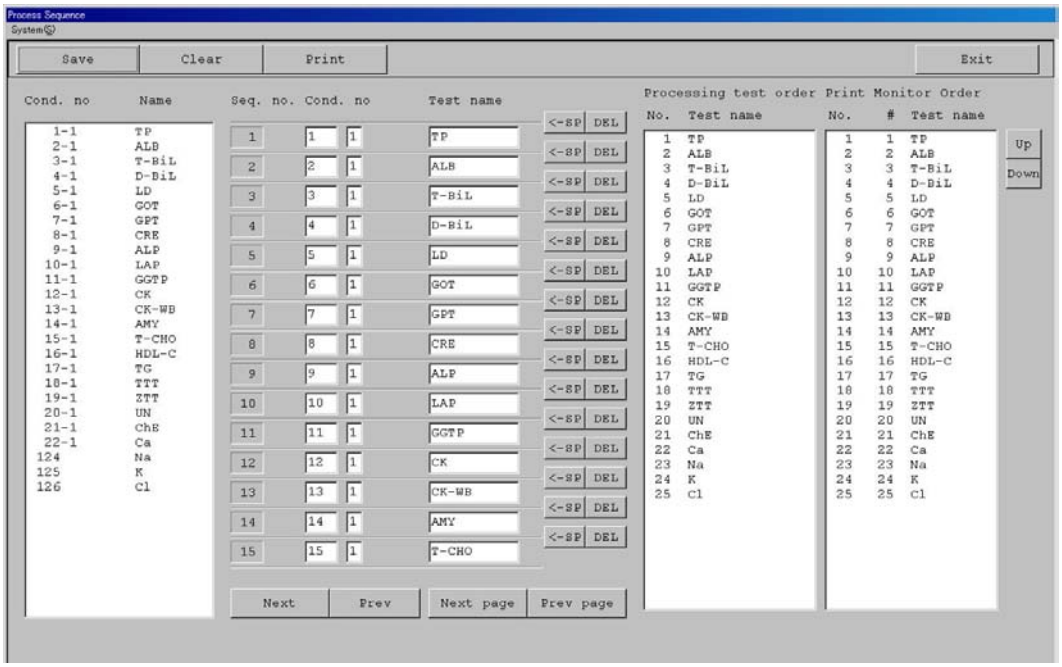
Select the order of tests that use the reagent specified by the [System Test #]. However, when two or more tests are performed on one sample, the following priority rules dictate the order of the tests:

Priority 1: Test that requires long reaction time

Priority 2: Contamination avoidance

2.2.3 [Process Sequence] window

Select [Setup] > [Process Sequence] to display the [Process Sequence] window. Select the order of tests by [Cond. No.] for data processing.



Select the data processing order

After the data processing order is selected in the [Process Sequence] window, the tests are displayed in the processing order in the [Test Table] in the [Order Entry] window (accessed from the [Request] button). The [Process Sequence #] is used as a test code in the laboratory information system (LIS).

The test code used when the analyzer is connected to the LIS can also be defined in the [Online Settings] window.

The "Cond. no" are listed in the left column for the tests with the measurement order defined in the [System Test List] window. Enter the "Cond. nos." of the tests you want to define under the [Cond. no.] column to the right of the [Seq. no.] column. After entering the [Cond. no.], the test name is automatically displayed in the [Test name] column. This "Test name" in the [Process Sequence] window can be edited if desired.

After the "Test name" is changed, the new name is displayed. However, note that the test name defined in the [Analytical Parameters (Chemistry)] window does not change.

Insert or delete a test

Click the [<-SP] button where you want to insert a test. Note that a field will be added and the “Seq. nos.” below the inserted test will adjust automatically.

Click the [DEL] button to delete a test. Note that a field will be deleted and the “Seq. nos.” below the deleted test will adjust automatically.

In order to delete a test without changing the “Seq. nos.”, use the [Clear] button on the top bar to display the [Clear] window in which the specified test entry can be deleted. Enter the Seq. no. of the test you want to delete in the [Clear no.] field and then click [OK]. The fields of the deleted test in [Process Sequence] window will be blank and the “Seq. nos.” of the tests below the deleted one do not change.

Test insertions and deletions are immediately reflected in the [Processing Test Order] and [Print Monitor Order] columns.

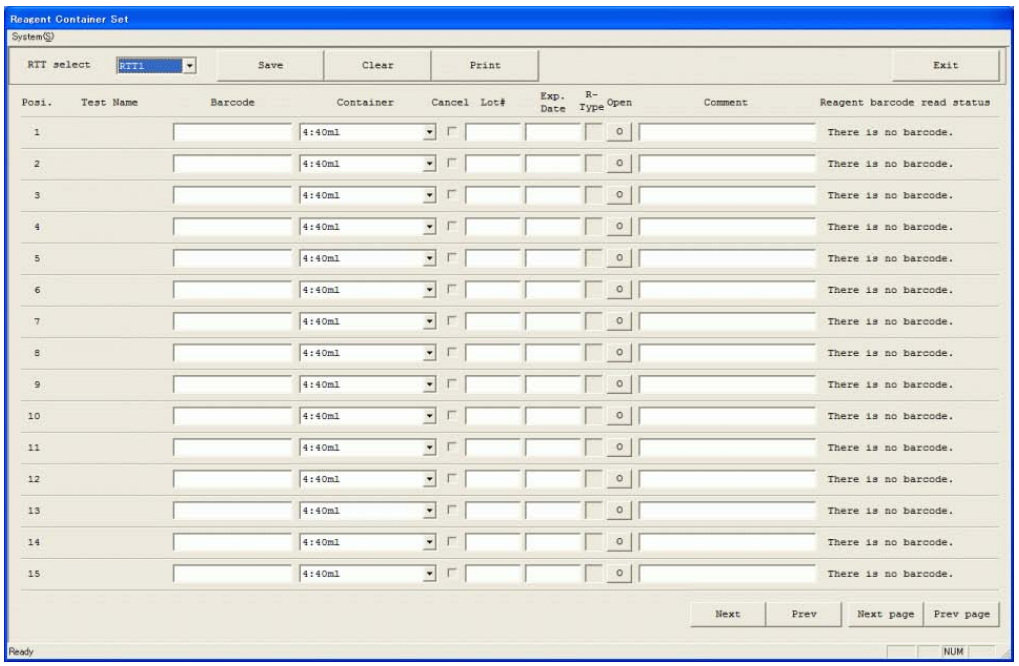
Selecting the display order of the tests on the monitor

Select and highlight a test in the [Print Monitor Order] column and click the [Up] button to move the test upward or the [Down] button to move it downward.

2.2.4 [Reagent Container Set] window

This window is used to define the container type placed in each position on the reagent tray (RTT).

Select [Reagent] > [Reagent Container Settings] to display [Reagent Container Set] window.



Select a container type in the [Container] column. Comments can be entered in the [Comment] column for each RTT position.

If "Avail." is selected for [Reagent barcode] in the [System Specification Settings] window (accessed from the [Setup] button), the analyzer reads the reagent barcode and the relevant data are displayed in the [Barcode], [Lot#], [Exp.Date (expiration date)] columns respectively.

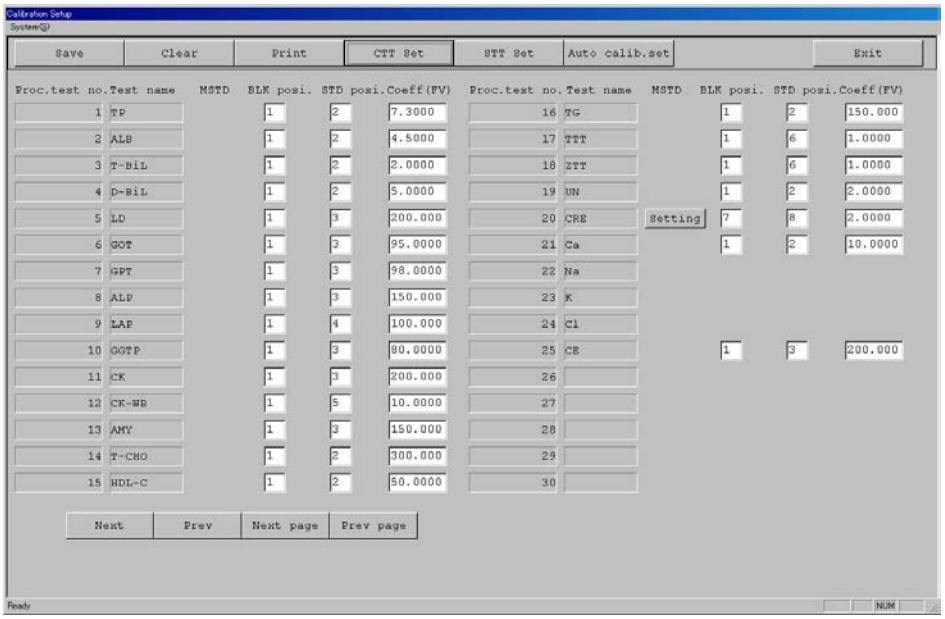
Entering the reagent expiration date and recording the reagent opening date

The [Reagent Container Set] window is also used for entering the expiration date and recording the opening date of the reagents without a barcode or that have an 8-digit barcode. Enter the expiration date in the field under the [Exp.Date] header and then click the button under the [Open] header to record the reagent was opened.

An 18-digit barcode on the reagent allows automatic entry of the lot number and expiration date when the analyzer reads the barcode. The analyzer assumes that the reagent bottle is opened when it reads the barcode. For reagent bottles with 18-digit barcode, just click the [Barcode Scan] button in [Reagent Test Monitor] window.

2.2.5 [Calibration Setup] window

Select [Calib.] > [Calibration Setup] to display the [Calibration Setup] window in order to enter the positions of the calibrators.



Defining [BLK posi.], [STD posi.], and [Coeff (FV)] values

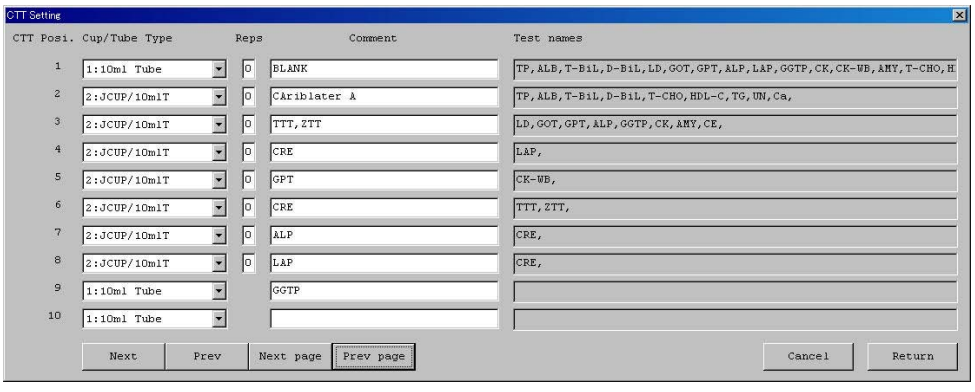
Enter the position (1-61) on the refrigerated sample tray (CTT) of the blank sample and the calibrator in the [BLK posi.] and [STD posi.] respectively for each test.

The field under the [FV] header automatically displays the value defined in the [Analytical Parameters (Chemistry)] window. You can edit the value here if desired; the edited value is reflected in the corresponding value in the [Analytical Parameters (Chemistry)] window.

[CTT Setting] window

Click the [CTT Set] button on the top bar to display the window below.

Following are the items to be defined in this window.



[Cup/Tube Type] Select the container type for the calibrator.

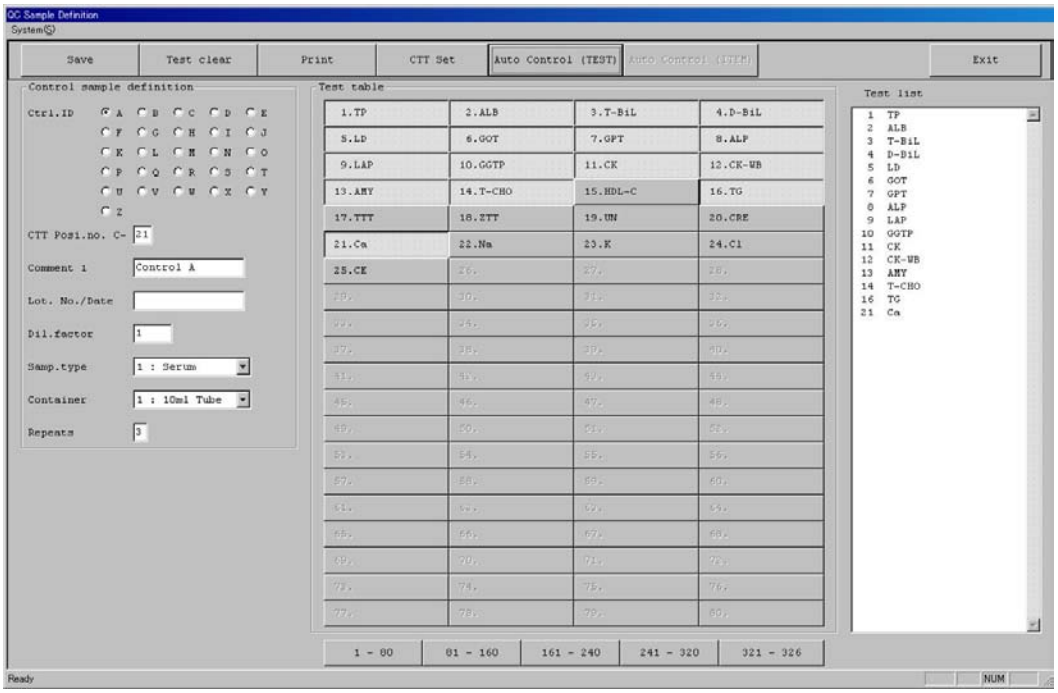
[Reps]	Indicate the number of measurement replicates for the calibrator. For example, if "5" is entered, the measurement is repeated 5 times. The final calibration value is obtained by averaging 3 measurement values excluding the highest and lowest values. If "2" is entered, the mean value of the two measurements will be the final result.
[Comment]	Enter a description of the calibrator. The description will carry forward to other relevant windows to assist in identifying the calibrator. This is a required field; a comment must be entered.

[Multi-Standard Setup] window

See Section 2.3.2 for setting up multi-standard measurement.

2.2.6 [QC Sample Definition] window

Select [QC] > [QC Sample Definition] to display the [QC Sample Definition] window below.



Settings for control samples

Up to 26 control samples (A-Z) can be utilized for quality control (QC).

① Enter the following items for each control sample.

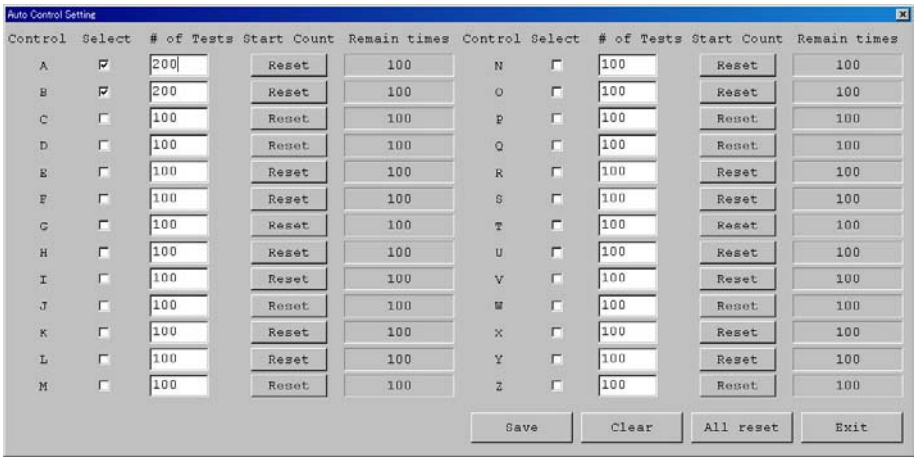
- [CTT Posi.no.]: position on the refrigerated tray.
- [Comment 1]: relevant comment for identifying control samples
- [Dil.Factor]: dilution factor
- [Samp.Type]: sample type
- [Container]: type of container
- [Replicates]: number of measurement times
- [Test table]: tests selected to run

② Entering the position on the CTT

Click the [CTT Set] button on the top bar to display the [CTT Setting] window.

Enter the values in the same way as described in the “Defining CTT settings” sub-section of “Section 2.2.5 [Calibration Setup] window.”

Click the [Auto Control (TOTAL TEST)] or [Auto Control (TEST)] button in the [QC Sample Definition] window to display the window below.



Enter the number of replicates in the field in the [# of Tests] column for each control sample. Click the [Reset] button to clear the value in the [Remain times] column for that row. Click the [All reset] button in the bottom of the window to clear all the values in the [Remain times] column. The number in the [Remain times] column is reset when the analyzer starts in the "New start" mode; they are not reset in the "Re-start" mode.

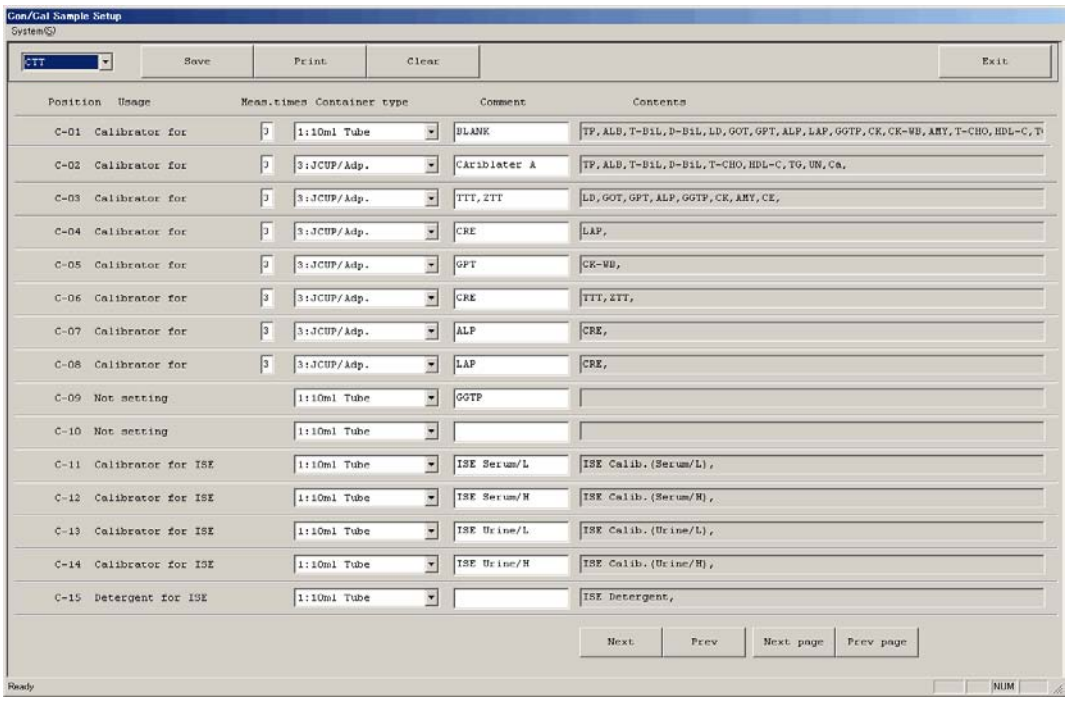
To select tests for which the control measurement is automatically performed, select [QC] > [Test Select], then select "3. Auto control samp. meas." in the [Test select] column and select the appropriate tests in the [Test table]. The control measurement is automatically performed for the selected tests only.

The method by which the number of automatic control sample measurement replicates is calculated and the tests on which the control measurement is performed depend on the [System Parameters] setting. For details, see “Section 5.4.2. Automatic control measurement” in “Chapter 5 Optional Functions.”

2.2.7 [Ctrl/Cal Sample Setup] window

This window is used to indicate the container type and number of replicates for calibrators and control samples.

Select [Setup] > [Ctrl/Cal Sample Setup] to display the window below:



① Select a tray.

Select "CTT", "STT-98", or "STT-99" in the field at the upper left corner.

"CTT" is used for calibrator, special diluents, detergents, and control samples.

"STT-98" and "STT-99" are used for standards with multiple data points.

② When "CTT" is selected, define the following parameters.

[Usage]	This field is automatically filled with the predefined value.
[Meas.times]	Enter the number of replicates.
[Container type]	Select a container type.
[Comment]	Enter a comment if desired.
[Contents]	This field is automatically filled with the predefined value.

③ When "STT-98" or "STT-99 is selected, define the following parameters.

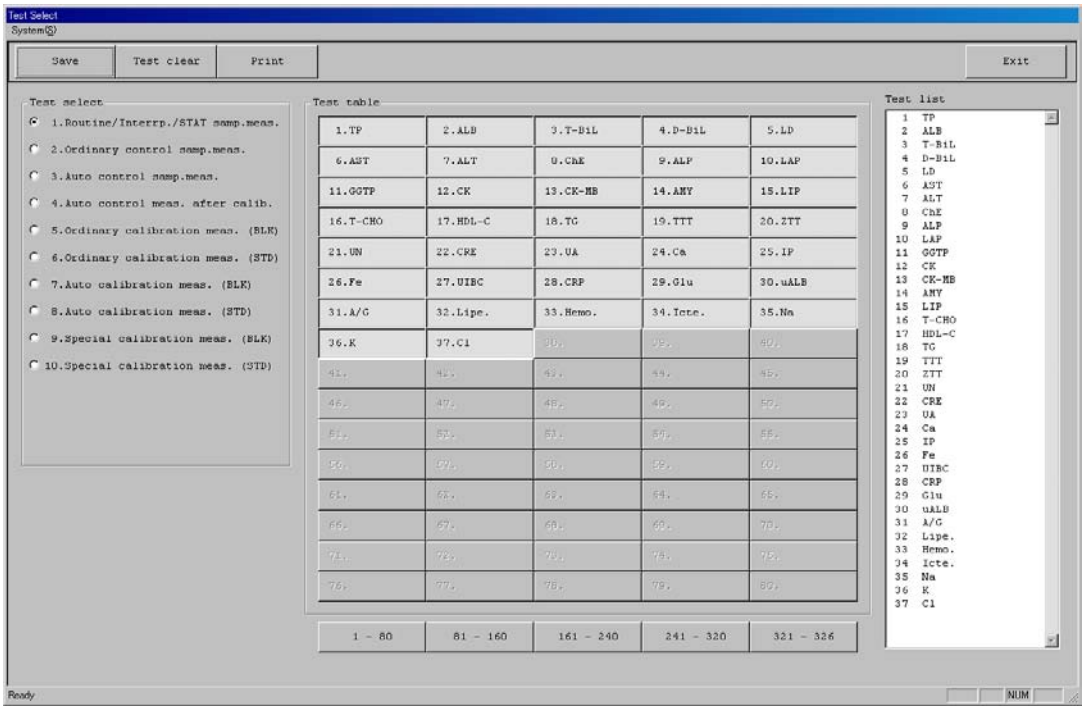
[Meas.times]	Enter the number of replicates.
[Container type]	Select a container type.
[Comment]	Enter a comment if desired.

2.2.8 [Test Select] window

This window is used to define the tests to perform by measurement type.

Any test not selected in this window will not be run, even if an order is placed.

Select [Request] > [Test Select] to display the window below.



① Select a measurement category in the [Test select] column.

The measurement types are classified into ten categories in the [Test select] column.

[Routine/Interrp./STAT samp.meas.]	Select when patient samples are measured.
[Ordinary control samp.meas.]	Select when ordinary control samples are measured.
[Auto control samp.meas.]	Select when control samples are automatically measured.
[Auto control meas. after calib.]	Select when control samples are measured after automatic calibration.
[Ordinary calibration meas. (BLK)]	Select when ordinary blank calibrators are measured.
[Ordinary calibration meas. (STD)]	Select when ordinary calibrators are measured.
[Auto calibration meas. (BLK)]	Select when ordinary blank calibrators are automatically measured.
[Auto calibration meas. (STD)]	Select when ordinary calibrators are automatically measured.
[Special calibration meas. (BLK)]	Select when an alternative blank calibrator is measured. This option is useful if you

change the tests for calibration depending on the day of the week.

[Special calibration meas. (STD)] Select when an alternative calibrator is measured. This option is useful if you change the tests for calibration depending on the day of the week.

② Select the tests desired in each measurement category.

Click the button with the test name on the [Test table] to select it.

The selected test button will appear depressed and the test name will be displayed in the [Test list] column on the right.

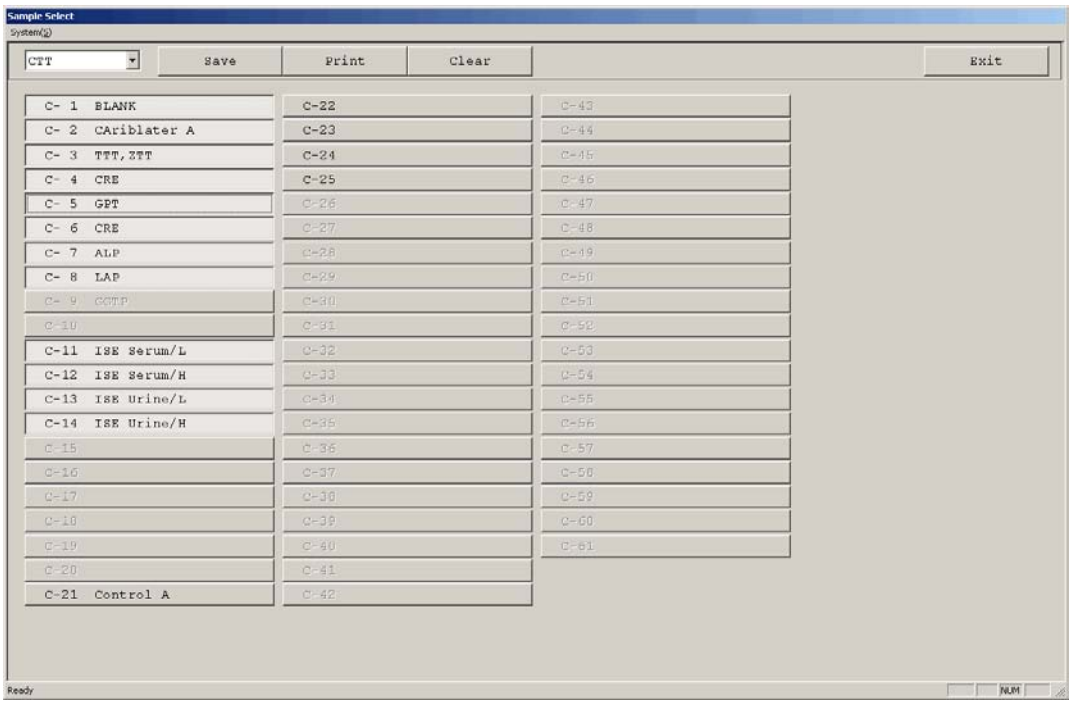
If a test is not selected in the [Test Select] window, any order to execute the test will be disregarded by the analyzer.

2.2.9 [Sample Select] window

This window is used to select calibrators and control samples on which measurement is performed.

The samples not selected in this window are not measured even if an order is placed.

Select [Calib.] > [Sample Select] to display the window below.



① Select a tray.

Select "CTT", "STT-98", or "STT-99" in the drop-down box at the upper left corner of the window.

② Select the samples to measure

Click the appropriate buttons to select the desired sample positions on each tray.

The selected buttons will appear depressed.

If a sample is not selected in the [Sample Select] window, any test ordered for the sample will be ignored.

2.3 Other Settings

This section describes optional and advanced settings.

2.3.1 Rerun

What is a rerun?

Measurement values are sometimes displayed with one or more flags.

Flags are posted under the following circumstances:

- When an abnormality is detected while processing the measurement data
- When the measurement data are out of the limit of linearity for the test
- When the measurement data are out of the normal range.
- When the reaction time course is abnormal
- When the reagent was short during measurement

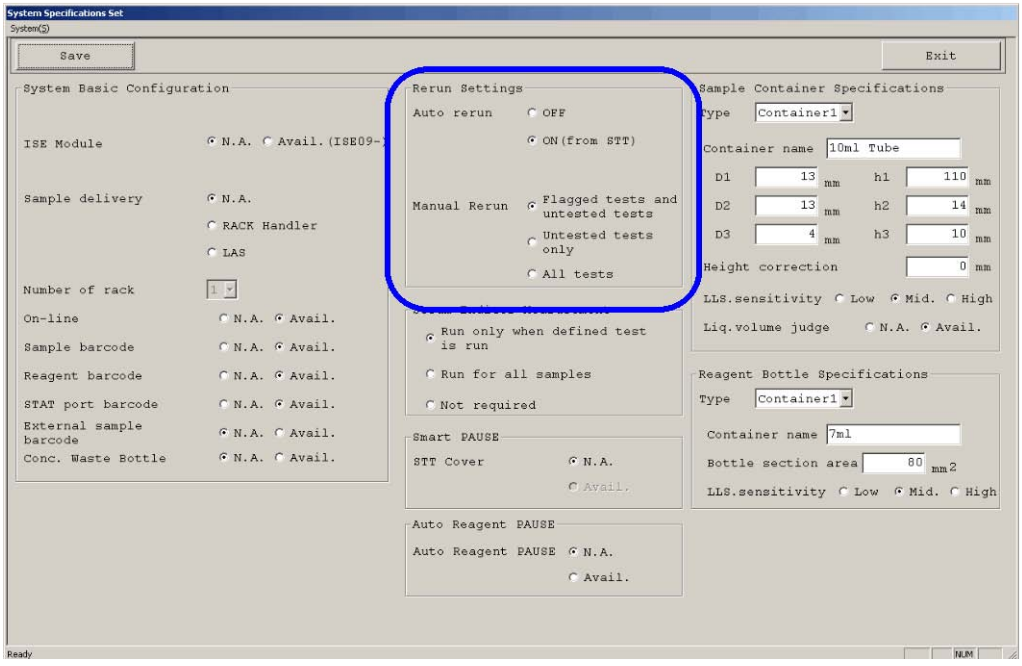
An automatic rerun can be selected in advance based on flagged data. The rerun conditions such as sample dilution or changed sample volume in measurement can also be selected in advance.

See Appendix 3 for further details on flags.

Selecting the type of rerun

When the system orders a rerun for the flagged value, you can choose whether to rerun the sample immediately or start the rerun later manually.

Select [Setup] > [System Specification Settings] to display the window below. Select automatic or manual rerun in the [Rerun Settings] column located in the upper section of the middle column of the window.



[Auto rerun]

[OFF] The rerun is not performed immediately but the rerun order is retained. You can perform a rerun of the ordered test later manually.

[ON (from STT)] The rerun is performed immediately when a rerun is ordered. When you select this option, you cannot remove the sample from the sample tray (STT) until the sampling is completed for rerun.

[Manual Rerun]

Three options are available: [Flagged tests and untested tests], [Untested tests only], and [All tests].

When you have selected "ON (from STT)" for [Auto rerun], you have to select [All tests].

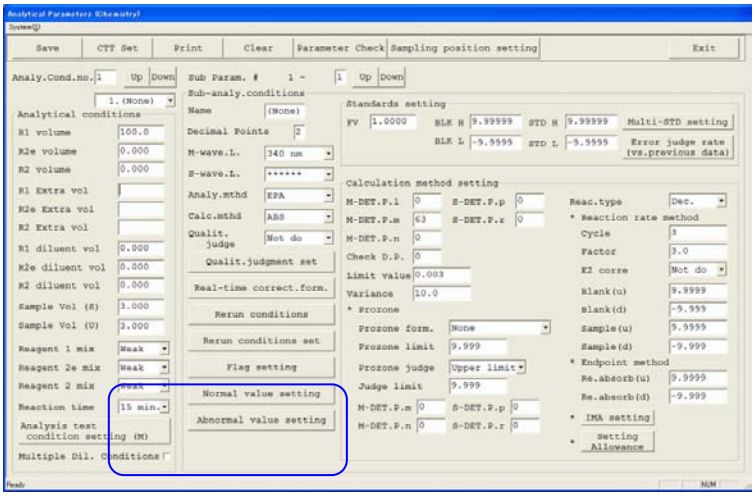
[Flagged tests and untested tests] Only the flagged test and the tests that were not completed in the initial run are to be performed on the same sample when a rerun is ordered.

[Untested tests only] Only the tests that were not completed in the initial run are to be performed on the same sample when a rerun is ordered.

[All tests] All tests are to be performed on the same sample when a rerun is ordered.

Setting the analytical conditions for rerun

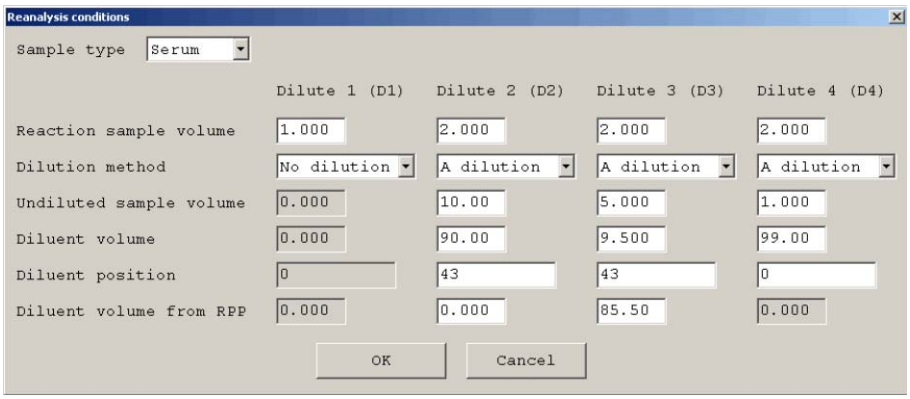
Select [Setup] > [Analytical Parameters (Chemistry)] to display the window below.



Define the "Rerun conditions" and "Rerun conditions set" as follows;

[Rerun conditions] window

Click the [Rerun conditions] button to display the window below.



Define the sample volume and dilution conditions for the rerun.

[Sample type] Select "Serum" or "Urine" as the sample type.

[Dilute 1] - [Dilute 4] Four different dilution conditions ([Dilute 1] to [Dilute 4]) can be defined.

Depending on the user interface, it may be displayed as [D1] - [D4] instead of [Dilute 1] - [Dilute 4].

[Reaction sample volume] Enter the sample volume to be dispensed in the reaction carousel (RVV) cuvette. Enter a value between 1 and 25 µL in 0.1µL increments.
When "No dilution" is selected for [Dilution method], the specified volume of undiluted sample is dispensed directly from the sample on the sample tray (STT).
When "A dilution" is selected, the specified volume of diluted sample is dispensed from the diluted sample in the reaction cuvette on the reaction carousel (RVV).

[Dilution method] Define whether to dilute the sample.
When "No dilution" is selected, the undiluted sample is dispensed directly from the sample on the STT into the cuvette on the RVV.
When "A dilution" is selected, the sample is diluted and then dispensed into the cuvette on the RVV.

[Undiluted sample volume] Enter volume of a sample before dilution between 1 and 25µL in 0.1 increments. The specified volume of the sample is dispensed into the reaction cuvette.

[Diluent volume] Enter a value between 25 and 200 (µL) in 0.1 increments.

[Diluent position] Enter the position number of the diluent to be placed on the reaction tray 1 (RTT1). Values can range from 0 to 50.
When "0" is entered, no diluent is placed on the RTT1; pure water from reagent probe 1 (RPP1) is dispensed into the cuvette according to the value entered for [Diluent volume].
When a number from 1 to 50 is entered, the diluent must be placed in the specified position on the RTT1. The RPP1 will dispense the diluent into the cuvette according to the volume entered for [Diluent volume].

[Diluent volume from RPP] Enter the volume of pure water dispensed from the RPP via the RPP tube. Enter a value between 5 and 200 (µL) in 0.1 increments. The pure water is used for diluting the diluent.
First, the RPP1 aspirates the diluent located on the RVV at the position specified for [Diluent position]. The amount aspirated is the volume entered for [Diluent volume]. Then, the aspirated diluent is dispensed together with pure water supplied from the RPP1 tube into the cuvette. The volume of pure water is the amount entered for [Diluent volume from RPP]. This function is practical when a condensed diluent is used.

The following is a description of the example settings illustrated on the above screenshot of the window.

The setting in the above window is an example. During actual operation, set the optimal values after taking into account of your own sample status and reagent performance.

[Dilute 1] The sample is not diluted, but a smaller volume of sample is used for measurement.
The sample volume is 1.0 µL.
This is an example of a rerun with a reduced sample volume.

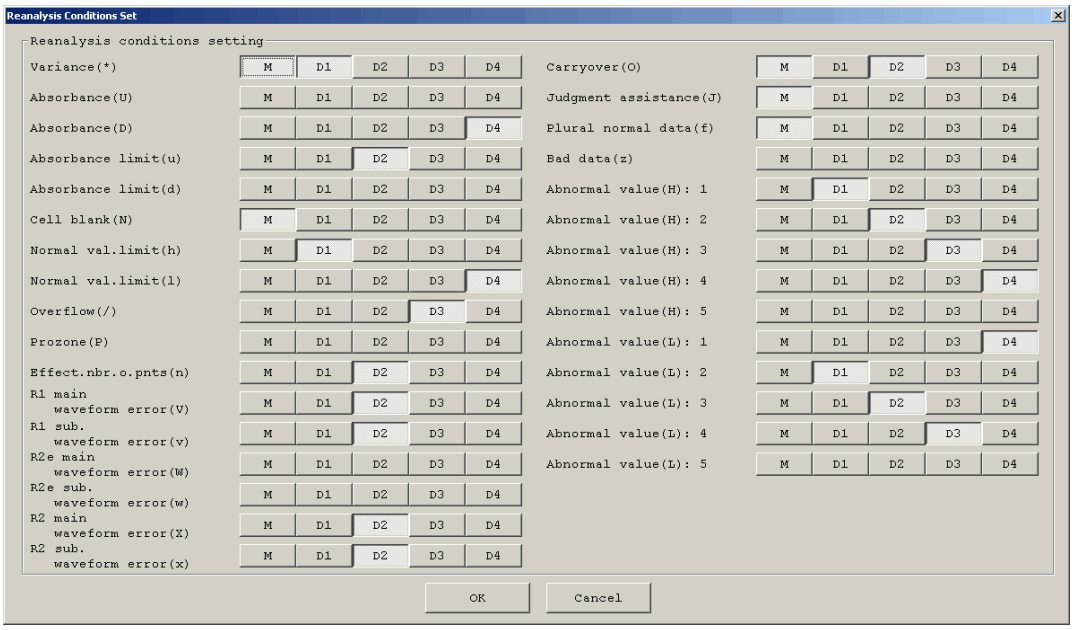
[Dilute 2] The primary sample of 10.0 µL is diluted with 90.0 µL of diluent dispensed from the RTT1. This results in a 10-fold dilution of the sample to be used for measurement. The sample volume used for the rerun is 2.0 µL. This is an example of a rerun with diluted sample.

[Dilute 3] 9.5µL of the diluent aspirated from the container on the RTT1 is further diluted with 85.5 µL of pure water supplied from the RPP1 tube. The resulting 95.0 µL of diluted diluent is used to dilute 5.0 µL of the primary sample. This results in a 20-fold dilution of the sample. The sample volume used for the rerun is 2.0 µL. This is an example of a rerun with the sample diluted with a diluent diluted with pure water.

[Dilute 4] 1.0 µL of the primary sample is diluted with 99.0 µL of pure water supplied from the RPP1 tube. This results in a 100-fold dilution of the sample. The sample volume used for the rerun is 2.0 µL. This is an example of rerun with a pure water-diluted sample.

[Rerun conditions set] window

Click the [Rerun conditions set] button to display the window below.



In this window, the rerun conditions can be defined by flags.

The descriptions indicate the type of abnormality with the flag notation in parentheses.

Only one rerun condition can be selected from M, D1, D2, D3, or D4 for each flag.

[M (Main)] means the condition applied in the initial run; [D1] - [D4] stand for [Dilute 1] - [Dilute 4].

If no rerun conditions are selected for a flag, a rerun will not be performed even if the flag is posted to the result data.

The following is an explanation of the example settings illustrated on the above screenshot of the window.

The setting in the above window is an example. During actual operation, set the optimal values after taking into account your own sample status, reagent performance and the meaning of the flag.

In the example above, when a test result of the initial run is flagged with an "h" (normal value limit) only, the [D1] or [Dilute 1] defined in the [Rerun conditions] window is applied for rerun.

When two or more flags are posted to the result data of a sample and the rerun conditions of those flags are different, a condition of the flag with the highest priority is applied in accordance with the hierarchy below.

- Order of priority of the flags in rerun conditions:
  Z>f>*>U>D>u>d>N>P>H>L>h>l>/>n>v>V>w>W>x>X>O>J

In the example above, when the flags "h" and "n" are posted to a test result, the condition [D1] is applied for rerun because "h" has the priority.

ATTENTION

When a ratio parameter is calculated between the results obtained from a test with sub-analysis conditions #1-3, the calculated parameter can be abnormal if the rerun dilution conditions of the sub-analysis conditions #1-3 are not the same.

2.3.2 Multi-Standard

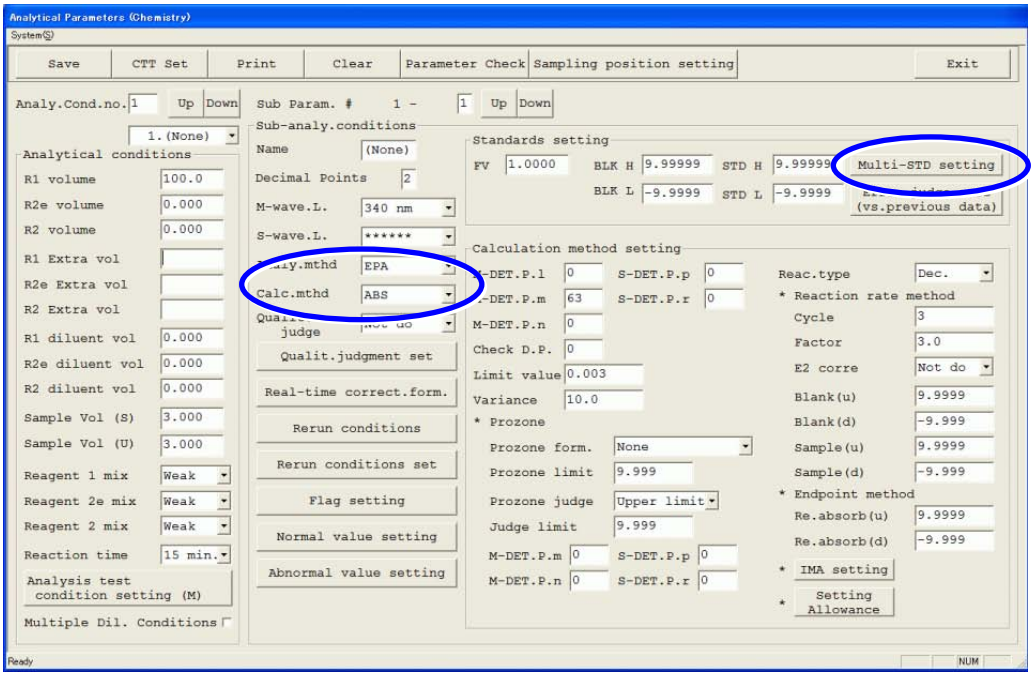
Features of multi-standard calibration

The BM6010/C supports tests that require multi-standard calibration. The following features are available.

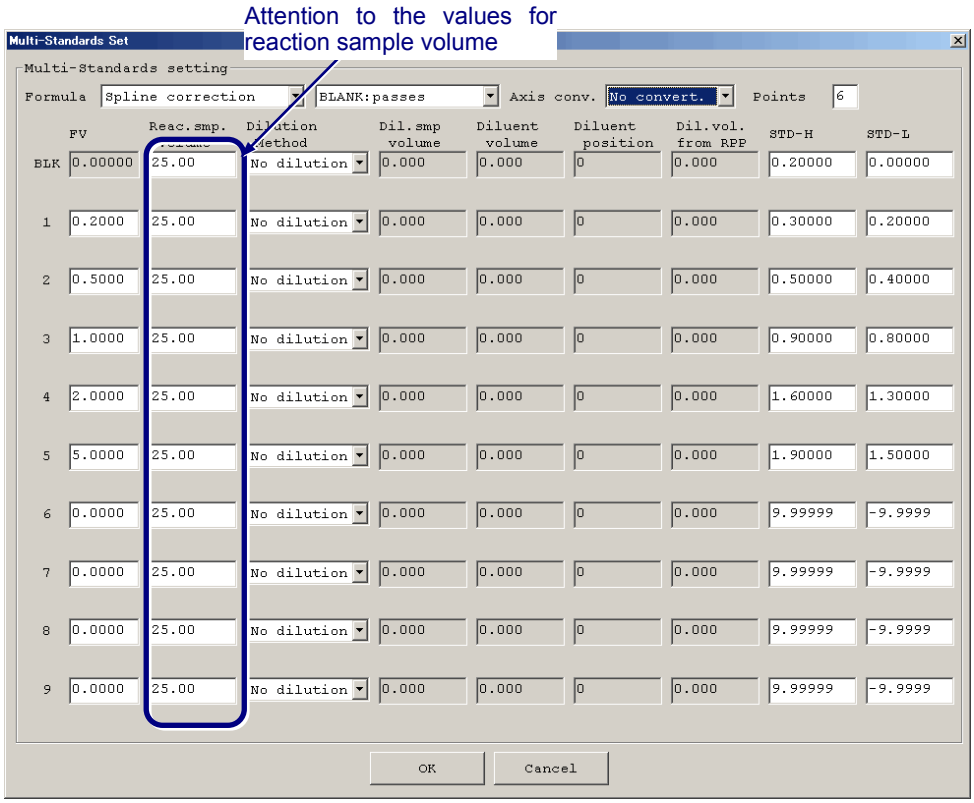
- Calibration with up to 10 data points.
- The following approximation formulas are available to generate a calibration curve: linear, quadratic, and cubic corrections, logit-log conversion, spline correction, etc. Logarithmic conversion can be applied to the axes as well.
- The calibration curve can be generated from measurement values alone without using blank sample.
- The calibration curve can be prepared with a series of dilutions for use in multi-point calibration by diluting a calibrator with different dilution factors.
- Simplified calibration is available using a blank sample and a single calibrator.
- The concentration of the sample in both serum and urine can be calculated using the calibration curve generated above.

Setting the analytical parameters

Select [Setup] > [Analytical Parameters (Chemistry)]. Select "MSTD" for [Calc.mthd] in the [Sub-analy.conditions] column located slightly to the left in the [Analytical Parameters (Chemistry)] window.



Then, click the [Multi-STD setting] button in the [Standard setting] column located in the upper right of the window. The [Multi-Standards Set] window is displayed.



Select the type of approximation formula, the use or omission of a blank solution, the axis conversion type, the number of data points, the measurement conditions including concentration and dilution, and the absorbance limit.

Select "BLANK is 0" when a calibration blank is available. The approximation formula will be generated so that the calibration curve will pass through point "0". In this case, the Y axis represents "ABS-RB" values.

Select "BLANK-Any Value" when the calibration blank is not available. All the data points from the calibrators will be used to generate the calibration curve which will therefore not necessarily pass through point "0". The Y axis represents "ABS" values.

The BM6010/C is capable of preparing a series of calibrator dilutions for multi-point calibration. This practical function will be described later.

[Formula] Select a type of approximation formula to generate the calibration curve after measurement.
Also, select "BLANK is 0" when the blank sample is used or "BLANK: Any value" when it is not used.

[Axis conv.] Select whether to apply logarithmic conversion to the axis of the calibration curve.
[No convert.]: No conversion is applied to either the X or the Y axis.

[Log.-linear]: Logarithmic conversion is applied to the X axis (concentration), but not to the Y axis.
[Log.-Log.]: Logarithmic conversion is applied to both the X and the Y axes.

[Points] Enter the number of data points to be used to generate the calibration curve.
Up to ten data points including the blank sample can be selected.

[BLK] or [0] - [9] The number that represents each standard. [BLK] is displayed when "BLANK is 0" is selected in the drop-down menu to the right of the [Formula] drop-down menu; [0] is displayed when "BLANK: Any value" is selected.
As many data points as defined in the [Points] field are measured.

[FV] Enter the corresponding concentration for each data point in the dilution series.
When the sample is diluted or when the value entered in this window is different from that entered in the [Sample Vol (S)] field in the [Analytical Parameters (Chemistry)] window, calculate the value to enter in [FV] using the following formula:

[FV] = C * (O/P) * (SV/SVo) * (TVo/TV)

C: Concentration of the calibrator

O: Serum dilution rate as specificed in the [Analysis test condition setting (M)] window

P: Dilution rate defined in this window

SVo: Value entered for [Sample Vol (S)] in the [Analytical Parameters (Chemistry)] window

SV: Value entered for [Reac.sam.volume] in this window

TVo: Total volume of the reaction sample entered in the [Analytical Parameters (Chemistry)] window

TV: Total volume of the reaction sample entered in this window and the [Analytical Parameters (Chemistry)] window

[Reac. smp. volume] Enter the sample volume to be dispensed into the reaction carousel (RVV) cuvette. Enter a value between 1 and 25 µL in 0.1µL increments.
When "No dilution" is selected for [Dilution method], the indicated volume of undiluted sample is dispensed.
When "A dilution" is selected, the indicated volume of

diluted sample is dispensed from the diluted sample into the reaction cuvette on the RVV.

The default value for the [Reac.smp.volume] is 25.0 µL. Be aware that the appropriate value will depend on the condition.

[Dilution Method] Select whether to dilute the sample.
When "No dilution" is selected, the undiluted sample is dispensed directly by the sample probe (SPP) into the reaction cuvette on the RVV.
When "A dilution" is selected, the sample is first diluted and then dispensed into the cuvette on the RVV.

[Dil. smp volume] Enter a value between 1 and 25 (µL) in 0.1 increments as the volume of undiluted sample.
The specified volume of the undiluted sample is dispensed by the SPP into a cuvette that already contains the diluents.

[Diluent volume] Enter a value between 25 and 200 (µL) in 0.1 increments.

[Diluent position] Enter the position number (1 – 50) on the reaction tray 1 (RTT1) in which the diluent will be placed.

When "0" is entered, no diluent is placed on RTT1. Pure water in the reagent probe 1 (RPP1) is dispensed into the cuvette according to the volume entered for [Diluent volume].
When a number from "1" to "50" is entered, place the diluent in the specified position on RTT1. The RPP1 dispenses the diluent into the cuvette according to the volume entered for [Diluent volume].

[Dil. vol. from RPP] Enter the volume of pure water dispensed from the RPP via the RPP tube. Enter a value between 5 and 200 µL in 0.1 increments. The pure water is used for diluting the diluent.
First, the RPP1 aspirates the diluent located on the specified RVV position according to the volume entered for [Diluent volume]. Then, it dispenses the diluent together with the pure water supplied from the RPP1 tube according to the volume specified for the [Diluent volume for diluent] into the cuvette.
This function is practical when a condensed diluent is used.

[STD-H]	Enter the upper limit for the absorbance. If the measurement value is greater than this limit, it is flagged with an "H".
[STD-L]	Enter the lower limit for the absorbance. If the measurement value is less than this limit, it is flagged with an "L".

Select conditions for measurement of the calibrators

Be sure to enter the same values for [Reac.smp.volume], [Dilution Method], [Dil.smp volume], [Diluent volume], [Diluent position], and [Dil.vol. from RPP] for calibration as were entered for sample analysis under sample type "serum" (when using this calibration data for serum tests) in the [Analysis test condition setting (M)]. In this way, the analytical conditions (sample dilution, sample volume, etc.) will be the same for both calibration and serum sample measurement.

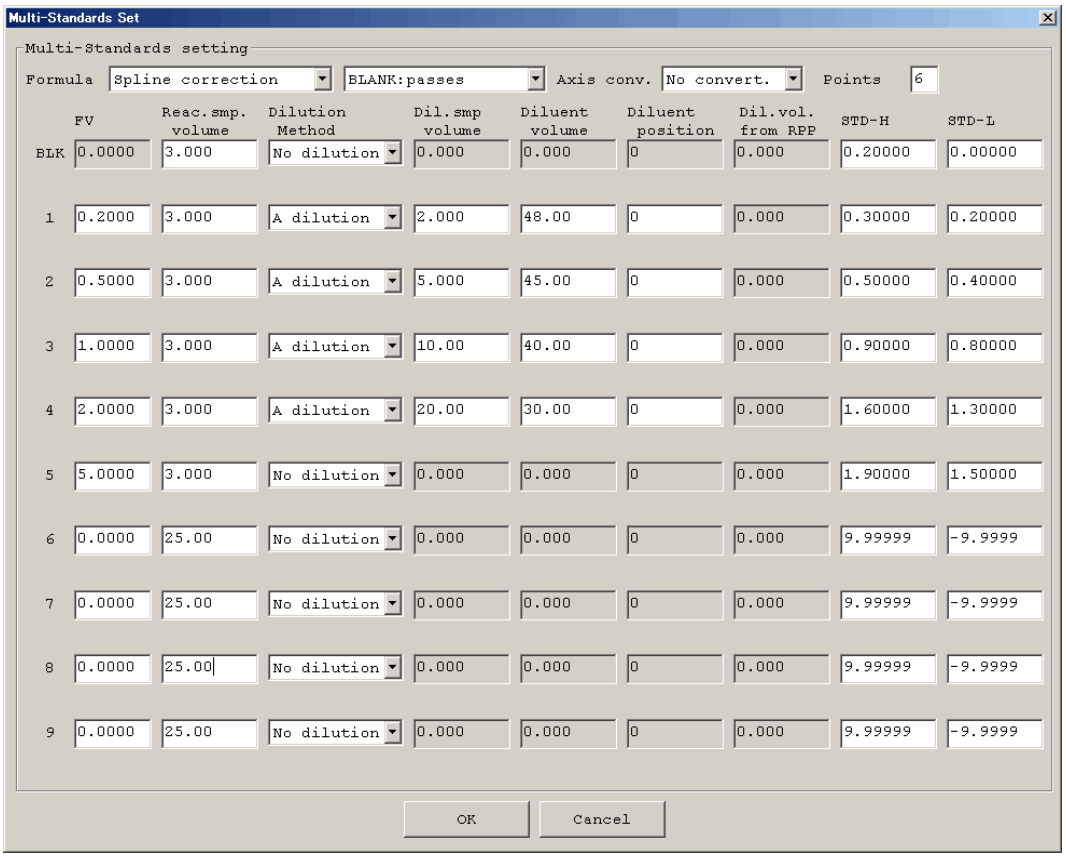
The default value for the [Reac.Smp.Volume] is 25.0 µL. Be sure to enter the same value that was entered for [Reaction sample volume] in the [Analysis test condition setting (M)] window.

Enter the concentration value of each calibrator as is in the field in the [FV] column.

Preparation of dilution series for a calibrator

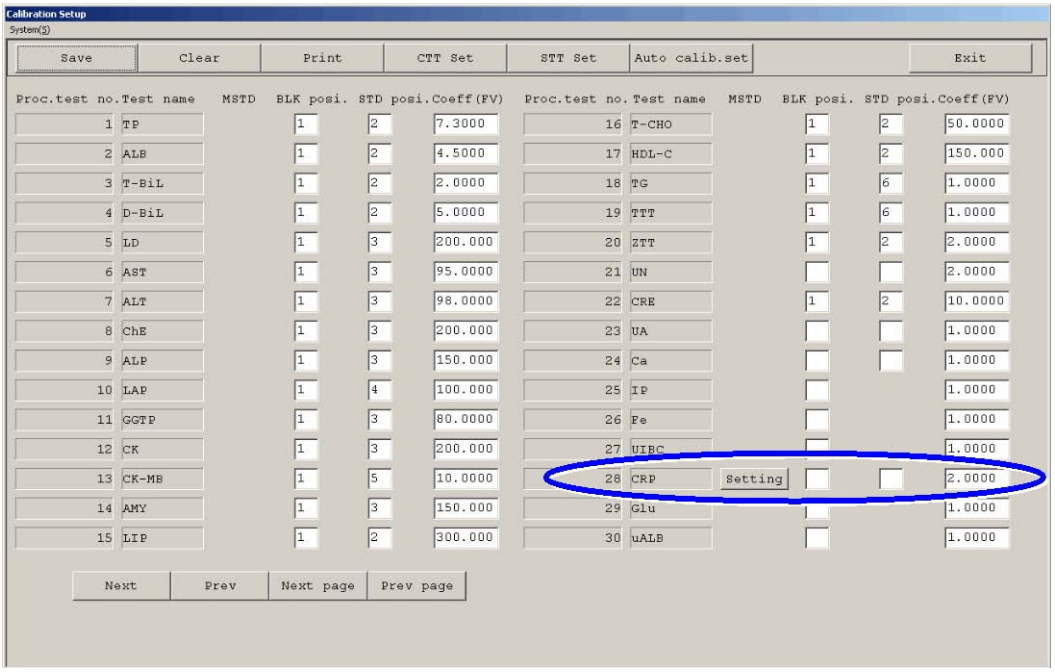
Define values for [Reac.samp.volume], [Dil.smp. volume], [Diluent volume], [Diluent postion], and [Dil.col. from RPP] to prepare dilution series of from a calibrator automatically.

The window below shows an example of settings used to dilute a high-concentration calibrator for the preparation of dilution series. In the [FV] column, be sure to enter the values obtained with the formula presented in the "FV" section above.



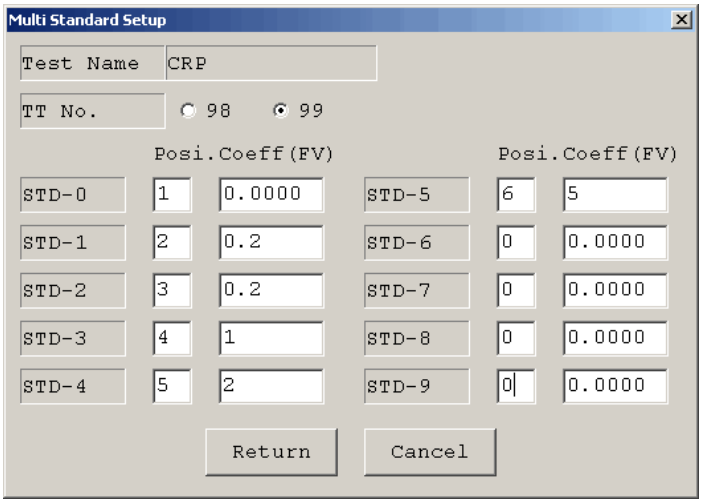
Entering the calibrator positions

Select [Calib.] > [Calibration Setup]. A [Setting] button is displayed under the [MSTD] header for multi-standard tests.



[Multi Standard Setup]

Click the [Setting] button to display the [Multi Standard Setup] window.

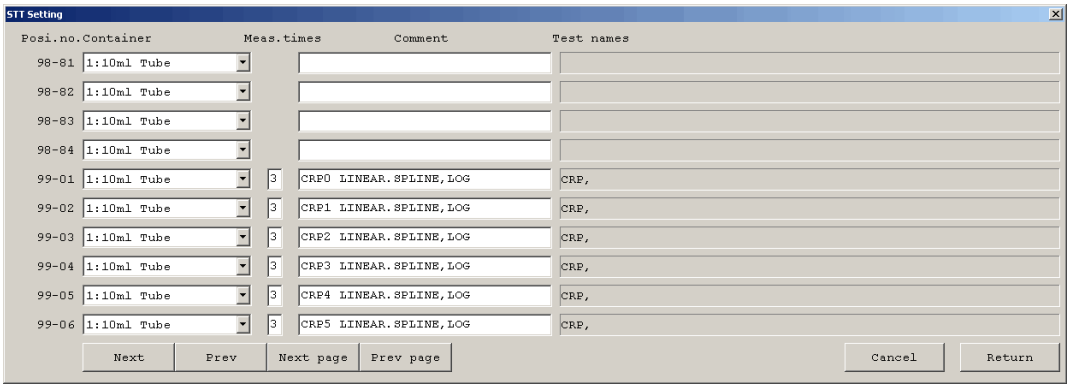


[TT No.] Select a STT number to set the calibrator. Multi-standard calibrators should be placed on the sample tray (STT) instead of the refrigerated sample tray (CTT). Select either "98" or "99".

[Posi.]	Enter the STT position numbers to set the calibrators. You can enter a same position number for two or more standards when you prepare dilution series from a calibrator.
[Coeff (FV)]	Enter the concentration values of the series. The meaning is the same as that of [FV] in the [Multi-Standards Set] window accessed from the [Analytical Parameters (Chemistry)] window. You can edit the concentration value here.
[Return] button	Click this button to save the values entered in this window before closing.
[Cancel] button	Click this button to close the window without saving the changes that have been made.

[STT Set]

Click the [STT Set] button on the top bar to display the [STT Setting] window.



[Posi.no.]	The number to the left of the dash represents the STT number and the number to the right of the dash represents the container position number.
[Container]	Select the container type for each position.
[Meas.times]	Enter a value between 0 and 5 to signify the number of replicates for each calibrator. Enter "0" if the calibrator should not be measured.
[Comment]	Enter a description of the calibrator. Be sure to enter a comment since it will be used to identify the calibrator in other windows.

Simplified calibration

After the multi-standard calibration is performed, a simplified calibration can be used using only two solutions: a blank sample and a single calibrator.

The simplified calibration is generated by correcting the Y-intercept and slope of the multi-standard calibration curve.

Multi-standard calibration is suggested when using a new lot of a reagent and simplified calibration may be used for daily analysis.
The simplified calibration is performed in the same way as a one-point calibration using a blank sample and a single calibrator.

① Select [Calib.] > [Calibration Setup] and enter the [BLK posi.], [STD posi.], and [Coeff (FV)] for tests that require multi-standard calibration.

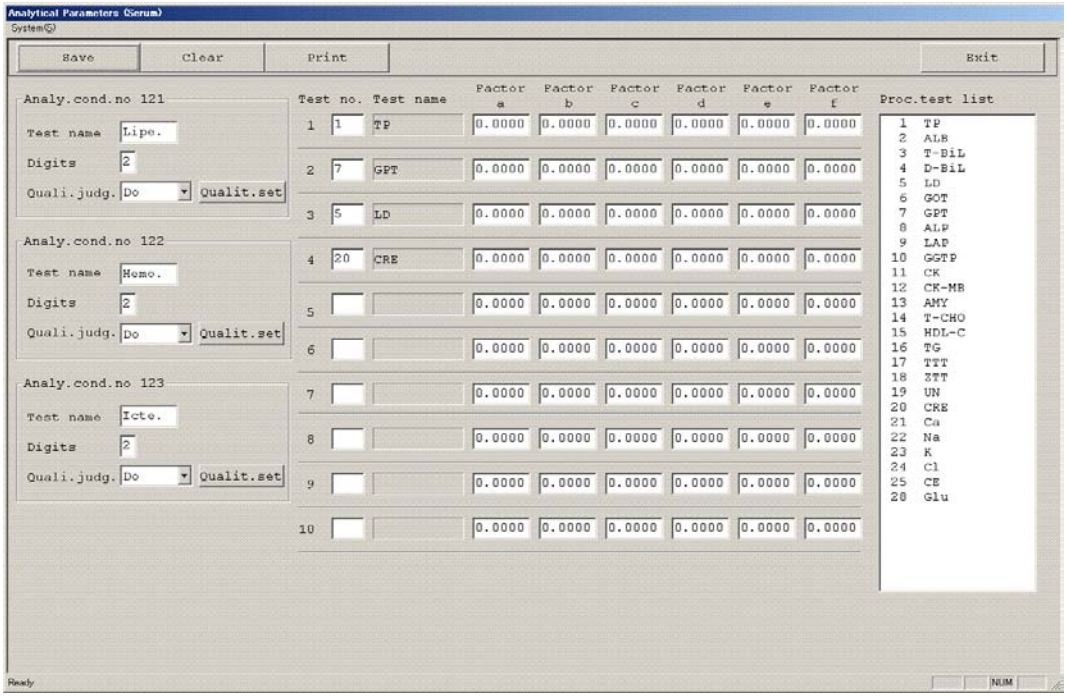
Set the blank sample and a calibrator on the refrigerated sample tray (CTT).
Click the [CTT Set] button to specify the positions in the [CTT Setting] window.

② Perform the ordinary calibration steps using a blank sample and a single calibrator for the tests that require multi-standard calibration.

Click the [START] button on the Operation Panel to display the [Start Conditions] window. Select "Analyze" for [one-pnt.smp.] in the [Calib.] column.
After calibration, the corrections are applied to the calibration curve.

2.3.3 Setting analytical conditions for serum indices

Select [Setup] > [Analytical Parameters (Serum)] to display the [Analytical Parameters (Serum)] window below.



Defining chemistry tests for serum index measurement

Define chemistry tests for serum indices measurement with the order of priority. At this time, define [Factor a] - [Factor f]. These factors are required for processing the serum index measurement values. Following is the referential information.

Reference information: formulas for calculating serum index values

The serum index values are calculated with the formulas below:

Lipemia＝a*ABS (A)

Hemolysis＝b*{ABS (B)－d*ABS (A)}

Icterus＝c*{ABS (C)－e*{ABS (B)－d*ABS (A)}－f*ABS (A)}

ABS (A): Absorbance in lipemia measurement

ABS (B): Absorbance in hemolysis measurement

ABS (C): Absorbance in icterus measurement

where the factors a, b, c, d, e, and f are constants.

Following is the explanation on these factors.

Factor for serum index analysis

The table below summarizes the constants for factors obtained in an experiment under the serum index measurement conditions described in the next section.

Factor	Value
a	1128.90
b	167.54
c	39.08
d	0.8987
e	0.1488
f	1.3289

Samples and measurement condition used to obtain the factors

Measured sample: Interference-Check A plus (Sysmex Corp,), Item #79370

Reagent used: Saline, Production#9351

Measurement condition R1: 100
Sample volume: 2
Dilution rate: 1

Item	Wavelength (λ)	Sample		Indicated value	Serum index Concentration
Icterus	478-505	Water			
		Bilirubin C	T-BIL	224 mg/dL	5 mg/dL
		Bilirubin F	T-BIL	184 mg/dL	5 mg/dL
		Hemoglobin	Hb	4500 mg/dL	
		Lipemia	Formazin Turbidity	21800	
Hemolysis	571-596	Water			
		Bilirubin C	T-BIL	224 mg/dL	
		Bilirubin F	T-BIL	184 mg/dL	
		Hemoglobin	Hb	4500 mg/dL	50 mg/dL
		Lipemia	Formazin Turbidity	21800	
Lipemia	658-694	Water			
		Bilirubin C	T-BIL	224 mg/dL	
		Bilirubin F	T-BIL	184 mg/dL	
		Hemoglobin	Hb	4500 mg/dL	
		Lipemia	Formazin Turbidity	21800	500

Factor correction

If the measurement conditions (values of R1, SV, and dilution factor) are different from those listed above, correct the factors a, b, and c using the formula below:

(a', b', c') ＝ {(R1+SV) / 102}× (2／SV) × dilution factor × (a, b, c)

a', b', c': corrected factors

R1: [volume of Reagent 1] + [volume of diluent used to dilute Reagent 1]

SV: [Serum reaction sample volume]

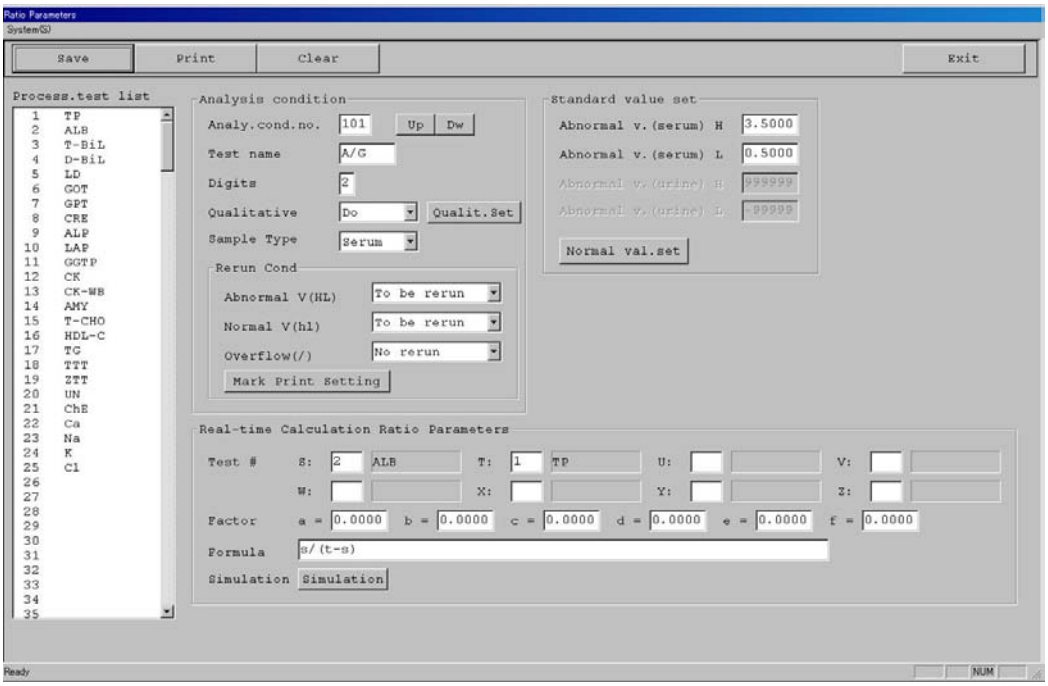
Dilution factor: ([undiluted serum sample volume]+[diluent volume for serum])/[undiluted serum sample volume]

Correct the factors a, b, and c according to the actual serum index tests.

2.3.4 [Ratio Parameters] window

The measurement results from different tests can be used to calculate a ratio between those values; this ratio is regarded as a test result. The calculation used to obtain this ratio is called a "ratio test". This window is used to set parameters for the ratio test.

Select [Setup] > [Ratio parameters].



Enter the values in the following columns in the window.

[Analysis conditions] Enter the same way as in the [Analytical Parameters (Chemistry)] window.

[Standard value set] Enter the same way as in the [Analytical Parameters (Chemistry)] window.

[Real-time Calculation Ratio Parameters]

[Test #S-Z] Enter the "Process Sequence nos." of the tests whose results are used for ratio calculation.

[Factor a-f] Enter the values of the constants (factors) used in the calculation formula.

[Formula] Enter the formula. Use the following characters to define the formula. (e.g. x / (y-x))

- [S]-[Z]: Measurement result (concentration) of the test used for ratio calculation
- [a]-[f]: Factor (as defined in the [Factor] fields)
- [*], [/], [+], [-]: Arithmetic operator
- [1]-[9], [.]: Constants
- [R()]: Root

[L()]: Log

[( ), [ ]], [^]: Operator

[Simulation] Click the [Simulation] button to see the result of the ratio calculation formula using the “test results”.

ATTENTION

When you perform a "ratio test” using results from tests with the same "Analy.Cond.no" but different "Sub Param. #", the result of ratio test may be abnormal. Be sure that the same dilution conditions are selected in the [Rerun Conditions Set] window.

2.3.5 Settings for quality control (QC)

This section describes the purpose and use of the quality control (QC) windows.

Types of QC

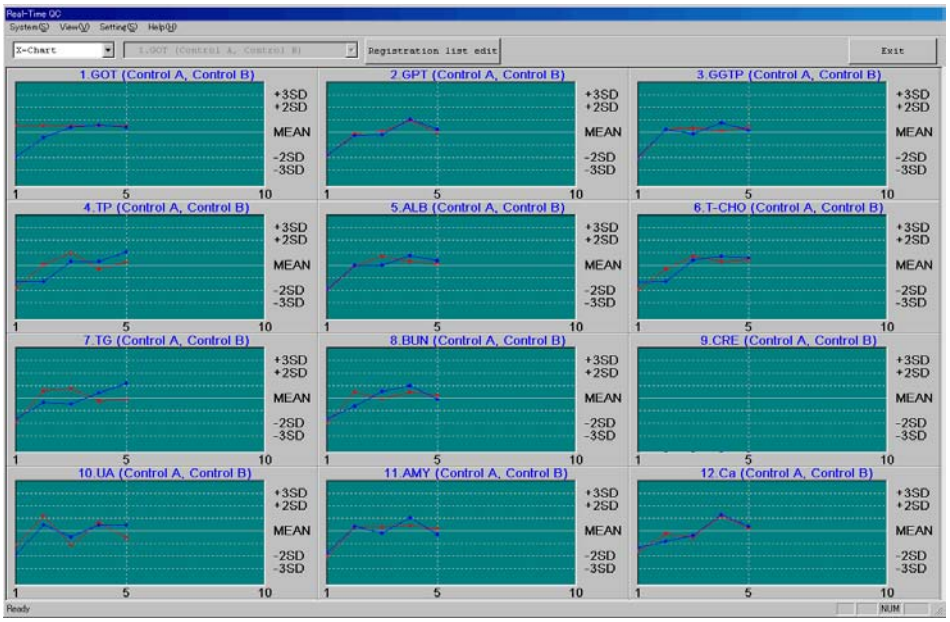
Three types of QC are available with the BM6010/C:

Real-Time QC	Uses twin plot graphs representing the values of the control samples measured up to the current time of the current day. The purpose is to review the quality of the current measurement.
Daily Precision Control	Uses X-charts representing the all the measurement data of the control samples completed in the day. The purpose is to review the quality of the current day's measurement.
QC Cumulative	Uses X-R charts of the daily control sample measurement values. The purpose is to review the quality of data measured over multiple dates.

[Real-Time QC] window

① Display the X-chart.

Select [QC] > [Real-Time QC] to display the window below.



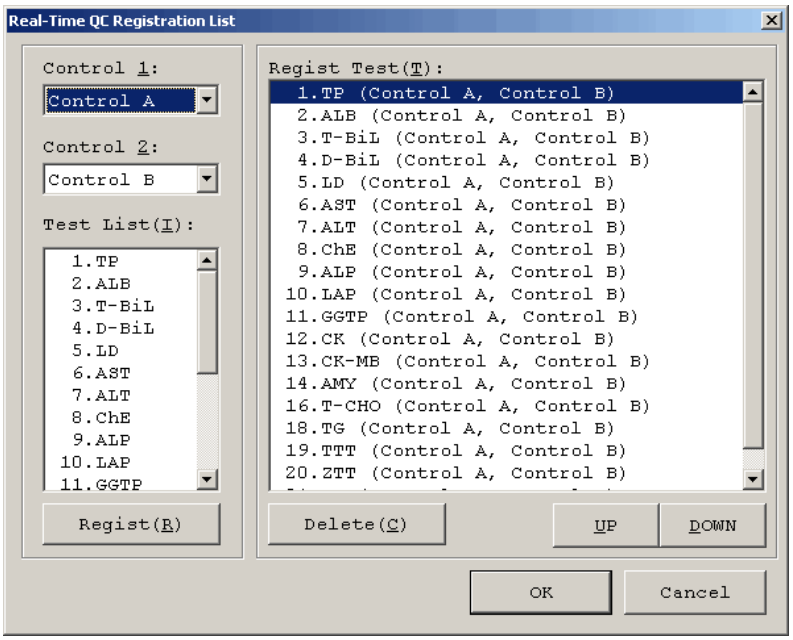
The X-chart displays measurement values of two defined control samples; a separate chart is used for each test. For correct X-chart display, the control samples and the chart-display settings should be properly defined as explained respectively in Steps 2 and 3 below.

② Define the control samples used for real-time QC.

Follow the steps below to specify the types of control samples.

a. Define the types of control sample.

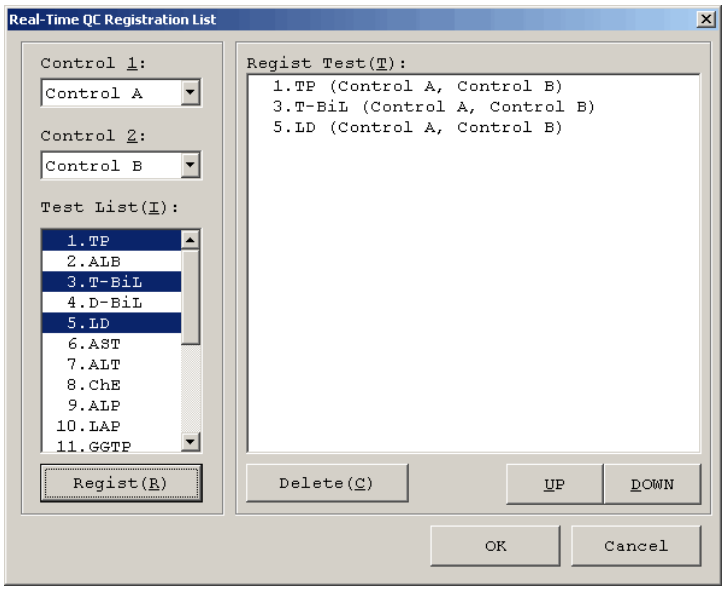
Click the [Registration list edit] button located in the upper middle part of the [Real－Time QC] window to display the [Real-Time QC Registration List] window.



Select the types of control samples for each test. Two types of the control sample should be selected for twin-plot graph representation. Select one type for both [Control 1] and [Control 2].

When setting the defaults, delete all entries in the [Regist Test] column. Select and highlight all entries in the [Regist Test] column, and then click the [Delete] button.

b. Select the tests.



Click and highlight the tests in the [Test List (I)]. Click the test names while pressing the [Shift] or [Ctrl] key to select multiple tests simultaneously. Click [Regist (R)] button to select the highlighted tests. Their names will be displayed in the [Regist Test (T)] column. Select all the tests required.

c. Define the chart display order on the monitor.

The charts of the tests are displayed in the monitor in the order shown in the [Regist Test (T)] column.

To change the order, select and highlight a test and move it upward or downward by clicking the [UP] and [DOWN] buttons respectively.

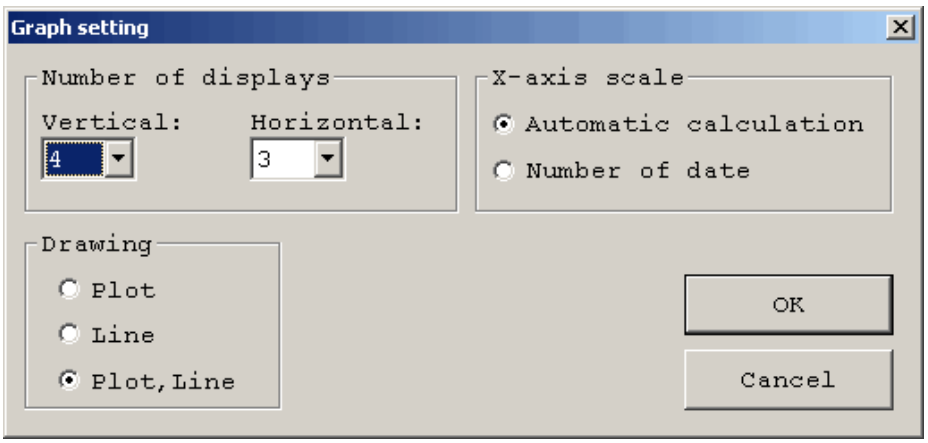
d. Save the settings

Click [OK] to save. The layout in the [Real-Time QC] window will change accordingly.

③ Choose the layout of X-charts in the [Real-Time QC] window.

a. Display the [Graph setting] window.

Click the [Setting (S)] command in the top bar of the [Real-Time QC] window and click the [Chart setting] option. The [Graph setting] window is displayed.



b. Choose the [Number of Displays]

Enter the number of charts to display vertically and horizontally respectively.

c. Select a [Drawing] type

Select the type of graphical display.

d. Select an [X-axis scale] type

[Automatic calculation] The chart is displayed with the optimal scale calculated on the basis of the number of measurement data. This is the default option.

[Number of data] The chart is displayed in the maximum size with all the measurement values. If the number of the values is small, the distant between plots will be too wide.

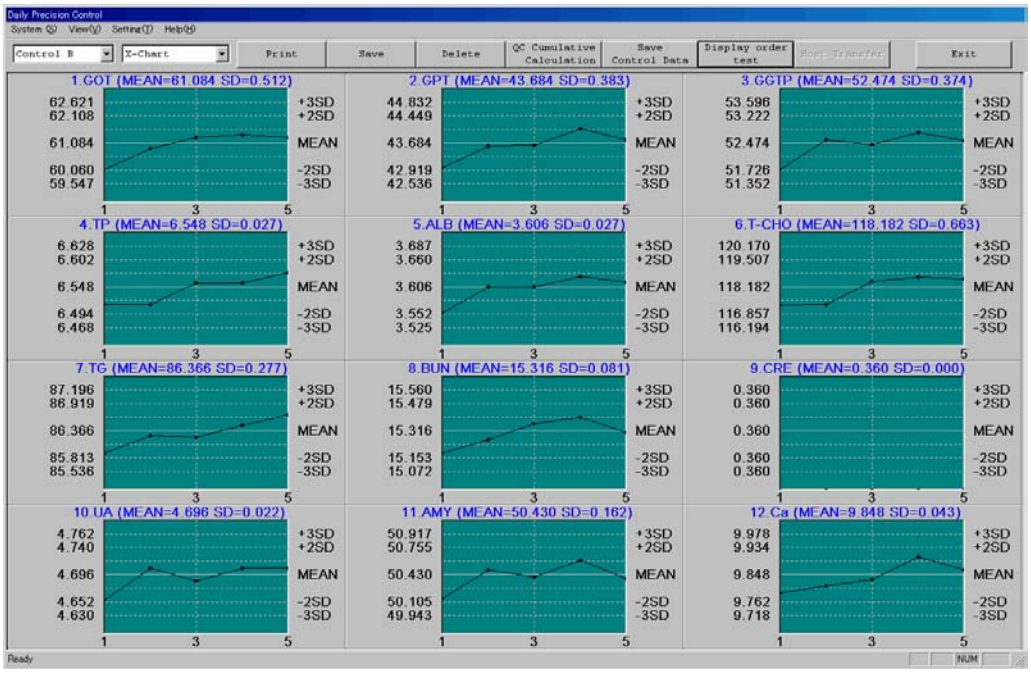
e. Save the settings.

Click [OK] to save the setting and close the window. The layout in the [Real-Time QC] window will change accordingly.

Quality control of the daily measurement

① Display the [Daily Precision Control] window.

Select [QC] > [Daily Precision Control] to open the [Daily Precision Control] window.



This window lists all the control sample measurement data since the analyzer started in the "New Start" mode in chronological order. The data are displayed by control sample type and by test. The instructions for selecting the tests and display order are described below in Step 3.

The charts are generated based on the reference values defined for each test (MEAN and SD) in the [Daily QC] column in the [QC] > [Control Data Registration] window. The scale is SD and the display range is up to +3SD to -3SD.

To display the data correctly, the display settings should be properly defined as explained below in Steps 2 and 3.

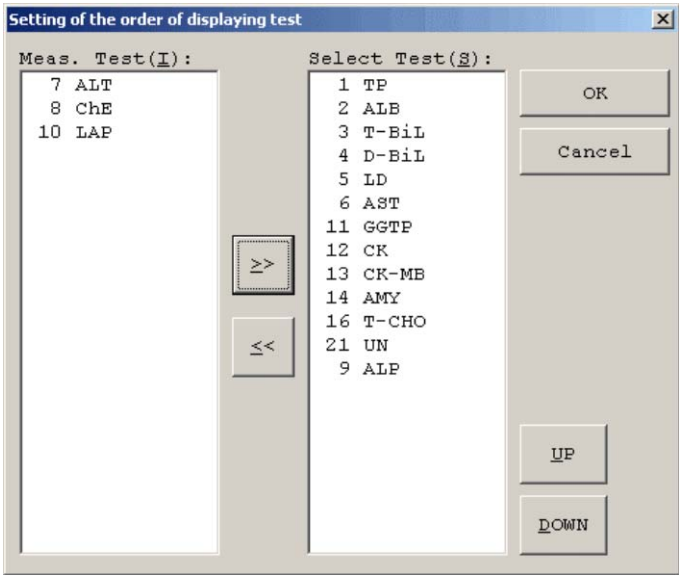
② Select the layout of the X-charts in the [Daily Precision Control] window.

Select options for the X-chart in the [Daily Precision Control] window in the same manner as in the [Real-Time QC] window.

③ Select the chart display order in the [Daily Precision Control] window.

a. Display the [Setting of the order of displaying test] window.

Click the [Setting] command in the top bar in the [Daily Precision Control] window and select [Setting of the order of display]. The window below is displayed.



b. Select the order in which the X-charts will be displayed.

Select and highlight the tests in the [Meas. Test] column, and then click the [>>] button to move them to the [Select Test] column. The X-charts of the tests are displayed in the order they appear in this column in the [Daily Precision Control] window.

Select a test and then use the [UP] or [DOWN] buttons to change the display order.

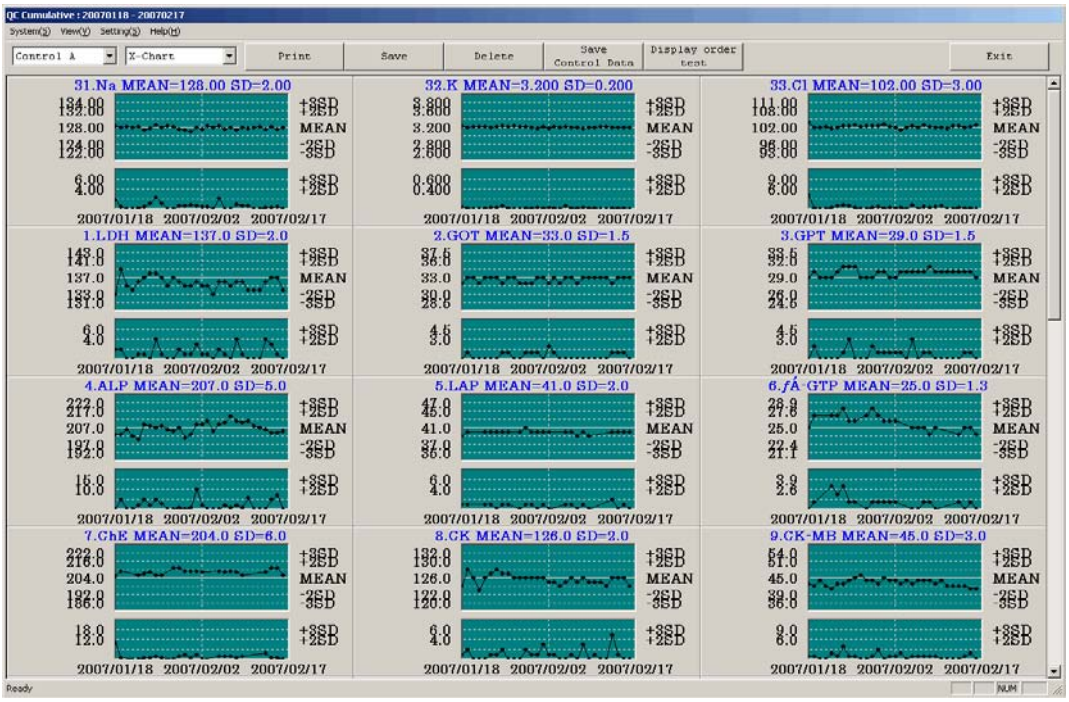
c. Save the settings.

Click [OK] to save the settings and close the window. The X-chart display order in the [Daily Precision Control] window will be updated accordingly.

Quality control of measurement data over multiple dates

① Display the [QC Cumulative] window.

Select [QC] > [QC Cumulative] to open the [QC Cumulative] window.



The data collection period is displayed next to the [QC Cumulative] window name on the blue title bar. The default period is the past 30 days. X-R charts representing the average and range of the daily control sample measurement values during this period are displayed. The charts are displayed by control sample type and by test. The instructions for selecting the tests and display order are described below in Step 3.

The charts are generated based on the reference values defined for each test (MEAN and SD) in the [QC Cumulative] column in the [QC] > [Control Data Registration] window. The scale is SD and the display range is up to +3SD to -3SD.

To display the data correctly, the display settings should be properly defined as explained below in Steps 2 and 3. Select the layout of X-charts in the [QC Cumulative] window

② Select options for the X-R chart in the [QC Cumulative] window in the same manner as in the [Real-Time QC] window.

③ Select the chart display order in the [QC Cumulative] window

Select the order of charts in the [QC Cumulative] window in the same manner as in the [Daily Precision Control] window.

2.3.6 Defining profiles

What is a profile?

A profile is a set of tests defined as a group. When selecting tests for each sample in the [Request] > [Order Entry] window, you can select multiple tests simultaneously by using a profile. It is efficient to define profiles depending on the purpose of analysis.

Defining a profile

Follow the steps below to define a profile.

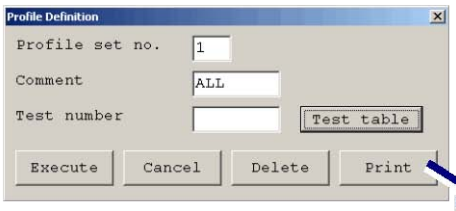
① Display the [Profile Definition] window

Select [Request] > [Order Entry]. Click the [Create Profile] button located nearly in the center of the top bar in the [Order Entry] window. The [Profile Definition] window is displayed.

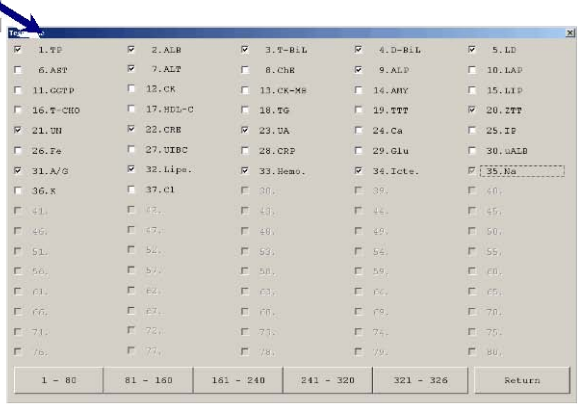
② Define a profile

Up to 150 profiles can be defined.

[Profile set no.]	Enter the profile number.
[Comment]	Enter a description of the profile that will be displayed in the [Order Entry] window.
[Test number]	Click the [Test Table] button located to the right of the field to display the [Test Table] window. Select tests for the profile by checking the appropriate box. Click [Return] to close the [Test Table] window. Click [Execute] in the [Profile Definition] window to save the profile of selected tests under the number indicated for [Profile set.no.] Click [Cancel] to return to the [Profile Definition] window without saving the settings.



Profile Definition window



Test Table window

Using a profile

① Display the [Order Entry] window

Select [Request] > [Order Entry] to display the [Order Entry] window.

② Click a profile name in the [Profiles] column

When selecting tests to run on a sample, click a profile name in the [Profiles] column instead of clicking test names individually in the [Test table] column. The tests that comprise the profile will be displayed in the [Test table] column.

2.3.7 Setting automatic startup/shutdown

Startup settings

"Startup" indicates the preparatory operations including "PRIME", "WASH", and "Cuvette blank" of the analyzer that is already in the [READY] mode.

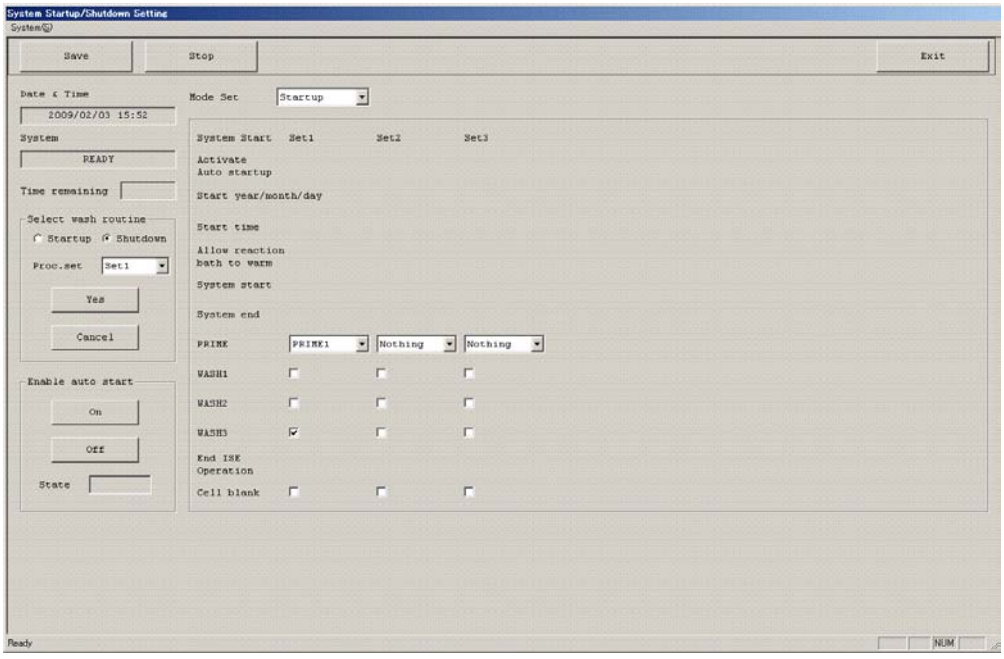
Default "Startup" settings

Choose the desired series of "startup" operations when the system is successfully initialized.

The default setting values are as follows:

[PRIME]	"PRIME1"
[WASH1]	Deselected (no check in the box)
[WASH2]	Deselected (no check in the box)
[WASH3]	Selected (check ✓ in the box)
[Cuvette blank]	Deselected (no check in the box)

- Steps for routine startup
- Visually check that the volumes of detergents and pure water are sufficient. If any volume is short, the defined operation may not be successfully performed.
- Select [Maint.] > [System Startup/Shutdown Setting] to display the [System Startup/Shutdown Setting] window.



- Select "Startup" for [Mode set] drop-down menu located at the top of the [System Startup/Shutdown Setting] window.

✔ Check the set values.

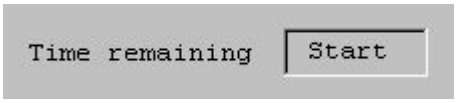
If you change any value in the window, be sure to click the [Save] button after making the change.

✔ Select "Startup" in the [Select wash routine] column on the left side of the window; select "Set1", "Set2" or "Set 3" in the [Proc.set] drop-down menu.

✔ Click [Yes] in the [Select wash routine] column.

If the system mode is [READY], the selected start-up operation(s) will begin.

If the system mode is not [READY], the [Time remaining] field will read "Start"and the selected operation will start as soon as the mode becomes [READY].



Once the start-up operation has begun, it proceeds automatically until the end. The current system mode and time remaining until the end of operation are indicated in the upper left field of the window. When [Cuvette blank] is selected, a pop-up window is displayed to register the cuvette blank result just before the cuvette blank measurement is completed. Select [save] or [no save]. When the selected start-up operations are all completed, the system mode returns to [READY].

If you want to stop the start-up procedure after it has started, perform one of the following measures:

- Click the [Stop] button in the [System Startup/Shutdown Setting] window.
- Click the [Cancel] button in the [Select wash routine] column of the [System Startup/Shutdown Setting] window.
- Click the [STOP] button in the Operation Panel

Shutdown settings

Select [Maint.] > [System Startup/Shutdown Setting] to choose settings for shutdown.

✔ Default "Shutdown" settings

Choose a series of "shutdown" operations to engage after the system finishes its normal operation. You can define the "shutdown" operations independently or to be combined with the automatic startup of the next day.

The default settings are as follows:

The Operate/standby switch in the power panel should be in the [PC CONTROL] position.

Shutdown both the workstation and the analyzer

[System p.s.]	Select "Power OFF" (check ✓ in the box)
[System end]	"Shutdown"
[PRIME]	"Nothing"
[WASH1]	Deselected (no check in the box)
[WASH2]	Selected (check ✓ in the box)
[WASH3]	Deselected (no check in the box)
[End ISE Operation]	Selected (check ✓ in the box)

Put the workstation in sleep mode and shutdown the analyzer to permit automatic startup

[System p.s.]	Select "Power OFF" (check ✓ in the box)
[System end]	"System End" (This is the status where the workstation is closed but the power is maintained.)
[PRIME]	"Nothing"
[WASH1]	Deselected (no check in the box)
[WASH2]	Selected (check ✓ in the box)
[WASH3]	Deselected (no check in the box)
[End ISE Operation]	Selected (check ✓ in the box)

Put the analyzer in sleep mode (maintain the power of the analyzer to permit automatic startup)

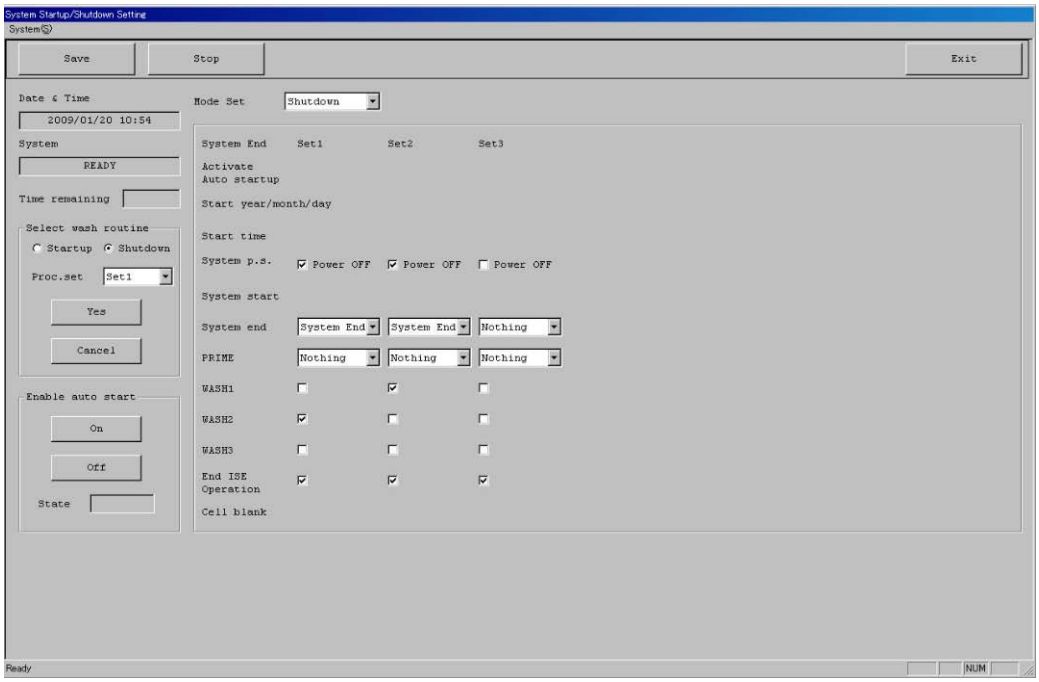
[System p.s.]	Deselect "Power OFF" (no check in the box)
[System end]	"Nothing"✍
[PRIME]	"Nothing"
[WASH1]	Deselected (no check in the box)
[WASH2]	Selected (check ✓ in the box)
[WASH3]	Deselected (no check in the box)
[End ISE Operation]	Selected (check ✓ in the box)

When "Nothing" is selected for [System end], the workstation must be shutdown manually before the time indicated for automatic startup. Automatic startup is not available when the workstation is not shutdown.

If "Shutdown" is selected for [System end], the analyzer's power will also be turned off in order to shutdown the workstation regardless of the [System p.s.] selection.

Steps for routine shutdown

- Visually check the volumes of detergents and pure water to be sure the quantities are sufficient for the shutdown procedures. If any volume is short, the defined operation may not be successfully performed.
- Select [Maint.] > [System Startup/Shutdown Setting] to display the [System Startup/Shutdown Setting] window.



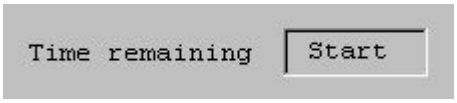
- Select "Shutdown" in the [Mode set] dropdown menu located in the upper part in the [System Startup/Shutdown Setting] window.
- Check the set values.

  If you change any value in the window, be sure to click the [Save] button after making the change.
- Select the wash routine.

  Select "shutdown" in the [Select wash routine] column in the left side of the window, and select "Set1", "Set2" or "Set 3" in the [Proc.set] drop-down menu.
- Save the shutdown setting

  Click [Yes] in the [Select Wash Routine] column. If the system mode is [READY], the selected shutdown procedure begins.

  If the system mode is not [READY], the [Time remaining] field reads "Start" and the defined shutdown procedure will begin as soon as the mode becomes [READY].



Once the shutdown operation has begun, it proceeds automatically until the end. The current system mode and remaining time to the end of operation are indicated in the

upper left field in the window. When the selected shutdown operation is completed, the analyzer and workstation enter the status indicated for [System end] in the [System Startup/Shutdown Setting] window.

If you want to stop the shutdown procedure after it has started, perform one of the following measures.

- Click the [Stop] button in the [System Startup/Shutdown Setting] window.
- Click the [Cancel] button in the [Select wash routine] column of the [System Startup/Shutdown Setting] window.
- Click the [STOP] button in the Operation Panel

The main valve and power supply for the pure water supply unit should be shut off separately from the above procedure.

Do not exit the system on the workstation during the shutdown procedure. Otherwise, the analyzer will enter in the [WAIT] mode and the selected shutdown procedure will not be completed.

Setting the automatic startup

Select [Maint.] > [System Startup/Shutdown Setting] to define settings for automatic startup. Select "Auto Startup" in the [Mode Set] dropdown menu.

For ordinary use

Choose the operations for automatic startup for each day of the week and the days on which to activate automatic startup (i.e. not on weekends). Set the values as follows:

[Activate Auto Startup]	Check the box next to the days of the week to use "Auto Startup". (Check✓ in the box)
[Start year/month/day]	Do not enter a value (except for [Auto startup by appointment] which is explained below)
[Start time]	Enter the time to start up (e.g. 0730 for seven thirty in the morning)
[Allow reaction bath to warm]	"Do" (check ✓ in the box)
[System start]	Select "New start"
[PRIME]	Select "PRIME1"
[WASH1]	Deselected (no check in the box)
[WASH2]	Deselected (no check in the box)
[WASH3]	Selected (check ✓ in the box)
[Cuvette blank]	Deselected (no check in the box)

Scheduling an automatic startup more than 7 days in the future

Use the [Auto Startup by Appointment] column to schedule an automatic startup in more than 7 days.

- Check the box next to "Active Auto startup" (check ✓ in the box)
- Enter the starting date [year/month/day]

  (e.g. 20110530 for May 30, 2011)
- Enter values for the fields from [Start time] to [Cuvette blank].
- Deselect all the days of the week for [Activate Auto Startup].

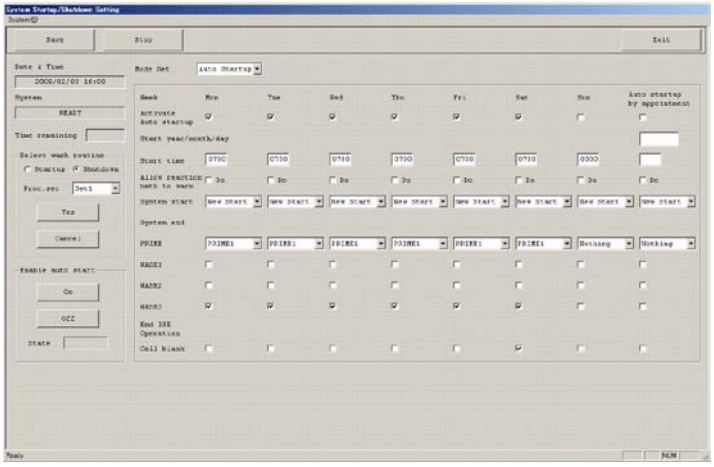
Steps for routine automatic start-up

The automatic startup feature starts-up the system automatically at a precise time (i.e. by the time you start working next morning or in the morning after the holiday). Usually, the automatic startup of the next working day is linked with the system shutdown of the current day.

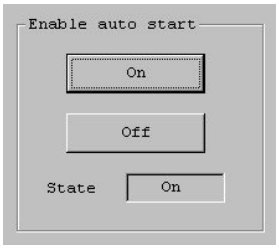
Steps for automatic startup alone

- Visually check the volumes of detergents and pure water required for automatic startup.

  If any volume is short, the selected operation may not be successfully performed.
- Select [Maint.] > [System Startup/Shutdown Setting] to display the [System Startup/Shutdown Setting] window.
- Select "Auto Startup" in the [Mode set] drop-down menu located in the upper part in the [System Startup/Shutdown Setting] window.
- Check the set values. If you change any value in the window, be sure to click the [Save] button after making the change.



✔ Click the [On] button in the [Enable auto start] column in the lower left hand corner of the window to activate "Auto startup". The [State] field will read "On".

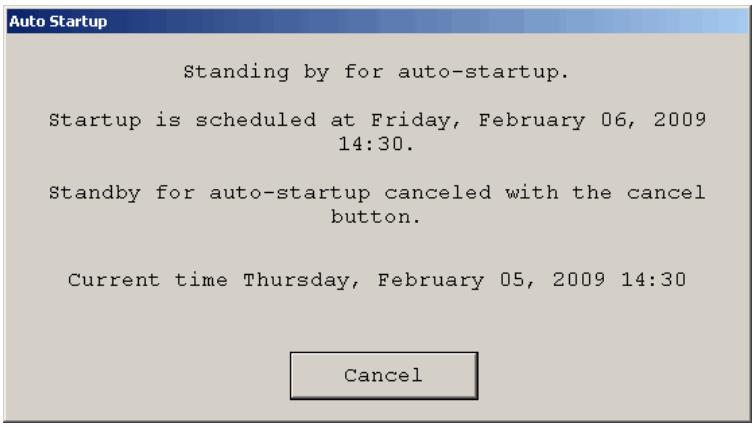


✔ Exit the system on the workstation as usual.

After the workstation is shut down, the window below is displayed and the system enters in “SLEEP” mode.

[SLEEP] mode will continue until automatic startup the next morning. The workstation is not powered off.

The Operate/standby switch in the power panel should be in the [PC CONTROL] position. If you want to turn off power of the analyzer.



The system will start-up automatically at the designated time and date. During automatic start-up, the [System Startup/Shutdown Setting] window is displayed and the current system mode and the time remaining until the end of automatic startup are displayed in the upper left fields. When [Cuvette blank] has been selected in the [System Startup/Shutdown Setting] window, a pop-up window is displayed to register the cuvette blank result just before the cuvette blank measurement is completed. When the automatic start-up procedures are completed, the system mode returns to [READY].

Linking shutdown with automatic start-up

In order to perform the linked operation properly, the Operate/standby switch must be turned to [PC CONTROL], "System End" must be selected in the [System End], and "Shutdown" must be selected in the [Mode Set] drop-down menu in the [System Startup/Shutdown Setting] window.

- Visually check the volumes of detergents and pure water required for shutdown and automatic startup. If any volume is short, the defined operation may not be successfully performed.
- Select [Maint.] > [System Startup/Shutdown Setting] to display the [System Startup/Shutdown Setting] window.
- Select "Auto Startup" from the [Mode set] drop-down menu located at the top of the [System Startup/Shutdown Setting] window.
- Check the set values.

  If you change any value in the window, be sure to click the [Save] button after making the change.

- Click the [On] button in the [Enable auto start] column in the lower left hand corner of the window to activate "Auto startup". The [State] field reads "On".
- Select the wash routine. Select "Shutdown" in the [Select wash routine] column located in the left hand side of the window, and select "Set1", "Set2", or "Set3" from the [Proc.set] drop-down menu.

Ensure that "Power OFF" is selected (check ✓ in the box) for [System p.s.] and "Shutdown" is selected for [System end].

- Click [Yes] in the [Select wash routine] column. A pop-up window will prompt you: "Start the shutdown process?". Click [Yes].

  If the system mode is [READY], the shutdown procedure will begin immediately.

  If the system mode is not [READY], the [Time remaining] field reads "Start" and the shutdown procedure will begin as soon as the mode becomes [READY].

From here, the procedure will be automatically carried out until the completion of the automatic startup the next morning. The current system mode and time remaining until the end of shutdown procedure are indicated in the upper left hand corner of the window. When the shutdown procedure is complete, the analyzer's power will be in the status selected in the [System p.s.] or [System end] fields in the [System Startup/Shutdown Setting] window. The message "Standing by for auto-startup." is displayed in the [Auto Startup] window.

The system will startup automatically as designated at the defined time and date. During automatic startup, the [System Startup/Shutdown Setting] window is displayed and the current system mode and the remaining time until the end of automatic startup are displayed in the upper left hand field.
When [Cuvette blank] is selected, a pop-up window is displayed to register the cuvette blank result just before the cuvette blank measurement is completed. Select [save] or [no save].
When all the setting values have been entered, the [Password] window is displayed.
Enter a [Username] and [Password] and click [OK].

See the above sections "Steps for routine shutdown" and "Setting the automatic startup."

.

Miscellaneous settings for automatic start-up and shutdown

- The table below summarizes the status of the analyzer's Operate/standby switch and the automatic start-up function.

Analyzer's power	Automatic startup
ON	Startup successfully
OFF	Startup the workstation only
PC CONTROL	Startup successfully

- To release the "standby" mode of the system waiting for automatic start-up, perform one of the following steps:
  - Click the [Off] button in the [Enable auto start] column of the [System Startup/Shutdown Setting] window.
  - If the [Auto startup] window is displayed, click the [Cancel] button in the window.
- To stop the automatic start-up operation of the system, perform one of the following steps:
  - Click the [Stop] button in the [System Startup/Shutdown Setting] window.
  - Click the [Cancel] button in the [Select wash routine] column of the [System Startup/Shutdown Setting] window.
  - Click the [STOP] button in the Operation Panel
- When [Cuvette blank] is selected and "Do" for [Allow reaction bath to warm], the analyzer will be in the [CB WATCH] mode (displayed in the Operation Panel) for 30 minutes after startup.
- The automatic start-up is canceled if the analyzer is in the status from which it cannot start (e.g. the analyzer is already in operation).

- When both [Week] and [Auto startup by appointment] are selected in the [System Startup/Shutdown Setting] window, the system will start-up at the earlier time. The automatic startup can be scheduled only once per day.
- Follow the steps below to wake the analyzer from the "sleep" mode to return it ready for start-up:
  - Click the [Cancel] button in the [Auto Startup] window, and then click the [OK] button in the [BioMajesty] Startup window.
- The startup procedure for the pure water supply unit (opening the main valve and turning on the unit) is not included in this automatic startup procedure.

Time required for start-up / shutdown

The approximate time required for each process is as follows.

Time required for individual process

Process	Values	Time
PRIME1	5 times for all steps	1 min
WASH1	5 times	14 min
WASH2	2 times	39 min
WASH3	Once	27 min
Cuvette blank	—	17 min

Time required for each procedure

Following is the approximate time required for each of the procedures

Startup

- PRIME1 + WASH3 ＝ 28 min
- PRIME1 + WASH3 + Cuvette blank ＝ 45 min

Shutdown

- WASH2 + System end + Shutdown the analyzer ＝ 40 min

Automatic startup

- PRIME1 + WASH3 ＝ 28 min
- PRIME1 + WASH3 + Cuvette blank (including warming up) ＝ 45 min

CONTENTS

Chapter

3 Preparation for Measurement

3.1 Preparing the Sample Containers

3.1.1 Sample containers

Acceptable sample containers

Specifications

The sample tray (STT) accepts containers conforming to the following specifications:

- Height: 75 - 100 mm
  Note the following:

  Sample tube shorter than 75mm may become stuck in the tray

  Sample tube higher than 100mm will contact the cover of the sample try and may be broken during analyzer operation.
- Outer diameter: 12.0 - 15.5 mm (including the label thickness)
  If sample tube with an outer diameter smaller than 12.0 mm is used, it can become unstable on the STT and may cause probe crash.
  If a sample tube with an outer diameter larger than 15.5 mm is used, the label may become dislodged or the sample tube itself may be damaged.
- If the small container, the "JCUP" (name shown in the application window) is used, use the JEOL-provided adapter with the JCUP.
- If you use a ‘off the shelf’ sample tube or container as an adapter, make sure that the JCUP does not contact the cover of the sample tray. Also, be sure that the JCUP does not fall into or get stuck in the sample tube or container before use.

Settings for sample container

Each combination of an adapter and sample container must be registered on the workstation. The following default values are set for the JEOL authorized products.

Container name	Description
10 ml tube	Sample tube with capacity of approx. 10 mL
Jcup/Adp.	A JEOL-provided cup to use in combination with the dedicated adapter.

- The consumables that JEOL provides are listed in Section 7.2: “Consumables and Spare Parts for Maintenance".
- If you want to use a new, unregistered sample container, register it in the [System Specifications Set] window. (Login level: “manager” or above.)

See the section 2.1.1 “System Specification Setting” for the registration steps.

3.1.2 Sample barcode

Barcode specifications

The table below summarizes the specifications of barcode systems that the system accepts.

Item	Specifications	Figure
Width of narrow bar (narrower bar)	0.19 - 1.0 mm	
Width of quiet zone (blank spaces on both ends of the bar)	At least 5 mm and at least 10 times the width of narrow bar.	(1)
Narrow bar / wide bar ratio (narrow bar / wide bar)	1: 2.5 - 1: 3.0 (recommended ratio: 2.5)	
Bar width	15 - 60 mm	(2)
Bar height	12 mm or greater	(3)
Space between bar and character	1 mm or greater (A space less than 1mm may cause a reading error)	(4)
Supported code types	CODE128, CODE39＊1, ITF＊1, NW-7＊1, JAN Check digit (CD) is recommended	
Number of digits for sample ID	CODE128:1-13digits Others:4- 13 digits	
Print quality PCS (reflection rate) ANSI X3.182 (quality standard)	 0.6 or more (75% or greater for white) Grade A or B (ANSI X3.182 guideline)	
Label	Black bar on white background	
Placing angle allowance	± 2 degrees	

Use of check digit (CD) is recommended to avoid erroneous readings. Although CD is an effective preventive method for erroneous readings, it does not guarantee 100% correct reading.

Acceptable barcode standards

Barcode standards acceptable for the BM6010/C are summarized in the table below with availability of the CD and start/stop character functions.

The following points must be taken into account when setting the barcode specifications:

- When the CD function is used, CD should appear in the end of the barcode number.
- The CD and start/stop characters are included within the bar, but not necessarily printed in the section for visual identification. Check the barcode specification with an expert in your software engineering group.

- The sample ID number is limited to between 4 and 13 digits. Note that when using CD and start/stop characters, they are included in the number of digits in the sample ID. (CD requires 1 digit and start/stop characters requires 2 digits.) .
- Up to four barcode types can be setup (Default settings are shown below). However, different settings for one barcode type (e.g. CODE128 with CD and without CD) cannot be set up.
- If you want to operate NW7 or ITF, the fixed digits is recommended to avoid erroneous readings.

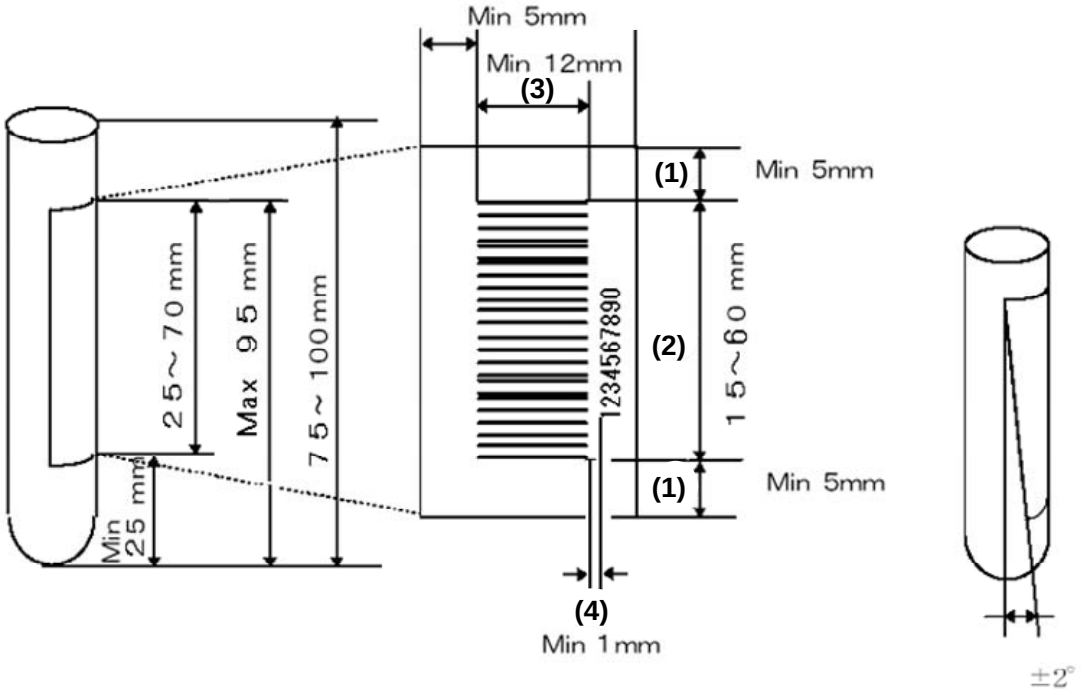
If you want to operate the system with a barcode setting that is not included in the default factory setting, please contact your local distributor.

Barcode Type	Function			Mandatory / Recommended	Default
	CD	CD Transmission	Start/stop Character Transmission		
CODE128	Available	N/A	—	Mandatory	○
ITF	Available	N/A	—	Recommended	○
		Available	—	Recommended	
	N/A	—	—	—	
JAN (13 digits)	Available	Available	—	Recommended	○
JAN (8 digits)	Available	Available	—	Recommended	
NW7	Available (Modulas16)	N/A	N/A	Recommended	○
	Available (another method)	Available or N/A	Available or N/A	Recommended	
	N/A	—	Available or N/A	—	
CODE39	Available	Available or N/A	Available or N/A	Recommended	
	N/A	—	Available or N/A	—	

Barcode standards acceptable for system

Labeling position

Place the sample barcode label properly on the sample container as shown below:



Correct Sample Barcode position

3.2 Preparing the Sample

3.2.1 Dispensing the sample into the sample container

- Check that the volume is sufficient for measurement.
  Required volume = (sample volume to be used in measurement) + (dead volume for the container)
- Because several tests are performed in one measurement, the required sample volume is the total sample volume for tests plus dead volume for the container. The required volume for one chemistry test is the sample volume plus 3 µl. However, for an ISE test (i.e. Na, K, or Cl), the required volume is 24µl regardless of the number of tests.
- The dead volume varies depending on the container size,

Container name	Dead volume
10 ml tube	200 µl
JCUP	50 µl

Dead volume for most commonly used containers

- If the container used for centrifugation is also used in the sample tray, ensure that the container has sufficient volume for the serum measurement as well as for the sample liquid level sensor. If the volume of serum is insufficient, the probe will aspirate the blood cell components underneath which may affect the measurement or cause probe clogging by the serum separator.
- If the serum volume is insufficient after centrifuge separation, transfer the serum to a new, smaller container such as the JCUP to increase the liquid depth for the sample probe. Ensure that no blood cell components are transferred to the new tube.

3.2.2 Notes for handling the sample

- Always ensure adequate sample storage. If left at room temperature too long, it can deteriorate the sample due to evaporation or alteration of components, therefore, may result in erroneous measurement results.
- Ensure that no fibrin or other foreign matter is present in the sample. Fibrin in the sample may result in clot formation in the sample probe (SPP) or SPP line resulting in erroneous measurements.
- Samples with high viscosity may clog the sample probe, resulting in erroneous measurements.
- If serum separator is added in the tube, ensure that the serum separator is properly centrifuged and is not floating in the serum sample. Serum separator in the serum can clog the sample probe and may cause erroneous measurement results.
- When using anticoagulant, follow the instruction of the reagent manufacturer. Improper use of anticoagulant can also cause erroneous measurement results.
- Ensure that no air bubbles are present in the sample. Air bubbles can cause aspiration error by the sample probe.
- Some coexisting substance in the sample may affect the reagent. Read the reagent manufacturer's package insert carefully for information.
- Please be sure to follow the manufacturer's instructions regarding the appropriate reagent for each test and sample type.

3.2.3 Notes for handling the sample for ISE measurement

Acceptable sample types

Serum, plasma, and urine are all acceptable samples for ISE measurement. Whole blood is not acceptable.

Effects from coexisting chemical substances

Anticoagulation agents

Lithium heparin contains lithium which is an ion that interferes with the measurement of sodium. Anticoagulant such as sodium heparin, EDTA-1K or EDTA-2K has sodium and potassium added to plasma. Therefore, the result value may be elevated if such anticoagulant is used.

Oxalic acid, citric acid and other similar substances can interfere with the measurement of chlorine.

Drug metabolites in serum

(a) Halogen-containing drugs:
Halogen metabolites are negative free ions that may elevate the Cl^- values.

(b) Bromisol (bromvalerylurea)
Sedatives, analgesics, and cold remedies may contain Br^- ions which can elevate Cl^- values.

(c) Vitamins
Vitamin preparations often contain additional salts such as hydrochloride, bromide, and nitrate. When these salts become free negative ions, Cl^- values may appear to be elevated.

Substances (principally ions) that may affect ISE measurement values

The table below shows the ion selective factors for coexistent ions for the Na^+, K^+, and Cl^- electrodes. The ion selective factor indicates the degree of sensitively to the coexistent ion in comparison with that to the target ion. The sensitivity to the target ion is defined as "1.0".

Ion selective factors for the Na, K, and Cl electrodes

Na electrode (membrane: crown ether)

Coexistent ion	Km,x
Potassium ion (K^+)	1.5×10^{-2}
Rubidium ion (Rb^+)	1.1×10^{-2}
Cesium ion (Cs^+)	9.0×10^{-3}
Ammonium ion (NH_4^+)	1.2×10^{-3}
Lithium ion (Li^+)	5.0×10^{-4}
Calcium ion (Ca^{2+})	9.9×10^{-5}
Magnesium ion (Mg^{2+})	8.1×10^{-5}

K electrode (membrane: crown ether)

Rubidium ion (Rb^+)	1.4×10^{-1}
Cesium ion (Cs^+)	4.2×10^{-3}
Ammonium ion (NH_4^+)	7.4×10^{-3}
Lithium ion (Li^+)	1.6×10^{-4}
Sodium ion (Na^+)	3.6×10^{-4}
Calcium ion (Ca^{2+})	1.1×10^{-5}
Magnesium ion (Mg^{2+})	6.5×10^{-6}

Cl electrode (Membrane: Super-layer solid molecule orientation membrane MO)	
Salicylate ion (C_6H_4（OH）COO^-)	3.3
Azide ion (N_3^-)	2.6
Thiocyanic ion (SCN^-)	7.0
Perchloric ion (ClO_4^-)	4.4
Iodine ion (I^-)	4.7
Nitrate ion (NO_3^-)	2.5
Bromine ion (Br^-)	2.1
Bicarbonate ion (HCO_3^-)	1.1×10^{-1}
Acetate ion (CH_3COO^-)	3.8×10^{-2}
Monovalent phosphoric ion ($H_2PO_4^-$)	6.0×10^{-3}
Bivalent phosphoric ion (HPO_4^{2-})	1.3×10^{-2}
Acetate ion (sulfate ion)	7.0×10^{-3}

3.2.4 Sample for simultaneous measurement of blood cell components (HbA1c) and plasma components

This section describes the conditions for simultaneous measurement of blood cell and plasma targets.

Conditions for centrifugation

Follow the reagent manufacturer instructions when preparing the centrifuged blood cell component sample.

The centrifugal force (CF) is calculated with the following formula.

$CF\ (g) = 1.118\times10^{-5} \times \text{rotor radius (cm)} \times rpm^2$

Setting analytical conditions for blood cell component

Set the analytical conditions for measuring blood cell component (HbA1c) as follows:

When setting diluent on the reagent tray 1 (RTT1), select [Setup] > [Analytical Parameters (Chemistry)] > [Analytic test condition setting (M)], and define the values as follows:

Item	Value
[Dilution condition]	"Do"
[Undiluted sample volume]	2.0 μl
[Diluent volume]	200.0 μl
[Diluent position]	RTT1 position where the diluent is loaded.

Be sure to read the package insert of the reagent used. If the insert indicates setting values other than described above, follow those described in the package insert.

Setting analytical conditions for plasma components

Set the analytical conditions for measuring tests such as glucose or 1.5-Anhydro-D-glucitol as follows:

- Select [Setup] > [Analytical Parameters (Chemistry)] > [Analysis test condition setting (M)]. Select “Not do" in [Dilution specification] in the [Analysis Test Condition Setting (M)] window.
- Click the [Sampling Position Setting] button in the top bar of the [Analytical Parameters (Chemistry)] window to open the [Sampling Position Setting] window. Select "Top" for the sampling position there.

Be sure to read the package insert of the reagent. If the insert indicates different settings, follow the indication of the package insert.

Sample surface level

For the sample that is aspirated from the “Bottom” position of the container, the sample surface level in the container must be 60 mm or lower (See Section 1.4.1: “Simultaneous measurement of blood cell components (HbA1c) and plasma components” in Chapter 1.) Any part of sample probe (SPP) higher than 60 mm cannot be washed; therefore, sample may be carried over to the next samples, resulting in incorrect measurement data. Insufficient washing of the sample probe can cause LLS errors and unsanitary conditions within the analyzer.

Settings for hemolysed sample

Set the dedicated diluent (lysis solution) on RTT1 for tests requiring hemolysed sample.

3.3 Setting the Sample on the Tray

Place the sample in the position designated by the settings or order and check the position, container, and type again to make sure if the sample is correctly loaded on the tray.

Placing the sample.

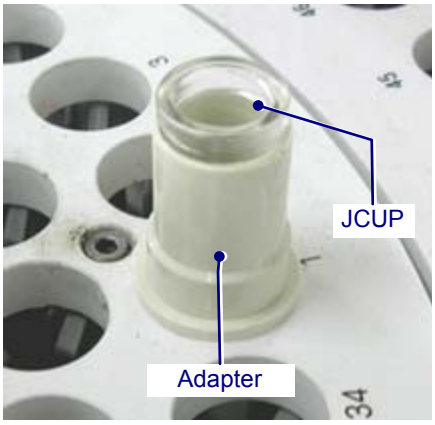
- Push the sample container down to the bottom of the sample tray or STAT port.
- Remove the cover (e.g. cap) of the sample container before placing the container in position. Otherwise, the container may contact the Sample tray (STT) cover, and the cover and/or container may be damaged.

Using a barcoded sample

- The barcode reader is located in the outer edge of the sample tray space and reads the barcode from the outside. Therefore, be sure to place the container so that the barcode label faces the outside of the tray.
- Ensure that the barcode label is securely attached to the container (i.e. no parts of the label are peeling off) when placing the container into the sample tray.

Using an adapter

- Set an appropriate adapter in a STT loading slot and place a JCUP inside.
- Place the adapter so that the side of the adapter with the narrower diameter faces upwards



- Place the adapter in the STT hole. Be sure that the adapter is securely set in position.
- Visually check that the JCUP placed in the adapter is not tilted or shifted in order to prevent oscillation within the machine.

3.4 Preparing the Reagents

Set reagents in the position designated by the settings, and check the position, bottle and type for each reagent to make sure if they are correctly loaded on the tray.

Reagent handling

- Handle and store the reagent properly in accordance with the manufacturer's instructions.
- Do not use expired reagents.
- Do not use reagents that contain layers of liquid paraffin. Paraffin layers may cause the reagent to be aspirated improperly.

Reagent filling

- Use a clean, dedicated bottle (provided by JEOL) to fill reagent.
- Do not add new reagent to a bottle containing remaining reagent.
- Reagents containing surfactants may form bubbles when refilled into the bottle. Bubbles can cause reagent aspiration error. Remove the bubbles if there are any.

Reagent bottle

- When using a bottle with barcode, check that the label is still intact and not soiled.

Setting the reagent bottle on the reagent tray (RTT)

- Set the reagent bottle firmly on the reagent tray so that the bottom is securely set in position. Check that it does not rattle.
- Use the dedicated reagent bottle adapter, provided by JEOL, when setting a smaller bottle.

How to use the bottle adapter

Following bottle adapters are available:

Type	Bottle size to support	Setting position on RTT
20 ml -> 40 ml	20 ml	Positions for 40 ml bottles
20 ml -> 70 ml	20 ml	Positions for 70 ml bottles
40 ml -> 70ml	40 ml	Positions for 70 ml bottles

1. Set the reagent bottle in the adapter as shown below.

20 ml - 40 ml	20 ml - 70 ml	40 ml - 70ml
		

- The barcode label must be securely attached.
- Ensure that the barcode visible at all times.

2. Place the bottle adapter with the bottle in the appropriate RTT position.

20 mL - 40 mL	20 mL - 70 mL	40 mL - 70mL
		

- Check that the bottle adapter and bottle are securely placed.
- Ensure that the barcode is sufficiently visible to the barcode reader.

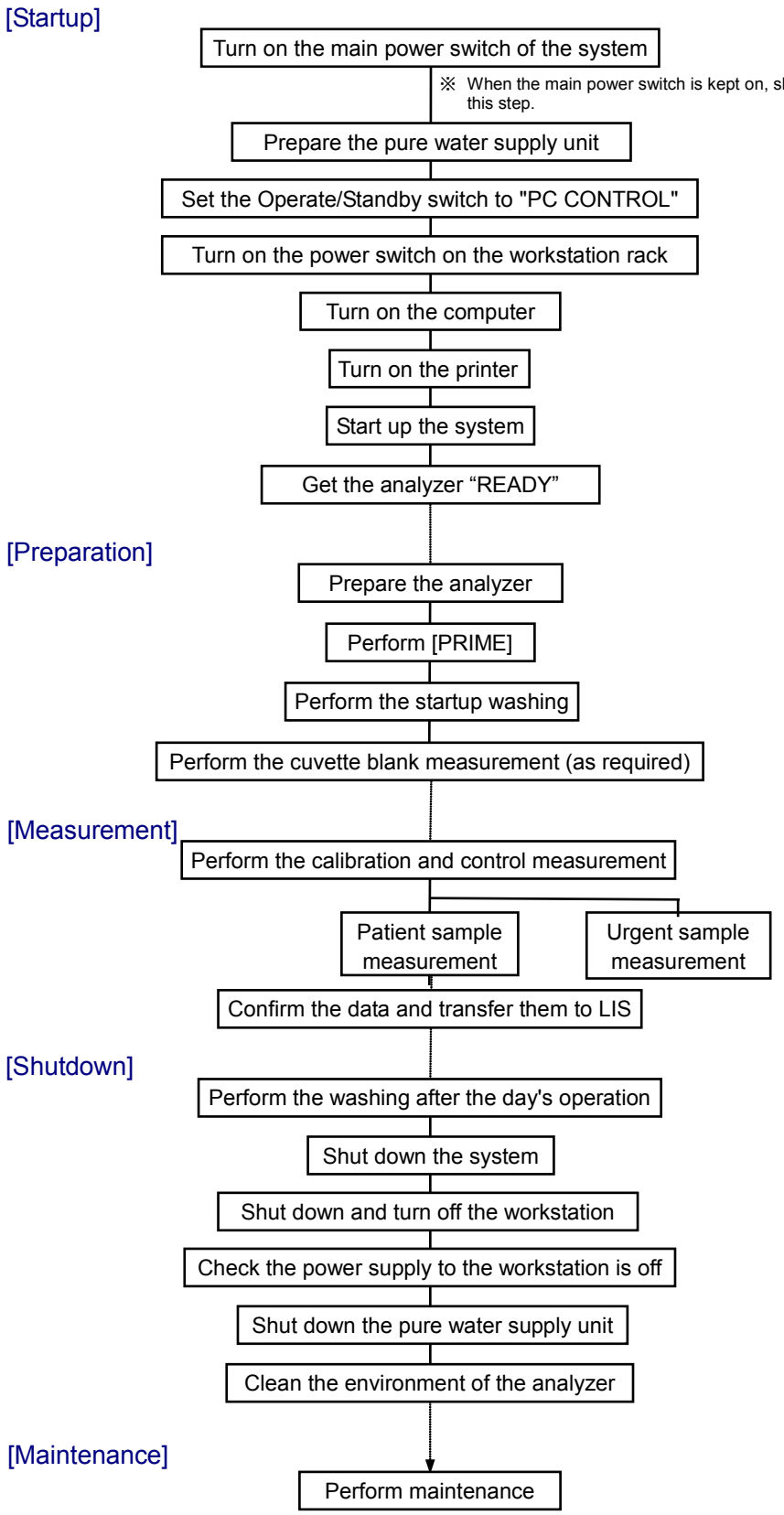
CONTENTS

Chapter

4 Routine Measurement

4.1 Routine Workflow

The following diagram shows the general workflow of the measurement with the analyzer BM6010/C.



4.2 Getting Started

Warning

Once the analyzer has been started, the probes and trays move before entering into the READY mode. Never touch the probes and trays while they are moving. This may lead to injury or infection of the operator, or damage to the analyzer.

Turn on the main power switch of the system.

✔ Turn on the main power switch of the system on the back panel of the analyzer.

Back side of the analyzer

With the main power turned on, the electric current goes through the Reagent Tray (RTT), Refrigerated Sample Tray (CTT), and ISE Unit.

Prepare the Pure Water Supply Unit.

Follow the instructions for your pure water supply unit to start it up and prepare a pure water supply to the analyzer.

Set the Operate/Standby switch to “PC CONTROL”.

Set the Operate/Standby switch to the “PC CONTROL” position to synchronize the startup and shutdown of the analyzer with the workstation.

Although you may set the Operate/Standby switch to ⊙ “ON” position, the analyzer does not synchronize with the workstation for startup and shutdown.

Set the Operate/Standby switch of the power panel to “PC CONTROL”.

Power panel

Start up the workstation.

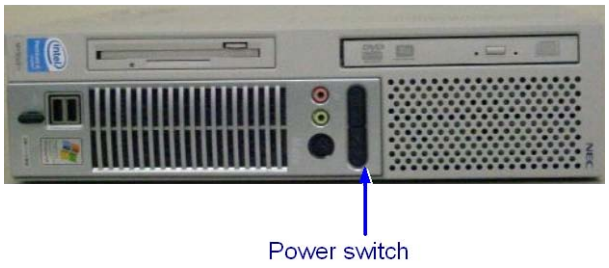
1) Turn on the power switch on the workstation rack.

Workstation

The LCD monitor and printer included in the workstation get turned on.

When they are not automatically turned on, manually turn them on.

2) Turn on the computer.



3) Check that the printer's “ready to print” switch is ON.

When this switch is OFF, you may not be able to print.

In approximately 1 minute after Step 2, “BioMajesty” startup window opens.

Start up the system

1) Select the starting mode of BioMajesty.

Select the starting mode according to the following features.

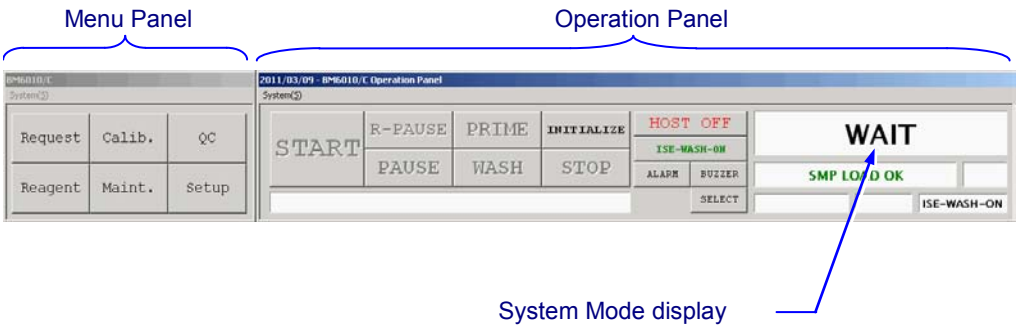
[New Start]: All the data and requests associated with the current "System Date" will be deleted.

[Re-Start]: The requests and data associated with the "System Date" will be retained and available for use.

BioMajesty Startup Window

2) Click the [OK] button on the BioMajesty Startup Window.

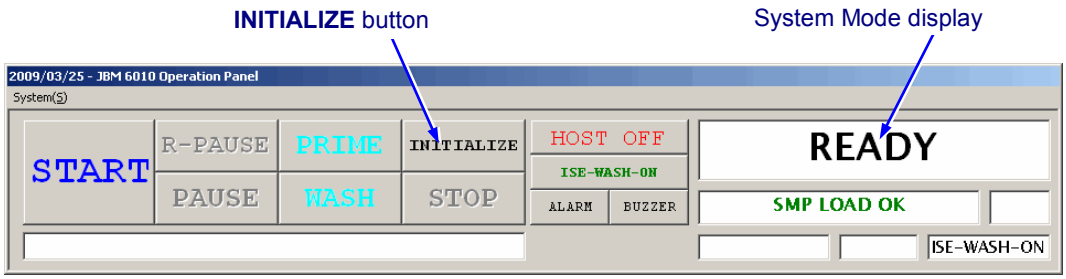
The system starts, and the Menu Panel and Operation Panel are displayed on the top of the screen as shown below. The analyzer is turned on automatically with the workstation, and the indication lamp on the status display/power panel lights on. The system mode displayed on the Operation Panel changes from "SYSTEM INIT" to "WAIT."



The Menu Panel and Operation Panel in the upper section of the monitor

Get the analyzer [READY]

- **If the system mode displayed on the Operation Panel is “WAIT,” click the [INITIALIZE] button on the panel to change the system mode to “READY”.**



Operation Panel

The initialization finishes approximately in one minute, and then the “READY” lamp on the status display/power panel of the analyzer lights on in green indicating the analyzer is now ready. During “initialization” of the analyzer, the system mode is displayed as “INITIALIZE.” When the initialization is completed and the analyzer is ready, the mode shown changes to “READY.”

If the startup fails, the red ALARM lamp on the status display/power panel lights with an alarm and the analyzer stops automatically. After solving the problem, click the [INITIALIZE] button in the Operation Panel to restart the system.

Click the [ALARM] button to display the error report for identification of the problem.

4.3 Preparing the Analyzer

Warning

When performing “Lamp energy check,” “WASH3,” or “Cuvette blank measurement,” the probes and trays move. Never touch the probes and trays while they are moving. This may lead to injury or infection of the operator, or damage to the analyzer.

4.3.1 Preparation before test run

The maintenance of the system must be performed as necessary besides the routine checks required before every operation. Refer to “Chapter 7 Maintenance” for details.

✔ Points to be checked for the workstation before measurement

i. Clean the LCD display and keyboard as required.

ii. Ensure that there is sufficient quantity of paper in the paper tray of the printer.

See your printer manual for loading the paper.

iii. Ensure that there is sufficient amount of ink / toner. If not, replace the cartridge.

If the printing shade is becoming light, replace the cartridge with a new one.

See your printer manual for cartridge replacement.

✔ Points to be checked for the analyzer before measurement

i. Clean the nozzles of the sample probe (SPP) and the reagent probes (RPP1/RPP2) as required and ensure the positions are correct.

ii. Clean the nozzles of the reaction carousel wash unit (WUD) as required.

iii. Clean the mixing rods (MIX1/MIX2) as required.

iv. Visually check the reagent trays (RTT), refrigerated sample tray (CTT) and the remaining volumes of detergents in the bottles, and replenish them as required.

The following table summarizes the types of detergents and other solutions and their locations.

See the following “Section 3) Replenish reagents” for replenishing the reagents.

Detergents and other solutions and their locations

Purpose	Location	Name of Detergent
Prevent contamination (alkaline)	Position #47 on RTT1 and RTT2	Reagent probe wash -1
Prevent contamination (acid)	Position #48 on RTT1 and RTT2	Reagent probe wash -2
WASH2 (daily)	Position #49 on RTT1 and RTT2	Reagent probe wash K (20%)
WASH2 (weekly)	Position #49 on RTT1 and RTT2	Reagent Probe Wash S (5%)
WASH 1-3 (daily and weekly)	Position #50 on RTT1 and RTT2	Pure Water
WASH1 (daily)	Position #50 on RTT1 and RTT2	Pure Water
	#50 on CTT	Pure water
Cuvette detergent (alkaline)	Detergent container	Cuvette wash solution
Cuvette blank measurement	Detergent container	Cuvette Conditioner EX
Sample dilution	Detergent container	Saline
Reaction bath oil	Detergent container	ACUR20

v. Check for any liquid leak from the pumps. If any, replace the entire pump head or the sealing materials.

✔ Points to be checked for the ISE unit before measurement

i. Check the remaining volumes of ISE buffer and internal standard are sufficient.

ii. If the amount is insufficient, replace the bottle with a new one.

After changing the ISE buffer bottle, set “15” times for the number of buffer priming.

Close the panel above the bottle compartment during measurement. The vibration via bottles may influence the ISE test values.

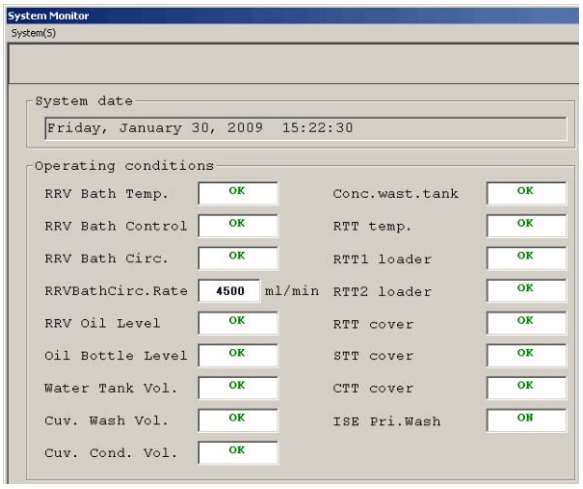
iii. When using the concentrated waste fluid tank, check if the room is sufficient. When replacing the buffer bottle, discard the waste fluid.

iv. Check there is no excess amount of crystalline substance formed around the ISE dilution bowl and waste fluid outlet. For any abnormal findings around this area, perform maintenance on the dilution bowl tray.

Settings and replenishments

1) Check the temperature

Select [Maint.] > [System Monitor] to check if the temperatures of the reaction carousel (RRV) and reaction tray (RTT) are acceptable and if the flow rate of the reaction bath oil is in the normal range.

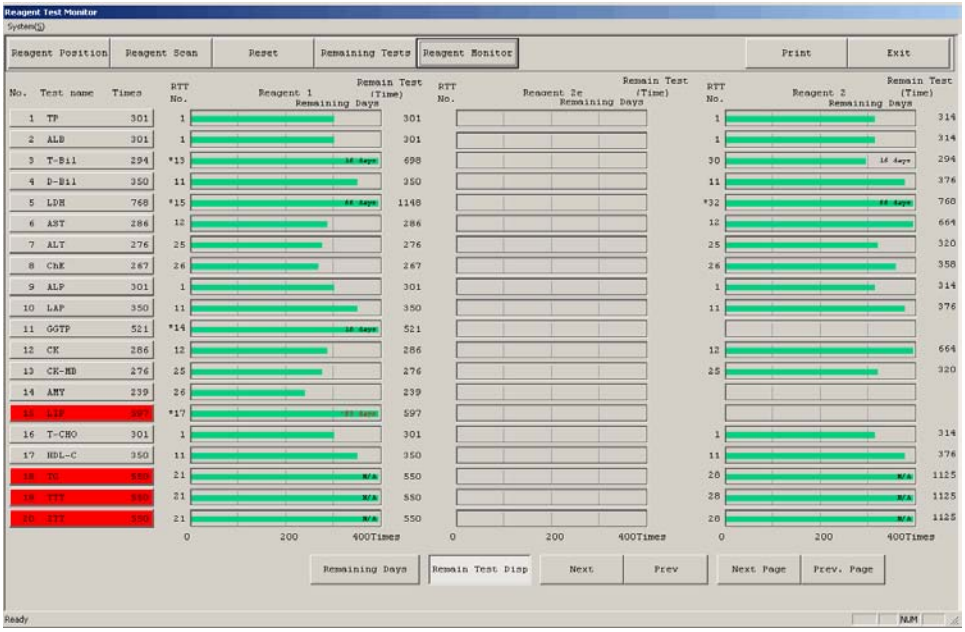


2) Define the analysis conditions

See “Chapter 2 Measurement Settings” for details.

3) Replenish reagents

i. Select [Reagent] > [Reagent Test Monitor] to open the window below.

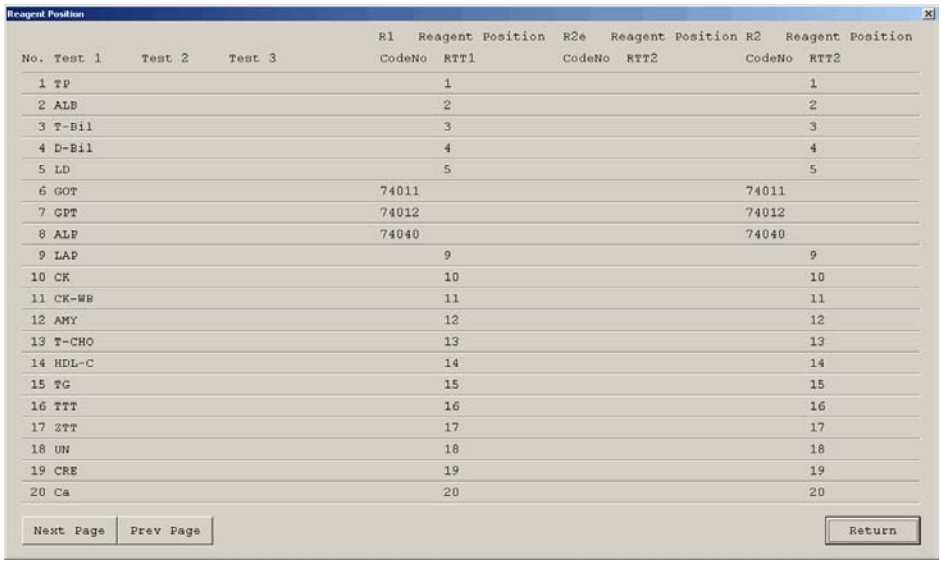


ii. Check the remaining volume of each reagent.

Write down the names of the tests for which reagents are insufficient.

iii. Click the [Reagent Position] button in the [Reagent Test Monitor] window

The window below is displayed.



iv. Check the RTT positions of the reagent bottles on the [Reagent Position] window.

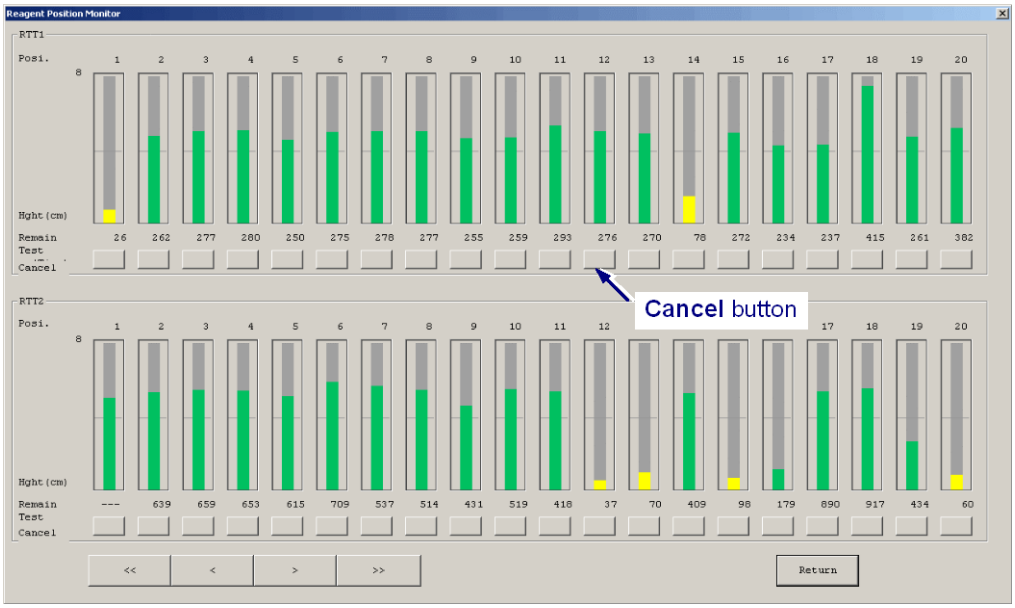
v. Replenish the reagent bottle.

The reagent contains surfactant. Pour it carefully into the bottle to avoid foaming.

When the reagent bottle has a barcode label on, ensure that it is legible and not peeled off.

vi. To check the reagent volume, select [Reagent] > [Reagent Test Monitor] > [Reagent Monitor] button.

The remaining reagent volume is displayed in the [Reagent Position Monitor] window.

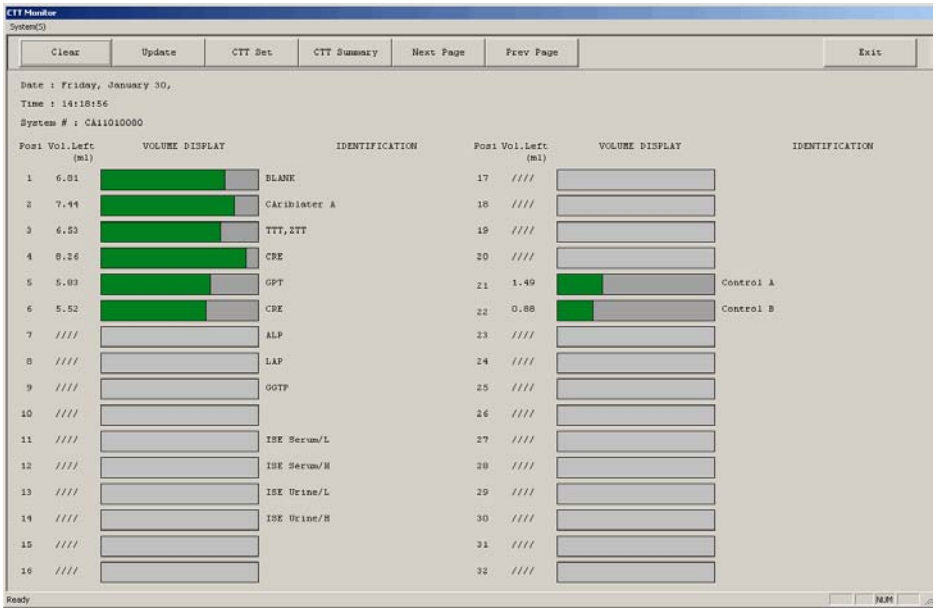


vii. Click the [Cancel] button underneath the reagent tray (RTT) position number as required.

This button is used to avoid using the reagent placed in the position.

If this button is pressed, the corresponding check box is checked in the [Reagent Container Set] window.

To see the volume of the sample set on the refrigerated sample tray (CTT), select [Reagent] > [CTT Monitor]. Note that the volume indicated in this window is the value detected by the liquid level sensor.

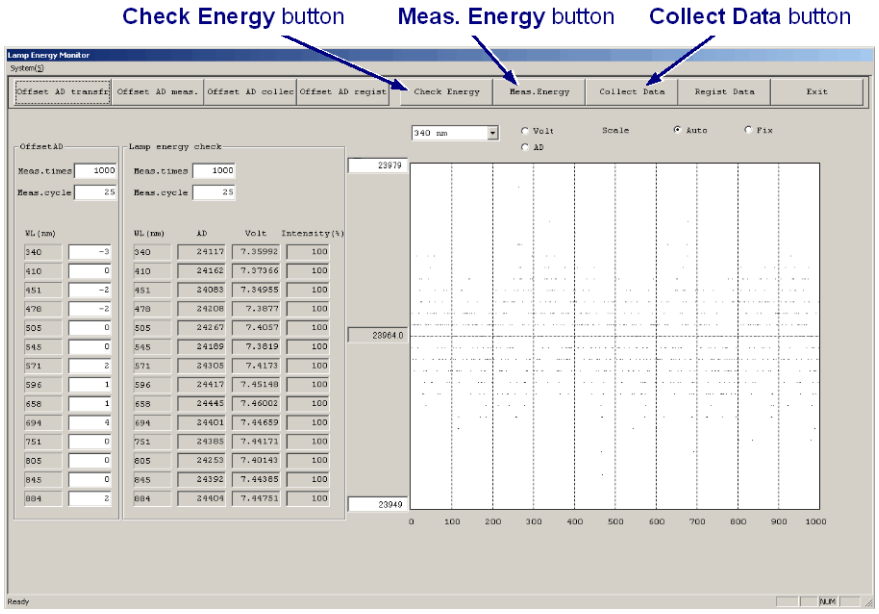


4) Check the lamp energy.

Check the lamp energy weekly in the [Lam Energy Monitor] window.

i. Select [Maint.] > [Lamp Energy]

The [Lamp Energy Monitor] window is displayed.



ii. Click the [Check Energy] button.

The reaction cuvette containing water moves to the detection position.

iii. Click the [Meas Energy] button.

Spectrophotometry is performed.

iv. Click the [Collect Data] button.

The measurement data is displayed.

If a value ≤ 80% is shown in the [Attenu] field, replace the lamp. Follow the steps described in “Chapter 7 Maintenance.”

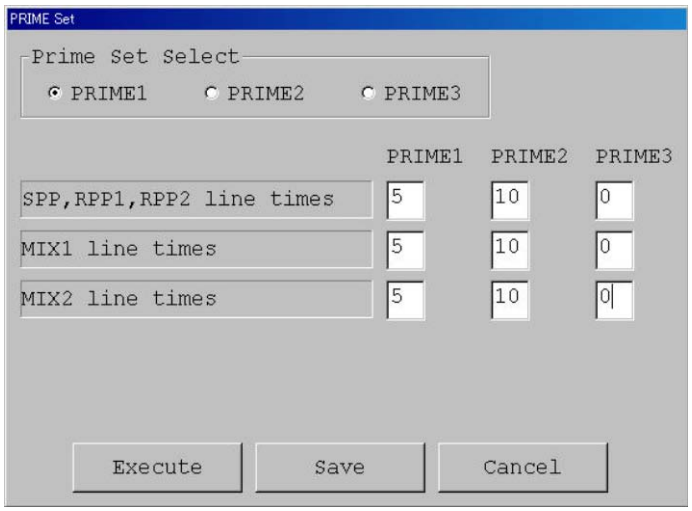
If a value ≤ 4V or ≥ 9V is shown in the [Volt] field, the optical system including spectrophotometer and lamp might have problems. Contact your local distributor for the problem related to [Volt]. Solve the problems before proceeding to the next step.

4.3.2 Priming

Priming has to be performed when the cuvette detergent (alkaline), cuvette blank sample or saline is replenished. Steps are as follows:

1) Click the [PRIME] button in the Operation Panel.

The [Prime Set] window is displayed.



2) Select [PRIME1] and click the [Execute] button.

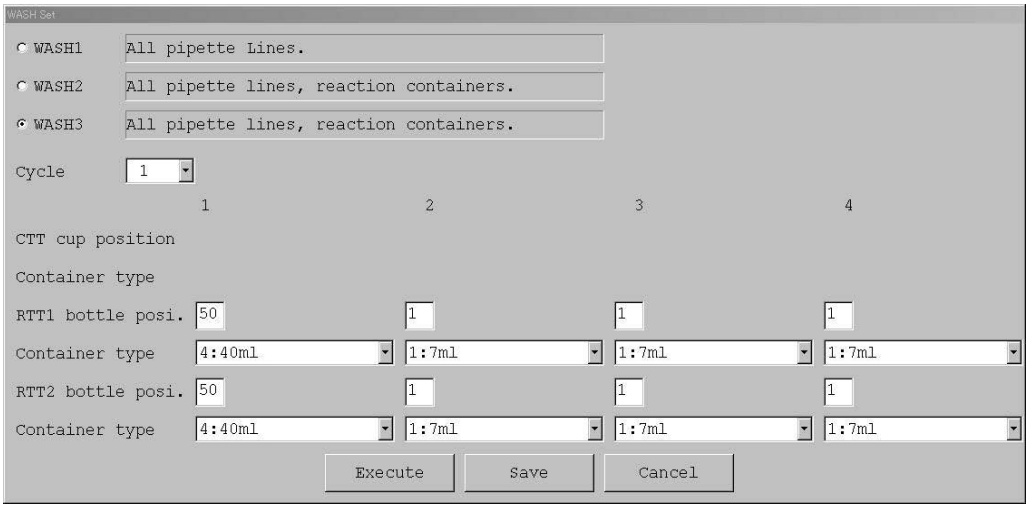
The priming [PRIME1] starts and finishes in approximately 5 minutes.

The numbers shown in the white boxes in the [PRIME Set] window indicate the number of priming to be performed. The figure shown above indicates that priming is performed for 5 times per line when “PRIME1” is selected. If you want to change the number of priming, change the number in the white box.

4.3.3 Washing at startup

1) Click the [WASH] button in the Operation Panel.

The [WASH Set] window is displayed.



2) Select [WASH3] and click the [Execute] button.

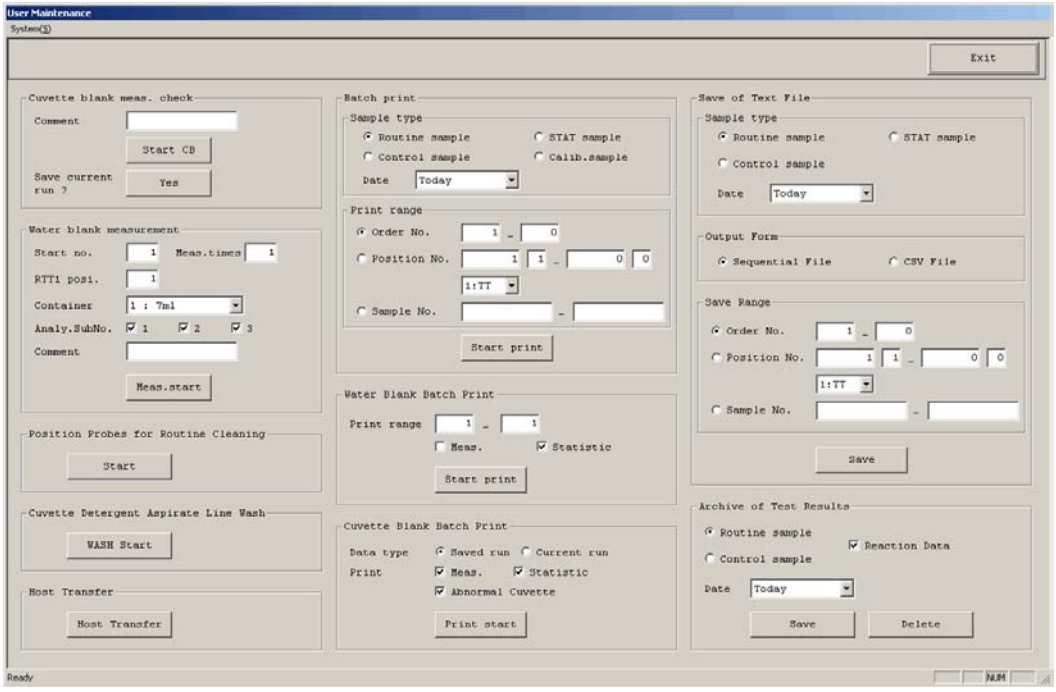
The [WASH3] begins and the startup washing finishes in approximately 27 minutes.

4.3.4 Cuvette blank measurement

Follow the steps below to measure the cuvette blank. Perform the cuvette blank measurement approximately once a week.

1) Click the [User Maintenance] button in the [Maint.] window.

The window below is displayed.



2) Click the [Start CB] button in the [Cell blank meas. check] field.

The cell blank measurement starts and finishes in approximately 17 minutes. The measurement data and summary are displayed on the workstation monitor.

3) When the measurement has been successfully completed, click the [Save] button.

The data are saved in the hard disk of the workstation.

```
CELL BLANK  DATE: 1997/10/13  TIME: 16:20  Comment:                    PAGE:  1

RRVNO  Kind    Mark          340    410    451    478    505    545    571    596
CB071  CB1                  1315   1363   1339   1289   1268   1229   1253
       CB2                  1315   1362   1339   1289   1268   1229   1252
       MEAN                 1315   1362   1339   1289   1268   1229   1253

CELL BLANK Statistics DATE: 1997/10/14  TIME: 10:54  Comment:

Wave  N    MAX          MIN          RANGE        MEDIAN       SD
340   221    0.142987     0.123695     0.019293     0.131638     0.002850
410   221    0.142611     0.129438     0.013173     0.135863     0.002030
451   221    0.140220     0.127685     0.012535     0.133691     0.001844
478   221    0.135328     0.122831     0.012497     0.128956     0.001870
505   221    0.133151     0.121184     0.011968     0.126909     0.001786
545   221    0.129350     0.117785     0.011565     0.123393     0.001763
571   221    0.131784     0.120348     0.011437     0.125860     0.001738
596   221    0.130219     0.118881     0.011338     0.124260     0.001702
658   221    0.133348     0.121990     0.011357     0.127339     0.001670
694   221    0.140073     0.128670     0.011402     0.134035     0.001667
751   221    0.126890     0.115489     0.011401     0.120454     0.001516
805   221    0.120842     0.109646     0.011196     0.114486     0.001510
845   221    0.139997     0.128906     0.011091     0.133541     0.001449
884   221    0.124415     0.113472     0.010944     0.117797     0.001397

CELL BLANK Abnormal   DATE: 1997/10/14  TIME: 10:54  Comment:

RRVNo Mark RRVNo Mark RRVNo Mark RRVNo Mark RRVNo Mark RRVNo Mark RRVNo Mark RRVNo Mark
   46 h     105 l     109 l     111 l     112 l     115 l     186 h     220 h
```

After the completion of measurement, the statistical results of the cuvette blank measurement are displayed on the [Realtime Monitor] window. You can print the results if necessary from the [User Maintenance] window. The position numbers of the flagged cuvettes are listed in the last part.

The measured value of a cuvette with flag “H” is higher and that with flag “L” is lower than the average by more than the absorbance ± 0.04. These cuvettes are not used for measurement.

When a significant number of cuvettes are flagged with H or L, perform one of the followings:

- Replace the reaction cuvettes with new ones.
- Perform [WASH] to clean the cuvettes.

4.4 Measurement

Warning

When performing calibration or patient sample analysis, the probes and trays move. Never touch the probes and trays while they are moving. This may lead to injury or infection of the operator, or damage to the analyzer.

4.4.1 Measurements of calibrators and control samples

Calibration must be performed before measurement.

For the ISE unit, calibration is required respectively for serum and urine. If the calibrator for urine is used for serum calibration, or vice versa, the precision and accuracy will be reduced. Also, note that the previous calibration values are cleared when calibration starts.

These measurements can be performed for chemistry tests and ISE tests either separately or simultaneously. In order to perform them simultaneously, preparation must be completed for both the chemistry and ISE tests. Following are the steps for the calibration (reagent blank and calibrator measurement) and the serum control measurement for quality control (QC) for chemistry tests.

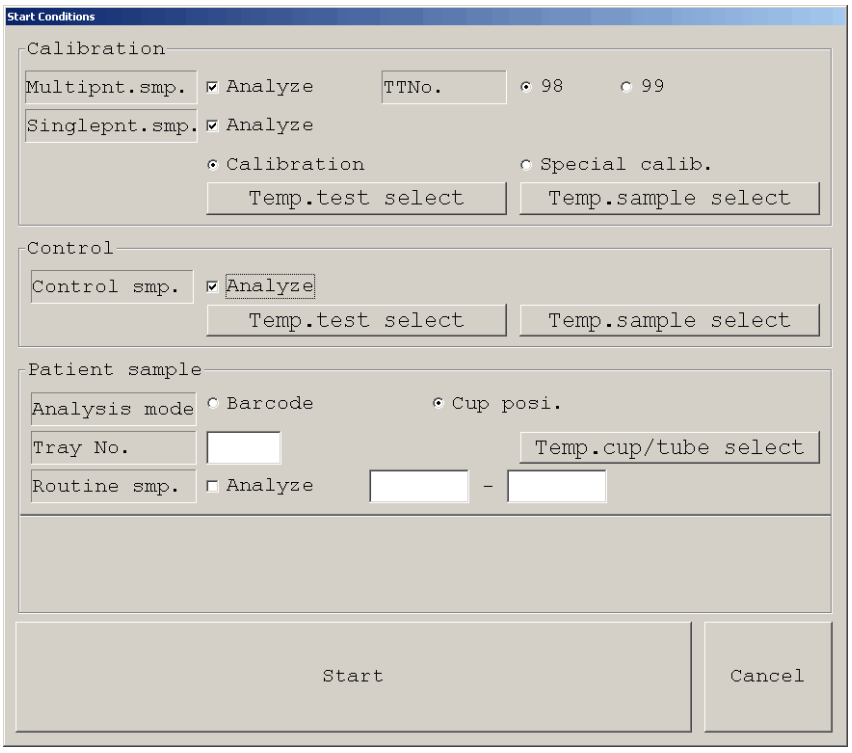
Calibration (reagent blank and calibrator measurement) and control sample measurement for chemistry tests

1) Prepare the samples.

Dispense the sample in the container specified in [QC] > [QC Sample Definition] window and set in the position defined in [Calibration] > [Calibration Setup] window.

2) Start measurement.

Click the [START] button in the Operation Panel. The [Start Conditions] window is displayed.



When there is a test which uses the multipoint calibrator, check the “Analyze” check box for [Multipnt.smp.] in the [Calibration] column.

Select either “98” or “99” for [TTNo].

Select “Analyze” for [Singlepnt.smp].

Select either “Calibration” or “ Special calib.”

Select “Analyze” for [Control smp.] in the [Control] column.

Click the [Start] button in the [Start Conditions] window.

The measurement starts and the results are generated.

By clicking the [Start] button, the calibration and control measurement begin, and the countdown for automatic calibration and the test time count for automatic control (item) are reset.

Calibration and control measurement for ISE test

1) Set calibrators.

Dispense the calibrators in the containers defined in the [CTT Setting] window accessed via [Setup] > [ISE Parameter Settings] > [CTT Set], and set the containers in the positions C-11 to C-14 defined in the [CTT Setting] window. For serum, set "Serum H-STD" and "Serum L-STD," and for urine, set "Urine H-STD" and "Urine L-STD." The measurement begins with "Serum" and "H-STD."

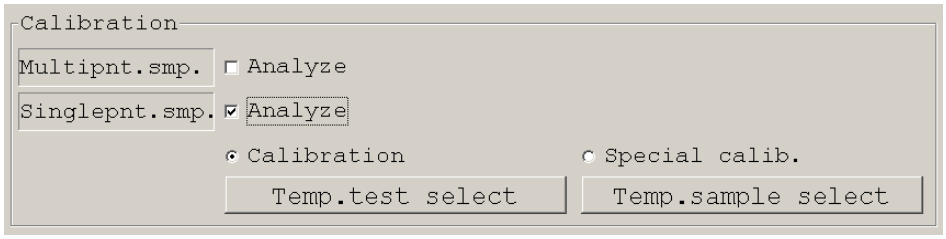
The default values are: C-11 to C-14. To change the position on the refrigerated sample tray (CTT), select [ISE Parameter Settings] > [CTT Setting] window.

2) Select the sample type and refrigerated sample tray (CTT) position.

For the sample type in the [ISE Parameter Settings] window, select "Serum/Urine" for [Serum/Urine] under [Calibration] in the [Electrolyte set] column. To select the CTT positions, open [QC] > [Sample Select], and click [C-11] to [C-14] buttons.

3) Select the type of calibration.

Click the [START] button in the Operation Panel to display the [Start Conditions] window. Select "Analyze" for [Singlepnt.smp] in the [Calibration] column.



Select either [Calibration] or [Special calib.].

These options are not displayed here if "Analyze" was not selected in Step 1.

4) Start calibration.

Click the [Start] button in the [Start Conditions] window. Measurement of ISE calibrators begins first. The measurement is repeated 3 - 8 times until the difference in the calibration value (the sample potential minus the buffer potential) between the current value and the previous value falls within the allowance.

When calibration of the ISE test is achieved, the calibration for chemistry measurement begins. The ISE calibration values are displayed in the [ISE Monitor] window for comparison with the previous values.

The calibration for the ISE test can also be performed independently from the [ISE Operation] window.

Measurement of control samples

1) Define the control samples in the [QC Sample Definition] window

Select [QC] > [QC Sample Definition] to define the control samples. (See Section 2.2.6.)

2) Set the control samples.

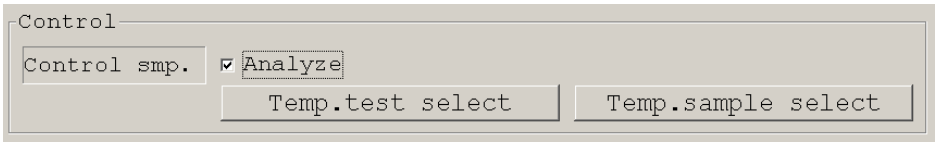
Dispense the control samples in the respective containers specified in the [QC Sample Definition] window, and set the containers in the refrigerated sample tray (CTT) positions specified in the same window.

3) Select the control samples in the [Sample Select] window.

Select [QC] > [Sample Select] to select the control samples defined in Step 1.

4) Click the [START] button in the Operation Panel.

The [Start Conditions] window is displayed.



5) Select “Analyze” for [Control smp.].

6) Click the [Start] button in the [Start Conditions] window.

If you do not intend to perform the control measurement, do not select “Analyze” for [Control smp.].

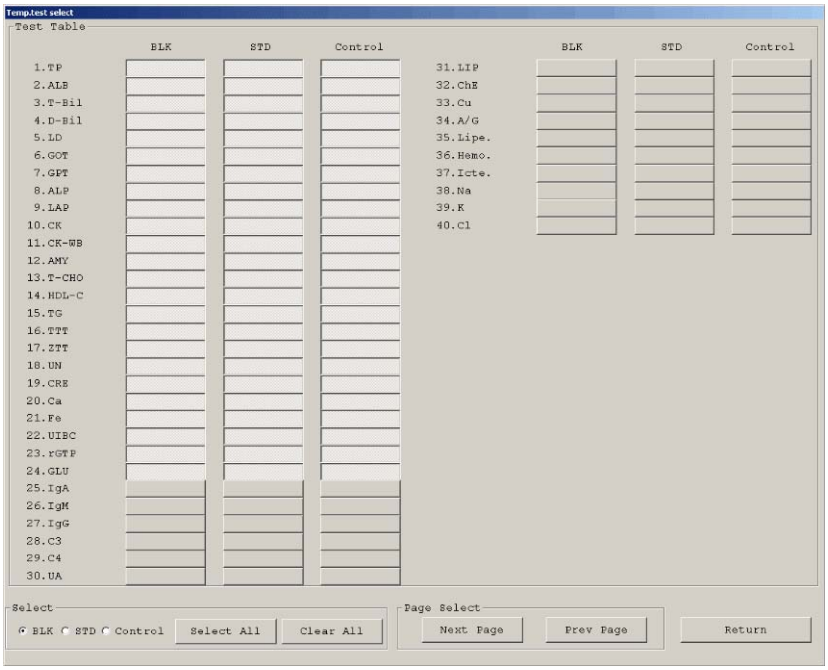
Changing tests for calibration and control measurement

You can temporarily change the test selection and sample selection respectively in the [Temp.test select] and [Temp.sample select] windows accessed via the [Start Conditions] window. Since this is only a temporary change, the original settings of [Test Select] and [Sample Select] remain the same.

This function is useful when you want to temporarily change the test or sample selection to perform another calibration and control measurement because the result of the calibration or control measurement was not valid.

[Temp.test select] window

Select [Start Conditions] > [Temp.test select] to open the [Temp.test select] window shown below.



Select tests for either [Calibration] or [Special calib.] depending on your selection in the [Start Conditions] window. Note that the changes made in this window are temporary.

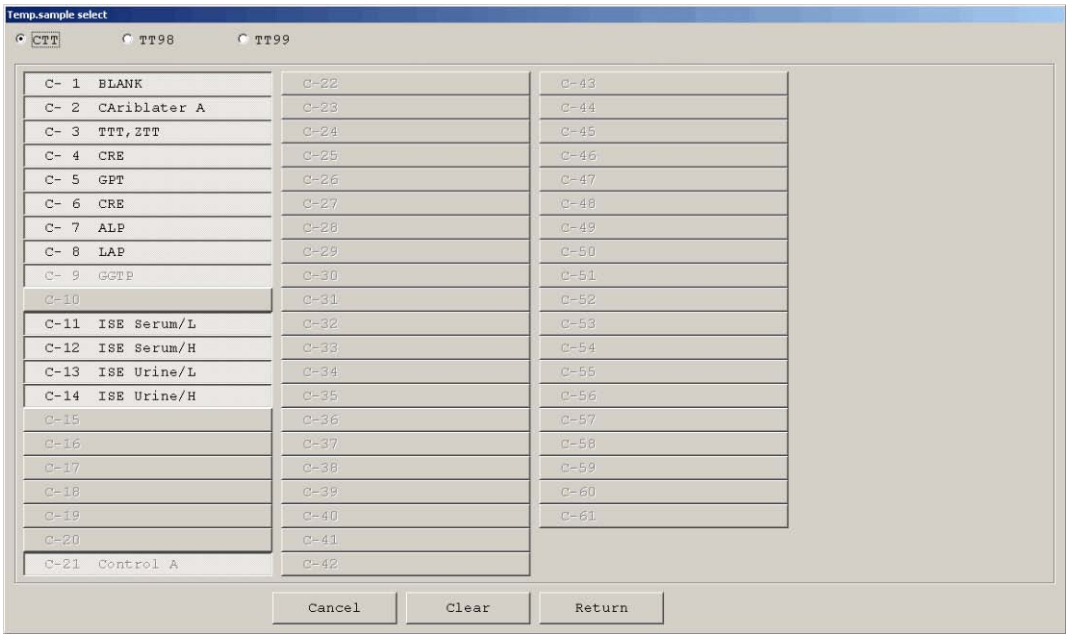
[Test Table] Select tests respectively for [BLK], [STD] and [Control] in this table.

[Select] In this column, select either [BLK], [STD], or [Control], and click the [Select All] button to chose all the tests selected above. Or, click [Clear All] to clear them all.

[Temp.sample select] window

Click the [Temp.sample select] button in the [Start Conditions] window to open the [Temp.sample select] window shown below. (If you have selected the [Temp.sample

select] button in the [Control] column in the [Start Conditions] window, the “TT98” and “TT99” options in the figure below are not shown.)



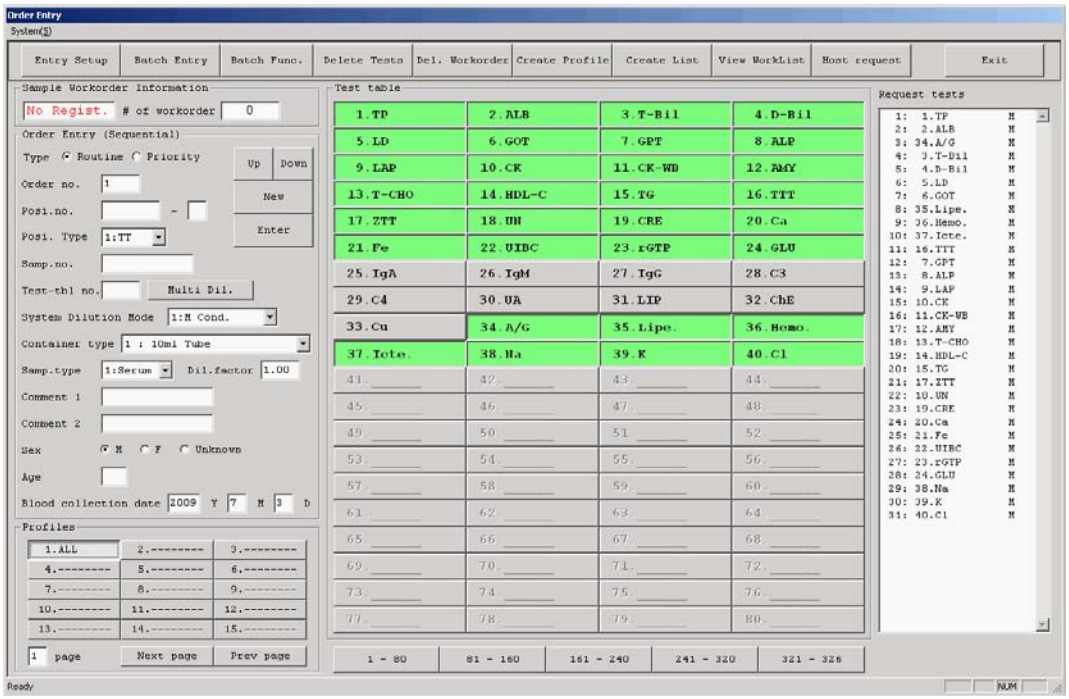
Change the samples selected in the [Sample Select] window temporarily here. The changes can be made respectively for [CTT], [STT98], and [STT99].

[Cancel] button	Click this button to cancel the temporary sample selection and return to the [Start Conditions] window.
[Clear] button	Click this button to clear all the selected items.

4.4.2 Patient sample measurement

1) Select [Request] > [Order Entry] to display the [Order Entry] window. Define tests for each sample here.

Tests to be performed on a sample are designated with the “Sequence numbers” and “Test name” defined in the [Process Sequence] window. If any one of the ions “Na,” “K,” and Cl” is designated, The ISE test is performed for all three ions. However, the result will be reported only for the ordered ion.



Measuring samples with no barcode label

Defining the sample individually by position numbers (sample tray (STT) and cup position numbers)

1. Click the [New] button in the [Order Entry (Sequential)] column on the left side of the [Order Entry] window.
2. For [Posi.no], enter the STT number in the first field and the cup position number in the second field.

   The analyzer has only one sample tray (STT), but more than 84 samples can be efficiently defined at one time by using virtual STTs in this manner. The STTs numbered 2 and upwards are those virtual trays. In actual operation, the measured samples are removed and new samples are added manually.

3. Select tests to perform on the sample in the [Test table].
4. From the drop-down menu of [System Dilution Mode], select one of the options explained below. You can set the mode for each test.

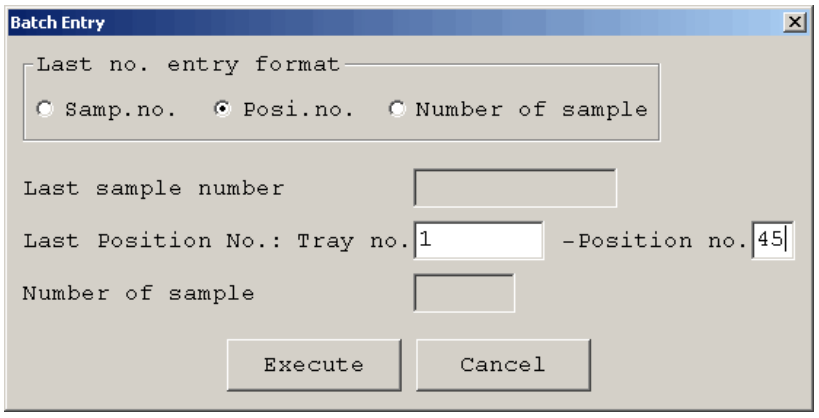
[M Cond]	The system measures the sample using the sample dilution condition specified in [Analytical conditions] in the [Analytical Parameters (Chemistry)] window.
[D1-D4 Cond.]	The system measures the sample using the sample dilution condition for rerun specified in the [Rerun Conditions Set] in the [Analytical Parameters (Chemistry)] window.

5. For [Container type], select the type of the container to be used for the sample.
6. For [Samp.type], select "1:Serum" for the serum measurement or "2:Urine" for the urine measurement.
7. For [Dil.factor], enter the dilution factor when using a diluted sample.
8. For [Comment], [Sex], [Age] and [Blood collection date], enter information as necessary.
9. Click the [Enter] button.

Defining a same measurement condition simultaneously for multiple samples by position numbers (the sample tray (STT) and cup position numbers)

Follow the same steps up to Step 8 described above (before clicking the [Enter] button).

9. Instead of clicking the [Enter] button, click the [Batch Entry] button on the command bar at the upper side of the [Order Entry] window. The [Batch Entry] window opens.



10. For [Last no. entry format], select "Posi. no."
11. For [Last position number], enter the last STT position number.

    Enter the tray number in the first field and the position number in the second field.

    When two or more STT numbers are used, the samples are automatically defined up to the position 84, and then the remaining samples are defined from the position 1 of the next STT number.
12. Click the [Execute] button.

✔ Measuring samples with barcode

Defining the samples individually by entering sample ID manually

1. Click the [New] button.
2. Enter the number on the barcode label manually in the [Samp.no.] field. The barcode number should comprise up to 13 alphanumeric characters (A-Z, a-z, and 0-9).
3. Click the tests to perform in the [Test table] column in the central part of the window.
4. From the drop-down menu of [System Dilution Mode], select one of the options explained below. You can set a mode for each test.

[M Cond] The system measures the sample using the sample dilution condition specified in [Analytical conditions] in the [Analytical Parameters (Chemistry)] window.

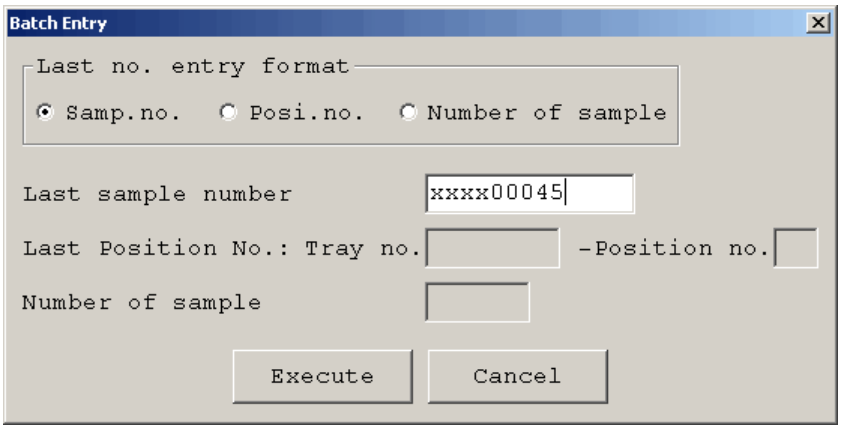
[D1-D4 Cond.] The system measures the sample using the sample dilution condition specified in the [Rerun Conditions Set] in the [Analytical Parameters (Chemistry)] window.

5. For [Container type], select the type of the container to be used for the sample.
6. For [Samp.type], select “1: Serum” for the serum measurement or “2: Urine” for the urine measurement.
7. For [Dil.factor], enter the dilution factor when using a diluted sample.
8. Fill in the [Comment], [Sex], [Age] and [Blood collection date] fields as required.
9. Click the [Enter] button.

Defining a same measurement condition simultaneously for multiple samples using sample ID

Follow the same steps up to Step 8 described above (before clicking the [Enter] button).

9. Instead of clicking the [Enter] button, click the [Batch Entry] button on the top bar in the [Order Entry] window. The [Batch Entry] window opens.



10. For [Last no. entry format], select “Samp.no.”
11. For [Last sample number], enter the last sample number.

The same test is registered for the successively numbered samples from the number you entered in the [Order Entry] window up to this number.

12. Click the [Execute] button.

2) Dispense the sample in the container and set on the sample tray.

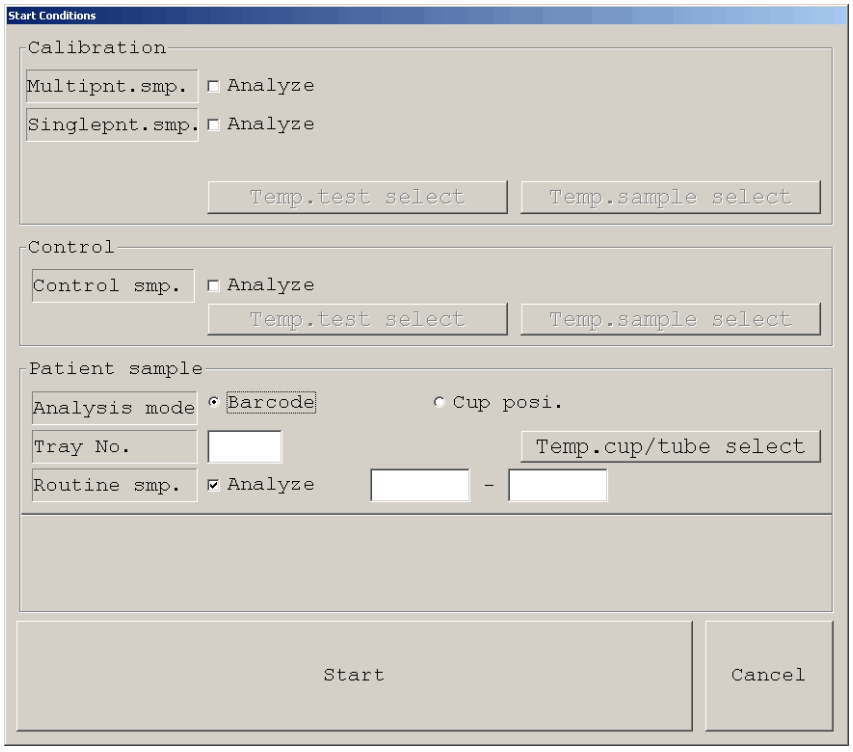
When you set a sample in a container, confirm no air is trapped in the container, especially near the bottom. If any air bubbles are formed when dispensing the serum in the sample container, be sure to remove them. Otherwise, the air bubbles will be aspirated to cause an abnormally low measurement value.

3) Select [Request] > [Test Select]. Select "Routine/Priority/STAT samp.meas." in the [Test select] column, and confirm that the target tests are shown selected in the [Test table] column.

Here you can deselect tests as required. However, this deselection is applied to all the samples.

4) Start measurement.

Click the [START] button in the Operation Panel. The [Start Conditions] window opens.



1. In the [Patient sample] column, select "Barcode" or "Cup posi." for [Analyze mode].

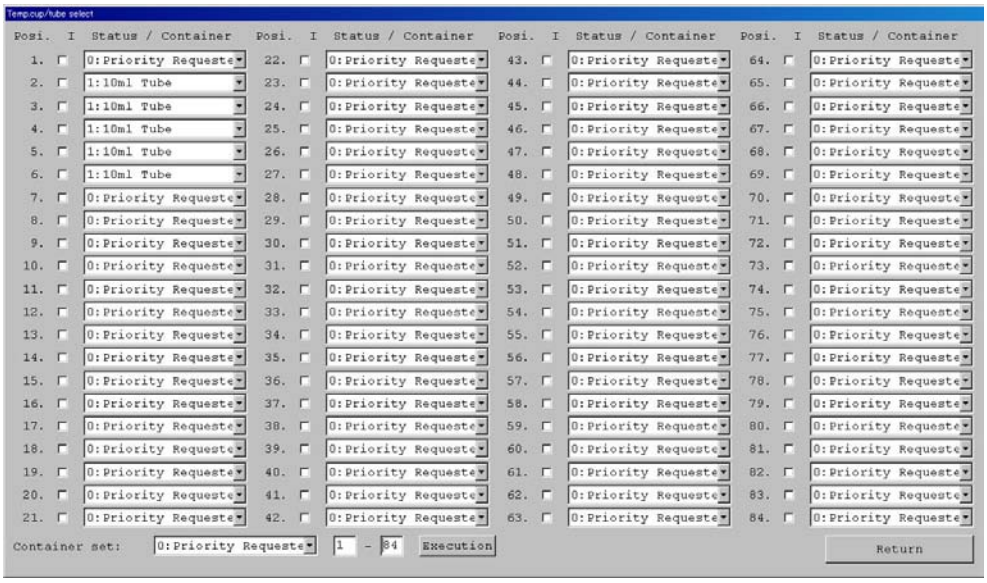
Select "Barcode" when the sample containers have barcode labels and you select to use them.

Select "Cup posi." when you use the sample tray (STT) and cup position numbers.

If you have chosen "Cup posi", enter the number in [Tray No.].

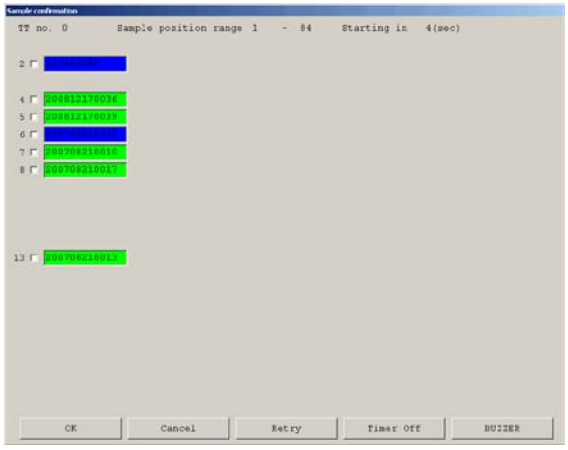
Skip this step if you have chosen [Barcode].

2. Check “Analyze” for [Routine smp.] in the [Patient sample] column. In the fields next to it, enter the STT position numbers used for measurement to define the range.
3. Enter the STT number in the first field and the cup position number in the second field. Skip this step if you have chosen [Barcode].
4. Click the [Temp.cup/tube select] button. The [Temp.cup/tube select] window opens.



If you use a type of the sample container that is different from the one already specified in the [Order Entry] window, you can change the value for each position by selecting a container type from the drop-down menu under the [Status/Container] header. Also, if you want to measure specific samples sooner than others samples, check the box under the “I” header for those specific samples. To return to the [Start Conditions] window, click the [Return] button. Note that the [Execution] button is used when you have made a change in the [Container set] setting to the left of the button.

5. Click the [Start] button in the [Start Conditions] window. If you have selected “Barcode,” the analyzer reads the barcode labels and then the [Sample Confirmation] window is displayed on the workstation monitor.



In the [Sample Confirmation] window, confirm that the correct barcode number is shown for each cup position on the STT. If the correct barcode number is not shown, you can manually enter the correct number in this window.

If the analyzer cannot read some of the barcodes of the samples for which tests have been registered in the [Order Entry] window (due to stains, etc.), you can re-register them by manually entering the barcode numbers in the fields that correspond to the container positions.

Here, you can also specify the priority of the samples to be measured by checking the corresponding boxes.

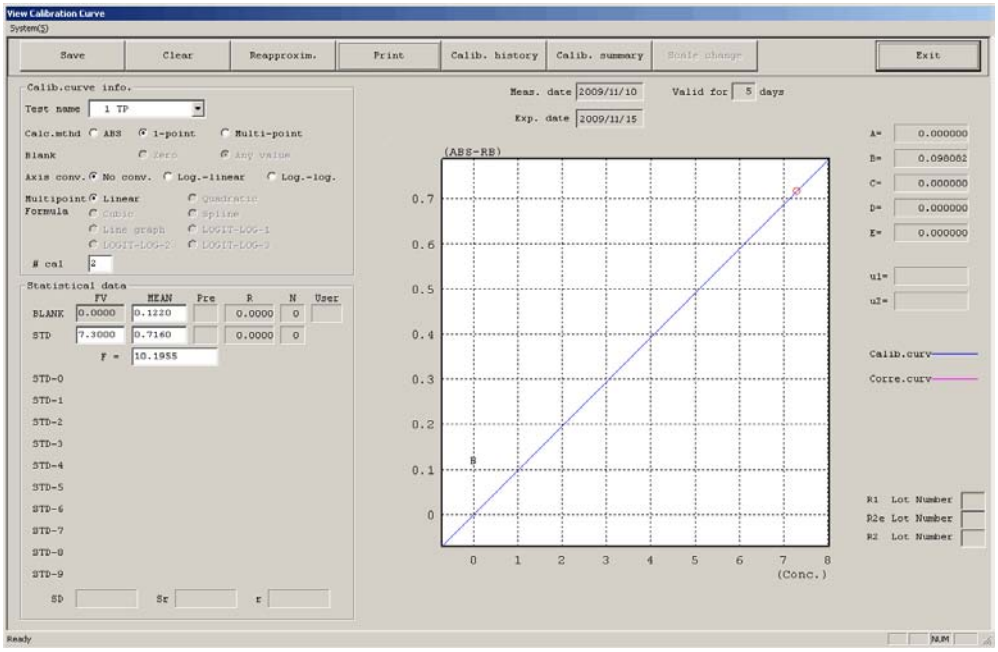
4.5 Checking the Calibration Results

Select [Calib.] > [View Calibration Curve] to view the calibration results in the [View Calibration Curve] window.

1) Display the calibration result of the test to check.

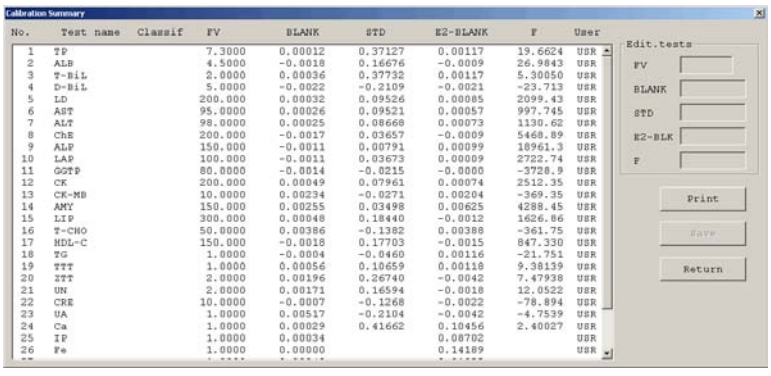
Select [Calib.] > [View Calibration Curve], and select the test from the [Test name] drop-down menu.

The calibration result is displayed for the selected test.



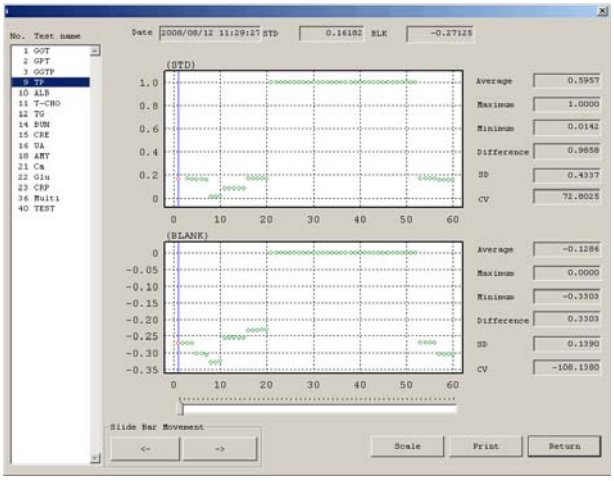
2) View the calibration summary with the detailed information.

Click the [Calib. Summary] button in the [View Calibration Curve] window. The [Calibration Summary] window opens as below.



3) View the calibration history.

Click the [Calibration History] button in the [View Calibration Curve] window. The [Calibration History] window opens. The calibration results of the past 60 calibrations can be checked here.



4) Perform calibration again if necessary.

If one or more tests show invalid calibration results, perform calibration again after eliminating the possible cause. Use the [Temp.test select] and [Temp.sample select] windows accessed from the [Start Conditions] window to select the test to be measured again.

4.6 Checking the Control Sample Measurement Results

Types of quality control (QC)

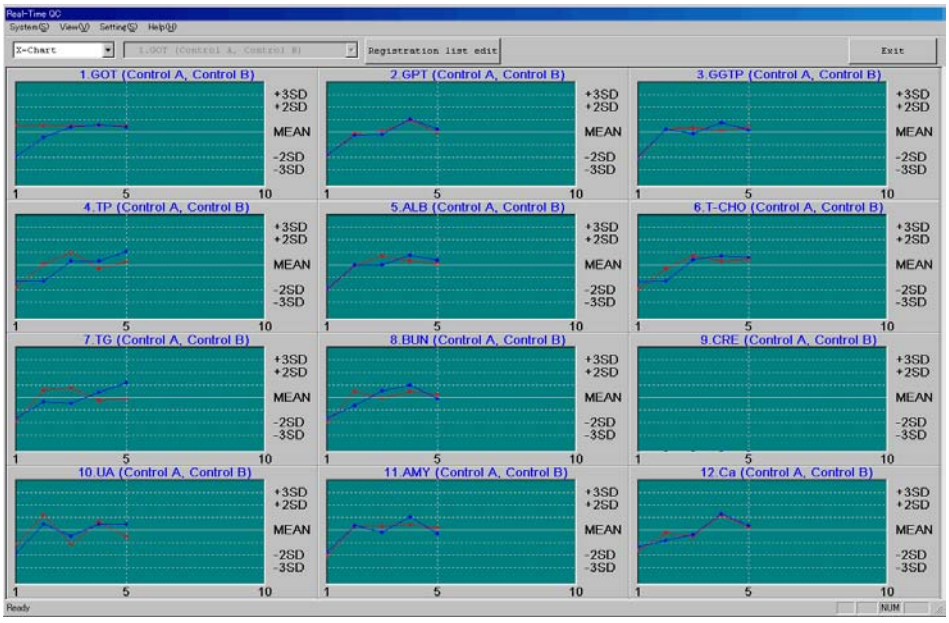
Three types of QC are available as follows.

Real-Time QC	Features a twin-plot chart using the data from the control samples collected from the start of the system by the [New Start] mode. It is used to check the precision of the current measurement data.
Daily Precision Control	Uses X-charts representing all the measurement data from the control samples completed in one day. The purpose is to review the quality of the current day's measurement.
QC Cumulative	Features X-R charts of the data from control sample measurements collected daily. It is used to compare precision amongst plural measurement days.

[Real-Time QC] window

1) Select [QC] > [Real-Time QC].

The window below is displayed.



The measurement data from two control samples are displayed in line plot respectively for the selected tests.

2) Check the range of the result values.

The chart display scale of each test is determined on the basis of the mean and standard deviation (SD) values for [Daily QC] in the [Control Data Registration] window accessed via the [QC] window. Check the range of the control measurement values so far in the day in relation to the Daily QC values.

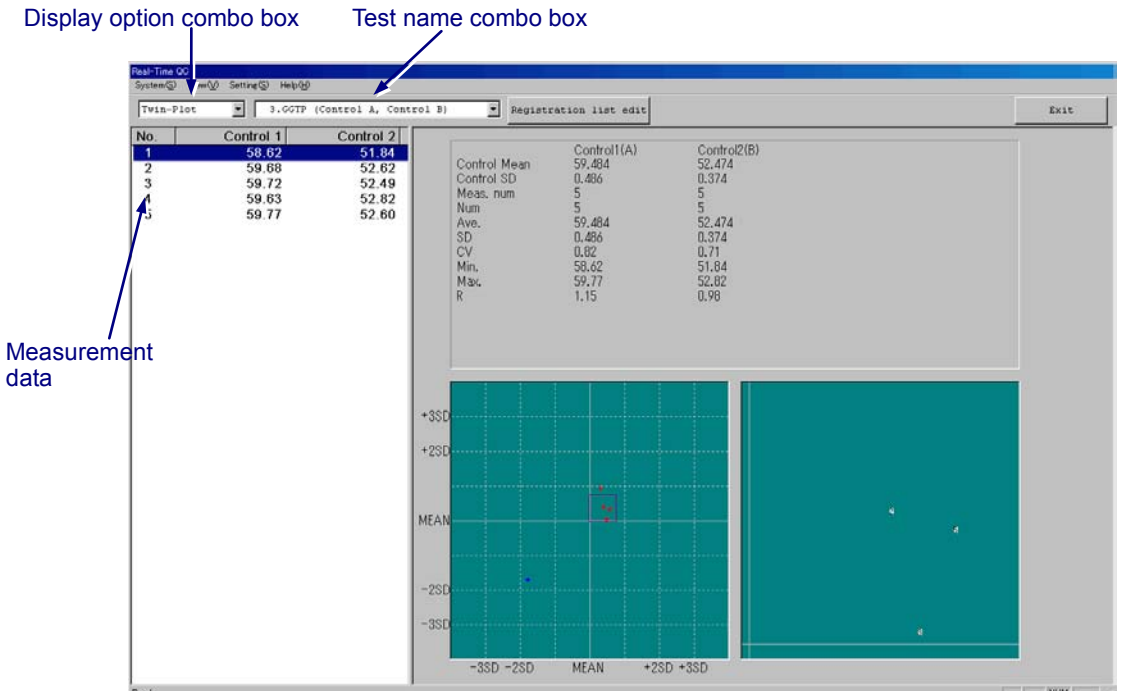
Also, when the results of control sample measurement fall within the following conditions, flags are displayed with the results.

- 2SD ≤ | (Result) − [Mean Value (X)] | ≤ 3SD. When the result value falls within this range, the flag "l" or "h" is posted with the value in the report.
- 3SD < | (Result) − [Mean Value (X)] |. When the result value falls within this range, the flag "L" or "H" is posted with the value in the report.

A posted flag indicates that the value is largely deviated in relation to the "Daily QC" values.

3) [Twin-Plot] display

Select "Twin-Plot" from the [View] drop-down menu on the top command bar in the [Real-Time QC] window. You can also select it in the display option drop-down menu on the upper-left side of the window.

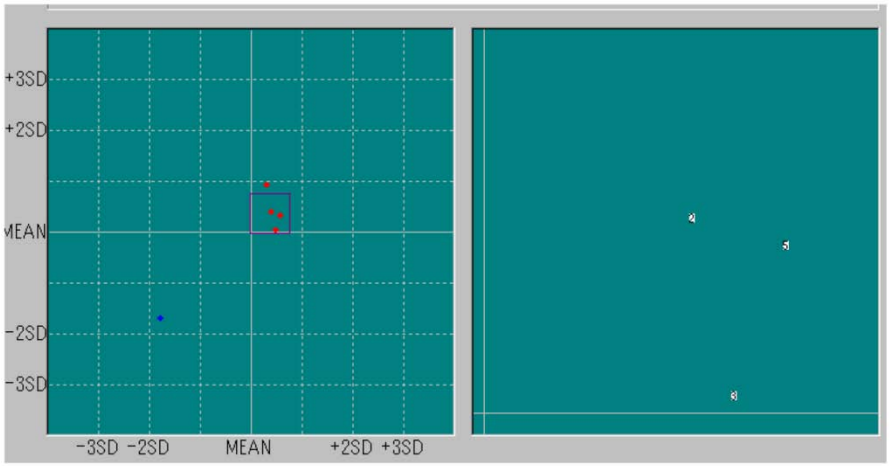


The twin plot chart representing the measurement values of the two selected control samples is displayed. To see the chart for another test, select that test in the second left drop-down menu under the top bar.

4) Check the range of the result values in the [Twin-Plot] display.

The values of the samples highlighted in the list on the left side of the window are plotted as blue dot in the graph on the left. The graph on the right shows the enlarged view of the area in the red frame.

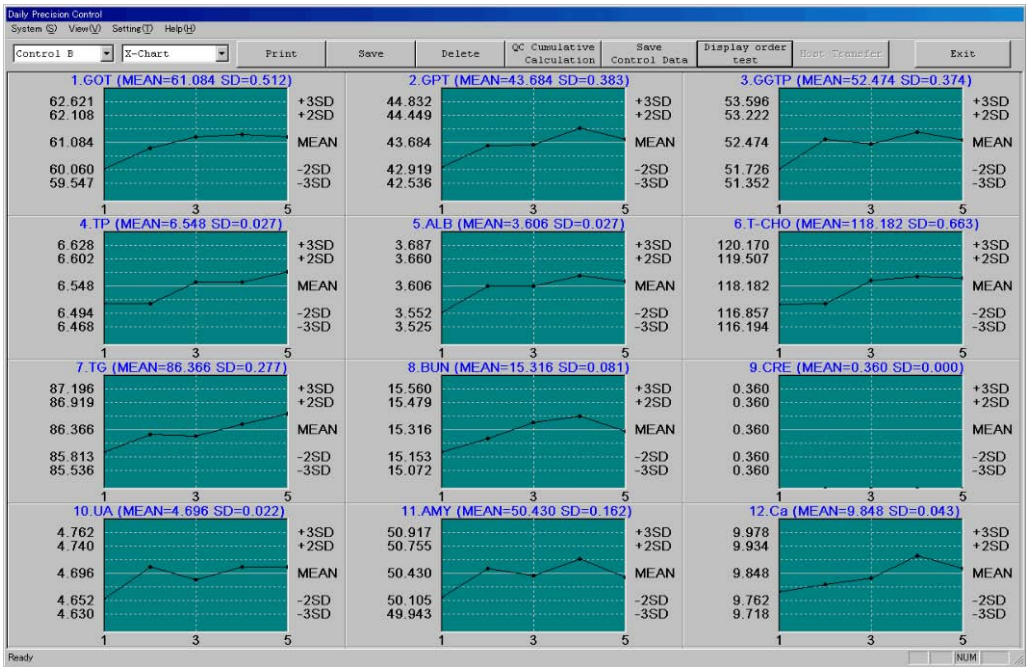
You can move the red frame on the left graph by clicking anywhere on the graph with a mouse. The new red-framed area is now shown magnified on the right graph.



Daily precision control ([Daily Precision Control] window)

1) Select [QC] > [Daily Precision Control].

The window below is displayed.



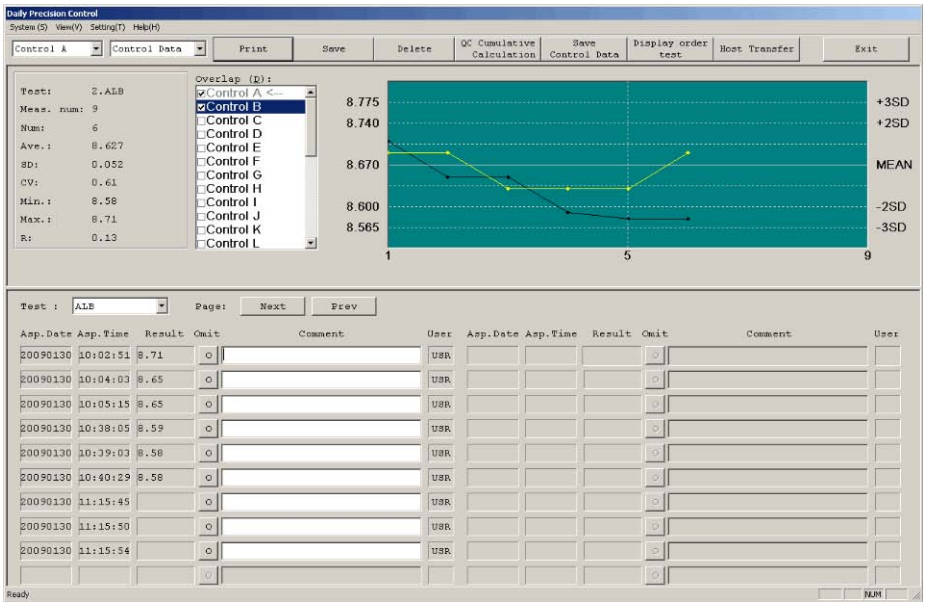
The results from the measurements of the control samples from the time the system started with [New Start] from the “BioMajesty” start-up window are shown in chronological order of measurement. The graphs are displayed by control sample and by test. The display scale for each test depends on the [Daily QC] values set in the [Control Data Registration] window.

2) Check the range of the result values.

Check the range of the control measurement values in comparison with that of the [Daily QC] values for each test. When the range is within ±2SD, the background of the chart is shown in green. When the range is greater than ±2SD, the background of the chart is shown in reddish brown.

3) Display the control sample data.

Select “Control Data” from the [View] drop-down menu on the top command tool of the [Daily Precision Control] window. You can also select it in the display option drop-down menu on the upper-left side of the window.



The control sample number, measurement values, statistical data and line-plot (X-chart) for the selected test are displayed by control sample. The test can be selected in the [Test] drop-down menu.

Up to 200 control samples can be displayed in the [Daily Precision Control] window. When more than 200 samples have been measured, only the most recent 200 samples are displayed in the reverse chronological order and the control sample number moves forward. The statistical processing takes into account only these 200 samples. The data from the samples preceding these 200 samples are deleted and cannot be retrieved.

4) Check the data.

After selecting a control sample, select a test in the [Test] drop-down menu located in the mid-level of the window. The measurement data of the control sample for the selected test are displayed.

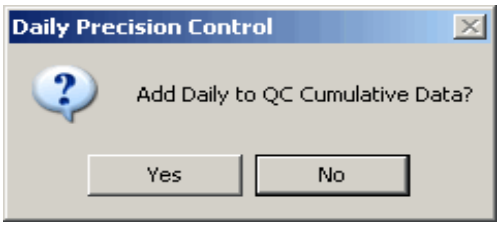
5) Exclude an arbitrary measurement value from statistical processing.

Click the [Omit] button to the right of the relevant measurement value shown in the lower half section in the [Daily Precision Control] window.

The measurement value is deleted. When a measurement value is excluded from statistical processing by clicking the [Omit] button, the comment field to the right is activated. You may enter the reason for exclusion.

Be sure to click [Save] after deleting a value.

The window below is displayed after the [Save] button is clicked.



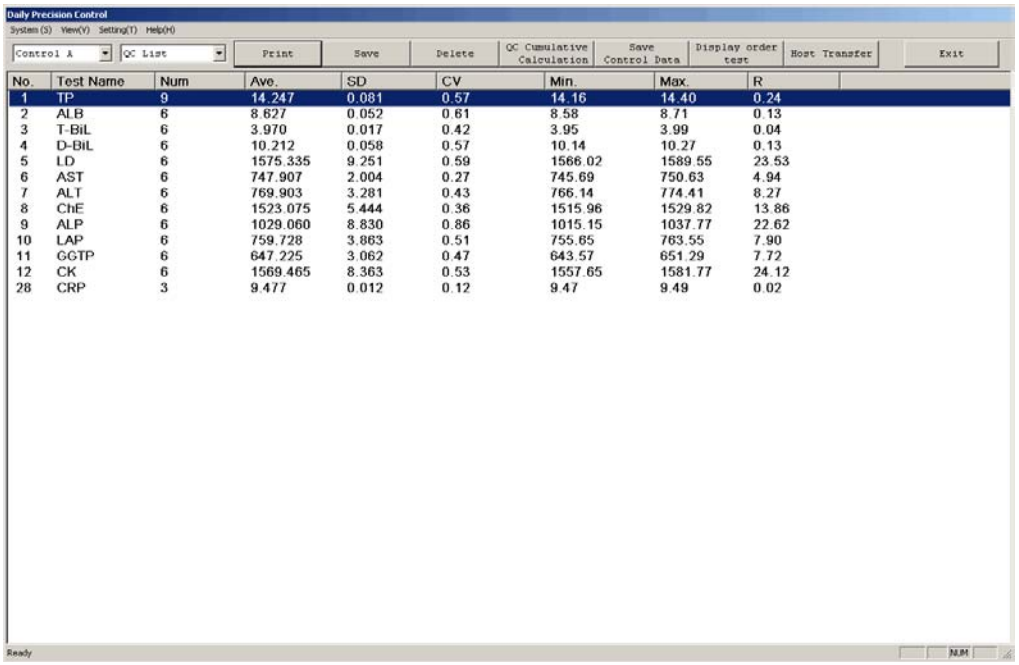
Click [Yes] to save the deletion of the value. The measurement value is excluded from the statistical processing to obtain the cumulative QC value.
Do not click [Save] if you do not want to exclude the measurement value from the processing.

The [Print], [Save], [Delete], [Save Control Data] and [Display order test] buttons are only effective for the type of control sample that is currently displayed. One button click does not affect all the sample types simultaneously.

Once the measurement value is deleted, it is deleted even when the [Save] button is not clicked. However, when the [QC Cumulative Calculation] button is clicked to calculate the cumulative QC value, the deleted value is retained.

6) Display the QC value list.

Select “QC list” from the [View] drop-down menu on the top command tool of the [Daily Precision Control] window. You can also select it in the display option drop-down menu on the upper-left side of the window. The following QC list is displayed.



No.	Test Name	Num	Ave.	SD	CV	Min.	Max.	R
1	TP	9	14.247	0.081	0.57	14.16	14.40	0.24
2	ALB	6	8.627	0.052	0.61	8.58	8.71	0.13
3	T-BiL	6	3.970	0.017	0.42	3.95	3.99	0.04
4	D-BiL	6	10.212	0.058	0.57	10.14	10.27	0.13
5	LD	6	1575.335	9.251	0.59	1566.02	1589.55	23.53
6	AST	6	747.907	2.004	0.27	745.69	750.63	4.94
7	ALT	6	769.903	3.281	0.43	766.14	774.41	8.27
8	ChE	6	1523.075	5.444	0.36	1515.96	1529.82	13.86
9	ALP	6	1029.060	8.830	0.86	1015.15	1037.77	22.62
10	LAP	6	759.728	3.863	0.51	755.65	763.55	7.90
11	GGTP	6	647.225	3.062	0.47	643.57	651.29	7.72
12	CK	6	1569.465	8.363	0.53	1557.65	1581.77	24.12
28	CRP	3	9.477	0.012	0.12	9.47	9.49	0.02

The statistical results are displayed by test for each control sample type.

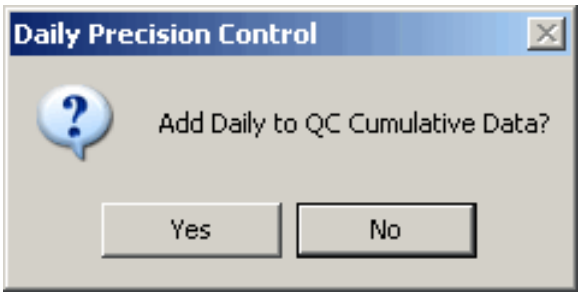
7) Check the data.

Follow Step 5 above if exclusion of some data is required.

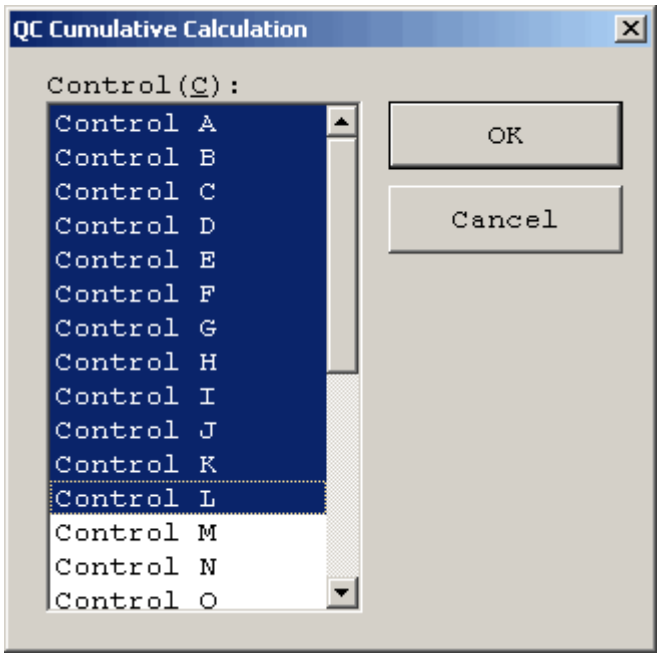
8) Register the data for cumulative QC calculation.

Click the [QC Cumulative Calculation] button.

The window below is displayed.



Click the [Yes] button to display the [QC Cumulative Calculation] window.

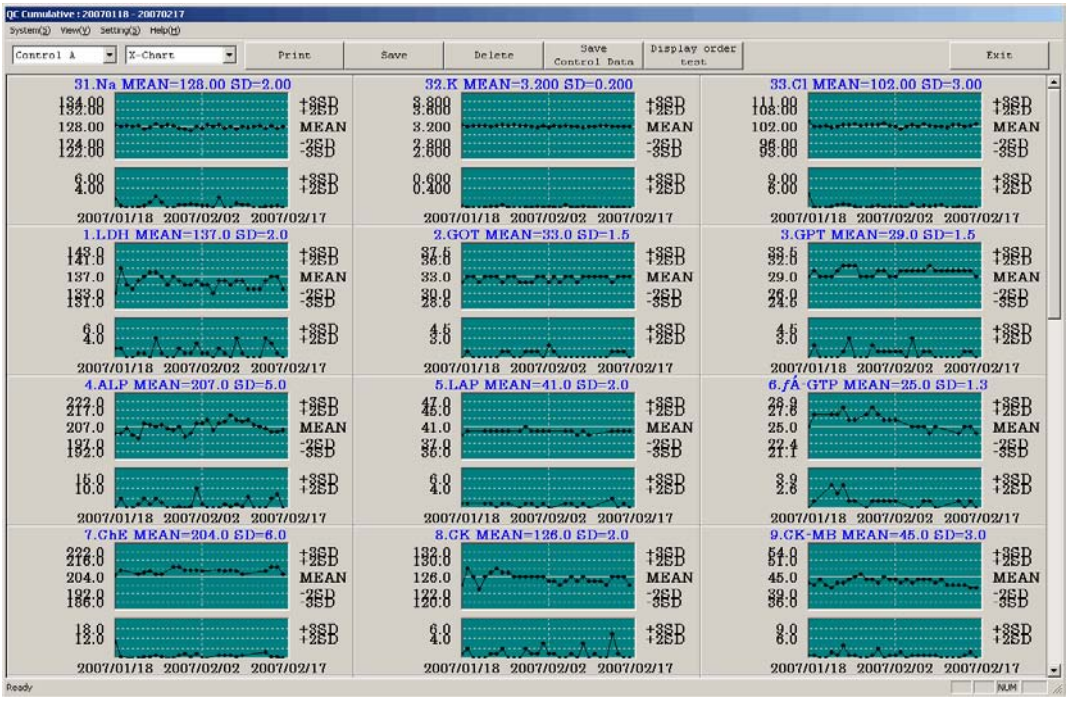


Click and highlight the control sample types to use and click [OK]. The mean value and range are registered as of the current system date to be used for cumulative QC calculation.

Quality control of the measurement data over multiple dates

1) Select [QC] > [QC Cumulative].

The window below is displayed.



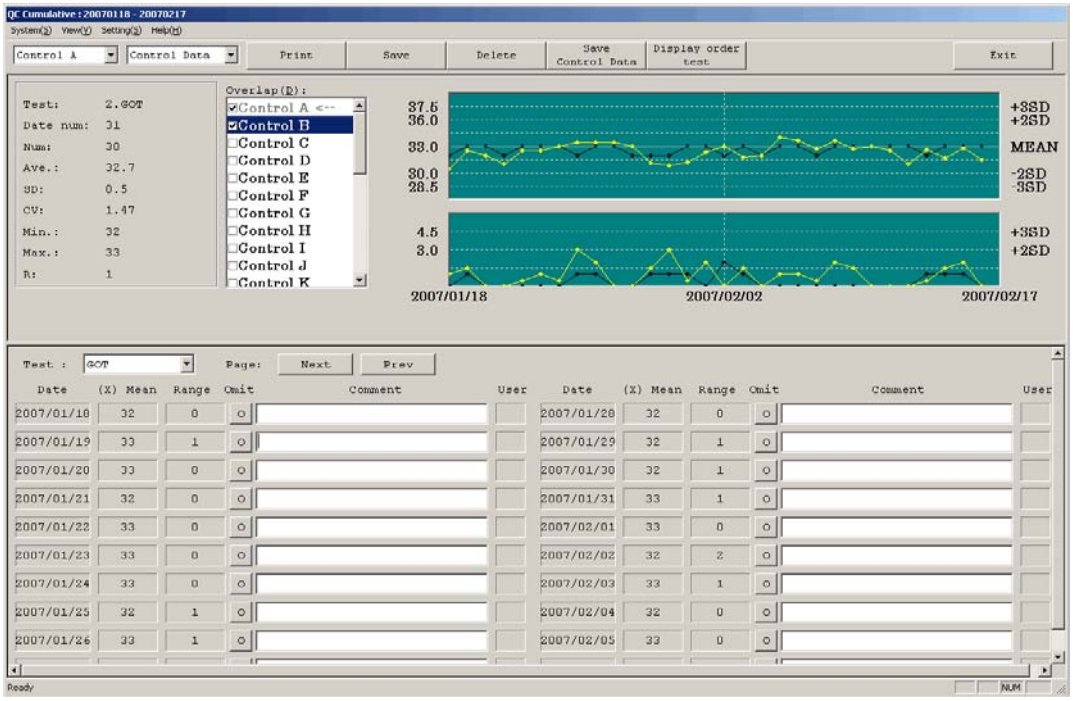
The data collection period is displayed on the left side in the blue upper border of the window. The default period is the last one month. The X-R charts represent the average and range of the daily control sample measurement values during this period. The graphs are displayed by control sample type and by test. Each graph is displayed in the scale defined in the [QC Cumulative] column in the [QC] > [Control Data Registration] window.

2) Check the range of the result values.

Check the range of the control values in comparison with the [Daily QC] values for each test. When the range is within ±2SD, the background of the chart is shown in white. When the range is out of this range, it is shown in green.

3) Display the control sample data.

Select “Control Data” from the [View] drop-down menu on the top command tool of the [QC Cumulative] window. You can also select it in the display option drop-down menu on the upper-left side of the window. The data is now displayed as below.



The date, mean value, value range, and other statistical results of the selected test are displayed in an X-R chart for the selected control sample type.

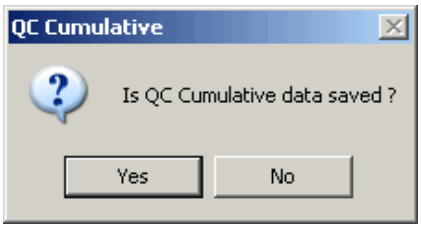
4) Check the data.

Select a test in the [Test] drop-down menu located in the mid-level of the window. The cumulative QC values for the selected test are displayed.

5) Exclude the cumulative QC value of an arbitrary date from the statistical processing.

Click the [Omit] button to the right of the relevant cumulative QC value in the data display section in the lower part of the window to delete the value. When a measurement value is excluded from statistical processing by clicking the [Omit] button, the comment field on the right side is activated. You may enter the reason for exclusion, for example.

Be sure to click [Save] after deleting a value. The value is excluded from the statistical processing to obtain the QC values. The window below is displayed after the [Save] button is clicked.



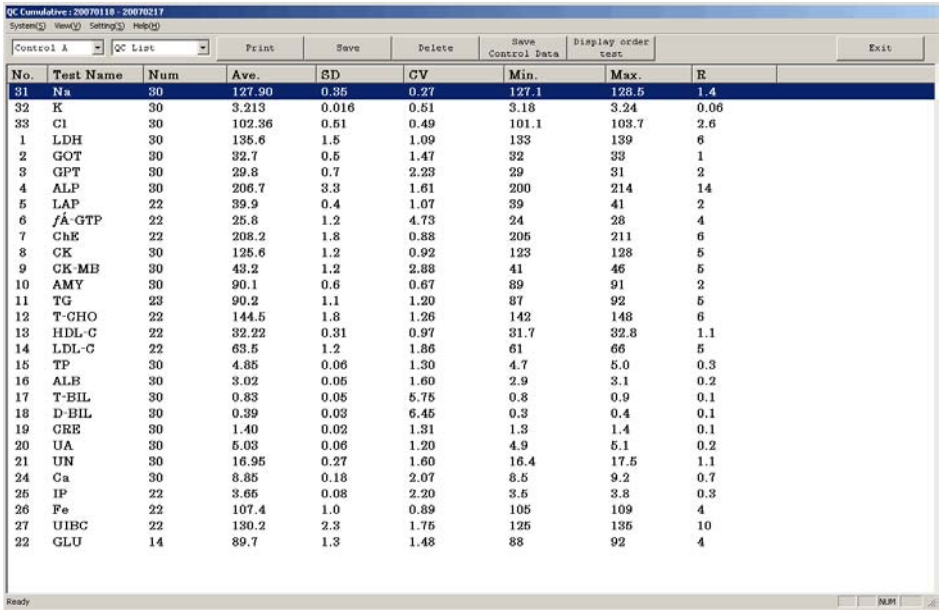
Click [Yes] to save the deletion of the value. The relevant value is excluded from the statistical processing to obtain the cumulative QC value.

Do not click [Save] if you do not exclude the measurement value from the processing.

The [Print], [Save], [Delete], [Save Control Data] and [Display order test] buttons are only effective for the type of control sample that is currently displayed. One button click does not affect all the sample types simultaneously.

6) Display the QC value list.

Select “QC list” from the [View] drop-down menu on the top command tool of the [QC Cumulative window. You can also select it in the display option drop-down menu on the upper-left side of the window. The following QC list is displayed.



No.	Test Name	Num	Ave.	SD	CV	Min.	Max.	R
31	Na	30	127.90	0.35	0.27	127.1	128.5	1.4
32	K	30	3.213	0.016	0.51	3.18	3.24	0.06
33	Cl	30	102.36	0.51	0.49	101.1	103.7	2.6
1	LDH	30	135.6	1.5	1.09	133	139	6
2	GOT	30	32.7	0.5	1.47	32	33	1
3	GPT	30	29.8	0.7	2.23	29	31	2
4	ALP	30	206.7	3.3	1.61	200	214	14
5	LAP	22	39.9	0.4	1.07	39	41	2
6	ƒÁ-GTP	22	25.8	1.2	4.73	24	28	4
7	ChE	22	208.2	1.8	0.88	205	211	6
8	CK	30	125.6	1.2	0.92	123	128	5
9	CK-MB	30	43.2	1.2	2.88	41	46	5
10	AMY	30	90.1	0.6	0.67	89	91	2
11	TG	23	90.2	1.1	1.20	87	92	5
12	T-CHO	22	144.5	1.8	1.26	142	148	6
13	HDL-C	22	32.22	0.31	0.97	31.7	32.8	1.1
14	LDL-C	22	63.5	1.2	1.86	61	66	5
15	TP	30	4.85	0.06	1.30	4.7	5.0	0.3
16	ALB	30	3.02	0.05	1.60	2.9	3.1	0.2
17	T-BIL	30	0.83	0.05	5.75	0.8	0.9	0.1
18	D-BIL	30	0.39	0.03	6.45	0.3	0.4	0.1
19	CRE	30	1.40	0.02	1.31	1.3	1.4	0.1
20	UA	30	5.03	0.06	1.20	4.9	5.1	0.2
21	UN	30	16.95	0.27	1.60	16.4	17.5	1.1
24	Ca	30	8.85	0.18	2.07	8.5	9.2	0.7
25	IP	22	3.65	0.08	2.20	3.5	3.8	0.3
26	Fe	22	107.4	1.0	0.89	105	109	4
27	UIBC	22	130.2	2.3	1.75	125	135	10
22	GLU	14	89.7	1.3	1.48	88	92	4

The cumulative QC values (statistical data of daily QC values) are displayed by test for each control sample type.

7) Check the data.

Follow Step 5 above if some data exclusion is required.

4.7 Urgent Sample Measurement

Two methods are available for urgent sample measurement: “Priority” and “STAT port.” “Priority” is a method by which the relevant sample defined as “Priority” is placed in the sample tray (STT) to be measured sooner than the other samples, while “STAT port” is used instead of STT to set an urgent sample to be measured ahead of other samples. The STAT port can accept only one sample at a time. Either method may be used, depending on the case.

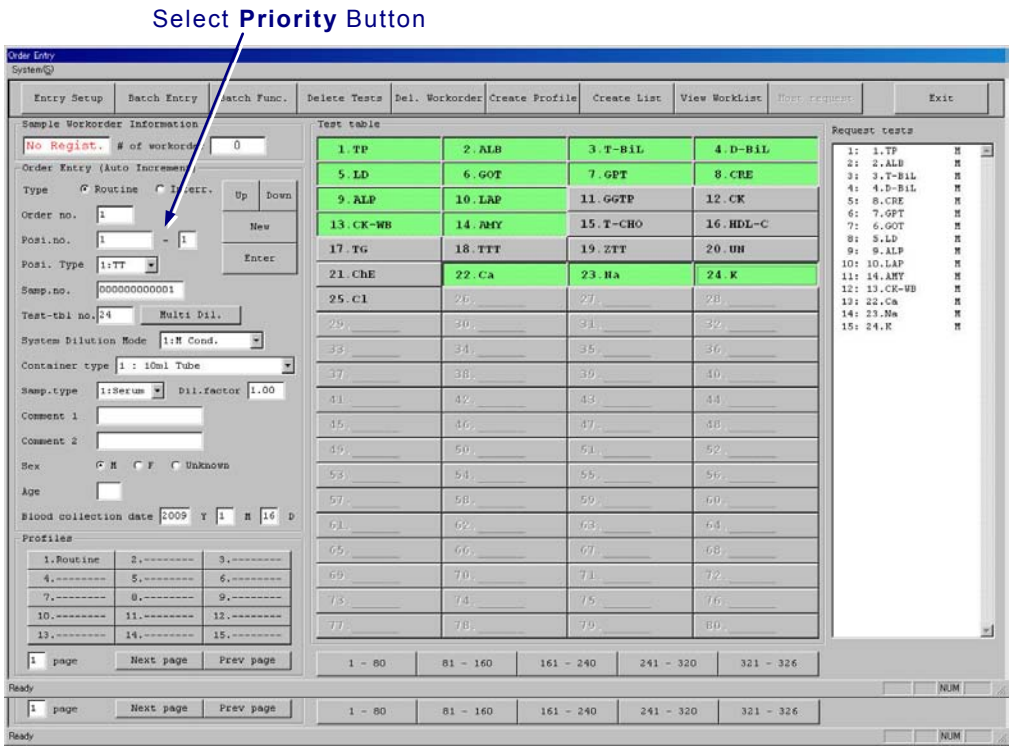
4.7.1 “Priority” measurement

The samples are defined as “priority” in the [Order Entry] window.

The [Temp.cup/tube select] and [Sample Confirmation] windows are also used for defining the “priority” samples.

[Order Entry] window

Select [Request] > [Order Entry]. Select “Priority” for [Type] in the Order Entry (Sequential] column in the left side of the [Order Entry] window when defining tests on the sample. The sample will be measured sooner than the other samples.



[Cup/Tube Assign] window

Select [Request] > [Cup/Tube Assign] to display the window below.

This window is used to define the priority, status and container type for each STT position. Check the box under the [Pri.] header corresponding to the relevant STT number to measure the samples sooner than non-priority samples. Setting in this window has priority over that in the [Order Entry] window.

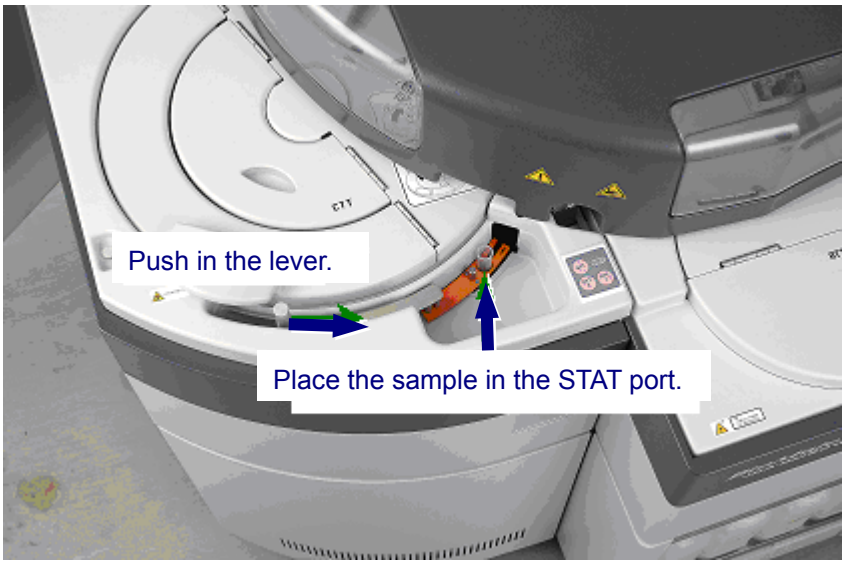
Also, a container type different from the one already specified in the [Order Entry] window can be defined here.

4.7.2 STAT port

Measurement from the STAT port is available when the system mode is [START], [READY], [Processing], or [PAUSE]. Only one sample can be set in the STAT port at a time. After sampling of the current sample is completed, the next sample can be placed in the STAT port.

1) Set the sample

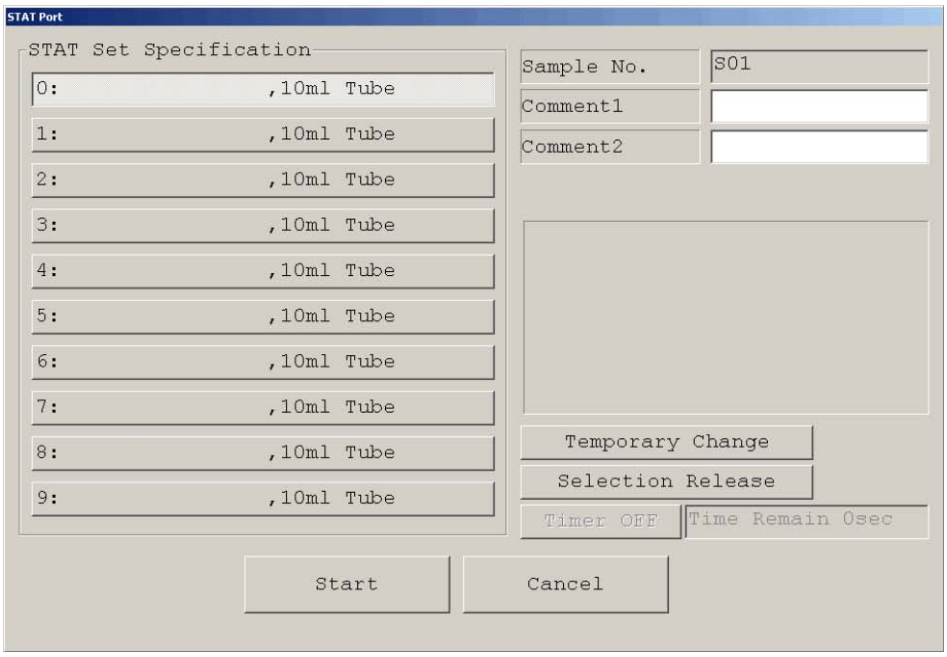
Set a sample in the port and push the lever in when the system mode is either [START], [READY], [Processing], or [PAUSE].



2) Define values in the [STAT port] window

When the sample is pushed in, the [STAT port] window is displayed. However, the window is not displayed in the [WAIT] mode or [Processing] mode, from which the measurement cannot be resumed.

The following [STAT port] setting is not required when the on-line order is received automatically. This automatic setting is defined in the [System Basic Configuration] column in the [System Specifications Set] window accessed from the [Setup] button in the Menu Panel. “Avail.” should be selected respectively for [On-line] and [STAT port barcode] there.



[STAT Set Specification] Select “0” - “9” for the test set to perform. As described above, there is no need to select if the on-line order is received automatically. In this case, when the [STAT Set Specification] button is clicked after the barcode is read, the STAT sample is numbered automatically from S01 and successively up to S100. To define the STAT test set, select [Setup] > [Setting System Parameter]. For [STAT Port Request Reflex Setting], select “0” - “9” to always use the same set or “99” to use the set selected for the previous STAT measurement. See “Section 5.9 [Setting System Parameters] window” in “Chapter 5 Optional Functions” as required.

The test set to use is defined in the [Request] > [STAT Order Setup] window.

[Sample No.] This field displays the sample ID automatically when the sample barcode is read. If the barcode is not readable or if you want to change the sample ID, enter a number manually using the keyboard.

	However, when “N.A.” is selected for [STAT port barcode] in the [System Basic Configuration] column in the [System Specification Settings] window accessed from the [Setup] button in the Menu Panel, the STAT sample will be numbered automatically from S01 successively up to S100. When the number exceeds S100, it returns to S01. In this case, the measurement value previously at S01 is overwritten, and cannot be retrieved. Also, the STAT sample ID will be reset when the analyzer starts in the [New Start] mode.
[Comment1 and 2]	Two fields are available to enter your comments in the [Comment 1] and [Comment 2]. You can define whether to display the comments with result or which comment to display as the [STAT Screen Comment Display Setting] option in the [Setting System Parameters] window.
[Barcode re-reading]	This button is to be displayed under the [Comment2] field. When the barcode reading was unsuccessful, click this button for re-reading. When it fails repeatedly, the barcode may not be readable. Attach a new barcode label on the sample container, or enter the code manually using keyboard.
Status box	In this space under [Comment2], the status of the current STAT port measurement is displayed (e.g. barcode reading error).
[Temporary Change] button	Use this button to change the content of the test set content temporarily. See the following “Section 3) Temporary change of the STAT port measurement setting.”
[Selection Release] button	Use this button to deselect the selected “STAT Set Specification.”
[Timer OFF] button	Use this button to deactivate the timer. The timer will not automatically start when a sample is placed in the STAT port. When “0” is selected for the [STAT Port Request Screen Timer] option in the [Setting System Parameters] window, the timer is defined to be always “off”, therefore, this button is not activated.
[Start] button	Use this button to start the measurement of the sample set in the STAT port.

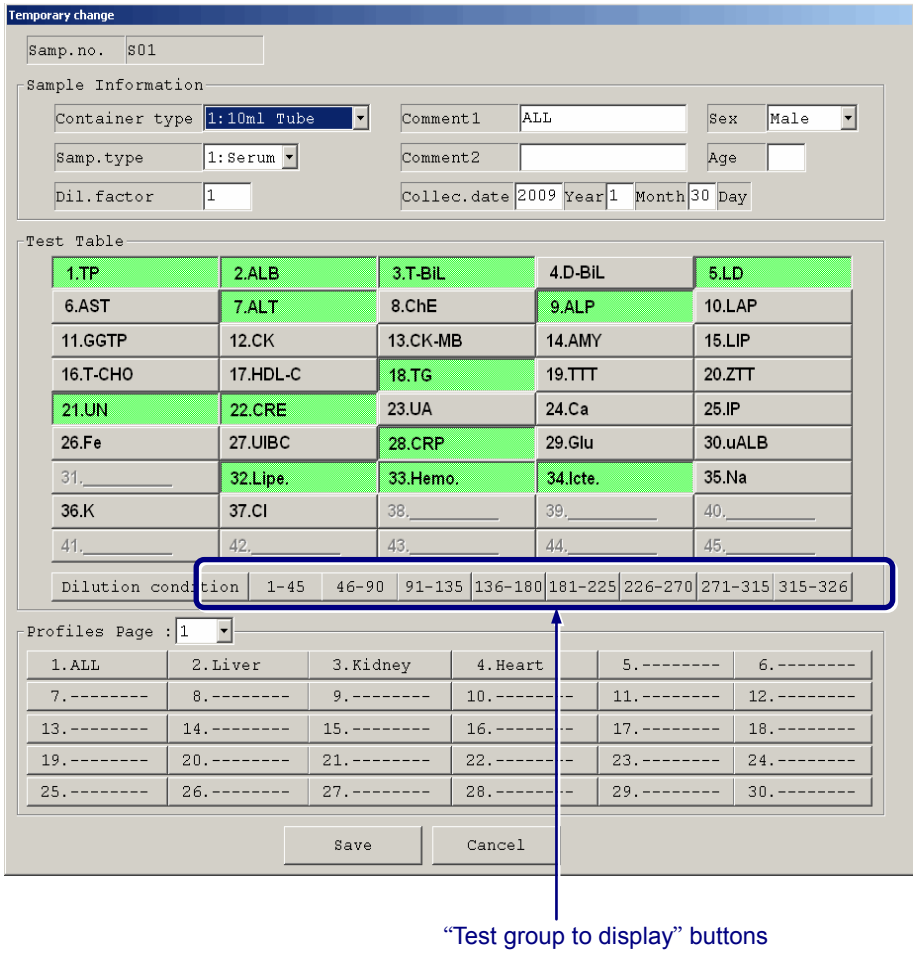
Click when you want to start the measurement before the counter beside the [Timer OFF] button finishes counting the remaining time down to “0”.

[Cancel] button — Measurement from the STAT port is canceled and the window is closed.

3) Temporary change of the STAT port measurement setting.

Display the [Temporary change] window

If you need to change the settings temporarily, click the [Temporary Change] button in the [STAT port] window to display the [Temporary Change] window below. Enter the following values for temporary changes.



[Samp.no.] — This field displays the sample ID.

[Sample Information] column

[Container type] — You can temporarily change the container type.

[Samp. type] — You can temporarily change the sample type.

[Comment] — Enter a comment.

[Sex] — You can temporarily change the gender of the patient.

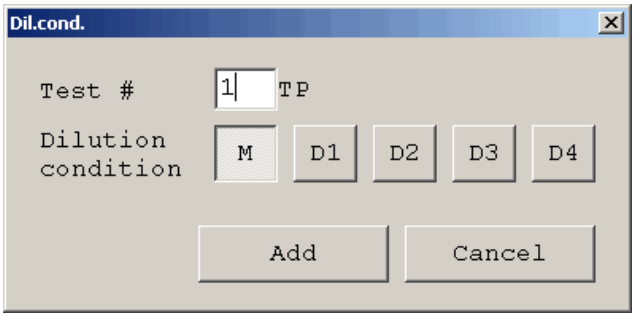
[Age] — Enter the age of the patient.

[Dil.factor] Enter a dilution factor when you use diluted sample. The result values are calculated automatically.

[Collec.date] Enter the sample collection date.

[Test Table] You can temporarily change the test selection.

[Dilution condition] button Click this button to display the window below. You can define the dilution condition by test. Two or more dilution condition can be defined. Click [Add] to add the selected dilution condition. Click [Cancel] to return to the previous window without adding the condition.



"Test group to display" buttons A group of 45 tests can be selected for display by clicking the button indicating the range of numbers.

[Profiles Page] field You can temporarily change the tests defined as a set. Click the buttons to select a set. Up to 150 sets of tests can be registered. The first 30 sets are represented by the buttons respectively. To display the next 30 sets of tests, select "2" in the [Profile Page] drop-down menu. For additional test sets, select an appropriate number in the box.

[Save] button Click this button to save and effectuate the temporary change.

[Cancel] button Click this button to close the window without saving the change to return to the previous window.

Start measurement after the temporary change.

After clicking the [Save] button, the [STAT port] window is displayed again. Click the [Start] button to start measurement under the modified conditions.

4) Dispensing the STAT sample

When the analyzer finished sampling from the STAT port, the [STAT port] window is aromatically closed.

If the [STAT port] window remains, some kind of error is suspected. Check the message in the status box in the [STAT port] window and act accordingly.

4.8 PAUSE / Smart PAUSE

"PAUSE" and "Smart PAUSE" are the functions that allow temporary suspension of measurement to add samples. The steps are as follows:

PAUSE

1) Set the analyzer to show "PAUSE" in the system mode box of the Operation Panel.

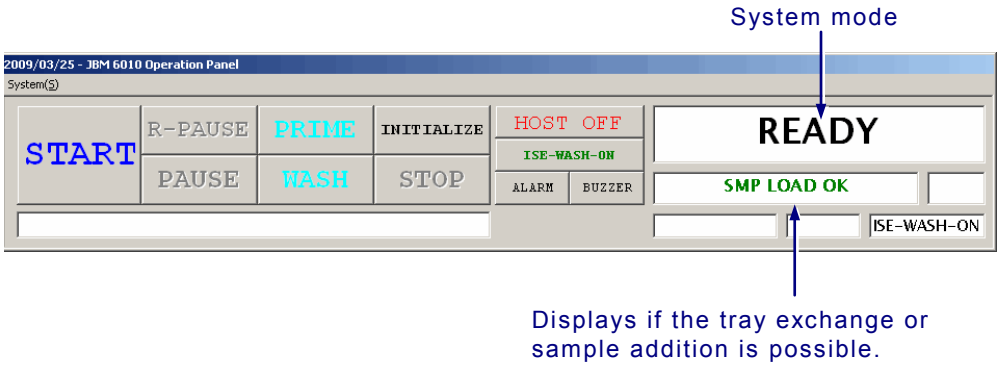
When the system mode is "START", click the [PAUSE] button and wait until "PAUSE" is displayed in the system mode box.

When the "Smart PAUSE" function is selected, the system mode shifts to "Smart PAUSE" by opening the cover of the sample tray (STT). The steps for setting "Smart PAUSE" are described on the next page.

When the system mode is already in "Processing" or "PAUSE", you do not need to change the mode to add samples and continue measurement.

2) Add samples when the Operation Panel displays "SMP LOAD OK" or "Append."

3) Click the [START] button in the Operation Panel to re-start the measurement. (If you set the samples defined with a different tray number in Step 2, you have to enter the tray number in the [Start condition] window before starting.)



Warning

When you change the tray or samples after clicking the [PAUSE] or [STOP] button during operation, be sure to follow the instructions displayed in the system mode box. When "SMP LOAD NG" or "No append" is displayed, the probes and trays move. Never touch the probes and trays while they are moving. This may lead to injury or infection of the operator from the contact with serum, or damage to the analyzer.

[PAUSE] button — Click to suspend the on-going sampling during operation. This button is used for the operation such as adding samples.

[STOP] button	Click to stop sampling during operation. Do not use this button in the ordinary situation.

Smart PAUSE

Smart PAUSE is the function that enables the analyzer to pause when the sample tray (STT) cover is opened and to resume measurement when it is closed. The setup steps are as follows:

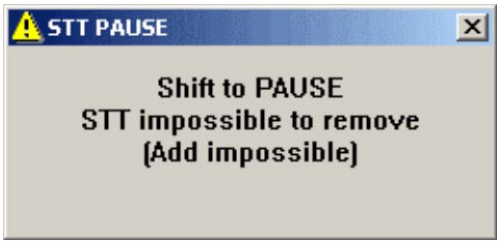
Setup steps

1. Select [Setup] > [System Specification Settings] to display the [System Specifications Set] window.
2. In the [System Basic Configuration] column, select “Avail.” for [Sample barcode].
3. In the [Rerun Settings] column, select “Flagged tests and untested tests” or “Untested tests only” for [Manual Rerun].
4. In the [Smart PAUSE] column, select “Avail.” for [STT Cover].

Workflow

1) Open the sample tray (STT) cover

The window below is displayed and the system mode shifts to “PAUSE”.



CAUTION

While the mode is shifting, the tray and probe move. It is dangerous to touch the moving trays or probes, ensure that the mode has certainly shifted to “PAUSE” before adding the samples.

2) The “Smart PAUSE” function is now applied

3) Add the samples

4) Close the STT cover

The system mode turns to “START”. (Smart START)

5) The analyzer reads the sample barcode labels.

6) The [Sample Confirmation] window is displayed.

When the timer counts down to “0” or when you click [OK], the measurement starts.

Conditions for application of the “Smart” functions

The “Smart” functions are performed when all of the following conditions are met.

Smart PAUSE

- When the STT cover is opened.
- The system mode is either “START”, “Proces.SHIFT”, “HOLD”, “HOLD SHIFT” or “WAIT”.
- “Avail.” is selected for the [Smart PAUSE] option in the [System Specification Settings] window.
- Analyze” is not selected for [Multipnt.smp.] in the [Calibration] column and “Cup posi.” is not selected for [Analysis mode] in the [Patient sample] column of the [Start Conditions] window.
- No pop-up window to be displayed by clicking a button in the Operation Panel is not being displayed.

Smart START

- When the STT cover is closed.
- The system mode is “Smart PAUSE”.

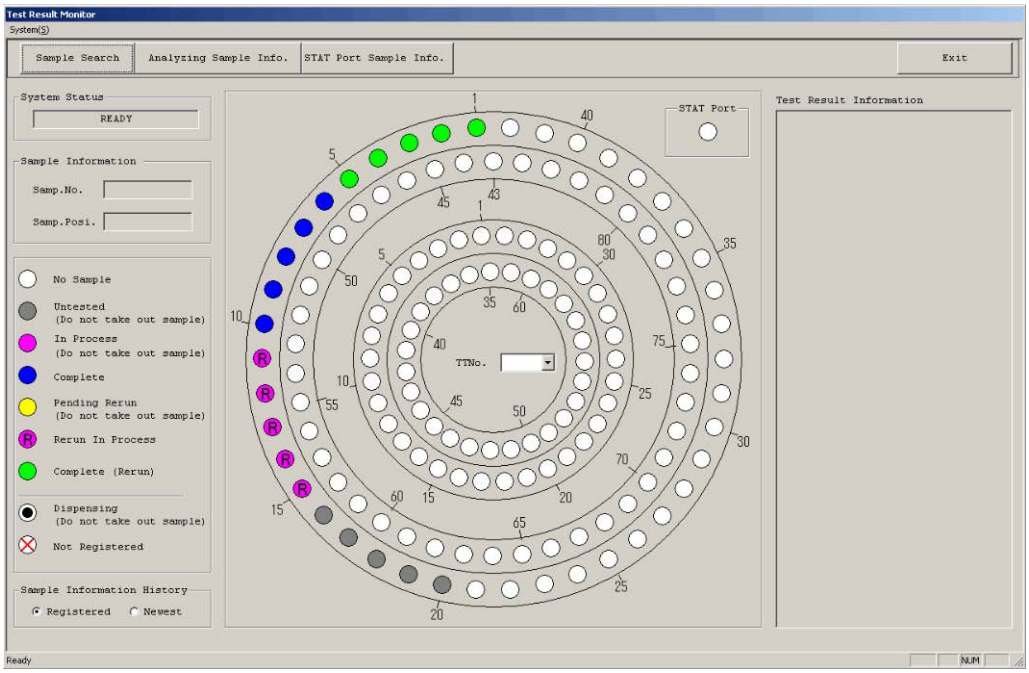
When you shifted the system mode to [PAUSE] by clicking the [PAUSE] button, you have to click the [START] button to resume the operation. In the “PAUSE” mode triggered by “Smart PAUSE,” you can click the [START] button to resume the operation after closing the cover. (Operation can be resumed only by closing the cover, too.)

The term “Smart PAUSE” is shown only in the Operation Panel. The term “PAUSE” is used for all the windows including “Error Report” window instead of “Smart PAUSE” even if the pause was the result of “Smart PAUSE”.

4.9 Checking the Measurement Data

4.9.1 Checking the chemistry analysis measurement results

Select [Setup] > [Test Result Monitor] to display the window below.

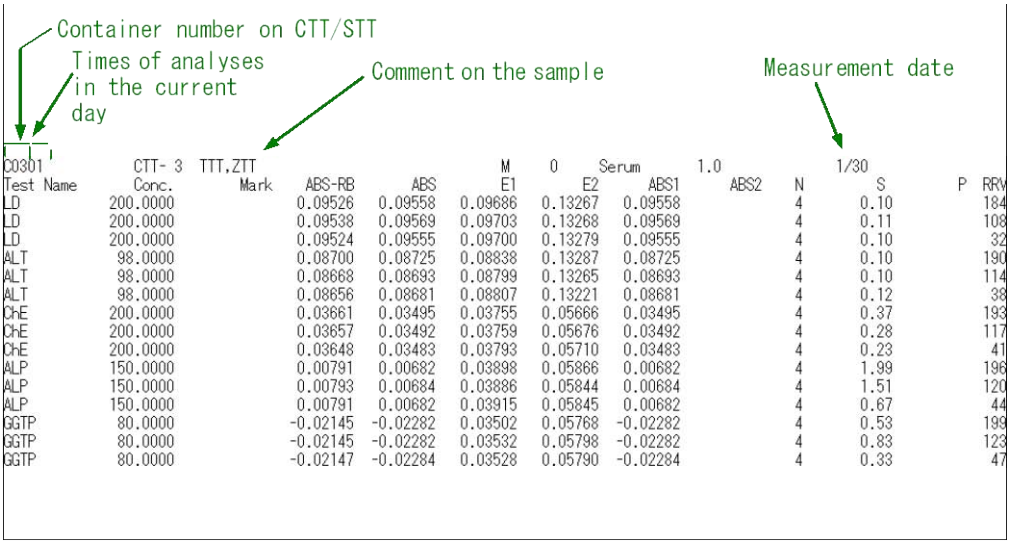


The measurement status and the most recent analysis data are displayed for each sample. The status and results are updated as the measurement proceeds. When the sampling is completed in the range of positions designated in the [Starting Conditions] window, the system mode shifts to “Processing”.

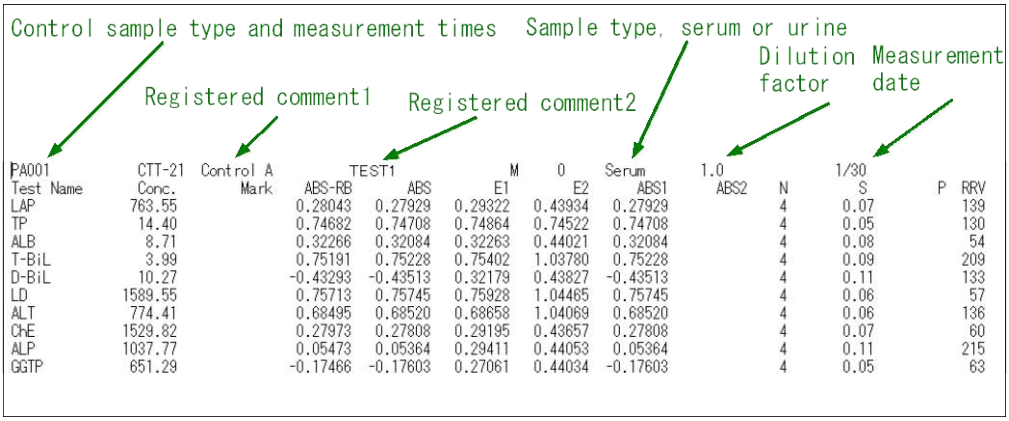
1) Check the values in the Realtime Monitor

Select [Request] > [Reatime Monitor] to open the window below. The displayed items vary depending on the setting defined in [Maint.] > [System Monitor] window.

Following is the description of the items.

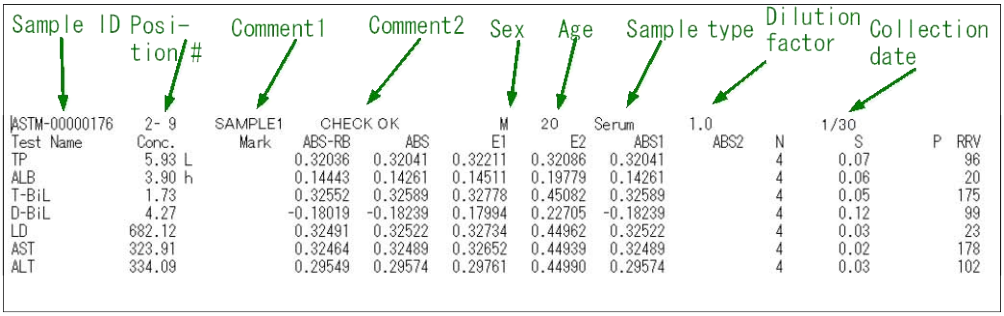


Example of displayed results of calibration



PA001	CTT-21	Control A	TEST1		M	0	Serum	1.0		1/30	
Test Name	Conc.	Mark	ABS-RB	ABS	E1	E2	ABS1	ABS2	N	S	P RRV
LAP	763.55		0.28043	0.27929	0.29322	0.43934	0.27929		4	0.07	139
TP	14.40		0.74682	0.74708	0.74864	0.74522	0.74708		4	0.05	130
ALB	8.71		0.32266	0.32084	0.32263	0.44021	0.32084		4	0.08	54
T-BiL	3.99		0.75191	0.75228	0.75402	1.03780	0.75228		4	0.09	209
D-BiL	10.27		-0.43293	-0.43513	0.32179	0.43827	-0.43513		4	0.11	133
LD	1589.55		0.75713	0.75745	0.75928	1.04465	0.75745		4	0.06	57
ALT	774.41		0.68495	0.68520	0.68658	1.04069	0.68520		4	0.06	136
ChE	1529.82		0.27973	0.27808	0.29195	0.43657	0.27808		4	0.07	60
ALP	1037.77		0.05473	0.05364	0.29411	0.44053	0.05364		4	0.11	215
GGTP	651.29		-0.17466	-0.17603	0.27061	0.44034	-0.17603		4	0.05	63

Example of displayed results of control sample measurement



ASTM-00000176	2- 9	SAMPLE1	CHECK OK		M	20	Serum	1.0		1/30	
Test Name	Conc.	Mark	ABS-RB	ABS	E1	E2	ABS1	ABS2	N	S	P RRV
TP	5.93 L		0.32036	0.32041	0.32211	0.32086	0.32041		4	0.07	96
ALB	3.90 h		0.14443	0.14261	0.14511	0.19779	0.14261		4	0.06	20
T-BiL	1.73		0.32552	0.32589	0.32778	0.45082	0.32589		4	0.05	175
D-BiL	4.27		-0.18019	-0.18239	0.17994	0.22705	-0.18239		4	0.12	99
LD	682.12		0.32491	0.32522	0.32734	0.44962	0.32522		4	0.03	23
AST	323.91		0.32464	0.32489	0.32652	0.44939	0.32489		4	0.02	178
ALT	334.09		0.29549	0.29574	0.29761	0.44990	0.29574		4	0.03	102

Example of displayed results of patient sample

See “Chapter 6 Data Processing” for the detailed data processing.

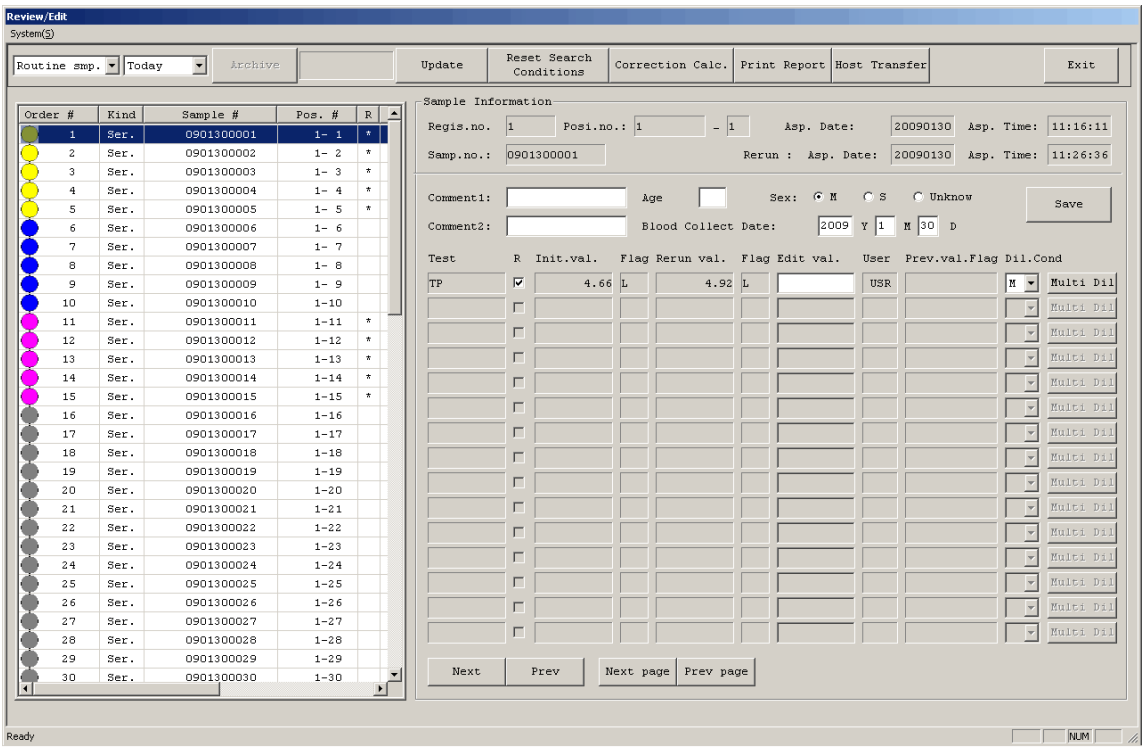
Test Name	The name of the test
Conc.	Concentration. The value “0” is displayed for all the reagent blank measurements. The factor value is displayed for calibrators. The concentration is displayed for control and patient samples.
Flag	The space to post flags for value judged as abnormal. For the types and details concerning the flags, see Appendix 3.
ABS-RB	For reagent blank measurement, the value obtained by subtracting the previously measured value from the current measurement value is displayed in order to determine the discrepancy between the two values. For calibrator, control, and patient sample measurement, the reaction absorbance (Reaction ABS value) obtained by subtracting the reagent blank from the measurement value is displayed. The ABS range is displayed for reaction rate assays (RRA), and the ABS value is displayed for end-point assays.
ABS	The absorbance calculated from the measurement value (including reagent blank) is displayed. The ABS range

	is displayed for reaction rate assay (RRA), and ABS value for end-point assay.
E1	When the check detection point (Check D.P.) is defined, the ABS value for the main wavelength is displayed. If not, the ABS value for the main wavelength at the main detection point .m (DET.P.m) is displayed.
E2	The median of the ABS values for the main wavelength at detection point (DET.P) 4 to 6 is displayed.
ABS1	The calculated absorbance at the main detection points (M-DET.P) is displayed. ABS is obtained by subtracting ABS2 from ABS1. ABS2 is the value corrected with regard to the liquid volume.
ABS2	Calculated absorbance at sub detection points (S-DET.P) is displayed.
N	The number of the main detection points (M-DET.P) used for calculation.
S	Variance shown in %
P	Calculated prozone value
RRV	The position number of the reaction cuvette used for measurement.

Confirm the data and transfer them to the laboratory information system (LIS)

2) Confirm the data on the display monitor

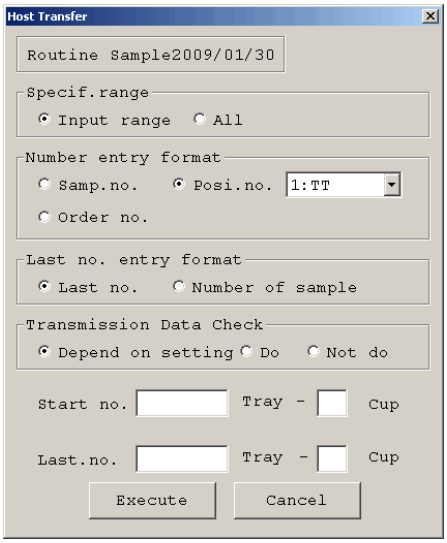
1. Select [Request] > [Review/Edit] to display the [Review/Edit] window below.



2. Select a sample in the box on the left side to display the relevant data in the columns on the right side.
3. Check the data and act accordingly when some flag(s) is posted.

3) Transfer the data

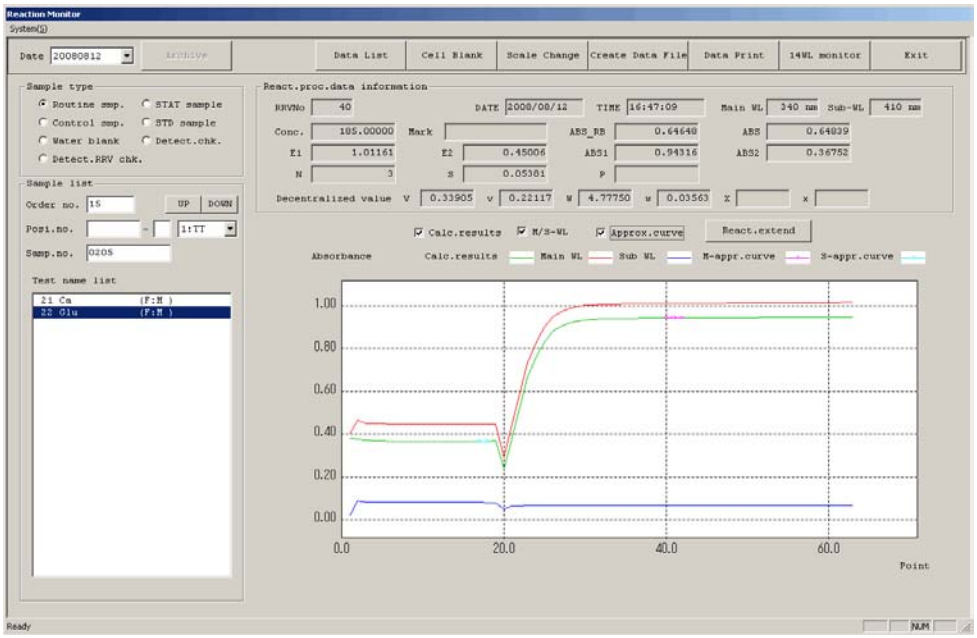
1. Click the [Host Transfer] button on the top bar of the window to open the window below.



2. Define the [Specif.range], [Number entry format], and [Last no. entry format] respectively.
3. Enter the [Start no.] and [Last no.], and then click the [Execute] button. The data in the define range will be transferred to LIS.

4) Check the data by the time course

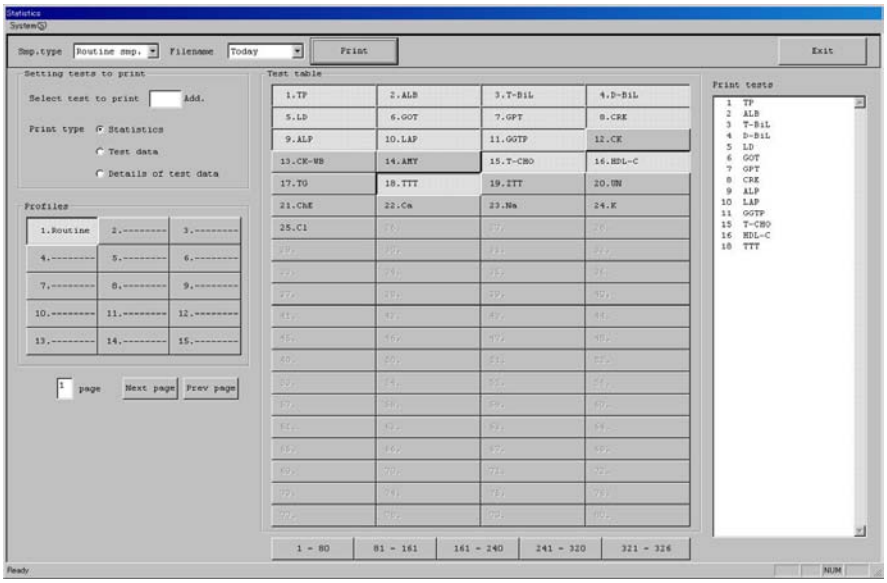
1. Select [Request] > [Reaction Monitor] to display the window below:



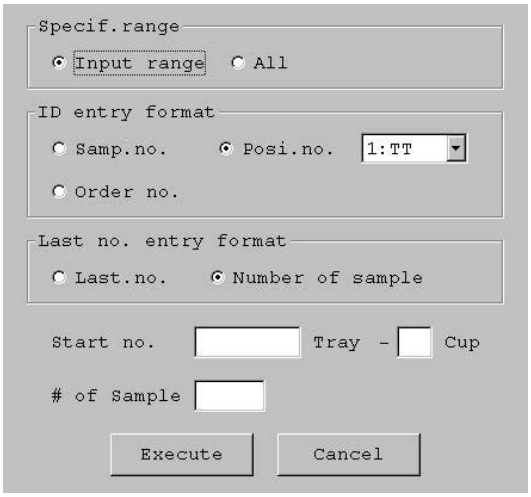
2. Enter the [Posi.no] or [Samp.no] in the [Sample list] column to designate the sample.
3. Click and select a test name displayed in the [Test name list] box.
4. Check the time course of each test by sample.

5) Print the data for checking

1. Select [Request] > [Statistics] to display the [Statistics] window below.



2. Select “Details of test data” for [Print type] in the [Setting tests to print] column.
3. Select the tests to print in the [Profile] or [Test Select] column.
4. Define the printing details and print the data.
5. Click the [Print] button to display the window below:



i. Define the detailed printing content.

Enter the [Specif.range], [ID entry format], and [Last no. entry format] respectively.

ii. Define the printing range.

Enter the [Start no.] and [Last.no.].

iii. Print the data

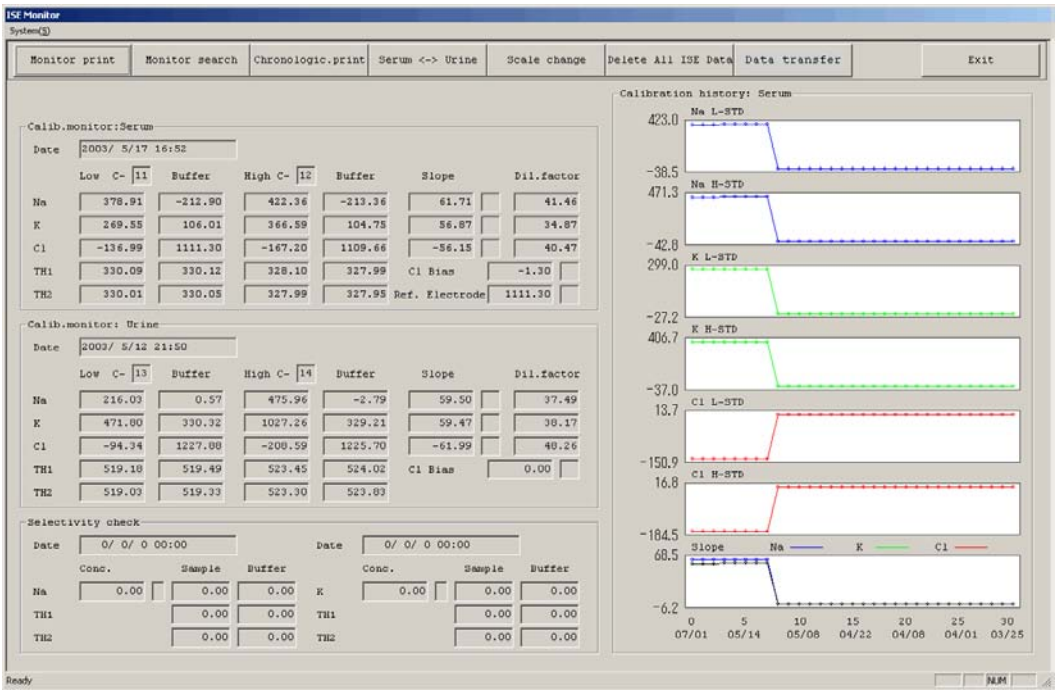
Click the [Execute]. The designated range of data is printed.

4.9.2 Checking the ISE test results

Display the [ISE Monitor] window

Select [Maint.] > [ISE Monitor] to display the window below.

This window is used to check the result of calibration and the time course.



[ISE Monitor] window

Features

This window is used for:

- Checking calibration results for the last 30 days. The latest data is transferred to the ISE unit during the [INITIALIZE] mode.
- Checking the chronologic changes of calibration results efficiently in the graphic display. Printing the calibration measurement data and results of the current data in the standard printing format and the calibration results only of past dates by using the [Monitor print] button.
- Selecting a set of calibration values from the sets retained in the past 30 days by using the [Monitor search] button to transfer the set with the [Data transf.] button. The system recognizes the transferred set to be the latest one.
- Checking the ion selectivity using the results of the latest ion selectivity check, because the time and the result values of the check are stored. Please note that the samples for the selectivity check (checking solutions for Na and K) are not included in the standard accessory set.
- Printing the results of up to 100 patient samples in the standard printing format using [Chronologic.print] button. The results are printed in reverse chronological order.

Command buttons

The table below summarizes the functions of the command buttons used for the above features.

Command buttons

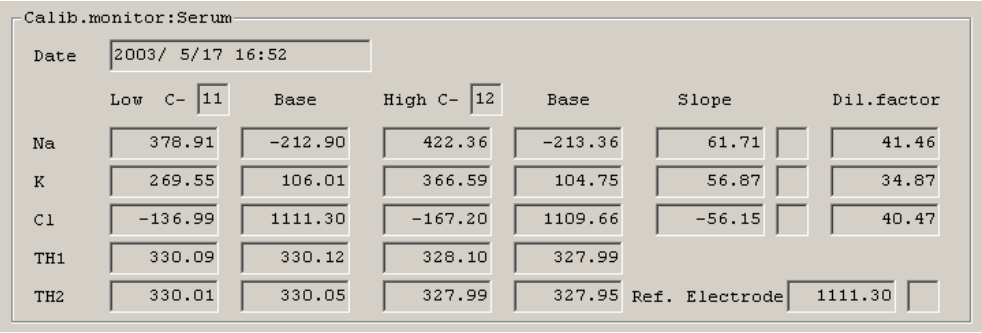
Name of the button	Function
Monitor print	Used for printing calibration results of the last 30 days. When you have selected “Latest data”, you can define how many latest data to print if the calibration was repeated several times. The measurement values and result values are printed in reverse chronological order.
Monitor search	Used for selecting a date from the last 30 days to show the data in the [Calib.monitor:..] columns
Chronologic.print	Used for printing the data from up to 100 patient samples in the standard printing format.
Serum <-> Urine	Used for toggling the calibration history graph between serum and urine.
Scale change	Used for changing the scale of the Y axis in the calibration history graph. When the ISE Monitor window is displayed, the Y axis is optimally adjusted. To edit the scale of the Y axis, enter appropriate values in the [Scale change] window and click [Execute]. The graphs are now displayed with the entered values. Click the [Default] button in the [Scale change] window to display the graph in the normal range of each test. The measurement value which was not displayed within the screen will be treated as range or slope error. To return to the automatically adjusted scale of the history graph, click the [serum <-> urine] or close and then re-open the window.
Delete All ISE Data	Used to clear all the calibration data stored in the system. This button is used on limited occasions such as when some error occurred in the calibration history graph due to a software upgrade. Do not use [Delete All ISE Date] under ordinary circumstances. Otherwise, the system will lose valid calibration values to use when an abnormality occurs in calibration. Be sure to backup the calibration data before clicking this button.

Name of the button	Function
Data transfer	Used for sending the data displayed in the [Calibration monitor] window to the ISE unit to overwrite the existing calibration values. When there is an error in the calibration data, the message “No calibration data” is displayed and no measurement is performed. This indicates that the calibration has not been successfully completed. When the maintenance related measurement such as interval check or CV check is performed, select the correct data using the [Monitor Search] button and display the valid values in the window. Then use this [Transfer data] button to transfer the displayed values to the ISE unit. Note) 1. When you click the [Transfer data] button during the [INITIALIZE] mode, the message “An error occurred during transmission” may be displayed. 2. The transferred data is recognized to be the latest data. 3. When you try to transfer the data with the flag “H” or “L” for “slope”, or “d” for “dilution factor”, the transfer will fail.
Exit	Close the [ISE Monitor] window

Columns in the window

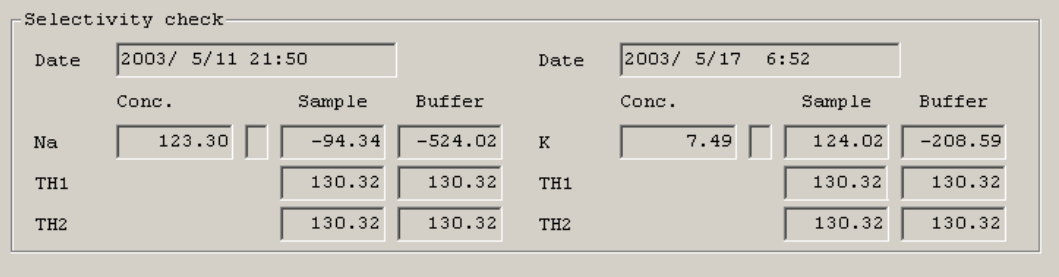
[Calib.monitor] column

The latest calibration values are displayed in this column. Use the [Monitor search] button to show past values. This column is for display purposes only. No entry is allowed. The following table summarizes the contents of the items in the column. They are shared by “Serum” and “Urine”.



Item	Description
Date	Shows the date and time when the calibration values were acquired.
C-	Indicates the position number of the refrigerated sample tray (CTT) defined respectively for L-STD and H-STD measurements.
Low	The fields under this header show the potential (sample potential minus buffer potential) of Na, K, and Cl electrodes obtained by L-STD measurement and the potentials of thermistors 1 and 2 (TH1 and TH2) when the L-STD sample potential is measured.
High	The fields under this header show the potential (sample potential minus buffer potential) of Na, K, and Cl electrodes obtained by H-STD measurement and the potentials of the thermistors 1 and 2 (TH1 and TH2) when the H-STD sample potential is measured.
Base	Indicates the buffer potentials of Na, K, and Cl electrodes and the potentials of TH1 and TH2. The values for L-STD and H-STD measurements are displayed accordingly.
Slope	Indicates the sensitivity of electrodes Na, K, and Cl. The flag [h] is posted when the measurement value is greater than the value defined for [Slope upper limit h] in the [ISE Parameter Settings] window, and the flag [l] is posted when the value is lower than the value defined for [Slope lower limit l]. When the value is out of the existing abnormal slope threshold, “L” or “H” is displayed. Use these flags to judge the timing of electrode replacement. When the slope is out of the abnormal threshold, the value will be “0” and the correct values cannot be calculated.
Dil.factor	The calculated dilution factors for Na, K, and Cl samples are displayed. The flag “d” is posted to alert to user to the dilution factor error when it is out of the dilution factor range. The calibration values cannot be correctly calculated.
Ref.Electrode	The flag “d” is posted when the value is 350 or lower. This signifies that it is time to use a new electrode.

[Selectivity check] column



This column shows the latest data but allows no entry. It is for display purposes only.

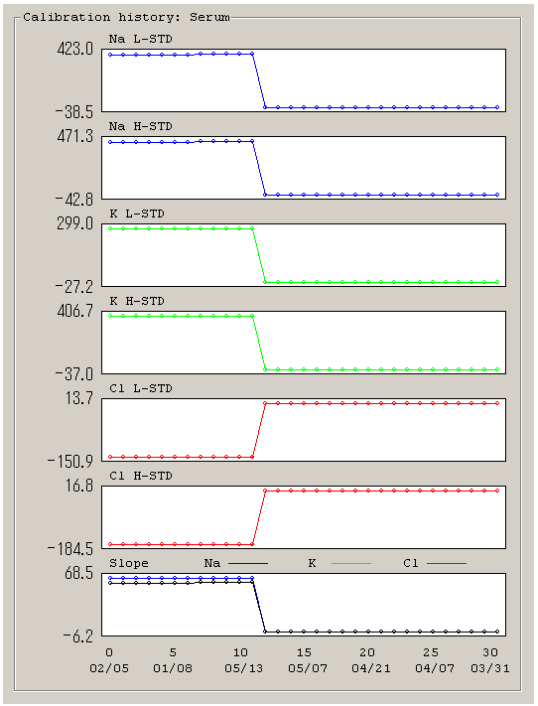
The selectivity of each electrode is measured three times and the mean value of the second and third results are displayed in the fields under the [Conc.], [Sample], and [Buffer] header respectively.

Please note that the samples used for the selectivity checks (checking solutions for Na and K) are not included in the standard accessory set, and must be purchased separately.

The following table summarizes the contents of the items in the column.

Item	Description
Date	Shows the selectivity check date of the Na and K electrodes, respectively.
Conc.	Shows Na and K concentration values measured at the selectivity check, respectively. When the concentration value is above the upper limit defined for selectivity, a “u” character is flagged in the box to the right of the concentration field. This means that there is inference by some other ion. These flags can be used to judge the timing of electrode replacement.
Sample	Shows the value obtained by subtracting the buffer potential from the sample potential regarding the selectivity check of the Na and K electrodes.
Buffer	Shows the buffer potential at the selectivity check measurement of the Na and K electrodes, respectively.

[Calibration history] column



For both serum and urine, the calibration values measured for the last 30 days are graphically displayed in this column. The latest value is shown on the left-most side.

The data is stored by date. Only the latest values of the date are stored.

The value obtained by subtracting the buffer potential from the sample potential is plotted by electrode (Na, K, and Cl) and by calibrator (H-STD and L-STD). The slope value in the bottom graph is plotted by all three electrodes Na, K, and Cl values. (Cl values with inverse plus and minus sign) Use this graph to judge the timing of electrode replacement.

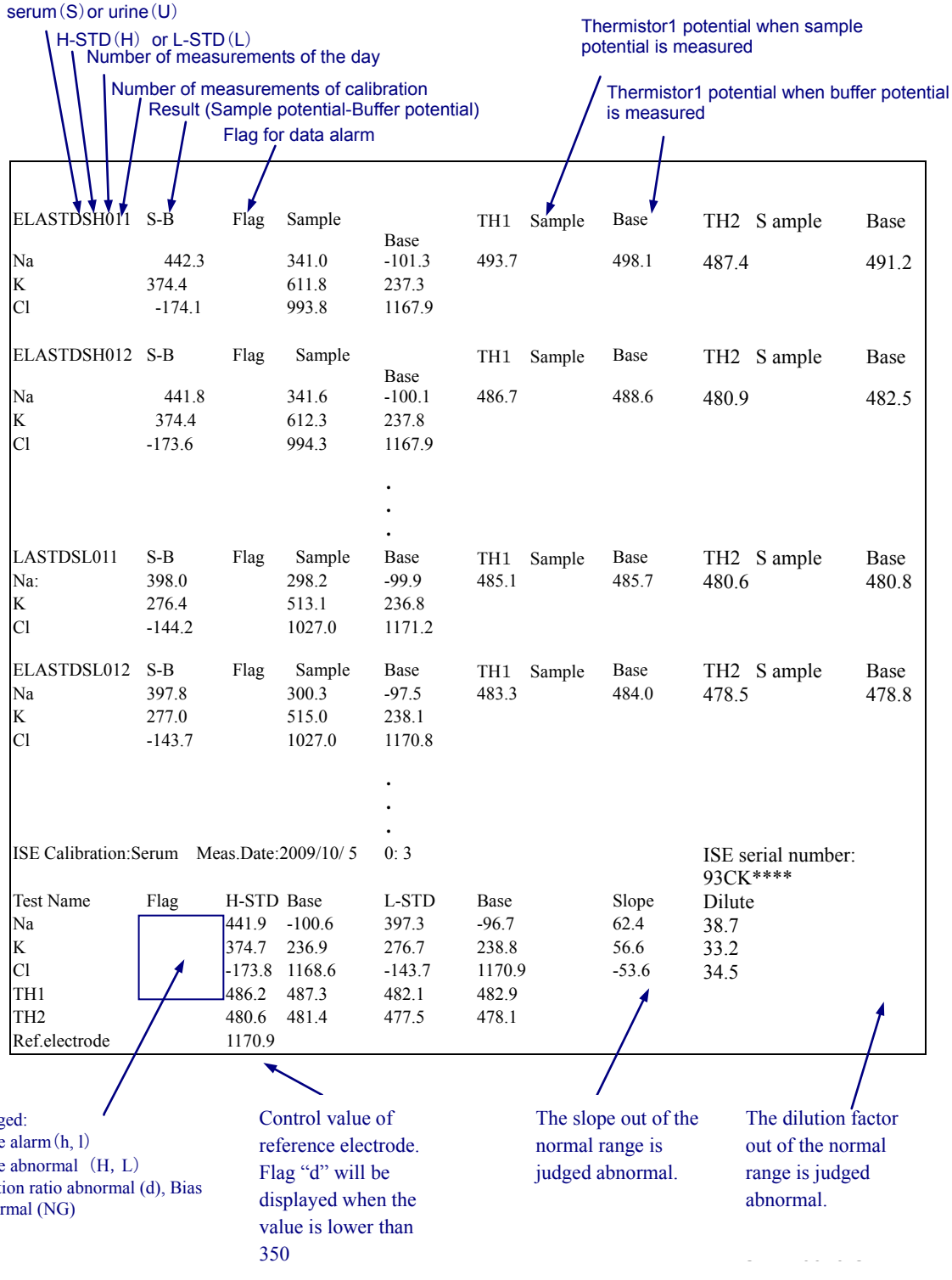
- Click the [Serum <-> Urine] button in the top bar to toggle the display between serum and urine.
- The Y axis is scaled automatically when the window is displayed.

Realtime monitor

As already described in the section 4.9.1, the realtime monitor allows you to check the ISE calibration and measurement values, too. Select [Request] > [Realtine Monitor] to display the [Realtime Monitor] window below. The ISE-related area is as follows:

Calibration data

Following is an example of serum calibration results.



- Under the [S-B] header, the mean values of the sample potential minus the buffer potential of the last two measurements are displayed.

- The temperature of calibrators (diluted with buffer solution) is measured every time and displayed under the [TH] header.
- The slope value and dilution factor are calculated from the measurement results of H-STD and L-STD calibrators and displayed respectively under the [Slope] and [Dilute] headers located in the lower right of the above chart.

- Select ［Maint.］> [ISE Monitor] to compare the results with the previous results.
- The slope value out of the 63 - 45* range indicates that it is time to replace the electrodes. At that time, the flag “l” or “h” is posted for warning.

  *The value range of the slope for flag display can be defined in the [ISE Parameter Settings] window.

- A slope value outside of the 65 - 38 range is judged abnormal, and the flag “H” or “L” is posted. You cannot change this value range.
- The dilution factor is the factor by which the calibrator is diluted with the buffer solution. It is calculated from the calibration data. If the calculated dilution factor is out of the 25 - 60 range, the flag “d” is posted and the data is treated as calibration error. The possible cause of the error may be degradation of the calibrator or buffer solution, or improper washing.
- When a calibration error occurs, the calibration data stored in the ISE unit is deleted. The previous data are retained in the [ISE Monitor] window and these data are transferred to the ISE unit as the latest data during the system [INITIATE] mode. These data will be used for calculating the measurement results.
- When the slope or dilution fraction is abnormal, the values in the [ISE Monitor] will be updated but cannot be used for measurement. In this case, either repeat the calibration, or transfer normal data from the [ISE Monitor] window to set the normal calibration data for measurement.

Patient sample measurement data

The [Realtime Monitor] window displays the patient sample measurement data as well.

Sample No.		Posi.No.	comment1	comment2	Sex		Age	Sample type	Dil.factor
Test Name	Conc.	Flag	SAMPLE	BASE	TH1.S	TH1.B	TH2.S	TH2.B	
Na	144		-33.8	-442.9	79.9	82.6	82.4	88.0	
K	3.9		278.4	-8.7	79.9	82.6	82.4	88.0	
Cl	94		899.7	1050.2	79.9	82.6	82.4	88.0	

Thermistor potential when sample potential is measured

Thermistor potential when buffer potential is measured

The displayed items are as follows:

- In the [Sample No.] line, the sample attributes are displayed.
  For [Sample No.], a sample ID or arbitrary registration number (up to 13 bytes) is displayed (e.g. “1”).
  [Posi.No.] is displayed in [TTNo.]－[Cup no.] or by the rack position (e.g. 1-1). For [Sex], “M” is displayed for male and “F” for female.
  For [Sample type], “S” is displayed for serum and “U” for urine.
  For [Dil.factor], the value entered in the [Order Entry] window is displayed for the sample diluted before measurement.
- The test names specified in the [ISE Parameter Settings] window are displayed for [Test Name].
- The number of decimals of the value in the [Conc. (concentration)] field has been defined in the [ISE Parameter Settings] window.
- The [Flag] field displays the flags selected for [Rerun cond.] in the [ISE Parameter Settings] window when the relevant abnormal values are obtained in measurement.

For details of flags, see “Appendix 3. Flags”

4.10 Rerun

When “ON (from STT)” is selected for [Auto.rerun] in the [Rerun Settings] column in the [System Specification Settings] window, the system automatically reruns the test which is judged the rerun is required.

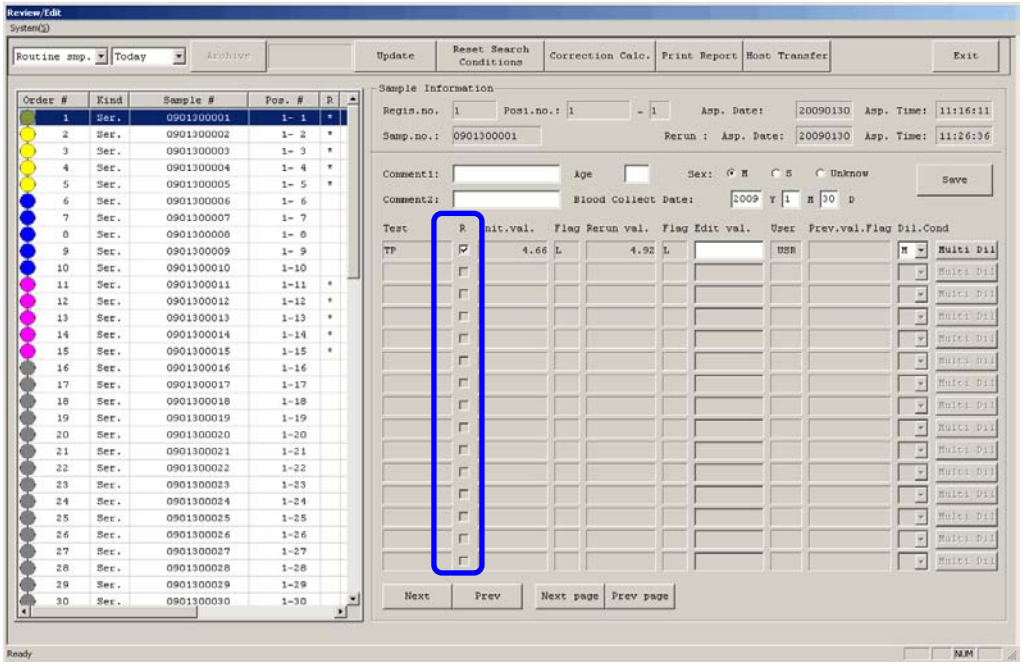
This section describes the steps necessary to define a rerun for a measured sample, and to perform it whether the automatic rerun is selected or not.

1) Select in advance “Flagged tests and untested tests” for [Manual Rerun] in the [Rerun Settings] column of the [System Specification Settings] window.

This allows the system to perform the “flagged tests and untested tests” in rerun.

2) Define the sample and measurement conditions for rerun

Select [Request] > [Review/Edit] to display the window below.



In the list box on the left, click the number under the [Order #] header to select the sample to rerun. The selected sample is shown highlighted and the fields in the [Sample Information] column are automatically populated with the corresponding values.

Check the tests to rerun in the box under the [R] header.

Select one from “M” - “D4” for [[Dil.Cond] and click the [Save] button. The diluent conditions “M” - “D4” are as follows:

“M” The sample volume defined either for [Sample Vol (S) or (U)] in the [Analytical conditions] columns in the [Analytical Parameters (Chemistry)] window is diluted in the condition defined in the [Analysis test condition setting (M)] window.

"D1" - "D4"	Rerun condition and dilution condition defined in [Rerun conditions] window accessed from [Setup] > [Analytical Parameters (Chemistry)] window

3) Rerun with the sample selected in Step 2

There are two cases for rerunning.

- When "N.A." is selected for [Sample barcode] in the [Setup] > [System Specification Settings] window, you do not have to change the sample position in the sample tray (STT), but rather enter the currently used "TrayNo." in the [Start Conditions] window displayed by clicking the [START] button in the Operation Panel and then click the [Start] button in the [Start Conditions] window.
- When "Avail." is selected for [Sample barcode] in the [Setup] > [System Specification Settings] window, you do not have to change the sample position in the sample tray (STT) nor enter the "TrayNo." in the [Start Conditions] window because the information is supplied by the barcode.

The tests defined for rerun repeated.

Apart from the defined tests, the following measurements may be performed simultaneously depending on the case.

- The tests for which the system has defined auto rerun but have not been performed yet.
- The tests that have been defined but have not been performed due to reagent shortage, etc.

When "N.A." is selected for [Auto.rerun] in the [Rerun Settings] column in the [System Specification Settings] window, the tests that the system has defined to rerun will remain unperformed. When "On (from STT)" is selected, usually the tests defined to rerun are automatically performed, except in select cases including some reagent shortages. In this latter case, the tests remain unperformed.

Define a dilution condition for the initial run of a test with a sample for which the value is expected to be high.

When the test value of a sample is known in advance to be high, define a dilution condition to apply to the initial run.

Select [Request] > [Order Entry]. In the window, select an option from [2: D1 cond.] to [5: D4 cond.] for [System Dilution Mode], or click the [Multi Dil.] button and select an option from "M" to "D4"

Thus, the sample is measured with the dilution condition in the initial run.

4.11 Check the Remaining Reagent Volume

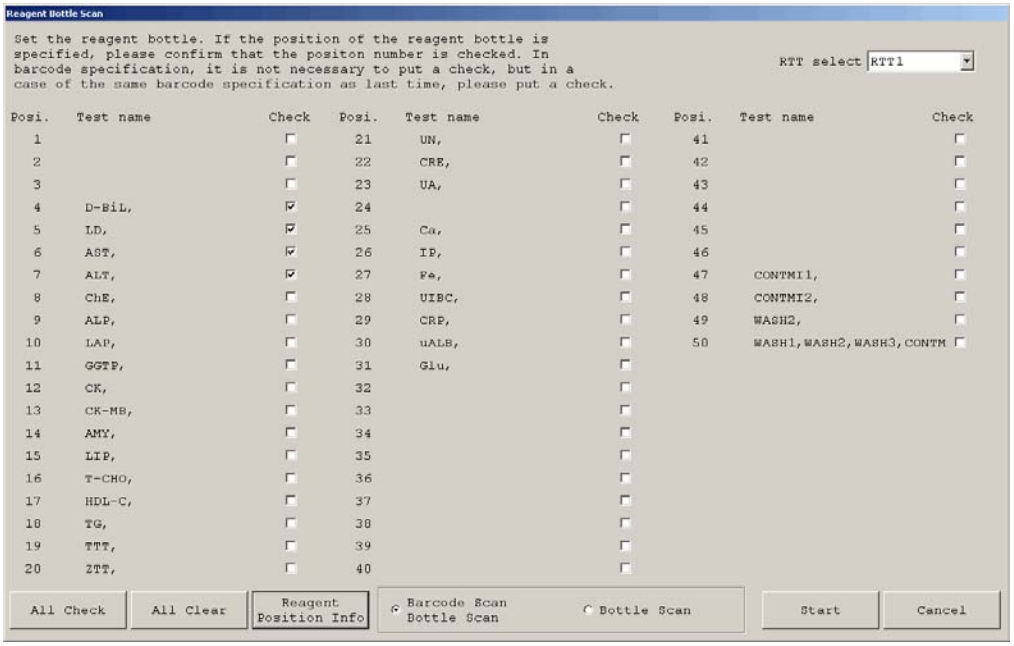
Select [Reagent] > [Reagent Test Monitor] to check the current volume of the reagents by test.

If you have replenished the reagents and want to check the remaining volume, follow the steps below.

Steps to scan the remaining reagent volume

1) Display the [Reagent Bottle Scan] window

Select [Reagent] > [Reagent Test Monitor], and click the [Reagent Scan] button. The window below is displayed.



2) Select a reagent tray “RTT”.

Select “RTT1” for [RTT select].

3) Select the positions of reagent bottles to check.

Click the boxes under the [Check] header corresponding to the positions of the reagent bottles to check in RTT1.

4) Change RTT

Select “RTT2” for [RTT select].

5) Select the positions of reagent bottles to check.

Click the boxes under the [Check] header corresponding to the positions of the reagent bottles to check in RTT2.

6) Scan the reagent bottles

Click the [Start] button to start the reagent scan.

The reagent probes check the remaining volume of reagents in the bottles in numerical order by position. This is accomplished by repeating aspiration/washing motions, although the reagents are not actually aspirated. During this operation, the Operation Panel displays “REAGENT SCAN” as the system mode. When the scan is completed, the mode returns to “READY”.

7) Check the volume

Check the remaining volume in the [Reagent Test Monitor] window.

4.12 R-PAUSE

"R-PAUSE" or "Reagent-PAUSE" is a feature that allows the system to suspend measurement temporarily in order to replace empty reagent bottles.

Click the [R-PAUSE] button in the Operation Panel. The system mode shifts to [R-PAUSE SHIFT] and then to [R-PAUSE]. At this point you can replace an empty reagent bottle.

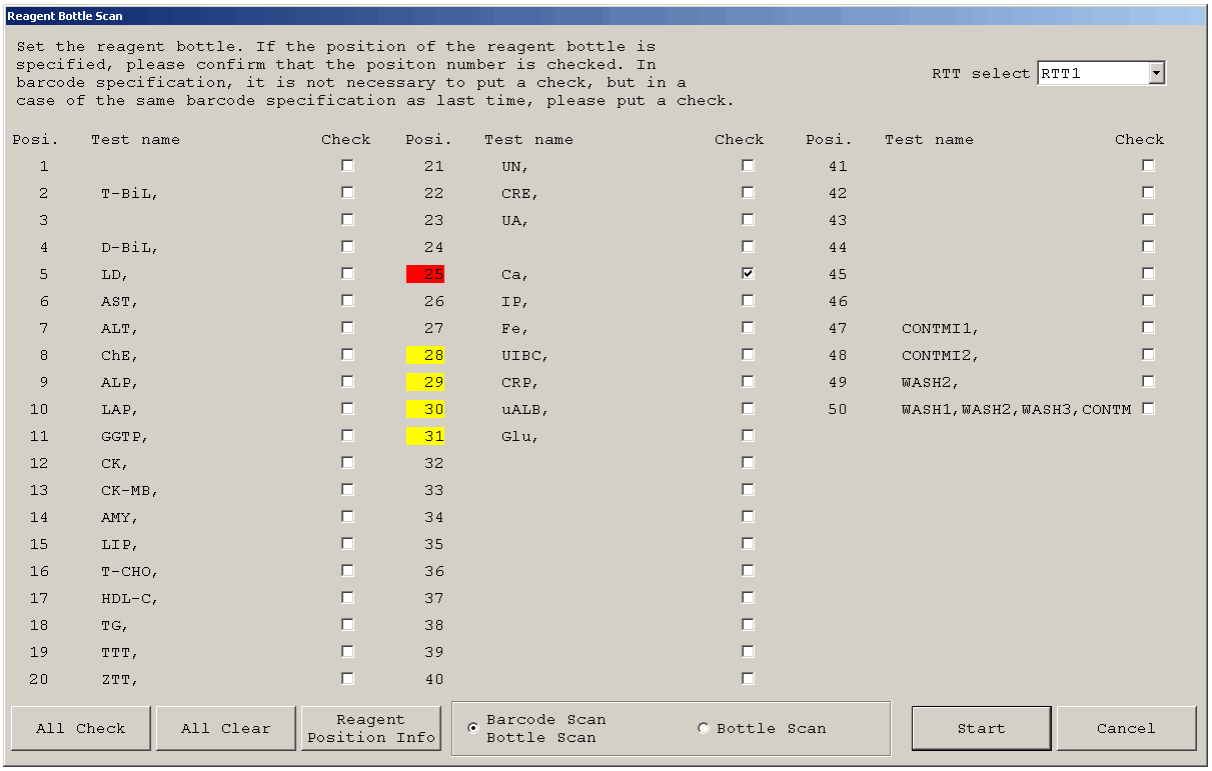
During "R-PAUSE", select [Request] > [Sample Log] window and confirm the event in the window.

Workflow

1. Click the [R-PAUSE] button on the Operational Panel.
2. The system mode shifts to "R-PAUSE SHIFT" and the sampling is suspended.
3. The mode shifts to "R-PAUSE"

   The mode shifts to "R-PAUSE" when the reagent dispensing is completed for the sample that had already been dispensed in the cuvette when the "R-PAUSE" button was clicked.

4. The [Reagent Scan] window is displayed. You can replenish the reagent or replace the reagent bottle as required



5. Select "Barcode Scan/Bottle Scan" or "Bottle Scan" and click the [Start] button. The barcode reading or reagent volume check is performed.

   When the reagent barcode is used for operation, ensure to select "Barcode Scan/Bottle Scan".

6. The measurement will resume automatically.

Setting the “Auto R-PAUSE” feature

“Auto R-PAUSE” is a feature that enables the system mode to shift to [R-PAUSE] automatically when a reagent shortage is detected during measurement. To use this feature, follow the steps below.

1) Select “1: W+Selection” for [Processing mode in no reagent] in the [Setting System Parameters] window.

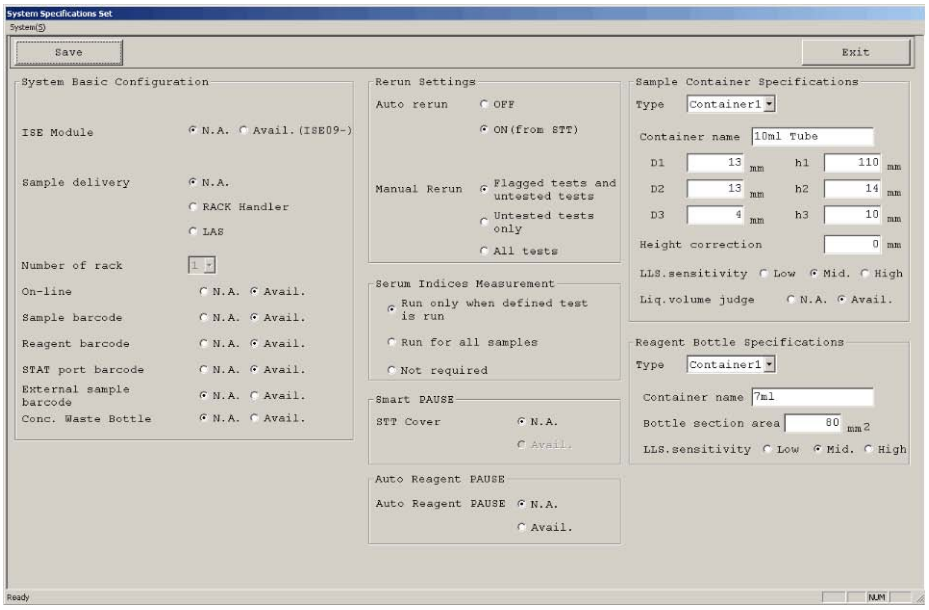
Select [Setup] > [Setting System Parameters] to display the [Setting System Parameters] window.

In the [Value] field for the parameter [Processing mode in no reagent], enter “1” that represents “1: W+Selection” in the [Comment] field.

Click the [Exit] button in the upper left section. A pop-up window is displayed and ask “Save and Exit?” Click [Yes] to close the window.

2) Select to use the “AUTO R-PAUSE” feature in the [System Specification Settings] window

Select [Setup] > [System Specification Settings] to display the [System Specification Settings] window. Define the following values.



[Auto Reagent PAUSE] Default value is “N.A.” Select “Avail.” to use the “Auto Reagent PAUSE” function.

Click the [Exit] button in the upper left section. A pop-up window is displayed and ask “Save and Exit?” Click [Yes] to close the window.

3) Enable the setting

Follow the steps described in the section 4.13 to shut down the analyzer once, and then restart it up with the “PC CONTROL” mode by “New Start”.

NOTES

- Reagent replacement is possible when the analyzer has finished dispensing all the scheduled reagents.
  When the [R-PAUSE] button is clicked, the sampling is suspended, but the reagents will be dispensed into the cuvettes that already contain samples.The dispensing of Reagent 2e and Reagent 2 should also be completed. Therefore, depending on when the [R-PAUSE] button is clicked and the number of tests scheduled for the samples, it may take more than 5 minutes for the system mode to shift to “R-PAUSE”.
- The [R-PAUSE] button is activated in the following system modes in which a reagent pause is possible.
  - START
  - Proces.SHIFT
  - HOLD When the analyzer is connected to a laboratory automation system (LAS) or a rack handler
  - HOLD SHIFT When the analyzer is connected to a LAS or a rack handler
  - WAIT When the analyzer is connected to a LAS or a rack handler
- In the [R-PAUSE] mode, samples cannot be replaced or added on the sample tray (STT) or the refrigerated sample tray (CTT).
  To replace or add samples, resume measurement from the “R-PAUSE” mode and click the [PAUSE] button.
- Even if the system detects a detergent, water, or diluent shortage, it will not enter automatically in the “R-PAUSE” mode.
  When replenishment or replacement is required, click the [R-PAUSE] button to shift the system mode to “R-PAUSE”.
- No automatic calibration is performed for the reagent replenished in the same bottle. If you want to perform calibration, follow the steps described in the section 4.4.1.
- Measurement from the STAT port is not available in the “R-PAUSE SHIFT” and “R-PAUSE” modes.
- When the reagent shortage is detected while “Auto Reagent PAUSE” function is selected and the [Sample confirmation], [Start Conditions], or [STAT Port] window displayed on the monitor, the system mode skips the “R-PAUSE SHIFT” mode to shift directly to “AUTO R-PAUSE.”

4.13 System End/Shutdown

Warning

When performing “WASH”, the probes and trays move. Never touch the probes and trays while they are moving. This may lead to injury or infection of the operator, or damage to the analyzer.

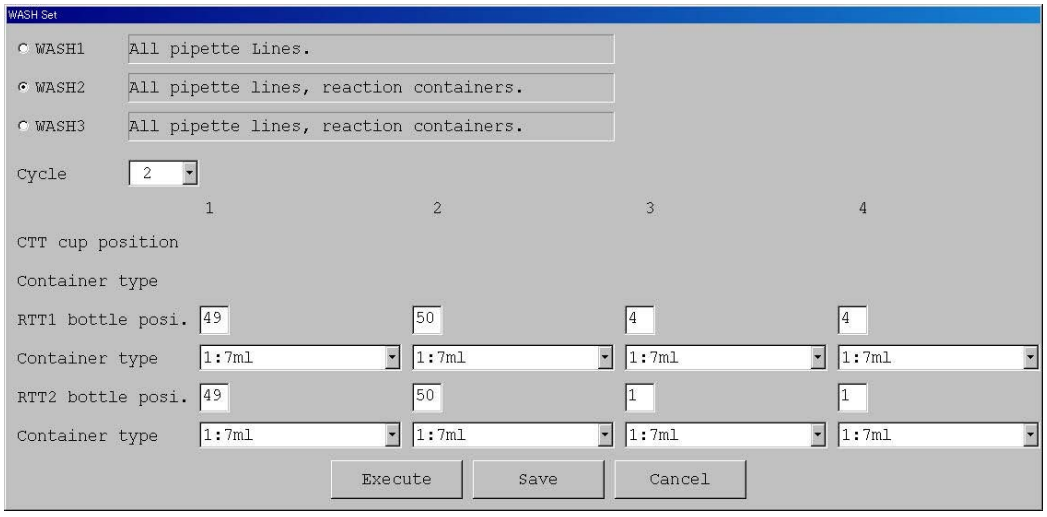
Washing after the day's operation

Perform the washing at the end of the day’s operation by following the steps below:

1) **Select [Setup] > [ISE Parameter Settings].**
2) **Select “with e.wash” for [WASH2] in the [Prime/Electrode Wash] section.**

   This set up is carried out only once at the beginning of washing. It is not necessary to repeat Steps 1 and 2 for every end-of-the-day wash.
3) **Place Reagent probe wash -K (20%) in position 49 and pure water in position 50 of the reagent trays (RTT) 1 and 2, respectively.**
4) **Set the ISE detergent solution and pure water in the respective containers defined in the [ISE Parameter Settings] window, and then place the containers in the positions defined in the same window.**
5) **1) Select the [WASH] button on the Operational Panel.**

   [The WASH Set] window is displayed.



6) **Select [WASH2] and click the [Execute] button.**

   WASH2 is performed, and the ISE unit is washed together with the chemistry analysis unit.

   This entire procedure lasts approximately 40 minutes.

   When a large quantities of urine or dialysate samples were analyzed during the day, replace the electrodes with the dummy electrodes and perform the line wash after the ISE wash (See Section 4.6).

After the line wash, be sure to perform calibration before the next measurement, as the line wash changes the condition of the electrodes.

Shutdown the system

1) Click the [System (S)] button in the upper left corner of the Menu Panel and select "Exit" in the drop-down menu.

The pop-up window is displayed and asks "OK to exit?"

2) Click the [Yes] button.

The pop-up window is displayed again and asks "Are you sure?"

3) Click the [Yes] button.

Approximately 15 seconds later, "BioMajesty" startup window is displayed.

"BioMajesty" startup window

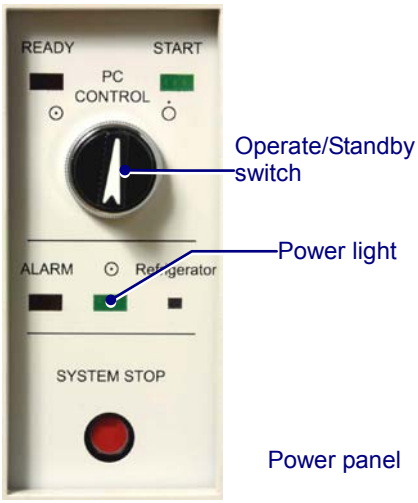
4) Click the [Shutdown] button.

The workstation shuts down and the power gets off. If "PC CONTROL" is selected by the Operate/Standby switch of the Power Panel of the analyzer, the analyzer turns the power off automatically.

Check the power supply status of the analyzer

Check that “PC CONTROL” is selected by the Operate/Standby switch and the power light is off in the Power Panel of the analyzer.

If ⊙ (ON) is selected by the Operate/Standby switch, turn it to ○ (OFF) once and then select “PC CONTROL”. If “PC CONTROL” is not selected, the analyzer does not turn on or off automatically with the workstation.



Turn the power off the workstation.

Workstation

The display and printer turn off automatically if their power supply is synchronized with the computer. If not, turn the individual switch off.

Shutdown the pure water supply unit

Follow the instruction of your pure water supply unit to end the unit. Close the main cock for safety.

CAUTION

Be sure to close the tap water supply cock during night hours when no users are present, as well as on holidays. The water pressure may be elevated, resulting in water leaks at the connections, which may cause water damage on the system.

Clean the environment of the analyzer

1) **Clean the floor around the analyzer with a vacuum cleaner.**
2) **Take care of the sample cups and other materials properly.**

4.14 Maintenance

Appropriate maintenance should be performed regularly as well as occasionally as required. Refer to “Chapter 7 Maintenance” for details.

CONTENTS

Chapter

5 Optional Functions

CONTENTS

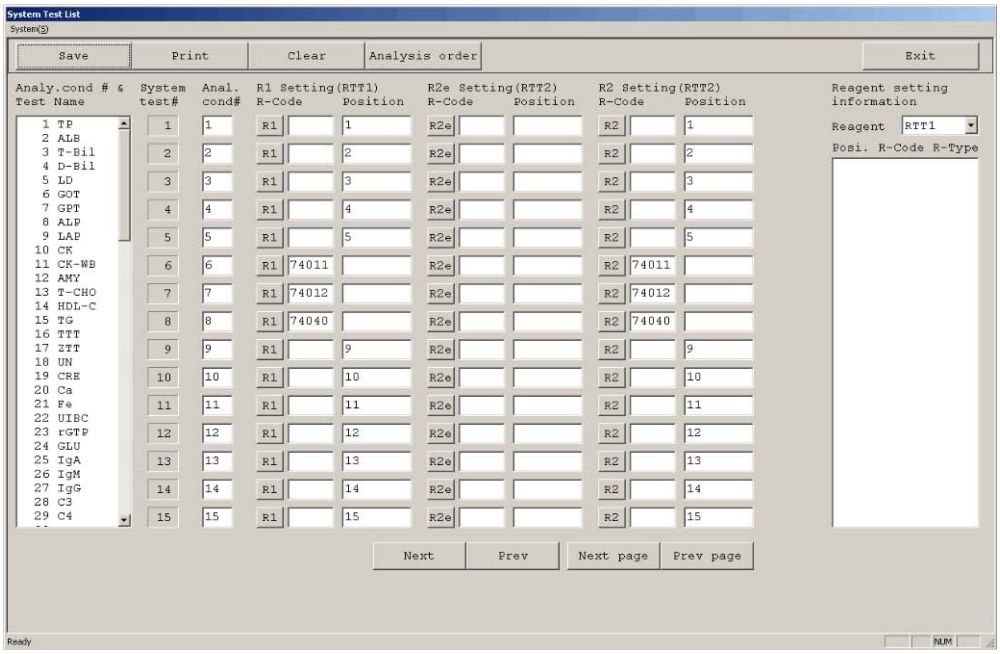
5.1 Handling and Setting Reagent Bottles

5.1.1 Using multiple bottles of a reagent for a test

Setting the analyzer to recognize multiple bottles of the same reagent

Frequently performed tests require larger volumes of reagent than other less often used tests. Therefore, it is practical to have several bottles of the same reagent on the reagent tray (RTT). Follow the steps below to set the analyzer to recognize multiple bottles of the same reagent:

1 Select [Setup] > [System Test List] to open the [System Test List] window.



2 Enter multiple position numbers in the [Position] fields for [R1], [R2e], and [R2] reagent bottles. For instance, if you want to set 3 bottles in positions 5, 6, and 7, enter [5, 6, 7] or [5-7] in the [Position] field.

3 Click the [Save] button in the upper left of the window to save the setting

When you are using reagent bottles with barcode, please see Section 5.1.2.

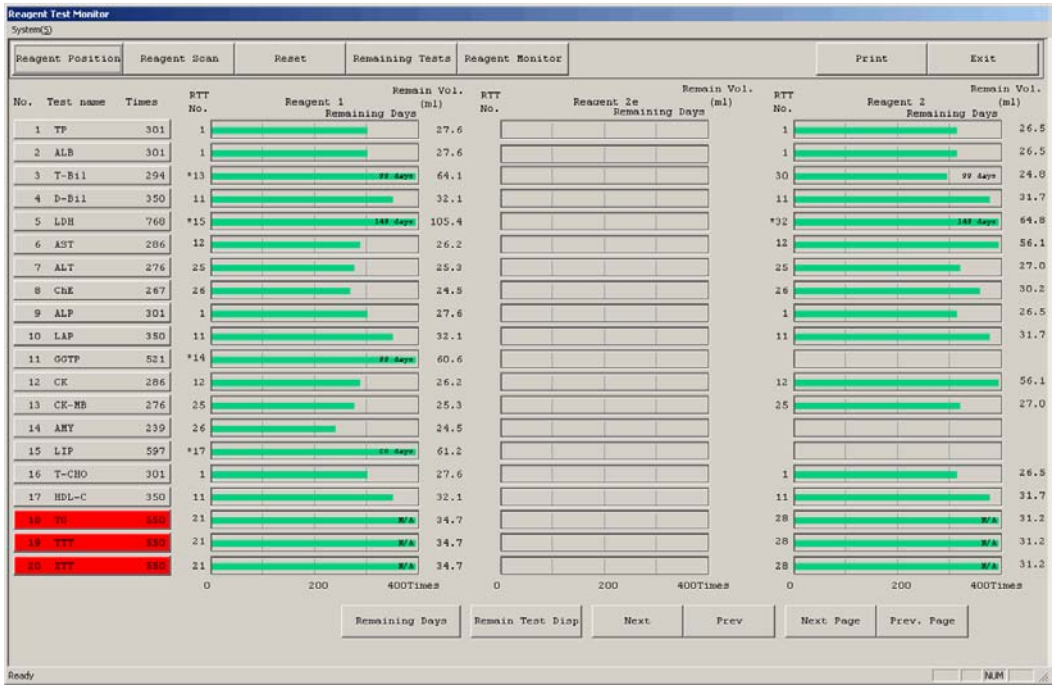
Bottle usage order

When the analyzer starts operation after multiple reagent bottles are set, it begins by using the bottle located at the lowest position number first. When the first bottle becomes empty, the analyzer uses the reagent bottle located at the next lowest position number.

When you replace the reagent bottles, select [Reagent] > [Reagent Test Monitor] and click the [Reset] button then click the [START] button on the Operation Panel. Alternatively, click the [Reagent Scan] button instead of the [Reset] button; after the reagent scan is completed, click the [START] button on the Operation Panel. The analyzer restarts and again uses the reagent bottle located at the lowest position number.

When the [Reset] button is pressed, the analyzer assumes the reagent bottle was replaced. After reset, bottle status is displayed either as "bottle capacity" or "indefinite" according to the selections made in the [Setting System Parameters] > [Reagent Reset] window.

See the details regarding [Reagent Reset] in “Section 5.9 Parameters in the [Setting System Parameters] Window" of this chapter.

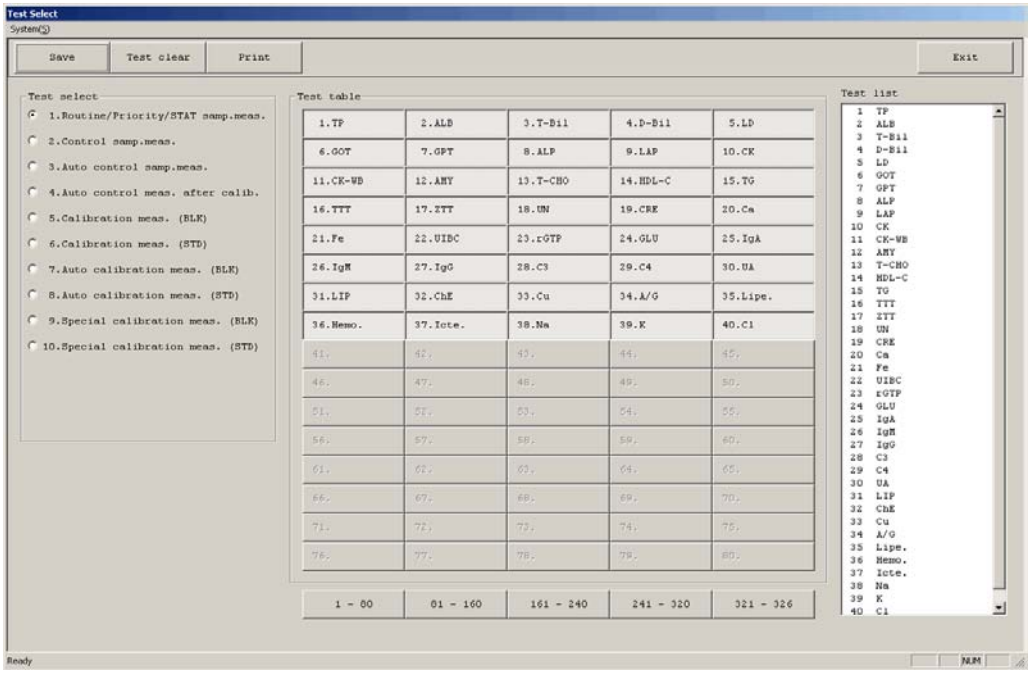


Automatic calibration for a new bottle

Automatic calibration can be selected for a new bottle of reagent when multiple reagent bottles are set for a test.

Select [Calib.] > [Calibration Setup] > [Auto Calibration Setting] for setup. For details, see “Section 5.4 Automatic Calibration and Automatic Control Measurement" of this chapter.

To select tests for automatic calibration, select [Request] > [Test Select]. Select [Auto calibration meas.] in the [Test Select] column then click the test name buttons in the [Test table] column. Auto calibration will be performed on the reagent bottles for the selected tests when the bottle is replaced to a new one.



5.1.2 Barcode on the reagent bottle

Functions of the reagent bottle barcode

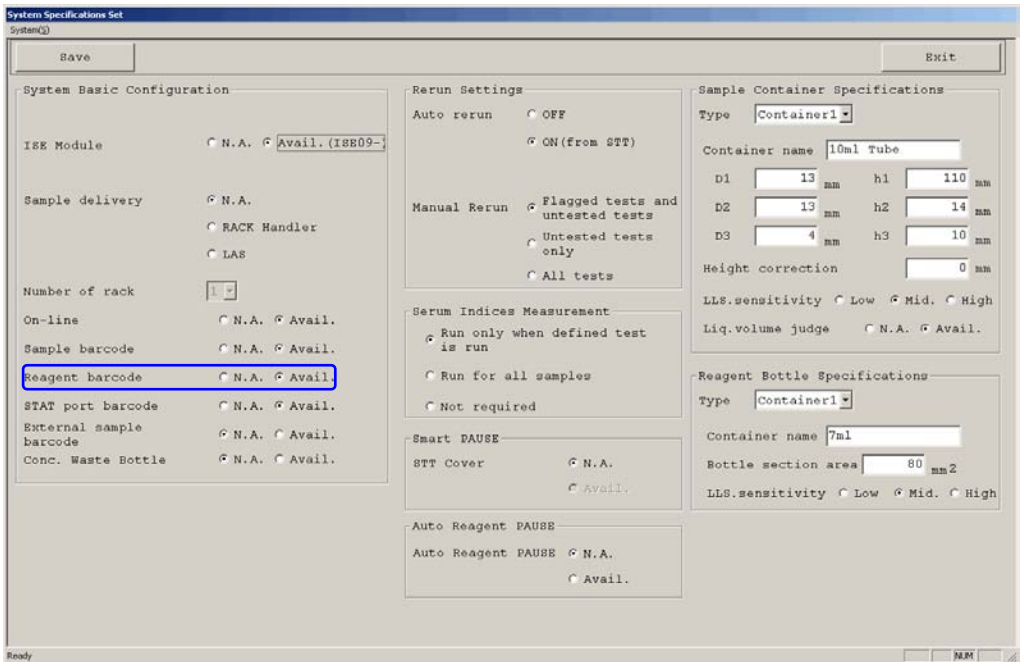
The barcode label placed on the reagent bottle contains information such as the name of manufacturer, test name, expiration date, and bottle capacity.

The following features are available when a bottle is set on the reagent tray (RTT) and the barcode is read.

- The expiration date can be checked on the workstation display.
- Reagent bottles can be set in arbitrary RTT positions.
- The bottle capacity is automatically recognized.

Selecting to use the barcode on the reagent bottle for identification

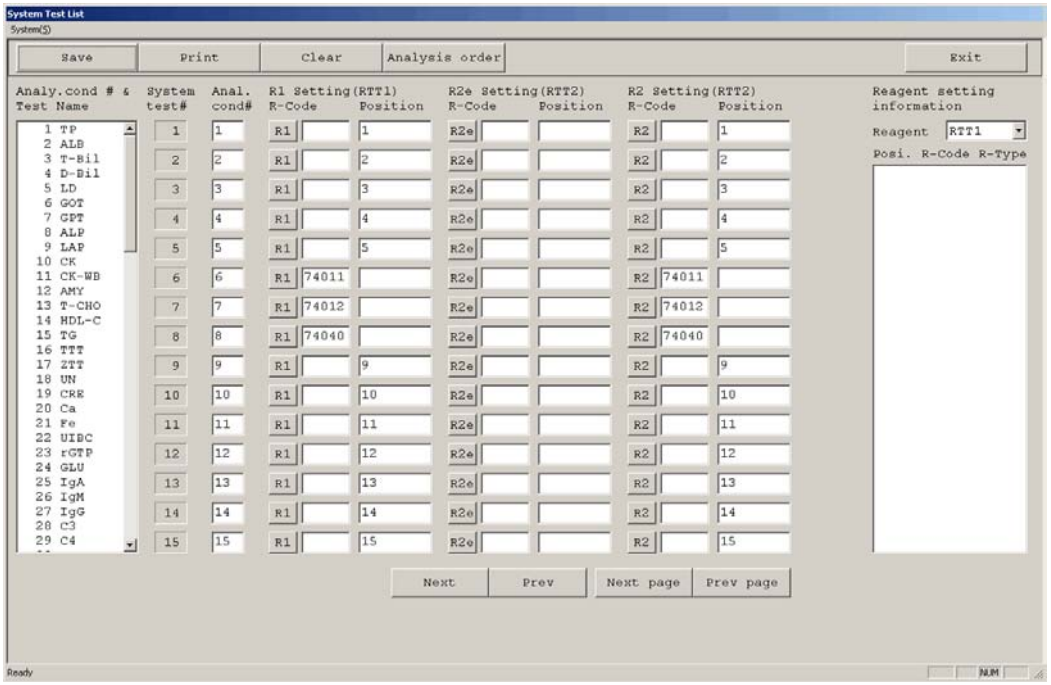
1 Select [Setup] > [System Specification Settings] to display the window below: Select "Avail." for the [Reagent barcode] field in the [System Basic Configuration] column.



2 Define the following values in the [Reagent Bottle Specification] column in the lower right side of the window.

[Type]	[Container name]	[Bottle section area]	[LLS (liquid level sensor) sensitivity]
[Bottle1]	7 mL	80 mm^2	Med.
[Bottle2]	20 mL	300 mm^2	Med.
[Bottle3]	70 mL	850 mm	Med.
[Bottle4]	40 mL	470 mm^2	Med.

3 Select [Setup] > [System Test List] to display the window below:



4 Enter a 5-digit identification number in the [R-Code] field.

Normally, the RTT position where the reagent bottle is placed is entered in the [Position] field of the test. However, when the reagent bottle barcode is used, leave the [Position] field blank but enter a 5-digit number in the [R-Code] field. The first 3 digits correspond to the manufacturer's name and the last 2 digits refer to the test. The manufacturer number can be found on the reagent's package insert. Otherwise, contact the reagent manufacturer.

Reading the barcode on the reagent bottle

Follow the steps below for the analyzer to read the barcode on the reagent bottle.

1 Check that the analyzer is at the halt in the [READY] mode.

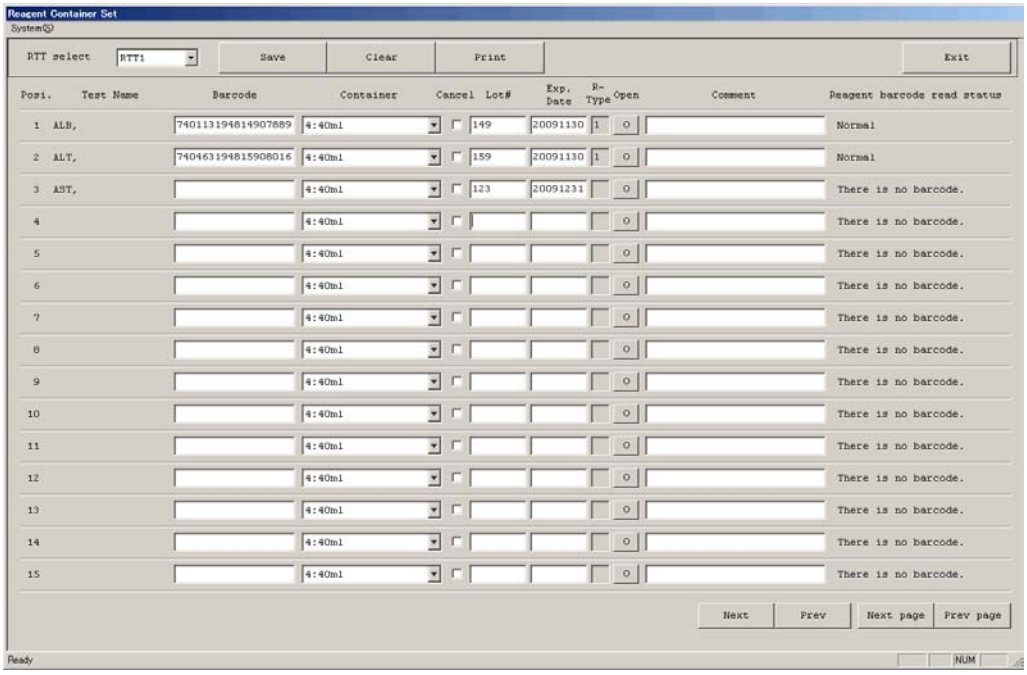
2 Set the reagent bottle on RTT.

You can place reagent bottles with a barcode label in arbitrary positions. You can also set multiple bottles of a reagent used for a test.

3 Select [Reagent] > [Reagent Test Monitor] and Click the [Reagent Scan] button.

As the RTT rotates, each reagent bottle barcode is read.

4 Select [Reagent] > [Reagent Container Set] to open the window below.



When the reading is complete, the following data are shown for each RTT position.

[Test Name]	Name of the test to which the reagent is allocated after reading.
[Barcode]	Code readout (simple enumeration)
[Container]	Bottle capacity identified by barcode
[Exp.Date]	Expiration date of the reagent
[R-Type]	Type of the reagent (R1, R2e, or R2)

Barcode reading enables automatic identification of the RTT position of the reagent bottle. After the barcodes have been read, measurement can begin as usual.

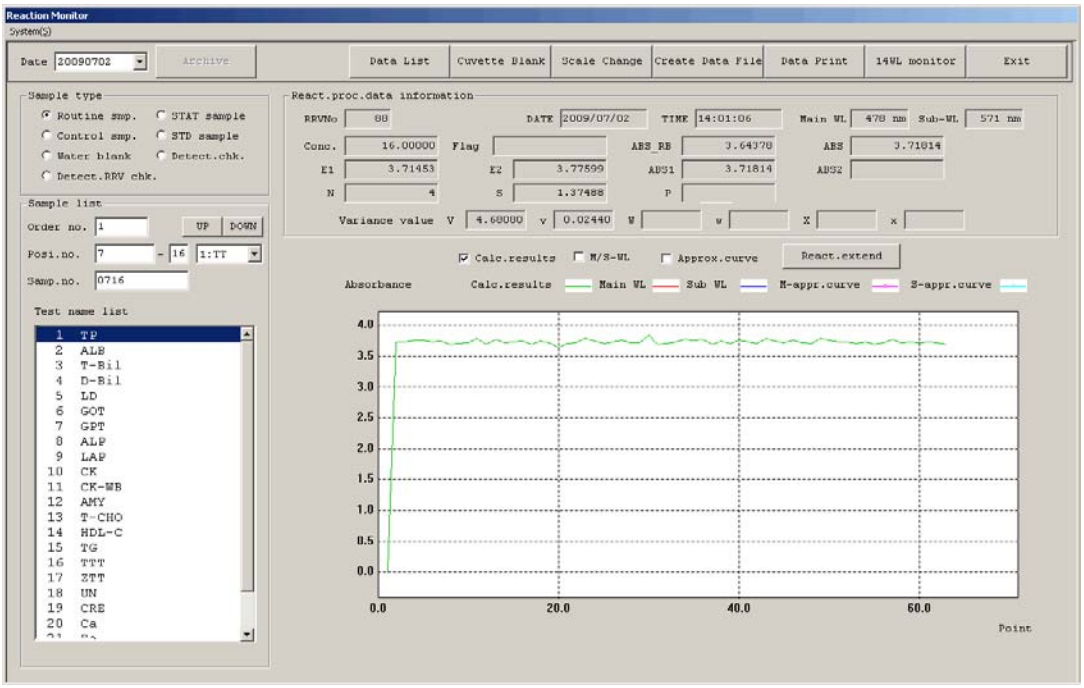
5.2 Checking the Data

5.2.1 Checking the reaction time course

Every 13.5 seconds, multiple spectrophotographic measurements are taken throughout a standard reaction process using all 14 wavelengths. In a standard reaction process, there are 63 total possible data points; if the reaction process is prolonged, there will be 134 data points.

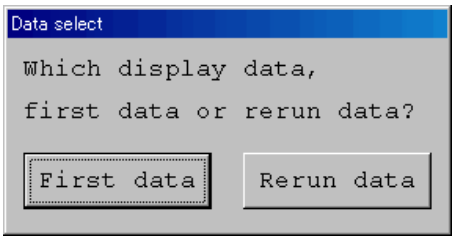
Window to check the reaction time course

1 Select [Request] > [Reaction Monitor] to display the window below:



2 Enter values in the [Sample type] and [Sample list] columns.

3 Click the test to check the reaction time course in the [Time name list] column.



If a test is performed only on the initial run, the time course is displayed immediately in the right side of the window.

If a test is performed on both the first run and the rerun, the dialog box on the left is displayed. Select either [First data] or [Rerun data] for display.

4 Select [Calc.results], [M/S-WL], or [Approx.curve] as required.

5 Press the [Data List] button on the top bar to show the measurement values.

6 Click the [Cuvette Blank] button to display the cuvette blank value used for the calculation.

7 Click the [14WL monitor] button to open the [14WL monitor] window. The reaction time courses are displayed for the 14 wavelengths including the one used for the calculation.

Change the value in the [Display conditions] column in the [14WL monitor] window, and then click the [Display switch] button to display the revised time course.

Data point time course

The following table lists each data point and the exact time obtained from the beginning of the reaction.

Measurement point	Time (s)	Remarks	Measurement point	Time (s)	Remarks
		−4.94 seconds, R1			
1	-1.765	6.77 seconds, sample, Mix1	72	1037.735	
2	11.768	Diluent aspiration	73	1051.268	
3	25.300		74	1064.800	
4	38.833		75	1078.333	
5	52.365		76	1091.865	
6	65.898		77	1105.398	
7	95.294	108.13 seconds, R2	78	1134.794	
8	108.827	Mix2	79	1148.327	
9	122.359		80	1161.859	
10	135.892		81	1175.392	
11	149.424		82	1188.924	
12	162.957		83	1202.457	
13	176.489		84	1215.989	
14	190.022	3-min reaction	85	1229.522	
15	203.554		86	1243.054	
16	217.087		87	1256.587	
17	230.619		88	1270.119	21-min reaction
18	244.152	4-min reaction	89	1283.652	
19	286.094	298.58 seconds, R3	90	1325.594	
20	299.627	Mix3	91	1339.127	
21	313.159	5-min reaction	92	1352.659	
22	326.692		93	1366.192	
23	340.224		94	1379.724	
24	353.757		95	1393.257	
25	367.289		96	1406.789	
26	380.822		97	1420.322	
27	394.355		98	1433.855	
28	407.887		99	1447.387	
29	421.420		100	1460.920	
30	437.283		101	1476.783	
31	450.816		102	1490.316	
32	464.348		103	1503.848	
33	477.881		104	1517.381	
34	491.413		105	1530.913	
35	504.946		106	1544.446	
36	518.479		107	1557.979	
37	532.011		108	1571.511	
38	545.544		109	1585.044	
39	559.076		110	1598.576	
40	572.609		111	1612.109	
41	586.141		112	1625.641	
42	599.674	10-min reaction	113	1639.174	
43	628.083		114	1667.583	
44	641.616		115	1681.116	
45	655.148		116	1694.648	
46	668.681		117	1708.181	
47	682.214		118	1721.714	
48	695.746		119	1735.246	
49	709.279		120	1748.779	
50	722.811		121	1762.311	
51	736.344		122	1775.844	
52	749.876		123	1789.376	
53	763.409		124	1802.909	
54	779.273		125	1818.773	
55	792.805		126	1832.305	
56	806.338		127	1845.838	
57	819.870		128	1859.370	
58	833.403		129	1872.903	
59	846.935		130	1886.435	
60	860.468		131	1899.968	
61	874.000		132	1913.500	
62	887.533		133	1927.033	
63	901.065	15-min reaction	134	1940.565	31-min reaction
		Washing			Washing

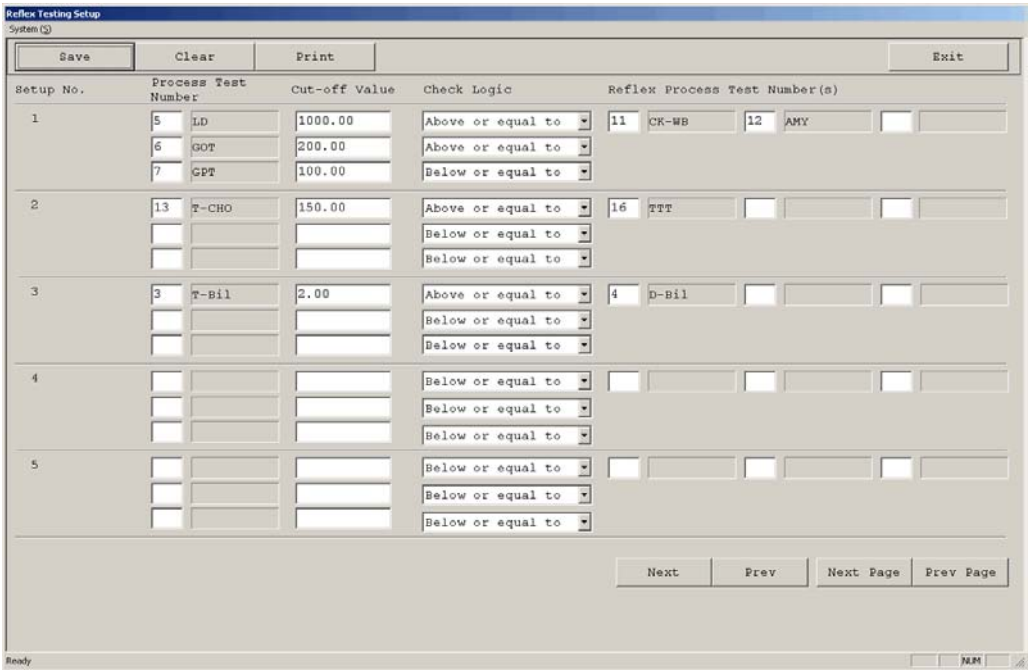
5.2.2 Reflex test

What is a reflex test?

A reflex test is a test which was originally unordered but is automatically performed on the basis of the result of an ordered test (primary test). Follow the steps below to schedule a reflex test.

Setting the reflex test function

Select [Setup] > [Reflex Test Settings] to open the [Reflex Testing Setup] window.



The following values are defined regarding the primary and reflex tests.

[Setup No.] Enter a setup no. (1 - 30)

[Process Test No.] Enter the process sequence number of the primary test. Up to 3 process sequences can be defined for a “Setup No.”

[Cut-off Value] Enter the reference value for judgment.

[Check Logic] Select either "Below or equal to" or "Above or equal to."

[Reflex Process Test Number(s)]
Enter the process sequence no. of the reflex test(s). Up to 3 tests can be defined for a setup.

When the primary test result meets all the conditions defined for a setup, the tests defined in the [Reflex Process Test Number(s)]] field are performed.

Performing a reflex test

A reflex test is automatically ordered when the primary test result meets the conditions for performing a reflex test. When the test to be added as reflex was already performed on the sample, the test is automatically excluded. Select [Setup] > [System specification settings]. If "STT rerun" is selected for [Auto.rerun] in the [Basic System Operation Mode] column, the reflex tests are automatically performed at the rerun sequence. The result obtained by the reflex test is considered to be the initial run data because the result of the reflex test was obtained for the first time. However, in this case, the automatic re-rerun will not be performed.

The reflex test results are sent to the LIS. However, in order to save the data in the LIS , a storage destination must be defined there.

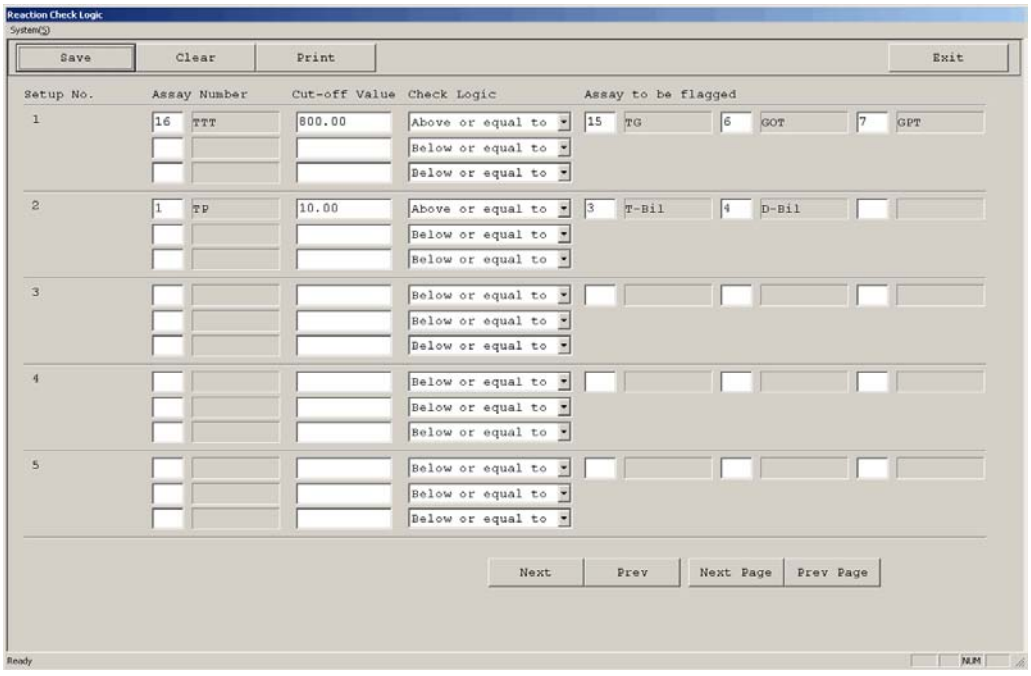
5.2.3 Setting reaction check logic

What is reaction check logic?

In evaluating the result of a test (primary test), the measurement values of another test may be useful. This test method is called reaction check logic. If selected, another related tests are automatically ordered when the primary test is ordered. When results (e.g. concentration, activity) of those tests are outside the reference range, they are taken into consideration for evaluation of the primary test result. Furthermore, an automatic rerun of the primary test can be set to be triggered by abnormal results from the reaction check logic.

Setting reaction check logic

Select [Setup] > [Reaction Check Logic] window for settings.



[Setup No.]	This number defines a set of tests (assays). Up to 30 sets can be defined.
[Assay Number]	Select another tests to be checked for reaction check logic (up to three) which will be ordered automatically when a primary test is ordered. To select a test, enter the “Process sequence number”.
[Cut-off Value (Conc.)]	Enter a threshold value (e.g. concentration, activity).
[Check Logic]	Select either [Above or equal to] or [Below or equal to] as judgment criteria.
[Assay to be flagged]	Enter the test number (“Process sequence” number) of the primary test(s). Up to three primary tests can be defined. All the tests to be checked for reaction check logic will be automatically ordered if at least one of these tests is ordered. If the result of one or more tests is out of the range defined in the [Cut-off Value] and [Check Logic] fields, the results of all the corresponding primary tests are flagged with "J".

Setting up an automatic rerun order

An automatic rerun can be selected for the primary test, triggered by abnormal values of the reaction check logic results. Select [Setup] > [Analytical Parameters (Chemistry)] > [Rerun conditions set] to open the [Rerun Conditions Set] window. For [Reaction Check Logic (J)], select the dilution condition (s) from [M] to [D4] as required (Multiple conditions can be selected).

When the results are marked with a "J" flag, a rerun is ordered for the primary test.

Example

See "Setup no.1" in the [Reaction Check Logic] window above as an example of how this feature works.

If the TG test result is a high value, the sample suggests the patient may have hyperlipidemia. The presence of hyperlipidemia may then affect the results of the HDL-C, AST, and ALT tests depending on reagent.

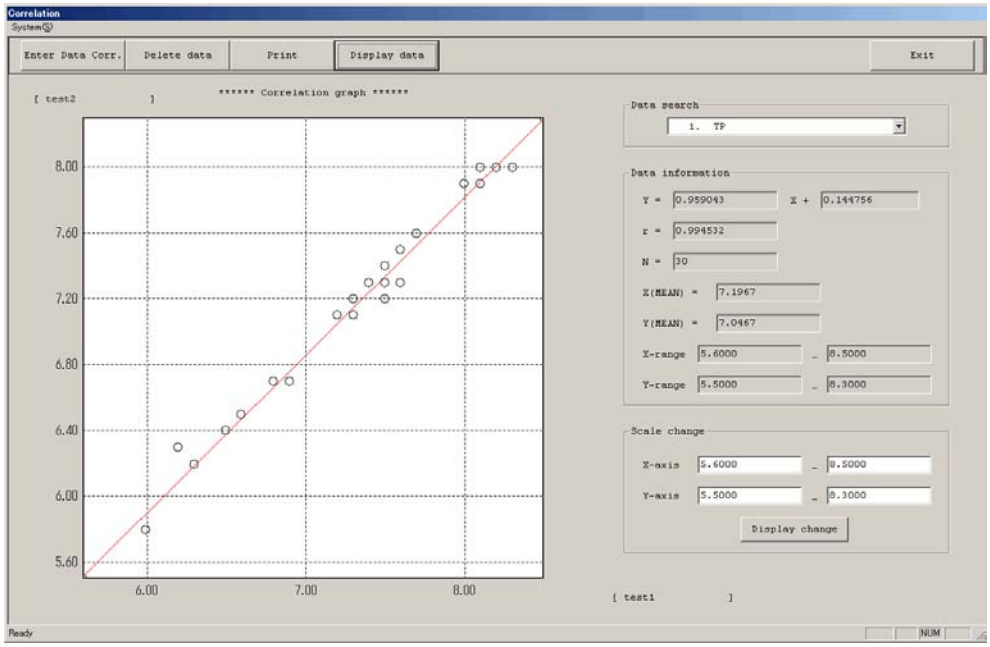
In the example above, when at least one of the three tests HDL-C, AST, and ALT is ordered, the TG test is automatically ordered as well. When the results of the TG test are $\geq$ 800 (mg/dL), the results of the HDL-C, AST, and ALT tests are all flagged with a "J". The "J" flag signifies that the TG test, the tests used for reaction check logic, shows a high value therefore the attention should be paid for the results of the HDL-C, AST, and ALT tests.

5.2.4 Generating correlation graph

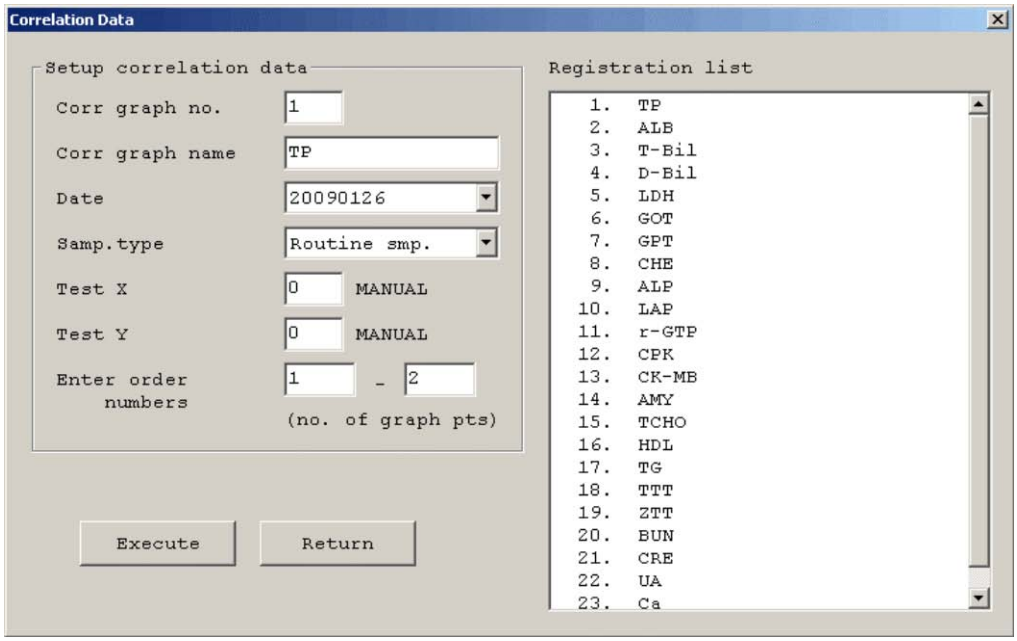
A graph can be generated showing data correlation between two tests performed with the BM6010/C. In addition, a graph can be generated showing data correlation between a test performed with a BM6010/C system and a test performed with another analyzer. Up to 100 correlation graphs can be generated; up to 1,000 data points can be integrated in the correlation graphs.

Steps for generating a graph are as follows:

1 Select [Request] > [Correlation] to display the window below.



2 Click the [Enter Data Corr.] button to display the window below.



The [Registration List] column shows the graphs already stored in the system.

3 Enter the values in the following fields:

[Corr graph no.]	Enter a number from 1 to 100 which is not listed in the [Registration List].
[Corr graph name]	Enter the name of the correlation graph.
[Date]	Select a measurement date.
[Samp.type]	Designate a sample type.
[Test X,Y]	Enter a test number in each field to generate a correlation graph between them. When you manually enter the data obtained in another system as shown in Step 9, leave these fields blank.
[Enter order numbers]	Enter the range of data to show in the graph. Use the number shown in the [Order no.] field in the [Order Entry] window.

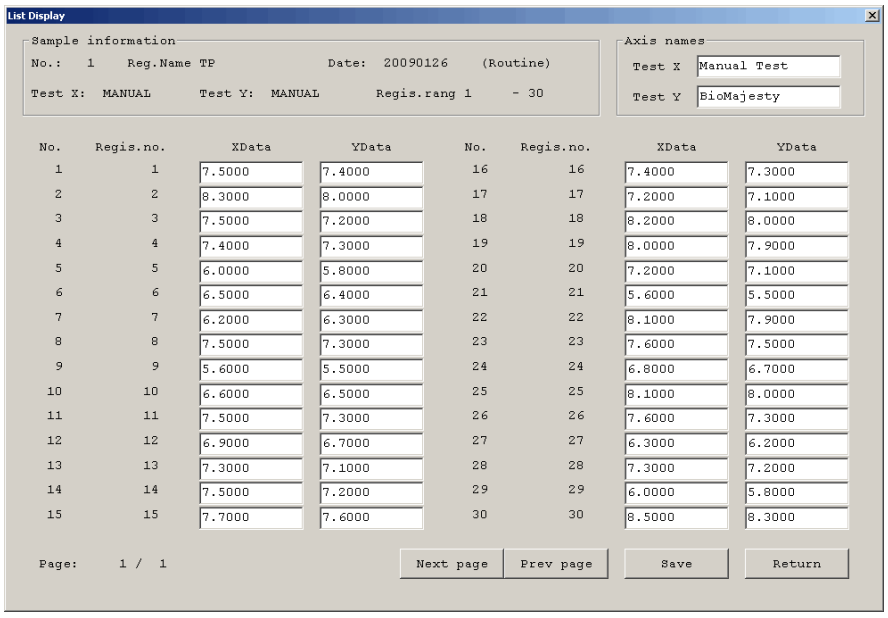
4 Click the [Execute] button to generate and save a new correlation graph. When using the external data, the graph is not generated at this step. Please refer to Step 9.

5 Click the [Return] button in the [Correlation data] window to close it.

6 Select the newly generated graph name in the [Data search] column in the [Correlation] window.

The generated correlation graph is displayed.

7 Click the [Display data] button to display the window below.



The data used for the correlation graph are displayed.

8 Enter the [Axis names].

9 When using the data of another analyzer, enter the values in the [Xdate] and [Ydata] columns.

You can also edit the data here if required.

Click the [Save] button to close the window. The correlation graph and related data are displayed. You can change the display scale using the [Scale change] column.

5.2.5 Automatic cuvette skipping based on the cuvette blank value

Measurement and registration of the cuvette blank value

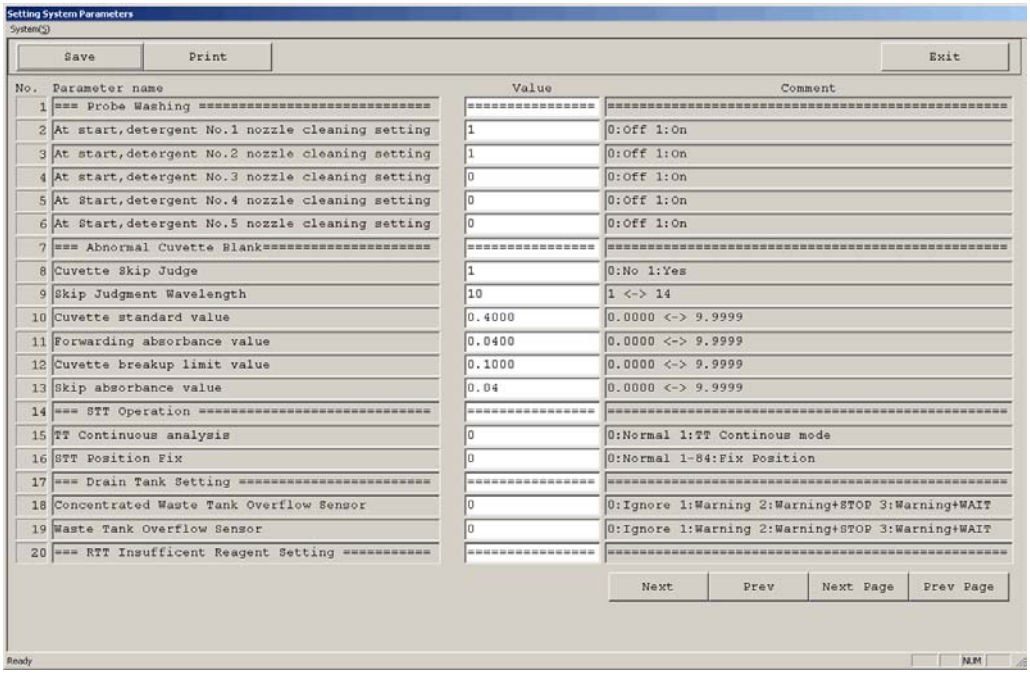
Select [Maint.] > [User Maintenance] to perform measurement and registration of a cuvette blank value. Cuvette blank value of each cuvette is measured and registered. When the obtained cuvette blank value deviates significantly from the mean of all cuvette blank values, an "H" or "L" flag is shown with the value; this cuvette is not used for measurement which is called automatic cuvette skipping. The decision to skip the cuvette is made using data generated from all wavelengths.

Pre-measurement judgment of the cuvette blank value

Before starting each sample measurement, the analyzer measures the cuvette blank value and compares it with the corresponding values already registered in the process described above. If a cuvette has a blank value that differs significantly from the registered value, it is not used for further measurements. Cuvette blank measurement made before analysis starts are analyzed using the wavelength specified in the [Setting System Parameters] window.

Setting limits for cuvette blank values

The following parameters used for the deciding whether to skip a cuvette blank are selected in the [Setup] > [Setting System Parameters] window.



[Cuvette Skip Judge] Select whether to skip or retain a cuvette with an abnormal pre-measurement blank value. Enter either “0” to retain the cuvette or “1” to skip the cuvette. ““1” is the default value.

[Skip Judgment Wavelength] Select a wavelength (“1”-“14”) to obtain the pre-measurement cuvette blank value for judgment. "10" (694 nm) is the default value.

[Cuvette standard value] Cuvette blank values of all cuvettes are measured in sequence. The median of the blank values of all cuvettes is calculated, and the deviation between the median and the blank value of each cuvette is evaluated. If a cuvette has a blank value that differs from the median by more than the value entered here, the cuvette is excluded from routine analysis. In other words, this value indicates the limit of the difference between a measured blank value and the median. "0.4" is the default value.

[Forwarding absorbance value] The cuvette blank is measured after each sample measurement to calculate absorbance. This measured cuvette blank value is compared with the previously obtained value for the cuvette. If the difference is equal to or greater than the value entered here, the cuvette blank is skipped and the previously obtained value is used instead. "0.04" is the default value.

[Cuvette breakup limit value] The cuvette blank is re-measured after each sample measurement to calculate absorbance. The cuvette

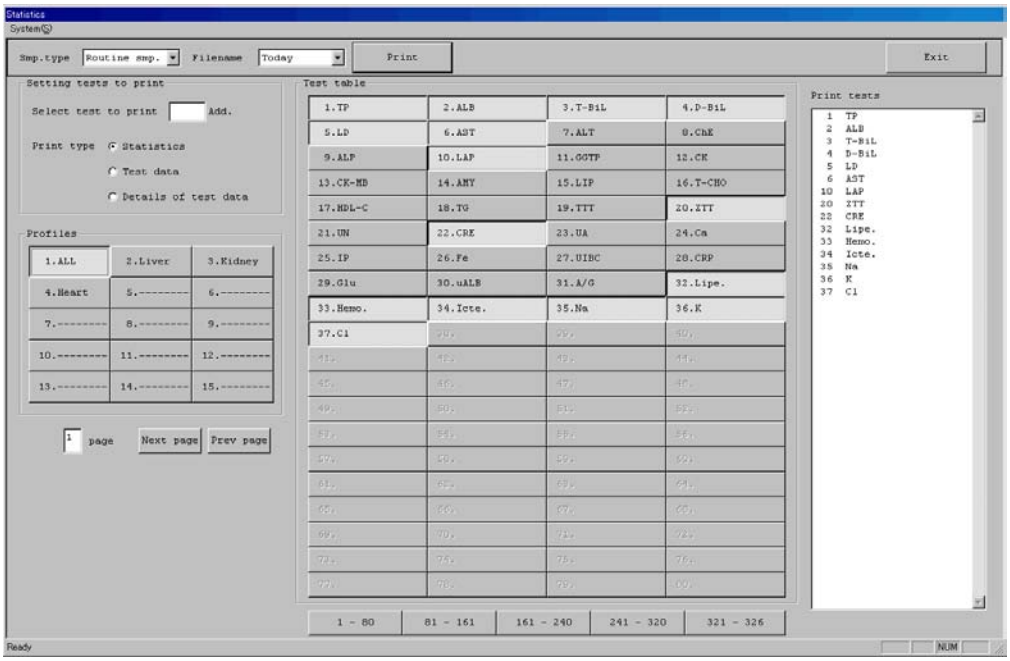
blank value is the mean value of two replicate measurements obtained by the detector. If the difference between the two measurements is equal to or greater than the value entered here, the sample data is flagged with "N". "0.1" is the default value.

[Skip absorbance value] The cuvette blank value from a previously used (now washed) cuvette is evaluated for abnormality before it is used for measurement. If the difference between the pre-measurement cuvette blank value and that entered in the [User Maintenance] window is equal to or greater than the value entered here, the cuvette is not used for measurement. "0.04" is the default value.

5.2.6 Displaying statistical information

The [Statistics] window provides statistical data including the mean, minimum, and maximum values.

Select [Request] > [Statistics] to display the window below. Define the items below.



Items in the upper left fields

[Smp.type] Select either [Routine sample] or [STAT sample].

[Filename] Select from the past seven measurement days including the current day.

Items in the [Setting tests to print] column

[Select test to print] Enter a number and a period (.) shown in the [Test table], or click a test shown in the [Test table] column. The selected tests are shown in the [Print tests] column in the right side of the window.

The tests can also be selected using the [Profile] column.

[Print type] Select from [Statistics], [Test data], or [Details of test data].

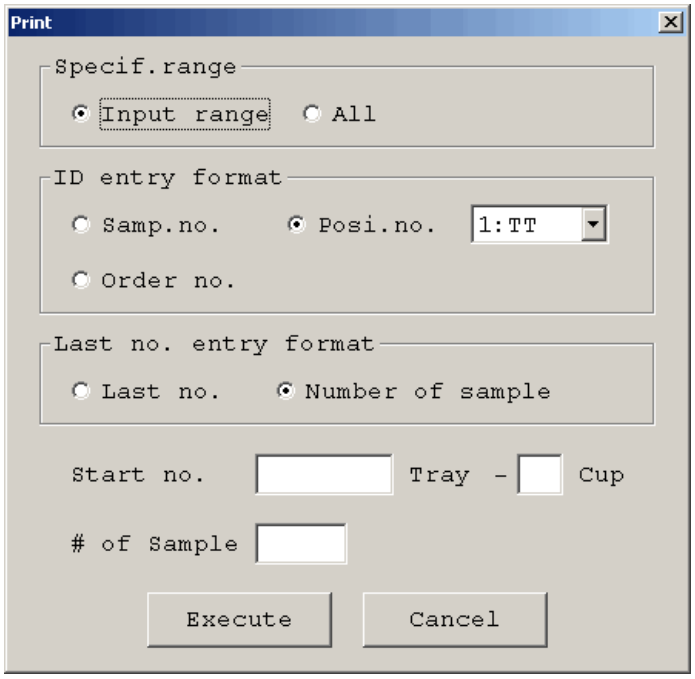
[Statistics] Print the values of average, maximum, minimum, difference, standard deviation, and coefficient of variation for ABS-R, ABS, ABS1, ABS2, E1, and E2 respectively.

[Test data] Print the values of average, maximum, minimum, difference, standard deviation, and coefficient of variation of the concentration.

[Details of test data] Print the measurement data and the values of average, maximum, minimum, difference, standard deviation, and coefficient of variation of the concentration.

[Print] button

Click this button to display the window below. Use this window to specify the printing range and submit a printing order as below.



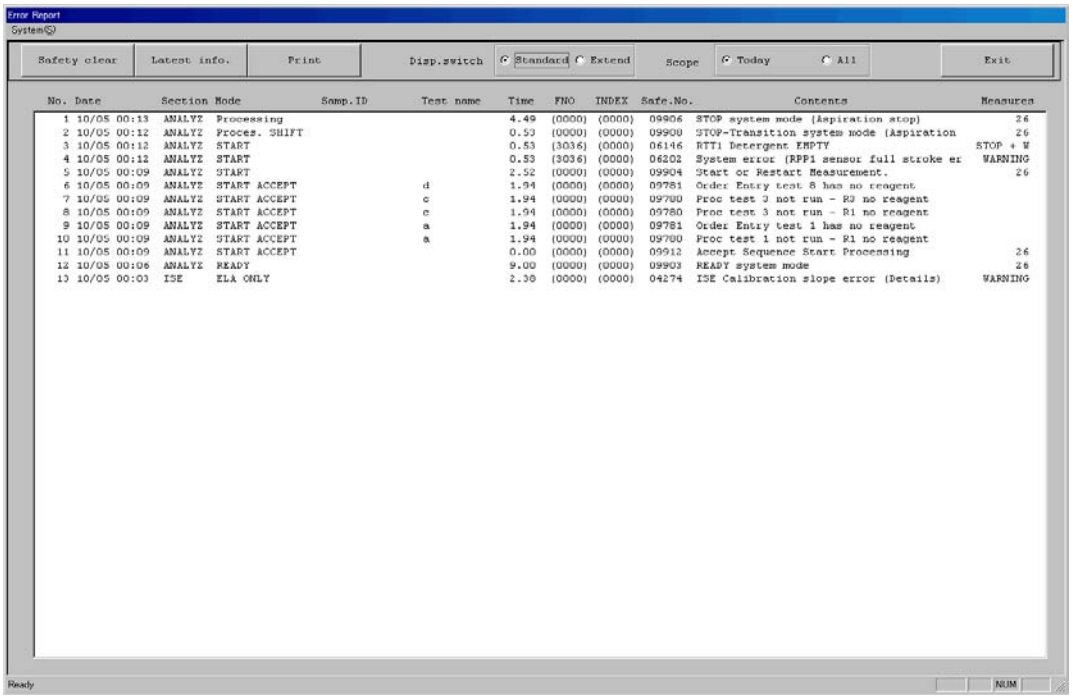
[Specif.range] Select either [Input range] or [All].

[ID entry format]	Select a format to specify the printing range. Options are [Samp.no.], [Posi.no.], or [Order no.]. If you select [Posi.no.], also select either [1:TT] or [2:RACK].
[Last no. entry format]	Select a format to specify the end of the printing range. Options are [Last no.] and [Number of sample].
[Start no.] [Last no.]	If you select "Last no." for [Last no. entry format] above, the [Last no.] field will appear. Enter a first data number in the [Start no.] field and the last data number in the [Last no.] field to specify the printing range.
[Execute]	Click this button to submit the printing order.

5.3 Error Report

In case of an error during analyzer operation, the following information is logged in the [Error Report] window: date, system mode, error code (Safe. no. in GUI), content, as well as the behavior and operation of the analyzer. Select [Maint.] > [Error Report] to display the window below.

Display options and scope can be selected with the radio buttons in the [Disp.switch] and the [Scope] fields in the top bar of the window. The items included in the error reports are as follows:



[Disp.switch]

Two display formats are available.

[Standard]	Items related to error incidence, system modes, and the operation order are displayed.
[Extend]	More detailed contents are displayed.

[Scope]

Two options are available for the date range.

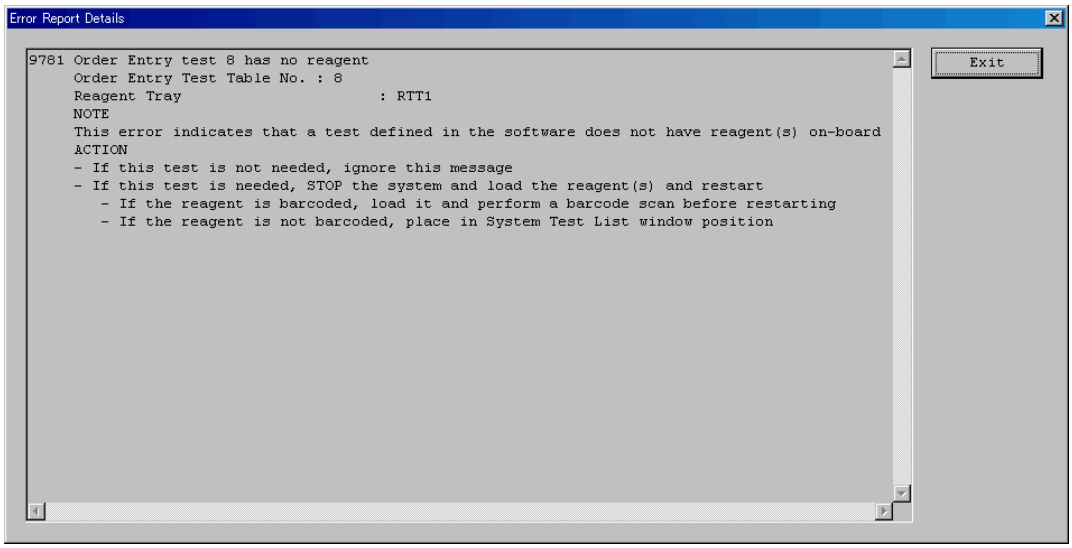
[Today]	Incidences on the current day are displayed.
[All]	Up to 10,000 past incidences are displayed.

Items included in the error report

[No.]	The previous incidences (up to 10,000) are numbered in reverse chronological order.

[Date]	Time and date of occurrence
[Section]	Unit related to the error (e.g. analyzer, workstation)
[Mode]	System mode in which the error occurred
[Samp.ID]	ID of the sample under measurement when the error occurred.
[Test name]	Name of the test being performed when the error occurred.
[Time]	Error occurrence time counted from the start of the corresponding measurement.
[FNO]	Function number of operation of the unit related with the error. This information is just for JEOL service engineers.
[INDEX]	Internal number of the error processing. This information is only for JEOL service engineers.
[Safe.No.]	Error code
[Contents]	Content of the error
[Measures]	Behavior of the system when the error occurred

You can check the detailed contents of each error. Move your mouse over the error listed and double click the left button of the mouse to display the [Error Report Details] window as below. The countermeasure is indicated under “ACTION.”



5.4 Automatic Calibration and Automatic Control Measurement

5.4.1 Automatic calibration

Types of automatic calibration

Two types of automatic calibration are available on the BM6010/C analyzer.

- Calibration after reagent bottle switch

  When multiple bottles of a reagent for a test are set to the reagent tray, calibration for the test is automatically performed whenever a bottle is switched to a new one. Automatic measurement of the control sample can also be set following calibration.

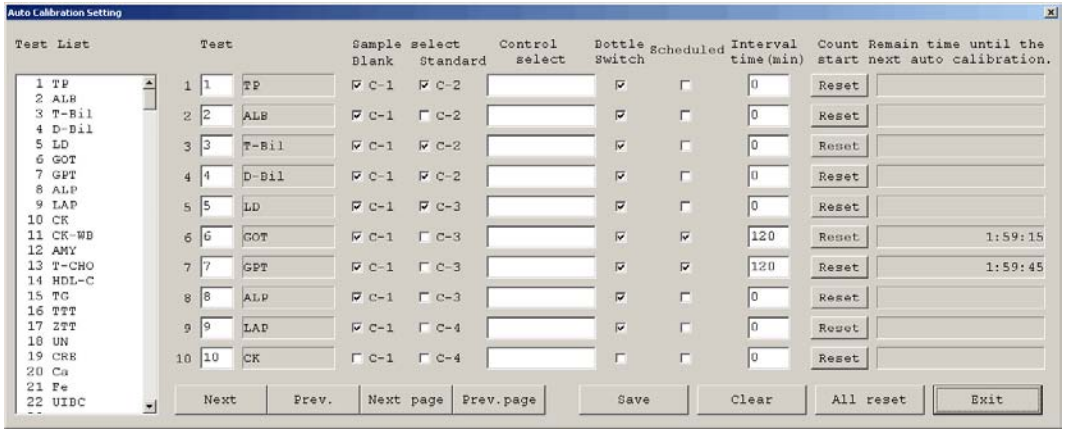
- Scheduled calibration

  The calibrator placed in the refrigerated tray is automatically measured at pre-defined intervals. Automatic measurement of the control sample can also be set following calibration. The system calculates the interval regardless of the operation status of the analyzer unless the power is turned off (the workstation is shut down). When the analyzer restarts after a system shutdown, calibration is automatically performed.

Setting automatic calibration

1 Select [Calib,] > [Calibration Setup] to display the [Calibration Setup] window.

2 Click the [Auto calib.set] button on the top bar to open the window below.



3 Setup [Blank], [Standard], and [Control select] for each test. Enter a control name in the [Control select] field that is measured at the same time with the calibrator.

4 Setup the calibration after bottle switch.

Click the box [✓] for [Bottle Switch] to perform an automatic calibration of the test when starting to use a new bottle.

5 Set scheduled calibration.

Enter a value for [Interval time (min.)] and check the box under the [Scheduled] header to start countdown of calibration time.

6 Click the [Save] button to save the entered values and close the [Auto Calibration Setting] window.

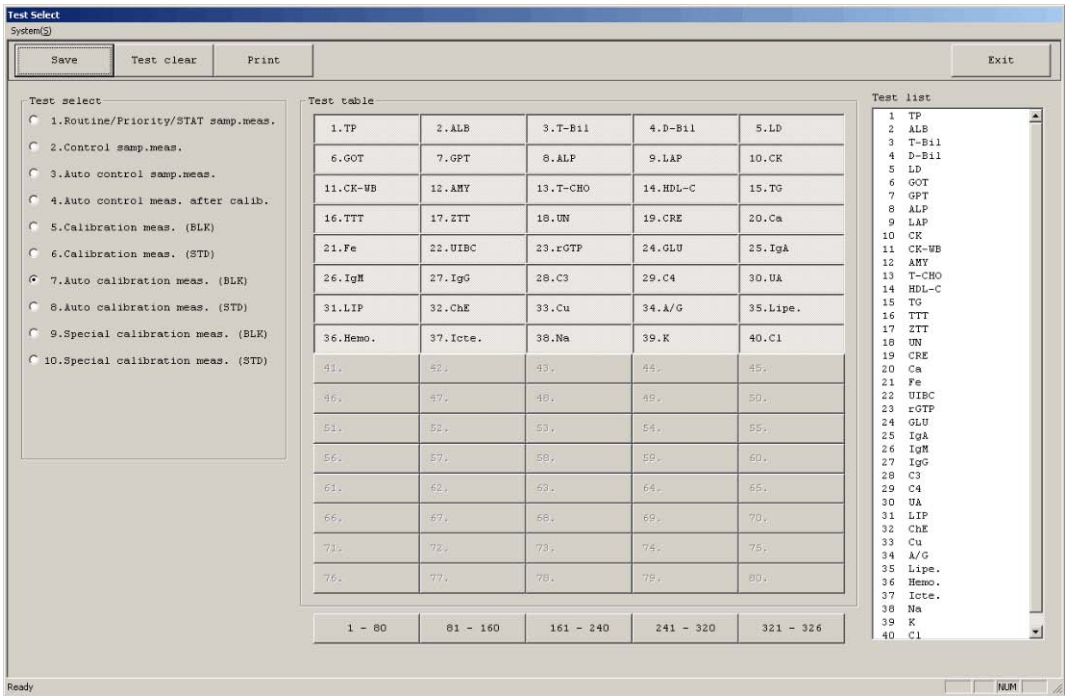
The positions of calibrators are the same as defined in the [Calibration Setup] window.

Activating automatic calibration

1 Select [Request] > [Test Select]. Select tests for [Auto calibration meas.(BLK)], [Auto calibration meas.(STD)], and [Auto control meas. After calib.] respectively in the [Test Select] window.

Automatic calibration and control measurement that follows will be performed only for the selected tests.

2 Click the [Exit] button to save the settings and close the [Test Select] window.



Scheduled calibration

With scheduled calibration, calibration is automatically performed at the specified interval. Once a calibration is complete, a new countdown starts for the next calibration.

When a scheduled time for calibration arrives but the analyzer is not in the analysis sequence, an automatic calibration is performed when the analyzer begins a new analysis sequence.

If a routine calibration is performed before the scheduled automatic calibration, scheduled automatic calibration will not be performed for the tests that were covered by the routine calibration. After completion of the automatic calibration, a new countdown starts for the next calibration.

5.4.2 Automatic control measurement

Test count for automatic control measurement

The automatic control measurement function allows automatic measurement of the control samples set in the refrigerated tray (CTT) after a specified number of tests are completed. The test count is reset when the analyzer is started as a “New Start” from the BM6010/C startup window. If “Re-start” is selected when starting up the system, the count is not reset. Calibrators and QC samples are excluded from the test count.

Setting the test count and tests for automatic control measurement

Select [Setup] > [Setting System Parameters] > [Automatic Control] to set the following parameters for automatic control measurement.

✔ [Automatic Control Counting method (0: Total tests, 1: Number of tests of each items)]

The following two options are available as the subject test to count from the completion of a control measurement to the next automatic control measurement.

"0: Total tests" All the tests defined for the control sample are performed when the test count reaches the number defined in the [# of Tests] field in the [Auto Control] window. ([QC] > [QC Sample Definition] > [Auto Control]) The value for [# of Tests] ranges from 100 to 99999.

"1: Number of tests of each items"

The number of test times is counted separately for each test, but the counting method varies according to the setting of [Auto Control Execution method in Each Assay (0: Each item 1:All items) as explained below.

[Auto.Control Execution method in Each Assay (0: Each item, 1: All item)]

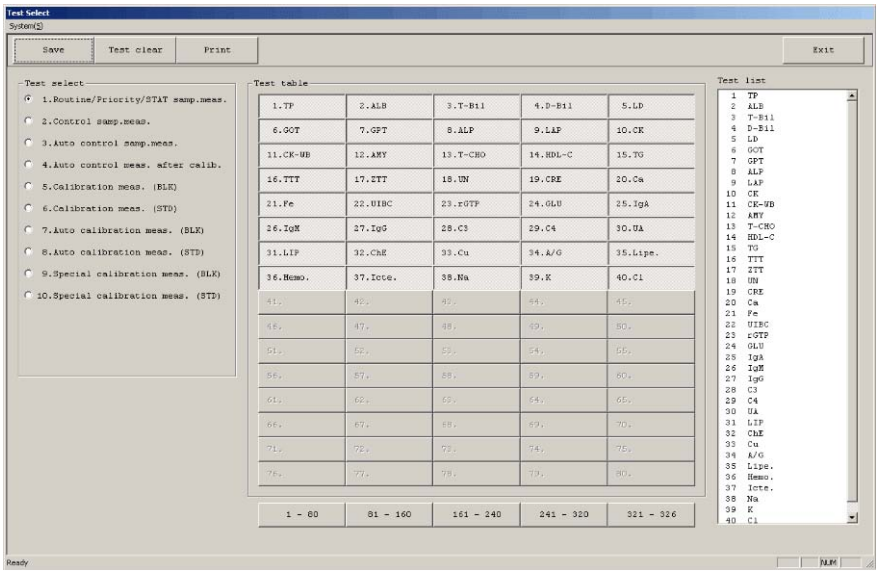
This parameter becomes selectable when "1: Number of tests of each item" is selected for the above [Automatic Control Counting method] parameter.

"0: Each item" The number of times a particular test is performed is calculated; when the count reaches the number entered for [# of Tests], the control measurement is performed for that test alone. Therefore, the same control sample is measured separately for each test, and only the test count for the test for which the QC sample is measured is reset.

"1: All items" The number of times a particular test is performed is calculated; when the count reaches the number entered for [# of Tests], the control measurement registered for the test is performed simultaneously for all the tests using the same control sample type if they have been performed in the course of counting. The control sample is not re-measured for the tests that have not been performed in the course of counting. The value for [# of Tests] can range from 5 to 10000.

Selecting the tests for automatic control measurement, and setting the test interval

1 Tests subject to the auto control measurement are selected as follows. Select [QC] > [Test Select] to display the window below.



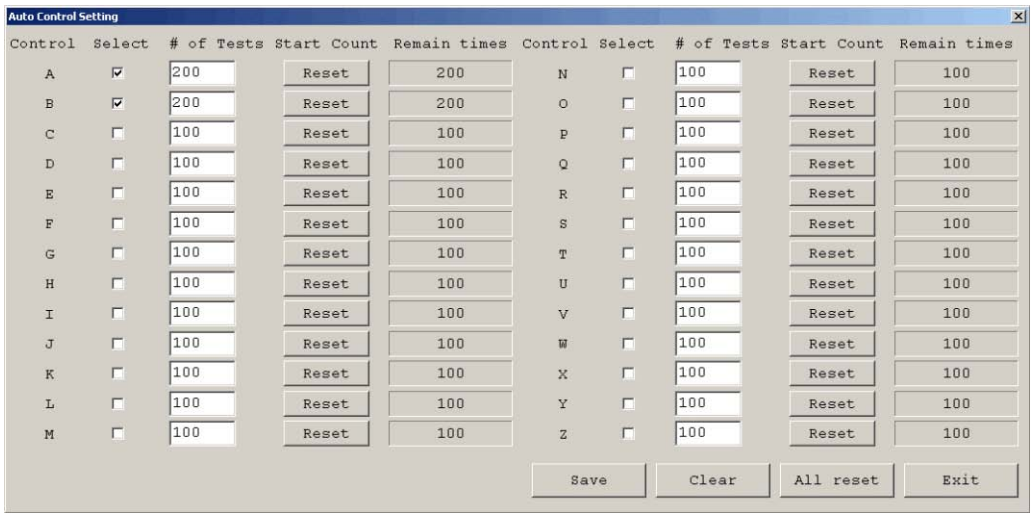
Select "Auto control samp.meas." in the [Test select] column in the left column and then select the tests subject to the automatic control measurement in the [Test Table] column in the middle pane. The selected tests are shown in the [Test list] column in the right of the window.

2 Click the [Save] button in the upper left of the window to save the setting. The automatic control measurement is performed only for the selected tests.

3 Tests performed on the control sample used in the auto control measurement are selected as follows. Select [QC] > [QC Sample Definition] to display the window below.

Select a control ID in the [Ctrl.ID] section, and select tests to perform for each control ID.

4 Click [Auto Control (TOTAL TEST)] button in the top bar to display the window below.



For each control sample, enter the number of test times in the [# of Tests] column that indicates the measurement interval, and click the check box in the [Select] column to show [✓] in it. Click the [Reset] button. Countdown starts in the [Remain times] column.

5 Click the [Save] button in the bottom of the window to save the setting.

Test count for the automatic control measurement

When an automatic control measurement time comes, the control samples are measured. Then, the test count is reset and a new count begins.

Also, when a routine control measurement is performed before the automatic control measurement timing, automatic control measurement is not performed but the [# of tests] gets reset, and a new count starts as if the measurement was performed.

5.5 Checking for Sample Carryover

5.5.1 Checking for sample carryover

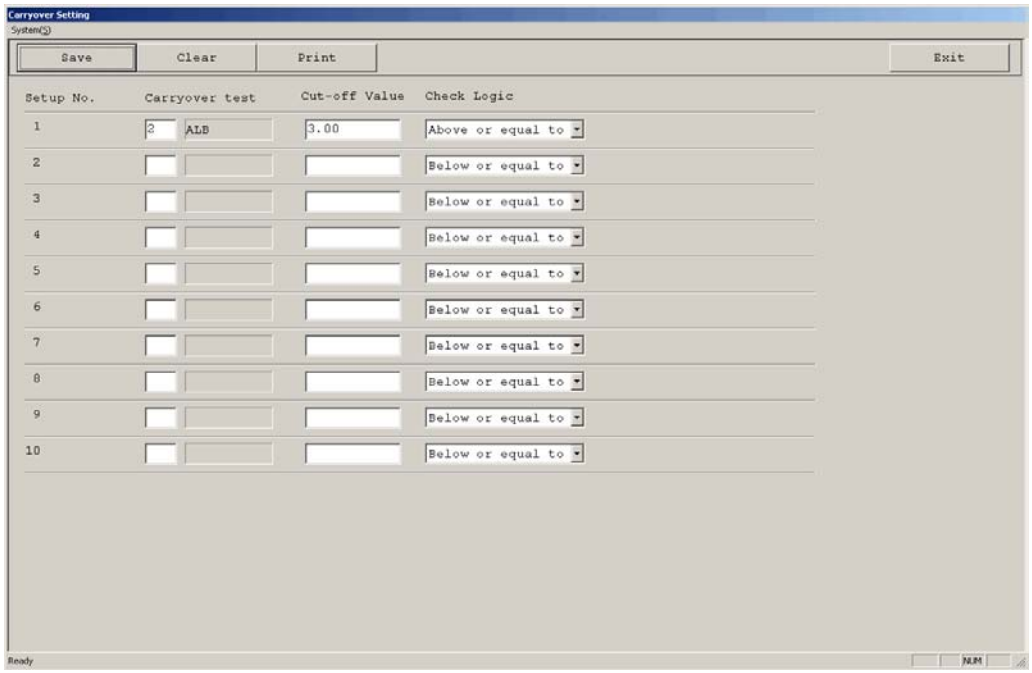
An abnormal measurement value for a sample may result from physical carryover of the previous sample into the reaction cuvette.

Method for the detection of sample carryover

To guard against possible sample carryover, whenever two successive samples show abnormal values for a test, the measurement value of the second sample is flagged. For the flagged sample, an automatic rerun for the test can be performed.

Parameters for carryover detection

Select [Setup] > [Carryover Setting] to define the following parameters in the [Carryover Setting] window.



[Setup No.] Number for a set of tests to check carryover. Up to 10 sets can be defined.

[Carryover test] Specify the test to check for carryover. Enter the test number defined in the [Analy.Con. no] field of the [Analytical Parameters (Chemistry)] window.

[Cut-off Value] Enter a threshold value (e.g. concentration, activity) of carryover. When the measurement values of two successive samples meet the condition set by the “cut-off value” and “check logic,” the carryover flag is posted to the second sample.

[Check Logic]	Select either [Above or equal to] or [Below or equal to] as judgment criteria.

Carryover detecting function

See the setting values in the [Carryover Setting] window above as an example of how the detecting function works.

Example

Two successive samples are both measured for "μ-ALB" and the measurement values of both the samples are 3.00 mg/dL or above, the μ-ALB measurement value of the second sample is marked with an “O” flag. Otherwise, no “O” flag is posted.

Setting up automatic rerun

You can set up automatic rerun with the predefined dilution rate for the sample marked with the carryover flag “O” Define automatic rerun and dilution rate for rerun as follows:

1. Select [Setup] > [Analytical Parameters (Chemistry)].
2. In the [Analytical Parameter (Chemistry)] window, click the [Rerun conditions set] button in the [Sub-analy.conditions] column.
3. Select the dilution condition from [M] to [D4] as required for [Carryover (O)] in the [Rerun Conditions Set] window (multiple conditions can be selected).
4. Click [OK] to close the [Rerun Conditions Set] window, and then click [Save] in the [Analytical Parameters (Chemistry)] window to exit.

5.5.2 Setting contamination avoidance

This section describes various kinds of contamination and the corresponding preventive measures.

Contamination of reagent probes and avoidance method

The BM6010/C analyzer features three-part reagent capability for a test. Two reagent probes, RPP1 and RPP2, are used for dispensing reagents. RPP1 dispenses reagent R1, and RPP2 dispenses R2e and R2. The table below summarizes how each reagent probe can contribute to contamination.

Actors in contamination

#	Reagent probe	Contaminating reagent	Reagent to be contaminated
1	RPP1	R1	R1
2	RPP2	R2e	R2e
3	RPP2	R2e	R2
4	RPP2	R2	R2e
5	RPP2	R2	R2

All the contamination scenarios listed above can be avoided.

Method of contamination avoidance

Contamination can be avoided by delaying a test that uses a reagent subject to contamination. Meanwhile, only alternate tests with no risk of reagent contamination are performed for a certain period of time.

If the reagent to be dispensed is subject to contamination as shown in the above table and all the other reagents have already been dispensed, the reagent probe is simply washed with the designated washing solution (“Reagent probe wash”).

In the combination of #3 in the above table, R2 is subject to contamination, R2 is dispensed before R2e. Thus, R2 contamination is avoided even if the probe is not washed.

The [Influence Effect] entered in the [Setup] > [Contamination Set] window is also taken into consideration.

Example of preventing the reagent probe from contamination

Condition:

Test producing contamination (Affecting Test) / Test subject to contamination (Affected Test): ALT > LDH

Influence effect: 2

Preventive detergent: reagent probe wash 1

Measurement orders and the result:

1. ALT → LDH → TP → ALB → ALP
   Contaminated
   LDH is measured immediately following ALT measurement. The result is affected by contamination.

2. ALT → TP → LDH → ALB → ALP
   Contaminated
   LDH is measured after 1 cycle following ALT measurement. The result is affected by contamination.

3. ALT → TP → ALB → LDH → ALP
   2 cycles
   No contamination
   After 2 cylcles following ALT measurement, LDH is measured.

4. ALT → Wash by detergent → LDH → ALB → .....
   No contamination

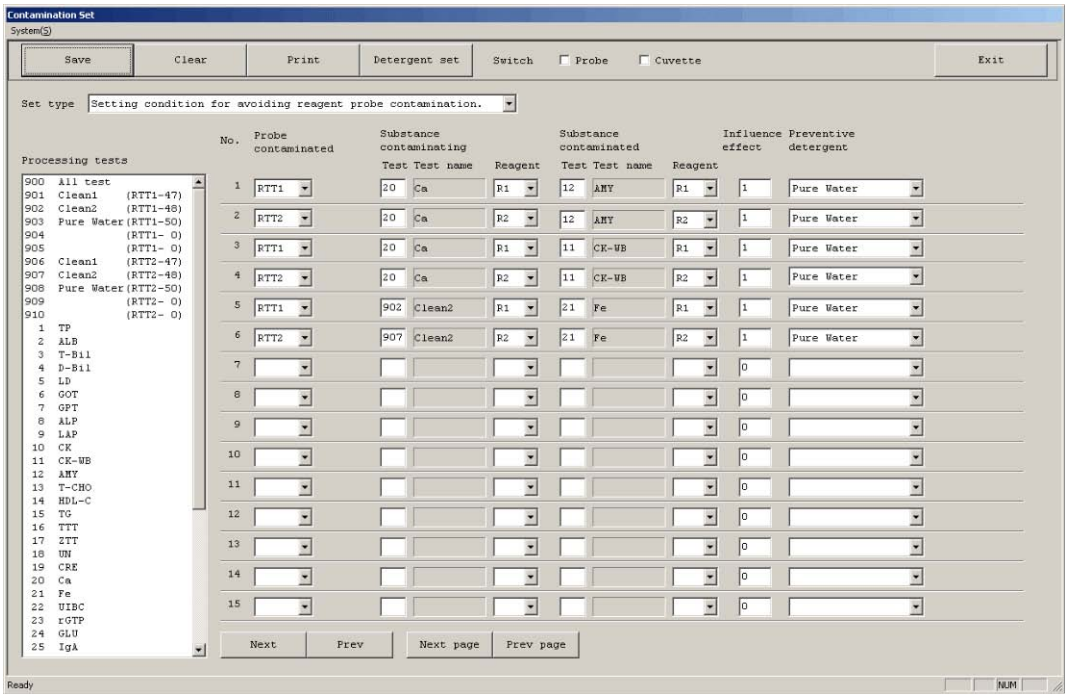
As shown in order #3, contamination can be avoided by changing the measurement order.

When the order cannot be changed, the reagent probe is washed with wash solution after measurement of ALT, and then LDH is measured (see order #4).

Defining the conditions for avoiding contamination of the reagent probe

1 Select [Setup] > [Contamination Settings] to display the window below. Place a checkmark next to [Probe] in the [Switch] field in the middle of the top bar. This activates the contamination avoidance function for probes.

2 Select "Setting condition for avoiding reagent probe contamination" for [Set type], and define the parameters as follows.



3 Click the [Detergent set] button on the top bar to define a wash solution. The [Detergent set] window is displayed. Enter "Pure water", "RPP Wash 1" or "RPP Wash 2" in the [Comment] column.

If the probe can be sufficiently cleaned with pure water, use "pure water". Otherwise, if "RPP Wash 1" and "RPP Wash 2" are effective, use "RPP Wash 1". If neither pure water nor "RPP Wash 1" is effective, use "RPP Wash 2".

4 Define [Influence effect (factor)]. When the probe is sufficiently cleaned with pure water, the influence effect is "1",

5 If the RPP Wash 1 or RPP Wash 2 is effective, calculate the influence effect as below:

Influence effect ＝ (Measurement order number of affected test)- (Measurement order number of test using affecting reagent) - 1

However, when the calculated influence effect is zero or lower, add the total number of tests. Also, when the calculated influence effect is 20 or greater, enter "20". However, if the reagent has a strong contamination effect, enter "999".

6 Define the [Influence effect] of the reagent probe wash detergents.

Enter the name of detergent in the [Substance contaminating] field. The effect of detergents can be nullified by wash with pure water. Enter "1" for [Influence effect].

7 Define contamination avoidance setting separately for R1 and R2.

Either the affecting test or affected test uses one-part reagent, set avoidance for R1 and R2.
Both the affecting test and affected test use one-part reagent, set avoidance for R1 only.

In the default setting of preventive detergent number, #901 and #906 indicate Reagent probe wash 1 (RPP Wash 1); #902 and #907 Reagent probe wash 2 (RPP Wash 2); and pure water #903 and #908.

The table below shows an example of set values.

No.	Probe	Affecting test/detergent	Re-agent	Affected test	Reagent	Influence effect	Number
1	RPP1	GPT	R1	LDH	R1	12	901(RPP Wash 1)
2	RPP2	GPT	R2	LDH	R2	12	906(RPP Wash 1)
3	RPP1	LAP	R1	CRP	R1	1	903(Pure water)
4	RPP2	LAP	R2	CRP	R2	1	908(Pure water)
5	RPP1	TCHO	R1	FCHO	R1	999	902(RPP Wash 2)
6	RPP2	TCHO	R2	FCHO	R2	999	907(RPP Wash 2)
7	RPP1	RPP WASH 2	R1	Fe	R1	1	903(Pure water)
8	RPP2	RPP WASH 2	R2	Fe	R2	1	908(Pure water)

Avoiding reaction cuvette contamination

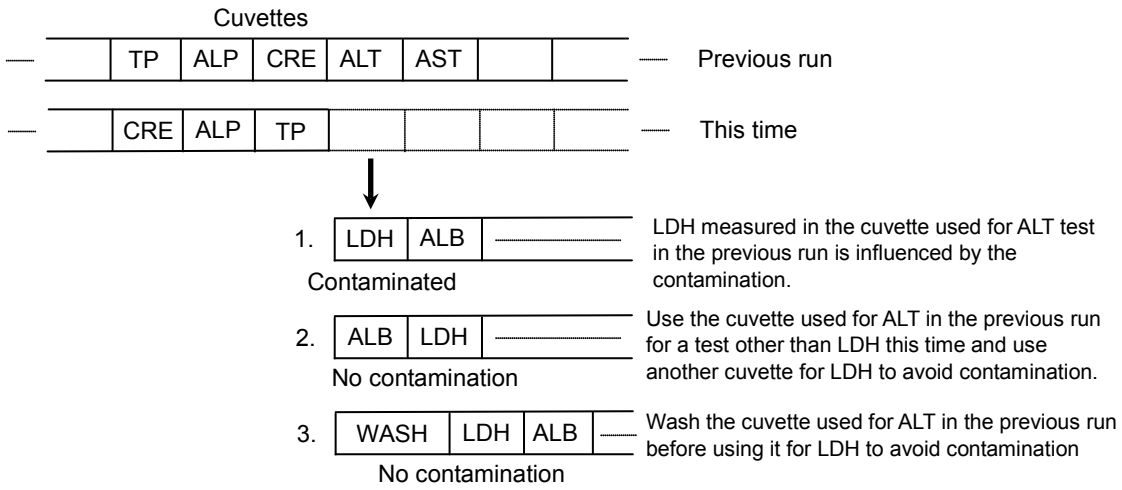
A cuvette used for an "affecting test" is subsequently used preferentially for tests that are not designated “affected tests” in order to avoid the necessity of a cuvette wash procedure. If the remaining tests are all “affected tests”, the cuvette is washed with the designated solution before proceeding to the next test assay. When an “affected test” is

the last assay of the measurement, all cuvettes are washed to prevent contamination in the next measurement.

Example of Reaction Cuvette Contamination Avoidance

Condition: Affecting test > affected test ALT > LDH

Detergent for contamination avoidance: Reagent probe wash 1



In order #2, contamination is avoided by changing the measurement order.

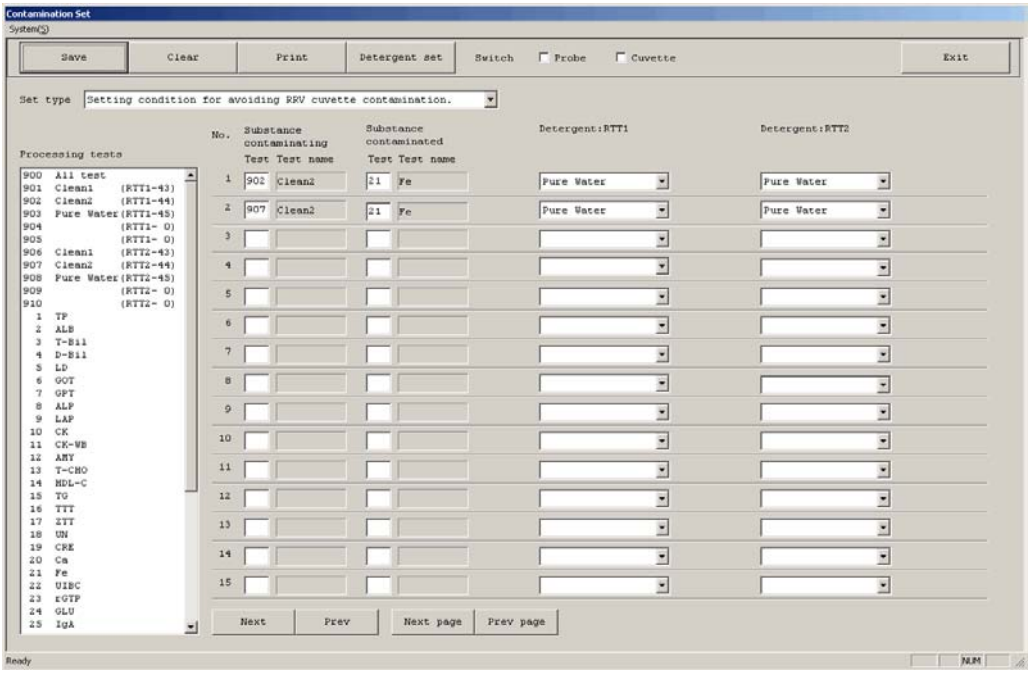
When the order cannot be changed, the cuvette is washed with detergent after the ALT test then LDH test is measured in the same cuvette.

It is also possible to setup a forced wash for contamination avoidance without changing the test order.

Defining conditions for avoiding contamination of reaction cuvettes

1 Select [Setup] > [Contamination Settings] to display the window below. Select [Cuvette] for [Switch] in the middle of the top bar. This activates the function of preventing the cuvettes from contamination.

2 Select "Setting condition for avoiding RRV cuvette contamination" for [Set type], and define the parameters as follows.



3 Select detergents to be used for contamination avoidance. Click the [Detergent set] button. The [Detergent set] window is displayed. Enter "Pure water", "RPP Wash 1", or "RPP Wash 2" in the [Comment] column.

If the probe can be sufficiently cleaned with pure water, use "pure water". Otherwise, if "RPP Wash 1" and "RPP Wash 2" are equally effective, use "RPP Wash 1". If neither pure water nor RPP Wash 1 is effective, use "RPP Wash 2".

4 For a combination of tests for which contamination can be avoided with a pure water wash, enter the “affecting test” in the [Substance contaminating] field and the “affected test” in the [Substance contaminated] field. When contamination cannot be avoided with a pure water wash, enter only the “affecting test” in the [Substance contaminating] field and enter "900 (All tests)" in the [Substance contaminated] field.

5 When a test can contaminate multiple tests such as A >B and A >C, select "900 (All tests)” in the [Substance Contaminating] field. Select a detergent which is effective for all tests.

Do not enter a test in two or more fields for [Substance contaminating].

Example: A > B Detergent: Pure water

A > C Detergent: Reagent probe wash 1

A > D Detergent: Reagent probe wash 2

For a combination containing all tests listed above, enter the tests as follows:

A > all tests Detergent: Reagent probe wash 2

6 Enter the [Influence effect] of the reagent probe wash detergents.

The effect of the detergents on test results can be nullified by another wash with pure water. Enter tests which can be affected by detergent contamination according to the procedure outlined in orders #4 and #5 in the example in the table below.

In the default setting of preventive detergent number, #901 and #906 indicate Reagent probe wash 1 (RPP Wash 1); #902 and #907 Reagent probe wash 2 (RPP Wash 2); and pure water #903 and #908.

The table below shows an example of set values.

Number	Affecting test	Affected test	Number	
			RPP1	RPP2
1	GPT	All tests (900)	901 (RPP Wash 1)	906 (RPP Wash 1)
2	LAP	CRP	903 (Pure water)	908 (Pure water)
3	TCHO	All tests (900)	902 (RPP Wash 2)	907 (RPP Wash 2)
4	Reagent probe wash 1	Fe	903 (Pure water)	908 (Pure water)
5	Reagent probe wash 2	Fe	903 (Pure water)	908 (Pure water)

5.6 Defining Report Formats and Printing the Reports

Reports

Reports can be printed from the workstation of the analyzer system BM6010/C.

Select [Setup] > [Print Form Settings] to open the window for setup.

To print a report, select [Request] > [Print Report], or [Request] > [Review/ Edit], and then click the [Print Report] button in the command bar in the window.

Setting up a reporting format

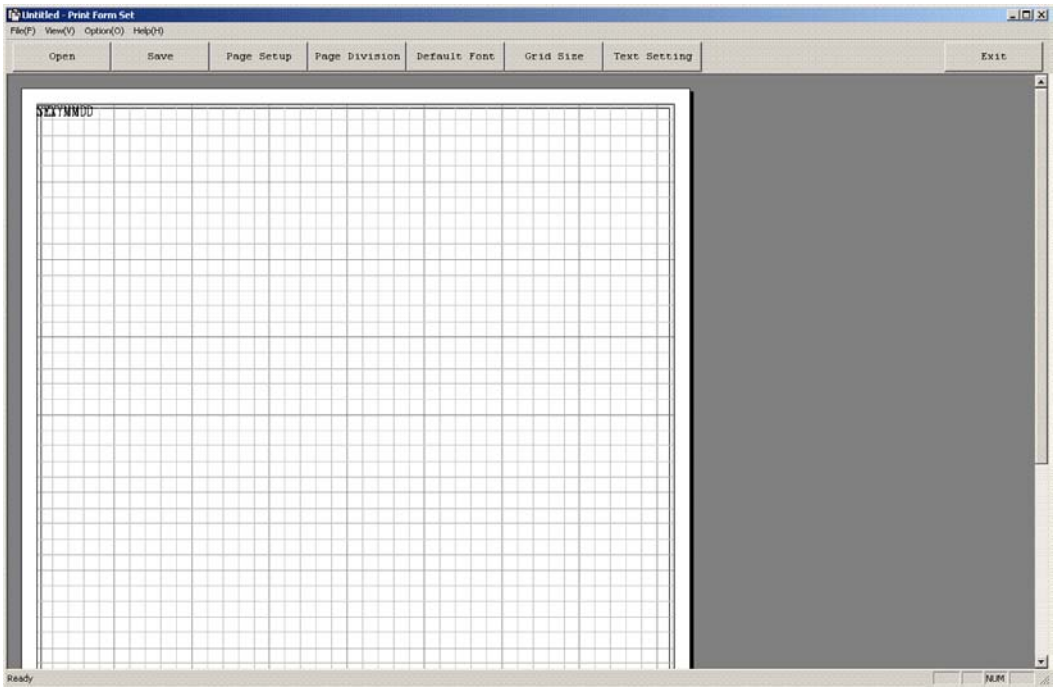
You can create a new report format or edit an existing format.

In either case, please note that if you click the [Exit] button without saving the created or edited format with the [Save] button, the format is not saved.

✔ Creating a new report format

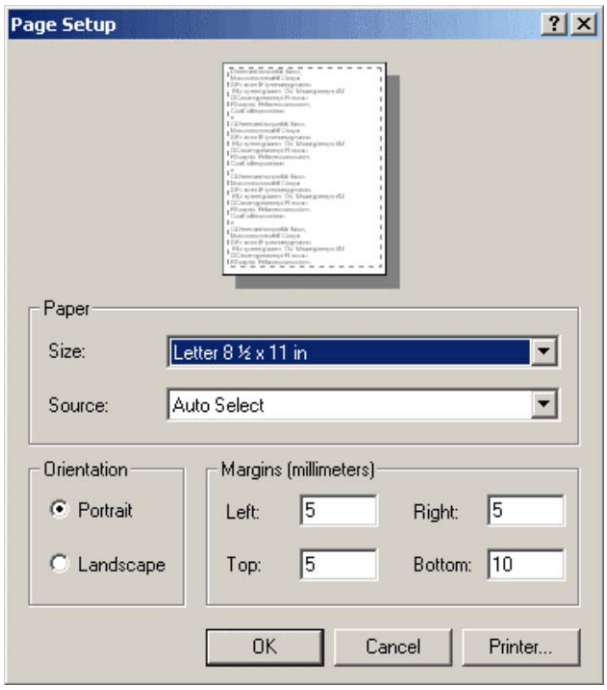
① Setting up a reporting format

1 Select [Setup] > [Print Form Setting] to display the window below.

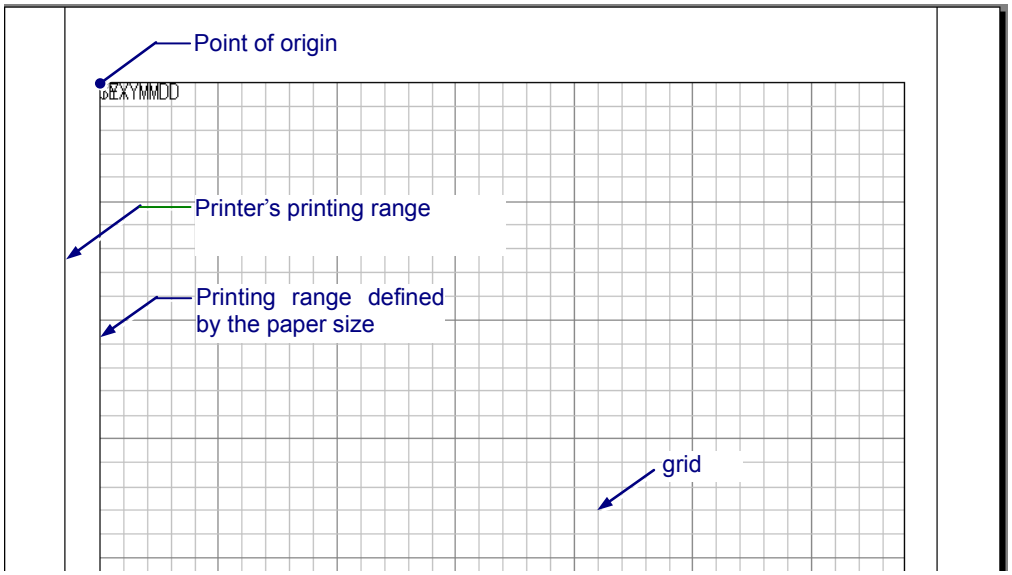


This window is used for setting up a format, checking printing performance, and saving the format:

2 To select the appropriate paper type, click the [Page Setup] button to display the window below:



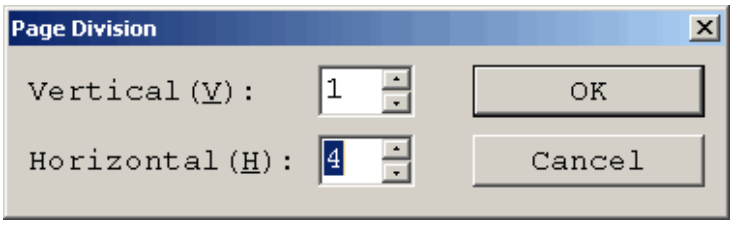
Set the paper type, printing margin, etc. in this window. Click [OK] to display the format page that has just been set up.



Enter the margins so that the printing range of the paper size will be within the print range of the printer.

Print a test page to confirm the paper size and range are correct. Also, adjust the vertical/horizontal positions of both the format and the paper.

3 Define the page division. Click the [Page Division] button to display the window below.

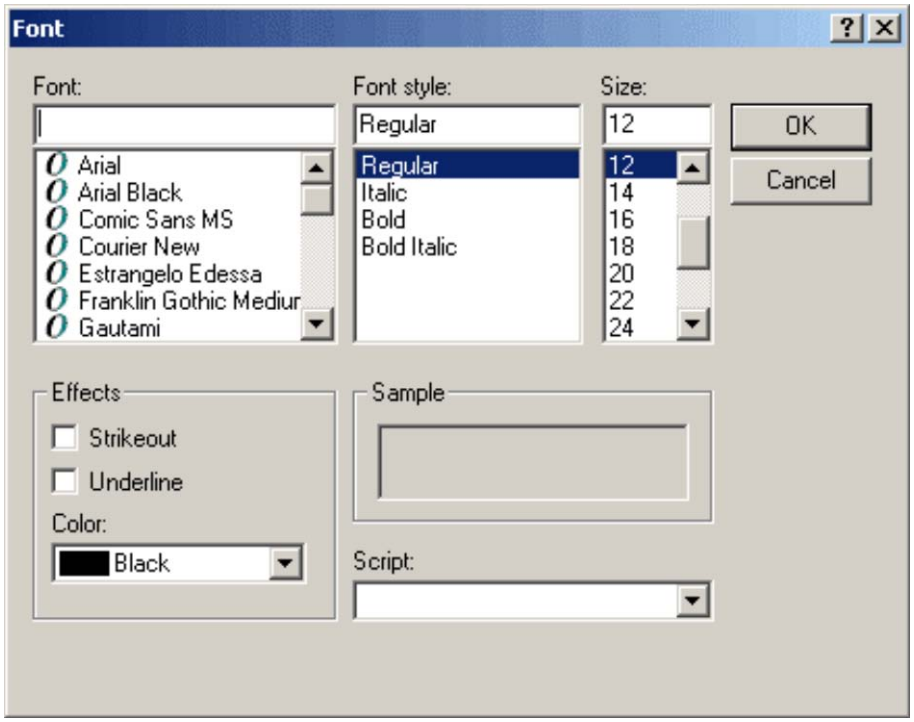


Decide how many parts into which to divide the page vertically and horizontally. Division into up to 10 parts is possible for each direction.

Click [OK] to view the formatted page.

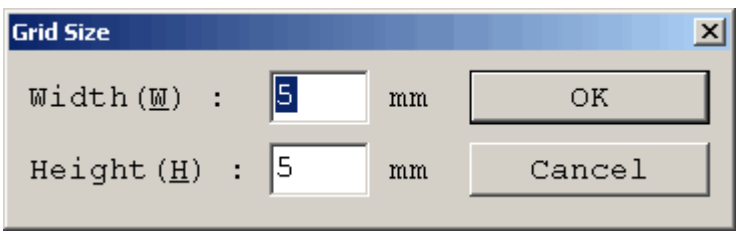
The format setup is commonly applied to the all divisions.

4 Setup the default font. Click the [Default font] button to display the window below.



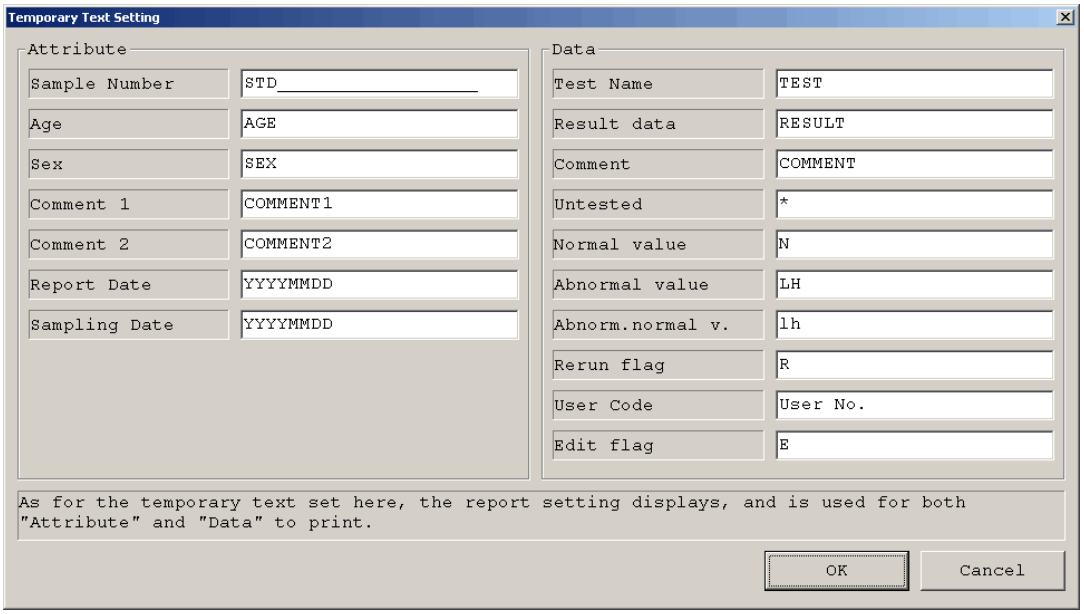
Select the default font. Designate the font type that is most frequently used to eliminate the need to modify the font type every time you generate a report.

5 Setup a grid size. Click the [Grid Size] button to display the window below.



This window is used to select the grid size to use when setting up a format. Method of adjusting the position will be described later in the [Property] window.

6 Select a temporary text format. Click the [Text Setting] button to display the [Temporary Text Setting] window.

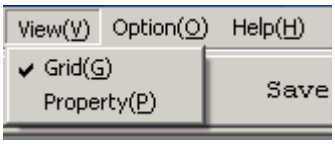


Use this window to enter temporary values that are displayed or printed during format setting instead of real data. Use the maximum length that actual data can be when a report is printed. These values are commonly applied to all reports.

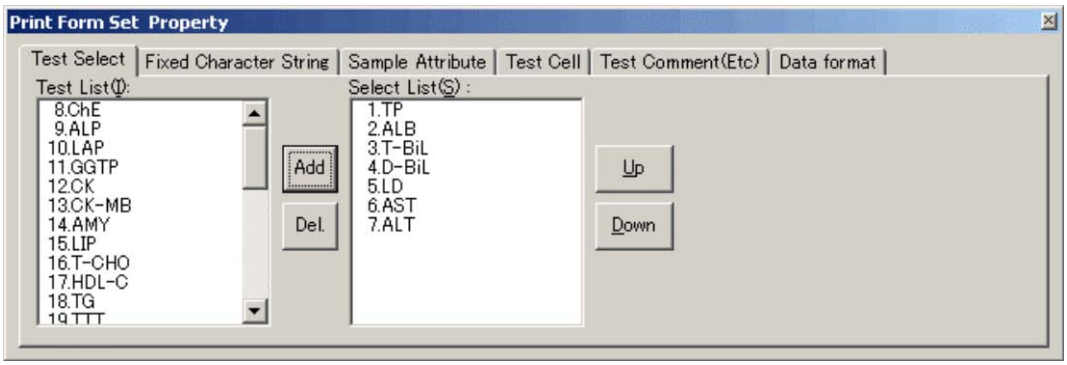
You can use the field of [Item comment] to show a value specific to a test such as unit of concentration.

② Setting up a detailed text format

1 Click [View] in the top command bar in the [Print Form Set] window and select "Property" in the drop-down menu. The [Print Form Set Property] window is displayed. Use this window to setup the detailed text format for printing.



2 Select the tests to show in the report in the [Test Select] tab page and define the display order.

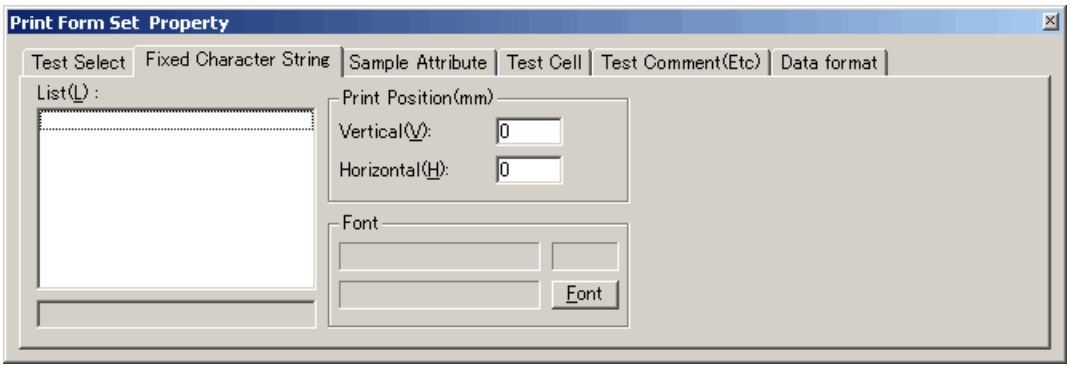


Select the tests to show in the report in the left [Test List] column and move them to the right [Select List] column. First select and highlight a test in the left column and click the [Add] button in the middle to move it to the right column. With the [Shift] key kept pressed, you can select multiple tests simultaneously.

The tests are printed in the order shown in the [Select List] column. To change the order, select and highlight the test and click the [Up] or [Down] button to move the test in that direction.

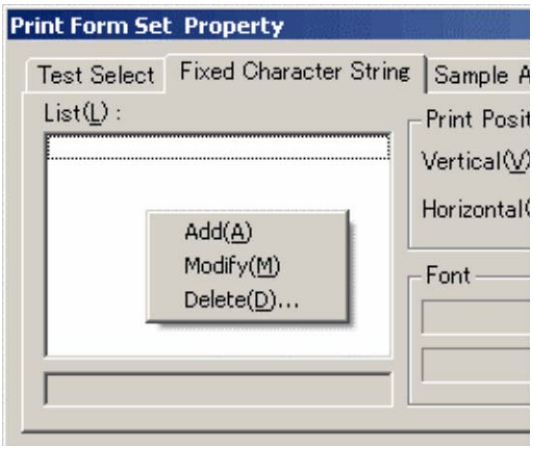
The created printing format can be exported to / imported from another BM6010/C system. However, the [Select List] often varies by system, therefore the list should be re-selected, that is, delete it once and define a new list. Also, when a select list is not registered or deleted in the system, the report cannot be printed.

3 Use the [Fixed Character String] tab page to setup the fixed character string and its location used in the report.

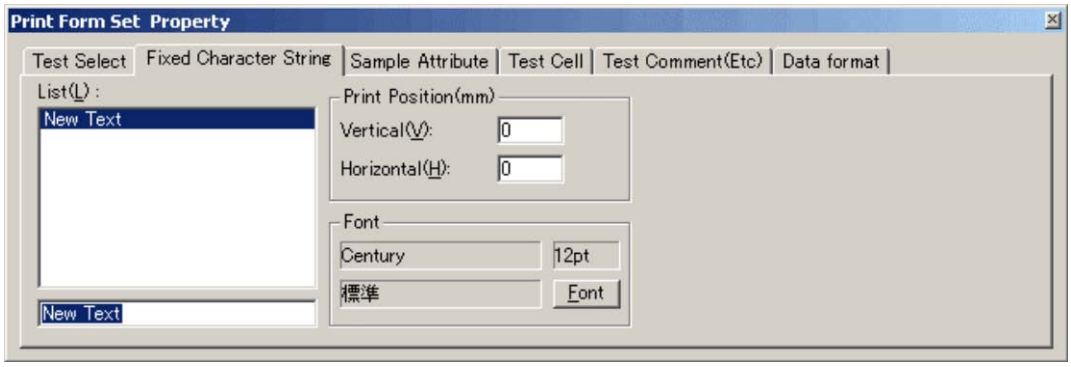


You can select the font type and size by character string. The setting steps are as follows:

(1) Make a right click on the mouse to show the menu below.



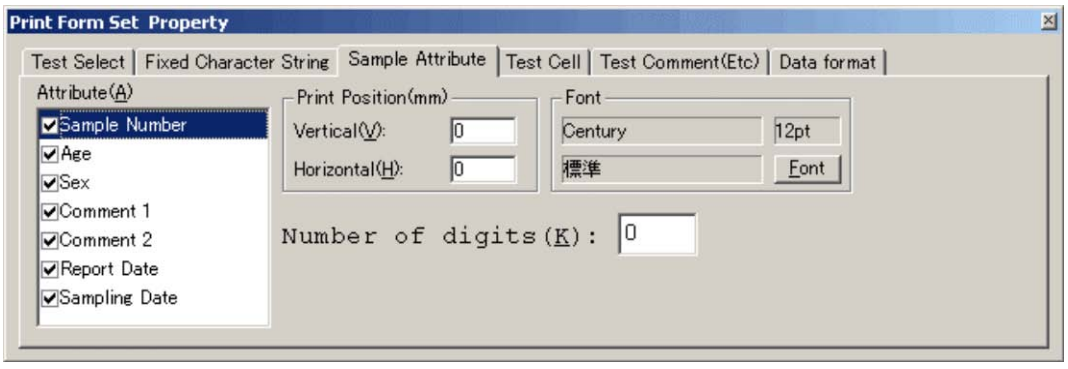
(2) Select [Add] to change the display as below.



(3) In the narrower field below [List(L):], enter the a text that is always used in the report. Then, move the cursor to the upper field and click in it to move the entered text to the upper field and confirm it.

(4) Set up [Print Position (mm)] and [Font] as checking them in the format page. [Print Position] accepts entry after the decimal point. The point of origin (the upper left corner) may look shifted depending on the font type selected.

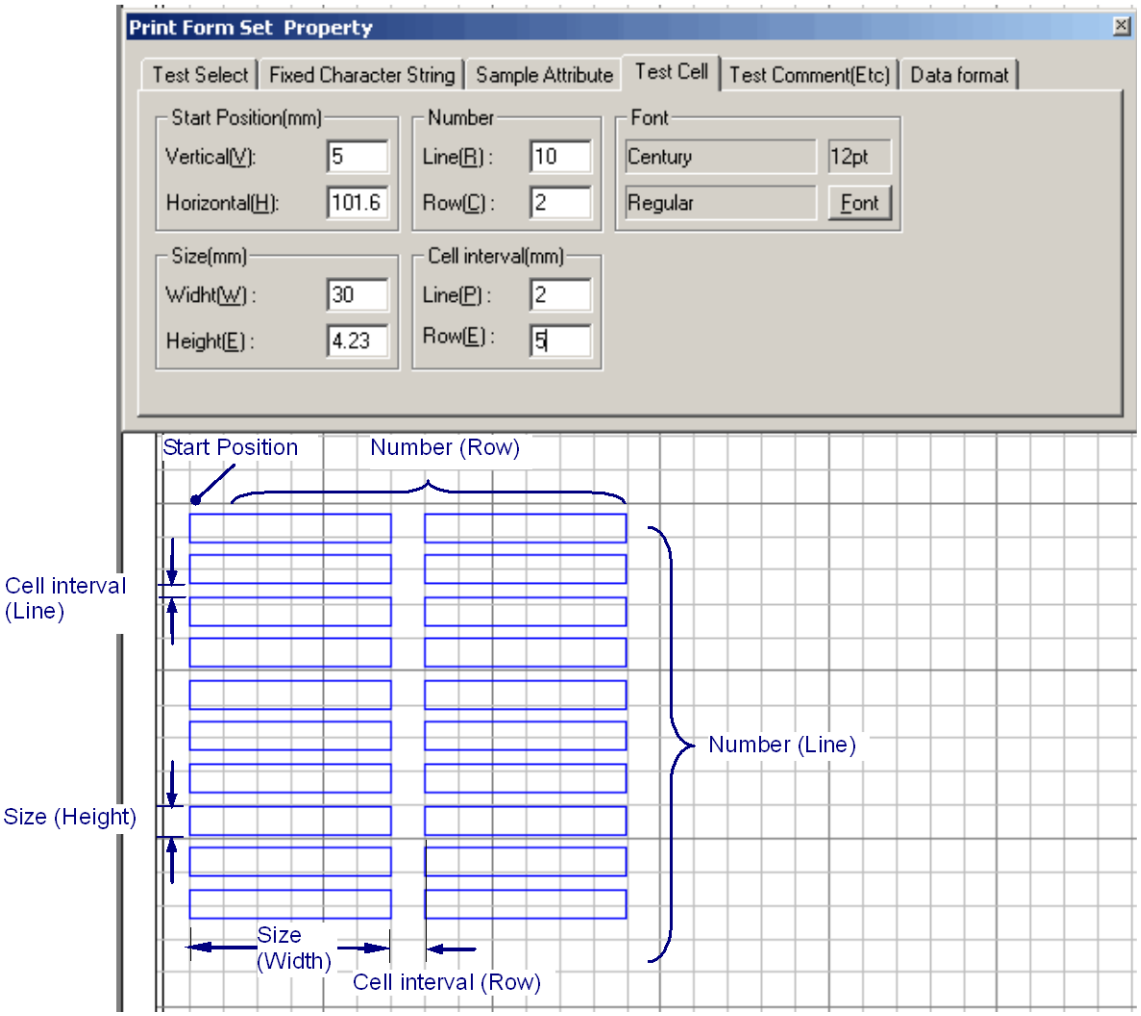
4 Use the [Sample Attribute] tab page to define the sample attributes to print in the report.



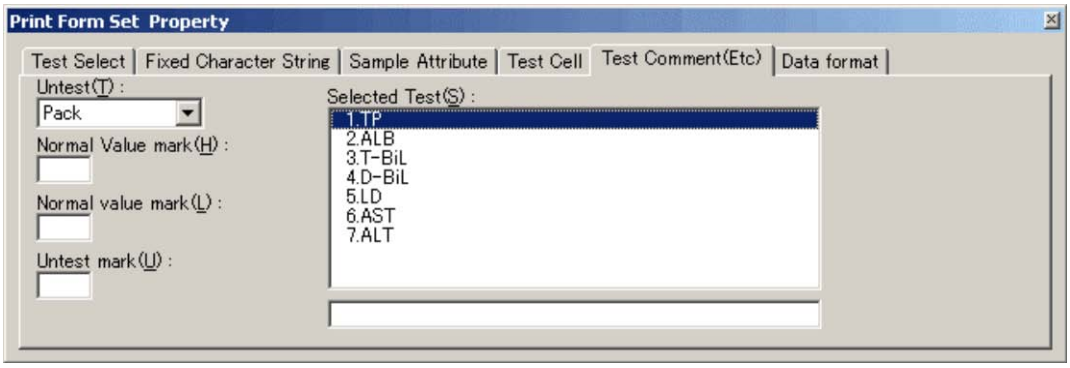
The items selected in the [Text Setting] tab page are displayed in the format page. Highlight and select to show ✓ for the item to be printed, and setup the printing position, font, and number of digits for each item. Click the mouse in an arbitrary position in the

format page to show the values in the defined positions. Adjust the positions by entering the values of "Print Position."

Use the [Test Cell] tab page to set up the fields to show the test results. Each of the fields will contain the value that is defined in the [Data format] tab page (to be described later). Only the tests selected in the [Test Select] tab page are displayed in the fields. The excessive fields are shown blank.



5 Use the [Test Comment (Etc)] tab page to enter a fixed character string for each test.



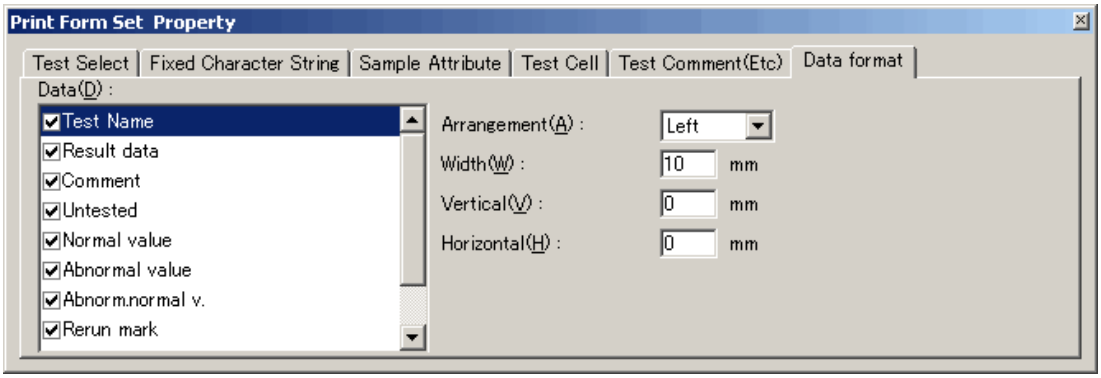
Click a test name to highlight, and enter a comment in the lower field under the [Selected Test] field.

Following items can be defined in the left side of the page.

[Untest (T)]: Select "Pack" in the drop-down menu to eliminate the space for tests not performed or "Unpack" to keep the space for them.

Use the [Normal Value flag (H/L)] fields and [Untest mark(U)] field if you want to change the flag from the default setting. Enter in the corresponding field the character that you want to use as flag.

6 Use the [Data format] tab to setup the printing positions of the values such as "Text name" and "Result data" defined in the [Test Cell] tab page.

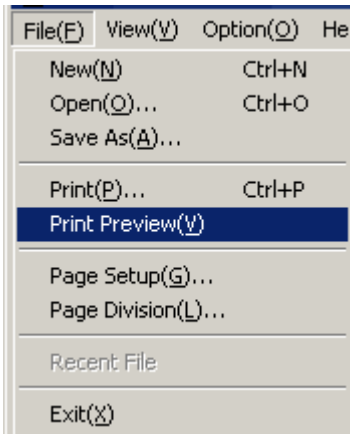


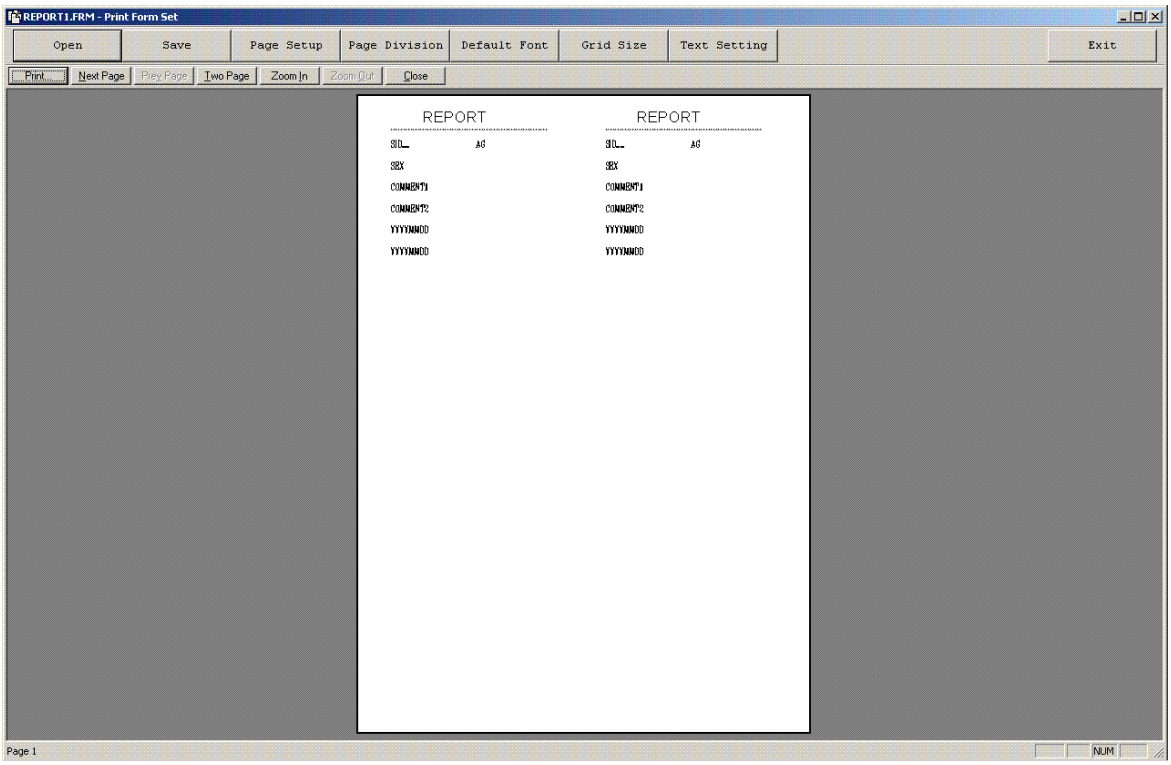
The point of origin is the upper left corner of the first cell. The font type selected in the [Test Cuvette] tab page is used, but the position can be adjusted in this page. The excessive characters over the value set as [Width] will be cut in the right side. The characters defined in the [Text Setting] tab page are displayed in the format page.

Click [X] in the upper right corner to close the [Print Form Set Property] window.

③ Check the format on the monitor

1 Click [File] in the top command bar in the [Print Form Set] window and select "Print Preview" to display the created format.

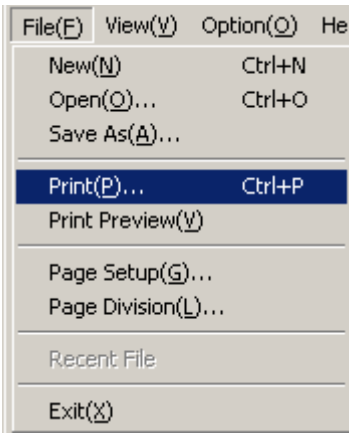




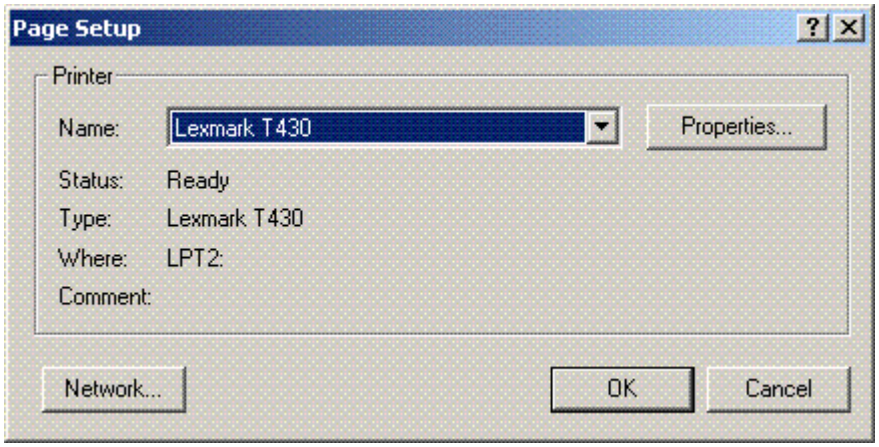
Click the [Close] button to close the display. If you use the [Exit] button in the [Print Form Set] window to close the window, the format created so far will be gone without being saved.

④ Print the page to check the format

1 Click [File] in the top command bar in the [Print Form Set] window and select "Print".



The window below is displayed.



2 Click [OK] to print the format and check the contents and positions.

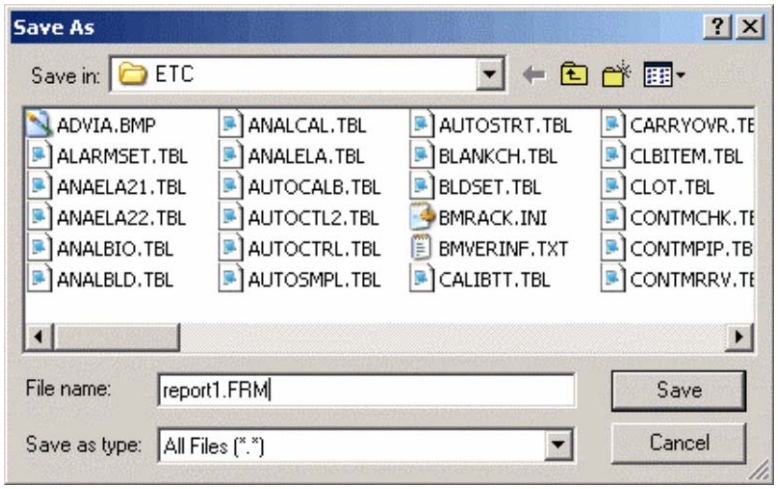
⑤ Save the printing format

1 Click the [Save] button

The window below is displayed.

2 Click [OK]

The window below is displayed.



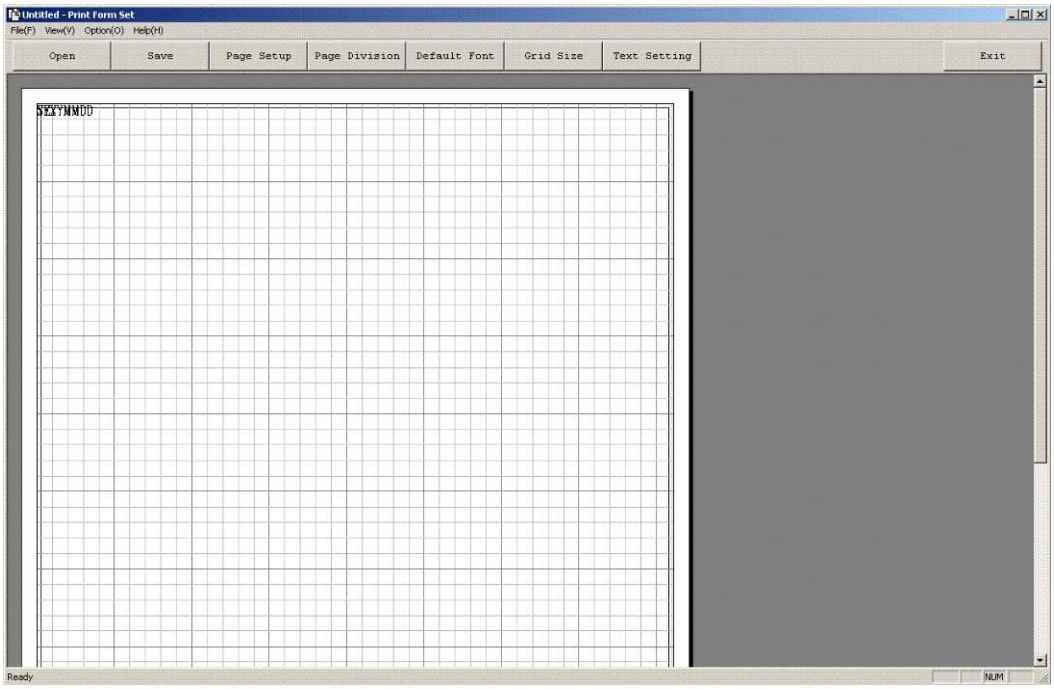
For a new format, "Untitled" is displayed in the [File name] field. Enter a name for the format in 8 alphanumeric characters (8 one-byte characters or 4 two-byte characters). This name is displayed when a report is printed in the format.

Be sure to save the format in the folder "ETC" as shown above. Otherwise, you cannot print nor backup the report in this format.

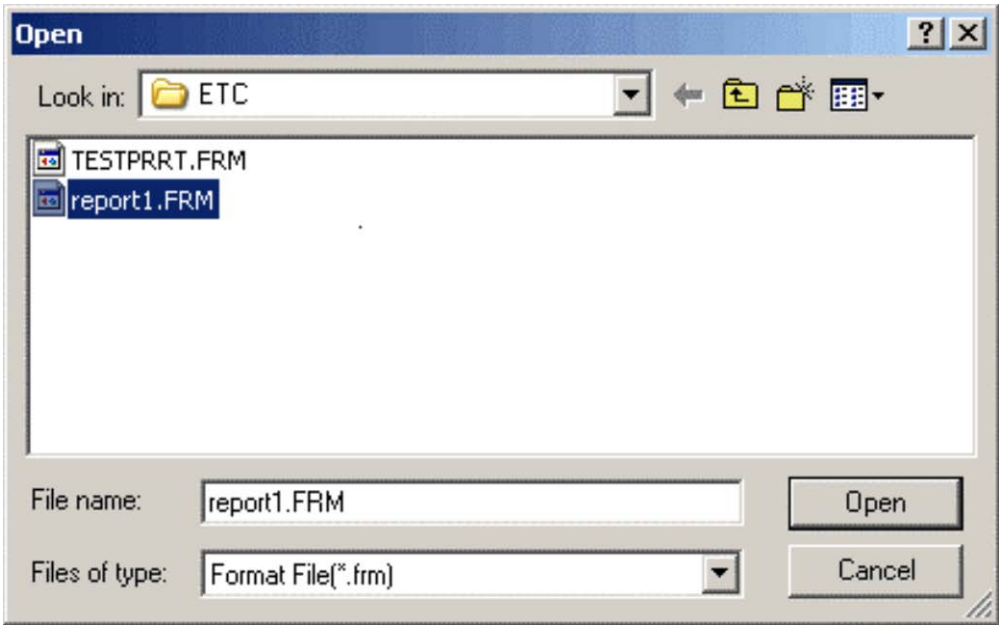
✔ Editing an existing printing format

① Retreaving an existing printing format

1 Select [Setup] > [Print Form Setting] to display the window below.



2 Click the [Open] button to display the window below.



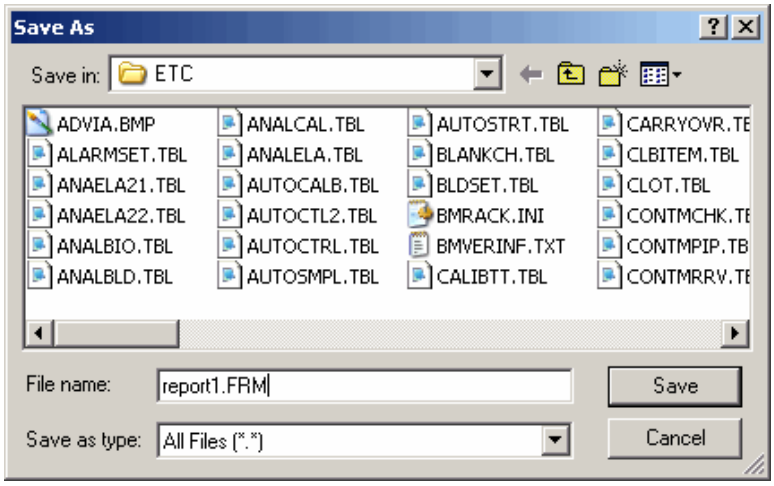
3 Select a file to edit and click [Open]. The selected format is displayed.

② **Edit the reporting format**

Follow the steps described in the section "Creating a new report format" to edit the contents and check the edited format.

③ **Save the edited format**

1 Click the [Save] button and click [OK] in the confirmation popup window. The following window is displayed.



2 The name of the current file is displayed. Click [Save] to overwrite it.

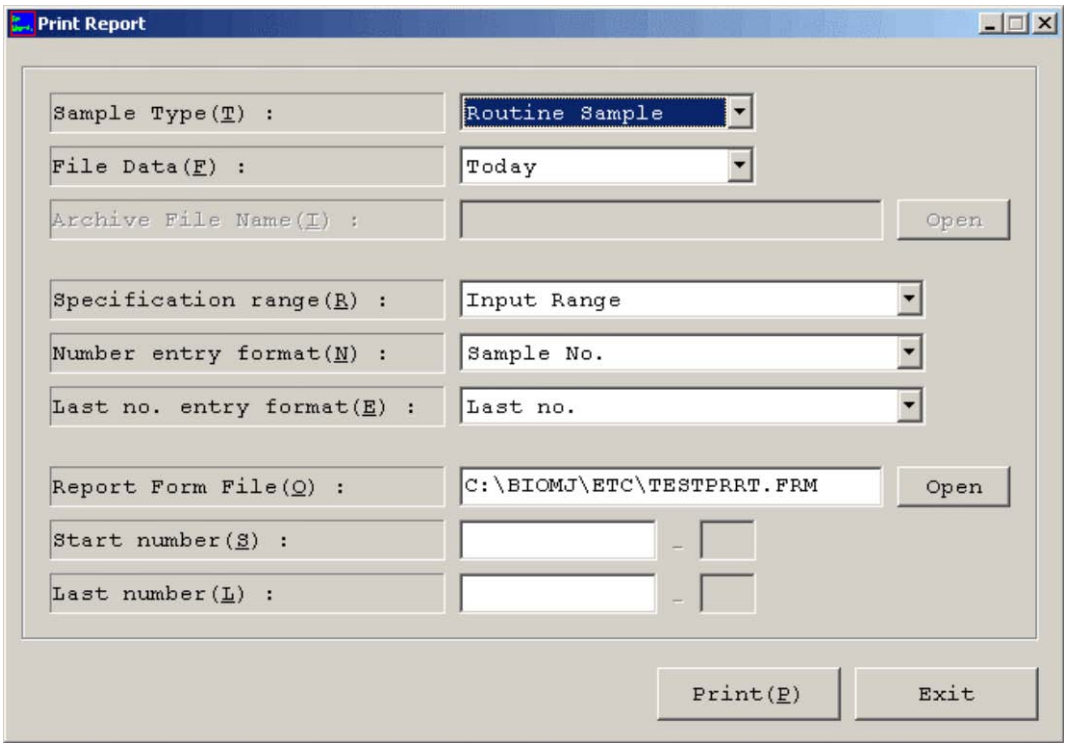
Printing a report

To print a report, select [Request] > [Print Report], or [Request] > [Review/Edit], and then click the [Print Report] button in the command bar in the window.

The measurement data of the last 7 days including the current day can be printed. Also, the data saved in an external media such as CD-RW can be printed. The measurement data of the reported sample are usually reviewed in the [Review/Edit] window.

✔ **Print a report of measurement data of the last 7 days including the current day.**

1 To print a report, select [Request] > [Print Report], or [Request] > [Review/ Edit], and then click the [Print Report] button in the command bar in the window. The window below is displayed.



2 For [Sample Type (T)], select either "Routine Sample", "STAT Sample" or "Control Sample."

3 Select the data range to print in the report in the [File Data] field. The option is "Archive" or a date.

When "Archive" is selected, refer to the next section "Printing the measurement results recorded in an external media".

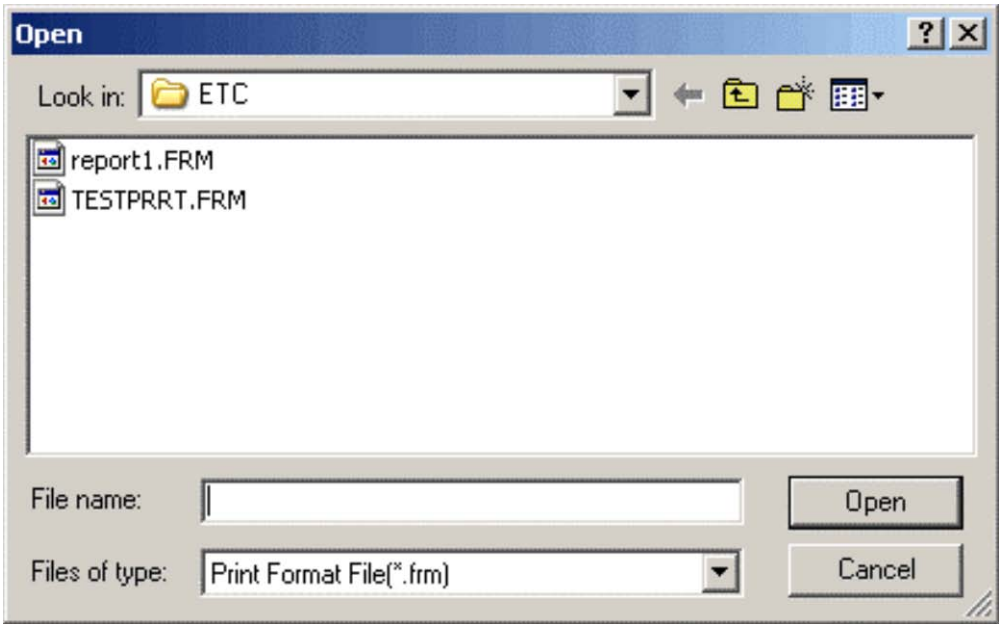
4 In the [Specification range] field, select "Input Range" to set the printing range or [All] not to. Once you select "All", you can enter a value only in the [Report Form File] window, and all the data in the media is printed.

5 When "Input Range" is selected, select an entry format in the [Number entry format] field. The option is "Sample No.", "Position No. (Rack No.)", "Position No. (TT. No.), or "Order No."

6 In the [Last no. entry format] field, select either "Last no." or "Number of samples" to define the end of the printing range.

7 Define a report format to use for printing

(1) Click the [Open] button to the right of the [Report Form File] field to display the window below.



(2) Click and select a format to use.

(3) Click the [Open] button.

The selected format is displayed as ¥BIOMJ ¥ETC¥xxxxxxx.Frm″ where xxxxxxx. is the format name in the [Report Form File (O)] field.

8 Enter the starting number in the [Starting number] field. Use the format selected in the [Number entry format] field.

9 Enter the last number to print or the total number of samples in the [Last number] field.

10 Click [Print] to print the report.

Print measurement data recorded in an external media (CD-RW)

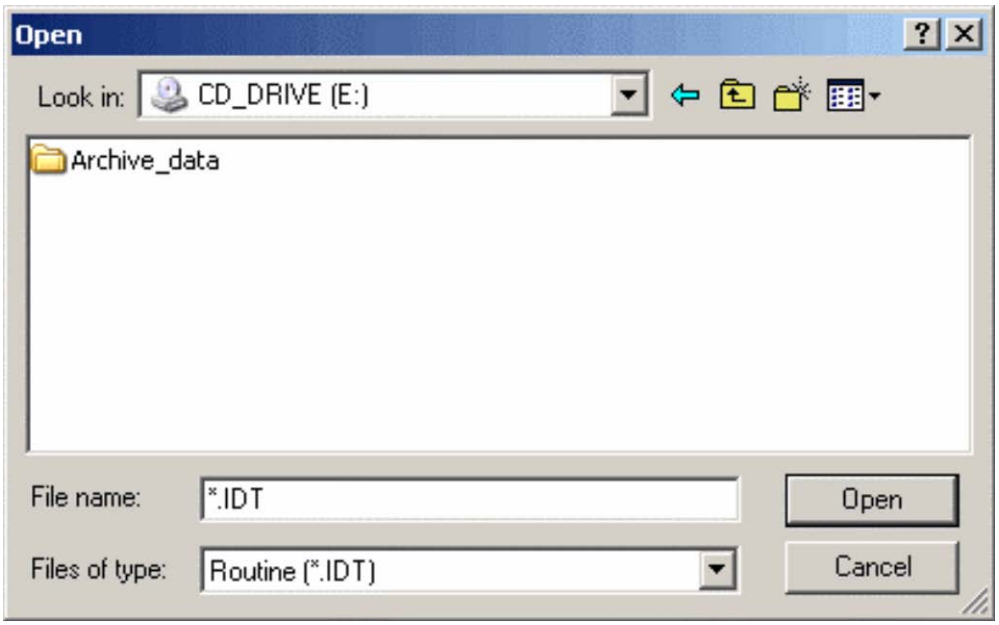
1 Select [Request] > [Print Report], or [Request] > [Review/ Edit], and then click the [Print Report] button in the command bar in the window to open the window below.

2 Select a [Sample Type] to show in the report.

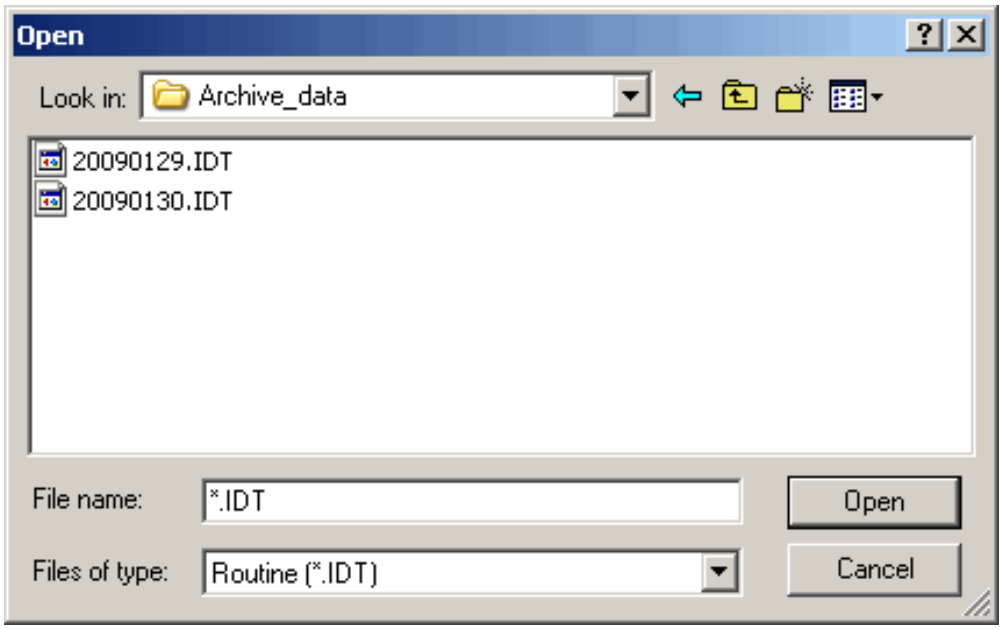
3 Mount a CD-RW in the media drive.

4 When "Archive" is chosen for [File Data (F)], the [Archive File Name (I)] becomes available.

5 Click the [Open] button to the right of the [Archive File Name (I)] field to display the window below.



6 Select a folder that stores the archive files to display the file names. Select a file and click [OK].



The selected file name is shown as "D:¥BIOMJ¥DATA¥YYYYMMDD" in the [Archive File Name] field.

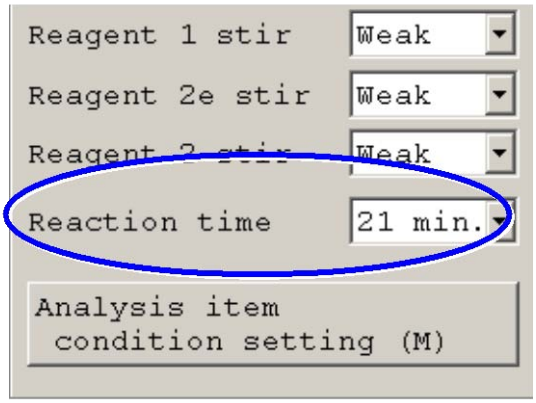
7 Set the values in the fields including [Specification range] as described from Steps 4 onwards in the previous section "Print a report of measurement data of the last 7 days including the current day." Then, print the report.

8 When printing is complete, remove the CD-RW from the driver.

5.7 Special analytical conditions

5.7.1 Round prolongation

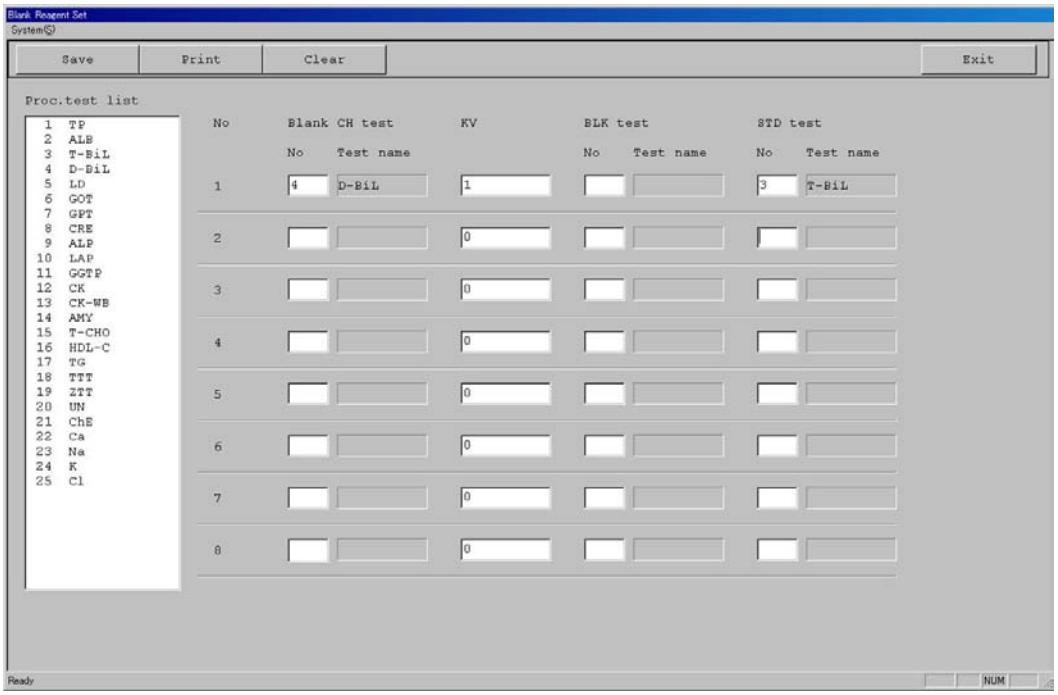
In the default setting, 15 minutes will elapse from the time reagent 1 and the sample are dispensed into the cuvette to the final wash. If the test requires a longer reaction time, 21 minutes or 31 minutes can be selected as the [Reaction time] in the [Analytical Parameters (Chemistry)] window.



A test for which a longer reaction time is required is called a "test of prolonged round." When measuring a test of extended round, the cuvette is not washed at the scheduled wash time and the reaction continues. Thus, the reaction carousel wash unit (WUD) does not lower. At the next scheduled wash time after 15 minutes, the cuvette will be washed. Nine cuvettes prior to and following the unwashed cuvette will also skip the scheduled wash (18 cuvettes in total). With “prolonged round tests”, the throughput of the analyzer is compromised.

5.7.2 Setting up a blank reagent

The blank reagent is defined in the [Blank Reagent Set] window (accessed via [Setup] > [Blank Reagent Settings]). This section describes precautions for settings under three conditions below:



When there is no BIL-B and the standard value of T-BIL is used as D-BIL standard value

- Do not define "T-BIL" for the [Blank CH test] column.
  Otherwise, "STD-OD" will be "0" for both of the tests, which will cause invalid results.
- Set "STD" as test condition of D-BIL, but do not use STD sample for measurement.
- "KV" is not used for calculation.
- The formula is as follows.

$$\text{D-BIL (Absorbance)} = FV_D \times \frac{\text{D-BIL(Samp)}}{\text{T-BIL(STD)}}$$

D-BIL (Samp) and T-BIL (STD) are the values obtained by subtracting reagent blank value from measurement absorbance.

No	Blank CH test		KV	BLK test		STD test	
	No	Test name		No	Test name	No	Test name
1	4	D-BIL				3	T-BIL
2							
3							

The number shown before the test is the corresponding “Process sequence number”.

When BIL-B is used and T-BIL value is used as standard value

- Do not define "STD test" for "T-BIL".
  Otherwise, "STD-OD" will be "0" for both of the tests, which will cause invalid results.
- Set "STD" as test condition of D-BIL, but do not use STD sample for measurement.
- Measure BLK and STD samples for BIL-B.
- Do not define [BLK test] for BIL-B.
- The analytical conditions for the tests (D-BIL and T-BIL) and BLK test should be the same except the conditions unique to each. Follow the instruction of the reagent manufacturer for the setting details for each test. When performing rerun, use the same conditions,
- "KV" for BIL-B is not used for calculation.
- The formula is as follows.

$$\text{T-BIL(absorbance)} = FV_T \times \frac{KV_T \times \text{T-BIL(Samp)} - \text{BIL-B(Samp)}}{KV_T \times \text{T-BIL(STD)} - \text{BIL-B(STD)}}$$

$$\text{D-BIL(absorbance)} = FV_D \times \frac{KV_D \times \text{D-BIL(Samp)} - \text{BIL-B(Samp)}}{KV_T \times \text{T-BIL(STD)} - \text{BIL-B(STD)}}$$

$$\text{BIL-B(absorbance)} = FV_B \times \frac{\text{BIL-B(Samp)}}{KV_T \times \text{T-BIL(STD)} - \text{BIL-B(STD)}}$$

D-BIL (Samp) and T-BIL(STD) are the values obtained by subtracting reagent blank value from measurement absorbance.

No	Blank CH test		KV	BLK test		STD test	
	No	Test name		No	Test name	No	Test name
1	23	T-BIL	1	25	BIL-B		
2	24	D-BIL	1	25	BIL-B	23	T-BIL
3	25	BIL-B				23	T-BIL

When another BLK is used for the test (e.g. Fe/Fe-B)

- Do not define "STD test" for Fe.
- Measure BLK and STD samples for both Fe and Fe-B tests
- Do not define [BLK test] for Fe-B.
- The analytical conditions of Fe, Fe-B, BLK tests should be the same except the conditions unique to each. Follow the instruction of the reagent manufacturer for the setting details for each test. When performing rerun, use the same conditions,
- "KV" for Fe-B is not used for calculation.
- The formula is as follows.

$$\mathrm{Fe\,(absorbance)} = \mathrm{FV_{Fe}} \times \frac{\mathrm{KV_{Fe}} \times \mathrm{Fe(Samp)} - \mathrm{Fe\text{-}B(Samp)}}{\mathrm{KV_{Fe}} \times \mathrm{Fe(STD)} - \mathrm{Fe\text{-}B(STD)}}$$

$$\mathrm{Fe\text{-}B\,(absorbance)} = \mathrm{FV_{FeB}} \times \frac{\mathrm{Fe\text{-}B(Samp)}}{\mathrm{KV_{Fe}} \times \mathrm{Fe(STD)} - \mathrm{Fe\text{-}B(STD)}}$$

D-BIL (Samp) and T-BIL (STD) are the values obtained by subtracting reagent blank value from measurement absorbance.

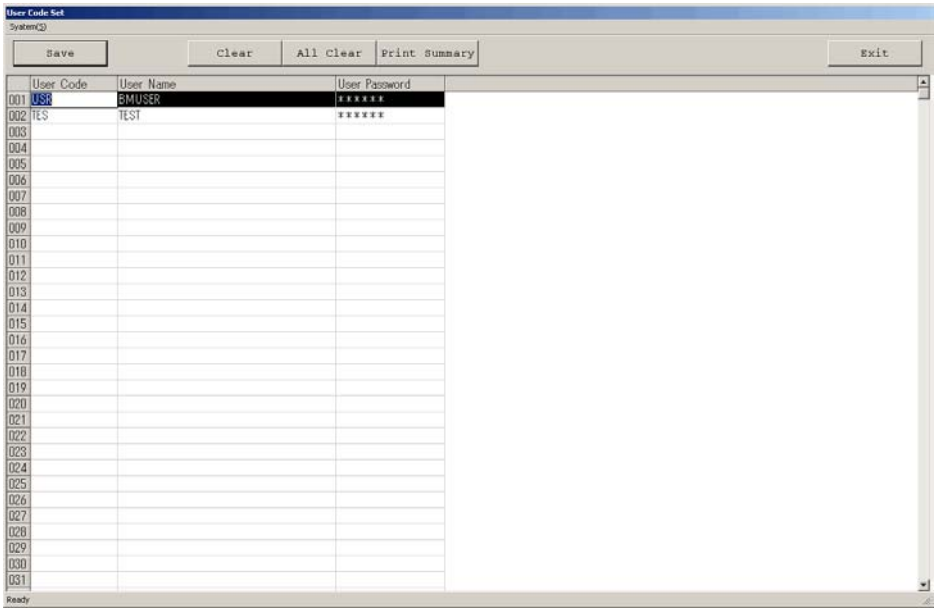
No	Blank CH test		KV	BLK test		STD test	
	No	Test name		No	Test name	No	Test name
1	16	Fe	1	17	Fe-B		
2	17	Fe-B				16	Fe
3							

5.8 Other Useful Features

5.8.1 User code settings

With a user code defined, the code is displayed in the [User] field when the user edited the measurement data in the [Review/Edit] or [View Calibration Curve] windows. This way, the editor is easily identified.

Select [Setup] > [Use Code Settings] to display the window below:



Values

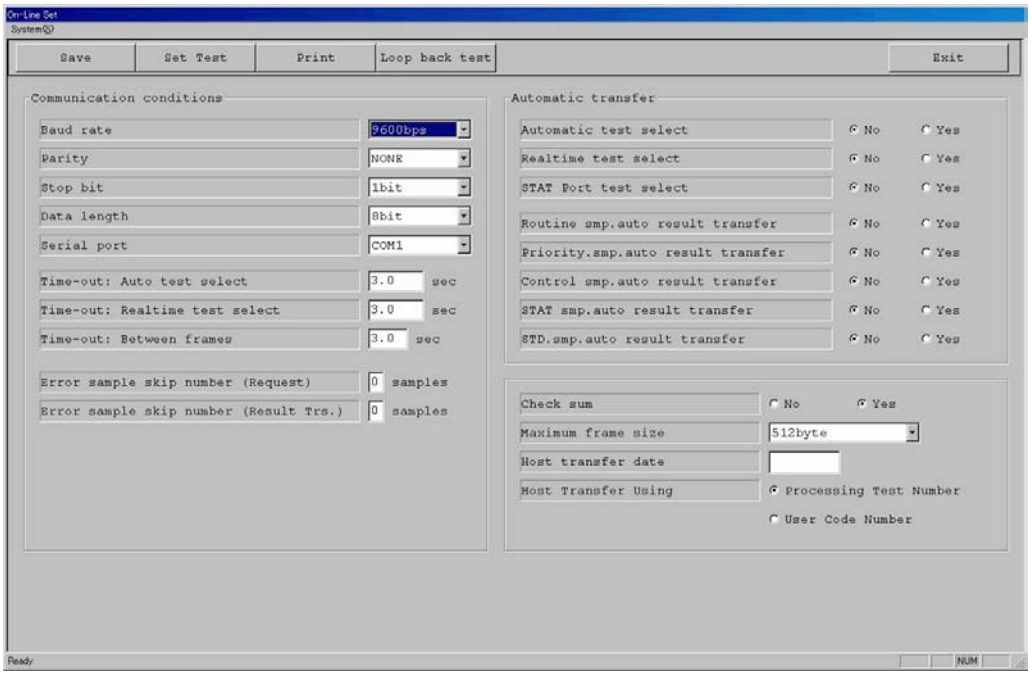
[User Code]	Use up to 3 (one-byte) alphanumeric characters. Up to 50 user codes can be defined.
[User Name]	Enter a user name with up to 25 one-byte alphanumeric characters for the use code.
[User Password]	Use up to 6 (one-byte) alphanumeric characters as password

To log in the system using the user code, click the [System] command in the upper left side of the system menu and select "Change User" in the dropdown menu. Enter the user name and password in the [Password] window.

Another [Password] window is accessible by selecting [System] > [Password]. Use this window to select the access level (either "User" or "Manager"). Note this window does not allow user login with the user name and password defined in the [User Code Settings] window.

5.8.2 Online settings

Select [Setup] > [Online Settings] to define various LIS parameters.



Parameters in the [Communication conditions] column

[Baut rate] Select one from "4800bps", "9600bps", "14400bps", "19200bps", "38400bps", "57600bps" and "115200bps." Default value is "9600bps."

[Parity] Select "NONE", "EVEN", or "ODD." Default value is "EVEN."

[Stop bit] Select either "1bit" or "2bit." Default value is "2bit."

[Data length] Select either "7bit" or "8bit." Default value is "8bit."

[Serial port] Select either "COM1" or "COM2." Default value is "COM1."

[Time-out: Auto test select] This parameter defines the transmission time-out duration for the order of an automatically selected test sent from the LIS to the BM6010/C workstation. Enter a duration in second that is added to the default time-out duration (42 seconds). Normally "18" is entered to make the total time-out to be 60 seconds.

[Time-out: Realtime test select]

The parameter defines the transmission time-out duration for the order of a test selected in real-time when the optional laboratory automation system (LAS)

is used. Enter a duration in second to be added to the default time-out duration. Default value is 10 seconds.

[Time-out: Between frames] This parameter defines the time-out between the frames when a communication message from the LIS comprises two or more frames. Enter a duration in second that is added to the default time-out duration of 5 seconds.

[Error sample skip number (Request)]

This parameter defines up to how many sample analysis orders are ignored if they are not properly received. Default value is "0" to avoid ignoring any order.

[Error sample skip number (Result Trs.)]

This parameter defines up to how many sample data are ignored if they are not properly sent. "0" is the default value.

Parameters in the [Automatic transfer] column

[Automatic test select] This parameter selects whether the analyzer sends inquiry to the laboratory information system (LIS) whether there are on-line test orders or not when the sample is dispensed from the sample tray (STT) for measurement.

[Real test select] This parameter selects whether the analyzer sends inquiry to the LIS whether there are tests ordered in real-time or not for a sample which is transported by the rack or laboratory automation system (LAS).

[Routine smp.auto result transfer]

This setting selects whether the results of routine sample measurements are transferred in real-time to the LIS.

[Priority smp.auto result transfer]

This parameter defines whether the results of priority sample measurements are transferred in realtime to the LIS or not.

[Control smp.auto result transfer]

This parameter defines whether the results of control sample measurements are transferred in realtime to the LIS or not.

[STAT smp.auto result transfer]

This parameter defines whether the results of STAT

sample measurements are transferred in realtime to the LIS or not.

[STD. smp.auto result transfer]

This parameter defines whether the results of calibrator measurements are transferred in realtime to the LIS or not.

Parameters in the lower right column of the window

[Check sum] This parameter defines whether check sum is used to verify the validity of an online message.

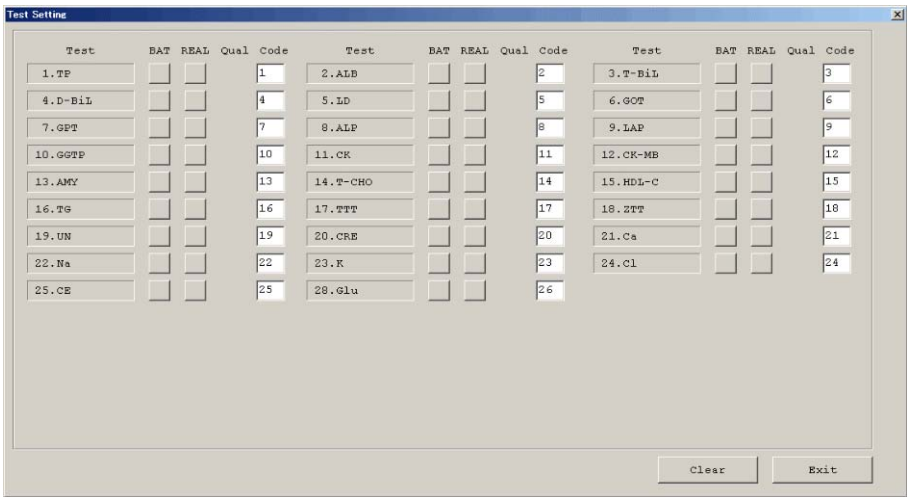
[Maximum frame size] Select "256byte" or "512byte" for the maximum size per frame of an online message.

[Host transfer date] When the LIS is operated on a date setting different from the system startup date of the analyzer, enter a date to match the communication date between the LIS and analyzer system. Default value is blank.

[Host transfer Using] Select "User Code Number" to use the user code number selected in the [Set Test] window or "Processing Test Number" when the user code number is not used. The parameters in the [Set Test] window are described below.
Select [Setup] > [Process Sequence] to define "Processing Test Numbers."

[Set Test] button

Click this button to display the window below. The following parameters are defined in this window.

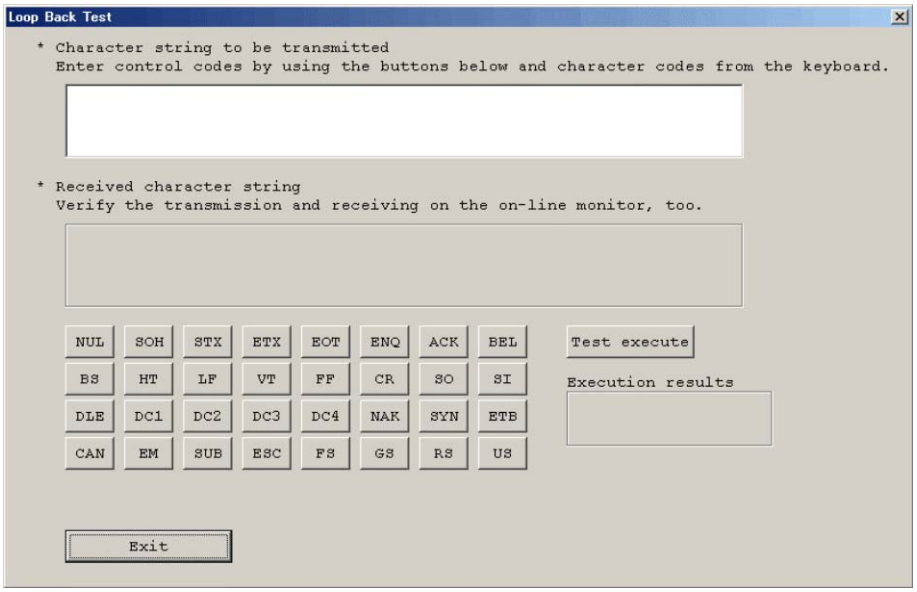


[BAT] Select this button to include the corresponding test in the batch data transfer.

[REAL]	Select this button to include the corresponding test in the realtime data transfer.
[Qual]	Select the button to send the qualitative data of the test designated with qualitative judgment.
[Code]	Enter an arbitrary test code if "User Code Number" is selected for [Host transfer Using]. It is practical to coordinate the code with that used in the LIS.

[Loop back test] button

Click this button to display the window below.

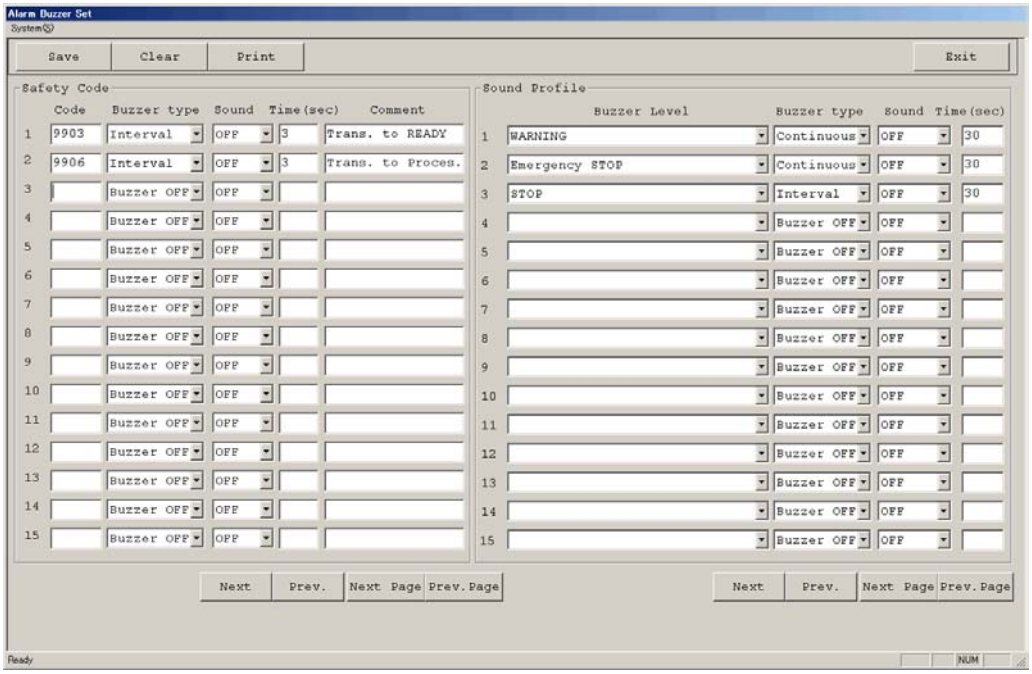


Loop back test is the dedicated application to check the function of online port of the BM6010/C system. A special connector is required to perform the test. This window is exclusively for JEOL service staff.

5.8.3 Alarm buzzer set

Select [Setup] > [Alarm Buzzer Set] to display the window below:

Use this window to setup the alarm goes off that the analyzer uses for notification. The default values are shown in the window.



Parameters in the [Safety Code] column

Set up the sound type and duration for each code.

[Safety Code] Enter the codes of errors that you want to use alarm sound. Use the error codes defined in the [Safe.No.] column in the [Maint.] > [Error Report] window.

[9903] is the code to indicate that the analyzer has entered in the [READY] mode.
[9906] is the code to indicate that the analyzer has entered in the [Processing] mode.
[1322] is the code to indicate that the analyzer has entered in the [START] mode for STT rerun from host (LIS).

[Buzzer type] Select the alarm type from "Buzzer OFF", "Continuous", and "Interval."

[Sound] This button is for use in future expansion. It is not used for the moment.

[Time (sec)] Enter the duration of the sound in second.

[Comment] Enter remarks such as the meaning of the code.

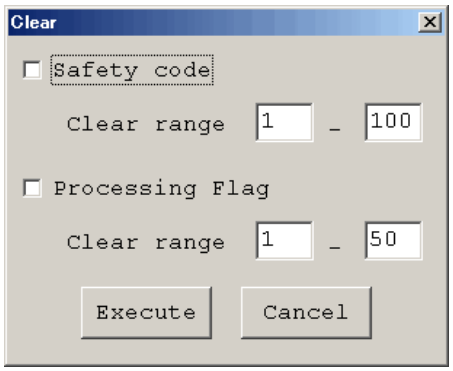
Parameters in the [Sound profile] column

Define the sound type and duration according to the status (buzzer level).

[Buzzer Level]	Buzzer type and duration can be defined according to the status when the error is detected. Select a status from "Blank", "WARNING", "Emergency STOP", "STOP", and "Error Report flag 11-50".
[Buzzer type]	Select an alarm type from "Buzzer OFF", "Continuous", and "Interval."
[Sound]	This button is for use in future expansion. It is not used for the moment.
[Time (sec)]	Enter the duration of the sound in second.

[Clear] button

Click this button to display the window below.

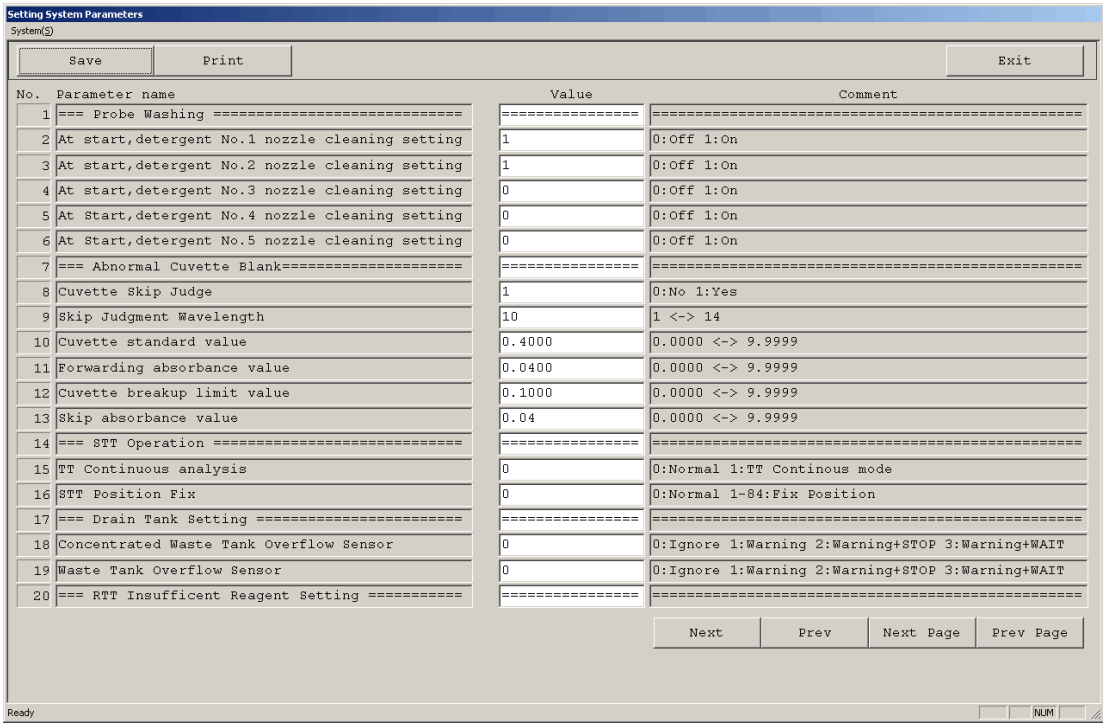


Use the [Clear] button to cancel the defined settings. Specify the range to clear with error (safety) code or processing flag.

5.9 Parameters in the [Setting System Parameters] Window

Select [Setup] > [Setting System Parameters] to open a window where you can define various settings regarding operation and data processing. Attention may be required for setting because an inappropriate setting may adversely affect operation and measurement data.

After setting the values, close the window, confirm the Operation Panel shows "READY" in the mode window, and press the [START] button. The defined settings are effective when the analyzer starts operation this way.



Columns

[Parameter name] The setting content is displayed.

[Value] Enter the value to define.

[Comment] Options or range of values is displayed.

5.9.1 [Probe Washing]

[At start detergent No.1 nozzle cleaning setting (0: Not, 1: Execute)]

[At start detergent No.2 nozzle cleaning setting (0: Not, 1: Execute)]

[At start detergent No.3 nozzle cleaning setting (0: Not, 1: Execute)]

[At start detergent No.4 nozzle cleaning setting (0: Not, 1: Execute)]

[At start detergent No.5 nozzle cleaning setting (0:Not, 1:Execute)]

These parameters define if the reagent probe is washed at the startup with the detergent defined in the [Detergent Set] window (Accessed by selecting [Setup] > [Contamination Settings] and clicking the [Detergent set] button). If the probes are not washed at the start of operation, the first measurement value may be incorrect due to the impurities remaining from the previous measurement. The default value is "1: Execute" to avoid contamination.

5.9.2 [Abnormal Cuvette Blank]

Refer to Section 5.2.5.

5.9.3 [STT Operation]

[TT Continuous analysis (0: Normal, 1:TT Continuous mode)]

Default value is "0" for routine measurement.
When "1" (continuous mode) is selected, you can specify up to 3 sample tray numbers successively (e.g. 1-3) in the [Tray No.] field in the [Patient sample] column of the [Start Conditions] windows. In this case, the tests performed on each sample remain the same as specified in the [Request] > [Order Entry] window. Also, when "1" is selected, the samples cannot be changed at the tray exchange, because the system does not stop measurement. Therefore, this option is not used for measurement but for special occasions such as investigation of test conditions. When "1" is selected, select "Cup posi." for [Analysis mode] in the [Patient sample] column in the [Start Conditions] window.

[STT Position Fix (0: Normal, 1-84: Fix Position)]

Default value is "0" for routine measurement.
When "1" - "84" is selected for a fixed position, the patient sample is aspirated at the sample tray (STT) position designated here. No matter what STT position is defined in the [Order Entry] window, all the samples are aspirated at this STT position, In this case, the tests performed on each sample remain the same as specified in the [Request] > [Order Entry] window. This option is used only in special occasions such as investigation of test conditions. When "1"- "84" (fixed

position) is selected, select "Cup posi." for [Analysis mode] in the [Patient sample] column in the [Start Conditions] window. If "Barcode" is selected, the analyzer will operate improperly. (This is a prohibited setting. Never select "Barcode" in this setting.)

5.9.4 [Drain Tank Setting]

[Concentrated Waste Tank Overflow Sensor]

This parameter is used to set the function of sensor to detect that the optional concentrated waste tank comes full. When "0" is selected, the function is not activated. When "1" is selected, an alarm goes off and a message is displayed on the Operation Panel when the tank becomes full. When "2" is selected, the alarm goes off and the message is displayed in the same way as when "1" is selected. Further, the analyzer stops the operation and enters the [STOP] mode. When "3" is selected, the alarm goes off and the message is displayed in the same way as when "1" is selected. Further, the analyzer stops the operation immediately and enters the [WAIT] mode. "0" is the default value because the tank is not included in the standard specification.

[Waste Tank Overflow sensor]

This parameter is used to set the function of sensor to detect that the optional waste tank comes full. When "0" is selected, the function is not activated. When "1" is selected, an alarm goes off and a message is displayed on the Operation Panel when the tank becomes full. When "2" is selected, the alarm goes off and the message is displayed in the same way as when "1" is selected. Further, the analyzer stops the operation and enters the [STOP] mode. When "3" is selected, the alarm goes off and the message is displayed in the same way as when "1" is selected. Further, the analyzer stops the operation immediately and enters the [WAIT] mode. "0" is the default value because the tank is not included in the standard specification.

5.9.5 [RTT Insufficient Reagent Setting]

[Processing mode in no reagent]

When the liquid level in the reagent bottle set in the

reagent tray (RTT) becomes lower than the height (in mm) from the bottom of the bottle defined for [Reagent empty RPP height] below, the analyzer judges the reagent is short. When "0" is selected, an alarm goes off and a message is displayed on the Operation Panel when the reagent bottle becomes empty. When "1" is selected, the alarm goes off and the message is displayed in the same way as when "0" is selected. Further, subsequently, the analyzer does not perform the tests using that reagent. When "2" is selected, the alarm goes off and the message is displayed in the same way as when "0" is selected. Further, the analyzer stops the operation and enters the [STOP] mode. When "3" is selected, the alarm goes off and the message is displayed in the same way as when "0" is selected. Further, the analyzer stops the operation immediately and enters the [WAIT] mode. "1" is the default value.

[Bottle change RPP height]

When multiple bottles of a reagent are set in multiple RTTs and the liquid level of the bottle in use becomes lower than the value (in mm) defined here, the analyzer stops aspirating reagent from the bottle and starts to aspirate from another bottle. "1.5 mm" is the default value. You can change the value in a value greater than that entered for [Reagent empty RPP height] below. If a value smaller than that, the analyzer judges the reagent is empty before changing the bottles, and mark the data with the "r" flag to show the reagent bottle was empty.

Please refer to “Section 5.1.1 "Using multiple bottles of a reagent for a test" of this chapter.

[Reagent empty RPP height]

When the liquid level of the reagent bottle in RTT becomes lower than the height (in mm) from the bottom of the bottle defined here, the analyzer judges the reagent has run out. Also the relevant data are flagged with "r" to indicate the reagent had run out. "1.0 (mm)" is the default value.

[Reagent Reset (0:Bottle Capacity , 1:Indefinite)]

This parameter selects the reagent volume after the [Reset] button is clicked in the [Reagent Test Monitor] window accessed via [Reagent]. When [0] (Bottle

Capacity) is selected, the analyzer assumes that the reagent bottle is full. (The reagent volume is assumed to be the value defined for each container in the [Reagent Bottle Specifications] column accessed via [Setup] > [System Specification Settings], the value defined in the [Container] column accessed via [Reagent] > [Reagent Container Settings].) When [1] (Indefinite) is selected, the analyzer assumes that the reagent volume is unknown. The [Vol.Left (ml)] field displays "- - -" and the [VOLUME DISPLAY] bar is shown in gray in the [Reagent Test Monitor] window.

5.9.6 [STT Sample Barcode Setting]

[Barcode digit limit (Lower)]

[Barcode digit limit (Upper)] The analyzer accepts a sample barcode with up to 13 digits. When using a fixed range of barcode digit number, enter the lower and upper limit respectively. When the barcode reader reads a sample barcode, if the digit number of the read barcode is not in the range defined here, the analyzer assumes it is a reading error. The value ranges between "0" and "13". Enter the smaller number for [Barcode digit limit (Lower)] and the larger for [Barcode digit limit (Upper)]. When "0" is selected, there will be no limit in the digit number. Default value is "0".

[Edit of STT Barcode Confirmation screen (0: Sample Setting Position, 1: All)]

When the sample barcode reading is completed, the [STT Barcode confirmation] window is displayed. When "0: Sample Setting Position" is selected, ID fields are displayed only for the positions where the samples are placed. When "1: All" is selected, all the ID fields are displayed whether the sample is placed or not.

[STT Barcode Error Process (0: Ignore, 1: Waiting+AutoStartoff)]

The parameter defines the procedure when a barcode reading error occurs, When "1" (Waiting + AutoStartoff) is selected; an error message is displayed when a barcode reading error occurs for a patient or blank sample. The analyzer will not start no matter what value is entered for [Sample Barcode Confirm time] (to be described below), unless you click the [Re-try] button in the [Sample confirmation] window. When

"0" (Ignore) is selected, no error message is displayed. However, when the sample barcode reading error may cause an erroneous sampling, the operation is stopped and a popup window is displayed to draw attention. In some cases when sample containers with and without barcode label are used together, "0" may be a better option.

[Sample Barcode Confirm time (10 – 10000, 0: timer off)]

This parameter defines the waiting time of the sample barcode confirmation window. When "0" is selected, sampling does not start until the [OK] button is clicked in the [Sample Barcode Confirm] window. When entering a number between 10 and 10,000, the sampling starts automatically after the defined time (in second) is elapsed. The numbers "1" - "9" are invalid.

5.9.7 [Automatic Control]

[Automatic Control Counting method (0: Total tests 1: Number of tests of each item)]

See "Section 5.4.2 Automatic control measurement" in this chapter.

[Auto.Control Execution method in Each Assay (0: Individual 1: All items)]

See "Section 5.4.2 Automatic control measurement" in this chapter.

5.9.8 [STAT Port]

[STAT Port Request Screen Timer (0: Timer OFF, 1-999: Timer (sec))]

This parameter selects the waiting time of the STAT port request window. When "0" is selected, sampling does not begin until the [OK] button is clicked in the [STAT Port] window. When entering a number between 1 and 999, the measurement begins automatically after the defined time (in second) is elapsed.

[STAT Port Request Reflex Setting (0-9: Specify.STAT Set, 99: Reflex of Last STAT Set)]

This parameter selects the STAT set to display in the [STAT port] window when a sample is set in the STAT port. When a value from "0" to "9" is entered, the corresponding STAT set is displayed. When "99" is entered, the STAT set used last time is displayed.

[STAT Screen Comment Display Setting (0: Not Display, 1:Comment1, 2:Comment2, 3:Both)]

This parameter selects the comment to display in the [STAT port] window. When "0" is selected, no comment is displayed; when "1" is selected, only

Comment 1 is displayed; when "2" is selected, only Comment 2 is displayed; when "3" is selected, both Comments 1 and 2 are displayed.

CONTENTS

Chapter

6 Data Processing

CONTENTS

6.1 Chemistry Analysis (Measurement of Absorbance)

6.1.1 Assay method

6.1.1a Assay methods

The table below summarizes the assay methods available with BM6010/C. Select [Setup] > [Analytical Parameters (Chemistry)] to setup the assay method.

List of Assays Available withBM6010/C

Analy. mthd	[Analytical Parameters (Chemistry)] Condition for setting points		Minimum total volume required (µL)	Calculated absorbance	Remarks
EPA	m<n, p=r=0		(S+V)≥80	A_{mn}	
	P<r, m<n		(S+Vp, m)≥80	$A_{mn}-k_{pm}\times A_{pr}$ +	Sample blank correction is possible
RRA	0≤l<m<n, p=r=0		(S+V)≥80	$\Delta A_{mn}(\Delta A_{ln})$	
	P<r, 0≤l<m<n		(S+Vp, m)≥80	$\Delta A_{mn}(\Delta A_{ln})-k_{pm}\times\Delta A_{pr}$	Sample blank correction is possible
2PA	m+2<n, p=r=0		(S+V)≥80	$\frac{(A_n+A_{n-1})-(A_m+A_{m+1})}{2t}$	
	P<r, 0≤l<m<n		(S+Vp, m)≥80	$\frac{(A_n+A_{n-1})-(A_m+A_{m+1})}{2t_{mn}} - \frac{k\{(A_r+A_{r-1})-(A_p+A_{p+1})\}}{2\,t_{pr}}$	Sample blank correction is possible
CRA	0<l≤4, 0<m<n	p, r≠0, p≠r	(S+Vp, m)≥80	$\frac{A(tr)-A(tp)}{ttr\ -tp}$	Rate assay
		p≠0(p=r or r=0)		$\Delta A(tp)=A\times k\times\exp(-k\times tp)$	Rate method
		p=0		$A(t_\infty)-A(0)$	End-point assay
IMA	0≤l<m<n, p=r=0		(S+V)≥80	$\Delta A_{mn}(\Delta A_{ln})$	
	P<r, 0≤l<m<n		(S+Vp, m)≥80	$\Delta A_{mn}(\Delta A_{ln})-k_{pm}\times\Delta A_{pr}$	Sample blank correction is possible

In the above table,

l, m, n, p, r: Data point.

S: Sample volume

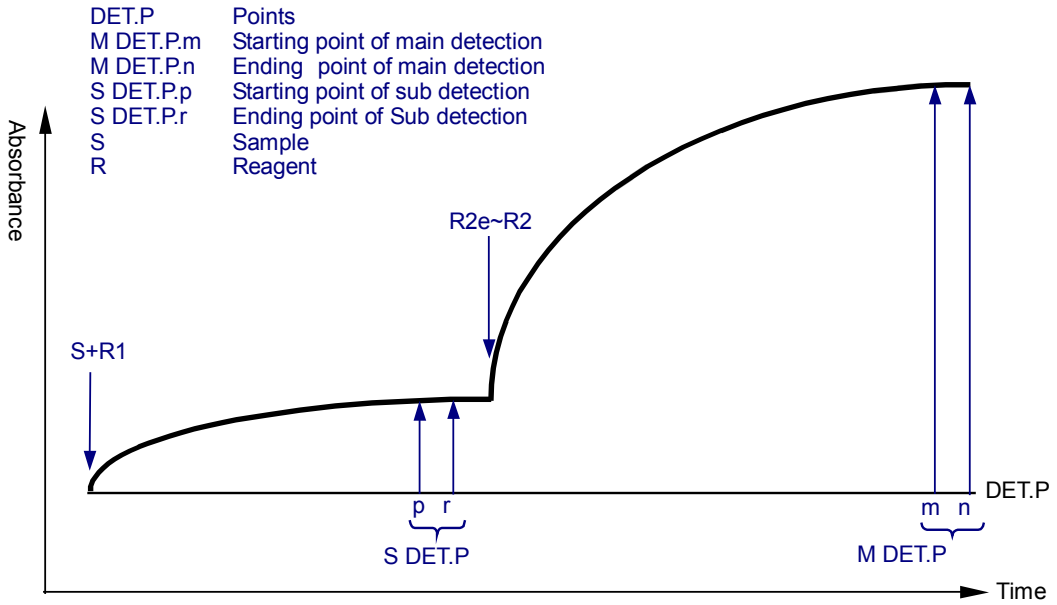
V, Vp, m: Reagent volume (total volume at the points p and m)

Amn: Mean absorbance between the points m and n. The highest and lowest values are excluded from calculation.

⊿Amn	Variance per minute in absorbance between the points m and n, calculated by least squares.
tmn	Time (min) between the points m and n.
A(tp)	Absorbance obtained from the approximation curve by assigning the time at the point p.
⊿A(tp)	The slope of the tangent line of the approximation curve at the point p.
kpm	Liquid volume correction factor＝(S＋Vp)／(S＋Vm)

6.1.1b End-point assay (EPA)

In EPA, the concentration is calculated from the absorbance at the certain time point after the reagent addition.



Typical reaction process in EPA and an example of setting the points

Enter the measurement conditions

In the Menu Panel, select [Setup] > [Analytical Parameters (Chemistry)]. Select "EPA" from the drop-down menu of [Analy.mthd] in the [Sub-analy.conditions] column in the [Analytical Parameters (Chemistry)] window.

Define the following parameters in the [Calculation method setting] column.

M-DET.P l＝0 (One point is not used in EPA)

m < n or m≠ 0 and n ＝0 (DET.P.m must be defined)

S-DET.P If you do not use "S-DET.P", be sure to enter p＝r＝0 .

If you use it, p < r or ≠p0 and R ＝ 0.

Calculated absorbance

When "S-DET.P" is not used

Calculate the mean absorbance in the range between the points m and n with the highest and lowest values excluded. Name this absorbance as "Abs1". With n = 0, take the median absorbance in the range of the points m, m+1, and m+2 as "Abs1".

Calculated absorbance Abs = Abs1

When "S-DET.P" is used

Calculate the mean absorbance in the range between the points p and r with the highest and lowest values excluded. Name this absorbance as "Abs2".

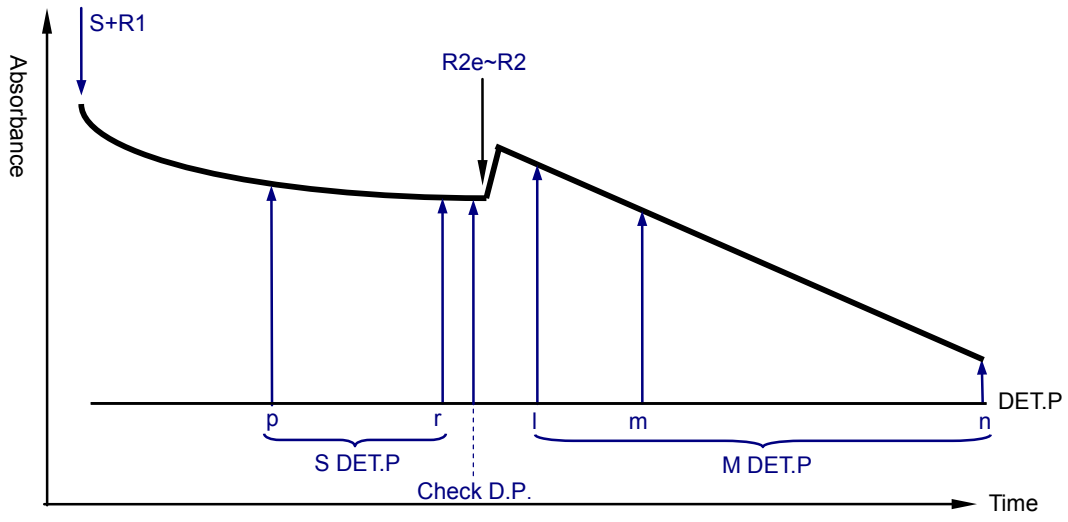
With r = 0, take the median absorbance in the range of the points p, p+1, and p+2 as "Abs2".

Calculated absorbance Abs = Abs1 - k x Abs2

Abs2 of S-DET.P can be used for correcting the blank correction of the sample. "k" is the volume correction factor.

6.1.1c Radio rate assay (RRA)

In RRA, concentration or activity is calculated from the variance per minute in absorbance between 2 points obtained with least squares.



Typical (decreasing) reaction process in RRA and an example of setting the points

Enter the measurement conditions

In the Menu Panel, select [Setup] > [Analytical Parameters (Chemistry)]. Select "RRA" from the drop-down menu of [Analy.mthd] in the [Sub-analy.conditions] column in the [Analytical Parameters (Chemistry)] window.

Define the following parameters in the [Calculation method setting] column.

M-DET.P With $l=0$ or $l \geq m$, points are not moved forward. (When the measurement values at some points are judged invalid by the method described later and excluded, and consequently the number of points becomes smaller than the defined number, the range for M-DET.P is expanded by moving the points consecutively forward from "1" to "n".)

With $1 < m$, when the absorbance of the main wavelength is over the absorbance limit, for example in case of a sample producing abnormally high value, the over-the-limit absorbance values are automatically excluded from calculation. Also, when the number of the measurement values is 3 or smaller, the points are moved forward consecutively up to "l" so that the number will be 4.

With DET.P.m, n, be sure to set $m < (n-4)$ and $m \neq 0$.

S-DET.P If you do not use "S-DET.P", be sure to enter $p=r=0$.

If you use it, set $p < r$.

E2 CORRECTION ([E2 CORRE])

Blank correction is applied to the sample measurement value outside the absorbance limit (d) [hereafter sample (d)] or [hereafter sample (u)]. Here, "d" stands for "lower" and "u" for "upper". This correction is called "E2 CORRECTION."

Sample measurement value corrected for the lower limit [Hereafter, corrected value (d)] = the sample (d) $+k\times$ (E2 value $-$ RBE2 value)

However, the correction is not applied when (E2 value $-$ RBE2 value) ≤ 0.

Here, E2 is the median of measurement values at the 3 E2 points for the main wavelength.

RBE2 indicates the E2 value at the reagent blank measurement.

"k" is the volume correction factor.

Calculated absorbance

When "S-DET.P" is not used

Calculate the variance per minute in absorbance from the measurement values at the M-DET.P points by least squares and name it as $\triangle$Abs1.

Calculated absorbance variance $\triangle$Abs = Abs1

When "S-DET.P" is used

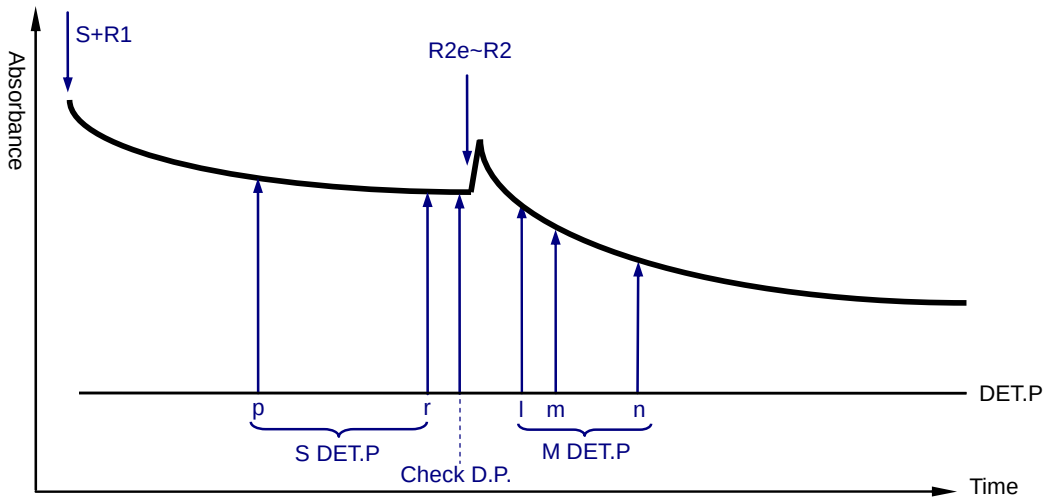
Calculate the variance per minute in absorbance from the measurement values in the range of the points "p" to "r" by least squares, and name it as ⊿Abs2.

Calculated absorbance variance ⊿Abs = ⊿Abs1−k×⊿Abs2

"k" is the volume correction factor.

6.1.1d 2-point assay (2PA)

2PA is a reaction rate assay where the concentration or activity is calculated from the variance per minute in absorbance between 2 points. "E2 CORRECTION" can be applied to the samples (u) and (d) as with RRA.



Typical (decreasing) reaction process in 2PA and an example of setting the points

Enter the measurement conditions

In the Menu Panel, select [Setup] > [Analytical Parameters (Chemistry)]. Select "2PA" from the drop-down menu of [Analy.mthd] in the [Sub-analy.conditions] column in the [Analytical Parameters (Chemistry)] window.

Define the following parameters in the [Calculation method setting] column.

M-DET.P With l=0 or l ≥ m, points are not moved forward.

Also, with 1 < m, when the number of the measurement values is 3 or smaller (e.g. a sample has produced abnormally high values), the points are moved forward consecutively up to "l" so that the number will be 4.

With DET.P.m, n, be sure to set m < (n−4) and m ≠ 0.

S-DET.P If you do not use "S-DET.P", be sure to enter p=r=0 .

If you use it, set p < r.

Calculated absorbance

When "S-DET.P" is not used

Variance in absorbance per minutes (⊿Abs1) is obtained by dividing the difference between the mean absorbance at the points "m" and "m+1" and that at the points "n", "n-1" by the time between the points.

Calculated absorbance variance ⊿Abs = ⊿Abs1

When "S-DET.P" is used

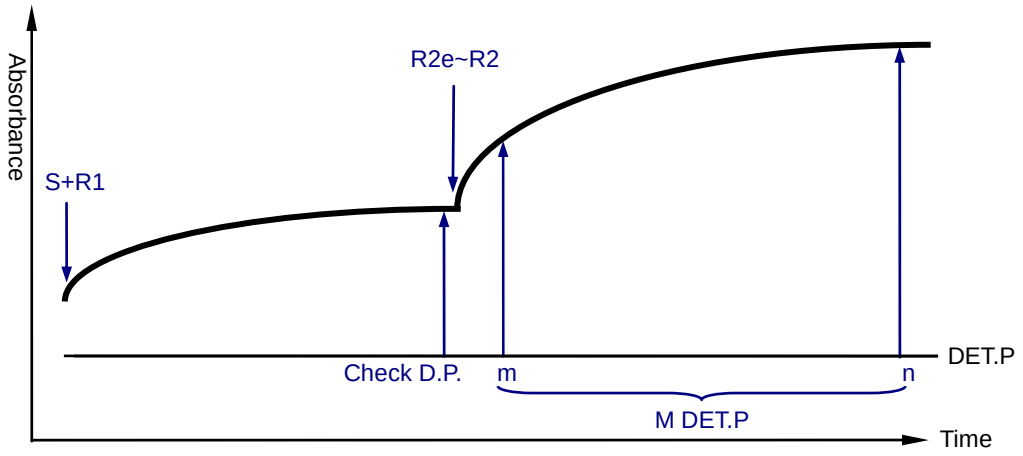
The variance in absorbance per minute (⊿Abs2) is obtained by dividing the difference between the mean absorbance at the points "p" and "p+1" and that at the points "r", "r-1" by the time between the points.

Calculated absorbance variance ⊿Abs = ⊿Abs1 - k×⊿Abs2

"k" is the volume correction factor.

6.1.1e CRA

In CRA, the approximation curve is obtained by least squares for response where the absorbance becomes constant over time, and then absorbance is calculated from the approximation curve with setting either absorbance variation or reaction time as infinite to obtain concentration or activity. "E2 CORRECTION" can be applied to the samples (u) and (d).



Typical (increasing) reaction process with CRA and an example of setting the points

Enter the measurement conditions

In the Menu Panel, select [Setup] > [Analytical Parameters (Chemistry)]. Select "CRA" from the drop-down menu of [Analy.mthd] in the [Sub-analy.conditions] column in the [Analytical Parameters (Chemistry)] window.

Define the following parameters in the [Calculation method setting] column.

M-DET.P Be sure to set $1 \leq l \leq 4$ for DET.P.l. Enter the trigger reagent number. Accurate reaction time is required for approximation in CRA. The reaction is assumed to begin at the time when this trigger reagent is dispensed.
With DET.P.m, n, be sure to set $m < n$ and $m \neq 0$. Calculate the approximation curve of the chemical kinetics by least squares from the absorbance values in the range of the points m to n. Set the range as large as possible to obtain the correct value.

S-DET.P Used for calculating the absorbance from the obtained approximation curve. The absorbance calculation varies depending on the setting.

Calculated absorbance

When S-DET.P is set with p = r ≠ 0 or p ≠ 0 and r = 0

Absorbance variance (⊿Abs) is calculated from the slope of the tangent line at the time "t(p)" on the approximation curve.

When S-DET.P is set with p < r

Absorbance variance (⊿Abs) is calculated from the slope of the line connecting the calculated absorbance values at the time "t (p)" and "t (r)".

When S-DET.P is set with p = r = 0.

Absorbance [Abs(t_∞)] is calculated with setting infinite for time of the approximation curve. Then the [Abs(t_∞)] is corrected for blank to obtain absorbance (Abs).

6.1.1f Immunoassay (IMA)

In IMA, concentration or activity is calculated from the variance per minute in absorbance between 2 points obtained with least squares. This method is effective when E2 CORRECTION is not applicable because the volume of the reagent 1 is too small, or when you want to correct the measurement for the serum blank in the one-part reagent

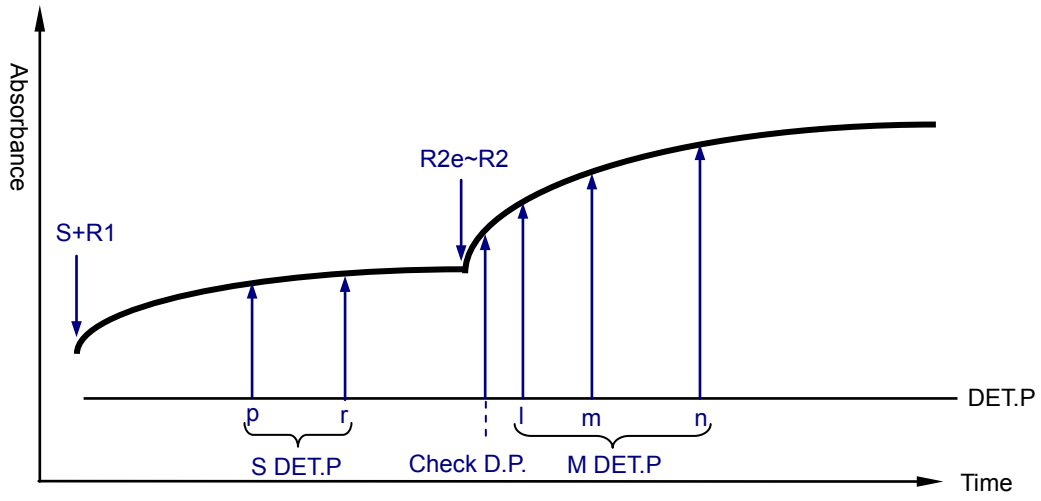
The difference from RRA is as follows:

- Check D.P. Correction

  When excluding the values using the absorbance limit of M-DET.P, absorbance at the Check D.P. is used for correction instead of the E2 point. This allows sample blank correction when the sample volume is small at the E2 point.

- Automatic update of the limit values

  During calibration, the absorbance limit and prozone limit values are calculated from the calibration data to allow automatic updating of the values.



Typical (increasing) reaction process with IMA and an example of setting the points

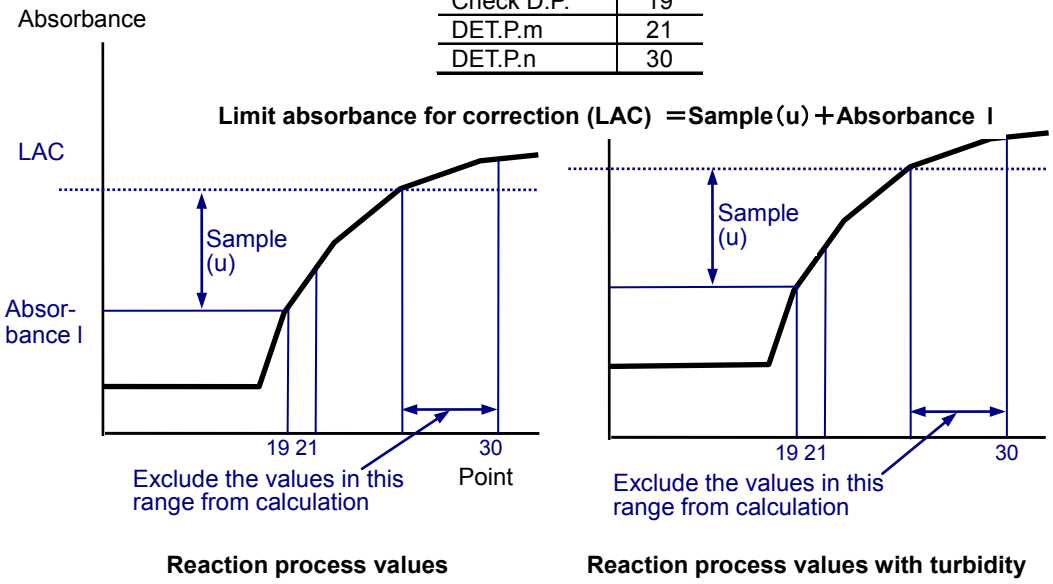
Enter the measurement conditions

In the Menu Panel, select [Setup] > [Analytical Parameters (Chemistry)]. Select "IMA" from the drop-down menu of [Analy.mthd] in the [Sub-analy.conditions] column in the [Analytical Parameters (Chemistry)] window.

Define the following parameters in the [Calculation method setting] column.

Check D.P. When the check D.P.＝0, no correction is applied to the absorbance limit. When the check D.P.>0, correction is applied to the sample (d) during the decreasing phase of reaction and to sample (u) in the increasing phase. This correction is called "Check D.P. Correction."
Corrected absorbance limit = Absorbance of the sample (d or u) +k × value at the check D.P.
Here, "k" is the volume correction factor.

Example of Check D.P. setting	
Check D.P.	19
DET.P.m	21
DET.P.n	30



M-DET.P With l＝0 or l ≥ m, points are not moved forward.

With 1 < m, when the absorbance with the main wavelength is over the absorbance limit, in the increasing phase of reaction (see the figure in the previous page), for example in case of a sample producing an abnormally high value, the over-the-limit absorbance values are automatically excluded from calculation. Also, when the number of the measurement values is 3 or smaller, the points are moved forward consecutively up to "l" so that the number will be 4.

With DET.P.m, n, be sure to set m < (n－4) and m≠ 0.

S-DET.P If you do not use "S-DET.P", be sure to enter p＝r＝0 .

If you use it, set p < r.

Calculated absorbance

The absorbance is calculated by the same formula as used in RRA (See Section 6.1.1c).

Automatic update of the limit values

During multi-point calibration, the absorbance limit and prozone limit values are calculated from the calibration data to allow automatic updating of the values. Generally, the reagents for immunoassay tend to vary by lot, therefore, the assay may not succeed with fixed limit values. In such a case, use this function.

Defining calibrators for each limit value and point in the reaction process

Select [Setup] > [Analytical Parameters (Chemistry)], and click the [Multi-STD setting] button to display the [Multi-Standards Set] window.

- Define the calibrators

  Enter the appropriate values in each line. The line "0" is for reagent blank and the lines 1 to 9 are for STD1 to STD9 respectively.

- Click the [IMA setting] button in the [Analytical Parameters (Chemistry)] window to display the [IMA Set] window.

- Enter [D.P. set l] and [D.P. set m].

  Specify the range of points in the reaction process for the main wave length of the selected calibrator to be used for automatic calculation

- Define [Factor d].

  Define the factor so that the variance in absorbance between the specified points will be the corresponding limit value. The value range is from -9.999 to 9.9999.

- Select whether or not to use the function of automatic update of the limit values in the respective [Auto. set] field.

  Select "Do." When "Not do" is selected, the limit values are not updated after calibration. If you do not want to update the values, select "Not do."

Calculation formula

The limit value calculation formulas for the blank samples (u) and (d), samples (u) and (d), and the prozone sample is:

$$\text{Limit Value} = \text{Factor d} \times (Am - A_1)$$

where, Am represents the absorbance with the main wavelength at the D.P. set m for the selected calibrator. When 0 is entered for [D.P. set m], Am equals 0.

where, A_1 represents the absorbance with the main wavelength at the D.P. set l for the selected calibrator. When 0 is entered for [D.P. set l, A_1 equals 0.

Displaying the updated limit values

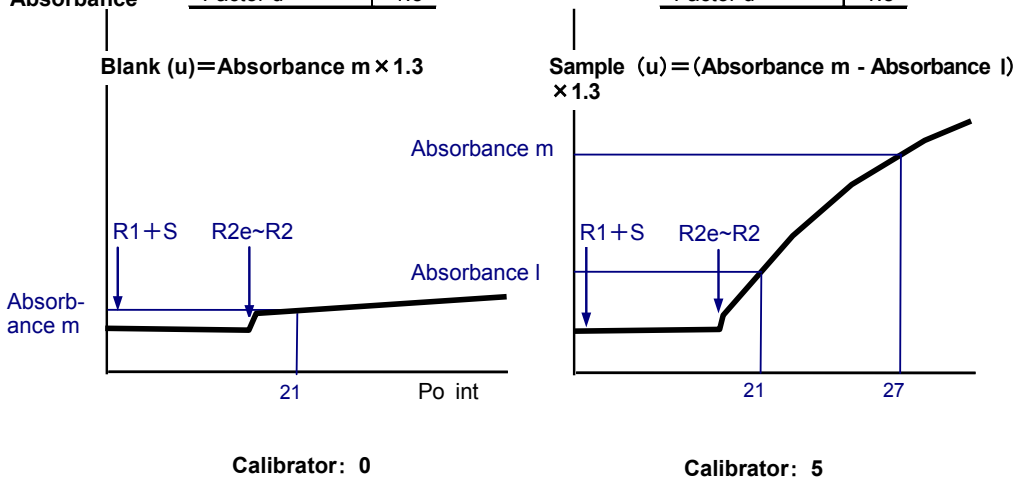
- Click [OK]. When the calibration is completed, the limit values in the [Analytical Parameters (Chemistry)] window are updated.

When the calculation results is outside the effective range (from -9.9999 to 99.9999), the limit values are not updated and the previous values are maintained.

Example of settings

IMA Blank (u)	
Calibrator	0
D.P.set l	0
D.P.set m	21
Factor d	1.3

IMA Sample (u)	
Calibrator	5
D.P.set l	21
D.P.set m	27
Factor d	1.3



6.1.2 Calibration

Calibration is an operation for generating a calibration curve used for converting the absorbance or its variance of the reaction solution into a concentration or activity value.

6.1.2a Methods of calibration

Calibration methods are summarized in the table below. The parameters are defined in the [Analytical Parameters (Chemistry)] window. Note that the calibration data for a test can be used for another test.

See "Section 5.7.2 Setting up a blank reagent" in “Chapter 5.

List of Calibration Methods

<table>
<tr><th colspan="3">Method</th><th>Number and type of calibrators</th><th>Conversion method for concentration</th></tr>
<tr><td colspan="3">Absorbance (ABS) calculation</td><td>Reagent blank</td><td>Reaction ABS x FV</td></tr>
<tr><td colspan="3">One-point calibration curve</td><td>Reagent blank 1
Standard</td><td>Reaction ABS x FV/(ABS of standard)</td></tr>
<tr><td rowspan="5">Multipoint calibration curve *1 (MSTD calculation)</td><td rowspan="3">• No conversion
• Semi-log transformation (The concentration is log-transformed.)
• Log transformation (Both the concentration and the reaction ABS are log-transformed.)</td><td>Linear function</td><td>Reagent blank and one or two calibrators</td><td>Calculate "a" from the calibration function "Y＝aX＋d" by l east squares approximation, and then convert it to concentration by false position method.</td></tr>
<tr><td>Quad-ratic function</td><td>Reagent blank and two or three calibrators</td><td>Calculate "a" and "b" from the calibration function "Y=aX^2＋bX＋d" by least squares approximation, and convert them to concentration by false position method.</td></tr>
<tr><td>Cubic function</td><td>Reagent blank and three or four calibrators</td><td>Calculate "a", "b" and "c" from the calibration function "Y=aX^2＋bX^2＋cX＋d" by lea st s quares approximation, and convert them to concentration by false position method."</td></tr>
<tr><td colspan="2">Broken line approximation</td><td>Reagent blank and one or two calibrators</td><td>Connect the points consecutively with the linear function Y = aX+d to obtain "a", and convert it to concentration by reverse calibration function of the corresponding absorbance.</td></tr>
<tr><td colspan="2">Spline interpolation</td><td>Reagent blank and two or three calibrators</td><td>Connect the points consecutively with the cubic function Y＝aX^3＋bX^2＋cX＋d to obtain "a", "b", and "c", and convert them to concentration by reverse calibration function of the corresponding absorbance.</td></tr>
<tr><td colspan="2">LOGIT-LOG1 function</td><td>Reagent blank and two or three calibrators</td><td>Calculate "a" and "b" from the calibration function "Y＝(a-d)/(1+X/b)+d" by least squares approximation, and convert them to concentration by false position method.</td></tr>
</table>

Method		Number and type of	Conversion method for concentration
	LOGIT-LOG2 function	Reagent blank and three or four calibrators	Calculate "a", "b", and "c" from the calibration function "Y=(a-d)/(1+(X/b)^{c})+d" by least squares approximation, and convert them to concentration by false position method.
	LOGIT-LOG3 function	Reagent blank and four or five calibrators	Calculate "a", "b", "c", and "e" from the calibration function "Y=(a-d)/(1+(X/b)^{c}exp(eX))+d" by least s quares approximation, and convert them to concentration by false position method.
	Simplified calibration*2	Reagent blank 1 calibrator	Calibration function "Fx" is obtained from the multipoint calibration curve and corrected with the reagent blank and a calibration value to obtain the function "Y=F(X)×u2+u1" which is used for conversion to concentration for each calibration method.

*1 Up to 9 calibrators can be measured in multipoint calibration except the reagent blank. If the reagent blank is not used, up to 10 calibrators can be measured.
In the calculation formulas of multipoint calibration (MSTD), X corresponds to concentration and Y to calculated absorbance.
In multipoint calibration curve with reagent blank, the X axis indicates concentration (reagent blank and FV1 to 9) and the Y axis shows reaction absorbance. In multipoint calibration curve without reagent blank, the X axis indicates concentration (FV0 to 9) and the Y axis shows calculated absorbance.
Calculated absorbance: Absorbance (ABS) of the calibrator
Reaction absorbance: Absorbance of the calibrator subtracted by reagent blank (ABS-RB)

*2 Simplified calibration uses a 2-point calibration curve for daily correction of the reagent blank and slope of the multipoint calibration curve that requires more calibrators to obtain. The calibration function F(X) must be obtained in advance with the selected calibrators.

6.1.2b Calibration

See "Section 2.2.5 Calibration Setup window" in “Chapter 2 for details of calibration settings

Measurement of the reagent blank

1 Select the tests for which the reagent blank will be m easured, in the [Calibration Setup] window.
2 Define the CTT No. and the position to set the reagent blank.
3 Define the replication number.
Measurement can be repeated up to 5 times.
4 Start the measurement.

The mean measurement value of the values except the smallest and largest values is retained and displayed in the [Calibration Summary] in the [View Calibration Curve] window.

Measurement of the calibrators (STD)

One-point calibration (Calculation for STD and simplified calibration)

1 Select the tests for which the calibrators will be measured, in the [Calibration Setup] window.
2 Define the CTT No. and the position to set the calibrator
3 Define the replication number.
Measurement can be repeated up to 5 times.
4 Start the measurement.

The mean measurement value of the values except the smallest and largest values is retained and displayed in the [Calibration Summary] in the [View Calibration Curve] window.

[Multi-Standard Setup] window

1 Select the tests for which the calibrators will be measured, in the [Calibration Setup] window.
2 Define the STT No. and the position to set the calibrator from the window displayed by clicking the [Setting] button on the MSTD column.
3 Define the replication number.
Measurement can be repeated up to 5 times.
4 Start the measurement.

The mean measurement value of the values except the smallest and largest values is retained and displayed in the [Calibration Summary] in the [View Calibration Curve] window as reaction ABS which is the absorbance subtracted by the reagent blank.

6.1.2c Absorbance (ABS) calculation

In calibration for the ABS calculation, only the reagent blank is measured. A constant FV is used for conversion to concentration.

6.1.2d One-point calibration

The concentration of reagent blank and a calibrator (STD) are measured for calibration.

Concentration of the standard is used as FV for conversion to concentration.

The following formula is used.

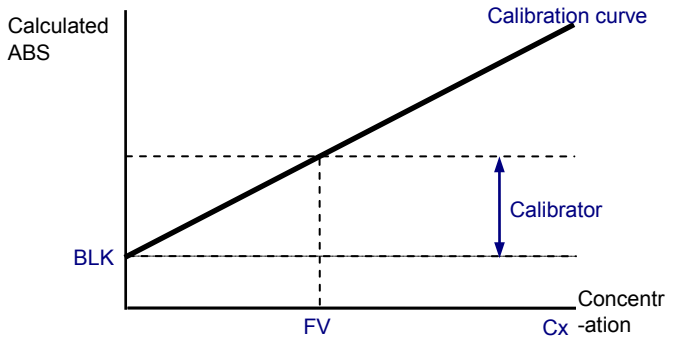
$$Cx = \text{Reaction ABS} \times FV \square \text{ (Reaction ABS of calibrator)}$$

Cx: Concentration or a unit of the measurement sample (hereafter referred to as concentration)

Reaction ABS: Reaction absorbance of the measurement sample

FV: Constant for calibration concentration

STD: Calibration value stored in the system



The following formula is used for calculating "F" (slope of the calibration curve).

$$F = FV / (\text{reaction ABS of STD})$$

6.1.2e Multipoint calibration (no conversion, linear, quadratic, and cubic functions)

Concentrations of the reagent blank and calibrators (STD) are measured. One up to ten calibrators can be used.

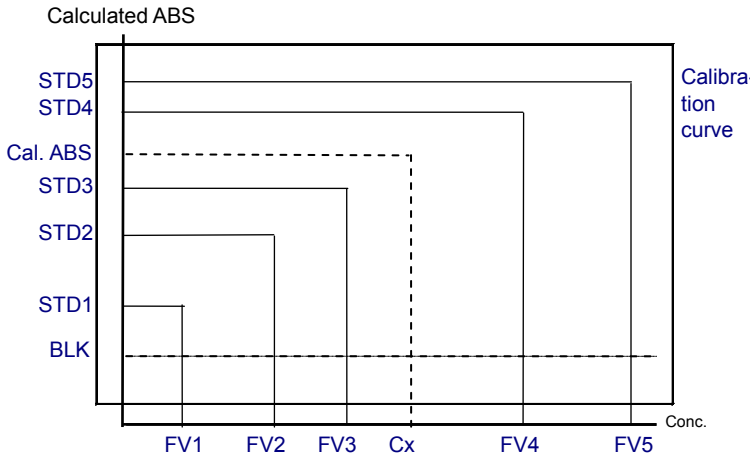
The calibration curve is calculated with the following formula.

$$\text{Calculated ABS} = a \times Cx^3 + b \times Cx^2 + c \times Cx + d$$

Calculated ABS: Calculated absorbance of the measurement sample

Cx: Concentration of the sample

a, b, c, d: Factors automatically calculated by curve approximation in calibration.



Up to 10 calibrators are used to calculate factors a, b, c, and d by least squares. In the above figure, the reagent blank and 5 calibrators are used. In linear function, a = b = 0, and in quadratic function, a=0. The number of calibrators must be at least the number of exponentiation powers plus 1 including the reagent blank. False power method is used to calculate Cx from the calculated ABS.

The calculation to obtain the factors a, b, c, and d varies as follows depending on the presence or absence of the reagent blank.

In the presence of the reagent blank, the calibration curve is obtained from the measurement results of the reagent blank and calibrators so that it should pass the origin (0, 0, or the blank point).

In the absence of the reagent blank, the curve does not necessarily pass the origin because it is obtained from the measurement results of calibrators only.

6.1.2f Multipoint calibration (semi-log transformation, linear, quadratic, and cubic approximations)

Concentrations of the reagent blank and calibrators (STD) are measured. One up to ten calibrators can be used.

The calibration curve is calculated with the following formula.

$$f(Cx) = \log(Cx/FVi + \sqrt{1 + (Cx/FVi)^2})$$

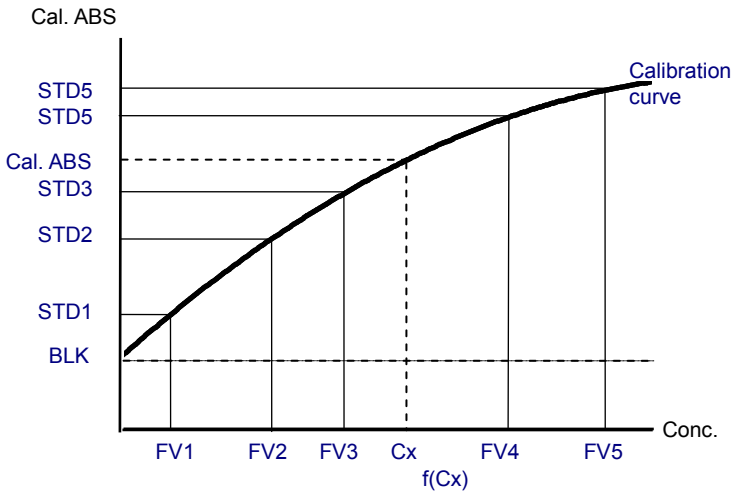
$$\text{Cal. ABS} = a \times f(Cx)^3 + b \times f(Cx)^2 + c \times f(Cx) + d$$

F (Cx): Axis transformed concentration

FVi: Concentration of the second highest calibrator

Calculated ABS: Calculated absorbance of the measurement sample

a, b, c, d: Factors automatically calculated by curve approximation in calibration



See the description under the graph in Section 6.1.2e for how to obtain the factors a, b, c, and d.

6.1.2g Multipoint calibration (log transformation, linear, quadratic, and cubic approximations)

Concentrations of the reagent blank and calibrators (STD) are measured. One up to ten calibrators can be used.

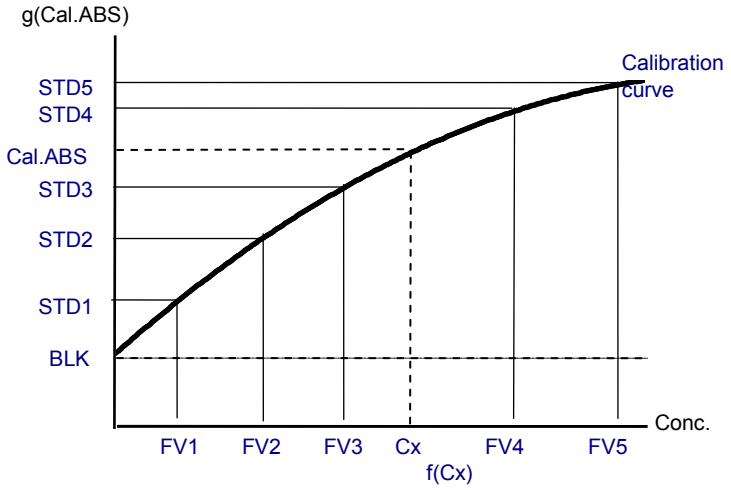
The calibration curve is calculated with the following formula.

$$f(Cx) = \log(Cx/FVi + \sqrt{1 + (Cx/FVi)^2})$$

$$g(Cal.ABS) = \log(Cal.ABS/Ai + \sqrt{1 + (Cal.ABS/Ai)^2})$$

$$g(Cal.\ ABS) = a \times f(Cx)^3 + b \times f(Cx)^2 + c \times f(Cx) + d$$

f (Cx):	Factor to convert absorbance to concentration
g (Calculated ABS):	Axis transformed calculated ABS
Cx:	Concentration of the sample
FVi:	The second lowest concentration of the calibrator
Calculated ABS:	Calculated absorbance of the measurement sample
Ai:	The second lowest calculated ABS of the calibrator
a, b, c, d:	Factors automatically calculated by curve approximation in calibration



See the description under the graph in Section 6.1.2e for how to obtain the factors a, b, c, and d.

6.1.2h Multipoint calibration (Broken line approximation)

Concentrations of the reagent blank and calibrators (STD) are measured. One up to ten calibrators can be used.

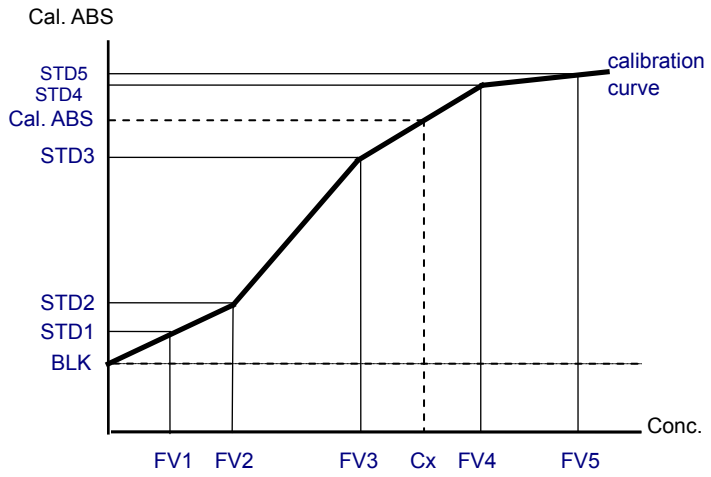
The calibration curve is calculated with the following formula.

$$Cal.ABS = a_i \times Cx + d_i$$

Calculated ABS: Calculated absorbance of the measurement sample

Cx: Concentration of the sample

a_i, d_i: Automatically obtained factors for each section of calibration (i=1 to 10)



Up to 10 calibrators can be used. In the above figure, the reagent blank and 5 calibrators are used. A linear function is obtained for each section of the curve by connecting two measurement points in the section. The number of calibrators must be at least two including the reagent blank. Set the calibrator in such a way that the concentration will be higher as the number of FV is larger. (i.e, the reagent blank or FV0 < FV1 < FV2 < FV3 ....) Click the [MSTD setting] button in the [Analytical Conditions (Chemistry)] window and enter the values in the fields under the [FV] header.

6.1.2i Multipoint calibration (Cubic spline interpolation)

Concentrations of the reagent blank and calibrators (STD) are measured. Two up to ten calibrators can be used.

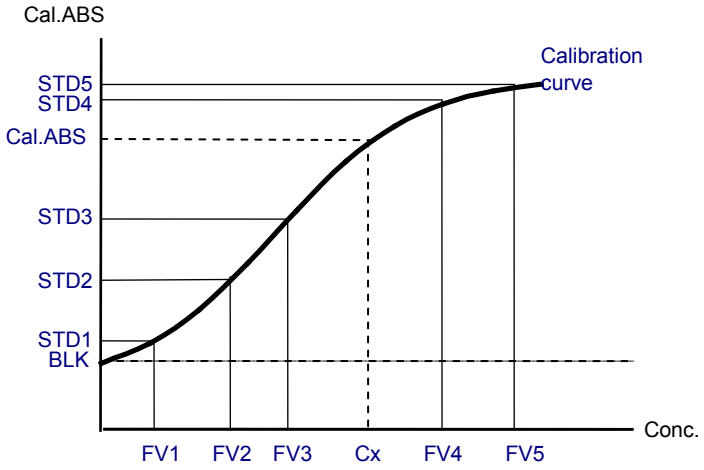
The calibration curve is calculated with the following formula.

$$\text{Cal. ABS} = a_i \times Cx^3 + b_i \times Cx^2 + c_i \times Cx + d_i$$

Calculated ABS: Calculated absorbance of the measurement sample

Cx: Concentration of the sample

a_i, b_i, c_i, d_i: Automatically obtained factors for each section of calibration (i = 1 to 10).



Up to 10 calibrators can be used. In the above figure, the reagent blank and 5 calibrators are used. A cubic function is obtained for each section of the curve by connecting three measurement points in the section. The number of calibrators must be at least three including the reagent blank. Set the calibrator in such a way that the concentration will be higher as the number of FV is larger. (i.e, the reagent blank or FV0 < FV1 < FV2 < FV3 ....) Click the [MSTD setting] button in the [Analytical Conditions (Chemistry)] window and enter the values in the fields under the [FV] header.

6.1.2j Multipoint calibration (LOGIT-LOG1 function approximation)

Concentrations of the reagent blank and calibrators (STD) are measured. Two up to ten calibrators can be used.

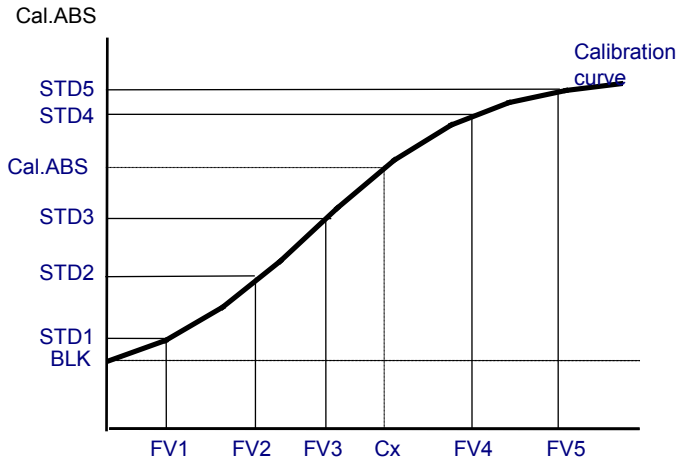
The calibration curve is calculated with the following formula.

$$\text{Cal. ABS} = \frac{a - d}{1 + (Cx/b)} + d$$

Calculated ABS: Calculated absorbance of the measurement sample

Cx: Concentration of the sample

a, b, d: Factors automatically calculated by curve approximation in calibration.



Up to 10 calibrators are used to calculate factors a, b, and d by Gauss-Newton algorithm. In the above figure, the reagent blank and 5 calibrators are used. The number of calibrators must be at least three including the reagent blank. False power method is used to calculate Cx from the calculated ABS.

Note: Do not define FV＝0 for any FV.

The calculation to obtain the factors a, b, c, and d varies as follows depending on the presence or absence of the reagent blank.

In the presence of the reagent blank, the calibration curve is obtained from the measurement results of the reagent blank and calibrators so that it should pass the origin (0, 0, or the blank point).

In the absence of the reagent blank, the curve does not necessarily pass the origin because it is obtained from the measurement results of calibrators only.

6.1.2k Multipoint calibration (LOGIT-LOG2 function approximation)

Concentrations of the reagent blank and calibrators (STD) are measured. Three up to ten calibrators can be used.

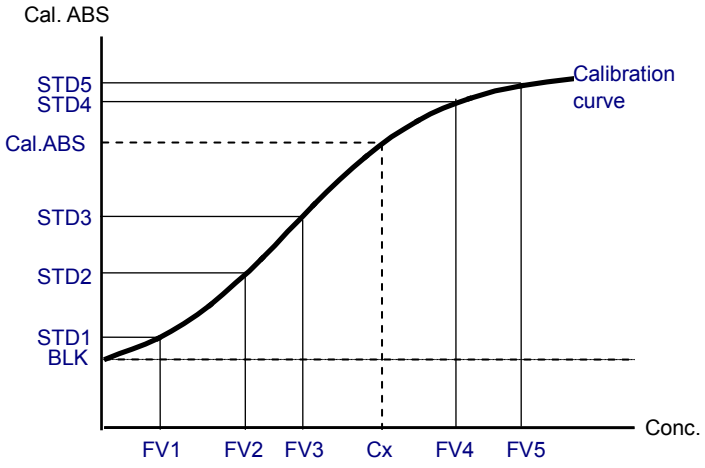
The calibration curve is calculated with the following formula.

$$\text{Cal.ABS} = \frac{a - d}{1 + (Cx/b)^{c}} + d$$

Calculated ABS: Calculated absorbance of the measurement sample

Cx: Concentration of the sample

a, b, c, d: Factors automatically calculated by curve approximation in calibration



See the description under the graph in Section 6.1.2j for how to obtain the factors a, b, c, and d. The number of calibrators must be at least four including the reagent blank.

6.1.2l Multipoint calibration (LOGIT-LOG3 function approximation)

Concentrations of the reagent blank and calibrators (STD) are measured. Four up to ten calibrators can be used.

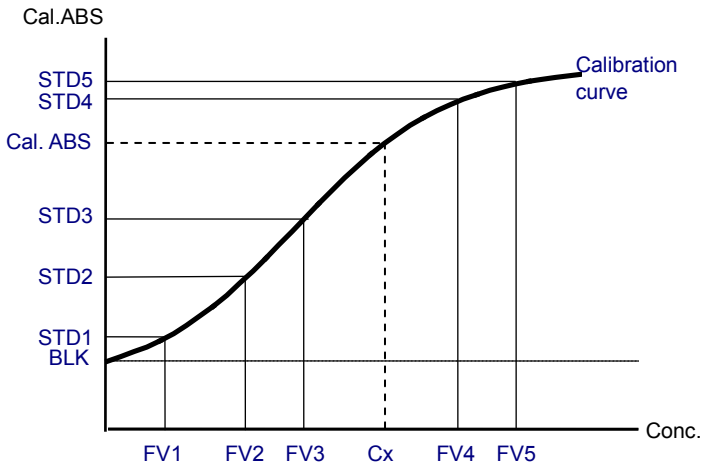
The calibration curve is calculated with the following formula.

$$\text{Cal. ABS} = \frac{a - d}{1 + (Cx/b)^{c} \times \exp(e \times Cx)} + d$$

Calculated ABS: Calculated absorbance of the measurement sample

Cx: Concentration of the sample

a, b, c, d, e: Factors automatically calculated by curve approximation in calibration



See the description under the graph in Section 6.1.2j for how to obtain the factors a, b, c, and d. The number of calibrators must be at least five including the reagent blank.

6.1.2m Simplified calibration

In multipoint calibration, the origin and sensitivity can be corrected by simplified calibration data using the reagent blank and a calibrator. The simplified calibration can be selected in the [Start Conditions] window. By this function, the multipoint calibration curve is optimized without performing another multipoint calibration measurement that is time consuming. To effectuate this simplified calibration, the original multipoint calibration curve must be stored and maintained and the reagent blank must be used.

The following formula is used for obtaining "U1" and "U2" described below. The original curve is represented by Calculated ABS= f (Cx), reagent blank by BLK, and a measurement value of a calibrator (FV) by STD.

$$U2 = \frac{STD - BLK}{f(FV) - MBLK}$$

$$U1 = BLK - U2 \times MBLK$$

U1 and U2 are further corrected by the formula below.

$$Cal.ABS = U2 \times f(Cx) + U1$$

Calculated ABS: Calculated absorbance of the measurement sample

Cx: Concentration of the sample

U1: Reagent blank for correction

U2: Proportional component for correction

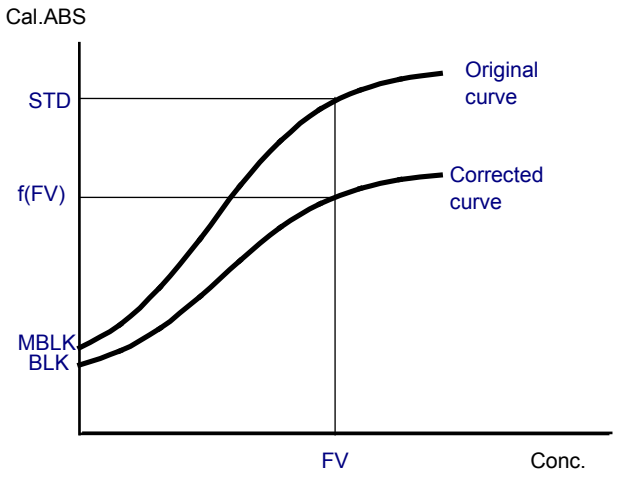
FV: Concentration of the calibrator used for simplified calibration

STD: Calculated absorbance of calibrator used for simplified calibration

BLK: Reagent blank value obtained by simplified calibration

f(FV): Calculated absorbance obtained by approximation from the absorbance of the calibrator of the same FV in the original multipoint calibration

MBLK: Reagent blank measured in the original multipoint calibration



After a new multipoint calibration curve is obtained, the values are reset to U1＝0 and U2＝1.

6.1.3 Data checking functions

The steps to check the measurement values manually are described in Section 5.2 in Chapter 5 of the Manual. Here are described various data checking functions that the application performs automatically. The measurement values that are highly suspected abnormal are checked and then automatically skipped from the calculation or marked with a flag.

6.1.3a Check for the reaction cuvettes

The cuvettes are checked as follows during the data processing.

- The reaction cuvette is measured after washing. When the difference between the measured value and the cuvette blank check value is larger than the set range, the cuvette is not used for measurement (auto skip).
- The reaction cuvette is measured twice after the cuvette wash. When the difference between two measured values is larger than the set range, sample measurement values obtained using the cuvette is flagged with "N".

6.1.3b Check with the reaction process

The absorbance at each point is checked for abnormality.

When the variance times 100 is over the limit value defined for each checking range, the flag is posted.

Abnormality may be caused by a defective photometry lamp, a defective detector, inadequate mixing, accidental addition of the sample, reagent, or washing solution in the cuvette, air bubbles, improper installation of the cuvette, etc.

Values of the main wavelength and sub wavelength can be both checked.

The checking range is automatically defined depending on the number of reagents.

Note this function may not work properly in combination with the prolonged round or delay time functions.

Check for the range selected automatically

In measurement with the one-part reagent, all points are checked from the dispensing of the reagent up to the last point except for the one immediately after mixing.

In measurement with two-part reagent, all points from the dispensing of the reagent 1 up to the dispensing of the reagent 2 are checked for the reagent 1, and all points from the dispensing of the reagent 2 up to the last point are checked for the reagent 2. For both sections, the point immediately after mixing is excluded.

In measurement of three-part reagent, all points from the dispensing of the reagent 1 up to the dispensing of the reagent 2e are checked for the reagent 1, all points from the dispensing of the reagent 2e up to the dispensing of the reagent 2 are checked for the reagent 2e, and all points from the dispensing of the reagent 2 to the last point are

checked for the reagent 2. For either section, the point immediately after mixing is excluded.

Take an example in case of measurement with two-part reagent. Following two combinations are possible.

1) Sample + Reagent 1 + Reagent 2e
2) Sample + Reagent 1 + Reagent 2

Judgment of abnormality

When the variance times 100 is over the limit value defined for [Setting Allowance] window in the [Analytical Parameters (Chemistry)] window, the value is flagged with "V", "v", "W", "w", "X" or "x" for each section.

Here, the variance is the difference in absorbance between two neighboring measurement points.

$$\text{Variance} \times 100 = \sqrt{\frac{\sum(\text{difference in value of two neighboring points})^2}{n-1}} \times 100$$

For the variance times 100, the value for each section is displayed in the [Realtime Monitor] and [Reaction Monitor] windows under the item name "S". Define the limit value on the basis of the values displayed in the windows.

The abnormal wave form can be detected by setting appropriate positive numbers as variance times 100 for the main or sub wavelength. The default value is "0" meaning no detection is applied.

6.1.3c Check with calculated ABS

Calculated ABS is obtained from the reaction ABS in the M-DET.P range according to the assay method. If the S-DET.P is designated, the calculation formula is as follows except for CRA.

$$\text{Cal. ABS} = \text{Cal. ABS (M - DET.P)} - K \times \text{Cal. ABS (S - DET.P)}$$

K: Volume correction factor.

The checking parameters are defined in the [Analytical Parameters (Chemistry)] window.

Checking absorbance of the reaction process with the main wavelength in the M-DET.P range.

When measuring the reagent blank

ABS with the main wavelength in the M-DET.P range is checked using blanks (u) and (d) to verify validity of the reagent.

- When blank (u) < ABS with main wavelength, the value is flagged with "U".
- When blank (d) < ABS with main wavelength, the value is flagged with "D".

Judgment of valid data and moving points forward

In the assay methods of RRA, 2PA, CRA, and IMA, the absorbance in the reaction process is checked in the M-DET.P range, using the ABS with the main wavelength.

In the judgment, the point where the value exceeds the limit absorbance due to the measurement of high concentration sample is excluded from calculation for the calculated ABS (M-DET.P) in the tests that use the variance of absorbance (e.g. GOT, GPT). This exclusion aims to avoid having an abnormally low calculated ABS which might result from including the measurement point where the value exceeds the limit absorbance.

The limit absorbance is the threshold value. The measurement value exceeding that value is judged abnormal.

- E2 CORRECTION or check D.P. correction

  If "Do" is selected for [E2 CORRECTION], the sample measurement value over the limit absorbance (u, d) is corrected in the assay methods except IMA.

  "E2 CORRECTION" is used for correcting the limit absorbance change due to turbidity in serum. The correction is applied for the points 4 to 6 in case turbidity is measured.

  However, the correction is not applied with (E2 value minus RBE value) ≤ 0.

E2 correction value = E2 value – E2 value at blank measurement

Correction sample (u, d) = *Sample*(u, d) + K × E2 value

K: Volume correction factor (K = total volume at E2 point divided by total volume at M-DET.P)

E2: E2 point measurement value of each sample

E2 blank value: The stored value at the reagent blank measurement. Correction is not applied with E2 value < 0.

With IMA, E2 CORRECTION is always applied even if "Not do" is defined.

Correction sample (u, d) = Sample (u, d) + K × *ValueatCheck*D.P.

K: Volume correction factor (K = total volume at E2 point divided by total volume at M-DET.P)

Note that no correction is applied with check D.P. point value = 0.

In the decreasing reaction, points except those where the correction sample (d) > ABS with main wavelength are excluded.

In the increasing reaction, points except those where the correction sample (u) < ABS with main wavelength are excluded.

When the measurement values at some points are judged invalid by the method described above and excluded, and consequently the number of points becomes smaller than the defined number, the range for M-DET.P is expanded by moving the points consecutively forward from "1" to "n". This adjustment is applied when the fewer points are defined for "l" than "m". With this adjustment, the measurement range is significantly expanded. However, the points are not moved forward in CRA.

When the number of points becomes 3 or smaller, the value is flagged with "d" in the decreasing reaction and "u" in the increasing reaction.

Checking by least squares

In RRA and IMA, the variance in absorbance per minute is calculated from the time and absorbance of the points by least squares.

The values judged to have a large discrepancy from the calculated line are excluded, and the least squares calculation is repeated until the defined repeat times (Cycle) are over or until there is no value to exclude.

- Usually "1" to "3" is defined for the Cycle.
- When the discrepancy is larger than the standard deviation of the Factor times discrepancy, it is judged to be large and the value at the point is excluded from calculation. Usually "2" or "3" is defined for the Factor.
- When the number of points is three or smaller, "n" is flagged.

Checking by the M-DET.P range

For the assay methods RRA, 2PA, CRA, or IMA,

- With the absorbance of correction sample (u) < ABS with the main wavelength in the decreasing reaction, the value is flagged with "U".
- With the absorbance of correction sample (u) > ABS with the main wavelength in the increasing reaction, the value is flagged with "D".

Checking with the Check D.P.

The Check D.P. point is set before or immediately after the addition of the trigger reagent to check if the reagent is consumed by some substance in the sample (e.g. pyruvic acid in GPT test).

For the assay methods RRA, "PA, CRA, and IMA, the ABS with the main wavelength is checked at the Check D.P. point

In the decreasing reaction,

Blank (u) < ABS with main wavelength, the value is flagged with "U".

Blank (d) > ABS with main wavelength, the value is flagged with "d".

In the increasing reaction,

Blank (u) < ABS with main wavelength, the value is flagged with "u".

Blank (d) > ABS with main wavelength, the value is flagged with "D".

Check for variance

- The variance in the valid data in the M-DET.P range is checked.
- When the variance of the calculated ABS is larger than the value defined for [Variance] in the [Analytical Parameters (Chemistry)] window, the calculated ABS is flagged with "*".
- Variance calculation varies by assay method.

  In EPA,

  $$\text{Variance} = (\text{Max ABS} - \text{Min. ABS}) \times 100 / |\text{Cal.ABS}|$$

  In CRA with p=0,

  $$\text{Variance} = \sqrt{\text{Square sum of the difference}/(n-2)} \times 100 / |\text{Cal.ABS}|$$

  In assay methods other than the above two,

  $$\text{Variance} = \sqrt{\text{Square sum of the difference}/(n-2)} \times 100/\text{time range}/ |\text{Cal.ABS}|$$

Prozone judge

- The judgment is applied to all the assay methods. Prozone judge checks the values in the reaction process.
- The variance of absorbance or rate of the variance between two ranges (M-DET range and S-DET range) is compared with the preset prozone limit value for prozone judgment
- The parameters below can be defined in the [Analytical Parameters (Chemistry)] window.
- Prozone form

  None Prozone judge is not performed

  RATE method • Define the points
  The ranges of M-DET.P (m, n) and S-DET.P (p, r) must be defined respectively, where $m \neq 0$, $n \neq 0$, $m < n$, and $p \neq 0$, $r \neq 0$, $p < r$.

Unless the above conditions are met, or any one point is set as "0", calculation fails, and not only Prozone judge is not performed but also the concentration is not calculated.

- The ranges of absorbance variances ⊿Amn[M-DET.P (m, n) and ⊿Apr[S-DET.P (p, r) are calculated respectively from the two ranges of prozone check points M-DET.P (m, n) and S-DET.P (p, r) by least squares. Then, the Prozone value is calculated using the following formula.
  Prozone value =△Amn/△Apr
- IF the absolute value of ⊿Apr is smaller than the [Judge limit] value, prozone judge is not performed. The value range for [Judge limit] is 0 to 9.999.
  When the normal value is near "0", that is ⊿Apr is small, "P" flag can be

posted to the value. This problem can be avoided by setting an appropriate Judge limit value.

Prozone formula

- Define the points

  The M-DET.P (m, n) range must be defined. The S-DET.P (p, r) range must be defined to perform a Prozone check for antigen re-addition method.. Here, $m \neq 0$, $n \neq 0$, $m \leq n$, and $p \neq 0$, $r \neq 0$, or $p \leq r$.

Unless the above conditions are met, calculation fails, and not only the prozone judge is not performed but also the concentration is not calculated.

- The ranges of absorbance variances ΔAmn[M-DET.P (m, n) and Δ Apr[S-DET.P (p, r) are calculated respectively by averaging the values except the largest and smallest absorbance of the two ranges of Prozone check points M-DET.P (m, n) and S-DET.P (p, r). Then, Prozone value is calculated using the following formula.

  When S-DET.P (p, r) is defined:

  $Prozonevalue = Amn - K \times Apr$ K: volume correction factor

  When the range of S-DET.P 8p, r) is defined as "0":

  $Prozonevalue = Amn$

This function only regulates the data processing method, and therefore is not limited to the reagents based on a specific measurement principle. Also, RATE method can be used successfully for Prozone judge in the antigen re-addition method.

- By the Prozone judge, the value is flagged with "P", if

  Prozone value > Prozone limit value (upper limit)

  Prozone value < Prozone limit value (lower limit)

Check for the reagent with the reagent blank measurement

The validity of the reagent is checked on the basis of the absorbance of the reagent blank during the reagent blank measurement.

✔ In Multi-Standard (MSTD)

- "H" is flagged in case of calculated ABS > Upper limit of the multi-standard reagent blank (BLK STD-H).
- "L" is flagged in case of calculated ABS < Lower limit of the multi-standard reagent blank (BLK STD-L).

✔ In measurement of other than MSTD (ABS, STD, and simplified calibration)

- "H" is flagged in case of calculated ABS > Upper limit of reagent blank (Standard value set BLK-H)
- "L" is flagged in case of calculated ABS < Lower limit of reagent blank (Standard value set BLK-L)

6.1.3d Check with reaction ABS

Reaction ABS is absorbance that depends on the concentration of the reaction solution. It is calculated by subtracting reagent blank from calculated ABS.

Reaction ABS = Cal. ABS – Kt × Reagent blank

Kt (volume correction factor) = Total volume of reaction solution ／ total volume at reagent blank measurement

The checking parameters are defined in the [Analytical Parameters (Chemistry)] window.

Check with calibrator

Calibrators and reagents are checked with the reaction ABS of calibrators.

✔ In Multi-Standard (MSTD)

- "H" is flagged in case of reaction ABS > Upper limit of the multi-point calibrator (n STD-H). Here "n" stands for the multi-point calibrator number.
- "L" is flagged in case of reaction ABS < Lower limit of the multi-point calibrator (n STD-L).

✔ In measurement other than MSTD (ABS, STD, and simplified calibration)

- "H" is flagged in case of reaction ABS > Upper limit of the calibrator (Standard value set STD-H).
- "L" is flagged in case of reaction ABS < Lower limit of the calibrator (Standard value set STD-L).

Check with absorbance at rerun

The reaction ABS is checked if the value is outside the dynamic range of reagent.

Calibrators, patient, and QC samples are checked as below:

In EPA,

Reaction ABS is compared with the absorbance at rerun (Re.absorb).

- "u" is flagged in case the reaction ABS > Re.absorb (u).
- "d" is flagged in case the reaction ABS < Re.absorb (d).

In the other methods,

Reaction ABS is not used for checking. Samples (u) and (d), and Check D.P. are used for checking the dynamic range of reagent.

6.1.3e Check by concentration and unit

The concentration and unit are calculated from the reaction ABS by the defined calibration.

When the concentration cannot be obtained

"C" flag is posted when the concentration cannot be obtained due to calibration error.

Check for the normal range

For patient samples

The values outside the normal range are checked. The normal range is defined by sex, age, and sample type in the [Normal Value Set] window accessed from the [Analytical Parameters (Chemistry)] window.

- "l" flag is posted in case the concentration or unit < value set for Normal Value Setting (l).
- "h" flag is posted in case the concentration or unit > value set for Normal Value Setting (h).

For QC samples

The fluctuation of QC sample measurement values is checked. The average and standard deviation (SD) are registered for each QC sample for management in the [Control Data Registration] window.

- "l" flag is posted in case of QC sample measurement value < Registered average minus 2 x SD.
- "h" flag is posted in case of QC sample measurement value > Registered average minus 2 x SD.

Check for the abnormal range

For patient samples

The values in the abnormal range are checked. The abnormal range is defined by sample type in the [Abnormal Value Set] window accessed from the [Analytical Parameters (Chemistry)] window.

- "L" flag is posted in case the concentration or unit < value set for Abnormal Value (L).
- "H" flag is posted in case the concentration or unit > value set for Abnormal Value (H).

For QC samples

The fluctuation of QC sample measurement values is checked. The average and standard deviation (SD) are registered for each QC sample for management in the [Control Data Registration] window.

- "L" flag is posted in case of QC sample measurement value < Registered average minus 3 x SD.
- "H" flag is posted in case of QC sample measurement value > Registered average minus +3 x SD.

6.1.3f Check for the calibration value compared with the previous value

The variance between the calculated calibrator ABS obtained this time and that of last measurement is checked whether it falls within the allowance (%).

The variance is calculated with the formula: | previous calibration value－current calibration value | / previous calibration value ×100 (%) . If this rate is higher than the allowance range, the value is judged as abnormal and flag "Z" is posted with the value. The new calibration value will not be used and the stored value is not updated.

Define value for [Error judge rate (vs.previous data)] window in the [Analytical Parameters (Chemistry)] window.

6.2 Principle of the Ion Selective Electrode (ISE) test

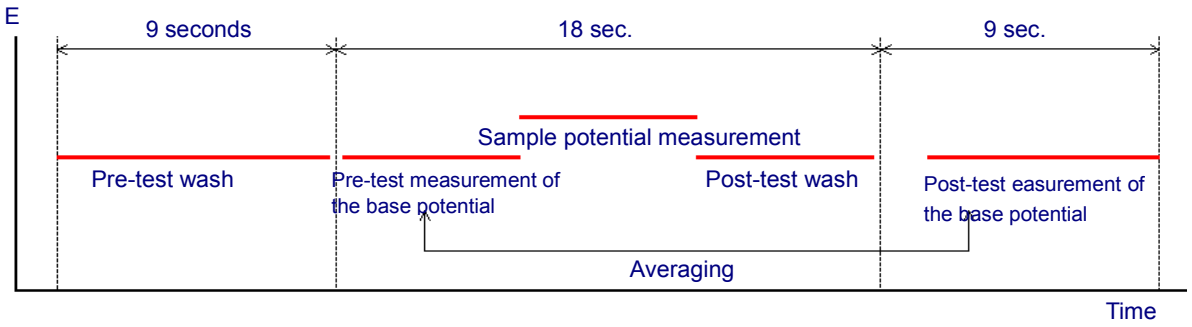
6.2.1 Measurement operation

Overview

- The usual measurement order is: pre-test wash > pre-test measurement of the base potential > measurement of the sample potential > washing > post-test measurement of the base potential.
- If the interval from the previous post-test measurement of the base potential is 15 seconds or longer, the pre-test wash is performed twice.

Workflow of the serum measurement

Single measurement



1 Pre-test wash

If the interval from the previous post-test measurement of the base potential is 15 seconds or longer, the pre-test wash is performed twice.

2 Pre-test measurement of the base potential

3 Measurement of the sample potential

4 Post-test wash

Post-test wash is performed to prevent the sample carryover.

For urine samples, the post-test wash lasts 9 seconds longer.

5 Post-test measurement of the base potential

If there is no further order of measurement, the post-test base potential is measured, and then the operation is terminated.

The average of the pre-test and post-test base potentials is used as the base potential used in calculating concentration.

Continuous measurement

The post-test base potential of a measurement is used as the pre-test base potential. This way, measurement continues at a rate of 18 seconds per sample.

6.2.2 Calibration

Process

- In calibration, two kinds of calibrator are used: high-density standard (H-STD) and low-density standard (L-STD). First the H-STD is measured. The value obtained in the first measurement is excluded, and the measurement is repeated up to 8 times until the variance between two successive measurement values falls in the calibration allowance range. The average of the last two values is stored as calibration value.
  If the value fails to fall in the allowance range even after 8 measurement times, it will be "Calibration LOW (HIGH) STD error."
  When the potential variance (sample potential minus buffer potential) fails to fall in the range, it will be "ISE Calibration range error."

Standard Solution	Na:	K	Cl
L-STD for serum	-50 to -20	-50 to -20	5 to 35
H-STD for serum	5 to 35	80 to 110	-40 to -10
L-STD for urine	-280 to -220	170 to 270	40 to 100
H-STD for urine	50 to 110	725 to 825	–95 to –35

Default range

Principle

In the ISE measurement, the variance in potential is measured between the reference (Ref.) electrode and corresponding ion selective electrode caused as reaction to the sample.

$$E = E_0 \pm (2.303 \times \frac{RT}{ZF}) \log a$$ Nerst equation (1)

E: Potential of the ion selective electrode (mV)

E0: Potential of the reference electrode (mV) or reference potential

R: Gas constant

Z: Ionic valency

F: Faraday constant

a: Ionic activity

T: Absolute temperature (K)

2.303×RT/ZF in the formula (1) is the theoretical slope of potentials, generally called "slope (S)". For the ion with 1 valency in 25℃, the potential of the ion selective electrode is 59.16 mV (-59.16 mV for Cl electrode).

Also, the following correlation is found among the following three parameters:

$$a = r \times c$$

a: Ionic activity (mol/l)

r: Activity factor

c: Ionic concentration

The Nernst equation (1) becomes as follows:

$$E = E_0 \pm S \times \log(r \times c)$$
$$= E_0 \pm (S \times \log r + S \times \log c) \quad (2)$$

When the solution is diluted with the ion strength adjustment buffer to have a homogeneous ion strength, the activity factor becomes constant and the equation (2) becomes as follows:

$$E = E_0' \pm S \times \log c \quad (3)$$

Also, if the internal standard solution of a known concentration is measured with each measurement, the potential of the internal solution (Eb) will be calculated using the equation (3) as follows:

$$E_b = E_0' \pm S \times \log c_b \quad (3a)$$

When deducting the equation (3a) from the equation (3), the reference potential disappears because it virtually does not change in a short time. The equation becomes as follows:

$$E - E_b = \pm S(\log c - \log c_b)$$
$$= \pm S \log(\frac{c}{c_b}) \quad (4)$$

Therefore, if the correlation between ion concentration and potential variance is calculated using the standard solution, the target ion concentration can be measured.

In BM6010/C, the sample is diluted with buffer solution.

When a sample of concentration (c_s) is diluted by the dilution factor (t), the concentration of the diluted sample (c_t) will be as follows:

$$c_t = \frac{c_s}{t} \quad (5)$$

Substitute *(c) in the equation (4) with* (c_t) to obtain the following equation.

$$E - E_b = S \times \log(\frac{c_s}{tc_b}) \quad (6)$$

The slope and dilution factor of the equation (6) can be obtained by measurement L-STD and H-STD calibrators of known concentration.

The potentials of the Na and K electrodes are displayed 10 times larger and that of the Cl electrode are 5 times larger of the measurement value during calibration.

CONTENTS

Chapter

7 Maintenance

CONTENTS

7.1 Maintenance Items

The maintenance items, including periodic checks and replacements, are summarized here separately for the chemistry analysis unit and for the ion selective electrode (ISE) unit. Refer to these lists for your regular or as-needed maintenance. Insufficient maintenance may cause inaccurate measurement results as well as system malfunction.

Some maintenance services require first unlocking and opening the top cover.

Refer to Section 1.8.2j for how to open the top cover.

7.1.1 Maintenance items for the chemistry analysis unit and the workstation)

Maintenance frequencies indicated in the table blow are based on usages of 50,000 chemistry measurements per month. Lighter usages still should be maintained at the frequencies indicated. If the usage is heavier, perform the services more frequently.

Item	Daily	Weekly	Monthly	Every 3 months	Every 4 months	As required	Remarks	Reference
Check water quality supplied from the pure water supply unit	○							7.3.1a
Check the probes for impurities	○							7.3.1b
Check the mixing rods for impurities	○							7.3.1c
Check the nozzles of the reaction carousel wash (WUD) unit for impurities	○							7.3.1d
Check the wash ports of probes and mixing rods for impurities	○							7.3.1e
Check the splash cover for impurities	○							7.3.1f
Check for potential leakage from pumps	○						Replace the seal when leakage is detected.	7.3.1g
Examine the remaining volume of the lamp coolant	○							7.3.1h
Check the lamp energy		○						7.4.1a
Cuvette blank measurement		○						7.4.1b
WASH2 with Reagent probe wash-S		○						7.4.1c
Shutdown the workstation		○						7.4.3a
Soak and wash the mixing rods			○					7.5.1a
Clean the sample setting areas in the Sample and refrigerated trays (STT and CTT) and the refrigerated reagent compartment in the reagent trays (RTTs)			○					7.5.1b

Item	Daily	Weekly	Monthly	Every 3 months	Every 4 months	As required	Remarks	Reference
Clean the chiller filter			○					7.5.1c
Clean the line filter of the large water supply pump (LWP)			○					7.5.1d
Clean the waste fluid lines of probe and mixing rod wash ports			○					7.5.1e
Clean the exterior panels of the analyzer			○					7.5.1f
Clean the vent fans and grids			○					7.5.1g
Clean the cuvette wash solution bottle and the conditioner bottle				○				7.6.1a
Clean the filters in the cuvette wash solution bottle and the conditioner bottle				○			The frequency depends on the quality of water.	7.6.1b
Clean the aspiration lines of the reaction carousel wash unit (WUD)				○				7.6.1c
Replace the spectrophotometer lamp				○			Replacement is suggested every 2000 hours of accumulated usage.	7.7.1a
Replace the reaction cuvettes					○		The frequency depends on the usage. Replacement is suggested every 10,000 whole blood samples analyzed for HbA1c.	7.7.1b
Disk defragmentation of the Windows XP-based workstation						○	Semiannually	7.7.2a
Replace probes						○		7.8.1a
Replace the seal of the pumps						○		7.8.1b
Remove clogs from the reaction carousel wash unit (WUD) nozzles						○		7.8.1c
Replace the mixing rods						○		7.8.1d
System backup to DVD						○	When the system setting is updated	7.8.3a
When the pure water bottle becomes empty						○		7.9.1
Degas the cuvette wash solution and conditioner lines						○		7.9.2

Item	Daily	Weekly	Monthly	Every 3 months	Every 4 months	As required	Remarks	Reference
In case of power outage						○		7.9.3
In case of a long-term suspension of operation						○	When the operation is suspended for 4 or more days	7.9.4

7.1.2 Maintenance items for the ISE unit

The ISE unit integrated into the analyzer requires specific maintenance services as described below. Maintenance frequencies indicated are based on usages of approximately 1,000 ISE measurements per month. Lighter usages still should be maintained at the frequencies indicated. If the usage is heavier, perform the services more frequently.

Item	Daily	Weekly	Monthly	Every 3 months	As required	Remarks	Section to refer to
Check the remaining volume of the ISE buffer solution	○					Replenish the buffer when the level is low. Replenishment is allowed only once.	7.3.2a
Check the internal standard (IS) solution	○					Replenishment is not allowed for IS solution.	7.3.2b
Wash the electrodes	○						7.3.2c
Wash the ISE dilution Bowl	○						7.3.2d
Wash the electrode lines	The frequency of washing the electrode lines depends on the number of dialysis samples measured, suggested as follows: Every three days for 500 or more dialysis samples per month Weekly for 100 to 499 dialysis samples per month Biweekly for up to 100 dialysis samples per month						7.4.2a
Clean the ISE waste-drain nozzle			○			Every time when a plasma sample is measured	7.5.2a

Item	Daily	Weekly	Monthly	Every 3 months	As required	Remarks	Section to refer to
Condition the Na and K electrodes					○	Perform on the day before the new electrodes are used.	7.8.2a
Replace the electrodes				○		Every 3 months or every 30,000 samples measured	7.8.2b
Post-maintenance restoration of the ISE unit					○		7.8.2c
Store the electrodes					○		7.8.2d

7.2 Consumables and Spare Parts for Maintenance

The spare parts listed below should be available at all times for proper maintenance and normal operation of the analyzer.

7.2.1 List of consumables

Name	Specification	Applicable unit / Quantity	Package Unit	Parts No.
Lamp Coolant-C	No dilution type	400 mL	1	780656661
Cuvette Wash Solution-7		2 L		780656644
Reagent Probe Wash-K		500 mL		780654056
Cuvette Conditioner-EX		2 L		780656652
Reaction carousel (RRV) Bath Oil	Incubation Bath Oil	5 kg		*
Reagent Probe Wash-S		500 mL	1	780654064
Halogen lamp, New		Spectrophotometer	1	335008844
RRV cuvettes		RRV cuvettes	1	844559351
Filter 10R	Super screen 10 mm D	For detergent and washing water	1	810371227
Filter set, large water supply pump (LWP)	PIS N02F-E80	For LWP line	1set	490029027
Filter holder for 10R filters	CA01609	Filter 10, holder for filter PE	1	644000988
Sample probe #6 sample probe (SPP)	SPP-BM6010	For sampling	1	780607414
Sample probe #6 RPP		For dispensing reagent	1	810610043
Rod (Mixing rod #24)	Titanium	Mixing unit	1	780656415
1 mm depth L-ring	1 mm depth with O-ring	SPP	2	406017808
5mm depth L-ring	5 mm depth with O-ring	RPP	2	811254780
OMNISEAL 14mm		Sampling and reagent wash pump (SRWP)	2	780655729
Reagent Probe Wash 1		250 mL		780654072
Reagent Probe Wash 2		250 mL		780654081
ISE Detergent Solution		ISE unit	100 mL × 2pc	780654099
ISE Buffer		ISE unit	2L × 1 pc	780654102
Internal Standard		ISE unit	200mL × 1pc	780609735
ISE serum standard set		ISE unit	100 ml × 1 set (H,L)	780654111

Name	Specification	Applicable unit / Quantity	Package Unit	Parts No.
ISE urine standard set		ISE unit	100 ml × 1 set (H,L)	780654129
Electrode-Na		ISE unit	1 pc	780654137
Electrode-K		ISE unit	1 pc	780654145
Electrode-Cl		ISE unit	1 pc	780654153
Electrode-Ref		ISE unit	1 pc	780654161
Selectivity-check solution	No.213303	ISE unit	50mL ×2pc	475011520
Reagent bottle 70 mL		For RTT		424011573
Reagent bottle 40 mL		For RTT		780640241
Sample cup		For sample (Jcup)		640057292
Tube		10 mL		424012383
Orange-G				780654048
Cooling circulator (C.C.) coolant		For C.C.		780654030

* Use JEOL specified incubation bath oil. Contact your local distributor for details.

7.2.2 Parts

Name	Specification	Applicable unit / Quantity	Package Unit	Part number
Guide (Sample cup holder)		Adaptor for Jcup		811279758
Tray (guide)		Guide for reagent bottle (20 mL)		780642945
Filter	Strainer	06F-PE140-00	1	490029159
Wide nozzle (L)	WV NOZZLE （72.5mm）WUD	Wide nozzle for aspirating cuvette wash solution	1	844354376
Nozzle (WUD1 and 5)	WUD nozzle lines 1 and 5	RRV wash pipe, set of 3	1	780640101
Nozzle (WUD2)	WUD nozzle line 2	RRV wash pipe, set of 3	1	780640110
Nozzle (WUD3)	WUD nozzle line 3	RRV wash pipe, set of 3	1	780640128
Nozzle (WUD4)	WUD nozzle line 4	RRV wash pipe, set of 3	1	780656687
Nozzle (WUD6)	WUD nozzle line 6	RRV wash pipe, set of 1	1	780640136
Cylinder 1mmD-D	PUMP V-S (D1)	SPP	1	811339521
Holder L-ring 1mmD-D	PUMP V-D (D1), with O-ring	SPP	1	780656075
Plunger 1mmD	PUMP V-D (D1)	SPP	1	812469461
Cylinder 5mmD	PUMP (D5)	RPP	1	812230761
Holder L-ring 5 mm	PUMP (D5)	RPP	1	811238644
Cylinder ASSY1mmD-S	For assembling PUMP V-S (D5) , plunger not included	RPP	1	844354279
Plunger 5mmD	PUMP (D5)	Ceramic plunger for RPP	1	812325451
Cylinder ASSY 14D	For assembling PUMP V-S (D14) , plunger and wash port not included	Sampling and reagent wash pump (SRWP)	1	780633989
Holder L-ring 14mm	PUMP (D14D)	Sampling and reagent wash pump (SRWP)	1	812232542
Plunger 14mmD	PUMP (D14D)	Ceramic plunger for SRWP	1	812325494
Medical silicon tube 1/3	1D×3D		1m	405002459
Silicon tube 1.5/3	1.5D×3D		1m	405007680
Teflon tube 1/2 (PTFE)	1D×2D		1m	405001291
Teflon tube 0.5/2 (PTFE)	0.5D×2D		10m	405002530
Teflon tube 1.4/2 (PTFE)	1.4D×2D		10m	405006063
Teflon tube 2/3	2D×3D		10m	405000677

Name	Specification	Applicable unit / Quantity	Package Unit	Part number
(PTFE)				
Pipe fitting (M6 resin)	CB17286	Pipe (outer diameter 2 mm)	20	810167816
Pipe fitting (M6SUS)	CB15092		10	640057594
Tube fitting washer	CB15093	Pipe (outer diameter 2 mm)	20	640057861
Tube fitting washer		Pipe (outer diameter 3mm)	20	780607015
Pipe fitting		for probe connection	10	811380548
Pump FP		Reaction bath oil supply	1	780633652
Thermistor No.04	709579	ISE unit	1pc	780607791
Thumbscrew	721085	ISE unit, for tightening the electrode	1pc	780607856
Dummy electrode with an O-ring	17399	ISE unit	1pc	780607805

7.2.3 Utensils

Name	Standard	User unit / Purpose	Package Unit	Part number
Flange roller #2		For processing Teflon pipes	1 set	420028056
Tube cutter	SMC/TK-3	For processing Teflon pipes	1 set	780634951
Wire			10 m	423202472
Jig for replacing the seals	G059		1 pair	780628314

7.3 Daily Maintenance

7.3.1 Chemistry analysis unit

7.3.1a Check water quality supplied from the pure water supply unit

Degraded water quality may affect measurements and cause erroneous results.

Check the pure water quality every day. The electrical conductivity of the water must be 1.0 µS/cm or lower. To improve the water quality, replace the ion exchange resin or take another appropriate measure as described in the instruction manual for the pure water supply unit.

The water quality can be checked only when the unit is actively purifying water. It cannot be checked even when the unit is turned on but not purifying water.

This section describes the water quality checking with the pure water supply unit, independent from the analyzer.

Required tools	N/A
Required time (estimated)	2 min
Frequency of service	Daily
System mode at service	-
Workflow	1. Turn the faucet on. 2. Turn on the power switch of the pure water supply unit. 3. Check the water quality.

7.3.1b Check the probes for impurities

Impurities on the inner or outer parts of the probe can form clogs and affect measurement accuracy. Visually inspect the probes daily for impurities.

Required tools	N/A
Required time (estimated)	1 min
Frequency of service	Daily
System mode at service	WAIT or READY
Task	Check the tip of the probe for impurities.

How to clean the probe

Clean the probe when it has impurities.

Required tools	Clean gauze (lint-free), pure water
Required time (estimated)	5 min
Frequency of service	As required
System mode at service	Analyzer's power is off.
Workflow	1. Remove the covers of sample trays (STT/CTT) and reagent trays (RTTs). 2. Clean the probe tips. 3. Return the STT/CTT and RTT covers.

The probe will rarely become clogged if daily and weekly "washes" are performed.

If clogging occurs, see "Section 7.8.1a Replacing the probe" for instructions regarding probe replacement.

Warning

- Read the "Safety Precautions" and "Usage Notes" before starting this task.

CAUTION

- Wear protective glasses, a mask, and gloves when you perform this service.
- Turn the Operate/Standby switch to the ⏻ "Off" position before starting to clean the probe. If you clean the probe with the switch in the "PC CONTROL" or "On" positions, the probe may move, causing damage to the probe or bodily injury.

1) Obtain a piece of gauze and a bottle of pure water.

2) Exit the workstation system and display the "BioMajesty" startup window on the monitor.

3) Turn the Operate/Standby switch to ⏻ (OFF).

CAUTION

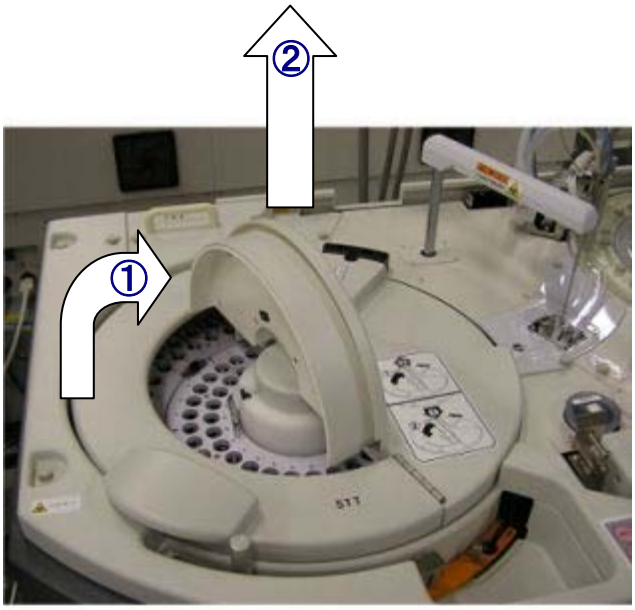
When the power is off, the probes may droop under by their own weight. The probes must be manually stabilized and monitored carefully.

4) Remove the tray covers.

1 STT/CTT covers

(a) Open the CTT cover first.

(b) Lift it to remove.



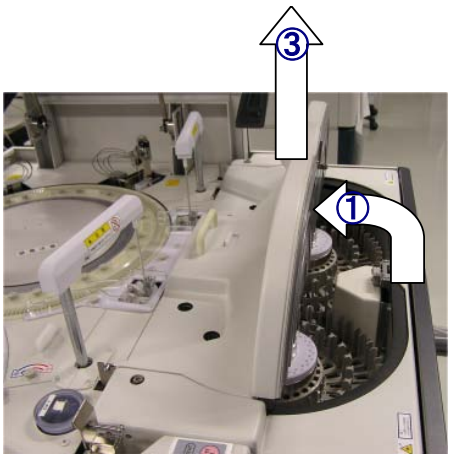
Removing the STT/CTT covers

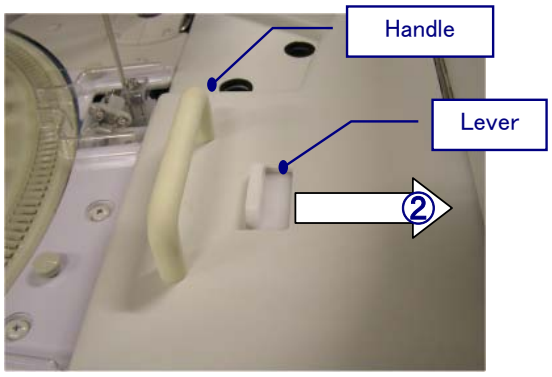
2 RTT cover

(a) Open the RTT cover.

(b) Slide the lever to the front side.

(c) Grip the handle and lift it to remove.





5) Move each probe to the position indicated below for cleaning.

Sample probe (SPP): Above STT

Reagent probes (RPP1, RPP2): Above RTT

6) Clean the probe tip with gauze dampened with pure water.

CAUTION

- Be careful not to jostle the probe tip with your hands or with the analyzer.
- During cleaning, position the probe such that cleaning materials do not fall into the samples or reagent bottles.
- Do not apply strong force to the probe.

Cleaning SPP

Cleaning RPP

7) When the cleaning is completed, move the probe manually into the wash port.

CAUTION

Be careful not to hit the probe tip anywhere. Avoid placing it just above the outlet of the wash solution (V block).

8) Return the removed tray covers.

9) Turn the Operate/Standby switch to "PC CONTROL."

If ⏻ (Off) or ⊙ (On) is selected, the analyzer does not turn on/off together with the workstation.

10) Select "Re-start" in the "BioMajesty" startup window to re-start the system.

Wait for several seconds and confirm the Operation Panel shows the system mode "WAIT."

11) Perform "INITIALIZE" and confirm the system mode shifts to "READY."

7.3.1c Check the mixing rods for impurities

Impurities on the mixing rod of the mixer unit (MIX1, MIX2) may cause cross contamination. Check the mixing rods for impurities every day.

Required tools	N/A
Required time (estimated)	1 min
Frequency of service	Daily
System mode at service	WAIT or READY
Task	Check the mixing rod for impurities.

How to clean the mixing rod

Clean the mixing rod when it has impurities.

Required tools	Clean gauze (lint-free), pure water, cotton swab
Required time (estimated)	5 min
Frequency of service	As required
System mode at service	Analyzer's power is off.
Task	Clean the mixing rod.

Warning

- Read the "Safety Precautions" and "Usage Notes" before starting this task.

CAUTION

- Wear protective glasses, a mask, and gloves when you perform this service.

- Turn the Operate/Standby switch to the "Off" position before starting to clean the mixing rods. If you clean the mixing rods with the switch in the "PC CONTROL" or "On" positions, the mixing rods may move, causing damage to the mixing rods or bodily injury.

Follow the steps below to clean the mixing rod when it has impurities.

1) **Obtain clean gauze, cotton swab, and pure water.**
2) **Confirm the system mode is "READY."**
3) **Exit the workstation system and display the "BioMajesty" startup window on the monitor.**
4) **Turn the Operate/Standby switch to ⏻ (OFF).**
5) **Clean the mixing rod with gauze dampened with pure water.**

CAUTION

Do not wipe the tip because it may become bent.

Cleaning the mixing rod

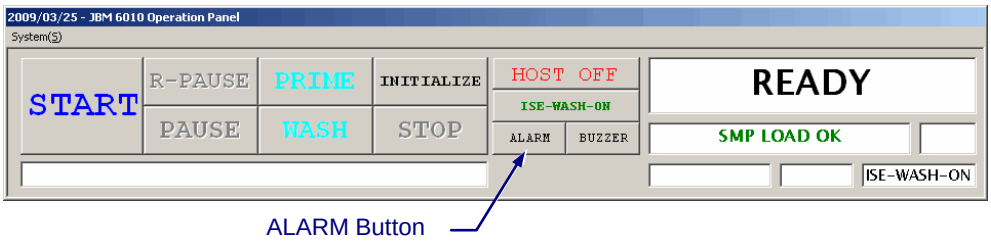
6) **After the cleaning is completed, turn the Operate/Standby switch to "PC CONTROL."**

   If ⏻ (Off) or ⊙ (On) is selected, the analyzer does not turn on/off together with the workstation.

7) **Select "Re-start" in the "BioMajesty" startup window to re-start the system.**

   Wait for several seconds and confirm the Operation Panel shows the system mode "WAIT."

8) Perform "INITIALIZE" and confirm the system mode turns to "READY."



7.3.1d Check the nozzles of the reaction carousel wash (WUD) unit for impurities

Detergent or washing solution remaining in the nozzles or lines of the WUD unit may cause clogs. If the lines connected to the nozzles deteriorate, they may leak. Check the nozzles of WUD unit daily for impurities.

Required tools	N/A
Required time (estimated)	1 min
Frequency of service	Daily
System mode at service	WAIT or READY
Task	Check the nozzles for impurities

How to clean the WUD nozzles

Follow the steps below to clean the WUD nozzles when they have impurities.

Required tools	Clean gauze (lint-free), pure water, 4mm Allen wrench
Required time (estimated)	5 min
Frequency of service	As required
System mode at service	Analyzer's power is off.
Workflow	1. Take out WUD. 2. Clean the nozzle tips. 3. Place back WUD. 4. Check the nozzle positions.

Warning

- Read the "Safety Precautions" and "Usage Notes" before starting this task.

CAUTION

- Wear protective glasses, a mask, and gloves when you perform this service.

- Turn the Operate/Standby switch to the "Off" position before starting to clean the WUD. If you clean the WUD with the switch in the "PC CONTROL" or "On" positions, the WUD may move, causing damage to the unit or bodily injury.

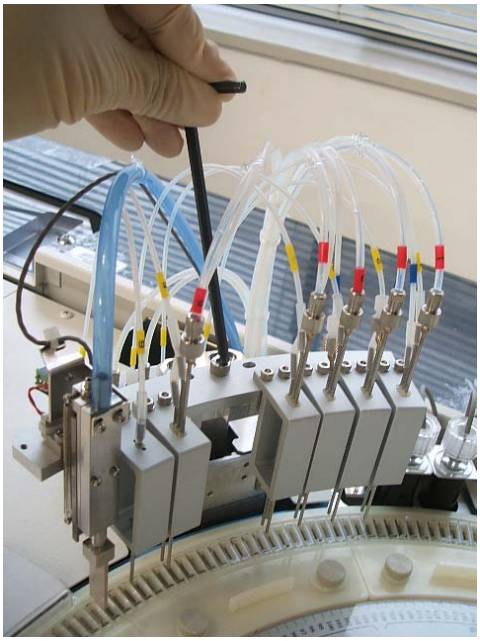
1) Obtain a piece of gauze dampened with pure water.

2) Confirm the system mode is "READY."

3) Exit the workstation system and display the "BioMajesty" startup window on the monitor.

4) Turn the Operate/Standby switch to ⏻ (OFF).

5) Loosen the fixing screw with 4 ㎜Allen wrench to take WUD out.

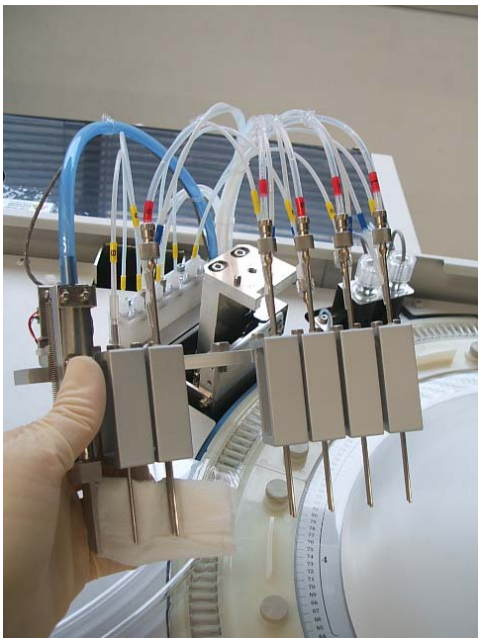


Taking out WUD

6) While securely holding the WUD unit, clean the nozzles with gauze dampened with pure water.

Prevent debris from falling into the reaction carousel by covering the carousel with gauze.

Be careful not to detach the lines connected to the nozzles.



Cleaning the nozzles

7) After the cleaning is completed, place back WUD.

1 Fix WUD in the correct position using the positioning pins on both sides of the fixing screw.

Confirm there is no space between WUD and the fixing location.

2 Check that each nozzle is positioned just above a cuvette.

3 Check that the lines are securely connected to the nozzles.

8) Turn the Operate/Standby switch to "PC CONTROL."

If ○ (Off) or ⊙ (On) is selected, the analyzer does not turn on/off together with the workstation.

9) Select "Re-start" in the "BioMajesty" startup window to re-start the system.

Wait for several seconds and confirm the Operation Panel shows the system mode "WAIT."

10) Perform "INITIALIZE" and confirm the system mode shifts to "READY."

11) Check the WUD position

1 Select [Maint.] > [Manual Operation], and double click [23.WUD] to display [WUD] window. Click the [Move] button in the window.

WUD lowers a little.

2 In the lowered position, check each nozzle is correctly in the midpoint of the cuvette.

3 Click the [Int.] button in the [WUD] window.

WUD returns to the home position.

4 Click [Exit] in the [WUD] window.

The [WUD] window is closed.

12) Perform "INITIALIZE" and confirm the system mode turns to "READY."

7.3.1e Check the wash ports of probes and mixing rods for impurities

When impurities deposit inside the wash ports of the probes, the mixing rods, and/or around the wash solution outlet (V block), the probes and mixing rods cannot be washed properly, and samples, reagents, or contaminated wash solutions may remain on the tips of the probes and mixing rods.

Check the wash ports for impurities daily.

Required tools	N/A
Required time (estimated)	1 min
Frequency of service	Daily
System mode at service	WAIT or READY
Task	Check the wash ports for impurities.

How to clean the probe wash port and the V block

When impurities deposit inside the wash port or on V block, follow the steps below for cleaning.

Required tools	Cotton swab, pure water
Required time (estimated)	5 min
Frequency of service	As required
System mode at service	Analyzer's power is off
Task	Clean the inside of the wash port and the V block.

Warning

- Read the “Safety Precautions” and “Usage Notes” before starting this task.

CAUTION

- Wear protective glasses, a mask, and gloves when you perform this service.

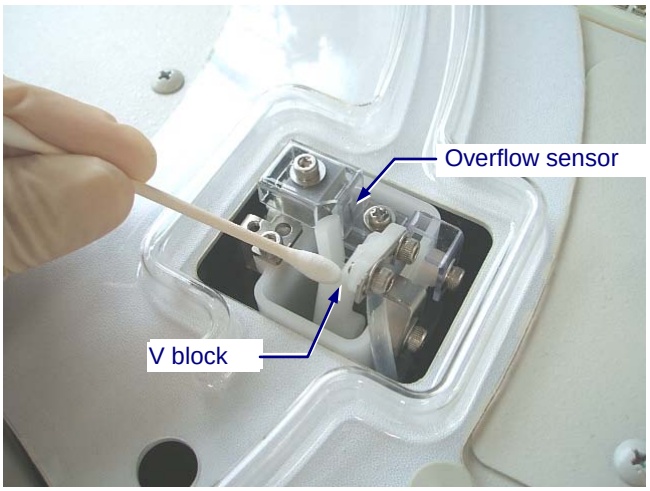
- Turn the Operate/Standby switch to the “Off” position before starting to clean the wash port and V block. If you clean them with the switch in the “PC CONTROL” or “On” positions, the probe may shift, causing damage to the probe or bodily injury.

1) **Obtain a piece of gauze, cotton swabs, and a bottle of pure water.**
2) **Confirm the system mode is "READY."**
3) **Select [Maint.] > [User Maintenance]. Click the [Start] button for [Position Probes for Routine Cleaning] in the window.**

   All probes move to the dispensing position over the reaction carousel cuvettes. The Operation Panel displays "WAIT" as the system mode.
4) **Exit the workstation system and display the "BioMajesty" startup window on the monitor.**
5) **Turn the Operate/Standby switch to ○ (OFF).**
6) **Pour pure water inside the wash port and on the V block from the bottle, and clean them with a cotton swab and gauze.**

CAUTION

Do not use strong force on the overflow sensor because it can easily become deformed.



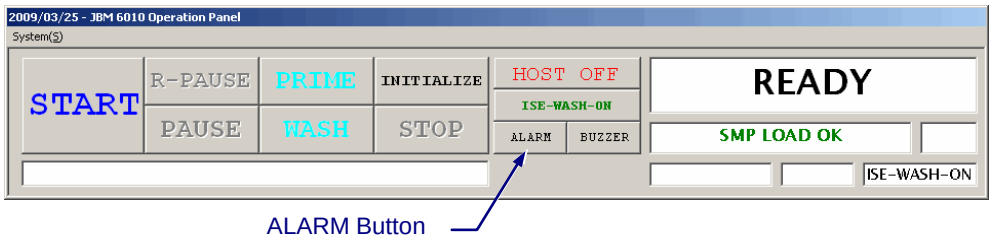
Cleaning the inside of the probe wash port and the V block

7) **After the cleaning is completed, turn the Operate/Standby switch to "PC CONTROL."**

   If ○ (Off) or ⊙ (On) is selected, the analyzer does not turn on/off together with the workstation.
8) **Select "Re-start" in the "BioMajesty" startup window to re-start the system.**

   Wait for several seconds and confirm the Operation Panel shows the system mode "WAIT."

9) Perform "INITIALIZE" and confirm the system mode turns to "READY."



How to clean the inside of the mixer wash port

When impurities deposit inside the wash port, follow the steps below for cleaning.

Required tools	Clean gauze (lint-free), pure water, cotton swab
Required time (estimated)	5 min
Frequency of service	As required
System mode at service	Analyzer's power is off.
Task	Clean the inside of the wash port.

Warning

- Read the sections of "Safety Precautions" and "Precautions For Use" before starting the task.

CAUTION

- Wear protective glasses, mask, and gloves when you perform the service.
- Turn the Operate/Standby switch to the ⏻ "Off" position before starting to clean the mixer wash port.

1) Obtain a piece of gauze, cotton swabs, and a bottle of pure water.

2) Confirm the system mode is "READY."

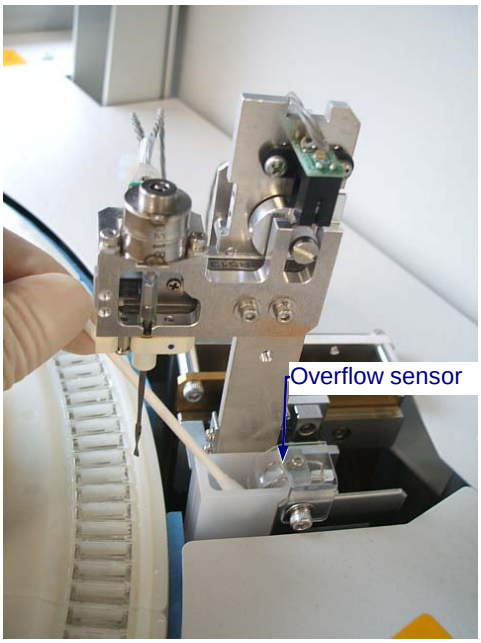
1 Exit the workstation system and display the "BioMajesty" startup window on the monitor.

3) Turn the Operate/Standby switch to ⏻ (OFF).

4) Pour pure water inside the wash port from the bottle, and clean it with gauze. Be careful not to hit or bend the mixing rod.

CAUTION

Ensure that the overflow sensor may not be deformed.



Cleaning the mixer wash port

5) Turn the Operate/Standby switch to "PC CONTROL."

If ○ (Off) or ⊙ (On) is selected, the analyzer does not turn on/off together with the workstation.

6) Select "Re-start" in the "BioMajesty" startup window to re-start the system.

Wait for several seconds and confirm the Operation Panel shows the system mode "WAIT."

7) Perform "INITIALIZE" and confirm the system mode shifts to "READY."

7.3.1f Check the splash cover for impurities

The splash cover protects the analyzer portion over which the probes move. The cover prevents water or reagents from splashing into the reaction cuvettes.

Check the splash cover for impurities every week.

Required tools	N/A
Required time (estimated)	1 min
Frequency of service	Daily
System mode at service	WAIT or READY
Task	Check the splash cover for impurities.

How to clean the splash cover

When the splash cover has impurities, follow the steps below for cleaning.

Required tools	Clean gauze (lint-free), pure water
Required time (estimated)	5 min
Frequency of service	As required
System mode at service	Analyzer's power is off.
Task	Clean the splash cover.

Warning

- Read the "Safety Precautions" and "Usage Notes" before starting this task.

CAUTION

- Wear protective glasses, a mask, and gloves when you perform this service.
- Turn the Operate/Standby switch to the ⏻ "Off" position before starting to clean the splash cover

1) Obtain a piece of gauze dampened with pure water.

2) Confirm the system mode is "READY."

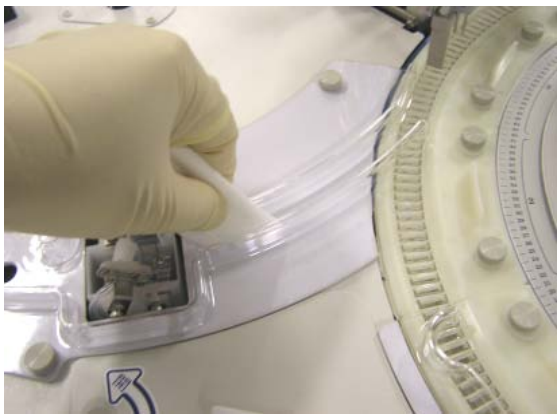
3) Exit the workstation system and display the "BioMajesty" startup window on the monitor.

4) Turn the Operate/Standby switch to ⏻ (OFF).

5) Clean off the impurities on the splash cover with gauze dampened with pure water.

Do not touch the probes.

Ensure that no debris may enter the cuvettes.



Cleaning the splash cover

6) After the cleaning is completed, turn the Operate/Standby switch to "PC CONTROL."

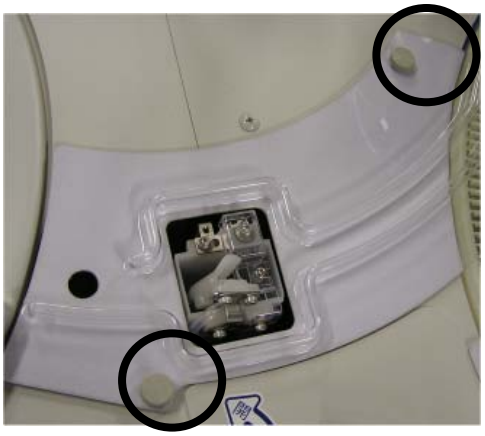
If ⏻ (Off) or ⊙ (On) is selected, the analyzer does not turn on/off together with the workstation.

7) Select "Re-start" in the "BioMajesty" startup window to re-start the system.

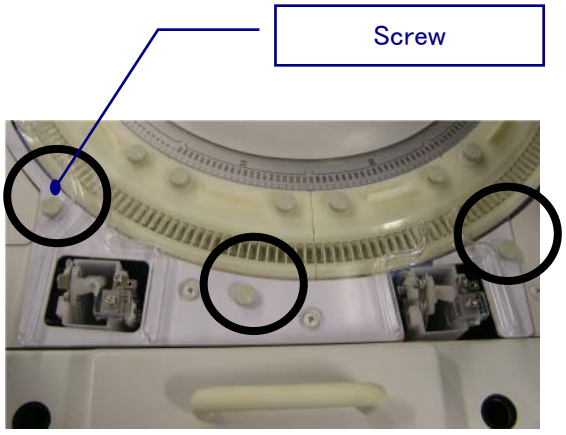
Wait for several seconds and confirm the Operation Panel shows the system mode "WAIT."

8) Perform "INITIALIZE" and confirm the system mode shifts to "READY."

When the impurity level is high, loosen the screws to remove the splash cover for washing.



Splash cover for the sample probe (SPP)



Splash cover for the reagent probes (RPP)

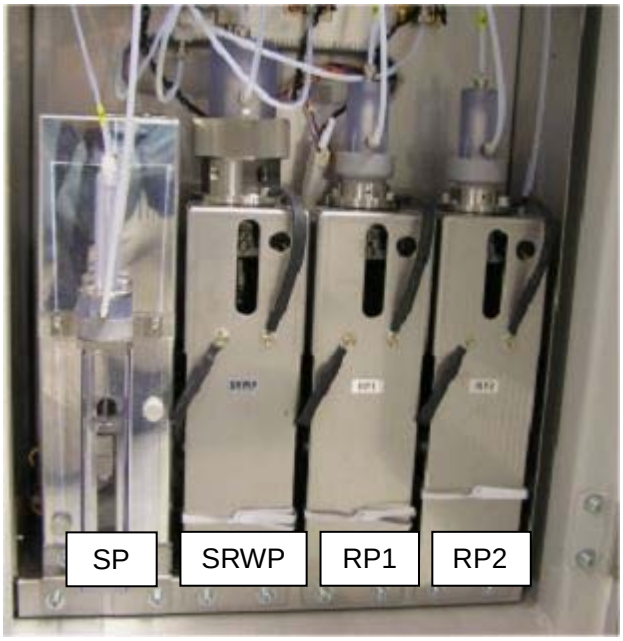
7.3.1g Check for potential leakage from pumps

If the seal surrounding the pump deteriorates, liquids may leak from the seal site.

Leakage decreases the flow rate and introduces air bubbles.

The steps for examining the sampling pump (SP) are different from those for the sampling and reagent wash pump (SRWP) and for reagent pumps 1 and 2 (RP1 and RP2).

Pump locations



Pump locations

How to check the liquid leakage and trapped air in SP

Check the following points for SP

Required tools	N/A
Required time (estimated)	3 min
Frequency of service	Daily
System mode at service	WASH or Processing
Task	Check there is no liquid leakage or trapped air in SP.

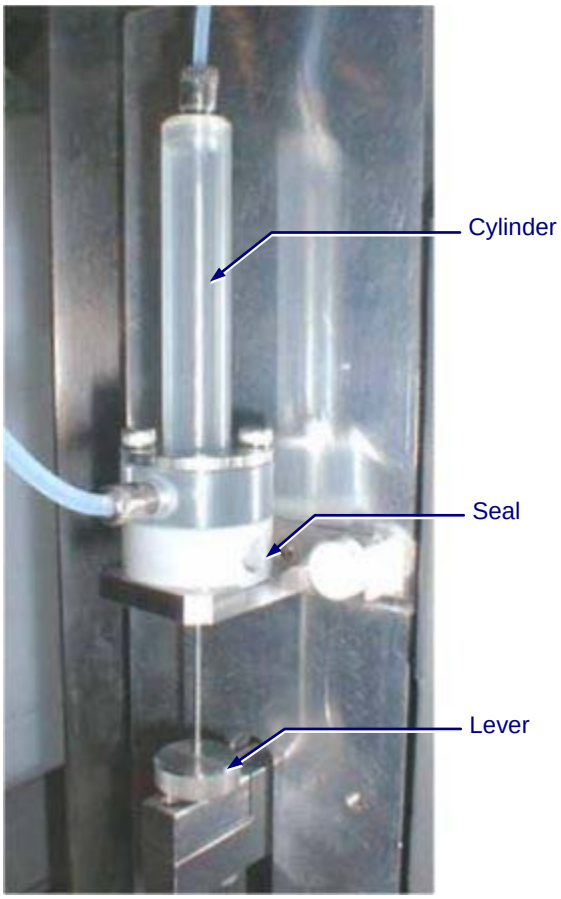
1) Perform "WASH" to check if the piston in the cylinder is moving up and down.

The SP can also be visually checked for leakage while the system is in Processing mode.

2) Check visually if no leakage is observed at the seal site.

3) Check visually if no leakage is observed around the lever.

4) Check visually if no air is trapped in the cylinder.



Sites to check visually

5) If leakage is observed, follow the steps described in Section 7.8.1b to replace the seal.

If air is found trapped in the cylinder, its source or point of entry must be determined.

How to check the liquid leakage and trapped air in RP1/RP2/SRWP

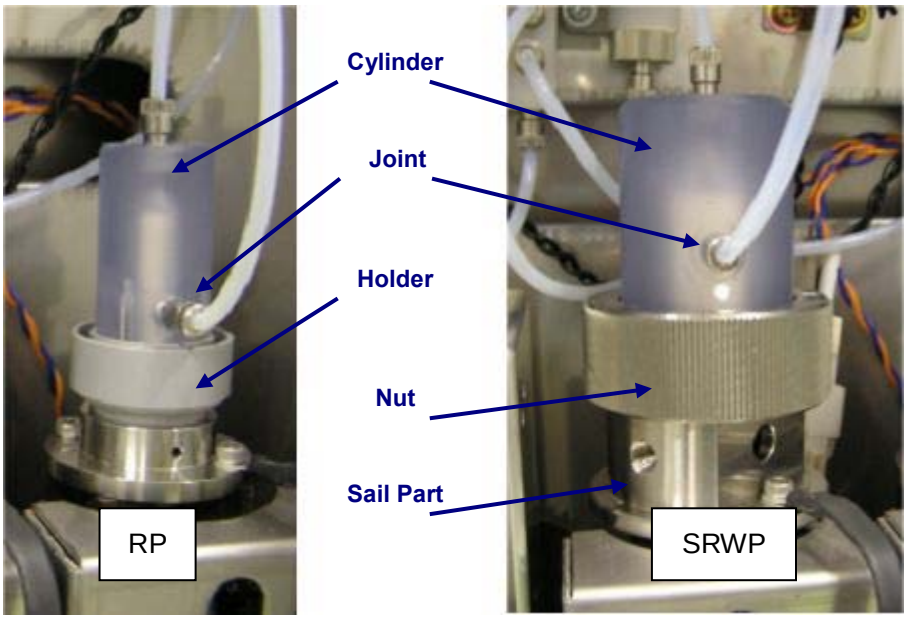
Check the following points in RP1/RP2/SRWP.

Required tools	Gauze as required
Required time (estimated)	3 min
Frequency of service	Daily
System mode at service	WASH or Processing
Task	Check there is no liquid leakage or trapped air in the pump.

1) Perform "WASH" to verify that the piston is moving vertically in the cylinder.

The RP1/RP2/SRWP can also be visually checked for leakage while the system is in Processing mode.

2) Check visually or dab with gauze to rule out leaks in the sealing site, at the connection joints, at the joint between the holder and the cylinder, or at the joint between the nut and the cylinder.



3) Check visually if no air is trapped in the cylinder.

4) If leakage is observed, follow the steps described in Section 7.8.1b to replace the seal.

If air is found trapped in the cylinder, its source or point of entry must be determined.

7.3.1h Examine the remaining volume of the lamp coolant

The spectrophotometer lamp is cooled by circulating coolant. If the coolant volume decreases and air bubbles form in the lamp coolant pump (CLP), the circulation will stop, and the temperature inside the lamp holder will rise. This process triggers an alarm signaling a lamp thermostat abnormality and turns off the lamp automatically.

Check the remaining volume of the coolant every day.

Required tools	N/A
Required time (estimated)	1 min
Frequency of service	Daily
System mode at service	READY
Task	Check the remaining volume of the lamp coolant.

CAUTION

Follow the steps below to determine the volume of lamp coolant.

1) Confirm the system mode is "READY."

2) Remove the cover over the lamp coolant tank to observe the coolant volume.

Two lines inside the tank indicate the 5-cm and 9-cm heights from the tank bottom. If the coolant level is between the two lines, there is no need for replenishment. When the level dips below the 5-cm line, follow the steps listed to replenish the coolant.

3) Close the cover over the lamp coolant tank.

How to replenish the lamp coolant

Follow the steps below to replenish the lamp coolant.

Required tools	Lamp coolant
Required time (estimated)	1 min
Frequency of service	As required
System mode at service	READY
Task	Replenish the lamp coolant.

Warning

- Read the "Safety Precautions" and "Usage Notes" before starting this task.

CAUTION

- Wear protective glasses, a mask, and gloves when you perform this service.

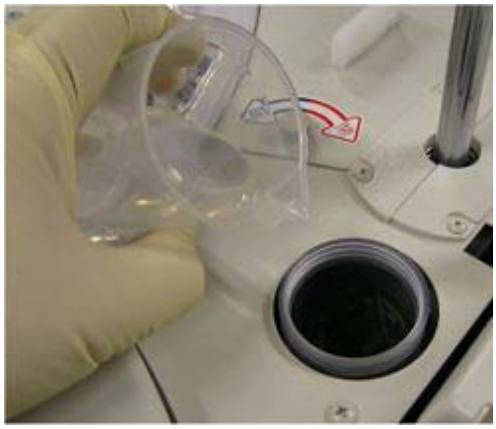
1) Obtain the lamp coolant.

The lamp coolant should not be diluted before use.

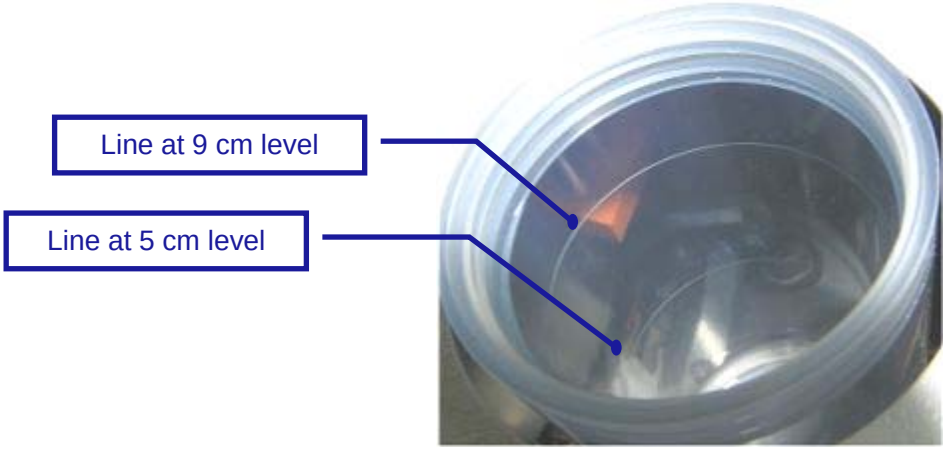
2) Manually turn the cover over the lamp coolant tank counterclockwise to remove it.

3) Pour the lamp coolant in a wash bottle or a beaker, and replenish the tank with lamp coolant to the 9-cm level.

Be careful not to spill the coolant when replenishing the tank.



Replenishing the lamp coolant



Level lines

4) Return the cover onto the lamp coolant tank.

How to replenish the coolant after the alarm sound

If the thermostat abnormality alarm sounds, check the coolant level. If the level is low, replenish the coolant, and then verify that the coolant in the tank is circulating. Click the [ALARM] button on the Operation Panel to release the alarm message. If no error is reported, wait 10 minutes to resume measurement.

If the coolant does not circulate, the lamp coolant pump (CLP) is not functioning, most likely because of air bubble formation. Contact your local distributor for service.

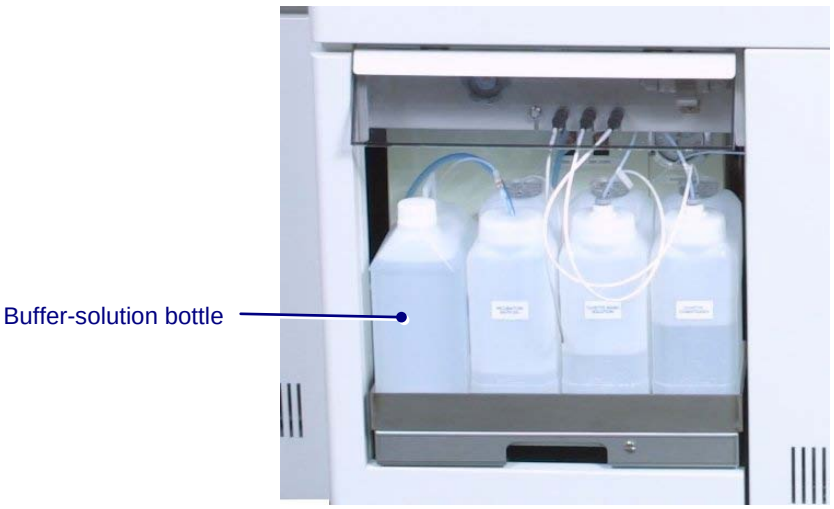
7.3.2 Ion selective electrode (ISE) unit

7.3.2a Check the remaining volume of the ISE buffer solution

Verify sufficient buffer solution volume before taking measurements. When the buffer volume becomes too low, the flag “r” will be posted to the test result. When the flag “r” is posted, the system mode shifts automatically to “Processing” to allow the buffer solution bottle to be replaced. Data collected when the “r” flag is posted can be considered accurate. However, if the buffer solution is not replenished and more measurements are taken, the flow rate will become insufficient and the level of buffer in the ISE dilution bowl lowers. Ultimately, measurements will be compulsorily suspended to ensure safety.

Keep the panel above the bottle compartment closed when running samples. Otherwise, the vibration of the bottles may influence the ISE test results.

Required tools	N/A
Required time (estimated)	1 min
Frequency of service	Daily
System mode at service	READY
Task	Check the volume of buffer solution



If the volume is insufficient, follow the steps below to replace the bottle.

Replacing the buffer solution bottle

Required tools	A buffer solution bottle for replacement
Required time (estimated)	5 min (time for calibration is not included)
Frequency of service	As required
System mode at service	READY
Workflow	1. Remove the buffer solution bottle. 2. Set a new buffer solution bottle. 3. Perform priming. 4. Perform calibration.

Follow the steps below to replace the bottle.

1) Remove the existing bottle.

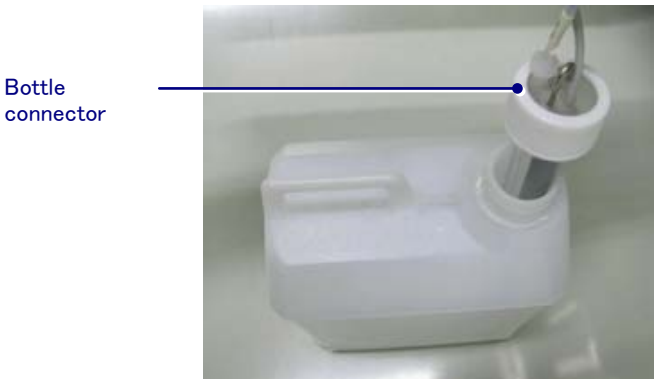
1 Lift the panel above the bottle compartment, and pull out the tray containing the bottles.

Be careful not to damage the tubing when pulling the tray.

1 Remove the bottle connector including a float switch.

2) Set out a new bottle.

1 Place the new buffer bottle in the tray. Uncap it and insert the bottle connector. Screw the connector to close the bottle.



2 Push the tray back in the compartment.

3) Perform priming from the [ISE Operation] window. (Section 7.10)

Set “15” for [Times] for the buffer solution to reach the ISE dilution bowl. Keep priming until no air bubbles come out. If air bubbles persist, check for any leakage or loose connection especially at the joints.

4) Perform calibration following priming.

7.3.2b Check the internal standard (IS) solution

Verify sufficient IS solution volume before starting calibration. When the volume becomes too low, the flag "r" will be posted to the test result. When the volume level is further down, the system automatically suspends measurement to ensure safety.

The remaining volume of IS solution is displayed in the [ISE Operation] window. (Section 7.10)

Keep the panel above the bottle compartment closed when running samples. Otherwise, the vibration of the bottles may influence the ISE test results.

Required tools	N/A
Required time (estimated)	1 min
Frequency of service	Daily
System mode at service	READY
Task	Check the level of the IS solution.

If the volume is insufficient, follow the steps below to replace the pack.

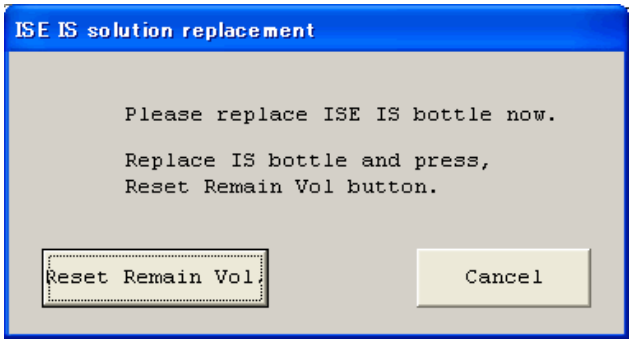
Replacing the IS solution pack

Follow the steps below to replace the pack.

Required tools	An IS solution pack for replacement
Required time (estimated)	5 min (time for calibration is not included)
Frequency of service	As required
System mode at service	READY
Workflow	1. Remove the IS solution pack. 2. Set out a new IS solution pack. 3. Perform line priming for IS. 4. Perform calibration.

1) Click the [Change] button beside [IS Remain Vol.] in the [ISE Operation] window.

The [ISE IS solution replacement] window is displayed.



[ISE IS solution replacement] window

The scheduled “WASH” is not performed when this window is displayed.

Replace the IS solution pack when the system mode is “READY” or “WAIT”. A dialog box is displayed to notify the user that the IS solution pack cannot be replaced when a scheduled ISE Wash is going on. Wait until the replacement becomes possible.

2) Remove the existing bottle.

1 Open the front door of the analyzer to remove the IS solution pack.

2 Detach the bottle connector.

3) Set out a new bottle.

1 Uncap the new IS solution pack and insert the bottle connector.

2 Place the new IS solution pack inside the analyzer.

4) Click the [Reset Remain Vol.] button in the [ISE IS solution replacement] window.

Confirm the remaining volume of IS solution is now reset.

5) Perform IS line priming from the [ISE Operation] window. (Section 7.10)

Define “10” for [Times] for the IS solution to reach the degasser.

Keep priming until no air bubbles come out. If air bubbles persist, check any leakage or loose connection especially at the joints.

6) Perform calibration following IS line priming.

7.3.2c Wash the electrodes

The electrodes are washed automatically with “WASH2” performed upon initiating the shutdown sequence at the end of the day.

Electrode wash is a default setting. You can change the option for [Prime/Electrode Wash/Final] in the [ISE Parameters of Setting] window.

Required tools	ISE Detergent Solution, dropper
Required time (estimated)	5 min
Frequency of service	Daily
System mode at service	READY
Task	Wash the electrodes.

Warning

- Read the “Safety Precautions” and “Usage Notes” before starting this task.

CAUTION

- Wear protective glasses, a mask, and gloves when you perform this service.

If the system is not automatically shut down at the end of the day or if the measurement data are unstable, wash the electrodes independently of the [WASH] operations, as follows:

1) **In the [ISE Operation] window, enter a position number for [Detergent posi.] and select “Sample cup (JCUP/Adp)” for [Container] in the [Wash Electrode] area.**

2) **Put 100µL of ISE Detergent Solution in the JCUP and place it on the defined position.**
3) **Click the [Execute] button.**

Electrode wash begins.

ISE Detergent Solution is dispensed twice. Do not touch the refrigerated sample tray (CTT) or ISE unit until the electrode wash is complete. Otherwise, your hand may be injured.

The display area of the [ISE Operation] window displays “Wash electrode running” and the remaining time in the [remain] field. You cannot suspend the electrode wash. If you want to stop it urgently, use the [SYSTEM STOP] button on the power panel of the analyzer.

7.3.2d Wash the ISE dilution bowl

Wash the ISE dilution bowl daily, either before or after running samples. If the buffer overflows for any reason, it must be washed separately from the daily wash.

Required tools	Pure water, cotton swab
Required time (estimated)	10 min
Frequency of service	Daily
System mode at service	READY
Workflow	1. Fill the dilution bowl with pure water. 2. Drain the dilution bowl. 3. Wipe to dry the remaining water. 4. Perform priming.

Warning

- Read the "Safety Precautions" and "Usage Notes" before starting this task.

CAUTION

- Wear protective glasses, a mask, and gloves when you perform this service.
- Be sure to change the status into [ISE-WASH-OFF] before performing the task. If you perform the task in the [ISE-WASH-ON] status, the scheduled wash is automatically activated, resulting in a serious accident or trouble.

1) Click the [ISE-WASH-ON] button on the Operation Panel to change the display to "ISE-WASH-OFF."

2) Remove the cover over the ISE sampling position.

Loosen 2 screws to remove the cover.

3) Loosen the screw that locks the stainless steel cover over the ISE unit, and slide the cover off.

4) Click [Execute] in the [Final Operation] area in the [ISE Operation] window to perform the "final operation" and fill the unit with water (☞Section 7.10). Or, drop 1 mL of pure water in the ISE dilution bowl with a dropper.

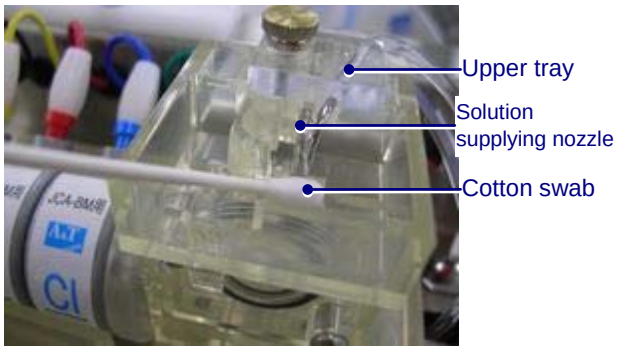
5) Wait 5 minutes.

Allow the system to idle for approximately 5 minutes to dissolve the impurities around the buffer outlet and nozzle.

6) Click [Execute] in the [Dil Bowl drain] area in the [ISE Operation] window.

The water in the ISE dilution bowl is drained.

7) Clean the remaining water or impurities around the nozzle with a cotton swab.



Cleaning the nozzle

Wipe the nozzle gently. A deformed or damaged nozzle may result in less accurate data.

8) Enter "3" for [Times] in the [Prime] area in the [ISE Operation] window, Click [Execute].

Priming begins.

7.3.2e Post-maintenance restoration of the ISE unit

After performing daily maintenance, restore the unit to measurement-ready status by doing the following:

1) Return the stainless cover to the unit and replace the screws.

Be careful not to damage the lines or dilution bowl when replacing the cover. Ensure that the cover is securely positioned in the gutters.

2) Attach the cover on the ISE sampling position with screws.

3) Click the [ISE-WASH-OFF] button on the Operation Panel to change the display to "ISE-WASH-ON."

7.4 Weekly Maintenance

7.4.1 Chemistry analysis unit

7.4.1a Check the lamp energy

Check the spectrophotometer lamp energy when the cuvettes are washed weekly in "WASH2." Measure the cuvette blank at this time.

In addition, the lamp energy and the cuvette blank should be measured upon replacing the lamp or cuvettes.

How to check the lamp energy

The lamp deteriorates over time. Check the lamp energy every week.

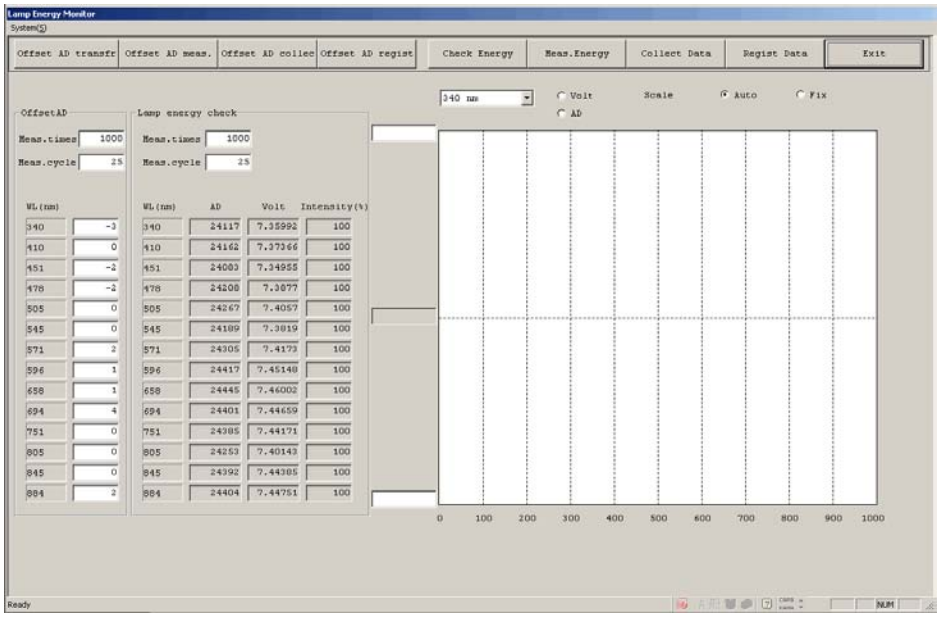
Required tools	Pure water
Required time (estimated)	5 min (WASH2 is not included)
Frequency of service	Weekly or every time after the lamp or cuvettes are replaced.
System mode at service	READY
Workflow	1. Set a pure water bottle on the reaction tray 1 (RTT1). 2. Check the lamp energy in the [Lamp Energy Monitor] window.

Follow the steps below for checking.

1) Perform "INITIALIZE" and shift the analyzer mode to "READY".

2) Select [Maint.] > [Lamp Energy Monitor].

The [Lamp Energy Monitor] window is displayed.

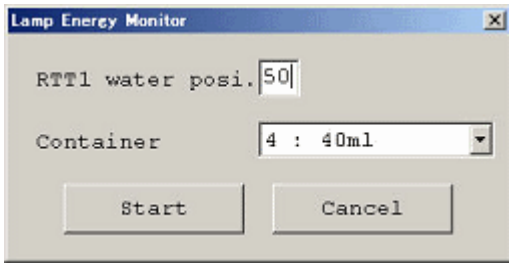


[Lamp Energy Monitor] window

3) Place a bottle of pure water on the position #45 of RTT1.

4) Click the [Check Energy] button.

The [Check Energy] window is displayed.



5) Enter “45” for [RTT1 water posi.], and click the [Start] button.

Once entered, the number is retained for the subsequent measurement.

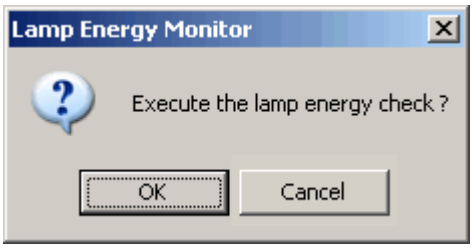
The reagent probe aspirates pure water from the bottle on RTT1 and dispenses it in the reaction cuvette #1. The reaction carousel (RRV) then rotates to position the cuvette for measurement. At this time, the analyzer will enter “WAIT” mode.

6) Enter “1000” for [Meas.times] and “100” for [Meas.cycle] in the [Lamp every check] column.

Once entered, the number is retained for the subsequent measurement.

7) Click the [Meas.Energy] button.

A pop-up window is displayed to ask “Execute the lamp energy check?”

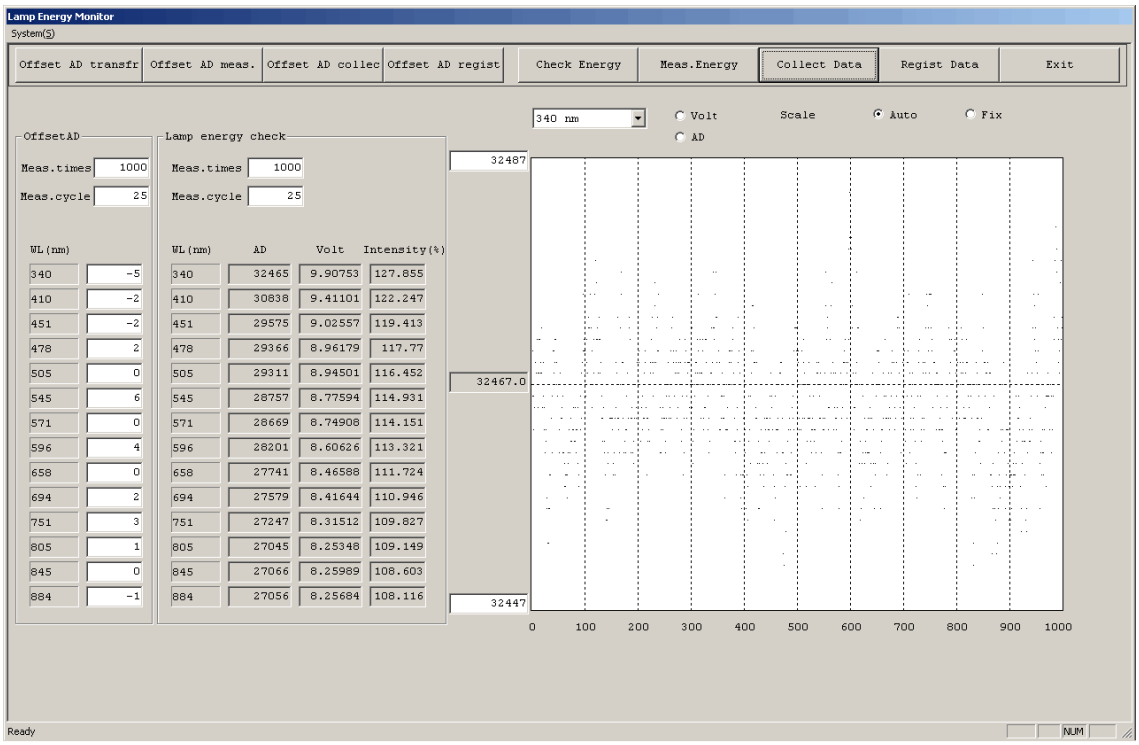


8) Click [OK].

The measurement takes no more than one second.

9) Click the [Collect Data] button.

The result of the lamp energy measurement is displayed.



Result of the lamp energy measurement

10) Select “340 nm” and “AD” in the section above the graph space. Also select “Auto” for [Scale]. Check the AD value of 340 nm in the graph.

The lamp energy values are plotted in the graph. The AD values at a wavelength of 340 nm are plotted on the Y axis. The lamp energy is regarded as normal when the difference between the largest and smallest values is 100 or less. The table to the left of the graph displays the lamp energies (AD values) at wavelengths of 340 nm to 884 nm. The lamp energy is considered normal if the values are between 10,000 and 30,000.

Under the [Intensity] header, the attenuation in intensity since the previous lamp or cuvette replacement is depicted. The value indicates the integrated intensities of the lamp energy and the cuvette #1.

If the values are not in the reference ranges, refer to “Section 8.4 Typical Error Messages and Countermeasures” and perform the countermeasures described for Error Message No. 0903 and 0904.

11) When you check the lamp energy in this window after replacing the lamp or cuvettes, click the [Regist Data] button.

A pop-up window is displayed to ask confirmation. Click [OK] in the window. The new data are registered for the reference value to calculate the attenuated intensity for future.

12) The system mode is still “WAIT”, Perform “INITIALIZE” to shift it to the “READY” mode.

7.4.1b Cuvette blank measurement

The reaction cuvette accumulates impurities over time and the absorbance will change accordingly. Measure the cuvette blank every week together with the lamp energy to check the changes.

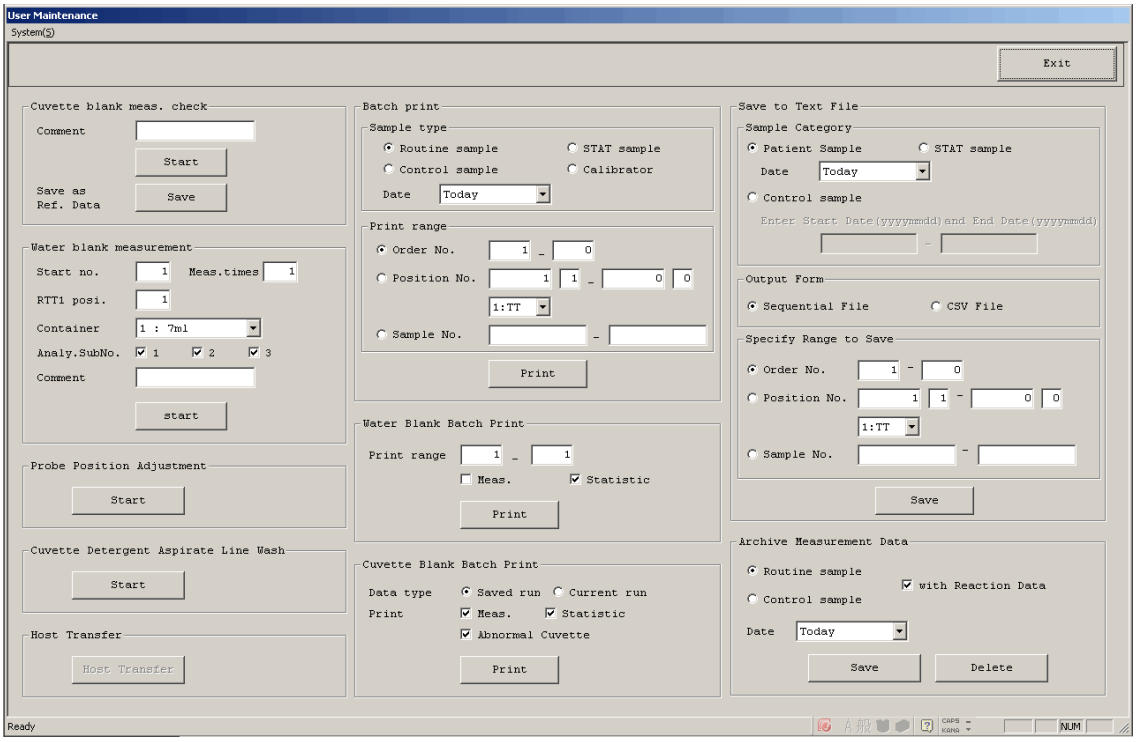
Required tools	N/A
Required time (estimated)	17 min (WASH2 is not included)
Frequency of service	Weekly or every time after the lamp or cuvette replacement
System mode at service	READY
Task	Perform the cuvette blank measurement from the [User Maintenance] window.

Follow the steps below to measure the cuvette blank.

1) Confirm the system mode is "READY."

2) Select [Maint.] > [User Maintenance].

The [User Maintenance] window is displayed.



3) Click the [Start] for [Cuvette blank meas. check].

The cuvette blank measurement begins. Select [Request] > [Realtime Monitor] to check the measurement value in realtime.

4) Check the result.

The cuvette blank measurement is completed in approximately 17 minutes. Select [Request] > [RealTime Monitor] to review the statistical data of the 231 cuvettes for abnormality.

To print the result, select [Current run] for [Data type], and select [Statistic] and [Abnormal cuvette] for [Print] in the [Cuvette Blank Batch Print] column in the lower middle part of the [User Maintenance] window.

CELL BLANK Statistics DATE: 2009/02/03 TIME: 13:06 Comment:

Wave	N	MAX	MIN	RANGE	MEDIAN	SD
340	231	3.426723	0.125891	3.300833	0.147264	0.470935
410	231	3.527188	0.121361	3.405827	0.143904	0.470154
451	231	3.429090	0.114867	3.314223	0.136516	0.460141
478	231	3.408240	0.111899	3.296341	0.133149	0.458259
505	231	3.533179	0.113467	3.419712	0.134356	0.464177
545	231	3.539253	0.114987	3.424266	0.137727	0.462419
571	231	3.577598	0.112588	3.465010	0.135951	0.464844
596	231	3.646218	0.109360	3.536859	0.133343	0.469629
658	231	3.767262	0.109954	3.657308	0.134795	0.486902
694	231	3.822309	0.108992	3.713318	0.133144	0.500398
751	231	3.767262	0.118763	3.648499	0.139695	0.511791
805	231	3.666235	0.126647	3.539589	0.140583	0.518517
845	231	3.654115	0.129821	3.524294	0.139478	0.522287
884	231	3.737299	0.130930	3.606368	0.139130	0.535837

CELL BLANK Abnormal DATE: 2009/02/03 TIME: 13:06 Comment:

RRVNo	Mark	RRVNo	Mark	RRVNo	Mark	RRVNo	Mark	RRVNo	Mark	RRVNo	Mark
31	H	34	H	110	H	113	H	186	H	189	H

Example of the result data

5) Register the data.

When the measurement is completed, a window is displayed where you can select whether or not to register the data. Click [Yes] to register the cuvette blanks.

If you click [No] in this window, the cuvette blank values are not registered and the window is closed. If you want to register the values afterwards, select [Maint.] > [User Maintenance] > [Cuvette blank meas. check], and click [Yes] for [Save current run?].

6) Check the abnormal cuvettes.

Select [Request] > [RealTime Monitor] and refer to [Abnormal cuvettes] to see if there were any abnormal cuvettes. If a flag such as “H” or “L” is posted for a cuvette, remove the cuvette holder that includes the abnormal cuvette according to the steps described in “Section 7.7.1b Replace the reaction cuvettes,” and inspect for abnormalities.

If no abnormality is visually detected, return the cuvette set to the carousel.

If a cuvette triggers an “L” or “H” flag indicating abnormal cuvette blank, it will be skipped and not used for measurement. Occasionally, impurities can be washed away during operation. If the cuvette blank is judged normal at the next blank measurement, it will automatically be used for the next sample measurement.

File the print outs of “Statistic” and “Abnormal cell” results to use for monitoring the cuvette status for management.

7.4.1c WASH2 with Reagent probe wash-S

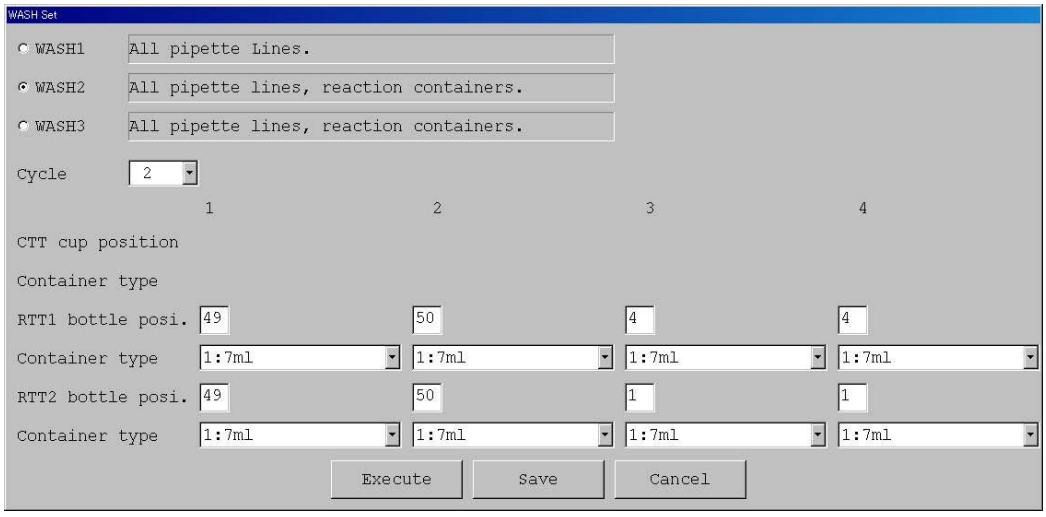
Reagent probe wash-K (20%) is used in the daily "WASH2" before shutting down the system at the end of the day, while Reagent probe wash-S (5%) is used in the weekly "WASH2" to clean the reaction cuvettes.

The cleaning steps are as follows:

1) Place Reagent probe wash-S at the position #49 on the reagent trays 1 and 2 (RTT1 and RTT2) and pure water bottle at the position #50 on both of the trays.

2) Click the [WASH] button in the Operation Panel.

The [WASH Set] window is displayed.



3) Select "WASH2" and click the [Execute] button.

"WASH2" begins and finishes in approximately 40 minutes.

7.4.2 Ion selective electrode (ISE) unit

7.4.2a Wash the electrode lines

Impurities deposited in the electrode lines may prevent proper drainage, consequently affecting measurement. Impurities accumulate faster as the number of sample measurements increases. Frequency of the electrode line wash should be based on the number of dialysis sample run as follows:

- Once in 3 days for 500 or more dialysis samples/month
- Weekly for 101-499 dialysis samples/month
- Biweekly for up to 100 dialysis samples/month

Required tools	Dummy electrode with O-ring and cap, ISE Detergent Solution, dropper
Required time (estimated)	25 min (time for calibration is not included)
Frequency of service	Depends on the number of samples measured
System mode at service	READY
Workflow	1. Remove the electrodes and set the dummy electrode. 2. Perform “STEP-1” of the line wash. 3. Perform “STEP-2” of the line wash. 4. Return the electrodes in place. 5. Perform calibration.

Warning

- Read the sections of “Safety Precautions” and “Precautions For Use” before starting the task.

CAUTION

- Wear protective glasses, a mask, and gloves when you perform this service.

- Be sure to change the status into [ISE-WASH-OFF] before performing the task. If you perform the task in the [ISE-WASH-ON] status, the scheduled wash is automatically activated, resulting in a serious accident or trouble.

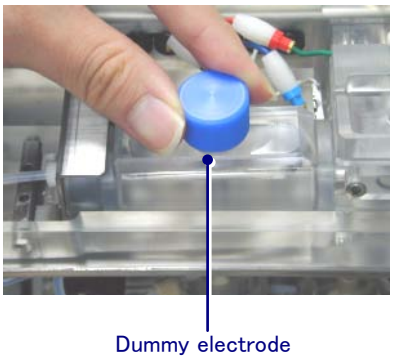
How to wash

The line wash consists of the following two steps. Perform them successively.

✔ Perform STEP-1 of the line wash.

1) **Click the [ISE-WASH-ON] button on the Operation Panel to change the display to "ISE-WASH-OFF."**
2) **Remove the cover over the ISE sampling position.**

   Loosen 2 screws to remove the cover.
3) **Loosen the screw that locks the stainless steel cover over the ISE unit to slide it off.**
4) **Remove the Na, K, Cl, and Ref. electrodes. (See "Section 7.8.2b")**
5) **Place the dummy electrode instead.**
6) **Uncap the dummy electrode.**

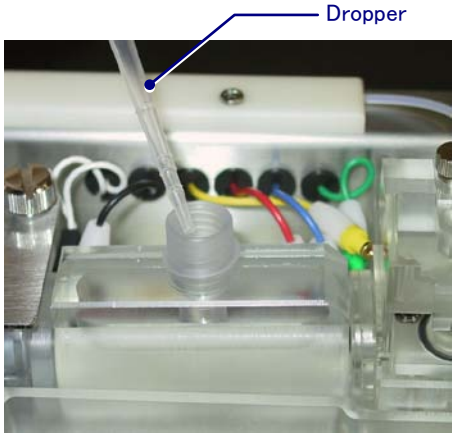


Dummy electrode

7) **Drop approximately 5 mL of ISE Detergent Solution with a dropper in the dummy electrode.**

Warning

ISE Detergent Solution contains sodium hypochlorite. Avoid contact with skin and eyes. If contact occurs, wash the site thoroughly with water and consult a physician.



Dropping the ISE Detergent Solution

8) Close the cap of the dummy electrode tightly.

CAUTION

Be sure to close the cap tightly.
The detergent solution is introduced to the ISE dilution bowl for washing. If the cap is damaged or not tightly closed, the detergent solution may leak and damage the device.

9) Click [Execute (STEP-1)] button in the [ISE line wash] area in the [ISE Operation] window. (See Section 7.10)

10) Click [Yes] in the pop-up window.

ISE line wash begins. The status "ISE line wash 1 Running" and the remaining time are displayed in the window. You cannot suspend the electrode wash. If you want to stop it urgently, use the [SYSTEM STOP] button on the power panel of the analyzer.

✔ Perform STEP-2 of the line wash.

1) After the STEP-1 is completed, replace the dummy electrode with Na, K, Cl, and Ref electrodes. (See "4.10 Setting the Electrode.")

Ref, Na, K, Cl electrodes

Placing back the electrodes

2) Click [Execute (STEP-2)] button in the [ISE line wash] area in the [ISE Operation] window. (See Section 7.10)

3) Click [Yes] in the pop-up window.

The wash begins and priming is repeated for 10 times. The status "ISE line wash 2 Running" and the remaining time are displayed in the window. You cannot suspend the procedure. If you want to stop it urgently, use the [SYSTEM STOP] button on the power panel of the analyzer.

4) Click the [ISE-WASH-OFF] button on the Operation Panel to change the display to "ISE-WASH-ON."

5) Perform calibration.

The environment around the electrodes has changed after the line wash. Be sure to perform calibration before starting measurement.

7.4.2b Post-maintenance restoration of the ISE unit

After the weekly maintenance service, restore the unit to be ready for measurement.

See Section 7.3.2e for procedure.

7.4.3 Workstation

7.4.3a Shutdown

Shut down the computer once a week to ensure the stable operation of the application.

Required tools	N/A
Required time (estimated)	5 min
Frequency of service	Weekly
System mode at service	-
Workflow	1. Shut down the computer. 2. Start up the computer.

CAUTION

- Ensure that the system mode is “READY” when you shut down the computer.

1) Click [System (S)] command on the top bar of the Menu Panel and select “Exit” in the drop-down menu. The system is closed and the “BioMajesty” startup window is displayed.

2) Click the [Shutdown] button.

When the system is shut down, the computer and the analyzer are both turned off.

3) Wait approximately 10 seconds to turn on the computer.

4) When the startup window is displayed, select [Re-start] for startup.

The analyzer is turned on. Wait for tens of seconds and confirm the Operation Panel shows the system mode “WAIT.”

Perform “INITIALIZE” and confirm the system mode turns to “READY.”

7.5 Monthly Maintenance

7.5.1 Chemistry analysis unit

7.5.1a Soak and wash the mixing rods

Impurities on the mixing rods can cause measurement errors. Inspect the mixing rods daily for impurities, and clean them accordingly. In addition, soak and wash the mixing rods once monthly as follows:

Required tools	Reagent probe wash-K, dropper
Required time (estimated)	15 min (WASH3 is not included)
Frequency of service	Monthly
System mode at service	READY
Workflow	1. Fill Reagent probe wash-K in the mixer wash port. 2. Perform “WASH.”

Warning

- Read the “Safety Precautions” and “Usage Notes” before starting this task.

CAUTION

- Wear protective glasses, a mask, and gloves when you perform this service.

How to clean the mixing rod

1) Confirm that the system mode is “READY” and the mixing rods are in the raised position.

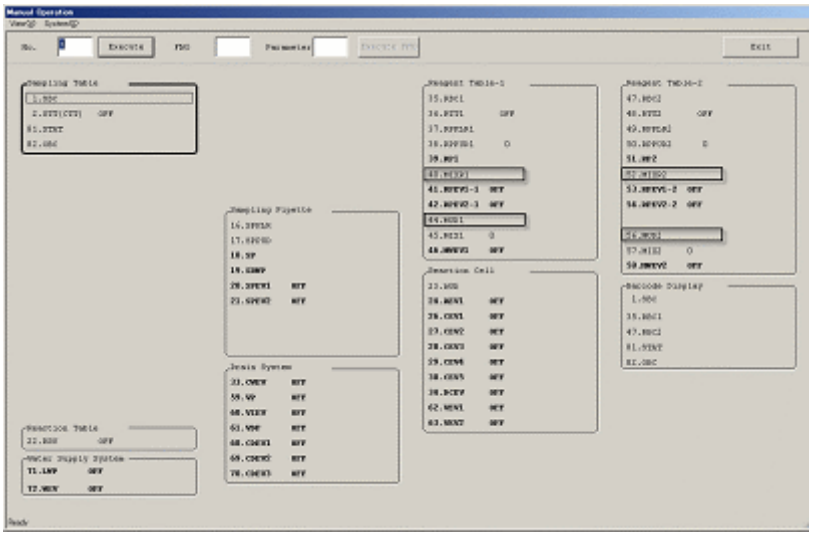
2) Aspirate the remaining water in the wash ports with a dropper.

Ensure that the dropper does not jostle the mixing rod.

3) Fill the undiluted Reagent probe wash-K with a dropper in the wash ports (Approximately 1 mL).

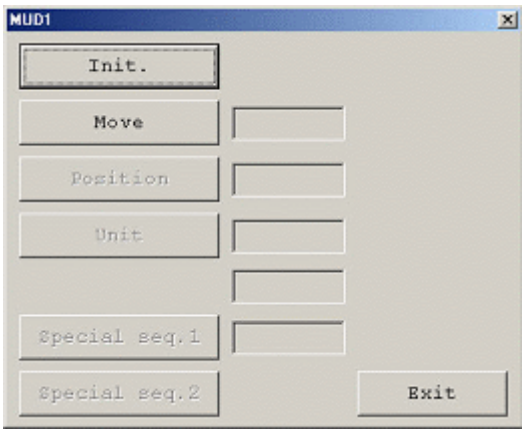
4) Wash the mixing rods.

1 Select [Maint.] > [Manual Operation].



Manual Operation window

2 Double click [44.MUD1]. The [MUD1] window is displayed where you can control the vertical motion of the mixer 1.



3 Click the [Init.] button.

The mixer 1 (MIX1) lowers in the wash port.

4 Double click [56.MUD2] to display the [MIX2] window where you can control the vertical motion of the mixer 2. Click the [Init.] button.

The mixer 2 (MIX2) lowers in the wash port.

5 Leave as is for approximately 10 minutes for soaking.

6 Double click [40.MIXR1] to display the [MIXR1] window where you can control the rotational movement of MIX1.

7 Click [Move] to rotate MIX1 once before stopping. Repeat it for 5 to 10 times.

Error occurs when you click the button while the mixer is still rotating. Wait for the mixer to stop before clicking again.

8 Double click [52.MIXR2] to display the [MIX2] window where you can control the vertical motion of the mixer 2. Click the [Move] button.

9 Rotate MIX2 in the same way as described in Step 7 to wash the impurities away.

10 Perform “INITIALIZE” and shift the system mode to “READY.”

11 Perform “WASH3” to wash away the detergent.

7.5.1b Clean the sample setting areas in the sample and refrigerated trays (STT/CTT) and the refrigerated reagent compartment in the reagent trays (RTTs)

The sample setting areas in STT/CTT and the refrigerated reagent compartment area in RTT become filthy with samples, reagents, and dusts. Clean the areas every month.

How to clean the sample setting areas in STT/CTT

Required tools	Clean gauze (lint-free)
Required time (estimated)	3 min
Frequency of service	Monthly
System mode at service	Analyzer's power is off.
Workflow	1. Remove the STT/CTT covers. 2. Remove the STT/CTT loaders. 3. Clean the areas where the loaders are set. 4. Return the STT/CTT loaders. 5. Return the STT/CTT covers.

Warning

- Read the "Safety Precautions" and "Usage Notes" before starting this task.

CAUTION

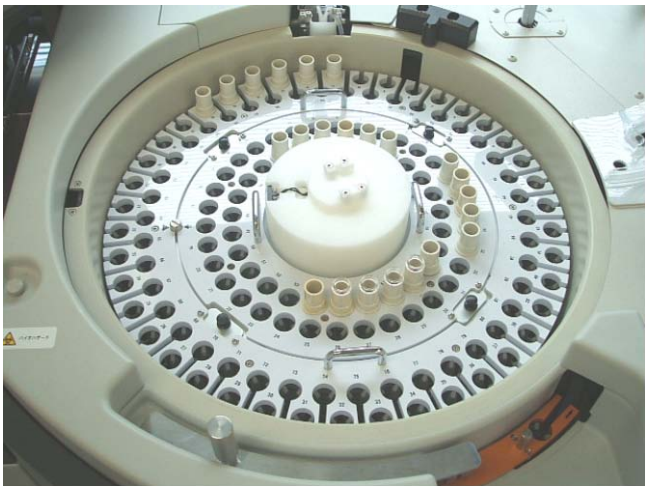
- Wear protective glasses, a mask, and gloves when you perform this service.
- Turn the Operate/Standby switch to the ⏻ "Off" position before starting to clean the sample setting areas.

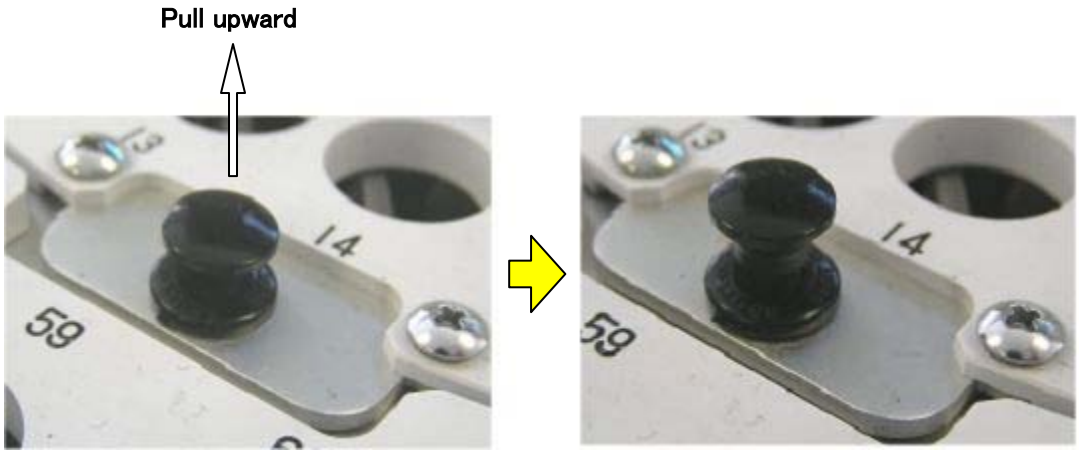
Follow the steps below for cleaning.

1) **Confirm the system mode is "READY."**
2) **Exit the workstation system and display the "BioMajesty" startup window on the monitor.**
3) **Turn the Operate/Standby switch to ⏻(OFF).**
4) **Remove the STT/CTT covers.**

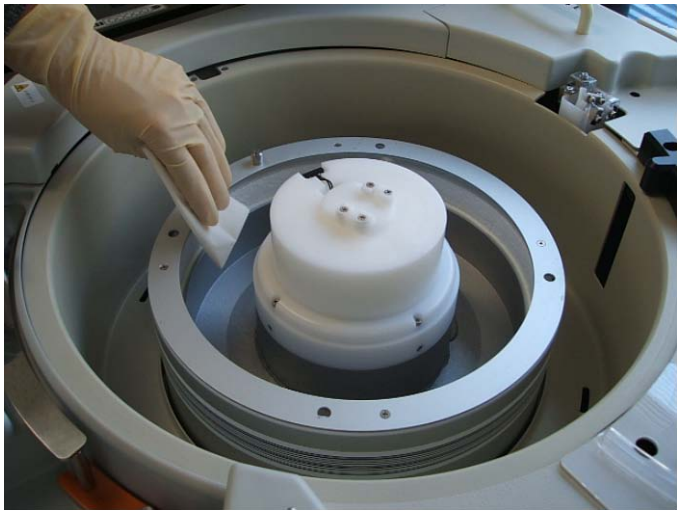
   See "Section 7.3.1b Check probes for impurities" for how to remove the covers.

5) Pull up two latches each on the STT/CTT to take out the loaders.





6) Clean the interior part with gauze.



Cleaning the sample setting area in STT/CTT

7) Return the STT/CTT loaders.

8) Reattach the STT/CTT covers

9) After the cleaning is complete, turn the Operate/Standby switch to "PC CONTROL."

If ⏻ (Off) or ⊙ (On) is selected, the analyzer does not turn on/off together with the workstation.

10) Select "Re-start" in the "BioMajesty" startup window to re-start the system.

11) Perform "INITIALIZE" and confirm the system mode shifts to "READY."

How to clean the RTT refrigerated reagent compartment

Required tools	Clean gauze (lint-free)
Required time (estimated)	10 min
Frequency of service	Monthly
System mode at service	Analyzer's power is off.
Workflow	1. Remove the RTT cover. 2. Remove the RTT loader. 3. Clean the areas where the loaders are set. 4. Clean the barcode reading window. 4. Return the RTT loaders. 5. Return the RTT cover.

Warning

- Read the "Safety Precautions" and "Usage Notes" before starting this task.

CAUTION

- Wear protective glasses, a mask, and gloves when you perform this service.
- Turn the Operate/Standby switch to the ⏻ "Off" position before starting to clean the refrigerated reagent compartment.

Follow the steps below for cleaning.

1) Confirm the system mode is "READY."

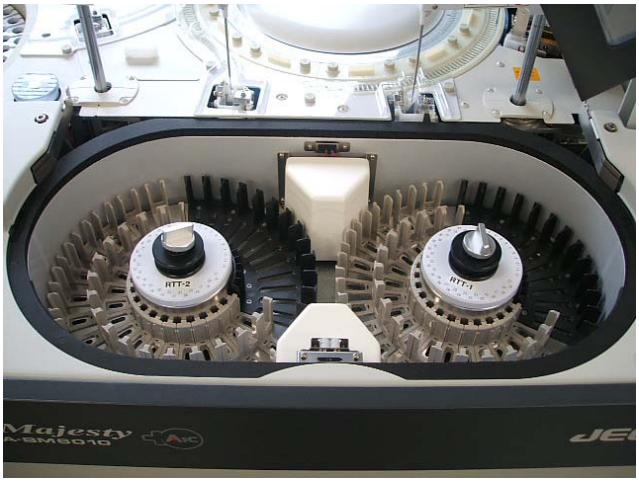
2) Exit the workstation system and display the "BioMajesty" startup window on the monitor.

3) Turn the Operate/Standby switch to ⏻ (OFF).

4) Remove the RTT cover.

See "Section 7.3.1b Check probes for impurities" for how to remove the cover.

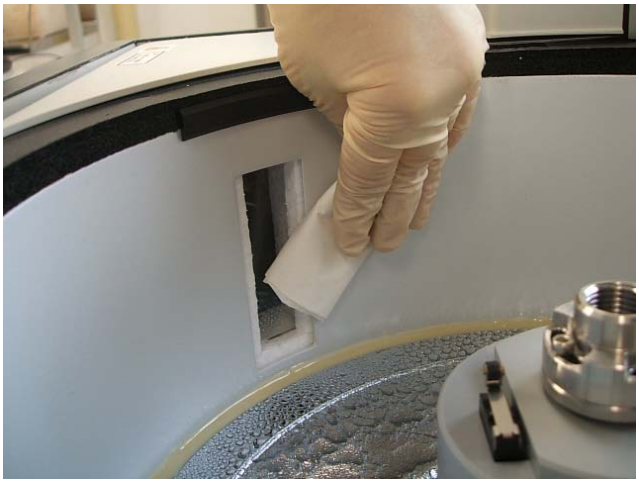
5) **Turn the central handle counterclockwise to loosen and pull it upward to take out the loader. Repeat this for the other loader.**



6) **Clean the water and impurities inside the compartment.**

Cleaning the refrigerated reagent compartment

7) **Clean the barcode reading window with dry gauze.**



Cleaning the barcode reading window

8) Return the RTT loaders.

Place the loader at the position where the▲ ma rk on the loader meets the pin.

When the loader is placed in the right position, turn the handle clockwise to tighten and fix.

9) Return the RTT cover.

See "Section 7.3.1b Check probes for impurities" for how to reattach the cover.

10) After the cleaning is complete, turn the Operate/Standby switch to "PC CONTROL."

If ○ (Off) or ⊙ (On) is selected, the analyzer does not turn on/off together with the workstation.

11) Select "Re-start" in the "BioMajesty" startup window to re-start the system.

Wait for several seconds and confirm the Operation Panel shows the system mode "WAIT."

12) Perform "INITIALIZE" and confirm the system mode shifts to "READY."

7.5.1c Clean the chiller filter

A filter is attached on the radiator of the coolant circulator (chiller). When this filter becomes dirty with dusts, heat radiation may be insufficient. Follow the steps below to clean the filter once a month.

Required tools	Vacuum cleaner
Required time (estimated)	3 min
Frequency of service	Monthly
System mode at service	Analyzer's power is off.
Workflow	1. Take out the filter. 2. Clean the filter with a vacuum cleaner. 3. Place the filter back in place.

Warning

- Read the "Safety Precautions" and "Usage Notes" before starting this task.

CAUTION

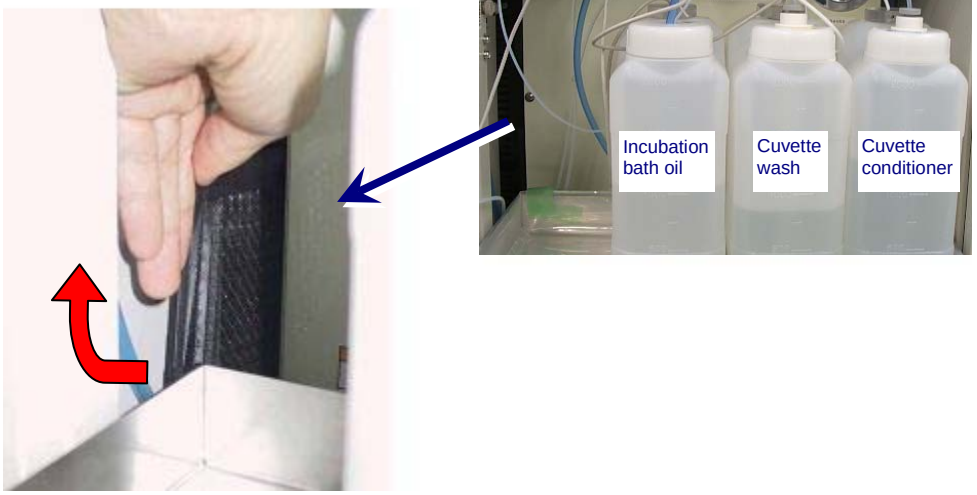
- Wear protective glasses, a mask, and gloves when you perform this service.

- Turn the Operate/Standby switch to the ⏻ "Off" position before starting to clean the chiller filter.

How to clean the chiller filter

1) **Confirm the system mode is "READY."**
2) **Exit the workstation system and display the "BioMajesty" startup window on the monitor.**
3) **Turn the Operate/Standby switch to ⏻(OFF).**
4) **Lift the panel above the bottle compartment located at the lower front side of the analyzer. Remove the ISE buffer bottle to access the left side.**

   Look inside and find the filter on the left side of the refrigeration unit in the back.



5) **Pull the filter outward and upward.**

   The filter is detached.

6) **Use a vacuum to clean dust from the filter.**

Cleaning the filter

7) Attach the filter in the original position and place the ISE buffer bottle back in position.

8) After the cleaning is complete, turn the Operate/Standby switch to "PC CONTROL."

If ○ (Off) or ⊙ (On) is selected, the analyzer does not turn on/off together with the workstation.

9) Select "Re-start" in the "BioMajesty" startup window to re-start the system.

Wait for several seconds and confirm the Operation Panel shows the system mode "WAIT."

10) Perform "INITIALIZE" and confirm the system mode shifts to "READY."

7.5.1d Clean the line filter of the large water supply pump (LWP)

Pressurized circulating water is supplied from the LWP line for washing mixing rods and probes. The pressure is set to 72 kPa to maintain a constant flow rate of cleaning water.

Debris in the LWP line may clog the probe or trigger a malfunction of the solenoid valves used for washing. The LWP line contains a filter to avoid these problems. If the filter becomes clogged, the washing water volume will become unstable, and an "abnormal LWP gauge error" will be displayed. Therefore, clean the filter monthly.

Required tools	Cloth (towel), brush (tooth brush is OK)
Required time (estimated)	10 min
Frequency of service	Monthly
System mode at service	Analyzer's power is off.
Workflow	1. Open the filter case and take out the filter. 2. Clean the filter with the brush. 3. Place the filter back in place. 4. Regulate the flow rate.

Warning

- Read the sections of "Safety Precautions" and "Precautions for Use" before starting the task.

CAUTION

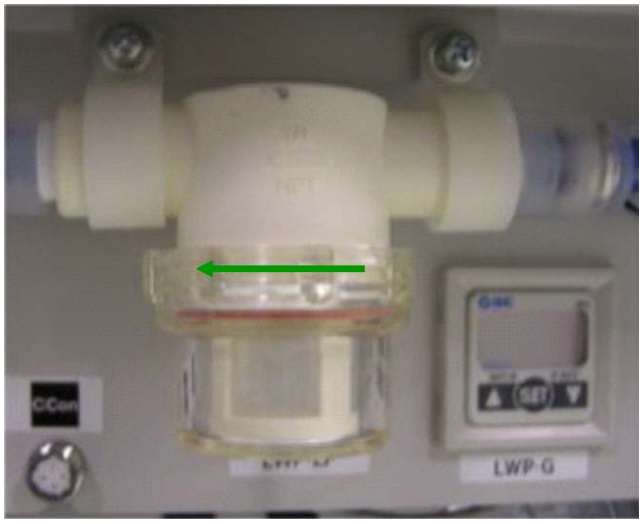
- Wear protective glasses, a mask, and gloves when you perform this service.

- Turn the Operate/Standby switch to the ⏻ "Off" position before starting to clean the LWP line filter.

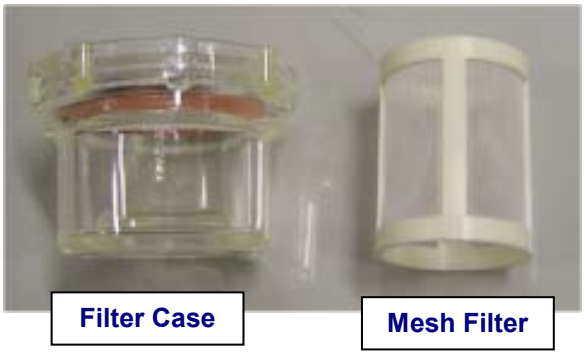
How to clean the LWP line filter

1) **Confirm the system mode is "WAIT" or "READY."**
2) **Exit the workstation system and display the "BioMajesty" startup window on the monitor.**
3) **Turn the Operate/Standby switch to ⏻ (OFF).**
4) **The filter case is fixed by turning clockwise. Therefore, turn it counterclockwise for detachment.**

   Water drops from the filter case when it is detached. Protect the floor underneath it with cloth.



5) **Take out the mesh filter from the case.**



6) **Immerse the filter in a container of water, and clean it using a brush. Rinse with pure water.**

   If the impurity level is high, soak the filter in a 1:20 dilution of Reagent probe wash-S for approximately 10 minutes, and rinse thoroughly

7) **After the cleaning is complete, place the filter in the case and attach the case back in place.**

8) Turn the Operate/Standby switch to "PC CONTROL."

If ⏻ (Off) or ⊙ (On) is selected, the analyzer does not turn on/off together with the workstation.

9) Select "Re-start" in the "BioMajesty" startup window to re-start the system.

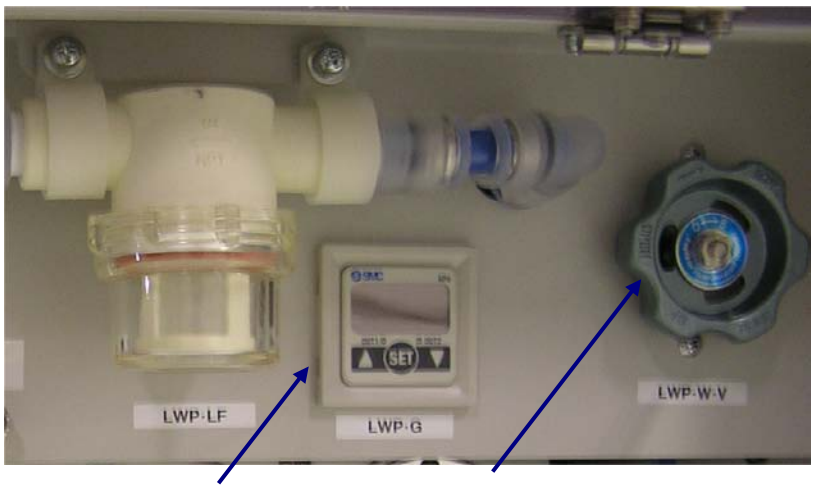
Wait for several seconds and confirm the Operation Panel shows the system mode "WAIT."

10) Perform "INITIALIZE" and confirm the system mode shifts to "READY."

11) Select [Maint.] > [Manual Operation], and click [71.LWP] in the window. Then press the [Enter] key on the keyboard to activate LWP. Check that no water leaks from the filter case.

If water leaks from the case, press [Enter] to stop LWP. Take the filter case out again, disassemble, reassemble it, and reattach. Press [Enter] again to activate LWP to check that no water leaks this time.

12) Turn the LWP regulator valve to regulate the LWP pressure gauge reads 70 - 72 kPa.



13) Press [Enter] to stop LWP.

14) Close the [Manual Operation] window.

15) Perform "INITIALIZE" and confirm the system mode shifts to "READY."

7.5.1e Clean the waste fluid lines of probe and mixing rod wash ports

Serum, reagents, and other liquids flow through the waste fluid lines of the probe and mixing rod wash ports. Over time, waste residue may clog the lines, blocking further waste liquid drainage. To prevent clogging, flush the waste fluid lines once monthly with Reagent probe wash-S.

Required tools	Reagent probe wash-S, pure water, syringe with tube 4x6
Required time (estimated)	10 min (WASH3 is not included)
Frequency of service	Monthly
System mode at service	Analyzer's power is off.
Workflow	1. Inject Reagent probe wash-S in the wash port. 2. Flush the port with pure water.

Warning

- Read the “Safety Precautions” and “Usage Notes” before starting this task.

CAUTION

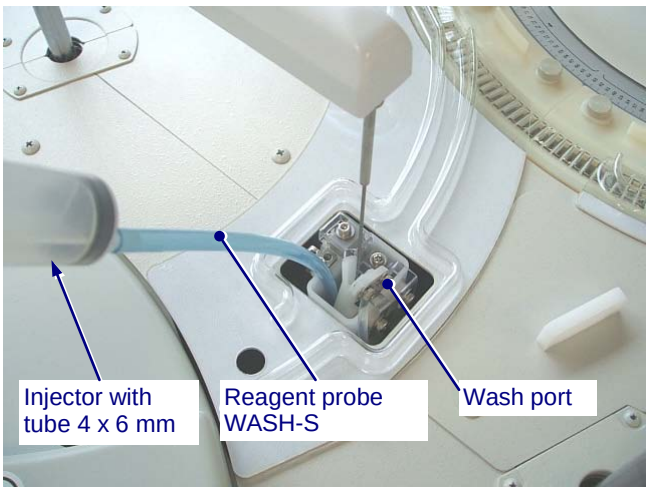
- Wear protective glasses, a mask, and gloves when you perform this service.
- Turn off the analyzer when washing the waste fluid lines of probe and mixing rod wash ports.

How to clean the waste fluid lines of probe and mixing rod wash ports

1) **Exit the workstation system and display the “BioMajesty” startup window on the monitor.**
2) **Turn the Operate/Standby switch to ⏻ (OFF).**

3) Set approximately 20 mL of Reagent probe wash-S in the injector with tube 4×6 mm, and inject it in the wash port.

Repeat this step for all the wash ports.



4) Wait for more than 5 minutes.

5) Set 20 mL of pure water in the injector, and inject it in the wash port. Check if it is drained smoothly.

Repeat this step for all the wash ports.

6) Turn the Operate/Standby switch to "PC CONTROL."

7) Select "Re-start" in the "BioMajesty" startup window to re-start the system.

8) Perform "INITIALIZE" and confirm the system mode shifts to "READY."

9) Click the [WASH] button, select "WASH3" in the [WASH set] window, and click [Execute].

Check that the liquid in the wash port is drained smoothly.

7.5.1f Clean the exterior panels of the analyzer

Clean the top cover, side cover, front panel and back panel of the analyzer once a month. Wring excess water from dampened gauze and wipe the surfaces of the covers and panels.

Required tools	Clean gauze (lint-free), pure water
Required time (estimated)	8 min
Frequency of service	Weekly
System mode at service	Analyzer's power is off.
Task	Clean the covers and panels of the analyzer.

Warning

- Read the "Safety Precautions" and "Usage Notes" before starting this task.

CAUTION	
	• Wear protective glasses, a mask, and gloves when you perform this service.
	• Turn the Operate/Standby switch to the ⏻ "Off" position before starting to clean the covers and panels. If you clean the covers and panels with the switch in the "PC CONTROL" or "On" positions, the gauze may be caught in the fan resulting in bodily injury. Wear insulating gloves while cleaning.
	• Only use water for cleaning. Cleaning with solvents such as alcohol may strip the paint.

How to clean the exterior panels of the analyzer

1) **Exit the workstation system and display the "BioMajesty" startup window on the monitor.**
2) **Turn the Operate/Standby switch to ⏻ (OFF).**
3) **Wring excess water from dampened gauze and wipe the surfaces of the covers and panels.**
4) **After the cleaning is complete, turn the Operate/Standby switch to "PC CONTROL."**

   If ⏻ (Off) or ⊙ (On) is selected, the analyzer does not turn on/off together with the workstation.
5) **Select "Re-start" in the "BioMajesty" startup window to re-start the system.**

   Wait for several seconds and confirm the Operation Panel shows the system mode "WAIT."
6) **Perform "INITIALIZE" and confirm the system mode shifts to "READY."**

7.5.1g Clean the vent fans and grids

Fans and grids for the heat vent are located on the rear of the analyzer. If they are coated with dust, the heat cannot be vented sufficiently. This may obstruct proper temperature control in the analyzer.

Two vent fans are located on the rear panel. Clean them every month.

Required tools	Vacuum cleaner
Required time (estimated)	10 min
Frequency of service	Monthly
System mode at service	Turn the main power off.
Task	Vacuum clean the vent fan and grids.

Warning

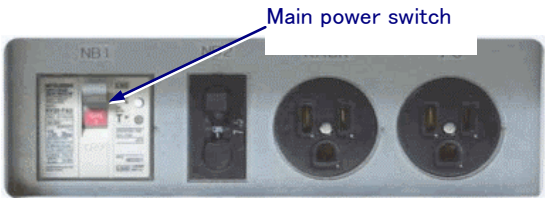
- Read the "Safety Precautions" and "Usage Notes" before starting this task.

CAUTION

- Wear protective glasses, a mask, and gloves when you perform this service.
- Be sure to turn off the main power switch located at the rear of the analyzer. If you clean the area with the power on, you may receive an electrical shock or be injured by the fan.

How to clean the fans

1) **Exit the workstation system and display the "BioMajesty" startup window on the monitor.**
2) **Turn the Operate/Standby switch to ⏻ (OFF).**
3) **Turn off the main power switch at the rear of the analyzer.**



4) Use a vacuum to clean the fan on the rear panel.

Cleaning the panel fan

5) Clean the vent grids on the right front and rear sides of the analyzer.

6) After the cleaning is complete, turn on the main power switch at the rear of the analyzer.

7) Turn the Operate/Standby switch to "PC CONTROL."

If ⏻ (Off) or ⊙ (On) is selected, the analyzer does not turn on/off together with the workstation.

8) Select "Re-start" in the "BioMajesty" startup window to re-start the system.

Wait for several seconds and confirm the Operation Panel shows the system mode "WAIT."

9) Perform "INITIALIZE" and confirm the system mode shifts to "READY."

7.5.2 Ion selective electrode (ISE) unit

7.5.2a Clean the ISE waste-drain nozzle

Impurities attached to the ISE waste-drain nozzle may block drainage, which affects measurement. Clean the ISE waste-drain nozzle when impurities are found.

Required tools	Clean gauze (lint-free) or Kimwipe
Required time (estimated)	5 min
Frequency of service	Monthly
System mode at service	READY
Workflow	1. Detach the ISE waste-drain nozzle. 2. Clean the ISE waste-drain nozzle. 3. Perform priming. 4. Attach the ISE waste-drain nozzle.

Warning

- Read the "Safety Precautions" and "Usage Notes" before starting this task.

CAUTION

- Wear protective glasses, a mask, and gloves when you perform this service.
- Be sure to change the status into [ISE-WASH-OFF] before performing the task. If you perform the task in the [ISE-WASH-ON] status, the scheduled wash is automatically activated, resulting in a serious accident or trouble.

1) Click the [ISE-WASH-ON] button on the Operation Panel to change the display to "ISE-WASH-OFF".

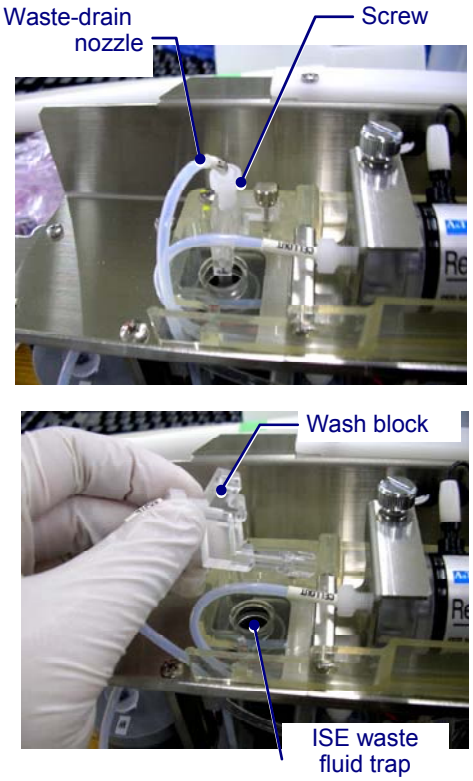
2) Remove the cover over the ISE sampling position.

Loosen the screw that locks the stainless steel cover over the ISE unit to slide it off.

3) Take the thumb screw off and take out the ISE waste-drain nozzle with the line kept attached. Clean the nozzle with gauze or a Kimwipe.

Be careful not to break the nozzle while cleaning.

4) If crystal is built up on the ISE waste fluid trap side, remove it with a cotton swab dampened with pure water.



Taking out the ISE waste-drain nozzle

5) Insert the waste-drain nozzle in the ISE waste fluid trap, paying attention not to break the line. Fit the wash block into the dented part of the ISE waste fluid trap and fix it with the screw.

The dented part serves to fix the nozzle in the center of the waste fluid trap.

6) Enter "5" for [Times] in the [Prime] area in the [ISE Operation] window, Click [Execute].

Check no solution remains in the waste fluid trap during priming to confirm no impurities has been accumulated or no screw has dropped in the waste fluid trap to block drainage.

7.5.2b Post-maintenance restoration of the ISE unit

After the monthly maintenance service, restore the unit to be ready for measurement. See Section 7.3.2e for procedure.

7.6 Maintenance to Perform Every Three Months

7.6.1 Chemistry analysis unit

7.6.1a Clean the cuvette wash solution bottle and the conditioner bottle

Impurities adhered to the inner walls of the cuvette wash solution bottle or the conditioner bottle may affect measurement values. Wash the bottles once every 3 months to ensure measurement accuracy. Follow the steps below for cleaning.

Required tools	Clean gauze (lint-free), Cuvette wash solution 7, Cuvette conditioner
Required time (estimated)	15 min
Frequency of service	Once in three months
System mode at service	READY
Workflow	1. Take the bottle out of the compartment. 2. Clean the bottle. 3. Place the bottle back in the compartment. 4. Perform priming

Warning

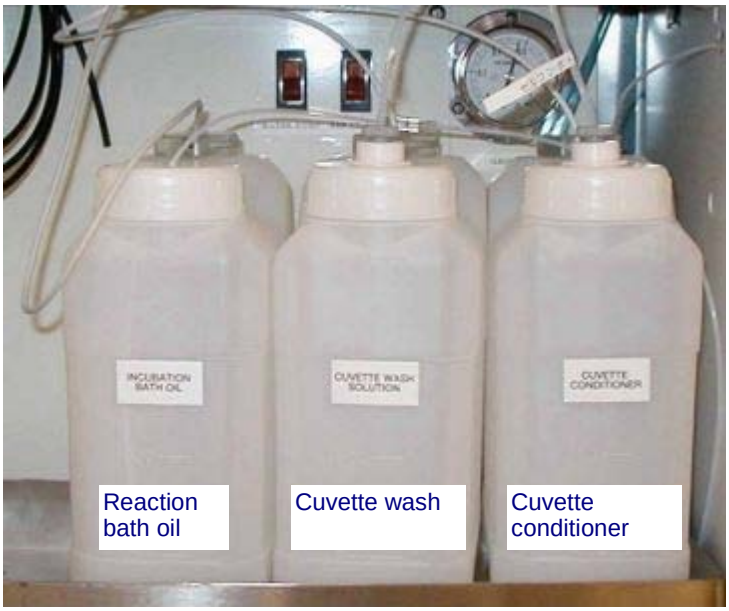
- Read the “Safety Precautions” and “Usage Notes” before starting this task.

CAUTION

- Wear protective glasses, a mask, and gloves when you perform this service.
- Do not use pure water to wash the reaction bath oil bottle. The reaction bath oil and water are immiscible.

How to clean the cuvette wash solution bottle and the conditioner bottle

1) Confirm the system mode is "READY."



2) Uncap the cuvette conditioner bottle and remove the line.

Using gauze, wipe away any conditioner remaining on the line and/or filter.

3) Turn the nut connecting the volume level sensor to the bottle counterclockwise, and pull the connector out.

Removing the connector

4) Remove the bottle.

5) Remove the volume level sensor from the bottle.

6) Discard the remaining cuvette conditioner from the bottle. Wash the inside of the bottle with pure water and then dry sufficiently.

Be careful not to spill water on the connector of the volume level sensor.

7) Pour new cuvette conditioner in the bottle, and attach the sensor to the bottle. Return the bottle with sensor in the compartment.

8) Insert the sensor connector, and turn the nut counterclockwise to fix.

Check the filter for impurities and clean it if it is not clean.

Check the filter holder reaches the bottom of the bottle.

See “Section 7.6.1b Clean the filter in the cuvette wash solution bottle and conditioner bottle” for the cleaning steps.

9) Clean the Cuvette wash solution bottle in the same way.

Be careful to set each bottle and connector in the right place.

10) After setting back the two bottles, perform [PRIME2] or [PRIME3] for 10 cycles for degassing the lines.

7.6.1b Clean the filters in the cuvette wash solution bottle and the conditioner bottle

Filters are present in the aspiration lines of each bottle in the detergent compartment (except for the reaction bath oil bottle).

If a filter becomes clogged, the required flow rate may not be met and/or air bubbles may be generated. Either of these issues can induce measurement errors. Clean them once every three month.

Required tools	Small brush (e.g. tooth brush)
Required time (estimated)	10 min
Frequency of service	Once in three months
System mode at service	READY
Workflow	1. Take out the line from the bottle and detach the filter. 2. Clean the filter with the brush. 3. Attach the filter. 4. Perform priming.

Warning

- Read the “Safety Precautions” and “Usage Notes” before starting this task.

CAUTION

- Wear protective glasses, a mask, and gloves when you perform this service.

How to clean the filters in the cuvette wash solution bottle and the conditioner bottle

1) **Confirm the system mode is "READY."**
2) **Turn the bottle cap counterclockwise to remove it, and take the line out of the bottle.**
3) **Turn and remove the tip of the filter holder to take out the filter.**

Taking out the filter

4) **Brush the filter with a small brush to remove impurities. Then wash it with pure water.**

5) **Insert and attach the cleaned filter on the tip of the holder.**

Be careful to place the filter in the right position. It is very thin and easily displaced.

After completion, place the line with the filter back in the bottle.

6) **Perform [PRIME2] or [PRIME3], setting "10" for [Cycle].**

During priming, check no bubble is generated in the line.

7.6.1c Clean the aspiration lines of the reaction carousel wash unit (WUD)

When WUD cleans the cuvettes, the blue-marked nozzles aspirate the reaction solution from the cuvette. Then the red-marked nozzles introduce wash solution into the cuvette. The yellow-marked nozzle continuously drains the wash solution to prevent overflow.

Crystallized serum or reagent may accumulate in the aspiration lines over time. This can lead to insufficient aspiration and potentially cause the cuvette to overflow. To avoid this, the aspiration lines must be cleaned regularly.

The aspiration line may become clogged if it aspirates dust or debris from the cuvette. If this occurs, prepare a nozzle cleaning wire and follow the steps described in "Section 7.8.1c Clean the clogging in the WUD nozzle" to remove clogs.

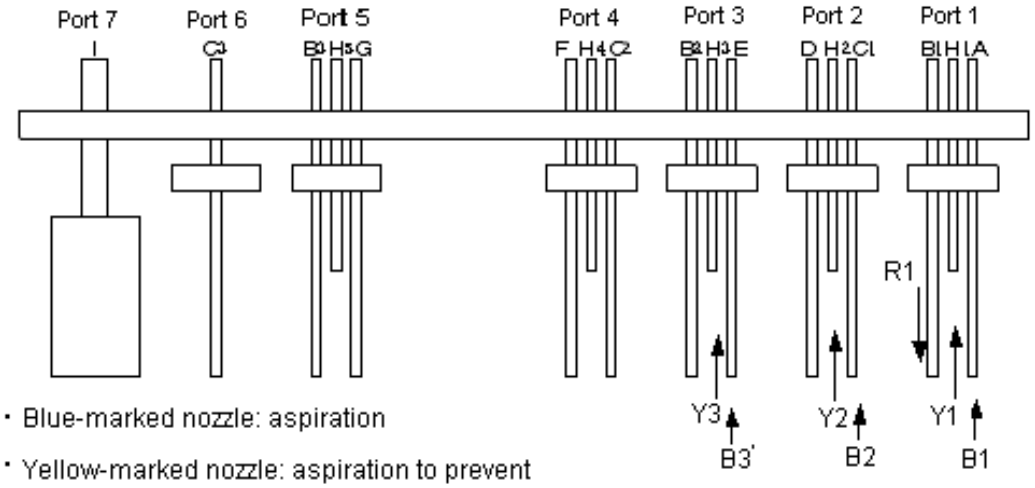
Required tools	4-mm Allen wrench, silicone line and container, or container to immerse the nozzle, hypochlorite solution diluted to 2.5-3%, or 1N NaOH solution, towel, plastic sheet.
Required time (estimated)	15 min (WASH3 is not included)
Frequency of service	Once in three months
System mode at service	READY
Workflow	1. Take out WUD. 2. Connect detergent to nozzle. 3. Start washing from the [User Maintenance] window. 4. Return WUD back. 5. Check the nozzle positions. 6. Perform "WASH."

Warning

- Read the "Safety Precautions" and "Usage Notes" before starting this task.

CAUTION

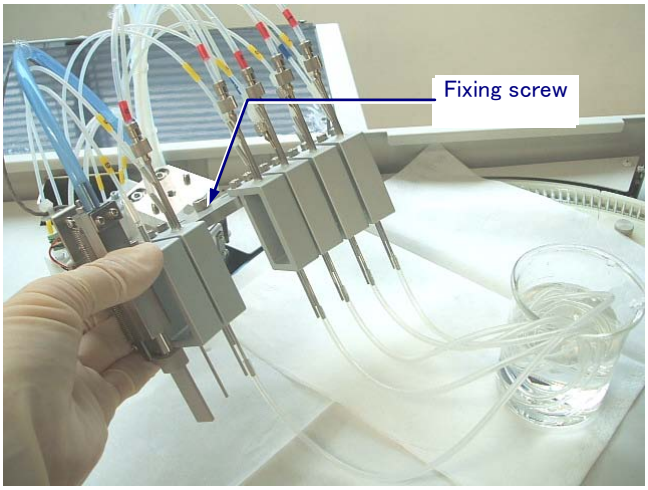
- Wear protective glasses, a mask, and gloves when you perform this service.



- Blue-marked nozzle: aspiration
- Yellow-marked nozzle: aspiration to prevent overflow
- Red-marked nozle: water or wash solution dispensing

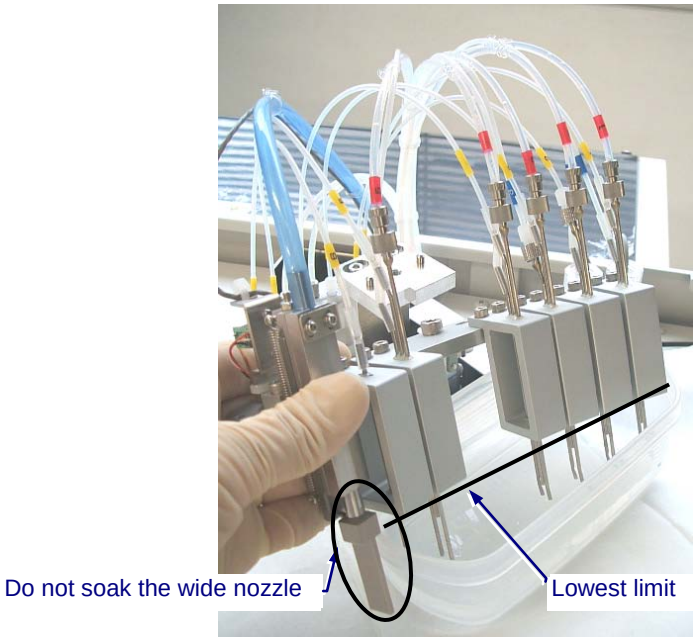
How to clean the aspiration lines of WUD

1) **Confirm the system mode is "READY." Cover the work space with towels and plastic sheets.**
2) **Loosen the fixing screws with a 4-mm wrench to remove WUD.**
3) **Check beneath the nozzles for impurities or clogs.**
4) **Attach the silicon lines onto the tips of the blue-marked and yellow-marked nozzles.**

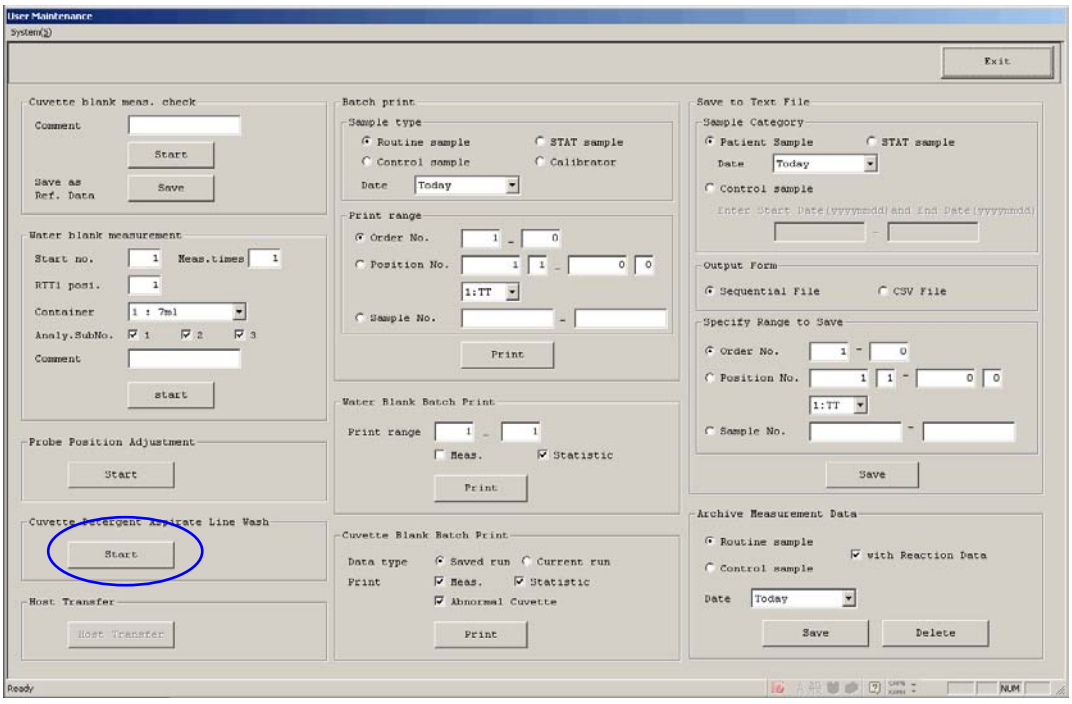


5) Place the ends of the tubes into a container containing 150 mL of either 50% hypochlorite solution or 1 N NaOH solution. (Do not use foamy detergent for cleaning, and never add more than 150 mL to the container.)

Most nozzles can be immersed directly into the solution, but do not immerse the apparatus beyond the nozzles. The wide nozzle cannot be immersed in the solution.

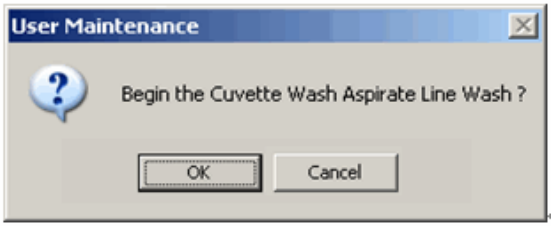


6) Select [Maint.] > [User Maintenance].



7) In the [User Maintenance] window, click [Start] in the [Cuvette Detergent Aspirate Line Wash] column, and Click [Yes] in the pop-up window.

The detergent is aspirated from the nozzles for one minute for cleaning.



8) When the aspiration is complete, the following message is displayed. Wait for 4-5 minutes. Then place the tubes in a container filled with 150 mL of pure water, and click [OK] in the window below.

The nozzles aspirate the pure water.

9) When the aspiration is complete, the window below is displayed. Click [OK] to close the window.

10) Detach the silicone tubes from the nozzle tips.

11) Wipe the nozzle tips with gauze, remove the towels and plastic sheets, and place WUD back.

12) Check no gap is between WUD and the fixing plate, and then fix the screw with the Allen wrench.

13) Perform “INITIALIZE.”

14) After "INITIALIZE" is complete, follow the steps below to check the position.

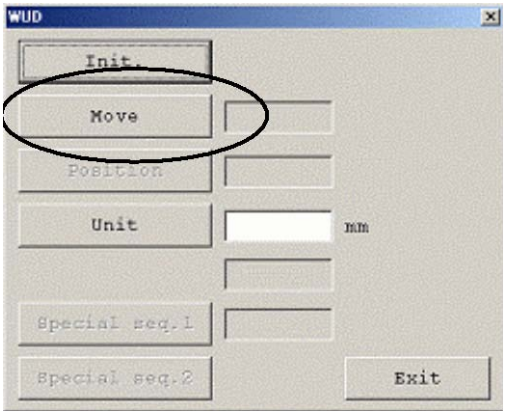
1 Select [Maint.] > [Manual Operation].

2 Double click [23.WUD] to display the [WUD] window. Click [Move].

WUD lowers a little. Check each nozzle is rightly lowered in the midpoint of the cuvette.

3 Click the [Init.] button to return WUD in the home position.

4 Click [Exit] to close the [WUD] window, and close the [Manual Operation] window.



15) Check no leakage is found at the joints of the lines.

16) Perform [WASH3] to check the solution does not overflow from the cuvettes.

7.7 Maintenance at 3-Month or Longer Intervals

7.7.1 Chemistry analysis unit

7.7.1a Replace the spectrophotometer lamp

A degraded lamp generates more noise and may induce measurement instabilities.

The following issues suggest that the lamp has degraded.

- Significant variations in measurement values.
- The lamp energy assessed using the [Check Energy] feature ([Lamp Energy Monitor]) returns variable results.
- The lamp has been used for more than 3 months.
- The lamp has been used for more than 2,000 hours. (This is comparable to 1 month of 24-hour continuous use.)

If lamp replacement is necessary, perform the following steps:

Required tools	Lamp for replacement
Required time (estimated)	70 min
Frequency of service	One of the incidents described above.
System mode at service	Analyzer's power is off.
Workflow	1. Remove the lamp cover. 2. Detach the lamp lead wires. 3. Take the lamp from the lamp house. 4. Place a new lamp. 5. Check the lamp energy and measure the cuvette blank.

Warning

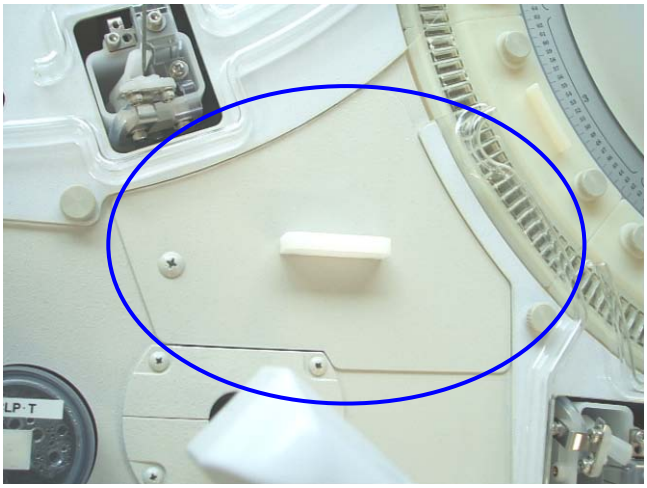
- Read the “Safety Precautions” and “Usage Notes” before starting this task.

CAUTION

- Be sure to turn off the analyzer when replacing the lamp. If you replace the lamp with the analyzer's power on, you may get a shock.

How to replace the spectrophotometer lamp

1) **Confirm the system mode is “WAIT” or “READY.”**
2) **Exit the workstation system and display the “BioMajesty” startup window on the monitor.**
3) **Turn the Operate/Standby switch to ○ (OFF).**
4) **Remove the lamp cover.**

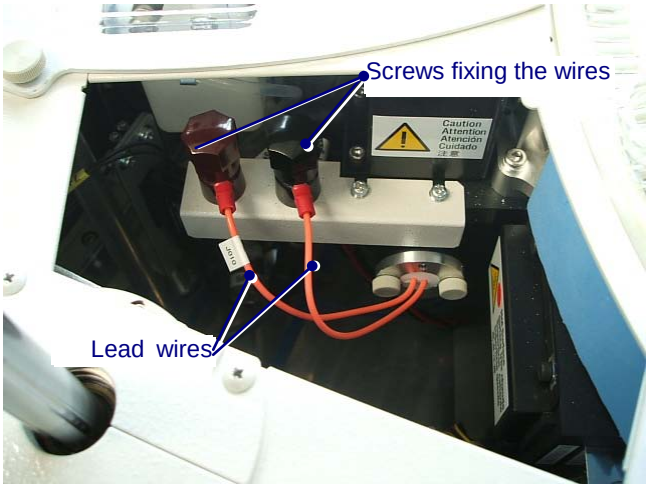


Lamp cover

Warning

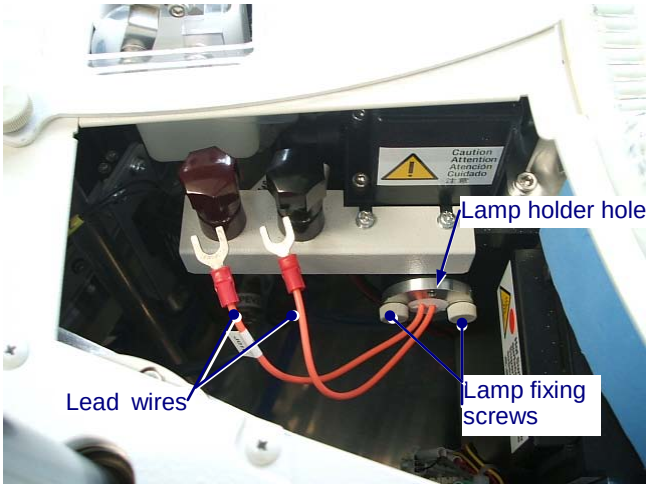
The lamp is extremely hot. Turn off the analyzer and allow the lamp to cool for at least 10 minutes before initiating the lamp replacement steps. Otherwise, serious burns may result.

5) **Manually loosen the screws fixing the lamp lead wires to detach them from the terminals.**



Loosening the screws fixing the lead wires

6) Manually loosen the screws fixing the lamp and take the lamp out of the house.



Inside of the lamp cover

7) Set a new lamp in the lamp holder and place a new lamp in the house. Turn the fixing screws manually to fix the lamp.

Align the locating pin to the lamp holder hole to set the lamp correctly in the lamp house.

CAUTION

Clean the lamp surface with ethanol-soaked gauze if required, and never touch it with your bare fingers.

8) Attach the lamp lead wires to the terminals.

9) When the replacement is complete, place the lamp cover back.

10) Turn the Operate/Standby switch to "PC CONTROL."

If ⏻ (Off) or ⊙ (On) is selected, the analyzer does not turn on/off together with the workstation.

11) Select "Re-start" in the "BioMajesty" startup window to re-start the system.

Wait for several seconds and confirm the Operation Panel shows the system mode "WAIT."

12) Perform "INITIALIZE" and confirm the system mode shifts to "READY."

13) Allow the system to idle for 30-40 minutes in the "READY" mode to ensure the stable function of the lamp.

14) Check the lamp energy in the [Lamp Energy Monitor] window, and measure the cuvette blank.

See Sections 7.4.1a and 7.4.1b in this chapter.

7.7.1b Replace the reaction cuvettes

Impurities can accumulate in the reaction cuvette and may affect measurement accuracy. The reaction cuvettes must be replaced every 4 months, as described below.

- Cuvettes used for HbA1c analysis should be replaced every 10,000 measurements.
- Certain combinations of reagents may require more frequent cuvette replacement

Required tools	New reaction cuvettes (11 cuvette holders containing 21 cuvettes in each holder, total of 231 cuvettes), Reagent probe wash-S
Required time (estimated)	30 min (WASH2 is not included)
Frequency of service	Every four months, or as required for the above conditions
System mode at service	Analyzer's power is off.
Workflow	1. Remove the reaction cuvettes. 2. Set new cuvettes. 3. Perform “WASH.” 4. Check the lamp energy and measure the cuvette blank.

Warning

- Read the “Safety Precautions” and “Usage Notes” before starting this task.

CAUTION

- Wear protective glasses, a mask, and gloves when you perform this service.

- Before replacing the reaction cuvettes, turn off the analyzer and workstation to prevent injury.
- Do not attach or detach the cuvette holder in the region through which the lamp light passes. Doing so could damage the spectrophotometer because the space between the detector and the cuvette is extremely narrow. Slowly rotate the reaction carousel by hand to move the cuvette holder away from this site, and then proceed with attachment/detachment.
- When attaching/detaching the cuvette holder, be careful not to drop the fixing screws into the reaction bath or any other compartment within the analyzer.

- When attaching new cuvettes, never touch the surface through which the lamp light passes.
- Handle the cuvettes very carefully. Never wipe the inner or outer surface of the cuvette with materials such as gauze, because these may scratch the surface of the cuvette.

How to replace the reaction cuvettes

The 11 cuvette holders (containing 21 cuvettes in each holder, total of 231 cuvettes) should be replaced all at once.

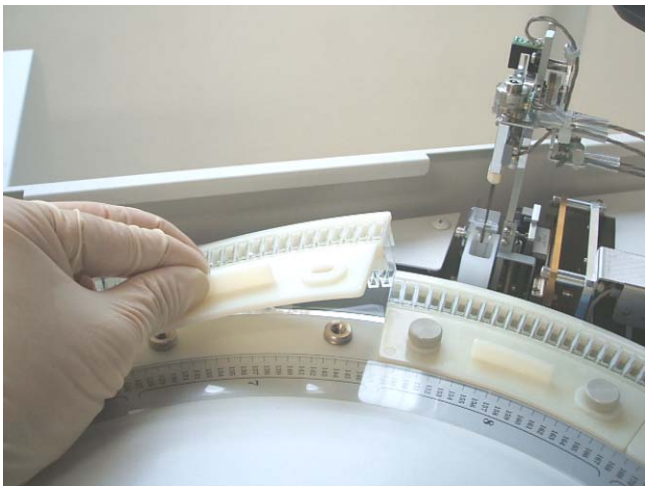
Follow the steps below for replacement.

1) **Exit the workstation system and display the "BioMajesty" startup window on the monitor.**
2) **Turn the Operate/Standby switch to ⏻ (OFF).**
3) **Manually loosen the fixing screws for the cuvette holder, and remove the holder. Continue removing all 11 cuvette holders on the reaction carousel.**

   Rotate the reaction carousel by hand when detaching and attaching each holder to avoid damaging the spectrophotometer site.

CAUTION

Do not remove the cuvette holder near the spectrophotometer site.



Detaching the cuvette holder

4) Attach new cuvette holders on the reaction carousel.

Firmly tighten the fixing screws of the cuvette holders.

CAUTION

Be careful not to damage the cuvettes when taking out a new cuvette holder from the packaging. Also, be careful not to hit the light passing side of the cuvette against the wall of the reaction bath unit.

5) Turn on the analyzer.

6) Turn the Operate/Standby switch to "PC CONTROL."

If ○ (Off) or ⊙ (On) is selected, the analyzer does not turn on/off together with the workstation.

7) Select "Re-start" in the "BioMajesty" startup window to re-start the system.

Wait for several seconds and confirm the Operation Panel shows the system mode "WAIT."

8) Perform "INITIALIZE" and confirm the system mode shifts to "READY."

9) Perform "WASH2" with Reagent probe wash-S diluted to 5%.

Replace the Reagent probe wash-K bottles placed on the #44 positions of the reagent trays 1 and 2 with the bottles with Reagent probe wash-S diluted to 5%.

Check the nozzles of the reaction carousel wash unit (WUD) will not hit the cuvettes during washing.

10) When the washing is completed, check the lamp energy and measure the cuvette blank (See Section 7.4.1b) and register the cuvette blank values.

7.7.2 Workstation

7.7.2a Disk defragmentation of the Windows XP-based workstation

The files stored in the hard disk drive of the workstation will fragment over time, which will negatively affect processing speed. Ultimately, this can lead to error messages such as “acquisition error.” As a countermeasure, regularly execute the “disc defragmenter” to optimize file storage.

Required tools	N/A
Required time (estimated)	Depend on the computer performance
Frequency of service	Semiannually
System mode at service	Analyzer’s power is off.
Task	Perform “disk defragmenter.”

How to defragment the disk

1) Exit the workstation system and click the [Cancel] button in the “BioMajesty” startup window.

The “BioMajesty” startup window is closed.

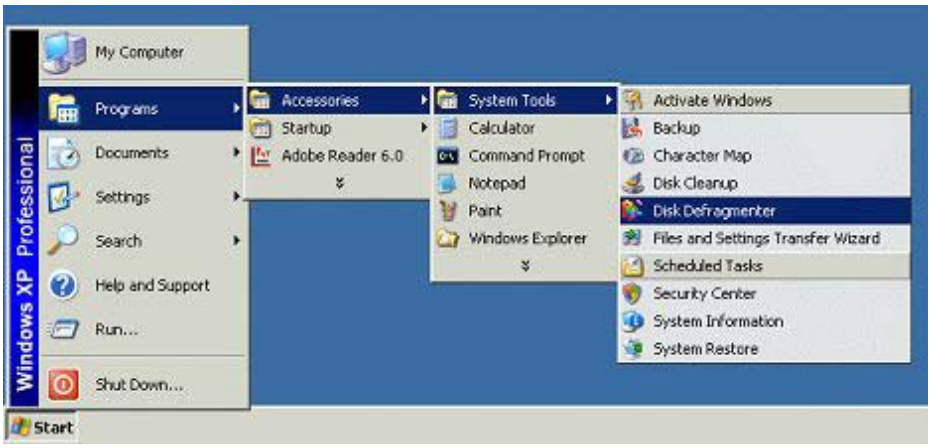
2) Click the [Start] button in the bottom left corner of the Windows display.

Windows menu is displayed.

3) Select [Program] > [Accessories] > [System Tools] > [Disk Defragmenter].

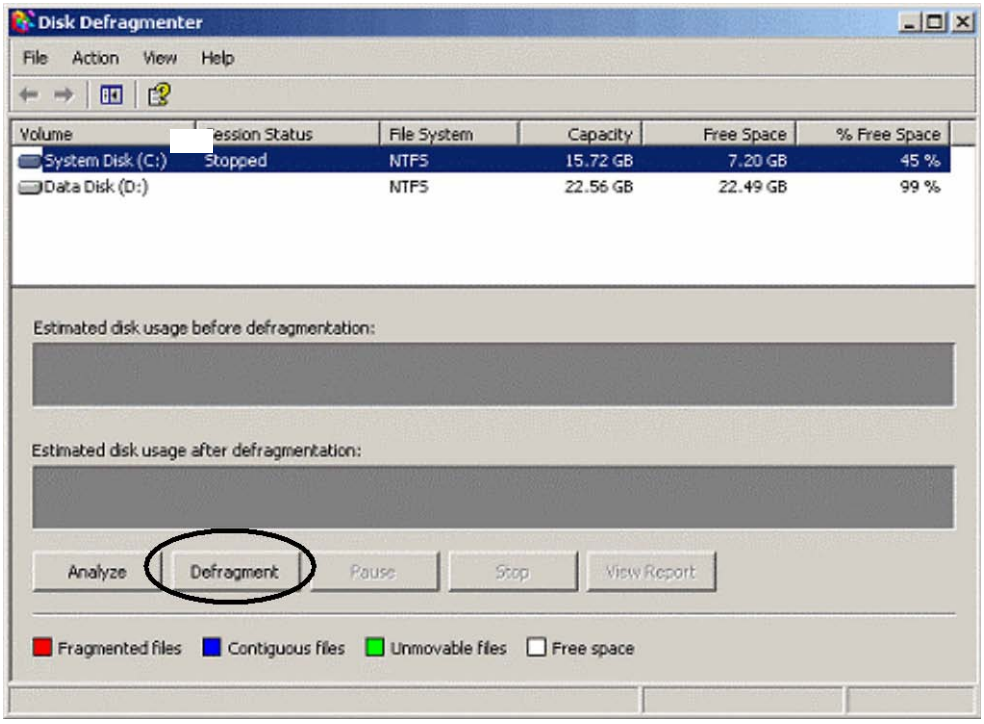
The [Disk Defragmenter] window is displayed.

Double click the [Disk Defragmenter] icon on your desktop if available.



4) Click and highlight "(C:)" under the header "Volume," and click the [Defragment] button.

Disk defragmentation begins.



5) When the [Disk defragmentation completed] window is displayed, close all the windows.

6) Click the [Start] button in the bottom left corner of the window.

Windows menu is displayed.

7) Click "Shutdown" to exit Windows and turn the power off.

The analyzer is turned off simultaneously by the "PC CONTROL" function.

8) 10 seconds later, turn the computer on.

9) In the [BioMajesty] window, select "Re-Start" on the same date to startup the system.

Wait for several seconds and confirm the Operation Panel shows the system mode "WAIT."

10) Perform "INITIALIZE" and confirm the system mode turns to "READY."

7.8 Maintenance Performed as Required

7.8.1 Chemistry analysis unit

7.8.1a Replace probes

Replace the probe if it becomes clogged with foreign matter or if it is deformed or broken.

Using a defective probe can cause wash solution to disperse during washing. A damaged probe also may damage a separate unit by accidental contact.

Required tools	Probe (for sample or reagent accordingly) , Phillips screwdriver, flat-bladed screwdriver, needle nose pliers, gauze
Required time (estimated)	10 min
Frequency of service	As required
System mode at service	Analyzer's power is off.
Task	1. Remove the probe. 2. Attach a new probe. 3. Check the position of the probe tip. 4. Perform “WASH.”

Warning

- Read the “Safety Precautions” and “Usage Notes” before starting this task.

CAUTION

- Wear protective glasses, a mask, and gloves when you perform this service.

Two kinds of probe are used in the analyzer.

- Sample probe (SPP)
- Reagent probe (RPP)

SPP has an integrated liquid level sensor and a “crash sensor,” which protects the probe from bumping into foreign matter while it is being lowered.
RPP also has an integrated liquid-level sensor.

Follow the steps below for replacement. Be sure to check the position after replacement.

How to replace SPP

1) **Confirm the system mode is “READY.”**
2) **Exit the workstation system and display the “BioMajesty” startup window on the monitor.**
3) **Turn the Operate/Standby switch to ⏻ (OFF).**

CAUTION

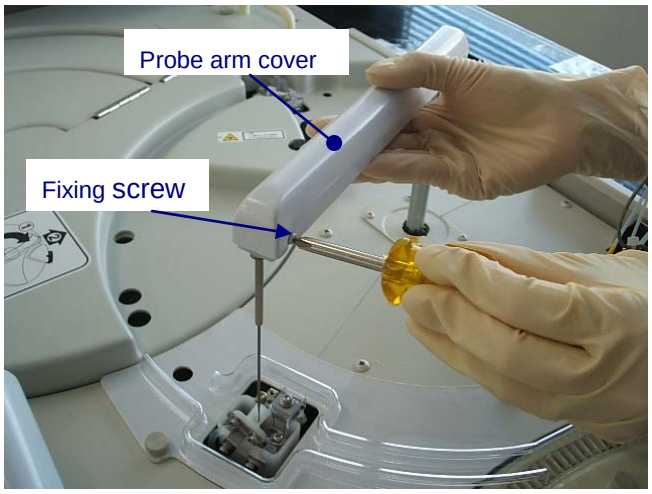
When the power is off, the SPP arm can be moved freely. However, if you push the arm downward, it may lower and be damaged upon contact with another object. Carefully steady the arm from below when replacing the probe.

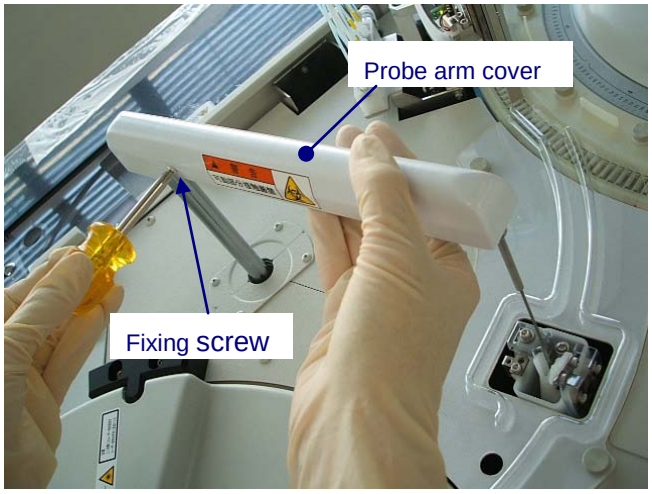
4) **Loosen the two fixing screws of the probe arm cover and lift the cover.**

Perform this service at the wash port position.

Do not remove the screws completely.

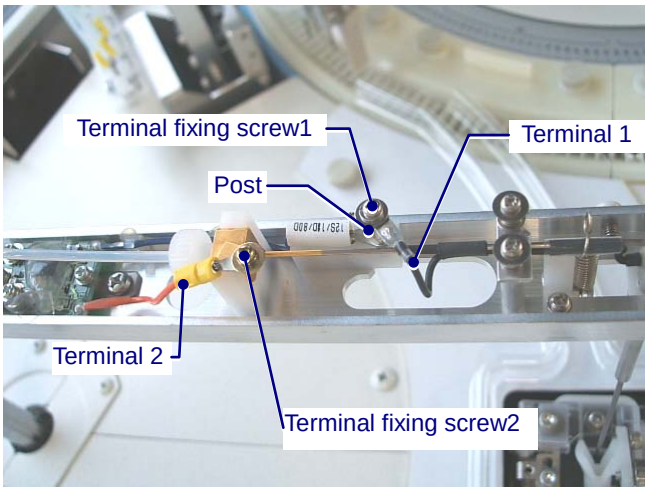
After lifting the cover, return the two screws to the probe arm. Once the probe is replaced, perform “WASH3” without the cover on.

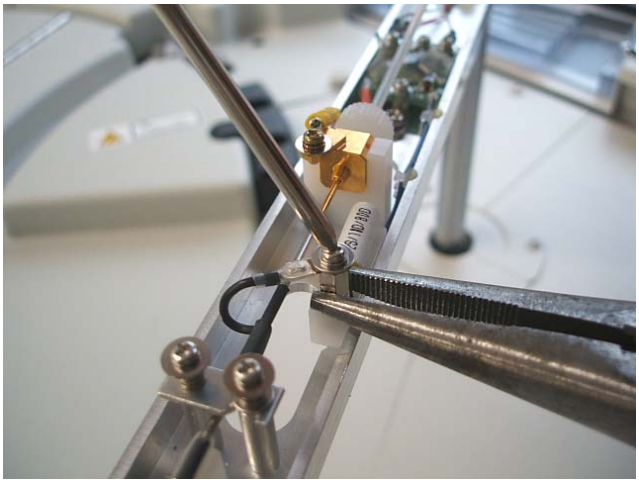




5) Loosen the Terminal 2 fixing screw with a Phillips screwdriver, and detach Terminal 2. Using pliers, hold the post steady, and loosen the Terminal 1 fixing screw to detach Terminal 1.

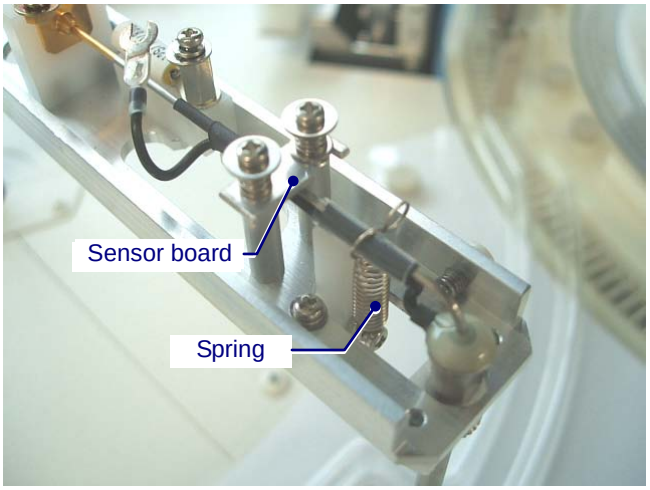
Loosen the screws, but do not remove them completely.



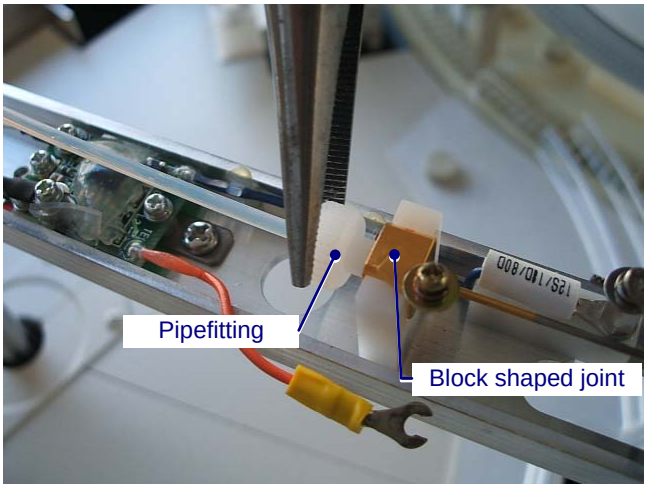


How to detach the terminal

The positions of the sensor board and the spring are shown in the figure below.

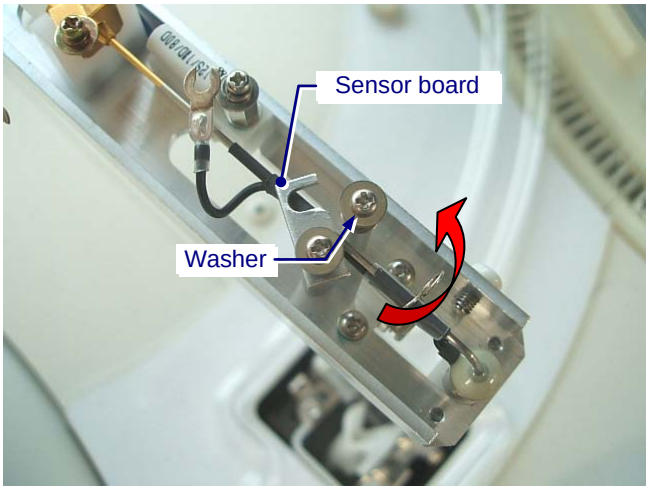


6) Holding the block-shaped joint steady with your fingers, loosen the pipe fitting by turning it counterclockwise with pliers. Using your fingers, pull the screw out completely.



7) Pinch the tip of the spring with pliers, and lift to detach it from the probe.

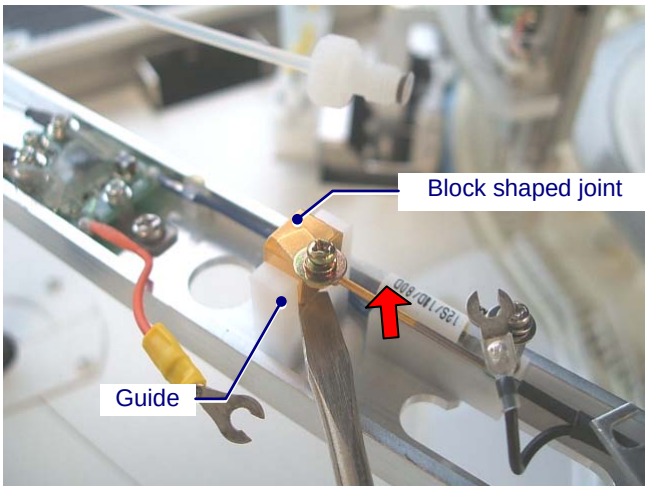
8) Rotate the sensor board with the U-cutting while lifting the washer.



9) Using a flat-bladed driver, lift and remove the block-shaped joint.

The block-shaped joint is located between the guide arms.

The joint is wider than the guide. Therefore, lift the protruding part from underneath using a flat-bladed driver.



10) Lift the probe slowly, and use your fingers to remove it.

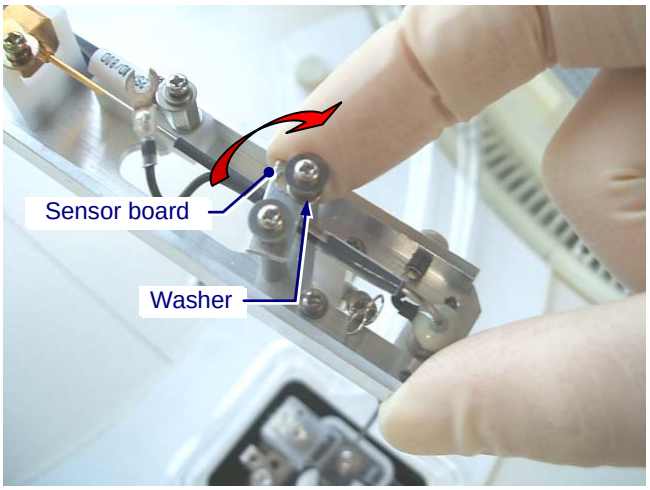
The probe cannot be removed if its tip is warped. Straighten it using pliers or cut the warped part.

11) Insert a new probe into the holder. Press the block-shaped joint straight down by hand to position it into the guide.

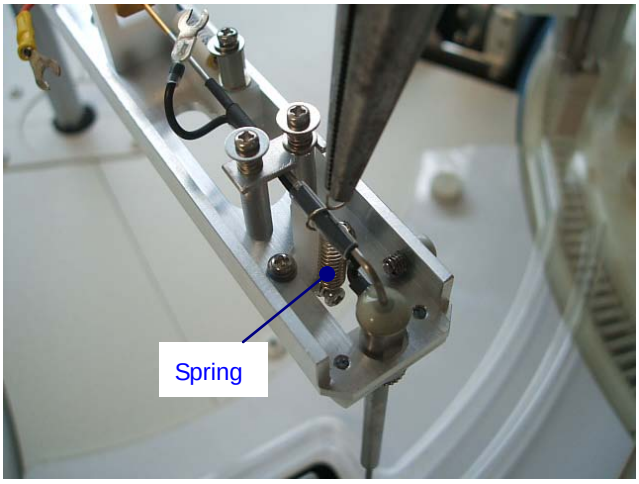
CAUTION

Carefully steady the arm from below when replacing the probe.

12) Lift the lower washer and rotate the sensor board so that the U-cutting fits around the washer.

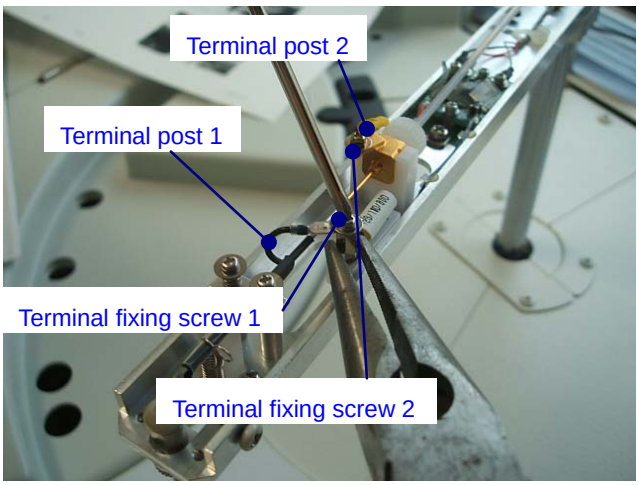


13) Pinch the tip of the spring with pliers and lift to attach it on the probe.



14) Insert Terminals 1 and 2 respectively into fixing screws 1 and 2. Tighten the screws using a Phillips screwdriver,

Tighten Terminal 1 while holding the post steady with the pliers to prevent it from rotating.



15) While holding the block-shaped joint steady, manually turn the pipe fitting clockwise, and tighten it securely.

Be careful not to deform the threads of the male screw. The first 2 or 3 rounds should be easy to turn.

16) Tighten approximately 30 degrees further using pliers.

17) Lift the probe arm with your fingers and turn it carefully. Verify that the probe tip passes safely through the midpoint of the wash port.

18) Turn the Operate/Standby switch to "PC CONTROL."

If ⏻ (Off) or ⊙ (On) is selected, the analyzer does not turn on/off together with the workstation.

19) Select "Re-start" in the "BioMajesty" startup window to re-start the system.

Wait for several seconds and confirm the Operation Panel shows the system mode "WAIT."

20) Perform "INITIALIZE" and check the probe moves normally and no leakage is observed at the block shaped joint.

During initialization, check that the probe moves normally and that no leakage is observed at the block-shaped joint.

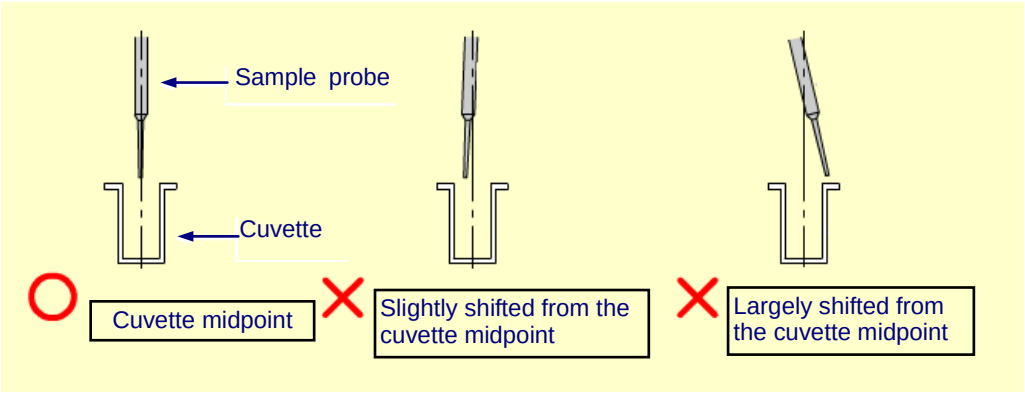
21) Check the position of the probe tip above the cuvette.

1 Click [Maint.] > [User Maintenance] to display the [User Maintenance] window.

2 Click the [Start] button in the [Position Probes for Routine Cleaning] column.

After some time, the probe moves over to the cuvette.

Check the probe tip is in the midpoint of the cuvette.



If it is a little shifted from the midpoint, bent the probe slightly for adjustment.

If it is greatly shifted from the midpoint, repeat the steps of detaching and re-attaching the probe.

22) Perform "INITIALIZE" and confirm the system mode shifts to "READY."

23) Perform "WASH3" and confirm the probe moves properly.

Check no leakage is observed at the joint.

If a "liquid level sensor error" occurs, repeat the steps of detaching and re-attaching the probe.

24) When the operation is complete and the system enters in the "READY" mode, attach the probe cover.

Replacing the reagent probes 1 and 2 (RPP1/RPP2)

1) Confirm the system mode is "WAIT" or "READY."

2) Exit the workstation system and display the "BioMajesty" startup window on the monitor.

3) Turn the Operate/Standby switch to ○(OFF).

CAUTION

When the power is off, the RPP arm can be moved freely. Carefully steady the arm from below when replacing the probe.

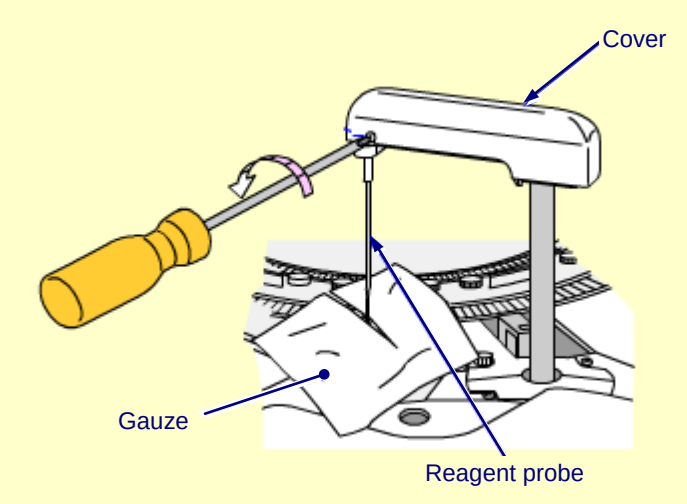
4) Using gauze or a Kimwipe, block the openings underneath to prevent screws from dropping into the cuvette or the wash port.

5) Loosen the two fixing screws of the probe arm cover and lift the cover.

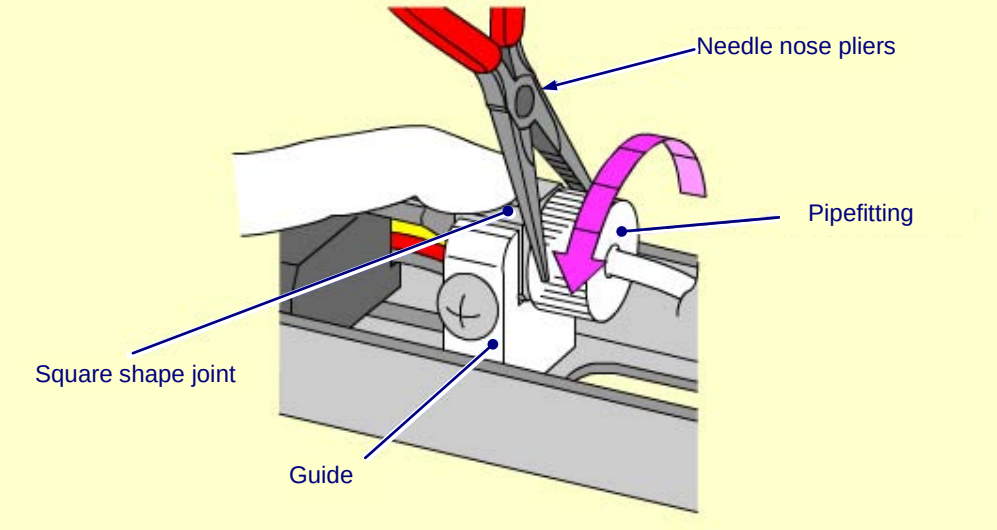
Perform this service at the wash port position.

Do not remove the screws completely.

After lifting the cover, return the two screws to the probe arm. Once the probe is replaced, perform “WASH3” without the cover on.

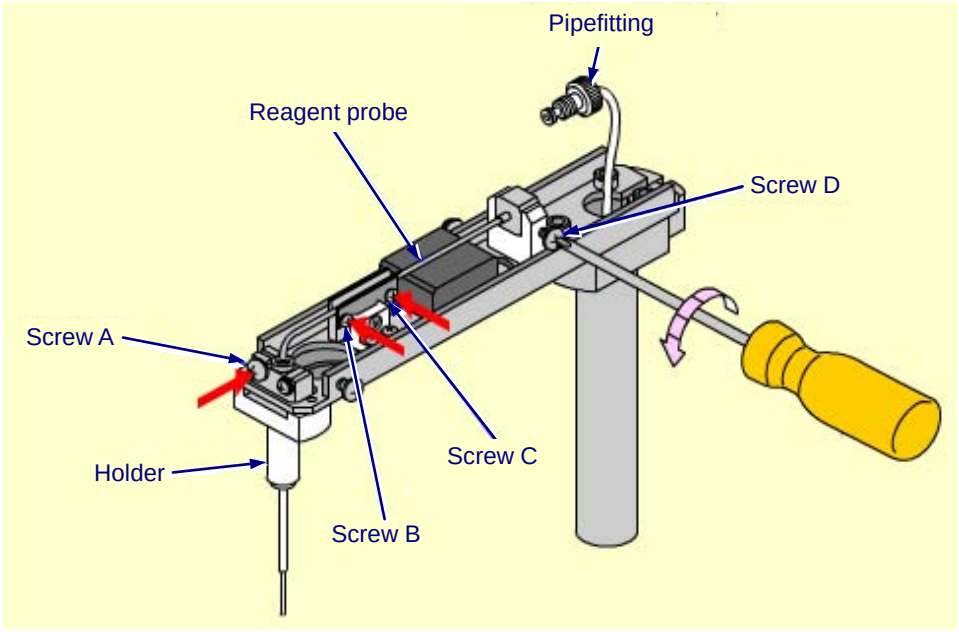


6) Holding the block-shaped joint steady with your fingers, loosen the pipe fitting by turning it counterclockwise with pliers. Using your fingers, pull the screw out completely

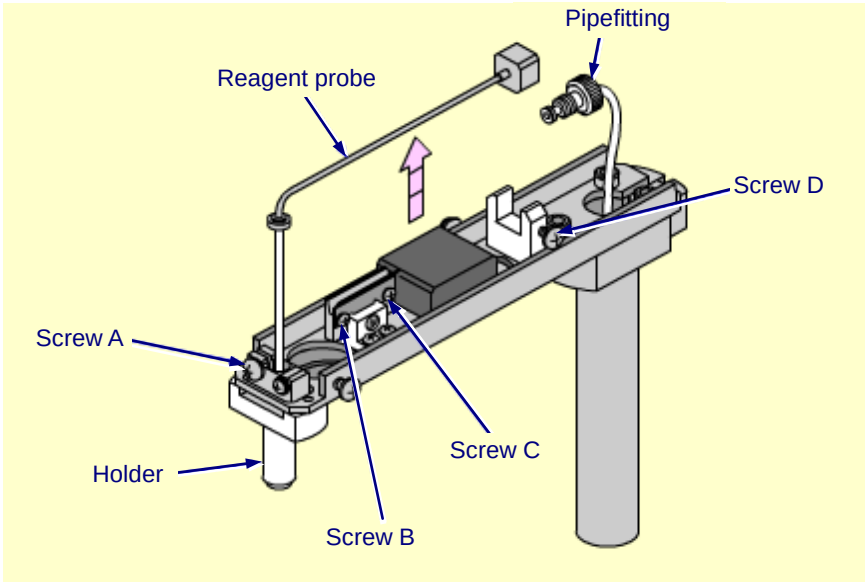


7) Loosen the probe fixing screws A, B, C, and D with a Phillips screwdriver.

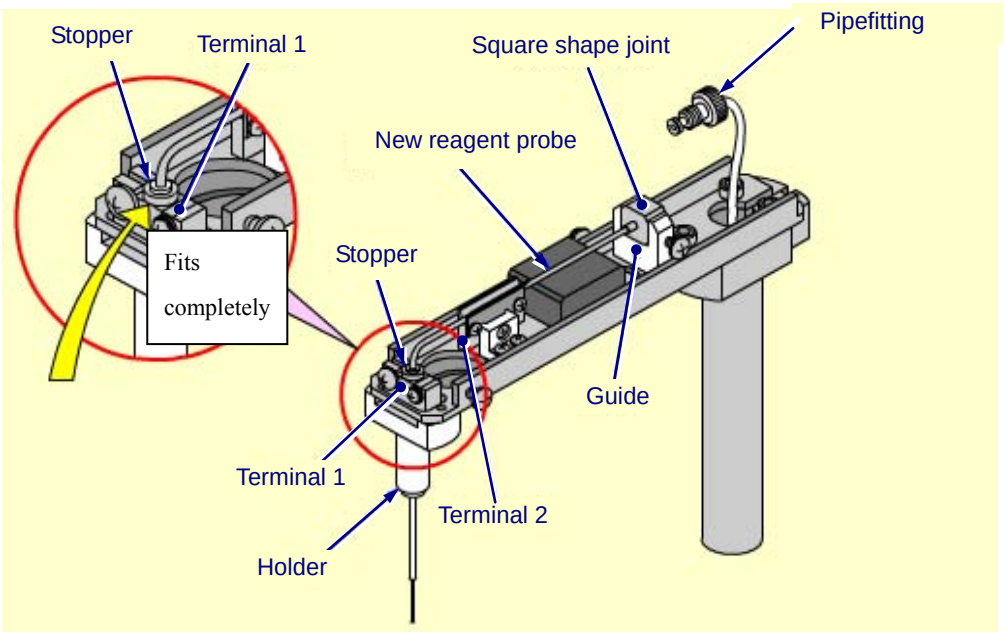
Do not remove the screws completely.



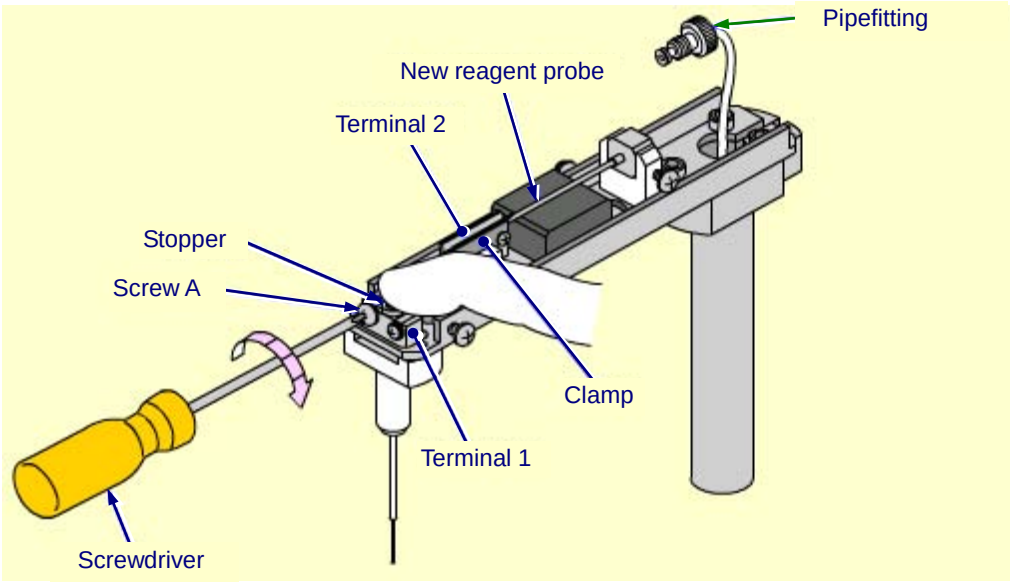
8) Using your fingers, lift the probe slowly to remove it.



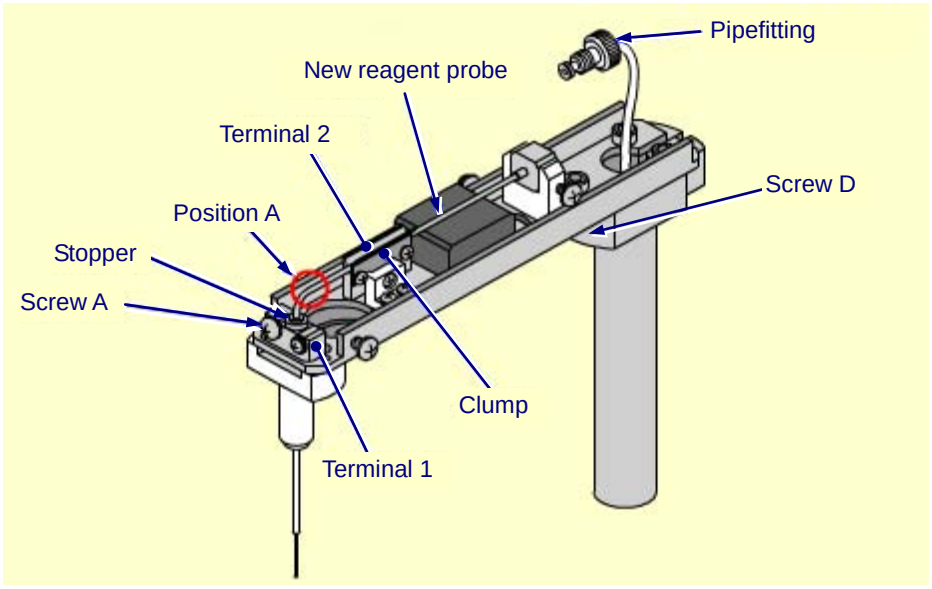
9) Insert a new probe into the holder until the stopper contacts Terminal 1.



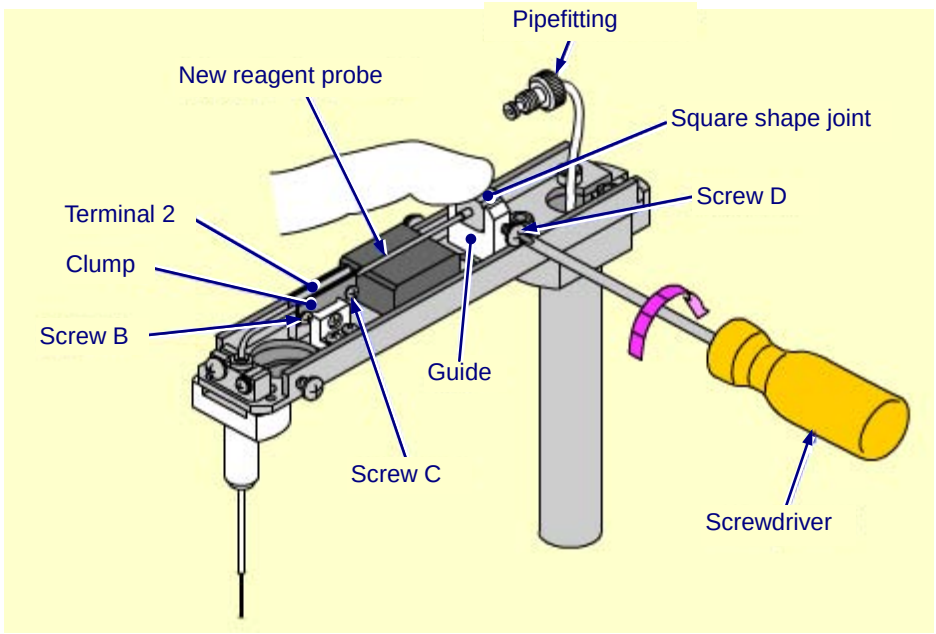
10) When the new probe is set successfully in Terminal 2, tighten Screw A while pressing the probe into Terminal 1 with your fingers.



11) Lift at Position A to verify that the probe is fixed securely.



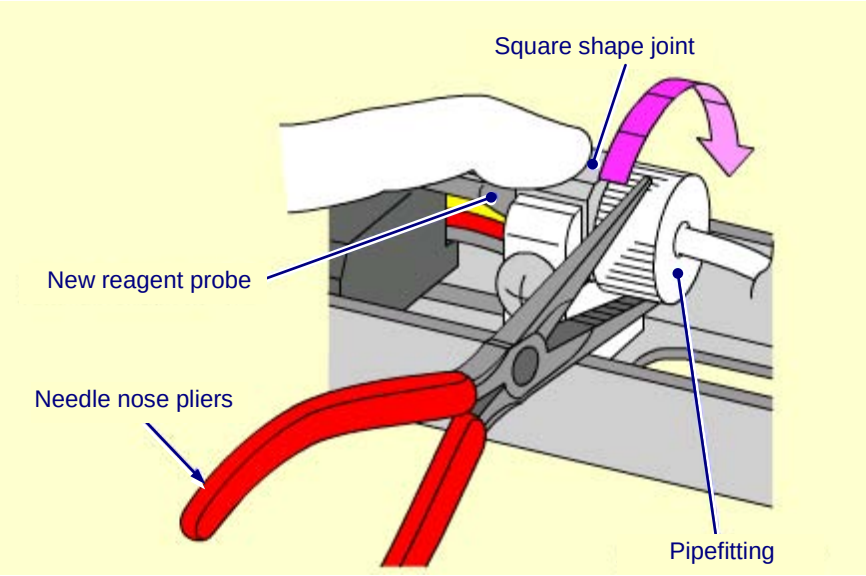
12) While pressing the block-shaped joint, securely tighten Screws B and C, and then lightly tighten Screw D.



13) While holding the block-shaped joint steady, manually turn the pipe fitting clockwise, and tighten it securely.

Be careful not to deform the threads of the male screw. The first 2 or 3 rounds should be easy to turn.

14) Tighten approximately 30 degrees further using the pliers.



15) Remove the gauze or Kimwipe spread over the openings.

16) Lift the probe arm with your fingers and move it carefully. Verify that the probe tip passes safely through the center of the wash port.

17) Turn the Operate/Standby switch to "PC CONTROL."

If ○ (Off) or ⊙ (On) is selected, the analyzer does not turn on/off together with the workstation.

18) Select "Re-start" in the "BioMajesty" startup window to re-start the system.

Wait for several seconds and confirm the Operation Panel shows the system mode "WAIT".

19) Perform "INITIALIZE" and confirm the system mode shifts to "READY."

Check the probe moves normally and no leakage is observed at the joint.

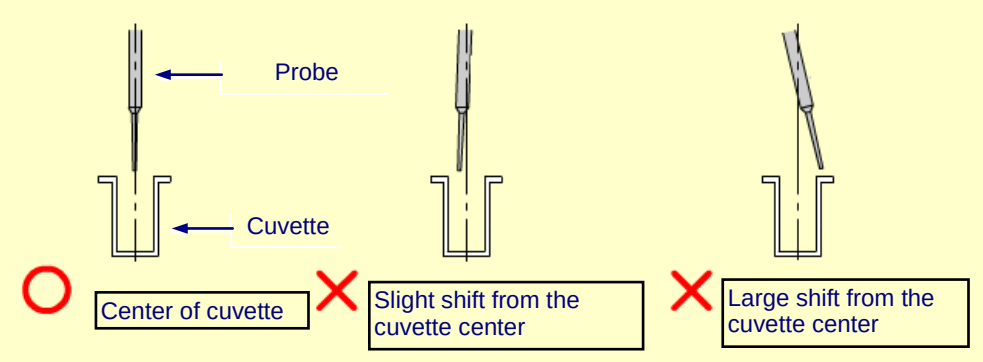
20) Check the position of the probe tip above the cuvette.

1 Click [Maint.] > [User Maintenance] to display the [User Maintenance] window.

2 Click the [Start] button in the [Position Probes for Routine Cleaning] column.

After some time, the probe moves over to the cuvette.

- **Check the probe tip is in the midpoint of the cuvette.**



If it is a little shifted from the midpoint, bent the probe slightly for adjustment.

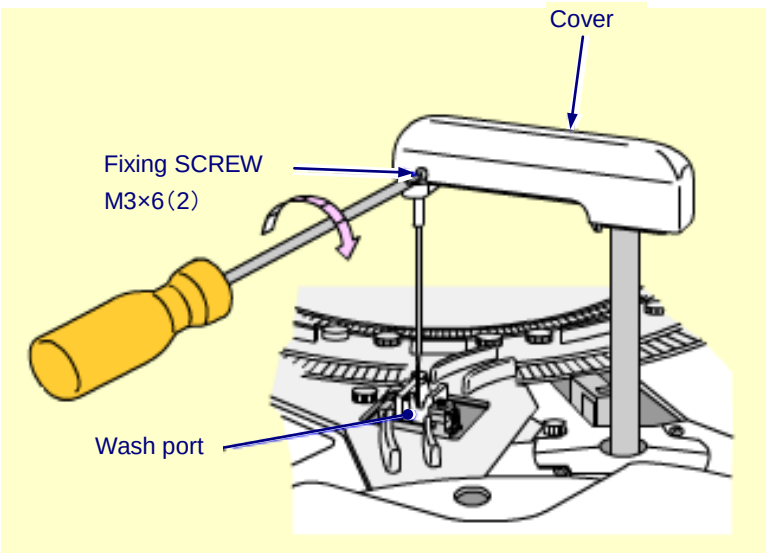
If it is widely shifted from the midpoint, start the assembly from the beginning again.

- **Perform "INITIALIZE" and confirm the system mode shifts to "READY."**
- **Perform "WASH3" and confirm the probe moves properly.**

Check no leakage is observed at the joint.

If a "liquid level sensor error" occurs, repeat the steps of detaching and re-attaching the probe.

- **When the operation is completed and the system enters in the "READY" mode, attach the probe cover.**



7.8.1b Replace the seal of the pumps

If the pump seals deteriorate, measurement values may become inconsistent. Follow the steps described in "Section 7.3.1g Check for potential leakage from pumps" to assess any leak. If leakage is observed, replace the seal.

Required tools	Clean gauze (lint-free), towel, pen, pliers, Phillips screwdriver, towel, Allen wrench, L-ring removal jig, L-ring fitting jig Sampling pump (SP): 1-mm seal - 1 pc Reagent pump (RP): 5-mm seal - 1 pc Sampling and reagent wash pump (SRWP); 14-mm seal - 2 pcs
Required time (estimated)	15 min
Frequency of service	As required
System mode at service	Analyzer's power is off.
Task	1. Take out the pump. 2. Disassemble the pump. 3. Replace the seal. 4. Assemble the pump. 5. Place the pump back. 6. Perform "WASH."

Warning

- Read the "Safety Precautions" and "Usage Notes" before starting this task.

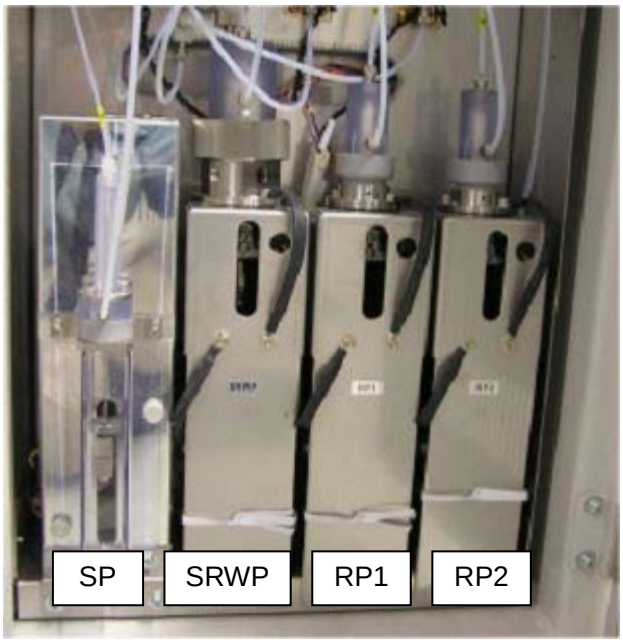
CAUTION

- Wear protective glasses, a mask, and gloves when you perform this service.
- Turn off the analyzer and workstation before removing or replacing the pump. Otherwise, the analyzer may operate, causing electrical shock or bodily injury.

How to take the pump out

1) **Confirm the system mode is "WAIT" or "READY."**
2) **Exit the workstation system and display the "BioMajesty" startup window on the monitor.**
3) **Turn the Operate/Standby switch to ⏻ (OFF).**

4) Open the front panel door.



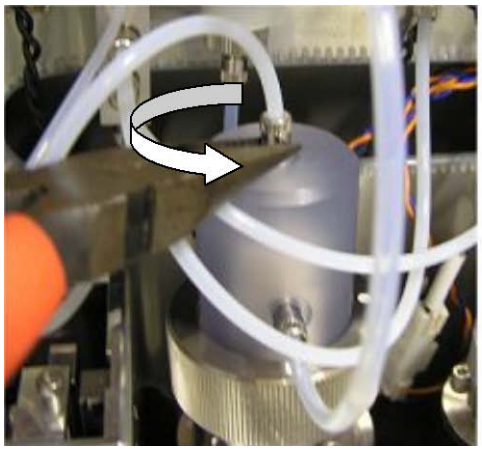
Pump location

The following steps describe removal of the sampling and reagent wash pump (SRWP). These steps also apply to removal of other pumps.

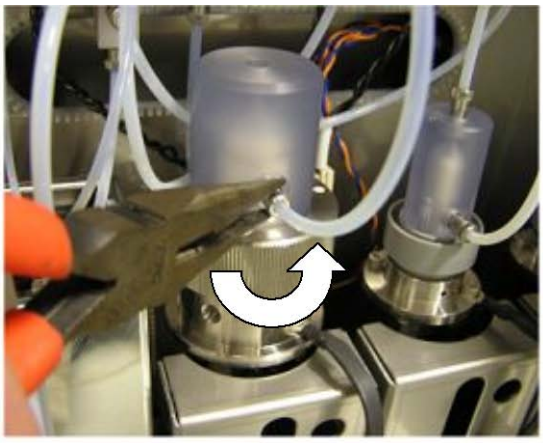
5) Using pliers, loosen the joint on the top of the cylinder, and remove it by hand.

When the joint is loose, the liquid inside will leak. Wipe it with gauze or a Kimwipe.

Each joint has its own location. Before removing it, mark the joint position to facilitate replacement.



Removing the joint on the top of the cylinder



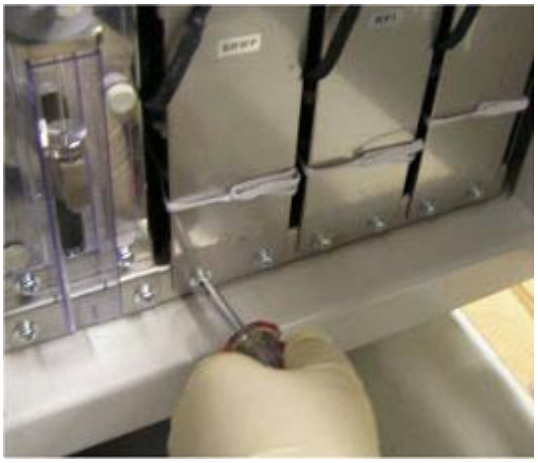
Removing the joint on the front side of the cylinder

6) Using pliers, loosen the joint on the front side of the cylinder, and remove it by hand. .

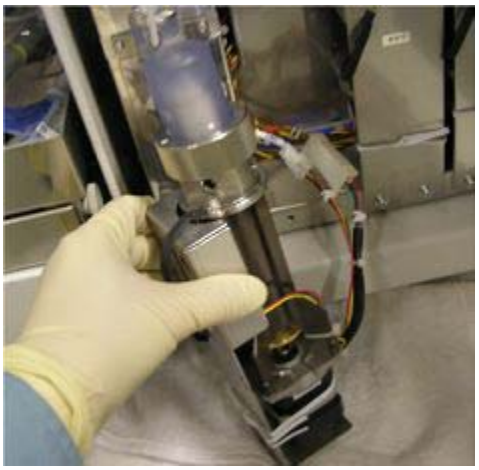
When the joint is loose, the liquid inside will leak. Wipe it with gauze or a Kimwipe.

Each joint has its own location. Before removing it, mark the joint position to facilitate replacement.

7) Using a Phillips screwdriver, remove the two screws that hold the pump in place. Pull the pump to remove.



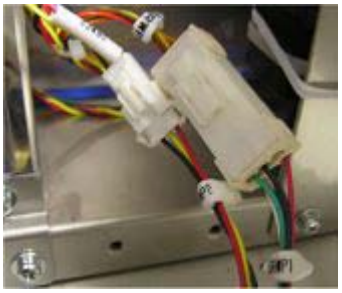
Removing the fixing screws of the pump

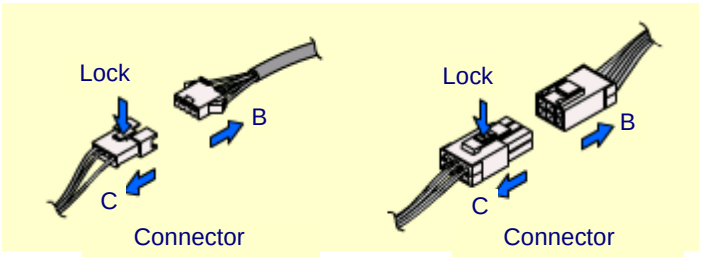


Pulling the pump forward

8) Pull the pump forward and remove the two connectors.

Press the lock release button lightly, and detach the connectors by pulling them in directions B and C.





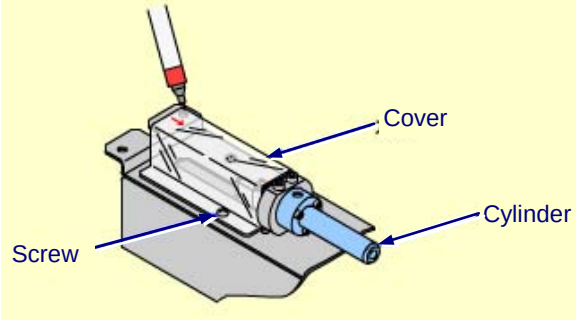
9) Place the pump on a flat surface cushioned with a towel or similar absorbent material while replacing the seal.

How to replace the 1-mm seal for the Sampling pump (SP)

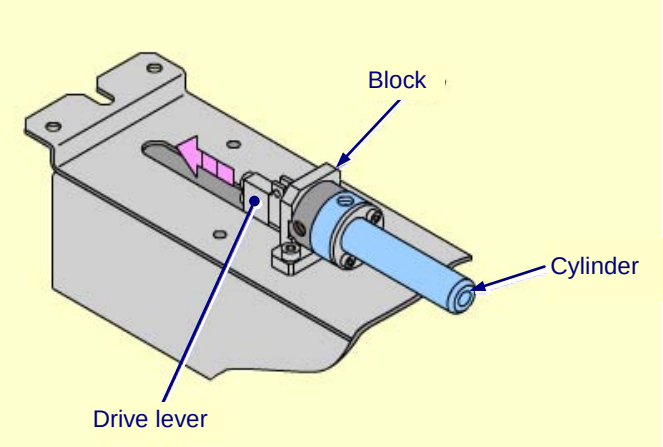
1) Obtain a 1-mm L ring.

2) Remove the two fixing screws, and then remove the cover.

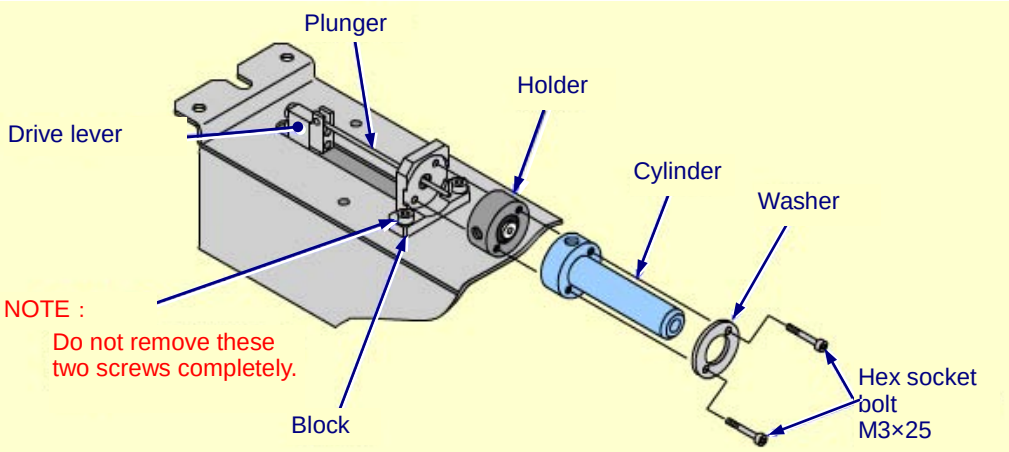
Each cover has its own direction for reattachment. Mark the direction to facilitate reassembly.



3) Move the drive lever slowly in the arrow direction until it contacts the end.



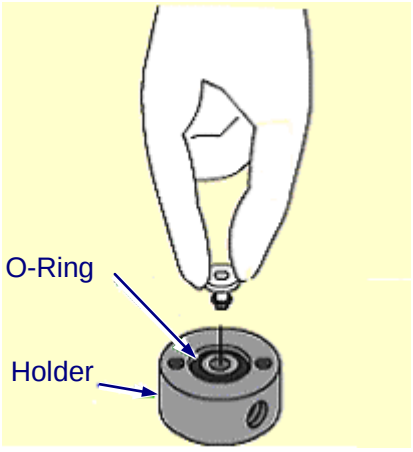
4) Remove the two hex socket bolts, then remove the washer, the cylinder, and the holder.



CAUTION

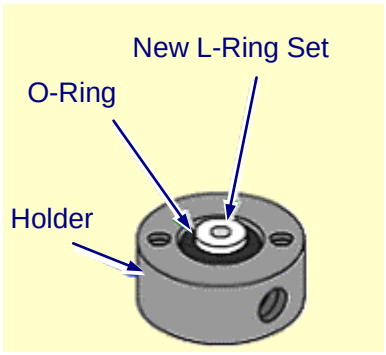
Be careful not to bend the plunger when removing the holder.

5) Remove the L-ring attached to the holder.



6) Place a new L-ring using the L-ring fitting jig.

Do not set an L-ring on the back side.

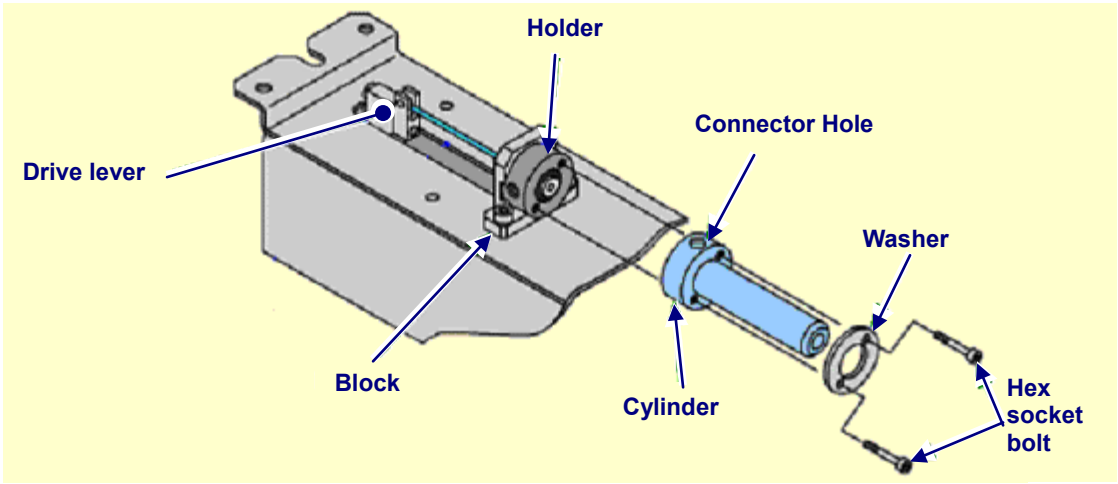


7) Insert the holder, the washer, and the cylinder through the plunger. Align the screw holes, and hold them in place using the hex socket bolts.

Tighten the bolts with the longer arm of an Allen wrench, alternating bolts to gradually bring them to the same tightness. Using the shorter arm of an Allen wrench, tighten each bolt 30 degrees further.

Place the holder such that the O-ring faces upward.

Set the cylinder with the connector hole facing the front of the pump.



8) **After attaching the cylinder, manually move the driver lever up and down to verify that it moves smoothly.**

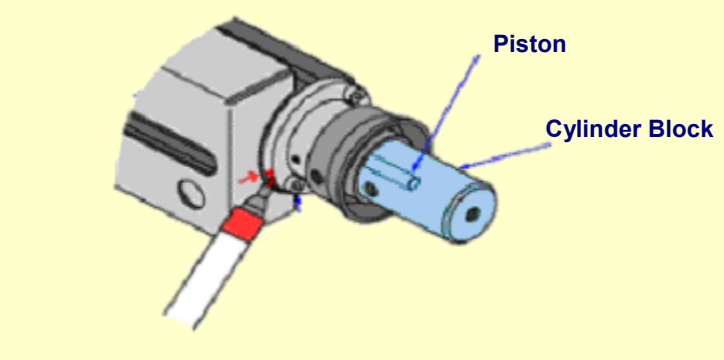
9) **Attach the cover.**

Be careful to place it in the correct direction.

Replace the 5-mm seal for Reagent pumps 1 and 2 (RP1/RP2)

1) **Obtain two 5-mm L-rings for each pump.**

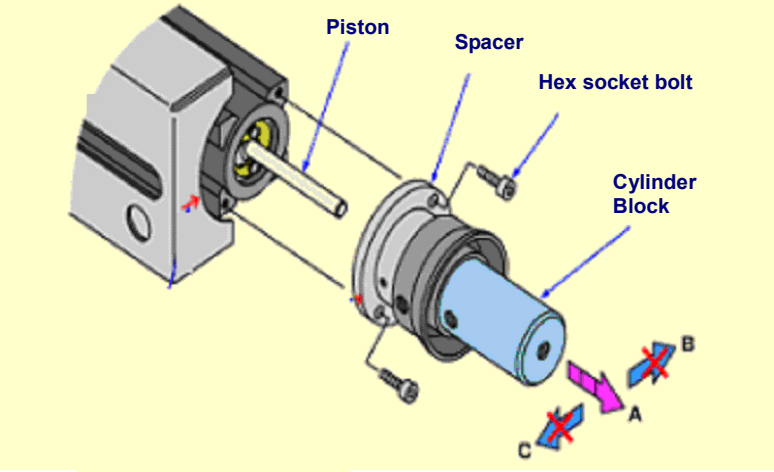
2) **Mark the alignment direction of the cylinder block.**



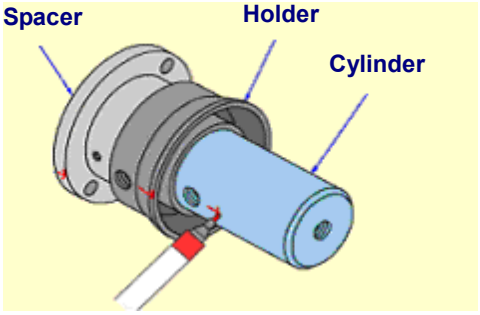
3) **Remove the two hex socket bolts and slide the cylinder block outward to remove.**

CAUTION

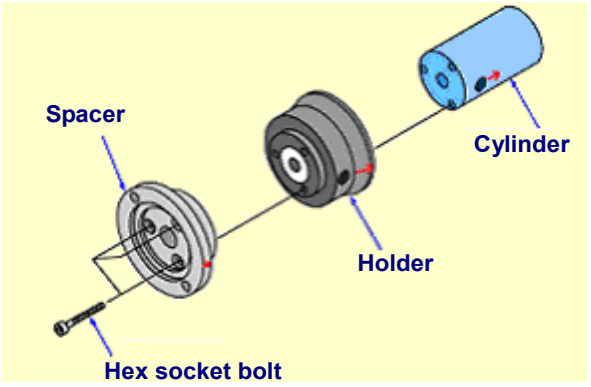
Pull in direction A to slide the cylinder block out. Do not wiggle the block while removing.



4) Before disassembling the cylinder block, mark the orientations of the holder and cylinder to facilitate reattachment.



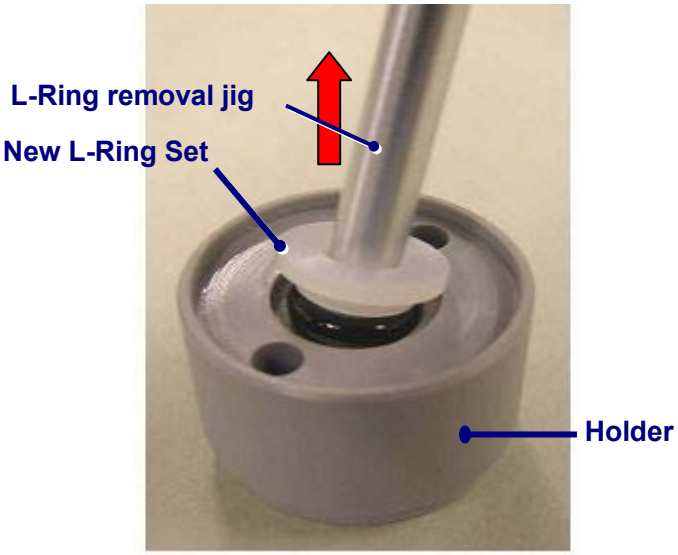
5) To disassemble the cylinder block, first remove the hex socket bolts holding the cylinder in place.



Disassembly scheme

6) Using the L-ring removal jig, take the L-ring out of the holder as follows.

1 Insert the removal jig approximately 5 mm into the L-ring.
2 Slightly angle the removal jig.
3 Lift at an angle to remove the L-ring.

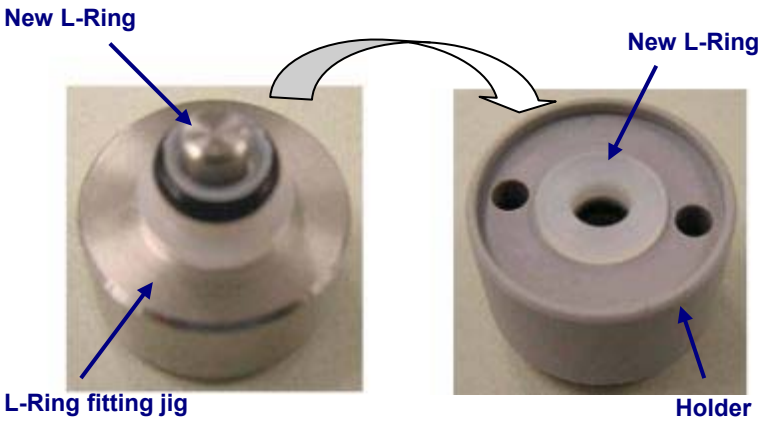


7) Using the L-Ring fitting jig, place the new L-ring into the holder as follows.

1 Insert a new L-ring into the L-ring fitting jig.

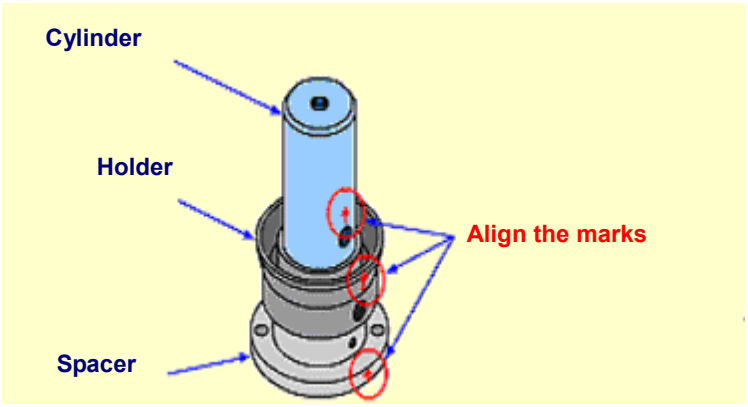
2 Plunge the fitting jig straight into the holder to attach the L-ring.

3 Slowly pull the fitting jig out.



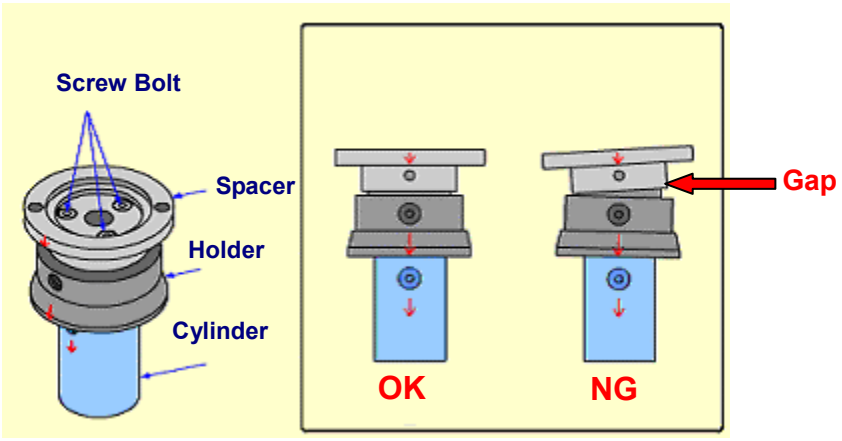
Attaching the new L-ring

8) Align the marks to reassemble the cylinder block.



Assembling the Cylinder Block 1

9) Assemble the parts of the block and lightly tighten the three fixing screws evenly.

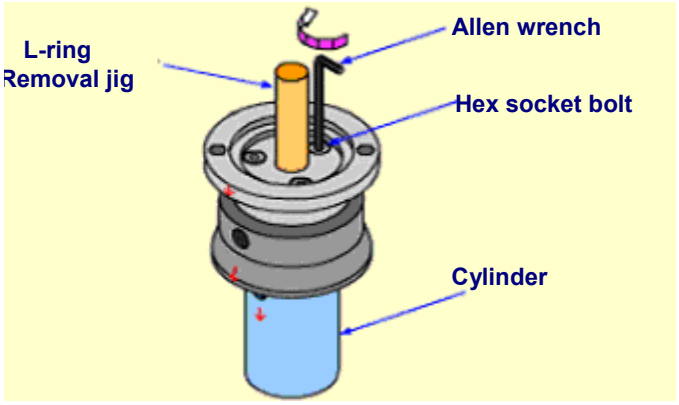


Assembling the Cylinder Block 2

10) Slowly insert the L-Ring removal jig into the cylinder block, and firmly tighten the three hex socket bolts.

Using the longer arm of an Allen wrench, tighten the bolts gradually and alternately to the same tightness.

Using the shorter arm of an Allen wrench, tighten the bolts 30 degrees further.

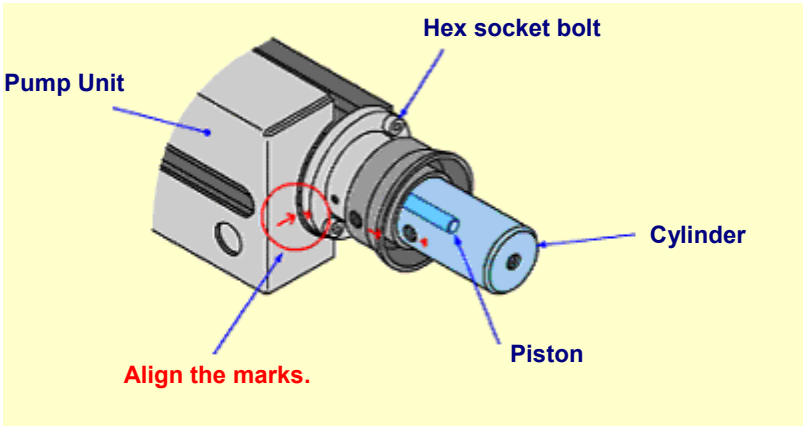


Assembling the Cylinder Block 3

11) Remove the L-ring removal jig slowly.

12) Slowly insert the cylinder block into the piston and secure it to the pump unit using the two hex socket bolts.

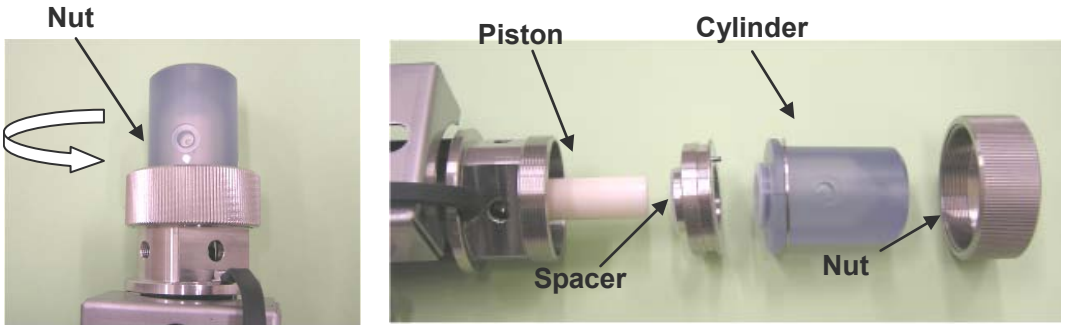
Set the cylinder with the connector hole facing the front.



How to replace the 14-mm OMNISEAL of the Sampling and reagent wash pump (SRWP)

1) Obtain two pieces of pump seal (OMNISEAL 14 mm).

2) Turn the nut counterclockwise to disassemble the cylinder block.



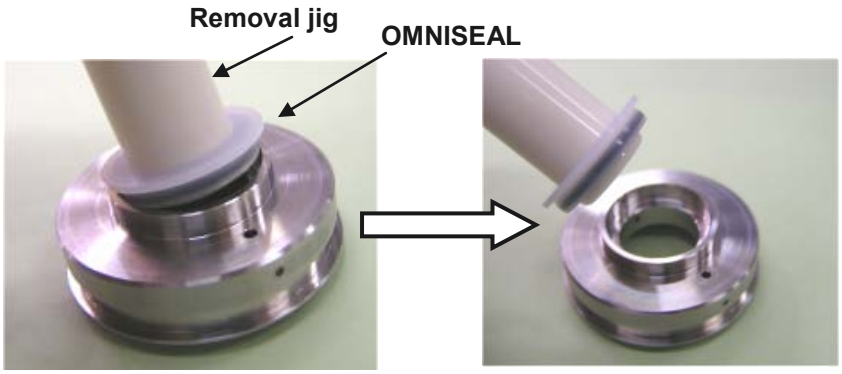
Disassembling the cylinder block

3) Using the removal jig, take the OMNISEALs out of the spacer and cylinder.

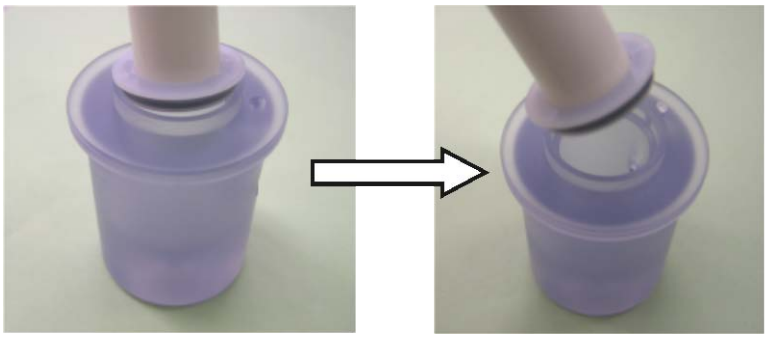
1 Insert the removal jig approximately 5 mm into the OMNISEAL.

2 Slightly angle the removal jig.

3 Lift at an angle to remove the OMNISEAL.



Removing the OMNISEAL from the spacer



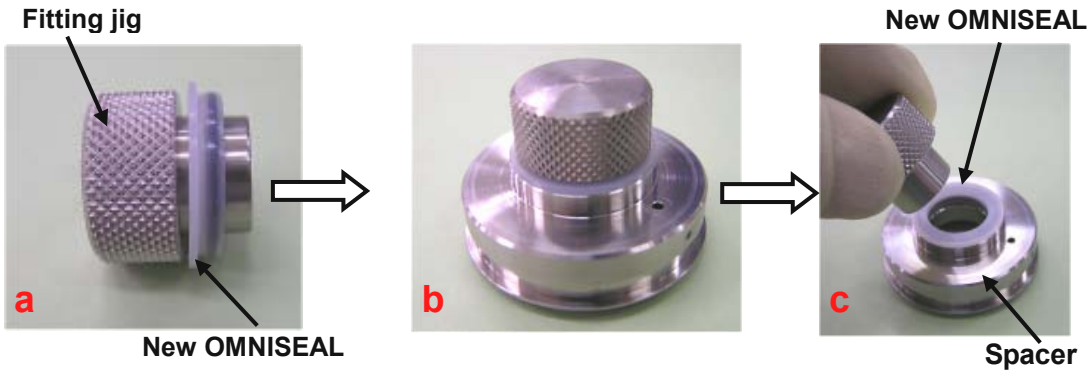
Removing the OMNISEAL from the cylinder

4) Using the fitting jig, place the new OMNISEALs in the spacer and cylinder.

1 Insert a new OMNISEAL into the L-ring fitting jig.

2 Plunge the fitting jig straight into the spacer and cylinder to attach the OMNISEAL.

3 Slowly pull the fitting jig out.



5) Assemble the cylinder block as follows.

In the SRWP, locate the pins on the holder and top of the spacer and the fitting holes on the bottom (where the OMNISEAL is attached) of the spacer and the cylinder. Assemble the unit with the pins and fitting holes aligned.

Pin on the holder

Fitting hole on the spacer

Pin on the spacer

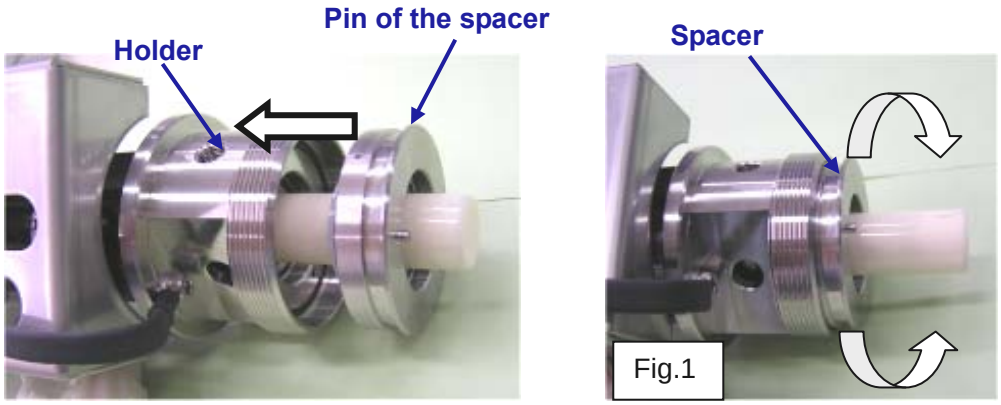
Fitting hole on the cylinder

1 Insert the spacer straight into the piston with the bottom side (where the OMNISEAL is attached) facing the holder.

Attach the spacer with the pin facing front, and ease the pin of the holder into the hole of the spacer.

2 Manually turn the spacer right and left to check the fitting.

If the spacer does not turn, the pin of the holder is positioned correctly in the hole of the spacer (See Figure.1).



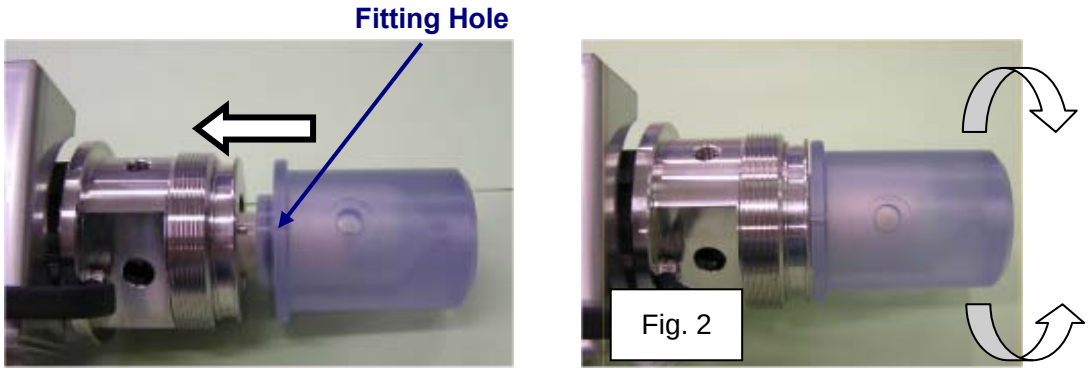
Checking the fitting

3 Insert the cylinder straight through the piston

Attach the cylinder with the hole facing front, and ease the pin of the spacer into the hole of the cylinder.

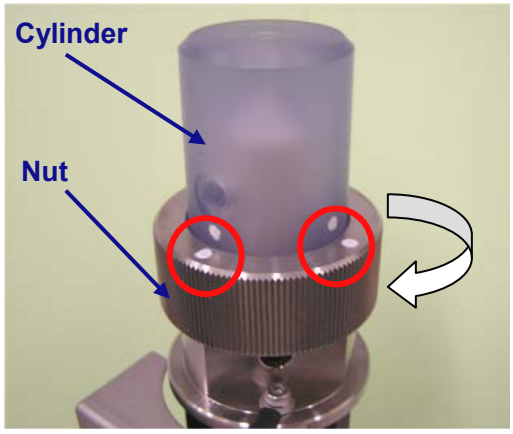
4 Manually turn the cylinder right and left to check the fitting

If the cylinder does not turn, the pin of the spacer is positioned correctly in the hole of the cylinder (See Figure 2).



Checking the fitting

5 Place the nut around the cylinder and turn clockwise until it is finger-tight. Align the marks on the nut and the cylinder.



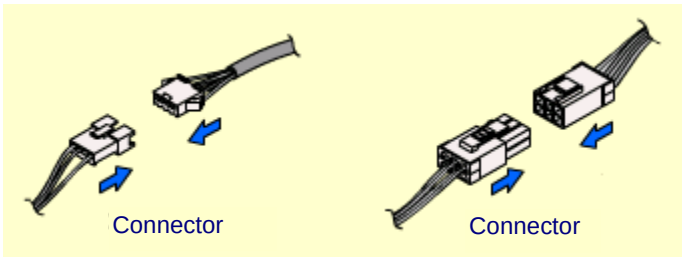
Assembling the Cylinder Block

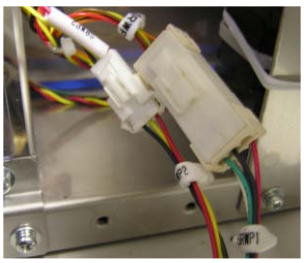
How to replace the pump and assess its motion

The following steps describe the installation of SRWP. The same steps apply to other pumps.

1) Join the two connectors.

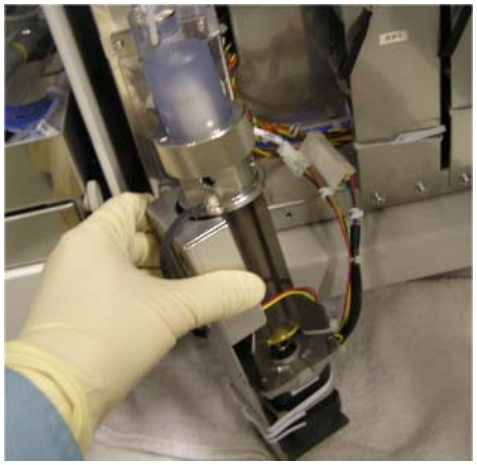
Interlock them in the correct direction.

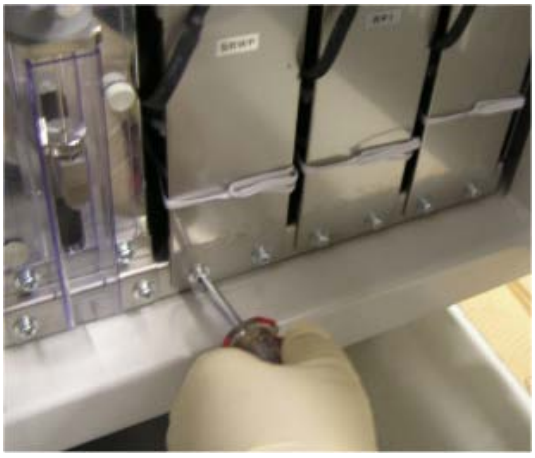




Connecting the connectors

2) Position the pump and hold it in place using the two fixing screws.





Placing and fixing the pump

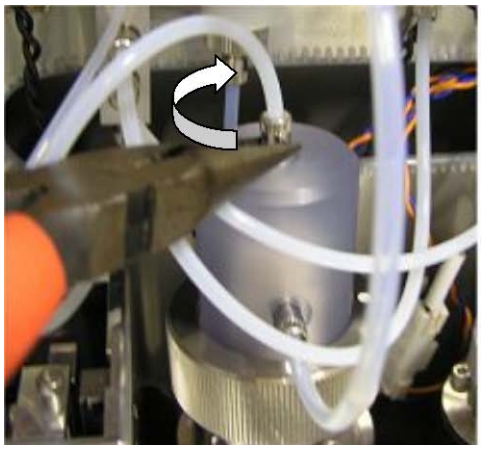
3) Attach the line joint to the top and front of the cylinder. Tighten the joint by turning it clockwise manually. Using pliers, tighten the joint approximately 45 degrees further.

Each joint is associated with a specific position. Reattach the joints according to the identification marks you made when detaching the joints.

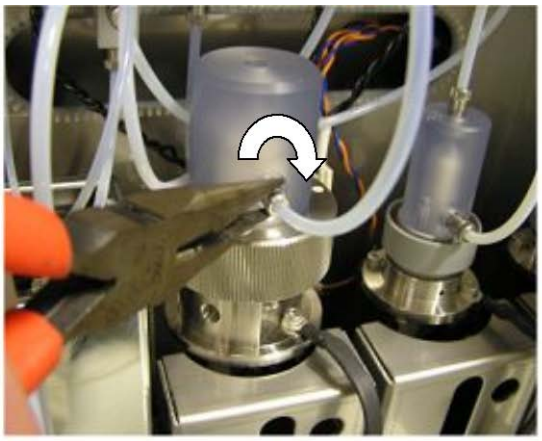
CAUTION

The screw threads can be damaged if the joint is angled during reattachment. Hold the joint parallel to the receiver when attaching.

The joint should turn easily by hand.



Attaching the joint on the top of the cylinder



Attaching the joint on the front side of the cylinder

4) Check the motion

1. Turn the Operate/Standby switch to "PC CONTROL."
2. Select "Re-start" in the "BioMajesty" startup window to re-start the system.
3. Perform "INITIALIZE" and confirm the system mode turns to "READY."
4. Perform "WASH3."
5. Check that no leakage is observed around the joint and pump seal, and that no air bubbles are trapped in the cylinder.

After the service, return the Operate/Standby switch on the power panel to the "PC CONTROL" position. If ○ (Off) or ⊙ (On) is selected, the analyzer does not turn on/off together with the workstation.

7.8.1c Remove clogs from the reaction carousel wash unit (WUD) nozzles

The nozzles will rarely become clogged if daily and weekly "WASH2" cycles are performed as recommended. However, if a drain nozzle aspirates dust or debris from a cuvette, the nozzle may clog, leading to improper aspiration.
If improper aspiration by the WUD results in overflow of wash solution from the cuvette, take the following measures.

Required tools	Clean gauze (lint-free), wire (fishing wire), 4-mm Allen wrench, Kimwipe, 2 pliers,
Required time (estimated)	10 min (WASH2 is not included)
Frequency of service	As required
System mode at service	Analyzer's power if off.
Task	1. Take out WUD. 2. Clean the nozzles. 3. Return WUD back. 4. Check the nozzle positions. 5. Perform "WASH."

Warning

- Read the "Safety Precautions" and "Usage Notes" before starting this task.

CAUTION

- Wear protective glasses, a mask, and gloves when you perform this service.
- When cleaning the WUD nozzles, be sure to turn off the analyzer and workstation.

How to remove clogs from the WUD nozzles

1) Obtain gauze and wire.

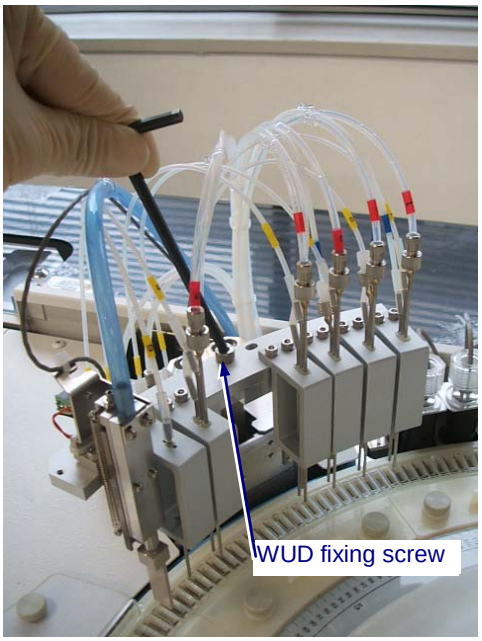
2) Confirm the system mode is "WAIT" or "READY."

3) Exit the workstation system and display the "BioMajesty" startup window on the monitor.

4) Turn the Operate/Standby switch to ⏻ (OFF).

5) To remove the WUD, loosen the fixing screws using a 4-mm Allen wrench.

Protect the cuvettes from debris by covering them with gauze or Kimwipes.



6) Detach the clogged nozzle and associated line of the port.

When the nozzle is detached from the line, liquid will drip from the nozzle tip. Use gauze to absorb the liquid.

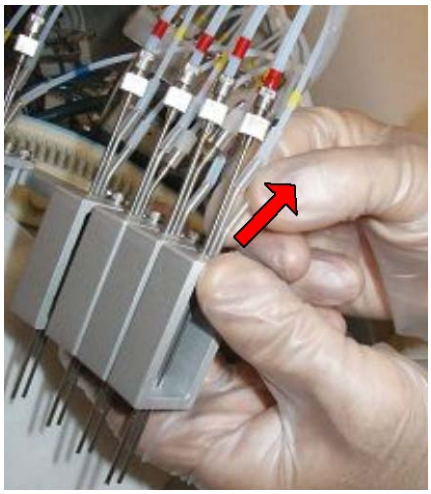
If two or more nozzles must be detached from the lines, mark the number of the line on each nozzle to avoid confusion when reassembling.

CAUTION

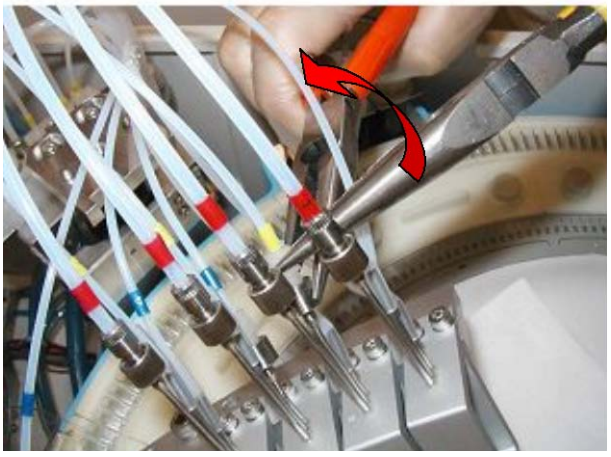
Do not detach the red-marked lines.

There are two types of connections: 1) a Silicon line, and 2) a joint

1) To remove a silicone line, pinch the line with your fingertips, lift upward, and pull out.

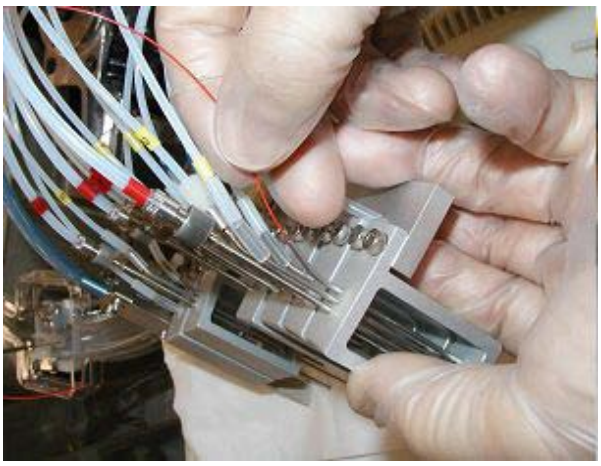


2) Use two pairs of pliers to remove a joint connection. Holding the metal joint on the nozzle side steady with one pliers, loosen the resin joint with the other, then continue to turn it manually to remove.



7) Insert a wire into the nozzle, and remove the clog.

Repeat for any additional clogged nozzles in the port.



8) Once the clog is removed, reconnect the nozzle to the line.

Ensure that nozzles are reconnected to the correct lines according to the markings made in Step 6.

1) For the silicone connection, wipe the nozzle thoroughly with gauze and carefully insert it into the tube.

2) For the joint connection, first twist the resin joint into the metal joint. Holding the metal joint with pliers, turn the resin joint manually to tighten. Using pliers, tighten the resin joint approximately 45 degrees further

9) Return WUD to its operating position.

1 Secure the WUD using the positioning pins on either side of the fixing screw hole.

Confirm that there is no space between WUD and the fixing location.

2 Verify that each nozzle is aligned above each cuvette.

3 Ensure that all lines are securely connected to their respective nozzles.

10) Remove the gauze or Kimwipe used in Step 5 to protect the cuvettes.

11) After the cleaning is complete, turn the Operate/Standby switch to "PC CONTROL."

If ○ (Off) or ⊙ (On) is selected, the analyzer does not turn on/off together with the workstation.

12) Select "Re-start" in the "BioMajesty" startup window to re-start the system.

Wait for several seconds and confirm the Operation Panel shows the system mode "WAIT."

13) Perform "INITIALIZE" and confirm the system mode shifts to "READY."

14) Check the WUD position

1 Select [Maint.] > [Manual Operation]. The [Manual Operation] window is displayed.

2 Double click [23.WUD] to open the [WUD] window. Click the [Move] button.

WUD lowers a little.

3 In the lowered position, check each nozzle is correctly in the midpoint of the cuvette.

4 Click the [Init.] button.

WUD returns to the home position.

5 Click the [Exit] button to close the [WUD] window.

6 Click the [Exit] button to close the [Manual Operation] window.

15) Perform [INITIALIZE] and check no leakage is observed around the line joints. Also, confirm the system mode shifts successfully to "READY."

16) Perform the routine [WASH2] to verify that the wash process functions normally in the port where the clogging occurred.

7.8.1d Replace the mixing rod

Impurities on the mixing rod of the mixer unit (MIX1, MIX2) may cause cross contamination. Replace the mixing rod when it is noticeably soiled, deformed, or broken.

Required tools	Clean gauze (lint-free), a new mixing rod for replacement
Required time (estimated)	3 min (WASH3 is not included)
Frequency of service	As required
System mode at service	READY
Workflow	1. Remove the mixing rod. 2. Attach a new mixing rod. 3. Clean the mixing rod. 4. Check the position of the mixing rod. 5. Perform “WASH.”

Warning

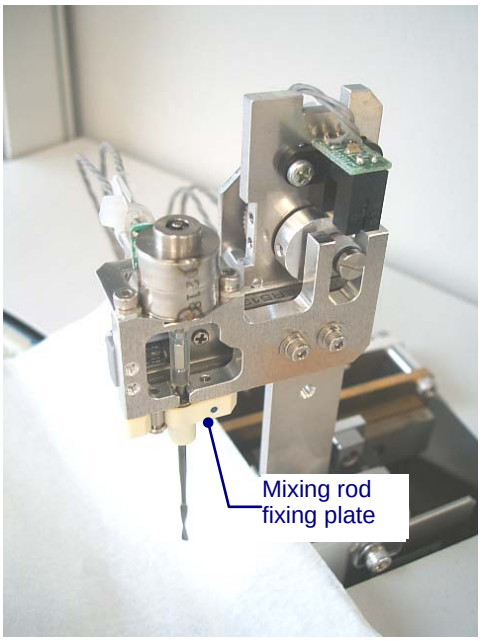
- Read the “Safety Precautions” and “Usage Notes” before starting this task.

CAUTION

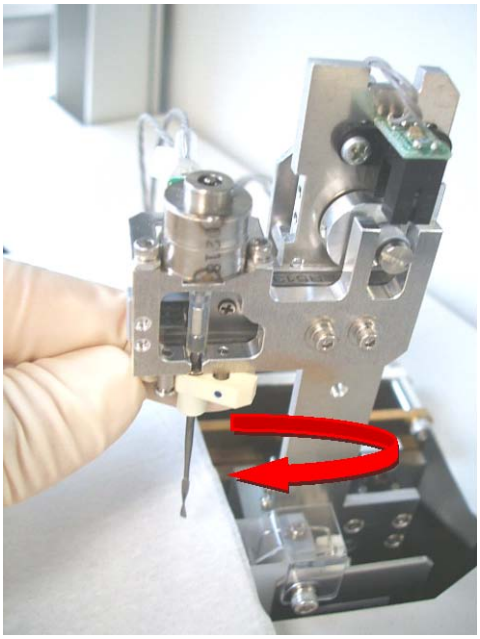
- Wear protective glasses, a mask, and gloves when you perform this service.

How to replace the mixing rod

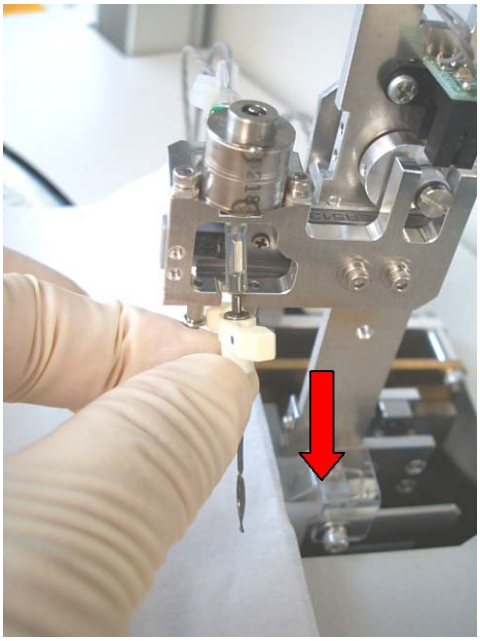
1) **Cover the cuvettes with gauze to protect them from debris or small parts entry.**



2) **Turn the resin fixing plate of the mixing rod clockwise (viewed from above).**

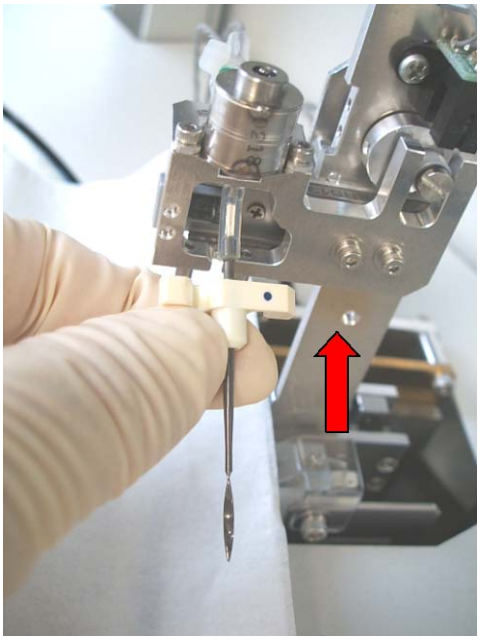


3) Pull the mixing rod downward and outward as directed in the figure below.

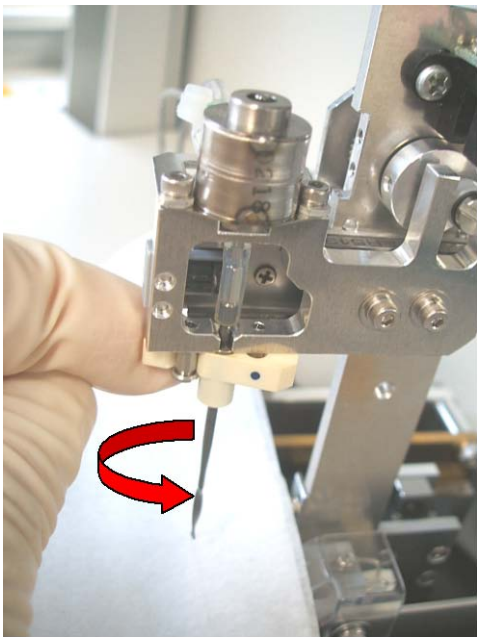


4) Insert a new mixing rod into the upper motor axis via the tip of the mixing rod's silicone line.

Be careful not to exert pressure on the tip of the mixing rod.



5) Reinsert the mixing rod by pushing it upward, and rotate it counterclockwise (viewed from above) to reattach.



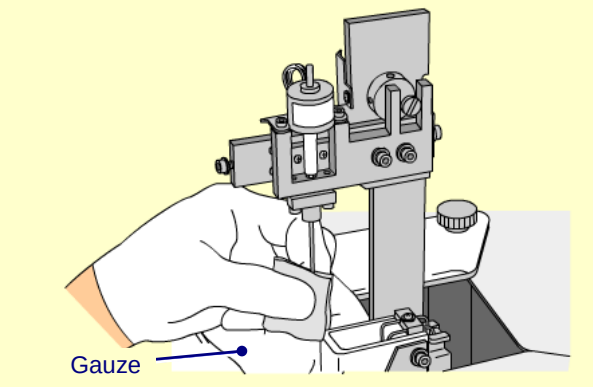
6) Using gauze, gently clean the mixing rod

Wipe the finger-touched sites with gauze.

Be careful not to exert pressure on mixing rod while cleaning.

CAUTION

Do not wipe the twisted part on the tip.



7) Remove the gauze spread out for protection.

8) Perform "INITIALIZE."

9) Verify the position of the mixing rod

1 Select [Maint.] > [Manual Operation]. The [Manual Operation] window is displayed.

2 Double click [44. MUD1] for the mixer 1 and [56. MUD2] for the mixer 2 to open the respective window.

3 Click the [Init.] button.

The mixing rod returns to the wash port.

4 Click the [Move] button twice.

The mixing rod lowers in the cuvette.

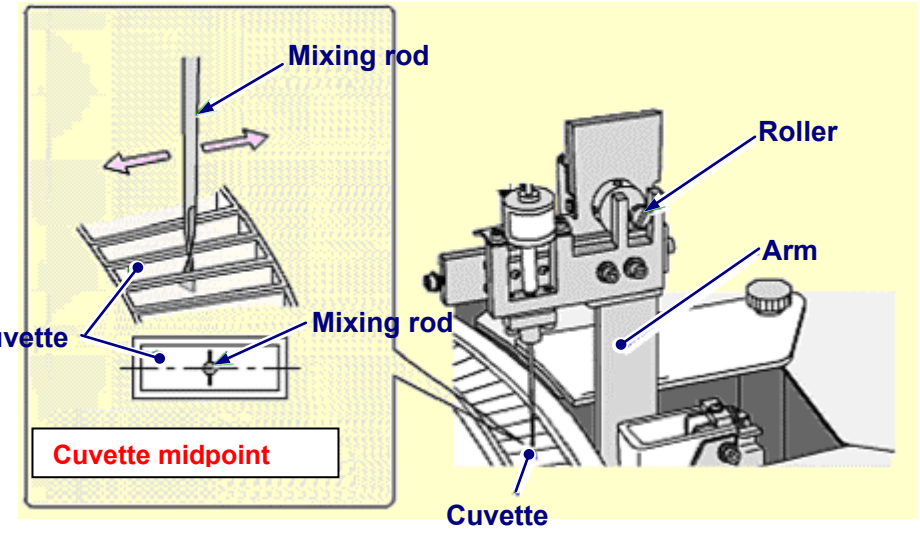
5 Click the [Exit] button.

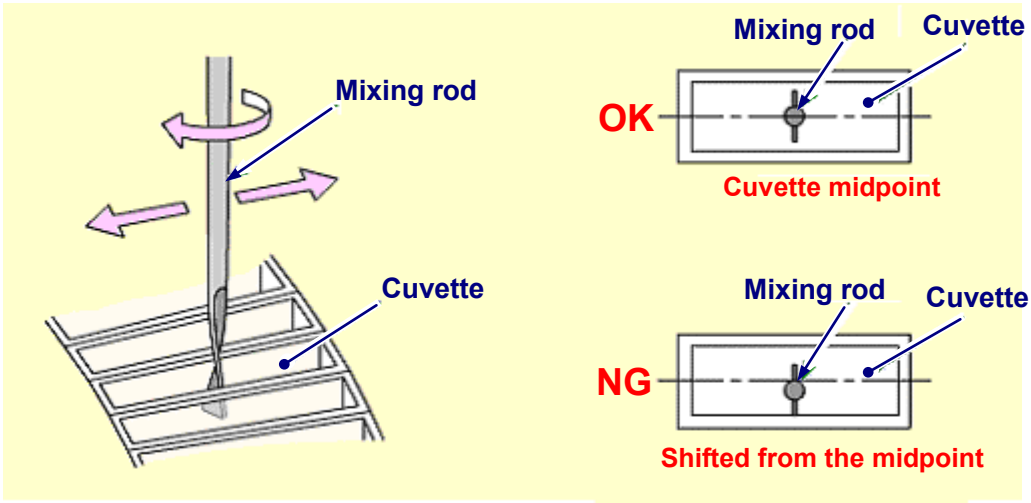
The [MUD1] or [MUD2] window is closed.

6 Double click [45. MIX1] or [57. MIX2] several times at some interval.

Check the mixing rod moves back/forth and right/left in the midpoint of the cuvette.

7 Close the [Manual Operation] window.





10) Perform "INITIALIZE" and confirm the system mode turns to "READY."

11) Perform "WASH3."

Verify that the mixing rod does not touch the cuvette when it moves back and forth.

7.8.2 Ion selective electrode (ISE) unit

7.8.2a Condition the Na and K electrodes

New Na and K electrodes may produce variable results during the first few measurement cycles due to their characteristics. To avoid this instability, follow the steps below to condition the electrode on the day before they are replaced.

Required tools	New electrode, pool serum, buffer solution, clean gauze (lint-free)
Required time (estimated)	15 min
Frequency of service	At the electrode replacement
System mode at service	READY
Workflow	1. Pour pool serum in the electrode. 2. Immerse the electrode in the buffer solution for one night. 3. Install the electrode in place and perform calibration.

Warning

- Read the “Safety Precautions” and “Usage Notes” before starting this task.

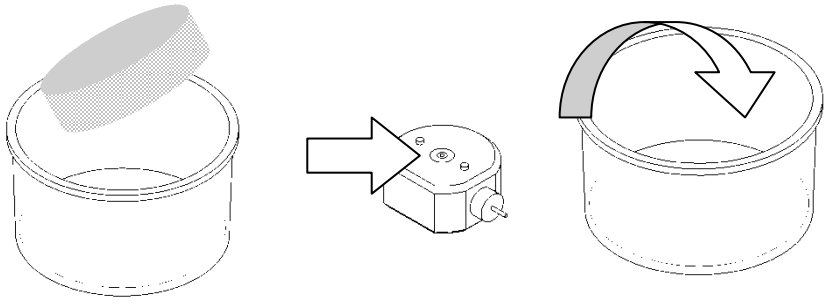
CAUTION

- Wear protective glasses, a mask, and gloves when you perform this service.

1) Take the ion-selective electrode from its packaging.

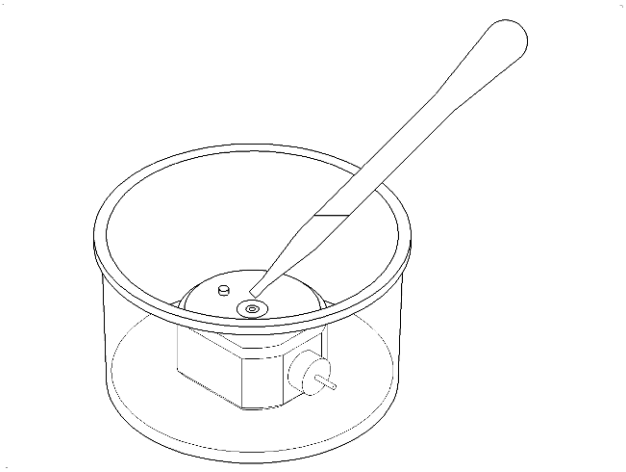
2) Remove the sponge from the package, and return the electrode in the package.

Do not remove the cap attached to the electrode terminal.



3) Pour 0.5 mL of the pool serum into the flow pass that goes through the electrode.

Ensure that the pooled serum penetrates the flow pass.



Warning

Be sure to use non-antigenic serum to avoid the chance of viral infection.

4) Add the ISE buffer solution to cover the whole electrode.

5) Leave it as is overnight in the room temperature.

6) Take the conditioned electrode from the packaging, wash it under running water, and dry it with gauze.

Remove the cap attached to the electrode terminal for cleaning.

Warning

Wear gloves when removing the electrode to avoid direct contact with serum. Serum possesses a risk of viral infection.

After completing the electrode conditioning as above, replace the electrode as indicated in the next section.

7.8.2b Replace the electrodes

The electrode is expendable. A degraded electrode can induce measurement instability. To avoid this, replace the electrode as required.

Warning

- Read the "Safety Precautions" and "Usage Notes" before starting this task.

CAUTION

- Wear protective glasses, a mask, and gloves when you perform this service.
- Be sure to change the status into [ISE-WASH-OFF] before performing the task. If you perform the task in the [ISE-WASH-ON] status, the scheduled wash is automatically activated, resulting in a serious accident or trouble.

Required tools	Electrode for replacement
Required time (estimated)	20 min (time for calibration is not included)
Frequency of service	Every three months or every 30,000 samples measured
System mode at service	READY
Workflow	1. Remove the old electrode. 2. Place a new electrode. 3. Perform calibration

Condition the new electrode before use. Without conditioning, the new electrode may take time before stable results are obtained.

Before every use, wash the reference electrode with water, and dry it thoroughly. If residual preservative solution remains on the electrode while it is being used, the connector area may rust and produce inaccurate measurement values.

Parts required for replacement

- Na, K, Cl, and Ref. electrodes (with O-ring)

How to replace the electrodes

✔ Preparatory step

♦ Click the [ISE-WASH-ON] button on the Operation Panel to change the display to "ISE-WASH-OFF."

✔ Remove the electrodes.

1) Loosen the two screws to remove the cover over the ISE sampling position.

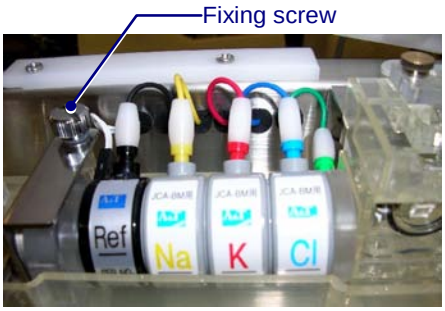
2) Loosen the screw that affixes the stainless steel cover to the ISE unit, and slide the cover off.

3) Prepare new electrodes.

The Cl and reference electrodes will be wet upon removal from their packaging. Dry the Cl electrode thoroughly by wiping. Wash the reference electrode with water, and wipe thoroughly before use.

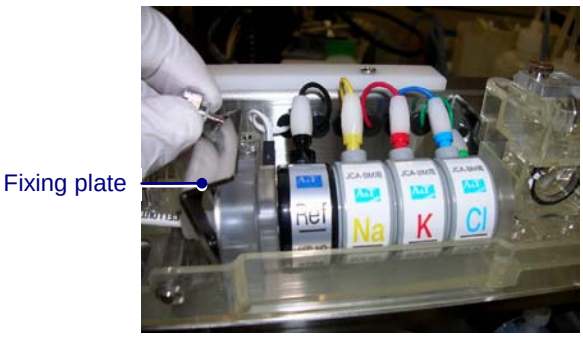
Use conditioned Na and K electrodes.

4) Remove the fixing screw that holds the electrodes in place.



Removing the fixing screw

Release the fixing plate. This will also release the electrode assembly.



Removing the fixing plate

5) Detach the connectors from the electrodes.

6) Remove the electrodes manually.

Removing the electrode

✔ Insert the new electrodes

New electrodes must be stored in the case until replacement. Follow the instruction below for installing the new electrodes.

1) Place the electrodes in their indicated positions.

Ensure that no gaps exist between the electrodes.

Interlock the depressions and protrusions of each successive electrode in the assembly.

CAUTION

An electrode without an O-ring will leak liquid.

2) Tighten the fixing screw by hand while pressing the fixing plate onto the electrode assembly.

3) Insert the electrode connectors.

Electrode color code
Yellow: Na
Red: K
Blue: Cl
Black: Ref

Inserting the connectors

If a gap is present between the electrodes, the fixing plate will not fit in place. Shift each electrode slightly to correct the interlocking. Never force the fixing plate in place; this may cause damage to the plate. Tighten the fixing screw sufficiently. A loose assembly can be released during measurement, causing liquid leakage and malfunction.

✔ Perform "INITIALIZE."

♦ **Click the [Execute] button to "Initialize" in the [ISE Operation] window. (See Section 7.10)**

Verify that liquid drains smoothly from the ISE dilution bowl during priming.

If liquid accumulates, press the "SYSTEM STOP" button to halt the analyzer.

Next, replace the electrodes with the dummy electrode, and perform the "INITIALIZE" function. If liquid drainage becomes normal, a clogged electrode caused the drainage failure.

Contact your local distributor in this case.

7.8.2c Post-maintenance restoration of the ISE unit

Following the maintenance procedure, perform the steps below to restore the unit for measurement.

1) Slide the stainless cover over the unit and secure it with screws.

Be careful not to damage the tubes or dilution bowl. Ensure that the cover is securely set in the gutters.

2) Attach the cover over the ISE sampling position.

3) After completing the above steps, wash the electrodes as shown in "Section 7.3.2c."

4) Perform calibration

Be sure to perform calibration after electrode replacement.

7.8.2d Store the electrodes

Store the unopened electrodes in the case provided in the dark at room temperature.

Wash the electrodes before removing them from the unit.

Once-used electrode is left out of the unit for more than 30 minutes, follow the steps below for storage.

Warning

- Read the “Safety Precautions” and “Usage Notes” before starting this task.

CAUTION

- Wear protective glasses, mask, and gloves when you perform the service.

How to store the electrodes

Item	Na:	K	Cl	Ref
Storage place	Refrigerator			Room temperature
Management	Place the electrode in the provided case as follows			
In the case	Buffer solution to cover the electrode		Buffer solution to cover the electrode	Pure water soaked sponge
Notes			Activity will be lost if the Cl- selective molybdenum oxide film dries out. The film exposed to the inner side of the flow pass is invisible from the outside. Immerse it in the ISE buffer solution when not in use.	The inner structure will shrink when dried. The life of the electrode will be shorter when it is in contact with a large amount of pure water. Never immerse in NaCl solution, as it generates a liquid-junction potential that interferes with measurement accuracy.
Precautions for use	Be sure to wash the connector with water before use to avoid rust formation. Bring the refrigerated electrode to room temperature to avoid data drift.			

Silver-lined part of the electrode may accumulate rust during long-term storage. To avoid rust formation, store the electrode with the cap that was originally attached to the electrode terminal.

7.8.3 Workstation

7.8.3a System backup to DVD

The BM6010/C application is based on the Windows XP Operating System. It consists of the analyzer's operation software, data processing software, and user-specific settings and data files. Because each user is associated with different settings, perform backup after modifying your settings.

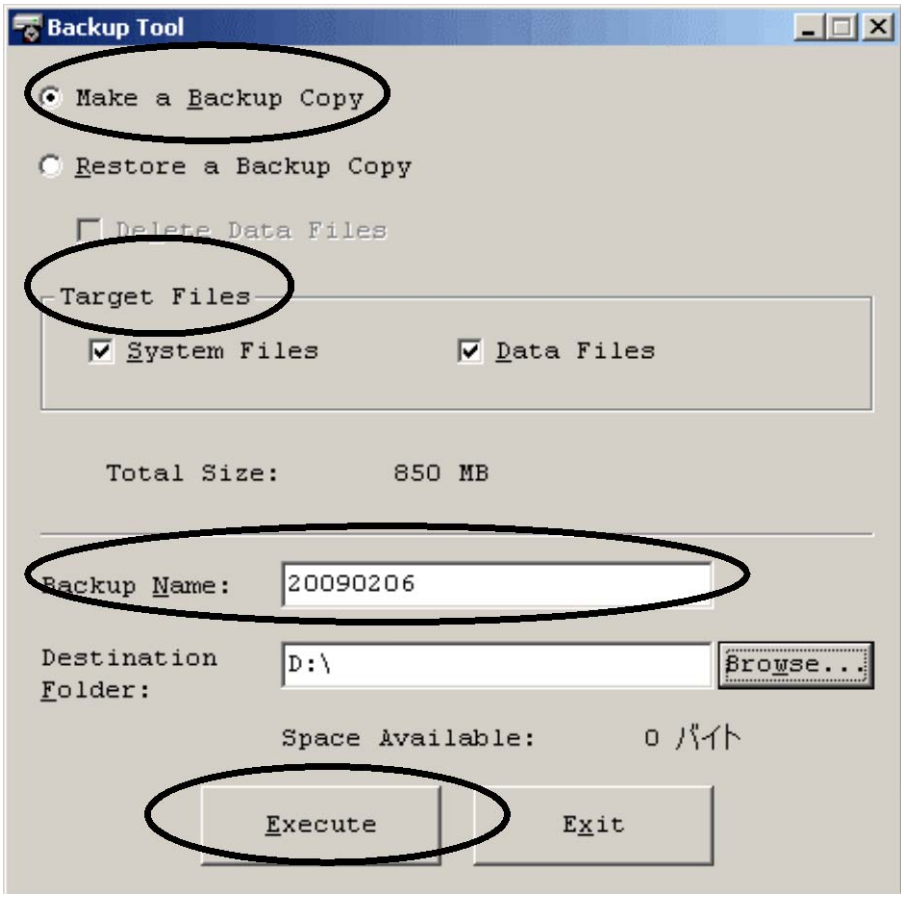
We recommend that the user create a duplicated DVD backup copy of the application.

Backup to DVD

Required tools	DVD disk (2 disks recommended)
Required time (estimated)	10 min
Frequency of service	After the settings have been modified, or before the hard disk is defragmented.
System mode at service	"BioMajesty" startup window
Workflow	1. Insert a DVD disk in the disk drive of the workstation computer. 2. Begin backup from the startup window.

DVD+RW or DVD+R disks are used for backup. Normally, when the system settings are saved to a DVD, a folder of the current date is generated, and the settings are copied there. A folder with the backup date also is added to the disk for every backup. Backup folders cannot be deleted from the DVD+R disk but can be deleted from the DVD+RW disk. Initiate the backup from the "BioMajesty" startup window.

1) **Confirm the system mode is "READY."**
2) **Exit the workstation system and display the "BioMajesty" startup window on the monitor.**
3) **Prepare a DVD disk and insert it in the DVD drive.**
4) **Click the [Back-up] button in the lower right of the "BioMajesty" startup window to display the [Backup Tool] window.**



5) Confirm that “Make a Backup Copy” is selected in the [Backup Tool] window.

6) Select “System Files” for [Target Files].

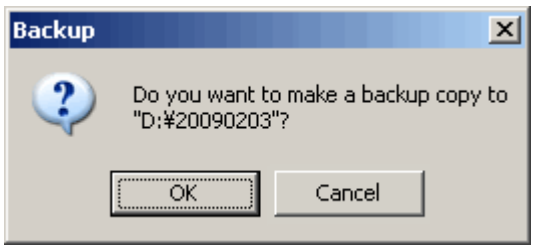
Deselect “Data Files.” Confirm that the “Total size” is smaller than the “Space Available.” If not, use a new disk.

7) Select “DVD drive” for [Destination Folder].

To select, use the [Browse...] button.

8) Click the [Execute] button.

A confirmation window will be displayed, asking <Do you want to make a backup copy to “D:/..."?> (the DVD drive is represented as "D:¥”). Click [OK] to begin Backup.



A new folder of the current date will be created in the DVD (D:¥) disk, shown as 20090203 in the above window. The settings are backed up in this folder.

9) When backup is completed, a confirmation window is displayed. Click [OK].

The window will close, and a [Backup Tool] window will be displayed.

10) Click the [Exit] button to return to the “BioMajesty” Startup window.

11) Take out the DVD disk, and mark it with the date/version prior to storage.

12) Duplicate this DVD for safety.

Alternately, the steps above can be repeated to create another backup disk directly.

When two or more analyzers are used, backup the system settings for each.

7.8.3b System restore using the backup disk

If system malfunction occurs, contact your local distributor before using the backup disk to restore your BM6010/C system application.

The system specifications and settings will be restored to the state that was last backed-up to the disk. Confirm that the current version of the application used in the system is the same as that stored in the disk.

1) Confirm the system mode is “WAIT” or “READY.”

2) Exit the workstation system and display the “BioMajesty” startup window on the monitor.

3) Insert the DVD disk created above in the disk drive.

4) Wait for a while and click the [Back-up] button in the lower right of the “BioMajesty” startup window to display the [Backup Tool] window.

5) Select “Restore a Backup Copy” in the window.

6) Click the [Browse] button for the [Source Folder] field to browse the DVD drive (indicated above as “D:¥”), Click and highlight the file of the date that you want to use for recovery. Click [OK].

7) The file name is displayed in the [Source Folder] field. Click [Execute] to begin restoration.

8) When the restoration is complete, the confirmation pop-up window is displayed. Click [OK] to close the window and return to the [Backup Tool] window.

9) Click [Exit] and return to the "BioMajesty" startup window.

10) Take out the DVD disk.

11) Start the system in the "New Start" mode.

Check and modify the settings if required before use.

Cuvette blank, calibration, and QC data are not restored. You need to obtain the new data.

7.9 Specific Cases

7.9.1 When the pure water bottle becomes empty

If you perform measurements with an insufficient supply of pure water, the “Pure tank supply Time Over-1” alarm will sound. If you continue to collect data during this status, the “Pure water tank float sensor LOW” alarm will sound. At this point, the analyzer will enter the “Processing” mode, and sample analysis will be suspended.

The large water pump (LWP) gauge will indicate an abnormality, and air bubbles will start to form in the LWP that supplies water to wash the outer wall of sample probe (outer wall) and mixing rod. Air bubbles also will form in the sampling and reagent wash pump (SRWP) that supplies wash water to the sample probe (inner wall).

When the “Pure water tank float sensor LOW” alarm sounds, press the [SYSTEM STOP] button, and put the system into “WAIT” mode. Then, follow the steps below.

Required tools	Gauze or Kimwipe
Required time (estimated)	20 min (WASH is not included)
Frequency of service	As required
System mode at service	WAIT
Workflow	1. Check the pure water supply unit. 2. Degas the pure water lines. 3. Perform “WASH” to degas the pumps.

Warning

- Read the “Safety Precautions” and “Usage Notes” before starting this task.

CAUTION

- Wear protective glasses, a mask, and gloves when you perform this service.

Steps to take after the pure water tank becomes empty

1) **Press the [SYSTEM STOP] button on the power panel of the analyzer to put the system in the “WAIT” mode.**
   Do not perform “INITIALIZE.”
2) **Select [Maint.] > [Manual Operation] to display the [Manual Operation] window.**

3) If the pure water supply unit has a problem, eliminate it and restore the unit to the normal status.

4) Wait for the pure water bottle to be filled.

When the bottle becomes full, [72.WEV] switches to "OFF" in the [Manual Operation] window.

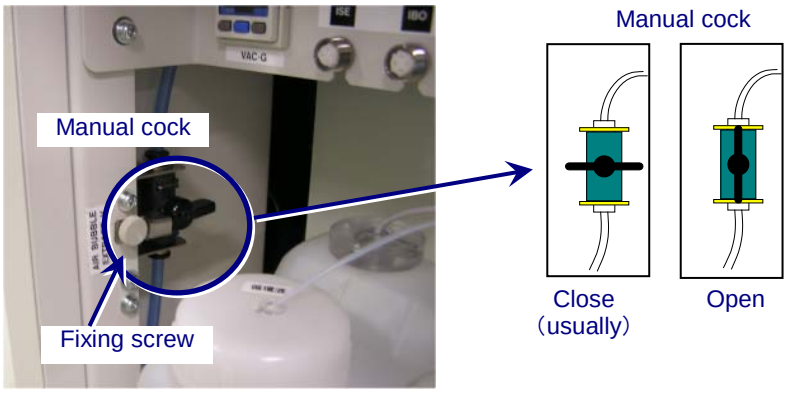
5) Degas the LWP.

1 Double click [59.VP] in the [Manual Operation] window to turn VP "ON."
Double click [61.VDP] in the [Manual Operation] window to turn VDP "ON."

2 Remove the fixing screw that secures the manual cock.

3 Open the manual cock for 3 seconds, then close it.

Do not keep opening the manual cock for more than 5 seconds a time.



4 Double click [61.VDP] to turn VDP "OFF."

5 Double click [59.VP] to turn VP "OFF."

6) Adjust the flow rate for LWP

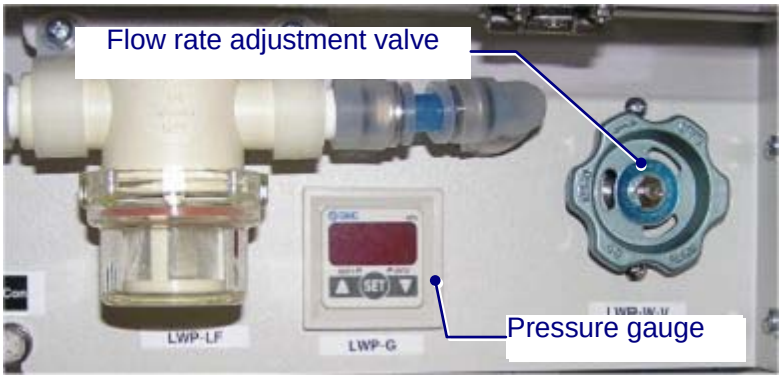
1 Double click [71.VWP] in the [Manual Operation] window to turn it "ON."

2 Turn the LWP regulator valve counterclockwise to the limit to open, and leave it in the open status for approximately 3 seconds.

In response, the alarm for abnormal LWP gauge should sound. Click the [BUZZER] button in the Operation Panel to stop the alarm.

3 Turn the LWP regulator valve clockwise to its limit to close it. Check the LWP pressure gauge reading.

Degassing is successful when the gauge reads > 100 kPa. If the pressure does not reach this level, air may be still trapped in the line. Repeat the opening/closing sequence with the LWP regulator valve 3–4 times at 20-second intervals, or click [71.LWP] to turn on and off for 3-4 times at 20 second intervals. If the pressure is still low, repeat the steps from 5 onwards.



4 When the pressure comes in the normal range, slowly turn the LWP regulator valve counterclockwise to regulate the pressure at 70 - 72 kPa.

Click the [ALARM] button in the Operation Panel to delete the error message.

7) Degas the probe wash port lines.

1 Confirm the pressure is in the range of 70 - 72 kPa.

2 Cover the sample probe (SPP) wash port with gauze or Kimwipe sheets.

This is for avoiding splash of water solution in case the wash solution may shoot out.

Covering the SPP wash port with 4-5 sheets of Kimwipe

3 Click [21.SPEV2] in the [Manual Operation] window.

Do not double click [21.SPEV2]. If you double click it, the solenoid valve 2 (SPEV2) for the sampling pump opens immediately to supply the wash solution.

4 Press the Enter key on the computer keyboard.

SPEV2 opens. If air is trapped, the sound of air purging will be heard for a few seconds. After this, no air bubbles will be evident.

5 Press the Enter key when no air bubble is evident.

SPEV2 closes and water supply stops.

If the sound of air purging is heard for more than 5 seconds, press the Enter key to close [SPEV2]. Press the Enter key again in a few seconds to open SPEV2. Confirm the purging sound is no longer heard.

Before you repeat the steps for confirmation, replace Kimwipe sheets.

6 Remove the gauze or Kimwipe sheets, and press the Enter key.

SPEV2 opens. Check if the wash solution comes out properly in the wash port.

7 After checking the proper supply of wash solution, press the Enter key again.

SPEV2 closes.

8 Repeat Steps 1 - 7 for the other probes and mixing rods respectively.

The following units require degassing.

Probe	Unit
SPP	21.SPEV2
RPP1	42.RPEV2-1
RPP2	54.RPEV2-2
MIX1	46.MWEV1
MIX2	58.MWEV2

8) After completing degassing the lines of all probe and mixer wash ports, close the [Manual Operation] window,

9) Perform “INITIALIZE” and confirm the system mode shifts to “READY.”

10) Check that no liquid leakage is observed in the analyzer.

11) Degas other lines.

1 Perform “PRIME2” or “PRIME3.” Set “10” for “Times” for all the three primings.

2 Perform “WASH3.”

7.9.2 Degas the cuvette wash solution and cuvette conditioner lines

If the nozzles aspirate air from empty detergent or cuvette conditioner bottles, follow the steps below to degas the lines.

When a large amount of air is trapped in the cuvette wash solution and conditioner lines, wash solution will drip from the R2 or R4 nozzles of WUD. If this occurs, stop the analyzer immediately.

Required tools	Clean gauze (lint-free) or Kimwipe
Required time (estimated)	10 min
Frequency of service	As required
System mode at service	WAIT
Workflow	1. Degas. 2. Perform “WASH3.”

Warning

- Read “Safety Precautions” and “Usage Notes” before starting this task.

CAUTION

- Wear protective glasses, a mask, and gloves when you perform this service.

How to degas the cuvette wash solution line

The analyzer is in the “WAIT” mode.

1) **Verify that the line joint is tightly connected to the cuvette wash solution bottle cap.**
2) **Confirm that there are no impurities on the mesh filter attached to the aspiration nozzle in the bottle.**
3) **Select [Maint.] > [Manual Operation] to display the [Manual Operation] window.**
4) **Double click [59.VP] to turn the VP “ON.”**
5) **Double click [24.AEV1] and [62.VEV1] to turn the solenoid valves “ON.”**
6) **Wait for 10 seconds and then perform “INITIALIZE” and confirm the system mode turns to “READY”**
7) **Perform “WASH3,” and confirm that solution does not drip from the R2 nozzle in the WUD. Confirm also that air does not intrude from the line joint attached to the solution bottle cap.**

How to degas the cuvette conditioner line

1) **Verify that the line joint is tightly connected to the cuvette wash solution bottle cap.**
2) **Confirm that there are no impurities on the mesh filter attached to the aspiration nozzle in the bottle.**
3) **Select [Maint.] > [Manual Operation]. The [Manual Operation] window is displayed.**
4) **Double click [59.VP] to turn the VP "ON."**
5) **Double click [34.DCEV] and [63.VEV2] to turn the solenoid valves "ON."**
6) **Wait for 10 seconds and then perform "INITIALIZE" and confirm the system mode turns to "READY."**
7) **Perform "WASH3," and confirm that solution does not drip from the R4 nozzle in the WUD. Confirm also that air does not intrude from the line joint attached to the solution bottle cap.**

7.9.3 Power outage

When a power outage is planned, turn off the power to the workstation and analyzer in advance. When the power is restored, startup the system as normal. If the power outage lasts for several hours, store the reagents in the refrigerator.

In case of an unexpected power outage, follow the steps below to restart the system.

If the system does not start normally after performing the following steps, the application may be broken. Contact your local distributor.

When the power is not restored after a power outage

1) **Confirm the Operate/Standby switch is in the "PC CONTROL" position. If the workstation has a power switch, set it in the off state.**

   Follow the steps below after the power is restored.
2) **Turn on the analyzer.**

   Turn on the work station if the workstation power does not turn on automatically with the analyzer.
3) **In the "BioMajesty" startup window, select "Re-Start" and press [OK].**

   Wait for several seconds and confirm the Operation Panel shows the system mode "WAIT."
4) **Perform "INITIALIZE."**

   Confirm the system mode enters the "READY" mode.
5) **Check if the data before power outage have been saved.**
6) **If the reagents have already been dispensed in the cuvettes, wash the cuvettes,**

   Perform "WASH3" to wash the cuvettes.

If they are left for over 30 minutes, perform “WASH2” with Reagent probe wash S (5% dilution).

When the power is restored soon after the power outage

If the workstation is on after the power restoration, follow the steps below.

1) If the “BioMajesty” startup window is displayed, click the [Shutdown] button to shut down the system as usual.

2) Turn off the workstation, and wait for approximately 20 seconds.

3) Turn on the workstation.

The “BioMajesty” startup window is displayed.

4) Select “Re-Start” and click [OK]

Wait for several seconds and confirm the Operation Panel shows the system mode “WAIT.”

5) Perform “INITIALIZE.”

Confirm the system mode enters the “READY” mode.

6) Check if the data before power outage have been saved.

7) If the reagents have already been dispensed in the cuvettes, wash the cuvettes,

Perform “WASH3” to wash the cuvettes.

If they are left for over 30 minutes, perform “WASH2” with Reagent probe wash S (5% dilution).

7.9.4 Long-term suspension of operation

If the analyzer is not used for 4 days or longer, the wash lines of the reaction carousel wash unit (WUD) may become dried and clogged. Follow the steps below before and after a long-term suspension of operation.

✔ Before a long-term suspension of operation

1) Perform "WASH2."

Perform "WASH2" after the day's operation as usual.

2) Fill the Cuvette conditioner and wash solution lines with pure water.

1 Remove the aspiration lines from the Cuvette conditioner and Cuvette wash solution bottles, rinse them, and place them in a beaker with approximately 500 mL of pure water.

Cover the bottles to protect them from dust and debris.

CAUTION

Leave the reaction bath oil (ACUR30) as is. (This is IMPORTANT.)

2 Perform "WASH3."

Fill the Cuvette conditioner and wash solution lines with pure water.

3) Fill the ISE drain line with pure water.

1 Replace the Na, K, Cl, and Ref. electrodes with the dummy electrode.

2 Fill the ISE dilution bowl with water using a dropper.

3 Select [Maint.] > [ISE Operation]. Enter "5" for [Times] in the [Dil Bowl drain] area, and click [Excute].

The ISE drain line is filled with pure water.

In case the system is not used for one month or longer, replace the buffer bottle with a water-filled container. Perform "Prime" after entering "50" for [Times] to fill all lines with water. Store the electrodes as instructed in the section 7.8.2d.

4) Store the reagents.

Cover the detergent and reagent bottles on the reagent tray (RTT) with parafilm.

Be sure to remove the cover before starting up the system next time.

5) Discard the detergent in the refrigerated sample tray (CTT).

6) End and shut down the system.

Deselect "Auto Startup" if it has been selected.

✔ After a long-term suspension of operation

1) Check that crystals have not formed on the tips of the metal nozzles of the WUD.

- Port 2 (Red 2): Cuvette wash solution
- Port 4 (Red 4): Cuvette conditioner

If crystal formation or clogging is suspected, take out the WUD unit and remove the crystal or clog by inserting a wire through the nozzle. (Do not disconnect the joint. See Section 7.8.1c)

2) Return the aspiration tubes to their respective bottles in the detergent compartment.

Remove the cuvette conditioner and wash solution lines that had been stored in pure water. Wipe them dry, and place them back in the bottle.

3) Start up the system.

4) Remove the dummy electrode and place the Na, K, Cl, and Ref. electrodes back.

5) Place the wash solutions on the refrigerated sample tray (CTT),

6) Return the reagents to the positions as before.

Remove the parafilms that cover the wash solutions and reagents on the reagent tray (RTT).

7) Perform “PRIME1.”

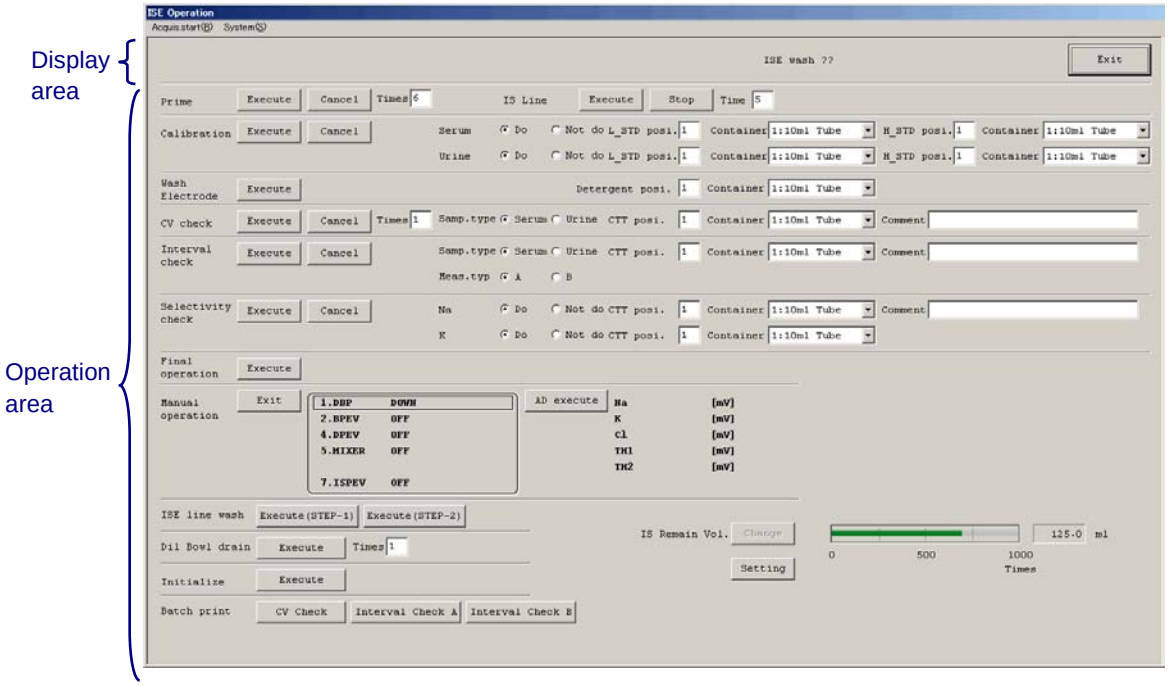
8) Perform “WASH3.”

After “WASH” begins, observe the movement of the WUD unit to ensure that the silicone lines do not disconnect, and that leakage does not occur.

9) Start the routine measurement.

7.10 ISE Operation Window

You can operate the ISE unit alone from the [ISE Operation] window. This section describes the operations of ISE unit available from this window, including those used for maintenance. Select [Maint.] > [ISE Operation] to display the [ISE Operation] window.



[ISE Operation] window

- The [ISE Operation] window consists of the display area and the operation area. The display area shows the operational status, operation time, and regular wash type. The operations are possible in the system modes of “WAIT” and “READY.”
- However, when the system mode is “WAIT,” only the functions “Initialize,” “Prime,” and “Manual operation” are available.
- Operations made from the [ISE Operation] window can be performed if the system mode is “READY,” and no other messages are displayed.
- When the following ISE operations are being performed, the system mode window in the Operation Panel shows “ISE only” or “ISE wash.” The display area in the [ISE Operation] shows the on-going ISE operation.
  - Calibration
  - Electrode wash
  - CV check
  - Interval check
  - Selectivity check
  - Final
  - ISE line wash

- The settings made in the [ISE Operation] window are only valid when the order is submitted using the [Execute] button in this window. The settings entered in this window do not affect the default settings.

When priming, electrode wash, or calibration is performed from the [PRIME], [WASH], or [START] button, the settings made in the [ISE Parameter Settings] window are used.

[Prime]

1) Enter 1 - 99 for [Times].

2) Click the [Execute] button.

The display area shows “Prime Running” with the approximate time until the end of priming.

3) Click [Cancel] to abort the operation.

[IS Line]

1) Enter 1 - 10 for [Times].

2) Click the [Execute] button.

The display area shows “IS line prime Running” with the approximate time until the end of the line priming.

At the end of operation, priming is automatically performed for 4 times.

3) Click the [Stop] button to abort the operation.

[Calibration]

1) Select “Serum” or “Urine” for the calibration type.

Check for “Do” to select. Both of [Serum] and [Urine] can be selected.

2) Enter the positions of the low-concentration standard (L-STD) and the high-concentration standard (H-STD) on the refrigerated sample tray (CTT) for the selected calibration type.

3) Select a container type in the [Container] field.

4) Position L-STD and H-STD in the selected container respectively and set them on the designated position.

Mix the solution well by inversion, and pour 500 µL into the sample container.

5) Click the [Execute] button.

Calibration begins and the display area shows “Calibration Running” with the remaining time until completion.

6) Click the [Cancel] button to abort the operation.

If the operation is canceled, the calibration values will not be updated. Wait for the system mode to display “READY” to restart the calibration.

[Wash Electrode]

1) Enter the CTT position # in the [Detergent posi.] field and select a container type.

2) Pour 100µL of the ISE Detergent Solution in the selected container and place it on the CTT position # designated in Step1.

3) Click the [Execute] button.

The display area shows “Wash Electrode running” with the approximate time until completion.

[CV check]

After completing the above maintenance services of the ISE unit, perform “CV (coefficient of variance) check” to assess the reproducibility of measurement values and the proper operation.

1) Select a sample type from serum and urine for [Samp.type].

2) Enter [CTT posi.] and select a container type for [Container] for the sample.

3) Set the sample in the selected container and place it on the designated CTT position #.

4) Enter 1 - 99 for [Times].

Approximately 30 µL of the sample is required for one check.

5) Enter comment as required in the [Comment] field.

The entered comment is displayed in the report. Use this function as required for data organization.

6) Click the [Execute] button.

The display area shows “CV check Running” with the approximate time until completion.

If the CV is measured for twice or more, the results will be processed statistically. When the measurement is performed only once, an alert is displayed to indicate that the measurement time is insufficient for statistical processing.

7) Click the [Cancel] button to abort the operation.

[Interval check]

The “Interval check” is performed at intervals to measure the data reproducibility and confirm the operation.

Two interval types are available. Type A is performed at intervals of 18–72 seconds, and type B is performed every 360 seconds.

1) **Select a sample type from serum and urine for [Samp.type].**
2) **Enter the CTT position # in the [CTT posi.] field and select “Tube” for [Container].**

   The measurement takes 40 - 60 minutes. Take the evaporation into consideration in selecting a tube capacity.

3) **Set the sample in the selected container and place it on the designated CTT position #.**

   The required sample volume is 1.5 mL or more.

4) **Select a check type from A or B for the [Mea.typ] field.**
5) **Enter comment as required in the [Comment] field.**

   The entered comment is displayed in the report. Use this function as required for data organization.

6) **Click the [Execute] button.**

   The check begins and the display area shows “Interval check Running” with the approximate time until completion.

7) **Click the [Cancel] button to abort the operation.**

[Selectivity check]

Check the selectivity of the electrodes using the selectivity check solution.

Different selectivity check solution is available respectively for Na and K electrodes.

1) **Select “Na” or “K”.**

   You can also select both.

2) **Enter the CTT position # and select a container type for the check solution corresponding to the selected electrode.**
3) **Put the selectively check solution in the selected container and place it on the designated CTT position #.**
4) **Enter comment as required in the [Comment] field.**

   The entered comment is displayed in the report. Use this function as required for data organization.

5) Click the [Execute] button for the selectivity check.

The check begins and the display area shows “Selectivity check Running” with the approximate time until completion.

The measurement is repeated three times and the second and third measurement values are averaged. When the value exceeds the upper limit of selectivity defined in the [ISE Parameter Settings] window, the third measurement value is flagged with a “u.” The measurement values are displayed with the date in the [ISE Monitor] window.

6) Click the [Cancel] button to abort the operation.

When aborted, the data are not statistically processed.

[Final operation]

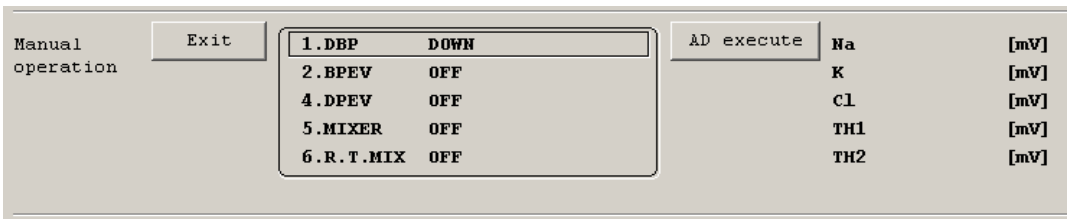
The “Final operation” is performed before shutting down the system at the end of the day. The ISE dilution bowl is filled with water, and the regular wash is automatically canceled, preventing buffer solution from being used.

1) Click the [Execute] button for the “Final operation.”

When the “Final operation” begins, “Final operation Running” is displayed along with the approximate time until completion. “Period wash OFF” also is displayed at this time. Pure water is dispensed into the dilution bowl five times, filling it with approximately 950 µL of water in total. This operation cannot be suspended.

To resume the sample run after the “Final operation,” select “INITIALIZE” from the Operation Panel or from the “ISE Operation” window. Perform a calibration to obtain the calibration values before running samples.

[Manual operation]



Use this area to operate each part of the ISE unit for maintenance or for assessing proper operation.

The manual operations are possible when the ISE unit is in the operable state, even if the system is in “WAIT” mode according to the Operation Panel.

Manual operation of ISE unit parts triggers a display of “Manual operation running.” The scheduled ISE wash then is automatically canceled.

When “Manual operation running” is displayed, only “Manual operation” and “INITIALIZE” can be performed. After completing the “Manual operation,”

be sure to click [Exit] in the “Manual operation” area, or click [Execute] for [Initialize] in the [Manual Operation] window. Confirm the display of “Final operation Running” disappears. Also, click the [ISE-WASH-OFF] button to turn to [ISE-WASH-ON] in the Operation Panel.

✔ Double click the abbreviated name of the part to operate.

Once the part name is clicked, an associated window will be displayed for operation. To operate another part, close this window.

Name of the part and operation

Abbreviation	Full name	Function	Operation
BP	Buffer pump	DOWN/UP	Click the [Toggle] button in the pop-up window.
		Initialize	Click the [Init.] button in the pop-up window.
BPEV	Buffer pump solenoid valve	OFF/ON	Double click [2.BPEV] or press [Enter] key on the keyboard.
DPEV	Drain pump solenoid valve	OFF/ON	Double click [4.DPEV] or press [Enter] key on the keyboard.
MIXER	Mixer	OFF/ON	Click the [**Toggle**] button in the pop-up window.
		Initialize	Click the [**INIT.**] button in the pop-up window.
ISPEV	Internal Standard solution solenoid valve	OFF/ON	Double click [7.ISPEV] or press [Enter] key on the keyboard.

✔ To measure the electrode potentials, click the [AD execute] button.

The potentials of Na, K, and Cl electrodes as well as Thermister1 and Thermister2 are displayed.

[ISE line wash]

In “STEP-1,” ISE Detergent Solution is introduced in the dummy electrode. The detergent solution backs up in the ISE dilution bowl and remains there for 1 minute. The detergent solution then fills the lines and remains there for another minute, cleaning the bowl and the lines.

In “STEP-2,” priming is repeated 10 times to restore the unit to a measurement-ready status.

When dialysis samples are run often, perform the line wash. See the maintenance table on page 5 for wash frequency.

Be sure to replace the electrodes with the dummy electrode when performing the line wash.

1) Click the [ISE-WASH-ON] button in the Operation Panel to turn it to [ISE-WASH-OFF].

2) Remove the Na, K, Cl, and Ref. electrodes in the ISE unit, and place the dummy electrode.

3) Uncap the dummy electrode, and add 5 mL of ISE Detergent Solution using a dropper.

4) Tighten the cap of the dummy electrode.

5) Click the [Execute (STEP-1)] button in the [ISE line wash] area.

The wash begins, and the display shows "ISE line wash1 Running." This function lasts approximately 16 minutes.

6) Once "STEP-1" is completed, replace the dummy electrode with the actual electrodes.

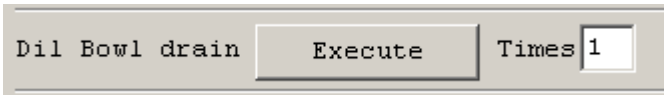
The wash is completed when the "ISE line wash1 Running" display disappears.

7) Click the [Execute (STEP-2)] button in the [ISE line wash] area.

This will initiate the wash, and the display will show "ISE line wash2 Running." Priming is automatically performed. This function lasts approximately 1 minute.

8) Click the [ISE-WASH-OFF] button in the Operation Panel to turn it to [ISE-WASH-ON].

[Dil Bowl drain]



Use this operation to drain the pure water and buffer solution remaining in the dilution bowl after washing.

1) Enter 1 - 99 for [Times].

Enter "5" for [Dil Bowl drain].

2) Click the [Execute] button in the [Dil Bowl drain] area.

Draining begins, and the display area shows "Dil Bowl drain Running" with the approximate time until completion.

[Initialize]

Use this operation after the manual operation of the parts of the ISE unit or troubleshooting.

✔ Click the [Execute] button.

Initialization begins and the display area shows “Initialize Running.” No remaining time is shown.

After the initialization is completed, the display of “Dilution Bowl drain” disappears.

If there is no problem remaining, each part of the ISE unit should be in the correct position.

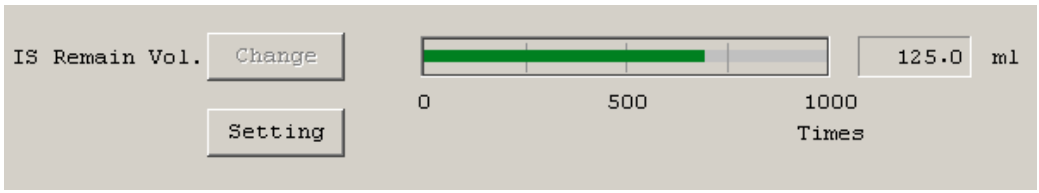
[Batch print]

You can print the most recent data of “CV check,” “Interval check A” and “Interval check B.”

✔ Click the button to print the relevant data.

A pop-up window is displayed. Click [YES]. The display area shows “Printing” and the data are printed.

[IS Remain vol.]



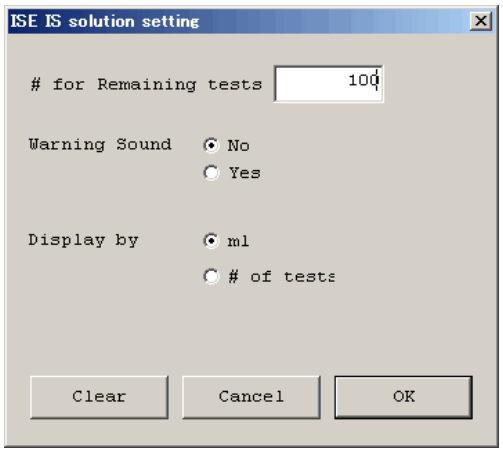
Use this area to check the remaining volume of the Internal Standard (IS) solution.

When you replace the IS bottle, click the [Change] button and follow the instruction displayed in the window.

See “Section 7.3.2b Check the remaining volume of IS solution” for the steps to replace the IS solution pack.

Setting button

Click this button to display the [ISE IS solution setting] window.



Define the alarm settings for the remaining volume. If the remaining volume becomes insufficient for the number of tests entered for [# for Remaining tests], the bar representing the volume will be displayed in yellow. Select “Yes” for [Warning sound] to sound an alarm when the volume becomes insufficient for the defined number of tests.

Select “ml” or “# of tests” under [Display by] as the parameter for the graphic display. The display of the [ISE IS solution remaining volume] window in the [Operation mode details] will follow the selected setting.

“# of tests” is calculated by dividing the remaining volume by the consumption volume per test. The test is assumed to be performed intermittently on serum, which consumes the maximum volume. Therefore, the calculated and actual remaining “Times” may differ. The “ml” reading indicates the accurate volume based on the system’s record of the actual consumed volume in total.

Click the [Clear] button to reset to the default setting.

Click [Cancel] to quit the window without saving the setting.

Click [OK] to save the setting and close the window.

7.11 Maintenance List

Use the list below to record the routine maintenance items.

Print or copy the list.

- Monthly list
- Annual list

Monthly Maintenance List

Month: _____

Daily Maintenance																															
Date	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Check water quality																															
Check the probes for impurities																															
Check the mixing rod for impurities																															
Check the nozzles of the WUD unit for impurities																															
Check the wash ports of probes and mixing rods for impurities																															
Check the splash cover for impurities																															
Check for potential leakage from pumps																															
Check the remaining volume of the lamp coolant																															
Check the level of the ISE Buffer																															
Check the level of the ISE Internal Standard solution																															
Wash the electrodes																															
Wash the ISE dilution bowl																															
Wash the electrode lines (*)																															

Weekly Maintenance	Week 1 Date:	Week 2 Date:	Week 3 Date:	Week 4 Date:	Week 5 Date:
Check the lamp energy					
Cuvette blank measurement					
WASH-2 with Reagent probe wash-S					
Wash the electrode lines (*)					
Shut down the workstation					

The optimal maintenance frequency depends on the usage for items with (*). Read the relevant chapter carefully to set the frequency.

Annual Maintenance List

Year: _____

Maintenance service performed at intervals of 1 - 6 months												
Date	/	/	/	/	/	/	/	/	/	/	/	/
Soak and wash the mixing rods												
Clean the sample setting areas in the STT/ CTT, and the refrigerated reagent compartment in RTTs												
Clean the chiller filter												
Clean the line filter of the LWP												
Clean the waste fluid lines of probe and mixing rod wash ports												
Clean the exterior panels of the analyzer												
Clean the vent fans and grids												
Clean the ISE waste drain nozzle												
Clean the cuvette wash solution and conditioner bottles												
Clean the filters in the cuvette wash solution and conditioner bottles												
Clean the aspiration lines of the reaction carousel wash unit (WUD)												
Disk defragmentation of the Windows XP-based workstation												

Parts Replacement / Irregular Maintenance Service												
	Date / Unit											
Regular replacement												
Replace the spectrophotometer lamp (*)												
Replace the reaction cuvettes (*)												
As required												
Replace probes (SPP, RPP1, RPP2)												
Replace the seal of the pumps (SP,RP1,RP2,SRWP)												
Replace the mixing rods (MIX1,MIX2)												
Replace the electrodes of the ISE unit (Ref,Na,K,Cl)												
Backup the system data on DVD												

The optimal maintenance frequency depends on the usage for items with (*). Read the relevant chapter carefully to set the frequency.

CONTENTS

Chapter

8 Troubleshooting

8.1 Emergency stop and steps to resume operation

1) If it is necessary to stop the analysis during operation, press the [SYSTEM STOP] button on the power panel.

The analyzer will stop operation immediately.

2) Restart the analyzer to the "READY" mode.

If reagents were being dispensed into the cuvettes at the emergency stop, the cuvettes will need to be washed. Perform the normal or weekly [WASH2] procedure as described in the chapters 4 and 7.

8.2 Resuming operation after manually turning off the analyzer

If you have started up the workstation without using the PC control function and turned off the analyzer manually, follow the steps below to resume operation with the PC control function.

1) Turn the operate/standby switch to the "OFF" position once and then to the "PC CONTROL" position.

2) Shut down the workstation once and restart.

1 Click the [System (S)] command button on the top bar in the Menu Panel and select "Exit (X)" in the drop-down menu.

A window is displayed to ask for confirmation.

2 Click [Yes].

Another window is displayed to ask for confirmation.

3 Click [Yes].

Approximately 15 seconds later, BioMagesty startup window is displayed.

3) Start up the workstation.

1 Select "Restart" as the start-up mode.

2 Click [OK]

Workstation is started and the Menu Panel and Operation Panel are displayed.

The system mode displayed in the Operation Panel changes into "WAIT" from "SYSTEM INIT."

3 Restart the analyzer to the [READY] mode.

If reagents were being dispensed into the cuvettes at the emergency stop, the cuvettes will need to be washed. Perform the normal or weekly [WASH2] procedure.

8.3 Alarm handling

Checking the alarm

When the system detects an error in analyzer function, an error message is displayed in the lower left space in the Operation Panel. Or the buzzer (alarm) sounds.

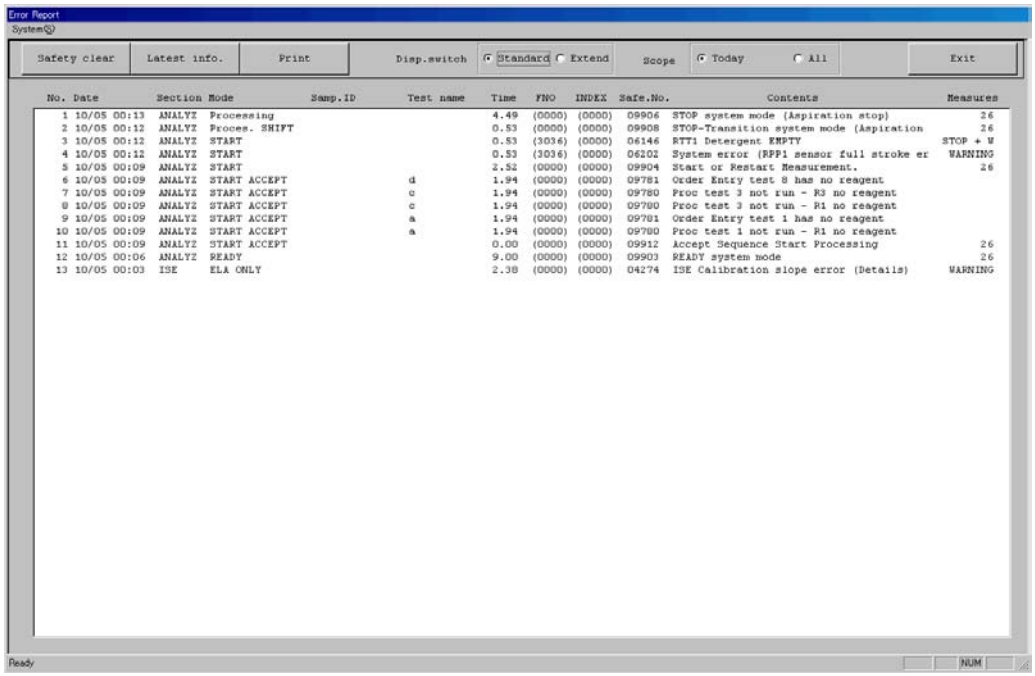
Click the [BUZZER] button to stop the sound.

Checking the error details

1) Click the [ALARM] button in the Operation Panel.

Or select [Maint.] in the Menu Panel and then [Error Report].

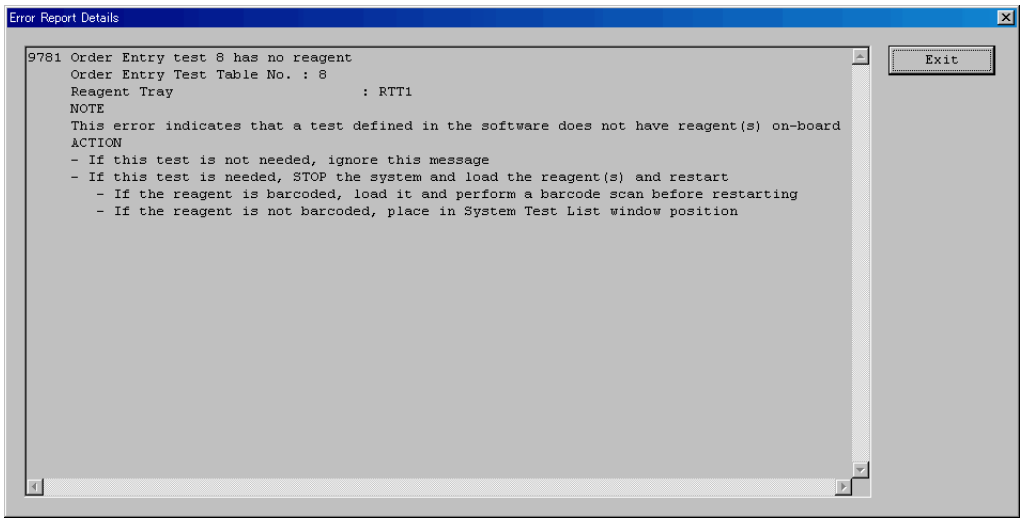
The [Error Report] window is displayed.



In this window, the error information is displayed in reverse chronological order (from latest to earliest).

2) Double-click the line of the event you would like to check.

The [Error Report Details] window shown below opens to display details of the error. Follow the instructions listed under "ACTION".



Types of alarms

Alarms sound both during operation and when the analyzer halts.

There are three ways the analyzer may respond after the alarm sounds:

- An alarm sounds and an error message is displayed while the operation continues.
- After the alarm sounds, sample dispensing stops, and the analyzer pauses in the "WAIT" mode after completing the ongoing measurements.
- After the alarm sounds, all operations immediately stop, and the analyzer pauses in the “WAIT” mode.

When the analyzer suspends in the “WAIT” mode after the alarm sound, it indicates a problem in the system that makes it unsafe to continue to use the analyzer. Do not restart the analyzer before fixing the problem.

8.4 Typical alarms and countermeasures

Alarm #	Error message / site	Cause / countermeasure
0903	Cuvette blank calculation error	【Cause】 1. A possible cause is an improper lamp function. The lamp function may be unstable immediately after replacement. 2. A possible cause is the degradation or insufficient washing of the reaction cuvette. 3. A possible cause is the shortage or waving of the reaction bath oil. 【Countermeasure】 1. Check the lamp energy. (Print the current [Lamp Energy Monitor] window for later comparison.) Change the lamp if the AD, voltage, or intensity value is abnormal. If the lamp has just been changed, leave it for approximately 30 minutes before checking the energy again. 2. Check the volume of reaction cuvette wash solution and c heck if the wash solution overflows. 3. Check the amount and f low rate of the reaction bath oil. If it is abnormal, replenish or regulate it. 4. Change the reaction cuvette. 5. If the above measures do not work, contact your local distributor.
0904	Cuvette blank calculation error Cuvette #1, flag #2 - The cuvette blank measurement results show the absorbance of the cuvette #1 is out of the ±0.04 range from the median cuvette blank value, therefore it is flagged with #2 (N, L, or H).	
1401 - 1411	System error or sample log (file) error	【Cause】 A possible cause is an i mproper PC data processing. 【Countermeasure】 If this error happens frequently, contact your local distributor.
2000 - 2199 2200 - 2220	Analytical condition error An error in sample / order data is detected.	【Cause】 A possible cause is an i mproper parameter, operation, or measurement. 【Countermeasure】 Check the error report details for the problem in the relevant sample data and analytical conditions, and perform corrective measures. If the error repeats, contact your local distributor.

Alarm #	Error message / site	Cause / countermeasure
2400 - 2428	Calculation error	【Cause】 Measurement / setting errors has caused an improper PC data processing. 【Countermeasure】 Check the error report details and the relevant settings. If the error repeats, contact your local distributor.
3001	LIS (Host) communication time-out	【Cause】 The workstation did not receive any signal from LIS within the defined time frame. 【Countermeasure】 Check if LIS is engaged in another processing. Select [Maint.] > [Communication Monitor] to check the values defined for time-out.
4201 - 4203	ISE communication errors	【Cause】 A possible cause is communication failure between the analyzer and the ISE unit. 【Countermeasure】 1. Exit and s hut down the system, then reboot. 2. If the problem is not solved, contact your local distributor.
4306	ISE Thermister error	【Cause】 A possible cause is failure or disconnection of the thermister, or di sconnection of the connector. 【Countermeasure】 Reconnect the connector.
4312 - 4319	ISE pump-related error	【Cause】 Functional failure of the pump 【Countermeasure】 1. "INITIALIZE" the system. 2. Perform "Priming" several times. 3. Power OFF and then ON the analyzer. 4. If the problem is not solved, contact your local distributor.
4327 - 4329	ISE calibration related error	【Cause】 The calibration result values are out of the reference range. 【Countermeasure】 1. Check the calibrator. 2. Perform calibration again. 3. If the problem is not solved, contact your local distributor.

Alarm #	Error message / site	Cause / countermeasure
6000 - 6002	Internal system error	【Cause】 Analyzer's internal communication or communication between analyzer and workstation fails. 【Countermeasure】 Exit the system and t hen reboot. If the problem is not solved, contact your local distributor.
6140	Diluent shortage in #1 Bottle position #2	【Cause】 The diluent level has reached the judgment level. The special diluents on the refrigerated tray (CTT) may be short. 【Countermeasure】 Check the remaining amount in the bottle and replenish as required.
6202 - 6203	RPP1 sensor full stroke error (detergent position) RPP2 sensor full stroke error (detergent position)	【Cause】 Reagent probe wash, pure water, or detergent may be short. (Reagent Tray (RTT) 1 or 2) 【Countermeasure】 Check the remaining amount in the bottle and replenish as required.
6208	WUD nozzle sensor error	【Cause】 The wide nozzle of the reaction carousel wash unit's (WUD) may be in contact with the cuvette and prevented to reach the bottom. 【Countermeasure】 1. Check the fixture and function as below. In case of trouble, follow the relevant steps described in Chapter 7: Maintenance. a) Check if the movement of WUD nozzles is blocked. b) Check if the WUD nozzles are fixed in the proper position. c) Check the fixture of the reaction cuvette. d) Check the fixture of the splash cover. e) Check if some foreign matter is blocking the reaction carousel movement. 2. Perform "INITIALIZE" several times and then perform "WASH" to check the movement. 3. If "INITIALIZE" fails or the error repeats, shut down and reboot the system. 4. If the problem is not solved, contact your local distributor.

Alarm #	Error message / site	Cause / countermeasure
6238 6240 6239 6241	MIX1 abnormal rotation speed MIX2 abnormal rotation speed MIXR1 abnormal rotation speed MIXR2 abnormal rotation speed	【Cause】 The number of the back and forth rotation movement of Mixer 1 or 2 (MIX1 or 2) may be out of the defined range. 【Countermeasure】 1. Remove the mixing rod and check the movement. If the movement is abnormal follow the steps to change the rod as described in Chapter 7: Maintenance. 2. Perform "INITIALIZE" and then select [Maint.] > [Manual Operation] and check the position of the mixing rod using, 40.MIXR1, 45.MIX1, 52.MIXR2, 57.MIX2. If the mixing rod is curved or misaligned, change or reattach it. 3. Perform "INITIALIZE" and "PRIME" several times. It they complete successfully, start the measurement while checking the status of the analyzer from time to time. 4. If "INITIALIZE" or "PRIME" fails and the error repeats, shut down the system and reboot. 5. If the problem is not solved, contact your local distributor.

<table>
<tr><th>Alarm #</th><th>Error message / site</th><th colspan="2">Cause / countermeasure</th></tr>
<tr><td rowspan="4">6255
-
6289</td><td>Clot A related errors
Abnormality detected when checking if the air pressure inside the probe returns to atmospheric after washing the inside of the probe in the carousel wash unit (WUD) with pressure from the pump</td><td>【Cause】
1. A possible cause is clot due to debris.
2. A possible cause is air trapped in the sample pump (SP) line or sampling and reagent wash pump (SRWP) line.
3. A possible cause is a defect in clot sensor.</td><td rowspan="4">【Countermeasure】
Check the followings. In case of trouble, follow the relevant steps described in Chapter 7: Maintenance.
1. [Common with Clots A - D] Check if air is trapped in the SP or SRWP lines,
If trapped, follow the steps to degassing the Large Water Pump (LWP) described in Chapter 7: Maintenance.
2. [Clot A] Follow the steps to clean or change the sample probe (SPP) tube described in Chapter 7: Maintenance.</td></tr>
<tr><td>Clot B related errors
Abnormality detected at the pressure check just before sample aspiration</td><td rowspan="3">【Cause】
1. A possible cause is air trapped in the SP or SRWP line.
2. A possible cause is a defect in clot sensor.</td></tr>
<tr><td>Clot C related errors
Abnormality detected at the pressure check when washing the inside of the probe with pressure from the pump</td></tr>
<tr><td>Clot E related errors
Abnormality detected when checking if the sensor is working properly just after starting operation from the [READY] mode</td></tr>
</table>

Alarm #	Error message / site	Cause / countermeasure	
6255 - 6289	Clot D related errors Abnormality detected by the pressure check at sample aspiration When this error message was once displayed for a sample but not for the next sample, the clot has been removed by probe wash with pressure from the pump.	【Cause】 1. A possible cause is fibrin deposed in the sample 2. A possible cause is the nozzle touching the bottom of the sample container due to the small sample volume. This error can occur when a small quantity is entered for "Sample Vol." in the [Analytical Parameters (Chemistry)] window and the nozzle touches the bottom of the sample container. The manufacturing variables of the container may contribute to this error.	3. [Clots B, C, and E] Perform "INITIALIZE" and "PRIME" several times. It they are completed successfully, start the measurement while checking the status of the analyzer from time to time. 4. [Clot D] Check the status of the sample. 5. If some foreign matter such as fibrin is found, take corrective measures, 6. If the error repeats, shut down the system and reboot. 7. If the problem is not solved, contact your local distributor.

Alarm #	Error message / site	Cause / countermeasure
9002	LWP gauge related errors	【Cause】 A possible cause is abnormal flow rate of the circulating water in the analyzer. 【Countermeasure】 1. Air may be trapped in the pure water circulation line. 2. Perform "INITAILIZE" and check the pressure gauge for the water circulation pump (LWP). If the pressure is 68 kPa or lower, degass the line. 3. Water supply may be improper. Check the status of the main valve of the water supply and the power status of the pure water supply unit.
9007	Leak under the pump compartment	【Cause】 Water leak is detected by the leak sensor placed in the lower back part of the pump compartment. 【Countermeasure】 Check the site and take an appropriate measure.
9010	Reaction bath (RRB) oil level is low.	【Cause】 The content of the RRB oil bottle may be insufficient. 【Countermeasure】 1. Remove the holder of reaction cuvettes to check the level of the RRB oil. 2. If the level is low, check the followings: a) Check the volume contained in the RRB oil bottle. Replenish it if it is insufficient. b) Check that the bottle and line are tightly connected and that the tube tip is securely inside of the RRB oil. 3. If the level of the oil is sufficiently high, check the followings: a) The liquid surface may be in motion so that the sensor detects the level incorrectly. b) Let the analyzer rest for approximately 5 minutes and see if the error repeats. 4. If the error persists, shut down, wait 5 minutes, then reboot. 5. If the problem is not solved, contact your local distributor.

Alarm #	Error message / site	Cause / countermeasure	
9012	RRB oil level sensor judgment logic failure	【Cause】 There are two sensors for the RRB level. One is for low level and the other for high. This error means a conflict that occurs between the values of the two sensors.	【Countermeasure】 1. The liquid surface may still be in motion after replenishment so that the sensor detects the level incorrectly. Let the analyzer rest for approximately 5 minutes and see if the error repeats. 2. If the error persists, shut down, wait five minutes, then reboot.. 3. If the problem is not solved, contact your local distributor.

CONTENTS

Chapter

9 Appendix 1: Saving test results as text file

9.1 Overview

The system can save and display the measurement results in two types of format. This chapter describes the procedure for saving results and how to read the output data.

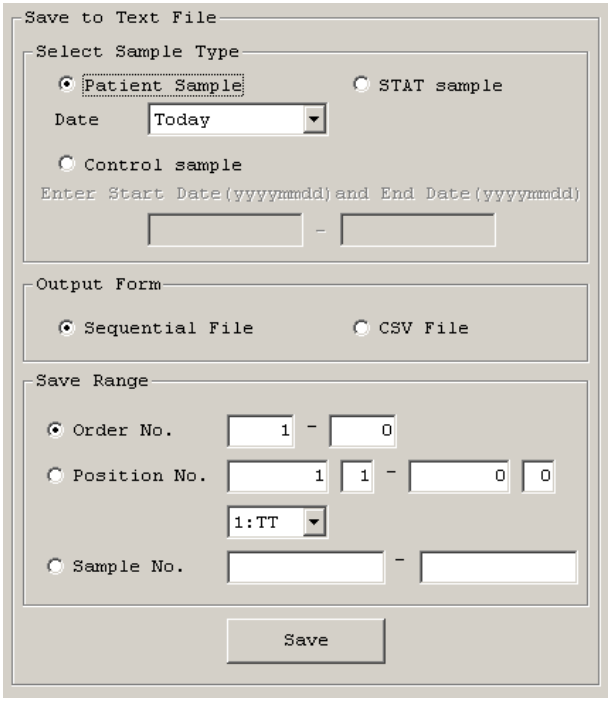
- The text file cannot be saved in the C:¥BIOMJ directory or its subdirectories. The data to be saved and displayed are the test results of the current day or those saved in the workstation regarding the routine samples including priority samples, STAT samples, and control samples.
- Please be sure there is sufficient free space available in your chosen file destination before attempting to save the text file, or the text file may not be successfully saved due to diskspace shortage.

9.2 Saving the Test Results

The [User Maintenance] window is used to save the test results as text file.

1) Select [Maint.] > [User Maintenance]

The [User Maintenance] window is displayed. In the [Save to Text File] column in the upper right side of the [User Maintenance] window, define the conditions to create a text file.



2) Select a [Sample type]

Select either "Patient Sample," "STAT Sample," or "Control Sample."

3) Select a [Date]

The default is "Today." When "Control Sample" is selected, enter the starting and ending dates from the last 60 days.

4) Select an [Output form]

Designate either "Sequential File" or "CSV File."

See “Section 9.3 Sequential File Display Format” and “Section 9.4 CSV File Display Format” for details on output formats.

5) Designate the range of data to be saved in the [Save Range] column.

Select one of the three designation methods below:

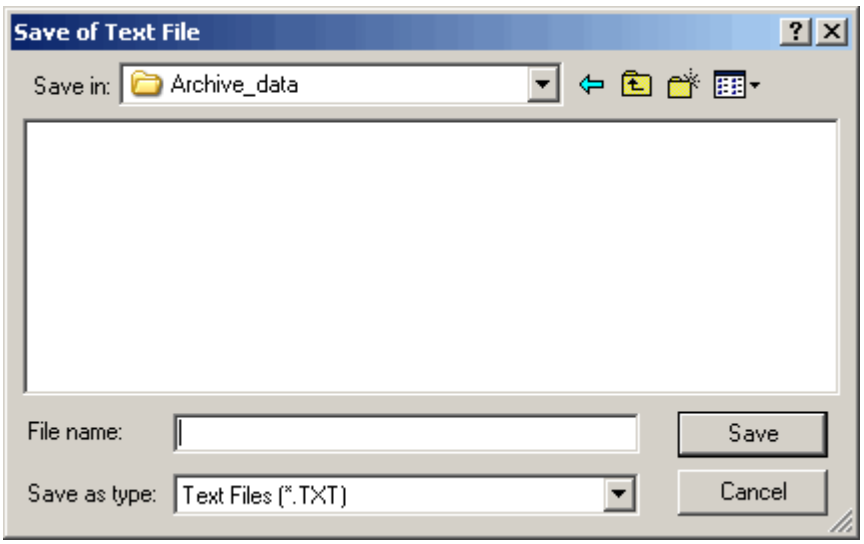
- Designation by "Order No."
- Designation by "Position No."

First, select "TT" or "RACK" and then enter the range.

- Designation by "Sample No."

6) Click the [Save] button

The [Save of Text File] window is displayed.



The default saving destination is "D:¥". The default extension is ".TXT" for sequential file and ".CSV" for CSV file.

7) Select the destination directory in the [Save in:] field, enter a file name in the [File name:] field, and then click the [Save] button.

The entered designations are saved. Close the [Save of Text File] window to return to the [User Maintenance] window.

9.3 Sequential File Display Format

Display format

```
[Sample Information]<CR><LF>
<Key word><TAB><data><CR><LF>
                :
[ITEM #]<CR><LF>
<Item Process Sequence No. ><TAB><Test item name><TAB><data>
<TAB><Mark><TAB><User code><CR><LF>
                :
 [Sample Information]<CR><LF>
<Key word><TAB><data><CR><LF>
                :
[ITEM #]<CR><LF>
<Item Process Sequence No. ><TAB><Test item name><TAB><data>
<TAB><Mark><TAB><User code><CR><LF>
```

Data for a single sample comprises the "Sample Information" section and the "ITEM #" section. The latter section contains the test results. "TAB" is used to separate the abbreviation of the test, its value, and the values in the "ITEM #" section. The abbreviation of the test in the "Sample Information" section is displayed whether or not there is a corresponding result; however, the test result is displayed only when the test is ordered.

Details of data display format for one sample

Sample Information section

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
[	S	a	m	p	l	e		I	n	f	o	r	m	a	t	i	o	n	]	CR	LF

○Sample ID

1	2	3	4	5	5+n1	6+n1
P	I	D	TAB	1*	CR	LF

n1 : byte count of the value in 1*

The field "1*" (the 5th byte) contains the sample ID (maximum size: 13 bytes).

The size varies by sample type.

IDs from PA001 to PZ200 are used for control samples, where PA - PZ indicate the control sample types and 001 - 200 indicate the number of measurement times for each sample type.

IDs in the format of “Cttnn” or “Mttnn” such as C0101 or M98010 are used for calibrators, where “tt” indicates the position number and “nn” the number of measurement times.

○Position number

1	2	3	4	5	5+n2	6+n2
P	O	S	TAB	2*	CR	LF

n2: byte count of the value in 2*

The field "2*" contains the position number (maximum size: 11 bytes).

When using the sample or refrigerated trays (TTs), the value will be TT# (1 - 97) - Cup No. (1 - 84).

When an optional rack is used, the value will be the rack number (00000001-99999999) - the position number (1 - 10).

When a barcode is used, the value will not be displayed (0 byte).

○Dilution factor

1	2	3	4	5	6	7	8	8+n3	9+n3
F	A	C	T	O	R	TAB	3*	CR	LF

n3: byte count of the value in 3*

The field "3*" contains the dilution factor (maximum size: 4 bytes including 1 digit after the decimal point).

Dilution factor 10 is displayed as 10.0.

○Container type

1	2	3	4	5	6	7	8	9	10	11	12
C	U	P		T	Y	P	E	TAB	4*	CR	LF

The field "4*" shows the container type (maximum size: 1 byte).

The value is 1 - 9.

○Sample type

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
S	A	M	P	L	E		T	Y	P	E	TAB	5*	CR	LF

The field "5*" shows the sample type (maximum size: 1 byte).

The value "1" indicates serum and "2" urine.

○Comment 1

1	2	3	4	5	6	7	8	9	10	10+n6	11+n6
C	O	M	M	E	N	T	1	TAB	6*	CR	LF

n6: byte count of the value in 6*.

The field "6*" contains the comment #1 (maximum size: 16 bytes.)

When no value is entered, nothing will be displayed (0 byte).

○Comment 2

1	2	3	4	5	6	7	8	9	10	10+n7	11+n7
C	O	M	M	E	N	T	2	TAB	7*	CR	LF

n7: byte count of the value in 7*.

The field "7*" contains the comment #2 (maximum size: 16 bytes).

When no value is entered, nothing will be displayed (0 byte).

○Age

1	2	3	4	5	5+n8	6+n8
A	G	E	TAB	8*	CR	LF

n8: byte count of the value in 8*.

The field "8*" contains the patient's age (maximum size: 3 bytes.)

When no value is entered, nothing will be displayed (0 byte).

○Sex

1	2	3	4	5	6	7
S	E	X	TAB	9*	CR	LF

The field "9*" shows the patient's sex (maximum size: 1 byte.)

The value "1" represents male, "2" female, and "3" unknown.

○The number of ordered tests

1	2	3	4	5	6	7	8	8+n10	9+n10
I	T	E	M		#	TAB	10*	CR	LF

n10: byte counts for the value in 10*

The field "10*" contains the number of ordered tests

(maximum size: 3 bytes).

✔ Test results section

○Test results

1	2	3	4	5	6	7	8	9	10
[	I	T	E	M		#	]	CR	LF

11*	TAB	12*	TAB	13*	TAB	14*	TAB	15*	CR	LF	
11*	TAB	12*	TAB	13*	TAB	14*	TAB	15*	CR	LF	

The number of results displayed is as defined in 10* above.

The field "11*" contains the Process Sequence number ranging from 1 to 326 (maximum size: 3 bytes).

The field "12*" contains the Test Name (maximum size: 10 bytes).

The field "13*" contains the measurement value.

The measurement value of concentration is right aligned with the total size of 9 bytes. The result value of qualification has a variable size with maximum of 6 bytes. When the test is not performed, no value is displayed (0 byte). For concentration, the number of digits after the decimal point varies according to the analytical conditions defined for each test. When the result is manually edited, an "E" mark is displayed at the top field and the total size is 10 bytes.

The field 14* contains the flag corresponding to the abnormality detected by the data check function (maximum size: 10 bytes).

When the test is not performed, no value is displayed (0 byte).

The results of a general test have 10 bytes and are displayed as below:

A general test is a chemical test, ratio test, or ISE test.

Chemical test

The first character (1st byte) in this field is the flag character H, L, h, or l as detected by data check.

The flag characters "S", "s", "r", "t", "A", "M", "Q", "G", "F", "c", "u", "d", "U", "D", "P", "*", "n","N", "R", "/", "V", "v", "W", "w", "X", "x", "C", "J", "O", "Z", "f", "q", "a", and "z" are shown left aligned from the second to tenth bytes when applicable. The flag characters exceeding the space limit are not shown.

Ratio test

The first character (1st byte) in this field is the flag character H, L, h, or l as detected by data check.

Two flag characters "R" and "/" are used for ratio tests. Two or more flag characters are displayed left aligned from the second byte onwards in the order of "R" and "/".

ISE test

The first character (1st byte) in this field is the flag character H, L, h, or l as detected by data check.

The flag characters "s", "S", "u", "*", "B", "r", "C", "T", "I", "d", "/", "R", "A", "Q", "G", "O", and "c" are shown left aligned from the second to tenth bytes when applicable.

For the flag display in all the test results above, if the number of flag characters is smaller than 10, a one-byte space (20H in the ASCII code) will be inserted in each empty space.

The serum test is not a general test, therefore, a 10-byte space will be inserted.

The 15* field contains the User Code (maximum size: 4 bytes).

```
Example of display format
[ITEM #]
1      AST_______      ___999.99       HsR_______      USR
2      ALT_______      ___999.99       _sR_______      USR
3      TP________      E___999.99      HsR_______      USR
4      HDL-C_____      ___999.99       __________      USR
                                    (" _ " indicates space)
```

9.4 CSV File Display Format

Display format

Sample Information section

1*	,	2*	,	3*	,	4*	,	5*	,	6*	,	7*	,	8*	,	9*	,	10*	,	

Test result section

11*	,	12*	,	13*	,	14*	,	15*	,	···	11*	,	12*	,	13*	,	14*	,	15*	,	CR	LF

1st test　　10th test

:

Sample Information section

1*	,	2*	,	*3	,	4*	,	5*	,	6*	,	7*	,	8*	,	9*	,	10*	,	

Test result section

11*	,	12*	,	13*	,	14*	,	15*	,	···	11*	,	12*	,	13*	,	14*	,	15*	,	CR	LF

Data for a single sample comprises the "Sample Information" section and the "ITEM #" section. The latter section contains the test results. Each value is in double quotation marks and a comma is inserted to separate the values. “CR” and “LF” mark the end of the sample result. Undefined values are not displayed, but the separator commas are. As many test results as ordered are displayed.

Details of data display format for one sample

Sample Information section

○Field "1*"

The field "1*" contains the sample ID (maximum size: 13 bytes).
The ID varies by sample type.

IDs from PA001 to PZ200 are used for control samples, where PA – PZ indicate the control sample types and 011 – 200 indicate the number of measurement times for each sample type.
IDs in the format of “Cttnn” or “Mttnn” such as C0101 or M98010 are used for calibrators, where “tt” indicates the position number and “nn” the number of measurement times.

○Field "2*"

The field "2*" contains the position number (maximum size: 11 bytes).
When the sample or refrigerated trays (TTs) are used, the value will be TT# (1 - 97) - Cup No. (1 - 84).
When an optional rack is used, the value will be the rack number (00000001-99999999) - the position number (1 - 10).
When the barcode is used, the value will not be displayed (0 character).

○Field "3*"

The field "3*" contains the dilution factor (maximum size: 4 bytes including 1 digit after the decimal point).
The dilution factor 10 is displayed as 10.0.

○Field "4*"

The field "4*" shows the container type (maximum size: 1 byte).
The value ranges 1 - 9, showing the container type.

○Field "5*"

The field "5*" shows the sample type (maximum size: 1 byte).
The value is "1" for serum or "2" for urine.

○Field "6*"

The field "6*" contains the comment #1 (maximum size: 16 bytes).
When no value is entered, nothing will be displayed (0 byte).

○Field "7*"

The field "7*" contains the comment #2 (maximum size: 16 bytes).
When no value is entered, nothing will be displayed (0 byte).

○Field "8*"

The field "8*" contains the patient's age (maximum size: 3 bytes).
When no value is entered, nothing will be displayed (0 byte).

○Field "9*"

The field "9*" contains the patient's sex (maximum size: 1 byte).
The value "1" represents male, "2" female, and "3" unknown.

○Field "10*"

The field "10*" contains the number of ordered tests (maximum size: 3 bytes).

✔ Test result section

○Field "11*"

The field "11*" contains the Process Sequence number (maximum size: 3 bytes.)
The value ranges from 1 to 326.

○Field "12*"

The field "12*" contains the Test Name (maximum size: 10 bytes.)

○Field "13*"

The field "13*" shows the test result.
The result value of concentration has fixed size of 9 bytes in total and is displayed right aligned. The result value of qualification has a variable size with maximum 6 bytes. When the test was not performed, no value is displayed (0 byte). For concentration, the number of digits after the decimal point varies according to the analytical conditions defined for each test.

○Field "14*"

The field 14* contains flag characters (maximum size: 11 bytes).
When no abnormality was detected, no value is displayed (0 byte).
The flag space for a general test has 11 bytes.

A general test is a chemical test, ratio test, or ISE test, and the flags are dispayed in the following manner.

Chemical test

The first character (1st byte) in this field is the flag character H, L, h, or l as detected by data check.
The flag characters "S", "s", "r", "t", "A", "M", "Q", "G", "F", "c", "u", "d", "U", "D", "P", "*", "n","N", "R", "/", "V", "v", "W", "w", "X", "x", "C", "J", "O", "Z", "f", "q", "a", and "z" are shown left aligned from the second to tenth bytes when applicable. The flag characters that are exceeting the space limit are not shown.

Ratio test

The first character (1st byte) in this field is the flag character H, L, h, or l as detected by data check.

Two flag characters "R" and "/" are used for ratio tests. Two or more flag characters are displayed left aligned from the second byte onwards in the order of "R" and "/".

ISE

The first character (1st byte) in this field is the flag character H, L, h, or l as detected by data check.

The flag characters "s", "S", "u", "*", "B", "r", "C", "T", "I", "d", "/", "R", "A", "Q", "G", "O", and "c" are shown left aligned as the second to tenth bytes when applicable.

For the flag display in all the test results above, if the number of flag characters is smaller than 11, a one-byte space (20H in the ASCII code) will be inserted in the empty space.

When the manual editing mark "E" is displayed as the first byte, either "H", "L", "h", or "l" will be the second byte, and then, the above characters will be shown left-aligned in the indicated order as the third to eleventh bytes if applicable.

In case of serum test, 10-byte space is displayed.

The field “15*” contains the User Code (maximum size: 4 bytes).

Example of display format of the test result section

,"1","AST_____","___999.99","HsR_____","USR_","2","ALT_____","___999.99","_sR_____","USR_","3","TP_____","___999.99","EHsR_____","USR_","4","HDL-C_____","___999.99","_____","USR_",

(" _ " indicates space)

CONTENTS

Chapter

10 Appendix 2: Using a Laboratory Automation System (LAS)

10.1 Overview

This chapter describes the specific operation of the BM6010/C analyzer system in combination with a laboratory automation system (LAS).

Handle the LAS according to the instructions given in the LAS manual.

Refer to "Section 1.5 Instructions for Installation and Connection Specifications of the BM6010/C System."

10.1.1 Operational types of the system connected with a LAS

The BM6010/C system is generally on-line with a LAS or a laboratory information system (LIS) to use samples that are externally delivered.

The operational type is thus different according to the functions of the LAS or LIS.

The table below summarizes the principal operational types.

Principal operational types of the analyzer system connected with a LAS/LIS

	Sample Identification	Sample supplier	Test registration with LIS	Operational type
1)	Barcode	LAS	Real-time	Patient sample is delivered externally.
2)	Barcode	LAS	Batch	Same as above, when automatic on-line communication is not available.
3)	Barcode	LAS	N/A	Same as above, when the order has been placed in advance via workstation.
4)	Barcode	Sample tray (STT)	Automatic	Used when samples are more efficiently measured using STT as in the case of priority and rerun samples.
5)	Barcode	STT	Batch	Same as above, when automatic on-line communication is not available.
6)	Barcode	STT	N/A	Same as above, when the order has been placed in advance via workstation.
7)	TT-CUP	STT	Automatic	Used to measure the samples for which barcode cannot be applied.
8)	TT-CUP	STT	Batch	Same as above, when automatic on-line communication is not available.
9)	TT-CUP	STT	N/A	Same as above, when the order has been placed in advance via workstation.

10.1.2 On-line communication during operation with a LAS

The table below summarizes the on-line communication flow for a sample between the analyzer and a LAS/LIS.

More details are available in "BM6010 Laboratory Information System On-Line Signal Specification" and " JCA-BM6010/C Laboratory Automation System Connection Specification."

On-line communication flow

Direction	Action	Remarks
LAS/LIS → BM	Notifies that LAS/LIS is ready.	At start
LAS/LIS ← BM	Notifies that BM is ready.	At start
LAS/LIS → BM	Notifies BM of the sample ID before the sample arrives at the sampling position.	
LAS/LIS ← BM	Inquires which tests are ordered for the sample.	
LAS/LIS → BM	Indicates which tests are ordered for the sample.	
LAS/LIS → BM	Requests BM to start sampling.	
LAS/LIS ← BM	Requests the sample ID to LAS/LIS for reconfirmation.	
LAS/LIS → BM	Sends the sample ID.	
BM	Aspirates and dispenses the sample.	
LAS/LIS ← BM	Indicates the end of sampling.	
LAS/LIS ← BM	Transfers the result at the completion of measurement.	

10.1.3 Use of the sample tray (STT) when the system is connected with a LAS/LIS

The sample tray (STT) is used exclusively for priority samples when the system is operating in the LAS/LIS mode (connected with a LAS/LIS).

Any samples that cannot be handled with the LAS/LIS are handled with the STT.

10.2 Setting the External Sample Delivery

This section describes the settings that require modification depending on the delivery method.

Double-check these settings when you have changed the sample delivery method.

The following windows are used for modifying the settings:

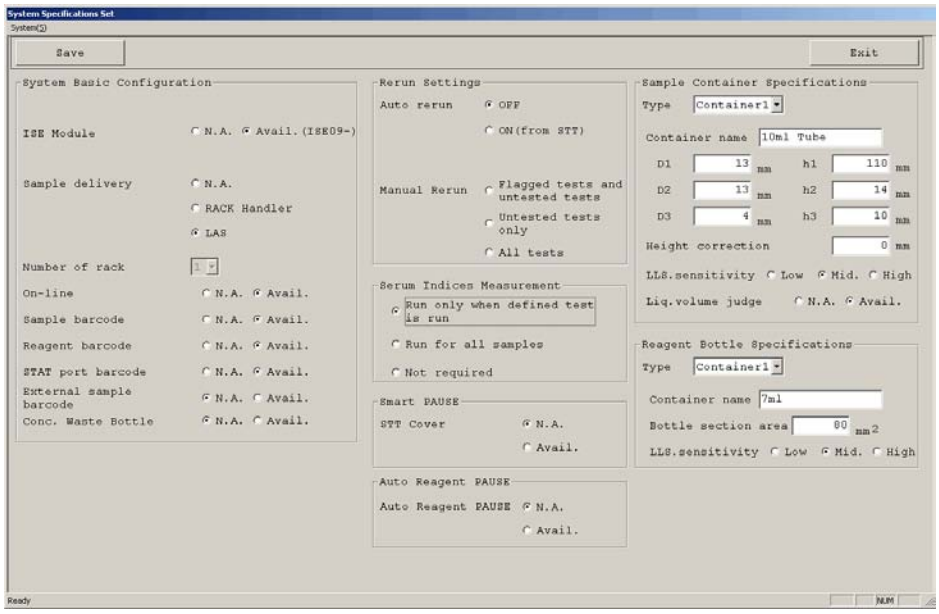
- [System Specification Set] window
- [Online Settings] window as required
- [System Monitor] window
- [Setting System Parameters] window as required

After setting the parameters, shut down the system once and then reboot. Select "New start" after changing a parameter, or otherwise, select "Restart" to reboot.

10.2.1 [System Specification Set] window

Use the [System Specification Set] window to use the analyzer with a LAS/LIS.

Select [Setup] > [System Specification Set] to open the window.



[System Specification Set] window

Define the following parameters in this window.

In the [System Basic Configuration] column, select "LAS" for [Sample delivery].

In the [Sample Container Specifications] column, define the types of container used in the LAS.

Steps to define the container types

When the sample is delivered via the LAS, the container type should be correctly defined so that the BM6010/C system can behave accordingly.

Warning

Be sure to specify the correct container type. Otherwise:

- The probe may not be lower appropriately into the container which will cause erroneous results or,
- The probe may break if it lowers too far into the container.

The container type can be defined by in one of three places:

- In the [Order Entry] window in the workstation
- Via the LIS
- Via the LAS

If different values are entered in the above places, the definition via the LAS has the priority.

The container type is identified by a sample container number which is predefined by the LAS/LIS. The same sample container will have a different number when used with the LAS/LIS than when used with the sample tray (STT). Generally, a common number is defined for the LAS and LIS, but the number used with the STT is the same that is defined in the [Cup/Tube Assign] window. The table below shows an example of set values.

Example of settings

Sample Container #	Type	Remarks
[Sample container 1]	10 mL sample tube	For STT
[Sample container 2]	JCUP B	For STT
[Sample container 3]		
[Sample container 4]		
[Sample container 5]	STAT sample container	For STT
[Sample container 6]	STAT urine sample container	For STT
[Sample container 7]		
[Sample container 8]		
[Sample container 9]	LAS sample container	For LAS/LIS

In the example above,

- when the container information is obtained via the LIS, all the containers will be “Sample container 9” for the LAS,
- otherwise, or when any of the other containers is used, designate the type for the [Container type] field in the [Order Entry] window.

The sample container for the LAS is already entered as "Sample container 9." If you wish to change it, the new number should be the same for the BM6010/C, the LAS, and the LIS settings. On the other hand, there is no restriction in adding or editing containers to be used only in the sample tray (STT).

When the LAS accepts two or more types of containers, they should be entered separately. If the LIS has a feature to designate the container type for each sample on the LAS sample delivery line, then “Sample Container #0(Priority Requested)” can be selected in the LAS to signify that the container type will be designated by the order. In this case, the container type is selected for each sample by the LIS.

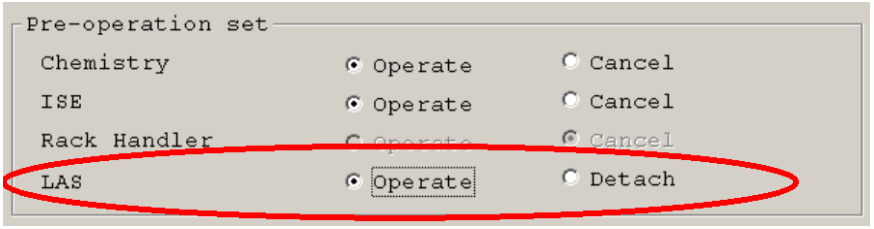
10.2.2 [Online Settings] window

Online settings related to the LAS can be modified if necessary.

See “Section 5.8.2 Online Settings” for details about the [On-line Settings] window.

10.2.3 [System Monitor] window

In order to use the LAS, select "Operate" for [LAS] in the [Pre-operation set] column in the [System Monitor] window. To access the [System Monitor] window, select [Maint.] > [System Monitor].



Selecting operation with a LAS in the [Pre-operation set] column in the [System Monitor] window

10.2.4 [Setting System Parameters] window

The window is used to modify LAS related parameters if required.

Select [Setup] > [Setting System Parameters] to open the window.

The default values are selected. Edit the values only when a modification is required for reasons such as a change in the LAS specification.

Refer to “Section 5.9 Parameters in the [Setting System Parameters] Window” for details on the [Setting System Parameters] window.

The LAS-related parameters and the default values are as follows:

[LAS First sample waiting time] 30 seconds

This is the time from the start of the analyzer by the LAS to the arrival of the first sample. If the sample is not delivered during this period, the analyzer enters into the [WAIT] mode.

[LAS Next sample waiting time] 30 seconds

This is the time from sending out the dispensed sample to the arrival of the next sample. If the next sample is not delivered during this period, the analyzer enters into the [WAIT] mode.

[LAS Max dummy cycle] 20 cycles

This is the maximum waiting time after the LAS sends a signal to the analyzer that the next sample is coming until the sample actually arrives at the sampling position. If the sample is not delivered during this period, the analyzer judges it as sample non-arrival error and enters into the [STOP] mode from which the operation cannot be resumed.

10.3 Analyzer Operation While Using a LAS

This section describes the typical steps of the analysis operation connected with a LIS/LAS.

10.3.1 Beginning analyzer operation

1) **Start the LIS.**
2) **Start the LAS.**
3) **Start the pure water supply unit.**
4) **Start BM6010/C.**

See “Section 4.2 Getting Started” for starting BM6010/C.

5) **Prepare the LAS for connection with the analyzer as required.**
6) **Begin operation of the BM6010/C connected with the LAS.**

When you start the LIS after starting the analyzer, inappropriate communication may occur. If so, delete these communication data before starting operation by clicking the [HOST ON] button on the Operation Panel to turn it to [HOST OFF], and then clicking it again to turn it back to [HOST ON].

10.3.2 Ending analyzer operation

1) Change the analyzer to the READY mode.

When the analyzer connected with the LAS has completed a measurement run, it enters into the [WATCH] mode instead of the [READY] mode.

Operation Panel showing the [WATCH] mode

Click the [STOP] button in the Operation Panel and wait for the mode window to indicate a change from [WATCH] to [READY] before ending analyzer operation.

2) Perform the routine ending operation.

See “Section 4.13 System End・Shutdown” for instructions for ending operation of the BM6010/C.

3) Perform the ending operation of the water supply unit.

4) Shut down the LAS.

5) Shut down the LIS.

10.3.3 Measurement of priority and rerun samples during operation with the LAS

Priority and rerun samples can be dispensed from the sample tray instead of the LAS external sample delivery system. Samples with an ID but no readable barcode label can be dispensed in the same way.

1) Enter the order information.

If the LIS has the relevant order information, the order is placed automatically online. Otherwise, follow the steps below to enter the order information at the workstation.

1 Select [Request] > [Order Entry].

The [Order Entry] window is displayed.

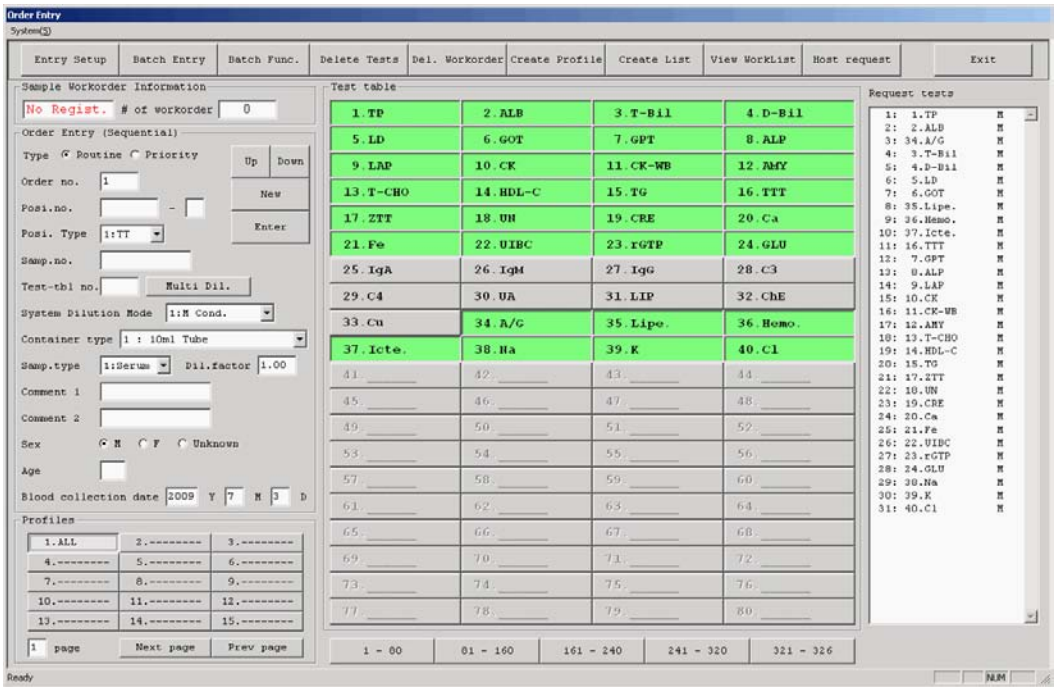


Figure 7. [Order Entry] window

2 Enter the sample ID in the [Samp.no.] field.

When the sample has no ID, enter a sample number (up to 13-digit arbitrary but unique number) for ordering.

3 Define a container type for the [Container type] field.

Skip this step if it has been already defined in the [Cup/Tube Assign] window.

2) Click the [PAUSE] button in the Operation Panel when the analyzer is in the [START] or [WAIT] mode during the operation with the LAS.

3) Wait until the "SMP LOAD OK (Append)" message is displayed under the [PAUSE] mode display.

Operation Panel showing the [PAUSE] mode and "SMP LOAD OK" notification.

Warning

Be sure to perform the following steps after confirming the analyzer is in the [PAUSE] mode and the panel shows "SMP LOAD OK (Append)." Otherwise, the probes move when the sample arrives via the LAS. Therefore, the operator risks injury by contact with the probe and possible infection via contact with the serum. Furthermore, the probes or trays may be damaged.

4) Place the sample in the sample tray.

Place the sample in a position assigned to the correct container, if it has been already defined in the [Cup/Tube Assign] window.

5) Click [START] in the Operation Panel.

The [Start Conditions] window is displayed.

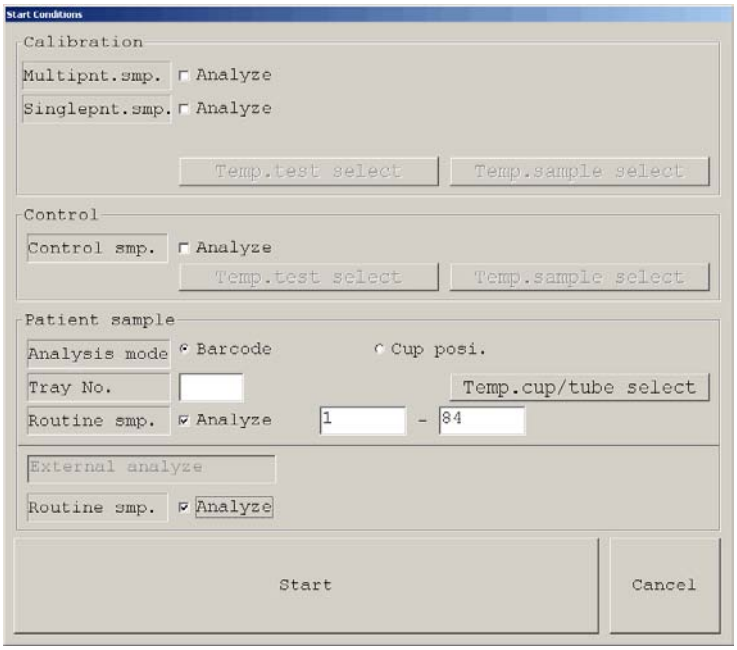


Figure 9. [Start Conditions] window

6) Define the container type.

Skip this step if it has been already defined in the [Cup/Tube Assign] window.

7) Define [Patient Sample] as shown in Figure 9.

For [Analysis mode], select "Barcode"

For [Routine samp.], select "Analyze", then enter [1] - [84] (sample tray (STT) positions).

For [Routine samp.] under [External analyze], select "Analyze"

Using these settings, the analyzer will complete the measurement of the samples dispensed from STT, then enter into the [WAIT] mode for the sample arrival via the LAS.

8) Click [START].

The analyzer will begin reading the barcode of the samples in the STT.

After reading the barcode, a confirmation window is displayed. The barcode can be edited here if required. If the barcode is not able to be read, enter the sample ID here.

9) Click [OK].

The analyzer starts measurement.

- Do not click the [HOST ON] button during operation with the LAS. If you click the button, the connection with the LIS will be cut off.
- The analyzer will complete reading the sample barcode and send a request to the LIS for an order on the sample ID.

10.3.4 Stand-alone operation of BM6010/C

In stand-alone operation, the analyzer is not connected to the LAS/LIS. It operates independently when the LAS and LIS are not in operation. The operational steps are as follows:

i. Select "Detach" for the LAS in the [System Monitor] window.

In “Detach” status, the analyzer does not respond to the LAS. Note that an error may occur on the LAS if the LAS is in operation.

ii. Click the [HOST ON] button on the Operational Panel to toggle it to [HOST OFF].

In [HOST OFF] status, the analyzer does not receive order information from the LIS nor will the measurement results be sent to the LIS.

iii. Follow the steps below to enter order information at the workstation.

1) Select [Request] > [Order Entry].

The [Order Entry] window is displayed.

2) Enter the sample ID in the [Samp.no.] field.

When the sample does not have a barcode, enter an arbitrary but unique ID for ordering.

3) Define the container type.

Skip this step if you define it during measurement or if it has been already allocated to the sample tray (STT) position in the [Cup/Tube Assign] window.

4) Place the sample in the STT.

5) Click [START] in the Operation Panel.

The [Start Conditions] window is displayed.

6) Define the container type.

Skip this step if it was defined in step 3 or if it has been already allocated to the STT position in the [Cup/Tube Assign] window.

7) Select "Barcode" for [Analysis mode].

8) Click [START].

The analyzer starts reading the barcode of the sample in the STT.

After reading the barcode, a confirmation window is displayed. The barcode can be edited here if required. If the barcode could not be read, enter the sample ID here.

9) Click [OK].

The analyzer starts measurement.

10.4 Resuming Operation after a Trouble

10.4.1 Steps for resuming operation when a trouble occurs with the LAS

1) The analyzer automatically stops.

When a trouble occurs on a sample on the LAS during sampling, the analyzer stops automatically.

The measurement continues for the dispensed samples.

2) Remove the samples from the LAS.

3) Troubleshoot the problem with the LAS.

See the instructions in the LAS manual for troubleshooting and how to remove the samples from the LAS.

4) Wait until the analyzer enters in the [READY] mode.

It may take some time before the analyzer enters in the [READY] mode because procedures such as a rerun order utilizing the sample tray (STT) or cuvette washing to eliminate contamination must be completed.

5) Prepare the LAS for operation.

6) Perform [INITIALIZE] of the analyzer to start the next measurement.

10.4.2 Steps for resuming operation when a trouble occurs with the analyzer

Cases in which the operation can be resumed

When the [STOP] button on the Operation Panel is pressed for some trouble, the mode will change in the following order: STOP shift - STOP - END - READY. In this case, the operation can be resumed as follows depending on the system mode of the analyzer.

- In the [STOP shift] or [STOP] mode:
  The analyzer can be restarted to continue measurement.
- In the [END] mode:
  Wait until the mode becomes [READY].
- In the [READY] mode:
  The analyzer can be restarted to continue measurement.

When the [STOP] button on the Operation Panel is pressed during measurement and the mode is forced to be [READY], the sample whose first barcode reading has already been finished will be skipped because the

order for the further barcode reading is canceled. A new measurement order should be placed for this sample.

Cases in which the operation cannot be resumed

When an accident occurs (e.g. the probe has hit something), the analyzer automatically stops and the mode shifts to [STOP]. When this occurs, the [PAUSE], [STOP] and [START] buttons on the Operation Panel are grayed out and cannot be used. In this case, please follow the steps below to resume the operation.

1) **Wait until the analyzer enters in the [WAIT] mode.**
   It may take some time before the analyzer will enter in the [WAIT] mode because procedures such as a rerun order utilizing the sample tray (STT) or cuvette washing to eliminate contamination must be completed.
2) **Remove the samples from the LAS.**
3) **Eliminate the cause of the trouble.**
   Check the error message and act accordingly.
4) **Perform the [WASH] procedure as required.**
   When the analyzer stops with the reagent dispensed in the reaction cuvettes, cuvette contamination may occur when measurement is resumed.
5) **Prepare the LAS for operation.**
6) **Perform [INITIALZE] of the analyzer to start.**
   Check the last sample that was measured properly and resume the measurement of the next sample and onwards.

Emergency Stop

When the [SYSTEM STOP] button on the analyzer is used, or when the operation cannot continue due to some problem in a unit, the analyzer makes an emergency stop. In this case, the analyzer enters into the [WAIT] mode.

1) **Remove the samples from the LAS.**
2) **Eliminate the cause of the trouble.**
3) **Perform the [WASH] procedure as required.**
   When the analyzer stops with the reagent dispensed in the reaction cuvettes, cuvette contamination may occur when measurement is resumed.
4) **Prepare the LAS for operation.**
5) **Perform [INITIALZE] of the analyzer to start.**

CONTENTS

Chapter

11 Appendix 3: Flags

This appendix 3 describes various flags with the required countermeasures to take. The cause of the flag posted on a data should always be identified.

CONTENTS

11.1 Flagging Function

The BM6010/C system checks the measurement values for abnormality, and a data with high possibility of abnormality is posted with the flag corresponding to the type of abnormality. This function is called flagging.

11.1.1 Flags used for the chemistry tests

Flags posting and rerun triggered by a flag can be setup in the [Analytical Parameters (Chemistry)] window.

List of flags

Flag	Incidence type	Judgment
S	System abnormality	
S	Sample shortage	
t	Diluent shortage	
r	Reagent shortage	
N	Cuvette blank abnormality	6.1.3a Check for the reaction cuvettes
u, U	Over the higher absorbance limit	6.1.3c Check with calculated absorbance (ABS) 6.1.3d Check with reaction ABS
d, D	Below the lower absorbance limit	6.1.3c Check with calculated ABS 6.1.3d Check with reaction ABS
*	Variance abnormality	6.1.3c Check with calculated ABS
n	Abnormality in the number of effective points (Effevt.nbr.o.pnts)	6.1.3c Check with calculated ABS
P	Prozone abnormality	6.1.3c Check with calculated ABS
h, l	Normal value limit	6.1.3e Check by concentration and unit
H, L	Abnormal value limit	6.1.3c Check with calculated ABS 6.1.3d Check with reaction ABS 6.1.3e Check by concentration and unit
R	Rerun data	
C	Calibration failure	6.1.3e Check by concentration and unit
V, v	Abnormal value with main wavelength in the section of reagent 1(V), Abnormal value with main wavelength in the section of reagent 1(v) R1 main waveform error (V), R1 sub waveform error (v)	6.1.3b Check with the reaction process
W, w	Abnormal value with main wavelength in the	6.1.3b Check with the reaction

Flag	Incidence type	Judgment
	section of reagent 2e (W), Abnormal value with main wavelength in the section of reagent 2e (w) R2e main waveform error (W), R2e sub waveform error (w)	process
X, x	Abnormal value with main wavelength in the section of reagent 2 (X), Abnormal value with main wavelength in the section of reagent 2(x) R2 main waveform error (X), R2 sub waveform error (x)	6.1.3b Check with the reaction process
A	Clot detection	
M	Mixer (Mix) error	
Q	Liquid level sensor error	
G	Probe hits something (Crash)	
F	Abnormal temperature (outside the range of 37°C±0.3) in the reaction bath (Temperance error)	
c	Calibration mismatch	
f	Multiple normal data error (Plural normal data)	
q	Borderline data	
a	No normal data	
z	Invalid data (Bad data)	
Z	Abnormal calibration data	6.1.3f Check with the previous STD value
///////	Overflow	

11.1.2 Flags used for the ISE tests

Flags posting and rerun triggered by a flag can be setup in the [Rerun Condition Set] window. Click the [Rerun cond.] button in each column in the ISE Parameter Setting] window to display the window.

List of flags

Flag	Incidence type	Judgment
S	Safety	
S	Sample shortage	
r	Buffer shortage	
T	Thermistor abnormality	
u	Abnormal selectivity	
C	Abnormal range	6.2.2 Calibration
*	H-STD error or L-STD error	
d	Abnormal dilution factor	6.2.2 Calibration
B	Abnormal liquid volume in the dilution bowl	
h, l	Normal value limit	6.2.2 Calibration
H, L	Normal value limit	6.2.2 Calibration
I	ID error	
R	Rerun data	
A	Clot	
G	Probe hits something (Crash)	
Q	Liquid level sensor error	
///////	Overflow	

11.2 Countermeasures for Flags in Chemistry Tests

11.2.1 S: System abnormality

An abnormality has occurred in the system, which might affect the measurement value.

Cause

Causes of the error can be identified by the error message displayed when the abnormality occurred.

Countermeasure

Click the [Alarm] button in the Operation Panel to display the [Error Report] window. Search the ID of the sample whose data is flagged with "S."

Click the corresponding line to show the [Error Report Details] window to see the content.

11.2.2 s: Sample shortage

The sensor in the sample probe judges the sample volume is short.

Cause

The sample volume is small.

A container different from the designated one is used.

The type of container is not correctly selected.

Impurities on the probe

Countermeasure

Check that sufficient volume of sample is in the container judged short of sample.

Check that the correct container type is selected in the [Order Entry] window.

Follow the steps to clean the probes described in "Section 7.3.1b Check the probes for impurities" in Chapter 7 of the manual.

11.2.3 t: Diluent shortage

The sensor in the sample probe judges the volume of the diluent on CTT is short.

Cause

The diluent volume is small.

Impurities on the probe

Countermeasure

Check that sufficient volume of diluent is in the container, and measure again.

Follow the steps to clean the probes described in “Section 7.3.1b Check the probes for impurities” in Chapter 7 of the manual.

11.2.4 r: Reagent shortage

The sensor in the reagent probe judges the reagent volume is short.

Cause

The reagent volume is small.

A container different from the designated one is used.

Impurities on the probe

Countermeasure

Check if the reagent container has sufficient volume of reagent, and if the volume is short, replenish it and measure the sample again.

Follow the steps to clean the probes described in “Section 7.3.1b Check the probes for impurities” in Chapter 7 of the manual.

11.2.5 N: Cuvette blank abnormality

The cuvette blank value is abnormal.

Judgment

The difference of pre-test cuvette blank values (CB1 and CB2) measured with 14 wavelengths is greater than the defined threshold value.

Cause

Foreign matter is attached to the nozzle(s) of the reaction carousel wash unit (WUD) or the nozzle(s) is (are) clogged, which prevents normal washing.

The reaction cuvette has accumulated impurities and the absorbance has changed accordingly.

The spectrophotometry lamp has deteriorated and the lamp energy has changed.

Countermeasure

Rerun with the same sample to check for abnormality.

Check if the WUD nozzles are free from foreign matter attached or clogged, if no liquid dripping from the nozzle, or if the wash solution overflows the cuvettes. See Section 7.3.1d Check the nozzles for the reaction carousel wash (WUD) unit for impurities for the steps to clean the nozzle, and Section 7.8.1c Remove the clogs in the WUD nozzles for how to remove the clogs of the WUD nozzles.

Check the lamp energy in the [Lamp Energy Monitor] window. Replace the lamp if the lamp energy is abnormal.

If it is normal, measure the cuvette blank values and check them again. If the cuvette blank values are abnormal, replace the cuvettes.

See “Section 7.4.1a Check the lamp energy” and “Section 7.4.1b Cuvette blank measurement of this chapter for checking the lamp energy and cuvette blank respectively.

11.2.6 u, U: Beyond the upper absorbance limit

The measurement value is beyond the upper limit of the parameter for abnormality detection during the reaction process.

Judgment

The relevant measurement value exceeds the upper absorbance limit defined as “blank (u)” and “sample (u)” in the [Analytical Parameters (Chemistry)] window, “absorbance limit (u)” in the [Rerun conditions Set] window, and “corrected sample (u)” calculated from “sample (u)” and E2 data (see Chapter 6).

Limit values can be defined in the [Analytical Parameters (Chemistry)] window and the [Rerun conditions Set] window accessed by clicking the corresponding button in the former window.

See “Section 6.1.1 Assay Method,” “Section 6.1.3c Check with calculated ABS” and “Section 6.1.3d Check with reaction ABS” for details.

In the assay methods RRA, 2PA, CRA, and IMA

Main Wavelength ABS is the value of “ABS1” displayed in the [RealTime Monitor] and [Reaction Monitor] windows.

When measuring the reagent blank

Flag “U” is posted when Main Wavelength ABS > blank (u).

When measuring patient samples or calibrators

- In decreasing reaction
  Flag “U” is posted when Main Wavelength ABS > corrected sample (u).
- In increasing reaction
  When Main Wavelength ABS > corrected sample (u), data points after the relevant point will be excluded.
  Flag “u” is posted when the number of remaining effective points is smaller than the number of points required for judgment.

When “Check D.P.” is defined.

- In decreasing reaction
  Flag “U” is posted when Main Wavelength ABS > blank (u) at the point defined as “Check D.P.”
- In increasing reaction
  Flag “u” is posted when Main Wavelength ABS > blank (u) at the point defined as “Check D.P.”

In the assay method EPA

When measuring patient samples or calibrators

Flag “u” is posted when Reaction ABS > Rerun absorbance (u)

Cause

The reagent may be handled inappropriately. See “Section 3.4 Preparing the reagents” in Chapter 3 of the Manual.

The sample may be handled inappropriately. See “Section 3.2 Preparing the sample” in Chapter 3 of the Manual.

Incorrect sample was used in the reagent blank measurement.

When measuring patient samples or calibrators

- The sample's lipemia, hemolysis, or icterus level is high
- The concentration of the sample is extremely high.

Countermeasure

First of all, check the following:

Reaction waveform in the [Reaction Monitor] window.

Whether the same flag is posted on the measurement value(s) of the other sample(s). In that case, see “Section 11.2.30 Multiple flags are posted simultaneously” in this Chapter.

Check the levels of lipemia, hemolysis, and icterus.

Verify if the sample is properly handled.

Verify if the reagent is properly handled.

In case the reaction waveform is abnormal

When abnormal spike noises or disturbance are observed in the waveform, perform rerun.

Verify the abnormality is reproduced with the rerun sample.
If the abnormality is not reproduced, possible causes are as follows:

The spectrophotometry lamp was the source of the spike noise.

Some foreign matter might possibly transverse the reaction carousel.

If the abnormality is reproduced,

If the waveform is normal and the flag is not posted on the values of other samples, the sample may be the cause of the abnormality.

Rerun the sample using different dilution factor.

11.2.7 d, D: Below the lower absorbance limit

The measurement value is outside the parameter range set for abnormality detection during the reaction process.

Judgment

The relevant measurement value falls below the lower absorbance limit defined as “blank (d)”, “sample (d)”, “absorbance limit (u)” at rerun, and “corrected sample (u)” calculated from sample (u) and E2 data.

Limit values can be defined in the [Analytical Parameters (Chemistry)] window and the Rerun conditions Set] window accessed by clicking the corresponding button in the former window.

See “Section 6.1.3c Check with calculated ABS” and “Section 6.1.3d Check with reaction ABS” of Chapter 6 of the Manual for details.

In assay methods RRA, 2PA, CRA, and IMA

When measuring the reagent blank

Flag “D” is posted when Main Wavelength ABS < blank (d).

When measuring patient samples or calibrators

- In decreasing reaction
  When Main Wavelength ABS < corrected sample (d), data points after the relevant point will be excluded.
  Flag “d” is posted when the number of remaining effective points is smaller than the number of points required for judgment.
- In increasing reaction
  Flag “D” is posted when Main Wavelength ABS < corrected sample (d).

When “Check D.P.” is defined.

- In decreasing reaction
  Flag “d” is posted when Main Wavelength ABS < blank (d) at the point defined as “Check D.P.”
- In increasing reaction
  Flag “D” is posted when Main Wavelength ABS < blank (d) at the point defined as “Check D.P.”

In assay method EPA

Reaction ABS is the value of “ABS” displayed in the [RealTime Monitor] and [Reaction Monitor] windows.

When measuring patient samples or calibrators

Flag “u” is posted when Reaction ABS > Rerun absorbance (u)

Cause

Possible causes are the same as those described in “Section 11.2.6. u, U: Beyond the upper absorbance limit.” Refer to the section.

Countermeasure

Possible causes are the same as those described in “Section 11.2.6. u, U: Beyond the upper absorbance limit.” Refer to the section.

11.2.8 ∗: Variance abnormality

The measurement value is over the upper limit of the parameter set for abnormality detection during the reaction process.

Judgment

The variance of measurement values in a zone of the reaction process exceeds the set value.

The value can be defined in the [Analytical Parameters (Chemistry] window.

See “Section 6.1.3c Check with calculated ABS” in Chapter 6 of the Manual.

Cause

The reagent may be handled inappropriately. See “Section 3.4 Preparing the reagents” in Chapter 3 of the Manual.

The sample may be handled inappropriately. See “Section 3.2 Preparing the sample” in Chapter 3 of the Manual.

The sample's lipemia, hemolysis, or icterus level may be high

Impurities may adhere to the mixing rod.

The spectrophotometry lamp may be degraded.

Countermeasure

First of all, perform the following:

Check the reaction waveform in the [Reaction Monitor] window.

Check whether the same flag is posted on the measurement value(s) of the other sample(s). In that case, see “Section 11.2.30 Multiple flags are posted simultaneously.”

Check the levels of lipemia, hemolysis, and icterus.

Verify if the sample is properly handled or not.

Verify if the reagent is properly handled or not.

Verify the mixing rods for impurities. If impurities are observed, clean the rods. See Section 7.5.1a for procedure.

✔ In case the reaction waveform is abnormal

When abnormal spike noises or disturbance are observed in the waveform, perform rerun.

If the abnormality is not reproduced, possible causes are as follows:

The spectrophotometry lamp was the source of the spike noise.

Some foreign matter might possibly transverse the reaction carousel.

If the abnormality is reproduced,

If the waveform is normal and the flag is not posted on the value from another sample, the sample may be the cause of the abnormality.
Rerun the sample using different dilution condition.

11.2.9 n: Number of effective points shortage

The number of points in the reaction process used for calculation falls short of the effective number.

Judgment

This flag is posted on the data in the assay methods of RRA. 2PA, CRA, and IMA when the number of effective points used in calculation is short.

See “Section 6.1.3c Check with calculated ABS” in Chapter 6 of the Manual for the details of calculation.

Cause

The measured values of the performed test may be abnormally high so that the points are moved forward. Consequently, the number of effective points falls short.

Countermeasure

Check the reaction waveform in the [Reaction Monitor] window to determine if the sample has produced abnormally high values. In that case, dilute and rerun the sample.

11.2.10 P: Prozone

Prozone error is detected from the reaction process data.

Judgment

The prozone value of the reaction process exceeds the prozone limit value.

Prozone limit value can be defined in the [Analytical Parameters (Chemistry)] window.

See “Section 6.1.3c Check with calculated ABS” in Chapter 6 of the Manual for the details of calculation and setting.

Cause

The sample may have produced abnormally high values. (“Prozone sample”)

Other possible causes are the same as those described in “Section 11.2.8 ∗: Variance abnormality.” Refer to the section.

Countermeasure

Check the reaction waveform in the [Reaction Monitor] window to determine if the sample has produced abnormally high values. In that case, dilute and rerun the sample.

11.2.11 h, l: Normal value limit

Flags “h” and “l” are posted to the patient and control sample data that are out of the defined normal range. They are also applied to the values of cuvette blank measured as user maintenance.

11.2.11a Patient sample

Judgment

The measurement value is out of the user defined normal value range.

h: Measurement value＞ Upper normal value limit

l: Measurement value < Lower normal value limit

Normal limit values can be defined in the [Analytical Parameters (Chemistry)] window.

Countermeasure

Follow the procedure specified in the user institution.

11.2.11b Control (QC) sample

Judgment

The measurement value is out of the control value range. The flags are posted in the following cases.

h: Measurement value＞ Mean＋2×SD

l: Measurement value＞ Mean - 2×SD

Select [QC] > [Control Data Registration] to define the mean value and SD in the [Control Data Registration] window.

Countermeasure

Follow the procedure specified in the user institution.

11.2.11c Cuvette blank measurement

Judgment

The measurement values of cuvette blank are judged for each of the 14 wavelengths by the condition below and the cuvette that meets the condition even for a wavelength is listed with the corresponding flag.

h: Cuvette blank − median cuvette blank of 231 cuvettes > 3 × SD

l: Cuvette blank − median cuvette blank of 231 cuvettes < 3 × SD

SD = standard deviation of the cuvette blank values stored in the system

Cause

The cuvette has impurities.

Countermeasure

These flags do not affect the measurement values.

If numerous cuvettes are listed with flag, perform “WASH2” with 1:20 diluted Reagent probe wash S.

If the situation does not improve, replace the cuvettes. See “Section 7.7.1b Replace the reaction cuvettes" in Chapter 7 of the Manual.

Remeasure the cuvette blank after replacement.

11.2.12 H, L: Abnormal value limit

Flags “H” and “L” are posted to the patient/control sample and calibration data that are beyond the defined upper limit value or below the defined lower limit value. They are also applied to the cuvette blank and water blank values measured as user maintenance that are in the define abnormal range.

11.2.12a Patient sample

Judgment

The measurement value is in the defined abnormal value range.

H: Measurement value > Upper abnormal value limit (H)

L: Measurement value < Lower abnormal value limit (L)

Abnormal limit values can be defined in the [Analytical Parameters (Chemistry)] window.

Countermeasure

Follow the procedure specified in the user institution.

11.2.12b Control (QC) sample

Judgment

The measurement value is out of the control value range. The flags are posted in the following cases.

H: Measurement value > Mean + 3 × SD

L: Measurement value > Mean + 3 × SD

Select [QC] > [Control Data Registration] to define the mean value and SD in the [Control Data Registration] window.

Countermeasure

Follow the procedure specified in the user institution.

11.2.12c Calibrator

Judgment

The judgment varies according to the sample type as follows.

The threshold values can be defined in the [Analytical Parameters (Chemistry)] window.

Reagent blank (including simplified calibration)

H: Measurement value > BLK H

L: Measurement value < BLK L

Calibrator (including simplified calibration)

H: Measurement value > STD H

L: Measurement value < STD L

Multi-point calibrator (MSTD)

H: Measurement value > BLK and STD-H for corresponding STD 1-5

L: Measurement value < BLK and STD-L for corresponding STD 1-5

Cause

The reagent may be handled inappropriately. See “Section 3.4 Preparing the reagent” in Chapter 3 of the Manual.

The sample may be handled inappropriately. See “Section 3.2 Preparing the sample” in Chapter 3 of the Manual.

Countermeasure

Verify if the reagent is properly handled.

Verify if the sample is properly handled.

11.2.12d Cuvette blank measurement

Judgment

The cuvette blank values are judged for each of the 14 wavelengths according to the condition below, and the cuvette that meets the condition even for one wavelength is listed with the corresponding flag.

H: Cuvette blank - median cuvette blank of 231 cuvettes > + cuvette reference value

L: Cuvette blank - median cuvette blank of 231 cuvettes < - cuvette reference value

Cause

The cuvette may have impurities, scratches, or foreign matter.

Countermeasure

Remove the flagged cuvette and check for impurities, scratches, and foreign matter. If it has scratches or irremovable impurities, replace the cuvettes. See “Section 7.7.1b Replace the reaction cuvettes” in Chapter 7 of the Manual.

11.2.13 R: Rerun data

The flag “R” is listed with the rerun data. It indicates the value is a rerun result.

11.2.14 C: Calibration error

The concentration cannot be obtained from the calibration curve.

Cause

Calibration was not performed, or failed.

Countermeasure

Perform calibration and confirm that a valid calibration curve is obtained. Then, start measurement again.

11.2.15 V, v: Abnormal value with main wavelength in the Reagent 1 zone (V), Abnormal value with sub wavelength in the Reagent 1 zone (v)

The measurement value is over the allowance set for abnormality detection during the reaction process.

Judgment

The variance of the points with main (V) or sub (v) wavelength in the zone (period) from Reagent 1 dispensing until Reagent 2e or 2 dispensing is over the defined allowance.

The allowance can be defined in the [Analytical Parameters (Chemistry)] window.

See “Section 6.1.3b Check with the reaction process” in Chapter 6 of the Manual for the details of calculation.

Cause

Possible causes are the same as those described in “Section 11.2.8 ∗:Variance abnormality.” Refer to the section.

Countermeasure

Take the same measures described in “Section 11.2.8 ∗:Abnormal variance” in this chapter.

11.2.16 W, w: Abnormal value with main wavelength in the Reagent 2e zone(W), Abnormal value with sub wavelength in the Reagent 2e zone(w)

The measurement value is over the allowance of the parameter set for abnormality detection during the reaction process.

Judgment

The variance of the points with main (W) or sub (w) wavelength in the zone (period) from Reagent 2e dispensing until Reagent 2 dispensing is over the defined allowance.

The allowance can be defined in the [Analytical Parameters (Chemistry] window.

See “Section 6.1.3b Check with the reaction process” in Chapter 6 of the Manual for the details of calculation.

Cause

Possible causes are the same as those described in “Section 11.2.8 ∗:Variance abnormality.” Refer to the section.

Countermeasure

Take the same measures described in “Section 11.2.8 ∗:Abnormal variance” in this chapter.

11.2.17 X, x: Abnormal value with main wavelength in the reagent 2 zone (X), Abnormal value with sub wavelength in the reagent 2 zone (x)

The measurement value is over the allowance of the parameter for abnormality detection during the reaction process.

Judgment

The variance of the points with main (X) or sub (x) wavelength in the zone (period) after Reagent 2 dispensing is over the defined allowance.

The allowance can be defined in the [Analytical Parameters (Chemistry] window.

See “Section 6.1.3b Check with the reaction process” in Chapter 6 of the Manual for the details of calculation.

Cause

Possible causes are the same as those described in “Section 11.2.8 ＊Variance abnormality.” Refer to the section.

Countermeasure

Take the same measures described in “Section 11.2.8 ＊Abnormal variance” in this chapter.

11.2.18 A: Clot error

The clot sensor in the sample probe (SPP) detects clot during sample aspiration.

Cause

The sample is highly viscous.

Fibrin or foreign matter is on the surface of the sample.

Serum separator is on the surface of the sample

The clog in SPP is not removed.

Countermeasure

Check the other measurement results with the sample flagged for clot error.

Check if some substance as fibrin is found on the sample surface, and remove if any. Perform rerun as required.

If the clot error persists with normal samples, replace SPP. See Section 7.8.1a Replace probes in Chapter 7 of the Manual.

11.2.19 M: Mixer error

The number of rotations or reciprocal movements of the mixing rod falls short of the defined number.

Cause

The mixing rod has impurities in the bearing area.

The mixing rod is broken.

The mixing rod is not attached properly.

The mixing motor malfunctions.

Countermeasure

Remove the rod and check if impurities adhere to the bearing area. If they do, clean the area.

Check if the mixing rod is broken. If it is, replace it. See “Section 7.8.1d Replace the mixing rod” in Chapter 7 of the Manual.

Check if the mixing rod is properly attached.

Check if the mixing rod fits in the midpoint of the cuvette. If it does not, contact your local distributor.

If the problem persists even after replacement, contact your local distributor.

11.2.20 Q: Liquid level sensor error

The sample probe (SPP) may have aspirated air during sample aspiration.

Cause

The sample has air bubbles.

Impurities adheres to SPP

Countermeasure

Check if air bubbles are observed in the sample, and remove them if any. Note that the air bubbles may have gone when checking.

Clean SPP if it has impurities. Follow the steps described in “Section 7.3.1b Check the probes for impurities” in Chapter 7 of the Manual.

11.2.21 G: Crash

The probe hits something during operation.

Crash can occur when SPP is aspirating the sample and when the reagent probes (RPP1/RPP2) are aspirating the reagents.

Cause

The sample container is covered.

The sample container is incorrectly selected.

The sample container is placed improperly in the sample tray (STT)/

The STT cover is not in the correct position.

The cover of the ISE unit is not in the correct position.

The splash cover is not in the correct position.

The reagent bottle is covered.

The reagent bottle is placed improperly in the reagent tray (RTT).

The RTT cover is not in the correct position.

Countermeasure

Display the error report and identify the probe that had the “crash.” (SPP, RPP2 or RPP2)

Confirm against what the probe “crashed.”

Based on the above information, identify and eliminate the cause of the “crash.”

Check if the probe is broken or bent. If it is, replace it. See “Section 7.8.1a Replace probes” in Chapter 7 of the Manual.

If it is not, check if the probe is attached properly. It may be displaced by the shock. Perform rerun. If the probe has some problem, replace it.

Check that the probe no longer “crashes” and the measurement value is normal.

11.2.22 F: Temperature error (outside the range of 37℃±0.3) of the reaction bath

The temperature of the reaction bath is outside the defined range.

Judgment

The temperature of the reaction bath is outside the range of 37℃±0.3.

Cause

The temperature of the reaction bath has not reached stability because the measurement was performed immediately after the startup of the system.

The temperature of the reaction bath cannot be controlled due to the extremely high or low ambient temperature.

Countermeasure

Wait until “OK” is displayed for [RRV Bath Temp.] and [RRV Bath Control] in the [System Monitor] window. After confirming that “OK” is displayed, start the measurement.

Operate the system in an environment that conforms to the installation requirement. (See “Section 1.6 Installation” in Chapter 1 of the Manual)

11.2.23 c: Calibration error

The combination of the reagent(s) and the calibration curve used for calculation is invalid.

Judgment

When the multiple bottles of a reagent are set on the reagent tray and the new calibration date is obtained after a bottle switch, the measurement value of the sample to which the reagent was dispensed from the new bottle is judged as calibration error until the new calibration becomes effective.

Countermeasure

Follow the procedure specified in the user institution.

11.2.24 f: Multiple normal data

The measurement value is outside the parameter range defined for abnormality detection.

Judgment

When a patient sample is measured simultaneously with the dilution conditions, M, D1, D2, D3, and D4 defined in the [Report data select] column in the [Abnormal value setting] window accessed from the [Analytical Parameters (Chemistry)], the result includes two or more measurement values that have neither the abnormal limit value flag “L” nor “H.” This is judged to be the “multiple normal data” error.

In the [Reporting data select], either “Low dilute data” or “High dilute data” can be selected in the [Data selection for data comment] column.

The value can be entered in the [Abnormal value setting] window displayed by clicking the [Abnormal value setting] button in the [Analytical Parameters (Chemistry)] window.

Countermeasure

Follow the procedure specified in the user institution.

11.2.25 q: Borderline data

The measurement value is outside the parameter range defined for abnormality detection.

Judgment

When a patient sample is measured simultaneously with the dilution conditions, M, D1, D2, D3, and D4 defined in the [Report data select] column in the [Abnormal value setting] window accessed from the [Analytical Parameters (Chemistry)], all the measurement values have the abnormal limit value flag “L” or “H”, where a value with a lower dilution condition is posted with H and that with a step-higher dilution condition is posted with L. A Borderline result is considered to exist between the two dilution conditions. In this case, the two measurement values are considered to be borderline data defined for “q: Borderline data” in the [Data selection for data comment] column in the [Abnormal value setting] window.

In the [Reporting data select], either “Low dilute data” or “High dilute data” can be selected in the [Data selection for data comment] column.

The value can be entered in the [Abnormal value setting] window displayed by clicking the [Abnormal value setting] button in the [Analytical Parameters (Chemistry)] window.

Countermeasure

Follow the procedure specified in the user institution.

11.2.26 a: No normal data

The measurement value is outside the parameter range defined for abnormality detection.

Judgment

When a patient sample is measured simultaneously with the dilution conditions, M, D1, D2, D3, and D4 defined in the [Report data select] column in the [Abnormal value setting] window accessed from the [Analytical Parameters (Chemistry)], all the measurement values have the abnormal limit value flag “L” or “H”, where no borderline data exist.

The value can be entered in the [Abnormal value setting] window displayed by clicking the [Abnormal value setting] button in the [Analytical Parameters (Chemistry)] window.

Countermeasure

Follow the procedure specified in the user institution.

11.2.27 z: Incorrect data, prozone

The measurement value is outside the parameter range defined for abnormality detection.

Judgment

When a patient sample is measured simultaneously with the dilution conditions, M, D1, D2, D3, and D4 defined in the [Report data select] column in the [Abnormal value setting] window accessed from the [Analytical Parameters (Chemistry)], the measurement values show conflicting “L” and “H” flags.

Example: A measurement value with a dilution condition is normal or posted with “L”, while a value with a higher dilution condition is posted with “H.”

The validity of the set values is judged by the user or the manufacturer of the reagent.
The value can be entered in the [Abnormal value setting] window displayed by clicking the [Abnormal value setting] button in the [Analytical Parameters (Chemistry)] window.

Countermeasure

Follow the procedure specified in the user institution.

11.2.28 Z: Calibration data abnormality

The result of calibration is abnormal.

Judgment

The reaction ABS of the currently obtained calibration data is beyond the allowance.

Allowance (%) < | Calculated ABS from the previous calibration - Calculated ABS of the current calibration | / Calculated ABS of the previous calibration x 100 (%)

Allowance can be defined in the [Analytical Parameters (Chemistry)] window.

Cause

The reagent may be handled inappropriately. See “Section 3.4 Preparing the reagents” in Chapter 3 of the Manual.

The sample may be handled inappropriately. See “Section 3.2 Preparing the sample” in Chapter 3 of the Manual.

Countermeasure

Verify that the reagent is handled properly.

Verify that the sample is handled properly.

Perform calibration again.

11.2.29 / : Overflow

The calculated concentration is beyond the range of the values that can be displayed.

In this case, “/////” is displayed for concentration.

Countermeasure

Check the calibration curve for abnormality.

The calculation formula may be erroneous when ratio parameter or realtime correction is used. Check the formula.

11.2.30 Multiple flags are posted simultaneously

Multiple types of flags below are posted for multiple tests and samples, Follow the steps below.

✔ Flags that require attention

U, u, D, d, ∗, n, P, H, h, L, l, V, v, W, w, X, x

✔ If the flags are posted for multiple tests and samples

The analyzer may have some problem.

The quality of water supplied from the pure water supply unit may be degraded. Check the water quality.

Check if the mixing rod has impurities. If it does, clean it. See Section 7.5.1a for procedure. If the impurities persist, replace the mixing rod.

Check if the mixing rod is broken. If it is, replace it. See Section 7.8.1d for procedure.

Check if the nozzles of the reaction carousel wash unit (WUD) are free from foreign matter attached or clogged, if the wash solution is improperly provided from the nozzles, or if the wash solution overflows the cuvettes. See "Section 7.3.1d Check the nozzles for the reaction carousel wash (WUD) unit for impurities" for the steps to clean the nozzle, and "Section 7.8.1c Remove the clogs in the WUD nozzles" for how to remove the clogs of the WUD nozzles.

Check if the sample probe and reagent probes are attached properly. If they are not, attach them properly.

Check if the sample probe and reagent probes have impurities. If they do, clean them. See Section 7.3.1b for the procedure to clean the probes.

Check if the sample probe and reagent probes are bent or clogged. If bent, broken, or clogged, replace the probe. See Section 7.8.1a for replacement.

Check the pumps for liquid leakage and air bubbles. Follow the steps described in "Section 7.3.1g Check for potential leakage from pumps" in Chapter 7 of the Manual.

Foreign matter such as solid substance or substance immiscible with the reaction bath oil may mix in the reaction bath oil. Remove the reaction cuvette holder to check if there is some foreign matter inside the reaction bath. If there is, contact your local distributor.

The reaction cuvette may have impurities. Measure the cuvette blank, and if the blank value is abnormal or the cuvettes are not replaced for a long period, perform "WASH2." If the problem persists, replace the cuvettes. See "Section 7.7.1b Replace the reaction cuvettes" in Chapter 7 of the Manual.

Check the lamp energy in the [Lamp Energy Monitor] window. Replace the lamp if the lamp energy is abnormal. See "Section 7.4.1a Check the lamp energy" in Chapter 7 for checking the lamp energy.

✔ If the flags are posted for multiple samples

When flags are posted for multiple samples for a single test, the reagent may be causing the problem. Check the following.

Whether the reagents are placed in the correct positions.

The reagent's expiration date. Do not use expired reagents.

Whether foreign matters or air bottles are observed in the reagent. Remove them, if any.

11.3 Countermeasures for Flags in ISE Tests

11.3.1 S: Safety

Refer to Section 11.2.1.

11.3.2 s: Sample shortage

Refer to Section 11.2.2.

11.3.3 r: Buffer shortage, Internal Standard (IS) solution shortage

This flag is posted in one of the following cases.

The buffer level has lowered below the specified range.

The calculated volume of remaining IS solution becomes zero.

Cause

The remaining buffer volume is small.

The level sensor is out of place.

The IS solution is used up based on the calculation.

Countermeasure

Check the buffer line and IS solution line for air bubbles. If air bubbles are observed, they may have affected the measurement values.

Replace the buffer or IS solution. See Section 7.3.2a and 7.3.2b of Chapter 7 of the Manual for the replacement steps of each bottle. Perform calibration after replacement.

Check the bottle sensor is in the correct position.

Perform measurement again.

11.3.4 T: Thermistor abnormality

The thermistor reading is abnormal.

Cause

The thermistor has some problem such as disconnection.

Countermeasure

Replace the thermistor.

11.3.5 u: Abnormal selectivity

The ion selectivity is beyond the defined upper limit of selectivity check.

Cause

The ion selectivity of the electrode has lowered.

Countermeasure

Replace the electrode.

11.3.6 C: Calibration error

When the calibrator is measured, the potential is abnormal.

Judgment

The difference in potential between the sample and base is outside the set range.

See 6.2.2 Calibration for the range.

Cause

The buffer is not flowing normally due to clogs, air bubbles in the flow line, etc.

The buffer has some problem such as water or foreign matters mixed in.

The IS solution is not flowing normally due to clogs, air bubbles in the flow line, etc.

The IS solution has some problem such as water or foreign matters mixed in.

The ISE standard solutions (H and L) are not placed in the correct positions.

The ISE serum standard solutions (H and L) are mistakenly used for urine measurement, and vice versa.

The ISE solution is degraded.

The electrodes are placed improperly in position.

The electrodes are degraded.

The sample probe (SPP) is not attached properly.

The sample pump (SP) has leakage. Air is trapped in the line.

Countermeasure

Dispense the ISE standard solutions again and perform calibration. At that time, verify the solutions are correctly set in the respective positions.

If the error repeats, follow the steps below and perform calibration again.

If the buffer and IS solution bottles have just been replaced, replace them again and perform buffer priming. Refer to Sections 7.3.2a and 7.3.2b.

Check if leakage is observed around the electrodes. If it is, remove the electrodes and verify the O-rings are certainly between the electrodes. If no problem is found, place the electrodes back and perform buffer priming.

Check the buffer and IS solution are drained in the ISE dilution bowl. If not, the line is clogged somewhere. Check the line.

Check the buffer line and IS solution line for air bubbles. If air bubbles are found, perform buffer priming.

Check if SPP is attached properly. See Section 7.8.1a of Chapter 7 for proper attachment.

Check if leakage or air bottles are observed in the sampling pump. Follow the steps described in "Section 7.3.1g Check for potential leakage from pumps" in Chapter 7 of the Manual.

Replace the electrodes. See Section 7.8.2b for replacement.

11.3.7 ∗: H-STD error or L-STD error (Variance)

The potentials measured during calibration vary substantially.

Judgment

When the difference of the consecutively measured sample and base potentials in calibration falls outside the defined range, the measurement is repeated up to 8 times.

If the difference is still outside the range even after 8 repeated times of measurement, this flag is posted.

The error is called L-STD error in L-STD measurement, and H-STD error in H-STD measurement.

Cause

Air is trapped in the buffer line.

Air is trapped in the IS solution line.

The electrodes are degraded.

SPP is not attached properly.

SP has leakage. Air is trapped in the line.

Countermeasure

Dispense the ISE standard solutions again and perform calibration.

If the error repeats, follow the steps below and perform calibration again.

Check the buffer line and IS solution line for air bubbles. If air bubbles are found, perform buffer priming.

Check if SPP is attached properly. See Section 7.8.1a of Chapter 7 for proper attachment.

Check if leakage or air bubbles are observed in SP. Follow the steps described in "Section 7.3.1g Check for potential leakage from pumps" in Chapter 7 of the Manual.

Wash the electrodes and electrode lines. See “Section 7.3.2c Wash the electrodes” and “Section 7.4.2a Wash the electrode lines” in Chapter 7 of the Manual.

Replace the electrodes. See Section 7.8.2b Replace the electrodes in Chapter 7 of the Manual.

11.3.8 d: dilution factor abnormality, Ref: Reference electrode abnormality

These errors occur at calibration. The indication and condition vary according to the electrode.

11.3.8a Na, K, and Cl electrodes

The dilution factor is outside the set range of 25 to 60.

Cause

Possible causes are the same as for the calibration range error. See “Section 11.3.6 C: Calibration error.”

Countermeasure

Take the same measures as for the calibration error. See “Section 11.3.6 C: Calibration error.”

11.3.8b Ref: Reference electrode

Control potential obtained by the reference electrode calibration is lower than the set value of 350.

Cause

The reference electrode is degraded.

Countermeasure

Replace the reference electrode.

11.3.9 B: Abnormal liquid volume in the dilution bowl

The liquid level of the dilution bowl is abnormal.

Judgment

The error is detected for too high or too low buffer level in the dilution bowl when the sample is dispensed in the ISE unit.

Cause

✔ **In case the level is too high**

The buffer is overflowing. The electrode is clogged or improperly attached.

Air bubbles are generated in the dilution bowl.

SPP has impurities at the tip or it is not attached properly.

In case the level is too low

The buffer is not dispensed. The line is clogged.

The buffer leaks around the electrodes.

Air is trapped in the buffer line.

SPP has impurities at the tip or it is not attached properly.

Countermeasure

When the buffer solution is overflowing from the dilution bowl, the electrodes may not be placed properly, or they may be clogged. Remove the electrodes to check for clogs. If no problem is observed, place them back properly. Wipe the inside of the dilution bowl completely. Perform buffer priming and confirm that no b uffer solution overflows.

Remove bubbles in the dilution bowl if any.

Wipe and dry the inside of the dilution bowl completely.

If the buffer solution is not dispensed in the dilution bowl, the line is clogged somewhere. Check the line.

If air bubbles are observed in the buffer line, check the joint of the buffer bottle for looseness.

If leakage is observed around the electrodes, remove them once, and then place them back. Wipe the surroundings of the electrodes completely. Perform buffer priming and check for any leakage.

Clean the probe tip. Follow the steps described in “Section 7.3.1b Check the probes for impurities” in Chapter 7 of the Manual.

Reattach the probe. See “Section 7.8.1a Replace probes” in Chapter 7 of the Manual.

11.3.10 h, l: Normal value limit

The flags “h” and “l” are posted to the measurement value outside a set range for patient/control/calibration measurement.

11.3.10a Patient sample

Judgment

The concentration is over the range of normal value defined in the [Normal Value Set] window accessed from the [ISE Parameter Settings] window.

Flag “h” is posted when Concentration > Upper limit of normal value range for corresponding age and sample type categories.

Flag “l” is posted when Concentration < Upper limit of normal value range for corresponding age and sample type categories.

Countermeasure

Follow the procedure specified in the user institution.

11.3.10b Calibration

Judgment

The slope is outside the slope range specified in the [Standard value set] column in the [ISE Parameter Settings] window. It is time to replace the electrodes.

Flag “h” is posted when the value is over the [Slope upper limit h].

Flag “l” is posted when the value is below the [Slope lower limit l].

The slope for Cl is negative, which is converted to positive in judgment.

Countermeasure

Follow the procedure specified in the user institution.

11.3.10c Control

Judgment

The measurement value is out of the control value range. The flags are posted in the following cases.

h: Measurement value > Mean＋2×SD

l: Measurement value < Mean＋2×SD

Select [QC] > [Control Data Registration] to define the mean value and SD in the [Control Data Registration] window.

Countermeasure

Follow the procedure specified in the user institution.

11.3.11 H, L: Abnormal value limit

The flags “H” and “L” are posted to the measurement value outside a set range for patient/control/calibration measurement.

11.3.11a Patient sample

Judgment

The concentration is over the range of abnormal value defined in the [Abnormal Value Set] window accessed from the [ISE Parameter Settings] window.

Flag “H” is posted when Concentration > Upper limit of abnormal value range for the corresponding sample type.

Flag “L” is posted when Concentration < Lower limit of abnormal value range for the corresponding sample type.

Countermeasure

Follow the procedure specified in the user institution.

11.3.11b Calibrator

Judgment

The slope is outside the specified slope range between 38 and 65.

Cause

The electrodes are degraded.

Countermeasure

Perform calibration again.

If the problem persists, replace the electrodes.

11.3.11c Control sample

Judgment

The measurement value is out of the control value range. The flags are posted in the following cases.

H: Measurement value > Mean + 3 × SD

L: Measurement value < Mean + 3 × SD

Select [QC] > [Control Data Registration] to define the mean value and SD in the [Control Data Registration] window.

Countermeasure

Follow the procedure specified in the user institution.

11.3.12 I: ID error

The sample ID measured does not correspond to the sample ID ordered.

The sample measured may be different from the sample ordered for some reason.

Countermeasure

Perform measurement again.

11.3.13 R: Rerun data

See “Section 11.2.13 R: Rerun data” in the “Countermeasures for Flags in Chemistry Tests” in this Chapter.

11.3.14 A: Clot error

See “Section 11.2.18 A: Clot error” in the “Countermeasures for Flags in Chemistry Tests” in this Chapter.

11.3.15 G: Crash

See “Section 11.2.21 G: Clash” in the “Countermeasures for Flags in Chemistry Tests” in this Chapter.

11.3.16 Q: Liquid level sensor error

See “Section 11.2.20 Q: Liquid level sensor error” in the “Countermeasures for Flags in Chemistry Tests” in this Chapter.