EU-5300 Pro/EU-5600 Pro

Automatic Urinalysis System

Operator's Manual

CE 0123

For this Operator's Manual, the issued Date is 2024-11.

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- the product is used in accordance with the instructions for use.

NOTE

- **This equipment must be operated by skilled/trained clinical professionals.**

⚠ WARNING

- **It is important for the hospital or organization that employs this equipment to carry out a reasonable service/maintenance plan. Neglect of this may result in machine breakdown or personal injury.**
- **This instrument is intended to be used by clinical laboratory professionals trained by Mindray or Mindray-authorized distributors.**

- **Be sure to use the instrument under specified environment in this manual. If not, the instrument may not work properly, the measurement may be unreliable, thus causing damage to the instrument and harm to the body.**

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- Malfunction or damage caused by improper operation or repair by unqualified or unauthorized service people.
- Malfunction of the instrument or part whose serial number is not legible enough.
- Others not caused by instrument or part itself.

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Table of Contents

1 Safety Information

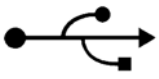
1.1 Labels and Symbols on the Analyzer

You may find the following symbols on the analyzer:

⚠ CAUTION

- **During the daily use of the analyzer, especially in the cleaning process, ensure the intactness of the labels.**

When you see...	It means
	CAUTION. Note: Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Biological risks
	PROTECTIVE CONDUCTOR TERMINAL
	Off (Power)
	On (Power)
	Alternating current
COM	Communication serial port
	Serial number

When you see...	It means
	In vitro diagnostic medical device
	Unique device identifier
	DATE OF MANUFACTURE
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	THE FOLLOWING DEFINITION OF THE WEEE LABEL APPLIES TO EU MEMBER STATES ONLY: THE USE OF THIS SYMBOL INDICATES THAT THIS PRODUCT SHOULD NOT BE TREATED AS HOUSEHOLD WASTE. BY ENSURING THAT THIS PRODUCT IS DISPOSED OF CORRECTLY, YOU WILL HELP PREVENT BRINGING POTENTIAL NEGATIVE CONSEQUENCES TO THE ENVIRONMENT AND HUMAN HEALTH. FOR MORE DETAILED INFORMATION WITH REGARD TO RETURNING AND RECYCLING THIS PRODUCT, PLEASE CONSULT THE DISTRIBUTOR FROM WHOM YOU PURCHASED THE PRODUCT.
	Warning of hand pricking
	USB port

When you see...	It means
	Stacking limit by number
	Do not roll
	This way up
	Fragile, handle with care
	Keep dry
	Direction when moving analyzer
	MANUFACTURER
	European Conformity
	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY

When you see...	It means
	THE FOLLOWING DEFINITION OF THE WEEE LABEL APPLIES TO EU MEMBER STATES ONLY: THE USE OF THIS SYMBOL INDICATES THAT THIS PRODUCT SHOULD NOT BE TREATED AS HOUSEHOLD WASTE. BY ENSURING THAT THIS PRODUCT IS DISPOSED OF CORRECTLY, YOU WILL HELP PREVENT BRINGING POTENTIAL NEGATIVE CONSEQUENCES TO THE ENVIRONMENT AND HUMAN HEALTH. FOR MORE DETAILED INFORMATION WITH REGARD TO RETURNING AND RECYCLING THIS PRODUCT, PLEASE CONSULT THE DISTRIBUTOR FROM WHOM YOU PURCHASED THE PRODUCT.

The general meaning assigned to geometric shapes, safety colors and contrast colors for safety signs are as follows:

Geometric shape	Meaning	Safety color	Contrast color	Graphical symbol color
	Warning	Yellow	Black	Black

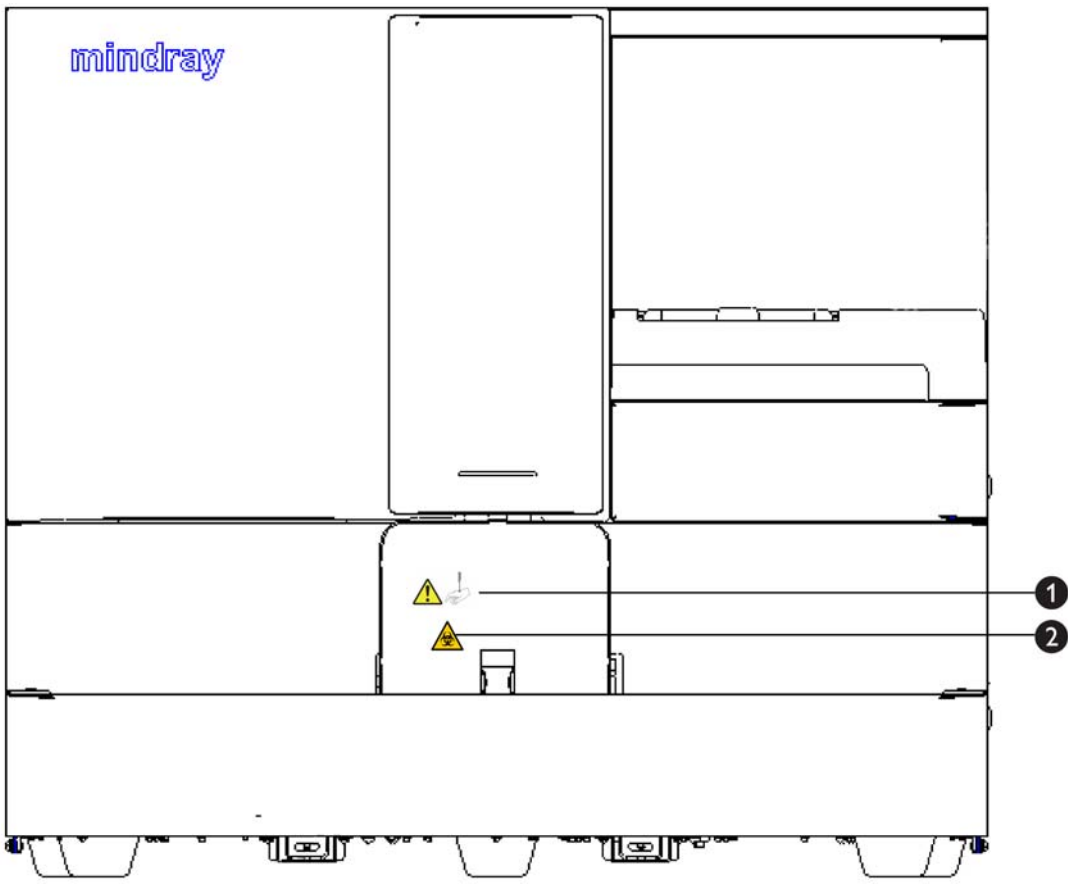


Figure 1-1 Warnings of hand pricking and biological risk on the front of the analyzer

1	Warning of hand pricking	WARNING 1. THE PROBE IS SHARP AND MAY CONTAIN BIOHAZARDOUS MATERIAL. EXERCISE CAUTION WHEN WORKING AROUND THE PROBE! 2. TO AVOID INJURY, IT IS PROHIBITED TO OPEN THE FRONT COVER WHEN THE ANALYZER IS WORKING!
2	BIOLOGICAL RISK	WARNING BIOHAZARD

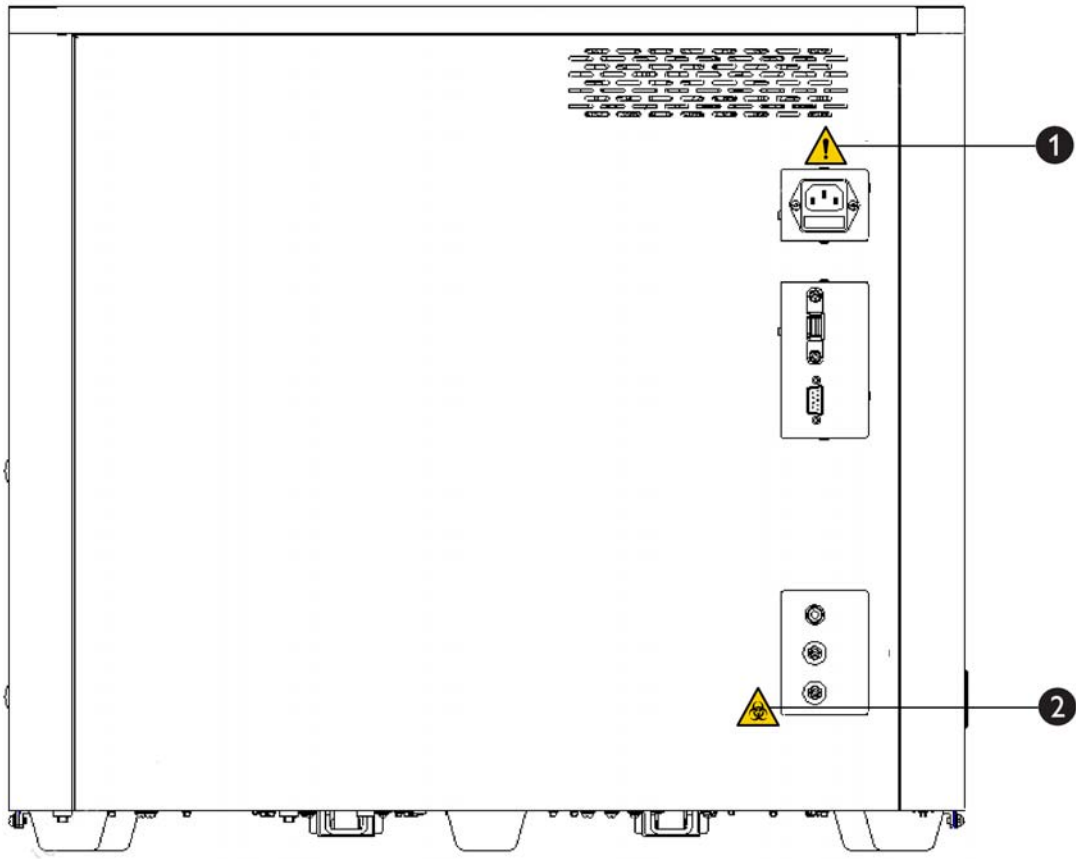


Figure 1-2 Warnings of power supply and biological risk on the back of the analyzer

1	Power supply warning	WARNING 1. CONNECT ONLY TO A PROPERLY EARTH GROUNDED OUTLET. 2. TO AVOID ELECTRIC SHOCK, DISCONNECT POWER CORD PRIOR TO MAINTENANCE. 3. REPLACE FUSE ONLY WITH THE TYPE AND RATING SPECIFIED.
2	BIOLOGICAL RISK	WARNING BIOHAZARD

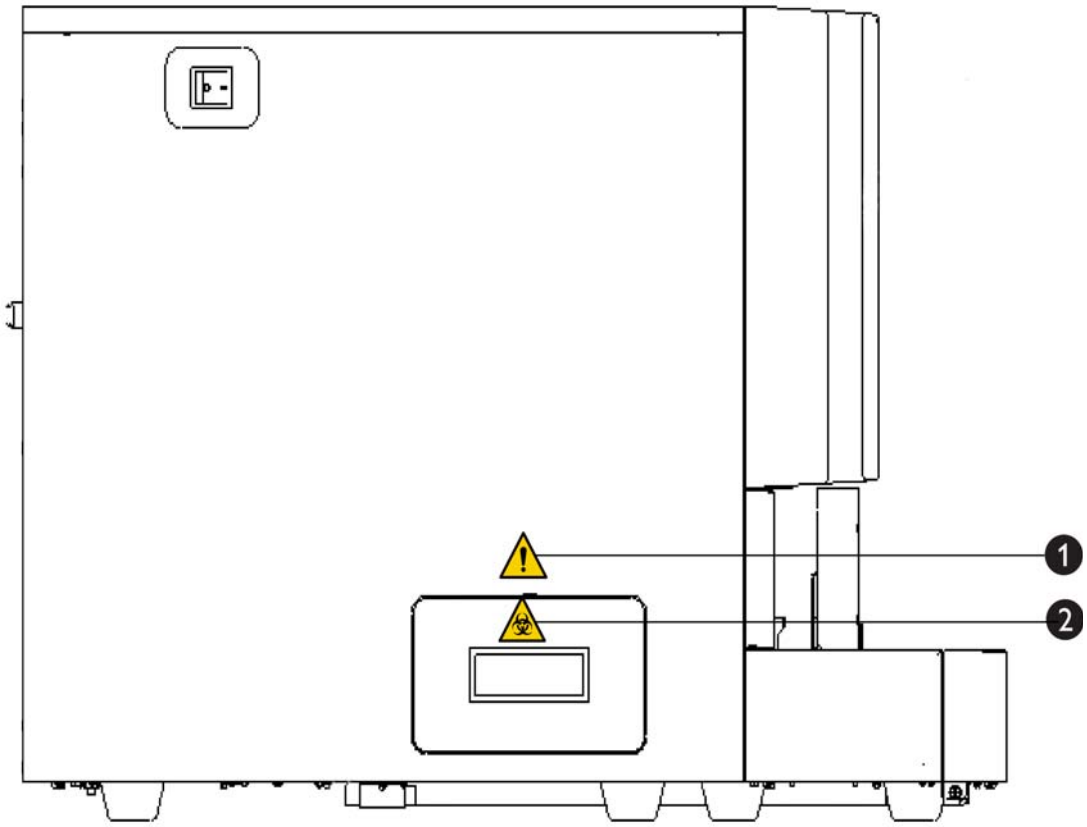


Figure 1-3 Warnings of biological risk on the left panel of the analyzer

1	ENERGY HAZARD	TO AVOID INJURY，IT IS PROHIBITED TO OPEN THE WASTE STRIP BOX WHEN THE ANALYZER IS WORKING!
2	BIOLOGICAL RISK	WARNING BIOHAZARD

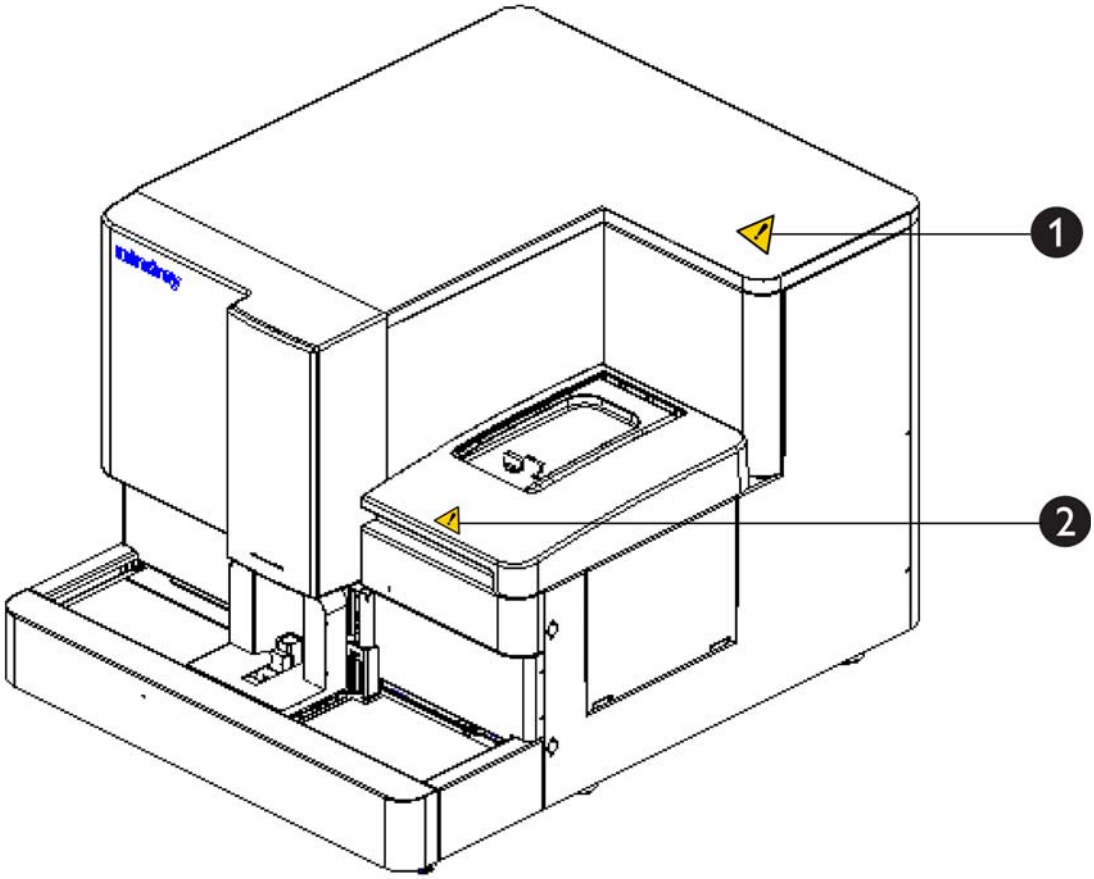


Figure 1-4 Warnings of energy hazard on the side top panel and strip selection assembly cover

1	ENERGY HAZARD	TO AVOID INJURY, IT IS PROHIBITED TO OPEN THE SIDE TOP PANEL WHEN THE ANALYZER IS WORKING!
2	ENERGY HAZARD	TO AVOID INJURY, IT IS PROHIBITED TO OPEN THE COVER OF STRIP SELECTION ASSEMBLY WHEN THE ANALYZER IS WORKING!

1.2 Safety Symbols and Messages

You will find the following warning symbols in this manual:

BIOLOGICAL RISK

- **Read the statement below the symbol. The statement is alerting you to a potentially biohazardous condition.**

WARNING

- **Read the statement below the symbol. The statement is alerting you to an operating hazard that can cause personnel injury.**

CAUTION

- **Read the statement below the symbol. The statement is alerting you to a possibility of system damage or unreliable analysis results.**

1.2.1 General Safety Messages

BIOLOGICAL RISK

- **The analyzer tests urine samples. Samples and waste can be potentially infectious. Wear proper personal protective instrument (e.g. gloves, lab coat, glasses, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.**
- **Be sure to dispose of reagents, waste, samples, consumables, etc. according to government regulations.**
- **If the main unit of the instrument leaks, the leaked liquid is potentially biohazardous.**
- **Discard the system according to government regulations.**
- **When the instrument is with error and need servicing, it is recommended to put warnings on the analyzer to prevent people touching it and avoid biohazard and other hazards.**
- **Broken tubes may cause biohazard and/or physical injury. Make sure to avoid placing the tubes upside down when loading samples. Exercise caution when loading tubes to tube racks or getting the tubes from the rack, be sure not to break the tubes.**
- **After replacing reagent containers, check the tubing connected to the cap assembly and be sure it is not bent over and works well. Otherwise, it may expose operators to infection and cause inaccurate measurement result.**
- **When using the waste container, make sure that the pickup tube of the bottle cap assembly of the waste container is located above the waste container, and the tube is smooth without bending. If the waste is discharged directly, make sure the waste pump is at a lower position than the waste outlet on the analyzer.**
- **Do not contact the patients' sample directly.**

⚠ WARNING

- **Before turning on the instrument, make sure the input voltage meets the requirement.**
- **When installing the instrument, ensure that the power switch is in close proximity to the equipment and within easy reach of you.**
- **Check the firmness of all the doors and covers before running the system. Be careful when opening/closing and removing/installing the doors, covers and boards of the analyzer, otherwise they may fall off and cause physical injury.**
- **Be sure all the safety measurements are adopted. It is prohibited to disable any safety device or sensor.**
- **Take action to any alarm and problem indication immediately.**
- **Only use the accessories and consumables manufactured or recommended by the manufacturer to achieve the promised system performance and safety. For more information, contact the manufacturer's Customer Service Department or your local distributor.**
- **Contact the manufacturer or authorized distributors in time if any damaged part is found.**
- **Be careful when opening/closing and removing/installing the doors, covers and boards of the system.**
- **Discard the system according to government regulations.**
- **Mindray does not claim the validity of the listed chemicals in infection control. For effective control of infection, please consult the Infection Prevention Department of the hospital or the epidemic professionals.**
- **Only install fuses of specified type and specification to prevent from fire hazard. If there is any problem with the fuse, contact Mindray Customer Service Department or your local distributor.**
- **Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the component authority of the country in which the user and/ or the patient is established.**

⚠ CAUTION

- **This equipment must be operated by professional inspectors, doctors, or experimenters that pass the training of Mindray or Mindray's distributors.**
- **Make sure to use the equipment strictly in accordance to the method specified in the instruction manual. If the analyzer is used in a manner not specified by the manufacturer, the protection provided by the analyzer may be impaired.**
- **Be sure to operate the system under the situation specified in this manual. Otherwise, the system will not work normally, the analysis results will be unreliable, the system components may be damaged and cause personal injury.**
- **Be sure to use the specified external devices only, and keep them away from water.**
- **External equipment such as computer and printer connected to the analyzer and digital interfaces must be authorized and complied with relevant safety and EMC standards (e.g. IEC 60950 Safety of Information Technology Equipment Standard (Class B)). Any person who connects additional equipment to the signal input or output ports and configures an IVD system, is responsible for ensuring that the system works normally and complies within the safety and EMC requirements. If you have any questions, consult the technical service department of your local representative.**
- **Be sure all the safety measurements are adopted. It is prohibited to disable any safety device or sensor.**
- **Do not touch the moving parts. Keep your clothes, hairs and hands away from the moving parts to avoid injury.**
- **The pusher will push the rack inside the autoloader. Make sure your hand is away from the rack before starting the autoloader.**
- **Transportation or installation by personnel not authorized or trained by Mindray may cause personal injury or damage to your analyzer. Do not install or transport your analyzer without the presence of personnel authorized by the manufacturer.**
- **The installation, authorization, upgrade and modification of the analyzer's system software must be performed by personnel authorized by Mindray. Be sure only the manufacturer-authorized software is installed on the computer.**
- **Using pinboard may bring electrical interference and the analysis results may be unreliable. Place the analyzer near the electrical outlet to avoid using the pinboard.**
- **Use the original power cord provided by the manufacturer. Using other electrical wire may damage the analyzer or lead to unreliable analysis results.**
- **Improper service may damage the system. Operators must follow the instruction of this Operator's Manual to perform maintenance operations. For problems not mentioned in this manual, contact Mindray customer service department .**
- **Only use component parts provided by Mindray for maintenance, otherwise it may cause damage.**
- **To ensure the device performance and safe use, only accessories specified by Mindray can be used. For more information, contact Mindray Service Department or you local distributor.**
- **If any of the pipes or fluidic components are worn out, stop using the analyzer and contact Mindray customer service department immediately for inspection or replacement.**
- **In case of a sudden power outage, shut down the power supply of the analyzer immediately. Before starting up the instrument, use the Probe Cleanser to soak the sample probe.**
- **If you accidentally spill hazardous material (for example, samples and reagents) on the instrument, clean and disinfect the instrument. Recommended cleaning agents and disinfectants include water and 75% ethanol. Do not use material that could corrupt metal (for example, 3% hydrogen peroxide). Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when conducting cleaning and disinfection.**
- **Perform regular cleaning on the covers of the analyzer. Use the specified materials to clean the equipment only. For any damage or accidents caused by the use of materials other than those specified, Mindray will not provide any warranty.**
- **Do not use any cleaning agents that could cause hazards as a result of a reaction with parts of the analyzer or with materials inside the analyzer. If there is any doubt about the compatibility of the cleaning agents with parts of the equipment or with material contained in it, please contact our customer service department or the local distributor.**

- **To ensure the accuracy of measurement result, do not mix the new container of reagent with the residues in the replaced container. Protect the reagent from being contaminated according to operation instruction of your laboratory.**
- **Use the reagents specified by the manufacturer only. Store and use the reagents as instructed by the instructions. Using controls of other manufacturers may lead to incorrect QC results.**
- **Pay attention to the expiration dates and open-container stability days of all the reagents. Use expired reagents may cause inaccurate measurement results.**
- **Be sure to shut down the analyzer by following the shutdown program. Otherwise the internal tubing may be contaminated causing inaccurate measurement results.**
- **Check if the reagent tubes are properly connected before using the analyzer, otherwise the measurement results can be unreliable.**

1.2.2 PC and Network Security

NOTE

- **Windows Defender has been installed on the computer to prevent from viruses, spyware, and malware attacks. Users shall scan for viruses periodically and update security patches.**
- **Install anti-virus software on the computer and scan for viruses periodically.**
- **Make sure to install only Mindray-authorized software on the computer.**
- **Data transmission must be performed in a close-loop network or virtual network. The network must be isolated.**
- **Users have the responsibility to protect the network authentication information, such as password and user information, from being obtained by unauthorized personnel.**
- **The installation, authorization, upgrade and modification of the system software must be performed by personnel authorized by Mindray.**

1.2.3 When the Instrument Operation Is Stopped for Maintenance, Transportation or Service

⚠ WARNING

- **Before maintaining, transporting or servicing the instrument, clean and sterilize the instrument cover, as well as the parts and components with biological risks (such as the sampling probe). Remind the persons who handle the instrument of the related risks.**

2 Using this Manual

2.1 Overview

This chapter describes how to use EU-5300 Pro/EU-5600 Pro Automatic Urinalysis System Operator's Manual. This manual is provided with the analyzer, and describes in detail the purpose, function and operation of the analyzer. Before using EU-5300 Pro/EU-5600 Pro, read and understand the contents to ensure the correct use of the analyzer to achieve its best performance, and ensure the safety of the operator.

NOTE

- **All illustrations in this manual are provided as examples only. They may not necessarily reflect your software setup or data displayed.**
- **This manual describes the use, functions and operation methods of the analyzers based on the most complete configuration; and some of the content may not be applicable to your analyzer. Contact Mindray if you have any questions.**

2.2 Who Should Read This Manual

This manual is intended to be read by clinical laboratory professionals to:

- learn about the hardware and software of the analyzer.
- set up system parameters.
- perform daily operating task.
- perform system maintenance and troubleshooting

2.3 How to Find Information

This operator's manual comprises 11 chapters and 7 appendices. Refer to the table below to find the information you need.

If you want to …	Refer to...
learn about the safety messages of the analyzer	***1 Safety Information***
learn about the intended use and parameters of the analyzer	***3 Understanding Your System***
learn about the composition, operation screen, and software of the analyzer	***3 Understanding Your System***
learn about how the analyzer works	***4 Understanding the Working Principles***
learn about the installation requirements of the analyzer	***5 Installing and Connecting the Instrument***
set system parameters such as parameter settings and maintenance settings	***6 Customizing the Analyzer Software***
learn about how to collect, prepare and analyze the samples	***7 Daily Operations***
learn about how to use the analyzer to perform daily operation tasks	***7 Daily Operations***
learn about how to review the saved analysis results	***8 Reviewing Sample Results***
learn about basic requirements of quality control and quality control methods of the analyzer	***9 Quality Control (QC) Program***
learn about how to maintain/test the analyzer	***10 Servicing Your Analyzer***
learn about the troubleshooting methods of the analyzer	***11 Troubleshooting***

If you want to …	Refer to...
view index	***F Index***
learn about the technical specifications of the analyzer	***A Technical Specifications***
view analyzer components and accessories	***B Analyzer Configuration***
view communication protocol related information	***C Communication***
view reference information	***D References***
view potential interference and limitations	***E Limitations***

2.4 Conventions Used in This Manual

This manual uses certain typographical conventions to clarify meaning in the text:

Format	Meanings
[××]	All capital letters enclosed in [ ] indicate a key name (either on the pop-up keyboard or the external keyboard), such as [ENTER].
"××"	Letters included in " " indicate text you can find on the screen of the analyzer.
XX	XX is the highlighted content
▌	Revision bar indicates update to previous version.

3 Understanding Your System

3.1 Overview

EU-5300 Pro/EU-5600 Pro Automatic Urinalysis System is an In Vitro Diagnostic device suitable for semi-quantitative or qualitative testing of human urine under laboratory environment conditions. The system uses digital imaging automatic recognition to perform analysis on the formed elements in the urine.

See below for configurations for different models.

Models	Number of count channels
EU-5300 Pro	2 Channels
EU-5600 Pro	4 Channels

3.2 Intended Use

Automatic Urinalysis system is an in vitro diagnosis device used for quantitative tests on human urine in laboratory environment. Clinically, the analyzer identifies and analyzes the formed elements in human urine, including Red Blood Cell, White Blood Cell, White Blood Cell Clump, Bacteria, Yeast, Squamous Epithelial Cell, Non-Squamous Epithelial Cell, Crystal, Hyaline Cast, Unclassified Cast, Mucous Strand, Sperm, Cocci, Bacillus, Mono-hydrate Calcium Oxalate Crystal, Di-hydrate Calcium Oxalate Crystal, Uric Acid Crystal and Ammonium Magnesium Phosphate Crystal.

The system can also used for semi-quantitative or qualitative testing of human urine with urinalysis test strips. It is suitable for routine clinical urine examination. The test items include: leukocyte, nitrite, urobilinogen, protein, potential of hydrogen, blood, specific gravity, ketone, bilirubin, glucose, Vitamin C, microalbumin, creatinine, calcium, color and turbidity.

NOTE

- **The operator needs to review and validate the proposed classification of each elements based on the element type.**
- **The operator needs to validate the results of the formed elements.**
- **This analyzer identifies the normal patient, with all normal system-generated parameters for In Vitro Diagnostic Use. The product flags or identifies patient results that require additional studies.**
- **The RUO parameters can be used as diagnosis basis.**

3.3 Measurement Parameters

3.3.1 Chemistry Test Parameters

The analysis system provides the following 16 chemistry test parameters and 2 RUO parameters.

Table 3-1 Urine Chemistry Test Parameters (14-Parameters)

Test Items	Abbreviation
Leukocyte	LEU
Nitrite	NIT
Urobilinogen	URO

Test Items	Abbreviation
Protein	PRO
Potential of Hydrogen	pH
Blood	BLD
Ketone	KET
Bilirubin	BIL
Glucose	GLU
Vitamin C	VitC
Microalbumin	mALB
Creatinine	CRE
Calcium	Ca
Specific Gravity	S.G.
Color	Color
Turbidity	Turb.

NOTE

- **When testing with 11-parameter test strips, creatitine, calcium and microalbumin are not provided.**

3.3.1.1 Research use only (RUO) parameters

Table 3-2 Urine Chemistry Test RUO Parameters

Test items	Abbreviation
Protein/Creatinine	P/C
Microalbumin/Creatinine	A/C

NOTE

- **The RUO parameters P/C and A/C are derived parameters and cannot be used for clinical diagnosis.**
- **The results of the P/C and A/C are provided only when 14-parameter test strips are used**
- **The RUO parameters are marked with "*" on the report result screen.**

3.3.1.2 Physical Parameters

Table 3-3 Parameters

Test items	Abbreviation
Specific Gravity (from test strip/ from physical module)	S.G.
Color	Color
Turbidity	Turb.

NOTE

- **When the function of "S.G. from Physical Module" is selected, the analyzer outputs turbidity and specific gravity from physical module.**

- **The software displays "Specific Gravity" for which is either from physical module or test strips. When "S.G. from Physical Module" is selected, the physical module of analyzer outputs the S.G. result which otherwise will be output through test strips when the function is deselected.**

3.3.2 Formed Element Test Parameters

The analysis system provides the following 45 formed element test parameters and 4 RUO parameters.

You can select the chemistry test parameters matched with the used urinalysis test strip according to your hospital conditions. You can also add or delete the formed element test parameters. A maximum of 30 user-defined parameters an be reported for manual identification.

Table 3-4 Urine formed element tests

Tested parameters	Abbreviation
Red Blood Cell	RBC
Normocyte	NOR-RBC
Abnormal Red Blood Cell Ratio	ABN-Ratio
Macrocyte	MAC-RBC
Microcyte	MIC-RBC
Annular Red Blood Cell	ANN-RBC
Acanthocyte	ACA-RBC
Humped Spherocyte	HUM-RBC
Jagged Red Blood Cell	JAG-RBC
Ghost Red Blood Cell	GHO-RBC
Crenocyte	CRE-RBC
Fragmented Red Blood Cell	FRA-RBC
Other Abnormal Red Blood Cell	OABN-RBC
Information of Red Blood Cell Morphology	MorInfo-RBC
White Blood Cell	WBC
Phagocyte	PHA
White Blood Cell Clump	WBCC
Squamous Epithelial Cell	SEC
Clue Cell	CLUC
Non-squamous Epithelial Cell	NEC
Urothelial Cell	UEC
Renal Tubular Epithelial Cell	RTEC
Other Epithelial Cell	OEC
*Decoy Cell	DEC
*Atypical Urothelial Cell	Atyp.C
Crystal	CRYS
Mono-hydrate Calcium Oxalate Crystal	CAOXM

Tested parameters	Abbreviation
Di-hydrate Calcium Oxalate Crystal	CAOXD
Uric Acid Crystal	UACR
Ammonium Magnesium Phosphate Crystal	AMPCR
Sodium Urate Crystal	SUCR
Calcium Phosphate Crystal	CPCR
Amorphous Salt Crystal	ASCR
Hyaline Cast	HYAC
Unclassified Cast	UNCC
Granular Cast	GRAC
Cellular Cast	CELC
Waxy Cast	WAXC
Blood Cast	BLDC
Other Unclassified Cast	OUNCC
Crystal Cast	CRYC
*Muddy Brown Cast	MUBC
Bacteria	BACT
Cocci	COCCI
Bacillus	BACILL
Yeast	YST
Mucous Strand	MUC
Sperm	SPRM
*Trichomonas vaginalis	TV

NOTE

- *** indicates RUO parameters.**
- **The system configures Mono-hydrate Calcium Oxalate Crystal, Di-hydrate Calcium Oxalate Crystal, Uric Acid Crystal and Ammonium Magnesium Phosphate Crystal as the subclass parameters of crystals by default and the parent-class parameter is the sum of that of all its subclasses. For changing the parent class of subclasses of crystals mentioned above, see *6.7.2.4 Customizing parent class parameters*.**
- **RBC= Normocyte + Anisocytosis.**
- **When the RBC results are greater than 0/μL, Normocyte (%)+ Anisocytosis(%)=100%.**
- **When the RBC results equal to 0/μL, Normocyte(%) = Anisocytosis (%)= 0%.**
- **Anisocytosis= Macrocyte+ Microcyte+ Acanthocyte+ Annular Red Blood Cell+ Humped Spherocyte+ Jagged Red Blood Cell+ Ghost Red Blood Cell+ Crenocyte+ Fragmented Red Blood Cell+ Other Abnormal Red Blood Cell.**
- **In "Information of Erythrocyte Morphology", you may choose qualitative parameters, including "-", "Iso RBC", "Dys RBC" and "Mix RBC" to custom the classification of abnormal red blood cells as needed.**

3.4 Product Description

3.4.1 Product Structure and Components

The analyzer consists of a fluidic module, optical module, mechanical module, circuit control module, sample analysis and processing software (Automatic Urinalysis System Software), as well as display and print module.

3.4.2 Major Modules and Components

See the figure of the analyzer below:

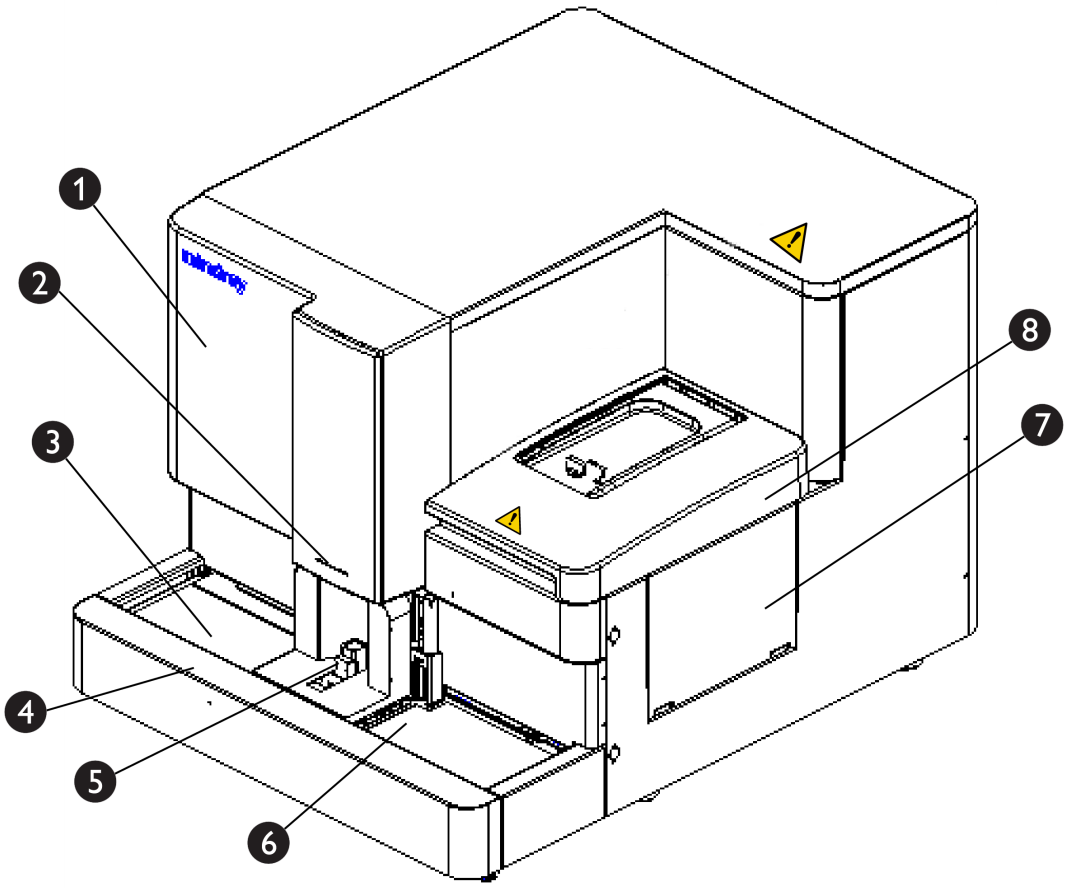


Figure 3-1 Analyzer overview (axis view)

1	Front cover	When necessary, hold the front cover to turn it upwards,	/
2	Status indicator	It tells about the status of the analyzer including ready (idle), running, error, and on/ off.	Stays in green: the analyzer is ready.
			Flickers in green: the analyzer is running or performing startup initialization.
			Flickers in yellow: the analyzer is in the process of startup self-test; or analyzer pauses working because the Diluent is used up.
			Stays in red: the analyzer is with error and cannot perform the analysis.

			Flickers in red: the analyzer is with error but is still running.
			Off: the analyzer is shutdown.
3	Unloading area	Completed samples are sent to the unloading area. Remove samples from the unloading area in time.	Unloads a maximum of 50 samples at one time (5*10-position tube rack)
4	Autoloader	The autoloader is located in the front of the analyzer. It automatically transports and loads the samples for analysis.	/
5	STA T sample tube holder	Place the STAT samples at the STAT tube holder for analysis. Place the tube containing the Probe Cleanser at the STAT tube holder to perform Probe Cleanser maintenance.	/
6	Loading area	Place the test tube rack loaded with samples in the loading area. The analyzer automatically sends the test tube rack to the instrument for analysis.	Loads a maximum of 50 samples at one time (5*10-position tube rack)
7	Test strip feeder	Place the test strips in the test strip feeder for chemistry analysis.	/
8	Cover of test strip feeder	Rotate to open the cover of the test strip feeder and place the strips.	/

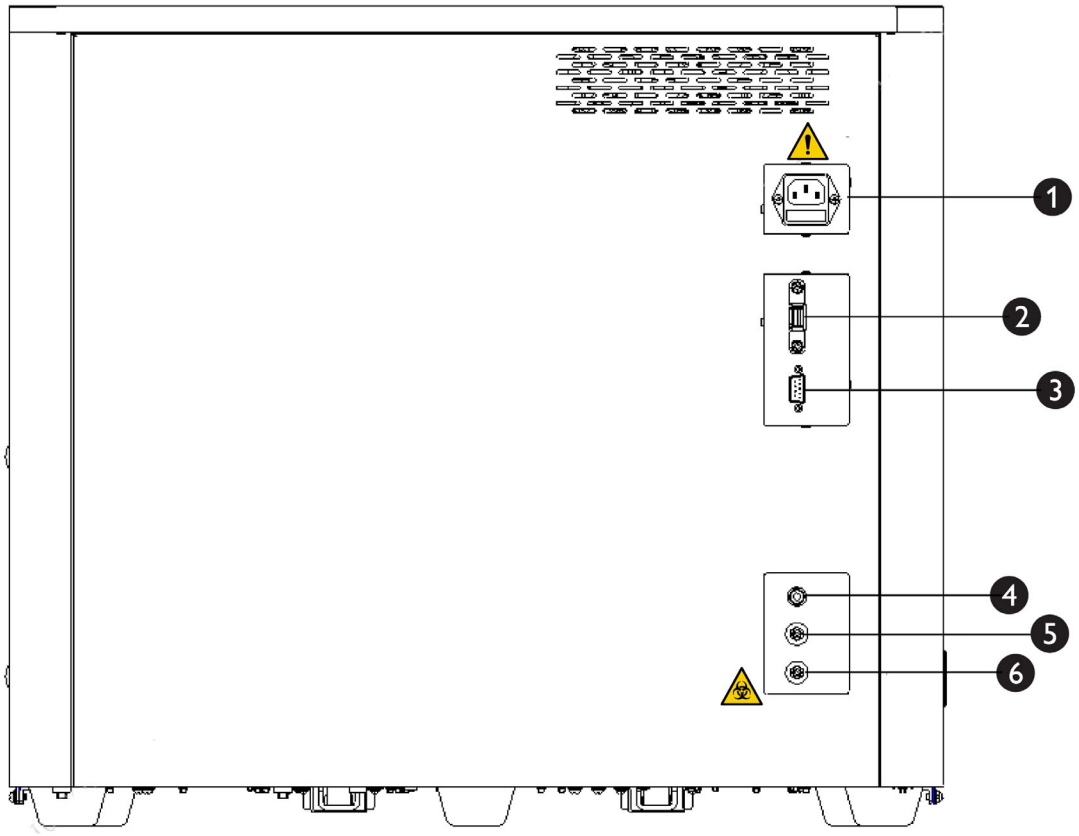


Figure 3-2 Rear view of the analyzer

1	Power socket	Connecting to power supply	/
2	Communication serial port (COM port)	Connecting the serial port wire to COM port on the computer	/

3	USB port	Connecting the USB video wire to the USB port on the computer	/
4	Waste sensor connector	When using waste containers to discharge the waste.	It is not necessary to connect this connector if the waste is drained directly.
5	Reagent connector	Connecting reagent	/
6	Waste outlet	When using waste containers to discharge the waste, connect the waste container to the outlet. When directly discharging the waste, connect the waste discharge tube.	/

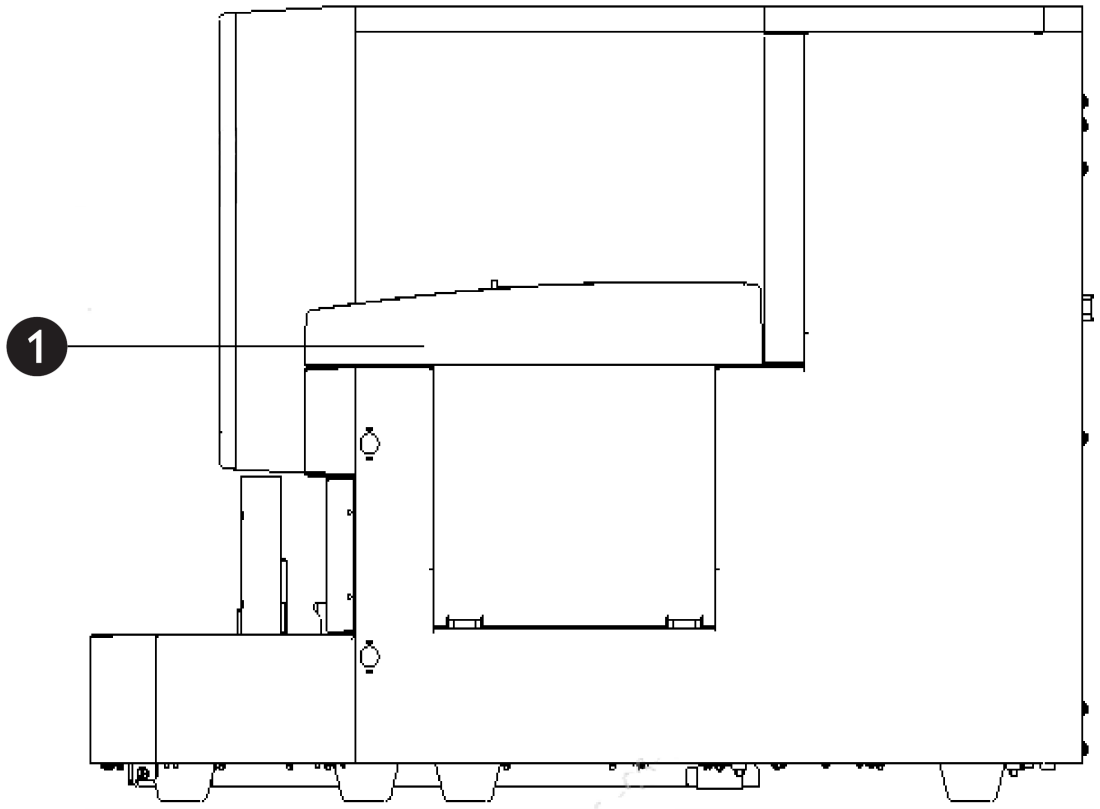


Figure 3-3 Right side view of the analyzer

1	Cover of test strip feeder	When necessary, pull down the strip selection assembly to the right to perform maintenance.	/

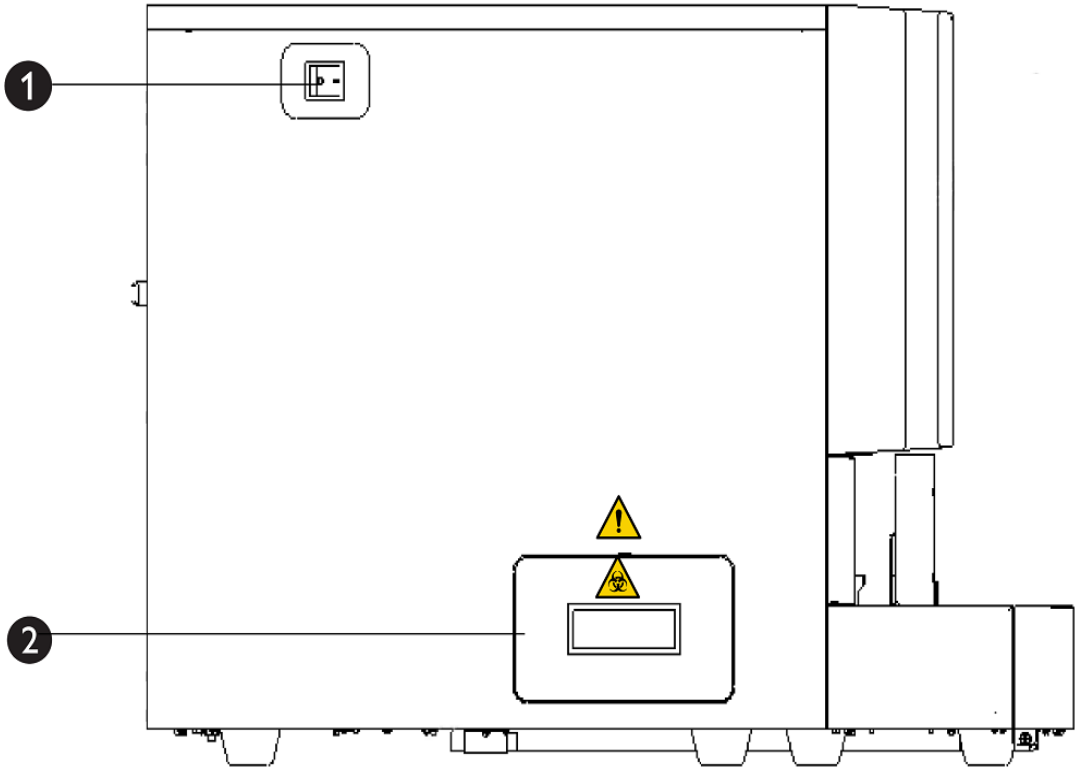


Figure 3-4 Left side view of the analyzer

1	Power switch of the analyzer	The main power switch is on the left side of the analyzer. It is used to start up or shut down the analyzer.	/
2	Waste strip box	The strips used in the dry chemistry analysis is recycled to the waste strip box. Clean the waste box regularly.	For methods of cleaning the waste strip box, see*10.5.2 Cleaning the Waste Strip Box*.

⚠ CAUTION

- **To avoid damage, do not turn on/off the power of the analyzer continually in a short time.**

3.5 Software System

NOTE

- **For problems not mentioned in this manual, contact Mindray customer service department for Mindray service advice.**
- **This instrument is intended to be used by clinical laboratory professionals trained by Mindray or Mindray-authorized distributors.**
- **The installation, authorization, upgrade and maintenance of the system software must be performed by Mindray. For more information about the software, contact Mindray customer service department.**

"Automatic Urinalysis System" Software is the software for the system. The analysis software is composed of PC application software including: user interaction interface, data management module and cell morphology analysis module.

"Automatic Urinalysis System" software is suitable for "EU-5300 Pro/EU-5600 Pro Automatic Urinalysis System" to perform routine urine test and output the results in the form of report.

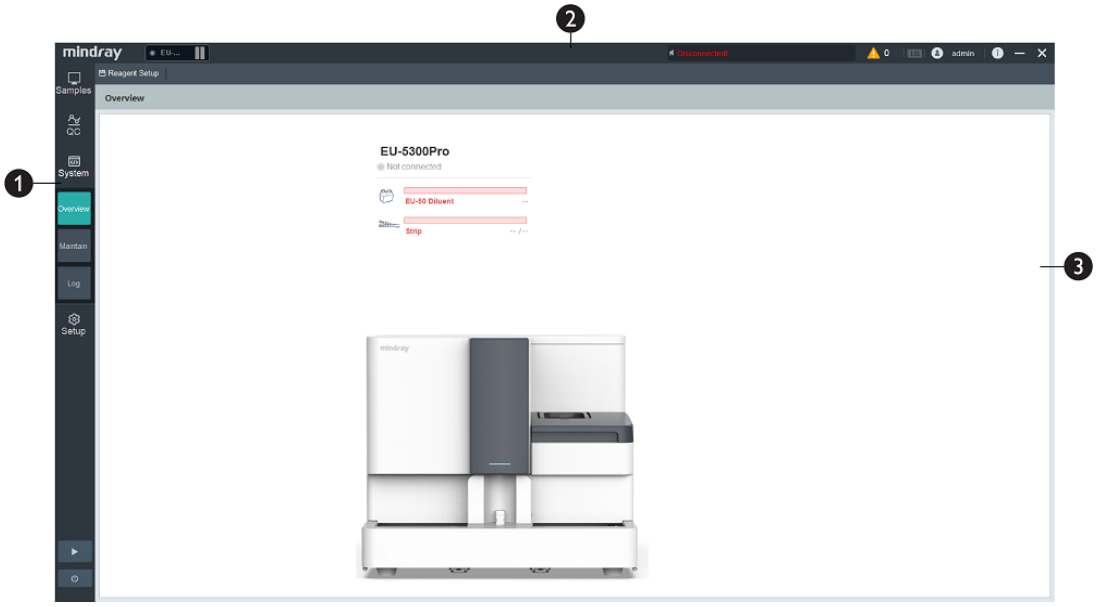


Figure 3-5 "Automatic Urinalysis System" software home screen

		Description
1	System menu button	Click to display corresponding interface.
2	Status bar	Click to display the connection status of the software and system, information of LIS connection, analyzer connection, user information and sample analysis.
3	Main information bar	Display different information under different menus.

3.5.1 Viewing the Software Version

Click the icon ⓘ at the upper right corner of the software to view the version information of the software.

3.5.2 Functionality

NOTE

- **When the maximum number of sample results has reached the upper limit, the newest results will overwrite the oldest. Be sure to backup important data to an external storage medium on a regular basis.**

3.5.2.1 Overview of software functions

This product is used in medical institution for chemistry measurement, imaging of formed elements, visible observation and description, auto-classification and counting of cells, split images of cell morphology display, real images and RBC phase.

Instruction to Application

The software supports users to perform the following operations:

- Setting sample orders;
- Viewing analysis status during the analysis process;
- Viewing the status of consumables;
- Viewing and adjusting the status of instrument parts;
- Configuring the software;
- Servicing and debugging the instrument;

- Switching login account;
- Viewing, editing and processing analysis result of the urine sample;
- Viewing, editing and processing the result of control sample;
- Communicating with main unit;
- Performing startup and shutdown of the instrument.

3.5.2.2 Software functions by access levels

The analyzer logs in with a user ID and password, supporting two levels for accessing control: the administrator access level and operator access level.

Table 3-5 Software functions by access levels

Main menu	Sub Menu	Functions	Administrator's level	Operator's level
Samples	/	**Sample Order**	√	√
		Order Setup	√	√
		Validate/Undo Valid.	√	√
		Re-search LIS	√	√
		Export	√	√
		Refresh	√	√
		Edit Sample ID	√	√
		Edit	√	√
		Comm.	√	√
		Print	√	√
		Restore	√	√
		Delete	√	√
		Data Snapshot	√	√
QC	**QC Setup**	/	√	√
	QC Graph	/	√	√
	QC table	/	√	√
System	**Overview**	/	√	√
	Maintain	**Manual Maintain**	√	√
	Log	**All**	√	√
		Setup Adjustment	√	√
		Other Logs	√	√
		Error Information	√	X
System Setup	/	**Instrument Connection**	√	√
		Users	√	√ (Password modification only)
		Normal Setup	√	√
		Para. Setup	√	X
		Auxiliary Setup	√	X

Main menu	Sub Menu	Functions	Administrator's level	Operator's level
		Reexam Setup	√	X
		Analyzer Setup	√	√
		Data Dictionary	√	√

NOTE

- **"√" indicates that the access level supports the corresponding function, while "X" indicates that the access level does not support corresponding the function.**

3.5.3 Performance Efficiency

For the requirements for input/ output devices, refer to ***A.12 Input and Output Device Requirements***.When configured requirements are met, for the maximum throughout of the analyzer, refer to *A.7 Product Performance*.

3.5.4 Compatibility

For requirements of input/ output devices, refer to ***A.12 Input and Output Device Requirements***.

The software of the analyzer is developed based in the following Off-the-Shelf software.

Table 3-6 Off- the-Shelf software

Name	Model	Version	Title	Manufacturer
Database	SQLite	3.9.2	Open-source	/

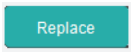
3.5.5 Usability

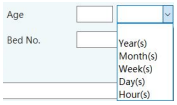
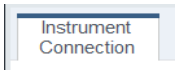
3.5.5.1 Software controls and basic operations

Table 3-7 Description of the software operations

Action	Meanings
Click	Left-click the mouse to select option and focus an input entry.
Double click	Double click the mouse twice continuously.

Table 3-8 Description of software controls of the analyzer

Controls	Examples	Meanings
Button		Click the button to perform operations or open dialog boxes.
Input box		Click the box to enter information
Radio buttons	Selected status 	When there is more than one radio button under an item, it is only allowed to select one of them.
	Not selected status 	/
Check box	Selected status 	When there is more than one check box under an item, you can check one or more of the boxes.

Controls	Examples	Meanings
	Not selected status ☐	/
Drop-down list:		Select an option from the pull-down list.
Tab		Click the tab to go to the corresponding tabbed page.

3.5.5.2 Icons of the software

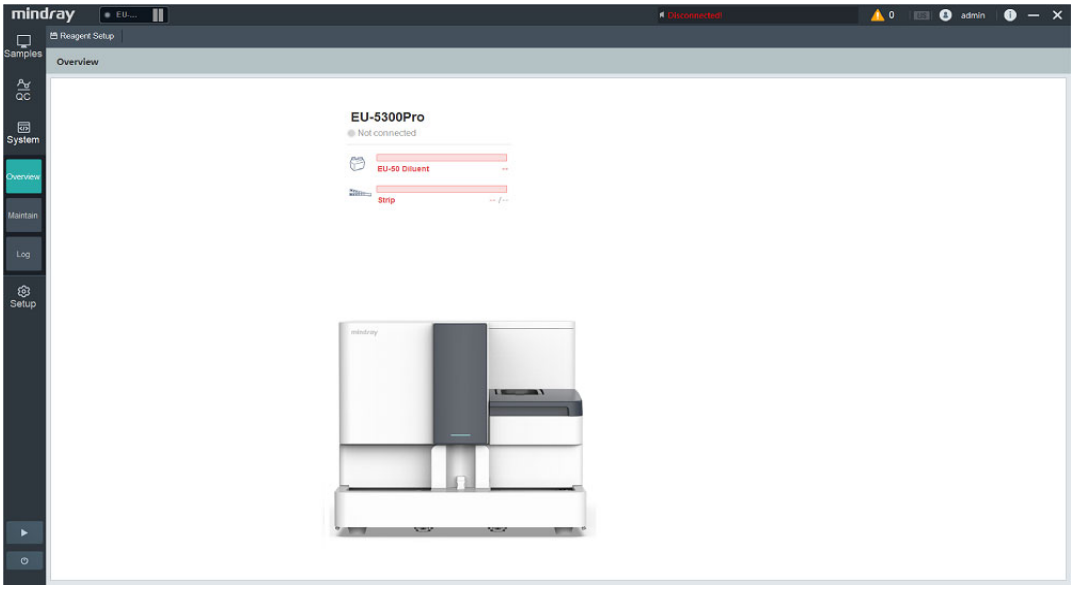


Figure 3-6 Instrument and LIS connection status

	Icons	Meanings
LIS connecting status indicator		Stay in green: the software is connecting to the software
		Flicker in green: the software is communicating with LIS (transmitting/ receiving sample data)
		Grey: the software is disconnected to LIS
		Yellow: errors exist when the software connects to LIS

	Icons	Meanings
Login user ID		Display the current user ID used to log in
Software version		Click the icon to view the version information of the software
Minimize		Click the button to minimize the software
Exit the software		Click to exit the software

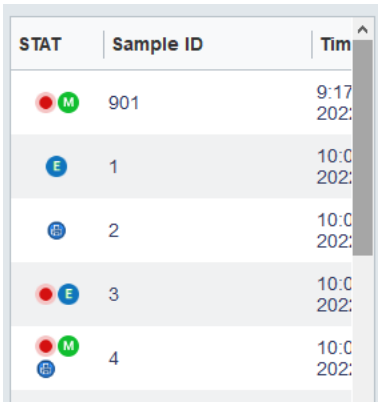


Figure 3-7 Sample Status Icons

NOTE

- **For details about sample status icons and meanings, refers to *Table 8-2 Sample status icons*.**

Figure 3-8 Analyzer Status Icons

	Icons	Meanings
Connection status indicators of analyzer and software		Stays in green: Analyzer is ready and in idle status.
		Flickers in green: Analyzer is running.
		Grey: the instrument is not connected to LIS.
		Red: Analyzer is in error status.

	Icons	Meanings
Reagent status indicator		Green: Diluent is sufficient
		Red: Diluent is not sufficient

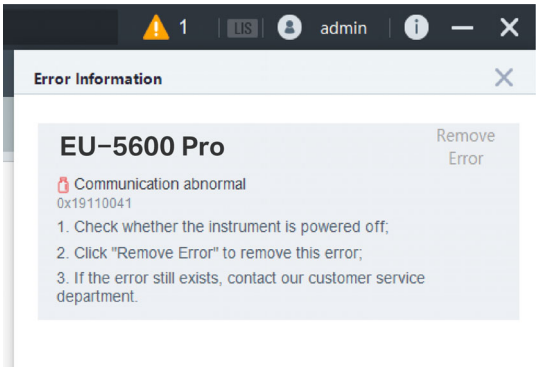


Figure 3-9 Error Icons

	Icons	Meanings
Error Icons		When error occurs, click the icon to check detailed error message. The number displayed beside the icon indicates the number of current errors.

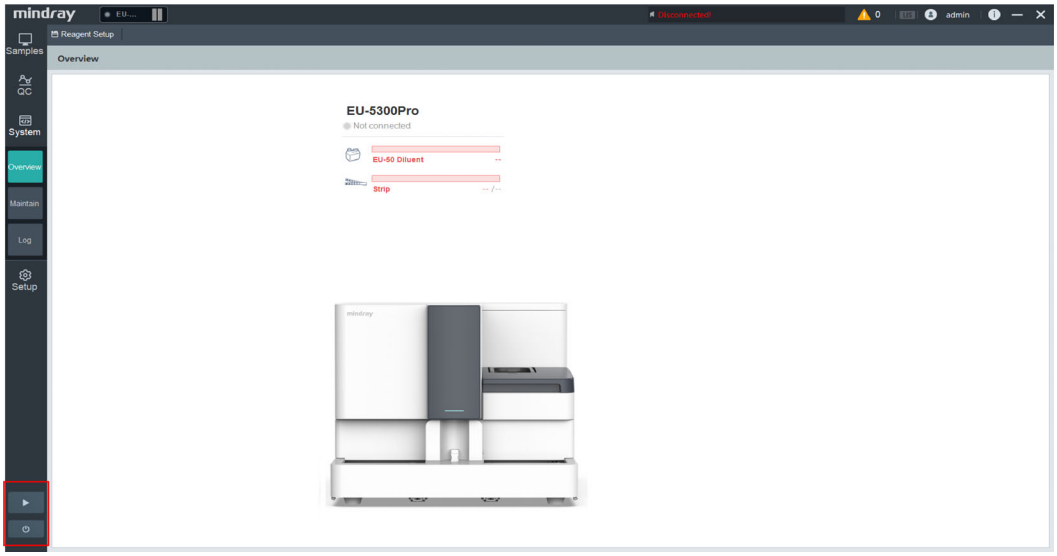


Figure 3-10 Shutdown and startup button

	Icons	Meanings
"Shutdown" Button		Click the button to perform shutdown procedure.
"Start" button		In auto-loading mode, click the button to start analysis.

3.5.6 Reliability

After each analysis, the analysis results are stored in sample library automatically.

The software can save 20,000 sample result records at maximum. When the number of stored sample results has reached the upper limit, the latest analysis results will overwrite the oldest. Software supports flash backup to protect data in case of unexpected shut-down or power outage.

You can check the existing record(s), print or process the sample results.

NOTE

- **Disk space with 4TB is recommended for installing the software server end.**
- **For requirements of input/ output devices, refer to *A.12 Input and Output Device Requirements*.**

3.5.7 Portability

The software shall be installed and connected by Mindray Service Department. When installing analyzer software, be sure to confirm whether the computer configuration and disk space meet the requirements.

NOTE

- **Disk space for installing the client end and server end of the PC application software should not be less than 1TB.**
- **For minimum requirements of input/ output devices, refer to *3.5.3 Performance Efficiency*.**

Unloading application software

When unloading the application software, it is needed to unload server end and client end.

1. Click "Start", the menu at the left corner of the computer, find the client end and server end and select "unload".
2. Complete unloading process according to software instructions.

3.5.8 Validity

For communicating with laboratory information management system/ LIS, software is required to support specific communication protocols. For more information, refer to ***C Communication***.

3.5.9 Efficiency

The product is verified to allow at least one end user to simultaneously access the PC application provided that the requirements of computer configuration are met. If more end-user connections are required, contact Mindray customer service department for assessment.

3.5.10 Freedom from Risk

Follow the instructions below to safeguard device stability and data security.

⚠ CAUTION

- **Windows Defender has been installed on the computer to prevent from viruses, spyware, and malware attacks. Users shall scan for viruses periodically and update security patches.**
- **Install anti-virus software on the computer and scan for viruses periodically.**
- **Make sure to install only Mindray-authorized software on the computer.**
- **Data transmission must be performed in a close-loop network or virtual network. The network must be isolated.**
- **Users have the responsibility to protect the network authentication information, such as password and user information, from being obtained by unauthorized personnel.**
- **The installation, authorization, upgrade and modification of the system software must be performed by personnel authorized by Mindray.**

3.5.11 Satisfaction

For feedback and questions about the software, contact Mindray customer service department.

3.5.12 Context Coverage

For communicating with laboratory information management system, specific communication protocol is accessible to software. For more information, refer to ***C Communication***.

3.6 Reagents,Test Strips and Controls

As the analyzer, reagents, test strips and controls are components of a system, performance of the system depends on the combined integrity of all components. You must only use the Mindray-specified reagents and controls in order to prevent analyzer damage and achieve optimal system performance. Do not use the analyzer with products from other suppliers. In such use, the analyzer may not meet the performance specified in this manual and may provide unreliable results. All references related to reagents in this manual refer to the reagents specifically formulated for this analyzer.

⚠ CAUTION

- **Each reagent, test strip and control package must be examined before use. Product integrity may be compromised in packages that have been damaged. Inspect the package for signs of leakage or moisture. If there is evidence of leakage or improper handling, do not use.**
- **Use the reagents, test strips and controls specified by the manufacturer only. Store and use the reagents and controls as instructed by instructions for use of the reagents and controls.**
- **Pay attention to the expiration dates and open-container stability days of all the reagents, test strips and controls. Be sure not to use expired reagents and controls. Otherwise, the measurement reliablity cannot be guaranteed.**
- **After installing a new container of reagent, keep it still for a while before use.**

NOTE

- **If you need to purchase reagent and consumables, please call Mindray Customer Service.**
- **For other information about reagents provided with instrument, refer to the instruction for use of corresponding reagents.**

The following reagents and controls work with the analyzer:

Table 3-9 Reagents, test strips and controls

	Reagent
Reagents for diluting samples and maintenance	Automatic Urinalysis System Reagent (EU-50)
	Probe Cleanser
Test strips	Urinalysis test strips
Controls	Urine Formed Element Controls

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4 Understanding the Working Principles

4.1 Overview

EU-5300 Pro/EU-5600 Pro Automatic Urinalysis System utilizes the chromogenic reaction of dry chemistry test strips and urine samples to calculate the concentration of sample components through measurement to obtain semiquantitative or qualitative results. The analysis system adopts the computer vision imaging and auto coordinate positioning and identifying technology, to perform morphology and quantitative analysis of the formed elements (for example, RBCs) in the urine.

4.1.1 Working Principle for Urine Chemistry Tests

The analyzer utilizes the basic principle of measuring reflection. When the light emitted from the light source strikes on the test strip reagent pads, the reagent pads reacts with different components in the urine sample, and show different colors. The color depth of reagent pads after reaction is proportional to the content concentration of the corresponding component in the urine. The analyzer performs semi-quantitative analysis of urine components based on the color development of the reagent pads.

The analyzer picks up the test strips from the strip feeder, and places the test strips on the test strip transportation module. The sampling probe aspirates samples from the sample tube and drips the sample of fix amount on each of the strip reagent pads. After reaction, the test strip is sent to the optical unit for analysis. After analysis, the test strip is transported to the waste strip box.

NOTE

- **The L15 white block on the test strip is used for:**
- **1. Obtaining color data of the sample;**
- **2. Removing the background color of the sample to faciliate the calculation of the chemistry tests.**

In the optical unit, the light emitting diode strikes the reagent pads, and the reflected light is received by the sensor (each test item corresponds to a specific wavelength). The intensity of the reflected light of a specific wavelength of the reagent pad corresponds to the concentration of the tested items contained in the sample.

Calculate the reflectance according to the following formula:

R=T/C

R: Reflectance

T: Reflection volume of the test item area

C: Reflection volume of compensation area

4.1.2 Urine Specific Gravity Measurement (Refractometry Method)

As different urine specific gravities indicate different refractive index, the analyzer measures the urine specific gravity by detecting the refraction angle when light passes through the prism filled with urine. This method is called refractometry method.

The light from LED diode passes through the gap and lens, and converges into a beam, which then goes through a prism filled with urine, and shoots to the sensor. Urine samples of different specific gravities change the refractive index and angles of the light passing through them to different extent. When the lights finally reach

the sensor, they are reflected as light spots at different positions. The following figure shows the schematic diagram and calculation formula for the refractometry method.

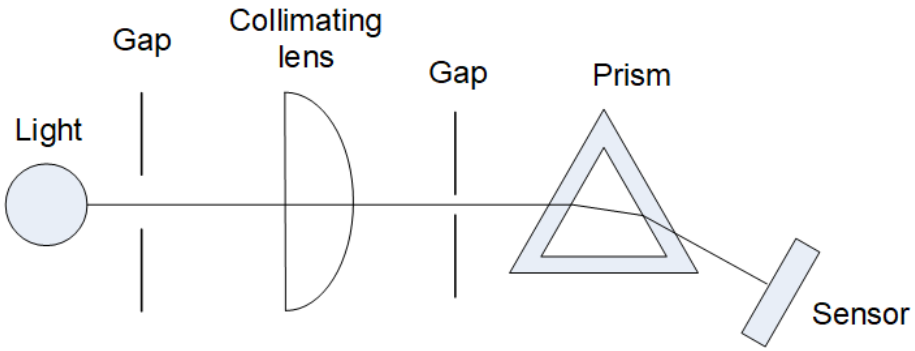

Figure 4-1 Schematic diagram of urine specific gravity retractometry method

Urine specific gravity is calculated per the following formula:

$SG_X = (SG_H - SG_L)$ o $(K_X - K_L) / (K_H - K_L) + SG_L$

Among them:

SG_H: specific gravity of high-specific gravity liquid

SG_L: specific gravity of low-specific gravity liquid

SG_X: specific gravity of sample

K_H: position factor of high-specific gravity liquid

K_L: position factor of low-specific gravity liquid

K_X: position factor of sample

4.1.3 Turbidity Measurement

The analyzer measures turbidity using the nephelometry method. When the incident light meets suspended particles in the solution, it will be scattered and absorbed. The greater is scattered light, the higher is turbidity. Therefore the turbidity can be measured through the scattered light. Urine turbidity is graded by three degrees: “clear”, “slightly turbid” and “turbid”.

It is calculated per the following formula:

$T= (SSC/ S_{FS} - R_{SC}/ R_{FS})/K$

Among them:

T: turbidity

S_{SC}: scattered light degree of sample

S_{FS}: transmitted light degree of sample

R_{SC}: scattered light degree of diluent

R_{FS}: transmitted light degree of diluent

K: factor

4.1.4 Color Measurement

The analyzer uses RGB color sensor to measure the colors. The light emitting white diode strikes on sample and is reflected, and reflected light passes through the color sensor, where its R, G and B values are detected. Then the analyzer measures sample color based on its R, G, B values.

4.1.5 Working Principle for Urine Formed Element Analysis

“Machine vision“ technology utilizes machine, sensors and computer to simulate the eyes, hands and brains of the laboratory professionals for measurement and judgment. When used in the analysis of urine formed elements, machine vision usually converts various urine formed elements into digital image signals through

visual perception devices such as CCD/CMOS and image acquisition card, and transmits the digital image signals to the computer processing and analysis system. The software extracts the targeted formed element images based on pixel distribution and grayscale change. After classification and calculation of the formed elements through modeling of characteristic space, calculation of characteristics set and stimulating neutral network of human brain for identification of formed elements, the system output the test results automatically.

The sampling probe injects sample to detection count bath, and then control system auto-focuses and photographs images, which are then identified, classified and counted by computer.

The process includes image pre-proccessing to remove noise interference, target segmentation to the images, then characteristics calculation on the segmented area, and the calculated results sent to neutral network for classification and identification.

4.2 Principle Diagram

The test strip feeder picks up test strips, and transports the strip with its specified surface facing upwards to the push assembly. The push assembly transports the test strip to strip transportation system. On the strip transportation system, the sampling probe aspirates and drips the sample on the test strips; then injects the sample into count bath. The analyzer then perform analysis of the test strips and outputs the results. The microscopic imaging system completes urine formed element detection and output the results,

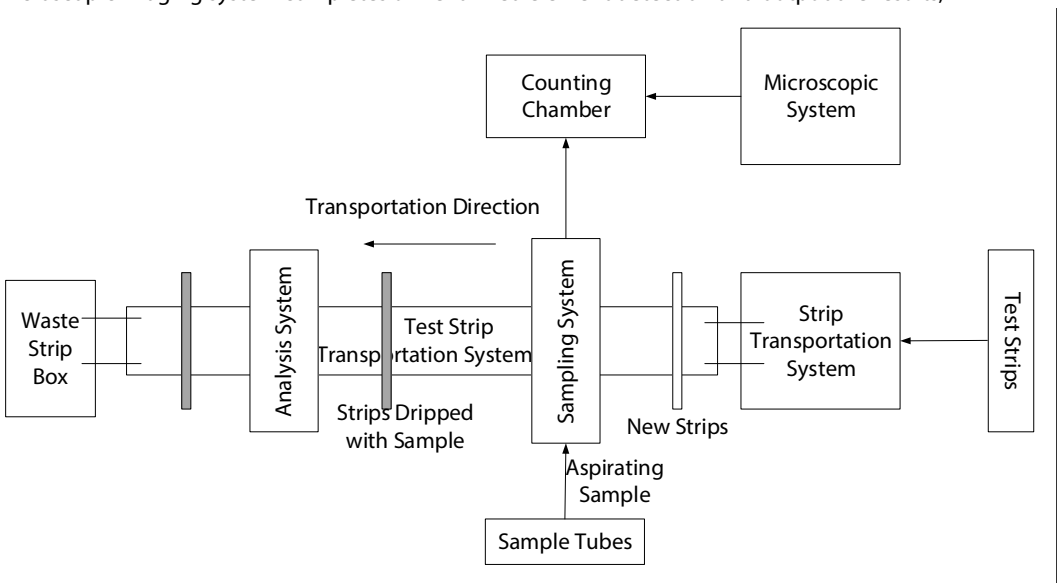

Figure 4-2 Principle Diagram

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5 Installing and Connecting the Instrument

5.1 Notes for Analyzer Installation

⚠ WARNING

- **The installation and transportation of the instrument shall be performed by personnel authorized or trained by Mindray. Your instrument has been tested before it is shipped from the factory. The instrument was carefully packaged and labels were placed to tell the carrier how to treat this instrument. When you receive your analyzer, carefully inspect the package. If you see any signs of mishandling or damage, contact Mindray Customer Service Department or your local distributor immediately.**
- **Transportation, unpacking, or installation by personnel not authorized or trained by the manufacturer may cause personal injury or damages to your analyzer. Do not install your analyzer without the presence of personnel authorized by the manufacturer. Do not install or transport your analyzer without the presence of personnel authorized by the manufacturer.**

NOTE

- **After you open the package, check the integrity of the product according to the packing list. If you find any part missing, contact Mindray Customer Service Department or your local distributor immediately.**
- **The installation, authorization, upgrade and modification of the system software must be performed by personnel authorized by the manufacturer.**
- **When installing the instrument, ensure that the power switch is in close proximity to the equipment and within easy reach of you.**
- **The safety of any system incorporating the equipment is the responsibility of the assembler of the system.**

5.1.1 Space Requirements

NOTE

- **For details about analyzer's dimensions and weights, refer to *A.9 Size, Dimension and Weight*.**

In consideration of instrument maintenance, heat dissipation, and the fluidic tubings free from being pressured at the back, check the site for proper space allocation. Therefore, in addition to the space required for the system itself, arrange for:

- During installation, no less than 15 cm clear space shall be reserved from the wall to facilitate heat dissipation.
- The width of the worktop shall be greater than 80 cm, the length shall be greater than 170 cm, and the worktop shall be able to bear the weight of 100kg or above.

5.1.2 Power Requirements

⚠ WARNING

- **Make sure the analyzer is properly grounded.**
- **When installing the instrument, ensure that the power switch is in close proximity to the equipment and within easy reach of you in order to power off the instrument effortlessly when necessary.**
- **Before turning on the instrument, make sure the input voltage meets the requirement.**

⚠ CAUTION

- **Using pinboard may bring electrical interference and the analysis results may be unreliable. Place the analyzer near the electrical outlet to avoid using the pinboard.**
- **Use the original power cord provided by the manufacturer. Using other electrical wire may damage the analyzer or lead to unreliable analysis results.**

Table 5-1 Power requirement

	Voltage	Frequency	Input Power
Main unit	100V-240V (±10%)	50 /60Hz(± 2%)	300 VA

5.1.3 Fuse Requirement

⚠ CAUTION

- **Only install fuses of specified type and specification to prevent from fire hazard.**
- **If there is any problem with the fuse, contact Mindray Customer Service Department or your local distributor.**

Table 5-2 Fuse requirement

	Specification Requirements
Fuse	φ5 T3AL250V

5.1.4 Environment Conditions

Table 5-3 Environment Conditions

	Normal operating environment conditions	Storage and transportation conditions	Operating conditions
Ambient temperature	15℃-30℃	-10℃-40℃	5℃-40℃
Relative humidity	≤80%	≤93%	≤80%
Atmospheric pressure	80kPa~106kPa	50kPa~106kPa	80kPa~106kPa

- The altitude shall not be more than 2,000 meters.
- The environment should be as free as possible from dust, mechanical vibrations, contamination, loud noises and electrical interference.
- It is advisable to evaluate the electromagnetic environment prior to operation of this analyzer.
- Do not use this instrument in close proximity to sources of strong electromagnetic radiation.
- Do not place the analyzer near brush-type motors, flickering fluorescent lights, and electrical contacts that regularly open and close.
- Do not place the analyzer in direct sunlight or in front of a source of heat or drafts.
- The environment shall be well ventilated.
- The table top must be stable and level, vibration and mechanical impact shall be avoided. Do not place the analyzer on a slope.
- Connect only to a properly earth grounded outlet.
- Only use this analyzer indoors.

5.1.5 Moving and Installing the Analyzer

Transportation and installation of the analyzer shall be conducted by manufacturer-authorized personnel. Do not move or install analyzer without the presence of manufacturer-authorized personnel.

⚠ WARNING

- **Transportation, unpacking, or installation by personnel not authorized or trained by the manufacturer may cause personal injury or damages to your analyzer. Do not install or transport your analyzer without the presence of personnel authorized by the manufacturer.**

⚠ CAUTION

- **When handling the instrument, lift it up according to the handling marks on both sides of the instrument.**

5.2 Connecting the Analyzer

Make sure the connections are correct and firm.

☣ BIOLOGICAL RISK

- **Be sure to dispose of reagents, waste, samples, consumables, etc. according to government regulations.**

⚠ WARNING

- **Diluent is irritating to eyes, skin and mucous membrane. Wear proper personal protective instrument (e.g. gloves, lab coat, glasses, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.**
- **If Diluent accidentally spills on your skin, wash the reagent off with plenty of water and if necessary, go see a doctor; if Diluent accidentally spills into your eyes, wash the reagent off with plenty of water and immediately go see a doctor.**

⚠ CAUTION

- **Users shall make sure data security when USB storage device connecting to the system.**
- **There are 2 ways of waste connection, one is using waste container, the other is discharging waste directly. When using the waste container, make sure that the pickup tube of the reagent cap assembly of the waste container is located above the waste container, and the tube is smooth without bending. If the waste is discharged directly, make sure the waste pump is at a lower position than the waste outlet on the analyzer.**

5.2.1 Connecting Power Supply and External Devices

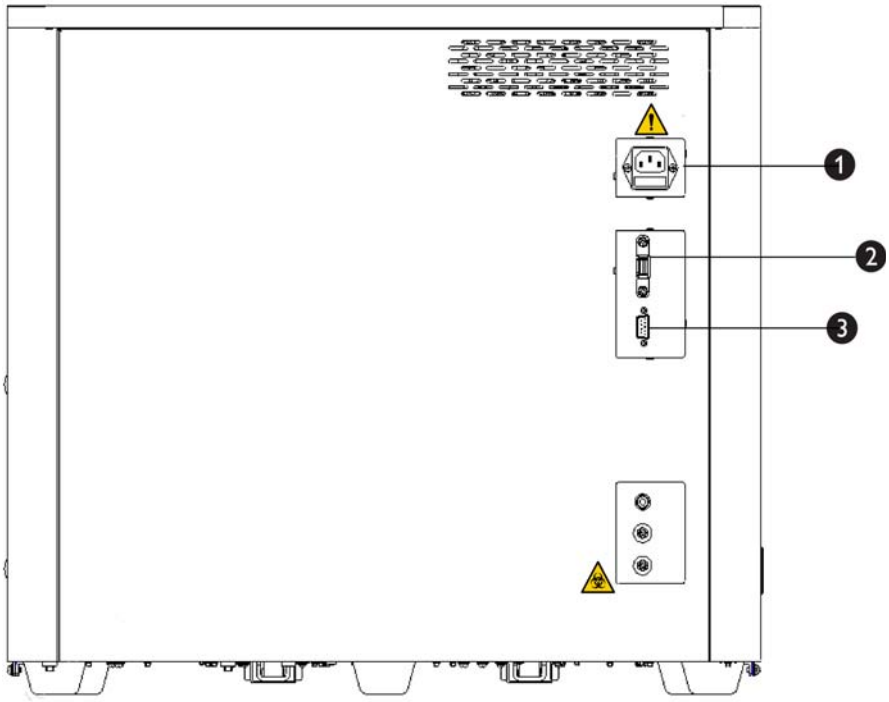

Figure 5-1 Connecting to Power Supply and Computer

1	Power socket	Connecting to power supply
2	Communication serial port (COM port)	Connecting the serial port wire to COM port on the computer
3	USB port	Connecting the USB video wire to the USB port on the computer

⚠ CAUTION

- **External equipment shall be protected from water.**

5.2.2 Connecting Reagent and Waste Tubes

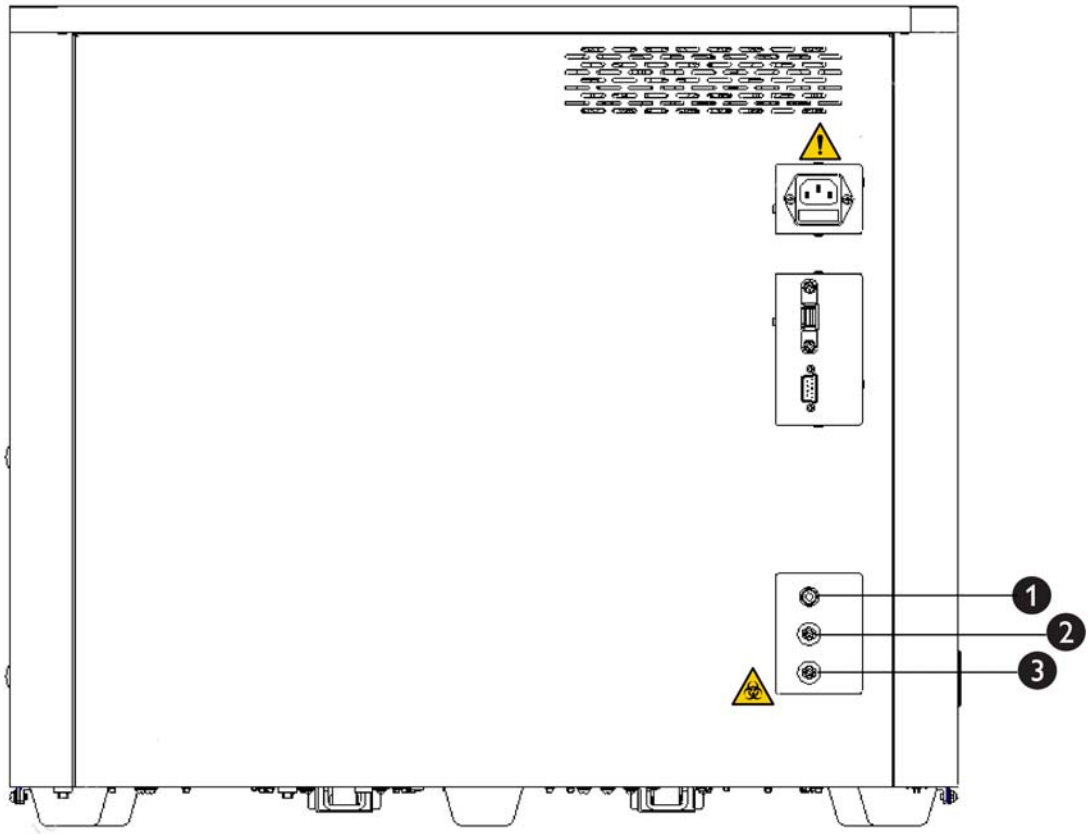

Figure 5-2 Connecting Reagent and Waste Tubes

1	Waste sensor connector	When using waste containers to discharge the waste, it is not necessary to connect this connector if the waste is drained directly.
2	Reagent connector	Black connector Connecting reagent
3	Waste outlet	Red connector When using waste containers to discharge the waste, connect the waste container to the outlet. When directly discharging the waste, connect the waste discharge tube.

NOTE

- **When connecting the reagents, make sure the color of the reagent container cap assembly is the same as that of the reagent inlet to which it is connected.**

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6 Customizing the Analyzer Software

6.1 Overview

The analyzer is initialized before it is shipped from the factory, and the interface of the software is set by default with the first startup. You can customize the software options as introduced in this chapter.

For the security of the settings and data, two access levels are provided to the operators of the analyzer: administrator and operator. The administrator access level provides the operators with access to more functions or settings, some of which can be configured to be accessible to operators.

⚠ CAUTION

- **Improper configurations may affect the working of the analyzer and result in in-accurate measurement results. It is recommended that the configuration of the analyzer should be performed by personnels trained or authorized by manufacturers. The manufacturer is not responsible for any damage caused by inappropriate configuration by non-authorized/trained personnels.**
- **For settings and functions allowed under "operator" and "administrator" levels, refer to *3.5.1 Viewing the Software Version*.**

6.2 Setting up for Interconnection of Multiple Servers

With the software, multiple servers can be interconnected. The test results (including history records) of the same sample on different servers can be displayed on the specified PC software screen at the same time, realizing centralized management of samples .

You need first to set central server and sub server before using this function.

■ Central server: On the central server, you can view, edit and review sample results on sub servers. All operations performed on the sample on the central server will be synchronized to sub servers.

NOTE

- **For setting central server, contact Mindray customer service department.**

■ Sub server: On the sub server, you can only process local sample results, and the processed results will be synchronized to the central server. You can set the sub server on the PC software on the central server.

6.2.1 Setting up sub server

Follow below instructions:

1. Log in the software on the central server as an administrator .
2. Click "**Setup**"- "**System Setup**"-"**labXpert conn. Setup**" to switch to the "**labXpert conn. Setup**".
3. Click "**New**" .
4. Enter sub server name and IP address .
5. Click other tabs, and follow the software instructions to save the settings .

6.2.2 Viewing interconnection of servers

Administrator can view central server and sub servers on the "**labXpert conn. Setup**"screen.

Follow below instructions:

1. Log in the PC software as an administrator.
2. Click "**Setup**"- "**System Setup**"-"**labXpert conn. Setup**" to switch to the "**labXpert conn. Setup**"screen.

√ On the computer that is configured as central server, you can view all the sub servers connected to it.

√ On the computer that is configured as sub server, you can view the central server it connects to.

6.2.3 Disconnecting sub server from central server

Follow below instructions to disconnect sub server from central server.

1. Log in the PC software on the central server as an administrator.
2. Click "**Setup**"- "**System Setup**"-"**labXpert conn. Setup**" to switch to the "**labXpert conn. Setup**" screen.
3. Select the sub server to be disconnected from the central server on the server list.
4. Click "**Delete**" button, and follow the software instructions to disconnect the sub server from the central sever.
5. Click other tabs, and follow the software instruction to save the settings.
6. Log in the PC software on the sub server as an administrator.
7. Click "**Setup**"- "**System Setup**"-"**labXpert conn. Setup**" to switch to the "**labXpert conn. Setup**" screen.
8. Click "**Delete**" button, and follow the software instructions to disconnect the central sever from the sub server.
9. Click other tabs, and follow the software instruction to save the settings.

NOTE

- **If you only delete sub sever from the server list on the central server, the central server will connect with the sub server again.**
- **If you delete the central server from the server list on the sub server, the central server can no longer receive sample data from the sub server.**

6.3 User Management Settings

Select "**Menu**" - "**System Setup**" - **Users**"to enter the "**Users**" screen. The list of all users who can log in the system is displayed.

The software has a built-in administrator account with the user name admin (initial password: admin), which can be deleted.

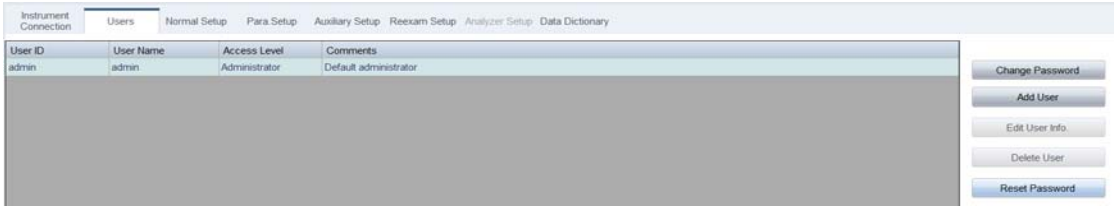


Figure 6-1 User management setting screen

Table 6-1 User management setting screen

Items	Description
User ID	The user ID used to log in.
User Name	User name
Access Level	User access levels, including: • Administrator • Operator
Comments	Notes about user information.

See below for setting descriptions:

Functions	Operation	Description
Add User	1. Select "**Menu**" - "**System Setup**" - **Users**" to enter the "**Users**" screen. 2. Select "**Add User**". 3. Enter user ID, user name, password, access level, and note. 4. Select "**OK**".	/
Editing user Information	1. Select "**Menu**" - "**System Setup**" - **Users**" to enter the "**Users**" screen. 2. Select the user to edit, and click "**Edit User Info.**". 3. The "**Edit User Info.**" dialog box displays. 4. Enter user ID, user access level, and note. 5. Select"**OK**".	• User name can not be edited. • You cannot edit the user account that currently logged in.
Reset Password	1. Select "**Menu**" - "**System Setup**" - "**Users**" to enter the "**Users**" screen. 2. Select a user account to reset, and click "**Reset Password**".	• The new password is the same as the current account ID.
Change Password	1. Select "**Menu**" - "**System Setup**" - **Users**" to enter the "**Users**" screen. 2. Select current account, and click "**Change Password**". 3. Enter the new password as prompted. 4. Select "**OK**".	• 5~20 digits can be entered. You can enter characters, numbers, letters and special characters. Passwords are case sensitive. • Only the password of the current user is allowed to be modified. • Password must contain at least five characters.
Delete User	1. Select "**Menu**" - "**System Setup**" - "**Users**" to enter the "**Users**" screen. 2. Select the user to edit, and click "**Delete User**". 3. The "**Delete**" dialog box displays. 4. Select "**Yes**".	• The current login user cannot be deleted. • Deleted user cannot be recovered.

6.4 Configuring Display Settings

6.4.1 Configuring Real Images Display Settings

You can configure the grid line scale for real images on the "**Display Setup**" screen.

After the grid line scale is set, the graphic area of the sample result interface will be displayed according to the scale.

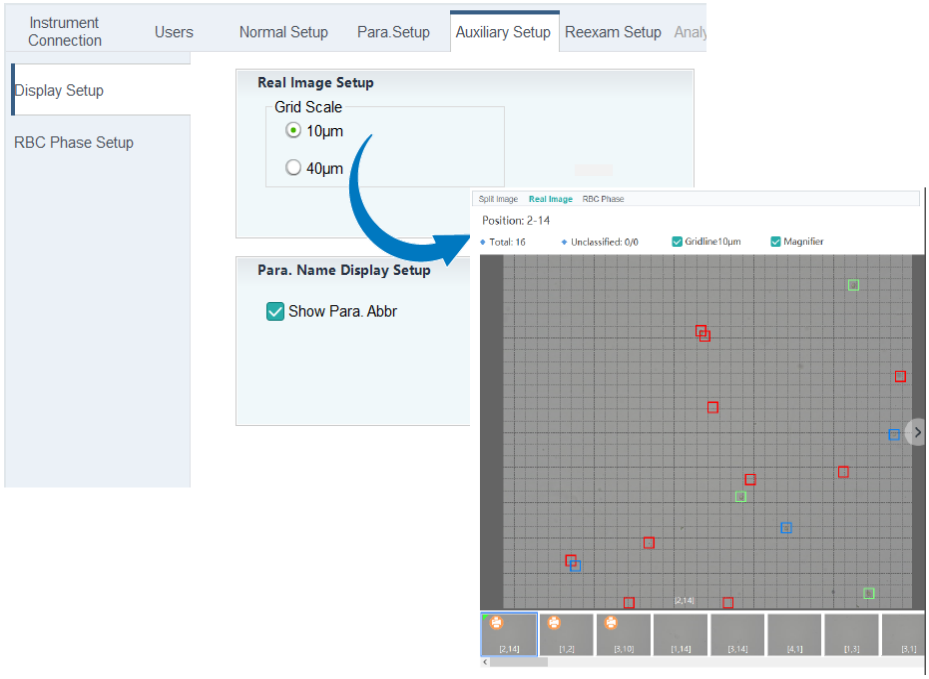


Figure 6-2 Configuring grid line scale for real images

1. Select "**System Setup**" -"**Display Setup**", and configure the grid line scale.
2. Select the desired scale:

- **10μm**
- **40μm**

6.4.2 Configuring High and Low Result Flags

When the quantitative parameter results exceed the reference interval, high/low result flags display by the parameter results. Customize the high/low result flags on the "**Display Setup**" screen.

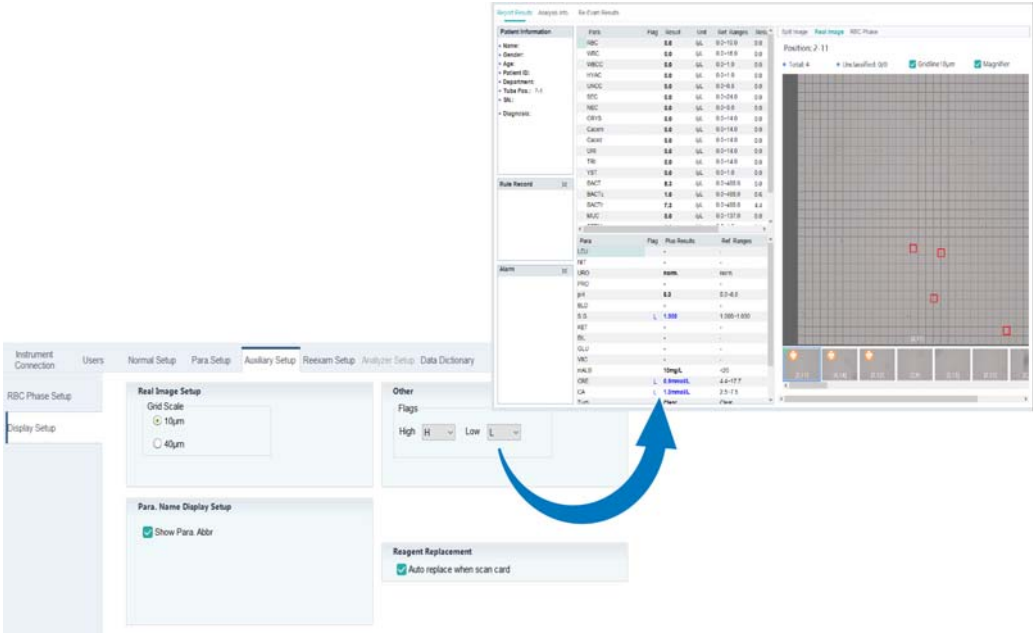


Figure 6-3 Customizing high and low parameter result flags

1. Select "**System Setup**" - "**Auxiliary Setup**" - "**Display Setup**" to enter the "**Display Setup**" screen.

2. Select the desired "**Flags**" from the pull-down list of "**High**" and "**Low**":

- **H** or **L**
- **h** or **l**
- ↑ or ↓

6.4.3 Customizing Parameter Display Settings

Customize the parameter displaying methods on the "**Display Setup**" screen.

When "**Show Para. Abbr**" is selected, the parameters display in their abbreviation format in the parameter results area, as well as on the real images, split images.

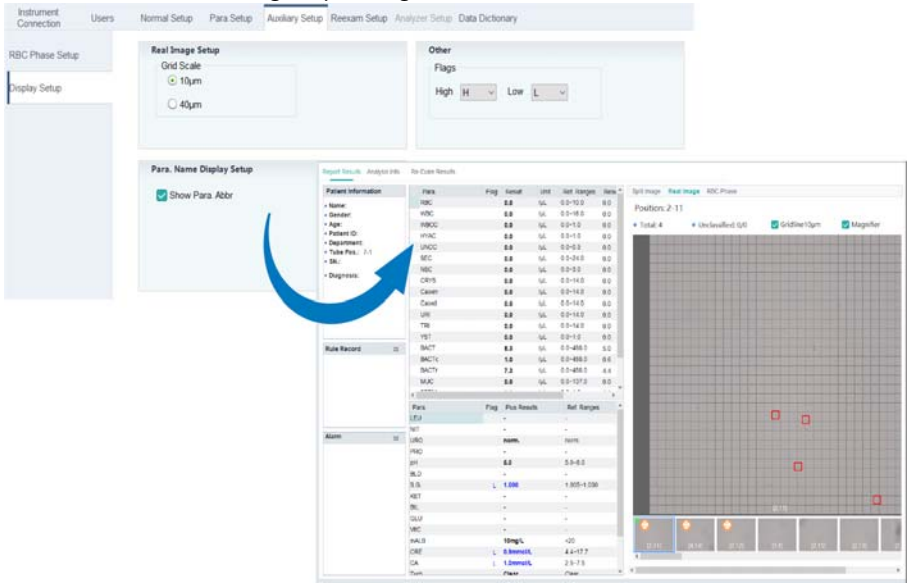


Figure 6-4 Customizing Parameter Display Settings

1. Select "**System Setup**" - "**Auxiliary Setup**" - **Display Setup**" to enter the "**Display Setup**" screen.
2. In the "**Para. Name Display Setup**" area, select to enable or disable "**Show Para. Abbr**".

6.4.4 Customizing Modes for Reagent Replacement in the Fluidics

After reagent replacement, the analyzer replaces the reagent in the fluidics.

The system supports the following two modes for the analyzer to perform the reagent replacement in the fludics.

Mode	Description
Auto mode	After entry of reagent barcode, the analyzer automatically replaces the reagent in the fluidics.
Manual mode	After entry of reagent barcode, you need to click "**Replace**" button to start replacing reagent in the fluidic system.

The auto mode is enabled by default. You can change to manual mode or re-enable auto mode by instructions below:

1. Click "**Setup**" - "**System Setup**" - "**Auxiliary Setup**" - **Display Setup**" to enter the "**Display Setup**" screen.
2. Enable or disable "**Auto replace when scan card**" in "**Reagent Replacement**" area.

NOTE

- **For more information about reagent replacement, refer to *10.2.2 Replacing Diluent*.**

6.5 Configuring Auto Maintenance for the Analyzer

When "**Auto Maintain. Setup**" is enabled and an analyzer connected to DMU meets the conditions for auto maintenance, the system will prompt to perform maintenance automatically to the analyzer.

Follow instructions below:

1. Click "**Setup**" - "**System Setup**" - "**Auxiliary Setup**" - **Display Setup**" to enter the "**Display Setup**" screen.
2. Select "**Enable Auto Maintain**" to enable the function.
3. When necessary, select the "hour", "minute" and "AM/PM" fields to edit them. You can adjust the values by directly entering a value by an external mouse or using the[up]/ [down] arrow of .

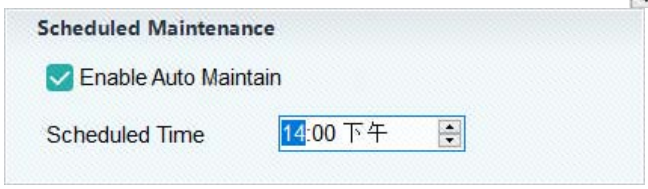


Figure 6-5 Editing status

4. Select any other tab and follow the software instruction to save the setting.

6.6 Configuring Print Template Settings

Customize the print template, the report/RUO parameters to be printed on the report, and select the default printer and set up automatic print samples as needed.

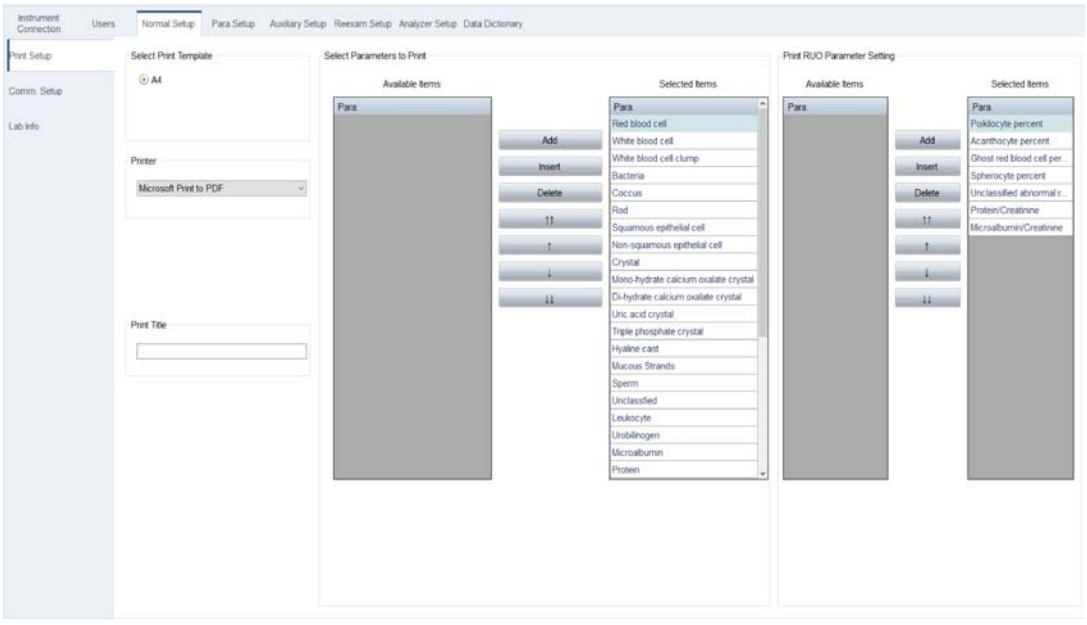
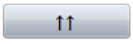
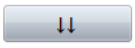


Figure 6-6 Print settings

6.6.1 Adding/deleting Report Parameter/RUO Parameters to be Printed

1. Select "**System Setup**" - "**Normal Setup**" - **Print Setup**" to enter the "**Print Setup**" screen.

2. In the "**Select Parameters to Print**"/"**RUO Para. Print Setup**" area, customize the parameters to be printed and their display order on the printed report.See below for setting description.

Functions	Description
Add	Add parameters to be printed. Select the items you want to add from the "**Available Items**" list and click "**Add**". √ Selected items will be added to the end of the "**Selected Items**" list.
Insert	Insert a parameter to be printed at a specific position. Select the item you want to add from the "**Available Items**" list, and click in the "**Selected Items**" list to select the item below which you want to insert the parameter. Click "**Insert**". √ Selected items will be added below the selected item.
Delete	Cancel items to be printed. Click and select the parameter(s) to be deleted in the "**Selected Items**" list. Click "**Delete**". √ Selected items will be removed from the "**Selected Items**" list and displayed in the "**Available Items**" list.
	Click the button to keep the selected item to the top.
	Click the button to move the selected item up by one position.
	Click the button to move the selected item down by one position.
	Click the button to keep the selected item to the bottom.

6.6.2 Selecting Print Paper Size

In the "**Select Print Template**" area, select the print paper size:

■ **A4**

6.6.3 Selecting Printer

In the "**Printer**" area, select the desired printer from the pull-down list.

6.6.4 Customizing Title of Printed Report

Enter the title of the printed report.

NOTE

- **A maximum of 200 characters can be entered.**

6.6.5 Customizing to Print Dual-unit Results

When "**Print dual-unit result**" is selected, the results display in two units on the printed report.

NOTE

- **For urine formed element test, only when "Enable Dual Units" is selected on the "Formed Element Para. Property" screen, the dual unit results will display on the printed report.**
- **For dry chemistry test, only when "Conventional" or "SI" is selected on the Chemistry Para. Property" screen, the dual unit results will display on the printed report.**
- **For the methods of customizing parameter units, refer to *6.4.3 Customizing Parameter Display Settings*.**

6.7 Configuring Parameter Properties

6.7.1 Configuring Chemistry Parameter Properties

On the "**Chemistry Para. Property**" screen, customize the chemistry test parameters to be reported and the units to be used when displaying the chemistry parameters.

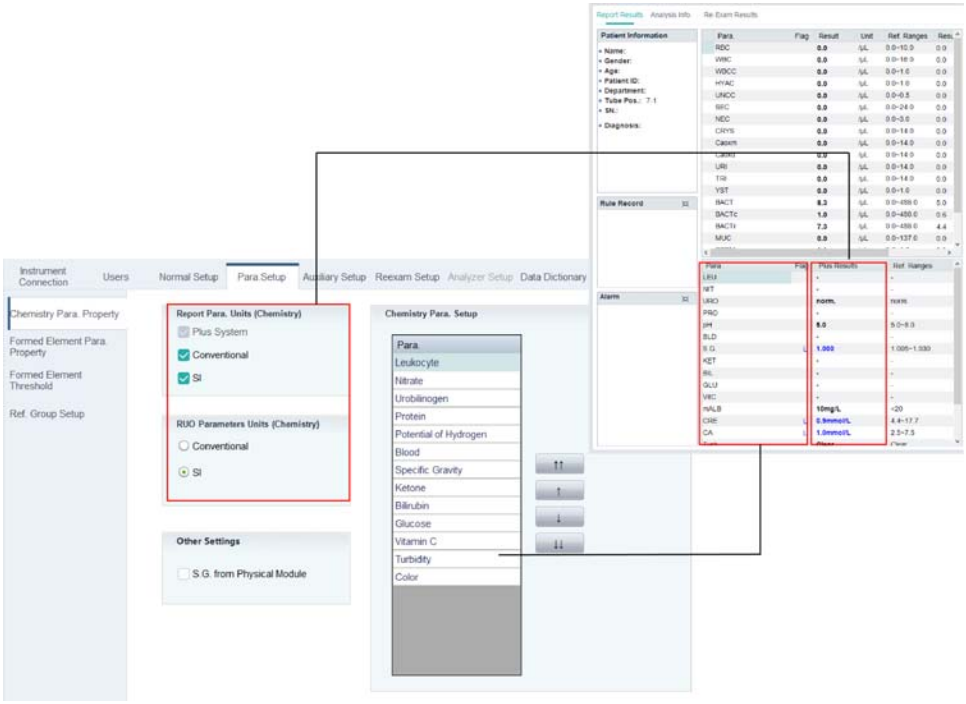


Figure 6-7 Configuring chemistry parameter property settings

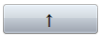
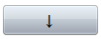
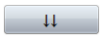
6.7.1.1 Configuring the chemistry parameters displaying order on the report

Follow below instructions:

1. Select "**System Setup**"- "**Para.Setup**" -" **Chemistry Para. Property**" to enter the "**Chemistry Para. Property**" screen.
2. In the "**Chemistry Para. Setup**" area, customize the parameters to display and the displaying order on the report as needed.

See below for setting descriptions:

Functions	Description
↑↑	Select the button to keep the selected item to the top.

Functions	Description
	Select the button to move the selected item up by one position.
	Select the button to move the selected item down by one position.
	Select the button to keep the selected item to the bottom.

6.7.1.2 Selecting chemistry tests parameter units

By default, the chemistry test report displays the parameter results with the plus system. When necessary, you can choose to display parameter results with "**Conventional**" or "**SI**" at the same time.

Follow below instructions:

1. Select "**System Setup**" -"**Para.Setup**" -"**Chemistry Para. Property**" to enter the "**Chemistry Para. Property**" screen.
2. In the "**Report Para. Units (Chemistry)**" or "**RUO Parameters Units (Chemistry)**" area, set the units in "**Conventional**" or "**SI**" displayed in chemistry parameter report results.

■ By default, the analyzer reports the report parameter results in plus system. On the screen, select "**Conventional**"/"**SI**" as the units of report results.

■ By default, the analyzer reports the RUO parameter results in international unit system. Select "**Conventional**" or "**SI**" as needed.

NOTE

- **When laboratory is connected to one-way or two-way LIS, after enabling "Conventional" or "SI", either of which together with the default unit (plus system unit) will automatically be transmitted to LIS. For quantitative parameters, only unit of plus system will be transmitted to LIS.**

6.7.1.3 Enabling physical measurement module specific gravity result

When "**S.G. from Physical Module**" is selected, the analyzer outputs specific gravity and turbidity parameters from the physical measurement module.

When "**S.G. from Physical Module**" is not selected, the analyzer outputs specific gravity through test strips.

Follow below instructions:

1. Select "**System Setup**"-"**Analyzer Setup**"-"**Maintenance Setup**".
2. In the "**Other settings**" area, select "**S.G. from Physical Module**".

NOTE

- **The function of "S.G. from Physical Module" is applicable in the instruments configured with physical module.**

6.7.2 Configuring Formed Element Parameter Properties

On the "**Formed Element Para. Property**" screen, customize the formed element test parameters to be reported, the display order of the parameters, the method of marking various cells/components on the real images, the parent-class parameter for the subclasses of crystals and user-defined parameters and the unit used when displaying the formed element parameters.

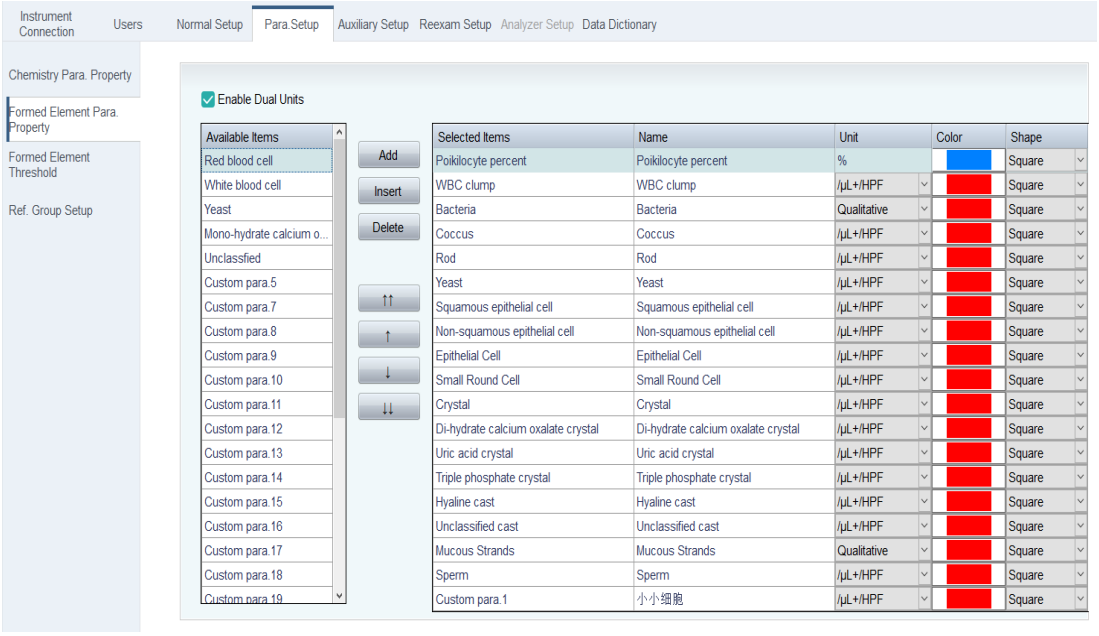


Figure 6-8 Configuring formed element parameter properties

6.7.2.1 Adding / deleting formed element report parameters

Formed element report parameters include the default tested parameters and the user-defined test parameters (30 parameters at most).

NOTE

- **When the analyzer is connected to LIS, the test results of user-defined test parameters will be transmitted to LIS.**

1. Select "**System Setup**" - "**Para.Setup**" - "**Formed Element Para. Property**" to enter the "**Formed Element Para. Property**" screen.
2. Customize the parameters to display and the displaying order on the report as needed.

.See below for setting descriptions:

Functions	Description
Add	Adding parameters to be reported. Select the items you want to add from the "**Available Items**" list and click "**Add**". √ Selected items will be added to the end of the "**Selected Items**" list.
Insert	Insert a parameter to be reported at a specific position. Select the item you want to add from the "**Available Items**" list, and click the "**Selected Items**" list to select the item below which you want to insert the parameter. Select "**Insert**". √ Selected items will be added below the selected item.
Delete	Cancel the items to be reported. Select and select the parameter to be deleted in the "**Selected Items**" list. Select "**Delete**". √ Selected items will be removed from the "**Selected Items**" list and displayed in the "**Available Items**" list.

Functions	Description
↑↑	Select the button to keep the selected item to the top.
↑	Select the button to move the selected item up by one position.
↓	Select the button to move the selected item down by one position.
↓↓	Select the button to keep the selected item to the bottom.

NOTE

- **When any subclass of crystals is deleted, the corresponding subclass(s) will not display in independent catagory in the split image or real image but change to display under the catagory of "Crystals".**
- **When any subclass of bacteria is deleted, the corresponding subclass(s) will not display in independent catagory in the split image or real image but change to display under the catagory of "Bacteria".**
- **When normal red blood cell is deleted, the normal and abnormal red blood cell will not display in independent catagory in the split image or real image but change to display under the catagory of "Red Blood Cell".**
- **For information of the subclasses of crystals and bacteria, see *3.3 Measurement Parameters*.**

The example below shows the change of catagory of Coccus in split image after it is deleted.

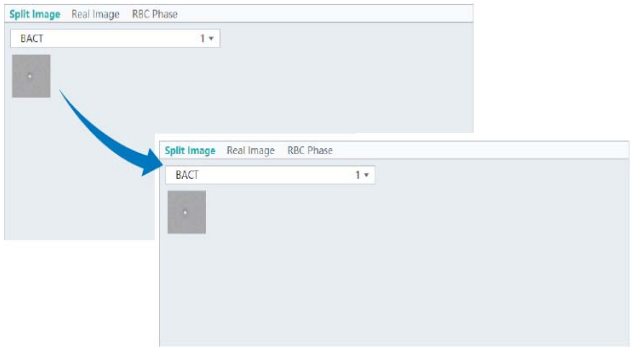


Figure 6-9 Change of catagory of Coccus

6.7.2.2 Customizing display name of formed element parameter

You can customize the display name of formed element parameter when needed. Follow below instructions:

1. Select "**System Setup**" - "**Para. Setup**" - "**Formed Element Para. Property**" to enter the "**Formed Element Para. Property**" screen.

2. Select the parameter to edit, click "**Name**" list and then enter the new parameter name.

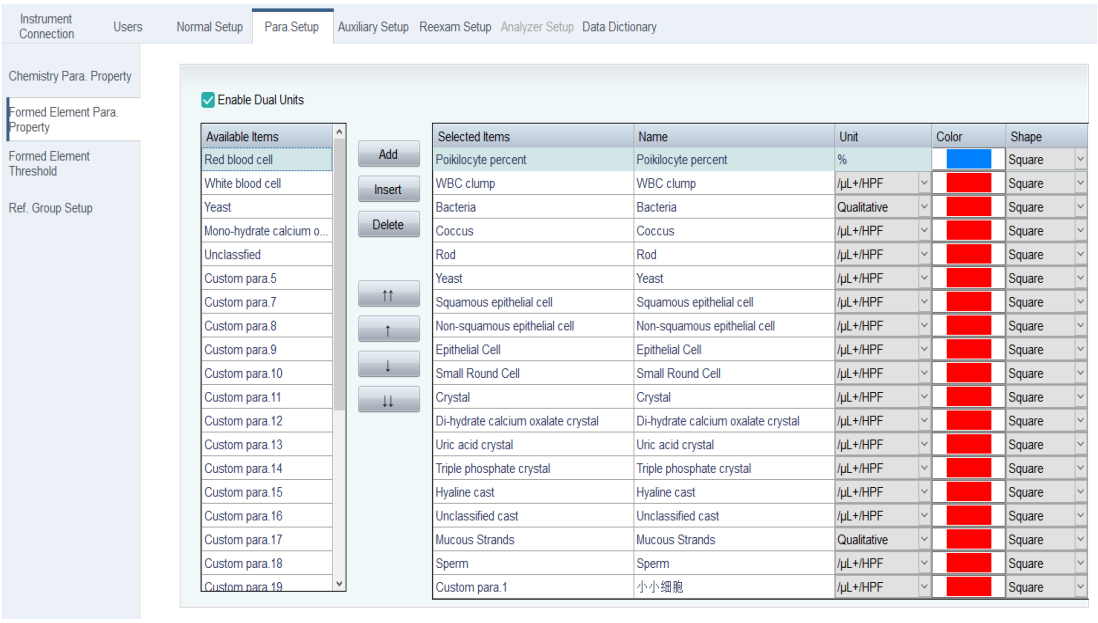


Figure 6-10 Formed element parameters

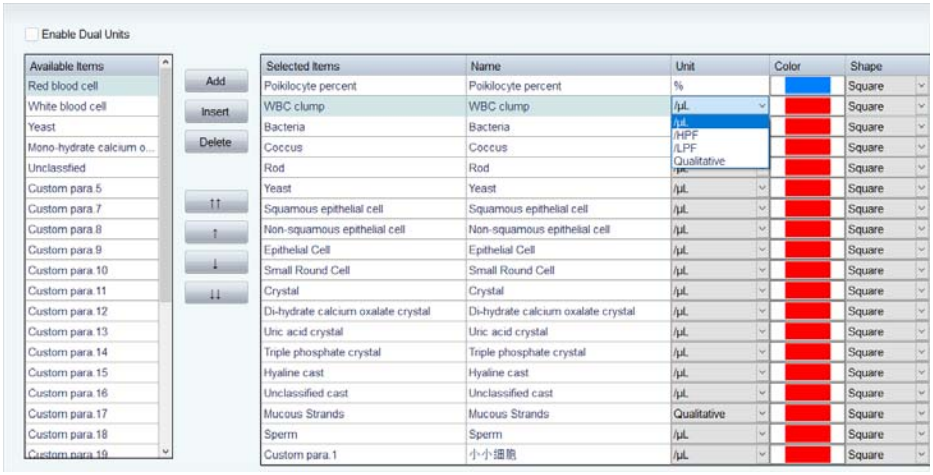
6.7.2.3 Customizing units of formed element parameter results

By default, the formed element test report displays the parameter results in the unit of /μL. You can enable "**Dual units**" to display results in both the "**/μL**" unit and in the "**/LPF**" or "**/HPF**".

Follow below instructions:

1. Select "**System Setup**" - "**Para.Setup**" - "**Formed Element Para. Property**" to enter the "**Formed Element Para. Property**" screen.
2. Select the desired unit from the "**Unit**" pull-down list of the corresponding parameter:

- Select quantitative unit "**/μL**", "**/HPF**", "**/LPF**"; Or select "**Qualitative**" to customize the parameter as qualitative parameter.
- When using single unit, do not select "**Enable Dual Units**, select the desired unit from the "**Unit**" pull-down list of the corresponding parameter.



■ "When dual units is needed, enable "**Enable Dual Units**", and select the desired unit from the "**Unit**" pull-down list of the corresponding parameter

√ After dual unit is enabled, report interface displays dual units besides parameter result.

NOTE

- **The "Poikilocyte" result displays in the unit of "%" and cannot be modified.**
- **By default, "Bacteria" and "Mucous" are quantitative parameters whose units are "Qualitative"; other parameters are qualitative parameters, which can be customized according to your need,**
- **Only quantitative parameters can display dual units.**
- **The analyzer has pre-set conversion factor. If needed to modify the conversion factor, please contact Mindray customer service department**
- **When your laboratory is connected to one-way or two-way LIS, the test results of dual unit will be automatically transmitted to LIS after dual unit is enabled.**

6.7.2.4 Customizing parent class parameters

For formed elements with subclass parameters, for example, bacteria and crystals, the system supports customizing parent-class and subclass relation. After setup of parent-class parameter, the subclass parameters are displayed under the collapsible list of its parent class and the parent-class parameter result is the sum of that of all its subclasses:

■ For bacteria, the system configures "bacteria" as the parent-class parameter for rod and coccus by default, which is unchangeable.

■ For crystals, the system configures "crystals" as the parent-class parameter for uric acid crystal, triple phosphate crystal, mono-hydrate calcium oxalate crystal and di-hydrate calcium oxalate crystal by default. You can change the parent-class for the crystal subclasses as needed.

■ You can also set up parent-class and subclass relation to user-defined parameters.

See below for detailed description.

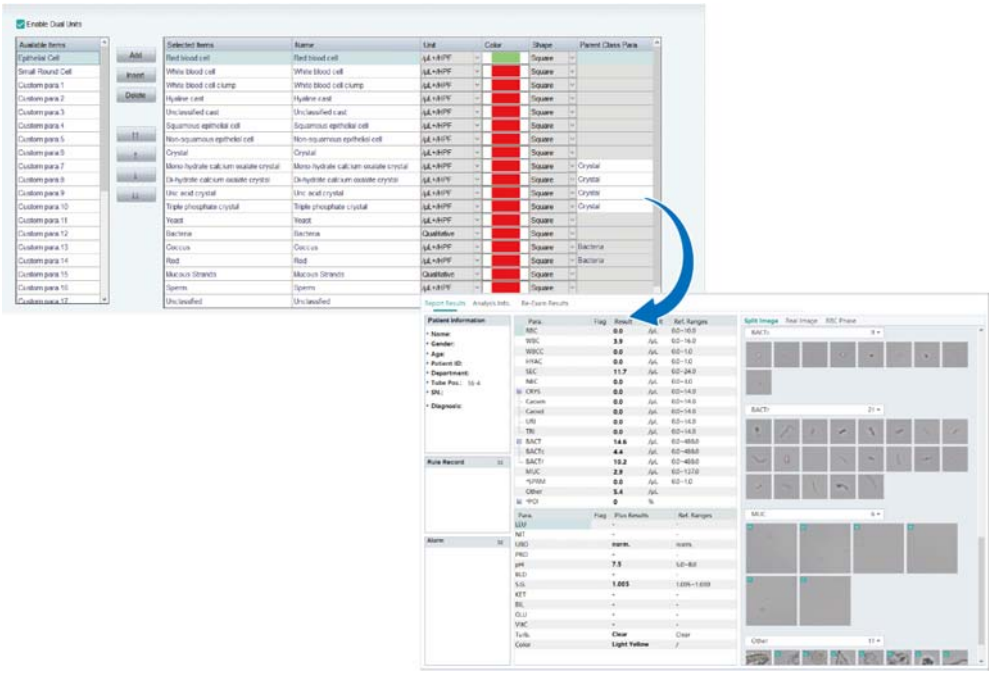
1. Select "**System Setup**" - "**Para.Setup**" - "**Formed Element Para. Property**" to enter the "**Formed Element Para. Property**" screen.
2. Select a parent class parameter for the corresponding subclass parameter from the drop-down list of "**Parent Class Para.**".

NOTE

- **The system does not support configuring a subclass parameter itself as its own parent class. For example, when customizing the parent-class parameter for "uric acid crystal", it is not allowed to set "uric acid crystal" as its parent class.**
- **You may select the report parameters that the system automatically detects and analyzes or user-defined parameter to be the parent-class parameter. When configuring a new user-defined**

parameter as the parent-class, it is needed to add it to the system first. For adding method, see*6.6.1 Adding/deleting Report Parameter/RUO Parameters to be Printed*.

√ After setup, the subclass will be moved to the collapsible list of its parent-class parameter.



NOTE

- **On the sample report screen, the subclasses are displayed under the collapsible list of its parent-class by default. Select "-" at the left of the parent-class to expand the list. After folded, "-" changes to "+", and you may select "+" to unfold it.**
- **When a subclass parameter is removed from "Formed Element Para. Property", the parameter result is still included in that of its parent-class. The removed subclass will not display as an independent catagory in the split image or real image but display under the catagory of parent-class. For adding and removing formed element report parameter, see *6.6.1 Adding/deleting Report Parameter/RUO Parameters to be Printed*.**
- **The parent-class parameter setup is applicable to sample report result. For customizing split and real image of subclass displaying under its parent class, see *6.6.1 Adding/deleting Report Parameter/RUO Parameters to be Printed*.**

6.7.2.5 Customizing cells/elements marking methods on the real images

After the formed element test, the system marks the detected cells/elements on the real image. You can change the marking of cell/ components as needed.

1. Select "**System Setup**" - "**Para. Setup**" - "**Formed Element Para. Property**" to enter the "**Formed Element Para. Property**" screen.
2. For each cell/element, click to select from their "**Color**" and "**shape**" drop-down lists to customize the methods to mark corresponding cells/components.

For example, RBCs are marked in “red rectangle“.

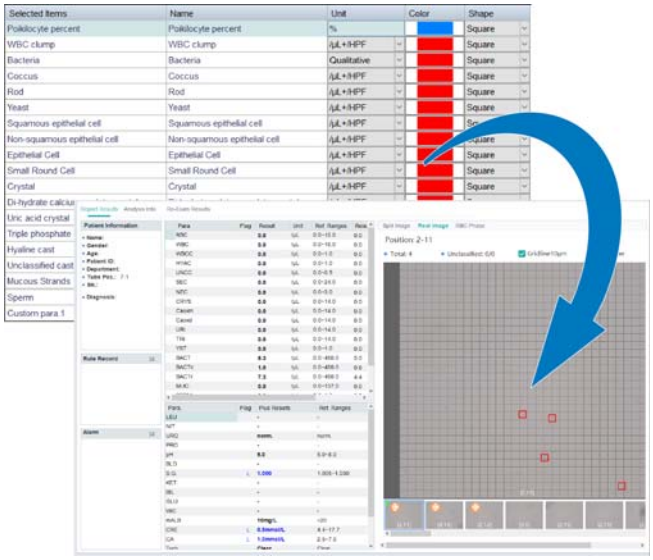


Figure 6-11 Method of marking cells/elements on the real images

6.7.3 Customizing Formed Element Thresholds

NOTE

- **In formed element test, by default, the system reports “Bacteria“ and “Mucous“ as qualitative parameters. According to your need, you can customize the unit of formed element to set the parameters as quantitative or qualitative parameters. For setting methods, see*6.7.2 Configuring Formed Element Parameter Properties*.**

Customize the threshold values of each magnitude section when reporting qualitative parameters in the “**Formed Element Threshold**“ screen.

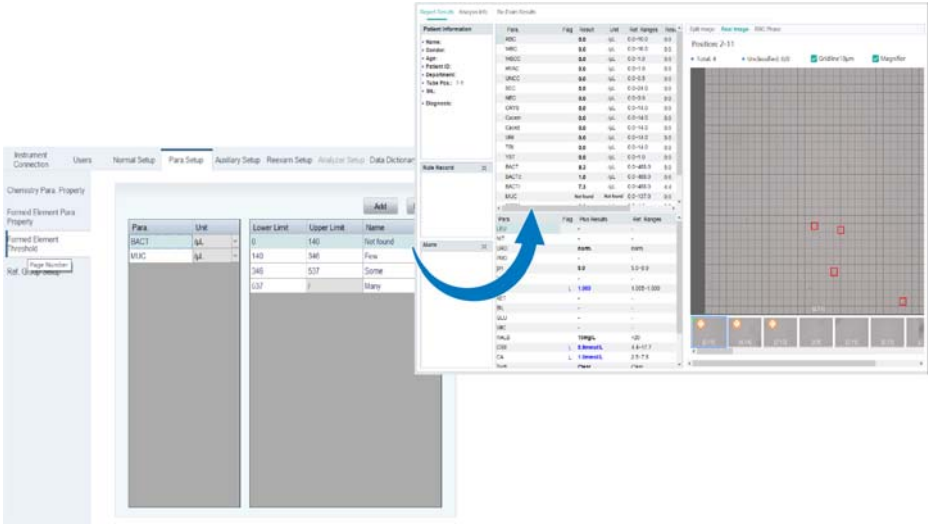


Figure 6-12 Configuring formed element thresholds

Follow below instructions:

1. Click "**System Setup**" - "**Para. Setup**" - "**Formed Element Threshold**" to enter the "**Formed Element Threshold**" screen.

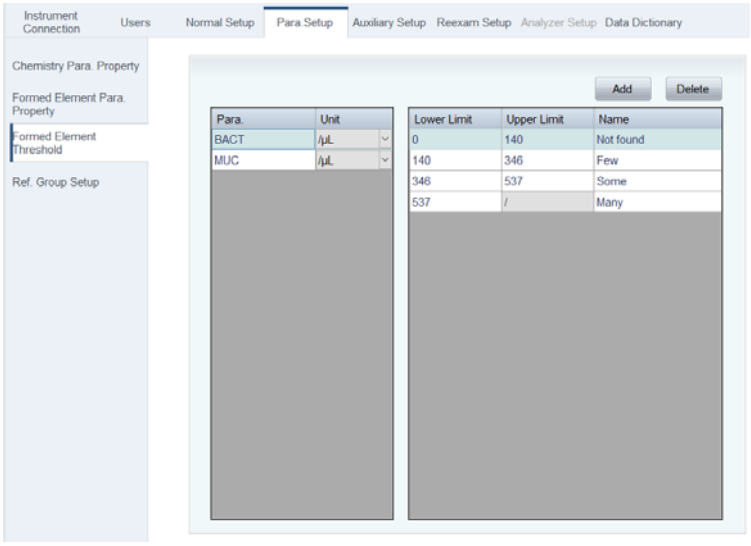


Figure 6-13 Configuring formed element qualitative parameter thresholds

NOTE

- **The parameters displayed on the "Formed Element Threshold" screen are those set to use "Quantitative" unit on the "Formed Element Para. Property" screen. Refer to "*6.7.2 Configuring Formed Element Parameter Properties*" for more details about setting up formed element units.**

2. Click to select a parameter, and then enter the name and the "**Upper Limit**" and "**Lower Limit**" thresholds for each magnitude section.

■ If needed, select "**Add**" to add new magnitude section;

■ If needed, select "**Delete**" to remove the magnitude section.

6.7.4 Configuring Reference Group

The "**Ref. Ranges**" screen provides 5 factory reference groups and 20 custom reference groups. You may select and customize reference intervals and reference groups.

The system first finds the matching reference group based on the age/gender conditions.

6.7.4.1 Configuring custom reference group

1. Select "**System Setup**"-"**Para.Setup**"-"**Ref. Group Setup**" to enter the "**Ref. Group Setup**" screen

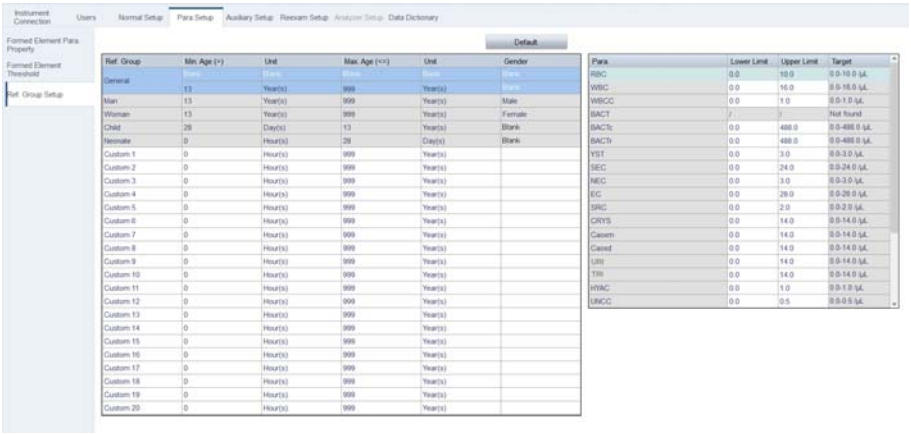
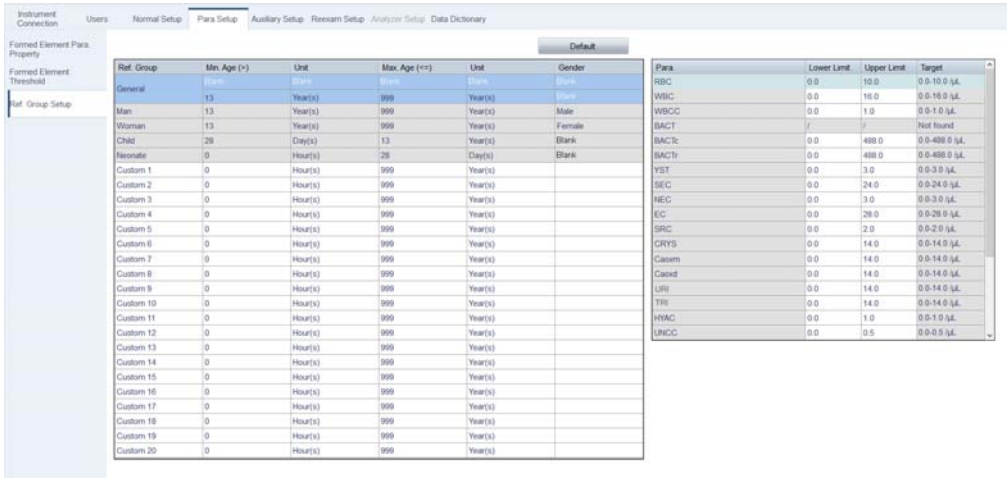


Figure 6-14 Reference group settings

2. (Optional) Select a custom reference group and edit gender information, as well as the upper and lower limits of age section.
3. (Optional) Edit the upper and lower limits of the parameter results of the reference group.
4. After editing, click other buttons on the screen to save the setting as the software prompts.

6.7.4.2 Editing reference group

1. Click "**System Setup**" - "**Para. Setup**" - "**Ref. Group Setup**" to enter the "**Ref. Group Setup**" screen.



2. Click to select a reference group, edit the upper and lower limits of age, and of the parameter results.

NOTE

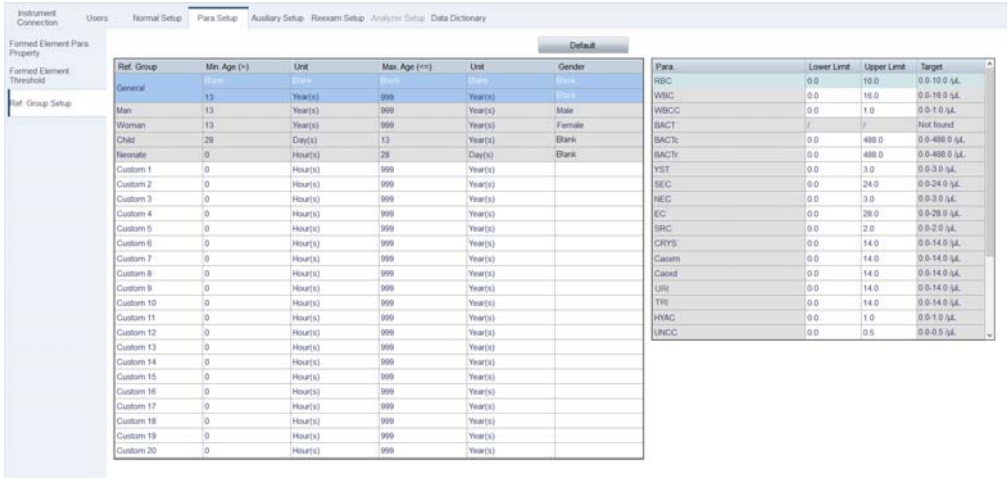
- **For the 5 factory reference groups, you can only edit the "Lower Limit" and "Upper Limit" of the parameter results.**
- **You cannot set reference intervals for qualitative parameters. For qualitative parameters, the result "Lower Limit" and "Upper Limit" display in "/", and the "Target" displays as "Not found".**
- **The units of "Lower Limit" and "Upper Limit" are consistent with settings in "Chemistry Chemistry Para. Property"and "Formed Element Para. Property" screen.**

3. After editing, click any button on the screen to save the setting as the software prompts.

6.7.4.3 Restoring to default reference group settings

Use the function to restore the modified reference group to default setting.

1. Select "**System Setup**" - "**Para.Setup**" - "**Ref. Group Setup**" to enter the "**Ref. Group Setup**" screen.



2. Select a reference group and select "**Default**".

√ The reference group restores the gender, upper and lower limits of age and parameter results to default settings.

6.8 Configuring Laboratory Information

Select "**System Setup**"- "**Normal Setup**"- "**Lab Info**" to enter "**Lab Info**" screen, and customize the laboratory information, including, laboratory name, director, contact information, postal code, installation date, customer service contact person, customer service contact information and notes.

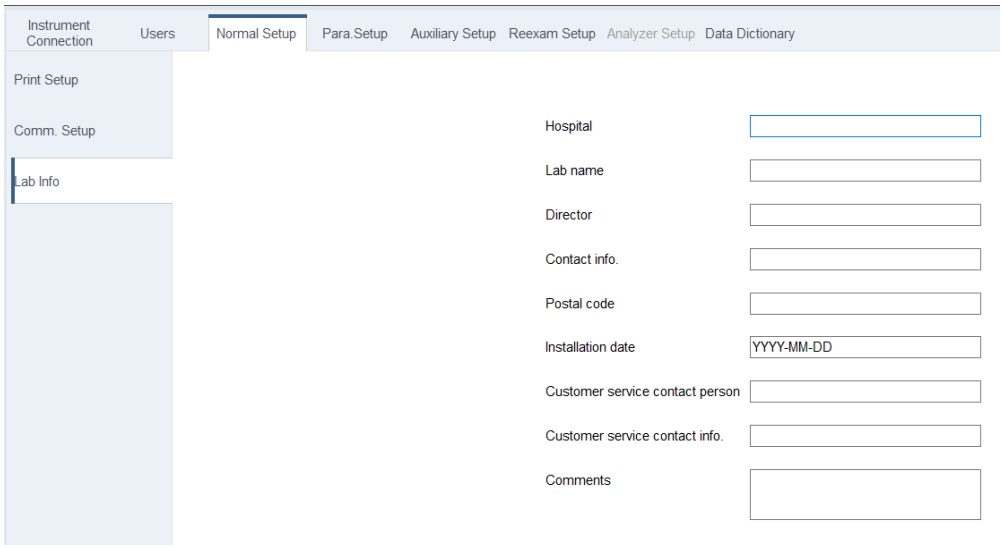


Figure 6-15 Laboratory information

6.9 Configuring the Method to Get Sample Information

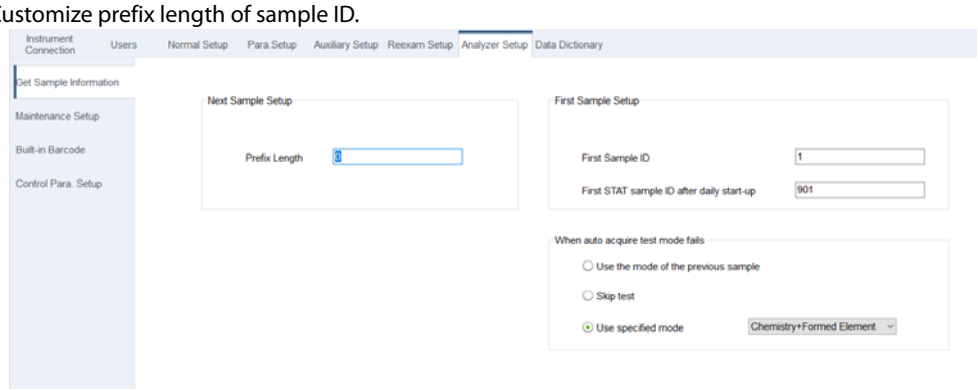
In "**Get Sample Information**" area, you can customize prefix length of the next sample, the first sample ID after analyzer startup, whether to enable auto-scan rack number and the method to when analyzer fails to inquiry test mode.Configure the method to get sample information

6.9.1 Configuring Next Sample Settings

Set up the "**Next Sample Setup**" when you need to manually enter sample IDs. After you enter the Sample ID for the first sample, the Sample IDs for the following samples will automatically increase. You can set up "**Prefix Length**" on this screen. For example, if you set "**Prefix Length**" to 6, the first 6 figures of the first sample will be applied to all the following sample IDs in the same batch.

Follow below instructions:

1. Select "**System Setup**" - "**Analyzer Setup**" - "**Get Sample Information**" to enter the "**Get Sample Information**" screen.
2. Customize prefix length of sample ID.



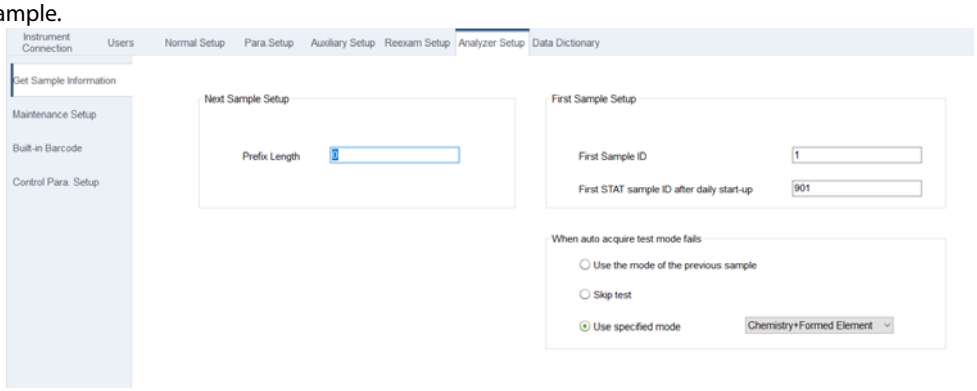
NOTE

- **The maximum prefix length of a sample ID does not exceed 20 digits.**

6.9.2 Configuring the Daily Start Sample ID

In the "**First Sample Setup**" area, you can customize the sample IDs for first sample (1 by default) and the sample ID for first STAT sample (901 by default) after startup each day.

1. Click "**System Setup**" - "**Analyzer Setup**" - "**Get Sample Information**" to enter the "**Get Sample Information**" screen.
2. In the "**First Sample Setup**" and "**First STAT sample ID after daily start-up**" input box, enter the ID of first sample.



6.9.3 Configuring the Method to Process Sample When Auto Acquire Mode Fails

Auto acquire test mode is supported only when laboratory is connected to two-way LIS.When the laboratory is connected to two-way LIS, "**Automatic Urinalysis System" (DMU)** automatically acquires analysis mode from LIS.

See below for possible causes of failure to acquire analysis mode:

- Failed to set up sample order in LIS
- Abnormal network connection
- Failed to auto scan the sample and generated the sample ID started with Inv.

NOTE

- **When "Re-exam" function is enabled, the system stop acquiring analysis mode from LIS. Therefore, you need to set up analysis mode for re-examination orders on the "Sample Order" screen for sample re-examination. After "Re-exam" is deselected, the system turns back to auto acquire mode.**
- **When the possible causes above are ruled out and LIS still can not acquire analysis mode, please contact Mindray Customer Service Department.**

The system will process the sample according to the pre-set method when auto acquire mode fails.

NOTE

- **The default specified mode is "Chemistry+ Formed element".**

You can change the method on "**Get Sample Information**" screen. Follow the instructions below:

1. Select "**Setup**"-"**System Setup**" - **"Analyzer Setup**" - "**Get Sample Information**" to enter the **"Get Sample Information**" screen.
2. In the "**When auto acquire test mode fails**" area, set the method.

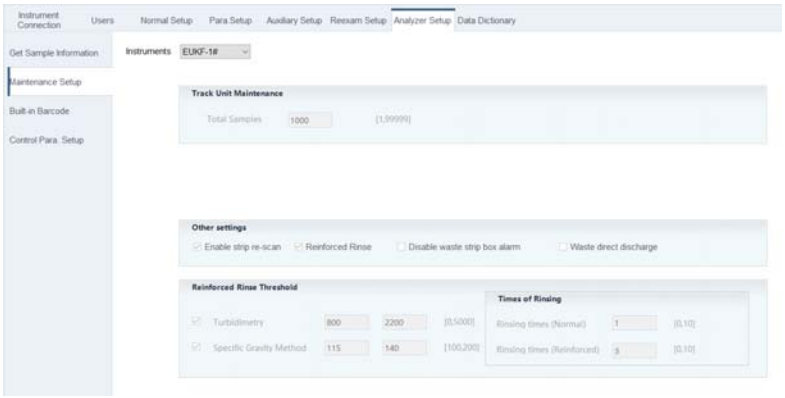
Options	Description
Use the mode of the previous sample	When failing to acquire analysis mode, the analyzer automatically tests the sample using the mode of the previous sample.
Skip test	When failing to acquire analysis mode, the analyzer skips this sample. You can check and find the possible causes of failure to acquire analysis mode and then re-test the sample.

Options	Description
Use specified mode	Set the specified mode according to your connecting situation of analyzers on DMU. When sample processing system is connected, you can select from: **Chemistry, Formed Element** and **Chemistry + Formed Element.**

3. When exiting the screen, save the settings as prompted.

6.10 Maintenance setup

In "**Maintenance Setup**" area, you can setpallet maintenance reinforced rinse,test strips re-scan function and waste strip box alarm.



6.10.1 Checking for Track Unit Maintenance Settings

In accordance with the needs in your laboratory, you can check for pallet maintenance in the "**Maintenance Setup**" area.

1. Select "**System Setup**"-"**Analyzer Setup**"-"**Maintenance Setup**"to enter"**Maintenance Setup**" screen.
2. Check for the track unit m maintenance strategy in the "**Pallet Manitenance**" area.

Specify the test sample size in the "**Total Samples**" text box. After the setting takes effect, when the number of tested samples reaches the specified number, the system prompts the user to perform pallet cleaning.

NOTE

- **For instructions on pallet cleaning and maintenance, refer to*10.4 Cleaning Pallet*.**

6.10.2 Checking for Test Strips Re-scan Function

The analyzer may fail to scan certain test strips due to various reasons (for example, test strips are not transported to scan position). When user selects "**Enable strip re-scan**", the analyzer pulls back the un-scanned test strips and re-scan it.

Follow below instructions:

1. Select "**System Setup**"-"**Analyzer Setup**"-"**Maintenance Setup**".
2. In the "**Other settings**" area, check for "**Enable strip re-scan**" function.

NOTE

- **To enable or dis-enable test strip re-scan function, please contact Mindray customer service department.**

6.10.3 Enabling Reinforced Rinse

In normal rinse mode, the analyzer rinses the fluidics once before analyzing the next sample.

When "**Reinforced Rinse**" is selected, if a high-turbidity sample is detected, the analyzer will perform an reinforced rinse (i.e., rinse for three times) to the fluidics before analyzing the next sample.

NOTE

- **Reinforced rinse takes more time than normal rinse.**

Follow below instructions:

1. Select "**System Setup**"-"**Analyzer Setup**"-"**Maintenance Setup**".
2. In the "**Other settings**" area, check for "**Reinforced Rinse**" function.

NOTE

- **The function of enforced rinse is applicable to the instruments configured with physical module.**
- **To enable or dis-enable test strip re-scan function, please contact Mindray customer service department.**

6.10.4 Checking for Waste Strip Box Alarm

This function is enabled by default. When the waste strip box is almost full, the software will alarm user to empty the waste strip box. You can cancel the waste strip box alarm as needed.

Follow below instructions:

1. Select "**System Setup**"-"**Analyzer Setup**"-"**Maintenance Setup**".
2. In "**Other settings**" area, check for "**Disable waste strip box alarm**" function.

NOTE

- **To enable or dis-enable test strip re-scan function, please contact Mindray customer service department.**

6.11 Configuring Barcode System

Configure the barcode systems on the "**Built-in Barcode**" screen.

1. Click "**System Setup**" - "**Analyzer Setup**" - **Built-in Barcode**" to enter the "**Built-in Barcode**" screen.
2. Click a barcode system to enter the corresponding settings tab.
3. Select the number of digits used in the "**Digits**" area. Click to select the "**All digits**" box to select all.
4. When "**Apply**" is selected, enable the current barcode type.
5. (Optional) If you are using **CODE39**, **ITF**, **CODABAR** with check digits, click to select the "**Check bits**" box.

NOTE

- **When using ITF, CODE39, CODABAR with check bits, the actual length of the barcodes should be the total length of the barcodes plus one check bits. For example, if the actual length is 9 digits and "Check bits" is selected, the barcode length should be "10".**

6. (Optional) Select other barcode systems as needed.

NOTE

- **For more information about analyzer-supported barcode systems and requirements, refer to *A.14 Barcode Specifications*.**
- **For barcode systems with check bits, use check digit in barcode labels whenever possible to reduce the rate of misreading.**

- **Configure the barcode systems and barcode lengths in accordance with the actual barcodes used in your laboratory.**
- **Do not select the barcode systems that are not used; otherwise misreading rate may increase.**
- **Do not use any bacodes that longer than 30 digits. Barcodes longer than 30 digits will not be read correctly.**

6.12 Configuring Instrument Connection Settings

Instrument connection setting is usually completed by manufacturer-authorized engineers when installing the instrument.

You can view the **Name**, **Serial No.**, **Type**, **Comm. Port** and other information of the instrument connected to the analyzer software on the "**System Setup**" - "**Instrument Connection**" screen.

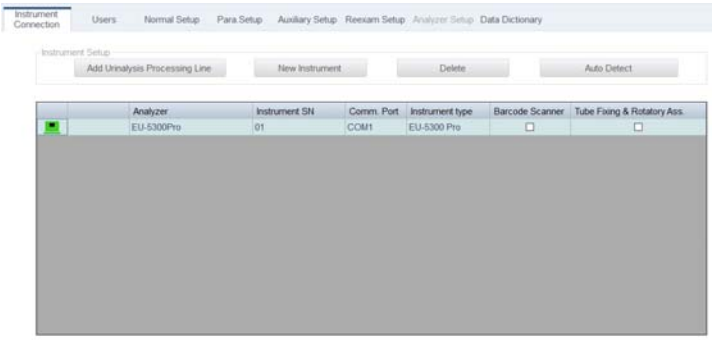


Figure 6-16 Instrument Connection

6.13 Configuring RBC Phase Settings

On the "**RBC Phase Setup**" screen, configure whether to display / output the RBC phase histograms and scattergrams, the conditions for outputting RBC phase histograms and scattergrams, and the types of RBC phase histograms and scattergrams.

If the RBC phase histogram and scattergram are enabled to display/ output, when chemistry analysis completes:

- Select "**RBC Phase**" in the graph area to view the RBC phase histograms and scattergrams.
- The printed report will include the RBC phase histograms and scattergrams.
- When the instrument is connected to LIS, RBC phase histograms and scattergrams will be transmitted to LIS.

1. When the analysis system is standby, select "**System Setup**"- "**Auxiliary Setup**"- "**RBC Phase Setup**" when the analyzer is standby.

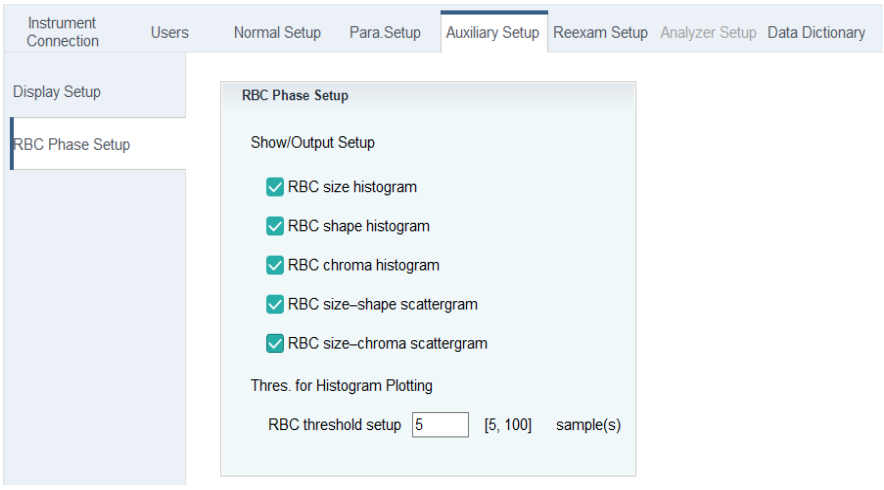


Figure 6-17 Enter the "RBC Phase Setup" screen

2. In the "**RBC Phase Setup**" area, click to select the histograms and scattergrams to be displayed.
3. Enter the RBC thresholds in the "**RBC threshold setup**" text box.

NOTE

- **Enter an integer between [5,100]. The default value is 5.**
- **"RBC threshold" is used for judging whether to display the RBC phase histograms. When the total number of normal red blood cells identified by the system exceeds the specified threshold, the analyzer displays and outputs the enabled histograms.**
- **When you select to display / output scattergrams, the RBC phase scattergrams will always be output, and not subject to the RBC threshold.**

4. When you exit this screen, the software will prompt to save the setting. Follow the software instruction to save the settings.

6.14 Configuring Re-exam Rules

- **Inappropriate auto re-exam rules may cause missing abnormal samples. It is recommended to set up re-exam rules with caution and by referring to references and other relevant literatures required by laboratory.**

You may set up re-exam rules on the "**Reexam Setup**" screen based on your laboratory protocols. When a sample meets the conditions in the re-exam rules, users need to validate the results or re-exam the sample.

When "**Re-exam rules**" is enabled:

- Samples that trigger re-exam rules are highlighted in yellow in the sample list, and the rule record area of the samples prompts "**Re-exam recommended: {0}**".
- Samples that have not triggered re-exam rules are automatically approved, and the samples in the sample list will display the "**Auto Validation OK**" mark .

6.14.1 Setting Re-exam Rules

The DMU software supports setting up re-exam rules. After re-exam rules are set up and enabled, when analysis results trigger the re-exam rules. the analyzer will perform re-examination to samples according to the specified re-examined method.

An re-exam rule consists of "**Re-exam Mode"**, "**Applicable Conditions"**, "**Exception**", "**Parameter Rules"** and "**FLAG Rules**".

When the analysis results meet the following conditions, re-exam rules will be triggered:

- when all the conditions in a rule are met;
- when any of exception conditions are not meet;
- when all the enabled rules in the "**Parameter Rules"** are met;
- when the flag alarm in the "**FLAG Rules**" are met

Follow the instructions to enter the re-exam rule interface.

1. Select "**System Setup**"-"**Reexam Setup**" to enter "**Reexam Setup**" screen when the analyzer is standby.

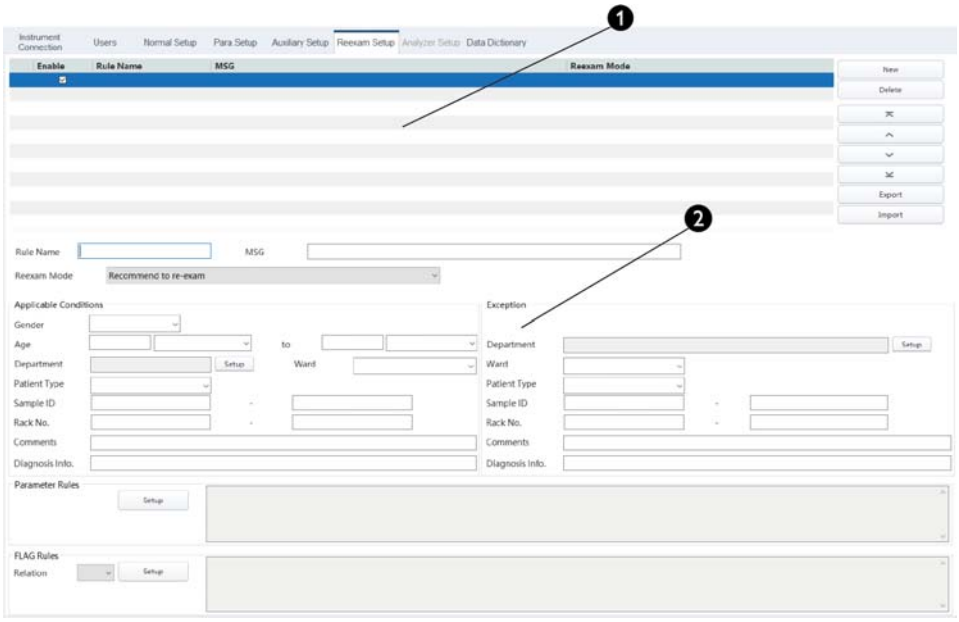


Figure 6-18 "Re-exam settings" screen

No.	Description
1	Rule list
2	Rule editing are

6.14.1.1 Setting up re-exam rules

1. Follow the instructions below to create an re-exam rule in the rule list.

When you need to...	You can...	Notes:
Add a rule	Select" **New**" to add an re-exam rule	Access level: operator"s level and aboves
Edit a rule	Select the rule in the list and edit it in the rule editing area	
Enable a rule	Select the rule in the rule list and select "**Enable**" in the rule editing area	
Disable a rule	Select the rule in the rule list and deselect the "**Enable**" in the rule editing area	
Delete a rule	Select he rule in the rule list and select "Delete". Follow the software instruction to delete it.	
Adjust the display sequence	Select to move the selected item to top.	
	Select to move the selected item up by one position	
	Select to move the selected item down by one position	
	Select to move the selected item to bottom	
Import a rule	Select "Import" and select the rule file to be imported in the pop-up dialog box. For obtaining rule file, contact Mindray customer service department. √ The imported rules cover the all the existing rules,	
Export a rule	Select "Export" and select the path where the rule file to be stored in the pop-up dialog box. √ All the customized rules will be exported	

2. Select the other tab on the interface and save as the software prompts.

6.14.1.2 Setting up Re-exam Conditions

Defining the "Rule Name" and the "MSG"

In the rule editing area, select "**Rule Name**" to enter a name for the new rule.

(Optional) If necessary, enter a message into the "**MSG**" edit box.

Selecting Re-exam modes

Re-exam modes	Description
Recommend to re-exam	Re-exam the analyzed sample based on the analyzed results. When needed, setup the re-exam order manually.

Defining the applicable conditions

When necessary, define the applicable conditions in the "Applicable Conditions" area.

See below for setting descriptions.

Gender	Select a gender from the pull-down list	/
Age	Set the upper and lower limits of age	/
Department	Set the department information	Administrators may select "**System Setup**"-"**Data Dictionary**" to enter the "**Data Dictionary**" setup screen, and enter frequently-used entries for "**Department**", "**Ward**", "**Patient Type**" and "**Comments**" to the dictionary. The entries in the "**Data Dictionary Item**" will display in the pull-down lists of the corresponding items in the "**Applicable Conditions**" area.
Ward	Set the ward information	
Patient Type	Define the patient type	
Sample ID	Define the range of applicable sample IDs	The samples whose sample IDs fall in the defined range of "**Sample ID**" comply with the rule.
Rack No.	Define the range of the tube rack No.	The samples whose rack No. fall in the defined range of "**Rack No.**" comply the rule.
Comments	Set up the comment messages as necessary	• When the information entered in the "**Comments**" box on the sample results screen includes the message entered here, the sample meets the "**Comments**" condition. • Users at administrator's level may set up templates messages for the "**Comments**" ("**System Setup**"-"**Data Dictionary Item**" will display in the pull-down lists of the corresponding items in the "**Applicable Conditions**" area.
Diagnosis Info.	Set up the diagnostic information messages as necessary.	When the information entered in the "**Diagnosis Info.**" box on the sample results screen include the message entered here, the sample meets the "**Diagnosis Info.**" conditions.

Editing the Exceptions

When necessary, define the exemption conditions in the "**Exception**" area.

If a sample meets any "Exceptions", the sample does not pass the manual review and the sample goes to the "**Reexam Condition"** checking point.

See below for setting descriptions.

Department	Set the department information. Multiple departments can be set once.	Administrators may select "**System Setup**"-"**Data Dictionary**" to enter the "**Data Dictionary**" setup screen, and enter frequently-used entries for "**Department**" to the dictionary. See*6.18 Configuring Data Dictionary*. Administrators can add/ delete customized departments. The added department will be selected by default.

Ward	Set the ward information	Administrators may select "**System Setup**"-"**Data Dictionary**" to enter the "**Data Dictionary**"setup screen, and enter frequently-used entries for "**Department**", "**Ward**", "**Patient Type**" and "**Comments**" to the dictionary. The entries in the "**Data Dictionary Item**" will display in the pull-down lists of the corresponding items in the "**Applicable Conditions**" area.
Patient Type	Define the patient type	
Sample ID	Define the range of applicable Sample IDs	The samples whose sample IDs fall in the defined range of "**Sample ID**" comply with the rule.
Rack No.	Define the range of the tube rack No.	The samples whose rack No. fall in the defined range of "**Rack No.**" comply the rule.
Comments	Setup the comment message as necessary	• When the information entered in the "**Comments**" box on the sample results screen includes the message entered here, the sample meets the "**Comments**" condition. • Users at administrator's level may set up templates messages for the "**Comments**" ("**System Setup**"-"**Data Dictionary Item**" will display in the pull-down lists of the corresponding items in the "**Applicable Conditions**" area.
Diagnosis Info.	Set up the diagnostic information messages as necessary	When the information entered in the "**Diagnosis Info.**" box on the sample results screen include the message entered here, the sample meets the "**Diagnosis Info.**" conditions.

Editing Parameter Rules

When necessary, define the parameter rules in the "**Parameter Rules**" area.

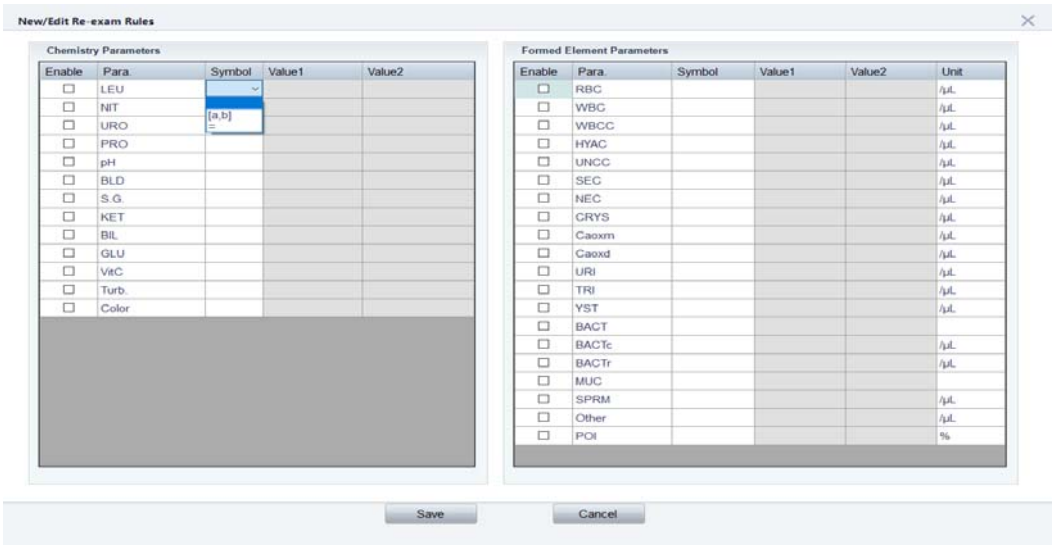
1. Configure chemistry rules as needed.

NOTE

- **Chemistry rules support range setting under "Plus System". You can set the parameter "=" a certain value, or set the allowed range of parameter values.**

a Select "**Enable**" besides the selected re-exam rule to enable the re-exam rule.

b Select a symbol from the "Symbol" drop-down list..



■ When "=/ "≠" is selected, select the plus system value from the drop-down list in **"Value1"**. When the chemistry test parameter result of the sample is equal to the specified value, the re-examination condition is met.

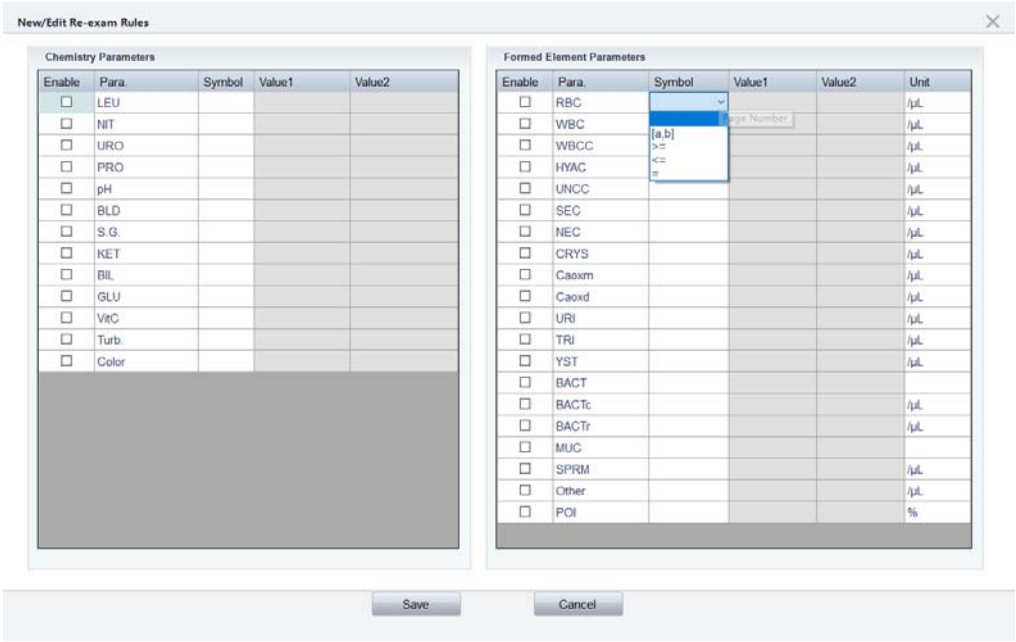
■ When [a,b] is selected, select the plus system value from the drop-down lists of **"Value1"** and **"Value2"** respectively, and when the chemistry test result of the sample is within the set range, the re-exam condition is met.

- For the **"Color"** parameter, you can only set the conditions as "=" or "≠" a specific value.

2. Configure "**Formed Element Rules**" as needed.

   a Select "**Enable**" besides the selected re-exam rule to enable the re-exam rule.

   b Select a symbol from the "Symbol" drop-down list..



Formed element parameters include qualitative parameters and quantitative parameters.

For quantitative parameters, select "[a, b]","> =","<=", or "=" from the drop-down list.

- When "> =","<=", or "=" is selected, enter the parameter value in "**Value 1**". When the formed element results of the sample are within the set range, the re-examination conditions are met.
- When [a, b] is selected, enter parameter values in **"Value 1**" and **"Value 2**" respectively. When the formed element parameter results are within the set range, the reexamination conditions are met.

For qualitative parameters, select "=" or "[a, b]" from the drop-down list.

- When "=" is selected, select quantitative magnitude from the "**Value1**" drop-down list. When the formed element parameter results are within the set range, the reexamination conditions are met.
- When "[a, b]" is selected, enter the quantitative magnitude in the "**Value 1**"and "**Value 2**" respectively. When the formed element parameter results of the sample are within the set range, the re-examination conditions are met.

3. Select **"OK**" button to save the re-exam rules after the re-exam rules are set.

√ The edited rules displays in the "Parameter Rules" area.

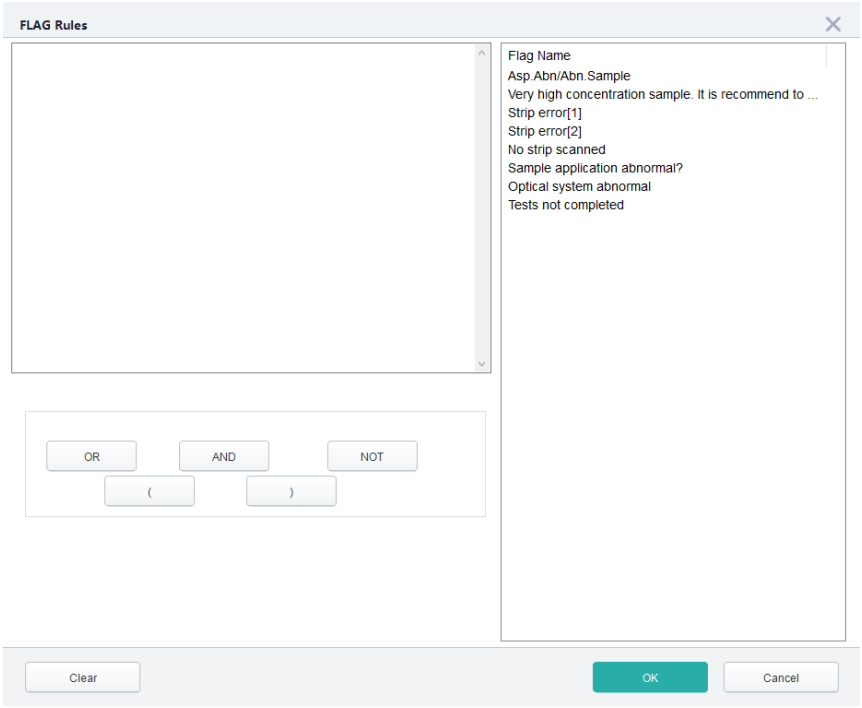
Editing FLAG rules

When needed, edit the flag rules in the "**FLAG Rules**" area.

1. Select "**Setup"** in the "**FLAG Rules**" area

√ The interface pops up "**FLAG Rules"** setup window.

2. Edit the flag rule.



3. (Optional) When more than one rules are defined, select the "**Relation**" between the rules.

AND	When the rules are combined with the "AND" condition, the sample meets the criteria only when all the rules are conformed with,
OR	When the rules are combined with the "OR" condition, the sample meets the criteria when any of the rules are conformed with.
NOT	When rules are combined with the "NOT" condition, the sample meets the criteria when none of the rules are conformed with.
( )	When a rule is set within ( ), this rule is taken as priority over the others when the rules are met at the same time.

4. Select" **OK**".

√ The edited flag rule displays in the "**FLAG Rules**" area.

NOTE

- **To edit or clear an existing rule, select the "setup" button to enter the rule setup screen, and then edit the rule, or select "Clear" to clear the rule.**

6.15 Configuring Communication Settings

When the laboratory is connected to the LIS, set up the network connection based on actual situation.

Before connecting to LIS, make sure that the computer where the software is installed is connected to the network that have access to the LIS.

1. Select "**More**" - "**System Setup**" - "**Normal Setup**" - "**Comm. Setup**".
2. Configure LIS network settings based on the actual situation of laboratory network connection, and select "**Network Connection**" or "**Shared folders**".

■ When you choose to use "**Network Connection**", you need to specify the client as a server or use the LIS as a server.

When you choose to use the analyzer software as server, select "**labXpert as Server**" and enter the port number (i.e., the port number of the computer that the software is installed).

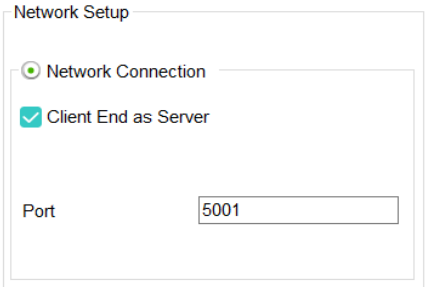


Figure 6-19 Specify "labXpert as Server"

When you choose to use LIS as the server, do not select "**labXpert as Server**". Enter IP address (IP address of computer on which LIS is installed) and port number (port number of computer on which LIS is installed).

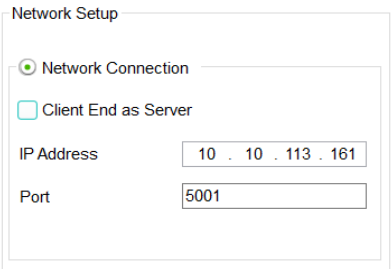


Figure 6-20 Use LIS as server

■ When you choose to use "**Shared folders**", specify the address of "**Send directory**" and "**labXpert to receive (orders)**".

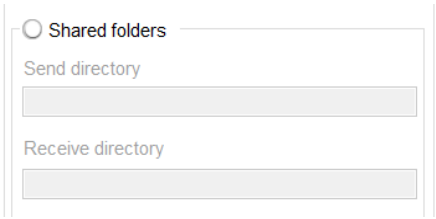


Figure 6-21 Using "Shared folders"

NOTE

- **When the shared folders are on the computer where the client server is installed, you only need to enter the folder names.**
- **When the shared holders are on the computer where the LIS is installed, enter the directory paths for the shared folder correctly, and give Guest users the authority of "visiting without password".**
- **For setting up the retention time of worklist, contact Mindray Customer Service Department.**
- **After you specify the shared folders, LIS and DMU communicates with each other in the following way: LIS automatically sends order to the "Receive directory"- software reads the orders from the "Receive directory" folder- software stores the sample results to the "Send directory" folder- LIS reads the results information from the "Send directory" folder.**

3. After the network setting is completed the LIS indicator LIS lights up on the status bar of the software.

NOTE

- **Contact Mindray Customer Service Department of the manufacturer for questions of connecting the software to LIS.**

6.16 Configuring Sample Transmission Methods

Click "**Menu**"- "**System Setup**" - "**Normal Setup**" -"**Comm. Setup**" to enter the "**Comm. Setup**" screen.

See below for setting descriptions.

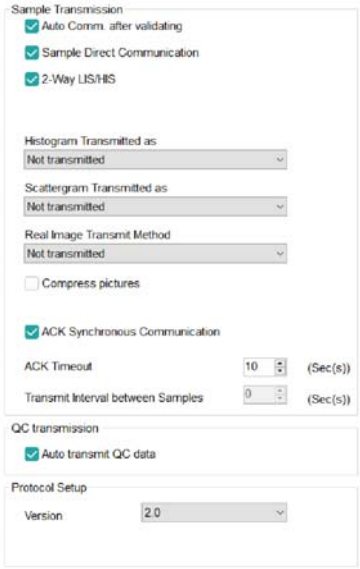


Figure 6-22 Sample transmission settings

See below for setting descriptions.

Functions	Description	Notes
Auto Comm. after validating	When "**Auto Comm. after validating**" is enabled, the system automatically transmits validated sample results to LIS.	/
Sample Direct Communication	When "**Sample Direct Communication**" is enabled, the DMU software communicates all sample results, validated or not validated, to LIS in real time. When "**Sample Direct Communication**" is not enabled, the system only communicates validated sample results to LIS.	/
2-Way LIS/HIS	When 2-Way LIS/HIS is used in the laboratory, check the check box for "**2-Way LIS/HIS**". • When you are using the 2-Way LIS/HIS, DMU automatically inquires information from the LIS/HIS. You do not need to enter Sample ID or rack No. (available only for sample processing system products). • If DMU is connected to LIS, but the option is not selected, DMU sends sample results to LIS, but will not inquire information from LIS.	/

Functions	Description	Notes
ACK Synchronous Communication	When **"ACK Synchronous Communication"** is selected, when software sends the result, it will wait for LIS to return the result confirmation message before sending the next message.	/
	In the "**ACK Timeout**" field, define the "**ACK Timeout**" time. "**ACK Timeout**" refers to the time for the software to wait for the LIS to return a confirmation message. When the LIS confirmation message is not received within the set time range, the software then sends the next result.	Allowed time range: [0-600] seconds.
Transmit Interval between Samples	The analyzer software sends the sample results to the LIS according to the **"Transmit Interval between Samples"** setting.	Allowed time range: [0-600] seconds. When "**ACK Timeout**" is not selected, you can configure the result sending interval.
Histogram Transmitted as/ Scattergram Transmitted as/ Real Image Transmit Method	Select from the drop-down list: • Not transmitted • In BMP bitmap • In PNG bitmap • In JPG bitmap	When "**Not transmitted**" is selected, the software does not transmit graphic data to LIS. When "**In BMP bitmap**"/ "**In PNG bitmap**"/ "**In JPG bitmap**" is selected, the software transmits the graphic data to LIS in BMP/PNG/ JPG format.
Compress pictures	Select to compress the image's size and resolution ratio	When selected, the size of images transmitted to LIS will be reduced to 80k and the resolution ratio to 1224× 1024. When not selected, the size of images transmitted to LIS is about 500~ 700k and the resolution ratio is 2448× 2048.
Transmit as picture's path	When selected, the software transmits the picture's path where the image is stored to LIS	If needed to set up "**Transmit as picture's path"**, contact Minday customer service department.

6.17 Configuring Version of Communication Protocol

1. Click "**Menu**"- "**System Setup**"- "**Normal Setup**"- "**Comm. Setup**" to enter the "**Comm. Setup**" screen.
2. Select the version of communication protocol from the drop-down list in "**Protocol Setup**" area.

NOTE

- **Contact the Customer Service Department of the manufacturer for questions of version of communication protocol.**

6.18 Configuring Data Dictionary

In "**Data Dictionary**" area, you can pre-set the entry options of "**Department**", "**Ward**", "**Patient Type**", "**Sample Type**", "**Comments**", "**Payer**", "**Delivered by**", "**Gender**", "**Age Unit**", "bed number" and "**Diagnosis Info.**" for fast input of relevant information.

The options pre-set in "**Data Dictionary Item**" area can be seen in the following areas:

- Under the pull-down lists in the "**Patient Information**" area of the "**Analysis Info.**" screen.
- Under the "**Department**" pull-down list, and the input boxes of "**Delivered by**", "**Diagnosis Info.**", and "**Comments** on the "**Adv. Search**" dialog box.

Enter the code or shortcut key of the pre-set item to an input box, the software automatically inputs the pre-set items; or you can directly select the pre-set options from pull-down list.

1. Click "**System Setup**" - "**Data Dictionary**" to enter the "**Data Dictionary**" screen.

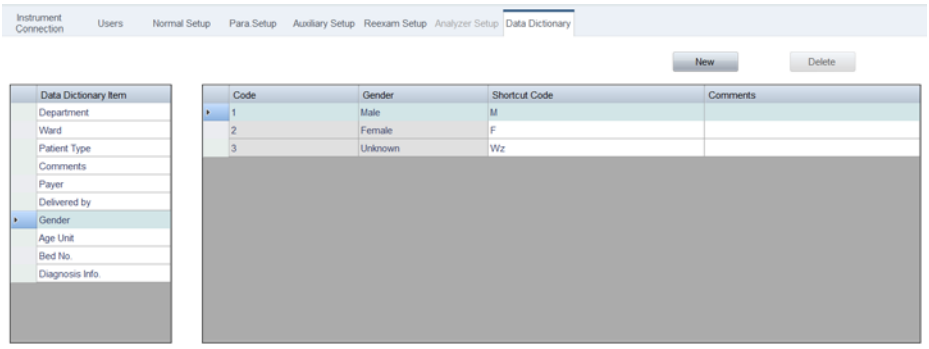


Figure 6-23 Data dictionary settings

2. Configure "**Data Dictionary Item**".

- To create new options for "**Data Dictionary Item**", click and select the item in the "**Data Dictionary Item**" area, then click "**New**" and enter detailed information in the entry area.
- To delete options for a **Data Dictionary Item**, click the item in the "**Data Dictionary Item**" area, then click "**Delete**".

NOTE

- **The input box of "Code"only allows digit entry.**

6.19 Configuring Sample List Field Display Settings

You can set the sample table fields displayed on the header of sample list area on "**Auxiliary Setup**" screen.

"**STAT**", "**Sample ID**" and "**Time**" are default displays. In addition, you can also add "**Name**", "**SN.**", "**Tube Pos.**" and "**Patient ID**" to the header of sample list.

1. Click "**Setup**" - "**System Setup**" - "**Auxiliary Setup**" - "**Display Setup**" to enter the "**Display Setup**" screen.
2. In "**Sample table fields**" area, customize the sample table fields to display and the displaying order in the header of sample list as needed.

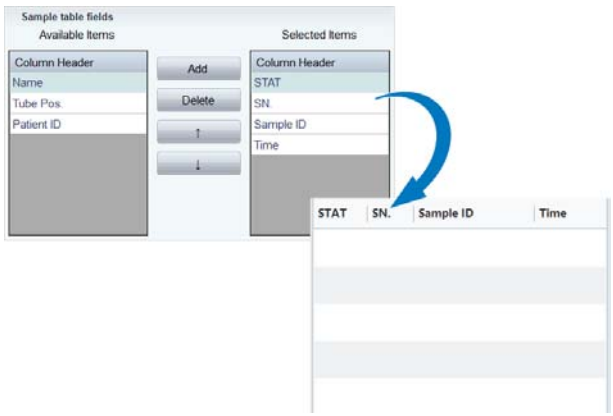


Figure 6-24 Sample table field settings

6.20 Configuring QC Sample ID

The analyzer supports setting up QC sample ID on the "**Control Para. Setup**" screen. After setup, control samples are allowed to placed in test tube rack for autoloading analysis. When the analyzer identifies the matched control sample ID, it will perform control analysis on the sample.

NOTE

- **Perform control analysis by setting QC sample ID is applicable to the laboratory connected to one-way or two-way LIS.**
- **Before control analysis, confirm the pre-set ID matched with the barcode ID on control sample.**
- **The system also supports application of control analysis order on QC Menu. For more information, refer to *9 Quality Control (QC) Program*.**

1. Click "**System Setup**" - "**Analyzer Setup**" - "**Control Para. Setup**" to enter the **"Control Sample ID Setting**" screen.
2. Select "**QC Sample ID**", and input QC sample ID in the edit box.

NOTE

- **A maximum of 19 characters can be entered in the edit box.**

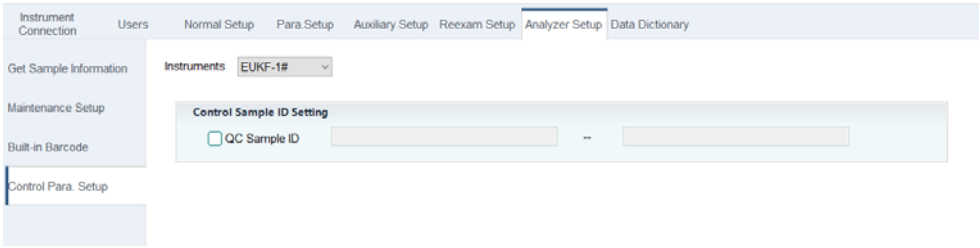


Figure 6-25 Setting control sample ID

√ After control sample ID setup completes, when the analyzer identifies the pre-set ID, it will perform control analysis.

√ After analysis, you can review the QC result on sample report screen and LIS.

6.21 Configuring Auto-transmission of QC Analysis Results

The analyzer supports QC results to be transmitted automatically after QC analsyis. Follow instructions below:

1. Click "**System Setup**" - "**Normal Setup**" - "**Comm. Setup**". to enter "**QC transmission**" screen.
2. Select "**Auto transmit QC data**", and save the settings as prompted.

√ When setting completes, the system will transmit the QC results to LIS automatically after analysis.

NOTE

- **The setting of auto transmission of QC results is applicable to the laboratory connected to one-way or two-way LIS.**

6.22 Configuring Client End for Result Reviewing

By configuring a DMU as the result-reviewing client on a separate computer, you can remotely review, edit and validate the results output from the original one (target client end).

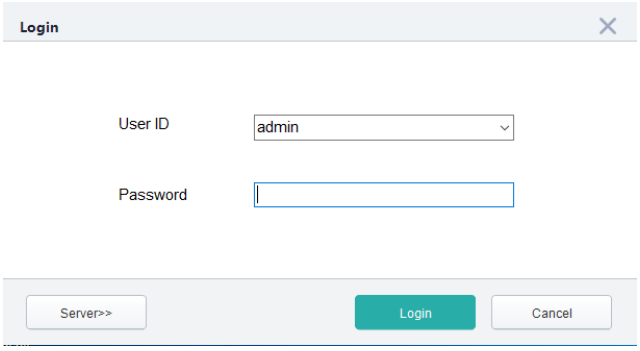
NOTE

- **Before configuration, acquire the IP address of the PC where the target client end is installed.**

- **An account can not be logged in the result-viewing and target client end at the same time.**

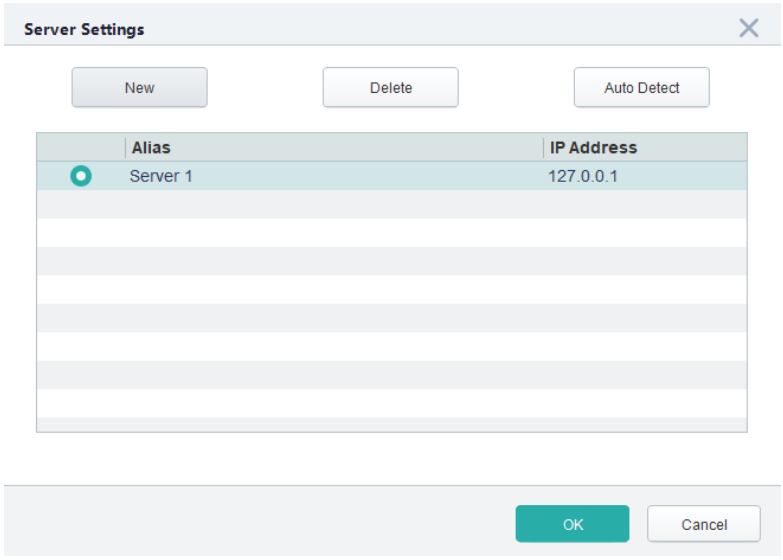
1. Open the DMU that needed to be configured as reviewing client end on the PC.

√ The log-in screen displays.



2. Select "**Sever>>**".

√ The "**Sever Settings**" screen displays.



3. You may add the IP address of the PC where the target client end is installed through the following method.

■ Select "**New**", manually input the IP address.

■ Select "**Auto Detect**". The "IP Address" list displays all the IP address searched automatically, you may select the needed one from the list. If the desired is not in the list, you may have to input it manually.

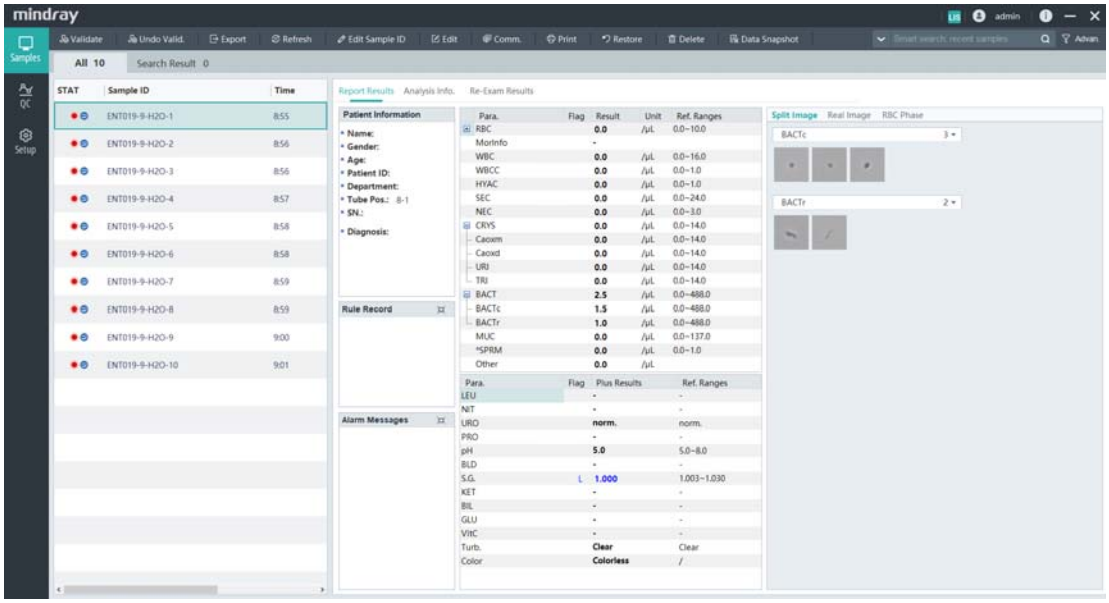
4. Select "OK" to return to log-in screen.

5. Enter the user name and password and log in.

NOTE

- **If it is unable to log in or access the server of target client end, you may try turning off the Windows defender firewall and logging in again. If it still does not work, contact the Customer Service Department of the manufacturer.**

√ The sample results of the target client end display.



NOTE

- **The sample screen of reviewing client end supports reviewing, editing and validating sample results and etc.; the QC screen supports checking QC result, QC tables and QC graphs; the system setup screen supports the currently log-in user to modify and reset password, add new users.**
- **After operations including editing, communicating, validating sample results and etc., the new information and status will be updated on the target client end synchronously.**

6. (Optional) If needed to exit reviewing client end, it is required to log out and return to the log-in screen. Then select "**Sever>>**". Select or add the IP address of "127.0.0.1" on or to the IP address list. Logging in with this default IP address, the software will returns to normal client end screen.

6.23 Configuring Piercing Sample Aspiration

The analyzer supports sample aspiration by piercing sample tubes with caps to proceed analysis.

NOTE

- **To enable/ disable the function of piercing sample aspiration, please contact Mindray customer service department.**
- **For applicable sizes of sample tubes with caps, see *A.1 Applicable Tubes*.**

6.24 Customizing Category Tabs

The sample list area on DMU displays "**All**" and "**Search Result**" tabs by default, and you can customize the tabs in accordance with your needs.

6.24.1 Adding new tabs

1. Select "**Setup**" - "**Customize Tab**" to switch to the "**Customize Tab**" screen.
2. Select one of the "**Custom**" tabs and select the check box of tab.
3. On the setup screen of tabs, enter the title and select the searching conditions.

Table 6-1 Sample category tab

Options	Description	Remark
Analyzer	When the software connects to multiple instruments, define to display the samples from (a) certain instrument(s).	/
Rack No.	Select to display the samples on all or (a) certain tube rack(s); or you can select to display the samples with "No tube rack". To display samples on (a) certain tube rack(s), select the "+" button and enter the tube rack range.	The "**No tube rack**" samples refer to the samples for which the system has not scanned a valid tube rack number; or the samples which are analyzed in the OV or CT mode.
Reexam Mode	Select to display samples in all re-exam modes, or only in certain re-exam modes ("**No re-exam**", "**Re-exam**" and "**Smear**".	"**No re-exam**": means the samples have not been re-examined in any form. "**Re-exam**": means the samples have been re-tested (on the same or another instrument, or having been diluted and re-tested, etc.)
Sample Status	Select to display samples in all states or in certain states ("**Auto Validated**", "**Manual Validated**", "**Microscopically Validated.**", "**Validate in advance**", "**Manual Validation**", "**Microscopic**", "**To be Done**", "**Report in advance**").	"**Auto Validated**": means the samples have been auto validated and are currently in the "Auto Validated" state (if the "STAT" column is displayed in the sample list, you can see the sample is marked by the A icon); "**Manual Validated**": means the samples have been manually validated and are currently in the "Manual Validated" state (if the "STAT" column is displayed in the sample list, you can see the sample is marked by the M icon); "**To be Done**": means the samples that still have tests to be done
Communication State	Select to display samples of all communication states or only in (a) certain communication state(s) ("**Transmitted**", "**Not commun.**", or "**Communication failed**".	/
More	Select to display samples in all or only in (a) certain barcode scan state • **Barcode Scan State** (**Scanning succeeded** and **Scanning failed**) • **Print State** (**Printed** and **Not printed**) Select the "Barcode Scan State"or "Print State" button to select the needed option from the pull-down list.	/
Flag	Select to display the samples with all types of flags or only certain types of flags ("**Error**").	/
Test Panel	Select to display samples run with any test panels or only with (a) certain test panel(s).	/

4. Select another tab, and save the setup as prompted.

√ The customized tabs display on the labXpert full view.

6.24.2 Customizing the tab displaying sequence

1. Select "**Setup**" - "**Customize Tab**" to switch to the "**Customize Tab**" screen.
2. Select the tab, and select arrow button on the right side to adjust the display sequence.

Table 6-2 Tab display sequence setup

Functions	Account Level Requirement	Description
<	Operator's level and above	Select to move the item one position leftward
>	Operator's level and above	Select to move the item one position rightward
|<	Operator's level and above	Select to move the item far leftward
>|	Operator's level and above	Select to move the item far rightward

6.24.3 Editing/resetting customized tabs

When these customized tabs are not applicable, you can edit the tabs or restore to system default status.

Perform the following procedures:

1. Select "**Setup**" - "**Customize Tab**" to switch to the "**Customize Tab**" screen.
2. Select the tabs, and perform the following procedures:

Functions	Description	Remark
Edit tabs	1. Select the tabs to edit. 2. On the setup screen of tabs, modify the title or change the searching conditions.	The tab title of "**All**" and "**Search Result**" cannot be modified. The searching conditions of "**Search Result**" cannot be changed.
Reset customized tabs	1. Select the tabs to edit. 2. Select "**Reset**" button on the setup screen of tabs. √ Reset the tab title and searching conditions to system default status.	/

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7 Daily Operations

7.1 Overview

This chapter provides step-by-step procedures for operating your analyzer on a daily basis, and focuses on sample analysis in different working modes.

7.2 Daily Operation Procedure

A flow chart indicating daily operating process is presented below:

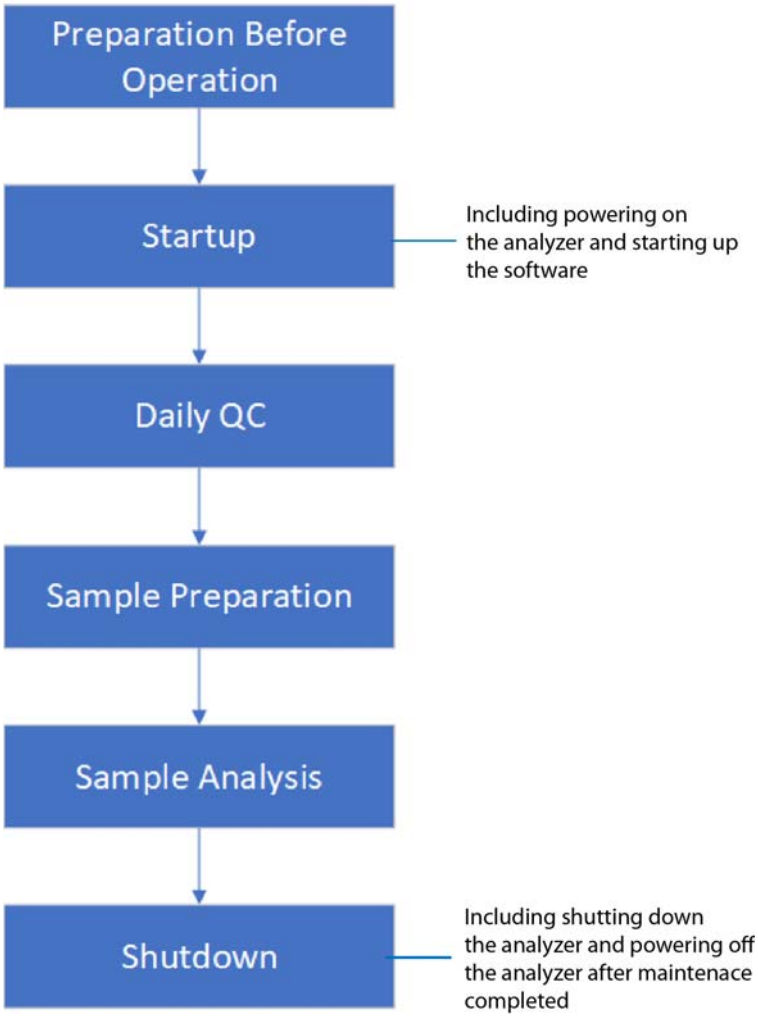


Figure 7-1 Daily operating process

7.3 Preparation before Operation

Perform the following checks before powering on the system.

BIOLOGICAL RISK

- **The analyzer tests urine samples. Samples and waste can be potentially infectious. Wear proper personal protective instrument (e.g. gloves, lab coat, glasses, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.**

- **Any waste materials and waste samples are potentially infectious and they shall be disposed of according to local governmental regulations.**

⚠ WARNING

- **Diluent is irritating to eyes, skin and mucous membrane. Wear proper personal protective instrument (e.g. gloves, lab coat, glasses, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.**
- **If Diluent accidentally spills on your skin, wash the reagent off with plenty of water and if necessary, go see a doctor; if Diluent accidentally spills into your eyes, wash the reagent off with plenty of water and immediately go see a doctor.**
- **Do not touch the moving parts. Keep your clothes, hairs and hands away from the moving parts to avoid injury.**

NOTE

- **Use the reagents specified by the manufacturer only. Store and use the reagents as instructed by instructions for use of the reagents.**
- **Check whether the reagent tubes are properly connected before using the specified the system.**
- **When the analyzer is going to be left idle over 15days, see *10.7.1 Before Long-time Not Using the Analyzer* for operations.**

Before powering on the system, follow below instructions to check if the system is ready.

■ Checking for waste box and waster container (when using waste container for draining)

- **Be sure to empty the waste strips in the waste strip box before testing.**
- **When using waste container, check and make sure the waste container is empty.**

■ Checking for fluidic tubes and power supply

- **Check and make sure the reagent and waste tubes are properly connected and not bent.**
- **Check and make sure the power cord of the instrument is properly plugged into the power socket.**

■ Checking for the tubes and tube racks are cleared on the analysis system.

- **Clear whether there are tubes and tube racks on STAT tube holder area. If there is, clear the tubes and tube racks.**
- **Clear whether there are tubes and tube racks on the loading area and unloading area of autoloader. If there is ,clear the tubes and tube racks.**

■ Checking for the consumables

- **Check whether there is enough Diluent in the Diluent container.**
- **Check whether there is enough test strip in the test strip feeder.**

■ Checking for pinter (optional)

7.4 Starting up the Analyzer

7.4.1 Powering on the Main Unit

1. Power on the analyzer.

√ The power indicator lights on.

2. The analyzer performs self-testing procedure. If any error occurs, the analyzer gives alarms. Handle the alarms according to instructions.

7.4.2 Logging in the Analyzer

NOTE

- **The system determines the access levels (administrator or normal user) by the login name and password. The accessible functions of the software screen depends on different access levels.**
- **If the software is not able to operated with multiple trys, please contact Mindray customer service department or your local distributor.**
- **After startup, please confirm the date/time of the analysis system is consistent with date/ time of the computer.**

Follow below instructions:

1. Start up the computer and display.
2. Confirm that the software server is running.

■ By default, the server starts automatically when the computer is powered on. When the server software is running, you can find the server icon in the task bar at the lower right corner of the computer display (*Figure 7-2 Server is running.*).

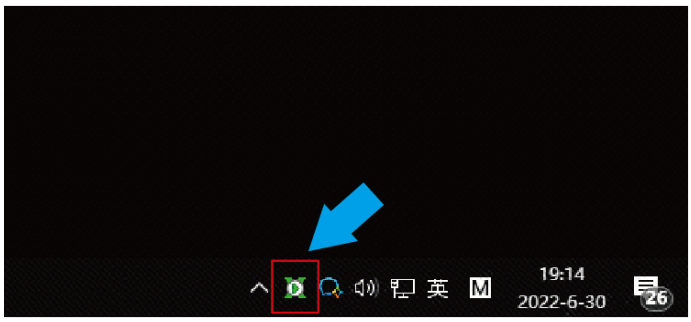


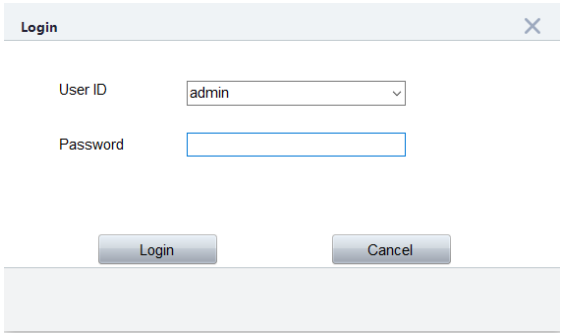
Figure 7-2 Server is running.

■ When the server is not running, double-click the server icon  on the computer desktop or click the server icon from the Start menu.

Figure 7-3 Server is not running

3. Double-click the software icon  on the computer desktop or from the Start menu to start the server.

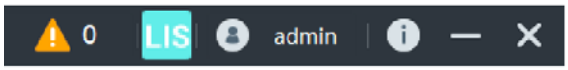
√ The **"Login"** dialog box displays.



4. Enter user ID and password and click "**Login**".

- The user name of in-built account of the instrument is "admin" and its password is "admin". The user name of operator is "user" and its password is "user".
- After login, you can create a new account or modify password see *6.3 User Management Settings*.

5. After logging in, check the LIS connectivity icon (if connected to LIS) at the upper right corner of the software screen. When the software connects to LIS, the LIS connectivity icon stays in green.



NOTE

- **If software accidentally exits, start the server first and then the client.**

After the software is started up, the analyzer perform system initialization automatically, which includes:

- Fluidic initialization
- Microscopic brightness auto-adjustment
- Microscope initialization

After system initialization, you can operate the analyzer.

7.4.3 Logging out and Switching users

1. Click the  button at the upper right corner of the software to log out.

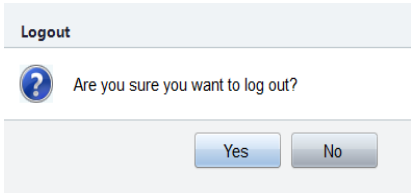


Figure 7-4 Logging out

2. Click **"Yes"**.

√ The **"Login"** dialog box displays.

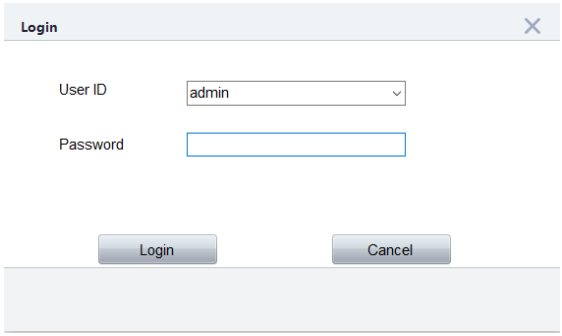


Figure 7-5 "Login" dialog box

3. Enter the user ID and password, and then click **"Login"**.

7.5 Checking Analyzer Status

After logging in, the software enters "**Overview**" screen. You can check the system status in the "**Overview**" screen.

- Check the LIS connectivity icon (if connected to LIS) at the upper right corner of the software screen. When the software connects to LIS, the LIS connectivity icon stays in green.

The picture below displays the icon status when the software connects to the main unit and LIS.

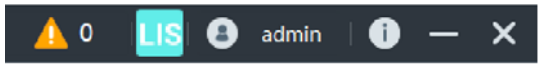


Figure 7-6 Analyzer connectivity icon and LIS connectivity icon

- Checking the analyzer status

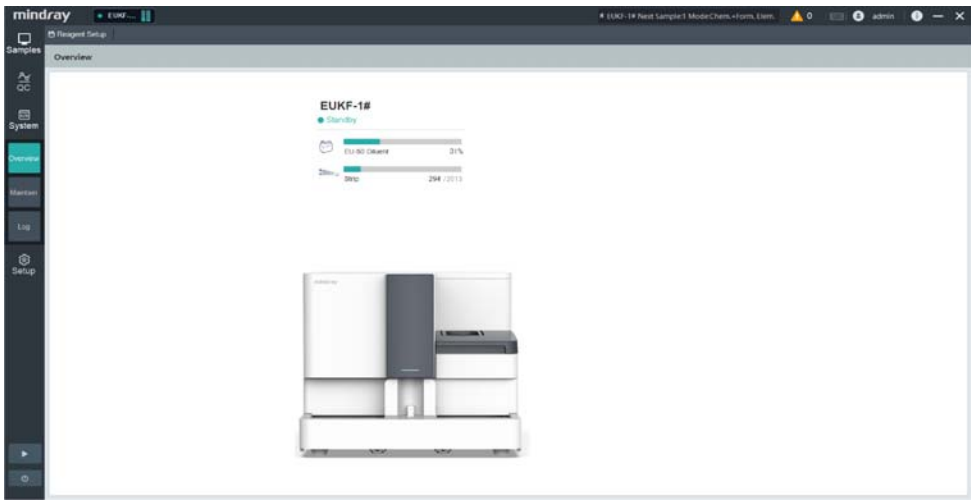


Figure 7-7 Analyzer status

Standby: analyzer is connected to software, and is ready to work.

Not connected: software is not connected to the analyzer. Check the analyzer status.

Error: error exists. Follow the software instruction to remove the errors first.

Running: software is working.

- Check whether Diluent is sufficient.

When Diluent is insufficient, the prompt box will be in red. Replace reagent in time when it is insufficient.

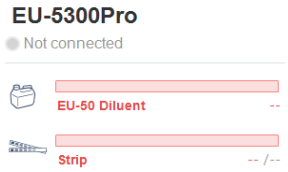


Figure 7-8 Diluent status

7.6 Performing Quality Control (QC)

Before running any samples, run the control analysis to ensure reliable results of test. See *9 Quality Control (QC) Program* for details.

7.7 Preparing Test Strips

Refill test strips in time when there is not enough test strips in the analyzer.

NOTE

- **Use the strips specified by the manufacturer only. Store and use the strips strictly following the strip instructions.**
- **Store necessary number of strips in the strip box only. When the strips are exposed in the air for a long time, they will absorb moisture or dust and result in incorrect test results.**
- **When placing the strips, do not touch the reagent pads, otherwise it may lead to incorrect test results.**
- **Do not use strips that are expired. Do not use the strips when their reagent pads are discolored, deformed or deteriorated.**

7.7.1 Refilling Test Strips

If the test strip in the test strip feeder is insufficient, refill test strips into it.

1. Open the top panel of the autoloader.
   a To unlatch the strip feeder, rotate the knob on the top panel of the strip feeder counter-clockwisely, to the direction marked [OPEN].

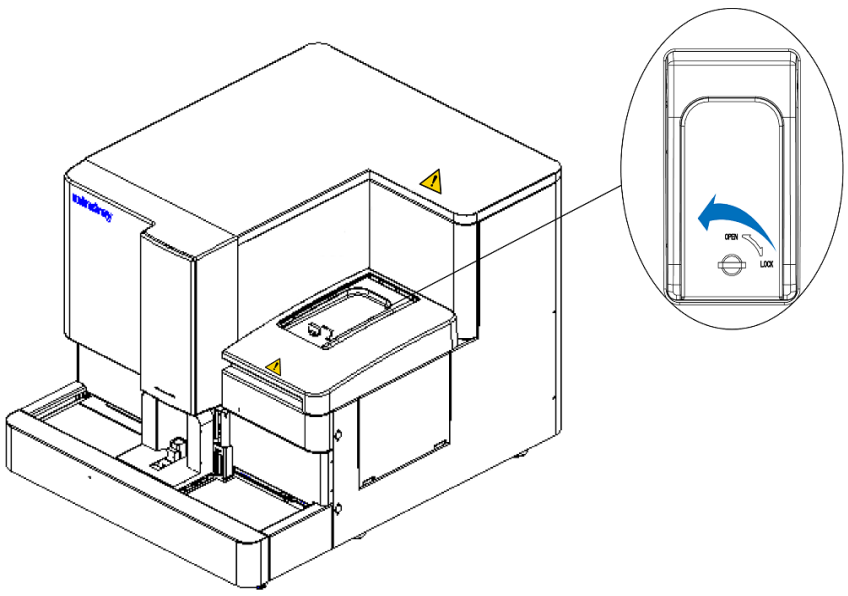


Figure 7-9 Unlatch strip feeder

b Open the top panel of strip feeder.

2. Take out the required number of strips from the strip cartridge and put them into the strip feeder. When placing the strips, make sure that the strip end with black squares should be in the direction toward the analyzer..

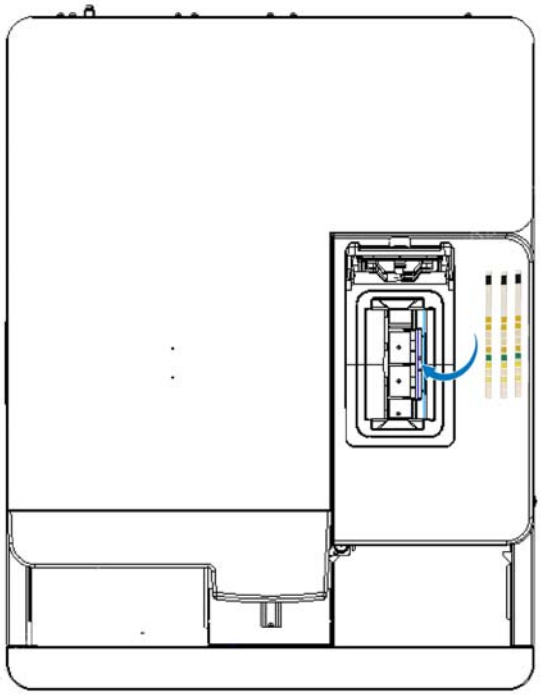
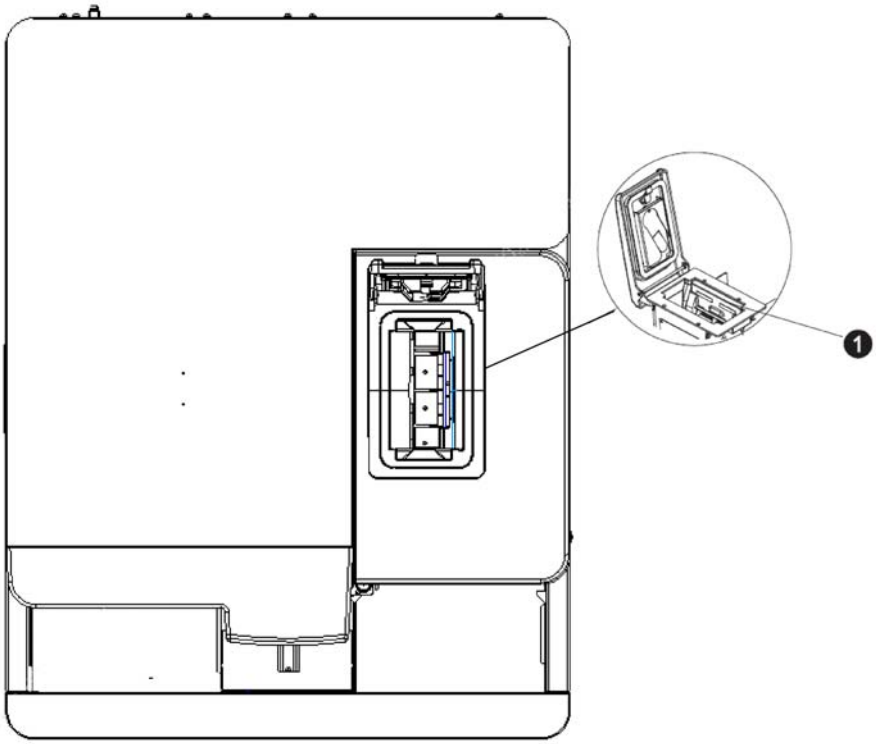


Figure 7-10 Placing test strips

3. Take out the dessicant from the strip cartridge.
4. Replace the old dessciant with the new one into the dessicant box and then put the dessicant box into the strip feeder.



5. Close the top panel of the strip feeder, rotate the knob to the direction marked [LOCK] to latch the autoloader.

NOTE

- **When a cartridge of strips is used out, recharge strips on the "Reagent Mgnt" screen. Refer to "*10.2.3.2 Registering new test strips information into the software*" for the instructions.**
- **Use the strips specified by the manufacturer only. Store and use the strips strictly following the strip instructions.**
- **Store necessary number of strips in the strip feeder only. When the strips have been exposed in the air for a long time, they will absorb moisture or dust and result in incorrect test results.**
- **Do not mix-use strips from different strip cartridges.**
- **When placing the strips, do not touch the reagent pads, otherwise it may lead to incorrect test results.**
- **Do not use strips that are expired. Do not use the strips when their reagent pads are discolored, deformed or deteriorated.**

7.8 Preparing Samples

BIOLOGICAL RISK

- **The test object of this product is urine. As it is not known that whether a specimen is infectious or to what degree it is infectious, operators must wear protective mask and gloves when operating. The operator shall perform proper disinfection procedures after the operation is completed.**
- **Any waste materials and waste samples are potentially infectious and they shall be disposed of according to local governmental regulations.**

NOTE

- **Do not reuse disposable products.**

7.8.1 Sample Requirements

The sample types supported by this analyzer include random urine, morning urine, catheter and suprapubic bladder puncture urine.

There is no special requirement for collection time, or follow instructions specified by the doctor.

7.8.1.1 Sample collection procedures and precautions

- Patients to take urine samples should live and eat as normal. Only before collecting samples, patients should stay in a quiet state, and clean the external genitalia, urethral orifice and surrounding skin. Female patients should especially pay attention to avoid vaginal secretions or menstrual blood polluting urine.
- Use disposable urine collection containers. The container should meet clinical urine sample collection requirements, be clean and leak-proof, and with material not reacting with urine.
- No special requirements for collection time, or collect the urine at the time doctor specified.

7.8.1.2 Required sample volume

Table 7-1 Minimum required sample volume and aspirated sample volumes

	Micro mode (mL)	Normal mode (mL)
Aspirated sample volume	1	1.7
Minimum required sample volume	2.3	3

NOTE

- **The minimum sample required volume mentioned above is verified using test tubes with specifications in *A.1 Applicable Tubes*.**

⚠ CAUTION

- **Insufficient sample volume may lead to inaccurate analysis results.**

7.8.1.3 Preparing, processing and storing samples

Close the sample tube cap, mix the sample by gently inverting the tube up and down. Avoid excessive bubbles in urine. Do not use too much force to avoid cell lysis.

- For specification requirements of urine sample tubes, see *A.1 Applicable Tubes*.
- Use fresh urine samples. When the sample is not tested within one hour, seal the urine sample and store it at 2℃~8℃. Samples should be restored to room temperature before testing.
- Mix the samples thoroughly before testing.

NOTE

- **Do not add preservatives, disinfectants or detergents to urine samples.**
- **Keep the urine samples away from direct sunlight.**
- **The container should be transparent, clean and leak-proof, made of inert and environmental friendly-material that do not react with urine.**
- **Do not centrifuge urine samples.**
- **If the container is capped, mix the sample by inverting the container.**

When using auto-loading sampling mode for sample analysis and auto-scanning sample barcode, be sure to stick barcode labels properly as shown in the figure.

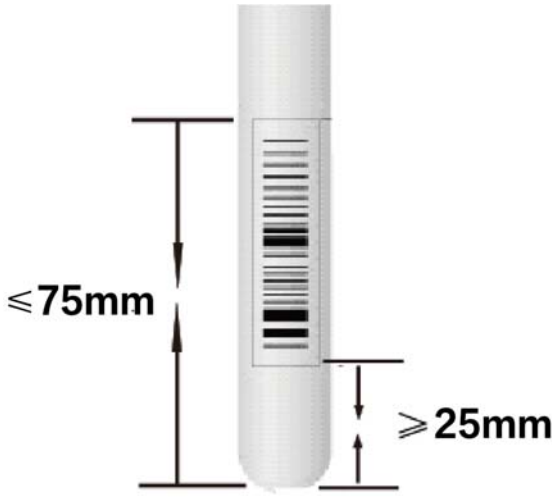


Figure 7-11 Barcode label pasting area

NOTE

- **The analyzer supports six code systems: CODE128, CODE39, ITF (Interleaved 2 of 5), CODE93, CODEBAR and UPC/EAN.**
- **See *A.14 Barcode Specifications* for specifications and parameters of barcode.**

7.9 Analyzing Samples

7.9.1 Checking before Analysis

Before performing analysis, confirm that the analyzer is in normal state, without errors or alarms.

7.9.2 Setting Up Analysis Orders

BIOLOGICAL RISK

- **The test object of this product is urine. As it is not known that whether a specimen is infectious or to what degree it is infectious, operators must wear protective mask and gloves when operating. The operator shall perform proper disinfection procedures after the operation is completed.**
- **The sampling probe tip is sharp and the urine on the probe is potentially biohazardous. Exercise caution to avoid contact with the probe.**
- **Any waste materials and waste samples are potentially infectious and they shall be disposed of according to local governmental regulations.**

CAUTION

- **Do not reuse disposable products.**

You can set up analysis orders in accordance with Internet connection conditions of your laboratory.

When connected to 2-Way LIS	Select from one of the following ways to set up analysis order: • DMU queries the sample order from LIS with sample ID • Set up the analysis order on DMU
When connected to 1-way LIS or Not Using LIS	Set up the analysis order on DMU and apply for orders according to your needs: • Tube worklists • Sample orders

NOTE

- **When the system detects a sample, it selects and performs the analysis order of the sample in the following order: re-exam orders > tube worklists >LIS orders (when the two-way LIS is connected) > > sample orders. For more information about re-exam orders, refer to *7.12 Validating and Re-examining Sample*.**

7.9.2.1 Setting up sample order

NOTE

- **For laboratories connected to two-way LIS, set up the sample order in LIS.**
- **When the analyzer is connected to one-way LIS or not connected to LIS, set up the sample order in the analyzer software (DMU).**

1. On the analyzer software, click "**Sample**"-"**Sample Order**"-"**Normal Samples**".
2. Enter / confirm "**Sample ID**".

■ When the analyzer has a built-in barcode scanner and the barcode on the sample tube is tact and clear, select "**Auto-scan sample ID**". When "**Auto-scan sample ID**" is selected, there is no need to enter "**Sample ID**" manually.

■ When "**Auto-scan sample ID**" is not selected, manually enter the sample ID of the first sample.

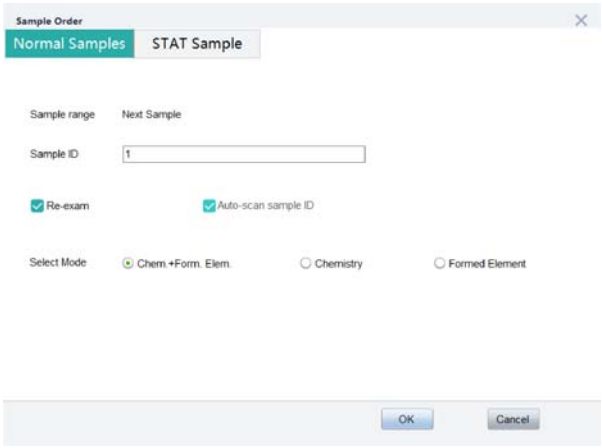


Table 7-2 Analyzing normal sample

NOTE

- **When "Auto-scan sample ID" is not selected, or the system has no built-in scanner, manually enter the sample ID of the first sample. The subsequent sample IDs will automatically increase by 1 based on the previous one.**

3. Select analysis mode:

■ Chemistry+ Formed element

■ Chemistry

■ Formed element

4. Click "**OK**" to save the order settings.

NOTE

- **Samples of the same batch are analyzed in the same mode.**
- **If the analysis system can not acquire analysis mode, refer to *6.9.3 Configuring the Method to Process Sample When Auto Acquire Mode Fails* to specify analysis mode for the sample.**

7.9.2.2 Setting up tube worklists

NOTE

- **Tube worklists are applicable only to sample processing systems.**

A tube worklist registers tube orders. You can specify test orders for each sample.

Follow the instructions below:

1. Select "**Samples**" - "**Order Setup**" to enter the "**Order Setup**" screen on the menu of the software.
2. Select "**Tube Worklist**".
3. Select "**New**".

√ The "**Batch New**" dialog box displays.

4. Set up tube worklists as instructed below:

Items	Description	Notes
Start Sample ID	The ID of the first new tube order.	The IDs in the tube worklists added in the batch will increase by one.
Quantity	The quantity of tube worklists i n this batch.	• A new batch supports 500 worklists at most; • The DMU supports 5,000 worklists at most.

Items	Description	Notes
Mode	Select the analysis mode of the tube lists.	Select at least one analysis mode.

5. Select "**OK**".

√ New tube worklists display in the **"Tube Worklist**" tab.

Selecting tube worklists

- Select single tube order: click the mouse to select a tube order;
- Select in-consecutive tube orders: press and hold the [ctrl] key on the keyboard, and click the mouse to select the tube orders;
- Select consecutive tube orders: press and hold the [shift] key on the keyboard, and click the mouse to select the first and last orders.

Editing tube worklists

The DMU supports editing tube worklists.

NOTE

- **You cannot edit a tube order when the analysis of the relevant sample has been started.**

1. Select the tube order in the worklist to be modified.

NOTE

- **You can select more than one tube orders at a time.**
- **To edit tube orders in batch, select the tube orders, and edit the one of the selected tube orders. The other selected tube orders will change accordingly.**

2. Select or clear the check box of the analysis mode.

Deleting tube orders

When the tube orders are not applicable, you can delete them.

NOTE

- **You cannot delete the tube orders when the relevant sample is being tested.**

Follow the instructions below:

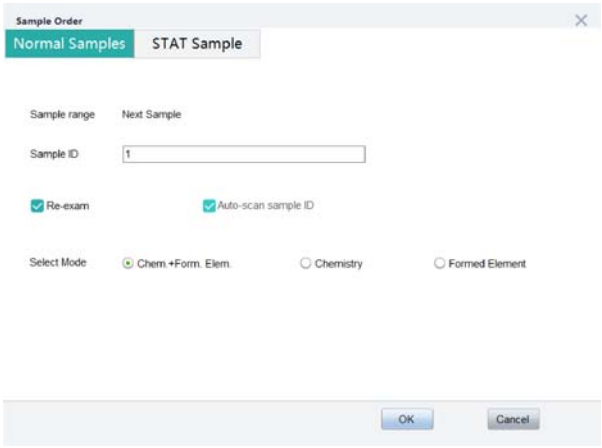
Operation	Step	Notes
Deleting selected tube worklists	1. Select the tube worklists to be deleted. 2. Select **"Delete**". 3. Select **"Yes**" in the displayed dialog box.	Several tube worklists can be deleted at the same time.
Deleting all tube worklists	1. Select **"Delete All**". 2. Select **"Yes**" in the displayed dialog box.	/

7.9.2.3 Setting up re-exam orders

When the test result is not as expected, you can set up a re-exam order to re-test the sample.

Follow the instruction below.

1. On the DMU, select "**Sample Order**".



√ "**Sample Order**" dialog box displays.

2. Set up sample ID.

NOTE

- **When the analyzer has a built-in barcode scanner and the barcode on the sample tube is complete and clear, select "Auto-scan sample ID". And there is no need to enter "Sample ID" manually.**
- **To enable the function of auto-scan sample ID, contact Mindray's Customer Service Department.**

3. Select "**Re-exam**".
4. Select the analysis mode in the "**Select Mode**" area

■ Chem.+Form.Elem.

■ Chemistry

■ Formed Element

5. Select "**OK**".

NOTE

- **After "Re-exam" function is enabled, the system stop acquiring analysis mode from LIS. Therefore, you need to set up analysis mode for re-examination orders on the "Sample Order" screen. After "Re-exam" is deselected, the system turns back to auto acquire mode.**
- **For reviewing re-examined results, see *8.2.9.2 Viewing re-tested results*.**
- **After re-examination, the sample report result area displays the latest re-examined result as report result. When needed to set up one of the previous testing results as the report result, you can see *8.2.9 Setting up Re-exam Orders* for further details.**
- **After re-examination, the system transmits the newest report result to LIS.**
- **STAT sample order does not support re-examination function. If you need to re-examine the STAT sample, please apply for a new STAT sample No. for further operation.**

√ After setup, the samples will be analyzed according to the order setup.

7.9.3 Starting Analysis

1. Place the prepared sample tubes without caps into a tube rack. Place the racks with tubes on the loading platform of the analyzer with the side opening facing the analyzer, and the side with "Mindray" mark facing yourself, as shown in the following figure .

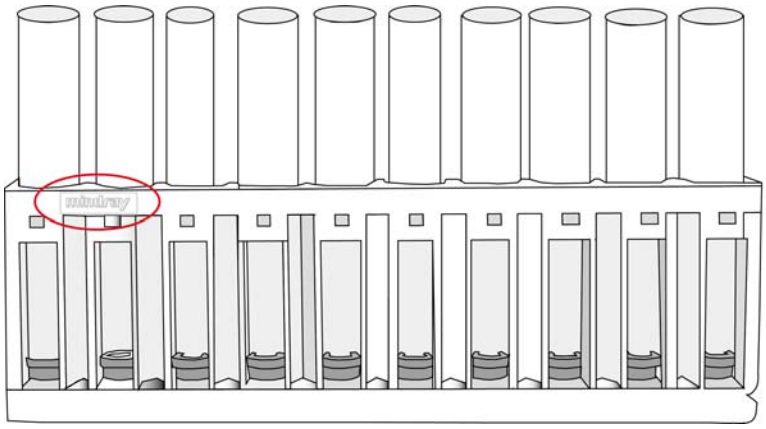


Figure 7-12 Placing tubes and tube racks

NOTE

- **Place the tube containing the sample upright to the bottom of the rack; the tubes cannot be tilted, otherwise the operation of the sampling probe will be affected.**

2. Click  on the software to start analysis.

√ The analyzer automatically transports the samples, and performs analysis.

√ The analyzer status area displays the sample IDs and the tests.

3. Completed samples are sent to the unloading area of the analyzer. Remove samples from the unloading area in time.

BIOLOGICAL RISK

- **Dispose of the remaining samples in accordance with the laboratory procedures and local regulations.**

NOTE

- **After the sample analysis is completed, the sample results display in the software result report screen.**

7.9.4 Analyzing STAT Samples

When there are STAT samples to be analyzed during the auto-loading analysis process, follow the instructions.

1. Enter the STAT Sample ID.

a On the software, click "**Sample**"-"**Sample Order**"-"**STAT**", manually enter or use barcode scanner (if there is) to enter the sample ID.

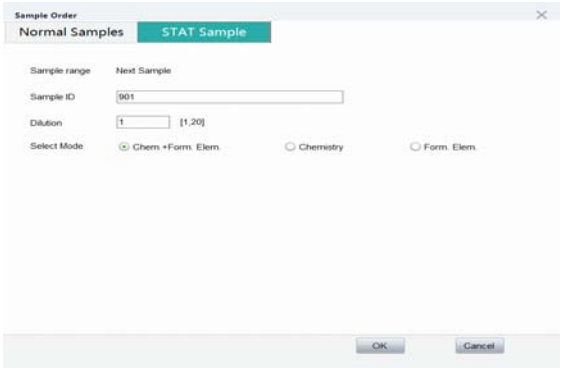


Figure 7-13 Analyzing STAT Samples

b Select analysis mode:

◆Chemistry+ Formed element

◆Chemistry

◆Formed element

c If the sample is diluted, input the dilution factor into the edit box of "**Dilution**".

NOTE

- **After setting dilution, the system will display the test result timed the dilution factor.**

d Select "**OK**" to save the sample ID.

2. After the STAT sample order is setup, remove the cap of prepared sample and place the sample tube into the initial position of STAT sample tube holder.

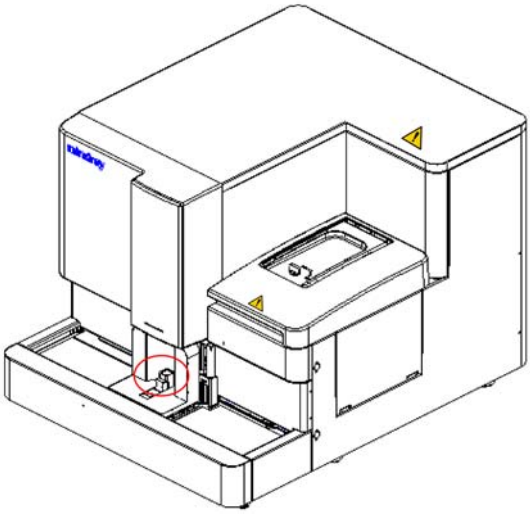


Figure 7-14 Placing STAT Samples

3. Manually transfer the STAT tube holder loaded with STAT sample to the analysis position, push the STAT tube holder forward to position and then loose your hand.

4. After STAT analysis, it is needed to retrieve the STAT sample manually by pulling the STAT tube holder to initial position. Before pulling, the STAT tube holder is locked in the analysis position, you need to push the tube holder forward to loose the lock first and then pull the STAT tube holder back.

When necessary, repeat steps 2 to 4 to run other samples.

NOTE

- **When the STAT sample ID is not set, software numbers the STAT samples according to the setting of "First STAT sample ID after daily start-up" on "System Setup"- "Analyzer Setup"- "Get Sample Information"- "First Sample Setup".**
- **STAT tube holder is a moving part. To avoid injury, withdraw your hand as soon as you place STAT sample to the tube holder.**
- **When there is a sample being analyzed in the auto-loading mode, after the current sample completes, the analyzer prioritizes the STAT sample analysis. After the STAT sample analysis is completed, if no other STAT sample tubes are placed within 10 seconds, analyzer switches to auto-loading analysis mode and continues auto-loading tests paused before.**

7.10 Viewing Sample Results

To view sample results on the report screen of the "Automatic Urinalysis System" software, refer to *8 Reviewing Sample Results*.

7.11 Shutting down

7.11.1 Shutting Down the Analyzer and the Software

NOTE

- **To ensure stable performance and accurate analysis results of the analysis system, be sure to shut down the analyzer after it has been running continuously for 8 hours, then power on again.**
- **Be sure to shut down the analyzer strictly as instructed below.**

1. On the analyzer software, click "  ".
2. Click "**OK**" on the prompted screen..

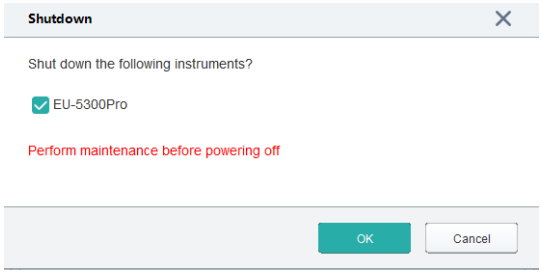


Figure 7-15 "Shutdown" dialog box

√ The software displays maintenance prompt.

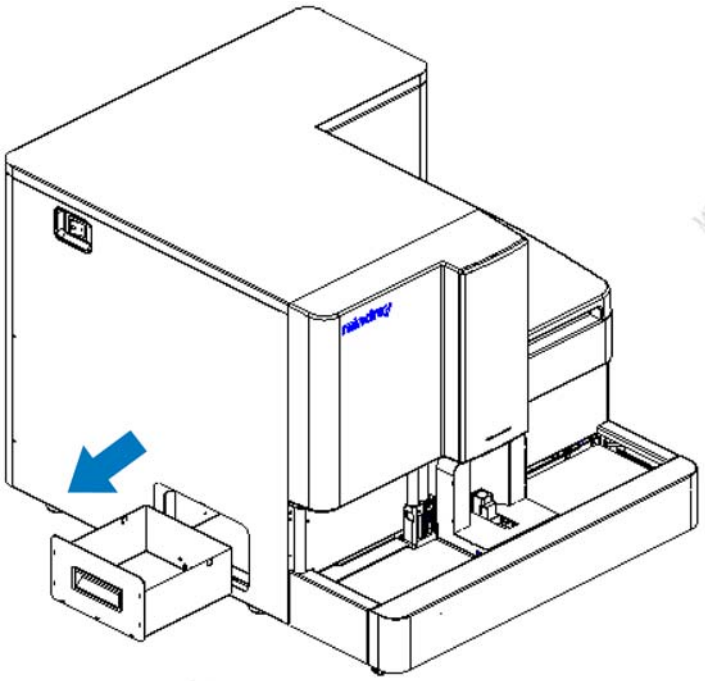
3. Perform cleanser maintenance by pouring cleanser in a tube and placing the tube into the STAT tube holder.
4. Click "**OK**" on the maintenance prompt.
5. After maintenance, shut off the software, computer, display and printer.
6. Power off the main unit of the analyzer.

NOTE

- **For details of cleanser maintenance, see √*After the auto maintenance function is enabled and when the analyzer connected to DMU meets the following conditions for auto maintenance, the software will prompt to perform relevant operations.*.**

7.11.2 Disposing of Analyzed Sample, Waste and Used Strips

1. Dispose of the analyzed samples and waste according to your laboratory protocol and local government regulations.
2. Pull out the waste strip box and empty the used strips according to your laboratory protocol.



7.12 Validating and Re-examining Sample

NOTE

- **For information of setting up re-exam rules, refer to *6.14 Configuring Re-exam Rules*.**

You can set up re-exam rules on "**Re-exam Setup**" screen according to your laboratory protocol. When a sample meets the conditions in the re-exam rules, users need to validate the results or re-exam the sample.

When "Re-exam Rules" is enabled:

- Samples that trigger re-exam rules are highlighted in yellow in the sample list, and the rule record area of the samples prompts "**Re-exam recommended: {0}**".
- Samples that have not triggered re-exam rules are automatically approved, and the samples in the sample list will display the "**Auto Validation OK**" mark A.

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8 Reviewing Sample Results

8.1 Overview

After every analysis cycle, the analyzer automatically saves the results into the sample database.

After a sample is tested, the software calculates the scanning outcome of the test strips to output the semi-quantitative sample results in plus system, processes the sample images, marks and identifies the formed elements on the images, calculates and categorizes their types. Then the analyzer counts the formed elements of each category, and converts the result to international system of units. The analyzer automatically saves sample results and images. When the maximum number has been reached, the newest result will overwrite the oldest.

See the following table about the sample result storage capacity of each model.

Table 8-1 Storage Capacity

Models	Storage Capacity
EU-5300 Pro/ EU-5600 Pro	20,000

NOTE

- **Software supports flash backup to protect data in case of unexpected shut-down or power outage. You can check the existing record(s), print or process the sample results.**

8.2 Reviewing Sample Results

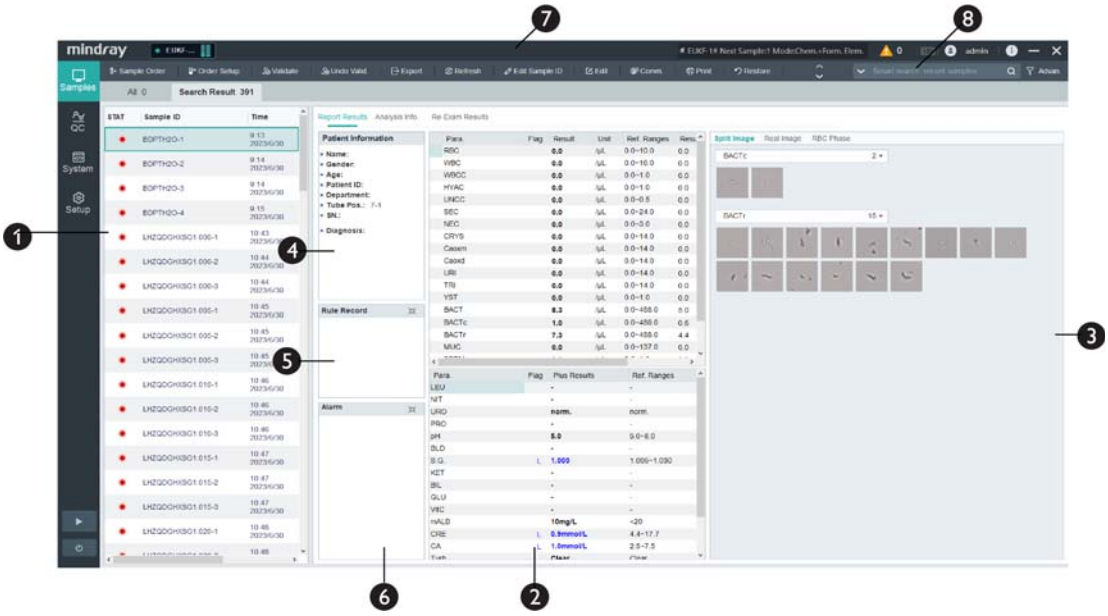


Figure 8-1 Software result report screen

1	Sample list area
2	Sample results area
3	Image area
4	Patient information area
5	Rule record area
6	Message area
7	Function buttons area
8	Search area

8.2.1 Viewing Sample List

The sample list area displays sample information including the sample status, sample IDs, test times, tube positions (for auto-loading tests) etc..

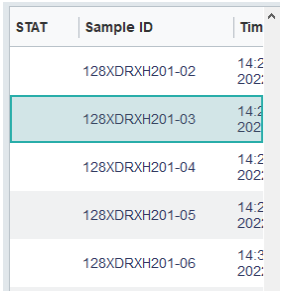


Figure 8-2 Sample list area

- Click "**All**", all samples tested on the current day display in the sample list area.
- When using the search function to search for samples, click "**Search Result**", and the sample list displays all the samples that meet the searching criteria.

The number displayed on the tab indicates the number of samples in the current classification.

8.2.1.1 Sample status bar

The **"STAT"** column displays current status of the samples.

See the following table for icons displayed in the column **"STAT"** and their meanings.

Table 8-2 Sample status icons

Icons	Notes
	The sample has been auto validated.
	The sample has been manually validated
	The sample record has been transmitted to LIS.
	The sample record has been printed.
	The sample has been flagged "positive"
	Sample result is suspicious, and needs to be reviewed.
	Aspirated sample volume is insufficient or the sample is abnormal, results need to be reviewed.
	Sample result is edited manually.

8.2.1.2 Customizing sample list

When necessary, you can customize the displaying order of sample records.

In the **"Sample List"** area, click on the header of "**Sample ID**" or "**Time**" column, and then the sample records display by "**Sample ID**" or "**Time**".

NOTE

- **For configuring the sample list field display and order, see *6.19 Configuring Sample List Field Display Settings*.**

8.2.1.3 Selecting one or more samples

Click to select the required sample.

Press and hold Ctrl key on the keyboard, and click with the mouse to select multiple samples.

8.2.1.4 Refreshing sample records

If you choose to arrange samples by "**Sample ID**", click the header of "**Sample ID**" to switch between displaying samples by Newly received samples are displayed above or below the list in ascending or descending order of "**Sample ID**".

If you choose to arrange samples in a way other than **"Sample ID**", when the software receives new samples, the newly arrived samples display after the last record in the sample list. Click **"Refresh**" or press the shortcut key F5 on the keyboard, to arrange the sample records based on the existing user-defined arrangement order.

8.2.2 Reviewing Sample Results

8.2.2.1 Reviewing chemistry analysis results

Click "**Report Results**" to review the dry chemistry analysis results.

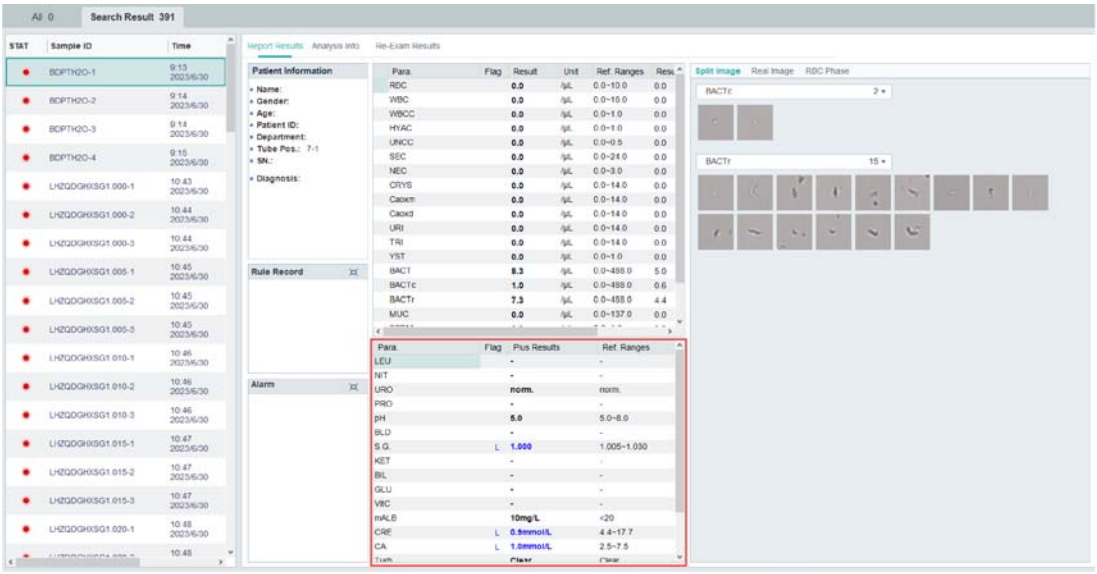


Figure 8-3 Chemistry test results

The "**Report Results** " area displays (in "**Plus Results**" and "**Conventional Unit**" by default), flags and parameter reference ranges.

NOTE

- **When you need to change the display form of sample results, refer to *6.7.1 Configuring Chemistry Parameter Properties*.**
- **When a parameter result exceeds the normal reference interval the "Flag" column in the "Chemistry Test Result Area" displays the high/low result flag ("H" or "L" by default). To change the "high/low result flag", refer to *6.4.2 Configuring High and Low Result Flags*.**
- **Items marked with * are Research Use Only (RUO) parameters.**
- ***Table 8-3 Chemistry test results magnitudes of different unit systems* compares the chemistry test results in plus system, conventional unit system and international unit system.**
- **When the chemistry test result shows "N/A", it means there may be bubbles in the sample, and the result is invalid.**
- **The chemistry test result "norm." is the abbreviation of "normal" which means that the result is within normal reference range.**
- **For reference interval of chemistry test results, refer to *Table 8-4 Reference interval of chemistry test results*.**

Table 8-3 Chemistry test results magnitudes of different unit systems

Parameters	Plus System	Conventional unit system	International unit system
LEU	-	0 Leu/µL	0 Leu/µL
	±	15 Leu/µL	15 Leu/µL
	1+	70 Leu/µL	70 Leu/µL
	2+	125 Leu/µL	125 Leu/µL
	3+	500 Leu/µL	500 Leu/µL
URO	norm.	1 mg/dL	17 µmol/L
	1+	2 mg/dL	35 µmol/L
	2+	4 mg/dL	70 µmol/L
	3+	8 mg/dL	140 µmol/L
mALB	10mg/L	1 mg/dL	0.01 g/L
	30mg/L	3 mg/dL	0.03 g/L
	80mg/L	8 mg/dL	0.08 g/L
	150mg/L	15 mg/dL	0.15 g/L
PRO	-	0 mg/dL	0 g/L
	±	15 mg/dL	0.15 g/L
	1+	30 mg/dL	0.3 g/L
	2+	100 mg/dL	1 g/L
	3+	300mg/dL	3 g/L
BIL	-	0 mg/dL	0 µmol/L
	1+	1 mg/dL	17 µmol/L
	2+	3 mg/dL	50 µmol/L
	3+	6 mg/dL	100 µmol/L
GLU	-	0 mg/dL	0 mmol/L
	±	50 mg/dL	2.8 mmol/L
	1+	100 mg/dL	5.6 mmol/L
	2+	250 mg/dL	14 mmol/L
	3+	500 mg/dL	28 mmol/L
	4+	1000 mg/dL	56 mmol/L
VitC	-	0 mg/dL	0 mmol/L
	1+	10 mg/dL	0.56 mmol/L
	2+	20 mg/dL	1.14 mmol/L
	3+	40 mg/dL	2.28 mmol/L

Parameters	Plus System	Conventional unit system	International unit system
S.G.(front test strips)	1.000	1.000	1.000
	1.005	1.005	1.005
	1.010	1.010	1.010
	1.015	1.015	1.015
	1.020	1.020	1.020
	1.025	1.025	1.025
	1.030	1.030	1.030
KET	-	0 mg/dL	0 mmol/L
	±	5 mg/dL	0.5 mmol/L
	1+	15 mg/dL	1.5 mmol/L
	2+	40 mg/dL	4.0 mmol/L
	3+	80 mg/dL	8.0 mmol/L
NIT	-	-	-
	+	+	+
CRE	0.9 mmol / L	10 mg/dL	0.9 mmol/L
	4.4 mmol / L	50 mg/dL	4.4 mmol/L
	8.8 mmol / L	100 mg/dL	8.8 mmol/L
	17.7 mmol / L	200 mg/dL	17.7 mmol/L
	26.5 mmol / L	300 mg/dL	26.5 mmol/L
pH	5.0	5.0	5.0
	5.5	5.5	5.5
	6.0	6.0	6.0
	6.5	6.5	6.5
	7.0	7.0	7.0
	7.5	7.5	7.5
	8.0	8.0	8.0
	8.5	8.5	8.5
	9.0	9.0	9.0
BLD	-	0 Ery / µL	0 Ery / µL
	±	10 Ery / µL	10 Ery / µL
	1+	25 Ery / µL	25 Ery / µL
	2+	80 Ery / µL	80 Ery / µL
	3+	200 Ery / µL	200 Ery / µL

Parameters	Plus System	Conventional unit system	International unit system
Ca	1.0 mmol / L	4 mg/dL	1.0 mmol/L
	2.5 mmol / L	10 mg/dL	2.5 mmol/L
	5.0 mmol / L	20 mg/dL	5.0 mmol/L
	7.5 mmol / L	30 mg/dL	7.5 mmol/L
	10.0 mmol / L	40 mg/dL	10.0 mmol/L
Color	Colorless	Colorless	Colorless
	Light Yellow	Light Yellow	Light Yellow
	Yellow	Yellow	Yellow
	Brown	Brown	Brown
	Red	Red	Red
	Other	Other	Other
Turb.	Clear	Clear	Clear
	Slightly Turb.	Slightly Turb.	Slightly Turb.
	Turbid	Turbid	Turbid
S.G. (from physical module)	[1.000, 1.050] Differentiating degree 0.001	[1.000, 1.050] Differentiating degree 0.001	[1.000, 1.050] Differentiating degree 0.001

Table 8-4 Reference interval of chemistry test results

Parameters	Plus system	Conventional unit system	International unit system
LEU	-	0Leu/μL	0Leu/μL
URO	norm.	1mg/dL	17μmol/L
mALB	<= 20mg/L	<= 2mg/dL	<= 0.02g/L
PRO	-	0mg/dL	0g/L
BIL	-	0mg/dL	0μmol/L
GLU	-	0mg/dL	0mmol/L
VitC	-	0mg/dL	0mmol/L
S.G.(from test strips)	1.005~1.030	1.005~1.030	1.005~1.030
KET	-	0mg/dL	0mmol/L
NIT	-	-	-
CRE	4.4~17.7mmol/L	50~200mg/dL	4.4~17.7mmol/L
pH	5.0~8.0	5.0~8.0	5.0~8.0
BLD	-	0Ery/μL	0Ery/μL
Ca	2.5~7.5mmol/L	10~30mg/dL	2.5~7.5mmol/L
Color	Yellow	Yellow	Yellow
Turb.	Clear	Clear	Clear

Parameters	Plus system	Conventional unit system	International unit system
S.G. (from physical module)	1.003-1.030	1.003-1.030	1.003-1.030
P/C	/	• Normal: < 150mg/g • Abnormal: 150~500mg/g • Highly abnormal: > 500mg/g	• Normal: < 16.95mg/mmol • Abnormal: 16.95~56.5mg/mmol • Highly abnormal: > 56.5mg/mmol
A/C	/	• Normal: < 30mg/g • Abnormal: 30~300mg/g • Highly abnormal: > 300mg/g	• Normal: < 3.4mg/mmol • Abnormal: 3.4~33.9mg/mmol • Highly abnormal: > 33.9mg/mmol

8.2.2.2 Formed Element Analysis Result

Click "**Report Results**" to review the formed element analysis results.

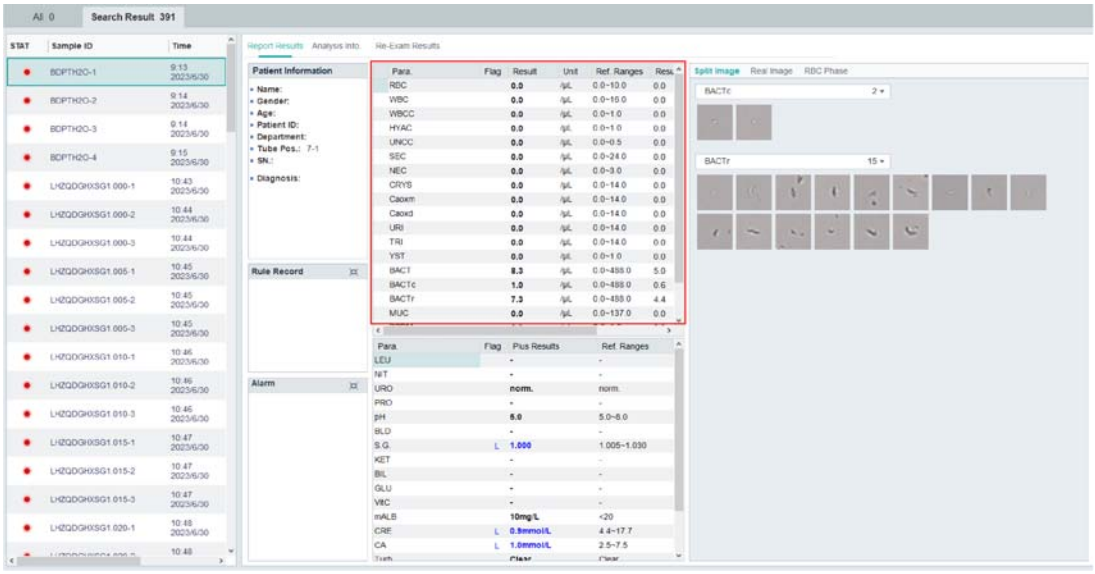


Table 8-5 Formed element test result

Click "**Report Results**" to review sample analysis results (displayed in the form of "**Num.**" and "**Result**" by default), flags, current unit and parameter reference range.

Among them:

- "**Num.**" displays the number of formed elements identified by the system in the current image.
- "**Result**" is concentration of the formed elements calculated by the system.

NOTE

- **When you select a parameter whose resultdisplays a high/ flow flag, the image area will jump to the split image of its catagory.**
- **When you need to change the display form of sample results, refer to *6.7 Configuring Parameter Properties*.**
- **When a parameter result exceeds the normal reference interval, the "Flag" column in the "Formed Element Analysis Result Area" displays the high/low result flag ("H" or "L" by default). To change the "high/low result flag", refer to *6.4.2 Configuring High and Low Result Flags*.**
- **Items marked with * are Research Use Only (RUO) parameters.**
- **For the parameters bacteria, coccus, rod, mucous strands and sperm, the analyzer provides semi-quantitative results, in pre-set magnitudes "Not Found", "Few", "Some" and "Many".**

8.2.2.3 Viewing sample flow

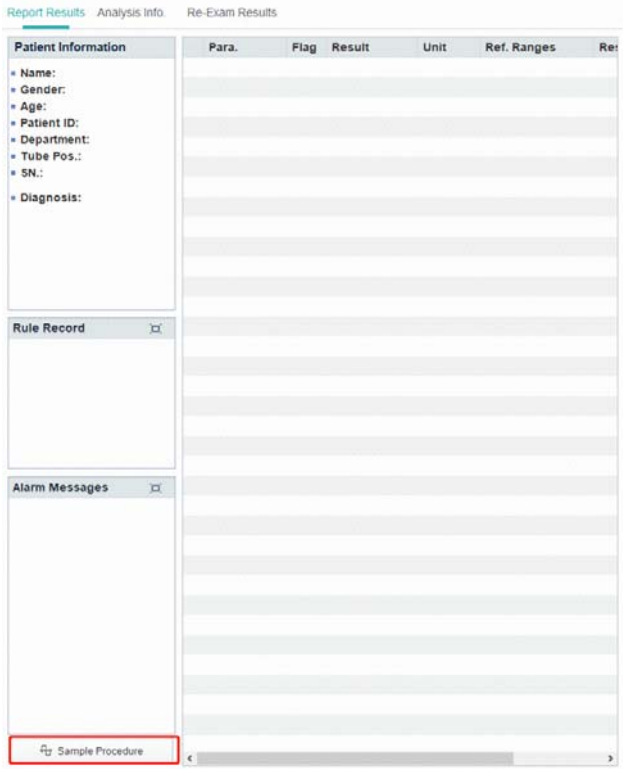
You may view the sample procedure on the "**Sample Flow Chart**" or "**Sample Flow List**".

Viewing sample flow chart

You can view the whole analysis work flow in the "**Sample Flow Chart**" area.

Follow instructions below to open "**Sample Flow Chart"**.

1. Select "**Sample Procedure**" button.



2. Select "**Sample Flow Chart**" in the dialog box displayed.

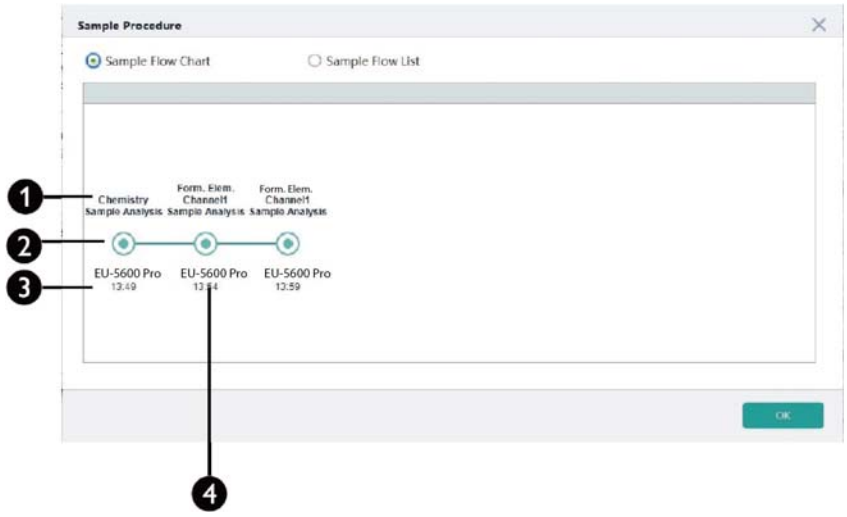


Figure 8-4 Sample Flow Chart

Table 8-6 Introduction to Sample Flow Chart

No.	Names	Descriptions
1	Analysis mode	Displaying the tests that have been completed or are being run or to be run at different nodes

No.	Names	Descriptions	
2	Sample status		The analysis at the node has not been run yet
			The analysis at the node has already been completed
			The analysis at the node is in process
3	Instrument name	Display the instrument that runs the tests at the correpsonding node	
4	Time	Display the time when the test is completed at the corresponding nodes	

Viewing sample chart list

You may review all the history operation on sample procedure list.

Follow instructions below to open "**Sample Flow List**".

Select "**Sample Procedure**" button, and then select "**Sample Flow List**" in the dialog box displayed.

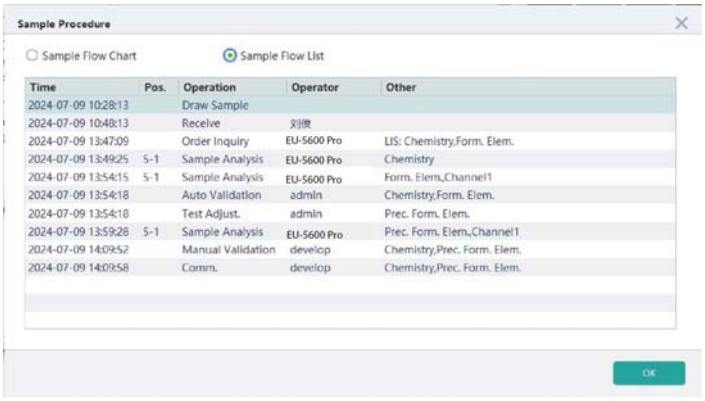


Figure 8-5 Sample Flow List

Items	Description
Time	The time when the corresponding operation is completed
Position	Sample tube position in the sample rack, displayed in the format: sammple rack No.-tube position
Operations	History operation to the sample. For details about sample operation, see *Table 8-7 Introduction to Tasks*.
Operators	The user ID of the operator who performed the corresponding operation, or the instrument on which the sample is processed.
Others	Display the additional information which is applicable to some operations only. For description of additional information, see *Table 8-7 Introduction to Tasks*.

Table 8-7 Introduction to Tasks

Point Names	Descriptions	Additional Information	Notes
Sample Analysis	The sample has been analzyed.	For such operation, the "Other" column displays the specific tests that have been run, including chemistry, formed element. For formed element tests, the column also displays the NO. of the channel where the tests have been run.	/
Auto Validation	The system evaluates the samples based on the re-exam rules.	For this operation, the "Other" column displays the tests that have been run for the sample.	/
Manual Validation	The sample results have been manually validated by a clinician.	For this operation, the "Other" column displays the tests that have been run for the sample.	/
Comm.	The DMU communicates the sample results to LIS	For this operation, the "Other" column displays the tests that have been run for the sample.	Available when connected to 2-way LIS
Draw Sample	A clinician collected the sample.	/	
Receive	The laboratory received the sample.	/	
2-way LIS inquiry abnormal	DMU failed to inquire information from the LIS	/	
Test Adjust.	A clinician manually adjusts the tests for the sample.	For this operation, the "Other" column displays the tests after adjustment.	/
Order Inquiry	The system inquires the sample order.	For this operation, the "Order" column displays the inquired tests for the sample and the source of the inquiry (for example, LIS, tube orders, rack orders, re-exam tests or using the default mode).	/

8.2.3 Parameter Flags

Analyzer provides the following parameter flags.

Flags	Meaning	Notes
"H" (default) and "L" (default) or **"** ↑ **"** and **"** ↓ **"** "h" and "l"	High and low result flags.	The analysis result exceeds the upper or lower limit of the reference interval, but still within the display range. **Note:** To customize the high and low result flags, refer to ***6.4.2 Configuring High and Low Result Flags***.
"E"	The result was edited directly..	Sample result has been manually edited by users.

Flags	Meaning	Notes
"e"	The result is calculated based on other parameters. It is changed because in accordance with the change of other parameters.	/

8.2.4 Message Area

The flag information area displays the clinical flags during chemistry analysis.

Table 8-8 Messages

Flag messages	Possible causes
Strip error [1]	Strips are placed in wrong direction (upside down).
Strip error [2]	Strips are placed in wrong direction (backside up).
No strip is scanned	Missing chemistry strips.
Sample application abnormal?	Chemistry reflection is out-of-range.
Optical system abnormal.	Chemistry optical system is abnormal.
Aspiration insufficient?	Bubbles in the sample. Aspirated sample is not sufficient.
Sample is too concentrated.	Sample is too concentrated, and out of linear range.
Tests not completed	Error occurs
Acanthocytes>5%, renal hematuria?	Acanthocytes accounting for more than 5% of total red blood cells

8.2.5 Viewing Real Images

During the formed element analysis, the system takes images for each sample.

Select a sample in the sample list area, click "**Real Image**" in the image area to view the photos of the samples.

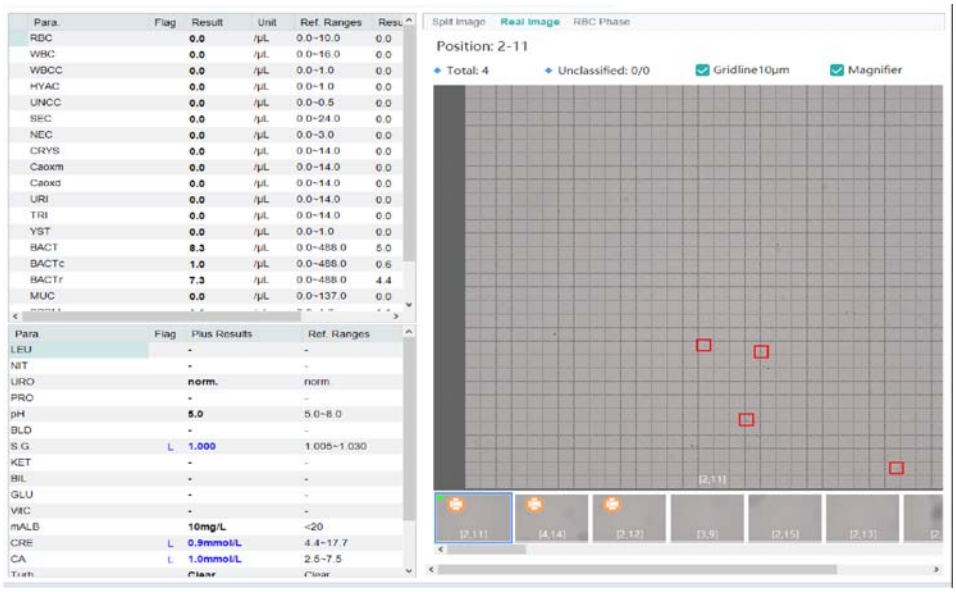


Figure 8-6 Real images

8.2.5.1 Introduction to real images

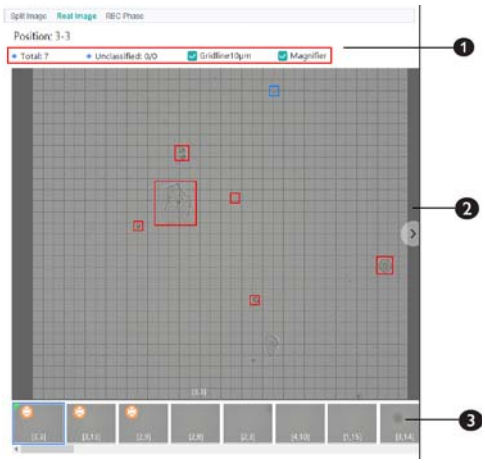


Figure 8-7 Description of real images

1	Real image information and toolbar
2	Real image area
3	Thumbnail area

Table 8-9 Real image information and toolbar

	Description	Notes
Position: {0}-{1}	The position of the image.	/
Total: {0}	The total number of formed elements or particles detected on the image.	/
Unclassified: {0}/{1}	Displaying the number of formed elements unclassified by the analyzer or categorized by users.	{0} indicates the number of unclassified formed elements in the current images. {1} indicates the number of unclassified formed elements in all images of the sample.
Magnifier	When "**Magnifier**" is selected, move the mouse to the vicinity of the formed elements to be viewed, and double-click the left mouse button to zoom in the picture.	/
Gridline	When "**Gridline**" is selected, grid lines displays in the image area according to the defined grid size.	You can choose to use the 40 μm or the 10 μm grid.

8.2.5.2 Real images

View the real images of the sample in the image area.

Click <- or -> , to browse/view the previous or the next real image.

You can also quickly locate the images you want to view by clicking the thumbnails in the thumbnail area.

8.2.5.3 Viewing/changing the formed elements categories

The analyzer marks system-identified cells/ formed elements with pre-defined shape.

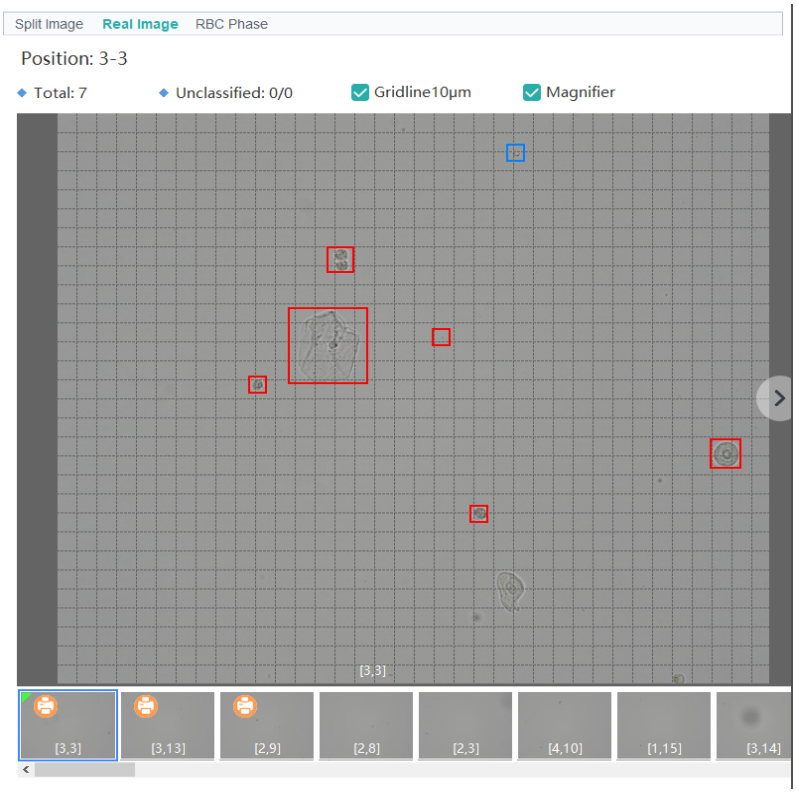


Figure 8-8 The marked cells/components on the real image

NOTE

- **You can customize the methods of marking each type of formed elements. For the instruction, refer to *6.7.3 Customizing Formed Element Thresholds*.**

Move the mouse to the frame border of a marked formed element, and the current category displays.

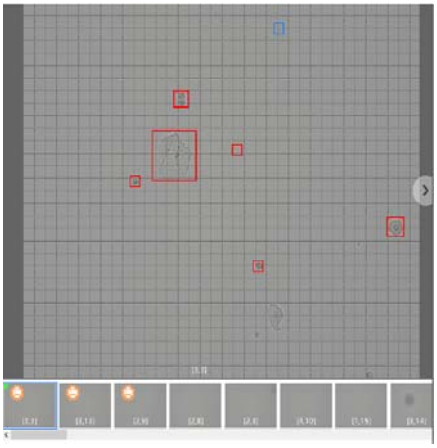


Figure 8-9 Viewing formed element categories

To change the formed element category, right-click the mouse and select another formed element category in the category list.

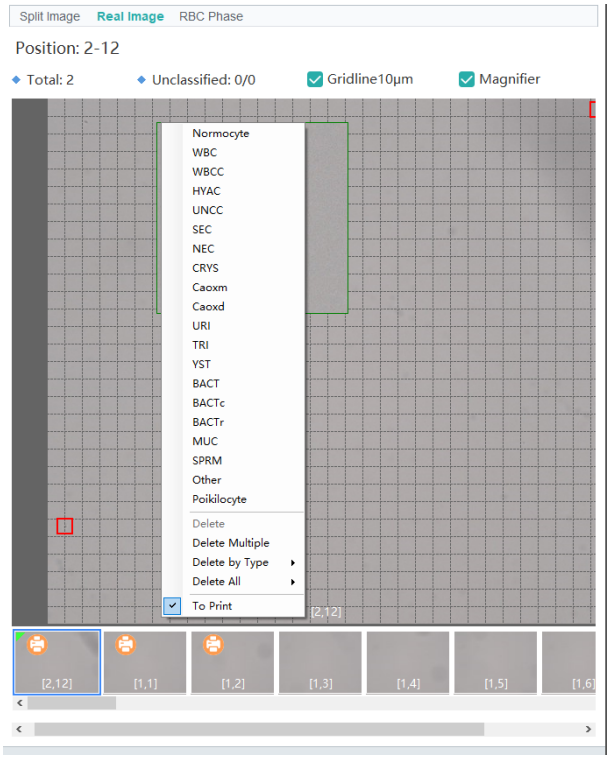
After changing the formed element category, click "**End Editing**" to refresh the sample parameter results.

8.2.5.4 Deleting marked cells/ formed elements

Follow the steps to remove a certain formed element or a certain category of formed elements.

1. Move the mouse over the frame border of a cell/ formed element and select the cell/ formed element.
2. Right-click the mouse.

√ The software displays the cell/ formed element category list.



3. Click "**Delete**" to delete the selected formed element.

■ Continuously deleting cells/ formed elements

1. Right-click the mouse on the real image.

√ The software displays the cell/ formed element category list.

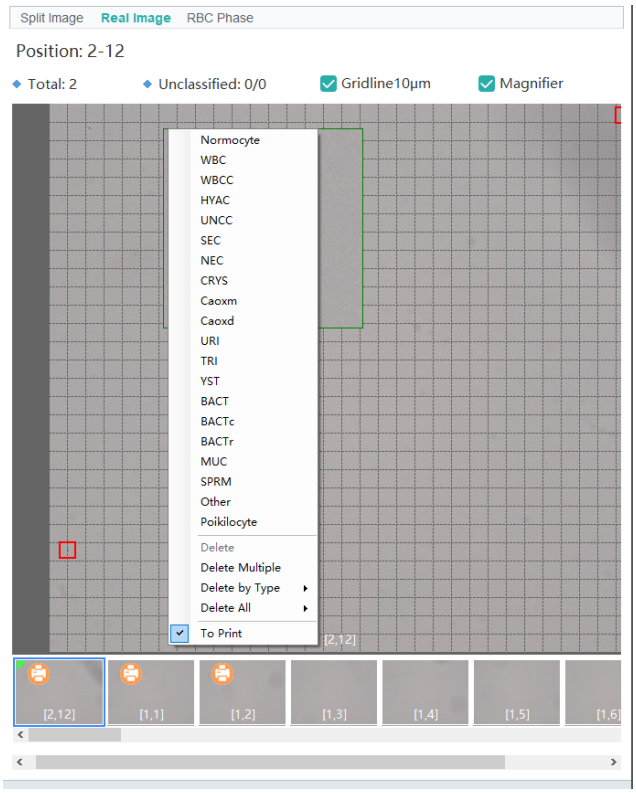


Figure 8-10 Formed element category list

2. Click "**Delete Multiple**".

√ The mouse cursor changes to an up arrow shape  .

3. Continuously click the marker frame of the formed element to be deleted.

■ Deleting a category of cell/ formed elements

1. Right-click the mouse on the real image.

√ The software displays the cell/ formed element category list.

2. Click "**Delete by Type**", select the cell/ formed element category to be deleted, and select "**Current Image**" or "**All Images**".

■ When "**Current Image**" is selected, the software deletes the marker frames of the selected cell/ formed element category in the current image.

■ When "**All Images**" is selected, the software deletes the marker frames of the selected cell/ formed elements in all images of the sample.

■ Deleting All

1. Right click the mouse on the real image.

√ The software displays the formed element category list.

2. Click "**Delete All**" and select "**Current Image**" or "**All Images**".

■ When "**Current Image**" is selected, the software deletes the cell marker frames of the selected cell category in the current image.

■ When "**All Images**" is selected, the software deletes the cell marker frames of the selected cell category in all images of the sample.

After changing the cell category, click "**End Editing**", and the sample parameter results will be refreshed, and an "E" mark appears in front of the parameter results.

8.2.5.5 Marking formed elements

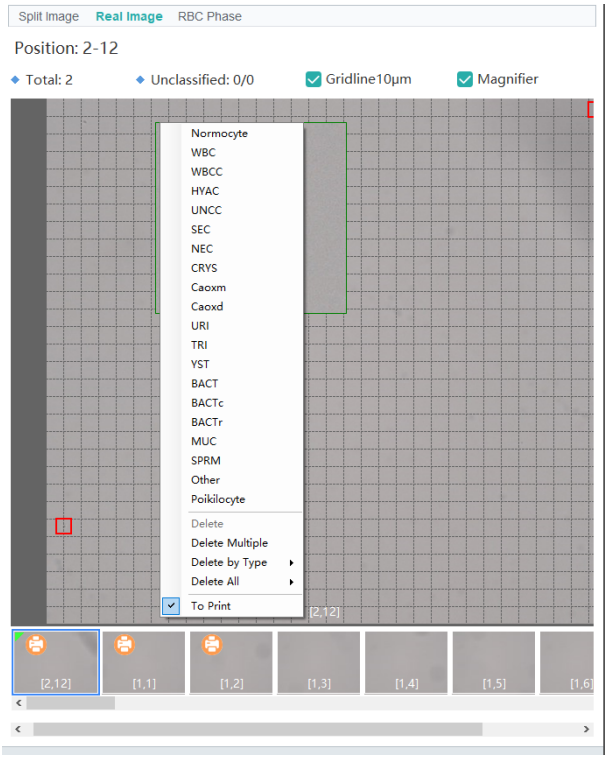
You can mark and classify the formed elements that are not identified by the system on the real images.

1. Right-click the mouse on the real image.

√ The software displays the formed element category list.

2. Select the desired category in the list.

√ The mouse cursor changes to a cross.



3. Move the cursor to frame the formed element.

√ After marking the formed element, the results of corresponding parameters update.

8.2.5.6 Viewing original real images

Enter tab "**Real Image**", double-click the image to open the original image.

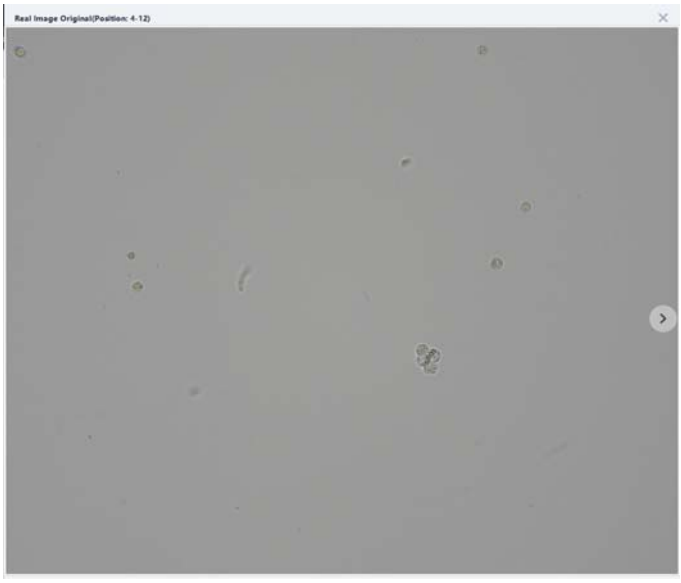


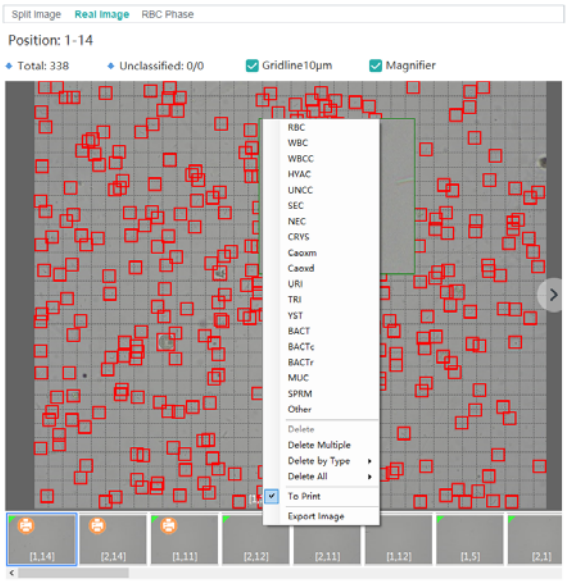
Figure 8-11 Viewing original real images

8.2.5.7 Exporting real images

The system allows exporting real images to local computer, follow below instructions:

1. Right-click the mouse on the real image.

√ The software displays the formed element category list.



2. Select "**Export Image"**.
3. Select the path for saving the image.

√ The image is exported successfully.

8.2.6 Viewing Split Image

View the "**Split Image**" of the samples in the "Image Area".

In the image area, click "**Split Image**" to view the split images of the sample.

The split image page shows the system-detected and manually marked formed elements and their numbers by category.

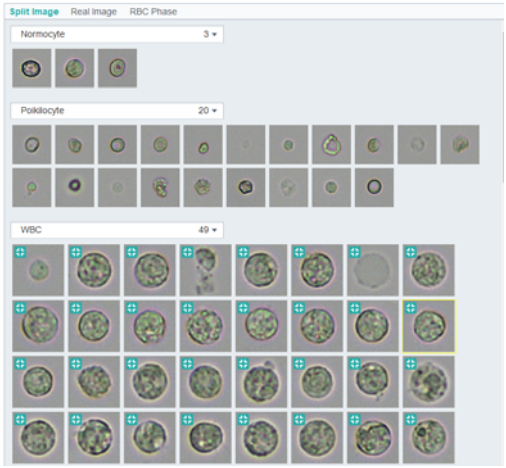


Figure 8-12 Viewing split Images

8.2.6.1 Adjusting cell category

When necessary, right-click a cell/component split image in the split image screen, and then select a new category for it.

Figure 8-13 Adjusting the cell/ formed element category in the split image screen

You can also click to select the formed element image, and drag it to the targeted category.

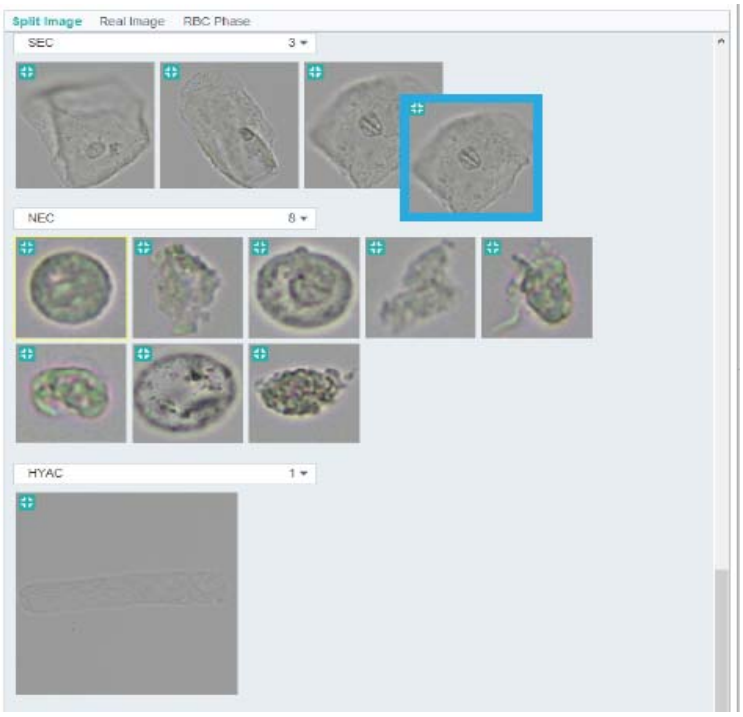


Figure 8-14 Selecting and dragging the formed elements

For the formed elements whose categories have been adjusted, is displayed at the right corner of its image.

Figure 8-15 Formed elements with category adjusted

Click "**End Editing**" to refresh the sample parameter results. An "E" or "e" mark is displayed before the updated parameter result.

With poikilocytes detection enabled, when poikilocytes images have been adjusted, the poikilocytes results and the RBC phase diagrams will be updated accordingly.

8.2.6.2 Show original

On the split image screen, double-click a formed element image to review the original image.

When reviewing the selected formed element (predefined in red rectangle) in the original image of "**Split Image**", the software displays other formed elements of the same category circled in yellow rectangle automatically. You can perform comparison analysis on them.

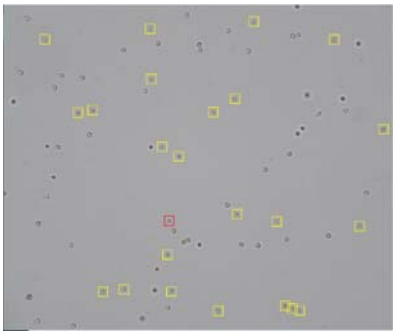


Figure 8-16 Viewing original image in "Split Image"

NOTE

- **To adjust or change the markings of cell/ formed elements in original image, see *6.7.2.5 Customizing cells/elements marking methods on the real images*.**

8.2.6.3 Deleting formed element images

On the split image screen, right-click the split image of a formed element and select "**Delete image**" to delete the component from the related category.

After deleting any split images, click "**End Editing**", and the sample parameter results will be refreshed. An "E" or "e" mark will be displayed in front of the updated parameter results.

In the real image, the marker frame of this element will also be removed.

With poikilocytes detection enabled, when poikilocytes images have been adjusted, the poikilocytes results and the RBC phase diagrams will be updated accordingly.

8.2.6.4 Selecting the images to be printed

By default, the software prints the first three real images of the sample.

Follow below instructions to print other images:

1. Browse to the images to be printed, and right-click the mouse.

2. Select "**To Print**".

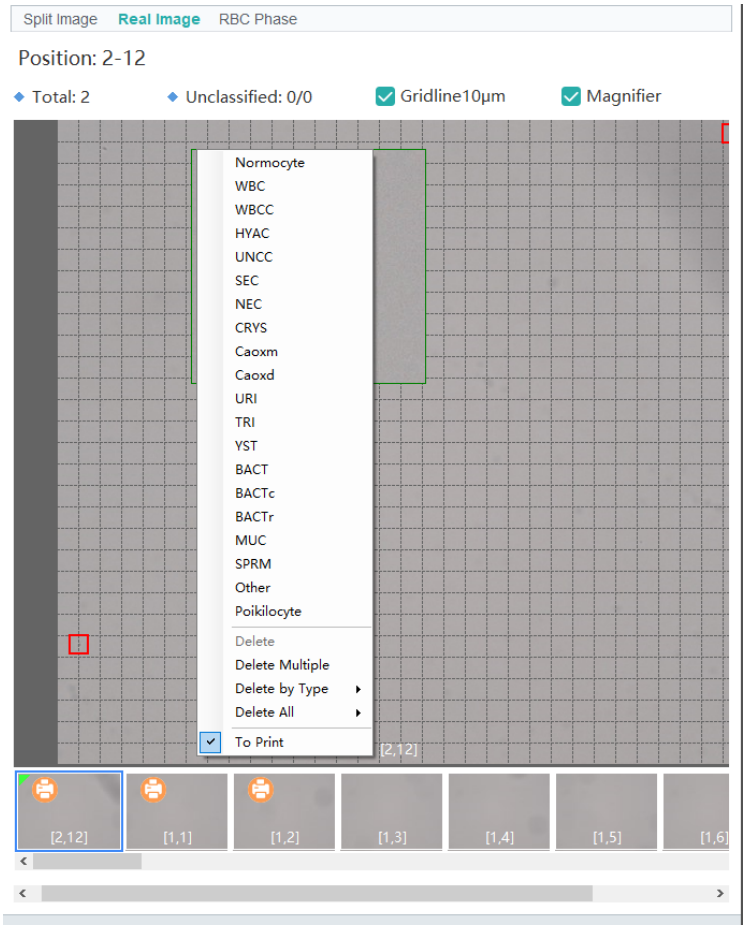


Figure 8-17 Selecting the images to be printed

√ When a real image is selected to be printed, the "printed" icon displays on its thumbnails.

Figure 8-18 Images to be printed

To cancel printing a photo, browse to the photo to be printed and click to clear the selection of "**To Print**".

Click "**Print**" to print sample results as well as the selected images.

NOTE

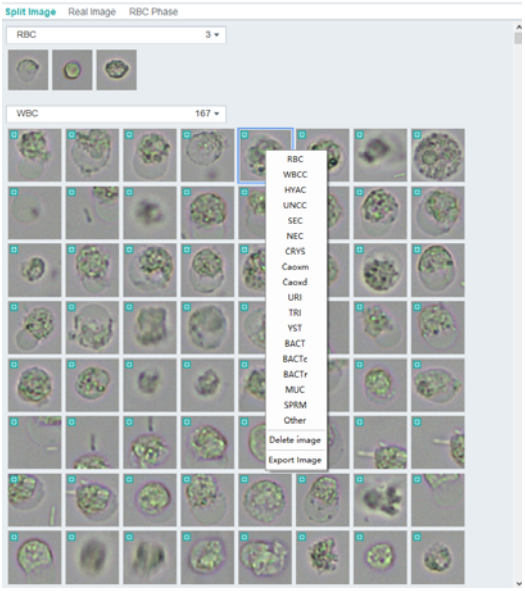
- **The number of printed images is related to the print template settings. To change the print template, contact the customer service department of the manufacturer.**

8.2.6.5 Exporting split images

The system allows exporting real images to local computer, follow below instructions:

1. Right-click the mouse on the split image.

√ The software displays the formed element category list.



2. Select "**Export Image**".
3. Select the path for saving the image.

√ The image is exported successfully.

8.2.6.6 Viewing thumbnails

Click the thumbnails in the thumbnail area to quickly locate and view photos.

Introduction to the icons on thumbnails

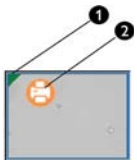


Figure 8-19 Icons on thumbnails

1	The icon indicates that the image has been viewed	/
2	The imaged is selected for printing.	Refer to *8.2.6.4 Selecting the images to be printed.*

8.2.7 Viewing Formed Element Images Under "Research Mode"

When "**Research mode**" is enabled, you may view clearer split image and real image of formed element.

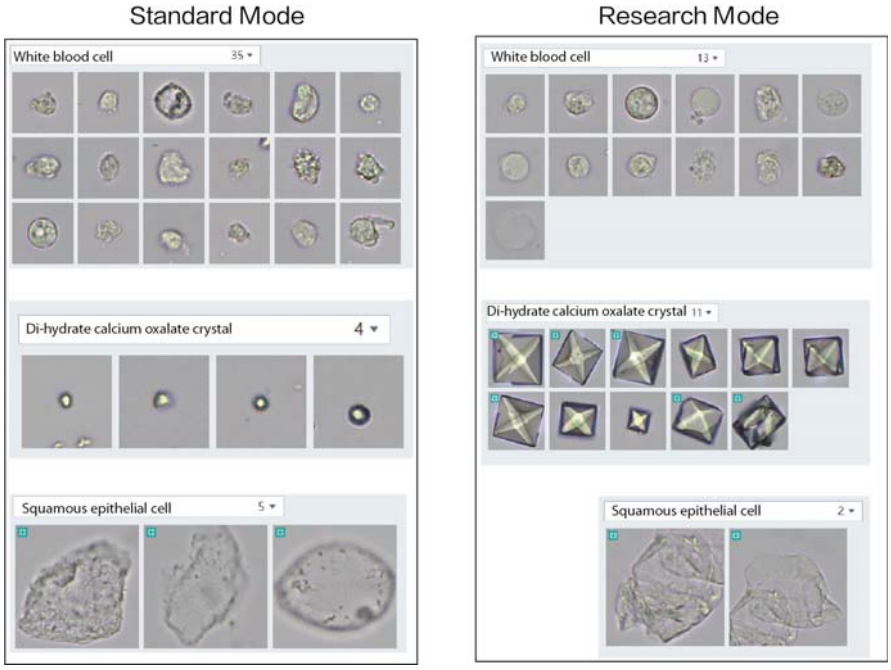


Figure 8-20 Standard mode and research mode

See below for detailed description for standard mode and research mode.

Table 8-10 Standard mode and research mode

Mode	Description	Applicable scenario
Standard mode	Recommended for daily tests. The analyzer takes photos of standard imaging quality.	Recommended for daily tests.
Research mode	Using this mode, the camera combines horizontal and vertical imaging angle to photograph the sample. After analyzed and calculated, the taken photos are merged into one with clear and high imaging quality.	Research mode applies to testing scenario where requirements for result of high imaging quality higher than test speed.

8.2.8 Viewing RBC Phase Settings

When the poikilocyte subclass parameters are enabled, "**RBC Phase**" graphs will also be displayed, including:

- **RBC size histogram**
- **RBC shape histogram**
- **RBC chroma histogram**
- **RBC size–shape scattergram**
- **RBC size–chroma scattergram**

NOTE

- **The RBC subclass parameters are enabled by default. To disable displaying red blood cell subclass parameters, contact the manufacturer's customer service department.**
- **For the settings of RBC phase graphs, refer to *6.13 Configuring RBC Phase Settings*.**

8.2.8.1 RBC size histogram

The RBC size histogram is plotted in the following way: the software first detects and obtains the real area data for each red blood cells, and converts the values with defined conversion coefficient. Then it calculates the interval probability statistics, and plots the data on the histogram.

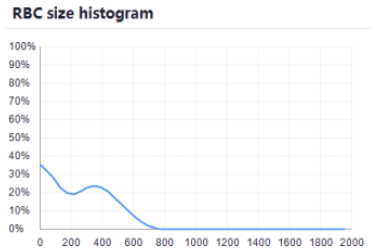


Figure 8-21 RBC size histogram

The abscissas on RBC size histogram represent the areas of red blood cells, while the ordinates indicate the sample frequency distribution of each intervals within the scope of abscissa.

8.2.8.2 RBC shape histogram

The RBC shape histogram is plotted in the following way: the software acquires the algorithm-calculated curvature data for each red blood cells, calculates the interval probabilities, and then plots the data on the histogram.

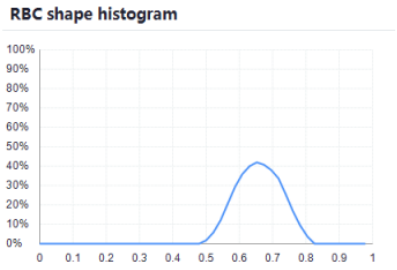


Figure 8-22 RBC shape histogram

The abscissas on RBC shape histogram represent the circular curvature of red blood cells. The closer it is to 1.0, the more perfect it is. The ordinates represent the frequency distribution of each intervals within the scope of abscissas.

8.2.8.3 RBC chroma histogram

The RBC chroma histogram is plotted in the following way: software acquires the algorithm-calculated grey values for each red blood cells, calculates the interval probabilities, and then plots the data on the histogram.

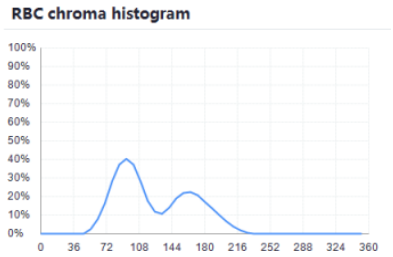


Figure 8-23 RBC chroma histogram

The abscissas of RBC chroma histogram represent the chromaticity of the RBCs. The closer the value is to 100, the darker the chromaticity is, meaning the formed elements are darker, and having less transparency. The closer the

value is to 0, the lighter the chromaticity is, meaning the formed elements are brighter, and having greater transparency. The ordinates indicate the frequency distribution of each intervals within the scope of abscissas.

8.2.8.4 RBC size – shape scattergram

The RBC size - shape scattergram is plotted in the following way: the software acquires the sizes (areas) and the shapes (circular curvature) data of each red blood cells, and plots the data on the scattergram.

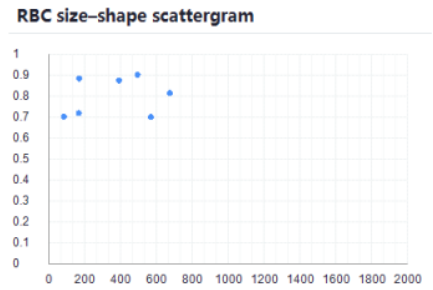


Figure 8-24 RBC size – shape scattergram

The abscissas of the RBC size-shape scattergram indicate the areas of RBCs, and the ordinates indicate the circular curvature.

8.2.8.5 RBC size – chroma scattergram

The RBC size – chroma scattergram is plotted in the following way: the software acquires the sizes (areas) and the curvature (gray value) data of each red blood cells, and plots the data on the scattergram.

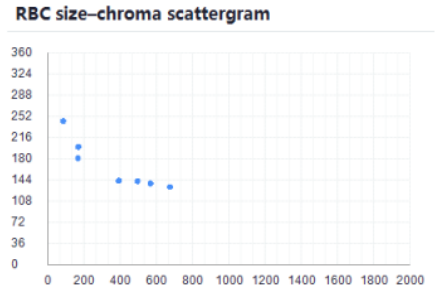


Figure 8-25 RBC size – chroma scattergram

The abscissas of the RBC size - chromaticity scattergram indicate the areas of RBCs, and the ordinates indicate the circular curvature.

8.2.9 Setting up Re-exam Orders

When the test result is not as expected, you can set up a re-exam order to re-test the sample.

8.2.9.1 Applying for re-exam sample orders

Follow the instruction below.

1. On the DMU, select **"Sample Order"**.

√ "**Sample Order**" dialog box displays.

2. (Optional) When DMU is connected to a sample processing system or multiple standalone analyzers, select the analyzers that are going to perform the testing from drop-down list of "**Module**".
3. Set up sample ID.

NOTE

- **When the instrument has a built-in barcode scanner and the barcode on the sample tube is complete and clear, select "Auto-scan sample ID". And there is no need to enter "Sample ID" manually.**
- **To enable the function of auto-scan sample ID, contact Mindray's Customer Service Department.**

4. Select "**Re-exam**".
5. Select the analysis mode in the "**Select Mode**" area.

NOTE

- **The analysis mode depends on the analyzer connected to DMU.**
- **When connecting to two-way LIS, you can enable "Auto acquire test mode" to acquire analysis mode from LIS.**
- **After "Auto acquire test mode" is enabled, the system will process the sample according to your pre-set method when auto acquire mode fails. For more about pre-setting the methods, see *6.9.3 Configuring the Method to Process Sample When Auto Acquire Mode Fails*.**

6. Select "**OK**".

√ After setup, the samples will be analyzed according to the order setup.

8.2.9.2 Viewing re-tested results

When a sample has been re-tested, click "**Re-Exam Results**" to see all the test results.

Figure 8-26 Re-Exam Results Interface

	Description	Other information
1	Total number of tests for a sample.	As the example shows, the sample has been tested twice.
2	It is a "Selected" icon. The sample result marked by this icon will be reported/printed.	Click the column head or click within each sample result column to switch the selection of sample result for reporting or printing.
3	Display the analyzer model and the test time.	/
4	Display the test results of the corresponding test.	/

8.2.10 Viewing Patient Information

The "**Patient Information**" area displays the patient's name, gender, age, patient ID, department, tube position and diagnosis information.

When necessary, click "**Analysis Info.**" to edit patient information.

8.2.11 Viewing Rule Records

The "**Rule Record**" area displays the samples that trigger re-exam rules.

During sample analysis, when a sample has triggered any re-exam rules you have set in "**System Setup**" - "**Validation Rules**", the triggered rules display in this area.

Click  to see the complete information when the rule record list is too long display the entire contents.

NOTE

- **You cannot edit rule records.**
- **When a sample has been re-examined and has multiple test results, the software will record all the rules triggered during analysis, but only will transmit the rules related to the finally reported results to LIS.**

8.2.12 Using Function Buttons

Click the function tool buttons to perform functions such as applying for analysis, validating/canceling validating samples, printing, editing samples, deleting sample records/samples or transmitting sample results to LIS.

Table 8-11 Function Tool Button Area

Button	Functions	Notes
Sample Order	Select "**Sample Order**" to set up normal sample order / STAT sample order..	For more information, refer to ***7.9.3 Starting Analysis***.
Order Setup	Select **"Order Setup**" to set up tube worklist and sample rack order.	For more information, refer to *7.9.2.2 Setting up tube worklists* .
Validate	Select one or more sample records and click "**Validate**" or press F9 on your keyboard, then the sample record(s) become "Validated".	Refer to ***8.2.17.1 Validating sample records***.
Undo Valid.	Select one or more sample records that have been validated, and click "**Undo Valid.**", the sample becomes "not validated".	Refer to ***8.2.17.2 Canceling validation***.
Export	Select "**Export**" to export the selected sample records and other related information to a local PC.	Refer to ***8.2.22 Exporting Sample Results***.
Refresh	Select "**Refresh**" or press F5 on your keyboard to refresh the sample list.	Refer to ***8.2.1.4 Refreshing sample records***.
Edit	Select "**Edit**" to edit analysis information of the selected samples (including patient information and sample information), as well as the **Report Results**.	Refer to ***8.2.14 Editing Sample Results***.
Comm.	When the analyzer software is connected to LIS, select one or more sample records that have been validated, and click "**Comm.**". The selected samples are sent to LIS.	Refer to ***8.2.20 Communicating Sample Results and Information to LIS***.
Print	Select one or more sample records and click **"Print**", to print the results of the sample record(s) report.	Refer to ***8.2.19 Printing Sample Results***.

Button	Functions	Notes
Restore	Select a sample record you have edited and click "**Restore**" to restore the sample back to original status.	Refer to ***8.2.15 Restoring Sample Results***.
Delete	Select one or more sample records and click "**Delete**" to delete the selected sample records.	Refer to ***8.2.16 Deleting Sample***.
Data Snapshot	Select one or more sample records and click "**Data Snapshot**" to save the sample results in the form of snapshot	Refer to ***8.2.23 Data Snapshot***

8.2.13 Using the Search Function

The search area provides smart search for today's samples and advanced search functions to help users quickly find sample records.

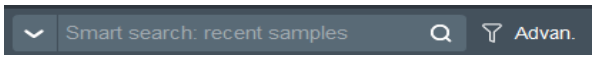


Figure 8-27 Search Area

8.2.13.1 Using smart search

The software supports to quickly search/locate the samples analyzed on the current day.

Click the pull-down arrow in the "Smart search/locate: samples today" field, and select "**Smart search: recent samples**" or "**Smart locate: samples today**",

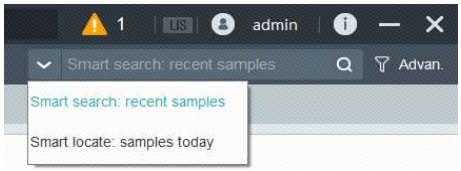


Figure 8-28 Smart search/locate samples of the day

- When "**Smart search: recent samples**" is selected, according to the search criteria, software locates samples in the defined period of time, and displays them under the "**Search Result**" tab.
- When "**Smart locate: samples today**" is selected, the found samples displays under the "**All**" tab, the software displays the results of the first sample in the list.

1. Enter the full or part of the department/comment/validator/diagnosis/tester/Sample ID/series number (SN)/ in the searching box to search for the sample to "**Smart search: recent samples**"/"**Smart locate: samples today**".

NOTE

- **By "Smart search: recent samples", it means that the software will search for samples of a recent period. You can define the period. For details, see *6.16 Configuring Sample Transmission Methods* section.**
- **Serial number will be generated only when the laboratory is connected to LIS.**
- **The function supports fuzzy search. For example, when you enter "6014", all samples with "6014" in their Sample IDs display.**

2. Click the search icon " " or press "Enter" on the keyboard.

√ The sample list area displays all eligible samples.

√ When using the smart search for today's samples function, the total number of samples searched is displayed on the "**Search Result**" tab.

8.2.13.2 Advanced search

1. Select "**Advan.**" next to the search box

√ The following dialog box displays.

Figure 8-29 Advanced search

2. (Optional) You can enter one or more search criteria, including "**Test Date**", "**SN.**", "**Sample ID**", "**Name**", "**Patient ID**", "**Department**", "**Operated by**", "**Validated by**", "**Delivered by**", "**Diagnosis Info.**" and "**Comments**". When you have defined more than one search criterion, the analysis system searches for the sample records that match all defined criteria.
3. (Optional) To search for samples in a specific sample status, select one or more sample status to search. You can search for samples by sample status, including "**Not commun.**", "**Not printed**", "**Un-validated**". When multiple status are selected, the analyzer searches for samples of any of the defined status.
4. Select "**OK**".

√ The sample list area displays all eligible samples.

√ The number on the "**Search Result**" tab indicates the total number of all eligible samples. The "**Search Result**" tab shows the total number of samples searched. Click "**Search Result**", and the sample list area displays all the samples that satisfy the search criteria.

NOTE

- **Serial number will be generated only when the laboratory is connected to LIS.**
- **The function supports fuzzy search. For example, when you enter "6012" in the sample ID field, all samples with "6012" in their Sample IDs will be displayed.**

8.2.14 Editing Sample Results

Follow below instructions to edit the results of report parameters and RUO parameters:

1. Select a sample to edit in the sample list area, and click "**Edit**" on the toolbar. You can also double-click the result of a parameter to modify it.

√ The "**Edit**" button changes to "**End Editing**".

2. Edit the results.
3. Click "**End Editing**" to complete the change.

Or click other buttons on the toolbar to exit the sample result editing interface. The software automatically saves the result changes.

√ After the results of the parameters are modified, an "E" or "e" displays in the "**Flag**" column, and E symbol appears beside the Sample ID in the sample list area.

NOTE

- **You cannot edit the results of a validated sample.**

8.2.15 Restoring Sample Results

When necessary, select one or more sample records you have edited and select "**Restore**".

√ All parameter results (including report parameters, RUO parameters and microscopic parameter results) of the currently selected sample are restored to their original values.

√ The "E" or "e" flag in the parameter result disappears.

8.2.16 Deleting Sample

When necessary, select one or more sample records and select "**Delete**" to delete the selected sample records.

8.2.17 Validating Sample Results/Canceling Validating Sample Results

8.2.17.1 Validating sample records

Select one or more modified sample records and select "**Validate**" or press F9 on your keyboard.

Consecutively select "**Validate**" or press F9 on your keyboard to validate the sample records in order.

√ The selected sample turns to the state of **"Validated"**, and the Ⓜ symbol appears beside the Sample ID in the sample list area.

8.2.17.2 Canceling validation

Select one or more sample records that have been validated, and select "**Undo Valid.**".

√ The selected samples turn back to the state of "not validated", and the Ⓜ symbol disappears from the sample list area.

8.2.18 Editing Sample ID

8.2.18.1 Quickly find the samples with invalid sample IDs

When the system fails to scan a sample ID, the system will automatically assign a sample ID to the sample (the ID starting with the prefix of "Inv.). You may quickly find the invalid sample through "" and edit its ID.

NOTE

- **For operation of editing sample ID, see *8.2.18.2 Editing Sample ID*.**

1. Select the sample record with the invalid sample ID in the sample list area.

√ The "" dialog box displays.

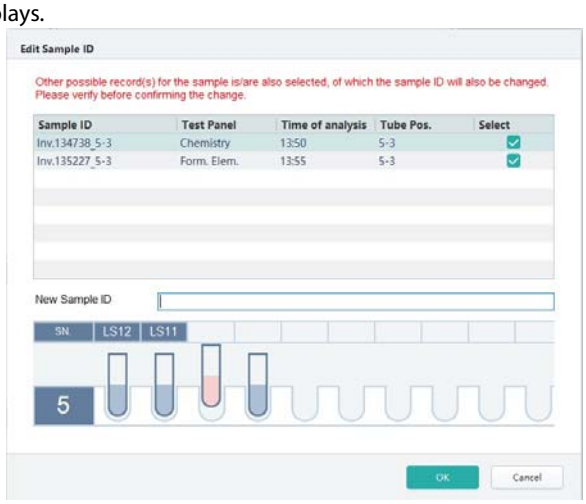


Figure 8-30 Finding the samples with Invalid Sample IDs- Report Screen

As shown in the picture above, the target sample is at the third position of tube rack NO.2.

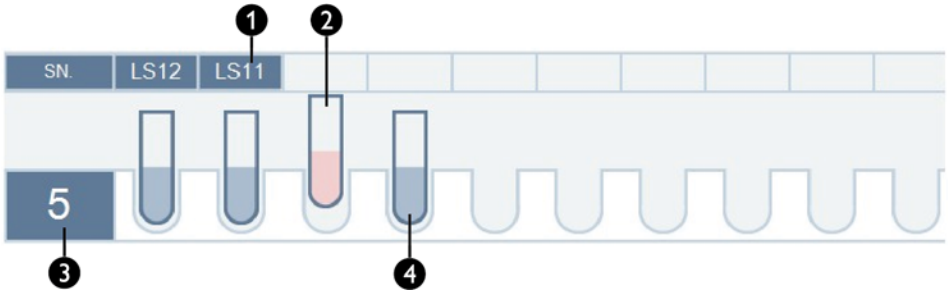


Figure 8-31 Where to find the sample with the invalid sample ID

1	The SN (serial number) of the sample of each tube position in the tube rack
2	The sample with the invalid sample ID
3	The NO. of the tube rack where the invalid sample is
4	From left to right, the tube icons represent the actual sample tubes at the tube position 1 to 10

8.2.18.2 Editing Sample ID

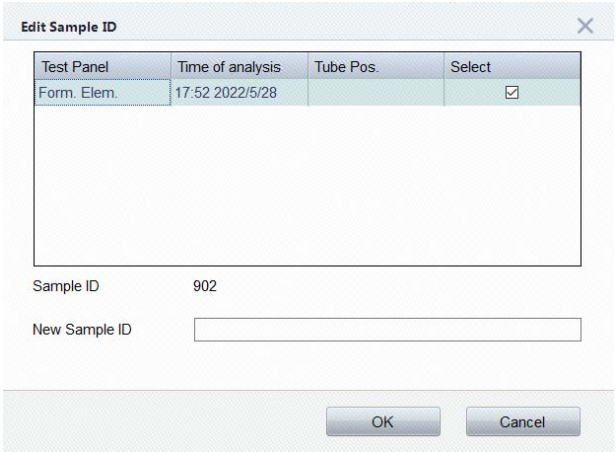
You may edit sample IDs by following either of the methods if needed:

- Editing in the "" tool bar;
- Editing in the "**Analysis Info.**"tab.

8.2.18.3 Editing sample IDs in "Edit Sample ID" tool bar

1. Select the sample record with the sample ID to be edited in the sample list area.
2. Select " button in the tool bar.

√ The "" dialog box displays.



3. Enter the correct sample ID into the input box of "".
4. Select "**OK**" to save the settings.

8.2.18.4 Editing sample IDs in "Analysis Info." tab

1. Select the sample record with the sample ID to be edited in the sample list area.
2. Select the edit box of"**Sample ID**" under the tab of "**Analysis Info.**" and enter the correct sample ID.
3. Select "**End Editing**" in th tool bar.

√ The system saves the new sample ID.

NOTE

- **The "Sample Barcode" area of the dialog box displays the photos of sample barcode taken by the analyzer during analysis. When the sample ID displayed on the photo is clear enough, you can enter the sample ID by referring to the photo.**

8.2.19 Printing Sample Results

Select one sample record from the sample list area, and select **"Print"** on the toolbar.

√ The software prints the sample result report.

NOTE

- **You cannot print reports for samples with invalid sample IDs. To print this sample, edit the sample ID first.**
- **For configuration methods of print template, refer to *6.5 Configuring Auto Maintenance for the Analyzer*.**
- **For configuration method of histogram and scattergram rules, refer to *6.15 Configuring Communication Settings*.**

8.2.20 Communicating Sample Results and Information to LIS

When the laboratory is connected to the 2-way LIS, you can set up for auto communication with LIS. The analyzer automatically communicates the sample results and information to the LIS.

NOTE

- **For setting up auto communication with LIS, refer to *6.15 Configuring Communication Settings*.**

Communicated samples will be marked by  in the sample list area.

When auto communication is not enabled, or the software fails to transmit some samples to LIS, select the samples to be communicated in the sample list area, and click **"Communication"** on the toolbar to communicate these samples to the LIS.

8.2.21 Checking Analysis Information

The **"Analysis Information"** screen displays **"Patient Information"** and **"Sample Information"**.

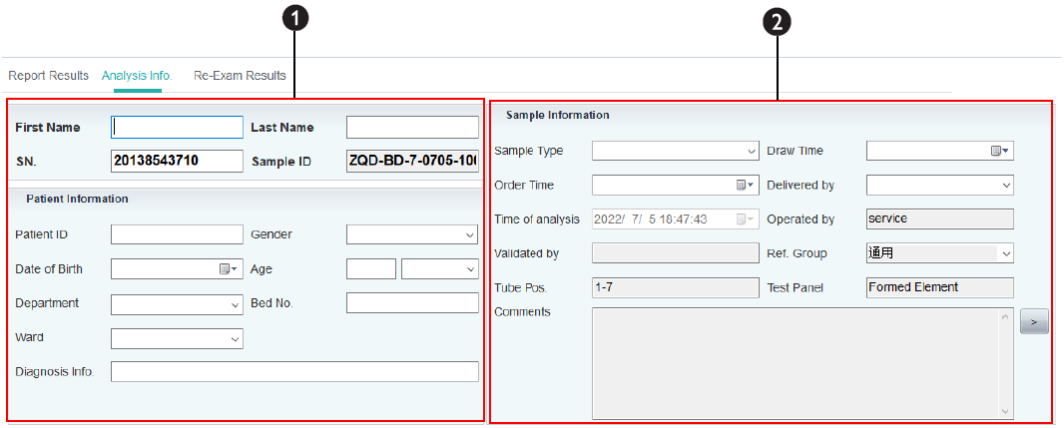


Figure 8-32 Analysis information screen

1	Patient information area
2	Sample information area

8.2.21.1 Patient information area and sample information area

The patient information area and sample information area display patient name, serial number, and other patient information.

When necessary, enter/edit the patient's name, serial number, sample ID and other patient information in the patient and sample information area of the "**Analysis Info.**" screen.

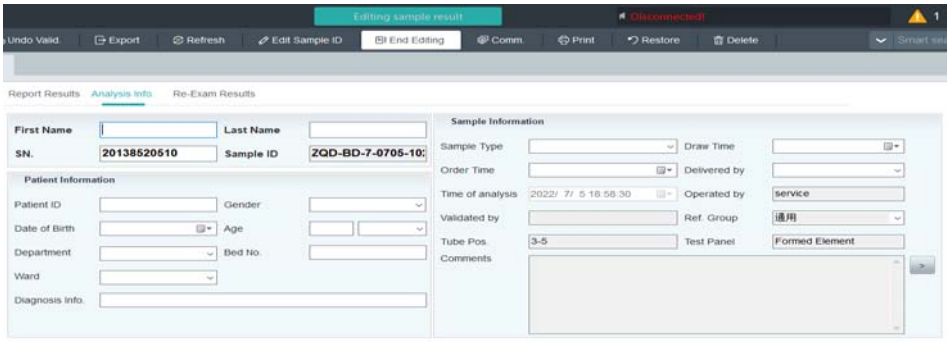


Figure 8-33 Editing sample analysis information

When editing patient information, a prompt of "**Editing sample result**" appears at the upper right corner of the screen, and a button of "**End Editing**" appears on the toolbar. After you have edited the patient information, click "**End Editing**" or any other button on the tool bar to exit the screen.

The information entered/edited in the patient information area and sample information area of the "**Analysis Info.**" screen also display in the "**Patient Information**" area of the **Report Results** screen as well as on the printed report.

Figure 8-34 Report result screen – patient information area

NOTE

- **You cannot edit the results of a validated sample.**

8.2.22 Exporting Sample Results

1. Select the sample record(s) in sample area, to be exported when one or more to be exported.

2. Click "**Export**".

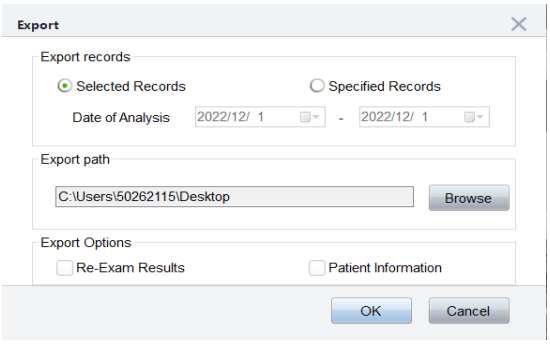


Figure 8-35 Export Sample Results

3. Select to export "**Selected Records**" or "**Specified Record**".

■ Select "**Selected Records**" to export the sample record(s) in the sample list area.

■ When "**Specified Record**" is selected, specify the time range of sample records to be exported in the "**Test Date**" area.

4. Click "**Browse**" to specify the "**Export Path**".

5. (Optional) Define the "**Export Options**".

■ The exported information of sample record(s) includes the sample information, analysis information and parameter results.

■ When "**Re-Exam Results**" is selected, export the re-test results.

■ When "**Patient Information**" is selected, export the re-test results.

6. Click **"OK"**.

√ Selected sample records are exported to PC.

8.2.23 Data Snapshot

When necessary, select the "**Data Snapshot**" button to save the sample results in the form of snapshot.

1. Select one or more sample records and click "**Data Snapshot**".

2. On the dialog box displayed, click "**Select Parameter**" to select the parameters and define the order of the parameters.

3. (Optional) When necessary, manually adjust the size of the parameter column.

■ Press the shortcut key [**Alt+ Print Screen**] on your external board to print the screen.

9 Quality Control (QC) Program

After a long period of use, the analyzer may have errors to a certain extend. The errors may lead to incorrect or unreliable analysis results. Quality control refers to daily monitoring on performance of the analyzers with value assigned controls. Users test controls using the same method used to test urine samples, and compares the results with the reference values of the controls through specific statistics methods. When the comparison results show large deviation, some measures should be taken.

The QC program provides an effective method for detecting possible errors. Only when users are familiar with the theory of quality control and master the practical procedures can they effectively eliminate the influence of errors on the analysis results.

This analyzer supports L-J QC. L-J QC refers to Levey-Jennings QC. In 1950s, Levey and Jennings introduced L-J QC graph into clinical laboratories. An L-J QC graph shows the difference between the test results of a control that are obtained by an instrument and the target values of the control so that laboratory operators judge the work status of the instrument.

The X-axis of an L-J QC graph shows the QC time while the Y-axis shows the reference values and limits of a control. Clinical laboratory operators can, based on actual situation of the laboratory, set the deviation limits of QC results relative to the reference values of the control (in the form of absolute value (SD) or percentage (CV%)). A control line is selected from the upper side and lower side of the control target value along the Y-axis, respectively, so that the operators can easily distinguish the differences between the test results and target value.

NOTE

- **Use the controls and reagents specified by the manufacturer only. Store and use the controls and reagents as instructed by their instructions for use.**
- **Only Mindray-specified controls shall be used. Using controls of other manufacturers may lead to incorrect QC results. Do not use controls of other manufacturers.**
- **Do not use expired controls.**

9.1 Setting up QC Files

Before running a new lot of controls, you must set up a QC file for each lot of controls.

NOTE

- **For files having the same QC type and level, only one of them can be "In Use".**
- **When necessary, you can modify the set QC file.**

9.1.1 L-J QC Setting Screen

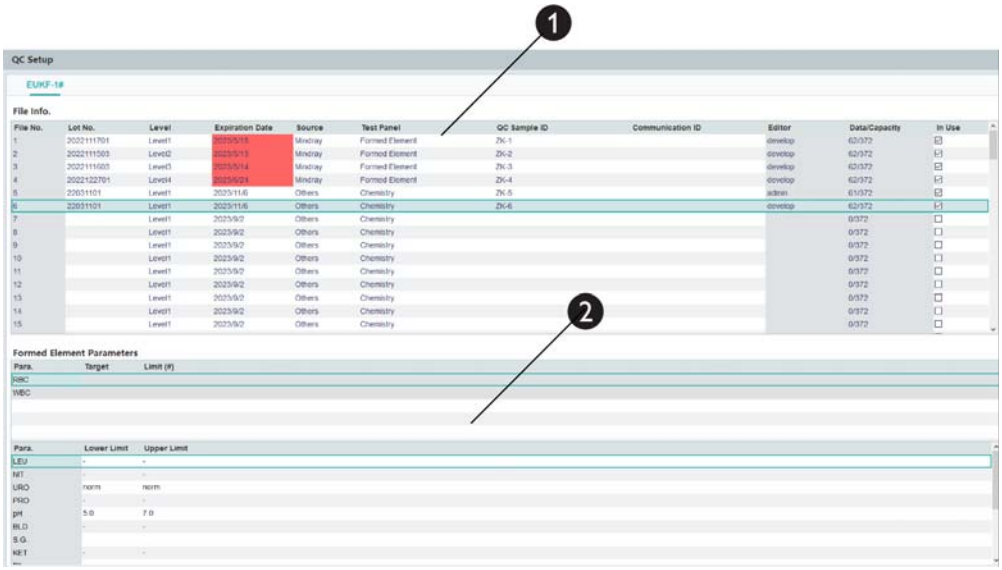


Figure 9-1 L-J QC settings

1	QC file setting area	**File No.**	The sequence number of the QC file in the system.	The file number is not editable. It is automatically assigned by the software. The software supports up to 100 QC files.
		Lot No.	Enter the lot No. of a control manually or by using an external barcode scanner to scan the barcode on the control tube.	Up to 16 digits can be entered. You can enter characters, numbers, letters and special characters. Chinese characters are not supported. The lot No. shall not be empty.
		Level	Select the level of control; there are 10 levels in total.	/
		Expiration Date	Enter the expiry date of the controls for each lot.	The expiry date cannot be earlier than the current system date. If the expiry date is earlier than the current system date, it will be highlighted with red background color.
		Source	Select the control type: "**Mindray**" and "**Other**".	/
		Test Panel	Select an QC analysis mode: "**Formed Element**", "**Chemistry**". or "**Chemistry+Formed element**".	/
		QC Sample ID	Enter "**QC Sample ID**". During analysis, when the instrument reads the ID, it recognizes the corresponding sample as the control sample. After the analysis completes, the results will be saved into the QC file of the QC sample ID.	You can enter letters, digits and all other characters on the keyboard (including special characters) for QC sample ID. Chinese and other languages (e.g. Japanese, Korean, etc.) are not supported
		Communication ID	Enter the "**Communication ID**" when using 2-way LIS. When QC sample data is transmitted to the LIS, the LIS identifies QC results by communication ID.	/
		Editor	The person who sets up the QC file.	/
		Data/ Capacity	The number of results that are stored in the QC file and the maximum amount of QC results that are allowed to be stored in the QC file.	Not editable. When the number of stored QC results reaches the upper limit, the latest QC result data will automatically overwrite the oldest data.

		In Use	Check the "**In Use**" box for corresponding QC file if needed.	For files having the same "**QC Sample ID**", only one of them can be "In Use". When there are more than one QC files having the same QC Sample ID, the newest file is "**In Use**" by default.
2	Reference value setting area	**Formed Element Parameters**	The available QC parameters of formed element analysis include: **RBC**, **WBC**, **EC**, **CRYS**, **HYA Cast**	Define the reference values and deviation limits of the QC parameters with reference to the target sheet of the corresponding lot of controls.
		Chemistry Parameters	The number of chemistry QC parameters depends on the strips currently used.	Find the reference values in the target sheet of the controls.

9.1.2 Setting up QC Files

Follow below instruction to set up QC file.

1. Click the "**QC**" shortcut icon  the "**QC**" screen.
2. Select a QC file (ranging from 1 to 100).
3. Select "**Formed Element**", "**Chemistry**" or "**Chemistry+Formed element**" under**"Test Panel**".
4. Enter the lot No. of the controls by one of the following ways

- **Manual entry**
- **Using external barcode scanner**

5. Enter other necessary QC file information.

NOTE

- **For details about related setting, refer to *9.1.1 L-J QC Setting Screen*.**
- **The analyzer also supports setting up QC sample ID on "Control Para. Setup" interface. After setup, when the analyzer identifies the pre-set ID, it will perform control analysis. For more information, see *6.20 Configuring QC Sample ID*.**

6. Click **"Save**" to save the QC information.

9.2 Performing L-J QC Analysis

NOTE

- **Ensure that a valid QC file is enabled before performing QC. Be sure that the level of the control to be run is the same with the current QC file, and the control is not expired.**

Check the following before running QC analysis:

■ Make sure that you have set a proper QC file correctly and the QC file is in the "**In Use**" state.

■ Make sure you have prepared the controls in accordance with your laboratory protocols, and the requirements in the Instruction for Use of the controls.

■ Make sure the analyzer is without error.

Place the prepared control sample into the STAT position or into tube rack for auto-loading analysis when control sample ID on "Control Para. Setup" screen. Analyze the QC samples using normal analysis process.

√ When analysis completes, the QC results will be displayed in the current screen and be saved in the QC file automatically.

NOTE

- **Up to 372 QC results can be saved in each QC file.**

9.3 L-J QC Review

The system supports the following two paths to review quality control result details.

	Path
When set up control analysis order on QC Menu	Review control results on QC
When set up control sample ID on "Control Para. Setup"	Review control results on LIS or Samples

Reviewing QC Results in the following ways:

- L-J Graph
- L-J Table

9.3.1 L-J QC Graph Review

NOTE

- **The following QC graph of control result is applicable to control analysis order set up on QC Menu. If you have set QC sample ID on" Analyzer Setup - Control Para. Setup" screen, review the corresponding QC graph on LIS.**

1. On the software, click "**QC**" shortcut icon QC.
2. Click "**QC Graph**" to enter the QC graph review screen.
3. Select QC file No., and the QC graph displays on the screen.

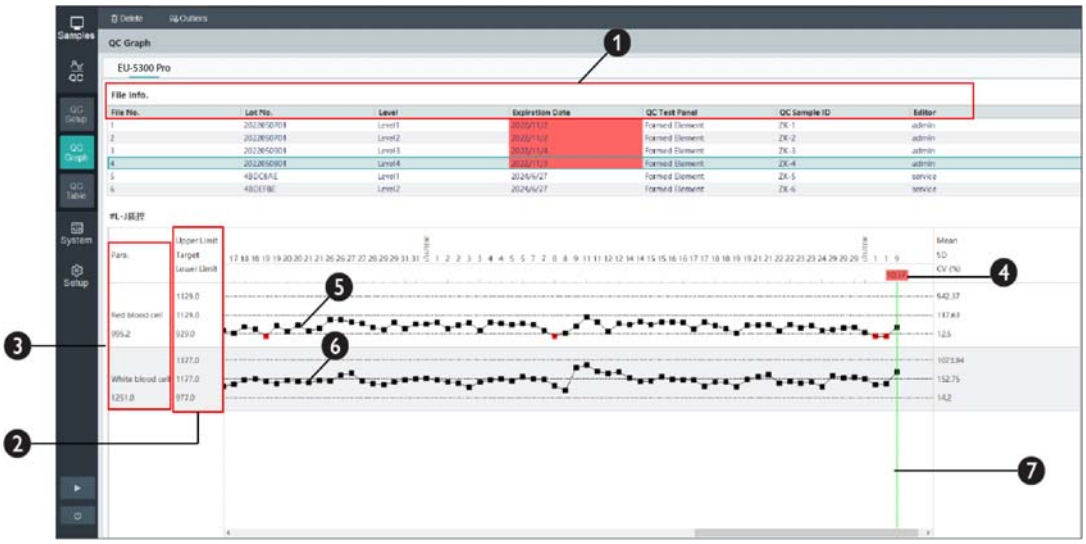


Figure 9-2 L-J QC Graph

		Description
1	QC information	The QC information area displays the QC file No., QC lot No., levels, expiry dates, control types, QC modes, QC sample IDs and editor information.
2	Upper limit, lower limit and reference value of available QC parameters.	/
3	Parameter QC results	The corresponding QC result of the QC point on the green line.
4	The saving time of the QC point	The saving date and time of the QC point on the green line.

		Description
5	QC curve	The line connecting all QC points of the same parameter to show the trend. The QC points in each graph are displayed from left to right according to the sequence from the earliest to the latest.
6	QC point corresponding to each QC result	The analysis result of the selected QC point is displayed under the parameter. A black QC point indicates the value is within the limit; a red QC point indicates the value is out of the limit.
7	Green line	The green vertical line is used to identify the QC points of the same analysis, all of which are displayed on the line when you select one of them.

Deleting QC data (Administrators)

When necessary, follow below instruction to delete the QC points:

1. On the software, click "**QC**" shortcut icon 

.
2. Click "**QC Graph**" to enter the QC graph review screen.
3. Select QC file No., and the QC graph displays on the screen.
4. Click **"Delete"**.
5. Select to delete "**Current Data**" or "**All Data**".

■ When you choose to delete the "**Current Data**", make sure you have selected the data to delete.

■ When you choose to delete **"All Data"**, all QC data in the corresponding QC file will be deleted. Click the **"OK"** button to delete specified data and close the dialog box.

9.3.2 QC Table Review

NOTE

- **The following QC tableof control result is applicable to control analysis order set up on QC Menu. If you have set QC sample ID on" Analyzer Setup - Control Para. Setup" screen, review the corresponding QC table on LIS.**

1. On the software, click "**QC**" shortcut icon 

.
2. Click "**QC Table**" to enter the "**QC Table**" screen.
3. Select QC file No., and the QC table will be displayed on the screen.

Introduction to L-J table

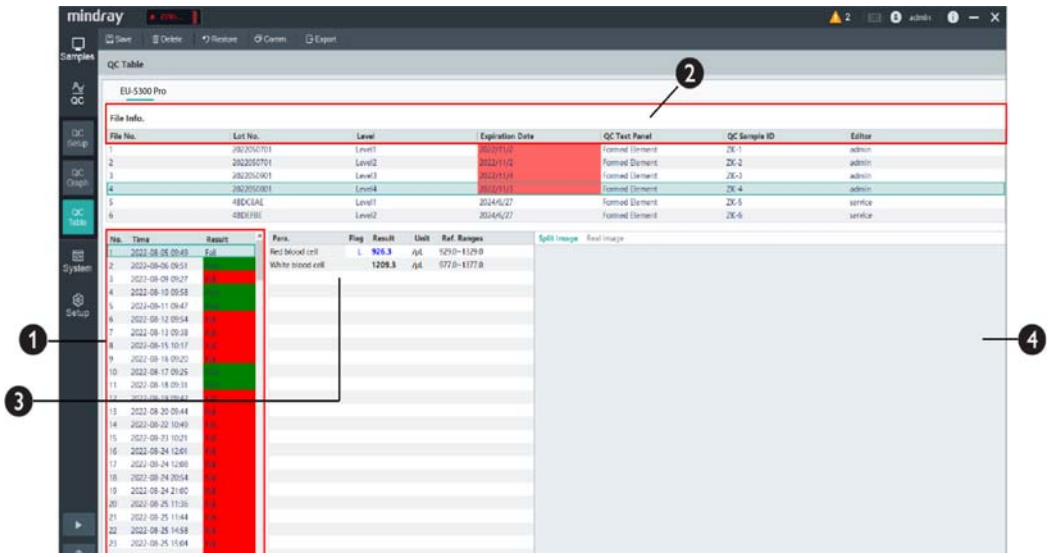


Figure 9-3 L-J QC table screen

		Description
1	QC sample list	Display the QC analysis records stored in the current QC file: When **"Result"** displays Pass, it means that the QC result is under control. When **"Result"** displays as Fail, it means that the QC result is out of control.
2	QC information	The QC information area displays the QC file No., QC lot No., levels, expiry dates, control types, QC modes, QC sample IDs and editor information.
3	QC results	Click on a QC record to view the corresponding QC results.
4	L-J Graph	Click a QC record to view the corresponding **"real image"** and **"split image"**.

9.3.3 Viewing Real Image and Split Image of Formed Element Control Result

For formed element control sample results, you can select control sample on QC record list on QC table interface to view the real image and split image of control analysis result.

1. On the software, click "**QC**" shortcut icon  .
2. Click "**QC Table**" to enter the "**QC Table**" screen.
3. Select QC file No., and the QC table will be displayed on the screen.
4. Selct the control sample on QC record list.

√ The software displays the corresponding real images and split images.

NOTE

- **When necessary, you can mark, delete, edit and change the information of formed element. It is of the same operation of normal sample. For more information, refer to *8.2.5 Viewing Real Images*.**

9.4 Analyzing Causes for Outliers

When the QC results falls out of control, follow the instructions below until the promble is solved.

1. Check the error message area on the software screen,if there is error message, refer to*11 Troubleshooting* for trouleshooting.
2. Check the setting content of the QC analysis order, if there is incorrect input, correct it.
3. Re-analyze the control sample.
4. If the QC results still falls out of control, open a new control to perform control analysis.
5. If the QC results still falls out of control, calibrate the analyzer.

If the problems cannot be solved by measures above, contact Mindray Customer Service Department.

10 Servicing Your Analyzer

10.1 Overview

Regular maintenance procedures are required to keep the analyzer in a good operating condition. This analyzer provides multiple maintenance functions for this purpose.

Perform Probe Cleanser maintenance to the fluidic system on a regular basis. In addition to clean the fluidic tubes, Probe Cleanser also has the ability of backflushing and unclogging.

NOTE

- **The analyzer is equipped with an sample filter. To prevent the filter from being clogged by accumulated foreign matters, a backflush function is designed in both the cleaning procedure of measurement and maintenance.**

This chapter introduces how to use the provided functions to maintain your analyzer.

BIOLOGICAL RISK

- **The test object of this product is urine. It is recommended that operators wear protective mask and gloves when operating, because the specific contamination degree or whether it has infectiousness cannot be determined. The operator shall be thoroughly disinfected after the operation is completed.**
- **Before maintaining, transporting or servicing the instrument, clean and disinfect the instrument cover, as well as the parts and components with biological risks (such as the sampling probe). Remind the persons who handle the instrument of the related risks.**

WARNING

- **Improper service may cause personal injury or damage the system. Operators must follow the instruction of this Operator's Manual to perform maintenance operations.**
- **Contact the Mindray or authorized distributors in time if any damaged part is found.**
- **Be sure to wear rubber gloves and use specified tools and accessories when inspecting, servicing or maintaining the system. Wash your hands with disinfectant after finishing the operations.**
- **Be careful when opening/closing and removing/installing the doors, covers and boards of the system.**

CAUTION

- **Improper service may damage the system. Make sure you service the instrument strictly as instructed by this manual.**
- **For problems not mentioned in this manual, contact Mindraycustomer service department for Mindray service advice.**
- **Only parts supplied by Mindray can be used for maintenance. For any questions, contact Mindray customer service department.**
- **Exercise caution to avoid contact with the sharp sampling probe when performing maintenance.**

10.2 When and Why to Perform the Maintenance

10.2.1 Scheduled Maintenance Programs

Table 10-1 Scheduled Maintain Policy

Item	When to perform	Tools needed	Other information
Maintenance with Probe Cleanser	Every day, during analyzer shut-down	Probe Cleanser	For methods of Cleanser maintenance, refer to ***10.2.5 Maintaining with Probe Cleanser***.
Cleaning count bath	According to the setup time by user	75% alcohol Clean and soft cloth	• By default setting, count bath is cleaned every 15 days. • For methods of cleaning count bath, see *10.3 Cleaning Count Bath* for details.
Cleaning waste strip box	Every 15 days	75% alcohol Clean and soft cloth/sponge/ brush	For methods of cleaning waste strip box, refer to *10.5.2 Cleaning the Waste Strip Box*.
Cleaning pallet	Every 15 days	75% alcohol Clean and soft cloth/sponge/ brush	For methods of cleaning pallet refer to *10.4 Cleaning Pallet*
Replacing desiccant	When opening a new strip canister	/	For methods of replacing desiccant, refer to ***7.7.1 Refilling Test Strips***

Table 10-2 Demand-based maintenance

Programs	When to perform	Other information
Pack-up	When the analyzer is going to be left idle for a long time (i.e., over 15 days).	Click "**System**"- "**Maintain**"- "**Manual Maintain**" to perform the programs. Refer to ***10.7 Before and After Long-time Not Using the Analyzer*** for details.
Fluidics emptying	Before you are going to move the analyzer to another position.	Click "**System**"- "**Maintain**"- "**Manual Maintain**" to perform the programs. Refer to ***10.6 Before Moving the Analyzer*** for details.
Priming	After replacing the expired reagents.	Click "**System**"- "**Maintain**"- "**Manual Maintain**" to perform the programs. Refer to ***10.2.2.3 Priming fluidic tubes after replacing expired reagents*** for details.
Fluidic Initialization	When necessary, perform the operation under the guidance of manufacturer Customer Service personnel.	/

10.2.2 Replacing Diluent

Replace Diluent when the reagent runs out, is insufficient or expired.

Replacing Diluent consists of 3 steps:

1. Installing a new container of Diluent.
2. Registering information of new Diluent to the software.
3. Replacing the old Diluent in the fluidic.

⚠ CAUTION

- **Do not mix the new container of reagent with the residue in the old reagent container to ensure accurate measurement.**

⚠ WARNING

- **Diluent is irritating to eyes, skin and mucous membrane. Wear proper personal protective instrument (e.g. gloves, lab coat, glasses, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.**
- **If Diluent accidentally spills on your skin, wash the reagent off with plenty of water and if necessary, go see a doctor; if Diluent accidentally spills into your eyes, wash the reagent off with plenty of water and immediately go see a doctor.**

10.2.2.1 Replacing reagent containers

⚠ WARNING

- **If Diluent accidentally spills on your skin, wash the reagent off with plenty of water and if necessary, go see a doctor; if Diluent accidentally spills into your eyes, wash the reagent off with plenty of water and immediately go see a doctor.**

NOTE

- **After replacing the reagent container, check the tubing connected to the cap assembly and make sure it is not bent over.f**

1. Open the cap of a new container as shown in the figure, and place the container next to the one to be replaced.
2. Turn the cap of the old container counterclockwise, and then take out the cap assembly with caution.

3. Insert the pickup tube of the cap assembly into the new container, and then turn the cap assembly clockwise until it is secured.

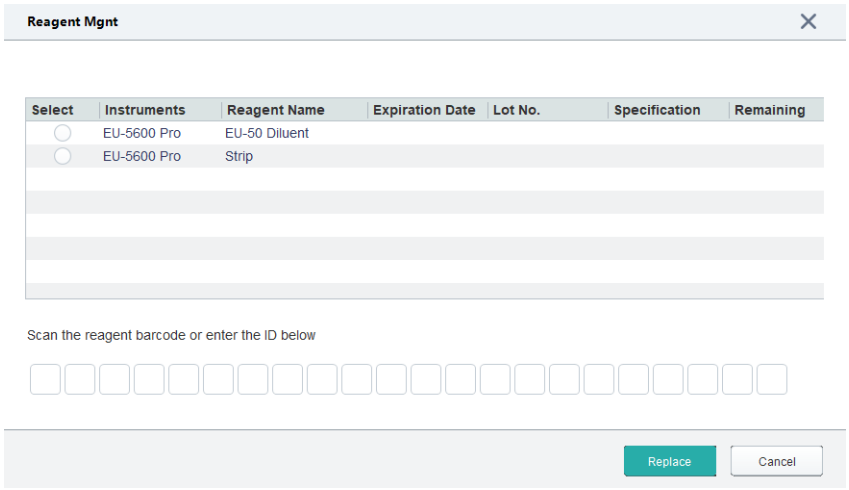
10.2.2.2 Registering new reagent information

After replacing the reagent, enter-registering the reagent information on the software by instructions below.

1. Enter "**Reagent Mgnt**" dialog box by one of the following ways.

When the analyzer is performing sample analysis	The "**Reagent Mgnt**" dialog box automatically displays.
When the analyzer is in idle status	• Click "**Reagent Setup**" on the "**Overview**" screen. • When the analyzer reports alarms for reagent, click ⚠ on the main interface of DMU, click "**Remove Error**" on the "**Error Information**" dialog box.

√ The "**Reagent Mgnt**" dialog box displays. By default, "**EU-50 Diluent**" is selected.



2. Manually enter the reagent barcode or scan the reagent barcode labels with a card scanner.
3. (Optional) In manual mode, click "**Replace**" to replace the reagent in the fluidics.

NOTE

- **By default, the analyzer automatically replaces the reagent in the fluidics. When necessary, you can change to manual mode. For more information, see *6.4.4 Customizing Modes for Reagent Replacement in the Fluidics*.**

√ If reagent barcode is valid, the analyzer automatically loads reagent information on the "**Reagent Mgnt**" dialog box.

10.2.2.3 Priming fluidic tubes after replacing expired reagents

After replacing expired reagents, remove the remaining expired reagents in the fludic tubes by following instructions below.

1. Click "**Maintain**"-"**Manual Maintain**" to enter the "**Manual Maintain**" screen
2. Click "**Prime**".

   √ After priming, the old reagents in the fluidic tubes are replaced.

10.2.3 Loading Test Strips

Replace the test strips when the strips run out, are insufficient or expired.

10.2.3.1 Placing test strips in the strip feeder

when there are insufficient test strips in the strip feeder, place new strips in the test strip box. For relevant operation, refer to *7.7 Preparing Test Strips*.

10.2.3.2 Registering new test strips information into the software

A box of test strip contains 10 test strip canisters. When user enters the barcode on the test strip box on "**Reagent Mgnt**", the software registers the number of test strips of 10 canisters.

During daily tests, you can place the whole box of test strips by batches as needed. The "**Reagent Info.**" area displays the total number and the remaining number of test strips.

When the whole box of test strips are used out, register a new box of test strips.

1. Enter "**Reagent Mgnt**" dialog box by one of the following ways.

When the analyzer is performing sample analysis	The "**Reagent Mgnt**" dialog box automatically displays.

When the analyzer is in idle status	• Click "**Reagent Setup**" on the "**Overview**" screen. • When the analyzer reports alarms for reagent, click on the main interface of DMU, click "**Remove Error**" on the "**Error Information**" dialog box.

√ The "**Reagent Mgnt**" dialog box displays. By default, "**Strip**" is selected. .

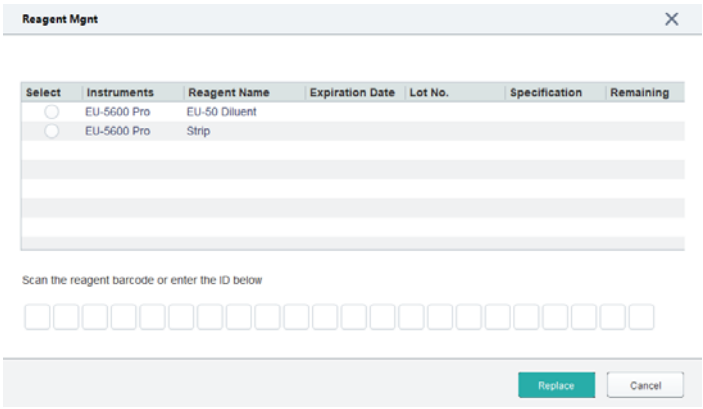


Figure 10-1 "Reagent Mgnt" dialog box

2. Manually enter the reagent barcode or scan the reagent barcode labels with a card scanner.

√ If strip barcode is valid, the analyzer automatically loads the strip information on the "**Reagent Mgnt**" dialog box.

10.2.4 Replacing Waste Container

When using waste containers to discharge waste, check whether the waste container is emptied before startup everyday.

When the analyzer alarms for "full waste container" in daily work, replace the waste container in time.

BIOLOGICAL RISK

- **Be sure to dispose of reagents, waste, samples, consumables, etc. according to government regulations.**
- **Waste can be potentially infectious. Wear proper personal protective instrument (e.g. gloves, lab coat, glasses, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.**

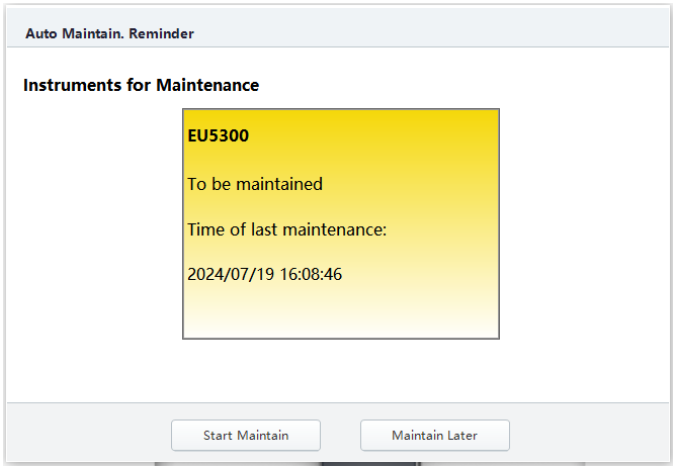
WARNING

- **Remove the waste container cap and replace the waste container only when the power indicator is nor flickering, in order not to make the waste overflow form the container.**
- **Make sure the analyzer already stops working before replacing the waste container. Do not replace the waste container during analyzing process.**

1. Get an empty waste container, remove the cap and place it next to the one to be replaced.
2. Turn the cap counterclockwise and remove the cap assembly from the old container with caution.
3. Insert the old cap assembly into the new container as vertically as possible, and secure the cap by turning it clockwise.
4. Cap the old container with the cap of the new one, and then dispose of the waste properly.
5. Click "**Remove Error**". The analyzer removes the error automatically.

√ After the auto maintenance function is enabled and when the analyzer connected to DMU meets the following conditions for auto maintenance, the software will prompt to perform relevant operations.

- When the analyzer has not been performed maintenance for the last 23 hours;
- When the time reaches the scheduled time for auto maintenance;
- The DMU software is currently at the "**Sample**", "**QC**" or "**System Setup**" interface.



NOTE

- **To configure auto maintenance for the analyzer, see *6.5 Configuring Auto Maintenance for the Analyzer*.**
- **For operations of Probe Cleanser Maintenance, see *10.2.5 Maintaining with Probe Cleanser*.**

- When "**Start Maintain**" is selected: after placing the tube with probe cleanser into STAT position according to instructions, the analyzer starts maintenance.T
- When "**Maintain Later**" is selected: the auto maintenance will be postponed and the software will prompt for auto maintenance 15 minutes later.

10.2.5 Maintaining with Probe Cleanser

⚠ WARNING

- **Avoid exposure to skin and mucous membranes. If cleanser accidentally spill on your skin, wash them off with plenty of water and go seek medical treatment if necessary.**
- **Avoid exposure to eyes. If you accidentally spill cleanser into your eyes, wash them off with plenty of water and go seek medical treatment if necessary.**

NOTE

- **Do not use expired Probe Cleanser.**
- **Dispose the waste, product residue and contaminated package in accordance with the local guidelines.**

During shutdown, software prompts to perform Probe Cleanser maintenance.

You can also go to "**Maintain**"-"**Manual Maintain**", click "**Maintain**" to start the Probe Cleanser maintenance.

√ Put Cleanser in the STAT tube holder, push it to STAT position, and click "**OK**".

Follow below instructions for Probe Cleanser maintenance:

1. Slowly pour Probe Cleanser into a clean tube, For recommended Probe Cleanser volume needed for each model, refer to. *Table 10-3 Prepared volume of Probe Cleanser*.

Table 10-3 Prepared volume of Probe Cleanser

Model	
EU-5300 Pro	4mL

Model	
EU-5600 Pro	6mL

2. Place the tube without cap containing the Probe Cleanser on the STAT tube holder.
3. Manually push the STAT tube holder loaded with Probe Cleanser to the analysis position, push the STAT tube holder forward to position and then loose your hand.
4. Click "**OK**" on the software screen.

√ The analyzer starts Probe Cleanser maintenance. A progress bar is displayed.

NOTE

- **In the process of maintenance, the software interface displays a progress bar, and the analyzer will aspirate the Probe Cleanser many times. Do not remove the Probe Cleanser before the progress bar disappears.**

5. After the Probe Cleanser maintenance completes, it is needed to remove the Probe Cleanser manually by pulling the STAT tube holder to initial position. Before pulling, the STAT tube holder is locked in the analysis position, you need to push the tube holder forward to loose the lock first and then pull the STAT tube holder back.

10.3 Cleaning Count Bath

When stains appear in the field, you should clean the surface of count bath. It is suggested to clean count bath on a regular basis.

Follow below instructions:

1. Power off the main unit of the analyzer.
2. Push the front cover of analyzer upward (1).
3. If the camera lens is right above the count bath, rotate the lens to reveal the count bath (2).
4. 3
5. Use cotton swab to clean the surface of count bath (*Figure 10-2 Cleaning count bath*, position 3) gently.

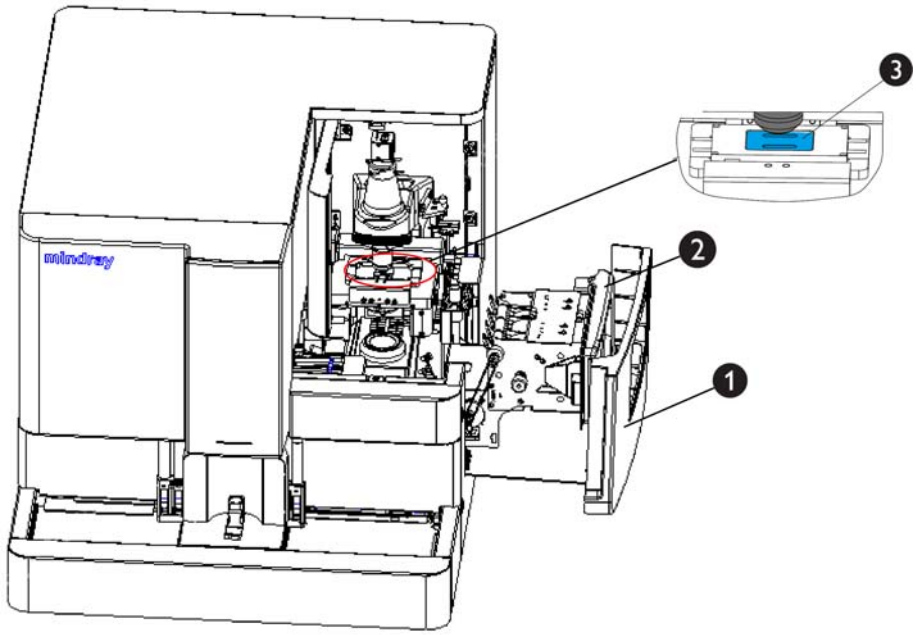


Figure 10-2 Cleaning count bath

6. After cleaning, close the front cover of the analyzer.

10.4 Cleaning Pallet

Clean the pallet regularly.

NOTE

- **Check the conditions of starting pallet cleaning on "System Setup"-"Analyzer Setup"-"Maintenance Setup" screen. For more information, refer to *6.10.1 Checking for Track Unit Maintenance Settings*.**

Follow below instructions:

After the number of sample tests reaches the specified value, when you perform shut-down procedure, the software will prompt the user to clean the pallet. The buzzer sounds, the indicator flashes in yellow, and the software prompts to perform the procedure.

1. Push up the top panel of strip feeder. Pull up and then put down the side door of the strip selection assembly (❶) to lay down the strip selection assembly (❷).

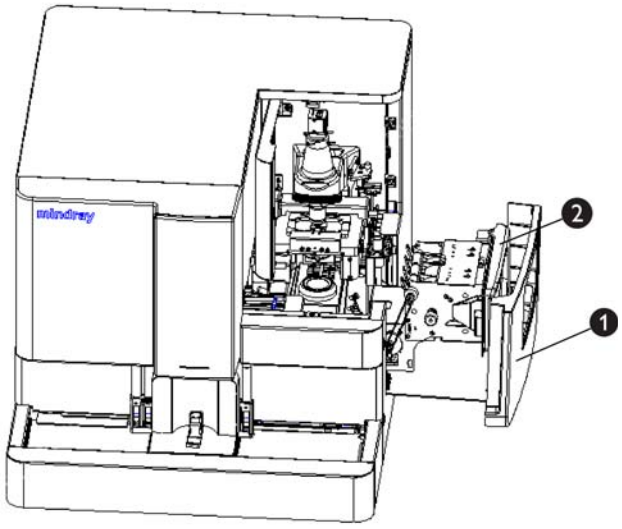


Figure 10-3 Cleaning pallet- lay down the strip selection assembly

2. Manually pull the pallet horizontally for 3 to 9 cm.

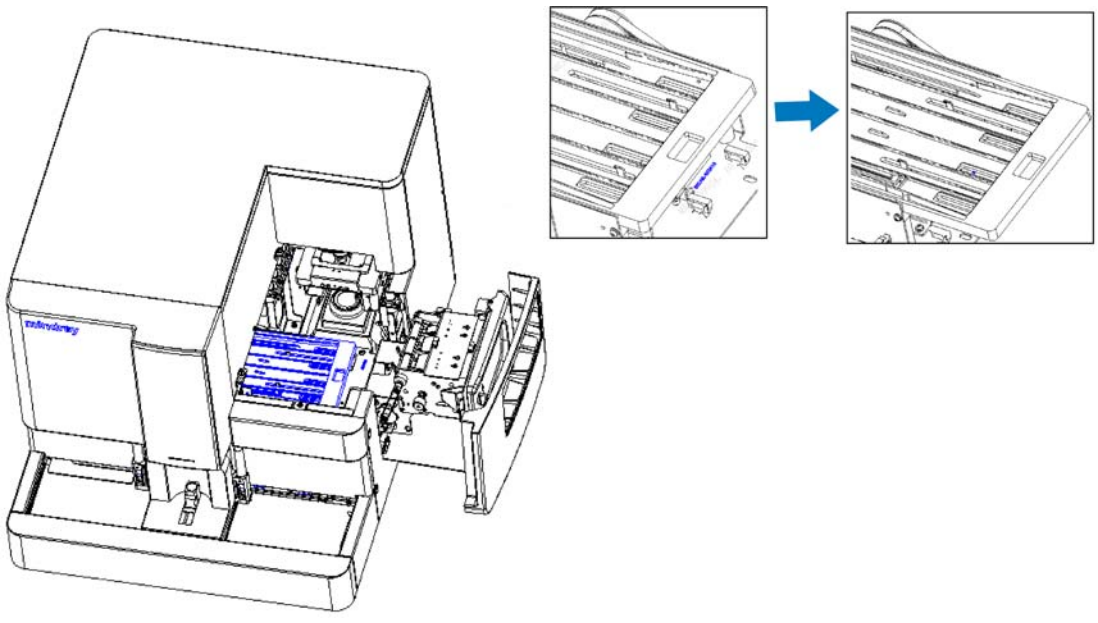


Figure 10-4 Cleaning pallet- pull the pallet

3. Tilt the pallet, pull it out slowly.

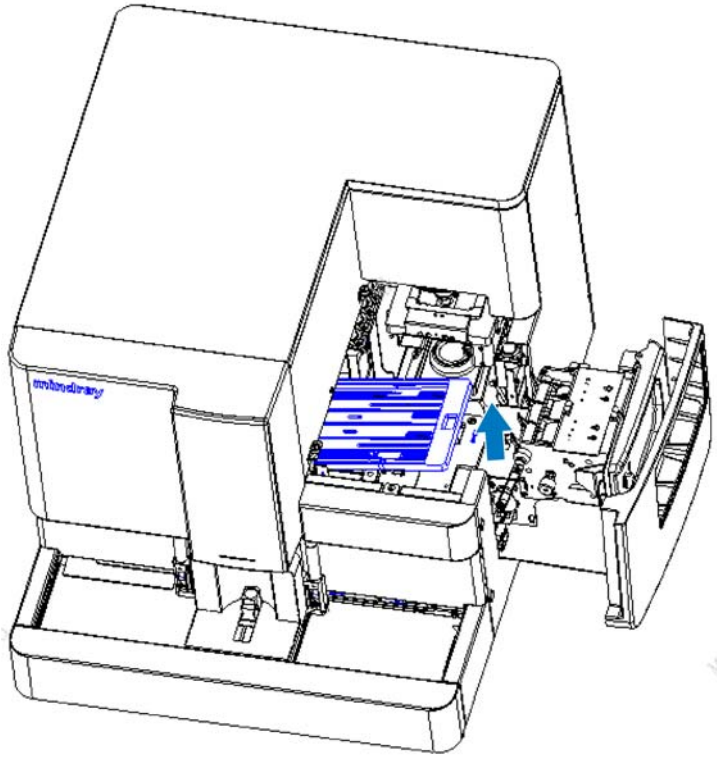


Figure 10-5 Cleaning pallet- Tilt the pallet upwards and pull it out

4. Use clean cotton cloth to wipe the surface of the pallet. After cleaning, put the pallet in a cool, shady and normal temperature place to dry.
5. After the pallet is dried, tilt the pallet and push it back into the analyzer. When the gripper is aligned with the oval shape hole of the pallet, lay down the pallet horizontally. Gently press the pallet down and push it inward into position.

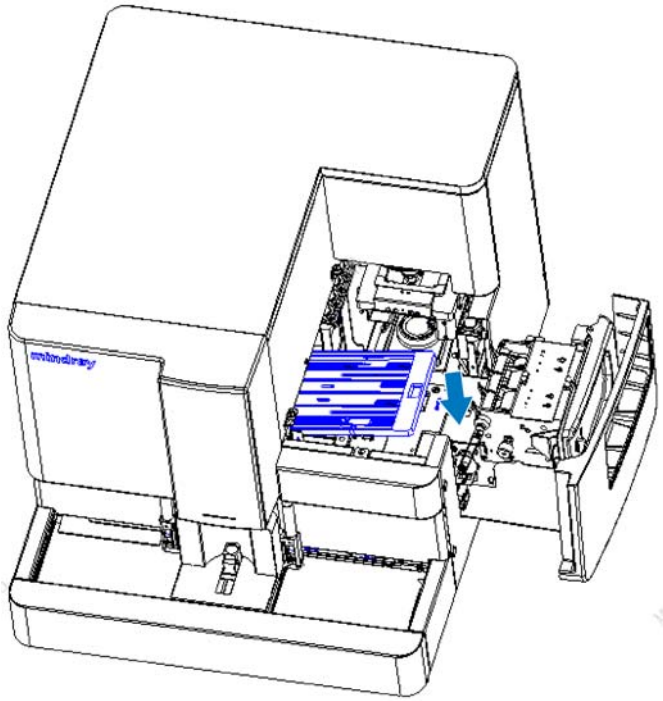


Figure 10-6 Cleaning pallet- lay down the pallet flat

6. Push back the strip selection assembly, close the side door of the strip selection assembly and close the top cover.
7. Click "**OK**" on the software to complete the maintenance.

10.5 Cleaning the Analyzer

10.5.1 Cleaning the cover of analyzer

BIOLOGICAL RISK

- **Mindray does not claim the validity of the listed chemicals in infection control. For effective control of infection, please consult the Infection Prevention Department of the hospital or the epidemic professionals.**

WARNING

- **Do not use any cleaning agents that could cause hazards as a result of a reaction with parts of the analyzer or with materials inside the analyzer. If there is any doubt about the compatibility of the disinfectant or cleaning agents with parts of the instrument or with material contained in it, please contact our Customer Service Department or the local distributor.**
- **If samples and reagents accidentally drop on the analyzer cover, clean and disinfect the instrument. Recommended cleaning agents and disinfectants include water and 75% ethanol. Do not use material that could corrupt metal (for example, 3% hydrogen peroxide). Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when conducting cleaning and disinfection.**

CAUTION

- **Perform regular cleaning on the covers of the analyzer. Use the specified materials to clean the equipment only. For any damage or accidents caused by the use of materials other than those specified, Mindray will not provide any warranty.**
- **Mindray does not claim the validity of the listed chemicals in infection control. For effective control of infection, please consult the Infection Prevention Department of the hospital or the epidemic professionals.**
- **The disinfection may damage the system to some extent. It is recommended to perform disinfection only when necessary according to your hospital maintenance plan. Remember to clean the equipment before disinfection.**

Perform regular cleaning on the covers of the analyzer.

Use clean cotton cloth to wipe the cover of the analyzer.

10.5.2 Cleaning the Waste Strip Box

Clean waste strip box every 15 days.

Follow below instructions:

1. Pull out the waste strip box on the left side of analyzer.

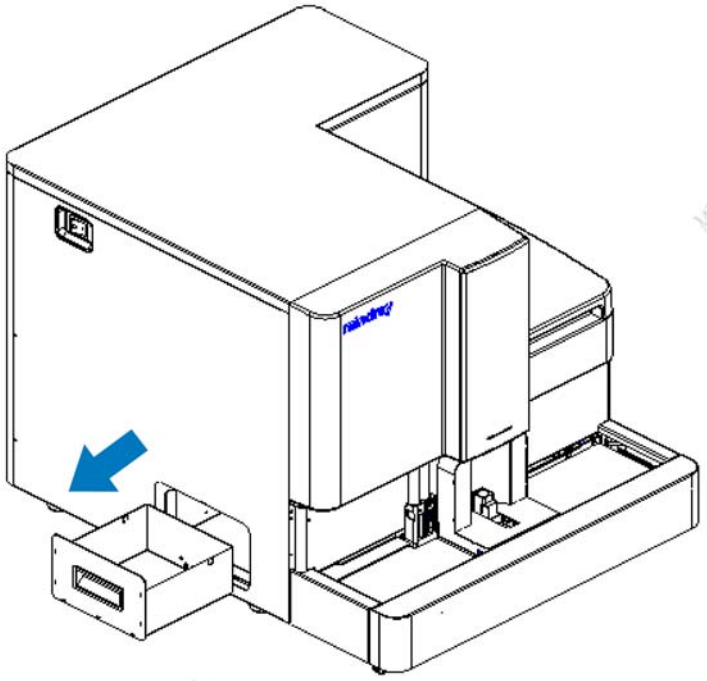


Figure 10-7 Open the waste strip box

2. Use clean cotton cloth dipped in 75% ethanol to wipe the waste strip box and then clean it with tap water after wiping.
3. After cleaning, dry the waste strip boxwith a clean tissue and then put it back.

10.6 Before Moving the Analyzer

If the instrument needs to be moved to other department temporarily, follow the instructions below before power off.

1. Remove the fluidic connector of reagent on the back panel of the analyzer.
2. Click "**Maintain**"-"**Manual Maintain**" to enter the "**Manual Maintain**" screen.
3. Click "**Drain**".
4. After draining the analyzer, perform shut-down procedure.

After shut down, remove the waste liquid connector and waste sensor connector (if using waste container) from the back panel of the analyzer.

10.7 Before and After Long-time Not Using the Analyzer

10.7.1 Before Long-time Not Using the Analyzer

NOTE

- **To perform "One-key Pack-up" procedure, prepare purified water in advance.**

If the instrument needs to be powered off for over 15 days, follow the below instructions before power off.

1. Click "**Maintain**"-"**Manual Maintain**" to enter the "**Manual Maintain**" screen.
2. Click "One-key Pack-up".
3. Complete pack-up operation as prompted, and then perform shut-down procedure.
4. After shut down, remove the waste liquid connector and waste sensor connector (if using waste container) from the back panel of the analyzer.

NOTE

- **For the analyzer shut-down procedure, refer to *7.10 Viewing Sample Results*.**
- **Dispose of analyzed samples, waste liquid, waste reagent and test strips according to laboratory procedures and local regulations.**
- **After shut-down, the analysis analyzer should be transported and stored under suitable environmental conditions. For storage and transportation environment requirements of the analyzer, refer to *5.1.4 Environment Conditions*.**

10.7.2 Re-starting up the Analyzer After Long-term Shut-down

When the instrument has been out of service for more than 15 days, connect the reagent, waste connector and waste sensor connector (if using waste container) before reuse.

10.8 Viewing and Exporting Analyzer Logs

The "Log" screen records all activities of the analyzer. It contributes significantly to searching for operation history and troubleshooting the analyzer.

The analyzer can store 500,000 records at most. If the number of logs exceeds the upper limit, the latest log will overwrite the oldest one. You can browse and print logs, but cannot delete them.

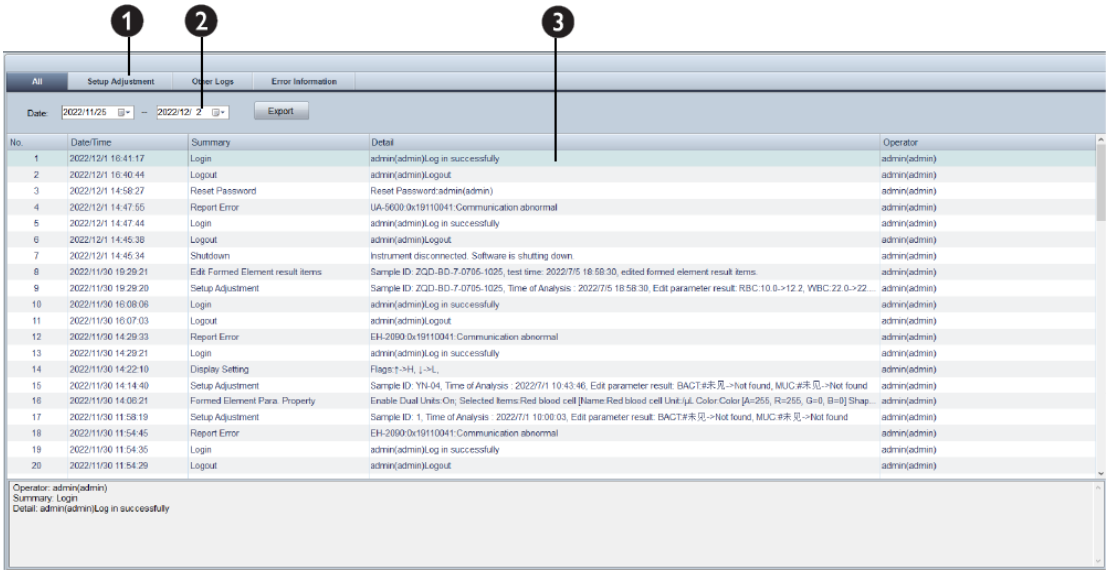


Figure 10-8 Log screen

		Description
1	Log categories	For the relevant log categories, refer to *Table 10-4 Log categories*.
2	Date range	Set a specific time range for viewing and exporting logs.
3	Log information area	This area displays the logs.
4	Details of logs	Click to select one piece of log in the table, and check the details in "Details of Logs" area.

Administrators and common users have different permissions to view the logs:

Table 10-4 Log categories

	Administrator level	Common user level
All	Review all categories of logs.	Review the logs for this common user level parameter adjustment, analyzer startup and shutdown, user logging out, etc.
Setup Adjustment	Review all setting adjustment logs under both administrator and common user access levels.	Review all setting adjustment logs under this common user access level.
Other Logs	Review the logs for analyzer startup and shutdown by the user.	Review the logs for analyzer startup and shutdown under this common user access level.
Error Information	Review error information and troubleshooting information of the analyzer.	Cannot review.

10.8.1 Reviewing Logs

Follow below instructions:

1. Click "**Log**" to enter the "**Log**" screen.
2. Click a log category to review the log you want.
3. (Optional) When necessary and define the time period for viewing the logs.

√ The screen displays the logs of specified category and date.

10.8.2 Exporting Logs

You may export the logs of specified time range to the computer.

Follow below instructions:

1. Click "**Log**" to enter the "**Log**" screen.
2. Click a log category to export the log you want.
3. (Optional) When necessary and define the time period for viewing the logs.

√ The screen displays the logs of specified category and time range.

4. Click "**Export**" and specify the export path by following the software instruction.

√ The analyzer automatically exports the logs of specified time range to the computer.

10.9 Wearing Parts

The analyzer has no wearing parts.

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11 Troubleshooting

11.1 Overview

This chapter contains information that is helpful in locating and correcting problems that may occur during operation of your analysis system.

NOTE

- **This chapter is not a complete service manual and is limited to problems that are readily diagnosed and/or corrected by the user of the analysis system.**

11.2 Error Messages and Solutions

During the operation, if any error is detected, the analyzer will beep and display the corresponding error message with indicator staying/ flickering in red.

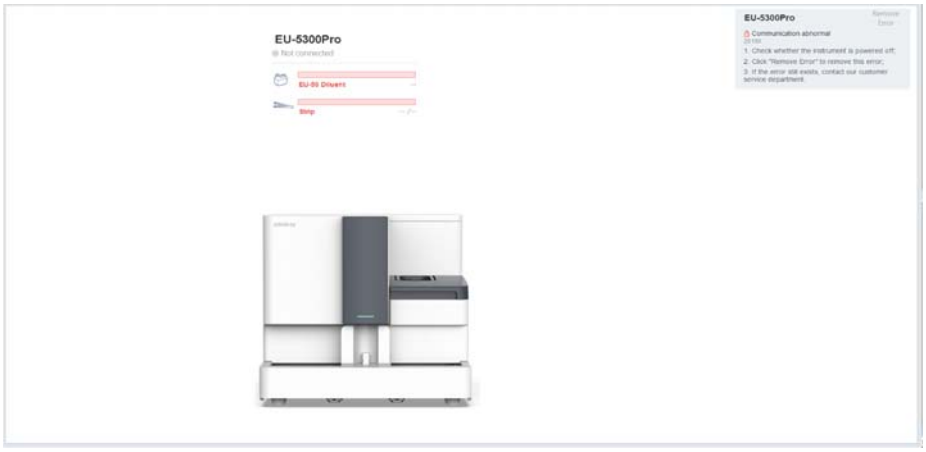
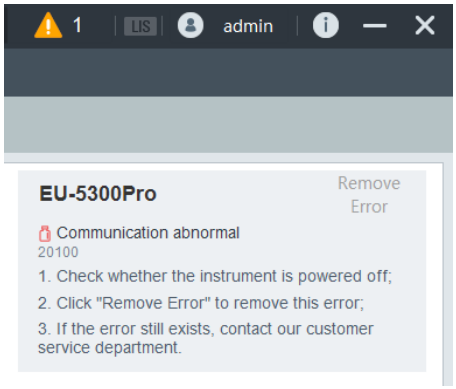


Figure 11-1 Error message area

Click  to view the details.



The following functions are provided:

■ Remove error

Click **"Remove Error"** to clear all the errors that can be removed automatically. For the errors that cannot be removed automatically, follow the troubleshooting method to solve them.

■ To mute the alarm sound

To mute the alarm, click/double at any position on the software interface, or scroll up/down the mouse, or press any key on your keyboard.

Table 11-1 Troubleshooting

Error code	Error Message	Troubleshooting
04009	Loading mechanism action error	1. Take away the tube racks in the sample loading area; 2. Click "Remove Error" to remove this error; 3. If the error still exists, contact our customer service department.
04217	Loading mechanism action error	1. Take away the tube racks in the sample loading area; 2. Click "Remove Error" to remove this error; 3. If the error still exists, contact our customer service department.
04109	Loading mechanism action error	1. Take away the tube racks in the sample loading area; 2. Click "Remove Error" to remove this error; 3. If the error still exists, contact our customer service department.
04010	Loading mechanism action error	1. Take away the tube racks in the sample loading area; 2. Click "Remove Error" to remove this error; 3. If the error still exists, contact our customer service department.
04306	Counter status error	1. Take away the tube racks in the sample loading area; 2. Click "Remove Error" to remove this error; 3. If the error still exists, contact our customer service department.
03003	Tube detection sensor abnormal	1. Take away the tube racks in the sample loading area; 2. Click "Remove Error" to remove this error; 3. If the error still exists, contact our customer service department.
06003	Detection module motor initialization failed	1. Click "Remove Error" to remove this error. 2. If the error still exists, contact our customer service department.
06103	Detection module motor initialization failed	1. Click "Remove Error" to remove this error; 2. If the error still exists, contact our customer service department.
06203	Detection module motor initialization failed	1. Click "Remove Error" to remove this error; 2. If the error still exists, contact our customer service department.
06104	Strip sensor error	1. Check whether the strip sensor is blocked; 2. Click "Remove Error" to remove this error; 3. If the error still exists, contact our customer service department.
05000	Strip picking initialization failed	1. Click "Remove Error" to remove this error. 2. If the error persists, contact our Customer Service Dept.
05100	Strip flipping initialization failed	1. Click "Remove Error" to remove this error. 2. If the error persists, contact our Customer Service Dept.
01003	Sampling assembly action abnormal	1. Click "Remove Error" to remove this error. 2. If the error still exists, contact our customer service department.

Error code	Error Message	Troubleshooting
01103	Sampling assembly action abnormal	1. Click "Remove Error" to remove this error. 2. If the error still exists, contact our customer service department.
01004	Sampling probe collision in vertical direction	1. Click "Remove Error" to remove this error; 2. If the error still exists, contact our customer service department.
20000	Waste box full	1. Empty the waste box; 2. If the error still exists, contact our customer service department.
05006	Strip placed in wrong direction	1.Check whether the strips are placed in the wrong direction; 2. Click "Remove Error" to remove this error; 3. If the error still exists, contact our customer service department.
05008	Strip tray empty	1.Place strips in the strip tray; 2. Click "Remove Error" to remove this error; 3. If the error still exists, contact our customer service department.
10000	Waste container full	1.Replace the waste container with an empty one; 2. Click "Remove Error" to remove this error; 3. If the error still exists, contact our customer service department.
10009	No Reagent	1.Replace the reagent container; 2. Click "Remove Error" to remove this error; 3. If the error still exists, contact our customer service department.
10010	Reagent expired	1.Replace the reagent container; 2. Click "Remove Error" to remove this error; 3. If the error still exists, contact our customer service department.
10011	Low volume of reagent	1. Click "Remove Error" to remove this error; 2. If the error still exists, contact our customer service department.
10014	No Reagent	1. Make sure the reagent containers are correctly connected; 2. Click "Remove Error" to remove this error; 3. If the error still exists, contact our customer service department.
30400	Microscope brightness initialization failed	1. Click "Remove Error" to remove this error; 2. If the error still exists, contact our customer service department.
30200	Channel 1 calibration failed	1. Click "Remove Error" to remove this error; 2. If the error still exists, contact our customer service department.
30201	Channel 2 calibration failed	1. Click "Remove Error" to remove this error; 2. If the error still exists, contact our customer service department.
30202	Channel 3 calibration failed	1. Click "Remove Error" to remove this error; 2. If the error still exists, contact our customer service department.

Error code	Error Message	Troubleshooting
30203	Channel 4 calibration failed	1. Click “Remove Error“ to remove this error; 2. If the error still exists, contact our customer service department.
30300	Channel 1 calibration failed	1. Click “Remove Error“ to remove this error; 2. If the error still exists, contact our customer service department.
30301	Channel 2 calibration failed	1. Click “Remove Error“ to remove this error; 2. If the error still exists, contact our customer service department.
30302	Channel 3 calibration failed	1. Click “Remove Error“ to remove this error; 2. If the error still exists, contact our customer service department.
30303	Channel 4 calibration failed	1. Click “Remove Error“ to remove this error; 2. If the error still exists, contact our customer service department.
40404	Plunger pump action abnormal	1. Click “Remove Error“ to remove this error; 2. If the error still exists, contact our customer service department.
40405	Plunger pump action abnormal	1. Click “Remove Error“ to remove this error; 2. If the error still exists, contact our customer service department.
20100	Communication error	1. Check whether the instrument is powered off; 2. Click “Remove Error“ to remove this error; 3. If the error still exists, contact our customer service department.
20101	Video connection failed	1. Check the video connection wires; 2. Click “Remove Error“ to remove this error; 3.If the error still exists, contact our customer service department.
01300	Plunger pump action abnormal	1. Click “Remove Error“ to remove this error; 2. If the error still exists, contact our customer service department.
05004	No Strips	1.Install new strips; 2. Click “Remove Error“ to remove this error; 3. If the error still exists, contact our customer service department.
40000	Analyzer not initiated during startup	1. Click “Remove Error“ to remove this error; 2. If the error still exists, contact our customer service department.
06105	No strip is detected	1. Check whether the strip sensor is blocked; 2. Check if there is any strip clogged in the pick unit; 3. Click “Remove Error“ to remove this error; 4. If the error still exists, contact our customer service department.
30002	Chemistry results abnormal	1.Check MCU version. Upgrade MCU and re-start the analyzer; 2. If the error still exists, contact our customer service department.

Error code	Error Message	Troubleshooting
30003	Chemistry results abnormal	1. Click "Remove Error" to remove this error; 2. If the error still exists, contact our customer service department.
30004	Chemistry results abnormal	1. Click "Remove Error" to remove this error; 2. If the error still exists, contact our customer service department.
30005	Chemistry results abnormal	1. Click "Remove Error" to remove this error; 2. If the error still exists, contact our customer service department.
30000	Chemistry results abnormal	1. Click "Remove Error" to remove this error; 2. If the error still exists, contact our customer service department.
05104	Strip flip failed	1. Check whether there are white scraps in the strip tray; 2.Check whether the parameters for pick motor release pos. is correctly set; 3. Click "Remove Error" to remove this error; 4. If the error still exists, contact our customer service department.
30204	Channel 1: position calibration failed during start-up	1.Check MCU version. Upgrade MCU and re-start the analyzer; 2. If the error still exists, contact our customer service department.
30205	Channel 2: position calibration failed during start-up	1.Check MCU version. Upgrade MCU and re-start the analyzer; 2. If the error still exists, contact our customer service department.
30206	Channel 3: position calibration failed during start-up	1.Check MCU version. Upgrade MCU and re-start the analyzer; 2. If the error still exists, contact our customer service department.
30207	Channel 4: position calibration failed during start-up	1.Check MCU version. Upgrade MCU and re-start the analyzer; 2. If the error still exists, contact our customer service department.
30304	Channel 1: position calibration failed during measurement	1.Check MCU version. Upgrade MCU and re-start the analyzer; 2. If the error still exists, contact our customer service department.
30305	Channel 2: position calibration failed during measurement	1.Check MCU version. Upgrade MCU and re-start the analyzer; 2. If the error still exists, contact our customer service department.
30306	Channel 3: position calibration failed during measurement	1.Check MCU version. Upgrade MCU and re-start the analyzer; 2. If the error still exists, contact our customer service department.
30307	Channel 4: position calibration failed during measurement	1.Check MCU version. Upgrade MCU and re-start the analyzer; 2. If the error still exists, contact our customer service department.

Error code	Error Message	Troubleshooting
20102	Camera disconnected	1.Check MCU version. Upgrade MCU and re-start the analyzer; 2. If the error still exists, contact our customer service department.
20103	Camera abnormal	1.Check MCU version. Upgrade MCU and re-start the analyzer; 2. If the error still exists, contact our customer service department.
04303	Tube rack moved abnormally	1.Clear all the tube racks on the autoloader of the malfunctioning analyzer; 2. Click "Remove Error" to remove this error; 3. If the error still exists, contact our customer service department. Note: do not manually move or touch tube racks in the feeding channel.
20104	Main unit disconnected	1.Check whether the analyzer is started up; 2. Click "Remove Error" to remove the error. If the error still exists, contact our customer service department.
04305	Counter error	1.Remove all the tube racks on the loading tray. 2.Click "Remove Error" to remove the error. 3.If the error still exists, contact our customer service department.
04218	Instruction error	1.Open the front cover and check whether there is test tube clamped in the manipulator; 2.Remove all the test tubes on the loading tray; 3.Click "Remove Error" to remove the error. 4.If the error still exists, contact our customer service department.
04219	Instruction error	1.Open the front cover and check whether there is test tube clamped in the manipulator; 2.Remove all the test tubes on the loading tray; 3.Click "Remove Error" to remove the error. 4.If the error still exists, contact our customer service department.
04220	Autoloader action abnormal	1.Clear all the tube racks on the analyzer; \r\n2. Click "Remove Error" to remove this error;\r\n3. If the error still exists, contact our customer service department.
30401	Channel 1 insufficient light brightness	1. Please contact our customer service department to adjust the light brightness.
30402	Channel 2 insufficient light brightness	1. Please contact our customer service department to adjust the light brightness.
30403	Channel 3 insufficient light brightness	1. Please contact our customer service department to adjust the light brightness.
30404	Channel 4 insufficient light brightness	1. Please contact our customer service department to adjust the light brightness.
30405	Channel 1 excessive light brightness	1. Please contact our customer service department to adjust the light brightness.
30406	Channel 2 excessive light brightness	1. Please contact our customer service department to adjust the light brightness.
30407	Channel 3 excessive light brightness	1. Please contact our customer service department to adjust the light brightness.
30408	Channel 4 excessive light brightness	1. Please contact our customer service department to adjust the light brightness.

Error code	Error Message	Troubleshooting
30409	Channel 1 bright. color temp. abnormal	1. Please contact our customer service department to adjust the light brightness.
30410	Channel 2 bright. color temp. abnormal	1. Please contact our customer service department to adjust the light brightness.
30411	Channel 3 bright. color temp. abnormal	1. Please contact our customer service department to adjust the light brightness.
30412	Channel 4 bright. color temp. abnormal	1. Please contact our customer service department to adjust the light brightness.
30413	Bright. self-test calculation abnormal	1. Please contact our customer service department to adjust the light brightness.
00401	Cistern floater status abnormal	1.Check whether there is reagent in the container, if not, replace with new reagent and remove tube rack; 2.2. Click "Remove Error" to remove this error; 3. If the error still exists, contact our customer service department.

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A Technical Specifications

A.1 Applicable Tubes

The analyzer supports conical-bottom and round-bottom urine test tubes, see below for detailed specifications:

■ Specifications of round-bottom test tubes

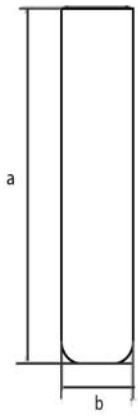


Figure A-1 Round-bottom urine test tube

Table A-1 Specifications of round-bottom test tube

Item	Specifications
Total length (a)	≤110mm
Diameter(b)	15~16mm

■ Specifications of conical-bottom test tubes

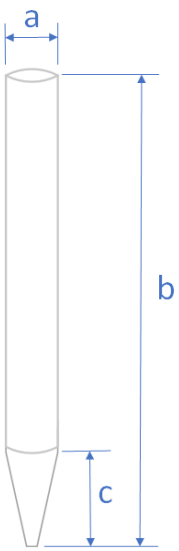


Figure A-2 Conical-bottom urine test tube

Table A-2 Specifications of conical-bottom urine test tube

Required specifications	
External dismeters (a)	Test tube(hard): 15-16mm
	Test tube(soft):13-14mm
Total height of test tube (b)	Test tube(hard): 100-110mm
	Test tube(soft): 95-110mm
Height of funnel shaped conical bottom(c)	＞22mm

■ Specifications of sample tube with caps

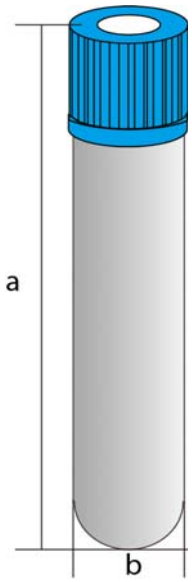


Figure A-3 Sample tubes with caps

Table A-3 Specifications of sample tubes with caps

Item	Specifications
Total length (a)	≤115mm
Diameter(b)	16~17mm

A.2 Reagent and Cleanser

Reagent	Intended Use
Automatic Urinalysis System Reagent (EU-50)	It is used for diluting samples before urine analysis and preparation of cell suspension.
Probe Cleanser	It is used to clean the instrument regularly.

NOTE

- **You must only use the Mindray-specified reagents in order to prevent analyzer damage and achieve optimal system performance. Do not use the analyzer with products from other suppliers. In such use, the analyzer may not meet the performanece specified in this manual and may provide unreliable results.**
- **If you need to purchase reagent, please call Mindray Customer Service.**

- **For other information about reagents provided with instrument, refer to the instruction for use of corresponding reagents.**

A.3 Urinalysis Test Strips and Reference Range

Refer to the Instruction for Use of Urinalysis Test Strips.

NOTE

- **Use the reagents and controls specified by the manufacturer only.**

A.4 Standard Greyscale Bar and Reference Range

Refer to the Instruction for Use of Standard Greyscale Bar.

A.5 Safety Classification

Level of transient over-voltage: Category II.

Rated pollution degree: Level 2.

A.6 Sampling Features

Table A-4 Minimum required sample volume and aspirated sample volume

	Micro mode (mL)	Normal mode (mL)
Aspirated sample volume	1	1.7
Minimum required sample volume	2.3	3

NOTE

- **The minimum sample required volume mentioned above is verified using test tubes with specifications in *A.1 Applicable Tubes*.**

⚠ CAUTION

- **Insufficient sample volume may lead to inaccurate analysis results.**

A.7 Product Performance

A.7.1 Throughput

Table A-5 Throughput of automatic urinalysis system

Throughput	Mode	EU-5300 Pro	EU-5600 Pro
Test duration of single sample:	/	No more than 120 seconds	No more than 120 seconds
Number of smaples tested continuously per hour:	• Chemistry+ Formed Element • Formed Element	No less than 70 tests/ hour	No less than 100 tests/ hour
	Chemistry	No less than 160 tests/hour	No less than 160 tests/hour

A.7.2 Resolution Ratio

The resolution ratio of formed element imaging system shall not be less than 800×600.

A.7.3 Fluidic Requirement

Fludics system should be working properly without leakage.

A.7.4 Limit of Detection (LoD)

The analyzer has the capacity to detect RBC and WBC samples with a concentration level of 5 cells /μL.

A.7.5 Repeatability

- The coefficient of variation (CV,%) of chemistry reflectance test results must be ⩽ 1.0.
- The coefficient of variation (CV) of the calculated results of formed elements meets the requirements of the following table.

Table A-6 Repeatability for formed element results

Formed elements	Concentration (cells /μL)	CV/%
Cells	50	⩽25
	200	⩽15

A.7.6 Chemistry Test Accuracy (with Urine Analysis Test Strips)

Test the reference solution on the analysis system: for all test items at all concentration levels, the deviation between the test results and the nominal values of the reference solution shall not exceed an order of one magnitude; and the deviation should not appear in the reversed direction. When testing positive reference solution, the analysis system shall not produce “negative“ results; and when testing negative reference solution, the analysis system shall not produce “positive“ results.

A.7.7 Identification Rate

A.7.7.1 Coincidence Rate between Test Result and Microscopic Examination Results

The analyzer has the capacity to detect the following formed elements, and the coincidence of the test results and the microscopic examination results meets the following specification.

Table A-7 Coincidence Rate between Test Result and Microscopic Examination Results

Formed elements	Compliance/%
RBC	⩾70
WBC	⩾80
Cast	⩾50

A.7.7.2 False-negative Rate

The false-negative rate of the analysis system should not be higher than 3%.

A.7.8 Stability

- The coefficient of variation (CV,%) of reflectance test results is less than ⩽1.0 within 8 hours after startup.
- The coefficient of variation (CV) of the cell count results should not exceed 15% within 8 hours after startup.

A.7.9 Carryover

	Carryover
Chemistry test	Test the positive samples with the highest concentration results of each test item except specific gravity and pH, and then test the negative samples, and the negative samples shall not be positive.
Formed element test	The carryover rate of formed element to cells should not be greater than 0.02%.

A.8 Contraindication

None

A.9 Size, Dimension and Weight

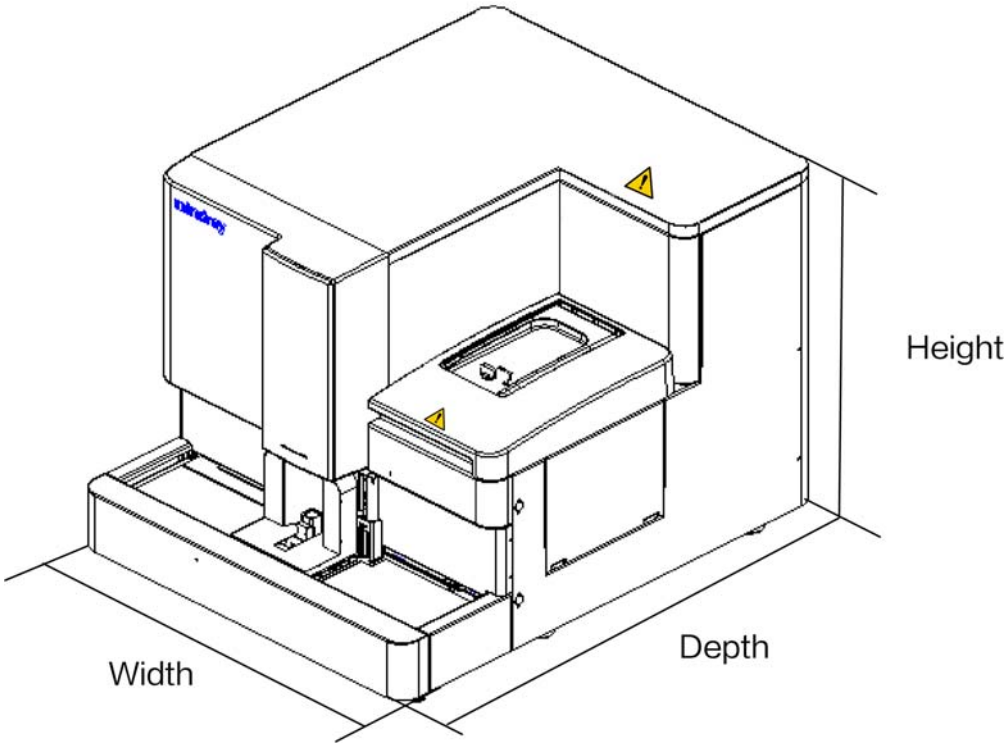


Figure A-4 Analyzer dimensions and weight

	Main Unit
Width (mm)	≤610
Depth (mm)	≤800
Height (mm)	≤550
Weight (kg)	≤80(with autoloader)

A.9.1 Power Supply Requirements

Table A-8 Power supply requirements

	Voltage	Frequency	Input Power
Main Unit	100V-240V (±10%)	50 /60Hz(± 2%)	300 VA

⚠ WARNING

- **Make sure the analyzer is properly grounded.**
- **When installing the instrument, ensure that the power switch is in close proximity to the equipment and within easy reach of you in order to power off the instrument effortlessly when necessary.**
- **Before turning on the instrument, make sure the input voltage meets the requirement.**

⚠ CAUTION

- **Using pinboard may bring electrical interference and the analysis results may be unreliable. Place the analyzer near the electrical outlet to avoid using the pinboard.**
- **Use the original power cord provided by the manufacturer. Using other electrical wire may damage the analyzer or lead to unreliable analysis result**

A.9.2 Fuse Requirement

Table A-9 Fuse requirement

	Specification Requirements
Fuse	φ5 T3AL250V

⚠ CAUTION

- **Only install fuses of specified type and specification to prevent from fire hazard.**
- **If there is any problem with the fuse, contact Mindray Customer Service Department or your local distributor.**

A.9.3 Environment Conditions

Table A-10 Environment Conditions

	Normal operating environment conditions	Storage and transportation conditions	Operating conditions
Ambient temperature	15℃-30℃	-10℃-40℃	5℃-40℃
Relative humidity	≤80%	≤93%	≤80%
Atmospheric pressure	80 kPa-106 kPa	50 kPa-106 kPa	80 kPa-106 kPa

Note: The altitude shall not be more than 2,000 meters.

- The environment should be as free as possible from dust, mechanical vibrations, contamination, loud noises and electrical interference.
- It is advisable to evaluate the electromagnetic environment prior to operation of this analyzer.
- Do not use this analyzer in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these may interfere with the proper operation.
- Do not place the analyzer near brush-type motors, flickering fluorescent lights, and electrical contacts that regularly open and close.
- Do not place the analyzer in direct sunlight or in front of a source of heat or drafts.
- The environment shall be well ventilated.
- The table top must be stable and level, vibration and mechanical impact shall be avoided. Do not place the analyzer on a slope.
- Connect only to a properly earth grounded outlet.

■ Only use this analyzer indoors.

A.10 Electromagnetic Compatibility (EMC)

The IVD device complies with the EMC standard IEC 61326-1 and IEC 61326-2-6.

For EMISSIONS and IMMUNITY specific requirements, see *Table A-11 GUIDANCE AND MINDRAY DECLARATION—ELECTROMAGNETIC EMISSIONS* and *Table A-12 GUIDANCE AND MINDRAY DECLARATION—ELECTROMAGNETIC IMMUNITY*.

⚠ WARNING

- **The IVD MEDICAL EQUIPMENT complies with the emission and immunity requirements described in this part of IEC 61326.**
- **This equipment is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments.**
- **This equipment is designed for use in a PROFISSIONAL HEALTHCARE FACILITY ENVIRONMENT. It is likely to perform incorrectly if used in a HOME HEALTHCARE ENVIRONMENT. If it is suspected that performance is affected by electromagnetic interference, correct operation may be restored by increasing the distance between the equipment and the source of the interference.**
- **The electromagnetic environment should be evaluated prior to operation of the device.**
- **Do not use this device in proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these can interfere with proper operation.**

NOTE

- **It is the manufacturer's responsibility to provide equipment electromagnetic compatibility information to the customer or user.**
- **It is the user's responsibility to ensure that a compatible electromagnetic environment for the equipment can be maintained in order that the equipment can be maintained in order that the device will perform as intended.**
- **The calculation formula to determine the separation distance between an IVD MEDICAL EQUIPMENT and a mobile phone is given by $d = 6/E \cdot \sqrt{P}$, where d is the minimum separation distance in meters, P is the maximum power in watts, and E is the immunity test level in V/m.**

Table A-11 GUIDANCE AND MINDRAY DECLARATION—ELECTROMAGNETIC EMISSIONS

GUIDANCE AND MINDRAY DECLARATION—ELECTROMAGNETIC EMISSIONS	
The system is intended for use in the electromagnetic environment specified below. The customer or the user of system should assure that it is used in such an environment.	
EMISSIONS TEST	**COMPLIANCE**
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class A
Harmonic Emissions IEC 61000-3-2	N/A
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	

Table A-12 GUIDANCE AND MINDRAY DECLARATION—ELECTROMAGNETIC IMMUNITY

GUIDANCE AND MINDRAY DECLARATION—ELECTROMAGNETIC IMMUNITY			
The system is intended for use in the electromagnetic environment specified below. The customer or the user of system should assure that it is used in such an environment.			
IMMUNITY TEST	**BASIC STANDARD**	**TEST VALUE**	**PERFORMANCE CRITERION**
Electrostatic Discharge (ESD)	IEC 61000-4-2	± 4 kV contact ± 2 kV, ± 4 kV, ± 8 kV air	B B
Electromagnetic field	IEC 61000-4-3	3 V/m (80 MHz to 6 GHz)	A
Electrical fast Transient / burst	IEC 61000-4-4	AC Power: ± 1 kV I/O single/Control[a]: ± 0.5 kV	B
Surge	IEC 61000-4-5	line-to-line: ± 0.5kV,1kV, ± 2kV line-to-ground: ± 0.5kV,1 kV	B B
Conducted RF	IEC 61000-4-6	3 V (150 kHz to 80 MHz)	A
Voltage dips, Short interruptions and voltage variation on power supply input voltage	IEC 61000-4-11	0 % during 0,5 cycles 0 % during 1 cycle 70 % during 25/30 cycles[b] 0 % during 250/300 cycles	B B C C
Power frequency magnetic field	IEC 61000-4-8	3 A/m (50 Hz, 60 Hz)	A
NOTE: [a] Only in case of line >3m [b] "25/30 cycles" means "25 cycles for 50 Hz test" or "30 cycles for 60 Hz test". Performance criterion: A: The equipment shall continue to operate as intended during and after the test. B: The equipment shall continue to operate as intended after the test. C: LOSS OF FUNCTION is allowed, provided the function is self-recoverable or can be restored by the operation of the controls.			

A.11 Acoustic Level

Not greater than 80dBA.

NOTE

- **It is recommend that the sound pressure level be measured or calculated by the RESPONSIBLE BODY both at the OPERATOR'S position in NORMAL USE and at whatever point 1 m from the ENCLOSURE of the equipment has the highest sound pressure level.**

A.12 Input and Output Device Requirements

The analyzer works with computers.

⚠ CAUTION

- **Be sure to use the specified devices only.**
- **External equipment connected to the analyzer and digital interfaces must be authorized and complied with relevant safety and EMC standards (e.g. IEC 60950 Safety of Information Technology**

Equipment Standard and CISPR 22 EMC of Information Technology Equipment Standard (Class B)). Any persons who connects additional equipment to the signal input or output ports and configures an IVD system, is responsible for ensuring that the system works normally and complies within the safety and EMC requirements. If you have any questions, consult the technical service department of your local representative.

A.12.1

Table A-13 Requirements for external computers

	Recommended Requirement
CPU	INTEL® CORE™ i3-12 or higher version, e.g. i3-12100
RAM	≥16.00GB DDR4
Hard disk	Capacity: ⩾1T Read and write method: perpendicular recording (CMR) Write speed: ⩾100MB/s
Solid state drive	256G
Operating system	Supporting Win10 64-bit
Network interface card (wired)	Quantity: ⩾1 Speed: gigabit
USB interface/ type	The amount of USB 3.0 interface at the back: ⩾1 The amount of USB interface on the front: at least 1
Video output interface	Suppporting HDMI
Extension interface:	Extension slot: serial extension card for channel 1, 1 serial port for extension card; serial port FIFO temporary storage⩾128byte
Input and output device	Mouse, keyboard, display and printer (supported)
Network	Supporting internal LAN

A.13 Electronic Interface Specifications

NOTE

- **Connection of the electronic interface to an IT network that includes other equipment could result in previously unidentified risks to patients, users or third parties; the responsible organization should identify, analyze, evaluate and control these risks.**

	Specifications	
Communication format (protocol) and relevant standards	USB port	Type A interface, complied with USB 3.0 standard (DC voltage 5V±5%: DC 500mA)
	COM port	DB9 male interface.complied with 3-wire RS232.
Time synchronization	Main unit synchronizes with PC every hour	

A.14 Barcode Specifications

The analyzer can read barcode labels pasted to test tubes to obtain sample IDs. The sample IDs read from the barcode will be stored and used as the only identification of the sample.

The barcodes shall meet the ID barcode specifications of the analyzer.

1. Supported barcode types

All code types and check digit supported by the analyzer are listed as follows.

Table A-14 Supported Barcodes

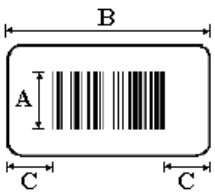
Code systems	Check Digit	Number of Digits
CODE128	Embedded	No more than 30 digits (sample ID)
UPC/EAN/JAN	Embedded	Fixed length: 8 or 13 digits
ITF (Interleaved 2 of 5)	Not used	No more than 30 digits (sample ID)
CODE39	Not used	No more than 30 digits (sample ID)
CODE93	Not used	No more than 30 digits (sample ID)
CODABAR	Not used	No more than 30 digits (sample ID)

2. Barcode label dimensions

Barcode height: A≥10mm

Label width: B≤50mm

Width of the clear area on each side: C ≥ 5 mm

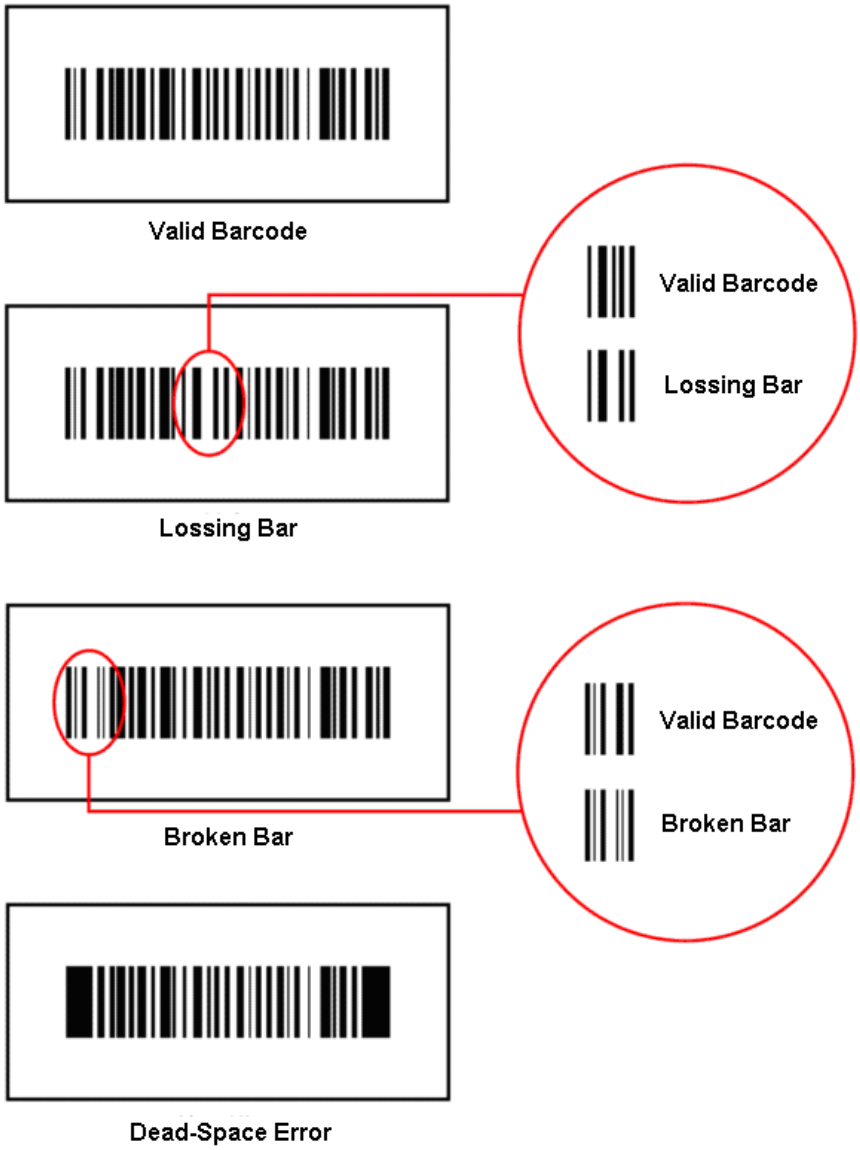


Width of the narrow bar: greater than 0.152mm

Code quality: According to ANSI MH10.8M standard, the code quality shall be Level C or above.

3. Examples valid and invalid barcode labels:

Use of invalid barcode labels shown in the following figures will increase the possibility of misreading. To ensure good readability, use valid labels.


Valid Barcode
Valid Barcode
Lossing Bar
Lossing Bar
Broken Bar
Valid Barcode
Broken Bar
Dead-Space Error


Partially missing -1
Fragmentary
Partially missing -2
Low contrast

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B Analyzer Configuration

NOTE

- **Actual accessories are subject to your product configurations.**
- **For information on the configured/optional accessories, please consult your sales representative.**

- Main unit of analyzer
- Reagent cap assembly
- Handheld card scanner
- Tilt-watch label
- Serial port cable
- USB video wires
- Urine test tubes
- 5L bottle
- Quality certificate
- Operator's manual
- Carton box
- Rubber cover
- Tube rack assembly
- Gray bar assembly
- Waste container cap assembly
- Software package
- Main power cords

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C Communication

The LIS/ HIS function of the analyzer enables the communication between the analyzer and the PC in laboratory through Ethernet, including sending analysis results to and receiving worklist from PC.

The LIS/HIS communication process involves the Mindray Private Communication Protocol. For more information about the connection control, and the introduction, message definition and examples, please contact Customer Service Department of the manufacturer for communication protocol details.

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D References

- Health Industry Standard of the People's Republic of China (WS/T229), Urine Physical, Chemical and Microscopic Examination Standards, 2002
- Urinalysis and Collection, Transportation and Preservation of Urine Specimens, Approved Guideline-Second Edition (NCCLS document GP16-A2)
- CLSI GP16-A3 Urinalysis; Approved Guideline-Third Edition, Clinical and Laboratory Standards Institute document

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E Limitations

E.1 Limitation of Test Method of Test Strips

1. As with all lab tests, definitive diagnostic or therapeutic decisions should not be based on single result or method.
2. This product can only be used for the determination of urine, and cannot be used in sample of other body fluids.
3. There is no direct contrast between the test values got through other ways and the test results of this product.

E.2 Limitation of Formed Element Analysis

Automatic Urinalysis System utilizes imaging technology of microscopic analysis. Due to limitations of the testing technology, potential interferences, for example, visual/ physical interference, may occur in the following scenario where analyzer may not automatically identify or misidentify formed elements. The images below are the images of high-concentration sample, which the analyzer may not automatically identify the formed elements in it. It is recommended to review the sample in the sample-reviewing window.

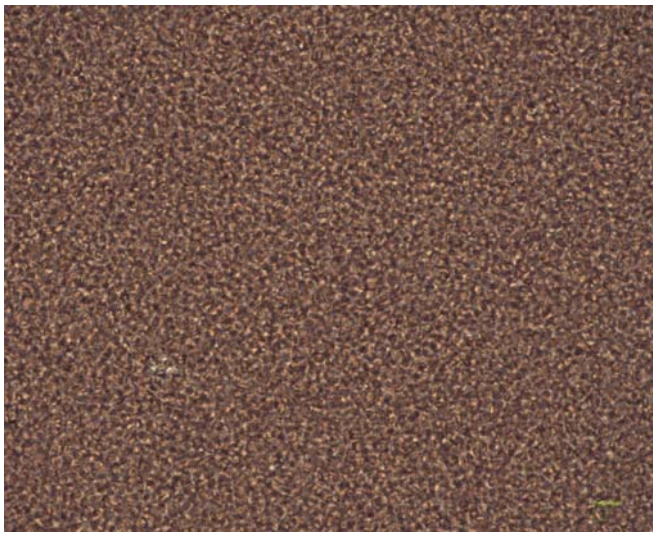

Figure E-1 Image 1 of High-concentration sample

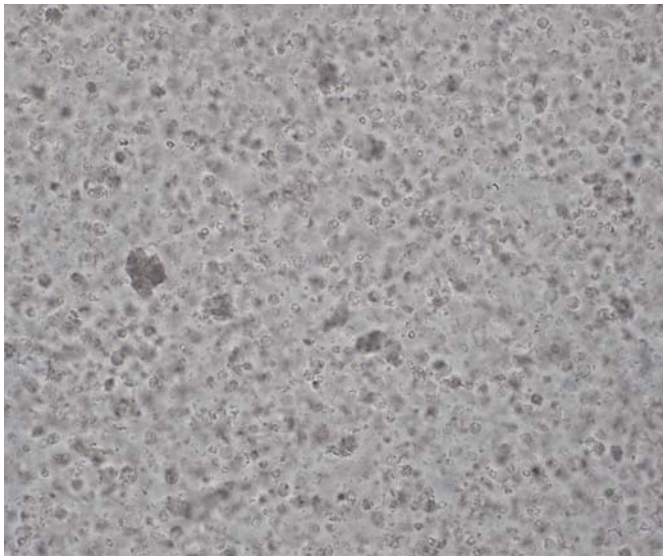

Figure E-2 Image 2 of high-concentration sample

F Index

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G Maintenance Logs

NOTE

- **This log table is designed per month use. If necessary, please make your own copies for use.**
- **For information on the maintenance procedure, see *10 Servicing Your Analyzer*.**

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Date	Cleaning and maintenance procedures	Date	Cleaning and maintenance procedures
1		17	
2		18	
3		19	
4		20	
5		21	
6		22	
7		23	
8		24	
9		25	
10		26	
11		27	
12		28	
13		29	
14		30	
15		31	
16			

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