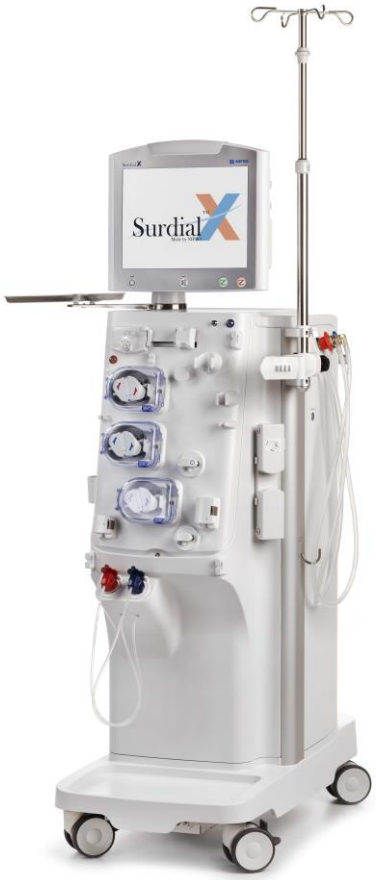
Single patient dialysis machine

Surdial X

Instruction Manual



⚠CAUTION

Read this instruction manual carefully before use.
Improper handling can result in an accident or malfunction.
Use the unit in accordance with this manual.
Keep this manual in an appropriate place to avoid misplacement.

Original Instructions

1. Preface

Thank you for purchasing NIPRO SINGLE PATIENT DIALYSIS MACHINE Surdial X.

Brief description

This is a single patient dialysis machine with a built-in dialysate preparation system and piston pump ultrafiltration control system. Preparation is based on a feedback control method.
Any other device or equipment need not to be used in combination with this machine for dialysis treatment. This machine controls and monitors dialysate circuit and extracorporeal blood circuit.
The extracorporeal blood circuit control panel is designed to allow easy settings and operations.

The blood can be heparinized either continuously or by one single bolus injection using the heparin pump.
The Surdial X can be used for either acetate dialysis or bicarbonate dialysis

The screen of the operation panel contains a clear 15 inch TFT color liquid crystal display with a touch panel. It allows dialogue-assisted operation and easy management of emergency situation during an alarm.

This machine reflects the state-of-art. This machine is classified in class IIb according to MDD and is equipped with all necessary safety device required for the performance and patient safety. Refer to chapter 11 for the applicable standards.

Important notices

This instruction manual describes proper and safe operation of the machine.
It is not intended for patient management.

Before using the machine, the responsible organization or person has to be instructed by the manufacturer how to use the machine and be familiar with the contents of the operating instructions

Read this instruction manual (and related instructions) carefully before use.
Understand the machine's features and handling instructions and use it properly.

This instruction manual describes operation with standard functions.

Service life

To guarantee the optimal lifetime of the Surdial X it is recommended to respect the regular care, maintenance and technical inspections of the machine.

Intended use of this machine

The Surdial-X can be used for patients with acute or chronic renal failure and when hemodialysis is prescribed by a physician. The Surdial-X is intended to be used by trained operators for hospital, health center or limited care. The system is a single patient hemodialysis system, which provides dialysis fluid with a prescribed concentration and temperature to be used for hemodialysis treatment.
The system is intended to be used with high and low permeability dializers.
The Surdial-X monitors during the dialysis treatment dialysate, blood circuit and machine functions.
The system tolerances (e.g. Fluid balance, air infusion) are designed to treat patients with their body weight of 30kg or more.

Depending on the model, the following types of therapies can be carried out:
Hemodialysis (HD)
Isolated ultrafiltration (ISO-UF)
Single needle dialysis (SN-DP/SN-CC)
Online Hemofiltration (O-HF in pre and post dilution)
Online Hemodialfiltration (O-HDF in pre and post dilution)
Single needle online Hemofiltration (SN-DP/SN-CC O-HF in pre and post dilution)
Single needle online Hemodialfiltration (SN-DP/SN-CC O-HDF in pre and post dilution)
All therapies can be carried out with different kind of UF, bicarbonate and sodium profiles.

Intended operators of this machine

This machine is intended to be operated by qualified doctors, nurses and clinical engineers with skills specific to dialysis treatment such as introduction of blood to extracorporeal blood circuit, etc. If the operator chooses to link this machine to third party software (applications), the operator bears all responsibility and liability in this respect. The manufacturer does not guarantee the compatibility of this machine with third party software (applications) nor that this machine will function correctly after being connected to third party software (applications), even when subsequently disconnected, and the manufacturer shall bear no responsibility nor liability in this respect.

The instruction manual contains any information for the use of this machine.
The information must be carefully studied before attempting to operate the machine

Contra-indications

This machine is not designed, manufactured, or sold for use other than for hemodialysis for patients with acute or chronic renal failure.
Attention should be paid to contra-indications valid for extracorporeal treatment in general.

Do not use high potassium percentage hemodialysis concentrates for HYPERKALEMIA.
Do not use potassium free hemodialysis concentrates for HYPOKALEMIA
uncontrollable coagulation anomalies.
A different method of extra-corporal treatment maybe indicated for hemodynamically unstable patients.

RISKS and BENEFITS of hemodialysis

Hemodialysis treatment improves uremia, anemia, hypertension, etc. However, it can also cause angialgia at puncture site, acceleration of hemorrhage, thrombosis and thrombemboli, infectious diseases, disconnection, air embolism, hypothermia, hypotension during hemodialysis, nausea, vomiting, disequilibrium syndrome, arteriosclerosis, cardiac failures, bone diseases, amyloidosis, arrhythmia, anemia, etc.

Responsibilities

The organizer of hemodialysis is considered to work under the correct circumstances by means:
- Compliance with national and local safety regulations
- The operating instructions must be available at all times
- Correct and safe state and placement of the machine.

Daily inspection by operator

Check the following items before and after using the equipment on the same day.
Ensure normal operation of the equipment.

(1) Look for abnormalities, such as leakage around the equipment.
Check for loosening of clamps for the water supply opening and drainage opening hoses.
(2) There is not residual chemical solution.
(3) Residual quantities of disinfection or acetic acid solution being enough.
(4) Consumption of disinfection or acetic acid solution being reasonable.
(5) The real concentration of dialysate being reasonable.
(6) There is no abnormal sound, a bad smell, over heat.
(7) Foreign substance such as disinfectant stain on the equipment exterior.
(8) Dialysate stain on the equipment. A dialysate stain can cause rust. Wipe it off immediately.
(9) Abnormality when the start-up test is performed.
(10) If the equipment will be in operation overnight, ensure that the coupler is fit firmly on the coupler holder.

(11) Confirm that dialyzer coupler is properly mounted.
(12) Correct syringe must be set.

Service and maintenance by technician

Service, maintenance, adjustments, repairs or modifications can only be performed by the manufacturer or technicians authorized by the manufacturer. Detailed information regarding maintenance is described in the service manual.

The manual is subject to any change without notice. Any changes will be released as new editions either supplements

Safety

The Surdial X complies with the following standards

JIS Z 0200 : 2013
JIS Z 0232 : 2004
IEC 60601-1 : 2005
IEC 60601-1-am1 : 2012
IEC 60601-1-2 : 2014
IEC 60601-1-6 : 2010
IEC 60601-1-6-am1 : 2013
IEC 60601-1-8 : 2006
IEC 60601-1-8-am1 : 2012
IEC 60601-1-10 : 2007
IEC 60601-1-10-am1 : 2013
IEC 60601-2-16 : 2012
IEC 80601-2-30 : 2013
IEC 60825-1 : 2014
IEC 62366 : 2007
IEC 62366-am1 : 2014
ISO 10993-1 : 2009

Equipment classification and handling precautions

Protections from electric shock for this machine are as follows:
Type of protection from electric shock: Class I ME equipment
Degree of protection from electric shock: Type B applied part (hydraulic circuit)
Type BF applied part (cuff)

Ensure the use of a protective earth connection.
The power plug is equipped with an earth connection.
Incorrect protective earth connection may cause electric shock in the event of malfunction due to electric noise or in the event of failure.

Precaution for fluid penetration

Keep the machine out of water.

Protection against water and hazardous micro particulate matter infiltration: Drip-proof equipment IPX1

Precaution for flammable atmospheres

Do not use this machine in flammable atmospheres.

Laser class and specification (BVM option)

Laser Product Class: Class 1 laser product

Wavelength: 905 nm

2. Safety Precautions

Proper operation and regular maintenance are essential for safe operation.
Thoroughly read and understand the safety precautions listed in this instruction manual before use.
Operation and safety precautions listed in this manual are specific intended for the use of this unit. If this unit is used for other purposes, which are not listed in this instruction manual, the user will be responsible for the consequential safety issues.

Initial start up

Before start up study the technical requirements in chapter 11 to ensure the machine works in the correct conditions.
Initial start up can only be performed by a qualified technician with use of the procedures described in the service manual.

Warning symbols

(1) Degree of safety hazard, damage and displays (attention-attracting symbols and signaling terms)

Degree of safety hazard and damage that result from improper handling is classified into 3 levels.
Each level will be indicated by a specific attention-attracting symbol and signaling term.

⚠DANGER

This indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.

⚠WARNING

It indicates a potentially hazardous which, if not avoided, could result in death or injury.

⚠CAUTION

This indicates a potentially hazardous, if not avoided, may result in moderate injury or damage in property.

(2) Annotation and its display

NOTE

Annotation is displayed. Use this as a reference when handling the unit.

Because of our ceaseless research and improvement, details of the design of the unit described in this manual may be slightly different from those of the unit you purchased. If you have any question about the unit you purchased or contents of this instruction manual, please contact the nearest branch or agency.

⚠ DANGER

- Read this instruction manual before using the unit.
  - When this machine is operated and maintained in a proper way, a safe and reliable treatment is warranted.
  - The manufacturer does not warrant the correct functioning of this machine in connection to third party software and/or software applications nor after the machine was connected to such third party software and/or software applications, even when subsequently disconnected. The operator should always verify the correct interaction between this machine and such software and/or software applications.
  - Before operating the unit, thoroughly read and understand this manual. Improper operation can lead to injury or abnormal operation. This unit should be operated by professionals only.
- Learn the methods to immediately stop the treatment.
  - To avoid serious problems, know how to quickly stop the operation.
  - Do not allow non-professionals to operate the unit without having proper instructions.
- Know how to respond when the unit stops for any reason.
  - Check the status of the unit and act in accordance with this manual.
- During the maintenance, special caution should be exercised for the electronic boards, electric wiring, and terminals.
  - Do not touch non-isolated electric wiring and terminals.
  - Do not touch the electronic boards with a wet hand.
  - Before touching the terminal block, disconnect the power plug from the power supply.
- During the connection/disconnection of a patient, special attention should be taken to avoid the following risks that can harm the patient.
  - Avoid air entrance into the patient.
  - Do prime the blood circuit before connecting the patient.
  - Do not connect the patient blood circuit during rinsing/disinfection.
  - Prevent the contact of harmful viruses and chemicals with the patient.
- Inappropriate connection of the blood circuit is dangerous for the patient. A bad connection can cause extracorporeal leakages. Improper pressure can result in rupture of the circuit. Ensure that the blood circuit is connected properly at all times.
- Before connecting the patient, ensure that the alarm of the unit is not interrupted. Treatment without using the alarm functions can cause great risks for the patient.
- Mixing of chlorine and decalcification solutions generates chlorine gases. Inhalation of these toxic gases is very dangerous. Ventilate the room, and be careful not to inhale the generated gases.

⚠ WARNING

- Connect this unit only to an electric power source with protective earth (commercial use) to avoid the risk of electric shock.
- Do not use the machine when a defibrillator is used on a patient (disconnect patient from unit) . It`s not allowed by classification, because maybe result of medical intervention is not given/reduced or the machine could be damaged. If the machine was connected when defibrillator was discharged, check all machine functions and perform electrical check.

- Electronic equipment producing radio waves should not be used in the same room or building as where this unit is used refer to chapter 11: Specification.
- Accessory equipment connected to the analog or digital interfaces must be certified according to the latest IEC standards related to the purpose of the machine. Anyone who connects additional equipment is responsible for ensuring that the system is conform the latest standards of IEC.
  - Avoid the use of electronic equipment that produces radio waves including cellular phones, transceivers, and radio-controlled toys. Use of this equipment inside of a hospital building can lead to malfunction of the machine. (refer also to chapter 11, specifications)
  - To prevent a possible accident, inform and instruct people not to carry or use radio-wave producing equipment in the hospital building.
- The operator has to verify all the entered parameters in the system are correct. Any deviation between the desired parameters and the displayed parameters must be corrected before using the machine.
- Venous pressure
  - Monitoring of the venous Pressure cannot always detect the disconnection of a venous needle from its access site, which may result in extracorporeal blood loss to the environment. When a venous needle disconnects from its access, pressure at the venous monitoring side may only decrease by the pressure maintained within the patient's access site. This pressure drop may be less than the width of the machine's venous pressure alarm window: in this particular case the disconnection of a venous needle from its access site is not detectable by the machine, even if pressure alarms and alarm windows are properly set.
  - To reduce the risk of needles disconnection:
  - Ensure that venous needle and line are firmly secured to the access site area according to your clinic's protocol.
  - Ensure that the patient access is visible at all times during the dialysis treatment.
  - Inspect frequently the patient's access.
  - Adjust properly the venous pressure alarm window: The venous pressure alarm lower limit should be set as closely as practical to the actual patient's venous pressure value without generating excessive nuisance alarms
- Do not change the setting values during treatment if there is no emergency.
  - Before selecting a function, ensure to understand the function thoroughly.
- Provide a drain opening in the floor.
  - Provide a drain opening near to the unit.
- Refer to the "Safety Precautions-16" before servicing the machine.
  - Maintenance should only be carried out after thoroughly reading and understanding the "Safety Precautions-16".
  - Maintenance should be performed in accordance with the directions.
  - Look for professional help for repair and maintenance actions not listed in the "Safety Precautions-16".
- Do not choose unnecessarily functions during the treatment.
- Do not tilt the unit more than 5 degrees. It can overturn.
- Equipment (including software and/or software applications), not permitted to be used together with this machine, may not be connected. The total electric leakage current from the unit and other equipment together can exceed the maximum allowable value.

- The operation and maintenance not specified by the manufacturer and the application of unspecified accessories (including software and/or software applications) may cause death or injury of the patient. The manufacturer is not responsible for the patient safety when the unit is operated, maintained, or calibrated by methods and/or with the use of third party materials (including software and/or software applications) not specified by the manufacturer. Trained and authorized personnel must operate the unit in accordance with the methods established by the manufacturer.
- Do not modify the unit nor any component thereof.
  Do not modify the software included in the unit.
  The manufacturer bears no responsibility nor liability in respect to modifications to the unit or any component thereof (including software and/or software applications) after the unit was connected to third party materials (including software and/or software applications), even when subsequently disconnected.
- Air bubbles may enter from the connecting point of the extracorporeal blood line at the downstream of the air bubble detector if negative pressure is created at the connecting point. It may occur during the single needle operation and when the central venous catheter is used.

⚠CAUTION

- Wear tools for protection when handling chemicals.
  - Wear protection glasses and rubber gloves when handling chemicals.
  - Characteristics of all chemicals being used should be realized to be able to treat appropriately when a trouble occurs.
  - Do not mix sodium hypochlorite with acetic acid, or peracetic acid
  - If mixed, it may produce chlorine gas harmful to humanbody
  - Inhalation of the generated chlorine gas will cause serious danger to the human body
- Before installing the unit, thoroughly read and understand the installation manual.
  - Only trained professionals may install the unit.
  - If the operator chooses to make use of this machine with the help of third party software and/or software applications and/or to link this machine to third party software and/or software applications, the operator bears all responsibility and liability in this respect. The manufacturer does not guarantee the compatibility of this machine with third party software and/or software applications nor that the machine will function correctly after being connected to third party software and/or software applications and the manufacturer shall bear no responsibility nor liability in this respect.
  - Install the unit in accordance with the installation manual.
- The connection of optional parts and the connection with an external unit should be performed after reading and thoroughly understanding the corresponding manuals.
  - Only trained professionals are allowed to do the connections.
- Check the dialysate parameters with external testing equipment before starting any treatment.
  - Verify the actual dialysate concentration by an osmometer, conductivity meter, flame photometer, etc.
  - Check if the displayed concentration level is accurate.
- Verify, at the end of the cleaning, that there is no residual chemical or acid present.

- Verify, at the end of the disinfection the presence of chemicals (sodium hypochlorite, peracetic acid, or other chemicals) using a test paper or reagent.

- Do not use any force on the display monitor and touch panel.
- Avoid using force on the display monitor during surface cleaning.
- Do not use hard or sharp objects to operate the touch panel. The touch panel can be damaged with operating malfunctions as a result.
- Ensure that setting values are not abnormal during treatment.

- Clean (disinfect and rinse) the unit thoroughly before use.
- Disinfection and rinse are necessary when the machine has been out of use for a long term.
- Disinfection and rinse are necessary when the machine has been out of use for a long term to flush the waste water.
- Chemical or heat disinfection is needed after each manipulation on the hydraulic circuit (repair, maintenance, …)

- Keep the machine always clean.
- Use aseptic technique for all blood-side connections
- Wipe off blood, dialysate, cleaning solutions carefully.
- Clean (disinfect and rinse) regularly.
- Note that some cleaning solutions such as “Irgasan” ruin the surface of the BP cover, etc.

- Some button operation cannot be accepted on some screens or during some processes.
- Use only dialysate concentrate containers with an appropriate label mentioning the composition of the concentrate. Respect the color code during the connection of the concentrates (red for A concentrate, blue for B concentrate).
- Technicians should use not contaminated tools and work under clean conditions
- When using Central venous catheters the following instructions must be followed. No other additional ME devices must be connected if these conditions are not fulfilled.
- Connect the dialysis system to a potential equalization conductor connection terminal of the Surdial X must be connected to the potential equalization of the electrical facility bus bar in order to avoid micro-shocks.
- If additional ME equipment is used, ensure that all leakage currents are below the limit as for CF applied parts.(below 10μA Max in normal conditions and below 50μA in single fault conditions.) This also applies for defibrillators. Which have no applied part type CF.
- Integrate all additional equipment to the potential equalization of the dialysis system
- This rule applies to all other electric ME equipment and non electric ME equipment (ex patient bed) which are used in the reachable area of the patient.

- Use disposable products with the CE marking only.
- Handle used disposables carefully to prevent infecting yourselves and other persons. Used disposables might be contaminated with viruses (hepatitis, aids, HIV, MRSA, …)
- To ensure the performance and safety of this unit, use water, dialysate concentrate, and fluid replacement with appropriate quality.

- The Blood Volume Measurement is a Class 1 laser product pursuant to IEC 60825-1: 2014. Read the instruction manual thoroughly before using the product.
- Operation and adjustment procedures which are not described in the instruction manual may lead to dangerous exposure to laser radiation.
- Disassembling the BVM module may result in exposure to Class 3B invisible laser radiation.

- Do not use broken or damaged BVM module.
- Do not stare at the invisible laser aperture through a mirror. It may hurt your skin or cornea.
- Physiological parameters which are measured by the BVM module are not intended for patient treatment or monitoring.
- As tests for the determination of the laser classification are limited to tests during normal operation, it may be the case for embedded laser products, that laser radiation above the AEL of the class of the product can become accessible during maintenance or service when the product is disassembled (see IEC60825-1 6.2.1).

Precautions

The following precautions should be noted when using this unit:

1. This unit should be operated by skilled personnel only.

2. Important notes concerning the installation of the machine:
   (1) Keep the unit out of water.
   (2) Only use the machine in normal conditions. Normal air pressure, temperature, humidity, wind, sunlight. No air containing dust, salt, sulfur…
   (3) Stability in terms of tilt, vibration, or impact (including those during delivery) should be taken care of.
   (4) Do not install the unit where chemicals are stored or gasses are generated.
   (5) Take care about the frequency, voltage, and allowed current /power consumption of the power source.
   (6) Connect the earth protection properly.
   (7) Confirm the default value of the treatment data and set intended parameter as necessary.

3. Important notes concerning the use of the machine:
   (1) Inspect touch panel sensitivity, polarity, dial settings, and meters. Verify that the machine operates properly.
   (2) Ensure that the earth protection is fully connected.
   (3) Verify that all cable connections are intact.
   (4) Exercise caution for concomitant use of equipment (including software and/or software applications), since it can result in false diagnosis or danger.
   (5) Re-examine the external circuit that will be connected directly to the patient.

4. Important notes concerning the operation of the machine:
   (1) Monitor the unit and patient for any abnormality at all times.
   (2) When an abnormality is discovered in the unit or patient, act appropriately (e.g., stop the operation after confirming the safety of the patient).
   (3) Do not allow the patient to touch the unit.

5. Important notes concerning the end of the treatment:
   (1) Turn the power off after returning operation buttons, dials, etc., to the original positions by the indicated processes.
   (2) Unplug the unit as necessary to remove from the power source.
   (3) When removing cables, do not apply inappropriate force such as pulling them by holding the cables.
   (4) Take care about the storage conditions:
      1) Keep the unit out of water.
      2) Store the unit in normal conditions. Normal air pressure, temperature, humidity, wind, sunlight. No air containing dust, salt, sulfur…
      3) Stability in terms of tilt, vibration, or impact (including those during delivery) should be taken care of.
      4) Do not store the unit where chemicals are stored or gasses are generated.

5) Clean accessories, cables, etc., and keep them in an organized way.
6) Ensure to keep the unit clean to be ready for the next use.

6. When the unit fails, do not attempt to fix it. Note the failure description on the machine and look for professional help.

7. Do not modify the unit nor any component thereof.
Do not modify the software included in the unit.
The manufacturer bears no responsibility nor liability in respect to modifications to the unit or any component thereof (including software and/or software applications) after the unit was connected to third party materials (including software and/or software applications), even when subsequently disconnected.

8. Maintenance (See on and after "Safety Precautions-16".)
(1) Ensure to maintain the unit and its parts.
(2) Ensure that the machine operates normally and safely after a long period out of use.

9. Check other handling precautions listed on the instruction manual of the unit.

Emergency Stop

⚠WARNING

- Before stopping the system emergently, ensure that it will not interfere with the treatment. If interference is a concern, stop the system after taking the necessary measures. Monitor the patient at all times even if treatment is complete.

Emergency stop using the I/O power key

In all processes, if abnormalities are found in the unit and if continued use of the unit would interfere with the treatment, press the I/O power key to turn off the system. (In such cases as the liquid crystal display is suddenly turned off, or the touch panel button does not work.)

⚠WARNING

- All movements in the liquid crystal display, dialysate circuit, blood pump, and heparin pump stop.

⚠CAUTION

- After recovering the system using the I/O power key, if abnormalities are found in the unit movements or it is impossible to continue using the unit, turn off the I/O power key and the power breaker to stop the unit. Contact the nearest branch or agency.

NOTE

- To operate the I/O power key, press it for more than 3.0 sec.

Emergency stop using the power breaker

When the I/O power key is turned on but the power breaker is turned off, the dialysis function stops and the power failure screen appears in the liquid crystal display. The power failure backup operation takes place thereafter.

⚠CAUTION

- When the I/O power key is turned on and the power breaker is turned off, the liquid crystal display, the touch panel, the blood pump, the single needle pump (option), the bubble detector, the heparin pump, the venous clamp and the arterial clamp operate in the power failure backup fashion. Turn off the Blood pump I/O button and Heparin pump I/O button when necessary. Additionally, the alarm buzzer goes off. Press the Mute key to mute.

Transporting the Unit and Prohibited Actions

⚠CAUTION

- Keep the transfer position when the unit is tilted more than 5 degrees. It can overturn.
- Hold the frame when the unit is lifted. Holding the cover may damage it and the unit may fall.

(1) Release 2 locks at the right front and the left front of the caster.
(2) Transport the unit in the stand up position (vertical to the floor).
(3) Always push the back of the unit when transporting.
(4) Four or more people should attend when the unit needs to be lifted. (Three people should lift it by holding the frame leg and the other person should support the head of the unit.)

NOTE

- Do not transport on a rugged road.
- If a bump of 1 cm or more is present, spread a flat board or iron plate that can support the weight of the unit on top of it before transporting or slowly jiggle the unit to go through the level difference.
- If a gap of 1 cm or more is present, spread a flat board or iron plate that can support the weight of the unit on top of it before transporting.
- All 4 casters should be in contact with the road when transporting.
- Support the front of the unit, because the center of mass is toward the back.
- When transporting on a slope, be sure to face the front of the unit on the mountain side.
- Ensure that no objects are in the way while transporting.
- When transporting by a track, do not lay the unit on its side.

Transfer position

Keep the transfer position described below for safety purposes when transporting the unit from room to room:

(1) Close all the covers.
(2) Stop water supply and central supply of dialysate to the machine from the facility.
(3) Open the System-Maintain-Flowchart screen and turn the “Forced Out” ON.
(4) Turn V46, V45, V43, V44, V53 and V35 ON, and turn these solenoid valves OFF several seconds later.
(5) Turn V48, V47, V29, V51, V53 and V35 ON, and turn these solenoid valves OFF several seconds later.
(6) Turn V55, V1, V10, V4 and V35 ON and confirm the pressure is released with the PD display value.
(7) Turn the Forced Out OFF.
(8) Turn off the I/O power key and the power breaker and disconnect the power plug from the power supply.
(9) Disconnect the LAN cable.
(10) Remove the supply/drainage line and the central hoses.
(11) Remove the blood circuit and the dialyzer.
(12) Put down the concentrate tank or unhang the concentrate bag
(13) Put down the chemical bottle.
(14) Remove all items on the tray and move the tray to the top of the unit.
(15) Unhang all items from the hanger.

Disposals

Disposal of the unit

The following are the precautions to be exercised when disposing the unit:

(a) Dispose resins (including the electric circuit board), rubbers, and electric wires as industrial wastes or in accordance with the rules practiced in your community.
(b) To distinguish iron from stainless steel, bring a magnet close to them: if attracted to the magnet, it is iron; if not, it is stainless steel. The surface of iron is painted or plated for anticorrosion.

Disposal of the Lead Acid battery for power failure backup

⚠DANGER

- The lead acid battery installed for power failure backup is specifically made for this unit. Connecting this battery in other equipment can cause it to leak, release heat, or burst.

Handling precautions

The lead acid battery can leak, release heat, or burst if the following precautions are not exercised. Be sure to take precautions.

-Do not throw it into fire or apply heat.
-Do not connect the positive and negative sides with metals, such as wire.
-Do not remove or scratch the external tube.
-Do not apply strong shock or throw it against an object.
-Do not disassemble or modify.

NOTE

- The lead acid battery is a consumable. It deteriorates in long-term use.
- The battery deteriorates even if the power failure backup operation is not performed.

⚠DANGER

- If fluid inside of the lead acid battery and lithium battery contacts eyes, it can result in blindness. Do not rub. Wash the eyes immediately with water. Receive treatment from a physician without delay.
- If fluid inside of the lead acid battery contacts skin or clothes, it can damage the skin. Wash it off with clean water without delay.

Upon disposing the product

Used lead acid battery is a valuable resource. Stick a tape on the terminal or connecting cord and bring it to the recycle shop that accepts lead acid batteries.

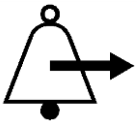
Symbols

Follow instruction manual

Degree of protection against electric shock: Type B

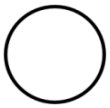
Degree of protection against electric shock: Type BF

Connector for nurse call button



Central alarm output

Power switch – ON



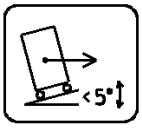
Power switch – OFF

Stand-by or preparatory state for a part of device

Alternating current

Protective earth terminal

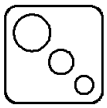
Potential equalization conductor connection terminal



Keep transport position when moving the device on more than 5-degree slope .

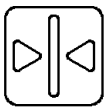
Alarm sounds mute switch

Blood pump switch
Green – ON
Red – OFF



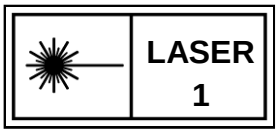
Bubble detector

Blood sensor



Clamp

Warning label: Hazard symbol for hazardous Laser Radiation (IEC60825-1:2014)



BVM module is a Laser Product Class 1 (IEC60825-1:2014)

This document is usable with the software version “1.506”. Check the list below for compliance with the software version and this document before use. The software version can be checked on the startup screen.

Document ID Number (as described on the rear cover)	Software Version
DN1138-2004	1.506

Precautions to be taken before handling

⚠CAUTION

- Do not connect the equipment to a patient during maintenance.

Service technician

Only Service technician who received a technical training of dialysis machines from Nipro, are allowed to maintain the machine. Otherwise, a person who is being supervised by a trained technician, is allowed to maintain the equipment.

Well-planned maintenance

Use of the equipment without planning maintenance, can decrease work efficiency and cause injury, accident, and errors. It can also interfere with the original purpose, maintenance. Schedule the time to maintain the equipment, and prepare necessary tools, parts, testing equipment, and documents in advance.

Clothes

Try to minimize injury and accident by wearing appropriate clothes to work on the equipment. Select clothes that do not attract a lot of electrostatics. Avoid exposing skin even if the surrounding temperature is high.

Handling the equipment

Work in accordance with the instructions. Read the attached Instruction Manual carefully. Transport and handle the equipment in accordance with the Manual.
Be sure to check the electric power line, water supply/drainage line, and other connection lines before working on the equipment.

Replacement parts

Use the parts specified by the manufacturer.

Liability for readjustment and repair

A person who readjusted or repaired unit or any component thereof (including software and/or software applications) is liable for consequential events. This includes modifications to the unit or any component thereof (including software and/or software applications) resulting from the connection to third party materials (including software and/or software applications), even when subsequently disconnected.

Daily inspection by operator

Check the following items before and after using the equipment on the same day.
Ensure normal operation of the equipment.

(1) There not being Abnormality, such as leakage around the equipment.
Check for loosening of clamps for the water supply opening and drainage opening hoses.
(2) There not being residual chemical solution.
(3) Residual quantities of disinfection or acetic acid solution being enough.
(4) Consumption of disinfection or acetic acid solution being reasonable.
(5) The real concentration of dialysate being reasonable.
(6) There not being abnormal sound, a bad smell, over heat.
(7) Foreign substance such as disinfectant stain on the equipment exterior.
(8) Dialysate stain on the equipment. A dialysate stain can cause rust. Wipe it off immediately.
(9) Abnormality when the start-up test is performed.
(10) If the equipment will be in operation overnight, ensure that the coupler is fit firmly on the coupler holder.
(11) Confirm that the equipment detects the coupler switch signal.
(12) The syringe must be filled with the preset infusing volume.

Monthly inspection

Clean the air filter of the fan.

Maintenance and inspection by service technician

Check the working hours. Perform a periodical inspection every 24 months.
See “Maintenance and Inspection Log” for items to be inspected.

Maintenance by service technician

Check the working hours. The service technician should maintain the hydraulic line and electrical board every 24 months.

Inspection after long-term storage

Before starting dialysis treatment after more than 1 month of storage, a disinfection and a water rinse of minimum 1 hour is required.
Also maintain and inspect the equipment in accordance with “4. Maintenance and Inspection Instructions.”

Technical Safety Inspection / Maintenance

The checks must be performed by the manufacturer's service support organization or a person authorized by them.
The person who maintains and inspects (a service technician or NIPRO personnel) must record the results in accordance with the instructions described in “Technical Safety Inspection / Maintenance”.
The Technical Safety Inspection should be implemented at least once every 24 months; maintenance every 24 month. All controls and comparisons should be carried out in warm condition (e.g. 5 Minutes rinse)! If defects or wear are detected, please exchange the worn parts and examine the item again. The Technical Safety Inspection, the maintenance procedures and further explanations on how to perform them are included in the Service Manual.

⚠CAUTION

- Dialysate and body fluid can cause infection. Never exchange parts before disinfection the hydraulic lines.

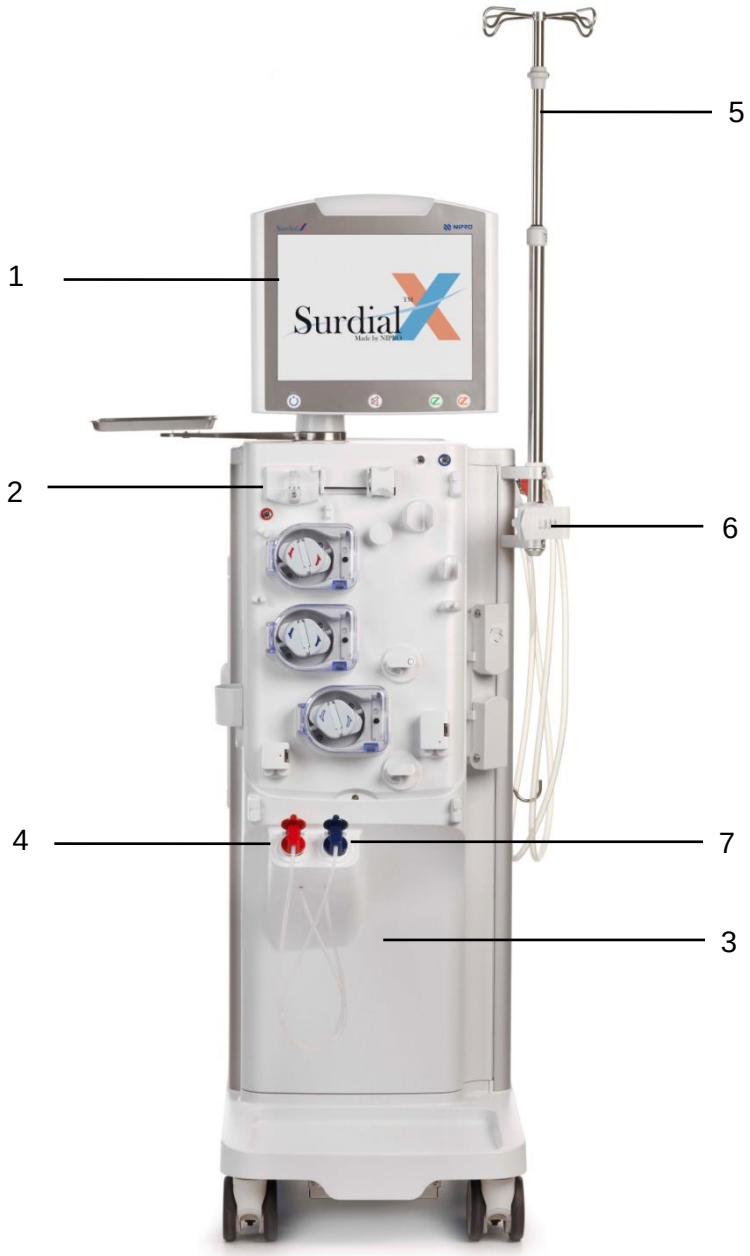
NOTE

- Execute maintenance and inspection, make sure to keep the maintenance record, and store the record properly.

Contents

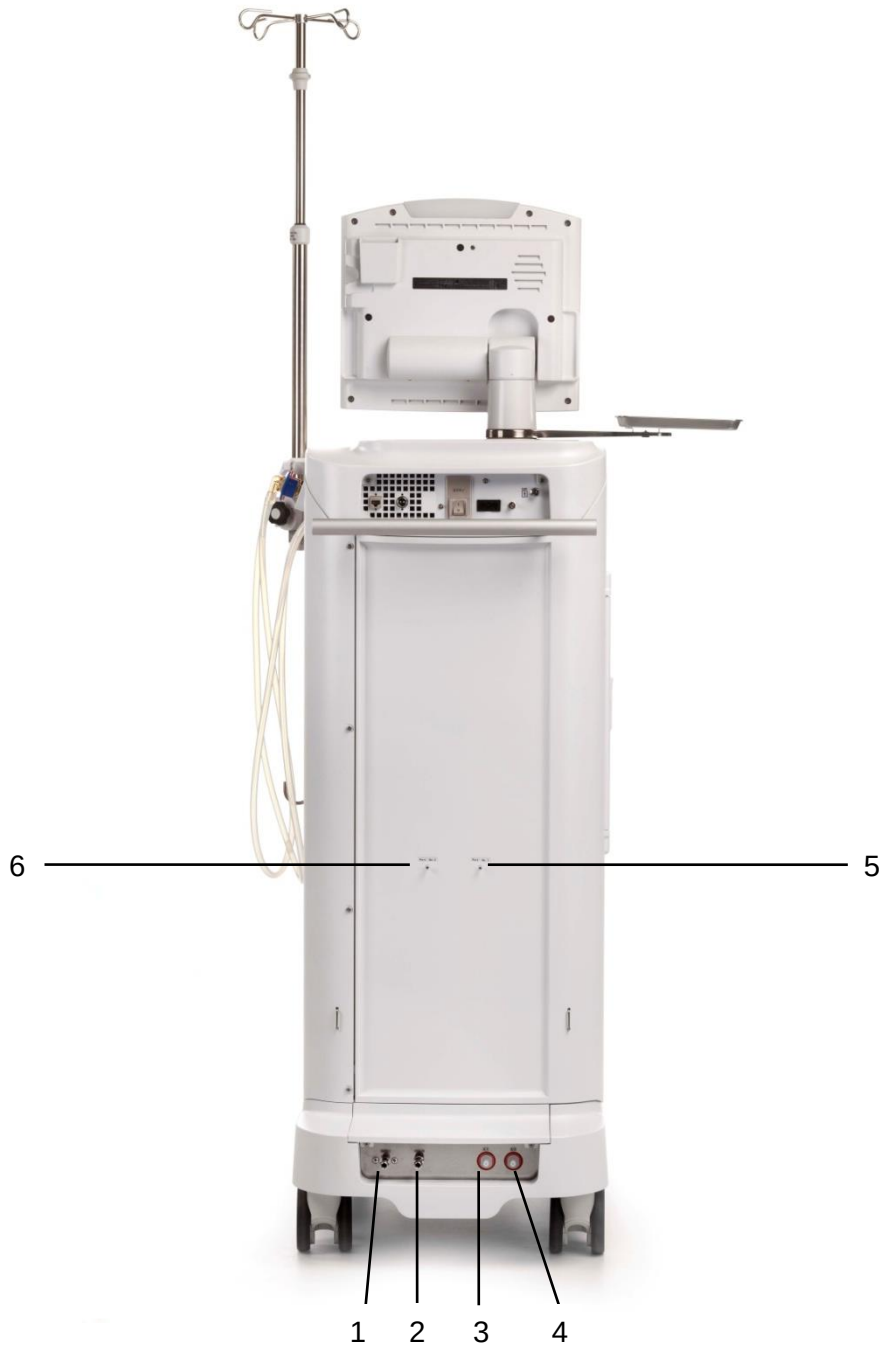
1. Unit configuration

1.1. Front view (General overview)



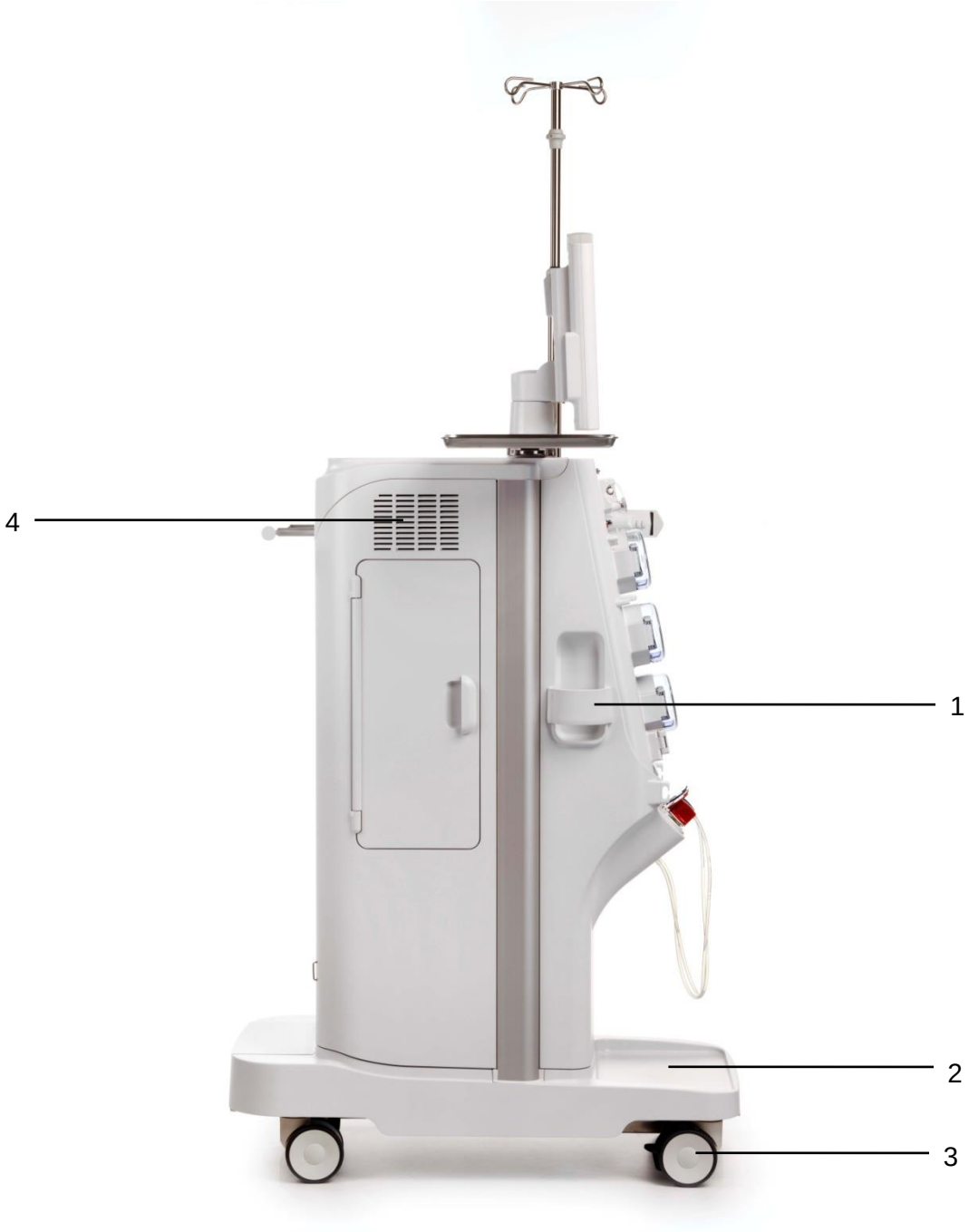
1 Monitor
2 Extracorporeal blood module
3 Hydraulics
4 Concentrate suction tube(White/Red)
5 IV pole
6 Dialyzer holder
7 Bicarbonate suction tube(Blue)

1.2. Rear view (General overview)



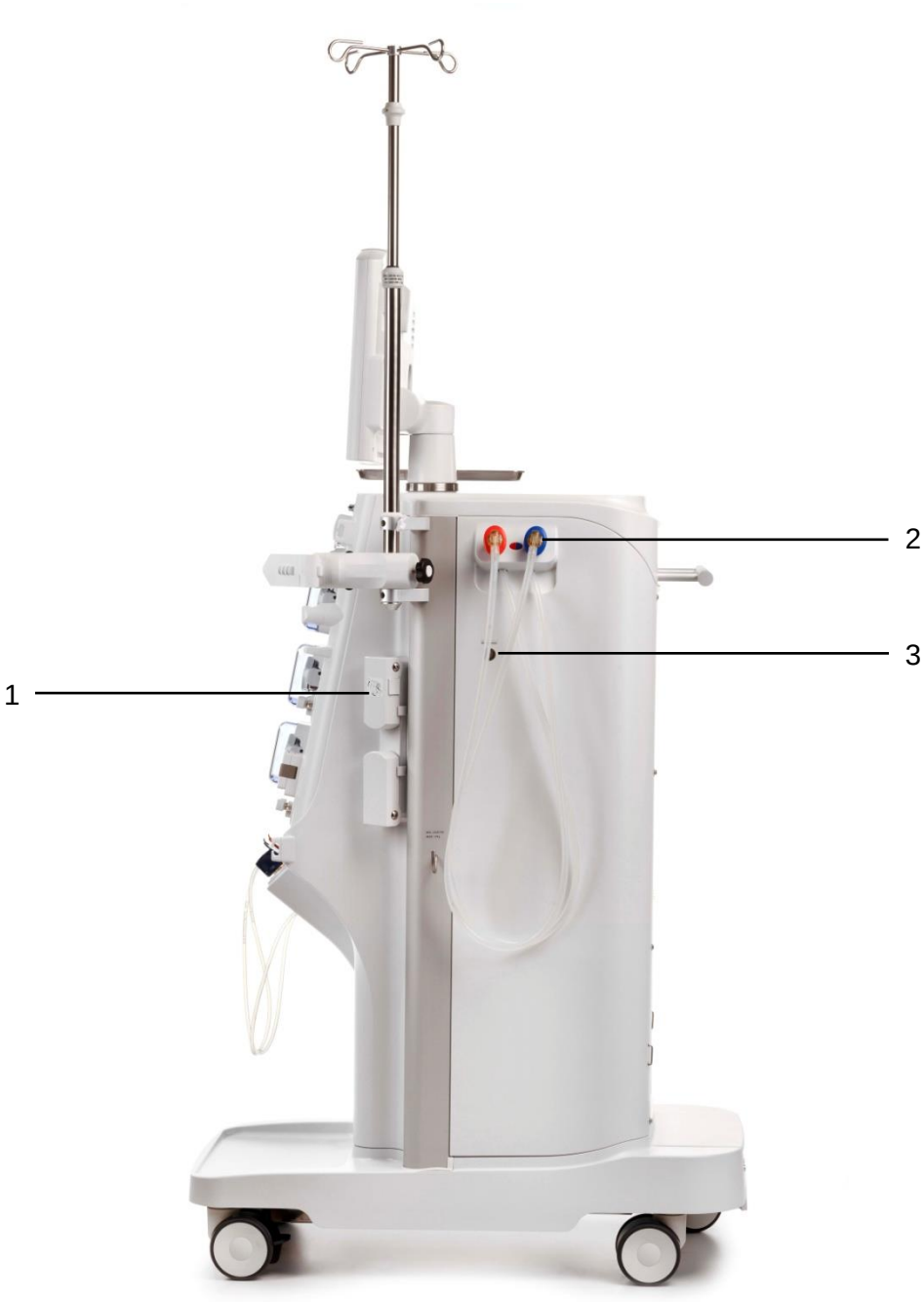
1 Water supply opening
2 Drainage opening
3 A1 port
4 A2 port (Option)
5 Disinfectant connector
6 Acid connector

1.3. Lateral view, left side (General overview)



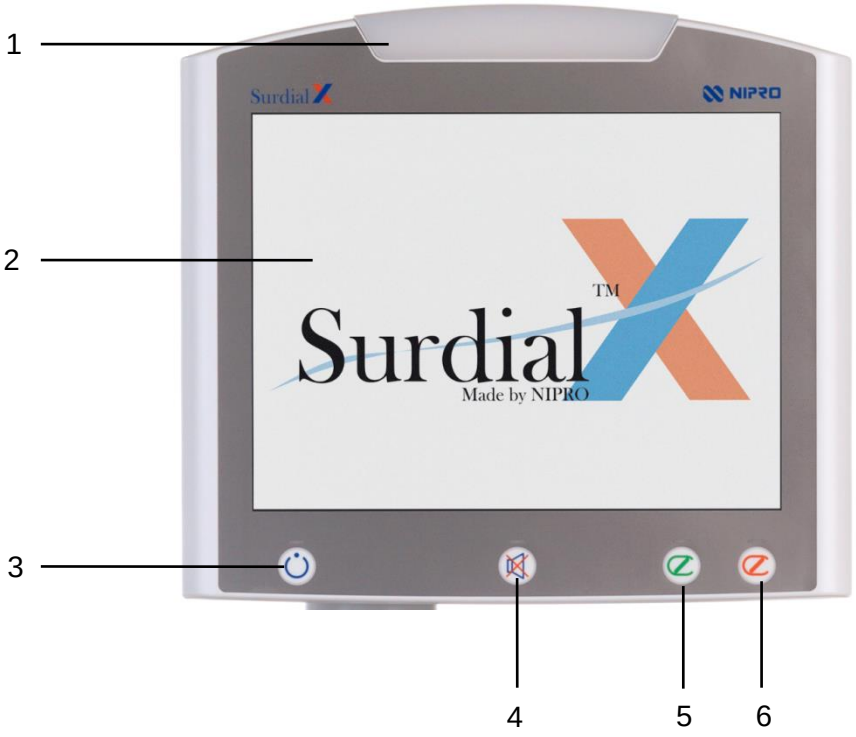
1 Cuff holder
2 Concentrate rack
3 Caster
4 FAN

1.4. Lateral view, right side (General overview)



1 Powder bicarbonate cartridge holder
2 Dialysate coupler module (bypass bridge)
3 Sample port

1.5. Monitor front



1 Operating mode indicator

2 Screen

3 I/O power key

The unit will be ready for use when the power breaker at the back of the unit and the I/O power key at the front are pressed.

Turning the I/O power key off stops all functions of the unit.

(The battery charging circuit, etc. is partially energized at this time.)

4 Mute key

The alarm buzzer which sounds in case of an alarm is stopped.

5 Blood system start

The blood pump is started.

6 Blood system stop

The blood pump is stopped.

I/O power key

The device will be ready for use when the power breaker at the back of the device and the I/O power key at the front are pressed. A green light will be lit when the I/O power key is pressed.

Turning the I/O power key off stops all functions of the device. Power failure backup operation stops also.
The I/O power key must be pressed for more than 3 seconds.

NOTE

- The following is relationships between the power breaker and the I/O power key:

		I/O power key	
		ON	OFF
Power breaker	ON	Normal operation	Stops operation Battery charged
	OFF	Blackout operation	Stops operation Battery not charged

When “Memory back up” is set to ON, a system status at the time of I/O power key off is stored so that the following status is restored when the I/O power key is turned ON next (to start the system).

When the I/O power key is turned off after patient connection, device restored from the state before the I/O power switch is turned off.

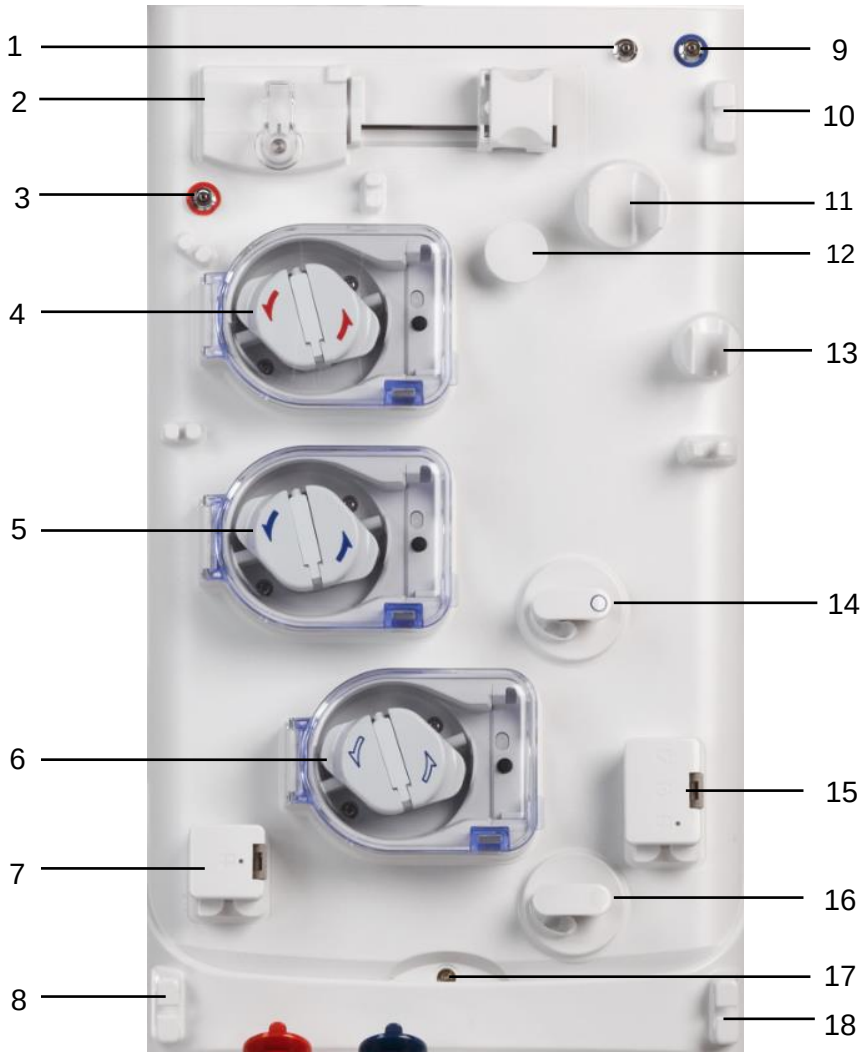
⚠CAUTION

- Before restarting operation, always check information in the message. After restarting operation as well, always check setting parameters and status of switches related to treatment.

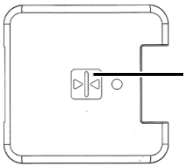
1.6. Monitor rear

1 Speaker
2 Recessed handle
3 Card slot (Option)

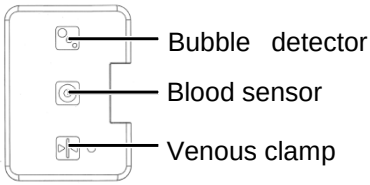
1.7. Extracorporeal blood module



1 SN pressure port
2 Heparin pump
3 Arterial pressure port
4 Blood pump
5 Single needle pump (Option)
6 Substitute pump (Option)
7 Arterial clamp box

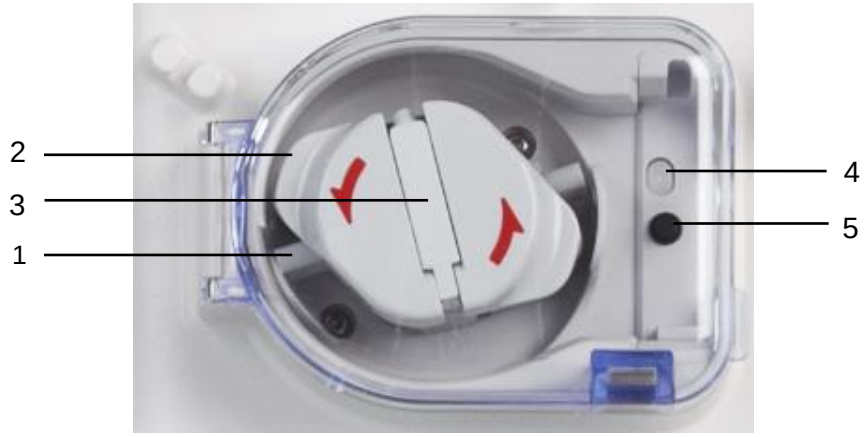


8 Line holder
9 Venous pressure port
10 Line holder
11 Drip chamber holder (Option)
12 Line guide
13 Drip chamber holder
14 Substitute port (Option)
15 Venous clamp box



16 Drain port
17 Leak sensor
18 Line holder

1.8. Blood pump, single needle pump, substitution pump and heparin pump

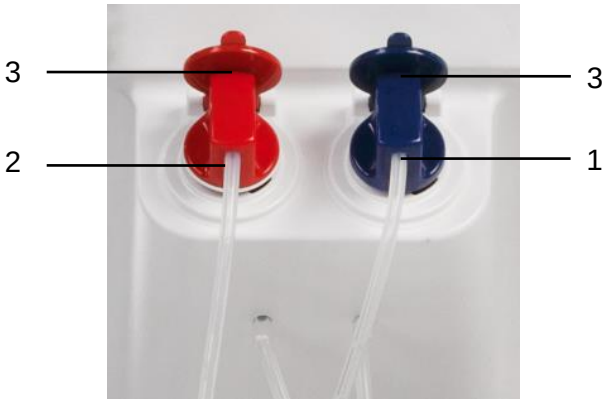


1 Tube guide
2 Rotor
3 Lever
4 Eject pin(Option)
5 Connector Switch(Option)

6 Syringe holder
7 Syringe stopper
8 Pusher

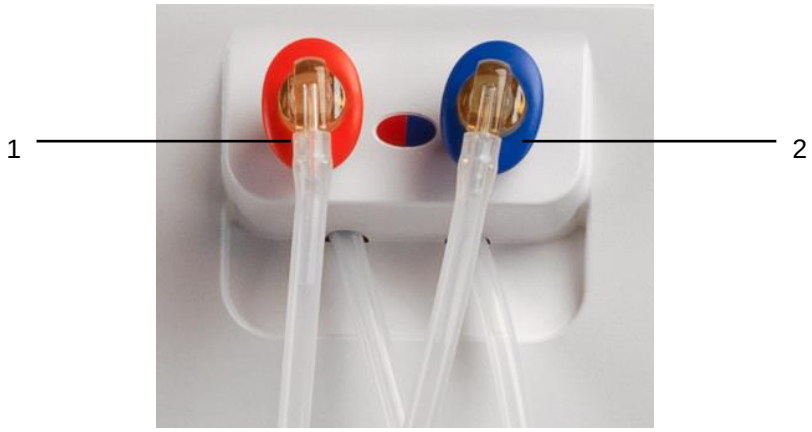
To move the pusher (8) push in and slide to the desired position.
The end of the syringe has to be pushed into the slide of the pusher (8).
Fix the syringe with syringe stopper (7).

1.9. A and BIC concentrate suction tube and rinse ports (concentrate module)



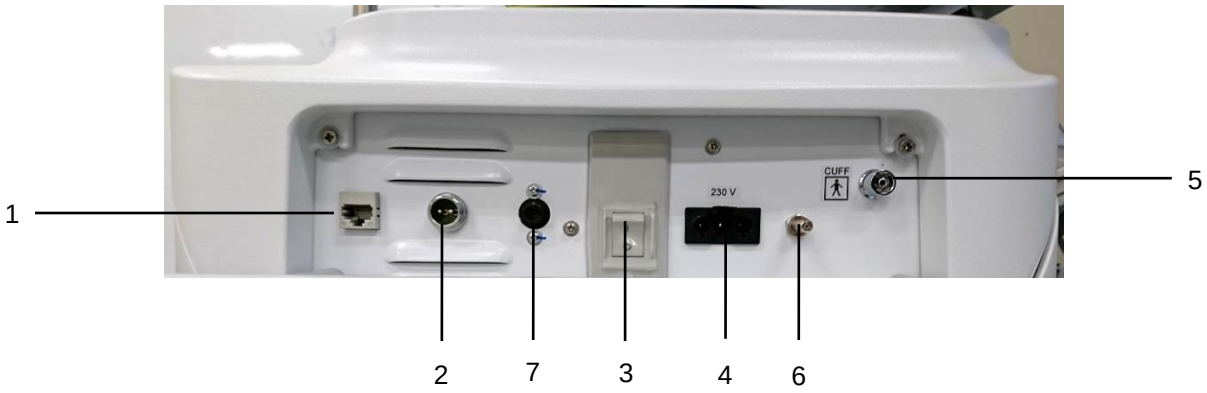
1 BIC concentrate suction tube (Option)
Turn anti clockwise to open and clockwise to close
2 A concentrate suction tube
Turn anti clockwise to open and clockwise to close
3 Concentrate flap

1.10. Dialyzer couplers and dialyzer coupler ports (dialysate module)



1 Dialysate return line(dialyzer coupler red)
2 Dialysate supply line(dialyzer coupler blue)

1.11. Power source components



1 LAN connector (Option)
For connecting to the NIPRO dialysis information management system

2 BPM remote button connector (Option)
For connecting the maker-specified blood pressure measurements module remote butt (NBR-8A-C: AIPHONE. Inc.）

3 Power breaker

4 Power cord connection
For connecting the maker-specified power cord with plug

5 Cuff connector (Option)
For connecting the maker-specified blood pressure measurement cuff
Refer to '14 Blood pressure monitor'

6 Potential equalization conductor connection terminal

7 Central Alarm Output connector (Option)

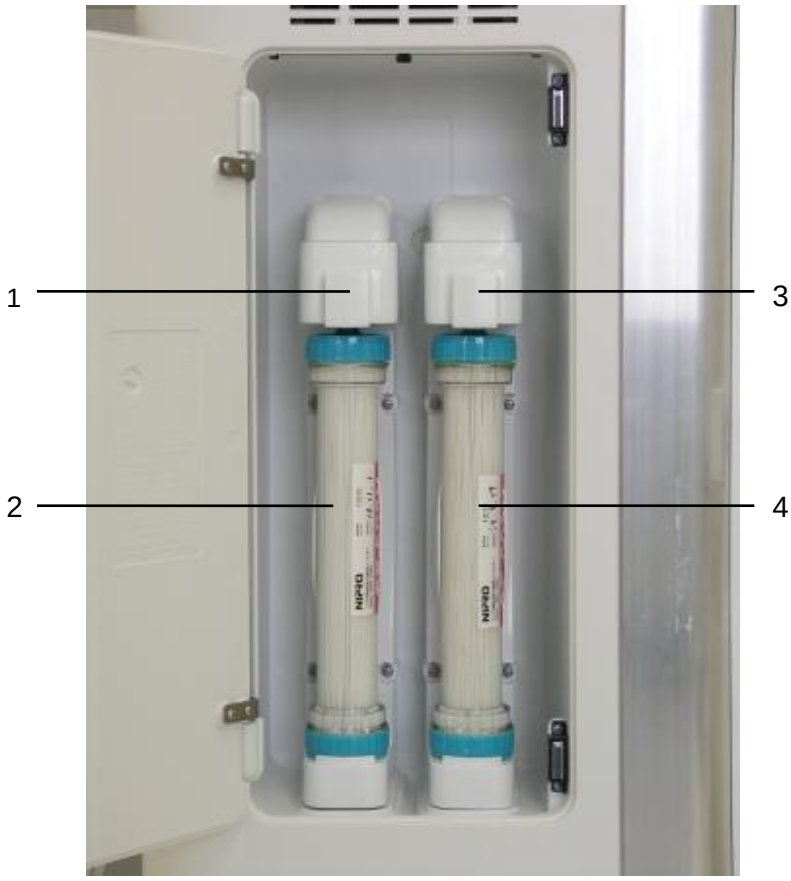
⚠WARNING

- This module and externally connected devices are not expected to be used as distributed alarm system stipulated in IEC60601-1-8.

⚠CAUTION

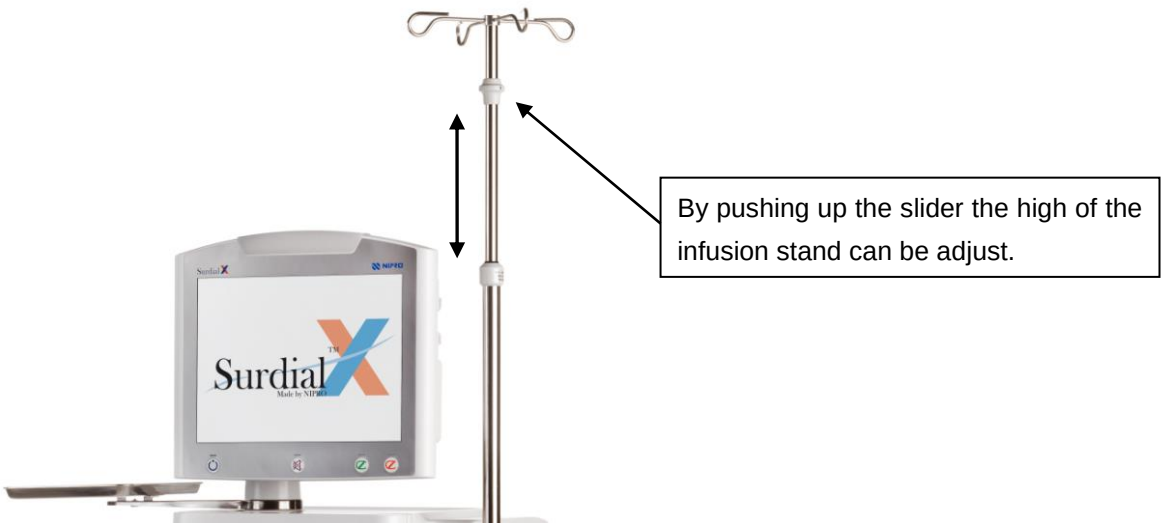
- Do not connect any external connection equipment other than the maker-specified. Doing so may cause malfunction or breakage of the equipment. The manufacturer bears no responsibility nor liability in this respect.
- Use a power plug suited to the electric rating designated on the nameplate. Otherwise, it may cause malfunction or breakage of the equipment.
- As for external connection equipment, connect such equipment in accordance with applicable IEC standards.
  (Example: IEC60950-1 for data processing equipment or IEC60601-1 for medical equipment)
  Personnel in charge of external equipment connection must take responsibility for the medical system configuration to meet the requirements of IEC60601-1. In case of any question or doubt, contact your nearest branch or sales office.

1.12. CF and CF coupler



1 CF1 holder
2 CF1
3 CF2 holder (Option)
4 CF2 (Option)

1.13. Adjust the IV pole



2. Message display monitor

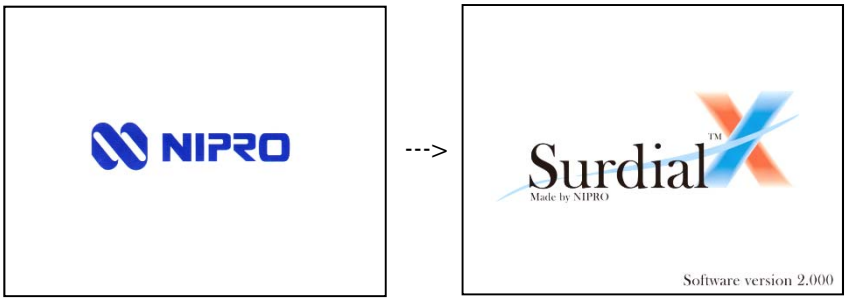
⚠CAUTION

- Some button operation cannot be accepted on some screens or during some processes.

2.1. At machine start-up

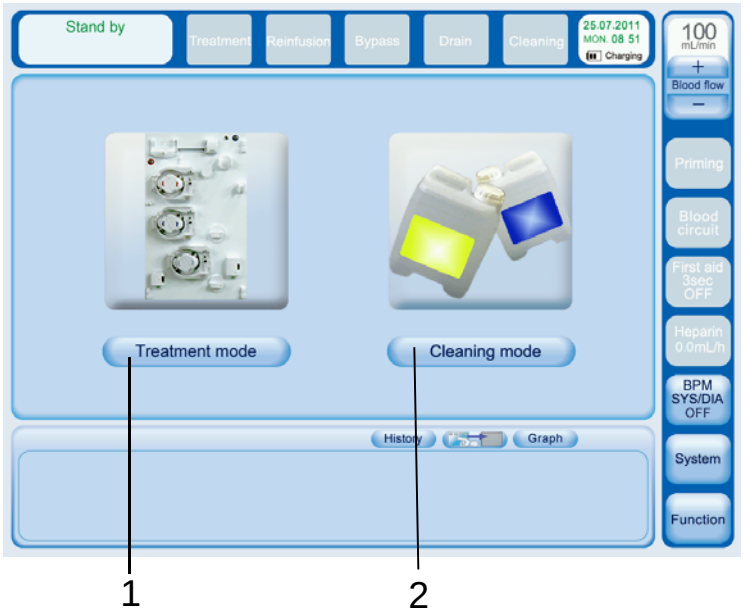
2.1.1. Start-up screen

Model name and software version are displayed.



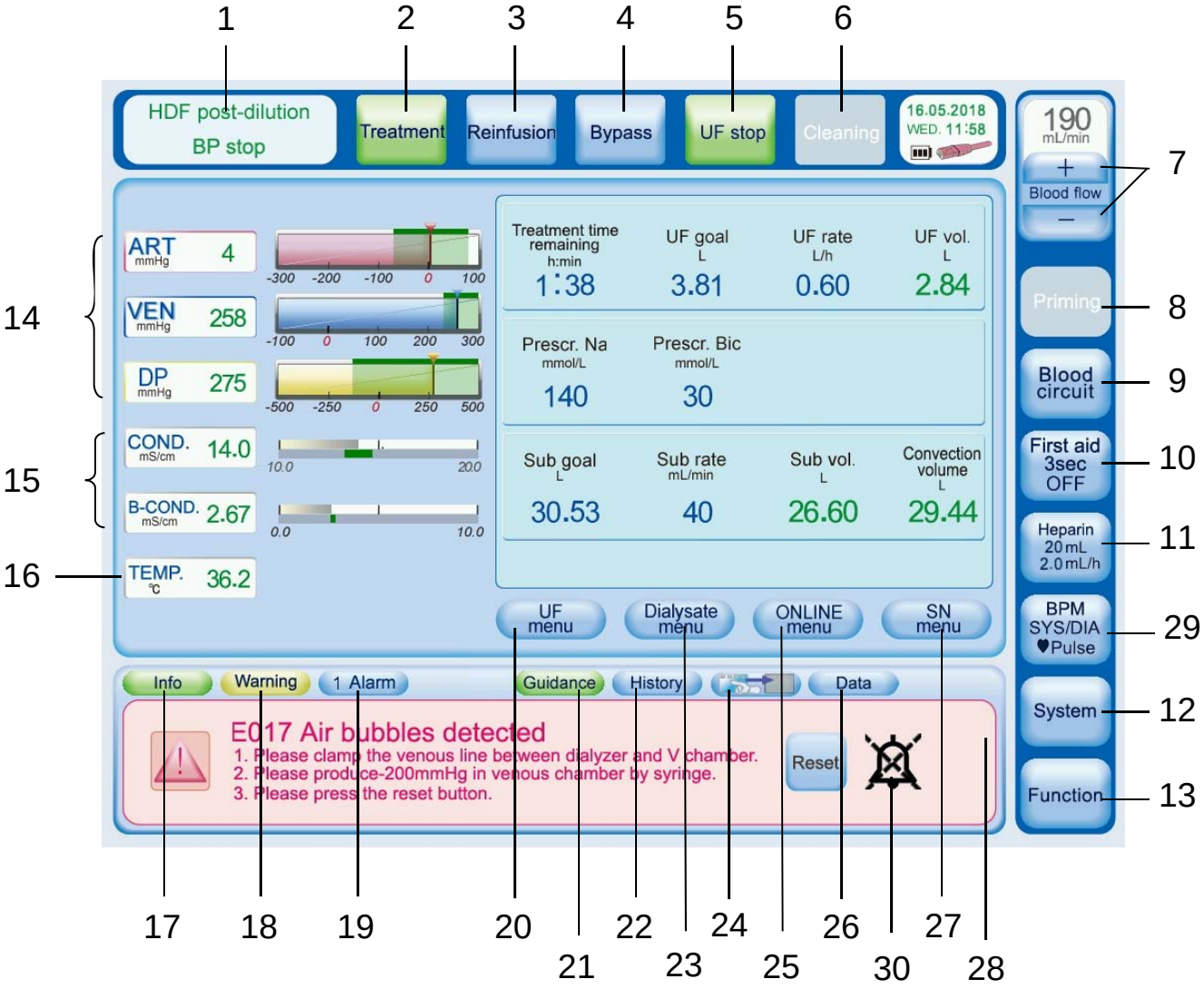
2.1.2. Selection screen

Select "Treatment mode" or "Cleaning mode".



No.	Name	Function
1	Treatment mode button	Button to go to Treatment mode
2	Cleaning mode button	Button to go to Cleaning mode

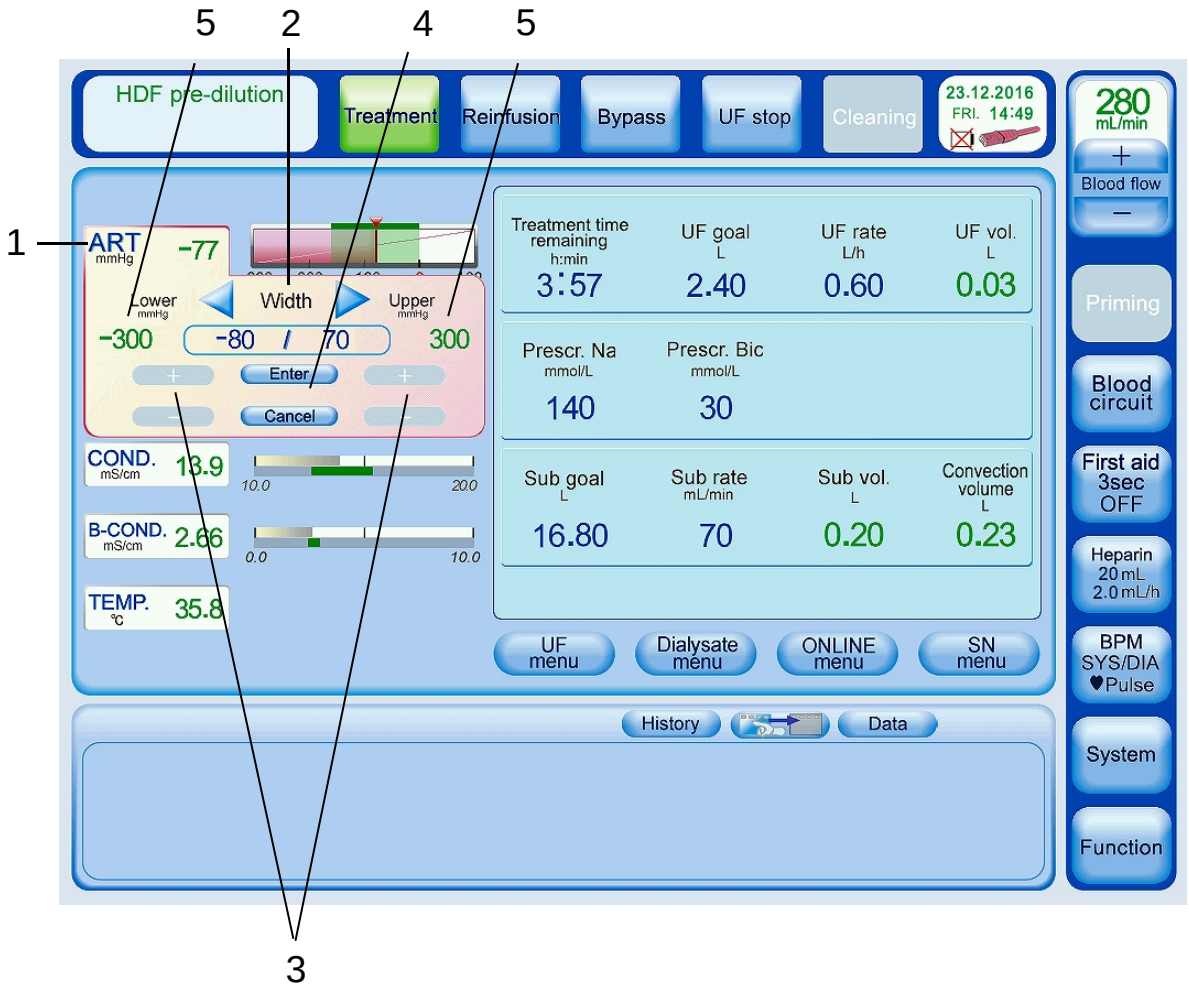
2.2. Treatment screen



No.	Name	Function
1	Operating mode	Operation mode is displayed (i.e. On-Line HDF).
2	Treatment button	Button to go to Treatment process from Preparation complete process and Reinfusion process
3	Reinfusion button	Button to go to Reinfusion process from Treatment process
4	Bypass button	Button to run dialysate via bypass during Preparation complete process, Treatment process and Reinfusion process
5	Drain button UF stop	Button to drain dialysate during Preparation complete process and Reinfusion process Button to stop UF during Treatment process
6	Cleaning button	Button to go to Cleaning mode from Preparation process, Preparation complete process and Reinfusion process
7	Blood flow +/- switch	Switch to change blood flow setting of blood pump
8	Priming button	Button to open Priming screen
9	Blood circuit button	Button to open Liquid adjustment screen on which you can adjust level of chambers
10	First aid button	If this button is pressed, some predetermined operations start.
11	Heparin button	Button to open menu screen about heparin
12	System button	Button to open System setting screen
13	Function button	Button to open Function setting screen
14	Pressure displays	Display boxes for actual arterial pressure, venous pressure and TMP. Touch the display box to open the Alarm Setting window.
15	Conductivity displays	Display boxes for actual dialysate conductivity and B concentrate conductivity. Touch the display box to open the Alarm setting window. The alarm setting values are not able to change.
16	Temperature display	Display box for actual dialysate temperature. Touch the display box to open the Alarm Setting window. The alarm setting values are not able to change.
17	Info button	Button to display information such as startup test result, operation manual and so on
18	Warning button	Button to display warning
19	Alarm button	Button to display alarm
20	UF menu button	Button to open UF menu screen
21	Guidance button	Button to display guidance
22	History button	Button to display treatment history
23	Dialysate menu button	Button to open Dialysate menu screen
24	Monitor symbol button	Button to disable button operation for a specified time To activate: push 3 sec. (some seconds: fe. to clean the screen.)
25	ONLINE menu button	Option ONLINE HDF; see chapter 13 option
26	Graph button	Button to display graph such as UF Na diagram and Pressure graph
27	SN menu button	Option Single needle pump; see chapter 12 option
28	Message display	Display area for various messages
29	BPM	Option BPM; see chapter 14 option
30	Audio paused symbol	Symbol indicating that the audio is paused

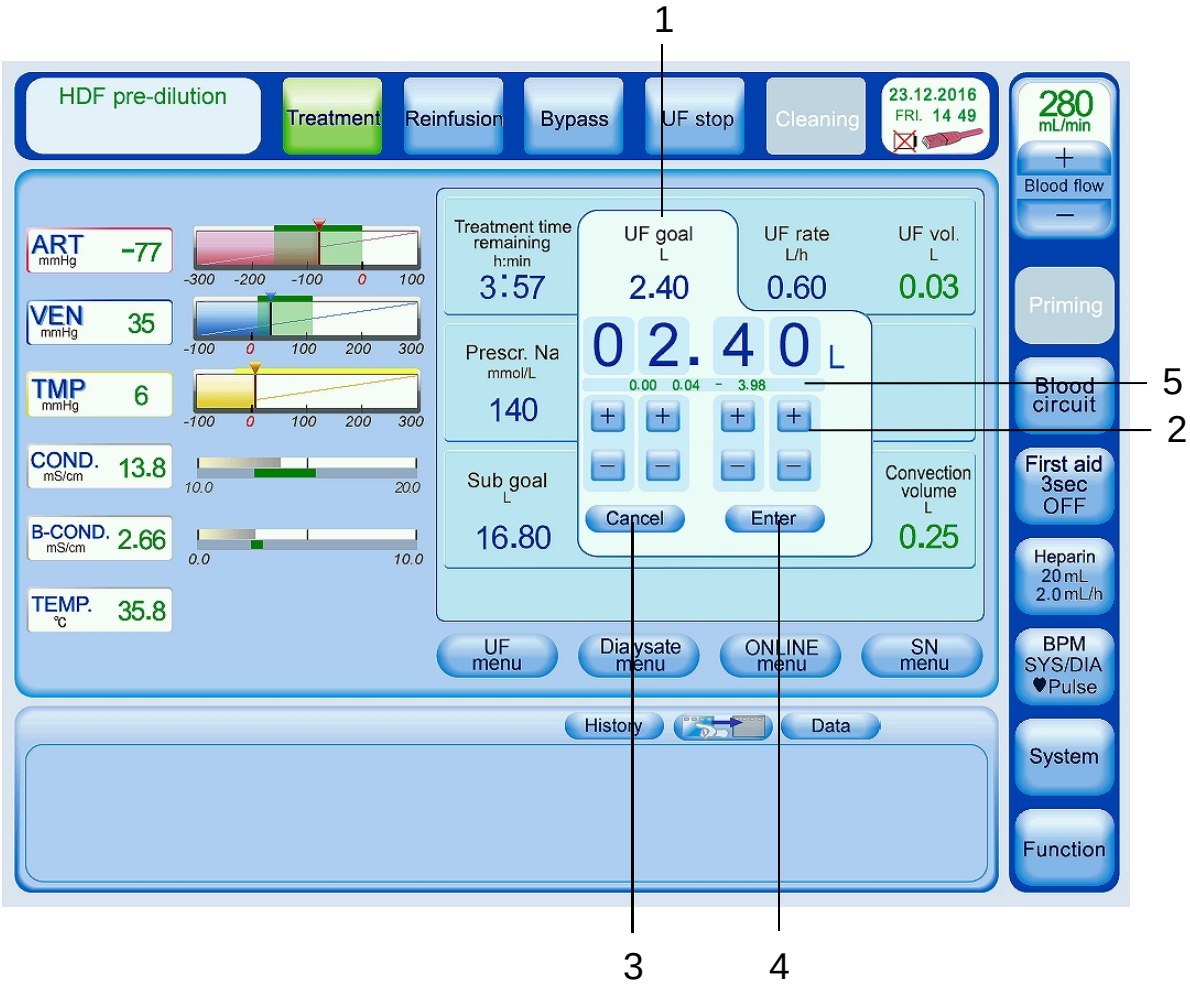
2.3. Examples for data entry (Treatment data)

Example: Arterial pressure alarm setting



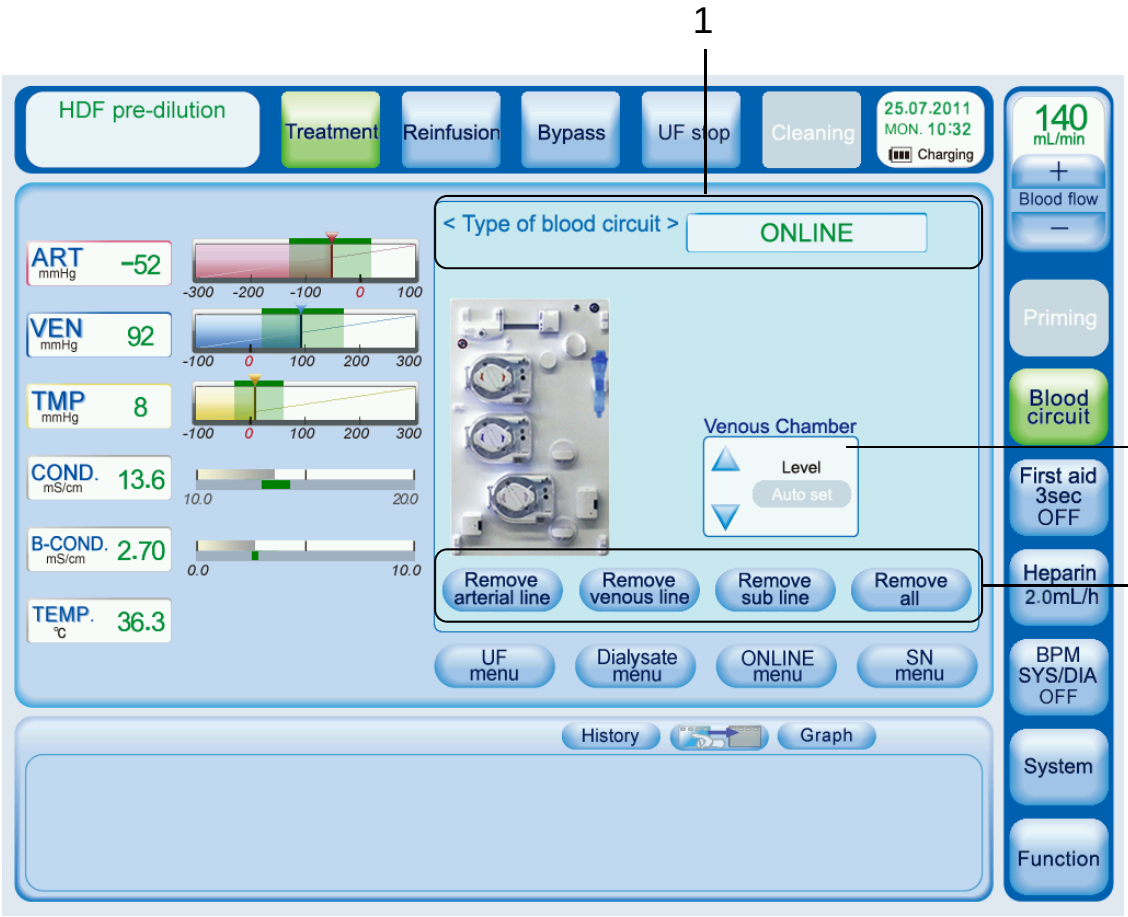
No.	Name	Function/Operation
1	Arterial pressure display	Touch the Pressure display box. The Alarm setting window will appear.
2	Width setting switch	Switch to change display range (width).
3	+/- switch	Switch to set the upper and lower limit for alarm
4	Enter button	Button to confirm the setting
5	Input limits	No values outside can be entered

Example: UF goal setting



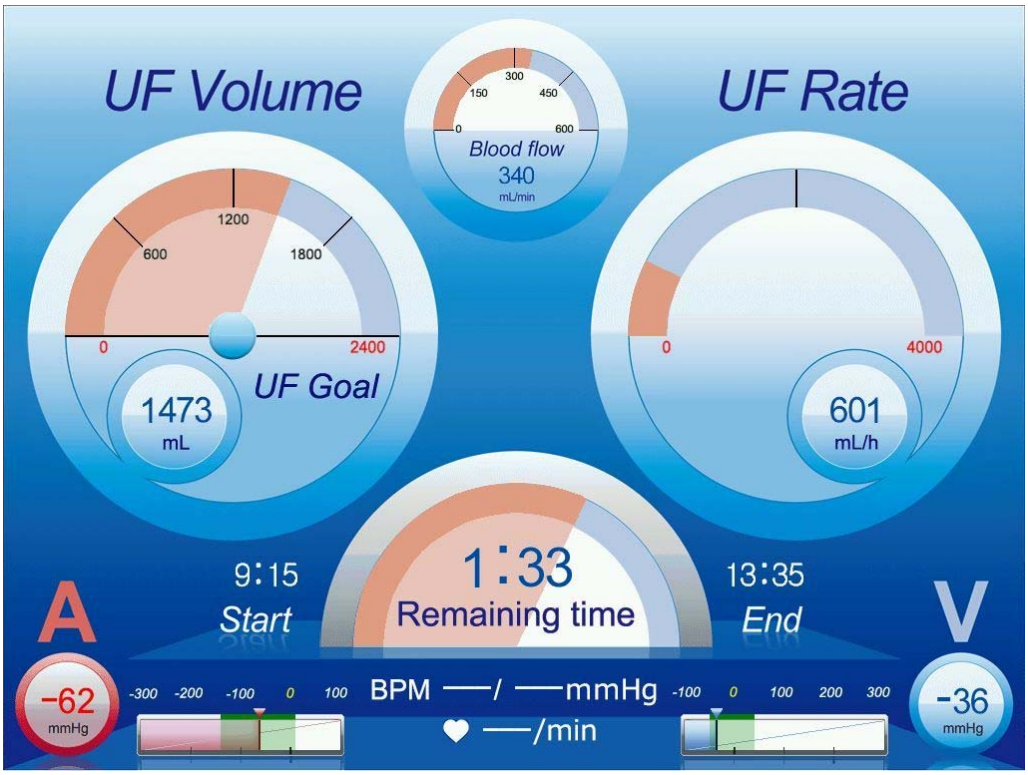
No.	Name	Function/Operation
1	UF goal display	Touch the UF goal display box. UF goal setting window will appear.
2	+/- switch	Switch to set the value for each digit
3	Cancel button	Button to cancel setting change
4	Enter button	Button to confirm setting
5	Input limits	No values outside can be entered

2.4. Level adjustment screen



No.	Name	Function/Operation
1	Treatment mode display	Types of treatment are displayed.
2	Level adjust switch	Switch to adjust liquid level
3	Remove line buttons	Button to remove blood line

2.5. Screen saver (Silent - screen)



Data displayed

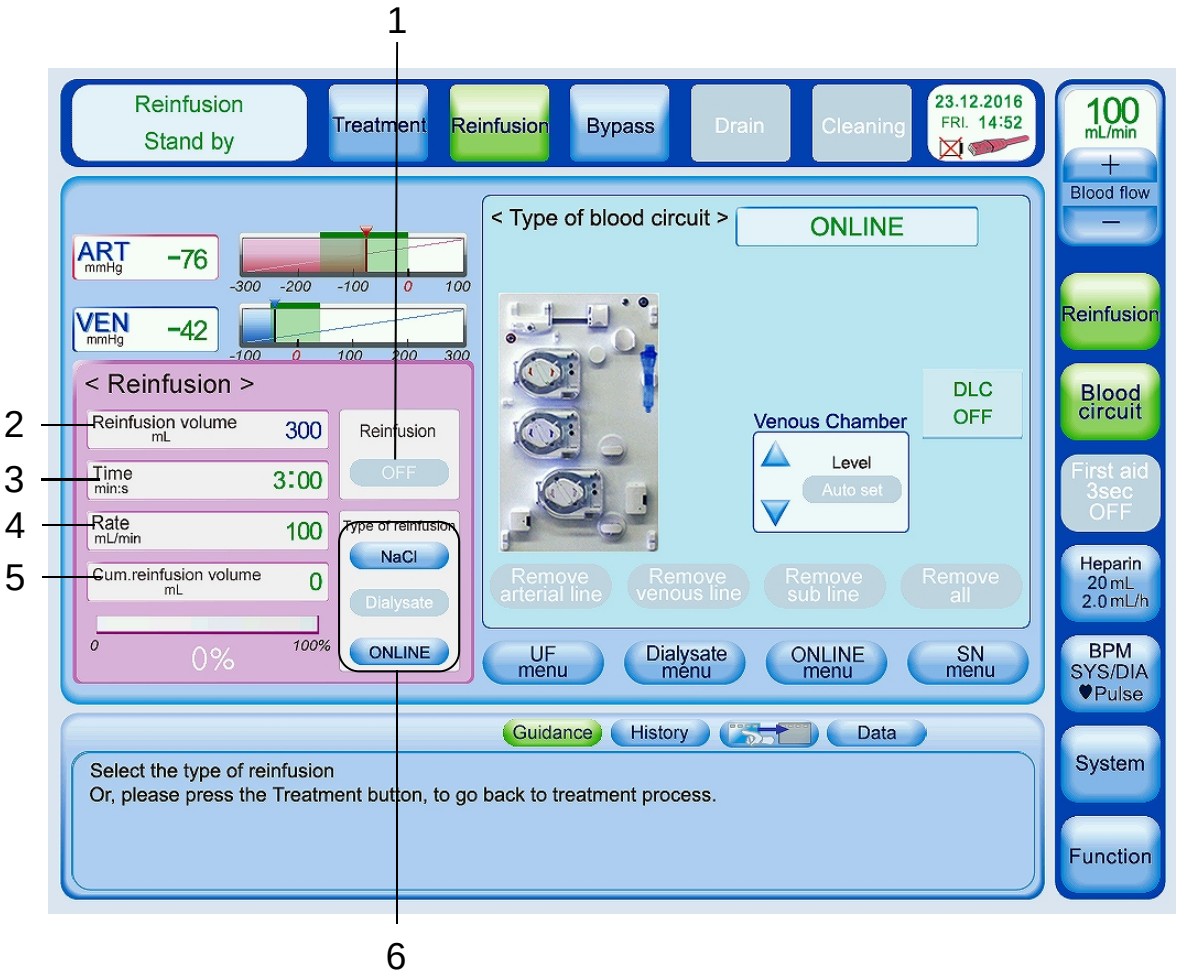
- UF volume, UF rate, UF goal
- Arterial pressure and Venous pressure
- Blood flow
- UF start time, UF remaining time, and UF goal time
- Blood Pressure Monitor (only when Blood pressure option is selected.)

This screen is activated during periods of user inactivity on the Treatment screen.
Time to activate can be set by an operator.

This screen disappears:

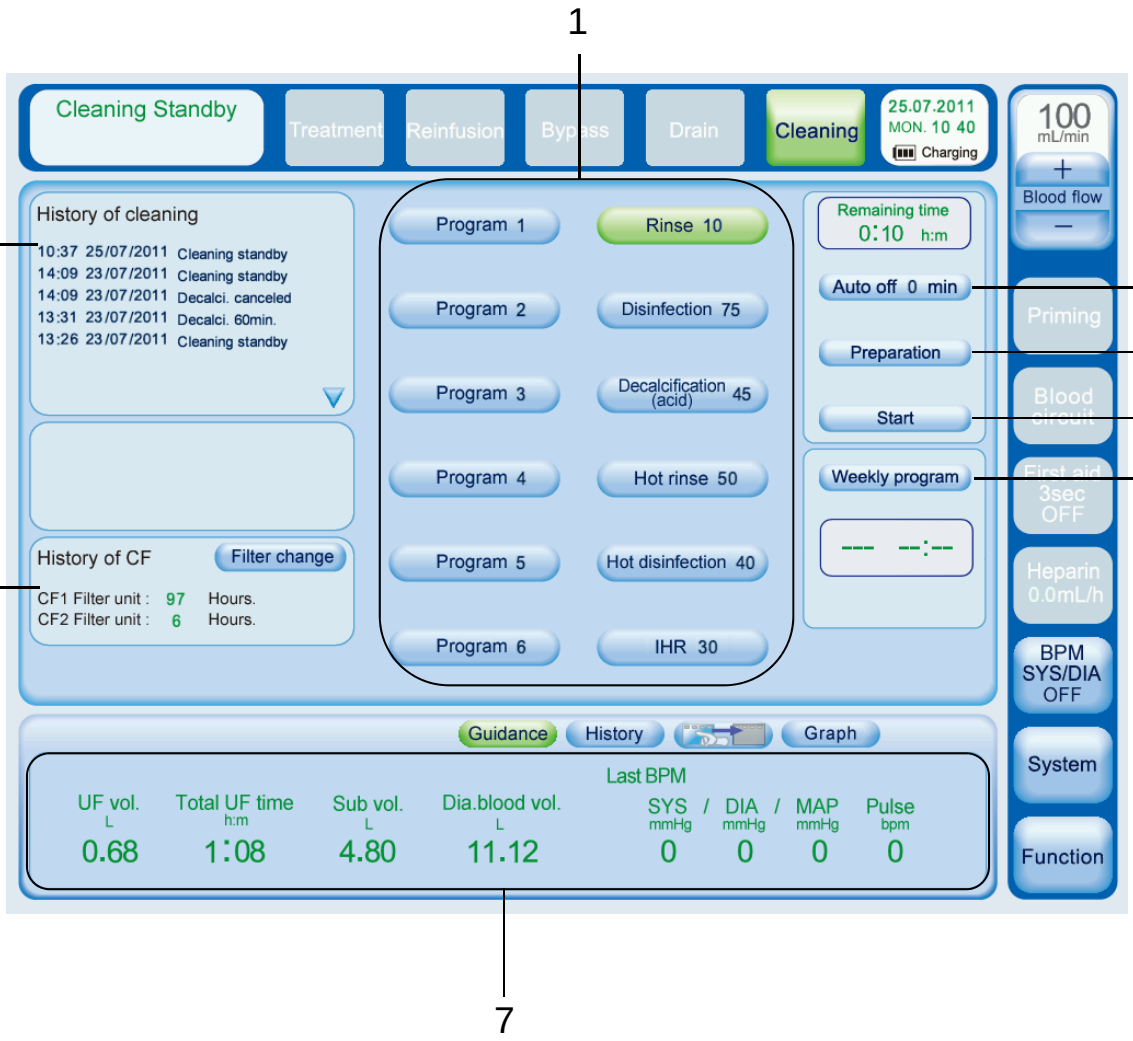
- when screen is touched
- when information or alarm should be displayed.
- when blood pressure starts to be measured.

2.6. Reinfusion screen



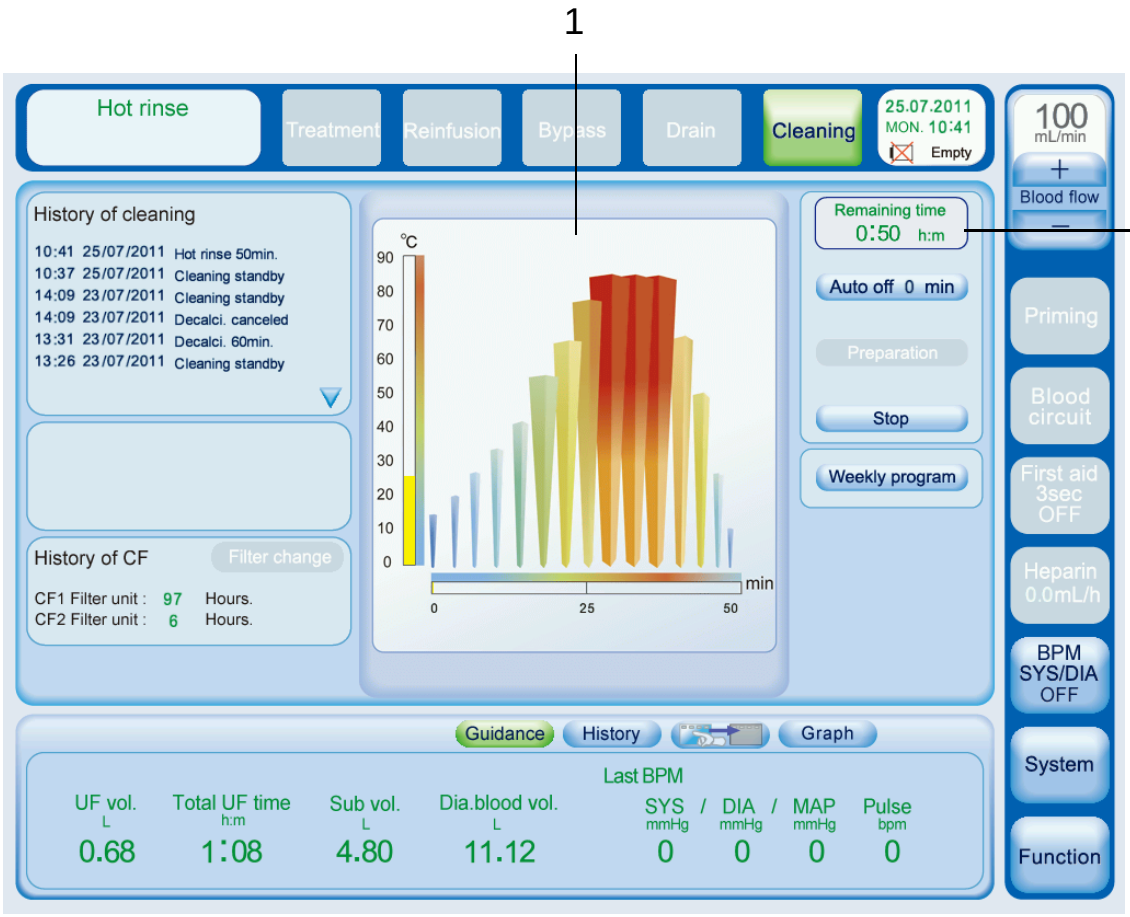
No.	Name	Function/Operation
1	Reinfusion I/O button	Button to start/stop reinfusion
2	Reinfusion volume display	Target reinfusion volume is displayed. Target reinfusion volume can be set by touching the reinfusion volume display box.
3	Reinfusion time display	Reinfusion remaining time is displayed
4	Reinfusion rate display	Reinfusion rate is displayed
5	Cum. Reinfusion volume display	Cumulative reinfusion volume is displayed.
6	Type of reinfusion	Button to select reinfusion type (NaCl or Dialysate or ONLINE)

2.7. Cleaning standby screen

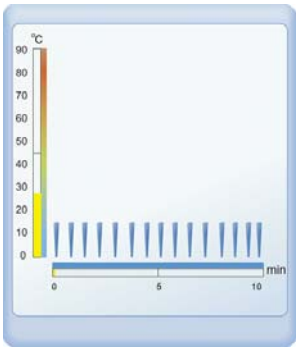


No.	Name	Function/Operation
1	Cleaning mode button	Button to select cleaning program/type
2	Auto off button	When the Auto off button is ON, machine is automatically turned off after cleaning is completed.
3	Preparation button	Button to go to Preparation process
4	Start button	Button to start cleaning This button changes to Stop button during cleaning.
5	History of cleaning	Cleaning history is displayed.
6	History of CF	Time of CF used is displayed. Filter change button is used to start CF change program.
7	Last treat	The latest treatment data is displayed
8	Weekly program	To activate the scheduled programs during the week

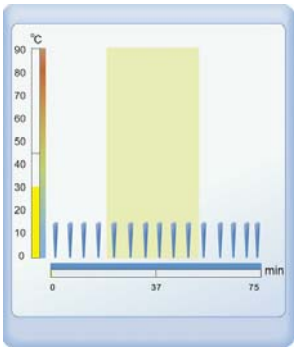
2.8. Cleaning execution screen for single step (Rinse)



Under Hot disinfection or Hot rinse



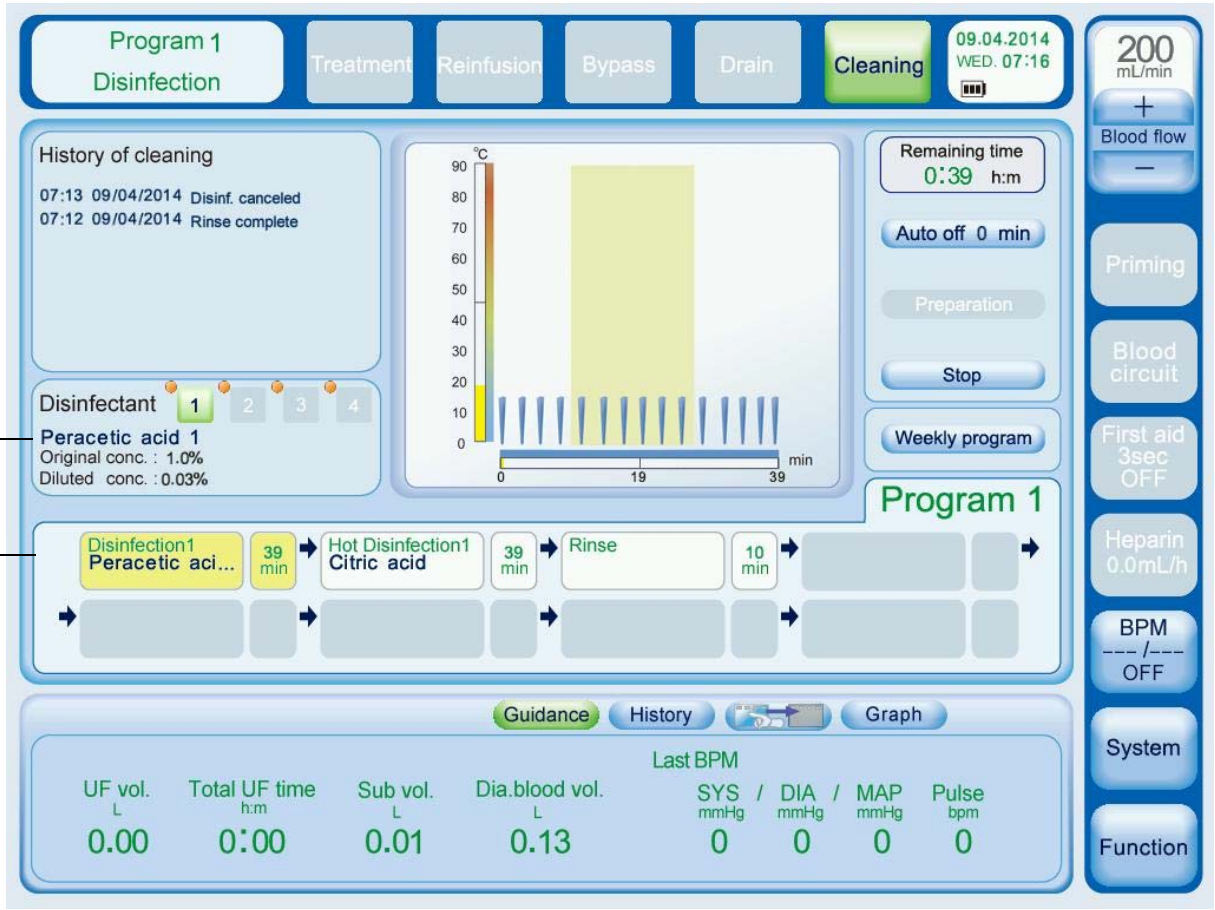
Under Water rinse



Under disinfection or de-calcification

No.	Name	Function/Operation
1	Cleaning graph	Graph of Cleaning execution time and Cleaning solution temperature are displayed.
2	Remaining time	Cleaning remaining time is displayed.

2.9. Cleaning execution screen for program (Program 1)



No.	Name	Function/Operation
1	Disinfectant setting	Original concentration and diluted concentration of disinfectant used for cleaning are displayed.
2	Cleaning program	Cleaning program is displayed.

3. Preparation

3.1. Turning on the Surdial X

1. Establish the water and power supply. (power breaker)
2. Press and hold the I/O power key for 3 seconds.
3. Start-up screen shows the machine type, the current software version for approx.10 seconds.

⚠ DANGER

- Verify that the system had a sufficient cleaning or disinfection.
- Before going to preparation verify that no amount of fluid remains in the system that can harm the health of the patient.
- Sample can be taken at the blue coupler and the substitution port, using the test method corresponding to the used disinfectant. If the test shows a residual concentration or in event of a positive pH reaction (acid based disinfectants pH≤4.5) restart a cleaning program.
- For peracetic acid based disinfectants use for example a peracetic acid test method.
- For sodium hypochloride based disinfectants use for example a potassium iodide starch paper.
- Observe the “use by” date of the indicator paper!
- Refer to chapter 6 cleaning.

3.2. Concentrate supply

⚠WARNING

- The concentrates are calibrated at first installation into different types. (BCx)
- For treatment make the correct choice according to the programmed concentrate types this is done in the dialyse menu.

⚠CAUTION

- Never use acid concentrate for acetate dialysis.
- Verify the label of the canister before use.
- Using acid concentrate for acetate dialysis will endanger the patient during treatment because of differences in dilutions compared with acetate concentrate.
- Because no BIC is used, the acid concentrate has no buffers to the safety of the patient.
- Only use concentrates prescribed by a physician.

Bicarbonate dialysis

To connect the acid container

1. Open the concentrate flap.
2. Place the red concentrate suction tube into the acid container.
3. Close the concentrate flap.

To connect the bicarbonate container

1. Open the concentrate flap.
2. Place the blue concentrate suction tube into the bicarbonate container.
3. Close the concentrate flap.

OR

To connect the B-cartridge

1. Open the B-cartridge arms.
2. Attach the NIPRO B cartridge.
3. Close the B-cartridge arms.

⚠CAUTION

- Only the B-cartridge supplied by NIPRO may be used.
- Make sure that the canister used contains enough concentrate and bicarbonate necessary for a complete dialysis treatment.
- Ensure that the concentrate displayed on the screen comply with the specifications mentioned on the acid canister. Assure that all settings are applied correctly. Any mistake can be danger for the patient.

3.3. Preparation

1. Press the Treatment mode button.
2. Start-up test starts.
3. An alarm sound is to be heard, to confirm the working condition of the acoustic alarm.
4. The light indicator is illuminated. Confirm its operating status.
5. Preparation process starts when the start-up test is completed.

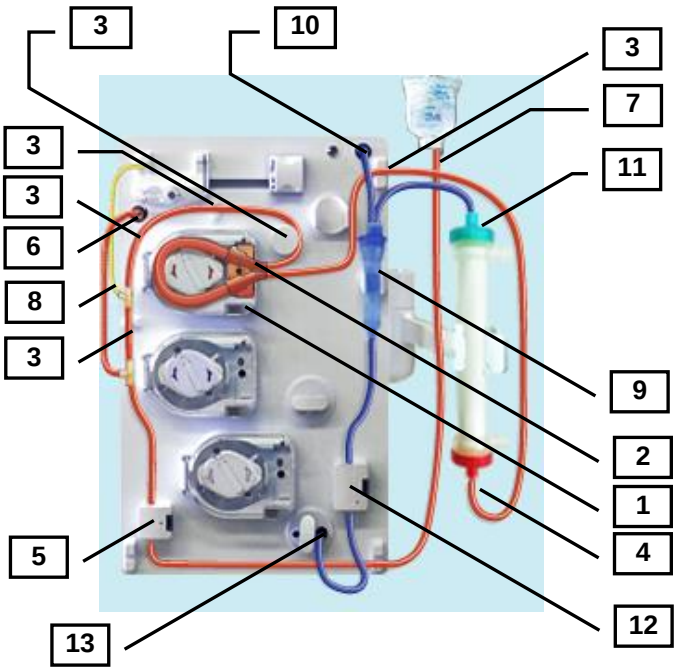
⚠WARNING

- Use the tube holder to install the blood line properly. Otherwise bending, tension, kinking or clogging of the tube may cause hemolysis. An alarm buzzer may not sound depending on differences between individual patients or treatment conditions.

⚠CAUTION

- If no alarm sound is to be heard, there will also be no acoustical alarm sound during treatment, either. In this case, do not make any treatment.
- Check that the light indicator lights in the order of "Red→Orange→Green→Red→Orange→Green" at the start of standby process. If even one of them does not light, refrain from using the system. Otherwise, the light indicator may not light even if an alarm occurs.
- The start-up test must have been completed successfully without fail before every treatment.
- Only use dialyzers with CE marking and correct fittings
- Hydrophobic filters must be used on the pressure lines of tubing systems to prevent (cross-) contamination.
- In case a hydrophobic filter gets wet, is blocked or penetrate throw you have to exchange the tubing system. Up to the position it could be possible to use instead a pressure measurement line with Luer lock connector. In this case clamp the defective line. If the pressure measurement units are contaminated (e.g. contact to blood), then all affected parts must be disinfected or replaced.
- Air bubbles may not be detected in the following cases:
  - ・ The air bubble detector is not installed in a proper position.
  - ・ Materials or media which block ultrasonic are used at the tube attachment area.
  - ・ Coagulation

3.4. Extracorporeal blood circuit with saline bag (HD)



Setting the arterial and venous blood circuit.

1. Open the arterial blood pump cover.
2. Insert the arterial pump segment into the blood pump until a signal is sounded.
3. Set the arterial blood line to the line holders. (five places)
4. Connect the arterial blood line to the dialyzer.
5. Insert the arterial blood line into the arterial clamp box.
6. Connect the arterial pressure line to the arterial pressure port.
7. Connect the arterial patient access to the saline bag.
8. Insert the syringe to the heparin pump and connect the syringe to the heparin line.
9. Insert the venous chamber into the venous chamber holder.
10. Connect the venous pressure line to the venous pressure port.
11. Connect the venous blood line to the dialyzer.
12. Connect the venous blood line in to the clamp box.
13. Connect the venous patient access to the drain port.

3.4.1. Dialyzer filling

NOTE

- “Please wait for Dialysate preparation completion” is displayed in Guidance while machine is preparation.
- ”Please connect the both dialyzer couplers to the dialyzer” is displayed in Info when machine is preparation complete.

1. Confirm that the machine is preparation complete.
2. Connect the blue coupler to the dialysate inlet port of the dialyzer.
3. Connect the red coupler to the dialysate outlet port of the dialyzer.

3.4.2. Priming of blood circuit

Starting the priming

1. The rinse volume and the flow of the blood pump are automatically set to the preset value. Change the rinse volume and the flow of blood pump if necessary.
2. Check the connection of arterial port and venous port, before priming process is start.
3. Press the Priming button.
4. Set the rinse volume.
5. Set the flow of the blood pump.
6. Press the blood flow ON/OFF button.

NOTE

- After checking the connection of arterial and venous port, please confirm that by pushing [reset] that the DLC can start.
- DLC (Dialyzer leak check) is effective, when "Dialysate infusion" is "ON" on the <Setting-7.Option> screen in the System menu.

Interruption of the priming process.

1. Press the blood flow ON/OFF button
2. Press the Remove all button in the blood circuit window if necessary, and follow the instructions.
3. Press the blood flow ON/OFF button again to continue the priming.

⚠CAUTION

- Air bubble alarm is not monitored during the blood circuit priming. Do not connect a patient during priming, because many air bubbles may enter the body if priming is performed with a patient connect.
- The prescribed priming volume of dialyzer depends on the manufacturer specifications.

Complete the priming process

1. When rinse volume achieved, blood pump stops and priming process is completed.
2. In addition, to priming process, the "Rinse" button is pushed. Rinse volume is added and Priming process is restarted.

NOTE

- Rinse volume change “Additional rinse volume” on the <Setting 9. Prep.rein> screen in the system menu.

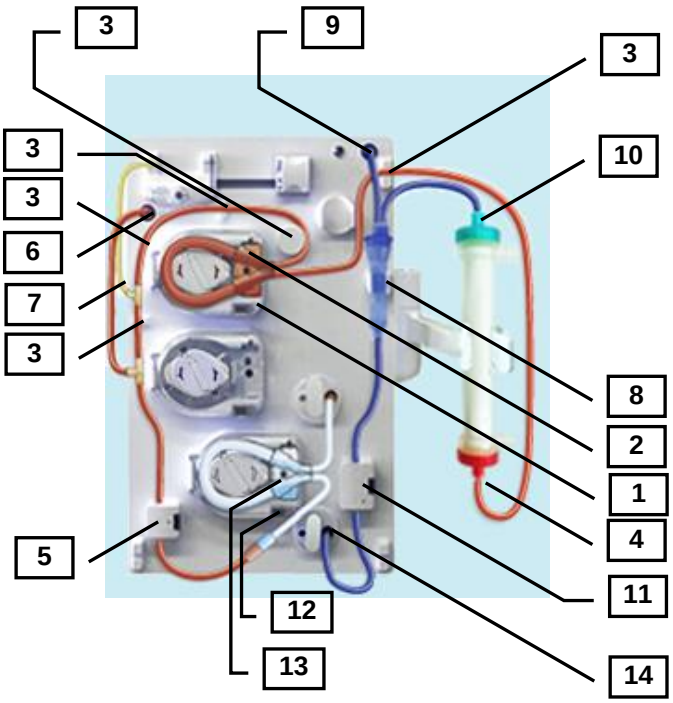
Pre-circulation process

1. Press the Circulation button.
2. Connect the venous line to the saline bag.
3. Close the drain port.
4. Press the Circulation start button

Interruption and restart of the pre-circulation process

1. Press the blood flow ON/OFF button.
2. Press the Remove all button in the blood circuit window if necessary, and follow the instructions.
3. "Rinse" in Guidance is selected or press the blood flow ON/OFF button again to continue pre-circulation.

3.5. Extracorporeal blood circuit with online solution (Online HDF)



Setting the arterial and venous blood circuit.

1. Open the arterial blood pump cover.
2. Insert the arterial pump segment into the blood pump until a signal is sounded.
3. Set the arterial blood line to the line holders. (five places)
4. Connect the arterial blood line to the dialyzer.
5. Insert the arterial blood line into the arterial clamp box.
6. Connect the arterial pressure line to the arterial pressure port.
7. Insert the syringe to the heparin pump and connect the syringe to the heparin line.
8. Insert the venous chamber into the venous chamber holder.
9. Connect the venous pressure line to the venous pressure port.
10. Connect the venous blood line to the dialyzer.
11. Connect the venous blood line in to the clamp box.
12. Open the substitution pump cover.
13. Insert the substitution pump segment into the substitution pump until a signal is sounded.
14. Connect the venous patient access to the drain port.

3.5.1. Dialyzer filling

NOTE

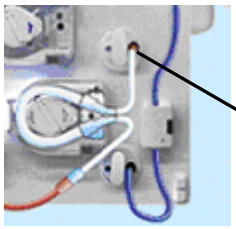
- “Please wait for Dialysate preparation completion” is displayed in Guidance while machine is preparation.
- ” Please connect the both dialyzer couplers to the dialyzer” is displayed in Info when machine is preparation complete.

1. Confirmed that the machine is in mode preparation complete.
2. Connect the blue coupler to the dialysate inlet port of the dialyzer.
3. Connect the red coupler to the dialysate outlet port of the dialyzer.

3.5.2. Priming of blood circuit

Starting the priming

1. The rinse volume and the flow of the blood pump are automatically set to the preset value. Change the rinse volume and the flow of blood pump if necessary.
2. Check the connection of arterial port and venous port, before priming process is start.
3. Press the Priming button.
4. Connect the substitution line to the substitution port.



5. Connect the arterial patient access to the substitution line.
6. Set the rinse volume.
7. Set the flow of the blood pump.
8. “Start priming online. 「OK」" in Guidance is selected or press the blood flow ON/OFF button.

NOTE

- When the bypass operates, priming process is interrupted.

Interruption and restart of the priming process

1. Press the blood flow ON/OFF button.
2. Press the Remove all button in the blood circuit window if necessary.
3. Press the blood flow ON/OFF button again to continue priming.

⚠CAUTION

- Do not connect a patient if the prescribed priming volume has not been reached.
- The prescribed priming volume of dialyzer depends on the manufacturer specifications.

Continuous priming process

1. When rinse volume achieved, continuous priming process start automatically.

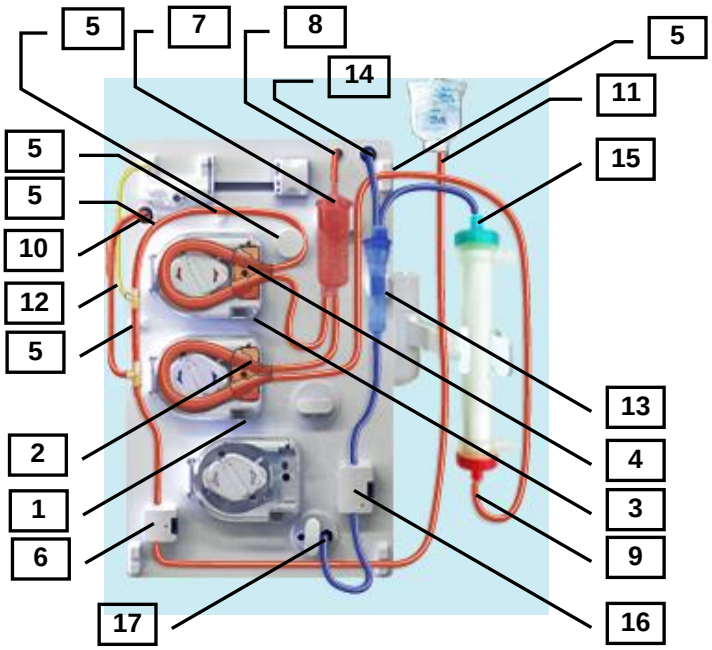
NOTE

- The blood pump flow is automatically reduced to 50 ml/min, and dialysate flows also into the dialyzer coupler side periodically.

Interruption and restart of the continuous priming process

1. Press the blood flow ON/OFF button
2. Press the Remove all button in the blood circuit window if necessary.
3. "Rinse" in Guidance is selected or press the blood flow ON/OFF button again to restart the continuous priming process.

3.6. Extracorporeal blood circuit with saline bag (Single needle HD)



Setting the arterial and venous blood circuit.

1. Open the venous pump cover.
2. Insert the venous pump segment into the venous pump until a signal is sounded.
3. Open the arterial blood pump cover.
4. Insert the arterial pump segment into the blood pump until a signal is sounded.
5. Set the arterial blood line to the line holders. (five places)
6. Insert the arterial blood line into the arterial clamp box.
7. Insert the SN chamber into the SN chamber holder.
8. Connect the SN chamber pressure line to the SN pressure port.
9. Connect the arterial blood line to the dialyzer.
10. Connect the arterial pressure line to the arterial pressure port.
11. Connect the arterial patient access to the saline bag.
12. Insert the syringe to the heparin pump and connect the syringe to the heparin line.
13. Insert the venous chamber into the venous chamber holder.
14. Connect the venous pressure line to the venous pressure port.
15. Connect the venous blood line to the dialyzer.
16. Connect the venous blood line in to the clamp box.
17. Connect the venous patient access to the drain port.

3.6.1. Dialyzer filling

1. Confirmed that the machine is preparation complete.
2. Connect the blue coupler to the dialysate inlet port of the dialyzer.
3. Connect the red coupler to the dialysate outlet port of the dialyzer.

NOTE

- “Please wait for Dialysate preparation completion” is displayed in Guidance while machine is preparation.
- ” Please connect the both dialyzer couplers to the dialyzer” is displayed in Info when machine is preparation complete.

3.6.2. Priming of blood circuit

Starting the priming

1. Press the Priming button.
2. Set the rinse volume.
3. Set the flow of the blood pump.
4. Press the blood flow ON/OFF button.

NOTE

- The rinse volume and the flow of the blood pump are automatically set to the preset value. Change the rinse volume and the flow of blood pump if necessary.
- Check the connection of arterial port and venous port, before priming process is start.
- DLC (Dialyzer leak check) is start, after check the connection of arterial port and venous port
- DLC (Dialyzer leak check) is effective, when "Dialysate infusion" is "ON" on the <Setting-7.Option> screen in the System menu.

Interruption of the priming process.

1. Press the blood flow ON/OFF button.
2. Press the Remove all button in the blood circuit window if necessary.
3. Press the blood flow ON/OFF button again to continue priming.

⚠CAUTION

- Do not connect a patient if the prescribed priming volume has not been reached.
- The prescribed priming volume of dialyzer depends on the manufacturer specifications.

Complete the priming process

1. When rinse volume achieved, blood pump stops and priming process is completed.
2. In addition, to execute priming process, the "Rinse" button is pushed. Rinse volume is added and Priming process is restarted.

NOTE

- Rinse volume change “Additional rinse volume” on the <Setting 9. Prep.rein> screen in the system menu.

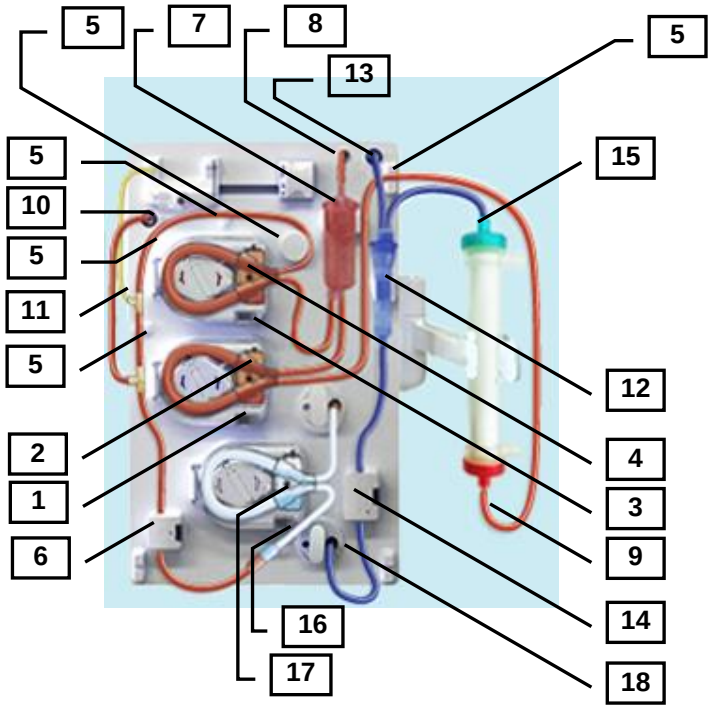
Pre-circulation process

1. Press the circulation button.
2. Connect the venous line to the saline bag.
3. Close the drain port.
4. Press the Circulation start button.

Interruption and restart of the pre-circulation process

1. Press the blood flow ON/OFF button.
2. Press the Remove all button in the blood circuit window if necessary.
3. "Circulation continue" in Guidance is selected or press the blood flow ON/OFF button again to continue pre-circulation.

3.7. Extracorporeal blood circuit with online solution (Single needle Online HDF)



Setting the arterial and venous blood circuit.

1. Open the venous pump cover.
2. Insert the venous pump segment into the venous pump until a signal is sounded.
3. Open the arterial blood pump cover.
4. Insert the arterial pump segment into the blood pump until a signal is sounded.
5. Set the arterial blood line to the line holders. (five places)
6. Insert the arterial blood line into the arterial clamp box.
7. Insert the SN chamber into the SN chamber holder.
8. Connect the SN chamber pressure line to the SN pressure port.
9. Connect the arterial blood line to the dialyzer.
10. Connect the arterial pressure line to the arterial pressure port.
11. Insert the syringe to the heparin pump and connect the syringe to the heparin line.
12. Insert the venous chamber into the venous chamber holder.
13. Connect the venous pressure line to the venous pressure port.
14. Connect the venous blood line in to the clamp box.
15. Connect the venous blood line to the dialyzer.
16. Open the substitution pump cover.
17. Insert the substitution pump segment into the substitution pump until a signal is sounded.
18. Connect the venous patient access to the drain port.

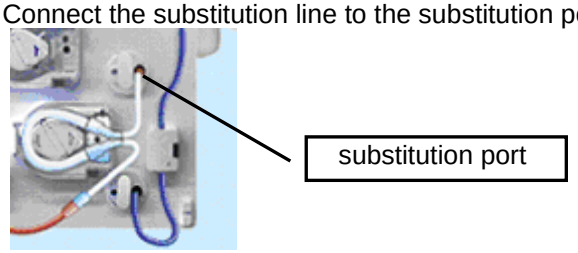
3.7.1. Dialyzer filling

1. Confirmed that the machine is in mode preparation complete.
2. Connect the blue coupler to the dialysate inlet port of the dialyzer.
3. Connect the red coupler to the dialysate outlet port of the dialyzer.

3.7.2. Priming of blood circuit

Starting the priming

1. Press the Priming button.
2. Connect the substitution line to the substitution port.



3. Connect the arterial patient access to the substitution line.
4. Set the rinse volume.
5. Set the flow of the blood pump.
6. “Start priming online. 「OK」" in Guidance is selected or press the blood flow ON/OFF button.

NOTE

- The rinse volume and the flow of the blood pump are automatically set to the preset value. Change the rinse volume and the flow of blood pump if necessary.
- Check the connection of arterial port and venous port, before priming process is start.
- When the bypass operates, priming process is interrupted.

Interruption and restart of the priming process

1. Press the blood flow ON/OFF button
2. Press the Remove all button in the blood circuit window if necessary.
3. Press the blood flow ON/OFF button again to continue priming.

⚠CAUTION

- Do not connect a patient if the prescribed priming volume has not been reached.
- The prescribed priming volume of dialyzer depends on the manufacturer specifications.

Continuous priming process

1. When rinse volume achieved, continuous priming process start automatically.

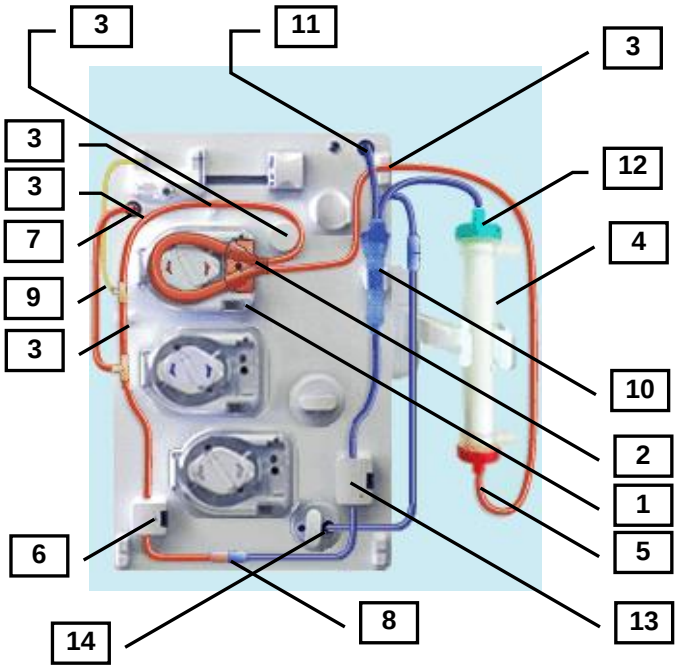
NOTE

- The blood pump flow is automatically reduced to 50 ml/min, and dialysate flows also into the dialyzer coupler side periodically.

Interruption and restart of the continuous priming process

1. Press the blood flow ON/OFF button
2. Press the Remove all button in the blood circuit window if necessary.
3. "Rinse" in Guidance is selected or press the blood flow ON/OFF button again to restart the continuous priming process.

3.8. DIF priming - Dialysate infusion with ELISIO H Series (HD)



Setting the arterial and venous blood circuit.

1. Open the arterial blood pump cover.
2. Insert the arterial pump segment into the blood pump until a signal is sounded.
3. Set the arterial blood line to the line holders. (five places)
4. Use "ELISIO H series" dialyzer which removes endotoxin in case of DIF.
5. Connect the arterial blood line to the dialyzer.
6. Insert the arterial blood line into the arterial clamp box.
7. Connect the arterial pressure line to the arterial pressure port.
8. Connect the arterial patient access to the venous patient access.
9. Insert the syringe to the heparin pump and connect the syringe to the heparin line.
10. Insert the venous chamber into the venous chamber holder.
11. Connect the venous pressure line to the venous pressure port.
12. Connect the venous blood line to the dialyzer.
13. Connect the venous blood line in to the venous clamp box.
14. Connect the overflow line to the drain port.

3.8.1. Dialyzer filling

NOTE

- “Please wait for Dialysate preparation completion” is displayed in Guidance while machine is preparation.
- ”Please connect the both dialyzer couplers to the dialyzer” is displayed in Info when machine is preparation complete.

1. Confirm that the machine is preparation complete.
2. Connect the blue coupler to the dialysate inlet port of the dialyzer.
3. Connect the red coupler to the dialysate outlet port of the dialyzer.

3.8.2. Priming of blood circuit

Starting the priming

1. The rinse volume and the flow of the blood pump are automatically set to the preset value.
2. Check the connection of arterial port and venous port, before priming process is start.
3. Press the Priming button.
4. Press the blood flow ON/OFF button.

NOTE

- The rinse volume and the flow of the blood pump are automatically set to the preset value.
- Check the connection of arterial port and venous port, before priming process is start.
- After checking the connection of arterial and venous port, please confirm that by pushing [reset] that the DLC can start.
- DLC (Dialyzer leak check) is effective, when "Dialysate infusion" is "ON" on the <Setting-7.Option> screen in the System menu.
- Use "ELISIO-H series" dialyzer which removes endotoxin in case of DIF.

Interruption of the priming process.

1. Press the blood flow ON/OFF button.
2. Press the Remove all button in the blood circuit window if necessary, and follow the instructions.
3. Press the blood flow ON/OFF button again to continue the priming.

⚠CAUTION

- Do not connect a patient if the prescribed priming volume has not been reached.
- The prescribed priming volume of dialyzer depends on the manufacturer specifications.

Continuous priming process

1. When rinse volume achieved, continuous priming process start automatically.

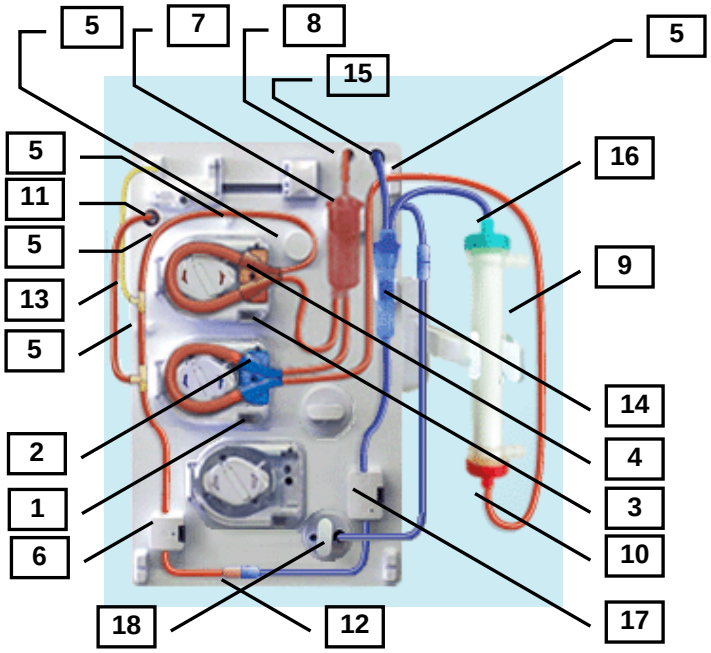
NOTE

- The blood pump flow is automatically reduced to 50 ml/min, and dialysate flows also into the dialyzer coupler side periodically.

Interruption and restart of the continuous priming process

1. Press the blood flow ON/OFF button.
2. Press the Remove all button in the blood circuit window if necessary.
3. "Rinse" in Guidance is selected or press the blood flow ON/OFF button again to restart the continuous priming process.

3.9. DIF priming - Dialysate infusion with ELISIO H Series (Single needle HD)



Setting the arterial and venous blood circuit.

1. Open the venous pump cover.
2. Insert the venous pump segment into the venous pump until a signal is sounded.
3. Open the arterial blood pump cover.
4. Insert the arterial pump segment into the blood pump until a signal is sounded.
5. Set the arterial blood line to the line holders. (five places)
6. Insert the arterial blood line into the arterial clamp box.
7. Insert the SN chamber into the SN chamber holder.
8. Connect the SN chamber pressure line to the SN pressure port
9. Use "ELISIO H series" dialyzer which removes endotoxin in case of DIF.
10. Connect the arterial blood line to the dialyzer.
11. Connect the arterial pressure line to the arterial pressure port.
12. Connect the arterial patient access to the venous patient access.
13. Insert the syringe to the heparin pump and connect the syringe to the heparin line.
14. Insert the venous chamber into the venous chamber holder.
15. Connect the venous pressure line to the venous pressure port.
16. Connect the venous blood line to the dialyzer.
17. Connect the venous blood line in to the venous clamp box.
18. Connect the overflow line to the drain port.

3.9.1. Dialyzer filling

NOTE

- “Please wait for Dialysate preparation completion” is displayed in Guidance while machine is preparation.
- ” Please connect the both dialyzer couplers to the dialyzer” is displayed in Info when machine is preparation complete.

1. Confirm that the machine is preparation complete.
2. Connect the blue coupler to the dialysate inlet port of the dialyzer.
3. Connect the red coupler to the dialysate outlet port of the dialyzer.

3.9.2. Priming of blood circuit

Starting the priming

1. The rinse volume and the flow of the blood pump are automatically set to the preset value.
2. Check the connection of arterial port and venous port, before priming process is start.
3. Press the Priming button.
4. Press the blood flow ON/OFF button.

NOTE

- The rinse volume and the flow of the blood pump are automatically set to the preset value.
- Check the connection of arterial port and venous port, before priming process is start.
- After checking the connection of arterial and venous port, please confirm that by pushing [reset] that the DLC can start.
- DLC(Dialyzer leak check) is effective, when "Dialysate infusion" is "ON" on the <Setting-7.Option> screen in the System menu.
- Use "ELISIO-H series" dialyzer which removes endotoxin in case of DIF.

Interruption of the priming process.

1. Press the blood flow ON/OFF button
2. Press the Remove all button in the blood circuit window if necessary, and follow the instructions.
3. Press the blood flow ON/OFF button again to continue the priming.

⚠CAUTION

- Do not connect a patient if the prescribed priming volume has not been reached.
- The prescribed priming volume of dialyzer depends on the manufacturer specifications.

Continuous priming process

1. When rinse volume achieved, continuous priming process start automatically.

NOTE

- The blood pump flow is automatically reduced to 50 ml/min, and dialysate flows also into the dialyzer coupler side periodically.

Interruption and restart of the continuous priming process

1. Press the blood flow ON/OFF button
2. Press the Remove all button in the blood circuit window if necessary.
3. "Rinse" in Guidance is selected or press the blood flow ON/OFF button again to restart the continuous priming process.

3.10. Setting treatment data

⚠CAUTION

- Check that the treatment parameters are as intended after setting.

Setting the UF parameters

1. Press the UF menu button.
2. Enter the desired treatment data by touching the numeric value.

NOTE

- The various treatment parameters for the individual patient must be taken into consideration before every treatment.
- In case the treatment parameters are entered automatically (e.g. using third party software and/or software applications), the operator must always check and confirm the correct treatment parameters.

Setting the Dialysate parameters

1. Press the Dialysate menu button.
2. Enter the desired treatment data by touching the numeric value.

Setting of heparin pump

1. Press the Heparin button.
2. Enter the desired parameters by touching the numeric value.

⚠CAUTION

- Do not start priming of the syringe connection tube or Heparin bolus by pressing the pusher by hand after inserting the syringe.
- After inserting the syringe, confirm that the heparin pump operates as intended by pressing the Heparin F.F button until Patient connect. Blood may flow backward into the syringe if the heparin pump does not operate properly.

NOTE

- Up to the setting:
  The heparin pump is automatically turned on when the blood pump is turned on.

Setting the concentration profiles

1. Press the profile button in the dialysate menu.
2. Enter the desired parameters.

NOTE

- The default concentration and UF profiles exist as 8 basically different profiles with step change.
- The Step time is decided, dividing the Treatment time remaining by settings (default 8).

- When you use the concentrate- and Uf-profiles in combination: the steps will always be linked.

Setting the UF profiles

1. Press the profile button in the UF menu.
2. Enter the desired parameters.

NOTE

- The default concentration and UF profiles exist as 8 basically different profiles with step change.
- The Step time is decided, dividing the Treatment time remaining by settings (default 8).
- When you use the concentrate- and Uf-profiles in combination: the steps will always be linked.

Setting the Single needle parameters

1. Press the SN menu.
2. Enter the desired parameters.

4. Treatment

4.1. Patient connection

⚠WARNING

- Back filtration may occur with high flux dialyzer with low or zero UF rates due to pressure gradients.
- Check blood loss frequency during dialysis because venous pressure sensor error is ±10mmHg though limited sensitivity of the sensor is 1mmHg and the machine is provided with protective system designed to minimize the error.
- Venous pressure monitoring is not a reliable method of detecting a detached needle.
- If arterial pressure before the blood pump is extremely low, sufficient blood flow cannot be secured and it may cause low effect of treatment.

4.1.1. Treatment prepared with saline bag (HD)

1. If turning in priming circulation mode: press the blood pump on/off button to stop the pump
2. If set priming volume is reached: pump stops automatically
3. The following 3 options display.
   A. Rinse
   B. Circulation
   C. Patient connect
4. Press the desired button.
   A Rinse and B Circulation: see Priming 3.4.2
   C. Patient connect button
      1. Press the Patient connect button.
      2. Disconnect the arterial line from the saline bag.
      3. Connect the arterial line to the patient.
      4. Disconnect the venous line from the drain port (in circulation: from saline bag)
      5. Close the drain port
      6. Connect the venous line to the patient.
      7. Press the OK button.
      8. Set the blood flow to the desired value.
      9. Blood detection: arterial and venous lines are connected? Push the OK button.
      10. Check parameters! Push the OK button.
      11. Treatment start automatically

NOTE

- Heparin pump is started automatically, if preset in the setting.

4.1.2. Treatment prepared with online solution (Online HDF)

1. Press the blood pump ON/OFF button. (The blood pump stops.)
2. The following 2 options display.
   A. Rinse
   B. Patient connect
3. Press the desired button.
   A. Rinse button
      Pressing the Rinse button will continue the continuous priming process.
   B. Patient connect button
      1. Press the Patient connect button, to exit the priming process.
      2. Disconnect the arterial line from the substitution line.
      3. Connect the substitution line before (Pre-dilution) or below (Post-dilution) the dialyzer.
      4. Connect the arterial line to the patient.
      5. Disconnect the venous line from the drain port.
      6. Close the drain port.
      7. Connect the venous line to the patient.
      8. Press the OK button.
      9. Set the blood flow to the desired value.
      10. Blood detection: arterial and venous lines are connected? Push the OK button.
      11. Check parameters! Push the OK button.
      12. Which substitution mode will be used in hemofiltration: Auto sub or Max-sub or Manual
      13. Treatment start automatically

NOTE

- Heparin pump is started automatically, if preset in the setting.

4.1.3. Treatment prepared with saline bag (SNHD)

1. If turning in priming circulation mode: press the blood pump on/off button to stop the pump.
   If set priming volume is reached: pump stops automatically
2. The following 3 options display.
   A. Rinse
   B. Circulation
   C. Patient connect
3. Press the desired button.
   A Rinse and B Circulation: see Priming 3.6.2
   C. Patient connect
4. The following 2 options display.
   A. Single needle connect
   B. Double needle connect
5. Press the desired button.
   A. Single needle connect button
      1. Adjust the level in the SN chamber to be 1 cm from the bottom of the chamber.
      2. Press the OK button when the level is properly set.
      3. Disconnect the arterial line from the saline bag.
      4. Connect the arterial line to the patient.
      5. Disconnect the venous line from the drain port (in circulation: from saline bag)
      6. Close the drain port

7. Connect the venous line to the patient.
8. Press the OK button.
9. Set the blood flow to the desired value.
10. Blood detection: arterial and venous lines are connected? Push the OK button.
11. Check parameters! Push the OK button.
12. Treatment start automatically.

NOTE

- The display of blood flow displays the set value regardless of movement or the stop of the blood pump. Confirm the Effective blood flow in single needle menu for average blood flow rate during single needle operation.
- Arterial and venous lines are connected to vascular access as well as Y-tube. For displaying of effective blood flow, the straight area of the Y-tube will be the re-circulation volume per cycle of single needle (standard double needle dialysis cannula). However, actual re-circulation volume could be different depending on the cannula actually used.

B. Double needle connect button

1. Adjust the level in the SN chamber to be middle of the chamber.
2. Follow the instructions to remove venous pump segment and to insert it again until signal is sounded
3. Disconnect the arterial line from the saline bag.
4. Connect the arterial line to the patient.
5. Disconnect the venous line from the drain port (in circulation: from saline bag)
6. Close the drain port
7. Connect the venous line to the patient.
8. Press the OK button.
9. Set the blood flow to the desired value.
10. Blood detection: arterial and venous lines are connected? Push the OK button.
11. Check parameters! Push the OK button.
12. Treatment start automatically

NOTE

- Heparin pump is started automatically, if preset in the setting.

4.1.4. Treatment prepared with online solution (SN Online HDF)

1. Press the blood pump ON/OFF button. (The blood pump stops.)
2. The following 3 options display.
   A. Rinse
   B. Single needle connect
   C. Double needle connect
3. Press the desired button.

   A. Rinse button

   Pressing the Rinse button will continue the continuous priming process.

   B. Single needle connect button

   1. Adjust the level in the SN chamber to be 1 cm from the bottom of the chamber.
   2. Press the OK button when the level is properly set.
   3. Disconnect the arterial line from the substitution line.

4. Connect the substitution line before (Pre-dilution) or below (Post-dilution) the dialyzer.
5. Connect the arterial line to the patient.
6. Disconnect the venous line from the drain port.
7. Close the drain port.
8. Connect the venous line to the patient.
9. Press the OK button.
10. Set the blood flow to the desired value.
11. Blood detection: arterial and venous lines are connected? Push the OK button.
12. Check parameters! Push the OK button.
13. Which substitution mode will be used in hemofiltration: Auto sub or Max-sub or Manual
14. Treatment start automatically.

NOTE

- The display of blood flow displays the set value regardless of movement or the stop of the blood pump. Confirm the Effective blood flow in single needle menu for average blood flow rate during single needle operation.
- Arterial and venous lines are connected to vascular access as well as Y-tube. For displaying of effective blood flow, the straight area of the Y-tube will be the re-circulation volume per cycle of single needle (standard double needle dialysis cannula). However, actual re-circulation volume could be different depending on the cannula actually used.

C. Double needle connect button

1. Adjust the level in the SN chamber to be middle of the chamber.
2. Follow the instructions to remove venous pump segment and to insert it again until signal is sounded
3. Disconnect the arterial line from the substitution line.
4. Connect the substitution line before (Pre-dilution) or below (Post-dilution) the dialyzer.
5. Connect the arterial line to the patient.
6. Disconnect the venous line from the drain port.
7. Close the drain port.
8. Connect the venous line to the patient.
9. Press the OK button.
10. Set the blood flow to the desired value.
11. Blood detection: arterial and venous lines are connected? Push the OK button.
12. Check parameters! Push the OK button.
13. Which substitution mode will be used in hemofiltration: Auto sub or Max-sub or Manual
14. Treatment start automatically

NOTE

- Heparin pump is started automatically, if preset in the setting.

4.2. Changing the Single needle setting

1. Press the single needle menu button.
2. Set the desired single needle parameters.

4.3. Setting the level in the SN chamber

1. Press the blood circuit button.
2. Press the arrowhead button of the SN chamber.
3. Adjust the level in the SN chamber to be 1 cm from the bottom of the chamber.
4. Press the OK button when the level is properly set.

4.4. Interrupting the Single needle treatment during the treatment

Single needle line in use with one needle. Switch to two needles

1. Press the Single needle menu button.
2. Press the Double needle ON/OFF button.
3. The following 2 options are displayed:
   A. Double needle start
   B. Single needle continue
   (When the Single needle continue button is pressed, the Single needle treatment resumes)
4. Press the Double needle start button
5. The blood pump and the venous pump stop.
6. Adjust the level in the SN chamber to be middle of the chamber. Confirm after with OK button
7. The venous pump segment is removed.
8. Connect the arterial and the venous blood line to the respective vascular access.
9. Open the venous pump door.
10. Remove the venous pump segment.
11. Insert the venous pump segment into the venous pump until a signal is sounded.
12. Close the venous pump door.
13. The blood pump rotates again.

4.5. Starting the Single needle treatment during the treatment

Single needle lines are inserted and primed; venous segment is not in use (double needle mode)

1. Press the Single needle menu button.
2. Press the Double needle ON/OFF button.
3. The following 2 options are displayed:
   A. Single needle start
   B. Double needle continue
   (When the Double needle continue button is pressed, the Double needle treatment resumes)
4. Press the Single needle start button.
5. The venous pump and the blood pump rotate, and then the pumps stop.
6. Adjust the level in the SN chamber to be 1 cm from the bottom of the chamber.
7. Connect the arterial and the venous blood line to the same vascular access.
8. Press the OK button.
9. The blood pump rotates again.

NOTE

- The display of blood flow displays the set value regardless of movement or the stop of the blood pump. Confirm the Effective blood flow in single needle menu for average blood flow rate during single needle operation.

4.6. Dialysate infusion

If the infusion is required during treatment, using “Dialysate infusion” function facilitates infusion. Please refer to “10.3 ONLINE menu” of “ch10 Other functions” for further details.

⚠CAUTION

- Make sure to implement the dialyzer leak check by DLC when using the dialysate infusion.
- Use "ELISIO-H series" dialyzer which removes endotoxin in case of DIF.
- Pressure exceeding the specification (500mmHg) may be applied to the dialyzer when Dialysate pressure max alarm is detected if Dialysate flow is set to 800mL/min and Fixed alarm point upper limit of Venous pressure to 480mmHg and DIF Bolus is performed. Visually confirm the dialyzer is not damaged first.

NOTE

- BP flow is changed automatically from “BP flow before implementation of Dialysate infusion” to” Dialysate Bolus rate” during Dialysate infusion
- The function is invalid during the bypass operation or ISO-UF operation.

5. Reinfusion

⚠WARNING

- Check blood loss frequency during dialysis because venous pressure sensor error is ±10mmHg though limited sensitivity of the sensor is 1mmHg and the machine is provided with protective system designed to minimize the error.
- Monitoring of the venous Pressure cannot always detect the disconnection of a venous needle from its access site, which may result in extracorporeal blood loss to the environment. When a venous needle disconnects from its access, pressure at the venous monitoring side may only decrease by the pressure maintained within the patient's access site. This pressure drop may be less than the width of the machine's venous pressure alarm window: in this particular case the disconnection of a venous needle from its access site is not detectable by the machine, even if pressure alarms and alarm windows are properly set.
- To reduce the risk of needles disconnection:
- Ensure that venous needle and line are firmly secured to the access site area according to your clinic's protocol.
- Ensure that the patient access is visible at all times during the dialysis treatment.
- Inspect frequently the patient's access.
- Adjust properly the venous pressure alarm window: The venous pressure alarm lower limit should be set as closely as practical to the actual patient's venous pressure value without generating excessive nuisance alarms.
- Venous pressure monitoring is not a reliable method of detecting a detached needle.

5.1. Reinfusion with saline bag.

5.1.1. Reinfusion achieving UF goal.

1. info : Treatment time reached display.
2. Press the Reset button.
3. The following guidance display.
   Stop treatment?
   A. Yes
   B. No (Treatment resumes)
   Press the desired button.

A. Yes button

1. Press the Yes button. (Reinfusion window displays.)
2. Perform the reinfusion operation.

5.1.2. Reinfusion aborting treatment.

1. Press the Reinfusion Button. (Reinfusion window displays.)
2. Perform the reinfusion operation.

5.1.3. Reinfusion operation.

1. Press the NaCl button.
2. The following guidance display.
   Please disconnect the arterial blood line from the patient, and connect it to the saline bag.
   A. OK
   B. Treatment continue (Treatment resumes)
3. Press the OK button. (The blood pump rotates at set at the prep.rein screen again.)
4. Reinfusion volume achieves or press the Reinfusion button.
5. The following guidance display.
   Reinfusion volume achieved (Reinfusion button pressed, it is not displayed.)
   A. Reinfusion continue (Reinfusion resumes)
   B. Remove lines
6. Press the Remove lines button.
7. The following guidance display.
   Are you sure, you want to remove blood circuit?
   A. Remove lines
   B. Reinfusion continue
8. Press the Remove lines button.

5.2. Reinfusion with online solution.

5.2.1. Reinfusion achieving UF goal.

1. info : Treatment time reached display.
2. Press the Reset button.
3. The following guidance display.
   Stop treatment?
   A. Yes
   B. No (Treatment resumes)
4. Press the desired button.

A. Yes button

1. Press the Yes button. (Reinfusion window displays.)

5.2.2. Reinfusion aborting treatment.

1. Press the Reinfusion Button. (Reinfusion window displays.)
2. Perform the reinfusion operation.

5.2.3. Reinfusion operation.

1. Press the ONLINE button.
2. The following guidance display.
   Please disconnect the arterial blood line from the patient, and connect it to the substitution line.
   A. OK
   B. Treatment continue (Treatment resumes.)
3. Press the OK button. (The blood pump rotates at set at Prep.rein screen again.)
4. Reinfusion volume achieves, or press the Reinfusion button.
5. The following guidance display.
   Reinfusion volume achieved (Reinfusion button pressed, it is not displayed.)
   A. Reinfusion continue (Reinfusion resumes.)
   B. Remove lines
6. Press the Remove lines button.
7. The following guidance display.
   Are you sure, you want to remove blood circuit?
   A. Remove lines
   B. Reinfusion continue
8. Press the Remove lines button.

5.3. DIF reinfusion - Dialysate infusion with ELISIO H Series

5.3.1. Reinfusion achieving UF goal.

1. info : Treatment time reached display.
2. Press the Reset button.
3. The following guidance display.
   Stop treatment?
   A. Yes
   B. No (Treatment resumes)
4. Press the desired button.

A. Yes button

1. Press the Yes button. (Reinfusion window displays.)

5.3.2. Reinfusion aborting treatment.

1. Press the Reinfusion Button. (Reinfusion window displays.)
2. Perform the reinfusion operation.

5.3.3. Reinfusion operation.

1. Press the Dialysate button.
2. The following guidance display.
   Please disconnect the arterial blood line from the patient, and connect it to the venous drip chamber. And close the arterial pressure line by the clamp.
   A. OK
3. Press the OK button.
4. Please make sure that the clamps on the Arterial line and Venous chamber are open.
   A. OK (The blood pump rotates at set at Prep.rein screen again.)
5. Reinfusion volume achieves.
6. The following guidance display.
   Reinfusion volume achieved.
   A. Reinfusion continue (Reinfusion resumes.)
   B. Remove lines
7. Press the Remove lines button.
8. The following guidance display.
   Are you sure, you want to remove blood circuit?
   A. Remove lines
   B. Reinfusion continue
9. Press the Remove lines button.

5.4. Reinfusion with saline bag. (Single needle double pump)

5.4.1. Reinfusion achieving UF goal.

1. info : Treatment time reached display.
2. Press the Reset button.
3. The following guidance display.
   Stop treatment?
   A. Yes
   B. No (Treatment resumes)
   Press the desired button.

A. Yes button

1. Press the Yes button. (Reinfusion window displays.)
2. Perform the reinfusion operation.

5.4.2. Reinfusion aborting treatment.

1. Press the Reinfusion Button. (Reinfusion window displays.)
2. Perform the reinfusion operation.

5.4.3. Reinfusion operation.

1. Press the NaCl button.
2. The following guidance display.
   To start reinfusion, please press SN chamber level adjustment button.
   A. SN chamber level adjustment
   B. Treatment continue (Treatment resumes)
3. Press the SN chamber level adjustment.
4. Adjust the SN chamber, and press the OK button.
5. The following guidance display.
   Please disconnect the arterial blood line from the patient, and connect it to the saline bag.
   OK
6. Press the OK button. (The blood pump rotates at set at the prep.rein screen again.)
7. Reinfusion volume achieves or press the Reinfusion button.
8. The following guidance display.
   Reinfusion volume achieved (Reinfusion button pressed, it is not displayed.)
   A. Reinfusion continue (Reinfusion resumes)
   B. Remove lines
9. Press the Remove lines button.
10. The following guidance display.
    Are you sure, you want to remove blood circuit?
    A. Remove lines
    B. Reinfusion continue
11. Press the Remove lines button.

5.5. Reinfusion with online solution. (Single needle double pump)

5.5.1. Reinfusion achieving UF goal.

1. info : Treatment time reached display.
2. Press the Reset button.
3. The following guidance display.
   Stop treatment?
   A. Yes
   B. No (Treatment resumes)
4. Press the desired button.

A. Yes button
1. Press the Yes button. (Reinfusion window displays.)
2. Perform the reinfusion operation.

5.5.2. Reinfusion aborting treatment.

1. Press the Reinfusion Button. (Reinfusion window displays.)
2. Perform the reinfusion operation.

5.5.3. Reinfusion operation.

1. Press the ONLINE button.
2. The following guidance display.
   To start reinfusion, please press SN chamber level adjustment button.
   A. SN chamber level adjustment
   B. Treatment continue (Treatment resumes)
3. Press the SN chamber level adjustment.
4. Adjust the SN chamber, and press the OK button.
5. The following guidance display.
   Please disconnect the arterial blood line from the patient, and connect it to the substitution line.
   OK
6. Press the OK button. (The blood pump rotates at set at Prep.rein screen again.)
7. Reinfusion volume achieves, or press the Reinfusion button.
8. The following guidance display.
   Reinfusion volume achieved (Reinfusion button pressed, it is not displayed.)
   A. Reinfusion continue (Reinfusion resumes.)
   B. Remove lines
9. Press the Remove lines button.
10. The following guidance display.
    Are you sure, you want to remove blood circuit?
    A. Remove lines
    B. Reinfusion continue
11. Press the Remove lines button.

5.6. DIF reinfusion - Dialysate infusion with ELISIO H Series (Single needle double pump)

5.6.1. Reinfusion achieving UF goal.

1. info : Treatment time reached display.
2. Press the Reset button.
3. The following guidance display.
   Stop treatment?
   A. Yes
   B. No (Treatment resumes)
4. Press the desired button.

A. Yes button

1. Press the Yes button. (Reinfusion window displays.)

5.6.2. Reinfusion aborting treatment.

1. Press the Reinfusion Button. (Reinfusion window displays.)
2. Perform the reinfusion operation.

5.6.3. Reinfusion operation.

1. Press the Dialysate button.
2. The following guidance display.
   To start reinfusion, please press SN chamber level adjustment button.
   A. SN chamber level adjustment
   B. Treatment continue (Treatment resumes)
3. Press the SN chamber level adjustment.
4. Adjust the SN chamber, and press the OK button.
5. The following guidance display.
   Please disconnect the arterial blood line from the patient, and connect it to the venous drip chamber. And close the arterial pressure line by the clamp.
   A. OK
6. Press the OK button.
7. Please make sure that the clamps on the Arterial line and Venous chamber are open.
   A. OK (The blood pump rotates at set at Prep.rein screen again.)
8. Reinfusion volume achieves.
9. The following guidance display.
   Reinfusion volume achieved.
   A. Reinfusion continue (Reinfusion resumes.)
   B. Remove lines
10. Press the Remove lines button.
11. The following guidance display.
    Are you sure, you want to remove blood circuit?
    A. Remove lines
    B. Reinfusion continue
12. Press the Remove lines button.

5.7. Emptying the dialyzer.

1. Make the dialyzer inlet port upper side.
2. Remove the blue coupler from Dialyzer and connect it to the coupler socket.
   (Dialyzer is being emptied.)
3. Remove the red coupler from Dialyzer and connect it to the coupler socket.
4. Close substitution port
5. Replace A concentration suction tube in concentrate module

5.8. Emptying the B-cartridge.

The B-cartridge is emptied after the treatment automatically.

Close the b-cartridge holders

⚠DANGER

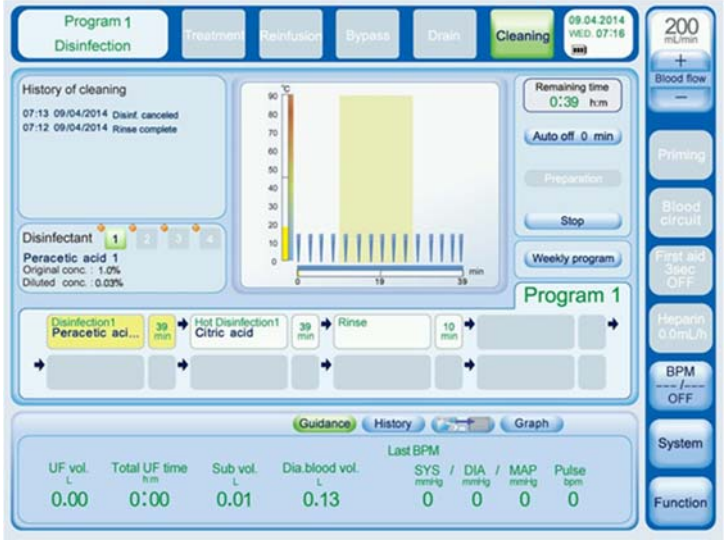
- For contamination concern, dispose used blood circuit, dialyzer, and the air filter of the venous pressure port in accordance with the disposal procedure for the Local regulations, hospital or facility.

6. Cleaning operation

Cleaning standby screen

Cleaning execution screen for Single cleaning (Rinse)

Cleaning execution screen for Program (Program 1-Rinse)



For detailed information regarding the screen refer to chapter 2, point 2.7

6.1. Setting of cleaning pattern

NOTE

- If no button is touched on the Cleaning standby or Cleaning complete screen for a certain time (the time set as "Back light auto off time" in Basic) in the Cleaning mode, the Message Display monitor turns off the back light to prevent the liquid crystal screen to be burnt.

6.1.1. Cleaning solution setting

No.	Action to be Taken
1	Press the System button.
2	Press the Setting button.
3	Press the 4 Cleaning button.
4	Press either of the following buttons: Disinfection button, Decalcification button, Hot Disinfection button or Hot Rinse button.
5	Press the button to be changed and change its settings.

⚠CAUTION

- Check original concentration and diluted concentration. If the setting is wrong, sufficient cleaning effect may not be obtained.
- Be careful about temperature settings. The boiling point of pure water falls by 0.027°C as atmospherical pressure falls by 1hPa. At the mountain top of 2000 meter from sea level, atmospherical pressure falls by 200hPa and boiling point decreases to 94.6°C.
- After setting, check that the selected cleaning step is displayed on the Cleaning screen.

6.2. Check before the cleaning operation

The following basic requirements must be fulfilled before the start of a cleaning program:

(1) The dialyzer couplers are set firmly to the machine and the flap is closed.
(2) Nozzles for A concentrate and B concentrate are securely set in the corresponding nozzle holders, and the cover flap is closed.
(3) The cartridge holder is completely closed
(4) Supply and drain is correctly connected
(5) For disinfection and decalcification, ensure that their original concentration and diluted concentration are properly set at the Cleaning solution setting screen.

Any failure to comply with the basic requirements will be indicated by a message on the display.

⚠CAUTION

- Input the same value as actual original concentration onto the Cleaning setting screen. The corrosion resistance of the dialysate circuit is not guaranteed if settings are wrong.
- Set original concentration and diluted concentration within the range of the specification. The corrosion resistance of the dialysate circuit is not guaranteed if settings are out of specification. (Refer to chapter 11 Specification)
- The surfaces of exterior parts and silicone tubes become hot during the Hot Rinse and Hot Disinfection operations. Keep highly flammable materials away from the hot surfaces.
- When using disinfectants, observe the manufacturer's instructions for use.
- When connecting the disinfectant container also observe the following criteria:

- The containers must be provided with a ventilation opening.
- The coding of the disinfection connectors.
- The disinfectant must match the respective disinfection program.
- Different disinfectants may not be mixed with each other.

- Prior to the use of disinfectants other than those listed in Chapter 11
- "Consumables", make sure these are efficient and are compatible with the materials affected in the hemodialysis system.
- Improper use of disinfectants (concentration, temperature range, dwell time) may cause damage to the hemodialysis system.

NOTE

- Flow alarms during cleaning programs will increase the length of the cleaning program at least by the time of the alarm.
- The count-down times shown during the cleaning programs are calculated values. This time may vary depending on the ambient conditions.

6.3. Check during cleaning operation

⚠WARNING

- The surfaces of exterior parts and silicone tubes become hot during the Hot Rinse and Hot Disinfection operations. Handle with care not to get burn injury.
- The inside of the dialysate circuit becomes very hot during the Hot Rinse and Hot Disinfection operations. Do not operate with uncovered machine.
- Temperatures of solution may rise to nearly 100°C during the Hot Rinse and Hot Disinfection operations. Do not touch spills when leakage is found. You may get burned.

6.4. Cleaning operation procedures

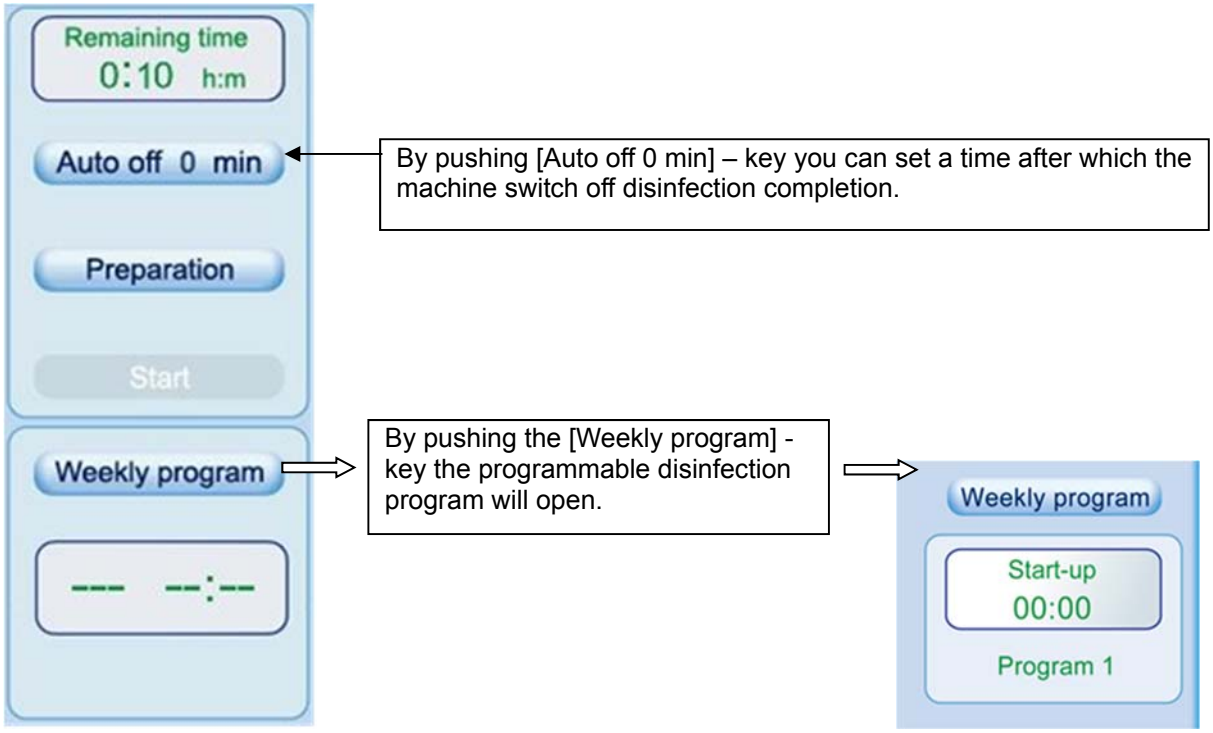
Automatic cleaning and single cleaning processes are described:

No.	Action to be Taken
1	In case of single cleaning, select the cleaning step.
2	Press the Start button. The Cleaning execution screen is displayed. In case of automatic cleaning, the first step of the program starts. In case of single cleaning, the selected cleaning step starts.
3	In case of automatic cleaning, the next step automatically starts when the predetermined time for each cleaning step ends. In case of single cleaning, the cleaning operation is complete.
4	In case of automatic cleaning, the Cleaning complete screen appears when all the predetermined steps end.

NOTE

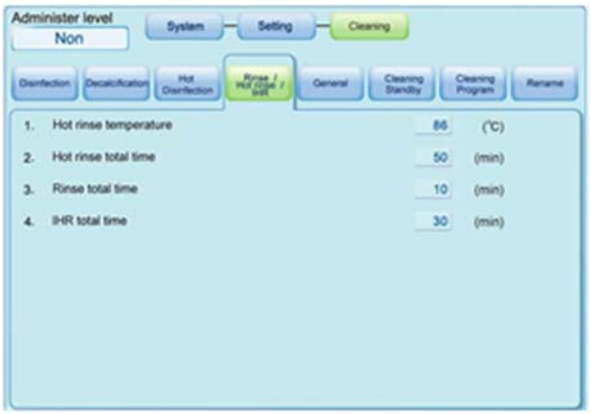
- The system cannot proceed into the Treatment mode during cleaning. Proceed after all cleaning movements are complete.
- When the Heat Exchanger option is not installed, the Cool Down operation using water below 18°C may accelerate degradation of parts. Appropriate temperature management of supply water is needed.

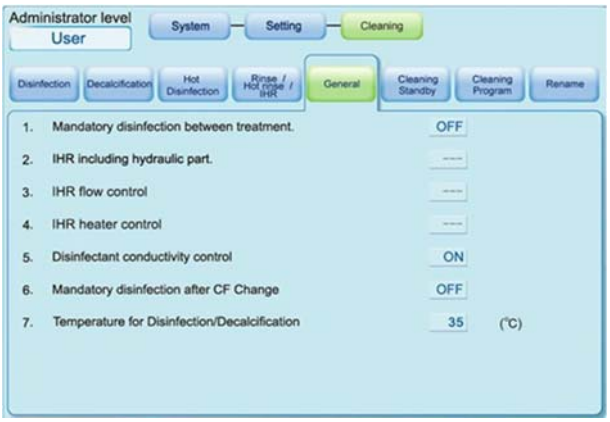
Add the use of the weekly program, auto off and the settings:

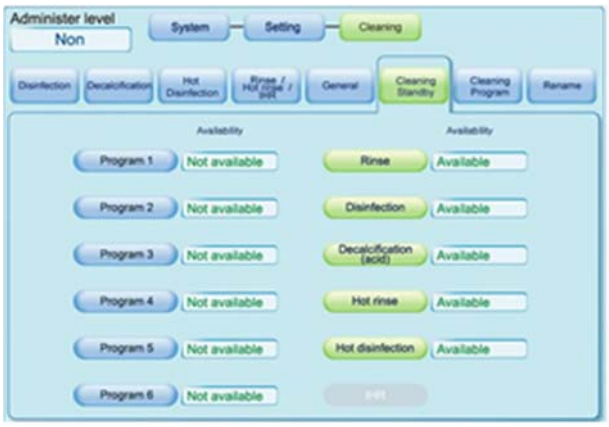


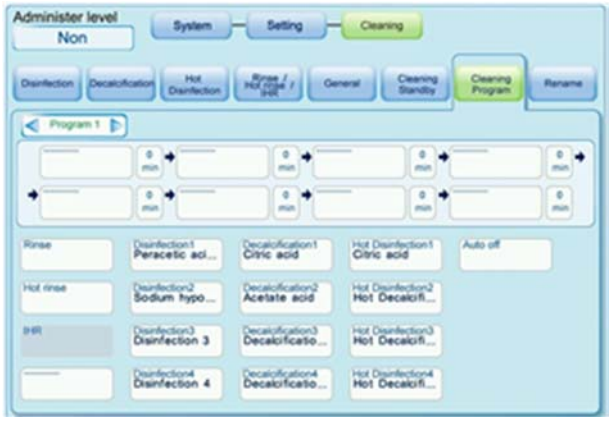
In the following screen it is possible to activate per day two individual programs at a selectable time. The plan is for the next 7 days.

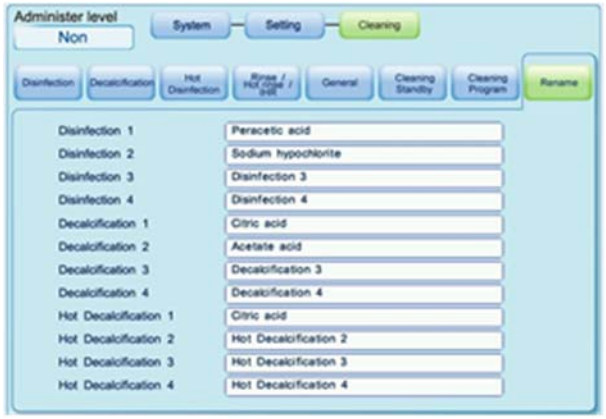
Settings regarding disinfection under [System] [Settings] [Cleaning]:




Administrator level
User
System
Setting
Cleaning
Disinfection
Decalcification
Hot Disinfection
Rinse / Hot rinse / IHR
General
Cleaning Standby
Cleaning Program
Rename
1. Mandatory disinfection between treatment. OFF
2. IHR including hydraulic part. ----
3. IHR flow control ----
4. IHR heater control ----
5. Disinfectant conductivity control ON
6. Mandatory disinfection after CF Change OFF
7. Temperature for Disinfection/Decalcification 35 (°C)


Administer level
Non
System
Setting
Cleaning
Availability
Availability
Program 1 Not available
Program 2 Not available
Program 3 Not available
Program 4 Not available
Program 5 Not available
Program 6 Not available
Rinse Available
Disinfection Available
Decalcification (acid) Available
Hot rinse Available
Hot disinfection Available


Administer level
Non
System
Setting
Cleaning
Program 1
Rinse
Hot rinse
IHR
Auto off


Administer level
Non
System
Setting
Cleaning
Disinfection 1 Peracetic acid
Disinfection 2 Sodium hypochlorite
Disinfection 3 Disinfection 3
Disinfection 4 Disinfection 4
Decalcification 1 Citric acid
Decalcification 2 Acetate acid
Decalcification 3 Decalcification 3
Decalcification 4 Decalcification 4
Hot Decalcification 1 Citric acid
Hot Decalcification 2 Hot Decalcification 2
Hot Decalcification 3 Hot Decalcification 3
Hot Decalcification 4 Hot Decalcification 4

6.5. Check after cleaning operation

After the cleaning operation, ensure that the system had a sufficient cleaning or disinfection and that no solution (disinfectant) is remaining.
(After cleaning, check if solution (disinfectant) is remaining inside of the dialysate circuit using a test paper or reagent.)
Sample can be taken at the blue coupler and the substitution port, using the test method corresponding to the used disinfectant. If the test shows a residual concentration or in event of a positive pH reaction (acid based disinfectants pH≤4.5) start a rinse program.
For peracetic acid based disinfectants use for example a potassium iodide starch paper
For sodium hypochlorite based disinfectants use for example a potassium iodide starch paper
Observe the “use by” date of the indicator paper!

⚠WARNING

- Recommended post rinse time setting is different from the previous type machine (S/N: xxDNxxxx , xxDRxxxx , xxDSxxxx or xxEJxxxx). Please avoid confusion with old and new.

⚠CAUTION

- It takes about 11 minutes at maximum to remove residual solution (disinfectant) completely by cleaning with water. Clean the machine completely with water so that no residual solution (disinfectant) exists.
- After the hot citric disinfection, it takes 8 minutes or more to remove residual citric acid. Clean the machine completely with water long enough to wash off citric acid.
- In use of the central system for A solution (option), implement proper pathway cleaning between A1 port to V46, A2 port to V48 at the facility side
- If the error occurs during disinfection, the disinfection process completes its operation to the end of post rinse, but the error message “Disinfection cancelled" remains in the disinfection history. Although the disinfection process should resume after recovering the error, shifting to the treatment process depends on an engineer's discretion. In this case, always ensure certainty of the disinfection first, and move to the preparation process.

NOTE

- Contact your nearest branch or sales office for the procedure in order to check the disinfection or cleaning effect.

6.6. Clean up and disinfection

To maintain the performance of the machine for a long period of time, be sure to clean and disinfect the machine after use and before storage.

NOTE

- To clean the screen use “monitor symbol” key to freeze all buttons for a determined time.

6.6.1. Cleaning and disinfecting of exterior

Be sure to clean and disinfect the exterior of the machine after use.

- Cleaning -

Wipe a stained part with dry and soft cloth.
When it is considerably stained, wipe the part with a squeezed cloth which is moisten with neutral detergent weakened with water, and after that, remove moisture with a soft cloth.

- Disinfection -

When blood attached the machine, wipe it with disposable paper towel or cloth, after that, wipe with water and then wipe it with sodium hypochlorite (1000ppm/0.1% dilution)). And wipe the part with a squeezed cloth which is moistened with water, and remove moisture with a soft cloth.

Do not use sodium hypochlorite concentrate directly.

⚠WARNING

- To avoid cross contamination among patients, clean and disinfect elaborately the venous (arterial, single needle) pressure port using cotton swabs etc.

⚠DANGER

- Do not mix sodium hypochlorite with acetic acid, citric acid or peracetic acid
- If mixed, it may produce chlorine gas harmful to humanbody
- Inhalation of the generated chlorine gas will cause serious danger to the human body
- Perform a hot citric disinfection after every treatment.

⚠CAUTION

- Do not use organic solvents such as thinner, benzene, rubbing alcohol at the time of cleaning. These chemicals damage the painted surface and plastics of the machine.
- Do not use the disinfectants containing quaternary ammonium compounds e.g. benzalkonium chloride or alkyldimethylbenzylammonium chloride.
- Exercise caution so that no fluids enter into the venous (arterial, single needle) pressure port. It can damage the sensor.
- At the time of cleaning and disinfecting, be sure to use gloves and tools for protection.

6.6.2. Cleaning of Interior

Be sure to clean the interior of the unit after use.

(a) For soils in the interior of the dialysate circuit, wipe with a cloth damped with water.
(b) When dialysate, concentrate or other solutions adhere to the dialysate circuit, wipe it off immediately. It can cause rust.

NOTE

- Turn off the I/O power key when cleaning the interior of the unit.

⚠WARNING

- Cleaning the electric circuit of the unit is extremely dangerous. No one other than the trained professionals should open the electric circuit cover.

NOTE

- By using the following surface disinfectants we make the experience that several components maybe damaged and the machine safety cannot guaranteed anymore. The manufacturer shall no longer have any liability
- Known products at the moment: Inside extra©, Melsept©, Terralin©
- Do not open the substitute port, drain port, Dialyzer coupler bypass, cartridge holder, Concentrate suction ports and not disconnect dialysis fluid filter when cleaning the surface. If this instruction is not followed, a disinfection program must be performed after cleaning the surface.

6.6.3. Disinfection of hydraulic circuit

Be sure to disinfect the hydraulic circuit after use.

⚠WARNING

- Be sure to disinfect the hydraulic circuit after use. If not disinfected for a long period of time, bacteria proliferate within the unit and they would enter patients through dialysis treatment. Patients will be in life-threatening danger.
- Confirm that disinfectant is enough in the stock solution bottle before every disinfection. If the bottle is empty during Disinfection mode, sufficient effect may not be obtained.
- Every disinfection, confirm by viewing that concentrate disinfectant must be supplied (aspirated) into the unit completely.
- If a disinfectant is not supplied (aspirated) because of a damaged electromagnetic valve or other reasons, it can cause cross contamination among patients.
- Confirm that residual disinfectant in the stock solution bottle is not increased after every Disinfection. If the disinfectant increased, sufficient disinfection might not be obtained.
- If a machine has been stored for a long time with citric acid remained in the disinfectant tube, or hot citric disinfection has not been performed for a long time, citric acid tends to crystallize in the tube (it crystallizes for about 3 days if the tube is not connected to the disinfectant tank). If hot citric disinfection is performed under such conditions, intended disinfection will not be expected because sufficient citric acid will not be sucked. Please open the right side cover and ensure that the tube between “V17→Disinfectant connector” and “V12→Disinfectant connector” has no crystallization of citric acid visually and by touching it before performing hot citric.

⚠CAUTION

- Observe the following otherwise bacteria may grow in the circuit, enter into the patients during treatment and endanger their lives.
- Disinfection of a route between the RO water supply port to V1 is not possible with this equipment. Sanitary control and disinfection need to be done on the facility side.
- When using central system for solution (option), disinfection of the route between the concentrate supply port A1 / A2 or B1 to V45 / V47 is not possible with this equipment. Sanitary control and disinfection need to be done on the facility side.

NOTE

- The consumption of disinfectant is 43.4 mL (up to option), when the original concentration is 6% and the diluted concentration is 0.1%. (With Online HDF option and B cartridge option model)
- The consumption of acid concentrate is 26.0 mL (up to option), when the original concentration is 50% and the diluted concentration is 0.5%.

6.6.3.1. Recommended concentration of disinfectants

Use of hot citric acid and sodium hypochlorite are recommended for the disinfection of the equipment.
Supply the equipment with disinfectant adjusted to the following concentration:

- Citric acid : 30 to 50%
- Sodium hypochlorite : 4 to 6 %

Check the descriptions on the container of the disinfectant and verify concentration, and adjust it before using if needed.

⚠CAUTION

- Lower concentrations or dilution will result in insufficient disinfection.

6.6.3.2. Recommended diluted concentration and disinfection Time

The following disinfection condition is recommended:

- Hot citric acid: diluted concentration 0.5%, setting time 31min or longer(HD＋online)
  diluted concentration 0.5%, setting time 29min or longer(HD)
- Sodium hypochlorite: diluted concentration 1000ppm/0.1%, setting time 38min or longer

⚠WARNING

- If diluted concentration of disinfectant is lower than recommended value, or disinfection time is less than the recommended time shown above, effective disinfection will not be achieved and bacteria may proliferate within the unit. Patients will be in life-threatening danger.
- Recommended disinfection setting is different from the previous type machine (S/N: xxDNxxxx , xxDRxxxx , xxDSxxxx or xxEJxxxx). Please avoid confusion with old and new.
- If Post rinse time is changed in disinfection, actual disinfection time increases/decreases correspondingly.
  Actual disinfection time = Total time - (Pre rinse time:7min + Post rinse time)
  In case post rinse time is extended, also change Total time setting.

⚠CAUTION

- When you disinfect with sodium hypochlorite, it takes about 15 minutes from the start of cleaning to fill dialysate circuit with sodium hypochlorite completely.

6.6.3.3. Recommended disinfection type

Hot citric acid and sodium hypochlorite are recommended.
Hot citric acid temperature setting is fixed at 70 °C by default.
Sodium hypochlorite is operable in the rage between 35 and 40°C. (35 °C by default)
At the 35 °C setting, disinfection is expected to complete with the dilution ratio and setting time described in the previous page.

⚠WARNING

- When HDF is performed and/or when dialyzers with high flux membrane are used: disinfection with sodium hypochlorite once a week is recommended. 30 Sodium-hypochlorite disinfections are possible in a life cycle of CF-609N.
- A temperature lower than 35 °C will result in insufficient disinfection and proliferation of bacteria in the unit. Patients will be in life-threatening danger.

⚠CAUTION

- Contact the nearest sales branch or representative to ask about the effect of disinfection by sodium hypochlorite and hot citric acid.

6.6.3.4. Hot Water Disinfection (HWD)

Under [System] [Settings] [Cleaning] [Rinse / Hot rinse / IHR] No.5 Hot Water Disinfection (HWD) can be turned ON. Then Hot rinse which is a cleaning mode will be changed to the HWD.
The HWD has been validated as disinfection method for the hydraulic circuit.
The duration of the HWD is fixed to 35 minutes. The temperature setting is fixed to 85°C.

⚠WARNING

- The sole use of HWD leads to calcification of the hydraulic circuit, which may damage the machine.
- Please perform decalcification based on 6.6.4.

⚠CAUTION

- Contact the nearest sales branch or representative to ask about the effect of disinfection by HWD.

6.6.4. Removing calcium from the hydraulic circuit

Remove calcium from the hydraulic circuit by the decalcification of the cleaning process.

⚠WARNING

- When a bicarbonate dialysate is used, calcium carbonate precipitates inside of the unit. Calcium carbonate precipitation makes it easier for bacteria to proliferate, which can then cause parts of the unit to malfunction. Remove calcium at least once a week.
- While cleaning, check regularly if acetic acid is supplied/aspirated into the unit and calcium is being removed. This should be checked approx. once a week. If acetic acid is not supplied/aspirated because of a damaged electromagnetic valve or other reasons, calcium cannot be removed.

7. Light indicator

7.1. Light indicator specifications

Light indicator blinks or lights depending on operations as follows.

process / condition	Standby	Cleaning standby	Cleaning	Preparation	Preparation complete	Treatment	Reinfusion
Alarm	Red blinking	Red blinking	Red blinking	Red blinking	Red blinking	Red blinking	Red blinking
Warning	Orange lighting	Orange lighting	Orange lighting	Orange lighting	Orange lighting	Orange lighting	Orange Lighting
First aid	---	---	---	---	---	Green lighting	---
Message	Green blinking	Green blinking	Green blinking	Green blinking	Green blinking	Green blinking	Green blinking
Normal	---	---	Orange lighting	Orange lighting	Orange blinking	Green lighting	Green blinking

The green light blinks even in a normal condition in case of the following:
- The blood pump is stopped during the dialysis process.
- Bypass operation is executed during the dialysis process.
- Ultrafiltration is stopped during the dialysis process.
- Treatment remaining time reached 0:00.

The orange light blinks even in a normal condition in case of the following:
- The blood pump is stopped during the reinfusion process.

The red light lights up even in a normal condition in case of the following:
- A power failure occurs.

Used Standards for light indicators:
-IEC60601-1 Point 7.8 / IEC 60073 [5]
-IEC 60601-1-8
-IEC 60601-2-16 point 201.7.8.1 and subclause 201.7.8.1

8. Alarm operations and recovery

When abnormalities are detected, the system alerts the operator by the alarm lights, indicator light, audible buzzers, and screen display of detailed alarm information. In addition, the safety system that allows automatic emergency operation such as dialysis interruption is installed for some alarms.

⚠WARNING

- If alarm occurs repeatedly, turn off the unit promptly, interrupt dialysis, and separate the patient from the unit. Continuous use can lead to severe hazard in the patient.
- Stay within the audible area of alarms during treatment. Perform necessary procedures if alarm goes off.

8.1. Description of alarms

8.1.1. Alarm messages

If some errors or abnormal conditions occur, the following three types of windows will appear to notify the operator of the error or the abnormal condition.

Information (light blue window)
Warning (light yellow window)
Alarm (red window)

NOTE

- Some alarms perform special alarm movements.
- The alarm sound can be changed in the System-Setting-Sound screen.

8.1.2. How to reset (recover)

To resume the normal unit operation after eliminating the cause of alarm emergence, perform the following operations.

Alarms and their main operations when errors are detected:

Error	Alarm operation		
	Buzzer	Light indicator	Main operation
When the venous pressure is equal to or exceeds the maximum/minimum alarm set values	Audible	blinking in red	Blood/heparin pumps stop. UF operation stops.
When the dialysate pressure is equal to or exceeds the maximum/minimum alarm settings, or When TMP exceeds the alarm set value	Audible	blinking in red	Blood/heparin pumps stop. UF operation stops. Venous circuit is clamped, but not for the TMP alarm.
Single bubble: When 30 µL or larger is detected	Audible	blinking in red	Blood/heparin pumps stop. UF operation stops. Venous circuit is clamped.
When the dialysis fluid temperature is lower than the minimum set value or higher than the maximum set value	Audible	blinking in red	Bypass operation. UF operation stops. Heater OFF.
When volume of blood detected by the blood leak detector is higher than a set value	Audible	blinking in red	Blood/heparin pumps stop. Bypass operation. UF operation stops.
When the OVERLOAD DETECTION button of the heparin pump operates (including injection completion)	Audible	-	Heparin pump stops.
When a unit-related error such as a temperature sensor error occur	Audible	blinking in red	The unit stops, etc.
When the measured conductivity of the dialysate which enters the dialyzer is equal to or exceeds the maximum/ minimum alarm set values	Audible	blinking in red	Bypass operation. UF operation stops.

Before Contacting Us

Check the following when errors are found in the unit. Contact nearest branch or agency if you cannot figure out the causes or if the errors are not listed in the following table.

Error	Cause	Countermeasure
The cleaning standby screen does not appear in spite of pressing the I/O power key.	The power cord is not connected to an outlet properly.	Connect the power cord to an outlet properly.
	The power cord is disconnected.	Check the outlet by connecting other electric appliances. If the power cord is disconnected, contact the agency where you purchased the unit.
The key light is not lit in spite of pressing the I/O power key.	The battery for power failure backup is low in charge and the power breaker is turned off.	Turn on the power breaker.
	Did not press the I/O power key for 0.5 consecutive sec or longer.	Press the I/O power key for 0.5 consecutive sec or longer.
Nothing or only a part of a display appears on the message display monitor.	Backlight is turned off.	Press the key on the operation panel.
	The connector to be connected to the message display monitor is off.	Connect the connector properly.
The dialysis temperature does not increase to the setting temperature.	The water supply temperature is low.	Set the water supply temperature properly Refer to “11. Specification”.
The dialysis temperature does not decrease to the setting temperature.	The water supply temperature is high.	Set the water supply temperature at least the setting temperature of the unit − 5°C.
The cleaning does not start.	The system is in the Cleaning standby process.	Touch the Rinse button. Then touch the Start button once.
	The liquid stopped due to alarm emergence.	Eliminate the cause(s) and reset the alarm.
The blood pump does not rotate (when power is on or in case of power failure).	The blood pump cover is open.	Close the blood pump cover firmly.
	The blood pump flow display is “0 mL/min”.	Set the correct flow rate.
	The blood pump stopped due to alarm emergence.	A blood circuit-related alarm is going off. Eliminate the cause(s) and reset the alarm.
The blood pump does not rotate (in case of power failure).	The battery for power failure backup is low in charge.	Charge the battery (energize the unit for 48 hours or longer).
	The life of the battery for power failure backup expired.	Replace the battery.

Error	Cause	Countermeasure
The heparin pump does not rotate (when power is on or in case of power failure).	The heparin pump flow display is “0.00 mL/h”.	Set the heparin pump follow as you desire.
	The blood pump stopped.	Move the blood pump.
	The heparin pump stopped due to overload.	Eliminate the cause(s) of overload.
	The estimated heparin infusion time is met.	Press the HP rate button if you need to infuse again.
	The system shows that the heparin pump infusion is complete.	Move the pusher to the right.
The heparin pump does not rotate (in case of power failure).	The battery for power failure backup is low in charge.	Charge the battery (energize the unit for 48 hours or longer).
	The life of the battery for power failure backup expired.	Replace the battery.
During the bicarbonate dialysis, the actual dialysate concentration is higher than the setting concentration.	The concentration of concentrate is high.	Use concentrate with a proper concentration.
	The concentrate to be used and dialysate type setting are different.	Correct the dialysate type setting.
During the bicarbonate dialysis, the actual dialysate concentration is lower than the setting concentration.	The concentration of concentrate is low.	Use concentrate with a proper concentration.
	The concentrate is not aspirated sufficiently because the concentrate tank is closed.	Make the air to flow better by loosening the cap for the concentrate tank, etc.
	The concentrate is not aspirated sufficiently because the silicone tube of the concentrate line of the dialysate circuit is bent or blocked.	Straighten or unblock the silicone tube.
	The concentrate to be used and dialysate type setting are different.	Correct the dialysate type setting.
	The concentrate connector is not inserted.	Inset them properly.
During the acetate dialysis, the actual dialysate concentration is higher than the setting concentration.	The concentration of concentrate is high.	Use concentrate with a proper concentration.
	The concentrate to be used and dialysate type setting are different.	Correct the dialysate type setting.

Error	Cause	Countermeasure
During the acetate dialysis, the actual dialysate concentration is lower than the setting concentration.	The concentration of concentrate is low.	Use concentrate with a proper concentration.
	The concentrate to be used and dialysate type setting are different.	Correct the dialysate type setting.
	The concentrate connector is not inserted.	Inset them properly.
The actual dialysate concentration does not match the displayed concentration.	Concentration adjustment has not been done properly.	Adjust the concentration by proper procedures.
	Contact failure of the conductivity sensor harness.	Eliminate the cause of contact failure of the conductivity sensor harness.
	Electrodes of the conductivity sensor are rusty.	Remove rust or exchange the electrodes.
Button operation does not work.	A button whose operation was not accepted by the system was touched.	Some button operations do not work depending on a screen display or process. Read the instruction manual again before operation.
	The connector on the PCB is off.	Connect the connector properly.

8.1.3. How to respond to alarms (flow chart)

Emergency of an abnormality
↓
The unit detects the abnormality and operates accordingly
↓
1 The operator mutes the buzzer
↓
2 The operator eliminates the cause of the alarm
↓
3 The operator resets the system

NOTE

- The alarm goes off again 120 seconds after ”1. The operator mutes the buzzer”.
- Some alarms automatically reset the system during “2. The operator eliminates the cause of the alarm”. Refer to “Trouble shooting” for details.

8.1.4. Alarm System mode

The system has 2 Alarm System modes and the operations of audible alarms and Light indicator in case of emergency are as follows:

(a) Normal mode

Refer to “8.2 Alarm operations” for audible alarms.

Refer to “7 Light indicator” for Light indicator.

(b) ICU mode

Audible alarms sound according to the priority of the ICU mode as follows:
High: A sound for high priority repeatedly sounds.
Medium: A sound for medium priority repeatedly sounds.
Low: A sound for low priority sounds once.
Light indicator function according to the priority of the ICU mode as follows:
High: Red flashing
Medium: Orange flashing
Low: Orange light

NOTE

- The mode is switched to the ICU mode when the “ICU mode” of the System-Setting-Sound is turned ON.
- Refer to the “Troubleshooting” for the priority of the ICU mode.
- If more than one alarm occurs, the alarm with higher level is prioritized regardless of the time occurred.
  If there are same level alarms, the alarm which occurs later is prioritized for the display.

8.2. Alarm operations

8.2.1. Types of alarms

(1) Danger

Alarms other than the following (2).

NOTE

- The alarm buzzer sound for Danger can be changed at the “Sound” in the SYSTEM “Setting”.

(2) Caution

- “Rinse volume reached”
- “Treatment time reached”
- “ISO-UF goal reached”
- “Reinfusion volume reached”
- “Cleaning complete”
- “Auto power off”

NOTE

- Melodies of the caution alarm buzzers can be changed at the “Sound” in the SYSTEM “Setting”.

8.3. List of most common alarms

8.3.1. Conductivity

Alarm name:	E27 Dialysate conductivity alarm E101 Solution B conductivity alarm
Machine action:	Bypass
Possible cause:	Conductivity exceeds the maximum set value for the alarm or falls below the minimum set value.
Suggested steps to solve:	Confirm that the actual concentration is within the set value. Confirm that appropriate concentrate is used. Confirm that no abnormality such as tube clogging is found in sensor or machine. Press [alarm reset] - key to confirm the alarm
If no action help:	Contact technical service for further assistance or repair

8.3.2. Venous pressure/ arterial pressure

Alarm name:	E7 Venous pressure max alarm E8 Venous pressure min alarm E23 Arterial pressure max alarm E24 Arterial pressure min alarm
Machine action:	BP stop, clamps close
Possible cause:	Venous pressure or arterial pressure exceeds the maximum set value for the alarm or falls below the minimum set value.
Suggested steps to solve:	Confirm that shunt section is not clogged or blood circuit is not bent. Confirm that the blood pump circulates without problems. Press [alarm reset] - key to confirm the alarm
If no action help:	Contact technical service for further assistance or repair

8.3.3. Temperature

Alarm name:	E12 Dialysate temp max alarm E13 Dialysate temp min alarm
Machine action:	Bypass
Possible cause:	Dialysate temperature exceeds the maximum set value for the alarm or falls below the minimum set value. (Dialysate Temp min alarm occurs if the alarm condition continues for five (5) seconds.)
Suggested steps to solve:	Confirm that the actual temperature is within the set value. Confirm that feeding temperature is appropriate. Confirm that no abnormality is found in sensor or heater. Press [alarm reset] - key to confirm the alarm
If no action help:	Contact technical service for further assistance or repair
Remark:	Dialysate Temp min alarm is not detected for 60 seconds after resetting.

8.3.4. Air bubbles

Alarm name:	E17 Air bubbles detected
Machine action:	Venous clamp close, BP stops
Possible cause:	Air bubbles are detected. 10 μL or larger single air bubble is detected. Cumulated amount of 0.3 μL or larger micro bubbles exceeds the set value for the alarm
Suggested steps to solve:	Check for air bubbles in blood circuit. Confirm that no abnormality is found in sensor. Follow the instructions on the screen to solve the problem Press [alarm reset] - key to confirm the alarm
If no action help:	Contact technical service for further assistance or repair

8.3.5. UFP

Alarm name:	E58 UFP error
Machine action:	Stops
Possible cause:	UF pump (UFP) rotation speed is significantly higher or slower than setting value.
Suggested steps to solve:	Confirm that no abnormality is found in UFP. Confirm that no abnormality is found in sensor.
If no action help:	Contact technical service for further assistance or repair

Alarm name:	E61 UFP rotation error
Machine action:	Stops
Possible cause:	UF pump (UFP) rotates backward.
Suggested steps to solve:	Confirm that no abnormality is found in UFP. Confirm that no abnormality is found in sensor.
If no action help:	Contact technical service for further assistance or repair

Alarm name:	E62 UFP speed error
Machine action:	Stops
Possible cause:	UF pump (UFP) rotation speed is a little higher or slower than setting value.
Suggested steps to solve:	Confirm that no abnormality is found in UFP. Confirm that no abnormality is found in sensor.
If no action help:	Contact technical service for further assistance or repair

Alarm name:	E108 UFP stop error
Machine action:	Stops
Possible cause:	UF pump (UFP) rotates even though it should be stopped.
Suggested steps to solve:	Confirm that no abnormality is found in UFP. Confirm that no abnormality is found in sensor.
If no action help:	Contact technical service for further assistance or repair

8.3.6. Blood leak

Alarm name:	E15 Blood leak alarm
Machine action:	BP stop, Bypass
Possible cause:	The blood leak value exceeds the blood leak alarm set value for five (5) consecutive seconds.
Suggested steps to solve:	Check for blood leak in the blood circuit. Confirm that no abnormality is found in dialyzer. Confirm that no abnormality is found in sensor.
If no action help:	Contact technical service for further assistance or repair

8.3.7. Blood pump

Alarm name:	E75 Blood pump error
Machine action:	BP stop, clamps close
Possible cause:	Blood pump rotation speed is significantly higher or slower than setting value. Blood pump rotates backward. Blood pump rotates even though it should be stopped.
Suggested steps to solve:	Confirm that no abnormality is found in blood pump.
If no action help:	Contact technical service for further assistance or repair

8.4. Screen failures

8.4.1. Operation on the screen impossible

When pressing the touch panel shows no reaction or dims the screen, execute reinfusion, using normal saline solution, in the following procedure and immediately separate the equipment and the patient.

* Press the Blood system stop switch to stop the blood pump.
* Remove the puncture section on the arterial side from the patient to connect it to the normal saline solution.
* When the single needle pump is equipped with a circuit, disconnect the tube in the procedure below:
  - Open the single needle pump cover.
  - Pull the lever forward and manually rotate the rotor in the counterclockwise direction while holding the lever.
  - Check that the tube is securely disconnected and close the pump cover.
* Clamp the venous line between dialyzer and V chamber. Produce minimum -200mmHg in venous chamber by a syringe. Press the Reset button.
  ("E18 Large bubbles detected" occurs but this alarm can be ignored.)
* Open the cover of the blood pump.
* Pull the lever forward and manually rotate the rotor in the counterclockwise direction while holding the lever. Visually check that no air bubbles enter the venous line.

8.5. List of alarms

Alarm name		Detection condition	Priority (ICU)
E001	Recovery from a power cut.	- AC supply power is ON. - Power breaker is ON.	LOW
E005	Dialysate pressure MAX alarm	PD value over the dialysate pressure maximum alarm value is detected continuously for 5 seconds.	LOW
E006	Dialysate pressure MIN alarm	PD value below the dialysate pressure minimum alarm value is detected continuously for 5 seconds.	LOW
E007	Venous pressure MAX alarm	PV value over the venous pressure maximum alarm value is detected for more than 2 seconds continuously.	MID
E008	Venous pressure MIN alarm	PV value below the venous pressure minimum alarm value is detected.	HI
E009	TMP alarm	TMP value over the TMP alarm value is detected for 5 seconds continuously.	MID
E010	TMP offset alarm	- TMP offset value below -200mmHg is detected. - TMP offset value over +150mmHg is detected.	LOW
E011	UFRP rate of change alarm	The change rate of the current UFRP from that of 20 rounds before exceeds the UFRP change rate alarm value.	LOW
E012	Dialysate TEMP MAX alarm	T4 over the dialysate temperature maximum alarm value is detected.	LOW
E013	Dialysate TEMP MIN alarm	T4 below the dialysate temperature minimum alarm value is detected.	LOW
E014	Overheated heater alarm	Operation of LS1a, LS1b or LS1c.	LOW
E015	Blood leak alarm	Change amount of BLD value over the blood leak alarm value is detected for 5 seconds continuously.	MID
E017	Air bubbles detected	- Single air bubble (over 10µL) signal is detected. - Signal indicating that a total of micro bubbles (over 0.3µL) is over the setting value is detected.	HI
E019	CD2 conductivity sensor alarm	CD2 value over 3.0mS/cm is detected 1 minute before water rinse is finished.	LOW
E020	CD3 conductivity sensor alarm	CD3 value over 3.0mS/cm is detected 1 minute before water rinse is finished.	LOW
E022	T3&T4 difference alarm	- During treatment Temperature difference over 1.2 °C between T3 and T4 is detected for 5 seconds continuously. - during hot rinse and hot citric rinse Temperature difference over 2.0 °C between T3 and T4 is detected for 5 seconds continuously.	LOW
E023	Arterial pressure MAX alarm	PA value over the arterial pressure maximum alarm value is detected.	MID

Alarm name		Detection condition	Priority (ICU)
E024	Arterial pressure MIN alarm	PA value below the arterial pressure minimum alarm value is detected for 2 seconds continuously.	MID
E025	FS1 sensor alarm	FS1 does not turn off when it should be turn off.	LOW
E027a	Dialysate conductivity alarm	- CD1 value over the dialysate conductivity maximum alarm value is detected. - CD1 value below the dialysate conductivity minimum alarm value is detected. - CD1 value is 15.6mS/cm or over. - CD1 value is 12.3mS/cm or less.	LOW
E027b	Dialysate conductivity alarm. Please check A concentrate.	CD1 value below -10% is detected for 5 seconds continuously.	LOW
E028	Air bubble sensor error (Self-test)	Air bubble CPU self-test alarm is detected (CPU_C).	MID
E030	Venous pressure MAX limit	PV value over 480 mmHg is detected.	MID
E031	Venous pressure MIN limit	PV value over -480 mmHg is detected.	MID
E032	Dialysate pressure MAX limit	PD value over 630mmHg is detected.	LOW
E033	Dialysate pressure MIN limit	PD value below -630mmHg is detected.	LOW
E034	T1 temperature sensor error	- T1 value below 0.5 °C is detected for 5 seconds continuously. - T1 value over 100.5 °C is detected for 5 seconds continuously.	LOW
E035	T2 temperature sensor error	- T2 value below 0.5 °C is detected for 5 seconds continuously. - T2 value over 100.5 °C is detected for 5 seconds continuously.	LOW
E036	T3 temperature sensor error	- T3 value below 0.5 °C is detected for 5 seconds continuously. - T3 value over 100.5 °C is detected for 5 seconds continuously.	LOW
E037	T4 temperature sensor error	- T4 value below 0.5 °C is detected for 5 seconds continuously. - T4 value over 100.5 °C is detected for 5 seconds continuously.	LOW
E038	HP revolving direction error	HP reversely rotates.	LOW
E039	Syringe not detected	Syringe has not been installed	LOW
E040	SNP stop error	SNP stops operation due to the following reason: - Cover open (120 seconds continuously) - Flow rate of 0mL/min - Stop switch ON	MID
E041	SNP revolving direction error	SNP rotates in the wrong direction for 2 seconds.	MID
E042	SNP speed error	Return speed is out of the setting speed allowable range.	MID
E043	SNP error	ALARM OUT from the SNP motor is fixed to Hi or Lo level.	MID
E044	SNP cover sensor error	SNPC1 signal and SNPC2 signal deviate for 2 seconds continuously.	MID

Alarm name		Detection condition	Priority (ICU)
E045	SFP stop error	SFP stops operation due to the following reason: 1) Cover open	LOW
E046	SFP revolving direction error	SFP rotates in the wrong direction for 2 seconds.	LOW
E047	SFP speed error	Return speed is out of the setting speed allowable range.	LOW
E048	SFP error	- ALARM OUT from the SFP motor is fixed to Hi or Lo level. - SFP does not stop even after +10% infusion of Cum. Bolus after ONLINE Bolus execution.	LOW
E049	SFP cover sensor error	SFPC1 signal and SFPC2 signal deviate for 2 seconds continuously.	LOW
E050	BP cover sensor error	BPC1 signal and BPC2 signal deviate for 2 seconds continuously.	MID
E051	Air bubble sensor error	- One of 4 kinds of alarms is received from air bubble CPU. - WD timer output level of air bubble sensor does not change for 2 seconds continuously. - "L" pulse is not input to BD signal for more than 600ms and BDFAULT, BDOPEN and BDADJ are "H". - D/A value periodically received from air bubble CPU and memorized D/A value are different.	MID
E052	Blood leak sensor error	BLD ≥ 251ppm is detected for 1 minute continuously at patient connection	MID
E053	BP stop error	BP stops operation due to the following reason: - Cover open (120 seconds continuously) - Flow rate of 0mL/min - Stop switch ON	MID
E054	CD1 conductivity sensor alarm	CD1 value over 10.0mS/cm is detected 1 minute before water rinse is finished. CD1 value over 10.0mS/cm is detected 1 minute before water rinse is finished.	LOW
E055	Water supply error	- FS1 detects OFF status for 1 second continuously within 3 seconds after switching the round. - PD does not increase over 200 mmHg in C0 process. - FS1 turns off for 5 seconds during J' step sequence.	LOW
E056	Short water supply	FS1 detects ON status for 1 second continuously within 15 seconds after switching the round.	LOW
E057	Short dialysate flow	FS2 detects ON for 1 second continuously even after the elapse of 120 seconds after switching the round.	LOW
E058	UFP error	0.10L/h difference from the preset rate is detected.	LOW
E059	Releasing air from AS2 error	FSW ON status is detected for 30 seconds continuously.	LOW

Alarm name		Detection condition	Priority (ICU)
E060a	Closed circuit leak error	Leak check value exceeds the detection value twice continuously.	LOW
E060b	Dialysate pressure gauge check error	Dialysate pressure has not reached 400mmHg even after UFP rotates 9 times CW.	LOW
E060c	Central system valve leak error	Central system valve (V45, V46, V47 and V48) does not operate properly.	LOW
E060d	Dialyzer leak check error	Leakage check value exceeded the detection value twice continuously.	LOW
E061	UFP rotation error	Shielding is detected in order of PH6→PH5 twice.	LOW
E062	UFP speed error	When a difference from the integrated rotation speed for 10 minutes is more than ±3 rotations.	LOW
E063	Heparin syringe infusion completed or the line is clamped.	LS3 ON.	LOW
E064	CLV position error	- Difference between LS5 and clamp control signal is detected for 1 second continuously. - LS5 ON when the clamp control signal is opened.	MID
E065	CLA position error	- Difference between LS10 and clamp control signal is detected for 1 second continuously. - LS10 ON when the clamp control signal is opened.	MID
E066	Sub port connection error Please check correct connection of substitution line to substitution port.	Leak check value exceeds the detection value twice continuously.	LOW
E067	Arterial pressure MAX limit	PA value over 480mmHg is detected.	MID
E068	Arterial pressure MIN limit	PA value over -480mmH is detected.	MID
E069	FS2 sensor alarm	FS2 does not turn off when it should be turn off.	LOW
E070	Air bubble sensor setting error	- Difference between the setting output to air bubble CPU and return signal from air bubble CPU is detected. - Difference of air bubble monitor start signal is detected.	MID
E071	HP drive error （PH7）	PH7 response cycle exceeds "ideal cycle±20%".	LOW
E072	HP drive error （PH8）	PH8 response cycle exceeds "ideal cycle±20%".	LOW
E073	BP revolving direction error	BP rotates in the wrong direction for 2 seconds.	MID
E074	BP speed error	Return speed is out of the setting speed allowable range.	MID
E075	BP error	ALARM OUT from the BP motor is fixed to Hi or Lo level.	MID
E076	CLV fan error	Alarm stop signal from the CLV fan is detected.	MID
E078	Close the sub-port	LS15 OFF.	LOW
E079	Close the drain port	LS16 OFF.	LOW
E080	BPM RAM error	RAM/ROM check result "42" is received.	HI

Alarm name		Detection condition	Priority (ICU)
E081	BPM ROM error	RAM/ROM check result "43" is received.	HI
E082	BPM error	Error code "E07, E08 or E09" is received from BPM2500.	HI
E083	BPM communication error	BPM communication error is detected.	HI
E084	BPM pressurization error	Error code "E03" is received.	HI
E085	SYS blood pressure max. error	Highest blood pressure (data transmitted from BPM2500)≧Highest blood pressure error (maximum)	HI
E086	SYS blood pressure min. error	Highest blood pressure (data transmitted from BPM2500)≦Highest blood pressure error (minimum)	HI
E087	DIA blood pressure max. error	Lowest blood pressure (data transmitted from BPM2500)≧Lowest blood pressure error (maximum)	HI
E088	DIA blood pressure min. error	Lowest blood pressure (data transmitted from BPM2500)≦Lowest blood pressure error (minimum)	HI
E089	Pulse-rate max. error	Pulse rate (data transmitted from BPM2500)≧Pulse rate error (maximum)	HI
E090	Pulse-rate min. error	Pulse rate (data transmitted from BPM2500)≦Pulse rate error (minimum)	HI
E091	BPM response error	No response from BPM2500	HI
E092	BPM communication port error	RS-232C port not normally opened at the start.	HI
E093	BP eject pin error (LS21b)	- LS21b does not turn OFF even after the elapse of 1 second during CW operation. - LS21b does not turn ON even after the elapse of 3 seconds during CCW operation.	LOW
E094	BP eject pin error (LS21a)	- LS21a does not turn ON even after the elapse of 1 second during CW operation. - LS21a does not turn OFF even after the elapse of 3 seconds during CCW operation.	LOW
E095	SNP eject pin error (LS22b)	- LS22b does not turn OFF even after the elapse of 1 second during CW operation. - LS22b does not turn ON even after the elapse of 3 seconds during CCW operation.	LOW
E096	SNP eject pin error (LS22a)	- LS22a does not turn ON even after the elapse of 1 second during CW operation. - LS22a does not turn OFF even after the elapse of 3 seconds during CCW operation.	LOW
E097	Sub-Pump eject pin error (LS23b)	- LS23b does not turn OFF even after the elapse of 1 second during CW operation. - LS23b does not turn ON even after the elapse of 3 seconds during CCW operation.	LOW

Alarm name		Detection condition	Priority (ICU)
E098	Sub-Pump eject pin error (LS23a)	- LS23a does not turn ON even after the elapse of 1 second during CW operation. - LS23a does not turn OFF even after the elapse of 3 seconds during CCW operation.	LOW
E099	SN average stroke volume min alarm	Calculated average stroke volume is below "S/N stroke volume min" in the SN menu.	MID
E100	Single switch time alarm	- Venous pressure does not reach the S/N press high point even after either (4000) / (BP flow rate) time or the elapse of 30 seconds. - Venous pressure does not reach the S/N press low point even after the elapse of "SN alarm low stroke time" during S/N operation.	MID
E101a	Solution B conductivity alarm	- CD2 over the dialysate conductivity maximum alarm value is detected. - CD2 below the dialysate conductivity minimum alarm value is detected.	LOW
E101b	Solution B conductivity alarm. Please check B concentrate.	CD2 value below 1.0mS/cm is detected.	LOW
E102	T5 temperature sensor error	- T5 value below 0.5 °C is detected for 5 seconds continuously. - T5 value over 100.5 °C is detected for 5 seconds continuously.	LOW
E103	SN pressure MAX limit	PSN value over 480 mmHg is detected.	MID
E104	SN pressure MIN limit	PSN value over -480 mmHg is detected.	MID
E105	SN pressure abnormal	- SN pressure change during S/N operation is below 10mmHg. - The S/N press high or low point is not reached even after supplying 10mL more than the setting stroke amount. - SN pressure exceeded +/- 10 mmHg in priming without SNP.	MID
E108	UFP stop error	- PH5→PH6 is detected when UFP is not operating. - PH6→PH5 is detected when UFP is not operating.	LOW
E111	T6 temperature sensor error	- T6 value below 0.5 °C is detected for 5 seconds continuously. - T6 value over 100.5 °C is detected for 5 seconds continuously.	LOW
E112	T7 temperature sensor error	- T7 value below 0.5 °C is detected for 5 seconds continuously. - T7 value over 100.5 °C is detected for 5 seconds continuously.	LOW
E113	T5&T6 difference alarm	Temperature difference over 1.2 °C between T5 and T6 is detected for 5 seconds continuously.	LOW
E114	Target temperature not reached	T1 below 70 °C is detected.	LOW

Alarm name		Detection condition	Priority (ICU)
E115	Please close the both B-cartridge arms completely.	- Rinse waiting LS7a or LS7b OFF when rinse start is ON - Rinse, water drain, deaeration LS7a or LS7b OFF	LOW
E118	T2 overheated	T2 over 100.0 °C is detected for 1 second continuously.	LOW
E119	Temperature is low	T1 below 70℃ is detected for 1 second continuously.	LOW
E120	Circulation flow stop	FS1 and FS2 detect no flow for 2 seconds continuously.	LOW
E121	Filtration max. Alarm Please increase blood flow, or decrease UFR/Sub rate	Return amount from the dialyzer during ultrafiltration or substitution fluid operation exceeds a blood circuit flow by a certain ratio.	LOW
E122	Dialysate flow error	- The average of the past 26 rounds of F_OUT is lowered than the dialysate setting value. - The average of the past 26 rounds of F_OUT exceeds the dialysate setting value by more than 10%.	LOW
E123	Dialysate flow control error	- F_OUT does not reach the setting flow even at P2 control voltage of 5.00 V - F_OUT exceeds the setting flow by more than +10% even at P2 control voltage of 1.00 V.	LOW
E124	No blood detected Blood sensor error	No blood is detected by blood sensor even when a certain amount of blood is supplied after patient connection.	MID
E125	Venous chamber level adjustment failure.	PH9 does not detect a fluid level while the level is increasing.	LOW
E127	Short chemical solution	F3 OFF (no solution) is detected during suction of chemical solution.	LOW
E128	T2&T5 difference error	T5 over T2 by more than 2 °C is detected for 5 seconds continuously.	LOW
E129	Chemical solution not detected. Please check the container.	CD2 value below a designated value is detected for 5 seconds continuously.	LOW
E130	Arterial pressure port test error	PA does not change more than 10mmHg.	LOW
E131	S/N pressure port test error	PSN does not change more than 5mmHg.	LOW
E132	Venous pressure port test error	- PV does not change more than 20mmHg. - PV does not change more than 10mmHg in 2 seconds after CLV is turned ON.	LOW
E133	Level adjustment pressure gauge error	PG1 (circuit internal pressure) over ±300mmHg is detected for 2 seconds continuously.	LOW
E134	No bloodline circuit clip detection at Blood pump. Please check the clip.	LS17 OFF.	MID

Alarm name		Detection condition	Priority (ICU)
E135	No bloodline circuit clip detection at Single needle pump. Please check the clip	LS18 OFF.	MID
E136	No bloodline circuit clip detection at substitution pump. Please check the clip.	LS19 OFF.	LOW
E137	Fan 3 error	An alarm stop signal is detected during operation of FAN3.	LOW
E138	Fan1 error	An alarm stop signal is detected during operation of FAN1.	LOW
E141	DRV fan error	An alarm stop signal is detected during operation of DRV FAN.	LOW
E143	Chemical solution temperature error	T4 value out of the setting temperature +4 °C / -2 °C.	LOW
E144	Valve movement error	Faulty valve state is detected.	LOW
E145	Sub / DIF bolus rate failure	Sub bolus infusion volume is out of the sub bolus target volume by more than ±10%.	LOW
E146	Heparin pump bolus rate failure	HP bolus infusion continues even after the target volume is reached.	LOW
E147	Post rinse time shortage error	Post rinse is completed before the preset time.	LOW
E148	Nurse call button has been pressed	Nurse call button has been pressed.	LOW
E149	Blood detected	Blood sensor detected the blood during priming or circulation.	LOW
E150	External liquid leak detected! Please check the blood circuit, drain port, and substitution port.	LD1 detected the water leak.	LOW
E151	Internal liquid leak detected! Please check the patient weight and inform technician.	LD2 detected the water leak.	LOW
E152	CD1&CD4 difference alarm	The difference between CD 1 and CD 4 continuously exceeded the reference value for 5 seconds.	LOW
E153	Power Failure	- AC supply power is OFF. - Power breaker is OFF.	LOW
E154	CFL1: Cut filter1 leak check error	Leakage check value exceeded the detection value twice continuously.	LOW
E155	CFL2: Cut filter2 leak check error	Leakage check value exceeded the detection value twice continuously.	LOW
E156	Please confirm the supply condition of concentrate.	Different concentrate was used.	LOW
E158	Air bubble sensor adjust error	Adjustment error alarm is detected.	MID

Alarm name		Detection condition	Priority (ICU)
E160	Air bubble sensor communication error	Communication error alarm is detected.	MID
E162	Water supply valve error	50mmHg or more pressure fluctuation occurs when the supply water valves (V1&V55) are checked in the C0 process.	LOW
E163	Reducing valve error	Pressure after completion of the supply water pressure check in the C0 process is 450mmHg or over.	LOW
E164	RBV has fall below RBVcrit. Please check patient condition and adjust the treatment settings if necessary.	RBV is RBVcrit or less.	LOW
E166	Air inlet for bicarbonate cartridge is blocked.	Air inlet for bicarbonate cartridge does not operate properly.	LOW
E168	UFP leak error	UFP leak check value exceeds the detection value.	LOW
E169	Cut Filter running time is reached, please replace the Cut Filter : System Blocked	After the cut filter change time is reached, the machine tries to move the process to the 4th preparation process without replacing the cut filter.	LOW
E300	SELF CHECK ALARM PWC power supply failure	Detected a failure of PWC board is detected.	MID
E301	SELF CHECK ALARM SFP power supply failure	Detected a failure of SFP-DRV board is detected.	MID
E302	SELF CHECK ALARM SNP power supply failure	Detected a failure of SNP-DRV board is detected.	MID
E303	SELF CHECK ALARM BP power supply failure	Detected a failure of BP-DRV board is detected.	MID
E304	SELF CHECK ALARM BLM power supply failure	Detected a failure of BLM board is detected.	MID
E305	SELF CHECK ALARM HDS power supply failure	Detected a failure of HDS board is detected.	MID
E306	SELF CHECK ALARM PNL power supply failure	Detected a failure of PNL board is detected.	MID
E307	SELF CHECK ALARM BLM-C CPU self test failure	Detected BLM CPU_C failure of Blood Control Board.	MID
E308	SELF CHECK ALARM HDS S CPU self test failure	Detected HDS CPU_S failure of Hydraulics Control Board.	MID
E309	ABNORMAL STATE ERROR	The process is moved without the touch key operation.	MID
E310	PARAMETERS INITIALIZATION	Initialization of setting value.	LOW
E311	SELF CHECK ALARM SFP:NG	Start up test of SFP was NG.	LOW
E312	SELF CHECK ALARM SNP:NG	Start up test of SNP was NG.	LOW

Alarm name		Detection condition	Priority (ICU)
E313	SELF CHECK ALARM BYPASS:NG	Start up test of BYPASS was NG.	LOW
E314	SELF CHECK ALARM COND.1 SENSOR :NG	Start up test of COND.1 was NG.	LOW
E315	SELF CHECK ALARM COND.2 SENSOR :NG	Start up test of COND.2 was NG.	LOW
E316	SELF CHECK ALARM COND.3 SENSOR :NG	Start up test of COND.3 was NG.	LOW
E317	SELF CHECK ALARM T4 SENSOR:NG	Start up test of T4 was NG.	LOW
E318	SELF CHECK ALARM T5 SENSOR:NG	Start up test of T5 was NG.	LOW
E319	SELF CHECK ALARM T1/T6 SENSOR:NG	Start up test of T1 or T6 was NG.	LOW
E320	SELF CHECK ALARM T7 SENSOR:NG	Start up test of T7 was NG.	LOW
E321	SELF CHECK ALARM UF PUMP:NG	Start up test of UFP was NG.	LOW
E322	SELF CHECK ALARM V.PRESS SENSOR:NG	Start up test of V. press sensor was NG.	LOW
E323	SELF CHECK ALARM A.PRESS SENSOR:NG	Start up test of A. press sensor was NG.	LOW
E324	SELF CHECK ALARM BLD:NG	Start up test of BLD was NG.	LOW
E325	SELF CHECK ALARM BLOOD PUMP:NG	Start up test of BP was NG.	LOW
E326	SELF CHECK ALARM PSN:NG	Start up test of PSN press sensor was NG.	LOW
E327	SELF CHECK ALARM PG1:NG	Start up test of PG1 press sensor was NG.	LOW
E328	SELF CHECK ALARM CLV:NG	Start up test of CLV was NG.	LOW
E329	SELF CHECK ALARM CLA:NG	Start up test of CLA was NG.	LOW
E330	SELF CHECK ALARM BATTERY ERROR	Detected voltage failure of BATTERY.	MID
E331	SELF CHECK ALARM PARAMETERS ERROR	Detected memory failure of Main control board PNL02.	MID
E332	SELF CHECK ALARM LEVEL ADJUSTER:NG	Start up test of Level adjuster pump was NG.	LOW
E333	SELF CHECK ALARM BLM CPU-S self test failure	Detected BLM CPU_S failure of Blood Control Board.	MID
E334	SELF CHECK ALARM BP CPU-S self test failure	Detected BP CPU_S failure of Motor Control Board.	MID
E335	SELF CHECK ALARM SNP CPU-S self test failure	Detected SNP CPU_S failure of Motor Control Board.	MID

Alarm name	Detection condition	Priority (ICU)
E336 SELF CHECK ALARM SFP CPU-S self test failure	Detected SFP CPU_S failure of Motor Control Board.	MID
E337 SELF CHECK ALARM PNL CPU-S self test failure	Detected PNL CPU_S failure of Main Control Board.	MID
E338 SELF CHECK ALARM HDS CPU-C self test failure	Detected HDS CPU_C failure of Hydraulics Control Board.	MID
E339 SELF CHECK ALARM BP CPU-C self test failure	Detected BP CPU_C failure of Motor Control Board.	MID
E340 SELF CHECK ALARM SNP CPU-C self test failure	Detected SNP CPU_C failure of Motor Control Board.	MID
E341 SELF CHECK ALARM SFP CPU-C self test failure	Detected SFP CPU_C failure of Motor Control Board.	MID
E342 SELF CHECK ALARM PNL CPU self test failure	Detected PNL CPU failure of Main Control Board.	MID
E343 SYSTEM COMMUNICATION ERROR	Communication error between CPU is detected.	MID
E344 SELF CHECK ALARM PWC CPU self test failure	Detected a failure of PWC board.	MID
E345 SELF CHECK ALARM PD SENSOR:NG	Detected a failure of PD.	LOW
E346 SELF CHECK ALARM BD CPU:NG	Start up test of BD CPU was NG.	MID
Treatment has been resumed, as the power supply was turned on with I/O button. Please reconfirm the treatment parameters.	The system starts up by I/O button.	LOW
Proper calibration is not performed.	R^2 value at the conductivity Cal completion was lower than the specified value.	LOW
Check the cuff and the pressure tubing	Error code is received.	HI
Please check the position and condition of the cuff	Error code is received.	HI
Measurement error due to movement	Error code is received.	HI
Measurement error due to insufficient pressure	Error code is received.	HI
Measurement error due to movement or irregular pulses.	Error code is received. Error code is received.	HI
Check the cuff and the body movement.	Error code is received.	HI
Measurement error with a faint pulse	Error code is received.	HI
Please close the pump covers.	The pump cover of the circuit opened during priming.	LOW
No UF parameters programmed	UF goal or UF rate is set to 0.00 when the Device shifts to Treatment process.	LOW
Please confirm treatment condition.	Turn First aid function OFF when activated.	LOW
The last disinfection was performed 3 days ago.	The Device is activated since previous disinfection finished 72 or more hours ago.	LOW

Alarm name	Detection condition	Priority (ICU)
Blood not detected	Blood sensor detects light emitting.	MID
Blood flow / Dialysate flow is too high, to turn on Auto sub. Please reduce Blood flow / Dialysate flow.	When Sub rate exceeds during Auto sub function is ON.	LOW
Treatment in progress! Please press and hold I/O switch for 5 seconds to turn off the device	I/O button is pressed during dialysis process.	LOW
Treatment is in bypass. Confirm if bypass should continue.	Manual Bypass operation exceeds the preset Bypass button notice time.	LOW
UF stop. Please confirm UF condition.	Manual UF stop status elapsed of UF stop button notice setting time.	LOW
Blood flow / Ratio is too high, to turn on Auto SN. Please reduce Blood flow / Ratio.	SNP flow exceeds 600mL/min when the Auto SN function is ON.	LOW
Max UF limit exceeded in Profile. Please check UFR setting in Profile, or decrease Sub rate.	Exceeded UFR limitation in UF profile.	LOW
Profile is not available as Step time is less than 5 minutes	When each step time is less than 5 minutes.	LOW
"Blood sample time" is longer than the "Treatment time remaining". Please reduce the "Blood sample time".	"Blood sample time" is set to be longer than "Treatment time remaining".	LOW
Please press Bypass button for blood sample, or stop the process with Reset button.	UF remaining time reaches Blood sample time.	LOW
Please check the venous pressure port line.	Venous pressure does not have amplitude more than the setting time and pressure.	LOW
Please check the arterial pressure port line.	Arterial pressure does not have amplitude more than the setting time and pressure.	LOW
Sub pump stopped. Please check Sub pump.	Sub pump I/O is turned OFF during HF.	MID
Please abort the priming, pressing the remove all button, to change the type of blood line.	Unrelated segment was inserted to the treatment mode selected during priming.	LOW
With this BP/SNP flow, the blood flow stops more than 2 minutes. Please increase the BP/SNP flow.	Stroke vol. / BP flow ≥ 2min Stroke vol. / SNP flow ≤ 2min	LOW
DIF bolus interrupted.	DIF bolus interrupted	LOW
HP bolus interrupted.	HP bolus interrupted	LOW
Heparin pump button is OFF. Please confirm heparin condition.	Time preset at “Heparin start button notice time “elapsed with the syringe placed during dialysis process and HP OFF.	LOW
UFR has been increased by **% compared with manually set UFR. Please check UFR.	The result of “UFR after offset / UFR before offset * 100” exceeds “System – Setting – Treatment – UF - 6. UFR increasing notice rate” setting.	LOW

Alarm name	Detection condition	Priority (ICU)
Effective treatment time has been shortened ** min. Would you like to continue with fixed treatment time?	Percentage of shortening of Treatment time remaining exceeds System - Treatment shortening time setting.	LOW
Sub goal has been decreased by **% compared with manually set Sub goal. Please check Sub goal.	The result of “Sub goal after offset / Sub goal before offset * 100” exceeds “System - Setting - Treatment - UF - 7. Sub goal decreasing notice rate” setting.	LOW
Please inspect the venous line from the venous access to the venous clamp and ensure no air bubbles are present.	CTS operation completes and “Treatment start” is selected.	MID
Machine is in bypass for more than **min. Please check the concentrate condition or machine condition.	Auto bypass has been performed more than the designated Auto Bypass notice time preset in the Parameter setting.	LOW
Disinfection was not completed, because machine did not meet the disinfection conditions.	An alarm which forcibly moves the state to Post rinse was detected during Disinfection or Hot disinfection.	LOW
Error reading card! Please check the card, or delete the card data.	- Patient card was inserted with the wrong direction - Patient card with damaged internal data was inserted - Non-dedicated card was inserted	LOW
Writing data to the patient card. Please don't remove the patient card.	Treatment data is written in the patient card	LOW
The parameter of red character are not available in the machine. Please put available parameters.	The value out of the settable range is set by the patient card.	LOW
Please check the treatment mode! Set treatment mode from Card system and manually set treatment mode may be different!	The treatment mode and the blood circuit condition set by the patient card and the set treatment mode are different.	LOW
Treatment time reached. Please insert the patient card, to save the treatment data!	The blood circuit condition and treatment mode are different from the treatment mode set by the patient card.	LOW
Inserted patient card is not matching to the registered patient! Please remove the card!	Different card was inserted after the card was removed when the patient card was valid.	LOW
Please do not remove the dialyzer couplers.	Automatic bypass condition was canceled after 30 minutes passed while waiting for the coupler to be connected to the dialyzer.	LOW
Max-Sub is deactivated because the type of treatment has been changed from post-dilution to pre dilution!	Treatment mode changed from ONLINE HDF or HF post-dilution to ONLINE HDF or HF pre-dilution when the Max-Sub is on.	LOW

Alarm name	Detection condition	Priority (ICU)
Max-sub function and Sub pump have been stopped due to the high TMP. Please check the dialyzer and set the sub rate manually.	- TMP is out of alarm setting range at the Max-sub start. - E009 TMP alarm was detected when Max-sub is on.	LOW
Patient information has been changed	- Patient information changed on Dose Finder screen - Patient information changed on the Dose Detector screen	LOW
ISO-UF is activated for more than 50% of the set treatment time - This leads to a limited detoxification Are you sure? Please confirm.	More than half of division has set the ISO-UF ON in the Profile setting screen.	LOW
Current blood leak alarm range exceeds 280ppm of the setting.	The blood leak alarm setting was set larger than 280 ppm.	LOW
Current conductivity alarm range exceeds +/-5% of the setting.	The conductivity alarm setting was set larger +/- 5%.	LOW
Please confirm the FAN condition on the left side of the machine.	Thermistor connected to CN110 on BLM-CPU board detects a temperature exceeding 50 °C.	LOW
Filtration rate is too high as compared with the current blood flow. Please increase blood flow, or decrease UFR/Sub rate.	Same as E121.	LOW
Sub goal has been changed. Please confirm the sub goal.	Treatment time remaining is manually changed, and as a result Sub goal is automatically changed.	LOW
Enpty card inserted! Please remove the card.	Empty card inserted.	LOW
BVM is turned off, since the treatment setting does not allow this measurement.	SNDP or Click Clack becomes activated and BVM is stopped.	LOW
BVM error	- Status errors are received for 3 consecutive times from the BVM module. - An error code is received from the BVM module.	LOW
BVM communication error	Communication from the BVM module cannot be received, or no response.	LOW
BVM syntax error	Incorrect communication syntax from the BVM module	LOW
The UF goal will be not achieved. Please reduce the UF Goal or prolong the treatment time.	UF volume cannot reach to UF goal	LOW
UFR MAX reached. Fixed Treatment Time has been switched OFF.	UF rate has reached the upper limit during the Fixed treatment time.	LOW
Cut Filter running time is reached, please replace the Cut Filter. X more treatments remaining.	After the cut filter change time is reached, the machine moves the process to the Preparation process without replacing the cut filter.	LOW

Alarm name	Detection condition	Priority (ICU)
HP rate is not entered	When the machine shifts to treatment process with the heparin pump flow rate set to 0.0 mL/h.	LOW
Please return the A concentrate nozzle.	- Cleaning standby process LS11 turns OFF during Priming inside the rinse port. - Cleaning process When LS11 is OFF.	LOW
Please return the B concentrate nozzle.	- Cleaning standby process LS12 turns OFF during Priming inside the rinse port. - Cleaning process When LS12 is OFF	LOW
Please connect both dialyser couplers to the dialyser.	When LS2a or LS2b is ON	LOW
Please connect both dialyser couplers to the device completely.	When LS2a or LS2b is OFF	LOW
Please remove the pump segment and close the pump covers to continue.	During startup test, BP or SFP cover was opened.	LOW
Please connect the online port	LS15 turns ON during ONLINE priming.	LOW
Please press Reset button after venous line has connected to the drain port.	Drain port is not opened after priming starts. (LS16 is not OFF)	LOW
Hot disinfection time is extended.	T1 was not able to maintain the preset temperature for more than 3 minutes.	LOW
Mandatory disinfection is required.	The dialysis process is transferred to the rinse waiting process.	LOW
Since AC power supply was not supplied, the device was not able to turn on at the set time.	Power failure is occurred at the time of Device activation by automatic power on function.	LOW
Machine is in bypass. Maximum blood flow is temporarily adjusted to 100ml/min and below	Bypass operation was performed during S/N operation.	LOW
Cut filter1 change time reached	Accumulation of Operation time exceeds its alarm range.	LOW
Would you like to perform an online priming? If yes, please insert the substitution clip correctry. If no, please close the sub port.	Sub port was opened while running priming mode which is not online priming.	LOW
Consumables time limit reached, Please change consumables.	Accumulation of Operation time exceeds its alarm range.	LOW
Timer expired	Set timer expired.	LOW
To start Click Clack, please turn off Auto-sub in ONLINE menu.	SN menu is opened on ONLINE circuit when Auto-sub function is ON.	LOW
The specified concentrate differs from the concentrate currently used. Please use the proper type of concentrate.	There is a gap with the conductivity of Calibration1 Step 1 when Calibration 2 dialysate is produced.	LOW

Alarm name	Detection condition	Priority (ICU)
HP infusion completed Please clamp the heparin line.	Elapse time of “Treatment time remaining” exceeds “HP stop time”.	LOW
Start up test completed	All items of startup test are passed.	LOW
Treatment time remaining has been extended	”Treatment time remaining” increases “Time” at the point of 0:00.	LOW
Cut filter2 change time reached	Accumulation of Operation time exceeds its alarm range.	LOW
Division number change? Selection will initialize the current pattern of the profile.	Setting - Characteristics - UF profile division number is selected.	LOW
Please connect the A nozzle to the concentrate.	When LS11 is ON. A setting in Dialysate menu: Front pipe	LOW
Please return the A nozzle to the sheath.	When LS11 is OFF. A setting in Dialysate menu: Central A1 or Central A2	LOW
Please connect the B nozzle to the concentrate. Close the B-cartridge arms completely.	When LS12 is ON, and LS7a, LS7b are OFF. B setting in Dialysate menu: Front pipe	LOW
Please connect the B nozzle to the concentrate.	When LS12 is ON. B setting in Dialysate menu: Front pipe	LOW
Please close the B-cartridge arm completely.	- Cleaning standby LS7a or LS7b OFF when rinse start is ON - Rinse, Filling process LS7a or LS7b OFF	LOW
Please install a B-cartridge. And press the reset button, to start priming.	When LS7a or LS7b is ON. B setting in Dialysate menu: B cartridge	LOW
Please return the B nozzle to the sheath.	When LS12 is OFF. B setting in Dialysate menu: B cartridge or Central B1	LOW
Please take a sample dialysate and measure the concentration. (mmol/L)	The conductivity stabilizes in Calibration2.	LOW
To start Click Clack, please turn off Max-sub in ONLINE menu.	SN menu is opened on ONLINE circuit when Auto-sub function is ON.	LOW
Max-sub system is setting the Sub goal.	Max-sub function is working.	LOW
Max-sub system deactivated. Sub rate has been changed.	Max-sub was turned off during Max-sub calculation.	LOW
To start profile, please change the design of the profile or change the selected concentrate.	Out of the range set for "Available range of concentrate of total, B" of "Concentration information" in Concentrate profile.	LOW
To change the type of concentrate, please turn off the profile in advance.	When changing "Type of Concentrate" when Profile is on, the running profile contains the division exceeding the upper or lower limit set values of the concentrate type after change.	LOW

Alarm name	Detection condition	Priority (ICU)
Dose Detector turned off, since the treatment setting does not allow this measurement.	Treatment mode has been changed that cannot be performed Dose Detector during Dose Detector running.	LOW
BVM is turned off.	- Stop button is manually pressed - Remove arterial line is performed - Remove all is performed - Open the cover of the BVM module during measurement	LOW
BVM Control has been stopped due to implausible measurement results.	The implausible measurement result is detected.	LOW

9. Power failure backup

In case of power failure:

During treatment:

The dialysate flow and it is monitoring are stopped. The liquid crystal display, the touch panel, the extracorporeal alarm system, the blood pump, the single needle pump, the bubble detector, the heparin pump, and the venous clamp are operated by the backup batteries for power failure.

During Start-up test, preparation, priming online, disinfection:

Display is active but actions are stopped. Priming with saline bag can continue.

⚠CAUTION

- If the data has been changed during the time of failure and then the system has recovered without shutting down, the changed data will be saved.

9.1. Specification of the battery for power failure backup

	Specification	Note
Nominal voltage	12.0 V	Two connected in series
Nominal capacity	7.2 Ah	

⚠WARNING

- Periodical inspection or replacement is required for the backup batteries for power failure.
- The backup batteries for power failure should be connected before the system is used.

NOTE

- Replace the backup batteries for power failure every 4 or 5 years
- The backup batteries for power failure are completely charged after approximately 48 hours charge.
- Refer to the regular inspection in the “Service Manual” for the method in order to check the charge state of the backup batteries for power failure and the replacement procedure.

9.2. Power failure backup

9.2.1. Alarm operation in case of power failure

9.2.1.1. Power failure alarm buzzer

Buzzer sounds in case of power failure. Buzzer can be stopped by the Mute key.

9.2.1.2. Backup operation stop buzzer

When the remaining battery level is low at power failure operation, “Battery charge is low” is detected and the buzzer sounds for a minute, and then the I/O power key is automatically turned OFF. (The display gradually turns darker, and then the button and other items become invalid.) The blood pump is stopped forcibly after detecting “Battery charge is low”.
Buzzer can be stopped by the Mute key.

NOTE

- The time between “Battery charge is low” detection and I/O power key is turn-OFF varies depending on the equipment status and age of backup batteries.

9.2.1.3. Message at power failure

In case of power failure, ”Power failure” is displayed on the display. In this case, immediately stop the ongoing treatment.

9.2.2. Blood pump operation in case of power failure

In case of power failure, the blood pump can be operated by the Blood pump I/O button, and the blood pump flow +/- switch.

- When the Blood pump I/O button is ON in case of power failure, the blood pump operates at the set rate, but can be adjusted. This set rat can set in System menu/ treatment/power failure.

- When the Blood pump I/O button is OFF in case of power failure, the blood pump can be operated by turning ON the Blood pump I/O button.

NOTE

- When the backup batteries for power failure are fully charged, the blood pump can operate for approximately 30 minutes with the blood pump flow at 200mL/min and the heparin pump flow at 2mL/h. (factory setting)
- When the backup operation stop buzzer sounds, the blood pump automatically stops.

9.2.3. Heparin pump operation in case of power failure

In case of power failure, the heparin pump can be operated by the Heparin pump I/O button and the heparin pump flow setting button.

- When the Heparin pump I/O button is ON in case of power failure, the heparin pump operates at the rate before the power failure.

NOTE

- The heparin pump is operated only when the blood pump is operated.
- When the backup batteries for power failure are fully charged, the heparin pump can operate for approximately 30 minutes with the blood pump flow at 200mL/min and the heparin pump flow at 2mL/h.

9.2.4. Bubble detector operation in case of power failure

In case of power failure, in single air bubble mode air bubble with 10 μL or more (flow rate at 200mL/min, fluid temperature at 37 ± 1.0 °C) can be detected. In the Micro bubble mode, air bubbles with 0.3 μL or more can be detected, and the alarm is triggered when the accumulated bubble amount reaches the setting values.

After BLM-CPU-E board : 4 steps of 1, 10, 50 and 300μL

Before BLM-CPU-D board : 3 steps of 1, 50 and 100μL

⚠CAUTION

- Due to the voltage reduction of the backup batteries for power failure, the air bubble alarm may be detected by mistake.

9.2.5. Pressure monitoring operation in case of power failure

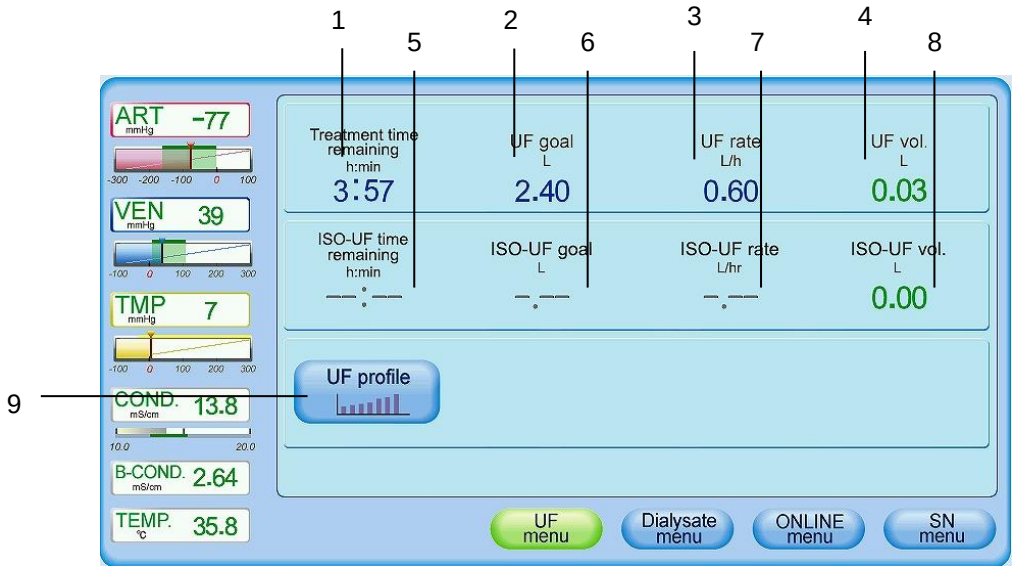
When the dialysis process or the return process is in process in case of power failure, the venous pressure, and arterial pressure, and SN pressure are continuously monitored. When alarm is detected, alarm operation is performed as before power failure.

9.2.6. Hydraulic line operation in case of power failure

All hydraulic lines stop in case of power failure.

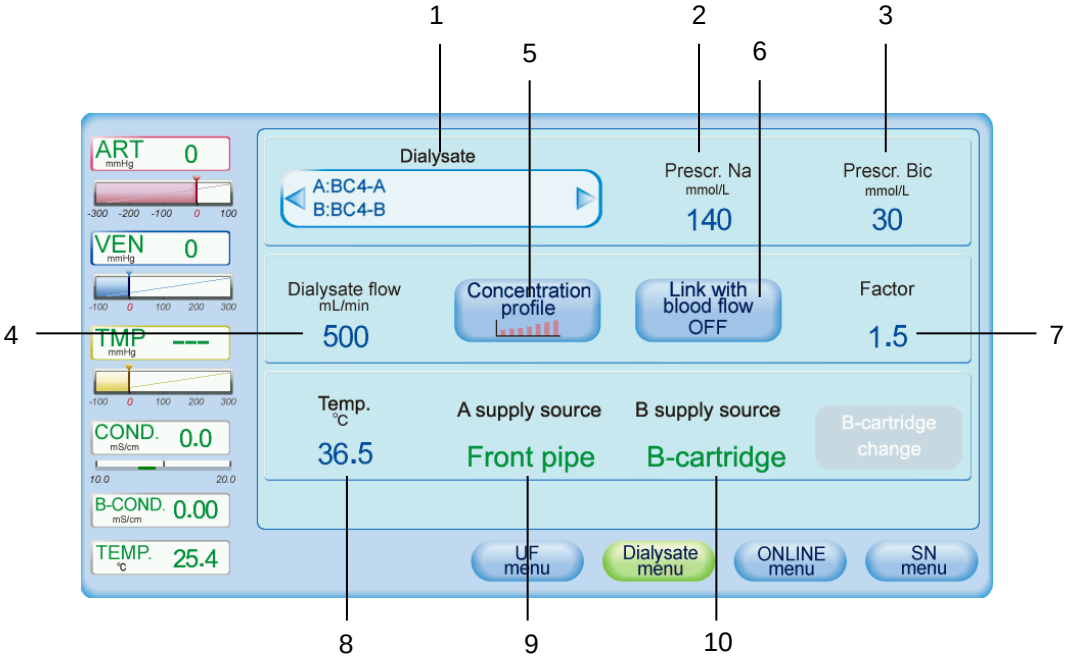
10. Other functions

10.1. UF menu



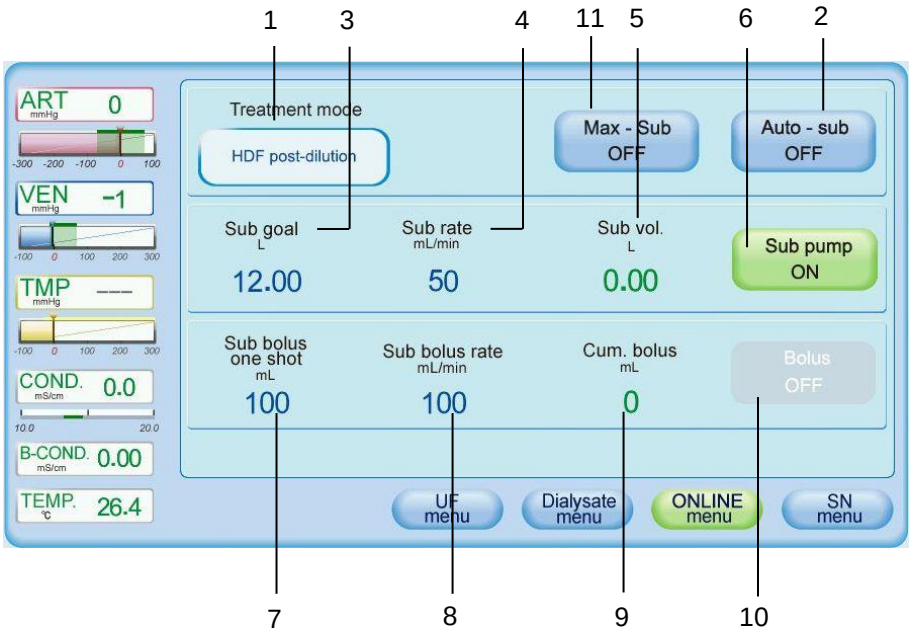
No.	Setting item	Default	Setting range	Setting step	Selection item
1	Treatment time remaining	Value set at System - setting - Treatment - UF - Initial treatment time	0:00 - 24:00	0:01	—
2	UF goal	Value set at System - setting - Treatment - UF - Initial UF goal	0.00 - 10.00	0.01	—
3	UF rate	Value set at System - setting - Treatment - UF - Initial UF rate	0.00, 0.10 - 4.00	0.01	—
4	UF vol.	0.00	0.00 - 10.00	—	—
5	ISO-UF time remaining	--:--	0:00 – 24:00	0:01	—
6	ISO-UF goal	-.--	0.00 – 10.00	0.01	—
7	ISO-UF rate	-.--	0.0,0.10 – 4.00	0.01	—
8	ISO-UF vol.	-.--	0.00 – 10.00	0.01	—
9	UF profile	OFF	—	—	—

10.2. Dialysate menu



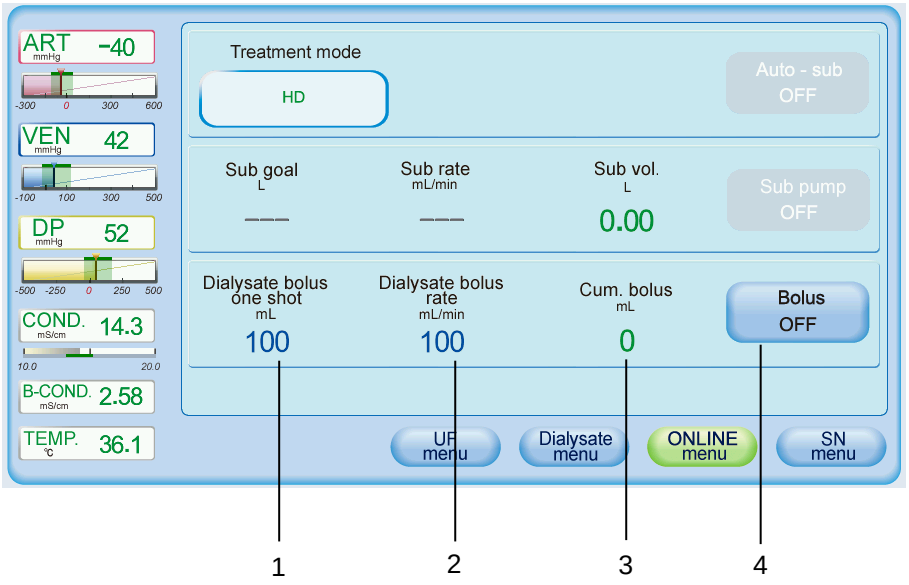
No.	Setting item	Default	Setting range	Setting step	Selection item
1	Dialysate	BC4	AC1, 2 BC1 - 10	-	Product name can be input.
2	Prescr. Na	Value set at System - Setting - Concentration - Concentration information	125 - 165	1	-
3	Prescr. Bic	Value set at System - Setting - Concentration - Concentration information	24 - 70	1	-
4	Dialysate flow	Value set at System - Setting - Treatment - Dialysate flow at the treatment start (HD) or Dialysate flow at the treatment start (ONLINE)	100 - 800	100	-
5	Concentration profile	OFF	-	-	ON/OFF
6	Link with blood flow	OFF	-	-	ON/OFF
7	Factor	Value set at System - setting - Treatment - Dialysate flow factor	1.0 - 3.0	0.1	-
8	Temp.	Value set at System - setting - Treatment - Initial Dialysate temperature	34.0 - 39.0	0.1	-
9	A supply source	Value set at System - Setting - Concentration - Concentration information	-	-	-
10	B supply source	Value set at System - Setting - Concentration - Concentration information	-	-	-

10.3. ONLINE menu



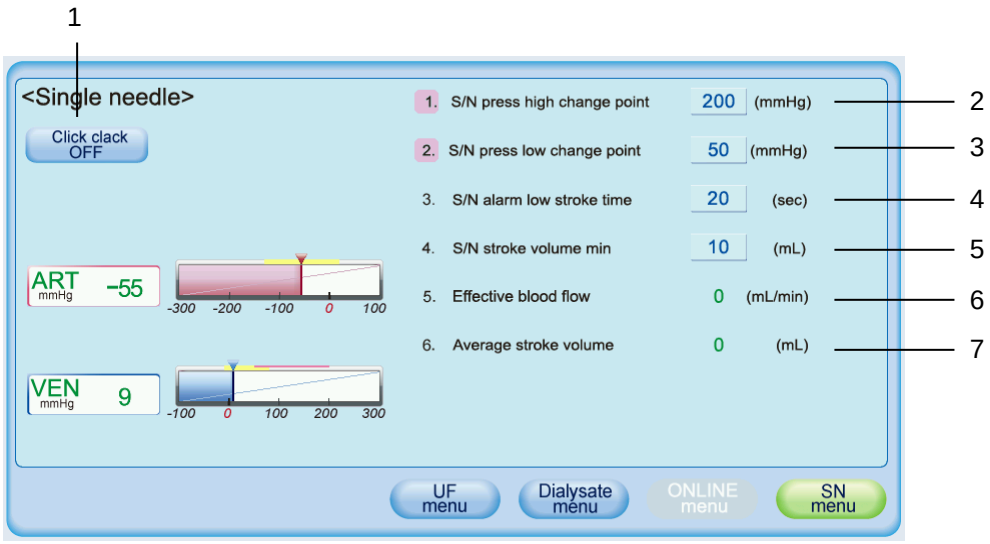
No.	Setting item	Default	Setting range	Setting step	Selection item
1	Treatment mode	Change by blood circuit	–	–	HDF post-dilution HDF pre-dilution HF post-dilution HF pre-dilution
2	Auto-sub ON/OFF	OFF	–	–	ON/OFF
3	Sub goal	Value of set at System - setting - Treatment - ONLINE - Initial Sub goal	1-600	1	–
4	Sub rate	Value set at System - setting - Treatment - ONLINE - Initial Sub rate	10 - 300	10	–
5	Sub volume	0.0	–	–	–
6	Sub pump I/O	OFF	–	–	ON/OFF
7	Sub Bolus one shot	Value set at System - setting - Treatment - ONLINE - Sub bolus one shot	10-200	10	–
8	Sub Bolus rate	Value set at System - setting - Treatment - ONLINE - Sub bolus rate	10-300	10	–
9	Cum. bolus	0	–	–	–
10	Bolus I/O	OFF	–	–	ON/OFF
11	Max-sub ON/OFF	OFF	–	–	ON/OFF

< Dialysate infusion >



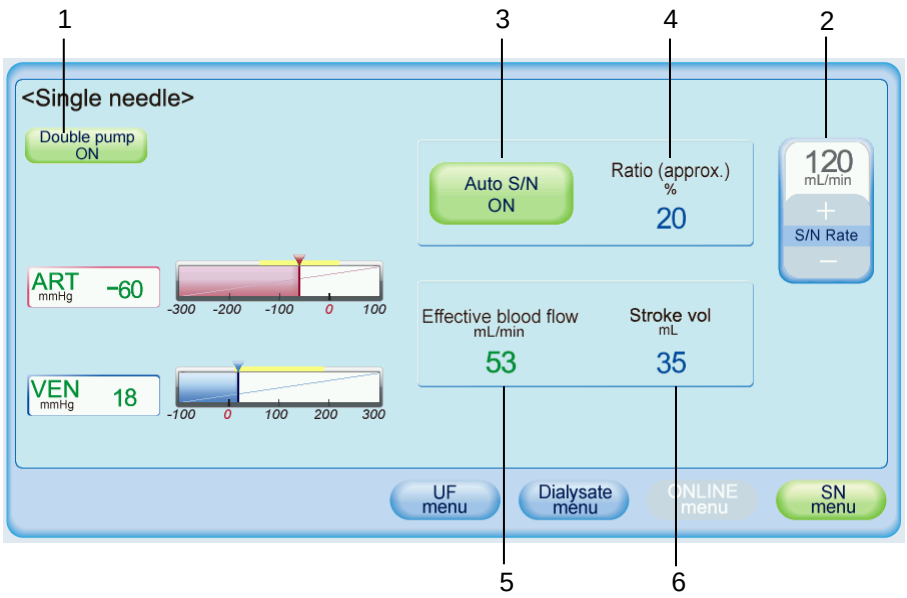
No.	Setting item	Default	Setting range	Setting step	Selection item
1	Dialysate Bolus one shot	Value set at System - setting - Treatment - ONLINE - Sub bolus one shot	10-200	1	–
2	Dialysate Bolus rate	Value set at System - setting - Treatment - ONLINE - Sub bolus one rate	10-300	10	–
3	Cum. bolus	0	–	–	–
4	Bolus I/O	OFF	–	–	ON/OFF

10.4. SN menu ＜**Click clack**＞



No.	Setting item	Default	Setting range	Setting step	Selection item
1	Click clack ON/OFF	-	-	-	ON/OFF
2	S/N press high change point	200	100 - 350	10	—
3	S/N press low change point	50	20 - 150	10	—
4	S/N alarm low stroke time	20	5 - 30	1	—
5	S/N stroke volume min	10	OFF,5 - 100	1	—
6	Effective blood flow rate	0	—	—	—
7	Average stroke volume	0	—	—	—

10.5. SN menu ＜**Double pump**＞

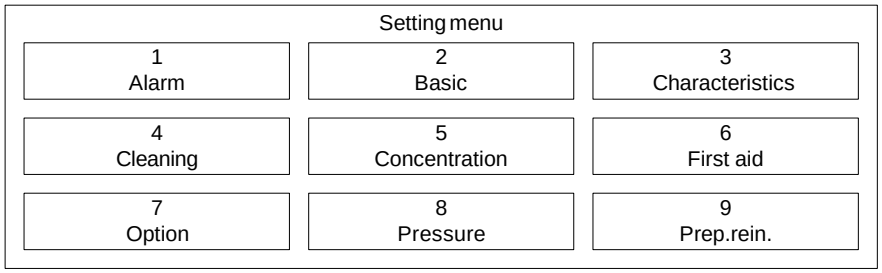


No	Setting item	Default	Setting range	Setting step	Selection item
1	Double pump ON/OFF	OFF	—	—	ON/OFF
2	S/N Rate	Equal to BP flow	10 - 600	5	—
3	Auto S/N	Yes	—	—	Yes/No
4	Ratio(approx)	20	-60 - 60	1	—
5	Effective blood flow	—	—	—	—
6	Stroke vol.	35	20 - 60	1	—

10.6. System screen

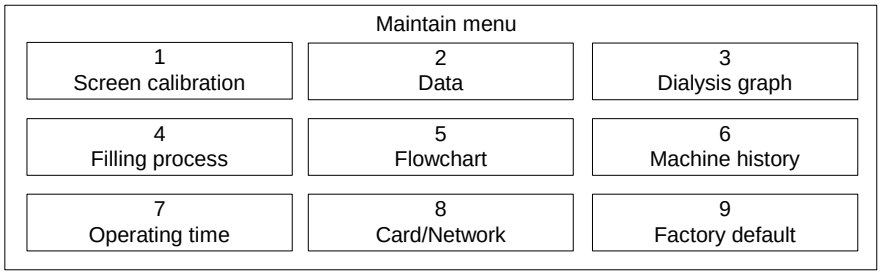
- How to open System menu screen
  Start up the machine.
  Press the System button.
  Select the type (Setting/Maintain).

The composition of each menu is as below:



(First page)

(Second page)



10.6.1. Setting menu

⚠WARNING

- Be aware that the alarm detecting conditions differ according to machines if the alarm setting values differ depending on machines.

NOTE

- The alarm setting values will be the same regardless of the types of the ALARM SYSTEM mode.

- Alarm

Setting item			Default	Min.	Max.	Setting step
1	SN. Pressure alarm upper limit	mmHg	400	40	480	10
2	SN. Pressure alarm lower limit	mmHg	10	-100	440	10
3	UFRP change rate alarm	%	100	10	100	1
4	Blood leak alarm	ppm	280	50	500	10
5	Temperature alarm upper limit	°C	39.0	37.5	40.0	0.1
6	Temperature alarm lower limit	°C	34.0	33.0	35.5	0.1
7[a)]	Bubble detect setting	µL	50	IND.10,1,50,100		
7[b)]	Bubble detect setting	µL	10	1,10,50,300		
8	ABD at Priming end	-	OFF	ON/OFF		-
9	Conductivity alarm upper width	%	5.0	2.0	9.9	0.1
10	Conductivity alarm lower width	%	-5.0	-9.9	-2.0	0.1
11	B-Conductivity alarm upper width	%	5.0	2.0	9.9	0.1
12	B-Conductivity alarm lower width	%	-5.0	-9.9	-2.0	0.1
13	Zero UFR set notice	-	OFF	ON/OFF		-
14	Zero HP rate set notice	-	OFF	ON/OFF		-
15	Bypass button notice time	min	2	OFF⇔2 - 10		1
16	UF stop button notice time	min	2	OFF⇔2 - 10		1
17	First aid button notice time	min	1	OFF⇔1 - 10		1
18	Back up battery check	-	ON	ON/OFF		-
19	BLD sensor alarm override time	min	OFF	OFF⇔0.5-10.0		0.1
20	Pressure change of Art. & Ven.	mmHg	2	0	9	1
21	Pressure change time of Art. & Ven.	sec	20	10	60	1
22	Filtration limit for double needle.	%	30	1	41	1
23	Filtration limit for single needle.	%	30	1	41	1
24	Venous alarm width reset time	sec	30	OFF⇔10-600		10

a) For the board before BLM-CPU-D
b) For the board after BLM-CPU-E

- Basic

Setting item			Default	Min.	Max.	Setting step
1	Back light auto off time	min	5	OFF⇔1 -240		1
2	Screen saver activation time	min	5	OFF⇔1-60		1
3	Screen saver type	-	1	1	2	1
4	Brightness	%	100	0	100	1
5	A.pressure graph pattern	-	1	1,2,3		-
6	V.pressure graph pattern	-	1	1,2		-
7	TMP.graph pattern	-	1	1,2		-
8	D.pressure graph pattern	-	1	1,2		-
9	Cleaning auto off time	min	0	0	30	1
10	Language	-	En	-	-	-
11	Message layer function	-	OFF	ON/OFF		-

- Characteristics

Setting item			Default	Min.	Max.	Setting step
1	UFP flow	mL/rev	0.750	0.300	1.000	0.001
2	Year	-	-	-	-	-
3	Month	-	-	-	-	-
4	Date	-	-	-	-	-
5	Time	-	-	-	-	-
6	Summer/Winter time	-	ON	ON/OFF		-
7	V.press offset	mmHg	0	-100	100	1
8	A.press offset	mmHg	0	-100	100	1
9	SN press offset	mmHg	0	-100	100	1
10	D.press offset	mmHg	0	-100	100	1
11	UF offset	mL/h	0	-99	99	1
12	UF offset(CF)	mL/h	0	-99	99	1
13	TMP offset	mmHg	0	0	100	1
14	BP mL/rev gain	-	9.6	5.0	15.0	0.1
15	BP mL/rev offset	-	0	-20	100	1
16	SNP mL/rev gain	-	9.6	5.0	15.0	0.1
17	SNP mL/rev offset	-	0	-20	100	1
18	SFP mL/rev gain	-	9.6	5.0	15.0	0.1
19	SFP mL/rev offset	-	0	-20	100	1
20	Memory back up	-	ON	ON	OFF	-
21	Venous chamber auto set volume	mL	15.0	1.0	25.0	0.1
22	UF profile division number	-	8	8,10,12		
23	Closed circuit check during treatment	min	60	OFF⇔30-120		10
24	Blood sensor sensitivity	V	1.0	0.0	5.0	0.1
25	BP/SNP at blood sample	mL/min	100	10	300	10

Setting item			Default	Min.	Max.	Setting step
26	Blood countdown time	sec	30	0	300	1
27	Fixed treatment time	-	OFF	ON/OFF		-
28	Sub port connection check after ONLINE priming	-	ON	ON/OFF		-
29	BPM remote button	-	ON	ON/OFF		-
30	Nurse call button	-	OFF	ON/OFF		-
31	Central Alarm Output Warning	-	OFF	ON/OFF		-
32	HD Tolerance	-	OFF	ON/OFF		-
33	Password(User)	-	0000	0000	9999	1
34	Sample Volume HD	mL	100	100	2000	100
35	Sample Volume HDF	mL	500	100	2000	100

- Cleaning – Disinfection

Setting item		Default	Min.	Max.	Setting step
Name of disinfectant1	-	Peracetic acid 1			
Original concentration	%	1.0	1.0	12.0	0.1
Diluted concentration	%	0.03	0.03	0.20	0.01
Total time	min	37	37	120	1
Post Rinse time	min	9	9	60	1
Conductivity control	mS/cm	0.1	0.1	15.0	0.1
Port No.	-	1	1	2	1
Name of disinfectant2	-	Peracetic acid 2			
Original concentration	%	1.0	1.0	12.0	0.1
Diluted concentration	%	0.03	0.03	0.20	0.01
Total time	min	37	37	120	1
Post Rinse time	min	9	9	60	1
Conductivity control	mS/cm	0.1	0.1	15.0	0.1
Port No.	-	1	1	2	1
Name of disinfectant3	-	Sodium hypochlorite			
Original concentration	%	12.0	1.0	12.0	0.1
Diluted concentration	%	0.10	0.10	0.20	0.01
Total time	min	38	38	120	1
Post Rinse time	min	11	11	60	1
Conductivity control	mS/cm	2.5	0.1	15.0	0.1
Port No.	-	1	1	2	1
Name of disinfectant4	-	Disinfection 4			
Original concentration	%	12.0	1.0	12.0	0.1
Diluted concentration	%	0.10	0.10	0.20	0.01
Total time	min	38	38	120	1
Post Rinse time	min	11	11	60	1
Conductivity control	mS/cm	2.5	0.1	15.0	0.1
Port No.	-	1	1	2	1

- Cleaning – Decalcification

Setting item		Default	Min.	Max.	Setting step
Name of disinfectant1	-	Citric acid			
Original concentration	%	70.0	30.0	70.0	0.1
Diluted concentration	%	1	1	5	1
Total time	min	40	40	120	1
Post Rinse time	min	14	10	60	1
Conductivity control	mS/cm	2.0	0.1	15.0	0.1
Port No.	-	2	1	2	1
Name of disinfectant2	-	Acetate acid			

Setting item		Default	Min.	Max.	Setting step
Original concentration	%	70.0	30.0	70.0	0.1
Diluted concentration	%	1	1	5	1
Total time	min	40	40	120	1
Post Rinse time	min	14	10	60	1
Conductivity control	mS/cm	0.5	0.1	15.0	0.1
Port No.	-	2	1	2	1
Name of disinfectant3	-	Decalcification3			
Original concentration	%	70.0	30.0	70.0	0.1
Diluted concentration	%	1	1	5	1
Total time	min	40	40	120	1
Post Rinse time	min	14	10	60	1
Conductivity control	mS/cm	3.0	0.1	15.0	0.1
Port No.	-	2	1	2	1
Name of disinfectant4	-	Decalcification4			
Original concentration	%	70.0	30.0	70.0	0.1
Diluted concentration	%	1	1	5	1
Total time	min	40	40	120	1
Post Rinse time	min	14	10	60	1
Conductivity control	mS/cm	3.0	0.1	15.0	0.1
Port No.	-	2	1	2	1

- Cleaning – Hot disinfection

Setting item		Default	Min.	Max.	Setting step
Name of disinfectant1	-	Citric acid			
Original concentration	%	50.0	30.0	50.0	0.1
Diluted concentration	%	0.50			
Total time	min	31	31	60	1
Temp	°C	70	70	80	1
Conductivity control	mS/cm	1.0	0.1	15.0	0.1
Port No.		2	1	2	1
Name of disinfectant2	-	Hot Decalcification 2			
Original concentration	%	30.0	30.0	50.0	0.1
Diluted concentration	%	0.50			
Total time	min	31	31	60	1
Temp	°C	70	70	80	1
Conductivity control	mS/cm	3.0	0.1	15.0	0.1
Port No.		2	1	2	1
Name of disinfectant3	-	Hot Decalcification 3			
Original concentration	%	30.0	30.0	50.0	0.1

Setting item		Default	Min.	Max.	Setting step
Diluted concentration	%	0.50			
Total time	min	31	31	60	1
Temp	°C	70	70	80	1
Conductivity control	mS/cm	3.0	0.1	15.0	0.1
Port No.		2	1	2	1
Name of disinfectant4	-	Hot Decalcification 4			
Original concentration	%	30.0	30.0	50.0	0.1
Diluted concentration	%	0.50			
Total time	min	31	31	60	1
Temp	°C	70	70	80	1
Conductivity control	mS/cm	3.0	0.1	15.0	0.1
Port No.		2	1	2	1

- Cleaning – Rinse/Hot rinse/IHR

Setting item		Default	Min.	Max.	Setting step
Hot rinse temperature	°C	70	70	80	1
Hot rinse total time	min	31	31	60	1
Rinse total time	min	10	5	120	1
IHR total time (IHR including hydraulic part.=ON)	min	30	30	200	1
IHR total time (IHR including hydraulic part.=OFF)	min	10	5	200	1
Hot Water Disinfection (HWD)	-	OFF	ON/OFF		-

- Cleaning – General

Setting item		Default	Min.	Max.	Setting step
Mandatory disinfection between treatment	-	OFF	ON/OFF		-
IHR including hydraulic part.	-	---	YES/NO		-
IHR flow control	-	---	100-800		100
IHR heater control	-	---	YES/NO		-
Disinfectant conductivity control	-	ON	ON/OFF		-
Mandatory disinfection after CF change	-	OFF	ON/OFF		-
Temperature for Disinfection/Decalcification	(°C)	35	35-40		1

- Cleaning – Cleaning standby

Setting item		Default	Min.	Max.	Setting step
Program1		Not available	Available , Not Available		
Program2		Not available	Available , Not Available		
Program3		Not available	Available , Not Available		
Program4		Not available	Available , Not Available		
Program5		Not available	Available , Not Available		

Setting item	Default	Min.	Max.	Setting step
Program6	Not available	Available , Not Available		
Rinse	Available	Available , Not Available		
Disinfection	Available	Available , Not Available		
Decalcification(acid)	Available	Available , Not Available		
Hot rinse / HWD	Available	Available , Not Available		
Hot disinfection	Available	Available , Not Available		
IHR	Not available	Available , Not Available		

- Concentration – Concentration information

Setting item		Default	Min.	Max.	Setting step
Concentrate Type			-	-	-
Na Concentration of A	mmol/L	110			
Na Concentration of B	mmol/L	30	24	70	1
HCO_3 conc. of B	mmol/L	30			
Prescribed Na	mmol/L	140	125	165	1
Available range of Na concentration of B (From)	mmol/L	24	24	30	1
Available range of Na concentration of B (To)	mmol/L	70	30	70	1
Available range of Na concentration of total (From)	mmol/L	125	125	140	1
Available range of Na concentration of total(To)	mmol/L	165	140	165	1
A supply source Front pipe		Front pipe , Central A1 ,Central A2			
B supply source Front pipe		Front pipe , B cartridge			
W+A Ratio		35.00	32.26	52.26	0.01
W+B Ratio		27.78	17.46	70.70	0.01
Mix Ratio(B)		1.26	0.50	2.00	0.01
Mix Ratio(W)		32.74	30.00	50.00	0.01
P3 one revolution volume	mL/rev	0.300	0.200	0.400	0.001
P4 one revolution volume	mL/rev	0.300	0.200	0.400	0.001
Chamber A Volume	mL	100.0	95.0	105.0	0.1
Chamber B Volume	mL	100.0	95.0	105.0	0.1
B canister with NaCl	-	OFF	ON/OFF		-
Initial Prescribed Na	mmol/L	140	125	154	1
Initial Prescribed Bic.	mmol/L	30	24	70	1

- First aid

Setting item			Default	Min.	Max.	Setting step
1	First aid function	-	ON	ON/OFF		-
2	UFR	L/h	---	0.00,0.10		
3	Dialysate flow bypass	-	No	Yes/No		-
4	Substitution pump stop	-	---	Yes/No		-

Setting item			Default	Min.	Max.	Setting step
5	Blood pump flow	mL/min	100	0	100	10
6	Blood pressure measurement	-	YES	Yes/No		-
7	Interval	min	OFF	OFF,5,10,15,30,45,60		
8	Quick I/O	-	---	ON/OFF		-

- Option

Setting item			Default	Min.	Max.	Setting step
1	BPM	-	ON	ON/OFF		-
2	Single needle pump	-	ON	ON/OFF		-
3	B powder	-	ON	ON/OFF		-
4	Central system(A1,A2)	-	ON	ON/OFF		-
5	Central system(A3)	-	ON	ON/OFF		-
6	Central system(B3)	-	OFF	ON/OFF		-
7	IHR	-	OFF	ON/OFF		-
8	ONLINE HDF	-	ON	ON/OFF		-
9	CF1	-	ON	ON/OFF		-
10	Voltage	V	230V	230V/110V		-
11	Dialysate infusion	-	OFF	ON/OFF		-
12	Dialyzer leak check	-	OFF	ON/OFF		-
13	Leakage sensor 1	-	ON	ON/OFF		-
14	Leakage sensor 2	-	ON	ON/OFF		-
15	Dose Finder	-	ON	ON/OFF		-
16	Dose Detector	-	ON	ON/OFF		-
17	BVM	-	OFF	ON/OFF		-
18	BVC	-	OFF	ON/OFF		-
19	Sample Mode	-	OFF	ON/OFF		-

- Pressure – Venous

Setting item		Default	Min.	Max.	Setting step
1.Fixed alarm point upper limit -HD, ISO-UF, On-Line HDF, On-Line HF	mmHg	300	40	480	10
1.Fixed alarm point upper limit -Single needle click-clack	mmHg	400	40	480	10
1.Fixed alarm point upper limit -Single needle double-pump	mmHg	400	40	480	10
2.Auto.set.alarm point upper width -HD	mmHg	70	20	200	10
2.Auto.set.alarm point upper width -ISO-UF	mmHg	70	20	200	10
2.Auto.set.alarm point upper width -On-Line HDF	mmHg	70	20	200	10
2.Auto.set.alarm point upper width -On-Line HF	mmHg	70	20	200	10
2.Auto.set.alarm point upper width -Single needle double-pump	mmHg	70	20	200	10
3.Auto.set.alarm point lower width -HD	mmHg	-20	-200	-20	10
3.Auto.set.alarm point lower width -ISO-UF	mmHg	-20	-200	-20	10
3.Auto.set.alarm point lower width -On-Line HDF	mmHg	-20	-200	-20	10
3.Auto.set.alarm point lower width -On-Line HF	mmHg	-20	-200	-20	10
3.Auto.set.alarm point lower width -Single needle double-pump	mmHg	-70	-200	-20	10
4.Fixed alarm point lower limit -HD, ISO-UF, On-Line HDF, On-Line HF	mmHg	-10	-100	440	10
4.Fixed alarm point lower limit -Single needle click-clack	mmHg	10	-100	440	10
4.Fixed alarm point lower limit -Single needle double-pump	mmHg	10	-100	440	10
5.Con/Rein alarm point lower limit -HD, ISO-UF, On-Line HDF, On-Line HF (Patient connect / Reinfusion point lower limit)	mmHg	-50	-50	300	10
5. Con/Rein alarm point lower limit -Single needle click-clack (Patient connect / Reinfusion point lower limit)	mmHg	-50	-50	300	10
5.Con/Rein alarm point lower limit -Single needle double-pump (Patient connect / Reinfusion point lower limit)	mmHg	-50	-50	300	10

- Pressure – Arterial

Setting item		Default	Min.	Max.	Setting step
1.Fixed alarm point upper limit -HD, ISO-UF, On-Line HDF, On-Line HF	mmHg	300	100	480	10
1.Fixed alarm point upper limit -Single needle click-clack	mmHg	300	100	480	10
1.Fixed alarm point upper limit -Single needle double-pump	mmHg	300	100	480	10
2.Auto.set.alarm point upper width -HD, ISO-UF, On-Line HDF, On-Line HF	mmHg	70	20	200	10
2.Auto.set.alarm point upper width -Single needle click-clack	mmHg	70	20	200	10
2.Auto.set.alarm point upper width -Single needle double-pump	mmHg	70	20	200	10
3.Auto.set.alarm point lower width -HD, ISO-UF, On-Line HDF, On-Line HF	mmHg	-70	-200	-20	10
3.Auto.set.alarm point lower width -Single needle click-clack	mmHg	-70	-200	-20	10
3.Auto.set.alarm point lower width -Single needle double-pump	mmHg	-70	-200	-20	10
4.Fixed alarm point lower limit -HD, ISO-UF, On-Line HDF, On-Line HF	mmHg	-300	-480	-100	10
4.Fixed alarm point lower limit -Single needle click-clack	mmHg	-300	-480	-100	10
4.Fixed alarm point lower limit -Single needle double-pump	mmHg	-300	-480	-100	10

- Pressure – Dialysate

Setting item		Default	Min.	Max.	Setting step
1.Fixed alarm point upper limit -HD, ISO-UF, On-Line HDF, On-Line HF	mmHg	500	100	640	10
1.Fixed alarm point upper limit -Single needle click-clack	mmHg	500	100	640	10
1.Fixed alarm point upper limit -Single needle double-pump	mmHg	500	100	640	10
2.Auto.set.alarm point upper width -HD	mmHg	400	20	400	20
2.Auto.set.alarm point upper width -ISO-UF	mmHg	400	20	400	20
2.Auto.set.alarm point upper width -On-Line HDF	mmHg	400	20	400	20
2.Auto.set.alarm point upper width -On-Line HF	mmHg	400	20	400	20
2.Auto.set.alarm point upper width -Single needle click-clack	mmHg	400	20	400	20
2.Auto.set.alarm point upper width -Single needle double-pump	mmHg	400	20	400	20
3.Auto.set.alarm point lower width -HD	mmHg	-400	-400	-20	20
3.Auto.set.alarm point lower width -ISO-UF	mmHg	-400	-400	-20	20
3.Auto.set.alarm point lower width -On-Line HDF	mmHg	-400	-400	-20	20
3.Auto.set.alarm point lower width -On-Line HF	mmHg	-400	-400	-20	20
3.Auto.set.alarm point lower width -Single needle click-clack	mmHg	-400	-400	-20	20
3.Auto.set.alarm point lower width -Single needle double-pump	mmHg	-400	-400	-20	20
4.Fixed alarm point lower limit -HD, ISO-UF, On-Line HDF, On-Line HF	mmHg	-500	-640	-40	10
4.Fixed alarm point lower limit -Single needle click-clack	mmHg	-500	-640	-40	10
4.Fixed alarm point lower limit -Single needle double-pump	mmHg	-500	-640	-40	10

-Pressure-TMP

Setting item		Default	Min.	Max.	Setting step
1.Fixed alarm point upper limit -HD, ISO-UF, On-Line HDF, On-Line HF	mmHg	450	0	700	10
1.Fixed alarm point upper limit -Single needle click-clack	mmHg	450	0	700	10
1.Fixed alarm point upper limit -Single needle double-pump	mmHg	450	0	700	10
2.Auto.set.alarm point upper width -HD	mmHg	150	20	500	10
2.Auto.set.alarm point upper width -ISO-UF	mmHg	100	20	500	10
2.Auto.set.alarm point upper width -On-Line HDF	mmHg	300	20	500	10
2.Auto.set.alarm point upper width -On-Line HF	mmHg	300	20	500	10
2.Auto.set.alarm point upper width -Single needle click-clack	mmHg	100	20	500	10
2.Auto.set.alarm point upper width -Single needle double-pump	mmHg	100	20	500	10
3.Auto.set.alarm point lower width -HD	mmHg	-100	-300	20	10
3.Auto.set.alarm point lower width -ISO-UF	mmHg	-100	-300	20	10
3.Auto.set.alarm point lower width -On-Line HDF	mmHg	-300	-300	20	10
3.Auto.set.alarm point lower width -On-Line HF	mmHg	-300	-300	20	10
3.Auto.set.alarm point lower width -Single needle click-clack	mmHg	-100	-300	20	10
3.Auto.set.alarm point lower width -Single needle double-pump	mmHg	-100	-300	20	10
4.Fixed alarm point lower limit -HD, ISO-UF, On-Line HDF, On-Line HF	mmHg	-30	-200	200	10
4.Fixed alarm point lower limit -Single needle click-clack	mmHg	-30	-200	200	10
4.Fixed alarm point lower limit -Single needle double-pump	mmHg	-30	-200	200	10

-Prep. rein.

Setting item			Default	Min.	Max.	Setting step
1	Rinse volume initial setting	mL	700	400	3000	100
2	Priming rate initial setting	mL/min	100	10	200	10
3	DIF rinse volume	mL	1000	700	5000	100
4	DIF circulation volume	mL	400	0	1000	100
5	Max BP flow in ONLINE	mL/min	200	10	400	10
6	Auto treatment start		ON	ON/OFF		
7	Reinfusion volume initial setting	mL	300	50	500	10
8	Reinfusion rate initial setting	mL/min	100	10	200	10
9	Max BP flow in reinfusion	mL/min	200	10	200	10
10	Alarm width fix time in reinfusion	sec	10	10	30	1
11	Additional rinse volume	mL	200	100,200,300,400,500		
12	BP stop at blood detected.		ON	ON/OFF		
13	Clean-Treatment-Start		OFF	ON/OFF		
14	Drain speed for CTS	mL/min	100	30	150	10
15	HD Arterial blood line Volume for CTS.	mL	50	0	50	10
16	SNDP Arterial blood line Volume for CTS.	mL	70	0	70	10
17	Venous blood line volume for CTS.	mL	50	0	50	10
18	Blood flow / SN flow at Patient connect	mL/min	100	10	300	10
19	DN arterial DIF Rein.ratio	%	50	10	90	1
20	DN venous DIF Rein. ratio	%	50	10	90	1
21	SNDP arterial DIF Rein. ratio	%	60	10	90	1
22	SNDP venous DIF Rein. ratio	%	40	10	90	1
23	DN arterial DIF Priming ratio	%	70	10	90	10
24	DN venous DIF Priming ratio	%	30	10	90	10
25	SNDP arterial DIF Priming ratio	%	70	10	90	10
26	SNDP venous DIF Priming ratio	%	30	10	90	10

-Sound

Setting item			Default	Min.	Max.	Setting step
1	Sound Volume		5	1	5	-
2	I/O (Power) on		1	OFF,1		-
3	Alarm		2	1	3	-
4	Warning		2	OFF,1,2		-
5	Info		1	OFF,1,2		-
6	Rinse volume reached		1	OFF,1 - 6		-
7	Treatment time reached		4	OFF,1 - 6		-
8	ISO-UF reached		5	OFF,1 - 6		-
9	Reinfusion volume reached		OFF	OFF,1 - 6		-
10	Cleaning complete		1	OFF,1 - 6		-

Setting item			Default	Min.	Max.	Setting step
11	Auto power off		2	OFF,1,2		-
12	Silent mode click sound		ON	ON/OFF		-
13	UF goal melody sounds time	sec	5	OFF,5 - 120		5
14	ICU mode		ON	ON/OFF		-

⚠WARNING

- If the “ICU ALARM SYSTEM” setting is turned ON, the ALARM SYSTEM mode is changed, and the alarm sound and the light indicator performance are changed. Be aware that the operation of alarm detection differs according to machines if the ALARM SYSTEM mode differs depending on machines.

- Treatment - UF

Setting item			Default	Min.	Max.	Setting step
1	Initial treatment time		4:00	0:00	24:00	0:01
2	Initial UF goal	L	0.0	0.0	4.0	0.1
3	Initial UF rate	L/H	0.00	0.00	1.00	0.01
4	UFR MAX(General)		1.0	0.1	4.0	0.1
5	UFR MAX(ISO-UF&Profile)		1.0	0.1	4.0	0.1
6	UFR increasing notice rate	%	10	1	30	1
7	Sub goal decreasing notice rates	%	10	1	30	1
8	Treatment shortening time	min	15	1	30	1

- Treatment - Dialysate

Setting item			Default	Min.	Max.	Setting step
1	Initial Dialysate temperature	°C	36.5	34.0	39.0	0.1
2	Dialysate flow at the treatment start(HD)	mL/min	500	100	800	100
3	Dialysate flow at the treatment start(ONLINE)	mL/min	500	100	500	100
4	Dialysate flow factor		1.5	1.0	2.0	0.1
5	Dialysate temperature offset(T3)	°C	0.0	0.0	1.0	0.1

- Treatment - ONLINE

Setting item			Default	Min.	Max.	Setting step
1	Initial Sub goal	L	12	1	600	1
2	Initial Sub rate	mL/min	50	10	300	1
3	Auto-sub ON/OFF rate(pre)	%	50	5	200	1
4	Auto-sub ON/OFF rate(post)	%	20	5	33	1
5	Sub bolus one shot	mL	100	10	200	10
6	Sub bolus rate	mL/h	100	10	300	10
7	Sub rate limitation with BP(post)	%	30	5	41	1
8	BP/SNP at bypass in HDF/HF post dilution	mL/min	100	10	200	5

- Treatment - Heparin

Setting item			Default	Min.	Max.	Setting step
1	HP flow rate	mL/h	2.0	0.0	10.0	0.1
2	Type of syringe		Syringe8	Set on the second page		-
3	HP bolus one shot	mL	4.0	0.5	10.0	0.1
4	Automatically use of heparin		ON	ON/OFF		-
5	Automatic bolus		OFF	OFF,PC,BD		-
6	Heparin stop time	min	OFF	OFF,1-120		1
7	Heparin pump button notice		ON	ON/OFF		-
-	Name	-	Custom setting			
-	Size	mL	20	10	30	1
-	Diameter	mm	20.0	10.0	30.0	0.1
-	Syringe1 - Syringe8	-	-	-	-	-
-	Available or Not available	-	Available	Available, Not available		-

- Treatment - Power failure

Setting item			Default	Min.	Max.	Setting step
1	BP flow in power failure	mL/min	100	30	300	10
2	SNP flow in power failure	mL/min	100	30	300	10

- Treatment – Max-sub

Setting item			Default	Min.	Max.	Setting step
1	Max-sub		ON	OFF/ON		
2	Max-sub-fixed TMP		ON	OFF/ON		
3	Target ratio of filtration against BF	%	45	OFF, 5 - 48		1
4	Measurement start of TMP flat point	%	25	5	40	1
5	SF increase in measurement 1	%	2	1	30	1
6	SF increase in measurement 2	%	1	1	30	1
7	Filtration rate change point	mmHg	40	1	40	1
8	Max-sub measurement step1	cycles	10	5	30	1
9	Max-sub measurement step2	cycles	20	5	30	1
10	Sub rate increase TMP border point	mmHg	70	10	70	1
11	Sub rate increase TMP stop point	mmHg	50	10	70	1
12	Max-sub compensation increasing TMP	mmHg	40	10	100	1
13	Max-sub rate compensation increasing TMP	%	2	1	20	1
14	Max-sub compensation decreasing TMP	mmHg	-30	-100	-10	1
15	Max-sub rate compensation decreasing TMP	%	1	1	20	1
16	Max-sub measurement frequency	min	0	0	120	10

Setting item			Default	Min.	Max.	Setting step
17	Max-sub MAX TMP border	mmHg	-120	-200	0	10
18	Fixed TMP alarm point upper limit	mmHg	450	0	700	1
19	Fixed TMP alarm point lower limit	mmHg	-30	-200	200	1
20	Auto. set. TMP alarm point upper width	mmHg	450	20	500	1
21	Auto. set. TMP alarm point lower width	mmHg	-300	-300	20	1
22	Max-sub light		OFF	OFF/ON		
23	Max-sub light MAX TMP increase border point	mmHg	50	30	100	10
24	Max-sub light MAX TMP border	mmHg	-50	-100	0	10
25	Max-sub light stop time	min	10	0	15	1

- Treatment - BVM

Setting item			Default	Min.	Max.	Setting step
1	Auto Start		OFF	OFF/ON		
2	Control mode		OFF	OFF / Na / UF / Na+UF		
3	RBV crit	%	88	60	95	1
4	UF Max (BVM)	L/h	1.50	1.00	4.00	0.1
5	UF Goal Deviation	%	5	OFF, 1	10	1
6	ΔBV UF Stop Point	%	3	1	10	0.1
7	Na Limit		1	1	3	1

10.6.2. Maintenance menu

The following values that are mentioned here could be changed without notes.

- Screen calibration

Screen for correcting touch panel position.

- Data - Pressure

Setting item			Default	Min.	Max.	Setting step
1	PV	mmHg	Only displayed	-	-	-
2	PA	mmHg	Only displayed	-	-	-
3	PSN	mmHg	Only displayed	-	-	-
4	PD	mmHg	Only displayed	-	-	-
5	TMP	mmHg	Only displayed	-	-	-
6	UF.COEFF	-	Only displayed	-	-	-
7	UFRP CHANGE RATE	%	Only displayed	-	-	-
8	TMP OFFSET	mmHg	Only displayed	-	-	-

- Data - Temperature Conductivity

Setting item			Default	Min.	Max.	Setting step
1	T1	°C	Only displayed	-	-	-
2	T2	°C	Only displayed	-	-	-
3	T3	°C	Only displayed	-	-	-
4	T4	°C	Only displayed	-	-	-
5	T5	°C	Only displayed	-	-	-
6	T6	°C	Only displayed	-	-	-
7	T7	°C	Only displayed	-	-	-
8	CD1	mS/cm	Only displayed	-	-	-
9	CD2	mS/cm	Only displayed	-	-	-
10	CD3	mS/cm	Only displayed	-	-	-

- Data - B.T.V

Setting item			Default	Min.	Max.	Setting step
1	TREATED BLOOD TIME	min	Only displayed	-	-	-
2	TREATED BLOOD VOLUME	L	Only displayed	-	-	-
3	(DIALYSATE)	L	Only displayed	-	-	-
4	(REINFUSION)	L	Only displayed	-	-	-
5	(ISO-UF)	L	Only displayed	-	-	-
6	(BYPASS)	L	Only displayed	-	-	-
7	CUM HEPARIN VOLUME	mL	Only displayed	-	-	-

- Data - BLD

Setting item			Default	Min.	Max.	Setting step
1	BLD VALUE	ppm	Only displayed	-	-	-
2	BLD AUTO ZERO	ppm	Only displayed	-	-	-
3	BLD REAL VALUE	ppm	Only displayed	-	-	-
4	DUMMY BLD VALUE	ppm	Only displayed	-	-	-
5	BLD VOLTAGE	V	Only displayed	-	-	-

- Machine history

Up to 15 histories of operations and alarm messages are displayed at the same time. Up to 200 histories are memorized.

888. 88 , 88 , 8888 88:88.88 <****> **********

(“No.”. “DD”,”MM”,”YYYY” “HH”:”MM”.”SS” <”Sequence step”> “Operation/alarm history”)

NOTE

- The “Sequence step” is a symbol given by the Manufacturer to operations in each dialysate circuit.
- The last history data is saved in case of power failure or when the battery remaining power becomes low during power failure and the main power is turned OFF. “E153 Power Failure” is recorded in the alarm history in case of power failure.
- Chronologically oldest incident will be deleted from the history data when the data exceeds 200.

- Operating time

Setting item			Default	Min.	Max.	Setting step
1	POWER	hours	0	-	-	-
2	V1	times	10000	0	30000	1
3	V4	times	10000	0	30000	1
4	V5a	times	10000	0	30000	1
5	V5b	times	10000	0	30000	1
6	V6a	times	10000	0	30000	1
7	V6b	times	10000	0	30000	1
8	V7a	times	10000	0	30000	1
9	V7b	times	10000	0	30000	1
10	V8a	times	10000	0	30000	1
11	V8b	times	10000	0	30000	1
12	V9a	times	10000	0	30000	1
13	V9b	times	10000	0	30000	1
14	V10	times	10000	0	30000	1
15	V11	times	10000	0	30000	1
16	V12DIAPH	times	1000	0	30000	1
17	V17DIAPH	times	1000	0	30000	1
18	V19	times	10000	0	30000	1
19	V21DIAPH	times	1000	0	30000	1
20	V23DIAPH	times	1000	0	30000	1
21	V24DIAPH	times	1000	0	30000	1
22	V27	times	10000	0	30000	1
23	V9c	times	10000	0	30000	1
24	V29	times	10000	0	30000	1
25	V30	times	10000	0	30000	1

Setting item			Default	Min.	Max.	Setting step
26	V31DIAPH	times	1000	0	30000	1
27	V33DIAPH	times	1000	0	30000	1
28	V34	times	10000	0	30000	1
29	V35	times	10000	0	30000	1
30	V36a(Op)	times	10000	0	30000	1
31	V36b(Op)	times	10000	0	30000	1
32	V36c(Op)	times	10000	0	30000	1
33	V43	times	10000	0	30000	1
34	V44	times	10000	0	30000	1
35	V45DIAPH	times	1000	0	30000	1
36	V46DIAPH	times	1000	0	30000	1
37	V47DIAPH	times	1000	0	30000	1
38	V48DIAPH	times	1000	0	30000	1
39	V51	times	10000	0	30000	1
40	V52	times	10000	0	30000	1
41	V53	times	10000	0	30000	1
42	V55	times	10000	0	30000	1
43	AS2 O-RING	hours	17000	0	30000	1
44	CF1(Op)	hours	1200	0	1800	1
45	CF2(Op)	hours	1200	0	1800	1
46	CF1 Disinfection	times	0	-	-	-
47	CF2 Disinfection	times	0	-	-	-
48	CF1 Treatment	times	0	-	-	-
49	CF2 Treatment	times	0	-	-	-

- Card/Network

  Refer to “16. Card/Network (Option)”

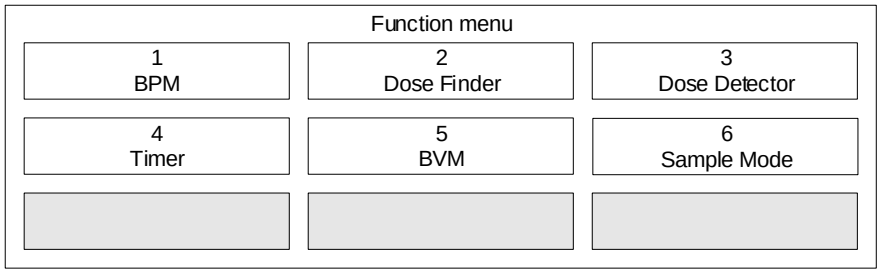
- Factory default

  Pressing the Initialize button on the screen for 3 consecutive seconds initializes the all alarm setting.

10.7. Function screen

- How to open Function menu screen
  Start up the machine.
  Press the Function button.
  Select the function.

The composition of each menu is as below:



10.7.1. BPM

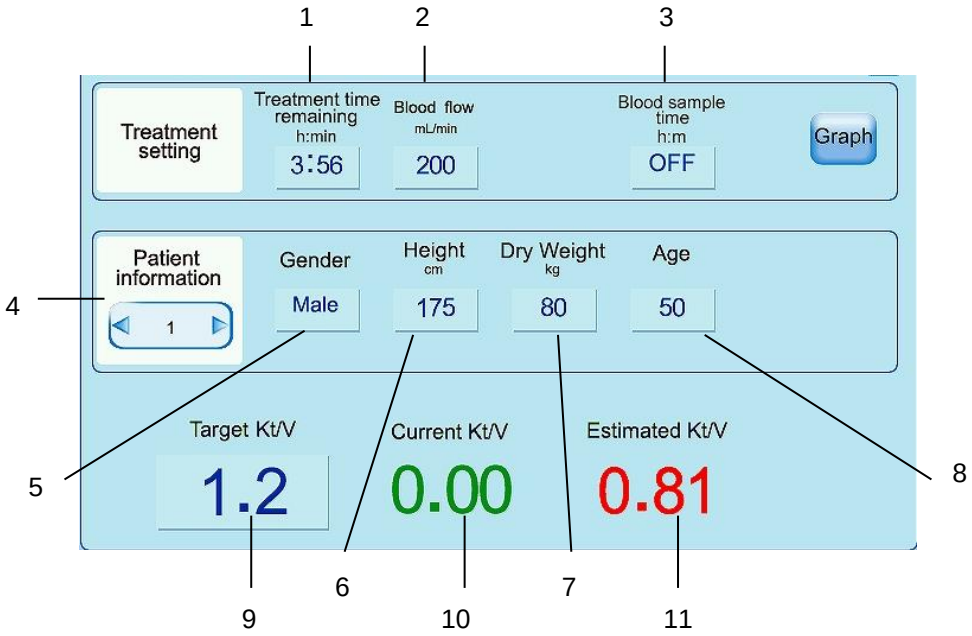
Refer to “14. Blood pressure monitor" for details.

10.7.2. Dose Finder

⚠CAUTION

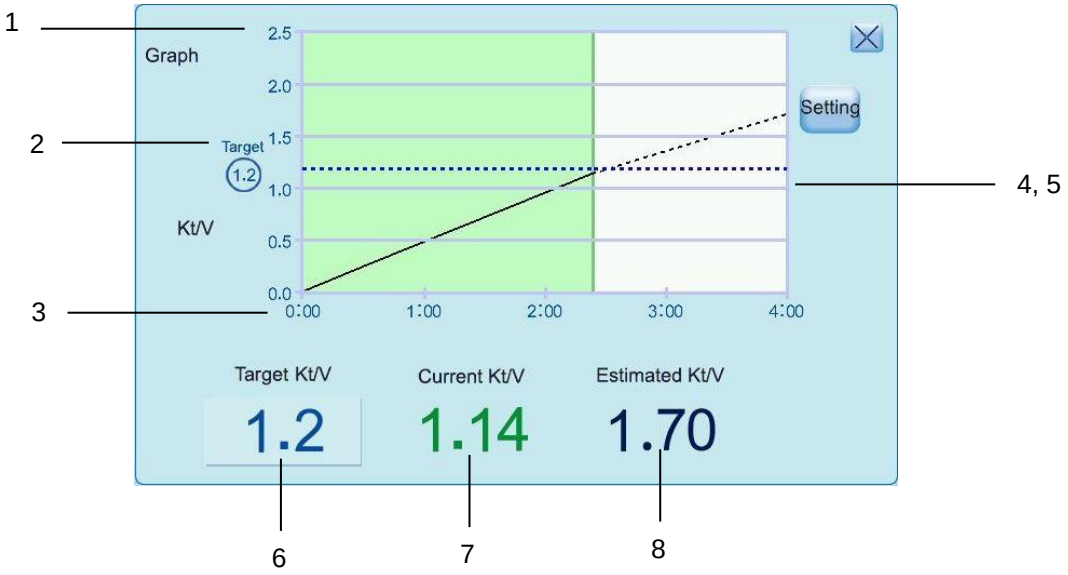
- The Dose-Finder attempted to predict the Kt / V of a therapy. The value cannot be used for the therapy adjustment. It is a not measured only a calculated value. The predicted Kt / V of the Dose-Finder and the actual Kt / V can differ from each other.

- Setting



No.	Setting item	Default	Setting range	Setting step	Selection item
1	Treatment time remaining	Value set at System - setting - Treatment - UF - Initial treatment time	0:00 - 24:00	0:01	-
2	Blood flow	200	10 - 600	5	-
3	Blood sample time	OFF	OFF, 0:01 - 24:00	0:01	-
4	Patient information	1	1 - 8	1	-
5	Gender	Male	Male - Female	-	-
6	Height	175	50 - 250	1	-
7	Dry Weight	80	20 - 300	1	-
8	Age	50	1 - 120	1	-
9	Target Kt/V	-	0.5 - 2.0	0.1	-
10	Current Kt/V	0.0	-	0.1	-
11	Estimated Kt/V	0.0	-	0.1	-

- Graph



No.	Setting item	Default	Setting range	Setting step	Selection item
1	Vertical axis：Kt/V	-	0.0 - 2.5	-	-
2	Target Kt/V horizontal line	-	-	-	-
3	Horizontal axis：Time	-	0:00 - Treatment time	-	-
4	Estimated Kt/V graph（dotted line）	-	-	-	-
5	Current Kt/V graph（solid line）	-	-	-	-
6	Target Kt/V	-	0.0 - 2.5	0.1	-
7	Estimated Kt/V	-	-	0.1	-
8	Current Kt/V	-	-	0.1	-

NOTE

- After treatment begins, the graph is not plotted for less than five minutes.
- ISO-UF execution time is not included at the treatment time.

10.7.3. Dose Detector

⚠CAUTION

- The Dose Detector attempted to predict the Kt / V of a therapy. The value cannot be used for the therapy adjustment. It is calculated from measured conductivity of CD1 and CD4. The predicted Kt / V of the Dose Detector and the actual Kt / V can differ from each other.

Measurement will not start if the treatment mode is ONLINE HDF pre-dilution, ONLINE HF pre-dilution or ONLINE HF post-dilution.
Measurement will not start if the dialysate mode is the AC mode.

- Start of the Dose Detector

Measurement automatically starts if the Dose Detector is ON in the Option setting.

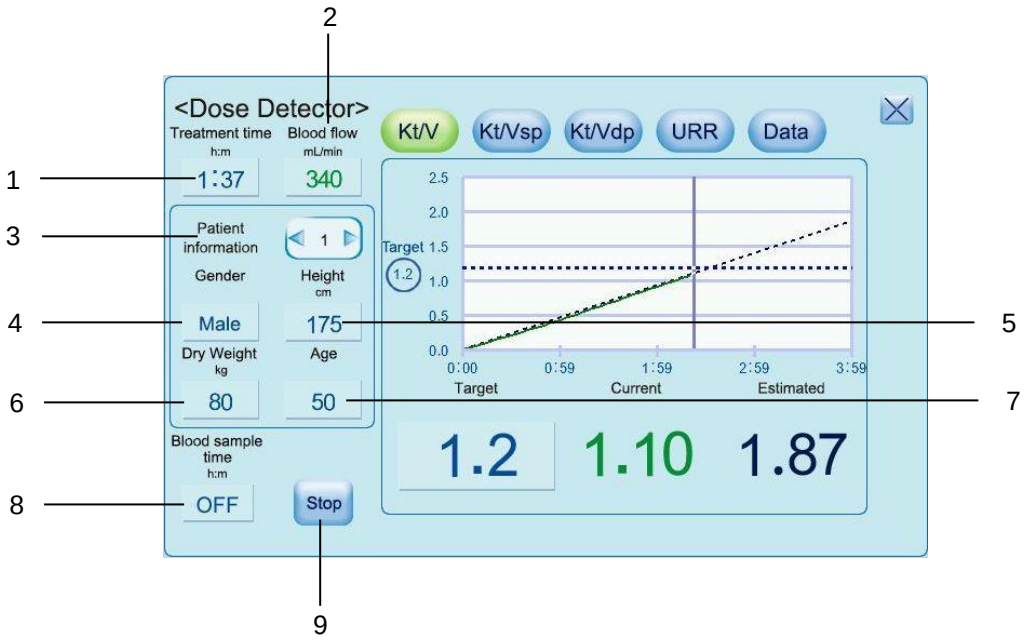
NOTE

- The concentration of dialysate automatically rises 5 mmol/L every 60 minutes 7 minutes after treatment start.
- It takes 5minuites to increase the concentration.

- Stop of the Dose Detector

Activate the Stop button on the Dose Detector screen.

- Setting

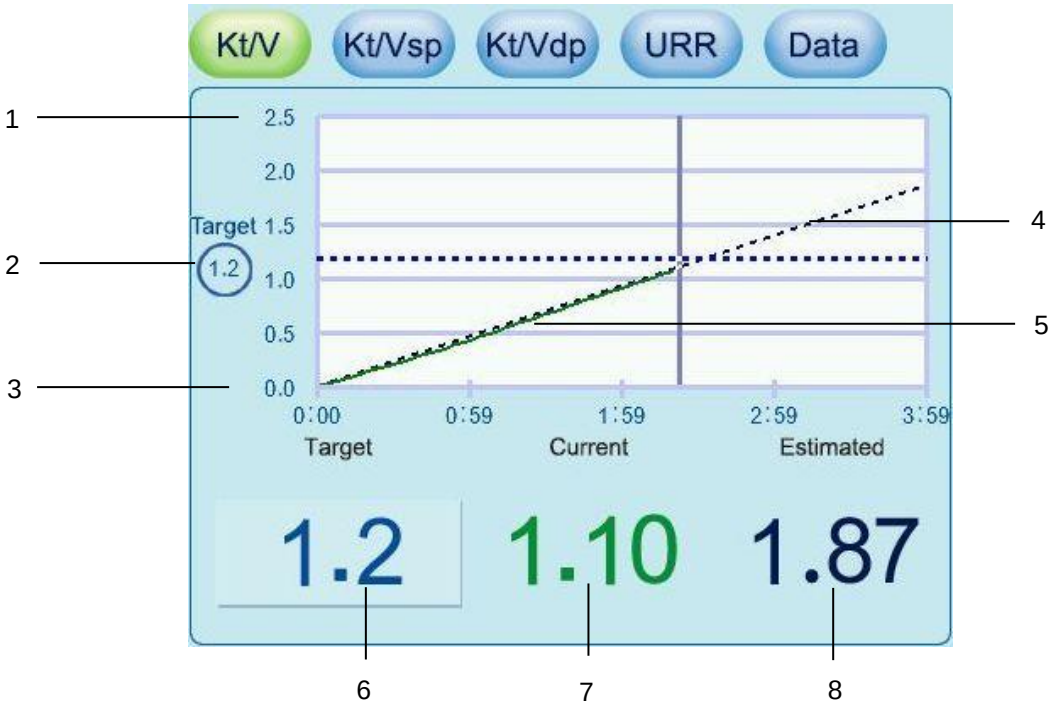


No.	Setting item	Default	Setting range	Setting step	Selection item
1	Treatment time	-	0:00 to 24:00	0:01	-
2	Blood flow	200	10 to 600	5	-
3	Patient information	1	1 - 8, PC	-	-
4	Gender	Male	Male, Female	-	-
5	Height	175	30 to 300	1	-
6	Dry Weight	80	1 to 300	1	-
7	Age	50	1 to 120	1	-
8	Blood sample time	OFF	OFF, 0:01 to 24:00	0:01	-
9	Stop	OFF	ON, OFF	-	-

These 8 parameters are linked to the Dose Finder.

Calculation of the Dose Detector stops if the STOP button is activated.

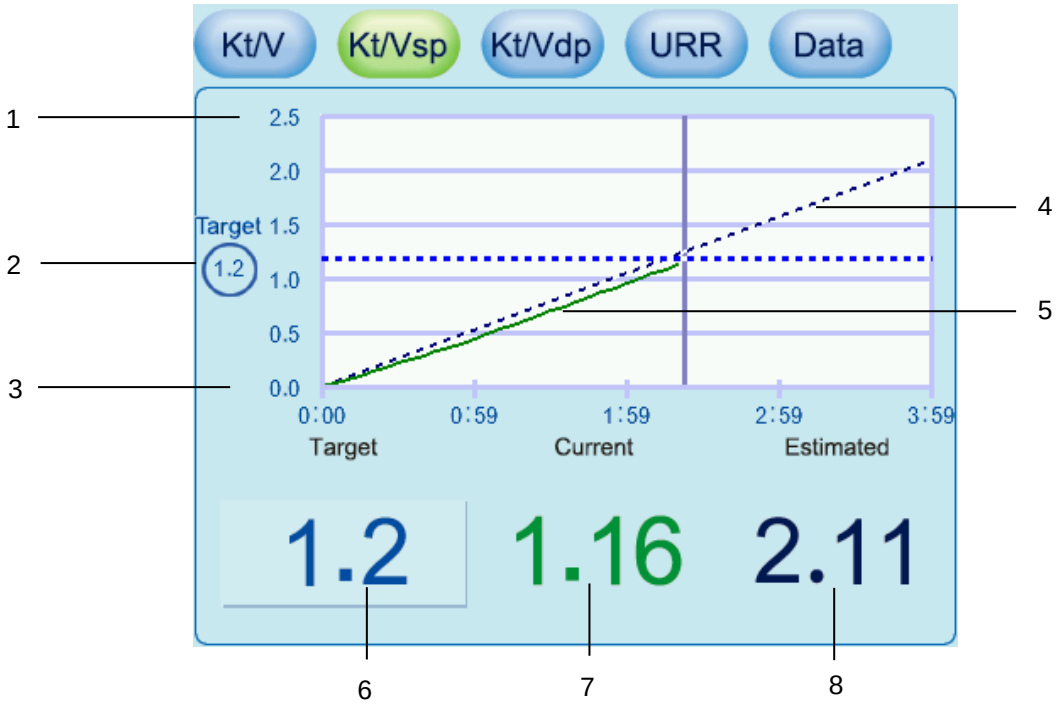
- Kt/V Graph



No.	Setting item	Default	Setting range	Setting step	Selection item
1	Vertical axis：Kt/V	-	0.0 - 2.5	-	-
2	Target Kt/V horizontal line	-	-	-	-
3	Horizontal axis：Time	-	0:00 - Treatment time	-	-
4	Estimated Kt/V graph（dotted line）	-	-	-	-
5	Current Kt/V graph（solid line）	-	-	-	-
6	Target Kt/V	-	0.0 - 2.5	0.1	-
7	Current Kt/V	-	-	-	-
8	Estimated Kt/V	-	-	-	-

The value and the graph will be in red if the “Estimated” is lower than the “Target”.

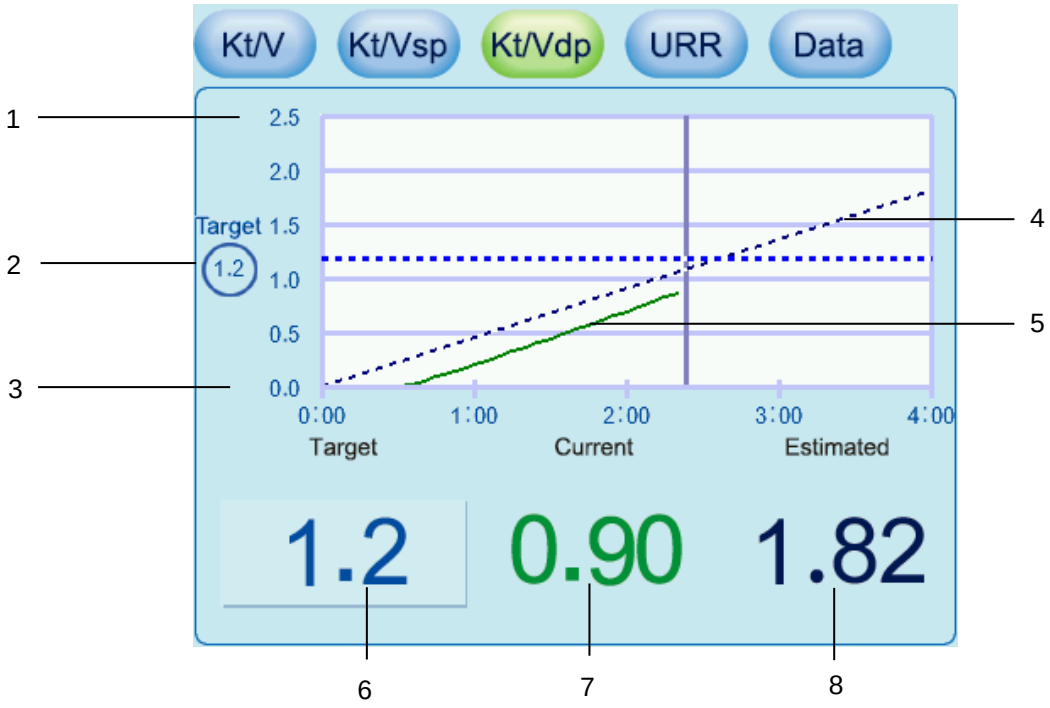
- Kt/Vsp Graph



No.	Setting item	Default	Setting range	Setting step	Selection item
1	Vertical axis：Kt/Vsp	-	0.0 - 2.5	-	-
2	Target Kt/Vsp horizontal line	-	-	-	-
3	Horizontal axis：Time	-	0:00 - Treatment time	-	-
4	Estimated Kt/Vsp graph（dotted line）	-	-	-	-
5	Current Kt/Vsp graph（solid line）	-	-	-	-
6	Target Kt/Vsp	-	0.0 - 2.5	0.1	-
7	Current Kt/Vsp	-	-	-	-
8	Estimated Kt/Vsp	-	-	-	-

The value and the graph will be in red if the “Estimated” is lower than the “Target”.

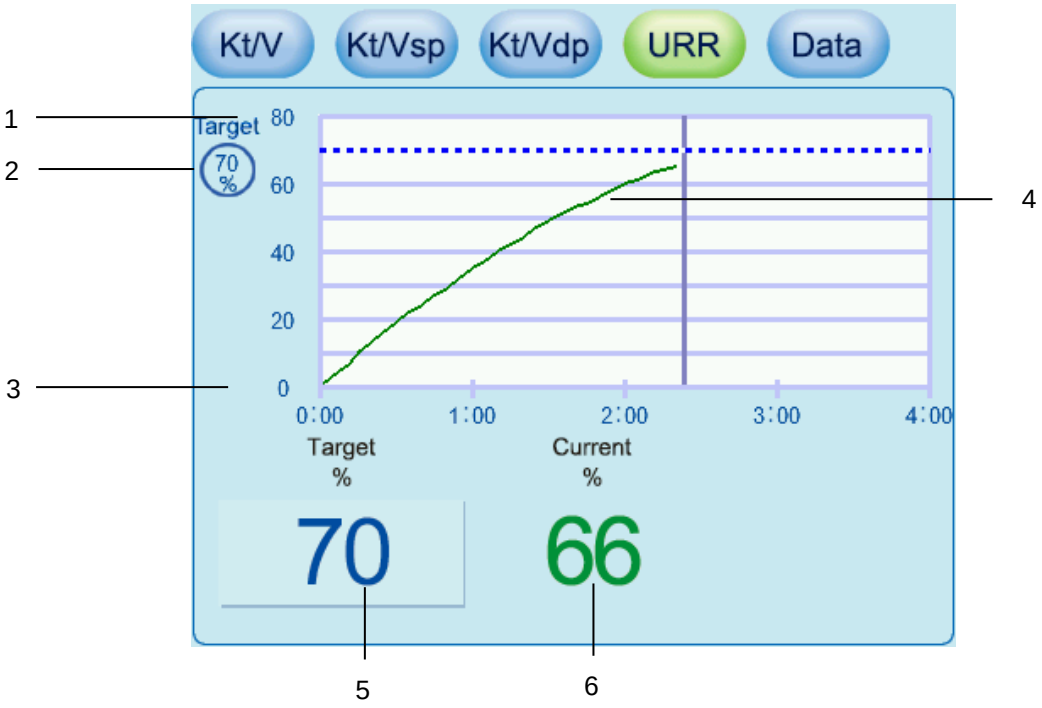
- Kt/Vdp Graph



No.	Setting item	Default	Setting range	Setting step	Selection item
1	Vertical axis：Kt/Vdp	-	0.0 - 2.5	-	-
2	Target Kt/Vdp horizontal line	-	-	-	-
3	Horizontal axis：Time	-	0:00 - Treatment time	-	-
4	Estimated Kt/Vdp graph（dotted line）	-	-	-	-
5	Current Kt/Vdp graph（solid line）	-	-	-	-
6	Target Kt/Vdp	-	0.0 - 2.5	0.1	-
7	Current Kt/Vdp	-	-	-	-
8	Estimated Kt/Vdp	-	-	-	-

The value and the graph will be in red if the “Estimated” is lower than the “Target”.

- URR Graph



No.	Setting item	Default	Setting range	Setting step	Selection item
1	Vertical axis：URR	-	0 - 80	-	-
2	Target URR horizontal line	-	-	-	-
3	Horizontal axis：Time	-	0:00 - Treatment time	-	-
4	Current URR graph (solid line)				
5	Target URR	-	0 - 80	0.1	-
6	Current URR	-	-	-	-

- Data

No.	Setting item	Default	Setting range	Setting step	Selection item
1	Kt/V	Only displayed			
2	Kt/Vsp	Only displayed			
3	Kt/Vdp	Only displayed			
4	Kt	Only displayed			
5	URR	Only displayed			
6	Clearance	Only displayed			

10.7.4. Timer

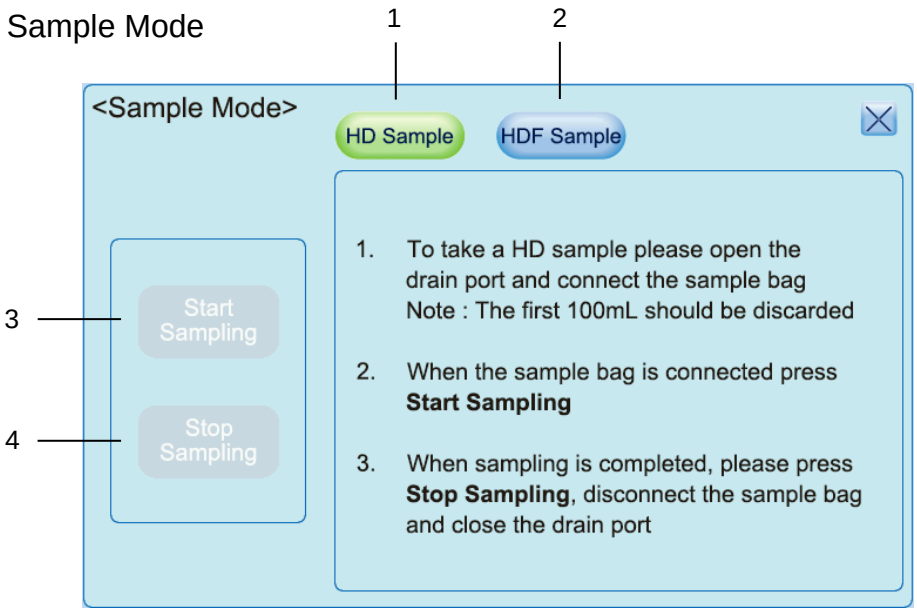
- Timer setting

Setting item	Default	Setting range	Setting step	Selection item
Remaining time	00:00:00	00:00:00 - 99:59:59	-	-
Start	-	-	-	-
Stop	-	-	-	-
Reset	-	-	-	-
Melody	2	1 - 6		

10.7.5. BVM

Refer to “18. Blood Volume Measurement" for details.

10.7.6. Sample Mode



No.	Setting item	Default	Setting range	Setting step	Selection item
1	HD Sample	-	-	-	-
2	HDF Sample	-	-	-	-
3	Start Sampling	OFF	-	-	ON/OFF
4	Stop Sampling	OFF	-	-	ON/OFF

10.8. First aid button

NOTE

- Press the first aid button for 3 seconds to execute a function set on the System - Setting - First aid screen.
- This button is valid only during the dialysis process.
- Turning [First air function] to OFF on the System-Setting-First aid screen invalidates this function and disables the First aid button.

10.8.1. Setting of First aid button

Operation to be executed while the first aid function is valid can be set on the System-Setting-First aid screen.

The first aid function itself can be set on the System-Setting-First aid screen.

10.8.2. Execution of First aid button

Press the First aid button for more than 3 seconds during the dialysis process.

The light indicator lights up in orange.

Operation set on the System-Setting-First-aid screen is executed.

10.8.3. Resetting of First aid button function

* The UF speed has been changed.
* The blood pump flow has been changed.
* The bypass operation is reset.
* The First aid button has been turned to OFF.

10.9. Changing the CF

⚠CAUTION

- Use the specified CF only.
- When using CF, follow the instructions below related to the hygiene.
- Do not use CF if the package is damaged.
- Open the package and remove protective straps just before use.
- Touch CF if necessary but by connector only.

NOTE

- Time for replacement is displayed on the Cleaning screen.
- Message about filter replacement is displayed when the cleaning program is selected.

10.9.1. Filter Replacement Rule

- Filter is defective. (A leak was found in the leak check test.)
- At the end of filter life time (Refer to below)

-When Peracetic acid is used.
200 treatments / approx. 1200 hrs.
30 Sodium-hypochlorite disinfections are possible in a life cycle of CF-609N.

-When Citric acid is used.
300 treatments / approx. 1800 hrs
30 Sodium-hypochlorite disinfections are possible in a life cycle of CF-609N.

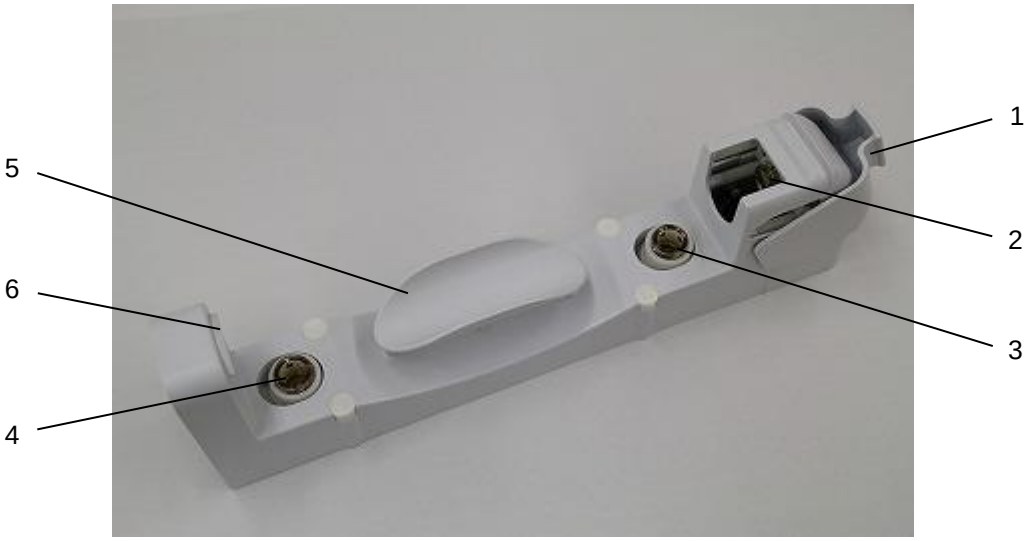
10.9.2. Filter Replacement

⚠CAUTION

- Follow the filter replacement procedure.

No.	Operation
1	The machine must be disconnected from a patient.
2	Go to the Cleaning screen and touch the Filter change button.
3	Replace the filter according to the guidance displayed on the screen.

The names of the CF holder parts are as follows:

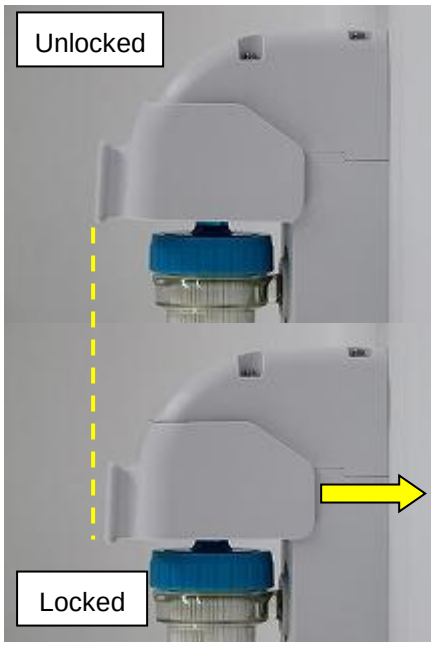


No.	Name
1	Swing cover
2	CF outlet connecting port
3	CF flushing line connecting port
4	CF inlet connecting port
5	CF guide
6	Bottom stopper

The following describes how to mount the CF holder:

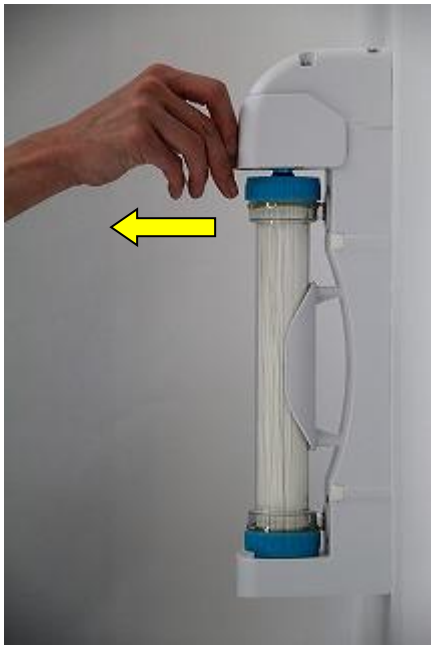
1. Insert the CF inlet and CF flushing line to each port of the CF holder, and firmly grip the CF and CF guide together.

2. Lower the Swing cover and keep gripping the CF until the cover is lowered until the end.



3. Confirm the Swing cover is at the locked position.

The followings describe how to dismount CF holder:



1. Pull the Swing cover to the arrowed direction.

2. Raise the Swing cover while placing a hand on the CF as it may pop out.

3. Raise the Swing cover until it snaps into place, and it will not be lowered by its own weight.

⚠CAUTION

- The CF will be mounted diagonally to the CF holder as shown below if it is pushed against the machine without gripping the CF guide. If the Swing cover is lowered with this condition, the CF outlet connecting port may not be connected properly or the CF may not be mounted properly because the bottom of the CF and the Bottom stopper interfere.

- Lowering the Swing cover with the CF mounted diagonally to the CF holder may damage the cover.
- Disinfect the machine after the filter replacement.

10.10. Single-Needle Click-Clack

10.10.1. Caution before Use of Single-Needle Click-Clack

Use this function exclusively for some cases, for example when stroke volume and re-circulation volume are significantly different. For the display of effective blood volume, 2 ml of re-circulation volume every Single-Needle Click-Clack cycle is taken into consideration when standard DN dialysis cannula is used. However actual re-circulation volume may differ from the display volume if another type of cannula is used.

The arterial and venous lines should be connected to the vascular access together with Y shaped tube.

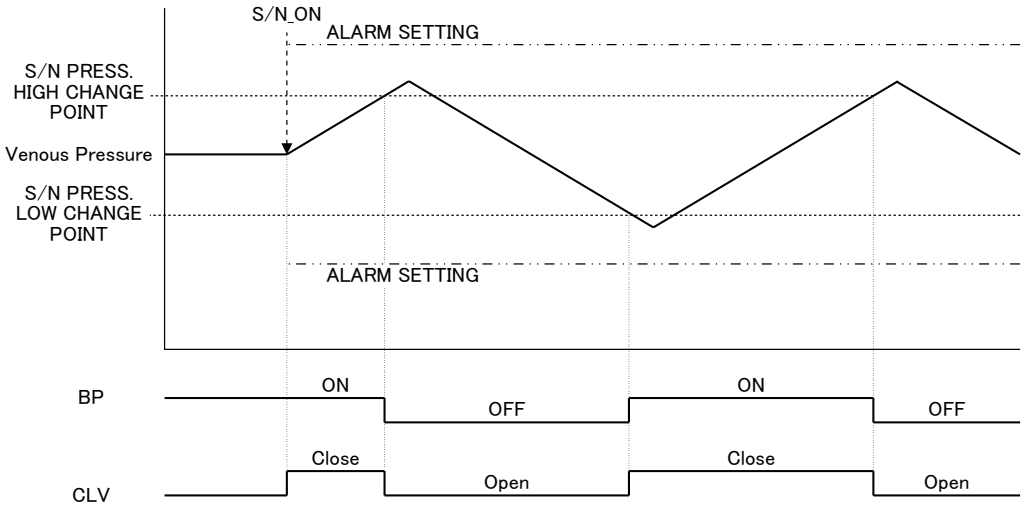
⚠CAUTION

- When a blood circuit for single needle is inserted, Single-Needle Click-Clack is not available.
- During preparation process, Single-Needle Click-Clack is available only when the rinse volume becomes minimum volume.
- You can start or stop Single-Needle Click-Clack any time during Double-Needle treatment.
- HDF being executed is stopped. Treatment continues by HD.
- On-line bolus can be injected any time.
- Reinfusion is available when ONLINE option is selected.

10.10.2. To Start Single-Needle Click-Clack

No.	Operation
1	Open the Single-Needle menu.
2	Set the target parameter button if you would like to change the parameter. Visually check the setting value after you change the setting.
3	Touch the Click-Clack button.

Refer to the following graph for the relationship between the blood pump operation and venous clamp operation and venous pressure value at the single needle operation.



The display of blood flow displays the set value regardless of movement or the stop of the blood pump. Confirm AVERAGE BLOOD FLOW RATE in single needle window for average blood flow rate during single needle operation.

10.10.3. To Stop Single-Needle Click-Clack

No.	Operation
1	Open the Single-Needle menu.
3	Touch the Click-Clack I/O button.

10.11. Password function

The password is requested in order to limit the settings and the operations of the screens not necessary for treatment to the responsible division only. Password entry is required when moving to these screens to prevent incorrect operation.

⚠CAUTION

- The password must be random choice of numbers other than the default. Prevent the password from being known to persons outside of the responsible division.

  Note) Do not use the following passwords:

  1111", "1234" etc

10.11.1. Displays that require a password

Only correct password entry allows the screen to move to other screens when the “BPM” switch or a specific switch in the “Setting” and the “Maintenance” tags is selected.

10.11.2. Conditions to invalidate a password

The password which is once accepted as valid in the “Setting” or the “Maintenance” tag is going to be valid until another tag is selected. Therefore, accessing other pages in the same menu will not require the password once the screen enters the “Setting” tag or the “Maintenance” tag.

⚠CAUTION

- Always close the menu to disable the password when treatment is started in order to prevent incorrect operation.

11. Specification

The specifications and appearance of the product may change without a previous notice for improvement.

11.1. Unit Specification

11.1.1. Model, Size and mass

	Specification	Note
Main unit size	H: 1625 +/- 10 mm (Without an IV pole) H: 1745 to 1995 +/- 10 mm (With an IV pole) W: 480 +/- 10 mm (Foot) D: 895 +/- 10 mm	None
Main unit mass	120 +/- 5 kg (Dry mass)	Type C Full option

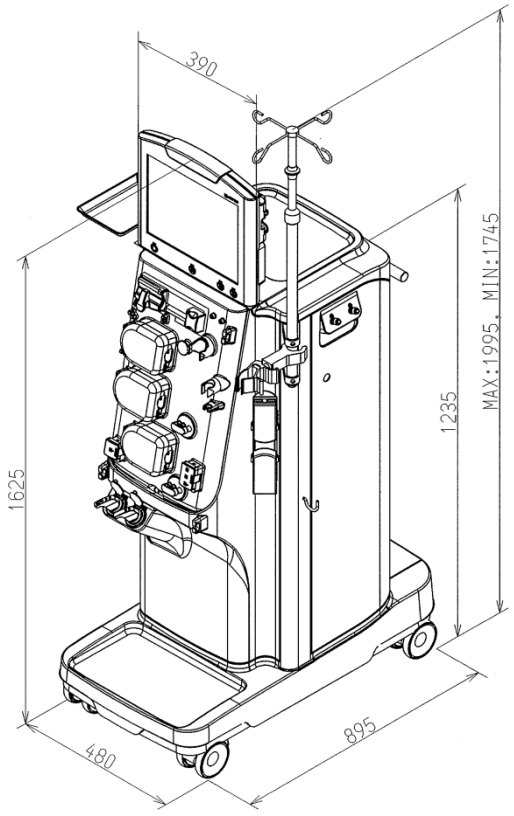


Figure 1-1 Outside dimensions of the equipment

NOTE

- Do not install the unit in a place where plugging/unplugging the power cord is difficult.

Drainage

Drainage flow must be 1500 mL/min or higher.
Keep the drainage tube 3 m or shorter.
The maximum height of the drain tube is 800 mm, with free outlet to avoid contamination.
The drain should contain a free fall distance of minimum 20 mm.

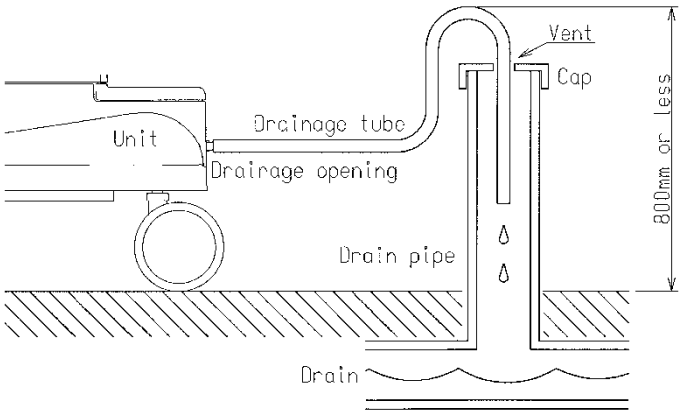


Figure 1-2 Drainage

⚠CAUTION

- Dispose the drain fluid according to regional regulations.

11.1.2. Electric rating

	Specification	Note
Power supply voltage Power supply frequency	230 V AC +/- 10 %, 50 Hz / 60 Hz 110 V AC +/- 10 %, 50 Hz / 60 Hz	The equipment is tuned using 200 V AC / 60 Hz or 100 V AC / 60 Hz due to the limitation of production facility.
Electricity power consumption	2000 VA or less	230 V AC: 2 heaters (1000 W + 500 W) 110 V AC: 2 heaters (1000 W + 500 W)
Length of the power cable	3.0 +/- 0.1 m (From the backside of the equipment to the tip of the plug)	230 V AC: Removable type 110 V AC: Fixed type

The electric power supply necessary for the operation of the Surdial X must conform to the respective laws and regulations in the customer's region.
Please follow the information in the technical manual for installation and use.

Electromagnetic emissions and electromagnetic immunity

The Surdial X is intended for use in the electromagnetic environment specified below.
The customer or the user of the Surdial X should assure that it is used in such an environment.

Intented environments

Electromagnetic environments	Professional healthcare facility environments
Effect of electromagnetic disturbance	Unintended alarm may be issued if Electromagnetic disturbance occurs.
Cable and accessories	Potential equalization conductor cable：attachment length 2.9 m LAN cable：Max 10 m（with shield） Remote button for NIBP/Nurse call button cable：NBR-8A-C-3 length 2.9 m

⚠WARNING

- Except for near a mobile phone, citizens band radio equipment, HF surgical equipment, MRI system and RF shielded room.
- Stop using the Surdial X adjacent to the equipment or observe to verify that the Surdial X is operating normally by maintaining a certain distance from it if it may cause harmful interference to the Surdial X.
- Maintaining 30 cm or more distance between portable and mobile RF communications equipment (transmitters) to prevent electromagnetic interference.
- The use of accessories and cables other than those specified, with the exception of parts sold by the manufacturer as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment.

Emissions test level

Item	Standard
Conducted emissions CISPR 11	Group1 Class B -Frequency band 0.15 to 0.50 MHz: Quasi-peak decreases from 63 dB to 56 dB with the logarithm of the frequency. Average decreases from 53 dB to 46 dB with the logarithm of the frequency. -Frequency band 0.50 to 5 MHz: Quasi-peak: 53 dB Average: 43 dB -Frequency band 5 to 30 MHz: Quasi-peak: 57 dB Average: 47 dB
Radiated emissions CISPR 11	Group1 Class B -Frequency band 30 to 230 MHz: 30 dB -Frequency band 230 to 1000 MHz: 37 dB
Harmonic emissions IEC 61000-3-2	Class A Max relative voltage change - dc: <= 3.3 % Relative steady state voltage change - dmax: <= 4 % Relative voltage change - d(t): 500 ms
Voltage fluctuations / flicker emissions IEC 61000-3-3	Short-term blinking - Pst: <= 1.0 Long-term blinking - Plt: <= 0.65

Immunity test level

Item	Standard
Electrostatic discharge immunity IEC 61000-4-2	Air discharge : ±15 kV Indirect contact : ±8 kV
Electrical fast transient/burst immunity IEC 61000-4-4	AC Power port：±2 kV(repetition frequency：100 kHz) Signal port：±1 kV(repetition frequency：100 kHz)
Surge immunity IEC 61000-4-5	Differential mode: ±1 kV Common mode: ±2 kV
Power frequency magnetic field immunity test IEC 61000-4-8	Test level 30 A/m
Voltage dips, short interruptions and voltage variations immunity IEC 61000-4-11	100 % voltage dip: for 0.5 cycle 100 % voltage dip: for 1 cycles 70 % voltage dip: for 25/30 cycles 100 % voltage dip: for 250/300 cycles
Radiated, radio-frequency, electromagnetic field immunity IEC 61000-4-3	Frequency band ：80 MHz to 2.7 GHz ：ISM Band (refer to IEC 60601-1-2：2014 Table 9) Test field strength: 3 V/m 80 % AM, 1 kHz Residence time: 3 seconds
Immunity to conducted disturbance, induced by radio-frequency fields IEC61000-4-6	Frequency band ：0.15 MHz to 80 MHz ：ISM Band (refer to IEC 60601-1-2：2014 Table 6) Test field strength ：3 Vrms 80 % AM, 1 kHz ：ISM Band　6 Vrms 80 % AM, 1 kHz Residence time: 3 seconds

⚠WARNING

- There is no guarantee that interference will not occur in a particular installation.
- Take the following measures if equipment causes harmful interference

- Increase the distance between the devices
- Connect the equipment to an outlet on a different circuit from that other device
- Contact the manufacturer or technician for help

11.1.3. Protection form

	Specification	Note
Type of protection from electric shock	Class I ME equipment	None
Degree of protection from electric shock	Dialysate circuit: Type B applied part Cuff: Type BF applied part	None
Protection against water and hazardous micro particulate matter infiltration	Drip proof equipment IPX1	All panels must be closed.

11.1.4. Conditions on the facility side

	Specification	Note
Water supply pressure	0.05 to 0.74 MPa (Normal pressure)	None
Water supply flow	900 mL/min or more (Dialysate flow 100 to 800 mL/min)	1200 mL/min or more at Sub bolus
Water supply temperature	5 to 30 °C	・ With 37 °C preset. ・ The water supply temperature must be 5 °C or more lower than the dialysate temperature set value. ・ The temperature change per min must be +/- 1 °C or lower.
Drainage volume	1500 mL/min or more	Length of the drain tube: 3 m or less Height: 0 to 80 cm from the floor
Water quality	Has to be suitable for dialyzing. (Water quality satisfying the provision of ISO 13959:2014) For ON-LINE HDF treatment, concentrates must satisfy the provision of ISO 13958:2014.	The quality of the water should comply with the local regulations. (e.g. European pharmacopoeia)
Range of Supply pressure from Central system	5 to 98 kPa	None

11.1.5. Environment

	Specification	Note
Surrounding space	Ensure following clearances enough for the outer size of the equipment: Top: 5 cm or more Side: 10 cm or more Back: 20 cm or more	A ventilating hole of 20 cm or more in diameter must be equipped for ventilation. Otherwise, any of top/side/back surface must be open.
Operating surrounding temperature	15 to 35 °C	At least 5 °C lower than the set value of dialysate.
Operating surrounding humidity	35 to 80 %RH	Non condensing.

	Specification	Note
Storage, transport temperature	With liquid in hydraulic circuit: 5 to 50 °C Without liquid in hydraulic circuit: -10 to 50 °C	None
Storage, transport humidity	35 to 85 %RH	Non condensing
Barometric pressure	When used, storage and transportation, 795 to 1062 hPa	None

⚠CAUTION

- If the unit is to be used after a period of 1 month or more, clean the unit thoroughly (for 1 hour or more). Subsequently, regular inspection should be performed in accordance with “Safety Precautions-16”.

11.2. Unit performance

11.2.1. Hydraulic Circuit Control

	Specification	Note
Dialysate flow	100 to 800 mL/min (100 mL/min increment)	None
Flow accuracy	0 to +10 % from the set value	None
Deaeration method	Vacuum deaeration method	None
Dissolved gas in dialysate	PO2 140 mmHg or less	Raw water PO2 200 mmHg (37 °C conversion) When the set temperature of dialysate is 37 °C.
Time until Preparation complete	Without CF: 7 minutes or less With CF1: 8 minutes or less ON-LINE HDF: 11 minutes or less	Supplied water temperature must be at least 5 °C lower than the dialysate set value. Surrounding temperature must be at least 5 °C lower than the dialysate set value.

11.2.2. UF control

	Specification	Note
Control Method	Closed capacity control method by the piston pump	None
Settable range	0.00, 0.10 to 4.00 L/h (0.01 L/h increment)	None
Accuracy	+/- 30 g/h	When the equipment adjustment condition is the same as factory default

11.2.3. Temperature control

	Specification	Note
Settable range	34.0 to 39.0 °C (0.1 °C increment)	None
Stability	Set value +/- 0.5 °C	None
Accuracy of indicated value	Mean temperature +/- 0.3 °C	Mean temperature is the mean value of dialysate temperature per minute.

NOTE

- Dialysate temperature lowers 1.4 °C or over at the inlet of a dialyzer if dialysate flow is 500mL/min, dialysate temperature setting 36.5 °C, and ambient temperature 23 °C.
- Dialysate temperature lowers 4.5 °C or over at the inlet of a dialyzer if dialysate flow is 100mL/min, dialysate temperature setting 39.0 °C, and ambient temperature 15 °C.
- Substitution fluid temperature lowers 1.9 °C or over at the outlet of a substitution fluid circuit if substitution flow is 150mL/min, dialysate temperature setting 36.5 °C, and ambient temperature 23 °C.
- Substitution fluid temperature lowers 3.2 °C or over at the outlet of a substitution fluid circuit if substitution flow is 30mL/min, dialysate temperature setting 36.5 °C, and ambient temperature 23 °C.
- Substitution fluid temperature lowers 12.9 °C or over at the outlet of a substitution fluid circuit if substitution flow is 10mL/min, dialysate temperature setting 39.0 °C, and ambient temperature 15 °C.

11.2.4. Conductivity control (BICARBONATE)

	Specification	Note
Dialysate preparation method	A Concentrate : Quantitative mixing method by the piston pump B Concentrate: Feedback control by the piston pump	None
Input range of Theoretical Concentration of Water+B (Concentration of Na+Electrolyte)	24 to 70 mmol/L (1 mmol/L increment)	None
Input range of Theoretical Concentration of Water+A+B (Concentration of Na+Electrolyte)	125 to 165 mmol/L (1 mmol/L increment)	None
Calibration method	Calibration value is input on the screen.	None
Input range of A-Conc dilution ratio	1/32.26 to 1/52.26 (0.01 increment)	None
Input range of B-Conc dilution ratio	1/17.46 to 1/70.70 (0.01 increment)	None
Calibration range of Na-conc.	Setting of Prescribed Na +/- 5mmol/L (1 increment)	None
Calibration range of B-conc.	Setting of Prescribed HCO3 of B +/- 5mmol/L (1 increment)	None
Stability	0.3 mS/cm or less	None

11.2.5. Conductivity control (ACETATE)

	Specification	Note
Dialysate preparation method	A Concentrate : Quantitative mixing method by the piston pump	None
Input range of Theoretical Concentration (Concentration of Na+Electrolyte)	125 to 165 mmol/L (1 mmol/L increment)	None
Calibration method	Calibration value is input on the screen.	None
Input range of Acetate dilution ratio	1/31.00 to 1/51.00 (0.01 increment)	None
Calibration range of Na-conc.	Setting of Prescribed Na +/- 5mmol/L (1 increment)	None
Stability	0.3 mS/cm or less	None

11.2.6. Cleaning

	Specification	Note
Chemical disinfection （Sodium Hypochlorite）	Setting range Concentrate concentration:1.0 to 12.0 % (0.1 % increment) Concentrate after dilution:0.10 to 0.20 % (0.01 % increment) Time : 38 to 120 min (1 min increment) Pre : 8 min (fixed) Post : 11 to 60 min (1 min increment) T1 temp : 35 to 40 °C (1 °C increment)	Time includes pre and post rinse time. Recommended condition ・Concentrate after dilution:0.10 % ・Cleaning time:38 min ・Post time:11 min ・T1 temp.:35 m
	Corrosion resistance Concentrate concentration:6 % or less Concentration after dilution / Time: 0.10 % or less / 1hr or less	
(Peracetic acid)	Setting range Concentrate concentration:1.0 to 12.0 % (0.1 % increment) Concentrate after dilution:0.03 to 0.20 % (0.01 % increment) Time : 37 to 120 min (1 min increment) Pre : 8 min (fixed) Post : 9 to 60 min (1 min increment) T1 temp : 35 to 40 °C (1 °C increment)	Manufacturer does not secure disinfection effects using peracetic acid. Use peracetic acid at each facility's discretion.
	Corrosion resistance Concentrate concentration:6 % or less Concentration after dilution / Time: 0.02 % or less / 1 hr or less	
Hot disinfection	Setting range Concentrate concentration:30.0 to 50.0 % (0.1 % increment) Concentrate after dilution:0.50 % (fixed) Time with ON-LINE HDF option : 31 to 60 min (1 min increment) Pre : 6.5 min (fixed) Post : 8 min (fixed) without ON-LINE HDF option : 29 to 60 min (1 min increment) Pre : 5.5 min (fixed) Post : 8 min (fixed) T2 Temp :96 °C (Fixed)	Time includes pre and post rinse time. Recommended disinfection ・Cleaning time 31 min (with ON-LINE HDF option) 29 min (without ON-LINE HDF option) ・T1 monitoring temp.: 70 °C
	Corrosion resistance Concentrate concentration:50 % or less Concentration after dilution: 1.0 % or less	

	Specification	Note
Decalcification (Acetic acid)	Setting range Concentrate concentration:30.0 to 70.0 % (0.1 % increment) Concentrate after dilution:1.00 to 5.00 % (1 % increment) Time : 25 to 120 min (1 min increment) Pre : 8 min (fixed) Post : 10 to 60 min (1 min increment) T1 temp : 35 to 40 °C (1 °C increment) Corrosion resistance Concentrate concentration: 50 % or less Concentration after dilution / Time: 2 % or less / 1h or less	None
Hot rinse	Setting range Time with ON-LINE HDF option : 31 to 60 min (1 min increment) Pre : 6.5 min (fixed) Post : 8 min (fixed) without ON-LINE HDF option : 29 to 60 min (1 min increment) Pre : 5.5 min (fixed) Post : 8 min (fixed) T2 Temp :96 °C (Fixed)	None
Hot Water Disinfection (HWD)	Setting range Time with ON-LINE HDF option : 35 min Pre : 6.5 min (fixed) Post : 8 min (fixed) T2 Temp :96 °C (Fixed) without ON-LINE HDF option : 35 min Pre : 5.5 min (fixed) Post : 8 min (fixed) T2 Temp :96 °C (Fixed)	T1 monitoring temp.: 85 °C
Rinse	Setting range Time: 5 to 120 min (1 min increment)	None
IHR	Setting range Time: 30 to 200 min (1 min increment) Flow :100～800 mL/min (100mL/min increment) T2 Temp :96 °C (Fixed) Heater control: ON/OFF Selection whether the hydraulic circuit is included or not	Water supply temperature: 85 to 90 °C

11.2.7. Blood pump, S/N Double pump

	Specification	Note
Method	2-roller	None
Rotation direction	Counter Clockwise rotation	None
Flow setting range	Standard tube: 0, 10 to 600 mL/min (5 mL/min increment)	Standard tube: Exclusive circuit φ8.00 x φ12.00 ± 0.15 mm t = 2.00 ± 0.1 mm
Flow accuracy	Set value +/- 10 %	Min. inlet pressure : -200 mmHg Max. outlet pressure : +500 mmHg Maximum flow may not be achieved due to fatigue of the rolling tube.

11.2.8. ON-LINE HDF pump

	Specification	Note
Method	2-roller	None
Rotation direction	Counter Clockwise rotation	None
Flow setting range	10 to 500 mL/min	Standard tube : exclusive circuit φ 8.00 x φ 12.00 ± 0.15 mm (t = 2.00 ± 0.1 mm)
Flow accuracy	Set value +/- 10 %	Min. inlet pressure : -200 mmHg Max. outlet pressure : +500 mmHg Maximum flow may not be achieved due to fatigue of the rolling tube.

11.2.9. Heparin pump

	Specification	Note
1 tube method	Nipro syringe 20 mL	None
Injection direction	Leftward only facing the equipment front side	None
Flow setting	0.0 to 10.0 mL/h (0.1 mL/h increment)	None
Flow accuracy	Machine accuracy +/- 1 % Flow accuracy +/- 10 %	When each setting of the syringe is proper Pressure range: 0 to 450 mmHg
Overload detection	Discharge pressure 1200 +/- 50 mmHg	Adjust with 20 mL Nipro syringe at default setting. Adjustment at the site is required if a different size syringe is used.
Fast-forward injection	10 mL : Approx. 550 mL/h (Approx. 9 mL/min) 20 mL : Approx. 900 mL/h (Approx. 15 mL/min) 30 mL : Approx. 1200 mL/h (Approx. 20 mL/min)	None
Pusher removal alarm	To detect loss of syringe	None
Rotation direction detection alarm	To inhibit counter rotation	None
Alarm for irregular injection rate	Alarm goes off when the injection rate deviates from the range of +/- 20 % of set value. (A pair of photo sensors is used for monitoring the injection rate.)	None
Bolus	0.5 to 10.0 mL (0.1 mL increment) Flow rate is same as fast-forward injection.	None

⚠CAUTION

- The heparin pump should be used only for infusion of heparin solution. Do not use this pump for infusion of any other solutions!

11.2.10. Consumption data / energy data

	Specification	Note
Supply water consumption	Treatment: Approx. 30L Hot rinse/Hot disinfection: Approx. 12L	per 1 hour treatment per 1 hot rinse
A Conc. consumption	Approx. 0.8L	per 1 hour treatment
B Conc. consumption	Approx. 1.5L	per 1 hour treatment
Power consumption	Treatment: Approx. 0.55kWh Hot disinfection: Approx. 0.68kWh	per 1 hour treatment per 1 disinfection
Energy emission to drainage	Treatment: Approx. 0.20kWh	per 1 hour treatment
Energy emission to environment	Treatment: Approx. 0.35kWh	per 1 hour treatment

The above describes the data when the machine is operated by default values with the supply water of 20 °C and the environmental temperature of 20°C.

Treatment conditions are as follows: HDF, 500mL/min of dialysate flow, 200mL/min of blood flow and 50mL/min of substitution flow.

11.3. Safety devices

11.3.1. Venous pressure monitor

	Specification	Note
Measurable range	- 500 to + 500 mmHg	None
Indicated value accuracy	+/- 10 mmHg	None

11.3.2. Arterial pressure monitor

	Specification	Note
Measurable range	- 500 to + 500 mmHg	None
Indicated value accuracy	+/- 10 mmHg	None

11.3.3. Venous Clamp

	Specification	Note
Function	Closes blood line at venous side.	Normally-closed type

11.3.4. Arterial Clamp

	Specification	Note
Function	Closes blood line at arterial side. (during Single needle treatment)	Normally-opened type

11.3.5. Bubble detector

	Specification	Note
Detection	Ultrasonic transmission method	None
Acceptable tube size	φ 4.3×φ 6.8 mm +/- 0.1 mm	None
Detection capability	Alarms when 10 μL and over single bubble is detected or 0.3 μL and over bubbles are detected and accumulated bubbles in the unit time (1 min) reach the set value. Setting value: 4 grades of 1, 10, 50, 300 μL *Single bubble is always monitored.	Flow 200 mL/min Flow temperature 37 ± 1.0 °C

11.3.6. Blood leak detector

	Specification	Note
Measurement	Optical (an infrared transmission method)	None
Measurement accuracy	+/- 100 ppm	0 to 850 ppm
Alarm setting	Setting range: 50 to 500 ppm (10 ppm increment) Detection point (Default: 280 ppm), (Ht 32 %)	None

11.3.7. Temperature monitor

	Specification	Note
Sensor method	Thermistor	None
Measurement accuracy	+/- 0.8 °C (At actual temperature 37 °C)	None
Alarm setting	Max setting range: 37.0 to 40.0 °C (0.1 °C increment) Min setting range: 33.0 to 36.0 °C (0.1 °C increment)	Mean temperature is the mean value of dialysate temperature per minute.

11.3.8. Conductivity monitor

	Specification	Note
Measurement	AC 2-Electrode type	None
Measurement accuracy	CD1：Display value +/- 2 % CD2：Display value +/- 2 % CD3：Display value +/- 2 % CD4：Display value +/- 2 %	CD1:10.0 to 20.0 mS/cm CD2:1.2 to 10.0 mS/cm CD3:1.2 to 10.0 mS/cm CD4:10.0 to 20.0 mS/cm
Alarm setting	Setting range: Base conductivity +/- 2.0 to +/- 9.9 % (0.1 °C increment)	None

11.3.9. Blood pump monitor

As protective system for blood coagulation, DC stepping motor including photo sensor is used in blood pump. The pump error (stop) caused by blood coagulation in blood line is detected by abnormal return pulse transmitted from the element and the alarm is activated for assuring patient safety.

11.3.10. UF monitor

The patient is protected from the volume of the UF that danger is caused by deflection from a set value by observing the rotational rate of the UF pump by using two photo sensors.
However, errors in the UF rate may exist to a maximum of 4% of the set value. This method does not detect UF rate errors from other sources such as leakage.

11.3.11. Alarm buzzer

	Specification	Note
Sound pressure	Alarm System mode: Normal mode (in case Alarm sound = 1) Max setting: Approx. 72 dB(A) to 79 dB (A) Min setting: Approx. 51 dB(A) to 58 dB (A) (in case Alarm sound = 2) Max setting: Approx. 72 dB(A) to 78 dB (A) Min setting: Approx. 50 dB(A) to 56 dB (A) (in case Alarm sound = 3) Max setting: Approx. 77 dB(A) to 83 dB (A) Min setting: Approx. 56 dB(A) to 61 dB (A) (in case Alarm sound = 4) Max setting: Approx. 65 dB(A) to 73 dB (A) Min setting: Approx. 44 dB(A) to 49 dB (A) (in case Alarm sound = 5) Max setting: Approx. 75 dB(A) to 78 dB (A) Min setting: Approx. 52 dB(A) to 55 dB (A) (Five stage setting) Alarm System mode: ICU mode High priority Max setting: Approx. 74 dB(A) to 78 dB (A) Min setting: Approx. 55 dB(A) to 61 dB (A) Medium priority Max setting: Approx. 73 dB(A) to 77 dB (A) Min setting: Approx. 53 dB(A) to 60 dB (A) Low priority Max setting: Approx. 70 dB(A) to 76 dB (A) Min setting: Approx. 52 dB(A) to 54 dB (A) (Five stage setting)	None
Muting time	2 minutes	None

⚠CAUTION

- Change the sound volume setting after confirming the alarm sound can be recognized.

11.3.12. Lamp

3 colors light indicator.

(Red color is blinking when an error is detected. Refer to chapter “7. Lamp" for details)

11.3.13. Alarms and their main operations when errors are detected

Error	Alarm operation		
	Buzzer	Light indicator	Main operation
When the venous pressure is equal to or exceeds the maximum/minimum alarm set values	Audible	blinking in red	Blood/heparin pumps stop. UF operation stops.
When the dialysate pressure is equal to or exceeds the maximum/minimum alarm settings, or When TMP exceeds the alarm set value	Audible	blinking in red	Blood/heparin pumps stop. UF operation stops. Venous circuit is clamped, but not for the TMP alarm.
Single bubble: When 30 µL or larger is detected	Audible	blinking in red	Blood/heparin pumps stop. UF operation stops. Venous circuit is clamped.
When the dialysis fluid temperature is lower than the minimum set value or higher than the maximum set value	Audible	blinking in red	Bypass operation. UF operation stops. Heater OFF.
When volume of blood detected by the blood leak detector is higher than a set value	Audible	blinking in red	Blood/heparin pumps stop. Bypass operation. UF operation stops.
When the OVERLOAD DETECTION button of the heparin pump operates (including injection completion)	Audible	-	Heparin pump stops.
When a unit-related error such as a temperature sensor error occur	Audible	blinking in red	The unit stops, etc.
When the measured conductivity of the dialysate which enters the dialyzer is equal to or exceeds the maximum/ minimum alarm set values	Audible	blinking in red	Bypass operation. UF operation stops.

11.4. Machine type

Type A: HD model

Type B: SNDP model

Type C: ON-LINE HDF + SNDP model

Type D: ON-LINE HDF model

11.5. UF control functions

(1) UF control

Closed circuit control system by the piston pump

(2) ISO-UF (Isolated Ultra Filtration)

Performs ultra-filtration only without haemodialysis.

(3) UF profile

Divides the time until UF completion into 8, 10 or 12, and performs the ultra-filtration operation at the set UF speed at every period.

ISO-UF are selectable in each step.

(4) Dialysate Bolus

Bolus with dialysate to the patient via specified dialyzer

(5) Dialysate priming

Priming of the blood circuit with dialysate via specific dialyzer

(6) Dialysate reinfusion

Reinfusion with dialysate via specific dialyzer

11.6. Hydraulic circuit control functions

(1) Control of Dialysate Flow

Varies the pump speed by the feedback control.

(2) Bicarbonate dialysis

A Concentrate: Quantitative mixing method by the piston pump

B Concentrate: Feedback control by the piston pump

Performing the conductivity calibration automatically configures the reference conductivity and monitors the conductivity with the value.

(3) Acetate dialysis

Quantitative mixing method by the piston pump.

Performing the conductivity calibration automatically configures the reference conductivity and monitors the conductivity with the value.

(4) Concentrate profile

Prepares the dialysate at the set concentrate with the set time interval.

The following setting range is available respectively.

A-PRO：125～160 mmol/L、B-PRO：24～45 mmol/L

It's possible to link with a UF profile.

(5) CF leak check

Filter membrane breakage in the CF is detected by negative pressure using the UF pump.

11.7. Brood circuit control functions

(1) Single needle (Single-pump)

One pump- One clamp/Single needle treatment by the venous side clamp and the blood pump

(2) Clean Treatment Start (CTS)

Drains priming solution from the hydraulic circuit through a dialyzer to perform blood removal.

(3) ON-LINE Bolus (only for Type C and D)

Bolus with dialysate to the patient

(4) ON-LINE priming (only for Type C and D)

Priming of the blood circuit with dialysate

(5) ON-LINE reinfusion (only for Type C and D)

Reinfusion with dialysate

(6) Single needle (Double pump)　(only for Type B and C)

Two pumps-Two clamps/Single needle treatment by the arterial side clamp and the venous side clamp and the blood pump and the single needle pump

11.8. Cleaning functions

(1) Cleaning program

6 types of independent cleaning

・Rinse, Disinfection 1 to 4, Acid 1 to 4, Hot rinse / HWD, Hot disinfection 1 to 4, IHR

6 types of automatic cleaning

・Automatic cleaning 1 to 6 (8 steps are assignable)

・8 items including Auto off and Standby are selectable in each step.

11.9. Other functions

(1) Start up test

Performs the startup tests at machine startup and before treatment

(2) Self-diagnosis function

Performs self-monitoring of the venous side air bubble detector during treatment

(3) Power failure backup

The liquid crystal display, the touch panel, the blood pump, the bubble detector, the heparin pump, the venous clamp and the pressure monitoring can be operated with the battery for the power failure backup at power failure.

Backup time is more than 30 minutes on a full charge (Factory default) .

(4) Kt/V (Dose finder)

The dialysis efficiency is calculated from the patient information, the dialysis time and the setting value of the blood pump flow. No accuracy because the value is a predicted value by calculation.

(5) Max-sub

Automatically sets the maximum Sub rate to the blood flow at the moment by the TMP.

It functions only when the Treatment mode is the ONLINE HDF post-dilution or the ONLINE HF post-dilution.

(6) Kt/V (Dose Detector)

The dialysis efficiency and Urea Reduction Rate are calculated from the setting of the dialysis time, blood flow and patient information and measured value of CD1, CD4.

11.10. Operation panel mechanism

(1) LCD and Touch panel

LCD : 15inch TFT color (1024×768 dot)

Touch panel : Analog

(2) Rotation mechanism of the operation panel

The operation panel rotates to the left, right, top and bottom with two axes.

11.11. Hydraulic circuit mechanism

(1) A nozzle and rinse port

Rinsing and disinfection are automatically performed with connecting the suction nozzle of concentrate to the rinse port.

(2) B-powder Assembly

A holder for removable B powder cartridge (Nipro Cart)

Dialysate is prepared using the B powder cartridge and B powder cartridge priming and drainage are performed.

(3) Heat Exchanger Assembly

Indirectly contacting used dialysate exchanges the heat to the supply water to compensate the performance.

(4) CF1 holder

A holder for removable cut filter (CF-609N)

No coupler for connecting the cut filter requires less labor when exchanging it.

(5) Water leak detection (LD2)

Detects water leak from the hydraulic circuit piping.

11.12. BSP panel mechanism

(1) Automatic pump Insert / removal

A mechanism the rolling tube of the blood circuit is automatically attached to and detached from the tubing pump.

(2) Drain port

A port to drain priming solution in the blood circuit to the inside of the hydraulic circuit.

(3) Water leak detection (LD1)

A mechanism which detects water leak from the ON-LINE port.

(4) Fluid level adjustment (SN drip chamber, Venous drip chamber)

A mechanism which varies the level of the drip chamber by filling or discharging air inside the chamber.

(5) Fluid level adjustment (Venous drip chamber)

A mechanism which automatically adjusts the level in the drip chamber by the level sensor during priming

(6) Double pumps - single needle (only for Type B and C)

A single needle pump (tubing pump) , PSN port and SN drip chamber holder for the double pumps-single needle treatment.

Treatment is performed interlocking the blood pump, venous side clamp, single needle pump and arterial side clamp. Level adjustment mechanism will be separately required to have the double pumps-single needle treatment.

(7) ON-LINE HDF unit (only for Type C and D)

The substitution fluid pump, the ON-LINE port and the CF2 holder for the ON-LINE HDF treatment.

Dialysate purified by the CF2 is obtained from the ON-LINE port and sent to the blood circuit by the substitution fluid pump.

11.13. Other mechanism

(1) Light indicator (3 colors: Red, Orange, Green)

Colors and illumination patterns are as follows:

Red flashing:	Alarm
Orange lighting:	Cleaning, Preparation
Orange flashing:	Preparation Complete
Green lighting:	Dialysis
Green flashing:	Reinfusion

(2) Dialysate concentrate rack

A rack for the A/B concentrate tank combined with the foot cover (The machine front)

(3) Acid / Disinfectant rack

A rack for the disinfectant concentrate tank combined with the foot cover. (The machine rear) A belt to secure the tank to the machine is attached.

11.14. Main display specifications

(1) UF volume

Digital display: 0.00 to 10.00 L

(2) UF goal

Digital display: 0.00 to 10.00 L

(3) UF rate

Digital display: 0.00, 0.10 to 4.00 L/h

(4) Treatment time remaining

Digital display: 0:00 to 24:00 h:min

(5) Sub volume

Digital display: 0.0 to 600.0 L

(6) Sub goal

Digital display: 0.0 to 600.0 L

(7) Sub rate

Digital display: 10 to 500 mL/min

(8) Venous pressure

Bar graph display and Digital display. Display range of the bar graph can be switched with the software.

Bar graph display -100 to +300 mmHg (Default)
-100 to +500 mmHg
Digital display -500 to +500 mmHg

(9) Arterial pressure

Bar graph display and Digital display. Display range of the bar graph can be switched with the software.
(Display range will be discussed separately.)

Bar graph display: -300 to +100 mmHg (Default)
-300 to +300 mmHg
-300 to +600 mmHg
Digital display -500 to +500 mmHg

(10) TMP (Venous pressure – Dialysate pressure)

Bar graph display: -100 to +300 mmHg(Default)
-100 to +500 mmHg
Digital display: -500 to +500 mmHg

(11) Dialysate pressure

Bar graph display and Digital display. Display range of the bar graph can be switched with the software.

Bar graph display: -500 to +500 mmHg(Default)
-300 to +300 mmHg
Digital display -650 to +650 mmHg

(12) Dialysate temperature

Digital display: 0.0 to 99.9 °C

(13) Dialysate conductivity

Digital display. A value compensated based on the reference temperature of 25 °C is displayed.

0.0, 3.0 to 20.0 mS/cm

(14) B-conductivity

Digital display. A value compensated based on the reference temperature of 25 °C is displayed.

0.00, 0.30 to 10.00 mS/cm

(15) Heparin pump flow

Digital display: 0.0 to 10.0 mL/h

Displays accumulated amount at fast forwarding and bolus injection

(16) Blood pump flow

Digital display: 0, 10 to 600 mL/min

(17) Dialysate flow

Digital display: 100 to 800 mL/min

(18) Display Language

English, Germany, French, Spanish, Italian, Greek, Russian, Dutch, Romanian, Czech, Swedish, Croatian, Polish, Turkish, Lithuanian, Ukrainian, Portuguese, Hungarian and Slovenian

11.15. Dialyzer

・ELISIO series dialyzer ・FB series dialyzer ・PUREFLUX series dialyzer
・SUREFLUX series dialyzer ・SURELYZER series dialyzer ・SOLACEA series dialyzer

⚠WARNING

- Use "ELISIO-H series" dialyzer which removes endotoxin in case of Priming, bolus and Reinfution by DIF function. Other dialyzer may permit the entry of endotoxin if its cut filter CF1 is damaged.

⚠CAUTION

- Expected performance or functions cannot be warranted if other than the specified is used.

11.16. Blood Lines

NIPRO blood lines for Surdial X are available.

⚠CAUTION

- Expected performance or functions cannot be warranted if other than the specified is used.

11.17. Syringes

NIPRO 20ml syringe coded SY3-20LC-EC is available.

⚠CAUTION

- Surdial X is verified for use with NIPRO 20ml syringe coded SY3-20LC-EC. To maximize operability for the user, the Surdial X is equipped with a heparin pump able to accommodate syringes from 10ml to 30ml; in case of use of syringes different from the NIPRO 20ml syringe coded SY3-20LC-EC, the user is responsible to verify correct operability. Expected performance or functions cannot be warranted if other than the specified is used.

11.18. Concentrates

11.18.1. Acetate

NIPRO solutions for acetate dialysis are available.

11.18.2. Bicarbonate

NIPRO solutions for bicarbonate dialysis are available.
Acid bicarbonate hemodialysis concentrate 1+44
Acid bicarbonate hemodialysis concentrate 1+34
For mixing with basic sodium hydrogen carbonate concentrate 8.4%

11.18.3. Powder Bicarbonate

NIPROCART is available.

11.19. CF

NIPRO:CF-609N

11.20. Option specification

11.20.1. Built-in Automatic Blood Pressure Measurement Module

Measures the blood pressure for adults and children by the module (M2500: OMRON HEALTHCARE Co., Ltd.) built in the equipment.

Exchanges data (SYS, DIA, MAP, HP) by connecting the module and main equipment via serial communication. The measurement start/stop and measurement result check are performed on the equipment screen.

Depending on the blood pressure measurement result, the equipment has the function to ease the burden on the patient.

11.20.2. External network (Option attached only before shipment)

An interface to connect the machine to the LAN network.

11.20.3. Card system (Option attached only before shipment)

An interface to read and write the patient card information.

11.20.4. Spike nozzle

A needle type nozzle to connect to an A concentrate bag.

A hook to hang the A concentrate bag on the right side of the equipment.

11.20.5. Central system (2 ports for A-concentrate / 1port for A-concentrate and 1port for B-concentrate)

Connection ports for the A-conc and the B-conc central system

Sucks up the concentrates from the permanently installed A and B tanks via the connecting ports.

11.20.6. Remote button for NIBP

A remote control button to externally control start and stop of the built-in blood pressure measurement module.

Uses the NBR-8A-C-3, AIPHONE Corporation

11.20.7. Nurse call button

A remote button to call a nurse.

It is shared use with the BPM remote button and pressing the BPM remote button will be a nurse call.

11.20.8. B nozzle and rinse port (Option attached only before shipment)

Rinsing and disinfection is performed with connecting the suction nozzle of B concentrate to the rinse port.

11.20.9. A bag connector nozzle

A nozzle to connect to a lure-connecting type A concentrate bag.

11.20.10. Front hook

A hook to hang an A concentrate bag on the front side of the equipment.

11.20.11. Blood volume measurement (BVM)

BVM measures relative hematocrit (HCT⊿BV), and relative hemoglobin (Hb⊿BV), relative blood volume (RBV) and reduction of the relative blood volume (⊿BV) are calculated based on the measured HCT⊿BV.

11.20.12. Central Alarm Output (CAO)

Send the alarm detection signal to the externally connected device, when Surdial X detects the alarm.

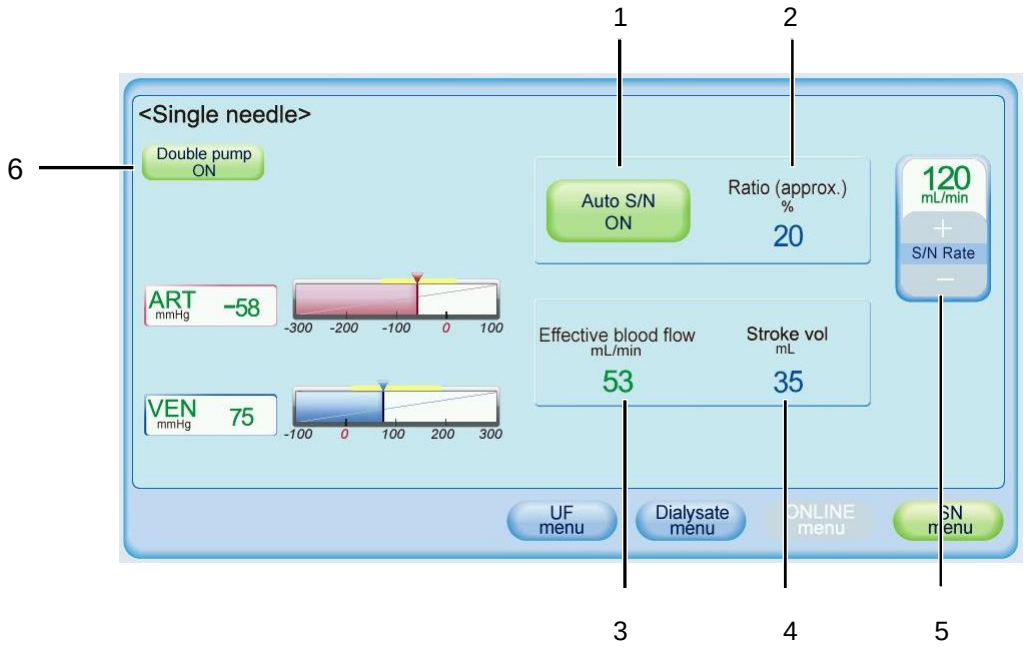
11.20.13. BVM control (BVC)

The UF rate and the dialysate concentration are automatically calculated based on the difference between the RBV reference line and the relative blood volume (RBV).

12. Single Needle Treatment (Option)

12.1. SN menu (Single Needle treatment menu)

Touch the SN menu button on the Treatment screen to open the Single needle menu.



1 Auto S/N

Pre-selecting Auto SN.

(In the Auto S/N mode, the ratio of the blood pump rate to the Single-Needle pump rate is defined automatically.)

2 Ratio (approx.)

The ratio of the blood pump rate to the Single-Needle pump rate.

3 Effective blood flow

The blood pump flow calculated from the time when the blood pump runs.

Effective blood flow = (BP flow x SNP flow) ÷ (BP flow + SNP flow)

4 Stroke vol.

The working volume inside of single needle chamber.

5 S/N Rate

Rocker switch for increasing “+ “/reducing “-“ the Single-Needle flow.

6 Double pump

When single needle bloodlines are inserted, double pump button is activated.

⚠WARNING

- The S/N treatment repeats blood collection and reinfusion based on the single needle pressure. Improper setting value results in improper blood collection and reinfusion. Set the proper value based on the physician's instructions.

⚠CAUTION

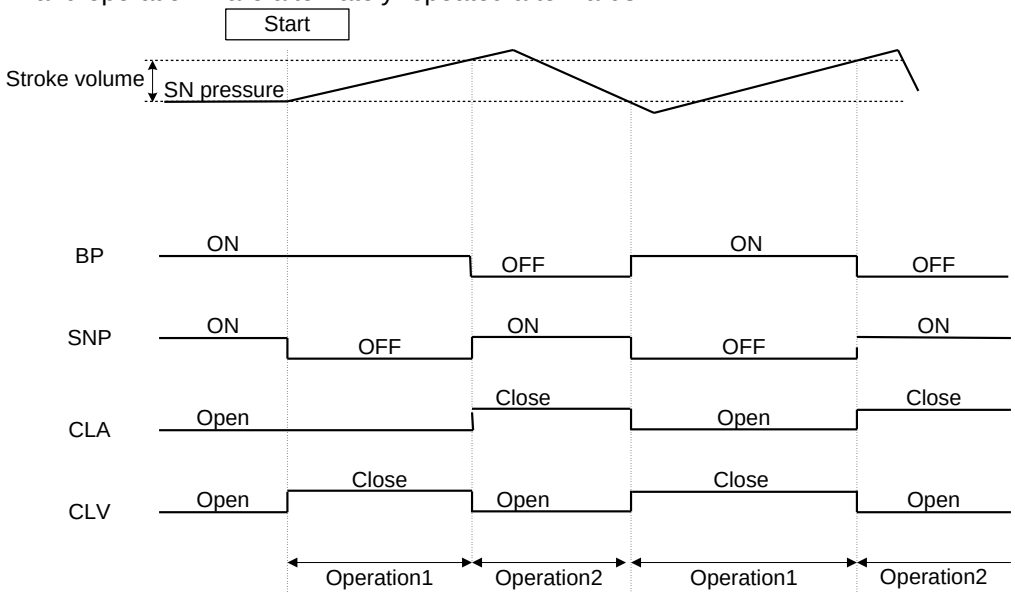
- Refer to "4. Treatment" for basic operations.

NOTE

- The treatment mode is changed from single needle to double needle if the I/O button of Single needle is turned off. Please follow the guidance indicated in the information window.

12.2. Single needle operation

The pump and the clamp are controlled as below during the double pump/single needle operation. Operation 1 and operation 2 are alternately repeated afterwards.



Operation 1: The blood pump is operated until the stroke volume is reached.
Stroke volume = "BP flow per rotation" x "BP rotation speed"
Operation 2: The single needle pump is operated until the stroke volume is reached.
Stroke volume = "SNP flow per rotation" x "SNP rotation speed"

NOTE

- When the heparine pump is operated at rapid feed or by one shot, the blood pump and the single needle pump are controlled to be rotated at the same time.

12.3. Alarms for single needle operation

E7 Venous pressure MAX alarm、E8 Venous pressure MIN alarm

This alarm is detected under the following conditions:

* A higher venous pressure than the venous pressure maximum alarm value is detected continuously for more than 2 seconds.
* A lower venous pressure than the venous minimum alarm value is detected.

NOTE

- The alarm setting value is monitored based on the value set on the System-Setting-Alarm-Venous screen.

E105 SN pressure abnormal

This alarm is detected under the following conditions:

* A difference between the maximum switching pressure and minimum switching pressure is less than 10mmHg at the start of single needle operation.
* The upper and lower SN pressure point is not reached even after 10 ml more as the set stroke volume in the SN chamber

E40 SNP stop error

This alarm is detected under the following conditions:

* The cover is opened and the single needle pump is stopped.

E41 SNP revolving direction error

This alarm is detected under the following conditions:
* The wrong direction of the single needle pump is detected for more than 2 seconds.

E42 SNP speed error

This alarm is detected under the following conditions:
* The return speed is out of the allowable range compared to the SN rate.

E43 SNP error

This alarm is detected under the following conditions:
* The alarm OUT from the SNP motor is fixed to the Hi level.

E44 SNP cover sensor error

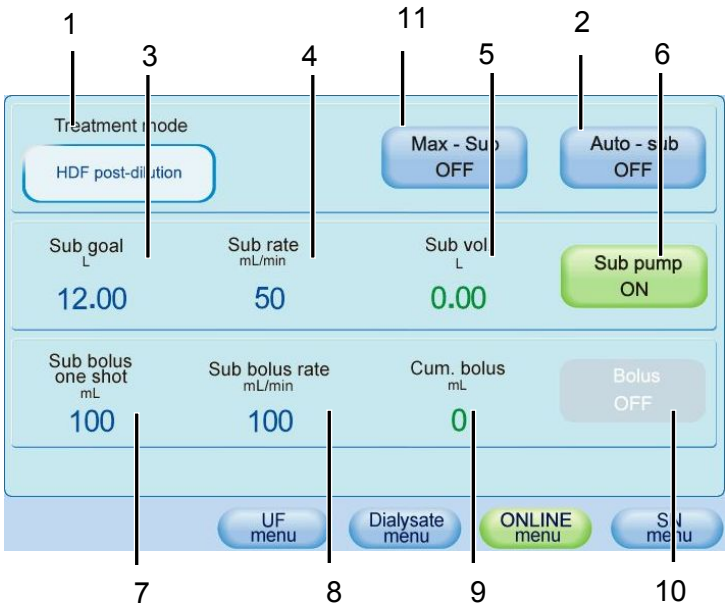
This alarm is detected under the following conditions:

* The SNPC1 and SNPC2 signals are deviated continuously for 2 seconds.

13. ONLINE (Option)

13.1. ONLINE menu screen

Press the ONLINE menu button. The following screen will appear.



1. Treatment mode

   Button to select treatment mode. Treatment modes HDF Pre-dilution, HDF Post-dilution, HF Pre-dilution and HF Post-dilution are available.

2. Auto-sub

   Button to start or stop auto fluid replacement

   The Sub pump rate changes according to the blood pump flow when I/O is ON.

   The flow of the substitution fluid pump changes according to that of the venous pump during double pump single needle treatment.

3. Sub goal

   Target fluid replacement volume

   Setting range: 0 to 600 L

4. Sub rate

   Fluid replacement rate

   Setting range: 10 to 500 mL/min

5. Sub volume

   Current fluid replacement volume

6. Sub pump I/O

   Button to operate fluid replacement pump

7. Sub Bolus

Settings for bolus injection (one-shot injection) are displayed.

Setting range: 10 to 200 mL

8. Sub Bolus rate

Rate for bolus injection

Setting range: 10 to 300 mL/min

9. Cum. Bolus

Cumulative bolus injection volume is displayed.

10. Bolus

Button to start bolus injection

11. Max-sub

Button to start or stop the Max-sub.

⚠WARNING

- Before each on-line HDF/on-line HF treatment, the unit must be heat-cleaned with citric acid, or a chemical disinfection with peracetic acid or sodium hypochlorite has to be carried out.
- The use of two CutFilters (dialysatefluid filter) is mandatory.

- First filter is placed after the dialysis fluid preparation.
- This filtered dialysis fluid will pass true the second filter just before it will be infused as substitution fluid in the bloodline.

- To guarantee the chemical quality, the regulation of the European Pharmacopeia in the form valid at the time are to be used while the regulations of the RKI (Robert Koch Institute) are to be consulted in order to ensure the microbiological quality.

NOTE

- See the "4. Treatment" for the ONLINE operation.

13.2. Specification

13.2.1. ON-LINE HDF pump

	Specification	Conditions/Note
Blood pump method	2 roller Auto space adjustment method	None
Rotation direction	Counter Clockwise rotation only	None
Flow range	Normal tube : 10 to 600 mL/min (Obtaining maximum flow may be impossible due to fatigue of the rolling tube.)	Normal tube : exclusive circuit φ8.00 x φ12.00 ± 0.15 mm
Flow accuracy	Set value ±10%	Min. inlet pressure : -200mmHg Max. outlet pressure : +500mmHg

13.2.2. Blood Lines

NIPRO blood lines for Surdial X are available.

NOTE

- For the pre-online HDF treatment or pre-online HF treatment, connect the tube from the substitution fluid pump to the port before the dialyzer
- For the post-online HDF treatment or post-online HF treatment, connect the tube from the substitution fluid pump to the port after the dialyzer.

13.2.3. CF endotoxin Retentive Filter

NIPRO:CF-609N

⚠WARNING

- Confirm if the Sub-port is closed visually when the treatment mode is other than Online treatment. when treatment is continued in the state of leakage.
- If the treatment is started while the CF leak check result is NG, endotoxin may enter the body. Replace the CF immediately and check that the leak check is passed. Then start the treatment.

13.3. Auto-sub function

In order to prevent hemo concentration (clotting), this function changes the substitution fluid pump flow according to the blood pump flow. In the SNDP treatment, this function changes the flow of the substitution fluid pump according to that of the venous pump flow (SNP).

The flow of the substitution fluid pump is calculated based on the following formula:

1) For HDF predilution and HF predilution

Substitution fluid pump flow = Blood pump flow x (Auto-Sub ON/OFF rate (pre) 100)

Auto-Sub ON/OFF rate (pre) is set on the System-Setting-Treatment-Online screen.

2) For HDF postdilution and HF postdilution

Substitution fluid pump flow = Blood pump flow x (Auto-Sub ON/OFF rate (post) 100)

Auto-Sub ON/OFF rate (post) is set on the System-Setting-Treatment-Online screen.

13.4. Bolus operation

This function supplies substitution fluid in emergency if the patient's blood pressure drops.
Turning ON the Bolus I/O under the following condition starts bolus operation.

* During the dialysis process
* Bypass operation is not executed (neither auto or manual).
* ISO-UF operation is not executed.
* Blood pump is not stopped.
* HDF postdilution, HDF predilution, HF postdilution or HF predilution is selected

During bolus operation, the cumulated volume of infusion to the cum. bolus section is displayed. After this operation is finished, the total infusion volume achieved during this treatment is displayed.

Turning OFF the Bolus I/O during bolus operation stops the operation forcibly to change to the normal substitution fluid operation.

⚠WARNING

- Whenever bolus substitution is given, please check the patient weight.

13.5. Max-sub function

This function automatically sets the maximum Sub rate to the blood flow at the moment by the TMP. It functions only when the Treatment mode is the ONLINE HDF post-dilution or the ONLINE HF post-dilution.

The Sub rate at the dialysis start is calculated based on the formula below:
Substitution fluid pump flow = Blood pump flow * Measurement start of TMP flat point

The Measurement start of TMP flat point is set on the System-Setting-Treatment-Max-sub screen.
The Sub rate is increased by a certain amount after a certain period of time.
The TMP is monitored and the Sub rate is confirmed as the Max-sub when the Sub rate is no longer increased.
The Sub rate is increased/decreased following the TMP fluctuation after the Max-sub is confirmed.

14. Blood Pressure Monitor (Option)

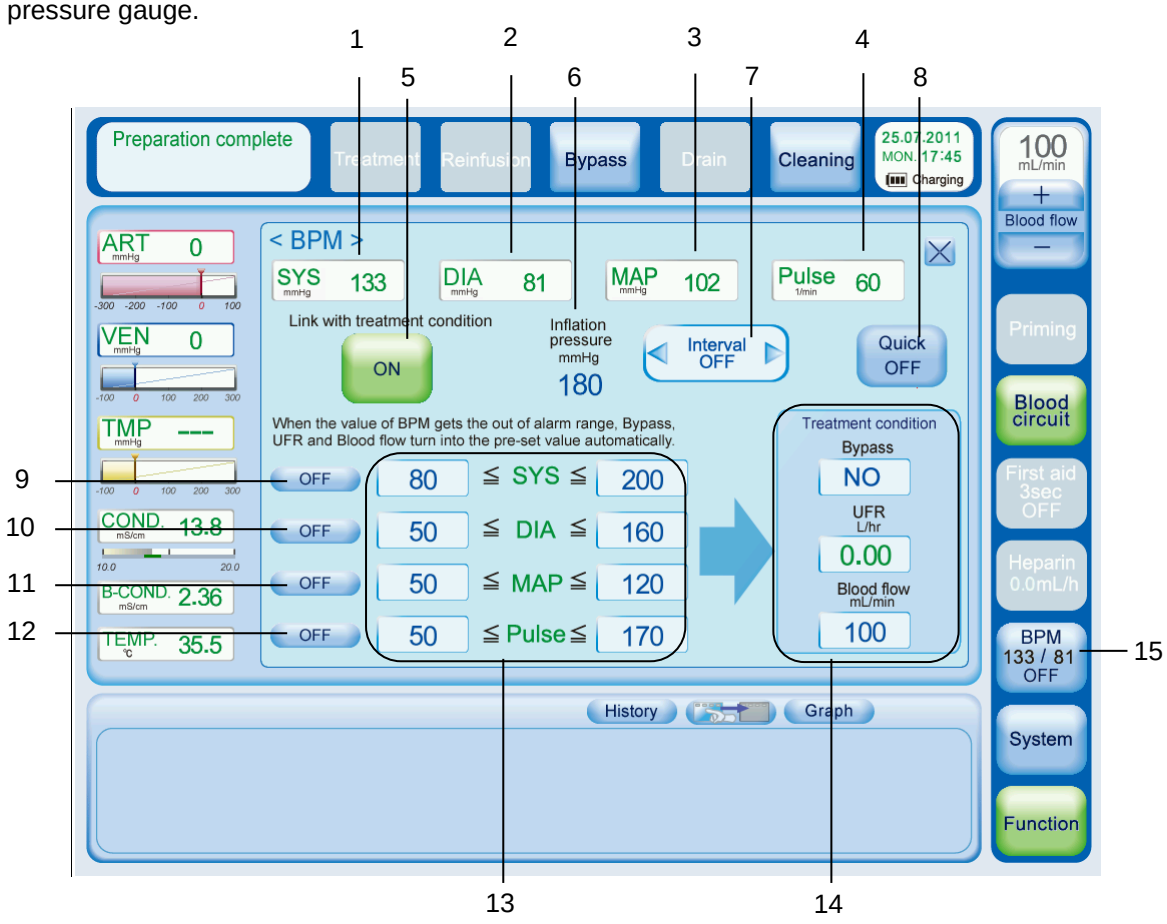
14.1. Precautions for Usage of Blood Pressure Monitor (option)

⚠CAUTION

- Use the specified accessories only. Using non-specified consumables or accessories may cause machine damages or inappropriate treatment result.
- Do not use for a baby or an infant child.
- Do not use if the tube is twisted or deformed.
- Pay attention not to interfere the patient blood circulation when using this option.

14.2. Blood pressure monitor screen

Selecting Function-BPM displays the following screen for setting various items related to the blood pressure gauge.



No.	Name	Description
1	SYS	Systolic blood pressure is displayed.
2	DIA	Diastolic blood pressure is displayed.
3	MAP	Mean blood pressure is displayed.
4	Pulse	Pulse is displayed.

No.	Name	Description
5	Link with treatment condition	Button to link monitoring with treatment condition. Blood pressure is measured automatically when the pre-set blood pressure get the out of range.
6	Inflation pressure	Initial cuff pressure is displayed. The inflation pressure is adjusted after the first measurement.
7	Interval	Monitoring cycle
8	Quick	Button to start/stop continuous measurement (Measurement time: approx. 5 minutes)
9	SYS	Button to start treatment depending on SYS
10	DIA	Button to start treatment depending on DIA
11	MAP	Button to start treatment depending on MAP
12	Pulse	Button to start treatment depending on Pulse
13	Alarm/link conditions	Alarm indication conditions can be displayed and alarm setting ranges can be set. Systolic blood pressure min. alarm≦SYS≦Systolic blood pressure max. alarm Diastolic blood pressure min. alarm ≦DIA≦Diastolic blood pressure max. alarm Pulse min. alarm ≦PULSE≦Pulse max. alarm
14	Treatment condition	UFR (Ultrafiltration rate) and BP flow during dependent treatment
15	BPM	Button to start/stop measurement

14.3. Attaching the cuff to a patient

Attach the cuff to a patient according to the following procedure.

No.	Procedure
1	Wrap the cuff around a bare arm or around an arm covered in thin clothing. Thick clothing or a rolled up sleeve will cause a major discrepancy in the blood pressure reading.
2	Wrap the cuff around the patient's arm so that the center of the cuff's rubber bladder sits on the artery of the upper arm. The hose should be brought out from the peripheral side without bending. (The Brachial artery is located on the inside of the patient's upper arm.
3	The adult cuff should be wrapped around the arm tightly enough so that only two fingers can be inserted under it, above and below the cuff.
4	Maintain the height of the cuff-wrapped upper arm artery to that of the heart's right ventricle during measurements.

⚠WARNING

- Measurement is not possible in the following cases:

  -Do not wrap a cuff around an arm receiving an intravenous drip or being used for blood transfusion, as this is dangerous.

- A misreading may occur in the following cases:

  -When the height of the cuff and the heart differ. A 10cm difference may cause the blood pressure reading to differ by a maximum of 7 to 8mmHg;

  -When the cuff is improperly sized or attached to the patient;

  -When the cuff is frayed. Do not use frayed cuff. The rubber bag may pop out when pressurized and, in some case, burst.

- Beware of kinks in the cuff hose.

  -If a blood pressure is taken with a kink in the hose, blood will be stopped in the arm because air cannot escape from the cuff, which may cause peripheral function damage.

14.4. Measurement

⚠WARNING

- If a measurement was not possible or the measurement readings seem dubious, check the condition of the patient and then confirm the readings using the auscultatory method or palpation method.
- Do not wrap a cuff around an arm receiving an intravenous drip or being used for blood transfusion, as this is dangerous.
- Do not use for an injured arm or an arm under treatment for measurement. It may worsen the condition.
- Consult the doctor before use if the patient has undergone a mastectomy.
- Monitoring ME equipment may temporarily lose some of its functions when the equipment is connected to the arm with the pressurized cuff.
- Measurement is not possible in the following cases:

  -When the patient has a peripheral circulation disorder, extremely low blood pressure or low body temperature;

  -When the patient has frequent arrhythmia. Even if a measurement is possible for such patient, the readings will not be very reliable.

- A misreading may occur in the following cases:

  -When there exist vibrations caused by heart massage, or faint, continuous vibrations applied from outside (e.g. technician contact). Or there exist body movements caused by patient seizure;

  -When the patient wears an improperly sized cuff;

  -When the patient moves or talks during measurement;

  -When the height of the cuff and the heart differ. A 10cm difference may cause the blood pressure reading to differ by a maximum of 7 to 8mmHg;

- Beware of kinks in the cuff hose and the silicone tube during measurements. Especially, take cautions when the patients changed their body postures.

  -When the kinked hoses are used, the air may remain in the cuff even if the cuff pressure reading indicates 0mmHg on the dialysis unit.

- Be aware that the alarm detecting conditions differ according to machines if the alarm setting values differ depending on machines.

⚠CAUTION

- Do not use the Blood Pressure Monitoring (BPM) module and a cardiac defibrillator at the same time. The functions of the BPM module are limited so that they can support only the optional functions of the dialysis unit.
- Check that the BPM module does not obstruct blood circulation of the patients for a long period.
- If the BPM module gets wet by water or other fluids, stop the dialysis unit immediately and then wipe off the fluids on the module completely.
- The continuous measurement mode may cause damage at the measurement site, depending on the patient's condition and cuff fitting technique. Consider the use of the continuous measurement mode carefully before starting.
- The Quick continuous measurement will not recover when the dialysis unit experiences power failure during the measurement and recovers.
- The alarm setting value is a common value regardless of the type of the ALARM SYSTEM mode.

14.5. BPM History screen

The blood pressure history can be confirmed in the Graph screen.

Data including measuring time, SYS, DIA, MAP, Pulse (SYS…Systolic Pressure, Dia…Diastolic Pressure, MAP…Mean arterial Pressure, Pulse…Pulse Rate) can be listed and stored up to a maximum of eighty records. When the number of records exceeds sixty, the oldest data will be overwritten first.

14.6. Messages

⚠WARNING

- If it is impossible to obtain a measurement, or if the measurement readings seem dubious, first check the status of the patient and then confirm the readings using auscultation or palpation.

Alarms and Messages related to measurement impossibilities

-The dialysis unit prompts a message when three measurement attempts fail, or if it has decided not to retry measurement further because of the appearance of error conditions.
-If the elapsed time for the measurement, including measurement retries, exceeds 160 seconds, the measurement is judged to be impossible.
-When a measurement becomes impossible, the dialysis unit prompts an alarm or an on-screen message along with a buzzer tone. To mute the buzzer, press the "MUTE" key.

Alarm and message	Check item
E84 BPM pressurization error The cuff pressure did not reach 10 mmHg within five seconds from the beginning of pressurization. Check the cuff & the pressure tubing The cuff pressure did not reach a preset pressure level within a preset time from the beginning of pressurization.	Check that the connection between the air hose and the dialysis unit or the cuff is not loosened. Check that the air filter for blood pressure gauge does not leak. Check that the cuff wrapping is not loosened.

Alarm and message	Check item
Please check the condition of applying cuff. The cuff pressure decreased to 10 mmHg before the measurement was completed.	Check the status of the patient, and also whether the cuff is fitted properly.
Measurement error with artificial motion Deflation was interrupted for more than 15 seconds due to patient's movements. Measurement error with insufficient pressure Pressurization was insufficient.	Check if the patient is shivering or arrhythmic. Hypertension or the patient's body movements may be a cause. Check also that the air filter for blood pressure gauge is not clogged.
Measurement error with artificial motion or irregular pulses Signals could not be collected properly. Measurement error with artificial motion or irregular pulses The measurement was impossible due to arrhythmia, the patient's movements, or other causes.	Check the status of the patient, and whether the patient is shivering or arrhythmic.
Check the cuff and the body motion Time including the duration of measurement retries exceeded 160 seconds from the beginning of the measurement. Check the cuff and the body motion Pulse count exceeded 160 during the measurement.	Check for causes that may prevent depressurization, such as the patient's body movement or air tube kinks.
Check the cuff and the body motion The cuff pressure exceeded 300 mmHg.	Check that the patient's arm is not bent, and check that there are no kinks in the cuff hose.
Measurement error with a faint pulse Pulse signals were too faint to measure.	Check the status of the patient, and also whether the cuff is fitted properly.
Check the cuff & the pressure tubing An infant cuff was used.	Use adult cuff. Check that the air filter for blood pressure gauge is not clogged.
E91 BPM response error	Communication error was detected.
E92 BPM communication port error	Communication error was detected.

The measurement can be restarted from the beginning by pressing the "BPM ON/OFF" button.

Alarms related to the data exceeding the set range

-The dialysis unit prompts an on-screen alarm when the measurement results exceed the ranges set in the screen for BPM function settings.

-The dialysis unit displays an alarm along with a buzzer sound. To mute the buzzer, press the "MUTE" key. However, the MAP is used only for the "Link with treatment condition" function and no buzzer sounds when exceeding the upper/lower limits.

Alarm display	Detection conditions
E85 SYS blood pressure max. error	SYS ≥ BPM SYS ALARM MAX
E86 SYS blood pressure min. error	SYS ≤ BPM SYS ALARM MIN
E87 DIA blood pressure max. error	DIA ≥ BPM DIA ALARM MAX
E88 DIA blood pressure min. error	DIA ≤ BPM DIA ALARM MIN
E89 Pulse-rate max. error	PR ≥ BPM Pulse ALARM MAX
E90 Pulse-rate min. error	PR ≤ BPM Pulse ALARM MIN

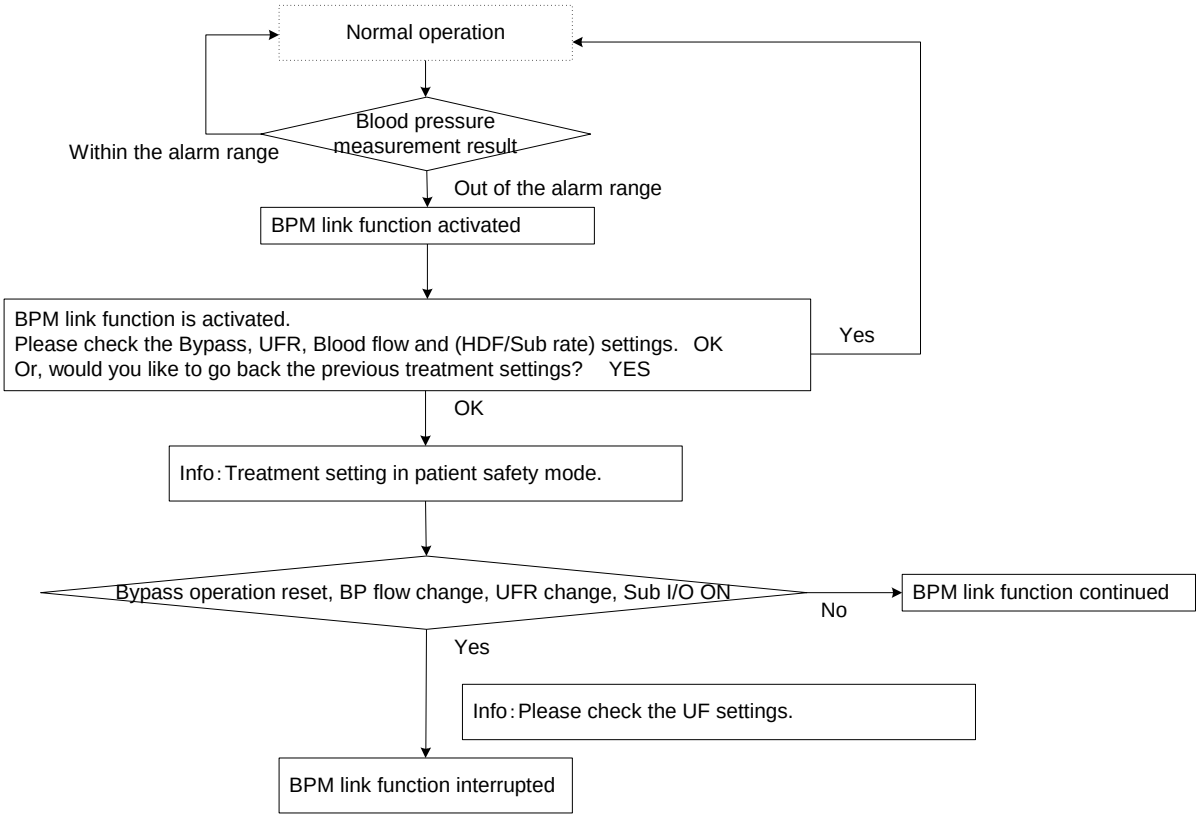
(SYS…Systolic Pressure, DIA…Diastolic Pressure, Pulse…Pulse Rate)

Setting item		Default	Max.	Min.	Setting step
BPM SYS ALARM MAX	mmHg	200	250	140	5
BPM SYS ALARM MIN	mmHg	80	150	60	5
BPM DIA ALARM MAX	mmHg	160	200	55	5
BPM DIA ALARM MIN	mmHg	50	120	40	5
BPM MAP ALARM MAX	mmHg	120	200	100	5
BPM MAP ALARM MIN	mmHg	50	90	30	5
BPM Pulse ALARM MAX	mmHg	170	200	55	5
BPM Pulse ALARM MIN	mmHg	50	165	40	5

The BPM measurement can be restarted from the beginning by pressing the “BPM ON/OFF” button.

Treatment condition link function

Turning ON the treatment condition link function executes setting conditions if the blood pressure setting value exceeds an alarm value.



Alarms related to system errors

-The dialysis unit prompts an on-screen alarm on screen when the BPM module fails.

-The dialysis unit displays an alarm along with a buzzer sound. To mute the buzzer, press the "MUTE" key.

Message display	Detection conditions
E82 BPM error	Single error was detected from the BPM.
E80 BPM RAM error	Error detected in the RAM of the BPM module.
E81 BPM ROM error	Error detected in the ROM of the BPM module.
E83 BPM communication error	Communication error was detected.

These alarms suggest the failure of the BPM module. In case of an emergency during use, it is possible to use a fresh power source for the main dialysis unit, but great caution should be exercised while the movement involved in this operation.

14.7. Specifications of the BPM module

Degree of protection from electric shock

Type BF

Measurements

Measurement method

Oscillometric

Measurement part

Upper arm

Pressure display range

0 – 300 mmHg

Pressure display accuracy

Within ±3 mmHg

Measurement mode

Adult mode

BP measurement ranges (adult)

Systolic (SYS) 20 – 280 mmHg

Average (MAP) 20 – 250 mmHg

Diastolic (DIA) 20 – 200 mmHg

BP measurement accuracy

Mean error and standard deviation as per AAMI SP-10

Measurement range of pulse rate

40 – 200 bpm (adult)

Pulse rate accuracy

The smaller of ±2% or ±2 bpm

Safety features

Maximum cuff pressure

In normal operation: 300 mmHg

In single failure: 330 mmHg

Time to pressurize the cuff

In normal operation: ≤ 160 sec

In single failure: ≤ 180 sec

Time to depressurize the cuff

In normal operation: ≥ 30 sec

In single failure: ≥ 30 sec

Dimensions

Manufacturer and Model

OMRON HEALTHCARE M2500

Exterior dimensions

40 mm (W) x 60 mm (H) x 105 mm (D)

Communication

Conforms to the communication specifications of OMRON HEALTHCARE M2500.

Application standards

EN1060-1: Non-invasive sphygmomanometers Part1.General requirements

EN1060-3: Non-invasive sphygmomanometers Part3.
Supplementary requirements for electro-mechanical blood pressure measuring systems

IEC80601-2-30: Medical electrical equipment- Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment

14.8. Technical Information

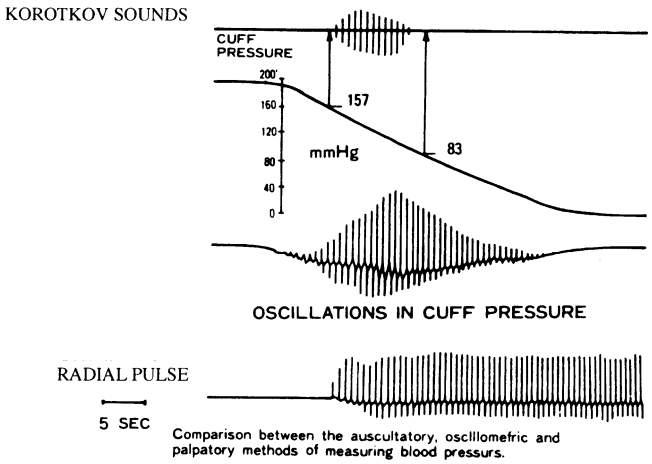
Principle of measurement

The blood pressure values are determined by measuring the small oscillations (changes) in the cuff pressure caused by the heart's contractions as the pressure in the cuff is released. Colin's measurement technology utilizes a unique deflation technique, Dynamic Linear Deflation. This cuff deflation technique allows a Colin monitor to measure each small change in the cuff pressure oscillations that directly correspond to the measurement's systolic, mean, and diastolic blood pressure values.

The cuff is first increased in pressure until it reaches a pressure above arterial occlusion.

As the cuff starts to deflate, the pulse rate of the patient is determined and the deflation speed of the cuff is modified to create a patient specific deflation speed. As the pressure decreases, small cuff pressure oscillations are recorded that correspond to the applied pressure of the blood under the cuff as the heart contracts. These oscillations increase in strength as the cuff pressure approaches the systolic blood pressure values. A sudden increase in oscillation amplitude indicates that the patient's systolic blood pressure is now able to push blood completely through beneath the cuff. The oscillation amplitude continues to increase as the pressure in the cuff is decreases until the mean blood pressure value is reached. The oscillation value strength then starts to diminish and finally drop off as the diastolic blood pressure value is reached.

The oscillometric method does not determine an instantaneous blood pressure reading like the auscultatory method employing a microphone-type auto blood pressure monitor but, as described above, determines blood pressure from an uninterrupted changing curve, which means that the oscillometric method is not easily affected by external noise and electrosurgical instruments.



Comparison between the auscultatory, oscillometric and palpatory methods of measuring blood pressurs.

<<From MEASUREMENT OF BLOOD PRESSURE, L.A. GEDDES>>

14.9. Maintenance

Maintenance of the BPM module

For continued safe use of the BPM module, perform the precision tests described in the subsection Precision tests every two years, and after any replacement or repair.

Preparation for the instrument tests

Prepare the following items before the precision tests:

①	Reference pressure gauge	1
②	500mL metallic tank	1
③	Syringe	1
④	Silicone tube (3 mm ID; 6 mm OD)	5
⑤	T-shaped connector	2
⑥	BPM Assy (attached to the machine)	1
⑦	Pean forceps	1
⑧	Stop watch	1

Adjust the reference pressure gauge so that its error is controlled within 0.8 mmHg. The capacity of the metallic tank should be within 500 mL±5%. If the silicone tube or the T-shaped tube is missing, contact the distributor and order a replacement.

Connection of the test circuit

Connect the silicone tube to the chassis joint, and set up a circuit according to Figure 14.10

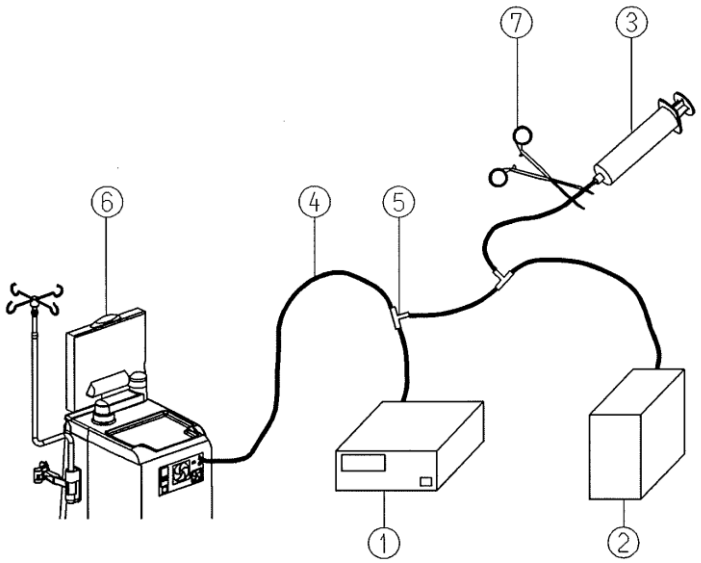


Figure 14.10

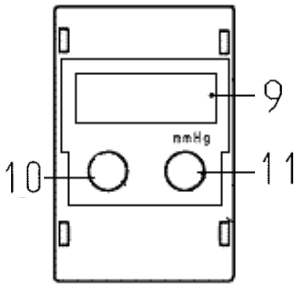
⚠CAUTION

- When setting up the circuit, beware of static charge build-up.
- Keep the reference pressure gauge at the same height as the BPM ASSY.

Precision tests

Pressure test

(1) Remove the silicone tube ④ from the circuit and allow it to come to ambient pressure.
(2) Change the “BPM” setting (System-Setting-Option) into “ON” from “OFF”. Next, change it into “OFF” from “ON” within 5 seconds immediately after that. (This enables the BPM ASSY to operate alone.)
(3) Press the Test Switch ⑪ to close the valve installed inside the BPM ASSY. (The valve toggles open or closed by pressing the Test Switch. Press the switch again to open the valve.)
(4) Ensure that the difference between the reading of the reference pressure gauge and that of the Pressure Display ⑨ is within ±6 mmHg under ambient pressure.
(5) Restore the silicone tube ④ connection.
(6) Pressurize the circuit using the syringe ③ until the reading of the reference pressure gauge ① reaches 50 mmHg.
(7) Ensure that the pressure reading on the Pressure Display at the BPM ASSY is within 50±3 mmHg. If the pressure reading exceeds this range, contact the distributor of the BPM module.
(8) Remove the silicone tube ④ from the circuit and allow it to come to ambient pressure.
(9) Pressurize the circuit using the syringe ③ until the reading of the reference pressure gauge ① reaches 200 mmHg.
(10) Ensure that the pressure reading on the Pressure Display at the BPM ASSY is within 200±3 mmHg. If the pressure reading exceeds this range, contact the distributor of the BPM module.
(11) Remove the silicone tube ④ from the circuit and allow it to come to ambient pressure.



Name of the BPM ASSY part

⑨	Pressure Display	1
⑩	BPM ON/OFF switch	1
⑪	Test Switch	1

Air leakage test

(1) Ensure that the valve of the BPM ASSY is closed.
(2) Pressurize the circuit using the syringe ③ until the reading on the reference pressure gauge ① reaches 50 mmHg.
(3) Pinch the silicone tube connected to the syringe ③ with pean forceps⑦.
(4) Leave the circuit to stand for one minute, and then check the reading on the reference pressure gauge ①.
(5) Leave the circuit to stand for another three minutes. (Use stop watch.)
(6) Check that the pressure change (i.e. air leakage) over three minutes is ≤10 mmHg. If the reading exceeds this range, return the BPM ASSY to the distributor.
(7) Pressurize the circuit using the syringe ③ until the reading of the reference pressure gauge ① reaches 200 mmHg.
(8) Pinch the silicone tube connected to the syringe ③ by pean forceps⑦.
(9) Leave the circuit to stand for one minute and check the reading on the reference pressure gauge ①.
(10) Leave the circuit to stand for another three minutes. (Use stop watch.)
(11) Check that the pressure change (i.e. air leakage) over three minutes is ≤ 10 mmHg. If the reading exceeds this range, return the BPM ASSY to the distributor.

NOTE

- Perform the precision tests at ambient temperatures between 15–25 °C.

15. Spike nozzle (Option)

15.1. Precautions when using a spike nozzle

⚠CAUTION

- Read and understand the installation procedures described in this manual before installing this machine.
- Only trained qualified personnel must install this machine.
- Install this option in accordance with the installation instructions.
- Be sure to confirm the operation after assembly.

15.2. Parameter setting

15.2.1. Setting of the spike nozzle

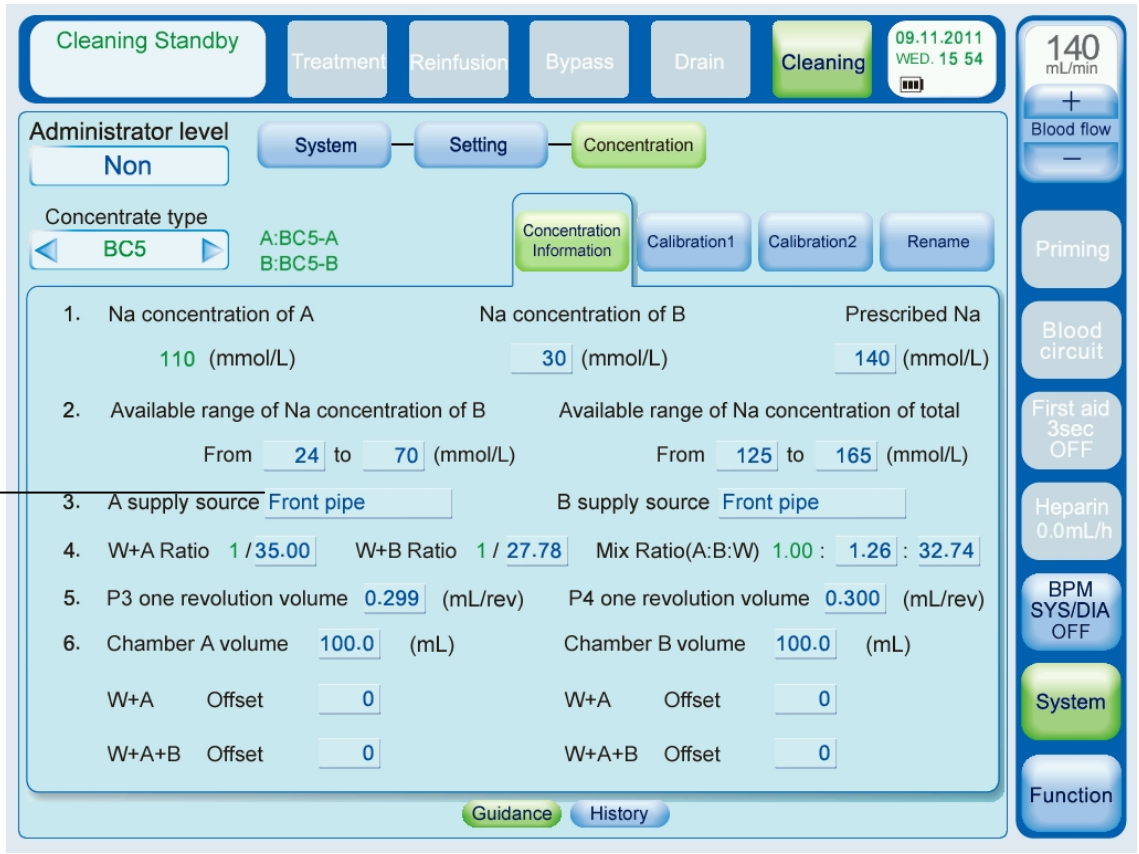


Fig.4 Setting screen

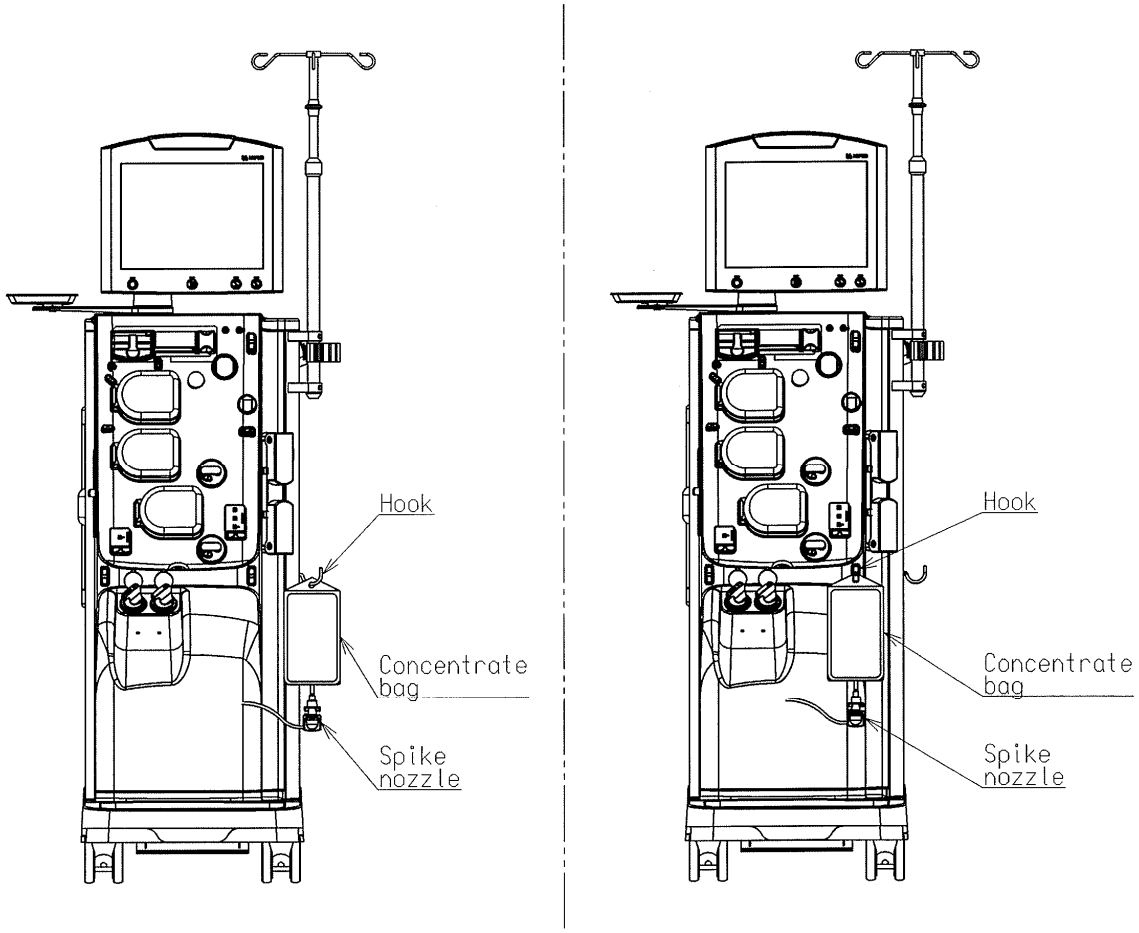
(1) Open “System – Setting – 5.Concentration” and “information” one by one.

(2) Set the “A supply source” to “Front pipe”.

NOTE

- Setting of the ”A supply source” is the same setting when A concentrate suction nozzle is used.

15.3. Connection to a concentrate bag



(1) Hang Concentrate bag on the front hook or the side hook.

(2) Insert Spike nozzle to the concentrate bag.

⚠CAUTION

- Use either one of the front or the side hook when hanging Concentrate bag on the hook. If both have maximum load simultaneously, it may impair the stability of the machine.

16. Card/Network (Option)

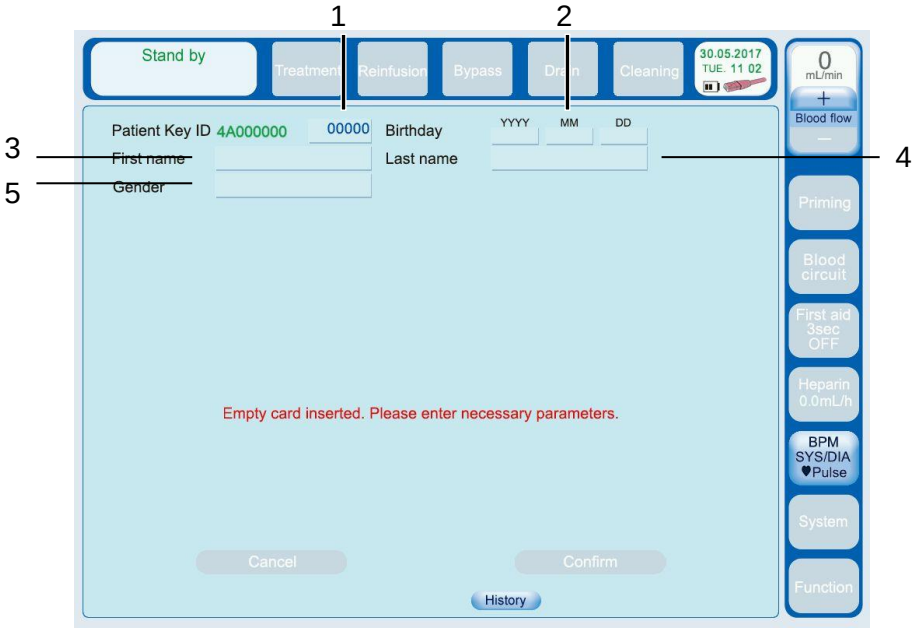
16.1. Patient card function

16.1.1. Card

Use Nipro card as shown below. Card slot is on the back of the operation screen.

ISO7816 in ID-1 format using a I2C memory of 512kb

16.1.2. Inserting blank card without patient information displays the following screen.



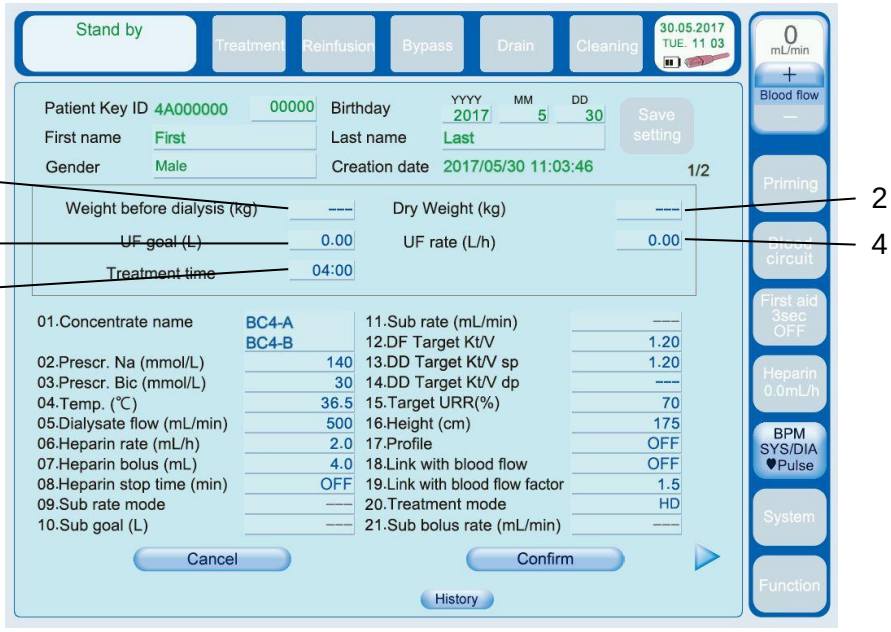
No.	Setting item	Default	Setting range	Setting step	Selection item
1	Patient Key ID	-	00000 to 65535	-	Numeric keypad
2	Birthday	-	1900 to 2050	-	—
3	First name	-	-	-	Keyboard
4	Last name	-	-	-	Keyboard
5	Gender	-	Female/male	-	—

Pressing ”Confirm” button after completion of patient information setting displays the setting on the screen.

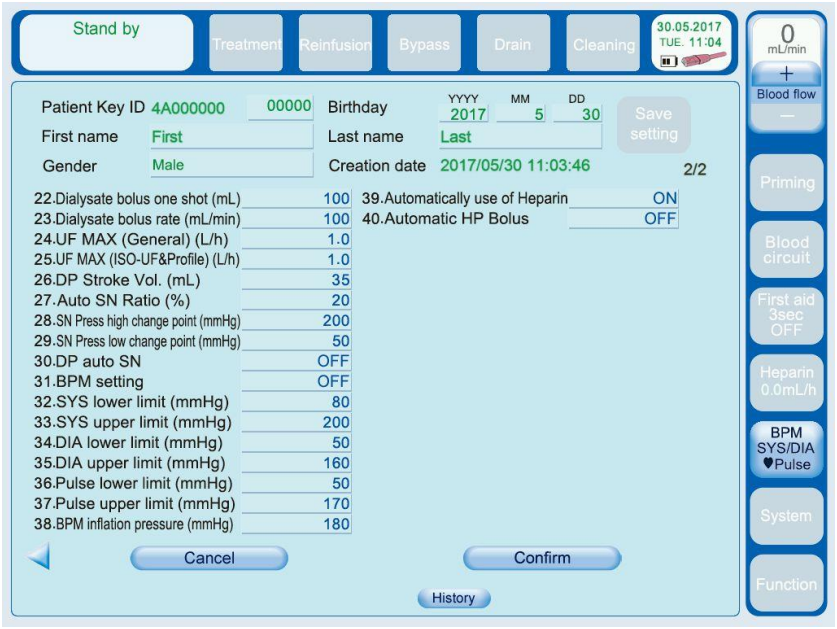
⚠CAUTION

- ”Confirm” button is not available unless all items are set.

16.1.3. Inserting the card with patient information displays the following screen.



1/2



2/2

No.	Setting item	Default	Setting range	Setting step	Selection item
1	Weight before dialysis(kg)	-	0 to 300	-	Numeric keypad
2	Dry weight(kg)	-	0 to 300	-	Numeric keypad
3	UF goal(L)	0.0	0 to 10	-	Numeric keypad
4	UF rate(L/h)	0.00	0 to 4.0	-	Numeric keypad
5	Treatment time	4:00	0:00 to 24:00	-	Numeric keypad

When reading from a patient card, please always check that there is no abnormality in the set value.
Above items are high severity set values.

Treatment data is as follows:

No.	Setting item	Default	Setting range	Setting step	Selection item
1	Concentrate name	BC4-A BC4-B	-	-	Arrow key
2	Prescr. Na	140	125 to 160	-	Numeric keypad
3	Prescr. Bic	30	24 to 70	-	Numeric keypad
4	Temp.	36.5	34.0 to 39.0	-	Numeric keypad
5	Dialysate flow	500	100 to 800	100	Arrow key
6	Heparin rate	2.0	0.0 to 10.0	-	Numeric keypad
7	Heparin bolus	4.0	0.5 to 5.0	-	Numeric keypad
8	Heparin stop time	OFF	OFF,1 to 120	-	Numeric keypad
9	Sub rate mode	-	---, Manual, Auto-sub, Max-sub	-	Arrow key
10	Sub goal	-	-,1 to 600	-	Numeric keypad
11	Sub rate	-	-.10 to 500	-	Numeric keypad
12	DF Target Kt/V	1.20	0.50 to 2.00	-	Numeric keypad
13	DD Target Kt/Vsp	1.20	---, 0.50 to 2.50	0.01	Numeric keypad
14	DD Target Kt/Vdp	-	---, 0.50 to 2.50	0.01	Numeric keypad
15	Target URR	%	0 to 80	1	Numeric keypad
16	Height	175	30 to 300	-	Numeric keypad
17	Profile	OFF	-	-	-
18	Link with blood flow	OFF	ON/OFF	-	Arrow key
19	Link with blood flow factor	1.5	1.0 to 2.0	-	Numeric keypad
20	Treatment mode	HD	HD/HDF pre HDF post HF pre/HF post	-	Arrow key
21	Sub bolus rate	-	-,10 to 300	-	Numeric keypad
22	Dialysate bolus one shot	100	-,10 to 200	-	Numeric keypad
23	Dialysate bolus rate	100	-,10 to 300	-	Numeric keypad
24	UF max(General)	1.0	0.10 to 4.00	0.01	Numeric keypad
25	UF max(ISO-UF & Profile)	1.0	0.10 to 4.00	0.01	Numeric keypad
26	DP Stroke Vol.	35	20 to 60	-	Numeric keypad
27	Auto SN Ratio	20	-60 to 60	-	Numeric keypad
28	SN Press high change point	200	100 to 350	-	Numeric keypad
29	SN Press low change point	50	20 to 150	-	Numeric keypad
30	DP auto SN	ON	ON/OFF	-	Arrow key
31	BPM setting	OFF	ON/OFF	-	-

No.	Setting item	Default	Setting range	Setting step	Selection item
32	SYS lower limit	80	60 to 95	5	Arrow key
33	SYS upper limit	200	140 to 250	5	Arrow key
34	DIA lower limit	50	40 to 95	5	Arrow key
35	DIA upper limit	170	105 to 200	5	Arrow key
36	Pulse lower limit	50	40 to 95	5	Arrow key
37	Pulse upper limit	160	105 to 200	5	Arrow key
38	BPM inflation pressure	180	100 to 200	1	Numeric keypad
39	Automatically use of Heparin	ON	OFF, ON	-	Arrow key
40	Automatic HP Bolus	OFF	OFF, PC, BD	-	Arrow key

- Sub goal is automatically calculated based on Treatment time and Sub rate at that moment.
  - Sub goal is automatically calculated without changing Sub rate when Treatment time remaining is changed.
  - Sub goal is automatically calculated without changing Treatment time remaining when Sub rate is changed.
  - Sub rate is automatically calculated without changing Treatment time remaining when Sub goal is changed.
- UF rate and UF goal are not saved in the card and “0” is displayed every time the card is inserted because they are variable setting values depending on treatment even if it is for identical patient.
- Saving data on Patient Card
  After confirming the displayed treatment data, press ”Save setting” button to save the settings.

16.1.4. Set the machine using the following procedure with patient card.

Before moving to Preparation mode

(1) Insert patient card to the machine.
(2) Set the profile of the patient on Patient registry screen if it has not been registered.
(3) Press ”Confirm” button to write the information in the card after setting the profile.
(4) After confirming the displayed treatment data, press ”Confirm” button to use the setting. Press “Cancel” button not to use the setting.
When the setting is changed, press ”Save setting” button to save the setting after changing it.
(5) Press “Confirm” button, and press “YES” button of the confirmation guidance to complete the read of patient card. The setting is displayed and the process automatically moves to Preparation.

After moving to Preparation mode

(1) Insert patient card to the machine.
(2) Set the profile of the patient on Patient registry screen if it has not been registered.
(3) Press ”Confirm” button to write the information in the card after setting the profile.
(4) After confirming the displayed treatment data, press ”Confirm” button to use the setting. Press “Cancel” button not to use the setting.
When the setting is changed, press ”Save setting” button to save the setting after changing it.
(5) Press “Confirm” button, and press “YES” button of the confirmation guidance to complete the read of patient card. The setting is displayed.

⚠WARNING

- Data received from the network is for reference only. Do not use it for diagnosis. Confirm whether the data is correct in case of using it.
- Connect external units compliant to IEC60601-1-8 to the machine. However, an alarm system will not be set up using the alarm occurrence information transmitted from the machine.
- Ensure that the patient's treatment condition preset in the machine is correct before treatment start and every time when the treatment condition is transmitted from the external units. Incorrect setting may cause serious damages to the patient.

⚠CAUTION

- "Confirm" button is not available unless all items are set.
- Confirm the patient card is his/her card.
- "At the time of reading and writing of data, there are 99.998% of reliability of the data in the check by CRC16. But it is not 100%. With regard to the serious impact setting values to patients, please confirm that there is no abnormality in the setting values before and after card insertion.
- Connect external devices compliant with relevant IEC.
  (Example: IEC60950-1 for Information technology equipment or IEC60601-1 for Medical electrical equipment)
  All personnel who connect the external units consist of the medical system, and therefore are liable to comply with IEC60601-1.
- Connecting the machine to the network may cause unacceptable risks not previously identified to patients, operators and third parties.
- Organizations, clinicians and persons responsible for the use and maintenance of the network connecting the machine should indentify, analyze, evaluate and manage the risks in conformity with IEC 80001-1:2010.
- Additional risk analysis will be required for new risks when the network is later changed.
- Following items should be included in the "Network change":
- Changes in the network construction
- Connection of additional item(s) to the network
- Removal of item(s) from the network
- Updating of the devices connected to the network
- Data may is unintentionally transmitted and received if the network is damaged. Ensure the presence or absence of the response message from the machine and that the content of the message is as expected.

16.1.5. Press “Profile” button to set each profile screen.

Profile screen is opened for setting when the setting button is selected. ON/OFF display on Patient card setting screen is determined by ON/OFF setting of Profile function. If ON is selected on Patient card setting screen, Preparation starts as Profile ON.

【Setting screen】

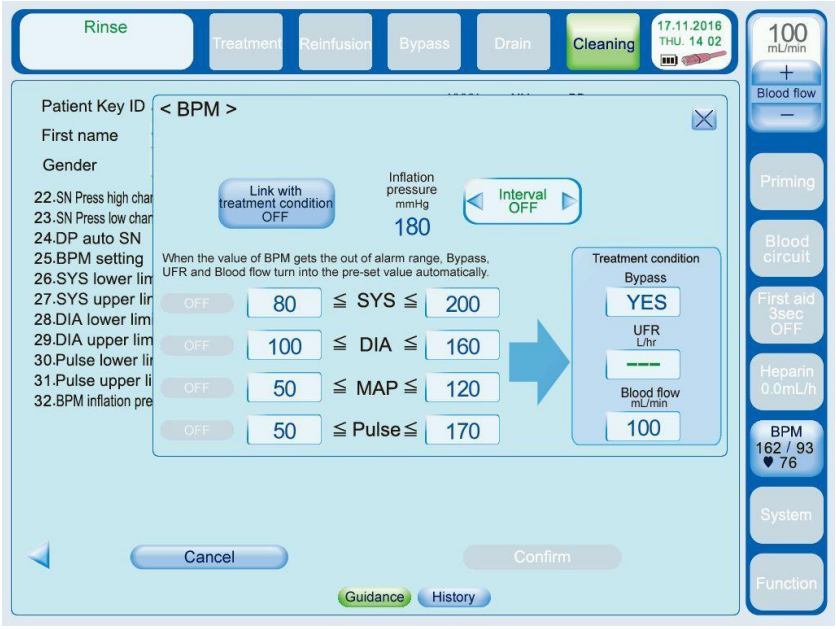
Pressing ⊠ button on the upper right corner closes the screen.

The set Profile pattern can be selected on Profile setting screen as ”No. PC”.

16.1.6. Press “BPM setting” button to set BPM screen.

When BPM setting is selected, Function-BPM setting screen is displayed and each setting is available. ON/OFF on Patient card setting screen will be ON if a setting value has changed from default and OFF if all is default.

【Setting screen】



Setting items are as follows:

Setting items	Unit	Default	Range	Remarks
SYS lower limit	mmHg	80	60 to 95	Set upper/lower limit to avoid the following: lower limit≧upper limit upper limit≦lower limit
SYS upper limit	mmHg	200	140 to 250	
Pulse lower limit	mmHg	50	40 to 95	
Pulse upper limit	mmHg	160	105 to 200	
MAP lower limit	mmHg	50	30 to 90	
MAP upper limit	mmHg	120	105 to 200	
DIA lower limit	mmHg	50	40 to 95	
DIA upper limit	mmHg	170	105 to 200	
BPM interval	min	OFF	OFF, 5, 10, 15, 30, 45, 60	
BPM inflation pressure	mmHg	180	100 to 200	
Link with treatment conditions Bypass	N/A	Yes	Yes, No	
Link with treatment conditions UFR	N/A	---	---, 0.00, 0.10	Forcibly --- if Bypass is Yes. If UF rate setting is 0.00L/h, 0.00L/h will turn green to avoid setting to 0.10.
Link with treatment conditions Blood Flow	N/A	100	30 to 300	

⚠CAUTION

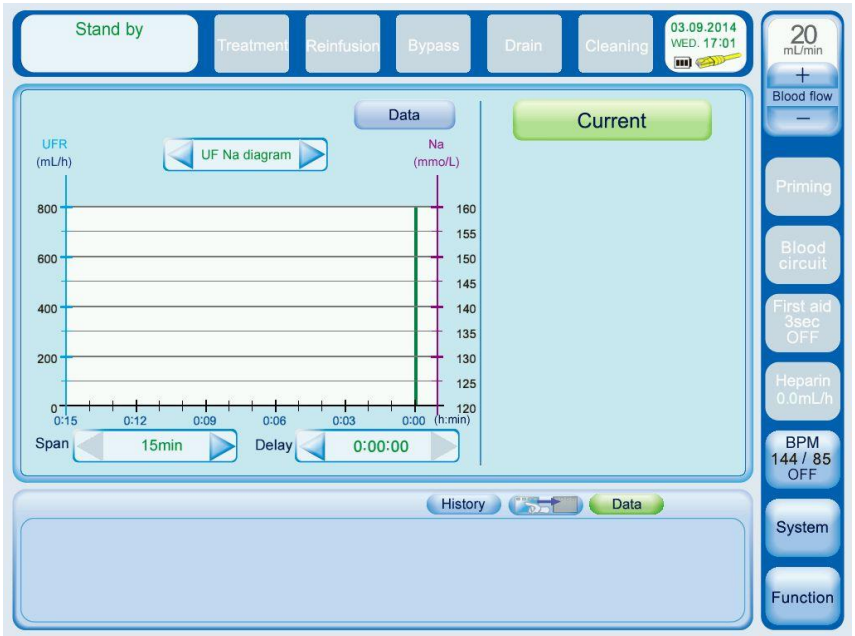
- Treatment history is not saved in the card if the card is removed during treatment.

16.1.7. Press “Graph” button to display treatment information.

Current treatment data and past 3 treatment data can be referred. Past 3 data saved in the patient card can be referred when the card it inserted.

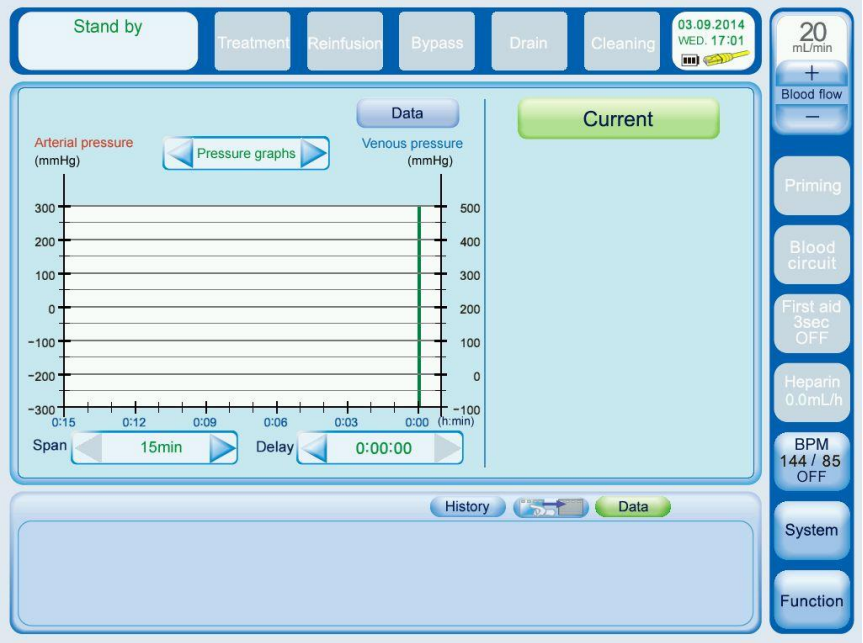
Basically, “Data” is shown, and Data screen is open when it is selected. The machine stores the patient’s past 3 treatment data, Treatment1, Treatment2 and Treatment3. When the card is inserted and “Confirm” button is pressed, “Data” changes to the patient name and 3 past patient’s data are stored in Treatment1, Treatment2, and Treatment3 respectively.

1) UFR setting and dialysate Na setting are displayed.
【UF Na diagram】



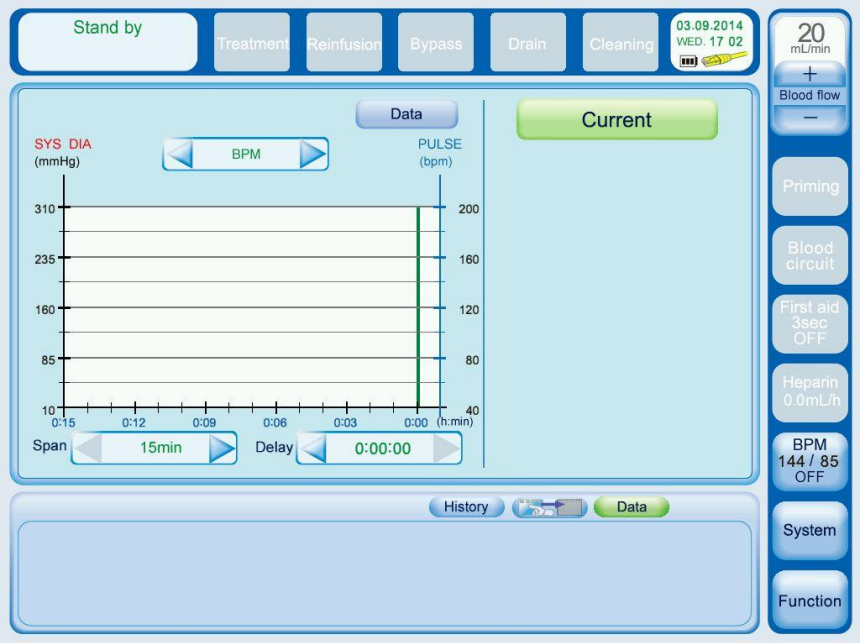
2) Arterial pressure and Venous pressure are displayed.

【Pressure graphs】



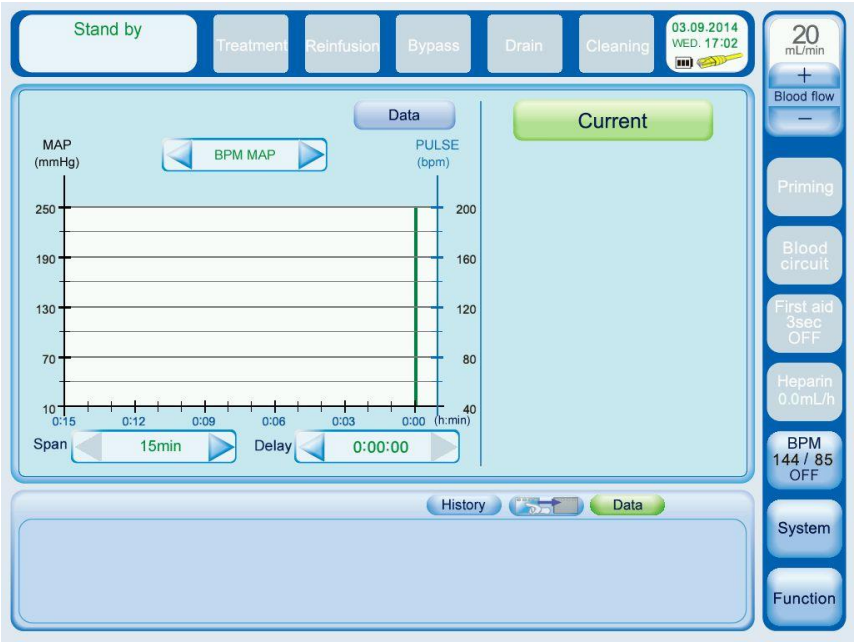
3) Manometer data “SYS, DIA, PULSE” is displayed.

【BPM】



4) Manometer data “MAP, PULSE” is displayed.

【BPM MAP】



5) Manometer data “History” is displayed.

【BPM history】

16.1.8. Press “Data button to display treatment information.

Pressing Data button displays treatment data on the left graph area.

Display items are as follows:

No.	Machine items	Unit
1	Performed treatment mode	N/A
2	Treatment time remaining	h:mim
3	UF volume	L
4	ISO-UF volume	L
5	Average UF rate	L/h
6	Effective dialysis time	h:mim
7	Total UF time	h:mim
8	DF Kt/V	N/A
9	DD Kt/V	N/A
10	DD Kt/V sp	N/A
11	DD Kt/V dp	N/A
12	DD Kt	L
13	Urea Reduction Rate	%
14	Average Clearance	mL/min
15	Average ISO-UF rate	L/h
16	Average blood flow	mL/min
17	Average Dialysate flow	mL/min
18	Average Dialysate temperature	°C
19	Sub volume	L
20	Convection volume	L
21	Average Sub rate	mL/min
22	Cum. Heparin volume	mL
23	Cum. Heparin bolus volume	mL
24	Average prescribed Na	mmol/L
25	Average prescribed Bic	mmol/L

No.	Machine items	Unit
26	Average Heparin rate	mL/h
27	Dial. Blood volume	L
28	Cum. Reinfusion volume	mL
29	Cum. Sub bolus	mL
30	Cum. DIF bolus	mL
31	Treat start time	N/A
32	Treat end time	N/A
33	HD Time	h:mim
34	HDF Pre Time	h:mim
35	HDF Post Time	h:mim
36	HF Pre Time	h:mim
37	HF Post Time	h:mim
38	ISO-UF time	h:mim
39	Average arterial pressure	mmHg
40	Average venous pressure	mmHg
41	Average TMP	mmHg
42	Average Dialysate pressure	mmHg
43	Average SN Stroke Volume	mL
44	SN Click Clack time	h:mim
45	Last Disinfection	N/A
46	Used SW Ver.	N/A
47	Dialysis device name	N/A
48	Dialysis device serial number	N/A
49	ΔBV	%

Other buttons

1) Current button
   Current treatment data is saved to “Current” any time.
   The time when Current data is transfer to Treatment1 is next Preparation button is pressed and Patient card is removed.
2) Treatment 1 button
   One treatment before data is stored.
3) Treatment 2 button
   Two treatment before data is stored.
4) Treatment 3 button
   Three treatment before data is stored.
   Time and date (YYYY-MM-DD 00:00:00) when treatment starts (the process moves to Dialysis) is displayed on each Treatment 1 to 3 button.
5) Patient card setting button
   Treatment settings saved in Patient card can be referred, but not edited. Pressing ⊠ button closes Patient card setting screen.

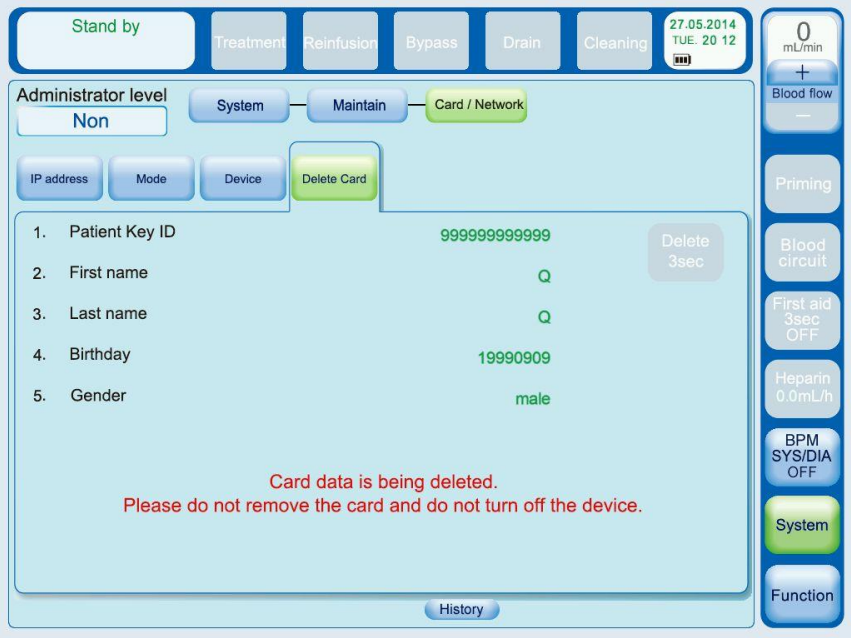
⚠CAUTION

- Treatment history is not saved in the card if the card is removed during treatment.

16.1.9. Press ”Delete” button to delete patient information.

Select Delete card tag on System – Maintain – 8. Card/Network screen.

Press “Delete” button for 3 seconds to delete the data saved in the card such as patient ID, name and birthday to be blank.



Item No.1 to 5 are displayed as “--------” when Delete Card has completed.

⚠CAUTION

- Do not remove the card while deleting the card data.
- The message is deleted and Delete Card operation is interrupted if the card is removed during the process.

16.1.10. Network status display

Icon indicating network status is located next to the icon indicating battery status.

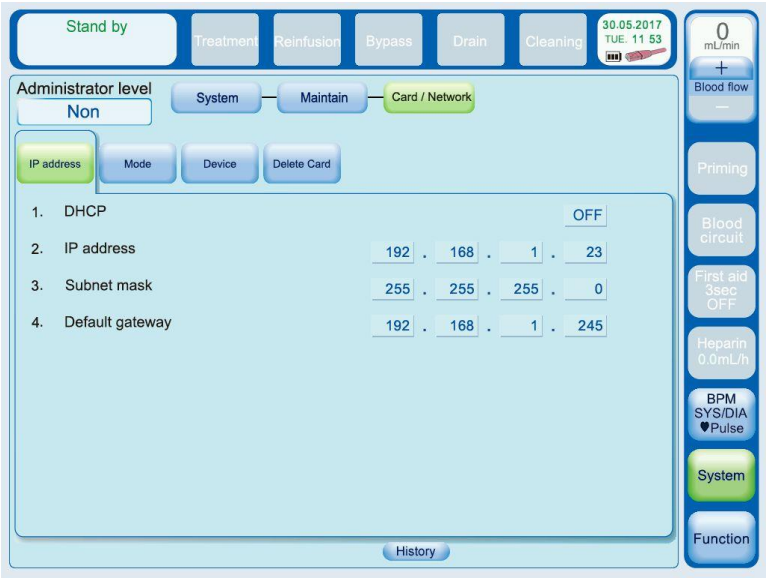
Network cable is not connected and server signal is not received. : Red
Although network cable is connected, server signal is not received. : Yellow
Network cable is connected and server signal is received. (Correct) : Green

If the connection is correct, Treatment data is transmitted to the host PC every 60 seconds from after patient connect to reinfusion process.

Please contact local agent for details such as software used for the host PC, transmission data operated by the software and its use.

16.1.11. System – Maintain – 8. Card/Network screen is opened.

1) ”IP address” screen

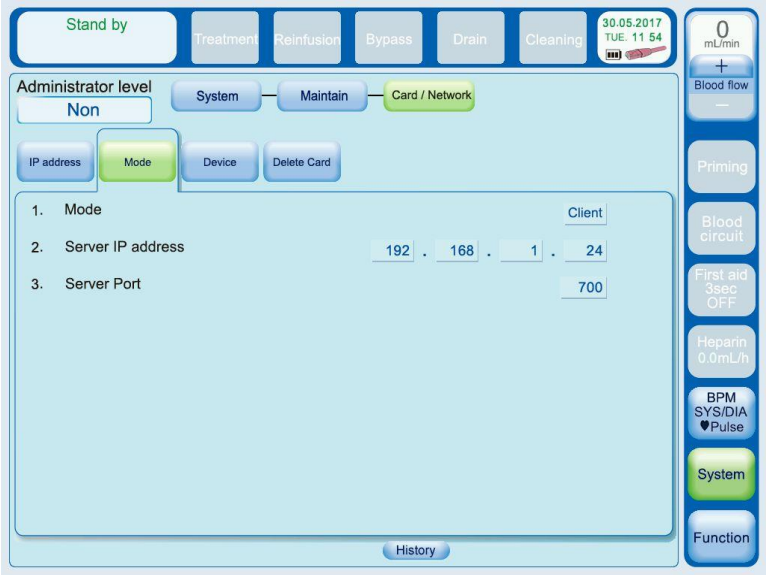


No.	Setting item	Default	Setting range	Setting step	Selection item
1	DHCP	ON	ON/OFF	-	Arrow key
2	IP address	192.168.1.23	000 to 255	-	Numeric keypad
3	Subnet mask	255.255.255.0	000 to 255	-	Numeric keypad
4	Default gateway	192.168.1.245	000 to 255	-	Numeric keypad

⚠CAUTION

- No.2 to 4 are not displayed when DHCP is ON.

2) ”Mode” screen

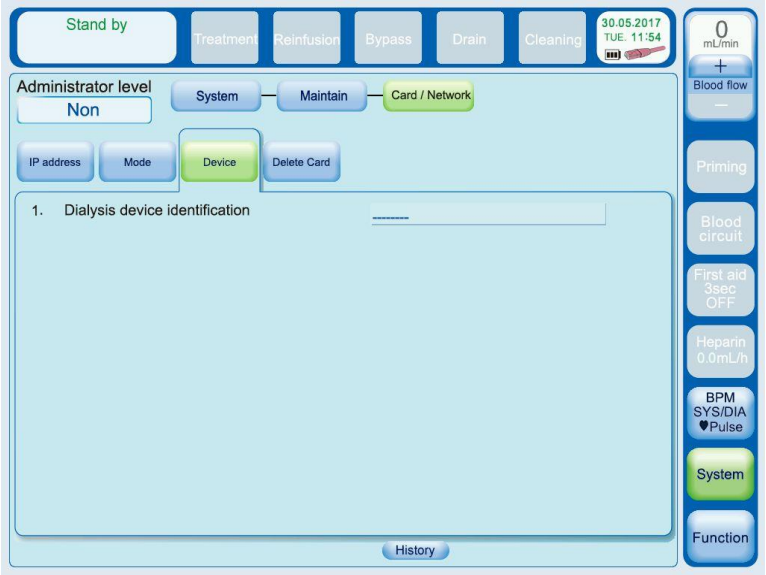


No.	Setting item	Default	Setting range	Setting step	Selection item
1	Mode	Client	Client/OFFLINE	-	Arrow key
2	Server IP address	192.168.1.24	000 to 255	-	Numeric keypad
3	Server Port	700	000 to 255	-	Numeric keypad

⚠CAUTION

- No.2 and 3 are not displayed when Mode is OFFLINE.

3) ”Device” screen



No.	Setting item	Default	Setting range	Setting step	Selection item
1	Dialysis device identification	--------	—		Key-Board

17. A bag connector nozzle (Option)

17.1 Precautions when using the A bag connector nozzle

⚠CAUTION

- Read and understand the installation procedures described in this manual before installing this machine.
- Only trained qualified personnel must install this machine.
- Install this option in accordance with the installation instructions.
- Be sure to confirm the operation after assembly.

17.2 Parameter setting

17.2.1 Setting of the A bag connector nozzle

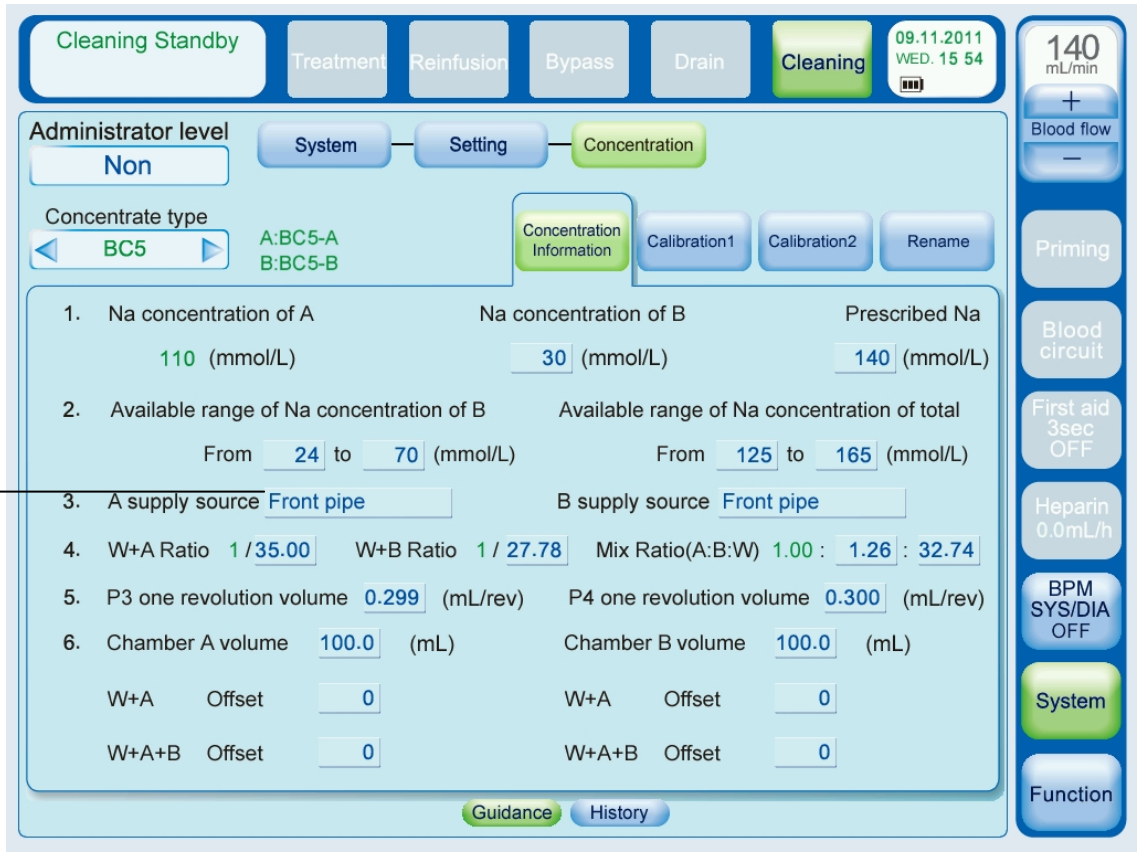


Fig.4 Setting screen

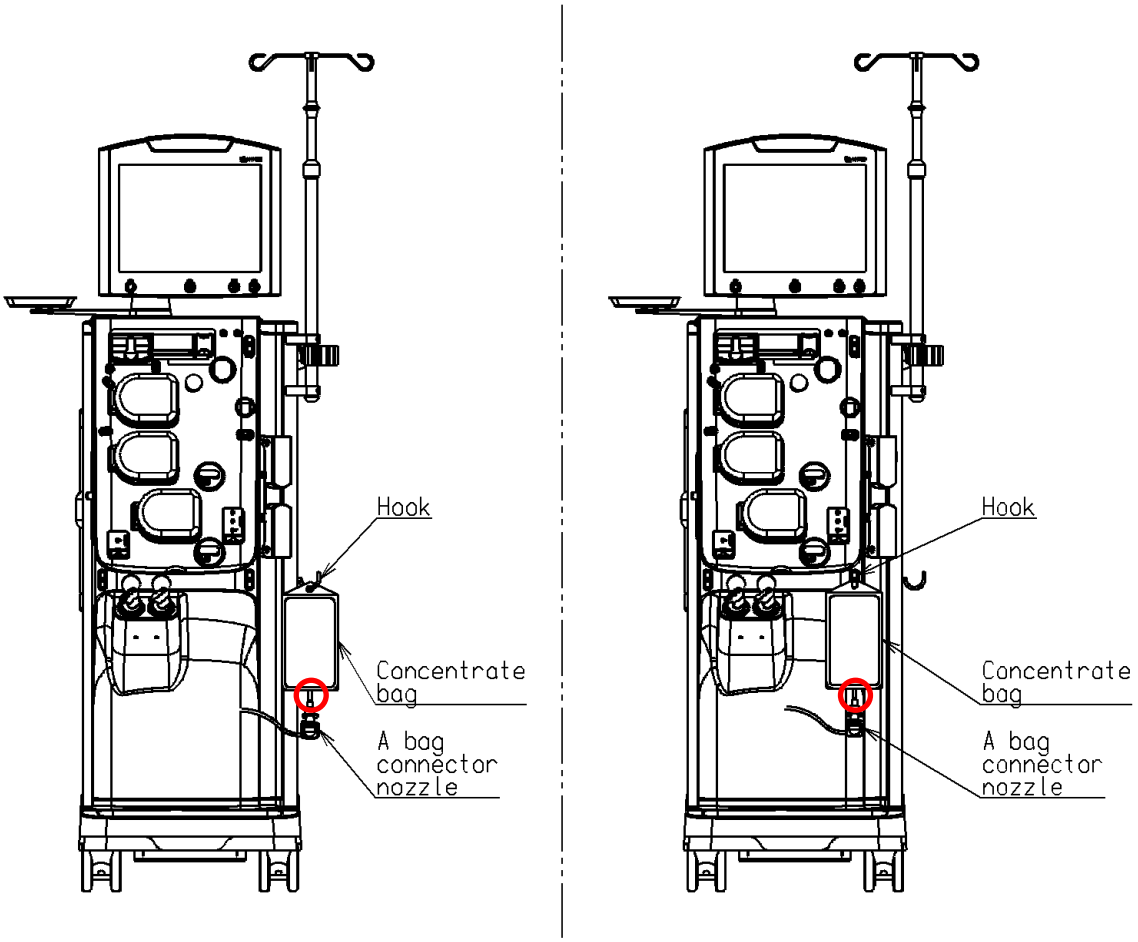
(1) Open “System – Setting – 5.Concentration” and “information” one by one.

(2) Set the “A supply source” to “Front pipe”.

NOTE

- Setting of the ”A supply source” is the same setting when A concentrate suction nozzle is used.

17.2 Connection to the A concentrate bag



(1) Hang the A concentrate bag on the front hook or the side hook.
(2) Connect the A bag connector nozzle to the A concentrate bag.

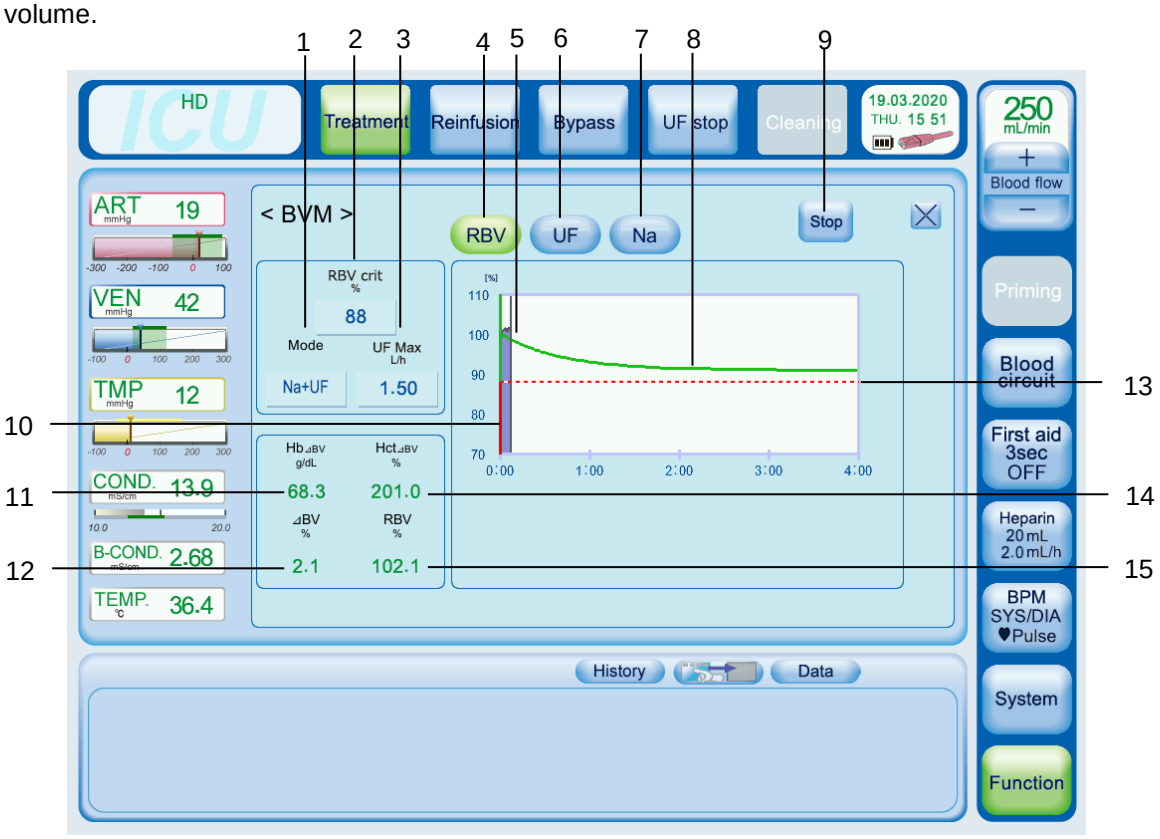
⚠CAUTION

- Use either one of the front or the side hook when hanging the A concentrate bag on the hook. If both have maximum load simultaneously, it may impair the stability of the machine.
- Remove an air bubble in the tube of the A concentrate bag which is indicated by red circle in the figure. When an air bubble was sucked at by P3, E27 Dialysate conductivity alarm may happen.

18. Blood Volume Measurement (Option)

18.1. Blood Volume Measurement screen

Selecting Function-BVM displays the following screen for setting various items related to the blood volume.



No.	Name	Description
1	Mode	Indicates the BVM control mode
2	RBVcrit (Setting)	Indicates a value which is the threshold of ⊿BV drop alarm
3	UF Max	Upper limit UF rate setting in BVM control mode
4	RBV	Pressing the button switches the graph screen for Blood Volume Measurement
5	RBV plot	Indicates variation of the RBV
6	UF	Pressing the button switches the graph screen for the BVM control when UF control is active
7	Na	Pressing the button switches the graph screen for the BVM control when Sodium control is active
8	⊿BV Reference Line	Indicates ⊿BV reference Line
9	Start / Stop button	Starts or stops measurement of the BVM module

No.	Name	Description
10	Green / Red zone	Green zone (the area between the RBV crit line and the green line): Ultrafiltration and sodium are regulated according to the measured relative blood volume and the calculated ideal curve. Red zone (the area below the RBV crit line): The red zone indicates the critical area. If the relative blood volume falls below the RBVcrit, the operator will be informed by the displayed message and the UF rate is automatically set to 0.1L/h to increase the relative blood volume again.
11	Hb⊿BV	Hemoglobin (g/dL)
12	⊿BV	Reduction of the relative blood volume (%)
13	RBVcrit (Line)	A line which indicates the threshold of ⊿BV drop alarm
14	$HCT_{\Delta BV}$	Relative HCT derived from optoacoustic response (%)
15	RBV	Relative Blood Volume (%)

18.2. Attaching the blood circuit

⚠CAUTION

- Unauthorized blood circuit prevents proper measurement.
- Install the blood circuit to the BVM module correctly.

Attach the blood circuit to the BVM module according to the following procedure.

No.	Procedure
1	Open the cover of the BVM module after placing the blood circuit into the tube holder.
2	Put the blood circuit into the slot of the BVM module. Be aware of kinking.
3	Close the cover. Confirm it is firmly closed. The interlock is activated if it is open, and the measurement will not start.

18.3. Measurement

NOTE

- The BVM module has not been tested for all possible abnormal blood conditions. The following conditions may lead to incorrect hematocrit measurement results:
  - Abnormal low hematocrit (e.g. due to sickle cell anemia)
  - Abnormal high hematocrit (e.g. due to polycythemia)
  - Macrocytic anemia
  - Hyperlipidemia
  - Forms of blood deformability illnesses
- The following situations may significantly affect the measurement:

- Drinking or eating during dialysis
- Abnormal patient conditions
- Pathological oxygenation status
- Blood characteristic affecting drugs (e.g. Anti-coagulants)
- High blood sugar during treatment
- Extensive postural changes during dialysis
- Strong bleeding (significant change of total number of red blood cells)
- Air bubbles in the blood circuit
- Hemolysis
- Abnormal Na+ Levels (Sodium unbalance)
- Pathologic blood compartments (e.g. Methemoglobins > 1%)

Start measurement

Press the “Start” button on the BVM screen.
The measurement starts and displaying of the measured value and graph plotting start after preset time elapses after treatment start.
If Auto start is ON, the measurement automatically starts and displaying of the measured value and graph plotting start after preset time elapses after treatment start.

NOTE

- Measurement will not start under the following conditions:
  - During Single needle treatment
  - An error related to the BVM is detected.
  - The cover of the BVM module is open.
  - More than 1 hour elapses after treatment start.

During measurement

Active state of the BVM module is indicated according to the Status Indicator.

LED is OFF: BVM stops
Red LED is ON: BVM error indicator. Indicates there is an error(s).
Green LED is ON: during BVM measurement

Stop measurement

Pressing the “Stop” button or interrupting treatment stops the measurement.

NOTE

- Measurement automatically stops under the following conditions:
  - Single needle treatment starts.
  - An error related to the BVM is detected.
  - The cover of the BVM module is open.

Re-start measurement

Pressing the “Start” button restarts the measurement after it is stopped if the measurement is allowed.

NOTE

- RBV will be reset to 100% if the measurement is restarted.

18.4. Messages

Alarm, Warning and Info issued by monitoring the measured value

Message display	Detection conditions
E164 RBV has fall below RBVcrit. Please check patient condition and adjust the treatment settings if necessary.	RBV is RBVcrit or less.
The UF goal will be not achieved. Please reduce the UF Goal or prolong the treatment time.	UF volume cannot reach to UF goal
BVM Control has been stopped due to implausible measurement results.	The implausible measurement result is detected.

Warning and Info related to end of measurement

Message display	Detection conditions
BVM is turned off, since the treatment setting does not allow this measurement.	SNDP or Click Clack becomes activated and BVM is stopped.
BVM is turned off.	- Stop button is manually pressed - Remove arterial line is performed - Remove all is performed - Open the cover of the BVM module during measurement

Warnings related to system errors

Message display	Detection conditions
BVM error	- Status errors are received for 3 consecutive times from the BVM module. - An error code is received from the BVM module.
BVM communication error	Communication from the BVM module cannot be received, or no response.
BVM syntax error	Incorrect communication syntax from the BVM module

Same warning will not be issued again until the screen goes back to the Mode select screen if a system error is issued.

18.5. Specifications of the BVM module

Measurements

$Hb_{\Delta BV}$ measurement range

6.8 – 20.4 %

ΔBV measurement range

-30.0 – +10.0 %

$HCT_{\Delta BV}$ measurement range

20 – 60 %

RBV measurement range

70 – 110 %

Dimensions

44 mm (W) x 36 mm (H) x 70 mm (D)

Application standards

IEC 60825-1:2014 Safety of laser products - Part 1: Equipment classification and requirements

18.6. Technical Information

Description

Measurement of hematocrit by the BVM module is based on the optoacoustic effect. Light irradiated from a diode is absorbed by hemoglobin which is the pigment of the red blood cells in blood and absorbed energy converts to local temperature rise and volume expansion. This thermal expansion generates acoustic waves in a medium. Capturing the acoustic wave by pressure sensitive element(s) estimates hematocrit since width of the acoustic wave reflects the ratio of red blood cells in blood.

Safety

The BVM module incorporates high-power pulse laser diode since invisible infrared laser pulse is used for the measurement.

Following risk mitigation warrants no dangerous exposure of invisible laser radiation to an operator or patient:
- Design which does not allow laser to be irradiated outside
- Cover interlock mechanism

18.7. Maintenance

How to configure the settings

Following items are set on the System – Setting – 11.Treatment – BVM screen.

- Treatment - BVM

Setting item			Default	Min.	Max.	Setting step
1	Auto Start		OFF	OFF/ON		
2	Control mode		OFF	OFF / Na / UF / Na+UF		
3	RBV crit	%	88	60	95	1
4	UF Max (BVM)	L/h	1.50	1.00	4.00	0.1
5	UF Goal Deviation	%	5	OFF, 1	10	1
6	ΔBV UF Stop Point	%	3	1	10	0.1
7	Average Na Deviation	mmol/L	3	1	10	1
8	Na Limit		1	1	2	1

Cleaning

⚠CAUTION

- Use recommended chemical solutions and follow the cleaning procedure.
- Do not use abrasive materials or solvents.
- Avoid exposure to mechanical forces.
- Make sure that cleaning agents or disinfectants do not enter the sensor.
- The sensor connecting plugs must only be plugged in when dry.
- Do not soak the BVM module and sensor in liquid.
- Never inspect the laser aperture with a reflective tool (e.g. dental mirror).

Cleaning of the BVM module can be done by dry wipe with a lint-free cloth or soft cleaning tissue.
The aperture of the laser needs to be free of soil. Therefore it is recommended to clean the aperture hole of the laser diode with Q-tip and isopropanol.

Disinfectant acceptable for exterior surface: 70% of isopropanol or 0.1% of sodium hypochlorite solution such as ActiDes

18.8. **BVM control**

Basic Principle

The aim of the BVM control is to prevent hypotensive episodes during the treatment. Ultrafiltration and/or sodium are adjusted in that way that the blood volume should follow the ΔBV Reference Line which is determined at the beginning of the treatment. The adjustment of ultrafiltration and sodium takes place in predefined physiological borders.

Before the treatment starts, the operator has to set the patient individual RBVcrit (critical relative blood volume).

The following modes are available:

1. UF control
2. Na control
3. Combination of UF and Na control

The control mode starts under 2 different conditions:

1. Automatic start of the measurement (measurement/control starts in every treatment)
2. Manual start of the measurement (measurement/control starts only when the user manually activates the control system)

⚠CAUTION

- The BVM control cannot be carried out in the following cases:
  - Single needle treatment
  - UF profile
  - ISO-UF

ΔBV Reference Line:

The ΔBV Reference Line represents the ideal curve of the relative blood volume. The Line is calculated based on the UF and Na control system.

Green/Red zone

Green zone:

Ultrafiltration and sodium are regulated according to the measured relative blood volume and the calculated ΔBV Reference Line.

Red zone:

The red zone indicates the critical area. If the relative blood volume falls below RBVcrit, the operator will be informed by the displayed message and the UF rate is automatically set to 0.1L/h.

UF control:

The UF control system regulates the UF rate based on the deviation between the actual measured RBV and the reference RBV from the ΔBV Reference Line.

When the RBV is higher than the ΔBV Reference Line, UF rate will be increased. The UF rate is limited by the “UF Max (BVM)” when the RBV is greater than the reference line.

When the RBV is lower than the ΔBV Reference Line, UF rate will be decreased.

Na control:

The Na control system regulates the prescribed Na based on the deviation between the actual measured RBV and the reference RBV from the ΔBV Reference Line.

When the RBV is higher than reference line, prescribed Na will be decreased.

When the RBV is lower than the reference line, prescribed Na will be increased.

The sodium control is carried out at pre-defined limits. It is ensured that the total sodium dose of the patient will never be higher compared with a treatment without sodium control. However, a negative deviation from the total sodium is allowed.

The operator has the possibility to define a negative deviation [mmol/L] from the prescribed sodium. Based on the setting, the system will calculate a lower sodium border.

The operator can choose between two different control limits:

Na Limit 1 is funnel-shaped and allows the system a bigger sodium range at the beginning of the treatment. During the course of the treatment the sodium range is decreased.

Na Limit 2 is constant during the whole treatment. The available sodium range doesn’t change during the course of the treatment.

Data Logging

The following values in one treatment are logged as a graph on the BVM screen:

1. Reference line
2. RBV
3. UF rate
4. Prescribed Na

The logging is performed once in every 10 seconds from treatment start to treatment end.

The logged graph remains even if a power failure occurs.

⚠CAUTION

- If the device shuts down during treatment, the logged graph will be erased

19. Central Alarm Output (Option)

19.1. Central Alarm Output function

A function to send detections signal to external device when the unit detects Alarm or Warning.
Available on the unit which the Central Alarm Output option is installed.

⚠WARNING

- Do not rely on the external system for alarm signal generation. The Surdial X is not able to detect a failure of the external system.

⚠CAUTION

- It takes the Surdial X 5 msec to detect an alarm and output the detection signal to the output port.
- It may take more than 120 seconds once an alarm condition starts and the alarm is issued depending on alarms.

NOTE

- Turning “System – Setting – Characteristics – No.31 Central Alarm Output Warning” ON includes “Warning” in the detection signals.

19.2. Specification

Relay output of potential free C contact.
Maximum voltage of contact: DC 30 V or less and AC 100 V or less
Maximum current of contact: 1A

Before Contacting Us

Check the following when errors are found in the unit. Contact nearest branch or agency if you cannot figure out the causes or if the errors are not listed in the following table.

Error	Cause	Countermeasure
The cleaning standby screen does not appear in spite of pressing the I/O power key.	The power cord is not connected to an outlet properly.	Connect the power cord to an outlet properly.
	The power cord is disconnected.	Check the outlet by connecting other electric appliances. If the power cord is disconnected, contact the agency where you purchased the unit.
The key light is not lit in spite of pressing the I/O power key.	The battery for power failure backup is low in charge and the power breaker is turned off.	Turn on the power breaker.
	Did not press the I/O power key for 0.5 consecutive sec or longer.	Press the I/O power key for 0.5 consecutive sec or longer.
Nothing or only a part of a display appears on the message display monitor.	Backlight is turned off.	Press the key on the operation panel.
	The connector to be connected to the message display monitor is off.	Connect the connector properly.
The dialysis temperature does not increase to the setting temperature.	The water supply temperature is low.	Set the water supply temperature properly Refer to “11. Specification”.
The dialysis temperature does not decrease to the setting temperature.	The water supply temperature is high.	Set the water supply temperature at least the setting temperature of the unit -5°C.

Error	Cause	Countermeasure
The cleaning does not start.	The system is in the Cleaning standby process.	Touch the Rinse button. Then touch the Start button once.
	The liquid stopped due to alarm emergence.	Eliminate the cause(s) and reset the alarm.
The blood pump does not rotate (when power is on or in case of power failure).	The blood pump cover is open.	Close the blood pump cover firmly.
	The blood pump flow display is “0 mL/min”.	Set the correct flow rate.
	The blood pump stopped due to alarm emergence.	A blood circuit-related alarm is going off. Eliminate the cause(s) and reset the alarm.
The blood pump does not rotate (in case of power failure).	The battery for power failure backup is low in charge.	Charge the battery (energize the unit for 48 hours or longer).
	The life of the battery for power failure backup expired.	Replace the battery.
The heparin pump does not rotate (when power is on or in case of power failure).	The heparin pump flow display is “0.00 mL/h”.	Set the heparin pump follow as you desire.
	The blood pump stopped.	Move the blood pump.
	The heparin pump stopped due to overload.	Eliminate the cause(s) of overload.
	The estimated heparin infusion time is met.	Press the HP rate button if you need to infuse again.
	The system shows that the heparin pump infusion is complete.	Move the pusher to the right.
The heparin pump does not rotate (in case of power failure).	The battery for power failure backup is low in charge.	Charge the battery (energize the unit for 48 hours or longer).
	The life of the battery for power failure backup expired.	Replace the battery.

Error	Cause	Countermeasure
During the bicarbonate dialysis, the actual dialysate concentration is higher than the setting concentration.	The concentration of concentrate is high.	Use concentrate with a proper concentration.
	The concentrate to be used and dialysate type setting are different.	Correct the dialysate type setting.
During the bicarbonate dialysis, the actual dialysate concentration is lower than the setting concentration.	The concentration of concentrate is low.	Use concentrate with a proper concentration.
	The concentrate is not aspirated sufficiently because the concentrate tank is closed.	Make the air to flow better by loosening the cap for the concentrate tank, etc.
	The concentrate is not aspirated sufficiently because the silicone tube of the concentrate line of the dialysate circuit is bent or blocked.	Straighten or unblock the silicone tube.
	The concentrate to be used and dialysate type setting are different.	Correct the dialysate type setting.
	The concentrate connector is not inserted.	Inset them properly.
During the acetate dialysis, the actual dialysate concentration is higher than the setting concentration.	The concentration of concentrate is high.	Use concentrate with a proper concentration.
	The concentrate to be used and dialysate type setting are different.	Correct the dialysate type setting.
During the acetate dialysis, the actual dialysate concentration is lower than the setting concentration.	The concentration of concentrate is low.	Use concentrate with a proper concentration.
	The concentrate to be used and dialysate type setting are different.	Correct the dialysate type setting.
	The concentrate connector is not inserted.	Inset them properly.
The actual dialysate concentration does not match the displayed concentration.	Concentration adjustment has not been done properly.	Adjust the concentration by proper procedures.
	Contact failure of the conductivity sensor harness.	Eliminate the cause of contact failure of the conductivity sensor harness.
	Electrodes of the conductivity sensor is rusty.	Remove rust or exchange the electrodes.
Button operation does not work.	A button whose operation was not accepted by the system was touched.	Some button operations do not work depending on a screen display or process. Read the instruction manual again before operation.
	The connector on the PCB is off.	Connect the connector properly.

Glossary

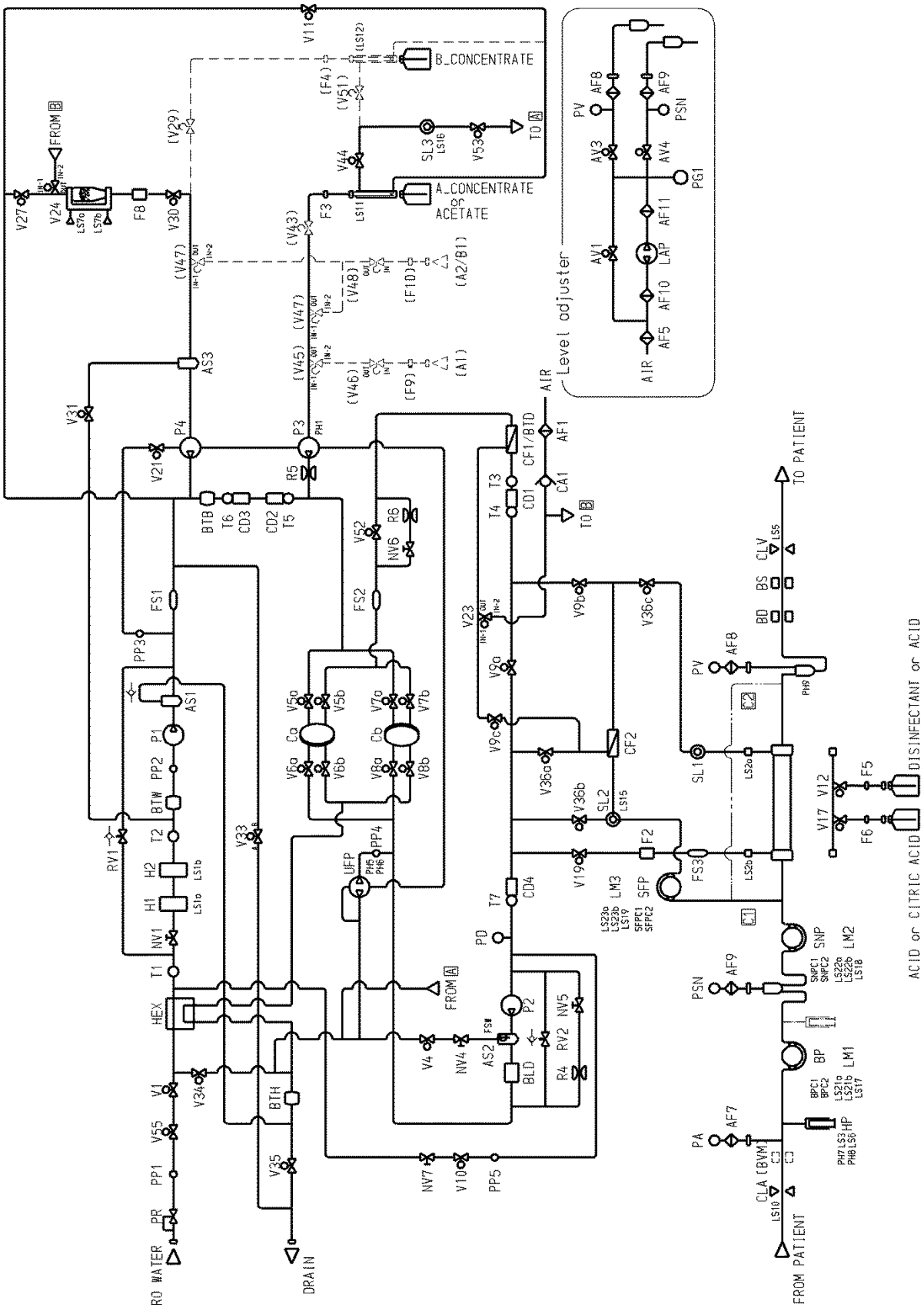
Glossary of terms used in this manual has the following meanings.

Terms	Meanings
3P outlet	AC outlet with a grounding terminal
Filling line	The hydraulic line between a water supply inlet and a chamber
Filling complete pressure	The liquid pressure in the filling line that is observed after a chamber is filled with liquid
Filling flow rate	The rate of water flown into a chamber
Air elimination tank	A part that eliminates air inside a closed line
Concentrate pump	The pump that controls infusion volume of dialysate concentrate and B concentrate
UF pump	The pump that controls ultrafiltration
Closed line	A closed line consists of a chamber, dialyzer, charging pump, coupler line, etc
ISO-UF	A therapy of only removing fluid without circulating dialysate solution
Preparation of solution	To prepare dialysate solution
Solution stop	A condition where the valve, pump and heater are stopped
Auto bypass	To automatically turn off and bypass V9b and V19 if a concentration value error, dialysate temperature error or blood leakage is detected
Auto gas purge	To discharge air from the air purge tank AS2 by automatically opening V4 and V10 if air in the hermetically-sealed circuit is trapped in the air purge tank AS2 and detected by the flow switch
Air bubble sensor	A sensor (detector) for detecting air bubbles in the venous blood circuit
Coupler line	A tube line from the dialysate solution feed port “TO DIALYZER” the dialysate sollution collection port “FROM DIALYZER”
Clamp operation	To prevent air bubble inflow or excessive pressure by closing the tube of the venous blood circuit by using a clamp (CLV)
Blood circuit	A tube used for circulating blood in the body
Blood pump	A pump used for circulating blood against resistance in the extracorporeal circuit and the dialyzer This system uses a roller-type pump.
Process switches	Switches for treatment mode, cleaning mode, preparation, reinfusion, treatment, etc.
Sequence	Continuous operation of solution circuit
CPU reset	To initialize the CPU functions
Heparin pump	Used to operate the pusher at a preset speed per unit hour By setting a syringe filled with heparin, a preset amount heparin per unit hour can be supplied from the connected blood circuit heparin line. If an excessive load is applied, the pump stops with a buzzer sound.
Single needle	A method of treatment through blood circuit, using a single injection needle
SN (single needle) warning setting time	The “single needle warning” is detected if time to reach the SN upper limit switching value from the SN lower limit switching value or time to reach the SN lower limit switching value from the SN upper limit switching value exceeds this setting value during single needle operation.

Terms	Meanings
Dialyzer	Medical equipment (artificial kidney) used for blood dialysis Fluid removal and dialysis are done through this dialyzer.
Chamber	A hermetically-sealed chamber for a certain amount of dialysate solution in the dialysis system
Display	A message display monitor (color LCD) on the operation panel to display various kinds of information (screens)
TMP (Trans-Membrane-Pressure)	Ultrafiltration pressure With this system, TPM is defined as “venous pressure – fluid pressure + TMP offset”.
TMP offset	A difference in head or difference in pressure due to a difference in mounting height between the venous pressure gauge and fluid pressure gauge This system calculates an average of one round of “fluid pressure – venous pressure” before starting the first fluid removal in the dialysis process or in one hour after starting dialysis in order to use it as TMP offset.
Conductivity	A value indicating a degree of electric conductivity, which is defined as the reciprocal of electric resistance indicating a difficulty of conductivity
Dialysis	A blood dialysis therapy to remove substances by diffusion
NC (normally closed)	In case of a valve, for example, it is closed when not energized and opened when energized.
Concentration	Electrolyte concentration of Na+
Highlighted display	A display which reverses the normal character color and background color as shown below A display which does not reverse the colors is called a normal display. Example) HIGHLIGHTED DISPLAY
Bypass	To turn off V9b and V19 not to feed dialysate solution to the dialyzer There are two kinds of bypasses, an “auto bypass” that is operated automatically and a “manual bypass” that is operated manually by the bypass button.
Buzzer	An acoustic alarm to indicate an error, if any
Priming	To fill the blood circuit and the dialyzer with saline before starting dialysis
Ht (hematocrit)	Red blood cells A hematocrit value 32%, for example, indicates that there are 3.2 million red blood cells per 1mm3 of blood.
Pre-washing	Preliminary washing
Hermetically-sealed circuit	A closed circuit which is composed of a chamber, a dialyzer, a dialysate pressure pump and a coupler line.
UFR (ultrafiltration rate)	A ultrafiltration rate which indicates an hourly ultrafiltration amount (L/h)
UFRP (ultrafiltration rate/pressure)	Ultrafiltration performance which indicates an hourly ultrafiltration amount (L/h∗mmHg) per 1 mmHg of ultrafiltration pressure (TMP)
Round	A cycle of chamber switching through the next chamber switching
Blood leak detector	A sensor which optically detects a leakage of blood into dialysate solution

Appendix

Dialysate circuit flowchart/List of Codes



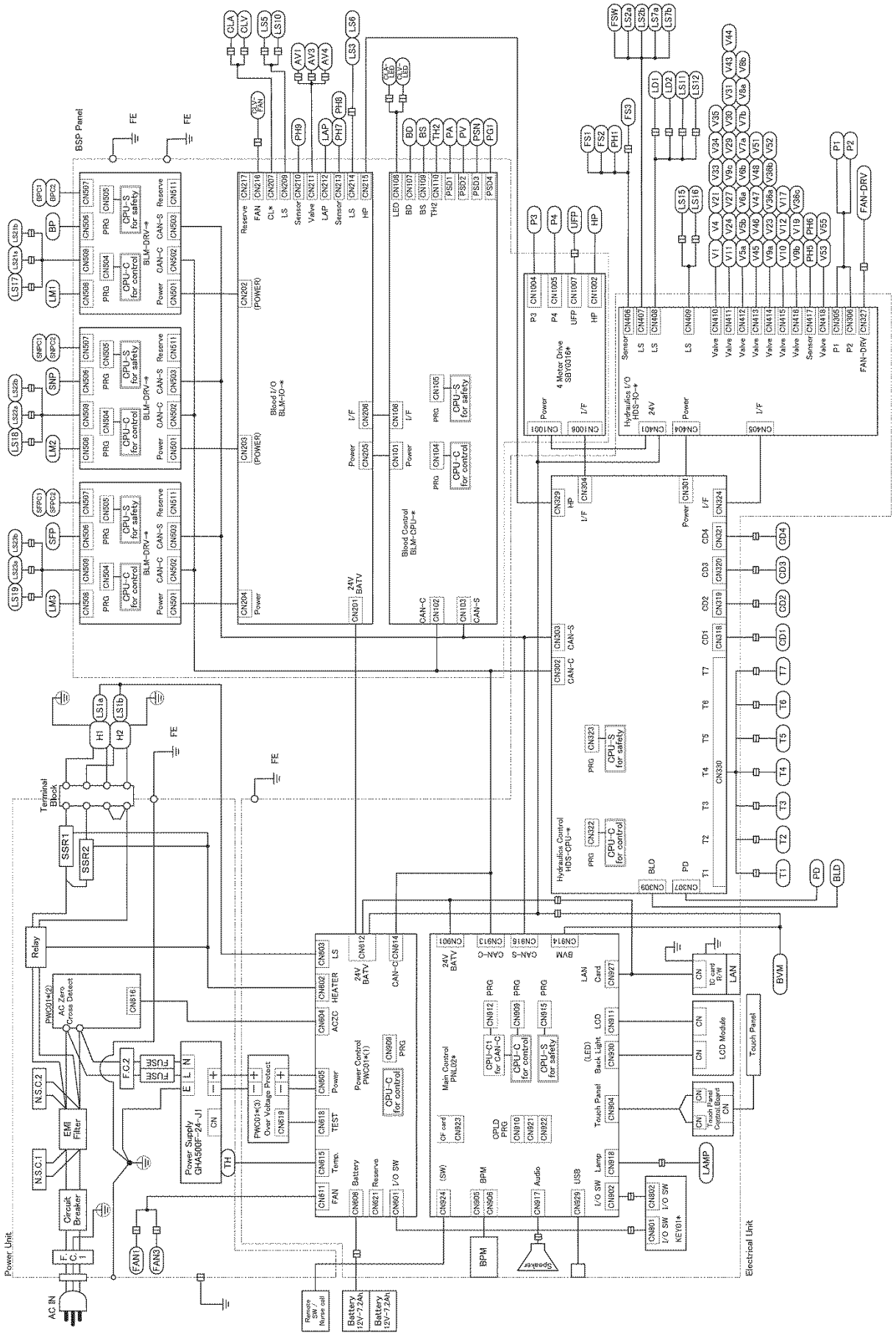
List of codes

Code	Name	Remarks
(AF1)	Air filter 1	Option
AF5	Air filter 5	
AF7	Air filter 7	
AF8	Air filter 8	
(AF9)	Air filter 9	Option
AF10	Air filter 10	
AF11	Air filter 11	
AS1	Degassing tank	
AS2	Air elimination tank1	
AS3	B powder concentrate air elimination tank	
BD	Bubble detector	
BLD	Blood leak detector	
BP	Blood pump	
BPC1	Blood pump cover switch	
BPC2	Blood pump cover switch	
BS	Blood sensor	
BTB	Buffer tank B	
(BTD)	Buffer tank D	Option
BTW	Buffer tank W	
BTH	Buffer tank H	
(BVM)	Blood Volume Measurement	Option
Ca	Chamber A	
Cb	Chamber B	
(CA1)	Check valve 1	Option
CD1	Dialysate conductivity sensor	
CD2	B concentrate conductivity sensor	
CD3	B concentrate conductivity sensor	
CD4	Dialysate conductivity sensor	
(CF1)	Micro ultrafiltration filter	Option
(CF2)	Micro ultrafiltration filter	Option
CLA	Arterial clamp	
CLV	Venous clamp	
F2	Dialysate filter	
F3	A concentrate filter	
F4	B concentrate filter	
F5	Disinfectant filter	
F6	Acid solution filter	
(F8)	B powder filter	Option
(F9)	Filter for central system A 1	Option
(F10)	Filter for central system A 2	Option
CLV-FAN	Fan to cool CLV solenoid	
FAN1	Fan to cool machine inside	
FAN3	Fan to cool machine inside	
DRV-FAN	Fan to cool DRV board	
FS1	Flow sensor for filling circuit	
FS2	Flow sensor for closed circuit	
FS3	Flow sensor for lack of disinfection	
FSW	Flow sensor switch at dialysate side	
H1	Heater	
H2	Heater	
(HEX)	Heat exchanger	Option
HP	Heparin pump	
LAP	Adjustment pump for chamber level	
LD1	Leak detector 1	
LD2	Leak detector 2	
(LM1)	Motor to remove BP blood circuit	Option
(LM2)	Motor to remove SNP blood circuit	Option
(LM3)	Motor to remove SFP blood circuit	Option
LMP	3-color light indicator	
LS1a	Temperature limit switch	
LS1b	Temperature limit switch	
LS2a	Coupler switch	
LS2b	Coupler switch	
LS3	Switch for heparin overload	
LS5	Location sensor for clamp	
LS6	Sensor for heparin pusher falling	
(LS7a)	Open/close sensor for B cartridge	Option
(LS7b)	Open/close sensor for B cartridge holder	Option
LS10	Location sensor for arterial clamp	
LS11	A concentrate connector	
LS12	B concentrate connector	
LS15	Location sensor for clean port1	
LS16	Location sensor for clean port2	
LS17	Sensor for BP tube attachment	
(LS18)	Sensor for SNP tube attachment	Option
(LS19)	Sensor for SFP tube attachment	Option
(Ls21b)	Original position detector for LM1	Option
(Ls21a)	Location detector for LM1	Option
(Ls22b)	Original position detector for LM2	Option
(Ls22a)	Location detector for LM2	Option
(Ls23b)	Original position detector for LM3	Option
(Ls23a)	Location detector for LM3	Option
NV1	Adjustment valve for filling volume	
NV4	Adjustment valve1 to remove gas	
NV5	Adjustment valve for dialysate flow rate	
NV6	Adjustment valve for dialysate flow rate	
NV7	Adjustment valve 2 to remove gas	
P1	Degassing pump	
P2	Filling pump	
P3	Pump for A concentrate	
P4	Pump for B concentrate	
PA	Arterial pressure sensor	
PD	Dialysate pressure sensor	
PG1	Liquid level adjustment pressure sensor	
PH1	Sensor for pump rotation of A concentrate	
PH5	Sensor for UF pump rotation	
PH6	Sensor for UF pump rotation	
PH7	Sensor for HP pump rotation	

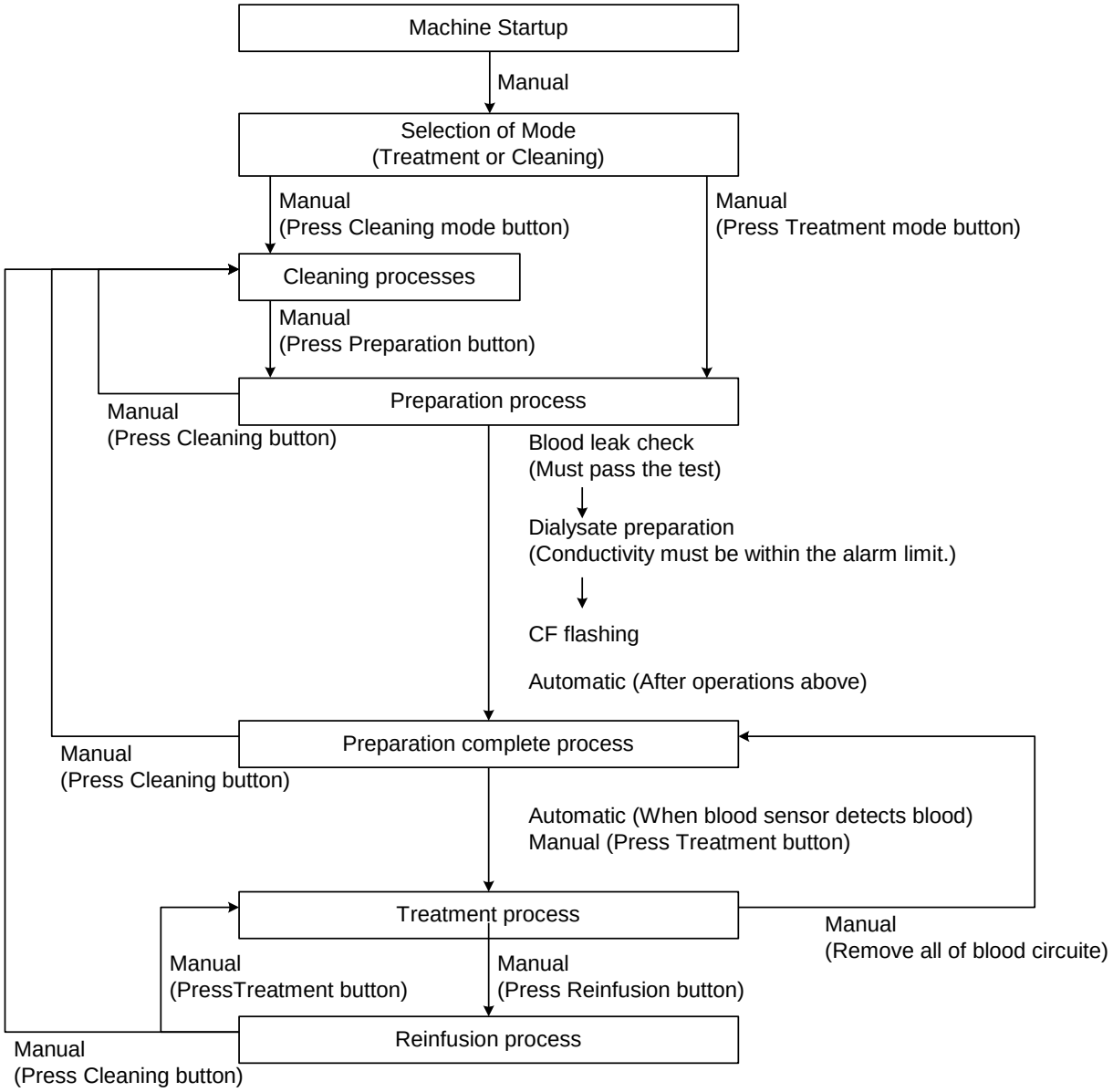
Code	Name	Remarks
PH8	Sensor for HP pump rotation	
PH9	Sensor to detect liquid level	
PR	Reducing valve to feed water	
(PSN)	Pressure at dialyzer inlet	Option
PV	Venous pressure sensor	
R4	Flow rate restriction connector 4	
R5	Flow rate restriction connector 5	
R6	Flow rate restriction connector 6	
RV1	Relief valve1	
RV2	Relief valve2	
(SFP)	Fluid replacement pump	Option
(SFPC1)	Fluid replacement pump cover switch	Option
(SFPC2)	Fluid replacement pump cover switch	Option
SL1	Sample port1	
(SL2)	Clean port 1	Option
SL3	Clean port 2	
(SNP)	2nd Blood pump	Option
(SNPC1)	2nd Blood pump cover switch	Option
(SNPC2)	2nd Blood pump cover switch	Option
SPK	Speaker	
T1	Temperature sensor 1	
T2	Temperature sensor 2	
T3	Temperature sensor 3	
T4	Temperature sensor 4	
T5	Temperature sensor 5	
T6	Temperature sensor 6	
T7	Temperature sensor 7	
UFP	Ultrafiltration pump	
V1	Solenoid valve to feed water	
V4	AS2 solenoid valve	
V5a	Solenoid valve A for fresh Ca	
V5b	Solenoid valve B for fresh Ca	
V6a	Solenoid valve A for Ca drainage	
V6b	Solenoid valve B for Ca drainage	
V7a	Solenoid valve A for fresh Cb	
V7b	Solenoid valve B for fresh Cb	
V8a	Solenoid valve A for Cb drainage	
V8b	Solenoid valve B for Cb drainage	
V9a	Solenoid valve A for bypass of dialysate	
V9b	Solenoid valve B for bypass of dialysate	
V9c	Solenoid valve for flushing CF1	

Code	Name	Remarks
V10	Solenoid valve to remove gas	
V11	Solenoid valve for rinse	
V12	Solenoid valve for disinfectant	
V17	Solenoid valve for decalcification	
V19	Solenoid valve C for bypass of dialysate	
V21	Solenoid valve for flushing	
(V23)	Solenoid valve for CF leak check	Option
(V24)	Solenoid valve to remove water from B powder	Option
(V27)	Solenoid valve to feed water to B powder	Option
(V29)	Solenoid valve 1 for B concentrate	Option
(V30)	Solenoid valve 2 for B concentrate	Option
(V31)	Solenoid valve 2 to de-air from B powder	Option
V33	Solenoid valve to relief hot water pressure	
V34	Solenoid valve for recirculation	
V35	Solenoid valve to block hot water	
(V36a)	Solenoid valve for flushing CF2	Option
(V36b)	Solenoid valve for leak check	Option
(V36c)	Solenoid valve for HF	Option
V43	Solenoid valve for sheath cleaning 1	
V44	Solenoid valve for sheath cleaning 1	
（V45）	Solenoid valve 1 for central system A1	Option
（V46）	Solenoid valve 2 for central system A1	Option
（V47）	Solenoid valve 1 for central system A2	Option
（V48）	Solenoid valve 2 for central system A2	Option
V51	Solenoid valve for sheath cleaning 2	
V52	Solenoid valve for flow change	
V53	Solenoid valve to for drain port	
V55	Solenoid valve to feed water	
AV1	Valve to relief level adjustment circuit pressure	
AV3	Valve to change venous level	
AV4	Valve to change SN level	

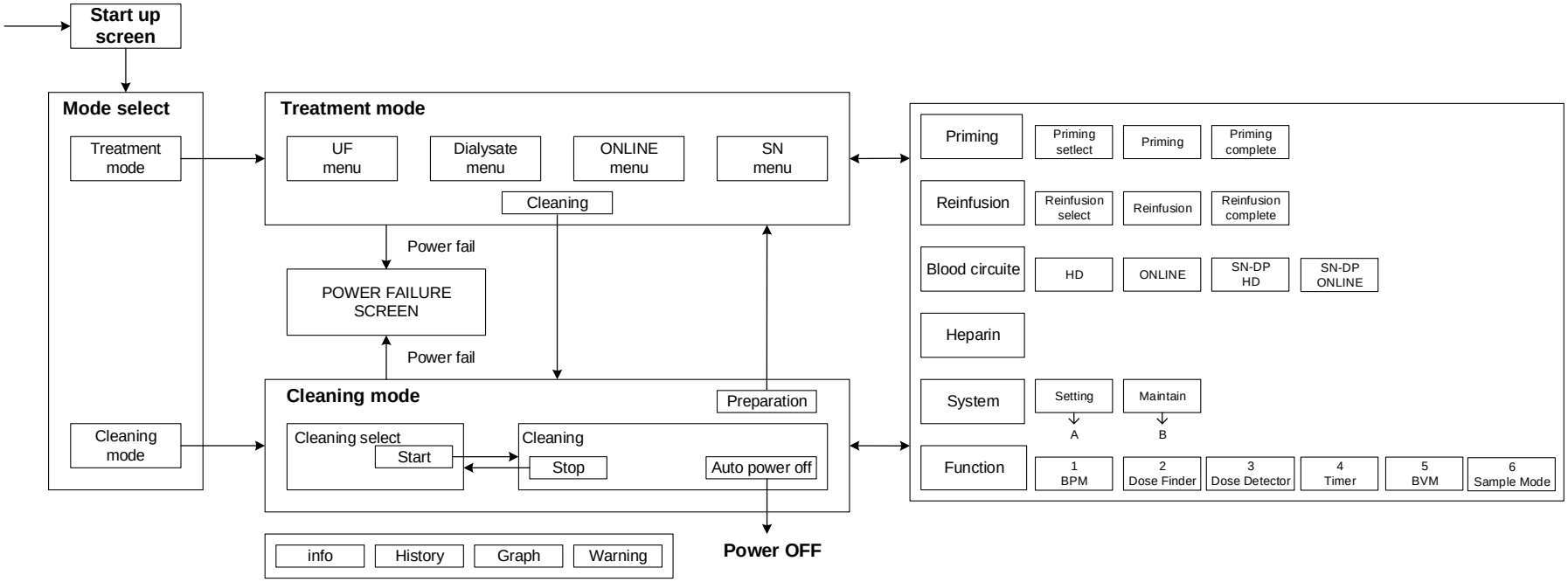
Electrical Construction

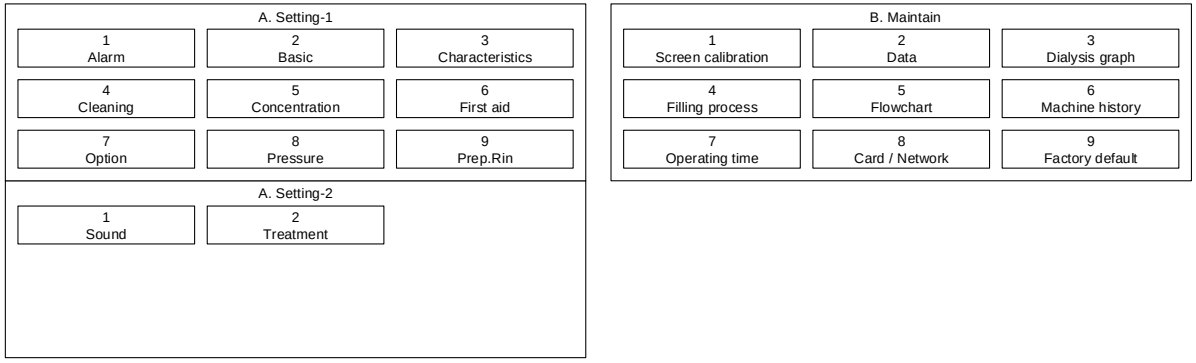


Process transition paths



Screen transition paths





Material(intended to come into contact with the water, dialysing fluid, dialysing fluid concentrate)

Acronym	Material name
PP	Polypropylene
VMQ	Silicone rubber
FKM	Fluoro rubber
PTFE	Polytetrafluoroethylene
FEP	Tetrafluoroethylene hexafluoropropylene copolymer
PVDF	Polyvinylidene fluoride
PPS	Polyphenylenesulfide
PSU（PSF）	Polysulfone
PPSU	Polyphenylsulfone
SUS316	Stainless steel
Al_2O_3	Alumina ceramics
Ti	Titanium alloys (Option)

Contents about Declaration of Conformity according to EC Machinery Directive (2006/42/EC)

1. The Manufacturer of the Products covered by this Declaration is:
   Nipro Corporation
   3-9-3, Honjo-Nishi, Kita-ku, Osaka 531-8510, Japan

2. The Products Covered by this Declaration:
   Generic denomination: Single Patient Dialysis Machine
   Model: Surdial X

3. The products identified above comply with the requirements of the Machinery Directive 2006/42/EC, and also comply with the requirements of the Medical Device Directive 93/42/EEC.

4. The manufacturer has applied the following harmonized standards:
   IEC 60601-2-16:2012, IEC 60601-1:2005, with am1:2012
   ISO 14971:2007, EN ISO 14971:2012, IEC62304:2006, IEC 60601-1-2:2014, IEC 60601-1-6:2010 with am1:2013, IEC 60601-1-10:2007 with am1:2013, IEC 60825-1:2014, IEC 62366:2007 with am1:2014, ISO 10993-1:2009, ISO 15223-1:2016 with corr.1 :2017

5. The manufacturer has applied the following technical standards:
   JIS Z 0200:2013, JIS Z 0232:2004, and JIS Z 8735:1981

Name and address of the person authorized to compile the technical file:
   Name: Minoru Doimoto, Deputy General Manager, Int'l RA/QA office, Int'l Div., Nipro Corporation
   Address: 3-9-3, Honjo-Nishi, Kita-ku, Osaka 531-8510, Japan

Airborne Noise Emissions

The A-weighted emission sound pressure level of this machine does not exceed 70 dB(A).

Examination conditions are as follows.

- A measuring instrument
  Sound level meter　LA-220
- The measuring method
  The A-weighted emission
  1 minute
- Operating process of this machine
  Dialysis process
- Measuring points
  Measuring points are at a distance of 1 meter from the front and the back of this machine and at a height of 1.6 meters from the floor.

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