Instructions for use

(Original Instruction)

Adamonitor SC

EMC **Conformed**

Identification No. : MSCV-1-E-7

CE 0123

Table of Contents

Chapter 1 Safety/Operating Precautions and Warning Labels

1.1 Warning, Caution, and Instruction in this Manual

In these Operating Instructions, the following symbols and terms are used according to purposes and degrees of importance. It is important to correctly understand the symbols and terms to ensure safe and effective use of the device.

⚠ WARNINNG

●Should this indication be neglected, such critical risks that could result in fatal injuries or serious physical injuries to the user may be expected. The term "serious injuries" may imply vision loss, physical injuries, burns (high-temperature, low-temperature), electric shock hazard, bone fracture, or intoxication that result in after effects and injuries that require hospitalization or long-term hospital visits for medical treatment. In addition, the term is also used when the risk of infection is assumed.

⚠ CAUTION

●Should this indication be neglected, such risks that could result in damages of the user, occurrence of property damage, or serious impact on the analysis result may be expected. The term "damage" may imply injuries, burns, electrical shock hazards that do not require hospitalization, or long-term hospital visits for medical treatment. The term "property damage" may imply a secondary disaster to the peripheral areas of the device.

⚠ Instruction

●Should this instruction be neglected, failures may be caused to the device as a result of improper handling.

1.2 Safety Precautions

Be sure to observe the precautions shown below to ensure safe and effective use of the device.

⚠ WARNING

1. Basic items related to the device

・Pay attention to the following items before using the device:

— Check that the protective earth is robustly connected.

— Check that the wire connection is correct and robust.

— Check the power supply.

・Pay attention to the following items while the device is in use:

— Strictly observe the precautions that are stated on the labels that are placed at various parts of the device and those that are described in this manual.

— Should a failure or an abnormal situation occur, immediately stop operating the device. Be sure to resume the operation after taking proper precautions. When the touch panel becomes out of order, do not use the device, adequately indicate that it is out of order, and contact the dealer from whom you purchased the device.

・Pay attention to the following item after using the device:

— Be sure to clean the device after use so as not to cause any problem when using the device next. Turn off the power to the device before starting cleaning.

2.Operating Precautions

・Persons other than those who have received the operation training shall not use the device. One-man operation of the device by person who has no professional knowledge shall be prohibited.

・Strictly observe the precautions that are described in this manual.

・Never remove the fixing screws of the rear cover to detach it during treatment.

3. Installation Environment

・Pay attention to electromagnetic wave or noise.

Install the device in a place where there is no equipment that generates unusual noise around the device. In the room where the device is installed, make it a rule to turn off the power of mobile phones, smartphones, etc. The device may malfunction when it is subject to influence from abnormal noise or electromagnetic waves of mobile phones, etc.

- The EMISSIONS characteristics of this device make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this device might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the device.
- Be sure to use the supplied power cable. Use of power cables other than the supplied could result in increased electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation.
- Install the device in a place where it is not exposed to splashed water.
- Install the device in a place where it is not subject to detrimental effects caused by atmospheric pressure, temperature, humidity, air ventilation, sunlight, dust, salt content, air containing sulfur content, etc.
- Do not install the device in a place where the power supply availability is not satisfactory.
- Pay attention to the state of stability regarding inclination, vibration, shocks (including the transportation phase), etc.
- Do not install the device in a place where chemicals are stored or gases are generated.
- Pay attention to the frequency, voltage and allowable current value (or power consumption) of the power supply.
- Be sure to connect the protective earth correctly.
- Consider the following conditions for the installation place and the operating environment:
  - Installation place: Indoor installation
    (The device shall not be exposed to direct sunlight.)
  - Ambient temperature: 10 to 35℃

(Sudden temperature change shall not be allowed)

- Relative humidity: 30% to 80% (No condensing)

Check with Chapter 3 "Installation" also.

4.Infection Prevention

・Be sure to use rubber gloves for medical use whenever the device is to be operated.
・In case the blood of patient adheres on the device, immediately wipe it off and execute disinfection and sterilization according to the rules of the facility.

5.Consumables

・Do not use parts other than the Adacircuit, 20 mL luer-locking type plastic syringe of designated manufacturers (TERUMO, NIPRO, JMS, TOP). It is possible not to obtain the syringe of the manufacturer you want in your regions. In this case, contact the distributor for details.
・Use of any Consumables other than the products designated by us may cause deteriorated performance and safety of the device. For more information on our designated consumables, refer to the operating instructions .
・Do not reuse blood circuits and syringes.
・Make sure to use normal saline or anticoagulant normal saline when cleaning and priming Adacircuit.

6. Notice to the user and / or patient

・Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

1.3 Operating Precautions

Be sure to observe the precautions shown below to ensure safe and effective use of the device.

⚠ WARNING

1. Operating Precautions

- Be sure to operate the device according to the procedures described in this manual whenever the device is operated.

2. Pay attention to the following items when using the device

- Do not forget to execute the pre-operation inspection to check the device functions correctly. (Refer to Chapter 8"Inspection")
- Be sure to re-check the external circuit that is directly connected to the patient.
- When applying the venous circuit tube, be sure to insert it robustly to the guide groove of the bubble sensor unit. If the application is insufficient, the device may not correctly function since the air bubbles in the venous circuit tube cannot be detected. Moreover, do not use ultrasound gel.

3. Pay attention to the following items when using the device:

- Do not take time and the dose exceeding the necessary ones for the treatment.
- Always watch the device in general and monitor there is no patient abnormality.
- Recheck the external circuit that is directly connected to the patient.
- In case any abnormality is detected with the device or the patient, be sure to take adequate measures, including shutting-down of the machine operations under safe condition ensured for the patient.
- Pay attention not to allow the patient to touch the device.
- Do not open the blood pump cover by mistake.

4. Pay attention to the following items after using the device:

- To turn off the power, press the power switch.
- When removing cables, etc. , do not apply excessive force to them, including

pulling the cable off by holding it at the cable.

・Regarding the storage place, pay attention to the following items:

— Store the device in a place where it is not subject to splashed water.

— Store the device in a place where it is not subject to detrimental effects caused by the atmospheric pressure, temperature, humidity, air ventilation, sunlight, dust, salt content, air containing sulfur content, etc.

— Pay attention to the state of stability regarding inclination, vibrations, shocks (including the transportation phase),etc.

— Do not store the device in a place where chemicals are stored or gases are generated.

— Store the device in a place other than a place of intense magnetic fields or strong electric fields.

・Keep accessories and codes, etc. tidy in order after cleaning them.

・Do not remodel the device.

・The device should be inspected monthly on a regular basis.

(Refer to Chapter 8 "Inspection")

・When the device that is not used for a while is used again, be sure to check before operation that it functions normally and in safe condition.

5. Disposition of Waste

・Regarding used blood circuits, there is a possibility of causing infections and special treatment is required when disposing of them. They must be adequately disposed of as medical waste according to the guidelines of the facility.

6. Others

・The destruction has to be performed by a service provider certified for the destruction according to the WEEE Directive; a certificate of destruction has to be filed.

NOTE)

If the device is set in a country outside of the EU, WEEE Directive is not applied.

1.4 Warning Labels and List of Indications

The contents of the warning labels that are to be attached to the device will be described hereunder.

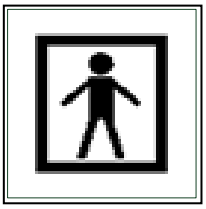
1.4.1 Warning Labels

-Warning labels are attached at the portions where some consideration needs to be given in terms of safety.
-Do not erase, damage, or peel off the warning labels by mistake.
-When warning labels become faint or peel, contact us.

Jamming (Prevention of Injury)
Be careful fingers or hands may be jammed when operating the cover, resulting in injury.

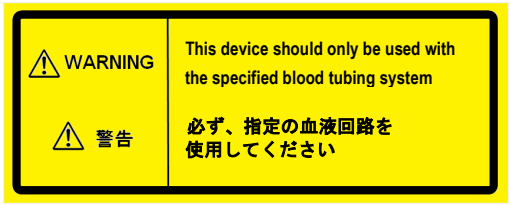
Biohazard
Handling must be done according to the specified method since there is a possibility of infection.

Fall
Touching this part could lead to the fall of device.



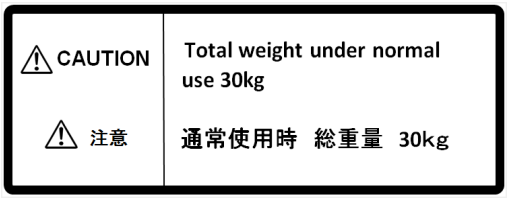
BF-Applied Part Mark
The label shows the classification of the applied part.

Refer-to-Manual Label
To prevent accidents, carefully read the Operating Instructions before use.



Specified Blood Tubing System

Be sure to use the blood tubing system dedicated for the device.



Device Total Weight

The label shows the total weight of device when used in a specified manner.
（Including Adastand and Blood Tubing System）

1.4.2 Signs Other Than Warning Signs

■Signs Other Than Warning Signs

ON	OFF
|	○

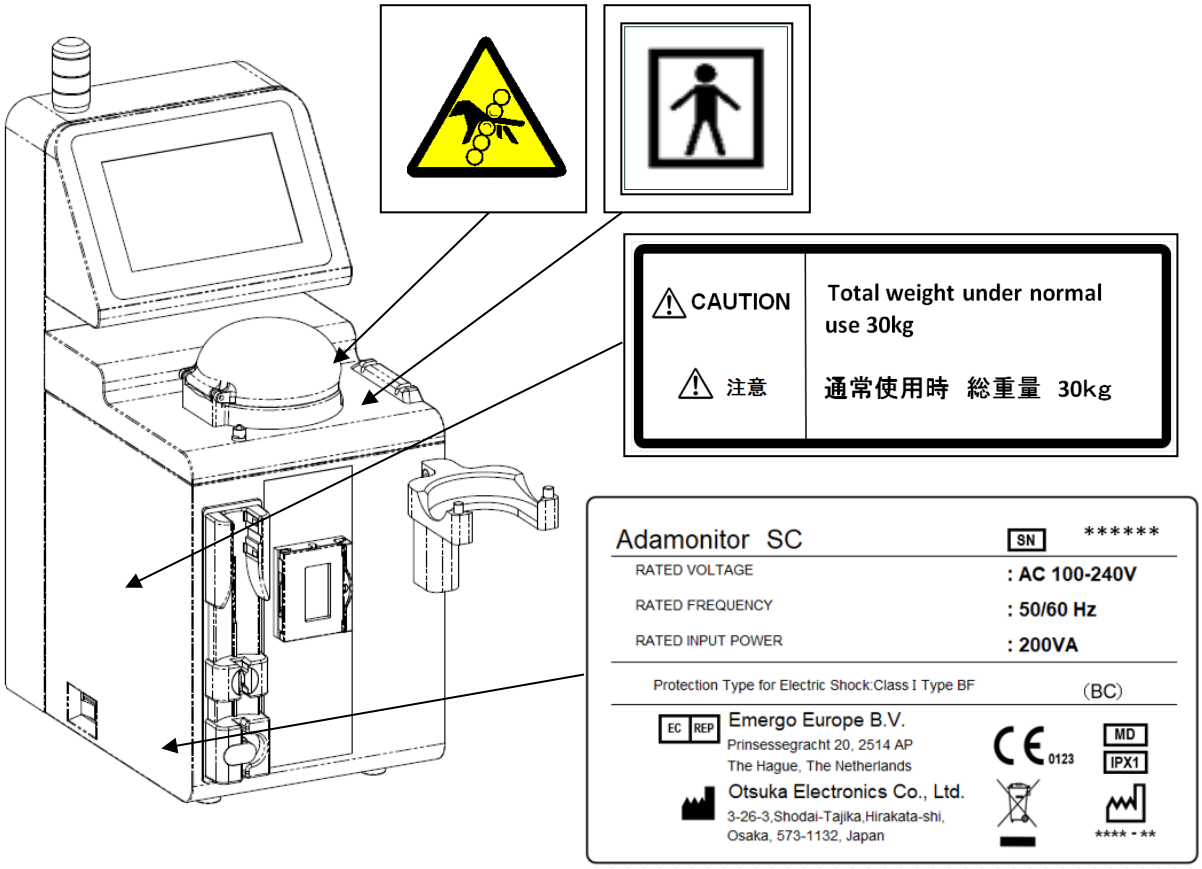
These signs are used to indicate the main power switch on the back of the device. The signs indicate:

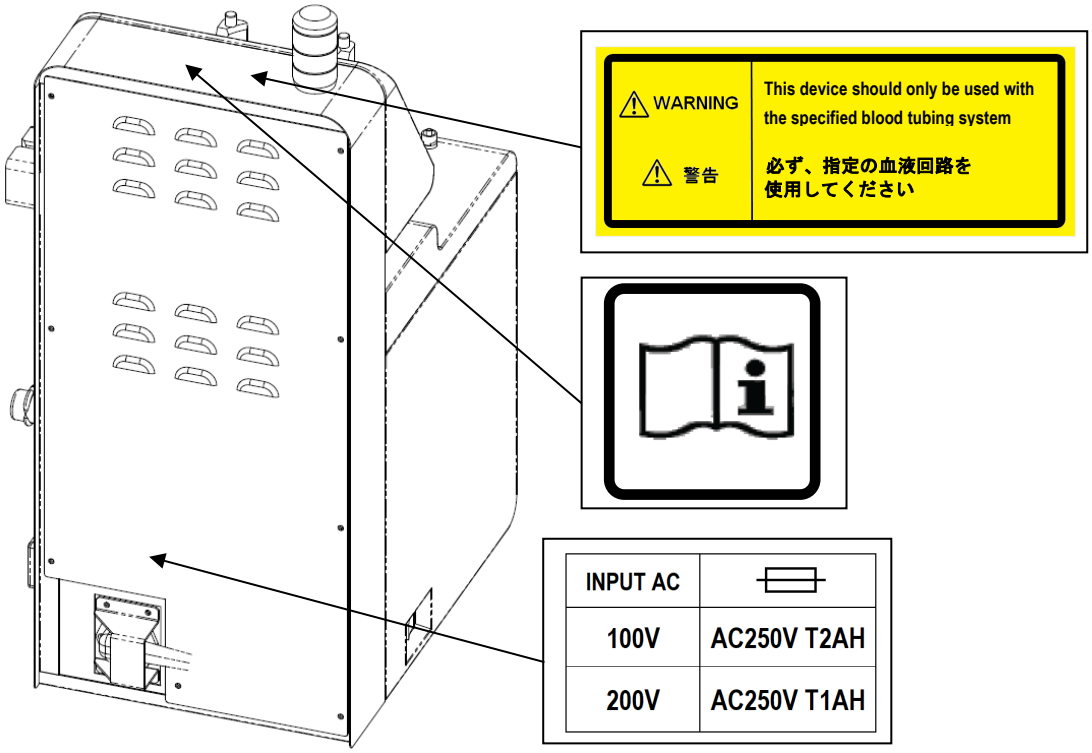
■List of symbols

CE	CE marking		Stacking Limit by Number
EC REP	Authorized European representative		This Way Up
SN	Serial Number		Keep Dry
	Manufacturer		Fragile, Handle with Care
	Date of manufacture		Humidity Limitation
	Waste Electrical and Electronic Equipment Directive		Temperature Limit
IPX1	International Protection Code (Liquid ingress protection)	MD	Medical Device

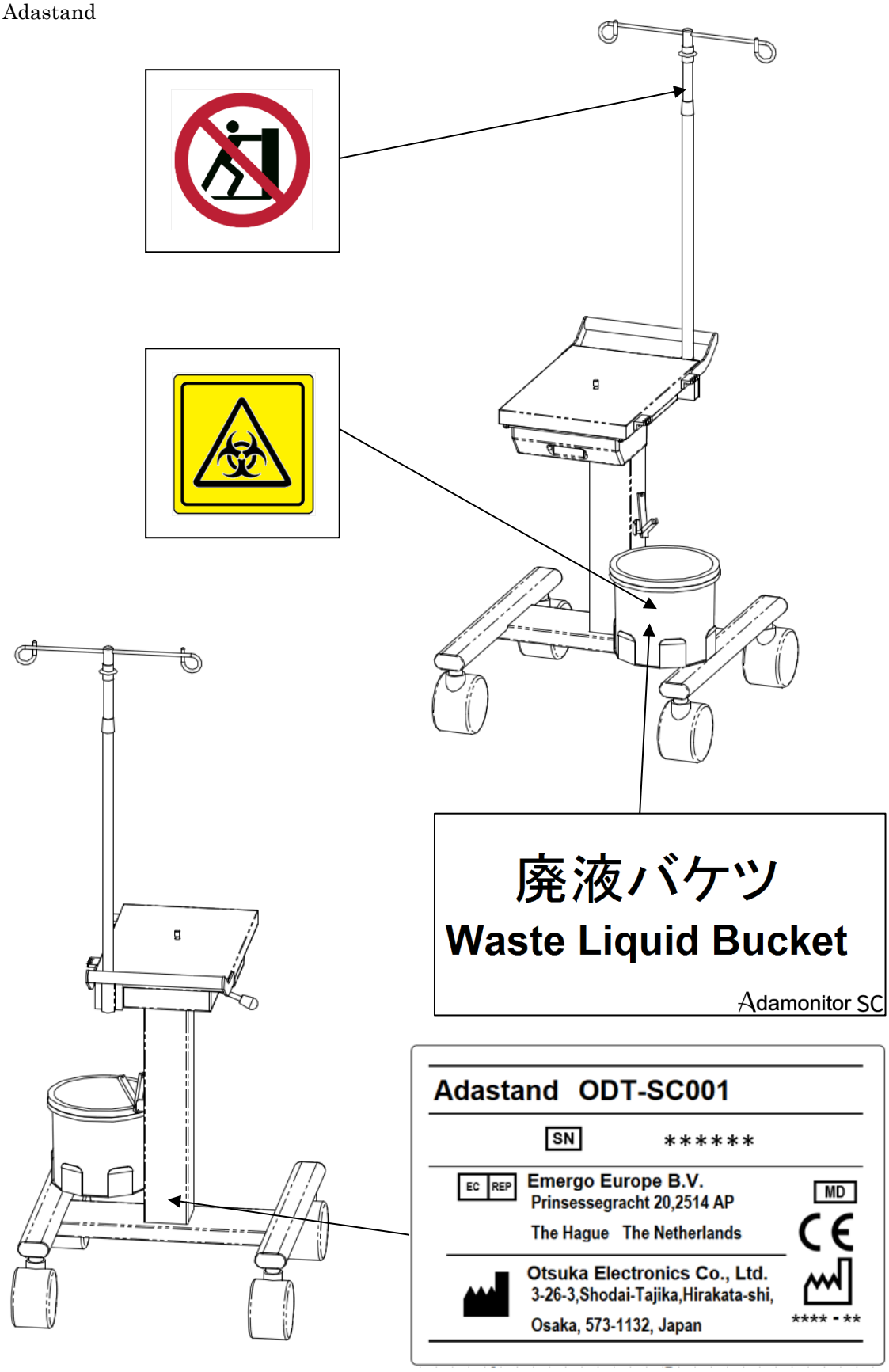
1.4.3 Warning Labels and List of Indication Attaching Positions

・Main unit of the device





・Adastand


廃液バケツ
Waste Liquid Bucket
Adamonitor SC
Adastand ODT-SC001
SN
******
EC REP
Emergo Europe B.V.
Prinsessegracht 20,2514 AP
The Hague The Netherlands
MD
Otsuka Electronics Co., Ltd.
3-26-3,Shodai-Tajika,Hirakata-shi,
Osaka, 573-1132, Japan
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Chapter 2　Outline of Device

2.1　Clinical Method

The ADAMONITOR provides the apheresis treatment in veno-venous technique for the extracorporeal circulation, offering a blood pump, monitoring equipment, and special safety mechanisms.

2.2　Intended Use of Device

The device ADAMONITOR SC is designed to maintain and monitor extracorporeal circulation of blood at selected flow, in connection with the use of the adsorptive apheresis column ADACOLUMN®, developed and manufactured by JIMRO Co.,Ltd., and the blood tubing system ADACIRCUIT .
The accessory ADASTAND is a stand only for ADAMONITOR SC.
When using ADAMONITOR SC, be sure to install it on the ADASTAND.

Indications
Indications mean clinical symptoms.
Separated from adsorptive apheresis column, Adamonitor SC has no indications.

WARNING

●Adamonitor SC treatment has not been fully investigated in pediatric patients.

2.3　Contraindications

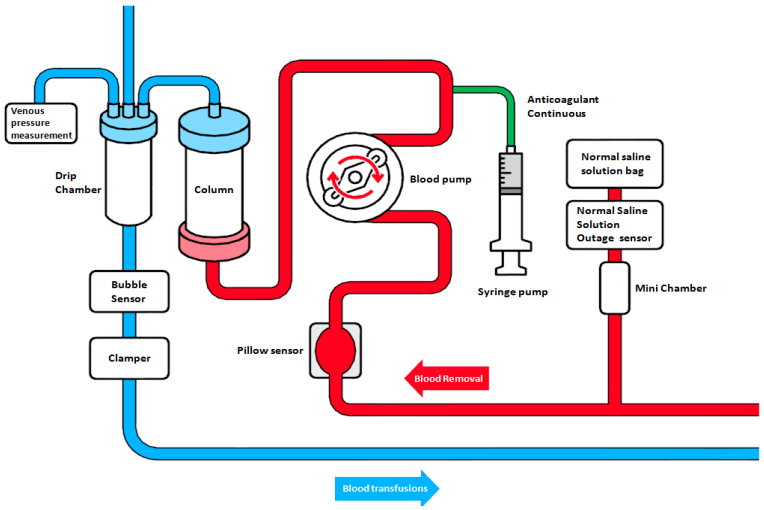
Contraindications that contribute to clinical efficacy and safety are as follows.

（1）The device may only be used by, or under supervision of, healthcare professionals trained for operating the device.

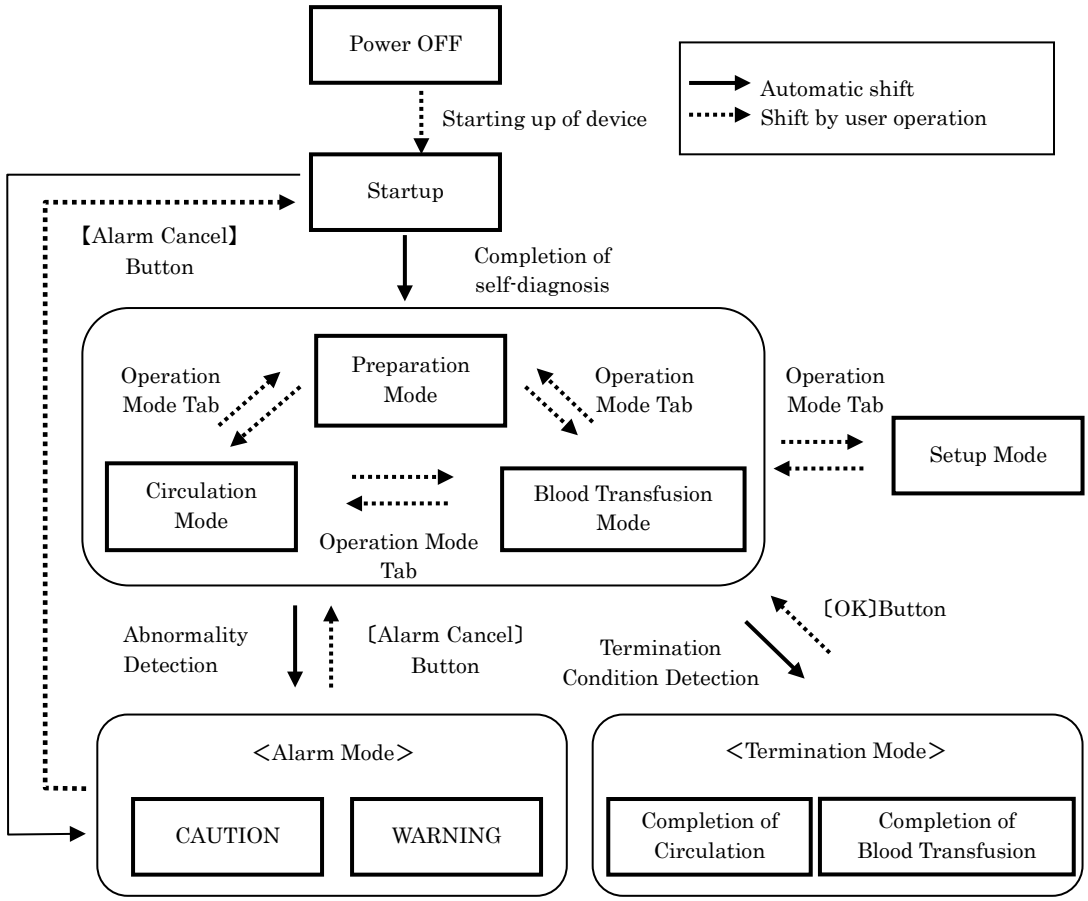
（2）Be sure to only use a specified blood tubing system and a specified apheresis column for the device. If any other blood tubing system or apheresis column is used, the performance of the device, including the flow rate control and alarm function, cannot be guaranteed.

2.4　Device Circulation Flow

A certain direction of flow is given to the blood by the blood pump.　The following follow chart shows the extracorporeal circulation of blood.　(For detailed specifications and operations of respective units, refer to Chapter 4“Configuration and Specifications”.)



2.5 Device Operation Mode



Supplement
・The〔Operation Mode〕tab indication shows disabled while the blood pump or the syringe pump is in operation and it is not possible to shift the Operation Mode.

Chapter 3 Installation

3.1 Unpacking

When the unpacking work is completed, check the quantity, contents, damage to exterior surfaces, etc.
When any problem is detected, contact the dealer from whom you purchased the device.

3.2 Installation Environment Conditions

To fully demonstrate the maximum capacity of the device for use, install the device by taking the following conditions into consideration as the installation environment:

- Installation place: Indoor (The device shall not be exposed to direct sunlight.)
- Ambient temperature: 10 to 35℃
- Relative humidity: 30 to 80% (No condensing)
- Atmospheric pressure: 70 to 106kPa
- Vibrations: There shall be no vibrations.
- Ambient environment: Dust and dirt shall be little and there shall be no corrosive atmosphere. Good ventilation shall be ensured.
- The device shall be installed so that the height difference between the patient and the device can be within ±20cm can based on the height of the patient.
- Do not install the device in a place where radio disturbances may occur or power supply availability is not satisfactory.

3.3 Storage/Transportation Conditions

Install the device in a place where it is not subject to detrimental effects caused by the atmospheric pressure, temperature, humidity, air ventilation, sunlight, dust, salt content, air containing sulfur content, etc., under stable conditions in terms of inclination, vibrations, etc.
Put the protection cover on the device and store and keep the device in a place where it is not subject to splashed water.
In addition, avoid inclination, vibrations, shocks, etc., during transportation within the following conditions:
The following conditions shall apply for the device packaged by the packaging box for the exclusice use of the device:

- Ambient temperature: −20 to 70℃
- Relative humidity : 10 to 100% (No condensing)

Even in case the distributor is involved in storage/transportation of the product, be sure to store the device while paying attention to the above-stated conditions.

3.4 Power-supply Facility

⚠ CAUTION

- **To prevent electric shock hazard when electric leakage occurs and to prevent noise to the electronic circuits, be sure to ground the protective earth. In preparation for electric leakage accident, ground the device with the grounding resistance of 100 ohms or below.**
- **Do not connect the protective earth to the gas pipe.**
- **To ground or remove the protective, be sure to disconnect the power cable from the wall outlet in advance.**
- **Be sure to use the supplied power cable. Use of power cables other than the supplied could result in increased electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation.**

For the device, the following power supply is required.
Check that the power supply facility satisfies the following conditions:

(1) The voltage fluctuation should be within rated voltage ±5%, provided that the operational range is within rated voltage ±10%.

(2) For the power supply, the capacity should be secured with sufficient margin by referring to the following table.

Unit	Voltage (V)	Current (A)	Power Consumption (VA)
Main unit	100-240	0.83-2.0	200

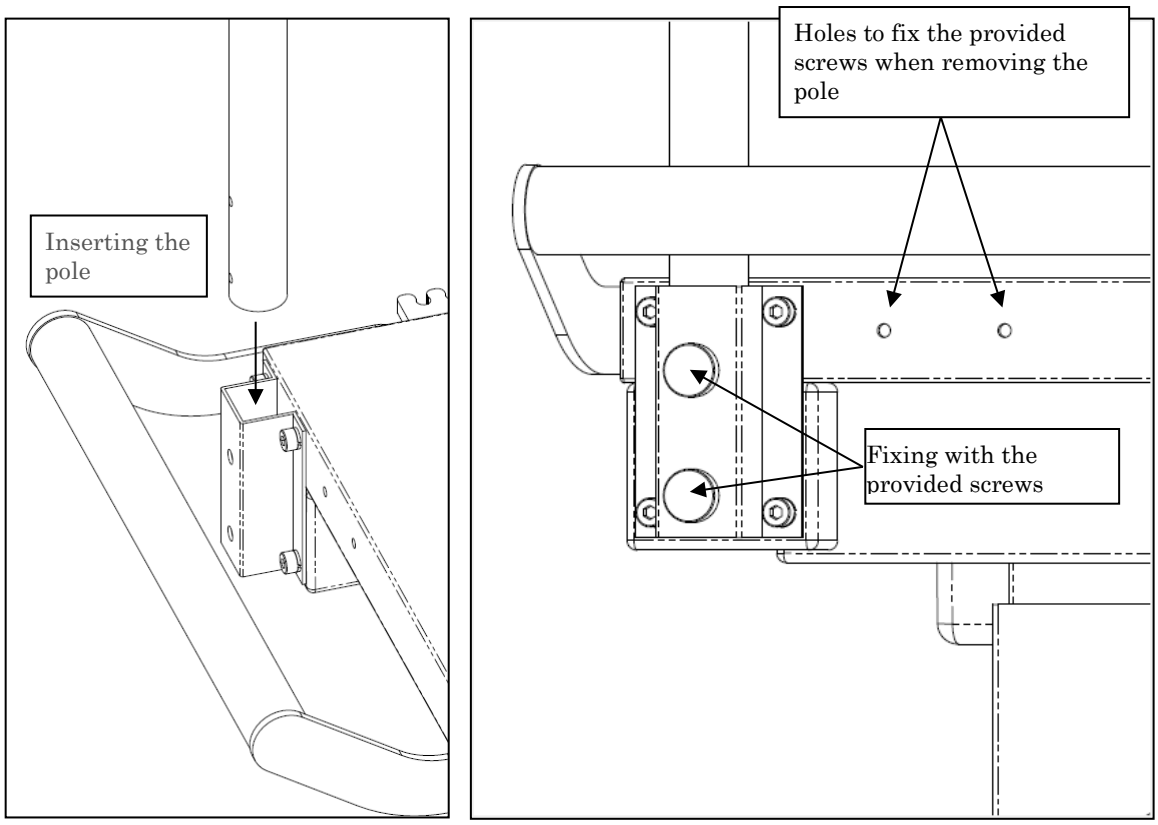
3.5 Installation Method

CAUTION

- **When the device is to be installed on the stand, be sure to use the optional Adastand.**
- **Be careful not to get injured when installing the device and disassembling the Adastand.**

Fix the pole to the stand as follow.

Fixation Method

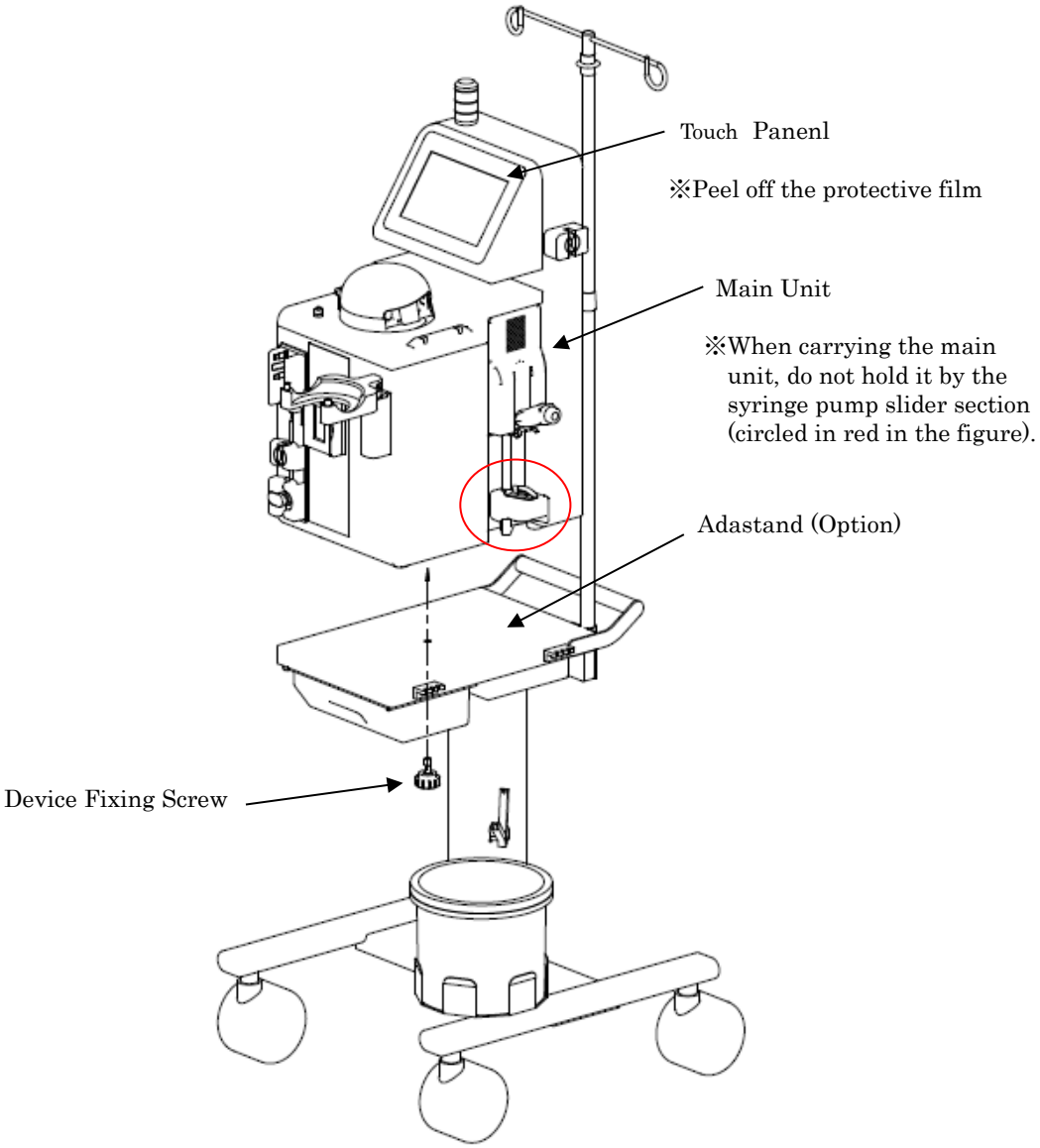


CAUTION

- **Make sure that the device is not installed on the Adastand before attaching / detaching the pole.**

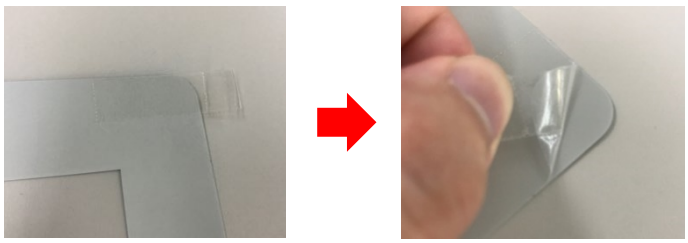
Install the main unit of the device as follow.

Installation Method



CAUTION

- **Peel off the protective film of the touch panel.**
- **When carrying the main unit, do not hold it by the syringe pump slider section.**

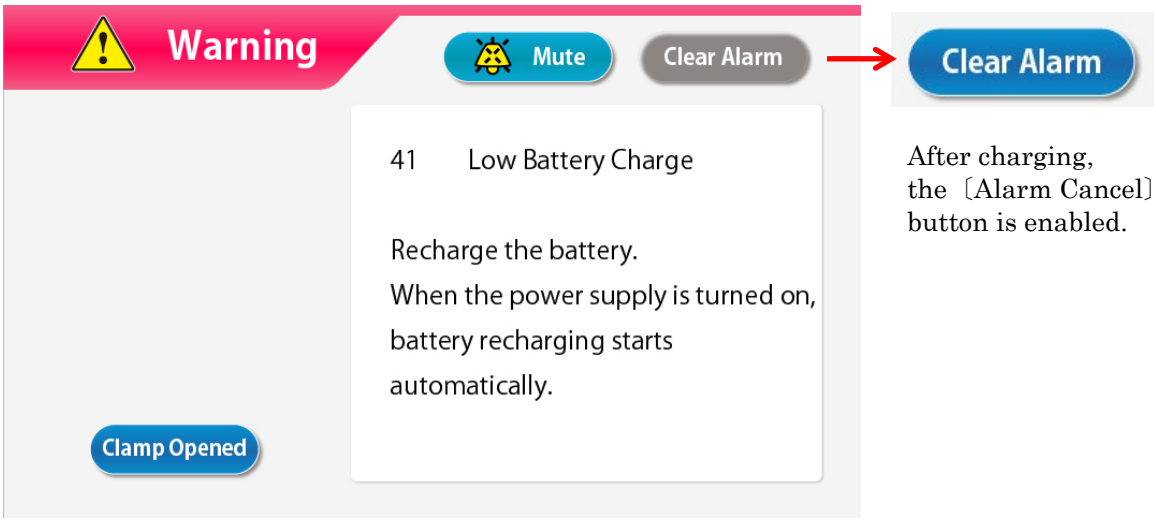


3.6 Inspection after Installation

After completing the installation, check that the self-diagnosis functions without problem by referring to Chapter 8 “8.1.1 Pre-operation Inspection”.

3.7 Battery Charging after Installation

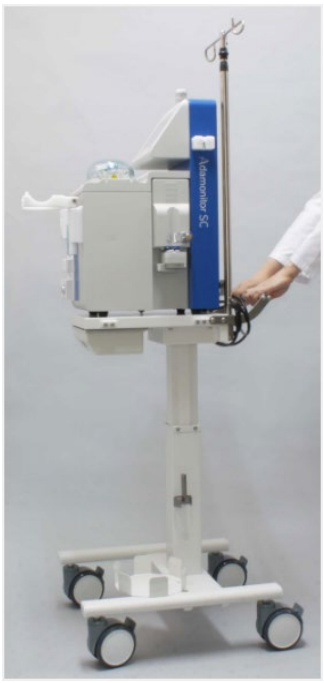
The device has the built-in sustainable power supply for alarm that is used for power failure only. After the installation (right after the purchase), be sure to feed power for two hours in a row to charge the battery.
In addition, when the device is not used for a long period of time (about one month), It is possible that the battery capacity is low and the error “41 Low Battery Charge” occurs. In this case, push the〔Sound Off〕button and charge the battery in the same way as done at the time of purchase.
When charging is completed, the〔Alarm Cancel〕button is enabled. If you push the button, the device is shifted to the [Preparation mode〕



After charging, the〔Alarm Cancel〕button is enabled.

3.8 Moving Method

Be sure to use the handle when moving the device.



3.9 List of Components

(1)Spare fuse. . . . . 2 pieces

(2)Instructions for use . . . . . 1 copy

(3)Protection cover . . . . . 1 piece

(4)WEEE dismantle instructions . . . . . 1 piece

3.10 Option

Item	PN
Adastand	ODT-SC001

Chapter 4 Configuration and Specifications

4.1 Name and Function of Each Part

Fig. 1 shows the name of each part of the device.

(1) Power Switch

-Turn the power ON/OFF.

(2) Touch Panel

-Use to perform various operations

-Display various errors and warnings

(3) Warning Lamp

-Indicate warnings

(4) Blood Pump

-This is a roller pump to transmit blood

(5) Blood Pump Cover

-This is the cover of the roller section of the blood pump

-Detect the open cover and stop the blood pump.

(6) Syringe Pump

-Execute continuous infusion of the anticoagulant.

(7) Normal Saline Solution Outage Sensor

-Detect the liquid outage when filling the blood circuit with the normal saline solution.

(8) Bubble Sensor

-Detect generation of bubble within the venous circuit.

(9) Venous Pressure Connector

-The connection port of the venous pressure sensor.

-Detect the pressure of the venous circuit with the venous pressure sensor incorporated in the device.

(10) Clamper

- Block the venous circuit when an error such as bubble detection occurs.

(11) Pillow Sensor (Negative Arterial Pressure Senor)

- Detect the negative pressure of the venous circuit.

(12) Cable Holder

- Fix the power cable to the device.

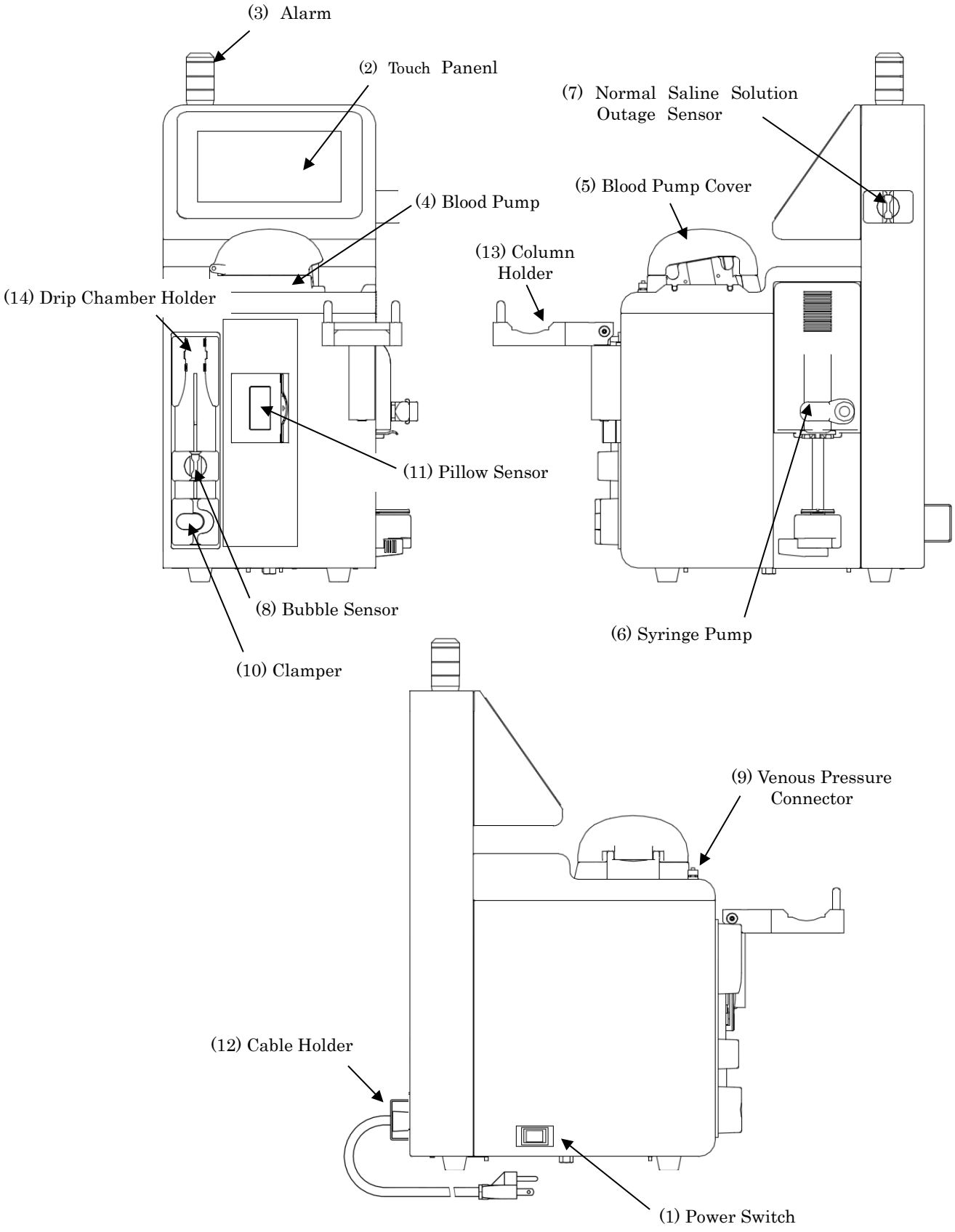
(13) Column Holder

- Set the Adacolumn

(14) Drip Chamber Holder

- Fix the drip chamber

Fig.1: Name of Each Part



4.2 Name of Each Part and Function of Adastand

Fig. 2 shows the name of each part of Adastand.

(1) Infusion Solution Hanger

- Hang the normal saline solution bag.

(2) Pole

- The height of the infusion solution hanger can be adjusted for 50cm.

(3) Handle

(4) Elevation Lever

- The height from the floor to the tabletop can be adjusted from 600mm to 800mm.

(5) Drawer

(6) Tube Clamp (2 pieces)

(7) Device Fixing Screw

(8) Waste Liquid Bucket

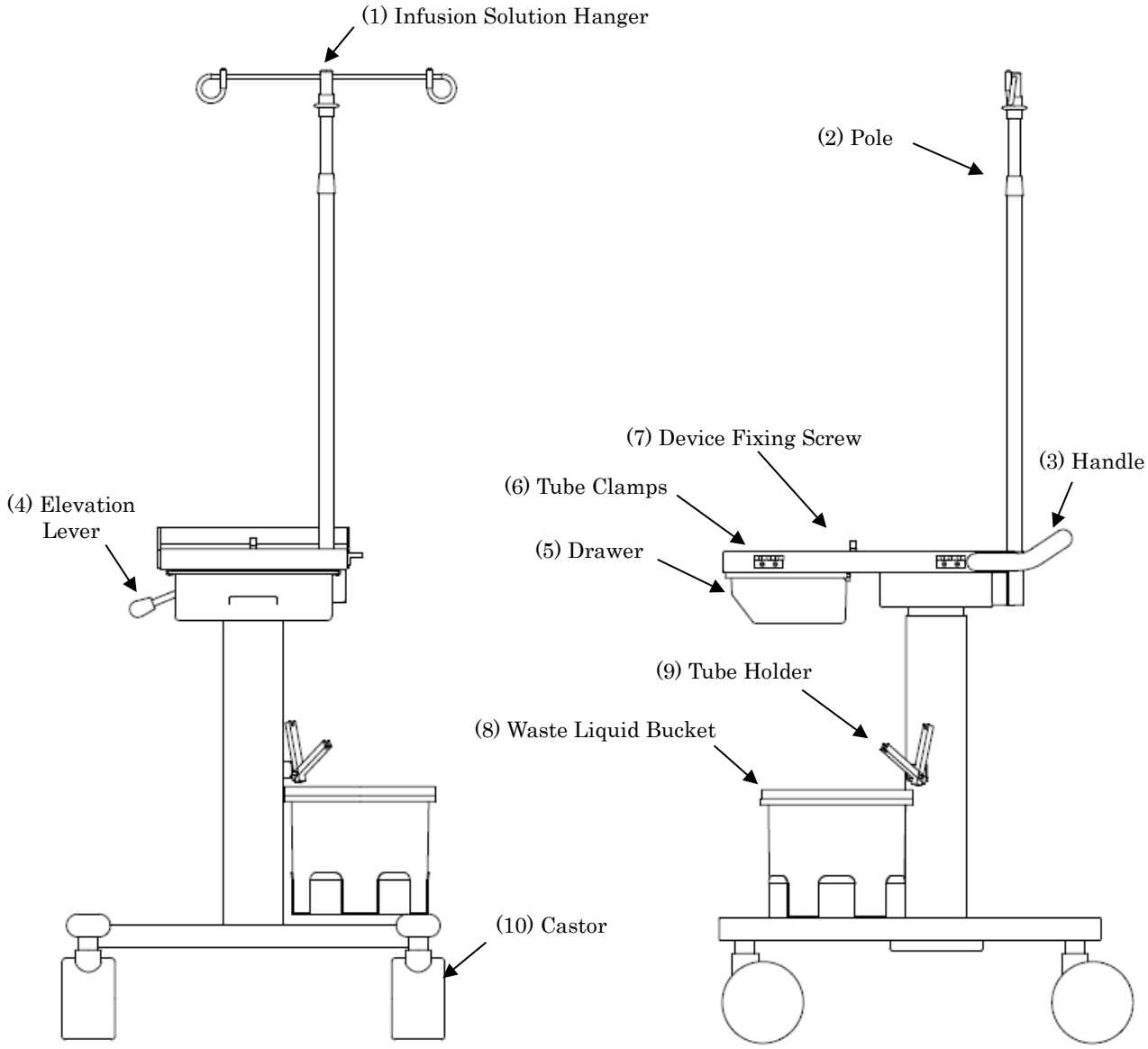
(9) Tube Holder

-Fix the tube above the waste liquid bucket.

(10) Castor

-Feature the locking mechanism.

Fig. 2: Name of Each Part



4.3 Specifications of Device

Rated voltage: 100-240V AC
Rated frequency: 50/60 Hz
Power consumption: 200 VA
Dimensions: 230mm (W) x 328mm(D) x 515mm(H)
Weight: Approx. 11kg

(1) Blood Pump

-Pump type:	Two-roller pump
-Present flow rate range:	Circulation stage: 10 to 50mL/min Preparation stage: 10 to 150mL/min
-Flow rate accuracy	±10%
-Default setup:	Two values can be set. Circulation flow rate setup Fast-forward flow rate setup.
-Safety mechanism:	Pump cover operation sensor Rotation Sensor

(2) Syringe Pump

-Present flow rate:	1 to 20mL/h
-Flow rate accuracy	1 to 4mL/h: ±15% 5 to 20mL/h: ±3%
-Default setup:	Two values can be set. Continuous infusion flow rate setup Fast-forward flow rate setup
-Safety mechanism:	Syringe sensor Syringe movement sensor Syringe completion sensor Plunger set sensor Plunger overload sensor Feed screw and nut of opening and closing sensor
-Applicable syringe:	TERUMO, NIPRO, JMS, TOP (20mL luer-locking type plastic syringe)

(3) Normal Saline Solution Outage Sensor
-Detection system: Ultrasonic system

(4) Bubble Sensor

- Detection system:	Ultrasonic system
- Detection sensibility:	Closed cell of 0.1mL or over
- Safety mechanism:	When the bubble sensor detects bubbles, the blood pump is immediately shut down, the bubble circuit is closed by the clamper, the abnormality is reported with warning buzzer, warning lamp, and monitor display. Almost no continuous air infusion measured (much lower than the value of 0.03mL/min).

(5) Internal Pressure of Venous Circuit

-Measurement region: Pressure in the drip chamber of venous blood circuit

-Measurement display range: -13.3 to 53.3kPa (−100 to 400mmHg)

-Venous pressure warning setup range: -13.3 to 53.3kPa (−100 to 400mmHg)

-Safety mechanism: When the pressure in the dip chamber or the venous circuit exceeds the venous pressure warning setup range, the blood pump is stopped automatically, and the abnormality is reported with the warning buzzer, warning lamp.

(6) Clamper

-Clamp pressure: 98kPa(1.0kgf／cm^2) or over

-Block-up system: Normal-open type

-Safety mechanism: When the device detects abnormality, the blood circuit is blocked up by the clamper.

(7) Pillow Sensor (Negative Arterial Pressure Sensor)

-Detection system: Mechanical switch

-Safety mechanism: When the abnormality (the pressure in the pillow becomes negative and the pillow shrinks due to blockage in blood vessel, etc) is detected by the negative arterial pressure sensor, the blood pump is immediately stopped, the blood circuit is closed by the clamper, and the abnormality is reported with the warning buzzer, warning lamp.

(8) Elapsed Time

- Time setup range: 1 to 180 minutes
This function is enabled only for use under the circulation mode.

- Default value setup: One value can be set up.(60min)

- Setup time: To confirm the setup time during the use under the circulation confirmation: mode, pressing the〔Setup〕button displays the setup time. The display can be switched to the elapsed time by pressing the〔Setup〕button again.

- Elapsed time: When the safety mechanism is activated while in use under the display circulation mode, the elapsed time is displayed continuously even when the device is re-activated.
pressing the〔Setup〕button again.
By turning the device off while the blood pump stops, the elapsed time is erased.
(Refer to Chapter 5 “5.1.5 Syringe Pump Panel”)

- Safety mechanism: When the setup time is due, the end of the treatment time is notified with the Treatment End buzzer and the warning lamp.
  Note that, however, the blood pump and the syringe pump will not be stopped to prevent blood coagulation.

(9) Warning Sound

- Volume: 65dB and over

(10) Warning Light

- Two-color display:

Preparation Mode:
Green light is on and off (while the blood pump is in operation)

Circulation Mode:
Green light is on steadily (while the blood pump is in operation)
Green light is on and off (note1) (after Setup Time elapse)

Blood Transfusion Mode:
Green light is on steadily (while the blood pump is in operation)
Green light is on and off (note1) (after Transfusion integrated amount reached 300mL)

Abnormal time:
Red light is on and off. (note1)

note1:Message is displayed at the same time.
(Refer to Chapter 7 " Alarm Function and Countermeasures")

(11) Device Classification

- Protection type against electric shock: Class 1 equipment
- Protection degree against electric shock: Type BF equipment
- Classification of applied part against harmful water entry: IPX1
- Classification of Operation/Drive mode: Continuous action device

(12) Specified blood tubing system and apheresis column

- Blood tubing system:

Product name	Supplier
ADACIRCUIT	Local Otsuka representative

- Apheresis column:

Product name	Supplier
ADACOLUMN®	Local Otsuka representative

4.4 Operation Principle

The device is a two-roller blood pump to execute extracorporeal circulation by using the depurator for blood cell removing depurator and the operating principle of the pump drive unit is as follows:

(1) Upon turning on the power, the self-diagnosis (self-check) regarding whether or not the clamper functions normally will be initiated automatically.

(2) When the self-check reveals no problem, an ending sound will be initiated, and the default setup value for venous pressure, blood pump flow rate, syringe pump flow rate and elapsed time on the〔Preparation Mode〕window will appear.

(3) To change the default setup value, choose and change the parameter to be changed on the Setup window.

(4) After setting the blood circuit and the normal saline solution, pressing the〔Start〕button on the Blood Pump panel under the〔Preparation mode〕rotates the roller to feed the normal saline solution for cleaning the circuit. When the solution is used up, the liquid outage is detected by the normal saline solution outage sensor to stop the roller.

(5) Next, after attaching the artery-side circuit to the patient, pressing the〔Start〕button on the Blood Pump panel under the〔Circulation mode〕implements the in-circuit blood substitution. By pressing the〔Start〕button again, the roller stops.

(6) After attaching the venous-side circuit to the patient, pressing the〔Start〕button on the Blood Pump panel under the〔Circulation mode〕rotates the roller to start the circulation work.

(7) During the work, when the error sensor is activated, the error signal is converted in to an electrical signal and transmitted to the warning device, thereby activating safety device to issue a warning sound, etc.

(8) When the safety device is activated, press the〔Sound Off〕button to stop the warning sound check the error to restore the device to the normal state. Then, press the〔Alarm Cancel〕button and press the〔Start〕button on the Blood Pump panel again, which ensures to continue to the work.

(9) When the present time is due, an ending sound will be activated. Press the〔Sound Off〕button to stop the sound, and press the〔Start〕button on the Blood Pump panel to stop the roller.

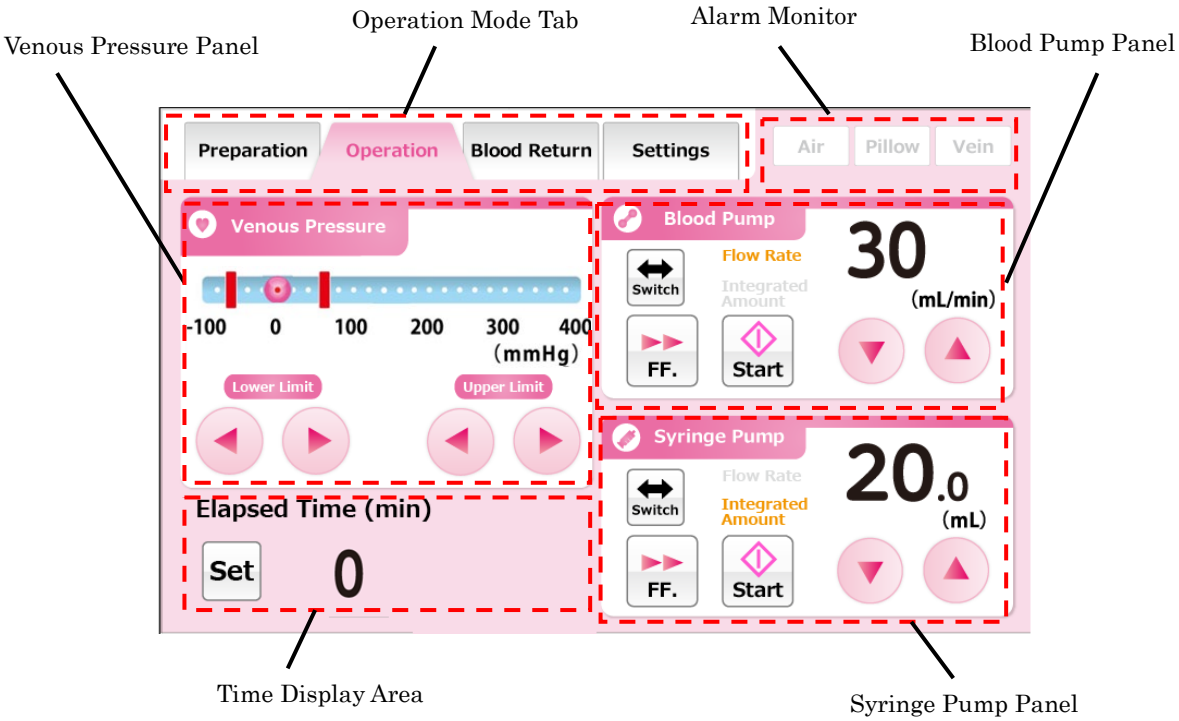
(10) After stopping the roller, press the〔Start〕button on the Blood Pump panel under the〔Blood transfusion mode〕to feed a certain amount of normal saline solution into the circuit to transfuse the blood to the patient.

Chapter 5 Window Configuration and Operation

In this Chapter, the window configuration and operation will be described. To ensure smooth window operation, be sure to understand how to see the window, operation of the buttons, etc, first.

5.1 Configuration and Operation of Main Window

This is the window on which preparation of treatment, circulation operation, blood transfusion operation and setting up of device are to be done.



5.1.1 Operation Mode Tab

Indicate the operation mode by using letters and background colors to the operator. In addition, pressing the tab enables to switch the operation mode. The outline of the operation modes and the corresponding background colors will be shown below.

Preparation Mode

This is the mode where the cleaning and priming of the blood circuit with the normal saline solution are executed. The background color is light blue.

Circulation Mode

This is the mode where treatment is expected by circulating the blood of patient. The background color is pink.

Blood Transfusion Mode

This is the mode where the blood is transfused to the patient. The background color is orange.

Setup Mode

This is the mode where setting up of the device is done, regarding normal range of venous pressure, flow rate of blood pump, flow rate of syringe pump, etc. The background color is green.

WARNING

●Be sure to check the operation mode whenever the device is to be operated. Incorrect use of the operation mode may cause death or serious harm to patient.

Supplement:
- The Circulation Mode tab and the Blood Transfusion Mode tab become activated after the normal end of the leak check.
Refer to Chapter 6 “6.3 Cleaning and Priming of Blood Circuit for details”.

5.1.2 Alarm Monitor

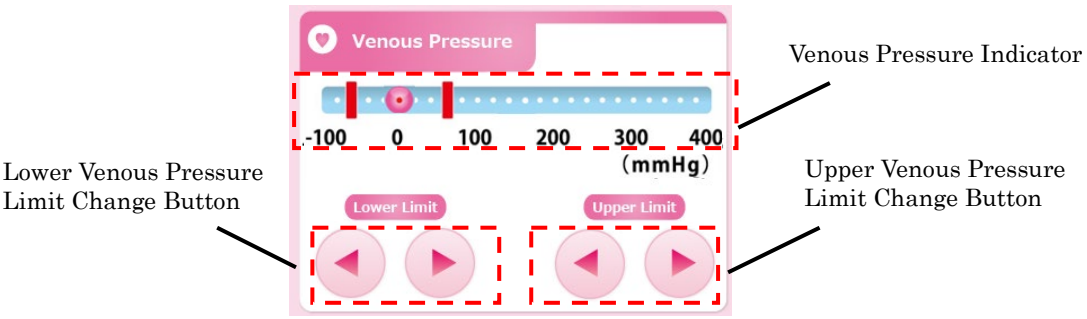
Display the state of venous-side bubble sensor, pillow sensor and venous pressure sensor in real time. When each sensor detects an error, the background color of the sensor is displayed in red.

Normal

Error

5.1.3 Venous Pressure Sensor

The venous pressure can be monitored and the normal range of venous pressure can be changed on this panel.



Checking the Venous Pressure Value

The mark on the venous pressure indicator shows the current venous pressure value.

Changing the Upper Venous Pressure Limit

Pressing the〔Upper Venous Pressure Limit Change〕button enables to move the red-color bar showing the lower venous pressure limit value.

Supplement:
- It is not possible to set the upper venous pressure limit value that is lower than the lower venous pressure limit value.
- The increment of the lower venous pressure limit value is 10mmHg or 1.33kPa.
- Pressing the〔Upper Venous Pressure Limit Change〕button for 20 seconds in a row generates an error as the touch panel failure. (Error Number 43)

Changing the Lower Venous Limit Value

Pressing the〔Lower Venous Pressure Limit Change〕button enables to move the red-color bar showing the lower venous pressure limit value.

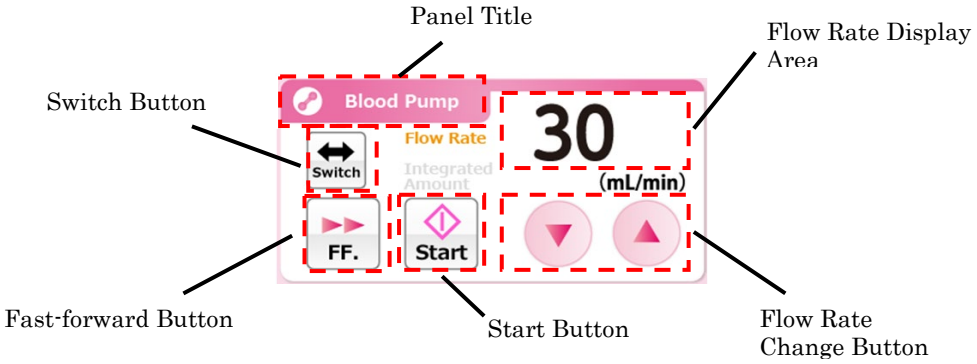
Supplement:
- It is not possible to set the lower venous pressure limit value that is higher than the upper venous pressure limit value.
-The increment of the lower venous pressure limit value is 10mmHg or 1.33kPa.
-Pressing the〔Lower Venous Pressure Limit Change〕button for 20 seconds in a row generates an error as the touch panel failure. (Error Number 43)

WARNING

●Set the venous pressure in an appropriate range by a healthcare professional.

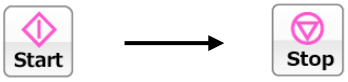
5.1.4 Blood Pump Panel

The control and the integrated amount of liquid delivery of the blood pump can be checked.



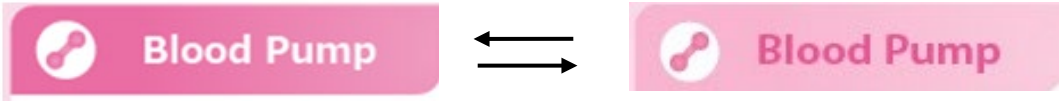
Activating the Blood Pump

Pressing and holding the〔Start〕button for about one second activates the blood pump. When the pump is activated, the〔Start〕button is switched to〔Stop〕button.



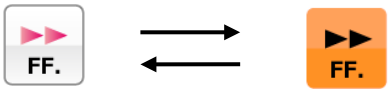
Supplement:
・An error occurs to prevent from forgetting to start when holding down the〔Start〕button for less than one second, (Error Number 05)

In addition, while the blood pump is in operation, the Panel Title blinks in two thick and thin colors.



Fast-forwarding the Blood Pump

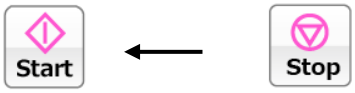
Pressing the〔Fast-forward〕button while the blood pump is in operation, the blood pump is activated at the fast-forwarding flow rate. While in the fast-forwarding operation, the〔Fast-forward〕button color is switched to orange. Pressing the〔Fast-forward〕button again operates the blood pump at the original flow rate, and the button color is switched to white.



Supplement:
- The〔Fast-forward〕button enabled only when the operation mode is the〔Preparation Mode〕.
- While the fast-forwarding operation, the fast-forward flow rate is displayed at the Flow Rate display area.

Stopping the Blood Pump

While the blood pump is in operation or in the fast-forward operation, pressing the〔Stop〕button stops the blood pump operation. When the blood pump stops, the〔Stop〕button is switched to the〔Start〕button.



Supplement
- The standstill time of blood pump is observed when being in the〔Circulation Mode〕 and the〔Blood Transfusion Mode〕.
  Caution is displayed every 5 minutes after the blood pump stops. (Error Number 06)
  Warning is displayed when 60 minutes have elapsed since the blood pump stops, and the treatment cannot be continued. (Error Number 47)

Changing the Flow Rate of Blood Pump

The flow rate of the blood pump can be changed by pressing the〔Flow Rate Change〕button.

Supplement:
- Irrespective of the start/stop state of the blood pump, the flow rate of the blood pump can be changed.
- While the blood pump is in operation, the change in flow rate is reflected on the blood pump operation in real time.
- Max. flow rate: 50 (mL/min)
- Min. flow rate: 10 (mL/min)
- Flow rate increment: 1 (mL/min)
- Pressing the〔Flow Rate Change〕button for 30 seconds in a row generates an error as the touch panel failure. (Error Number 43)

Changing the Fast-forward Flow Rate of Blood Pump

Pressing the〔Flow Rate Change〕button while the fast-forwarding operation of the blood pump enables to change the fast-forward flow rate of the blood pump.

Supplement
- Max. flow rate: 150 (mL/min)
- Min. flow rate: 10 (mL/min)
- Flow rate increment: 1 (mL/min)

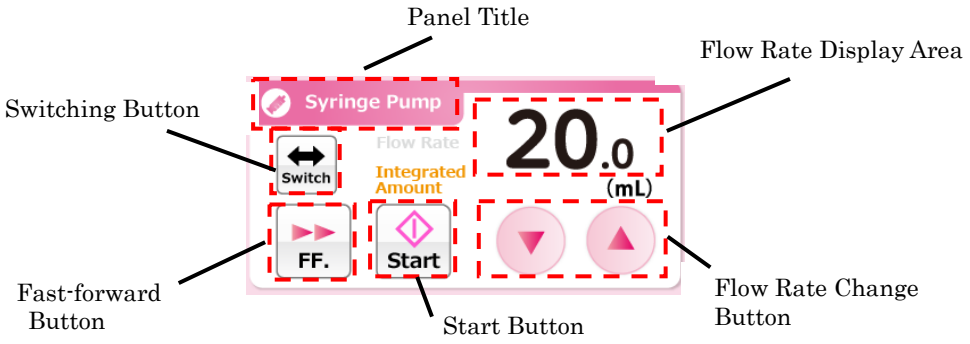
Checking the Integrated Amount of Liquid Delivery of Blood Pump

Pressing〔Switch〕button displays the integrated amount of liquid delivery of the blood pump in the Flow Rate Display Area.

Supplement
- For〔Blood Transfusion mode〕and the〔Preparation mode〕, the operation of the blood pump is not added to the integrated amount of liquid delivery.

5.1.5 Syringe Pump Panel

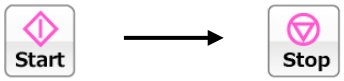
Control of the syringe pump and the integrated amount of liquid delivery can be checked on this panel.



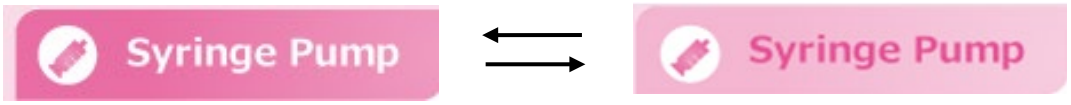
Supplement:;
- The Syringe Pump Panel becomes disabled when the operation mode is 〔Blood Transfusion Mode〕
- When the use of the syringe pump is in the〔Disabled〕position under the Setup mode, the Syringe Pump Panel becomes disabled.

Activating the syringe Pump

Pressing and holding the〔Start〕button for about one second activates the syringe pump. When the pump is activated, the〔Start〕 button is switched to the〔Stop〕button.



In addition, while the syringe pump is in operation, the Panel Title blinks in two thick and thin colors.

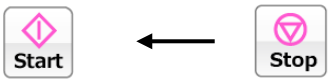


Fast-forwarding the Syringe Pump

Pressing the〔Fast-forward〕button with the syringe pump is in a stop, the syringe pump is activated at the fast-forwarding flow rate. While the〔Fast-forward〕button is pressed, the〔Start〕button becomes disable, and the color of the〔Fast-forward〕button is switched to orange. The〔Fast-forward〕 button is released, the syringe pump stops, and the color of the〔Fast-forward〕button is switched to white.

Supplement;
-When the operation mode is the〔Preparation Mode〕, the〔Fast-forward〕 button is enabled only when the syringe pump is stopped.
-When the operation mode is the〔Circulation Mode〕, the〔Fast-forward〕 button is enabled only when the blood pump is operation and the syringe pump is stopped.
-While in the fast-forwarding operation, the fast-forward flow rate is displayed at the Flow Rate display area.
-Fast-forward flow range: 400 (mL/h)
-Fast-forward flow range can not be changed

Stopping the Syringe Pump
While the syringe pump is in operation, pressing the〔Stop〕button stops the syringe pump operation.
When the syringe pump stops, the〔Stop〕button is switched to the〔Start〕button.



Changing the Flow Rate of Syringe Pump
The flow rate of the syringe pump can be changed be changed by pressing〔Flow Rate Change〕button. The flow rate that is currently set up is displayed in the〔Flow Rate Display Area〕.

Supplement:
- Irrespective of the start/stop state of syringe pump, the flow rate of the syringe pump can be changed.
- While the syringe pump is in operation, the change in flow rate is reflected on the syringe pump operation in real time.
- The fast-forward flow rate cannot be changed.
- Max. flow rate: 20 (mL/h)
- Min, flow rate: 1 (mL/h)
- Flow rate increment: 1 (mL/h)
- Pressing the〔Flow Rate Change〕button for 18 seconds in a row generates an error as the touch panel failure. (Error Number 43)

Checking the Integrated Amount of Liquid Delivery of Syringe Pump
Pressing the〔Switch〕button displays the integrated amount of liquid delivery of the syringe pump in the Flow Rate Display Area.

Supplement:
- Operation of the syringe pump under the〔Preparation mode〕and the〔Circulation mode〕are added to the integrated amount of liquid delivery.

5.1.6 Time Display Area

The circulation time can be checked and changed in this area.

Supplement:
- The Time Display Area is displayed only under the〔Circulation mode〕.

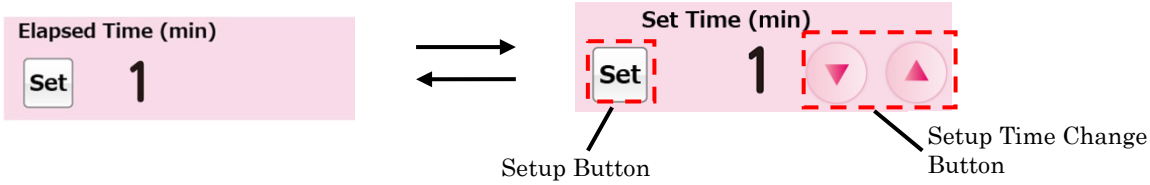
Checking the Elapsed Time

Under the state that the〔Setup〕 button is not pressed, the Time Display Area displays the〔Elapsed Time〕.

Supplement:
- Elapsed time increment: 1 minute

Checking the Elapsed Time

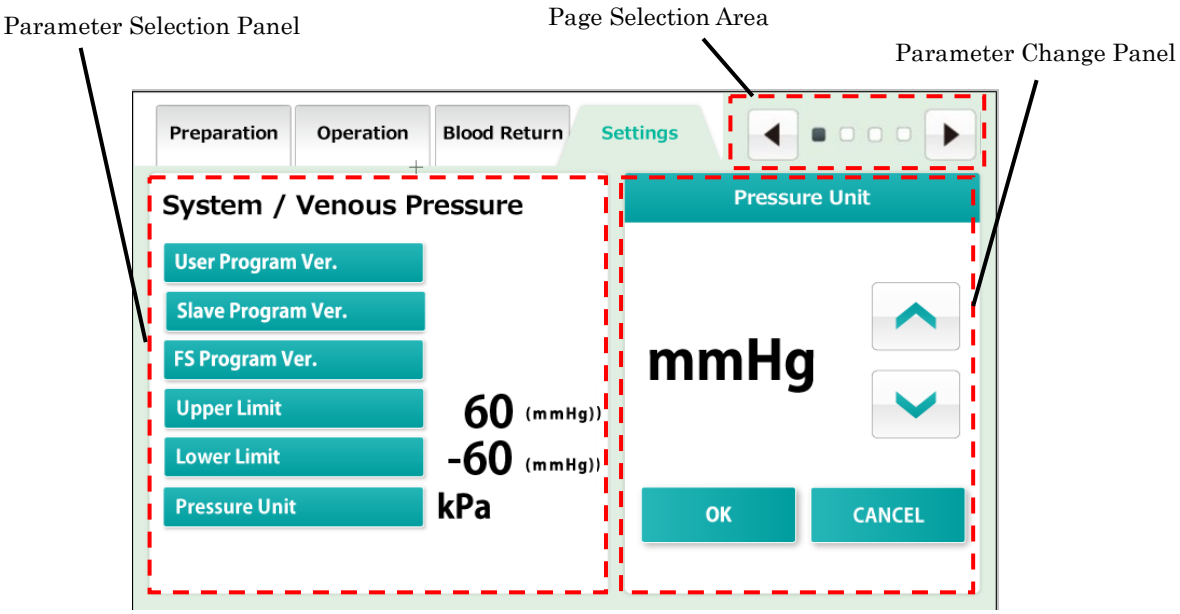
Pressing the〔Setup〕 button display〔Setup Time〕in the Time Display Area. In addition, the color of the setup button is switched to orange, and the〔Setup Time Change〕 button appears. Pressing〔Setup〕 button again〔Elapsed Time〕 will be displayed in the Time Display Area.



Supplement:
- Setup time increment: 1 minute
- The setup time can be set up to a maximum of 180 minutes.
- The setup time is reflected in real time on the system each time the〔Setup Time Change〕 button is pressed.
- Pressing the〔Setup Time Change〕 button for 33 seconds in a row generates an error as the touch panel failure. (Error Number 43)

5.2 Configuration and Operation of Setup Window

This is the window on which the default setups of the device are viewed and changed and the error history is confirmed.

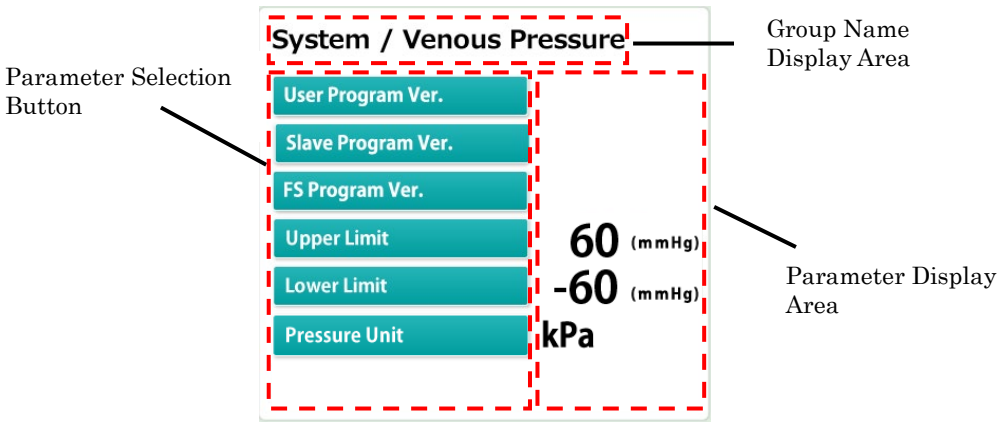


Supplement:

- At time of re-booting the device, a series of treatment phases is assumed to be completed, and the device setups are overwritten with the values set up on this window. Note, however, that only while the blood pump or the syringe pump is in operation, when the device is subjected to abnormal end due to power failure, etc., the device setup made before the power failure will be maintained even after the device is rebooted.

5.2.1 Parameter Selection Panel

The current device setups can be checked on this panel.



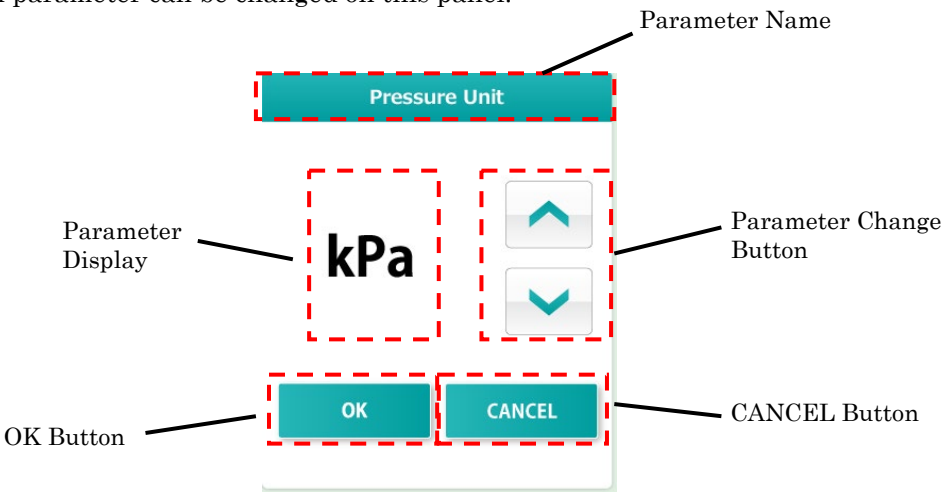
Checking the Group
The Setup mode consists of four groups of System information, Venous Pressure, Blood Pump, and Syringe Pump. The name of currently displayed group in displayed in the〔Title Display Area〕

Choosing the Parameter
Press the〔Parameter Selection〕button of the parameter to be changed. The chosen parameter is reflected on the〔Parameter Change〕panel.

Checking the Parameter
The current setup value is displayed in the〔Parameter Display Area〕located to the right of the〔Parameter Selection〕button of the parameter to be checked.

5.2.2 Parameter Change Panel

The chosen parameter can be changed on this panel.



Changing the Parameter
The content of〔Parameter Display Area〕can be changed by pressing the〔Parameter Change〕button.

Fixing the Parameter Changed
The content of〔Parameter Display Area〕can be fixed by pressing the〔OK〕button.
The content fixed is saved on the system and reflected on the Parameter Selection Panel.

Restoring the Parameter Changed
The changed content can be restored to the before-change state by pressing the〔CANCEL〕button.

> Supplement:
> - When the change is fixed by pressing the〔OK〕button, the change cannot be restored to the before-change state even when the〔CANCEL〕button is pressed.

5.2.3 Page Selection Area

The setup window consists of four pages. The ■ mark shows the current page.
Transition of page can be done by pressing the〔Feed Page〕button of〔Return Page〕button.

"System/Venous Pressure" page

Confirming the current software version and setting the venous pressure panel.

"Blood Pump" page

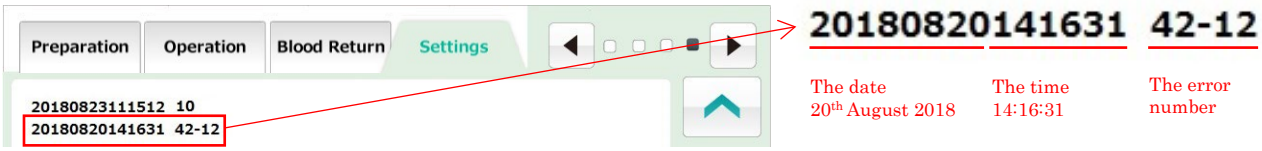
Setting the blood pump panel.

"Syringe Pump" page

Setting the Syringe Pump Panel.

"Error History" page

The date and time when an error occurred and the error number is displayed from the newest to the oldest. The maximum number of lines that can be displayed is 1000.



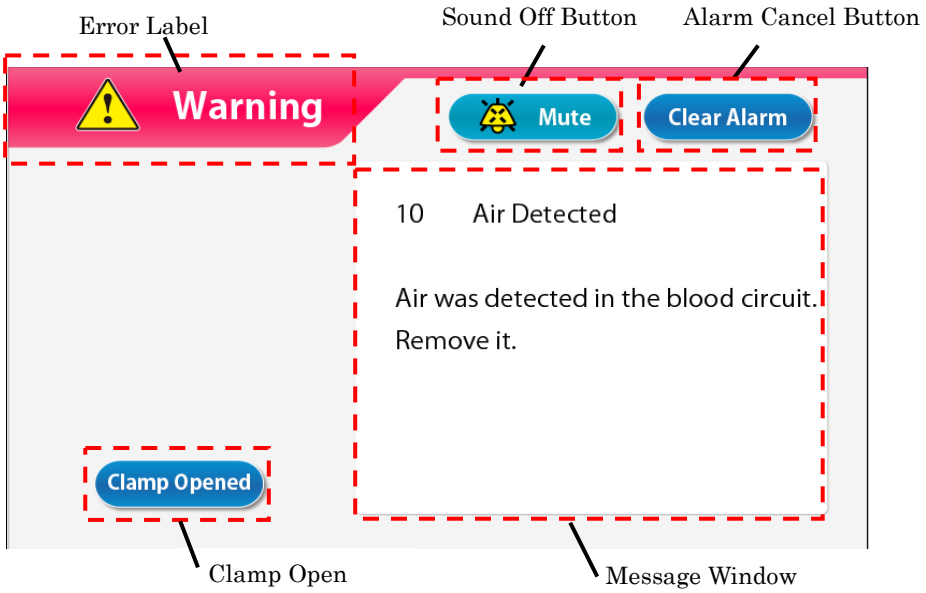
Supplement:
-Refer to Chapter 6 "6.7 Checking and Changing the Device Setups for details of setting".

CAUTION

●Check that the syringe to be used actually and the syringe that is set for the device agree. When the syringe that is different from the setup is used, flow rate accuracy and the safety function of the syringe pump will not operate correctly.

5.3 Configuration and Operation of Error Window

Names of the major parts of the window will be shown below.
This window is displayed when the device detects any error. When an error is detected, it is displayed in the window in the style shown below.



Check the error message, and eliminate the error cause as instructed on the message window or according to" Chapter 7 "Alarm Function and Countermeasures"

Cancelling the Alarm Sound

To cancel the alarm sound, press the〔Sound Off〕button. The display in the window remains and only the alarm sound is cancelled.

> Supplement:
> - When two minutes elapse after pressing the〔Sound Off〕button, the alarm sound will be re-initiated.

Cancelling the Alarm State

To cancel the alarm state, press the〔Alarm Cancel〕button. The alarm lamp will go off, the alarm sound is cancelled, and the〔operation mode〕is restored to the mode (main window) available when the error occurred.

> Supplement:
> - Even when the〔Alarm Cancel〕button is pressed, the operating condition of the clamper remains unchanged. However, only when the error "41 Low Battery Charge" occurs during the self-diagnosis, the alarm sound does not occurs if you push the [Sound Off] button once. Refer to Chapter 3 "3.7 Battery Charging after Installation".

Opening the Clamp

When operating the clamper, press the〔Sound Off〕button and then press the〔Clamp Open〕button.

> Supplement:
> - The〔Clamp Open〕button is enabled only when the〔Sound Off〕button is pressed.

Message Window

The error message and the countermeasure are displayed in the window.

Chapter 6 Operation Method

6.1 Starting Up the Device

Turning on the power

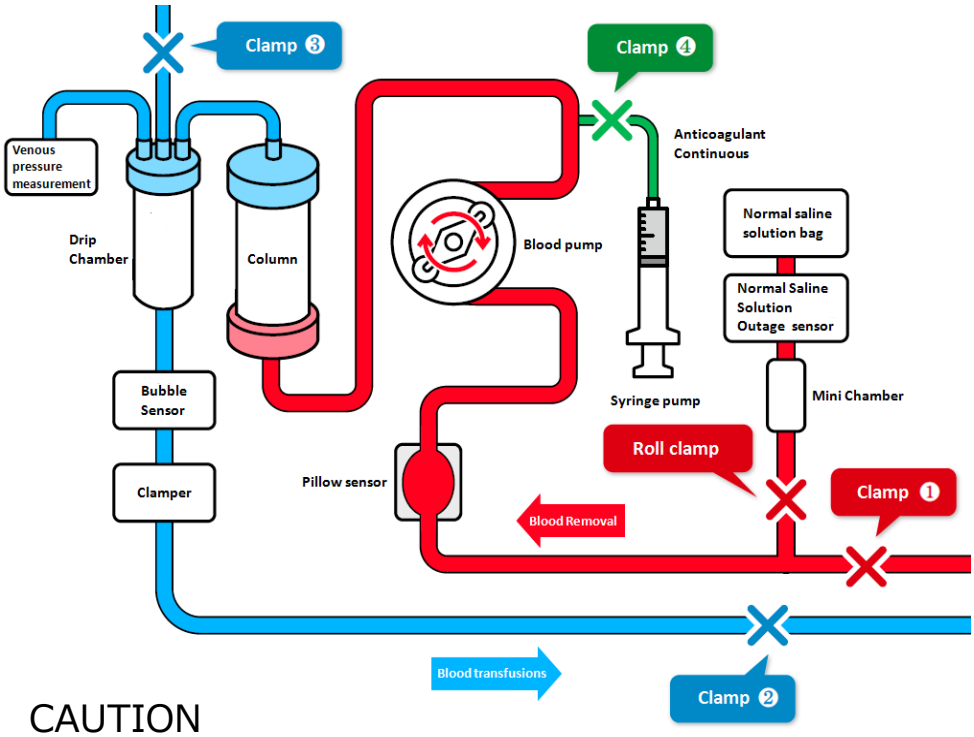
1. Pressing the power switch starts the inspection operations, including illumination of self-diagnosis lamp and the alarm lamp, and check if the clamper operates correctly. Check the device condition according to Chapter 8 “8.1.1 Pre-operation Inspection”.
2. If there is no abnormality found in the result of self-diagnosis, the main window will be displayed on the touch panel.

> Supplement:
> - Remove the syringe when starting up the device. If a syringe is detected during self-diagnosis, syringe detection error will be generated. (Error Number 04)

6.2 Mounting the Blood Circuit

The figure blow shows a diagram of the blood circuit.
For details on the blood circuit, see the operating instructions supplied with the specified blood circuit.

Circuit Diagram



⚠ CAUTION

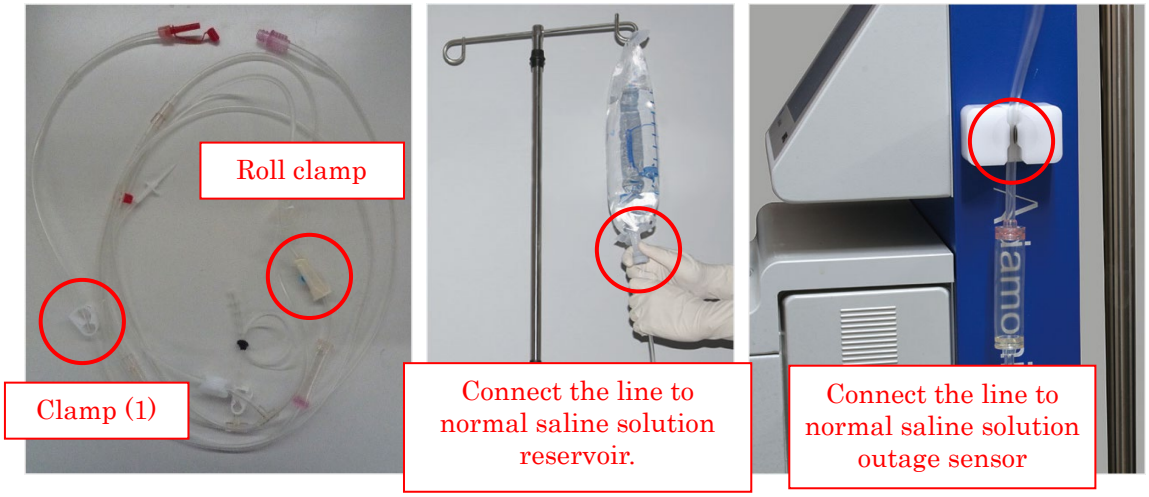
- **After mounting the blood circuit, check if there is no breaking and twisting on the circuit. The safety mechanism has the potential not to detect the hazardous condition in some cases.**

(1) Installing the Normal Saline Solution

Set the normal saline solution bag on the Adastand.

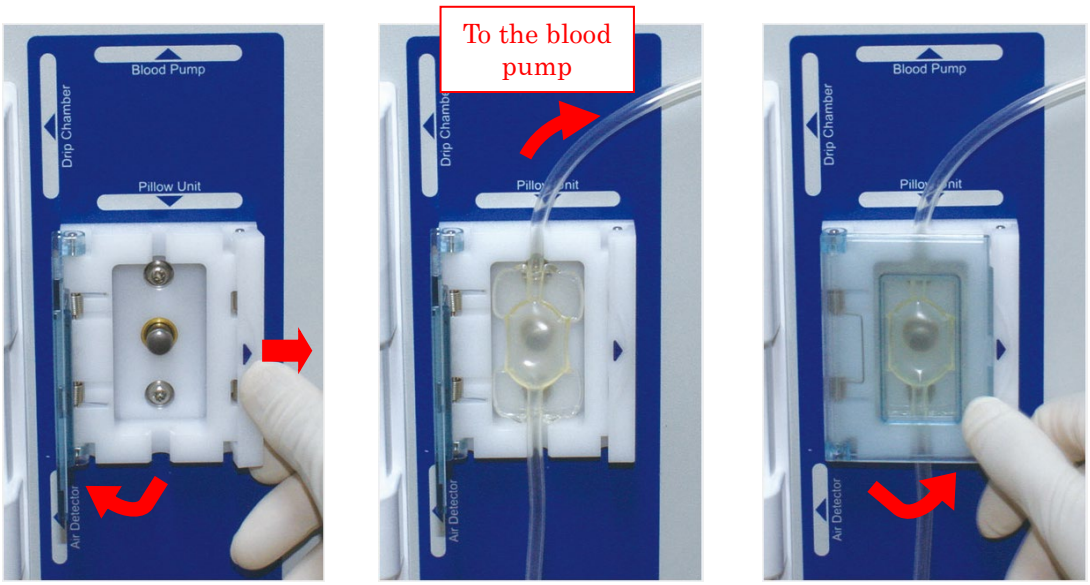
(2) Connecting the Blood Removal-side (Red)

1. Close the clamp (1) of the blood removal-side circuit (red) and the roll clamp of the normal saline solution line.
2. Connect the normal saline solution line to the normal saline solution bag and then to the normal saline solution outage sensor.

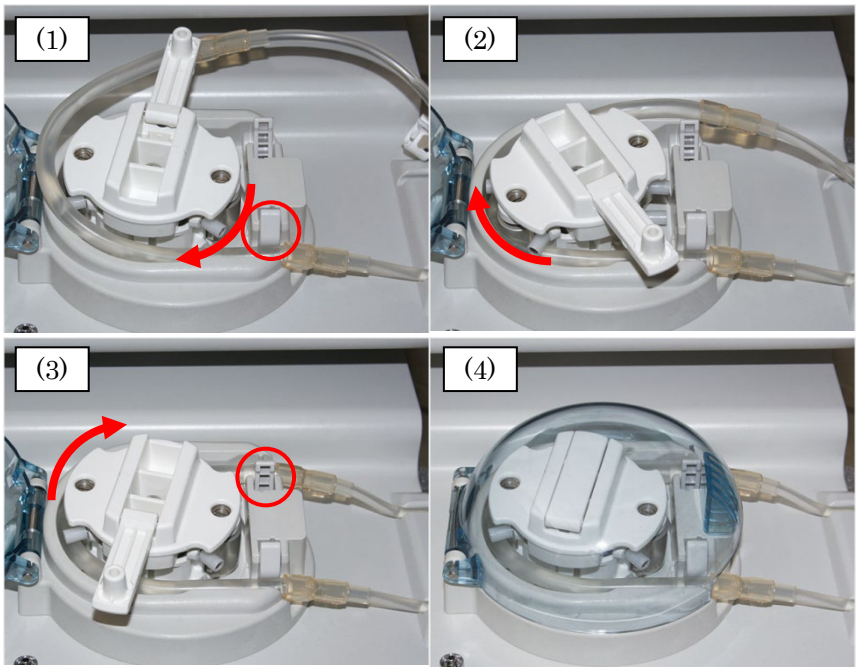


3. Set the pillow to the pillow sensor.

> Supplement:
> - At this time, the pillow should be mounted so that the blood can flow from bottom up.



4. Mount the pump tube to the blood pump.



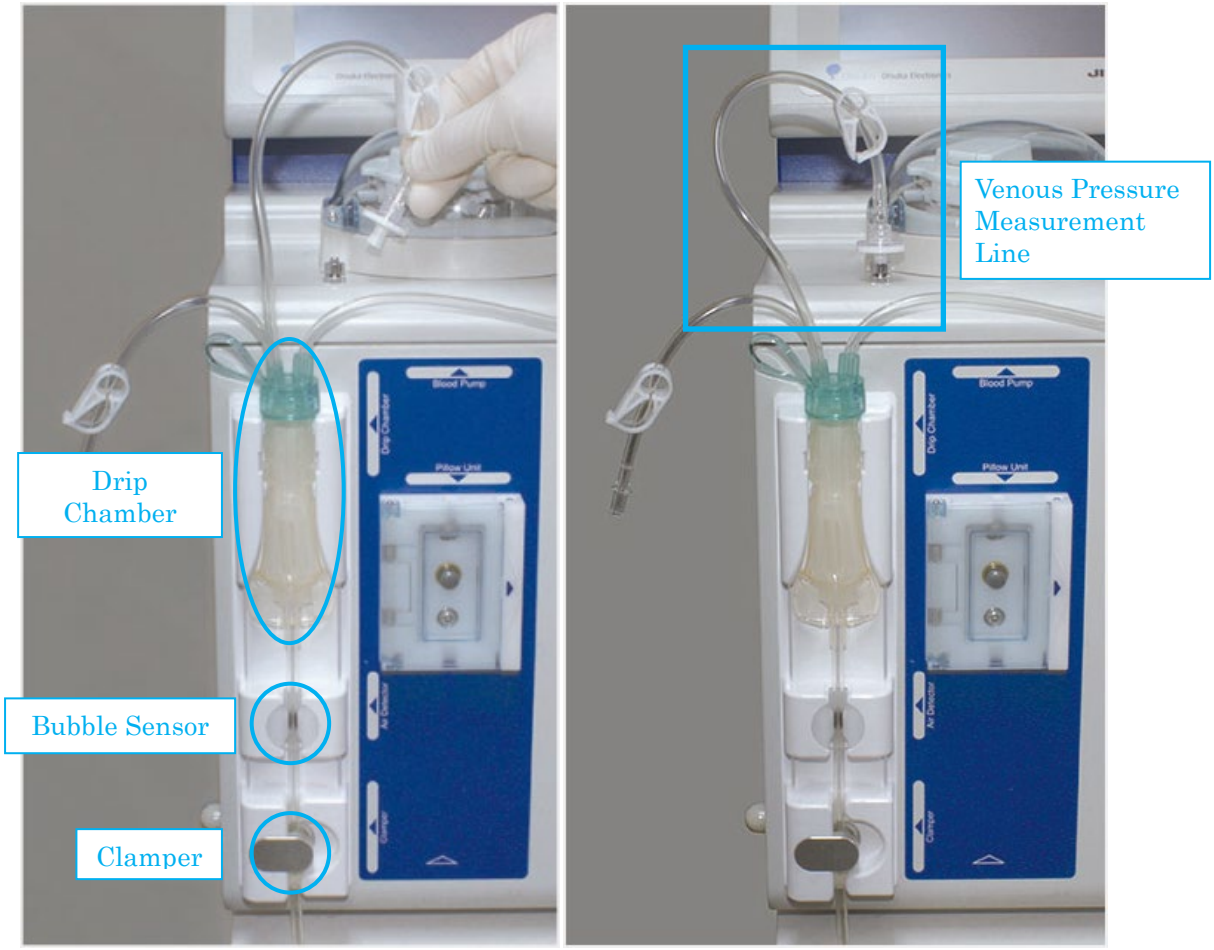
Supplement:
(1) Mount the pump tube to the guide on the front side.
(2) Rotate the pump roller manually to roll the pump tube into the pump roller.
(3) Mount the pump tube to the guide on the back side.
(4) Close the cover.

(3) Connecting the Column and the Circuit

1. Connect the blood removal-side (red) and the blood transfusions side circuit (blue) to the Adacolumn, respectively.

(4) Setting the Blood Transfusion-side Circuit (Blue)

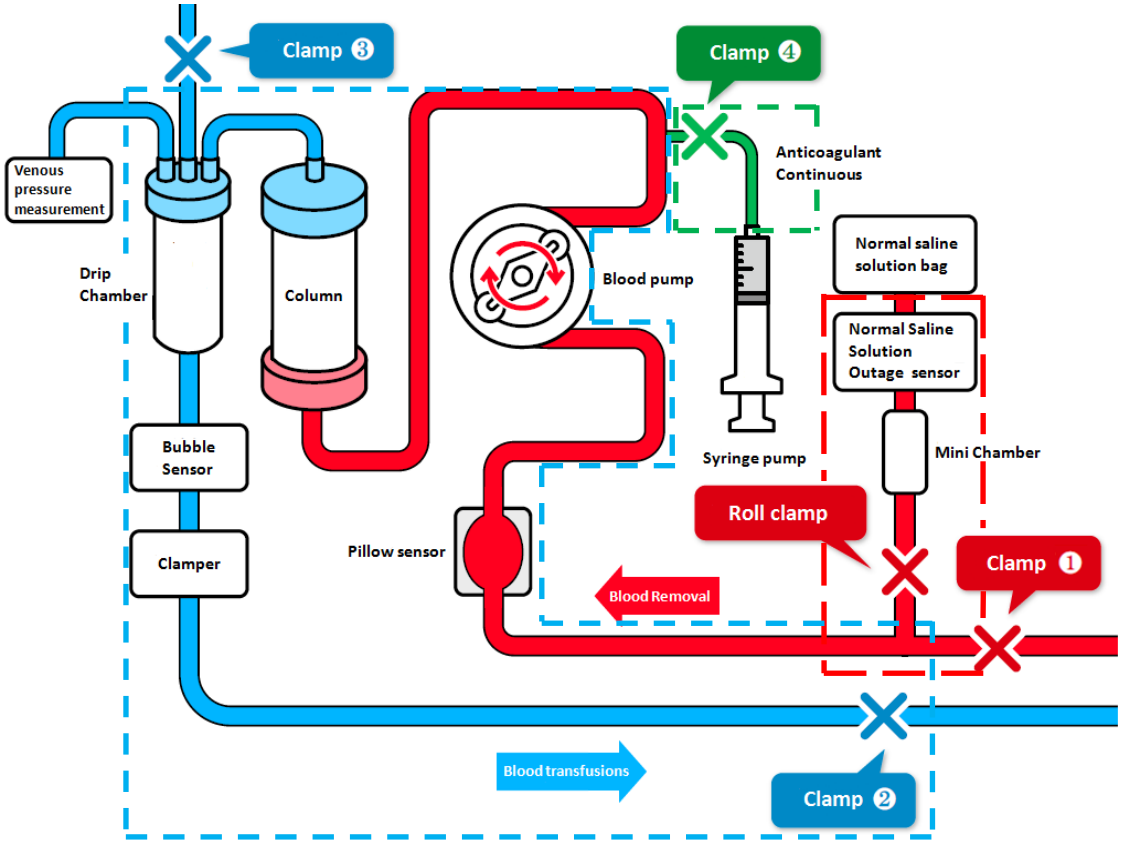
1. Set the drip chamber on the drip chamber holder and venous line on the bubble sensor and the clamper respectively.
2. Connect the venous pressure measurement line to the venous pressure connector via the protection filter.



3. Lead the indwelling needle (blood access) connection section (Blue) into the drain bucket to hang on the tube holder. At this time, close the Clamp (2).

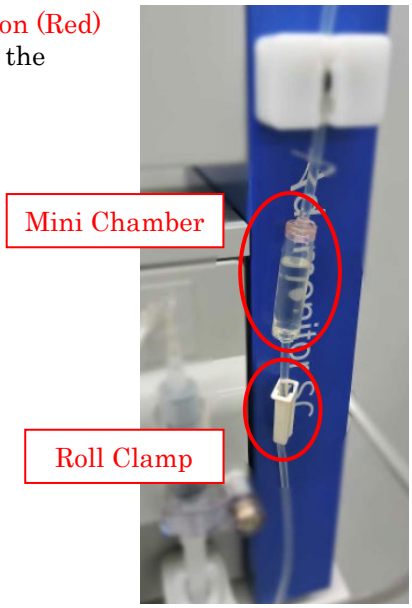
6.3 Cleaning and Priming of Blood Circuit

Circuit Diagram



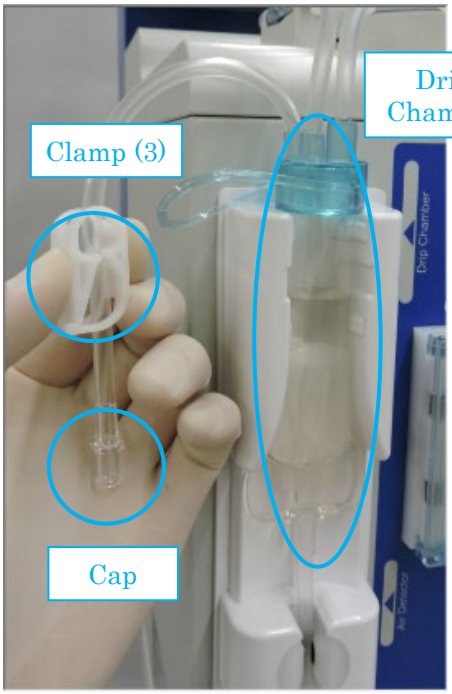
(1) Charging the Blood Removal-side Circuit (Red) (the red dotted line in square in the Circuit Diagram)

1. Fill the mini chamber on the normal saline solution line and open the roll clamp.
2. Lead the indwelling needle (blood access) connection section (Red) into the drain bucket and open Clamp (1) to clean inside of the circuit and bleed air.
3. Close Clamp (1)



(2)Rotating the Pump for Cleaning/Debubbling （In-column/Blood Transfusion-side Circuit (Blue)）(the blue dotted line in square in the Circuit Diagram)

1. Open Clamp (2). The roller starts to rotate by pressing the 〔Start〕 button of the blood pump under the〔Preparation mode〕.
2. Press the〔Fast-forward〕button to clean and debubble inside the Adacolumn/circuit at the flow rate of about 100mL/min. *Shake the column well to fully remove the bubbles.
3. When the debubbling in the column is completed, use the〔Stop〕button to stop the blood pump.
4. Close Clamp (2) and open the cap of the liquid level adjustment line of the drip chamber and Clamp (3).
5. Press the〔Start〕button again to rotate the blood pump and stop the pump when the liquid level in the drip chamber reaches around 3/4 level.
6. Close the cap of the liquid level adjustment line and Clamp (3), and open Clamp (2).



Supplement:
For the cleaning and debubbling, 1500mL of normal saline solution is used.
Before replacing the normal saline solution bag, be sure to stop the blood pump.

(3) Implementing the Leak Test

1. Check that the clamp (4) of the anticoagulant continuous infusion is closed.
2. Press〔Leak Check〕button of the venous pressure panel under the〔Preparation mode〕.
3. The clamper closes and the blood pump starts to operate.
4. The blood pump stops automatically when the venous pressure reaches 200mmHg.
5. Watch the venous pressure indictor to check there is no pressure drop. The leak check will be completed, if there is no problem found,

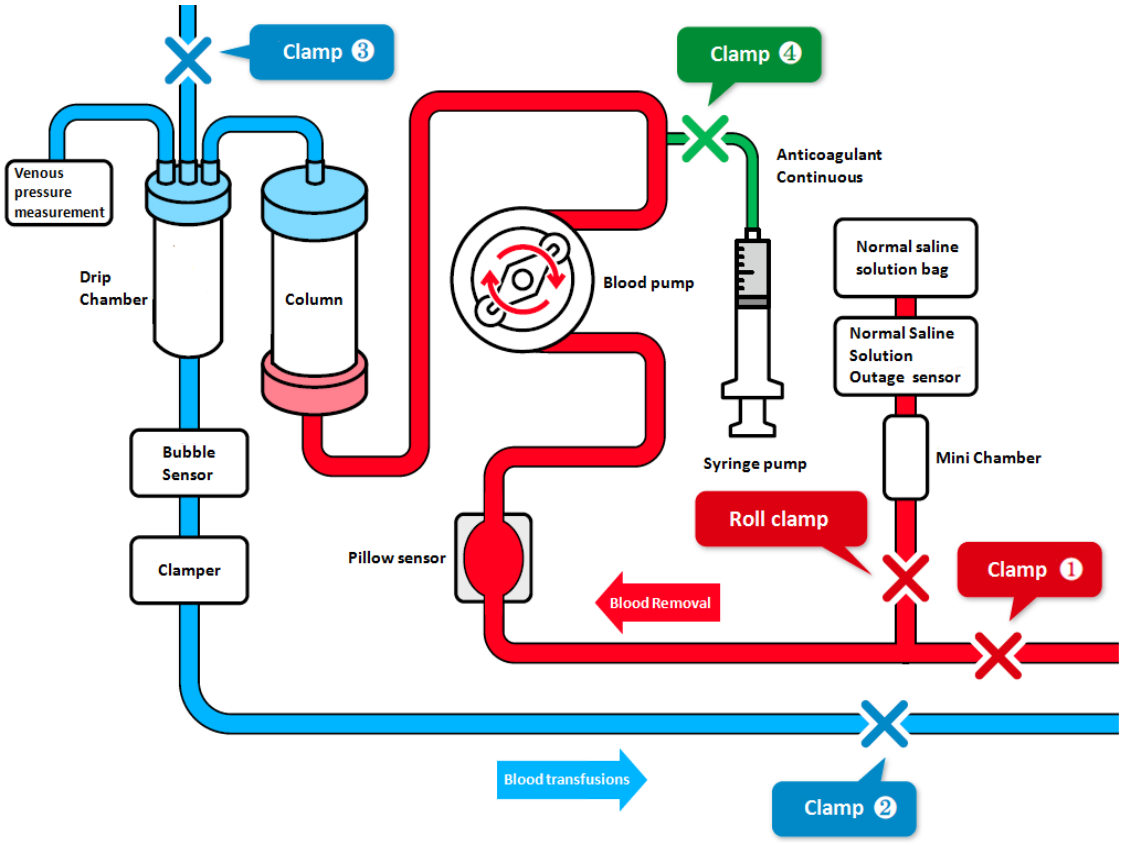
> Supplement:
> - After the blood circuit priming, make sure to implement the leak test before replacing the inside of circuit with the blood.
> - Where there the〈Leak Check〉error (Error No. 50), check the following:
>
> If the column and the Blood Removal-side Circuit (Red) and the column, and the Blood Transfusion-side (Blue) are properly connected, respectively.
> If the venous pressure line and venous pressure connector are connected properly.
> If the clamp of the venous pressure line is open.

> Supplement:
> - Circulation Mode Tab and Blood Transfusion Mode Tab become activated after the normal end of the leak check.

(4) Replacement of Anticoagulant Normal Saline Solution

1. Replace the normal saline solution line with the anticoagulant normal saline to replace the inside of column and circuit.

6.4 Anticoagulant Line Cleaning, and Mounting and Priming of the Syringe



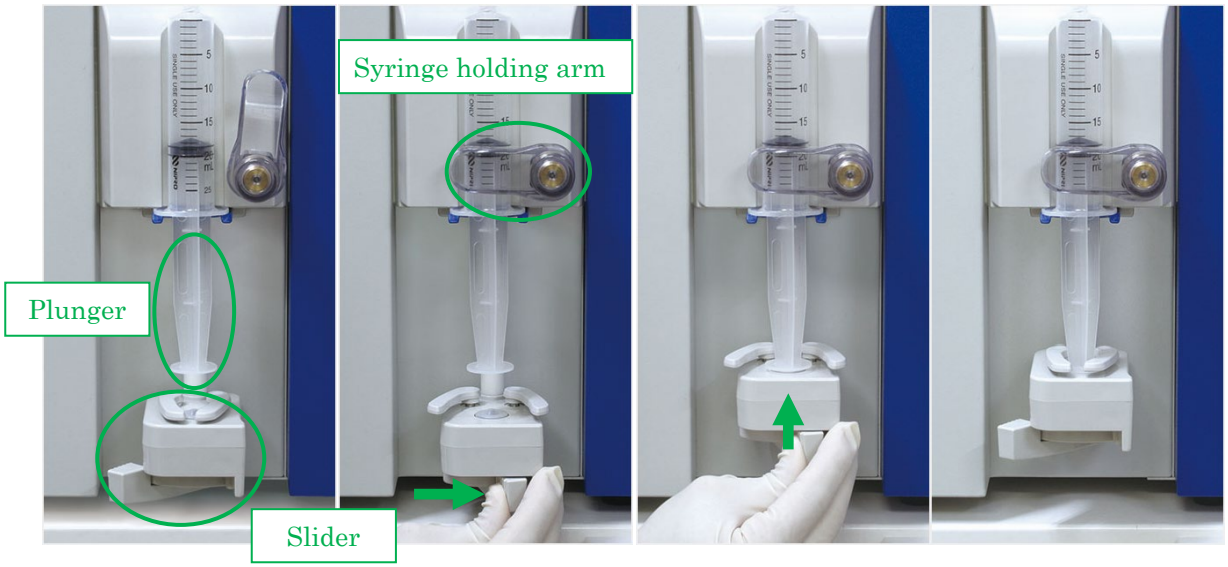
(1) The Line of the Continuous Infusions of anticoagulant Cleaning

1. Close clamp (2) of the blood transfusion-side circuit.
2. Open clamp (4) and cap.
3. Press the〔Start〕button to fill the inside of line with the normal saline solution, and press the〔Stop〕button after cleaning the inside of line.
4. Close clamp (4).

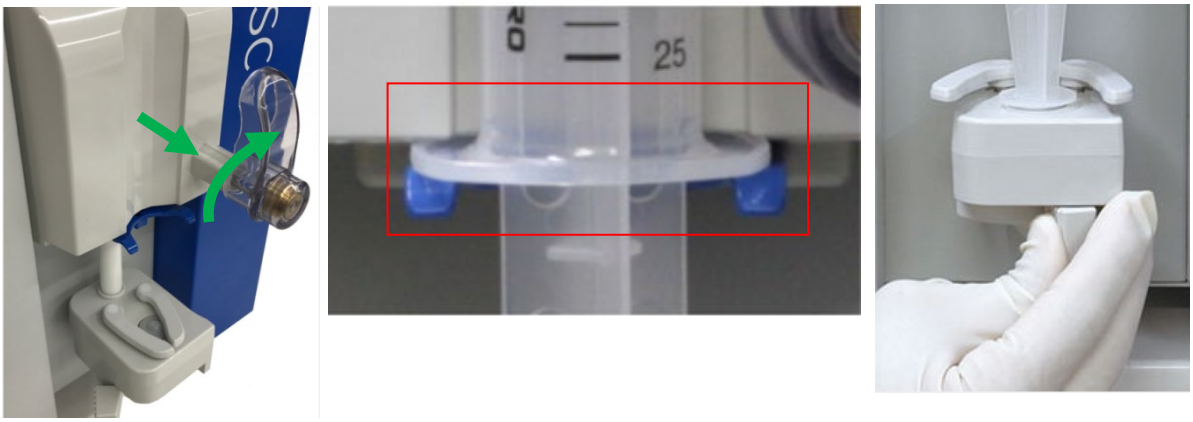
> Supplement:
> ・Check if the anticoagulant line is properly positioned in order that the waste drops into the waste bucket.

(2) Connecting the Anticoagulant Continuous Infusion Line

1. Connect the anticoagulant continuous infusion line to the syringe.
2. Set the syringe in which the anticoagulant is filled on the syringe pump, and then hold the syringe by the syringe holding arm.
3. Push the lever until it reaches the stopper to unlock the slider, raise the slider in that state until it comes into firm contact with the end of the plunger, and then release the lever to lock the slider.



Supplement:
- To turn the syringe holding arm, first, pull it forward and then turn it.
- Make sure to hook the flange part to the blue holder below when setting the syringe.
- Make sure to push the lever into the stopper while moving the syringe pump manually.

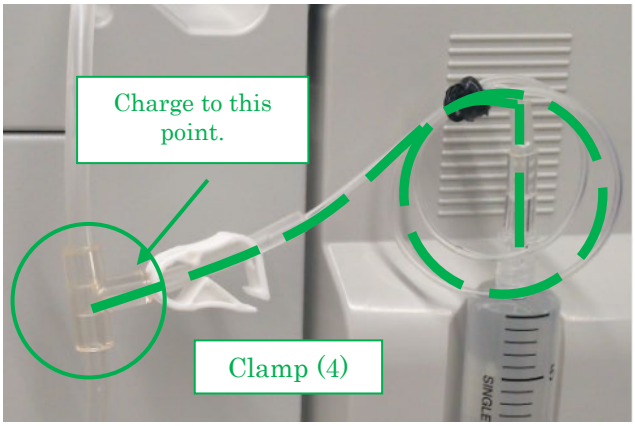


WARNINNG

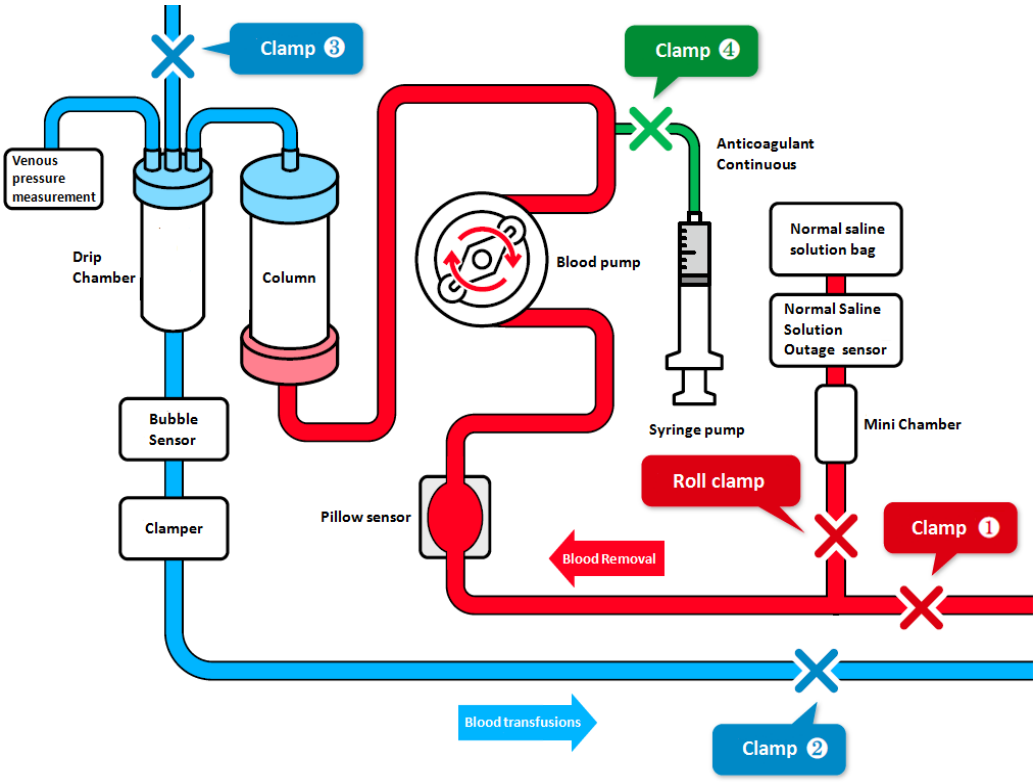
●Check that the syringe is compatible with the device. Using a non-compatible syringe may affect the flow rate precision and the syringe safety functions may not function correctly.

(3) Charging the Anticoagulant Continuous Infusion Line（Circuit Diagram Green dotted frame）

1. Open Clamp (4) to press the〔Fast-forward〕button of the syringe pump under the〔PPreparation mode〕, and charge the anticoagulant continuous infusion line.
2. Stop charging the anticoagulant when it is filled to the branching point as shown below and close Clamp (4).



6.5 Blood Circulation



1. Provide the patient with a blood access by using the blood access catheter (herein after referred to as the “indwelling needle”).
2. Connect the indwelling needle with the blood removal-side circuit and the blood transfusion-side circuit.
3. Adjust the height of Adastand so that the height of device is within about±20cm from the position of the patient.

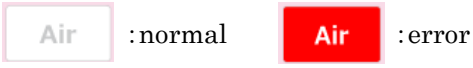
Supplement:
If the position of the device is higher than the position of the patient, the venous pressure decreases. If the position of the device is lower that the position of the patient, the venous pressure increases.

4. Set the upper and lower limits of venous pressure for each patient.

CAUTION

●Set the venous pressure in an appropriate range by a healthcare professional.

5. Open Clamp (1) and Clamp (2).
6. Before starting the treatment, visually confirm that the blood circuit is inserted to the bubble sensor correctly and detect normally.



7. Press the〔Start〕button of the blood pump under the〔Circulation mode〕to rotate the blood pump,and start the treatment.

Supplement:
The pop-up screen to confirm that the upper and lower limit value of venous pressure has been changed to the right range, is displayed when pressing the〔Start〕button of the blood pump under the〔Circulation Mode〕and the〔Transfusion Mode〕.

CAUTION

●Pay attention that there is no problem for the blood removal/venous pressure right after starting the treatment, in particular. Thereafter,continuously check for any change in the venous pressure.

8. Open Clamp(4) to start the continuous infusion of anticoagulant.

CAUTION

●The amount of anticoagulant necessary may vary according to patients' condition (weight, disease, sensitivity to anticoagulant, etc.). The attending physician should assess what is the appropriate dosage. If any abnormalities, caused by excessive or insufficient volume of anticoagulant, are observed during the apheresis, appropriate measures should be taken immediately. Thereafter,continuously check for any change in the venous pressure.
●Do not use more than one anticoagulant solution for anticoagulation within one treatment session.

9. When the preset time is due, an end sound will be initiated.(Press the〔Sound Off〕button to prepare for removal of the blood removal-side indwelling needle, etc.)
10. Press the〔Stop〕button to stop the blood pump and the syringe pump.
    * Even when the treatment time has elapsed, the blood pump will not stop automatically.
    * Close Clamp (4) since the blood may flow back when the venous pressure is high.

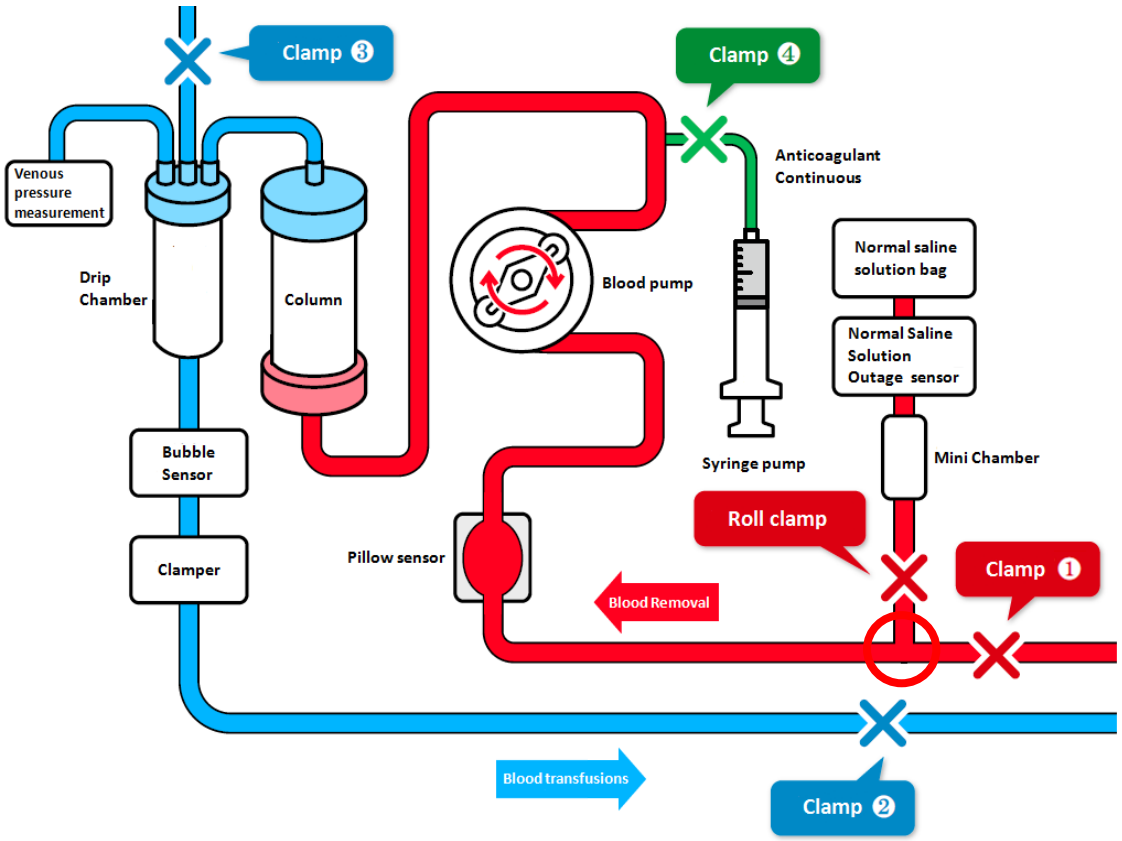
6.6 Blood Transfusion

1. Set the normal saline solution for blood transfusion.
2. Flip the column vertical and reset it to the holder.
3. Close Clamp (1) of the blood removal-side circuit and remove the indwelling needle at the blood removal-side from the patient.
4. Press the〔Start〕button on the blood pump under the〔Blood transfusion mode〕to rotate the blood pump, and open Clamp (1).

> Supplement:
> The pop-up screen to confirm that the upper and lower limit value of venous pressure has been changed to the right range, is displayed when pressing the〔Start〕button of the blood pump under the〔Circulation Mode〕and the〔Transfusion Mode〕.

* When the blood is circulating under the〔Blood transfusion mode〕, the bubble sensor and the venous pressure sensor will be activated.

5. When the blood is returned to the branching point (the red circle in the following figure) of the normal saline solution line, close clamp (1) and open Roll Clamp.
6. Feed the normal saline solution and, when the blood recovery is completed, press the〔Stop〕button to stop the blood pump.
7. Close Clamp (2) of the blood transfusion-side circuit, and remove the indwelling needle at the blood transfusion side from the patient.



6.7 Checking and Changing the Device Setups

Under the Setup mode, the default setups of the device shown below can be checked and changed.

6.7.1 Checking the Software Version

In “System/Venous Pressure” on the first page of the Setup mode, the version of the software that controls the device can be checked.

6.7.2 Setting Up the Normal Range of Venous Pressure

To change the default value of the upper and the lower limit values of the normal range of venous pressure, press the〔Venous Pressure Upper Limit〕 button or the〔Venous Pressure Lower Limit〕 button in “System/Venous Pressure” on the first page of the Setup mode.

Supplement:
- Setup range of venous pressure upper limit value:
  -90 to 400 (mmHg) or -12.0 to 53.3 (kPa)
- Setup range of venous pressure lower limit value:
  -100 to 390 (mmHg) or-13.3 to 52.0 (kPa)
- Setup increment: 10 (mmHg) or -1.33 (kPa)
- It is not possible to set the value that is lower than the lower venous pressure limit value for the upper limit value of the venous pressure normal range.
- It is not possible to set the value that is higher than the upper limit value of the venous pressure normal range for the lower limit value of the venous pressure normal range.

6.7.3 Setting Up the Leak Check

The leak check is limited to［Use］.

6.7.4 Setting Up the Pressure Indication Unit

To change the indication unit of pressure, press the〔Pressure Unit〕 button in “System/Venous Pressure” on the first page of the Setup mode. For the press unit,〔mmHg〕 or〔kPa〕can be chosen.

Supplement:
- Setup item:〔mmHg〕 or〔kPa〕
- The pressure unit chosen is reflected on the Venous Pressure panel on the main window, and on the setup mode.

6.7.5 Setting Up the Circulation Time

To change the default value of the circulation time, press〔Setup Time〕in "Blood Pump" on the second page of the setup mode.

Supplement:
- Circulation time setup range: 1 to 180 (min.)
- Setup time incensement: 1 (min.)
- Even when the setup time is changed on the main window, it is resent to the default value of the setup mode when the device is rebooted.

6.7.6 Setting Up and Checking the Blood Pump Flow Rate

To change the default value of the blood pump flow rate, press〔Blood Pump Flow Rate〕button in "Blood Pump" on the second page of the Setup mode.

Supplement:
- Flow rate setup range: 10 to 50 (mL/min)
- Flow rate setup increment: 1 (mL/min)
- Default setup: 30 (mL/min)
- Even when the blood pump flow rate is changed on the main window, it is reset to the default value of the setup mode when the device is rebooted.

6.7.7 Setting Up and Checking the Blood Pump Fast-forward Flow Rate

To change the default value of the blood pump fast-forward rate, press〔Blood Pump Fast-forward Flow Rate〕button in "Blood Pump" on the second page of the Setup mode.

Supplement:
- Flow rate setup range: 10 to 150(mL/min)
- Flow rate setup increment: 1 (mL/min)
- Default setup: 100 (mL/min)
- Even when the blood pump Fast-forward Flow rate is changed on the main window, it is reset to the default value of the setup mode when the device is rebooted.

6.7.8 Setting Up the Blood Pump Automatic Stop Function at the Time of Blood Transfusion

The blood pump automatic stop function automatically stops the blood pump when the liquid delivery amount at the time of blood transfusion reaches 300mL. To change the enabled or disable status of the function, press〔Blood Pump Automatic Stop Function at the Time of Blood Transfusion〕button in "Blood Pump" on the second page of the Setup mode.

Supplement:
- Setup item:〔Use〕or〔Unuse〕
- Default setup:〔Use〕

6.7.9 Checking the Blood Pump Total Operation Time

The total time of the blood pump is recorded in units of an hour. To check the total operation time of the blood pump, refer to〔Blood Pump Total Operation Time〕in "Blood Pump" on the second page of the Setup mode.

Supplement:;
- Indication unit:(h)

6.7.10 Setting Up and Checking the Syringe Pump Flow Rate

To change the default value of the syringe pump flow rate, press〔Syringe Pump Flow Rate〕button in "Syringe Pump" on the third page of the Setup mode.

Supplement:
- Flow rate setup range: 1 to 20 (mL/h)
- Flow rate setup increment: 1 (mL/h)
- Even when the syringe pump flow rate is changed on the main window, it is reset to the default value of the setup mode when the device is rebooted or when the blood transfusion is completed.

6.7.11 Setting Up and Checking the Syringe Pump Flow Rate

To check the value of the syringe pump flow rate, press〔Flow Rate of Syringe Pump〕button in "Syringe Pump" on the third page of the Setup mode.

Supplement:
- Fast-forward flow rate: 400 mL/h
- The flow rate is fixed and it cannot be changed.

6.7.12 Setting Up and Checking the Use/Unuse Setup of Syringe Pump

Whether the syringe pump is enabled or disenabled can be set up. To change the enabled/ disabled setup of syringe pump, refer to〔Syringe Pump Fast-forward Flow Rate〕in "Syringe Pump" on the third page of the Setup mode.
When〔Unuse〕is chosen for the syringe pump, the indication of the syringe pump panel on the main window becomes invalid, thereby inhibiting the syringe pump operation.

Supplement:;
- Setup item;〔Use〕 or〔Unuse〕
- Default setup:〔Use〕

6.7.13 Setting Up the Syringe Pump Interlocked Mode

The interlocked mode of syringe pump is a function to automatically activate the syringe simultaneously when the blood pump is activated under the〔Circulation Mode〕. To change the setup of the syringe pump interlocked mode, press〔Syringe Pump Interlocked Mode〕button in "Syringe Pump" on the third page of the Setup mode.

Complement:
- Setup item:〔Use〕 or〔Unuse〕
- Default setup:〔Use〕

6.7.14 Setting up the Syringe Type to be Used

Set up the manufacturer of the syringe to be used. To change the syringe type, press〔Syringe Type〕button in "Syringe Pump" on the third page of the setup mode,

Supplement:
- Setup item:〔NIPRO〕/〔TERUMO〕/〔TOP〕/〔JMS〕
- Default setup:〔TERUMO〕

CAUTION

●Check that the syringe to be used actually and the syringe that is set for the device agree. When the syringe that is different from the setup is used, the flow rate accuracy and the safety function of the syringe pump will not operate correctly.

6.7.15 Checking the Syringe Pump Total Operation Time

With this device, the total time of the syringe pump is recorded in units of an hour. To check the total operation time of the syringe pump, refer to〔Syringe Pump Total Operation Time〕 in “Syringe Pump” on the third page of the Setup mode.

Supplement:
- Indication unit: (h)

6.7.16 Factory Default Device Constants

The factory default device constants will be described below:

Parameter	Initial Value	Unit
Setup time (default value)	60	min
Blood pump flow rate (default value)	30	mL/min
Blood pump fast-forward flow rate	100	mL/min
Syringe pump flow rate (default value)	20	mL/h
Syringe pump fast-forward flow rate ※	400	mL/h
Syringe pump enabled or disabled	Use	—
Syringe pump interlocked mode	Use	—
Syringe type	TERUMO	—
Venous pressure upper limit (default value)	60	mmHg
Venous pressure lower limit (default value)	−60	mmHg
Pressure unit	mmHg	—
Blood pump automatic stop function at the time of blood transfusion	Use	—

Chapter 7　Alarm Function and Countermeasures

When an error caused by wrong operations or hardware failure, or an error caused by the safety function of the device is detected, the device will be shifted to the alarm status in real time.

7.1　Alarm Function

Alarm functions that are enabled differ depending on whether the operation mode is either or Self-Diagnosis, Preparation Mode, Circulation Mode or Blood Transfusion Mode. The alarm functions that are enabled by each operation mode and behaviors of the device will be described hereunder.

When the alarm functions of the device detect an abnormality, the alarm sound occurs and the error is displayed. Since the message described on the list of the next page is displayed on the error screen, treat it according to the list. (Refer to Chapter 5 [5.3 Configuration and Operation of Error Window] about the error screen for details.)

Supplement:

Even when the〔Alarm Cancel〕button is pressed, the operating condition of the clamper remains unchanged.

However, only when the error “41 Low Battery Charge” occurs during the self-diagnosis, the alarm sound does not occurs if you push the〔Sound Off〕button once. Refer to Chapter 3 “3.7 Battery Charging after Installation”.

7.1.1 List of Alarm Functions during Self-Diagnosis

The alarm functions that are enabled by the self-diagnosis function will be described below:

Error Number	Error Type	Error Message	Error Handling	Blood Pump	Syringe Pump	Clamper	Alarm Lamp	Alarm Buzzer
04	Caution	Syringe detected	The syringe was detected in initializing. Remove the syringe from the syringe pump.	—	—	—	Blinking Red	ON
20	Warning	Pump Cover Opened	Close the pump cover and then resume operation.	Stop	Stop	Close	Blinking Red	ON
21	Warning	Clamper Open/Close Error	Restart the power supply. If the same error is detected again after the restart, please contact the dealer at which you purchased the product.	Stop	Stop	—	Blinking Red	ON
40	Warning	Previous Run Aborted	The previous run aborted.	Stop	Stop	Close	Blinking Red	ON
41	Warning	Low Battery Charge	Recharge the battery. When the power supply is turned on, battery recharging starts automatically.	—	—	—	Blinking Red	ON
42	Warning	Electronic Component Error (Main Unit) note	Restart the power supply. If the same error is detected again after the restart, please contact the dealer at which you purchased the product.	—	—	—	Blinking Red	ON

note: For details, refer to page 70

43	Warning	Electronic Component Error (Touch Panel)	Restart the power supply. If the same error is detected again after the restart, please contact the dealer at which you purchased the product.	—	—	—	Blinking Red	ON
44	Warning	Electronic Component Error	Restart the power supply. If the same error is detected again after the restart, please contact the dealer at which you purchased the product.	—	—	—	Blinking Red	ON
46	Warning	System Error	A system error was detected. Restart the power supply. If the same error is detected after the restart, please contact the dealer at which you purchased the product.	—	—	—	Blinking Red	ON

7.1.2 Warning Function under Preparation Mode

The alarm functions that are enabled when the preparation mode is activated will be described below:

Error Number	Error Type	Error Message	Error Handling	Blood Pump	Syringe Pump	Clamper	Alarm Lamp	Alarm Buzzer
01	Caution	Caution: Syringe near empty.	The volume of liquid remaining in the syringe has fallen below 1mL. When the syringe needs to be replaced, stop the syringe pump and then replace it with new one.	—	Continuation	Open	Blinking Red	ON

02	Caution	Saline run out detected	The saline run out was detected. When cleaning is to be performed continuously, replace the saline bag with new one and then press the〔Start〕button of the blood pump again.bag with new one and then press the〔Start〕button of the blood pump again.	Stop	—	Open	Blinking Red	ON
05	Caution	Forgetting to start pump	To start the pump, please press the〔Start〕button for over 1 second.	—	—	—	Blinking Red	ON
07	Caution	A leak check	A leak check is not completed. The blood pump is not activated.	—	—	—	Blinking Red	ON
12	Warning	Venous Pressure Error (Upper Limit)	The venous pressure has exceeded the upper limit.	Stop	Stop	Close	Blinking Red	ON
20	Warning	Pump Cover Opened	Close the pump cover and then resume operation.	Stop	—	Close	Blinking Red	ON
21	Warning	Clamper Open/Close Error	Restart the power supply. If the same error is detected again after the restart, please contact the dealer at which you purchased the product.	Stop	Stop	—	Blinking Red	ON

22	Warning	Blood Pump Rotation Error	Restart the power supply. If the same error is detected again after the restart, please contact the dealer at which you purchased the product.	Stop	—	Close	Blinking Red	ON
31	Warning	Syringe Placement Error	The syringe is not placed correctly, or the syringe retaining arm is not placed in the correct position.	—	Stop	Open	Blinking Red	ON
32	Warning	Syringe Plunger Placement Error	The syringe plunger is not placed correctly.	—	Stop	Open	Blinking Red	ON
33	Warning	Syringe Pump Error	Restore the power supply. If the same error is detected again after the restart, please contact the dealer at which you purchased the product.	—	Stop	Open	Blinking Red	ON
34	Warning	Syringe Slider Position Error	Replace the syringe plunger in the correct position.	—	Stop	Open	Blinking Red	ON
35	Warning	Syringe Blocked	The syringe or the syringe line is blocked.	—	Stop	Open	Blinking Red	ON

36	Warning	No Anticoagulant Agent Remaing	The liquid in the syringe has run out.	—	Stop	Open	Blinking Red	ON
42	Warning	Electronic Component Error (Main Unit) note	Restart the power supply. If the same error is detected again after the restart, please contact the dealer at which you purchased the product.	Stop	Stop	Close	Blinking Red	ON
43	Warning	Electronic Component Error (Touch Panel)	Restart the power supply. If the same error is detected again after the restart, please contact the dealer at which you purchased the product.	Stop	Stop	Close	Blinking Red	ON
44	Warning	Electronic Component Error	Restart the power supply. If the same error is detected again after the restart, please contact the dealer at which you purchased the product.	Stop	Stop	Close	Blinking Red	ON
46	Warning	System Error	A system error was detected. Restart the power supply. If the same error is detected after the restart, please contact the dealer at which you purchased the product.	Stop	Stop	Close	Blinking Red	ON

note : For details, refer to page 70

50	Warning	Leak Detected in Blood Circuit	A leak was detected between the blood pump and the clamper in the blood circuit.	Stop	—	Close	Blinking Red	ON
—	—	completion of Leak Check	No leak was detected between the blood pump and the clamper in the blood circuit.	Stop	—	Open	Blinking Green	

7.1.3 Alarm Functions under Circulation Mode

The alarm functions that are enabled when the circulation mode is activated will be described below:

Error Number	Error Type	Error Message	Error Handling	Blood Pump	Syringe Pump	Clamper	Alarm Lamp	Alarm Buzzer
01	Caution	Caution: Syringe near empty.	The volume of liquid remaining in the syringe has Fallen below 1mL. When the syringe needs to be replaced, stop the syringe pump and then replace it with new one.	Continuation	Continuation	Open	Blinking Red	ON
03	Caution	Syringe detected.	The syringe was detected in initializing. Remove the syringe from the syringe pump.	Continuation	Continuation	Open	Blinking Red	ON
05	Caution	Forgetting to start pump	To start the pump, please press the〔Start〕button for over 1 second.	—	—	—	Blinking Red	ON
06	Caution	Blood pump stop time	Over 5 minutes passed after the blood pump stopped.	—	—	—	Blinking Red	ON
10	Warning	Air Detected	Air was detected in the blood circuit. Remove it.	Stop	Stop	Close	Blinking Red	ON

11	Warning	Blood Removal Pressure Error	The blood removal pressure has fallen out of the normal range.	Stop	Stop	Close	Blinking Red	ON
12	Warning	Venous Pressure Error (Upper Limit)	The venous pressure has exceeded the upper limit.	Stop	Stop	Close	Blinking Red	ON
13	Warning	Venous Pressure Error (Lower Limit)	The venous pressure has fallen below the lower limit.	Stop	Stop	Close	Blinking Red	ON
20	Warning	Pump Cover Opened	Close the pump cover and then resume operation.	Stop	Stop	Close	Blinking Red	ON
21	Warning	Clamper Open/Close Error	Restart the power supply. If the same error is detected again after the restart, please contact the dealer at which you purchased the product,.	Stop	Stop	—	Blinking Red	ON
22	Warning	Blood Pump Rotation Error.	Restart the power supply. If the same error is detected again after the restart, please contact the dealer at which you purchased the product,	Stop	Stop	Close	Blinking Red	ON

31	Waring	Syringe Placement Error	The syringe is not placed correctly, or the syringe retaining arm is not placed in the correct position.	Continuation	Stop	Open	Blinking Red	ON
32	Warning	Syringe Plunger Placement Error	The syringe plunger is not placed correctly.	Continuation	Stop	Open	Blinking Red	ON
33	Warning	Syringe Pump Error	Restart the power supply. If the same error is detected again after the restart, please contact. the dealer at which you purchased the product.	Continuation	Stop	Open	Blinking Red	ON
34	Warning	Syringe Slider Position Error	Replace the syringe plunger in the correct position.	Continuation	Stop	Open	Blinking Red	ON
35	Warning	Syringe Blocked	The syringe or the syringe line is blocked.	Continuation	Stop	Open	Blinking Red	ON
36	Warning	No Anticoagulant Agent Remaing	The liquid in the syringe has run out.	Continuation	Stop	Open	Blinking Red	ON
42	Warning	Electronic Component	Restart the power supply. If the same error is detected again after the restart, please contact	Stop	Stop	Close	Blinking Red	ON

		Error (Main Unit) note	the dealer at which you purchased the product.					
43	Warning	Electronic Component Error (Touch Panel)	Restart the power supply. If the same error is detected again after the restart, please contact the dealer at which you purchased the product.	Stop	Stop	Close	Blinking Red	ON
44	Warning	Electronic Component Error	Restart the power supply. If the same error is detected again after the restart, please contact the dealer at which you purchased the product.	Stop	Stop	Close	Blinking Red	ON
46	Warning	System Error	A system error was detected. Restart the power supply. If the same error is detected after the restart, please contact the dealer at which you purchased the product.	Stop	Stop	Close	Blinking Red	ON
47	Warning	Blood pump stop time	Over 60 minutes passed after the blood pump stopped. The blood pump is not activated.	Stop	Stop	Close	Blinking Red	ON
—	—	completion of treatment	Set time has been elapsed. When the treatment is finished, stop the blood pump.	Continuation	Continuation	—	Blinking Green	

note : For details, refer to page 70

7.1.4 Alarm Functions under Blood Transfusion Mode

The alarm functions that are enabled when the blood transfusion mode is activated will be described below:

Error Number	Error Type	Error Message	Error Handling	Blood Pump	Syringe Pump	Clamper	Alarm Lamp	Alarm Buzzer
05	Caution	Forgetting to start pump	To start the pump, please press the〔Start〕button for over 1 second.	—	—	—	Blinking Red	ON
06	Caution	Blood pump stop time	Over 5 minutes passed after the blood pump stopped.	—	—	—	Blinking Red	ON
10	Warning	Air Detected	Air was detected in the blood circuit. Remove it.	Stop	—	Close	Blinking Red	ON
12	Warning	Venous Pressure Error (Upper Limit)	The venous pressure has exceeded the upper limit.	Stop	—	Close	Blinking Red	ON
13	Warning	Venous Pressure Error (Lower Limit)	The venous pressure has fallen below the lower limit.	Stop	—	Close	Blinking Red	ON
20	Warning	Pump Cover Opened	Close the pump cover and then resume operation..	Stop	—	Close	Blinking Red	ON
21	Warning	Clamper Open/Close Error	Restart the power supply. If the same error is detected again after the restart, please contact the dealer at which you purchased the product.	Stop	—	—	Blinking Red	ON
22	Warning	Blood Pump Rotation Error.	Restart the power supply. If the same error is detected again after the restart, please contact the dealer at which you purchased the product,	Stop	—	Close	Blinking Red	ON

42	Warning	Electronic Component Error (Main Unit) note	Restart the power supply. If the same error is detected again after the restart, please contact the dealer at which you purchased the product.	Stop	—	Close	Blinking Red	ON
43	Warning	Electronic Component Error (Touch Panel)	Restart the power supply. If the same error is detected again after the restart, please contact the dealer at which you purchased the product.	Stop	—	Close	Blinking Red	ON
44	Warning	Electronic Component Error	Restart the power supply. If the same error is detected again after the restart, please contact. the dealer at which you purchased the product.	Stop	—	Close	Blinking Red	ON
46	Warning	System Error	A system error was detected. Restart the power supply. If the same error is detected after the restart, please contact the dealer at which you purchased the product.	Stop	—	Close	Blinking Red	ON
47	Warning	Blood pump stop time	Over 60 minutes passed after the blood pump stopped. The blood pump is not activated.	Stop	—	Close	Blinking Red	ON
—	—	completion of Blood Return	The blood pump was stopped, because the integrated amount reached 300mL during Blood Return.	Stop	—	—	Blinking Green	

note : For details, refer to page 70

Supplement:
- The detail category of the error “42 Electronic Component Error (Main Unit)” is described below.

-

Error Number	Detail	Error Number	Detail
42-1	Blood Pump Rotational Speed Error	42-11	Venous Pressure Measurement Error
42-2	Syringe Pump Traveling Speed Error	42-12	Sensor Power Supply Voltage Measurement Error 1
42-3	Pillow Sensor Error	42-13	Sensor Power Supply Voltage Measurement Error 2
42-4	Venous Pressure Sensor Error	42-14	Sensor Power Supply Voltage Measurement Error 3
42-5	Data Writing Error	42-15	CPU Power Supply Voltage Measurement Error 2
42-6	Bubble Sensor Error	42-16	24V Power Supply Voltage Switching Error
42-7	Normal Saline Solution Outage Sensor Error	42-17	Battery Status Error
42-8	Battery Switch Voltage Measurement Error	42-18	Alarm Functions Enable Status Error
42-9	CPU Power Supply Voltage Measurement Error 1	42-19	ADC Reading Error 1
42-10	Battery Voltage Measurement Error	42-20	ADC Reading Error 2

Chapter 8 Inspection

8.1 Inspection

When any problem occurs regarding the confirmations and understandings, and for placing an order for maintenance service, contact the dealer from whom you purchased the device.

⚠ WARNING

●When the device is out of order, do not try to disassemble or repair it without permission, put an "Out of Order" tag on the device, and ask the professional for repair. Do not detach the cover of the device or do not try to remodel the device.

8.1.1 Pre-operation Inspection

Refer to the supplement "Operation Inspection Sheet."

- Check that the there is no damage on the power cord and the exterior part of the device and that the grounding cable is connected robustly.

(1) Checking electronic parts.
(2) Checking if the display turns on.
(3) Checking the power failure error.
(4) Checking if the alarm lamps turn on green, and off.
(5) Checking if the device makes the ending sound and mutes.
(6) Checking if the alarm lamps turn on red, and off.
(7) Checking if the device makes the alarm sound and mutes.
(8) Checking the pump cover.
(9) Checking the battery voltage.
(10) Checking if the clamper opens and closes.
(11) Checking the bubble Sensor.
(12) Checking the pillow sensor.
(13) Checking the venous pressure.

When the error presents, the error detection indication (Error Nos.: 04、20、21、40、41、42、43、44 and 46) will be displayed. Please follow the instructions.

⚠ CAUTION

●When the device is not used for a long period of time (about one month), the battery capacity of the alarm continuous power supply battery for use of power failure may have been reduced. Be sure to charge the battery in the same way as taken when installing the device.
(Refer to Chapter 3 "3.7 Battery Charging after installation")

◇ Check that

- The buzzer sound is activated when each of the buttons on the touch panel is pressed.
- The pump stops and the Pump Cover Open error (Error No. 20) is issued, the alarm lamp blinks and the alarm sound is activated, when the cover is opened.
- The venous pressure on the monitor indicates "0 kPa" (0 mmHg) or its vicinity when in the status where the venous pressure connector and the circuit are not connected.
- The pressure meter on the venous pressure panel swings right and left when the syringe is connected to the venous pressure connector and when the upper limit value or the lower limit value of the setting is exceeded, the〔vein〕of the alarm monitor lights up and the〔vein〕of the alarm monitor turns off when it falls within the upper limit value and the lower limit value of the setting.
- The blood circuit is correctly set and the blood circuit is ready for cleaning and priming under the〔Preparation mode〕, check that the〔Air〕of the alarm monitor goes off when the normal saline solution is filled to the blood bubble sensor unit.
- When the pillow of the blood circuit is mounted on the pillow sensor and the pillow cover is closed, check that the〔Pillow〕of the alarm monitor goes off and it illuminates when the pillow is detected.

8.1.2 Check while In Use and After Use

- When a contamination caused by chemical liquid such as the normal saline solution or blood exists or blood exists on a moving part of a detection part, wipe it off.
- Visually check that there is no problem at each part.
- Check for any abnormality sound during operation.・

8.1.3 Periodic Inspection

Refer to the supplement Periodic Inspection Sheet

Execute the following inspection once a month to check the device:

◇ Check that:

- When a contamination caused by chemical liquid, such as the normal saline solution or blood exists on a moving part, a detection part, or an indicator, wipe off.
- There is no abnormal sound or abnormal operation while the device is in operation visually check that there is no problem at respective parts.
- The buzzer sound is activated when each of the buttons on the touch panel is pressed.
- The pump stops and the Pump Cover Open error (Error No. 20) is issued, the alarm lamp blinks and the alarm sound is activated, when the cover is opened during operation.
- The venous pressure on the monitor indicates “0 kPa” (0 mmHg) or its vicinity when in the status where the venous pressure connector and the circuit are not connected.
- The pressure meter on the venous pressure panel swings right and left when the syringe is connected to the venous pressure connector and when the upper limit value or the lower limit value of the setting is exceeded, the〔vein〕of the alarm monitor lights up and the〔vein〕of the alarm monitor turns off when it falls within the upper limit value and the lower limit value of the setting.
- The blood circuit is correctly set and the blood circuit is ready for cleaning. Under the〔Preparation mode〕, check that the〔Air〕of the alarm monitor goes off when the normal saline solution is filled to the blood bubble sensor unit.
- When the pillow of the blood circuit is mounted on the pillow sensor and the pillow cover is closed, check that the〔pillow〕of the alarm monitor goes off and it illuminates when the pillow is detected.
- The alarm lamp blinks for at least one minute and the alarm sound continues to be activated when turning off the power while rotating the blood pump under the〔Circulation mode〕.

  Note: After executing the inspection, turn on the power again, and check that the error “abnormal termination at the time of previous operation” (Error No. 40) is

displayed. Thereafter, press the〔Alarm Cancel〕button to cancel the error code.

8.1.4 Cleaning

Before implementing the cleaning work, be sure to use rubber gloves and wipe off contaminations on device surface, pillow sensor, cover of blood pump and cables by using a cloth impregnated with ethyl alcohol, etc.

8.1.5 Inspection by the Service Dealer

Here are items to be checked by the service dealer.
Annual inspection is recommended to ensure that the device is used safely.

Appearance Check

- Cleaning
- Condition Confirmation of each part.

Function Check

- Confirmation of Safety Function
- Confirmation of Alarm Function

Performance Check

- Performance Confirmation of Blood Pump
- Performance Confirmation of Syringe Pump
- Comprehensive Performance

Chapter 9 Warranty

9.1 Information on Warranty

(1) The warranty certificate will be delivered to you after the dealer entered the specified items. Check the content and keep the certificate in a safe place.

(2) The warranty period shall be one year from the date of purchase.

(3) If you have a question on the after-sales service such as repair during the warranty period, contact the dealer from whom you purchased the device.

(4) For the repair work of the device after the warranty period has expired, contact the dealer. In case the function can be retained by repair, we will repair the device on a charged basis according to the customer's requirement.

(5) Regarding consumable parts, they will be provided on a charged basis even within the warranty period.

(6) The following items shall be executed from the warranty.

1) Failures that are attributed to improper operations.
2) Failures that are attributed to use under improper installation condition.
3) Failures that are attributed to disassembly or remodeling.
4) Failures that are attributed to earthquake, disaster, etc.
5) Failures and breakages that are attributed to the damage from moving and transporting by customers, or a fall.
6) Failures that are attributed to unforeseen occurrence under the standard of science and technology as of product shipment.

(7) The expected service-life of the product shall be eight years as the voluntary standards.
It should be noted that the warranty shall be subject to the periodical inspection executed according to Chapter 8 "8.1 Inspection", and the implementation of repair or overhaul that is found to be necessary as a result of the inspection.

9.2 Contact Address

Manufacturer and supplier:

Otsuka Electronics Co., Ltd.

3-26-3 Shodaitajika, Hirakata-shi, Osaka, 573-1132 , Japan

Distributor:

Adacyte Therapeutics, S.L.

Jesus Serra Santamans, 5, 08174 Sant Cugat del Valles (Barcelona) Spain

Authorized Representative:

Emergo Europe B.V.

Prinsessegracht 20, 2514 AP The Hague

The Netherlands

For inquiries, contact the nearest sales office.

9.3 Supplement

Supplement：Periodic Inspection Sheet

Periodic Inspection Sheet

Device Name	Date of Inspection	. .	
	Inspection result	Inspector	Administrator
Adamonitor SC (Serial No.)	OK・NG		

	Check item	Result
1	There is no damage on the power cord and the exterior part of the device and that the grounding cable is connected ro	OK・NG
Self-diagnosis (Close the blood pump cover and turn on the power without setting the blood circuit and syringe)		Result
2	Checking electronic parts.	OK・NG
3	Checking if the display turns on.	OK・NG
4	Checking the power failure error.	OK・NG
5	Checking if all the alarm lamps turn on and off.	OK・NG
6	Checking if the device makes the ending sound and mutes.	OK・NG
7	Checking if the device makes the alarm sound and mutes.	OK・NG
8	Checking the blood pump cover.	OK・NG
9	Checking the battery voltage.	OK・NG
10	Checking if the clamper opens and closes.	OK・NG
11	Checking the bubble Sensor.	OK・NG
12	Checking the pillow sensor.	OK・NG
13	Checking the venous pressure.	OK・NG

What to do if there is an abnormality detection indication during self-diagnosis	Error Number	Treatment method
	04	Please remove the syringe from the syringe pump and then push the Alarm Cancel Button.
	20	Please close the cover of the blood pump and then push the Alarm Cancel Button.
	21	Restart the power supply. If the same error is detected again after the restart, please contact the dealer at which you purchased the product.
	40	Please push the Alarm Cancel Button. Self-diagnosis is skipped and the screen changes to the screen at the time of last operation termination.
	41	Recharge the battery. When the power supply is turned on, battery recharging starts automatically.
	42	Restart the power supply. If the same error is detected again after the restart, please contact the dealer at which you purchased the product.
	43	Restart the power supply. If the same error is detected again after the restart, please contact the dealer at which you purchased the product.
	44	Restart the power supply. If the same error is detected again after the restart, please contact the dealer at which you purchased the product.
	46	Restart the power supply. If the same error is detected again after the restart, please contact the dealer at which you purchased the product.

	Pre-operation and Periodic Inspection	Result
14	The buzzer sound is activated when each of the buttons on the touch panel is pressed.	OK・NG
15	The pump stops and the Pump Cover Open error (Error No. 20) is issued, the alarm lamp blinks and the alarm sound is activated, when the cover is opened during operation.	OK・NG
16	The venous pressure on the monitor indicates “0 kPa” (0 mmHg) or its vicinity when in the status where the venous pressure connector and the circuit are not connected.	OK・NG
17	The pressure meter on the venous pressure panel swings right and left when the syringe is connected to the venous pressure connector and when the upper limit value or the lower limit value of the setting is exceeded, the [vein] of the alarm monitor lights up and the [vein] of the alarm monitor turns off when it falls within the upper limit value and the lower limit value of the setting.	OK・NG
18	The blood circuit is correctly set and the blood circuit is ready for cleaning and priming under the preparation mode, check that the [Air] of the alarm monitor goes off when the normal saline solution is filled to the blood bubble sensor unit.	OK・NG
19	When the pillow of the blood circuit is mounted on the pillow sensor and the pillow cover is closed, check that the [pillow] of the alarm monitor goes off and it illuminates when the pillow is detected.	OK・NG
	Check while In Use and After Use and Periodic Inspection	Result
20	Check for any abnormality sound during operation.	OK・NG
21	When a contamination caused by chemical liquid such as the normal saline solution or blood exists or blood exists on a moving part of a detection part, wipe it off.	OK・NG
	Periodic Inspection	Result
22	The alarm lamp blinks for at least one minute and the alarm sound continues to be activated when turning off the power while rotating the blood pump under the circulation mode.	OK・NG

Chapter 10 Index

Index

EMC technical data

IMMUNITY TEST LEVELS for each IMMUNITY test and EMISSONS compliance class and group

Emission

Test items	Classified Class	Pass/Fail
Mains terminal dissturbuce voltage (conducted EMISSON)	Group1 class A	Pass
Electromagnetic radiation disturbance (radiated RF EMISSON)	Group1 class A	Pass
Harmonic current EMISSIONS	Harmonic class A	Pass
Voltage changes, voltage fluctuations and flicker EMISSION	dmax b	Pass

Immunity/ENCLOSURE PORT

Test items	Test level	Pass/Fail
ELECTROSTATIC DISCHARGE	±8kV（contact） ±2kV,±4kV,±8kV,±15kV（air）	Pass
Radiated RF EM fields IMMUNITY	3V/m 80MHz～2.7GHz 80%AM at 1kHz	Pass
IMMUNITY to proximity fields from RF wireless communications equipment	See “Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment”	Pass
Power frequency magnetic fields IMMUNITY	30A/m 50Hz	Pass

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency	Band	Modulation	Immunity TEST LEVEL	Pass/Fail
385MHz	380-390MHz	Pulse modulation/18Hz50%	27V/m	Pass
450MHz	430-470MHz	FM±5kHz deviation,1kHz sine	28V/m	Pass
710MHz	704-787MHz	Pulse modulation /217Hz50%	9V/m	Pass
745MHz				
780MHz				
810MHz	800-960MHz	Pulse modulation/18Hz50%	28V/m	Pass
870MHz				
930MHz				
1720MHz	1700-1990MHz	Pulse modulation/217Hz50%	28V/m	Pass
1845MHz				
1970MHz				
2450MHz	2400-2570MHz	Pulse modulation/217Hz50%	28V/m	Pass
5240MHz	5100-5800MHz	Pulse modulation/217Hz50%	9V/m	Pass
5500MHz				
5785MHz				

Immunity/Input a.c. power PORT

Test items	Test level	Pass/Fail
Electrical fast transients/bursts IMMUNITY a.c. mains	±2kV 100kHz repetition frequency	Pass
Surges IMMUNITY	±0.5kV, ±1kV（Line-to-line） ±0.5kV, ±1kV、±2kV（Line-to-ground）	Pass
IMMUNITY to conducted DISTURBANCES induced by RF fields (conducted RF DISTURBANCE IMMUNITY) a.c. mains	3V 0.15MHz～80MHz 6V in ISM bands Between 0.15MHz and 80MHz 80%AM at 1kHz	Pass
Voltage dips IMMUITY	0%U_T 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0%$U_{T,1}$ cycle and 70%U_T:25/30 cycle Single phase: at 0°	Pass
Short interruptions and Voltage variations IMMUNITY	0%U_T:250/300cycle	Pass

Adamonitor SC

Identification Number: MSCV-1-E-7

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⚠ CAUTION

1. Please note that the content in the operating instructions is subject to change without notice.
2.

EC REP

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The Netherlands

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