CAPIOX®
Emergency Bypass System

Instructions for use

TERUMO

CARDIOVASCULAR

Indications for Use

The CAPIOX Emergency Bypass System (EBS) is authorized to be used by healthcare providers (HCP) in the hospital setting for providing long-term (> 6 hours) respiratory or cardiopulmonary support to treat patients 18 years or older with Coronavirus Disease 2019 (COVID-19) who have acute respiratory failure or acute cardiopulmonary failure, where other available treatment options have failed, and continued clinical deterioration is expected or the risk of death is imminent.

Contraindications

- Known heparin sensitivity
- Inferior vena cava filter

Disclaimers

- The CAPIOX EBS has neither been cleared or approved for providing long-term (> 6 hours) respiratory or cardiopulmonary support to treat patients 18 years or older with Coronavirus Disease 2019 (COVID-19) who have acute respiratory failure or acute cardiopulmonary failure, where other available treatment options have failed, and continued clinical deterioration is expected or the risk of death is imminent; and,
- The CAPIOX EBS has been authorized for the above emergency use by FDA under an EUA; and,
- The CAPIOX EBS has been authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Contact Information

- Product Surveillance can be reached at 800-521-2818 x6066 or tcvs.aacomplaints@terumomedical.com
- Customer Service can be reached at 800-521-2818 x6929 or cvscustomerservice@terumomedical.com
- Tech Support can be reached at 800-521-2818 x6932 or tech.support@terumomedical.com

CAPIOX®
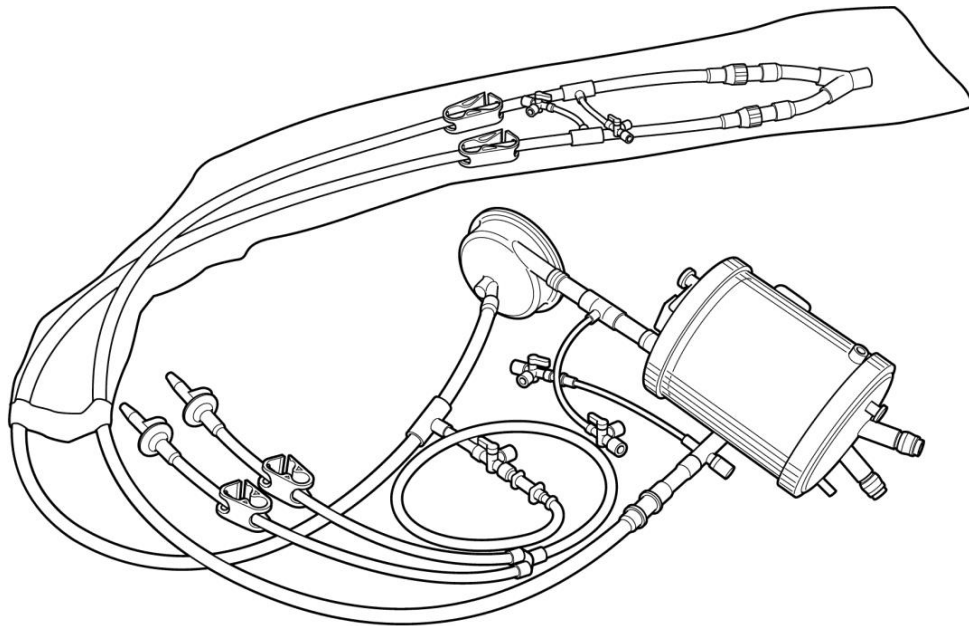## EBS™Circuit with X coating™

Instructions for use

TERUMO
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CAPIOX® EBS™ Circuit with X coating™

Instructions for Use

Please read this Instructions for Use carefully before use, and use this product according to the instructions described here.

TERUMO

Symbols on the packages of this product

Symbols	Instructions
REF	Catalogue number
LOT	Batch code
(hourglass symbol)	Use-by date
(factory symbol)	Manufacturer
(book with i symbol)	Consult instructions for use
(circle with 2 crossed out)	Do not re-use
(STERILIZE crossed out with 2)	Do not resterilize
STERILE EO	Sterilized using ethylene oxide
(sun symbol)	Keep away from sunlight
(umbrella symbol)	Keep dry
(glass symbol)	Fragile, handle with care
(damaged package symbol)	Do not use if package is damaged
(thermometer symbol)	Temperature limit
(two up arrows)	This way up
(crossed symbol)	Non-pyrogenic

Contents/Description of Product

Contents

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Description of Product

This Product is a kit consisting of membrane oxygenator with microporous polymethylpentene hollow fibers, a centrifugal pump to send blood, and blood tubing. It is intended for use during extracorporeal circulation for cardiovascular surgery and ECLS (Extracorporeal Life Support). Blood and gas flow on the outside and inside of fiber respectively in the membrane oxygenator. Straight path design employed in the centrifugal pump reduces disorder in blood flow and minimizes blood component damage.

The blood contacting surfaces are coated with Xcoating.

This product is used with CAPIOX SP Pump Console SP-101 or CAPIOX Centrifugal Pump Controller SP-200 as a driving instrument of the centrifugal pump.

Structure

Three way stop cock (normal type)

Venous line (blue)

Arterial line (red)

Sampling line

EBS connector (for lock connector)

Centrifugal pump

Oxygenator

Priming line

Plastic spike for priming

Water port

Thermistor probe

Clamp

Gas port (GAS IN)

Sampling port

Flow meter connector

Three way stop cock (high flow type)
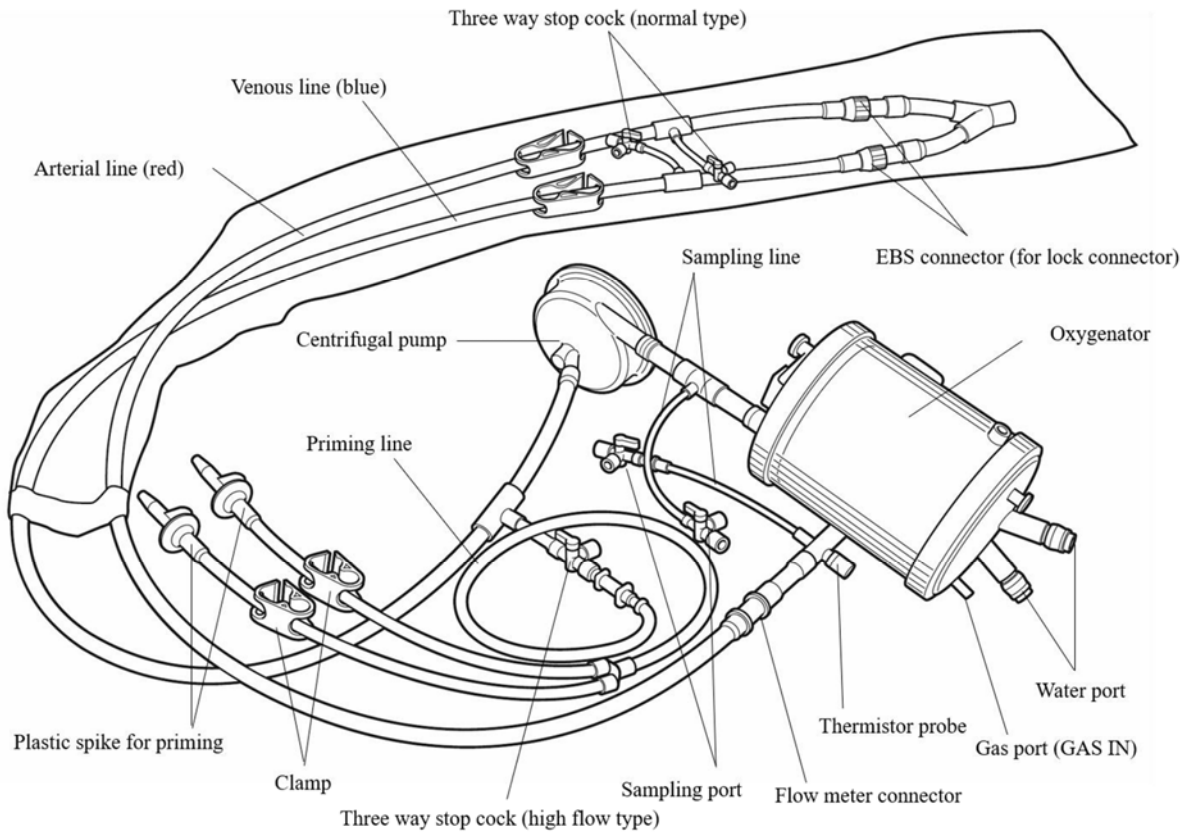
WARNINGS/PRECAUTIONS

Precautions for operation

WARNINGS ・ **Adequate heparinization of the blood is required to prevent blood coagulation in the system.**

・Never clamp the venous line (blue) during circulation. Otherwise, pressure inside of the pump will turn into negative, which is a potential hazard of producing gas bubbles.

・Always close the branch line of the venous line (blue) during circulation. Otherwise, pressure in this part will turn into negative, which is a potential hazard of intermixing bubbles.

・DO NOT OBSTRUCT GAS OUTLET PORT. Avoid build-up of excess pressure in the gas phase to prevent gaseous emboli entering the blood phase.

・The oxygenator must be positioned lower than the patient. Pressure in the blood phase should always be higher than that in the gas phase to prevent gaseous emboli entering the blood phase.

・The gas flow should not exceed 20L/min. Excessive gas flow will bring about pressure increase in the gas phase, allowing gaseous emboli to enter the blood phase.

・Do not exceed a 15℃ (27℉) temperature difference between blood and water in heat exchanger to prevent gas dissolved in blood from forming bubbles.

・This product should be used under monitoring. If abnormalities such as product-damage and deteriorated performance are observed, replace the product with a new one properly after ascertaining the state of patient. There are possibilities that increasing blood cell damage or blood coagulation is formed, or the circulation is obstructed.

PRECAUTIONS ・ This product should be used by a physician or under the supervision and/or direction of a physician.

・This product is sterilized by ethylene oxide gas.

・For single use only. Do not reuse. Do not resterilize. Do not reprocess. Reprocessing may compromise the sterility, biocompatibility and functional integrity of the device.

・Do not use if the unit package or the product has been damaged or soiled. Use it immediately after opening the unit package and dispose of it safely after use.

・Spare pack of CAPIOX EBS Circuit should be available for emergency exchange.

・Do not allow solvents such as alcohol, ether, acetone, etc. to come in contact with the device as it may cause damage to the device.

・Use CAPIOX SP Pump Console SP-101 and CAPIOX Centrifugal Pump Controller SP-200 according to the instructions described in the Instructions for Use.

・Set this product correctly with a holder or a drive motor.

・The centrifugal pump of this product contains a magnet. Therefore, keep away from metals and magnetic tapes.

・Use this product at flow rate lower than the maximum 7 L/min.

・Do not exceed the maximum pump speed of 3000rpm. Otherwise, it would increase blood damage and cause breakage of this product and leakage.

・Do not install or remove the pump until the motor has completely stopped.

・All procedures must be aseptically performed.

・Perform priming procedure using crystalloid solution which contains no blood, plasma and/or blood derived products.

・For monitoring temperature, Y.S.I. 400 Series manufactured by Measurement Specialties Inc. can be used. Use it with its exclusive cable.

・In case of using CAPIOX EBS Cannula Kit, follow instructions described in the Instructions for Use.

・Water pressure at the heat exchanger inlet should not exceed 196kPa (2kgf/cm^2). Pressure greater than 196kPa (2kgf/cm^2) may cause leaks or damage to the device.

Precaution for storage

PRECAUTION ・Pay attention not to wet the device. Avoid direct sunlight, extreme temperature and humidity for storage.

Thoroughly read "Warnings/Precautions" (Page 4 - 5) before use.

Instructions for use

Set Up

1. Set a holder and a drive motor.
   - Fix the drive motor to the holder tightly with screws for the drive motor (Figure 1).

Figure 1

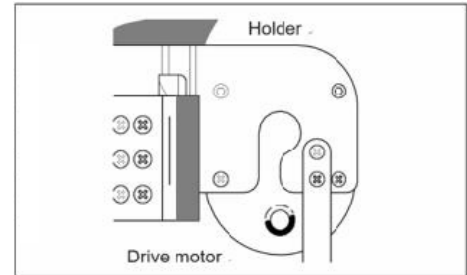2. Fix the holder to the pole with a pole clamp of the holder (Figure 2).

3. Take the product out of the unit package and confirm there is nothing wrong.

   CAUTION
   - Do not use if the unit package or the product been damaged or soiled.
   - When using CX∗XSA0171, CX∗XSA0173 σCX∗XSA0251, do not hold the product by the tube between oxygenator and centrifugal pump.
   This may cause heavy load at the connection parts of tubing and lead to leakage.
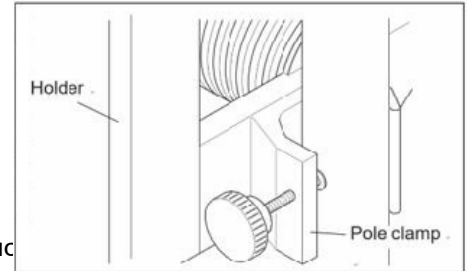
Figure 2

4. Confirm that all the screws of 3-way stopcocks, caps and connectors are fixed tightly, and that the clamps of the arterial line (red), the venous line (blue) and the priming line are open.
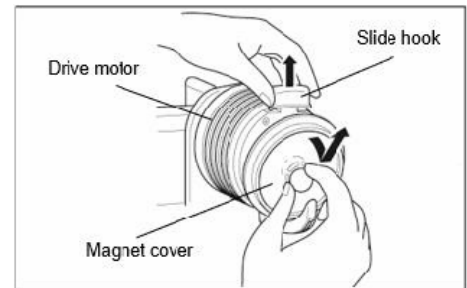
Figure 3

5. Set the centrifugal pump to the drive motor fixed to the holder. (For CX∗XSA: Remove the cover of the centrifugal pump.)
   ①Remove the magnet cover from the drive motor (Figure 3).
   ②Insert the rim of the centrifugal pump into the fixed hook of the drive motor (Figure 4).
   ③Insert the rim of back side of the oxygenator into the fixed hook of the holder (XX∗EB04), and push forward and set the oxygenator (Figure 5).

Figure 4
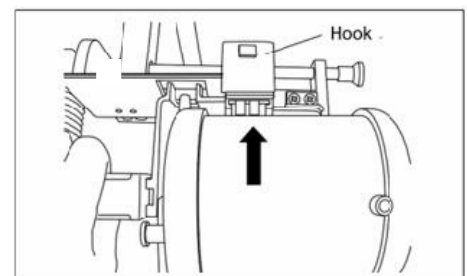
Figure 5

・ Make sure that the underside of the centrifugal pump is in close contact with the pump receptacle and that the slide hook is in position (Figure 6).

・ Make sure that the rim of back side of the oxygenator and the hook of the exclusive holder are connected to the slide hook (Figure 7).

・ Only when the display of the motor rpm indication shows "0", the centrifugal pump can be attached or detached .
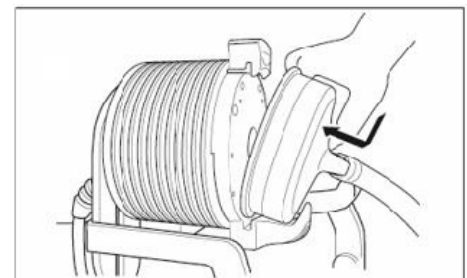

Figure 6

Hook
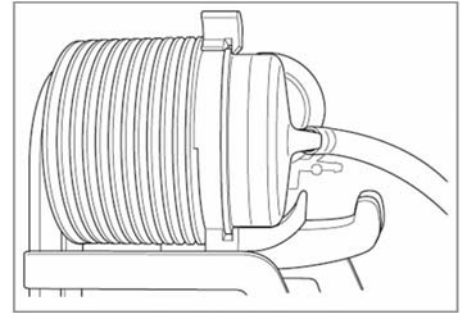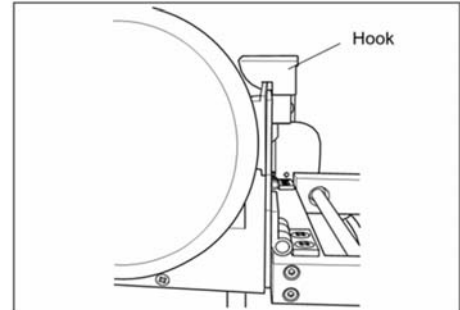
Figure 7 .

6. Connect the water lines (inner diameter of the tube; 12.7mm (1/2") or couplers) to the water ports of CAPIOX EBS circuit (Figure 8-a, 8-b).

7. Start water circulation through heat exchanger and circulate for at least 5 minutes. Check for leaks.

CAUTION Do not use an oxygenator that leaks. Replace it with another EBS circuit.

8. Connect the thermistor probe and the temperature monitor cable (Figure 8-c).

CAUTION For a monitor, Y.S.I. 400 Series manufactured by Measurement Specialties Inc. can be used. Use it with its exclusive cable.

9. Connect the gas line (inner diameter of the tube; 6.4mm (1/4")) to the gas port (GAS IN) (Figure 8-d).

WARNING Do not block the gas port (GAS OUT).

a. Water line (WATER IN)
Water port
b. Water line (WATER OUT)
c. Thermistor probe
d. Gas line
Gas port (GAS IN)

Figure 8

10. After the circuit was assembled, confirm all parts are connected properly, and the tubes are not folded or kinked.

11. When using with CAPIOX SP Console SP-101:
Attach the CAPIOX SP Pump Flow Sensor 3/8" to the flow connector on the arterial line following the Instructions for Use of CAPIOX SP Pump Console SP-101.

CAUTIONS
- Ultrasonic sensor gel must be fully applied to the flow connector.
- When a flow connector is connected with a flow sensor, attach recommended ultrasonic gel (AQUASONIC 100 made by Parker) adequately between the flow sensor and flow connector. Do not use gel which solvents are included such as alcohol, thinner and amine, etc. These solvents may cause damage the sensor and connector.

12. When using with CAPIOX Centrifugal Pump Controller SP-200:
Attach the ABD/Flow Sensor to 3/8" tubing, following the Instruction for Use of CAPIOX Centrifugal Pump Controller SP-200.

CAUTION
- When attaching the ABD/Flow Sensor, apply enough vaseline to evenly coat the detection window of the clamp-on ABD/Flow sensor. If the amount of vaseline applied is insufficient, the Flow Signal Unstable Alarm may be issued, and air bubbles may not be detected.
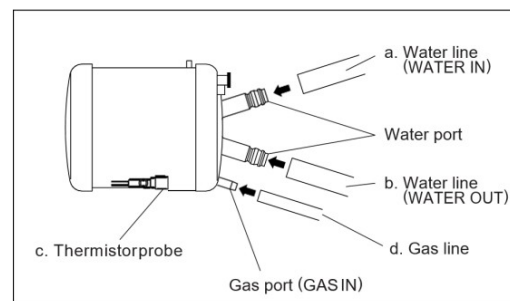
13. After the circuit was assembled, confirm all parts are connected properly, and the tubes are not folded or kinked.

Priming procedure

・ This product should be primed with crystalloid solution which contains no blood, plasma and/or blood derived products.

　・ In case of adding blood or plasma, etc. in the priming solution, after priming, follow the procedure below.

　・ Infuse blood or plasma, etc. from the priming line.

　・ At the same time, remove the clear priming solution from the sampling line to replace in the circuit.

Figure 9

1. Set the circuit at the lower position than the oxygenator.

2. Remove the protection cap from the plastic spike after closing the clamp on the priming line. Then connect the plastic spike to a bag or a bottle filled with priming solution.

3. After confirming that the 3-way stopcock on the priming line is open, release the clamp.

Figure 10

4. Fill the tubing circuit except the centrifugal pump and the oxygenator with priming solution.

CAUTION　It may take more time for priming if a large quantity of bubbles remains in the circuit.

5. Fill the oxygenator and the centrifugal pump with priming solution.

Figure 11

6. After the circuit is fully primed or almost fully primed, pull out the handle of the exclusive holder (XX∗EB04) (Figure 9).

7. Unlock the rotation of the exclusive holder (XX∗EB04) (Figure 10) and rotate the whole holder 90 degrees (Figure 11).

CAUTIONS　・ After the rotation, lock the rotation, and make sure that the holder is fixed.

Figure 12

　・ When rotating 90 degrees, the tube must be put on the holder for rotation not to fold the circuit (Figure 12).

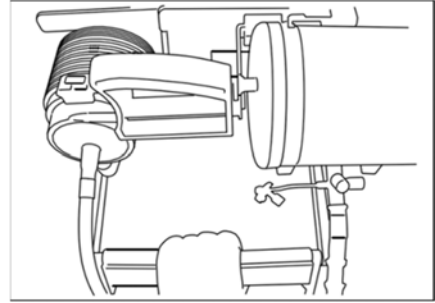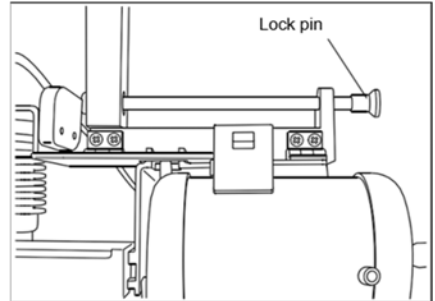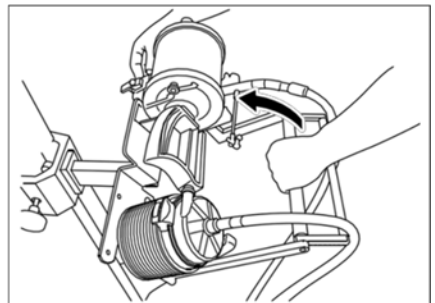　・ Pay attention to prevent the tubing from tucking in during rotation.
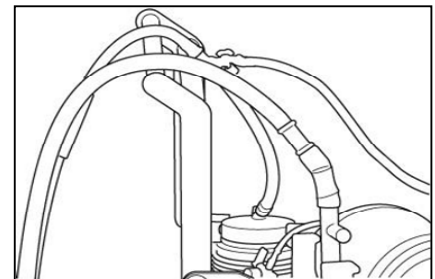
8. Press the Auto-Priming button or the icon of the applicable
    centrifugal pump controller.
    The Auto-Priming function works on the centrifugal pump to
    turn intermittently.
    The procedure to expel bubbles in the circuit through
    microporous of the oxygenator is automatically performed.

    | CAUTION | Do not operate the centrifugal pump without filling
    it with priming solution. Otherwise, the centrifugal
    pump may get damaged.

9. Confirm that bubbles in the circuit are completely removed
    while the centrifugal pump turns intermittently. At this time,
    remove the cap (with air filter) of the sampling port on the
    sampling line of the oxygenator and open the 3-way stopcock,
    and then remove bubbles from the sampling line using a
    syringe.

    | CAUTION | When bubbles remain at the junction parts of
    connectors etc., remove them by tapping the parts.

10. Hold the handle for rotation of the exclusive holder (XX∗EB04)
    and unlock the rotation. Then rotate the holder 90 degrees and
    replace it at the previous position (Figure 13). Put away the
    handle for rotation depending on the situation.

    | CAUTION | After the rotation, lock the rotation, and make sure
    that the holder is fixed.
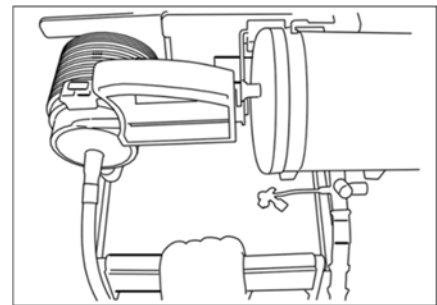
Figure 13

11. Press the Auto-Priming button or the icon again to compete
    auto priming.

12. Confirm that the motor rpm adjustment knob of the centrifugal
    pump console is at the position of "0".

13. With the pump outlet clamped, set the pump speed to
    3000rpm (maximum speed) for approximately 30 seconds.
    Since this condition makes internal pressure of the centrifugal
    pump maximum, check it for something wrong such as
    leakage from EBS circuit.

    | CAUTIONS | ▪ Do not operate the centrifugal pump for a long
    time with its outlet clamped, which will raise the
    temperature of the priming solution.
    ▪ Do not use when something wrong is noted and
    replace the EBS circuit with a new one.

14. Turn the motor rpm adjustment knob to "0" and stop the rotation of the pump.

15. Pulling up the slide hook of the drive motor, remove the centrifugal pump from the drive motor (Figure 14).
    After confirming that the centrifugal pump has been thoroughly primed and there is nothing wrong with it, set the pump to the drive motor again.

CAUTIONS   ・Only when the display of the motor rpm indication shows "0", the centrifugal pump can be attached or detached.
          ・ In case that the bubbles still remain in the centrifugal pump, set the centrifugal pump to the drive motor again, and remove them circulating priming solution.
          ・After the bubbles were completely removed from the circuit, until the extracorporeal circulation starts, stop the centrifugal pump with its pump speed "0". Do not continue circulation excessively.

Figure 14

16. Close the clamp and the 3-way stopcock on the priming line.

CAUTION   If circulation starts without closing the clamp and the 3-way stopcock, air will enter the circuit. Therefore, be sure to close them.
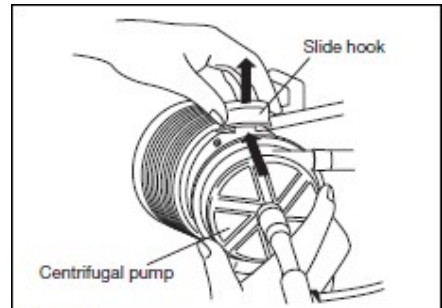
Connection

1. Close clamps of the arterial line (red) and venous line (blue) from over the clean cover (Figure 15).
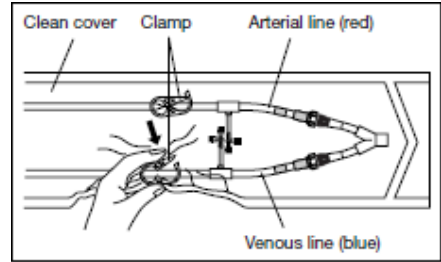
Figure 15

2. Remove the clean cover pulling from the corner (Figure 16).
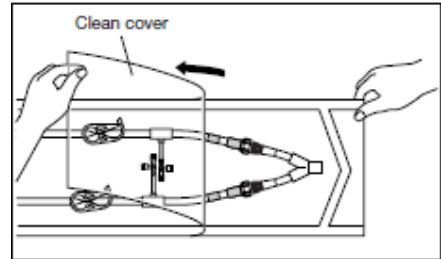
Figure 16

3. Loosen each screw wing for the arterial line and the venous line to remove the bypass connector (Figure 17).
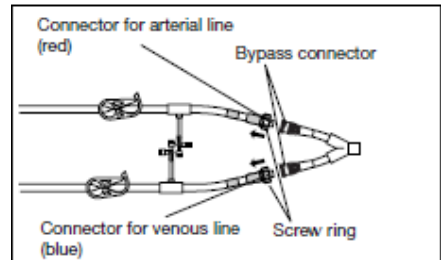
Figure 17

4. Connect the inserted arterial cannula (red) to the arterial line (red) and the inserted venous cannula (blue) to the venous line (blue) respectively (Figure 18) (Figure 19).

   CAUTION   When the arterial and venous cannulas are connected to corresponding lines, prevent them from kinking. Otherwise, flow rate will not be secured, and it may lead to damage of cannulas.
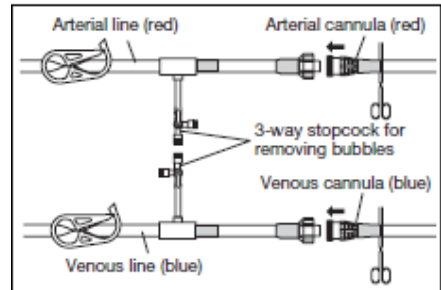
Figure 18

5. Take off the cap (with air filter) from the 3-way stopcock for removing bubbles, and remove bubbles remaining in the circuit using a syringe.

   CAUTION   The 3-way stopcock must be closed after completing removal of bubbles.
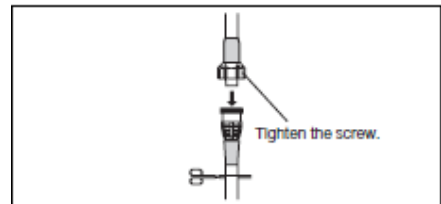
6. Fix the circuit to the patient or the bed.

   CAUTION   Pay attention not to fold or kink the circuit.

Figure 19

Initiation of BYPASS

WARNINGS	・ Prior to starting circulation, confirm that priming line is closed as well as 3-way stopcocks for removing bubbles and those of the sampling port. If the 3-way stopcocks are not closed, bubbles may enter the circuit as the pressure inside the venous line (blue) is negative during circulation.

・ Prior to delivering gas, confirm that the gas port (GAS OUT) is not blocked up. Otherwise, the pressure of the gas side in the oxygenator will increase, and bubbles will flow into the blood side.

・ Make sure that the underside of the centrifugal pump is in close contact with the pump receptacle and that the slide hook is in position.

1. Open the clamp of the venous line (blue) and forceps on the tube of the venous cannula (blue).

WARNING	Do not operate the pump with the venous line (blue) clamped. Otherwise, negative pressure would be generated inside the pump and bubbles would be formed in the blood.

2. Start the rotation of the centrifugal pump and set the pump speed at around 1000rpm.

3. Gradually release the clamp on the arterial line (red) to start circulation (Figure 20).

CAUTION	After-load pressure higher than the pump's outlet pressure causes back flow of the blood. To prevent this, do not unclamp the outlet of the pump at the start of circulation, until an adequate outlet pressure has been reached. (Refer to the data on Pump performance (19 page).)

Arterial cannula (red)

Arterial line (red)

Figure 20

4. Start gas supply.

CAUTIONS	・ Start gas supply only after blood circulation is initiated.

・ Start gas supply with V/Q = 1 and FiO_2 = 100%.

5. Adjust the pump speed of the centrifugal pump console for appropriate flow rate.

During perfusion

WARNING	Never clamp the venous line (blue) during circulation. Otherwise, negative pressure would be generated inside the pump and bubbles would be formed in the blood.
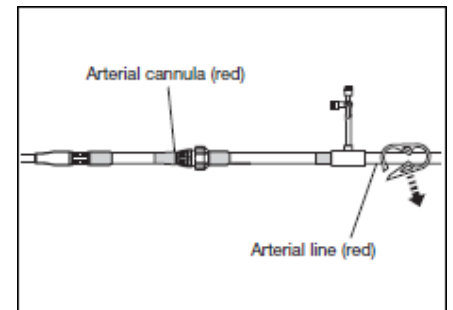
CAUTIONS ・ Carefully adjust the pump speed to control the
blood flow, because the blood flow varies
depending on the load applied to the pump (the
patient's arterial pressure, resistance of the circuit).

・ Control blood flow by adjusting the pump speed.
Partially clamping the outlet of the pump to control
the blood flow may increase the blood damage.

・ Entry of massive air into the pump will cause the
pump to deprime and the blood flow to stop.
When resuming circulation, stop the pump
once and remove the air.

・ After-load pressure higher than the pump's outlet
pressure causes back flow. When decreasing
the pump speed, adjust the pump speed
taking care not to cause back flow.

1. Collect blood from the sampling line of the oxygenator
(Figure 21).

WARNING Never collect blood from branch lines of the arterial
line (red) and the venous line (blue). Otherwise,
bubbles may enter the circuit.
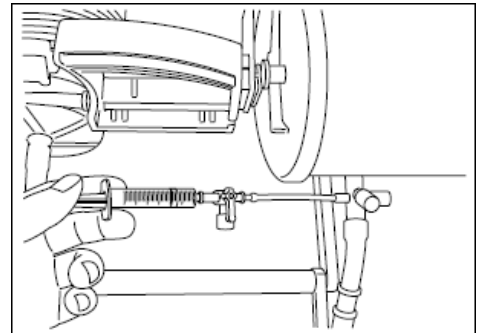
Figure 21

2. Measure blood gases and make necessary adjustments as
follows:
a) Control PaO$_2$ by changing concentration of oxygen in
ventilating gas using gas blender.
- To decrease PaO$_2$, decrease FiO$_2$.
- To increase PaO$_2$, increase FiO$_2$.
b) Control PaCO$_2$ by changing the total gas flow.
- To decrease PaCO$_2$, increase total gas flow.
- To increase PaCO$_2$, decrease total gas flow.

CAUTION - A minimum of 0.5L/min oxygen gas flow is needed
when blood is circulated. Less than 0.5L/min oxygen
gas flow may result in inadequate gas exchange.

- During circulation, always carefully monitor the patient blood condition and the oxygenator gas exchange performance. If gas exchange performance deteriorates, temporarily raise the gas flow rate to flush the inside of the fiber and try to recover performance.

  The gas flow rate for flushing is 20 L / min, the time is 10 seconds. If the performance does not recover immediately, it is considered to be caused by plasma leak. Therefore, replace this product with a new one without repeating the flush. A phenomenon called wet lung may occur when water condensation occurs inside fibers of microporous membrane oxygenators with blood flowing exterior to the fibers. This may occur when oxygenators are used for a longer period of time.

Termination of BYPASS

1. At the termination of circulation, clamp the arterial line (red) by forceps etc. taking care that no back flow occurs. After that, stop the pump by adjusting pump speed to 0.
2. Immediately after stopping the pump, stop gas supply.

CAUTIONS
- Do not supply gas while the circulation stops. When gas is supplied in case of recirculation, check blood gas pressure.
  Excessive gas supply may cause low $PaCO_2$, alkalosis and blood damage.
- When stopping circulation, be sure to clamp the outlet of the pump and then stop the motor. Do not clamp the venous line (blue) first.
- Do not operate the pump for a long time with its outlet clamped. The temperature within the pump may rise and increase blood damage.
- After-load pressure higher than the pump's outlet pressure causes back flow. While circulation is terminated, clamp both the arterial line (red) and the venous line (blue).

Circuit replacement

CAUTIONS ・Always prepare the spare circuit for emergency
replacement.
・Exchange all of the circuit when a problem occurs
in the oxygenator or the centrifugal pump.
・All procedures must be aseptically performed.

1. Perform priming procedure with the spare applicable centrifugal
pump controller or the backup controller. Then clamp the arterial
line (red) and the venous line (blue).

2. Disconnect the lines from the cannulas while taking care not to
spill the blood.
Method in detail: Clamp the clamping tube of the cannulas and
close the clamps on the lines. Loosen the screw rings of the
arterial line and the venous line and then disconnect the lines.

3. Connect the cannulas with a newly primed EBS circuit.

4. Open the clamp on the venous line (blue) and the forceps on
the venous cannula (blue).

5. Start the rotation of the centrifugal pump and set the pump
speed at around 1000rpm.

6. Gradually release the forceps and the clamp on the arterial
cannula (red) and the arterial line (red) to start circulation.

CAUTION   After-load pressure higher than the pump's outlet
pressure causes back flow. To prevent this, do not
unclamp the outlet of the pump at the start of
circulation, until an adequate outlet pressure has
been reached.

Data

O₂ transfer

O₂ transfer rate(mL/min) vs Blood flow rate(L/min)

500	
400	
300	
200	
100	
0	0 2 4 6 8

Blood flow rate(L/min)

<Conditions>
Blood   :Bovine Blood
Hb   :12±1g/dL
pH   :7.4
SvO2   :65±5%
PvCO2   :45±5mmHg
B.E.   :0±5mEq/L
V/Q   :1.0
Blood Temperature:37±1℃

CO₂ transfer

CO₂ transfer rate(mL/min) vs Blood flow rate(L/min)

500	
400	
300	
200	
100	
0	0 2 4 6 8

Blood flow rate(L/min)

<Conditions>
Blood   :Bovine Blood
Hb   :12±1g/dL
pH   :7.4
SvO2   :65±5%
PvCO2   :45±5mmHg
B.E.   :0±5mEq/L
V/Q   :1.0
Blood Temperature:37±1℃
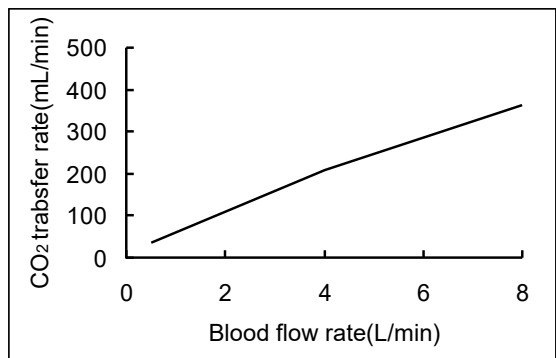
Heat exchanger performance factor

Performance Factor $\left(\dfrac{Tbo - Tbi}{Twi - Tbi}\right)$ vs Blood flow rate(L/min)
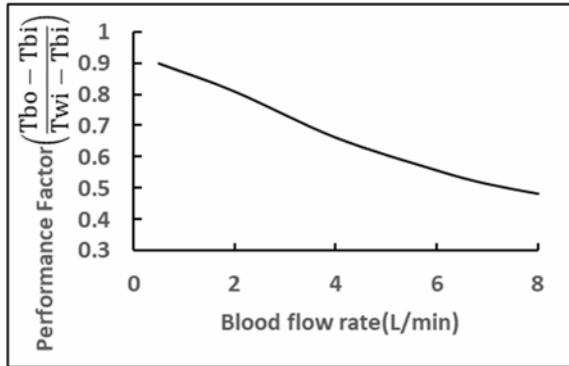
<Conditions>
Blood   :Bovine Blood
Hb   :12±1g/dL
Tbi   :30±1℃
Twi   :40±1℃
Water flow rate   :15 L/min

Pump performance

SP45   SL45

Outlet pressure(mmHg) vs Blood flow rate(L/min)

Legend:
- 1000 rpm
- 1500 rpm
- 2000 rpm
- 2500 rpm
- 3000 rpm

Specifications

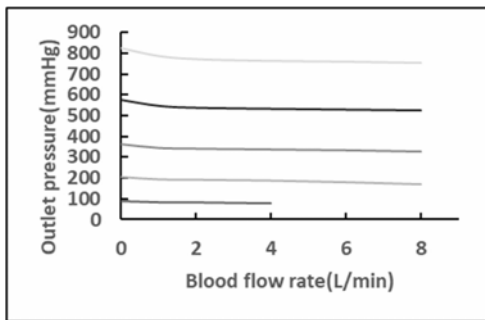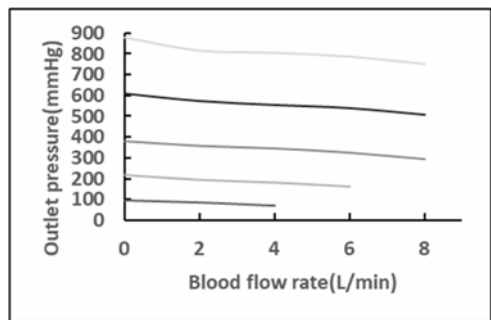| Code number	CX∗XSA	CX∗XSA0171	CX∗XSA0173	CX∗XSA0251
Sterilization	Ethylene oxide gas			
Priming volume	550 mL	620mL	620mL	740mL
Centrifugal pump	SP45	SL45	SL45	SL45
Maximum blood flow rate	7 L/min			
Minimum blood flow rate	0.5 L/min			
Maximum pressure	1000 mmHg (133 kPa)			
Connector for venous cannula	Lock connector			
Connector for arterial cannula	Lock connector			

Items	Specifications
Oxygenator	
Fiber surface area/material	Approx. 2.5m^2 / Poly methyl pentene
Heat exchanger surface area/material	Approx. 0.22m^2 / Stainless steel
Purge port	Luer port
Gas port (Gas in)	1/4" (6.4 mm)
Gas port (Gas out)	1/4" (6.4 mm)
Water port	1/2" (12.7mm) Couples connect fitting
Thermistor probe	Blood outlet port
Centrifugal pump	
Maximum pump speed	3000rpm
Maximum outlet pressure	800mmHg (107kPa)
Applicable console	CAPIOX SP Pump Console SP-101 (Code number: ME∗SP101K, ME∗SP101K2, ME∗SP101K3, ME∗SP101S, ME∗SP101S2, ME∗SP101S3) CAPIOX Centrifugal Pump Controller SP-200 (Code number: ME∗SP200C, ME∗SP200C2, ME∗SP200C3)
Applicable drive motor	CAPIOX SP Pump Drive Motor (Code number) ME∗SP101M, ME∗SP200M
Applicable flow sensor	CAPIOX SP Pump Flow Sensor 3/8" (9.5 mm) (Code number: ME∗FS38) ABD/Flow Sensor (Code number: ME∗SPFAS01, ME∗SPFAS02)

Accessories (Sold separately)

Applicable holder	CAPIOX EBS Circuit Holder (Code number: XX∗EB04)
Applicable cannula	CAPIOX EBS Cannula KIT For the code number, refer to the Instructions for Use of the Cannula Kit.

Applicable temperature monitor	YSI temperature YSI400 Series (Measurement Specialties Inc.)

Disclosable Information

- How to sterilize
- List of raw materials used for blood path
- Data on plasma leakage of semipermeable membrane
- Pressure drop of the blood path at the range of blood flow rates specified by the manufacturer for clinical use
- Pressure drop of the gas path at the maximum blood and gas flow rate specified by the manufacturer for clinical use
- Information on blood cell damage
- Information on particulate emissions from the membrane oxygenator with microporous Poly methyl pentene hollow fiber
- Tolerance range of data provided

Limited Warranty

TERUMO Corporation warrants that the product has been manufactured and packaged with reasonable care, and will be free from defects under normal and proper use. TERUMO Corporation will not be liable for any direct or indirect, incidental, special, general or consequential loss, damage, or expense from the use of this product. TERUMO Corporation's sole obligation under this warranty shall be to repair or replace, at its option, any product that it believes was defective at the time of shipment if notice thereof is receives before the expiration date indicated on the package.

THIS WARRANTY IS THE SOLE AND ONLY WARRANTY OF TERUMO CORPORATION AND IS EXPRESSLY IN LIEU OF AND EXCLUDES ANY OTHER EXPRESSED OR IMPLIED WARRANTY OF ANY KIND, INCLUDING THE WARRANTY OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE. IN ADDITION, THE REMEDIES SET FORTH HEREIN ARE THE SOLE REMEDIES AVAILABLE TO ANY PERSON OR ENTITY.

No agent, employee or representative of TERUMO Corporation has any Authority to change, Amend or alter the foregoing or assume or bind TERUMO Corporation to any additional liability or responsibility in connection with this product.
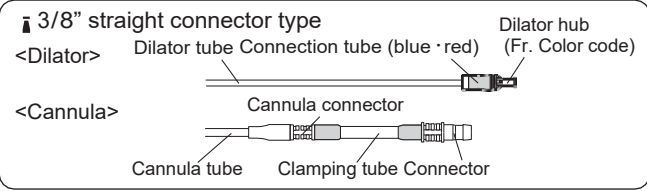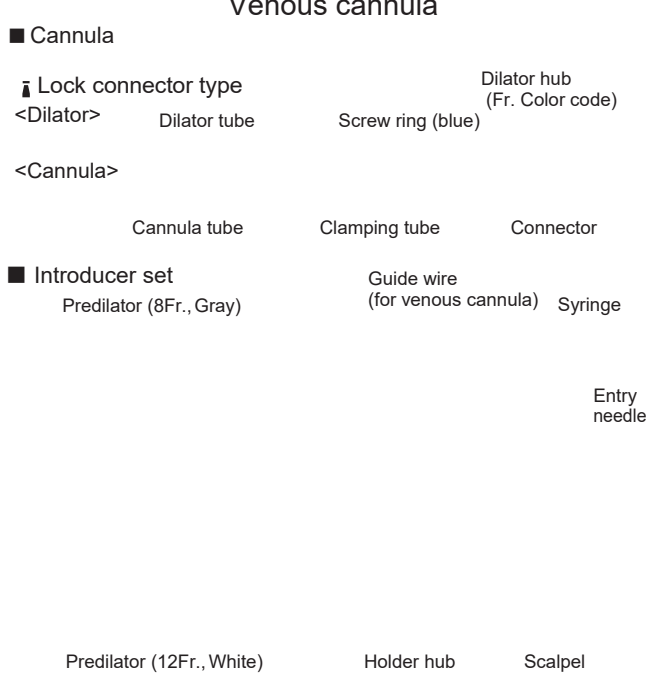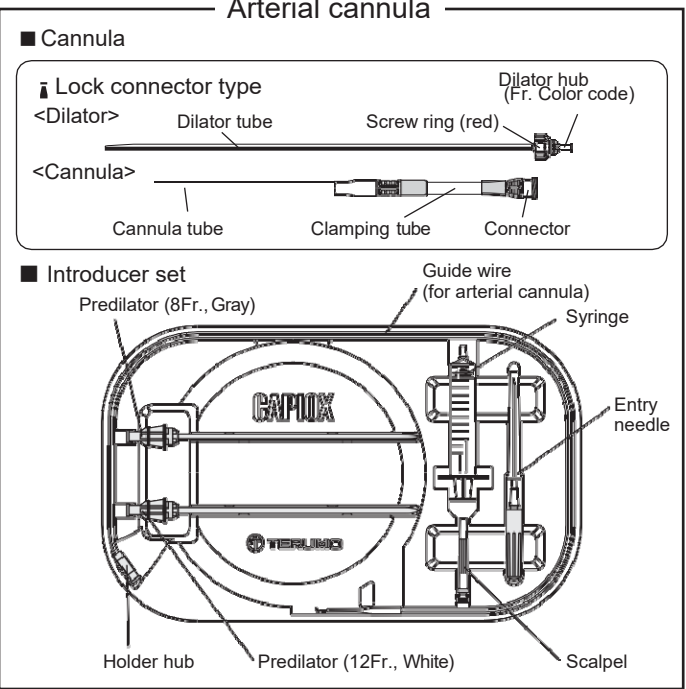
CAPIOX®
EBS Cannula Kit™ with X coating™

Instructions for use

TERUMO
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Product overview/Name of each part

This product is a kit consisting of cannulas to connect to a blood circuit for extracorporeal circulation to send or drain blood after percutaneously inserting cannulas into blood vessels and supporting tools for catheterization.

This product is composed of one cannula, one dilator, one entry needle, one guide wire, predilators (8 Fr., 12 Fr.), one syringe and one scalpel.

X coating is coated at the contact surface of the cannula with blood.

Arterial cannula

■ Cannula

Lock connector type

<Dilator> Dilator tube   Screw ring (red)   Dilator hub (Fr. Color code)

<Cannula>

Cannula tube   Clamping tube   Connector

■ Introducer set

Predilator (8Fr., Gray)   Guide wire (for arterial cannula)   Syringe

CAPIOX   Entry needle

TERUMO

Holder hub   Predilator (12Fr., White)   Scalpel

3/8" straight connector type

<Dilator>   Dilator tube Connection tube (blue · red)   Dilator hub (Fr. Color code)

<Cannula>   Cannula connector

Cannula tube   Clamping tube Connector

Venous cannula

■ Cannula

Lock connector type

<Dilator>   Dilator tube   Screw ring (blue)   Dilator hub (Fr. Color code)

<Cannula>

Cannula tube   Clamping tube   Connector

■ Introducer set

Predilator (8Fr., Gray)   Guide wire (for venous cannula)   Syringe

Entry needle

Predilator (12Fr., White)   Holder hub   Scalpel

Warnings and Precautions

WARNINGS
- Do not use any metal sheath.
  Pulling the guide wire by using a metal sheath or forwarding a metal sheath while the guide wire is indwelled may cause fracture of the guide wire and desquamation of plastic parts, which may require withdrawal.
- **Though X coating is coated at the contact surface of the cannula with blood, appropriate heparinization should be performed to avoid blood coagulation.**

PRECAUTIONS
- The guide wire develops its lubricity only when the surface is wet. Wet the surface of the guide wire before handling by filling the holder with heparinized saline in advance.
- This device should only be used by properly trained and qualified personnel.
- This product is sterilized by ehylene oxide and is intended for single use only. Do not resterilize nor reuse.
- Do not use if the unit package or the product has been damaged or soiled. Use immediately after opening the unit package and dispose of safely after single use to avoid risk of infection.
- Do not use any organic solvent such as alcohol and ether with this product. Plastic parts composing this product may be damaged due to these solvents.
- All procedures must be aseptically performed.

heparinized saline

hen, remove the

gh the plastic

e wire to move.

ot to make mistake.
ned.

Guide wire

(8Fr.)

of connection tube
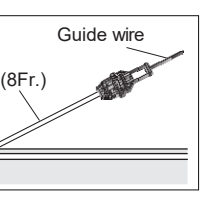
Dilator
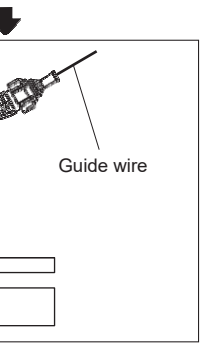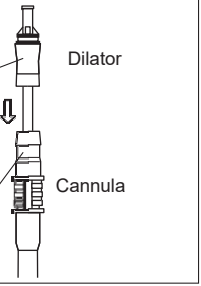
Cannula

Guide wire

of connection tube

Dilator hub

---

injection or sampling is required, pull out only the guide wire and perform the required procedure by using the dilator hub (Figure 7).

> **Warning** When only the cannula is indwelled, forwarding the cannula may damage the wall of the vessel. Special caution should be taken for this.

17. Upon completing insertion of the arterial and venous cannulas, connect the connector of the cannula to the circuit for the extracorporeal circulation (Figure 8-1, Figure 8-2) and remove bubbles remaining in the connector from the circuit side by using a syringe.

> **Caution**
> ▪ Pay attention not to kink the cannula and the circuit when they are connected. Otherwise, blood flow will not be secured and the cannula and the circuit may be damaged.
> ▪ Do not mistake the arterial line (pump outlet) and the venous line (pump inlet), when the arterial and venous cannulas and the arterial and venous lines are connected.

18. Confirm the position of the tip of the cannula by X-ray, and fix the cannula to the skin so that it cannot be moved or come off.

> **Caution** Pay attention not to kink the cannula when it is fixed. Otherwise, blood flow will not be secured and the cannula may be damaged.

19. After opening the clamp of the venous line and the forceps on the venous cannula (blue) (Figure 9-1-[1], Figure 9-2-[1]), open the clamp of the arterial line and the forceps on the arterial cannula (red) (Figure 9-1-[2], Figure 9-2-[2]). Then start circulation by operating at the circuit side (Figure 9-1, Figure 9-2). For procedures and steps on extracorporeal circulation, follow the instructions described in the Instructions for Use of circuit.

> **Warning** In case that a centrifugal pump is used for extracorporeal circulation, do not run it with the venous line clamped. It results in negative pressure inside of the pump, which may produce bubbles in blood.

> **Caution** In case that a centrifugal pump is used for extracorporeal circulation, do not unclamp the forceps on the clamping tube of the arterial cannula until an adequate outlet pressure of the pump has been reached. Otherwise, back flow of the blood will occur due to the patient's

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● While holding the cannula, slowly pull out the guide wire and the dilator. When they are pulled out to the point of the clamping tube of the cannula, clamp it with a forceps not to spill blood (Figure 7).

> **Caution** Do not perform the manipulation with a forceps at any other parts than the clamping tube. Or, the cannula may be damaged.

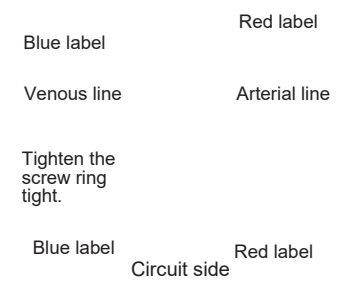Figure 8-1 Case of lock connector
Cannula side

Blue label

Red label

Venous line

Arterial line

Tighten the screw ring tight.

Blue label

Red label
Circuit side

Figure 8-2 Case of connection tube
Cannula side

Blue label

Red label

Venous line

Arterial line

Blue label

Red label

Cut of the connector

Circuit side
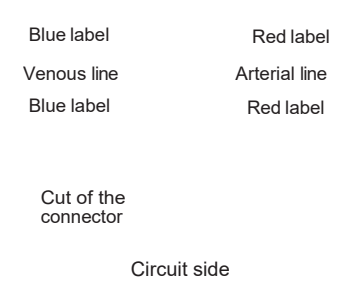
Figure 9-1 Case of lock connector
Cannula side

Venous cannula

Arterial cannula

Open [1]

Open [2]

Blue label

Red label

Circuit side
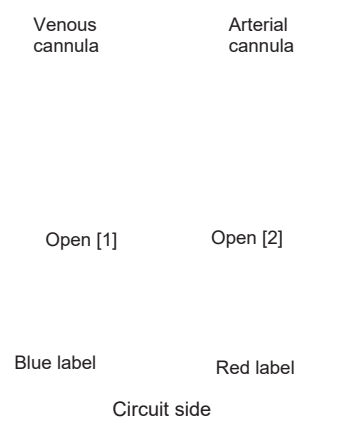
Figure 9-2 Case of connection tube
Cannula side
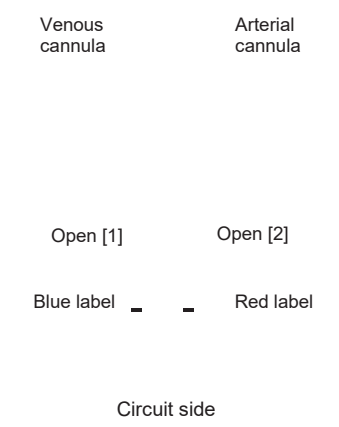
Venous cannula

Arterial cannula

Open [1]

Open [2]

Blue label

Red label

Circuit side

CAPIOX®
Centrifugal Pump Controller SP-200

Instructions for use

TERUMO
CARDIOVASCULAR

CAPIOX®
Centrifugal Pump Controller SP-200

Instructions for use

Store this instruction manual in a convenient location for future reference whenever necessary. Read the instructions carefully before using the product, and operate in accordance with instructions. Perform maintenance and inspections to ensure safe use and extend the life of this product.

TERUMO

Contents

Read this instruction manual carefully to fully understand this product and ensure its safe use.
Conduct safety training sessions for this product before use. For an explanation regarding the introduction of this product, consult with Terumo's service representative.

Contents

Purpose, Overview and Features of the Product

Purpose and Overview

This product is a drive system for operating a disposable centrifugal pump which mainly perfuses blood in the blood circuit of the heart-lung machine.

Product Features

◆ Excellent operability and visibility
- A visible and intuitively controllable large screen (7.5 inches)
- Small and lightweight (approximately 8 kg); uses a lithium ion battery
- Auto-priming function
- A flow sensor for the ultrasonic transit system is used

◆ Safety functions
- An air bubble sensor, two pressure sensors and two temperature sensors are installed
- Coast control function (the motor speed is automatically controlled when air bubbles are detected and the Pressure Alarm is activated)
- Easy-to-understand alarm and alert functions
- History function (trend charts, event lists, output data to USB memory)

System Configuration Example (When Attached on the Cart)

Gas cylinder

Infusion bags

CAPIOX centrifugal pump

Hand Crank

CAPIOX
EBS™ Circuit with X coating™

Gas blender

Drive Motor
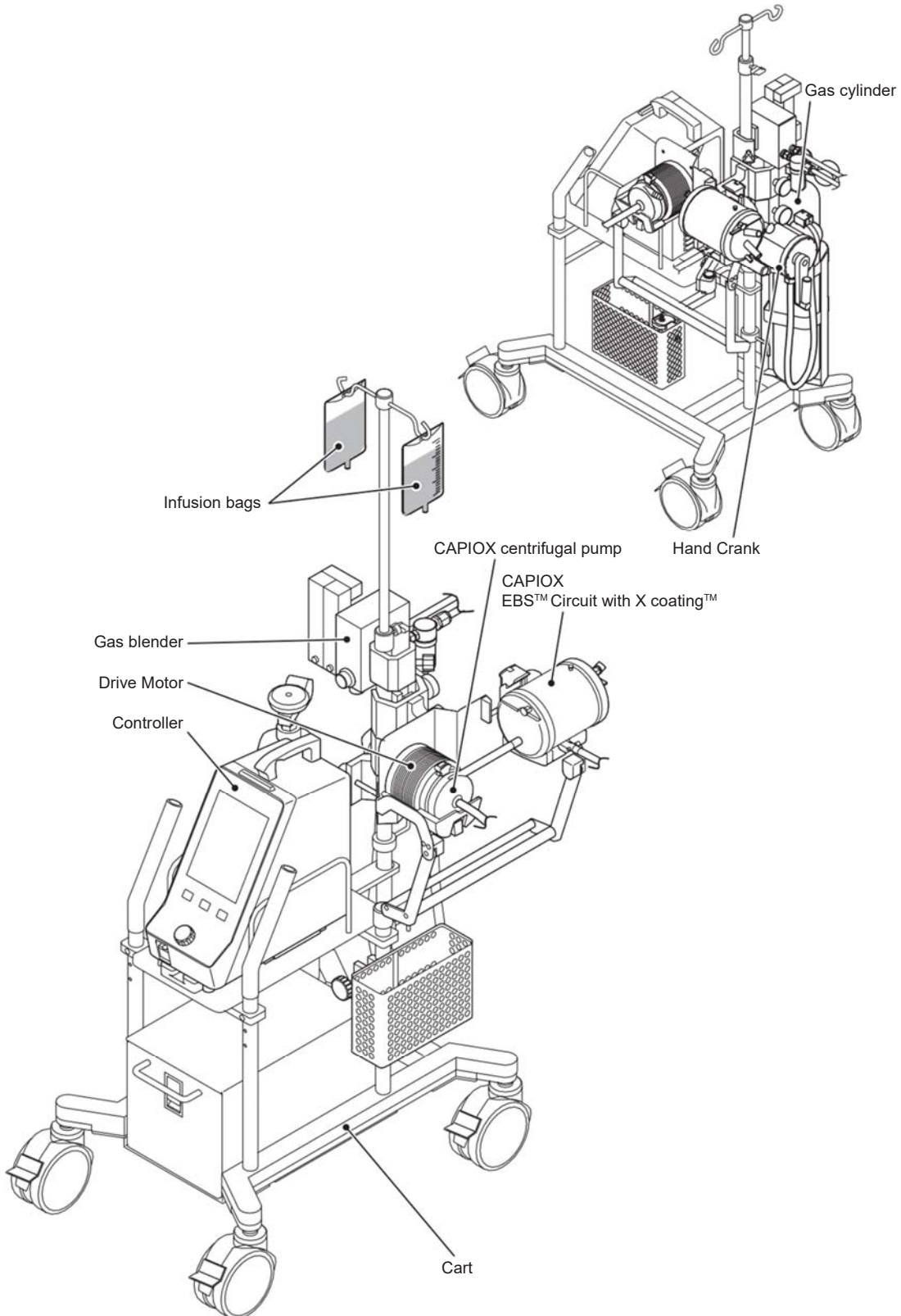
Controller

Cart

- For information on the attaching method, refer to "Attaching the Controller to the Cart" (page 29) and "Attaching Other Products to the Cart" (page 61).
- We do not deal in gas blenders and gas cylinders.

Controller

◆ Front view

Handle
Used when carrying the Controller.

LCD touch panel display
Displays the operating status and messages of the system.
Various setups can be made through the touch panel operation. The screen can be operated while wearing surgical gloves.

Auto priming button
Starts and stops the intermittent operation (auto-priming) of the Drive Motor.
The button is lit in orange while auto-priming is performed.

Power button
Turns the power on or off.

Status lamp
Indicates the operating status of this system through changes in colour.
Green (lights up): indicates the system is operating normally.
Yellow (lights up): indicates the system has detected a low priority alert.
Yellow (flashes): indicates the system has detected a middle priority alert.
Red (flashes): indicates the system has detected a high priority alarm.

Coast release button*
Used to further decelerate (coast release) the motor speed after reaching the coast speed while decelerating.
Flashes in orange when the motor speed has reached the coast speed while decelerating.

Key lock button
Locks the touch panel and the button operation.
The button is lit in orange while key lock is activated.
The power button is operable while key lock is activated.

Battery indicator lamp
Displays the battery charge level. (For details, refer to "Battery-powered Operation" (page 72).)

◆ Control panel

Flow indicator
Displays the circulating flow.

Motor speed indicator
Displays the motor speed.
When a high priority alarm caused by the device is issued, the motor speed and the error number are displayed alternately.
(For the details of the error numbers, refer to "List of Alarm Messages" (page 134).)

Motor speed knob*
When you turn the knob clockwise, the motor speed increases, and when you turn the knob counter-clockwise, the motor speed decreases.

AC power lamp
Lit in green when AC power is supplied.

Charge lamp
Lit in green when the battery is charged.

Motor speed indicator lamp*
Displays the motor speed indicated value coupled with the operation of the motor speed knob and the coast speed.
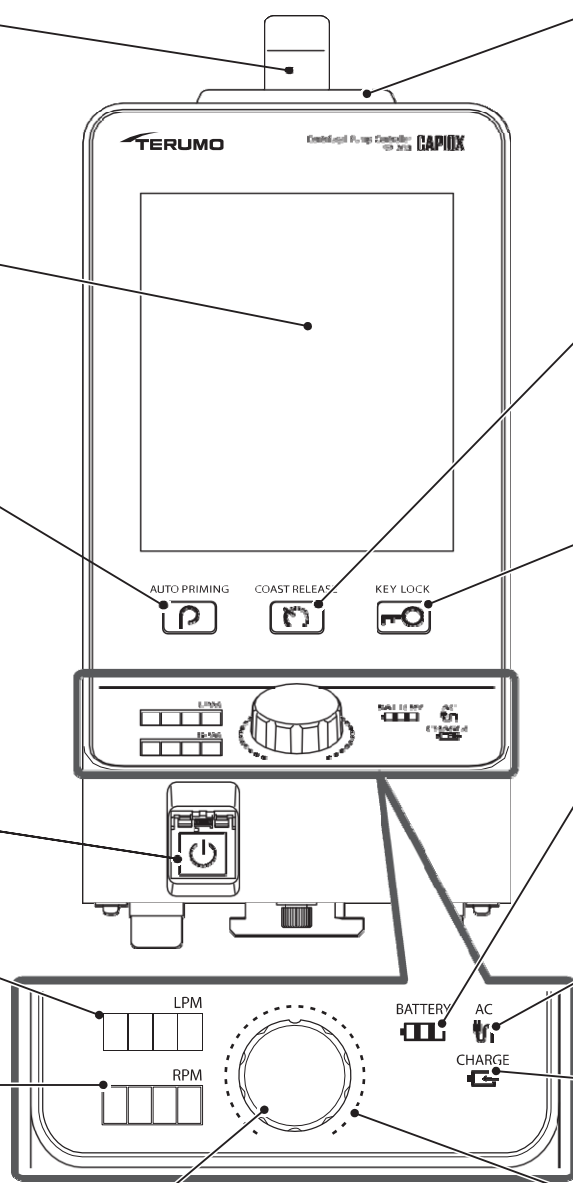
* Also refer to "Device Behaviour in Relation to the Coast Speed" (page 8).

◆ Rear view

CDI® port
Connects to the CDI500.

USB port
Connects with a USB memory drive.

Fast clamp connector
Connects with the Fast Clamp.

Temperature sensor connector (T1 and T2)
Connects with the Temperature Sensor Cable.

Drive motor connector
Connects with the Drive Motor.

ABD/Flow sensor connector
Connects with the ABD/Flow Sensor.

Air outlet

LAN port
Connects with a LAN cable.

Pressure sensor connector (P1 and P2)
Connects with the Pressure Sensor Cable.

Potential equalization terminal
Connects with a ground cable. (Use when necessary.)

Fuse holders
Builds in fuses. (Type and rating: T8AH250V)

AC power inlet
Connects with an AC power cable. (Pull out the AC power cable when shutting off AC power.)

◆ Bottom view

Latch block
Used for securing with the Cart (an optional product).

Air inlet (with filter)

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Device Behaviour in Relation to the Coast Speed

As the motor speed slows and reaches coast speed (*), the system maintains that motor speed. This is to avoid back flow of circulation if users further decrease the motor speed. In order to decrease the motor speed to less than the coast speed, confirmation (coast release) is required.

The following example describes a case in which the motor speed is increased from 0 RPM to 2000 RPM (1) and then the speed is decreased to 0 RPM (2).

* Coast speed can be set within the range of 500 to 2000 RPM (factory setting: 1250 RPM).
   Set the motor speed at which back flow does not occur in accordance with clinical requirements. (Refer to "Setting the Coast Speed" (page 108).)

(1) When the motor speed is increased from 0 RPM to 2000 RPM

0 RPM   Coast speed   2000 RPM

Motor speed

Coast speed

❶ Only the lamp to indicate the coast speed is lit in orange. (This lamp is always lit while powered on)

Coast speed

❷ Lights up in orange until it reaches the coast speed.

Coast speed

❸ Lights up in green when it exceeds the coast speed.

(2) When the motor speed is decreased from 2000 RPM to 0 RPM

❻ **Coast release**

The coast release is performed with either of the following methods:

Message display
Press [OK] to decrease the motor speed less than the coast speed.

COAST RELEASE

The Coast release button flashes in orange.
Press the button to decrease the motor speed less than the coast speed.

0 RPM   Coast speed   2000 RPM

Motor speed

Coast speed

❽ Only the lamp to indicate the coast speed is lit in orange. (This lamp is always lit while powered on)

Coast speed

❼ When further decreasing the motor speed, the orange lamp is turned off.

Coast speed

❺ When decreasing the motor speed to the coast speed, it maintains the coast speed. The message is displayed, and the coast release button flashes in orange.

Coast speed

❹ When decreasing the motor speed, the green lamp is turned off.

LCD Touch Panel Display (When Operating Normally)

◆ Main screen

* When you tap each function, you can directly proceed to the corresponding Setup screen.

Number	Name	Description
a	**Count up timer indicator (1)**	Displays the count up time of the count up timer 1 (date: two digits, hour: two digits, minute: two digits, second: two digits).
b	**Count up timer indicator (2)**	Displays the count up time of the count up timer 2 (date: two digits, hour: two digits, minute: two digits, second: two digits).
c	**Battery status indicator**	**100%** : Displays the battery charge level. **97%** : The flashing arrow indicates the battery is being charged. For details about the battery charge level, refer to page 73.
d	**Clock**	Displays the current time.
e	**AC power indicator**	Displays the connection status of the AC power cable. : Connected to AC power : Disconnected from AC power (On Battery)
f	**Flow indicator**	Displays the circulating flow and the setup conditions of the safety connection. **Setup conditions of the safety connection (Back Flow Alarm)** Displayed when the safety connection is set to [Message Only]. Displayed when the safety connection is set to [Clamp+Pump stop].

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Number	Name	Description
g	**Flow bar indicator**	Displays the circulating flow with a bar. The set thresholds of the High Flow Alarm/Low Flow Alarm are indicated with "△".
h	**Motor speed indicator**	Displays the motor speed of the Drive Motor.
i	**Perfusion index indicator**	Displays the perfusion index value by inputting height and weight in the BSA setup.
j	**Action status indicator**	The blue indicator changes when the system is operating.
k	**Message area**	Displays icons and messages such as the operating conditions, alarms, etc. For details about the alarm messages, refer to page 134.
l	**Setup icon**	Opens the "setup menu" screen.
m	**Clamp status icon**	Displays the status of the Fast Clamp.
		Indicates that the alarm of the Fast Clamp is not issued.
		Indicates that a high priority alarm caused by the device is issued at the Fast Clamp.
		Indicates that a high priority alarm caused by the living body is issued at the Fast Clamp.
		Indicates that a low or middle priority alarm caused by the device is issued at the Fast Clamp.
		Indicates that the function of the Fast Clamp is off.

Note

• The measured values of the flow are displayed in numerical indication (f flow indicator) and bar indication (g flow bar indicator). The response of the numerical indication is slower to improve the display stability.

Number	Name	Description
n	ABD status icon	Displays the setup conditions of the air bubble detector function, the status of the alarm and the setup conditions of the safety connection.

The setup conditions and the status of the alarm

	Description
	Displays the setup conditions of the safety connection at the left side of the icon. Also, the icon indicates that the alarm relating to the air bubble detector function has not been triggered. **Setup conditions of the safety connection (Air Bubble Detected Alarm)**

	Displayed when the safety connection is set to [Message Only].
	Displayed when the safety connection is set to [Pump Coast].
	Displayed when the safety connection is set to [Clamp+Pump stop].

	Indicates that a high priority alarm relating to the air bubble detector function caused by the device has been triggered.
	Indicates that a high priority alarm relating to the air bubble detector function caused by the living body has been triggered.
	Indicates that the air bubble detector function is off.

Number	Name	Description
o	Auto priming icon	Starts and stops the intermittent operation (auto-priming) of the Drive Motor. The icon is lit in green while auto-priming is performed.
p	Key lock icon	Locks the touch panel and the button operation. The icon is lit in green while key lock is activated.
q r	Pressure indicator (P1 and P2)	Displays the pressure value and the setup condition of the safety connection. **Setup conditions of the safety connection (Pressure Alarm (over pressure/low pressure))**

Over pressure		Displayed when the safety connection is set to [Message Only].
		Displayed when the safety connection is set to [Pump Coast].
Low pressure		Displayed when the safety connection is set to [Message Only].
		Displayed when the safety connection is set to [Pump Coast].

When the pressure measuring function is off, the whole pressure indicator is displayed in grey.

Number	Name	Description
s t	Temperature indicator (T1 and T2)	Displays the temperature. When the temperature measuring function is off, the whole temperature indicator is displayed in grey.

LCD Touch Panel Display (When Issuing Alarm)
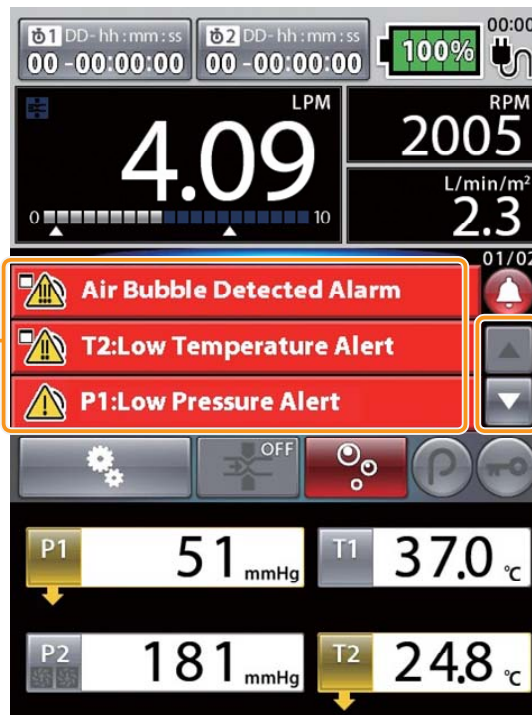
Message area
Of the issued alarms, the message is displayed from the high priority message in order of the corresponding priority. When you tap each message, the information about the troubleshooting is displayed.
Three items can be displayed on the screen at a time.
When more than one alarm are issued, the messages light up in the colour of the higher priority alarm.

Red: when a high priority alarm is issued.
Yellow: when a low or middle priority alert is issued.

When you tap ▲ or ▼ , you can scroll up and down the message area to view all of the issued alarm messages.

Icon		Description
		High priority alarm message
		Middle priority alarm message
		Low priority alarm message
▯		Displayed at the upper left of the icon when the alarm messages remain unread.
		Messages other than the alarm
Alarming	**Alerting**	Indicates that the alarm is sounding. Tap the icon to mute the alarm.
Alarming	**Alerting**	Indicates that the alarm is muted. The muted condition of the alarm is awaken by tapping the icon. However, when two minutes have passed without resolving the alarming condition, the alarm starts to sound again. When another alarm is issued, the alarm starts to sound as well.

Display Units of the Controller

In this manual, units are written corresponding to the Controller display as follows:

	Display on the LCD touch panel display	Description (unit)
Flow	LPM	Liters per minute (L/min)
Motor Speed	RPM	Rotations per minute (r/min)

Optional Accessories

Standard accessories supplied with this system:
● AC power cable (1)
● Instructions for use (1)
● Backup kit (1)

Backup Controller (1)
Drive Motor (without a pole clamp) (1)
AC power cable (1)
Screwdriver (+) (1)
Extra screws (to fix the drive motor) (2)
Instructions for use (Backup Controller) (1)

Optional Products

◆ Drive Motor

(Catalogue number: ME＊SP200M)
Magnets in the motor and in the centrifugal pump are joined magnetically, and the rotating body in the centrifugal pump is rotated with the DC brushless motor. This Drive Motor can be secured to a pole with the pole clamp.

Cable
Motor
Pole clamp
Slide hook
Magnet cover
Plug
Fixed hook
Pump receptacle
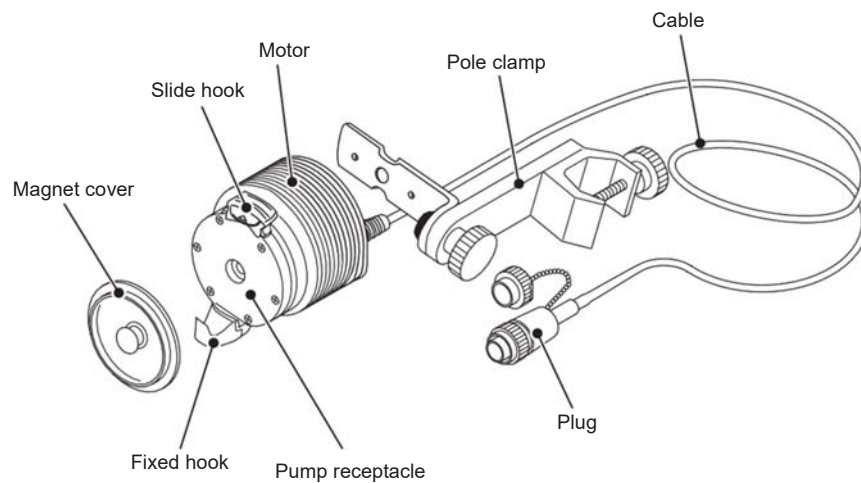
◆ ABD/Flow Sensor

Product name: CAPIOX Centrifugal Pump Controller SP-200 ABD/Flow Sensor

Manufacturer: Transonic Japan

(Catalogue number: ME∗SPFAS01 (for standard tube circuit), ME∗SPFAS02 (for soft tube circuit))

An ultrasonic transmission sensor and a receiving sensor are built in. The flow is measured by the ultrasonic transit method, and air bubbles are detected by the change in the ultrasonic receiving level.

The ABD/Flow Sensor is attached to the blood circuit tube (inner diameter 9.5 mm (3/8 inches)).

Plug

Cable

Clamp-on ABD/Flow sensor
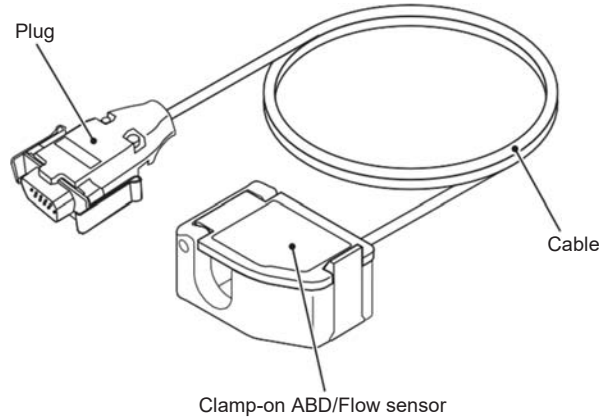
◆ Fast Clamp

(Catalogue number: ME∗SPCLP01)

When air bubbles are detected or back flow occurs, the blood circuit is instantly blocked off with the plunger.

The Fast Clamp is attached to the blood circuit tube (inner diameter 9.5 mm (3/8 inches)).

Lid

Clamp ready lamp

Plunger

Latch

Cable

Lever

Plug

Fixing block
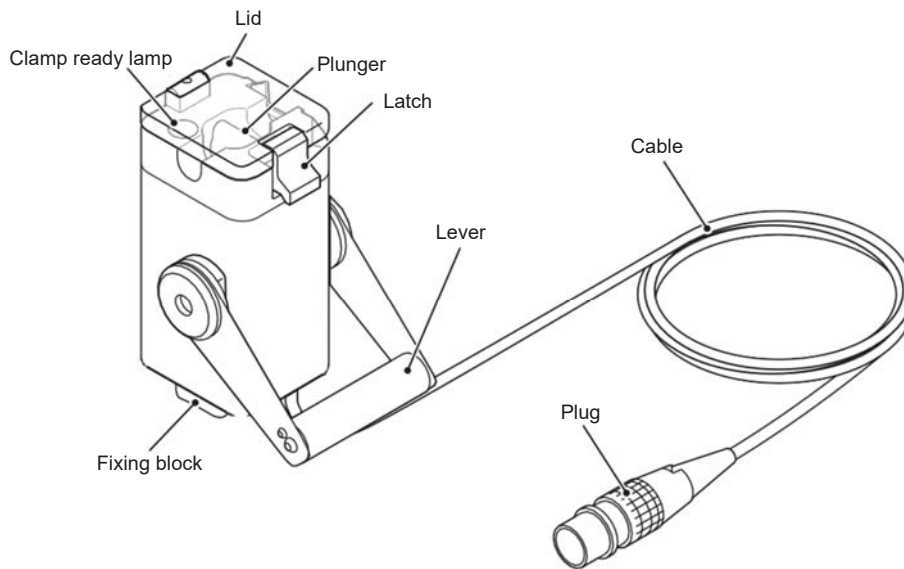
◆ Temperature Sensor Cable

(Catalogue number: XX∗SPCBL011 (blue), XX∗SPCBL012 (red))

When measuring temperature, connect the applicable temperature sensor (CAPIOX Luer Thermistor) to the Controller.

Plug

Temperature sensor connector
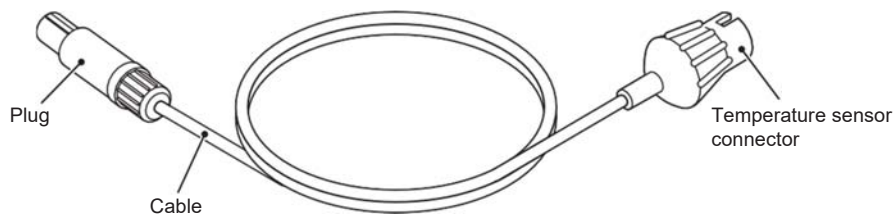
Cable

◆ Pressure Sensor Cable

(Catalogue number: XX*SPCBL021)

When measuring pressure, connect the pressure sensor which complies with the ANSI/AAMI BP22:1994 to the Controller. The pressure sensors MP5100 (TW) and MP5200 (TW) made by Edwards Lifesciences Corporation are recommended for use.

Plug

Cable

Pressure sensor connector
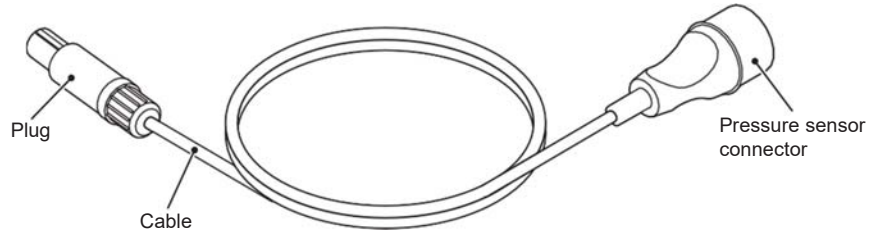
◆ CDI Communication Cable

(Catalogue number: XX*SPCBL031)

When transmitting the flow information to the CDI System 500, connect the CDI System 500 to the Controller.
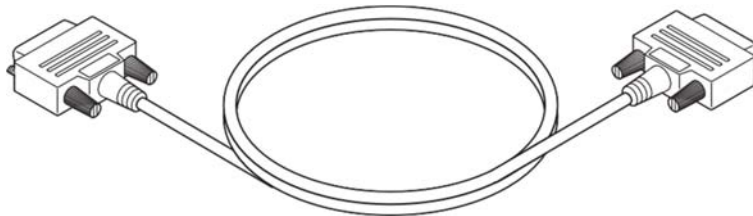
◆ Hand Crank

(Catalogue number: XX*SP05)

When the centrifugal pump cannot be operated by the Controller, use the Hand Crank for manual operation.
For information on the usage method, refer to the instructions for use of the Hand Crank.

Pole clamp

RPM display

Handle

Gear box

Crank

Fixed hook

Pump receptacle

Slide hook

Flexible shaft
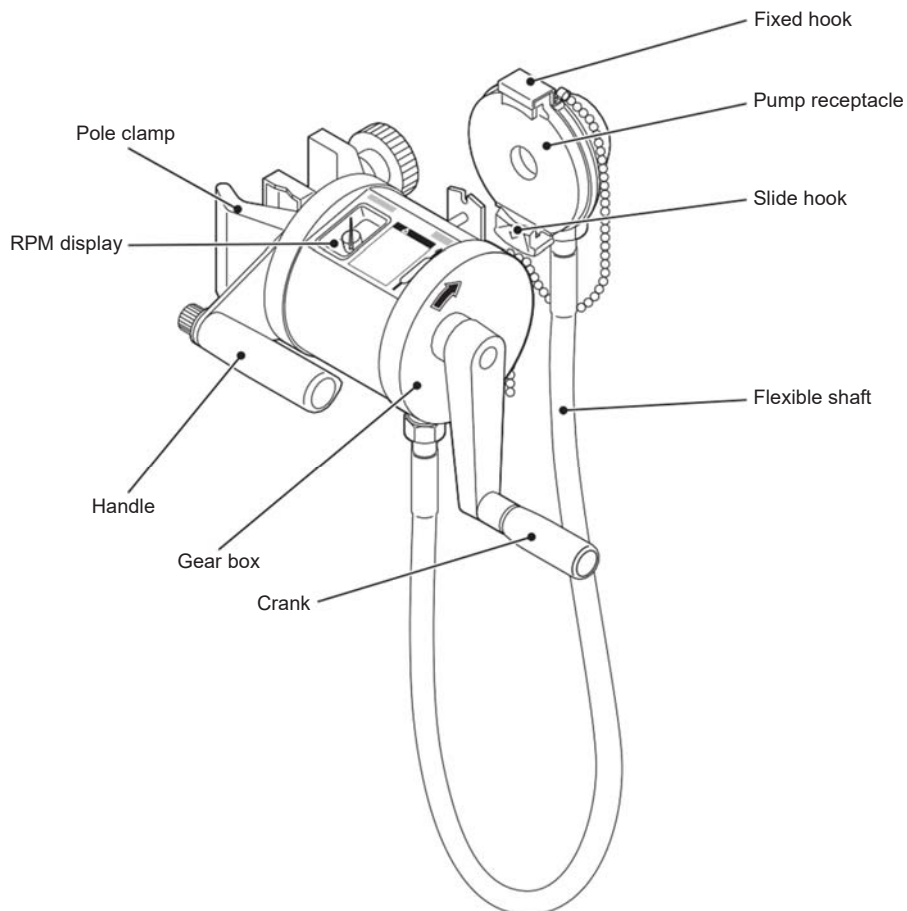
◆ Fast Clamp Arm

(Catalogue number: XX∗SPCLP02)

When securing the Fast Clamp, use this fixture with flexible arm.

The Fast Clamp can be attached in multiple configurations because of the flexible arm type.
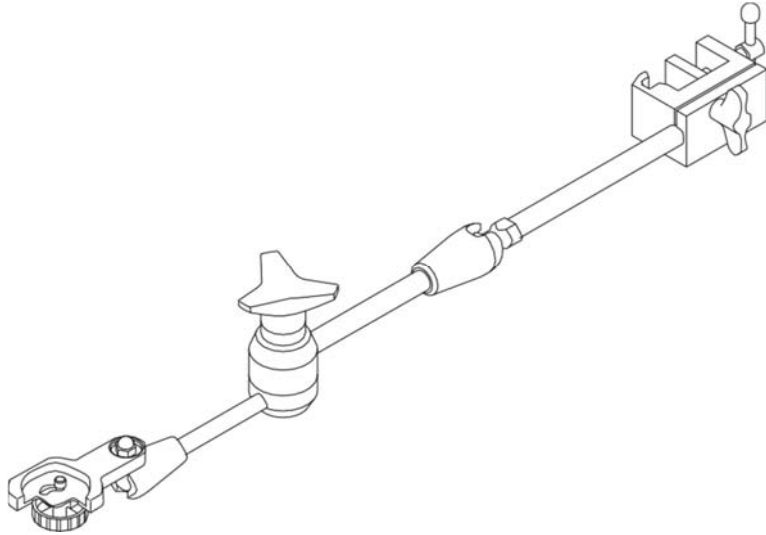
◆ Fast Clamp Attachment (for EBS)

(Catalogue number: XX∗SPCLP01)

When securing the Fast Clamp, use this fixture with the CAPIOX EBS Circuit Holder.
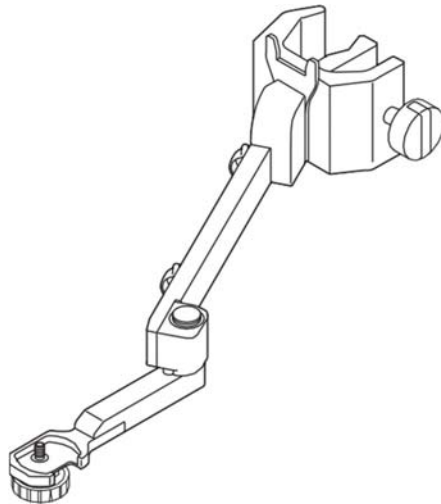
◆ Cart

(Catalogue number: XX*SPCRT01)
The entire system can be mounted on this cart. Since infusion bags, gas cylinders and gas blenders can also be attached, the cart can support transportation during extracorporeal circulation.
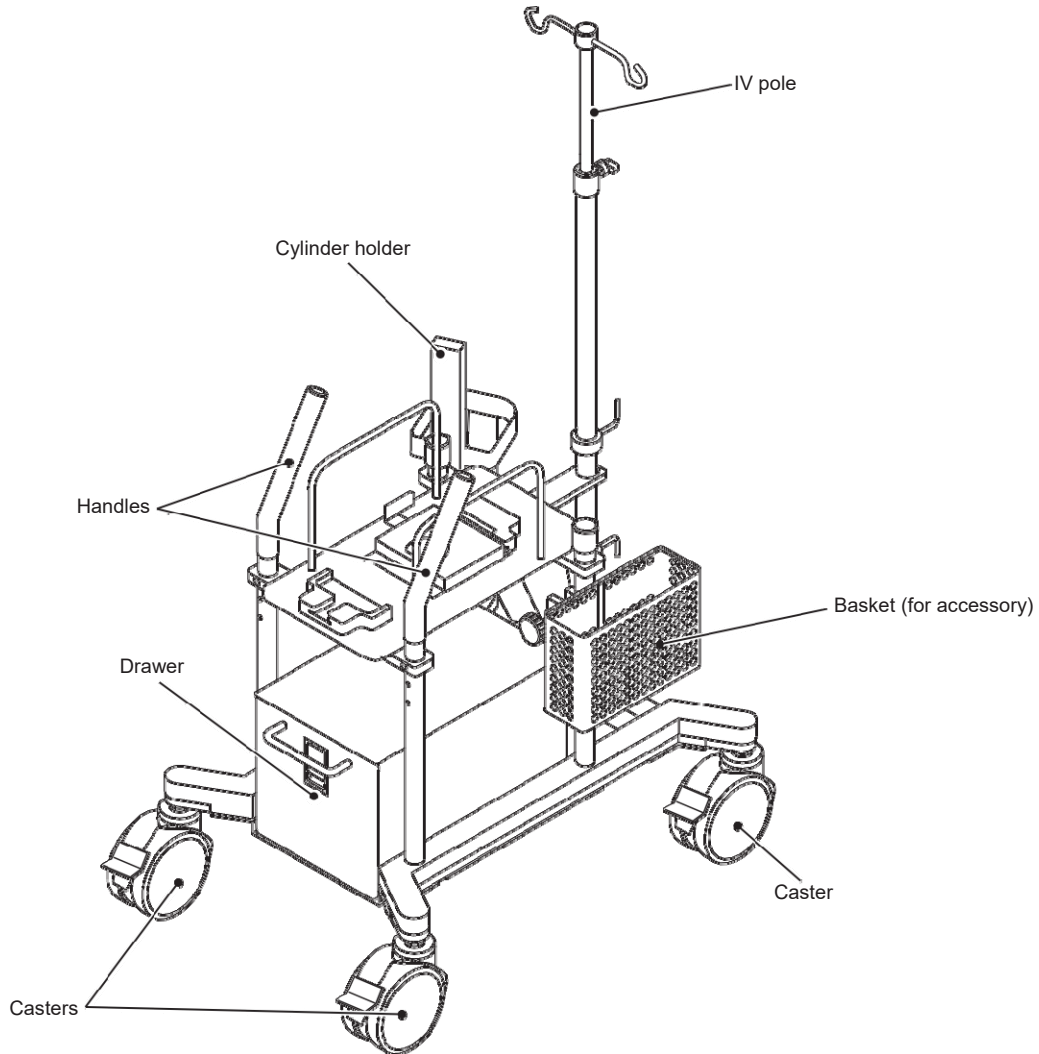
IV pole

Cylinder holder

Handles

Basket (for accessory)

Drawer

Caster

Casters

◆ Related components

- CAPIOX centrifugal pump
- CAPIOX EBS Circuit with X coating
- CAPIOX Luer Thermistor
- CDI System 500
- Pressure sensor (complied with ANSI/AAMI BP22:1994) * Limited to those that can be connected to connectors.

Cautions

- Do not use this system with any equipment other than the dedicated medical equipment. If equipment other than the dedicated medical equipment is used, this may result in decreased performance.
- Do not attach the ABD/Flow Sensor and the Fast Clamp to any tube other than the dedicated tube (internal diameter: 9.5 mm (3/8 inches)). If a tube other than the dedicated tube is used, this may result in decreased performance.
- Do not use any cable other than the included AC power cable. Otherwise an electric shock or short circuit may occur resulting in failure of this system.
- Make sure to use a pressure sensor which conforms to ANSI/AAMI BP22:1994. If a pressure sensor that does not conform to the aforementioned standard is used, this may result in decreased performance.
- Before use, check the instructions for use of the medical supplies and medical equipment that are used in combination.
- Use the following dedicated devices for this system. Drive Motor (Catalogue No.: ME∗SP200M), Hand Crank (Catalogue No.: XX∗SP05), ABD/Flow Sensor (Catalogue No.: ME∗SPFAS01, ME∗SPFAS02), Temperature Sensor Cable (Catalogue No.: XX∗SPCBL011, XX∗SPCBL012), Pressure Sensor Cable (Catalogue No.: XX∗SPCBL021), Fast Clamp (Catalogue No.: ME∗SPCLP01), CDI Communication Cable (Catalogue No.: XX∗SPCBL031), Cart (Catalogue No.: XX∗SPCRT01), Fast Clamp Attachment (for EBS) (Catalogue No.: XX∗SPCLP01), Fast Clamp Arm (Catalogue No.: XX∗SPCLP02). If other devices are used, this may result in decreased performance. In addition, influence may be given to the emission level of electromagnetic wave and the tolerance of this system.

To ensure safe and correct use of this product, please observe all precautions.
Non-compliance with precautions and incorrect use may result in damage or injury.
The following are symbols used in this manual and their meanings:

| Warning | This label preceding a precaution indicates that there will be a possible risk of death or personal injury if the precaution given is not complied with. |

| Caution | This label preceding a precaution indicates that there will be a possible risk of personal injury or property damage if the precaution given is not complied with. |

Use

Warnings

(All equipment)

• Always prepare a backup system (the Backup Controller, the Hand Crank, etc.) to maintain circulation during an emergency. [Circulation cannot be maintained during an emergency.]

• Monitor the circulation status (the operation status of the system, blood storage state of a reservoir, etc.) during extracorporeal circulation without fail. [1. As this system does not have a function to monitor the status of the patient, the system cannot detect when the status of the patient changes even if the system operates properly. 2. The system cannot detect the leakage of liquid (including blood) caused by damage to the extracorporeal circulation circuit. 3. It is possible that the system will not detect a flow abnormality, even if the ABD/Flow Sensor is used. 4. This system may not operate in accordance with the specifications if the system is used together with another system.]

• The Drive Motor and the Hand Crank contain magnets, and therefore do not bring metal objects or magnets near these devices. [Malfunction may occur.]

• Adjust the motor speed of the centrifugal pump so that the pressure at the blood flow path of the oxygenator is always higher than the pressure at the gas passage. [If the pressure at the gas passage is higher than the pressure at the blood flow path, air may enter into the blood.]

• When using devices (mobile phones, radio devices, electrosurgical knives, defibrillators, etc.) that emit an electromagnetic wave near this system, they should be used as far away as possible. This system should use a power supply isolated from these devices and should obtain secure grounding. [Malfunction in this system caused by electronic interference may result in critical harm to the patient.]

• Do not use this system with other equipment placed next to it or stacked together. [Malfunctions may occur due to electromagnetic interference.]

• This system requires special attention to electromagnetic compatibility ("EMC") and must be used in accordance with the EMC information described in "For Medical Staff" in this instructions for use.

• Do not clamp the blood inlet line of the centrifugal pump during circulation. [Air bubbles may occur in the blood as the inside of the centrifugal pump is negatively pressured.]

• When using this system, do not touch the following 2 places at the same time. [Otherwise an electric shock or short circuit may occur.]
  • Patient and connector at the back of the Controller
  • Patient and connector at the front of the Backup Controller

• Do not use this system for the following purposes.
  • Usage other than percutaneous cardiopulmonary support/ECMO/ECLS, open heart surgery and aortic surgery
  • Long-term use in bridge to transplant or pending recover of the natural heart

(Controller/Backup Controller)

• Connect the AC power cable to the AC power inlet of the Controller or the Backup Controller until you hear a click. Subsequently, check that the AC power lamp in the control panel of the Controller is lit. [If the connection is insufficient, the Controller will be powered by the battery. And therefore the battery will be depleted, the devices will shut down and circulation will not be maintained. (The battery is installed only in the Controller and not in the Backup Controller.)]

• When the Controller signals the Serious System Error (device alarm (high priority)) attach the centrifugal pump with the Drive Motor connected to the Backup Controller or the Hand Crank to maintain circulation. When the Backup Controller signals the Serious System Error (Overspeed Rotation Alarm), attach the centrifugal pump with the Hand Crank to maintain circulation. [Otherwise, the pump may stop and may cause injury to the patient.]

Warnings

- When installing the system in an ambulance and transferring a patient in the event of an emergency, make sure the power supply of the ambulance is always higher than the total consumption power for all electric devices installed. [If the supply power of the ambulance becomes insufficient, the device shuts down and circulation cannot be maintained.]

(Controller)

- Use the AC power source as the primary power source. [Battery is used as an auxiliary power source when the AC power source cannot be used sufficiently, such as during transportation, electric failure, etc. If the battery is depleted and charging is insufficient, the Controller will not be able to operate by the battery during an emergency such as electric failure.]
- Set the safety connection and record its setting. Confirm that the device is operating as intended by the safety connection. [If the setting is wrong, the Controller may not operate as intended.]
- Do not attach the Fast Clamp to the blood inlet line of the centrifugal pump. [Air bubbles may occur if the blood inlet line is clamped, as the inside of the centrifugal pump will be negatively pressurized.]

(ABD/Flow Sensor)

- When attaching the ABD/Flow Sensor, apply enough vaseline to evenly coat the detection window of the clamp-on ABD/ Flow sensor. [If the amount of vaseline applied is insufficient, the Flow Signal Unstable Alarm may be issued and air bubbles may not be detected.]

Cautions

(All equipment)

- If the circulation is performed by satisfying all the following settings, do not remove the ABD/Flow Sensor from the extracorporeal circulation circuit or from the Controller. [The Air Bubble Detected Alarm may be issued and the Fast Clamp may work unintentionally.]
  - Air bubble detection : On
  - Fast clamp function: On
  - Safety connection of the Air Bubble Detected Alarm: Clamp+Pump stop
- Make sure to use a pressure sensor which conforms to ANSI/AAMI BP22:1994. [If a pressure sensor that does not conform to the aforementioned standard is used, this may result in decreased performance.]
- Do not operate the centrifugal pump without filling the pump with liquid beforehand. [Damage may occur to the rotary sliding part.]
- Use this system while paying attention not to let air in the blood circulation circuit. [Health damages may occur to the patient.]
- When attaching or detaching the centrifugal pump to or from the Drive Motor or Hand Crank, confirm that the Drive Motor or Hand Crank are stopped. [The centrifugal pump may start or stop its rotation unintentionally.]
- Attach the centrifugal pump while adjusting the Drive Motor position so as not to let the fixed hook and the extracorporeal circulation circuit connection part interfere. [The fixed hook or centrifugal pump may be damaged.]
- When attaching the centrifugal pump to the Drive Motor or Hand Crank, confirm that the bottom surface of the centrifugal pump is in close contact with the pump receptacle and that the slide hook is securely in position. [If rotation starts while the slide hook is not secured due to residue of blood and drug solution, the centrifugal pump may detach from the pump receptacle.]
- Perform the flow adjustment by changing the motor speed of the centrifugal pump. [If the adjustment is performed by partially clamping the blood outlet line of the centrifugal pump, damage to the blood may be increased.]
- While circulating, maintain the motor speed at a speed higher than that at which the Low Flow Alarm is issued (the speed at which back flow does not occur due to the height gradient or the patient's blood pressure). [Back flow of blood may occur.]
- When circulating or priming, if a significant amount of air enters the centrifugal pump causing the pump to idle and circulation to stop, perform the following procedures: After clamping the blood outlet line of the centrifugal pump, stop the rotation of the pump. Remove the air and release the clamp to restart circulation. [Otherwise, the centrifugal pump may start idling and circulation may not start.]
- Be cautious in motor speed adjustment when decreasing the motor speed of the centrifugal pump. [Back flow of blood may occur.]
- Do not rotate the centrifugal pump for a long period of time (multiple hours) while clamping the blood outlet line of the centrifugal pump. [The priming solution may be denatured due to heating. The blood may be damaged due to heating.]
- When weaning, be sure to clamp the blood line and then stop the rotation of the centrifugal pump. [If the rotation of the centrifugal pump stops without clamping the blood line, blood may flow back.]

┌─ Cautions ───┐

• When this system is used for negative-pressure blood removal aid, be cautious as the correlation between the flow and motor speed of the centrifugal pump will change according to the strength of negative pressure applied to the reservoir.

• When the Drive Motor is removed, place a cap on the plug. [Equipment may be damaged.]

• Ensure the Pressure Sensor Cable and the Temperature Sensor Cable are connected to the correct channel. [The detected pressure or temperature may not be displayed in a proper position on the screen.]

• When a pressure sensor is used, keep in mind that pressure sensor measurement errors may affect the pressure value indicated and the operation of the Pressure Alarm. [Pressure sensor measurement errors may occur due to occlusion of tube or cannula placement.]

• Do not use this system with any equipment other than the dedicated medical equipment. [If equipment other than the dedicated medical equipment is used, this may result in decreased performance.]

• When using this medical equipment in a clinical treatment, refer to the latest information such as academic guidelines.

• Before use, check the instructions for use of the medical supplies and medical equipment that are used in combination.

• This system is to be used under the constant supervision of doctors, or qualified persons who have received direction or instructions from such doctors, who are familiar with operative procedures in which extracorporeal circulation of open-heart surgery is applied or who are familiar with operative procedures involving percutaneous cardiopulmonary support. [Health damages may occur on the patient if it is mistakenly used.]

• Before using this system or when reusing it after not having used for a long time, make sure to conduct a pre-usage inspection to ensure that the system operates normally and safely. If any abnormality is found, do not use this system. [This may result in decreased performance.] Contact Terumo's service representative for inspection and repair.

• If this system is used in a cardiac catheterization laboratory, ICU, CCU or chest operating room, connect the system to the centralized ground centre. [If it is not connected, electric shock may occur.]

• Use this system only after ensuring the power supply is sufficient. [If total power consumption exceeds the supply limit after the system is connected, this may affect other equipment. Additionally, as the Controller operates on battery if the supply power is insufficient, the Controller cannot be used in an emergency.]

• Use the following dedicated devices for this system. Drive Motor (Catalogue No.: ME＊SP200M), Hand Crank (Catalogue No.: XX＊SP05), ABD/Flow Sensor (Catalogue No.: ME＊SPFAS01, ME＊SPFAS02), Temperature Sensor Cable (Catalogue No.: XX＊SPCBL011, XX＊SPCBL012), Pressure Sensor Cable (Catalogue No.: XX＊SPCBL021), Fast Clamp (Catalogue No.: ME＊SPCLP01), CDI Communication Cable (Catalogue No.: XX＊SPCBL031), Cart (Catalogue No.: XX＊SPCRT01), Fast Clamp Attachment (for EBS) (Catalogue No.: XX＊SPCLP01), Fast Clamp Arm (Catalogue No.: XX＊SPCLP02). [If other devices are used, this may result in decreased performance. In addition, influence may be given to the emission level of electromagnetic wave and the tolerance of this system.]

• Do not attach the ABD/Flow Sensor and the Fast Clamp to any tube other than the dedicated tube (internal diameter: 9.5 mm (3/8 inches)). [If a tube other than the dedicated tube is used, this may result in decreased performance.]

• Do not use any cable other than the included AC power cable. [Otherwise an electric shock or short circuit may occur resulting in failure of this system.]

• Connect to a grounded AC power source. [If used without grounding, the electrical safety of this system is not guaranteed.]

• Avoid sudden temperature changes even when operating within the system's indicated temperature specifications. [Condensation inside the system results in damage, time degradation, and decreased performance.]

• The cables (the Drive Motor, the ABD/Flow Sensor, the Temperature sensor cable, the Pressure Sensor Cable, the Fast Clamp, the LAN cable, the CDI Communication Cable, the AC power cable, etc.) used for this system should not be pinched with forceps or equipment, e.g. caster, or punctured with a needle. Protect the cables laid across the floor from being damaged by casters. [If a cable is damaged, electric shock or fire may occur, and decreased performance may result.]

• When using this system, pay attention to how the cables (the Drive Motor, the ABD/Flow Sensor, the Temperature sensor cable, the Pressure Sensor Cable, the Fast Clamp, the LAN cable, the CDI Communication Cable, the AC power cable, etc.) lay on the floor. [An operator may trip over the cables and fall.]

• If this system is tainted with blood, wipe the system immediately with a damp (not wet) soft cloth. Be sure to wear gloves to prevent infection. [Infection may occur.]

• Since this system is precision equipment, it should not be used if it has received any impact (drop to floor, falling, violent shock). [Even though no fault is observed in the system appearance, internal components may damage. This may result in decreased performance (flow rate accuracy and various alarm functions, etc.), and therefore inspection is required.]

• Do not take this system into or used in a control area for radiation devices/MRI or inside a hyperbaric oxygen therapy room. If the system is brought into these environments, immediately discontinue use. [This system is not designed to be used in these environments. Malfunction, damage or degradation of this system may occur or it may lead to explosion.]

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┌─ Cautions ───┐

- Since this system does not have an airtight structure, it should not be used or stored in an active gas environment (including sterilizer gas), nebulizer-sprayed environment, high-humidity environment, etc. [Taking the system to these environments leads to the electronic components inside the system being affected and there may be subsequent damage and time degradation which will cause failure of this system.]
- This system should not be used in a flammable environment. [The system may catch fire or explode.]
- Do not use this system as a suction device. [The system equipment is not intended to perform sucking operations.]
- Do not disassemble, make alterations (including actions that interfere with the functionality or performance such as taping the LCD or a movable part) to, or repair this system. [This may result in failure, damage or device performance degradation of this system.]
- Execute maintenance and inspections periodically for devices in the backup kit. When executing maintenance and inspections, use the Drive Motor and the AC power cable included in the backup kit. [Due to a low frequency of use, the abnormality may not be detected.]
- Prevent physical shock to the pump receptacles of the Drive Motor and the Hand Crank. [The internal magnets of these devices may be damaged.]
- If there is physical damage, such as a crack, to the centrifugal pump and the detection window of the ABD/Flow Sensor, do not use the device. [Leakage of blood may occur, and decreased performance may result.]
- When attaching or detaching the Drive Motor or the ABD/Flow Sensor to or from the Controller, turn off the power. [It may cause a failure for the Controller.]
- When attaching or detaching the Drive Motor to or from the Backup Controller, turn off the power. [It may cause a failure for the Backup Controller.]
- Before attaching the Drive Motor, the ABD/Flow Sensor, the Temperature Sensor Cable, the Pressure Sensor Cable, the Fast Clamp, the LAN cable and the CDI Communication Cable to the Controller, ensure the connectors and plugs are not damaged. Similarly, before attaching the Drive Motor to the Backup Controller, ensure the connectors and plugs are not damaged. If a connector pin is damaged or twisted, replace the system with a spare one and do not use it. [This may result in decreased performance.]
- Since drug solution may cause a short circuit, ensure that the connecting sections (the Drive Motor, the ABD/Flow Sensor, the Pressure Sensor Cable, the Temperature Sensor, the Fast Clamp, the LAN cable and the CDI Communication Cable) are not wet when connecting plugs to connectors. If moisture is present, ensure that the power is turned off and the AC power cable is removed from both this system and grounded AC power source, and then thoroughly wipe with a dry soft cloth. [Since this system does not have a waterproof structure, drug solution and moisture may affect the electrical components inside, and cause a malfunction.]
- This system should not be used in a place where vibration, dust, mist, corrosive gas, etc., occurs or in a place where the system is sprayed with liquid. If liquid such as blood and drug solution is spilled on this system, thoroughly wipe with a dry soft cloth. [This may result in decreased performance, and may cause a malfunction.]
- Do not touch the inside of the drive motor connector, the ABD/Flow sensor connector at the back of the Controller or the drive motor connector at the front of the Backup Controller. Be sure to set up and operate within specified environmental humidity levels. (Including attaching or detaching connector.) [It may cause static electricity resulting in failure or malfunction.]
- When disposing of this system, dispose properly according to your local regulations.

(Controller/Backup Controller)
- Do not touch the AC power cable with wet hands and do not use a broken AC power cable. [Otherwise an electric shock or short circuit may occur.]
- After circulation, make sure to rotate the motor speed knob to stop the Drive Motor and then turn off the power. [The Drive Motor may fail.]
- Do not place objects near the AC power inlet and keep the AC power inlet away from walls. [The AC power cable cannot be removed if other objects are in close proximity.]
- Do not place the Controller and the Backup Controller on a soft surface such as a bed. [The system may drop or fall. The air inlet (with filter) at the bottom surface of the Controller and the Backup Controller may be closed.]

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Cautions

- When used in the vicinity of an electrosurgical knife (Medical radio knives are surgical equipment for incision and coagulation by high energy radio frequency current), it may cause malfunction due to the noise of high-frequency current. Check the following before use.
  (1) Electrosurgical knives have a different level of high-frequency noise emission depending on the types. Do not use old models (vacuum tube gap type) in combination particularly as the noise levels from those are higher.
  (2) The distance from the electrosurgical knife cord (knife holder, knife cord and return electrode cord) and electrosurgical knife body to this system should be kept as far away as possible (25 cm or more).
  (3) The electrosurgical knife and this system should be operated by a power supply from a separate system, and both should be securely grounded.
- When an electrosurgical knife is used, ensure a return electrode is properly attached. [If an electrosurgical knife is used while a return electrode is not properly attached, burning of the electrode attaching part, a failure or malfunction of this system may occur.]

(Controller)

- Make sure to use CDI System 500 (TCVS product codes: 500A, 500AV, 500AHCT, 500AVHCT) for the CDI port of the Controller. [Otherwise an electric shock or short circuit may occur resulting in failure of this system.]
- Do not connect the USB port of the Controller to any device that is not bus powered. [Otherwise an electric shock or short circuit may occur resulting in failure of this system.]
- Do not allow the blood circuit, etc. to contact the LCD touch panel display. [If the blood circuit, etc. mistakenly contacts the screen, system malfunction may occur.]
- The air bubble detector function is intended to detect air bubbles entering the blood inlet line. Therefore when the air bubble detector function turns on, attach the ABD/Flow Sensor at the blood inlet port of the centrifugal pump. [As air bubbles entering the blood inlet line are destroyed and dispersed by the centrifugal pump, the air bubbles may not be detected if the ABD/Flow Sensor is attached at the blood outlet line.]
- Set the alarm threshold and air bubble detection sensitivity and record the settings. In addition, if the alarm threshold is set to be extremely large or extremely small, the alarm may not work. Be careful to it. [If the setting is wrong, the Controller may not operate as intended.]
- The display screen and the Operation panel (buttons, etc.) of the Controller should not be pressed with excessive force and should not be operated with a pointed object. [It may cause damage to or failure of the display screen or the Operation panel.]
- Do not use this system if it is exposed to strong light such as direct sunlight. [This may obstruct you seeing of the LCD touch panel screen.]
- When the Controller is transported while in use, do not touch the buttons, etc. inadvertently or use the key lock function. [Otherwise it may result in an unintended operation (stop, start, power on/off).]
- Prior to first use of the Controller, or if unused for a long period, connect this system to an AC power supply and provide a sufficient charge (6 hours or more). [If not sufficiently charged, this system may not be able to operate using the internal battery during a power failure, etc.]
- When the Low Battery Alarm or the Battery Empty Alarm is issued, immediately connect the Controller to the AC power source. [As this system may stop, health damages may occur on the patient.]
- When charging the Controller during storage, ensure the charge lamp in the control panel is lit. [The charge may not be performed properly, which may result in no power supply in an emergency situation.]
- When charging the Controller during storage, charge it after turning the power off. [If the power is ON, it will continue to update the history information and data will be deleted from the oldest case and cannot be confirmed.]
- When using the external communication function, pay particular attention, as it is more susceptible to the effect from an electrosurgical knife, mobile phone, radio device, defibrillator, etc. Regularly check that this system is operating normally. [The Controller may become vulnerable to the influence.]
- When the external communication function is used, pay attention to the operating hours on battery. [Operating hours will be shortened.]

(Backup Controller)

- When moving the system while the Backup Controller is being used, do not touch switches carelessly. [An unintentional operation (stop, start or ON/OFF of power) may occur.]
- Before pressing the power switch of the Backup Controller, confirm that the motor speed knob is set at "0". [If the motor speed knob is not set to "0", the Drive Motor will immediately drive with that setting value.]
- Do not use any Drive Motor other than the included Drive Motor or the Drive Motor sold separately (Catalogue No.: ME*SP200M) with the Backup Controller. [This may result in decreased performance. In addition, influence may be given to the emission level of electromagnetic wave and the tolerance of this system.]

┌─ Cautions ───

(Hand Crank)

• When using the Hand Crank, attach it to a pole securely after ensuring there is enough space and tube length so that the crank can rotate smoothly. [It may become impossible to maintain circulation.]

• Do not exceed the maximum motor speed of 3000 RPM. [This may cause problems to the centrifugal pump or blood damages may occur.]

• Do not place heavy items on the flexible shaft or do not bend the shaft by applying excessive force.

(Drive Motor)

• When attaching the centrifugal pump to the Drive Motor, be careful not to pinch your finger. [Your finger may be injured.]

• Do not hang cables (the Drive Motor, the ABD/Flow Sensor) or AC power cable on the fixed hook. [The fixed hook may be damaged.]

• When the centrifugal pump is not used, attach the magnet cover to the pump receptacle of the Drive Motor.

(ABD/Flow Sensor)

• When using the ABD/Flow Sensor, use it after cleaning the detection window. [It may not correctly detect flow and air bubbles.]

• When the air bubble detector function turns on, pay attention to the handling of the blood circuit and the ABD/Flow Sensor. [If a physical shock occurs to the blood circuit or to the ABD/Flow Sensor, or if the latch is touched carelessly resulting in the detachment of the ABD/Flow Sensor from the tube, the Air Bubble Detected Alarm will be issued.]

• When the air bubble detection sensitivity is high, attach the sensor so that the ABD/Flow Sensor detection window and the direction of gravitational force are orthogonal. [It may not correctly detect air bubbles.]

(Cart)

• Keep the cart's casters in a locked position except when transporting the cart. [The Cart may move unintentionally, causing attached products to fall.]

• Use both hands to grasp the cart's handles. [If it is not held properly, the cart may move in an unexpected direction and risk patient injury.]

• Do not put any objects other than those specified for use with the system at the upper part of the Cart. Do not lean on the Cart. [The Cart may fall or topple.]

• When the Cart is not being used, place it in a stable place. [This system may fall leading to failure.]

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Storage

┌─ Cautions ──┐

- Do not expose this system to direct sunlight or ultraviolet irradiation for a long period of time. [The exterior may experience colour change, deformation or deterioration.]
- Do not store this system in a place with a high level of vibration, dust, mist or corrosive gas.
- Do not store this system in a place where an environment of atmospheric pressure, temperature, humidity, ventilation, or corrosive conditions may cause an adverse effect.
- Do not store this system in a storage area for chemicals or in a place where gases are generated.
- Keep magnetic media, such as hard disks, away from the Drive Motor and the Hand Crank as these devices contain magnets. [Magnetic medium may be damaged.]
- Do not store this system under high temperature and high humidity.

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Maintenance and Inspection Items

┌─ Cautions ──┐

- Clean the system before and after using. When disinfecting, do not use a sterilizer. Use a soft cloth (damp with disinfectants) to wipe the system, and wipe off the disinfectants with a soft cloth (damp with cold/lukewarm water), and then thoroughly wipe off any moisture with a dry soft cloth. Follow the instructions for use of each disinfectant (regarding degree of dilution, etc.). Examples of disinfectants (ingredient names) which can be used are listed below. Chlorhexidine gluconate/Benzalkonium chloride
- If this system is tainted with blood, wipe the system immediately with a damp (not wet) soft cloth. Be sure to wear gloves to prevent infection. [Infection may occur.]
- When liquids (bloods or drug solution, etc.) come into contact with the pump receptacle of the Drive Motor or the Hand Crank, immediately wipe them off and clean the devices thoroughly. [If coagulated liquids (bloods or drug solution, etc.) are adhered to the pump receptacle of the Drive Motor or the Hand Crank, the slide hook may not move.]
- Turn the system off and disconnect the AC power cable and cables (the Drive Motor, the ABD/Flow Sensor, the Temperature Sensor Cable, the Pressure Sensor Cable, the Fast Clamp, the LAN cable, the CDI Communication Cable) before cleaning. [Otherwise the system may fail or an electrical shock may occur.]
- Do not wash this system with running water or while immersed in water as this may cause damage or failure of the system. [This system does not have a waterproof structure.]
- Do not wipe with organic solvent such as alcohol or thinner, or with povidone-iodine. [Using organic solvent or any disinfectants other than those permitted for use may result in damage to or failure of this system.]
- Do not subject this system to ethylene oxide gas (EOG) sterilization or high pressure steam sterilization, or immerse this system in disinfectant solution. [The system may fail.]
- Do not let anesthetic drugs come into contact with the system or accessories. [The system or accessories may be damaged.]
- Do not use an electric dryer to dry this system. [This system may be damaged.]
- Do not use any replacement parts other than those specified. [This may result in decreased performance.]
- Check displays to ensure this system will operate properly. [This system may not operate as intended.]
- Do not store the battery in a discharge status. [Storing the battery left in a discharge status may cause degradation, resulting in making the battery unavailable in emergency situations.]
- Periodically check the deterioration status of the battery. [Depending on the deterioration status of the battery, the capacity may not be enough for the system to be powered by the battery, even if all of the battery indicator lamps on the control panel and the battery status indicator on the LCD touch panel display light up when connected to the AC power source (even if the battery voltage is normal).]

└──┘

Precautions Regarding Installation on Ambulance

Warning
• When installing the system in an ambulance and transferring a patient in the event of an emergency, make sure the power supply of the ambulance is always higher than the total consumption power for all electric devices installed. [If the supply power of the ambulance becomes insufficient, the device shuts down and circulation cannot be maintained.]

Caution
• Avoid sudden temperature changes even when operating within the system's indicated temperature specifications. [Condensation inside the system results in damage, time degradation, and decreased performance.]

<Power consumption examples>
CAPIOX Centrifugal Pump Controller SP-200
Maximum 250VA (Steady-state)
Maximum 400VA (Peak: when the Drive Motor is rapidly accelerating, auto-priming is operating)

1. Ensure the battery of this system is fully charged.
   • All segments of the battery symbols on both the display and control panel are fully lit.
2. After connecting this system to a power source in an ambulance, ensure that AC power is being supplied to this system.
   • The AC power lamp is lit.
     When the AC power lamp is turned off, the system is operating on battery. (Refer to page 72.)
3. Ensure the Hand Crank is prepared.

Warnings
• Always prepare a backup system (the Backup Controller, the Hand Crank, etc.) to maintain circulation during an emergency. [Circulation cannot be maintained during an emergency.] • Monitor the circulation status (the operation status of the system, blood storage state of a reservoir, etc.) during extracorporeal circulation without fail. [1. As this system does not have a function to monitor the status of the patient, the system cannot detect when the status of the patient changes even if the system operates properly. 2. The system cannot detect the leakage of liquid (including blood) caused by damage to the extracorporeal circulation circuit. 3. It is possible that the system will not detect a flow abnormality, even if the ABD/Flow Sensor is used. 4. This system may not operate in accordance with the specifications if the system is used together with another system.]

Before use, carefully read the instructions for use and the preceding Precautions (pages 19 to 26).

Warnings

- Always prepare a backup system (the Backup Controller, the Hand Crank, etc.) to maintain circulation during an emergency. Circulation cannot be maintained during an emergency.
- Do not use this system for the following purposes.
  - Usage other than percutaneous cardiopulmonary support/ECMO/ECLS, open heart surgery and aortic surgery
  - Long-term use in bridge to transplant or pending recover of the natural heart

Cautions

- This system is to be used under the constant supervision of doctors, or qualified persons who have received direction or instructions from such doctors, who are familiar with operative procedures in which extracorporeal circulation of open-heart surgery is applied or who are familiar with operative procedures involving percutaneous cardiopulmonary support. Health damages may occur on the patient if it is mistakenly used.
- Before using this system or when reusing it after not having used for a long time, make sure to conduct a pre-usage inspection to ensure that the system operates normally and safely. If any abnormality is found, do not use this system. This may result in decreased performance. Contact Terumo's service representative for inspection and repair.

When Using for the First Time

Connect to the AC power supply and charge (6 hours or more) with the power turned off until the charge lamp turns off. Then, set the date and time to record history correctly. (Refer to "Setting the Date and Time" (page 109).) Also, the administrator needs to preset various functions in accordance with the environmental conditions. For details about how to set, refer to "Admin Setup" (page 99).

Touch Panel Operations

Tap the icons displayed on the LCD touch panel display. (Figure 1-1)
Release your finger on the panel and tap it again when the panel does not respond.
The screen can be operated while wearing surgical gloves.

Note

- You may have unintended responses when you tap simultaneously multiple parts on the panel.
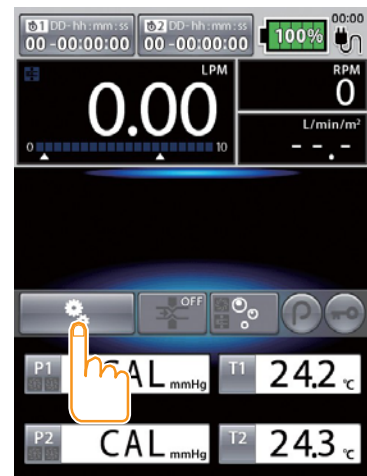
Figure 1-1

Caution

- The display screen and the Operation panel (buttons, etc.) of the Controller should not be pressed with excessive force and should not be operated with a pointed object. It may cause damage to or failure of the display screen or the Operation panel.

Preparation Before Use

The preparation steps prior to using are shown below.

```
┌─────────────────────────┐
│  Prepare the Necessary  │  ☞page 29
│        Devices          │
└─────────────────────────┘
            │
            ▼
┌─────────────────────────┐
│ Attach the Controller to│  ☞page 29
│        the Cart         │
└─────────────────────────┘
            │
            ▼
┌─────────────────────────┐
│ Connect to AC Power     │  ☞page 31
│        Cable            │
└─────────────────────────┘
            │
            ▼
┌─────────────────────────┐
│  Connect to Drive Motor │  ☞page 33
└─────────────────────────┘
            │
            ▼
┌─────────────────────────┐
│ Connect to ABD/Flow     │  ☞page 36
│        Sensor           │
└─────────────────────────┘
```

When using the air bubble detector function, **after connecting the ABD/Flow Sensor and turning the power on,** turn the setup of the air bubble detector function on.

Use the temperature measuring function — YES → Connect to Temperature Sensor Cable ☞page 37

NO

When using the temperature measuring function, **after connecting the Temperature Sensor Cable and turning the power on,** turn the setup of the temperature measuring function of the channel to be used on.

Use the pressure measuring function — YES → Connect to Pressure Sensor Cable ☞page 37

NO

When using the pressure measuring function, **after connecting the Pressure Sensor Cable and turning the power on,** turn the setup of the pressure measuring function of the channel to be used on.

Use the Fast Clamp — YES → Connect to Fast Clamp ☞page 38

NO

When using the Fast Clamp, **after connecting the Fast Clamp and turning the power on,** turn the setup of the Fast Clamp on.

Continue to "Inspection Before Use"
☞page 122

Preparing the Necessary Devices

Prepare the following devices.
● Controller
● AC power cable
● Drive Motor
● ABD/Flow Sensor
● Applicable centrifugal pump
● Vaseline
● Applicable blood circuit (including oxygenator, etc.)
● Priming solution

Prepare the following devices if necessary.
● Cart
● Fast Clamp Arm
● Fast Clamp Attachment (for EBS)
● Fast Clamp
● Applicable temperature sensor (CAPIOX Luer Thermistor)
● Temperature Sensor Cable
● Applicable pressure sensor
● Pressure Sensor Cable
● Dedicated holder for applicable blood circuits

Attaching the Controller to the Cart

For instructions on attaching other products, refer to "Attaching Other Products to the Cart" (page 61).

Cautions

• Do not place the Controller on a soft surface such as a bed. The system may drop or fall. The air inlet (with filter) at the bottom surface of the Controller may be closed.
• When the Cart is not being used, place it in a stable place.
---

1. Lock all casters of the Cart with each stopper. (Figure 1-2)
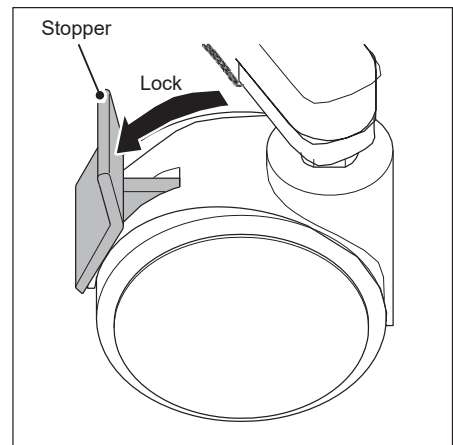
Figure 1-2

2.   **Pull the lever of the Cart in the direction of the arrow. (Figure 1-3** a**)**

3.   **Align the rubber feet of the front side of the Controller with the Cart guide, and place the Controller on the Cart. (Figure 1-3** b**)**

Note

• At this time, the rubber feet are elevated.

Figure 1-3

4.   **Pull the lever of the Cart in the direction of the arrow to secure the Controller to the Cart. (Figure 1-4)**

Check

• The Controller is secured to the Cart.

Figure 1-4

Connecting to AC Power Cable

Warning

• Connect the AC power cable to the AC power inlet of the Controller until you hear a click. Subsequently, check that the AC power lamp in the control panel of the Controller is lit. If the connection i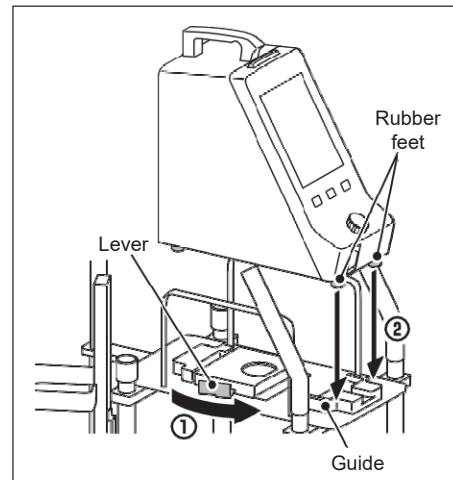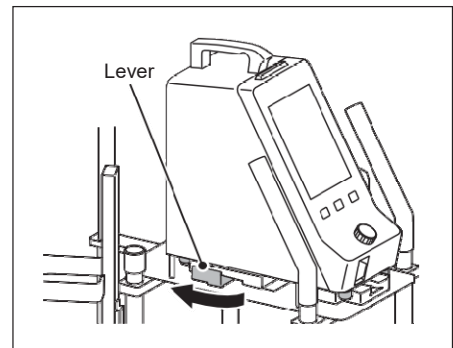s insufficient, the Controller will be powered by the battery. And therefore the battery will be depleted, the devices will shut down and circulation will not be maintained.

Cautions

• Do not use any cable other than the included AC power cable. Otherwise an electric shock or short circuit may occur resulting in failure of this system.
• Prior to first use of the Controller, or if unused for a long period, connect this system to an AC power supply and provide a sufficient charge (6 hours or more). If not sufficiently charged, this system may not be able to operate using the internal battery during a power failure, etc.
• Use this system only after ensuring the power supply is sufficient. If total power consumption exceeds the supply limit after the system is connected, this may affect other equipment. Additionally, as the Controller operates on battery if the supply power is insufficient, the Controller cannot be used in an emergency.
• Connect to a grounded AC power source. If used without grounding, the electrical safety of this system is not guaranteed.
• The cables (the Drive Motor, the ABD/Flow Sensor, the Temperature sensor cable, the Pressure Sensor Cable, the Fast Clamp, the LAN cable, the CDI Communication Cable, the AC power cable, etc.) used for this system should not be pinched with forceps or equipment, e.g. caster, or punctured with a needle. Protect the cables laid across the floor from being damaged by casters. If a cable is damaged, electric shock or fire may occur, and decreased performance may result.
• When using this system, pay attention to how the cables (the Drive Motor, the ABD/Flow Sensor, the Temperature sensor cable, the Pressure Sensor Cable, the Fast Clamp, the LAN cable, the CDI Communication Cable, the AC power cable, etc.) lay on the floor. An operator may trip over the cables and fall.

1.   Insert the AC power cable into the AC power inlet until you hear a click. (Figure 1-5)

When it is fully inserted, the AC power cable is locked in the AC power inlet.

`Check`

• The AC power cable will not disconnect even if you pull it toward you while holding the connector of the AC power cable.
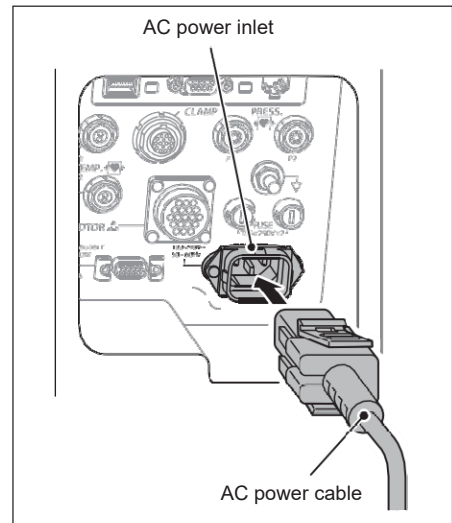
Figure 1-5

When removing the AC power cable, pull it out straight while pressing the latches as shown in the figure. (Figure 1-6)
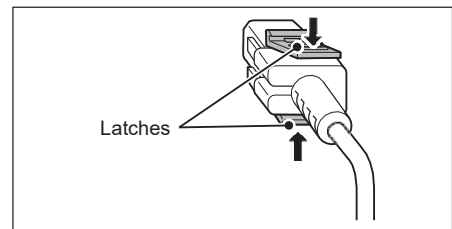

Figure 1-6

2.   Plug in the AC power cable to the grounded AC power source.

`Check`

• The AC power lamp is lit.

`Note`

• When the AC power cable is connected to the grounded AC power source, the battery can be charged even if the system power is turned off. The charge lamp is lit while charging the battery.

Connecting to Drive Motor

Caution
• Do not use this system with products other than those listed in "Optional Products" (refer to page 13).

◆ Using the CAPIOX EBS Circuit Holder

1. **Remove the pole clamp attached to the Drive Motor with a screwdriver (+). (Figure 1-7)**
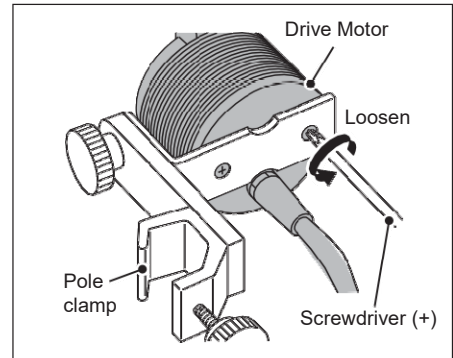
Screws are used in step 2.

Figure 1-7

2. **Attach the Drive Motor to the CAPIOX EBS Circuit Holder.**

By using the screws removed in step 1, attach the Drive Motor with the screwdriver (+).

Attach the Drive Motor in the lower screw holes. (Figure 1-8)
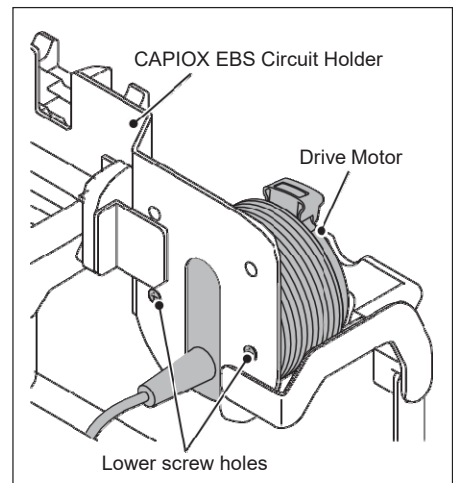
Figure 1-8

3. **Attach the CAPIOX EBS Circuit Holder to the IV pole of the Cart and secure it with the knob. (Figure 1-9)**

Check

• The CAPIOX EBS Circuit Holder is secured.

Figure 1-9

4. **Remove the plug cap of the Drive Motor. Insert the plug into the drive motor connector on the rear panel. (Figure 1-10** a**) Then, turn the lock ring clockwise until you hear a click. (Figure 1-10** b**)**

When removing the plug of the Drive Motor, turn the lock ring counter-clockwise until you hear a click, and pull it out straight.

Figure 1-10

◆ **Using the pole clamp that comes with the Drive Motor**

1. **Attach the pole clamp to the IV pole of the Cart and secure it with the knob. (Figure 1-11** a**)**

Check

• The pole clamp is secured.

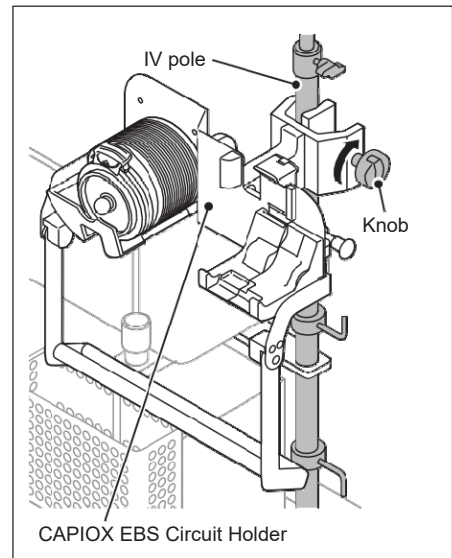**2.** **Adjust the angle of the motor with the angle adjustment knob. (Figure 1-11** b**)**

Figure 1-11

3. **Remove the plug cap of the Drive Motor. Insert the plug into the drive motor connector on the rear panel. (Figure 1-12 a) Then, turn the lock ring clockwise until you hear a click. (Figure 1-12 b)**

    When removing the plug of the Drive Motor, turn the lock ring counter-clockwise until you hear a click, and pull it out straight.
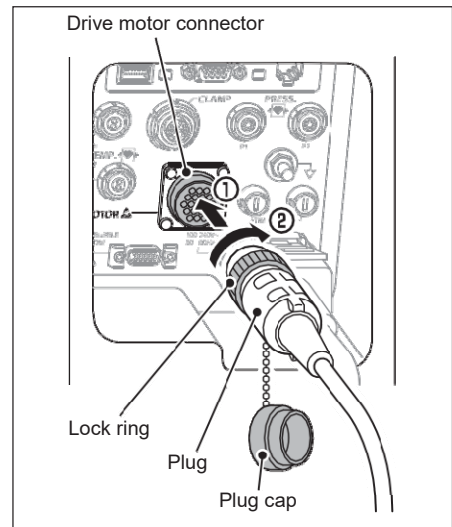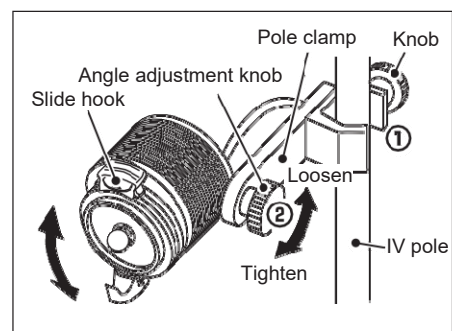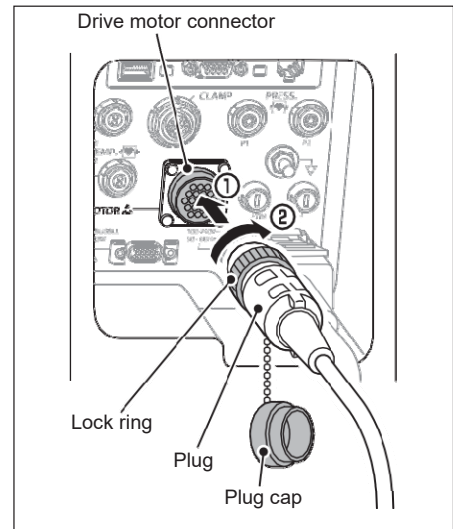

Figure 1-12

Cautions

- When attaching or detaching the Drive Motor or the ABD/Flow Sensor to or from the Controller, turn off the power. It may cause a failure for the Controller.
- Before attaching the Drive Motor, the ABD/Flow Sensor, the Temperature Sensor Cable, the Pressure Sensor Cable, the Fast Clamp, the LAN cable and the CDI Communication Cable to the Controller, ensure the connectors and plugs are not damaged. If a connector pin is damaged or twisted, replace the system with a spare one and do not use it. This may result in decreased performance.
- Since drug solution may cause a short circuit, ensure that the connecting sections (the Drive Motor, the ABD/Flow Sensor, the Pressure Sensor Cable, the Temperature Sensor, the Fast Clamp, the LAN cable and the CDI Communication Cable) are not wet when connecting plugs to connectors. If moisture is present, ensure that the power is turned off and the AC power cable is removed from both this system and grounded AC power source, and then thoroughly wipe with a dry soft cloth. Since this system does not have a waterproof structure, drug solution and moisture may affect the electrical components inside, and cause a malfunction.
- Do not touch the inside of the drive motor connector, the ABD/Flow sensor connector at the back of the Controller. Be sure to set up and operate within specified environmental humidity levels. (Including attaching or detaching connector.) It may cause static electricity resulting in failure or malfunction.
- Adjust the Drive Motor position so as not to let the fixed hook and the extracorporeal circulation circuit connection part interfere. The fixed hook or centrifugal pump may be damaged.
- Do not hang cables (the Drive Motor, the ABD/Flow Sensor) or AC power cable on the fixed hook. The fixed hook may be damaged.

Connecting to ABD/Flow Sensor

When using the air bubble detector function, confirm that the setup of the air bubble detector function is on. (Refer to "Confirming the Setup" (page 48).)

1. Insert the plug of the ABD/Flow Sensor into the ABD/Flow sensor connector on the rear panel until you hear a click. (Figure 1-13)

ABD/Flow sensor connector

Plug

Figure 1-13

Check

• The ABD/Flow Sensor will not disconnect even if you pull it toward you while holding the plug of the ABD/Flow Sensor.
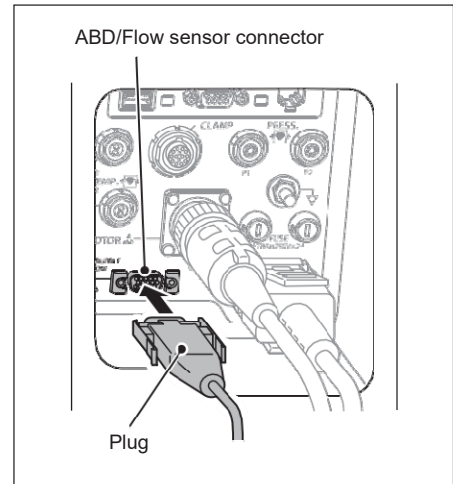
When removing the plug, pull it out straight while holding the plug latches of the ABD/Flow Sensor. (Figure 1-14)
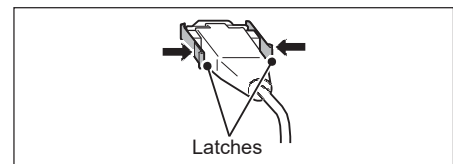

Latches

Figure 1-14

Cautions

• If there is physical damage, such as a crack, to the detection window of the ABD/Flow Sensor, do not use the ABD/Flow Sensor.
• When attaching or detaching the Drive Motor or the ABD/Flow Sensor to or from the Controller, turn off the power. It may cause a failure for the Controller.
• Before attaching the Drive Motor, the ABD/Flow Sensor, the Temperature Sensor Cable, the Pressure Sensor Cable, the Fast Clamp, the LAN cable and the CDI Communication Cable to the Controller, ensure the connectors and plugs are not damaged. If a connector pin is damaged or twisted, replace the system with a spare one and do not use it.
• Do not touch the inside of the drive motor connector, the ABD/Flow sensor connector at the back of the Controller. Be sure to set up and operate within specified environmental humidity levels. (Including attaching or detaching connector.) It may cause static electricity resulting in failure or malfunction.
• Since drug solution may cause a short circuit, ensure that the connecting sections (the Drive Motor, the ABD/Flow Sensor, the Pressure Sensor Cable, the Temperature Sensor, the Fast Clamp, the LAN cable and the CDI Communication Cable) are not wet when connecting plugs to connectors. If moisture is present, ensure that the power is turned off and the AC power cable is removed from both this system and grounded AC power source, and then thoroughly wipe with a dry soft cloth. Since this system does not have a waterproof structure, drug solution and moisture may affect the electrical components inside, and cause a malfunction.

Connecting to Temperature Sensor Cable

This section describes the step for using the temperature measuring function.

When using the temperature measuring function, confirm that the setup of the temperature measuring function of the channel to be used is on. (Refer to "Confirming the Setup" (page 48).)

1. Align the plug of the temperature sensor with the slot of the temperature sensor connector on the rear panel, and insert the plug into the connector (T1 or T2). (Figure 1-15)

Do not forcefully insert the plug.

Temperature sensor connector

Plug

Figure 1-15

When removing the plug, pull it out straight while holding the outer ring of the plug of the Temperature Sensor Cable. (Figure 1-16)

Plug

Figure 1-16

Connecting to Pressure Sensor Cable

This section describes the step for using the pressure measuring function.

When using the pressure measuring function, confirm that the setup of the pressure measuring function of the channel to be used is on. (Refer to "Confirming the Setup" (page 48).)

1. Align the plug of the Pressure Sensor Cable with the slot of the pressure sensor connector on the rear panel, and insert the plug into the connector (P1 or P2). (Figure 1-17)

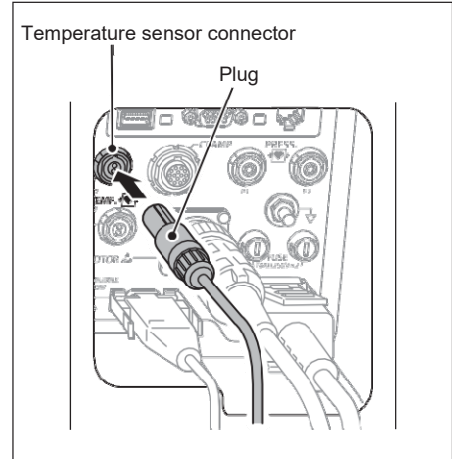Do not forcefully insert the plug.

Pressure sensor connector

Plug

Figure 1-17

When removing the plug, pull it out straight while holding the outer ring of the plug of the Pressure Sensor Cable. (Figure 1-18)
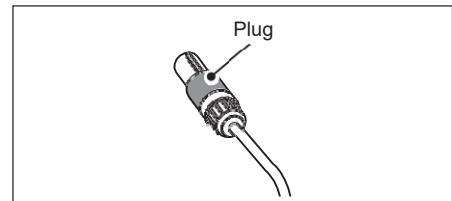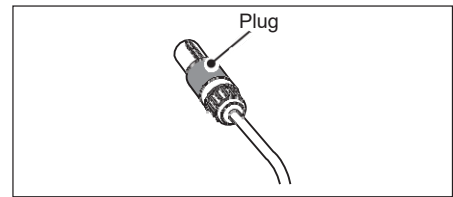

Figure 1-18

Connecting to Fast Clamp

This section describes the steps for using the Fast Clamp.

When using the Fast Clamp, confirm that the setup of the Fast Clamp is on. (Refer to "Confirming the Setup" (page 48).)

◆ Using the Fast Clamp Attachment (for EBS)

1. Lower the handle of the CAPIOX EBS Circuit Holder, and insert the Fast Clamp Attachment (for EBS) as shown in the figure. (Figure 1-19)
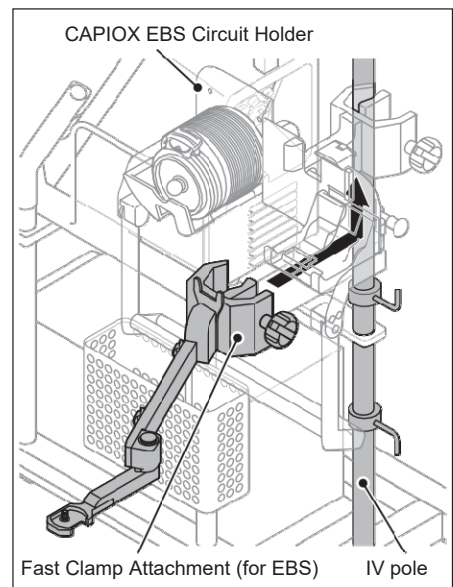
Figure 1-19

2. Align the guide plate of the Fast Clamp Attachment (for EBS) to the arm of the CAPIOX EBS Circuit Holder. (Figure 1-20 a)

3. Secure it with the knob. (Figure 1-20 b)

Checks

• The Fast Clamp Attachment (for EBS) is secured.
• The clamps of the Fast Clamp Attachment (for EBS) and the CAPIOX EBS Circuit Holder are in contact.

Figure 1-20

4. **Attach the Fast Clamp to the Fast Clamp Attachment (for EBS) (Figure 1-21** a**), and secure it with the knob. (Figure 1-21** b**)**

Check

• The Fast Clamp is secured.
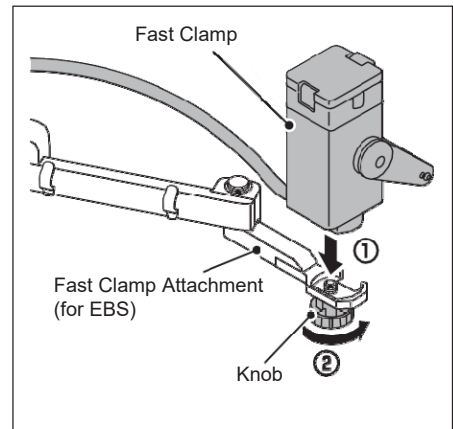
Figure 1-21

5. **Hang the cable of the Fast Clamp along the cable clamps. (Figure 1-22)**
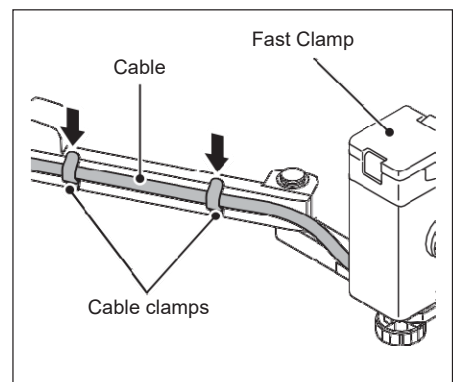
Figure 1-22

6. **Insert the plug of the Fast Clamp into the fast clamp connector on the rear panel. (Figure 1-23)**

Align the plug of the Fast Clamp with the slot of the fast clamp connector, and insert the plug until you hear a click.
Do not forcefully insert the plug.
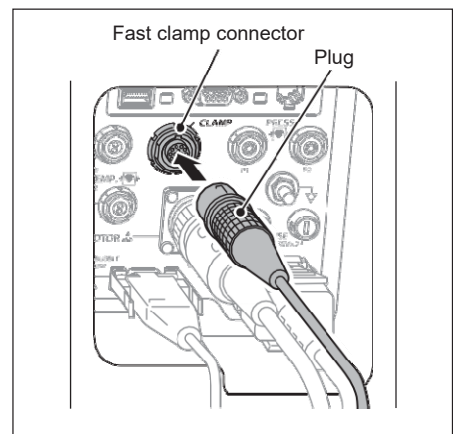
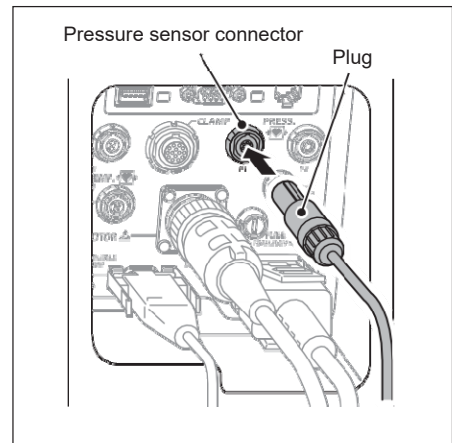Figure 1-23

When removing the plug, pull it out straight while holding the outer ring of the plug of the Fast Clamp. (Figure 1-24)
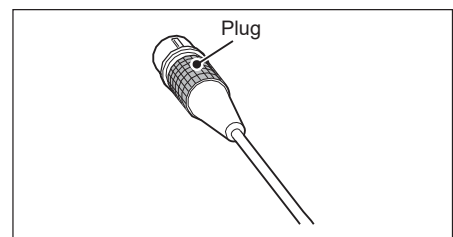
Figure 1-24

◆ Using the Fast Clamp Arm

1. Confirm that the knobs (two places) of the Fast Clamp Arm are secured. (Figure 1-25)

If the knobs are not secured, the Fast clamp holder may move and it may cause the Fast Clamp fall when you attach the Fast Clamp.
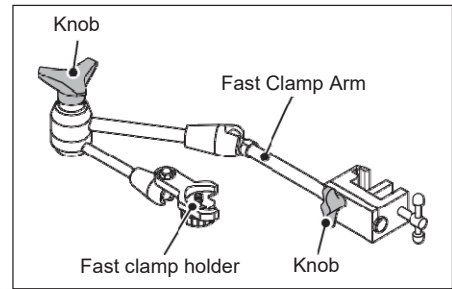
Figure 1-25

2. Attach the Fast Clamp Arm to the IV pole of the Cart (Figure 1-26 a**), and secure it with the knob. (Figure 1-26** b**)**

Check

• The Fast Clamp Arm is secured.
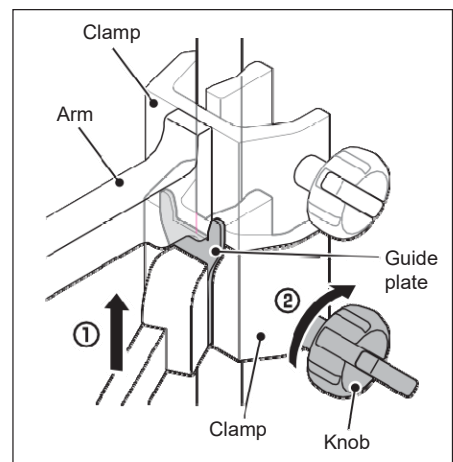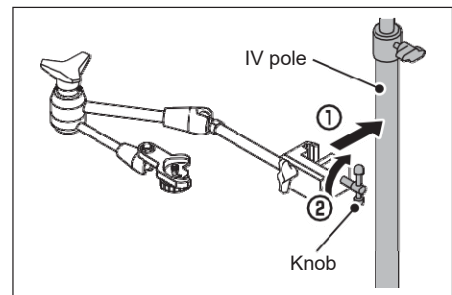

Figure 1-26

3. Attach the Fast Clamp to the Fast Clamp Arm (Figure 1-27 a**), and secure it with the knob. (Figure 1-27** b**)**

Check

• The Fast Clamp is secured.
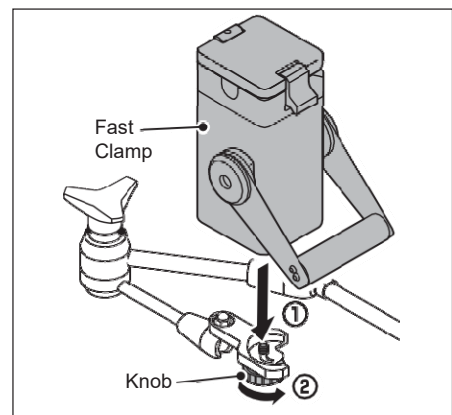
Figure 1-27

4. Insert the plug of the Fast Clamp into the fast clamp connector on the rear panel. (Figure 1-28)

Align the plug of the Fast Clamp with the slot of the fast clamp connector, and insert the plug until you hear a click.
Do not forcefully insert the plug.

Figure 1-28

When removing the plug, pull it out straight while holding the outer ring of the plug of the Fast Clamp. (Figure 1-29)

Figure 1-29

Inspection Before Use

Perform the prior-to-use inspection by following "Inspection Before Each Use" (Refer to page 122).

Preparing Circulation

The preparation steps for circulation are shown below.

```
┌────────────────────────┐
│  Centrifugal Pump      │
│  Connection            │  ☞ page 43
│  to the Tube Pack      │
└────────────────────────┘
            │
            ▼
┌────────────────────────┐
│ Attach the Centrifugal │
│ Pump to the Drive Motor│  ☞ page 43
└────────────────────────┘
            │
            ▼
┌────────────────────────┐
│ Attach the ABD/Flow    │
│ Sensor                 │  ☞ page 44
└────────────────────────┘
            │
            ▼
      Use the                    YES    ┌─────────────────────────┐
   temperature    ──────────────────────│ Attach the Temperature  │
    measuring                           │ Sensor                  │  ☞ page 46
    function                            │ (CAPIOX Luer Thermistor)│
            │ NO                        └─────────────────────────┘
            ▼
   Use the pressure             YES     ┌─────────────────────────┐
  measuring function ───────────────────│ Attach the Pressure     │  ☞ page 46
            │ NO                        │ Sensor                  │
            ▼                           └─────────────────────────┘
┌────────────────────────┐
│ Fill Priming Solution  │  ☞ page 46
└────────────────────────┘
            │
            ▼
┌────────────────────────┐
│ Turn the Power On      │  ☞ page 47
└────────────────────────┘
            │
            ▼
┌────────────────────────┐
│ Confirm the Setup      │  ☞ page 48
└────────────────────────┘
            │
            ▼
┌────────────────────────┐
│ Auto-priming           │  ☞ page 49
└────────────────────────┘
            │
            ▼
   Use the pressure             YES     ┌─────────────────────────┐
  measuring function ───────────────────│ Calibration of the      │  ☞ page 50
            │ NO                        │ Pressure Sensor         │
            ▼                           └─────────────────────────┘
      Use the Fast              YES     ┌─────────────────────────┐
        Clamp      ─────────────────────│ Attach the Fast Clamp   │  ☞ page 51
            │ NO                        └─────────────────────────┘
            ▼
┌────────────────────────┐
│ Inspection Before      │
│ Circulation Starts     │  ☞ page 125
│ (Before Each Use)      │
└────────────────────────┘
            │
            ▼
     Continue to "Starting
     Circulation" ☞ page 55
```
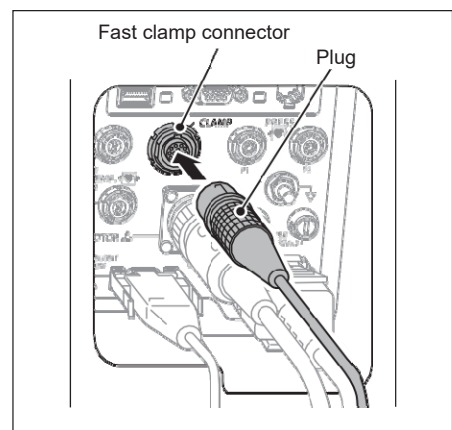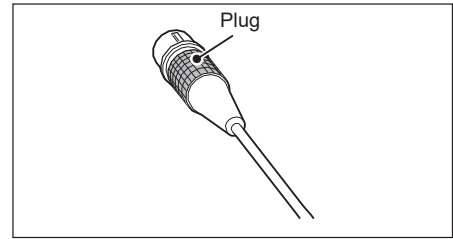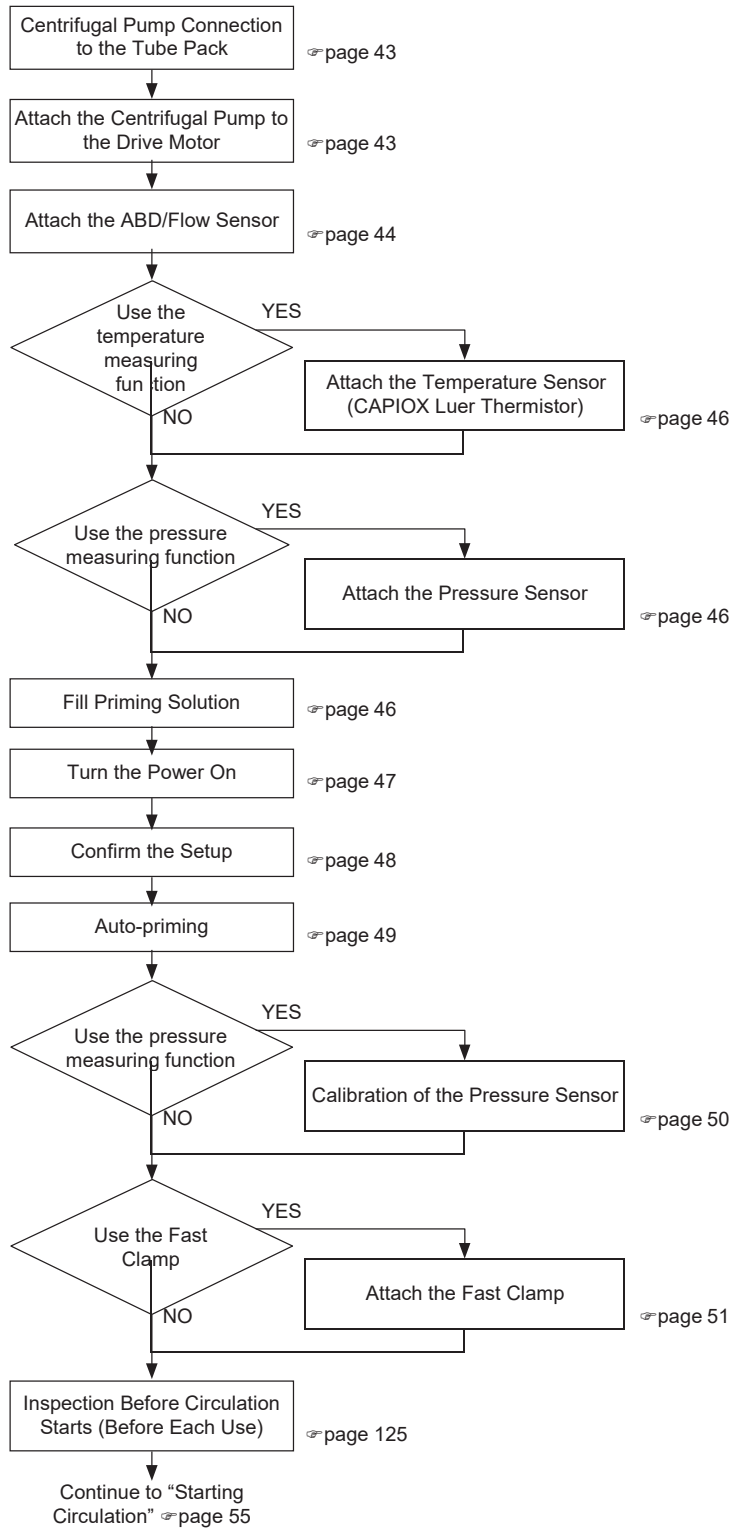
Centrifugal Pump Connection to the Tube Pack

> **Caution**
>
> • Do not use this system with any centrifugal pump other than the dedicated centrifugal pump (CAPIOX centrifugal pump, CAPIOX centrifugal pump as the component product of the CAPIOX EBS Circuit with X coating). If a centrifugal pump other than the dedicated centrifugal pump is used, this may result in decreased performance.

1. Take out the centrifugal pump from the packaging and confirm that there are no abnormalities.

2. Connect the extracorporeal circulation circuit line to the blood inlet port and the blood outlet port of the centrifugal pump. (Figure 1-30)

> **Caution**
>
> • If there is physical damage, such as a crack, to the centrifugal pump, do not use the centrifugal pump.

Blood inlet port   Centrifugal pump
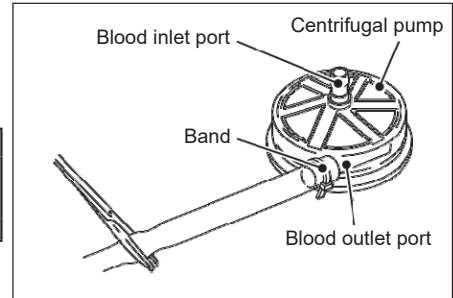
Band

Blood outlet port

Figure 1-30

Attaching the Centrifugal Pump to the Drive Motor

1. Remove the magnet cover of the Drive Motor. (Figure 1-31)

Pull the slide hook of the Drive Motor, and remove the magnet cover at an angle.

> **Warning**
>
> • The Drive Motor contains magnets, and therefore do not bring metal objects or magnets near the device. Malfunction may occur.

> **Cautions**
>
> • Prevent physical shock to the pump receptacles of the Drive Motor. The internal magnets of the device may be damaged.
> • When the centrifugal pump is not used, attach the magnet cover to the pump receptacle of the Drive Motor.
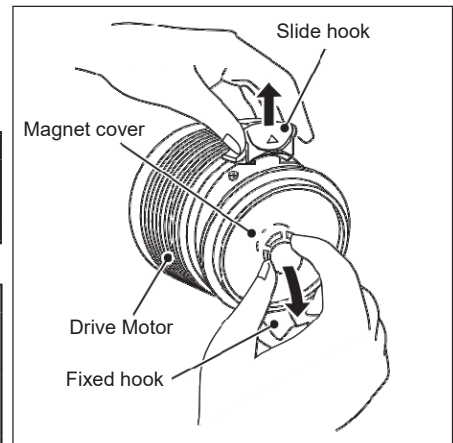

Slide hook

Magnet cover

Drive Motor

Fixed hook

Figure 1-31

2. Attach the centrifugal pump to the pump receptacle of the Drive Motor. (Figure 1-32)

Insert the rim of the centrifugal pump into the fixed hook of the Drive Motor and press the pump against the slide hook to attach.

Check

• The centrifugal pump is securely attached with the slide hook and the fixed hook.

Slide hook   Centrifugal pump
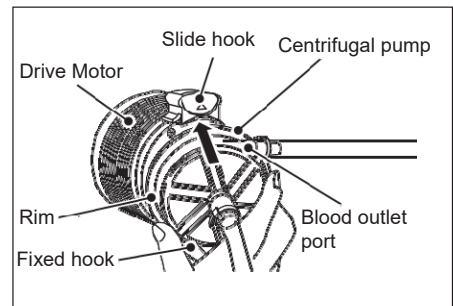
Drive Motor

Rim

Blood outlet port

Fixed hook

Figure 1-32

Cautions

- Do not operate the centrifugal pump without filling the pump with liquid beforehand. Damage may occur to the rotary sliding part.
- When attaching or detaching the centrifugal pump to or from the Drive Motor, confirm that the Drive Motor is stopped.
- Attach the centrifugal pump so as not to let the fixed hook and the extracorporeal circulation circuit connection part interfere. The fixed hook or centrifugal pump may be damaged. (Figure 1-33)
- When attaching the centrifugal pump to the Drive Motor, confirm that the bottom surface of the centrifugal pump is in close contact with the pump receptacle and that the slide hook is securely in position. If rotation starts while the slide hook is not secured due to residue of blood and drug solution, the centrifugal pump may detach from the pump receptacle.
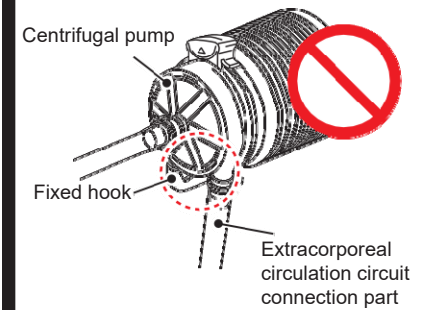
WRONG

Figure 1-33

Attaching the ABD/Flow Sensor

When using the air bubble detector function, confirm that the setup of the air bubble detector function is on. (Refer to "Confirming the Setup" (page 48).)

Cautions

- Do not attach the ABD/Flow Sensor to any tube other than the dedicated tube (internal diameter: 9.5 mm (3/8 inches)). If a tube other than the dedicated tube is used, this may result in decreased performance.
- The air bubble detector function is intended to detect air bubbles entering the blood inlet line. Therefore when the air bubble detector function turns on, attach the ABD/Flow Sensor at the blood inlet port of the centrifugal pump. As air bubbles entering the blood inlet line are destroyed and dispersed by the centrifugal pump, the air bubbles may not be detected if the ABD/Flow Sensor is attached at the blood outlet line.

1. **Release the latch of the clamp-on ABD/Flow sensor (Figure 1-34 a), open the lid (Figure 1-34 b), and then apply vaseline to the detection window of the ABD/Flow Sensor.**

Warning

- When attaching the ABD/Flow Sensor, apply enough vaseline to evenly coat the detection window of the clamp-on ABD/Flow sensor. If the amount of vaseline applied is insufficient, the Flow Signal Unstable Alarm may be issued and air bubbles may not be detected.
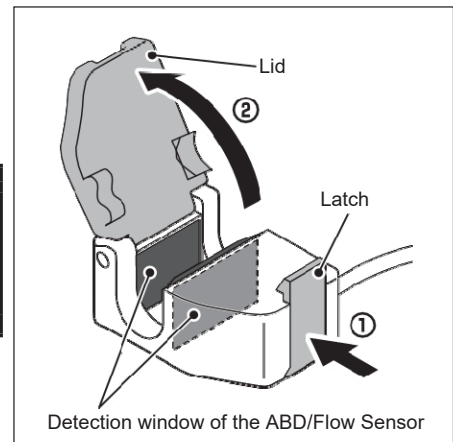

Figure 1-34

2. Attach the clamp-on ABD/Flow sensor to the blood circuit tube. (Figure 1-35, Figure 1-36)

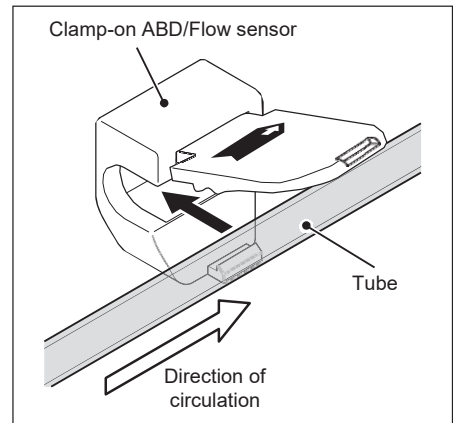Fully insert the blood circuit tube into the detection window of the clamp-on ABD/Flow sensor.
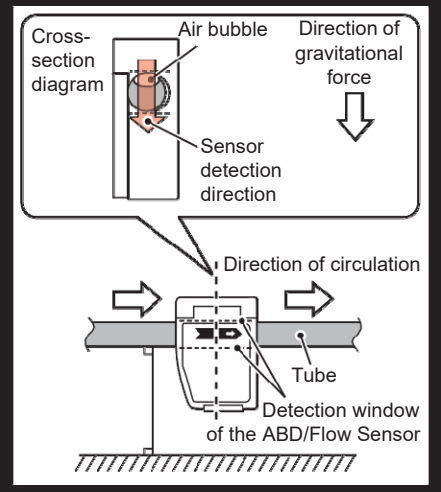

Figure 1-35

Caution

- When the air bubble detection sensitivity is high, attach the sensor so that the ABD/Flow Sensor detection window and the direction of gravitational force are orthogonal. It may not correctly detect air bubbles. (Figure 1-36)
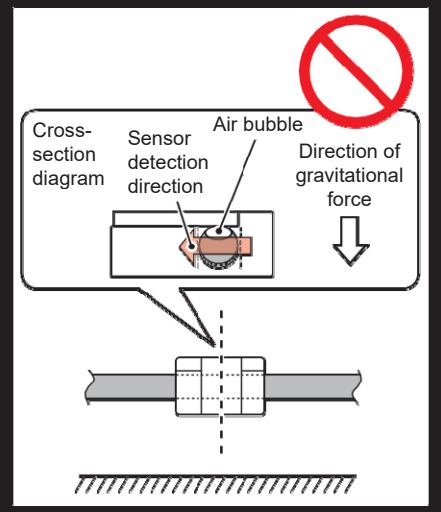
CORRECT

WRONG

Figure 1-36

3. **Close the lid of the clamp-on ABD/Flow sensor.
(Figure 1-37)**

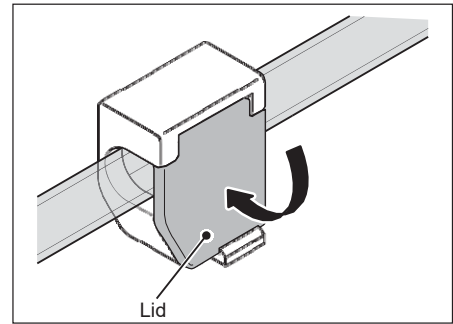   Press the lid until you hear a click.

Figure 1-37

Attaching the Temperature Sensor (CAPIOX Luer Thermistor)

This section describes the step for using the temperature measuring function. When using the temperature measuring function, confirm that the setup of the temperature measuring function of the channel to be used is on. (Refer to "Confirming the Setup" (page 48).)

1. **Attach the connector of the Temperature Sensor Cable to the CAPIOX Luer Thermistor which is connected to the extracorporeal circulation circuit line. (Figure 1-38)**
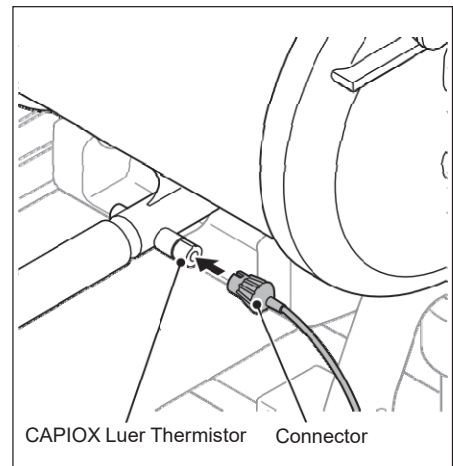

CAPIOX Luer Thermistor   Connector

Figure 1-38

Attaching the Pressure Sensor

This section describes the step for using the pressure measuring function. When using the pressure measuring function, confirm that the setup of the pressure measuring function of the channel to be used is on. (Refer to "Confirming the Setup" (page 48).)

1. **Attach the connector of the Pressure Sensor Cable to the pressure sensor which is connected to the extracorporeal circulation circuit line. (Figure 1-39)**
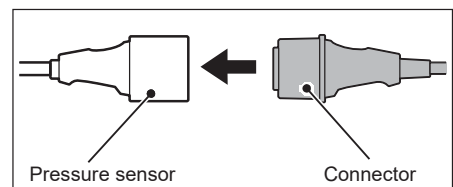

Pressure sensor   Connector

Figure 1-39

Filling Priming Solution

1. **Fill the extracorporeal circulation circuit with the priming solution by gravity.**

Turning the Power On

1. **Press the power button. (Figure 1-40)**
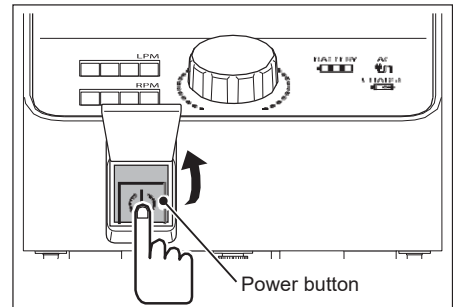

Power button

Figure 1-40

2. **The LCD touch panel display is lit, and the Controller is activated.**

    After the start screen is displayed with an activation sound, the main screen appears. (Figure 1-41)

Figure 1-41

Warnings

- Use the AC power source as the primary power source. Battery is used as an auxiliary power source when the AC power source cannot be used sufficiently, such as during transportation, electric failure, etc. If the battery is depleted and charging is insufficient, the Controller will not be able to operate by the battery during an emergency such as electric failure.
- When the Controller signals the Serious System Error (device alarm (high priority)), attach the centrifugal pump with the Drive Motor connected to the Backup Controller or the Hand Crank to maintain circulation. Otherwise, the pump may stop and may cause injury to the patient.

Confirming the Setup

1. **Tap the setup icon on the main screen. (Figure 1-42)**

Figure 1-42

2. **Tap the Alarm Setup List icon. (Figure 1-43)**

Figure 1-43

3. **Confirm the on/off setup of the various functions, the alarm threshold value and the setup of the safety connection. (Figure 1-44)**

Figure 1-44

Note

• To change the setup, refer to the following sections of the "user setup".
   • Setting Pressure Measuring Function   ☞page 85
   • Setting Temperature Measuring Function   ☞page 88
   • Setting Flow Alarms   ☞page 84
   • Setting the Air Bubble Detector Function   ☞page 90
   • Setting the Fast Clamp   ☞page 90
   • Setting the Safety Connection   ☞page 91

Auto-priming

You can perform the priming easily by using the auto-priming function.

> **Caution**
>
> • When priming, if a significant amount of air enters the centrifugal pump causing the pump to idle, stop the rotation of the pump. Remove the air and start priming again.

1. **Start the auto-priming after filling the priming solution. The following two methods are available.**

   When auto-priming is started, the indicators light on the auto priming icon (green) and on the auto-priming button (orange). The centrifugal pump rotates intermittently in auto-priming mode. When CAPIOX EBS Circuit with X coating is used, the air bubbles in the circuit will be removed through oxygenator membrane.

   <<Operation from the main screen>>
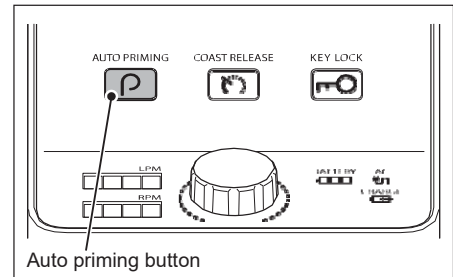   **Tap the auto priming icon. (Figure 1-45)**

Auto priming icon

Figure 1-45

   <<Operation from the control panel>>
   Press the auto priming button on the control panel. (Figure 1-46)

   > **Note**
   > • Auto-priming can be started only when the motor speed is "0".

Auto priming button

Figure 1-46

2. **Remove air from the branch lines while the centrifugal pump is rotating.**

   Remove the port cap of the sampling line of the oxygenator and attach a syringe. And then, open the three way stopcock. Remove air of the oxygenator connection section by lightly tapping with your palm.

3. **After confirming that the air bubbles in the blood circuit have been removed, stop auto-priming.**

   <<Operation from the main screen>>
   Tap the auto priming icon. (Figure 1-45)

   <<Operation from the control panel>>
   Press the auto priming button on the control panel. (Figure 1-46)

Checks
• The motor speed becomes "0".
• The auto priming icon and the auto priming button indicators are turned off.

Notes
• Auto-priming setting (on time/off time/motor speed) can be changed. For details about how to set, refer to "Setting Auto-priming" (page 106).
• When 30 minutes have passed after starting the auto-priming, the auto-priming will automatically stop and "Auto-priming Stopped" will be displayed on the message area.

Calibration of the Pressure Sensor

When using the pressure measuring function, confirm that the setup of the pressure measuring function of the channel to be used is on. (Refer to "Confirming the Setup" (page 48).)

Caution
• Check the instructions for use of the pressure sensor before use.

1.   **Tap the setup icon on the main screen. (Figure 1-47)**

Figure 1-47

2.   **Tap the Pressure Alarm icon. (Figure 1-48)**

Figure 1-48

3.   **Tap [CAL] of the pressure sensor (P1 or P2) to which you want to perform calibration. (Figure 1-49)**
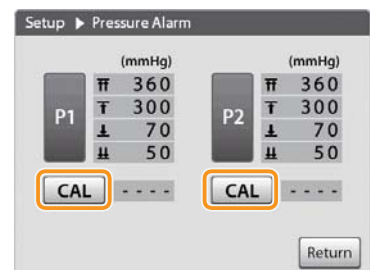

Figure 1-49

4. **After confirming the message displayed and expose the pressure sensor to the air, tap [OK]. (Figure 1-50)**
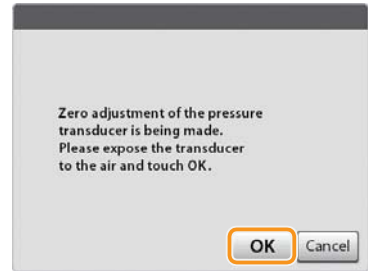
Calibration of the pressure sensor is started.

Figure 1-50

When calibration has been finished normally, "0" will be displayed at the side of [CAL]. (Figure 1-51)
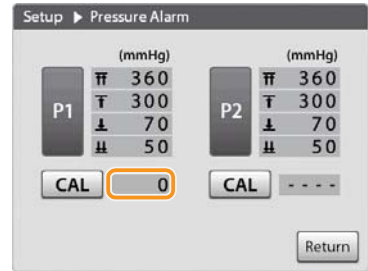When any number other than "0" or "----" is displayed, perform calibration again.

Figure 1-51

Attaching the Fast Clamp

When using the Fast Clamp, confirm that the setup of the Fast Clamp is on. (Refer to "Confirming the Setup" (page 48).)

Warning
• Do not attach the Fast Clamp to the blood inlet line of the centrifugal pump. Air bubbles may occur if the blood inlet line is clamped, as the inside of the centrifugal pump will be negatively pressurized.

Caution
• Do not attach the Fast Clamp to any tube other than the dedicated tube (internal diameter: 9.5 mm (3/8 inches)). If a tube other than the dedicated tube is used, this may result in decreased performance.

◆ Using the Fast Clamp Attachment (for EBS)

1. **While holding the lid of the Fast Clamp, pull up the lever until you hear a click. (Figure 1-52)**

> The plunger is set at the open position.
> To close the plunger manually, use [Clamp] button on the Fast clamp screen. (Refer to page 57.)

Check
• After pulling up the lever, the lever has returned to the original position.

Note
• If the lever does not return to the original position, pull down the lever. If it does not return to the original position, a failure may have occurred.
  Stop using the system immediately, and contact Terumo's service representative.
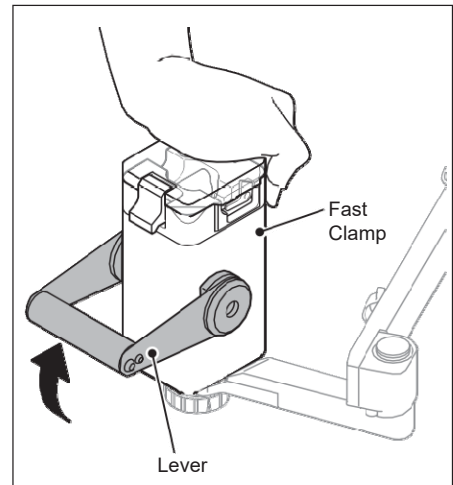
Figure 1-52

2. **Release the latch of the Fast Clamp lid, and open the lid. (Figure 1-53)**
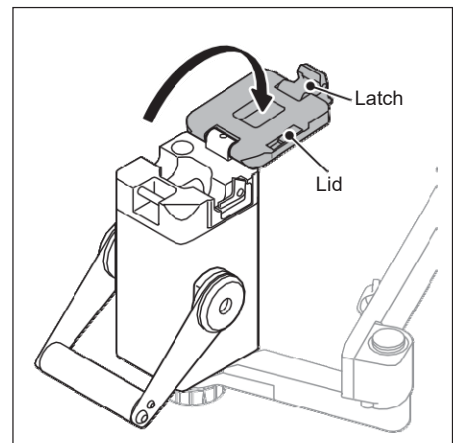
Figure 1-53

3. **Move the Fast Clamp as necessary and insert the tube into the groove. (Figure 1-54)**

Note
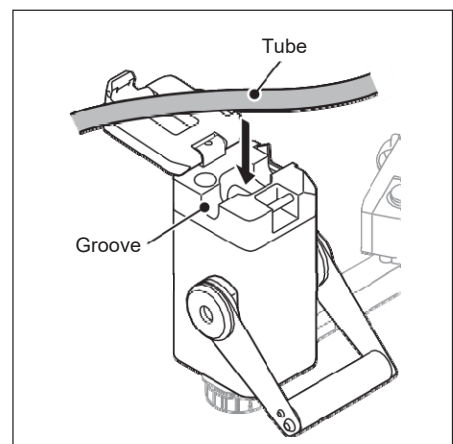• When inserting the tube, avoid excessive bending which may degrade the flow.

Figure 1-54

52

4. **Close the lid of the Fast Clamp, and close the latch. (Figure 1-55)**

    | Check |

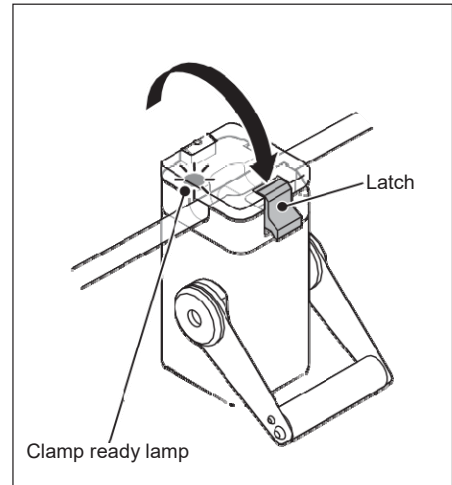   • The clamp ready lamp is lit in green.

Figure 1-55

◆ Using the Fast Clamp Arm

1. **Holding the Fast Clamp by hand, loosen the knob of the Fast Clamp Arm by turning it counter-clockwise (Figure 1-56 a), and then move the Fast Clamp to any position.**
    After moving to the position, secure it by turning the knob of the Fast Clamp Arm clockwise. (Figure 1-56 b)

    | Check |

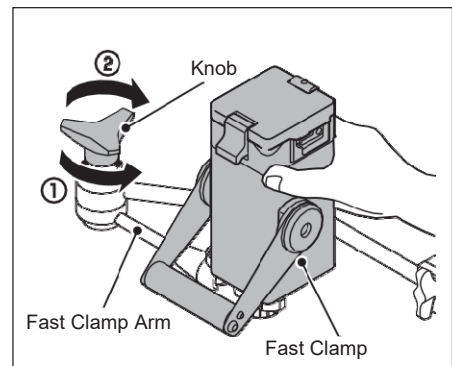   • The Fast Clamp Arm is secured.

Figure 1-56

2. **To change the direction of the Fast Clamp, hold the Fast Clamp, loosen the fixing knob by rotating counter-clockwise. (Figure 1-57 a) Rotate the Fast Clamp. (Figure 1-57 b)**
    Then secure the fixing knob by turning clockwise. (Figure 1-57 c)

    | Check |

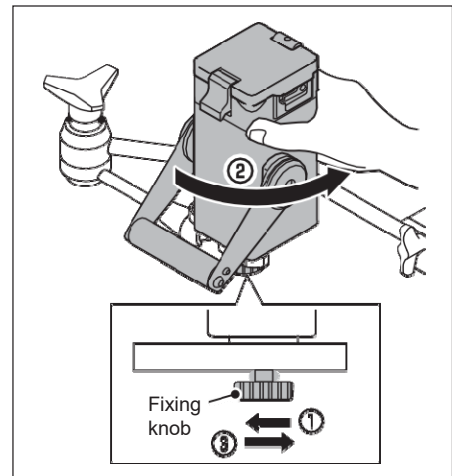   • The Fast Clamp is secured.

Figure 1-57

3.   While holding the lid of the Fast Clamp, pull up the lever until you hear a click. (Figure 1-58)

The plunger is set at the open position.
To close the plunger manually, use [Clamp] button on the Fast clamp screen. (Refer to page 57.)

Check

• After pulling up the lever, the lever has returned to the original position.

Note

• If the lever does not return to the original position, pull down the lever. If it does not return to the original position, a failure may have occurred.
  Stop using the system immediately, and contact Terumo's service representative.
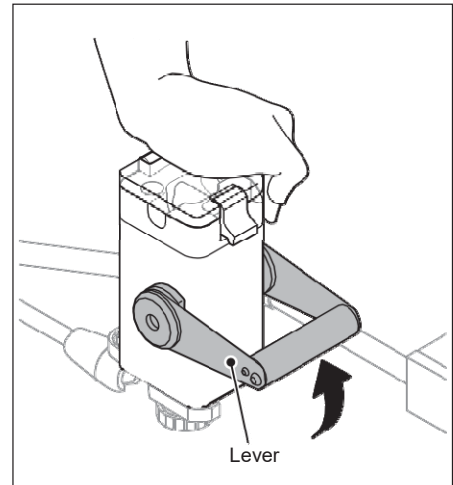

Figure 1-58

4.   Release the latch of the Fast Clamp lid, and open the lid. (Figure 1-59)
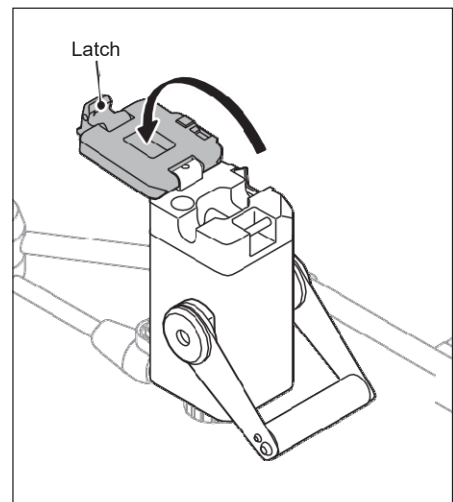

Latch

Figure 1-59

5.   Insert the tube for the blood line into the Fast Clamp. (Figure 1-60)

Note

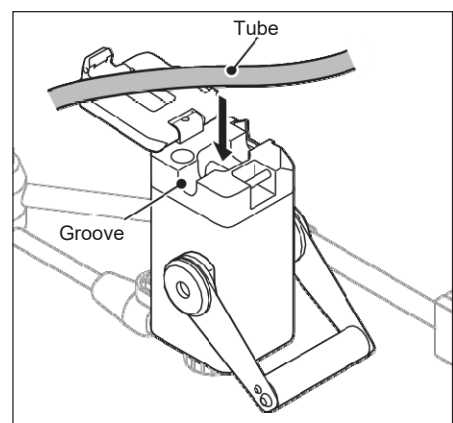• When inserting the tube, avoid excessive bending which may degrade the flow.

Tube

Groove

Figure 1-60

54

6. **Close the lid of the Fast Clamp, and close the latch. (Figure 1-61)**

Check

• The clamp ready lamp is lit in green.

Latch

Clamp ready lamp

Figure 1-61

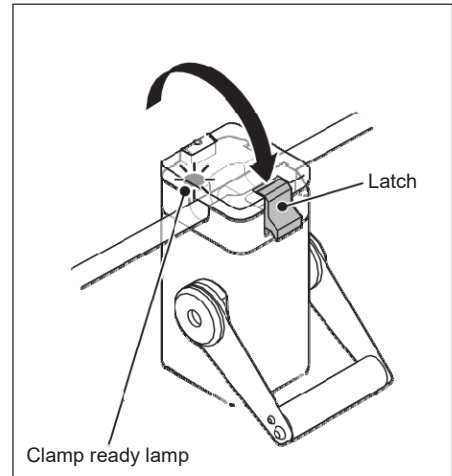## Inspection Before Circulation Starts

Perform the inspection before circulation starts by following "Inspection Before Circulation Starts (Before Each Use)". (Refer to page 125.)

Starting Circulation

Cautions

• Do not use this system as a suction device. The system equipment is not intended to perform sucking operations.
• Use this system while paying attention not to let air in the blood circulation circuit. Health damages may occur to the patient.
• When this system is used for negative-pressure blood removal aid, be cautious as the correlation between the flow and motor speed of the centrifugal pump will change according to the strength of negative pressure applied to the reservoir.
• Do not let anesthetic drugs come into contact with the system or accessories. The system or accessories may be damaged.

1. **Confirm that the Motor speed indicator in the LCD or the motor speed indicator in the control panel indicates "0".**

2. **Clamp the blood outlet line of the centrifugal pump. (Figure 1-62) Turn the motor speed knob to the coast speed. Gradually release the clamp of the blood outlet line.**

Clamp

Blood outlet line

Figure 1-62

Note

• For details about how to operate the centrifugal pump, refer to the instructions for use of the centrifugal pump to be used.

3. **While monitoring the flow, adjust the motor speed to achieve the necessary flow.**
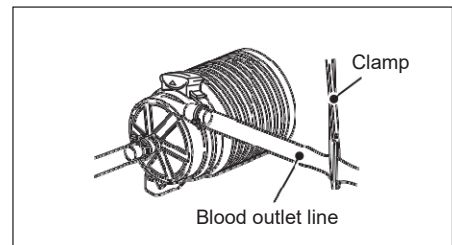
During Circulation

┌─ Warnings ───┐

- Monitor the circulation status (the operation status of the system, blood storage state of a reservoir, etc.) during extracorporeal circulation without fail. 1. As this system does not have a function to monitor the status of the patient, the system cannot detect when the status of the patient changes even if the system operates properly. 2. The system cannot detect the leakage of liquid (including blood) caused by damage to the extracorporeal circulation circuit. 3. It is possible that the system will not detect a flow abnormality, even if the ABD/Flow Sensor is used. 4. This system may not operate in accordance with the specifications if the system is used together with another system.
- Do not clamp the blood inlet line of the centrifugal pump during circulation. Air bubbles may occur in the blood as the inside of the centrifugal pump is negatively pressured.

└──┘

┌─ Cautions ───┐

- Avoid sudden temperature changes even when operating within the system's indicated temperature specifications. Condensation inside the system results in damage, time degradation, and decreased performance.
- When the Controller is transported while in use, do not touch the buttons, etc. inadvertently or use the key lock function. Otherwise it may result in an unintended operation (stop, start, power on/off).

└──┘

┌─ Note ─┐

• The measured flow value is displayed numerically on the LCD and Control panel. It is also displayed as a bar indication on the LCD. The response of the numerical indication is slower to improve the display stability.

When an alarm is issued, the alarm message is displayed on the message area.
(For details, refer to "List of Alarm Messages" (page 134).)

┌─ Cautions ───┐

- Perform the flow adjustment by changing the motor speed of the centrifugal pump. If the adjustment is performed by partially clamping the blood outlet line of the centrifugal pump, damage to the blood may be increased.
- While circulating, maintain the motor speed at a speed higher than that at which the Low Flow Alarm is issued (the speed at which back flow does not occur due to the height gradient or the patient's blood pressure). Back flow of blood may occur.
- When circulating or priming, if a significant amount of air enters the centrifugal pump causing the pump to idle and circulation to stop, perform the following procedures: After clamping the blood outlet line of the centrifugal pump, stop the rotation of the pump. Remove the air and release the clamp to restart circulation.
- Be cautious in motor speed adjustment when decreasing the motor speed of the centrifugal pump. Back flow of blood may occur.

└──┘

Weaning

Cautions

- When weaning, be sure to clamp the blood line and then stop the rotation of the centrifugal pump. If the rotation of the centrifugal pump stops without clamping the blood line, blood may flow back.
- Do not rotate the centrifugal pump for a long period of time (multiple hours) while clamping the blood outlet line of the centrifugal pump. The priming solution may be denatured due to heating. The blood may be damaged due to heating.
- After circulation, make sure to rotate the motor speed knob to stop the Drive Motor and then turn off the power.
- When the Drive Motor is removed, place a cap on the plug.

1. **When weaning, operate the clamp while paying attention to back flow.**

2. **Turn the motor speed knob counter-clockwise to change the motor speed to 0 RMP to stop the Drive Motor. (Figure 1-63)**

   For details about how to stop the motor, refer to page 8.

Motor speed knob

Figure 1-63

Note

• By performing the above procedure, some alarms and alerts are displayed on the message area. This, however, is part of the end process and not a malfunction.

Check

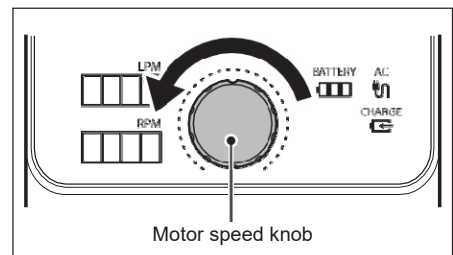• The motor speed turns to "0", and the flow turns to "0.00".

◆ If using the Fast Clamp

Close the plunger of the Fast Clamp before finishing the case and store it in a closed (up) position.

3. **Tap the setup icon (Figure 1-64), and tap the Fast clamp icon on the Setup screen. (Figure 1-65)**

   The Fast clamp screen opens.

Figure 1-64

Figure 1-65

57

4. **Tap [Clamp] (Figure 1-66) to close (up position) the plunger of the Fast Clamp.**
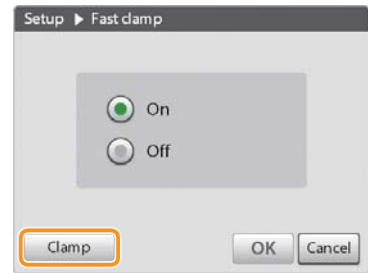
Note

• Perform with the tube attached.

Figure 1-66

5. **Tap [Cancel] to close the screen. (Figure 1-67)**

Figure 1-67

Turning the Power Off

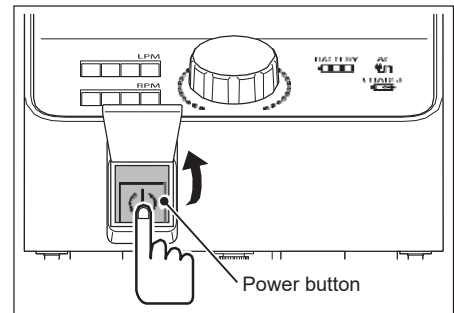**1.** **Press the power button. (Figure 1-68)**

Power button

Figure 1-68

2. **Tap [OK] after confirming the message displayed. (Figure 1-69)**

"Now Shutting Down" is displayed on the message area, and the power is turned off.

Note

• The power can be also turned off by pressing twice or pressing and holding the power button.

Figure 1-69

Using the Cart

Casters

Lock all casters of the Cart with each stopper. (Figure 1-70)

> **Caution**
>
> • Keep the cart's casters in a locked position except when transporting the cart. The Cart may move unintentionally, causing attached products to fall.
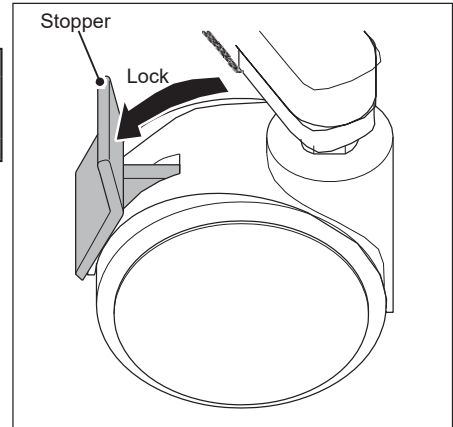

Figure 1-70

IV Pole

Adjust the height (maximum: about 1.7 m) of the IV hanger, and secure it with the knob. (Figure 1-71)
Two packs of 500 mL solution can be hung on the IV hanger.
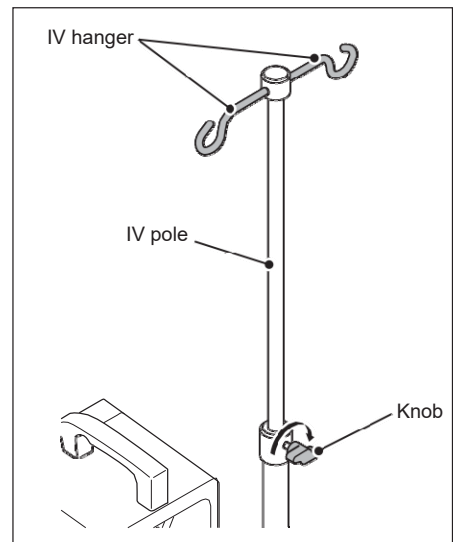
Figure 1-71

Cable Hook

Wind the cable (AC power cable, etc.) around the cable hooks. (Figure 1-72)
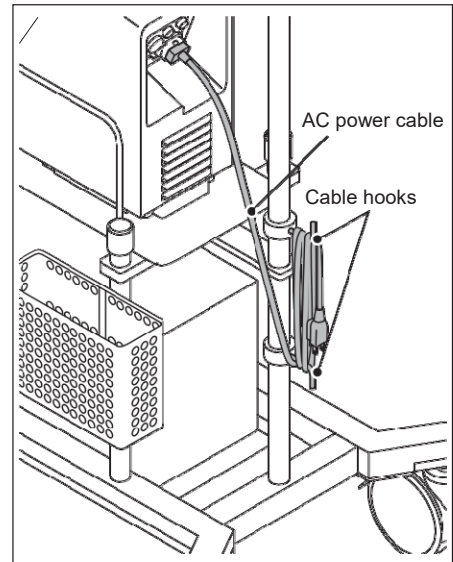

AC power cable

Cable hooks

Figure 1-72

Drawer

The drawer has a lock mechanism to prevent popping out.
Pull forward the lock release plate to open the drawer. (Figure 1-73)
To close the drawer, push the drawer back until you hear a click.
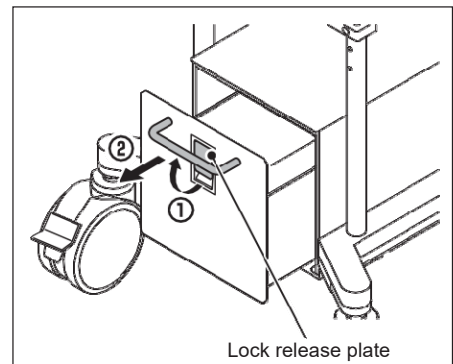The Backup Controller can be stored in the drawer.

Lock release plate

Figure 1-73

Moving the Cart

Move the Cart by holding the handles with the caster locks released. (Figure 1-74)
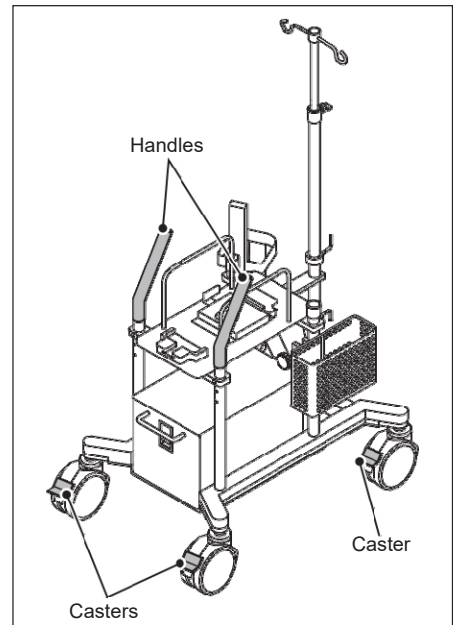
Figure 1-74

Attaching Other Products to the Cart

Attach the following products to the Cart with its casters locked.
To secure the products to the IV pole, attach it below the level of the IV pole knob.

Attaching the Gas Blender

1.   Attach the gas blender to the front side poles (Figure 1-75) or to the IV pole (Figure 1-76).

Be careful not to bend the gas hose.

Check

• The gas blender is secured.

Refer to the instructions for use of the gas blender (e.g., mounting instructions).

Figure 1-75

Figure 1-76

Attaching the Oxygen Cylinder

1. Attach the cylinder holder to the rear side pole, and secure it with the knobs. (Figure 1-77)

Check

• The cylinder holder is secured.
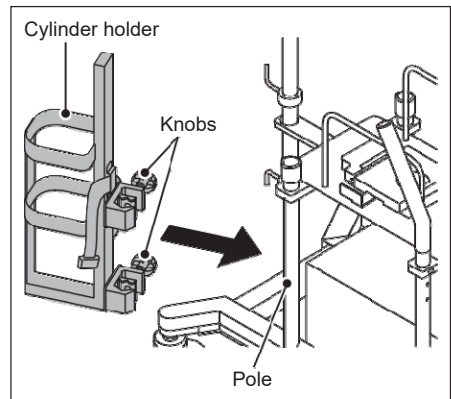
Figure 1-77

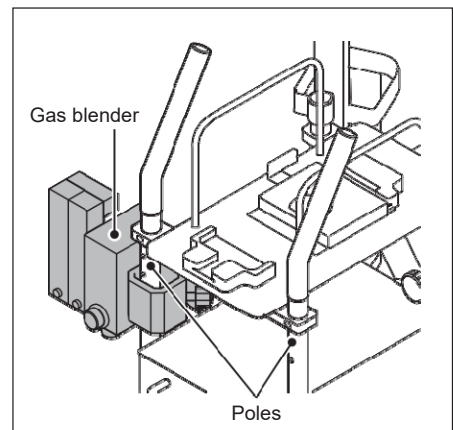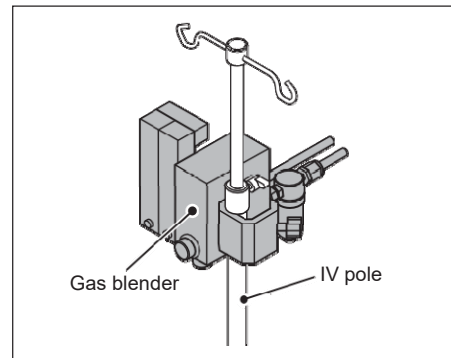**2. Place the oxygen cylinder into the cylinder holder. (Figure 1-78)**

Secure the oxygen cylinder with the belt when you move the cart.
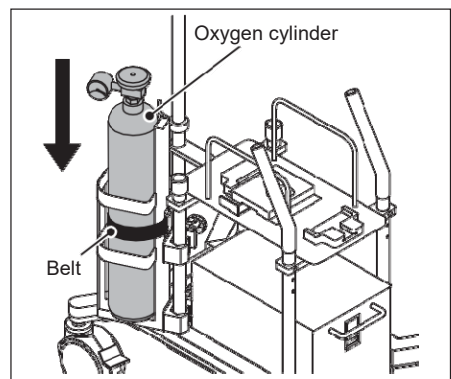
Figure 1-78

Attaching the CAPIOX EBS Circuit Holder

1. Attach the CAPIOX EBS Circuit Holder to the IV pole, and secure it with the knob. (Figure 1-79)

Attach it on the opposite side of the cylinder holder.

Check

• The CAPIOX EBS Circuit Holder is secured.
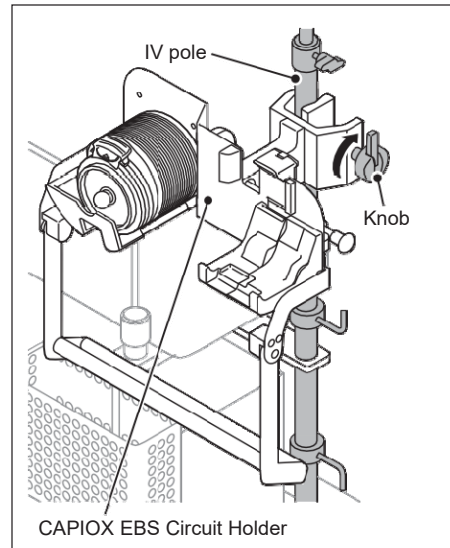
Figure 1-79

Attaching the Fast Clamp Attachment (for EBS)

Refer to the steps 1 to 3 of page 38 "Connecting to Fast Clamp ◆ Using the Fast Clamp Attachment (for EBS)".

Attaching the Basket

1. Attach the basket to a pole, and secure it with the knob. (Figure 1-80)

Position the basket so that it does not interfere with nearby components.

Check

• The basket is secured.
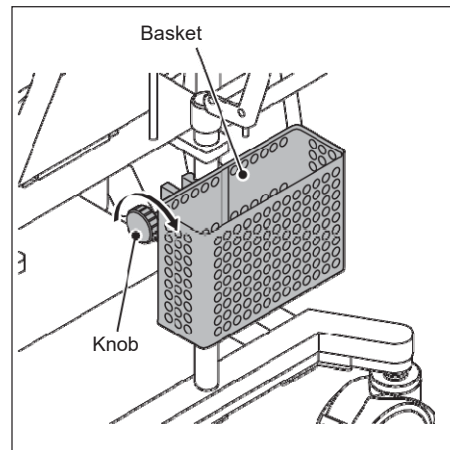
Figure 1-80

Attaching the Hand Crank

1.   Attach the Hand Crank to the IV pole, and secure it with the knob. (Figure 1-81)

Caution
• When using the Hand Crank, attach it to a pole securely after ensuring there is enough space and tube length so that the crank can rotate smoothly. It may become impossible to maintain circulation.

Checks

• The Hand Crank is secured.
• The flexible shaft is attached at a height where it does not come into contact with the caster or the ground.

Figure 1-81

This section describes the following functions.

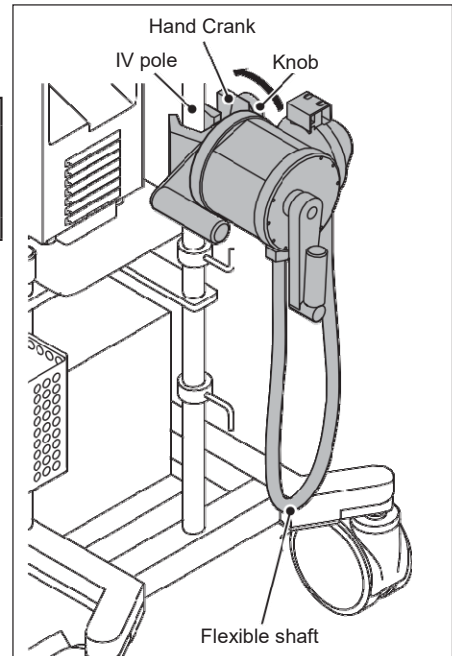| Function		Function description	Reference
Safety connection		Sets up the behaviours responding to the Pressure Alarm (over pressure/ low pressure), the Air Bubble Detected Alarm and the Back Flow Alarm.	☞page 65
Battery-powered operation		Runs the Drive Motor on a battery if the AC power supply fails.	☞page 72
Key lock		Tapping and button operation are turned off to prevent inadvertent operation while the system is running.	☞page 74
Count up timer		A timer for counting up. The elapsed time can be checked.	☞page 75
Count down timer		A timer for counting down. Notifies with a sound and screen display when the set time has elapsed.	☞page 76
Perfusion index calculation		Calculates the body surface area using DuBois or Boyd formula when the patient information (height and weight) is input. Calculates the perfusion index with the body surface area and flow, and displays the index on the main screen.	☞page 77
History		Records and displays the alarms issued during circulation.	☞page 77
	Trend chart	Indicates the circulation status in a time-series chart.	☞page 77
	Event list	Displays the list of alarms, etc.	☞page 78
	Output data to USB memory	Outputs the records, such as motor speed, flow, pressure, temperature and alarms, etc. as data. * The data can be output after weaning (the status of Drive Motor stop).	☞page 78
LAN communication		Communicates the records of alarms, etc., motor speed, flow, pressure and temperature with network equipment through LAN.	☞page 78
CDI communication		Outputs the flow information to the CDI System 500.	☞page 82

Safety Connection

This system can set up the behaviours (safety connections) responding to the Pressure Alarm (over pressure/low pressure), the Air Bubble Detected Alarm and the Back Flow Alarm. This section describes the Controller setup of a to d in the table and the responses to the safety connection.

	Without safety connection	With safety connection	
	Message only	Pump coast	Clamp+pump stop
Pressure Alarm (over pressure/low pressure)	○	a	
Air Bubble Detected Alarm	○	b	c
Back Flow Alarm	○		d

[Message Only]:
Displays a message when alarm is detected.
[Pump Coast]:
Displays a message when alarm is detected and sets the motor speed to the coast speed.
[Clamp+Pump stop]:
Displays a message when alarm is detected, closes the extracorporeal circulation circuit line with the Fast Clamp and stops the Drive Motor.

─ Warning ─────────────────────────────

• Set the safety connection and record its setting. Confirm that the device is operating as intended by the safety connection.
  If the setting is wrong, the Controller may not operate as intended.

---

a When the safety connection of the Pressure Alarm (over pressure/low pressure) is set to "Pump Coast"

(This example describes when pump coast is activated when the Over Pressure Alarm is issued for P1.)

◆ Setting of the Controller

1. **Turn the P1 pressure measuring function on.**

   For details about how to set, refer to "Setting Pressure Measuring Function" (page 85).

2. **Set the safety connection of the P1 Over Pressure Alarm to "Pump Coast".**

   For details about how to set, refer to "Setting the Safety Connection" (page 91).

Note

• When activating the safety connection, be sure to also turn on the pressure measuring function. The safety connection is not activated without the pressure measuring function.

◆ Actions after activating the safety connection

1. **When the Pressure Alarm is issued, the motor speed is lowered to the coast speed.**

   The status lamp starts to flash in red and the alarm sounds, while "P1:Over Pressure Alarm" and "P1 Over: Pump Coasting" are displayed on the message area. (Figure 2-1)

Figure 2-1

Note

• When the motor speed is equal to or less than the coast speed, the safety connection is not activated.

2. **Remove the cause of the Pressure Alarm.**

   For details about how to handle, refer to "Alarms and Troubleshooting" (page 132).

3. **While monitoring the pressure and the flow, adjust the motor speed to achieve the necessary flow.**

   The status lamp is lit in green, and the alarm sound stops.
   "P1 Over: Pump Coasting" on the message area is turned off.

b When the safety connection of the Air Bubble Detected Alarm is set to "Pump Coast"

◆ Setup of the Controller

1. Turn the air bubble detector function on.

For details about how to set, refer to "Setting the Air Bubble Detector Function" (page 104).

2. Set the safety connection of the Air Bubble Detected Alarm to "Pump Coast".

For details about how to set, refer to "Setting the Safety Connection" (page 91).

Note
• When activating the safety connection, be sure to set the air bubble detector function on. The safety connection is not activated without the air bubble detector function.

◆ Actions after activating the safety connection

1. When the Air Bubble Detected Alarm is issued, the motor speed is lowered to the coast speed.

The status lamp starts to flash in red and the alarm sounds, while "Air Bubble Detected Alarm" and "Air Bubble: Pump Coasting" are displayed on the message area. (Figure 2-2)

Note
• When the motor speed is equal to or less than the coast speed, the safety connection is not activated.

2. Remove the air bubble from the blood circuit.

For details about how to handle, refer to "Alarms and Troubleshooting" (page 132).

Figure 2-2

3. Tap [Air Bubble Detected Alarm] on the message area, and after confirming the displayed message, tap [OK]. (Figure 2-3)

The Air Bubble Detected Alarm is cleared, and "Air Bubble Detected Alarm" on the message area is turned off.

Note
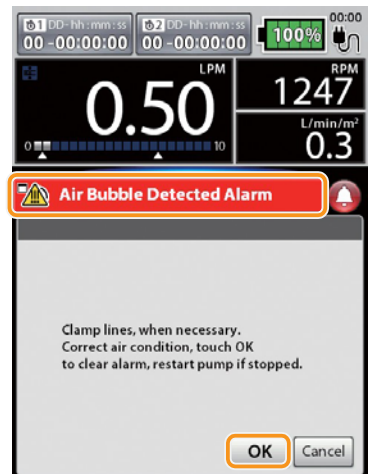• The Air Bubble Detected Alarm can also be cleared by performing the step 4.

Figure 2-3

4. **While monitoring the flow, adjust the motor speed to achieve the necessary flow.**

    The status lamp is lit in green, and the alarm sound stops.
    "Air Bubble: Pump Coasting" on the message area is turned off.

⊏ When the safety connection of the Air Bubble Detected Alarm is set to "Clamp+Pump stop"

◆ Setup of the Controller

1. **Turn the Fast Clamp on.**

    For details about how to set, refer to "Setting the Fast Clamp" (page 90).

2. **Turn the air bubble detector function on.**

    For details about how to set, refer to "Setting the Air Bubble Detector Function" (page 90).

3. **Set the safety connection of the Air Bubble Detected Alarm to "Clamp+Pump stop".**

    For details about how to set, refer to "Setting the Safety Connection" (page 91).

Note

• When activating the safety connection, be sure to set the Fast Clamp and the air bubble detector function on.
  The safety connection is not activated without the air bubble detector and the Fast Clamp functions.

◆ Actions after activating the safety connection

1. **When the Air Bubble Detected Alarm is issued, the Fast Clamp is closed (up position) and the Drive Motor stops.**

    The status lamp starts to flash in red and the alarm sounds, while "Air Bubble Detected Alarm", "Air Bubble: Clamp Close" and "Air Bubble: Pump Stop" are displayed on the message area. (Figure 2-4)

Notes

• If the Fast Clamp is not ready to work (conditions such as "Clamp Not Ready" or "Clamp Closed"), the Drive Motor will not stop even when the system issues the alarm.
• After the Fast Clamp is closed by the activated safety connection, if the pump starts without the Fast Clamp being opened but by opening the lid, the message "Air Bubble: Clamp Close" will remain on the screen. The message is cleared when the Fast Clamp is opened by following Step 5.
• After the Fast Clamp is closed by the activated safety connection, if the pump starts without the Fast Clamp being opened but by opening the lid and an air bubble is again detected while the message "Air Bubble: Clamp Close" is displayed, the Drive Motor will stop and the message "Clamp Occlusion Error" will be displayed.

Figure 2-4

2. Clamp the blood line of the patient side of the Fast Clamp with forceps. (Figure 2-5)
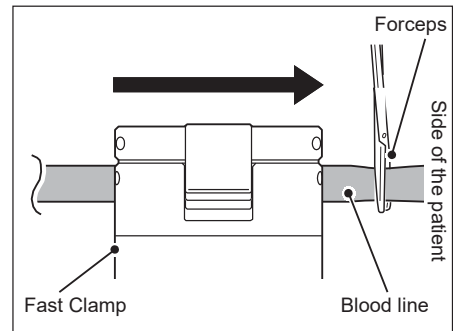

Figure 2-5

3. Remove the air bubble from the blood circuit.

For details about how to handle, refer to "Alarms and Troubleshooting" (page 132).

4. Tap [Air Bubble Detected Alarm] on the message area, and after confirming the displayed message, tap [OK]. (Figure 2-6)

The Air Bubble Detected Alarm is cleared, and "Air Bubble Detected Alarm" on the message area is turned off.

| Note |

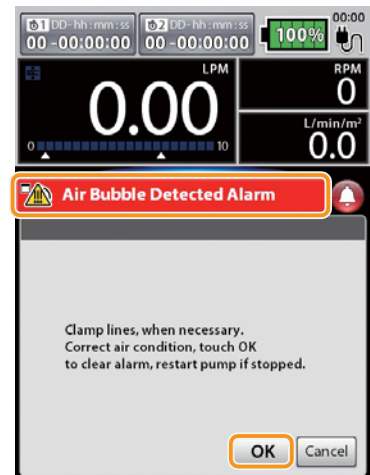• The Air Bubble Detected Alarm can also be cleared by performing the step 5 or step 6.

Figure 2-6

5. Pull up the lever of the Fast Clamp until you hear a click, and remove the occlusion with the Fast Clamp. (Figure 2-7)

"Air Bubble: Clamp Close" on the message area is turned off.

| Check |

• After pulling up the lever, the lever has returned to the original position.

| Note |

• If the lever does not return to the original position, pull down the lever. If it does not return to the original position, a failure may have occurred.
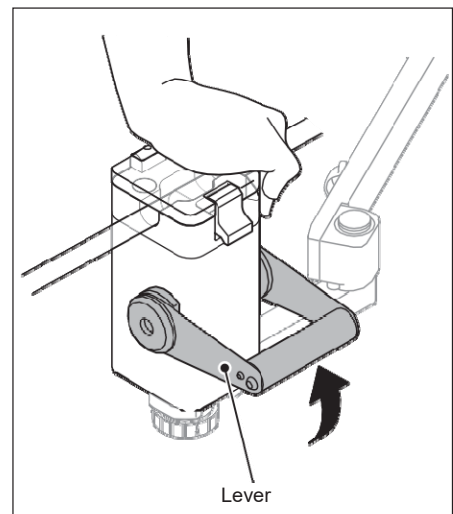 Stop using the system immediately, and contact Terumo's service representative.

Figure 2-7

6. **Keep clamping the blood line with forceps. Turn the motor speed knob to adjust the motor speed to a speed that does not cause back flow. Gradually release the clamp of the blood line.**

   The status lamp is lit in green, and the alarm sound stops.
   "Air Bubble: Pump Stop" on the message area is turned off.

7. **While monitoring the flow, adjust the motor speed to achieve the necessary flow.**

---

d When the safety connection of the Back Flow Alarm is set to "Clamp+Pump stop"

◆ Setup of the Controller

1. **Turn the Fast Clamp on.**

   For details about how to set, refer to "Setting the Fast Clamp" (page 90).

2. **Set the safety connection of the Back Flow Alarm to "Clamp+Pump stop".**

   For details about how to set, refer to "Setting the Safety Connection" (page 91).

> Note

- When activating the safety connection, be sure to set the Fast Clamp on. The safety connection is not activated without the Fast Clamp function.

◆ Actions after activating the safety connection

1. **When the Back Flow Alarm is issued, the Fast Clamp is closed (up position) and the Drive Motor stops.**

   The status lamp starts to flash in red and the alarm sounds, while "Back Flow: Clamp Close" and "Back Flow: Pump Stop" are displayed on the message area. (Figure 2-8)

> Notes

- If the Fast Clamp is not ready to work (conditions such as "Clamp Not Ready" or "Clamp Closed"), the Drive Motor will not stop even when the system issues the alarm.
- After the Fast Clamp is closed by the activated safety connection, if the pump starts without the Fast Clamp being opened but by opening the lid, the massage "Back Flow: Clamp Close" will remain on the screen. The message is cleared when the Fast Clamp is opened by following Step 3.
- After the Fast Clamp is closed by the activated safety connection, if the pump starts without the Fast Clamp being opened but by opening the lid and an air bubble is again detected while the message "Back Flow: Clamp Close" is displayed, the Drive Motor will stop and the message "Clamp Occlusion Error" will be displayed.

Figure 2-8

2. Clamp the blood line of the patient side of the Fast Clamp with forceps. (Figure 2-9)
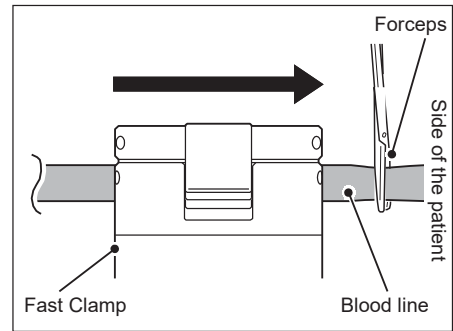

Figure 2-9

3. Pull up the lever of the Fast Clamp until you hear a click, and remove the occlusion with the Fast Clamp. (Figure 2-10)

The plunger is set at the open position, and "Back Flow: Clamp Close" on the message area is turned off.

Check

• After pulling up the lever, the lever has returned to the original position.

Note

• If the lever does not return to the original position, pull down the lever. If it does not return to the original position, a failure may have occurred.
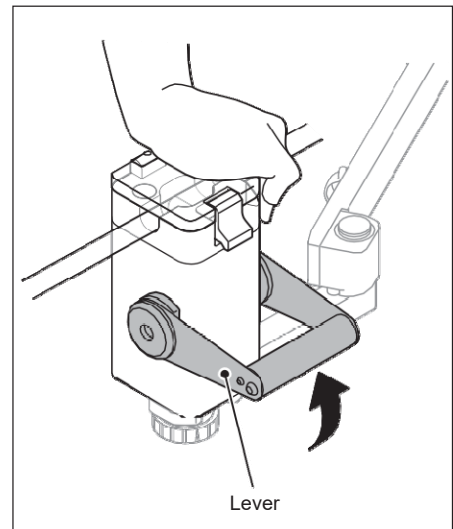 Stop using the system immediately, and contact Terumo's service representative.

Figure 2-10

4. Keep clamping the blood line with forceps. Turn the motor speed knob to adjust the motor speed to a speed that does not cause back flow. Gradually release the clamp of the blood line.

The status lamp is lit in green, and the alarm sound stops.
"Back Flow: Pump Stop" on the message area is turned off.

5. While monitoring the flow, adjust the motor speed to achieve the necessary flow.

Battery-powered Operation

The Controller contains battery. If the AC power supply is lost or not sufficient, the AC power is automatically switched to battery power. The battery will supply power for about an hour. (On the condition that a new battery is charged for more than six hours, and then it is used with 2500 RPM motor speed and 4 LPM (L/min) flow)
The battery is recharged by connecting the Controller to the AC power source. For details about how to connect to the AC power source, refer to "Connecting to AC Power Cable" (page 31).

Display	Connected to AC power/Charging	On battery
Control panel	BATTERY AC CHARGE Charging: lights up	BATTERY CHARGE
LCD touch panel display	00:00 97% Charging: flashes	00:00 97%

◆ Switching from AC power to battery-powered operation

1. **As soon as the power source switches to battery, "Battery-powered operation started" is displayed on the message area, and an alarm sounds. (Figure 2-11)**

   The status lamp flashes in yellow.

2. **Tap [Battery-powered operation started] displayed on the message area. (Figure 2-11)**

Figure 2-11

3. **Tap [OK] to return to the main screen. (Figure 2-12)**

   When Cancel is tapped, it returns to step 1.
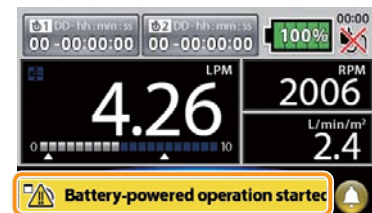

Figure 2-12

4. **"On Battery" is displayed on the message area. (Figure 2-13)**
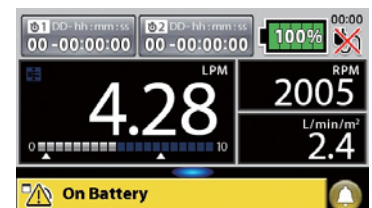
   The status lamp is lit in yellow.

Figure 2-13

72
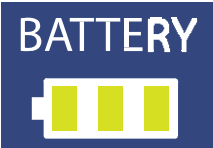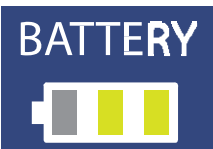
◆ Battery charge level display

(On LCD touch panel display) Battery status indicator*		(On control panel) Battery indicator lamp		Battery charge level
	Five segments (green)		Three segments (green)	100%
	Four segments (green)			80 - 99%
	Three segments (green)		Two segments (green)	60 - 79%
	Two segments (green)			40 - 59%
	One segment (green)			20 - 39%
	One segment (red)		One segment (red)	0 - 19%

* The value of the battery charge level is displayed in one percent increments.

Warnings

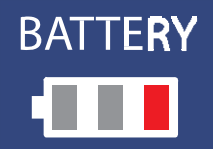- Use the AC power source as the primary power source. Battery is used as an auxiliary power source when the AC power source cannot be used sufficiently, such as during transportation, electric failure, etc. If the battery is depleted and charging is insufficient, the Controller will not be able to operate by the battery during an emergency such as electric failure.
- Connect the AC power cable to the AC power inlet of the Controller until you hear a click. Subsequently, check that the AC power lamp in the control panel of the Controller is lit. If the connection is insufficient, the Controller will be powered by the battery. And therefore the battery will be depleted, the devices will shut down and circulation will not be maintained.

Cautions

- When the Low Battery Alarm or the Battery Empty Alarm is issued, immediately connect the Controller to the AC power source.
- Do not store the battery in a discharge status. Storing the battery left in a discharge status may cause degradation, resulting in making the battery unavailable in emergency situations.

Key Lock

Locking the LCD touch panel and control panel prevents inadvertent operation.

1. **<<Operation from the main screen>>**

Tap the key lock icon on the LCD touch panel display. (Figure 2-14)

The key lock icon is lit in green, and the key lock turns on.
The key lock button on the control panel is lit in orange at the same time.

Key lock icon

Figure 2-14

<<Operation from the control panel>>

Press the key lock button on the control panel. (Figure 2-15)

The key lock button is lit in orange, and the key lock turns on.
The key lock icon on the LCD touch panel display is lit in green at the same time.
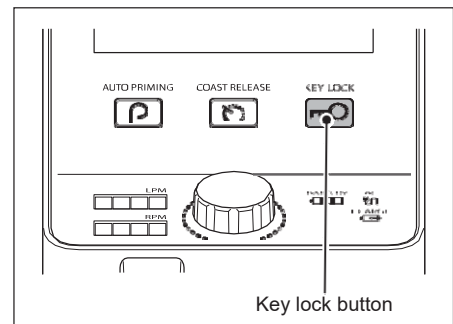
Key lock button

Figure 2-15

Note

• If the key lock is turned on during setting up menus, the contents being set will be cancelled, and the key lock will be turned on.

◆ Disabling the key lock

1. **<<Operation from the main screen>>**

Touch the LCD touch panel display and tap [OK] after confirming the message displayed. (Figure 2-16)

The key lock is disabled.

<<Operation from the control panel>>

Press the key lock button on the control panel and press the key lock button again after confirming the message displayed.
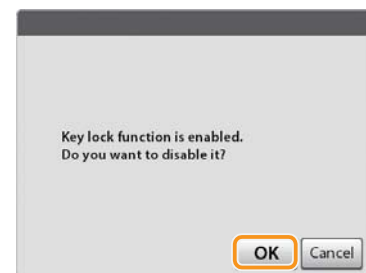
The key lock is disabled.

Figure 2-16

Notes
- When tapping [Cancel], the key lock is not disabled, and the key lock remains enabled.
- When an alarm or alert is issued while key lock is enabled, the key lock is automatically cancelled, and the colour indicators on the key lock icon and key lock button will turn off.

Count Up Timer

This system has two count up timers.
When the power is turned on, "00-00:00:00" is displayed in the count up timer indicator.

◆ Starting/stopping the timer

1.   Tap the count up timer indicator. (Figure 2-17)

The following figures show the count up timer 1 being used.
The timer starts and the elapsed time is displayed.
While the timer is activated, it is lit in green.
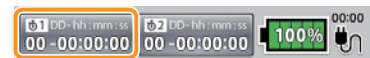
Figure 2-17

2.   Tap the count up timer indicator again. (Figure 2-18)
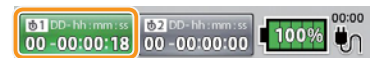
Figure 2-18

The timer count is stopped. When the timer is stopped, its colour will return to grey. (Figure 2-19)

Figure 2-19

◆ Restarting the timer

1.   While the timer count is stopped, tap the count up timer indicator. (Figure 2-20)
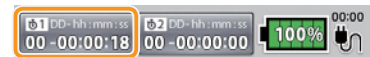
Figure 2-20

2.   Tap [Restart], and tap [OK]. (Figure 2-21)

Figure 2-21

The timer count restarts. (Figure 2-22)
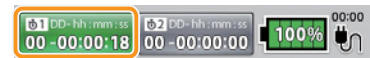
Figure 2-22

◆ Resetting the timer

1. **While the timer count is stopped, tap the count up timer indicator. (Figure 2-23)**

Figure 2-23

2. **Tap [Reset], and tap [OK]. (Figure 2-24)**

Figure 2-24

The timer count is reset, and the indication returns to "00-00:00:00". (Figure 2-25)

Figure 2-25

Count Down Timer

A count down timer can be set. When the set time has passed, you will be informed by sound and screen indication.
The maximum duration that can be set is 9 hours, 59 minutes and 59 seconds.
For details about the procedures, refer to "Setting Count Down" (page 94).
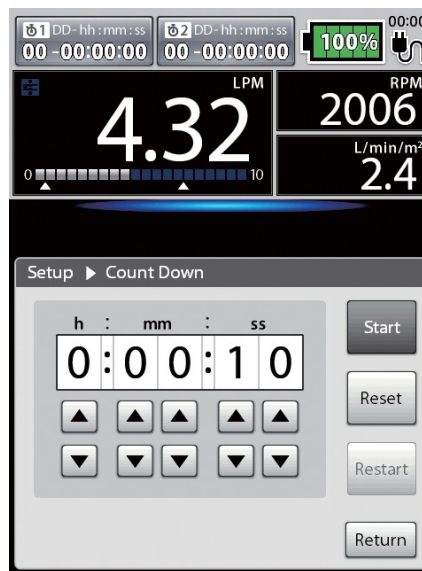
Perfusion Index Calculation

The body surface area (BSA) is calculated using Dubois or Boyd formula when the patient information (height and weight) is input.
The perfusion index calculated by the BSA and flow data is displayed on the main screen.
For details about how to set height and weight, refer to "Setting BSA" (page 93).

Perfusion index indicator
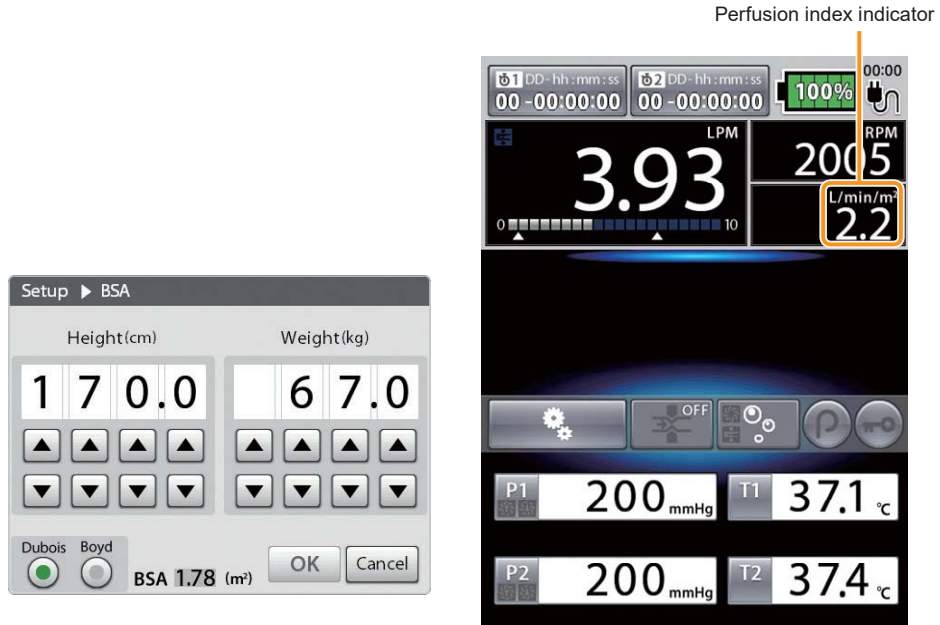
History

While the power is on, this function records data (motor speed, flow, pressure, temperature) and events. When the power is turned off, the trend chart and the event list will be reset, but the recorded history data is stored in the device.

Trend Chart

The trend chart displays the motor speed, flow and pressures recorded.
For details about the procedures, refer to "Trend chart" (page 95).
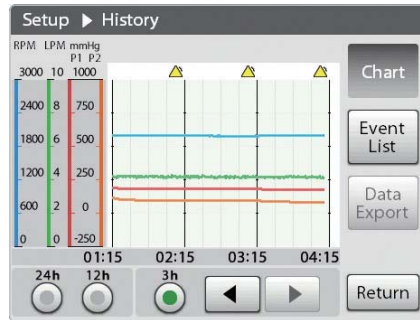
When 3h is selected, tap ◀ or ▶ to change the timeline of the chart.

Event List

The system records the alarms and alerts displayed during operation. The event list displays those events with date and time.
For details about the procedures, refer to "Event List" (page 96).
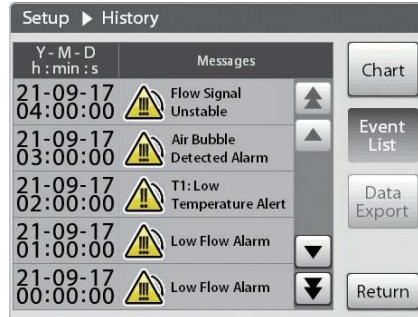
Output Data to USB Memory

The information recorded in the history can be exported as a log file.
For details about the procedures, refer to "Output data to USB memory" (page 96).

LAN Communication

During circulation, motor speed, flow, pressure, temperature, and event information can be transmitted to network equipment such as PCs. To use this function, connect the Controller to network equipment with a LAN cable, and turn the setting of the LAN communication function of the Controller on. For details about how to set up the LAN communication function, refer to "Setting LAN" (page 110).

Configuration of the Controller and Network Equipment

A direct connection between the Controller and network equipment with a LAN cable is recommended. Contact Terumo's service representative regarding a connection through a switching hub.

Note

• The pin assignment of the Controller side is fixed at MDI-X. Select cables in accordance with the connected equipment.

Connected equipment	Usable cable
Equipment with AutoMDI/MDI-X function	Straight cable (both ends: TIA/EIA-568-A) Cross cable (one side: TIA/EIA-568-B)
MDI equipment	Straight cable
MDI-X equipment	Cross cable

Setting of the Controller

The following parameters can be set for the Controller. For details about how to operate the screen, refer to "Setting LAN" (page 110). Contact Terumo's service representative regarding a connection through a switching hub.

Parameter	Description
MAC address filtering	Sets to perform communication with specific MAC addresses only.
Source IP address	IP address for the Controller. Selects to specify the IP address on the screen, or to obtain it automatically from the DHCP server.
Subnet mask	A number used to determine the subnet (subnetwork) which an IP address belongs to. Selects to specify the subnet mask on the screen, or to obtain it automatically from the DHCP server.
Destination IP address	IP address of the device to which the communication is being established.
Destination port	TCP socket communication port of the device to which the communication is being established.

Specification of Network Communication (Format)

Communication between network equipment is conducted with TCP. Network equipment serves as the TCP server, and the Controller serves as the TCP client.

XML is used as the data format. Export data is output every second.
The beginning of an exported file is an XML declaration and transmitted with an XML instance added.

The XML declaration is described in the following format.
<?xml version="1.0 " encoding="UTF- 8"?>

The XML instance is described in the following format.
<NEO_DATA Year="2013" Month="10" Day="03" Hour="15" Minute="21" Second="15" Sequence="0000000680" MAC="EF:F9:D9:A8:CD:B4">
<Flow Ch="1"><Value>4.50</Value><Unit>LPM</Unit></Flow>
<Pressure Ch="1"><Value>354</Value><Unit>mmHg</Unit></Pressure>
<Pressure Ch="2"><Value>700</Value><Unit>mmHg</Unit></Pressure>
<Temperature Ch="1"><Value>25.6</Value><Unit>deg C</Unit></Temperature>
<Temperature Ch="2"><Value>4.0</Value><Unit>deg C</Unit></Temperature>
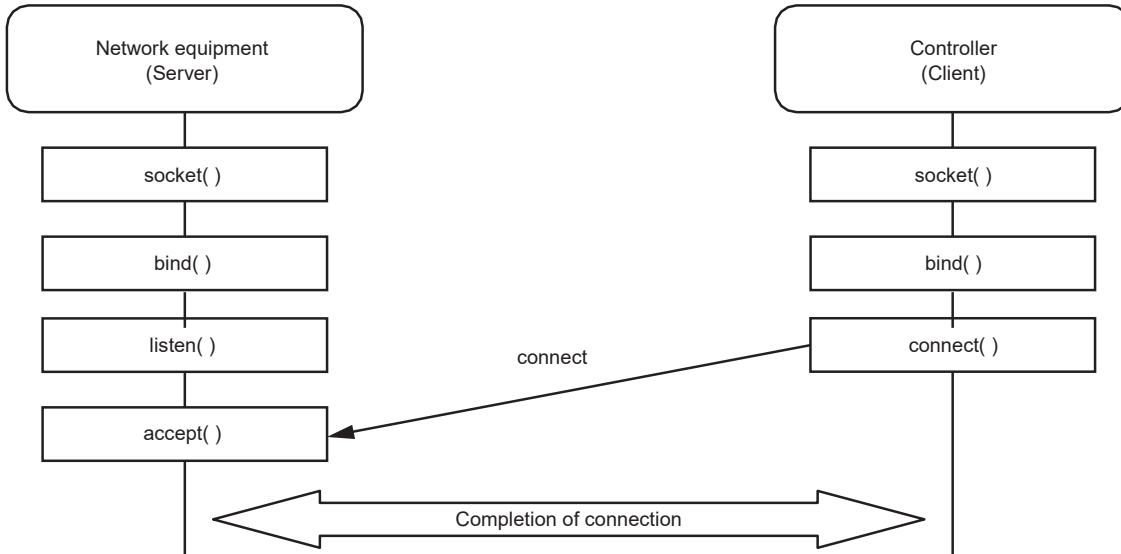<Speed Ch="1"><Value>925</Value><Unit>RPM</Unit></Speed>
<Alarm><Value>0x000000000020000112040003E0000000001000000000000</Value></Alarm>
</NEO_DATA>

Refer to the table below for an explanation of each item.

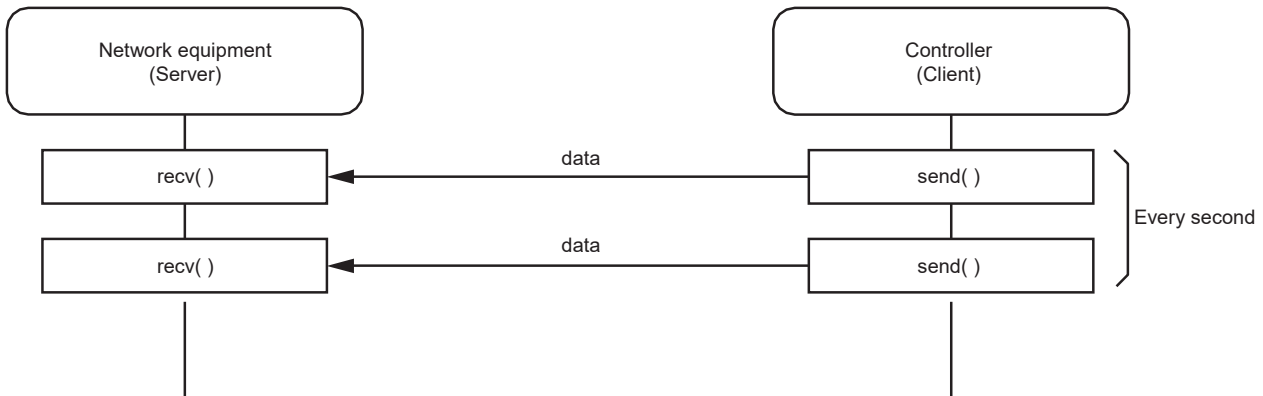| Item	Overview	Description	Remark
Data start	Indicates the data start.	Year/month/ day/hour/ minute/second, sequence number, MAC address	AD four digits for year, 01 to 12 for month, 01 to 31 for day, 00 to 23: 24-hour clock for hours, 00 to 59 for minutes, 00 to 59 for seconds, and a built-in clock of the Controller is used as a calendar. The sequence number is cycled by taking numerical numbers between 0000000000 to 4294967295, and 0 suppression is not performed. MAC addresses are characteristic numbers of the Controller.
Flow value	Indicates flow values.	Flow value, unit	The flow value is from -9.99 to 9.99 or NG, the last number 0 is not omitted, and when the flow is NG, an invalid value is indicated. The unit is LPM (L/min).
Pressure 1 ch	Indicates pressure value 1 ch.	Pressure value, unit	The pressure value is from -250 to 900 (mmHg), from -33.3 to 120.0 (kPa), or NG, and the value is zero-suppressed, and when NG, an invalid value is indicated. The unit is mmHg or kPa.
Pressure 2 ch	Indicates pressure value 2 ch.		
Temperature 1 ch	Indicates temperature value 1 ch.	Temperature value, unit	The temperature value is from 0.0 to 50.0 or NG, the value is zero-suppressed, the last number 0 is not omitted, and when the temperature value is NG, an invalid value is indicated. The unit is deg C.
Temperature 2 ch	Indicates temperature value 2 ch.		
Motor speed	Indicates motor speed.	Motor speed, unit	The motor speed is from -9999 to 9999 or NG, the value is zero-suppressed, and when the motor speed is NG, an invalid value is indicated.
Alarm	Indicates alarms.	Alarm status	Indicates an alarm occurrence status of 192 bits.
Data end	Indicates the data end.		

Specification of Network Communication (Sequence)

The Controller connects TCP connection to the port of the designated IP address and transmits data. Network equipment serves as the TCP Server and waits for the connection from the Controller.

The flow when the communication connection is started is shown below.

```
Network equipment                                    Controller
   (Server)                                           (Client)

  socket( )                                           socket( )

   bind( )                                             bind( )

  listen( )              connect                      connect( )

  accept( )  <─────────────────────────────

          <═════ Completion of connection ═════>
```

The Controller transmits data to the TCP connection. The Controller does not perform the delivery confirmation of the application level. Therefore, a response from network equipment is not needed. The Controller transmits data every second.

```
Network equipment                                    Controller
   (Server)                                           (Client)

   recv( )  <──────── data ────────              send( )
                                                                  } Every second
   recv( )  <──────── data ────────              send( )
```

The flow when the communication is disconnected is shown below.
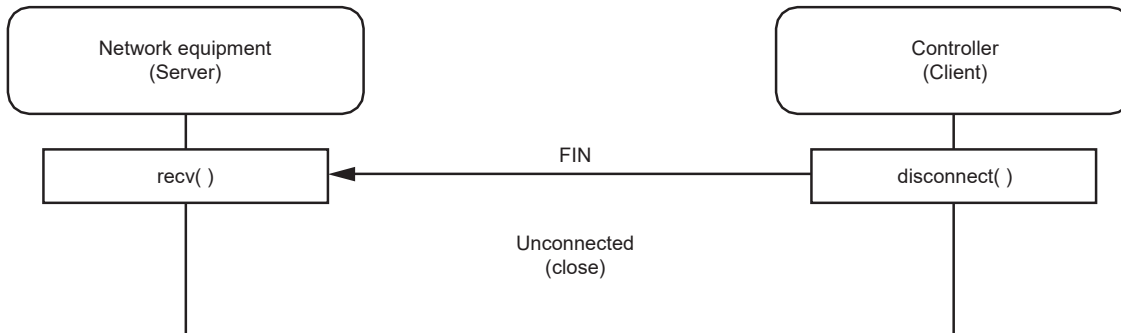
CDI Communication

The flow information can be transmitted to the CDI System 500.
Before the power is turned on, connect the CDI port of the Controller to the pump interface terminal of the CDI System 500 with the CDI Communication Cable, and turn the setting of the CDI communication function of the Controller on. For details about how to set, refer to "Setting the Communication with CDI" (page 116).

Note

• For details about how to use the CDI System 500, refer to the instructions for use of the CDI System 500.

Two Types of Setup modes

This system can set up various menus through two types of system setup.

User setup	The settings can be changed in accordance with the change of the patient's status and use conditions. The changes made are returned to the settings of the admin setup when the power is turned off. For details about how to set, refer to "User Setup" (pages 83 to 98).
Admin setup	Admin menu settings can be registered in accordance with hospital procedures and protocols. (The admin setting will be maintained even after the power is turned off.) Access to the admin setup is protected by passwords. For details about how to set, refer to "Admin Setup" (pages 99 to 119).

User Setup

With the user setup, the settings can be changed in accordance with the change of the patient's status and use conditions. Tap the icon of the menu you want to set, and then the Setup screen opens.
Check the corresponding item for the setup method of each menu.

Note

• The settings which were set in the user setup are returned to the settings of the admin setup when the power is turned off.
  To maintain altered settings even after turning the power off, make changes through the admin setup.

Setup Screen

Icon name	Function	Initial setting value	Reference page
Flow Alarm	Sets the threshold value of the Flow Alarm.	The admin setting set under "Flow Preset" in the admin setup.	page 84
Pressure Alarm	Sets the on/off status of the pressure measuring function, threshold value for the Pressure alarm and Pressure Alert for every channel.	The admin setting set under "Pressure Preset" of the admin setup.	page 85
Temperature Alarm	Sets the on/off status of the temperature measuring function and threshold value for the Temperature Alert for every channel.	The admin setting set under "Temperature Preset" of the admin setup.	page 88
Fast clamp	Sets the on/off status of the Fast Clamp.	The admin setting set under "Fast clamp" of the admin setup.	page 90
Air Bubble	Sets the on/off status of the air bubble detector function.	The admin setting set under "Air Bubble" of the admin setup.	page 90
Safety Connection	Sets up the behaviours responding to the Pressure Alarm (over pressure/low pressure), the Air Bubble Detected Alarm and the Back Flow Alarm.	The admin setting set under "Safety Connection" of the admin setup.	page 91

Icon name	Function	Initial setting value	Reference page
Alarm Setup List	Displays the settings of each menu by list.	The list of admin settings set under the each menu of the admin setup.	page 92
BSA	Inputs the Patient's height and weight to calculate the BSA value and perfusion index value.	Height: ---.- Weight: ---.-	page 93
Count Down	Sets the count down timer.	0:00:00	page 94
History	Displays the trend chart and the event list. The history can be exported to a USB memory drive as log data.		page 95
Admin Setup	Opens the admin setup menu.		page 99

Setting Flow Alarms

The threshold value (setup range: 0.0 to 9.9 LPM (L/min)) of the Flow Alarm can be set.

1. Tap the Flow Alarm icon. (Figure 3-1)

The Flow Alarm screen opens.

Figure 3-1

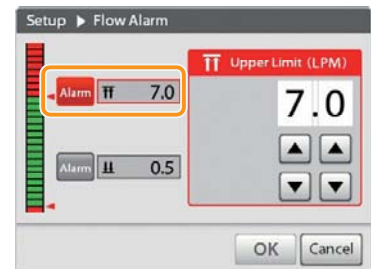**2. Confirm that [Alarm] of the upper limit is selected. (Figure 3-2)**

Figure 3-2

3. Tap ▲ or ▼ to input the upper limit value you want to set. (Figure 3-3)

" ◄ (red)" indicates the threshold value of the High Flow Alarm in accordance with an input flow value.

Figure 3-3

4.   **Tap [Alarm] of the lower limit. (Figure 3-4)**

Figure 3-4

5.   **Tap [▲] or [▼] to input the lower limit value you want to set. (Figure 3-5)**

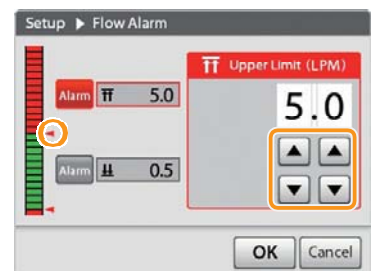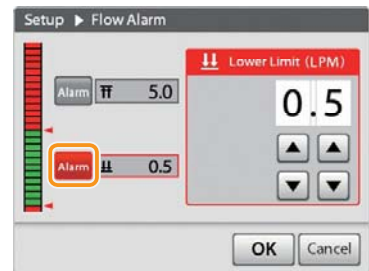"◀ (red)" indicates the threshold value of the Low Flow Alarm in accordance with an input flow value.
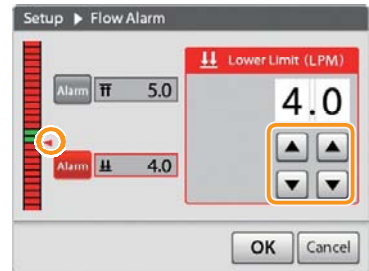
Figure 3-5

6.   **Tap [OK] to complete the setting. (Figure 3-6)**
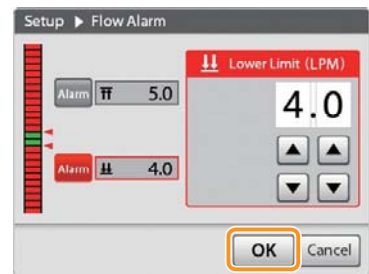
Figure 3-6

Notes

• If you do not tap [OK], the changes to the setting will not take effect.
• The Low Flow Alarm is issued when flow has fallen below the set threshold value. When the lower limit value is set at 0.0 LPM (L/min) and the flow is 0.00 LPM (L/min), the Low Flow Alarm is not issued.

Setting Pressure Measuring Function

The following settings are available:
• The on/off status of the pressure measuring function
• The threshold values of Pressure Alarm and Pressure Alert (setup range: -250 to 900 mmHg [-33.3 to 120.0 kPa])

1.   **Tap the Pressure Alarm icon. (Figure 3-7)**

The Pressure Alarm screen opens.

Figure 3-7

2. Tap the channel (P1 or P2) you want to set. (Figure 3-8)

The following figures show the example when [P1] is selected.
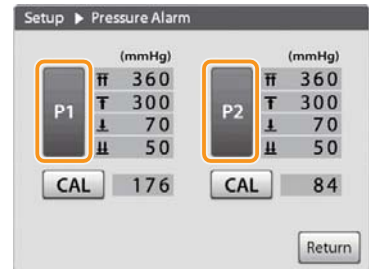
Figure 3-8

<<Setting the on/off status of the pressure measuring function>>

3. Tap [On] or [Off]. (Figure 3-9)

When turning it off, tap [OK] to complete the setting.

Figure 3-9

<<Setting the threshold value of the Pressure Alarm>>

4. Confirm that [Alarm] of the upper limit is selected. (Figure 3-10)

Figure 3-10

5. Tap ▲ or ▼ to input the upper limit value you want to set. (Figure 3-11)

" ◀ (red)" indicates the threshold value of the Over Pressure Alarm in accordance with an input pressure value.

Figure 3-11

6. Tap [Alarm] of the lower limit. (Figure 3-12)

Figure 3-12

7. **Tap ▲ or ▼ to input the lower limit value you want to set. (Figure 3-13)**

    " ◄ (red)" indicates the threshold value of the Low Pressure Alarm in accordance with an input pressure value.
    Proceed to "Setting the threshold value of the Pressure Alert".
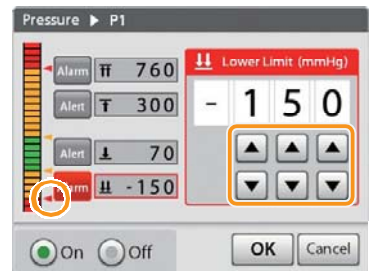
Figure 3-13

<<Setting the threshold value of the Pressure Alert>>

8. **Tap [Alert] of the upper limit. (Figure 3-14)**

Figure 3-14

9. **Tap ▲ or ▼ to input the upper limit value you want to set. (Figure 3-15)**
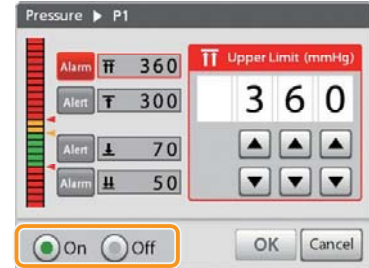
    " ◄ (yellow)" indicates the threshold value of the Over Pressure Alert in accordance with an input pressure value.

Figure 3-15

10. **Tap [Alert] of the lower limit. (Figure 3-16)**

Figure 3-16

11. **Tap ▲ or ▼ to input the lower limit value you want to set. (Figure 3-17)**

    " ◄ (yellow)" indicates the threshold value of the Low Pressure Alert in accordance with an input pressure value.

Figure 3-17

12. Tap [OK] to complete the setting. (Figure 3-18)

Figure 3-18

Notes

• If you do not tap [OK], the changes to the setting will not take effect.
• The lower/upper limits of the alarm cannot be input unless the values are higher/lower than those of the alert. When the values cannot be input, check that the values of the lower/upper limits of the alarm are correct in relation to the lower/upper limits of the alert.

Setting Temperature Measuring Function

The following settings are available:
• The on/off status of the temperature measuring function
• The threshold value of the Temperature Alert (setup range: 0.0 to 50.0°C)

1. Tap the Temperature Alarm icon. (Figure 3-19)

The Temperature Alarm screen opens.

Figure 3-19

2. Tap the channel ([T1] or [T2]) you want to set. (Figure 3-20)

The following figures show the example when [T1] is selected.
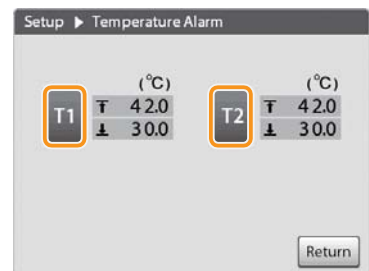
Figure 3-20

<<Setting the on/off status of the temperature measuring function>>

3. Tap [On] or [Off]. (Figure 3-21)

When turning it off, tap [OK] to complete the setting.

Figure 3-21

<<Setting the threshold value of the Temperature Alert>>

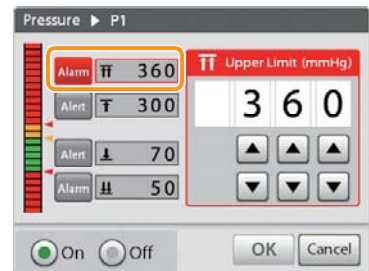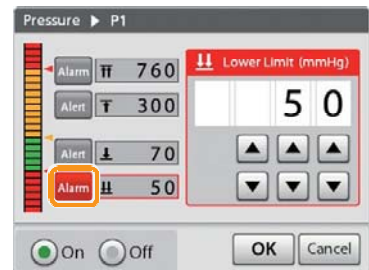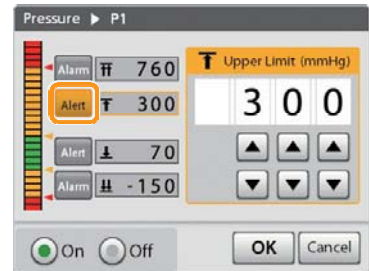4. **Confirm that [Alert] of the upper limit is selected. (Figure 3-22)**
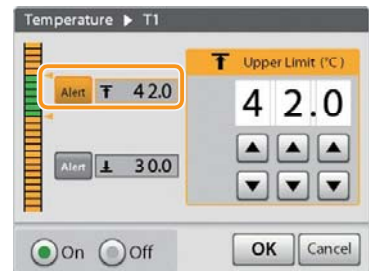
Figure 3-22

5. **Tap ▲ or ▼ to input the upper limit value you want to set. (Figure 3-23)**

   " (yellow)" indicates the threshold value of the High Temperature Alert in accordance with an input temperature.
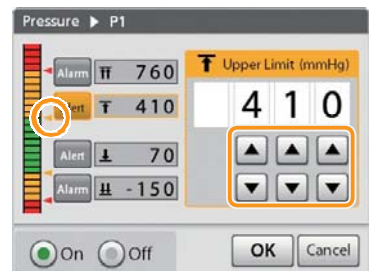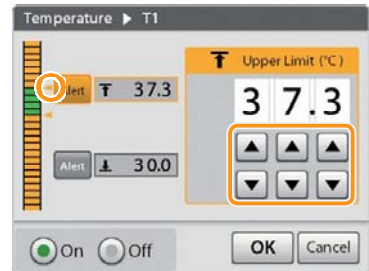
Figure 3-23

6. **Tap [Alert] of the lower limit. (Figure 3-24)**
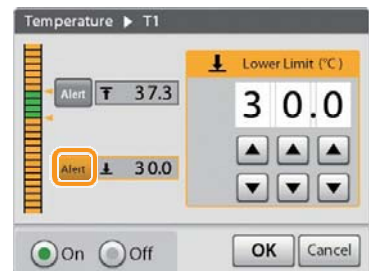
Figure 3-24

7. **Tap ▲ or ▼ to input the lower limit value you want to set. (Figure 3-25)**

   " (yellow)" indicates the threshold value of the Low Temperature Alert in accordance with an input temperature.
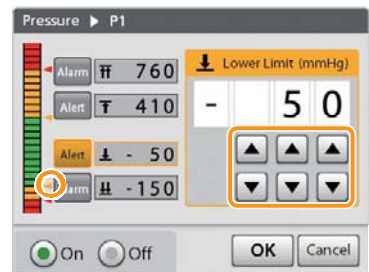
Figure 3-25

8. **Tap [OK] to complete the setting. (Figure 3-26)**
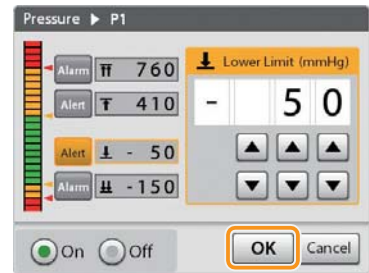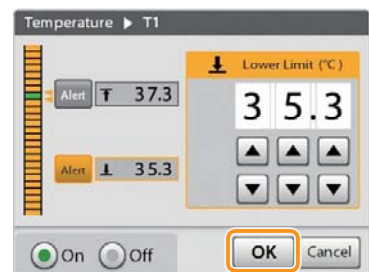
Figure 3-26

Note
• If you do not tap [OK], the changes to the setting will not take effect.

Setting the Fast Clamp

The on/off status of the fast clamp function can be set.

1.   Tap the Fast clamp icon. (Figure 3-27)

The Fast clamp screen opens.

Figure 3-27

2.   After tapping [On] or [Off], tap [OK] to complete the setting. (Figure 3-28)
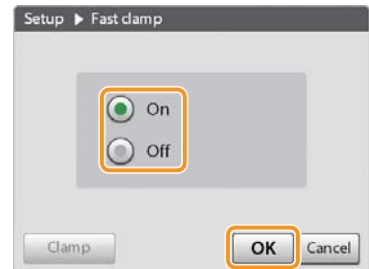
Figure 3-28

Note

• If you do not tap [OK], the changes to the setting will not take effect.

<Indication of the clamp status icon>
The icon indication changes in accordance with the status of the Fast Clamp.
For details, refer to "LCD Touch Panel Display (When Operating Normally)" (page 9).

Setting the Air Bubble Detector Function

The on/off status of the air bubble detector function can be set.

1.   Tap the Air Bubble icon. (Figure 3-29)

The Air Bubble screen opens.

Figure 3-29

2.   After tapping [On] or [Off], tap [OK] to complete the setting. (Figure 3-30)
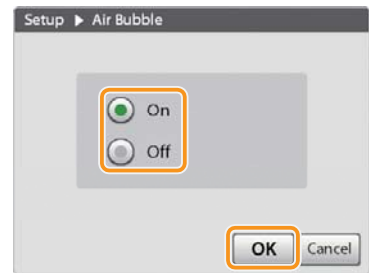
Figure 3-30

Notes

• If you do not tap [OK], the changes to the setting will not take effect.
• The air bubble detection sensitivity can be adjusted only through the admin setup.

<Indication of the ABD status icon>
The icon indication changes in accordance with the status of the air bubble detector function.
For details, refer to "LCD Touch Panel Display (When Operating Normally)" (page 9).

Setting the Safety Connection

Response behaviours (Message Only/Pump Coast/Clamp+Pump stop) to the Over/Low Pressure Alarm, Air Bubble Detected Alarm and Back Flow Alarm can be set.

1.   Tap the Safety Connection icon. (Figure 3-31)

The Safety Connection screen opens.

Figure 3-31

2.   Tap the response behaviour you want to set for each alarm. (Figure 3-32)

[Message Only]:
    Displays a message when the alarm is detected.
[Pump Coast]:
    Displays a message when the alarm is detected and changes the motor speed to the coast speed.
[Clamp+Pump stop]:
    Displays a message when the alarm is detected, closes the extracorporeal circulation circuit line with the Fast Clamp and stops the Drive Motor.
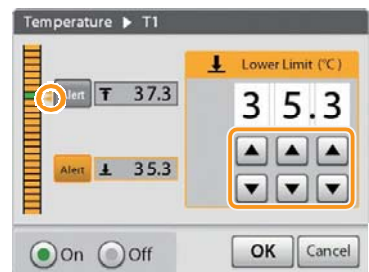

Figure 3-32

3.   Tap [OK] to complete the setting. (Figure 3-33)

Figure 3-33

Notes

• If you do not tap [OK], the changes to the setting will not take effect.
• For details about the safety connection, refer to "Safety Connection" (page 65).

Alarm Setup List

The on/off status of various functions, alarm or alert threshold values and the settings of the safety connections can be confirmed in the list. Also, all of the settings can be reset to the admin setting.

1. Tap the Alarm Setup List icon. (Figure 3-34)

The Alarm Setup List screen opens.

Figure 3-34

<<To confirm the alarm settings>>

2. After confirming the settings, tap [Return]. (Figure 3-35)

Figure 3-35

<<To reset to the admin setting>>

2. Tap [Admin Setting]. (Figure 3-36)
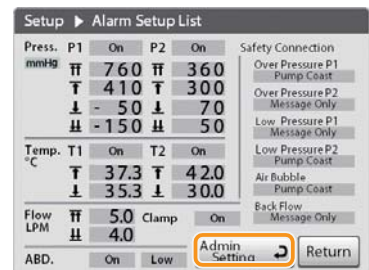
Figure 3-36

3. Tap [OK]. (Figure 3-37)

The settings displayed in the screen of the Alarm Setup List are reset to the admin setting.
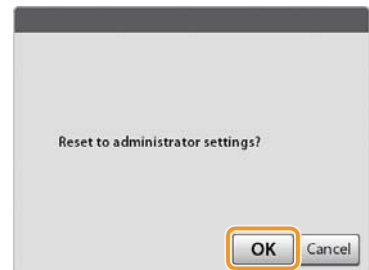
Figure 3-37

Setting BSA

When you input the patient's height and weight, you can check the calculated BSA (body surface area) value.
Subsequently, the perfusion index is displayed in the perfusion index indicator on the LCD touch panel display. For details about the perfusion index indicator, refer to "LCD Touch Panel Display (When Operating Normally)" (page 9).

1. **Tap the BSA icon. (Figure 3-38)**

    The BSA screen opens.

    Figure 3-38

2. **Tap ▲ or ▼ to input height and weight values. (Figure 3-39)**

    The height and weight can be set within the ranges below.
    Height: 40.0 to 250.0 cm
    Weight: 1.0 to 300.0 kg

    Figure 3-39

3. **Tap [Dubois] or [Boyd] for the calculation method of BSA. (Figure 3-40)**

    The BSA value is displayed in accordance with the selected calculation method.

    Figure 3-40

4. **Tap [OK] to complete the setting. (Figure 3-41)**

    Figure 3-41

Note

• If you do not tap [OK], the changes to the setting will not take effect.

Setting Count Down

A count down timer can be set. When the set time has passed, you will be informed by sound and screen indication.
The maximum duration that can be set is 9 hours, 59 minutes and 59 seconds.
Count Down screen

Number	Icon	Description
a	Start ⇕ Stop	Count down starts. When count down starts, [Start] changes to [Stop]. Count down stops. When count down stops, [Stop] changes to [Start].
b	Reset	The timer returns to 0 hours 00 minutes 00 seconds.
c	Restart	While counting down : Returns to the set time of the timer and restarts the count down. While stopping count down: Returns to the set time of the timer.

◆ **Starting/Ending the Count Down Timer**

1.　**Tap the Count Down icon. (Figure 3-42)**

　　The Count Down screen opens.

Figure 3-42

2.　**Tap ▲ or ▼ to input the time you want to set. (Figure 3-43)**

Figure 3-43

3.   Tap [Start]. (Figure 3-44)

Count down starts.
When count down starts, [Start] changes to [Stop].

Note

• The count down continues even if another screen is opened.

Figure 3-44

4.   When the count down is finished, "Count-down Ended" is displayed on the message area with a sound. (Figure 3-45)
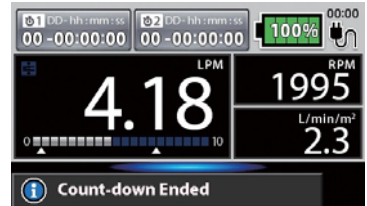
Figure 3-45

5.   Tap "Count-down Ended". (Figure 3-46)

Note

• If the count down screen is displayed when the count down ends, the screen of step 6 is displayed.
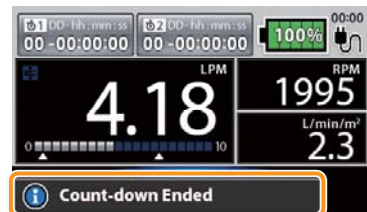
Figure 3-46

6.   When the screen to confirm timer end is displayed, tap [OK] or [Cancel]. (Figure 3-47)

[OK]:   Returns the timer to the set time and restarts the count down.
[Cancel]: Ends the use of the count down timer.

Tap [OK] or [Cancel] to stop the sound.
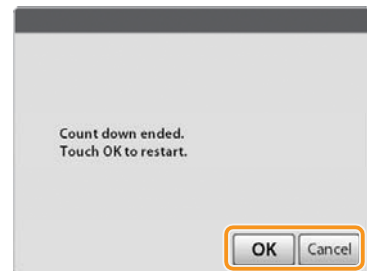
Figure 3-47

History

Data (motor speed, flow, pressure, temperature) and events are recorded. (History function)

◆ Trend chart
Motor speed, flow, and pressure which have been recorded since power was turned on are displayed in the chart.

1.   Select a time axis. (Figure 3-48)

[24h]: Displays the data of the last 24 hours.
[12h]: Displays the data of the last 12 hours.
[3h]: Displays the data of the last 3 hours.
       Tap ◄ or ► to adjust the time frame by one-hour intervals. It can retrieve up to the previous twelve hours.
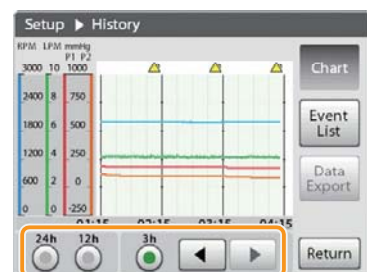
Figure 3-48

◆ Event List

Up to 256 alarms and alerts issued after the power was turned on are displayed in the list.

1. Tap [Event List]. (Figure 3-49)

Figure 3-49

2. Up to five events are displayed per page.

To scroll, tap ▲ or ▼.
When jump to the previous/next page, tap ⬆ or ⬇. (Figure 3-50)

Figure 3-50

◆ Output data to USB memory

The information recorded in the history can be exported as a log file.
When exporting log data, insert a USB memory drive into the USB port on the back panel beforehand.
Data can be exported only when the Drive Motor is stopped.

1. Tap [Data Export]. (Figure 3-51)

Figure 3-51

2. Up to five pieces of history are displayed per page.

To scroll, tap ▲ or ▼.
When jump to the previous/next page, tap ⬆ or ⬇. (Figure 3-52)
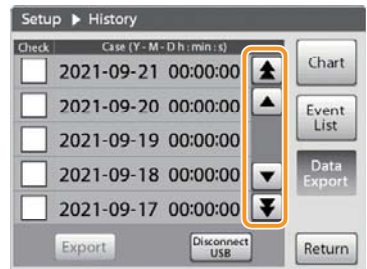
Figure 3-52

3. **Tap the check box of the log file to export to insert a check mark. (Figure 3-53)**

Figure 3-53

4. **Tap [Export]. (Figure 3-54)**

   The mounting process of the USB memory drive is performed and the log data export process to the USB memory drive is started.
   The export status to the USB memory drive is displayed by percentage. (Figure 3-55)
   When the data export finishes, the screen will display a log output complete message. (Figure 3-56)

Figure 3-54

5. **Tap [OK]. (Figure 3-56)**

Figure 3-56

6. **Tap [Disconnect USB]. (Figure 3-57)**

   [Disconnect USB] is turned off, and the USB memory drive can be removed.

Figure 3-57

Notes

- Use USB memory drives formatted in the form of FAT or FAT 32.
- Do not connect equipment other than USB memory drives to the USB port.
- When [Cancel] is tapped while exporting log data, the export cancels.
- While exporting log data, the Drive Motor cannot be used.
- While exporting log data, a new log cannot be recorded in the history.
- When a USB memory drive is removed or the power is turned off while exporting, the USB memory drive may be damaged.
- The export status of the log may remain at 0% for several tens of minutes.

Log data
- Log data collected from power on till power off is counted as a single case.
- In the system, the log data of each case is stored separated by measured data such as flow values and the event data such as alarms/alerts.
- The maximum number of log data stored in the system is 50 cases, 600,000 data points or 120,000 events. When any of these reaches the upper limit, the oldest log is overwritten with the newest log.

Logs of measured data
- Logs are usually stored each minute. However, logs are stored each second in the following cases:
  1) Alarm status
  2) When the flow value, pressure value and temperature value are close to the threshold values
  3) While operating the motor speed knob

Note

- If the system is stored with the power on, the log data will reach the maximum storage number, and the oldest data will be deleted and overwritten.

Logs of event data
- Stored when the alarm is issued and cancelled.

Admin Setup

Admin menu settings can be registered in accordance with hospital procedures and protocols. (The admin setting will be maintained even after the power is turned off.) Access to the admin setup is protected by passwords.

Opening the Admin Setup

1.   **Tap the setup icon on the main screen. (Figure 3-58)**

Figure 3-58

2.   **Tap the Admin Setup icon. (Figure 3-59)**

Figure 3-59

3.   **Tap ▲ or ▼ to input the password. (Figure 3-60)**

The default setting is 0000.

Figure 3-60

4.   Tap [OK]. (Figure 3-61)

Figure 3-61

Notes

• When the input password is wrong, "Authentication failed." is displayed. Tap [Return], and restart from step 2.
• When using for the first time, changing the password is recommended.

◆ Changing the password

1.   Perform steps 1 to 3 of "Opening the Admin Setup" (page 99).

2.   Tap the check box of [Change Password] to insert a check mark, and tap [OK]. (Figure 3-62)

Notes

• When the input password is wrong, "Authentication failed." is displayed. Tap [Return], and restart from step 2 of "Opening the Admin Setup" (page 99).
• If you have forgotten your password that you set, ask Terumo's service representative for initialization of password.

Figure 3-62

3.   Tap ▲ or ▼ to input a new password you want to set, and tap [OK]. (Figure 3-63)
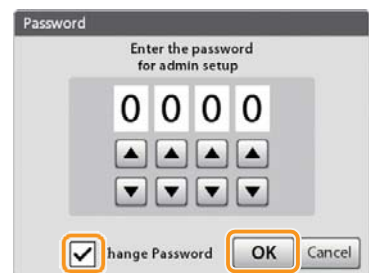
Figure 3-63

4.   Input the password again, and tap [OK]. (Figure 3-64)

Figure 3-64

5. Tap [OK] after confirming the message displayed. (Figure 3-65)

The password is changed.

The password has been changed.

OK
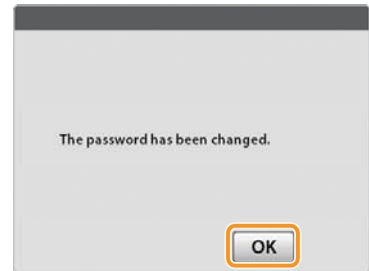
Figure 3-65

Admin Setup Screen

Tap the icon of the menu you want to set, and then the Admin Setup screen opens.
Check the corresponding item for the setup method of each menu.

Icon name	Function	Factory setting	Remark	Reference page
Flow Preset	Sets the admin setting of the Flow Alarm threshold.	Alarm upper limit: 7.0 LPM (L/min) Alarm lower limit: 0.5 LPM (L/min)	The setting will take effect after restarting.*	page 102
Pressure Preset	Sets the on/off status of the pressure measuring function and the admin setting of the threshold for the Pressure alarm and Pressure Alert for every channel. The display unit can also be set.	Alarm upper limit: 360 mmHg Alert upper limit: 300 mmHg Alert lower limit: 70 mmHg Alarm lower limit: 50 mmHg	The setting will take effect after restarting.*	page 103
		On/Off: On		
		mmHg/kPa: mmHg	The setting will take effect instantly.	
Temperature Preset	Sets the on/off status of the temperature measuring function and the admin setting of the threshold value for the Temperature Alert for every channel.	Upper limit temperature: 42.0°C Lower limit temperature: 30.0°C	The setting will take effect after restarting.*	page 104
		On/Off: On		
Fast clamp	Sets the on/off status for the admin setting of the Fast Clamp.	On/Off: Off	The setting will take effect after restarting.*	page 104
Air Bubble	Sets the on/off status of the air bubble detector function and the admin setting of the detection sensitivity.	On/Off: On	The setting will take effect after restarting.*	page 104
		Detection sensitivity (High/ Medium/Low): Low	The setting will take effect instantly.	

Icon name	Function	Factory setting	Remark	Reference page
Safety Connection	Sets the admin setting of response behaviours when the Pressure Alarm, the Air Bubble Detected Alarm and the Back Flow Alarm are issued during circulation.	Over Pressure P1: Message Only Over Pressure P2: Message Only Low Pressure P1: Message Only Low Pressure P2: Message Only Air Bubble: Message Only Back Flow: Message Only	The setting will take effect after restarting.*	page 105
Alarm Setup List	Displays the admin setting of each menu in a list.	The value set at each menu of the admin setup is displayed in a list.	The setting will take effect after restarting.*	page 105
Auto-Priming	Sets the on time/off time and on time motor speed during auto-priming.	On time: 5.0 s Off time: 1.0 s Motor Speed: 3000 RPM	The setting will take effect instantly.	page 106
Coast Speed	Sets the coast speed.	Coast speed: 1250 RPM	The setting will take effect instantly.	page 108
Date & Time	Sets the date and time.	The date and time were set at the time of manufacture. (Japan time)	The setting will take effect instantly.	page 109
LAN	Sets the connection environment of the LAN.	PC/Server IP: 0.0.0.0 MAC: 0-0-0-0-0-0 Port: 0 DHCP: On Controller IP: 0.0.0.0 Subnet Mask: 0.0.0.0 On/Off: Off	The setting will take effect instantly.	page 110
CDI	Sets the on/off status of the communication with CDI.	On/Off: Off	The setting will take effect instantly.	page 116
Language	Changes the displayed language.	Language (English/　　): English	The setting will take effect after restarting.	page 118
Volume Brightness	Adjusts the alarm volume and brightness on the LCD touch panel display.	Volume (Large/Middle/Small): Large Brightness (Light/Moderate/Dark): Light	The setting will take effect instantly.	page 118

* The setting can also take effect through the method described in "Alarm Setup List" (page 92).

Flow Preset

The admin setting of the threshold value (setup range: 0.0 to 9.9 LPM (L/min)) when the Flow Alarm is issued can be set.
For details about how to set, refer to "Setting Flow Alarms" (page 84).

Note

• The changes to the setting will take effect after restarting.

Pressure Preset

The following admin setup values can be set:
• The on/off status of the pressure measuring function
• The threshold of the Pressure Alarm and the Pressure Alert (setup range: -250 to 900 mmHg [-33.3 to 120.0kPa])
• Pressure indication unit

For details about how to set the pressure measuring function on/off and the threshold values of the Pressure Alarm and the Pressure Alert, refer to "Setting Pressure Measuring Function" (page 85).
This section describes the setup procedures for the display unit of the pressure.

Note
• The pressure measuring function turns on/off, and the threshold values of the Pressure Alarm and the Pressure Alert will take effect after restarting. The display unit of the pressure will take effect instantly.

1. **Tap the Pressure Preset icon. (Figure 3-66)**

   The Pressure Preset screen opens.

Figure 3-66

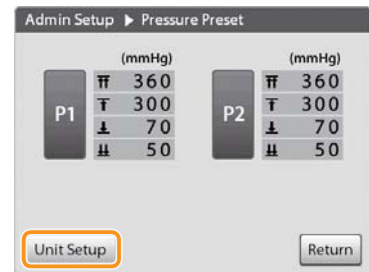2. **Tap [Unit Setup]. (Figure 3-67)**

Figure 3-67

3. **Tap the unit to be used in the unit indication, and tap [OK]. (Figure 3-68)**

Figure 3-68

Note
• If you do not tap [OK], the changes to the setting will not take effect.

Temperature Preset

The following admin setup values can be set:
• The on/off status of the temperature measuring function
• Threshold value of the Pressure Alert (setup range: 0.0 to 50.0°C)

For details about how to set, refer to "Setting Temperature Measuring Function" (page 88).

Note

• The changes to the setting will take effect after restarting.

Setting the Fast Clamp

The admin setup value for the fast clamp function can be set on/off.

For details about how to set, refer to "Setting the Fast Clamp" (page 90).

Note

• The changes to the setting will take effect after restarting.

Setting the Air Bubble Detector Function

The following admin setup values can be set:
• The on/off status of the air bubble detector function
•   Air bubble detection sensitivity (High/Medium/Low)

For details about how to set the preset value of the air bubble detector function, refer to "Setting the Air Bubble Detector Function" (page 90).
This section describes the setup procedures for sensitivity of the air bubble detector function.

Note

• The on/off setting for the air bubble detector function will take effect after restarting. The sensitivity setting will take effect instantly.

1. **Tap the Air Bubble icon. (Figure 3-69)**

   The Air Bubble screen opens.

Figure 3-69

2. **Tap the Sensitivity you want to set. (Figure 3-70)**

   [High]:   Air bubbles larger than 0.05 cm^3 are detected (at flow of 4.20 LPM (L/min) or less)
   [Medium]: Air bubbles larger than 0.2 cm^3 are detected (at flow of 7.00 LPM (L/min) or less)
   [Low]:   Air bubbles larger than 0.5 cm^3 are detected (at flow of 7.00 LPM (L/min) or less)

Figure 3-70

3. **Tap [OK] to complete the setting. (Figure 3-71)**
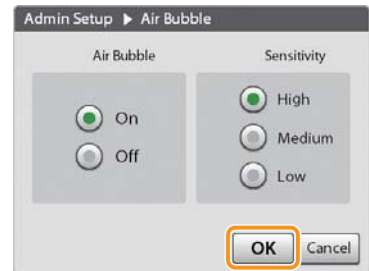
Figure 3-71

Note
• If you do not tap [OK], the changes to the setting will not take effect.

Setting the Safety Connection

The admin setup of response behaviours (Message Only/Pump Coast/Clamp+Pump stop) for the Pressure Alarm, the Air Bubble Detected Alarm and the Back Flow Alarm can be set up.

For details about how to set, refer to "Setting the Safety Connection" (page 91).

Note
• The changes to the setting will take effect after restarting.

Alarm Setup List

The on/off status of various functions, alarm or alert threshold values and the settings of the safety connections can be confirmed in the list. Also, all admin setup values can be reset to the factory settings as follows.
For details about how to confirm the settings using the list, refer to "Alarm Setup List" (page 92).
This section describes the procedures for returning all the admin setup values to the factory settings.

◆ **Resetting to the factory settings**

1. **Tap [Setup for Shipment] on the Alarm Setup List screen. (Figure 3-72)**

Figure 3-72

2. **Tap [OK]. (Figure 3-73)**

The settings displayed in the Alarm Setup List screen will be reset to the factory settings.

Figure 3-73

Setting Auto-priming

The following values can be set:
• On time and off time (setup range: 0.5 to 10.0 s)
• Motor speed (setup range: 1000 to 3000 RPM)

◆ Setting Time

1. **Tap the Auto-Priming icon. (Figure 3-74)**

   The Auto-Priming screen opens.

   Figure 3-74

2. **Tap [Time Setup]. (Figure 3-75)**
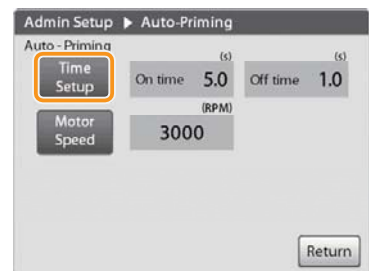
   Figure 3-75

3. **Tap ▲ or ▼, and input the time for "On (s)" and "Off (s)" you want to set. (Figure 3-76)**

   Figure 3-76

4. **Tap [OK] to complete the setting. (Figure 3-77)**
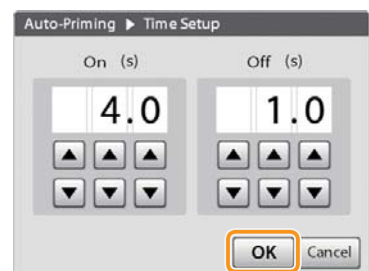
   Figure 3-77

Note

• If you do not tap [OK], the changes to the setting will not take effect.

◆ Setting the motor speed

1.   Tap the Auto-Priming icon. (Figure 3-78)

> The Auto-Priming screen opens.

Figure 3-78

2.   Tap [Motor Speed]. (Figure 3-79)
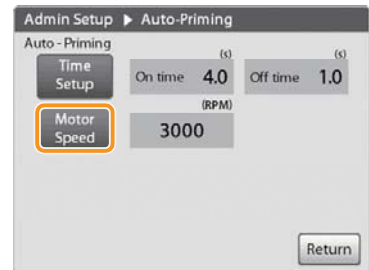
Figure 3-79

3.   Tap ▲ or ▼ to input the motor speed you want to set. (Figure 3-80)
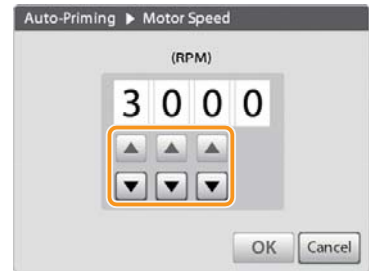
Figure 3-80

4.   Tap [OK] to complete the setting. (Figure 3-81)
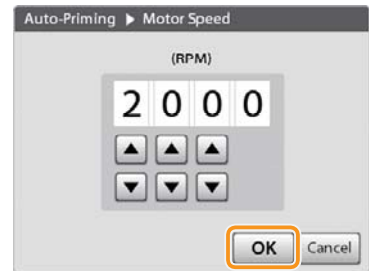
Figure 3-81

| Note |

• If you do not tap [OK], the changes to the setting will not take effect.

Setting the Coast Speed

The coast speed (the minimum motor speed which does not cause back flow, setup range: 500 to 2000 RPM) can be set.

1. **Tap the Coast Speed icon. (Figure 3-82)**

    The Coast Speed screen opens.

Figure 3-82

2. **Tap ▲ or ▼ to input coast speed you want to set. (Figure 3-83)**

Figure 3-83

3. **Tap [OK] to complete the setting. (Figure 3-84)**

Figure 3-84

Notes

• If you do not tap [OK], the changes to the setting will not take effect.
• The indicated value of actual motor speed may differ from the coast speed setting due to the circulation conditions, etc. of the blood circuit.

Setting the Date and Time

The date and time can be set.

1. **Tap the Date & Time icon. (Figure 3-85)**

   The Date & Time screen opens.

   Figure 3-85

2. **Tap the item you want to set. (Figure 3-86)**

   The following screen examples show when [Year] is selected.

   Figure 3-86

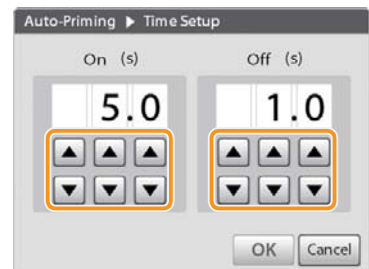3. **Tap [▲] or [▼] to input the setting value you want to set. (Figure 3-87)**

   Figure 3-87

4. **Tap [OK] to complete the setting. (Figure 3-88)**

   Figure 3-88

Notes

• If you do not tap [OK], the changes to the setting will not take effect.
• The date and time cannot be set while the motor is running.
• Set the date and time before using the system for the first case in order to properly record history.
• The clock accuracy is within ±5 seconds per day (at 25 °C).
• While setting the date and time, the Drive Motor cannot be used.
• If the date and time are set, the trend chart and the event list will be reset to the start of the case, but the recorded history data until the date and time change will be stored in the log.

Setting LAN

The following values can be set:
• LAN connection environment
• The on/off status of LAN communication

◆ Setting the IP address of the PC/server

1.   Tap the LAN icon. (Figure 3-89)

   The LAN screen opens.

Figure 3-89

2.   Tap [IP] of [PC/Server]. (Figure 3-90)

   The IP (PC/Server) screen opens.

Figure 3-90

3.   Tap the button of the address value you want to input. (Figure 3-91)

   The following screen examples show when the top button is selected.

Figure 3-91

4.   Tap ▲ or ▼ to input the IP address of the destination PC/server you want to set. (Figure 3-92)

   The input range is 0 to 255.

Figure 3-92

5. **Input the values into all of the boxes with the same operation as in steps 3 and 4. (Figure 3-93)**

Figure 3-93

6. **Tap [OK] to complete the setting. (Figure 3-94)**

    Proceed to "Setting the MAC Address".

Figure 3-94

Note

• If you do not tap [OK], the changes to the setting will not take effect.

◆ Setting the MAC Address

1. **Tap [MAC] of [PC/Server]. (Figure 3-95)**

    The MAC screen opens.

Figure 3-95

2. **Tap the button of the address value you want to input. (Figure 3-96)**

    The following screen examples show when the top button is selected.

Figure 3-96

3. **Tap ▲ or ▼ to input the MAC address of the destination PC/server you want to set. (Figure 3-97)**

   The input range is 00 to FF.

Figure 3-97

4. **Input the values into all of the boxes with the same operation as in steps 2 and 3. (Figure 3-98)**
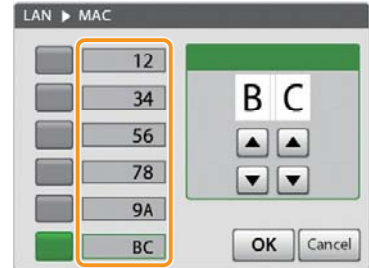
Figure 3-98

5. **Tap [OK] to complete the setting. (Figure 3-99)**

   Proceed to "Setting the Communication Port".

Figure 3-99

| Note |

• If you do not tap [OK], the changes to the setting will not take effect.

◆ Setting the Communication Port

1. **Tap [Port] of [PC/Server]. (Figure 3-100)**

   The Port screen opens.
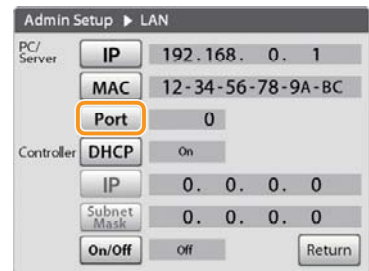
Figure 3-100

2. **Tap ▲ or ▼ to input the communication port of the destination PC/server you want to set. (Figure 3-101)**

The input range is 0 to 65535.
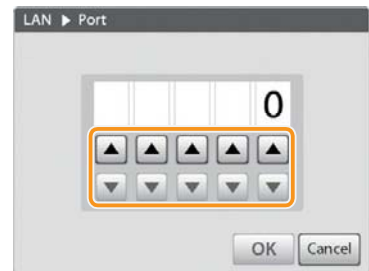
Figure 3-101

3. **Tap [OK] to complete the setting. (Figure 3-102)**

Proceed to "Setting the DHCP".
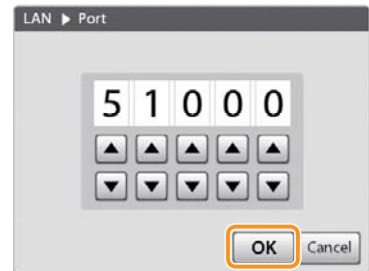
Figure 3-102

◆ Setting the DHCP

1. **Tap [DHCP] of [Controller]. (Figure 3-103)**

The DHCP screen opens.
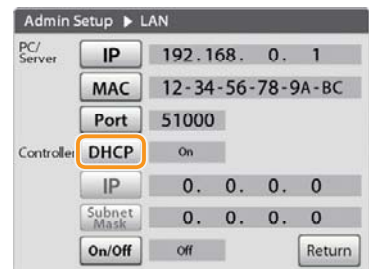
Figure 3-103

2. **Select [On] or [Off]. (Figure 3-104)**

The following screen examples show when [Off] is selected.
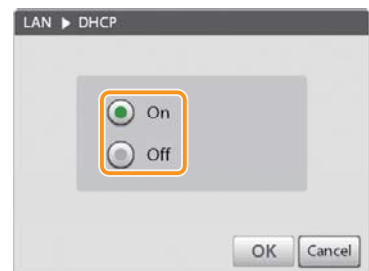
Figure 3-104

3. **Tap [OK] to complete the setting. (Figure 3-105)**

When the DHCP setting is set to [On], proceed to "Setting the On/Off status of the LAN communication" (page 116).
When set to [Off], proceed to "Setting the IP address of the Controller".

Figure 3-105

| Note |

• If you do not tap [OK], the changes to the setting will not take effect.

◆ Setting the IP address of the Controller

1.   Tap [IP] of [Controller]. (Figure 3-106)
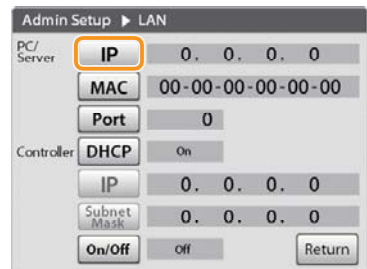
The IP (Controller) screen opens.
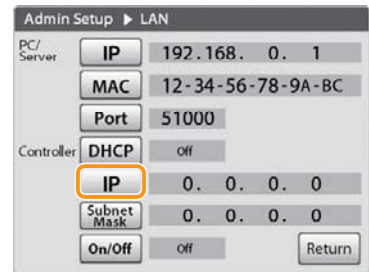
Figure 3-106

2.   Tap the button of the address value you want to input. (Figure 3-107)

The following screen examples show when the top button is selected.
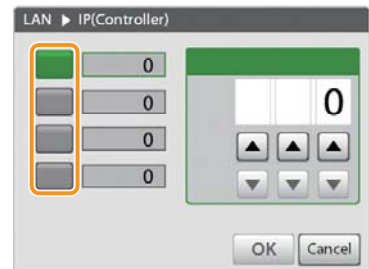
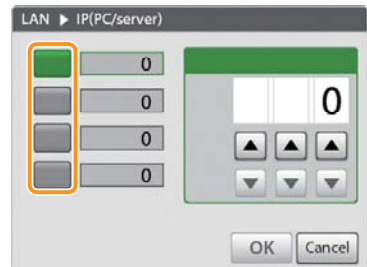Figure 3-107

3.   Tap ▲ or ▼ to input the IP address of the Controller you want to set. (Figure 3-108)
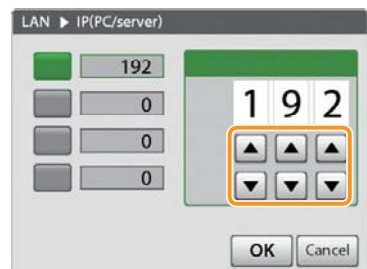
The input range is 0 to 255.

Figure 3-108

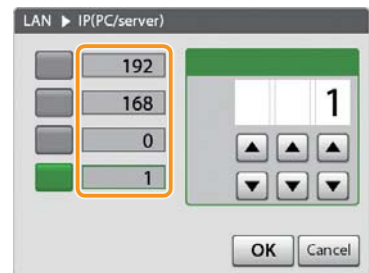**4.   Input the values into all of the boxes with the same operation as in steps 2 and 3. (Figure 3-109)**
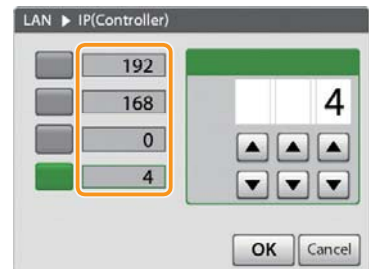
Figure 3-109

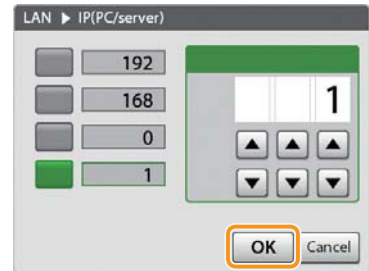**5.   Tap [OK] to complete the setting. (Figure 3-110)**

Proceed to "Setting the Subnet Mask".
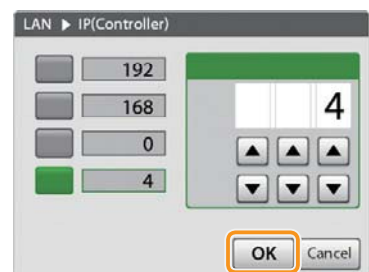
Figure 3-110

Note

• If you do not tap [OK], the changes to the setting will not take effect.

◆ **Setting the Subnet Mask**

1. **Tap [Subnet Mask] of [Controller]. (Figure 3-111)**
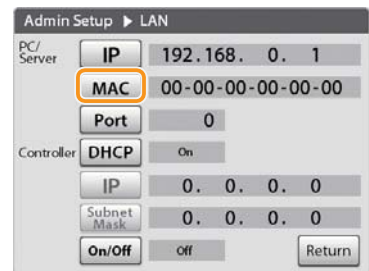
    The Subnet Mask screen opens.
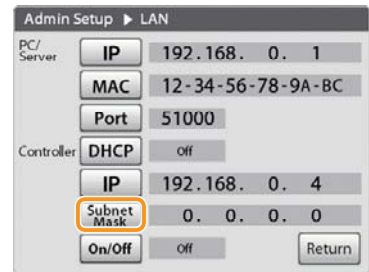
Figure 3-111

2. **Tap the button of the address value you want to input. (Figure 3-112)**

    The following screen examples show when the top button is selected.

Figure 3-112

3. **Tap [▲] or [▼] to input the subnet mask of the Controller you want to set. (Figure 3-113)**

    The input range is 0 to 255.
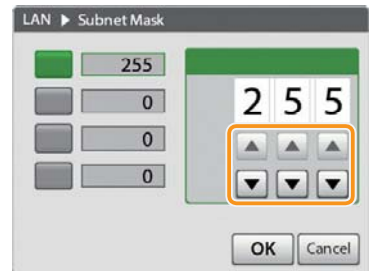
Figure 3-113

4. **Input the values into all of the boxes with the same operation as in steps 2 and 3. (Figure 3-114)**
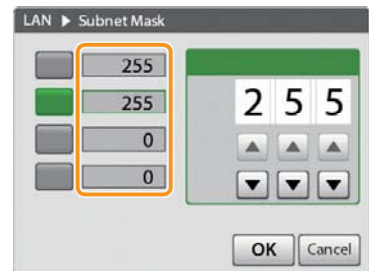
Figure 3-114

5. **Tap [OK] to complete the setting. (Figure 3-115)**

    Proceed to "Setting the On/Off status of the LAN communication".
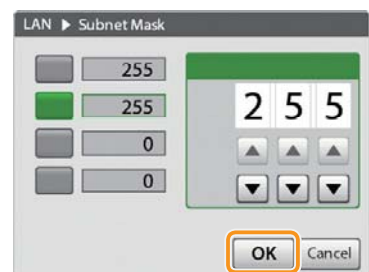
Figure 3-115

Note
• If you do not tap [OK], the changes to the setting will not take effect.

◆ Setting the On/Off status of the LAN communication

1.　Tap [On/Off] of [Controller]. (Figure 3-116)

The On/Off screen opens.
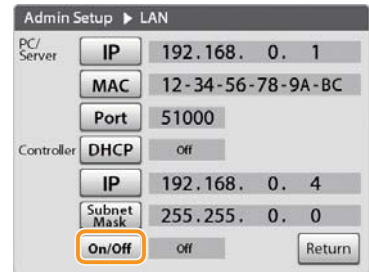
Figure 3-116

2.　Select [On] or [Off]. (Figure 3-117)

When [Off] is selected, the setting values thus far are maintained, but communication is not performed.
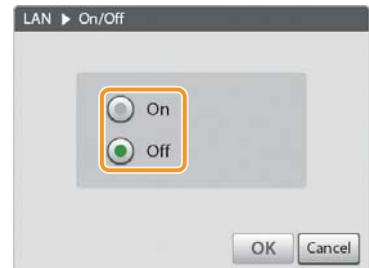
Figure 3-117

3.　Tap [OK] to complete the setting. (Figure 3-118)
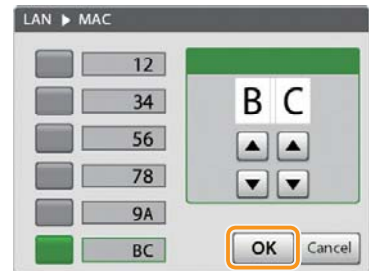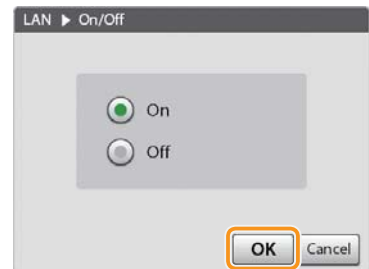

Figure 3-118

Note

• If you do not tap [OK], the changes to the setting will not take effect.

Setting the Communication with CDI

The on/off status of the CDI communication can be set.

1.　Tap the CDI icon. (Figure 3-119)

The CDI screen opens.

Figure 3-119

2. **Select [On] or [Off] of the CDI screen. (Figure 3-120)**

Figure 3-120

3. **Tap [OK] to complete the setting. (Figure 3-121)**

Figure 3-121

Note

• If you do not tap [OK], the changes to the setting will not take effect.

Setting the Language

The language to be displayed (English/日本語) can be set.

Note

• The changes to the setting will take effect after restarting.

1. **Tap the Language icon. (Figure 3-122)**

    The Language screen opens.

Figure 3-122

2. **Select the language to be displayed. (Figure 3-123)**

Figure 3-123

3. **When you tap [OK], a screen informing you to restart the system is displayed. After confirming the display contents, tap [OK]. (Figure 3-124)**

    The changes to the setting take effect, and the power is turned off automatically.
    After the power is turned off, turn the power on again.

Figure 3-124

Notes

• The display language cannot be changed while the Drive Motor is activated.
• If you do not tap [OK], the changes to the setting will not take effect.

Setting the Volume and the Brightness

The following values can be set:
• Speaker volume (Large/Middle/Small)
• Brightness of the LCD touch panel display (Light/Moderate/Dark)

1. **Tap the Volume Brightness icon. (Figure 3-125)**

    The Volume Brightness screen opens.

Figure 3-125

2. Select the volume level. (Figure 3-126)

Tap [Large], [Middle], or [Small].

Figure 3-126

3. Select the brightness level. (Figure 3-127)

Tap [Light], [Moderate], or [Dark].

Figure 3-127

4. Tap [OK] to complete the setting. (Figure 3-128)

Figure 3-128

Notes

• If you do not tap [OK], the changes to the setting will not take effect.
• The volume differs according to the volume setting and the priority of the alarm.
  The relationship of the volume setting and the alarm sound pressure is as follows:
  Volume setting [Large]: 65 to 85 dB
  Volume setting [Middle]: Between [Small] and [Large]
  Volume setting [Small]: 45 dB or higher
  (Measured in ambient noise of 10 dB or less and with one meter distance.)
  The relationship between the priority of the alarm and the sound pressure is as follows:
  High priority ≥ Middle priority ≥ Low priority

After Use

In order to ensure the safe use of this system, make sure it is cleaned after use and stored in an appropriate environment. If the system is used while it is dirty, the system may not operate properly or may cause a malfunction.

Cleaning

Cautions

- Since this system does not have an airtight structure, it should not be used or stored in an active gas environment (including sterilizer gas), nebulizer-sprayed environment, high-humidity environment, etc. Taking the system to these environments leads to the electronic components inside the system being affected and there may be subsequent damage and time degradation which will cause failure of this system.
- Clean the system before and after using. When disinfecting, do not use a sterilizer. Use a soft cloth (damp with disinfectants) to wipe the system, and wipe off the disinfectants with a soft cloth (damp with cold/lukewarm water), and then thoroughly wipe off any moisture with a dry soft cloth.
- If this system is tainted with blood, wipe the system immediately with a damp (not wet) soft cloth. Be sure to wear gloves to prevent infection.
- When liquids (bloods or drug solution, etc.) come into contact with the Drive Motor, immediately wipe them off and clean the device thoroughly. If coagulated liquids (bloods or drug solution, etc.) are adhered to the pump receptacle of the Drive Motor, the slide hook may not move.
- Turn the system off and disconnect the AC power cable and cables (the Drive Motor, the ABD/Flow Sensor, the Temperature Sensor Cable, the Pressure Sensor Cable, the Fast Clamp, the LAN cable, the CDI Communication Cable) before cleaning. Otherwise the system may fail or an electrical shock may occur.
- Do not use an electric dryer to dry this system. This system may be damaged.
- Do not wash this system with running water or while immersed in water as this may cause damage or failure of the system. This system does not have a waterproof structure.
- Do not wipe with organic solvent such as alcohol or thinner, or with povidone-iodine. Using organic solvent or any disinfectants other than those permitted for use may result in damage to or failure of this system.
- Do not subject this system to ethylene oxide gas (EOG) sterilization or high pressure steam sterilization, or immerse this system in disinfectant solution.
- Since drug solution may cause a short circuit, ensure that the connecting sections (the Drive Motor, the ABD/Flow Sensor, the Pressure Sensor Cable, the Temperature Sensor, the Fast Clamp, the LAN cable and the CDI Communication Cable) are not wet when connecting plugs to connectors. If moisture is present, ensure that the power is turned off and the AC power cable is removed from both this system and grounded AC power source, and then thoroughly wipe with a dry soft cloth. Since this system does not have a waterproof structure, drug solution and moisture may affect the electrical components inside, and cause a malfunction.

Examples of disinfectants (ingredient names) which can be used are listed below.

Examples of Cleaning Disinfectants (Ingredient Names)

Ingredient Name	Dilution (e.g.)
Chlorhexidine gluconate	5%
Benzalkonium chloride	10%

When using a disinfectant solution, refer to instructions for use (Regarding dilute concentration, etc.) of each disinfectant solution.
If you have any questions, contact Terumo's service representative.

Cleaning Method

Clean immediately with a damp (not wet) soft cloth.

When cleaning the ABD/Flow Sensor, use a soft cloth soaked in water or lukewarm water and squeezed well to wipe off the vaseline applied to the detection window (Figure 4-1) of the ABD/Flow Sensor.
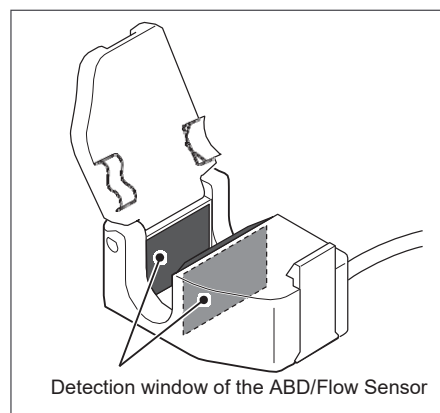
Detection window of the ABD/Flow Sensor

Figure 4-1

Storage

Ensure that the battery is charged in preparation for the next use.
Store the system in a location where it is not exposed to moisture, sunlight, high temperature, or high humidity.
Storage conditions: Ambient temperature -20 to 45 °C, relative humidity 10 to 95% RH (non-condensing)

Cautions

- Do not expose this system to direct sunlight or ultraviolet irradiation for a long period of time. The exterior may experience colour change, deformation or deterioration.
- Do not store this system in a place with a high level of vibration, dust, mist or corrosive gas.
- Do not store this system in a place where an environment of atmospheric pressure, temperature, humidity, ventilation, or corrosive conditions may cause an adverse effect.
- Do not store this system in a storage area for chemicals or in a place where gases are generated.
- Do not store this system under high temperature and high humidity.
- Do not store the battery in a discharge status. Storing the battery left in a discharge status may cause degradation, resulting in making the battery unavailable in emergency situations.
- Keep magnetic media, such as hard disks, away from the Drive Motor as the device contain magnets.

Maintenance and Inspections

To ensure safe operation and the longest possible life, perform periodic maintenance and inspections. If any fault is detected, immediately stop using the system and contact Terumo's service representative.

> **Cautions**
>
> - Since this system is precision equipment, it should not be used if it has received any impact (drop to floor, falling, violent shock). Even though no fault is observed in the system appearance, internal components may damage. This may result in decreased performance (flow rate accuracy and various alarm functions, etc.), and therefore inspection is required. Contact Terumo's service representative for inspection.
> - Do not disassemble, make alterations (including actions that interfere with the functionality or performance such as taping the LCD or a movable part) to, or repair this system. This may result in failure, damage or device performance degradation of this system.
> - Execute maintenance and inspections periodically for devices in the backup kit. When executing maintenance and inspections, use the Drive Motor and the AC power cable included in the backup kit. Due to a low frequency of use, the abnormality may not be detected.
> - Check displays to ensure this system will operate properly.

Maintenance and Inspections by Users

This section describes the inspection items, inspection method and inspection cycle.

Items to Prepare

Prepare the following before inspection:

1. **Vaseline (used in the inspection before circulation starts)**

2. **Stopwatch (used in the six-month inspection)**

Inspection Before Each Use

Confirm the contents in the following sequence before each use:
- Inspection of the external appearance
- Inspection of the start-up sequence
- Inspection of the battery-powered operation function
- Inspection of the Drive Motor Disconnected Alarm function and the ABD/Flow Sensor Disconnected Alarm function

◆ Inspection method of the external appearance (Before each use)

1. **There are no significant scratches or damage in the appearance.**

2. **There are no scratches or pinch marks on the outer covering of the cables.**

3. **There are no foreign items or damage in the connectors.**

4. **Turn the motor speed knob and check that it turns smoothly.**

◆ Inspection method of start-up sequence (Before each use)

1. **Connect the AC power cable to the Controller.**

2. **Plug in the AC power cable to the grounded AC power source.**

3. **Connect the Drive Motor and the ABD/Flow Sensor.**

4. **Turn on the power.**

Checks
- The following buttons and indicators in the control panel flash three times:
  - Auto priming button
  - Coast release button
  - Key lock button
  - Flow indicator
  - Motor speed indicator
- The status lamp flashes from green to yellow to red.
- The motor speed indicator lamp turns from green to orange in a clockwise direction.
- The battery indicator lamp flashes twice repeatedly in the following sequence:

 → →

- After the start screen is displayed with an activation sound, the main screen appears.

<Confirmation items after the main screen is displayed>
- The Serious System Error or the System Error is not issued.
- The AC power lamp is lit and the AC power indicator is .
- There is more than 70% battery charge level.
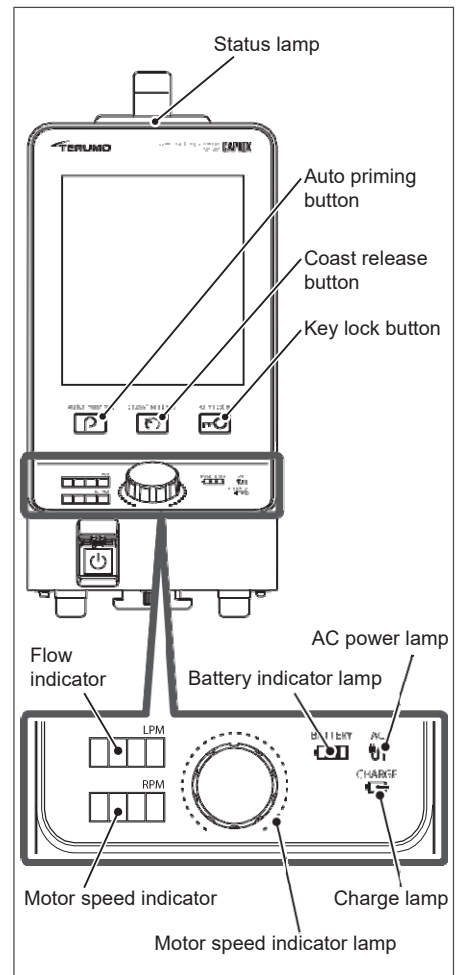
◆ Inspection method of the battery-powered operation function (Before each use)

1. **Unplug the AC power cable.**

Checks
- The Battery-powered operation started Alarm is issued.
- The AC power lamp turns off.
- The AC power indicator changes to .

2. **Tap [Battery-powered operation started] displayed on the message area and tap [OK] after confirming the message displayed. (Figure 5-1)**

   The On Battery Alarm is issued.

AC power is lost.
Check AC power supply.
Touch OK to clear the alarm.

OK   Cancel

Figure 5-1

3. **Change the motor speed to 3000 RPM.**

   At this time, do not attach the centrifugal pump.

4.   Plug in the AC power cable.

Checks
• The On Battery Alarm stops.
• The AC power lamp is lit.
• The AC power indicator changes to 🔌.

5.   Change the motor speed to 0 RPM to stop the Drive Motor.

6.   Turn off the power.

◆ **Inspection method of the Drive Motor Disconnected Alarm function and the ABD/Flow Sensor Disconnected Alarm function (Before each use)**

1.   Disconnect the plug of the Drive Motor and turn on the power.

Check
• "Drive Motor Disconnected" is displayed on the message area and an alarm sounds. (Figure 5-2)

Figure 5-2

2.   Tap 🔔. (Figure 5-3)

Check
• The alarm is muted.

Figure 5-3

3.   Turn off the power and connect the Drive Motor.

4.   Disconnect the plug of the ABD/Flow Sensor and turn on the power.

Check
• "ABD/Flow Sensor Disconnected" is displayed on the message area and an alarm sounds. (Figure 5-4)
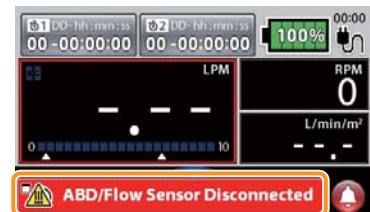
Figure 5-4

5.   Tap 🔔. (Figure 5-5)

Check
• The alarm is muted.
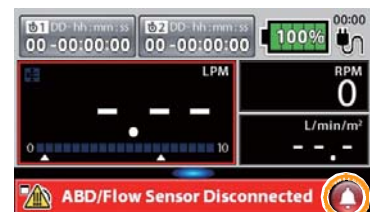
Figure 5-5

6.   Turn off the power and connect the ABD/Flow Sensor.

Inspection Before Circulation Starts (Before Each Use)

After priming, perform the inspections in the following sequence before circulation starts:
• Inspection of the motor drive
• Inspection of the ABD/Flow Sensor
• Inspection of the Fast Clamp

◆ Inspection method of the motor drive (Before each use)

1.   Clamp the blood outlet line of the centrifugal pump (Figure 5-6), change the motor speed to 3000 RPM, and rotate it for approximately 30 seconds.

Figure 5-6

Check

• There is no liquid leakage, rotation deflection of the centrifugal pump or abnormal sounds from the Drive Motor.

Caution

• Do not rotate the centrifugal pump for a long period of time (multiple hours) while clamping the blood outlet line of the centrifugal pump. The priming solution may be denatured due to heating. The blood may be damaged due to heating.
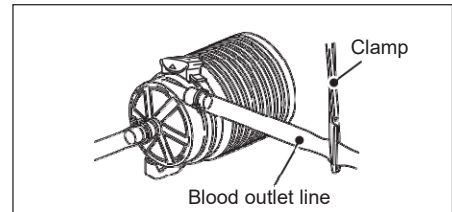
2.   Change the motor speed to 0 RPM to stop the centrifugal pump.

Check

• The centrifugal pump is stopped.

3.   Pull up the slide hook of the Drive Motor (Figure 5-7 a) and remove the centrifugal pump from the Drive Motor. (Figure 5-7 b)

Figure 5-7

Check

• There is no abnormality in the centrifugal pump.

Caution

• When attaching or detaching the centrifugal pump to or from the Drive Motor, confirm that the Drive Motor is stopped.
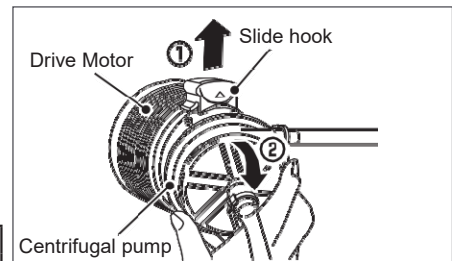
4.   Attach the centrifugal pump into the Drive Motor and remove the clamp of the blood outlet line.

For instructions on installing the centrifugal pump, refer to "Attaching the Centrifugal Pump to the Drive Motor" (page 43).

◆ Inspection method of the ABD/Flow Sensor (Before each use)

1.   Apply vaseline in the detection window of the ABD/Flow Sensor and attach the clamp-on ABD/ Flow sensor to the tube of the blood circuit.

2.   Change the motor speed.

Check

• The flow is displayed in the LCD.

3. Change the motor speed to 0 RPM to stop the centrifugal pump.

◆ Inspection method of the Fast Clamp (Before each use)

When using the Fast Clamp, follow the procedures below to perform the inspection:

1. **Attach the tube of the blood line to the Fast Clamp.**

2. **Tap the setup icon. (Figure 5-8)**

Figure 5-8

3. **Tap the Fast clamp icon on the Setup screen. (Figure 5-9)**

   The Fast clamp screen opens.

Figure 5-9

4. **Tap [Clamp] to operate the Fast Clamp. (Figure 5-10)**

   Check

   • The plunger is closed (up position).

Figure 5-10

5. **Tap [Cancel] to close the screen. (Figure 5-11)**

Figure 5-11

6. **While holding the lid of the Fast Clamp, pull up the lever until you hear a click. (Figure 5-12)**

`Check`

• After pulling up the lever, the lever has returned to the original position.

`Note`

• If the lever does not return to the original position, pull down the lever. If it does not return to the original position, a failure may have occurred.
Stop using the system immediately, and contact Terumo's service representative.
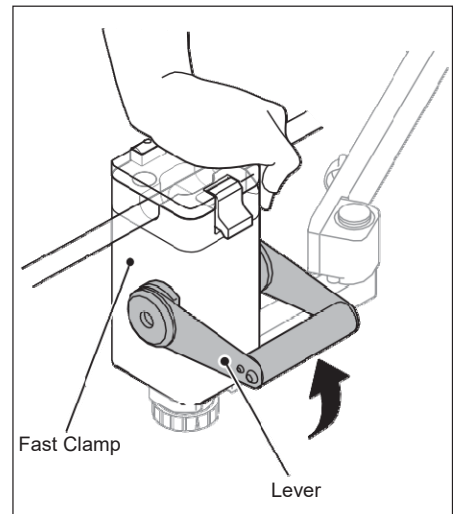
Figure 5-12

Six-month Inspection

◆ Inspection method of the battery

This system has a built-in battery as a back up power source.
As the battery deteriorates regardless of use, periodical replacement is necessary.
Replacement period of the battery differs based on the environment and frequency of use of the Controller. The battery should be replaced if an abnormality is found in the following inspection. It should also be replaced after approximately two years of use, even if no abnormality is found.
Inspect the battery once every six months with the following procedures:

1. **Connect the AC power cable to the Controller.**

2. **Plug in the AC power cable to the grounded AC power source.**

3. **Charge the battery until the charge lamp turns off. (Figure 5-13)**
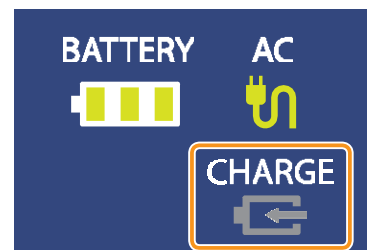
Figure 5-13

4. **Turn on the power.**

`Check`

• There is more than 70% battery charge level.

5. **Unplug the AC power cable and change the motor speed to 3000 RPM with the centrifugal pump not attached to the Drive Motor. At this time, the Battery-powered operation started Alarm is issued. Tap [Battery-powered operation started] displayed on the message area and tap [OK] after confirming the message displayed. (Figure 5-14)**

    Measure the elapsed time with a stopwatch.

6. **Maintain the status in step 5 until the power of the Controller turns off.**

Figure 5-14

Check
- The system can operate for more than three hours.

7. **Plug in the AC power cable to charge the battery until the charge lamp turns off.**

    Measure the elapsed time with a stopwatch.

Check
- The charge lamp turns off within six hours.

Cautions
- Do not store the battery in a discharge status. Storing the battery left in a discharge status may cause degradation, resulting in making the battery unavailable in emergency situations.
- Do not disassemble, make alterations (including actions that interfere with the functionality or performance such as taping the LCD or a movable part) to, or repair this system. This may result in failure, damage or device performance degradation of this system.

Note
- Since the battery is built-in, contact Terumo's service representative when replacing it.

SP-200 Maintenance/Inspection Check List

Serial number:	Date: / / Person in charge:		
	Check items		
	Inspection before each use		
Inspection of the external appearance (Before each use)	• Are there any significant scratches or damage in the appearance?	Pass	Fail
	• Are there any scratches or pinch marks on the outer covering of the cables?	Pass	Fail
	• Are there any foreign items or damage in the connectors?	Pass	Fail
	• When turning the motor speed knob, does it turn smoothly?	Pass	Fail

Inspection of start-up sequence (Before each use)	• Do the following buttons and indicators in the control panel flash three times?
	  • Auto priming button
	  • Coast release button
	  • Key lock button
	  • Flow indicator
	  • Motor speed indicator
		Pass	Fail

	• Does the status lamp flash from green to yellow to red?	Pass	Fail
	• Does the motor speed indicator lamp turn from green to orange in a clockwise direction?	Pass	Fail
	• Does the battery indicator lamp flash twice repeatedly in the following sequence? (None, none, red) (None, green, green) (Green, green, green)	Pass	Fail
	• When the start screen is displayed, is an activation sound heard?	Pass	Fail
	• Does the main screen appear?	Pass	Fail
	<Confirmation items after the main screen is displayed>		
	• Is the Serious System Error or the System Error issued?	Pass	Fail
	• Is the AC power lamp lit and is the AC power indicator 🔌?	Pass	Fail
	• Is there more than 70% battery charge level?	Pass	Fail
Inspection of the battery-powered operation function (Before each use)	<When the AC power cable is unplugged>		
	• Is the Battery-powered operation started Alarm issued?	Pass	Fail
	• Does the AC power lamp turn off?	Pass	Fail
	• Does the AC power indicator change to ✖?	Pass	Fail
	<When the AC power cable is plugged in>		
	• Does the On Battery Alarm stop?	Pass	Fail
	• Does the AC power lamp light up?	Pass	Fail
	• Does the AC power indicator change to 🔌?	Pass	Fail
Inspection of the Drive Motor Disconnected Alarm and the ABD/Flow Sensor Disconnected Alarm (Before each use)	<When the plug of the Drive Motor is disconnected and the power is turned on>		
	• Is "Drive Motor Disconnected" displayed on the message area and does an alarm sound?	Pass	Fail
	• Does the alarm mute when tapping 🔕?	Pass	Fail
	<When the plug of the ABD/Flow Sensor is disconnected and the power is turned on>		
	• Is "ABD/Flow Sensor Disconnected" displayed on the message area and does an alarm sound?	Pass	Fail
	• Does the alarm mute when tapping 🔕?	Pass	Fail

Serial number:	Date: / / Person in charge:		
Check items			
Inspection before circulation starts (Before each use)			
Inspection of the motor drive (Before each use)	• Are there any abnormalities such as liquid leakage or rotation deflection of the centrifugal pump or abnormal sounds from the Drive Motor while the blood outlet line of the centrifugal pump is clamped and the centrifugal pump is rotated at a speed of 3000 RPM for approximately 30 seconds?	Pass	Fail
	• Does the centrifugal pump stop when the motor speed is changed to 0 RPM?	Pass	Fail
Inspection of the ABD/ Flow Sensor (Before each use)	• Is the flow displayed in the flow indicator in the LCD when the centrifugal pump is rotated?	Pass	Fail
Inspection of the Fast Clamp (Before each use)	• Is the plunger closed (up position) after the Fast Clamp is operated by tapping the [Clamp]?	Pass	Fail
	• Does the lever return to the original position after pulling it up until you hear a click? If not, does the lever return to the original position when it is pulled down?	Pass	Fail
Overall judgement **(If any one item is judged as fail, repairs are necessary. Immediately stop using the system and contact Terumo's service representative.)**		Pass	Fail
Remarks:			

Serial number:	Date: / / Person in charge:		
Check items			
Six-month inspection (Once every six months)			
Inspection of the battery (Once every six months)	• Is there more than 70% battery charge level when the battery is charged until the charge lamp turns off?	Pass	Fail
	• Can the system operate for more than three hours on battery power with the motor speed set at 3000 RPM?	Pass	Fail
	• Does the charge lamp turn off within six hours when charging starts after the power is turned off?	Pass	Fail
Overall judgement **(If any one item is judged as fail, repairs are necessary. Immediately stop using the system and contact Terumo's service representative.)**		Pass	Fail
Remarks:			

Maintenance and Inspection Items by Terumo's Service Representative

Periodic Inspection

In order to use the system safely, please request for Terumo's service representative to perform a periodical inspection (inspections, adjustments and repairs using dedicated tools and measuring equipments for various function and performance tests) approximately once a year (paid service), apart from the usual maintenance and inspection. As a result of the inspection, replacement of parts other than periodically replaced parts may also be required. For details, consult with Terumo's service representative.

Terumo's request to users:
• When ordering repairs or maintenance/inspection, if there is a possibility of infection, disinfect the product in advance.

Replacement Parts

Periodically replaced parts
Periodically replaced parts are "parts" that gradually deteriorate or become worn over time and require replacement in order to maintain the accuracy and performance of the system. The following parts are required for replacements according to the number of years that have elapsed since its initial use:

Part name	Elapsed years	Replacement reason
Battery	2 years	Even when charged, the battery charge level indication decreases after a short period of time.
Filter	1 year	Intake efficiency decreases due to clogging. Dust collecting effect decreases due to deterioration over time.
Gasket	2 years	Dust collecting effect and drip proof performance decrease due to deterioration over time.

Caution

• Do not use any replacement parts other than those specified. This may result in decreased performance.

* Depending on frequency and environment of use, the time for replacement may vary. Consult your Terumo's service representative regarding the need for replacement.
* Service life of the Controller, the Backup Controller, the Drive Motor, the ABD/Flow Sensor, the Fast Clamp, the Cart, the Fast Clamp Attachment (for EBS), the Fast Clamp Arm after designated maintenance, inspection and the replacement of expendable supplies are implemented is six years (by self-certification). Service life of the Pressure Sensor Cable, the Temperature Sensor Cable, the CDI Communication Cable after designated inspection is implemented is two years (by self-certification). The service life of the equipment is at least 6 years in the case of standard use. If service life is exceeded, be sure to ask Terumo for a comprehensive inspection and repair including parts replacement.
* Terumo will retain periodically replaced parts and maintenance parts for eight years after the end of production of this system. In addition, of the parts used are commercial products that are available generally. After long periods of time following the initial release of the product, some parts may become unavailable even before the eight year period due to issues such as parts manufacturers discontinuing production of necessary parts.
* When disposing of the Controller, dispose it properly according to your local regulations.

Recycle of Rechargeable Battery

• This Controller contains a lithium ion battery.
• When disposing of this Controller, remove and recycle the rechargeable battery.

廢電池請回收

Alarms and Troubleshooting

When an alarm/error occurs, the factors below may be the cause. Follow the procedure for dealing with each alarm/error as it arises. If the abnormality persists, the system may have failed. Stop using the system immediately and contact Terumo's service representative.

Troubleshooting

Occurrence	Cause	Action
The power does not turn ON.	• The battery charge level is low and the AC power source is not connected.	• Connect the AC power source. (Refer to page 31.)
When the AC power source is cut off, the system does not switch to the battery-powered operation and the power turns off.	• The battery has little power left.	• Charge battery. (Refer to page 72.)
	• The battery has deteriorated or is damaged.	• Contact Terumo's service representative.
The AC power lamp does not light up. (AC power source cannot be connected)	• The AC power source is not properly connected.	• Reconnect the AC power cable. (Refer to page 31.)
	• The AC power cable is internally disconnected.	• Contact Terumo's service representative.
The charge lamp does not light up. (Cannot charge)	• The battery is fully charged.	• When battery is fully charged, it cannot be charged further. There is no abnormality.
	• The battery is deteriorated or in failure.	• Contact Terumo's service representative.
Even though charging is completed (the charge lamp is off), the battery charge level is less than 100%.	• The battery has deteriorated.	• When battery charge level is less than 70%, contact Terumo's service representative for replacement of the battery.
	• The battery is damaged. • An abnormality occurred in the system.	• Contact Terumo's service representative.
The time indication is not correct.	• The time lags due to time accuracy.	• Set the time again. (Refer to page 109.)
The motor speed is displayed as "----", and the centrifugal pump does not rotate.	• The Drive Motor is not properly connected.	• Reconnect the Drive Motor. (Refer to page 33.)
	• The Drive Motor has failed.	• Contact Terumo's service representative.
Auto-priming does not start.	• The Drive Motor is running.	• Execute auto-priming after stopping the Drive Motor. (Refer to page 49.)
	• The battery charge level is low and the AC power source is not connected.	• Execute auto-priming after connecting the AC power source.
The flow is displayed as "-.--". The flow does not stabilize.	• The ABD/Flow Sensor is not properly connected.	• Reconnect the ABD/Flow Sensor. (Refer to page 36.)
	• The ABD/Flow Sensor is not properly attached on the tube.	• Reattach the ABD/Flow Sensor on the tube. (Refer to page 44.)
	• The detection window of the ABD/Flow Sensor is dirty.	• Remove the ABD/Flow Sensor from the tube to clean (Refer to page 84.), reapply vaseline and reattach on the tube. (Refer to page 44.)
	• The ABD/Flow Sensor has failed.	• Contact Terumo's service representative.
The pressure is displayed as "---". The pressure does not stabilize.	• The Pressure Sensor Cable is not properly connected.	• Reconnect the Pressure Sensor Cable. (Refer to page 37.)
	• The pressure sensor is not properly connected.	• Reconnect the pressure sensor. (Refer to page 46.)
	• The pressure sensor has failed.	• Replace the pressure sensor.
	• The Pressure Sensor Cable has failed.	• Contact Terumo's service representative.
Calibration cannot be implemented. "0" does not display even after calibration is implemented.	• Pressure within the usage environment is not stable.	• Calibrate the system in an environment where the pressure is stable.

Occurrence	Cause	Action
The temperature is displayed as "--.-". The temperature is not stable.	• The Temperature Sensor Cable is not properly connected.	• Reconnect the Temperature Sensor Cable. (Refer to page 37.)
	• The CAPIOX Luer Thermistor is not properly connected.	• Reconnect the CAPIOX Luer Thermistor. (Refer to page 46.)
	• The CAPIOX Luer Thermistor has failed.	• Replace the CAPIOX Luer Thermistor.
	• The Temperature Sensor Cable has failed.	• Contact Terumo's service representative.
The Clamp ready lamp does not light up.	• The Fast Clamp is not properly connected.	• Connect the Fast Clamp. (Refer to page 38.)
	• The fast clamp function is not on.	• Enable the fast clamp function. (Refer to page 90.)
	• The safety connection which allows the Fast Clamp to operate has not been set.	• Set the safety connection. (Refer to page 91.)
	• The tube has not been securely set. • The lid is not properly closed.	• Set the tube and close the lid. (Refer to page 51.)
The Fast Clamp cannot be clamped from the button on Fast clamp screen.	• The tube has not been securely set. • The lid is not properly closed.	• Set the tube and close the lid. (Refer to page 51.)
	• The fast clamp function is not on.	• Enable the fast clamp function. (Refer to page 90.)
	• The Drive Motor is running.	• Execute the clamp after stopping the Drive Motor.
The key lock function does not activate.	• An alarm other than the On Battery Alarm is issued.	• Resolve the cause of the alarm. (Refer to page 134.)
	• Log data is being exported.	• The key lock function does not activate while log data is being exported. This is not a malfunction.
The count-down ended sound does not sound.	• An alarm is issued.	• When an alarm is issued, the alarm sound has priority over the count-down ended sound. This is not a malfunction.
The button that exports history data to a USB memory drive does not function.	• The Drive Motor is running.	• Output data to the USB memory drive after stopping the Drive Motor.
"Failed to output the log to the USB." is displayed.	• The USB memory drive cannot be written.	• Enable the USB memory drive writable, and try to export the data again.
A USB memory drive is not recognized.	• Removal of the previous USB memory drive was not properly executed.	• Turn off the power of the Controller, and turn on the power again. • Enable the USB memory drive writable, and try to export the data again.
The password to open admin setup is lost.		• Contact Terumo's service representative to initialize the password.

List of Alarm Messages

When an alarm is issued, an alarm message is displayed on the message area and the alarm continues to sound. To mute the alarm, tap 🔴 🟡. However, if two minutes elapse and the cause of the alarm condition is not resolved, the alarm will start to sound again. The alarm also starts to sound when another alarm is issued.

When two or more alarms are issued simultaneously, the alarms will be displayed on the message area from high to low priority and the system will adopt the alarm with the highest priority. Clear each alarm condition and confirm no other alarm is remaining.

When an alarm with an error code is issued, the motor speed indicator displays the motor speed and error code alternately.

Message display	Cause/Occurrence	Action	Priority	Error code
Serious System Error[*1]	Detected an equipment abnormality which may prevent circulation from being maintained.	The equipment may have failed. Maintain circulation by switching to the Backup Controller or to the Hand Crank. After taking the above precautions, contact Terumo's service representative.	High	E9xx[*1]
Battery Empty	Detected that battery is depleted.	Maintain circulation by immediately supplying AC power or by switching to the Backup Controller or to the Hand Crank.	High	E908
Low Battery	Detected the battery charge level is low.	Maintain circulation by immediately supplying AC power or by switching to the Backup Controller or to the Hand Crank.	High	E968
Drive Motor Disconnected	Detected that the Drive Motor is disconnected.	Turn off the power and reconnect the Drive Motor. Turn off the power to reconnect the Drive Motor and turn on the power again.	High	E999
ABD/Flow Sensor Disconnected	Detected that the ABD/Flow Sensor is disconnected.	Turn off the power and connect the ABD/Flow Sensor. Turn off the power to reconnect the ABD/Flow Sensor and turn on the power again.	High	E931
Flow Signal Unstable[*2]	Detected that the ultrasonic reception strength of the ABD/Flow Sensor is unstable.	Attach the ABD/Flow Sensor to the tube. Remove the ABD/Flow Sensor from the tube to clean, reapply Vaseline and reattach to the tube.	High	E907
Back Flow Alarm[*2]	Detected that the flow is below 0 LPM (L/min).	a Check that the ABD/Flow Sensor is attached in the proper direction. b Check that there is no abnormality in the blood circuit. c Adjust the motor speed to render appropriate flow.	High	
Back Flow: Clamp Close / Back Flow: Pump Stop	Detected that the Fast Clamp operated as the safety connection of the Back Flow Alarm and circulation stopped.	Handle according to "d When the safety connection of the Back Flow Alarm is set to "Clamp+Pump stop"" (page 70).	High	

[*1]: There may be some cases in which there is no message display nor error code. In addition, the error code varies according to location in the system where the error is detected.

[*2]: An alarm is not issued until the motor speed indicated value exceeds the coast speed after the Drive Motor starts running.

Message display	Cause/Occurrence	Action	Priority	Error code
Low Flow Alarm*2	Detected that flow has fallen below the setup flow alarm threshold.	**a** Check that there is no abnormality in the blood circuit. **b** Adjust the motor speed to render appropriate flow.	High	
High Flow Alarm*2	Detected that flow has exceeded the setup flow alarm threshold.			
Air Bubble Detected Alarm*2*3	Detected air bubbles that correspond to the setup sensitivity.	**a** Check that the ABD/Flow Sensor is not detached from the tube. **b** Cancel the Air Bubble Detected Alarm. (Tap [Air Bubble Detected Alarm] ⇨ Confirmation message displays ⇨ Tap [OK] after confirmation)	High	
		a Remove air bubbles. **b** Cancel the Air Bubble Detected Alarm. (Tap [Air Bubble Detected Alarm] ⇨ Confirmation message displays ⇨ Tap [OK] after confirmation)		
Air Bubble: Clamp Close	Detected that the Fast Clamp operated as the safety connection of the Air Bubble Detected Alarm and circulation stopped.	Handle according to "**c** When the safety connection of the Air Bubble Detected Alarm is set to "Clamp+Pump stop"" (page 68).	High	
Air Bubble: Pump Stop				
Air Bubble: Pump Coasting	Detected that the safety connection of the Air Bubble Detected Alarm operated and the motor speed changed to the coast speed.	Handle according to "**b** When the safety connection of the Air Bubble Detected Alarm is set to "Pump Coast"" (page 67).	High	
P1:Low Pressure Alarm*2*3	Detected that the pressure has fallen below the setup pressure alarm threshold.	**a** Check that there is no abnormality in the blood circuit. **b** Adjust the motor speed while checking the flow.	High	
P2:Low Pressure Alarm*2*3				
P1:Over Pressure Alarm*2*3	Detected that the pressure has exceeded the setup pressure alarm threshold.			
P2:Over Pressure Alarm*2*3				
P1 Low: Pump Coasting	Detected that the safety connection of the Pressure Alarm operated and the motor speed changed to the coast speed.	Handle according to "**a** When the safety connection of the Pressure Alarm (over pressure/low pressure) is set to "Pump Coast"" (page 66).	High	
P2 Low: Pump Coasting				
P1 Over: Pump Coasting				
P2 Over: Pump Coasting				
Clamp Closed*3	Detected that the blood circuit has been clamped by the Fast Clamp through an operation other than the safety connection of the Air Bubble Detected Alarm or the Back Flow Alarm.	Operate the lever of the Fast Clamp and set the plunger to the release position. (Refer to "Attaching the Fast Clamp" (page 51).)	High	E984

*2: An alarm is not issued until the motor speed indicated value exceeds the coast speed after the Drive Motor starts running.

*3: An alarm is issued only when the associated function is set to [On].

Message display	Cause/Occurrence	Action	Priority	Error code
Clamp Occlusion Error*³	Detected a clamp operation abnormality of the Fast Clamp.	**a** Check that the tube is properly placed and that the lid is properly closed. **b** Clamp the tube using forceps when necessary. * When cancelling the alarm, disable the fast clamp function.	High	E901
System Error	Detected an equipment abnormality requiring inspection after use.	The system may have failed. Do not disconnect the AC power source. In addition, contact Terumo's service representative as soon as the current case ends.	Medium	
Battery-powered operation started	Detected that battery-powered operation has started.	If this alarm is issued unintentionally, check the supply of AC power.	Medium	
		When intentionally stopping the supply of AC power due to transportation or other purposes, cancel the Battery-powered operation started Alarm. (Tap [Battery-powered operation started] ⇨ Confirmation message displays ⇨ Tap [OK])		
T1:Low Temperature Alert*²*³	Detected that the temperature has fallen below the setup temperature alert threshold.	**a** Check that there is no abnormality in the blood circuit. **b** Check the hot and cold water tank.	Medium	
T2:Low Temperature Alert*²*³				
T1:High Temperature Alert*²*³	Detected that the temperature has exceeded the setup temperature alert threshold.			
T2:High Temperature Alert*²*³				
On Battery	Detected that the operation is continuously battery-powered after confirming the operation of the Battery-powered operation started Alarm.	Restart the AC power supply as soon as possible while monitoring the battery charge level.	Low	
T1:Temp. Sensor Disconnected*²*³	Detected that the temperature sensor (the CAPIOX Luer Thermistor) is disconnected.	Connect the Temperature Sensor Cable to the temperature sensor (the CAPIOX Luer Thermistor). Connect the cable to the Controller.	Low	
T2:Temp. Sensor Disconnected*²*³		Reconnect the Temperature Sensor Cable to the temperature sensor (the CAPIOX Luer Thermistor). Connect the cable to the Controller.		
		Replace the Temperature Sensor Cable or the temperature sensor (the CAPIOX Luer Thermistor).		
P1:Pressure Sensor Disconnected*²*³	Detected that the pressure sensor is disconnected.	Connect the Pressure Sensor Cable to the pressure sensor. Connect the cable to the Controller.	Low	
P2:Pressure Sensor Disconnected*²*³		Reconnect the Pressure Sensor Cable to the pressure sensor. Connect the cable to the Controller.		
		Replace the Pressure Sensor Cable or the pressure sensor.		

*²: An alarm is not issued until the motor speed indicated value exceeds the coast speed after the Drive Motor starts running.

*³: An alarm is issued only when the associated function is set to [On].

Message display	Cause/Occurrence	Action	Priority	Error code
P1:Low Pressure Alert*2*3	Detected that the pressure has fallen below the setup pressure alert threshold.	**a** Check that there is no abnormality in the blood circuit. **b** Adjust the motor speed while checking the flow.	Low	
P2:Low Pressure Alert*2*3				
P1:Over Pressure Alert*2*3	Detected that the pressure has exceeded the setup pressure alert threshold.			
P2:Over Pressure Alert*2*3				
Clamp Disconnected*3	Detected disconnection of the Fast Clamp.	Connect the Fast Clamp.	Low	
		Reconnect the Fast Clamp and turn on the power again.		
Safety connection is not set*2*3	Detected that the Fast Clamp is on, while clamp closed is not selected in the safety connection settings.	Check the safety connection settings.	Low	
Clamp Not Ready*2*3	Detected that the Fast Clamp is not prepared for use.	**a** Set the tube at the Fast Clamp and close the lid. **b** Set the tube again and close the lid.	Low	
Clamp Error*3	Detected failure of the Fast Clamp.	The Fast Clamp may have failed. Stop using the Fast Clamp and contact Terumo's service representative.	Low	
LAN Connection Error*3	Detected an abnormality of the LAN communication connection.	**a** Check that a proper cable is being used to connect with the external device. **b** Check the communication settings between the Controller and the external device.	Low	
CDI Connection Error*3	Detected an abnormality of the CDI communication connection.	**a** Check that a proper cable is being used to connect with CDI System 500. **b** Check the communication settings between the Controller and CDI System 500.	Low	

*2: An alarm is not issued until the motor speed indicated value exceeds the coast speed after the Drive Motor starts running.

*3: An alarm is issued only when the associated function is set to [On].

Specifications

System Specifications (Controller)

Product name	CAPIOX Centrifugal Pump Controller SP-200
Catalogue number	ME∗SP200C (Identification code: SP200C∗): Controller ME∗SP200C2 (Identification code: SP200C2∗): Controller ME∗SP200C3 (Identification code: SP200C3∗): Controller ME∗SP200M: Drive Motor ME∗SPFAS01: ABD/Flow Sensor (for standard tube circuit) ME∗SPFAS02: ABD/Flow Sensor (for soft tube circuit) ME∗SPCLP01: Fast Clamp XX∗SPCBL011: Temperature Sensor Cable (blue) XX∗SPCBL012: Temperature Sensor Cable (red) XX∗SPCBL021: Pressure Sensor Cable XX∗SPCBL031: CDI Communication Cable XX∗SPCLP01: Fast Clamp Attachment (for EBS) XX∗SPCLP02: Fast Clamp Arm XX∗SPCRT01: Cart
Drive Motor drive function	Motor speed range: 0 - 3000 RPM Motor speed error: ±1.5% (at 1000 RPM or more)
Flow measuring function	Measuring range: -9.99 to 9.99 LPM (L/min) Measuring accuracy: ±10% (from -7.00 to -1.01 LPM (L/min) and 1.01 to 7.00 LPM (L/min)) ±0.1 LPM (L/min) (-1.00 to 1.00 LPM (L/min)) When attaching to dedicated tube (inner diameter 9.5 mm (3/8 inches)), and when hematocrit value is 40%, liquid temperature is 37°C and ambient temperature is 25°C
Air bubble detector function	Low sensitivity: Detects air bubbles of 0.5 cm^3 or more (at flow 7.00 LPM (L/min) or less) Medium sensitivity: Detects air bubbles of 0.2 cm^3 or more (at flow 7.00 LPM (L/min) or less) High sensitivity: Detects air bubbles of 0.05 cm^3 or more (at flow 4.20 LPM (L/min) or less) Detection sensitivity can be turned on/off and set
Temperature measuring function (2 channels)	Measuring range: 0.0 - 50.0°C Apparatus accuracy: ±0.3°C Function can be turned on/off and set for each channel
Pressure measuring function (2 channels)	Measuring range: -250 to 900 mmHg (-33.3 to 120.0 kPa) Apparatus accuracy: ±3% (-250 to -101 mmHg and 101 to 900 mmHg) ±3 mmHg (±0.4 kPa) (-100 to 100 mmHg) Function can be turned on/off and set for each channel
Auto-priming function	Run the Drive Motor intermittently to eliminate air bubbles. The available operation settings are as follows: Motor speed: From 1000 to 3000 RPM Motor on time: From 0.5 to 10.0 seconds Motor off time: From 0.5 to 10.0 seconds
Blood circuit occlusion function	This function occludes the blood circuit by using the Fast Clamp when air bubbles or back flow is detected. Function can be turned on/off

Alarms and safety functions			Air Bubble Detected Alarm, Flow Alarm, Back Flow Alarm, Pressure Alarm (High priority), Pressure Alarm (Low priority), Temperature Alarm, Low Battery Alarm, Battery Empty Alarm, Battery-powered operation started Alarm, On Battery Alarm, Serious System Error Alarm (High priority), System Error Alarm (Medium priority), CDI Connection Error / LAN Connection Error Alarm, Drive Motor Disconnected Alarm, ABD/Flow Sensor Disconnected Alarm, Flow Signal Unstable Alarm, Pressure Sensor Disconnected Alarm, Temperature Sensor Disconnected Alarm, Clamp Closed Alarm, Clamp Occlusion Error Alarm, Clamp Error Alarm, Clamp Not Ready Alarm, Clamp Disconnected Alarm, Re-alarm
Available functions			Perfusion index calculation function, Count up timer function, Count down timer function, Key lock function, History function, External communication function, Date and time setting, Language setting, Volume setting, LCD touch panel display brightness setting, Pressure unit setup, Admin setup, Alarm/safety apparatus operation setting reset function
Use conditions			Ambient temperature: 10 to 40°C Relative humidity:　　30 to 85% RH (non-condensing) Pressure:　　　　　　80 to 106 kPa
Storage conditions or transport conditions			Ambient temperature: -20 to 45°C Relative humidity:　　10 to 95% RH (non-condensing) Pressure:　　　　　　70 to 106 kPa
Power supply			AC100-240V∼ 50-60 Hz Battery (lithium ion battery) • Run time:　　　　One hour or more (running [*], when fully charged) • Charging time: Within six hours (While power is OFF or running [*] with AC power connected) *: Motor speed 2500 RPM, flow 4.00 LPM (L/min), apparatus operated with all sensors on, ambient temperature 25°C, new battery
Power consumption			250 VA (Steady-state) 400 VA (Peak: When the motor is rapidly accelerating, auto-priming is operating)
Fuse			Time-lag fuse (Type and rated voltage: T8AH250 V) Voltage rating: 250 V Current rating: 8 A Interrupt rating: 1500 A at 250 V
Classification	**Electric shock protection**		Class I device and internal power source device Defibrillation-proof type CF applied part (Pressure sensor, temperature sensor)
	The classification for use with flammable anaesthetics		Device not suitable for use around flammable gas
	Mode of operation		Continuous operation
	Protection against harmful ingress of water or particulate matter		IP42 (Controller) IP54 (Fast Clamp)
Dimensions, unit weight	**Controller**	**Dimensions**	160 mm (width) x 300 mm (height) x 330 mm (depth) * Excluding handle, rubber feet, and protrusions
		Unit weight	8 kg
	Drive Motor	**Cable length**	3 m
		Unit weight	2.6 kg
	ABD/Flow Sensor	**Cable length**	2.8 m
	Fast Clamp	**Cable length**	1.8 m
		Unit weight	1.7 kg

Dimensions, unit weight	Temperature Sensor Cable	Cable length	2.8 m
	Pressure Sensor Cable	Cable length	2.3 m
	CDI Communication Cable	Cable length	2 m
	AC power cable	Cable length	3 m
	Cart	Dimensions	466 mm (width) × 1728 mm (maximum height) x 642 mm (depth) * Excluding width and depth of caster
		Unit weight	35 kg

Related components			• CAPIOX centrifugal pump
			• CAPIOX EBS Circuit with X coating
			• CAPIOX Luer Thermistor
			• CDI System 500
			• Pressure sensor
			  (Compliant with ANSI/AAMI BP22:1994)
			   * Limited to items that can be connected to connectors.

Accessories

• AC power cable (1)
• Instructions for use (1)
• Backup kit (1)
  <Contents>
  • Backup Controller (1)
  • Drive Motor (without pole clamp) (1)
  • AC power cable (1)
  • Screwdriver (+) (1)
  • Extra screws (to fix the drive motor) (2)
  • Instructions for use (Backup Controller) (1)

* See the instructions for use (Backup Controller) included in the backup kit for system specifications (Backup Controller).

The specifications and external appearance of the product may be changed without notice for the purpose of improvement.

Units Available

Catalogue number	Plug type	Voltage	Socket type
ME*SP200C	American type	100 to 120 V	
ME*SP200C2	UK type	100 to 240 V	
ME*SP200C3	European type	100 to 240 V	

This product is a system that conforms to the EMC (electromagnetic compatibility) standard, IEC 60601-1-2:2007 required for the safe use of medical electrical equipment.

EMC (Electromagnetic Compatibility)

EMC (electromagnetic compatibility) refers to the ability to satisfy the following two items:
• It does not produce noises which cause unacceptable damage or interference to surrounding electronic equipment. (Emission)
• It can withstand an electromagnetic environment in which radio frequency interference are emitted from surrounding electronic equipment and can continue to perform the functions of the equipment. (Immunity)

The EMC standards, typified by IEC 60601-1-2:2007, are standards prescribed to ensure that effects of noise generated by medical equipment on other equipment and the effects received from electromagnetic waves generated by other equipment (mobile phones and the like) is kept under a certain level so that medical electrical equipment is used safely.
IEC 60601-1-2:2007 (sect. 6.8.2.201) requires that detailed information regarding EMC environment for the safe functioning of equipment be provided to the user, so technical explanation regarding EMC is given below. (For details, refer to IEC 60601-1-2:2007.)

EMC Technical Information

Medical electrical equipment requires particular care in regards to EMC, and it is necessary to install and use the equipment in accordance with the following EMC information.

Warnings

- This system requires special attention to electromagnetic compatibility and must be used in accordance with the EMC information described in "For Medical Staff" in this instructions for use.
- When using devices (mobile phones, radio devices, electrosurgical knives, defibrillators, etc.) that emit an electromagnetic wave near this system, they should be used as far away as possible. This system should use a power supply isolated from these devices and should obtain secure grounding. Malfunction in this system caused by electronic interference may result in critical harm to the patient.
- Do not use this system with other equipment placed next to it or stacked together.

Table 1 – Guidance and MANUFACTURER'S declaration – ELECTROMAGNETIC EMISSIONS – for all ME EQUIPMENT and ME SYSTEMS (see 5.2.2.1 c)

Guidance and manufacturer's declaration – electromagnetic emissions		
The CAPIOX Centrifugal Pump Controller SP-200 is intended for use in the electromagnetic environment specified below. The customer or the user of the CAPIOX Centrifugal Pump Controller SP-200 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment** – **guidance**
RF emissions CISPR 11	Group 1	The CAPIOX Centrifugal Pump Controller SP-200 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The CAPIOX Centrifugal Pump Controller SP-200 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Table 2 – Guidance and MANUFACTURER'S declaration – electromagnetic IMMUNITY –
for all ME EQUIPMENT and ME SYSTEMS (see 5.2.2.1 f)

Guidance and manufacturer's declaration – electromagnetic immunity			
The CAPIOX Centrifugal Pump Controller SP-200 is intended for use in the electromagnetic environment specified below. The customer or the user of the CAPIOX Centrifugal Pump Controller SP-200 should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the CAPIOX Centrifugal Pump Controller SP-200 requires continued operation during power mains interruptions, it is recommended that the CAPIOX Centrifugal Pump Controller SP-200 be powered from an uninterruptible power supply or a battery.
Power frequency (50-60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note • U_T is the a.c. mains voltage prior to application of the test level.			

Table 3 – Guidance and MANUFACTURER'S declaration – electromagnetic IMMUNITY –
for LIFE-SUPPORTING ME EQUIPMENT and ME SYSTEMS (see 5.2.2.2)

Guidance and manufacturer's declaration – electromagnetic immunity			
The CAPIOX Centrifugal Pump Controller SP-200 is intended for use in the electromagnetic environment specified below. The customer or the user of the CAPIOX Centrifugal Pump Controller SP-200 should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 TEST LEVEL**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[a]	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the CAPIOX Centrifugal Pump Controller SP-200, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d=1.2\sqrt{P}$
	10 Vrms 150 kHz to 80 MHz in ISM bands[a]	10 V	$d=1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	$d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[c] should be less than the compliance level in each frequency range.[d] Interference may occur in the vicinity of equipment marked with the following symbol: (((•)))

Notes
1. At 80 MHz and 800 MHz, the higher frequency range applies.
2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.
b. The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.
c. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the CAPIOX Centrifugal Pump Controller SP-200 is used exceeds the applicable RF compliance level above, the CAPIOX Centrifugal Pump Controller SP-200 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the CAPIOX Centrifugal Pump Controller SP-200.
d. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 5 – Recommended separation distances between portable and mobile RF communications equipment and the ME EQUIPMENT or ME SYSTEMS – for LIFE-SUPPORTING ME EQUIPMENT and ME SYSTEMS (see 5.2.2.2)

Recommended separation distances between portable and mobile RF communications equipment and the CAPIOX Centrifugal Pump Controller SP-200				
The CAPIOX Centrifugal Pump Controller SP-200 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the CAPIOX Centrifugal Pump Controller SP-200 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CAPIOX Centrifugal Pump Controller SP-200 as recommended below, according to the maximum output power of the communications equipment.				
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m			
	150 kHz to 80 MHz outside ISM bands $d=1.2\sqrt{P}$	**150 kHz to 80 MHz in ISM bands** $d=1.2\sqrt{P}$	**80 MHz to 800 MHz** $d=1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.12	0.23
0.1	0.38	0.38	0.38	0.73
1	1.2	1.2	1.2	2.3
10	3.8	3.8	3.8	7.3
100	12	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.				

Notes

1. At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
2. The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.
3. An additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.
4. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

This section describes the symbols used with the CAPIOX Centrifugal Pump Controller SP-200.

Symbol	Description of Symbols	Symbol	Description of Symbols
REF	Catalogue number	---	Direct current
S N	Serial number		Consult instructions for use
LOT	Batch code	#	Contents
	Manufacturer		Temperature limitation
IP42	IEC 60529 Degrees of protection provided by enclosures (IP code)	%	Relative humidity limitation
IP54	IEC 60529 Degrees of protection provided by enclosures (IP code)		This way up
	Defibrillation-proof type CF applied part		Keep away from rain
	Pushing prohibited		Fragile, handle with care
	Stand by	n	Stacking limit by number
	Caution for static electricity		Do not stack
	Potential equalization terminal		Keep away from sunlight
~	Alternating current		

See pages 6, 9 to 12 for symbols on the control panel and LCD touch panel display.

Memo

FOR INFORMATION ABOUT TERUMO PRODUCTS

- If this product should fail to perform as intended, immediately stop using the product and contact the nearest branch or sales office of TERUMO.

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