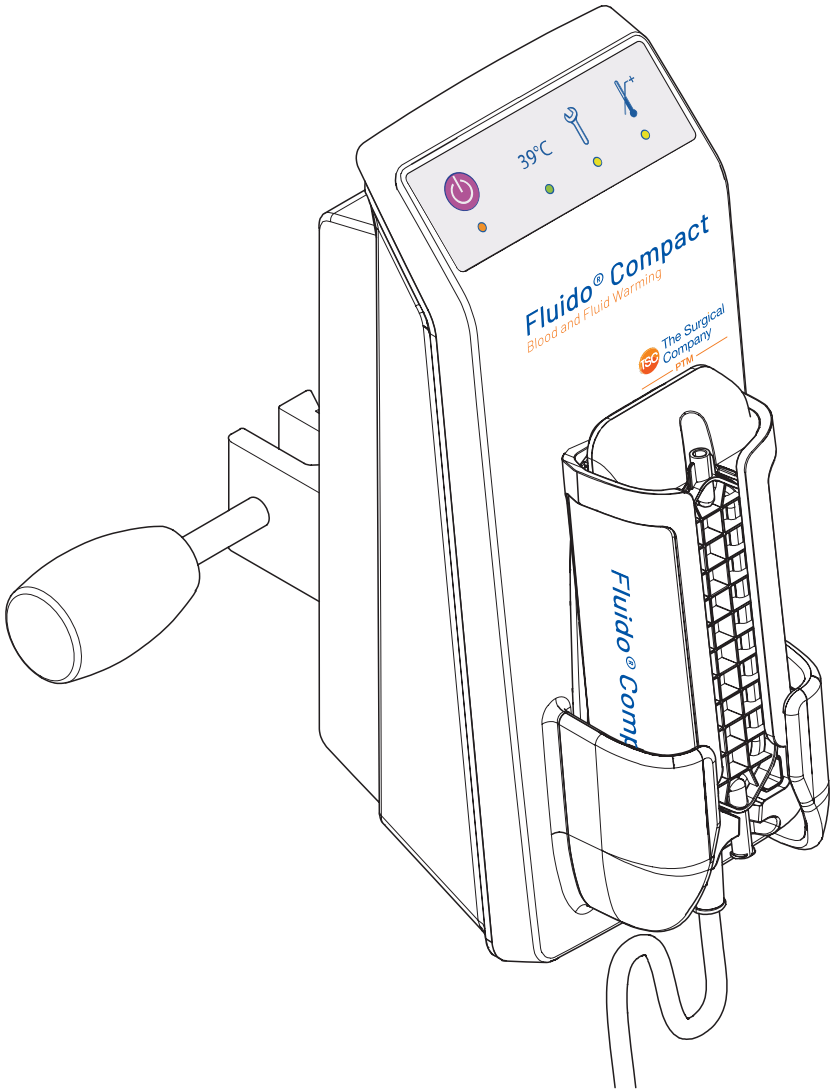
Fluido® Compact

Blood and Fluid Warming



User Manual / Technical Manual

Blood and Fluid Warming System

2023
Original instructions
Version: INT/R683-EN/4-07/23

The Surgical Company
PTM

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Contents

1 General information

1.1 About this manual

In this manual, you can find important information about how to operate the Fluido® Compact Blood and Fluid Warming System.

The device has the following modules:

- Fluido® Compact Contol Module (hereafter referred to as 'control module')
- Fluido® Compact (hereafter referred to as ‘warming module’)
- Two different disposable sets (referred to as 'disposable set'):
  - Fluido® Compact Standard Set (hereafter referred to as ‘standard set’)
  - Fluido® Compact Standard Set with drip chamber (hereafter referred to as ‘standard set with drip chamber’)
- Fluido® Compact Holder for Warming Module (hereafter referred to as ‘holder’)

The manual assists with the operation and the maintenance of the device in a safe and responsible manner.

Make sure that you use the most recent version of this manual. The updated manuals can be found at: *www.tsc-group.com/ptm*. Read this manual carefully. Perform the procedures in the sequence given. Always keep the manual with the device.

Please refer to the Fluido® Compact Blood and Fluid Warming System technical manual for maintenance, repair and calibration instructions. The technical manuals are available for download at the business partner menu of the The Surgical Company International B.V. website.

1.2 Intended use

The device is developed to supply warm fluids to a patient. The Fluido Compact Standard Set is developed for adults.

Use the device for warming:

- Crystalloid IV-fluids
- Synthetic Colloid IV-fluids
- Packed red blood cells

1.3 Contact

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3821 AH Amersfoort
The Netherlands

Tel: +31 (0)33 450 72 50

E-mail: *info.ptm@tsc-group.com*
Website: *www.tsc-group.com/ptm*

Refer to the website for local distributors.

1.4 Warranty

For the warranty provisions, refer to the website: *www.tsc-group.com/ptm*.

1.5 Authorisation of personnel

Caution! The Fluido® Compact Blood and Fluid Warming System may only be operated and/or serviced by duly trained and certified personnel who have been authorized to operate this system. For the avoidance of doubt, the instructions contained in this User Manual are solely intended for properly authorized personnel. [C059].

1.6 Warning, caution and note

Every "warning", "caution" and "note" is identified by a unique number in the format [W/C/N###]. [N015]

A "note" provides more information. [N000]

Warning!

A "warning" tells you that there is a risk of personal injury or death. [W000]

Caution!

A "caution" tells you that:

- there is a risk of damage to the device, and/or
- there is a risk of damage to other equipment. [C000]

1.7 Disclaimer

The information and/or instructions mentioned in this manual do not contain any advice regarding a medical treatment in the broadest sense of the term. This manual is provided for general informational/educational purposes and is meant as a guideline for the proper usage of the medical device(s) in question. Accordingly, before taking any actions based on this manual, the user shall be obliged to consult with the appropriate medical and healthcare professionals such as trained and certified clinicians.

The description and instructions regarding the medical device(s) mentioned in this manual have been compiled with the greatest possible care. Nonetheless, the user should be aware that The Surgical Company International B.V. can and may have made certain alternations and/or improvements regarding these medical device(s) which may not yet be adequately described in the current copy of the manual. Advisory notices and field safety corrections are always provided for important alterations in product use. All users are strongly advised to make sure that they consult the most recent version of the manual. The updated manuals are available for download at the The Surgical Company International B.V. website: *www.tsc-group.com/ptm*. Users are notified of updates to the manual by their distributor.

1.8 Intellectual property statement

This manual contains proprietary information of The Surgical Company International B.V. and all data mentioned herein are protected by copyright and patent laws and any other applicable statutory provisions regarding the protection of intellectual property, and may therefore not be reproduced, republished, disclosed to third parties, transmitted, displayed, broadcast or otherwise exploited in any manner whatsoever without the explicit prior written consent of The Surgical Company International B.V. The name and logo of The Surgical Company International B.V. and all related trademarks, trade names, and other intellectual property are and shall remain the exclusive property of The Surgical Company International B.V. and cannot be used without the latter's express prior written consent.

1.9 Frequently asked questions (FAQ)

Please contact your local distributor for an up-to-date overview of frequently asked questions with respect to the Fluido® Compact products.

2 Safety

2.1 General safety precautions

Refer to *Cleaning* on page 39 for general safety precautions.

2.1.1 Warnings

Warning!

- Use the device as intended. Refer to *Intended use* on page 6. [W053]
- Do not place the device near heat sources such as warming blankets or warming mattresses. [W068]

Materials

Warning!

- Use blood products that comply with local regulations. [W001]
- Do not mix red blood cells with drugs. See *Literature* on page 12: 3 and 4. [W003]
- Use saline solution (0.9 % Sodium Chloride) to dilute red blood cells to reduce the viscosity. See *Literature* on page 12: 1 and 2. [W004]
- Do not mix dextrose solution (5 %) with blood components. This can cause haemolysis. See *Literature* on page 12: 4 and 5. [W005]
- Do not use the device for warming whole blood, platelets, cryoprecipitates or granulocyte suspense. [W006]
- Prime the disposable sets with a sterile NaCl 0.9 % solution [W081]

Before operation

Warning!

- The Fluido® Compact Warming system is to be used only with the Fluido® Compact Control module and disposable sets. [W069]
- Do not use the device if the warming surface is damaged (e.g. dents, cracks). Take the device out of service and contact the hospital service department or the local supplier. [W011].
- Do not use the device in any of the following cases. Clean and dry the warming surface if:
  - the warming surface is wet (e.g. leaked IV fluids/blood, cleaning agents).
  - the warming surface is dirty (e.g. coagulated blood). [W070]
- Use a new hospital IV administration set for every application. (See *Literature* on page 12: 4). [W071]

- Follow the standard IV line protocols for priming the complete infusion set and the disposable set before connecting to a patient. Take care to ensure there is no air in the lines that may cause air embolism. [W020]
- Make sure that only authorised personnel use the device. [W023]
- Do not use a leukocyte reduction filter in combination with the disposable set. [W019]

Operation

Warning!

- Temporary interruption of the mains supply will place the device into standby mode and treatment will be discontinued. [W107]
- Do not position the warming module close to the head of the patient if inhaler therapy is used. [W072]
- If fluid leakage is observed, stop the fluid flow, and open the slider to disengage the device from operating. [W073]
- Warming IV fluids/blood may result in outgassing. Outgassing is more likely to occur when refrigerated fluids are used. Check the disposable set every 15 minutes for accumulated gas bubbles. These can cause air embolism. If bubbles are detected, re-prime the system, make sure that all air is removed and reconnect it to the patient. [W025]
- If the IV line runs dry, disconnect it from the patient. Re-prime the system, make sure that all air is removed and reconnect it to the patient. [W074]
- Do not use the disposable set for a period longer than 24 hours per patient. [W075]
- If the warming module is placed near the patient, make sure that:
  - it is placed on a stable surface;
  - it is placed near the patient infusion site;
  - the cable clamp is secured to the patient coverings;
  - the distance between the cable clamp and warming module is less than 10 cm. [W082]

After operation

Warning!

- Do not disconnect the device when it is on. Put the device into standby mode before disconnecting from the mains. [W077]
- Wait a few seconds after stopping the IV fluid/blood flow before removing the cassette of the disposable set. [W078]
- The device and its disposables may be a potential biohazard during and after use. Handle and dispose of in accordance with accepted medical practice and applicable local regulations. [W032]

Cleaning

Warning!

- Before you clean and desinfect the device, disconnect the power supply cord to eliminate risk of electrocution. [W051]
- After applying blood products, clean the hospital administration set with saline. [W031]
- If necessary, clean the warming module according to the hospital guidelines. See *Cleaning* on page 39. [W083]

2.1.2 Cautions

Caution!

- Do not use a sharp object to press the buttons on the control panel. [C002]
- Do not use the device outside the environmental specifications: see *Specifications* on page 53. [C005]
- Do not modify the device. Use of power supply cords or spare parts for internal components other than as specified by the manufacturer may lead to hazardous situations. [C007]

Materials

Caution!

- Never use defective disposable cassettes. Check the disposable for damage such as leakage, punctures and disconnected tubes. [C016]
- The disposable set only fits in the device when inserted in the correct direction. Do not use excessive force to insert the disposable set. [C032]

Before operation

Caution!

- The control module must be securely mounted. [C003]
- Connect the mains plug(s) to earthed wall socket(s) only. [C008]
- Install the device in such a way that you can easily disconnect the mains plug(s) from the wall socket in the event of an emergency. [C009]

Operation

Caution!

Do not block the ventilation openings of the control module. [C010]

Caution!

- Do not use dripping wet cloths. [C035]
- Do not use ketones (MEK, acetone, etc.) or abrasive cleaners. [C036]
- Do not use steam sterilization (autoclave) or dry heat to sterilize the device. [C037]
- Make sure that fluids cannot enter the electrical areas of the device. [C038]
- Do not use alcohol-based disinfectants (except isopropyl alcohol and ethanol dillutions). [C053]
- Do not use acid-based cleaners. [C054]
- Do not exceed the concentration specified by the manufacturer or use premixed solutions. [C055]
- Do not place the device upside down or on its sides. [C056]
- Make sure that you do not damage the user interface of the devices. If the user interface is wet, still dirty or damaged, do not use the device and replace the affected module. [C047]

2.1.3 Notes

- Use a high-flow system in case that the flows required are more than 100 ml/ min for more than 5 minutes. [N070]
- The device is not intended to control the core temperature of the patient by itself. The device is intended as a tool to help maintain a normothermic core temperature while monitoring the patient's core temperature directly by a dedicated sensor inside the patient's body. [N069].
- To remove all power, disconnect the power supply cord. [N040]
- The position of the warming module depends on the position of the IV catheter. [N041]
- The disposable can be interchanged between devices as long as they are not used with different patients or for longer than 24 hours. [N042]
- If the device gives a 'Technical Error' indication (see *Overview of the Control panel* on page 23), contact your local distributor or service department. [N043]
- When contacting the hospital service department or the local supplier for technical support, make sure to have the serial numbers and MOD records noted. [N024]

2.2 Literature

1. Reserved operations Blood transfusion, Jacques, M.B., Directorate Education & Training, 2008, Leids Universitair Medisch Centrum; Reader, 2009-04-06.

2. Guidelines for the use of blood warming devices, AABB, 2002.

3. Handbook of Transfusion Medicine, DBLL McClelland, UK blood service 4th Edition, ISBN 0-11-322677-2. 3. Handbook of Transfusion Medicine, DBLL McClelland, UK blood service 54th Edition, ISBN 0-11-7068462-2.
4. Blood and Transplant annual report, NHS, accounts : 2021 to 2022.
5. Influence of Dextrose of heparinized blood. Fantl P, Morris K.N. Thorax 1965: 20(4):372-5

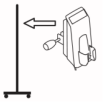
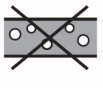
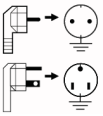
If you require a copy of the presented literature, contact your local distributor [N001]

2.3 Symbols

Rx Only	Federal US law restricts this device to sale by or on order of a physician.
IPX1	The device is protected against dripping water (according to IEC 60529).
IPX4	The device is protected against splashing water (according to IEC 60529).
P	Pressurized device (according to ISO 1135-5 and ISO 8536-8)
UL CERTIFIED SAFETY US-CA E348441	UL certified as to electrical shock, fire and mechanical hazards only, in accordance with ANSI/AAMI ES60601-1:2005 + C1:2009 + A2:2010 + A1:2012, IEC 60601-1-6:2010 + A1:2013, CAN/CSA-C22.2 No. 60601-1:2014, CAN/CSA-C22.2 No. 60601-1-6:2011 + A1:2015
	Caution: risk of electrical shock.
CE 0344	CE marking of conformity
MD	Medical Device
SN	Serial number
REF	Catalogue / article number / part number
QTY	Quantity
STERILE EO	Method of sterilisation: ethylene oxide.
VOL	Priming volume

	Batch code / lot number
	Manufacturer
	Manufacturing date
	Number of drops per ml
	Transport and storage ambient temperature limits
	Transport and storage relative humidity limits
	Transport and storage atmospheric pressure limits
	Do not use the device if the package is damaged.
	Keep away from sunlight.
	Keep away from rain.
	AC voltage
	Type BF applied parts (according to IEC 60601-1)

	Class II equipment
	Fuse
	Expiry date (year/month)
	Single patient use only. Do not reuse.
	Not made with natural rubber latex.
	Read the user manual.
	Consult the instructions for use.
	Dispose according to European Community Directive 2012/16/EU (WEEE)
	Caution. Consult the instructions for use for important cautionary information.
	Check the device and the power cords for damage. Do not use the device if it is damaged.
	Do not use a damaged disposable set to prevent damage to the device.
	Do not immerse the device. Clean the appliance with standard cleaning agents. See *Cleaning* on page 39.

	Attach the device to a pole before you use the device.
	De-aerate the disposable set before you use the device.
	Make sure that the pressure does not exceed 300 mmHg. Do not use a pressure device without pressure indicator or a manually driven pressure device.
	Plug the device into an earthed mains socket.
	Do not move the device on a pole during use. Remove the device from the pole before you move it.
	Non-pyrogenic
	When (dis)connecting the interface cable, make sure the mains plug is disconnected from the electrical outlet (see *Warnings* on page 9).
	The Fluido® Compact Control module and the Warming module are MR unsafe.

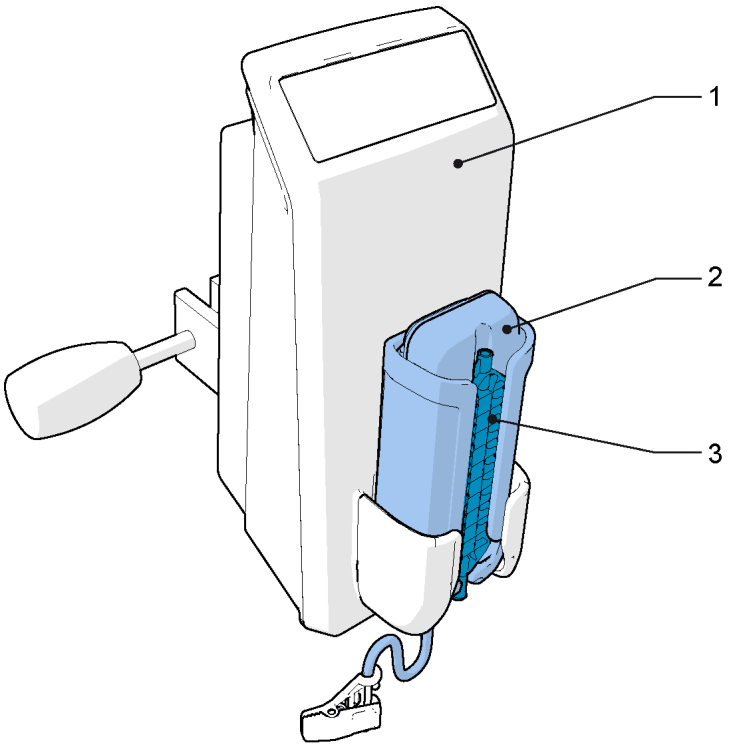
3 Description

The Fluido® Compact System is a Blood and Fluid Warming System. The system is suitable for low to moderate flow applications. For high flow applications (higher than 100 ml/min) the use of a Fluido® AirGuard System is recommended.

The Fluido® Compact System uses conduction heating technology to warm blood and fluids. Based on in-line sensors, the system calculates the energy required to safely warm the infusates.

3.1 Overview of the device

The Fluido® Compact System consists of a control module, a warming module and a disposable set, as seen in the picture below.

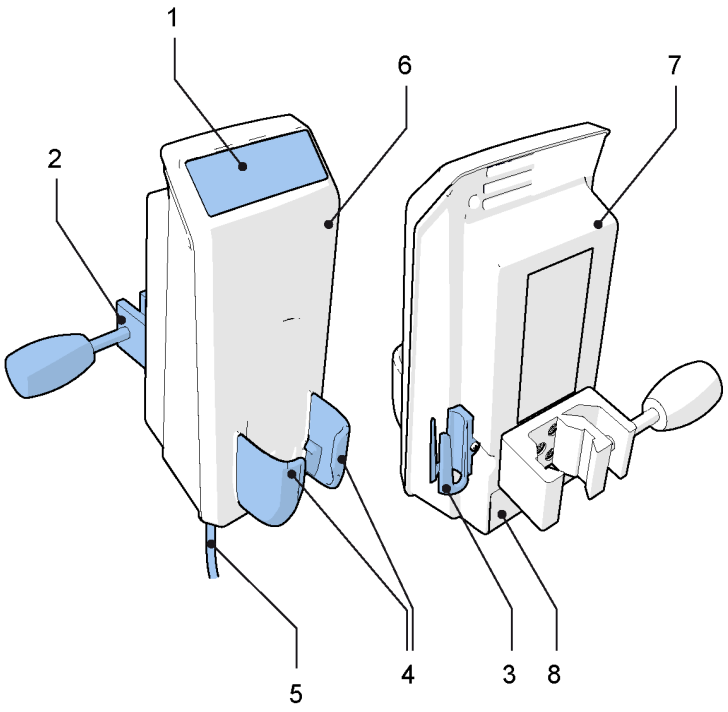


1. Control module
2. Warming module
3. Disposable set

3.2 Overview of the Control module [REF 650100]

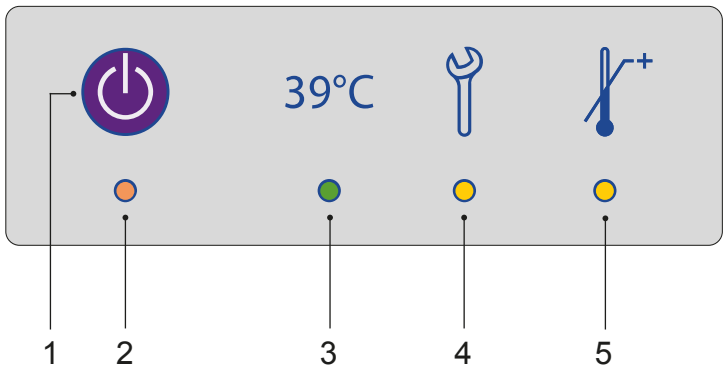
The control module supplies the warming module with the necessary power to heat fluids to the desired setpoint. This module has a user interface that indicates the status of the device.

The control module consists of the following components:



1. Control panel
2. Universal clamp
3. Drip chamber holder
4. Warming module holder
5. Power supply cord
6. Front cover
7. Back cover
8. Hatch

The control panel contains the following buttons and indicators:

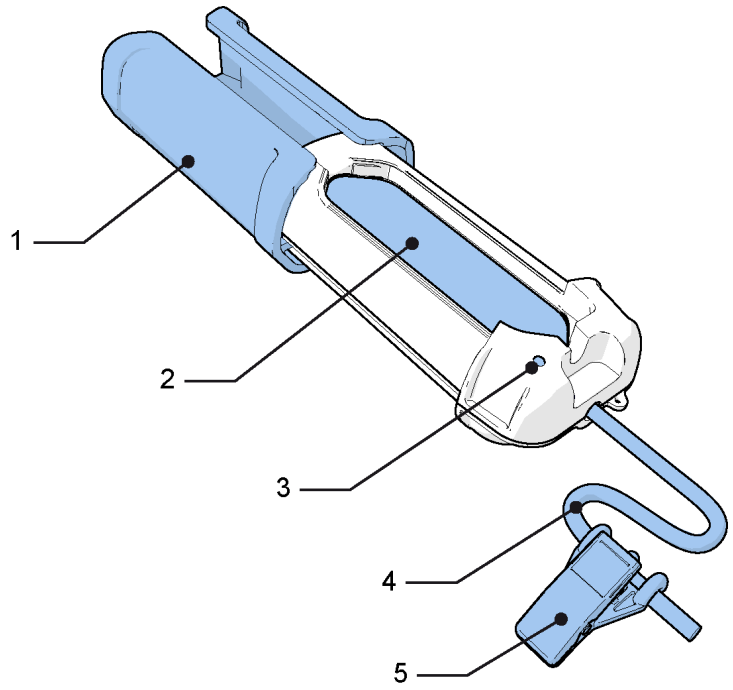


1. Standby/on button
2. Standby/on indicator
3. Setpoint indicator
4. Technical error
5. Overtemperature indicator

3.3 Overview of the Warming module [REF 650200]

The warming module is the heating element of the system. It hosts the disposable cassette and provides the required and controlled heating power to warm up fluids to the device setpoint.

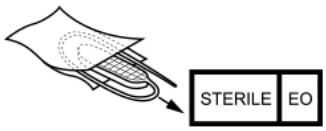
The warming module consists of the following components:



1. Slider
2. Warming interface
3. Status indicator
4. Interface cable
5. Cable clamp

3.4 Overview of the disposable sets

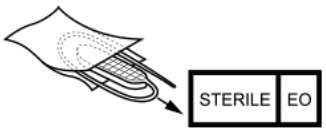
Warning!

- 

  The disposables are provided in a sterile state. Use clean disposable sets and use them in the sterile field only. Once removed from the packaging, use the disposable set immediately. The disposable set can be used for a maximum of 24 hours. [W080]

- 

  Do not use the disposable set if the package is damaged. [W109]

- 

  The disposables are provided in a sterile state. Use clean disposable sets and use them in the sterile field only. Once removed from the packaging, use the disposable set immediately. The disposable set can be used for a maximum of 24 hours. [W080]

- 

  Do not use the disposable set if the package is damaged. [W109]

Caution!

Never use defective disposable cassettes. Check the disposable for damage such as leakage, punctures and disconnected tubes. [C016]

The disposables enable the device to transfer the produced heat to the fluids circulating through the tubing and cassette. The disposables are single-use only and provided sterile.

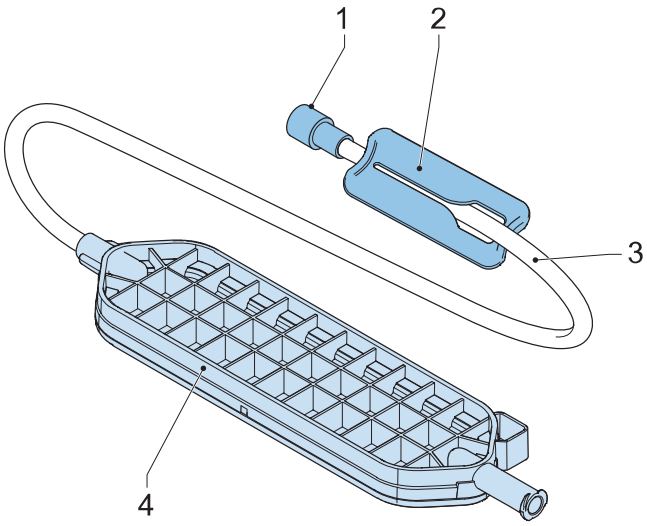
The disposables consist of a cassette of polycarbonate with a coated metallic plate that enables the heat transfer. The inlet and outlet of the cassette are provided with universal luer lock connectors.

The Fluido® Compact System may only be used with the following Fluido® Compact disposable sets and accessories:

- Fluido® Compact Standard Set
- Fluido® Compact Standard Set with drip chamber

3.4.1 Overview of the Standard Set [REF 672000]

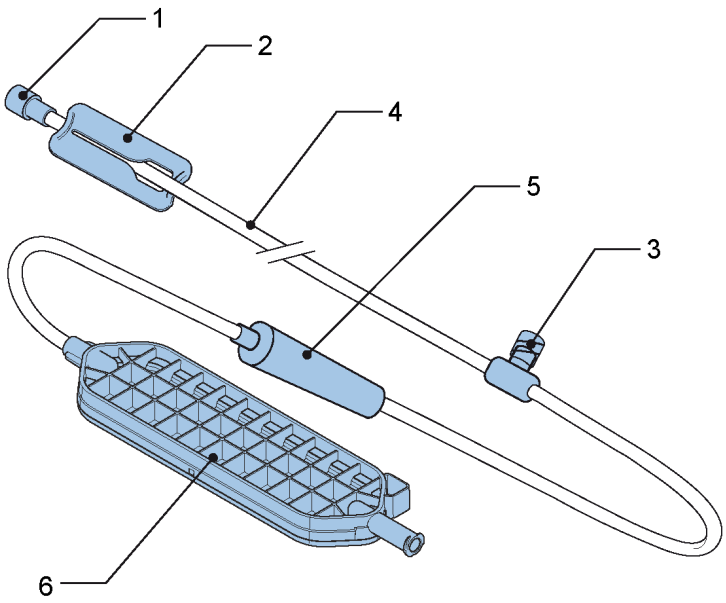
The Standard Set consists of the following components:



1. Patient line connector
2. Slide clamp
3. Patient line
4. Cassette with connector

3.4.2 Overview of the Standard Set with drip chamber [REF 672100]

The Standard Set with drip chamber consists of the following components:

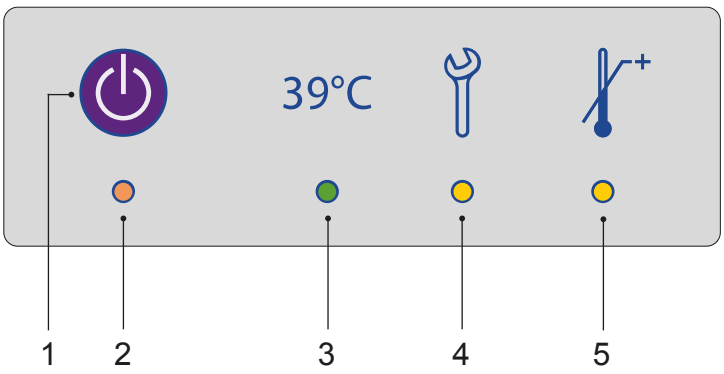


1. Patient line connector
2. Slide clamp
3. T-connector (female) with cap
4. Patient line
5. Drip chamber
6. Cassette with connector

- The Standard Set with drip chamber might not be available in some markets. For more information contact your local distributor. [N036]
- The drip chamber is meant to be used as a deaeration chamber. [N037]

3.5 Overview of the Control panel

The control panel contains the following buttons and indicators:



1. Standby/on button
2. Standby/on indicator
3. Setpoint indicator
4. Technical error
5. Overtemperature indicator

3.6 Indicator behavior

Control module indicator (see *Overview of the Control module [REF 650100]* on page 18)

Indicator	Behaviour	Meaning
Standby/on	Off	The device is not powered.
	Orange continuous	The device is in standby mode.
	Green continuous	The device is operational.
Setpoint	Off	The device has not detected the disposable.
	Green continuous	The derived fluid temperature at the outlet of the disposable cassette is within range (39 ± 2 °C). See *System performance* on page 26.
	Green flashing	The Setpoint has not been reached.
Technical error	Yellow continuous	A technical error is detected. This visual indicator is accompanied with an audible signal.
Overtemperature	Yellow blinking	Overtemperature protection circuit has been triggered. See*Overtemperature indicator* on page 24.

Warming Module indicator

Indicator	Behaviour	Meaning
Status	Orange continuous	No disposable set is present or the disposable set is placed incortrectly.
	Green continuous	The disposable set is installed correctly. The system is warming.

3.6.1 Set-point-indicator

The system controls the fluid outlet temperature to 39°C and does this with an accuracy of ± 2°C. The set point indicator indicates if the derived fluid temperature at the outlet of the disposable cassette is within range (39 ± 2°C) or not.

The required amount of heating power depends on the fluid flow rate and the fluid inlet temperature. When the required heating power exceeds the maximum effective heating power, the system is no longer able to warm the fluid to 39°C and the outlet temperature will be lower.

Extending the patient line can result in lower fluid temperatures at the end of the patient line.

3.6.2 Repair required indicator

Perform the following steps when the repair required indicator is active (continuously yellow):

1. Check if the interface cable of the warming module is correctly attached and locked to the control module.
2. Reset the device: Disconnect the power supply cord, wait a few seconds and reconnect the power supply cord.

   If the problem persists, the system needs to be replaced.

3.6.3 Overtemperature indicator

Perform the following steps when the overtemperature indicator is active (continuously yellow):

If the problem persists, the system needs to be replaced.

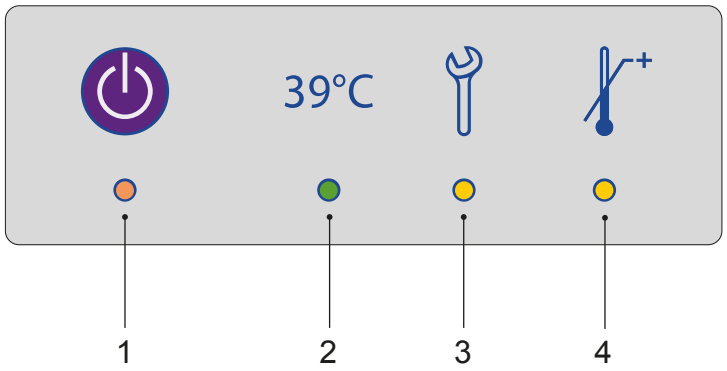
1. Check the disposable cassette for air or air bubbles. If air or air bubbles are present, prime the set again (see Prime the standard set on page 25).

2. Check if the warming surface of the warming module is wet or contaminated. If wet or contaminated, clean and dry the surface (see *Cleaning* on page 39).
3. Reset the device: Disconnect the power supply cord, wait a few seconds and reconnect the power supply cord.

   If the problem persists, the system needs to be replaced.

In case of overtemperature, both the repair required and overtemperature indicators are active (continuously yellow). When the system is warming, an audible alarm (repeating beep) is also active.

3.6.4 Indicator summary



	Response Expected				
ID	**Control module**				**Summary**
		39°C			
1	Off	Off	Off	Off	Device not plugged in
2	Orange	Off	Off	Off	Device is in standby
3	Green	Green	Yellow	Yellow	Indicator test running
4	Green	Off	Off	Off	Device on with no disposable
5	Green	Blinking	Off	Off	Device has not reached the setpoint
6	Green	Green	Off	Off	Device is warming fluids at the right setpoint (39 ± 2 °C
7	Green	Off	Yellow	Off	Technical error
8	Green	Off	Off	Blinking	Overtemperature error
9	Green	Off	Yellow	Blinking	Technical and overtemperature error

3.7 Indicator functionality verification

The alarm system is tested during the device startup when pressing the standy button. At this moment, an audible signal will be triggered and all the panel indicators will be lit

Warning! Ensure that the indicators are working and illuminating correctly before using the device. In the situation that the indicators are not correctly illuminated or the acoustic signal cannot be heard during startup, stop using the device and contact your local technical department [W119].

3.8 System performance

The system controls the fluid outlet temperature to 39 ± 2 °C measured at the end of the cassette in an environment at 20 ± 2 °C. The setpoint indicator shows if the temperature is within range.

Warning! Do not start infusing cold fluids before the device has detected the disposable. [W103]

- The required amount of heating power depends on the fluid flow rate and the fluid inlet temperature. When the required heating power exceeds the maximum power, the system is no longer able to warm the fluid to 39 ± 2 °C and the outlet temperature will be lower. [N066]
- The temperature at the end of the patient line depends on the fluid flow rate and environmental conditions. [N067]
- Extending the patient line can result in lower fluid temperatures at the end of the patient line. [N035]
- Flow changes must be done progressively and not suddenly to ensure the optimal performance of the device. [N068]

4 Installation

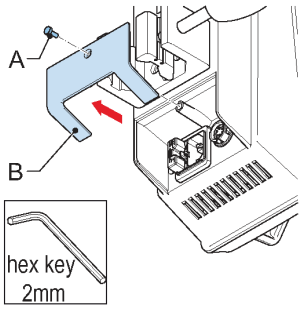
4.1 Transport and storage

Store the device and accessories according to the transport and storage recommendations. See *Specifications* on page 53.

4.2 Install the cables

4.2.1 Remove hatch

1. Remove the bolt (A) from the hatch, using a 2 mm hex key. The used bolt is: M3×8 A2-70 DIN7984.
2. Remove the hatch (B).

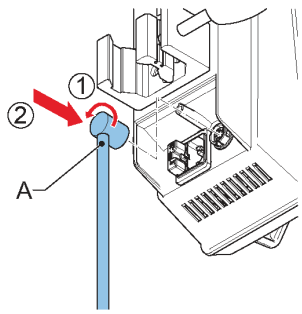


4.2.2 Install the cables

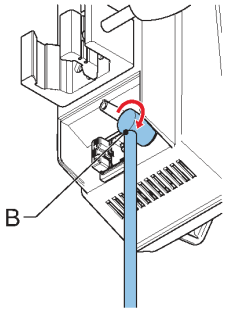
Caution!

Before connecting the interface cable, make sure the mains plug is disconnected from electrical outlet. [C048]

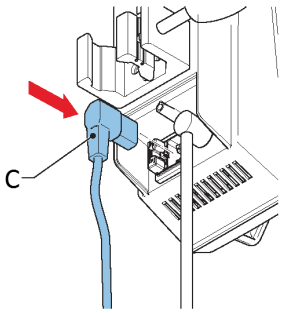
1. Turn the connector ring on the interface cable (A) to the open position.
2. Connect the interface cable.

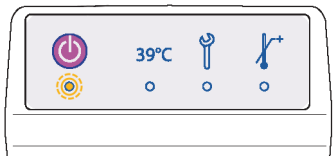


3. Turn the connector ring on the interface cable (B) to the locked position.



4. Connect the power supply cord (C).



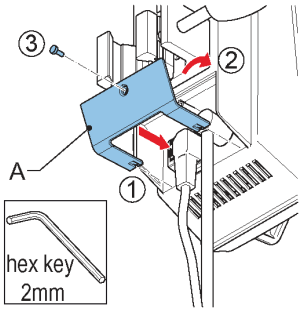
Expected indicator response


Refer to *Troubleshooting* on page 59 it the device gives a different response than the described expected response.

5. Place the hatch (see *Place hatch* on page 28).

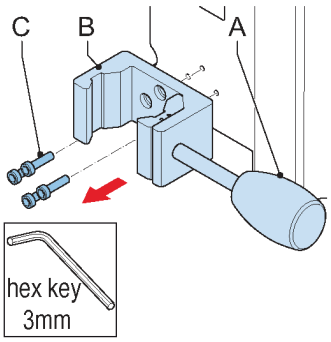
4.2.3 Place hatch

1. Place the lower parts of the hatch (A).
2. Rotate the hatch upwards until it is closed.
3. Fasten the bolt in the hatch.

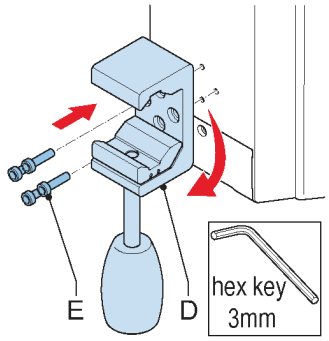


4.3 Change the rotation of the universal clamps (optional)

1. Turn the universal clamp 90° if you want to install the universal clamp to a bed rail:
   Turn the knob (A) until the universal clamp (B) is fully open.
2. Loosen the bolts (C), using a 3mm hex key.
   The used bolts are: M5X12 A2–70 DIN7984.



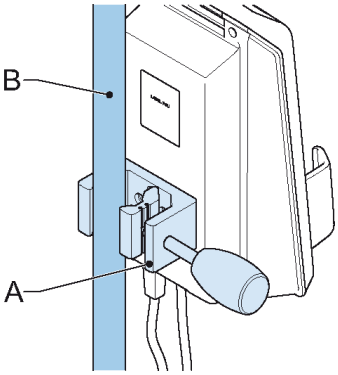
3. Turn the universal clamp (D) 90°.
4. Fasten the bolts (E).



4.4 Attach the device

- When installing the device, make sure that the operator can read the control panel from his normal working position. [N038]
- The clamp can also be rotated 90° to fit DIN rails. Please refer to the technical manual for more information. [N039]

1. Open the universal clamp (A).
2. Position the control module such that universal clamp is placed correctly on the IV pole (B) or bed rail.
3. Close the universal clamp.



Caution!

Make sure that the device is securely clamped to the pole before operation. [C040]

5 Operation

5.1 Safety Instructions before operation

Warning!

- Do not add calcium-rich supplements as priming solution before the infusion of blood to prevent blood clots. [W007]
- Make sure that only authorised personnel use the device. [W023]
- The Fluido® Compact Blood and Fluid Warming System is to be used only with the Fluido® Compact control module and Fluido® Compact disposable sets. [W069]
- The use of cold fluids might lead to outgassing. When infusing cold fluids below room temperature, use a Fluido® Compact Standard Set with drip chamber and check it every 15 minutes for air. In case the Fluido® Compact Standard Set with drip chamber is not available in your region, make sure to prewarm the fluids at room temperature to reduce the outgassing.[W110]
- Do not use the device if the warming surface is damaged (e.g. dents, cracks). Take the device out of service and contact the hospital service department or the local supplier. [W011]

Caution!

- Do not block the ventilation openings of the control module. [C010]
- The control module must be securely mounted. [C003]
- Connect the mains plug(s) to earthed wall socket(s) only. [C008]
- Install the device in such a way that you can easily disconnect the mains plug(s) from the wall socket in the event of an emergency. [C009]

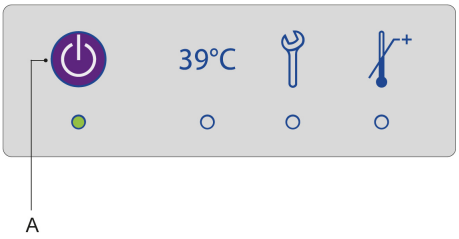
- To remove all power, disconnect the power supply cord. [N040]
- The device is approved for electromagnetic interference according to IEC 60601-1-2. Details on electromagnetic compatibility can be found in *Electromagnetic compatibility* on page 55.

5.2 Preparation before operation

Before you prepare the device, ensure that the device is installed correctly (refer to *Installation* on page 27).

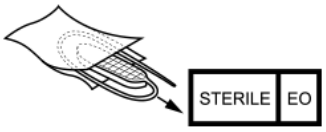
5.2.1 Turn the device on

1. Connect the device to the power outlet.
   The standby/on indicator on the control module will light orange.
2. Push the standby/on button (A).
   - You will hear a single beep.
   - The indicators on the control module flash one time.
   - The standby/on indicator should stay green.
   - The status indicator on the warming module is now orange.



5.2.2 Install the disposable set

Warning!

- 

  The disposables are provided in a sterile state. Use clean disposable sets and use them in the sterile field only. Once removed from the packaging, use the disposable set immediately. The disposable set can be used for a maximum of 24 hours. [W080]

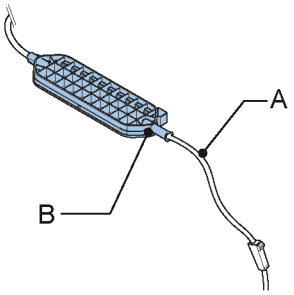
- 

  Do not use the disposable set if the package is damaged. [W109]

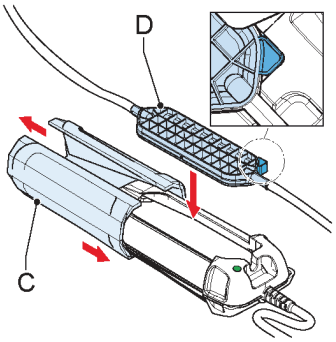
Caution!

Never use defective disposable cassettes. Check the disposable for damage such as leakage, punctures and disconnected tubes. [C016]

1. Unpack and inspect the disposable set.
2. Connect the hospital administration set (A) to the cassette of the disposable set (B).
3. Take the warming module out of the warming module holder.



4. Open the slider (C) of the warming module.
5. Put the cassette of the disposable set (D) in the warming module. The cassette fits in only one way.



Caution!

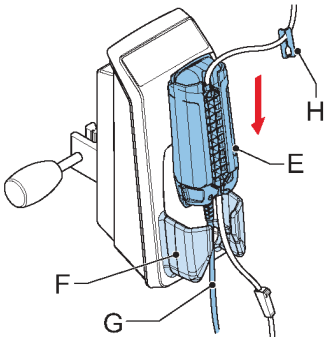
The disposable set only fits in the device when inserted in the correct direction. Do not use excessive force to insert the disposable set. [C032]

6. Close the slider.
The status indicator on the warming module is now green, indicating that the device is warming.
Refer to *Warming module* on page 61 if the status indicator stays orange.

When the status indicator on the warming module stays orange the detection of the disposable set failed.

- Remove the set (see *Stop the device* on page 37)
- Check the heating surface for damages and contamination.
- Check the cassette of the disposable set for damages and contamination.
- Prime the disposable set (see *Prime the standard set* on page 33)
- Install the disposable set again.
- Wait until the set point indicator LED on the control module stays green.

7. The setpoint indicator should flash green until the required temperature is reached.
8. Put the warming module (E) in the warming module holder (F) with the interface cable (G) downwards.



Warning! If the warming module is placed near the patient:

- Make sure it is placed on a stable surface.
- Make sure it is placed near the patient infusion site.
- Make sure the cable clamp is secured to the patient coverings.

- Make sure the distance between cable clamp and warming module is less than 10 cm.

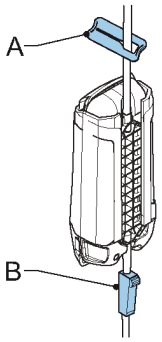
5.2.3 Prime the standard set

Warning!

- Follow the standard IV line protocols for priming the complete infusion set and the disposable set before connecting to a patient. Be careful that no air remains in the lines. It may cause air embolism. [W020]
- Prime the disposable sets with a sterile NaCl 9 % solution [W081]

Prime the hospital administration set and the standard set.

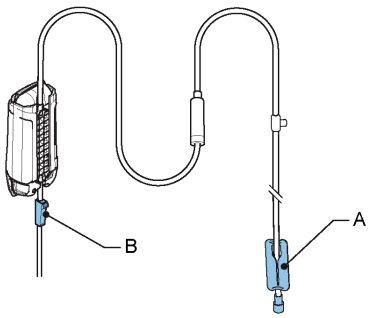
1. Hold the standard set in the upright position.
2. Open the slide clamp (A) of the standard set.
3. Open the roller clamp (B) of the hospital administration set. Make sure that there is no air left in the system.
4. Close the roller clamp.



5.2.4 Prime the standard set with drip chamber

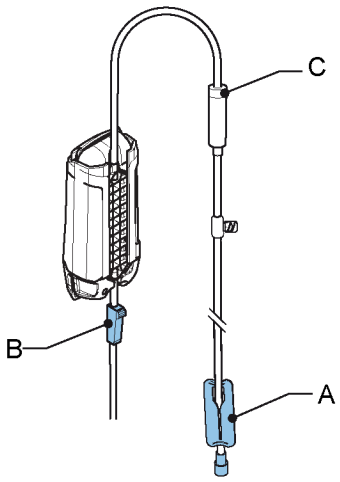
Prime the hospital administration set and the standard set with drip chamber.

1. Hold the standard set with drip chamber in the upright position and the drip chamber upside down.
   Make sure that the slide clamp (A) of the standard set with drip chamber and the roller clamp (B) of the hospital administration set are open.
   Make sure that there is no air left in the system.
2. Close the roller clamp.
3. Place the drip chamber upright in the holder.

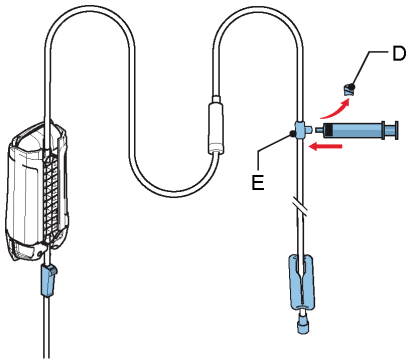


5.2.5 Deaerate standard set with drip chamber

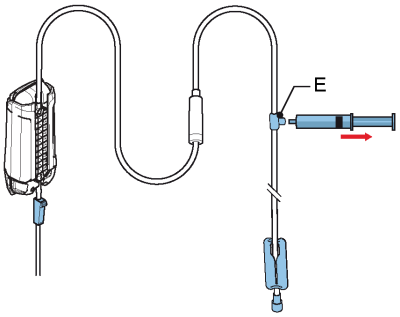
1. Hold the disposable set in the upright position.
   Make sure that the slide clamp (A) of the disposable set is closed and the roller clamp (B) of the hospital administration set is open.
2. Hold the drip chamber (C) upside down.



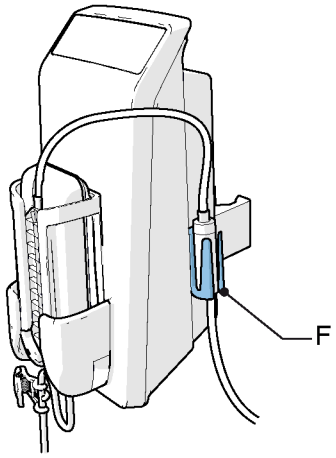
3. Remove the cap (D) from the T-connector (E) and connect to a syringe.
4. Remove excess air from the system.



5. Disconnect the syringe from the T-connector (E) and reconnect the cap.



6. Put the drip chamber back in the holder (F).



Warning!

If fluid leakage is observed, stop the fluid flow, and open the slider to disengage the device from operating. [W073]

The disposable can be interchanged between Fluido® Compact devices as long as they are not used with different patients or for longer than 24 hours. [N042]

5.3 Operate the device

Warning!

- 

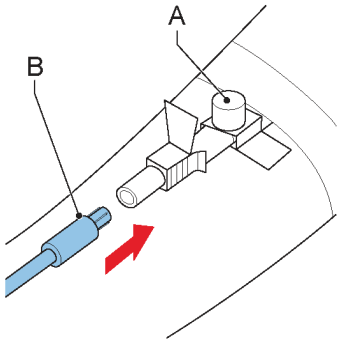
  Only use a pressure device, such as a syringe, at an injection point at the end of the patient line (A). Using a pressure device on the cold side of the cassette might damage its sealing and produce leakages. [W076]

- 

  Make sure that the pressure on the line does not exceed 300 mmHg. [W062]

Before you operate the device, prepare the device (refer to *Preparation before operation* on page 30).

Put the warming module near the patient.

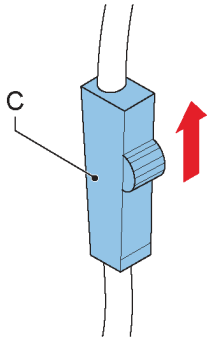


Warning!

Do not position the warming module close to the head of the patient if inhaler therapy is used. [W072]

- The position of the warming module depends on the position of the IV catheter. [N041]
- The device is not equipped with an isolating switch. Temporary interruption of the mains supply will place the device into standby mode and treatment will be discontinued. [N002]

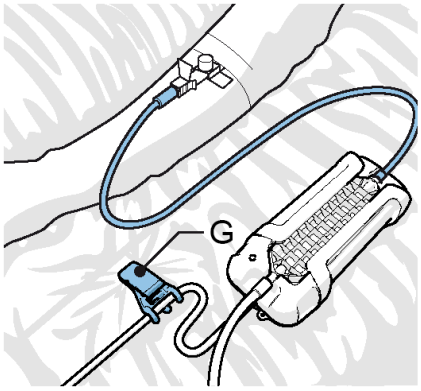
2. Connect the patient line (B) to the IV catheter.
3. Open the roller clamp (C).



Warning!

Do not make abrupt changes in the flow during operation. Changes in flow must be smooth and progressive. [W108]

4. The warming module can be placed near the patient infusion site. Secure the cable clamp (G) to the patient coverings.



Warning!

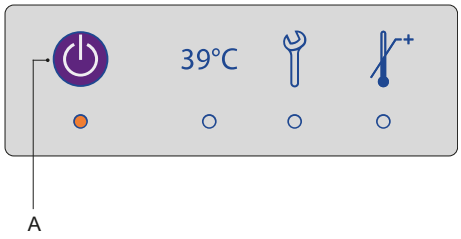
If the warming module is placed near the patient, make sure that:

- it is placed on a stable surface;
- it is placed near the patient infusion site;
- the cable clamp is secured to the patient coverings;
- the distance between the cable clamp and warming module is less than 10 cm. [W082]

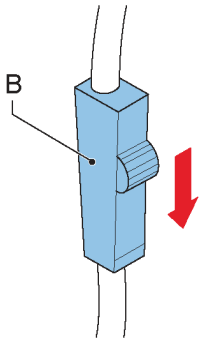
5. Make sure that the slide clamp (A) is open.

5.4 Stop the device

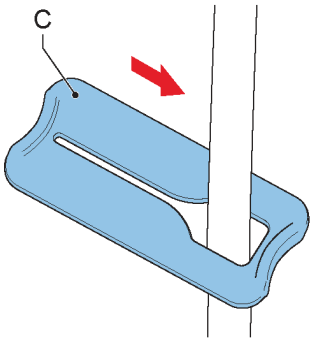
1. Push the standby/on button (A).
   The status indicator of the warming module is now orange.



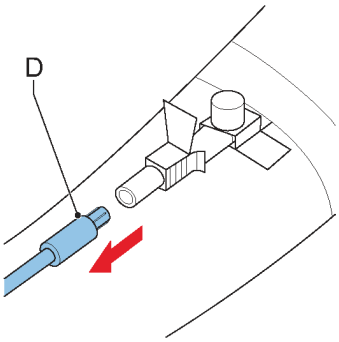
2. Close the roller clamp (B) of the hospital administration set.



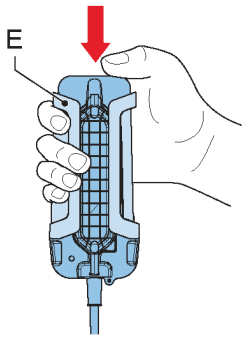
3. Close the slide clamp (C) of the patient line.



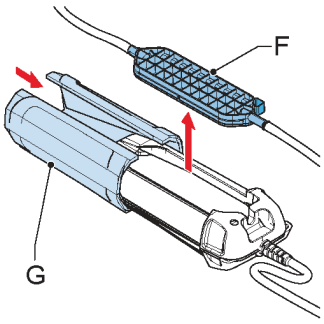
4. Disconnect the patient line (D) from the IV catheter.



5. Open the slider (E).



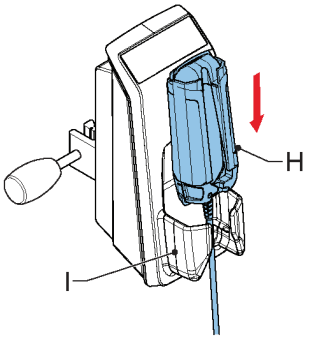
6. Remove the disposable set (F) from the warming module.



Warning!

If necessary, clean the warming module according to the hospital guidelines. See *Cleaning* on page 39. [W083]

7. Close the slider (G).
8. Put the warming module (H) in the warming module holder (I).
9. Dispose of the disposable set appropriately.



Warning!

The device and its disposables may be a potential biohazard during and after use. Handle and dispose of in accordance with accepted medical practice and applicable local regulations. [W032]

6 Maintenance

If the device gives a ‘repair required’ indication (see *Overview of the Control panel* on page 23), contact your local distributor or service department. [N043]

For the device, several spare parts are available (see *Repair* on page 42). The heating element of the warming module cannot be changed

If a problem occurs with the system, please refer to *Troubleshooting* on page 59.

If you contact the hospital service department or the local supplier for technical support, make sure that you have the serial number and MOD record of the affected device. You can find the device serial number on the product label.

6.1 Precautions

Warning!

- Maintenance may only be performed by trained biomedical technicians or engineers. [W049]
- Preventive maintenance needs to be performed on an annual basis. Please refer to the Fluido® Compact technical manual for maintenance, repair and calibration instructions. [W050]

Caution!

End users should not open the modules of the system. End users should not try to repair the system in the event of a malfunction. This can damage the appliance and will void the warranty. [C034]

When contacting the hospital service department or the local supplier for technical support, make sure to have the serial numbers and MOD records noted. [N024]

6.2 Cleaning

6.2.1 General cleaning procedure

Warning!

Before you clean the device, disconnect the power supply cord to eliminate risk of electrocution. [W051]

Caution!

- Do not use dripping wet cloths. [C035]
- Do not use ketones (methyl ethyl ketone [MEK], acetone, etc.) or abrasive cleaners. [C036]
- Do not use steam sterilization (autoclave) or dry heat to sterilize the device. [C037]
- Do not immerse the device in liquids. Otherwise, the device can be damaged. [C004]
- Make sure that fluids cannot enter the electrical areas of the device. [C038]
- Do not place the device upside down or on its sides. [C063]
- Make sure that you do not damage the interface of the devices. If the interface is wet, still dirty or damaged, do not use the device and replace the affected module. [C047]
- Use one of the following cleaning solutions:
  - 90% (or 70%) isopropyl alcohol
  - mild detergent solution - See User Manual / Technical Manual: *Maintenance* on page 39
  - diluted chlorine bleach (30 ml/l water)
  - ammonia based cleaners
  - glutaraldehyde-based cleaners 2.4%
  - hydrogen peroxide 3%

The cleaning procedure in this chapter is applicable to all modules of the device. [N044]

Cleaning

Warning! Clean the device immediately after becoming dirty to reduce the risk of infection for the patient. [W114]

After each use, clean all exterior surfaces of the reusable components according to the following validated cleaning procedure.

1. Visually inspect the components to ensure there is no visible damage or deterioration of the enclosures such as cracks, or deterioration of the labels and power cord. Do not clean if there is a defect and contact The Surgical Company International B.V. or your local distributor.
2. Immerse a soft cloth or sponge as an applicator into the cleaning solution consisting of mild liquid detergent soap and warm tap water mixture. Squeeze out the excess solution so that the applicator is not dripping. Wipe or scrub the entire surface of the enclosure and control panels thoroughly. Use a soft brush with a cleaning solution to clean the power cord if necessary.
3. To remove dried blood, clean with 3% hydrogen peroxide or water diluted chlorine bleach (30 ml/l) with a soft cloth.

4. Rinse a separate soft cloth or sponge in room temperature tap water. Squeeze out excess water so that the applicator is not dripping. Wipe all of the aforementioned surfaces thoroughly. Repeat rinsing the cloth or sponge several times with fresh running water during this process to ensure all visible detergent residue is removed from the device.
5. Dry the item with a hand towel or soft cloth.
6. Visually inspect all components to ensure that they have been thoroughly cleaned. Repeat cleaning procedure if necessary
7. After thoroughly cleaning all exterior surfaces of the reusable components, perform disinfection according to the following validated disinfection procedure.
8. If the device is determined not to be visually clean at the end of the cleaning step, the user should either repeat the relevant previous cleaning steps or safely dispose of the device, so that a visibly soiled device is not used again.

Disinfection:

Warning! Only disinfect the device after conducting the cleaning procedure as described above. [W115]

After cleaning, disinfect all exterior surfaces of the reusable components according to the following validated disinfection procedure.

9. Disinfect all exterior surfaces of the reusable components with one of the following validated disinfectants, which can be safely used without causing damage to the enclosure:
   - 70 % ethyl alcohol (ethanol)-based disinfectants, contact time ≥ 7 minutes
   - 70 % isopropyl alcohol (isopropanol)-based disinfectants, contact time ≥ 7 minutes

   Follow the disinfectant user instructions, including the application method.
10. After thoroughly disinfecting, rinse a soft cloth or sponge in room temperature tap water. Squeeze out excess water so that the applicator is not dripping. Wipe all surfaces thoroughly to remove residual disinfectant.
11. Dry the item with a hand towel or soft cloth.
12. Store the clean device in a non-contaminated area when not in use.

6.2.2 After cleaning

Warning!

Do not use the device in any of the following cases.

- The warming surface is damaged (e.g. dents, cracks).
- The warming surface is wet (e.g. leaked IV fluids/blood, cleaning agents).
- Make sure that the unit is clean and dry before using it.
- The warming surface is dirty (e.g. coagulated blood). [W084]

Clean and dry the surface after cleaning. If the device is still dirty, take the device out of service.

7 Repair

Warning!

- The Fluido® Compact System must not be serviced or repaired while in use with a patient. [W086]
- The device may only be opened or repaired by certified technicians. [W087]
- Only service clean and decontaminated devices. [W088]
- Before opening the device, make sure the mains power cable is unplugged. [W089]
- After repair, always test the device according to *Test the device* on page 49 [W090].

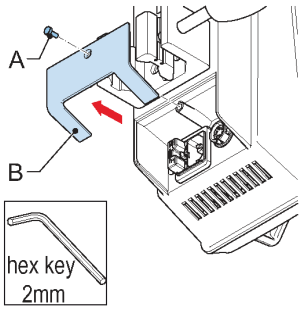
Refer to *Troubleshooting* on page 59 if the device gives a different response than expected response described in the procedure.

For a list of available spare parts, please visit our website: *www.tsc-group.com/ptm*. Repairs may only be performed by trained biomedical technicians or engineers. These must be trained by authorized personnel from The Surgical Company International B.V.. Any unauthorized repair might void the warranty.

7.1 Hatch

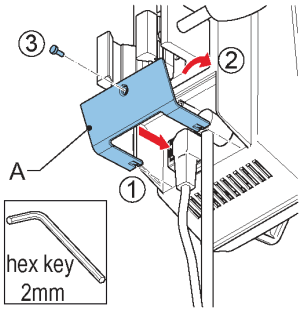
7.1.1 Remove hatch

1. Remove the bolt (A) from the hatch, using a 2 mm hex key. The used bolt is: M3×8 A2-70 DIN7984.
2. Remove the hatch (B).



7.1.2 Place hatch

1. Place the lower parts of the hatch (A).
2. Rotate the hatch upwards until it is closed.
3. Fasten the bolt in the hatch.



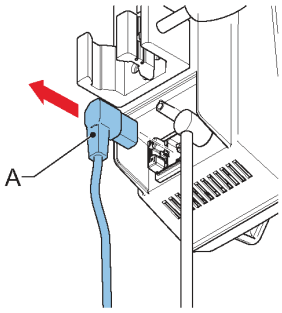
7.2 Cables

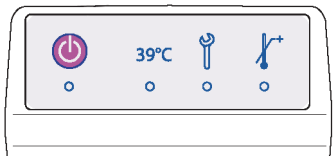
It is sometimes necessary to remove the cables as part of another repair procedure.

Caution!

When disconnecting the interface cable, make sure the mains plug is disconnected from electrical outlet first. [C050]

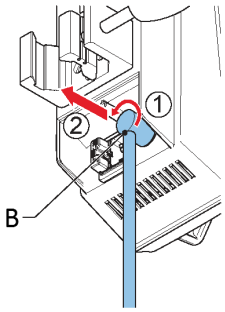
1. Remove the hatch (see *Remove hatch* on page 27).
2. Disconnect the power supply cord (A).



Expected indicator response
 The indicator in the warming module is also off.

Refer to *Troubleshooting* on page 59 if the device gives a different response than the described expected response.

4. Turn the connector ring on the interface cable (B) anticlockwise to the open position.
5. Disconnect the interface cable.



7.3 Fuse

The fuse must be replaced after it is tripped.

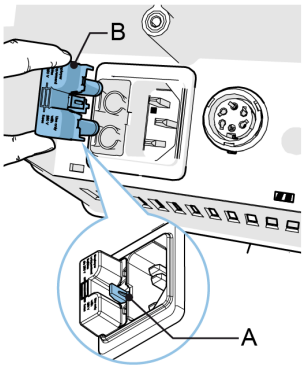
Warning!

Always replace the fuse with a new fuse of the correct type. Incorrect fuse replacement might constitute a fire or electrical hazard. [W091]

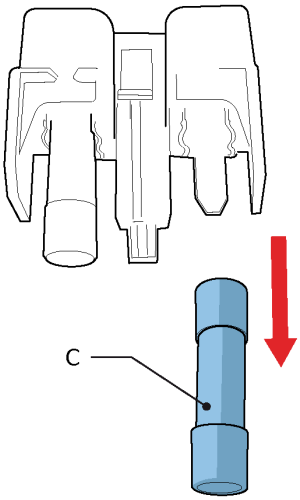
Caution!

Always investigate the reason of a tripped fuse. Solve the underlying issue before replacing the fuse and putting the device into use. If damage to the device has emerged during the investigation, do not put the device into use and contact your distributor. [C051]

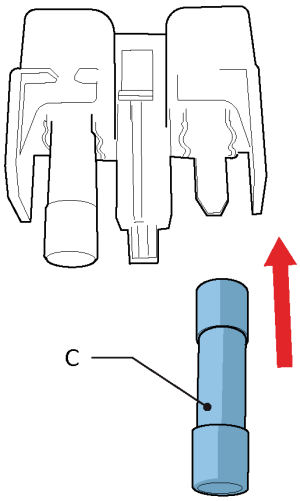
1. Remove the hatch (see *Remove hatch* on page 27).
2. Disconnect the power supply cord and the interface cable (see *Cables* on page 43).
3. Push the locking pin (A) inward and remove the fuse holder (B).



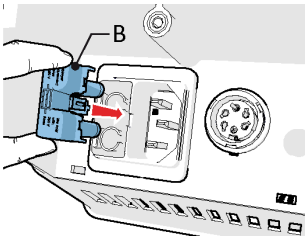
4. Remove the fuse (C).



5. Place the replacement fuse (C). For the fuse specifications, see *Specifications of the device* on page 53.



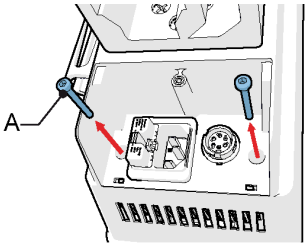
6. Place the fuse holder (B).
7. Connect the interface cable and the power supply cord (see *Install the cables* on page 27).
8. Place the hatch (see *Place hatch* on page 28).



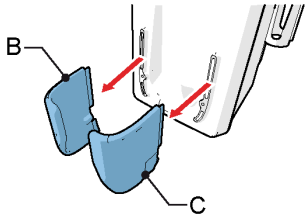
7.4 Warming module holder

The warming module holder must be replaced in case it shows signs of damage.

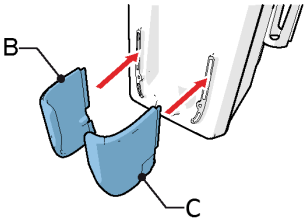
1. Remove the hatch (see *Remove hatch* on page 27).
2. Disconnect the power supply cord and the interface cable (see *Cables* on page 43).
3. Remove two bolts (A) from the back cover, using a 2-mm hex key.



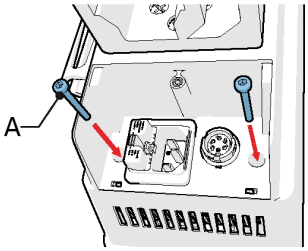
4. Remove the left (B) and right (C) parts of the warming module holder.



5. Place the left (B) and right (C) parts of the replacement warming module holder.



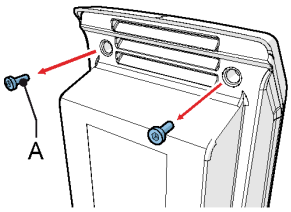
6. Fasten two bolts (A) from the back cover, using a 2-mm hex key.
7. Connect the interface cable and the power supply cord (see *Install the cables* on page 27).
8. Place the hatch (see *Place hatch* on page 28).



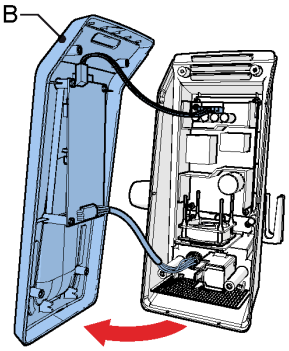
7.5 Front cover and control panel

When the front cover or control panel is damaged it needs to be replaced.

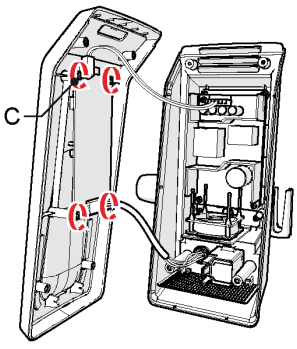
1. Remove the hatch (see *Remove hatch* on page 27).
2. Disconnect the power supply cord and the interface cable (see *Cables* on page 43).
3. Remove the warning module holder (see *Warming module holder* on page 45).
4. Remove two bolts (A) from back cover, using a 2-mm hex key.



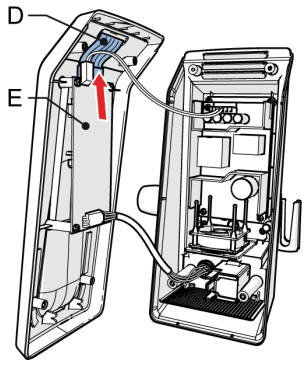
5. Carefully lift the front cover (B).



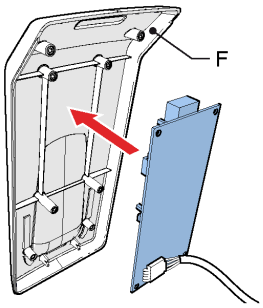
6. Remove four bolts (C), using a Torx T9 key.



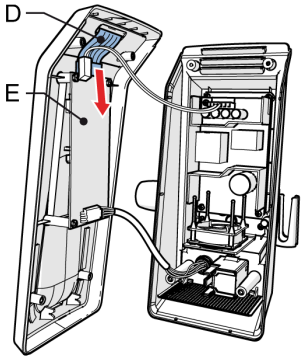
7. Disconnect the user interface flat cable (D) from the controller board (E).



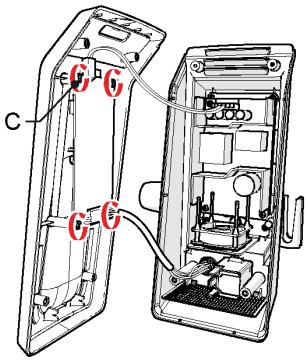
8. Remove the front cover with user interface (F).
9. Mount the replacement front cover with user interface (F).



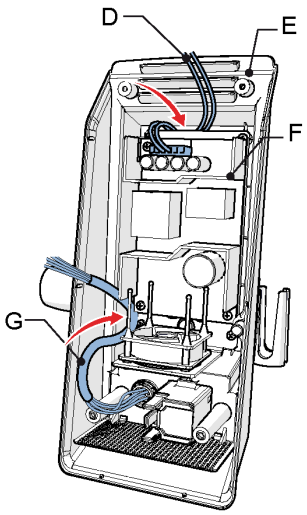
10. Connect the flat cable from the user interface (D) to the controller board (E).



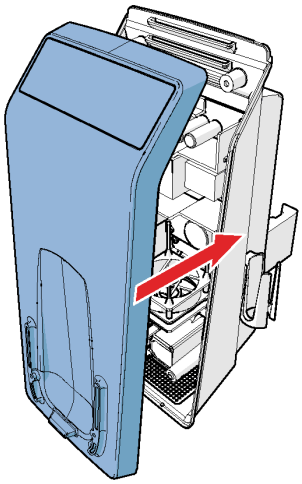
11. Fasten four bolts (C), using a Torx T9 key.



12. Place the fan cable (G) between the back cover (H) and the power board (I). Do the same with the controller cable (J).



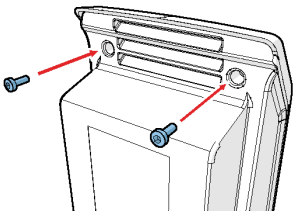
13. Carefully place the front cover on the back cover.



Caution!

Make sure no cables are clamped when the front cover is placed on the back cover. [C052]

14. Align the front cover with the back cover and fasten two bolts, using a 2-mm hex key.



15. Place the warming module holder (see *Warming module holder* on page 45).
16. Connect the interface cable and the power supply cord (see *Install the cables* on page 27).
17. Place the hatch (see *Place hatch* on page 28).

8 Test the device

The following tests must be performed on a yearly basis and after every repair, before the device is put into operation.

- *Electrical safety test* on page 49.
- *System operation test* on page 50.
- *Overtemperature indicator test* on page 51.

8.1 Electrical safety test

This test is performed to evaluate the electrical safety of the device.

8.1.1 Necessary items

- the device
- IV pole (optional)
- saline or other crystalloid fluids
- standard set
- syringe or hospital administration set
- medical electrical safety tester capable of body floating testing (refer to IEC 60601-1)
- metal catheter

8.1.2 Preparation

1. Connect a metal catheter to the end of the patient line.
2. Open the clamps on the hospital administration set and the patient line.
3. Make sure that the complete standard set and the catheter are primed.
4. Close the clamps of the hospital administration set.
5. Connect the metal part of the catheter to the safety tester. This is an applied part on the terminal of the safety tester.

8.1.3 Procedure

1. Perform the electrical safety test, refer to IEC 60601-1, for a class II, Body Floating Device.
2. Verify that the device passed the test and record any findings.

Warning!

Do not put the device into use and contact your local distributor if the device fails to meet any criteria of this test. [W092]

8.2 System operation test

This test is performed to evaluate the correct operation of the device.

8.2.1 Necessary items

- the device
- IV pole (optional)
- saline or other crystalloid fluids 20 ± 1 °C
- standard set
- hospital administration set
- measuring cup or scale and timing device to measure the flow rate
- thermometer to measure the outlet temperature

8.2.2 Preparation

1. Put the warming module in a horizontal position.
2. Make sure that the output of the patient line is a minimum of 130 millimetres higher than the device to simulate a venous pressure.
3. Put the end of the patient line in the measuring cup.
4. Adjust the height of the bag that contains IV fluid so the vertical distance between the bottom of the bag is 1 meter higher than the end of the patient line.
5. Make sure that the environmental temperature is 20 ± 2 °C.

8.2.3 Procedure

1. Push the standby/on button to start warming.
2. Adjust the roller clamp of the hospital administration set until the flow is within the operating parameters of the device.
3. Measure the actual flow rate by measuring the increase in volume (ml) IV fluid in the measuring cup over a period of time.

   The flow rate must be within 5–100 ml/min.
4. Measure the IV fluid temperature at the end of the patient line (40 centimetre) by placing the temperature probe in the fluid flow.

   Do not drip on the thermometer.

   The temperature must be within 36.5–41.0 °C.
5. Verify that the device passed the test and record any findings.

Warning!

Do not put the device into use and contact your local distributor if the device fails to meet any criteria of this test. [W092]

If environmental temperature is lower than indicated, the infusate is colder than indicated or the patient line is longer than indicated, the fluid temperature may be lower than expected. [N047]

8.3 Overtemperature indicator test

This test is performed to evaluate the correct functioning of the overtemperature indicator.

Warning!

Be careful when you use hot water. [W093]

8.3.1 Necessary items

- the device
- IV pole (optional)
- water at 49–55 °C
- standard set
- hospital administration set
- syringe with male Luer Lock

8.3.2 Preparation

1. Push the standby/on button to put the device in standby mode.
2. Prime/flush the standard set.
3. Close the roller clamp and the clamp on the patient line.
4. Disconnect the hospital administration set from the standard set.
5. Fill a syringe with male Luer Lock with water at 49–55 °C.
6. Connect the syringe to the standard set.
7. Open the clamp on the patient line.

8.3.3 Procedure

1. Push the standby/on button to start warming.
2. Open the slider a few millimetres until the setpoint indicator is off.
3. Flush the hot water into the standard set.
4. Make sure that the overtemperature indicator turns on and that the audible signal is triggered.

5. Verify that the device passed the test and record any findings.

Warning!

Do not put the device into use and contact your local distributor if the device fails to meet any criteria of this test. [W092]

9 Specifications

9.1 Specifications of the device

General specifications

Part number (control and warming module)	650000
Part number control module	650100-
Part number warming module	650200
Voltage	100 – 240 V~ (50/60 Hz)
Maximum power	160 W
Fuses control module	2 × T 3.15A H 250V
Dimensions control module (H × W × D)	285 × 120 × 195 mm
Dimensions warming module (H × W × D)	165 × 75 × 50 mm
Length of power cable	400 cm
Length of interface cable	180 cm
Weight of control module	1700 g
Weight of warming module	450 g
Control module class (IEC 60529)	IPX1
Warming module class (IEC 60529)	IPX4
Class IEC 60601-1[2]	Class II, Body Floating The third conductor in the power supply cord is only a functional earth.
Class (MDD93/42/EEC)[2]	Class II b
Flow range	5 – 100 ml/min at T_{in} = 20 °C and T_{env} = 20 °C
Input temperature range	4 – 30 °C
Temperature limits	Within safe range according to ASTM F2172-02
Safety cut-off temperature	47 °C

Environmental specifications

Ambient temperature	15 °C to 30 °C
Relative humidity	30 % to 75 %

[1] XX refers to a generic identifier related to the country distributor. It might not be present.
[2] Control module and warming module.

Atmospheric pressure	70 kPa to 106 kPa

Transport and storage specifications

Ambient temperature	-40 °C to 50 °C
Relative humidity	10 % to 90 % (non-condensing)
Atmospheric pressure	50 kPa to 106 kPa

9.2 Specifications of the disposable sets

General specifications

Part number standard set	672000
Part number standard set with drip chamber	672100
Maximum pressure	300 mmHg
Priming volume standard set	4 ml
Priming volume standard set with drip chamber	15 ml
Patient line length standard set	40 cm
Patient line length standard set with drip chamber	70 cm
Free flow (300mmHg, no IV catheter attached)	400 ml/min
Plasticizer PVC components Tri (2-Ethylhexyl) Trimellitate (TOTM a.k.a.TEHTM	

Disposable sets do not contain Bis(2-ethylhexyl) phthalate (DEHP) as plasticizer in the PVC components.

Transport specifications

Ambient temperature	-20 °C to 40 °C
Relative humidity	10 % to 90 % (non-condensing)
Atmospheric pressure	50 kPa to 106 kPa

Storage specifications

Store in a dry and dark place under warehouse conditions, between 2 °C and 30 °C.	
Relative humidity	10 % to 90 % (non-condensing)
Atmospheric pressure	50 kPa to 106 kPa

10 Electromagnetic compatibility

Warning!

- Use of accessories, transducers and cables other than those specified or provided by The Surgical Company International B.V. for this device could result in increased electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation. [W054]
- Use of this device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this device and the other equipment should be observed to verify that they are operating normally. [W055]
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this device could result. [W056]

- The emissions characteristics of this device make it suitable for use in industrial areas and hospitals (CISPR 11 class A). [N002]
- The device will produce an audible signal when the power supply experiences a drop in voltage of more than 30%. Refer to *Troubleshooting* on page 59 if this occurs. [N031]
- This device complies with IEC 60601-1-2:2014 for electromagnetic compatibility. However, if electromagnetic interference with nearby devices is experienced, the user is encouraged to take one or more of the following measures:
  - Isolate the offending device.
  - Reorient or relocate this device.
  - Increase the distance between the interfering device and this device.
  - Use an alternative mains socket.

  If electromagnetic incompatibility still occurs, please contact your distributor. [N032]

10.1 Electromagnetic immunity

Guidance and manufacturer's declaration

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

Immunity test	IEC60601 test level
Electromagnetic discharge (ESD) EN-IEC 61000-4-2 (2009)	± 8 kV contact
	± 15 kV air
Electrical fast transient (EFT)/burst EN-IEC 61000-4-4 (2012)	± 2 kV
Surge EN-IEC 61000-4-5 (2014)	± 1 kV L-N
	± 2 kV L-PE/N-PE
Voltage dips, short interruptions and voltage variations on power supply input lines EN-IEC 61000-4-11 (2004)	0% U_T for 0.5 cycle
	0% U_T for 1 cycle
	70% U_T for 25/30 cycles
	0% U_T for 250/300 sec
Power frequency (50/60 Hz) magnetic field IEC EN-IEC 61000-4-8 (2010)	30 A/m
Conducted RF EN-IEC 61000-4-6 (2014)	3 Vrms + 6 Vrms (ISM + Amateur)
Radiated RF EN-IEC 61000-4-3 (2006) + A1 (2008) + A2 (2010)	3 V/m
Proximity fields from RF wireless communications equipment EN-IEC 61000-4-3 (2006) + A1 (2008) + A2 (2010)	9-28 V/m
Electrical transient conduction along supply lines ISO 7637-2 (2004)	Not applicable (system not intended for use in vehicles)

10.2 Electromagnetic emissions

Guidance and manufacturer's declaration

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

Emissions test	Compliance
RF emissions CISPR 11 (2015)	Group 1
RF emissions CISPR 11 (2015)	Class A
Harmonic emissions IEC 61000-3-2 (2018)	Not applicable (the device 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).
Voltage fluctuations/flicker emissions IEC 61000-3-3 (2017)	

10.3 Recommended separation distances

Recommended separation distances between portable and mobile RF communications equipment and the device

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

	Separation distance (d) according to frequency of transmitter		
Rated maximum output power of transmitter	**150 kHz to 80 MHz**	**80 MHz to 800 MHz**	**800 MHz to 2.5 GHz**
0.01 W	0.12 m	0.12 m	0.24 m
0.1 W	0.37 m	0.37 m	0.74 m
1 W	1.17 m	1.17 m	2.34 m
10 W	3.69 m	3.69 m	7.38 m
100 W	11.67 m	11.67 m	23.34 m

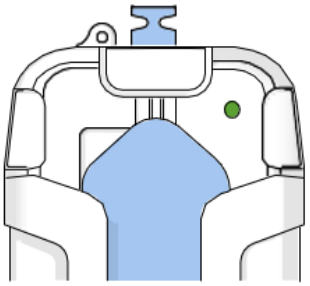
- At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. [N033]
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. [N034]

11 Troubleshooting

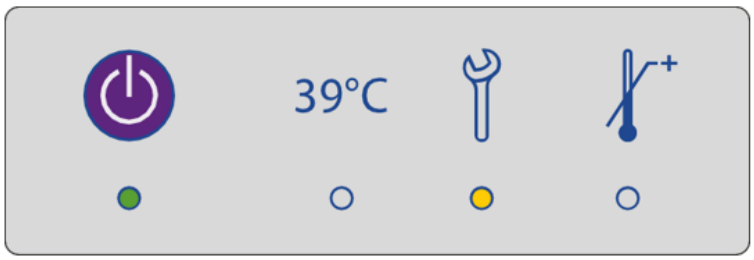
11.1 Control module

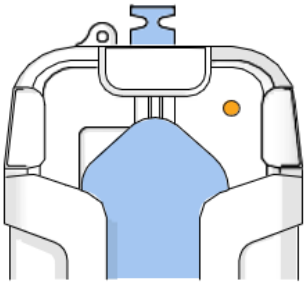
If a problem occurs, a combination of indicators will light to specify the problem. The following tables may assist the end user when troubleshooting the device. The lighted indicators are shown by a coloured circle in the images.

If the problem persists, do not use the module. In the event of any technical assistance being needed, contact the technical service or the local supplier.

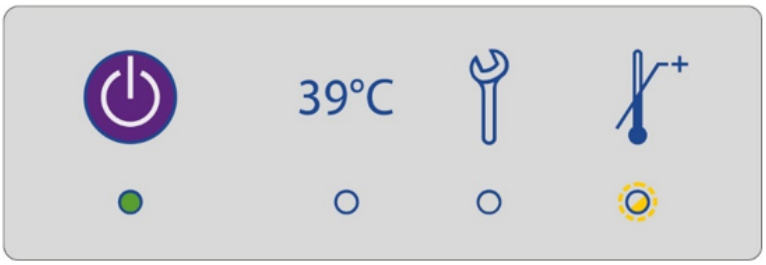


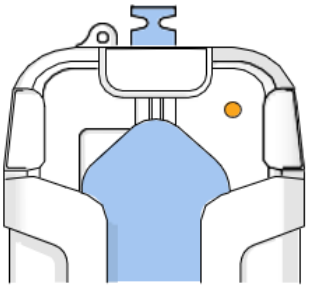
Problem	Possible cause	Solution
The flow temperature is below 37 °C.	The flow rate is too high.	If possible: decrease the flow rate.
	The fluid inlet temperature is too low.	Pre-warm the fluid to ambient temperature.
The flow temperature is over 41 °C (within ASTM F2172-02:2011) limits).	The flow has stopped.	If possible: increase the flow rate.
	The flow rate is too low.	
	The disposable cassette is empty.	If the standard set is used: prime the standard set again. See *Prime the standard set* on page 33.
	There are air bubbles in the disposable cassette.	If the standard set with drip chamber is used: prime and deaerate the standard set with drip chamber again. See *Prime the standard set with drip chamber* on page 33 and *Deaerate standard set with drip chamber* on page 34.





Problem	Possible cause	Solution
There is no contact between the control and warming modules.	The interface cable is not connected properly.	Make sure that the warming module interface cable is attached correctly and locked to the control module.
	The device needs to be reset.	Disconnect the power supply cord, wait a few seconds and reconnect the power supply cord.





Problem	Possible cause	Solution
Temperature sensors measured an elevated temperature	There are air bubbles in the disposable cassette.	Prime the standard set again. See *Prime the standard set* on page 33.
		Prime and deaerate the standard set with drip chamber again. See *Prime the standard set with drip chamber* on page

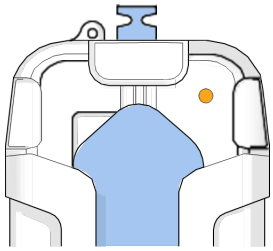
Problem	Possible cause	Solution
		33 and *Deaerate standard set with drip chamber* on page 34.
	The warming surface of the warming module is wet or contaminated.	Clean and dry the surface, see *Cleaning* on page 39.
	The flow rate is too low.	If possible: increase the flow rate.
	The device needs to be reset.	Disconnect the power supply cord, wait a few seconds and reconnect the power supply cord.
Excessive temperature	The infusate is too warm.	Make sure that the fluids comply with the specified input temperature range, see *Specifications of the device* on page 53.
	The fluid is too warm.	When clinical situation allows, increase the flow rate.
	The disposable set is empty.	Prime the disposable set.
	The disposable set is not placed correctly.	Remove and reinsert the disposable set.
	There is a device malfunction.	Contact the hospital service department or the local supplier.

If the temperature of the fluid is above the safety limits, the system cut-off circuit will be triggered and the fluid will stop warming. The overtemperature indicator will be active (blinking yellow) and an audible signal will be triggered.

11.2 Warming module

If the status indicator on the warming module stays orange, the detection of the disposable set failed or there is an issue with the device.

1. Remove the set (see *Stop the device* on page 37).
2. Check the heating surface for damages and contamination.
3. Check the cassette of the disposable set for damages and contamination.



4. Prime the disposable set (see *Prime the standard set* on page 33).
5. Install the disposable set again.
6. Wait until the setpoint indicator on the control module stays green.

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