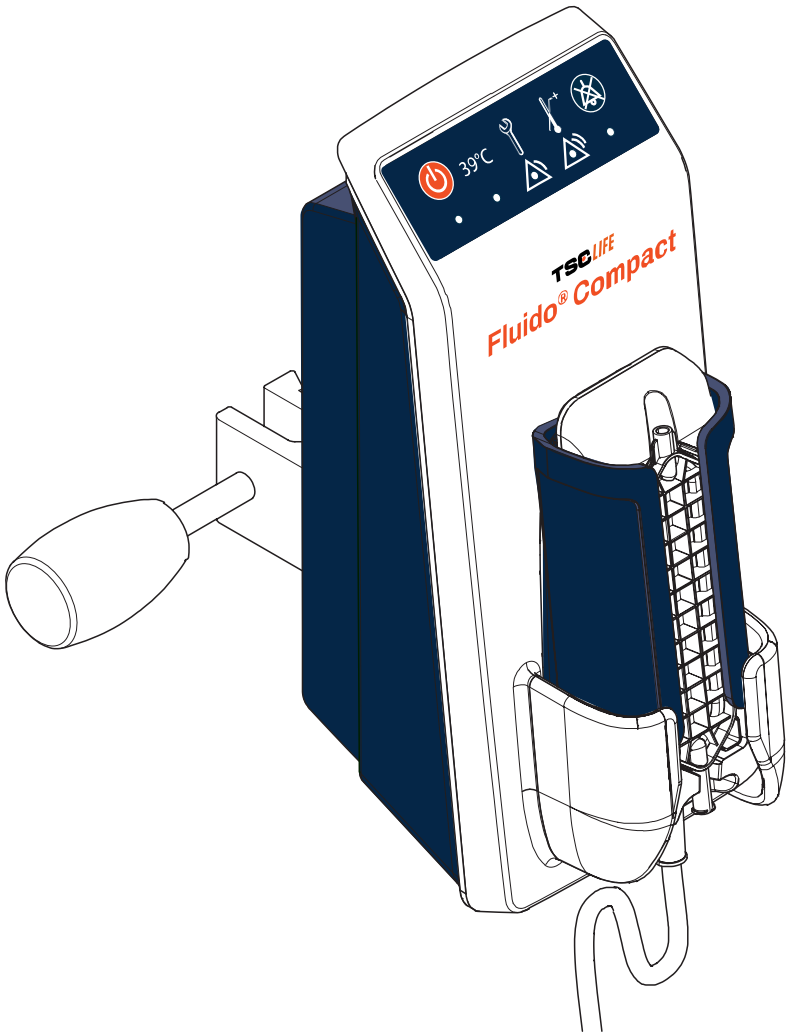
TSC LIFE

Innovation with purpose

Fluido® Compact



Technical Manual

Blood and Fluid Warming System

℞ Only

2025 | Original instructions | INT/R1008-EN/3-11/25 [US version]

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Contents

1 General information

1.1 About this manual

In this manual, you can find important information about how to maintain and service the Fluido® Compact System.

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

Make sure that you have the most recent version of this manual. To obtain the latest manual, please contact your TSC Life sales representative to obtain the latest version. Perform the procedures in the sequence given. Always keep the manual with the device.

Refer to the Fluido® Compact System user manual for operating instructions. Please contact your TSC Life sales representative in case you need the user manual.

1.2 Warning, caution and note

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

A "note" provides more information. [N000]

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

1.3 Intended use

The Fluido® Compact System can be used with patients who require fluid warming prior to the administration of blood products or IV fluids, to help prevent hypothermia. The system is intended to be used in a healthcare environment by healthcare professionals, e.g. nurses, medical specialists, doctors. Only medical professionals shall interact with the system. The devices must only be used on the order of a physician.

1.4 Indications for use

The device can be used with the following products:

- Plasma
- Packed red blood cells
- Crystalloid intra venous (IV) fluids
- Synthetic Colloid intra venous (IV) fluids

The system is indicated to be used in a healthcare environment to help prevent hypothermia. The devices can be used in the full clinical environment. The Fluido® Compact System can be used in adult and pediatric patients (weighing 3.5 kg or more) who require fluid warming prior to the administration of blood products or IV fluids to help prevent hypothermia. The system is intended to be used by healthcare professionals, e.g., nurses, medical specialists, and doctors.

1.5 Contact

TSC Life US, Inc.
6400 S Fiddlers Green Circle, Suite 305
Greenwood Village, CO 80111
United States

Phone: (765) 205-6030
E-mail: ***letsconnect@tsc-life.com***
Website: ***www.tsc-life.com***

Refer to the website for more information.

1.6 Authorisation of personnel and training

Caution!

The Fluido® Compact 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 authorised personnel [C059].

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. Users are notified regarding updates to the manual by their TSC Life sales representative.

The original instructions in this document were created in English. All other language versions are translations of the original instructions. In the event of ambiguity and/or disputes, the English text always takes precedence.

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.

2 Contraindications, warnings, cautions and notes

2.1 Contraindications

The Fluido® Compact System should not be used for the administration of drugs or blood and fluids mixed with pharmacological substances.

2.2 General safety precautions

2.2.1 Warnings

Warning!

- Use the device as intended. Refer to ***Intended use*** on page 5 [W053].
- Do not place the device near heat sources such as warming blankets or warming mattresses [W068].
- 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].

Materials

Warning!

- Use blood products that comply with local regulations [W001].
- Do not use fluids with a temperature below 4 °C or above room temperature. The high viscosity of blood at low temperatures increases the risk of blood clots [W002].
- Do not mix red blood cells with drugs. See ***Literature*** on page 50: 2 and 3 [W003].
- Use saline solution (0.9 % Sodium Chloride) to dilute red blood cells to reduce the viscosity. See ***Literature*** on page 50: 1 [W004].
- Prime the Fluido® Compact IV sets with a sterile NaCl 0.9 % solution [W081].
- Do not mix dextrose solution (5 %) with blood components. This can cause haemolysis. See ***Literature*** on page 50: 2 and 3 [W005].
- Do not use the device for warming whole blood, platelets, cryoprecipitates or granulocyte suspense [W006].
- Do not add calcium-rich supplements as priming solution before the infusion of blood to prevent blood clots [W007].

Prior to operation

Warning!

- The Fluido® Compact System is to be used only with Fluido® Compact IV set [W085].
- 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 TSC Life sales representative[W011].
- Make sure that there is a physician's order for switching on and continued use of the device [W012].
- Do not use a leukocyte reduction filter in combination with the Fluido® Compact IV set [W019].
- 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 50: 3) [W071].
- Follow the standard IV line protocols for priming the complete infusion set and the Fluido® Compact IV 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 the Fluido® Compact IV set if the package is damaged [W109].

Operation

Warning!

- In the event of a power interruption, the device will not produce any audible signal to indicate the loss of power [W106].
- 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 [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. Check the IV set every 15 minutes for accumulated gas bubbles. These can cause air embolism [W025].
- Check the patient's condition and temperature at least every 15 minutes [W021].
- 

Make sure that the pressure on the line does not exceed 300 mmHg when using the device. Do not use a pressure device without pressure indicator or an in-line manually driven pressure device [W029].
- 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 service the device while it is being used or connected to the mains [W022].
- Do not use the system for a period longer than 24 hours per patient [W075].

- 

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

- 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 Fluido® Compact IV set [W078].
- 

  The device and its Fluido® Compact IV sets 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 disinfect the device, remove attached Fluido® Compact IV sets and disconnect the power supply cord [W051].
- After applying blood products, clean the hospital administration set with saline [W031].
- If necessary, clean the warming module according to the hospital guidelines. Refer to ***General cleaning procedure*** on page 27 [W083].
- 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).
  - The warming surface is dirty (e.g. coagulated blood) [W084].

2.2.2 Cautions

Caution!

- Do not use a sharp object to press the buttons on the control panel [C002].
- Do not immerse the device in liquids. Otherwise, the device can be damaged [C004].
- Do not use the device outside the environmental specifications: see ***Environmental specifications*** on page 45 [C005].
- Keep the device away from portable and mobile radio-frequency communications equipment and high-frequency surgical instruments or endocardial catheters. Portable and mobile radio-frequency communication equipment and high-frequency surgical instruments or endocardial catheters may cause the device to operate incorrectly [C006].
- 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].
- 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].

Materials

Caution!

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

Prior to 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].

Cleaning

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].
- Make sure that fluids cannot enter the electrical areas of the device [C038].
- Do not use alcohol-based disinfectants (except isopropyl alcohol and ethanol dilutions) [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].

2.2.3 Notes

- Use a high-flow warming system in case that the flows required are more than 100 ml/min for more than 5 minutes [N70].
- The device is not intended to control the core temperature of the patient by itself [N69].
- 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 Fluido® Compact IV set can be interchanged between Fluido® Compact devices as long as they are not used with different patients or for longer than 24 hours [N042].
- If the device gives a technical alarm (refer to ***Control panel*** on page 14), contact the 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. You can find the device serial number and MOD record on the product label [N024].

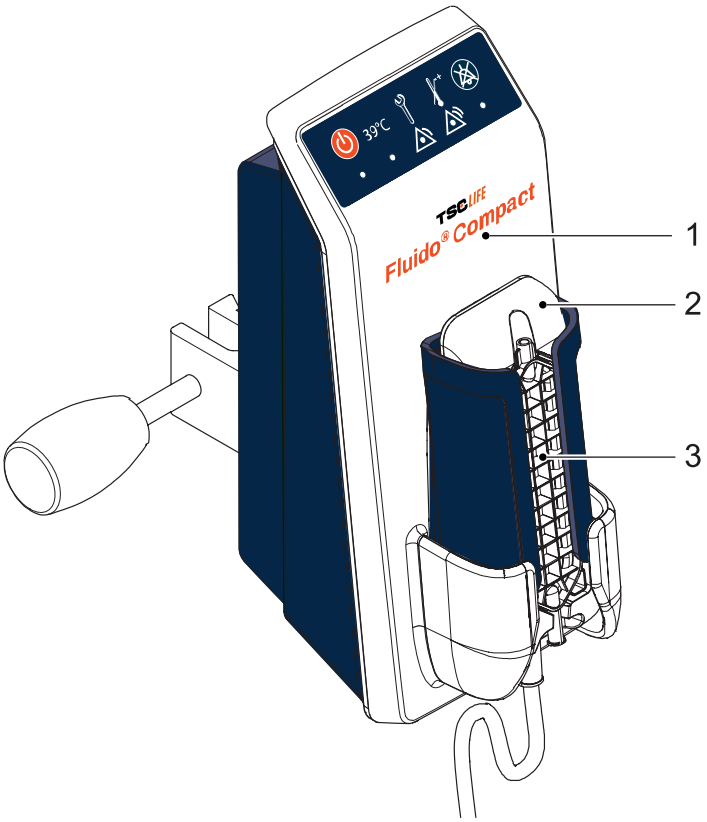
3 Description

The Blood and Fluid Warming System is a Fluido® Compact System. The system is suitable for low to moderate flow applications. For high flow applications (higher than 100 ml/min for more than 5 minutes) the use of a high flow system is recommended.

The Blood and Fluid Warming 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 system

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

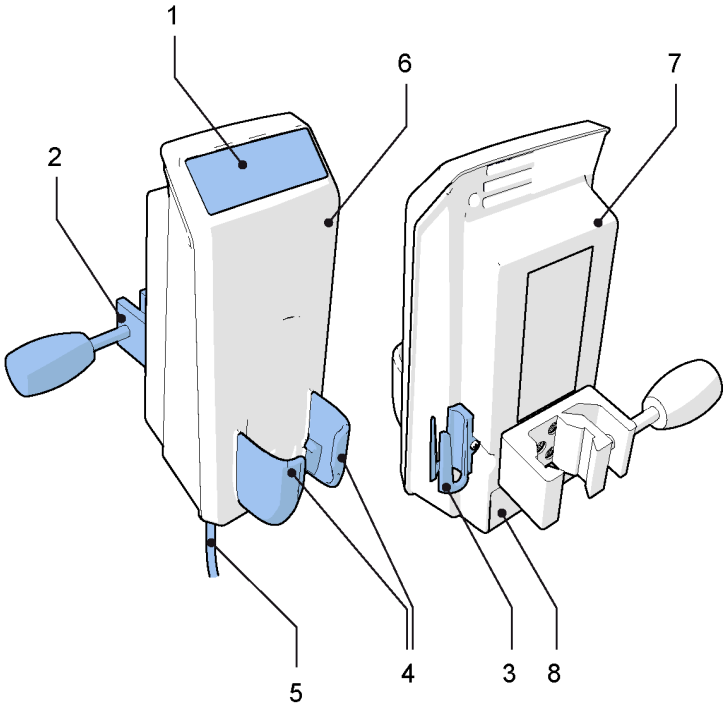


1. Control module
2. Warming module
3. Fluido® Compact IV set

3.1.1 Control module

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.

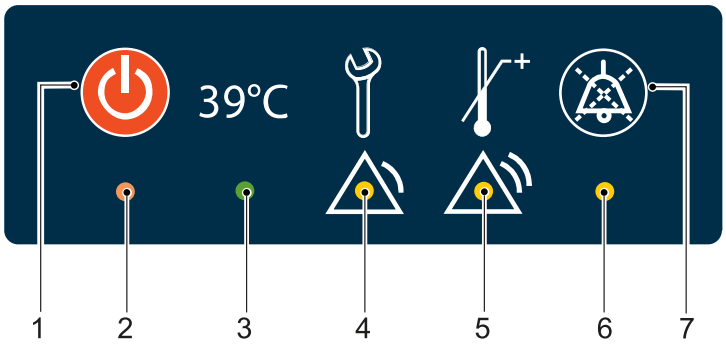
The control module consists of the following components:



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

3.1.1.1 Control panel

The control panel contains the following buttons and indicators:



1. Standby/on button
2. Standby/on indicator
3. Setpoint indicator
4. Technical alarm indicator
5. Overtemperature alarm indicator
6. Temporarily alarm suppression indicator
7. Temporarily alarm suppression button

3.1.1.1.1 Visual and audible warning systems

The device is equipped with visual and audible warning systems to inform the user of excessive heating temperatures and/or technical malfunction. These alarms or information signals are present on the panel of the control module.

If an error occurs, an audible alarm sounds and the relevant indicator(s) on the control panel will blink or light up continuously. It is also possible to temporarily suppress the audible alarm.

There are different alarms (A) and information signals (I):

- I.1 Temperature indication
- I.2 Alarm silenced
- A.1 Technical alarm
- A.2 Overtemperature alarm

These alarms/indicators are described in the sections below.

3.1.1.1.2 Overtemperature alarm

The overtemperature alarm is triggered according to the limits stated in ASTM F2172-02:2011. The device has, by design, a safety tolerance to prevent thermal injury or damage to the infusates.

This alarm is a latching alarm, which means that the alarm will remain present if triggered even if the cause of the issue was resolved. The reset of the alarm will take place after power-cycling the device and only if the issue has been resolved.

When the alarm is triggered, the device immediately stops warming to prevent any unnecessary risks to the patient.

Caution!

In case that the overtemperature alarm has been triggered, it is recommended to prime the set again before continuing operation and check if the heater and device are in order. If the overtemperature alarm continues, stop using the device and contact the technical department [W112].

3.1.1.1.3 Temporarily audible alarm suppression

The audible alarm may be suppressed for up to 2 minutes by pressing the temporarily audible alarm suppression button. This suppression is temporary and will resume if the device is still powered and in an alarm state.

3.1.1.1.4 Alarm specifications

The characteristics of the audible burst per alarm are described below.

Priority	Duration of burst	Frequency of pulse	Pulse count	Interval
Low	200 ms	659 Hz	2	30 s
	150 ms	0 Hz		
	200 ms	523 Hz		
Medium	150 ms	523 Hz	3	6 s
	150 ms	0 Hz		
	150 ms	587 Hz		
	150 ms	0 Hz		
	150 ms	659 Hz		

3.1.1.1.5 Alarm delays

The maximum allowable delay between the detection of the alarm situation and the triggering of the alarm is less than 1 second.

3.1.1.1.6 Position, sound levels and indicators

The alarms have a visual and an audible signal that ensure the correct communication of the alarm condition. The evaluation of the alarms present in this device per IEC 60601-1-8:2012 has determined that the operator shall be within 1.3 m from the device to be able to hear the auditory alarm in a noisy clinical setting (63 dB background noise). Visual indicators allow the operator to determine that an alarm condition exists at a distance of 4 m, up to an angle of 22 °. At a distance of 1 m, the alarm conditions are clearly distinguishable up to an angle of 58 °.

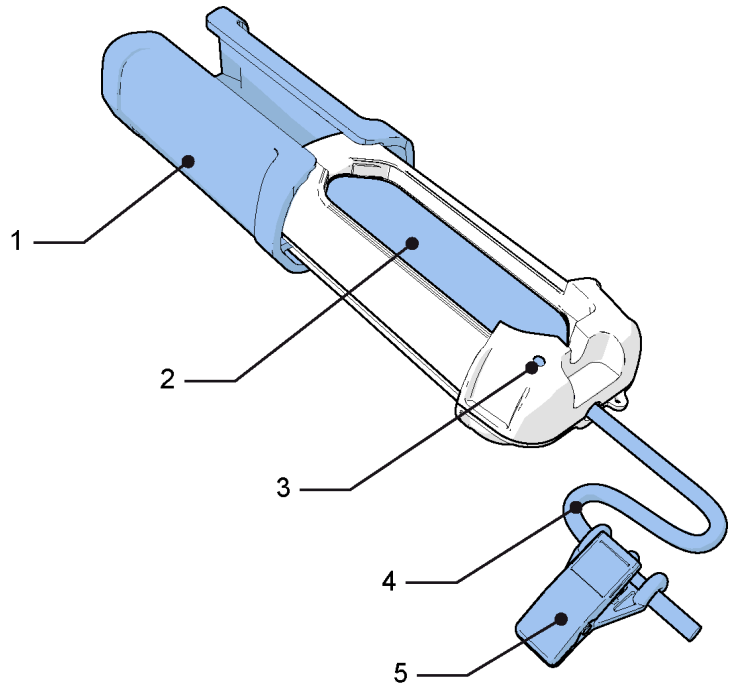
Warning!

The operator shall be aware of the operating environment when using the device. A noisy environment could difficult the hear of audible signals. Stay within the recommended distance while operating the device and periodically monitor the status of the device [W113].

3.2 Warming module

The warming module is the heating element of the system. It hosts the Fluido® Compact IV set cassette and provides the required and controlled heating power to warm up fluids to the device set-point.

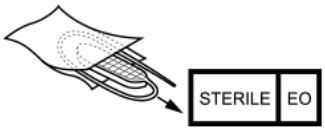
The warming module consists of the following components:



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

3.3 Fluido® Compact IV set

Warning!



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

Caution!

Never use defective Fluido® Compact IV sets. Check the Fluido® Compact IV set for damage such as leakage, punctures and disconnected tubes [C016].

The Fluido® Compact IV sets enable the device to transfer the produced heat to the fluids circulating through the tubing and cassette. The Fluido® Compact IV sets are single-use only and are provided sterile.

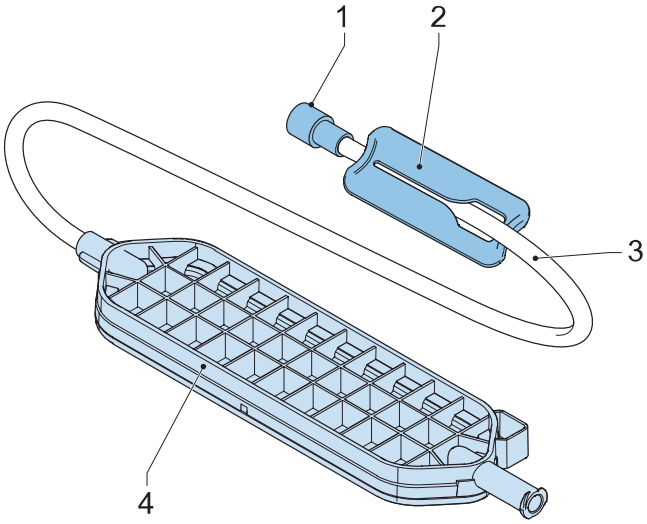
The Fluido® Compact IV set consist of a cassette of polycarbonate with a coated metallic plate that enables the heat transfer. The inlet and outlet of the cassette are provided with universal luer lock connectors.

The Blood and Fluid Warming System may only be used with the following Fluido® Compact IV sets and accessories:

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

3.3.1 Overview of the Fluido® Compact IV Standard Set

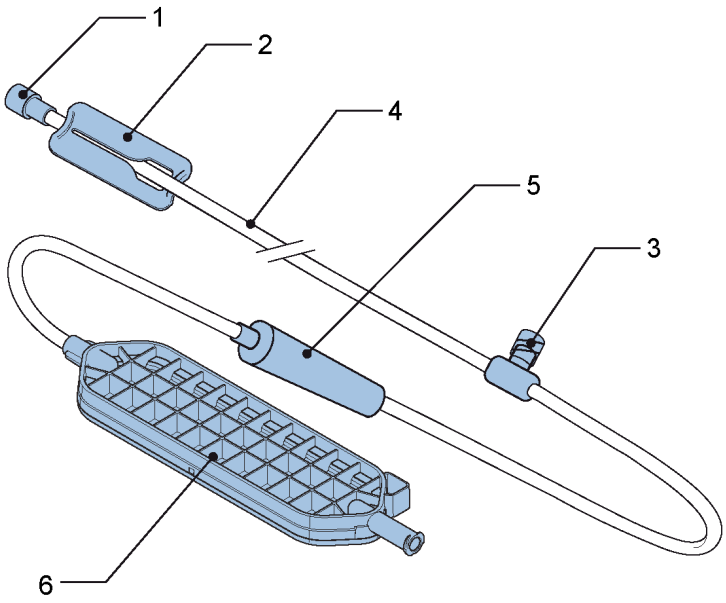
The Fluido® Compact IV Standard Set consists of the following components:



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

3.3.2 Overview of the Fluido® Compact IV Standard Set with drip chamber

The Fluido® Compact IV Standard Set with drip chamber consists of the following components:



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

- The drip chamber is meant to be used as a deaeration chamber. [N037]

3.3.3 Fluido® Compact Holder for warming module

The Fluido® Compact holder for warming module provides maximum flexibility in placing the warming module close to the patient taking into account the different mounting options in the hospital . The holder consists of the following components:

1. Holder
2. Turning knob
3. Clamp

4 Set-up

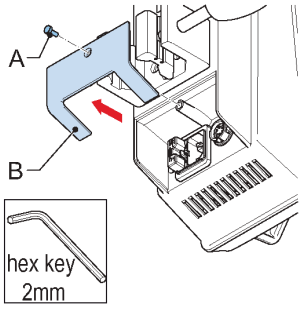
4.1 Transport and storage

Store the device and accessories according to the transport and storage recommendations. See *Transport and storage specifications* on page 45.

4.2 Install the cables

4.2.1 Remove the 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).

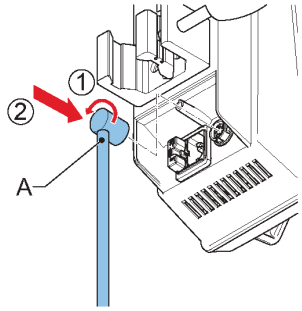


4.2.2 Connect the cables

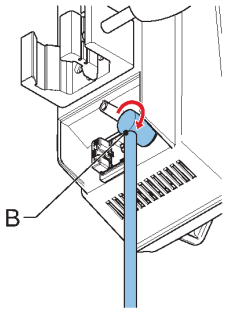
Caution!

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

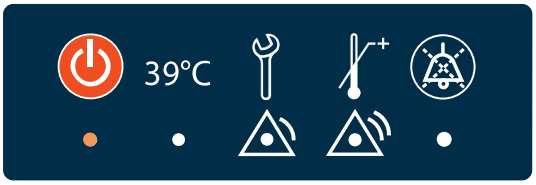
1. Turn the connector ring on the interface cable (A) to the open position.
2. Connect the interface cable.



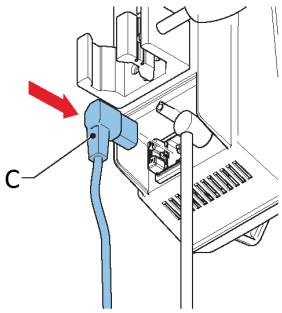
3. Turn the connector ring on the interface cable (B) to the locked position.



4. Connect the power supply cord (C).
Expected indicator response



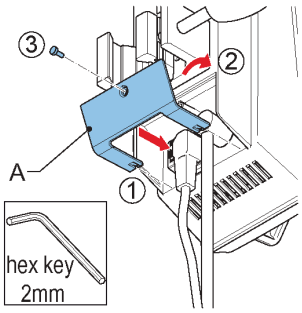
Refer to *Visual and audible warning systems Control module* on page 40 if the device gives a different response than the described expected response.



5. Place the hatch (see *Place the hatch* on page 22).

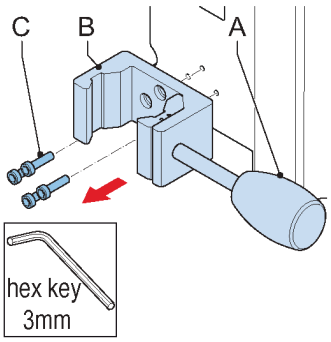
4.2.3 Place the hatch

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.

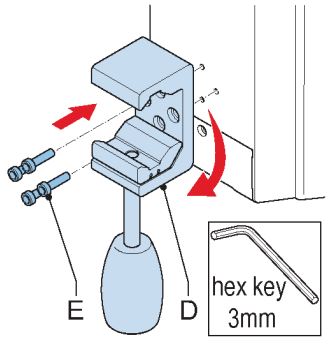


4.3 Change the rotation of the universal clamps (optional)

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.



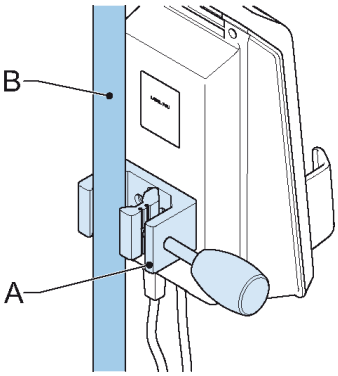
3. Turn the universal clamp (D) 90°.
4. Fasten the bolts (E).



4.4 Attach the device

When installing the device, make sure that the operator can read the control panel from his normal working position [N046].

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



Caution!

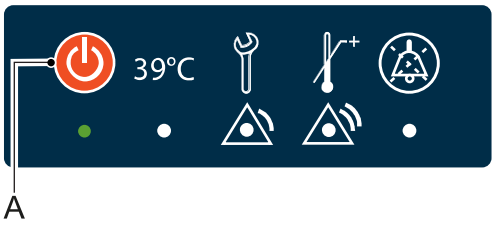
Make sure that the device is securely clamped to the pole before operation. [049]

4.5 Start the device

The following instructions show the steps necessary to start the device and verify correct functioning.

1. Press the Standby/on button (A).

The correct functioning of all indicators is tested.

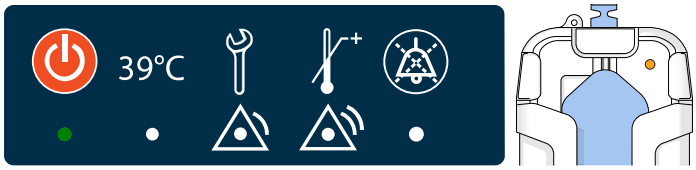


The following response is expected for the duration of 1 second.

Expected indicator response

Subsequently, the following response is expected.

Expected indicator response

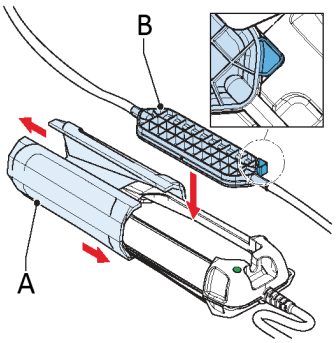


Refer to *Visual and audible warning systems Control module* on page 40 it the device gives a different response than the described expected response.

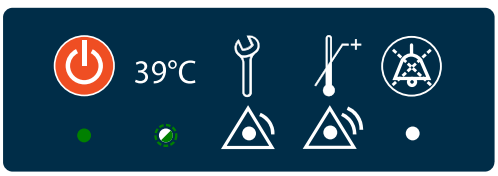
4.6 Install the Standard Set

1. Open the slider (A) of the Warming Module.
2. Insert the set cassette (B).
3. Close the slider again.

   The setpoint indicator will blink, indicating that the temperature output is adjusted.

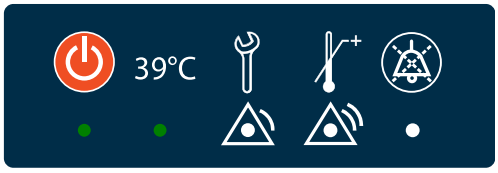


Expected indicator response



After reaching the setpoint, the following response is expected.

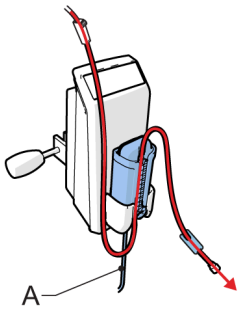
Expected indicator response



Refer to *Visual and audible warning systems Control module* on page 40 it the device gives a different response than the described expected response.

4.7 Warming up fluids

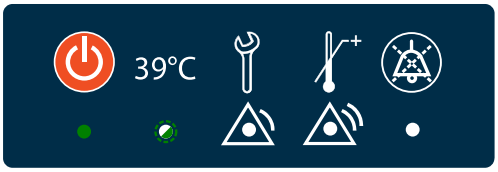
1. Place a saline solution bag with an overhead of 1 meter and connect it to the IV set.
2. Adjust the roller clamp of the hospital administration set until a correct flow of 50 ± 5 ml/min is reached.
   Flow direction is as indicated when the warming module is placed in the warming module holder with the interface cable (A) downward.



3. Measure the actual flow rate by one of the following methods:
   - Count the drops in the drip chamber from the hospital administration set (check the drops/ml of the drip chamber for the conversion to ml/min).
   - Measure the increase in fluid volume (ml) in the measuring cup over a period of time.
   - Measure the increase in weight of the fluid on the weighing scale over a period of time (check the density of the used fluid for conversion to ml/min).
4. Make sure that the fluid temperature at the end of the patient line is close to 39 °C after 3 minutes, taking into consideration thermal losses in the line.

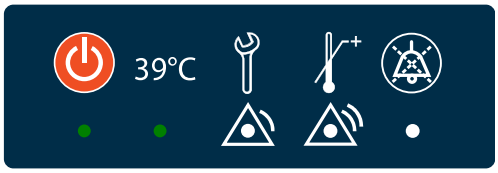
The blinking setpoint indicator is expected for maximal 60 seconds, while the setpoint has not been reached.

Expected indicator response



After reaching the setpoint, the following response is expected.

Expected indicator response



Refer to ***Visual and audible warning systems Control module*** on page 40 if the device gives a different response than the described expected response.

If the temperature is below 37 °C or over 41 °C, the setpoint indicator will blink. In any of these cases, check if the following aspects of the measurement are performed correctly:

- Flow (50 ± 5 ml/min).
- Flow direction (from female Luer lock towards the end of the patient line).
- Environmental temperature (20 ± 2 °C).
- Incoming fluid temperature (20 ± 1 °C).
- In–line fluid temperature measurement at end of patient line.

If the measurement was performed correctly, test the device as described in ***Test the device*** on page 36.

5 Cleaning

5.1 General cleaning procedure

Warning!

Before you clean and disinfect the device, remove attached Fluido® Compact IV sets and disconnect the power supply cord [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 alcohol-based disinfectants (except isopropyl alcohol and ethanol dilutions) [C060].
- Do not use acid-based cleaners [C061].
- Do not exceed the concentration specified by the manufacturer or use premixed solutions [C062].
- 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].

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 your TSC Life sales representative.

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 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 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 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.

5.2 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.

6 Repair

Warning!

- The Blood and Fluid Warming 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 36 [W090].

Refer to ***Visual and audible warning systems Control module*** on page 40 if the device gives a different response than expected response described in the procedure.

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.. It is not possible or allowed to repair the Warming module. Any unauthorized repair might void the warranty.

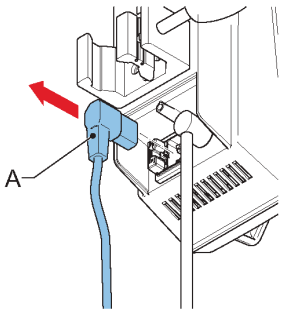
6.1 Disconnect the cables

In some cases is may be necessary to remove the cables as part of a repair procedure.

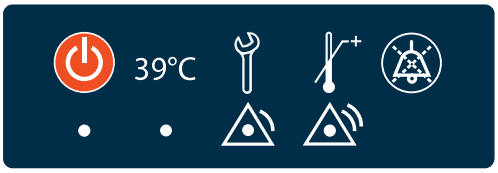
Caution!

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

1. Remove the hatch (see ***Remove the hatch*** on page 21).
2. Disconnect the power supply cord (A).

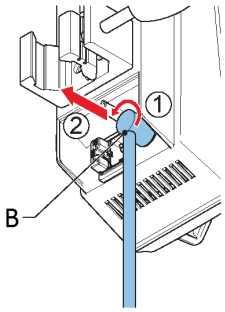


Expected indicator response



Refer to ***Visual and audible warning systems Control module*** on page 40 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.



6.2 Exchange the fuse

The fuse must be replaced after it is tripped.

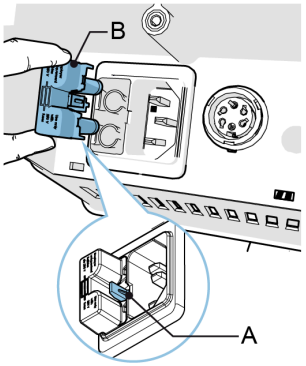
Warning!

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

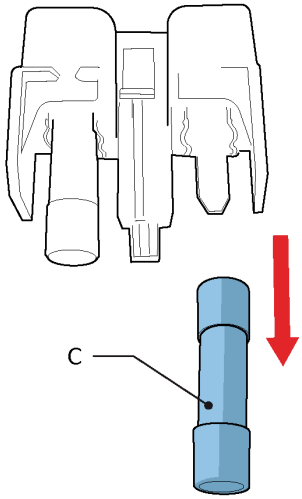
Caution!

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]

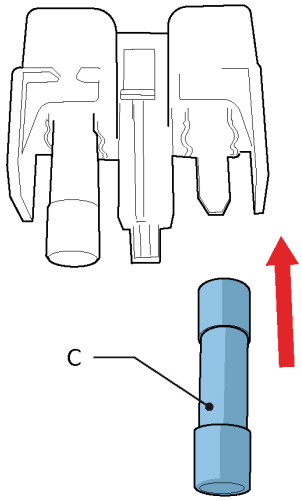
1. Remove the hatch (see ***Remove the hatch*** on page 21).
2. Disconnect the power supply cord and the interface cable (see ***Disconnect the cables*** on page 30).
3. Push the locking pin (A) inward and remove the fuse holder (B).



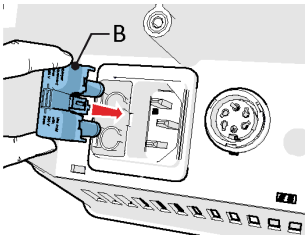
4. Remove the fuse (C).



5. Place the replacement fuse (C). For the fuse specifications, see ***Specifications of the device*** on page 44.



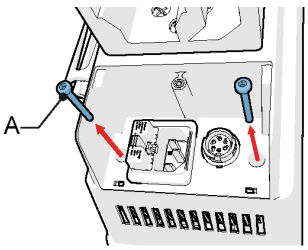
6. Place the fuse holder (B).
7. Connect the interface cable and the power supply cord (see ***Connect the cables*** on page 21).
8. Place the hatch (see ***Place the hatch*** on page 22).



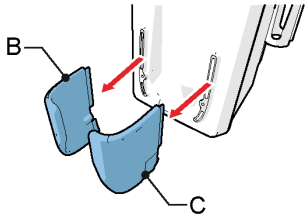
6.3 Replace the warming module holder

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

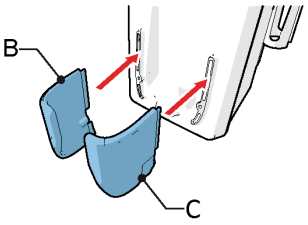
1. Remove the hatch (see ***Remove the hatch*** on page 21).
2. Disconnect the power supply cord and the interface cable (see ***Disconnect the cables*** on page 30).
3. Remove two bolts (A) from the back cover, using a 2-mm hex key.



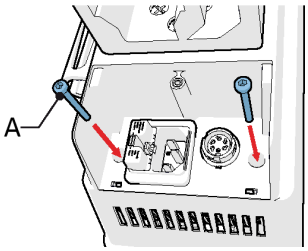
4. Remove the left (B) and right (C) parts of the warming module holder.



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



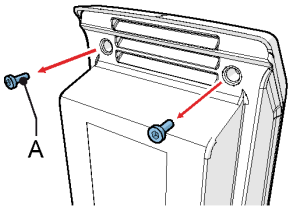
6. Fasten two bolts (A) from the back cover, using a 2-mm hex key.
7. Connect the interface cable and the power supply cord (see ***Connect the cables*** on page 21).
8. Place the hatch (see ***Place the hatch*** on page 22).

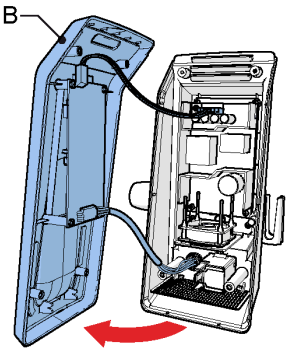


6.4 Replace the front cover and the control panel

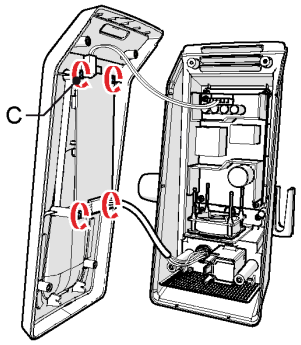
When the front cover or control panel is damaged it needs to be replaced.

1. Remove the hatch (see ***Remove the hatch*** on page 21).
2. Disconnect the power supply cord and the interface cable (see ***Disconnect the cables*** on page 30).
3. Remove the warning module holder (see ***Replace the warming module holder*** on page 32).
4. Remove two bolts (A) from back cover, using a 2-mm hex key.
5. Carefully lift the front cover (B).

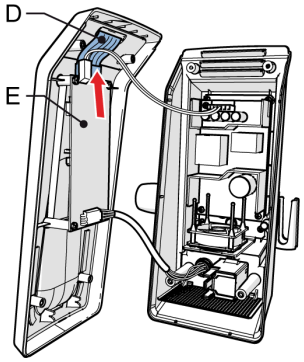




6. Remove four bolts (C), using a Torx T9 key.

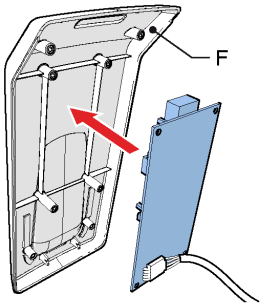


7. Disconnect the user interface flat cable (D) from the controller board (E).

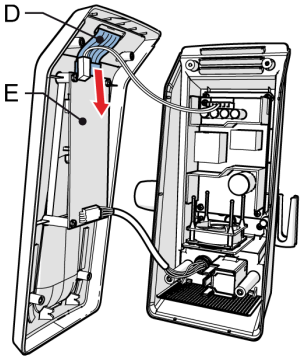


8. Remove the front cover with user interface (F).

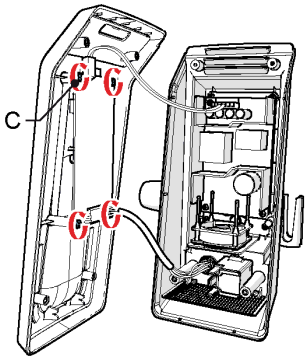
9. Mount the replacement front cover with user interface (F).



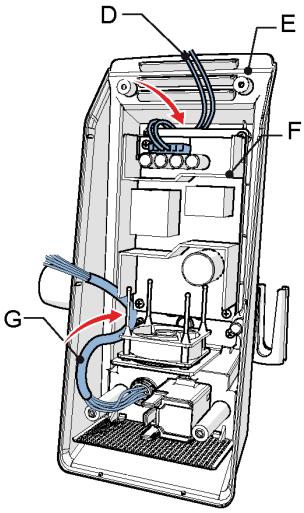
10. Connect the flat cable from the user interface (D) to the controller board (E).



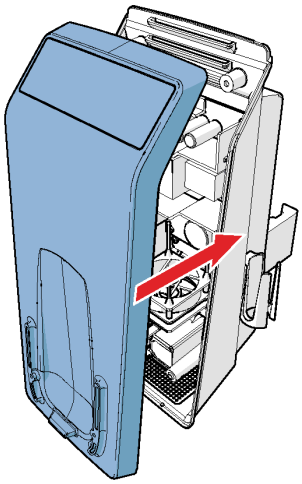
11. Fasten four bolts (C), using a Torx T9 key.



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



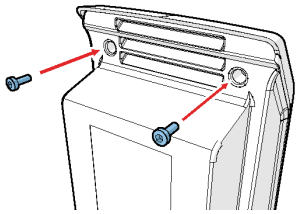
13. Carefully place the front cover on the back cover.



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 ***Replace the warming module holder*** on page 32).

16. Connect the interface cable and the power supply cord (see ***Connect the cables*** on page 21).

17. Place the hatch (see ***Place the hatch*** on page 22).

7 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 36.
- *System operation test* on page 37.
- *Overtemperature indicator test* on page 38.

7.1 Electrical safety test

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

7.1.1 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

7.1.2 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.

7.1.3 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].

7.2 System operation test

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

7.2.1 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

7.2.2 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.

7.2.3 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].

7.3 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].

7.3.1 Necessary items

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

7.3.2 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.

7.3.3 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].

8 Visual and audible warning systems Control module

8.1 Indicator response

If the device is not working properly, or gives a different response than expected, check the indications on the device. If the issue persists:

- Note the response. Also note the procedure and the process step at which the response occurred.
- Proceed to ***Cross-check modules*** on page 42.

Table 1: Indicator response list on page 40 shows all the possible device responses. A description of each response is described in detail in *Table 2: Solutions list* on page 41.

	Response Expected					
ID	**Control module**					**Warming module**
						
1	○ Off	○ Off	○ Off	○ Off	○ Off	○ Off
2	● Orange	○ Off	○ Off	○ Off	○ Off	○ Off
3	● Green	● Green	● Yellow	◔ Blinking	● Yellow	● Green
4	● Green	○ Off	○ Off	○ Off	○ Off	● Orange
5	● Green	◔ Blinking	○ Off	○ Off	○ Off	● Green
6	● Green	● Green	○ Off	○ Off	○ Off	● Green
7	● Green	○ Off	● Yellow	○ Off	○ Off	● Orange
8	● Green	○ Off	○ Off	◔ Blinking	○ Off	● Orange
9	● Green	○ Off	● Yellow	◔ Blinking	○ Off	● Orange
10	● Green	○ Off	● Yellow	○ Off	○ Off	○ Off
11	● Green	○ Off	● Yellow	○ Off	● Yellow	● Orange
12	● Green	○ Off	● Yellow	◔ Blinking	● Yellow	● Orange
13	● Green	○ Off	○ Off	◔ Blinking	● Yellow	● Orange

Table 1: Indicator response list

ID	Situation	Probable cause	Troubleshooting
1	Device is not powered.	Device is not connected.	See ***Connect the cables*** on page 21.
		Defective power supply cord.	See ***Disconnect the cables*** on page 30 and ***Connect the cables*** on page 21.
		Broken fuses.	See ***Exchange the fuse*** on page 31.
		Damaged power supply or electronics.	Contact the manufacturer.
2	Device is on standby mode.	Device is not turned on.	Press the Standby/on button.
		Defective button.	See ***Replace the front cover and the control panel*** on page 33.
3	Indicator test is running.	Device is being turned on.	Wait for a few seconds until the test has been finalized.
4	Device is on but no IV set has been detected.	User has not placed a IV set on the device.	Place a IV set and see if the device switches to the heating mode.
		Slider is not closed properly.	Open and close the slider and verify that the device starts heating.
		Warming module is contaminated and not detecting the IV set.	Clean the warming module and ensure that there are no spills or particles that could prevent good contact between the heater and the IV set.
5	Output fluid temperature is not within range.	System is still adjusting the output temperature.	Wait for up to three minutes.
		Fluid flow is inversed.	Make sure that the flow direction is correct.
		Input fluid temperature is too low or flow is too high.	Both the fluid input temperature and flow shall be within the specified range for the device to be able to reach 39 ± 2 °C
6	Normal operation.	Device is working properly.	N/A
7	Technical alarm.	Interface cable is not correctly connected.	See ***Connect the cables*** on page 21.
		Interface cable is defective.	See ***Disconnect the cables*** on page 30 and ***Connect the cables*** on page 21.
		Issue with the electronics.	Swap the modules to identify the source of the problem. Contact the manufacturer.
8	Overtemperature protection circuit has been activated.	Input fluid is too warm.	Ensure that the input fluid is within the specified temperature range.
		Sudden flow stop.	Ensure that a sudden flow stop does not trigger the overtemperature circuit. Prime

ID	Situation	Probable cause	Troubleshooting
			the set if the overtemperature circuit has been triggered.
		Issue with the electronics.	Swap the modules to identify the source of the problem. Contact the manufacturer.
9	Technical and overtemperature alarm triggered.	A failure in the device electronics has triggered both alarms simultaneously.	Swap the modules to identify the source of the problem. Contact the manufacturer.
10	Technical alarm.	Interface cable is not correctly connected.	See ***Connect the cables*** on page 21.
		Interface cable is defective.	See ***Disconnect the cables*** on page 30 and ***Connect the cables*** on page 21.
		No connection to the warming module.	Swap the modules to identify the source of the problem. Contact the manufacturer.
11	Technical alarm suppressed.	Technical alarm has been silenced.	Press the silence button once more to unmute the alarm.
12	Overtemperature alarm suppressed.	Overtemperature alarm has been silenced.	Press the silence button once more to unmute the alarm.
13	Technical and overtemperature alarm suppressed	All alarms have been silenced	Press the silence button once more to unmute the alarms.

Table 2: Solutions list

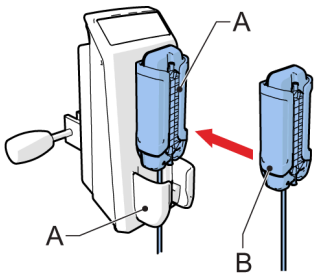
8.2 Cross-check modules

When an issue persists, do a cross-check to determine if the problem lies with the control module or the warming module.

8.2.1 Interchange the warming module

1. Reset the Control Module by unplugging the power supply cord.
2. Repeat all process steps with the original control module (A) and a warming module without an issue (B).

See ***Disconnect the cables*** on page 30 and ***Connect the cables*** on page 21.

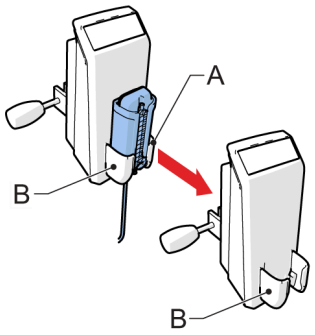


If the issue returns with the interchanged warming module (B), the control module (A) is likely to be defective.

8.2.2 Interchange the control module

1. Reset the Control Module by unplugging the power supply cord.
2. Repeat all process steps with the original warming module (A) and a control module without an issue (B).

See ***Disconnect the cables*** on page 30 and ***Connect the cables*** on page 21.



If the issue returns with the interchanged control module (B), the warming module (A) is likely to be defective.

8.3 RMA preparation

When one of the modules is defective, prepare the module for RMA (return merchandise authorisation) by filling out this table. Then contact your local distributor and provide the recorded details.

	Item	Note
1	Ref number of the defective module(s).	
2	Serial number of the defective module(s).	
3	Response given by the device according to *Table 1: Indicator response list* on page 40.	
4	Procedure and process step at which the issue occurs.	

Table 3: RMA preparation table

9 Specifications

9.1 Specifications of the device

General specifications

Part number (control and warming module)	650000-US
Part number control module	650100-US
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	Class II, Body Floating The third conductor in the power supply cord is only a functional earth.
Flow range[1] [2]	5 – 100 ml/min at T_{in} = 20 °C and $T_{ambient}$ = 20 °C
Input temperature range	4 – 30 °C
Temperature limits	Within safe range according to ASTM F2172-02:2011
Safety cut-off temperature	42 °C
Sound pressure (audible signal)	Low priority: 47.2 dB Medium priority: 54.0 dB

The essential performance of the device is to warm fluids within the safe temperature and time limits according to ASTM F2172-02:2011.

[1] Tested with water at 20 ± 1 °C, temperature measurement at the end of the cassette.
[2] Incoming fluid temperature of 20 °C, normothermic flow defined between 36 °C and 37.5 °C.

Environmental specifications

Ambient temperature	15 °C to 30 °C
Relative humidity	30 % to 75 %
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 Fluido® Compact IV 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 (300 mmHg, no IV catheter attached)	400 ml/min

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) [N003].
- The device will produce an audible signal when the power supply experiences a drop in voltage of more than 30%. Refer to ***Visual and audible warning systems*** 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 TSC Life sales representative [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 Literature

1. Guidelines for the use of blood warming devices, AABB, 2002.
2. Handbook of Transfusion Medicine, DBLL McClelland, UK blood service 4th Edition, ISBN 0-11-322677-2.
3. Blood and Transplant, NHS, December 2009 version 1.
4. Fantl and Morris, Thorax (1965),20,372, Influence of dextrose on heparinized blood.

12 Symbols

℞ 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, ANSI/AAMI/IEC 60601-1-8:2006 + A1:2012, CAN/CSA-C22.2 No. 60601-1:2014, CAN/CSA-C22.2 No. 60601-1-6:2011 + A1:2015, CAN/CSA-C22.2 No. 60601-1-8:2008 + A1:2014
MD	Medical Device
SN	Serial number
REF	Catalogue / article number / part number
QTY	Quantity
STERILE EO	The Fluido® Compact IV sets are sterile. Method of sterilisation: ethylene oxide.
LOT	Batch code / lot number
MOD	Device revision number (modification)
	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
	Risk of electrical shock.
	Type BF applied parts (according to IEC 60601-1)
	Class II equipment

	Fuse
	Expiry date (year/month)
	Single patient use only. Do not reuse Fluido® Compact IV sets.
	The Fluido® Compact IV sets are not made with natural rubber latex.
	Read the user manual.
	Consult the instructions for use.
	Dispose of according to local regulations.
	Caution. Consult the instructions for use for important cautionary information.
	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.
	Non-pyrogenic
	The Fluido® Compact Control module and the Warming module are MR unsafe.

Manufactured by:

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℞ Only