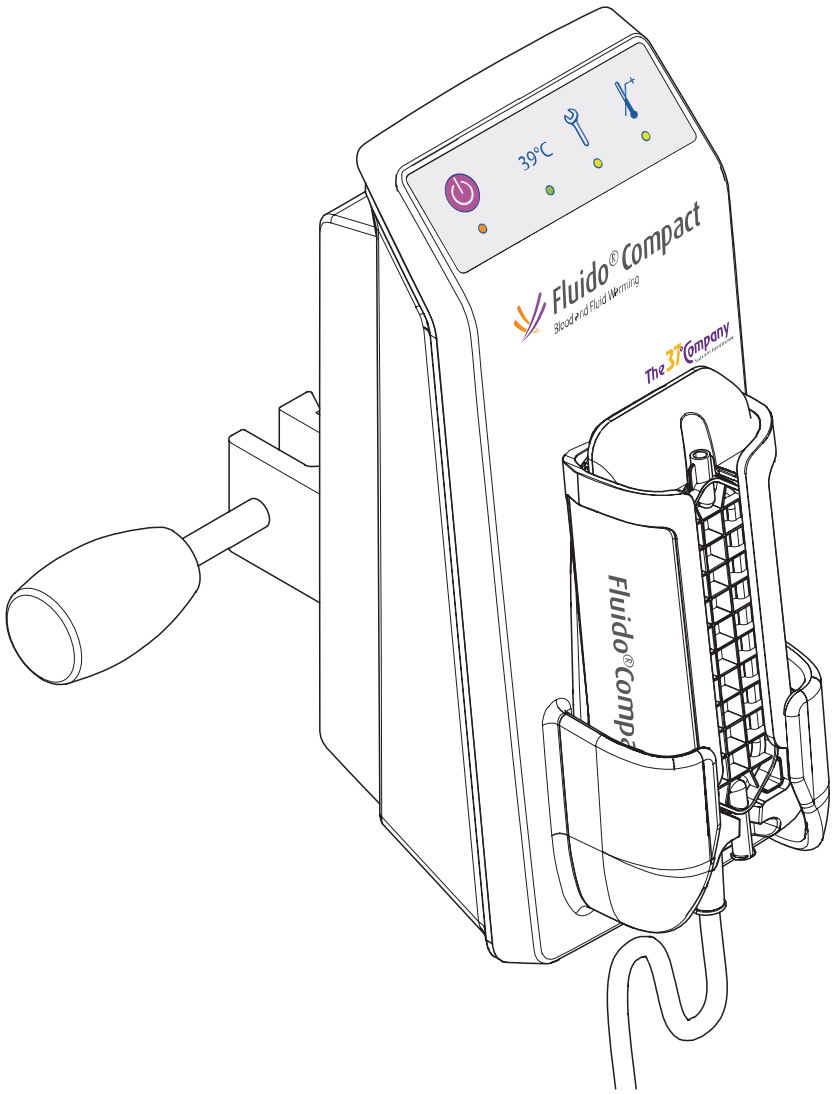
Fluido® Compact

Blood and Fluid Warming



User Manual / Technical Manual

Version: INT/R683-EN-3-10-17

The 37°Company

Solutions for Patient Warming

This page intentionally left blank!

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 (hereafter referred to as ‘the device’).

The device has the following modules:

- Fluido®*Compact* Control Module (hereafter referred to as ‘control module’)
- Fluido®*Compact* Warming Module (hereafter referred to as ‘warming module’)
- Two different disposable sets (referred to as 'diposable sets'):
  - 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’)

The manual helps you with the operation and the maintenance of the device, in a safe and responsible manner.

Read this manual carefully. Complete all the procedures. Do the procedures in the given sequence. Always keep the manual near the device.

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

The 37Company
Beeldschermweg 6F
NL-3821 AH Amersfoort
The Netherlands

Tel: +31 (0)33 450 72 50
Fax: +31 (0)33 450 72 60
E-mail: info@the37company.com
Website: www.the37company.com

1.4 Warranty

For the warranty provisions, refer to the website: www.the37company.com.

1.5 Authorisation of personnel

Make sure that only authorised personnel use the device.

1.6 Warning, caution and note

Warning!

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

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.

A "note" gives more information.

1.7 Disclaimer

The manufacturer reserves all rights. No part of this document may be reproduced or published, electronically, mechanically, in print, photographic print, on microfilm or by any other means whatsoever, without the explicit consent of The 37Company.

The content of this document has been compiled with the greatest possible care and this information can be regarded as reliable. Nevertheless, the manufacturer reserves the right to make alterations and improvements to the device. These may not yet have been described in the instructions. The manufacturer cannot be held liable for the final outcome of the patients' treatment.

This document contains proprietary information that may not be disclosed to third parties. This document may not be used without the explicit written consent of the manufacturer.

These instructions are intended for personnel authorised to work with and/or service the medical device described in this manual.

2 Safety

2.1 General safety precautions

Refer to *Cleaning* on page 30 for specific safety precautions.

2.1.1 Warnings

- Use the device as intended. See *Intended use* on page 6.
- Do not place the device on a warming matrass or under a warming blanket.

Materials

- Use blood products that comply to EU and/or US standards.
- Do not mix red blood cells with drugs. See *Literature* on page 9: 3 and 4.
- Use saline (0.9% Sodium Chloride) to dilute red blood cells to lower the viscosity. See *Literature* on page 9: 1 and 2.
- Do not mix dextrose solution (5%) with blood components. This can cause haemolysis. See *Literature* on page 9: 4 and 5.
- Do not use the device for warming whole blood, platelets, cryo-precipitates or granulocyte suspense.

Before operation

- The Fluido®*Compact* Warming Module is to be used only with the Fluido®*Compact* Control Module and Fluido®*Compact* disposable sets.
- Do not use the device if the warming surface is damaged (e.g. dents, cracks). Take the device out of service.
- 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).
- Use a new hospital administration set for every application. (See *Literature* on page 9: 4).
- Use disposable sets. Use each disposable set for only one patient. Do not use a disposable set if the expiration date has passed.
- 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 to cause an air embolism.
- Do not use the device outside the environmental specification. See also *Specifications* on page 43.

Operation

- Do not position the warming module close to the head of the patient if inhaler therapy is used.
- If fluid leakage is observed, stop the fluid flow, and open the slider to disengage the device from operating.
- Warming IV fluids/blood could result in outgassing. Check the disposable set every 15 minutes on accumulated gas bubbles. These can cause air embolism.
- If the IV line runs dry, disconnect it from the patient. Re-prime the system and ensure that all air is removed and reconnect it to the patient.

- The disposable set should not be used for longer than 24 hours.
- Only use a syringe at an injection point at the end of the patient line.

After operation

- The heating surface of the warming module and the cassette of the disposable set can get quite warm when heating cold IV fluids/blood at high flow rates. Wait a few seconds after stopping the IV fluid/blood flow before removing the cassette of the disposable set.
- After applying blood products, clean the hospital administration set using one priming volume of saline.
- This device may be a potential biohazard during and after use. Handle and dispose in accordance with acceptable medical practice and applicable regulations.

Other

- Modification of this equipment is not allowed.

2.1.2 Cautions

- Obey local regulations.
- Take care that the device is not dropped, to reduce the risk of damage.
- When (dis)connecting the interface cable, make sure the mains plug is disconnected from the electrical outlet.

2.1.3 Notes

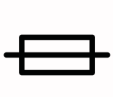
- Use the Fluido®*AirGuard System* if a higher flow or a larger volume is requested.
- The device is not intended to control the core temperature of the patient by itself. The device is intended as a tool to maintain a normothermic core temperature while monitoring the patient's core temperature directly by a dedicated sensor inside the patient's body.

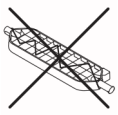
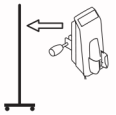
2.1.4 Literature

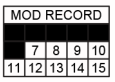
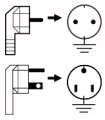
1. Reserved operations Blood transfusion, Jacques, M.B., Directorate Education & Training, 2008, Leids Universitair Medisch Centrum; Reader, 2009-04-06.
2. Guidelines for the use of blood warming devices, AABB, 2002.
3. Handbook of Transfusion Medicine, DBLL McClelland, UK blood service 4th Edition, ISBN 0-11-322677-2.
4. Blood and Transplant, NHS, December 2009 version 1.
5. Fantl and Morris, Thorax (1965),20,372, Influence of dextrose on heparinized blood.

2.2 Symbols

IPX1	Protected against falling water - Equivalent to 3-5 mm rainfall per minute for a duration of 10 minutes. Unit is placed in its normal operating position (according to IEC 60529).
IPX4	Protected against splashing water - Water spraying at all angles at 10 litres/min at a pressure of 80-100 kN/m^2 for 5 min. (According to IEC 60529).
P	Pressure
	Do not use the device if the package is damaged.
Rx Only	Caution: Federal US law restricts this device to sale by or on order of a physician.
	As to electrical shock, fire and mechanical hazards only in accordance with ANSI/ AAMI ES60601-1: A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, CSA CAN/ CSA-C22.2 NO. 60601-1:14, IEC 60601-1 Edition 3.1 (2012), IEC 60601-1-6:2010 (Third Edition) + A1:2013.
	Caution: risk of electrical shock.
SN	Serial number
REF	Catalogue / article number
QTY	Quantity
STERILE EO	Sterilized using ethylene oxide
LOT	Batch code / lot number

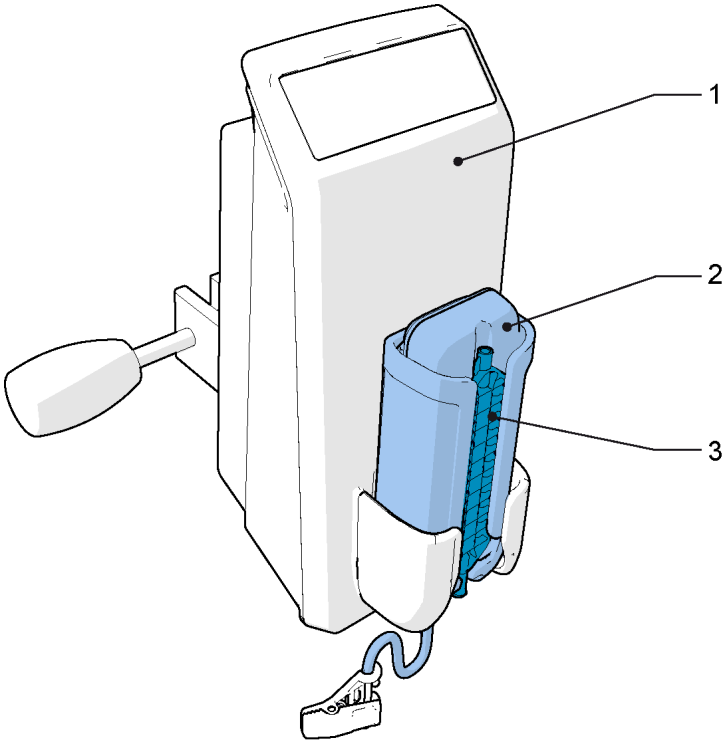
	Manufacturer
	Transport and storage ambient temperature range
	Transport and storage relative humidity range
	Transport and storage atmospheric pressure range
	Keep away from sunlight.
	Keep away from rain.
	AC voltage
	Type BF applied parts (according to IEC 60601-1)
	Expiry date, year/month
	For single patient use only. Do not re-use.
	Not made with natural rubber latex.
	Fuse

	Manual must be read.
	Consult the instructions for use.
	CE mark conform EU directive 93/42/EEC
	Dispose according to European Community Directive 2002/96/EC (WEEE).
	Caution. Check the instructions for use for important cautionary.
	Standby/on
	Upper limit temperature
	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 30.
	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 (manually) operated pressure device without a pressure indicator.
	Modification update, example = MOD 6
	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.
	Class II equipment with functional earthing
	Non-pyrogenic
	When (dis)connecting the interface cable, make sure the mains plug is disconnected from the electrical outlet (see *Warnings* on page 8).

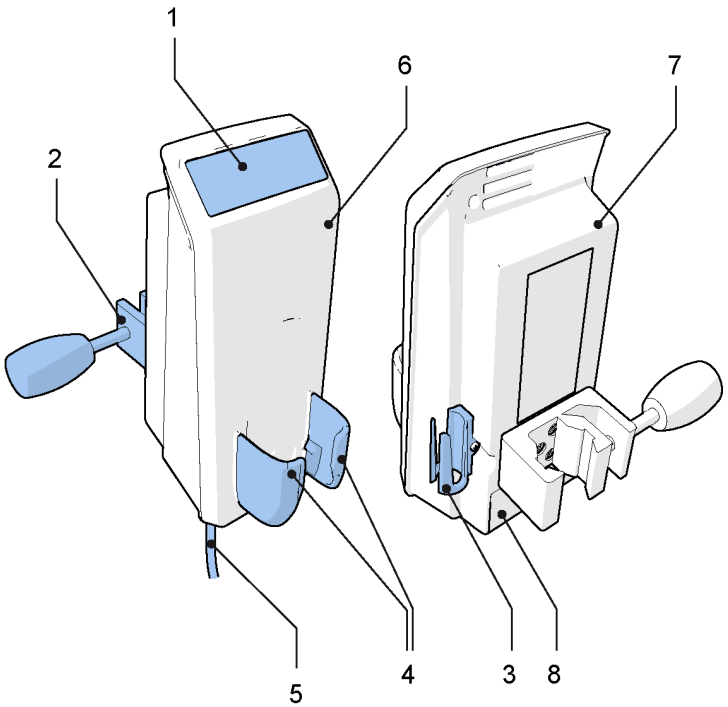
3 Description

3.1 Overview of the device



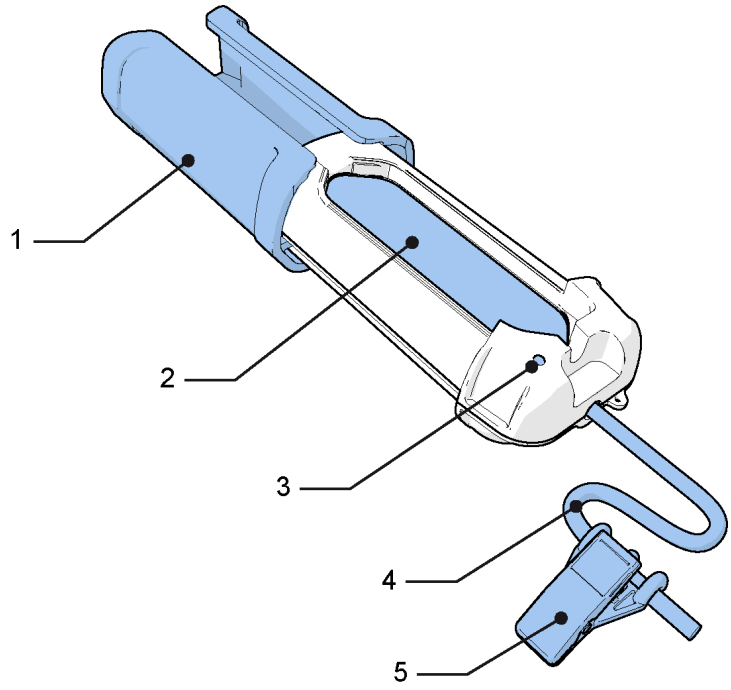
1. Control module (see *Overview of the control module [REF 650100]* on page 14)
2. Warming module (see *Overview of the warming module [REF 650200]* on page 15)
3. Disposable set (see *Overview of the disposable sets* on page 15)

3.2 Overview of the control module [REF 650100]



1. Control panel (see *Overview of the control panel* on page 16)
2. Universal clamp
3. Drip chamber holder
4. Warming module holder
5. Power supply cord
6. Front cover
7. Back cover
8. Hatch

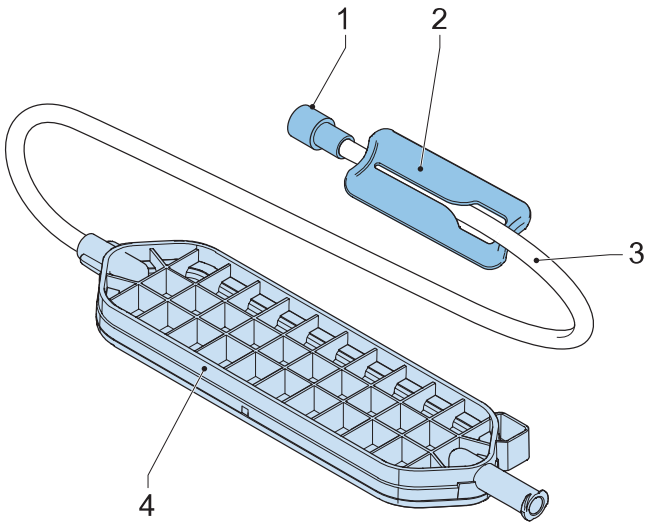
3.3 Overview of the warming module [REF 650200]



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

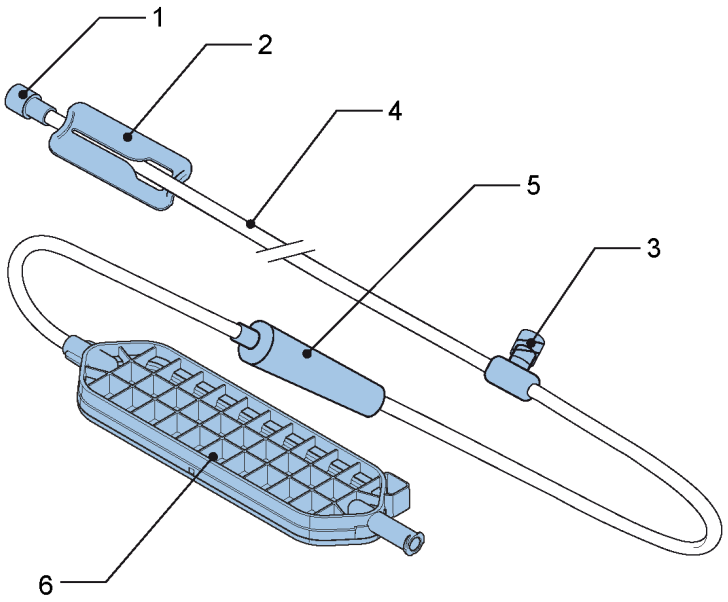
3.4 Overview of the disposable sets

3.4.1 Standard Set [REF 672000]



1. Luer-Lock (male)
2. Slide clamp
3. Patient line
4. Cassette with Luer-Lock (female)

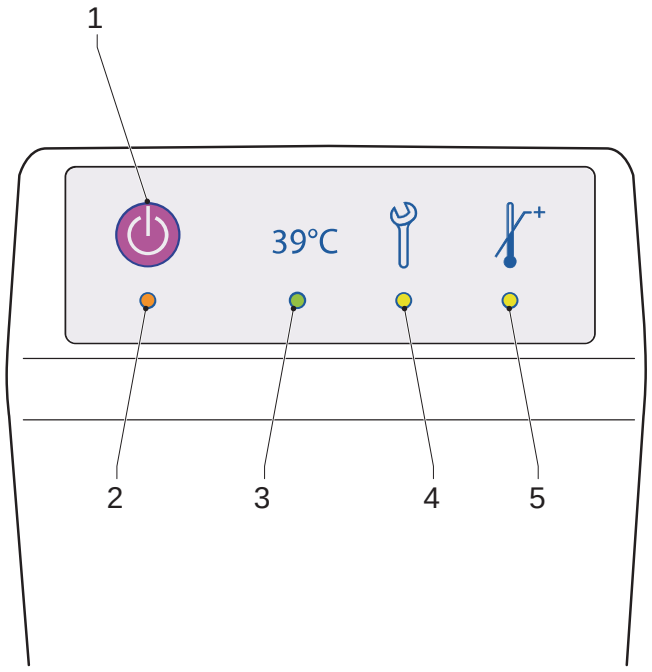
3.4.2 Standard Set with drip chamber [REF 672100]



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

- Standard Set with drip chamber [672100] is not available in the U.S.
- The drip chamber on the standard set with drip chamber is meant to be used as a deaeration chamber.

3.5 Overview of the control panel



1. Standby/on button
2. Standby/on indicator LED
3. Set point indicator LED
4. Repair required indicator LED
5. Overtemperature indicator LED

3.6 Indicator LED behaviour

Control module indicator LEDs (see *Overview of the control panel* on page 16)

Indicator LED	Behaviour	Meaning
Standby/on	Off	The device is not powered.
	Orange continuous	The device is in standby mode.
	Green continuous	The device is operational.
Set point	Green continuous	The derived fluid temperature at the outlet of the disposable cassette is within range (39 ± 2°C). See *Set point indicator* on page 18.
	Green flashing	The derived fluid temperature at the outlet of the disposable cassette is out of set point range.
Repair required	Yellow continuous	An error is detected. The device cannot be used. When the system is warming an audible alarm (repeating beep) is also active. See *Repair required indicator* on page 18.
Overtemperature	Yellow continuous	The safety circuit of the device has measured a too high temperature. See *Overtemperature indicator* on page 19.

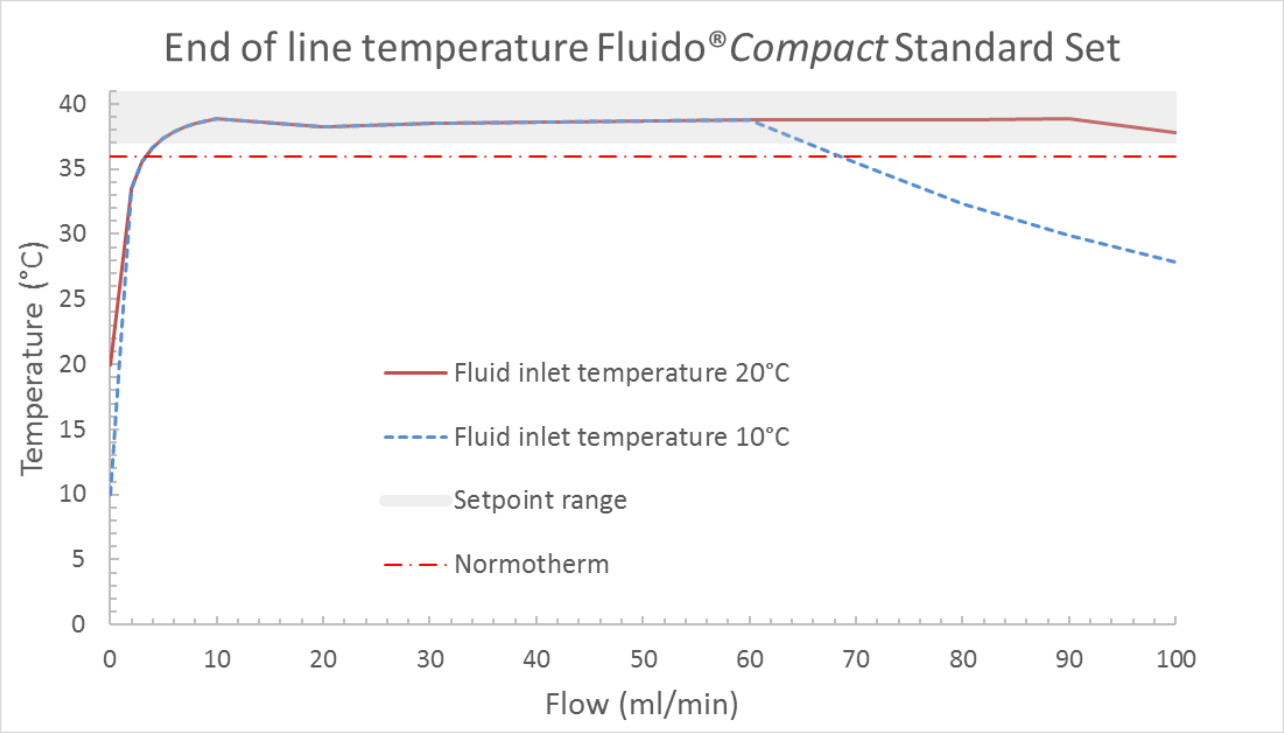
Warming module indicator LEDs (see *Overview of the warming module [REF 650200]* on page 15)

Indicator LED	Behaviour	Meaning
Status	Orange continuous	No disposable set is installed or the disposable set is installed incorrectly.
	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 maximum effective heating power is 125W. 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. In addition, temperature at the end of the patient line depends on the fluid flow rate and environmental conditions. If the fluid inlet temperature and environmental temperature are 20°C, the temperature at the end of the patient line is 39 ± 2°C at flow rates from 5 to 100 ml/min. The following graph shows the end of patient line fluid temperatures for different flow rates at a fluid inlet temperature of 10°C and 20°C in an environment of 20°C.



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 LED is active (continuously yellow).

- Check if the interface cable of the warming module is correctly attached and locked to the control module.
- 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 LED is active (continuously yellow).

- 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).
- 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 30).
- 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 LED indicators are active (continuously yellow). When the system is warming, an audible alarm (repeating beep) is also active.

4 Installation

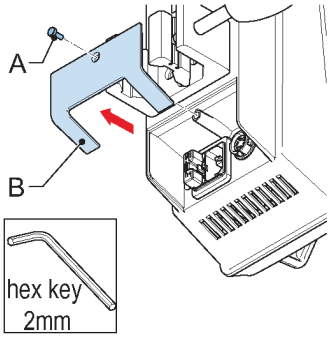
4.1 Transport and storage

Store the device and accessories according to the transport and storage recommendations. See *Specifications* on page 43.

4.2 Install the cables

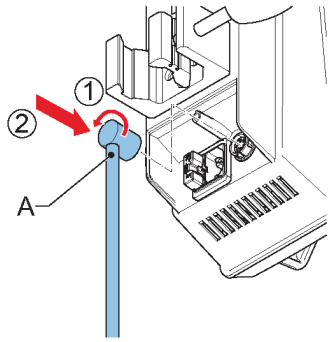
4.2.1 Remove the hatch

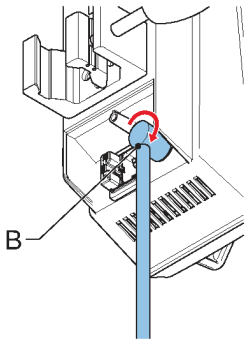
1. Remove the bolt (A) from the hatch, using a 2 mm hex key. The used bolt is: M3X8 A2-70 DIN7984 A.
2. Remove the hatch (B).



4.2.2 Install the interface cable

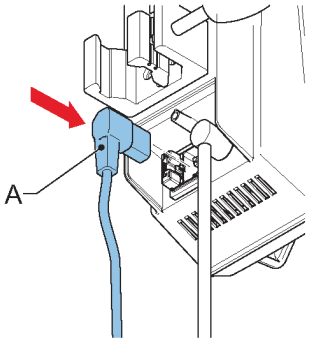
1. Turn the connector ring on the interface cable (A) to the open position.
2. Connect the interface cable.
3. Turn the connector ring on the interface cable (B) to the locked position.





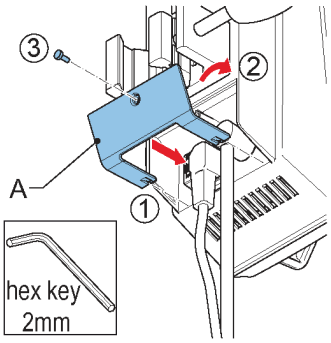
4.2.3 Install the power supply cord

1. Connect the power supply cord (A).



4.2.4 Place the hatch

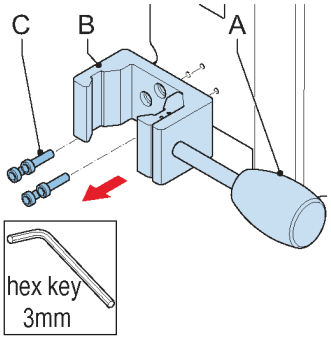
1. Place the lower parts of hatch (A).
2. Rotate the hatch upwards until it is closed.
3. Fasten the bolt in the hatch.

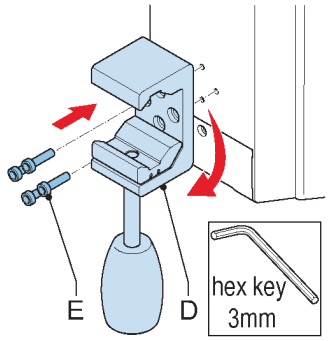


4.3 Change the rotation of the universal clamps (optional)

Turn the universal clamp 90° if you want to install the universal clamp to a bed rail:

1. 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).

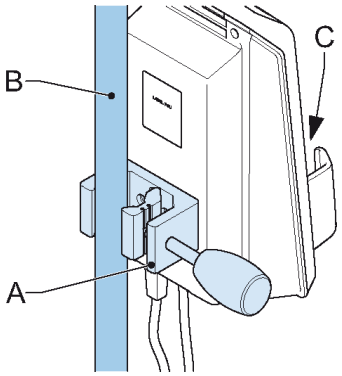




4.4 Attach the device

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

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.
4. Put the warming module in the warming module holder (C).



5 Operation

5.1 Safety instructions before operation

Warning!

- Do not add calcium rich supplements (such as Hartmann's solution or Ringers lactate) as priming solution to blood to prevent blood clots.
- Do not use blood stored below 2°C to prevent blood clots.
- The device is tested with blood stored at 4-6°C.
- Do not use a leukocyte reduction filter in combination with the disposable set.
- Do a check on the device after a temporary interruption of the mains supply. The device does not have an isolating switch. After an interruption of the supply mains, the device is in standby mode.
- Make sure that there is a physician order for switching on the device and for continued use.
- Make sure that the power supply cord can be disconnected easily in case of an emergency.
- To remove all power, disconnect the power supply cord.
- Check the patient's condition and temperature at least every 15 minutes.
- Do not maintain the device while it is in use with a patient.
- Make sure that only authorised personnel use the device.

Caution!

Obey this procedure if there is interference with random devices:

- Stop random devices one by one to isolate the offending device.
- Put the other receiving device to a different location.
- Put the device that interferes further away from the device or use a different socket.
- Contact your local dealer if you need help.
- Use only specified power supply cords to prevent increased emission or decreased immunity of the unit.

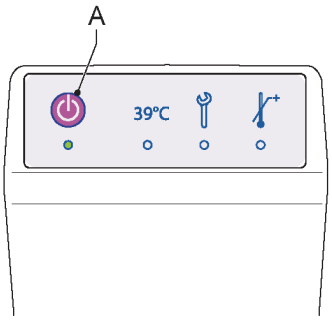
The device is approved for electromagnetic interference according to IEC 60601-1-2. Details on electromagnetic compatibility can be found in *Electromagnetic compatibility* on page 46.

5.2 Preparation before operation

Before you prepare the device, ensure that the device is installed correctly (refer to *Installation* on page 20).

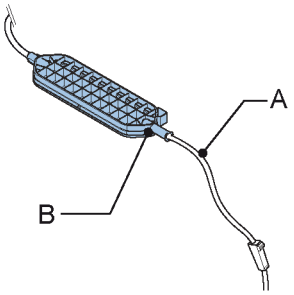
5.2.1 Turn the device on

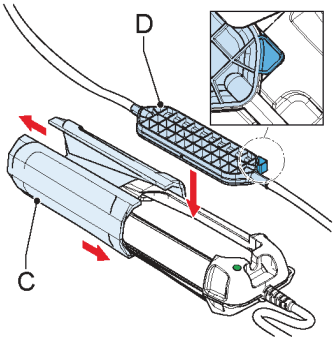
1. Connect the power supply cord to the socket.
   The standby/on indicator LED on the control module is now orange.
2. Push the standby/on button (A).
   - You will hear a single beep.
   - The indicator LEDs on the control module flash one time.
   - The standby/on indicator LED stays green.
   - The status indicator LED on the warming module is now orange.



5.2.2 Install the disposable set

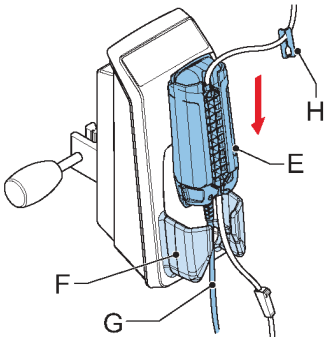
1. Unpack and inspect the disposable set.
2. Connect the hospital administration set (A) to the cassette of the disposable set (B).
3. Take the warming module out of the warming module holder.
4. Open the slider (C) of the warming module.
5. Put the cassette of the disposable set (D) in the warming module. The cassette fits in only one way.
6. Close the slider.
   The status indicator LED on the warming module is now green, to indicate that the disposable set is detected and positioned correctly.





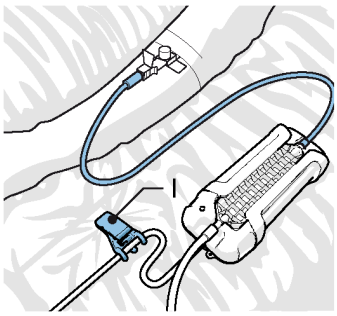
When the status indicator LED on the warming module stays orange the detection of the disposable set failed.

- Remove the set (see *Stop the device* on page 27).
- 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 25).
- Install the disposable set again.
- Wait until the set point indicator LED on the control module stays green.



7. The set point indicator LED flashes 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.
The warming module can be placed near the patient infusion site. Secure the cable clamp (I) to the patient coverings.



Warning!

If the warming module is placed near the patient:

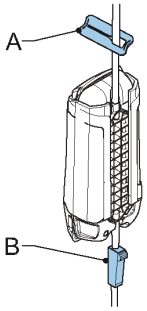
- Make sure it is placed on a stable surface.
- Make sure it is placed near the patient infusion site.
- Make sure the cable clamp is secured to the patient coverings.
- Make sure the distance between cable clamp and warming module is less than 10 cm.

9. Make sure that the slide clamp (H) is open.

5.2.3 Prime the standard set

Prime the hospital administration set and the standard set.

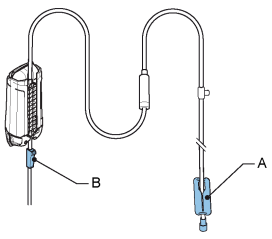
1. Hold the standard set in the upright position.
Make sure that the slide clamp (A) of the standard set and the roller clamp (B) of the hospital administration set are open.
Make sure that there is no air left in the system.
2. Close the roller clamp.



5.2.4 Prime the standard set with drip chamber

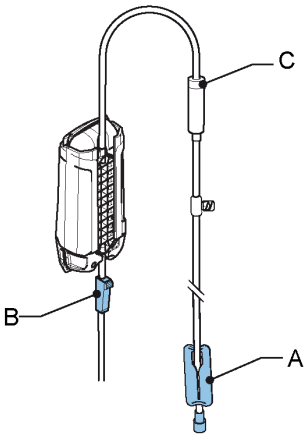
Prime the hospital administration set and the standard set with drip chamber.

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 drip chamber holder.

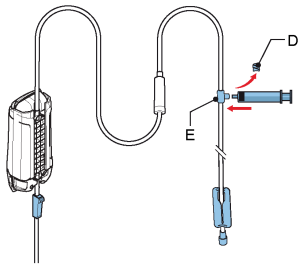


5.2.5 Deaerate standard set with drip chamber

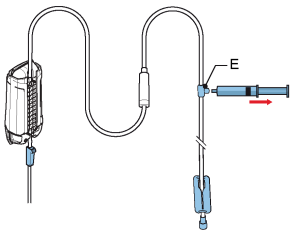
1. Hold the disposable set in the upright position.
   Make sure that the slide clamp (A) of the disposable set is closed and the roller clamp (B) of the hospital administration set is open.



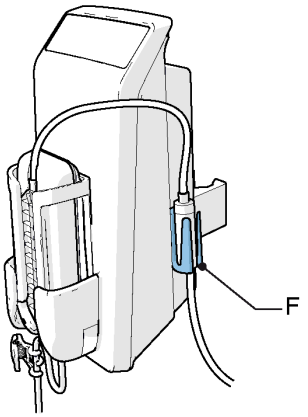
2. Hold the drip chamber (C) upside down.
3. Remove the cap (D) from the T-connector (E) and connect to a syringe.



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 drip chamber holder (F).



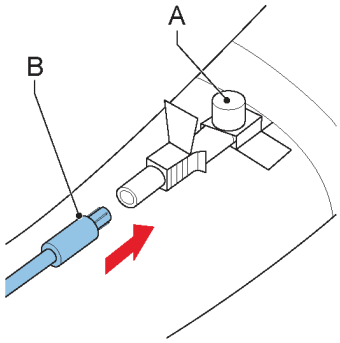
Warning!

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

5.3 Operate the device

Before you operate the device, prepare the device (refer to *Preparation before operation* on page 23).

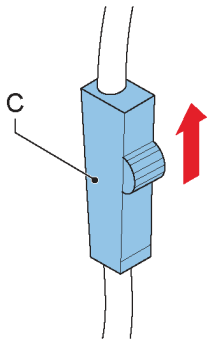
1. Put the warming module near the patient.



Warning!

- Do not position the warming module close to the head of the patient if inhaler therapy is used.
- Only use a syringe at an injection point (A) at the end of the patient line.

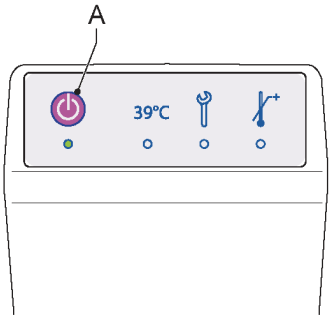
The position of the warming module depends on the position of the IV catheter.



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

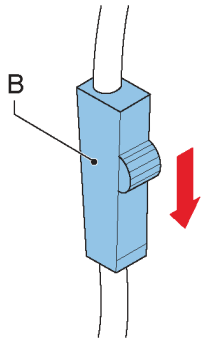
5.4 Stop the device

1. Push the standby/on button (A).

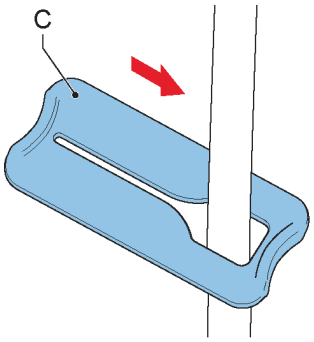


The status indicator LED of the warming module is now orange.

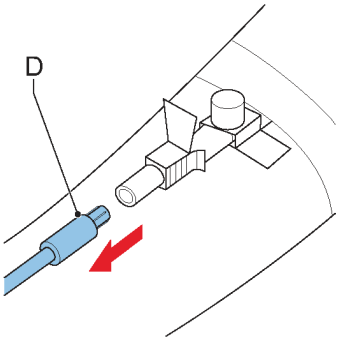
2. Close the roller clamp (B) of the hospital administration set.



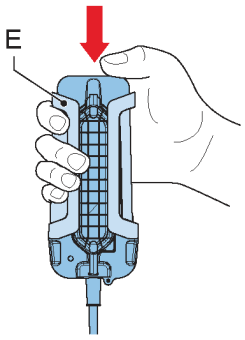
3. Close the slide clamp (C) of the patient line.



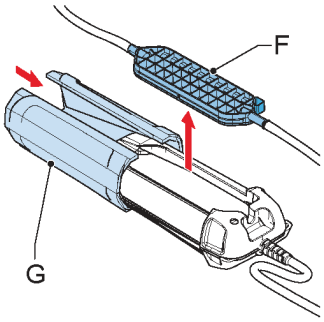
4. Disconnect the patient line (D) from the IV catheter.



5. Open the slider (E).



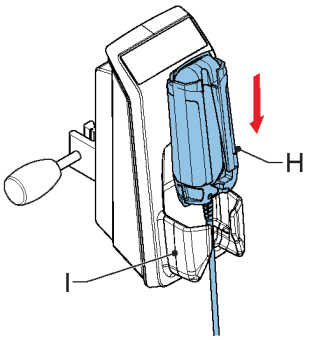
6. Remove the disposable set (F) from the warming module.



Warning!

If it is necessary, clean the warming module, according to hospital guidelines. See *Cleaning* on page 30.

7. Close the slider (G).
8. Put the warming module (H) in the warming module holder (I).



9. Dispose the disposable set.

6 Maintenance

For the device, several spare parts are available (see *Repair* on page 32). The heating element of the warming module cannot be changed.

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 warming module or control module depending on which device support is needed.

You can find the serial number of the control module on the back, just above the universal clamp. The serial number of the warming module is on the slider.

If the device gives a 'repair required' indication (see *Indicator LED behaviour* on page 17), contact your local distributor.

Warning!

The device should be tested at least once a year, see *Test the device* on page 40.

The essential performance of the device is to warm fluids within the safe temperature and time limits according to ASTM F2172-2. Testing is required to validate if the device still complies with its essential performance.

6.1 Cleaning

6.1.1 General cleaning procedure

Warning!

Before you clean the device, disconnect the power supply cord.

Caution!

- Do not use dripping wet cloths.
- Do not use ketones (MEK, acetone, etc) or abrasive cleaners.
- Do not use steam sterilization (autoclave), EO sterilization or dry heat to sterilize the device.
- Make sure that water cannot come in the electrical areas of the device.
- Clean the device from too much detergent or disinfectant.
- Let the device air dry.
- To clean the outer surface of the device, use a soft cloth lightly dampened with a solution of hand warm water and a mild detergent or a non-staining hospital disinfectant.
- Use one of the following cleaning solutions:
  - 90% (or 70%) isopropyl alcohol
  - mild detergent solution

- diluted chlorine bleach (30 ml/l water)
- ammonia based cleaners
- glutaraldehyde-based cleaners 2.4%
- hydrogen peroxide 3%

6.1.2 Cleaning of the warming module

Caution!

To clean the warming module:

- Use solutions with less than 2.4% glutaraldehyde.
- Obey the manufacturer's recommendations, see *General cleaning procedure* on page 30.

Caution!

Make sure that you do not damage the interface of the warming module. If the interface is wet, still dirty or damaged, do not use the device and replace the warming module.

6.1.3 Cleaning of the control module

Caution!

To clean the control module:

- Use solutions with less than 2.4% glutaraldehyde.
- Obey the manufacturer's recommendations, see *General cleaning procedure* on page 30.

Caution!

- Make sure that fluids cannot come in the control module.
- Make sure that the control module is dry before you use it again.

6.1.4 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)
- the warming surface is dirty (e.g. coagulated blood)

Clean or dry the surface or take the device out of service if necessary.

7 Repair

For a list of available spare parts, please visit our website: *www.the37company.com*.

Warning!

- The device may only be opened or repaired by certified technicians.
- Before opening the device, make sure the mains power cable is unplugged.
- After repair, always test the device according to *Test the device* on page 40.

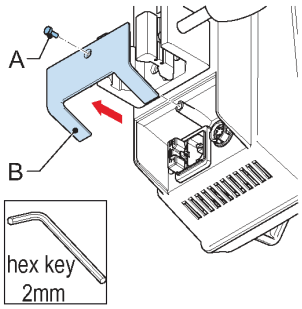
Caution!

- Place the device on a soft and stable surface.
- Wear latex gloves and static discharger when handling internal components.

7.1 Hatch

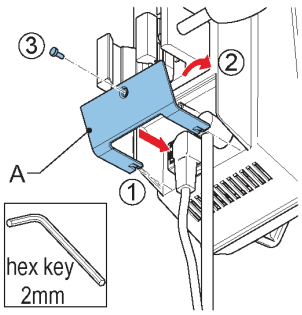
7.1.1 Remove hatch

1. Remove the bolt (A) from the hatch, using a 2mm hex key.
   The used bolt is: M3X8 A2-70 DIN7984.
2. Remove the hatch (B).



7.1.2 Place hatch

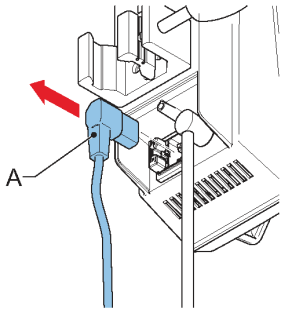
1. Place the lower parts of the hatch (A).
2. Rotate the hatch upwards until it is closed.
3. Fasten the bolt in the hatch.



7.2 Cables

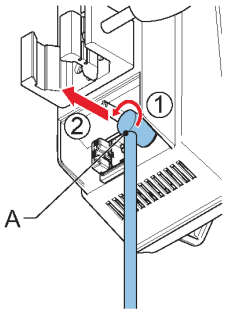
7.2.1 Disconnect power supply cord

1. Remove the hatch (see *Remove hatch* on page 32).
2. Disconnect the power supply cord (A).



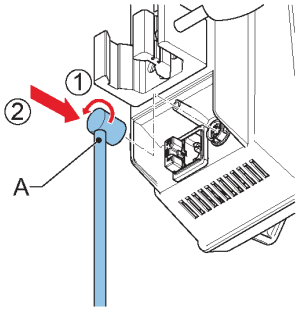
7.2.2 Disconnect interface cable

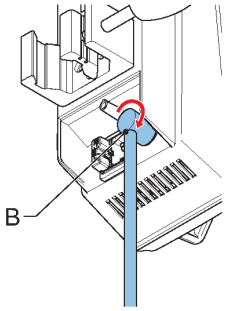
1. Remove the hatch (see *Remove hatch* on page 32).
2. Turn the connector ring on the interface cable (A) to the open position.
3. Disconnect the interface cable.



7.2.3 Connect interface cable

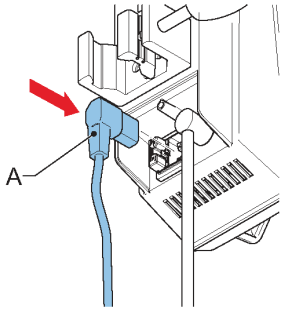
1. Turn the connector ring on the interface cable (A) to the open position.
2. Connect the interface cable.
3. Turn the connector ring on the interface cable (B) to the locked position.
4. Place the hatch (see *Place hatch* on page 32).





7.2.4 Connect power supply cord

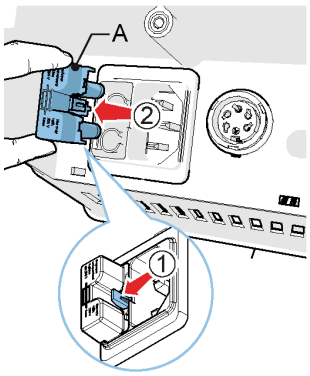
1. Connect the power supply cord (A).
2. Place the hatch (see *Place hatch* on page 32).



7.3 Fuse

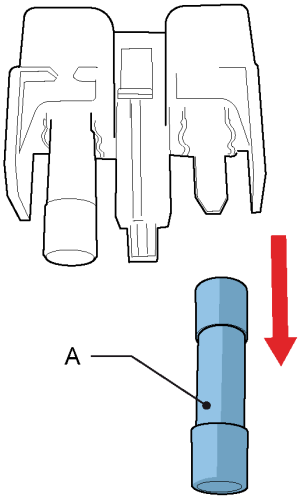
7.3.1 Remove fuse holder

1. Remove the hatch (see *Remove hatch* on page 32).
2. Disconnect the power supply cord (see *Disconnect power supply cord* on page 33) and interface cable (see *Disconnect interface cable* on page 33).
3. Push the locking pin inward and remove the fuse holder (A).



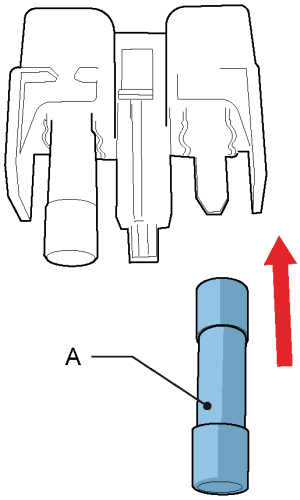
7.3.2 Remove fuse

1. Remove the hatch (see *Remove hatch* on page 32).
2. Disconnect the power supply cord (see *Disconnect power supply cord* on page 33) and interface cable (see *Disconnect interface cable* on page 33).
3. Remove the fuse holder (see *Remove fuse holder* on page 34).
4. Remove the fuse (A).



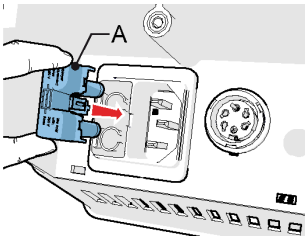
7.3.3 Place fuse

1. Place the fuse (A). For the fuse specifications, see *Specifications of the device* on page 43.
2. Place the fuse holder (see *Place fuse holder* on page 35).
3. Connect the interface cable (see *Connect interface cable* on page 33) and power supply cord (see *Connect power supply cord* on page 34).
4. Place the hatch (see *Place hatch* on page 32).



7.3.4 Place fuse holder

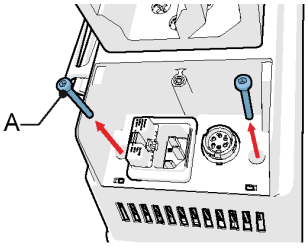
1. Place the fuse holder (A).
2. Connect the interface cable (see *Connect interface cable* on page 33) and power supply cord (see *Connect power supply cord* on page 34).
3. Place the hatch (see *Place hatch* on page 32).

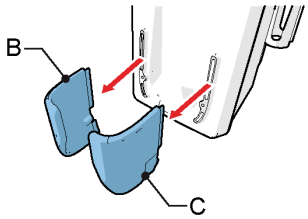


7.4 Warming module holder

7.4.1 Remove warming module holder

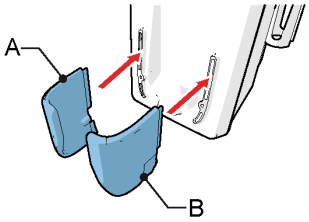
1. Remove the hatch (see *Remove hatch* on page 32).
2. Disconnect the power supply cord (see *Disconnect power supply cord* on page 33) and interface cable (see *Disconnect interface cable* on page 33).
3. Remove two bolts (A) from the back cover, using a 2mm hex key.
4. Remove the left (B) and right (C) warming module holder parts.

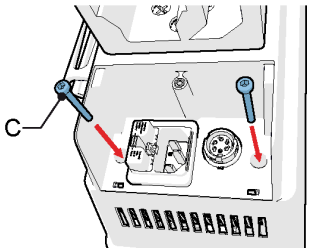




7.4.2 Place warming module holder

1. Place the left (A) and right (B) warming module holder parts.
2. Fasten two bolts (C) from the back cover, using a 2mm hex key.
3. Connect the interface cable (see *Connect interface cable* on page 33) and power supply cord (see *Connect power supply cord* on page 34).
4. Place the hatch (see *Place hatch* on page 32).

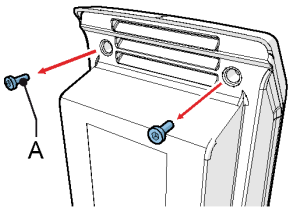




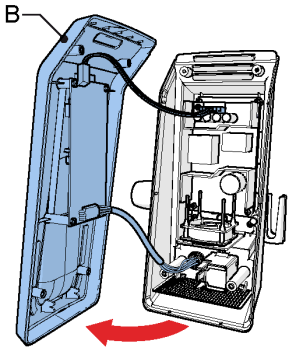
7.5 Front cover and control panel

7.5.1 Remove front cover and control panel

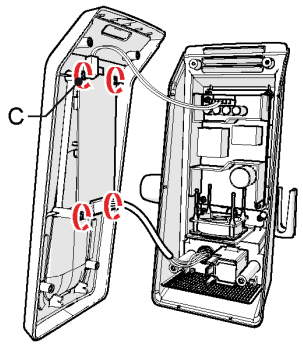
1. Remove the hatch (see *Remove hatch* on page 32).
2. Disconnect the power supply cord (see *Disconnect power supply cord* on page 33) and interface cable (see *Disconnect interface cable* on page 33).
3. Remove the warning module holder (see *Remove warming module holder* on page 35).
4. Remove two bolts (A) from back cover, using a 2mm hex key.



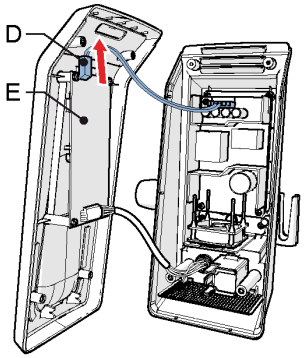
5. Carefully lift the front cover (B).



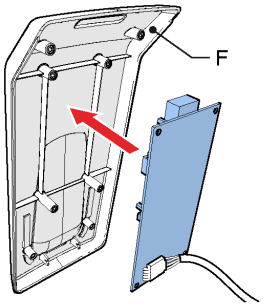
6. Remove four bolts (C), using a Torx T9 key.



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

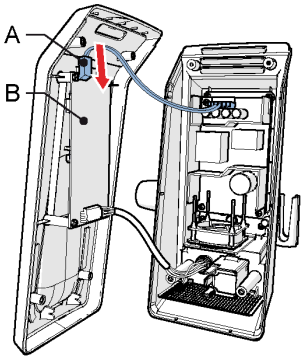


8. Remove the front cover with user interface (F).

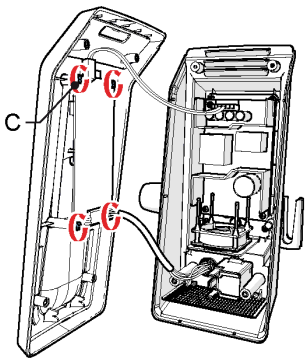


7.5.2 Place front cover and control panel

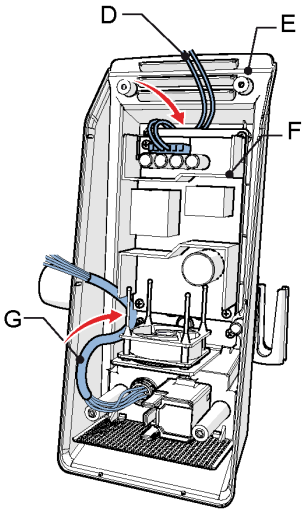
1. Connect the flat cable from the user interface (A) to the controller board (B).



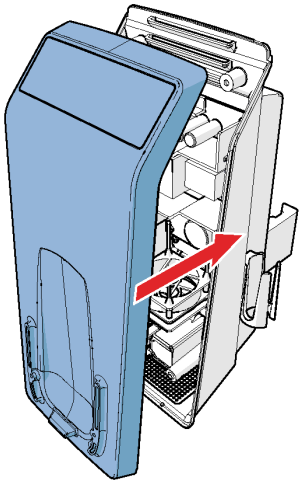
2. Fasten four bolts (C), using a Torx T9 key.



3. Place the fan cable (D) between the back cover (E) and the power board (F). Do the same with the controller cable (G).



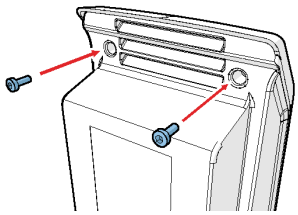
5. Carefully place the front cover on the back cover.



Caution!

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

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



7. Place the warming module holder (see *Place warming module holder* on page 36).

8. Connect the interface cable (see *Connect interface cable* on page 33) and power supply cord (see *Connect power supply cord* on page 34).
9. Place the hatch (see *Place hatch* on page 32).

8 Test the device

Caution!

Do the following tests once per year or after repair.

- Electrical safety test, see *Electrical safety test* on page 40
- System operation test, see *System operation test* on page 40
- Overtemperature alarm test, see *Overtemperature alarm test* on page 41

8.1 Electrical safety test

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 (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 free of air.
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. Do the electrical safety test, refer to IEC 60601-1, for a class II, Body Floating Device.

8.2 System operation test

8.2.1 Necessary items

- the device
- IV pole (optional)
- saline or other crystalloid fluids 21 ± 3°C
- standard set
- hospital administration set
- measuring cup 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 21 ± 3°C and draft-free.

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 correct.
3. Measure the actual flow rate by measuring the increase in volume (millilitre) IV fluid in the measuring cup over a period of time.
4. Make sure that the IV fluid temperature at the end of the patient line (40 centimetre) is between 37-41°C after temperature stabilisation for the flow rate range of 5-100 millilitre/ minute.

If environmental temperature is lower than indicated, fluid temperature may be lower than 37°C at end of patient line.

8.3 Overtemperature alarm test

Warning!

Be careful when you use hot water.

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 put the device in on mode.
2. Open the slider a few millimetres until the set point indicator LED is off.
3. Flush the hot water into the standard set.
4. Make sure that the over temperature alarm starts.
5. Close the clamps.

9 Specifications

9.1 Specifications of the device

General specifications

Part No. device (control module + warming module)	650000
Part No. control module	650100
Part No. warming module	650200
Modification (MOD)	1, 2, 3
Fuse control module	2x T3.15AH 250V
Voltage	100 – 240V~ (50/60 Hz)
Maximum power	160 W
Dimensions control module	H: 285 mm W: 120 mm D: 195 mm
Dimensions warming module	H: 165 mm W: 75 mm D: 50 mm
Length power cable	400 cm
Length interface cable	180 cm
Weight control module	< 1700 g
Weight warming module	< 450 g
Class (IEC 60529) control module	IPX1
Class (IEC 60529) warming module	IPX4
Class IEC 60601-1	Class II, Body Floating The third conductor in the power supply cord is only a functional earth.
Class (MDD93/42/EEC)	Class II b
Flow range (39 ± 2°C) standard set	5 – 100 ml/min at T_{in} = 20°C & T_{env} = 20°C
Flow range (Normothermic) standard set with drip chamber	15 – 100 ml/min at T_{in} = 20°C & T_{env} = 20°C
Input temperature range	5 – 30°C
High temperature limit	Within safe range according to ASTM F2172-02 (2011)

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 70°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. no. standard set	672000
Part. no. standard set with drip chamber	672100
Maximum pressure	300 mmHg
Priming volume standard set	4 ml (5 ml with 300 mmHg pressure)
Priming volume standard set with drip chamber	15 ml (16 ml with 300 mmHg pressure)
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) Note: 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, preferable between 2°C and 30°C.	
Relative humidity	10% to 90% (non-condensing)

Atmospheric pressure	50 kPa to 106 kPa

10 Electromagnetic compatibility

10.1 Electromagnetic immunity

Guidance and manufacturer's declaration - electromagnetic immunity

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

Warning!

- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

The Emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the equipment.

Immunity test	IEC60601 test level
Electrostatic 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-IEC61000-4-5 (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 cycles
Power frequency (50/60 Hz) magnetic field IEC EN-IEC 61000-4-8 (2010)	30 A/m

Immunity test	IEC60601 test level
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 – electromagnetic emissions

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

Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class A
Harmonic emissions IEC 61000-3-2	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	

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

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

The 37Company
Beeldschermweg 6F
NL-3821 AH Amersfoort
+31 (0)33 450 72 50

www.the37company.com
info@the37company.com

CE 0344