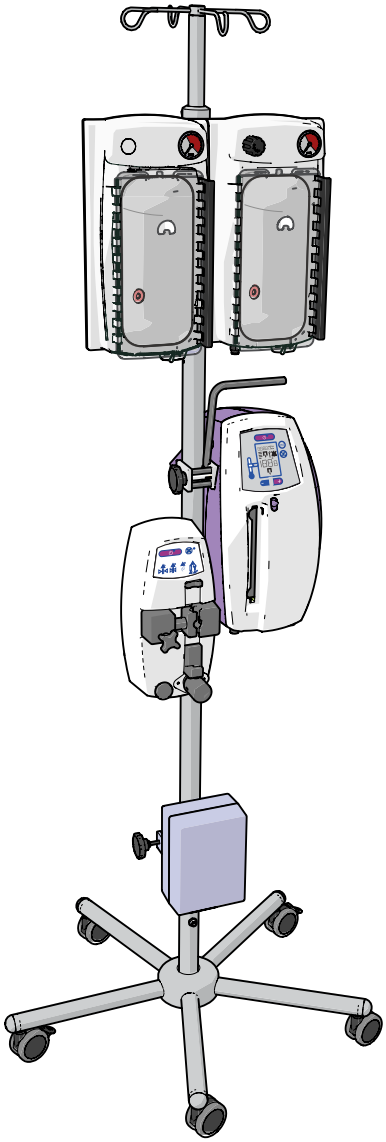
Fluido®

Blood and Fluid Warming



User Manual

Fluido® AirGuard System

Date of issue: May, 2023
Original instructions
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The Surgical Company

PTM

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Contents

1 General information

1.1 About this manual

In this manual, you can find important information about how to operate the Fluido® AirGuard System (hereafter referred to as 'the system').

The manual assists with the operation and maintenance of the system in a safe and responsible manner. If during use or servicing any serious incident occurs, this should be reported to manufacturer and competent authority as soon as possible.

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

To ensure the essential performance of the system, yearly maintenance is required. Functional testing is mandatory to be performed after every maintenance. Please refer to the Fluido® AirGuard System technical manuals for maintenance, repair and calibration instructions. The Fluido® AirGuard System technical manuals are available for download at the business partner menu of the The Surgical Company International B.V. website.

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® AirGuard System is developed to supply warm fluids to adult patients.

The system can be used to warm the following fluids:

- Crystalloid Intravenous (IV) fluids
- Synthetic Colloid Intravenous (IV) fluids
- Packed red blood cells, platelets, and blood components

1.4 Indications for use

The Fluido® AirGuard System is indicated for warming blood and fluids before IV administration to patients in variety of clinical situations. The warm blood or fluid administration helps maintain normothermia.

1.5 Contact

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The Netherlands

Tel: +31 (0)33 450 72 50
E-mail: *info.ptm@tsc-group.com*
Website: *www.tsc-group.com/ptm*

Refer to the website for local distributors.

1.6 Frequently asked questions (FAQ)

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

1.7 Warranty

The Fluido® AirGuard System is subject to a warranty declaration, which can be found on the company's website: *www.tsc-group.com/ptm* or obtained through your local distributor. Users are advised to take note of the relevant terms and conditions of this warranty.

1.8 Authorisation of personnel and training

Caution! The instructions contained in this manual are solely intended for authorised and certified personnel to work with and/or service the medical device(s) described herein. [C020]

1.9 Disclaimer and intellectual property statement

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

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

1.10 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, notes and symbols

The system was designed and built with safety in mind. Read and understand the contraindications, warnings, cautions and notes before using the system.

2.1 General safety precautions

2.1.1 Warnings

Warning!

- Use the system as intended. Refer to *Intended use* on page 7. [W053]
- Obey local regulations. [W057]

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 12, references 3 and 4. [W003]
- Use saline solution (0.9% Sodium Chloride) to dilute red blood cells to reduce the viscosity. See *Literature* on page 12, references 1 and 2. [W004]
- Do not mix dextrose solution (5%) with blood components. This can cause haemolysis. See *Literature* on page 12, references 4 and 5. [W005]
- Do not use the system for warming whole blood, cryoprecipitates or granulocyte suspension. [W006]
- Do not add calcium-rich supplements (such as Hartmann’s solution or Ringers lactate) as priming solution before the infusion of blood to prevent blood clots. [W007]

Prior to operation

Warning!

- Unlock the brakes on the IV Pole before moving the system. [W009]
- Do not use the system if one or more of its modules are damaged (e.g. dents, cracks). Take the system out of service and contact the hospital service department or the local supplier. [W011]
- Make sure that there is a physician's order for switching on and continued use of the system. [W012]

- Use a new hospital IV administration set for every application with a Fluido® Standard Set. (See *Literature* on page 12, reference 4). [W013]
- Use the system only with a Fluido® Standard Set, a Fluido® Trauma Set or a <keyword keyref="model"/> Trauma Plus Set. [W015]
- Use each disposable set for only one patient. [W017]
- Do not use a disposable set if the disposable has expired. [W018]
- Do not use a leukocyte reduction filter in combination with the disposable set. [W019]
- Follow the standard IV line protocols for priming the complete infusion set and the disposable set before connecting to a patient. Take care to ensure there is no air in the lines that may cause air embolism. [W020]
- Check the patient's condition and temperature at least every 15 minutes. [W021]
- Do not service the device while it is being used. [W022]
- Make sure that only authorised personnel use the system. [W023]

Operation

Warning!

- Do not position the system close to the head of the patient if inhaler therapy is being used. [W024]
- The use of the Fluido®Air Guard is mandatory when giving pressurized infusion. Failure to do so may lead to air embolisms. [W103]
- Warming IV fluids/blood components may result in outgassing. This can cause air embolisms. Check the disposable set every 15 minutes for accumulated gas bubbles. If there is air present in the deaeration chamber, remove the air to avoid that the Air Guard shut off valve will clamp the IV line. [W025]
- If the IV line runs dry, disconnect it from the patient, prime the system again and ensure that all air is removed, and then reconnect it to the patient. [W026]
- The disposable set should not be used for longer than 24 hours. [W027]
- If a problem with the Fluido® Air Guard cannot be solved immediately, remove the IV and deaeration chamber from the Air Guard (see *Releasing the IV line from the Air Guard shut-off valve* on page 42) and perform a continuous check for foam and bubbles. [W028]
- Make sure that the pressure on the line does not exceed 300 mmHg when using the system. Do not use a pressure device without pressure indicator or an in-line manually driven pressure system (hand bulb). This can cause hypovolemia due to hypoperfusion and mild hypothermia. [W029]
- Do not pull or push the tubing when attaching or removing the IV bag. Use the spike grip to attach or remove the spikes from the IV bag, to prevent leakage resulting in disruption of treatment and possible hypovolemia to the patient. [W111].

After operation

Warning!

- After applying blood products, clean the hospital administration set with saline. [W031]
- 
  The active devices and its disposables may be a potential biohazard during and after use. Dispose of the active devices and disposables after cleaning and disinfection, according to validated cleaning procedures:
  - Handle and dispose of in accordance with accepted medical practice and applicable local regulations.
  - Dispose the single-use disposables with other biohazardous medical waste, in closed bins and sent for medical burn waste according to applicable local regulations. [W032]

2.1.2 Cautions

Caution!

- Do not use a sharp object to press the buttons on the control panel. [C002]
- The device must be securely mounted. [C003]
- Do not immerse the devices in liquid. Immersing the device in liquid may damage the device. [C004]

Prior to operation

Caution!

- Do not use the system outside the environmental specifications: see *Specifications* on page 63. [C005]
- Keep the devices 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 system to operate incorrectly. [C006]
- Do not modify the devices. Use of power supply cords or spare parts for internal components other than as specified by the manufacturer may lead to hazardous situations. [C007]
- Connect the mains plug(s) to earthed wall socket(s) only. [C008]
- Install the devices in such a way that you can easily disconnect the mains plug(s) from the wall socket in the event of an emergency. [C009]
- Do not block the ventilation openings of the device. [C010]
- Make sure that the brakes on the Fluido® IV Pole are locked when using the system. [C011]

- Do not use the system on surfaces with an inclination > 2.5°. [C013]
- Do not exceed the safe load of 6 kg. The maximum capacity of each hook of the IV Pole is 1 kg. [C014]
- After any temporary interruption of the mains power supply, refer to *Power supply interruption* on page 51. [C015]

2.1.3 Notes

- In the event of a power interruption, the Blood and Fluid Warmer will not produce any audible signal to indicate the loss of power. [N001]
- The device is not equipped with an isolating switch. Temporary interruption of the mains supply will place the system into standby mode and treatment will be discontinued. [N002]

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. Carson, J.L., Guyatt, G., Heddle, N.M., Grossman, B.J., Cohn, C.S., Fung, M.K., Gernsheimer, T., Holcomb, J.B., Kaplan, L.J., Katz, L.M. and Peterson, N., 2016. Clinical practice guidelines from the AABB: red blood cell transfusion thresholds and storage. Jama, 316(19), pp.2025-2035.
3. D. Norfolk, Handbook of Transfusion Medicine, 5th Edition, United Kingdom Blood Services, 2013.
4. Blood and Transplant, NHS, December 2009 version 1.
5. Fantl, P. and Morris, K.N., 1965. Influence of dextrose on heparinized blood. Thorax, 20(4), p.372.

2.2 Device safety symbols

This section contains a list of symbols used for the Fluido® AirGuard System.

Rx Only	Caution: 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).

P	Pressure indication (according to ISO 8536-8)
	Risk of electrical shock.
	Connect the device to an earthed socket only. Risk of electrical shock exists if the equipment is not connected to a properly grounded receptacle.
SN	Serial number
REF	Catalogue/article number/part number
VOL	Storage volume (according to ISO 1135-5)
	Manufacturer
MOD: 12	MOD stands for the modification update (in this example: modification update 12)
	Transport and storage ambient temperature limits
	Transport and storage relative humidity limits

	Transport and storage atmospheric pressure limits
	Type CF applied parts (according to IEC 60601-1)
	AC voltage
	Fuse
	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.
	Equipotentiality
	Read the user manual.
	Consult the instructions for use.
	CE marking of conformity

Air Guard module

As to electrical shock, fire, and mechanical hazards only: 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

Other modules

As to electrical shock, fire, and mechanical hazards only: ANSI/AAMI ES60601-1:2005 + C1:2009 + A2:2010 + A1:2012, IEC 60601-1-6:2010 + A1:2013, CAN/CSA-C22.2 No. 60601-1:2014, CAN/CSA-C22.2 No. 60601-1-6:2011 + A1:2015

Dispose according to local regulations.

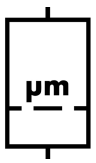
Expiry date (year/month)

Caution. Consult the instructions for use for important cautionary information.

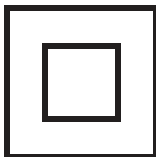
Single patient use only. Do not reuse disposable sets.

The disposable sets do not contain natural latex components.

The disposable sets are sterile. Method of sterilisation: ethylene oxide.



Filter mesh size

	Number of drops per ml
	Batch code/lot number
	Class II equipment
	Quantity
	Do not use the device if the package is damaged.
	Keep away from sunlight.
	Keep away from rain.
	Low priority alarm indication on control equipment
	Medium priority alarm indication on control equipment
	High priority alarm indication on control equipment

	Temporarily audible signal suppression - "audio paused"
	Non-pyrogenic
	Device power On/Standby
	Repair required
	Date of manufacture
	Distributor
	Contains or presence of phthalate: bis (2-ethylhexyl) phthalate

3 Description

The Fluido® AirGuard System is a Blood and Fluid Warming System. The system is suitable for both moderate (50- 150 ml/min) and high flow applications (> 150 ml/min). Pressurized flow is indicated for flow requirements > 100 ml/min, this can be achieved by to the use of the Pressure Chamber as part of the Fluido® AirGuard System. For low flow applications the use of a Fluido® Compact device is recommended. The system is only to be used with adults; the system is not to be used for paediatric use.

The Fluido® AirGuard System uses infrared heating technology to warm blood and fluids. Based on in-line sensors, the Fluido® Blood and Fluid Warming System calculates the energy required to safely warm the perfusates. The compressor and pressure chamber ensure pressurized flow can be achieved (>100 ml/min). This allows for higher flow rates when indicated by the clinical health care professional. When these flowrates (>100 ml/min) are required the FFluido® AirGuard System is recommended [NICE, CG65; German guideline, S3].

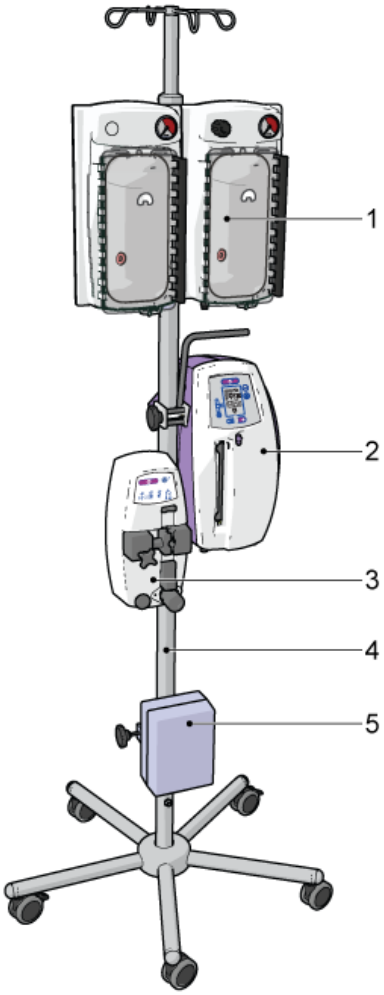
The essential performance of the Fluido® AirGuard System is:

- To warm fluids within the safe temperature and time limits according to ASTM F2172-02.
- To prevent air from entering the patient line.

3.1 Overview of the system

The Fluido® AirGuard System consists of the following modules:

Module	Function
Blood and Fluid Warmer	Warms the fluid to the set temperature. This is the central module of the system.
Air Guard	Monitors the fluid for the presence of air bubbles and prevents air bubbles from reaching the patient.
Pressure Chambers	Hold the IV fluid or blood bags and control the flow of the fluid by increasing or decreasing the pressure.
Compressor	Supplies pressure to the Pressure Chambers.
IV Pole	Ensures a stable operating platform for the system.



1. Pressure Chambers
2. Blood and Fluid Warmer
3. Air Guard
4. IV Pole
5. Compressor

These modules are intended to be used in combination. [N003]

3.2 Blood and Fluid Warmer

The Fluido® Blood and Fluid Warmer is a blood and fluid warmer. This section describes the different parts of the device.

3.2.1 Overview

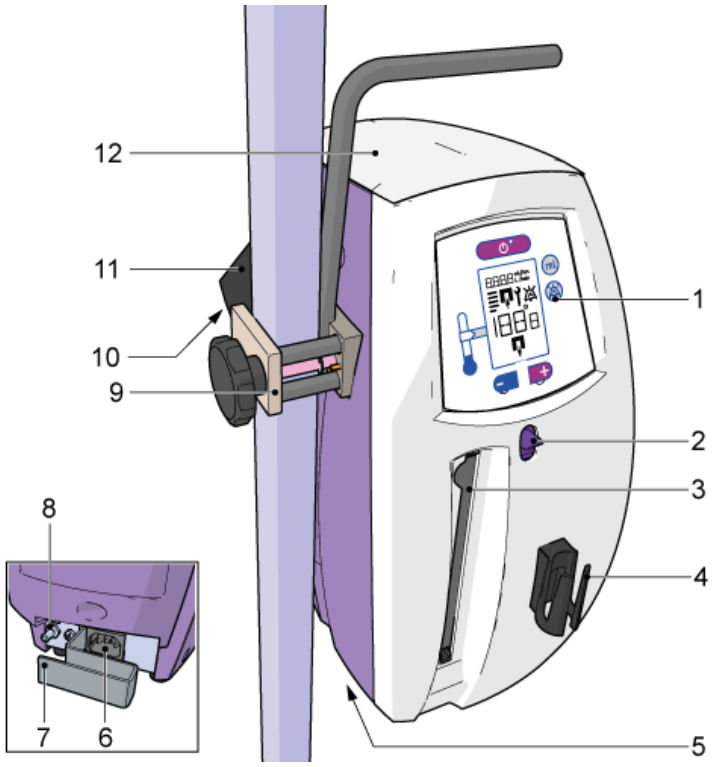
The Fluido® Blood and Fluid Warmer is the module that uses infrared technology to warm up the fluids. The Fluido® Blood and Fluid Warmer uses Fluido® disposable sets for intravenous administration.

Warning!

Ensure that the air deflector is correctly installed in the device before operation. It prevents air from blowing towards the operator. [W058]

Caution!

The top sticker is an integral part of the Fluido® Blood and Fluid Warmer and prevents fluid ingress from the top of the device. Do not attempt to remove the top sticker. [C001]

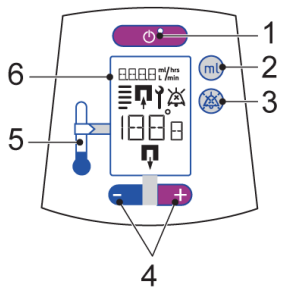


1. Control panel
2. Eject button for disposable set cassette
3. Slot for disposable set cassette
4. Deaeration chamber holder
5. Ventilation openings
6. Power supply cord connection
7. Cord anchor
8. Potential equalisation terminal[1]
9. Mounting clamp
10. Ventilation openings
11. Air deflector
12. Top sticker

3.2.2 Control panel

The control panel is located at the front of the device and can be operated by pressing the buttons located in the panel. All settings are visible on the display and the desired temperature can be selected by pressing the temperature selection buttons. By pressing the flow/volume button, the display will indicate the total volume dispensed by the unit. When a fault condition is detected, an audible signal will be triggered and the control thermometer turns red.

[1] The potential equalisation terminal prevents potential differences of the conductive parts of the device coming in contact with the end user. Refer to the requirements of IEC 60601-1 Clause 16 for Medical Electrical systems.

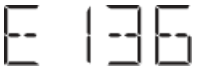


1. On/standby button and indicator
2. Flow/volume button
3. Audible signal suppression button
4. Temperature selection buttons (+/-)
5. Control thermometer
6. Display

Display

This section explains the items shown on the display of the Blood and Fluid Warmer.

Display	Description
60 ml/min	Flow indicator (ml/min)
2.37 L	Volume indicator (l)
560 hrs	Number of operating hours
	Insert the disposable set into the device.
	Remove the disposable set from the device.
1001 hrs 	Between 1000-1500 operating hours: If you switch on the device, the display shows the symbol for 5 seconds. You can still operate the device, but maintenance must take place before 2001 operating hours.
1501 hrs 	Between 1500-2000 operating hours: If you switch on the device, the display shows the symbol continuously. You can still operate the device, but maintenance must take place before 2001 operating hours.
2001 hrs 	After 2000 operating hours: If you switch on the device, the display shows the symbol continuously and a continuous audible signal will sound. You can still operate the device, but maintenance must take place within 48 operating hours.

Display	Description
	Lamp replacement indicators (five lamps): If a specific bar flashes, contact the hospital service department or the local supplier to replace the relevant lamp.
	Maintenance/malfunction. In the event of a malfunction: reset the device or contact the hospital service department or the local supplier if the issue persists.
	Audible signal suppression
	Set temperature at the end of the line.
	Maximum temperature, monitored when the IV fluid leaves the cassette
	Tilt sensor error
	Error code
	The internal temperature is too high to switch on the device (after safety temperature check).

Control Thermometer

The table below shows the different states of the temperature control thermometer.

Indication	State	Cause
	The control thermometer is not illuminated.	The device does not warm the blood or fluid in the cassette.
	The lower section is green.	The end temperature is more than 1 °C lower than the set temperature.
	The lower and middle sections are green.	The end temperature is equal to the set temperature.

Indication	State	Cause
	The top section is red.	The input temperature or the output temperature is higher than the set temperature. An audible signal is triggered.
	The entire control thermometer is red.	There is a defect. An audible signal is triggered. The display shows the maintenance/malfunction symbol to indicate that maintenance must take place.

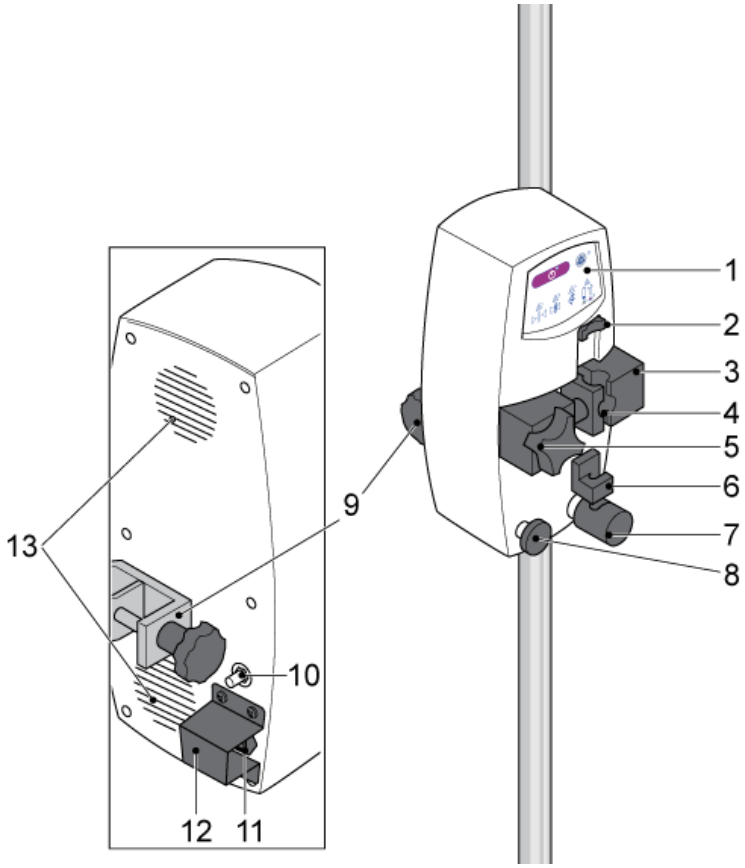
Refer to *Troubleshooting: Blood and Fluid Warmer* on page 51 for troubleshooting. [N005]

3.3 Air Guard

The Fluido® Air Guard detects air in the de-aeration chamber of the Fluido® Disposable Sets by means of an ultrasonic sensor. This section describes the different parts of the device.

3.3.1 Overview

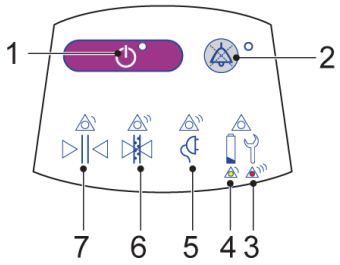
The tube downstream of the deaeration chamber is fixed into a shut-off valve. As soon as the sensor detects that the fluid level inside the deaeration chamber has fallen below a fixed level, the shut-off valve closes the supply tube, thus preventing air from being supplied to the patient.



1. Control panel
2. Upper limit strut
3. Ultrasonic sensor
4. Deaeration chamber holder
5. Lock knob of the deaeration chamber holder
6. Lower limit strut and tube sensor
7. Shut-off valve and lock knob of the shut-off valve
8. Counteracting knob
9. Mounting clamp
10. Potential equalisation terminal[2]
11. Power supply cord connection
12. Cord anchor
13. Ventilation openings

3.3.2 Control panel

The control panel is located at the front top of the Fluido® Air Guard and can be operated by pressing the buttons located in the panel.



1. Power on/standby button and indicator
2. Audible signal suppression button and indicator
3. Repair/error indicator
4. Low battery indicator
5. Mains power failure indicator
6. Air detection indicator
7. Tube detection indicator

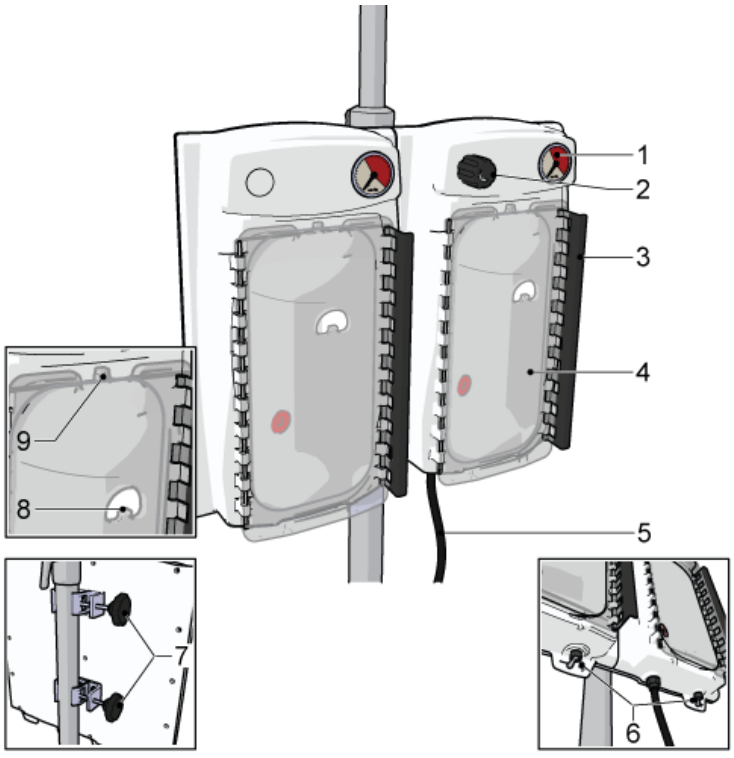
[2] The potential equalisation terminal prevents potential differences of the conductive parts of the device coming in contact with the end user. Refer to the requirements of IEC 60601-1 Clause 16 for Medical Electrical systems.

Alarm indicator	Priority	Cause
	Low	Tube detection Low battery
	Medium	Air detection Mains power failure
	High	Repair/error indicator

Refer to *Troubleshooting: Air Guard* on page 55. [N008]

3.4 Pressure Chambers

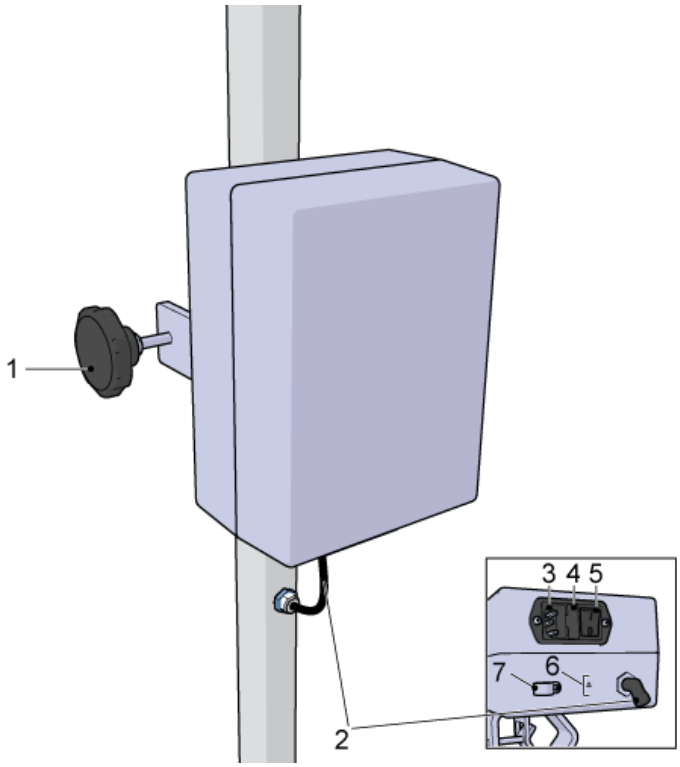
The Fluido® Pressure Chambers can pressurise small (500 ml) and large (1000 ml) IV fluid or standardised (ISO 15747:2019) blood bags used in the Blood and Fluid Warming System. The module consists of a dual chamber configuration with a common pressure regulator and individual pressure gauges (manometers). The air required to pressurise the chambers is supplied by the Fluido® Compressor.



1. Pressure gauge
2. Pressure regulator
3. Closure lid
4. Door
5. Air inlet tube
6. Pressure selector
7. Mounting clamps
8. Attachment point for IV bag (500 ml)
9. Attachment point for IV bag (1000 ml)

3.5 Compressor

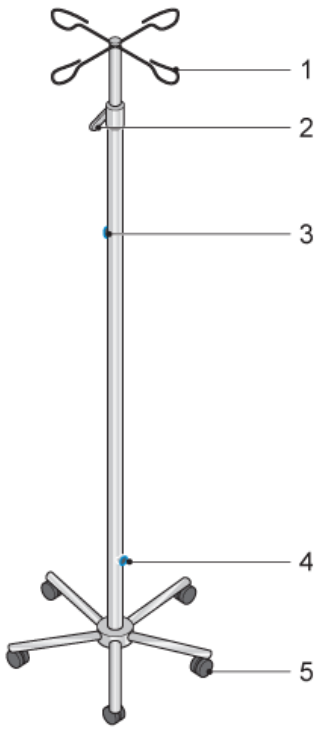
The Fluido® Compressor module supplies pressurised air to the Fluido® Pressure Chambers.



1. Mounting clamp
2. Air outlet tube
3. Power supply cord connection
4. Fuse holder
5. On/off switch
6. Air inlet
7. Cord anchor

3.6 IV Pole

The Fluido® IV Pole is an integral part of the Fluido® AirGuard System. The Fluido® IV Pole consists of a base with 5 locking rollers (anti-static and free of natural rubber latex) and a height adjustable IV pole. All modules of the Fluido® AirGuard System can be safely and securely fastened to the Fluido® IV Pole to ensure a stable and safe work environment. Furthermore, the Fluido® IV Pole features internal tubing to connect the Fluido® Pressure Chambers with the Fluido® Compressor and a suspension point for IV bags.



1. Suspension point for IV bag
2. Height adjustment lever
3. Air inlet tube connection (Pressure Chambers)
4. Air outlet tube connection (Compressor)
5. Wheel castor (incl. brake)

3.7 Disposable sets

A Fluido® disposable set consists of a cassette, IV tubing and patient line, which includes a deaeration chamber. The cassette can be used for both moderate and high flow applications. The fluid is mixed well due to the channel configuration inside the cassette.

The front of the Fluido® cassette is made of transparent plastic and partially coated with a reflective layer. The back of the cassette is made of black plastic.

Caution!

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

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

- Fluido® Standard Set
- Fluido® Trauma Set
- Fluido® Trauma Plus Set

Caution!

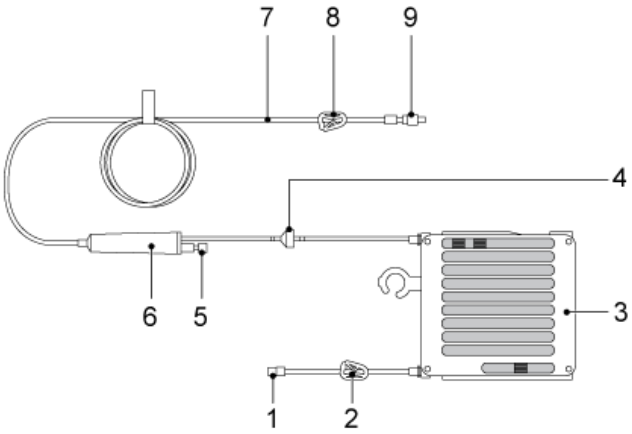
Do not use the Fluido® Irrigation Set or alternative types of de-aeration chambers or disposable sets in combination with the Fluido® AirGuard System. [C017]

Warning!

The disposables are provided in a sterile state. Ensure that they are handled in a sterile field. [W059]

3.7.1 Fluido® Standard Set

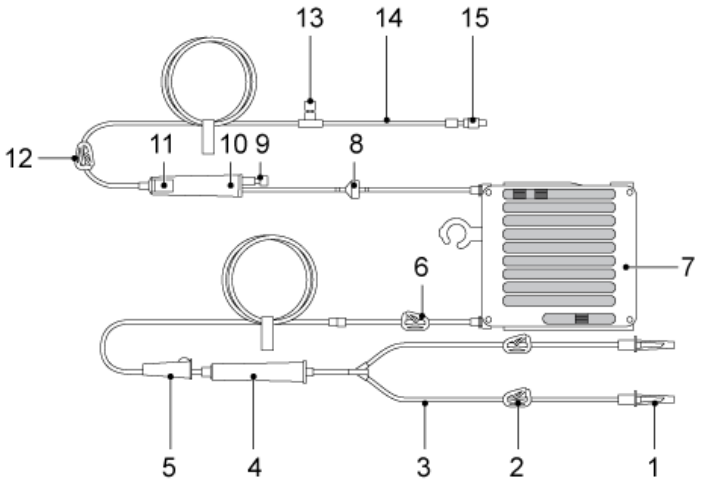
The Fluido® Standard Set is ideal for moderate flow rates. This Standard Set may be attached to a commercial IV set. The Fluido® Standard Set contains a deaeration chamber, a non-return valve and the patient line.



1. Hospital IV set connection
2. Clamp
3. Cassette
4. Non-return valve
5. Deaeration valve
6. Deaeration chamber
7. Patient line
8. Clamp
9. Patient line connector

3.7.2 Fluido® Trauma Set

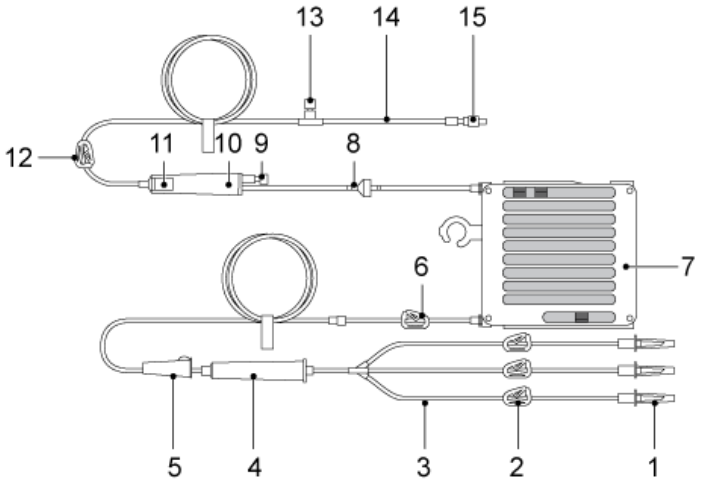
The Fluido® Trauma Set is a Y-type administration set with two spikes and is ideally suited for very high flow rates. This set contains a deaeration chamber and non-return valve, administration point and filter. The set is connected to the patient through a patient line, which is included in the set.



1. Spike
2. Clamp
3. IV administration line
4. Drip chamber
5. Roller clamp
6. Clamp
7. Cassette
8. Non-return valve
9. Deaeration valve
10. Deaeration chamber
11. Filter
12. Clamp
13. Administration port
14. Patient line
15. Patient line connector

3.7.3 Fluido® Trauma Plus Set

The Fluido® Trauma Plus Set is a Y-type administration set with three spikes and is ideally suited for very high flow rates. This set contains a deaeration chamber with non-return valve, administration point and filter. The set is connected to the patient through a patient line, which is included in the set.



1. Spike
2. Clamp
3. IV administration line
4. Drip chamber
5. Roller clamp
6. Clamp
7. Cassette
8. Non-return valve
9. Deaeration valve
10. Deaeration chamber
11. Filter
12. Clamp
13. Administration port
14. Patient line
15. Patient line connector

4 Set-up

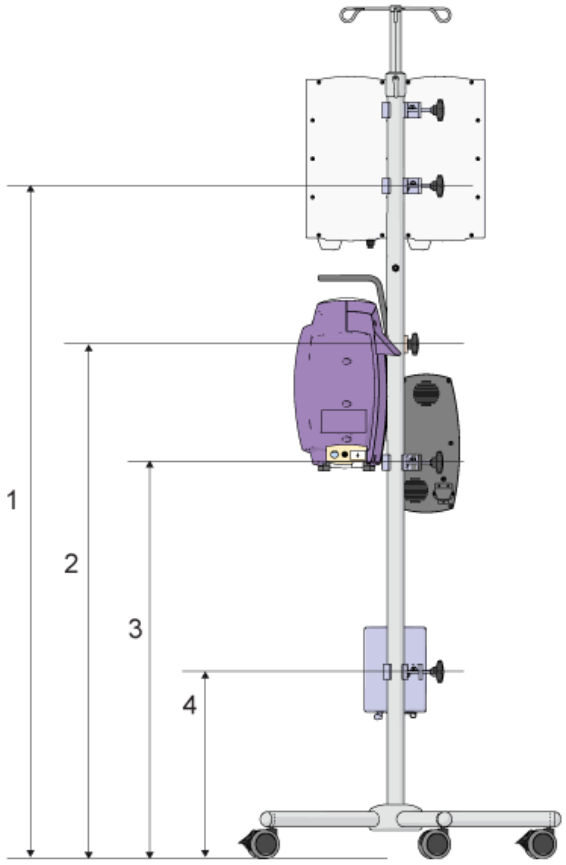
4.1 Transport and storage

Transport and store the system and modules according to the *Environmental conditions for transport and storage* on page 63.

Transport and store the disposable sets according to the *Environmental conditions for transport* on page 67 and *Environmental conditions for storage* on page 67.

4.2 Mounting heights for modules

For stability, visibility of control panels and ergonomics, use the recommended mounting heights for the modules. [N009]



1. Pressure Chambers: 150 cm
2. Blood and Fluid Warmer: 110 cm
3. Air Guard: 85 cm
4. Compressor: 35 cm

5 Operation

5.1 Safety instructions before operation

Warning!

- Before operating the system, first read the sections *Materials* and *Prior to operation* in *Warnings* on page 9. [W033]
- Make sure all the modules are securely attached to the Fluido® IV Pole before operation. [W060]
- Do not use the system outside of the operating conditions. Overheating may cause haemolysis and hypoxemia. [W102]

Caution!

In the event of interference with other devices, follow these instructions:

- Turn off random devices one by one to isolate the offending device.
- Change the location of the device that suffers from interference.
- Increase the physical distance between devices and plug them into alternative wall sockets.
- Contact your local dealer if the issue persists.
- Use only the power supply cords specified to prevent increased emissions or decreased immunity to electromagnetic noise.

The system is approved for electromagnetic interference according to IEC 60601-1-2. Details on electromagnetic compatibility can be found in *Electromagnetic compatibility* on page 70. [C019]

Contact your local distributor to see a video of the instructions for use. [N010]

5.1.1 Cybersecurity

The Fluido® Irrigation contains firmware, and can be connected to software during servicing only. During intended use, the device is used ‘stand-alone’ without (attainable) external connections. The system cannot be connected to any other devices during use with a patient. During intended use there is no risk of cybersecurity threats. To protect the essential performance of the device, it is equipped with two independent circuits, where the safety controller serves as secondary safety mechanism. The output and safety temperature output are compared to match. Various thermometers control or detect the device temperature on various locations. If the device is out of specification errors are triggered.

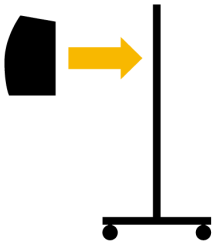
5.2 Preparation

Warning!

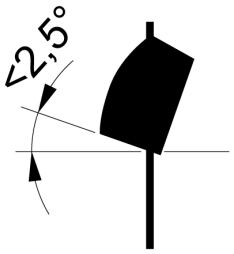
Ensure that the Fluido® Blood and Fluid Warmer is not damaged and that the ventilation grids (on the side and bottom of the device) are not covered. Overheating may cause haemolysis and hypoxemia. [W061]

Caution!

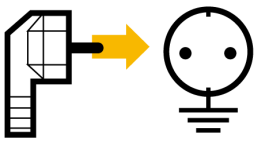
- Before using the Fluido® Blood and Fluid Warmer, it should be attached to a (Fluido®) IV Pole. [C021]



- The Fluido® Blood and Fluid Warmer should hang upright on the (Fluido®) IV Pole. Any variation from this must not exceed an angle of 2.5° forward or backward. [C022]

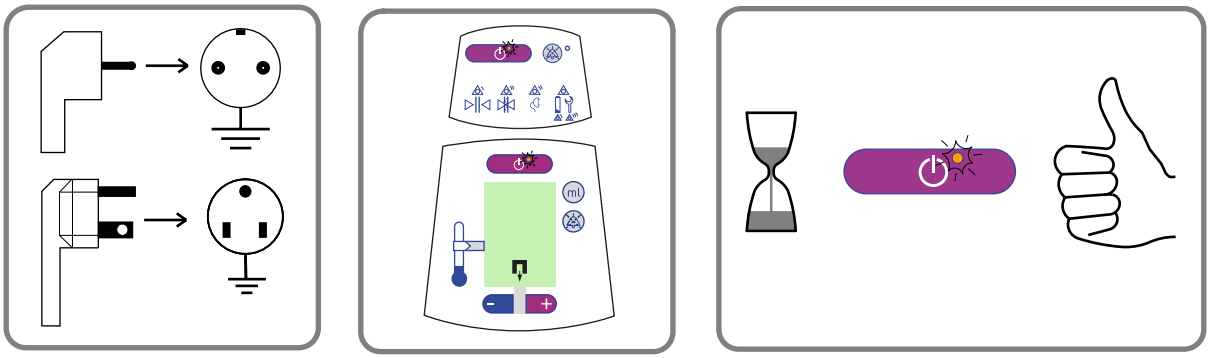


- Before using the Fluido® Blood and Fluid Warmer, it must be plugged into the mains power supply. The device must be connected to an earthed wall socket. [C023]



5.3 Prepare for use

5.3.1 Connect the Fluido® AirGuard System to the mains voltage



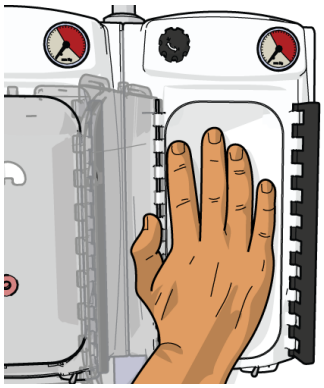
1. Connect the mains plug of the single, dual or triple power cord adapter to a grounded electrical outlet.
2. The On/Standby indicator on the the Fluido® Blood and Fluid Warmer illuminates orange and performs a self-test during which the display glows green and the 'remove cassette' symbol flashes.
3. After 4 seconds the 'remove cassette' symbol disappears and the Fluido® Blood and Fluid Warmer System is in standby mode.

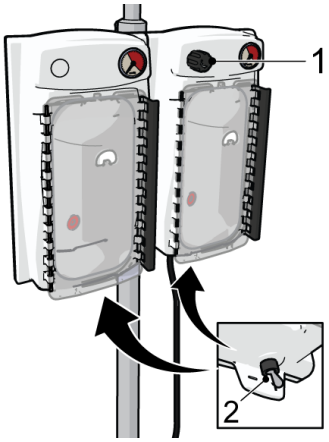
5.3.2 Prepare

5.3.2.1 Preparing the Pressure Chambers

Follow these steps to prepare the Fluido® Pressure Chambers for use.

1. Check whether the Fluido® Pressure Chambers are connected to the Compressor.
2. Set the pressure selector (2) to "-".
3. Manually press the bladder to fully deflate it.
4. If the bladder pressure needs to be adjusted, turn the pressure regulator (1) fully anticlockwise ("-").





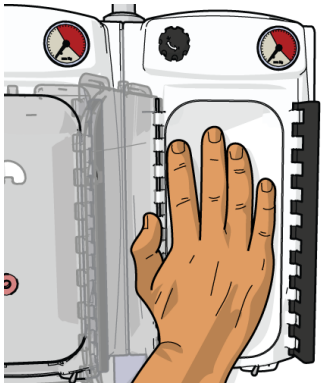
5.3.2.2 Suspending an IV bag

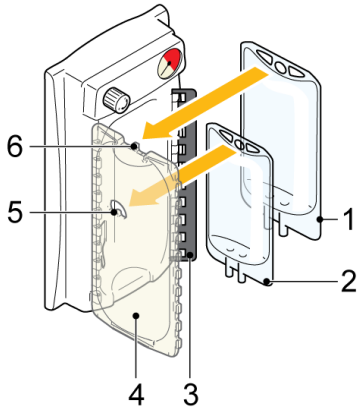
Follow these steps to attach an IV bag.

Caution!

- Do not use any rigid containers (glass or plastic IV bottles). Only use 500 ml and 1000 ml IV bags. [C024]
- When you lock the door, make sure that the connectors of the IV bags are not caught. [C025]
- Do not close the door when the bladder is inflated. [C026]
- Open the pressure chamber door carefully. [C027]

1. Suspend an IV bag:
   a. Suspend a large IV bag (1000 ml) (1) from the top attachment point (6) at the pressure chamber door. *OR*
   b. Suspend a small IV bag (500 ml) (2) from the bottom attachment point (5) at the pressure chamber door.
2. Close the door (4) and lock it with the closure lid (3).





5.3.2.3 Inserting a disposable set

Warning!

- Do not use damaged disposable sets. Prior to use, inspect the cassettes:
  - Check the cassette for cracks. [W034]
  - Check the reflective (metallic) layer on top of the cassette for damage. If damaged, this may cause haemolysis and hypoxemia. [W035]
  - Check the plastic layer on top of the cassette for damage. [W036]
  - Check the IV lines for punctures or damage. [W037]
- Use new disposable sets and use them in the sterile field only. Once removed from the packaging, use the disposable set immediately. The disposable set can be used for a maximum of 24 hours. [W039]

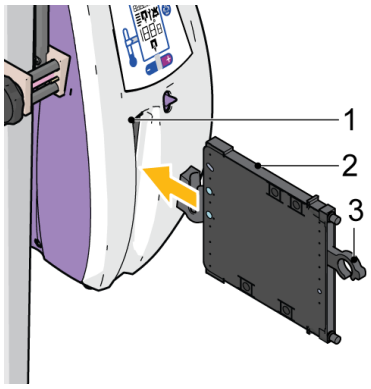
Caution!

- Only use sets compatible with the device:
  - Fluido® Standard Set [C028]
  - Fluido® Trauma Set [C029]
  - Fluido® Trauma Set Plus [C030]
- The disposable set only fits in the device when inserted in the correct direction. Do not use excessive force to insert the disposable set. [C032]

In the following pictures the IV lines are not shown. [N012]

Follow these steps to insert a disposable set.

1. Hold the cassette (2) by the clamp (3).
2. Insert the cassette into the slot (1) until you hear a "click" sound. The display will show the temperature and the flow rate.



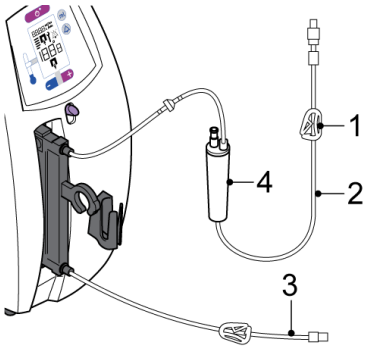
5.3.2.4 Priming the disposable set

Warning!

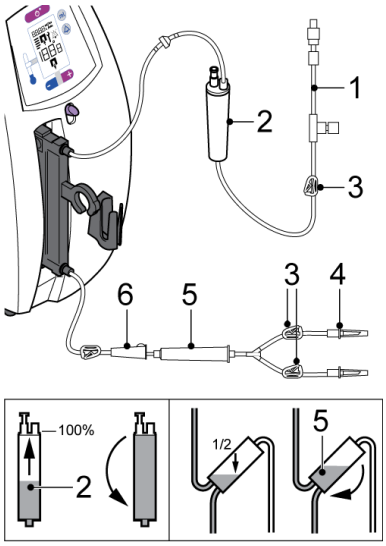
- Before you prime a Fluido® Standard Set, prepare the hospital IV administration line in accordance with the hospital or local guidelines (as appropriate). [W040]
- Prime and flush the disposable sets with a crystalloid IV fluid. [W041]

Follow these steps to prime the Fluido® Standard Set and Fluido® Trauma Set Plus.

1. Close the clamps (1) of the disposable set.
2. Remove the protective cap from the IV administration line (3).
3. Connect the IV administration line (3) to the hospital IV administration line.
4. Hold the deaeration chamber (4) upside down.
5. Open the clamps (1).
6. Wait until the deaeration chamber (4) is filled with fluid.
7. Place the deaeration chamber (4) in the upright position and place it in the holder.
8. Proceed to deaerate the rest of the patient line (2) by circulating the fluid through the lines until no air is present.
9. Close the clamps (1) of the disposable set.



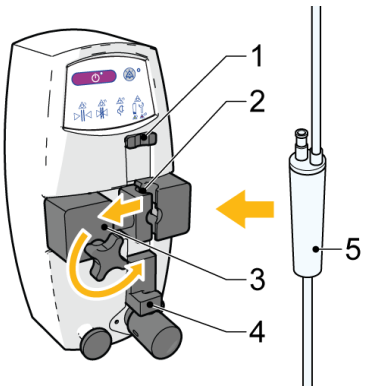
Follow these steps to prime the Fluido® Trauma Set or Fluido® Trauma Plus Set.



1. Close the clamps (3) of the disposable set.
2. Remove the protective cap from the IV administration line (4).
3. Connect the IV administration line (4) to the hospital IV bag and make sure that the roller clamp (6) is open.
4. Hold the drip chamber (5) upside down.
5. Open the clamps (3) of the disposable set. Make sure not to open the clamp of the unused spikes.
6. Fill the drip chamber (5) with fluid halfway. Place the drip chamber in the upright position (5).
7. Close the roller clamp (6) and hold the deaeration chamber (2) upside down.
8. Open the roller clamp (6).
9. Fill the deaeration chamber (2) completely.
10. Place the deaeration chamber (2) in the upright position in the holder.
11. Proceed to deaerate the rest of the patient line (1) by circulating and discarding the fluid through the lines until no air is present.
12. Close the roller clamp (6).

5.3.2.5 Placing the deaeration chamber in the Air Guard

Follow these steps to place the deaeration chamber in the Air Guard device.

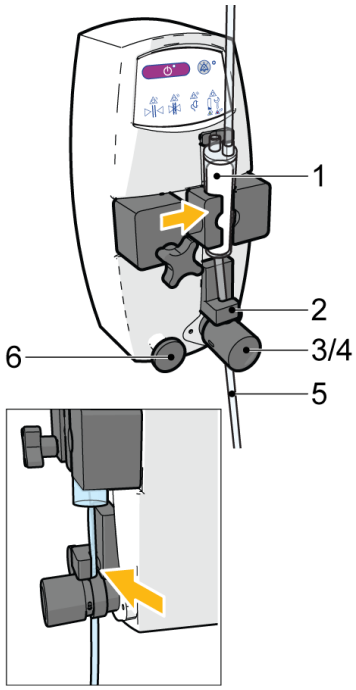


1. Turn the lock knob (3) anticlockwise and hold it to open the deaeration chamber holder (2).
2. Place the deaeration chamber (5) between the upper limit strut (1) and lower limit strut (4).
   Make sure that the broadest part of the deaeration chamber touches the upper limit strut.
3. Release the lock knob (3) to close the deaeration chamber holder (2).

5.3.2.6 Placing the tube into the shut-off valve of the Air Guard

Follow these steps to place the tube into the shut-off valve.

1. Press the lock knob (3) and pull the counteracting knob (6) at the same time to open the shut-off valve (4).
2. Place the tube (5) into the centre of the shut-off valve (4).



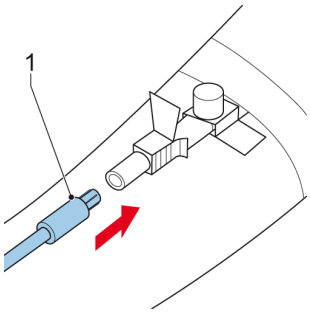
Caution!

Make sure that the tube (5) downstream of the deaeration chamber (1) goes straight through the tube sensor (2) and the shut-off valve (4). [C033]

3. Release the lock knob (3) to close the shut-off valve (4).

5.3.2.7 Connecting the IV-line of the disposable set to the patient

1. Connect the patient line to the patient (1).



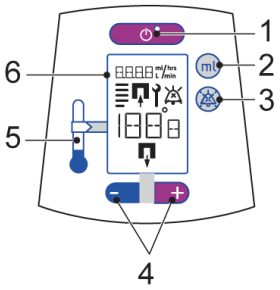
5.3.3 Power On

5.3.3.1 Switching on the Blood and Fluid Warmer

Follow these steps to turn on the Fluido® Blood and Fluid Warmer.

Before you turn on the module, make sure that no disposable set has been inserted into the device. [N011]

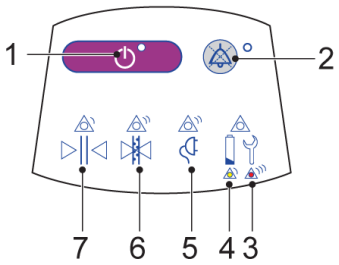
1. Press the on/standby button (1).
   The on/standby indicator (1) will light green.
   An audible signal will sound.
   The display (6) will briefly show all the symbols on the screen.
   The control thermometer (5) will briefly light green and red.
   The display (6) will show the symbol that tells you to insert the disposable set.
   The device is now switched on.



5.3.3.2 Switching on the Air Guard

Follow this step to switch on the Fluido® Air Guard.

1. Press the on/standby button (1).
   The on/standby indicator (1) should light green.
   The tube detection indicator (7) should light green.
   The device is now switched on.



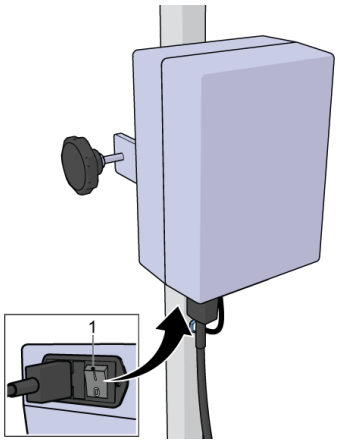
Warning!

If the patient line tube of the disposable set is placed incorrectly in the shut-off valve, the tube detection indicator (7) will flash yellow. [W045]

5.3.3.3 Switching on the Compressor

Follow these steps to switch on the Fluido® Compressor.

1. Place the on/off switch (1) in the "I" position.



The on/off switch is located at the bottom of the Fluido® Compressor. [N014]

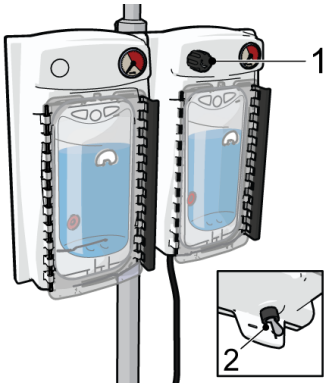
5.3.3.4 Pressurising the bladders of the Pressure Chambers

Caution!

Make sure that the closure lid is closed before inflating the bladder. [C034]

Follow these steps to pressurise the bladders.

1. To inflate the bladder:
   a. Set the pressure selector located at the bottom of the pressure chamber (2) to "+".
   b. Slowly turn the pressure regulator (1) clockwise.
2. Set the pressure regulator (1) to the specified pressure (indicated on the pressure gauge).
3. If the set pressure is too high, set the pressure selector (2) to "-" to deflate the bladder, turn the pressure regulator (1) anticlockwise and set the pressure selector (2) to "+" to inflate the bladder again.



Warning!

During a mains power failure, the Fluido® Compressor will not pressurise the bladder. This could result in a reduction of the fluid flow rate. Switch to gravitational feed by suspending the IV bags on the suspension points of the IV pole. [W044]

5.4 During use

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

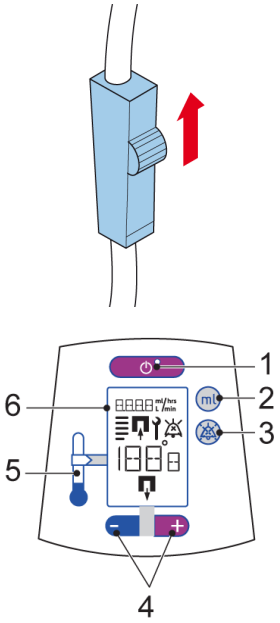
5.4.1 Warming up blood and fluids

Warning!

- Make sure that the display on the control panel of the Fluido® Blood and Fluid Warmer shows the initial temperature (37°C) before warming up blood or fluids. A wrong initial temperature recording may lead to mild hypo-/ hyperthermia in the patient, or haemolysis and hypoxemia. [W046]
- Make sure that the pressure on the line does not exceed 300 mmHg. This can cause hypovolemia due to hypoperfusion and mild hypothermia. [W062]

Follow these steps to warm up blood and fluids.

1. Adjust the desired flow with the roller clamp (only for Trauma disposable sets).
2. Set the appropriate temperature by using the temperature selection buttons (4) on the control panel of the device.
   The device will warm up the fluids and it will show the control thermometer indicator (5) green when the temperature setpoint is reached.
   The display (6) will show the estimated flow rate.

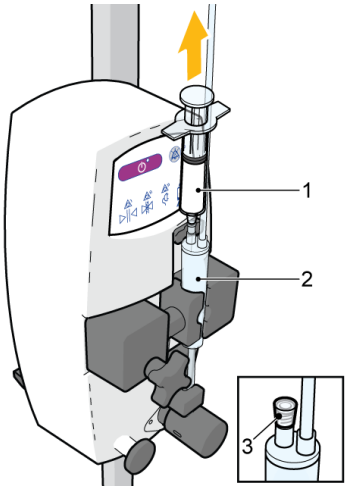


5.4.2 Deaerating the deaeration chamber

If the air detection warning indicator of the Fluido® Air Guard becomes active due to air or foam being detected, the shut-off valve will close and the fluid administration will be stopped.

Follow these steps to deaerate the deaeration chamber.

1. Remove the deaeration valve cap from the deaeration chamber (3).
2. Put a syringe (1) into the deaeration valve and lightly press the syringe to open it. It is recommended that a Luer Lock syringe (20 ml or larger) is used.
3. Remove the air and/or the foam until the deaeration chamber (2) is filled with fluid.
4. Put the deaeration valve cap back on to the deaeration chamber. If the fluid level increases over the ultrasonic sensor, the device will open the shut-off valve after a few seconds.

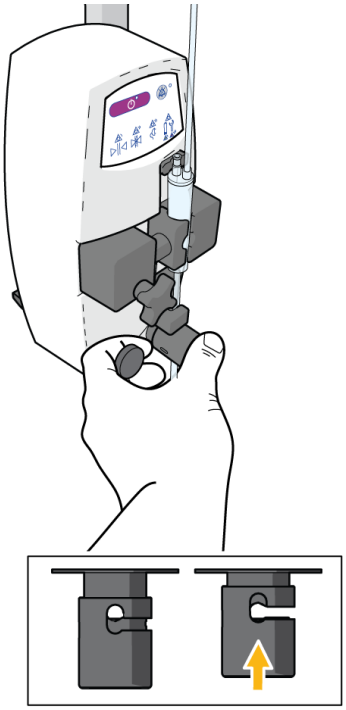


5.4.3 Releasing the IV line from the Air Guard shut-off valve

The shut-off valve is an electrically operated, spring loaded valve which closes the downstream tube after receiving a closing command from the ultrasonic sensor (via the controller board). The shut-off valve is in closed position when it is not powered. Under all conditions this valve can be manually overridden. If the shut-off valve is closed due to a low fluid level, the deaeration chamber has to be manually deaerated as described in *Deaerating the deaeration chamber* on page 41.

Follow these steps to manually release the IV line from the Fluido® Air Guard:

1. Hold the counteracting knob with your left-hand forefinger and the middle finger.
2. Press and hold the shut-off valve with your thumb. You can now remove the IV line with your right hand.



5.4.4 Suppressing the audible signal

The Fluido® Air Guard and Blood and Fluid Warmer both have an audible signal suppression button. It is recommended that the causes of the alarms are addressed immediately after the signal sounds.

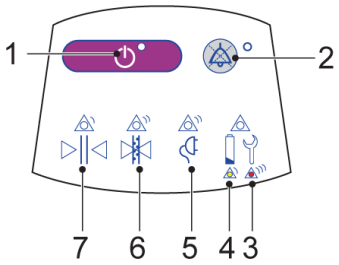
The visual alarm indicators appear on the front panel only, so the device needs to be positioned in front of the operator to ensure that alarm priority and type are correctly perceived.

Warning!

Medium and high priority alarms on the Fluido® Air Guard must be resolved immediately, as they result in the fluid administration ceasing. In this state, the device cannot perform its essential function. [W048]

Follow this step to suppress the audible signal on the Fluido® Air Guard.

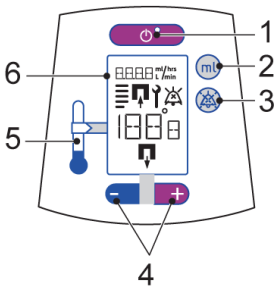
1. If an audible signal sounds, press the audible signal suppression button (2) to mute the sound for three minutes.
   The audible signal suppression indicator (2) will light orange.



- If the audible signal is suppressed, it will automatically reset after the ultrasonic sensor detects fluid. [N016]
- If the audible signal suppression button (2) is pressed again, the signal will sound again and the audible signal suppression indicator will turn off. [N017]

Follow this step to suppress the audible signal on the Fluido® Blood and Fluid Warmer.

1. Press the audible signal suppression button (3) to mute the sound for three minutes.
   The audible signal suppression indicator will appear on the display (6).



If the audible signal suppression button (3) is pressed again, the audible signal will sound again and the audible signal suppression indicator will switch off in the display (6). [N018]

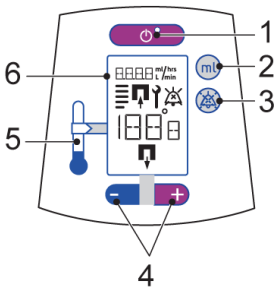
5.4.5 Extra functions of the Blood and Fluid Warmer

The display on the control panel of the Blood and Fluid Warming System can show additional information with respect to the fluid supplied.

Follow this step to change the flow/volume display (6).

1. Press the flow/volume button (2) to alternate between the display of:

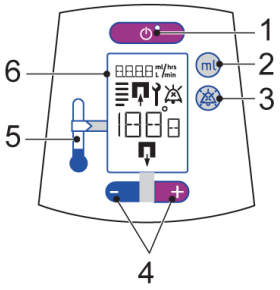
- Flow
- Volume
- Flow and volume



Follow these steps to reset the volume indicator to 0.

1. Press and hold the flow/volume button (2).
2. Press the temperature selection button (-) (4).
3. Release both buttons.

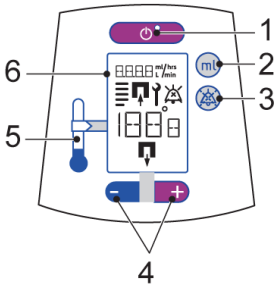
The volume indicator resets to 0.



The volume indicator automatically resets to 0 after 15 minutes of non-operation. [N019]

Follow this step to display the temperature at the end of the line (T_{out}).

1. During operation, press both temperature setting buttons (+/-) (4).

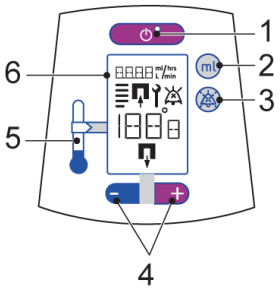


5.4.6 Resetting the Fluido® Blood and Fluid Warmer

Some Fluido® Blood and Fluid Warmer malfunctions can be resolved by resetting the device. The Blood and Fluid Warming System cannot be reset in standby mode. A reset can only be performed if the device is on and the maintenance/malfunction indicator is showing. [N022]

Follow this step to reset the device.

1. Press the temperature selection buttons (4) together with the flow/ volume button (2) for 2 seconds.



The device will perform a power cycle to the display and the error should disappear.
If the problem persists, do not use the device and contact the hospital service department or the local supplier.

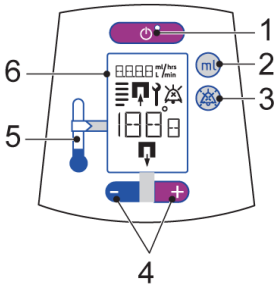
5.5 Post-operative procedures

Do not perform post-operative procedures while the device is in use.

5.5.1 Stopping the system

Follow this step to stop warming fluids.

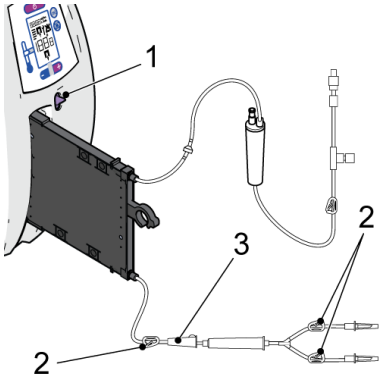
1. Press the on/standby button (1) on the Fluido® Blood and Fluid Warmer.
   The on/standby indicator (1) will light orange.



When the device enters the standby mode, fluids will not be warmed up by the device. However, the administration of fluids will continue. [N020]

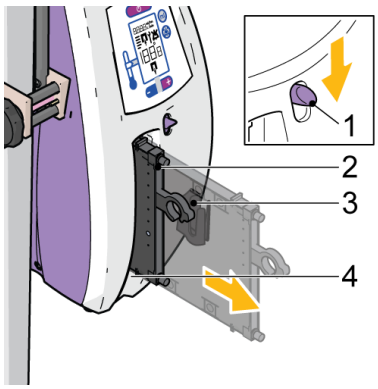
Follow these steps to stop fluid administration.

1. Close the clamps (2) and the roller clamp (3) on the disposable set.
   Fluid administration is now stopped.



Follow these steps to remove a disposable set.

1. Press the eject button (1).
2. Hold the cassette (2) by the clamp (3).
3. Remove the cassette (2) from the slot (4).
4. Dispose of the set appropriately.



Warning!

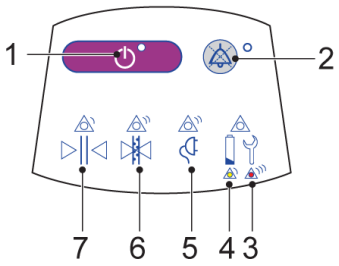
The active devices and its disposables may be a potential biohazard during and after use. Dispose of the active devices and disposables after cleaning and disinfection, according to validated cleaning procedures:

- Handle and dispose of in accordance with accepted medical practice and applicable local regulations.
- Dispose the single-use disposables with other biohazardous medical waste, in closed bins and sent for medical burn waste according to applicable local regulations. [W032]

5.5.2 Putting the Air Guard in standby mode

Follow this step to put the Fluido® Air Guard in standby mode.

1. Press the on/standby button (1).
The on/standby indicator (1) will light orange.
The module will enter the standby mode.

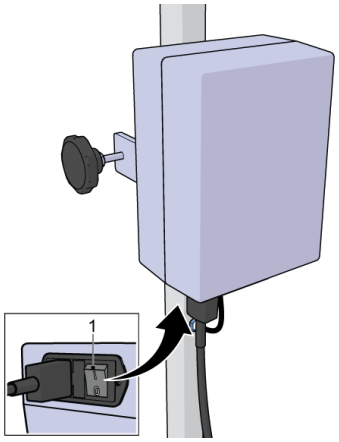


5.5.3 Switching off the Compressor

Follow this step to switch off the Fluido® Compressor:

1. Place the on/off switch (1) in the "0" position.

The on/off switch is located at the bottom of the Fluido® Compressor. [N023]



6 Maintenance

If a problem occurs with the system, please refer to *Troubleshooting* on page 51.

6.1 Precautions

Warning!

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

Caution!

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

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

6.2 Cleaning

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

Warning!

Before you clean and disinfect the device, remove attached disposables and disconnect the power supply cord. [W051]

Caution!

- Do not use dripping wet cloths. [C035]
- Do not use ketones (methyl ethyl ketone, 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 and do not 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. [C039]
- 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]

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

1. Visually inspect the components to ensure there is no visible damage or deterioration of the enclosures such as cracks, or deterioration of the labels and power cord. Do not clean if there is a defect and contact The Surgical Company International B.V. or your local distributor.
2. Immerse a soft cloth or sponge as an applicator into the cleaning solution consisting of mild liquid detergent soap and warm tap water mixture. Squeeze out 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 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.

6.3 Disinfection

Disinfect the device only after conducting the cleaning procedure as described in *Cleaning* on page 48.

Disinfection is a procedure for removing (biological) contaminations.

1. After cleaning, disinfect all exterior surfaces of the reusable components with one of the following disinfectants, which can be safely used without causing damage to the enclosure:
   - 70% ethyl alcohol (ethanol) based disinfectants. Contact time ≥ 7 min.
   - 70% isopropyl alcohol (isopropanol) based disinfectants. Contact time ≥ 7 min.

   Refer to the disinfectant instructions for use, including the application and method.
2. 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.
3. Dry the item with a hand towel or soft cloth.
4. Store the clean device in a non-contaminated area when not in use.

7 Troubleshooting

7.1 Power supply interruption

When the mains power is turned off, the modules should respond as follows.

Module	Response
Blood and Fluid Warmer	Will turn off. If the mains power is restored within 30 seconds, the Fluido® Blood and Fluid Warmer will skip the self-test and continue with the previous temperature setting.
Air Guard	Will close the shut-off valve and will give an audible signal for a limited amount of time.
Compressor	Will turn off.
Pressure Chambers	No response. The Fluido® Pressure Chambers are not powered electrically but are supplied by the compressor.

Warning! During a mains power failure, the Fluido® Compressor will not pressurise the bladder of the Fluido® Pressure Chamber. This could result in a reduction of the fluid flow rate. Switch to gravitational feed by suspending the IV bags on the suspension points of the IV pole. [W052]

7.2 Blood and Fluid Warmer

If a problem occurs, an audible signal and visual indications will be triggered. To mute the audible signal, refer to *Suppressing the audible signal* on page 43.

Some malfunctions may be resolved by resetting the device. Refer to *Resetting the Fluido® Blood and Fluid Warmer* on page 44.

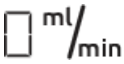
The following tables may assist the end user when troubleshooting the device. In the event of any technical assistance being needed, contact the hospital service department or the local supplier.

Indicator	Problem	Possible cause	Solution
	The on/standby indicator is off.	No power.	Make sure that the power cord is undamaged and plugged in. Replace the cord if necessary. Make sure that the device is connected to a wall socket with an earth connection.
		Malfunction.	Contact the hospital service department or the local supplier.

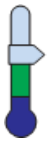
Indicator	Problem	Possible cause	Solution
	The on/standby indicator is off.	Malfunction.	Contact the hospital service department or the local supplier.
	An audible signal sounds.		

Indicator	Problem	Possible cause	Solution
	The on/standby indicator turns off during use.	Power failure.	Restore the power. If the power is not restored within 30 seconds, the process will restart automatically. In the event that the power is not restored, remove the cassette and restart the device.
	An audible signal sounds.		

Indicator	Problem	Possible cause	Solution
	The device does not start.	An incorrect cassette has been inserted into the device or the cassette is not properly inserted.	Use the correct disposable set. Make sure that the cassette is properly inserted.
	The 'remove disposable' symbol shows.		

Indicator	Problem	Possible cause	Solution
	The display shows that there is no flow.	The clamps are closed.	Open the clamps.
		The flow is < 11 ml/min.	Increase the flow.
		There is a blockage in the deaeration system.	Replace the set.
		There is a kink in the tubing.	Straighten the tubing.
		The fluid bag is empty.	Replace the fluid bag.

Indicator	Problem	Possible cause	Solution
	The control thermometer is entirely red.	Malfunction.	Stop using the device and contact the hospital service department or the local supplier.
	The display shows the maintenance symbol.		
	An audible signal sounds.		

Indicator	Problem	Possible cause	Solution
	The bottom section of the control thermometer is green.	The flow is too high.	Decrease the flow.
		The end temperature is still not at the set temperature after using the disposable set for a few minutes.	

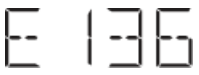
Indicator	Problem	Possible cause	Solution
	The three middle bars of the lamp replacement indicator flash.	One of the lamps is defective.	Contact the hospital service department or the local supplier.
	The display shows the maintenance symbol.		
	An audible signal sounds. The device keeps operating.		

Indicator	Problem	Possible cause	Solution
	The top or bottom bar of the lamp replacement indicator flashes.	One of the lamps is defective.	Contact the hospital service department or the local supplier.
	The control thermometer is entirely red.		
	The display shows the maintenance symbol.		
	An audible signal sounds.		
	The device stops operating.		

Indicator	Problem	Possible cause	Solution
	The control thermometer is entirely red.	The module is not mounted in a vertical position on the IV Pole. The angle variation exceeds 2.5° forward or backward.	Reposition the module on the IV Pole and make sure that the modules are straight.
	The display shows the letter 't'.		
	The device stops operating.		

Problem	Possible cause	Solution
The cassette does not eject from the slot when the eject button is pressed.	Malfunction.	Leave the cassette in place and contact the hospital service department or the local supplier.

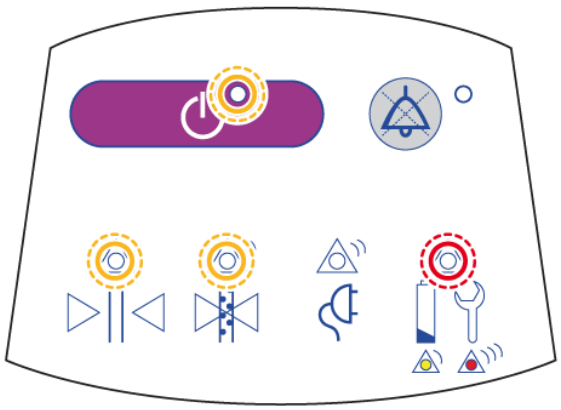
Problem	Possible cause	Solution
The cover of the slot for the disposable set is blocked.	The cover is defective.	Contact the hospital service department or the local supplier.
	The slot for the disposable set is dirty.	

Indicator	Problem	Possible cause	Solution
	The display shows an error code.	Malfunction.	Press the temperature setting buttons (+/-) to obtain the error code during an audible signal.
			Reset the error code to check whether the current error code is the actual error code: Press and hold the temperature setting buttons (+/-) together with the flow/volume button for 2 seconds.
			If the audible signal persists, record the error code and contact the hospital service department or the local supplier.

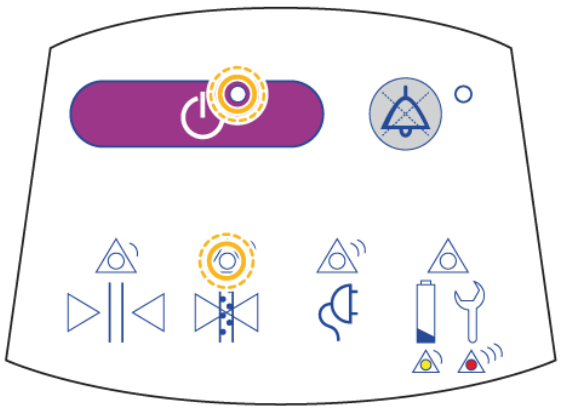
7.3 Air Guard

If a problem occurs, a combination of indicators will light to specify the problem. The following tables may assist the end user when troubleshooting the device. The lighted indicators are shown by a coloured circle in the images. The device will only start if there are no issues with the alarm functionality. Once per year all alarm conditions must be tested during the regular maintenance.

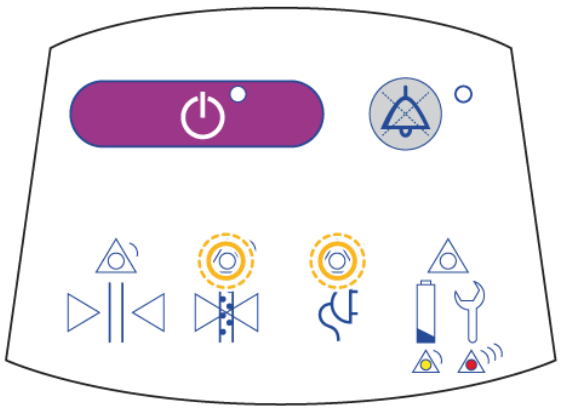
If a problem with the Fluido® Air Guard cannot be solved immediately, during operation, remove the IV and deaeration chamber from the Fluido® Air Guard and perform a continuous check for foam and bubbles. Abort the procedure if necessary. See *Releasing the IV line from the Air Guard shut-off valve* on page 42. Do not use the Fluido® Air Guard until the problem is resolved. In the event of any technical assistance being needed, contact the hospital service department or the local supplier.



Problem	Possible cause	Solution
Air or foam is detected by ultrasonic sensor.	There is a failure in the shut-off valve. The sensor operates correctly.	Remove the IV line and deaeration chamber from the Air Guard and perform a continuous check for foam and bubbles. Refer to *Releasing the IV line from the Air Guard shut-off valve* on page 42. Abort the procedure if necessary.
		If the problem persists: Contact the hospital service department or the local supplier.

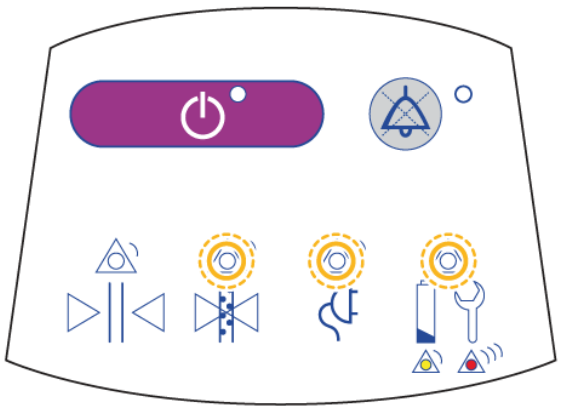


Problem	Possible cause	Solution
Air or foam is detected by ultrasonic sensor.	There is a leakage upstream of the infusion line.	Check the couplings. Check the spike at the fluid bag. Deaerate the deaeration chamber. Refer to *Deaerating the deaeration chamber* on page 41.
	The fluid bag is empty. Air is pumped through the line from the pressure chamber.	Replace the empty fluid bag. Prime the deaeration chamber.
The ultrasonic sensor does not work properly.	The deaeration chamber is placed incorrectly against the ultrasonic sensor.	Check the deaeration chamber holder. Check the deaeration chamber. Clean the ultrasonic sensor with a humidified cloth or alcohol wipes.



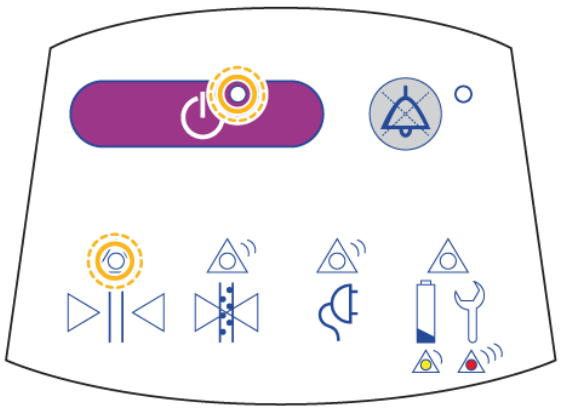
Problem	Possible cause	Solution
No mains power for several seconds.	A mains power failure.	Make sure that the power cord is connected to an earthed wall socket. Make sure the extension cord is properly connected and the device is switched on (if applicable). In the event that there is air in the line, proceed to deaerate it. Refer to *Deaerating the deaeration chamber* on page 41.
The device is not operative.		
The battery is low (< 50 %).	The indicators and alarms have been enabled and the power supply has been interrupted for a long period of time.	Restore power to the device. The battery will be recharged after 6 to 12 hours of operation.

- In the event of a mains power failure the shut-off valve will close automatically. [N026]
- Only indicators and alarms are battery-operated. The battery condition can become insufficient to enable the indicators and alarms. [N027]



Problem	Possible cause	Solution
No mains power for a long period of time.	A mains power failure.	Make sure that the power cord is connected to an earthed wall socket. Make sure the extension cord is properly connected and the device is switched on (if applicable). In the event that there is air in the line, proceed to deaerate it. Refer to *Deaerating the deaeration chamber* on page 41.
The device is not operative.		
The battery is low (< 50%).	The indicators and alarms have been enabled and the power supply has been interrupted for a long period of time.	Leave the device connected to the mains power. The battery is recharged after 6 to 12 hours of operation.

In the event of a mains power failure the shut-off valve will close automatically. [N026]



Problem	Possible cause	Solution
Fluid is detected by the ultrasonic sensor, but the tube is not detected by the tube sensor.	The tube is outside the tube sensor and the shut-off valve.	Place the tube inside the tube sensor and the shut-off valve.
	The tube sensor is dirty.	Clean the tube sensor with a moist cloth or alcohol tissues.

7.4 Pressure Chambers

The following tables may assist the end user when troubleshooting the device. If the problem persists, do not use the module. In the event of any technical assistance being needed, contact the hospital service department or the local supplier.

Problem	Possible cause	Solution
The bladder does not inflate.	No air supply.	Check the air supply.
	Leakage at internal couplings.	Press the internal tubing tightly to the couplings.
	The pressure selector is defective.	Contact the hospital service department or the local supplier.
	The pressure regulator is defective.	Contact the hospital service department or the local supplier.
	The non-return valve is defective.	Contact the hospital service department or the local supplier.
	Bladder air leakage.	Contact the hospital service department or the local supplier.

Problem	Possible cause	Solution
	The overpressure relief valve is defective.	Contact the hospital service department or the local supplier.

Problem	Possible cause	Solution
Long bladder inflation time. Low air pressure.	Bad external pneumatic connections between Fluido® Compressor and Fluido® Pressure Chambers.	Press the external tubing tightly to the couplings.
	Leakage at internal couplings.	Press the internal tubing tightly to the couplings.
	The pressure regulator is defective.	Contact the hospital service department or the local supplier.
	Leakage at connection between elbow coupling and bladder tube.	Contact the hospital service department or the local supplier.
	Bladder leakage.	Contact the hospital service department or the local supplier.

7.5 Compressor

The following tables may assist the end user when troubleshooting the device. If the problem persists, do not use the module. In the event of any technical assistance being needed, contact the hospital service department or the local supplier.

Problem	Possible cause	Solution
Low air pressure Low air flow.	Leakage.	Check the pneumatic couplings between the Fluido® Compressor and the Fluido® Pressure Chamber.
	The external air tubes are kinked.	Check for kinked air tubes between the Fluido® Compressor and the Fluido® Pressure Chamber.
	The external air tubes are obstructed.	Clean the air tubes.

Problem	Possible cause	Solution
	The air filter is dirty.	Contact the hospital service department or the local supplier.
	The internal air supply couplings are loose.	Contact the hospital service department or the local supplier.
	Pump leakage.	Contact the hospital service department or the local supplier.

8 Specifications

8.1 Environmental conditions for operation

Description	Specification
Ambient temperature	15 °C ~ 30 °C
Relative humidity	30% ~ 75%
Atmospheric pressure	70-106 kPa

8.2 Modules

8.2.1 Environmental conditions for transport and storage

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

8.2.2 Blood and Fluid Warmer

230 Volt version

Description	Specification
Part number	651230
Voltage	220-240 V~
Frequency	50/60 Hz
Maximum current	6 A
Dimensions (H × W × D)	435 × 250 × 315 mm
Fuses	2× T8 AH, 250 V
Weight	9.5 kg
Setpoint temperature	30 °C ~ 39 °C., increments of 1 °C
Maximum output temperature (T_{out})	43 °C
Accuracy of output temperature (T_{out})	± 2.0 °C
Warning indication limit (software)	46 °C

Description	Specification
Accuracy of flow meter	± 20%
Warming and measurement technology	Infrared
Warming lamps	300 W (4×)
Flow lamp	150 W (1×)
GMDN code	47623
Classification (IEC 60529)	IPX1
Classification (IEC 60601-1)	Class I, Cardiac Floating
Classification (MDR (EU) 2017/745)	Class IIb - 0344
Product lifetime	7 years

115 Volt version

Description	Specification
Part number	651115
Voltage	110-120 V~
Frequency	50/60 Hz
Maximum current	12 A
Dimensions (H × W × D)	435 × 250 × 315 mm
Weight	9.5 kg
Fuses	2× T15 AH, 250 V
Setpoint temperature	30 °C ~ 39 °C., increments of 1 °C
Maximum output temperature (T_{out})	43 °C
Accuracy of output temperature (T_{out})	± 2.0 °C
Warning indication limit (software)	46 °C
Accuracy of flow meter	± 20%
Warming and measurement technology	Infrared
Warming lamps	300 W (4×)
Flow lamp	150 W (1×)
GMDN code	47623
Classification (IEC 60529)	IPX1
Classification (IEC 60601-1)	Class I, Cardiac Floating
Classification (MDR (EU) 2017/745)	Class IIb

Description	Specification
Product lifetime	7 years

8.2.3 Air Guard

230 V version

Description	Specification
Part number	660400
Voltage	220-240 V~
Frequency	50/60 Hz
Maximum current	0.2 A
Dimensions (H × W × D)	310 × 150 × 190 mm
Weight	4.5 kg
Sound pressure (audible signal)	Low priority: 52 dB(A)
	Medium priority: 52 dB(A)
	High priority: 54 dB(A)
GMDN code	47040
Classification (IEC 60529)	IPX1
Classification (IEC 60601-1)	Class I, Cardiac Floating
Classification (MDR (EU) 2017/745)	Class I
Product lifetime	7 years

115 V version

Description	Specification
Part number	661400
Voltage	110-120 V~
Frequency	50/60 Hz
Maximum current	0.3 A
Dimensions (H × W × D)	310 × 150 × 190 mm
Weight	4.5 kg
Sound pressure (audible signal)	Low priority: 61.5 dB(A)
	Medium priority: 60.7 dB(A)

Description	Specification
	High priority: 60.7 dB(A)
GMDN code	47040
Classification (IEC 60529)	IPX1
Classification (IEC 60601-1)	Class I, Cardiac Floating
Classification (MDR (EU) 2017/745)	Class I
Product lifetime	7 years

8.2.4 Pressure Chambers

Description	Specification
Part number	660300
Dimensions (H × W × D)	370 × 400 × 150 mm
Weight	4.2 kg
Maximum overpressure	330 mmHg
Accuracy pressure	± 33 mmHg (10%)
GMDN code	38468
Classification (MDR (EU) 2017/745)	Class IIa
Product lifetime	7 years

8.2.5 Compressor

Description	Specification
Part number	660200A
Voltage	100-240 V~
Frequency	50/60 Hz
Maximum power	6-16 VA
Dimensions (H × W × D)	210 × 150 × 150 mm
Weight	1.3 kg
Fuses	2 × T0.2 AH, 250 V
Airflow	3 l/min. (unloaded)
Maximum pressure	1.0 bar/750 mmHg

Description	Specification
GMDN code	31253
Classification (IEC 60529)	IPX1
Classification (IEC 60601-1)	Class I, Cardiac Floating
Classification (MDR (EU) 2017/745)	Class I
Product lifetime	7 years

8.2.6 IV Pole

Description	Specification
Part number	660500-B
Height	1920-2230 mm ± 10 mm
IV Pole diameter (Ø)	38 mm
Wheelbase diameter (Ø)	740 mm
Weight	13 kg
Total system mass	39 kg
GMDN code	36069

8.3 Disposable sets

8.3.1 Environmental conditions for transport

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

8.3.2 Environmental conditions for storage

Description	Specification
Ambient temperature	2 °C ~ 30 °C
Relative humidity	10% ~ 90% (non-condensing)
Atmospheric pressure	50-106 kPa

8.3.3 Fluido® Standard Set

Description	Specification
Part number	671200
Patient line	150 cm
Maximum pressure	300 mmHg
Maximum flow[3]	400 ml/min.
Normothermic flow[4]	20-400 ml/min.
Storage volume	90 ml (40°C)
GMDN code	47622

8.3.4 Fluido® Trauma Set

Description	Specification
Part number	671500
Patient line	150 cm
Maximum pressure	300 mmHg
Maximum flow[3]	800 ml/min.
Normothermic flow[4]	20-600 ml/min.
Drops per ml	16
Storage volume	160 ml (40°C)
Filter	263 µm (± 20 µm)
GMDN code	47622

[3] Free flow with 300 mmHg without catheter attached.
[4] Incoming fluid temperature of 20 °C and output flow between 36 °C and 37.5 °C.

8.3.5 Fluido® Trauma Plus Set

Description	Specification
Part number	671700
Patient line	200 cm
Maximum pressure	300 mmHg
Maximum flow[3]	900 ml/min.
Normothermic flow[4]	30-600 ml/min.
Priming volume	155 ml
Filter	263 µm (± 20 µm)
GMDN code	47622

9 Electromagnetic compatibility

Warning!

- Use of accessories, transducers and cables other than those specified or provided by The Surgical Company International B.V. of 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). If it is used in a residential environment (for which CISPR 11 class B is normally required), this device may not offer adequate protection to radio frequency communication services. The user may need to take mitigation measures, such as relocating or reorienting the device. [N030]
- The device will produce an audible signal when the power supply experiences a drop in voltage of more than 30%. Refer to *Troubleshooting* on page 51 if this occurs. [N031]
- This device complies with IEC 60601-1-2:2014 for electromagnetic compatibility. However, if electromagnetic interference with nearby devices is experienced, the user is encouraged to take one or more of the following measures:
  - Isolate the offending device.
  - Reorient or relocate this device.
  - Increase the distance between the interfering device and this device.
  - Use an alternative mains socket.

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

9.1 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)

9.2 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)	

9.3 Recommended separation distances

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

The system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the system 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]

10 Disposal

Warning!

- After applying blood products, clean the hospital administration set with saline. [W031]
- The device and its disposables may be a potential biohazard during and after use. Handle and dispose of in accordance with accepted medical practice and applicable local regulations. [W032]

10.1 Active devices

The active devices may be a potential biohazard during and after use. Dispose of the active devices after cleaning & disinfection, according to validated cleaning validation. Handle and dispose of in accordance with accepted medical practice and applicable local regulations.

In the EU following the Waste Electrical and Electronic Equipment (WEEE) Directive.

10.2 Disposables

The active devices may be a potential biohazard during and after use. After applying blood products, clean the hospital administration set with saline. Dispose the single-use disposables with other biohazardous medical waste, in closed bins and sent for medical burn waste according to local regulations.

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