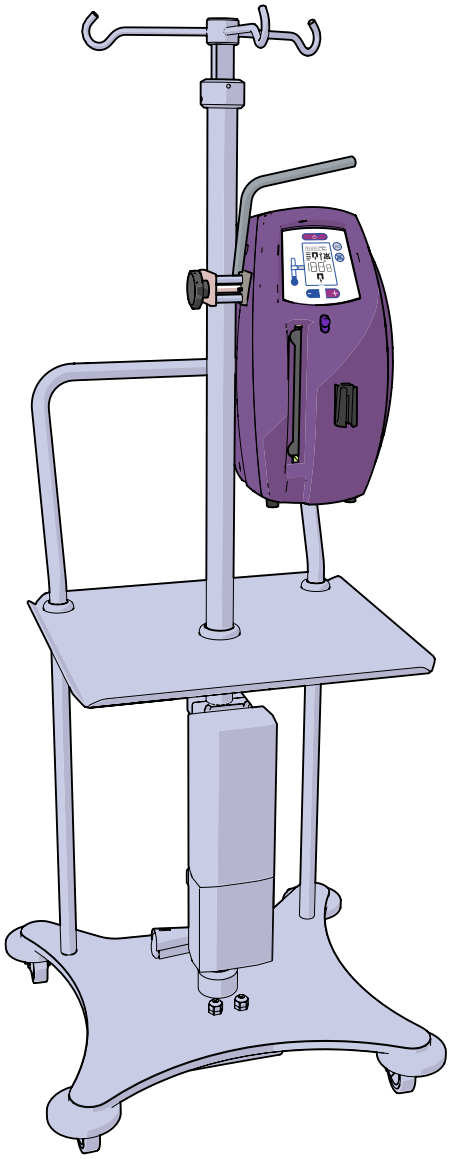
Fluido® Irrigation

Fluid Warming



User Manual

Fluido® Irrigation

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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® Irrigation (hereafter referred to as 'the device').

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 device, yearly maintenance is required. Functional testing is mandatory to be performed after every maintenance. Please refer to the Fluido® Irrigation technical manuals for maintenance, repair and calibration instructions. The Fluido® Irrigation 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 device, 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® Irrigation is developed to warm irrigation fluids to adult patients.

The device can be used to warm the following fluids:

- Crystalloid fluids
- Glucose fluids
- Distilled water
- Urea-based fluids
- Ringer's lactate solution
- Glycine solution
- Mannitol solution
- Sorbitol solution

1.4 Indications for use

The Fluido® Irrigation is indicated to be used in healthcare environments to help prevent hypothermia. The devices can be used in the full clinical environment.

1.5 Contact

The Surgical Company International B.V.
Beeldschermweg 6F
3821 AH Amersfoort
The Netherlands

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

Refer to the website for local distributors.

1.6 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® Irrigation 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 and may not be construed as containing 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 use of or reliance upon any information contained in this manual as medical advice is and shall solely remain at the user's risk. The Surgical Company International B.V. cannot be held liable for the outcome of a patient's treatment with the use of the medical device(s) described herein.

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. All users are therefore 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*.

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

1.10 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

2 Contraindications, warnings, cautions, notes and symbols

The device 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 device as intended. Refer to *Intended use* on page 6. [W053]
- Obey local regulations. [W057]

Materials

Warning!

- Use irrigation products that comply with local regulations. [W008]
- Do not use irrigation products with a temperature below 4°C or above room temperature. [W009]

Prior to operation

Warning!

- Unlock the brakes on the Fluido® PowerLifter II or the Fluido® IV Pole before moving the system. [W010]
- Do not use the device if it is damaged (e.g. dents, cracks). Take the device 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 administration set for every application with a Fluido® Irrigation URO Set. [W014]
- Use the device only with a Fluido® Irrigation URO Set and Fluido® Irrigation accessories. [W016]
- Use each disposable set for only one patient. [W017]
- Do not use a disposable set if the disposable has expired. [W018]
- 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 device close to the head of the patient if inhaler therapy is being used. [W024]
- The disposable set should not be used for longer than 24 hours. [W027]
- 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]
- In case of Transurethral Resection of the Prostate (TURP) procedure, please refer to the working pressures recommended by the specific guidelines. Elevated working pressures may be related to a higher incidence of TURP syndrome. [W030]

After operation

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]

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 device in liquid. Immersing the device in liquid may damage the device. [C004]

Prior to operation

Caution!

- Do not use the device outside the environmental specifications: see *Specifications* on page 43. [C005]

- Keep the device away from portable and mobile radio-frequency communications equipment and high-frequency surgical instruments or endocardial catheters. Portable and mobile radio-frequency communication equipment and high-frequency surgical instruments or endocardial catheters may cause the system to operate incorrectly. [C006]
- Do not modify the device. Use of power supply cords or spare parts for internal components other than as specified by the manufacturer may lead to hazardous situations. [C007]
- Connect the mains plug(s) to earthed wall socket(s) only. [C008]
- Install the device in such a way that you can easily disconnect the mains plug(s) from the wall socket in the event of an emergency. [C009]
- Do not block the ventilation openings of the device. [C010]
- Make sure that the brakes on the Fluido® PowerLifter II or the Fluido® IV Pole are locked when using the system. [C012]
- Do not use the system on surfaces with an inclination > 2.5°. [C013]
- After any temporary interruption of the mains power supply, refer to *Power supply interruption* on page 38. [C015]

2.1.3 Notes

- In the event of a power interruption, the device 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]

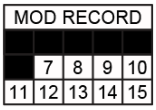
2.1.4 Literature

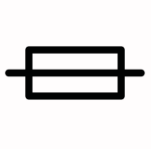
1. M. J. Pit, R. J. Tegelaar, and P. L. Venema, “Isothermic irrigation during transurethral resection of the prostate: Effects on peri-operative hypothermia, blood loss, resection time and patient satisfaction,” Br. J. Urol., vol. 78, no. 1, pp. 99–103, 1996.
2. J. W. H. Evans, M. Singer, S. W. V. Coppinger, N. Macartney, J. M. Walker, and E. J. G. Milroy, “Cardiovascular performance and core temperature during transurethral prostatectomy,” Journal of Urology, vol. 152, no. 6 I. pp. 2025–2029, 1994.
3. M. Monga, B. Comeaux, and J. A. Roberts, “Effect of Irrigating Fluid on Perioperative Temperature Regulation during Transurethral Prostatectomy,” Eur. Urol., vol. 29, no. 1, pp. 26–28, 1996.
4. S. Mirza, S. Panesar, K. J. AuYong, J. French, D. Jones, and S. Akmal, “The Effects of Irrigation Fluid on Core Temperature in Endoscopic Urological Surgery,” J. Perioper. Pract., vol. 17, no. 10, pp. 494–503, Oct. 2007.

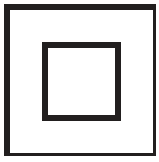
5. P. S. Heathcote and P. M. Dyer, “The Effect of Warm Irrigation on Blood Loss during Transurethral Prostatectomy under Spinal Anaesthesia,” Br. J. Urol., vol. 58, no. 6, pp. 669–671, Dec. 1986.

2.2 Device safety symbols

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

	Caution: Federal US law restricts this device to sale by or on order of a physician.
	The device is protected against dripping water (according to IEC 60529).
	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.
	Serial number
	Catalogue/article number/part number
	Manufacturer
	MOD stands for the modification update (in this example: modification update 6)
	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.
	Equipotentiality
	Read the user manual.
	Consult the instructions for use.
	CE marking of conformity

	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.
	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.
	Temporarily audible signal suppression - "audio paused"
	Non-pyrogenic
	Device power On/Standby
	Repair required

3 Description

The Fluido® Irrigation is a Fluid Warming System. The system is suitable for all applications, from moderate to high flows. The Fluido® Irrigation uses infrared heating technology to warm fluids. Based on in-line sensors, the Fluido® Irrigation calculates the energy required to safely warm the fluid. The system is only to be used with adults, the system is not to be used for paediatric use.

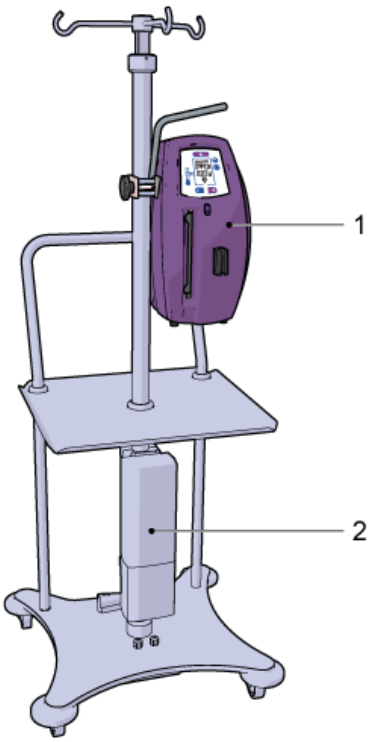
The essential performance of the Fluido® Irrigation is:

- To warm fluids within the safe temperature and time limits according to ASTM F2172-02.

3.1 Overview of the system

The Fluido® Irrigation consists of the following modules:

Module	Function
Irrigation Fluid Warmer	Warms the fluid to the set temperature.
PowerLifter II	Ensures a stable operating platform for the system and regulates the flow.



1. Irrigation Fluid Warmer
2. PowerLifter II

The Fluido® PowerLifter II is a separate device to adjust the height of the irrigation fluid bags. This allows flow regulation by generating pressure overhead. The description and instructions for use for the Fluido® PowerLifter II are covered in a separate manual.

The Fluido® Irrigation can also be mounted on the Fluido® IV Pole. [N004]

3.2 Irrigation

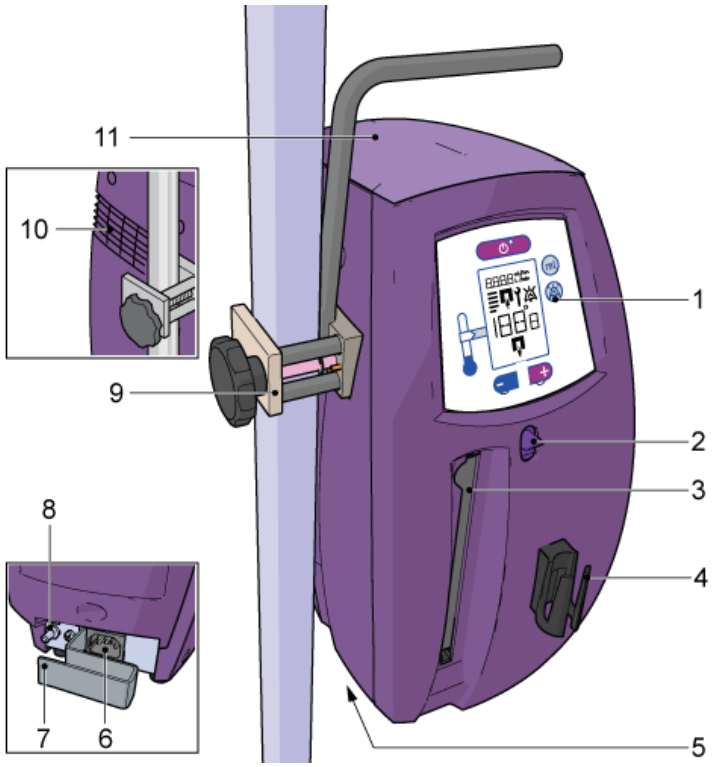
The Fluido® Irrigation is an easy-to-operate fluid warmer. This section describes the different parts of the device.

3.2.1 Overview

The Fluido® Irrigation is the module that uses infrared technology to warm up the fluids. The Fluido® Irrigation uses Fluido® Irrigation disposable sets for fluid irrigation.

Caution!

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

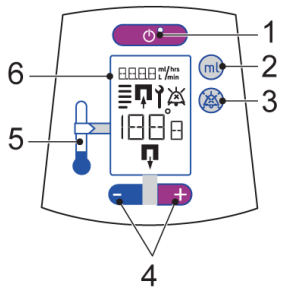


1. Control panel
2. Eject button for disposable set cassette
3. Slot for disposable set cassette
4. Deaeration chamber holder
5. Ventilation openings
6. Power supply cord connection
7. Cord anchor
8. Potential equalisation terminal[1]
9. Mounting clamp
10. Ventilation openings
11. Top sticker

[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.

3.2.2 Control panel

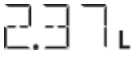
The control panel is located at the front of the device and can be operated by pressing the buttons located in the panel. All settings are visible on the display and the desired temperature can be selected by pressing the temperature selection buttons. By pressing the flow/volume button, the display 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.

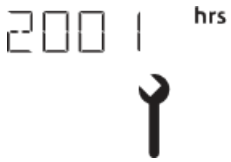
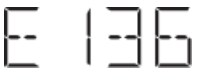


1. On/standby button and indicator
2. Flow/volume button
3. Audible signal suppression button
4. Temperature selection buttons (+/-)
5. Control thermometer
6. Display

Display

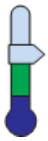
This section explains the items shown on the display of the Irrigation.

Display	Description
	Flow indicator (ml/min)
	Volume indicator (l)
	Number of operating hours
	Insert the disposable set into the device.
	Remove the disposable set from the device.
	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.

Display	Description
	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.
	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.
	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 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.
	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.

- The end temperature cannot be guaranteed when an extension line is being used. [N006]
- Refer to *Troubleshooting: Fluido® Irrigation* on page 38 for troubleshooting. [N007]

3.3 Disposable sets

A Fluido® disposable set consists of a cassette and tubing. In the cassette the fluid flow is warmed and mixed. The flow range of the cassette is designed to be used for both moderate and high flow applications.

The front of the Fluido® cassette is made of transparent plastic. 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® Irrigation may only be used with the following Fluido® disposable sets and accessories:

- Fluido® Irrigation URO Set
- Fluido® Irrigation URO Patient line
- Fluido® Irrigation URO Spike Set

Caution!

Do not use the Fluido® Standard Set, Fluido® Trauma Set, Fluido® Trauma Plus Set, alternative types of de-aeration chambers or disposable sets in combination with the Fluido® Irrigation. [C018]

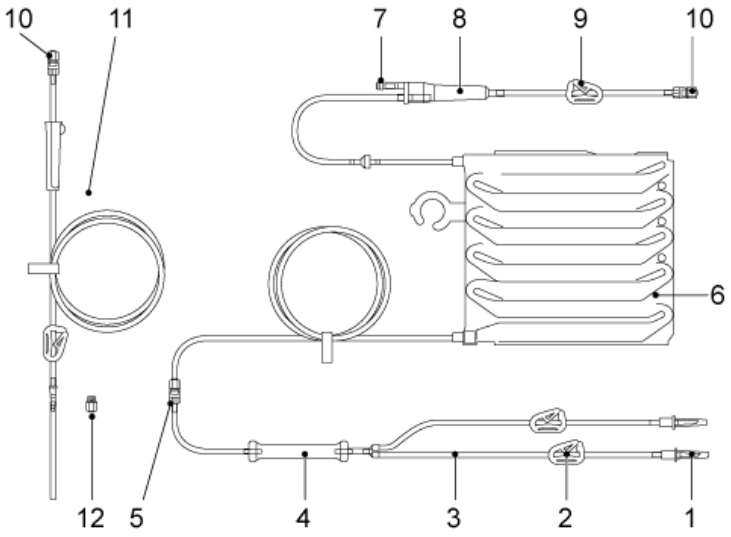
Warning!

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

3.3.1 Fluido® Irrigation URO Set

The Fluido® Irrigation URO Set is designed for urological interventions. It contains a deaeration chamber integrated with a non-return valve. The set includes a separate patient line and a Luer Lock bore cap.

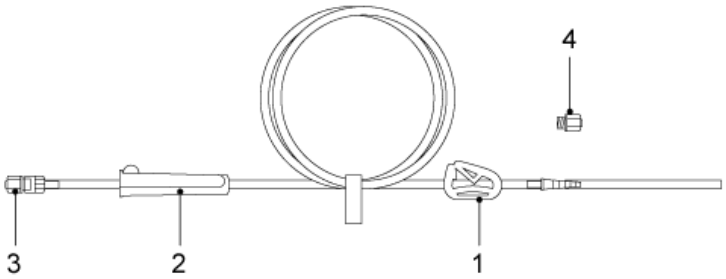
This set must only be used in combination with the Fluido® Irrigation URO patient line, Irrigation URO Spike Set and Irrigation URO Female Cap.



1. Spike
2. Clamp
3. Spike line
4. Drip chamber
5. Spike set Luer Lock connection
6. Cassette
7. Air relief valve
8. Deaeration chamber
9. Clamp
10. Patient line connector
11. Patient line (separate)
12. Luer Lock bore cap

3.3.2 Fluido® Irrigation URO Patient line

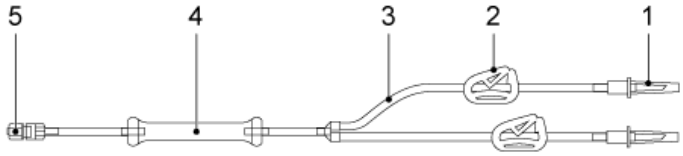
The Fluido® Irrigation URO Patient line is a patient line with an extra Luer Lock cap. This patient line must only be used in combination with the Fluido® Irrigation URO Set and/or URO Spike Set.



1. Clamp
2. Roller clamp
3. Patient line connector
4. Luer Lock cap

3.3.3 Fluido® Irrigation URO Spike Set

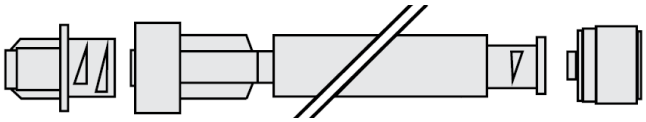
The Fluido® Irrigation URO Spike Set is a drip chamber with spikes. This set must only be used in combination with the Fluido® Irrigation URO Patient line.



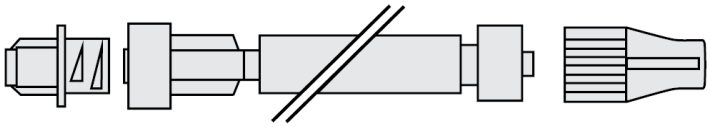
1. Spike
2. Clamp
3. Spike line
4. Drip chamber
5. Spike Set Luer Lock connection

3.3.4 Fluido® Irrigation connectors

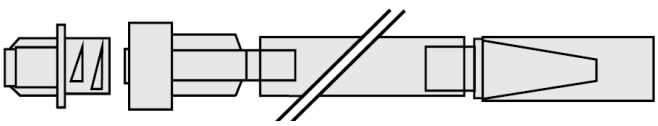
The Fluido® Irrigation URO sets can also be connected to an irrigation pump using specifically developed connectors:



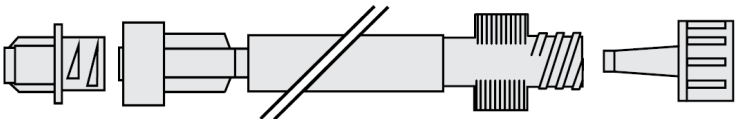
Fluido® Irrigation Female connector



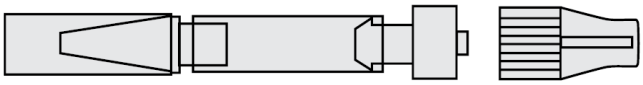
Fluido® Irrigation Male connector



Fluido® Irrigation Catheter connector



Fluido® Irrigation Funnel connector



Fluido® Irrigation Luer Lock Male connection

4 Set-up

4.1 Transport and storage

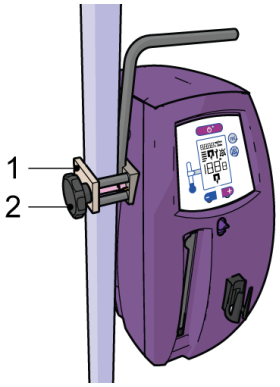
Transport and store the system and modules according to the *Environmental conditions for transport and storage* on page 43.

Transport and store the disposable sets according to the *Environmental conditions for transport* on page 45 and *Environmental conditions for storage* on page 45.

4.2 Attaching the Fluido® Irrigation PowerLifter II or IV Pole

Follow these steps to attach the Fluido® Irrigation to the PowerLifter II or the Fluido® IV Pole.

1. Turn the lock knob (2) anticlockwise to open the mounting clamp (1).
2. Mount the device to the IV pole with the mounting clamp (1).
3. Turn the lock knob (2) clockwise to close the mounting clamp (1).



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]

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 49. [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.

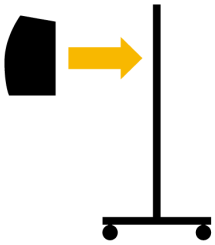
5.2 Preparation before operation

Warning!

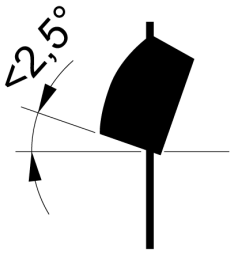
Ensure that the Fluido® Irrigation is not damaged and that the ventilation grids (on the side and bottom of the device) are not covered. [W061]

Caution!

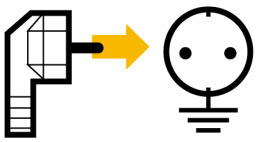
- Before using the Fluido® Irrigation, it should be attached to a Fluido® PowerLifter II or (Fluido®) IV Pole. [C021]



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



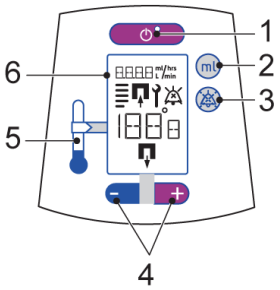
- Before using the Fluido® Irrigation, it must be plugged into the mains power supply. The device must be connected to an earthed wall socket. [C023]



5.2.1 Switching on the Irrigation

Follow these steps to turn on the Fluido® Irrigation.

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



1. Connect the mains plug of the power supply cord adapter to an earthed wall socket.
   The device will perform a self-test.
   The 'remove cassette' symbol will flash during the self-test.
   The display (6) will light green.
   The on/standby indicator (1) will light orange.
   The device is now in standby mode.
2. 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.

5.2.2 Inserting and removing a disposable set

Warning!

- Do not use damaged disposable sets. Prior to use, inspect the cassettes:
  - Check the cassette for cracks. [W034]
  - Check the plastic layer on top of the cassette for damage. [W036]
  - Check the spike line and irrigation line for punctures or damage. [W038]
- Use clean disposable sets and use them in the sterile field only. Once removed from the packaging, use the disposable set immediately. The disposable set can be used for a maximum of 24 hours. [W039]

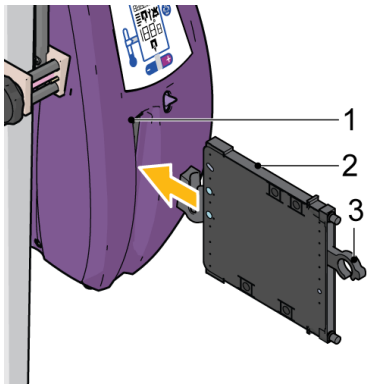
Caution!

- Only use sets and accessories compatible with the device. [C031]
- 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 disposable lines are not shown. [N013]

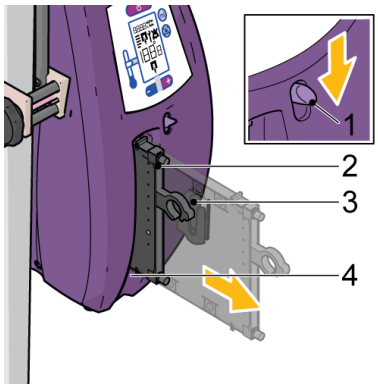
Follow these steps to insert a disposable set.

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.



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).

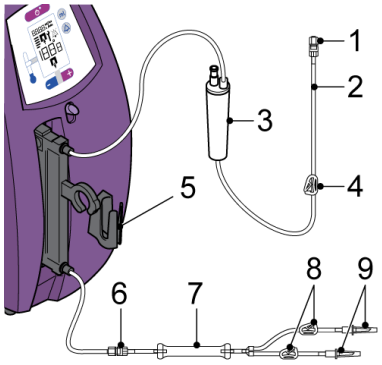


5.2.3 Priming the disposable set

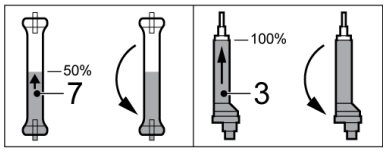
Warning!

- Before you prime a Fluido® URO Set, prepare the patient line and Spike Set. [W042]
- Prime the disposable sets with a crystalloid irrigation fluid. [W043]

Follow these steps to prime the Fluido® Irrigation URO Set.

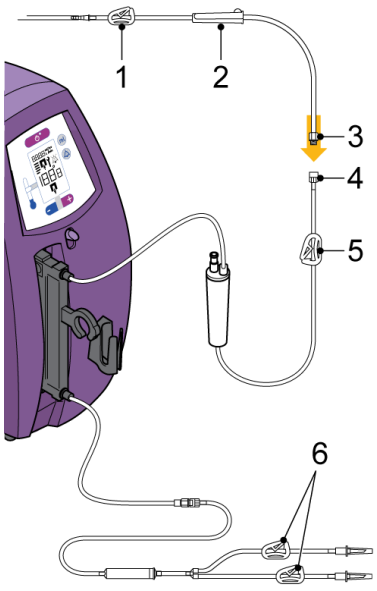


1. Close the clamps (4), (8) of the disposable set.
2. Connect the spikes (9) to the hospital irrigation fluid bag.
3. Open the clamps of the disposable set (4), (8).
   Make sure not to open the clamp of the unused spike.
4. Hold the drip chamber (7) upside down.
5. Partially open the protective cap (1) to regulate priming.
6. Wait until the drip chamber (7) is half filled with fluid.
7. Place the drip chamber (7) in the upright position.
8. Turn the deaeration chamber (3) upside down.
9. Fill the deaeration chamber (3) entirely with fluid.
10. Turn the deaeration chamber (3) upright again.
11. Deaerate the rest of the line by circulating the fluid through the lines until no air is present.
12. Close the protective cap (1).
13. Close the clamps of the disposable set (4), (8).
14. Place the de-aeration chamber in the holder (5) of the Fluido® Irrigation.



The Fluido® Irrigation URO Set is now primed.

Follow these steps to prime the Fluido® patient line.



1. Take the Fluido® Irrigation URO patient line out of the packaging and place it in the sterile field.
2. Remove the protective caps (4) from the disposable set and the URO patient line (3) and connect the two.
3. Close the roller clamp (2).
4. Open the clamps (1), (5) and (6).
   Make sure not to open the clamp of the unused spike.
5. Deaerate the rest of the Fluido® Irrigation URO patient line by opening the roller clamp (2).
6. Close the roller clamp (2).

The Fluido® Irrigation URO Set and URO patient line are now primed.

5.3 Operate the device

Before you operate the system, prepare the device (refer to *Preparation before operation* on page 26).

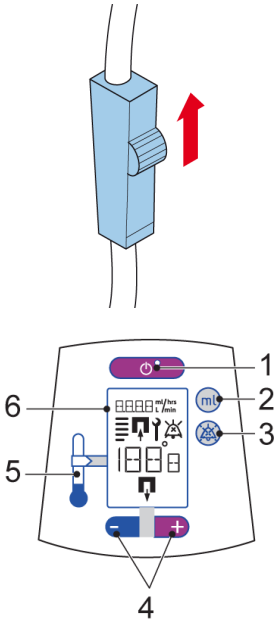
5.3.1 Warming up fluids

Warning!

- Make sure that the display on the control panel of the Fluido® Irrigation shows the initial temperature (37°C) before warming up fluids. [W047]
- Make sure that the pressure on the line does not exceed 300 mmHg. [W062]

Follow these steps to warm up fluids.

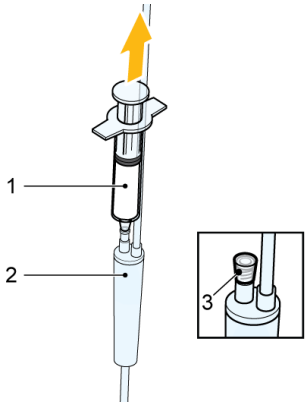
1. Connect the device to the operating instrument.
2. Adjust the desired flow with the roller clamp or by changing the height of the irrigation bags.
3. Set the appropriate temperature by using the temperature selection buttons (4) on the control panel of the device.
   The device will warm up the fluids 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.



5.3.2 Deaerating the deaeration chamber

If the deaeration chamber is filled more than one quarter with air, the chamber must be deaerated as follows:

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.

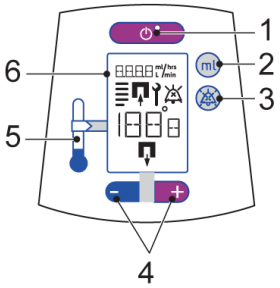


5.3.3 Suppressing the audible signal

The Fluido® Irrigation has an audible signal suppression button. It is recommended that the causes of the alarms are addressed immediately after the signal sounds.

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

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).



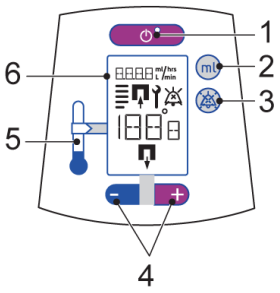
If the audible signal suppression button (3) is pressed again, the audible signal will sound again and the audible signal suppression indicator will switch off in the display (6). [N018]

5.3.4 Extra functions of the Fluido® Irrigation device

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

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

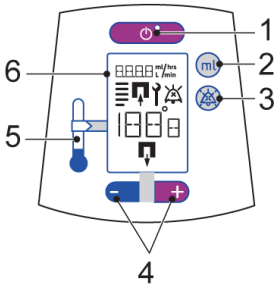
1. Press the flow/volume button (2) to alternate between the display of:
   - Flow
   - Volume
   - Flow and volume



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.

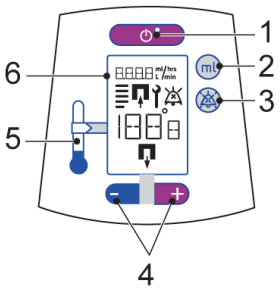
The volume indicator resets to 0.



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).



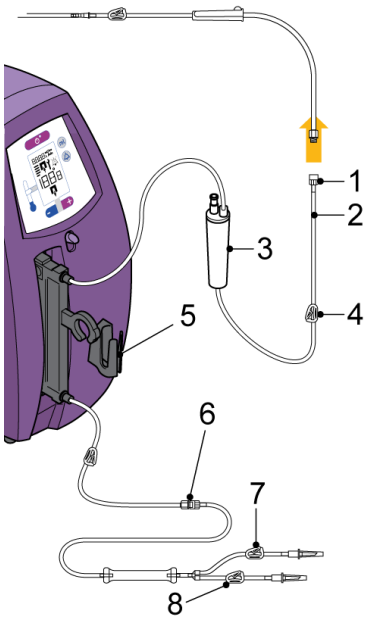
5.4 Post-operative procedures

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

5.4.1 Post-operative non-heated irrigation

Follow these steps to stop warming fluids but continue irrigating.

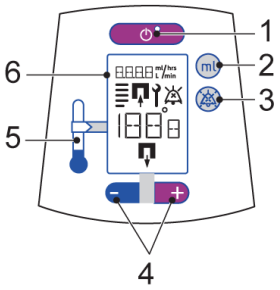
1. Close all clamps (4), (7), (8).
2. Disconnect the used URO patient line from the Fluido® Irrigation URO Set (1).
3. Disconnect the used URO patient line from the working element.
4. Connect the new Spike Set to the URO patient line (6).
5. Connect the patient line with the spike set to an urinary catheter.
6. Open the clamps (4), (7), (8) to start irrigating.



5.4.2 Stopping the device

Follow this step to stop warming fluids.

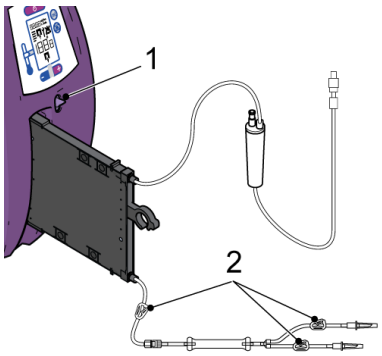
1. Press the on/standby button (1) on the Fluido® Irrigation.
   The on/standby indicator (1) will light orange.



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 (3) on the disposable set.
   Fluid administration is now stopped.
2. Press the eject button (1) on the Fluido® Irrigation to remove the disposable set from the module.
3. 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:

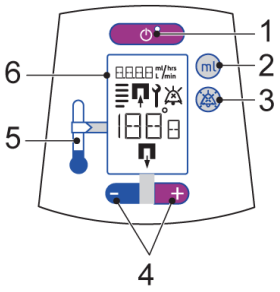
- Handle and dispose of in accordance with accepted medical practice and applicable local regulations.
- Dispose the single-use disposables with other biohazardous medical waste, in closed bins and sent for medical burn waste according to applicable local regulations. [W032]

5.4.3 Resetting the Fluido® Blood and Fluid Warmer

Some Fluido® Blood and Fluid Warmer malfunctions can be resolved by resetting the device. The 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.

6 Maintenance

If a problem occurs with the device, please refer to *Troubleshooting* on page 38.

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

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 36.

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 device should respond as follows.

Device	Response
Irrigation	Will turn off. If the mains power is restored within 30 seconds, the Fluido® Irrigation will skip the self-test and continue with the previous temperature setting.

7.2 Fluido® Irrigation

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 31.

Some malfunctions may be resolved by resetting the device. Refer to *Resetting the Fluido® Blood and Fluid Warmer* on page 34.

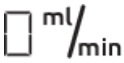
The following tables may assist the end user when troubleshooting the device. In the event of any technical assistance being needed, contact the hospital service department or the local supplier.

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.

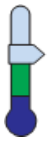
Indicator	Problem	Possible cause	Solution
	The on/standby indicator is off. An audible signal sounds.	Malfunction.	Contact the hospital service department or the local supplier.

Indicator	Problem	Possible cause	Solution
	The on/standby indicator turns off during use. An audible signal sounds.	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.

Indicator	Problem	Possible cause	Solution
	The device does not start. The 'remove disposable' symbol shows.	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.

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.	

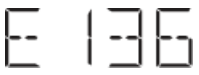
Indicator	Problem	Possible cause	Solution
	The three middle bars of the lamp replacement indicator flash.	One of the lamps is defective.	Contact the hospital service department or the local supplier.
	The display shows the maintenance symbol.		
	An audible signal sounds. The device keeps operating.		

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.

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 Irrigation

230 Volt version

Description	Specification
Part number	651230-I
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-I
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

8.3 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® Irrigation URO Set

Description	Specification
Part number	670800-B
Total length	150 cm
Maximum pressure	300 mmHg
Maximum flow[2]	1400 ml/min
Normothermic flow[3]	50 ~ 680 ml/min.
Priming volume	220 ml
GMDN code	45644

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

8.3.4 Fluido® Irrigation URO Patient Line

Description	Specification
Part number	680801-B
Total length	225 cm
GMDN code	45644

8.3.5 Fluido® Irrigation URO Spike Set

Description	Specification
Part number	680803-B
Number of spikes	2
Total length	75 cm
GMDN code	45644

8.4 Accessories

8.4.1 Fluido® Irrigation Female Connector

Description	Specification
Part number	680910
Total length	15 cm
Connector side A	Male Luer
Connector side B	Female Luer
GMDN code	45644

8.4.2 Fluido® Irrigation Male Connector

Description	Specification
Part number	680911
Total length	16 cm
Connector side A	Male Luer
Connector side B	Male Luer
GMDN code	45644

8.4.3 Fluido® Irrigation Catheter Connector

Description	Specification
Part number	680912
Total length	21 cm
Connector side A	Male Luer
Connector side B	Catheter
GMDN code	45644

8.4.4 Fluido® Irrigation Funnel Connector

Description	Specification
Part number	680913
Total length	20 cm
Connector side A	Male Luer
Connector side B	Funnel
GMDN code	45644

8.4.5 Fluido® Irrigation URO Male Connection

Description	Specification
Part number	680805
Total length	10 cm
Connector side A	Male Luer
Connector side B	URO Connector
GMDN code	45644

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 38 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.

The Surgical Company

PTM

The Surgical Company International B.V.
Beeldschermweg 6F
3821 AH Amersfoort
+31 (0)33 450 72 50

www.tsc-group.com/ptm
info.ptm@tsc-group.com

CE 0344