

TSC The Surgical Company International B.V.



www.fluidoirrigation.nl

User Manual

Fluido® Irrigation Fluid Warmer

Article number: 651230-l

	reword	
Dis	sclaimer	
1	Temperature Management	
2	Fluid Warming	
3	Fluido® Irrigation Fluid Warmer	5
4	Description of the Fluido® Irrigation	
	4.1 The Fluido [®] <i>Irrigation</i> Fluid Warmer	
	4.2 The Control Panel	
	4.2.1 Control Panel Symbols	
	4.2.2 Control thermometer	
	4.3 Fluido [®] <i>Irrigation</i> Disposable Sets and Accessories 4.3.1 Description of cassette	
5	4.3.1 Description of cassette Preparing the Fluido® Irrigation for use	
6	User instructions	
U	6.1 Connection to power supply	
	6.2 Switching on	
	6.3 Positioning the Fluido® <i>Irrigation</i> URO Set	13
	6.4 Priming Fluido [®] <i>Irrigation</i> URO Set	13
	6.4.1 Priming the Fluido® Irrigation URO Set	13
	6.4.2 Priming the Fluido® Irrigation URO Patient line	14
	6.5 Start Warming	
	6.6 De-aeration	15
	6.7 Stop warming	16
	6.8 Post-operative options	
	6.8.1 Post-operative non-heated irrigation	
	6.8.2 Fluido [®] <i>Irrigation</i> URO Spike Set	
	6.8.3 Fluido [®] <i>Irrigation</i> URO Female cap	
7	Extra options	
8	Problems and solutions	
9	Symbols and Warnings & Precautions	
	9.1 Symbols	
40	9.2 Warnings & precautions	
10	Maintenance	
11 12	Storage and cleaning	
	WarrantySpecifications	
13	opediidaliolis	∠0

Foreword

Congratulations on your purchase of the Fluido® Irrigation Fluid Warmer.

This device is developed in accordance with the latest safety standards. We wish you every success in preventing and controlling hypothermia and we are sure that the Fluido[®] *Irrigation* Fluid Warmer can help you to do so. Please read this manual carefully before working with the Fluido[®] *Irrigation*.

If you identify any improvements and/or discover any other applications during the use of the Fluido[®] *Irrigation* products, please let us know.

TSCI (The Surgical Company International B.V.)

Disclaimer

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

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

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

These instructions are intended for personnel authorised to work with the medical device described in this manual

1 Temperature Management

Hypothermia, an abnormal drop in body temperature, is a threat to human life. Hospital patients in particular run serious risks if their body temperature falls below 36 °C. The risk of hypothermia is particularly high at times when they are vulnerable, such as pre-, per-, and post-surgical procedures. Factors that can contribute to hypothermia include the duration of the surgical procedure, the location of the wound, the amount of blood loss, the surface area of the wound, the environmental temperature and the anaesthetic technique.

2 Fluid Warming

The use of irrigation fluids can cause hypothermia. If inadequately warmed the fluids can exacerbate drops in temperature. Many of these operations are carried out under regional anaesthesia, which has been shown to attenuate the thermogenic response to hypothermia, it showed a clinically significant, adverse, hemodynamic response in those patients who were not warmed aggressively. Hypothermia can be reduced by the use of irrigation fluid that has been warmed.

3 Fluido® Irrigation Fluid Warmer

The Fluido® Irrigation makes it possible to warm fluids, fast safe and easy.



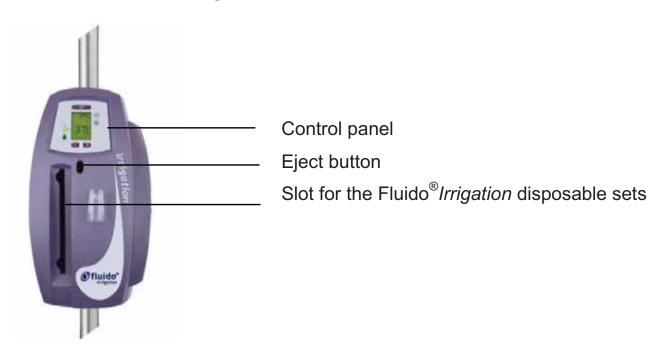
Fluido[®]*Irrigation* Fluid Warmer (651230-I)

Fluido® PowerLifter II (I-U02237)

4 Description of the Fluido®Irrigation

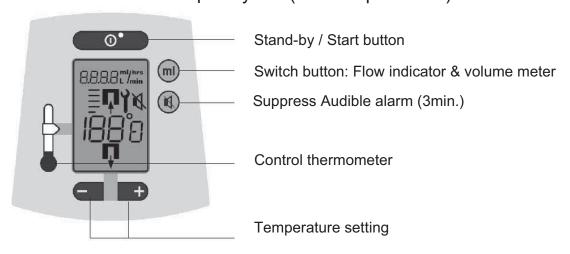
The Fluido[®] *Irrigation* (651230-I) is a fluid warmer that is easy to operate. Five lamps ensure rapid fluid warming. The Fluido[®] *Irrigation* comes with disposable sets for irrigation (see Chapter 4.3).

4.1 The Fluido[®] *Irrigation* Fluid Warmer



4.2 The Control Panel

The control panel is easy to use and the display shows all required information. The control thermometer at the left side indicates continuously whether the end of the line temperature equals the set temperature¹. In case of a malfunction, an audible alarm sounds and the control thermometer turns completely red (see Chapter 4.2.2).



¹ The end temperature cannot be guaranteed when an extension line is being used. Please pay attention to the margins mentioned in the Technical Data Sheet, Chapter 13.

6

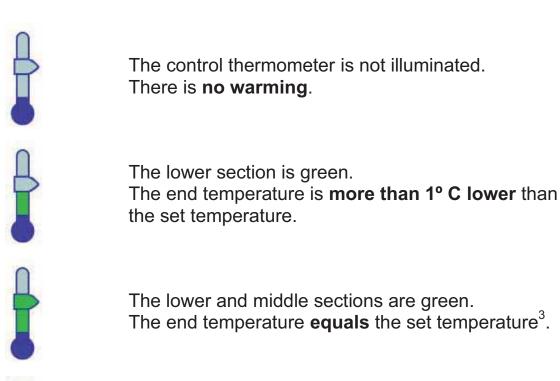
Control Panel Symbols 4.2.1

5 0 [™] / _{min}	Flow in ml per minute, increments of 1ml (0-20), 5ml (20-150) and 10ml (as of 150)
2.37.	Total volume in litres
550 hrs	Total hours that the Fluido® Irrigation has been in operation
hrs	Displayed between 1000 and 1500 operating hours for 5 sec. after switching ON the Fluido [®] <i>Irrigation</i> . It is still possible to operate the Fluido [®] <i>Irrigation</i> but maintenance must take place ² .
15[] hrs	Displayed between 1500 and 2000 operating hours continuously after switching ON the Fluido Irrigation. It is still possible to operate the Fluido Irrigation but maintenance must take place Irrigation.
EIII I hrs	Displayed after 2000 operating hours continuously after switching ON the Fluido <i>Irrigation</i> , joined by a continuous audible beep. This beep can be suppressed for 3 minutes after pressing the button. It is still possible to operate the Fluido <i>Irrigation</i> but maintenance must take place ³ .
	Status of the five lamps. A flashing bar shows that the relevant lamp needs replacing
₽	Insert the cassette of the Fluido® Irrigation disposable set into the Fluido® Irrigation
Y	There is a malfunction. Reset the Fluido® Irrigation or contact your service centre
K	Audible alarm suppressed
376	Set temperature at the end of the line

 $^{^2}$ Maintenance can only be done by a trained/certified technician of your local supplier or the manufacturer. 3 Please pay attention to the margins mentioned in the Chapter 13.

Ţ	Remove the cassette from the Fluido [®] <i>Irrigation</i> Fluid Warmer
<u> </u>	Tilt sensor alarm
8 138	Alarm code

4.2.2 Control thermometer



The top section is red.

The incoming temperature or the output temperature is higher than the set temperature. An alarm signal sounds.

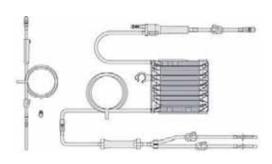
The entire control thermometer is red. There is a **malfunction**. An alarm signal sounds and a spanner symbol appears (see Chapter 8).

4.3 Fluido® Irrigation Disposable Sets and Accessories

The Fluido[®] *Irrigation* shall only be used with Fluido[®] *Irrigation* disposable sets. A Fluido[®] *Irrigation* disposable set consists of a cassette with the accompanying tubing.

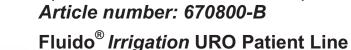


Pressure must not exceed 300 mmHg. Usage of a (manually operated) pressure device without a pressure indicator is NOT allowed!



Fluido® Irrigation URO Set

This is a Urology set, which is suitable for Urology. Its capacity is 680 ml/min (normothermic flow). It is a complete set, including a separate patient line and a Luer Lock bore cap. The de-aeration chamber contains a backflow valve. The priming volume is 220 ml. This URO Set shall only be used in combination with the Fluido **Irrigation** Irrigation** Irrigation** URO Patient Line, URO Spike Set and URO Female Cap.





This is a patient line with extra Luer Lock cap that shall only be used in combination with the Fluido Irrigation URO Set and/or URO Spike Set

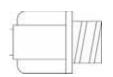
Article number: 680801-B



Fluido® Irrigation URO Spike Set

This is a URO Spike Set; a drip chamber with spikes that shall only be used in combination with the Fluido® *Irrigation* URO Patient Line.

Article number: 680803-B



Fluido® Irrigation URO Female Cap

This is a bore cap that shall only be used in combination with the Fluido[®] *Irrigation* URO Set.

Article number: 680804

4.3.1 Description of cassette

The core of the heating cassette consists of ten channels through which the fluid flows. Two partitions in the bends ensure that the fluid is mixed well. The flow and temperature are measured at four measuring points. The front of the Fluido[®] *Irrigation* disposable cassette is transparent. The back is made of black plastic.

Use

The disposable cassette is sterile packed. Please check the tube connections before use. The disposable cassette must be undamaged and clean and can be used for a maximum of 24 hours.





In order to avoid damaging the Fluido® Irrigation, do not use damaged cassettes.



Pressure must not exceed 300 mmHg. Usage of a (manually operated) pressure device without a pressure indicator is NOT allowed!

5 Preparing the Fluido® Irrigation for use



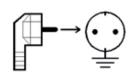
Before using the Fluido[®] *Irrigation*, it should be attached to a (Fluido[®]) IV-pole or Fluido[®] Powerlifter II



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



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

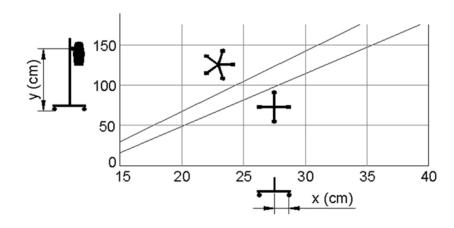


Plug the unit into the main supply. The Fluido[®] *Irrigation* will first perform a self-test*. When the display unit is illuminated green and the light from the stand-by button turns orange, the Fluido[®] *Irrigation* is ready for use.

* If a cassette is inside the Fluido[®]*Irrigation*, the test is automatically postponed until after removal of the cassette!

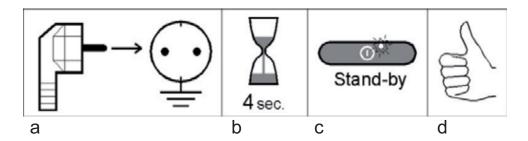
If required, a safety test in accordance with the hospital protocol will follow.

To ensure that the Fluido[®] *Irrigation* is stable, the wheelbase of the IV-pole must be in a certain ratio to the height of the Fluido[®] *Irrigation* clamp. See below graph for use with a 4 or 5 wheel support IV-pole.



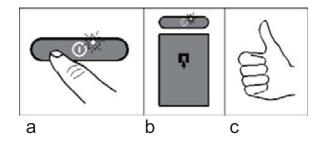
6 User instructions

6.1 Connection to power supply



- a. Plug the unit into an earthed socket.
- b. The Fluido® Irrigation will now perform a four-second self-test, which includes a light flash.
- c. The display panel will illuminate green and the light next to the stand-by button will turn orange.
- d. The Fluido[®] Irrigation is now in Stand-by.

6.2 Switching on



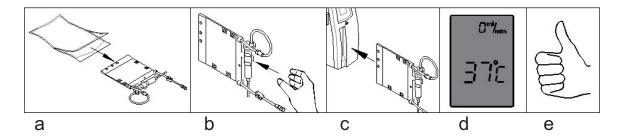
- a. Switch the Fluido[®] *Irrigation* on by pressing the Stand-by button.
- b. A short audible signal will sound. The display will briefly show all symbols and the control thermometer will illuminate green and red for a moment. The light at the side of the Stand-by button will then turn green and the following symbol will appear on the display

panel: 🔽.

c. The Fluido[®] *Irrigation* is now ready for use.

If the Fluido[®] *Irrigation* is not in use for 15 minutes, it will automatically switch to Stand-by and the light at the side of the Stand-by button will turn back to orange.

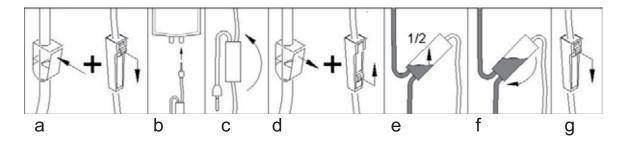
6.3 Positioning the Fluido® Irrigation URO Set



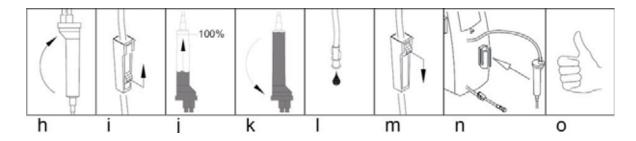
- a. Inspect the package to make sure that it is undamaged. Take a Fluido® Irrigation URO Set out of the packaging.
- b. Hold the disposable cassette by the clamp next to the drip chamber, with the clamp at the top.
- c. Insert the disposable cassette vertically into the Fluido[®] *Irrigation*, until you hear a 'click'.
- d. The display panel will now show the temperature and flow.
- e. The Fluido® Irrigation URO Set is now positioned.

6.4 Priming Fluido® Irrigation URO Set

6.4.1 Priming the Fluido® Irrigation URO Set

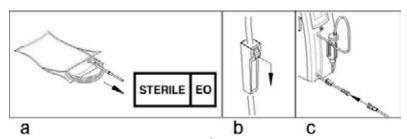


- a. Close all the clamps on the Fluido® Irrigation URO Set.
- b. Spike the drip fluid container.
- c. Hold the drip chamber of the giving set upside down.
- d. Open all the clamps except the one on the unused spike.
- e. Allow the drip chamber to half-fill with fluid.
- f. Turn the drip chamber upright again.
- g. Close the roller clamp.

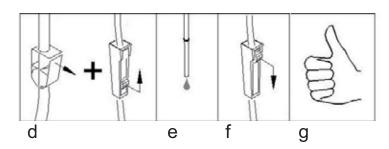


- h. Turn the de-aeration chamber upside down.
- i. Open the roller clamp.
- j. Fill the de-aeration chamber full with fluid.
- k. Turn the de-aeration chamber upright again.
- I. De-aerate the rest of the line.
- m. Close the roller clamp.
- n. Place the de-aeration chamber in the holder of the Fluido[®] *Irrigation*.
- o. The Fluido® Irrigation URO Set is now primed.

6.4.2 Priming the Fluido[®] *Irrigation* URO Patient line



- a. Take the Fluido® Irrigation URO Patient Line out of the packaging and place it in the sterile field.
- b. Close the roller clamp of the Fluido® Irrigation URO Patient Line.
- c. Remove the protective caps from the disposable cassette and the URO Patient Line and connect the two.



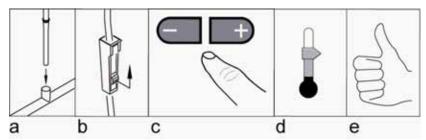
- d. Open the roller clamps from top to operating element.
- e. De-aerate the rest of the Fluido® Irrigation URO Patient Line.
- f. Close the roller clamp.
- g. The Fluido[®] Irrigation URO Set and URO Patient Line are now primed.

6.5 Start Warming

The Fluido[®] *Irrigation* is switched on and a Fluido[®] *Irrigation* URO Set has been positioned. The initial temperature is shown on the display panel. The default temperature setting is 37° C.

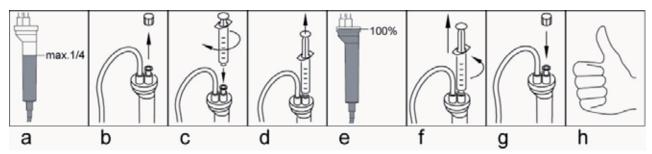


Pressure must not exceed 300 mmHg. Usage of a (manually operated) pressure device without a pressure indicator is NOT allowed!



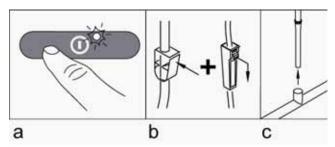
- a. Remove the protective cap and connect the system to the operating element.
- b. Regulate the flow with the roller clamp.
- c. Set the required temperature using the + and buttons.
- d. The Fluido® Irrigation warms the fluid. The display indicates the flow per minute and the control thermometer will be illuminated green, including the arrow.
- e. The fluid at the end of the Fluido[®] *Irrigation* URO Patient Line is the correct (set) temperature.

6.6 De-aeration

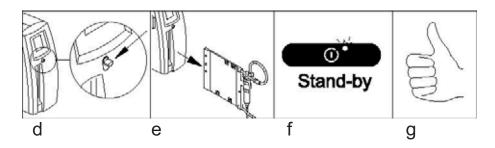


- a. De -aeration shall take place when the de-aeration chamber is filled with one-quarter of air.
- b. Twist off the cap of the de-aeration chamber.
- c. Twist a syringe with Luer Lock onto the opening of the de-aeration chamber.
- d. Suck the air from the de-aeration chamber.
- e. Fill the de-aeration chamber full with fluid.
- f. Remove the syringe from the de-aeration chamber.
- g. Replace the cap on the de-aeration chamber.
- h. The de-aeration chamber is now properly de-aerated.

6.7 Stop warming



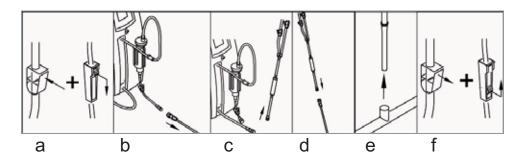
- a. First press the stand-by button (the fan will continue for another 2 minutes).
- b. Close the clamps.
- c. Disconnect the working element.



- d. Press the eject button. The disposable cassette will eject.
- e. Remove the disposable cassette.
- f. An orange light will come on next to the stand-by button.
- g. The Fluido® Irrigation is now in Stand-by and ready for re-use.

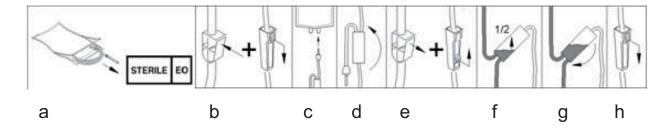
6.8 Post-operative options

6.8.1 Post-operative non-heated irrigation

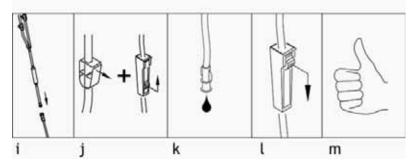


- a. Close all clamps
- b. Disconnect URO Patient Line from the Fluido® Irrigation URO Set
- c. Disconnect the spike set from the Fluido® Irrigation URO Set
- d. Connect the spike set of the URO Set to the URO Patient Line.
- e. Remove the URO Patient Line from the working element and connect it to a urinary catheter
- f. Open the clamps to start irrigating

6.8.2 Fluido[®] Irrigation URO Spike Set



- a. Take the Fluido[®] *Irrigation* URO Spike Set out of the packaging and slide the clamps down to the center of Y section.
- b. Close the clamps of the Fluido® Irrigation URO Spike Set.
- c. Spike the drip fluid container.
- d. Hold the drip chamber of the giving set upside down.
- e. Open all the clamps except the one on the unused spike.
- f. Allow the drip chamber to half-fill with fluid.
- g. Turn the drip chamber upright again.
- h. Close the clamp.



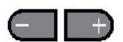
- i. Connect the URO Spike Set to the URO Patient Line
- j. Open the clamps.
- k. De-aerate the rest of the patient line.
- I. Close the roller clamp.
- m. The Fluido[®] Irrigation URO Spike Set is primed.

6.8.3 Fluido[®] Irrigation URO Female cap

The Fluido[®] *Irrigation* URO Set includes an extra URO Female Cap. The URO Female Cap is also available as a separate article. The URO Female Cap can be connected to the Fluido[®] *Irrigation* URO Set.

7 Extra options

Request total operating time



To see the total number of hours that the Fluido[®] *Irrigation* has been in operation, press the + and – buttons while **in stand-by** for a few seconds. The total number of hours will be displayed.

Request total volume



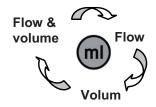
To see the total volume of fluid warmed, press the button during operation or in stand-by. The total volume will be displayed in litres.

Reset total volume



To reset the total volume, press the and button for five seconds, the volume counter will return to 0. The counter will automatically return to 0 after 15 minutes during stand-by,

Request alternating volume and flow



There are three options: the display panel can show the flow, the volume or both, alternately. Press the button to alternate the readings. See the illustration.

• Suppress audible alarm



The audible alarm can be suppressed for three minutes. Press the [®] button. The ^ℵ symbol will appear on the display panel.

Add to restored volume



In stand-by, press the button, hold it and then press the button to switch on. Now the total volume will be stored in the memory. The next given volume will be added cumulative.

8 Problems and solutions

In the event of an alarm, follow the steps in the procedure below.

1

2



Suppress the alarm

To obtain the alarm code, press the

+ and – button together (at the same time)

The code will appear on the display panel

Reset the Fluido® Irrigation by taking the following actions:



Press the + and the - button together

B **ml**

Hold the + and – together with the ml button

c \(\frac{1}{2}\)

Hold these 3 buttons for 2 seconds

The Fluido® will now be ready to use

If the alarm keeps appearing, take a note of the alarm code and contact the service centre.

Do not use the Fluido[®] *Irrigation* if one of the following situations arises (and cannot be solved), unless stated otherwise.

	Problem	Cause	Solution
0,	The stand-by button is not lit	No power Fluido®Irrigation	Check the plug, socket and earth
		malfunction	Contact the service centre
4	The stand-by button is not illuminated and there is a continuous alarm signal	Control system malfunction	Contact the service centre
Separate Sep	The Fluido® Irrigation does not start and the 'remove cassette' symbol is flashing	There is a Standard Set or Trauma set in the Fluido® Irrigation (instead of a URO Set)	Remove the cassette and place the Fluido [®] <i>Irrigation</i> URO Set
		The URO Set is in the unit during the self-test	Remove the cassette Press the stand-by button and wait 10 sec. The symbol appears in the display panel
4	The lamp next to the stand-by button goes out during use and the alarm sounds	Power failure	Restore power. If this takes place within 30 sec., the process will restart automatically. If not, remove the cassette and restart the Fluido®Irrigation.
		Clamps are closed	Open the clamps
i.j.m/	Fluido [®] Irrigation shows there is no flow	Blockage in system	Replace drip system
U /min		Bend in tube	Unbend tube
		Fluid is used up	Replace fluid bag
	Control thermo- meter entirely red, spanner appears and continual alarm signal	Control system malfunction and / or the temperature of the fluid is equal to or higher than 45° C.	Contact the service centre
	Top section of control thermometer is red, pulsing signal heard and no flow–registration.	Temperature of incoming or outgoing fluid exceeds the set temperature	Stop administration of warmed fluid Fluido®Irrigation automatically stops warming and restarts warming when temperature is lowered If the Fluido®Irrigation stays
- Imin		l	I alo i lalao irrigation stays

Problem	Cause	Solution
		alarming: Check sensors, use RS-232 tool to check individual temperature readings
On stand-by, the middle three bars flash, spanner symbol appears and alarm signal sounds	One of these lights is defective.	Contact the service centre to replace the light.
Top or bottom bar flashes, control thermometer is completely red, spanner symbol appears and alarm signal sounds continuously	Major light is defective	Contact the service centre to replace the light.
Thermometer is completely red, 't' appears on the display panel	The Fluido® Irrigation doesn't hang upright on the IV-pole. The angle of variation exceeds 2,5° forwards or backwards.	Hang the Fluido [®] <i>Irrigation</i> upright, the alarm will automatically disappear.
Slot cover sticks	Damage or dirt	Contact the service centre.
Fluid leaks from Fluido [®] <i>Irrigation</i> slot	The Fluido [®] <i>Irrigation</i> set is leaking	Stop administration and remove the cassette. Contact the service centre.
The eject button does not work	Damage or malfunction	Leave the cassette in place and contact the service centre.

9 Symbols and Warnings & Precautions

9.1 Symbols

C € ₀₃₄₄	CE marking of conformity 0344 = identification number of Notified Body (KEMA Quality)
SN	Serial number
REF	Part number
$\Box \mathbf{i}$	See manual/instructions for use
***	Manufacturer
FUSE 2x T8 H250V	Fuse type
\sim	AC voltage
IPX1	Protection against vertically falling fluid drops (according to IEC 60529)
•	Type CF equipment (according to IEC 60601-1)
\Rightarrow	Equipotentiality
-40 °C 70 °C	Transport and storage ambient temperature range
10% 100%	Transport and storage relative humidity range
X	Dispose in accordance with European Community Directive 2002/96/EC (WEEE)
STERILE EO	Sterile, method of sterilisation; ethylene oxide
LOT	Lot number
	Expiry date, year/month
(2)	For single patient use only. Do not re-use, risk of cross contamination

DEHP	This medical device contains phthalates (DEHP). It has been confirmed that DEHP poses no general risk to human health. Areas of possible risk might be the following special patients groups: • Children • Pregnant or nursing women TSCI recommends that the physician evaluates the risk and benefits of using the Fluido disposables in the treatment of the above mentioned special patient groups on a case by case basis. For more information see www.dehp-facts.com
\triangle	Caution
LANEX	Does not contain latex components

9.2 Warnings & precautions

4	Electrical shock hazard. Do not disassemble the Fluido [®] <i>Irrigation</i> . There are electrically live parts inside the Fluido [®] <i>Irrigation</i> .
*	The Fluido® Irrigation must not be used if damage has occurred.
溷	The Fluido [®] <i>Irrigation</i> disposable set must not be used if damage occurs.
	Connect the Fluido®Irrigation to an earthed socket only.
M	To avoid injury or damage to the Fluido® Irrigation, do not use damaged cassettes.
•	The giving set should be de-aerated with irrigation fluid before the Fluido® Irrigation is used. Pressure must not exceed 300 mmHg! Usage of a (manually operated) pressure device without a pressure indicator is NOT allowed!
25	The Fluido® Irrigation must hang upright on the IV-pole. The angle of variation must not exceed 2.5° forward or backward.
N/L	Do not use Fluido [®] <i>Irrigation</i> near flammable anaesthetics, to avoid the risk of explosion.

*	The Fluido [®] <i>Irrigation</i> should not be moved on a IV-pole during use. Remove the Fluido [®] <i>Irrigation</i> before moving.
10	Maintenance and repairs should be performed by qualified medical instrument technicians only.
	Do not immerse the Fluido [®] <i>Irrigation</i> in fluid. Clean the appliance with standard cleaning agents: a moist cloth or alcohol tissues.
> <u></u>	To keep the Fluido [®] <i>Irrigation</i> stable, the wheelbase of the IV-pole must be in a particular ratio to the clamp height. See the diagram in chapter 5 Preparing the Fluido® Irrigation for use
	Warning: remove the air deflector if the Fluido® Irrigation is in operational use at a table or mounted to the Fluido® Powerlifter II
\triangle	 The Fluido® is certified according IEC 60601-1-2 for electromagnetic interference. However, if nevertheless interference effects with different devices occur, the user is encouraged to correct the interference by one or more of the following measures: Turn devices in the vicinity off and on to isolate the offending equipment. Reorient or relocate the other receiving device. Increase the distance between the interfering equipment and the Fluido® Irrigation Fluid Warmer, use another power socket. If assistance is required, please contact your local dealer. Using power cords or replacement parts for internal components other than specified by TSCI may result in increased emission or decreased immunity of the Fluido® Irrigation Fluid Warmer
\triangle	 The Fluido[®] Irrigation URO set, URO Patient Line and URO Spike Set shall be used for warming irrigation fluids only. The Fluido[®] shall not be used for warming platelets, cryoprecipitates or granulocyte suspense.
\triangle	Check patient's condition & temperature at least every 15 minutes

10 Maintenance

The Fluido[®] *Irrigation* has no parts that can be maintained by users. Users should not repair or open the Fluido[®] *Irrigation* in the event of a malfunction. This can damage the appliance and will invalidate the guarantee. The TSCI service centre should service the appliance at least once a year.

Have the Fluido[®] *Irrigation* serial number ready when you contact the TSCI service centre for technical support. The serial number is on the back of the Fluido[®] *Irrigation*.

11 Storage and cleaning

Keep the appliance and all parts in a cool, dry place when they are not in use. Wipe down the Fluido[®] *Irrigation* with standard cleaning agents: a moist cloth or alcohol tissues.

12 Warranty

The manufacturer guarantees end users that, for a period of 1 year from date of dispatch, every Fluido[®] *Irrigation* blood and fluid warmer will be free of material and finishing defects with normal use and maintenance.

The warranty does not apply to any item that is not produced or approved by the manufacturer if this item is the cause of the malfunction. The manufacturer has no obligation under this warranty to perform repairs or replacements resulting partially or in full from accidents, errors or negligence on the part of the user.

This warranty applies only to the use of the Fluido[®] *Irrigation*. If this warranty is invoked, the relevant part shall be properly packed and returned to the local supplier.

13 **Specifications**

Article number Fluido® Irrigation Fluid Warmer	651230-I	
Voltage	230 VAC	
Frequency	50 / 60 Hz	
Current	6 A	
Peak Power	1400 W	
Fuses	8 A	
GMDN codes	47623 and 45644	
Weight	± 9.5 kg	
Dimensions	387 mm x 215 mm x 255 mm	
Classification (MDD 93/42/EEC)	Class IIb	
Classification (IEC 60601-1)	Class I, CF	
Classification (IEC 60529)	IPX1	
Max. temperature of T _{out}	43°C	
Alarm limit (software)	46°C	
Alarm limit (hardware)	47.5°C ± 0.5°C	
Normothermic flow	50 – 680 ml/min	
Set point temperature	30 – 39°C	
Unit of temperature increase	1 °C	
Display type	Green lit LCD	
Heating and measuring technology	Infrared	
Accuracy of temperature at Tout	± 2.5°C	
Accuracy of flow measurement	± 20%	
Environmental conditions		
Ambient temperature ⁵	15 – 30°C	
Relative humidity	30% to 75%	
Atmospheric pressure	700 hPa – 1060 hPa	
Transport and storage conditions		
Ambient temperature	-40 to 70°C	
Relative humidity	10 – 100 % (non-condensing)	
Atmospheric pressure	500 hPa - 1060 hPa	

 $^{^4}$ This is not the accuracy at the end of the line. T_{out} is the temperature of the blood and fluid at the T_{out} sensor (temperature sensor inside the cassette near the outlet) 5 A change in the environmental temperature can be of influence to the temperature at the end of the line

²⁶

Partner in Patient Temperature Management

TSCI is a leading European company in the field of hypothermia and offers a complete range of innovative solutions for patient temperature management.

Fluido® and Mistral-Air® are registered trademarks of TSCI.

Fluido® products are covered by the following European patents:1313521 and 1446179. Other patents pending.

TSCI The Surgical Company International B.V.

Beeldschermweg 6F 3821 AH Amersfoort The Netherlands

T +31 (0)33 450 72 50 F +31 (0)33 450 72 60 contact@tsci.nl www.tsci.nl



