Blood and Infusion Warmer

FT2800

Operator's Manual

(Edition: 06/2022/ En)

KEEWELL MEDICAL TECHNOLOGY CO., LTD

CE 0482

IMPORTANT:

- These instructions are an essential part of the device.
- They must be kept in a suitable place near the device and should accompany the device if it is transferred to other users.
- For proper and safe use of this device it is essential that the warnings and safety instructions, as well as the instructions for use are read and carefully observed by all users before first using the device.
- It is the responsibility of those using the device to fully acquaint themselves with its proper use and operation.
- If a malfunction is suspected, the device is to be taken out of service immediately and sent to the supplier for examine and repair.

CONTENT

DESCRIPTION

- The Blood and Infusion Warmer FT2800 can be used in all applications in which hypothermia of the patient through cold transfusions and infusion solutions is to be prevented. It is consisted of the main body, 2 flexible warming profiles, fastening unit and power cable. The main body has two independent symmetrical control units. During the operation, the infusion tube is inserted into the warming profile. The intelligent micro-computer processing control system works separately and automatically to heat up the two profiles homogeneously and continually adjusts heating state. At the same time, the heat is transferred into the flowing liquid in the tubing placed in the profile, to rise the temperature of the liquid. It is equipped with double independent temperature protection systems to ensure the safety of use.
- The temperature of warming profile can be set between 33°C and 41°C in steps of 0.1°C and is displayed on the LED screen. The device can memorize the last set temperature automatically.
- The alarm and self-test functions for over-temperature and under-temperature incorporated into the device assures safe operation.
- A standard infusion tubing (5.0mm in O.D and 1.4m in length) may be used in

conjunction with the FT2800.

- The temperature shown in the display corresponds to the temperature of the warming profile.
- The temperature of the fluid to be heated that is reached at the end of the warming section depends on various factors, such as, the fluid's input temperature, the flow rate, the set temperature, the ambient temperature, etc.

The following graph shows a typical initial temperature curve

(Initial temperature Fluid and ambient temperature: 20℃)

Infusion rate（ml/min）	1	5	10	15	20	25	30	35	40	45	50	55	60	65	70	75
One profile（℃）	41	37.6	35.3	33.3	32	30.7										
Dual profile（℃）	41	41	40.8	39.3	38.2	37.2	36	34.8	33.8	33.2	32.8	32.3	31.7	31	30.5	30

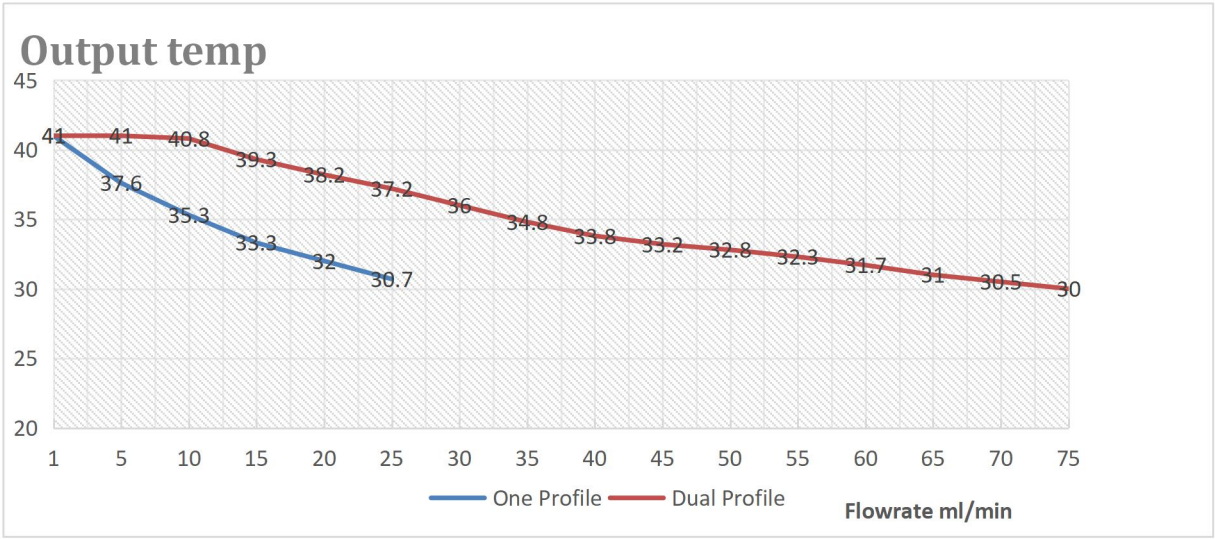


Fig. 1: Typical starting temperature of the fluid that has passed through at different flow rates

Applied part

The warming profile which is applied part of the medical device is type "BF". The electrical conductors in the warming profile have been insulated from the other parts of the medical device to such a degree that no current higher than the allowable PATIENT LEAKAGE CURRENT flows if an unintended voltage originating from an external source is connected to the PATIENT, and thereby applied between the PATIENT CONNECTION and earth.

The warming profile is defibrillation-protected and supplied with safety extra-low voltage.

CONTRAINDICATION

It is forbidden to be used on the severe cardiopulmonary dysfunction patients.
The device may not be used to warm living organisms, objects.
It is forbidden to use for heating the drug liquid which the normal effect would be influenced after heating.

WARNINGS

- If the over-temperature alarm is triggered, the supply of liquid to the patient must be immediately stopped by disconnecting the connection tube to the patient. The medium being used in the device must no longer be administered to the patient.
- In the event of any suspected malfunction while in operation, the supply of liquid to the patient must be immediately stopped by disconnecting the connection tube to the patient. The medium being used in the device must no longer be administered to the patient. Switch off the heating or unplug the mains plug.
- The device must not be used in rooms subject to explosion hazard.
- The device may only be fastened to infusion stands or tripods which are suitable due to their stability and load capacity.
- The device must not be immersed in liquids or sterilized with steam or by thermochemical methods.
- All extraneous influences such as radiation, electromagnetic interference or high temperature are to be kept to minimum.

- Do not bend, fold, cut or stick pointed objects into the warming profile.
- Keep the warming profile in the open air. Do not cover it with decorations, cloths, bedding or warm-air blankets. Do not expose it to direct sunlight or heat radiation and do not lead it in or through incubators.
- Do not cool or warm the warming profile from outside.
- Do not cover or seal the ventilation slots on the back of the main body.
- The overheating of the infusion fluid may be caused if the infusion flow is stopped while the warming profile is on heating.
- Only sterile consumable materials may be used in conjunction with the FT2800.
- Repairs and modifications to the device may only be carried out by persons or service centers authorized by Keewell.

- The device is equipped with a POTENTIAL EQUALIZATION CONDUCTOR, it is intended solely for connecting with other devices in equipotential. The terminal shall not be used for a PROTECTIVE EARTH CONNECTION.
- The device must be disconnected from the mains before the housing is opened.

SAFETY INSTRUCTIONS

The device must only be used in areas in which the electrical installations are in accordance with the rules and regulations in force. To avoid electrical shock, the device must only be connected to a properly grounded power source.

The device must not be used in the following circumstances:

- If the device or the warming profile is damaged or one of the front film layers becomes detached.
- If the device has been exposed to a hard physical shock (e.g. dropped, hit or shaken).
- If the device has been immersed in water.
- If the device has triggered an over - temperature alarm protection that was not caused by external factors.
- If the device has triggered a sensor malfunction alarm.
- If the mains power cord or plug is damaged.
- If the device has given somebody an electric shock.

- If the fixing clamp is damaged and no longer assure safe clamping to the infusion stand.

Should a malfunction be evident, suitable warning signs should be attached to the device to ensure that it cannot be used before necessary service and repair work has been carried out.

Appearance and Control Panel

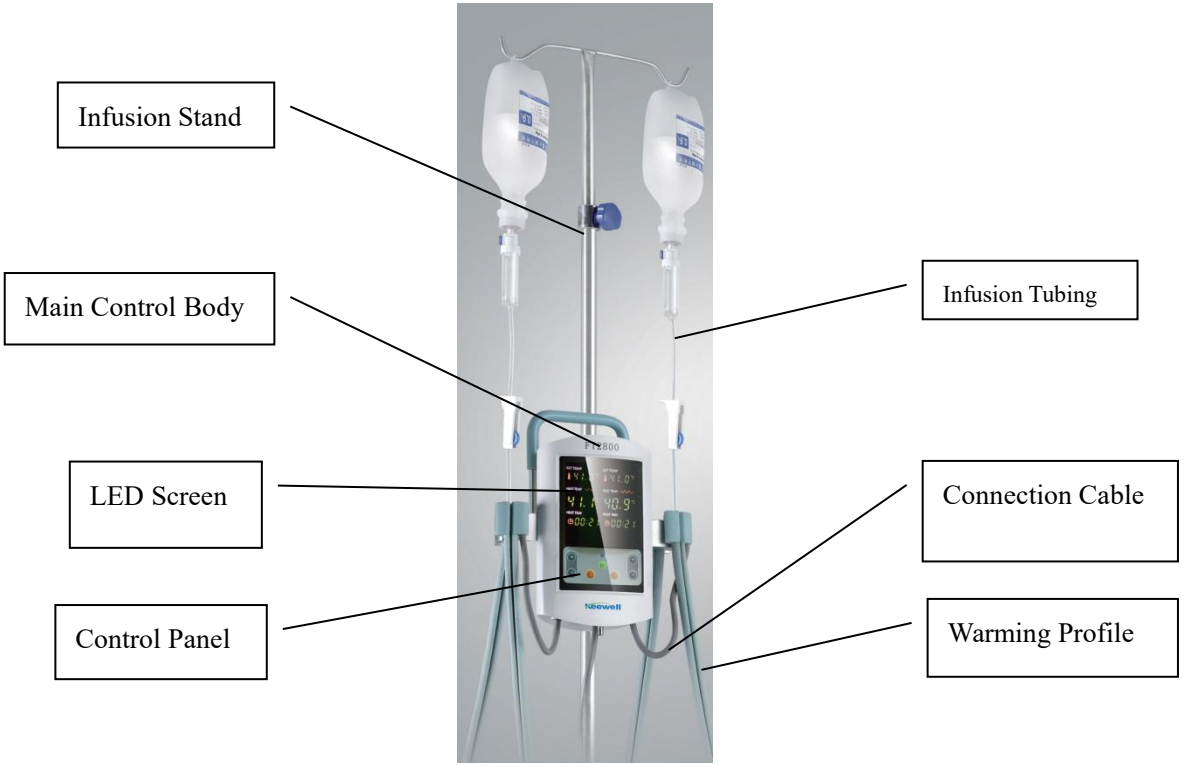


Fig. 2: General illustration

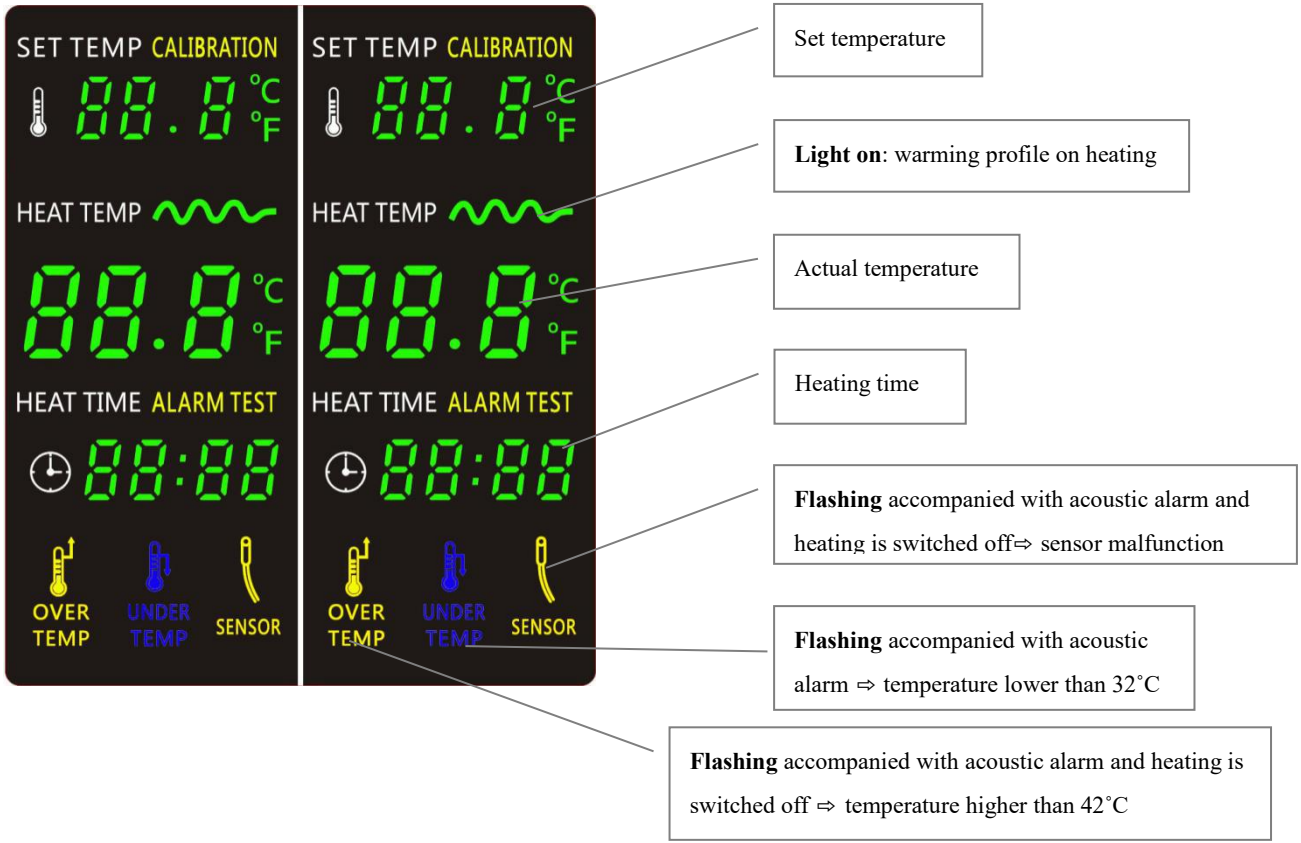


Fig. 3: Illustration of LED screen(*The same indications for the symmetric unit on the left)

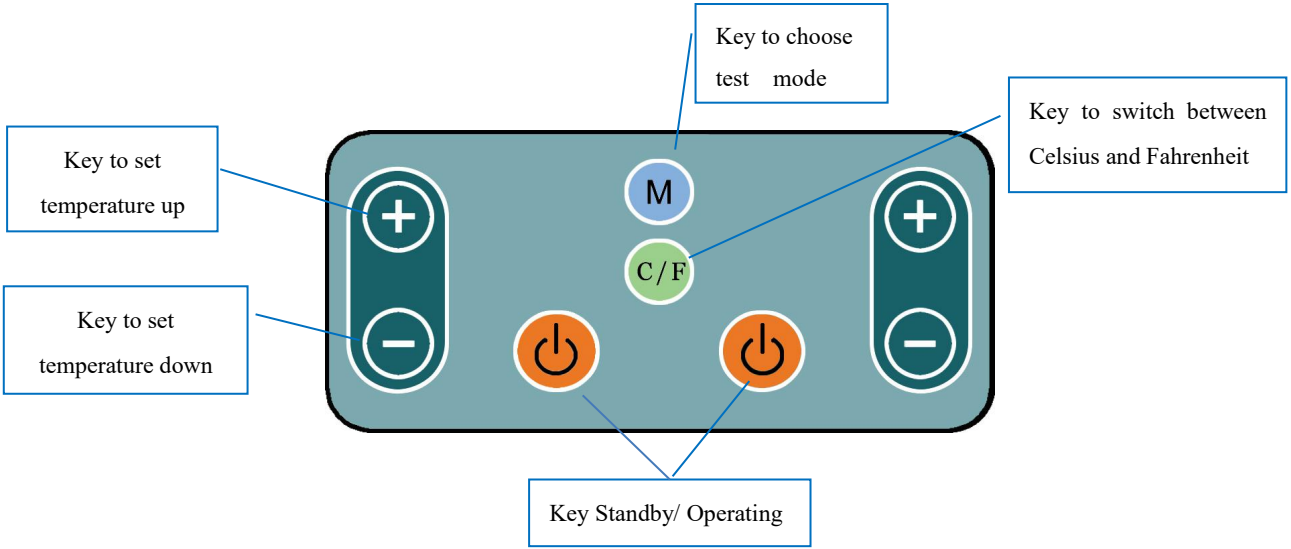


Fig.4: Illustration of the control panel

(*The same indications for the symmetric units. The M key and C/F key for both uses.)

- The device can be fixed to the infusion stand or other support by using the clamp at the back.
- Only use infusion stands or supports which be capable of supporting a minimum of ten pounds (4.5 kg) and with a minimum 60cm diameter wheelbase.
- Make sure that they are sufficiently stable to against tipping over.

Warning: After the device be fixed stable, it cannot be pull or application of force any way to avoid the infusion stands or supports tipping over. Failure to do so may result in damage to the device, the device may drop down with the infusion line and prevent or interrupt the infusion flow.

SAFETY CHARACTERISTICS

Low temperature information signal

The low temperature information signal is activated when the temperature of the warming profile drops below 32**°C**. In this event the under - temperature LED indicator  lights up accompanied with the acoustic signal.

The low temperature information signal is deactivated during the first 5 minutes after switching on.

Over - temperature alarm

The over - temperature alarm is activated when the temperature of the warming profile exceeds 42°C. In this event the over - temperature LED indicator  lights up accompanied with the acoustic signal and the heating is switched off.

To reset the device or switch off the alarm, the device must first be disconnected from the power supply and the temperature drops below 42.0°C.

Sensor malfunction alarm

In the event of sensor malfunction, the  indicator will light up, the "HEAT TEMP" area will display a "LL" code accompanied with acoustic alarm and the device will stop working. Return it to the supplier or the manufacturer for a service.

This alarm can be triggered when the temperature of the warming profile is below -5.0°C or above 45.0°C.

Attention:

The over – temperature alarm can also be triggered by exposure to sunlight, extraneous heat, as well as the infusion fluid is pre-warmed to higher than 42˚C before it is flowing through the warming profile. To reset the alarm, the mains plug must be pulled out.

All alarms are alarms of "Low priority" according to EN 60601-1-8 "Collateral standard: Alarm systems"

The alarm system does not have to be verified. The alarm limits cannot be adjusted. The risk management process has found that a shutdown of the alarms is not meaningful, because it is desirable that the error (e.g. high temperature) is detected. Resetting of the alarm is only possible through disconnection of the device from mains. The operator station is in front of the device.

Attention:

The operation temperature is designed within a safe range of 33- 41℃. If the temperature exceeds 42±1℃, 43±2℃ in faulty situations, the independent high temperature protection incorporated into the device will cut off the heating power. Over-heating may cause hemolysis and vessel hurt. Thus it is requested for the operator that in the event of any suspected malfunction while in operation to stop the supply of liquid immediately by disconnecting the tube to the patient. The medium being used in the device must no longer be administered to patient.

Alarm overview

	Software high temperature alarm	**Hardware-high temperature alarm**	**Sensor malfunction alarm**
Condition	The high temperature alarm is triggered when the temperature of the warming profile exceeds 42°C (108℉). When the temperature of the warming profile exceeds 43°C, a "HH" code and the target temperature will display alternately. When it reaches to 45°C, a "HH" code is displayed.	The high temperature alarm is triggered when the warming profile exceeds 43°C (110℉).	Self-test detects a sensor malfunction.
Consequence	The heater is switched off.	The heater is switched off.	The heater is switched off.

Resetting	The alarm can only be reset by pulling out the mains plug.	The alarm can only be reset by pulling out the mains plug.	The alarm can only be reset by pulling out the mains plug.
Visual signal	The over - temperature LED indicator  lights up	The over - temperature LED indicator  lights up	The  indicator lights up, the "HEAT TEMP" area will display a "LL" code
Audio signal	Continuous tone will be emitted once every 15 seconds and ring twice each time.	Continuous tone will be emitted once every 15 seconds and ring twice each time.	Continuous tone will be emitted once every 15 seconds and ring twice each time.
	Frequency: 325Hz | sound pressure level: min.60dBA		
Priority as per EN 60601-1-8	Low priority	Low priority	Low priority

Information signals

	Low temperature information signal
Condition	If the temperature of the warming profile drops below 32°C (89°F). The audio low temperature signal is deactivated during the first 300 seconds after switching on.
Consequence	No consequence in relation to the function of the device. (information only)
Resetting	Automatically when the temperature rises above 32**°C.**
Visual signal	The low temperature LED indicator  lights up.
Audio signal	1 pulse with 1s duration every 30s Frequency: 325Hz | sound pressure level: min.60dBA

INSTALLATION AND OPERATION PROCEDURE

Installation:

Check whether the device is damaged. Please do not use it if any damage has been found.

- Fix the device firmly to the infusion stand at the position of 20-30cm below the infusion/blood bag, using the clamp at the back, then screw the fastening screw. The device is almost equal to the drip bucket.
- Only use infusion stands or poles that are sufficiently stable.
- Before connecting to mains power supply, check the voltage specified on the device label.
- Connect power cable to power supply. The display lights on and beeps. The device is in STANDBY mode.

Warning

Do not locate the device at the position where it is difficult to be disconnected from the mains power.

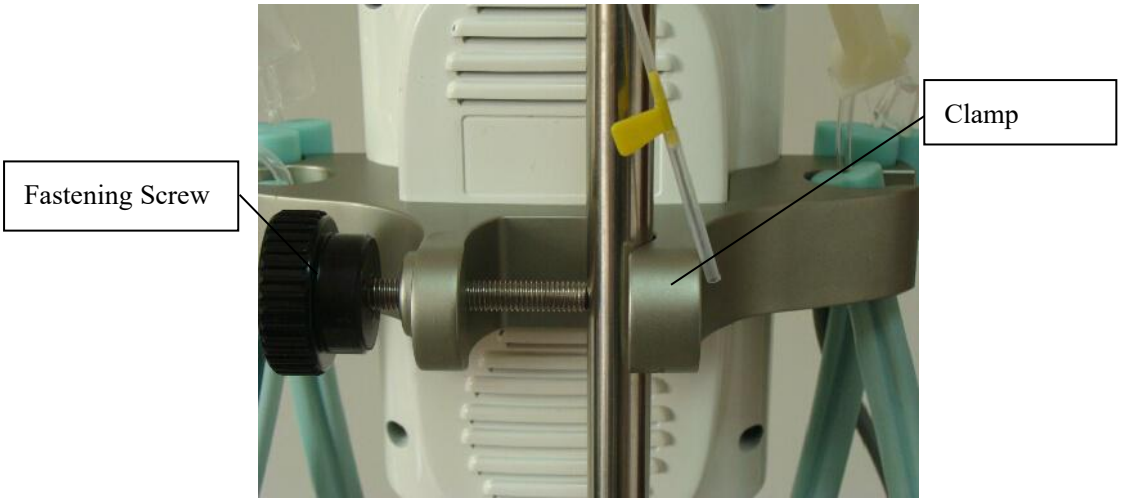
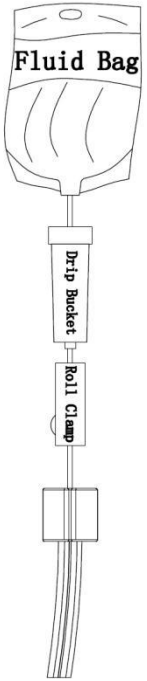


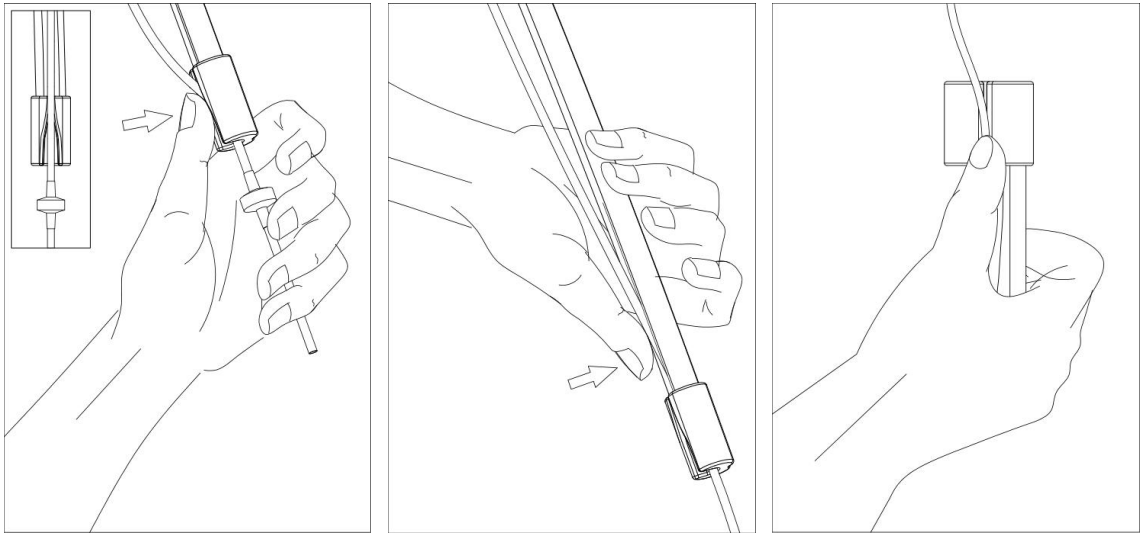
Fig. 5: Illustration of the fastening clamp

Operation procedure

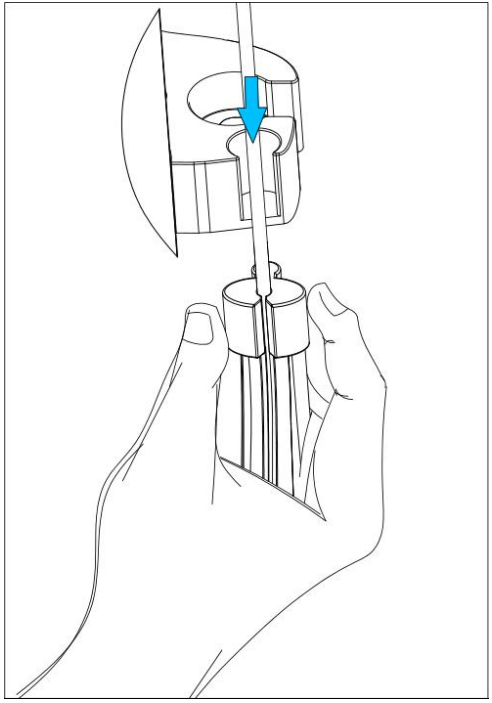
- Glide the roll clamp next to the drip bucket. Empty the air in tubing to make infusion channel ready.



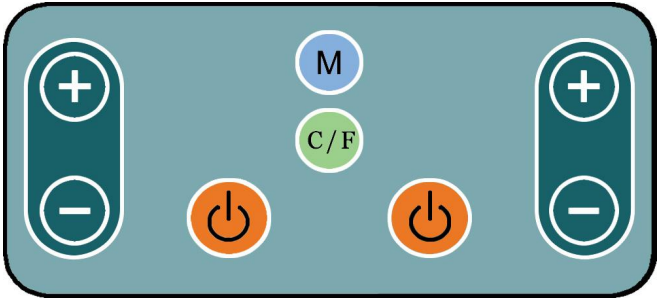
- Take the primed infusion tubing at 2-3cm to the end of patient side to insert in the tail (small end) of the warming profile. Afterwards move your thumb over the infusion tubing and press it gently into the groove towards the head (big end) of the warming profile, until the infusion tubing is completely wrapped in the warming profile. If the infusion tubing is not long enough, the head side of the warming profile can be unfilled.



- Place the head and end of the warming profile into the holder to prevent the infusion tube contacting with the ground.



- Press the  or  key to select the desired temperature.
- Adjust the appropriate infusion rate. As soon as infusion is started, press the key  to start warming.



- Resetting of temperature can only be performed in Standby mode.
- If the infusion needs to be stopped for more than 3 minutes, press the key  to stop warming. By press the key  again to resume it.

Warning: The warming profile must not be placed directly on patient's skin to prevent scald by build-up heat.

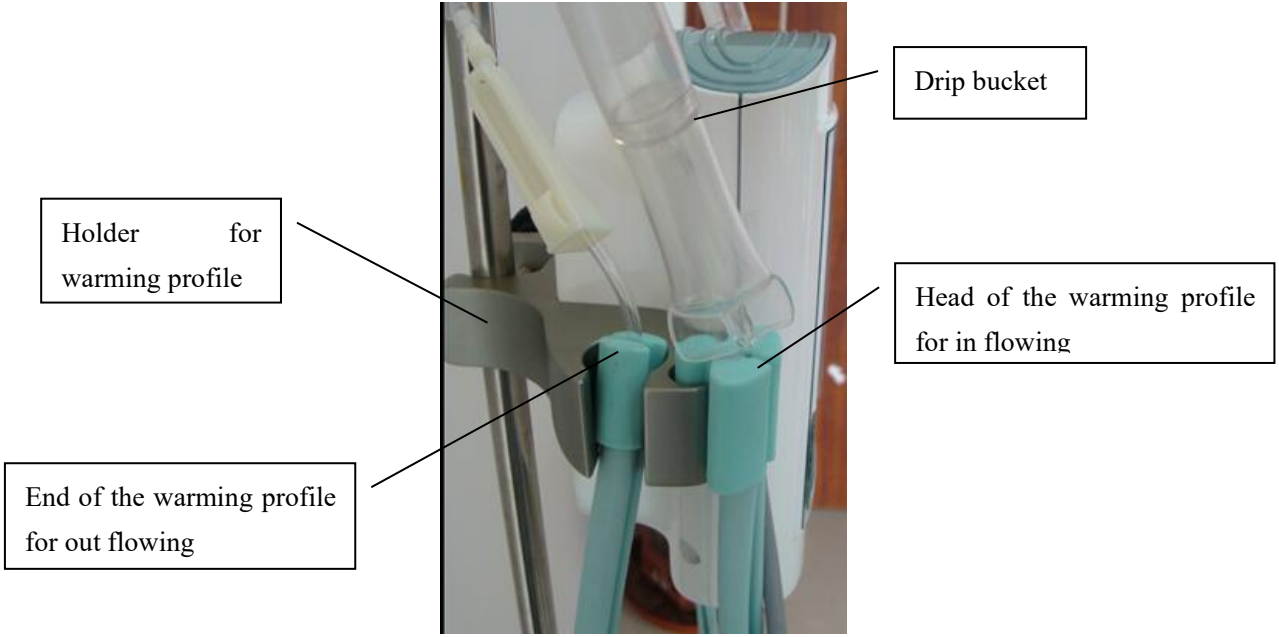


Fig. 6: Illustration of the holder of warming profile

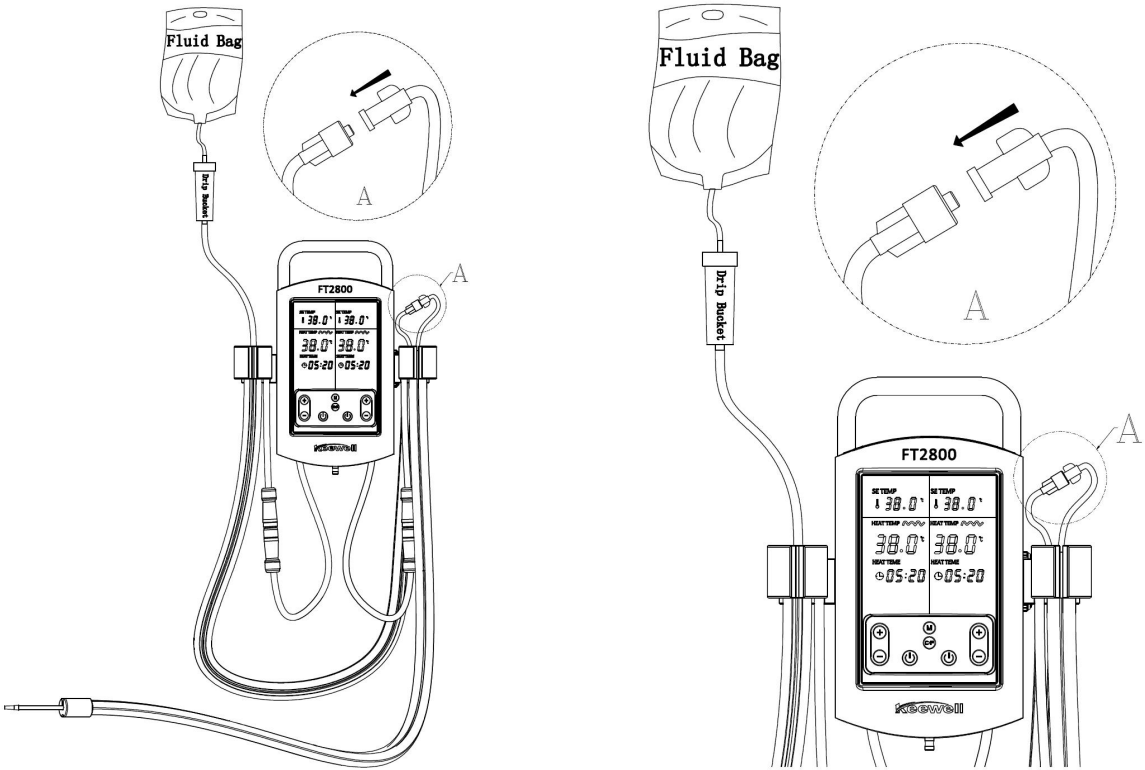


Fig. 7: Illustration of the warming profiles combined to use

Shutting down the device

- Press the key  to enter STANDBY mode.
- Release all pressure in the infusion system by switching off the pressure cuffs or infusion pumps.
- Remove the consumable material from the warming profile and dispose it according to the relevant regulations.
- Disconnect the device from the power supply. Clean and disinfect the equipment according to instructions.

WARNING

If the over- temperature alarm is triggered or any suspected malfunction be perceived while in operation, the supply of liquid to the patient must be immediately stopped. Lock the connection tube to the patient; release all pressure in the infusion system by switching off the pressure cuffs or infusion pumps. Switch the device off or pull the mains plug out. The medium being used in the device must no longer be administered to the patient.
Wait about 5 minutes until the warming profile has cooled down. Switch the device on again. If the fault occurs again, the device must be inspected by a trained service technician.

MAINTENANCE

- Always keep the surface clean.
- The device may only be cleaned by using a soft cloth and mild water-soluble cleaning agents or special cleaning agents for plastics.
- Only disinfect the device with a disinfectant based on alcohol.
- Avoid any force on the shell of the device.
- The device should be returned to dealer if it is dropped or damaged or if any malfunctions described in the instructions occur.

Before cleaning or disinfection, the device must always be disconnected from the mains power supply.

PERIODIC INSPECTIONS

Periodic inspections should be carried out at least every 12 months.

- The device needs to be checked before use again after a long period of non-use.
- Checking should be carried out after any big removal of the device.

All the checking should be performed in room temperature (23±2°C） and no air flowing condition. The two symmetric units must be checked separately.

Checking the warming up time, accuracy of the temperature, over-temperature alarm，low temperature information signal

The sensor of a suitable contact thermometer (tolerance ± 0.15°C) is fixed in the groove of the warming profile at the position of around 15cm to the tail end by using a piece of tube. Place the head and tail end of the warming profile into the holder. Set temperature at 41.0˚C and start to operate. The device should reach 36°C within 2 minutes. Hold on for 5 minutes, and

then press the key  to return to STANDBY mode. Press on the  key and  key simultaneous until the sign 

is flashing. The device is now in over-temperature alarm testing mode. The corresponding unit will heat up to 42°C. The over - temperature alarm should be triggered at a temperature of 42.1°C. In this event the sign  lights up, accompanied with acoustic signal. The heating is switched off automatically. The continuously decreasing of the temperature is observed. In the temperature range of 32°C - 42°C, compare the measured value and on the device displayed value. The difference must not exceed ± 1.0°C. When the displayed temperature is lower than 32°C, the low temperature information signal should be triggered.

If there is a malfunction, the device can no longer be used until the necessary repairs have been carried out.

TROUBLE SHOOTING

Fault	Possible Causes	Remedy
Nothing illuminates on the panel	● Lack of / incorrect power supply ● Mains connection cable or mains plug defective ● Power unit malfunction ● Control unit defective	● Check socket/fuse, compare mains voltage with details on rating plate ● Call a service person
 Lights up accompanied with acoustic alarm.	**Over- temperature alarm:** ● Fluids were pre-warmed to above 42℃ before being run through the warmer ● Disconnect the power supply, reconnect after	● Discontinue infusion of fluids. Do not warm fluids before infusing them through the device.

	the temperature drops down and turn on the device. If fault remain, →Defect on control unit ● Sunlight, heating, air-conditioning, the temperature of warming profile exceed 42°C	● Call a service person ● Select a different location
 Lights up, the "HEAT TEMP" area will display a "LL" code accompanied with acoustic alarm.	● Sensors defect ● The temperature of the room or the warming profile is below -5.0°C or above 45.0°C.	● Call a service person ● Find a suitable environment for the application

 Lights up accompanied with acoustic alarm	**Low temperature information signal:** ● The input temperature of the fluid to be heated is too low or the flow rate is too high. ● The room temperature or the warming profile temperature is far below the permissible ambient temperature ● Connecting cable or the warming profile broken ● PCB unit defective	● Lower the flow rate or preheat the fluid in another way ● Find a suitable environment for the application ● Call a service person

MANUFACTURER'S DECLARATION

The blood and infusion warmer FT2800 is a medical product as defined by Directive 93/42/EEC.

This is documented with the CE mark.

Notified Body: MEDCERT, Approval Number CE0482.

KEEWELL hereby confirms that the FT2800 comply with Directive of the European Parliament 2011/65/EU RoHS (Restriction of Hazardous Substances).

EMC DECLARATION

Table 201 – Guidance and manufacturer's declaration – electromagnetic emissions – for all EQUIPMENT and SYSTEMS

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration – electromagnetic emissions</th></tr>
<tr><td colspan="3">The FT2800 is intended for use in the electromagnetic environment specified below. The customer or the user of the FT2800 should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF emissions

EN55011</td><td>Group 1</td><td>The FT2800 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions
EN55011</td><td>Class B</td><td rowspan="3"></td></tr>
<tr><td>Harmonic emissions
EN 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions
EN 61000-3-3</td><td>Complies</td></tr>
</table>

Table 202 – Guidance and manufacturer's declaration – electromagnetic immunity – for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration – electromagnetic immunity			
The FT2800 is intended for use in the electromagnetic environment specified below. The customer or the user of the FT2800 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) EN 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst EN 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of atypical commercial or hospital environment.
Surge EN 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV Differential mode ± 2 kV common mode	Mains power quality should be that of atypical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of atypical commercial or hospital environment. If the user of the FT2800 requires continued operation during power mains interruptions, it is recommended that the FT2800 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field EN 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of atypical location in a typical commercial or hospital environment.
NOTE	U_T is the a. c. mains voltage prior to application of the test level.		

Table 204 – Guidance and manufacturer's declaration – electromagnetic immunity – for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration – electromagnetic immunity			
The FT2800 is intended for use in the electromagnetic environment specified below. The customer or the user of the FT2800 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RFEN 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the FT2800, including cables, than there commended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = [\frac{3.5}{V_1}]\sqrt{P}$
Radiated RFEN 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = [\frac{3.5}{E_1}]\sqrt{P}$ 80MHz to 800MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800MHz to 2,5 GHz

			where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m) .[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

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

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the FT2800 is used exceeds the applicable RF compliance level above, the FT2800 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the FT2800.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 206 – Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM – for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the FT2800			
The FT2800 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the FT2800 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the FT2800 as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output Of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = [\frac{3.5}{V_1}]\sqrt{P}$	**80 MHz to 800 MHz** $d = [\frac{3.5}{E_1}]\sqrt{P}$	**800 MHz to 2,5 GHz** $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73

1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

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

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

SYMBOLS

The following symbols may appear in this manual, on the device, or on it's accessories. Some of the symbols represent standards and compliances associated with its use.


Caution: Consult accompanying documents


CE Mark: conforms to essential requirements of the Medical Device Directive 93/42/EEC. The four-digit number is the identification no. of the notified body.


Date of manufacture


Manufacturer


Serial number


Medical device


DISPOSAL: Do not dispose this product as unsorted municipal waste. Collection of such waste separately for special treatment is necessary.

This symbol points out that the operator must read the instructions for use before using the device.

Increasing temperature setting

Decreasing temperature setting

Standby / Operating

Testing Mode

Switch key between Celsius and Fahrenheit

Over - temperature alarm

Low temperature information signal

Sensor fault

 Warming profile is switched on

 Temperature setting

 Warming time

 Defibrillation- protection

 Potential Equalization Conductor

 Side up

 Keep away from water

 Fragile

TECHNICAL DATA

Model:	FT2800
Power supply:	a.c.100 - 240V/50-60 Hz
Power input:	2.1A/ a.c.115V 1.2A/ a.c.230V
Fuse:	2×T4A/250V
Type of protection against electric shock:	Class I
Degree of protection against electric shock:	BF Applied part; Defibrillation-protected
Degree of protection against ingress of liquids:	IPX2
Temperature setting:	33°C ~ 41°C (91~106℉) (0.1°C /1℉ increments)
Accuracy:	±1℃ (±2℉)
Overheat switch off:	42±1℃/43±2℃ (108±2℉/110±4℉)
Low temperature information signal:	32℃ (89℉)

Warming up time:	approx. 2 minutes, 20℃~36℃（68℉~97℉）
Operating mode:	Continuous
MDD Classification:	IIb according to rule 9
Dimension control body: (W×D×H))	200×130×250mm
Dimension control unit overall: (W×D×H)	215×136×250mm
Net weight:	2.3kg
Warming profile:	length 1.4 m, for infusion tube ∅3.5-5mm(O.D.)
(Refer to the label on device)	length 1.4 m, for infusion tube ∅6-7mm(O.D.)
Heating power:	120W
Power consumption:	Max 180VA

OPERATING AND STORAGE CONDITIONS

OPERATING

Temperature: 5～30°C

Relative humidity： ≤80 % , noncondensing

Air pressure: 700～1060 hPa

STORAGE

Temperature: -10～55°C

Relative humidity: ≤93 %, noncondensing

Air pressure: 500～1060 hPa

MANUFACTURER LIABILITY

The manufacturer and the supplier of the device reject all liability if:

- the device is not used in accordance with the instructions for use
- the operating personnel are inadequately qualified or are not sufficiently informed about the functioning of the device on the basis of the instructions for use and the safety instructions
- repairs are not performed exclusively by the manufacturer or by persons and service centers expressly authorized by manufacturer
- The device is used in places in which the electrical installations do not comply with the applicable national standards, or if power supply during the period of the use of the device is not guaranteed
- original spare parts and materials are not used or the maintenance interval is not complied with

Disposal of the device and its accessories is carried out in accordance with the applicable local regulations.

WARRANTY CONDITIONS

The manufacturer guarantees that any material or structural defect occurring within the warranty period will be repaired free of charge. A claim under this warranty can only be made under the following conditions:

- Proper agreement of the manufacturer or supplier regarding the malfunction for which a claim is being made under warranty.
- Return the device according to the request: clean and sterilize the device before return, pack into the original case or a suitable case if the original packing case is missing.
- Presentation of a legible copy of the invoice for the exact device, with the purchase date clearly visible.
- As detail as possible to describe the malfunctions.

Even in the warranty period, the manufacturer and supplier of the device will not be held responsible for any liability, if

- The device is not used and assembled properly in accordance with the instructions for use.
- The operating personnel are inadequately qualified or have not been adequately trained to operate the device based on the instructions for use and the safety advice.
- The operator has not followed the instructions in the manual to check and maintain the

device properly.

- Repairs are not instantly and completely carried out by the manufacturer or by explicitly authorized persons and service agents.
- The device has been replaced by any material which is not provided by the manufacturer.
- The device has been repaired by any person who is not authorized by the manufacturer.
- If the device is not accord with warranty conditions, consumer must be charged with all repairing costs, and afford the risks during the transportation.

On request the manufacturer will supply servicing instructions that contain all the required circuit diagrams, list of parts, inspection instructions and service information by means of which suitably trained and qualified technical personnel can repair all the parts of the device that the manufacturer considers to be repairable.

Manufacturer

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