Blood and Infusion Warmer

QW618

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 examination and repair.

CONTENT

DESCRIPTION

- The Blood and Infusion Warmer QW618 can be used in all applications in which hypothermia of the patient through cold transfusions and infusion solutions is to be prevented. The intelligent circuit control system of the device operates and deals with the temperature signals sent by high-precision sensors, and continually adjusts heating state, in order to rapidly keep the surface temperature of the heat exchanger at the set temperature. At the same time, the heat is transferred into the flowing liquid in the tubing placed in the grooves of the heat exchanger, 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 heating element can be set between 37°C and 42°C in steps of 0.1°C and is displayed on LED screen .The device can memorize the last set temperature automatically.
- The alarm and self-test functions for high and low temperature that are incorporated into the device assure safe operation.
- A sterile tubing with 5.0mm in O.D and 3.6m in length may be used in conjunction with the QW618.
- The temperature shown in the display corresponds to the temperature of the heat exchanger. The output temperature of the fluid at the end of the warming section

depends on various factors such as the fluid's input temperature, the set temperature， the flow rate, the ambient temperature, etc.

The following table shows the interaction.

Output temperature vs. Flow rate

(Room temperature at 25℃, extension set 3.6m in length winded 11 circles)

FlowRate	Initial Fluid Temperature: 10℃		Initial Fluid Temperature: 20℃	
	Set Temperature 38℃	Set Temperature 40℃	Set Temperature 38℃	Set Temperature 40℃
	Output Fluid Temperature		Output Fluid Temperature	
15 ml/min	34℃	35℃	34℃	35℃
35ml/min	33℃	34℃	33.5℃	35℃
50 ml/min	31℃	32℃	32℃	33.5℃
65 ml/min	29℃	30℃	31.5℃	32.5℃
80 ml/min	27.5℃	28.5℃	30℃	31℃
100 ml/min	27℃	27.5℃	29.5℃	30℃

CONTRAINDICATION

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.
It is forbidden to be used on the severe cardiopulmonary dysfunction patients.

WARNINGS

- If the high 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.
- Only sterile consumable materials may be used in conjunction with the QW618.
- Repairs and modifications to the device may only be carried out by persons or service centers authorized by Keewell.

SAFETY INSTRUCTION

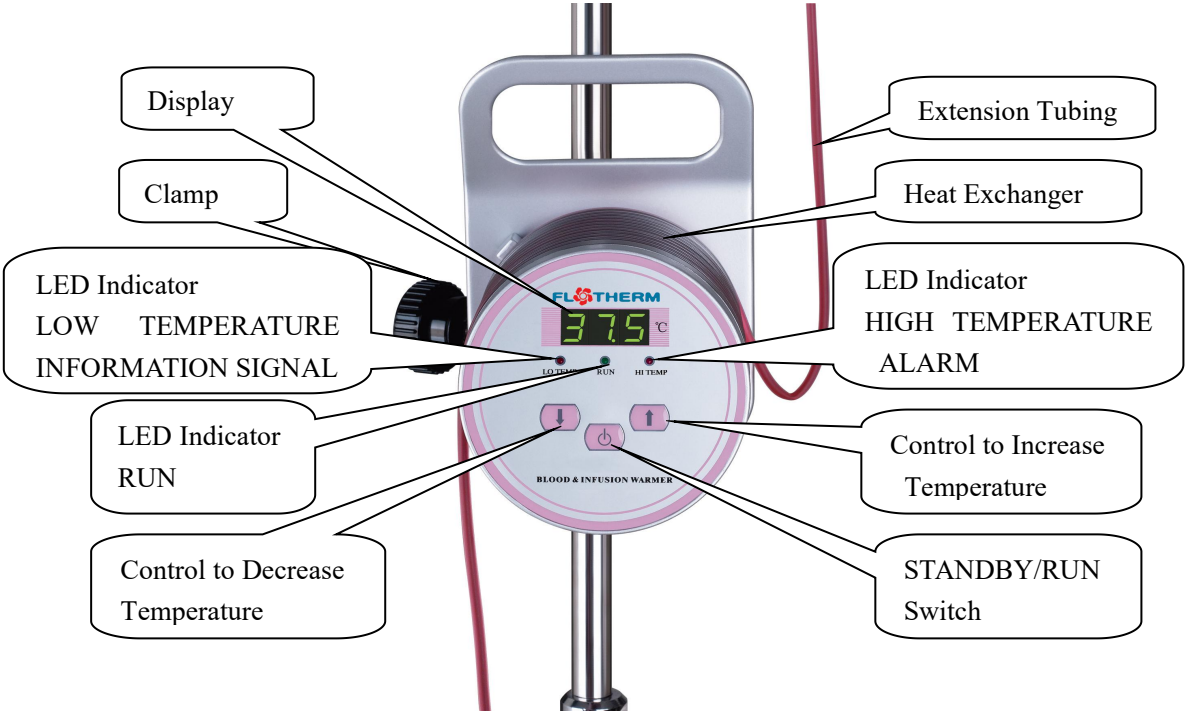
⚠ **The device must only be used in areas in which the electrical installations are in accordance with the rules and regulations in force. To avoid electrical shock, the device must only be connected to a properly grounded power source.**

The device must not be used in the following circumstances:

- If the device 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 a high temperature alarm or a backup high temperature 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



SAFETY CHARACTERISTICS

Low temperature information signal

The low temperature information signal is activated when the temperature of the heat exchanger drops below 35.9**℃**. In this event the blue LO TEMP LED indicator lights on with an audio alarm**,** a "LLL" code is displayed.

The low temperature information signal is deactivated during the first 2 minutes after switching on.

High temperature alarm

The high temperature alarm is activated when the temperature of the heat exchanger exceeds 43.1°C. In this event the yellow HI TEMP LED indicator lights on with an audio alarm, a "HHH" code is displayed 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 43.0°C.

Backup high temperature protection

In the event of the first 43.0°C high temperature protection malfunction, backup high temperature protection is activated when the temperature of the heat exchanger exceeds 45±3℃. In this case the heating is switched off. Unplug the mains plug, return it to the dealer or the manufacturer for a service.

Sensor malfunction alarm

In the event of sensor malfunction, the yellow HI TEMP LED indicator lights up, go with an audio alarm, and a "LLL" or a "HHH" code is displayed. In this case 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 heat exchanger is below -5.0°C or above 45.0°C.

⚠ **Attention:**

The high temperature alarm can also be triggered by exposure to sunlight, extraneous heat, etc. 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 37 - 42℃. If the temperature exceeds 43℃, 45℃, 45±3℃ 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 I	**Software high temperature alarm II**	**Sensor malfunction alarm**
Condition	The high temperature alarm is triggered when the temperature of the heat exchanger exceeds 43.1°C.	The high temperature alarm is triggered when the temperature of the heat exchanger exceeds 45°C.	Self test detects a sensor malfunction.
Consequence	The heater is switched	The heater is switched	The heater is switched

	off.	off.	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	Yellow HI TEMP LED indicator lights on + a "HHH" code is displayed	Yellow HI TEMP LED indicator lights on	A "LLL" or a "HHH" code is displayed
Audio signal	Audio alarm will be emitted once every 15 seconds and ring twice each time.	Audio alarm will be emitted once every 15 seconds and ring twice each time.	Audio alarm 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

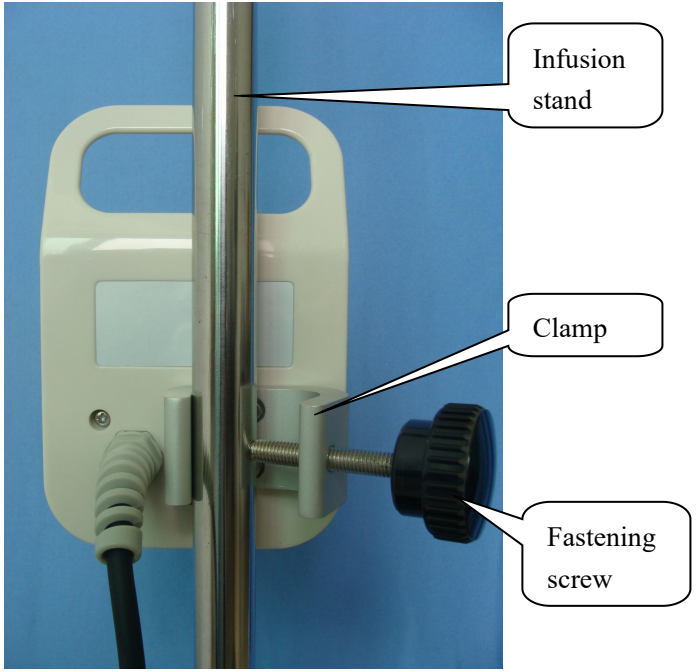
	Low temperature information signal
Condition	If the temperature of the heat exchanger drops below 35.9°C. The audio low temperature signal is deactivated during the first 120 seconds after switching on.
Consequence	No consequence in relation to the function of the device. (information only)
Resetting	Automatically when the temperature rises above 35.9**°C.**
Visual signal	Blue LO TEMP LED indicator lights on + a "LLL" code is displayed.
Audio signal	1 pulse with 1s duration every 15s 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 using the clamp at the back, then screw the fastening screw.
  Only use infusion stands or poles that are sufficiently stable.
- Before connecting to mains power supply, check the voltage specified on the device label.
- Connecting power cable to power supply.

The device is in STANDBY mode.
The display shows the setting temperature.



Operation procedure

- Select a suitable consumable material of infusion or transfusion. The length of tube between the heat exchanger and the patient must be at least 40cm and the tube must not be stretched.
- Beginning from the back of the heat exchanger, gently wind the infusion tube anti-clockwise towards the front. The tube must be completely inserted into the groove. It is suggested that the distance between the heat exchanger and the patient should not longer than 80cm.
- Empty the air in tubing to make infusion channel ready.
- Press the key ↑ or the key ↓ to set the desired temperature. The display shows the setting temperature.
- Press the key ⏻ , the RUN LED indicator lights up. The device works now with the target temperature. The display shows the actual temperature. Resetting of temperature can only be performed in Standby mode.

Shutting down the device

- Press the key ⏻, the RUN LED indicator goes out .The device is now in STANDBY mode.

- Release all pressure in the infusion system by switching off the pressure cuffs or infusion pumps.
- Remove the consumable material from the heat exchanger and dispose it according to the relevant regulations.
- Disconnect the device from the power supply. Clean and sterilize the equipment according to instructions.

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 sprayer of alcohol-based standard sterilizing agents can be used for sterilizing.
- 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.

Checking the control temperature on the groove of the heat exchanger

Preheat the device to 38.0°C, and hold on for 5 minutes. The sensor of a suitable contact thermometer (tolerance ± 0.15°C) is fixed to the middle groove of the device by using a piece of tube. The measured value is read after it has stabilized. The difference must not exceed ± 0.5°C. There is a malfunction if a difference from control temperature of greater than ± 0.5°C is obtained.
It can no longer be used until the necessary repairs have been carried out.

Checking the high temperature alarm

Preheat the device to 42.0°C and wait for the temperature to stabilize. Press the key ⏻, the device is now in STANDBY mode. Press the key ↑ and the key ↓ synchronously. The device now heats up to a target temperature of 43.0°C.The high temperature alarm should be triggered at a temperature of 43.1°C. In this event visual and audio alarm signals and "HH" code are given and the heating is switched off. There is a malfunction if the high temperature alarm is not triggered.

MANUFACTURER'S DECLARATION

The blood and infusion warmer QW618 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 QW618 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

Guidance and manufacturer's declaration – electromagnetic emissions		
The QW618 is intended for use in the electromagnetic environment specified below. The customer or the user of the QW618 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions EN55011	Group 1	The QW618 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.
RF emissions EN55011	Class B	
Harmonic emissions EN 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions EN 61000-3-3	Complies	

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

Guidance and manufacturer's declaration – electromagnetic immunity			
The QW618 is intended for use in the electromagnetic environment specified below. The customer or the user of the QW618 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 a typical 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 a typical 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 a typical commercial or hospital environment. If the user of the QW618 requires continued operation during power mains interruptions, it is recommended that the QW618 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 a typical 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 QW618 is intended for use in the electromagnetic environment specified below. The customer or the user of the QW618 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF EN 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 QW618, including cables, than the recommended 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 RF EN 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 QW618 is used exceeds the applicable RF compliance level above, the QW618 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the QW618.

[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 QW618			
The QW618 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the QW618 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the QW618 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.

 Authorized Representative in the European Community

 Date of manufacture

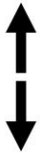
 Manufacturer

 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.



Control for increasing temperature setting

Control for decreasing temperature setting

Control for switching On / Standby

Type B applied part

TECHNICAL DATA

Model:	QW618
Power supply:	a.c.230 V / 50-60 Hz or a.c.110 V / 50 Hz check the voltage specified on the device label
Power consumption:	Max. 250 VA
Type of protection against electric shock:	Class I
Degree of protection against electric shock:	B
Degree of protection against ingress of liquids:	IPX4 splash proof
Fuse:	F1, F2: 230V: 2xT1.6AL/250V 110V: 2xT3.15AL/115V
Temperature setting:	37°C ~ 42°C (0.1°C increments)
Display Accuracy:	±0.5℃
Overheat switch off:	43℃/45℃/45±3℃
Low temperature information signal:	36℃
Operating mode:	Continuous
Classification:	IIb according to rule 9
Dimension control body: (W×D×H)	100×170×210mm
Dimension control unit overall: (W×D×H)	138×170×210mm
Net weight:	1.3kg

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 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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