ENG

Instructions for use

protherm II

Blood and Infusion Warmer

Edition 2017-11-21 | 220 – 240 V

BIEGLER
medizinelektronik

IMPORTANT

These directions are essential for operating the device. They must therefore be kept in a suitable place near the device, and should be kept with the device if it is given to other users.

For proper and safe use of this device, it is essential that the following warnings and safety instructions, as well as the operating instructions, 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 suitable warning signs should be attached to the device to ensure that it is not used before the required service and repair work has been carried out.

Table of contents

1 WARNINGS AND SAFETY INSTRUCTIONS

- In the event of any suspected malfunction while in operation, the device should be immediately removed from service and not used for infusions or transfusions until appropriate investigations have demonstrated that there has been no impairment.
- Unplugging the mains plug is the only safe way to disconnect from the mains power supply. Place the device so that it can easily be disconnected from the mains.
- 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.
- The system must be depressurized before opening the device by switching off the pressure cuffs or infusion pump and releasing the pressure remaining within the system. Closing the system forcibly when the warming bags are full and under pressure may cause the warming bag to burst. The maximum pressure of the system must not exceed 300 mmHg.
- The device may only be fastened to infusion stands or tripods which have sufficient stability and load capacity to support the device.
- The device must only be used in areas in which the electrical installations are in accordance with the standards and regulations in force. To prevent the risk of an electric shock the device shall only be connected to a supply network with protective earth connection.
- The device must not be used in rooms with potential explosion hazard.
- The device must not be immersed in liquids or sterilized with steam or by thermochemical methods.
- All extraneous influences such as electromagnetic waves or high temperatures are to be kept to a minimum.
- The device can be influenced by other devices or equipment nearby or it can influence them. It is subject to special precautions regarding electromagnetic compatibility (EMC). Portable and mobile RF communication equipment can affect medical electrical equipment.
- Avoid exerting force to the device or its accessories.
- If the device is dropped, damaged due to force, or functions in a way other than described in the operating instructions, stop using the device immediately and return it to the service center.
- Persons and services authorized by BIEGLER must carry out repairs and modifications on the device.

- Periodic technical safety inspections must be carried out as described in the "Periodic inspections" section.
- No mechanical or electrical modifications may be made to the components of the warming system.
- The device may not be set up and operated in direct proximity to devices which generate high levels of excess heat.
- Only sterile BIEGLER consumable materials may be used in conjunction with the protherm II.

Safety Instructions for consumable materials:

- The consumable materials are intended for single use only.
- Only sterile consumables or material specified by BIEGLER or approved by BIEGLER for use with this device may be used in conjunction with the protherm II.
- Only use items with intact individual packaging.
- Consumables are only for one-time use (disposable).

  The reuse of disposable products results in possible infection risks for the patient or user. Product contamination may lead to health problems, diseases or death of the patient.
- Do not re-sterilize!

The protherm II may not be used if:

- the case is damaged or one of the front film layers becomes detached.
- the device has been exposed to a hard physical shock (e.g. dropped, hit or shaken).
- the device has been immersed in water.
- the device has triggered a high temperature alarm that was not caused by external factors.
- the mains power cord or plug is damaged.
- the device has given somebody an electric shock.
- the fixing clamp is damaged in such a way that safe clamping to the infusion stand is no longer guaranteed.

If there is a malfunction, suitable warning signs should be attached to the device to ensure that it is not used until the required service and repair work has been carried out.

2 DESCRIPTION

2.1 GENERAL DESCRIPTION

The BIEGLER protherm II is a warmer for infusions and transfusions at high flow rates. The device operates on the basis of the dry heat principle and uses warming plates heated on both sides.

The medium is heated rapidly, efficiently and gently by using three independently controlled heat zones.

The design of the casing allows rapid and simple fitting to any suitable infusion stand. The plate temperature can be set between 37 °C and 41 °C in steps of 0.5 °C and is displayed as an illuminated band.

The preset temperature after switching on the protherm II is 38.5 °C.

The alarm and self-test functions for high and low temperature that are incorporated into the device assure safe operation.

2.2 SCOPE OF DELIVERY

Blood and infusion warmer protherm II and instructions for use

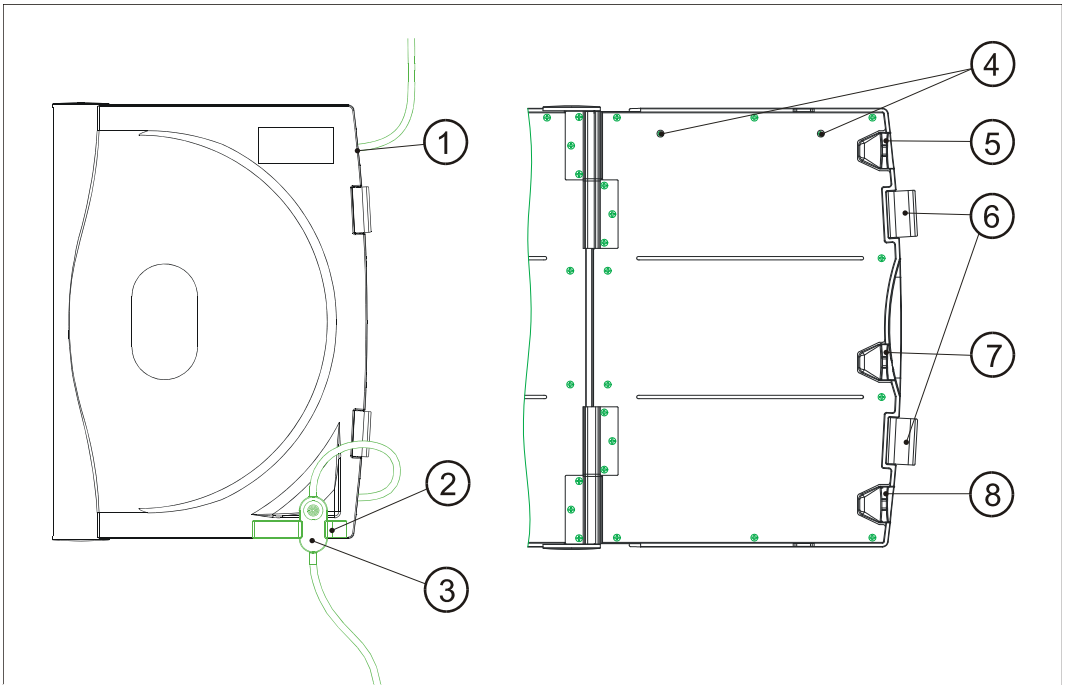
2.3 CONSUMABLE MATERIAL

Large bag Order number: FP1003001

- completely covers heating area; includes two drip chambers with thrombosis filters, air trap and injection port close to the end of the tube

3 INITIAL OPERATION

3.1 SETTING UP PROCEDURE



Diag. 1

1 Entry of liquid
2 Mounting for the air trap
3 Air trap
4 Attachment hooks for warming bag
5 Tube holder
6 Clips for closure of device
7 Tube holder
8 Tube holder

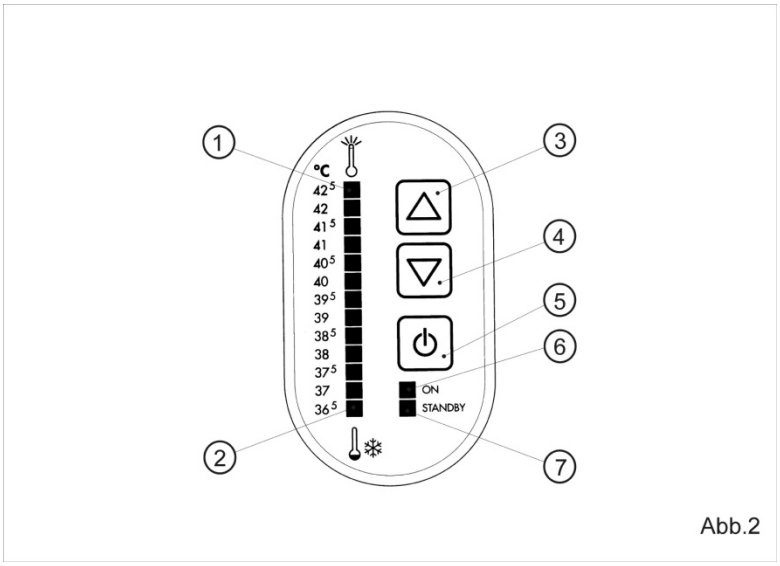


Abb.2

Diag. 2

1 Temperature scale
2 Temperature scale
3 Control to increase temperature
4 Control to decrease temperature
5 ON / STANDBY switch
6 LED ON
7 LED STANDBY

Observe the directions for use! Handling of this device requires knowledge and adherence to these instructions. The protherm II and accessories may only be used by qualified specialized staff. The patient must be monitored throughout the procedure.

Fix the BIEGLER protherm II firmly to the infusion stand using the clamps at the back. Only use infusion stands or poles that are sufficiently stable.

Connect power cable to power supply. Before connecting to the mains power supply, check the voltage specified on the device label. The device gives a short beep and the standby light (Diag.2/7) lights up.

If a different temperature to 38.5 °C is desired, it can be preset in Standby mode using the controls △ and ▽ (Diag.2/3 and Diag.2/4). If an adjustment control is pressed, the visual display indicates the existing preset temperature. By repeated operation of the control △ or ▽ the temperature can be reset. The indicator automatically goes out after approximately 7 seconds. Resetting of temperature can only be performed in Standby mode.

Heating of the protherm II can be started by pressing the control ⏻ (Diag.2/5). The protherm II attains the set target temperature within 1 minute. The indicator display shows the actual temperature (± 0.5 °C) as an illuminated band.

Open the device: release the two clips on the right (Diag.1/6) by pressing the button on the clip and open the device. The heating zones are visible, the attachment hooks for the warming bag are on the reverse at the top (Diag.1/4).

Hang the warming bag on the attachment hooks (Diag.1/4) and push the tube outlets into the tube holders (Diag.1/5, 7, 8). The tube with the two drip chambers must be placed at the top, the tube to the air trap below (Diag.1/3). The warming bag hangs without creases in the open device.

Close the protherm II and lock with the clips on the right side (Diag.1/6). Place the air trap in the mounting provided (Diag.1/2).

Fill the system. Take care that filling proceeds without air bubbles occurring.

When the device is opened, the system must not be under pressure. Closing the system when it is under pressure can cause the warming bag to burst. The clips are designed so that they resist opening above a certain operating pressure. The device must not be forcibly opened.

3.2 ALARMS

The protherm II can trigger two types of temperature alarm:

	Software high temperature alarm	Hardware high temperature alarm
Condition	The high temperature alarm is triggered when the temperature of one of the 6 heating plates rises above 43.0 °C.	If the temperature rises above 45 °C due to a software error, at 46 °C ± 3 °C a hardware high temperature alarm is triggered.
Consequence	The heating plates are switched off.	The heating plates are 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. Wait for the temperature switch to cool down.
Visual signal	Yellow alarm LEDs + all green LEDs constantly on.	Yellow alarm LEDs + all green LEDs constantly on.
Audio signal	Continuous tone 3.6 kHz 71 dBA	Continuous tone 3.6 kHz 71 dBA
Priority as per EN 60601-1-8	Low priority	Low priority

Information signals

	Low temperature information signal
Condition	When the average temperature of the three zones drop below 36.5 °C.
Consequence	No consequences in relation to the function of the device. (information only)
Resetting	Automatically when the temperature rises above 36.5 °C.
Visual signal	Green LED 36.5 °C flashes at 1 Hz 50 % duty cycle
Audio signal	500 ms long pulse 3.6 kHz every 1 s – 71 dBA

The low temperature alarm is activated when the average temperature from the three zones fall below 36.5 °C. The audio low temperature alarm is deactivated during the first 60 seconds after switching on.

The high temperature alarm is activated when the temperature of one of the six heating plates exceeds 43.0 °C. In this event visual and audio alarm signals are given and the heating plates in all the zones are switched off. To reset the device or switch off the alarm, the device must first be disconnected from the power supply.

Attention: The temperature alarm can also be triggered by external factors, e.g. exposure to sunlight.
To reset the alarm, the mains plug must be pulled out.

All alarms are alarms of “Low priority” according to EN 60601-1-8.

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.

3.3 SHUTTING DOWN THE DEVICE

After being used for treatment, the device is shut down as follows:

Switch the device into Standby mode using control  (Diag.2/5).

Depressurize the system by switching off any pressure cuffs or infusion pumps used. Empty and disconnect the system as far as possible.

Release the two clips on the right (Diag.1/6) and open the device.

Remove the bag from the attachment hooks (Diag.1/4) and dispose of it according to the applicable local regulations.

Disconnect the device from the power supply and clean and disinfect it as described in the section „cleaning and disinfection“.

3.4 TROUBLESHOOTING

Error	(possible) Cause	Solution
LEDs do not light up	No power supply	Insert the mains plug
No LEDs light up, even though mains plug is inserted and mains voltage available	Device defective	Return device for servicing
Device sounds alarm and does not heat	Internal error	Return device for servicing
<36.5° LED and device issues short signals in 1 second intervals.	Low temperature information signal has been triggered	The low temperature information signal is automatically cancelled after reaching >36.5 °C.
Alarm LEDs light up, audio alarm (continuous tone)	Device was overheated	Allow device to cool down. If the error occurs again → return device for servicing

4 MAINTAINANCE

The protherm II is designed as a low-maintenance device. For long-term maintenance of quality and functional safety, the following points have to be observed:

- Always keep the device clean (see the "Cleaning and disinfection" section).
- Periodic technical safety inspections must be carried out as described in the "Periodic inspections" section.

5 CLEANING AND DISINFECTION

Important: Before cleaning or disinfecting, the device must always be disconnected from the mains power supply by pulling the plug.

The device may only be cleaned using a soft cloth with water-soluble, non-aggressive cleaning agent or a special cleaning agent for plastics.

For the purposes of disinfection, only ready-made alcohol-based spray disinfectants (e.g. Meliseptol Foam pure, BRAUN) must be used and the manufacturer's instructions must be followed.

Do not disinfect the device with steam (i.e. in autoclaves), hot air or thermochemical cleaning solutions.

6 PERIODIC INSPECTIONS

The periodic technical safety inspections (according to the local standards in force - e.g. EN 62353) on the protherm II must be carried out at least every 12 months, by persons authorized to carry out such inspections based on their training, knowledge and practical experience.

The results of the periodic inspection must be documented, along with the date, the inspecting agency and the device number.

During the measurements, the heating device may not be exposed to sunlight, draughts or other conditions which could affect the measurement.

Important: If a malfunction is discovered during the periodic inspection, suitable warning signs should be attached to the device to ensure that it is not used before the required service and repair work has been carried out.

CHECKING THE WARM-UP PERIOD

This is the time taken by the protherm II to heat up to 38.5 °C from room temperature. If this time is much more than one minute, there is a malfunction.

CHECKING THE CONTROL TEMPERATURE

The control temperature is checked on the lower third of the rear heating plates, about 7 cm from the right-hand edge of the device. The sensor of a suitable contact thermometer (tolerance ± 0.15 °C) is fixed to this place e.g. using adhesive tape.

The check is performed with the device closed and at a temperature setting of 38.5 °C. The measured value is read after it has stabilized. The difference must not exceed ± 0.5 °C. This check is carried out on each of the three heating areas. If there is a difference of greater than ± 0.5 °C from the control temperature, there is a malfunction.

CHECKING THE LOW TEMPERATURE ALARM

Preheat the device to 38.5 °C, then disconnect the mains plug. Hold down the controls ⏻ and ▽ and reconnect the mains plug. Push the ⏻ switch. The device is now in an operational state where all the alarms are active, but the heating is switched off. The protherm II now slowly cools down. When the temperature drops below the 36.5 °C threshold, the low temperature alarm should be active.
For reasons of safety, short beeping sounds are given at intervals of a second in this operational mode. There is a malfunction if the low temperature alarm is not triggered.

CHECKING THE HIGH TEMPERATURE ALARM

Preheat the device to 41 °C and wait for the temperature to stabilize, then disconnect the mains plug. Hold down the controls ⏻ and △ and reconnect the mains plug. Push the ⏻ switch. The device now heats up to a target temperature of 43.5 °C. Observe the temperature indicator carefully. The high temperature alarm should be triggered at a temperature of 43.0 °C.
For reasons of safety, short beeping sounds are given at intervals of a second in this operational mode. There is a malfunction if the high temperature alarm is not triggered.

VISUAL CHECK OF GENERAL CONDITION

The device should be checked for mechanical damage (general condition) and for the completeness of the stickers, particularly the device label on the reverse. If there is mechanical damage to the device which could cause risk of injury or impair its functionality, this constitutes a malfunction.

ELECTRICAL SAFETY

All relevant electrical safety data should be checked, particularly the earth conductor resistance and leakage current. If a measured value is outside of the specified tolerance, there is a malfunction.

7 MANUFACTURER LIABILITY

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

- the device is not used in accordance with the directions for use.
- the user is not sufficiently informed about the functioning of the device corresponding with the directions for use and the safety instructions.
- repairs are not performed exclusively by the manufacturer or by persons and service centers expressly authorized by the manufacturer.
- the device is used in places in which the electrical installations do not comply with the applicable national standards, or if the power supply during the period of use of the device is not guaranteed.
- original spare parts are not used or the maintenance interval is not adhered to.

8 WARRANTY CONDITIONS

The manufacturer guarantees that all flaws of material and workmanship which arise within 24 months from the date of purchase will be repaired free of charge.

Claims are only accepted under the following terms:

- The manufacturer and/or supplier is informed immediately of the fault for which the warranty claim is being made.
- The instructions of the manufacturer and/or supplier regarding storage or return of the device are complied with.
- Presentation of a legible copy of the invoice for the device concerned, showing the date of purchase.
- An exact description of the defects or malfunctions identified by the customer.

The manufacturer's warranty will be void if it is found that the maintenance, disinfection and inspection instructions have not been followed according to the operating instructions, the device has been damaged by force or operating error, or has been used in any way contrary to the operating and safety instructions. The warranty will also be void if original BIEGLER materials were not used as replacement parts, or measures for repair were undertaken by persons not authorized by the manufacturer or supplier.

If the manufacturer is required to meet a warranty claim in accordance with these terms, the customer shall bear the costs and risks of transport of the device from and to the place of use.

The manufacturer and/or supplier shall under no circumstances assume liability for slight negligence. The compensation for lost earnings and profits is likewise excluded.

9 RETURN OF DEVICES

Devices must be carefully cleaned and disinfected before being placed in the original packaging for returning.

If the original packaging is no longer available, the product has to be suitably packaged for the method of dispatch.

10 DISPOSAL

Dispose of the device and its accessories in accordance with the applicable local regulations.

11 ELECTROMAGNETIC COMPLIANCE

Table 201

Guidance and manufacturer´s declaration – electromagnetic emission		
The protherm II is intended for use in the electromagnetic environment specified below. The customer or the user of the protherm II should assure that it is used in such an environment.		
Interference emission measurements	**Compliance**	**Electromagnetic environment - guidance**
RF emissions acc. to CISPR 11	Group 1	The protherm II 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 acc. to CISPR 11	Class B	The protherm II is suitable for use in all establishments, including domestic establishments and those directly connected to the public power supply network that also supplies buildings used for domestic purposes.
Emission of harmonics acc.to IEC 61000-3-2	Class A	
Emission of harmonics acc.to IEC 61000-3-3	Compliant	

Table 202

Guidelines and manufacturer´s declaration – electromagnetic interference resistance			
The protherm II is intended for use in the electro-magnetic environment specified below. The customer or the user of the protherm II should assure that it is used in such an environment.			
Interference resistance test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment-guideline**
Electrostatic discharge IEC 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 %.
Fast transient /electrical bursts acc. to IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surges as per IEC 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 of the supply voltage acc. to IEC 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 protherm II requires continued operation during power mains interruptions, it is recommended that the protherm II be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 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 AC mains voltage prior to application of the test level.			

Table 204

Guidelines and manufacturer´s declaration – electromagnetic interference resistance			
The protherm II is intended for use in the electro-magnetic environment specified below. The customer or the user of the protherm II should assure that it is used in such an environment.			
Interference resistance test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidelines**
Conducted RF IEC 61000-4-6	3 V 150 kHz to 80 Mhz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the protherm II, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.17\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	**10 V/m**	$d = 0.35\sqrt{P}$ 80Mhz to 800MHz $d = 0.7\sqrt{P}$ 800MHz to 2,5GHz 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 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 protherm II is used exceeds the applicable RF compliance level above, the protherm II should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the protherm II. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 206

Recommended safety distances between portable and mobile RF telecommunications devices and the protherm II			
The protherm II is intended for use in an electro-magnetic environment in which radiated RF disturbances are controlled. The customer or the user of the protherm II can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the protherm II as recommended below, according to the maximum output power of the communications equipment			
	Protection distance according to transmitter frequency m		
Rated maximum output power of transmitter W	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 0.35\sqrt{P}$	800 MHz to 2,5 GHz $d = 0.7\sqrt{P}$
0.01	0.12	0.04	0.07
0.1	0.37	0.11	0.22
1	1.17	0.35	0.70
10	3.69	1.11	2.21
100	11.67	3.50	7.0
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.			

12 MANUFACTURER'S DECLARATION

The blood and infusion warmer protherm II as well as BIEGLER consumables (Heating bags) are medical products as defined by Directive 93/42/EEC.

This is documented through the CE mark.
Notified Body: TÜV SÜD Product Service, Approval Number CE0123

13 SYMBOLS

CE 0123	Certifies compliance with the Directive 93/42/EEC
	Observe the instructions for use
	Do not dispose of this product as unsorted municipal waste
	Control for increasing the temperature setting
	Control for decreasing the temperature setting
	Control for switching on / standby
	AC voltage
SN	Serial number
IPX4	Degree of protection against the ingress of splashing water
	Application part type B
	Manufacturer
 **2015**	Date of manufacture
	Protective earthing
	"Do not open while pressurised" see also Section 1 Warnings and safety instructions

 Humidity limitation

 Protect from heat and radioactive sources

 Temperature limit

 Keep dry

 Fragile, handle with care

 Catalogue number

Symbols for consumables

 Sterile by ethylene oxide

 Designation of the batch

 Expiration date

 One-time use only

14 OPERATING AND STORAGE CONDITIONS

Permissible environmental conditions for the device and accessories:

	Transport and storage	**Operating**
Temperature	10 – 40 °C	10 – 30 °C
Relative humidity	30 – 75 %	30 – 75 %
Ambient pressure	700 – 1060 hPa	700 – 1060 hPa

 Important: Values higher or lower than the ranges specified above may cause damage to the device or its accessories.

15 TECHNICAL DATA

Device:	**Blood and Infusion Warmer**
Type designation:	protherm II
Voltage:	220 - 240 V / 50 Hz
Power consumption:	1400 W
Protection class:	I
Degree of protection:	Type B
Degree of prot. against ingress:	IPX4
Fuses:	primary 2x T 6.3 AL 250 V secondary T 500 mAL 250 V
Control temperature:	37 °C – 41 °C, in 0.5 °C steps
Over temperature switch-off:	43.0 °C / 43.5 °C / 45 °C ± 3 °C
Audio alarm frequency:	3600 Hz; sound pressure level 71 dbA
Low temp. information signal:	500 ms / 1 s; sound pressure level 71 dBA
Lowest liquid temperature:	6 °C (inlet temperature)
Max. system pressure:	300 mmHg
Classification:	IIb according to Rule 9
Operating mode:	Continuous operation
Dimensions:	W x H x D 300 x 400 x 120 mm
Weight:	5.2 kg

16 MANUFACTURER

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