Instructions for use

Barkey plasmatherm

Version 1 EN

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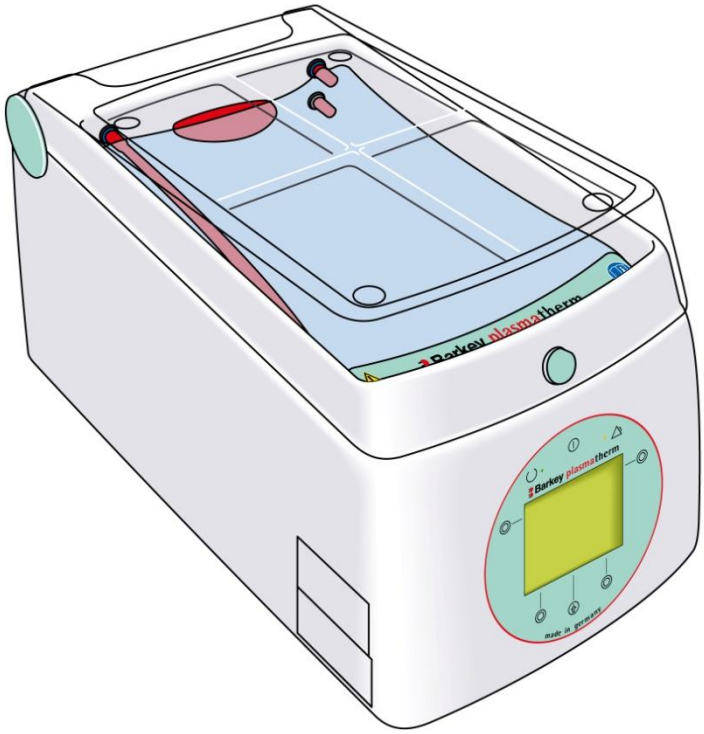
for SN 1107500 onwards



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Declaration of Conformity

ISO Certificate

Barkey plasmatherm device master data sheet

1 Introduction

Congratulations on your decision to use the Barkey plasmatherm for the

- timed heating of whole blood and blood products
- thawing and timed heating of fresh frozen plasma (FFP)
- thawing and timed heating of HPC (stem cells)
- heating and maintaining the warmth of non-denaturable infusion solutions and other materials in continuous mode.

You have opted for a high-quality product that will give reliable service for many years.

In these instructions you will find all the information you require about the functions, operation and use of the Barkey plasmatherm.

1.1 Pictograms, words and symbols

These instructions use the following pictograms, symbols and words to highlight warnings and special advice:

⚠ **WARNING**	If disregarded: danger to persons.
⚠ **CAUTION**	If disregarded: danger to property, the device or basic device functions.
i **NOTE**	Additional useful advice and information. (the "i" stands for "information".)

You will find the following symbol in instructions about the use and maintenance of the device:

►	Instruction step. Carry out this step as indicated.

i **NOTE**

The symbols representing the controls and device displays, and the symbols used on device labels, are listed and described in the Chapter Symbols in these instructions.

1.2 Target group

These instructions are intended for use by:

- Medical specialists in hospitals who hold a recognised vocational qualification in human medicine,

CAUTION

Only persons who meet this criterion may use the device.

1.3 What you must bear in mind at all times

You must follow the conditions of use and safety advice contained in this instruction manual at all times when using the device. This will ensure that the device is handled properly and that patients and users cannot be put at risk and equipment cannot be damaged.

Barkey GmbH & Co. KG can accept no liability for damage caused as a result of failure to follow these instructions.

WARNING

These instructions for use are an integral part of the product. They must be retained throughout the life of the product and handed to any subsequent owner or user. Please ensure that any supplementary instructions which may be issued are kept together with the original instructions.

Carefully read through these instructions before using the device.

Please follow the advice about the intended use of the device in the Chapter Intended purpose and the safety information provided in the Chapter Safety advice. For a better understanding of these chapters you should familiarise yourself with the basic functions of the device as described in the Chapter Description of the device.

You should also comply with the requirements for the training and skills of persons using the device, as indicated in the Chapter Target group.

Medical electrical devices are subject to special safety measures in regard to EMC (electromagnetic compatibility), and you should therefore always ensure that the device is installed and operated in accordance with the EMC advice contained in these instructions.

1.4 Conformities

Please read the declaration of conformity in the Appendix to these instructions.

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1.5 Copyright

These instructions for use and all illustrations they contain are protected by copyright. Translation, duplication, reprinting, extraction of images, reproduction using photographic technology and storage and processing in electronic systems, even only excerpts, and any alterations shall require the written authorisation of Barkey GmbH & Co. KG. Any further usage which goes beyond the use of the contents described in connection with the product purchased is not permitted.

Third party products, protected trademarks etc. are always stated without reference to the registration or copyright status. Existing industrial property rights and registered trademarks are explicitly acknowledged.

We reserve the right to make typographical errors and mistakes, also changes in the interest of technical progress, or which are necessary due to changes in regulations.

2 Description of the device

The Barkey plasmatherm is used primarily for thawing and heating fluids contained in bags or bottles and which are intended for medical transfusion or infusion in living organisms. Typically these fluids are whole blood, blood products, blood preparations and infusion solutions.

2.1 Components of the Barkey plasmatherm

1. Heating chamber cover	Covers the heating chamber while heating or thawing is in progress
2. Filler opening	The filler opening is used to fill the device with heat transfer fluid
3. Paddle	Gently agitates FFP´s during the heating process
4. Heating cushion	Heat transfer fluid flows through the heating cushions. The cushions heat the materials placed in the device and keep them warm.
5. Cover locking/release button	The locking/release button is used to open and close the heating chamber cover
6. Operating panel	The Barkey plasmatherm has an operating panel on the front of the device with a multi-line display, 6 buttons and 2 lamps (LEDs).

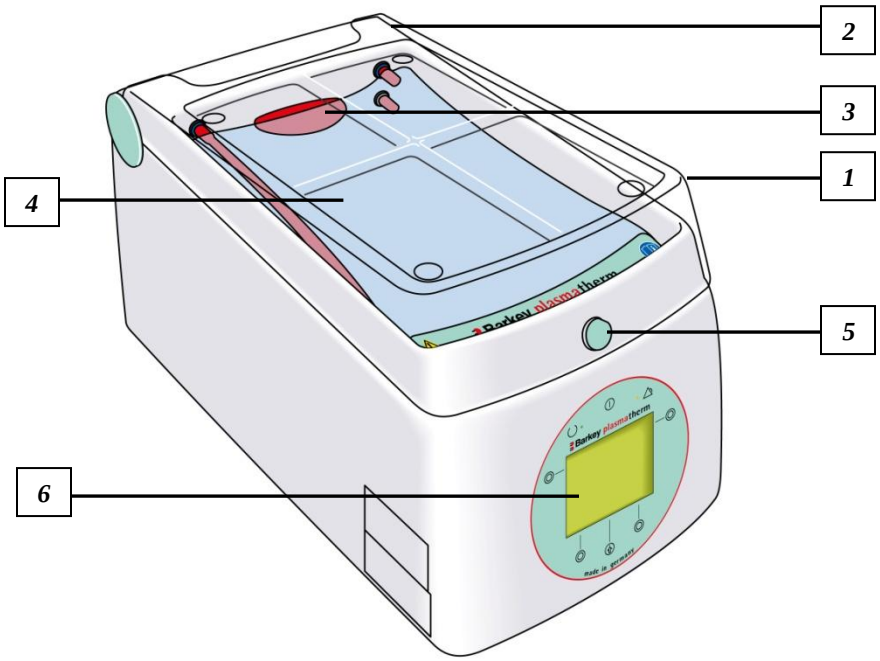

Figure 1: Barkey plasmatherm

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2.2 Technical description

The Barkey plasmatherm is configured as an electronically regulated dry heating device with an enclosed heating chamber. Bags of fresh frozen plasma (FFP), blood and erythrocyte concentrates (EC), cryoconserved preparations, cryoconserved stem cells (HPC = haematopoietic progenitor cells) or infusion solutions are placed between soft heating cushions made from a flexible synthetic material. A heat transfer fluid (distilled or demineralised water) flows through the heating cushions which heat up the materials placed in the device and keep them warm.
All heating is controlled by heating programs. To heat a particular preparation, the user selects the appropriate program on the operating panel using the display and buttons. Different functions of the device act on the preparation depending on the program selected. A number of preferences can also be set. The following table provides an overview of these:

Program name	User preselectable	Acting special functions
		Undulation**
BLOOD	Heating time	no
PLASMA*	Heating time	yes
HPC***	Heating time	yes
USER	various parameters can be set as required	adjustable or selectable
CONTINUOUS OPERATION	no	no

* The setpoint temperature can be increased to +45°C to accelerate the thawing of frozen plasma conserves. The process now operates at a temperature of +45°C and is monitored and timed by the program.

** An undulation function which agitates the heated materials is provided for mixing certain materials such as plasma (FFP, **f**resh **f**rozen **p**lasma).

*** HPC ⇔ Haematopoietic progenitor cells (stem cells)

CAUTION

With plasma, thorough mixing of the bag's contents is essential as all protein precipitates (cryoproteins) must be dissolved before the plasma can be used.

2.3 Symbols

2.3.1 Operating panel symbols

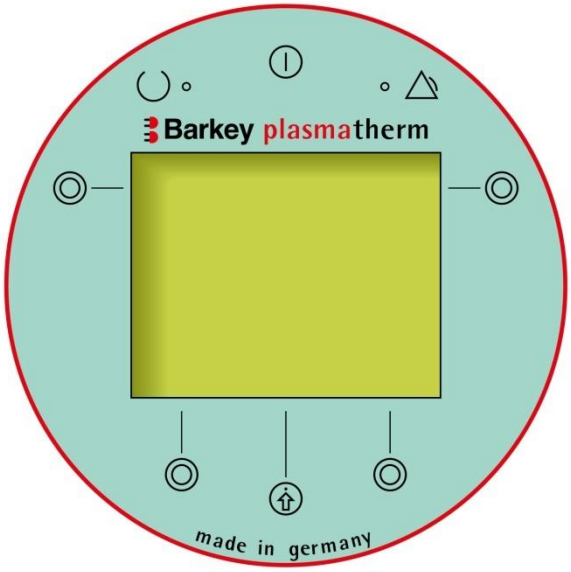

Figure 2: Operating panel

The Barkey plasmatherm has an operating panel on the front of the device with a multi-line display, 6 buttons and 2 lamps (LEDs).

The display

- displays the menu system for the operation of the device,
- displays information about the currently running program and its status, and
- outputs warning and error messages.

An audible signal draws your attention to the fact that a program has finished, warns of operator error or indicates that an error has occurred. A message is additionally shown in the display in the event of errors.

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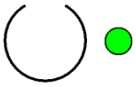
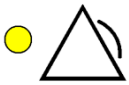
The display elements and controls are identified by symbols as described in the following table:

	Device On/Off button.
	Function button or selection button for menu navigation. The button's particular function is indicated in the display.
	Confirm button for menu navigation. This button is used to acknowledge / confirm the function which currently appears in the display.
	The green light (LED) shows that the device has been switched on.
	The yellow light (LED) indicates a device malfunction.

2.3.2 Symbols used on labels

Labels showing printed symbols are affixed to the device. These have the following meaning:

IPX 1	This symbol means that the device is protected against vertically dripping water according to IEC 601-1 in its intended operation conditions.
2010	This symbol shows the year of manufacture as a four-digit number.
CE 0123	This symbol declares that the device conforms to Medical Device Directive 93/42/EEC of 14 June 1993. The four-digit number indicates the appointed body (TÜV SUED Product Service GmbH) which supervises the manufacturer's quality assurance system.
	This symbol indicates the month and year in which the next safety inspection is due.
	This symbol advises you that you must read the instruction manual supplied thoroughly.
	This hazard symbol advises you that failure to follow the instructions contained in the instruction manual can result in hazards to patients, the device user or the device itself.
	This symbol advises you that the device must be disconnected from the mains supply before the device housing can be opened by removing the device screws.
	This symbol (on a label inside the device) informs you of the earth connection.

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2.4 Intended purpose

The Barkey plasmatherm is a thawing and heating device intended for the following applications:

- timed heating of whole blood and blood products
- thawing and timed heating of frozen plasma conserves
- thawing and timed heating of HPC (haematopoietic progenitor cells)
- heating and maintaining the warmth of non-denaturable infusion solutions and other materials in continuous operation.

The Barkey plasmatherm can be used whenever it is desirable to prevent the cooling of patients as a result of transfusions, infusion solutions or other materials.

These summarised statements on the intended use of the device are supplemented in this instruction manual by specific descriptions of the various different applications and of the handling of the device. You will find these descriptions in the Chapters Safety advice to Operation of this instruction manual. Please use these chapters to find specific information about usage of the device in individual cases.

2.5 Contraindication

The device must not be used to heat or keep warm animals or to thaw, heat or keep warm objects or fluids of any kind except those as described under ‘Intended purpose’.

There are no known contraindications when thawing and/or heating blood and blood products.

2.6 Overtemperature protection

Independent overtemperature protection systems monitor the temperature of the device.

In the event of a fault or if an overtemperature limit is reached, the device's heating is switched off, the yellow LED in the display and operating panel lights up and a continuous alarm tone sounds.

Should this occur, switch off the device or disconnect the mains plug and wait for the device to cool down. This may take several minutes. Then switch on the device again, however the fault will return if the cause of the problem has not been rectified.

WARNING

If the overtemperature alarm sounds, any preparations that are in the device must be removed and checked before being transferred to the patient.

The Barkey plasmatherm must not be used if it has a fault. The device should be examined by Barkey GmbH & Co. KG or authorised personnel.

2.7 Safety features

- Safe, gentle thawing and heating conditions for the Blood, Plasma and HPC programs are ensured by a dual overtemperature protection which switches off the device in the event of overtemperature
- Proven not to destroy important and sensitive biological components of blood and blood products as a result of excessive temperatures or violent mechanical agitation
- Automatic detection of possible leaks by moisture sensors in the heating chamber
- The device uses a dry heating process that prevents the contents of damaged conserves (hairline cracks) being contaminated by the heat transfer fluid
- The heating procedure can be monitored. Fluid leakage is easy to detect through the use of transparent heating cushions, the light colours used in the heating chamber and white dry-paper (filter paper) on the heating chamber floor
- Plain text displays in the local language
- Clearly arranged and labelled displays and controls
- The device is designed for continuous operation
- Synthetic enclosure is corrosion free and saves energy
- The device is stable, designed not to tip over, and has non-slip feet

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3 Safety advice

3.1 Safety advice on the use of the device

⚠ **WARNING**	Before using the device, carefully read and familiarise yourself with these instructions and the user documentation for the optional accessories.
	Only use the device in accordance with the regulations as described previously in this chapter and in accordance with the processes described in this instruction manual.
	When heating blood and blood products, always ensure that the operating temperature and time limit are not exceeded. Remove and transfuse immediately when signal sounds!
	The blood products may only be heated and/or thawed with the programs specifically intended for them.
	If infusion solutions or medications are heated in the Barkey plasmatherm, you must ensure that their efficacy is maintained during heating and that the timed heating is approved by the manufacturer of the medication.
	If preparations leak, this is due to previously damaged conserve bags (e.g. hairline cracks, damage in transit). The sensors in the Barkey plasmatherm detect leaking moisture and stop the heating process.
	The undulation function is only activated in the Plasma and HPC programs. Do not use the undulation function for blood conserves due to possible mechanical damage and agglutination of erythrocytes.
	The device must not be used if it has a fault. The device should be examined by Barkey GmbH & Co. KG or authorised personnel.

3.2 Safety advice on handling the device

⚠ **WARNING**	Before using the device, carefully read and familiarise yourself with these instructions and the user documentation for the optional accessories.
	All electrical installations must comply with the relevant applicable regulations and standards in addition to the specifications stated by the manufacturer.
	Only power supply connections supplied by Barkey GmbH & Co. KG which are designed for the device's rated voltage may be used.
	The mains plug must be removed from the mains socket to ensure safe isolation of the device from the power supply.
	The device contains no parts which can be repaired by the user. Do not attempt to repair the device yourself. You should contact the manufacturer or your medical service technician who can request information about repairs from the manufacturer if necessary. Repairs and modifications to the device may only be carried out by Barkey GmbH & Co. KG or authorised personnel.
	The heating cushions of the device must not be allowed to come into contact with sharp-edged objects.
	The heating chamber and the heating cushions must be cleaned and disinfected at least once per week! The filter paper must be replaced after each cleaning.
	An annual safety inspection must be carried out by qualified service technicians **or** employees of Barkey GmbH & Co. KG.
⚠ **CAUTION**	The water must be changed once a year! You should always add two micropur tablets when refilling.
	Do not tilt the device when it is switched on!
	The battery (lithium battery CR 1225, 3 V) must be replaced every three years by qualified service personnel or employees of Barkey GmbH & Co. KG.
	Repairs and modifications to the device may only be carried out by qualified service technicians or by employees of Barkey GmbH & Co. KG.
	The device's rating plate is on the left-hand side of the housing.

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3.3 Safety advice on environmental influences

⚠ **WARNING**	The influence of strong electromagnetic fields (e.g. through the use of HF therapy or surgical devices) can lead to malfunctions in the Barkey plasmatherm. If interference of this type occurs, increase the distance between the Barkey plasmatherm and the device causing the interference, or operate the devices at different times. The Barkey plasmatherm works perfectly within the limit values set in the EN 60601-1-2 standard. The device can be influenced outside the limit values set by EN 60601-1-2.
	Portable and mobile HF communication equipment such as mobile phones can affect the device.
	Do not use the device in the immediate vicinity of • flammable materials (e.g. gases, liquids), • flammable mixtures of anaesthetic substances with air, • flammable mixtures of anaesthetic substances with oxygen or nitrous oxide whose flashpoint is below 50°C. It is imperative that the device is not used in areas in which alcohol disinfectants and anaesthetising substances are being used simultaneously.
	The device may not be set up or operated in the immediate vicinity of devices with a high heat output.
	The device must be positioned so as to ensure an unrestricted flow of air around its base.

3.4 Electromagnetic properties / safety distances

3.4.1 Electromagnetic emission

Guidelines and manufacturers declaration - Electromagnetic emission		
The Barkey plasmatherm is intended for operation in one of the environments listed below. The customer or user of the Barkey plasmatherm must ensure that it is operated in one of these environments.		
Radiated EMI measurements	**Compliance**	**Electromagnetic environment - guidelines**
HF outputs in accordance with CISPR 11	Group 1	The Barkey plasmatherm uses high-frequency energy for internal functions only. This means that HF emission is very low, and neighbouring electronic devices are unlikely to be affected.
HF outputs in accordance with CISPR 11	Class B	The Barkey plasmatherm is suitable for use in buildings other than residential and those which are directly connected to a public supply network which is also used to supply buildings used for residential purposes.
Harmonic output in accordance with IEC 61000-3-2	Class A	
Emission of voltage fluctuations/ flicker according to IEC 61000-3-3	Complies	

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3.4.2 Electromagnetic immunity

Guidelines and manufacturers declaration - Electromagnetic immunity			
The Barkey plasmatherm is intended for operation in one of the electromagnetic environments listed below. The customer or user of the Barkey plasmatherm must ensure that it is operated in one of these environments.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - Guideline**
Static discharge (ESD) according to IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	The floor should be constructed in wood or concrete or be covered with ceramic tiles. If the floor is covered with synthetic material, the relative humidity must be at least 30%.
Rapid transient electrical noise/ bursts according to IEC 61000-4-4	± 2 kV for power cords ± 1 kV for input and output cords	± 2 kV for power cords ± 1 kV for input and output cords	The quality of the supply voltage should comply with a typical business or hospital environment.
Surges according to IEC 61000-4-5	± 1kV voltage phase-to-phase ± 2kV voltage phase-to-earth	± 1kV voltage phase-to-phase ± 2kV voltage phase-to-earth	The quality of the supply voltage should comply with a typical business or hospital environment.
Voltage dips, short-time interruptions and fluctuations in supply voltage according to IEC 61000-4-11	< 5 % U_T (> 95 % drop of U_T) for 1/2 period	< 5 % U_T (> 95 % drop of U_T) for 1/2 period	The quality of the supply voltage should comply with a typical business or hospital environment. If the user of the Barkey plasmatherm requires continued use even if the power supply is interrupted, we recommend that the Barkey plasmatherm is connected to an uninterruptible power supply or battery.
	40 % U_T (60 % drop in U_T) for 5 periods	40 % U_T (60 % drop in U_T) for 5 periods	
	70 % U_T (30 % drop in U_T) for 25 periods	70 % U_T (30 % drop in U_T) for 25 periods	
	< 5 % U_T (> 95 % drop of U_T) for 5 s	< 5 % U_T (> 95 % drop of U_T) for 5 s	
Magnetic field at supply frequency (50/60 Hz) according to IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields at mains frequency should comply with the typical values as found in business and hospital environments.
NOTE: U_T is the mains AC supply before applying the test rule			

Guidelines and manufacturers declaration - Electromagnetic immunity			
The Barkey plasmatherm is intended for operation in one of the electromagnetic environments listed below. The customer or user of the Barkey plasmatherm must ensure that it is operated in one of these environments.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guideline**
Conducted HF interference according to IEC 61000-4-6 Radiated HF interference according to IEC 61000-4-3	3 V_{eff} 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V_{eff} 150 kHz to 80 Mhz 3 V/m 80 MHz to 2.5 GHz	Portable and mobile radio sets should not be used within a distance from the Barkey plasmatherm, including cords, that is less than the recommended safety distance as calculated by the relevant equation for the transmit frequency. **Recommended safety distance** $d = 1.17\sqrt{P}$ for 150 kHz to 80 MHz $d = 1.17\sqrt{P}$ for 80 MHz to 800 MHz $d = 2.33\sqrt{P}$ for 800 MHz to 2.5 GHz where P is the nominal power of the transmitter in Watts (W) as stated by the transmitter manufacturer, and d is the recommended safety distance in metres (m). The field strength of stationary transmitters should always be less than the compliance level [b] at all frequencies in accordance with an on-site investigation[a]. Interference is possible near devices that display 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 cases. The propagation of electromagnetic variables is affected by absorption and reflection of buildings, objects and people.			
[a] The field strength of static transmitters, such as base stations of radio telephones and mobile land radios, amateur radios, AM and FM radio and television transmissions cannot be accurately theoretically determined in advance. You should consider carrying out a site survey to determine the electromagnetic environment with regard to static transmitters. If the measured field strength at the location where the Barkey plasmatherm is being used exceeds the above compliance levels, the Barkey plasmatherm should be monitored to ensure that the device is functioning as intended. If unusual performance characteristics are observed, additional measures such as changing the alignment or location of the Barkey plasmatherm may be necessary. [b] The field strength should be less than 3 V/m in the frequency range 150 kHz to 80 MHz.			

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3.4.3 Recommended safety distance

Recommended safety distances between portable and mobile HF telecommunications devices and the Barkey plasmatherm

The Barkey plasmatherm is intended for operation in an electromagnetic environment in which HF interference is controlled. The customer or user of the Barkey plasmatherm can help avoid electromagnetic interference by observing the minimum distance between portable and mobile HF communications devices (transmitters) and the Barkey plasmatherm as stated below, depending on the output power of the communication device.

Nominal transmitter power W	**Safety distance depending on transmitter frequency m**		
	150 kHz to 80 MHz $d = 1{,}17\sqrt{P}$	**80 MHz to 800 MHz** $d = 1{,}17\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2{,}33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1,17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters whose maximum nominal output is not given in the above table, the recommended safety distance *d* in metres (m) can be determined using the equation belonging to the appropriate column, where *P* is the maximum nominal output of the transmitter in Watts (W) as stated by the transmitter manufacturer.

NOTE 1 The higher frequency level applies at 80 MHz and 800 MHz.

NOTE 2 These guidelines may not apply in all cases. The propagation of electromagnetic variables is affected by absorption and reflection of buildings, objects and people.

4 Operation

4.1 Putting into service

If you are putting a new or repaired device into service, you should first

- select a suitable location for it
- connect the necessary cords
- and fill the device with heat transfer fluid.

CAUTION

You must disinfect the heating cushions and heating chamber before using the device. This procedure is described in the Chapter Cleaning of these instructions.

4.1.1 Siting the device

The Barkey plasmatherm is designed for use as a fixed installation inside buildings. It is not intended for mobile use.

The Barkey plasmatherm must be set up on a stable, hard and level surface. Unobstructed access to the device from above and in front must be guaranteed.

CAUTION

The device must be lifted by a minimum of 2 people. When carrying, grip the device by the bottom edge only. Recesses are provided in the base for safe carrying.

CAUTION

The device is ventilated from below. It should therefore **not** be placed on a soft surface into which its feet could sink. There must be a minimum distance of 50 mm on 3 sides of the Barkey plasmatherm between it and walls, cabinets or other devices.

CAUTION

When selecting the location for the device, it is imperative that you maintain the distances stated in the Chapter Safety advice on environmental influences of this instruction manual from other devices with electromagnetic emission.

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4.1.2 Connecting the power cord, printer and barcode scanner

Optional peripheral devices such as a log printer or a barcode scanner can be connected to the Barkey plasmatherm. If you wish to use such devices, we recommend that you also connect their cables when the power cord of the Barkey plasmatherm is connected to the device.

CAUTION

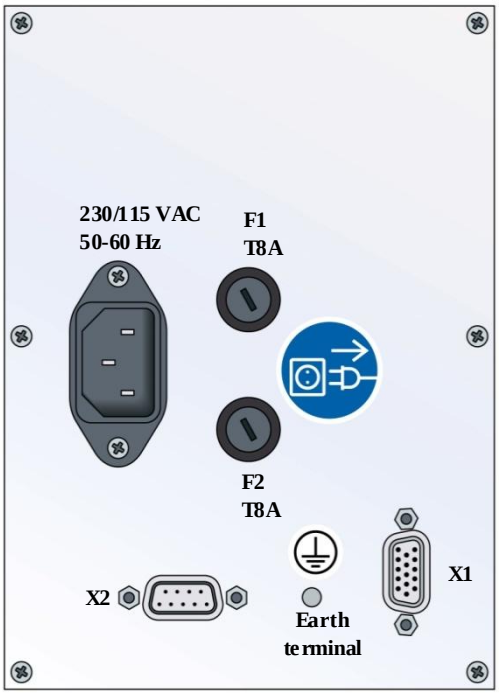
The Barkey plasmatherm may only be operated with the following two peripheral devices:

- EPSON TM-U220B-007 needle printer
- Honeywell CCD barcode scanner 3800g

These two devices together with their user documentation are available as accessories from Barkey GmbH & Co. KG. The use of other devices is not permitted.

If an optional peripheral device is connected to the Barkey plasmatherm for the first time, the appropriate signal connection for the peripheral device must be activated before it can be used. Details are described in a separate service description which can be requested from Barkey GmbH & Co. KG.

The device's termination panel is located on the underside (front left). The panel provides:



- a mains power socket (230/115 VAC 50-60 Hz / for non-heating appliances)
- a socket (X2) for optional connection of a log printer
- a socket (X1) for optional connection of a barcode scanner
- two mains fuses (F1 and F2, screw-in fuse holders)
- earth terminal
- a sticker with the labels the sockets in the termination panel

Figure 3: Terminal panel sticker

► Lift the device at the front or left to gain access to the sockets.

► Connect the supplied mains power cord with its plug for non-heating appliances to the non-heating appliance socket. The cord runs towards the back of the device.

CAUTION

Only use the power cord supplied. It is fitted with a non-heating appliance angle-entry plug and is matched to the device's operating voltage.

CAUTION

Cords may only be connected to the optional accessories, the printer or the barcode scanner when the Barkey plasmatherm has been turned off and the printer has been turned off.

► Connect the cable supplied with the printer with its smaller plug to socket X2. (This plug does not fit socket X1.) Using a suitable screwdriver, secure the plug in position with its two captive screws.

CAUTION

Only use the cable supplied to connect the printer.

► Connect the other end to the printer. Using a suitable screwdriver, secure the plug in position with its two captive screws.

► Connect the barcode scanner cord to socket X1. (This plug does not fit socket X2.) Using a suitable screwdriver, secure the plug in position with its two captive screws.

► Connect the printer to the mains using the cord supplied, and then switch the printer on.

NOTE

Do not forget to activate the device connections of the peripherals you are using when connecting peripherals to the Barkey plasmatherm for the first time. Details are described in a separate service instruction which can be requested from Barkey GmbH & Co. KG.

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4.1.3 Switching on

► Press the top button on the operating panel to turn the device on.

The green LED on the left-hand side of the operating panel lights up to show that the device has been switched on. The white background lighting and the yellow LED flash twice and an acoustic signal sounds at the same time.

CAUTION

Make sure that you can see that the device flashes and hear an acoustic signal. This will ensure that the displays and controls are functioning correctly.

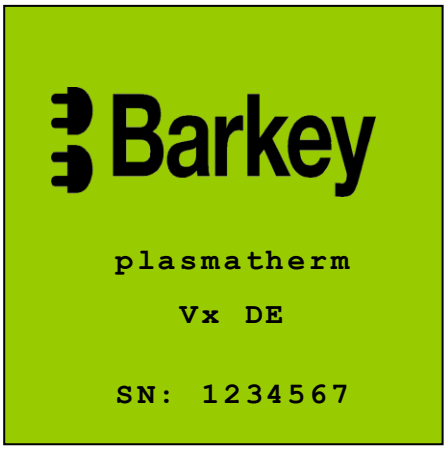

Figure 4: Login screen

When the device has been correctly filled with heat transfer fluid, the following information appears in the display for a maximum of 5 seconds:

- the Barkey logo
- the device name
- the software version Vx (x: current version)
- the abbreviation for the language variant (in the example shown: DE for German)
- the serial number (SN)

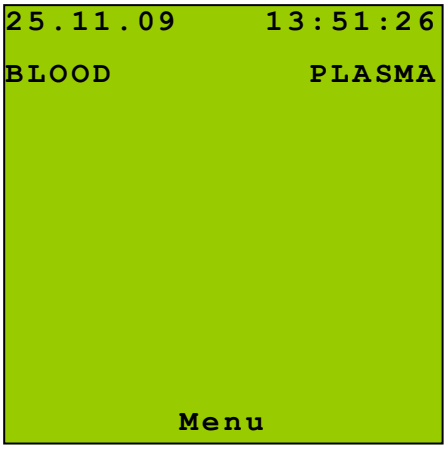

Figure 5: Main screen with program shortcuts

You will now see the main screen in the display:

- at top left is the current date and at top right the current time
- right and left are the shortcuts for the preset programs using the two top selection buttons, e.g. "BLOOD" and "PLASMA"
- and the entry "Menu" which launches the plasmatherm menu system when the confirm button is pressed.

If a barcode scanner is connected and the device connection is activated, the main screen displays additional information which can be used to scan in up to 8 sample IDs as well as the user ID. Details on scanning in barcodes are given in Chapter 4.7.

► If a log printer is connected to the Barkey plasmatherm and the corresponding device connection is activated, switch the printer on as well.

The Barkey plasmatherm is now ready for operation.

NOTE

The device can be switched off at any time by pressing the top button on the operating panel.

4.1.4 Switching on if the fill level is too low

If the fill level in the Barkey plasmatherm is too low when it is switched on, the menu for filling the tanks is shown first after the initial screen. The prompt "Fill Tank" is additionally highlighted by flashing.

NOTE

You cannot quit this menu until a certain level is reached in the tank or the device is switched off again.

Figure 6: Low fill level, "FILL Tank" prompt

When the tank is filled and the required level has been reached, the "FILL Tank" prompt is replaced by the information "Tank is FULL" which also flashes. An intermittent acoustic signal also sounds.

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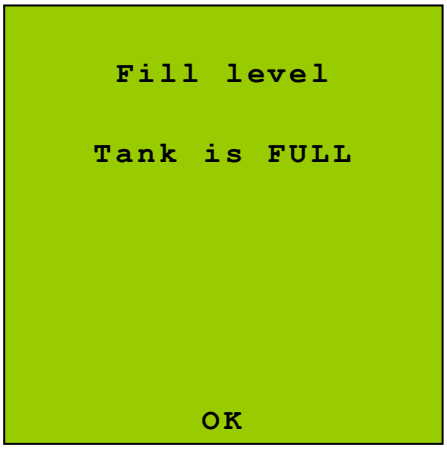

Figure 7: Confirmation with "OK" is possible

The text "OK" at bottom centre now indicates that the confirm button is assigned the acknowledge function. Pressing the confirm button ("OK") automatically restarts the Barkey plasmatherm and displays the main screen with the user menu.

4.1.5 Filling

To fill the device you will need approx. 9 litres of distilled or demineralised water and two micropur tablets.

► When filling the device from empty, switch the device on with the On/Off button. It will now display a message asking you to fill the water.

► To fill with water, select the fill level display described in the Chapter Filling with water from the menu.

► Place two micropur tablets in the filler opening.

⚠ **CAUTION**

Always add two micropur tablets to the distilled or de-mineralised water.

For devices supplied new or exchange devices, or following maintenance and repairs, the two micropur tablets are always already inside the tank for the heat transfer fluid.

► Place a suitable funnel in the filler opening and fill up the device with the necessary quantity of de-mineralised or distilled water:

- approx. 9 litres when filling from empty
- approx. 1 litre when topping up after a warning or error message prompting you to top up

► Stop filling immediately you hear the acoustic signal and see the message "Tank is FULL".

► Acknowledge the message with the confirm button ("OK").

► Screw the plug back into the filler opening. Use a coin or similar to tighten the plug.

The device is now correctly filled with heat transfer fluid.

Proceed as following to bleed the heating cushions:

- ► Pull the left-hand top tube out of the push-fit connector so that the water can rise in the water ducts.
- ► Wait for around 5 seconds. Now re-connect the tube to the push-fit connector.
- ► First, start a program without any product to heat.
- ► If the pump does not immediately pump heat transfer fluid into the cushions, stop the program and start it again after waiting for a short time. If necessary, repeat the start and stop operations a few times until the pump starts pumping fluid.
- ► Once the heating cushions have been filled, open the cover of the heating chamber.
- ► Squeeze out any air bubbles present in the cushions with your hands, pressing towards the right-hand tube connection. Any bubbles removed can be heard as a gurgling sound.
- ► Close the cover so that the heating cushions fill up again.
- ► If there are still significant amounts of air in the heating cushions, the process must be repeated.

Small bubbles disappear once the heat transfer liquid has been warmed up.

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4.2 Opening the heating chamber

► Press the green button on the front of the device above the operating panel to open the heating chamber, and guide the automatically raised heating chamber cover until it stops.

The cover should remain closed when the device is not in use.

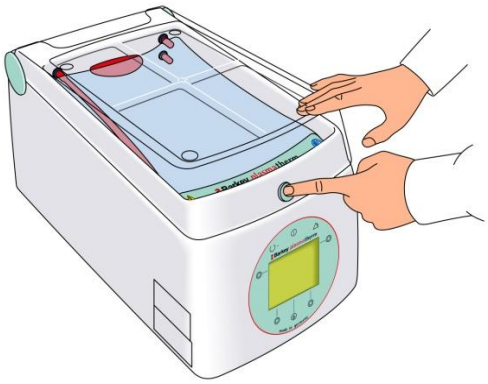

Figure 8: Cover locking/release button

Press the button to open the heating chamber. The cover lifts automatically, so should be guided with one hand to its end stop as shown.

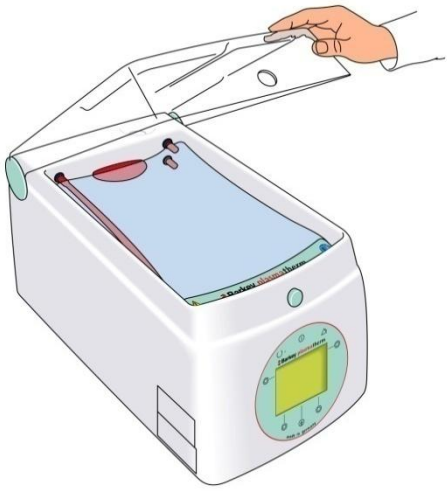

Figure 9: Cover open

To close the heating chamber, press the cover down until you hear the button engaging in the hole in the cover.

WARNING

Keep your fingers away from the edge of the cover! There is a danger of crushing.

CAUTION

Programs will only run when the heating chamber cover is closed. Otherwise the device will sound an intermittent acoustic signal and display a warning message (see the Chapter Selecting and starting the “PLASMA” program).

4.3 Loading

The Barkey plasmatherm can be loaded with product in two ways:

1. between the heating cushions (effective loading)
2. between dry-paper (filter paper, see also the Chapter Dry paper) and the lower cushion (in an emergency only; this option is intended for emergencies and involves a longer warm-up phase because the product on the bottom of the heating chamber is not heated from both sides.)

► Lift up the heating cushions by the grip and place the product to be heated or thawed in the required position.

WARNING

Do not place conserves beneath the paddle. The paddle is marked red to aid identification.

► Place the heating cushions back over the conserves without any folds if possible.

► Close the heating chamber cover until the cover button engages.

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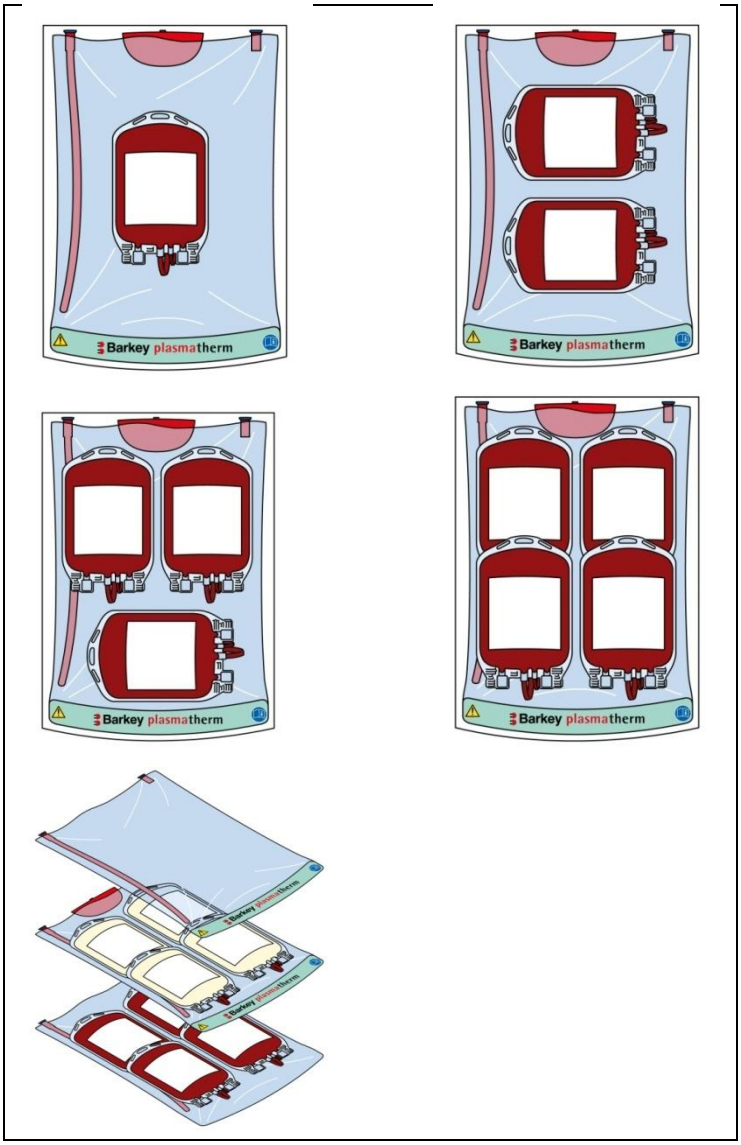

Figure 10: Optional loading positions for conserves

4.4 Selecting and starting a program with the menu system

The main screen is displayed automatically when the Barkey plasmatherm is switched on.

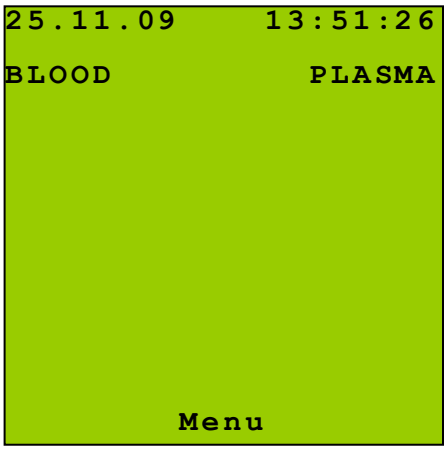

Figure 11: Main screen

A program can be selected with the menu system or with the top two function buttons which are pre-assigned programs and can be used as selection shortcuts. Assigning the shortcut programs is described in the following chapters.

The left and right-hand function buttons can be used to select and start the defined programs ("BLOOD" and "PLASMA" in this example).

The confirm button ("Menu") takes the user to the main menu of the user menu.

The route that uses the main menu is described below.

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4.4.1 Selecting and starting the "PLASMA" program

► In the main screen, press the confirm button ("Menu") to start the menu system.

► The main menu of the user menu provides 4 options.

Figure 12: Main menu of the user menu

► Using the left or right-hand selection button ("▼" or "▲"), select "Program", then press the "OK" button to confirm your choice.

You will now see the "Program" submenu; the user has a choice of 5 programs:

"PLASMA"	for thawing FFP´s
"BLOOD"	for heating blood or EC´s
"HPC"	for thawing stem cells
"USER"	a user-configurable program for clinic-specific standards
"CONTINUOUS"	for heating and keeping warm non-denaturable infusion solutions

The selection of the "PLASMA" program is described here by way of example; to select the "BLOOD", "HPC", "USER" and "CONTINUOUS" programs, proceed as described for the "PLASMA" program

Figure 13: User menu - Program

► Select the required program with the left or right-hand selection button ("▼" or "▲"), e.g. "Start PLASMA", then press the "OK" button to confirm your choice.

WARNING

Plasma, blood and HPC may only be heated for a limited period of time!
Do not use the device to keep these products warm indefinitely!

WARNING

Blood/whole blood may not be heated up if the current operating temperature of the device is over 37 °C. The device will display a warning message in this case.

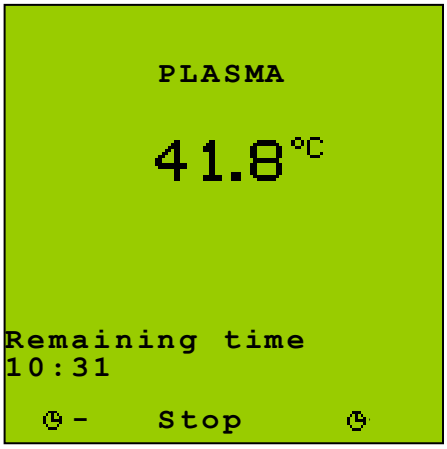

Figure 14: "PLASMA" program

► When a program is started, the display will show the program name, the current water temperature and the current remaining time, among other information.

When a program is started, the heating cushions fill with heat transfer fluid and bed the transfusion product in. The heat transfer fluid is heated up and circulates in the heating cushions. The program's remaining runtime is shown in the display.

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Preferences may be set up for the various programs:

- The heating duration can be preset for the "PLASMA", "BLOOD" and "HPC" programs.
- With the "PLASMA" program, the nominal temperature of the heat transfer fluid can be preset in the service menu. Details are described in a separate service description which can be requested from Barkey GmbH & Co. KG.
- Other parameters for the "USER" program can also be preset in the service menu. Details are described in a separate service description which can be requested from Barkey GmbH & Co. KG.

Changing the remaining time for the "PLASMA", "BLOOD", "HPC" and "USER" programs with the left-hand ("◷-") or right-hand selection button ("◷+") is described in the Chapter Changing the remaining time.

If the confirm button ("Stop") is pressed while a program is running, the program is cancelled and the main screen is displayed again (see the Chapter Messages after the end of a program).

NOTE

Since no remaining time is active with the "CONTINUOUS" program, the display shows "--:--". Changing the remaining time is not possible.

4.4.2 Changing the remaining time

While a program is running, the user can alter the remaining time – usually between 30s and 99min – with the left or right-hand selection button ("◷-" or "◷+"). If the current remaining time is already less than 30s, then this counts as the minimum permitted input so that the remaining time cannot be unintentionally increased.

NOTE

Since no remaining time is active with the "CONTINUOUS" program, the display shows "--:--". Changing the remaining time is not possible.

If the current remaining time can be changed, it is initially frozen for the current program when one of the two selection buttons ("◷-" or "◷+") is pressed. Depending on which button is pressed, the displayed remaining time is then rounded up or down to the nearest whole 10s and the display flashes to optically highlight the active remaining time adjustment.

After the remaining time has been changed, pressing the confirm button ("OK") enters the new setting, and the current program is resumed.

If neither one of the two selection buttons ("◷-" or "◷+") nor the confirm button ("OK") is pressed within 5s, any new remaining time that has been selected will be rejected, the original remaining time is reactivated and the current program is resumed.

4.4.3 Messages at the start of a program

Blood/whole blood should not be heated if the current operating temperature of the device is over 37 °C, for example if you have previously thawed and heated plasma and you then activate a program for heating blood/whole blood. You can nevertheless still start the "BLOOD" program.

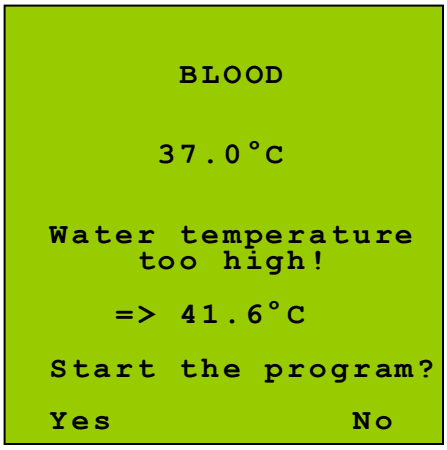

Figure 15: Message "Water temperature too high!"

- ► Acknowledge the display with the left-hand selection button ("Yes") to start the program despite the water temperature being too high.
- ► Acknowledge the display with the right-hand selection button ("No") if you do not wish to start the program.

4.4.4 Messages while a program is running

If the heating chamber cover is opened while a program is in progress, the remaining time is 'frozen', a message appears in the display and heat transfer fluid circulation is paused. An intermittent acoustic signal sounds if the cover is not closed within 16s.

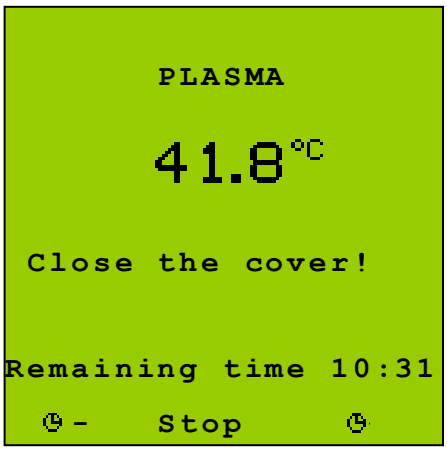

Figure 16: Message "Close the cover!"

- ► Close the heating chamber cover to resume the program.

NOTE

If paddle motion was active when the cover was opened, it will not resume until the heating cushions have sufficiently filled again.

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When a program has been started, the connection between the device and a connected log printer is verified if a printer has been configured in the service menu. If the printer is not connected, or if it is switched off or has a fault, the user is made aware of this by a flashing icon ("") in the top left corner of the screen. If this happens, no further data is sent to the printer while the current program is in progress, but this will not affect the actual heating operation.

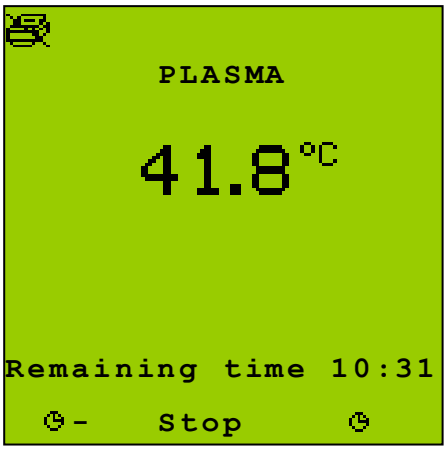

Figure 17: Printer message

- ► Connect the printer up to the Barkey plasmatherm and check that it is operating correctly.
- ► If necessary, cancel the program and start it again for correct logging.

Whatever the status of the printer connection after the program starts, there is no further check on the printer during the ongoing program.

When a program has been started, the connection to an IT network is also verified if this has been configured in the service menu. If the Barkey plasmatherm is not connected to the network, or if the network connection is faulty or the remote terminal is not ready or has a fault, the user is made aware of this by a flashing icon ("") in the top left corner of the screen. If this happens, no further data is sent to the IT network while the current program is in progress.

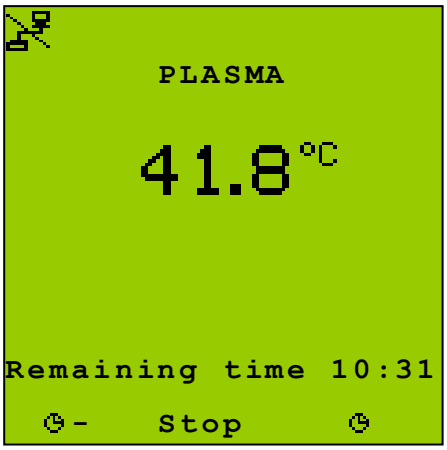

Figure 18: IT message

- ► If necessary, connect the Barkey plasmatherm to the network and ensure that the remote terminal is ready for operation and fault-free.
- ► If necessary, cancel the program and start it again for correct logging.

Whatever the status of the IT connection after program start, there is no further check on the connection during the ongoing program, but this does not affect the actual heating operation.

If a "Lack of water" message as described in the Chapter Messages after the end of a program is acknowledged 4 times at the end of a program without water being topped up, then an active program will be immediately cancelled the next time low water is detected.

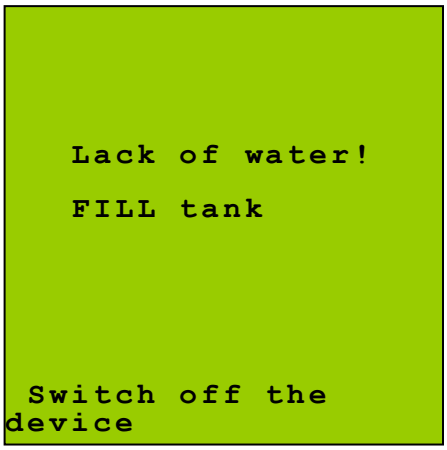

Figure 19: Message "Lack of water!"

- ► Switch off the device.
- ► Switch the device on again.
- ► Top up with water as described in Chapter 5.3.2

4.4.5 Messages after the end of a program

When the heating duration has elapsed, the flashing message "Program complete" appears and an intermittent signal sounds. This indicates that the program has finished and prevents inadvertent further heating.

Figure 20: Program complete

- ► Open the heating chamber cover

or

- ► Acknowledge the end of the program with the confirm button ("OK")

If a lack of water was previously detected while the program was running, then another message is displayed when the "Program complete" message is acknowledged.

As well as an appropriate on-screen message being displayed, an intermittent acoustic signal is sounded. This will be a rapid sequence of pulses to distinguish the signal from the signal that indicates the normal end of a program. Here again, the message must be acknowledged by pressing the confirm button ("OK").

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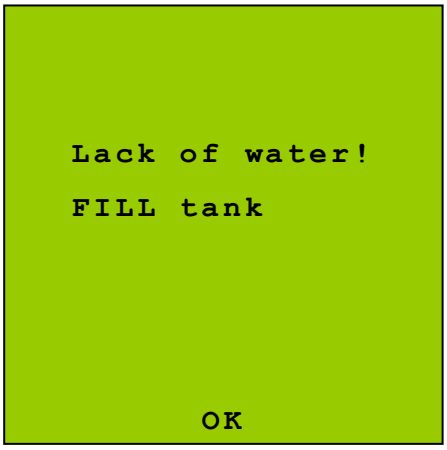

- ► Acknowledge the message with the confirm button ("OK")
- ► Top up with water as described in Chapter 5.3.2

Figure 21: "Lack of water" message at the end of a programme

NOTE

This message is also output if the program is cancelled manually or as the result of an error.

NOTE

If this message is acknowledged 4 times without water being topped up, then an active program will be immediately cancelled the next time low water is detected (see the Chapter Messages while a program is running).

4.4.6 Presetting the heating duration of the "PLASMA" program

This chapter describes how to preset the heating duration, taking the "PLASMA" program as an example; to preset the heating duration of the "BLOOD", "HPC" and "USER" programs, please proceed as described for the "PLASMA" program.

WARNING

Plasma, blood and HPC may only be heated for a limited time! You must not use this device for keeping these products warm indefinitely!

► In the main screen, press the confirm button ("Menu") to start the menu system.

Figure 22: User menu

The user menu appears.

► Using the left or right-hand selection button ("▼" or "▲") in the user menu, select "Heating duration", then press the "OK" button to confirm your choice.

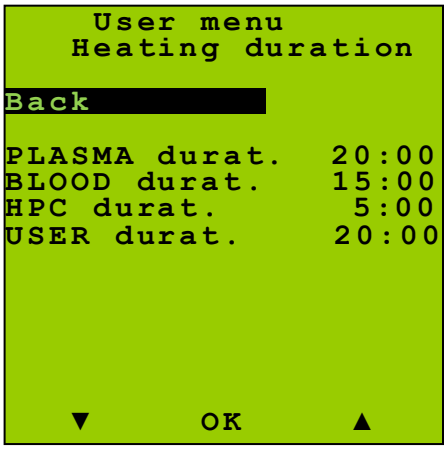

Figure 23: Heating duration menu

In this submenu you can select the required program using the left or right-hand selection button ("▼" or "▲") and then press the confirm button ("OK") to activate the change to the corresponding heating duration.

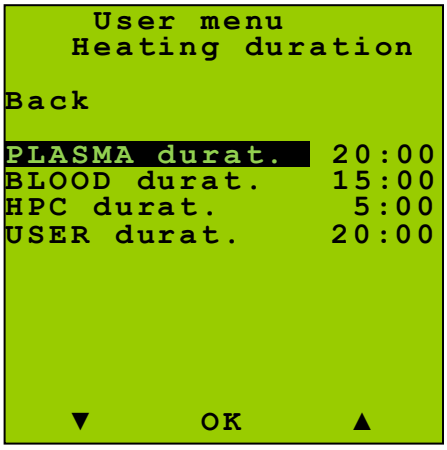

Figure 24: Setting the heating duration for the "PLASMA" program

You will now see this display for setting the heating duration for the "PLASMA" program.

► Press the confirm button ("OK").
The flashing heating duration can now be set individually for the selected program by using the left or right-hand selection button ("◷-" or "◷+").

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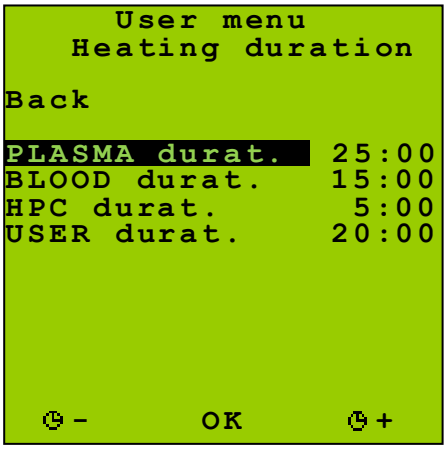

Figure 25: Changed heating duration for the "PLASMA" program

► When you have changed the heating duration press the confirm button ("OK").

Pressing the confirm button ("OK") will enter the currently set heating duration for the selected program ("PLASMA" in this example). The required option can now be selected again with the left or right-hand selection button ("▼" or "▲").

Figure 26: User menu

► In the heating duration menu, select "Back" to return to the user menu.

The heating duration has been successfully changed. To change the heating durations for "BLOOD", "HPC" and "USER", please proceed as described above.

4.4.7 Guideline values for the heating duration when thawing FFP

When a program is in progress, the Barkey plasmatherm main screen displays the temperature of the heat transfer fluid. This displayed temperature is not the same as the temperature in the blood products.

The heating duration (i.e. the length of time which the Barkey plasmatherm needs to thaw one or four FFP´s simultaneously, for example) will depend on a number of additional factors (such as the initial temperature of the FFP´s, the temperature of the heat transfer fluid, the fill volume of the FFP´s, the number of FFP´s, choice of program etc.).

The guideline values listed in Table 2 (guideline heating duration in minutes to reach at least 5°C in each FFP) and Table 3 (guideline heating duration in minutes to reach 33°C) apply under the conditions indicated in Table 1.

NOTE

Different conditions (such as the starting temperature of the FFP´s, the temperature of the heat transfer fluid, the fill volume of the FFP´s, the number of FFP´s, choice of program etc.) may result in different heating durations.

NOTE

Conditions:

"PLASMA" program selected

Size of the FFP´s (170 x 110 x 20 mm)

Filling volume per FFP approx. 250 ml/preparation

Starting temperature: - 35°C

Outer packaging: none

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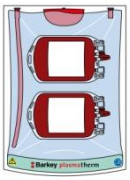
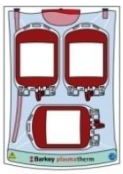
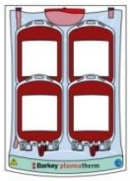
Conditions

Program	FFP Dimensions	Filling volume per FFP	Loaded with 1 FFP	Loaded with 2 FFP´s	Loaded with 3 FFP´s	Loaded with 4 FFP´s
PLASMA	(approx. 170 x 110 x 20 mm) no additional packaging	250ml				

Heating duration in minutes to reach 5°C

System temperature	Number of FFP´s (see Table 1 for layout)			
	1	2	3	4
45°C	11	11	12	12
37°C	14	14	15	15

Heating duration in minutes to reach 33°C

System temperature	Number of FFP´s (see Table 1 for layout)			
	1	2	3	4
45°C	14	14	16	20
37°C	22	22	24	30

4.4.8 Presetting the heating duration and starting the "BLOOD" program

WARNING

Plasma, blood and HPC may only be heated for a limited period of time!
Do not use the device to keep these products warm indefinitely!

WARNING

Blood/whole blood may not be heated up if the current operating temperature of the device is over 37 °C. The device will display a warning message in this case.

The process for presetting the heating duration and starting the "PLASMA" program is described in the Chapters Selecting and starting the “PLASMA” program and Messages at the start of a program; to preset the heating duration and start the "BLOOD" program, please proceed in the same way but select "BLOOD" instead of "PLASMA" as the program.

4.4.9 Presetting the heating duration and starting the "HPC" program

WARNING

Plasma, blood and HPC may only be heated for a limited period of time!
Do not use the device to keep these products warm continuously!

The process for presetting the heating duration and starting the ”PLASMA” program was described in the Chapters Selecting and starting the “PLASMA” program and Messages at the start of a program; to preset the heating duration

and start the ”HPC” program, please proceed in the same way but select ”HPC” instead of ”PLASMA” as the program.

4.4.10 Presetting the heating duration and starting the "USER" program

WARNING

Plasma, blood and HPC may only be heated for a limited period of time!
Do not use the device to keep these products warm indefinitely!

WARNING

Blood/whole blood may not be heated up if the current operating temperature of the device is over 37 °C. The device will display a warning message in this case.

The process for presetting the heating duration and starting the "PLASMA" program was described in the Chapters Selecting and starting the “PLASMA” program and Messages at the start of a program; to preset the heating duration and start the "USER" program, please proceed in the same way but select "USER" instead of "PLASMA" as the program.

Other parameters in the "USER" program can only be set in the service menu (see separate service instructions). Since there is a danger that the products that are being heated might be impaired or destroyed due to incorrect parameter settings, you should always observe the following safety information.

WARNING

The undulation function should not be used while heating up blood conserves or erythrocyte concentrates so as to avoid mechanical stress on the cellular material or prevent agglutination.

WARNING

Setting up the "USER" program should only be carried out and documented by experienced medical personnel to prevent harmful operating temperatures and times.

4.4.11 Heating in continuous operation

WARNING

Plasma, blood and HPC may only be heated for a limited period of time!
Do not use the device to keep these products warm indefinitely!

You may only use continuous operation for non-denaturable products such as common salt solution!

Starting the "PLASMA" program was described by way of example in the Chapters Selecting and starting the “PLASMA” program and Messages at the start of a program; to start the "CONTINUOUS" program, please proceed in the same way but select "CONTINUOUS" instead of "PLASMA" as the program.

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NOTE

Time settings and undulation functions are not available in continuous operation.

4.5 Function button assignment

The top two function buttons on the operating panel are assigned programs which you can start as soon as you switch on the device without going through the menu system.

In the "Function Buttons" option of the user menu, you can assign the two buttons as shortcuts for the programs which you use most frequently, or you can assign any desired programs.

Figure 27: User menu

- ► In the main screen, press the confirm button ("Menu") to start the menu system.

The user menu appears.

- ► Using the left or right selection button ("▼" or "▲") in the user menu, select "Function Buttons", then press the "OK" button to confirm your choice.

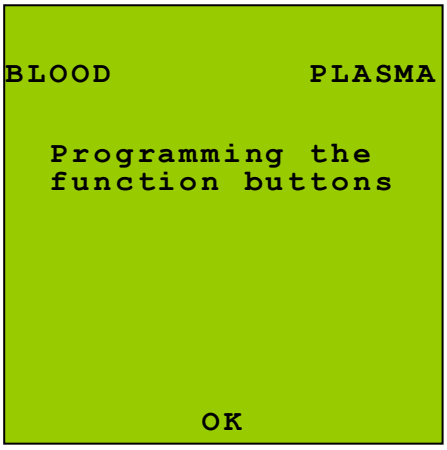

Figure 28: Assigning shortcut programs to the top two function buttons

A screen is displayed showing both currently set shortcut programs, e.g. "BLOOD" and "PLASMA" as shown in the adjacent figure.

- ► Press the top left-hand function button repeatedly until the desired program is displayed on the left.
- ► Similarly, assign a program to the top right-hand function button.
- ► Now confirm your choices by pressing the confirm button ("OK") once the two programs have been assigned as required.

These settings are retained until the buttons are re-assigned.

4.6 Fill level display

The "Fill level" option is used to check the current fill level in the Barkey plasmatherm. Depending on the level, the message "FILL Tank" (i.e. water is low) or "Tank is FULL" (there is sufficient heat transfer fluid) is displayed.

Figure 29: User menu

► In the main screen, press the confirm button ("Menu") to start the menu system.

The user menu appears.

► Using the left or right-hand selection button ("▼" or "▲") in the user menu, select "Fill Level", then press the "OK" button to confirm your choice.

Figure 30: Fill level menu - "FILL Tank" message

The filling status will be displayed as shown in the adjacent figure. Depending on the level, the message "FILL Tank" (i.e. water is low) or "Tank is FULL" (there is sufficient heat transfer fluid) is displayed.

CAUTION

If "FILL Tank" is displayed as shown in the example, you must top the device up with distilled or demineralised water. To do this, proceed as described in the Chapter Filling with water of these instructions for use.

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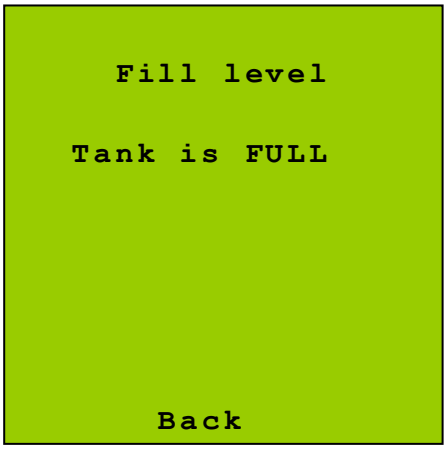

Figure 31: Fill level menu - "Tank is FULL" message

If the tank contains sufficient heat transfer fluid, then "Tank is FULL" is displayed as the status. The display's background lighting flashes and an intermittent acoustic signal sounds.

► Press the confirm button ("Back") to return to the user menu.

4.7 Barcode scanner

If a barcode scanner is connected to the Barkey plasmatherm DTM and properly configured in the service menu, then the user ID and up to 8 sample ID's can be scanned in in the main screen.

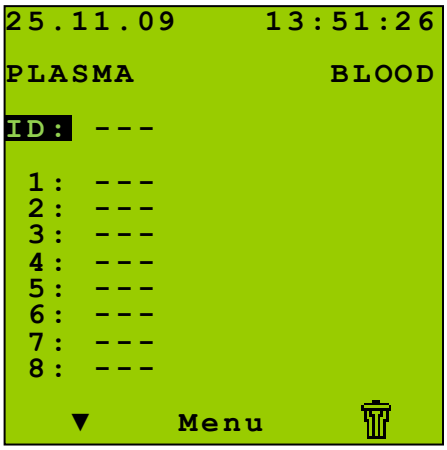

Figure 32: User ID and sample ID

If no user ID or sample ID has yet been scanned in, the reverse highlighted text "ID": marks the cursor position for entering the user ID. When the appropriate barcode has been scanned in, it is displayed at the "ID" position and the input cursor moves down automatically to the position for the first sample ID ("1:"). If a user ID is not required, you can scan in a dummy code or move to the position of the first sample ID by pressing the left-hand selection button ("▼"). You can now scan in the corresponding sample ID. The cursor moves automatically to the next position after each scan.

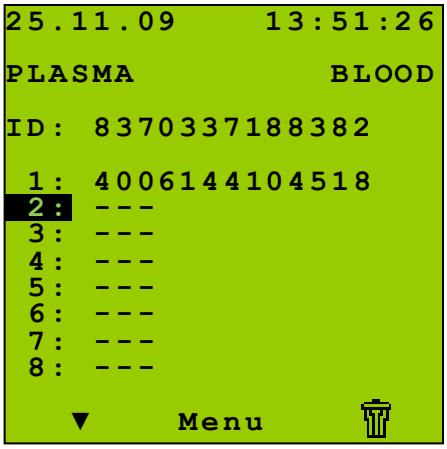

Figure 33: Scanned user ID and sample ID

It is not necessary to scan in all 8 sample ID's. A program can be started at any time.

If an 8th sample ID is scanned in however the insertion point will move to the "▼" icon and this will also be shown reverse highlighted. No more barcodes can now be scanned in.

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If you wish to correct or delete the user ID, you must select the "ID" position with the left-hand selection button ("▼"). After a further scan operation the user ID is then over-written with the currently scanned barcode, and the insertion point moves to position "1:".

If the right-hand selection button (" 🗑 ") is pressed at the position "ID:", then the user ID is deleted. Here again, the insertion point then moves to position "1:".

Correcting or deleting a sample ID is done in the same way.

The barcodes for the user ID and for the 8 sample ID's are automatically deleted when a program has properly completed. If a program is cancelled either manually or because an error occurs, the data are initially retained. They can be deleted manually if required, as described above. All scanned in barcodes will in any case be deleted when the device is switched off.

5 Cleaning and care

5.1 Cleaning

The Barkey plasmatherm's smooth surfaces and rounded corners make it simple and easy to clean.

The surfaces of the device should be cleaned and wipe-disinfected regularly, if possible after every use,

WARNING

Before cleaning or wipe-disinfecting the device:

- Switch off the plasmatherm by operating its On/Off button and disconnect its mains plug from the mains socket.
- Do not pour cleaning fluid or disinfectant directly onto the device. Always moisten a cloth and then use this cloth to clean the device.
- Never pour cleaning fluid into the device's ventilation holes.
- Do not disinfect the device with steam (e.g. in the autoclave), hot air or thermochemical cleaning solutions.

You should use standard commercial preparations based on alcohol without oxygen-releasing components (with sodium hypochlorite with 1.4% bleach solution or aldehyde content < 0.2%) as a disinfectant.

► If possible clean the device with a solution of soap and water.

► Dry the surfaces and use a surface disinfectant.

► **Follow the application time stated by the disinfectant manufacturer!**

► After allowing the disinfectant to act, dry the device off with disposable tissues.

WARNING

The user must not use any other cleaning or decontamination methods than those recommended by the manufacturer.

If you intend to use alternative cleaning products or decontaminants, you must first consult the manufacturer to ensure that the proposed methods will not damage the device.

Otherwise we would refer you to the hygiene procedures and regulations which apply in your hospital.

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5.2 Dry paper

When the device is shipped, the heating chamber floor is lined with filter paper (dry paper) for hygiene control. The dry paper will indicate any leaks in the conserves or contamination within the device itself, enabling early recognition.

If the filter paper becomes moist, the two sensors (metal contacts) on the heating chamber floor are short-circuited, triggering an audible signal and a flashing warning message in the display.

► Replace the dry paper after carrying out a full cleaning routine.

NOTE

Dry paper can be ordered from Barkey GmbH & Co. KG:
Article No. 212.10005, pack of 60 sheets

5.3 Changing the water

You will need two micropur tablets for the annual water change.

When the water is changed every year, there will be no long-term bacterial growth provided micropur tablets and distilled or demineralised water are used.

NOTE

Micropur tablets can be ordered from Barkey GmbH & Co. KG if required.

Please proceed as follows to replace the water:

5.3.1 Draining off the water

► Switch off the device with the On/Off button.

WARNING

Do not pull the device further forward than indicated in the following step!

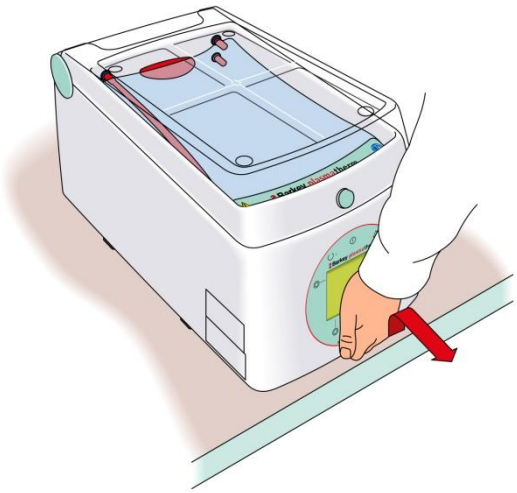

Figure 34: Pulling the device forward

► Pull the device forward over the front edge of the surface on which it is standing, so that its front projects by approx. 15 cm.

► Two extra feet under the device prevent it tipping forward.

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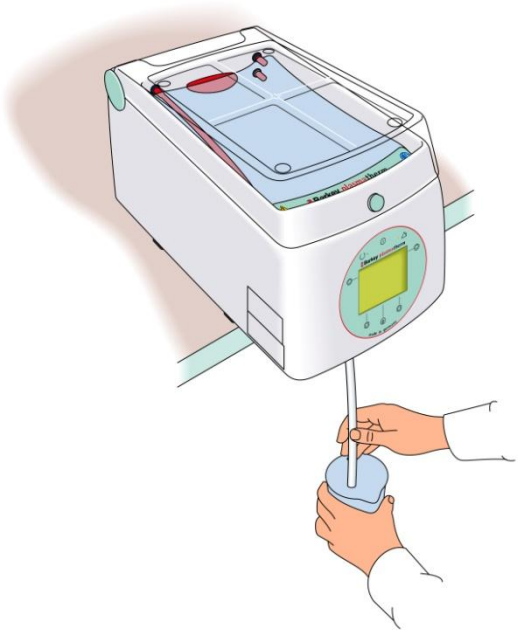

Figure 35: Drain tube

► Pull the drain tube downwards out of its recess in the base of the device and hold the end of the tube over or in a container ready to catch the heat transfer liquid.

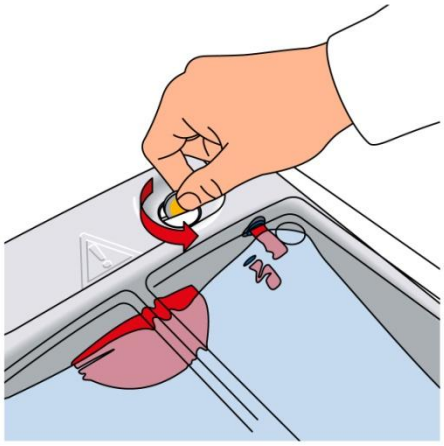

Figure 36: Filler opening with plug

► Unscrew the plug from the filler opening (at back right on the top of the device) by turning it anticlockwise. Use a coin for this purpose.

Figure 37: Opening the drain cock

► Open the drain cock by turning it anticlockwise (90º). Allow the heat transfer liquid to drain off.

► Lift the heating cushions slightly and ensure that they drain completely.

► Hold the device firmly and tilt it gently forward until it is completely empty.

► Now close the drain cock, push the drain tube back into its recess in the base of the device so that it is retained by the studs located on either side, and push the device back so that it is standing fully on its base.

5.3.2 Filling with water

► If you are not filling the device from empty but just topping it up:
Unscrew the plug from the filler opening as described in the Chapter Draining off the water.

► When filling the device from empty, switch the device on with the On/Off button.
It will now display a message asking you to fill with water.

► To fill with water, select the fill level display described in the Chapter Fill level display from the menu.

► Place two micropur tablets in the filler opening.

CAUTION

Always add two micropur tablets to the distilled or de-mineralised water.

For devices supplied new or exchange devices, or following maintenance and repairs, the two micropur tablets are always already inside the tank for the heat transfer fluid.

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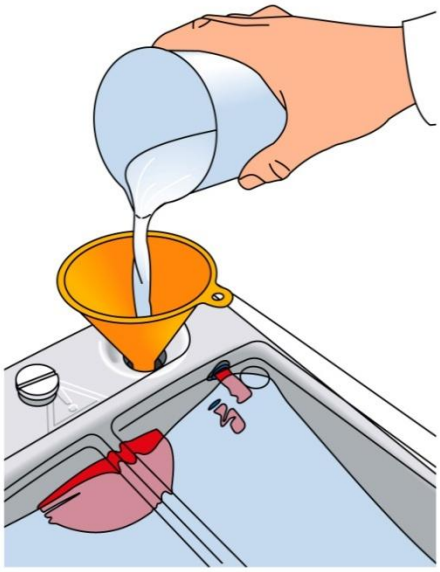

Figure 38: Filling

► Place a suitable funnel in the filler opening and fill the device with the necessary quantity of de-mineralised or distilled water:

- approx. 9 litres when filling from new
- approx. 1 litre when topping up after a warning or error message prompting you to top up

► Stop filling immediately you hear the acoustic signal and see the message "Tank is FULL".

► Press the confirm button ("OK").

► Screw the plug back into the filler opening. Use a coin to tighten it up.

The device is now correctly filled with heat transfer fluid.

Proceed as following to bleed the heating cushions:

► Pull the left-hand top tube out of the push-fit connector so that the water can rise in the water ducts.

► Wait for about 5 seconds. Now re-connect the tube to the push-fit connector.

► First, start a program without any material to heat.

► If the pump does not immediately pump heat transfer fluid into the cushions, stop the program and start it again after waiting for a short time. If necessary, repeat the start and stop operations a few times until the pump starts pumping fluid.

► Once the heating cushions have been filled, open the cover of the heating chamber.

► Squeeze out any air bubbles present in the cushions with your hands, pressing towards the right-hand tube connection. Any bubbles removed can be heard as a gurgling sound.

► Close the cover so that the heating cushions fill up again.

► If there are still significant amounts of air in the heating cushions, the process must be repeated.

► Small bubbles disappear once the heat transfer liquid has warmed up.

6 Maintenance

Besides cleaning the device and performing the electrical safety checks according to Regulation BGV A3*, other maintenance measures that must be carried out are a regular safety check and regular battery replacement.

These two operations may only be carried out by qualified service personnel or employees of Barkey GmbH & Co. KG. Training for medical technicians in checking and repairing the Barkey plasmatherm is available at the factory of Barkey GmbH & Co. KG. Please call us on +49 (5202) 9801-30 for information about current availability and costs.

At the end of these instructions you will find a blank form for a device master data sheet. This can be used as the front page for a service history in which all maintenance work should be recorded.

* BGV A3 ⇔ Regulation for the Prevention of Industrial Accidents (Electrical Systems and Equipment)

6.1 Technical safety inspection (TSI)

As with all electronic devices, the Barkey plasmatherm's temperature setting is dependent on normal ageing and on the tolerances of the electronic components.

To ensure that the temperature settings on the Barkey plasmatherm are always within the stated tolerances, a technical safety inspection (TSI) must be carried out each year by qualified service personnel or by employees of Barkey GmbH & Co. KG (see Section 6 MPBetreibV*).

The technical safety inspection should include the mandatory annual electrical safety check on the Barkey plasmatherm.

The Barkey plasmatherm always runs a self-check when it is switched on, so a technical safety inspection essentially covers the measuring functions of the device. Safety inspections also include checking the ventilation grilles at the air intake and outlet and cleaning them as necessary.

All the work necessary for servicing and the TSI is described in a separate service manual which can be requested from Barkey GmbH & Co. KG.

* MPBetreibV ⇔ Operators of Medical Products Directive

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6.2 Replacing the battery

The device battery (lithium battery CR 1225, 3 V) must be replaced every 3 years.

CAUTION

Only qualified service personnel and employees of Barkey GmbH & Co. KG may replace the battery. Please dispose of any batteries properly in accordance with regulations. The device clock will need to be reset after replacing the battery.

7 Error messages

Errors which require the device to be restarted or attended to by a technician are indicated by a plain text message on the display and an error number that is stored in the device for subsequent diagnosis. The yellow fault lamp (LED) on the operating panel is also activated and a continuous warning tone is sounded by the signal generator.

When an error message occurs requiring the device to be switched off, proceed as follows:

- ► Note the error message.
- ► Make a note of the error number and serial number.
- ► Switch off the device.
- ► Contact your medical technical service or the service department of Barkey GmbH & Co. KG.

NOTE

In certain circumstances the serial number of the device may not be shown when an error message occurs.

NOTE

The device's rating plate will be found at the front on its left-hand side.

The last 6 errors which have occurred can be retrieved in the service menu. Details are described in a separate service description which can be requested from Barkey GmbH & Co. KG.

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7.1 Moisture sensors

If any liquid has leaked inside the device heating chamber, the moisture sensors in the base of the chamber trigger an intermittent acoustic signal and a warning message flashes in the display.

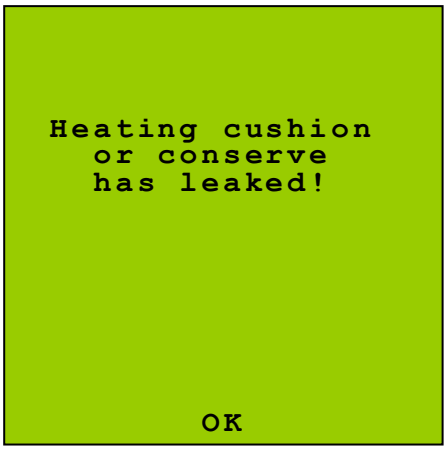

Figure 39: Moisture sensor message

- ► Press the confirm button ("OK").
- ► Switch off the device.
- ► Clean, disinfect and dry the heating cushion and the heating chamber.
- ► Replace the filter paper (dry-paper).

7.2 Overtemperature

The error message is initiated when the device detects an overtemperature condition.

Figure 40: "Overtemperature!" error message

- ► Note the error message.
- ► Make a note of the error number (xxx) and serial number (SN).
- ► Switch off the device and allow it to cool down.

An overtemperature condition can occur for a variety of reasons. Further diagnosis is possible by reference to the error number (see also the Chapter Error numbers). In order to be certain that there is an error in the device, you must switch it on again after allowing it to cool down.

If the error message reappears, please contact your medical technical service or the service department of Barkey GmbH & Co. KG stating the error number and the serial number.

7.3 Paddle blocked

If the paddle for the special "Undulation" function is blocked, the following error message is displayed:

```
     ! Error!
 Paddle blocked!

 Error number: 098
    SN: 1234567

 Switch off the
device
```

Figure 41: "Paddle blocked!" error message

- ► Note the error message.
- ► Make a note of the error number (098) and serial number (SN).
- ► Switch off the device.

7.4 Tank is empty

If the tank is empty or if the level in the tank has fallen below a critical level for the heating, the following error message is displayed:

```
     ! Error!
   Tank is empty!

 Error number: 100
    SN: 1234567

 Switch off the
device
```

Figure 42: "Tank is empty!" error message

- ► Note the error message.
- ► Switch off the device.
- ► Top up with water as described in the Chapter Filling with water.

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7.5 Device errors

Device errors can have a variety of reasons. Further diagnosis is possible by reference to the error number (see also the Chapter Error numbers)

Figure 43: "Device error!" error message

- ► Note the error message.
- ► Make a note of the error number (xxx) and serial number (SN).
- ► Switch off the device.

7.6 Error numbers

The numbers of the errors which require the device to be switched off are listed in the table below. Errors which require the system to be restarted with action on the part of the user are greyed.

Error number	Error description	Comments
10, 11	Display fault	There may not be any text visible in the display. The display may not be correct.
20 to 23	Internal device error	
30, 31	Checksum of the internal device data is incorrect	
32	Checksum of the program memory is incorrect	
33	Checksum of the data memory is incorrect	
40	Clock is incorrect	
41	Error setting clock time	
42	Error setting date	
43	Error reading clock time	
44	Error reading date	
45	Clock not running	Replace battery (by authorised specialists only). Then set time and date.
60	The watchdog timer has detected an error.	
70 to 73	Error with temperature measurement / temperature sensors	Possible cause: sensor open circuit / short-circuit
80 to 81	Overtemperature (software) during temperature measurement	Restart system / allow device to cool down
90	Pump and heater supply voltage not available.	Possible cause: overtemperature
91	Faulty program function	
92	Overtemperature (electronic) during temperature measurement	Restart system / allow device to cool down
97	Faulty undulation function.	
98	No power supply for paddle motor.	Restart system / remove paddle blockages
100	Fill level in tank is critical; heater has been switched off	Restart system / top up the tank
110	Communication / interface fault	

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Customer Service: +49 (5202) 9801-30 Fax: +49 (5202) 9801-99 - e-mail: info@barkey.de

8 Warranty and disclaimer

The warranty period for the Barkey plasmatherm is 24 months from purchase.

Barkey GmbH & Co. KG gives this warranty in lieu of other warranties on this product granted under contract or statute, including other statutory warranties of marketability or of fitness for a particular purpose, and gives no other commitments.

Because Barkey GmbH & Co. KG has no control whatsoever over the quality of servicing work that is not carried out by Barkey personnel, and because Barkey GmbH & Co. KG cannot control the effects which such servicing and repairs might have on the device and its serviceability, Barkey GmbH & Co. KG cannot accept any liability for damage to property, personal injury or consequential losses arising out of the use of a device which has not been repaired or serviced by Barkey service personnel.

Barkey GmbH & Co. KG accepts no responsibility for indirect losses or consequential losses of any kind and limits its obligations solely to the repair or replacement of the device.

Barkey GmbH & Co. KG accepts no responsibility or liability whatsoever for the use of accessories other than those indicated in these instructions for use, for the use of non-original components or for any use/installation which does not conform to the instructions for use accompanying such components. The use of components and accessories other than those referred to in the instructions for use shall result in a reduction of the manufacturer's warranty for the device.

Barkey GmbH & Co. KG only holds itself responsible for effects on the safety, reliability and performance of the device when

- extensions, resettings, modifications or repairs are carried out by persons it has authorised, and
- the technical safety inspections and servicing has been demonstrably carried out by suitable specialists at the prescribed intervals and as directed by the manufacturer, and
- the electrical installation at the point of use complies with the local regulations and the device data and, where applicable, with IEC requirements
- the device is used in accordance with these instructions for use, and
- the electrical safety has been demonstrably checked and tested according to the applicable regulations and at the prescribed intervals.

WARNING

Barkey GmbH & Co. KG can accept no liability for modifications and repairs to the devices made by the purchaser or unauthorised third parties without consulting the supplier.

We advise you to have any necessary repairs and regular servicing carried out by Barkey GmbH & Co. KG.

9 Customer service

The Barkey plasmatherm is maintenance free and reliable. Should a repair be necessary despite our careful choice of components and high quality of manufacture, please note:

Please return faulty devices for recycling repair to Barkey GmbH & Co. KG. Barkey GmbH & Co. KG will ensure that materials are properly separated, graded and recycled.

We advise you to have any necessary repairs carried out by Barkey GmbH & Co. KG or to have your technicians attend special product training courses in testing and servicing.

On request and on payment of a nominal charge the manufacturer can supply service instructions containing all necessary circuit diagrams, parts lists, test and inspection procedures and service information enabling appropriately trained and qualified technicians to repair all parts of the device which the manufacturer regards as repairable.

If the device cannot be repaired or serviced on site, it must be returned.

Please note the following rules **before dispatching** the device:

- Return the device for recycling repair only to Barkey GmbH & Co. KG or its authorised distributor.
- **The device must be cleaned and if necessary disinfected before it is dispatched.**
- The returned device must not pose any kind of health risk, e.g. as a result of toxic, carcinogenic, biohazardous or radioactive substances. The sender shall be held liable for any losses caused by inadequate cleaning and disinfection.
- Each returned device must be accompanied by a formal certificate of cleaning. Blank forms for this purpose are obtainable from Barkey GmbH & Co. KG on request.
- For safety reasons, devices which have not been cleaned or which are not accompanied by a certificate of cleaning will be returned to sender without being examined or repaired.
- **Please follow the cleaning and disinfection procedures described in these instructions for use.**
- Returned devices should be accompanied by a brief description of the fault as this will save you the cost of expensive fault finding.
- Please pack the device for dispatch to Barkey GmbH & Co. KG so that it cannot be damaged in transit. Barkey GmbH & Co. KG can accept no liability for damage in transit due to inadequate packing.

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The customer service department of Barkey GmbH & Co. KG is available for support and assistance as follows

Monday to Friday	07.00 - 20.00
Saturday and Sunday	10.00 - 18.00
on	+49(0)5202- 9801-30.
email:	info@barkey.de

WARNING

Barkey GmbH & Co. KG accepts no liability for modifications or repairs to the devices carried out by the user or by unauthorised third parties without first consulting the supplier.

Our conditions for repair and assembly and our warranty conditions apply. Our products are supplied according to the "General Conditions for the Supply of Products and Services of the Electrical and Electronics Industry".

10 Factory settings of the programs

PLASMA program

Nominal temperature	45	°C
Heating duration	20	min
Paddle delay	2	min
Paddle time	18	min
Paddle active	18	min
Paddle inactive	0	min

BLOOD program

Nominal temperature	37	°C
Heating duration	15	min
Paddle delay	0	min
Paddle time	0	min
Paddle active	0	min
Paddle inactive	0	min

HPC program

Nominal temperature	37	°C
Heating duration	5	min
Paddle delay	0.5	min
Paddle time	4.5	min
Paddle active	4.5	min
Paddle inactive	0	min

USER program

Nominal temperature	37	°C
Heating duration	20	min
Paddle delay	2	min
Paddle time	18	min
Paddle active	18	min
Paddle inactive	0	min

CONTINUOUS program

Nominal temperature	37	°C
Heating duration	continuous	
Paddle delay	0	min
Paddle time	0	min
Paddle active	0	min
Paddle inactive	0	min

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11 Specifications

Manufacturer	Barkey GmbH & Co. KG Gewerbestrasse 8 33818 Leopoldshoehe Tel.: +49 (5202) 9801-0 Fax: +49 (5202) 9801-99	
Type	Barkey plasmatherm	
Order No.	212.10043	230 VAC / 50 - 60 Hz
	212.10044	115 VAC / 60 Hz
Typical capacity	4 bags / 500 ml or 2 bags / 800 ml Emergency: 8 bags / 250 ml	
Power supply	230 VAC / 50 - 60 Hz or 115 VAC / 60 Hz	
Typical power consumption	< 0.25 W < 35 Watt < 75 W 1600 Watt	Standby Program pause Program "PLASMA" 45°C max.
Sound pressure level	< 45 dB(A)	
Current consumption	7 A at 230 VAC 14 A at 115 VAC	max. max.
Fusing	8 A slow at 230 VAC 15 A slow at 115 VAC	
Battery type	Lithium CR 1225, 3 V	
Interfaces/devices	optional: Barcode scanner Log printer	
Overtemperature protection	software controlled: electronic:	setpoint + 1.0 °C 48 ± 1.0 °C
Temperature setting	Variable from Default setting	+37 to +45 °C +37 °C
Display accuracy	± 0.1 °C	
	Operation	Storage/transport
Ambient temperature	+10 to +40 °C	-20 to +70 °C
Humidity (non condensing)	30 to 75 %	30 to 90 %
Air pressure	700 to 1060 hPa	700 to 1060 hPa
Operating mode	Continuous	

Dimensions		(w x d x h mm)
	Cover closed	340 x 600 x 320 mm
	Cover open	340 x 600 x 720 mm
Weight empty	18 kg	
Fill quantity	approx. 9 litres	
Refill quantity	approx. 1 litre (device warning)	
Protection rating	I	
MDD classification	II a	
Enclosure class	IP21	
Identification	CE 0123	

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Barkey plasmatherm device master data sheet

Device name:	_____
Serial numbers:	_____
Inventory number:	_____
Device location:	_____
Commissioned on:	_____
Identification:	CE 0123
Manufacturer:	Barkey GmbH & Co. KG Gewerbestrasse 8 33818 Leopoldshoehe
Phone:	+49 (5202) 98010
Fax:	+49 (5202) 980199
email:	info@barkey.de

Barkey

Declaration of conformity
Barkey plasmatherm

Manufacturer:	Barkey GmbH & Co. KG Gewerbestrasse 8 33818 Leopoldshoehe Germany Tel.: [int] + 49 5202 9801-0 Fax: [int] + 49 5202 9801-99
Device:	Thawing and warming device
Type of device:	plasmatherm DTM
serial number:	from SN 1107326
Classification:	Class II b, (role 9, clause 1 part 2)
Class of protection:	I
Marking:	CE 0123 (according to article 17 of Council Directive 93/42/EEC concerning medical devices*)
Notified Body:	TUEV SUED Product Service GmbH, Ridlerstr. 65, 80339 Muenchen, Germany

For the above-mentioned medical device Barkey on its own authority declares the observance of the Essential Requirements (Annex 1) of the Council Directive 93/42/EEC concerning medical devices*)

It is in particular guaranteed by the following standards:

IEC 60601-1:1988 + A1:1991 + A2:1995
IEC 60601-1-2:2007, modified

The observance of the Essential Requirements and of the standards is documented by a certified quality management system according to ISO 13485:2003** and Annex II.3 of Council Directive 93/42/EEC concerning medical devices*

* Council Directive 93/42/EEC of 14 June 1993 concerning medical devices last amended by the Article 2 of Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 already have been incorporated
** Requirements of ISO 13485:2007 already have been incorporated

Leopoldshoehe, 22.03.2010

Location, Date

Thomas Barkey
Managing Director

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

CERTIFICATE

No. Q1N 07 06 23355 011

Product Service

Holder of Certificate:

Barkey

Barkey GmbH & Co. KG
Gewerbestr. 8
33818 Leopoldshöhe
GERMANY

Facility(ies):

Barkey GmbH & Co. KG
Gewerbestr. 8, 33818 Leopoldshöhe, GERMANY

Certification Mark:

TÜV SÜD ISO 13485:2003

Scope of Certificate:

Design and development, production, distribution and servicing of warming devices for use in medical technique

Applied Standard(s):

ISO 13485:2003
Medical Devices –
Quality Management Systems –
Requirements for regulatory purposes

The Certification Body of TÜV PRODUCT SERVICE GMBH certifies that the company mentioned above has established and is maintaining a quality system which meets the requirements of the listed standards. See also notes overleaf.

Report No.: **71321645**

Valid until: **2010-06-30**

Date: 2007-07-01

TÜV SÜD PRODUCT SERVICE 302202

TÜV SÜD Product Service GmbH
Zertifizierstelle
Ridlerstr. 65 · 80339 München
Germany

ZLG

Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
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