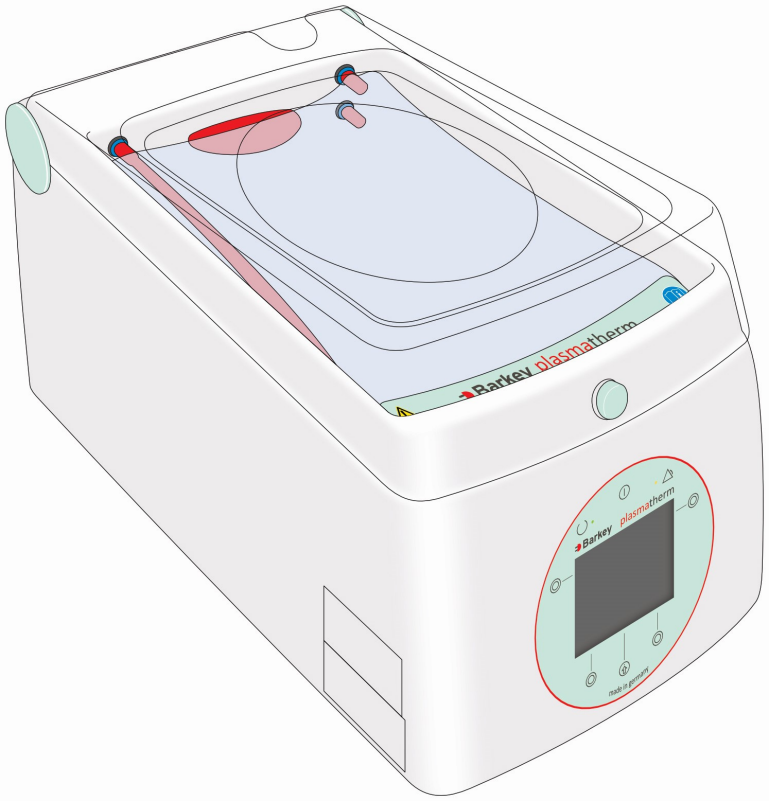
Instructions for Use

Barkey plasmatherm

Version 4 GB

Issue 2022-08-19



Manufactured by:
Barkey GmbH & Co. KG
Gewerbestrasse 8
33818 Leopoldshoehe
Germany

CE 0123

Contents

Appendix:

1 Introduction

Many congratulations on your decision to use 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 keeping warm non-denaturable infusion solutions and other materials in continuous mode.

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

In this user manual you will find all the information you require about the functions, operation and application of the Barkey plasmatherm.

1.1 Pictograms, signal words and symbols

This user manual uses the following pictograms and symbol words to highlight warnings and special advice:

WARNING	If not observed: Danger to people, property, the device or basic functions of the device.
CAUTION	General information.
NOTE	Additional useful instructions and information. (the “i” stands for “information”.)

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

►	Step contained in instructions. Carry out this step as indicated.

NOTE

The symbols representing the controls and device displays, and the symbols used on device labels, are listed and described in Chapter 2.3 in this user manual.

Barkey GmbH & Co. KG - Gewerbestrasse 8 - 33818 Leopoldshoehe - Switchboard: +49 (5202) 9801-0
Customer service: +49 (5202) 9801-30 - Fax: +49 (5202) 9801-99 - E-Mail: info@barkey.de

1.2 Target group

This user manual is intended for use by:

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

WARNING

Only persons who meet this criterion may use the device.

1.3 Important things to observe

You must follow the conditions of use and safety advice contained in this user 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 accepts no liability for damage caused as a result of failure to follow this manual.

WARNING

This user manual is 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 manual.

Carefully read through the user manual before using the device.

Please follow the advice about the intended use of the device in Chapter 2.4 and the safety information provided in Chapter 3. For a better understanding of these chapters, you should familiarise yourself with the basic functions of the device as described in Chapter 2.

You should also comply with the requirements for the training and skills of persons using the device, as indicated in Chapter 1.2.

Medical electrical devices are subject to special safety measures with regard to EMC (electromagnetic compatibility). Make sure that the device is installed and commissioned in accordance with the EMC advice contained in this user manual.

ATTENTION

Any serious incidents that occur with the Barkey plasmatherm must be reported to the manufacturer and the responsible authorities of the member state concerned in which the user is located.

1.4 Conformities

The product Barkey plasmatherm fulfils the regulatory and normative requirements for medical devices. The declaration of conformity as well as product and QM-certificates can be requested at info@barkey.de.

1.5 Copyright

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 on living organisms. Typically, these fluids are whole blood, blood products, blood preparations and infusion solutions.

The material to be heated is inserted between two heating cushions bags through which a heat transfer fluid flows. A large display shows the program progress and the current temperature during a tempering process.

The Barkey plasmatherm is equipped with an independent overtemperature protection, described in chapter 2.7, which excludes a heating of the heat transfer fluid in the heating cushions to temperatures of 4°C above the maximum temperature setting even in the event of a defect in the temperature control.

2.1 Components of the Barkey plasmatherm

1. Filler opening	The filler opening is used to fill the device with heat transfer fluid.
2. Paddle	Gently agitates the FFP's during the heating process.
3. Heating chamber cover	Covers the heating chamber while heating or thawing is in progress.
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 multiline display, 6 buttons and 2 lamps (LEDs).

Barkey GmbH & Co. KG - Gewerbestrasse 8 - 33818 Leopoldshoehe - Switchboard: +49 (5202) 9801-0
Customer service: +49 (5202) 9801-30 - Fax: +49 (5202) 9801-99 - E-Mail: info@barkey.de

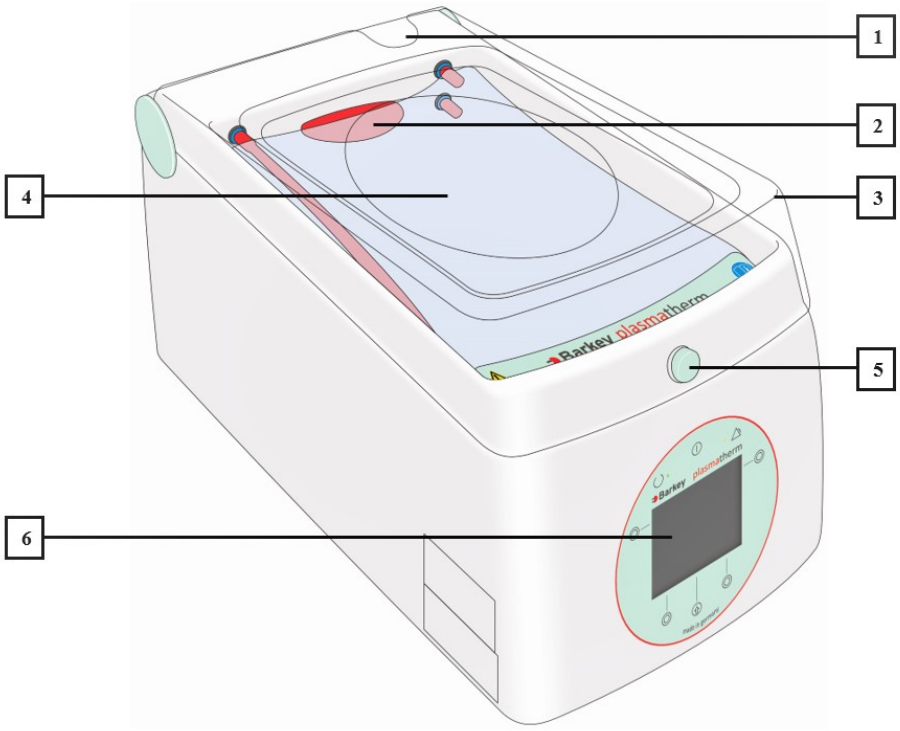


Figure 1: Barkey plasmatherm

2.2 Technology description

The Barkey plasmatherm is configured as an electronically regulated dry heating device with an enclosed heating chamber. The bag of fresh frozen plasma (FFP), blood and erythrocyte concentrates (EC), cryoconserved preparations, cryoconserved stem cells (HPC = hematopoietic 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	Can be preset by the user	Acting special function
		Undulation*
BLOOD	Heating time	No
PLASMA	Heating time	Yes
HPC**	Heating time	Yes
USER	several parameters can be freely adjusted	Adjustable or selectable
CONTINUOUS	No preselectable Options	No
OCTAPLAS	No preselectable options	Yes

* An undulation function which agitates the heated materials is provided for mixing certain materials such as plasma (FFP, Fresh Frozen Plasma).

** HPC ⇔ Hematopoietic 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.

Barkey GmbH & Co. KG - Gewerbestrasse 8 - 33818 Leopoldshoehe - Switchboard: +49 (5202) 9801-0
Customer service: +49 (5202) 9801-30 - Fax: +49 (5202) 9801-99 - E-Mail: info@barkey.de

2.3 Symbols

2.3.1 Operating panel symbols

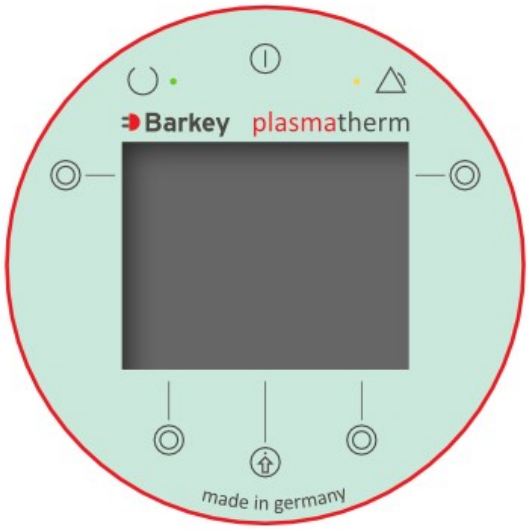


Figure 2: Operating panel

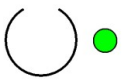
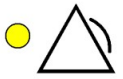
The Barkey plasmatherm has an operating panel on the front of the device with a multi-line display, 6 buttons and 2 lamps (LEDs).

The display

- for displaying 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 acoustic signal generator draws your attention to the fact that a program has finished, warns of operator error or signals that an error has occurred. A message is additionally shown in the display in the event of errors.

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 Label symbols

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

IP 21	This symbol means that the device is protected from touch by fingers and other foreign objects greater than 12.5 millimeters and that the device is protected against vertically dripping water (incident angle to the vertical 0°) according to IEC 60529 in its intended operating conditions.
	This symbol shows the year of manufacture as a four-digit number.
CE 0123	This symbol declares that the device conforms with REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices. The four-digit number indicates the appointed body (TÜV SUED Product Service GmbH) which supervises the manufacturer's quality assurance system.
	This symbol identifies the month and the year in which the next safety inspection must be carried out.
	This symbol advises you that you must comply with the user manual supplied.
	This hazard symbol advises you that failure to follow the instructions contained in the user manual can result in hazards to patients, the device user or the device itself.
	This symbol indicates that the mains plug must be withdrawn from the socket before the device housing is opened.
	This symbol (on a label inside the device) informs you of the earth connection.
	This symbol indicates that this product may not be disposed of with normal household waste. This product must be taken to a specialist disposal company or returned to the manufacturer for disposal.

	This symbol indicates that the device meets the following safety standards for the USA and Canada: Medical – General Medical Devices Only in relation to electric shock, fire, and mechanical risks In compliance with ANSI/AAMI ES60601-1(2005) + AMD1(2012), CAN/CSA C22.2 NO.60601-1(2014)
	This symbol indicates that the device is a medical device
	This symbol displays the name and the address of the manufacturer of the medical device

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 products
- thawing and timed heating of HPC (hematopoietic progenitor cells)
- heating and keeping warm of non-denaturable infusion solutions and other materials in continuous mode.

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 user manual by specific descriptions of the various different applications and of the handling of the device. You will find these descriptions in Chapters 3 to 4 of this user manual. Please use these chapters to find specific information about how to use the device in individual cases.

2.5 Device versions

There are four different device versions. These are differentiated by different power supplies and the option of an additional network connection. The network version, the so-called TCP version, enables the transfer of data from a tempering process directly into a customer's software or for display in a supplied program. For the TCP version, separate activation instructions detailing the connection and operation of the network should be followed.

This user manual only addresses the connection and operation of the standard version with the printer interface.

Device name and network connection identifies each device version:

Device name	For network connection: (voltage/frequency)
Barkey plasmatherm	220-240 V, 50/60 Hz
Barkey plasmatherm	100-120 V, 50/60 Hz
Barkey plasmatherm TCP	220-240 V, 50/60 Hz
Barkey plasmatherm TCP	100-120 V, 50/60 Hz

2.6 Contraindications

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 in the intended purpose.

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

2.7 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. After this you may switch the device on again. However, if the cause of the fault has not been remedied the error will recur.

WARNING

If the overtemperature alarm sounds, any preparations that are in the device must be removed and checked to ensure they can still be used before for being transferred to the patient.

The Barkey plasmatherm must not be used if it is faulty. The device should be examined by Barkey GmbH & Co. KG or by an authorised person.

Barkey GmbH & Co. KG - Gewerbestrasse 8 - 33818 Leopoldshoehe - Switchboard: +49 (5202) 9801-0
Customer service: +49 (5202) 9801-30 - Fax: +49 (5202) 9801-99 - E-Mail: info@barkey.de

2.8 Safety features

- Safe, gentle thawing and heating conditions for all programs are ensured by a dual overtemperature protection which remains switched off 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 bags (hairline cracks) being contaminated by the heat transfer fluid.
- The heating process 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
- Device is designed for continuous operation
- Synthetic enclosure is corrosion free and saves energy
- Stable, designed not to tip over, non-slip device feet

3 Safety information

3.1 Safety information for using 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 user manual.
	When heating blood and blood products, always ensure that the operating temperature and time limit are not exceeded. Remove and transfuse immediately if signal sounds.
	The blood products may only be heated and/or thawed with the programs specifically intended for them.
	If infusion solutions or medicaments 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 medicament.
	If preparations leak, this will be 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 activated only in the “PLASMA”, “HPC”, “OCTAPLAS” and “USER” programs. Do not use the undulation function for blood bags due to possible mechanical damage and agglutination of erythrocytes.
	The device must not be used if it is faulty. The device should be examined by Barkey GmbH & Co. KG or by an authorised person.

Barkey GmbH & Co. KG - Gewerbestrasse 8 - 33818 Leopoldshoehe - Switchboard: +49 (5202) 9801-0
Customer service: +49 (5202) 9801-30 - Fax: +49 (5202) 9801-99 - E-Mail: info@barkey.de

3.2 Safety instructions for 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. To avoid the risk of an electric shock this device may be plugged only into a mains power supply which is provided with an earth conductor.
	Only power supply connections supplied by Barkey GmbH & Co. KG which are designed for the device 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. Please contact the manufacturer or your medical technician service who can request information about overhauls from the manufacturer if necessary. Repairs and modifications to the device may only be carried out by Barkey GmbH & Co. KG or by authorised persons.
	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.
	A technical safety inspection must be carried out annually by qualified service personnel **or** employees of Barkey GmbH & Co. KG.
	The water must be changed once a year. It is recommended to add a means for drinking water treatment (Katadyn Micropur classic) to the water, if appropriate means are approved in the respective country of use.
	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 personnel or by employees of Barkey GmbH & Co. KG.
	The device's rating plate is on the left-hand side of the housing.

3.3 Safety advice and environmental influences

WARNING	Medical electrical devices are subject to special safety measures with regard to EMC (electromagnetic compatibility). Make sure that the device is installed and operated in accordance with the EMC information contained in these instructions for use.
	The Barkey plasmatherm may be operated in clinics and hospitals, doctors' surgeries and facilities which are directly connected to the public electricity supply network, in accordance with the standard EN 60601-1-2.
	The Barkey plasmatherm functions perfectly under electromagnetic interferences within the limit values of the standard EN 60601-1-2. If influence from strong electromagnetic fields outside the limit values of the standard EN 60601-1-2 is experienced (e.g. as a result of HF treatments or surgical devices), the control accuracy of the Barkey plasmatherm may be restricted or malfunctions may occur. In the case of such interference, increase the clearance between the device affected by the interference and the device causing the interference, or do not operate both devices simultaneously.
	The Barkey plasmatherm may not be located directly next to or stacked with other devices. If operations near to or stacked with other devices are necessary, the Barkey plasmatherm should be observed to check its correct operation in this layout.
	Portable and mobile HF communications equipment, such as radios, as well as accessories belonging to them such as antenna cables and external antennae, may affect the Barkey plasmatherm and should not be used at a distance of less than 30 cm (12 inches) away from the Barkey plasmatherm and its connection cables.
	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 laughing gas whose flashpoint is below 50°C. In particular, it is imperative that the device is not used in areas where alcohol disinfectants and anaesthetising substances are being used at the same time.

Barkey GmbH & Co. KG - Gewerbestrasse 8 - 33818 Leopoldshoehe - Switchboard: +49 (5202) 9801-0
Customer service: +49 (5202) 9801-30 - Fax: +49 (5202) 9801-99 - E-Mail: info@barkey.de

WARNING	Only cables delivered by Barkey GmbH & Co. KG, which are designed for the nominal voltage of the device, may be used. Barkey GmbH & Co. KG does not offer converters for the Barkey plasmatherm. The Barkey plasmatherm may only be operated with the accessories listed in these instructions for use. The use of other accessories, other converters or other cables may result in increased electromagnetic emission or reduced electromagnetic immunity of the device and lead to incorrect operation.
	The device may not be set up or operated in the immediate vicinity of devices with a high waste heat output.
	When setting up the device there must be an unrestricted flow of air around its base.
	The device has not been tested for interference by strong magnetic fields. Strong magnetic fields may interfere with how the device functions. Therefore, the device may not be operated in magnetic resonance rooms or in the vicinity of magnetic resonance imaging devices.

3.4 Electromagnetic compatibility

3.4.1 Electromagnetic outputs

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 emissions are very low, and neighbouring electronic devices are unlikely to be affected.
HF outputs in accordance with CISPR 11	Class B	The Barkey plasmatherm may be operated in accordance with the EN 60601-1-2 standard in clinics and hospitals, as well as medical practices and facilities directly connected to the public supply network.
Harmonic output in accordance with IEC 61000-3-2	Class A	
Output of voltage fluctuations/ flickering to IEC 61000-3-3	Complies	

3.4.2 Electromagnetic immunity

Guidelines and manufacturers declaration - Electromagnetic immunity			
The Barkey plasmatherm is intended for operation in any 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) to IEC 61000-4-2	± 8 kV Contact discharge ± 15 kV air discharge	± 8 kV ± 15 kV	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 in accordance with IEC 61000-4-4	± 2 kV 100kHz repetition frequency	± 2 kV	The quality of the supply voltage should comply with a typical business or hospital environment.
Surge voltages in accordance with IEC 61000-4-5	± 1 kV line to line ± 2kV line to earth	± 1kV ± 2 kV	The quality of the supply voltage should comply with a typical business or hospital environment.
Voltage dips and voltage interruptions in accordance with IEC 61000-4-11	0 % U_T; ½ period at 0, 45, 90, 135, 180, 225, 270 and 315 degrees	0 % U_T; ½ period at 0, 45, 90, 135, 180, 225, 270 and 315 degrees	The quality of the supply voltage should comply with a typical business or hospital environment. If the user of the Barkey plasmatherm requires continued operation even if the power supply is interrupted, we recommend that the Barkey plasmatherm is connected to an uninterruptible power supply or to a battery.
	0 % U_T; 1 period at 0 degrees	0 % U_T; 1 period at 0 degrees	
	70 % U_T; 25 periods	70 % U_T; 25 periods	
	0 % U_T; 5 seconds	0 % U_T; 5 seconds	
NOTE: UT is the mains AC supply before applying the test rule			

Barkey GmbH & Co. KG - Gewerbestrasse 8 - 33818 Leopoldshoehe - Switchboard: +49 (5202) 9801-0
Customer service: +49 (5202) 9801-30 - Fax: +49 (5202) 9801-99 - E-Mail: info@barkey.de

Guidelines and manufacturers declaration - Electromagnetic immunity			
The Barkey plasmatherm is intended for operation in any 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 - guidelines**
Conducted disturbances, induced by high-frequency fields in accordance with IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 80 % amplitude modulation at 1 kHz 6 V in ISM and amateur radio frequency bands between 0.15 MHz and 80 MHz 80 % amplitude modulation at 1 kHz	3 V 6 V	Portable and mobile HF communications equipment, such as radios, as well as accessories belonging to them such as antenna cables and external antennae, may affect the Barkey plasmatherm and should not be used at a distance of less than 30 cm (12 inches) away from the Barkey plasmatherm and its connection cables. Disturbances are possible in the vicinity of devices which bear the following symbols.
High frequency electromagnetic fields in accordance with IEC 61000-4-3	10 V/m 80 MHz up to 2.7 GHz 80 % amplitude modulation at 1 kHz	10 V/m	
NOTE 1: With 80 MHz and 800 MHz the higher frequency range applies. NOTE 2: The ISM bands are 6,765 MHz to 6,795 MHz, 13,553 MHz to 13,567 MHz, 26,957 MHz to 27,283 MHz and 40.66 MHz to 40.70 MHz. The amateur radio bands are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7.0 MHz to 7.3 MHz, 10.10 MHz to 10.15 MHz, 14.0 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz. NOTE 3 These guidelines may not be applicable in all cases. The propagation of electromagnetic variables is influenced through absorptions and reflections from buildings, objects and people.			

Guidelines and manufacturers declaration - Electromagnetic immunity			
The Barkey plasmatherm is intended for operation in any 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 - guidelines**
High frequency electromagnetic fields in the immediate vicinity of wireless communication devices in accordance with IEC 61000-4-3	27 V/m 385 MHz Pulse modulation 18 Hz	27 V/m	Portable and mobile HF communications equipment, such as radios, as well as accessories belonging to them such as antenna cables and external antennae, may affect the Barkey plasmatherm and should not be used at a distance of less than 30 cm (12 inches) away from the Barkey plasmatherm and its connection cables. Disturbances are possible in the vicinity of devices which bear the following symbols. 
	27 V/m 450 MHz Frequency modulation ± 5 kHz hub, 1 kHz sinus	27 V/m	
	9 V/m 710 MHz, 745 MHz, 780 MHz Pulse modulation 217 Hz	9 V/m	
	28 V/m 810 MHz, 870 MHz, 930 MHz, Pulse modulation 18 Hz	28 V/m	
	28 V/m 1.72 GHz, 1.845 GHz, 1.97 GHz, Pulse modulation 217 Hz	28 V/m	
	28 V/m 2.45 GHz, Pulse modulation 217 Hz	28 V/m	
	9 V/m 5.24 GHz, 5.50 GHz, 5.785 GHz, Pulse modulation 217 Hz	9 V/m	
NOTE: These guidelines may not be applicable in all cases. The propagation of electromagnetic variables is influenced through absorptions and reflections from buildings, objects and people.			

4 Operation

4.1 Getting started

If you are using a new or repaired device you should first

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

CAUTION

You must carry out a disinfectant wipe of the heating cushions and heating chamber before using the device. See chapter 5.1 in this user manual for details of this procedure.

4.1.1 Setup location

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, simple operation of the device from above and in front must be guaranteed

WARNING

Whenever possible the device should be carried by 2 people. When carrying, grip the device by the bottom edge only. Recesses are provided in the base for safe carrying.

WARNING

The device is ventilated from below. It should therefore not be placed on a soft underlay 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.

WARNING

When selecting the location for the device, it is imperative that you maintain the distances stated in Chapter 3.3 of this user manual from other devices with electromagnetic emission.

WARNING

Install the device so that the mains plug is accessible at all times and the mains plug can easily be withdrawn from the socket, for instance in an emergency.

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 signal cords to the device at the same time as connecting the Barkey plasmatherm power cord.

CAUTION

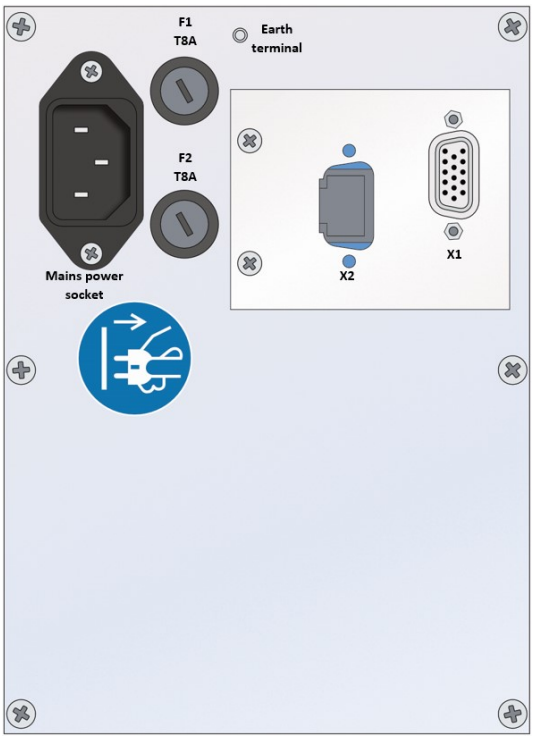
The Barkey plasmatherm may only be operated with the following two peripheral devices:

- EPSON TM-U220B-007 dot matrix printer
- Honeywell CCD-barcode scanner Hyperion 1300g

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 connection area is located on the underside (front left). The connection area contains:



- a mains power socket (socket for a low power device)
- a socket (X2) for optional connection of a log printer
- a socket (X1) for optional connection of a barcode scanner
- two main fuses (F1 and F2, screw in fuse holders)
- earth terminal
- a sticker with the labels for the sockets in the connection area

Figure 3: Connection area label

- ► Lift the device at the front or left to gain access to the sockets.
- ► Connect the supplied mains power cord with its plug for low-power devices to the low-power device socket. The cord runs towards the back of the device.

CAUTION

Use only the power cord supplied. It is fitted with a low-power device angled-entry plug and it is matched to the device's operating voltage.

WARNING

To avoid the risk of an electric shock this device must be plugged only into a mains power supply which is provided with an earth conductor.

CAUTION

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

- ► Connect the smaller plug of the signal cord supplied with the printer to socket X2. (The plug will not fit socket X1). Fix the plug into position with the integrated screws using a suitable screwdriver.

CAUTION

Only use the signal cord supplied to connect the printer.

- ► Connect the other end to the printer. Fix the plug into position with the integrated screws using a suitable screwdriver.
- ► Connect the barcode scanner cord to socket X1. (The plug does not fit into socket X2). Fix the plug into position with the integrated screws using a suitable screwdriver.
- ► 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.

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 emits an acoustic signal. This will ensure that the displays and controls are functioning correctly.

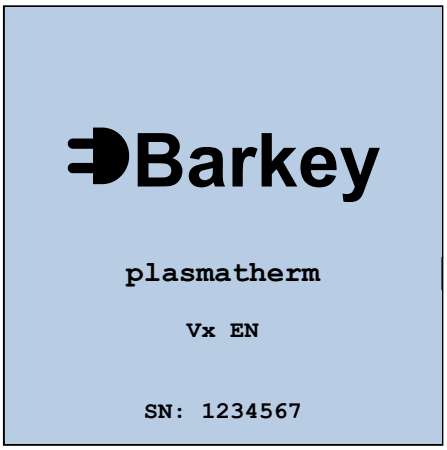


Figure 4: Login screen

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

- the Barkey-logo
- the device name
- the software version Vx (x: current version)
- the abbreviation for the language variant (the example shows: EN for English)
- the serial number (SN)

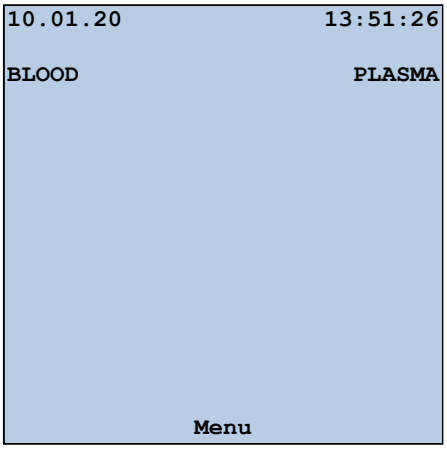


Figure 5: Main screen with shortcut programs

You will now see the main screen in the display:

- at the top left is the current date and at the 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 (ID). Details on scanning in barcodes are provided in Chapter 4.7.

► If a log printer is connected to the Barkey plasmatherm and the respective device connection is activated: switch this 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 tank is shown first after the initial screen. The prompt “Fill the 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: Tank level too low, prompt “Fill the tank!”

When the tank is filled and the required level has been reached, the “Fill the tank!” prompt is replaced by the information “Tank is full” which also flashes. An intermittent acoustic signal also sounds.

Figure 7: Confirmation with “OK” available

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. It is recommended to add a drinking water treatment agent (Katadyn Micropur classic) to the water, if appropriate agents are approved in the respective country of use.

- ► 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 from the menu, as described in Chapter 4.6.
- ► 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 when 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.

Barkey GmbH & Co. KG - Gewerbestrasse 8 - 33818 Leopoldshoehe - Switchboard: +49 (5202) 9801-0
Customer service: +49 (5202) 9801-30 - Fax: +49 (5202) 9801-99 - E-Mail: info@barkey.de

Proceed as follows to bleed the heating cushions:

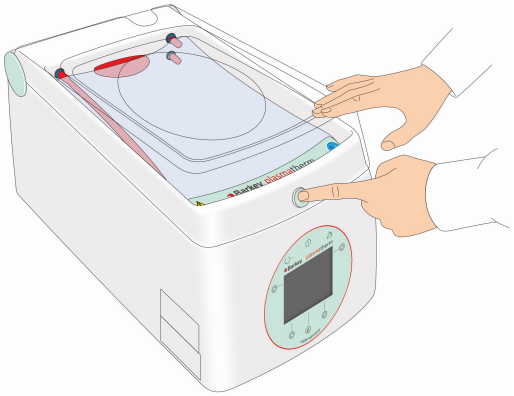
- ► Pull the left-hand top tube out of the push-fit connector so that the water can rise in the water ducts.
- ► Wait for around 5 seconds. Now re-connect the tube to the push-fit connector.
- ► First, start a program without any material to heat.
- ► If the pump does not immediately pump heat transfer fluid into the cushions, stop the program, wait a short time, and start it again. 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 righthand 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 runs off.

4.2 Opening the heating chamber

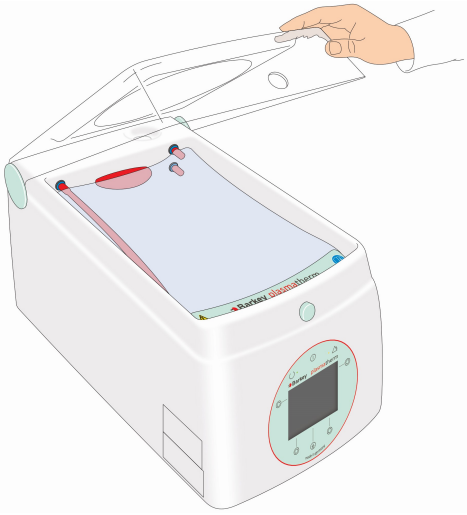
► Press the green button on the front of the device above the operating panel to open the heating chamber, and guide the automatically raised heating chamber cover as far as the stop.

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



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

Figure 8: Locking / unlocking button



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

Figure 9: Cover open

WARNING

Keep your fingers away from the edge of the cover! Otherwise, there is a danger of crushing.

CAUTION

Programs will run only when the heating chamber cover is closed. Otherwise the device will sound an intermittent acoustic signal as well as displaying a warning message.

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 Chapter 5.2) 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.).

Proceed as follows to load the device:

► 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 bags beneath the paddle. The paddle is marked red for identification.

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

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

► Position the bags as shown in figure 10.

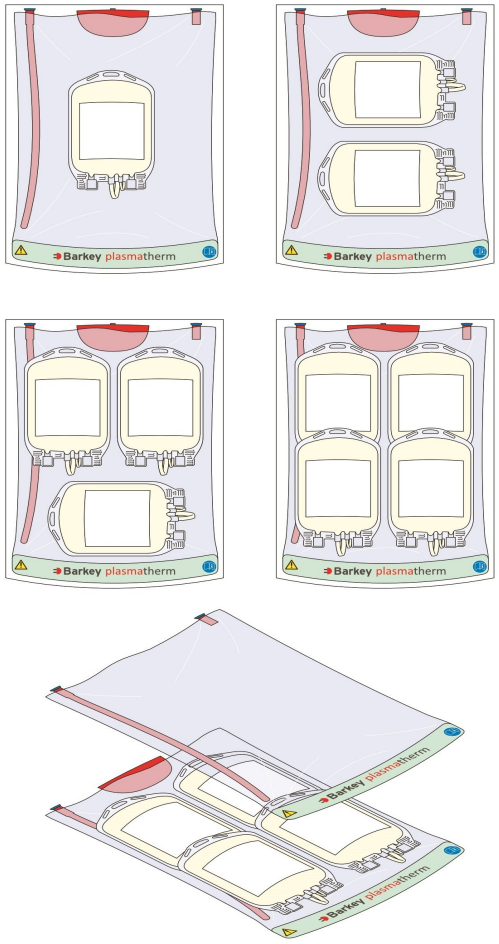


Figure 10: Optional loading positions for bags

4.4 Selecting and starting a program with the menu system

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

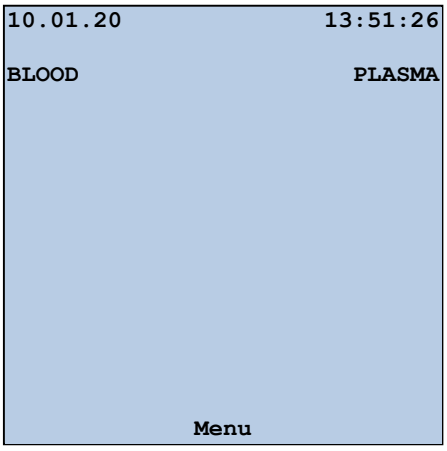


Figure 11: Main screen

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.

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.

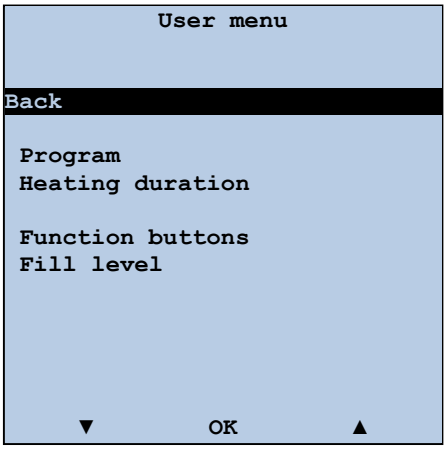


Figure 12: Main menu of the user menu

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

You will now see the submenu “Program”; the user has a choice of 6 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 de-naturable infusion solutions
“OCTAPLAS”	for thawing and heating OCTAPLAS

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

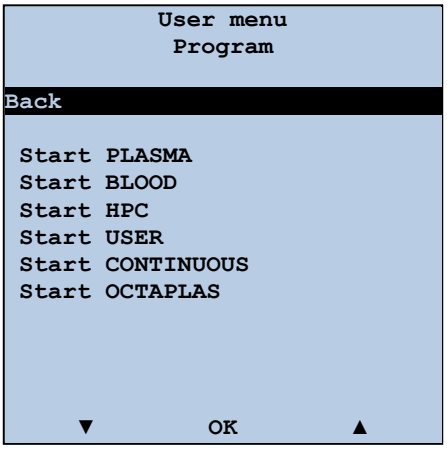


Figure 13: “User menu” - “Program”

► 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, HPC, and OCTAPLAS may only be heated for a limited time! You must not use this device for keeping these products continuously warm!

WARNING

Blood/whole blood, HPC and OCTAPLAS should 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.

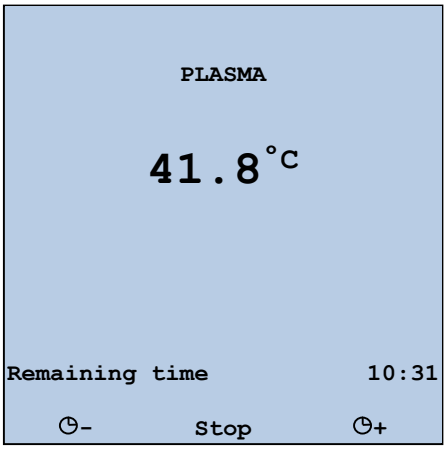


Figure 14: "PLASMA" program

► 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.

Preferences may be set up for the various programs:

- The heating duration can be preset for the "PLASMA", "BLOOD", "HPC" and "USER" 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 button ("◷-") or right-hand button ("◷+") is described in chapter 4.4.2. The procedure to change the remaining time for "OCTAPLAS" is described in chapter 4.4.12.

If the confirm button ("Stop") is pressed while a program is running, the program is cancelled and the main screen is displayed again.

NOTE

Since no remaining time is active with the "CONTINUOUS" program, the display shows "--:--" in this case. The remaining time cannot be changed.

Barkey GmbH & Co. KG - Gewerbestrasse 8 - 33818 Leopoldshoehe - Switchboard: +49 (5202) 9801-0
Customer service: +49 (5202) 9801-30 - Fax: +49 (5202) 9801-99 - E-Mail: info@barkey.de

4.4.2 Changing the remaining time

While a program is running, the user can alter the remaining time - usually between 30 s and 99 min with the left-hand or right-hand selection button ("◷-" or "◷+"). If the remaining time is already less than 30 s, this value is taken as the minimum permitted input so as not to increase the remaining time unintentionally.

NOTE

Since no remaining time is active with the "CONTINUOUS" program, the display shows "--:--" in this case. The remaining time cannot be changed.

In the "OCTAPLAS" program, the remaining time can only be extended once for 15 minutes. A more detailed description can be found in chapter 4.4.12.

If the current remaining time can be changed, it is frozen for the current program the first time one of the two selection buttons ("◷-" or "◷+") is pressed. Depending on which button was pressed, the displayed remaining time is then rounded up or down to the nearest whole 10s and the display flashes to highlight visually 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 of the two selection buttons ("◷-" or "◷+") nor the confirm button ("OK") has been pressed within 5 s, any new remaining time that was 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, HPC and OCTAPLAS must not be heated up if the current operating temperature of the device is over 37 °C. This may happen if for example you thawed out and heated up plasma and then called up a program for heating blood/whole blood. The "BLOOD", "HPC" and "OCTAPLAS" programs can still be started in spite of the high water temperature warning.

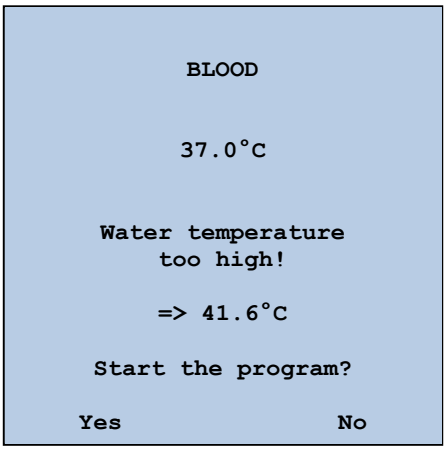


Figure 15: Message "Water temperature too high!"

- ▶ 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 righthand 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. If the cover is not closed within 16 s an intermittent acoustic signal will sound.

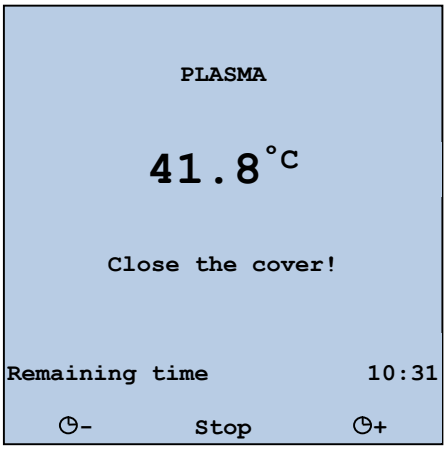


Figure 16: Message "Close the cover!"

► 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.

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 are sent to the printer while the current program is in progress, but this will not affect the actual heating operation.

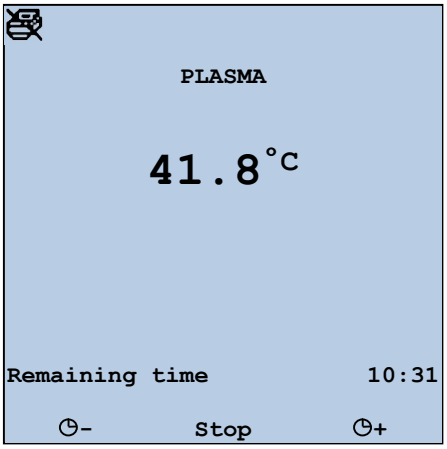


Figure 17: Printer message

► 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 program start, 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 are sent to the IT network while the current program is in progress.

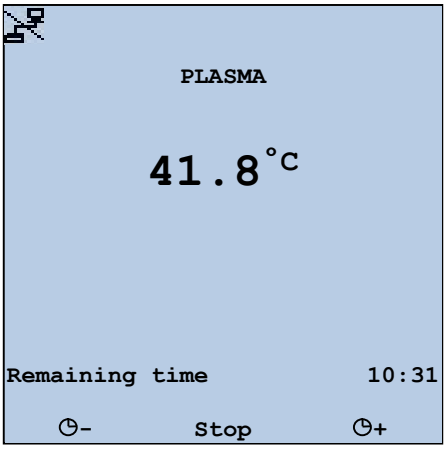


Figure 18: EDP-message

- ▶ 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 chapter 4.4.5 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.

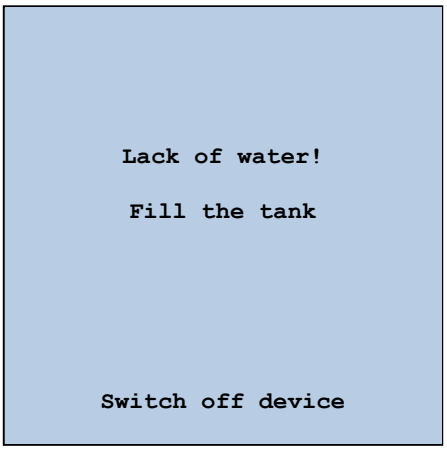


Figure 19: “Lack of water!” message

- ▶ Switch off the device.
- ▶ Switch the device on again.
- ▶ Fill up with water as described in chapter 5.3.2.

4.4.5 Messages after the end of a program

Once the heating duration has elapsed, the flashing message “Program completed” appears and an intermittent signal sounds. This indicates that the program has finished and prevents inadvertent longer heating.

Figure 20: End of program

► 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 completed” 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”).

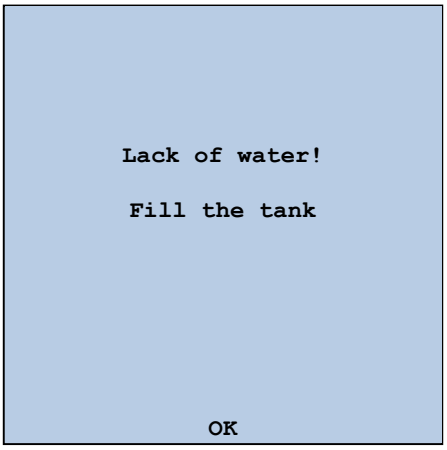


Figure 21: “Lack of water!” message at the end of a program

- ▶ Acknowledge the message with the confirm button (“OK”)
- ▶ Fill up with water as described in chapter 5.3.2.

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 chapter 4.4.4).

4.4.6 Presetting the heating duration of the “PLASMA” program

This chapter describes how to preset the heating duration of the “PLASMA” program by way of example; to preset the heating duration of the “BLOOD”, “HPC” and “USER” programs, please proceed as described for the “PLASMA” program. No tempering time can be preset for the “OCTAPLAS” program.

WARNING

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

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

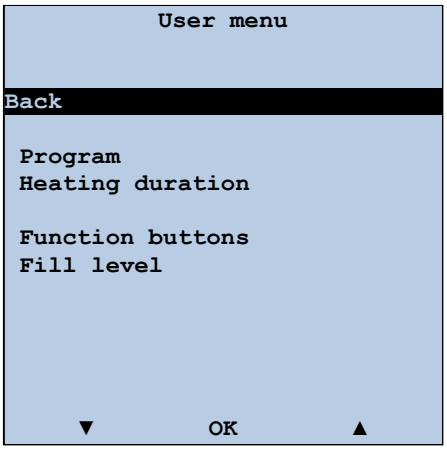


Figure 22: “User menu”

The user menu appears.

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

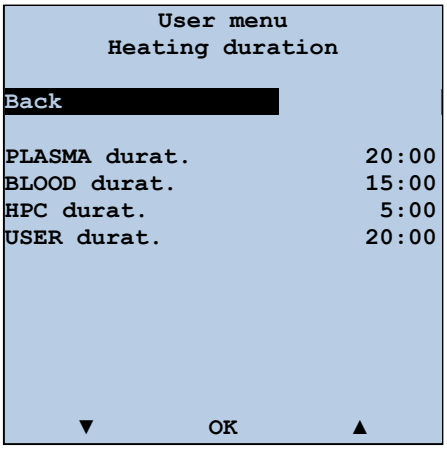


Figure 23: “Heating duration” menu

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.

Barkey GmbH & Co. KG - Gewerbestrasse 8 - 33818 Leopoldshoehe - Switchboard: +49 (5202) 9801-0
Customer service: +49 (5202) 9801-30 - Fax: +49 (5202) 9801-99 - E-Mail: info@barkey.de

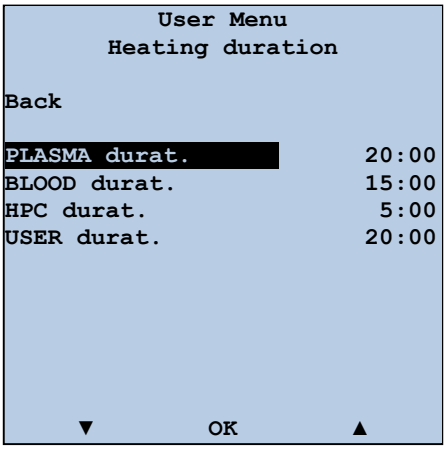


Figure 24: Setting the heating duration for the "PLASMA" program

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 "◷+").

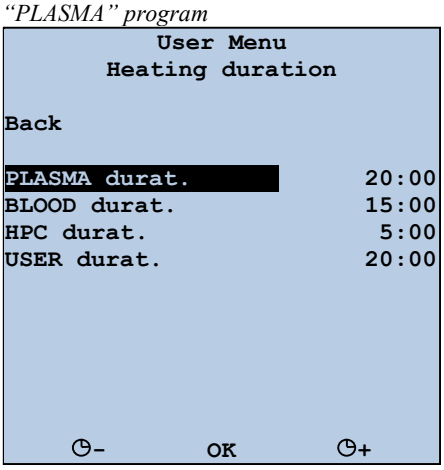


Figure 25: Changing the heating duration for the "PLASMA" program

► 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-hand or right-hand selection button ("▼" or "▲").

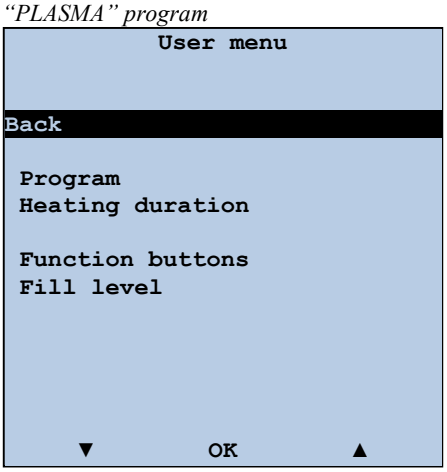


Figure 26: "User menu"

► 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 FFPs simultaneously, for example) will depend on a number of additional factors (such as the initial temperature of the FFPs, the temperature of the heat transfer fluid, the fill volume of the FFPs, the number of FFPs, choice of program etc.).

The guideline values listed in Table 2 (guideline heating duration in minutes to reach “without ice” 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 FFPs, the temperature of the heat transfer fluid, the fill volume of the FFPs, the number of FFPs, choice of program etc.) may result in different heating durations!

NOTE

Conditions:

“PLASMA” program selected

Size of the FFPs (170 x 110 x 20 mm)

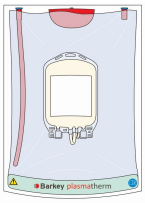
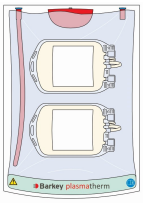
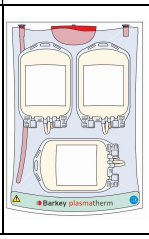
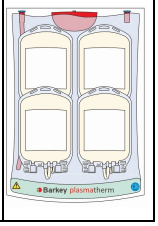
Filling volume per FFP approx. 250 ml/preparation

Initial temperature: - 35°C

Packaging: none

Barkey GmbH & Co. KG - Gewerbestrasse 8 - 33818 Leopoldshoehe - Switchboard: +49 (5202) 9801-0
Customer service: +49 (5202) 9801-30 - Fax: +49 (5202) 9801-99 - E-Mail: info@barkey.de

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) without any additional packaging	250ml				

Heating duration in minutes to reach “without ice”

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, HPC and OCTAPLAS may only be heated for limited periods of time!
Do not use this device to keep these products warm continuously!

WARNING

Blood/whole blood, HPC and OCTAPLAS 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 chapter 4.4.1 and 4.4.6 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, HPC and OCTAPLAS may only be heated for limited periods of time!
Do not use this device to keep these products warm continuously!

WARNING

Blood/whole blood, HPC and OCTAPLAS 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 chapter 4.4.1 and 4.4.6; 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, HPC and OCTAPLAS may only be heated for limited periods of time!
Do not use this device to keep these products warm continuously!

WARNING

Blood/whole blood, HPC and OCTAPLAS 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 chapter 4.4.1 and 4.4.6. 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 comply with the following safety information:

WARNING

The undulation function should not be used while heating up blood products or erythrocyte concentrates so as to avoid mechanical stress on the cellular material and 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, HPC and OCTAPLAS may only be heated for limited periods of time!
Do not use this device to keep these products warm continuously!

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 Chapters 4.4.1 and 4.4.6; to start the “CONTINUOUS” program, please proceed in the same way but select “CONTINUOUS” instead of “PLASMA” as the program.

NOTE

Temperature settings, time settings and undulation functions are not available in continuous operation.

4.4.12 Selecting and starting the “OCTAPLAS” program

WARNING

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

WARNING

Blood/whole blood, HPC and OCTAPLAS 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.

As an example, chapters 4.4.1 and 4.4.6 describe how to start the “PLASMA” program. To start the “OCTAPLAS” program, follow the same steps, but select “OCTAPLAS” instead of “PLASMA”.

In the “OCTAPLAS” program, the OCTAPLAS is heated for 30 minutes at 37 °C. If loaded with three to four bags, the heating time can be extended once for 15 minutes, increasing the total program time to 45 minutes.

The bags containing OCTAPLAS are placed in the Barkey plasmatherm in the same way as all other products.

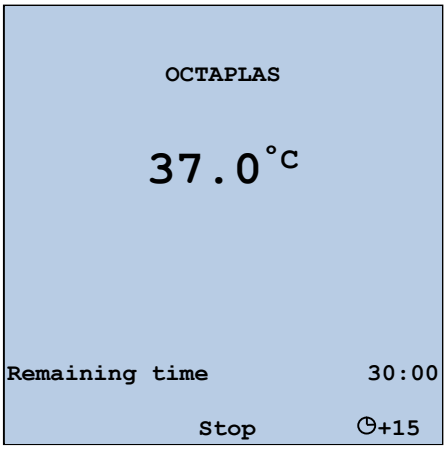


Figure 27: "OCTAPLAS"

If you wish to heat one to two bags of OCTAPLAS, proceed as follows:

► Start the program.

► Do not extend the heating time.

The bags will be heated for 30 minutes at 37°C.

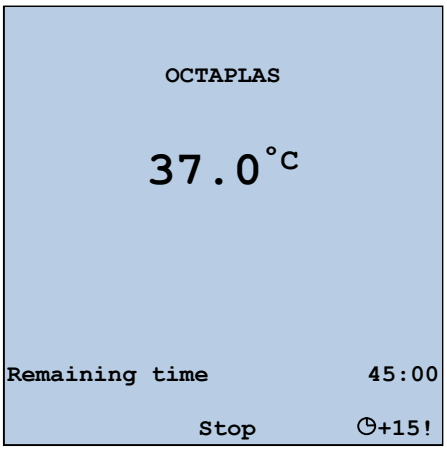


Figure 28: Remaining Time

If you wish to heat three to four bags of OCTAPLAS, proceed as follows:

► Start the Program.

► Press the "+15" button.

The remaining time will flash on the display.

► Press "OK" to confirm.

The displayed remaining time will stop flashing. The program will heat the conserves for a total of 45 minutes.

If the remaining time has been extended, an exclamation mark will appear after "+15". The remaining time cannot be extended again.

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.

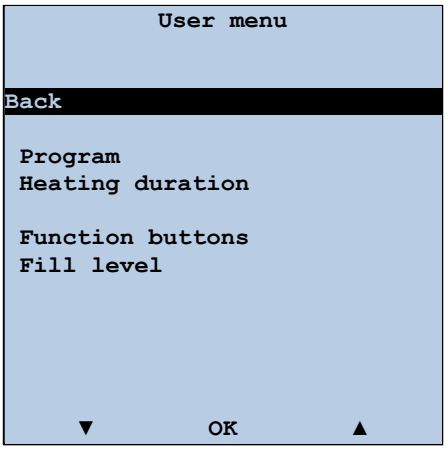


Figure 29: “User menu”

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

The user menu appears.

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

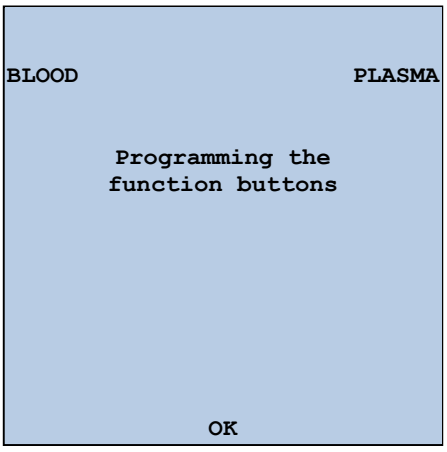


Figure 30: Assigning shortcut programs to the top two function buttons

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 fill level, the message “Fill the tank!” (i.e. lack of water) or “Tank is full” (sufficient heat transfer fluid) is displayed.

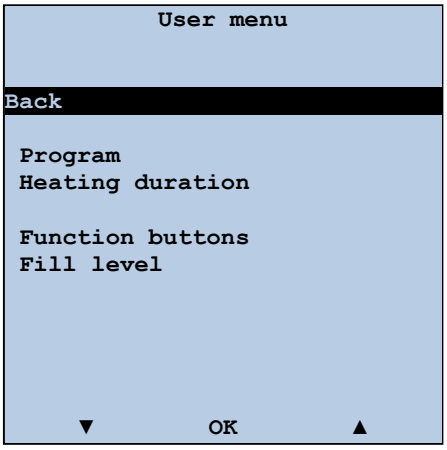


Figure 31: “User menu”

► 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 “Fill level”, then press the “OK” button to confirm your choice.

Figure 32: “Fill level” menu – “Fill the tank!” message

The filling status will be displayed as shown in the adjacent figure. Depending on the fill level, the message “Fill the tank!” (i.e. lack of water) or “Tank is full” (sufficient heat transfer fluid) is displayed.

WARNING

If “Fill the 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 chapter 5.3.2 of this user manual.

Figure 33: "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 and properly con-figured in the service menu, then the user ID (ID) and up to 8 sample IDs can be scanned in the main screen.

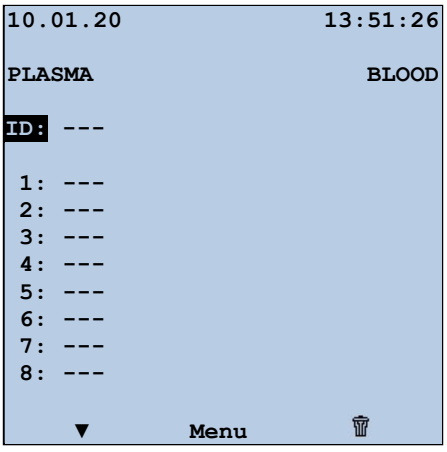


Figure 34: User ID and sample ID

If no user ID and no sample ID have been scanned in, the inverted text displays "ID:" at the user ID input position. 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 you do not wish to input a user ID 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.

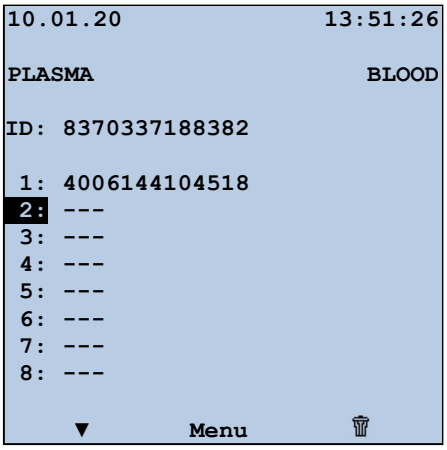


Figure 35: Scanned-in user ID and sample ID

It is not absolutely necessary to scan in all 8 sample IDs. A program can be started at any time.

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

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 overwritten with the currently scanned barcode, and the insertion point moves to position "1:".

If at the position "ID:" the right-hand selection button ("🗑") is pressed, 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 (ID) and for the 8 sample IDs are automatically deleted when a program has properly completed. If a program is cancelled either manually or because of an error, 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 Barkey plasmatherm by operating its On/Off button and disconnect its mains plug from the mains socket.
- Do not pour cleaning fluid or disinfectant directly on to 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 oxygenreleasing 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 time 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 Barkey GmbH & Co. KG.

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, please refer to the hygiene measures and regulations which apply in your hospital.

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 bags or contamination within the device itself, enabling early recognition.

If the filter paper becomes moist, a conductive bridge is created between the two sensors (metal contacts) on the heating chamber floor. This triggers an acoustic 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.

5.3 Changing the water

If the water is changed after one year, no germ formation is to be expected when using appropriate agents for drinking water treatment and distilled or demineralized water.

NOTE

If necessary, Micropur tablets can be requested from Barkey GmbH & Co. KG if appropriate means are approved in the respective country of use.

Please proceed as follows to replace the water:

5.3.1 Draining off water

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

WARNING

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

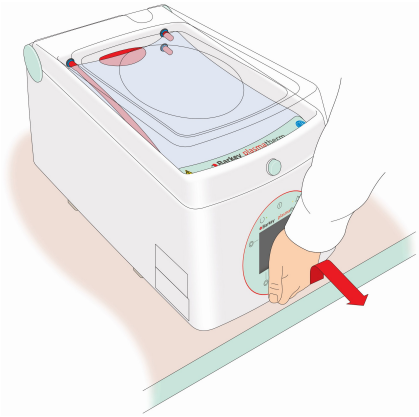


Figure 36: Pulling the device forward

- Pull the device forward over the front edge of the surface on which it is standing so that its front overhangs by approx. 15 cm.
- Two extra feet under the device prevent it tipping forward.

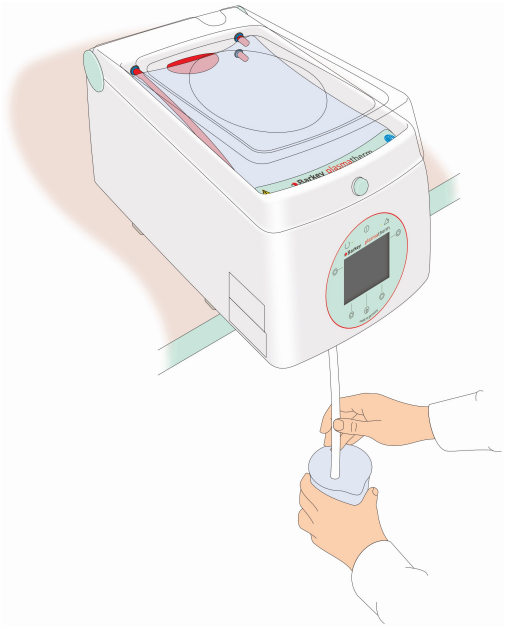


Figure 37: Drain tube

- 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.

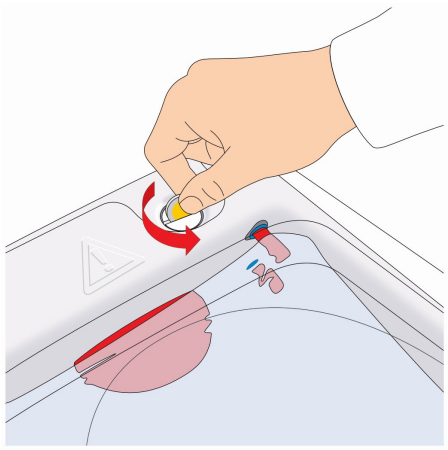


Figure 38: Filler opening with plug

- 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.

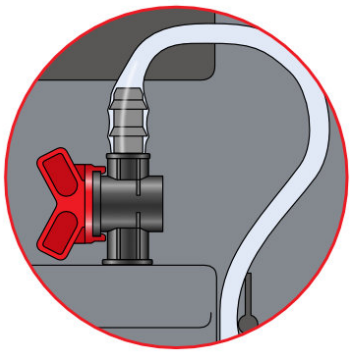


Figure 39: Opening the drain cock

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

- ► Lift the heating cushions slightly and ensure that they are completely empty.
- ► 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 completely filling the device but merely topping it up:
  Unscrew the plug from the filler opening as described above Chapter 5.3.1.
- ► 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 from the menu, as described in Chapter 4.6.

CAUTION

It is recommended to add a means for drinking water treatment (Katadyn Micropur classic) to the water, if appropriate means are approved in the respective country of use.

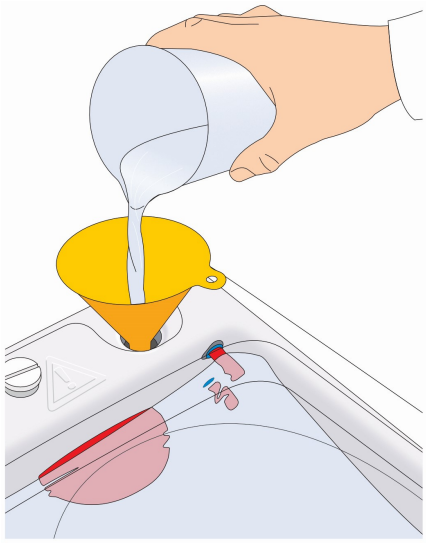


Figure 40: Filling the device

- ▶ 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 when an acoustic signal sounds and the following message appears: “Tank is full”.
- ▶ Press the confirm button (“OK”).
- ▶ Screw the plug back into the filler opening. Use a coin to tighten it.

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 material to heat.
- ▶ If the pump does not immediately pump heat transfer fluid into the cushions, stop the program, wait a short time, and start it again. 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 air bubbles disappear when the heat transfer fluid runs off.

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 be carried out only 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 Barkey GmbH & Co. KG factory. Please call us on +49 (5202) 9801-30 for information about current availability and costs.

At the end of this manual 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 A3 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.

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

When the Barkey plasmatherm device is switched on, it performs a self-check. Technical safety inspections therefore deal mainly with the device's measurement functions. 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 for the TSI is described in a separate service manual which can be requested from Barkey GmbH & Co. KG.

6.2 Replacing the battery

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

WARNING

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 the battery has been replaced.

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.
- ► Notify your medical technical service or the service department of Barkey GmbH & Co. KG

NOTE

In some cases, the serial number of the device will not be shown with an error message.

NOTE

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

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

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.

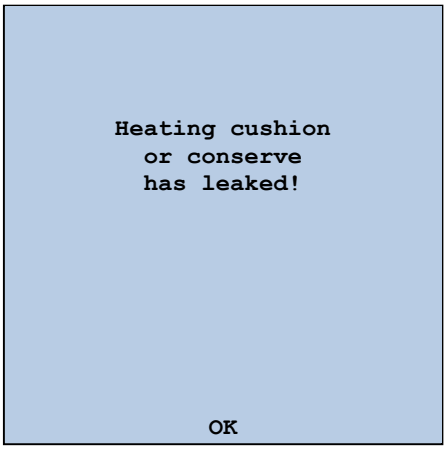


Figure 41: Moisture sensor messages

- ▶ 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 42: “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 Chapter 7.6). 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 appears again, please contact your medical technical service or the Barkey GmbH & Co. KG service department stating the error number and the serial number.

Barkey GmbH & Co. KG - Gewerbestrasse 8 - 33818 Leopoldshoehe - Switchboard: +49 (5202) 9801-0
Customer service: +49 (5202) 9801-30 - Fax: +49 (5202) 9801-99 - E-Mail: info@barkey.de

7.3 Paddle blocked

If the paddle for the special “Undulation” function is blocked, the following error message will be displayed:

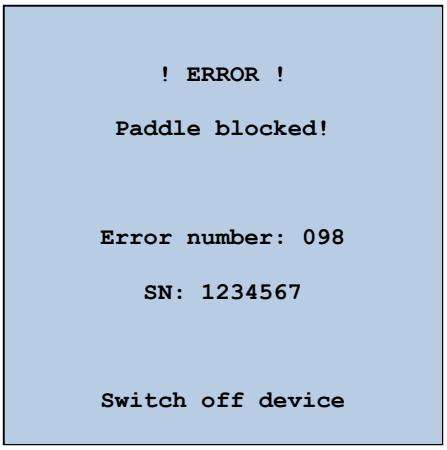


Figure 43: “Paddle blocked!” error message

- ▶ Note the error message.
- ▶ Make a note of the error number (098) and serial number (SN).
- ▶ Switch off the device and allow it to cool down.

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:

Figure 44: “Tank is empty!” error message

- ▶ Note the error message.
- ▶ Switch off the device.
- ▶ Fill up with water as described in chapter 5.3.2.

7.5 Device errors

Device errors can have various causes. Further diagnosis is possible by reference to the error number (see also chapter 7.6)

Figure 45: "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 those 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 out.

Barkey GmbH & Co. KG - Gewerbestrasse 8 - 33818 Leopoldshoehe - Switchboard: +49 (5202) 9801-0
Customer service: +49 (5202) 9801-30 - Fax: +49 (5202) 9801-99 - E-Mail: info@barkey.de

Error messages

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 for internal device data is incorrect	
32	Checksum for the program memory is incorrect	
33	Checksum of the data memory is incorrect	
40	Clock is incorrect	
41	Error when setting clock time	
42	Error when setting date	
43	Error when reading clock time	
44	Error when reading date	
45	Clock not running	Replace the battery (by authorised specialist staff only). Then set the time and date
60	The “watchdog timer” has detected an error.	
70 to 73	Error with temperature measurement / temperature sensors	Possible cause: sensor breakdown / sensor 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 any paddle blockages
100	Fill level in tank is critical; heater has been switched off	Restart system / top up the tank
110	Communication / interface fault	

Barkey GmbH & Co. KG - Gewerbestrasse 8 - 33818 Leopoldshoehe - Switchboard: +49 (5202) 9801-0
Customer service: +49 (5202) 9801-30 - Fax: +49 (5202) 9801-99 - E-Mail: info@barkey.de

8 Warranty and liability disclaimer

The warranty for the Barkey plasmatherm is 24 months from shipment.

Barkey GmbH & Co. KG grants this warranty in place of contractually or legally required warranties on this product, including other statutory guarantees of marketability or suitability for a particular use, and accepts no other liabilities.

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 evaluate 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 categorically declines all responsibility whatsoever for indirect damages or consequential damages of any type and restricts its liabilities exclusively to 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 this user manual, for the use of non-original components or for any use/installation which does not conform to the user manual accompanying such components. The use of components and accessories other than those referred to in the user manual shall result in a reduction of the manufacturer's warranty for the device.

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

- expansions, new settings, 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 this user manual, and
- the electrical safety has been demonstrably checked and tested according to the applicable regulations and at the prescribed intervals.

CAUTION

Barkey GmbH & Co. KG accepts 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 necessary repairs and regular servicing carried out by Barkey GmbH & Co. KG.

Barkey GmbH & Co. KG - Gewerbestrasse 8 - 33818 Leopoldshoehe - Switchboard: +49 (5202) 9801-0
Customer service: +49 (5202) 9801-30 - Fax: +49 (5202) 9801-99 - E-Mail: info@barkey.de

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 or repair to Barkey GmbH & Co. KG. Barkey GmbH & Co. KG will ensure that materials are properly separated, sorted and disposed of.

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 or damage caused by inadequate cleaning and disinfection.
- Each returned device must be accompanied by a formal certificate of cleaning. Forms for this purpose are obtainable from Barkey 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 this user manual.
- Please send a brief description of the fault along with the device. This will save you the cost of expensive fault diagnosis.
- 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.

The Barkey GmbH & Co. KG customer service department can be reached at

www.barkey.de

CAUTION

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 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”.

Barkey GmbH & Co. KG - Gewerbestrasse 8 - 33818 Leopoldshoehe - Switchboard: +49 (5202) 9801-0
Customer service: +49 (5202) 9801-30 - Fax: +49 (5202) 9801-99 - E-Mail: info@barkey.de

10 Factory settings of the programs

"PLASMA" Program

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

"BLOOD" Program

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

"HPC" Program

Set temperature	37	°C		
Heating duration	5	min	0	sec
Paddle delay	0	min	30	sec
Paddle time	4	min	30	sec
Paddle active	4	min	30	sec
Paddle inactive	0	min	0	sec

"USER" Program

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

"CONTINUOUS" Program

Set temperature	37	°C		
Heating duration	-	permanent		
Paddle delay	0	min	0	sec
Paddle time	0	min	0	sec
Paddle active	0	min	0	sec
Paddle inactive	0	min	0	sec

Barkey GmbH & Co. KG - Gewerbestrasse 8 - 33818 Leopoldshoehe - Switchboard: +49 (5202) 9801-0
Customer service: +49 (5202) 9801-30 - Fax: +49 (5202) 9801-99 - E-Mail: info@barkey.de

“OCTAPLAS” Program

Set temperature	37	°C		
Heating duration	30	min	0	sec
Paddle delay	2	min	0	sec
Paddle time	28	min	0	sec
Paddle active	28	min	0	sec
Paddle inactive	0	min	0	sec

Barkey GmbH & Co. KG - Gewerbestrasse 8 - 33818 Leopoldshoehe - Switchboard: +49 (5202) 9801-0
Customer service: +49 (5202) 9801-30 - Fax: +49 (5202) 9801-99 - E-Mail: info@barkey.de

11 Specifications

Manufacturer	Barkey GmbH & Co. KG Gewerbestrasse 8 33818 Leopoldshoehe Tel.: +49 (5202) 9801-0 Fax: +49 (5202) 9801-99	
Type	Barkey plasmatherm	
Typical capacity	4 bags / ≤ 500 ml or 2 bags / ≤ 1000 ml	
Power supply	220-240 VAC 50/60 Hz or 100-120 VAC 50/60 Hz	
Typical max power consumption	< 0,25 W < 35 W < 75 W 1600 W 1350 W	Standby Program break “PLASMA” 45°C program 230 VAC 50/60 Hz 115 VAC 50/60 Hz
Sound pressure level	< 45 dB(A)	
Current consumption	7 A at 230 VAC 12 A at 115 VAC	max. max.
Fuse rating	Microfuse T 8A H / 250 VAC Microfuse T 15A / 125 VAC	
Battery type	Lithium battery CR 1225, 3 V	
Interfaces / devices	Barcode reader Log printer; alternative network interface (TCP)	
Overtemperature protection	software-controlled: electronic:	set value + 1.0 °C (tolerance +0,5°C) 48 ± 1.0 °C
Temperature setting	selectable from standard setting	+37 to + 45 °C +37 °C
Temperature accuracy	setpoint ± 0.5°C	
Display accuracy	± 0.5 °C	
	Operation	Storage/Transport
Ambient temperature	+10 to +40 °C	-20 to +70 °C
Relative atmospheric humidity (non- condensing)	30 to 75 %	30 to 90 %
Air pressure	700 to 1060 hPa	700 to 1060 hPa
Operation type	continuous operation	

Dimensions		(B x T 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	
Top-up quantity	approx. 1 litre (device warning)	
Protection class	I	
MDR-classification	II a	
Moisture protection	IP 21	
Certification	CE 0123	

Barkey plasmatherm device master data sheet

Device designation:	_____
Serial numbers:	_____
Inventory number:	_____
Set-up location:	_____
Commissioning date:	_____
Identification:	CE 0123
Manufacturer:	Barkey GmbH & Co. KG Gewerbestrasse 8 33818 Leopoldshoehe
Telephone:	+49 (5202) 98010
Fax:	+49 (5202) 980199
E-mail:	info@barkey.de