OPERATION MANUAL

SERVICE-INFORMATION

transfusio - therm 3000

CE

EICMED GmbH
Rudolf-Diesel-Str. 5
D-37308 Heilbad Heiligenstadt
Tel: +49/3606/607925
Fax: +49/3606/5071353

E-Mail:info@eicmed.de

Contents

I Illustration

II Tabel

If the transfusio - therm is not used in accordance with the manufacturer's operating instructions, the intended protection may be impaired!

Illustration 1: Mandatory sign „Observe instructions“ according to EN ISO 7010

IMPORTANT NOTE:

With the mandatory sign, we point out the compliance with operating instructions in order to understand and avoid potential hazards.

Intended use

The **transfusio-therm 3000** is used for thawing and warming up blood and blood plasma.

Intended use:

The **transfusio-therm 3000** is a device for thawing fresh-frozen plasma (FFP) and for heating all commercially available bag preserves of whole blood and erythrocyte concentrates (RBC) in sizes from 100 ml to 600 ml.

In accordance with the "Notice of the guidelines for collecting blood and blood components and for the use of blood products (hemotherapy) according to §§ 12 and 18 of the Transfusion Act (TFG) (amendments and supplements 2010) of May 4th, 2010" this is limited Warming of blood components for the following indications:

- Massive transfusions with delivery of more than 50 ml RBC per minute,
- Patients who were hypothermic before the transfusion,
- Patients with chronic cold agglutinin disease and high-titre cold antibodies,
- Patients who react to the cold stimulus from chilled blood with vasospasm
- and transfusions and exchange transfusions in newborns.

Based on the temperature rise, the device recognizes which power input is required. The goal is a linear progression up to the target temperature, regardless of whether plasma or EK bag food was used. A mixed allocation with both goods is also possible. In this case, the machine adapts to the faster increase and can regulate the power input by means of a stepless inverter. Bag recognition is therefore not necessary. The initial temperature of the bag influences the performance of the device, so we would like to point out that you should put the bag in a polystyrene container after removing it from the cooling container.
A bag that has already been heated should not be reheated.

Contraindications

The device may ONLY be used for defrosting/heating the respective canned goods in bags.

It is not permitted to heat other canned goods in bags!

1. Installation

1.1 Determination of the delivery condition

Upon delivery, the shipment must be checked for completeness or possible damage and transport damage. The device should not be used if the packaging is damaged.

The transport box can be opened after removing the handles.
The device has a weight of approx. 30 kg and should be
be removed by two people using the side handles of the device.

After unpacking, the **transfusio-therm 3000** must be checked by authorized specialist personnel (according to the attachment) for:

- Completeness of the delivery (**transfusio-therm 3000**, mains connection cable, short and long instructions for use)
- possible damage to the device
- proper condition of the door and handle
- any damage to the plastic parts in the interior
- correct opening and closing of the door
- Unclosed ventilation openings

1.2 Installation oft he device / safety distances

According to IEC 61010, the transfusio-therm 3000 must not be set up in the vicinity of the patient (minimum distance 1.5 m). The user must not touch the device and the patient at the same time.

The **transfusio-therm 3000** was designed for safe operation under the following installation conditions:
a) Indoor use/storage only
b) Altitude up to 2000 m
c) Air-conditioned room 25°C (± 5°C)
d) max. relative humidity 80% at temperatures up to 30°C, linear
decreasing to 50% relative humidity at 40°C
e) Mains voltage supply fluctuations up to ±10% of mains
tension
f) transient overvoltages up to the values of the overvoltage
Category II, the rated surge voltage is 2,500 volts.
g) intermittent overvoltages occurring in the mains power supply
h) applicable degree of pollution, according to the foreseen
environment (degree of pollution 2: is non-conductive pollution that can become conductive through occasional condensation or hand perspiration)

The **transfusio-therm 3000** must be set up on a level, safe surface (device weight approx. 30 kg) at an ergonomically sensible working height.

Installation near direct sources of heat or on devices that emit heat themselves (e.g. on refrigerators) is not permitted.
To ensure adequate ventilation of the device, a distance of 40 mm must be maintained on all sides of the device. A 40 mm wide spacer is attached to the rear, which ensures the required spacing on the rear of the device.

Do not use spacers as carrying handles!

**The ventilation openings on the back wall
and on the bottom of the device must not be covered.**

**Before the first start-up, the device is accordingly
point 4. "Cleaning and maintenance instructions".**

**In order to disconnect the transfusio-therm 3000 from the power
the power switch can be used. The device is to be set up in such a way
that the separating device can be actuated at any time.**

Medical electrical devices are subject to special precautionary measures with regard to electromagnetic compatibility (EMC). EMC instructions regarding installation and operation must be observed. (pt. 4)

Medical devices can be affected by mobile portable HF communications equipment.WARNUNG:

The use of this device directly next to other devices or stacked with other devices (with the exception of the transfusi-therm 3000) should be avoided, as this could result in faulty operation. If use in the manner described is nevertheless necessary, this device and the other devices should be observed to ensure that they are working properly.

WARNING:
Portable or mobile HF communication devices (e.g. radio devices or mobile phones) can affect **transfusio-therm 3000** beeinflussen. Therefore, a distance must be kept between the devices.

The **transfusio-therm 3000** can interfere with other devices. Neighboring devices must therefore be monitored. If interference occurs, the devices must be spatially separated or the operator must take additional shielding measures.

1.3 Electrical connection

The electrical connection between the device and the power supply is established via the detachable mains connection cable supplied. This must not be replaced by inadequately dimensioned power cords.

The power cord must meet the following specifications:
With molded PVC angle protective contact plug (type B1) of protection class I. With double protective contact and kink protection. IEC 884-1 (DIN 49441 R2). The PVC appliance socket for protection class I has anti-kink protection and is double-insulated for T 65 °C. EN60320-1/C13.

Kabel-Anwendung	Ausführung	Anschluss A	Stecker-Ausführung	Anschluss B	Kabellänge	Kabel-Typ	Nennspannung	Produkt-Art
Kaltgeräte	Anschlusskabel	Schutzkontakt-Stecker	Einseitig gewinkelt	Kaltgeräte-Buchse C13	2,50m	H05VV-F 3G 1 mm²	230 V	Kaltgeräte Anschlusskabel

Tabel 1: Technical cata power cable transfusio-therm 3000

No other accessories are available.

Using longer cable lengths could result in increased emissions or reduced immunity. Use of any cable other than the above is not permitted. Incorrect operation could be the result.

The initial start-up is only to be carried out by service personnel trained by the manufacturer.

The **transfusio-therm 3000** may only be connected to a protective contact socket that is secured according to the device data.

The safety of the system into which the **transfusio-therm 3000** is integrated is the responsibility of the system installer.

The **transfusio-therm 3000** is intended for use in the electromagnetic environment specified below. The customer or the user of the **transfusi-therm 3000** should ensure that it is used in such an environment.

2. Instructions use for

2.1 Explanation of connection elements

On the back of the device there is a mains input socket in which the mains switch is integrated, including the fuse elements (2 x T 10A H 250V). The connection point for equipotential bonding is right next to it.

2.2 Erklärung der Bedienungs- und Displayanzeige

The display, various signal lights and the 6 operating buttons are located directly above the door (Figure 2).

Illustration 2: Display, various signal light and confirmation buttons

Assignment/removal button left (A1) and right (A2)

Start button for program ice-free

37°C *Start button for target temperature 37°C*

Stop button

Button Standby

The current temperature of the can is shown on the corresponding display. All buttons on the control panel are equipped with LEDs that prompt for actions or signal current operating states.

- Blinking YELLOW: Call for action
- GREEN steady: selected program choice
- GREEN flashing: end of process
- Flashing RED: Trouble

2.3 Disassembly and assembly oft he mixing unit

The complete mixing unit (troughs, drive plate, metal inserts) can be removed from the interior of the transfusi-therm 3000 for better cleaning. The trays with the metal inserts are removed first, then the drive plate is lifted up and out. After cleaning (point 6) all parts are to be wiped dry and re-inserted in reverse order.

Please note:

- ⚠ **All parts must interlock positively during assembly.**
- ⚠ **It is important to ensure that all components are complete.**
- ⚠ **If components are damaged during disassembly/assembly, the functionality of the machine will be impaired.**

2.4 General device description

The **transfusio-therm 3000** is based on a calculated housing for the homogeneous distribution of the HF energy of a magnetron.
The bag preserves up to a volume of 600 ml are heated by an HF microwave generator up to a specified target temperature. There are two receptacles for the bags in the device.
During the heating process, the temperature is constantly monitored via 2 infrared sensors per bag and shown on 2 displays. When the set temperature is reached on a bag, heating is stopped immediately and the process is indicated by the temperature on the display. If both receptacles are used, the heating of the second preserve can be continued after the removal of this preserve, if this is necessary.

The device can be used to thaw and heat FFP-GFP (blood plasma), blood and erythrocyte concentrates. In order to ensure that the bag contents are heated homogeneously, the bags are mixed with a movement during heating.

The user is constantly informed about the current temperatures via the displays. If errors or deviations are detected by the two-channel safety and protection systems, these are signaled on the operating unit (LED button) and also acoustically and the device is switched off immediately.

The user has 2 different programs to choose from and can select heating up to ice-free or 37°C. Ice-free means that the coldest measured temperature of the bag is 10 seconds above 18°C. The final temperature can therefore vary greatly. The selected start button shows the selected program with a green LED.

A double monitoring circuit ensures that the HF microwave generator only works when the door of the HF room is closed.

2.5 Commissioning / operating sequence

1. **Connect the device to the power supply**
2. **Switch on the device at the mains switch (rear of the device)**
3. **Press the standby button to switch on the device**
4. At this point, the device checks all safety-relevant systems in a self-test, an acoustic signal sounds and the LEDs light up simultaneously in the colors green, yellow and red.
5. **Open the door**
6. **Remove tub**
   ⚠ Wipe dry bags
7. **Place the bag in the tub according tot he pictogram (figure 3)**
8. **If necessary, insert another bag (repaet steps 5 and 6)**
9. **Insert the tub in the drive plate in a form fitting manner**
10. **Close the door**
11. **Confirm the insert**
    The assignment buttons request confirmation of the assignment of the respective recording by means of a flashing LED. By pressing the button, the display changes to the measured temperature.

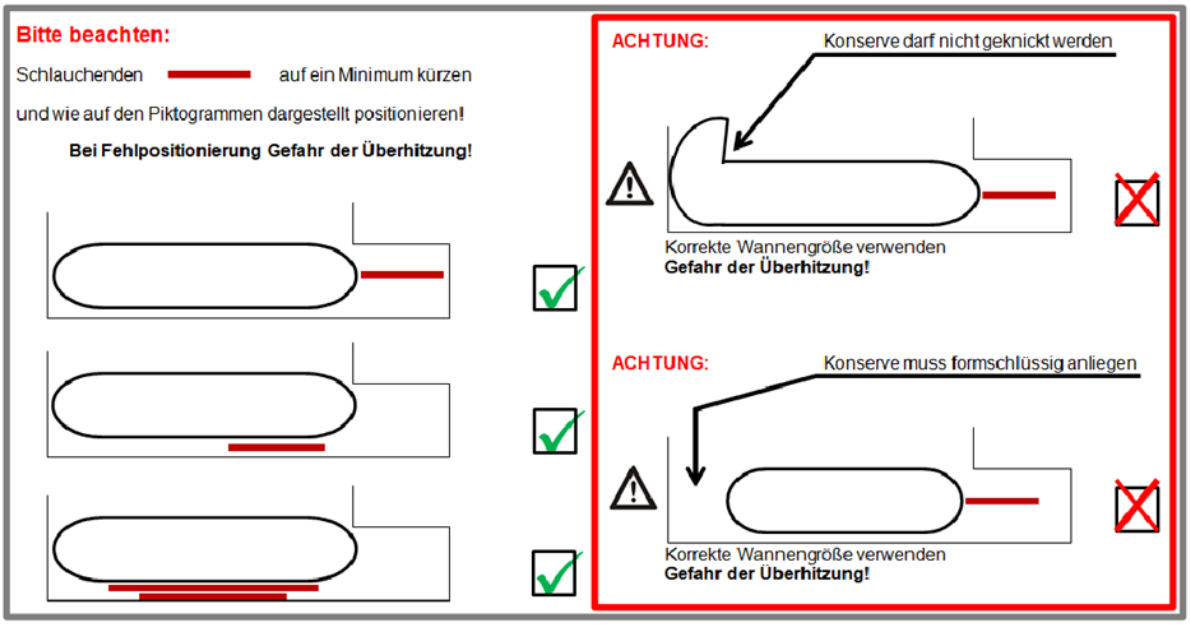
12. **Program choice / Start**
    The start button for the target temperature ice-free/37°C prompts you to select the target temperature with a flashing LED. Pressing the target temperature button starts the heating process.
13. **Target temperature reached**
    When a bag has reached the set temperature, the device switches off the heating. A tone sounds and the LED of the assignment button for the corresponding recording flashes green.
    Pressing the confirmation button associated with the canned food intake confirms that the target temperature has been reached. The display switches off the temperature display and the allocation button flashes yellow.
14. **Open the door**
15. **Removal of the corresponding bag**
    The tub is removed together with the bag. After removing the bag from the tub, check it for damage and temperature. If necessary, the tub should be wiped dry. After closing the door, the heating process for the remaining bag will continue after renewed confirmation.
16. **If necessary, insert new bag**
    The empty compartment can be occupied again immediately and is brought to the target temperature that has already been selected.
17. **If no more bags are to be heated, the machine must be put into standby. The mains switch on the back should only be activated after the machine has cooled down (fan noise).**

All start and target temperatures are recorded and saved by the device.

3. Safety instructions

The transfusio-therm 3000 is intended exclusively for thawing and heating of commercially available bag preserves with plasma (FFP), whole blood and erythrocyte concentrates (ERC). Other objects, especially metal parts, may not be brought into the interior. Misuse of the device is not permitted. The ventilation openings must not be covered.

Incorrect operation (e.g. incorrect insertion of the bags) could cause the blood/FFP to overheat. The machine detects any overheating and automatically reduces the machine's performance, which can result in a considerable lengthening of the process. Please note the following illustration:



Illustraion 3: pictogram

The occurrence of protein denaturation in FFP bags and coagulum formation in EK bags is possible after the bag has been overheated. After removal, the bag must be checked for integrity.

It may only be operated by trained personnel. THE DECISION TO TRANSFUSION IS THE RESPONSIBILITY OF THE USER.

The safety distance from medical devices to the mobile phones most frequently used by private individuals (2 W/frequency range: 800-2500 MHz) is 3.3 m.

In order to ensure trouble-free operation of the device, it is recommended to keep the bags dry and to free the trays from condensation residues (polystyrene container).

<u>Erytrozytenkonzentrate (EK) or whole blood</u>
(Be sure to observe the notes and pictograms)

- Always check the tubs for cleanliness, wipe dry if necessary

- Shorten hose ends that are not required to a minimum.
- If there is no label on one side of the bag, place that side up.
- Roll up the remaining hose ends and place under the bag
- It is essential to ensure that all hose ends are fixed and do not hang out.

Plasma (FFP)

(Be sure to observe the notes and pictograms)

- Always check the tubs for cleanliness, wipe dry if necessary
- BE SURE to remove the double bag
- Hose connections when kinked frozen down
- Remove protruding labels
- Remove condensed water residue and frost from bags before inserting them (Styrofoam containers prevent frost from forming)

As the manufacturer, EICMED GmbH assumes no responsibility for the use of the heated bag.

3.1 Notes on mechanic

To ensure safe operation, the **transfusio-therm 3000** is only to be connected according to the information in the operating instructions. The instructions for setting up and connecting the device must be observed. The device must not be switched on without the mixing unit being properly seated. Any interventions and repairs must not be carried out yourself, as this could result in considerable danger for the user. All interventions, apart from the technological assignment and cleaning activities in the device, may only be carried out by service personnel trained by the manufacturer.

3.2 Notes on the electrical system

The device is connected to the mains using a supplied connection cable. This must not be replaced by inadequately dimensioned power cords.

The power supply must be protected with at least 10A (230V/50Hz) and an FI circuit breaker.

The mains socket should be located as close as possible to the rear wall of the device.

The safety of the system into which the **transfusio-therm 3000** is integrated is the responsibility of the system installer.

For cleaning or maintenance, the device must be disconnected from the mains by pulling out the mains plug.

The connecting cable is only to be pulled out of the connection socket by its connecting plug.
The cleaning instructions in Section 4 must be observed.
If unusual noises, smoke or fire occur, switch off the device, pull out the mains plug and inform customer service.

3.3 Notes for high frequency

The preservesbags are heated with a microwave generator using high-frequency radiation (HF radiation).
The heating room or HF room is sealed against high frequencies on all sides. This is guaranteed on the one hand by the closed welded construction of the heating room and on the other hand by the high-frequency safe door seal. Several safety devices are in place.

Please note:

After removing the bags from the cooling container, the condensation on the surface of the bags could cause frost to form. Therefore, we would like to point out that the bags should be placed in a Styrofoam container after they have been removed from the cooling circuit.

The device may only be operated by trained personnel.

To avoid the emission of harmful microwave energy, the device must not be started if:

- Objects are trapped between the door and the housing;
- • the door or hinges are damaged;
- • the door seal cover is dirty or damaged;
- • the door is warped; hard closes;
- • the hinges are not tight;
- • the door handle has come loose;
- • the door is not firmly closed;
- • the door seal counter surface of the housing is no longer flat.

If one of the aforementioned defects is found, the device should not be operated.

3.4 Setpoint shutdown

The setpoint switch-off is the switch-off when the target temperature of the bag has been reached after it has been heated. The target temperature is selected when heating starts by selecting the program (ice-free or 37°C).

3.5 Protective shutdown (Software)

A protective shutdown is understood to mean a shutdown of the device due to an error message, based on the display of the two both sights. The safety shutdown of the device or the corresponding bag is indicated to the operating personnel by a red LED signal lamp.

The bag intake blocked in this way cannot be reassigned until the self-test has been successfully run through again. Any bag in this receptacle must be removed. The temperature must be checked and if the temperature exceeds 42°C or there is visible damage, the bag must be destroyed. The protective shutdown is reset when the device is switched on again. If a protective shutdown occurs repeatedly due to this bag intake, the responsible service department must be contacted.

3.6 Safety shutdown 1st system (CTRL 1) and 2nd system (CTRL 2)

A safety shutdown occurs if there is a fault in the overall system of the device. The device switches off automatically. The safety shutdown is indicated to the operating personnel by the continuous red light on the stop button. In addition, a continuous acoustic signal sounds. The device must be switched off at the mains switch. All bags that have been put in must be removed, the temperature checked and, if the temperature exceeds 42°C or there is visible damage, the bags must be destroyed.

The device remains locked when it is switched on again. Pull out the mains plug and contact Technical Service.

3.7 Self test

To check the effectiveness of the above protection systems, the device may have to be switched off and then on again. It then goes through a self-test during which the protection systems are checked. After passing the self-test, the device is ready for use.

4. Electromagnetic compatibility

Medical electrical equipment is subject to special precautions regarding EMC and must be installed and put into service according to the guidelines given below. Portable and mobile HF devices (e.g. mobile phones) can affect medical electrical devices.

The **transfusio-therm 3000** was tested for interference emission and interference immunity according to DIN EN 60601-1-2:2016-05, EN 60601-1-2:2015 and IEC-60601-1-2:2014. It was a complete test according to the EMC Directive 2014/30/EU and the Medical Devices Act 93/42/EEC.

Operating mode during EMC testing: Thawing and heating of -30°C ice in two 2 liter containers.

Warning:
The use of other accessories, other converters and other cables than those specified or provided by the manufacturer of this device can result in increased electromagnetic interference emissions or reduced interference immunity of the device and lead to incorrect operation.

Warning:
When using the transfusio-therm 3000 , ensure that the device is not used in the vicinity of sources of intensive electromagnetic interference, in particular HF surgical devices (distance > 5m).

4.1 Essential feature

The essntials featrues of the **transfusio-therm 3000** are:

- Homogeneous heating
- Heating to target temperature or ice-free
- Undamaged bags
- Warming in the designated time window

A failure of the essential performance characteristics due to EMC interference is recognized and evaluated by the control electronics. This results in a safety or protective shutdown (see point 3.5; 3.6).

4.2 Manufacturer guideline – Electromagnetic emissions

Interference Emission Measurement	**Accordance**	**Electromagnetic environment - guidelines**
HF-emissions according to CISPR11	Group 2	The transfusio-therm 3000 uses HF energy to treat matter.
	Class A	The properties of this device determined by emissions allow its use in industrial areas and in hospitals (CISPR 11, class A). In domestic use (which typically requires Class B according to CISPR 11) this device may not provide adequate protection from radio services. If necessary, the user must take remedial measures such as relocating or reorienting the device.
Emission of harmonics according to IEC61000-3-2	n/a	
Emission of voltage fluctuations / flicker after IEC61000-3-3	n/a	

Tabel 2: Electromagnetic Emissions according to DIN EN 60601-1-2:2015

4.3 Manufactrurer's Guidance – Electromagnetic Immunity

Immunity Tests	IEC 60601-1-2 Test level	In accordance	Electromagnetic environment
discharge of static electricity (ESD) according to IEC 61000-4-2	± 8 kV contact discharge ± 15 kV air discharge	yes	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity must be at least 30%.
High-frequency electromagnetic fields IEC 61000-4-3	3 V/m, 80 MHz bis 2,7 GHz, 80% AM bei 1 kHz	yes	Professional healthcare facilities
Radio frequency electromagnetic fields in the immediate vicinity of wireless communication devices IEC 61000-4-3	385 MHz PM 18 Hz, 50%, 27 V/m	yes	
	450 MHz PM 18 Hz, 50%, 28 V/m	yes	
	710 MHz, 745 MHz, 780 MHz PM 217 Hz, 50 %, 9 V/m	yes	
	810 MHz, 870 MHz, 930 MHz PM 18 Hz, 50 %, 28 V/m	yes	
	1720 MHz, 1840 MHz, 1970 MHz PM 217 Hz, 50 %, 28 V/m	yes	
	2450 MHz PM 217 Hz, 50%, 28 V/m	yes	
	5240 MHz, 5500 MHz, 5785 MHz PM 217 Hz, 50%, 9 V/m	yes	
fast transient electrical disturbance variables/bursts IEC 61000-4-4	± 2 kV for power lines 100 kHz refresh rate	yes	Professional healthcare facilities
Surhe voltages (Surges) IEC 61000-4-5	± 1 kV Line-Line ± 2 kV Line - Earth	yes	Professional healthcare facilities
Conducted interference, induced by high-frequency fields according to IEC 61000-4-6	3 V, 150 kHz bis 80 MHz, 6 V in ISM-frequency bands between 0,15 MHz and 80 MHz; 80% AM for 1 kHz	yes	Professional healthcare facilities

Voltage dips, short-term interruptions and fluctuations in the supply voltage according to IEC 61000-4-11	0% UT (<100% dip in UT) for 1/2 period at 0, 45, 90, 135, 180, 225, 270, 315 degrees; 0% UT (100% dip in UT) for 1 period; 70% UT (30% dip in UT) for 25 periods at 0 degrees; 0% UT (< 100% dip in UT) for 5 s	yes	Mains power quality should be that of a typical commercial or hospital environment. If the user of the transfusi-therm 3000 requires continued operation even when the power supply is interrupted, it is recommended that the transfusi-therm 3000 be fed from an uninterruptible power supply.
Magnetic field at the supply frequency (50/60 Hz) according to IEC 61000-4-8	30 A/m	yes	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Transmission of transient electrical disturbances via supply lines (use in motor vehicles) according to ISO 7637-2	n/a		Device does not fall within the area of application (motor vehicle)

Tabel 3: Immunity standard according to DIN EN 60601-1-2

4.4 Recommended safety distances

Das transfusio-therm 3000 ist für den Betrieb in der unten angegebenen elektromagnetischen Umgebung bestimmt. Der Kunde oder der Anwender des transfusio-therm 3000 sollte sicherstellen, dass es in einer solchen Umgebung benutzt wird.

The transfusio-therm 3000 is intended for operation in the electromagnetic environment specified below. The customer or the user of the transfusio-therm 3000 should ensure that it is used in such an environment.

	Protective distance depending on the transmission frequency in m		
Rated power of the transmitter W	**150 kHz bis 80 MHz d={ 3,5/V1 }√P**	**80 MHz bis 800 MHz d={ 3,5/E1}√P**	**800 MHz bis 2,5 GHz d={ 7/E1 }√P**
0,01	**0,058**	**0,035**	**0,07**
0,1	**0,18**	**0,11**	**0,22**
0	**0,58**	**0,35**	**0,70**
10	**1,85**	**1,11**	**2,21**
100	**5,83**	**3,50**	**7,00**

Tabel 4: Recommended safety distances between portable and mobile HF telecommunication devices and the transfusi-therm 3000, according to DIN EN 60601-1-

For transmitters rated at a maximum power not listed in the table above, the recommended separation distance d in meters (m) can be determined using the equation associated with the appropriate column, where P is the maximum power rating of the transmitter in watts (W) as specified by the transmitter manufacturer.

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

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

WARNING:

Portable HF (radio frequency) communications equipment (including their accessories such as antenna cables and external antennas) should be used no closer than 30cm from the device.

4.5 EMV-Disturbance variables / basic security

If the essential performance features can no longer be used or can only be used to a limited extent as a result of the presence of EMC interference, the device will display an error message as a result of a self-test carried out at the start of operation.
During operation, the device goes into safety or protective shutdown due to a disturbance.
Um das zu vermeiden sind unbedingt die Herstellerangaben zu den Aufstellbedingungen zu beachten.

In addition, the cyclic STP/MTP must be commissioned by the manufacturer and the cleaning and disinfection instructions must be followed.

The product life cycle of the transfusi-therm 3000 is 10 years, this includes all EMC relevant components. The user does not have to take on any maintenance work for EMC resistance. Only a visual inspection of the mechanical components, such as the door seal or housing parts in general, must be guaranteed.

5. Supplies

Mains connection cable (for technical data see item 1.3 Electrical connection)
-
-

6. Cleaning and maintenance instructions

The **transfusio-therm 3000** is a high quality product. The structure paint or powder coating guarantees perfect hygienic conditions for defrosting and heating. The device should be cleaned before it is used for the first time and whenever necessary. **The device may only be cleaned when the mains plug is unplugged.** Allow the device to cool down after use.

All surfaces and the assemblies listed below must be cleaned with a damp cloth - also slightly soaked - with disinfectants approved in hospitals by wiping with disinfectant. **The removable components of the mixing unit can be cleaned under running water if they are heavily soiled.**

The operator must ensure that the manufacturer or his representative is consulted if there is any doubt as to the compatibility of decontamination or cleaning agents with parts of the device or with the substances contained therein.

Exterior surfaces

Only use a damp cloth with a mild detergent to clean the device. No scouring agents, scratching or sharp objects may be used.

Sealing surfaces

The sealing surfaces (front surface of the housing on four sides around the interior and on the inside of the door) must be kept particularly clean in order to ensure the safe functioning of the device. Therefore, these surfaces should be cleaned regularly with a damp cloth. If the sealing surfaces are damaged or the door is damaged, the device must not be switched on, since HF may escape.

Inner space

The interior paintwork meets the requirements for medical products and may only be wiped off with a damp cloth using commercially available disinfectants approved in accordance with medical regulations.

Spray disinfection must not get into the opening of the temperature sensors, which are located on the top of the interior.

Mixing unit

The complete mixing unit can be removed from the interior for better cleaning. After removing the trays, the drive plate can be pulled out by lifting it forwards. The mixing unit should be cleaned with a damp cloth or under running water if it is heavily soiled.

The assembly of the mixing unit takes place in reverse order. The rear recess of the drive plate must be placed on the driver. The tubs can then be inserted. When assembling, make sure that the components are positioned correctly and straight.

It is not permitted to operate the device if the mixing unit is not properly seated.

7. Disposal

There are no special or unusual hazards for the environment when the product is disposed of. We expressly point out that the devices will be taken back by EICMED GmbH free of charge after decommissioning and will be disposed of properly in accordance with the municipal waste management guidelines.

8. Warranty / Disclaimer

The manufacturer gives a warranty of 24 months from the date of sale. If a defect occurs in the device during the warranty period, the defect will be remedied (spare parts and labour) free of charge. This refers to demonstrably defective workmanship or material defects. Normal wear and tear, intentional or negligent damage, damage caused by non-observance of the operating instructions, incorrect mains voltage and mains frequency or damage caused by abnormal environmental conditions are excluded. Also excluded from the warranty are interventions by service or specialist personnel who have not been trained by the manufacturer.

If the operator refuses to carry out the annual safety and metrological test (STP/MTP) according to the manufacturer's information, we hereby expressly point out that the same does not assume any liability in the event of an incident.

The manufacturer generally assumes no responsibility for indirect damage or consequential damage.

9. Service / error code reading and error message

In the event of a fault, download the EICMED GmbH fault report log from the Internet at www.eicmed.de and send the completed form to customer service by fax or e-mail.

The serial number of **transfusio-therm 3000** in question must be given when reporting faults or ordering spare parts.

The maintenance and repair of the transfusi-therm 3000 may only be carried out by service personnel trained by the manufacturer. All guarantee and services provided by the manufacturer EICMED GmbH are carried out by customer service.

Only original parts obtained from the manufacturer may be used for repairs to the **transfusio-therm 3000.**

An annual Safety Technical Inspection (STP) and a
Device and temperature measurement test (MTP) are mandatory.

Before any maintenance work or repairs, the device must be thoroughly cleaned by the operator in accordance with the applicable hygiene regulations.

10. Technical data - transfusio-therm 3000

Device for thawing and heating of blood plasma (FFP), whole blood and erythrocyte concentrates (EK)

Processor-controlled monitoring and regulation of the thawing and heating process

Gentle swivel mechanism supports the homogeneous heating of the preserves.

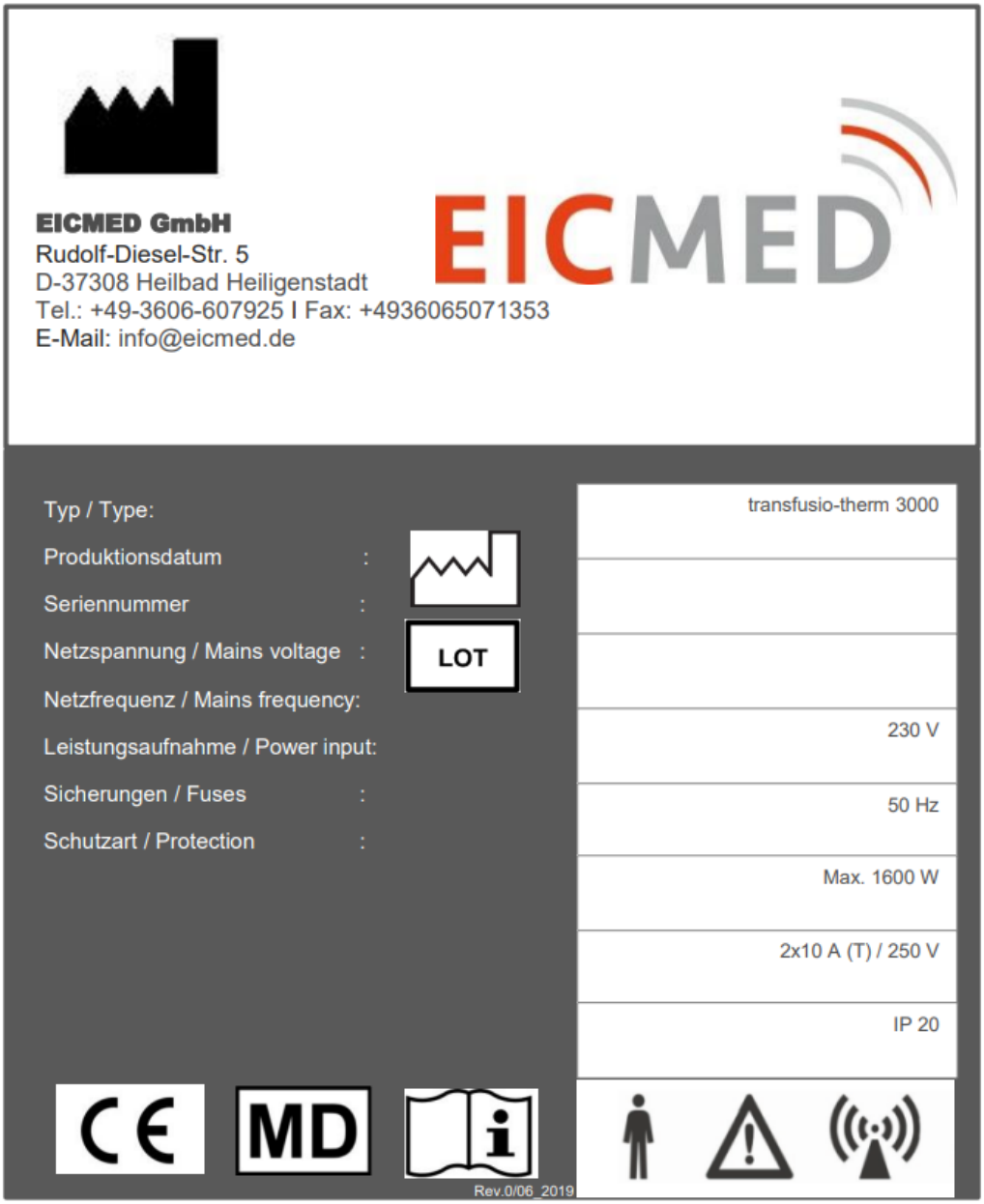
Single and double filling with preserves from a bag volume of 100 ml to 600 ml is possible.

selectable program ice-free / 37°C

Temperature accurancy:	bei ± 4°C in the bag
Magnetron operating frequency	2450 MHz, +/- 50 MHz
High frequency performance:	max. 850 W
Type and frequency characteristics of the modulation:	CW with performance change over several seconds
Power connection:	230 V / ±10 %
Mainy frequency:	50 Hz
Power consumption:	max. 1600 W
Backup values:	10 A träge (250 V)
Protcetion class:	I
Degree of protection:	IP20
Dimensions (H/W/D):	680 x 475 x 335 mm
Weight:	30 kg
Shutdown temperature of the protection system:	>39°C
Shutdown temperature of the security system:	>42°C

Service: **EICMED GmbH**
Rudolf-Diesel-Straße 5
D-37308 Heilbad Heiligenstadt
Tel.: 0 36 06 / 60 79 25 oder 60 78 93
Fax: 0 36 06 / 5 07 13 53
E-Mail: info@eicmed.de
www.eicmed.de

Type label:



Designed to be operated by one person

Warning of a danger point

Electromagnetic field warning

III Attachments

FB-01 STP
FB-02 MTP
FB-03 Fault Report Form