EIC Umwelt- und Medizintechnik Ltd.
..:: AQUA ..:: MED ..:: THERM

OPERATING INSTRUCTIONS

SERVICE INFORMATION

transfusio - therm® 2000

CE 0123

MODELS:

"transfusio - therm® 2000 - Universal"

"transfusio - therm® 2000 - Plasma fast thawing"

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MTK Record (annual General and Temperature Measuring Check)
Fault Reporting Form

(Can be downloaded from the internet at
www.eic-ltd.de)

Function / normal use / contra-indications

“Universal” Model

The “Universal” model of *transfusio-therm® 2000* is a device for the ***thawing of Fresh-Frozen Plasma (FFP) and warming of any conventional type of blood bags from Whole Blood to Erythrocyte Concentrates (EC) of sizes from 100 ml to 600 ml.***

Through an integrated temperature measurement, the type of content of inserted blood bags is determined *(FFP, Whole Blood or EC)*. According to the type of content, bags are warmed either at full power *(FFP)* or with regulated power *(Whole Blood and EC)*.

Pursuant to the Document Publishing the Guidelines for the Collection of Blood and Blood Components and for the Use of Blood Products (Haemotherapy) in Accordance with Sections 12 and 18 of the German Transfusion Act (TFG), as Modified and Amended in 2010, the heating of blood components is restricted to specific indications:

- Massive transfusions exceeding 50 ml of EC per minute
- Patients suffering from low temperature prior to a transfusion
- Patients suffering from chronic cold agglutinin disease and high titers of cold reactive antibodies
- Patients reacting with vasospasm to the cold stimulus originating from cooled blood
- Transfusions and exchange transfusions in newborns

“Plasma fast thawing” Model

In contrast to the “Universal” model, the “Plasma fast thawing” model of *transfusio-therm® 2000* must **only** be used for the ***thawing and warming of conventional plasma bags of sizes from 100 ml to 600 ml***. Bags are warmed at full power (FFP) from the start.

With devices of both models, temperatures of inserted bags must not exceed +12°C in order to prevent repeated warming of bags.

Contra-Indications:

The “Plasma fast thawing” model must not be used for warming erythrocyte concentrates (EC) or Whole Blood. !

Each model must only be used for thawing / warming of such bag contents as indicated for the respective model. !

Warming of any other bag contents is not allowed!

Putting into operation

1.1 Establishing the condition of the equipment on delivery

The consignment is to be inspected for completeness or possible damage, as well as damage incurred in transit. The crate used for transportation can be opened after setting the code on the combination lock, which is noted in the invoice. Because of the weight of the equipment of approx. 60 kg, the equipment should be always removed by two people from the crate used for transporting. The hinged grip mounted in the side wall of the equipment pointing upwards is to be raised and taken hold of. At the same time, the moulded grip, likewise mounted in the base of the equipment, to be found according to the transport position on the right side, is now to be gripped. The equipment is removed by lifting from the crate used for transportation and then put down in a vertical position on the feet.

After the equipment has been unpacked, the *transfusio-therm® 2000* must, in any case, be controlled by a suitably qualified person with reference to the following points:

- the completeness of the delivery (*transfusio-therm® 2000*, mains connection cable, documentation / instructions for use)
- damage to the equipment
- mandatory locking of the rotating device available
- the correct condition of the door, the two door contact pins and the grips
- that the door sealing is not damaged (no scratches)
- that the door opens and closes without problems
- that the ventilation openings are not sealed

1.2 Setting up the equipment / Safety distances

The ***transfusio-therm® 2000*** must be placed on an even surface, at a safe location. It is to be set up in dry, air-conditioned rooms at normal room temperatures and not in the direct vicinity of any heat sources or any devices emitting heat (e.g. refrigerators).

In order to ensure adequate cooling of the equipment, a distance of 40 mm is to be maintained on all sides around the blood-warming equipment. At the rear of the equipment, a spacing device has been mounted, which ensures that the necessary mandatory distance is maintained at the rear of the equipment. **WARNING! The spacer must not be used as a grip for lifting the equipment.** The ventilation openings on the rear wall and those at the base of the equipment must not be covered.

!

If the equipment is used in areas where patients are also present, the PE plug at the rear of the equipment should be connected.

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Before putting the equipment into operation for the first time, the equipment is to be cleaned in accordance with **4. Advice concerning cleaning and maintenance**.

RECOMMENDED SAFETY DISTANCES BETWEEN PORTABLE AND MOBILE HF TELECOMMUNICATION DEVICES AND "transfusio-therm 2000" DIN EN 60601-1-2, 6.8.3.201, Table 206

The equipment is designed for use in an electromagnetic environment with controlled HF interference. The user of the equipment can help avoid electromagnetic interference by ensuring that the following minimum safety distances are maintained between the equipment and any portable and mobile HF telecommunication devices (transmitter) - depending on the nominal output of the communication device.

	Safety distance depending to the transmission frequency in m		
Nominal output of the transmitter in W	150 kHz to 80 MHz $d=\{ 3.5/V_1 \}\sqrt{P}$	80 MHz to 800 MHz $d=\{ 3.5/E_1\}\sqrt{P}$	800 MHz to 2.5 GHz $d=\{ 7/E_1 \}\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.33

With transmitters of a nominal output not given in this table, the recommended safety distance d in metres (m) can be calculated based on the equation given for the appropriate transmission frequency, where P is the maximum nominal output of the transmitter in Watt (W) according to the information supplied by the transmitter manufacturer.

NOTE 1: With frequencies of 80 MHz or 800 MHz, the higher frequency range should be applied.

NOTE 2: These guidelines may not be applicable in all cases, as the spreading of electromagnetic interference can be influenced when it is absorbed and/or reflected by buildings, objects and human beings.

1.3 Electrical connection

In accordance with the delivery contract, the *transfusio-therm® 2000* is manufactured in the constructional design which the customer has ordered. Consequently, the design may differ with reference to the mains frequency and the mains voltage (100V / 110 V / 230 V; 50 Hz / 60 Hz). The voltage specified on the type plate must be identical with the mains voltage and the corresponding mains frequency.
The electrical connection between the equipment and the power supply system is implemented using the connecting cable delivered with the equipment.

The first putting into operation is only to be carried out by service personnel trained by the manufacturer.

1.4 Models

The *transfusio - therm® 2000* is available in two versions:

"***transfusio - therm® 2000 - Universal***"
"***transfusio - therm® 2000 - Plasma fast thawing***"

Commissioning of the equipment is identical for each version.

2. Instructions for use

2.1 Description of the operating and connecting elements

On the front side of the equipment, on the right, below the door to the warming compartment, there is the mains switch which is provided with an integrated green light. Directly above the door, there is the display; various signal lights, as well as the four control keys (Fig. 2.1).

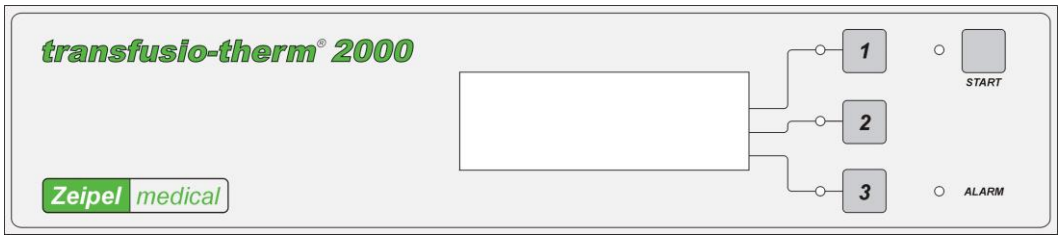


Figure 2.1: Display, various signal lights, as well as control keys

(1) Control key intake 1, with three-coloured (green, yellow, red) LED at the side
(2) Control key intake 2, with three-coloured (green, yellow, red) LED at the side
(3) Control key intake 3, with three-coloured (green, yellow, red) LED at the side
(4) Start key with yellow LED at the side
(5) Alarm light with integrated red-coloured LED

Digital display / operating control

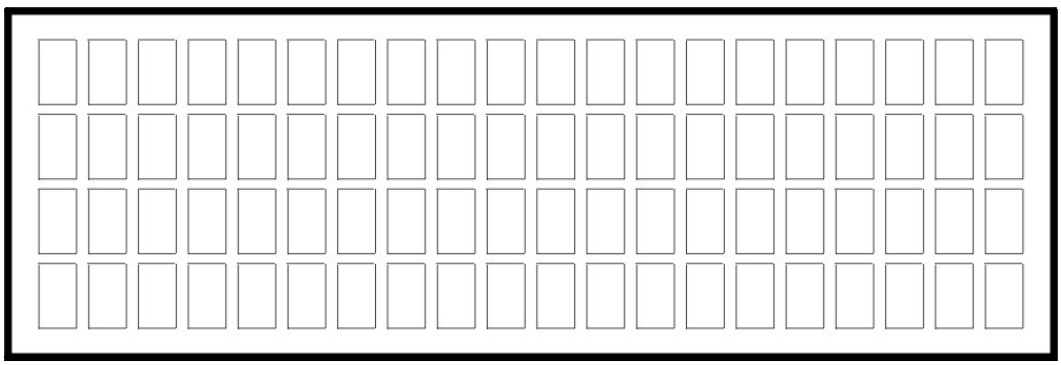


Fig. 2.2: digital display with four lines, each with 20 letters

Line 1 Status line
Line 2 Display text intake 1
Line 3 Display text intake 2
Line 4 Display text intake 3

On the rear side of the equipment, there is a multiple-pole cable connection box.

2.2 Dismounting and mounting of the rotating device

In order to improve cleaning, the complete rotating device can be removed from the interior of the *transfusio-therm® 2000*. So that this can be achieved, remove safety hook on left rear side of centre receptacle and than pull off rotating device forwards. The spring plate and the inertial force plates can be removed by means of the four screws.

The rotating device can be cleaned using a damp cloth, or lightly soaked with conventional disinfectant, **but should never be cleaned under running water**. After cleaning has been successfully completed, all parts are to be wiped dry or allowed to dry. Then the spring plates and the inertial force plates are to be screwed in place again and the attachment screws are to be screwed tight. **Warning! Loose screws may result in damage!**
The complete rotating device should be pushed back from the front until it contacts the shaft. Watch the right placement of the spring in the drive shaft. Then the safety catch must again be inserted. This must likewise be inserted up to its stop in the rotating device. The firm seating of the rotating device should be controlled before putting the equipment into operation once more. **The operation of the *transfusio-therm® 2000* with the rotating device not having firm seating or with the safety catch not completely inserted is not permitted. Serious damage to the rotating device or the motor drive shaft will result in the breakdown of the equipment.**

Please see part 6 of these Operating Instructions for detailed service information regarding the rotating device.

2.3 General description of the equipment

2.3.1 “Universal” Model

The transfusio - therm® 2000 - Universal is a device for the thawing and warming of any conventional type of blood bags from fresh-frozen plasma (FFP) to whole blood to erythrocyte concentrates (EC) of sizes from 100 ml to 600 ml.

The warming of the stored blood is carried out using a HF microwave generator. The energy produced by the HF microwave generator is distributed and reflected by a baffle plate in a HF chamber, which is high-frequency dense on all sides, in the outward direction.

There are three universal stored blood intakes mounted on a special rotating device which is mounted in the HF chamber. In these stored blood intakes, all known forms of stored blood in bags with a volume of up to 600 ml can be evenly laid flat without a changeover being required.

An even and homogeneous warming of the stored blood with an HF output connected is achieved by the rotary movement of the stored blood intake and the gentle, thorough mixing of the stored blood combined with this. The changes in the direction of the rotary movements take place very gently, in order to prevent the foaming up of the stored blood.

The recognition of the stored blood (FFP, whole blood or EC) is implemented by measuring the temperature of the stored blood placed in the equipment. In this way, it can be determined whether the warming can take place at full output (FFP) or with a rhythmic output (whole blood or EC).

During the warming process, the temperature is constantly measured, and on reaching the set temperature for the stored blood, the HF output is switched off, and the removal of the stored blood is requested by means of an audio as well as a visual signal.

If more than one stored blood product is present in the equipment, the warming procedure is continued, following removal of the stored blood product which has been warmed to its set temperature and after closing the door, until the set temperature for the additional stored blood has been reached.

Because of the clearly organised display, simple and uncomplicated operator control is ensured.

In order to ensure greater equipment safety, the ***transfusio-therm® 2000*** is equipped with a two-channel protective system. At the same time, the microcomputer system takes over, in addition to a control function, also the function of the first protective system. The second protective system (fault reporting bar) is constituted by a discretely constructed monitoring logic.

Monitor switching ensures that the HF microwave generator only operates when the door to the HF chamber is closed.

Faults and deviations from the normal operating procedure are recognised by the respective safety system and are signalled to the operator, by means of visual or visual and auditory signals.

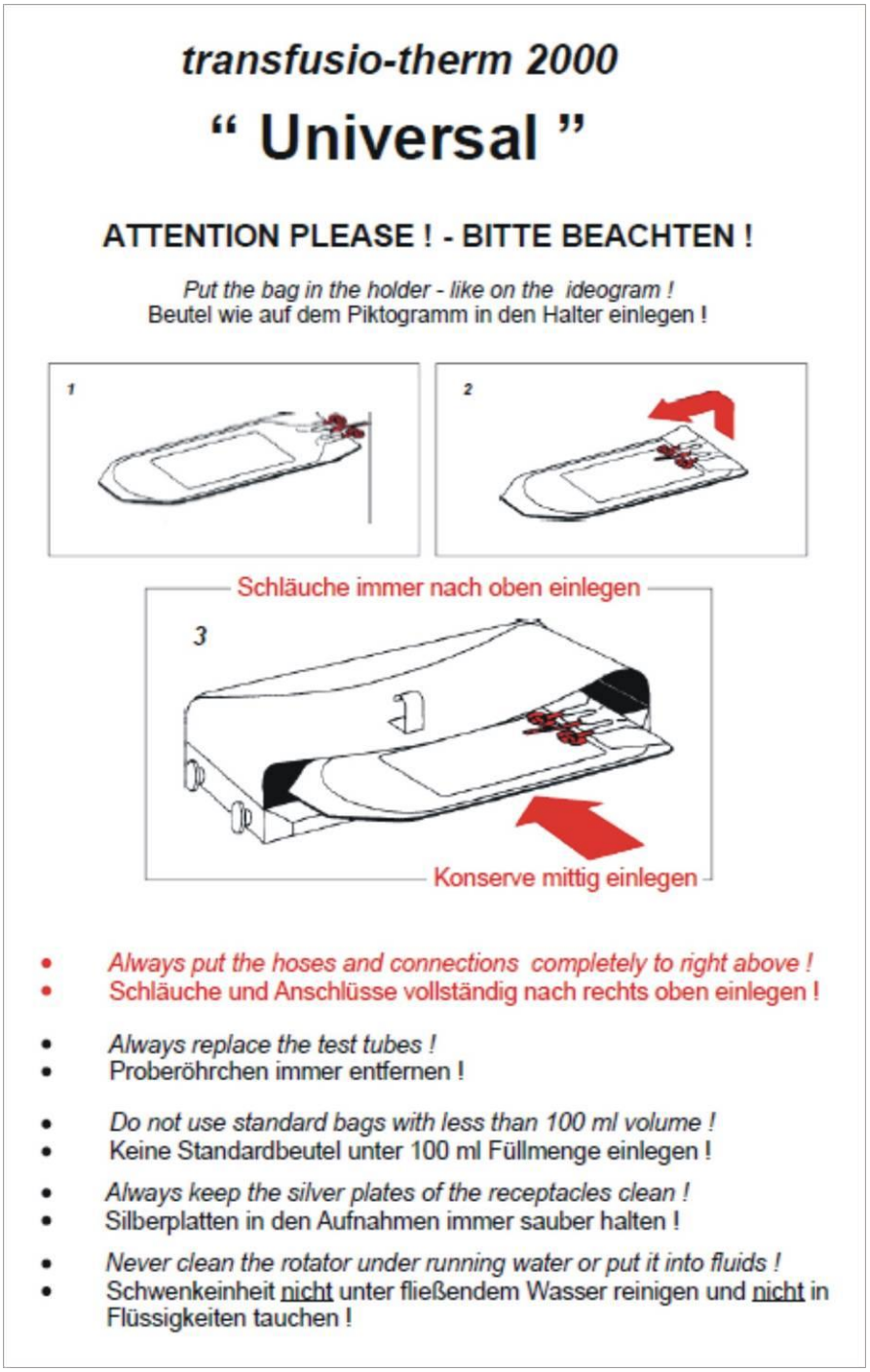
In the event of switching off of a stored blood intake, for reasons of safety, the stored blood located in the equipment must be removed and its temperature must be checked. If its temperature exceeds 41°C or the bag shows any signs of damage, the blood bag must be disposed of. Then work can subsequently be continued with the non-blocked, stored blood intakes.

In the event of a switching off for reasons of protection, all stored products which have been placed in the equipment must be removed and their temperature must be checked. Blood bags with temperatures exceeding 41°C must be disposed of. The equipment is to be switched off immediately. When the equipment is switched on again, the equipment will carry out an independent test; if this is successful, the protective switch will be reset and the equipment can be used again, normally. If switching off for reasons of protection or safety recur or the independent test is unsuccessful, the equipment is to be switched off, the mains plug is to be pulled out and the service department is to be notified.

Erythrocyte concentrates (EC) or whole blood

(Make sure you follow instructions and pictograms on door and receptacles!)

- Always check that silver plates of receptacles are clean
- Remove pilot tubes and surplus tube ends
- If one side of the blood conserve does not bear labels, place this side facing downwards.
- Roll up remaining tube ends and place to the right side.
- Make absolutely sure that all tube ends are fixed and not hanging out.
- EC conserves can also be placed in an additional bag (e.g. Topphit-Zip bag) to prevent the pilot tubes from hanging out. The EC conserves must:
  a) be placed in the protective bag with the pilot tubes turned onto the labelled side of the conserve and then inserted into the blood intake.
  b) The bag must not project between the conserve and measuring plate.
- Do not insert standard bag filled with less than 100 ml.



2.3.2 "Plasma fast thawing" Model

In contrast to the "Universal" model, this model is not equipped with a feature for the recognition of the type of bag content, as it is suitable for plasma bags only. The bag is warmed up at full power in order to ensure fast thawing (FFP).

The "Plasma fast thawing" Model must not be used for warming erythrocyte concentrates (EC) or whole blood.

!

Plasma (FFP)

(Make sure you follow instructions and pictograms on door and receptacles!)

- Always check that silver plates of receptacles are clean
- Insert blood conserves in double bag (if available)
- If tube connections are frozen in a bent position insert at top right; if straight, to right.
- Do not insert standard bag filled with less than 100 ml

2.4 Engaging the equipment, Operating sequence

1. **Mains switch on**
2. **Open door**
3. **Prepare blood conserves**
   (Temperature of blood bags to be inserted < 12°C!)
4. **Lift the spring plate of a free intake upwards**
5. **Insert blood conserves in middle, with contact to silver plate**
6. **If needed, insert additional bags of stored blood (repeat steps 3 to 5)**
7. **Close the door**
8. **Confirm that the intakes are allocated**
   The control light allocated to the particular, newly occupied stored blood intake will flash with a yellow colour. The occupation of the stored blood

intake which has just been reserved must be confirmed by operating the confirmation key allocated to the particular stored blood intake. Following this confirmation of reservation, the respective control light will display continuous yellow light. If the reservation of all the newly allocated stored blood intakes is confirmed, the start release will be activated, which can be recognised by the yellow flashing light displayed by the start control light.

9. **Start**
   If start release has been activated, which can be recognised by the yellow flashing light on the start control light, the warming of the stored blood can be started by operating the start key, with the door closed. The start control light then has continuous yellow light. The rotating device starts up and, following recognition of starting criteria, the HF generator is connected. When subsequently FFP stored blood (storage temperature –28 °C to –35 °C) is placed in the equipment, the HF is connected with full output, otherwise rhythmic operation will take place, with a consequently reduced output, for careful warming of whole blood and EC.
   Based on temperature of the conserve the unit recognises whether one or more conserves have been warmed up. If this is the case the unit will switch off automatically, a red signal appears at the receptacle in question, an intermittent sound is heard and the display does read 'remove/check conserve'. In such an event remove the conserve, check its temperature and/or replace the conserve exactly as per instructions on the pictogram. After reconfirming that receptacle has been filled and renewed start, conserves will be warmed up automatically.
   When using the „Universal“ model and with frozen fresh frozen plasma conserves (FFP) a star appears after occupation of the stored blood in the display after identification. This star is extinguished when approx. +20°C is attained, and an acoustic signal shows that the conserved blood can be removed as required (has thawed). If the conserved blood is not removed, heating will continue to the set-point temperature.
10. **Set temperature has been reached**
    When an inserted stored blood product has reached the set temperature, the equipment switches off the warming process. An intermittent sound is produced and the corresponding control light flashes with a green colour.
11. **Confirm set temperature**
    The reaching of the set temperature is confirmed by operating the respective confirmation key allocated to the stored blood intake. The corresponding control light displays continuous green light and the intermittent sound is silenced. Display reads 'remove conserve'.
12. **Open door**
13. **Removal of the particular stored blood bags**
    If accidentally the wrong stored blood is removed from another receptacle, the operator will be requested to also confirm this incorrect removal.
14. **If desired, insert new bags of stored blood (repeat steps 3 to 5)**
15. **Close door**
16. **If new bags of stored blood have been inserted, steps 8 and 9 must be repeated. Otherwise, provided that other stored blood bags are still located in the intakes, following closing of the door, the renewed**

starting up of the rotary device will be implemented and, after approx. 10 seconds, the HF generator will be connected (continue with steps 10 to 15).

17. **If no other bags of stored blood are to be warmed, the mains switch is to be switched off.**

3. Safety advice

The *transfusio-therm® 2000* is only to be used for defrosting and warming of conventional bags of stored blood with plasma, whole blood and erythrocyte concentrates. Other objects, in particular metal parts, may not be placed in the interior of the equipment. Use not in accordance with the intended purpose of the equipment is not permitted. The ventilation openings must not be covered.

<u>The configuration "Plasma fast thawing" MUST not be used for warming of erythrocyte concentrates.</u> !

Identification of device: Display 7.01 = universal device
Display 8.20 = plasma thawing device

or according to the door pictogram

Faulty operation (false insertion of the bagged preserves) may occasionally result in overheating of the preserves.

Overheating of the respective preserve may cause protein denaturation with FFP preserves and coagulation with EK preserves.

Only instructed personnel may operate the machine! !

The clearance distance of medical devices to most popular mobile telephones of private persons (2 W/frequency range: 800-2500 MHz) is 3,3 m.

3.1 Advice concerning the mechanics

In order to ensure safe operation, the ***transfusio-therm® 2000*** is only to be connected in accordance with the descriptions of the operating instructions. The advice concerning setting up and connecting the equipment is to be observed. The equipment is not to be switched on without the rotating device being correctly mounted and secured. No intervention or repairs may be carried out independently, as this may result in serious danger to the user. All interventions, except for technological covering and cleaning of the equipment, must be carried out by qualified personnel who have been trained by the manufacturer.

3.2 Advice concerning the electronics

The equipment is connected to the mains supply by a connecting cable supplied with the equipment. The power supply system must be minimally protected with 10 A (230 V) or 20 A (100/110 V) and a F1 protective switch.

The mains wall socket should, if possible, be located near to the rear wall of the equipment. When the equipment is used in areas where patients are also present, the PE plug at the rear of the equipment should be connected.

During cleaning or maintenance of the equipment, the equipment is to be disconnected from the power supply system by pulling out the power plug.

The connecting cable is only to be pulled from the wall socket at its connecting plug. The advice regarding cleaning given in section 6 should be observed.
Should unusual noises, smoke or fire occur, the equipment is to be switched off and the customer service department is to be informed!

3.3 Advice concerning high frequency

The warming of the blood bags is effected by a microwave generator using high-frequency (HF) radiation.
The warming chamber or HF chamber is high frequency dense on all sides. This is guaranteed, on the one hand, by the closed welded construction of the warming chamber and, on the other, as a result of the high frequency door sealing. Several safety devices guarantee this requirement.

The equipment is only to be operated by instructed personnel.

In order to prevent the emission of damaging microwave energy, the equipment may not be started when:

- objects are jammed between the door and the housing
- the door or the hinges are damaged
- the door seal is dirtied or damaged
- the door is misplaced
- the contact pins are damaged, bulk or bent
- the hinges are not firmly fixed
- the door handle has loosened
- the door is not firmly closed
- the door seal counter-surface of the housing is no longer even

The equipment is not to be operated if any of the above-listed defects are present.

3.4 Switching off the set point temperature

The expression “switching off the set temperature point” means switching off the equipment on reaching the set temperature for the bags of blood, following successful warming. The set temperature is specified by the customer when ordering the equipment ***transfusio-therm® 2000*** and is set programmed by the manufacturer. The set temperature can vary between +25°C or +30°C (Plasma fast thawing) and +30°C or +35°C or +37 °C (Universal).

3.5 Switching off for safety reasons

What is meant by “switching off for safety reasons” is switching off the equipment because of the reporting of a fault with reference to one of the three stored blood intakes. The switching off of the equipment for safety reasons is indicated to the operating personnel in the display and by means of a LED signal light, which lights up red.
The blocked stored blood intake may not be occupied again. Remove any stored blood in this intake and check the temperature. If temperature is above 41°C or the bag shows any sign of damage, it must be destroyed. The switching off for safety reasons is reset on switching on the equipment once more. In the event of reoccurrence of switching off of this stored blood intake for safety reasons, the service department is to be informed.
The stored blood located at the two remaining intakes can be continued to be warmed. These blood conserve intakes may also be once more occupied.

3.6 Switching off for protection of the equipment

Protective switching exists when a fault in the complete system of the equipment has occurred. The equipment will be automatically switched off. The protective switching off of the equipment is signalled to the operating personnel in the display and by means of the continuous red light of the alarm light. In addition, a continuous acoustic signal sounds. The equipment is to be switched off at the power supply switch. All stored blood bags are to be removed, the temperature must be checked. If temperature is above 41°C or the bags show any signs of damage, they must be destroyed.

When the equipment is switched on once more, the equipment will effect an independent test; if necessary, the protective switching will be reset and the equipment can be used normally again. On recurrence of protective or safety switching off, or if the independent test is unsuccessfully, the equipment is to be switched off and the power supply plug pulled out. The service department should be informed.

4. Advice concerning cleaning and maintenance

The ***transfusio-therm® 2000*** is a superior quality product. The lacquering or powder coating of the structure guarantees the faultless hygienic prerequisites for defrosting

and warming. The equipment should be cleaned before being put into operation for the first time, as well as when it is necessary. **The cleaning of the equipment may only be carried out after the power supply plug has been pulled out.** Following operation, the equipment should be allowed to cool.

Any surfaces and the components named below can be cleaned with conventional hospital disinfectants applied with a damp or slightly soaked cloth. **They must never be cleaned under running water or be submerged in water or cleaning detergents.**

Outside surfaces
Only a damp cloth with a mild detergent should be used for cleaning the equipment. No scouring agents or objects which would scratch or which have pointed surfaces are to be used.

Surfaces of seals
The surfaces of seals (front surface of the housing on four sides and the interior, and on the insides of doors) must be especially kept clean, in order to ensure the safe functioning of the equipment. Therefore, these are to be regularly cleaned with a damp cloth. If the surfaces of the seals or the door are damaged, the equipment must not be switched on in order to prevent the escape of HF.

Interior
The lacquering of the interior of the equipment fulfils the requirements for medical products and may only be wiped out with a damp cloth with conventional disinfectants permitted by medical regulations.

Rotating device
In order to achieve better cleaning, the complete rotating device can be removed from the interior. To achieve this, remove safety hook on left rear side of centre receptacle and than pull off rotating device forwards. The spring plate can be removed using the milled-edge screws. The rotating device can be cleaned with a damp cloth and should never be cleaned under running water.
In order to avoid damage, the temperature sensor measurement points (silver plates) are to be cleaned especially carefully. At the same time make sure that no traces of labels or several labels of blood conserves remain on the temperature sensor points (silver plates). Otherwise remove remnants at once. After cleaning has been successfully carried out, all parts are to be wiped dry and allowed to dry. Then the spring plates are to be screwed on again and the screws are to be firmly screwed. The complete rotating device should be slid onto the shaft up to the stop at the front paying attention to the position of the spring in the drive shaft. The securing catch must be once more inserted. This should be inserted until contact is made with the rotating device.
The firm seating of the rotating device is to be checked before putting the equipment into operation once more. If display reads: “Attention! Check fit of rotating device”, switch off the unit and recheck fit of rotating device.

Motor shaft and plug fixture of rotating device

The motor shaft and plug fixture of the rotating device may only be cleaned dry and must **not by any means** be treated with oils or other lubricants as this may inhibit electrical conduction. !

If the display reads **Attention! Check the fitting of rotating device**, switch off the equipment, recheck and make sure that the rotating device sits correctly.
Operation of the equipment with the rotating device not firmly seated or with the securing catch not completely inserted is not permitted.

5. Guarantee

The manufacturer grants a 24-month guarantee from the date of purchase. If, during the guarantee period, a defect in the equipment should appear, the elimination of the fault (replacement parts and hours of work) will be carried out free of charge. The guarantee refers to demonstrable defective construction or defects in material. Normal use, deliberate damage or damage caused by negligence, damage caused by non-observance of the instructions for use, using an incorrect power supply voltage or frequency, or damage caused by other abnormal environmental conditions is excluded from the guarantee. Likewise, any intervention carried out by persons who are not service personnel or specialists trained by the manufacturer are excluded from the guarantee.

6. Service / Determining error codes and reporting faults

Warning! Microwave energy! !

Determining error codes:

When switching on the tt 2000, press Key 3 until the error code is shown on the display. Use Key 1 to page to error No. 31.

Number of heated conserves: press Key 2

With any malfunction, download the fault reporting form of EIC Umwelt- und Medizintechnik Ltd. on the Internet under www.eic-ltd.de and fax or e-mail once completed to the customer service department.

Please make sure to indicate the serial number of your ***transfusio-therm® 2000*** in any fault reporting forms or spare part orders you submit. When reporting faults of the rotating device, please indicate the serial number of the rotating device concerned (see label on cross rail or stamped in number on the flange).

Any ***transfusio-therm® 2000*** with a serial number of 1 0801 261 and higher is equipped with a rotating device with a reinforced safety hook for the locking of the rotating device (spare part E 10021.1). This is indicated with the serial number of the rotating device (e.g. SWE 261 B - for a broad safety hook; SWE 136 S - for a slim

safety hook). Please include this information in your fault reporting form, as it is necessary to ensure correct fault elimination.

Maintenance and repair of the ***transfusio-therm® 2000*** may only be carried out by service personnel trained by the manufacturer. All guarantee and services provided by the manufacturer EIC Umwelt- und Medizintechnik Ltd. are carried out by the customer service department.

An annual Safety Check (STK) as well as an annual General and Temperature Measuring Check (MTK) are demanded.

7. Technical data - *transfusio-therm® 2000*

- Equipment for defrosting and warming blood plasma (FFP), whole blood and erythrocyte concentrates (EC)
- Processor-controlled monitoring and control of the defrosting and warming process
- Careful rotary mechanics promotes the homogeneous warming of the stored blood
- Individual, double and triple equipping with stored blood, with a bag volume of up to 600 ml is possible
- The time required for defrosting and warming is, depending on the size and the number of the stored blood bags which have been inserted, 4 to 15 min

Can be delivered with the following set temperatures:	
“Universal”	+ 30°C or +35°C or +37°C
“Plasma fast thawing”	+ 25°C or +30°C
Temperature accuracy “Universal”:	+ 2°C/- 4 °C in the blood bag
Temperature accuracy “Plasma fast thawing”:	± 4°C in the blood bag
Operating frequency, magnetron:	2450 MHz +/- 50 MHz
High frequency output:	max. 850 W
Mains connection:	230V or 110 V
Mains frequency:	50 Hz or 60 Hz
Power input:	max. 1300 W
Fuse value:	10 A inert (230 V) 16 A inert (100/110V)
Safety class:	Safety class 1
External dimensions (H/W/D):	680 x 460 x 540 mm
Weight:	60 kg
Switching off temperature, safety system:	39°C
Switching off temperature, protective system:	41°C

Licence: No. G5 05 10 39637 005 / according to appendix III 93/42/EEC
- TÜV Product Service Munich -

Service: **EIC Umwelt- und Medizintechnik Ltd.**
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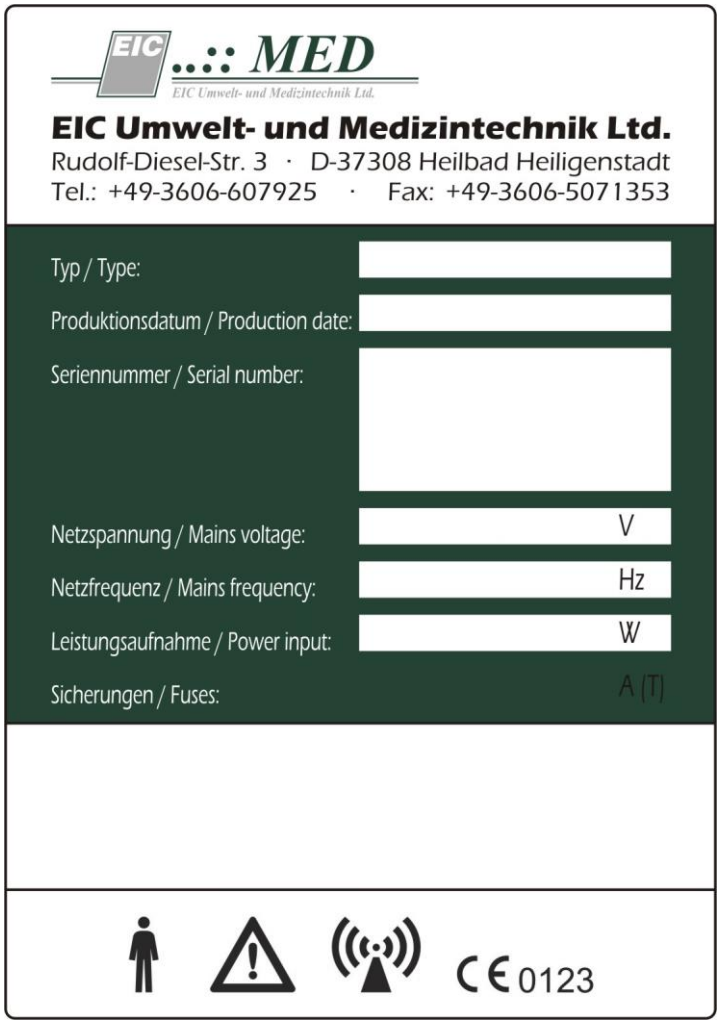
www.eic-ltd.de

Type plate:



Designed for operation by a human operator

Generic warning

Non-ionising radiation hazard

CE 0123

ID number of the certifying body
(TÜV Product Service GmbH, Munich)

Appendices:
STK Record (annual Safety Check)
MTK Record (annual General and Temperature Measuring Check)
Fault Reporting Form