

# Operator Manual

Version 11  
REF: IB-15-08



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Dok. Nr. 1040-0045-011 (Operator Manual).doc

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# 1 For your safety

## 1.1 Customer service information

For service assistance and to order accessories or replacements parts call Connectorate AG customer service department

Phone +41 44 740 73 34  
 Fax +41 44 740 73 32  
 Mail [info@connectorate.ch](mailto:info@connectorate.ch)

Warranty arrangements are in accordance with EC Directive 44/1999/CE. Any damage due to improper use is not covered by the warranty.

When contacting customer service, always state product model and serial number. This information will be found on the end of the table with the irrigation pump control.

## 1.2 How to use this manual

Do not use the BACKTHERM<sup>®</sup> table without having a thorough understanding of assembly, sterilization procedures, operation and all components, functions, controls and limitations of this backtable.

This Manual is about using BACKTHERM<sup>®</sup> table for organ reconstruction work under optimal thermal and preservation conditions during organ transplantation. It does not give instructions on clinical procedures during organ preparation.

The Manual describes how to use the BACKTHERM<sup>®</sup> table correctly to enable you to perform the maintenance correctly and maximize the function of this surgical tool.

## 1.3 Notes on safety and icons

Throughout this Manual Icons are used to alert the reader of special situations. The following symbols are used.

### Symbol name and significance

	<i>Warning</i>	A Warning indicates an action or procedure which, if not performed correctly, can result in injury or a safety hazard. Comply strictly with the instructions and proceed with care.
	<i>Caution</i>	A Warning indicates an action or procedure which, if not performed correctly, can result in injury or a safety hazard. Comply strictly with the instructions and proceed with care.

### Icons on labels

	<i>Waste Electrical &amp; Electronical Equipment (WEEE)</i>	This Symbol is based on European Union Directive 2002/96/EEC. The disposal to municipal waste is prohibited for equipment subject to this directive. This equipment must be collected separately and treated or recycled.
	<i>Information</i>	This Symbol is a reference to consider this Operator Manual for detail information regarding the BACKTHERM <sup>®</sup> device and the accessories.



*Conformity*

This Symbol is referred the device is in conformity with the medical device directive 93/42/EEC and certified by the Notified Body SwissTS.

Coolant R134a  
0.340 kg

*Compressor  
coolant*

The BACKTHERM<sup>®</sup> table includes a compressor unit with 340g R134a as a coolant. It has been established that the coolant poses no threat to health. Servicing must only be carried out by authorized service personnel only.

## 1.4 Intended use

The BACKTHERM<sup>®</sup> instrument is intended to be used in a surgical room as receptacle for implants needing organ reconstruction work before implantation under hypothermic organ preservation conditions by accurate and complete temperature control and optimal storage conditions in eventual subsequent waiting conditions.

## 1.5 Warranty information

Connectorate guarantees the BACKTHERM<sup>®</sup> to perform as specified for 12 months following installation of the System.

This warranty is valid only to the first registered end-user. This warranty does not apply to normal wear and tear or to defects, malfunctions or failures that result from the abuse, neglect, improper installation or maintenance, alteration, modification or misuse of the equipment. This warranty represents CONNECTORATE's sole liability or contract for the product. Connectorate shall not be responsible for any direct, incidental, consequential or exemplary damages suffered by any party, whether or not that party has been advised of the possibility of such damage.

## 1.6 Declaration of Conformity

See delivery documentation.

## 2 General description

Prior to their implantation, organs to be transplanted are prepared on a backtable. Usually, they are partially immersed in a stainless steel vessel with some preservation solution and with ice bags which are melting, depending on room temperature. It is thereby impossible to control the real temperature of the organ being prepared. Experimental evidence has shown that the temperature of human grafts in ice packed vessels drop initially to 0.7°C and then rise up to 10°C during the time that vascular reconstruction, splitting or reduction (as in liver transplantation) or when anatomical problems occur. Such a methodology cannot guarantee optimal thermal conditions for the organ implant during a long period of time.

In order to correct this thermal variability, CONNECTORATE developed a new type of backtable in which the temperature can be continually and precisely maintained. BACKTHERM® is the name of this new table.

**In the BACKTHERM®, a mechanical cooling system** controls the temperature on a outer vessel of stainless steel. An inner vessel which fits tightly in the outer vessel serves as container for the preservation solution and the implant. This inner vessel is completely separated from the cooling system and is fully autoclavable after each use. The implant is placed on an autoclavable metallic screen grid made of stainless steel that fits on the bottom of the outer vessel.

**The Preservation Solution in the inner vessel is mixed and distributed** with a magnetically driven autoclavable immersion pump that ensures a homogeneous temperature throughout the vessel.

**An irrigation device**, called the "FOUNTAIN PACK SYSTEM ", may be controlled in intensity and orientation which will allow the preservation solution to cool and nourish the parts of the implant that are not immersed in the solution. In order to ensure the proper functioning of the pump and the irrigation device, it has to be replaced for each procedure.

**The speed of the irrigation pump can be continuously adjusted with the help of the control knob on the right side of the display box. Right turns increases, left turns decreases the speed of the pump.**

Throughout the implant preparation work, **the vessel temperature is continuously monitored** with a LED temperature display and an internal data logging device which allows the surgeon to monitor the thermal conditions during the procedure. An alarm system will warn the operator of any malfunction.

The BACKTHERM® is easy to clean and resistant to all common disinfectants.

## 3 System Installation

### 3.1 Unpacking

During unpacking, confirm that the components are defect free.

Report transport damage to the **transport company** within 48 hours.

The BACKTHERM® is shipped on a pallet and has to be removed carefully with the help of the included ramp.



*Warning*

The BACKTHERM® is heavy (115kg), at least 2 people are required to safely handle it.

### 3.2 Power requirements

The BACKTHERM® uses the following electrical services:

220 to 230 VAC, 50 Hz

Protection class I



*Warning*

High voltage electrical circuits are accessible if the side covers are removed. Only qualified service personnel should attempt to open the side covers. Serious injury or death may occur as a result of exposure to electrical circuits in the unit interior.

The BACKTHERM® must be connected to a properly grounded power source in compliance with the local electrical codes.

### 3.3 Moving the table

The BACKTHERM® has 18 cm diameter locking wheels with dust caps allowing you to move the Table around the surgical suite and between rooms. Before moving, the Table has to be turned off and the main electrical cable unplugged.

## 4 Instrument handling precautions

### 4.1 Operating precautions

Highly flammable materials and oxygen lines should be kept clear from the immediate area surrounding the BACKTHERM<sup>®</sup>, as **the instrument is not explosion proof**. Although the probability of combustion is remote, flammable anaesthetics should not be used near the instrument.

Contact with liquids such as alcohol or disinfectant is allowed.

**A 70 % alcohol solution may be used for cleaning** the surface of the instrument.

The BACKTHERM<sup>®</sup> may be used in an environment up to 70 % humidity and a temperature till 28°C.

### 4.2 Storage

The instrument consisting of highly corrosion resistant stainless steel does not need any chemically protective action, but should be covered against dust contamination during temporary storage periods. If the instrument has not been in use for a period longer than 9 month, you have to service and recalibrate the instrument before operation.

### 4.3 Transportation

If the components of the BACKTHERM<sup>®</sup> are exposed to excessive mechanical shock during transportation (> 2m/s), proper functioning cannot be guaranteed and the service representative must be contacted.

### 4.4 Maintenance and Servicing



#### *Caution*

No part of BACKTHERM<sup>®</sup> may be serviced by users. The instrument includes a HEPA filter which needs to be checked for integrity every 12 months. The temperature sensors require yearly calibration. All services must be performed by Connectorate or an authorized service centre. Do not modify anything on the BACKTHERM<sup>®</sup>. Only genuine parts obtained from Connectorate may be used. Should any non-Connectorate parts be used, the warranty will be void. For each BACKTHERM<sup>®</sup>, a specific service contract must be signed between Connectorate and the customer indicating the conditions of response.

## 5 System description

### 5.1 Functional components

The complete BACKTHERM® table consists of 5 main components and the sterile drapery (not visible).

#### Organ container

Removable, with handles and lid, with bottom plate and Fountain Pack, autoclavable.

#### Stainless steel working table unit

with refrigeration unit and HEPA air circulation.



#### Display box

With control unit and temperature display, settings for pump unit, alarm reset, power switch.

#### Power inlet / outlet

Height control unit  
Footswitch for height adjustment

#### 5.1.1 Working table



**Fig. 1:** Complete working table with all components and accessories.

The Table Box includes the cooling system and the magnetic pump drive. It contains also a controlled air flow circuit. Any air, before it reaches the surgery room, passes through a 99.999 %

HEPA filter system. The box serves also as working table and platform for instruments with sufficient space for two surgeons to work on the transplant.

### 5.1.2 Height control unit

The lower part of the Table Box includes a lift device. **With footswitch activation you may adjust the height of the Box**, as needed by the surgeon in charge. The outside pedal lifts up, the inside pedal moves the Box down.



**Fig. 2:** Footswitch for high adjustment of the working table

**The Working box has large locking wheels which will allow you to move BACKTHERM® inside rooms.** Disconnect power before moving the Table. A short interruption of electricity for only 1 to 3 minutes will not disturb the System since all the Components are self priming and the liquid temperature changes very slowly.

### 5.1.3 Display Box

**The display** shows the temperature of the preservation solution inside the organ container in 0.1°centigrade units.



The Table includes an acoustic **temperature alarm system**. When the temperature is outside the set limits ( $\pm 0.5^{\circ}\text{C}$ ), as when you add an organ or additional preservation solution, the temperature will be different than the Organ Container and the alarm will sound and remain on until the temperature recovers to the set value.

**An alarm reset button** (red light push button on the lower left of the Display Box) will silence the alarm for 12 minutes. Should the temperature not recover within this time the alarm will sound again. In order to avoid unnecessary long alarm periods add pre-cooled solutions only (see also page 14).

The original temperature and alarm settings can be changed by authorized service person.

### 5.1.4 Organ container

The organ container contains three components: vessel, the bottom plate and the glass lid.

1. The vessel is a 5 liter capacity, polished stainless steel container that serves as receptacle for the transplant. The top diameter of 30 cm is sufficient to accept large organs.

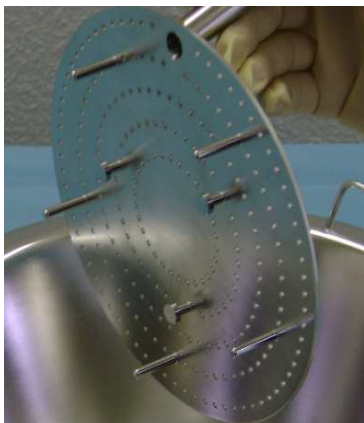


**Fig. 3:** Vessel ready for installation



**Fig. 4:** Vessel with bottom plate

2. Perforated stainless steel **bottom plate** with 9cm long tubing holder, 3 cams for circulation pump attachment, and 5 feet.



**Fig. 5:** Bottom view with 3 cams and 5 feet.



**Fig. 6:** Top view with tubing holder

3. **The glass lid** should be sterilized with the Vessel. It allows for observation of the organ while covered thus stabilizing the temperature in protected storage while waiting for implantation of the organ.



**Fig. 7:** Glass lid



**Fig. 8:** Glass lid installed to the organ container

## 5.2 Accessories

A complete list of approved accessories can be found in the current data sheet, available on the website: [www.backtherm.ch/accessories](http://www.backtherm.ch/accessories).

### 5.2.1 Fountain Pack

Fountain Pack will be delivered as single-use accessory which contains a **self priming circulation pump** and a flexible **irrigation arm** with inner silicone tubing, connectors and flexible tube holder made of POM. The pump speed is regulated by the black turning knob on the right side of the display box. The Fountain pack is a magnetically driven immersed circulation pump with fountain device for continuous and complete feeding of preservation solution to all parts of the transplant.



**Fig. 9:** The product is delivered clean and dust-free in a hermetically sealed bag



**Fig. 10:** Fountain pack installed to the bottom plate

### 5.2.2 Sterile drapery

Connectorate offers a specially designed sterile instrument cover (IB-15-45). The sterile cover is water resistant and includes an opening for the organ vessel and a transparent part for reading and resetting instrument parameters.

Only the Connectorates sterile drapery can guarantee complete sterility of the device. Please follow carefully the instruction when placing the drape on the device. It will allow you the sterile opening of the cover and the precise orientation on the drape regarding the instrument openings.



**Fig. 11:** Installation of the sterile drapery



**Fig. 12:** Sterile drapery installed and ready for surgery

### 5.2.3 Medical light

The flexible light is a medical examination light with a light head with outer ring and a movable arm. The arm fits into BACKTHERM® holding mechanism.



**Fig. 13:** Medical light especially designed for BACKTHERM®



**Fig. 14:** Medical light gives optimal light conditions for the surgeon

#### Specification

The light illuminates the area of the organ container with a high intensity light beam of 35`000 Lux with day light character. It will allow the surgeon to execute microsurgical work under optimal light conditions



*Warning*

The light **runs under 230 Volt**. Any damage of cables or switches can cause electroshocks if not taken care immediately by an electrician.



*Warning*

The upper dome like **light head will become hot** and can cause burnings if it gets touched while light is turned on and also till 15minutes after turning off the light. To prevent burnings, the light head contains an outer ring, enough distant for not to become warmed up during use of the instrument. **Always move the lamp by means of this ring structure.**



*Warning*

Due to the hot part of the light, it cannot be used in area with **explosives**.



*Warning*

The high density of the light can cause **damages to your eyes** if you expose your eyes to the light beam.



*Warning*

**Danger of Infections:**  
Before using the light be assured that the surface area of the light has been treated carefully with disinfectant following your local needs and regulations.  
The following disinfection products are recommended:  
*Lysoformin, Dismozon, Hexaquart plus, Sagrotan*

## 6 Device specifications

### *Dimensions*

- Adjustable height of working platform
  - Max 126 cm
  - Min 96 cm
- Width 134 cm
- Depth 57 cm
- Net weight 1115 kg

### *Material*

- Working table Stainless steel 1.4301 polished
- Organ vessel Stainless steel, 1.4404 or 316L

### *Temperature & humidity*

- Operating temperature range 15 to 28°C
- Storage temperature range 0 to 30°C
- Transportation temperature range -15 to 50°C
- Humidity requirements 20 to 70% rH, non condensed

### *Power requirements*

- Power inlet 220 – 230 VAC, 50 Hz, 450 VA
- Fuse 2x T6.3A H / 250 V
- Power Outlet Max. 2 A for examination light only

## 7 Settings



*Caution*

All parameter settings have to be carried out by trained service personnel only.

### 7.1 Temperature

Temperature is defined to 4°C as default.

### 7.2 Range of alarm

**Alarms** are to be set by the same instrument, by defining the lowest and highest temperature value before the alarm sound shall be activated.

Alarm can be delayed any time by any person by pushing the red round button.

The **time delay** of the alarm activation is however set by trained personnel only through a time relay inside the display box. We recommend with respect to the cooling system a general delay of 10 minutes.



**Fig. 15:** Location of the alarm reset knob

### 7.3 Pump speed

The pump speed can be controlled by any person through turning the black control knob on the right side of the display box.

A full turn of 360° will modulate the pump efficiency from dripping (zero) to approximately 1200 ml /min. (full turn).

Please be careful not to splash over the instrument.



**Fig. 16:** Location of the pump speed turning knob




*Caution*


Right turns increases, left turns decreases the speed of the pump.

## 8 Preparation and handling

### 8.1 Cleaning of basic instrument

	<p><i>Caution</i></p>	<p>Be prepared also for long term storage of the system since transplantation often follows unpredictable timing. For long term storage keep the instrument under a cover.</p>
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For first use or after a longer period of non-use clean the BACKTHERM® as follows:  
Cleanse the instrument surface with warm water and a mild detergent (Deconex).  
Afterwards treat the surface with disinfectant spray (as in use in your hospital) including the wheels.

	<p><i>Caution</i></p>	<p>We recommend storing the instrument after the cleaning in a controlled zone.</p>
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### 8.2 Cleaning of organ container

The empty vessel and, separately, the bottom plate (without tubing device or pump) and the glass lid should be rinsed 2-3 x in distilled water.

Soak pieces above by fully immersing in 2.% Deconex 53 plus during 45 minutes.

After treatment, instruments should be rinsed thoroughly with water and before drying with demineralised water.

The vessel can now be assembled for autoclaving.


### 8.3 Fountain pack assembly

The Fountain Pack is delivered as an accessory in double bags, clean but not sterile.

You have to unpack the first bag with protective gloves and in sterile coatings in a controlled entry zone (according your local structure) and move then into the controlled zone with the inner bag for pump mounting.



**Fig. 17:** unpack the Fountain Pack components

	<p><i>Warning</i></p>	<p>All components from the fountain pack accessory must be sterilized by steam sterilisation based on internal clinic procedures. Do not sterilize by plasma sterilisation or EtO gas sterilisation.</p>
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## 8.4 Pump mounting

The fountain pack is mounted into the bottom plate as follows.

### Pump:

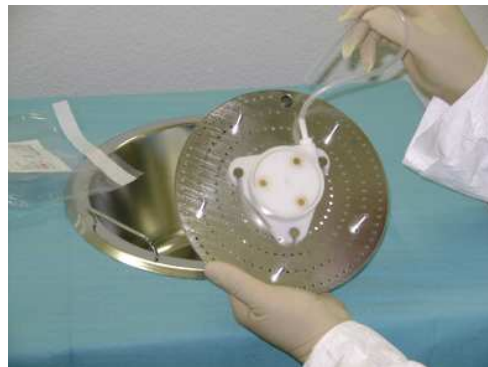
Take the bottom plate and insert the pump firmly into the three cams.



**Fig. 18:** Installation of the pump

### Silicone tubing:

Push the silicone tubing from the bottom through the tubing holder.



**Fig. 19:** Installation of silicone tube

### Silicone tubing:

Pull it fully through and keep it torsion free.



**Fig. 20:** no torsion on silicone tube

### Carryflex tubing:

Then pull the silicone tubing carefully through the Carryflex tubing.



**Fig. 21:** Installation of Carryflex

Carryflex tubing:  
Screw the Carryflex onto the tubing holder of the bottom plate by the connector. Hand-tightening is sufficient.



Fig. 22: Tighten of the Carryflex

You put the pump system carefully into the organ vessel.  
Now you orient the sprinkling device towards the centre of the container in order to prevent unexpected sprinkling outside.  
Finally you close the lid.



Fig. 23: Finalised for sterilisation

## 8.5 Sterilisation



*Caution*

The complete organ container is packed in two layers of solid paper adapted for autoclaves containing indicators for sterility and autoclaved during 18 min at 134°C.



*Caution*

**Gas sterilization with ethylene oxide or chlorine dioxide are not allowed!**



*Warning*

The preparation of the bottom plate, vessel and glass lid is time consuming and does not tolerate any mistake regarding cleaning and sterilization.

We recommend therefore:

- Prepare the components hours or a day ahead of a possible transplantation date and store it in a controlled zone.
- Have one additional vessel ready for unexpected problems.

## 8.6 Installation of sterile drapery

Draperies are delivered sterile in a tear off pack. The folding of the drapery allows efficient placing of the cover as illustrated below.

Orient the opening of the drapery exactly over the working table opening ;  
the transparent part of the drapery must be oriented towards the medical light



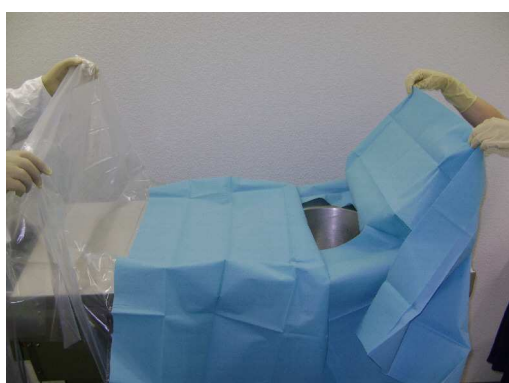
**Fig. 24:** unpack the sterile drapery and put it on the working table



**Fig. 25:** unfold the drapery across and then alongside



**Fig. 26:** unfold and cover on the working table



**Fig. 27:** The drapery should be unfolded by two cooperating persons



**Fig. 28:** the transparent part should cover the control box so the display will be visible



### *Warning*

The opening of the drapery and the opening of the working table has to be aligned carefully. The opening of the drapery is 2 cm smaller than the opening of the device. This "overhang" will allow - after placing the organ container - the complete shielding of any instrument part towards the surgery area.

## 8.7 Transfer solution

Add 80ml "cold dissipation solution" to the inner vessel before placing the organ container into the instrument. It will keep the inner vessel sterile and represents an efficient thermal contact between inner and outer vessel.



Fig. 29: unpack the cold dissipation solution



Fig. 30: fill in 80 ml cold dissipation solution into inner vessel



Fig. 31: Install the organ container complete

Before transplant arrival, the sterile Vessel is filled with 2 to 3 litres of preservation solution which should be circulated until everything reaches the pre-set temperature.

We recommend adding pre-cooled solutions to the organ container. When the organ arrives in the transportation container, transfer it immediately, together with the transportation medium into the organ container.

If desirable, add more pre-cooled preservation solution.



Fig. 32: Fill in preservation solution



*Warning*

The total volume should never exceed 5 **litres**.

## 9 Data control and administration

### 9.1 Data output

The device is equipped with a RS232 port which allows the data of the temperature readings to be downloaded on a PC.

### 9.2 Data input

See chapter “Settings” on page 15.

### 9.3 Temperature control

The temperature of the preservation solution is set to be within +/- 0.5 °C of set temperature (4 °C). Submersible sterile temperature logger may be used inside organ container under the bottom plate for data confirmation.



*Caution*

Making a rough check on the temperature readings of the preservation solution on the occasion of each use by a regular thermometer or sensor is recommended.



*Caution*

Regular thermometer may differ in readings up to 1°C. It is critical to get the thermometer equilibrated with the medium before reading.

Connectorate offers the biannual service for calibration of the system with certified sensors. Sensor adjustments have to be done by trained service peoples only.

## 10 Trouble shooting



### Caution





If any problem arises with temperature or sprinkling during the surgery which cannot be simply cured as outlined below, do not intend to repair the instrument but switch immediately the instrument off and replace organ vessel in use with a spare container containing ice packs (traditional cooling system) and place it into the instrument.

Problem	Cause	Solution
<i>System does not start</i>	Power cord not fully connected Main switch off or damaged Fuse broken	⇒ Correct connection ⇒ Second round of switching ⇒ Fuse replaced by technician*
<i>Sprinkling does not start</i>	Magnetic coupling not reached  Low water level Pump broken	⇒ Remove outer vessel, check for any objects in the inner vessel ⇒ check for correct aligning of the drapery ⇒ check for a clean sensor area on the inner vessel rim place outer vessel back again, restart ⇒ add liquid (min 1 lt) ⇒ Replacing the single use pump, see chapter Fountain Pack
<i>Temperature is not correct</i>	No cold dissipation solution False readings of control thermometer Temperature regulation broken	⇒ add solution ⇒ check with second thermometer ⇒ if it happens during surgery start using the emergency container with ice, call immediately for service
<i>System cannot be moved easily</i>	Some brakes set	⇒ Release all brakes


\* The fuse type is defined on the device label.

## 11 Maintenance work

### 11.1 Security

	<i>Warning</i>	BACKTHERM® contains <b>electrical installations</b> which may cause deadly shocks if you get in contact inadvertently.
	<i>Warning</i>	BACKTHERM®, an instrument of about 100 kg, has wheels and <b>may move unpremeditated</b> .
	<i>Warning</i>	BACKTHERM® includes a <b>HEPA filter which does not tolerate any mechanical damage</b> without damaging also the integrity of the filter.
	<i>Warning</i>	BACKTHERM® has a refrigeration unit which needs <b>licensed personnel for handling of the coolant</b> .

Therefore it is for your safety:

	<i>Caution</i>	Maintenance work has to be strictly done by qualified service personnel only.
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### 11.2 Service calendar


<b>Object</b>	<b>Responsible</b>	<b>Work to be done</b>	<b>Frequency</b>
<i>HEPA Filter</i>	Service engineer	Integrity test	⇒ Every 12 month
<i>Temperature sensor</i>	Service engineer	Calibration	⇒ Every 12 month
<i>Refrigeration unit</i>	Service engineer	Efficiency test	⇒ Every 12 month
<i>Electrical</i>	Service engineer	SN EN 62353 recurrent and test after repair Bulb replacement, check cable integrity	⇒ Every 12 month ⇒ If needed, every 12 month

## 12 Appendix

### 12.1 Electromagnetic compatibility (EMC)

Changes or modifications to this system not expressly approved by the manufacturer may result in increased emissions or decreased immunity performance of the equipment or system and could cause EMC issues with this or other equipment. This system is designed and tested to comply with applicable regulations regarding EMC and shall be installed and put into service according to the EMC information stated as follows.

	<i>Warning</i>	Use of portable phones or other radio frequency (RF) emitting equipment near the system may cause unexpected or adverse operation.
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	<i>Warning</i>	The equipment or system shall not be used adjacent to, or stacked with, other equipment. If adjacent or stacked use is necessary, the equipment or system shall be tested to verify normal operation in the configuration in which it is being used.
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#### Compliant Cables and Accessories

The table below lists cables, transducers, and other applicable accessories for which the manufacturer claims EMC compliance.

**NOTE:** Any supplied accessories that do not affect EMC compliance are not listed.

Part No.	Type	Description	Length max.
Mains cord			< 3m


	<i>Warning</i>	The use of accessories, transducers and cables other than those specified may result in increased emissions or decreased immunity performance of the equipment or system.
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Table 1:

Guidance and manufacturer's declaration – electromagnetic emissions		
The EQUIPMENT is intended for use in the electromagnetic environment specified below. The customer or the user of the EQUIPMENT should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The EQUIPMENT uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The equipment is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Table 2:

<b>Guidance and manufacturer's declaration – electromagnetic immunity</b>			
The EQUIPMENT is intended for use in the electromagnetic environment specified below. The customer or the user of the EQUIPMENT should assure that it is used in such an environment.			
<b>Immunity tests</b>	<b>IEC 60601 Test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment - guidance</b>
Electrostatic discharge (ESD)  IEC 61000-4-2	± 6 kV Contact discharge  ± 8 kV Air discharge	± 6 kV Contact discharge  ± 8 kV Air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst  IEC 61000-4-4	± 2 kV for power supply lines  ± 1 kV for input/output lines	± 2 kV for power supply lines  ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge  IEC 61000-4-5	± 1 kV differential mode  ± 2 kV common mode	± 1 kV differential mode  ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines  IEC 61000-4-11	< 5 % $U_T$ (> 95 % dip in $U_T$ ) for 0,5 cycle  40 % $U_T$ (60 % dip in $U_T$ ) for 5 cycles  70 % $U_T$ (30 % dip in $U_T$ ) for 25 cycles  < 5 % $U_T$ (> 95 % dip in $U_T$ ) for 5 sec	< 5 % $U_T$ (> 95 % dip in $U_T$ ) for 0,5 cycle  40 % $U_T$ (60 % dip in $U_T$ ) for 5 cycles  70 % $U_T$ (30 % dip in $U_T$ ) for 25 cycles  < 5 % $U_T$ (> 95 % dip in $U_T$ ) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: $U_T$ is the a.c. mains voltage prior to application of the test level.			

Table 3:






Guidance and manufacturer's declaration – electromagnetic immunity			
The EQUIPMENT is intended for use in the electromagnetic environment specified below. The customer or the user of the EQUIPMENT should assure that it is used in such an environment.			
Immunity tests	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
			<p>Portable and mobile RF communications equipment should be used no closer to any part of the EQUIPMENT, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p><b>Recommended separation distance:</b></p>
Conducted RF IEC 61000-4-6	3 V rms 150 kHz to 80 MHz outside ISM bands	3 V rms	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2,5 GHz
			<p>where <math>P</math> is the maximum output power rating in the transmitter in watts (<math>W</math>) according to the transmitter manufacturer and <math>d</math> is the recommended separation distance in metres (<math>m</math>).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range.<sup>b</sup></p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p><sup>a</sup> Fixed strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To access the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the EQUIPMENT is used exceeds the applicable RF compliance level above, the EQUIPMENT should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the EQUIPMENT.</p>			
<p><sup>b</sup> over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			





Table 4:

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT			
The EQUIPMENT is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the EQUIPMENT can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the EQUIPMENT as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (P) W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.1	0.1	0.2
0.1	0.4	0.4	0.7
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance $d$ in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where $P$ is the maximum output power rating of the transmitter in watts (W) according to the higher frequency range applies.			
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			





## 12.2 Device label

<b>backtherm</b>	
Intended use of Backtherm is to prepare organs before transplantation	to be used only by a physician or trained clinical personnel
REF IB-15-08	SN 13
220 - 230 V ~ / 50 Hz / 450 VA Fuse: 2x T6.3A H / 250 V	
Power outlet: Max. 2A, for examination light only	Coolant R134a 0.340 kg
	  1253
<small>Art. No. 101685</small> Manufactured by: Connectorate AG Bernstrasse 390 CH-8953 Dietikon, Switzerland Tel: +41 (44) 740 73 33 Fax: +41 (44) 740 73 32	




## 12.3 Fountain pack label

<b>Fountain Pack</b>		to be used only by Physicians or Practitioner	
This product is intended to be used only with the Backtherm			
contains 3 <b>unsterile</b> Fountain Packs	<b>unsterile</b> to be cleaned before sterilized	   pending	store on a dry place at room temperature
REF IB-15-30 LOT 08/01/05			
Manufactured by: 		Connectorate AG Bernstrasse 390 CH-8953 Dietikon Switzerland Phone +41 (0) 44 740 73 33 Fax +41 (0) 44 740 73 32	




## 12.4 Circulation pump label

<b>Circulation Pump</b>		to be used only by Physicians or Practitioner	
This product is intended to be used only with the Backtherm			
contains 1 <b>unsterile</b> Magnetic Pump System	<b>unsterile</b> to be cleaned before sterilized	   pending	store on a dry place at room temperature
REF IB-15-31 LOT 08/01/05			
Manufactured by: 		Connectorate AG Bernstrasse 390 CH-8953 Dietikon Switzerland Phone +41 (0) 44 740 73 33 Fax +41 (0) 44 740 73 32	

## 12.5 Tubing Kit, Carryflex label

<b>Tubing Kit</b> This product is intended to be used only with the Backtherm		to be used only by Physicians or Practitioner	
contains 1 <b>unsterile</b> Flex Tubing Kit	<b>unsterile</b> to be cleaned before sterilized	 	store on a dry place at room temperature
REF IB-15-32 LOT 08/01/05			
Manufactured by: 		Connectorate AG Bernstrasse 390 CH-8953 Dietikon Switzerland Phone +41 (0) 44 740 73 33 Fax +41 (0) 44 740 73 32	

## 12.6 Table Cover label

<b>Sterile Table Cover</b> This product is intended to be used only with the Backtherm		to be used only by Physicians or Practitioner	
contains 3 <b>sterile</b> Table Cover	150x220 cm 2 layers	 	store on a dry place at room temperature
REF IB-51-15-22 LOT P2008-48	transparent side on the left		
Manufactured by: Raguse 		Connectorate AG Bernstrasse 390 CH-8953 Dietikon Switzerland Phone +41 (0) 44 740 73 33 Fax +41 (0) 44 740 73 32	