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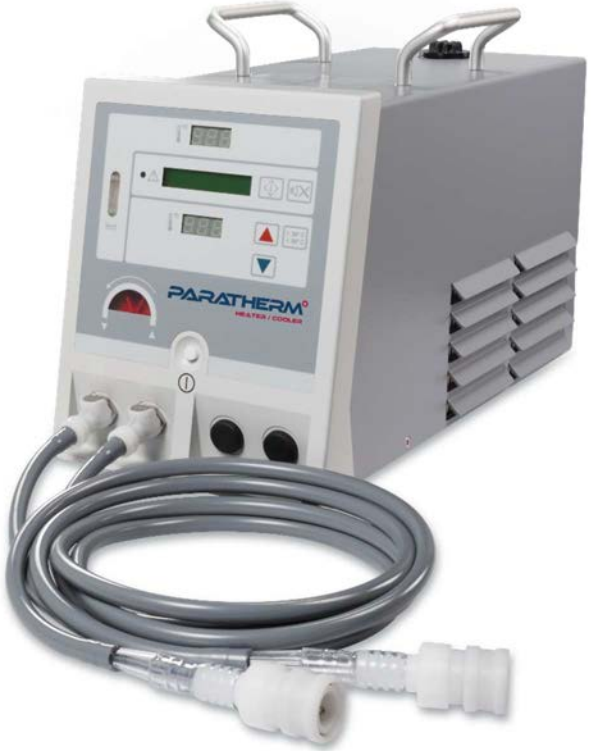
operate your way

ParaTherm Hypo/Hyperthermia Unit for Extracorporeal Bypass

Operating Instructions

PARATHERM
HEATER / COOLER



Australia

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1.0 General

Read the information provided here so that you can quickly become familiar with the ParaTherm and use its functions to its full extent.

1.1 Information on these Instructions

These operating instructions are a component of the ParaTherm (referred to in the following as unit) and provide important information for the commissioning, safety, proper use and maintenance of the unit.

All figures and drawings in these operating instructions are for general illustration purposes and are not definitive for the details of their construction. The operating instructions must always be available, preferably in the vicinity of the unit. They must be read and applied by all persons who are responsible for the:

- Commissioning,
- Operation,
- Cleaning,
- Maintenance,
- Troubleshooting of the unit

1.2 Warning Notices

The following warning notices are used in these operating instructions:

⚠DANGER

A warning notice of this danger level indicates an impending dangerous situation.
If the dangerous situation is not avoided, this can lead to serious injury or even death.
- Follow the instructions in this warning notice to prevent people from death or serious injury.

⚠WARNING

A warning notice of this danger level indicates a potentially dangerous situation.
If the dangerous situation is not avoided, this can lead to serious injury.
- Follow the instructions in this warning notice to prevent people from injury.

⚠CAUTION

A warning notice of this danger level indicates a potentially dangerous situation.
If the dangerous situation is not avoided, this can lead to minor or moderate injury.
- Follow the instructions in this warning notice to prevent people from injury.

A warning notice of this danger level indicates a potential material damage.
If the situation is not avoided, this can lead to material damage.
- Follow the instructions in this warning notice to prevent material damage.

NOTE

A note indicates additional information which makes it easier to work with the unit.

1.3 Limitation of Liability

All technical information, data and notes for installation, operation and maintenance included in these instructions are current at the time of printing and are written to the best of our knowledge in consideration of our experiences and knowledge to date. No claims can be derived from the details, figures and descriptions in these instructions.

The manufacturer accepts no liability for damages as a result of:

- Non-observance of the instructions
- Improper use
- Improper repairs
- Technical changes
- Use of impermissible spare parts
- Unauthorised reconstruction and modification

1.4 Copyright Protection

1.5 Manufacturer Contact Details

For questions on the service, maintenance or safety check, please directly contact Chalice Medical.

Chalice Medical Ltd.
Unit 1 Drayton Court
Manton Wood Enterprise Park
Worksop, Nottinghamshire, S80 2RS

Telephone: +44 (0) 1909 470 777
Email: enquiries@chalicemedical.com
Web: www.chalicemedical.com

1.6 Warranty

The ParaTherm carries a warranty of 1 years.

2.0 Safety

This chapter provides you with important safety information on working with the unit. This unit complies with the stipulated safety requirements. However, improper use can cause personal and material damage.

2.1 Proper use

This unit is only intended for cooling or heating water circulating through the heat exchanger of a membrane oxygenator which are used to cool down or warm up a patient. Any other use or use extending beyond this is deemed inappropriate.

The Paratherm Heater/cooler should not be used for cardiopulmonary bypass associated with open cardiothoracic surgery.

⚠WARNING

Danger due to improper use!

The unit may present a risk if it is not used correctly and/or is used in a different way.

- Only use the unit for its intended purpose.
- Follow the procedures described in these operating instructions.

Any claims as a result of damage due to improper use are excluded. The operator alone shall bear the risk.

2.2 Personal Requirements

NOTE

- Work on the unit may only be performed by persons that are authorised to do so based on their training and qualifications. The persons must also be instructed by the operator.
- Personnel to be trained, taught, instructed or those undergoing general training may only work on the unit whilst under the constant supervision of an experienced person.
- Persons that are under the influence of drugs, alcohol or medication that affects reaction times may not work on this unit.
- This unit can present a risk if it is improperly used by untrained personnel.
- In addition to the operating instructions, observe the universally valid, legal and other obligatory regulations for accident prevention and for environmental protection as well as general health and safety requirements. The operator must instruct their personnel accordingly.

2.3 General Safety Information

NOTE

Observe the following general safety information for safe handling of the unit:

- Ensure that the unit (mains cable, housing, couplings etc.) are in good condition before commissioning.
- Lay hoses without creases and kinks.
- Do not touch the hoses with pointed or sharp objects. The system cannot work correctly with perforated water hoses.
- When used with an oxygenator, fill the unit tank with sterile water only.
- Only operate unit if the tank is closed with the screw cap.
- Position unit horizontally and operate; inclination of installation area ≤ 3%.
- Height difference between unit and the heat exchanger of a membrane oxygenator < 1m.
- Do not cover unit; there are ventilation slots on the bottom and back; there are ventilation slots and inlet ports for ventilators on the sides.
- Observe automatic functional test when switching on.
- Carry out automatic functional test manually at least once a day during continuous operation.

NOTE

- Check the water flow and water level of the unit regularly during operation.
- Only operate unit with sufficient water level.
- Keep to ambient temperature range (10-40°C) and storage temperature range (3-60°C)
- Only operate the unit with original accessories.
- Do not operate unit in an environment rich in oxygen or in the presence of flammable gases.
- In hyper/hypothermia operation, do not use or combine the unit together with other heat sources.
- Do not operate the unit near heat sources (spotlights, direct sunlight, radiators/heaters etc.).
- Carry out maintenance and safety checks in accordance with these operating instructions.
- If discoloured water is observed, remove the ParaTherm from service. Clean in accordance with Appendix 1 and test for contamination.
- Any reported contamination issues should be communicated directly to Chalice Medical Ltd.

2.4 Hazard Sources

2.4.1 Risk of overheating or overcooling

⚠WARNING

There is a risk of the patient becoming overheated or overcooled.

- The patient's body temperature must be monitored at all times.

3 Transport and Installation

3.1 Delivery Specification and Transport Inspection

The delivery specification of the ParaTherm consists of:

- ParaTherm
- Mains cable
- Operating instructions
- Hose extension

NOTE

- Check the delivery for completeness and visible damage.
- Report an incomplete delivery or damage due to insufficient packaging or due to transport to the shipper, the insurance company and the supplier immediately.

3.2 Unpacking

To unpack the unit:

- Take the unit out of the box and remove the packaging material.
- Place the unit on a sufficiently load-bearing, even and horizontal surface.

⚠CAUTION

Condensation in the unit may cause it to fail.

- After unpacking, the unit must be acclimatised for at least two hours before commissioning when there are temperature differences of more than 8 °C of the intended ambient operating temperature.

3.3 Disposal of Packaging

The packaging protects the unit from transport damage. The packaging materials are selected on the basis of environmentally friendly and disposal-related factors and are therefore recyclable.

Feeding the packaging back into the material cycle saves raw materials and decreases generated waste.

NOTE

- If possible, keep the original packaging throughout the unit's lifetime so as to be able to repack the unit properly in case of repair.

4 Commissioning

This chapter provides you with important information on commissioning the unit. Observe the information to prevent hazards and damage.

4.1 Safety Information

⚠WARNING

Personal and material damage may occur when commissioning the unit!

Observe the following safety information to prevent hazards:

- The weight of the unit is approx. 17 kg.
- The unit should only be transported, unpacked and installed by two people.

4.2 Installation

4.2.1 Requirements at the Installation/operating site

For a safe and fault-free operation of the unit, the installation site must:

- be load-bearing (unit weight approx. 17 kg).
- be even.
- be horizontal (inclination ≤ 3%).
- provide 20 cm of space on both sides of the unit.
- ensure the unit is sufficiently ventilated on all sides

⚠CAUTION

- If the unit is not horizontal, the incorrect water level is shown on the indicator at the front of the unit.

For optimal operation of the unit, the operating site should have the following ambient conditions:

- ambient temperature: 23°C ± 3 °C
- relative air humidity: 60 % ± 15 %
- air pressure: 860 hPa to 1060 hPa (645 mmHg to 795 mmHg)

⚠CAUTION

Condensation in the unit may cause it to fail.

- At temperature differences of more than 8°C of the intended ambient operating temperature when installing the unit, acclimatise the unit for at least two hours before commissioning.

4.3 Connecting the ParaTherm

⚠WARNING

The ParaTherm must be cleaned thoroughly before clinical use! Please refer to Appendix 1 for information on the cleaning protocols.

The one way valve should be checked before first use (please refer to Appendix 1 1.14).

⚠WARNING

Hazard due to water in connection with electricity.

- Only connect the unit to the mains once it has been filled.

4.3.1 Filling the system with water

- Unscrew the cap of the water filler neck (17), e. g. with a coin. Make sure you do not lose the sealing ring of the cap.
- Observe the water level indicator (3) whilst filling. The water level should be slightly below the MAX mark after filling.
- Fill the unit with sterile water.
- Screw the screw cap of the water filler neck hand-tight again after filling until it is impermeable.

NOTE

The use of a disproportionately high amount of disinfectant can reduce the lifetime of unit parts that come into contact with water. When cleaning the unit, observe cleaning APPENDIX 1.

⚠WARNING

Hazard due to water in connection with electricity.

Water can conduct electrical current.

- If water has overflown when filling the unit, then the unit must first be dried thoroughly and may only be connected to the mains and switched on once it is completely dry.

4.3.2 Connecting the ParaTherm to the Heat Exchanger of the membrane Oxygenator

- The hose bracket - to attach the bracket, loosen the two knurled screws on the left-hand side of the unit and then use them to fasten the bracket.
- Push the hose device couplings of a hose extension onto the coupling pair on the unit.
- The couplings are then correctly connected to each other when the locking mechanisms on the couplings are engaged in their corresponding counterparts in such a way that the connection will no longer come loose by itself.
- You can loosen the coupling again by pushing the metal plate on the hose coupling and pulling the coupling out.

NOTE

- The water flow through the heat exchanger of the membrane oxygenator must run counter current to the blood flow through the membrane oxygenator.
- Water hoses to the heat exchanger of the membrane oxygenator can be decoupled when the unit is switched on.
- It is normal for the couplings to drip slightly when doing this and this is not an indication for a leak or defect.
- In heating mode at 39°C: Reduce the nominal temperature slightly before decoupling the heat exchanger of the membrane oxygenator.
- In cooling mode at 15°C: Increase the nominal temperature slightly before decoupling the heat exchanger of the membrane oxygenator.
- The water in the unit circuit may otherwise briefly go above the upper or lower limit temperature and the unit may trigger various alarms.

4.3.3 Electrical Connection

⚠CAUTION

Hazard due to electrical current

Defective cables and/or plugs as well as faults in the power supply can cause a fatal electric shock!

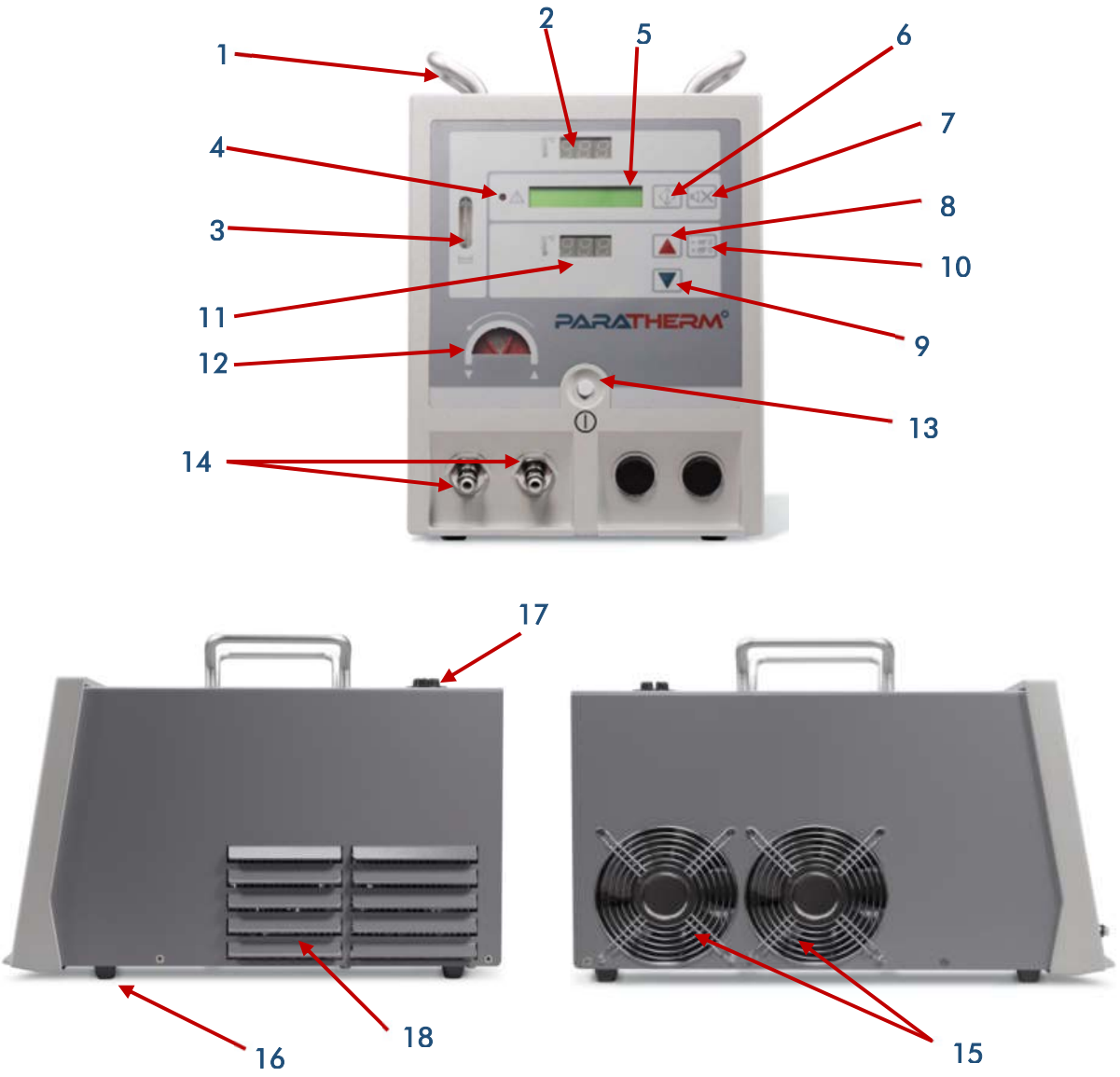
- Check that unit cables and plugs are in good condition before connecting!
- To prevent the risk of electric shock, this unit must only be connected to a power supply with a protective conductor!

- For a safe and fault-free operation of the unit, the following information must be considered when connecting to the power supply:
- Before connecting the unit, compare the connection data (voltage and frequency) on the type plate with those of your electricity network. These data must correspond so that no damage is done to the unit. In case of doubt, ask your electrician.
- The power socket must be protected with a 16A circuit breaker.
- Connect the unit to the power supply using the cable provided. The connector plug is on the back of the unit (see further on, unit views, and operating and display elements).
- Power supply at the installation site must meet the requirements for electrical systems in hospitals and medical environments (see VDE 0100 Part 710:2002-11 "Electrical safety in medical environments.")

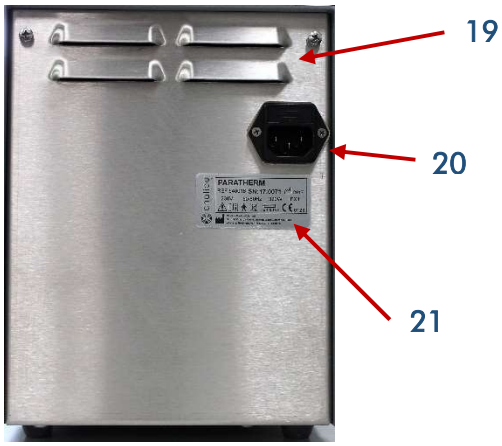
5.0 Composition and Function

This chapter provides you with important information on the composition and function of the unit.

5.1 Unit views, Operating and Display elements



1) Handles	10) Release <35°C / > 38°C
2) Temperature Display for lines (external loop)	11) Temperature display nominal value
3) Water level indicator	12) Water flow display
4) Fault lamp	13) Mains switch
5) Display for status and fault messages	14) Hose couplings
6) Functional test	15) Air inlet fans
7) Alarm off	16) Feet
8) Nominal value higher	17) Water filler neck with screw cap
9) Nominal value lower	18) Air exhaust vent



Rear view
19) Air Vents
20) Mains connector plug
21) Chalice back plate

5.2 Safety Devices

5.2.1 Sensors

In operation, the ParaTherm monitors:

- the water level in the unit
- whether the water temperature in the circuit corresponds with the set nominal value
- whether mains voltage is present
- whether its own functional safety is ensured and issues alarms when faults occur (see further on)

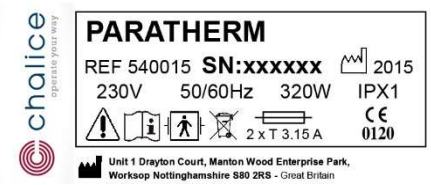
⚠WARNING

The application system ParaTherm has no metrological monitoring function with respect to the patient.

- The core temperature of the patient to be treated must be monitored regularly independent of the application system.
- The temperature settings of the transition temperatures with regards to the heat exchanger of the membrane oxygenator must be entered on the system manually by the user and corrected or adapted in accordance with the individual course of therapy.
- **The system may only be put into operation by users who are qualified for its proper use!**

5.3 Type Plate

The type plate with the connection and performance data is on the back of the unit:



5.4 Function

5.4.1 Basic Principles

The water in the unit is cooled down or warmed up in the temperature range of 15°C and 39°C in a water tank with thermoelectric elements and constantly discharged through the heat exchanger of the membrane oxygenator using a rotary pump.

The ParaTherm is characterised by its simple and safe use, its reliability and its compact design.

Through its electronic control, the temperature transfer to the patient can be accurately adjusted whilst at the same time maintaining high operational safety.

The transition temperature to the patient when warming up must not normally exceed 40°C in order to exclude the risk of pyrexia during longer periods of use. This risk does not only apply to temperatures that are too high, but also to those that are too low. To minimise this risk when a fault occurs during warming, the ParaTherm switches off electronically and electrically above a water temperature of 41.5°C.

Transition temperatures of < 35 °C and > 38 °C must be sensibly set and appropriately monitored by the user.

By doing this, the danger of a local temperature rise will be practically eliminated.

Operating the ParaTherm is simple and intuitive, thereby preventing misuse.

⚠WARNING

Danger from overestimating/underestimating the system's performance!

The unit may also present a risk when used correctly if desired temperatures are not physically reached under the given operating conditions.

The reliable therapeutic use of the system requires the user to carefully assess the risks and permanently monitor and tend to the patient.

5.5 Indications

The ParaTherm can generally be used in hypo/hyperthermia treatment for:

- Heat supply in the case of intraoperative or postoperative hypothermia.
- Heat supply or heat withdrawal to stabilise the patient's temperature (normothermia).
- Heat withdrawal in case of malignant hyperthermia.

The ParaTherm can be specifically used in hypo/hyperthermia for support with:

- therapeutic hypothermia in intensive care (mild hypothermia),
- neuroprotection for patients after cardiac arrest,
- neuroprotection for cerebral trauma, stroke and in neurosurgery,
- myocardial protection after myocardial infarction
- induced hypothermia in asphyctic newborns

⚠WARNING

Danger from overestimating/underestimating the system's performance!

The unit may also present a risk when used correctly:

- When not properly observing physical connections of external unit accessories.
- In the case of Individual and incalculable patient reactions.

The reliable therapeutic use of the system requires the user to carefully assess the risks and permanently monitor and tend to the patient.

5.6 Side Effects

There are no known side effects for the materials used in the heat exchanger of the membrane oxygenator.

For a heat transfer and the associated targeted rise of the patient's temperature, there is always a risk of pyrexia in the case of longer periods of use and excessive temperatures.

In the case of a cold transfer and the targeted reduction in patient temperature therapeutic Hypothermia there are side effects such as the following:

- Autonomous reactions (shivering among other things)
- Electrolyte disorders

- Higher diuresis (diuresis fluctuations)
- Hyperglycaemia (glycaemic fluctuations)
- Higher blood loss (due to reduced coagulation factors among other things)
- Change in pharmacokinetics
- Higher wound infection rate (sepsis)
- Risk of decubitus

In addition, a reversible pupil dilation may occur; wide fixed pupils in the case of an overcooled patient must therefore not be an indication of serious brain damage.

5.7 Contraindications

- Advanced malignant underlying disease
- Persistent state of shock / cardiopulmonary instability
- Pregnancy
- Coma of different origin
- Body temperature below 30 °C when raising
- Time interval when starting resuscitation and cardiac arrest over 15 minutes
- Distal use of an arterial clamp

⚠WARNING

Uncontrolled hypo/hyperthermia associates the patient with increased mortality.

- If the core body temperature falls below 32°C, there is a risk of life-threatening complications such as cardiac arrhythmias, metabolic disturbances and cardiac arrest.
- After hypothermia treatment, the patient should be warmed up again at no more than 0.25°C – 0.5°C per hour. Warming up too quickly also causes arrhythmias and ventricular fibrillation with subsequent risks.
- When using on ischaemic limbs, there is a greater threat of tissue damage and shock.

⚠CAUTION

For the low-risk and reliable application of the hypo/hyperthermia treatment, it is highly important to constantly monitor the core body temperature externally, e.g. by measuring in the bladder.

- The therapeutic moderate-mild to moderate hypothermia treatment requires the user to carefully assess the risks and permanently monitor and tend to the patient with respect to any side effects that may occur, the prophylaxis of pressure ulcers and the performance of the system.
- Due to the good heat conductivity of water, the patient can cool down when the unit is switched off or when the heat exchanger of the membrane oxygenator is decoupled from the unit.
- No distal use of an arterial clamp!

NOTE

Due to constant new findings in the area of hypo/hyperthermia, the information provided here does not claim to be current and complete.
Chalice Medical accepts no responsibility and liability for misuse or negligence and can neither give any medical recommendations nor procedures. The user must independently weigh up what they use and how they act.

6.0 Handling and Operation

This chapter provides you with important information on handling the unit. Observe the information to prevent hazards and damage.

Before first use or when not used for more than 7 days, the unit must be cleaned in accordance with appendix 1

6.1 Before switching on

6.1.1 Tests on the unit

Check the unit for external damage.

Check the water level before and after:

- Switching on the unit
- Connecting the heat exchanger of the membrane oxygenator.

The water level must be between both marks on the water level indicator (3), preferably just below the maximum mark. The filling difference between both marks is approx. 0.5 litre.

Refill the water if:

- The water level is below the minimum mark.

- You want to connect an unfilled heat exchanger of a membrane oxygenator and the water level is below the maximum mark.

6.1.2 Heat Exchanger of a membrane Oxygenator

- Only connect original ParaTherm hose to the ParaTherm.
- Check the heat exchanger of the membrane oxygenator for external damage before connection to the ParaTherm.
- Always test the heat exchanger of a membrane oxygenator for water leaks before clinical use.

Heat exchanger of the membrane oxygenators can be couple and decoupled whether the unit is switched on or off.

NOTE

Decoupling a heat exchanger of a membrane oxygenator when the unit is switched on:

- In heating mode: Reduce the nominal temperature slightly before decoupling the heat exchanger of a membrane oxygenator, the water in the unit circuit is otherwise briefly warmed up above the nominal temperature and the unit may trigger the alarm TEMP.DIFF >1°C (depending on the time elapsed).
- In cooling mode: If necessary, increase the nominal temperature before decoupling the heat exchanger of a membrane oxygenator. The water in the unit circuit is otherwise briefly cooled down below the nominal temperature and the unit may trigger the alarm TEMP.DIFF >1°C (depending on the time elapsed).

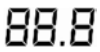
6.2 Switching on when first commissioning

- Switch on the unit using the pressure switch; when switched off, the switch is flush with the front cover.
- If the set nominal value is greater than 38°C or lower than 35°C, check whether it is correct and only press the release button if it is.
- Connect the hose pipes of the ParaTherm to the heat exchanger of a membrane oxygenator.
- Run the unit for approx. ten minutes to remove the air from the circuit in the unit.
- Check the heat exchanger of the membrane oxygenator for water leaks.
- Check the water level on the indicator (3); if necessary, switch off the unit using the pressure switch, disconnect the plug from the mains and refill water.
- Reconnect the unit to the mains, switch it on and run it again.
- If air locks are encountered within the system the hose pipes should be manipulated to enable the air to enter the ParaTherm.

- Check the water level on the indicator (3) again; if necessary, switch off the unit using the pressure switch, disconnect the plug from the mains and refill with sterile water.

6.2.1 Switching on in control mode 

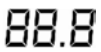
- Switch on the unit using the pressure switch; when switched off, the switch is flush with the front cover.
- If the set nominal value is greater than 38°C or lower than 35°C, check whether it is correct and only press the release button if it is.
- Check the water level on the indicator (3), especially if you have connected an unfilled heat exchanger of a membrane oxygenator.
- After use, switch the unit off using the pressure switch and disconnect the plug from the mains.

6.3 Functional Test 

The unit carries out a functional test after switching on.
During the test, observe whether the displays react as described in the following:

- A short acoustic alarm shows that the unit is ready for a possible power failure alarm

The unit now checks its autonomous protection device and:

- Shows the result in the display (5)
- The temperature displays (2) and (11) show 

- The fault lamp (4) lights up
- The acoustic alarm is on.

This test takes a few seconds.

⚠CAUTION

If the functional tests did not complete successfully, the unit is no longer fail safe.

Do not operate unit if:

- The unit does not issue the short signal tone for the power failure alarm when switching on.
- The automatic functional test automatically switches the unit off because it has detected a defect in the independent protection device.
- One or more displays are defective.

In these cases, have the unit checked by ParaTherm customer service.

6.4 Setting Temperature

- Set the nominal value for the water temperature - i.e. the temperature of the water running to the heat exchanger of a membrane oxygenator with the two arrow buttons (8) and (9). The temperature can be set between 15 and 39 °C in steps of 0.1°C. The temperature display (11) shows the set nominal value.

• For nominal temperature values above 38 °C, press the arrow button (8) and the release button (10) at the same time.

• For nominal temperature values below 35 °C, press the arrow button (9) and the release button (10) at the same time.

⚠WARNING

- Below a temperature of 35 °C, heat is withdrawn from the patient to a heightened degree.
- Above a temperature of 38 °C, heat is supplied to the patient to a heightened degree.
- Pressure necrosis and/or burns can be caused to areas of the body that are exposed to heightened pressure at any temperature. This particularly applies to longer uses and for patients at risk.

⚠CAUTION

The desired nominal value is influenced by external conditions; e.g. under certain circumstances, very high or low nominal values are not reached at high or low ambient temperatures and/or when connecting two heat exchangers of a membrane oxygenator. In this case, set a lower or higher nominal value until the unit can safely control the temperature.

Check the water flow on the display (12)!

Heat transfer:

A heat transfer (heat emission or heat withdrawal) between the patient and the heat exchanger of a membrane oxygenator only takes place if the temperature within the heat exchanger of a membrane oxygenator is greater or lower than the skin temperature of the patient.

The degree of heat transfer is directly proportional.

• To the temperature difference of the skin temperature and the water entering the heat exchanger of a membrane oxygenator.

Example of temperature difference:

The heat transfer from the heat exchanger of a membrane oxygenator to the patient doubles if the temperature difference between the heat exchanger of a membrane oxygenator is doubled.

Due to the thermoregulation of the patient, this is only approximate.

6.5 Temperature control mode

⚠WARNING

There is a risk of the patient becoming overheated or overcooled.

- The patient's body temperature must be monitored when the ParaTherm is used clinically.

If the set nominal temperature value is between 35°C and 38°C, then the unit starts operating automatically after switching on and after the functional test, and adjusts the water temperature in the circuit to the set value.

If the set nominal value is greater than 38 °C or lower than 35°C, the unit issues an acoustic alarm and the message "NOMINAL VALUE <35/>38°C!", "RELEASE BUTTON" appears in the display (10).

Check whether the nominal value is correct and do not press the release button (10) until it is.

The unit starts the temperature control mode and shows "HEATING ACTIVE" or "COOLING ACTIVE" in the display (5).

⚠CAUTION

Only leave the water circulating around the heat exchanger of the membrane oxygenator in control mode.

Due to the good heat conductivity of water, the patient can cool down when the unit is switched off or the water pipes are disconnected from the heat exchanger of the membrane oxygenator.

NOTE

If a desired nominal value is not reached within 60 mins after the system is switched on due to external conditions, an alarm message (TEMP.DIFF >1 °C) appears (see, Alarm description in operation);

In this case, adapt the nominal value to the displayed actual value.
Check the water flow on the display (12)!

6.6 Obligations during operation

NOTE

Due to constantly progressing, new findings in the area of hypo/hyperthermia, the medical information does not claim to be complete. Chalice Medical accepts no responsibility and liability whatsoever for misuse or negligence and can neither give any medical recommendations nor procedures. The user must independently weigh up what they use and how they act.

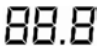
6.7 System-related

Check water flow

During operation, regularly check the water flow in the unit and the heat exchanger of the membrane oxygenator. There is an impeller wheel (12) in the inspection window of the water flow display. When the water flow is optimal, the individual wheels are not noticeable.

Carry out functional test 

During a longer operating period, check the independent protection device manually at least once a day. To do this, press the functional test button during operation (6). The unit now tests its safety electronics:

- The alarm sounds
- The temperature displays show 
- The red fault lamp (4) lights up
- The display shows FUNCTIONAL TEST.
- If the test is successful, the display shows the message FUNCTIONAL TEST OK - the unit enters into control mode automatically.

⚠CAUTION

If the test is not successful, the unit is no longer fail-safe. In this case:

- Do not continue using the unit on the patient.
- Have the unit checked by the customer service.

Check temperature control mode

During a longer period of operation, regularly check the nominal and actual values of the temperature displays.

6.8 Operator Language

The status and fault messages in the display (5) can be shown in the following languages: German, English, French, Spanish, Italian and Polish.
You can adjust the language for the display as follows:

- Switch on unit
- Press and hold the "Alarm OFF" (7) button for approx. 4 sec.; the last language set appears in the display.
- Press the arrow button "nominal value higher" (8) until the desired language appears in the display.

- Approx. 10 secs after the last input, the unit returns to its original operating state and the last language shown is active.

7.0 Alarms

7.1 General

The unit always issues a visual and acoustic alarm. The operator thereby acknowledges a malfunction quickly, which increases the operating safety. The fault status that caused the alarm is shown in the display (5) (except in the case of a mains failure alarm).

The alarms are assigned a medium priority. If not taken into account, the following events can develop:

- Minor injuries or inconveniences within a period of time that is not usually sufficient for manual corrective action (instantaneous).
- Reversible injuries within a period of time that is usually sufficient for manual corrective action (immediate).
- Death or irreversible injuries within an undefined period of time which is greater than the period of time stated under "immediate" (delayed).

If the system issues an alarm message for the reasons stated, this can be overridden as follows depending on the expected event.

- Pressing the "Alarm OFF" (7) button interrupts the acoustic alarm for 10 minutes. The fault message can be read in the display (5). The flashing fault lamp (4) stays on as long as the alarm condition remains. The alarm condition can be corrected in accordance with the alarm message in the display (5).

- The unit switches off all functions. The acoustic alarm cannot be interrupted. Switch off the unit at the mains (13), take it out of operation and have it checked by a service technician if necessary (customer service / medical engineering).

NOTE

Before the "Alarm OFF" (7) button or the mains switch (13) is pressed to disable the alarm or to take the unit out of service, read the fault message in the display!

Alarm description in operation

Display message: WATER LEVEL!?

The unit issues this alarm if the water level sinks below the MIN mark on the water level indicator (3) during operation. The display shows "WATER LEVEL!?" the yellow fault lamp flashes and a pulsating signal tone sounds.

- Press the "Alarm OFF" (7) button to interrupt the acoustic alarm for 10 minutes.

- Refill the water promptly with sterile water until the water level is just below the MAX mark again (see "Filling the system with water").

⚠CAUTION

- If the water level is too low, sufficient water circulation is no longer guaranteed.
- Too low a water level can cause damage to unit components and can therefore also cause the unit to fail.

Display message: TEMP.DIFF>1°C

The unit issues this alarm if the water temperature deviates from the set nominal temperature value by more than 1°C during operation. The display shows "TEMP.DIFF. >1°C", the yellow fault lamp flashes and a pulsating signal tone sounds.

- Press the "Alarm OFF" (7) button to interrupt the acoustic alarm for 10 minutes.
- Change the nominal value until the unit can safely control the temperature.

NOTE

- Coupling and decoupling a heat exchanger of the membrane oxygenator during operation can cause a temperature difference, which triggers the alarm.
- At unfavourable room temperatures and/or when connecting two heat exchangers in parallel, the alarm can be triggered because the specified nominal value can require more time to reach the set temperature.
- After switching on the unit and changing the nominal temperature value, this alarm function is disabled for a defined period of time.

Display message: ALARM TEST DEFECTIVE, CUSTOMER SERVICE

The unit triggers this alarm if it detects a fault during an automatic or manual functional test or finds that the autonomous protection device is not responding. The display shows "ALARM TEST DEFECTIVE" and "CUSTOMER SERVICE", the red fault lamp (4) flashes and a pulsating signal tone sounds.

The acoustic alarm cannot be interrupted using the "Alarm OFF" (7) button.

- Switch off the unit at the mains (13).
- Switch the unit back on.

⚠CAUTION

If the unit still issues an alarm, then take it out of operation and have it checked by a service technician (customer service / medical engineering).

Display message: UNDERTEMPERATURE CHECK UNIT

The unit triggers this alarm if the water tank temperature falls below the measuring range (approx. 9 °C). The display shows "UNDERTEMPERATURE" and "CHECK UNIT". The red fault lamp (4) flashes and a pulsating signal tone sounds. The temperature display shows. – – . –

The acoustic alarm cannot be interrupted using the "Alarm OFF" (7) button.

- Switch off the unit at the mains (13).
- Take the unit into a warmer environment and wait approx. 2 hrs.
- Switch the unit back on.

⚠CAUTION

- Only store the unit in the permissible temperature range (10-40°C) for doing so, otherwise it may be damaged.
- Only operate the unit in the permissible temperature range (10-40°C) for doing so otherwise it does not function in a fail-safe manner and may be damaged (Observe, Requirements for installation and operating site!)

If the unit still issues an alarm, then take it out of operation and have it checked by a service technician (customer service / medical engineering).

Display message: CHECK UNIT, CUSTOMER SERVICE

The unit triggers this alarm for various defects. The display shows "CHECK UNIT" and "CUSTOMER SERVICE", the red fault lamp (4) flashes and a pulsating signal tone sounds.

The acoustic alarm cannot be interrupted using the "Alarm OFF" (7) button.

- Switch off the unit at the mains (13).

Take the unit out of operation and have it checked by a service technician (customer service / medical engineering).

7.2 Mains failure alarm

The unit triggers this alarm if the power supply fails during operation. The red fault lamp (4) is on and the signal tone sounds. All other displays are not functioning. The energy storage device in the unit receives the alarm for at least 10 minutes without power.

The alarm cannot be interrupted with the "Alarm OFF" (7) button.

- Switch off the unit at the mains (13).

NOTE

The alarm goes out automatically when the power supply returns.

The last set temperature is saved in the unit.

When reconnecting the power supply, the saved temperature must be checked by the user and released before the unit goes back into control mode (see Operation).

NOTE

For cleaning instructions, please see Appendix 1.

8.0 Maintenance and Safety check

This chapter provides you with important information on the maintenance of the unit. Observe the information to prevent damage due inadequate maintenance of the unit and to ensure the fail-safe operation.

8.1 Maintenance

We recommend concluding a contract with Chalice Medical. By concluding a maintenance contract, you meet the requirements:

- Of BetrSichV BGV A2 (VBG 4) new BGV A3,
- Of the medical device directive 93/42/EEC,
- Of MPBetreibV,

Which require the units to undergo regular technical checks.

Furthermore, maintenance carried out by our experts guarantees the maximum operational safety and durability of the unit.

NOTE

With correct handling and regular maintenance, an application (lifetime) over 5 years can be achieved. An extended warranty may be available past this warranty.

With proper handling of the hose extensions, the lifetime of these required accessory products can result from natural ageing and wear from use.

8.2 Safety Check

To ensure the legal conformity and operational safety according to Medical product directive 93/42/EEC (App. I, Point 13.6.d) and MPBetreibV (§ 6(1)), a safety check must be carried out on the unit every 12 months.

The operator is responsible for carrying out the safety check correctly. Due to MPBetreibV (§ 6 (4) 1. + 3.), the safety check can only be carried out by Chalice Medical or a qualified person. The safety check covers at least the following points:

- Checking the unit and the application parts for external damage, wear, ageing and legibility of the displays and labels
- Measuring the protective conductor resistance and the earth leakage current according to the test device and the manufacturer's instructions
- Checking all functions in accordance with the operating instructions
- Checking all safety functions in accordance with manufacturer's instructions
- Checking the sensors in accordance with manufacturer's instructions (Chalice Medical) provides authorised persons a service manual for this).

NOTE

To ensure conformity with legal safety regulations, we recommend that you conclude a safety check contract with authorised companies for carrying out the recommended annual safety check.

⚠CAUTION

In the case of heavily contaminated units or accessory parts sent in for maintenance or repair, whereby the suspect of contamination comes from contact with particular germs (e.g. MRSA), the system must undergo an additional (chemo thermal) treatment before a technical revision or damage analysis is done. The pre-disinfected and packed for transport with a suitable disinfection agent in accordance with the decontamination regulations and material compatibility.

Otherwise, we reserve the right not to accept these or added costs resulting from this will be paid by the customer.

9.0 Troubleshooting

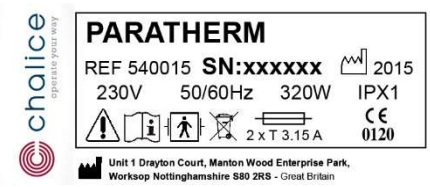
This chapter provides you with important information on fault localisation and troubleshooting. Observe the information to prevent hazards and damage.

9.1 Safety Information

⚠CAUTION

- Repairs on electrical units may only be carried out by experts, who may have been trained by the manufacturer.
- Considerable danger for the user and damage to the unit can result from incorrect repairs.

ParaTherm Heater Coolers have a type plate, stating the connection and performance data, attached to the back of the unit. An example of the type plate is shown below.



Note – SN is a unique Serial (or Identification) Number issued on new ParaTherm Heater Coolers

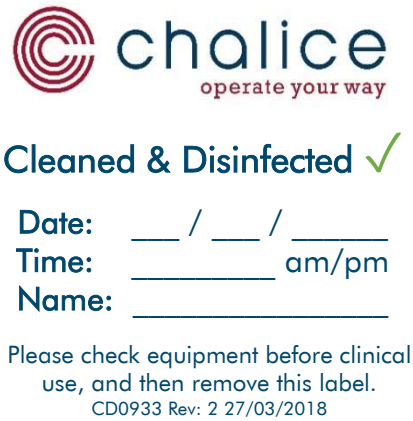
Three labels are also placed on the ParaTherm Heater Cooler indicating:

- Calibration dates,
- Re-test dates and
- CD0933 - ParaTherm Heater Cooler Cleaned

Examples labels

Calibration label

Re-test label



The following warning/caution labels are attached to the inner packaging:

Warning!
Residual disinfectant (caustic) may be present in the bag Always wear PVC or rubber gloves & eye protection upon removal

Caution
Do not pick up by the hose couplings

NOTE

If the unit is opened by unauthorised persons, the guarantee and warranty claims are lost.

- Repairs on the unit may only be carried out by Chalice Medical by experts trained and/or authorised by Chalice Medical.

9.2 Fault causes and Troubleshooting

Fault	Possible Causes	Remedies
No or insufficient water circulation	1) Hoses kinked 2) Couplings are not engaged 3) Unit is positioned above the minimum height between the heat exchanger of the membrane oxygenator and the ParaTherm 4) Intense foam formation 5) Pump worn/defective	1) Ensure correct laying and positioning 2) Insert couplings firmly into each other 3) Position the ParaTherm at the correct height in relation to the heat exchanger of the membrane oxygenator 4) Replace water* 5) Customer Service*
Couplings stiff Coupling connection drips constantly	Sealing ring dry and brittle Exterior, visible sealing ring damaged or missing	Grease sealing ring with Vaseline, silicone grease or similar Replace sealing ring*
Coupling valve of the non-connected coupling drips constantly	1) Inner sealing ring damaged 2) Inner sealing ring contaminated	1) Customer service* 2) Insert and loosen coupling several times, if necessary customer service
Alarm + Display message: "ALARM TEST DEFECTIVE" "->CUSTOMER SERVICE"	1) Independent protection device defective 2) Pump defective electrically	Customer service*
Alarm + Display message: "TEMP.DIFF. >1°C"	Coupling or decoupling of the heat exchanger of the membrane oxygenator during operation	Acknowledge alarm with "Alarm OFF" button
Alarm + Display message every 10 mins: "TEMP.DIFF. >1°C"	1) Cooling power insufficient 2) Cooling elements or pump defective 3) Intense foam formation in the tank 4) Bypass interrupted	1) See next line 2) Customer service* 3) Replace water* 4) Customer service*
Nominal value is not reached during cooling	Cooling power insufficient.	Consider replacing ParaTherm with alternative cooling unit.
Alarm + Display message: "WATER LEVEL!? "	1) Water level too low 2) Unit is not horizontal	1) Refill water 2) Position unit horizontally

Can be acknowledged for 10 mins. using the "Alarm OFF" button	3) Sensor deviation	3) Customer service*
Alarm + Display message: "CHECK UNIT" "->CUSTOMER SERVICE"	1) Various defects 2) Water tank empty 3) Sensor break/closure T1 4) Sensor closure T2	1) Customer service* 2) Refill water* 3) Customer service* 4) Customer service*
Alarm + Display message: "CHECK UNIT" "UNDERTEMPERATURE"	1) Unit too cold (< 9°C) 2) Sensor break T2 3) Water tank frozen	1) Heat up unit at room temperature 2) Customer service* 3) Defrost unit*; Examine unit for frost damage (Is water flowing out of the unit?) Customer service
Entire device not functioning acoustic alarm	1) Mains failure 2) Mains connector no contact 3) Fuse defective 4) Unit defective	1) Switch off unit until power returns 2) Check connector on unit and in socket for correct fit 3) Customer service* 4) Customer service*

*Switch off unit immediately

10.0 Disposal of old unit

Electrical and electronic old units still contain several valuable materials. However, they also contain harmful substances that were necessary for its function and safety.

In residual waste or when handling incorrectly, these can damage human health and the environment. This unit must not be disposed of with the general commercial and domestic waste!

NOTE

- According to the user waste regulations, the heat exchanger and membrane oxygenator should be incinerated at a clinically approved disposal centre.

11.0 Technical data and Accessories

11.1 Technical data

ParaTherm:

Unit No. (REF): 540016/EU (220V/230V)
540021 (115V)

Rated voltage: 230VAC 50Hz / 115VAC 60Hz / 220VAC 60Hz	Safety shutdown: 41.1-41.5°C (autonomous) this results in a max. Temperature of < 41°C
Power input: 320 W	Measuring range: approx. 9-50°C
Current consumption: approx. 1.5A (220V/230V)/ 3A (115V)	Measurement error 1: < +0.1°C (Display – Water temperature)
Correction value: 0.5°C (Water temp. -temp.-display)	Measurement error 2: < +0.5°C (Display - Contact surface temperature)
Sensor element: 2 x NTC 5K	Nominal value range: 15-39°C

Pump capacity: max. 5.5 l/min., max. 0.21 bar	Heating capacity: approx. 750W max. (at 27°C)
Cooling power: approx. 500W max. (at 27°C)	Warm-up time: approx. 5-10 mins. (20-37°C)
Cooling down time: approx. 5-10 mins. (20-15°C)	Type of protection IP: IP X1 (drip proof)
Class/type of protection: I, BF (defibrillation protected – IEC60601-1)	Fuse rating: 2x T 3.15A; L 250V (220V/230V) 2x T 5A; L 250V (115V)
Ambient temperature: 10-40°C	Risk class (93/42/EEC): II b
Transport/storage temperature: 3-60°C	Relative air humidity: approx. 30-70%
Tank Volume: approx. 0.5/0.8 l (min/max)	Air pressure: 700-1060mbar
Ambient temperature: 10-40°C	Permissible height difference: max. 1 m (Unit)
Dimensions (WxHxD): approx. 200 x 290 x 440 mm	Weight (with empty water tank): approx. 17 kg
Noise emission: approx. 50 dB(A) (1 m)	Alarm level: > 55 dB(A) (3 m)
Test basis: Medical product directive 93/42/EEC, DIN EN 60601-1, DIN EN 60601-1-2	Power supply: Must correspond with VDE 0100 Part 710:2002-11 "Electrical safety in medical environments"

Subject to technical changes

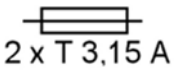
⚠WARNING

- It is not permitted to make changes to the ParaTherm.

11.2 Accessories – re-order details

- CMH016 - Water Cables with Hansen Connectors
- CM9202 - Air Vent Tubing Pack

11.3 Symbols



Unit fuse

Caution is advised! (E.g. Do not operate in the presence of flammable gases)

Disposal

Construction year

Manufacturer

12.0 Manufacturer's declaration and Guidelines

Chalice Medical declare that the medical device ParaTherm Hypo / Hypothermia Unit for Extracorporeal Bypass have been classified as being of Class IIB and are in conformity with products produced under the directive 93/42/EEC

Tables for medical electrical units General Details: - reduced version

Table 201

Line		
1	Guidelines and manufacturer's declaration – Electromagnetic emissions	
2	The unit or system is intended for use in an environment such as that specified in the tables and texts in these operating instructions. The customer or user of the unit or system should ensure that it is operated in such an environment.	
3	Fault emission measurements	Agreement
4	HF emissions According to CISPR 11	Group 1
6	HF emissions According to CISPR 11	Group B
7	Emissions of harmonic components according to IEC 61000-3-2	Class A
8	Emissions of voltage fluctuations/flickering	Not applicable
9	According to IEC 61000-3-3	see 6.8.3.201 a) 3 and image 201

Table 202:

Immunity tests	IEC 60601 test level	Agreement level
Discharge of static electricity (ESD) according to IEC 61000-4-2	±6 kV contact discharge ±8 kV air discharge	±6 kV contact discharge ±8 kV air discharge
Fast transient electrical disturbance variables / bursts According to IEC 61000-4-4	±2 kV for mains cables ±1 kV for input and output cables	±2 kV for mains cables ±1 kV for input and output cables
61000-4-4 Surges according to IEC 61000-4-5	±1 kV differential mode voltage ±2 kV common mode voltage	±1kV differential mode voltage ±2kV common mode voltage
Voltage drops, short interruptions and fluctuations in supply voltage according to IEC 61000-4-11	<5 % UT (>95 % drop in UT) for ½ period 40 % U (60 % drop in UT) for 5 periods 70 % UT (60 % drop in UT) for 25 periods	<5 % UT (>95 % drop in UT) for ½ period 40 % U (60 % drop in UT) for 5 periods 70 % UT (60 % drop in UT) for 25 periods
Magnetic field for the supply frequency (50/60 Hz) according to IEC 61000-4-8	<5 % UT (>95 % drop in UT) for 5 s 3 A/m	<5 % UT (>95 % drop in UT) for 5 s 3 A/m

Table 204: Non-life-sustaining systems

Immunity tests	IEC 60601 test level	Agreement level
Conducted HF faults according to IEC 61000-4-6	3 Veff 150 kHz to 80 MHz	3 V
Radiated HF disturbance variables according to IEC 61000-4-3	3 Veff 80 MHz to 2.5 GHz	3 V/m
Radiated HF disturbance variables according to EN 60601-2-35	10 V/m	10 V/m

Table 206: Protection ratios for wireless telecommunications installations

Protection ratio independent of the frequency transmission.

Nominal rating of the transmitter	150 kHz to 80 MHz	80 MHz to 800MHz	800 MHz to 2.5 GHz
W	d=P*exp0.5*3.5/V1	d=P*exp0.5*3.5/E1	d=P*exp0.5*7/E1
0,01	0.12 m	0.12 m	0.24 m
0,1	0.37 m	0.37 m	0.74 m
1	1.17 m	1.17 m	2.34 m
10	3.69 m	3.69 m	7.38 m
100	11.67 m	11.67 m	23.34 m

13.0 Brief Instruction

- Connect the unit to the mains.
- Connect the ParaTherm to the heat exchanger of the membrane oxygenator.
- Check the water level on the unit.
- Switch on the unit via the mains switch (0 / I) and observe automatic functional test.

• If the nominal temperature value is >38°C or <35°C when switching the unit on, an alarm sounds.

- Acknowledge and commission by pressing the release button.

• Set the temperature using the arrow buttons.

• For temperatures above 38 °C, press the arrow button and release button at the same time.

• For temperatures below 35 °C, press the arrow button and release button at the same time.

- Check the water flow window to verify water is flowing through the water hoses.
- Monitor the patient's body temperature.

- Monitor the water level and water flow on the unit.

• During continuous operation, carry out the functional test manually once a day using the "Functional test" button.

• Acoustic warnings can be interrupted using the "Alarm OFF" button.

- Alarms of medium priority cannot be interrupted. Switch off the unit at the mains (13).

NOTE

For certain faults, the unit switches off all functions. Take the unit out of operation and hand it over to a service technician to check and re-establish operational safety.

⚠WARNING

There is a risk of the patient becoming overheated or overcooled.

- Monitor the patient's body temperature when the ParaTherm is used to circulate water through the heat exchanger of the membrane oxygenator while in clinical use.

⚠CAUTION

Do not put the unit into operation if:

- The display has failed,
- Individual segments on a temperature display have failed (temperature can no longer be read safely),
- The red fault lamp (4) stays on or does not come on at all (functional test),
- The signal tone continues to sound or does not sound at all (functional test),
- The unit does not react when pressing buttons,
- The unit does not react as described in chapter "Functional test" when switching on or during the functional test.
- The unit has not been cleaned in accordance with appendix 1

Notes

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