



ParaTherm Heater Cooler for Extracorporeal Life Support

Operating & Cleaning Instructions



PARATHERM[®]
HEATER / COOLER



English

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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
- Non-compliance with servicing requirements

1.4 Copyright Protection

This documentation is protected by copyright. All rights, even in part, including those of photomechanical reproduction, copying and distribution by means of special processes (for instance data processing, data carriers and data networks), are reserved by Chalice Medical Ltd. Subject to contextual and technical changes.

1.5 Manufacturer Contact Details

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

Chalice Medical Ltd.

Manton Wood Enterprise Park
Worksop, Nottinghamshire, S80 2RS, UK

Telephone: +44 (0) 1909 470 777

Email: enquiries@chalicemedical.com

Web: www.chalicemedical.com

1.6 Warranty

The ParaTherm carries a warranty of **2 year**.

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 Intended Use

The ParaTherm is intended for altering the temperature of water circulating through the synthetic heat exchanger of a membrane oxygenator, used to maintain normothermia of a patient during ECLS procedures such as ECMO. Any other use or use extending beyond this is deemed inappropriate. The ParaTherm is not intended to be used during cardiopulmonary bypass (CPB) procedures. The ParaTherm is for use in a professional healthcare facility environment only. The ParaTherm does not have direct or indirect contact with the patient. The ParaTherm is not in contact with organs, body parts, tissues, or fluids.

2.2 Intended Patient Target Groups

The ParaTherm and Accessories is intended to be used in a broad population of patients, including all ages of patients. The patients for whom ECLS/ECMO is indicated are refractory to other measures of life support and the use of such procedures is decided based on individual patient risk profiles.

2.3 Device Users

The ParaTherm is intended to be used by appropriately trained and qualified healthcare professionals who are experienced in ECMO procedures.

NOTE

Only to be used with a synthetic heat exchanger. Not to be used with a synthetic heat exchanger manufactured using PUR. Metal heat exchangers must **not** be used.

From this point forward reference to the synthetic heat exchanger will be shortened to heat exchanger. When an oxygenator is referenced, it refers to a device which contains a synthetic heat exchanger.

2.4 Clinical Benefits

The clinical benefit of the ParaTherm is the safe and effective heating and cooling of blood during extracorporeal life support, which in turn enables the continued effective maintenance of normothermia of the patient in a myriad of scenarios.

2.5 Personal Requirements

Training can be provided by Chalice Medical Ltd on request.

2.6 Combination Products

Compatibility, performance, connection and requirement of devices to be used in combination with the ParaTherm Heater/Cooler.

All devices listed are CE marked.

Device	Performance Requirements	Connection to the ParaTherm Requirements	Connection from the ParaTherm Requirements	Test Standards
Oxygenator	Water flow range 1 – 15 l/min	3/8" Hansen Type Coupler	3/8" Hansen Type Coupler	ISO 80601-2-35 Section 201.15.4.101
Synthetic Heat Exchanger	Water flow range 1 – 15 l/min	3/8" Hansen Type Coupler	3/8" Hansen Type Coupler	ISO 80601-2-35 Section 201.15.4.101
Connectors & Hoses	Water flow range 1 – 15 l/min	3/8" Hansen Type Coupler	3/8" Hansen Type Coupler	ISO 80601-2-35 Section 201.15.4.101

⚠ 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.

2.7 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. The ParaTherm is fitted with “void if broken” stickers to prevent unauthorised accesses.
- 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.

⚠WARNING

All units must be serviced on an annual basis as per the Service Due Label located on the unit. Please contact Chalice Medical Ltd or your distributor to arrange this.
ParaTherms must be returned with their power cables and water lines.

2.8 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 $\leq 3\%$.
- Height difference between unit and the heat exchanger of a membrane oxygenator $< 1\text{ m}$.
- 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 just below maximum.
- Keep to ambient temperature range (10-40°C)
- Only operate the unit with original accessories.
- 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 section 14 and test for contamination.
- Any reported contamination issues should be communicated directly to Chalice Medical Ltd.

2.9 Hazard Sources

2.9.1 Risk of overheating or overcooling

▲WARNING

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

The operator should continuously monitor the patient's body temperature during use of the ParaTherm.

2.9.2 Equipment Stacking

▲WARNING

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

2.9.3 Accessories

▲WARNING

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

NOTE

Any missing accessories or components should be reported to Chalice Medical Ltd.

2.9.4 Proximity Field

▲WARNING

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ParaTherm, including cables specified by the manufacturer. Otherwise, the performance of the equipment could result in degradation.

2.9.5 Electromagnetic Disturbances

▲WARNING

The essential performance of the device, heating and cooling water, may be lost or degraded due to electromagnetic disturbances. Performance failure will trigger the alarm system to warn the user.

2.9.6 Monitoring

▲WARNING

The ParaTherm should be monitored regularly to ensure the device is functioning in case there is a failure of the alarms which would notify the user.

2.9.7 Material Degradation

▲WARNING

Any signs of material degradation shall result in the unit no longer being used and must be reported to Chalice Medical Ltd.

3.0 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.

NOTE

- Always keep the original packaging to provide transport protection when returning the unit for service/repair.
- For requested additional ParaTherm Accessories, please retain the original packaging which holds the labelling for the accessories

4.0 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 $\leq 3\%$).
- provide 20 cm of space on both sides of the unit.
- ensure the unit is sufficiently ventilated, e.g. in a trolley, also from above.

⚠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: $23^{\circ}\text{C} \pm 3^{\circ}\text{C}$
- relative air humidity: $60\% \pm 15\%$
- air pressure: 860 hPa to 1060 hPa (645 mmHg to 795 mmHg)

4.3 Connecting the ParaTherm

⚠WARNING

The ParaTherm must be cleaned thoroughly before clinical use! Please refer to section 14 for information on the cleaning protocols.

The one-way valve should be checked before first use (please refer to section 14.13).

⚠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.
- Once completed replace the water filler cap, hand tight.

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 the procedure as described further on.

⚠WARNING

Hazard due to water in connection with electricity.
Water can conduct electrical current.

- If water has overflowed 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.

⚠CAUTION

Risk of potential aerosolisation.

The screw cap must be fully screwed down prior to operation during clinical use, this will prevent any potential aerosol generated within the water tank from being released in to the surrounding environment.

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. Ensure that the connection between the water hoses and the ParaTherm are secure and that there are no leaks.
- 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 off.
- 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.

⚠CAUTION

- Decoupling a heat exchanger of a membrane oxygenator from the unit could lead to potential contamination of the environment via splashing of water. It is recommended that this is to be performed in a non-clinical area to reduce the risk of contamination within the clinical setting.

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!

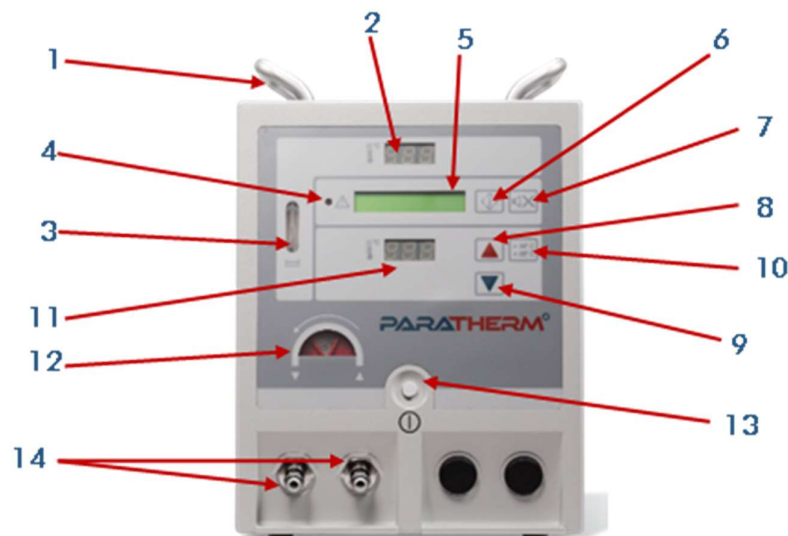
For a safe and fault-free operation of the unit, the following information must be considered when connecting to the power supply:

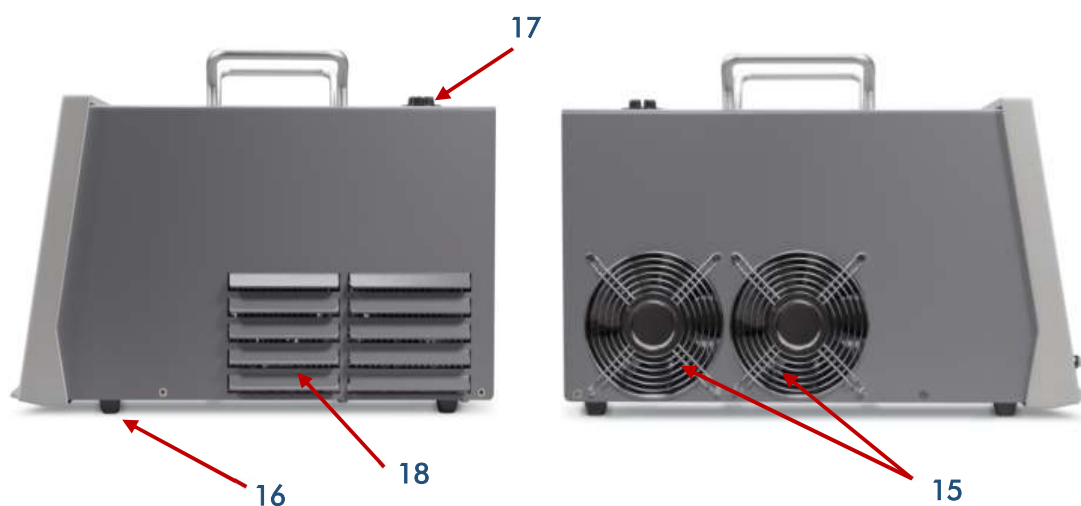
- Before connecting the unit, compare the connection data (voltage and frequency) on the type plate with those of your electricity network. These data must correspond so that no damage is done to the unit. In case of doubt, ask your electrician.
- The power socket must be protected with a 16A circuit 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 710:2012-10 "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 $<35^{\circ}\text{C}$ / $> 38^{\circ}\text{C}$
2) Temperature Display for Water Tank	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

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 Function

5.3.1 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 incorrectly 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.

5.4 Indications

The ParaTherm is used to stabilise or maintain the patient's temperature (normothermia) during extracorporeal life support (ECLS) procedures such as ECMO, by altering the temperature of water flowing through the heat exchanger component of an oxygenator. There are two modalities of ECMO – venoarterial (VA) and venovenous (VV).

Conditions that can benefit from the use of VV-ECMO include but are not limited to:

- acute respiratory distress syndrome (severe bacterial or viral pneumonia, aspiration syndromes, alveolar proteinosis, Wegener's granulomatosis),
- extracorporeal assistance to provide lung rest (airway obstruction, pulmonary contusion, smoke inhalation),
- lung transplant (primary graft failure after lung transplantation, bridge to lung transplant, intra-operative),
- lung hyperinflation (status asthmaticus),
- pulmonary haemorrhage or massive haemoptysis,
- congenital diaphragmatic hernia,
- meconium aspiration.

Conditions that can benefit from the use of VA-ECMO include but are not limited to:

- cardiogenic shock /severe cardiac failure due to almost any cause (acute coronary syndrome, cardiac arrhythmic storm refractory to other measures, sepsis with profound cardiac depression, myocarditis, pulmonary embolism, isolated cardiac trauma, acute anaphylaxis),
- postcardiotomy (inability to wean from cardiopulmonary bypass after cardiac surgery),
- post heart transplant (primary graft failure after heart or heart-lung transplantation),
- chronic cardiomyopathy (as a bridge to longer term VAD support, or as a bridge to decision),
- peri-procedural support for high-risk percutaneous coronary interventions,
- bridge to transplant.

▲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 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
- Any other use or use extending beyond ECLS or ECMO is contraindicated. The ParaTherm must not be used during cardiopulmonary bypass procedures.

5.7 Limitations

Limitations of the ParaTherm are as follows:

- The device is to be used with water only
- The device temperature range is limited to 15-39°C
- The device is only to be used with a synthetic heat exchanger (part of the membrane oxygenator)
- The device is only for use in ECMO (not cardiopulmonary bypass)

5.8 Side Effects

There are no known side effects associated with the ParaTherm.

▲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.

▲CAUTION

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

NOTE

Due to constant new findings in the area of normothermia, the information provided here does not claim to be current and complete.

Chalice Medical Ltd 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.

NOTE

Any serious incident that has occurred in relation to the device, should be reported by the user to the manufacturer via the sales manager and to quality@chalicemedical.com and the competent authority with jurisdiction in the locale in which the user is established.

6.0 Handling and Operation

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

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.

Before clinical use 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).

⚠CAUTION

Decoupling a heat exchanger of a membrane oxygenator from the unit could lead to potential contamination of the environment via splashing of water. It is recommended that this is to be performed in a non-clinical area to reduce the risk of contamination within the clinical setting.

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.

⚠CAUTION

There is a risk of aerosolisation and splash contamination.

- Refilling the tank during operation will require removal of the screw cap, which could lead to potential contamination of the environment via aerosol release from the tank. It is recommended that this is to be performed in a non-clinical area to reduce the risk of contamination within the clinical setting.
- Refilling the tank with sterile water may cause splashing of water already in the tank to contaminate the surrounding environment. It is recommended that this is to be performed in a non-clinical area to reduce the risk of contamination within the clinical setting.

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 **88.8**

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 **88.8**
- 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 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.
- Excessive room temperature may decrease the efficiency of the ParaTherm if cooling of a patient is required.

⚠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 patient's core temperature.

The degree of heat transfer is directly proportional to the temperature difference of the patient 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 (5).

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 normothermia, the medical information does not claim to be complete. Chalice Medical Ltd 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 **88.8**
- The yellow 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).

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").

This alarm is also triggered if there is no flow of water within the device, this can be from pump failure, a blockage within the device, or decoupling of the water lines. Flow of water through the device can be checked by observing the red impeller wheel at the front of the device.

Trouble shooting these faults is detailed within section 9.2 – Fault Causes and Troubleshooting

⚠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.
- A water level that has dropped from the MAX mark to be below the MIN mark and trigger this alarm may indicate a leak from the unit or from the heat exchanger of the membrane oxygenator. Please check for any visual signs of leakage from these areas.

⚠CAUTION

There is a risk of aerosolisation and splash contamination.

- Refilling the tank during operation will require removal of the screw cap, which could lead to potential contamination of the environment via aerosol release from the tank. It is recommended that this is to be performed in a non-clinical area to reduce the risk of contamination within the clinical setting.
- Refilling the tank with sterile water may cause splashing of water already in the tank to contaminate the surrounding environment. It is recommended that this is to be performed in a non-clinical area to reduce the risk of contamination within the clinical setting.

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.

This alarm also will warn the user if the temperature within the device drops below 15°C or rises above 39°C. The actual temperature of the water within the device is displayed on the bottom LED screen (point 2 of the ParaTherm diagram).

If the set temperature is not reached within 60 minutes this alarm is also triggered or if there is no flow within the device.

Trouble shooting these faults is detailed within section 9.2 – Fault Causes and Troubleshooting

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 FAIL, CALL 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 FAIL" and "CALL SERVICE", the yellow 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).

⚠CAUTION

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 1, CALL SERVICE

The display shows "CHECK UNIT 1" and "CALL SERVICE", the yellow 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).

This alarm is triggered if the temperature of the water within the ParaTherm is 40.8°C or if there is short circuiting of the temperature sensors. Details on troubleshooting and fault causes are detailed under section 9.2.

Display message: CHECK UNIT 2, TEMPERATURE LOW

The unit triggers this alarm if the water tank temperature falls below the measuring range (approx. 6 °C). The display shows "CHECK UNIT" and "TEMPERATURE LOW". The yellow 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 into a warmer environment and wait approx. 2 hrs.
- Switch the unit back on.

The temperature of the water within the device will be displayed for the user. If the temperature within the device is still within 15°C and 39°C, the alarm may have been triggered due to a sensor break within the device. If this occurs the device should be removed from service and reported to Chalice Medical Ltd.

Display message: CHECK UNIT 3, CALL SERVICE

The display shows "CHECK UNIT " and "CALL SERVICE", the yellow 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).

This alarm is triggered if the temperature of the water within the ParaTherm drops below 4°C, or if the temperature of the water is between 41.1° C - 41.5° C.

7.2 Mains failure alarm

The unit triggers this alarm if the power supply fails during operation. The yellow 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 section 14

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 a maintenance contract with Chalice Medical Ltd.

Maintenance carried out by our experts guarantees the maximum operational safety and durability of the unit.

NOTE

An Expected Lifetime of the ParaTherm is 5 years as long as the service requirements are met. The ParaTherm has a warranty of 2 years with correct handling, maintenance and annual service. An extended warranty may be available past this time.

The ParaTherm accessories should be checked regularly for any signs of damage.

8.2 Safety Check

To ensure the legal conformity and operational safety according to Medical Device Regulation 2017/745, a safety check must be carried out on the unit every 12 months.

The operator is responsible for carrying out the safety check correctly. The safety check can only be carried out by Chalice Medical Ltd 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 Ltd) provides authorised persons a service manual for this).

⚠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 (chemothermal) 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.



CD1623 image post-September 2021



(01)5060912580118 (11)240313 (21)17.0058
CD1618-REV 0-21/07/21

CD1618 image UDI Label

The GTIN barcode containing the UDI, as well as the CE mark is contained on a separate label which is attached to the back of the unit by Chalice Medical Ltd.

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

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

- CD0617 - Calibration label.
- CD0618 - Electrical safety label.
- CD0933 - Cleaned & Disinfected label.
- CD1512 – Service Label

Examples labels

Calibration label



Electrical safety label.



Cleaned & Disinfected ✓

Date: ____ / ____ / ____

Time: _____ am/pm

Name: _____

Please check equipment before clinical use, and then remove this label.

CD0933 Rev: 2 27/03/2018



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



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 Ltd by experts trained and/or authorised by Chalice Medical Ltd.

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 FAIL" "->CALL SERVICE"	1) Independent protection device defective 2) Pump defective electrically 3) TECs defective electrically	Customer service*
Alarm + Display message: "TEMP.DIFF. >1°C"	1) Temperature not reached within 60 minutes 2) T1-T2 is > 1.0°C and longer than 10 seconds) 3) Lack of flow (misconnection or blockage)	1) Customer service*
Nominal value is not reached during cooling	Cooling power insufficient.	Consider replacing ParaTherm with alternative cooling unit.
Alarm + Display message: "WATER LEVEL!?" Can be acknowledged for 10 mins. using the "Alarm OFF" button	1) Water level too low 2) Unit is not horizontal 3) Sensor deviation 4) Defective pump 5) Lack of flow (misconnection or blockage) 6) Coupling or decoupling of the heat exchanger of the	1) Refill water 2) Position unit horizontally 3) Customer service* 4) Check the water line connections 5) Check the water lines for blockages or kinks

Fault	Possible Causes	Remedies
	membrane oxygenator during operation	6) Reconnect heat exchanger of the membrane oxygenator
Alarm + Display message: "CHECK UNIT 1" or "CHECK UNIT 3"->"CALL SERVICE"	1) Sensor break/short circuit T1 2) Sensor break/short circuit T2 3) Water temperature > 40.8° C 4) Water temperature > 4° C 5) Water temperature > 41.1° C - 41.5° C	1) Customer service*
Alarm + Display message: "CHECK UNIT 2" -> "LOW TEMPERATURE"	1) Unit too cold (<6°C) 2) Sensor break T1/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 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*
Language resets to German	Unplugged without switching off the device. Internal battery dead.	See 6.8 Customer service to replace battery

* Switch off immediately and replace if in clinical use. Inform Chalice Medical Ltd.

If a fault is suspected with the ParaTherm while in clinical use, the device should be turned off removed from the clinical setting and replaced. Chalice Medical Ltd. should be immediately contacted.

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!

Old units can be returned to Chalice Medical Ltd for appropriate disposal.

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

Nominal voltage: 230VAC 50/60Hz / 110/115VAC 50/60Hz / 220VAC 60Hz	Ambient temperature: 10-30°C
Power input: 320 W	Relative air humidity: approx. 30-70%
Nominal temperature range: 15-39°C	Air pressure: 700-1060mbar
Safety shutdown: 41.1-41.5°C (autonomous) this results in a max. Temperature of < 41°C	Tank Volume: approx. 0.65/0.75 l (min/max)
Correction value: 0.5°C (Water temp. -temp.-display)	Current consumption: approx. 1.5A (220V/230V)/ 3A (110/115V)
Sensor element: 2 x NTC 5K	Permissible height difference: max. 1 m (Unit)

<u>Pump capacity:</u> max. 5.5 l/min., max. 0.21 bar	<u>Dimensions (WxHxD):</u> approx. 200 x 290 x 440 mm
<u>Warm-up time:</u> approx. 5-10 mins. (20-37°C)	<u>Weight (with empty water tank):</u> approx. 17 kg
<u>Cooling down time:</u> approx. 5-10 mins. (20-15°C)	<u>Noise emission:</u> 35-45 dB(A)
<u>Fuse rating:</u> 2x T 3.15A; L 250V (220V/230V) 2x T 5A; L 250V (110/115V)	<u>Alarm level:</u> > 70 dB(A)
<u>Type of protection IP:</u> IP X1 (drip proof)	<u>Test basis:</u> Medical Device Regulation 2017/745, EN 60601-1, EN 60601-1-2
<u>Type of protection:</u> Class I Electric shock protection (60601-1)"	<u>GMDN Code -</u> 63370
<u>Risk class MDR 2017/745:</u> II b	<u>EMDN Code -</u> Z12019008
<u>Use Classification:</u> Multiple patient, multiple use	

Subject to technical changes

⚠ WARNING

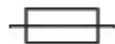
It is not permitted to make changes to the ParaTherm.

11.2 Accessories – re-order details

- Water Cables with Hansen Connectors
- Air Vent Tubing Pack
- IEC 60320 Power Cable – Plastro Mayer – H05VV-F3-G1

Recommend using the above accessories supplied by Chalice Medical Ltd to ensure compatibility.

11.3 Explanation of Symbols Used

Manufacturer - accompanied by the name and address of the manufacturer		Refer to instruction manual/ booklet symbol – indicates to the user to refer to the instruction manual	
WEEE Symbol – indicates device is not for general waste		Identifies fuse boxes or their locations	
Medical Device Symbol – indicates the item is a medical device		Consult electronic Instructions for Use.	
Protected against dripping water	IPX1	Catalogue Number – accompanied by the catalogue number for the medical device	
Quantity Symbol – Addition of number to determine how many products are in the packaging		CE Marking of Conformity - Indicates device is in conformity with the requirements of MDR 2017/745	
Date of Manufacture - accompanied by a date to indicate the date of manufacture, expressed as YYYY-MM-DD		Keep away from sunlight Symbol – indicates a medical device that needs protection from light sources	
Serial Number – accompanied by the serial number for the medical device		Keep Dry Symbol – indicates a medical device that needs to be protected from moisture	

Fragile, handle with care Symbol – indicates a medical device that can be broken or damaged if not handled carefully		Language Symbol – Assigned as required	
EC Authorised Representative - accompanied by the name and address of the authorised representative in the European Community		'Wear protective gloves'	
'Wear eye protection'		Importer	
Do not use if packaging is damaged.		Consult Instructions for Use.	

12.0 Guidelines and Manufacturer's declaration

Chalice Medical Ltd declare that the medical device ParaTherm Heater Cooler for Extracorporeal Life Support have been classified as being of Class IIb and are in conformity with products produced under the regulation 2017/745.

Guidelines and manufacturer's declaration – Electromagnetic emissions	
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.	
For Professional Healthcare Facility Environment	
Fault Emission Measurements	Agreement
Conducted RF Emissions	Class B
Radiated RF Emissions	Class B
Emissions of harmonic components according to EN 61000-3-2	Class A
Emissions of voltage fluctuations/flickering According to EN 61000-3-3	Pst Dmax

Immunity tests	60601 Test Levels	Agreement Level
Discharge of static electricity (ESD) according to EN 61000-4-2	±8 kV contact discharge ±15 kV air discharge	±8 kV contact discharge ±15 kV air discharge
Fast transient electrical disturbance variables / bursts According to EN 61000-4-4	±2 kV	±2 kV
Surges according to EN 61000-4-5	± 0.5 and 1kV line to line ± 0.5, 1 and 1kV line to earth	± 0.5 and 1kV line to line ± 0.5, 1 and 1kV line to earth
Voltage drops, short interruptions and fluctuations in supply voltage according to EN 61000-4-11	0 % UT; 0,5 cycle 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	0 % UT; 0,5 cycle 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle

Magnetic field for the supply frequency (50/60 Hz) according to EN 61000-4-8	30A/m	30A/m
Conducted disturbances induced by RF fields EN 61000-4-6: 2014	3Vrms 0.15-80MHz 6Vrms in ISM bands between 0.15MHz and 80MHz.	3Vrms
Radiated RF EM fields EN 61000-4-3	3V/m 80-2700MHz	3V/m

Immunity to proximity fields from RF wireless communication equipment

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
385	380-390	TETRA	Pulse Modulation 18Hz	1.8	0.3	27
450	430-470	GMRS 460 FRS460	FM ±5kHz deviation 1kHz sinewave	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse Modulation 217Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900 TETRA 800 iDEN 820 CDMA 850 LTE Band 5	Pulse Modulation 18Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse Modulation 217Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation 217Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse Modulation 217Hz	0.2	0.3	9

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.

- 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 yellow 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

14.0 Cleaning and Disinfecting

It is important that the following cleaning and maintenance procedures are read carefully and followed as recommended by Chalice Medical Ltd.

Unless using disposable hoses, the same hoses should always be used with the same ParaTherm Heater/Cooler. Labelling these with the same label as the device will help to ensure this.

The user must check every oxygenator used with the ParaTherm Heater/Cooler prior to clinical use to ensure absence of leaks in the heat exchanger area of the oxygenator. To do this, connect the ParaTherm water lines to the oxygenator. The water must be left to re-circulate inside the heat exchanger for a minimum of 5 minutes to check that the structure of the heat exchanger is leak free and that there are no leaks from the water area.

Cleaning protocol for the ParaTherm Heater/Cooler (hereafter called 'ParaTherm')

14.1 Cleaning and Disinfection Guide for the ParaTherm

Before routine daily cleaning of the ParaTherm is performed standard Health and Safety measures must be taken. These include:

- Wash hands and dry thoroughly.
- Apply disposable gloves and apron.
- Apply nose and mouth mask
- Apply suitable eye protection.

14.2 Cleaning and Disinfecting

Observe the following information to prevent damage due to incorrect cleaning of the ParaTherm.

⚠CAUTION

Sensitive surfaces

The surfaces of the unit can be destroyed if the wrong cleaning or disinfection agent is used.

- For all surfaces and parts, only use disinfection agent based on aldehydes, ammonium components or alcohols which do not corrode ABS plastic as well as PVC and PU.
- If possible, do not use a disinfection agent based on phenol derivatives since these shorten the lifetime of plastics.

For routine daily cleaning while the unit is in clinical use.

For disinfecting the unit surface, including the water hoses we recommend using a wipe or surface disinfection product approved by your hospital infection control department. Commonly used products include those products in Tables 1 and 2 below. Carefully follow the manufacturer's instructions when using the disinfection agent.

Table 1. Commonly used products included on the RKI or DGHM list

Product Name	Manufacturer
Bacillol	Bode
Mikrozid AF	Schulke & Mayer
CaviWipe	Metrex

Table 2. Other commonly used products

Product Name	Manufacturer
Clinell Universal Wipes	Clinell
Super Sani Cloth	PDI

Contamination with blood or bodily fluids.

If blood or other bodily fluid contamination is suspected, Chlorine releasing solution 1% must be used prior to the use of other cleaning solutions.

Recommended level, Equivalent to 10,000 ppm of available chlorine e.g. Actichlor.

When the device is not in operation following use or cleaning, it must be stored dry to ensure that an environment in which microbes can grow is not created.

14.3 Ventilation slots

Daily, make sure the ventilation slots are clear and not blocked to allow air to move freely in and out to prevent the device overheating.

When cleaning around the ventilation slots, care must be taken not to allow liquid to enter the ventilation slots and come into contact with electrical connections situated within the case.

While undertaking daily cleaning of the unit, if a build-up of dust is seen within the ventilation slots, this should be removed once the unit has been removed from clinical use by a qualified service technician (customer service, medical engineering). The unit must never be opened by a non-technically trained person.

Every six months the ventilation slots should be closely examined for damage and that they are clear, open and free from foreign objects. Any corrective action should be carried out by a technically trained person.

⚠CAUTION

Do not use any other cleaning or decontamination processes other than those recommended by Chalice Medical Ltd. Carefully follow this IFU.

Only in this way can it be ensured that these processes do not damage the unit.

Sterile water must be used within 48 hours of opening.

14.4 Cleaning the ParaTherm after each Clinical Use.

Unit Name/Number:

Cleaned by:

Date:/...../.....

Clean the ParaTherm tank and hoses after each clinical use.

It is recommended that, after each clinical use, the ParaTherm with the oxygenator still connected should be removed to a non-clinical area before disconnecting the water pipes to the oxygenator. This will reduce the possibility of aerolization of water droplets entering the atmosphere within the clinical setting.

⚠CAUTION

Cleaning Solution

Use a suitable stabilised 7.5% hydrogen peroxide product for cleaning and disinfectant of this medical device. The product should be undiluted and from an un-opened bottle. Do not store for re-use once opened.

⚠CAUTION

If the patient is situated within an infection control area, a risk assessment should be undertaken to establish if the hoses to the oxygenator should be disconnected within the infected controlled area to allow contaminated material to be safely contained before leaving the isolated location.

Remove the ParaTherm to a non-clinical well-ventilated area before cleaning the tank and hoses.

⚠CAUTION

It is advisable that the water lines and the ParaTherm are either given names or are numbered and that the water lines are cleaned at the same time as the ParaTherm corresponding to that name or number.

- Disconnect unit from the mains and remove to a non-clinical area with good ventilation.
- Place the unit onto a draining device (e.g. rinsing tank or draining board by the side of a sink).
- Unscrew the cap of the water filler neck.
- Allow the water to drain out of the unit via the water hoses with the aid of the hose connector (Fig.1) until the unit and the water hoses are completely clear of water.



Figure 1.

- e. Once the tank and water hoses are clear of water, reconnect both hoses together via the hose connector, figure 1.
- f. Pour 5mls of cleaning solution into a small clean disposable pot.
- g. Using a sterile swab dip this into the cleaning solution and clean the inside of the filling port on the ParaTherm.
- h. Using a new swab, place this in the cleaning solution and clean both the inside and the outside of the filling cap. Make sure the cleaning solution covers the entire surface area.
- i. Discard any remaining cleaning solution.
- j. Pour the correct volume of cleaning solution as shown in table 1a into a small clean measuring pot.
- k. Pour 500mls of the required cleaning solution into the top of the ParaTherm. Prime the hoses and pour a further 200mls into the tank a total of 700mls (as per table 1a).

Table 1a.

ParaTherm part	Volume of cleaning solution required
ParaTherm water tank	700mls
3m water lines	192mls
2m water lines	128mls
50 cm recirculation line	16mls

- l. Turn the ParaTherm on and then agitate the ParaTherm to make sure all surfaces within the water tank come into contact with the hydrogen peroxide.
- m. Allow the hydrogen peroxide to circulate for two minutes.
- n. Now turn off the ParaTherm and add the remainder of the hydrogen peroxide.
- o. Turn the ParaTherm back on and allow to circulate and run for two hours but make sure the red wheel is turning.
- p. The filler cap should be left off during the cleaning and rinsing stages.

⚠CAUTION

During cleaning, screwing the filler cap down into a fully sealed position, followed by running with cleaning solution at 37°C for a prolonged period of time, will cause a build-up of pressure within the water tank. Due to the ParaTherm being a sealed unit this pressure will have no way of escape. To avoid this, it is essential that the cap is not screwed down fully during this part of the cleaning cycle.

Do not overfill the ParaTherm with cleaning solution. The level of cleaning solution, indicated by the water level indicator on the front of the ParaTherm, must **always** read between the MIN & MAX level indicators.

- q. During the cleaning cycle, the temperature should be set to 37°C
- r. Once two hours have elapsed, the ParaTherm must be drained and then rinsed through with sterile water.
- s. Turn the power off, drain the ParaTherm, disconnect the water lines via the water hose connector.
- t. Once the ParaTherm is empty, reconnect the hoses.
- u. Place the required volume of sterile water into a clean measuring pot.
- v. Refill the ParaTherm with the sterile water.
- w. Gently agitate the ParaTherm to allow the sterile water to contact all surface areas within the water tank.
- x. Turn the power on and run for ten minutes at 37°C.
- y. Turn the power off and disconnect the hoses and allow the sterile water to drain out.
- z. Turn the ParaTherm off and reconnect the water hoses together again.
- aa. Once the ParaTherm is empty, the filler cap can be loosely fitted to the top of the tank.

If the unit is to be used clinically, refill the unit with the correct volume of sterile water including the volume required for the attached heat exchanger of the membrane Oxygenator. The hose connector should be removed and stored in a clean sealed box.

- bb. If the ParaTherm is not required for immediate use, it should be placed in a secure area with the water lines and labelled with the date it was cleaned.
- cc. Testing the water sample.
- dd. It is advisable to test the water sample for the level of residual Hydrogen Peroxide. If the level is too high, further rinses with sterile can be completed through steps t to y.

14.5 Unit not required for immediate clinical use

Any units that are out of use or have not been stored and not maintained through the weekly disinfectant cycle must be disinfected using the decontamination procedure as per section 14.4 prior to use.

14.6 Regular Cleaning Intervals.

To reduce the possibility of Mycobacterium contamination within the ParaTherm, the cleaning procedure detailed in section 14.4 should be undertaken every 7 days.

⚠CAUTION

If the patient remains on ECMO longer than 7 days a risk assessment should be undertaken to determine the risks of disconnecting the ParaTherm while in use within the clinical setting against a possible risk of water spillage causing aerosolisation of water vapour within the clinical setting.

14.7 Cleaning hose extensions after clinical use.

For disinfecting the hose extensions outer surface, we recommend a surface, wipe or spray disinfection in accordance with product recommended by your infection control department or those commonly used in Tables 1 and 2 (see Section 14.2). Follow the manufacturer's instructions when using the disinfection agent.

Only use the hose extension again when the disinfection agent has completely evaporated.

Check the hose extension for damage, deformation or tears; replace damaged accessories.

⚠CAUTION

Emergency situations while the ParaTherm is in Clinical Use.

If the ParaTherm or any device connected to the ParaTherm has to be removed while in clinical use, time permitting, the new device should be pre-reconnected to the ParaTherm away from the clinical setting.

Once the change out is completed the old device should be disconnected from the ParaTherm away from the clinical setting and in a non-clinical environment.

Patient safety and clinical risk must be observed and documented.

14.8 Maintenance every Six Months.

Hose couplings –

Inspect the sealing rings (O-rings) on all couplings every 6 months to ensure that they are intact. Any signs of cracks or damage, please contact Chalice Medical Ltd directly or via your distributor.

14.9 Water Sampling for Microbiological testing.

Follow any national recommended procedures for microbial checking of heater coolers.

The ParaTherm Heater/Cooler uses a closed system which, when used in accordance with the IFU, should not allow aerosolisation of water. However, there is a remaining residual risk that patient infection could still occur when using a contaminated device.

Within the Public Health England document titled, 'Infections Associated with Heater Cooler Units Used in Cardiopulmonary Bypass and ECMO' there is an advisement that:

'We advise that where not specified by the manufacturer, microbiological drinking water quality standards should be derived from the EU Drinking Water Directive (98/83/EC) standards for water in containers, with maximum counts being⁶:

E. coli 0/250 ml
Pseudomonas aeruginosa: 0/250 ml
Colony count 22C: 100/ml
Colony count 37C: 20/ml

At present, this is only an advisement with regards standards for microbiological testing.

14. 10 Topping up the water tank during routine operation.

⚠CAUTION

Do not remove the ParaTherm filler cap and refill with sterile water if there are patients present that are undergoing open surgical procedures. There is a risk of aerosolisation of water droplets while the cap is removed, along with splash contamination from pouring sterile water into the ParaTherm tank. Remove to a non-clinical environment for this.

If the water level drops below the minimum level during routine operation this can be topped up, but the following must be adhered to:

- a. Wash hands
- b. Apply disposable gloves.
- c. Apply disposable apron.
- d. Apply suitable eye protection.
- e. Remove filler cap from ParaTherm.
- f. Pour sterile water into the ParaTherm to the maximum filling level.
- g. Care must be taken not to overfill the device.
- h. Replace filler cap to ParaTherm.
- i. Remove protective gloves, apron and eye protection.
- j. Wash hands.

14.11 Documentation.

It is recommended that a detailed record is kept of: -

- a. Time and date ParaTherm and hoses were cleaned.
- b. Micro-bacteriological result for each ParaTherm and hoses cleaned.
- c. Patient identification related to each ParaTherm used clinically.
- d. Maintenance record.

14.12 Tubing within the ParaTherm and water lines.

Internal tubing within the ParaTherm is silicone and contains no plasticizers. Water hoses supplied with the ParaTherm are Di (2-ethylhexyl) phthalate (DEHP) free. If disposable water hoses are to be used, these must be DEHP free also.

Chalice Medical can supply disposable water lines that are DEHP free – contact Chalice for details.

14.13 Pressure testing the internal one-way valve.

Within the ParaTherm there is a one-way valve that allows air into the system but will not allow water vapour out. The valve competency can be accessed after each clinical use via the use of a pressure testing system available from Chalice Medical Ltd. Part no U-CM9185A

The pressure testing system comprises of a short water circuit attached to a pressure manometer line. Once the system is closed, the pressure can be increased to a maximum of 50mmHg and held. Any drop in pressure would signify a faulty one-way valve. A replacement should be fitted by a suitably qualified technical engineer.

15.0 Further Information

It is encouraged to electronically record the Unique Device Identifier (UDI) of products that are supplied. Along with a physical copy of the IFU, a QR code is provided on the product packaging to allow users to obtain a PDF version of the IFU.

For further information or additional copies of the IFU, they can be obtained from enquiries@chalicemedical.com.

16.0 Economic Operator Contacts

EC Authorised Representative



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EC Importer



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3. Nontuberculous *Mycobacterium* Infections Associated with Heater-Cooler Devices: FDA Safety Communication. US Food and Drug Administration. Protecting and Promoting Your Health. October 15, 2015. <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm466963.htm>
4. S Haller 1 , C Höller 2 , A Jacobshagen 3 , O Hamouda 1 , M Abu Sin 1 , DL Monnet 4 , D Plachouras 4 , T Eckmanns 1 1. Department for Infectious Disease Epidemiology, Robert Koch Institute (RKI), Berlin, Germany 2. Bavarian Health and Food Safety Authority (LGL), Oberschleißheim, Germany 3. Federal Institute for Drugs and Medical Devices (BfArM), Bonn, Germany 4. European Centre for Disease Prevention and Control (ECDC), Stockholm, Sweden. Contamination during production of heater-cooler units by *Mycobacterium chimaera* potential cause for invasive cardiovascular infections: results of an outbreak investigation in Germany, April 2015 to February 2016
5. CHALICE MEDICAL LTD, Manton Wood Enterprise Park, Worksop, Nottinghamshire, S80 2RS, United Kingdom. Tel: +44(0)1909 470 777, Email: enquiries@chalicemedical.com.
6. Infections Associated with Heater Cooler Units Used in Cardiopulmonary Bypass and ECMO. Public Health England. Protecting and improving the nation's health. Version 1.0. October 2015
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