



ParaTherm Hypo/Hyperthermia
Unit for Extracorporeal Bypass
Cleaning and Disinfectant Instruction
Appendix 1

PARATHERM[®]
HEATER / COOLER

Australia



Appendix 1 - Cleaning and Disinfecting

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

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')

1.1 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:

- a. Wash hands and dry thoroughly.
- b. Apply disposable gloves.
- c. Apply disposable apron.
- d. Apply suitable eye protection.

1.2 Cleaning and Disinfecting of the ParaTherm

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 a cleaning or 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 or 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.

1.3 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. 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.

1.4 Disinfecting the ParaTherm after each Clinical Use.

Unit Name/Number:

Disinfected by: Date:/...../.....

Disinfect 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 hose to the oxygenator. This will reduce the possibility of aerolization of water droplets entering the atmosphere within the clinical setting.

▲ CAUTION

Disinfection Solution

Use only Amity HP75 for disinfection of this medical device. This solution must only be used undiluted

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 disinfecting the tank and hoses.

- a. Disconnect unit from the mains and remove to a non-clinical area with good ventilation.
- b. Place the unit onto a draining device (e.g. rinsing tank or draining board by the side of a sink).
- c. Unscrew the cap of the water filler neck.
- d. 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.

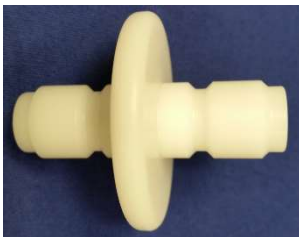


Figure 1.

- 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 disinfecting solution into a small clean disposable pot.
- g. Using a sterile swab dip this into the disinfecting solution and clean the inside of the filling port on the ParaTherm.
- h. Using a new swab, place this in the disinfecting solution and clean both the inside and the outside of the filling cap. Make sure the disinfecting solution covers the entire surface area.
- i. Discard any remaining disinfecting solution.
- j. Pour the correct volume of disinfecting solution as shown in table 1a into a small clean measuring pot.
- k. Pour half of the required disinfecting solution (as per table 1a) into the top of the ParaTherm.

Table 1a.

ParaTherm part	Volume of disinfecting solution required
ParaTherm water tank	600mls
3m water lines	192mls
2m water lines	128mls
50 cm recirculation line	16mls

- l. Replace the filler cap.

- m. Before reconnecting the ParaTherm to the mains electrical supply, gently agitate the ParaTherm to allow the disinfecting solution to contact all surface areas within the water tank. Gently rotate/tip the device front to back (repeat this action twice). This will ensure that the tubing connected to the water level indicator is disinfected.
- n. Reconnect the ParaTherm to the electrical mains supply.
- o. Switch the ParaTherm on and agitate the water lines to remove air from within them.
- p. Switch the ParaTherm off. Unscrew the filler cap and pour the remaining disinfecting solution in to the top of the ParaTherm.
- q. Place the filler cap over the water filler neck, but **do not** screw the filler cap down.

▲CAUTION

During disinfection, screwing the filler cap down into a fully sealed position, followed by running with disinfecting 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 disinfection cycle.

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

- r. Switch the ParaTherm on. Make sure the red wheel on the front of the ParaTherm is rotating.
- s. Set the temperature to 37°C.
- t. Leave the ParaTherm running for two hours with the filler cap **not** screwed down.
- u. Empty the ParaTherm by disconnecting the hoses.
- v. Once the ParaTherm is empty, reconnect the hoses.
- w. Place the required volume of sterile water into a clean measuring pot.
- x. Refill the ParaTherm with the sterile water.
- y. Gently agitate the ParaTherm to allow the sterile water to contact all surface areas within the water tank.
- z. Disconnect the hoses and allow the sterile water to drain out.
- aa. Once completed, drain the system.
- bb. 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.

Decontamination Protocol

Any device found with a positive microbiological growth as a result of in-hospital routine testing is considered to be contaminated.

Contaminated devices are to be cleaned as per steps a-z of 1.4, ensuring steps k-z are repeated second time.

1.5 Units not required for immediate clinical use

Any units that are out of use and have not been maintained through the weekly disinfectant cycle must be disinfected using the decontamination procedure as per section 1.4

1.6 Regular Disinfection Intervals.

To reduce the possibility of Mycobacterium contamination within the ParaTherm, the disinfecting procedure detailed in section 1.4 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 aeorisation of water vapour within the clinical setting.

1.7 Cleaning and disinfecting the water hose after clinical use.

For disinfecting the water hose 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 1.2). Follow the manufacturer's instructions when using the disinfection agent.

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

Check the water hose 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.

1.8 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 directly or via your distributor.

1.9 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 aerolisation 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/C) 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.

1.10 Water Testing Pre Disinfecting⁷.

For water testing Pre-disinfecting refer to the referenced document 7 (page8)

Procedural steps.

Health and Safety.

1. Wash hands.
 2. Apply disposable gloves.
 3. Apply disposable apron.
 4. Apply suitable eye protection.
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- a. The ParaTherm should be connected and running for a minimum of five minutes before water sampling is performed.
 - b. Stop the water circulating.
 - c. Turn off the ParaTherm.
 - d. Clamp both the inlet and outlet hoses.
 - e. Disconnect the water hoses via the hose connector.
 - f. Remove the clamp from the outlet line and allow at least 50 mls of water to drain out.
 - g. Re-clamp the line.
 - h. Thoroughly clean the end of the outlet hose with an alcohol based swap and then discard.
 - i. Open the water collection container and place under the water outlet hose.
 - j. Care must be taken not to touch the container with the water hose.
 - k. Gentle release the clamp and fill the container to the required level.
 - l. Replace the clamp on the water hose.
 - m. Place the lid on the water container and send for testing.
 - n. Now carry out decontamination as outlined in section 1.4
 - o. Ideally the water sampling should take place just prior to the machine undergoing its disinfection cycle.
 - p. Sodium thiosulphate should be added to the water collection pots to neutralise hypochlorite before water sampling as per local protocol – a final concentration of at least 18mg/L is advised, but pre-dosed bottles with 20mg/L are available and acceptable.
 - q. Water should be sampled from the outlet of the hoses.
 - r. A volume of 100ml per sample is suggested.
 - s. The recommended volume of water (as per the manufacturer of the bottles) should be sampled if bottles pre-dosed with sodium thiosulphate are used.
 - t. If the water is not processed immediately, it should be stored between 2°C and 8°C for up to 24 hours
 - u. Testing procedure should be performed in accordance with document:

'Protocol for Environmental Sampling, Processing and Culturing of Water and Air Samples for the Isolation of Slow-Growing Mycobacteria Standard operating procedure 7'.

1.11 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 aerolization of water droplets while pouring sterile water into the ParaTherm. 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.

1.12 Documentation.

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

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

1.13 Tubing within the ParaTherm and water hose.

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 hoses that are DEHP free.

Part no U-CM55-00-22

1.14 Pressure testing the internal one-way valve.

Within the ParaTherm there is a one way valve that allows air in to 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. 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.

References:

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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>
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5. CHALICE MEDICAL LTD, Unit 1 Drayton Court, 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
7. Protocol for Environmental Sampling, Processing and Culturing of Water and Air Samples for the Isolation of Slow-Growing Mycobacteria Standard operating procedure. Public Health England. Protecting and improving the nation's health. Version 1.0. October 2015.



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