AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

GUIDANCE for health service organisations

# National Infection Control Guidance

## Non-tuberculous *Mycobacterium* infections associated with heater-cooler devices

**November 2022**

**Key Points**

**Heater cooler devices used in cardiac surgery may be contaminated with *Mycobacterium* or other water-borne non-*Mycobacterium* species. Exposure of patients to the aerosolised exhaust from these devices may cause infection which may not be clinically apparent for several years after exposure.**

**Health service organisations must have in place systems to identify and manage risks associated with heater cooler devices and mitigate these risks.**

**This guidance provides advice on the infection prevention and control strategies to be employed to minimise the risk of non-tuberculous *Mycobacterium* infection associated with heater cooler devices.**

### Background

Heater cooler devices (HCDs) with built in water reservoirs may be contaminated with *Mycobacterium chimaera (M. chimaera)* or less frequently, *M. abscessus, M. chelonae* complex or other water-borne non-mycobacterium species.[1,2]

Eleven patient cases of *M. chimaera* infection have been identified in Australia, with four associated deaths.[1] The risk of *M. chimaera* infection in patients undergoing open-heart surgery has been estimated as 0.4-16 per 10,000 patient-years.[1] Infections are predominantly associated with cardiac surgery involving the insertion of prosthetic material, such as valve replacement or grafts.[3-5]

In Australia, confirmed cases of infection have been associated with contaminated Stöckert 3T Heater-Cooler devices manufactured prior to September 2014 by LivaNova PLC (formerly Sorin Group Deutschland GmbH).[1,2] Internationally, there have also been reports of contamination in[1,2]:

- Maquet HCU 20 devices
- Maquet HU 30 devices
- Maquet HU 35 devices
- CardioQuip Modular Cooler-Heater (MCH) – 1000 devices
- Hemotherrm 400CE devices
- ParaTherm Heater/Cooler devices.

The Therapeutic Goods Administration (TGA) has conducted a product safety review for all HCDs available in Australia. For information on this this review visit the TGA website.

## Action for health service organisations

### 1. Governance

Each health service organisation where HCDs are used should designate a senior member of staff to coordinate risk management strategies such as:

- Identifying and testing HCDs and all their attachments
- Reporting the results of confirmed HCD contamination to the TGA, the manufacturer of the device, and the relevant state or territory government contact (see Sections 6 and 7)
- Policies and procedures to minimise exposure risk to patients, and to enable service continuity (see Sections 2 to 6)
- Communicating the potential for risk and local response strategies to senior management, relevant clinicians, and primary health providers e.g. the hospital executive, infection prevention and control, infectious diseases, cardiac surgery, perfusion, anaesthesia, clinical microbiology and anatomical pathology services
- Systems for maintaining records of HCD testing, maintenance, and use (see Section 3)
- Protocols for use of HCDs that have been sent overseas for repair.

### 2. Testing for mycobacterial contamination

Microbiological baseline testing of all HCDs in service should be undertaken to determine their status. Testing should be performed by a laboratory specified by the relevant state or territory government contact (see Section 7).

The current Public Health Laboratory Network (PHLN) guidelines[6] recommendations are:

- Undertake two tests on HCD water samples:
  - Heterotrophic plate count which is a surrogate measure of cleanliness/overall water quality (results usually take three to five days)
  - *Mycobacterium* cultures (results usually take six to nine weeks)
- Follow-up testing should be scheduled in accordance with the manufacturer's instructions
- Follow the manufacturer's instructions on the required frequency of water monitoring. Where information from the manufacturer is not available and the initial sample from the HCD is negative, follow-up testing should occur at least every three months
- The HCD should be connected and running for at least five minutes before water samples are collected and sampling should take place immediately prior to the HCD undergoing its disinfection cycle
- A sample of at least 100mL should be collected from each water reservoir, including water tanks and overflow receptacles. For HCDs with two tanks, one sample should be collected from the patient circuit and another from the cardioplegia circuit
- Sample labelling should include date, hospital name, HCD serial number and other product identification details (e.g. asset number), sample site (i.e. which circuit), sampling time and details of a designated point of contact for results
- If not processed immediately, samples should be stored between 2°C and 8°C, and for no longer than 24 hours
- Laboratory results should be returned to the designated senior person in the health service organisation for further action and reporting.

The PHLN, through the Royal College of Pathologists of Australia Quality Assurance Program, will undertake validation of current testing methodologies. Enquiries about this program should be directed to the PHLN Secretariat**:** phln.secretariat@health.gov.au.

## 3. Record keeping

Health service organisations should ensure that the following information is recorded:

- HCD details, including make, model, serial number, date of manufacture and date of commissioning
- Details of routine HCD maintenance and disinfection procedures for each HCD
- Bacterial surveillance details, including sampling dates, samples collected and test results
- Patient details for each procedure in which a HCD has been used
- Details of the specific HCD used should be documented in the patient's healthcare record
- Evidence of compliance with documentation requirements e.g. audit data.

## 4. Routine maintenance, cleaning, and disinfection

Health services should strictly adhere to all maintenance, cleaning and disinfection of HCDs according to current Instructions for Use and any additional guidance material provided by the manufacturer (e.g. medical device corrections, operating instructions).

The following actions should also be undertaken for all HCDs:

- To minimise the risk of aerosolisation, water reservoirs should only be filled and emptied outside the operating theatre and external circuits should not be emptied until the patient has left the operating theatre[1]
- Where possible, inspect the HCD for visible biofilm or contamination in tubing and other components, including hidden tubes such as overflow tubes. If water is cloudy or discoloured, or internal surfaces are discoloured, remove the HCD from service
- Consult infection control/ infectious diseases personnel for appropriate measures. Consider appropriate action regarding use of contaminated HCDs (see Section 6)
- For HCDs that are in service and for which laboratory results are not yet available, change water daily where practical, to reduce the concentration of any contamination that may be present, and to reduce the risk of microorganisms being aerosolised[7]
- Use only sterile water or tap water that has been passed through a filter of less than or equal to 0.22µm to rinse, fill, refill or top-up HCD water tanks. De-ionised water and sterile water created through reverse osmosis are not recommended as these may cause corrosion.[8] Water additives should be used only in accordance with the manufacturer's Instructions for Use. Similar processes should be considered when making ice for use in a HCD
- Filters should be replaced at least monthly or more frequently if recommended by the manufacturer
- Each machine should have dedicated and labelled hoses and connectors.[1]

## 5. Placement and positioning of HCDs

The optimal placement strategy is to directly exhaust the HCD outside the operating theatre by moving it into an adjacent dedicated utility room. Alternatively, consider construction of an enclosure with independent exhaust systems for use of HCDs.[3] It is advisable to contact the manufacturer or supplier of the HCD to discuss how placement and positioning will affect the functioning of the device.

If the above options are not feasible, the following are recommended:

- Position the HCD as far away as possible from the patient and surgical field
- Direct the vent exhaust away from the patient and surgical field, and as close as possible to the suction exhaust outlet of the operating theatre, to mitigate the risk of aerosolising heater-cooler tank water into the sterile field
- Do not place external water overflow containers from the HCD in the path of HCD airflow (inflow or exhaust)[5]
- Only use 3T machines if the aerosol exhaust device is in place and is functioning correctly.

## 6. Contaminated HCDs

All positive test results indicating HCD contamination should be reported to the manufacturer, the TGA using the Users Medical Device Incident Report and the relevant state/territory contact. (see Section 7). Positive test results should also be recorded in line with local state/territory polices.

The TGA recommends the following risk stratification approach[1]:

- For Stöckert 3T HCDs that have been manufactured **before September 2014**, consider transitioning away from the use of these devices for open-chest cardiac surgery until the manufacturer has implemented strategies for these devices to mitigate the risk of patient infection Use of these devices should be limited to emergent and/or life-threatening situations if no other HCDs are available. Strict compliance with all other recommendations detailed in this document is essential if these devices remain in service.
- For Stöckert 3T HCDs that have been manufactured **after September 2014** and all other HCDs, follow the recommendations detailed in Sections 1–5 above
- Emergency use of a contaminated device (e.g., replacement device cannot be sourced immediately) should only occur after consideration in conjunction with relevant stakeholders (e.g. clinicians undertaking the proposed surgical procedure, infection control teams) in line with local policies and state, territory, or jurisdictional contacts.
- Ensure that the risk of infection associated with HCDs is communicated to all patients as part of the consent process.
- Consider performing environmental, air and water sampling and monitoring if HCD contamination is suspected. Environmental monitoring requires specialised expertise and equipment to collect and process samples, which may not be feasible in all facilities.

## 7. State or territory contacts

If you require further information or advice on issues related to HCDs, please contact your state or territory contact listed below.

| State / Territory | State or Territory contacts |
|---|---|
| **ACT** | **Vanessa Johnston**<br>Public Health Physician ACT Health<br>**T:** 02 5124 9247<br>**E:** vanessa.johnston@act.gov.au |
| **NSW** | **Kathy Dempsey**<br>NSW Chief ICP/HAI Advisor, Clinical Excellence Commission<br>P: 02 9269 5614<br>E: kathy.dempsey@health.nsw.gov.au |
| **QLD** | **Kathryn O'Brien**<br>Communicable Diseases Infection Management<br>P: 07 3328 9717<br>E: CDIMManagers@health.qld.gov.au<br>Cc: Kathryn.Obrien2@health.qld.gov.au |
| **SA** | **SA Health**<br>Communicable Disease Control Branch, Infection Control Service<br>P: 08 742 57161<br>E: HealthICS@sa.gov.au |
| **TAS** | **Annie Wells**<br>Director CDPU<br>P: 03 6222 7699<br>E: anne.wells@health.tas.gov.au |
| **VIC** | **Amy Shields**<br>Medical Device Recall Coordinator<br>E. safetyreviews@safercare.vic.gov.au |
| **WA** | **Rebecca McCann**<br>Program Manager HAI Unit<br>P: 08 9222 2043<br>E: Rebecca.McCann@health.wa.gov.au |
| **NT** | **Mary-Rose Godsell**<br>Senior Nursing Advisor – Infection Prevention and Management<br>P: 08 8944 8013<br>E: Mary-Rose.Godsell@nt.gov.au |

## 8. Other resources

**Therapeutics Goods Administration**
https://www.tga.gov.au/alert/infections-associated-heater-cooler-devices

**Public Health Laboratory Network**
http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-phln-guidance-survey-mycobacterium-heater-cooler.htm

## Disclaimer

The content of this document is published in good faith by the Commission for information purposes. The document is not intended to provide clinicians or patients with guidance on particular healthcare choices. You should contact your healthcare provider for information or advice on particular healthcare choices.

The Commission does not accept any legal liability for any injury, loss or damage incurred by the use of, or reliance on, this document.

## References


1. Therapeutic Goods Administration. Infections associated with heater-cooler devices 2019 [updated 16 April 2019]; available from: https://www.tga.gov.au/alert/infections-associated-heater-cooler-devices.
2. Food and Drug Administration.FDA's ongoing evaluation and continued monitoring of reports of nontuberculous mycobactera infections associated with water-based heater-cooler devices. [Online] 2022 [cited 15 September 2022]; Available from: FDA's Ongoing Evaluation and Continued Monitoring of Reports of Nontuberculous Mycobacteria Infections Associated with Water-Based Heater-Cooler Devices | FDA.
3. Haller S, Holler C, Jacobshagen A, Hamouda O, Abu Sin M, Monnet DL, et al. 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. Eurosurveillance. 2016;21(17):1-6.
4. Hasse B, Hannan M, Keller PM, Maurer FP, Sommerstein R, Mertz D, et al. International Society of Cardiovascular Infectious Diseases Guidelines for the Diagnosis, Treatment and Prevention of Disseminated *Mycobacterium chimaera* Infection Following Cardiac Surgery with Cardiopulmonary Bypass. J Hosp Infect. 2019;*in press*.
5. Sax H, Bloemberg G, Hasse B, Sommerstein R, Kohler P, Achermann Y, et al. Prolonged outbreak of *Mycobacterium chimaera* infection after open-chest heart surgery. Clin Infect Dis. 2015 July 1, 2015;61(1):67-75.
6. Public Health Laboratory Network. PHLN Guidance and Survey regarding *Mycobacterium chimaera* & heater-cooler units. [Online] 2016 [cited 22 December, 2016]; Available from: http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-phln-guidance-survey-mycobacterium-heater-cooler.htm.
7. Sommerstein R, Ruegg C, Kohler P,7Bloemberg G, Kuster SP, Sax H. Transmission of *Mycobacterium chimaera* from heater-cooler units during cardiac surgery despite an ultraclean air ventilation system. 22. 2016;6:1008-13.
8. Food and Drug Administration. Information for health care providers. [Online] 2016 [cited 16 August 2016]; Available from: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/CardiovascularDevices/Heater-CoolerDevices/ucm492583.htm.