Public Services Delivery
Scotland

NHS SCOTLAND

NHS Scotland Guidance for Decontamination and testing of Cardiac Heater Cooler Units (HCUs)

Version 1.3

4 November 2026

Antimicrobial Resistance & Healthcare Associated Infection (ARHAI) Scotland
An NHS Scotland Assure Service, part of Public Services Delivery Scotland

Version history

Version	Date	Summary of changes
V1.0	28 March 2019	First version
V1.1	21 March 2024	Correction made to Table 4.2.10 (TVC limits changed from per ml to per 100ml).
V1.2	14 November 2025	Correction made to Table 4.2.10 and appendix 1 and appendix 2 (changing TVC limits from per 100ml to per ml).
V1.3	4 November 2026	Interim amendments made to the guidance on air sampling following rapid review undertaken in 2025. Routine air sampling no longer advised.

In 2025, ARHAI Scotland undertook a rapid review examining the role of environmental sampling, including air sampling, in the management of HCUs. The review found that routine air sampling is not supported by the current evidence base or identified guidance documents. However, air sampling may provide useful information regarding aerosolisation and support risk assessment and investigation activities in specific circumstances. These findings have informed an SBAR and interim amendments to this guidance pending future full review.

Terminology used within the guidance document

The terms **“User”** and **“Operator”** are distinct and defined terms used throughout this guidance and associated SOPs.

The **“User”** is the manager responsible for decontamination and production of fit-for-purpose cardiac heater cooler units (HCU) (for example unit manager and/or lead perfusionist).

The **“Operator**” is the person physically performing the decontamination processes (for example perfusionist, decontamination technician or healthcare support worker).

An “**Operator” is not a “User”**. However, in small units or in exceptional circumstances a “**User**” can be an “**Operator**” if sufficiently trained.

“Heater cooler water circuits” describes all components of the HCU inclusive of the pump, hot and cold water tanks, associated accessories and all interconnecting tubing.

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1. Purpose

This guidance sets out the operational procedures covering decontamination of heater cooler units (HCU) used during cardiac surgeries, microbiological testing and associated actions based on water and air results.

Throughout the guidance document the term “HCU” will be used when referring to general HCU guidance. In some cases, reference will be made to specific models of HCU.

2. Background search of relevant evidence

Mycobacterium chimaera (M. chimaera) is a nontuberculous mycobacterium which is a member of the *Mycobacterium avium* complex, and closely related to *Mycobacterium intracellulare* which until recently would have been identified as *M. intracellulare*.[1]

M. chimaera is an environmental organism which is commonly found in tap water. Clinically the bacterium is associated with respiratory disease or disseminated disease in immunocompromised patients.

M. chimaera has been implicated in over 100 cases of prosthetic valve endocarditis and disseminated mycobacterium disease throughout Europe and the USA since 2011 which has been linked to contaminated water heater cooler units (HCUs) used during cardiac surgery.[2-8] However, due to the long latency period and challenges on the correct identification of the bacteria, the actual numbers could be underreported.[8] The findings of the retrospective case finding exercise carried out by Public Health England (PHE) and the other UK devolved nations found no cases of *M. chimaera* infection associated with cardiopulmonary bypass in Scotland.[5]

HCUs are used during cardiac surgery procedures for cooling or warming the patient connected to an extracorporeal perfusion circuit, keeping the patient’s body temperature constant during procedures. There is no contact (except in very rare cases) between the patient and the water circulating through the HCU or the perfusion circuit.[9] However, nontuberculous mycobacteria (NTM) can be aerosolised

by the HCU to the vicinity.[2] Ultraclean air ventilation systems have proven to be inefficient against *M. chimaera* infections,[10] thus the HCU decontamination processes is crucial.

Following a voluntary Field Safety Notice (FSN) by manufacturers of HCUs, a revised decontamination and microbiological monitoring process was developed for HCUs in the UK to:

i) identify any units which may be contaminated with *M. chimaera* (or any other pathogen), and

ii) establish routine decontamination and microbiological monitoring for HCUs with negative test results.

Contaminated HCUs have been implicated in other post cardiac surgery infections with pathogens such as *Pseudomonas aeruginosa (P. aeruginosa)*, *Legionella* species, other nontuberculous Mycobacterium, gram-negative bacteria and fungi.[11] Therefore, whilst development of this guidance is in response to possible contamination of HCUs with *M. chimaera,* following this guidance and compliance with manufacturers' decontamination instructions will minimise the risk of HCUs with any pathogens.

To inform the production of this guidance HPS undertook visits to each of the Scottish cardiac centres which use HCUs. Processes and procedures as well as facilities were observed in the decontamination of the units and the changing of water within the water tanks. A survey was also undertaken to ascertain practice and procedures for cardiac centres within NHS England. Forty-six centres were contacted with 10 responses. From the visits and the survey findings, Scottish cardiac centres only use the Sorin 3T HCU, cardiac centres in England use Sorin 3T, Maquet HC40, or a combination of both. This guidance document applies to all models of HCU which are used within NHS Scotland.

3. Roles and responsibilities for healthcare workers involved with the decontamination of HCUs

3.1 Decontamination lead or nominated person

Is responsible for:

- the decontamination of HCUs within the department
- providing effective and technically compliant decontamination services for HCUs in accordance with manufacturer's instructions and this best practice guidance
- implementing an operational policy for decontamination for HCUs in accordance with the policies outlined in Section 4. (Decontamination Policy)
- monitoring the implementation of the policy. This can be done using the policies outlined in Section 4

3.2 User

- The responsibility for decontamination of HCUs rests with the person designated as the "User", for example unit manager, lead perfusionist.
- The User's responsibilities include ensuring that the management of HCU decontamination is in accordance with HCU equipment manufacturer's instructions, and this guidance document.
- The User should identify their local decontamination lead to ensure they have the appropriate contact regarding decontamination expertise.

3.3 Operator

Is responsible for:

- performing HCU decontamination procedures, decontamination equipment cleaning, ensuring HCUs are fit for purpose and maintaining records for traceability purposes (for instance perfusionist or decontamination technician)
- arranging routine maintenance by medical physics colleagues
- arranging routine testing with agreed testing laboratory

The Operator should be trained in HCU decontamination and deemed competent by the User (unit manager).

4. Cardiac heater cooler unit decontamination policy

4.1 Guidance

In accordance with the Scottish Appendix of PHE Guidance; Infections Associated with Heater Cooler Units Used in Cardiopulmonary Bypass and ECMO,[12] and information for healthcare providers in the UK, NHS boards who use heater cooler units (of any brand and model) should ensure that:

- a full maintenance check is performed of HCUs every 1,000 operating hours or annually as a minimum
- only trained personnel maintain HCUs. This may be either a local medical device technician or manufacturer technician or a combination of both
- a full local risk assessment is conducted, at a minimum reviewed annually and acted upon, and a local Quality Assurance Programme is in place covering the use of the device
- devices are microbiologically monitored according to the manufacturer's instructions supplemented by the main guidance document for cardiothoracic services[11]

- cleaning and disinfection regimes are in use as directed by manufacturers and as supplemented by MHRA, for example Medical Device Alerts
- cleaning and disinfection regimes in addition to above follow standard infection control precautions (SICPs) laid out in the National Infection Prevention and Control Manual (NIPCM)[13].
- an area is allocated solely for the decontamination of HCU in accordance with SHBN 01 01.[14] This area should include as a minimum:
    - clinical hand wash basin
    - decontamination sink
    - separate filtered tap
    - drainage facility for emptying tanks (clinical hand wash basin or decontamination sink should not be used)
    - storage cabinet (COSHH standard) for the storage of chemicals used during disinfection process and water treatment within HCU tanks
    - storage or shelving for equipment used for cleaning the decontamination area
    - storage or shelving for accessory equipment for the HCUs used for the decontamination process
    - storage or shelving for personal protective equipment (PPE) used for the decontamination of HCU
    - storage or shelving for decontamination and monitoring records pertaining to all HCU
    - flooring and surfaces which should be of a wipeable material which can withstand contact with the cleaning materials used to decontaminate HCU
    - local extract ventilation (LEV) which should be installed to minimise the exposure of staff to chemicals used for the decontamination process and tank sanitisation. If LEV not possible then PPE should be available for staff to use during times of exposure to chemicals

- PPE is worn during all decontamination and operational maintenance tasks. Staff should follow the guidance on PPE use within the NIPCM[13] and COSHH[15]
- heater cooler units (HCUs):
    - are positioned outside theatre where possible
    - if HCUs have to be in the theatre:
        - attention should be given to positioning as described in the main guidance document, or
        - the HCUs should be retrospectively fitted with a vacuum pump which reduces exhaust emissions from the rear of the machine by attaching the vacuum pump to the hospital suction system; or seek advice from the manufacturer in achieving this safely without affecting device performance
- when not in use HCUs should be stored in a clean designated environment to reduce the risk of contamination of the unit from the surrounding area
- only filtered tap water is used for filling hot and cold HCU tanks and for the decontamination procedure:
    - the filter should incorporate a 0.2µm membrane
    - the filtered tap should only be used for the purpose of filling HCU tanks and for decontamination of the water circuits
- a Legionella risk assessment for the HCUs has been undertaken according to the guidance set out in the Health and Safety Executive Approved Code of Practice (L8):[16] This should include the risks to potentially exposed healthcare staff in addition to exposure risks for patients
- impact on cardiothoracic surgical services is minimised where possible. Decisions regarding delaying or continuing surgery must be made by the individual NHS Board in consultation with ARHAI Scotland
- traceability of HCUs is ensured. Individual units used for any surgery or ECMO should be recorded, tracing the individual unit to all patients for which

it was used. Time and date of use through the use of the equipment serial number should be recorded as a minimum

- HCUs are returned to manufacturers for deep cleaning:
    - if water or air sample results are positive for Mycobacterium or Legionella species
    - if TVC counts remain elevated despite local review of operational process and assurance of decontamination practices
    - if repair or maintenance procedures have been performed
- HCUs which have had a positive air or water sample results for *M. chimaera*, Legionella species, *P. aeruginosa* or persistent high TVCs and undergone a deep clean by the manufacturer can be put back into use following three negative subsequent air and water sample results. The decision to commence use of a HCU should be undertaken following discussion with the infection control doctor (ICD), medical physics, perfusion team and approved by the local water group
- notification of HCU related issues are made to the Incident Reporting and Investigation Centre (IRIC) and/or ARHAI Scotland as appropriate, for example any problems encountered with the unit functionally, including cleaning and disinfection (IRIC), patient harm (IRIC/ARHAI), and new cases of *M. chimaera* infection (NHS board health protection teams and ARHAI Scotland)
- Healthcare Improvement Scotland (HIS) and the Healthcare Environment Inspectorate (HEI) are provided with evidence that NHS Board responsibilities for the decontamination, maintenance and water testing of HCUs have been addressed and embedded into practice if requested.

4.2 Manufacturers High Level Disinfection (HLD) processes

HCUs should be decontaminated following the manufacturers high level disinfection (HLD) processes.

4.2.1 A full disinfection procedure (surface disinfection and disinfection of the water circuits)

Should be undertaken:

- prior to initial operation
- prior to storage of the HCU
- fortnightly, when air and water sample results have been persistently negative for more than six months
- weekly, for a minimum of six months following a positive water or air sample result for *M. chimaera*, Legionella species or *P. aeruginosa:*
    - The HCU can only be reinstated for use following a deep clean by the manufacturer and that negative air and water samples have been obtained as per section 4.2.7.
    - The decision to move to fortnightly testing where water and air samples have been persistently negative (for six months) will follow discussion with the infection control doctor, medical physics, perfusion team and approval of the local Water Safety Group.
- The decision to use a HCU for cardiac surgery if water and/or air sample results are positive for *M. chimaera*, Legionella species, *P. aeruginosa* or high TVCs must be made by the individual NHS Board in consultation with ARHAI Scotland.
- Staff should follow the full disinfection procedure described in the manufacturer's instructions following SICPs within the NIPCM and PPE requirements of COSHH regulations.

4.2.2 Surface disinfection

- Should be undertaken before and after each use.
- Staff should follow the surface disinfection procedure described in the manufacturer's instructions following SICPs within the NIPCM and PPE requirements of COSHH regulations.

4.2.3 Changes of water within the HCU

Are required:

- weekly when air and water sample results have persistently tested negative for *M. chimaera*, Legionella species, *P. aeruginosa* or high TVCs for more than six months
- daily for a minimum of six months following a positive air or water sample result. The decision to move to weekly water changes where air and water testing has been persistently negative will follow discussion with the ICD, medical physics, perfusion team and approval of the local Water Safety Group

Hydrogen peroxide must be added to the clean water (in accordance with manufacturer's instructions) following water changes to ensure water quality is maintained.

Staff should follow manufacturer's instructions for changing the water in HCUs, following SICPs within the NIPCM and PPE requirements of COSHH regulations.

4.2.4 Hydrogen peroxide monitoring of HCU water tanks

- Hydrogen peroxide (HP) levels should be measured and recorded daily in accordance with manufacturer's instructions.
- Hydrogen peroxide level monitoring records should be retained in accordance with all HCU monitoring or cleaning records.

- Hydrogen peroxide levels will fall during the seven-day period however concentrations should not fall below 100ppm.
- Staff should follow SICPs within the NIPCM and PPE requirements of COSHH regulations for monitoring HP levels.

4.2.5 HCU overflow bottles

- Should be disinfected fortnightly during the full disinfection procedure or sooner if they are full and require to be emptied.
- If the HCU overflow bottle is attached to the hospital vacuum system as a precautionary measure during use (in the event of the overflow bottle filling during use) the HCU should be disconnected from the hospital vacuum system after each use. The hospital suction liners should be disposed of in accordance with local policy.
- Staff should follow manufacturer's instructions for disinfecting HCU overflow bottles and SICPs within the NIPCM and PPE requirements of COSHH regulations.

4.2.6 Tubing used with the HCU

- Should be changed annually as per manufacturer's instructions as a minimum.
- Following a change of the tubing a full disinfection of the system should be performed as per section 4.2.1.
- Only tubing certified for use with drinking water systems can be used with HCUs. See manufacturer's instructions for product information.
- Tubing changes should be performed in accordance with SICPs within the NIPCM and PPE requirements of COSHH regulations.

4.2.7 Water and air monitoring for HCUs

- Only staff trained to take water and/or air samples from HCUs should undertake this process.
- Staff authorised to undertake water and air sampling must follow manufacturer's instructions (where available) and a validated process agreed locally with the ICD and microbiology laboratory.
- Frequency of water and air testing may be increased at the request of the ICD following positive microbiological results, ongoing contamination concerns or incident investigations. Air sampling should be considered on a risk-assessed basis where findings are expected to support risk assessment, incident management or decision making. Management of water sampling results should follow Appendix 1. Where targeted air sampling is undertaken, results should be managed in accordance with Appendix 2.
- All water and air sample results should be sent to the ICD and lead perfusionist. A copy of any positive laboratory reports for *M. chimaera*, Legionella species, *P. aeruginosa* or high TVCs should be copied to ARHAI Scotland for consideration.
- HCU water and air samples should be reviewed at the local water safety group and/or the local infection control committee as routine.

4.2.8 Water testing

- Water samples should be taken fortnightly and tested for total viable bacterial counts (TVCs) as long as test results remain within parameters. Samples should be taken monthly for *M. chimaera* and Legionella species.
- Microbiology staff or estates staff will provide the containers for collection of the water samples.
- *Mycobacterium* cultures take eight weeks to process however subsequent samples should continue to be taken and submitted whilst results are awaited. This allows clear identification of time if a look back exercise is required if positive results are reported.

- *Legionella, Pseudomonas* species and coliforms results are generally available within a few days. This is subject to local testing arrangements.
- Staff should follow manufacturer's instructions for the taking of water samples from the HCU and SICPs within the NIPCM and PPE requirements of COSHH regulations.

4.2.9 Air testing

- Air sampling may be considered as part of a targeted, risk-based investigation where findings are expected to:
    - support assessment of aerosolisation from HCUs
    - support patient or service risk assessment
    - assist incident or outbreak investigations
    - investigate suspected HCU contamination
    - assess the impact of device defects, breaches in integrity or maintenance concerns
    - support decision making regarding remediation and ongoing management

  This should be discussed with the ICD, microbiology laboratory and other relevant specialists where appropriate.
- *Mycobacterium* cultures take eight weeks to process however subsequent samples should continue to be taken and submitted whilst results are awaited. This allows clear identification of time if required a look back exercise if positive results are reported.
- Air sampling should follow manufacturer's instructions (where available) and the validated process agreed locally with the ICD and microbiology laboratory.
- Staff should follow manufacturer's instructions for the taking of water samples from the HCU and SICPs within the NIPCM and PPE requirements of COSHH regulations.

4.2.10 Water monitoring result parameters and actions

Water tests	Satisfactory	Unsatisfactory
Total viable counts (TVC)	<100cfu/ 1ml	>100cfu/1ml Remove machine from use if possible. Re-test and disinfect HCU system. Contact ICD for advice. If not possible to remove from use risk assess need for use against elevated result. TVC re-test <100cfu/ml. Send subsequent samples to achieve 3 satisfactory TVC results. Once 3 are achieved return to service and continue to monitor as per section 4.2.7. TVC re-test >100cfu/ml. Investigate possible cause including testing and decontamination procedures. Have hydrogen peroxide levels been optimal within the unit? TVC re-test >100cfu/ml consider returning HCU to manufacturer for a service and deep clean.
Legionella spp	0	> 0 Remove machine from use if possible. Re-test and disinfect HCU system Contact ICD for advice. If not possible to remove from use risk assess need for use against elevated result. *Legionella* re-test 0. Send subsequent samples to achieve 3 negative *Legionella* results. Once 3 are achieved return to service and continue to monitor as per section 4.2.7. Have hydrogen peroxide levels been optimal within the unit? Check PAL filter used to fill tanks and consider changing

Water tests	Satisfactory	Unsatisfactory
		filter Consider testing outlet for legionella species. Report Legionella to local health protection team as per Legionella reporting procedure. Consider returning HCU to manufacturer for a service and deep clean.
Mycobacterium chimaera	0	>0 Remove machine from use if possible. Re-test and disinfect HCU system. Contact ICD for advice. If not possible to remove from use risk assess need for use against elevated result. (discuss with ARHAI Scotland). *M. chimaera* re-test 0. Send subsequent samples to achieve 3 negative *M. chimaera* results. Once 3 are achieved return to service and continue to monitor as per section 4.2.7. Have hydrogen peroxide levels been optimal within the unit? Check PAL filter used to fill tanks and consider changing filter Consider testing outlet for *M. Chimaera.* Consider whether targeted air sampling would support assessment of aerosolisation risk, patient exposure risk or incident management. Consider returning HCU to manufacturer for a service and deep clean.
Mycobacterium species – other than Chimaera	0	>0 Remove machine from use if possible. Re-test and disinfect HCU system. Contact ICD for advice. If not possible to remove from use risk assess need for use against elevated result. (discuss with ARHAI Scotland).

Water tests	Satisfactory	Unsatisfactory
		Mycobacterium re-test 0. Send subsequent samples to achieve 3 negative *Mycobacterium* results. Once 3 are achieved return to service and continue to monitor as per section 4.2.7. Have hydrogen peroxide levels been optimal within the unit? Check PAL filter used to fill tanks and consider changing filter Consider testing outlet for *Mycobacterium species.* Consider whether targeted air sampling would support assessment of aerosolisation risk, patient exposure risk or incident management. Consider returning HCU to manufacturer for a service and deep clean.
Pseudomonas aeruginosa	0	>0 Remove machine from use if possible. Re-test and disinfect HCU system Contact ICD for advice. If not possible to remove from use risk assess need for use against elevated result. *P. aeruginosa* re-test 0. Send subsequent samples to achieve 3 negative *P. aeruginosa* results. Once 3 are achieved return to service and continue to monitor as per section 4.2.7. Have hydrogen peroxide levels been optimal within the unit? Check PAL filter used to fill tanks and consider changing filter Consider testing outlet for *P. aeruginosa.* Consider returning HCU to manufacturer for a service and deep clean.

Water tests	Satisfactory	Unsatisfactory
Coliforms	0	> 0 Remove machine from use if possible. Re-test and disinfect HCU system. Contact ICD for advice. If not possible to remove from use risk assess need for use against elevated result. Coliform re-test 0. Send subsequent samples to achieve 3 negative coliform results. Once 3 are achieved return to service and continue to monitor as per section 4.2.7. Have hydrogen peroxide levels been optimal within the unit? Check PAL filter used to fill tanks and consider changing filter Consider testing outlet for coliforms. Consider returning HCU to manufacturer for a service and deep clean.

See Appendix 1 where this information is presented as algorithm.

4.2.11 Air sampling investigation results and actions

Where air sampling is undertaken, it should be regarded as an adjunct investigation tool and findings interpreted alongside:

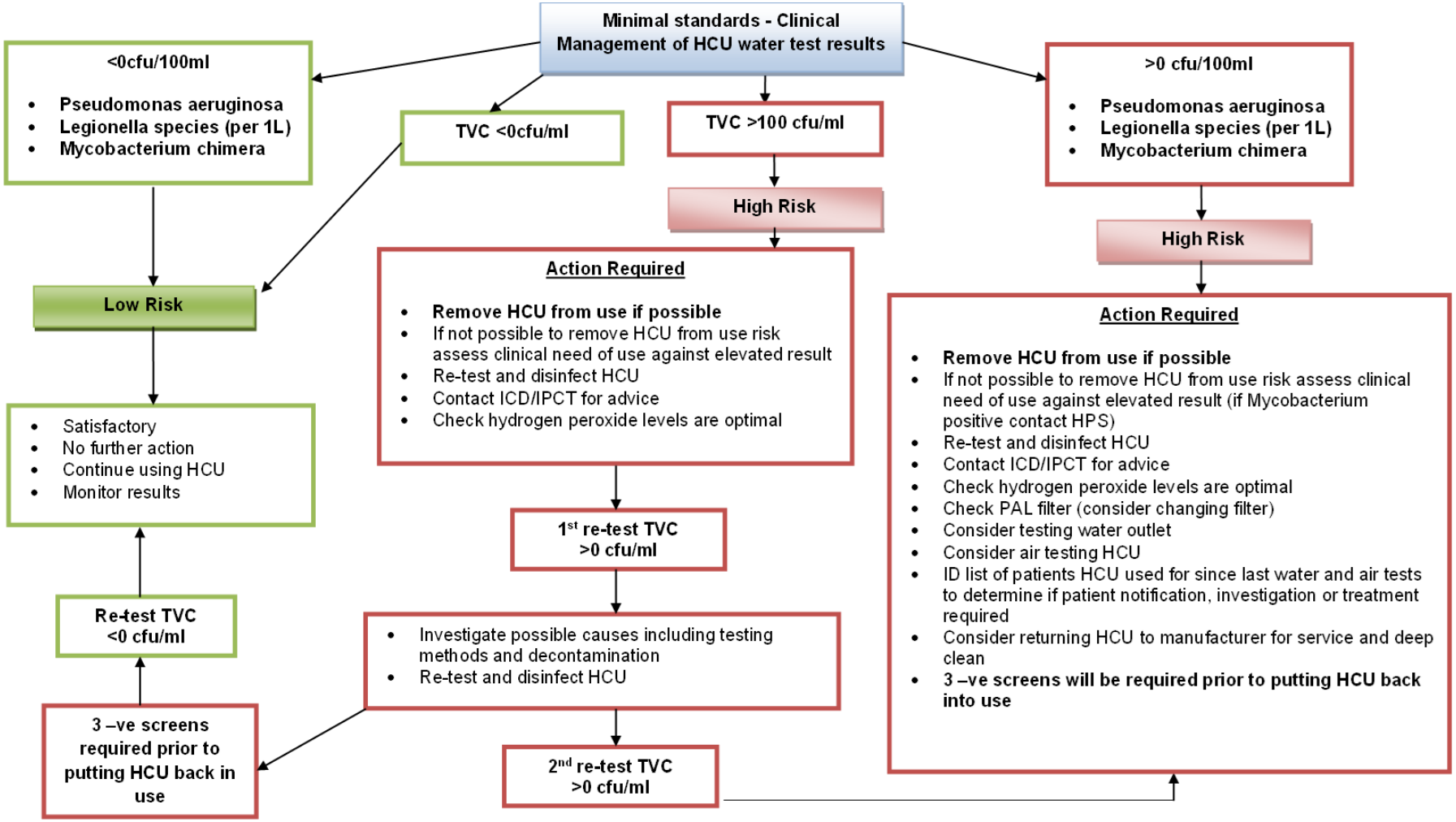
- water sample results
- device maintenance records
- engineering and environmental assessments
- microbiological findings
- epidemiological information
- clinical risk assessment

Air sampling results should not be used in isolation to determine device safety or patient risk.

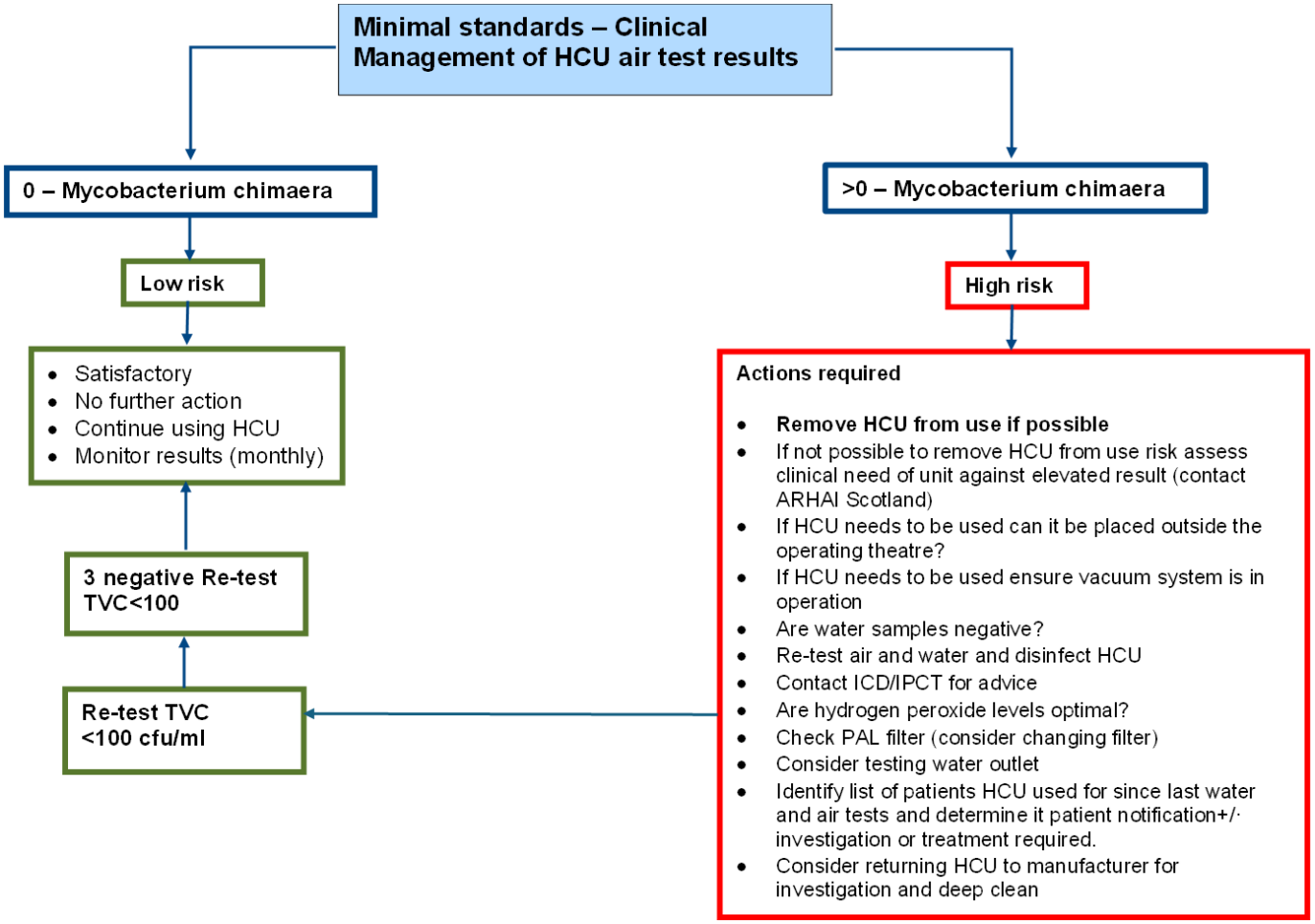
Air tests	Satisfactory	Unsatisfactory
***Mycobacterium Chimaera* and other Mycobacterial species**	0	>0 Remove machine from use if possible. Re-test water and air samples and disinfect HCU system. Contact ICD for advice. If not possible to remove from use risk assess need for use against elevated result. (discuss with ARHAI Scotland). *Mycobacterium* re-test 0. Send subsequent samples to achieve 3 negative *M. chimaera* results. Once 3 are achieved return to service and continue to monitor as per section 4.2.7. Have hydrogen peroxide levels been optimal within the unit? Check PAL filter used to fill tanks and consider changing filter Consider testing water outlet for *M. Chimaera* and other Mycobacterial species. Consider returning HCU to manufacturer for a service and deep clean.

See Appendix 2 where this information is presented as algorithm for use by the clinical team.

Appendix 1: Algorithm for Clinical Management of Cardiac Heater Cooler Unit (HCU) water test



Appendix 2: Algorithm for clinical management of targeted cardiac heater cooler unit (HCU) air test results



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