2025 Heater Cooler Unit (Contamination)

date	29/05/2025
Category	Heater Cooler unit
Category 2	Circuit contamination
Severity	Good Catch Near Miss
Description:	Earlier this year, our hospital replaced our paediatric ECMO Fleet. This involved the acquisition/replacement of four new Maquet HU35 devices. On receiving these four new devices, they were all cleaned (per our cleaning protocol, in-line with the manufacturer IFU). Approximately one week after cleaning, we collected water samples from each of the devices. We have been subsequently notified by the Mycobacterium Lab that these four devices are culture positive for Mycobacterium Chimera. The new HU35 units were only ever stored in the same location once, at initial delivery (when sealed and dry), then were stored in separate locations (except for when cleaned in the perfusion setup room). All devices were cleaned in the perfusion room on 24/03/25, and cleaning was performed by 2 different people. Water sampling was performed on 28/04/25. All samples were collected by the same individual; however, 13 samples from 11 different devices were collected on this date and only the samples for these 4 new HU35 units were positive for M. Chimaera (Existing HU35 devices and CPB 3T HCU devices all negative). Since all of these devices units were cleaned and sampled in the same setup room, and sampled by the same person on the same day it is not possible that contamination occurred from the environment or the individual at either of these times.
GOOD CATCH - what went well	These devices were newly acquired from Getinge and had not yet been introduced into clinical use. Water cleaning and sampling was performed in accordance with our department policy. Until a resolution is reached (awaiting response from Getinge) we have continued using our old HU35 units (all negative for m. chimera at time of testing)
What could we do bette	We could have performed a 'deep disinfection clean' when the devices first arrived, prior to sampling. Although we have a protocol for routine water cleaning and sampling, testing of new devices is not currently written into this. The 'good catch' in this instance reflect that it is necessary to include this in future.
Preventive actions	Supplier has been notified. All four devices have been quarantined. Will we ensure our water testing policy is updated to include a statement on testing new devices and wait for negative culture results to be returned before bringing new devices into clinical use.
Type of incident:	Equipment
Discussed with team:	Yes
Hospital incident filed	Yes
Ext Authority Advised	No