September 30, 2020

Doug Platt
CEO

CUSTOMER COMMUNICATION

Dear Customer,

The purpose of this letter is to inform you of the potential risk of device contamination and patient infections associated with the use of the MCH-1000 devices. There is the potential for organisms (including NTM) to grow in the water tanks of any cooler-heater device, and contaminated water from any cooler-heater device has the potential to aerosolize into the operating room during surgery which could lead to patient infection.

CardioQuip is aware of the three NTM patient infections at a single facility involving the use of the MCH-1000 devices. These patients developed sternal surgical site infections with *Mycobacterium abscessus* after undergoing cardiothoracic surgery. CardioQuip and the FDA are investigating the issue, but the pathway of infection to the patient has yet to be determined.

To mitigate patient risk, CardioQuip recommends the following measures:

- Strictly adhere to the maintenance activities of cleaning and disinfection found on pages 39-41 of the MCH Operator/Service Manual (https://www.cardioquip.com/s/MCH-Operators-Manual-R2-hj4p.pdf)
- Perform annual preventive maintenance by an authorized CardioQuip technician as outlined on pg. 41 of the MCH Operator/Service Manual (https://www.cardioquip.com/s/MCH-Operators-Manual-R2-hj4p.pdf).
- Do not use unfiltered tap water to rinse, fill, refill or top-off water tanks since this may introduce organisms. **Use only sterile water or water that has been passed through a filter of less than or equal to 0.22µm.** When making ice needed for patient cooling during surgical procedures use only sterile water or water that has been passed through a filter of less than or equal to 0.22µm. Deionized or reverse osmosis-treated water are not recommended because they may promote corrosion of the metal components of the system.
- Use new accessories, tubing, connectors when using a different cooler-heater device to prevent cross contamination.
- Clean and disinfect all accessories connected to the cooler-heater according to the respective manufacturers' instructions for use. Device contamination can occur from sources such as environmental contamination or device contact with contaminated accessories.
- Immediately remove from service devices that have tested positive for NTM or show signs of device contamination, such as cloudiness or discoloration.

CardioQuip is in communication with the FDA to develop a more comprehensive understanding of these risks, and to determine any further action. We will keep you apprised of any relevant information as it becomes available. Any adverse event or problem experienced may be reported directly to CardioQuip by phone +1(979) 691-0202 or Melanie Harry at regulatory@cardioquip.com. You can also report directly to the FDA's MedWatch Adverse Event Reporting program either online (www.fda.gov.MedWatch/report.htm) , by regular mail, or by fax to +1 (800) FDA-0178.

Respectfully,

Doug Platt
CEO