



URGENT MEDICAL DEVICE CORRECTION MCH-1000 COOLER HEATER

Attention: Perfusionists; Biomedical Engineering

Subject: Addressing concerns surrounding the potential contamination of CardioQuip devices, how to mitigate these issues, and how CardioQuip will assist in this process.

Affected Product(s): MCH Operator's/Service Manual R2 2016 (PN: 1000-05-1177)
Modular Cooler-Heater 1000(i) Standard Unit (MCH-1000(i))
Modular Cooler-Heater 1000(i) Refrigeration Module (MCH-10RMS)
Modular Cooler-Heater 1000(m) Compact Unit (MCH-1000(m))
Modular Cooler-Heater 1000(m) Thermoelectric Cooling Lid (MCH-11TEC)
All lots are affected

Effective Date: July 30, 2021

REASON FOR COMMUNICATION

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-series devices and the steps CardioQuip is taking to address these issues. MCH-series devices are indicated to supply temperature-controlled water to heat exchange devices to help control a patient's temperature during extracorporeal circulatory support or thermal regulation procedures lasting not longer than six hours. There is the potential for organisms (including Nontuberculous mycobacteria (NTM)) to grow in the water systems of any heater-cooler device, and contaminated water from any heater-cooler device has the potential to aerosolize into the operating room during surgery which could lead to patient infection.

This recall provides a labeling update for the MCH Operator's/Service Manual with additional guidance for proper MCH-1000 water-quality maintenance and device inspection.

CORRECTIVE ACTION

CardioQuip is aware of reports of device contamination and patient infections, including NTM infections, involving the use of MCH-series devices and is investigating each instance with the utmost care. In the future, CardioQuip intends to provide users with (1) an improved cleaning and disinfection procedure and (2) mitigations that reduce microbial risk between reprocessing cycles to lower the potential for device contamination and to lower patient risk.

CardioQuip is working to implement such procedures. In the interim, CardioQuip recommends the following measures to reduce the risk of device contamination:

1. Replace copies of the current MCH Operators/Service Manual R2 2016 with the updated version MCH Operators/Service Manual R3 2021 provided as of July 30, 2021 on our website: <http://www.CardioQuip.com/resources>. This new version includes revisions that reflect the content in this letter.
2. Only use sterile or 0.22-micron-filtered water. Do not use tap water to rinse, fill, refill, or top-off water tanks, as this may introduce microorganisms into the water path.
3. When making ice needed for patient cooling during surgical procedures, use only sterile or 0.22-micron-filtered water.

4. Strictly adhere to the maintenance activities of cleaning and disinfection found on pg. 47-51 of the new MCH Operator/Service Manual R3 2021.
5. Schedule annual preventive maintenance by an authorized CardioQuip technician as outlined on pg. 51 of the new MCH Operator/Service Manual R3 2021.
6. Clean and disinfect all accessories connected to the cooler-heater according to the respective manufacturer's instructions for use. Device contamination can occur from sources such as environmental contamination or device contact with contaminated accessories.
7. Ensure all modules and accessories, including the Refrigeration Module and TEC lid, are cleaned and disinfected at the same time as the MCH unit according to the Maintenance section of the new MCH Operator/Service Manual R3 2021.
8. Do NOT move modules or accessories between cooler-heater devices to prevent possible cross-contamination.
9. Immediately remove from service devices that show signs of contamination in the tank or water path, such as cloudiness or discoloration. Contact CardioQuip Customer Service to receive assistance with contaminated devices.
10. Please forward this notice to all device users and other parties within and outside your organization that need to be aware of this correction.

CardioQuip continues to develop a more comprehensive understanding of these risks and determine further action. If you have a device that is experiencing contamination issues, please contact CardioQuip via phone or email to receive assistance with on-site service, depot service, and/or internal water path replacement.

CardioQuip Customer Service: +1 (979) 691-0202
Monday— Friday 8 A.M. – 5 P.M. CT
service@cardioquip.com

RECEIPT AND UNDERSTANDING OF CORRECTIVE ACTION

Receipt and understanding of the corrective action outlined in this letter is required from each CardioQuip customer. **Please complete and return the enclosed response form** as soon as possible to acknowledge receipt of this notification and to inform CardioQuip, LLC that you have performed and completed the requested actions.

To return the form via email, send to: FCA1000@cardioquip.com

To return the form via mail, send to: CardioQuip, LLC, 8422 Calibration Ct., College Station, TX 77845

To return the form via fax, send to: (979) 691-0206

To complete the form online, please visit <http://www.cardioquip.com/fca>

Please return or submit the form within 5 business days of receipt.

REPORTING OR ADVERSE EVENTS

Any adverse events experienced relating to CardioQuip devices, specifically those affected by this communication, should also be reported to the FDA's MedWatch Program:

Phone: +1 (800) FDA-1088

Web: www.fda.gov/medwatch/report.htm



RESPONSE FORM

Customer Communication Letter, "MCH-1000 Urgent Device Correction - July 2021"

Please fill out this form to acknowledge receipt of notification. Return the completed form by mail to CardioQuip, LLC, 8422 Calibration Ct., College Station, TX 77845, by fax to (979) 691-0206, or scan and email to FCA1000@cardioquip.com.

I have read and understand the field notification instructions.

Number of affected CardioQuip devices in inventory at facility: _____

Please list your CardioQuip Serial Numbers (8 Digit number starting with 1016, 1116, 1216, 1316):

I have replaced our current MCH Operator/Service Manual with the updated manual.

Signature

Date

Printed Name

Title

Facility Name

Facility Address, City, ST ZIP

Phone Number

Email Address

Return this form by mail, fax, or email **within 5 business days of receipt.**

CardioQuip, LLC

8422 Calibration Ct.
College Station, TX 77845

Fax: (979) 691-0206

Email: fca1000@cardioquip.com