CardioQuip

URGENT MEDICAL DEVICE CORRECTION
MCH-1000(i) REFRIGERATION MODULE (MCH-10RMS)

Attention:	Perfusionists; Biomedical Engineering
Subject:	Addressing concerns surrounding the potential aerosolization risk of CardioQuip devices and how to mitigate these issues.
Affected Product(s):	Modular Cooler-Heater 1000(i) Refrigeration Module (MCH-10RMS) Modular Cooler-Heater 1000(i) Airflow Redirection Hood (MCH-10ARH) 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 correction identifies the Airflow Redirection Hood as a possible risk mitigation component for patient infection.

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 patient infection:

1. The optional Airflow Redirection Hood (MCH-10ARH) may be installed onto the Refrigeration Module (MCH-10RMS) as a potential mitigant to aerosolization. This device is attached overtop the Refrigeration Module and directs exhaust downwards, thereby redirecting potential aerosols downwards and away from the surgical field.

   Refer to the MCH Operator/Service Manual R3 2021 for installation instructions. Contact your local CardioQuip representative for assistance purchasing the optional Airflow Redirection Hood for your Refrigeration Module.

2. Ensure all modules and accessories, including the Airflow Redirection Hood and Refrigeration Module, are cleaned and disinfected at the same time as the MCH unit according to the Maintenance section on pg. 47 of the MCH Operator/Service Manual R3 2021.

3. Do NOT move modules or accessories between cooler-heater devices to prevent possible cross-contamination.

4. 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 any questions or concerns regarding the Refrigeration Module (MCH-10RMS), optional Airflow Redirection Hood (MCH-10ARH), or proper device maintenance procedures, please contact CardioQuip via phone or email at:

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: FCA10RMS@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

CardioQuip

RESPONSE FORM

Customer Communication Letter, "MCH-10RMS Aerosolization Risk Mitigation - 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 FCA10RMS@cardioquip.com.

☐ I have read and understand the field notification instructions.

Number of affected CardioQuip devices in inventory at facility: _____

Please list your CardioQuip MCH-10RMS Serial Numbers (8 digit number starting with 1216):

_____ _____

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: fca10rms@cardioquip.com