FAQ "MCH-1000 Cooler Heater Urgent Medical Device Correction"

Frequently Asked Questions (FAQ) Update regarding CardioQuip's "MCH-1000 Cooler Heater Urgent Medical Device Correction" Letter, July 2021

CORRECTION LETTER

Q: What is the purpose of this letter?

This letter informs CardioQuip customers of a labeling update for the CardioQuip MCH-1000 and associated modules. The new MCH-1000 Operator/Service Manual R3 2021 includes updated procedures and water quality standards to reduce the risk of device contamination.

Q: Is this a recall?

This process is classified as an FDA-requested, firm-initiated voluntary recall. This recall initiates a correction of the MCH-1000 Operator/Service Manual and does not require modification or removal of any devices.

Q: What actions should I take as part of this recall?

Replace your **MCH Operator/Service Manual R2 2016** with the updated **MCH Operator/Service Manual R3 2021**, and carefully review the other **Corrective Action** items listed in the communication.

To acknowledge receipt and implementation of letter, please fill-out and return Acknowledgment of Receipt form (pg. 3 of Device Correction Letter) by August 13, 2021.

To return the form, choose a delivery method below:

Email to: FCA1000@cardioquip.com
Fax to: 979-691-0206
Mail to: CardioQuip, LLC, 8422 Calibration Ct. College Station, TX 77845

To complete the form online, visit

https://www.cardioquip.com/fca1000

Q: Where can I get my copy of the updated MCH-1000 Operator/Service Manual?

To download the new MCH-1000 Operator/Service Manual R3 2021, visit the CardioQuip resource page:

www.cardioquip.com/resources

To request a paper copy, please contact CardioQuip service:

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

CardioQuip

Q: What changes need to be made to the MCH-1000 device itself?

No changes need to be made to any of MCH-1000 series devices.

Q: What are the changes in the updated MCH-1000 Operator/Service Manual?

The MCH-1000 Operator/Service Manual R3 2021 has been revised to provide updated instructions for proper device use, inspection, maintenance, and risk mitigation. These changes include:

- Requirements to use the MCH-1000 devices with 0.22-micron filtered water or sterile water. Tap water cannot be used to rinse, fill, refill, or top-off the water tank.
- Additional warnings instructing the user to ensure ice is made of sterile or 0.22-micron filtered water, to remove contaminated devices from service, to contact CardioQuip if your device shows visual signs of contamination, and to avoid moving modules and accessories between devices.
- More specific instructions for proper water quality inspection, external tubing inspection, and internal tubing inspection.
- More information about the optional Airflow Redirection Hood usage and installation.
- Requirements to perform surface maintenance with EPA-registered tuberculocidal disinfectant wipes.
- More detailed instructions for external tubing maintenance and replacement.

DEVICE CONTAMINATION

Q: How is this related to CardioQuip's Customer Communication Letter from September 2020?

The corrective actions listed in the September 2020 Customer Communication Letter are identical to the corrective actions in this recall. This recall was initiated to ensure mitigations listed in the September 2020 communication are implemented into the most recent copy of the MCH-1000 Operator/Service Manual.

Q: Does every cooler-heater device have the ability to be contaminated?

The FDA has stated that “there is the potential for microorganisms (including NTM) to grow in the water tanks of any heater-cooler device”. No heater-cooler currently on the market is manufactured as a sterile device.

https://www.fda.gov/medical-devices/what-heater-cooler-device/recommendations-use-any-heater-cooler-device

Q: What considerations should be made about my water source?

To prevent your unit from becoming contaminated, it is important to periodically test your water source for bacterial contamination. Any water that is used to fill, refill, or make ice to add to the MCH-1000 must be sterile or 0.22-micron filtered.

Q: How many reports have documented microbial contaminations in CardioQuip MCH-1000 Devices?

According to the FDA Maude database, since 2016 there have been 10 reports of microbial contamination for MCH-1000 devices. This accounts for 0.71% of all microbial contamination reports in the DWC product code category, despite the MCH-1000 garnering an estimated 75% of heater-cooler market share during that period.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM; Product Problem: Microbial Contamination of Device, Product Code: DWC; date range: January 1, 2016 to July 14, 2021.

Q: Does CardioQuip recommend units being placed outside of the OR?

CardioQuip recommends your MCH-1000 devices stay within the operating room following the setup procedures listed in the MCH-1000 Operator/Service Manual. CardioQuip does not endorse the use of MCH-1000 devices outside the operating room, as modifications to the device produce unpredictable results and an inevitable decrease in performance.

Q: How often should I test my device for microbial contamination?

CardioQuip does not require regular water-quality testing. With the revised MCH-1000 Operator/Service Manual R3 2021, CardioQuip has implemented a more robust and frequent inspection of the water tank, internal tubing, and external tubing, and has provided specific instructions in the case visual contamination is identified. Please refer to **Maintenance** section beginning on **pg 47** in the updated MCH Operator/Service Manual.

MCH-1000 OPERATOR/SERVICE MANUAL QUESTIONS

Q: Can I use distilled water in my MCH-1000?

Distilled water can be used, as long as the distilled water has been verified to be sterile or passed through a 0.22-micron filter. To verify this, contact your distilled water manufacturer for more detailed information on the quality of their distilled water. CardioQuip still recommends customers avoid deionized water due to the risk of component corrosion.

Q: Can I still use ice in my MCH-1000?

Any ice that you add to your MCH-1000 devices must be formed from sterile or 0.22-micron filtered water. Bacteria or other contaminants in ice may become a source of contamination in the MCH-1000 device if proper water-quality procedures are not followed.

Q: Will CardioQuip release new cleaning and disinfection protocols for the MCH-1000?

CardioQuip is in the process of validating an updated cleaning and disinfection procedure, which will provide further protections to reduce the risk of bacterial contamination and proliferation. We will continue to provide updates as they develop.

Q: When will CardioQuip be releasing a new cleaning and disinfection protocol?

CardioQuip plans to release the updated cleaning and disinfection protocol for all MCH-1000 devices and associated models as soon as they are validated (in the next 12 to 24 months). Additional customer communication letters and labeling updates will be provided to customers when these procedures are implemented.

SERVICING AND SUPPORT

Q: If I have identified contamination in my device, how will CardioQuip provide support?

For all devices showing visual signs of bacterial contamination, CardioQuip recommends you remove the device from service and contact CardioQuip Customer Service and immediately. Our customer service team will help identify possible causes of contamination and potentially schedule depot servicing and water path replacement if necessary.

Q: What if I have additional questions regarding the MCH-1000?

Please contact CardioQuip Customer Service with your additional questions regarding MCH-1000 devices, this recall, or the corrective action items.

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

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