

## Frequently Asked Questions (FAQ) Update regarding CardioQuip's "MCH-1000(i) Refrigeration Module (MCH-10RMS) Urgent Medical Device Correction" Letter, July 2021

### CORRECTION LETTER

#### ▼ Q: What is the purpose of this letter?

The letter informs CardioQuip customers of the availability of the optional Airflow Redirection Hood (MCH-10ARH). This device is attached to the Refrigeration Module (MCH-10RMS) and directs exhaust downwards, thereby redirecting potential aerosols downwards and away from the surgical field.

#### ▼ Q: What actions should I take as part of this correction?

CardioQuip recommendations are listed in the *Corrective Action* section of the customer letter. They include:

- Installing the optional Airflow Redirection Hood (MCH-10ARH)
- Ensuring all modules and accessories are cleaned and disinfected at the same time as the MCH unit as outlined in Maintenance section of MCH-1000 Operator/Service Manual R3 2021 (pg. 47).
- Not moving modules or accessories between cooler-heater devices to prevent possible cross-contamination.
- Forwarding the Device Correction letter to all device users and other parties that need to be made aware.

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: FCA10RMS@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/fca10rms>

#### ▼ Q: Is the use of MCH-10ARH mandatory? Can I operate my MCH-10RMS Refrigeration Module without one?

The Airflow Redirection Hood is an optional addition to your Refrigeration Module. The presence or absence of the hood will have no effect on the ability of your Refrigeration Module to properly cool the water in your MCH-1000(i) device.

▼ **Q: If the Airflow Redirection Hood is not mandatory, what purpose does it serve on my Refrigeration Module?**

The Airflow Redirection Hood is a precautionary component that redirects the airflow from the lateral exhaust vents on the Refrigeration Module. The FDA requested that we notify customers of this possible risk-mitigating component while validation testing on our updated cleaning and disinfection procedure is completed.

▼ **Q: Is this in response to patient death/harm?**

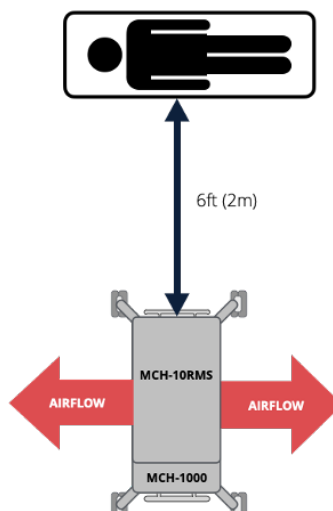
Since its release in 2016, there have been zero cases of documented NTM infection with the Refrigeration Module present in the operating room.

▼ **Q: Does the MCH-10RMS Refrigeration Module aerosolize bacteria?**

As CardioQuip works to validate a new cleaning and disinfection procedure for the MCH-1000 series devices, we are also conducting extensive aerosolization testing to quantify their aerosolization potential. To date, there has been no evidence to implicate the CardioQuip MCH-1000 series devices in patient infection caused by aerosolization of bacteria. Previous testing (available upon request) with Sandia National Laboratories has shown there is an extremely low risk of aerosolization when using the MCH-1000 and Refrigeration Module.

▼ **Q: What is the proper orientation of the MCH-10RMS Refrigeration Module in the OR?**

The Refrigeration Module employs a low-airflow heat exchanger that is designed to function safely and efficiently within the airflow pattern of a standards-compliant Surgical Ventilation System, when positioned as shown in the diagram. The MCH-1000(i) should be positioned at least 6ft (2m) from the patient, with the rear-panel water connectors pointing either directly toward, or directly away from, the patient. In this position, the Refrigeration Module exhaust air flows parallel to the operating table.



**Q: How do I order an Airflow Redirection Hood for my Refrigeration Module?**

To order an MCH-10ARH Airflow Redirection Hood, visit [www.CardioQuip.com/sales](http://www.CardioQuip.com/sales) to connect with your local authorized CardioQuip representative.

**Q: What is the price of the MCH-10ARH? Are there discounts available?**

The Airflow Redirection Hood currently lists for \$1049.00. Orders received before November 1, 2021, are subject to a 10% discount.

**Q: How do I install the Airflow Redirection Hood?**

The MCH-10ARH requires a #2 Phillips screwdriver for installation. Installation instructions are available on **pg. 37** of the revised MCH-1000 Operator/Service Manual R3 2021 and also at CardioQuip's resource page: [www.cardioquip.com/resources](http://www.cardioquip.com/resources).

**Q: Does installing the MCH-10ARH Airflow Redirection Hood change the way I can orient my MCH-1000(i)?**

No. CardioQuip always recommends the most risk-averse layout for any cooler-heater device and associated accessories. Whether you choose to implement the Airflow Redirection Hood or not, you must orient your device according to **pg. 36** of the MCH-1000 Operator/Service Manual R3 2021 to ensure the lateral exhaust vents on the Refrigeration Module flows parallel to the operating table.

**Q: What if I have additional questions about my MCH-10RMS Refrigeration Module or MCH-10ARH Airflow Redirection Hood?**

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

**CardioQuip Customer Service**

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Monday— Friday 8 A.M. – 5 P.M. CST

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