

FAQs regarding FDA Safety Communications: Mycobacterium chimaera Infections ~December 16, 2019~

On June 1, 2016, the FDA issued a Safety Communication to provide new information about *Mycobacterium chimaera* (*M. chimaera*) infections associated with the use of the LivaNova3T[®] on patients who have undergone cardiothoracic surgeries. The FDA then issued an updated Safety Communication (Reference FDA Safety Communication: *UPDATE: Mycobacterium chimera Infections Associated with LivaNova PLC (formerly Sorin Group Deutschland GmbH) Stöckert 3T Heater-Cooler System*) dated October 13, 2016.

Quest Medical, Inc. (Quest) is aware that some customers choose to use the MPS[®], MPS[®] 2, or the MPS 2L¹ (MPS) Console with a Heater Cooler Device (HCD). This communication is intended to answer questions our customers have raised concerning the FDA's Safety Communication. This communication may be updated as new information becomes available.

Question 1: Has Quest validated a water circulation system disinfection procedure that is safe for use with the MPS and effective at preventing *M. chimaera* biofilm formation?

Answer: Quest has validated a procedure that meets the AAMI TIR 12 requirements for intermediate-level disinfection of water circulation systems. This procedure has been reviewed and cleared by the FDA per 510(k) # K173716. Reference the MPS Operations Manual 903691 Revision J for specific disinfection instructions.

Question 2: The Heater Cooler (HCD) IFU recommends specific solutions to be used to disinfect the HCD. Will use of these solutions affect the performance of the MPS Console?

Answer: The water circulation system of the MPS Console is compatible with Minncare[®] HD, Cidex[®] OPA, and Metricide[®] 28, provided the disinfection frequency does not exceed once every two weeks for a lifetime of ten years. Validation records are on file at Quest.

The above solutions have received 510(k) clearance by FDA as high level disinfectants, effective against Nontuberculous Mycobacteria (NTM). The FDA recommends the water quality should be periodically monitored as part of an ongoing quality control program.

Question 3: Some components in the water circuit contraindicate the use of Hydrogen Peroxide. Is the use of Hydrogen Peroxide safe with the MPS?

Answer: The MPS Operations Manual recommends maintaining the water circuit with 100 – 250ppm H₂O₂. This concentration of H₂O₂ has been validated as safe for use with our stainless steel heat exchangers.

Question 4: The MPS Operations Manual contains the following warning against using chlorine bleach:

¹ Available in Canada only.
MPSU 19-001

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Do not use bleach or any chlorine based cleaning solutions in the MPS water circulation system. Chlorine may damage the heat exchanger, resulting in water to blood leakage AND possible patient injury.

At least one HCD manufacturer is recommending the use of chlorine bleach for disinfection. Considering our HCD is connected to the MPS Console, is it possible to disinfect the MPS Console with the same solution?

Answer: Chlorine bleach is corrosive to stainless steel heat exchangers. Our concern is the risk of damage to the heat exchanger component of the MPS Delivery Set. Corrosion may result in a breach of the stainless-steel bellows and result in a water-to-blood leak. Given the FDA Safety Communication concerning the importance of disinfection, we acknowledge customers may choose to utilize chlorine bleach to disinfect the MPS Console. Customers who choose to use chlorine bleach solution on the MPS Console must drain the solution from the MPS after the cleaning program is executed. The system is to be rinsed with sterile or filtered water twice and drained. Store the MPS Console as prescribed in the User Manual, and fill with filtered or sterile water prior to use.

Question 5: How can I mitigate the risk of aerosolizing water into the sterile field and exposing the patient while using the MPS system?

Answer: The MPS Console is a closed system when used as intended by itself (without the HCD). To maintain and assure a closed system, the lid of the hypothermic reservoir must remain in the closed position when in use.

Ensure the water circulation system is turned OFF prior to re-filling the hypothermic reservoir with ice.

When used with an HCD, continue to follow the recommendations provided by the FDA in their October 13, 2016 Safety Communication.

Additionally, an MPS Console that is not in use should be properly cleaned, drained, and stored in a cool, dry location.

Question 6: What other risk mitigation measures are recommended?

Answer: The FDA recommends using sterile water or water that has been passed through a filter of less than or equal to 0.22 micron to rinse, fill, refill, top-off water tanks, or for making ice intended for use with the system. Deionized water or sterile water created through Reverse Osmosis (RO) are not recommended because they may promote corrosion of the metal components within the MPS Console's water circulation system.

Question 7: How can the MPS 2L provide further risk mitigation against biofilm formation?

Answer: The following components have been removed from the MPS 2L Console:

- Circulation Pump

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- Water Reservoir
- Heater Cartridges
- Circulation Hot/Cold Valve
- Thermal Cutout

The MPS 2L water circuit design addresses the following potential root causes of mycobacteria infections associated with heater-cooler devices as identified by the FDA in *FDA's Ongoing Investigation and Continued Monitoring of Reports of Nontuberculous Mycobacteria Infections Associated with Heater-Cooler Devices*²:

- **Aerosolization of NTM Bacteria Grown in Water Tanks:** The MPS 2L System does not have a water tank. The device is also fully sealed and enclosed. The MPS 2L System, when used in accordance with the instructions for use, eliminates risks from water contamination and water agitation inside water tanks.
- **Laminar Flow Disruption/ Heater-Cooler Designs:** The design of the MPS 2L System significantly differs from Heater-Cooler devices which have water tanks and exhaust fans that can disrupt the protective nature of laminar air flow in an operating room environment.

The simplified design of the MPS 2L water circuit allows the console to be easily drained. To minimize the risk of biofilm formation within the water circuit, drain the water circuit after each use and before storage per the instructions in the MPS Operations Manual CMA 007.

It is necessary for the hospital to follow internal hospital procedures and manufacturer's recommendations for maintaining the heater cooler device's water circulation system to ensure that the MPS 2L water circulation system does not become contaminated.

Question 9: *The MPS Operations Manual Section 8.2 shows the Water Circuit Adapter is required to circulate disinfectant solution through the MPS Console. We have misplaced our Water Circuit Adapter. Can we use an MPS Heat Exchanger for this purpose?*

Answer: The Water Circuit Adapter (catalogue number 5001110) may be ordered directly from Quest Medical, Inc. (call (972) 390-7173 or email custserv@questmedical.com). If our customers choose to use the MPS Heat Exchanger for this purpose, the heat exchanger must first be removed from the MPS Delivery Set. An MPS Heat Exchanger that has been used to recirculate cleaning solution must never be used for the delivery of cardioplegia solution to a patient.

Question 10: *We use our HCD units to supply water flow to the MPS Consoles. Can we circulate the disinfectant solutions through both the HCD and the MPS Console simultaneously, as that is how they are used?*

² <https://www.fda.gov/medical-devices/what-heater-cooler-device/fdas-ongoing-investigation-and-continued-monitoring-reports-nontuberculous-mycobacteria-infections>

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Answer: Our customers who choose to disinfect their HCD units and MPS console as one circuit must consider the combined water volumes of both systems, including tubing, in their calculations to ensure they are complying with the recommended concentrations for the disinfectant they are using. The water circulation system within the MPS Console is 550 milliliters. It is the customer's responsibility to ensure that there is adequate disinfection throughout the entire circuit. Customers who choose to disinfect their HCD unit as one circuit with the MPS console are to use the MPS water circulation system cleaning program accessed by pressing the [H2O Circ] function key as described in the MPS Operations Manuals Section 8.3.

Question 11: *The disinfection procedure prescribed in MPS Operations Manual 903691 Revision J is burdensome to end users. What additional activities is Quest undergoing to minimize this burden?*

Answer: The disinfection procedure contained in the MPS Operations Manual Revision J has been validated as safe and effective to mitigate risks associated with M. chimaera biofilm formation. To minimize the burden associated with executing the disinfection procedure, Quest is performing long-term validation studies to extend the disinfection frequency requirement to once per 28 days. We expect to receive FDA clearance in Q2 2020. Additionally Quest is developing alternate device solutions that do not require water circuit disinfection. Your Sales Manager can advise on the status of project development and FDA clearance as projects evolve.

Question 12: *What if I have additional questions related to the MPS Console?*

Answer: The reference documents included with this communication may answer your questions:

- *Quest MPS® Console Operations Manual, 903691*
- *Important Information Concerning MPS 2L Console Features and Functionality, CMA007*
- *MPS Instructional: Purging Air from the Circulation System, 903905*
- *MPS Accessories in Product Catalog*

You may also call the 24-Hour MPS Technical Service Support at (888) 510-7623.