

FAQs regarding FDA Safety Communications: Mycobacterium chimaera Infections ~November 30, 2016~

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® or MPS® 2 (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.

Question 1: *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. The MPS Operations Manuals provide instructions for using the system's water cleaning program.

Question 2: *The MPS Operations Manuals contain the following warning against using chlorine bleach:*



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: Given the FDA Safety Communication concerning the importance of disinfection, we acknowledge customers may choose to utilize chlorine bleach to disinfect the MPS Console. The chlorine bleach solution must be drained from the MPS after the cleaning program is executed. The system is to be rinsed with sterile or filtered water twice and drained. Store as prescribed in the User Manual, and fill with filtered or sterile water prior to use. **Reminder:** 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.*

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Question 3: 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 4: 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 5: 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 Rev. E,*
- *MPS Instructional: Purging Air from the Circulation System, 903905 Rev. A,*
- *MPS Accessories in Product Catalog.*

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

NEW - Question 6: The MPS Operations Manuals Section 8.3 show the Water Circuit Adapter is required to circulate cleaning 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.

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NEW - Question 7: 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?

*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.*

This communication may be updated as new information becomes available.