

3T Heater-Cooler System Summary of Deep Cleaning Procedure

July, 2019

Dear Valued Customer:

Purpose of this Letter

The purpose of this letter is to provide an overview of the deep cleaning procedure for 3T Heater-Cooler Systems. This procedure is performed by LivaNova authorized representatives at the manufacturer or manufacturer-authorized locations, but not at customer sites. It is important to be clear that this procedure has not yet been cleared by FDA, but are being conducted under a voluntary recall initiated by LivaNova. **PLEASE NOTE: This information is not intended to replace, amend or supplement the information already provided to you through the product operating instructions and/or field safety notices.**

Deep Cleaning & Device Modification

Some customers will have their devices deep cleaned in addition to the vacuum and sealing modifications in order to increase effectiveness of the upgrades.

Deep Cleaning Summary

Deep Cleaning consists of 1) functional testing, 2) decalcification, 3) biofilm removal, 4) vacuum & seal upgrades, 5) chemical disinfection, 6) hot water disinfection, 7) final functional test & water sampling, and 8) drying.

- 1) Functional Testing
 - a. The heater-cooler is tested to ensure it is operating properly prior to the deep cleaning procedure. Any needed repairs are performed prior to moving forward with deep cleaning.
- 2) Decalcification
 - a. The heater-cooler is filled with a blend of decalcifier and filtered water and the fluid circuits are activated to circulate the mixture.
 - b. The machine is drained and the decalcifier is allowed to react in the machine. Visual confirmation using an endoscope is performed to confirm successful decalcification.
 - c. The decalcifier solution is drained and the heater-cooler is filled with filtered water. The fluid circuits are activated to rinse any residual decalcifier solution.
- 3) Biofilm Removal
 - a. Water-contact parts are disassembled, cleaned, and disinfected using disinfection spray and wipes.
 - b. In certain hard-to-reach areas, single use brushes are also used to mechanically remove any biofilm formations that may be present.
 - c. Figure 1 shows examples of components before and after biofilm removal.



Figure 1: Heater-Cooler components before (*left*) and after (*right*) biofilm removal

- 4) Vacuum & Sealing Upgrades
 - a. The Vacuum and Sealing upgrades, as summarized in Customer Letter IM-02616 A, are performed after biofilm removal, and before chemical disinfection.
- 5) Chemical Disinfection
 - a. The heater-cooler is filled with a blend of chemical disinfectant and filtered water and the fluid circuits are activated to circulate the mixture.
 - b. The chemical disinfectant is drained and the heater-cooler is filled with filtered water. The fluid circuits are activated to rinse any residual chemical disinfectant.
- 6) Hot Water Disinfection
 - a. The heater-cooler is filled with filtered water and the fluid circuits are connected to a heating/cooling thermostat.
 - b. Hot water (>70°C) is circulated throughout the machine's fluid pathways.
- 7) Final Functional Test & Water Sampling
 - a. After the hot water from #6 is drained, the heater-cooler is filled with filtered water.
 - b. A final functional check is performed according to the heater-cooler's preventive maintenance guidelines.
 - c. The fluid circuits are activated and a water sample is taken to verify that the water quality meets drinking water standards (<100 colony forming units/ml) and that there is no detectable level of Nontuberculous mycobacteria.
 - d. The heater-cooler is quarantined and not released until acceptable water sample results are received.
- 8) Drying
 - a. The heater-cooler is dried using an air-drying device.
 - b. Complete drying is verified using visual inspections, endoscope inspection, and indicator papers.