

3T Heater-Cooler System

Overview of Vacuum & Sealing Upgrades for Your 3T Device

July, 2019

Dear Valued Customer:

Purpose of this Letter

The purpose of this letter is to provide an overview of the vacuum & sealing design upgrades made to your 3T Heater-Cooler. It is important to be clear that these upgrades have 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.**

Vacuum & Sealing Design Upgrade

The addition of vacuum capability will be applied to the heater-cooler in order to support the collection of aerosol emission from the 3T heater-cooler water tanks. In order to achieve aerosol collection, a service technician will open the 3T heater-cooler to access the internal water tanks, perform a basic cleaning of the inner tank components of your device and then seal off the internal openings.

1) Cleaning

- a. The internal components of the 3T water tanks will be disassembled and cleaned thoroughly with approved disinfectant chemicals and disinfectant wipes.
- b. After the upgrade to the 3T heater-cooler is complete, a standard chemical disinfection process will be applied.

2) New & Improved Seals

- a. 23 new or improved seals will be added, as shown in the following examples.



Figure 1: Silicone Gaskets will be added to the Temperature Sensor Mount (*left*) and between the tanks and tank lid (*right*)

3) Openings Sealed Off

- a. 27 small openings will be sealed using sealants, plugs & heat shrink sealing material, as shown in the following examples.

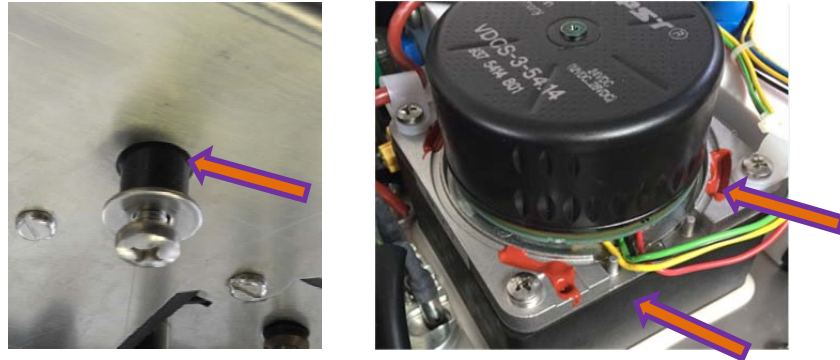


Figure 2: Plug applied to the tank lid, inside tank (*left*) and holes in water pump housing filled with silicone sealant and heat shrink sealing material (*right*)

4) New Vacuum Gauge Added to 3T Heater-Cooler

- a. Additionally, a vacuum gauge will be added to the top of the heater-cooler which displays the level of vacuum applied within the tank. The new gauge is used to verify that the minimum operating vacuum level is > 50 Pa when Full Open source vacuum is applied per the IFU.

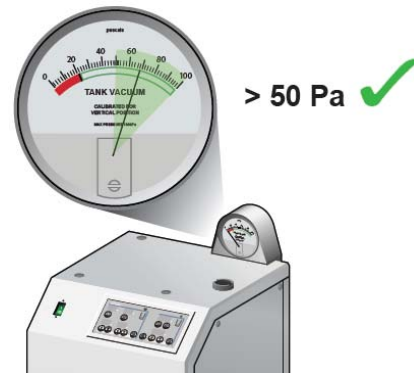


Figure 3: New Vacuum Gauge

Following completion of the 3T upgrade, the service technician will apply the minimum required vacuum flow of 20 L/min and verify that the minimum operating vacuum of ≥ 50 Pa is achieved. (**Note:** During normal use, Full Open source vacuum flow is required to guarantee that the minimum vacuum flow of 20 L/min is achieved.)

The service technician will also apply a standard disinfection process after the upgrade is complete.

Additional Design Changes

Additional design changes have been identified through LivaNova's post-market surveillance and continuous improvement processes. These upgrades will be implemented at no cost to our customers and are summarized below.

1) Pump Design Changes to Reduce Surface Erosion

- a. A new nozzle is added to the patient tank stirrer pump to direct flow away from the evaporator cooling coil to reduce surface erosion.

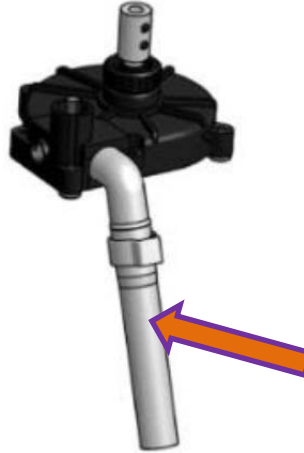


Figure 4: The new nozzle on the patient tank stir pump directs flow away from the evaporator cooling coil

- b. Current pump tubing will also be replaced with clear PFA tubing. The new tubing has increased chemical resistance, reduces mechanical force applied to the pumps, and includes a sleeve for an improved connection to the pumps.

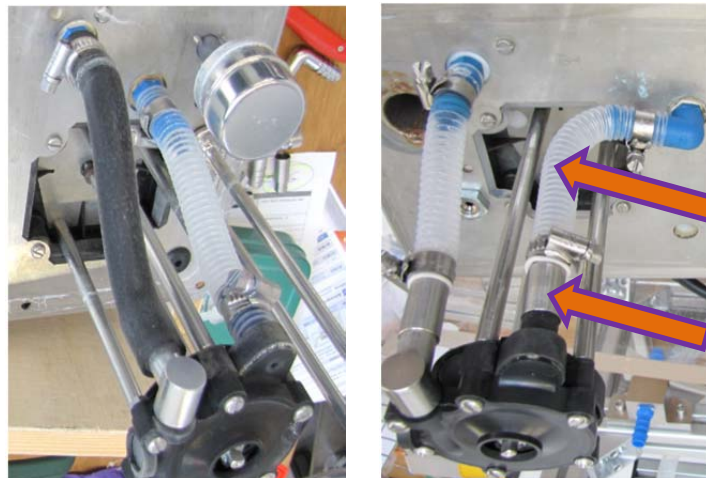


Figure 5: Current tubing (*left*) will be replaced with clear PFA corrugated tubing (*right*).

- 2) Lower overflow port plugged, upper overflow port opened
 - a. Plugging the lower port and opening the upper port provides increased capacity in the 3T Heater-Cooler System water tanks to avoid excess overflow of the Aerosol Collection Set canister.

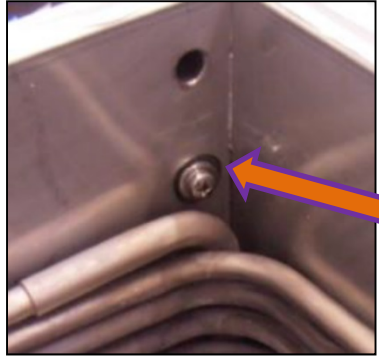


Figure 6: The lower overflow port will be plugged

- 3) Cardioplegia Valve Block Design Changes
 - a. The 3T cardioplegia valve block plug materials will be changed to Polyphenylene sulfide and Stainless Steel to provide increased chemical resistance. The design of the plugs has also been improved to eliminate dead legs inside the valve block fluid pathways.

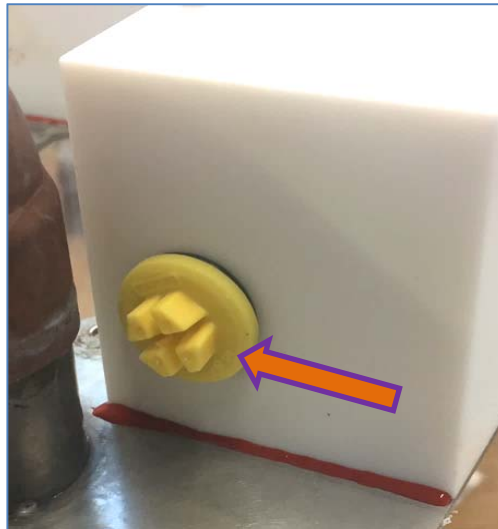


Figure 7: Upgraded 3T cardioplegia valve block plug

4) One Way Valve Design Changes

- a. The one way valves connected to the ball valves on the back of the machine allow for emptying of the water circuits. Current one way valves will be replaced with new one way valve designs which have a smaller air inlet port. The new one way valves reduce velocity of returned water to tanks to minimize pressure spikes in the Heater-Cooler 3T tanks during the empty cycle.



Figure 8: Current Snuffle Valves (*left*) will be replaced with new Snuffle Valves (*right*)

Note: Close one valve at a time during the water circuit empty phase to minimize pressure spikes.

Changes to Device Functionality

- 1) Use of the heater-cooler during a procedure to adjust temperatures and control pumps is unchanged. However, there are a few additional checks to conduct during cases once your device has been upgraded:
 - a. To avoid disturbances in the laminar flow area of the operating theatre, make sure that a portable vacuum system is placed in such a way that the exhaust flow is not directed towards the operating field, but towards the exhaust vent system.
 - b. Monitor the heater-cooler vacuum gauge during the procedure, and verify that > 50 Pa is displayed with the Full Open vacuum source flow applied.
 - i. Note that a minimum of 20 L/min vacuum flow at the source is required. Flow rates greater than 20 L/min are acceptable.

2) Aerosol Collection Set (050900100)

- a. The most apparent change in the upgrade is the requirement to use and maintain the Aerosol Collection Set, which is designed to generate vacuum pressure within the 3T water tanks and to collect and isolate aerosol emissions.
- b. The Aerosol Collection Set has a 3 day use.
- c. The set consists of a waste canister with internal bacterial filter located in the lid of the canister, which is connected to the overflow port of the 3T (short tube) and to the vacuum source (long tube).



Figure 9: Aerosol Collection Set contents

3) Connecting the Aerosol Collection Set

- a. The Aerosol Collection Set is attached to the 3T Heater-Cooler System water overflow port located on the back of the machine. The aerosol collection canister is connected to the available OR vacuum source. The use of a vacuum source water trap is required to collect formed condensation. See Figure 10.

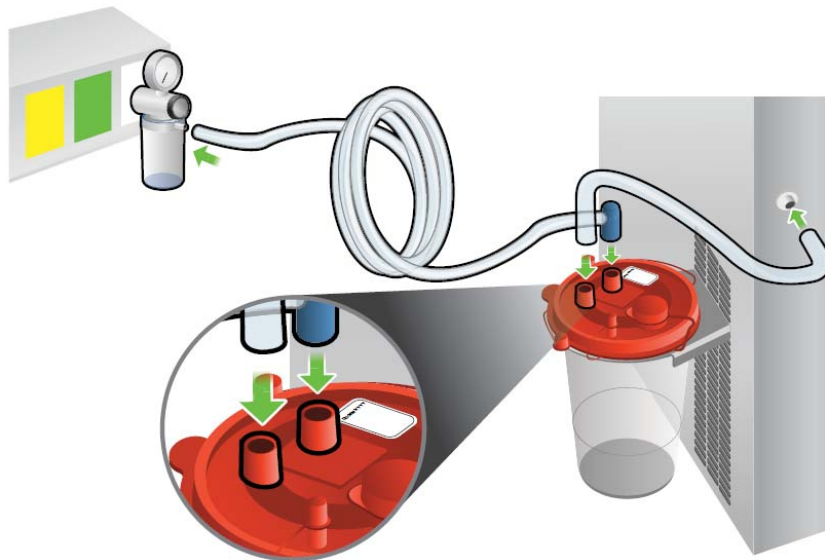


Figure 10: Connection of Aerosol Collection Set to 3T and vacuum source

4) Pre-procedure checks of the Aerosol Collection Set

- a. Before starting the 3T Heater-Cooler, verify the following items related to the Aerosol Collection Set:
 - i. The waste canister's installation date is not more than 3 days old. If older than 3 days, discard and install a new Collection Set. (Note that the Collection Set must also be replaced after the water in the heater-cooler is changed or after the heater-cooler is disinfected.)
 - ii. Confirm connections to the Aerosol Collection Set, 3T Heater-Cooler, and Vacuum Source are secure.
 - iii. Verify zero setting of the vacuum gauge prior to applying vacuum source, adjust to zero if needed using adjustment screw on face of vacuum gauge.
 - iv. With the external vacuum source set to Full Open flow, verify that the vacuum gauge displays > 50 Pa.

Note: >100 Pa is possible and acceptable.

5) Waste Container Volume

- a. Before each procedure and after emptying the circuits verify that the waste container volume does not exceed 0.5 L.
 - i. If the volume is > 0.5 L, empty the aerosol collection set according to the 3T Instructions for Use.
 - ii. Empty the waste container outside of the OR, if possible.
 - iii. Do not expose the canister lid internal bacteria filter to water. Exposure of the hydrophobic bacteria filter to water will seal the filter, which will stop vacuum flow and the aerosol collection canister's ability to collect and segregate aerosol. The aerosol water volume collected is identified as a potential biohazard.

6) Perform all other standard 3T system checks as described per the 3T Operating Instructions.

7) Acceptable Error Codes During the Initial Filling of the Water Tanks

- a. The 3T Heater-Cooler System will perform a self-test during the initial filling of the water tanks.
- b. During this time, error codes **08**, **19** or **23** may be displayed. These error codes are acceptable and indicate that there is residual air present within the 3T pumps, and you may continue using the heater-cooler. These error codes will resolve once the air is displaced with water.
- c. If the error codes continue to be displayed after self-test and do not resolve, or other error codes are displayed, refer to **Chapter 8** of the 3T Heater-Cooler System Operating Instructions to interpret the error codes and to determine the appropriate action.



Figure 11: Error codes on the 3T display will flash between error and code number

Verification of Design Changes

1) Microbiological Testing conducted at worst-case conditions in a highly controlled aerosol test chamber environment. Positive and Negative controls were tested in addition to Test Conditions.

a. Test conditions included:

- i. Water circuit loaded with *M. chimaera* concentration of 1×10^6 CFU/ml (16.2L volume at this concentration)
- ii. Warming (temperatures ranged from 18-40°C) and Emptying phases tested
- iii. Range of vacuum pressures tested (20,35,50,75,100,150 and >150Pa)

b. Study results included:

- i. Negative controls all had <1 CFU/m³
- ii. Positive control with *M. chimaera* concentration $> 1 \times 10^5$ CFU/m³ during warming and emptying phases
- iii. All Test devices show $>99.9\%$ (3 Log reduction) of *M. Chimaera* aerosol emission, as summarized in the following figures

Phase: Warming				Phase: Emptying Controlled			
% Reduction vs Positive Control				% Reduction vs Positive Control			
Pressure (Pa)	Test Device 1 (CFU/m3)	Test Device 2 (CFU/m3)	Test Device 3 (CFU/m3)	Pressure (Pa)	Test Device 1 (CFU/m3)	Test Device 2 (CFU/m3)	Test Device 3 (CFU/m3)
20	100	100	100	20	100	99.9888	100
35	100	100	100	35	100	100	100
50	99.9995	99.9991	100	50	100	100	99.9999
75	100	100	100	75	100	99.9991	100
100	100	100	100	100	100	100	99.9998
150	100	100	100	150	100	100	100
Max	100	100	100	Max	100	100	100

Figure 12: % Reductions in Emissions for a control device vs an upgraded device with vacuum applied for the warming (*left*) and controlled valve closure (*right*) phases

Ordering & Contact Information

Aerosol Collection Sets (Catalog Number 050900100)

Aerosol Collection Sets can be purchased through the LivaNova Customer Service Center at 1-866-332-1375. The catalog number is 050900100 and each package consists of 12 Aerosol Collection Sets and one Instructions For Use (IFU) Document.

- For each 3T unit to be upgraded, LivaNova will ship one case of Aerosol Collection Sets to the customer at no cost, to ensure that every 3T device is covered for the first calendar month.
- To cover the second calendar month and beyond, customers should start ordering the Aerosol Collection Set on a regular basis through the LivaNova Customer Service Center.

Vacuum Extension Line (Catalog Number 050900111)

It is important to assess the layout of your OR prior to the completion of the Vacuum & Sealing upgrade. If your 3T is more than 3.5 meters away from the vacuum source, you may need to order an additional extension line and connector. If so, you can order catalog number 050900111. The extension lines come in a case of 50 units.

If you have further questions about your 3T Heater-Cooler, please reach out to your local LivaNova Account Sales Representative or contact our internal team at 3T.US@livanova.com.