



Health innovation that matters

**May 2017 - Frequently Asked Questions (FAQs) regarding the 3T FSN Update on Cardiac Surgery Mycobacterium Risks - Sorin Heater-Cooler Device Upgrade/Design Modification – Valid Outside of the United States**

1. *What does the 3T Heater-Cooler Vacuum & Sealing Upgrade ("3T V&S Upgrade") consist of?*
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<sup>1</sup> LivaNova PLC is a U.K. holding company with a number of wholly-owned subsidiaries, including LivaNova Deutschland GmbH and Sorin Group USA, Inc. In this document, we refer to all entities using the brand name LivaNova

20. Can I use a different canister already present in the hospital?
  21. When should the Aerosol Collection Set be replaced?
  22. Which kind of vacuum source is recommended? Are there specific requirements?
  23. If a central vacuum source is not available in the OR, what are my options?
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  25. Is the 3T V&S Upgrade solution available also for 1T devices?
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**1. Q: What does the 3T Heater-Cooler Vacuum & Sealing Upgrade consist of?**

A: The 3T Heater-Cooler Vacuum & Sealing Upgrade ("3T V&S Upgrade") consists primarily of a modification of the 3T design to include improved internal sealing and addition of a vacuum system to new and existing devices. These changes are intended to further reduce the risk of possible dispersion of aerosols from the 3T Heater-Cooler devices in the operating room.

**2. Q: How is the "3T Heater-Cooler Vacuum & Sealing Upgrade" (3T V&S Upgrade) addressing the issue of aerosolization?**

A: The 3T V&S Upgrade solution is capable of collecting and sequestering any aerosol from the 3T Heater-Cooler device (3T HCD) and preventing it from entering into the sterile field.

**3. Q: How can the 3T V&S Upgrade prevent aerosols from being dispersed in the OR?**

A: The 3T V&S Upgrade solution includes the application of a vacuum solution capable of connecting the 3T HCD to a vacuum source (i.e. central hospital vacuum source or stand-alone vacuum source) and the regular use of a disposable suction canister with an antibacterial filter (Aerosol Collection Set).

The disposable set is intended to (i) receive the water that might overflow from the tanks when the water contained in the external circuitry is returned in the tanks at the end of the CPB procedure (just like the current overflow bottle), and (ii) collect and segregate any aerosols generated by the agitation of the water in the tanks when the 3T is switched on.

The collection of aerosols is achieved by the airflow generated by the pressure difference between the inside of the tank and the suction canister connected to the vacuum source. The sequestration of any aerosol is achieved by the antibacterial filter located at the outlet port of the suction canister before the vacuum source.

**4. Q: Is the 3T V&S Upgrade approved in all countries?**

A: LivaNova has recently obtained CE mark for "3T V&S Upgrade," and is currently working with local competent authorities to obtain approval for this solution in each country. The company will soon start the roll-out of these design upgrades on a global basis, as we obtain approval by local regulatory agencies. Timeline for clearance may significantly vary country by country, therefore implementation will start earlier in some regions (see also #13).

**5. Q: Who will install the 3T V&S Upgrade on my 3T devices?**

A: The 3T V&S Upgrade will be done by a 3<sup>rd</sup> party service partner company who operates on behalf of LivaNova and whose technicians are properly trained to perform this task.

**6. Q: Who will pay the costs for the installation of the 3T V&S Upgrade?**

A: The installation of the 3T V&S Upgrade will be performed by the company at no cost to our customers.

**7. Q: When will the 3T V&S Upgrade be installed at my institution?**

A: The plan for upgrades is defined at a country level with priorities set country by country and hospital by hospital. Our LivaNova local sales representatives are the contact point for any specific information.

**8. Q: Who should I contact to get my 3T devices upgraded?**

A: LivaNova or LivaNova's 3<sup>rd</sup> party service partner will contact customers for appointments over the next months, depending on local approvals and implementation plans in each country (see also #13)

**9. Q: Where will the installation of the 3T V&S Upgrade be performed?**

A: Due to the nature of the work, the 3T V&S Upgrade requires the device to be removed from the operating theatre and placed in a separate room until the upgrade work is complete

**10.Q: How long will it take to install the 3T V&S Upgrade on one 3T device?**

A: It will take about 10 hours to upgrade one 3T device. Technicians will preferably complete the upgrade in one day; however, depending on the circumstances it may be necessary to complete the work the following day.

**11.Q: What is needed in the hospital for the 3T V&S Upgrade?**

A: In order to ensure a smooth and effective upgrade process, please ensure the following items are readily available at the hospital for the technicians that will perform the upgrade

1. Vacuum source capable of 20 l/min flow or greater (see also #22, #23 and #24)
2. Space/Room (outside the operating theatre) to perform a 10 hour upgrade
3. Filtered water supply to perform descaling and disinfection
4. Waste buckets to dispose of any contaminants removed from the water circuit
5. Drain to dispose the water circulated during the descaling and disinfection

**12.Q: How can I ensure that my institution will not need to cancel surgeries while all my devices are upgraded?**

A: LivaNova will coordinate with your facility in an effort to minimize any disruption during the 3T V&S Upgrade. The upgrade will be planned in advance on a date agreed between the customer and LivaNova's 3<sup>rd</sup> party service partner company, taking into consideration customer needs and schedules.

**13.Q: How long will it take LivaNova to upgrade all the 3T devices in the field?**

A: Implementation of the 3T V&S Upgrade will begin soon for the initial approved countries. The company anticipates continuing the upgrade process through the end of 2017 for the European Union and through the remainder of 2018 globally, as we obtain approval by local regulatory agencies in each country.

**14.Q: Can I perform the disinfection less frequently once my 3T device is upgraded?**

A: No, the routine maintenance of the device will continue to be a key measure to ensure the water inside the tank remains clean.

**15.Q: Will all 3T devices be eligible for the 3T V&S Upgrade?**

A: Yes. All 3T devices currently present in the field will be eligible to receive the 3T V&S Upgrade, regardless of their manufacturing date or whether or not the device has shown evidence of contamination. It is possible that some devices may not be able to receive the 3T V&S Upgrade as a result of age, condition from lack of maintenance, or other factors. In such cases, we will work with your facility on an alternative solution.

**16.Q: If my 3T device is contaminated with *M. chimaera*, should I ask for the deep disinfection service or the 3T V&S Upgrade?**

A: As per 2016 FSN Update, 3T units that are confirmed to be contaminated with M. chimaera should be placed outside of the OR or returned to LivaNova for a deep disinfection before being returned to clinical use. These units will also receive the 3T V&S Upgrade before being returned to the hospital. LivaNova is offering the deep disinfection service free of charge and in priority for devices that are confirmed to be M. chimaera contaminated.

Please refer to the LivaNova web site at <http://www.livanova.sorin.com/3T-out-us> for more information on how to request a deep disinfection service from LivaNova.

**17.Q: Will the 3T V&S Upgrade be done on devices undergoing deep disinfection service at a LivaNova deep disinfection site?**

A: Beginning July, all devices returned for deep disinfection in our Munich facility (or other LivaNova deep disinfection sites) will also receive the 3T V&SW Upgrade while undergoing the deep disinfection service. Other LivaNova deep disinfection sites will upgrade devices returned for deep disinfection as the 3T V&S Upgrade is approved by the local regulatory agency for that country.

**18.Q: What is the 3T Aerosol Collection Set?**

The 3T Aerosol Collection Set (the disposable components of the 3T V&S Upgrade) consists of a suction canister, a suction canister lid and two pieces of tubing; the longer piece of tubing includes a 90° connector for connection to the vacuum port on the lid of the canister.

**19.Q: How can I order the 3T Aerosol Collection Set?**

A: The disposable to be used as part of 3T V&S Upgrade can be ordered from LivaNova by means of the following item:

- 3T Aerosol Collection Set                      Item 050900100      (12 units per box)

At the time of the 3T V&S Upgrade, LivaNova will ship to each customer, for each 3T unit to be upgraded, one case of 3T Aerosol Collection Sets (containing 12 units) 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 3T Aerosol Collection Set on a regular basis from LivaNova Customer Service. Until we build up our inventory levels and reach adequate stock, we will limit the number of sets to be ordered for each 3T unit to 1 case/month.

Depending on the layout of the OR, in case the 3T HCD is more than 3,5 mt away from the vacuum source, customers may need to order an additional extension line (366 cm)

- ¼" ID vacuum extension line with connector, 366 cm (12 ft) Item 050900111  
(50 units per box)

It is expected that only a limited number of hospitals will need the ¼" ID vacuum extension line with connector, therefore this item will not be shipped automatically at the time of the 3T V&S Upgrade, but will have to be ordered, if needed.

**20.Q: Can I use a different canister already present in the hospital?**

A: LivaNova has validated the 3T V&S Upgrade as a system using a specific canister and tubing. We cannot guarantee that the use of an alternate disposable could provide an effective prevention against possible aerosol emission.

**21.Q: When should the Aerosol Collection Set be replaced?**

A: As per 3T Aerosol Collection Sets Instructions for Use, after 3 calendar days of installation, the Aerosol Collection Set has to be replaced and discarded.

**22.Q: Which kind of vacuum source is recommended? Are there specific requirements?**

A: The use of a central hospital vacuum source is recommended for use with this disposable. The vacuum source must be capable of 20 l/min flow or greater.

**23.Q: If a central vacuum source is not available in the OR, what are my options?**

A: If a central hospital vacuum source is not available the use of a portable vacuum system capable of 20 l/min flow per ISO 10079-1 for Medical Suction Equipment is required. The portable vacuum source must be specified for medical applications and fulfill the requirements of IEC 60601-1 and IEC 60601-1-2.

**24.Q: Is LivaNova selling the portable vacuum system?**

A: No, LivaNova is not selling the portable vacuum system but we have identified a suitable device that meets all requirements. Please contact your local sales representative, who will be able to provide you specific information about this possible option.

**25.Q: Is the 3T V&S Upgrade solution available also for 1T devices?**

A: The 3T V&S Upgrade is not currently available for 1T devices.