March 2019

Frequently Asked Questions (FAQs) regarding: URGENT FIELD SAFETY NOTICE

3T Heater Cooler Design & Operating Instructions update

Valid Outside the United States only

Design Upgrade:

1. **Q: Why is LivaNova[1] releasing this Field Safety Corrective Action (FSCA) and related Field Safety Notice (FSN)?**
   A: As part of our continuous improvement process, we have developed design changes for the 3T heater-cooler devices[2] (3T HCD) aiming to address specific issues, identified through our post-market surveillance system. The changes covered by this design upgrade are described in the FSN issued in March 2019.
2. **Q: To which 3T HCD devices is this FSCA applicable?**
   A: This FSCA is applicable to all 3T devices that are equipped with the vacuum and sealing design solution.
3. **Q: Can it be that my cooling coil has eroded due to the current design of the stirrer pump?**
   A: Yes, we have identified a small region on the surface of the cooling coil located in the Patient Tank where surface erosion is caused by the flow of the stirrer pump. The modification of the stirrer pump is designed to reduce flow velocity at the surface of the cooling coil reducing the potential for premature failure of the 3T HCD cooling system.
4. **Q: Can the above mentioned cooling coil erosion affect performances?**
   A: No. The HC3T will continue to function as designed with this surface erosion.
5. **Q: Will LN replace also the cooling coil?**
   A: No. Replacing the HC3T cooling coil due to this surface erosion is not required.
6. **Q: If the H2O2 concentration is rapidly degrading in my 3T device, can this be linked with the erosion of the cooling coils that LivaNova is addressing with this field action?**
   A: No, the erosion of the cooling coil caused by the stirrer pump is not linked to the rapid degradation of H2O2 concentration. The cooling coils are constantly submerged in a mixture of filtered tap water and different chemicals (Hydrogen Peroxide or Disinfectants). When the device is operated, this fluid is subjected to temperatures cycles (heating and cooling) and fluid flow streams generated by the internal pumps within the water tank. In this working environment multiple degradation processes can take place. In some cases, the combination of these phenomena can lead to a progressive degradation of the cooling coil over time.

Operating Instructions (OI) Update:

7. **Q: Why is LivaNova releasing a new version of the OI? Does it mean that the previous version was not effective to control the level of bacteria growth inside the 3T HCD?**
   A: The new Operating Instructions consolidate in one document the content of the previous Operating Instructions and of all the additional information released through FSNs by LivaNova since 2015. With respect to the routine disinfection protocol and any instructions intended to control bacteria growth inside the 3T HCD, there is no change versus the instructions previously provided and communicated by LivaNova.

---

[1] LivaNova PLC is a U.K. holding company with a number of wholly-owned subsidiaries, including LivaNova Deutschland GmbH. In this document, we refer to all entities using the brand name LivaNova.

[2] The 3T is a non sterile heating-cooling machine manufactured by LivaNova Deutschland GmbH. It is used to control patient's body temperature over a cardiopulmonary bypass procedure.

8. **Q: To which devices are the new Operating Instructions applicable?**
   A: The new version of the Operating Instructions is applicable to all active 3T devices equipped with the vacuum and sealing design solution.
9. **Q: What should I do when I receive the new revision of the Operating Instructions?**
   A: When you receive the new revision of the OI, please apply it immediately to all active 3T devices equipped with the vacuum and sealing design solution and scrap any previous revision at your facility, including all FSNs released by LivaNova since 2015. Previous Operating Instructions and FSNs are made obsolete by the new version of the OI.
10. **Q: Why are the new Operating Instructions delivered on paper and not in electronic format?**
    A: There are very strict regulations related to Operating Instructions. European regulations, as well as regulation of some other International countries require any device to be equipped with Operating Manuals on paper and in local language (or multiple languages, depending from the country).
11. **Q: When will the new version of the Operating Instructions be delivered at my facility on paper?**
    A: LivaNova will roll-out this FSCA starting from early March. A paper copy of the new OI in your language (or multiple languages for countries whose regulations require it) will be delivered to your hospital together with the FSN communication. A response form is also provided and should be completed and returned, per instructions provided in the FSN.
12. **Q: I have a functional 3T and I have not received the new OI. Who can I contact?**
    A: Please send an e-mail to the following address: customerquality@livanova.com. LivaNova will check and provide you specific instructions.
13. **Which sections of the Operating Instructions have been modified vs. the previous Operating Instructions?**
    A: The Operating Instructions have been completely revised. There is not a side by side comparison of what has changed in this most recent version vs. the previous version.
14. **Q: Are these new 3T Operating Instructions including all FSNs previously released by LivaNova, starting from 2015?**
    A: Yes. The new Operating Instructions consolidate the content of all Field Safety Notices previously released by LivaNova since 2015.
15. **Q: Will it be possible to download the OI in electronic format from on the LivaNova website?**
    A: LivaNova has proactively investigated the possibility to implement a website to download OI electronic copies. Due to current regulatory requirements in Europe, this is not yet possible at the moment. LivaNova will continue to investigate in this direction. We will inform our customers should there be any related update, as soon as it is available.
16. **Q: When will the new OI be released with new 3T devices produced by LivaNova?**
    A: All new 3T devices produced by LivaNova will be now be equipped with the new OI, starting from serial numbers 16S3xxxx, which has been produced end of December 2018.
17. **Q: To whom can I address technical questions regarding the new OI?**
    A: Please contact your LivaNova local sales/service representatives or send an e-mail to the following address: customerquality@livanova.com.)

General Information:

18. **Q: To whom is this FSN communication addressed within the hospital?**
    A: The FSN will be delivered to the users. Furthermore the FSN will be delivered to other designated roles depending on local requirements (e.g in UK this will be delivered to ''MDSO'', in France to the ''Correspondant de MaterioVigilance'' and ''Directeur de l'établissement'', in Italy to the ''Direttore Sanitario'', ..).

19. **Q: Where can I find other information and answers to questions related to the 3T heater cooler, that are not related to this field action?**

A: A newly consolidated and updated FAQ document will soon be released on the LivaNova website, in addition to this FAQ, which is specifically related to FSN issued by LivaNova in March 2019. The new FAQ document contains answers to general questions frequently received on the 3T heater cooler device.

20. **Q: Are there any videos to illustrate the updated OI?**
    A: Videos referred to the updated operating instructions for several key sections of the manual are planned to be released and uploaded on the 3T LivaNova website page, out of USA section

Design Upgrade - implementation:

21. **Q: When will this design upgrade be rolled out and when will it be completed?**
    A: LivaNova will roll-out this design upgrade in Europe and other International countries (outside the United States) starting from early March, and is currently working with local competent authorities to obtain approval in each country. Timeline for clearance may significantly vary country by country, therefore implementation will start earlier in some regions and proceed as we obtain approval by local regulatory agencies.

22. **Q: Who will install this design upgrade on my 3T devices?**
    A: This design upgrade will be done by a 3rd party service partner company who operates on behalf of LivaNova and whose technicians are properly trained to perform this task. In general, the 3rd party service partner company that has completed the vacuum & sealing upgrade will also execute this further design upgrade.

23. **Q: Who will pay the costs for the installation of this design upgrade?**
    A: The installation of this design upgrade will be performed by LivaNova at no cost to our customers.

24. **Q: When will this design 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. Please contact your LivaNova local sales/service representatives for any specific additional information.

25. **Q: Who should I contact to get my 3T devices upgraded?**
    A: LivaNova or LivaNova's 3rd party service partner will contact customers for appointments over the next months, depending on local approvals and implementation plans in each country.

26. **Q: Where will the installation of this design upgrade be performed?**
    A: Due to the nature of the work, the 3T design upgrade requires the device to be removed from the operating theatre and placed in a separate room until the upgrade work is complete

27. **Q: How long will it take to install this design upgrade on one 3T device?**
    A: It will take about 5 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.

28. **Q: What is needed in the hospital for this design 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. Space/Room (outside the operating theatre) to perform a 5 hour upgrade
    2. Filtered water supply to perform descaling and disinfection
    3. Waste buckets to dispose of any contaminants removed from the water circuit
    4. Drain to dispose the water circulated during the descaling and disinfection

29. **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 design **upgrade.** The upgrade will be planned in advance on a date agreed between the customer and LivaNova's 3rd party service partner company, taking into consideration customer needs and schedules.

30. **Q: How long will it take LivaNova to upgrade all the 3T devices in the field?**
A: Implementation of the design upgrade will begin in March 2019 for the initial approved countries. LivaNova anticipates continuing the design upgrade process through, at least, the end of June 2020, on global basis. Delay may occur in specific countries due to registration timelines.