

October 2018

Frequently Asked Questions (FAQs) regarding the 3T Field Safety Notice Update on Mitigating Potential Cardiac Surgery Infection Risks – Hydrogen Peroxide Concentration Decrease

Valid Outside the United States only

Hydrogen Peroxide Concentration Decrease:

- 1. Q: Does this new daily hydrogen peroxide level monitoring process mean the current disinfection process does not work?**

A: No. LivaNova Deutschland GmbH has defined a procedure to maintain the water quality in the Heater-Cooler device at drinking water level. The procedure in the 3T Operating Instructions specifies that the water circuit has to be disinfected with certain disinfectants before first use and then every two weeks. To maintain the water quality, 150 ml of medical grade 3% hydrogen peroxide (H₂O₂) must be added to the filtered tap water used to fill the tanks every 7 days. The purpose of adding the hydrogen peroxide is to limit microbial growth between the regular disinfection cycles performed every 14 days. The implementation of the new daily hydrogen peroxide level monitoring process does check the effectiveness of the hydrogen peroxide preservation over a 7 day period but does not mean that the current disinfection is not effective.

- 2. Q: If my device has been upgraded do I still need to follow the new daily hydrogen peroxide monitoring process?**

A: Yes, the upgrade kit prevents the release of aerosols from the 3T device and thus reduces the risk of patient infections caused by air transmissions. But the upgrade kit does not mitigate the risk related to direct water contact. Therefore, it is important to maintain the water quality at drinking water level to prevent any nosocomial infections caused by direct water contact. Consequently, it is important to monitor the effectiveness of the water preservation.

- 3. Q: Why is LN just now communicating / addressing this corrosion and hydrogen peroxide level issue?**

A: LivaNova performed a confirmatory validation of the efficacy of the water preservation solution (addition of hydrogen peroxide). The results of the tests performed have confirmed that water preservation solution is effective in limiting the growth of micro-organisms on new machines. However, the efficacy was not confirmed on some clinically-aged devices. Our investigation revealed that copper was exposed if the nickel coating corroded off the evaporator coil. The copper interacted with the hydrogen peroxide and reduced the effective concentration. Therefore an increase in microbial counts (HPC) over the 7 days operating period was observed, and was above the specification of 100 CFU/ml.

- 4. Q: Why do the cooling coils degrade over time?**

A: To support optimum heat transfer the 3T device uses nickel-plated copper cooling coils in the Patient and Cold Cardioplegia tanks. 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 (e.g. galvanic corrosion, disinfectant chemical corrosion, erosion and mechanical stresses). In some cases, the combination of these phenomena can lead to a progressive degradation of the cooling coil over time.

- 5. Q: I have an older device; does this mean I have a degraded cooling coil? Will LN replace my coil?**

A: Degradation of the cooling coil will occur over time and is dependent on the frequency of use and the frequency

of chemical disinfections. Older devices will typically show more degradation versus newer devices. LivaNova will not replace the cooling coil unless under warranty.

6. Q: Can I visually inspect my device to determine if I have a degraded cooling coil? If my cooling coil is not degraded do I still need to follow the new daily hydrogen peroxide process?

A: To avoid possible damage to the 3T device, inspection of the cooling coils must be performed by a certified service technician. Inspection can be done by either disassembling the device or by means of an endoscope inserted into the temperature probe openings located on top of the 3T tanks. Even if the cooling coil is not degraded it is important to follow the daily monitoring of the hydrogen peroxide concentration in order to maintain the effectiveness of the hydrogen peroxide as a water preservation method.

7. Q: What is LN doing to address/stop the cooling coil corrosion?

A: The stirrer pump that is located in the 3T patient tank will be replaced with a new design as a part of the overall 3T sealing upgrade and vacuum solution. This design upgrade to the stirrer pump will reduce the rate of surface erosion of the cooling coil caused by the flow stream originating from the stirrer pump.

8. Q: Do I have to perform daily monitoring on devices that are not going to be used that day?

A: Yes, you should monitor the hydrogen peroxide levels on days when the device is not in use and take the actions recommended in the Operating Instructions to prevent an increase in microbial growth during the time period the machine is not in use. If the device will not be monitored for more than a day (e.g. over a weekend), the device must be completely drained.

9. Q: How was the hydrogen peroxide 100 ppm guide developed/established?

A: In 2011, at the recommendation of a water hygiene expert, the company revised the 3T Operating Instructions to include steps to achieve water quality that meets the standard for German drinking water (≤ 100 CFU/ml). These changes included the addition of hydrogen peroxide to the water as a preservative. During verification testing of the preservation it was observed that hydrogen peroxide levels above 100 ppm kept the water within the specified drinking water limit.

10. Q: What make and model of test strips do I need to use for the hydrogen peroxide testing, and can I use other test strips not mentioned in the FSN?

A: The concentration in the water can be measured semi-quantitatively by visual comparison of the reaction zone of a test strip (e.g. MQuant, Peroxide Test, Method: colorimetric with test strips, 100-1,000 mg/l H₂O₂, Reference 1.10337.0001) with the fields of a color scale. Other commercially available colorimetric test strips that provide a 100 - 1,000 mg/l H₂O₂ range of testing are acceptable

11. Q: Where can I purchase the H₂O₂ test strips?

A: H₂O₂ concentration test strips are available from various laboratory supply websites such as www.fishersci.com, www.sigmaldrich.com and www.thomassci.com.

12. Q: What do I have to do with my 3T units on days when there are no cases (i.e. weekends)?

A: If the 3T heater cooler is not intended to be used for more than a day, you may monitor the hydrogen peroxide level on days when the machine is not in use. Alternatively, if the device will not be used or monitored for more than a day (e.g. over a weekend), the device must be completely drained.

13. Q: At what point can I stop testing the hydrogen peroxide levels?

A: If the device is not used for more than a day (e.g. over the weekend), the device must be completely drained. At this time the monitoring can be stopped until the device is brought back into service. For long term storage of the heater-cooler refer to Section 6.5 of the Operating Instructions, Preparing the heater-cooler for storage.

14. Q: If I cannot keep my hydrogen peroxide level at the required ratio, does it mean my machine is damaged?

A: Frequent addition of hydrogen peroxide is an indication that the cooling coil is degraded. However, this does not indicate that the machine is damaged and unable to function. If the reaction zone of the test stripe shows hydrogen peroxide concentrations below 100mg/l H₂O₂, add an additional 100ml of medical grade 3% hydrogen peroxide to the water tanks as described in the Daily Hydrogen Peroxide Monitoring Instructions set forth in the Medical Device Correction. This will limit the bacteria growth at an acceptable level. Daily monitoring of hydrogen peroxide concentration levels should allow you to maintain the required ratio.

15. Q: Will this negatively impact the functionality and/or reliability of my device?

A: Frequent addition of hydrogen peroxide is an indication that the cooling coil is degraded. However, this frequent addition does not indicate that the machine is damaged and unable to function.

16. Q: If my hydrogen peroxide test does not meet the minimum level and I drain and refill the device (with water and hydrogen peroxide), do I need to test the hydrogen peroxide level again before putting the device back into service?

A: Yes, hydrogen peroxide concentration should be tested every day in each of your devices. If the 3T heater-cooler is not monitored daily for hydrogen peroxide concentrations, drain the water tanks. Hydrogen peroxide concentration testing should be performed prior to using the device in a procedure. Please refer to the Daily Hydrogen Peroxide Monitoring Instructions set forth in the Medical Device Correction.

17. Q: If I cannot get my hydrogen peroxide levels above the minimum, can I continue using my device?

A: Yes. Please refer to the Daily Hydrogen Peroxide Monitoring Instructions set forth in the Medical Device Correction.