LivaNova

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# MEDICAL DEVICE CORRECTION

## Mitigating Potential Cardiac Surgery Infection Risks

Hydrogen Peroxide Concentration Monitoring
and Availability of 3T Design Upgrade

October 18, 2018

Dear Valued Customer:

**Purpose of this Letter**

The purpose of this letter is to advise you that LivaNova Deutschland GmbH ("LivaNova" or "the Company") is executing a voluntary medical device correction for the 3T Heater-Cooler Systems ("3T"). This letter describes immediate action to be taken by you.

**Reason for this Medical Device Correction**

This medical device correction is to:

1) Provide you updated instructions to monitor the concentration of hydrogen peroxide in the water circuit to verify that sufficient concentration of hydrogen peroxide is present to limit microbial growth, and to adjust the concentration of hydrogen peroxide if it drops below 100 ppm. This regimen enhances the regimen outlined in Section 6.4 of the Operating Instructions; and

2) Inform you of a design upgrade (vacuum canister and internal sealing) that reduces the risk of potential emission of aerosols from the 3T.

**Risk to Health**

The 3T Operating Instructions establish disinfection procedures that are designed in part to maintain water quality at a total heterotrophic plate count (HPC) <100 CFU/ml within the 3T heater-cooler water circuit. If the hydrogen peroxide concentration within the water circuit drops below 100 ppm, microorganisms may start to grow in the period between bi-weekly disinfection cycles, possibly to a concentration that exceeds this specification. Although an increased HPC count suggests the growth of microorganisms, it does not necessarily follow that devices are contaminated with non-tuberculosis mycobacteria ("NTM"), whose growth rate extends beyond the 14 days between disinfections.

Although the water in the 3T heater-cooler unit does not come into direct contact with the patient, users should be mindful that aerosols are emitted when the 3T is used, primarily during the patient warming phase and at the end of a procedure, when water is returned to the tanks. Depending on the characteristics of the bacteria and the concentration of bacteria in the water in the tanks, these aerosols may carry bacteria into the operating room environment. Another risk of contamination for the patient is a direct contact transfer of water/solution droplets containing water-borne, pathogenic microorganisms into the surgical field. Some of these microorganisms, such as *M. chimaera*, could lead to cardiovascular infection, including endocarditis or other deep-surgical-site infections if they come in contact with the patient. These risks were most recently described in the Field Safety Notice issued on October 13, 2016[1].

[1] http://www.livanova.sorin.com/products/cardiac-surgery/perfusion/hlm/3t

LivaNova has observed that in a limited number of devices tested after a period of clinical use, the concentration of hydrogen peroxide decreased rapidly to zero within a day. In the devices where rapid hydrogen peroxide loss occurred, LivaNova observed the degradation of a nickel coating on cooling coils in the tanks, resulting in exposed copper. LivaNova believes the rapid hydrogen peroxide decrease may be caused by a reaction between the exposed copper and the hydrogen peroxide.

The decrease of hydrogen peroxide below 100 ppm was not observed in all tested devices. The rate of decrease is expected to vary by device, and can be dependent on a number of factors such as age or overall condition of the device, past maintenance practices, and local water conditions.

## Actions to be taken by the Customer/User

### Daily Hydrogen Peroxide Monitoring

- Users should monitor the hydrogen peroxide concentration in the water solution on a daily basis to verify that sufficient concentration of hydrogen peroxide is present in the water circuit of the device. A decrease in hydrogen peroxide over the 7-day-period until the next water change is expected, however the hydrogen peroxide concentration should remain above 100 ppm. Detailed instructions are found in **Attachment 1**, titled *Daily Hydrogen Peroxide Monitoring Instructions.* Please read those instructions carefully and follow them.

### 3T Design Upgrade

- LivaNova has developed a vacuum canister and internal sealing design change that is intended to further mitigate (but does not eliminate) the risk of airborne transmission of non-tuberculosis mycobacterium ("NTM") from the 3T device. Important instructions that ensure the effectiveness of this modified design will be provided at the time of the upgrade. A LivaNova representative or local agent will contact you to plan the upgrade of your affected products. No other actions by the user are required at this time, other than to continue to follow the 3T Operating Instructions and the attached Daily Hydrogen Peroxide Monitoring Instructions, and to return the Customer Response Form in **Attachment 2**. For those users that have devices undergoing deep cleaning, your device will be upgraded at the deep cleaning facility.

## Affected Product

| Product Code | Product Description |
|---|---|
| 16-02-80 | Heater-Cooler 3T, 230V |
| 16-02-81 | Heater-Cooler 3T, 240V |
| 16-02-82 | Heater-Cooler 3T, 208V |
| 16-02-83 | Heater-Cooler 3T, 127V |
| 16-02-85 | Heater-Cooler 3T, 120V |
| 16-02-95 | Heater-Cooler 3T, 200V |

Note: This Medical Device Correction includes all Heater-Cooler 3T devices sold in the United States and currently in your possession.

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**Transmission of this Medical Device Correction**

Please complete and return the attached Customer Response Form (see Attachment 1) by fax to (303) 467-6502 or by email to USFSN@livanova.com.

Please ensure that this Medical Device Correction is communicated to all personnel within your organization who need to be aware of it. If you have transferred a 3T to a third party, please communicate this information to them and inform the LivaNova Quality Assurance Team at USFSN@livanova.com. Please maintain awareness on this notice and the resulting action for an appropriate period of time to ensure effectiveness of the corrective action.

**Contact reference person**

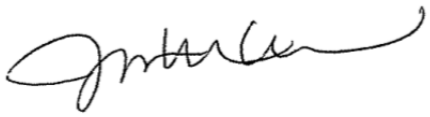
You may find further information about this issue on the LivaNova website at www.livanova.sorin.com/3T.
For questions about this Medical Device Correction, please contact (800) 986-4702 or e-mail USFSN@livanova.com.

A copy of this letter has been provided to the Food and Drug Administration (FDA), who is aware of these actions. Adverse reactions or quality problems experienced with the use of this product may be reported to LivaNova at customerquality@livanova.com or the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

Online: www.fda.gov/MedWatch/report.htm
Regular Mail: use postage-paid FDA form 3500 available at www.fda.gov/MedWatch/getforms.htm and mail to MedWatch, 5600 Fishers Lane, Rockville, Maryland, 20852-9787
Fax: (800) FDA-0178
Phone: (800) FDA-1088

Thank you for your cooperation in this matter. LivaNova is committed to provide quality products and service to its customers and we apologize for any inconvenience this situation may have caused.

Sincerely,



Joan Ceasar
Vice President, Clinical, Quality & Regulatory Services

Enclosed:
Attachment 1: Daily Hydrogen Peroxide Monitoring Instructions
Attachment 2: Customer Response Form

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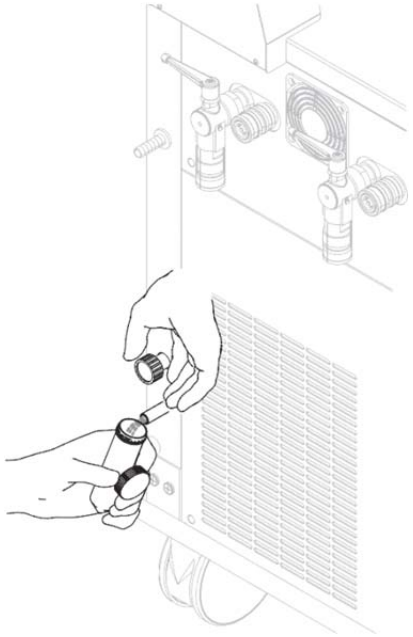
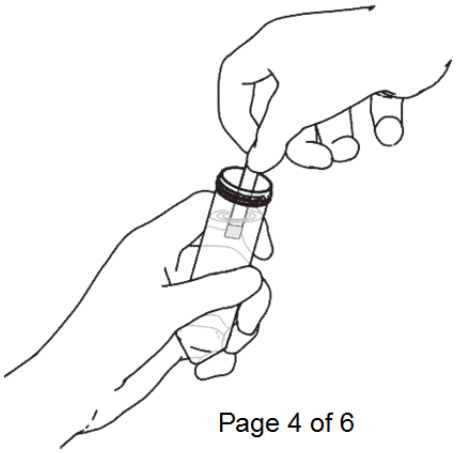
**ATTACHMENT 1**
**Daily Hydrogen Peroxide Monitoring Instructions**

1. Hydrogen peroxide concentration should be tested every day in each of your devices. If the heater-cooler is not monitored daily for hydrogen peroxide concentrations, drain the water tanks. Testing should be performed prior to using the device in a procedure.
2. The hydrogen peroxide concentration in the water circuit 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.
3. Before measuring, open the drain valve of the patient circuits (see 3T Operating Instructions, *Section 3.2 Structure of the heater-cooler*), drain 100 ml of water and discard it.
4. Leave the drain valve open and drain a minimum volume of 5 mL from the water jet into a sterile sample container for measurement and then close the drain valve.



5. Immerse the reaction zones of the test strip in the collected water sample for the reaction time specified in the instructions for use delivered with the peroxide test strips.



6. Shake off excess liquid from the test strip and after the specified reaction time compare the color fields on the packaging and the color of the reaction zone on the test strip. Determine which of the color fields on the label matches the reaction zone color best. Read off the corresponding result in mg/l $H_2O_2$.

7. If the color of the reaction zone shows $H_2O_2$ concentrations less than 100 mg/l $H_2O_2$ perform the following steps to add an additional volume of $H_2O_2$:

   - Prior to adding hydrogen peroxide empty all water circuits back to the tank by closing the circuit valves with circuit pumps powered on. Power off circuit pumps.
   - Add an additional 100 ml dose of medical grade 3% hydrogen peroxide to the water tanks as described in section 5.2 of the Instructions for Use, Filling the Water Tanks.
   - To ensure a homogeneous hydrogen peroxide solution in all water tanks, perform the mixing procedure steps as described in section 5.2 of the Instructions for Use, Filling the Water Tanks.

8. If the hydrogen peroxide concentration is greater than or equal to 100 mg/l $H_2O_2$:

   - There is no additional action to be taken other than to continue daily monitoring of hydrogen peroxide concentration.

   Note: If during the measuring step you need to refill, add pre-mix medical grade 3% hydrogen peroxide solution with filtered tap water at a 1:91 ratio (e.g. 10 ml hydrogen peroxide mixed with 910 ml filtered tap water). Add the mixture to the tank until the second green LED of the water level display for the patient circuit lights up.

9. 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 and take the above recommended actions depending on the level measured. 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. For long term storage of the heater-cooler refer to section 6.5 of the Operating Instructions, Preparing the heater-cooler for storage.

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**ATTACHMENT 2**
**Customer Response Form**

MEDICAL DEVICE CORRECTION

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October 18, 2018

According to our records you received one or more 3T Heater-Cooler devices.

Customer Name: _____

Address: _____
_____
_____
_____

1. We have reviewed and understand the attached Medical Device Correction □ Yes □ No

2. We DO NOT understand the Medical Device Correction and request more information □ Yes □ No

If "no" was indicated in the statement above Question #1, or "yes" indicated in Question #2, please explain:

_____

_____

Other questions:

_____

_____ _____
Name (Print) Title

_____ _____
Signature Date

Thank you for your cooperation in completing this Customer Response Form.
Please return to USFSN@livanova.com or fax to (303) 467-6502 at your earliest convenience.

Adverse reactions or quality problems experienced with the use of this product may be reported to LivaNova at customerquality@livanova.com or the FDA's MedWatch Adverse Event Reporting program either online (www.fda.gov/MedWatch/report.htm), by regular mail or by fax to (800) FDA-0178.