

URGENT FIELD SAFETY NOTICE

3T Heater Cooler Design & Operating Instructions update

FSCA Identifier: CP-MUN-2018-009

Affected Devices: All 3T Heater-Cooler Devices

Date: March 07, 2019

Attention: Users of the heater cooler devices (Cardiac Surgery Operating Room Responsible, Cardiac surgeons, Perfusionists, biomedical engineers/technicians, Hygiene Specialists, Risk/ Safety Managers)

Dear Valued Customer:

Reason for this Letter and affected products

The purpose of this letter is to inform you that LivaNova¹ is initiating a design upgrade for 3T heater cooler devices² (3T) equipped with the vacuum and sealing design solution.

LivaNova is also releasing an updated version of the Operating Instructions for these devices.

This communication applies to the following Part Numbers:

Part Number	Description
16-02-80	Heater-Cooler 3T, 230V
16-02-81	Heater-Cooler 3T, 240V/60Hz
16-02-82	Heater-Cooler 3T, 208V/60Hz
16-02-83	Heater-Cooler 3T, 127V/60Hz
16-02-85	Heater-Cooler 3T, 120V/60Hz

Description of the addressed issues and corrective measures

1. Design upgrade

As part of our continuous improvement process, we have developed design changes aiming to address specific issues, identified through our post-market surveillance system:

- Evaporator coil erosion: the current design of the stirrer pump inside the Patient tank directs water flow to a narrow area of the evaporator cooling coil, thus exacerbating the erosion of the surface of the cooling coil in this location. Ultimately, erosion can result in the creation of a hole in the evaporator, affecting cooling function performance, and in some cases, triggering total shutdown of the device. The newly designed stirrer pump will redirect this water flow away from the cooling coil reducing the potential for erosion on the surface of the cooling coil in this location.
- Change over valve³ failure or performances issues: the current design of the change over valve block for the Cardioplegia tanks allows humid air charged with chemicals used during disinfection to enter into the stepper motor, thus leading to the corrosion of a stepper motor bearing that controls

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.

³ The change over valve allows the user to switch between cold and warm Cardioplegia tank of the 3T to get the desired temperature range.

the selection of the Warm or Cold Cardioplegia tank. Change over valve failure can lead to the cardioplegia solution not being cooled or warmed. The design change will prevent humid air from entering the valve block assembly.

- Air vent valves (AVV)⁴ leakage: corrosion residues may hinder the AVV to close properly, resulting in leakages in certain positions of the ball valve. The new AVV design will allow yearly replacement of this part during preventive maintenance operations. This event is not likely to cause any harm to the patient or user.
- Water drain valve⁵ leakage: investigation revealed material abrasion of an internal component in the valve (called the O-ring). A highly abraded O-ring may cause leakage from the valve in the valve open position. The O-ring will be replaced during preventive maintenance operations. This event is not likely to cause any harm to the patient or user.

For all 3T devices in use at your facility, LivaNova will implement the above described changes.

2. Operating Instructions update

Since 2015, LivaNova has issued different Field Safety Notices to provide additional instructions for the users in relation to potential Nontuberculous Mycobacteria (NTM) contamination Risk.

LivaNova is now releasing a new revision of the Operating Instructions that is applicable to all 3T devices already equipped with the vacuum and sealing design solution. The new Operating Instructions will not directly affect the patient but will consolidate the content of the previously released Field Safety Notices.

What actions should be taken by the Customer/User?

1. Design update

No action by the user is required at this time. LivaNova will deploy this update to all 3T units currently in use at your facility⁶. A LivaNova representative or local agent will contact you to plan the upgrade.

2. Operating Instructions update

The new version of the Operating Instructions will be delivered at your facility. Please apply immediately this new revision of the Operating Instructions to all active 3T devices equipped with the vacuum and sealing design solution and scrap any previous revision at your facility.

3. Return Customer Response Form

Please complete and return the attached Customer Response Form (see **Attachment 1**) by e-mail to (Livanova.FSCA@postdienst.de; FAX +4989321995-55).

Transmission of this Field Safety Notice

Please ensure that this Field Safety Notice is passed on to all personnel within your organization who need to be aware of it.

In case you have transferred products to a third party, please pass this information on to them and also inform the below mentioned contact person.

⁴ These 3 valves are used to open and close the corresponding water circuit.

⁵ This valve is used to drain the heater cooler device.

⁶ In case the 3T upgrade announced in Field Safety Notice reference 9611109-05/05/17-004-C has not been deployed yet to all or part of your active 3T, LivaNova will execute both upgrades at the same time.



Health innovation that matters

Contact reference person

For questions regarding this Field Safety Notice, please contact your LivaNova representative [Phil.Smith@livanova.com]., or LivaNova Customer Quality at LivaNova.FSCA@livanova.com.

A copy of this Field Safety Notice has been provided to the appropriate Regulatory Agency in your country who is aware of these actions.

Thank you for your cooperation in this matter. LivaNova is committed to providing quality products and we apologize for any inconvenience this may have caused.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Galasso', is positioned above the printed name.

Barbara Galasso
Customer Quality Manager
Cardiopulmonary Equipment

Enclosed:

Attachment 1: Customer Response Form

Customer Response Form URGENT FIELD SAFETY NOTICE

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07, March 2019

According to our records, you have one or more 3T Heater-Cooler devices in your possession. Thank you for your cooperation for the execution of this action.

Please complete this Customer Response Form and return it to LivaNova – (Livanova.FSCA@postdienst.de; FAX +4989321995-55).at your earliest convenience, and if possible within one month after reception, to avoid repeated notification of this information.

Adverse reactions or quality problems experienced with the use of this product may be reported to LivaNova via your LivaNova representative [Phil.Smith@livanova.com].or directly to customerquality@livanova.com.

1. We have reviewed and understood the attached Field Safety Notice. The information and required actions have been brought to the attention of all relevant users:
 Yes No
2. We DO NOT understand the Field Safety Notice and/or request more information:
 Yes No

If "No" was indicated in answer to Question #1, or "Yes" to Question #2, please explain:

3. We have received the updated Operating Instructions described in this letter:
 Yes No

Facility Name: _____

Customer Name & Title: _____

City & Country: _____

Signature

Date