Records processed under FOIA Request 2023-9067; Released by CDRH on 05-23-2024

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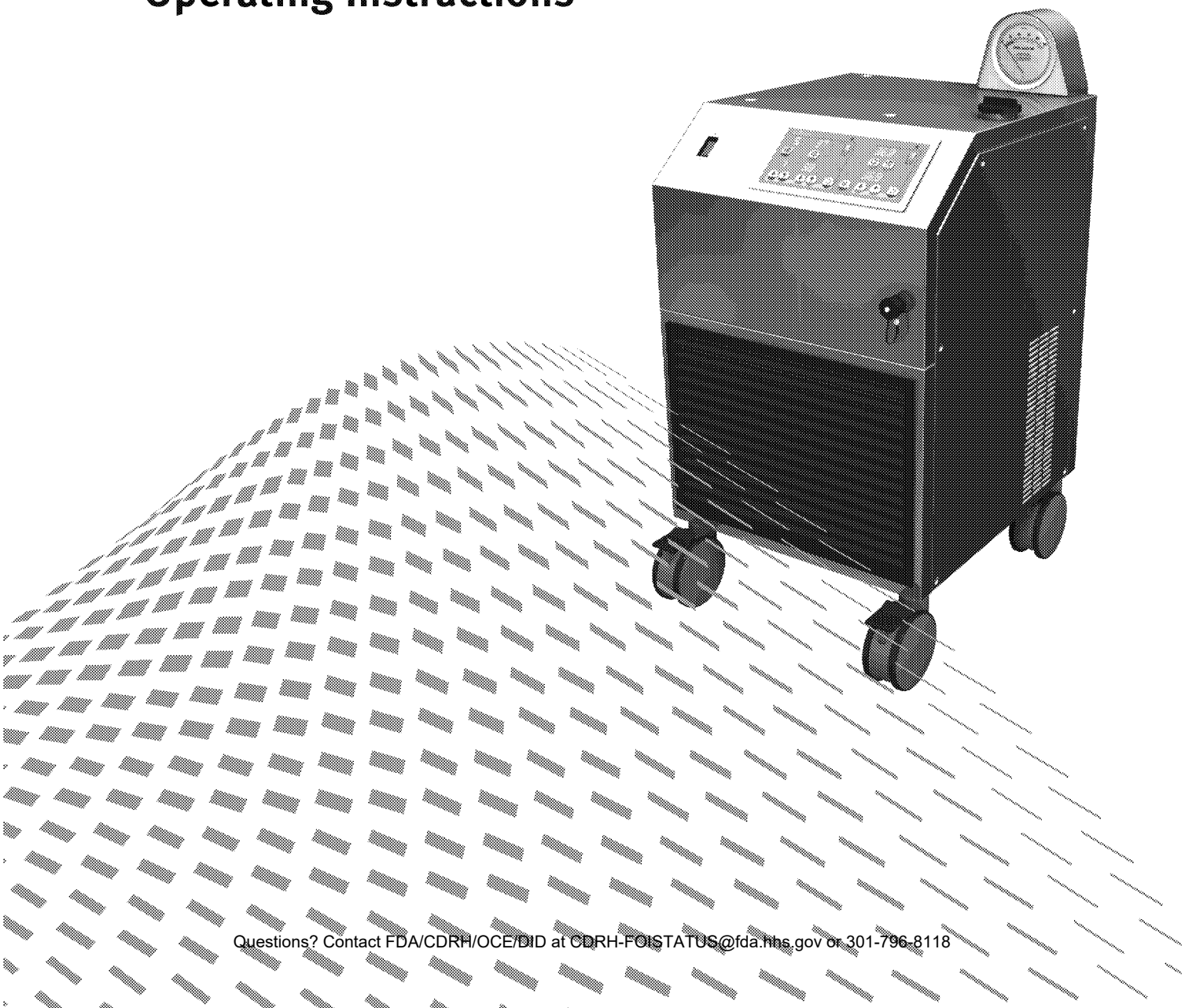
Heater-Cooler System 3T
Operating Instructions



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LivaNova
Health innovation that matters

March 3, 2022

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Subject: **Traditional 510(k) Premarket Notification**
Expansion of product servicing offer: Deep Cleaning
Brand name: (b)(4) Heater-Cooler System 3T
Manufacturer: LivaNova Deutschland GmbH

Attn: Nicole Gillette, Assistant Director (Acting), Cardiovascular Devices (OHT2) Circulatory Support, Structural and Vascular Devices (DHT2B)

Dear Madam/Sir:

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act ("FDC Act"), LivaNova PLC1 ("LivaNova" or the "Company"), is submitting the attached premarket notification ("510(k) Notification") to expand the Deep Cleaning service approved by FDA in April 2018 under 21 CFR 806 into general use, unrelated to corrections and removals.

The changes proposed in the current 510(k) include the offering of a Deep Cleaning service by LivaNova to customers. The Deep Cleaning process was approved for implementation under 21 CFR 806 by the FDA in April 2018 (b)(4) This 510(K) requests FDA clearance to offer the Deep Cleaning service outside of 21 CFR 806 conditions. The safety of the 3T Heater Cooler device is ensured by the regular disinfection and cleaning, monitoring of the bacteria levels and by the aerosol collection set, as described in the Operating Manual that was cleared in K191402. The Deep Cleaning service is intended to address cases where heavily contaminated devices cannot meet the acceptable level described in section 6.5.2 of the Operating Instructions. In this situation, to allow the device to return to clinical use, the customer may choose to return the device for the Deep Cleaning service. The Deep Cleaning service is intended to reduce bioburden levels within the water circuit, thereby reducing the risk of NTM Aerosolization in the clinical setting. There are no changes to design or intended use. We note that the documents contained herein were substantively reviewed by FDA under (b)(4) supplements S031 (2018) and K191402.

We have also included additional information as a follow-up from (b)(4) S031 in Attachment 1.1.

Prior 510(k) clearances for the subject device include K052601 and K191402.

3T Heater Cooler is not an in vitro diagnostic.

[1] LivaNova PLC is a U.K. holding company with a number of wholly-owned subsidiaries, including LivaNova Deutschland GmbH and Sorin Group Italia S.r.l. For this presentation, we will refer to all entities using the brand name LivaNova.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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LivaNova
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General information for the subject device is provided in the table below.

General Information	
Trade Name	(b)(4) Heater-Cooler System 3T
Common Name	Controller, Temperature, Cardiopulmonary Bypass
Predicate 510(k)	(b)(4) Heater-Cooler System 3T K191402
Product Code	DWC
Classification	Class II
Review Panel	Cardiovascular Devices (OHT2) Circulatory Support, Structural and Vascular Devices (DHT2B)
Manufacturer	LivaNova Deutschland GmbH
Registration #	9611109

This premarket notification is organized following the recommendations contained in the CDRH guidance titled Format for Traditional and Abbreviated 510(k)s (September 13, 2019). As recommended in the FDA guidance, a table summarizing the device design and use is provided in the following table.

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?		X
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?		X
Is the device implanted?		X

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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LivaNova

Health innovation that matters

The materials contained herein are considered confidential and proprietary materials by LivaNova. Consequently, the produced documents have been marked confidential, in their entirety, as nonpublic and confidential information and exempted from disclosure under the Freedom of Information Act by virtue of 18 U.S.C. § 1905. LivaNova asks that FDA notify us if any information produced by LivaNova is to be shared with any non-governmental entity or person. LivaNova asks to be given the opportunity to substantiate the confidentiality of any such document, and LivaNova reserves its rights to seek a protective order if the agency feels it is necessary to share any of these documents with a non-governmental entity or person.

One electronic copy ("eCopy") is being provided with this submission, and the eCopy is an exact duplicate of the paper copy.

To conform to the agency's September 13, 2019, Guidance for Industry and FDA Staff: Refuse to Accept Policy for 510(k)s, Attachment 3.1 of this submission includes the agency's Refuse to Accept checklist and a guide to where in the submission the elements required for a complete 510(k) submission per 21 C.F.R. 807.87 are located.

Thank you in advance for your consideration of our application. Should you have any questions on this submission, please feel free to contact me directly via email at:

Contact Information	
Primary contact person	**Alternate contact person**
Julia E. Leslie, PhD Sr Director, Regulatory Affairs, Cardiac Surgery Julie.Leslie@LivaNova.com	Florian Goetz Sr Regulatory Affairs Specialist Florian.Goetz@LivaNova.com

Sincerely,

(b)(6)

Julia E. Leslie, PhD
Sr Director, Regulatory Affairs, Cardiac Surgery
LivaNova

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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LivaNova Deutschland GmbH
Julia Leslie
Senior Director, Regulatory Affairs CS
Lindbergh Strasse 25
Munchen, BY 80939
Germany

Re: K220635
Trade/Device Name: (b)(4) Heater-Cooler System 3T
Regulation Number: 21 CFR 870.4250
Regulation Name: Cardiopulmonary bypass temperature controller
Regulatory Class: Class II
Product Code: DWC
Dated: October 12, 2022
Received: October 14, 2022

Dear Julia Leslie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for

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devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Nicole Gillette
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

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OPERATIONAL QUALIFICATION REPORT

(b)(4)

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Consult Memorandum

U.S. FOOD & DRUG ADMINISTRATION

Date: April 22, 2022

From: Jon Weeks, PhD.
Microbiologist
CDRH/OSEL/DBCMS

Elaine Mayhall, PhD.
Chemist
OHT4/DHT4B/THT4B2

To: Jacob Morand
Lead Reviewer
CDRH/OHT2/DHT2B/THT2B2

Subject: K220635
(b)(5) Heater-Cooler System 3T
LivaNova Deutschland GmbH

Scope: (b)(5)

Recommendation: (b)(5)

(b)(5)

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(b)(5)

Jon Weeks -S Digitally signed by Jon Weeks -S Date: 2022.04.22 15:02:00 -04'00'

Jon W. Weeks, PhD.
Microbiologist
CDRH/OSEL/DBCMS

Elaine S. Mayhall -S Digitally signed by Elaine S. Mayhall -S Date: 2022.04.26 10:07:42 -04'00'

Elaine Mayhall, PhD.
Chemist
CDRH/OHT4/DHT4B

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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10. DEVICE DESCRIPTION

The 3T System was originally cleared under K052601 on June 6, 2006, as a cardiopulmonary bypass temperature controller under regulation number 21 C.F.R. § 870.4250 (Product Code DWC). The 3T System operates by circulating heated or cooled water through circuits that regulate cardioplegia and patient temperature. The 3T System is cleared by FDA as a non-sterile device and is intended to be used in the non-sterile area of the user's facility. It is not possible or necessary to maintain sterility of the device or water circuit during device operation.

Clearance of K191402 allowed LivaNova to implement its (b)(4)

(b)(4)

This 510(k) notice included a full validation of the effectiveness of the disinfection process in the Operating Manual. Note that there have been no changes to the Final Configuration as cleared under K191402, including the risk mitigations or the disinfection process described in the Operating Manual.

The changes proposed in the current 510(k) include the offering of a Deep Cleaning service by LivaNova to customers. The Deep Cleaning process was approved for implementation under 21 CFR 806 by the FDA in April 2018 (b)(4) This 510(K) requests FDA clearance to offer the Deep Cleaning service outside of 21 CFR 806 conditions. The safety of the 3T Heater Cooler device is ensured by the regular disinfection and cleaning, monitoring of the bacteria levels and by the aerosol collection set, as described in the Operating Manual that was cleared in K191402. The Deep Cleaning service is intended to address cases where heavily contaminated devices cannot meet the acceptable level described in section 6.5.2 of the Operating Instructions. In this situation, to allow the device to return to clinical use, the customer may choose to return the device for the Deep Cleaning service. The Deep Cleaning service is intended to reduce bioburden levels within the water circuit, thereby reducing the risk of NTM Aerosolization in the clinical setting.. There are no changes to design or intended use.

10.1. INTENDED USE / INDICATIONS FOR USE

The Heater-Cooler 3T System is used to circulate water through heat exchangers to warm or cool a patient during cardiopulmonary bypass procedures lasting 6 hours or less.

10.2. GENERIC DEVICE GROUP

Product Code	DWC Controller, Temperature, Cardiopulmonary Bypass Regulation Number: 870.4250

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10.3. INTENDED USE ENVIRONMENT

There are no proposed changes to the intended use environment.

The Final Configuration of the 3T System is intended to be used with tubing between the 3T System and accessory devices not exceeding 5 meters in length.

10.4. SYSTEM OVERVIEW

Technological Characteristics

There are no proposed changes to the device design or functionality.

(b)(4)

Overview
The 3T System is a stand-alone, heating/cooling base unit that allows for the attachment of three (3) water circuits:

- One water circuit is for connection to the heat exchanger of an oxygenator, an accessory device.
- One water circuit is for connection to a heating/cooling blanket, an accessory device.
- One water circuit is for connection to the cardioplegia heat exchanger, an accessory device.

The Heater-Cooler 3T contains three (3) internal water tanks.

- One of the internal water tanks supplies both the oxygenator and the heating/cooling blanket circuits. This tank temperature can be set from (b)(4) Celsius.
- One of the internal water tanks supplies cold water to the cardioplegia circuit. This tank temperature can be set from (b)(4) degrees Celsius.
- One of the internal water tanks supplies warm water to the cardioplegia circuit. This tank temperature can be set from (b)(4) degrees Celsius.

The following components and accessories are also available for the 3T System:

1. Heating-cooling blankets
2. Various cables and water circuit tubing:
   - 25 meter length (b)(4) tube to allow the user to set up the three circuits (oxygenator, blanket and, cardioplegia).
   - Three (3) metal tubing connectors (½ inch, 90° angle) and three (3) metal tubing connectors (½ inch, straight) for connecting the water circuit tubing with the tubing for the oxygenator or other accessories (such as heating-cooling blankets).
   - Potential equalization cable (grounding cable).
   - Optional Controller Area Network (CAN) cable for communicating with heart-lung machines.

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To further mitigate the potential risk of airborne transmission of water circuit contaminants if the user fails to adequately perform the disinfection and water maintenance practices, LivaNova developed an aerosol mitigation solution (See Section Aerosol Mitigation Solution below).

3T System Base Unit

Sample illustrations of the 3T System are provided below. Specifically, Figure 1 provides a numbered illustration of the 3T System (Front and Rear). Numbers shown in Figure 10.4-1 are defined in Table 10.4-1.

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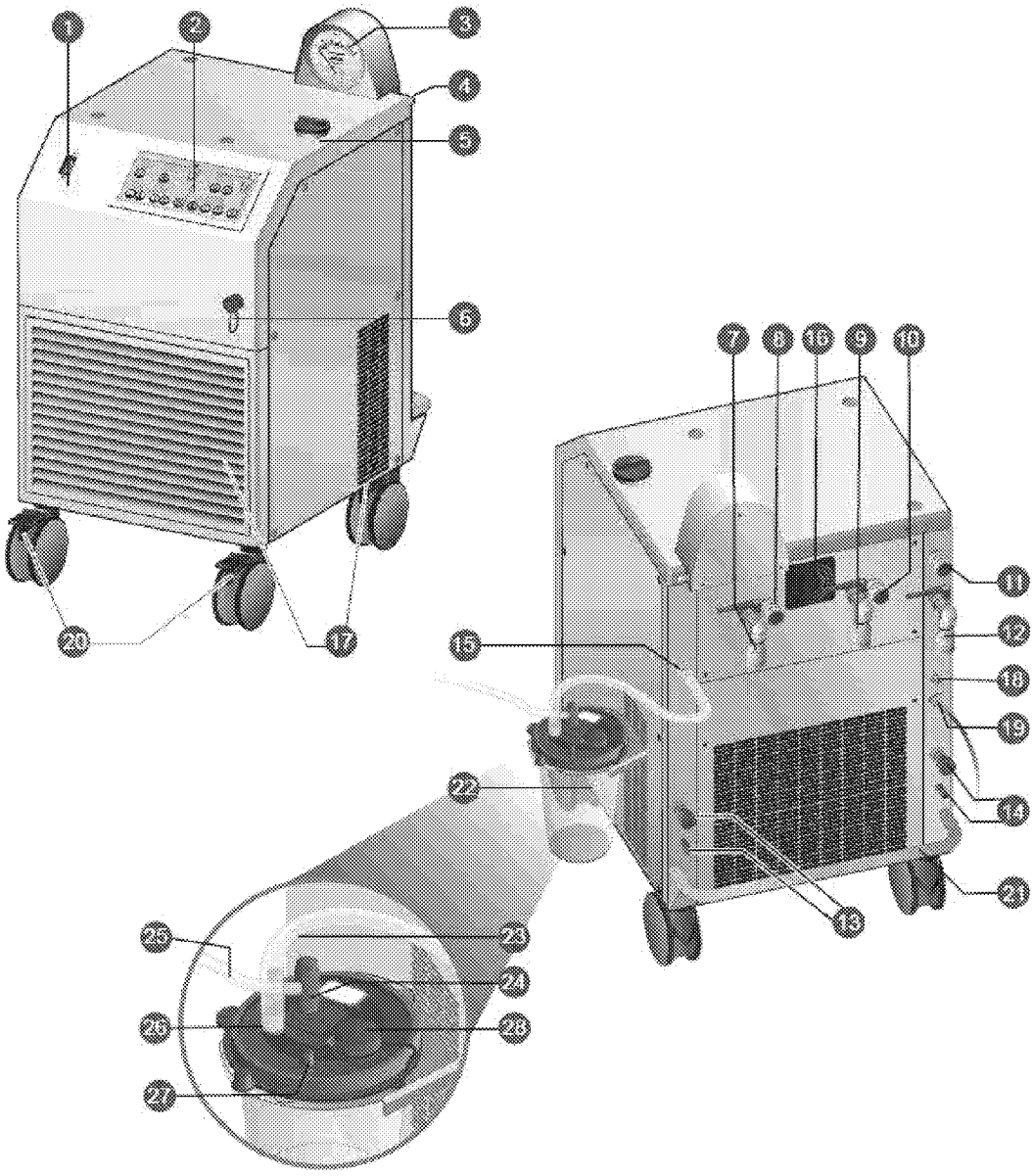

Figure 10.4-1 Numbered illustration of 3T System

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Item	Name	Function(s)
1	Mains power switch	(b)(4)
2	Control panel	
3	Vacuum gauge with scale	
4	Vacuum gauge service port	
5	Filler neck with cap	
6	CAN jack with cover	
7	Patient 2 circuit outlet connector with valve lever	
8	Patient 2 circuit inlet connector	
9	Patient 1 circuit outlet connector with valve lever	
10	Patient 1 circuit inlet connector	
11	Cardioplegia circuit inlet connector	
12	Cardioplegia circuit outlet connector with valve lever	

Table 10.4-1 Legend for Figure 10.4-1

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Item	Name	Function(s)
13	Patient 1, Patient 2 circuit drain valve	(b)(4)
14	Cardioplegia circuit drain valve	
15	Overflow outlet	
16	Fan	
17	Ventilation grill	
18	Potential equalization point	
19	Power cable	
20	Castors	
21	Bumper	
22	Aerosol collection container (with tubing)	
23	Connection line (short line)	
24	Vacuum port (V)	
25	Vacuum source line	
26	Patient port (P)	
27	Tandem port (T)	
28	Pour spout (S)	

Table 10.4-1 Legend for Figure 10.4-1, continued

The patient circuit module is composed o[redacted] (b)(4)

(b)(4)

The cardioplegia circuit module is compose[redacted] (b)(4)

(b)(4)

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(b)(4)

The cooling system consists of a (b)(4)

(b)(4)

Aerosol Mitigation Solution ***(Cleared under K191402)***

(b)(4)

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(b)(4)

Vacuum Canister and Internal Sealing Solution (Cleared under K191402)

(b)(4)

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Clinical-Use Diagram

There are no proposed changes to the clinical use.

The figure below provides a diagram as an overview and an example of a functional clinical set-up.

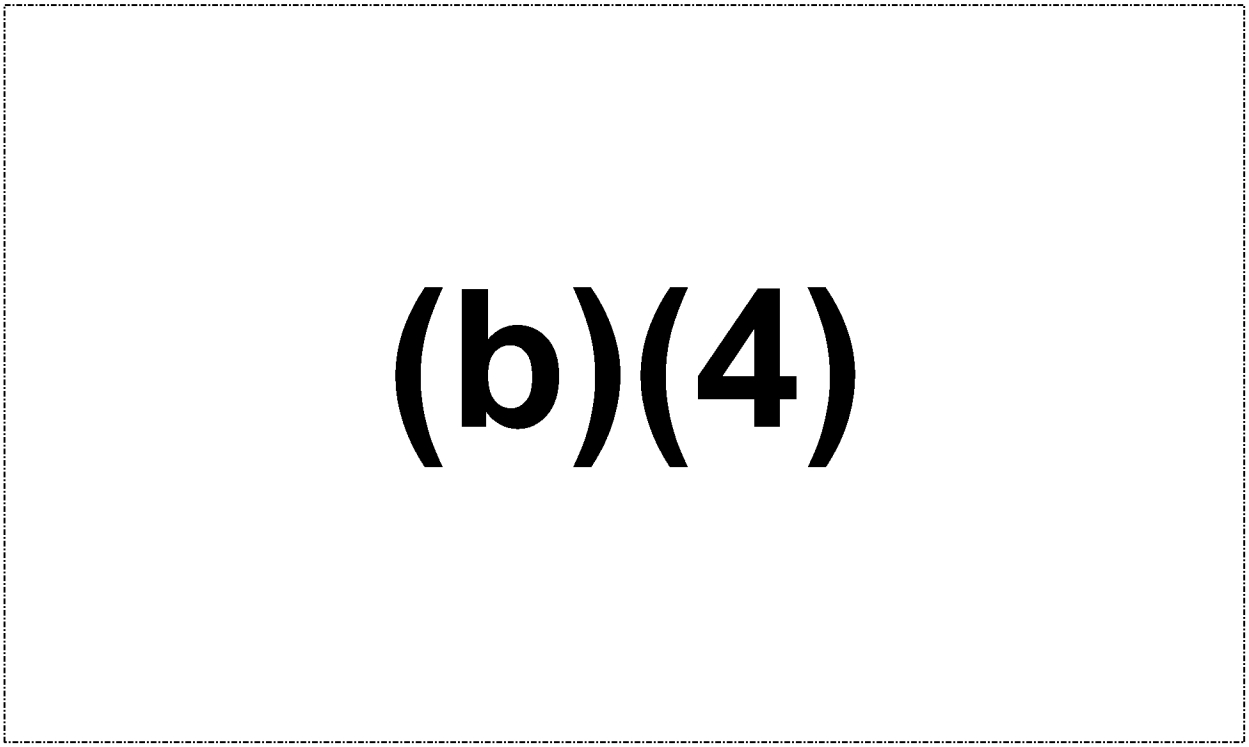
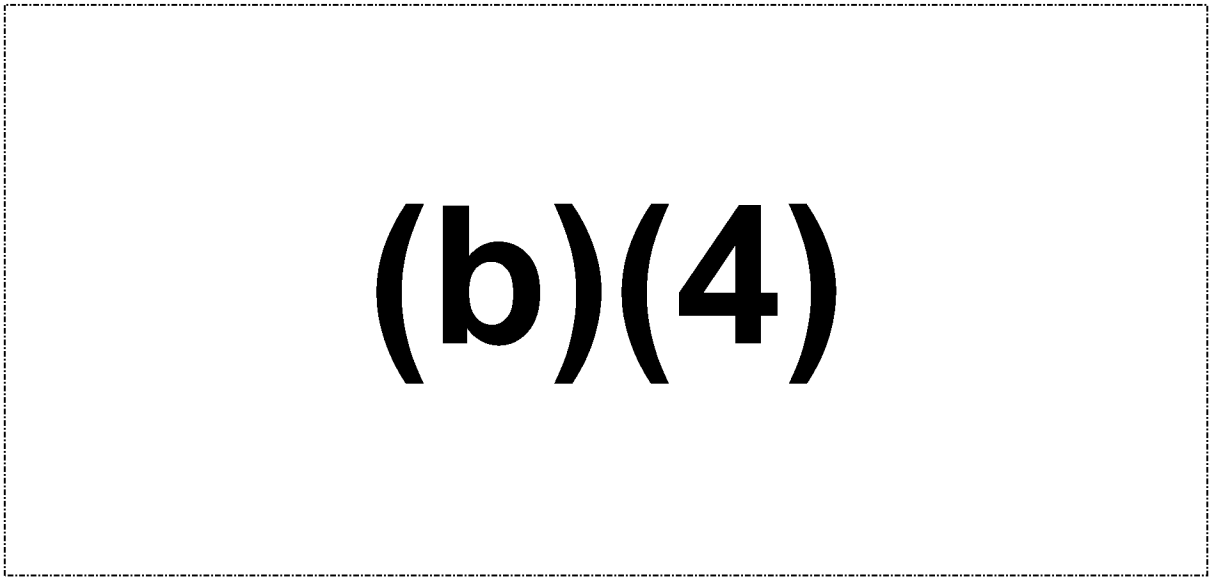


Figure 10.4-2 Example of a clinical-use set-up

Processing Steps of Interest



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(b)(4)

Proposed Deep Cleaning Process

LivaNova is proposing to offer customers an optional Deep Cleaning Process. The Deep Cleaning Process is controlled (b)(4) (b)(4) (Att 10.1) and (b)(4) (Att 10.2).

(b)(4)

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The Deep Cleaning Process in place at LivaNova Deutschland is described below.

Process Overview

(b)(4)

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(b)(4)

Additional Details Related to Steps of Interest:

(b)(4)

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Note: The Deep Cleaning Process is controlled within the Quality Management System in (b)(4). The SOP has been (b)(4) since it was submitted to FDA in (b)(4) S031 in January 2018.

The changes to the SOP are listed in the Revision History in the SOP.

Key updates are:

Rev.	CO	Description of Change

(b)(4)

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10.5. PRINCIPLES OF OPERATION

LivaNova submitted the 3T Deep Cleaning Process for review by the United States Food and Drug Administration ("FDA") in January 2018, and in April 2018 FDA allowed LivaNova to begin implementing the 3T Deep Cleaning Process in the US under 21 CFR 806. The 3T Deep Cleaning Process removes (b)(4)

(b)(4)

10.6. TECHNICAL CHARACTERISTICS

The main specifications of the 3T System are summarized in Table 10.6-1 below.

Table 10.6-1: Product Specifications

Dimensions, Weight and Operating Conditions	
Width	500 mm (19.8 inches)
Height	975 mm (38.4 inches)
Depth	680 mm (26.8 inches)
Weight (when empty)	100 kg (220.5 lbs.)
Operating temperature	(b)(4)
Storage temperature	
Relative humidity (operational and storage)	
Operating altitude (atmospheric pressure)	
Electrical Specifications	
Drip proof	(b)(4)
Input current	16 A
Input voltage (variants are device specific)	208V (±10%)/ 60 Hz 120V (±10%)/ 60 Hz
General Performance	
Heating performance	(b)(4)
Cooling performance	
Noise level	
Minimum level patient circuit	
Maximum level patient circuit	
Water flow for patient circuits	
Water flow for cardioplegia circuit	
Water pressure in circuits	
Normal range patient circuit	
Normal range cardioplegia cooling circuit	
Normal range cardioplegia warming circuit	

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Software Description

(b)(4)

As an optional feature of LivaNova's heart-lung machine models S5 and C5 Systems, the 3T System can be connected to these heart lung machine systems via the CAN connecting cable.

Control Functions for the Hypothermia Feature
For the hypothermia feature, the software controls the following:

(b)(4)

Control Functions for the Cardioplegia Feature
For the cold cardioplegia feature, the software controls the following:

(b)(4)

For the warm cardioplegia feature, the software controls the following:

(b)(4)

Monitoring Functions
Various monitoring functions, self-tests, and self-diagnostic functions can trigger errors or alarms. (b)(4)

(b)(4)

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(b)(4)

Components and Accessories

(b)(4).

a) Heating-Cooling Blankets

The 3T System can be used simultaneously for heating or cooling the oxygenator's heat exchanger and heating / cooling blankets. (b)(4)

(b)(4)

b) Water Circuit Tubing

The water circuit tubing and connectors consists of a 25 meter length (b)(4) tube to allow the user to set up the three circuits (oxygenator, blanket and, cardioplegia). The 25 meter length PE tube is cut by the user to a desired length with a maximum length of 5 meters from the 3T System to the accessory per the proposed Operating Instructions. The water circuit also includes stainless steel hose connectors with a male plug (three (3) straight connectors and three (3) angled connectors having a diameter of ½ inch) for 3T System outlet/inlet water circuit connection.

c) Cables

The electrical cables consist of a ground connection for electrical discharge, and an optional CAN connecting cable to allow serial communication between the 3T System and a heart lung machine.

d) Remote Operation

As an optional feature of LivaNova's heart-lung machine models S5 and C5 Systems, the 3T System can be connected to a heart lung machine via a CAN connecting cable. This optional feature allows a user to perform certain of the basic functions of the 3T System by operating the S5 and C5 Systems using tubing of lengths up to 5 meters. These functions include (1) starting, stopping, and putting into standby mode the patient circuits and cardioplegia circuit; (2) entering set values for the temperatures of the circuits; and (3) providing indication of an error condition that would be displayed on the 3T System.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

10.7. MATERIALS

(b)(4)

3T Heater Cooler equipment is non-invasive medical electrical equipment. 3T Heater Cooler does not come into physical contact with the patient; it has no applied parts.
The device is constructed from a range of metals and polymers.

From an electrical point of view, no electrical current can be transmitted to the patient.

10.7.1. TISSUE-CONTACTING COMPONENTS AND THEIR MATERIALS

Not applicable. No components of the 3T Heater Cooler are tissue or blood-contacting.

10.8. PACKAGING CONFIGURATION

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

(b)(4)

10.9. LABELING

(b)(4)

3T Heater Cooler equipment is accompanied with operating instructions, product labels, and packaging labels, provided with each shipment.

The cleared labeling is provided in **Section 13.**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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LivaNova

Health innovation that matters

October 12, 2022

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Subject: **Response to AINN K220635**
(Traditional 510(k) Premarket Notification)
Expansion of product servicing offer: Deep Cleaning
Brand name: (b)(4) Heater-Cooler System 3T
Manufacturer: LivaNova Deutschland GmbH

Attn: Nicole Gillette, Assistant Director (Acting), Cardiovascular Devices (OHT2) Circulatory Support, Structural and Vascular Devices (DHT2B)

Dear Madam/Sir:

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act ("FDC Act"), LivaNova PLC1 ("LivaNova" or the "Company"), is submitting responses to the AINN received for K220635 related to expand the Deep Cleaning service approved by FDA in April 2018 under 21 CFR 806 into general use, unrelated to corrections and removals.

(b)(4)

Prior 510(k) clearances for the subject device include K052601 and K191402.

3T Heater Cooler is not an in vitro diagnostic.

General information for the subject device is provided in the table below.

General Information	
Trade Name	(b)(4) Heater-Cooler System 3T
Common Name	Controller, Temperature, Cardiopulmonary Bypass
Predicate 510(k)	(b)(4) Heater-Cooler System 3T **K191402**
Product Code	DWC
Classification	Class II

[1] LivaNova PLC is a U.K. holding company with a number of wholly-owned subsidiaries, including LivaNova Deutschland GmbH and Sorin Group Italia S.r.l. For this presentation, we will refer to all entities using the brand name LivaNova.

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LivaNova

Health innovation that matters

Review Panel	Cardiovascular Devices (OHT2) Circulatory Support, Structural and Vascular Devices (DHT2B)
Manufacturer	LivaNova Deutschland GmbH
Registration #	9611109

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One electronic copy ("eCopy") is being provided with this submission, and the eCopy is an exact duplicate of the paper copy.

Thank you in advance for your consideration of our application. Should you have any questions on this submission, please feel free to contact us directly via email at:

Contact Information	
Primary contact person **(out of office October 20- Nov 1, 2022)**	**Alternate contact person**
Julia E. Leslie, PhD Sr Director, Regulatory Affairs, Cardiac Surgery Julie.Leslie@LivaNova.com	Florian Goetz Sr Regulatory Affairs Specialist Florian.Goetz@LivaNova.com

Sincerely,

(b)(6)

Julia E. Leslie, PhD
Sr Director, Regulatory Affairs, Cardiac Surgery
LivaNova

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LivaNova Deutschland GmbH

3T Heater Cooler Deep Cleaning

AINN RESPONSE
K220635

Lindberghstr. 25
80939 Munich
Germany

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: Leslie, Julie <julie.leslie@livanova.com>
Sent: Tuesday, November 8, 2022 7:12 AM
To: Morand, Jacob <Jacob.Morand@fda.hhs.gov>; Goetz, Florian <Florian.Goetz@livanova.com>
Subject: [EXTERNAL] RE: K220635-S001 Interactive Review

CAUTION. This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Jacob,

Attached please find the (b)(4)

(b)(4)

OLD:

Text, letter

Description automatically generated

NEW:

Thanks for your review,

Julie

From: Leslie, Julie
Sent: Monday, November 7, 2022 10:12 AM
To: Morand, Jacob <Jacob.Morand@fda.hhs.gov>; Goetz, Florian <Florian.Goetz@livanova.com>
Subject: RE: K220635-S001 Interactive Review

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-9067; Released by CDRH on 05-23-2024

Hi Jacob,

Thank you, and apologies for the late response. We are preparing (b)(4) and will have it to you by the deadline.

Please let us know if there are any other requests during the interactive review.

Thanks,
Julie

From: Morand, Jacob <Jacob.Morand@fda.hhs.gov>
Sent: Monday, October 31, 2022 6:49 PM
To: Goetz, Florian <Florian.Goetz@livanova.com>; Leslie, Julie <julie.leslie@livanova.com>
Subject: [EXTERNAL] K220635-S001 Interactive Review

Hello Florian and Julie,

(b)(4)

Best,

Jacob Morand
Lead Reviewer

Center for Devices & Radiological Health
U.S. Food and Drug Administration
White Oak Bldg 66, New Hampshire Ave, Silver Spring, MD 20993
Phone: 1 (301) 796-1127
Jacob.Morand@fda.hhs.gov

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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K220635/S001

October 12, 2022

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Subject: Response to AINN K220635
(Traditional 510(k) Premarket Notification)
Expansion of product servicing offer: Deep Cleaning
Brand name: (b)(4) Heater-Cooler System 3T
Manufacturer: LivaNova Deutschland GmbH

Attn: Nicole Gillette, Assistant Director (Acting), Cardiovascular Devices (OHT2) Circulatory Support, Structural and Vascular Devices (DHT2B)

Dear Madam/Sir:

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act ("FDC Act"), LivaNova PLC[1] ("LivaNova" or the "Company"), is submitting responses to the AINN received for K220635 related to expand the Deep Cleaning service approved by FDA in April 2018 under 21 CFR 806 into general use, unrelated to corrections and removals.

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Prior 510(k) clearances for the subject device include K052601 and K191402.

3T Heater Cooler is not an in vitro diagnostic.

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General Information	
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Common Name	Controller, Temperature, Cardiopulmonary Bypass
Predicate 510(k)	(b)(4) Heater-Cooler System 3T K191402
Product Code	DWC
Classification	Class II

[1] LivaNova PLC is a U.K. holding company with a number of wholly-owned subsidiaries, including LivaNova Deutschland GmbH and Sorin Group Italia S.r.l. For this presentation, we will refer to all entities using the brand name LivaNova.

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Health innovation that matters

Review Panel	Cardiovascular Devices (OHT2) Circulatory Support, Structural and Vascular Devices (DHT2B)
Manufacturer	LivaNova Deutschland GmbH
Registration #	9611109

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One electronic copy ("eCopy") is being provided with this submission, and the eCopy is an exact duplicate of the paper copy.

Thank you in advance for your consideration of our application. Should you have any questions on this submission, please feel free to contact us directly via email at:

Contact Information	
Primary contact person **(out of office October 20- Nov 1, 2022)**	**Alternate contact person**
Julia E. Leslie, PhD Sr Director, Regulatory Affairs, Cardiac Surgery Julie.Leslie@LivaNova.com	Florian Goetz Sr Regulatory Affairs Specialist Florian.Goetz@LivaNova.com

Sincerely,

(b)(6)

Julia E. Leslie, PhD
Sr Director, Regulatory Affairs, Cardiac Surgery
LivaNova

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Document Number : (b)(4)

Document Revision : (b)(4)

Document Title : (b)(4)
Label for Heater Cooler

Effective Date: 05 Nov 2021

Expiration Date:

Notes :

Previous Number: **Change Number:** (b)(4)

Document Type: (b)(4)

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Signature Manifest

Document Number (b)(4) **Revision:** (b)(4)

Title: (b)(4) Label for Heater Cooler

All dates and times are in Central European Time.

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Label-Nr. [Label-No.]	(b)(4)

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1. Label Material / label material

(b)(4)

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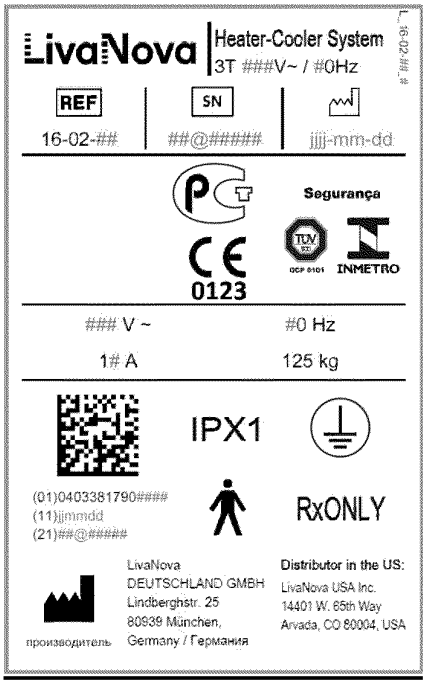
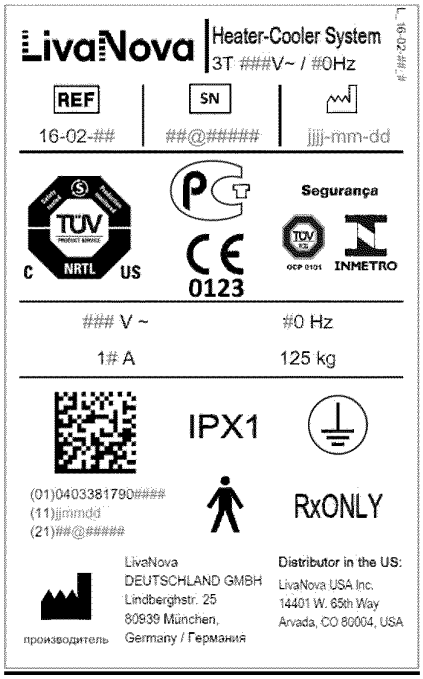
2. Label Inhalt / label content

(b)(4)

Layout A



Layout B



Label ID	Revision	REF	DI (01)	[V]	[Hz]	[A]	Layout

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PERFORMANCE QUALIFICATION (PQ) PROTOCOL

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2021-8077 Released by CDRH on 05-23-2024

Installation Qualification (IQ)

Peracetic Acid Disinfection

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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5.0 510(k) SUMMARY

The Company's 510(k) Summary is provided on the following pages.

Records processed under FOIA Request 2023-9067; Released by CDRH on 05-23-2024

510(k) SUMMARY

(b)(4)

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-9067; Released by CDRH on 05-23-2024

From: Leslie, Julie <julie.leslie@livanova.com>
Sent: Friday, April 22, 2022 8:43 AM
To: Morand, Jacob <Jacob.Morand@fda.hhs.gov>
Subject: [EXTERNAL] RE: K220635 Interactive Review Questions

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Hello,

Please find attached LivaNova's responses to the interactive review questions. Please let me know if there are any further requests.

Have a good weekend,

Julie Leslie, PhD
Director, Regulatory Affairs, Cardiac Surgery

julie.leslie@livanova.com
www.livanova.com

From: Leslie, Julie
Sent: Wednesday, April 20, 2022 2:14 PM
To: Morand, Jacob <Jacob.Morand@fda.hhs.gov>
Subject: RE: K220635 Interactive Review Questions

Hello,

Thank you for the interactive questions. We received them and will provide you responses by Friday.

Many thanks,

Julie Leslie, PhD
Director, Regulatory Affairs, Cardiac Surgery

julie.leslie@livanova.com
www.livanova.com

From: Morand, Jacob <Jacob.Morand@fda.hhs.gov>
Sent: Tuesday, April 19, 2022 4:35 PM
To: Leslie, Julie <julie.leslie@livanova.com>
Subject: [EXTERNAL] K220635 Interactive Review Questions

Ms. Leslie,

I hope this email finds you well. I am Jacob Morand the Lead Reviewer with the FDA. While going over the submission, the team had a few questions. Please see below:

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-9067; Released by CDRH on 05-23-2024

(b)(4)

Please provide a response by Friday 04/22/2022.

Thank You,

Jacob Morand
Lead Reviewer

Center for Devices & Radiological Health
U.S. Food and Drug Administration
White Oak Bldg 66, New Hampshire Ave, Silver Spring, MD 20993
Phone: 1 (301) 796-1127
Jacob.Morand@fda.hhs.gov

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From: Leslie, Julie <julie.leslie@livanova.com>

Sent: Wednesday, November 9, 2022 9:59 AM

To: Morand, Jacob <Jacob.Morand@fda.hhs.gov>

Subject: RE: [EXTERNAL] RE: K220635-S001 Interactive Review

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Hi Jacob,

Please see the attached (b)(4) copy.

(b)(4)

Let me know if there are any other requests.

Thanks,

Julie

From: Morand, Jacob <Jacob.Morand@fda.hhs.gov<mailto:Jacob.Morand@fda.hhs.gov>>

Sent: Wednesday, November 9, 2022 3:43 PM

To: Leslie, Julie <julie.leslie@livanova.com<mailto:julie.leslie@livanova.com>>

Subject: RE: [EXTERNAL] RE: K220635-S001 Interactive Review

Julie,

(b)(4)

Best,

Jacob

From: Leslie, Julie <julie.leslie@livanova.com<mailto:julie.leslie@livanova.com>>

Sent: Tuesday, November 8, 2022 7:12 AM

To: Morand, Jacob <Jacob.Morand@fda.hhs.gov<mailto:Jacob.Morand@fda.hhs.gov>>; Goetz,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-9067; Released by CDRH on 05-23-2024

Florian <Florian.Goetz@livanova.com<mailto:Florian.Goetz@livanova.com>>

Subject: [EXTERNAL] RE: K220635-S001 Interactive Review

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Hi Jacob,

(b)(4)

Thanks for your review,

Julie

From: Leslie, Julie

Sent: Monday, November 7, 2022 10:12 AM

To: Morand, Jacob <Jacob.Morand@fda.hhs.gov<mailto:Jacob.Morand@fda.hhs.gov>>; Goetz, Florian <Florian.Goetz@livanova.com<mailto:Florian.Goetz@livanova.com>>

Subject: RE: K220635-S001 Interactive Review

Hi Jacob,

Thank you, and apologies for the late response. We are preparing the updated (b)(4) and will have it to you by the deadline.

Please let us know if there are any other requests during the interactive review.

Thanks,

Julie

From: Morand, Jacob <Jacob.Morand@fda.hhs.gov<mailto:Jacob.Morand@fda.hhs.gov>>

Sent: Monday, October 31, 2022 6:49 PM

To: Goetz, Florian <Florian.Goetz@livanova.com<mailto:Florian.Goetz@livanova.com>>; Leslie, Julie <julie.leslie@livanova.com<mailto:julie.leslie@livanova.com>>

Subject: [EXTERNAL] K220635-S001 Interactive Review

Hello Florian and Julie,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-9067; Released by CDRH on 05-23-2024

(b)(4)

Please provide updated (b)(4) for review by 11/10/2022. Happy to chat further to address any questions related to this request.

Best,

Jacob Morand

Lead Reviewer

Center for Devices & Radiological Health

U.S. Food and Drug Administration

White Oak Bldg 66, New Hampshire Ave, Silver Spring, MD 20993

Phone: 1 (301) 796-1127

Jacob.Morand@fda.hhs.gov<mailto:Jacob.Morand@fda.hhs.gov>

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_____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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9.0 DECLARATIONS OF CONFORMITY AND SUMMARY TEST REPORTS

LivaNova is not declaring conformity with any FDA recognized consensus standards. Accordingly, no declaration of conformity consistent with FDA's guidance document entitled, "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices" (September 14, 2018) is provided in this submission.

The following standards were utilized in the development of the Final Configuration 3T System:

Standard	Title	FDA recognition number
IEC 60601-1 2005 A1:2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	19-4
IEC 60601-1-2 Edition 4.0 2014	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests	19-8
IEC 62366-1 Edition 1.0 2015	Medical devices - Part 1: Application of usability engineering to medical devices	5-114
IEC 62304 Edition 1.1 2015	Medical device software - Software life cycle processes	13-79
ISO 14971 Third Edition 2019	Medical devices - Application of risk management to medical devices	5-125
EN 55011/CISPR 11 2009+A1:2010	Industrial scientific and medical (ISM) radio-frequency equipment - Electromagnetic disturbance characteristics - Limits and methods of measurement	NR
IEC 61000-3-2 2005+A1:2008+A2:2009	Harmonic current emissions	NR
IEC 61000-4-2 2008	Electrostatic discharge immunity test (ESD)	NR
IEC 61000-4-3 2006+A1:2007+A2: 2010	Radiated, radio-frequency, electromagnetic field immunity test	NR
IEC 61000-4-4 2012	Electrical fast transient / burst immunity test (BURST)	NR
IEC 61000-4-5 2005	Surge immunity test (Surge)	NR
IEC 61000-4-6 2013	Immunity to conducted disturbances, induced by radio-frequency fields	NR
IEC 61000-4-8 2009	Power frequency magnetic field immunity test	NR

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IEC 61000-4-11 2004	Voltage dips, short interruptions and voltage variations immunity test	NR
ISTA 1A 2014	Integrity Performance Test Procedure for Packaged Products 150 lbs (68 kg) or Less	NR
ISTA 2B 2012	Integrity Performance Test Procedure for Packaged Products over 150 lbs (68 kg)	NR
EN ISO 11607-1 2009+A1:2014	Packaging for terminally Sterilized medical devices, Part 1: Requirements for materials, sterile barrier systems and packaging systems	14-530
IEC 60529 2001	Degrees of protection provided by enclosures	NR
ASTM F960 V86	Standard Specification for Medical and Surgical Suction and Drainage Systems	NR
ASTM F1980 V07	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical	14-497
AAMI HE75 2009	Human Factors Engineering - Section 9 - Usability Testing	5-57
ANSI/AAMI/IEC 62366-1 2015	Medical devices - Part 1: Application of Usability Engineering to Medical Devices	5-114
ASTM G71-81 2014	Standard Guide for Conducting and Evaluating Galvanic Corrosion Tests in Electrolytes	NR
ASTM G46-94 2018	Standard Guide for the Examination of Pitting Corrosion	NR
ANSI/ASHRAE/ASHE 170 2017	Ventilation of Health Care Facilities	NR
F2101-19	Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of *Staphylococcus aureus*	6-427
ANSI/ASHRAE Addendum b to ANSI/ASHRAE Standard 52.2 2007	Method of Testing General Ventilation Air-Cleaning Devices for Removal Efficiency by Particle Size	NR

Table 9.1.-1 List of utilized and/or recognized consensus standards

The extent to which each of these consensus standards was utilized in the Company's performance testing is described in the test reports.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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510(k) SUMMARY

I. SUBMITTER

Name:	LivaNova Deutschland GmbH
Address:	Lindberghstrasse 25 D-80939 München, Germany
Establishment Registration Number	9611109
Contact Person:	Julia E. Leslie, PhD
Phone:	+49 89 323 01 141
Email:	julie.leslie@livanova.com
Secondary Contact:	Florian Goetz
Phone:	+49 89 323 01 236
Email:	florian.goetz@livanova.com
Date Prepared:	February 28, 2022

II. DEVICE

Proprietary Name:	Heater-Cooler System 3T
Common Name:	Cardiopulmonary bypass temperature controller
Classification Name:	Controller, Temperature, Cardiopulmonary Bypass
Regulation Number:	21 CFR 870.4250
Product Code:	DWC
Device Class:	Class II

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III. PREDICATE DEVICE INFORMATION

Heater-Cooler System 3T with the Deep Cleaning service is substantially equivalent in function and intended use to **Heater-Cooler System 3T (K191402).**

IV. INDICATIONS FOR USE

The Heater-Cooler System 3T is used to circulate water through heat exchangers to warm or cool a patient during cardiopulmonary bypass procedures lasting 6 hours or less.

V. DEVICE DESCRIPTION

The Heater-Cooler System 3T is an independent (i.e., independent of the water supply) 3-circuit heating/cooling base unit that includes three water circuits (two circuits for the patient supplied by one tank (for the heating/cooling blanket, the oxygenator) and one interchangeable heating/cooling circuit for cardioplegia. If required, patient and cardioplegia circuits can be switched off separately, in order to increase the activated functional group's heating and/or cooling performance.

The following optional components and accessories are also available for the Heater-Cooler System 3T:

1. Heating-cooling blankets;
2. Water circuit tubing; and
3. Various cables.

The Heater-Cooler System 3T includes a disposable aerosol collection set that consists of a canister connected to the Heater-Cooler System 3T and the user facility's vacuum source that captures emissions that are drawn from the tank using negative pressure created by the user facility's vacuum.

The changes proposed in the current 510(k) include the offering of a Deep Cleaning service by LivaNova to customers. The safety of the Heater-Cooler System 3T is ensured by the regular disinfection and cleaning, monitoring of the bacteria levels and by the aerosol collection set, as described in the Operating Manual that was cleared in K191402. The Deep Cleaning service is intended to address cases where heavily contaminated devices cannot meet the acceptable level described in section 6.5.2 of the Operating Instructions. In this situation, to allow the device to return to clinical use, the customer may choose to return the device for the Deep Cleaning service. The Deep Cleaning service is intended to reduce bioburden levels within the water circuit, thereby reducing the risk of NTM Aerosolization in the clinical setting. There are no changes to design or intended use.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Heater-Cooler System 3T and its predicate have the same intended use, clinical setting, target user, target patient population, and principle of operation.

VII. PERFORMANCE DATA

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The following non-clinical testing was performed to support the substantial equivalence of the Heater-Cooler System 3T, with the Deep Cleaning service, to its legally marketed predicate device:

- Process Validation of Deep Cleaning service
  - Installation Qualification
  - Operational Qualification
  - Process Qualification

Animal testing was not required to demonstrate the substantial equivalence of the Heater-Cooler System 3T to its predicate device and is not included as part of this premarket notification.

Clinical testing was not required to demonstrate the substantial equivalence of the Heater-Cooler System 3T to its predicate device and is not included as part of this premarket notification.

VIII. CONCLUSION

Based on the indications for use, technological characteristics, results of non-clinical testing, and comparison to predicate devices, the Heater-Cooler System 3T with the Deep Cleaning service is substantially equivalent to its predicate device (K191402).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Contains Nonbinding Recommendations

Print Form

510(k) Acceptance Checklist

Not for use with Third Party 510(k)s

Choose Submission Type: ☒ **Traditional** ☐ **Abbreviated** ☐ **Special**

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k) #: K Date Received by DCC:

Lead Reviewer:

Center: Office: Division:

Decision:

○ Accept. If Accept, notify submitter.

○ Refuse to Accept. If Refuse to Accept, notify submitter electronically and include a copy of this checklist.

Is an Addendum attached?: ○ Yes ◉ No Click paperclip icon on the left panel if Addendum is attached.

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during substantive review.

IMPORTANT - Many checklist elements include additional details regarding information to address the element that can be seen by hovering over the element (Example - Element 4 in Section A of the checklist).

Preliminary Questions

Answers in the shaded blocks indicate consultation with a Center advisor is needed. (Boxes checked in this section represent FDA's preliminary assessment of these questions at the time of administrative review.)	Yes	No	N/A
1 Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product (per 21 CFR 3.2(e)), or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action, and inform management. *Provide a summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* If the product does not appear to be a device or such a combination product, mark "No."	☒	☐	
Comments:			
2 Is the submission with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the submission is not with the appropriate Center or you are unsure, consult with the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide a summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* If submission should not be reviewed by your Center mark "No."	☒	☐	
Comments:			

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3 If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: **a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?** **b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?** If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide a summary of Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* If the answer to either question above is no, mark "No." If there was no RFD, mark "N/A."	☐	☐	☒
Comments:			
4 Is the submission for a combination product that contains as a constituent part a drug that has the same active moiety as an approved drug with exclusivity as described in 21 USC 503(g)(5)(C)(ii)-(v) (section 503(g)(5)(C)(ii)-(v) of the FD&C Act)? If "Yes," then contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide the summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.*	☐	☒	☐
Comments:			
5 Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), consult with the appropriate CDRH or CBER staff during the acceptance review, provide a summary of the discussion with them, and indicate their recommendation/action in the comment section below. If 510(k) is not the appropriate regulatory submission, mark "No."	☒	☐	
Comments: Class II, Product Code DWC			
6 Is there a pending PMA for the same device with the same indications for use? If "Yes," consult your management and CDRH Office of Product Evaluation and Quality/Office of Regulatory Programs/Division of Regulatory Programs 1 (Submission Support) (OPEQ/ORP/DRP1) or appropriate CBER staff to determine the appropriate action.	☐	☒	
Comments:			
7 If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If "Yes," consult with the CDRH Office of Product Evaluation and Quality/ Office of Clinical Evidence and Analysis/Division of Clinical Science and Quality (OPEQ/OCEA/DCEA1) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action, provide a summary of the discussion with them, and indicate their recommendation/action. If no clinical studies have been submitted, mark "N/A." Check on the AIP list at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/application-integrity-policy/application-integrity-policy-list.	☐	☐	☒
Comments:			

- If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.
- If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.
- If the answer to 4 is "Yes," then contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer, provide a summary of the discussion with them, and indicate their recommendation/action.
- If the answer to 5 is "No," the lead reviewer should consult management and other Center resources to determine the appropriate action.
- If the answer to 6 is "Yes," then stop review of the 510(k), contact the CDRH/OPEQ/ORP/DRP1, or appropriate CBER staff.
- If the answer to 7 is "Yes," then contact CDRH/OPEQ/OCEA/DCEA1 or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with DCEA1 or BMB Staff, and indicate their recommendation/action.

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Organizational Elements

Failure to include these items should not result in an RTA designation.

*Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	*Page #
1) Submission contains a Table of Contents	☒	☐	3-5
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	☒	☐	all
3) All pages of the submission are numbered. *All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2…).*	☒	☐	
4) Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special). *If type of 510(k) is not designated, review as a Traditional 510(k).*	☒	☐	3-1
Comments: see cover letter			

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during RTA review.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
A. Administrative					
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	☒	☐		☐	
2) Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form (Form 3514, available at https://www.fda.gov/media/72421/download)):				☒	
a) Device trade/proprietary name	☒	☐			3-1
b) Device class and panel OR Classification regulation OR Statement that device has not been classified with rationale for that conclusion	☒	☐			3-2
Comments: see cover letter					
3) Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance "Alternative to Certain Prescription Devices Labeling Requirements," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/alternative-certain-prescription-device-labeling-requirements.) *See recommended* format (https://www.fda.gov/media/86323/download).	☒	☐		☐	4-1
4) Submission contains a 510(k) Summary or 510(k) Statement.	☒	☐		☐	5-1
5) Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(l) *See recommended format (https://www.fda.gov/medical-devices/premarket-notification-510k/premarket-notification-truthful-and-accurate-statement).*	☒	☐		☐	6-1
6) Submission is a Class III 510(k) device.	☐		☒	☐	
7) Submission contains clinical data	☐		☒	☐	
8) The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Q-Submission, IDE, PMA, etc.). **OR** States that there were no prior submissions for the subject device.	☒	☐		☐	3-1
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed.	☒	☐	☐		12-1
9) The submission utilizes voluntary consensus standard(s) (See section 514(c) of the FD&C Act). *This includes both FDA-recognized and non-recognized consensus standards.*	☒		☐	☐	9-1
a) The submission cites FDA-recognized voluntary consensus standard(s).	☒		☐		9-1

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
i) The submission includes a Declaration of Conformity (DOC) as outlined in FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices. **OR** If citing general use of a standard as noted in FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," the basis of such use is included along with the underlying information or data that supports how the standard was used.	☒	☐			9-1
b) The submission cites non-FDA-recognized voluntary consensus standard(s).	☒		☐		
i) The basis of use is included along with the underlying information or data that supports how the standard was used.	☒	☐			
Combination Product Provisions - Per 503(g) of the FD&C Act. Select "N/A" if the product is not a combination product. 21 CFR 3.2(e). The remaining criteria in this section will be omitted from the checklist if "N/A" is selected. If you are unsure if the product is a combination product, consult with the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.			☒		
B. Device Description					
12) The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding the device description that is applicable to the subject device.	☐		☒	☐	
13) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).	☒	☐		☒	10
Comments: Operating Instructions attachments 13.1,13.2 and 13.3					
14) The submission includes descriptive information for the device, including the following:				☐	
a) A description of the principle of operation or mechanism of action for achieving the intended effect.	☒	☐			10
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	☒	☐	☐		10
c) A list and description of each device for which clearance is requested.	☒	☐	☐		10
d) Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. **OR** Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device).	☒	☐			10
15) Device is intended to be marketed with accessories and/or as part of a system.	☒		☐	☐	
a) Submission includes a list of all accessories to be marketed with the subject device.	☒	☐			10
b) Submission includes a description (as detailed in item 14(a), 14(b) and 14(d) above) of each accessory.	☒	☐	☐		10

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
c) A 510(k) number is provided for each accessory that received a prior 510(k) clearance. **AND** A statement is provided that identifies accessories that have not received prior 510(k) clearance.	☒	☐			10
C. Substantial Equivalence Discussion					
16) Submitter has identified a predicate device(s), including the following information:				☐	
a) Predicate device identifier provided (e.g., 510(k) number, De Novo number, reclassified PMA number, classification regulation reference, if exempt (e.g., 21 CFR 872.3710), or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online (https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/preamendment-status).*	☒	☐			12
b) The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing).	☒	☐			12
17) Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] *See the FDA guidance document "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k for more information on comparing intended use and technological characteristics.*				☐	
a) Indications for Use	☒	☐			12
b) Technology, including technical specifications, features, materials, and principles of operation	☒	☐			12
D. Proposed Labeling (see also 21 CFR part 801 and 809 as applicable)					
18) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).	☒	☐		☒	13
a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).	☒	☐			4,5,13
b) Labeling includes: - Statements of conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) **AND** - Includes adequate directions for use (see 21 CFR 801.5) **OR** - Submission states that device qualifies for exemption per 21 CFR 801 Subpart D	☒	☐			13
Comments: Section 13 labeling. Operating Instructions 13.1, 13.2, 13.3 and Device Labels attachment 13.4, ACS label 13.5 and Vacuum EC label attachment 13.6					

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
19) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	☒	☐		☐	13
20) Labeling includes the prescription statement [see 21 CFR 801.109(b)(1)] or Rx Only symbol (see also Section 502(a) of the FD&C Act and FDA's guidance "Alternative to Certain Prescription Device Labeling Requirements," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/alternative-certain-prescription-device-labeling-requirements.	☒	☐	☐	☐	13
21) The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding labeling that is applicable to the subject device.	☐		☒		
22) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.	☐	☐	☒	☐	
E. Sterilization					
If an *in vitro* diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.			☐		
☐ Provided sterile, intended to be single-use					
☐ Requires processing during its use-life					
☒ Non-sterile when used (and no processing required)					
☐ Information regarding the sterility status of the device is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ Sterility status not needed for this device (e.g., software-only device)					
☐ Sterility status needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *Please refer to the FDA guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling, for additional information.*					
F. Shelf Life					
27) Proposed shelf life/expiration date stated **OR** Statement that shelf-life is not applicable because of low likelihood of time-dependent product degradation	☒	☐	☐	☐	14
28) For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf life.	☐	☐	☒	☐	
29) Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH, osmolality, etc.). **OR** Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.	☒	☐		☐	14

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
G. Biocompatibility					
If an vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.			☐		
Submission states that there: (one of the below must be checked)		☐		☐	15-1
☐ Are direct or indirect tissue-contacting components.					
☒ Are no direct or indirect tissue-contacting components.					
☐ Information regarding tissue contact status of the device is not provided (if this box checked, please also check one of the two boxes below).					
☐ Tissue contact information not needed for this device (e.g., software-only device)					
☐ Tissue contact information needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
H. Software					
Submission states that the device: (one of the below must be checked)		☐		☐	16
☒ Does contain software/firmware					
☐ Does not contain software/firmware					
☐ Information on whether device contains software/firmware is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ Software/firmware information not needed for this device (e.g., surgical suture, condom)					
☐ Software/firmware information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
33) Submission includes a statement of software level of concern and rationale for the software level of concern.	☒	☐		☐	16-1
34) All applicable software documentation provided based on level of concern identified by the submitter, as described in "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-submissions-software-contained-medical-devices, or the submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has identified an alternate approach with a rationale).	☒	☐		☐	
I. Cybersecurity					
Submission states that the device: *(one of the below must be checked)*		☐		☐	16-8
☒ Does contain any external wired and/or wireless communication interfaces (Wired: USB, ethernet, SD, CD, RGA, etc. or Wireless: Wi-Fi, Bluetooth, RF, inductive, Cloud, etc.)					
☐ Does not contain external interfaces as described above					
☐ Information on whether device has external interfaces is not provided. (If this box is checked, please also check one of the two boxes below.)					

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
☐ Cybersecurity information not needed for this device (e.g., surgical suture, condom)					
☐ Cybersecurity information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
35) All applicable documentation identified by the submitter, as described in "Guidance for the Content of Premarket Submissions for Management of Cybersecurity in Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-management-cybersecurity-medical-devices-0. **OR** Submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has identified an alternate approach with a rationale).	☒	☐		☐	
J. Electrical Safety and EMC					
Electrical Safety Submission states that the device: *(one of the below must be checked)*		☐		☐	17-1
☒ Does require electrical safety evaluation					
☐ Does not require electrical safety evaluation					
☐ Information on whether device requires electrical safety evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ Electrical safety information not needed for this device (e.g., surgical suture, condom)					
☐ Electrical safety information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
36) Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, a device-specific standard), **OR** Submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	☒	☐		☐	17-1
EMC Submission states that the device: (one of the below must be checked)		☐		☐	17-1
☒ Does require EMC evaluation					
☐ Does not require EMC evaluation					
☐ Information on whether device requires EMC evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ EMC information not needed for this device (e.g., surgical suture, condom)					
☐ EMC information is needed or need unclear					

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
37) Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, the device-specific standard) **OR** Submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	☒	☐		☐	17-1
K. Performance Data - General					
If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from checklist if "N/A" is selected. Performance data criteria relating to IVD devices is addressed in Section K.			☐		
38) Summaries of the non-clinical laboratory studies and full test reports* are provided. *Summary and full test report content recommendations can be found in FDA's guidance "Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket. If a submitter chooses to declare conformity to a voluntary consensus standard that FDA has recognized, submission of a full test report may not be necessary. Refer to 9a. See FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices.	☒	☐	☐	☐	18-3
a) Submission includes an explanation of how the data generated from each test supports a finding of substantial equivalence (e.g., comparison to predicate device testing, dimensional analysis, etc.).	☒	☐			
39) The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding performance data that is applicable to the subject device.	☐		☒	☐	
40) If literature is referenced in the submission, submission includes:			☐	X	
a) Legible reprints or a summary of each article.	☒	☐			
b) Discussion of how each article is applicable to support the substantial equivalence of the subject device to the predicate.	☐	☒			
Comments: Literature is used to support test method; not as verification or validation data to support SE					
41) For each completed animal study, the submission provides the following:			☒	☐	
L. Performance Characteristics - In Vitro Diagnostic Devices Only **(Also see 21 CFR 809.10(b)(12))**					
Submission states that the device: (one of the below must be checked)				☐	
☐ is an in vitro diagnostic device.					

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
☒ is not an in vitro diagnostic device.					
If "is not" is selected, the performance data-related criteria below are omitted from the checklist.					

Records processed under FOIA Request 2023-9067; Released by CDRH on 05-23-2024

Digital Signature Concurrence Table

Reviewer Sign-Off	
Management Sign-Off (digital signature optional)*	

* Management review of checklist and concurrence with with decision required.

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U.S. FOOD & DRUG ADMINISTRATION

Food and Drug Administration
CDRH/OPEQ/OHTII/DHTIIB
AWL RMONR
Global Work Location
Silver Spring, MD 20705

Premarket Notification 510(k) Review

Date: November 10, 2022

Reviewer: Jacob Morand

510(k)# K220635/S001 Subject: Traditional

Applicant: LivaNova Deutschland GmbH	**Device Trade Name:** (b)(5) Heater-Cooler System 3T
Contact Name: Julia Leslie	**Contact Title:** Senior Director, Regulatory Affairs CS
Correspondent Firm: LivaNova Deutschland GmbH	**Phone:** 49 (89) 323-01141 **Email:** julie.leslie@livanova.com
Received Date: October 14, 2022	**Due Date:** November 17, 2022
Pro Code(s): DWC **Class:** II **Reg #:** 870.4250	**Reg Name:** Cardiopulmonary Bypass Temperature Controller

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K191402	DWC	Heater-Cooler System 3T	LivaNova Deutschland GmbH

Recommendation

(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Digital Signature Concurrence Table (Doc ID: 04500.14.06)	
This document represents a high-level summary of the Agency's determination on whether the applicant's device is substantially equivalent to a legally marketed predicate device. In determining whether the subject device is substantially equivalent to a predicate device, we carefully considered the relevant regulatory and statutory criteria for Agency decision-making under 21 CFR part 807 and section 513(i) of the Federal Food, Drug and Cosmetic Act (FD&C Act). We considered the burden that may be incurred by the applicant's attempt to follow the premarket notification process. The deficiencies provided in this review, if any, represent the required minimum information necessary to support a substantial equivalence determination. Therefore, we believe that we have considered the least burdensome requirements, under section 513(i)(1)(D) of the FD&C Act, for a 510(k) determination of substantial equivalence.	
Reviewer Sign-Off	Jacob Morand -S Digitally signed by Jacob Morand -S Date: 2022.11.10 13:16:49 -05'00'

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-9067; Released by CDRH on 05-23-2024

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approved: OMB No. (b)(4)
Expiration Date: June 30, 2023
See PRA Statement on last page.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(If known)*
03/02/2022	(b)(4)	

SECTION A TYPE OF SUBMISSION

PMA & PDP
- ☐ Original
- ☐ Modular Submission
- ☐ Amendment
- ☐ Report (annual or PAS)
- ☐ Report Amendment
- ☐ Other:
  - ☐ Premarket Report (reprocessed SUD)
  - ☐ Licensing Agreement

PMA/PDP Supplement
- ☐ 180 day - PAS protocol or labeling change, location change, trade name change
- ☐ 180 day - Design or labeling change
- ☐ Special CBE
- ☐ Panel Track
- ☐ 30-day Notice
- ☐ Real-time Review
- ☐ Amendment to PMA/PDP Supplement

510(k)
- ☒ Original Submission:
  - ☒ Traditional
  - ☐ Special
  - ☐ Abbreviated
  - ☐ 3rd Party Traditional
  - ☐ 3rd Party Special
  - ☐ 3rd Party Abbreviated
  - ☐ Dual Track (Dual 510(k) and CLIA Waiver by Application)
- ☐ Amendment
- ☐ Supplement

CLIA

CLIA Categorization Record (CR)
- ☐ Original
- ☐ Amendment

CLIA Waiver by Application (CW)
- ☐ Original
- ☐ Amendment
- ☐ Supplement

Q-Submission
- ☐ Pre-Submission
- ☐ Informational Meeting
- ☐ Submission Issue Meeting
- ☐ Day 100 Meeting
- ☐ Agreement Meeting
- ☐ Determination Meeting
- ☐ Study Risk Determination
- ☐ Other *(Specify below)*

IDE
- ☐ Original IDE:
  - ☐ Amendment to Original IDE
- ☐ Supplement:
  - ☐ Amendment to Supplement
- ☐ Report:
  - ☐ Amendment to Report

HDE
- ☐ Original Submission
- ☐ Amendment to Original
- ☐ Report
- ☐ Report Amendment
- ☐ HDE Supplement:
  - ☐ 75-day Supplement
  - ☐ 30-day Notice
  - ☐ Special CBE
  - ☐ Amendment to Supplement

Class II Exemption Petition
- ☐ Original Submission
- ☐ Additional Information

Emergency Use Authorization
- ☐ Original
- ☐ Supplement
- ☐ Amendment
- ☐ Report

De Novo
- ☐ Original:
  - ☐ Direct
  - ☐ Post-NSE
- ☐ Amendment
- ☐ Supplement

Pre-Emergency Use Authorization
- ☐ Original
- ☐ Supplement
- ☐ Amendment

Other Submission
- ☐ 513(g)
- ☐ Appeal
- ☐ Other *(Briefly describe submission below)*

Expanded Access to Devices
- ☐ Compassionate Use Request **NOT associated with an IDE**
- ☐ Follow-up Report for Compassionate Use **NOT associated with an IDE**
- ☐ Emergency Use Follow-up Report **NOT associated with an IDE**

SECTION B APPLICANT / SPONSOR

Company/Institution Name		Establishment Registration Number/FEI *(if known)*
LivaNova Deutschland GmbH		9611109
Street Address		**City**
Lindbergh Strasse 25		Munchen
State/Province	**ZIP/Postal Code**	**Country**
BY	80939	Germany

Contact Name	Contact Title
Julia E. Leslie, PhD	Senior Director, Regulatory Affairs CS
Division Name *(if applicable)*	**Phone Number *(including area code)***
Cardiopulmonary	+49 89 323 01 141
Fax Number *(including area code)*	**Contact Email Address**
	julie.leslie@livanova.com

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SECTION C OFFICIAL CORRESPONDENT (e.g., may be a consultant and/or 510(k) Third Party) (if different from Section B)

Company/Institution Name		Establishment Registration Number/FEI *(if known)*
Street Address		City
State/Province	ZIP/Postal Code	Country

Contact 1 Name	Contact 1 Title
Contact 1 Division Name *(if applicable)*	Contact 1 Phone Number *(including area code)*
Contact 1 Fax Number *(including area code)*	Contact 1 Email Address
Contact 2 Name	Contact 2 Title
Contact 2 Division Name *(if applicable)*	Contact 2 Phone Number *(including area code)*
Contact 2 Fax Number *(including area code)*	Contact 2 Email Address
Contact 3 Name	Contact 3 Title
Contact 3 Division Name *(if applicable)*	Contact 3 Phone Number *(including area code)*
Contact 3 Fax Number *(including area code)*	Contact 3 Email Address

To add another set of Section C items, please click on the button to the right. May be repeated as needed. Add Section C

SECTION D INTENDED USE POPULATION

Check all that apply.

- ☐ Adults Only (greater than 21 years of age)
- ☒ Adults and Pediatrics
- ☐ Neonate/Newborn (birth through 28 days)
- ☐ Infant (from 29 days to 2 years of age)
- ☐ Child (from 2 years to 12 years of age)
- ☐ Adolescent (from 12 years to 18 years of age)
- ☐ Transitional Adolescent A (18 through 21 years of age)
- ☐ Transitional Adolescent B (18 through 21 years of age)
- ☐ Other *(Specify below)*

SECTION E PRODUCT INFORMATION – APPLICABLE TO ALL SUBMISSIONS

	Trade Name
1	(b)(4) Heater-Cooler System 3T
2	
3	
4	
5	

Common/Generic Name *(Include if no Trade Name)*
Cardiopulmonary bypass temperature controller

Records processed under FOIA Request 2023-9067; Released by CDRH on 05-23-2024

SECTION F PRIOR RELATED SUBMISSIONS FOR THIS DEVICE OR STUDY

FDA document numbers of all prior related submissions *(regardless of outcome)* or state no prior submission in box 1.

1 K052601	2 (b)(4)	3 K191402
4	5	6
7	8	9
10	11	12

SECTION G PRODUCT CLASSIFICATION – APPLICABLE TO ALL SUBMISSIONS

Product Code(s) *(when applicable) (If more than one, please separate with commas.)*

DWC

C.F.R. Section *(If applicable)*	Classification Panel/Medical Specialty
21 CFR 870.4250	

Device Class

☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

SECTION H1 REASON FOR APPLICATION – PMA, PDP, OR HDE

☐ New Device
☐ STED

☐ Post-approval Study Protocol

☐ HDE Request for Annual Distribution Number (ADN)

☐ Change in Design, Component, or Specification:
- ☐ Software/Hardware
- ☐ Color Additive
- ☐ Material
- ☐ Specifications
- ☐ Other *(Specify below)*

☐ Location Change:
- ☐ Manufacturer
- ☐ Sterilizer
- ☐ Packager

☐ Report Submission:
- ☐ Annual or Periodic
- ☐ Post-approval Study

☐ Process Change:
- ☐ Manufacturing
- ☐ Packaging
- ☐ Sterilization
- ☐ Vendor/Supplier Change
- ☐ Other *(Specify below)*

☐ Labeling Change:
- ☐ Indications
- ☐ Instructions
- ☐ PAS update
- ☐ Performance Characteristics
- ☐ Shelf Life
- ☐ Trade Name
- ☐ Other *(Specify below)*

☐ Amendment:
- ☐ Withdrawal
- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Address
- ☐ Request for Extension
- ☐ Response to FDA Correspondence
- ☐ Other *(Specify below)*

☐ Bundle Submission – *If this is selected, list in the spaces below any PMAs in the Bundle.*

1	2	3
4	5	6
7	8	9

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SECTION H2 REASON FOR APPLICATION – IDE

☐ Original IDE

☐ Supplement:
- ☐ New Study/New Protocol
- ☐ Change in Correspondent
- ☐ Change in Manufacturer
- ☐ Change in Sponsor
- ☐ Change in Design
- ☐ Change in Informed Consent
- ☐ Change in Manufacturing
- ☐ Change in Protocol
- ☐ 5-Day Notice – Device or Manufacturing
- ☐ 5-Day Notice – Protocol
- ☐ Compassionate Use Request (under an IDE)
- ☐ Live Case Request
- ☐ Request Deviation from Protocol
- ☐ Expansion of Study (Study/Sites)
- ☐ Extension of Time to Submit Annual Report or Respond to FDA Letter

Supplement *(Continued)*
- ☐ Request for Waiver
- ☐ IRB Certification
- ☐ Request for CMS Recategorization
- ☐ Study Resumed
- ☐ Study Suspension
- ☐ Other *(Specify below)*

☐ Report:
- ☐ Adverse Effect
- ☐ Final, Study Completed
- ☐ Annual Progress
- ☐ Interim Progress
- ☐ Semiannual Investigator List
- ☐ Failure to Obtain Informed Consent
- ☐ Compassionate Use Follow-up
- ☐ Emergency Use
- ☐ Live Case Follow-up
- ☐ Completion of Patient Enrollment
- ☐ Completion of Patient Follow-up
- ☐ Other *(Specify below)*

☐ Amendment to Original IDE:
- ☐ Amendment Before Final Decision
- ☐ Response to Refuse to Accept
- ☐ Response to Disapproval
- ☐ Response to Approval with Conditions
- ☐ Withdrawal
- ☐ Other *(Specify below)*

☐ Amendment to Supplement:
- ☐ Response to Disapproval
- ☐ Response to Approval with Conditions
- ☐ Withdrawal
- ☐ Amendment Before Final Decision (additional Information)
- ☐ Other *(Specify below)*

☐ Amendment to Report:
- ☐ Response to Deficiency Letter
- ☐ Withdrawal
- ☐ Amendment Before Final Decision (additional Information)
- ☐ Other *(Specify below)*

SECTION H3 REASON FOR SUBMISSION – Q-SUBMISSION

☐ Pre-Submission:
- ☐ Request Face-to-Face Meeting
- ☐ Request Teleconference
- ☐ Request Email Response
- ☐ Submit Meeting Minutes
- ☐ Request Meeting Minutes Disagreement T-con

☐ Submission Issue Meeting:
- ☐ Request Face-to-Face Meeting
- ☐ Request Teleconference
- ☐ Request Email Response
- ☐ Submit Meeting Minutes
- ☐ Request Meeting Minutes Disagreement T-con

☐ Additional Information

☐ Change in Legal Entity:
- ☐ Change in Correspondent
- ☐ Change in Sponsors
- ☐ Change in Manufacturer
- ☐ Other *(Specify below)*

☐ Agreement Meeting:
- ☐ Request Face-to-Face Meeting
- ☐ Request Teleconference

☐ Determination Meeting:
- ☐ Request Face-to-Face Meeting
- ☐ Request Teleconference

☐ Informational Meeting:
- ☐ Request Face-to-Face Meeting
- ☐ Request Teleconference
- ☐ Submit Meeting Minutes
- ☐ Request Meeting Minutes Disagreement T-Con

☐ Other *(Specify)*:

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SECTION H4 REASON FOR SUBMISSION – 510(k)

- ☒ Original
- ☐ Withdrawal of Original
- ☐ Amendment Before Final Decision:
  - ☐ Change in Ownership
  - ☐ Change in Correspondent
  - ☐ Withdrawal
- ☐ Amendment After Final Decision
- ☐ Supplement:
  - ☐ Response to Refuse to Accept (RTA)
  - ☐ Response to Additional Information Request
  - ☐ Withdrawal
- ☐ Reprocessed SUD
- ☐ Corrective Action
- ☐ STED
- ☐ Third Party *(Complete Section C)*
- ☐ Other Reason *(Specify)*:

Information on devices to which substantial equivalence is claimed *(If known)*

	510(k) Number	*Trade Name*	*Submitter*	*Product Code*
Primary Predicate (A)	K191402	(b)(4) Heater-Cooler System 3T	LivaNova Deutschland GmbH	DWC
Predicate or Reference Device (B)				

To add another Predicate or Reference Device (B) entry row, please click on the button to the right. May be repeated as needed. Add Device Information

SECTION H5 DE NOVO SUBMISSIONS

- ☐ Post NSE De Novo: Number of the 510(k) that was NSE'd in the past 30 days:
- ☐ Withdrawal

SECTION H6 REASON FOR APPLICATION – CLIA

Includes CLIA Parent Document number, CR number, or CW number.

- ☐ **CLIA Categorization Record (CR):**
  - ☐ CLIA Categorization of marketed device (include marketing submission number)
  - ☐ CLIA Categorization of device exempt from premarket review
  - ☐ Additional information regarding an open CR (include CR number)
- ☐ **CLIA Waiver by Application (CW):**
  - ☐ Request for CLIA Waiver by Application for marketed device (include marketing submission number)
  - ☐ Request for Dual 510(k) Clearance and CLIA Waiver by Application (include Pre-submission number)
  - ☐ Response to FDA correspondence
  - ☐ Additional information regarding an open CW (include CW number)
- ☐ **Other Reason** *(Specify)*

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SECTION I MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

Applicable only to IDEs

Note: Submission of this information does not affect Registration and Listing.	FDA Document Number *(if known)*

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager/Relabeler

Company/Institution Name		Establishment Registration Number/FEI *(if known)*
Street Address		City
State/Province	ZIP/Postal Code	Country

Contact 1 Name	Contact 1 Title
Contact 1 Division Name *(if applicable)*	Contact 1 Phone Number *(including area code)*
Contact 1 Fax Number *(including area code)*	Contact 1 Email Address

Contact 2 Name	Contact 2 Title
Contact 2 Division Name *(if applicable)*	Contact 2 Phone Number *(including area code)*
Contact 2 Fax Number *(including area code)*	Contact 2 Email Address

Contact 3 Name	Contact 3 Title
Contact 3 Division Name *(if applicable)*	Contact 3 Phone Number *(including area code)*
Contact 3 Fax Number *(including area code)*	Contact 3 Email Address

To add another set of Section I items, please click on the button to the right. May be repeated as needed. Add Section I

SECTION J UTILIZATION OF STANDARDS

Note: Please see guidance document titled "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices" for details on the Declaration of Conformity.

How to fill out this section:

Recognition Number: State the FDA recognition number. If the standard is not recognized, write **NR**.

Declaration of Conformity or General Use: Select 'Declaration of Conformity' if including a "Declaration of Conformity to a Recognized Standard" statement. For all other uses, select 'General Use' and indicate if you have made deviations from the Recognized/Non-recognized standard.

Standard: State the Standards Development Organization (SDO), the Designation Number (including year), and the Title.

Location: State the section and/or the page number(s) in the submission where the standard is applied.

Examples

	Recognition Number	Declaration of Conformity or General Use		Standards Development Organization (SDO), Designation Number-Year, and Title	Location
1 X	8-185	Declaration of Conformity	*If General Use,* Deviation?	ASTM F451-08, standard specification for acrylic bone cement.	Section 3, p. 15
2 X	3-44	General Use	*If General Use,* Deviation? Yes	AAMI ANSI BP22:1994 (R) 2011 Blood Pressure Transducers	Section 4, p. 32

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Entries for Utilization of Standards

	Recognition Number	Declaration of Conformity or General Use		Standards Development Organization (SDO), Designation Number-Year, and Title	Location
1 X	19-4	General Use	*If General Use*, Deviation? No	IEC 60601-1 2005 A1:2012	Section 9
2 X	19-8	General Use	*If General Use*, Deviation? No	IEC 60601-1-2 Edition 4.0 2014	Section 9
3 X	5-114	General Use	*If General Use*, Deviation? No	IEC 62366-1 Edition 1.0 2015	Section 9
4 X	13-79	General Use	*If General Use*, Deviation? No	IEC 62304 Edition 1.1 2015	Section 9
5 X	5-125	General Use	*If General Use*, Deviation? No	ISO 14971 Third Edition 2019	Section 9
6 X	NR	General Use	*If General Use*, Deviation? No	EN 55011/CISPR 11 2009+A1:2010	Section 9
7 X	NR	General Use	*If General Use*, Deviation? No	IEC 61000-3-2 2005+A1:2008+A2:2009	Section 9
8 X	NR	General Use	*If General Use*, Deviation? No	IEC 61000-4-2 2008	Section 9
9 X	NR	General Use	*If General Use*, Deviation? No	IEC 61000-4-3 2006+A1:2007+A2: 2010	Section 9
10 X	NR	General Use	*If General Use*, Deviation? No	IEC 61000-4-4 2012	Section 9
11 X	NR	General Use	*If General Use*, Deviation? No	IEC 61000-4-5 2005	Section 9
12 X	NR	General Use	*If General Use*, Deviation? No	IEC 61000-4-6 2013	Section 9
13 X	NR	General Use	*If General Use*, Deviation? No	IEC 61000-4-8 2009	Section 9
14 X	NR	General Use	*If General Use*, Deviation? No	IEC 61000-4-11 2004	Section 9
15 X	NR	General Use	*If General Use*, Deviation? No	ISTA 1A 2014	Section 9
16 X	NR	General Use	*If General Use*, Deviation? No	ISTA 2B 2012	Section 9
17 X	14-530	General Use	*If General Use*, Deviation? No	EN ISO 11607-1 2009+A1:2014	Section 9
18 X	NR	General Use	*If General Use*, Deviation? No	IEC 60529 2001	Section 9
19 X	NR	General Use	*If General Use*, Deviation? No	ASTM F960 V86	Section 9
20 X	14-497	General Use	*If General Use*, Deviation? No	ASTM F1980 V07	Section 9
21 X	5-57	General Use	*If General Use*, Deviation? No	AAMI HE75 2009	Section 9

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22 X	5-114	General Use	*If General Use*, Deviation? No	ANSI/AAMI/IEC 62366-1 2015	Section 9
23 X	NR	General Use	*If General Use*, Deviation? No	ASTM G71-81 2014	Section 9
24 X	NR	General Use	*If General Use*, Deviation? No	ASTM G46-94 2018	Section 9
25 X	NR	General Use	*If General Use*, Deviation? No	ANSI/ASHRAE/ASHE 170 2017	Section 9
26 X	6-427	General Use	*If General Use*, Deviation? No	F2101-19	Section 9
27 X	NR	General Use	*If General Use*, Deviation? No	ANSI/ASHRAE Addendum b to ANSI/ASHRAE Standard 52.2 2007	Section 9

To add another row for Section J, please click on the button to the right. May be repeated as needed.
(To remove a particular row, please click on the "X" button at the beginning of the row.)

Add Row/Standard

SECTION K UTILIZATION OF CDRH GUIDANCE DOCUMENTS

How to fill out this section:

Title: Enter the title of the guidance documents used in the preparation of your premarket submission. CDRH guidance documents can be found at ***http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm***.

Entries for Utilization of CDRH Guidance Documents

	Title of Guidance Document
1 X	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (2005)
2 X	Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions (2019)
3 X	Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices (2018)
4 X	Format for Traditional and Abbreviated 510(k)s 2019

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This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average .5 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
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Office of Chief Information Officer
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Document Number : (b)(4)

Document Revision : (b)(4)

Document Title : HC3T - Usage of (b)(4) on CAN bus line

Effective Date: 10 Oct 2022

Expiration Date:

Notes :

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K220635
LivaNova Deutschland GmbH
Trade/Device Name: (b)(4) Heater-Cooler System 3T
Contact Name: Julia Leslie

This document is being communicated via e-mail as an attachment. The date on which FDA sent this e-mail is the official date of this correspondence.

We have reviewed your submission K220635 and have determined that additional information is required. Your file is being placed on hold pending a complete response to the attached deficiencies.

Please submit your response, referencing the submission number K220635 to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Please refer to the eCopy guidance at https://www.fda.gov/media/83522/download for current information on eCopy requirements.

Your response is due within 180 days from the date of this request, which is the hold date plus 180 days. If a complete response is not received in CDRH's Document Control Center by this date, we will consider this submission to be withdrawn, and we will delete it from our review system.

You may not market this device until you have received a letter from FDA allowing you to do so. If you market the device without FDA clearance, you will be in violation of the Federal Food, Drug, and Cosmetic Act.

If you would like a meeting or teleconference with the review team and management to discuss your planned approach for responding to the attached deficiencies, please submit your request for feedback as a Submission Issue Q-Submission (Q-Sub). Please note that a Submission Issue Q-Sub does not take the place of a formal response to this email notification. As noted above, FDA will consider this submission to be withdrawn if FDA does not receive, in a submission to the Document Control Center, a complete response to all of the attached deficiencies within 180 calendar days of the date of this request.

This request for additional information has undergone supervisory review to ensure that the deficiencies cited are least burdensome and relevant to the marketing decision. Please see the revised guidance "Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions" issued on September 29, 2017 (https://www.fda.gov/media/71735/download) for clarification regarding major and minor deficiencies.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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MAJOR DEFICIENCY LIST

The Agency has identified major deficiencies that if not adequately resolved, may preclude a favorable decision on the marketing application.

(b)(4)

FDA is offering a teleconference within 10 calendar days from the date on this letter to address any clarification questions you may have pertaining to the deficiencies. If you are interested in a teleconference, please provide (1) proposed dates and (2) a list of your clarification questions via email at least 48 hours before the teleconference to the lead reviewer assigned to your submission. We would like to emphasize that

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the purpose of the meeting is to address specific clarification questions. Please note that if the specific clarification questions are not received at least 48 hours before the teleconference, the review team might not be able to provide feedback. The teleconference is not intended for review of new information, test methods or data; these types of questions could be better addressed via a Submission Issue Q-Submission (Q-Sub). For additional information regarding Q-Subs, please refer to the Guidance for Industry and FDA Staff on Medical Devices: Requests for Feedback and Meetings for Medical Device Submissions at https://www.fda.gov/media/114034/download.

Least Burdensome (LB) Flag

The LB flag is an approach to allow submitters the opportunity for the informal review by or on behalf of Division management of an issue raised in an FDA request for additional information (i.e., a deficiency letter). The goal of the LB flag is to quickly address FDA requests that submitters do not believe are least burdensome or when submitters believe they are being held to a different standard than their legally marketed predicate device. The LB flag is not intended to clarify deficiencies, is not an appeal under 21 CFR 10.75, and is not intended to provide a review of a proposed response to deficiencies.

If you would like to throw the LB flag, FDA has several criteria that should be met before you submit your request:

- You should have tried to address your concern by discussing it with Division management before attempting to throw the LB flag. This discussion with Division management may take place as part of a teleconference (such as the voluntary teleconference held within 10 days following transmission of an Additional Information letter to clarify deficiencies), email, or a Q-Submission Submission Issue Request.
- Your flag should generally be limited to two topic areas. Topic areas are common premarket review deficiency categories that apply to many device types across multiple reviewing Divisions. Examples of topic areas include biocompatibility, sterility, reprocessing, software, electromagnetic compatibility, wireless, electrical safety, clinical, and non-clinical performance testing.
- If you would like to discuss issues pertaining to more than two topic areas, you should contact OPEQSubmissionSupport@fda.hhs.gov for more information.
- You should throw the LB flag within 60 calendar days of the date that FDA sent the deficiency letter.

Upon meeting the criteria, you should send a short email (e.g., 1-2 page) that includes: 1) a summary of the deficiencies under disagreement, 2) a summary of relevant communications with Division management, and 3) a proposed path forward. The LB flag should be sent to the lead reviewer and their Assistant Director. You should also copy OPEQSubmissionSupport@fda.hhs.gov on your LB flag email request. Within two business days of your email, your request will be acknowledged by the reviewing Division. If you do not meet the criteria for the LB flag, you will be notified in this acknowledgement email.

Your LB flag should contain sufficient information to determine whether the deficiency letter was not least burdensome, or you are being held to a different standard than your predicate device. FDA may request a phone call with you to discuss your concern further and intends to communicate feedback from Division management on LB flags through email no later than 21 calendar days of their receipt. Please note that the LB flag does not change the deadline for your response to the Document Control Center. If you have any questions, please contact OPEQSubmissionSupport@fda.hhs.gov.

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From: Leslie, Julie <julie.leslie@livanova.com>

Sent: Tuesday, November 8, 2022 7:12 AM

To: Morand, Jacob <Jacob.Morand@fda.hhs.gov>; Goetz, Florian <Florian.Goetz@livanova.com>

Subject: [EXTERNAL] RE: K220635-S001 Interactive Review

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Hi Jacob,

Attached please find the updated (b)(4)

(b)(4)

n

Thanks for your review,

Julie

From: Leslie, Julie

Sent: Monday, November 7, 2022 10:12 AM

To: Morand, Jacob <Jacob.Morand@fda.hhs.gov<mailto:Jacob.Morand@fda.hhs.gov>>; Goetz, Florian <Florian.Goetz@livanova.com<mailto:Florian.Goetz@livanova.com>>

Subject: RE: K220635-S001 Interactive Review

Hi Jacob,

Thank you, and apologies for the late response. We are preparing the u (b)(4) and will have it to you by the deadline.

Please let us know if there are any other requests during the interactive review.

Thanks,

Julie

From: Morand, Jacob <Jacob.Morand@fda.hhs.gov<mailto:Jacob.Morand@fda.hhs.gov>>

Sent: Monday, October 31, 2022 6:49 PM

To: Goetz, Florian <Florian.Goetz@livanova.com<mailto:Florian.Goetz@livanova.com>>; Leslie, Julie <julie.leslie@livanova.com<mailto:julie.leslie@livanova.com>>

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Subject: [EXTERNAL] K220635-S001 Interactive Review

Hello Florian and Julie,

(b)(4)

Please provide updated (b)(4) for review by 11/10/2022. Happy to chat further to address any questions related to this request.

Best,

Jacob Morand

Lead Reviewer

Center for Devices & Radiological Health

U.S. Food and Drug Administration

White Oak Bldg 66, New Hampshire Ave, Silver Spring, MD 20993

Phone: 1 (301) 796-1127

Jacob.Morand@fda.hhs.gov<mailto:Jacob.Morand@fda.hhs.gov>

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14.0 STERILIZATION AND SHELF LIFE

The 3T System is cleared by FDA as a non-sterile device and is intended to be used in the non-sterile area of the user's facility. It is not possible to maintain sterility of the water circuit during device operation. The addition of the Deep Cleaning Process presented in this submission does not affect the non-sterile profile of the device.

The device also does not have a labeled shelf life.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Signature Manifest

Document Number: (b)(4) **Revision:** (b)(4)

Title: Heater-Cooler system 3T EMC Test with Document Review (b)(4)

All dates and times are in Central European Time.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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12. SUBSTANTIAL EQUIVALENCE

3T Heater Cooler, with the proposed optional Deep Cleaning Process, is proposed to be substantially equivalent to its predicate, 3T Heater Cooler (K191402). LivaNova has made the determination based on the intended use/ indication for use, operational characteristics, fundamental design characteristics, and fundamental technological characteristics.

Substantial Equivalence Chart

	3T System with Optional Deep Cleaning Process	**Cleared 3T System (K191402)**	**Difference**
Indications for Use	The 3T System is used to circulate water through heat exchangers to warm or cool a patient during cardiopulmonary bypass procedures lasting 6 hours or less	The 3T System is used to circulate water through heat exchangers to warm or cool a patient during cardiopulmonary bypass procedures lasting 6 hours or less	No change
User Population	Clinical personnel (e.g., qualified perfusionists) and Maintenance personnel (e.g., biomedical engineers/technicians who may perform maintenance on the 3T System)	Clinical personnel (e.g., qualified perfusionists) and Maintenance personnel (e.g., biomedical engineers/technicians who may perform maintenance on the 3T System)	No change
Primary Technological Characteristics	An independent (i.e., independent of the water supply) 3-circuit heating/cooling base unit that includes three water circuits (two circuits for the patient supplied by one tank (for the heating/cooling blanket, the oxygenator) and one interchangeable heating/cooling circuit for cardioplegia	An independent (i.e., independent of the water supply) 3-circuit heating/cooling base unit that includes three water circuits (two circuits for the patient supplied by one tank (for the heating/cooling blanket, the oxygenator) and one interchangeable heating/cooling circuit for cardioplegia	No change

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Accessories	Optional components and accessories include heating-cooling blankets and various cables and tubing	Optional components and accessories include heating-cooling blankets and various cables and tubing	No change
Dimensions (W x H x D(depth))	50 x 97.5 x 68 cm	50 x 97.5 x 68 cm	No change
Input Voltage	208V/ 60 Hz 120V/ 60 Hz	208V/ 60 Hz 120V/ 60 Hz	No change
Operation	Stand alone and optional remote operation feature as part of cleared S5/C5 heart-lung machine	Stand alone and optional remote operation feature as part of cleared S5/C5 heart-lung machine	No change
Software	**(b)(4)**		
Sterilization	Intended as non-sterile and for use in the non-sterile area of the user's facility	Intended as non-sterile and for use in the non-sterile area of the user's facility	No change

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Operating principle and technological characteristics

The 3T Heater Cooler, with the proposed Deep Cleaning Process, has the same operating principles and technological characteristics as its predicate. There are no changes to intended purpose, design, or functionality.

Conclusion

Based on the information provided, LivaNova has determined that the 3T Heater Cooler, with the proposed Deep Cleaning Process, is substantially equivalent to the 3T Heater Cooler and that any differences are minor and raise no new issues of safety or effectiveness.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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13.0 PROPOSED LABELING

The current 510(K) does not include changes to the labeling cleared under K191402.

The labeling cleared under K191402 are provided.

		Attachment
1. 3T System Operating Instructions (b)(4)	Operating Instructions include instructions on utilizing 3T Heater Cooler, vacuum canister, and internal sealing solution, including use of the Aerosol Collection Set.	Att 13.1 (b)(4) (b)(4)
2. Quick Reference Guide (QRG)	The Quick Reference Guide contains a summary of the routine water maintenance and preservation activities that must be performed on defined periodic frequencies. The Quick Reference Guide also contains a description of the 3T System and its control panel, the maintenance calendar (reproduced from the Operating Instructions), a pre-procedure checklist, and a summary of the installation, use, and disposal of the Aerosol Collection Set.	Att 13.2 (b)(4) (b)(4)
3. Aerosol Collection Set Insert (b)(4) (b)(4)	The Aerosol Collection Set Insert contains simple, pictorial step-by-step instructions for connecting, using and disposing the Aerosol Collection Set that is consistent with the information provided in the proposed Operating Instructions.	Att 13.3 (b)(4) (b)(4)
4. 3T System Device Labels	The 3T System is available in two voltage ratings in the United States; 120V and	Att 13.4 (b)(4) (b)(4)

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(b)(4) See Specification (b)(4)	208V.	
5. Aerosol Collection Set Labels (b)(4) (b)(4)	Labels for the Aerosol Collection Set	Att 13.5 (b)(4) (b)(4)
6. Vacuum Extension Line Label (b)(4) (b)(4) (b)(4)	The label for the optional vacuum extension line that attaches to the Aerosol Collection Set	Att 13.6 (b)(4) (b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: DCCLetters@fda.hhs.gov [DCCLetters@fda.hhs.gov]
Sent: 10/14/2022 4:29:39 PM
To: julie.leslie@livanova.com
CC: DCCLetters@fda.hhs.gov
Subject: K220635/S001 Acknowledgement Letter
Attachments: K220635-S001-Acknowledgement Letter.pdf

October 14, 2022

Thank you for your submission. We have attached your acknowledgement letter for your records. If you have any questions about your acknowledgement letter, please contact us at DCCmailroom@fda.hhs.gov. Please do not reply to this email.

*** This is a system-generated email notification ***

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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U.S. FOOD & DRUG ADMINISTRATION

Acknowledgement Letter

10/14/2022

Julia E. Leslie, Senior Director, Regulatory Affairs CS, Cardiopulmonary
LivaNova Deutschland GmbH
Lindbergh Strasse 25
Munchen,
BY 80939 GERMANY

Dear Julia E. Leslie:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the address listed below. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please contact the Office of Product Evaluation and Quality (OPEQ) submission support at (301) 796-5640 or OPEQSubmissionSupport@fda.hhs.gov .

Submision Number: K220635/S001
Received: 10/14/2022
Applicant: LivaNova Deutschland GmbH
Device: (b)(4) Heater-Cooler System 3T

We will notify you when the review of this submission document has been completed or if any additional information is required.If you are submitting new information about a submission for which we have already made a final decision, please note that your submission will not be re-opened. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm .

Sincerely yours,

Center for Devices and Radiological Health

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LivaNova

Health innovation that matters

March 3, 2022

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Subject: Traditional 510(k) Premarket Notification
Expansion of product servicing offer: Deep Cleaning
Brand nam (b)(4) Heater-Cooler System 3T
Manufacturer: LivaNova Deutschland GmbH

Attn: Nicole Gillette, Assistant Director (Acting), Cardiovascular Devices (OHT2) Circulatory Support, Structural and Vascular Devices (DHT2B)

Dear Madam/Sir:

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act ("FDC Act"), LivaNova PLC1 ("LivaNova" or the "Company"), is submitting the attached premarket notification ("510(k) Notification") to expand the Deep Cleaning service approved by FDA in April 2018 under 21 CFR 806 into general use, unrelated to corrections and removals.

The changes proposed in the current 510(k) include the offering of a Deep Cleaning service by LivaNova to customers. The Deep Cleaning process was approved for implementation under 21 CFR 806 by the FDA in April 2018 (b)(4). This 510(K) requests FDA clearance to offer the Deep Cleaning service outside of 21 CFR 806 conditions. The safety of the 3T Heater Cooler device is ensured by the regular disinfection and cleaning, monitoring of the bacteria levels and by the aerosol collection set, as described in the Operating Manual that was cleared in K191402. The Deep Cleaning service is intended to address cases where heavily contaminated devices cannot meet the acceptable level described in section 6.5.2 of the Operating Instructions. In this situation, to allow the device to return to clinical use, the customer may choose to return the device for the Deep Cleaning service. The Deep Cleaning service is intended to reduce bioburden levels within the water circuit, thereby reducing the risk of NTM Aerosolization in the clinical setting. There are no changes to design or intended use. We note that the documents contained herein were substantively reviewed by FDA under (b)(4) supplements S031 (2018) and K191402.

We have also included additional information as a follow-up from (b)(4) in Attachment 1.1.

Prior 510(k) clearances for the subject device include K052601 and K191402.

3T Heater Cooler is not an in vitro diagnostic.

[1] LivaNova PLC is a U.K. holding company with a number of wholly-owned subsidiaries, including LivaNova Deutschland GmbH and Sorin Group Italia S.r.l. For this presentation, we will refer to all entities using the brand name LivaNova.

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General information for the subject device is provided in the table below.

General Information	
Trade Name	(b)(4) Heater-Cooler System 3T
Common Name	Controller, Temperature, Cardiopulmonary Bypass
Predicate 510(k)	Stöckert Heater-Cooler System 3T **K191402**
Product Code	DWC
Classification	Class II
Review Panel	Cardiovascular Devices (OHT2) Circulatory Support, Structural and Vascular Devices (DHT2B)
Manufacturer	LivaNova Deutschland GmbH
Registration #	9611109

This premarket notification is organized following the recommendations contained in the CDRH guidance titled Format for Traditional and Abbreviated 510(k)s (September 13, 2019). As recommended in the FDA guidance, a table summarizing the device design and use is provided in the following table.

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?		X
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?		X
Is the device implanted?		X

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LivaNova

Health innovation that matters

The materials contained herein are considered confidential and proprietary materials by LivaNova. Consequently, the produced documents have been marked confidential, in their entirety, as nonpublic and confidential information and exempted from disclosure under the Freedom of Information Act by virtue of 18 U.S.C. § 1905. LivaNova asks that FDA notify us if any information produced by LivaNova is to be shared with any non-governmental entity or person. LivaNova asks to be given the opportunity to substantiate the confidentiality of any such document, and LivaNova reserves its rights to seek a protective order if the agency feels it is necessary to share any of these documents with a non-governmental entity or person.

One electronic copy ("eCopy") is being provided with this submission, and the eCopy is an exact duplicate of the paper copy.

To conform to the agency's September 13, 2019, Guidance for Industry and FDA Staff: Refuse to Accept Policy for 510(k)s, Attachment 3.1 of this submission includes the agency's Refuse to Accept checklist and a guide to where in the submission the elements required for a complete 510(k) submission per 21 C.F.R. 807.87 are located.

Thank you in advance for your consideration of our application. Should you have any questions on this submission, please feel free to contact me directly via email at:

Contact Information	
Primary contact person	**Alternate contact person**
Julia E. Leslie, PhD Sr Director, Regulatory Affairs, Cardiac Surgery Julie.Leslie@LivaNova.com	Florian Goetz Sr Regulatory Affairs Specialist Florian.Goetz@LivaNova.com

Sincerely,

(b)(6)

Julia E. Leslie, PhD
Sr Director, Regulatory Affairs, Cardiac Surgery
LivaNova

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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LivaNova Deutschland GmbH

3T Heater Cooler Deep Cleaning

510(k) Premarket Notification (Traditional)

Lindberghstr. 25
80939 Munich
Germany

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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LIST OF ATTACHMENTS

Att 1.1 Additional Information Follow-up from Q160637_S031

Att 1.1-1 Hertiani 2018

Att 10.1 [redacted]

Att 10.2 [redacted]

Att 13.1 [redacted]

Att 13.2 [redacted]

Att 13.3 [redacted]

Att 13.4 [redacted] Device Labels

Att 13.5 [redacted] ACS Label

Att 13.6 [redacted] Vacuum EL Label

Att 17.1 [redacted] EMC Test Report

Att 18.1 [redacted] --Process Validation Protocol_Deep Disinfection

Att 18.2 [redacted] Process Validation Report_ Deep Disinfection Process

Att 18.3 [redacted] IQ Report

Att 18.4 [redacted] IQ Protocol

Att 18.5 [redacted] IQ Report

Att 18.6 [redacted] IQ Protocol

Att 18.7 [redacted] IQ Report

Att 18.8 [redacted] OQ Protocol

Att 18.9 [redacted] OQ Report

Att 18.10 [redacted] OQ Protocol

Att 18.11 [redacted] OQ Report

Att 18.12 [redacted] OQ Protocol

Att 18.13 [redacted] OQ Report

Att 18.14 [redacted] Deep Disinfection Process PQ Protocol

Att 18.15 [redacted] Summary

Att 3.1 510(k) RTA checklist

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

From: Leslie, Julie <julie.leslie@livanova.com>
Sent: Wednesday, November 9, 2022 9:59 AM
To: Morand, Jacob <Jacob.Morand@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K220635-S001 Interactive Review

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Hi Jacob,

Please see the attached (b)(4)

(b)(4)

Let me know if there are any other requests.

Thanks,
Julie

From: Morand, Jacob <Jacob.Morand@fda.hhs.gov>
Sent: Wednesday, November 9, 2022 3:43 PM
To: Leslie, Julie <julie.leslie@livanova.com>
Subject: RE: [EXTERNAL] RE: K220635-S001 Interactive Review

Julie,

(b)(4)

Best,
Jacob

From: Leslie, Julie <julie.leslie@livanova.com>
Sent: Tuesday, November 8, 2022 7:12 AM
To: Morand, Jacob <Jacob.Morand@fda.hhs.gov>; Goetz, Florian <Florian.Goetz@livanova.com>
Subject: [EXTERNAL] RE: K220635-S001 Interactive Review

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Hi Jacob,

(b)(4)

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Text, letter

Description automatically generated

(b)(4)

Thanks for your review,

Julie

From: Leslie, Julie
Sent: Monday, November 7, 2022 10:12 AM
To: Morand, Jacob <Jacob.Morand@fda.hhs.gov>; Goetz, Florian <Florian.Goetz@livanova.com>
Subject: RE: K220635-S001 Interactive Review

Hi Jacob,

Thank you, and apologies for the late response. We are preparing the updated (b)(4) and will have it to you by the deadline.

Please let us know if there are any other requests during the interactive review.

Thanks,
Julie

From: Morand, Jacob <Jacob.Morand@fda.hhs.gov>
Sent: Monday, October 31, 2022 6:49 PM
To: Goetz, Florian <Florian.Goetz@livanova.com>; Leslie, Julie <julie.leslie@livanova.com>
Subject: [EXTERNAL] K220635-S001 Interactive Review

Hello Florian and Julie,

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Please provide updated (b)(4) for review by 11/10/2022. Happy to chat further to address any questions related to this request.

Best,

Jacob Morand
Lead Reviewer

Center for Devices & Radiological Health
U.S. Food and Drug Administration
White Oak Bldg 66, New Hampshire Ave, Silver Spring, MD 20993
Phone: 1 (301) 796-1127
Jacob.Morand@fda.hhs.gov

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Document Number : (b)(4)

Document Revision : (b)(4)

Document Title : 3T Vacuum Extension Line

Effective Date: 17 Nov 2020

Expiration Date:

Notes :

(b)(4)

Previous Number:

Change Number: (b)(4)

Document Type: (b)(4)

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The emissions limits, IEC 60601 test levels and tests specified by this collateral standard do not address electromagnetic compatibility of electrical equipment at very close distances.

Unless all electrical equipment is compatible with respect to both electric fields and magnetic fields at very close distances over the entire range of expected frequencies, separation is prudent.

If it is essential to use the Heater-Cooler System 3T very close to other electrical equipment, it is prudent to determine, by observation, if the performance of either product is affected by unintended electromagnetic coupling. If this happens, the user is encouraged to try to correct the interference by one or more of the following measures:

- re-orient or relocate the equipment
- increase the amount of space between the equipment
- connect the equipment to separate power sources

Note: If the Heater-Cooler System 3T is operated directly next to other high frequency (HF) surgical devices such as electrocautery and diathermy, this can lead to EMC interference and potentially to:

  - Display of wrong data or state (temperature, pump or water level status)
  - Remote connection down or disturbed
  - Components (partly) damaged
  - Electrical safety impaired

The use of the Heater-Cooler System 3T along with HF surgical devices must be observed with increased attention. When unusual behavior is observed, please follow the measures listed above to increase the distance between equipment and cables and restart the device.

In case an error code is displayed, refer to the troubleshooting section in chapter 8.1.4 to identify the impaired functionality and how to restore it.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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PROCESS VALIDATION PLAN (PVP)

HEATER COOLER 3T DEEP DISINFECTION PROCESS

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5.0 510(k) SUMMARY

The Company's 510(k) Summary is provided on the following pages.

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510(k) SUMMARY

I. SUBMITTER

Name:	LivaNova Deutschland GmbH
Address:	Lindberghstrasse 25 D-80939 München, Germany
Establishment Registration Number	9611109
Contact Person:	Julia E. Leslie, PhD
Phone:	+49 89 323 01 141
Email:	julie.leslie@livanova.com
Secondary Contact:	Florian Goetz
Phone:	+49 89 323 01 236
Email:	florian.goetz@livanova.com
Date Prepared:	February 28, 2022

II. DEVICE

Proprietary Name:	Heater-Cooler System 3T
Common Name:	Cardiopulmonary bypass temperature controller
Classification Name:	Controller, Temperature, Cardiopulmonary Bypass
Regulation Number:	21 CFR 870.4250
Product Code:	DWC
Device Class:	Class II

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III. PREDICATE DEVICE INFORMATION

Heater-Cooler System 3T with the Deep Cleaning service is substantially equivalent in function and intended use to **Heater-Cooler System 3T (K191402).**

IV. INDICATIONS FOR USE

The Heater-Cooler System 3T is used to circulate water through heat exchangers to warm or cool a patient during cardiopulmonary bypass procedures lasting 6 hours or less.

V. DEVICE DESCRIPTION

The Heater-Cooler System 3T is an independent (i.e., independent of the water supply) 3-circuit heating/cooling base unit that includes three water circuits (two circuits for the patient supplied by one tank (for the heating/cooling blanket, the oxygenator) and one interchangeable heating/cooling circuit for cardioplegia. If required, patient and cardioplegia circuits can be switched off separately, in order to increase the activated functional group's heating and/or cooling performance.

The following optional components and accessories are also available for the Heater-Cooler System 3T:

1. Heating-cooling blankets;
2. Water circuit tubing; and
3. Various cables.

The Heater-Cooler System 3T includes a disposable aerosol collection set that consists of a canister connected to the Heater-Cooler System 3T and the user facility's vacuum source that captures emissions that are drawn from the tank using negative pressure created by the user facility's vacuum.

The changes proposed in the current 510(k) include the offering of a Deep Cleaning service by LivaNova to customers. The safety of the Heater-Cooler System 3T is ensured by the regular disinfection and cleaning, monitoring of the bacteria levels and by the aerosol collection set, as described in the Operating Manual that was cleared in K191402. The Deep Cleaning service is intended to address cases where heavily contaminated devices cannot meet the acceptable level described in section 6.5.2 of the Operating Instructions. In this situation, to allow the device to return to clinical use, the customer may choose to return the device for the Deep Cleaning service. The Deep Cleaning service is intended to reduce bioburden levels within the water circuit, thereby reducing the risk of NTM Aerosolization in the clinical setting. There are no changes to design or intended use.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Heater-Cooler System 3T and its predicate have the same intended use, clinical setting, target user, target patient population, and principle of operation.

VII. PERFORMANCE DATA

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The following non-clinical testing was performed to support the substantial equivalence of the Heater-Cooler System 3T, with the Deep Cleaning service, to its legally marketed predicate device:

- Process Validation of Deep Cleaning service
  - Installation Qualification
  - Operational Qualification
  - Process Qualification

Animal testing was not required to demonstrate the substantial equivalence of the Heater-Cooler System 3T to its predicate device and is not included as part of this premarket notification.

Clinical testing was not required to demonstrate the substantial equivalence of the Heater-Cooler System 3T to its predicate device and is not included as part of this premarket notification.

VIII. CONCLUSION

Based on the indications for use, technological characteristics, results of non-clinical testing, and comparison to predicate devices, the Heater-Cooler System 3T with the Deep Cleaning service is substantially equivalent to its predicate device (K191402).

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U.S. FOOD & DRUG ADMINISTRATION

Food and Drug Administration
CDRH/OPEQ/OHTII/DHTIIB
AWL RMONR
Global Work Location
Silver Spring, MD 20705

Premarket Notification 510(k) Review

Date: April 26, 2022

Reviewer: Jacob Morand

510(k)# K220635 Subject: Traditional

Applicant: LivaNova Deutschland GmbH	**Device Trade Name:** (b)(5) Heater-Cooler System 3T
Contact Name: Julia Leslie	**Contact Title:** Senior Director, Regulatory Affairs CS
Correspondent Firm: LivaNova Deutschland GmbH	**Phone:** 49 (89) 323-01141 **Email:** julie.leslie@livanova.com
Received Date: March 4, 2022	**Due Date:** June 2, 2022
Pro Code(s): DWC **Class:** II **Reg #:** 870.4250	**Reg Name:** Cardiopulmonary Bypass Temperature Controller

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K191402	DWC	Heater-Cooler System 3T	LivaNova Deutschland GmbH

Recommendation

(b)(5)

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Digital Signature Concurrence Table (Doc ID: 04500.14.06)	
This document represents a high-level summary of the Agency's determination on whether the applicant's device is substantially equivalent to a legally marketed predicate device. In determining whether the subject device is substantially equivalent to a predicate device, we carefully considered the relevant regulatory and statutory criteria for Agency decision-making under 21 CFR part 807 and section 513(i) of the Federal Food, Drug and Cosmetic Act (FD&C Act). We considered the burden that may be incurred by the applicant's attempt to follow the premarket notification process. The deficiencies provided in this review, if any, represent the required minimum information necessary to support a substantial equivalence determination. Therefore, we believe that we have considered the least burdensome requirements, under section 513(i)(1)(D) of the FD&C Act, for a 510(k) determination of substantial equivalence.	
Reviewer Sign-Off	Jacob Morand -S Digitally signed by Jacob Morand -S Date: 2022.04.28 17:12:57 -04'00'

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November 16, 2022</br></br> We have completed our review. Please refer to the attached letter for details.

If you have any questions, please contact the lead reviewer assigned to your submission, Jacob Morand.

 *** This is a system-generated email notification ***

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16. SOFTWARE

This submission does not include proposed changes to software. There have been no changes to the software since K162118. Updated documentation was provided in K191402. The following is an overview of the software cleared in (b)(4) and K191402. There is no new information in this software section compared to K191402.

A. Previously Submitted Information

Software changes to the 3T System generally were previously described in the catch-up 510(k) notice submitted in 2016 (K162118), and are being incorporated here by reference. The (b)(4) submission includes discussion of the software level of concern (b)(4) as well as a general description of the software and its functionality, a hazard analysis, the Software Requirements Specifications (SRS), Architecture Design, Software Design Specification (SDS), traceability analysis, the software life cycle development plan, verification and validation testing, revision history, and unresolved anomalies.

(b)(4)

LivaNova has since adopted its own procedure for any further software development activity. In K191402, the Company provided updated versions of the following documentation:

- K191402 (b)(4), Software Requirements Specification
- K191402 (b)(4), Architecture Design Chart
- K191402 (b)(4), Software Detail Design Specification
- K191402 (b)(4), Input-Output-Verification Matrix (IOV) for Software Subsystem
- K191402 (b)(4), Software Design Plan
- K191402 (b)(4) Firmware Development and Firmware Maintenance
- K191402 (b)(4) Remote Control Verification Protocol/Report
- K191402 (b)(4) and (b)(4) Risk Assessment and Control Procedure and Risk Analysis Table (respectively)

LivaNova also conducted further testing to baseline the current version of the 3T System's software (b)(4)

(b)(4)

(b)(4) Testing was conducted to support the following:

- Verification of the functional and capability requirements of the functions accessible from the user interface (provided as K191402 (b)(4)),
- Verification of the run-time performance of software within the context of an integrated system was demonstrated in test report (b)(4) provided as K191402 (b)(4)

(b)(4)

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(b)(4)

• Verification of the CAN bus (cable) communication requirements (provided as provided as K191402 (b)(4)

• Verification of the service mode options (provided as K191402 (b)(4)); and

• Verification of the run-time performance of software within the context of an integrated system for 200-240V 3T Systems as established in (b)(4) was demonstrated in test report (b)(4) provided as K191402 (b)(4)

(b)(4)

(b)(4)

B. Remote Operation of the Device
1. Software Description

(b)(4)

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(b)(4)

b) Operating Environment

(b)(4)

c) Programming Language

(b)(4)

d) *Hardware Platform*

(b)(4)

Communication:

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(b)(4)

The control system also includes the user interface that consists of the control panel (keys and display unit), remote control interface, and service interface.

Protection System: (b)(4)

(b)(4)

e) ***Operating System***

No operating system is used.

f) ***Off-the-Shelf Software***

(b)(4)

(b)(4)

2. Hazards Related to Remote Operation

The Company previously provided a summary of the manner in which LivaNova's hazard analysis was conducted. With this 510(k) notice, the Company is providing its updated Risk Management Plan, Risk Assessment and Control procedure, Risk Management Plan, Risk Management Report, and Input-Output-Verification Matrix (IOV). The Risk Assessment and Control procedure also includes a table list of assessed hazards (see (b)(4). These documents are provided in **K191402 Attachment C** (b)(4)

(b)(4)

3. Software Requirements Specifications (SRS)

The Company's updated Software Requirements Specification document is provided in **K191402** (b)(4) Section 3.4.8 identifies the requirement specifications for the remote operation of the 3T System.

4. Architecture Design Chart

The Company's updated Architecture Design Chart is provided in (b)(4)

(b)(4)

A flow diagram demonstrating the controls related to the "CAN" cable is provided in **Figure 1** below:

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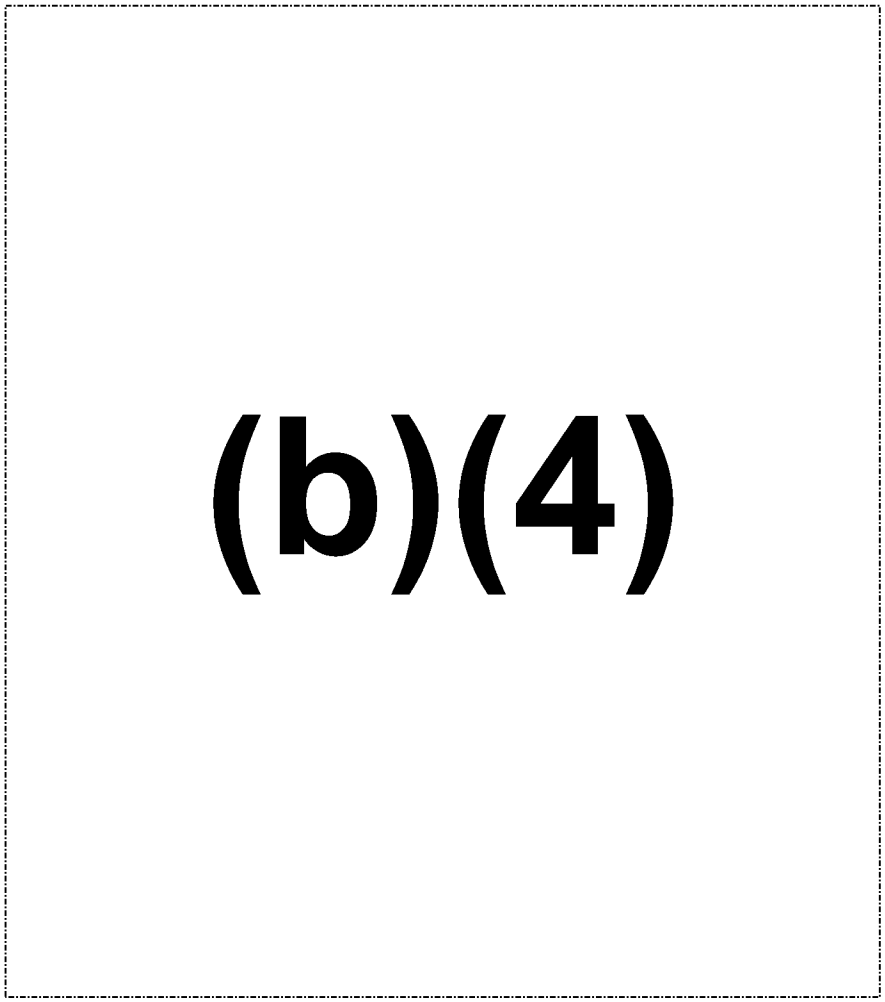

5. Software Design Specification (SDS)

The Company's updated Software Design Specifications (SDS) document is provided in **K191402** [redacted] (b)(4). Section 5 of the document discusses the remote operation of the device in further detail.

6. Traceability Analysis

The traceability matrix for the 3T System software links the Hazard Analysis with the Software Requirements Specification and test documentation. A copy of the 3T System traceability matrix for the Software Subsystem is provided in **K191402** [redacted] (b)(4). A summary of the remote control requirements traceability is provided below in **Figure 2**.

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(b)(4)

7. Software Development Environment Description

(b)(4), the information was previously provided in (b)(4) LivaNova has since developed procedures for future software development, which are provided in (b)(4) Software Development Plan, and **K191402** (b)(4) Firmware Maintenance

(b)(4)

8. **Verification and Validation Documentation**

In addition to the testing that was conducted, described, and provided in (b)(4), the Company has undertaken further testing to verify and validate that the remote operation functionality operates as intended. To do so, testing was conducted to verify the ability to remotely:

- (b)(4)

The testing conducted is summarized in **K191402** (b)(4). All test cases passed.

9. **Revision Level History Log**

(b)(4)

The updated revision level history log is provided below from Section 2.1 of the Software Design Plan document. This updated log describes, in further detail, the major changes that accompanied each

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version of the device (b)(4) (b)(4). See above and **K191402** (b)(4) for further verification testing specifically related to the remote operation of the device.

Version	Change Order # (b)(4)	Change Order # (b)(4)	Change Order Date (b)(4)	Description of change(s)
(b)(4)				

10. **Unresolved Anomalies (Bugs or Defects)**

(b)(4)

(b)(4). A list of those anomalies, annotated with an explanation of any potential impact of each anomaly on safety or effectiveness, is provided in **K191402** (b)(4) Attachment C Section 2.3. All of the identified anomalies

(b)(4)

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11. **Cyber and Information Security**

(b)(4)

(b)(4) The Company controls the integrity of the software by putting in place the following controls:

(b)(4)

12. **Run Time Error Detection**

(b)(4)

(b)(4) The results of this analysis, including the tools, techniques, strategy, and regression testing, are discussed in more detail in **K191402** (b)(4)

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Document Number : (b)(4)

Document Revision : (b)(4)

Document Title : Disinfection procedure HC3T

Effective Date: 07 Oct 2019

Expiration Date:

Notes :

Previous Number:

Change Number: (b)(4)

Document Type: (b)(4) - Procedure

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From: Leslie, Julie <julie.leslie@livanova.com>

Sent: Friday, April 22, 2022 8:43 AM

To: Morand, Jacob <Jacob.Morand@fda.hhs.gov>

Subject: [EXTERNAL] RE: K220635 Interactive Review Questions

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Hello,

Please find attached LivaNovaâ€™s responses to the interactive review questions. Please let me know if there are any further requests.

Have a good weekend,

Julie Leslie, PhD

Director, Regulatory Affairs, Cardiac Surgery

julie.leslie@livanova.com<mailto:julie.leslie@livanova.com>

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From: Leslie, Julie

Sent: Wednesday, April 20, 2022 2:14 PM

To: Morand, Jacob <Jacob.Morand@fda.hhs.gov<mailto:Jacob.Morand@fda.hhs.gov>>

Subject: RE: K220635 Interactive Review Questions

Hello,

Thank you for the interactive questions. Weâ€™ve received them and will provide you responses by Friday.

Many thanks,

Julie Leslie, PhD

Director, Regulatory Affairs, Cardiac Surgery

julie.leslie@livanova.com<mailto:julie.leslie@livanova.com>

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From: Morand, Jacob <Jacob.Morand@fda.hhs.gov<mailto:Jacob.Morand@fda.hhs.gov>>

Sent: Tuesday, April 19, 2022 4:35 PM

To: Leslie, Julie <julie.leslie@livanova.com<mailto:julie.leslie@livanova.com>>

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Subject: [EXTERNAL] K220635 Interactive Review Questions

Ms. Leslie,

I hope this email finds you well. I am Jacob Morand the Lead Reviewer with the FDA. While going over the submission, the team had a few questions. Please see below:

(b)(4)

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(b)(4)

Please provide a response by Friday 04/22/2022.

Thank You,

Jacob Morand

Lead Reviewer

Center for Devices & Radiological Health

U.S. Food and Drug Administration

White Oak Bldg 66, New Hampshire Ave, Silver Spring, MD 20993

Phone: 1 (301) 796-1127

Jacob.Morand@fda.hhs.gov<mailto:Jacob.Morand@fda.hhs.gov>

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Document Title : Stöckert S5 EMC Test Report (b)(4)

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5.0 510(k) SUMMARY

The Company's 510(k) Summary is provided on the following pages.

Records processed under FOIA Request 2023-9067; Released by CDRH on 05-23-2024

510(k) SUMMARY

(b)(4)

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U.S. FOOD & DRUG ADMINISTRATION

K220635
LivaNova Deutschland GmbH
Trade/Device Name: (b)(4) Heater-Cooler System 3T
Contact Name: Julia Leslie

This document is being communicated via e-mail as an attachment. The date on which FDA sent this e-mail is the official date of this correspondence.

We have reviewed your submission K220635 and have determined that additional information is required. Your file is being placed on hold pending a complete response to the attached deficiencies.

Please submit your response, referencing the submission number K220635 to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Please refer to the eCopy guidance at https://www.fda.gov/media/83522/download for current information on eCopy requirements.

Your response is due within 180 days from the date of this request, which is the hold date plus 180 days. If a complete response is not received in CDRH's Document Control Center by this date, we will consider this submission to be withdrawn, and we will delete it from our review system.

You may not market this device until you have received a letter from FDA allowing you to do so. If you market the device without FDA clearance, you will be in violation of the Federal Food, Drug, and Cosmetic Act.

If you would like a meeting or teleconference with the review team and management to discuss your planned approach for responding to the attached deficiencies, please submit your request for feedback as a Submission Issue Q-Submission (Q-Sub). Please note that a Submission Issue Q-Sub does not take the place of a formal response to this email notification. As noted above, FDA will consider this submission to be withdrawn if FDA does not receive, in a submission to the Document Control Center, a complete response to all of the attached deficiencies within 180 calendar days of the date of this request.

This request for additional information has undergone supervisory review to ensure that the deficiencies cited are least burdensome and relevant to the marketing decision. Please see the revised guidance "Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions" issued on September 29, 2017 (https://www.fda.gov/media/71735/download) for clarification regarding major and minor deficiencies.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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MAJOR DEFICIENCY LIST

(b)(4)

FDA is offering a teleconference within 10 calendar days from the date on this letter to address any clarification questions you may have pertaining to the deficiencies. If you are interested in a teleconference, please provide (1) proposed dates and (2) a list of your clarification questions via email at least 48 hours before the teleconference to the lead reviewer assigned to your submission. We would like to emphasize that

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the purpose of the meeting is to address specific clarification questions. Please note that if the specific clarification questions are not received at least 48 hours before the teleconference, the review team might not be able to provide feedback. The teleconference is not intended for review of new information, test methods or data; these types of questions could be better addressed via a Submission Issue Q-Submission (Q-Sub). For additional information regarding Q-Subs, please refer to the Guidance for Industry and FDA Staff on Medical Devices: Requests for Feedback and Meetings for Medical Device Submissions at https://www.fda.gov/media/114034/download.

Least Burdensome (LB) Flag

The LB flag is an approach to allow submitters the opportunity for the informal review by or on behalf of Division management of an issue raised in an FDA request for additional information (i.e., a deficiency letter). The goal of the LB flag is to quickly address FDA requests that submitters do not believe are least burdensome or when submitters believe they are being held to a different standard than their legally marketed predicate device. The LB flag is not intended to clarify deficiencies, is not an appeal under 21 CFR 10.75, and is not intended to provide a review of a proposed response to deficiencies.

If you would like to throw the LB flag, FDA has several criteria that should be met before you submit your request:

- You should have tried to address your concern by discussing it with Division management before attempting to throw the LB flag. This discussion with Division management may take place as part of a teleconference (such as the voluntary teleconference held within 10 days following transmission of an Additional Information letter to clarify deficiencies), email, or a Q-Submission Submission Issue Request.
- Your flag should generally be limited to two topic areas. Topic areas are common premarket review deficiency categories that apply to many device types across multiple reviewing Divisions. Examples of topic areas include biocompatibility, sterility, reprocessing, software, electromagnetic compatibility, wireless, electrical safety, clinical, and non-clinical performance testing.
- If you would like to discuss issues pertaining to more than two topic areas, you should contact OPEQSubmissionSupport@fda.hhs.gov for more information.
- You should throw the LB flag within 60 calendar days of the date that FDA sent the deficiency letter.

Upon meeting the criteria, you should send a short email (e.g., 1-2 page) that includes: 1) a summary of the deficiencies under disagreement, 2) a summary of relevant communications with Division management, and 3) a proposed path forward. The LB flag should be sent to the lead reviewer and their Assistant Director. You should also copy OPEQSubmissionSupport@fda.hhs.gov on your LB flag email request. Within two business days of your email, your request will be acknowledged by the reviewing Division. If you do not meet the criteria for the LB flag, you will be notified in this acknowledgement email.

Your LB flag should contain sufficient information to determine whether the deficiency letter was not least burdensome, or you are being held to a different standard than your predicate device. FDA may request a phone call with you to discuss your concern further and intends to communicate feedback from Division management on LB flags through email no later than 21 calendar days of their receipt. Please note that the LB flag does not change the deadline for your response to the Document Control Center. If you have any questions, please contact OPEQSubmissionSupport@fda.hhs.gov.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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20.0 PERFORMANCE TESTING – CLINICAL

This section does not apply because 3T Heater Cooler with the Deep Cleaning process did not require clinical data to demonstrate substantial equivalence.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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LivaNova
Health innovation that matters

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Document Number : (b)(4)

Document Revision (b)(4)

Document Title : Heater-Cooler system 3T EMC Test - RFID immunity IEC 61000-4-39:2017
(b)(4)

Effective Date: 04 Oct 2022

Expiration Date:

Notes :

Previous Number: **Change Number:**

Document Type: (b)(4)

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17.0 ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

As described in K162118 (submitted July 29, 2016), LivaNova previously conducted testing in accordance with the 2nd edition of the IEC standard for the U.S. released versions of the 3T System.

As described in K191402, the Company conducted electromagnetic compatibility and electrical safety testing of a 3T System to assure compliance with FDA's recognized consensus standard IEC 60601-1-2:2014 (Recognition Number 19-8).

Although the 3T HC met the required electromagnetic compatibility and electrical safety requirements as submitted in K191402, LivaNova made (b)(4) to meet compliance with IEC TR 60601-4-3 Edition 2.0 2018-12 section 4.2.168. (b)(4) (b)(4) according to IEC TR 60601-4-3 Edition 2.0 2018-12. (b)(4) according to IEC TR 60601-4-3 Edition 2.0 2018-12 section 4.2.168. T (b)(4) (b)(4)

The tested 3T System met the following emission and immunity standards:

- IEC 60601-1-2:2014 – Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
- EN 55011: 2009 + A1:2010 – Industrial scientific and medical (ISM) radio-frequency equipment – Electromagnetic disturbance characteristics – Limits and methods of measurement
- EN 61000-3-2:2006 + A1:2009 + A2:2009 – Harmonic current emissions
- EN 61000-4-2:2009 / IEC 61000-4-2:2008 – Electrostatic discharge immunity test (ESD)
- EN 61000-4-3:2006 + A1:2008 + A2:2010 / IEC 61000-4-3:2006 + A1:2007 + A2:2010 – Radiated, radio-frequency, electromagnetic field immunity test
- EN 61000-4-4:2012 / IEC 61000-4-4:2012 – Electrical fast transient / burst immunity test (BURST)
- EN 61000-4-5:2006 / IEC 61000-4-5:2005 – Surge immunity test (Surge)
- EN 61000-4-6:2014 / IEC 61000-4-6:2013 – Immunity to conducted disturbances, induced by radio-frequency fields
- EN 61000-4-8:2010 / IEC 61000-4-8:2009 – Power frequency magnetic field immunity test
- EN 61000-4-11:2004 / IEC 61000-4-11:2004 – Voltage dips, short interruptions and voltage variations immunity test

The 3T System-specific compliance criteria were as follows:

- (b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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A summary of the testing and results is provided below. Each test was repeated for different power supply voltages: 208 V / 60 Hz; and 120 V / 60 Hz, unless otherwise noted. The full test reports are included as **Attachment 17.1 (b)(4)**

Test	Test Description	Report Reference
Emission:		
(b)(4)		**Attachment 17.1 (b)(4)** (b)(4) pages 13-26
		Attachment 17.1 (b)(4) (b)(4) pages 27-34
		Attachment 17.1 (b)(4) (b)(4) pages 35-36;
Immunity:		
(b)(4)		**Attachment 17.1 (b)(4)** (b)(4) pages 37-39
		Attachment 17.1 (b)(4) (b)(4) pages 40-42
		Attachment 17.1 (b)(4) (b)(4) pages 43-44

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(b)(4)

Attachment 17.1 (b)(4) (b)(4) pages 45-46

Attachment 17.1 (b)(4) (b)(4) pages 47-49

Attachment 17.1 (b)(4) (b)(4) pages 50-51

Attachment 17.1 (b)(4) (b)(4) pages 52-53

Attachment 17.1 (b)(4) (b)(4) pages 54-55

The 3T System is labeled in compliance with the IEC 60601-1-2:2014 standard's labeling specifications..

3T System Device under Test

The testing described above was conducted on a configuration of the 3T System that (b)(4) (b)(4).

Test Unit	(b)(4)	Equivalent to final configuration for EMC/EMI Test
120 V		Yes
208 V		Yes

(b)(4)

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U.S. FOOD & DRUG ADMINISTRATION

LivaNova Deutschland GmbH
Julia Leslie
Senior Director, Regulatory Affairs CS
Lindbergh Strasse 25
Munchen, BY 80939
Germany

Re: K220635
Trade/Device Name: (b)(4) Heater-Cooler System 3T
Regulation Number: 21 CFR 870.4250
Regulation Name: Cardiopulmonary bypass temperature controller
Regulatory Class: Class II
Product Code: DWC
Dated: October 12, 2022
Received: October 14, 2022

Dear Julia Leslie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Nicole Gillette
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

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18.0 PERFORMANCE DATA

LivaNova Deutschland GmbH develops, tests and validates its products according to written procedures in compliance with 21 CFR §820.30, to ensure that the design process is controlled and that the device meets the intended use, customer needs, as well as regulatory requirements.

Design controls and risk analysis measures were applied to the development of **3T Heater Cooler Deep Disinfection Process**. The risk analysis method used to assess the impact of the modifications was a Failure Modes and Effects Analysis (FMEA), in compliance with the requirements of the ISO 14971: 2019 (*Medical devices – Application of risk management to medical devices*) standard.

As discussed in **Section 16**, the risk analysis performed (b)(4)

(b)(4)

The proposed change in this 510(k) relates to the proposed Deep Disinfection service process. Therefore, for all other categories, the previously submitted and cleared testing remains applicable, and is not being submitted again in this 510(k).

V&V Summary Table	Test Category	Required for Proposed Change	Supports a finding of substantial equivalence
Table 1	Cleaning/Disinfection Process Validation	(b)(4)	
N/A	Chemical Disinfection Effectiveness using: • (b)(4) •		

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		(b)(4)
N/A	Side-by-side performance testing: 3T Heater Cooler, compared to its predicate, 3T Heater Cooler	
N/A	Design verification	
N/A	Packaging Validation	
N/A	Labeling Validation	
N/A	Human Factors Validation	
See Section 17	Electrical Safety/EMC Type Testing	

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Validations Tracing to Deep Cleaning Process Overview

(b)(4)

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(b)(4)

The design verification and validation tests that were performed for this change as a result of this risk analysis assessment are listed in **TABLE 1** below.

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TABLE 1: NON-CLINICAL BENCH PERFORMANCE TESTING

Test(s) performed (ID)	Test(s) performed (Title)	Objective(s) of the test(s)	Device Description/ Sample Size	Test Method/ Applicable Standards	Acceptance Criteria	Results summary	Discussion/ Conclusions	Location of complete test report
(b)(4)								Att 18.1 Att 18.2
								Att 18.3
								Att 18.4 Att 18.5

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(b)(4)

Att 18.6
Att 18.7

Att 18.8
Att 18.9

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(b)(4)

Att 18.10
Att 18.11

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(b)(4)

Att 18.12
Att 18.13

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(b)(4)

Att 18.14
Att 18.15

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(b)(4)

These reports are in German. They are available upon request.

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(b)(4)

These reports are in German. They are available upon request.

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15.0 BIOCOMPATIBILITY

The 3T System is a non-patient contacting medical device. As such, biocompatibility testing in accordance with FDA's Guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" (June 16, 2016), is not required and therefore is not included in this 510(k) submission.

No changes are proposed to the design or user cleaning or disinfecting instructions. The following is an except from K191402.

As provided in a 21 C.F.R. Part 806 report submitted to FDA on June 23, 2017 (b)(4) LivaNova completed a toxicology evaluation per ISO 10993-17: 2009, Biological evaluation of medical devices: Part 17, Establishment of allowable limits for leachable substances, to address the risk of indirect patient contact with hydrogen peroxide added to the water tanks to maintain water quality. The indirect contact potentially occurs via (b)(4) (b)(4)

(b)(4)

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(b)(4)

(b)(4) The final toxicology assessment was provided in K191402 Attachment 17.1.

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7.0 CLASS III SUMMARY AND CERTIFICATION

The Class III Summary and Certification is not applicable to this submission as the device is currently cleared as a Class II device (Regulation number 21CFR870.4220, Product Code DTQ).

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Research Article

Efficacy of Thymol and Eugenol Against Polymicrobial Biofilm

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ABSTRACT

Biofilms associated with human infection have high levels of pathogenicity due to their resistance to antibiotics. The discovery of an active antibiofilm agent against polymicrobial biofilms is a necessary consequence for coping with biofilm-related infections. Thymol and Eugenol are essential oils that have potential as antibacterial and antifungal. This study aimed to determine the effectiveness of thymol and eugenol inhibits *C. albicans, P. Aeruginosa, E. coli S. aureus* and polymicrobial biofilm. Biofilm formation inhibition assay and biofilm degradation assay of thymol and eugenol were determined using microtiter broth method.The antibiofilm efficacy of thymol and eugenol towards polymicrobial biofilms were analyzed by calculating minimum biofilm inhibitor concentration ($MBIC_{50}$) and minimum biofilm eradication concentration ($MBEC_{50}$) values. The data were analyzed using *Statistical Package for the Social Sciences* (SPSS) with 95% confidence level. Thymol and eugenol showed inhibitory activity against the formation of mono and polymicrobial biofilms of the microbial tested.The result also demonstrated an evidence of activity of thymol and eugenol in breaking down mono and polymicrobial biofilm. Therefore, thymol and eugenol serves as a potential source for new antibiofilm drugs towards polymicrobial biofilm.

Key words: Thymol, Eugenol, polymicrobial biofilm, $MBIC_{50}$, $MBEC_{50}$

INTRODUCTION

Biofilm-related infections are an increasing health problem worldwide, especially patients suffering from immune system disorders such as HIV, cancer, organ transplants and malnutrition. Biofilm associated with human infection may contribute tomicrobial resistance towards antibiotic used. It is estimated that 65% of all hospital-related infections is caused by biofilms which includes its attachment on medical devices such as catheters and biomaterials (Furukawa *et al.*, 2006). Biofilm in nature consists of mixture of various strain and even various species of microbes living together. The microbial diversity in polymicrobial biofilms adds complexity in the eradication process (Liu *et al.*, 2000).

Many recent research on biofilm eradication have been done on single species microbial biofilms. However, polymicrobial biofilms can cause chronic infections while synergistic interactions in of the polymicrobials affects the physiological function of biofilms by resulting increased resistance and virulence (Burmølle*et al.*, 2014). The formation of biofilms from both bacterial polymicrobials (Gram positive and Gram negative) as well as fungi especially from the genus *C. albicans* is responsible for the onset of disease in humans. Some literature explain that bacteria synergistically can form biofilms with other bacterial species, and physically and physiologically the structure of the biofilm becomes thicker and stronger (Andersson*et al.*, 2008; Cowan *et al.*, 2003; Leriche *et al.*, 2003).

Thymol and Eugenolare both found in plant essential oils. Thymol has a broad spectrum antimicrobial activity, and has been the subject of several studies *in vitro* (Dorman and Deans, 2000).Thymol and eugenol had activity inhibit mono-species biofilm *S. aureus* and *E. coli* (Nestro *et al.*, 2007; Kim *et al.*, 2016). Despite being potential as antibiofilm against single species microbes, no reports on their effects eugenol against polymicrobial biofilms consists of *P. aeruginosa, E. coli, S. aureus, C.*

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albicans. Research on such topic is essential to evaluate the effectiveness of eugenol and thymol, as antibiofilm in polymicrobial cultures.

MATERIALS AND METHODS

Materials used were thymol (Sigma-Aldrich, Germany), eugenol (Sigma-Aldrich, Germany), crystal violet (Merck, Germany), ethyl acetate (Merck, Germany), *Brain Heart Infusion* (Oxoid) (Merck, Germany), ethanol 95% (Merck, Germany), nystatin (Sigma-Aldrich, Germany), chloramphenicol (Sigma-Aldrich, Germany).

Equipments

Some equipments used in this research were *Laminar Air Flow*, incubator (IF-2B) (Sakura, Japan), *micropipette pipetman* (Gilson, France), *multichannel micropipette* (Socorex, Swiss), *microplate flat-bottom polystyrene 96 well* (Iwaki, Japan), *mikrotiter plate reader* (Optic Ivymen System 2100-C, Spain), spectrophotometry (Genesys 10 UV Scanning, 335903) (Thermo Scientific Spectronic, USA), *autoclave* (Sakura, Japan), analytical scales (AB204-5, Switzerland).

Bacterial Strains

A standardstrain of *Saureus* ATCC 25923, *Ecoli* ATCC 25922, *Paeruginosa* ATCC 27853, wascultured in tryptic soy broth (TSB) medium and incubated at 37°C for 72h. *Calbicans* ATCC 10231 was cultured in Sabouraud Dextrose Broth (SDB) medium and incubated at 37°C withagitation (120rpm) for 24h. The optical densities (OD_{600}) of microbial cultures will be adjusted to 0.1 (equal of the 0.5 McFarland standard ~$1.5x10^8$ CFU/mL), and subsequently diluted in fresh medium to OD_{600} 0.01 for each microbial species.

Biofilm Formation Inhibition and Biofilm Eradication Assay *in Vitro*

In order to determine the isolate eugenol and thymol activity toward formation and degeneration of biofilm, a *microtiter plate polystyrene flat bottom 96-well* was used (Pierce *et al.,* 2008). A 100µL of *C. albicans* suspension (10^7 CFU/mL) was inserted in each well *microtiter plate*, *C. albicans* were incubated at 37°C for 90min for biofilm-adhesion phase. After the incubation, plates were washed using 150µL of sterile aquadest for three times in order to nullify the non-adhesive cells. A 100µL of media contained eugenol and thymol with different concentrations (1% v/v, 0.5% v/v, 0.25% v/v, 0,125% v/v), was added to each washed-well. Media with methanol were used as diluting controland microbe suspensions were used as negative control. As the positive control, a microbe suspension with nystatin 1% was used, and a media without microbe growth was used as media control. The plates were incubated in 37°C for 24h to form the mid-phase biofilm and 48h for maturating phase. Plates were washed with distilled water for three times. A 125µL solution of crystal violet 1% was added to each well in order to color the formed biofilm. The plates were incubated in a room temperature for 15min. After incubation, the microplates were washed with running water for three times to clean the crytal violet's remains and A 200µL of ethanol 96% was added to each well. The *Optical Density* (OD) reading was performed with microplate reader on the wavelength of 595nm. The testing was performed in three times replication. The percentage of inhibition and degeneration for every eugenol and thymol concentration was counted using the formula below:

$$\frac{\text{Od growth control} - \text{Od sample}}{\text{Od growth control}} \times 100$$

The amount of sample that could inhibit at least 50% of the biofilm formation can be considered as minimum biofilm inhibitory concentration ($MBIC_{50}$) and minimum biofilm eradication concentration ($MBEC_{50}$) (Pratiwi *et al* 2015). The testing for polymicrobial biofilm *C. albicans, E. coli, P. aeruginosa* and *S. aureus* was performed under the same methods with the monospecies *C. albicans.* In other hand, the biofilm testing towards *E. coli, P. aeruginosa* and *S.* aureus was similar to the monospecies testing without incubation of *C. albicans* at ±37°C for 90min for adhesion phase. A microbial suspension that already given an antibiotic namely chloramphenicol 1% v/v, was used as control-antibiotic.

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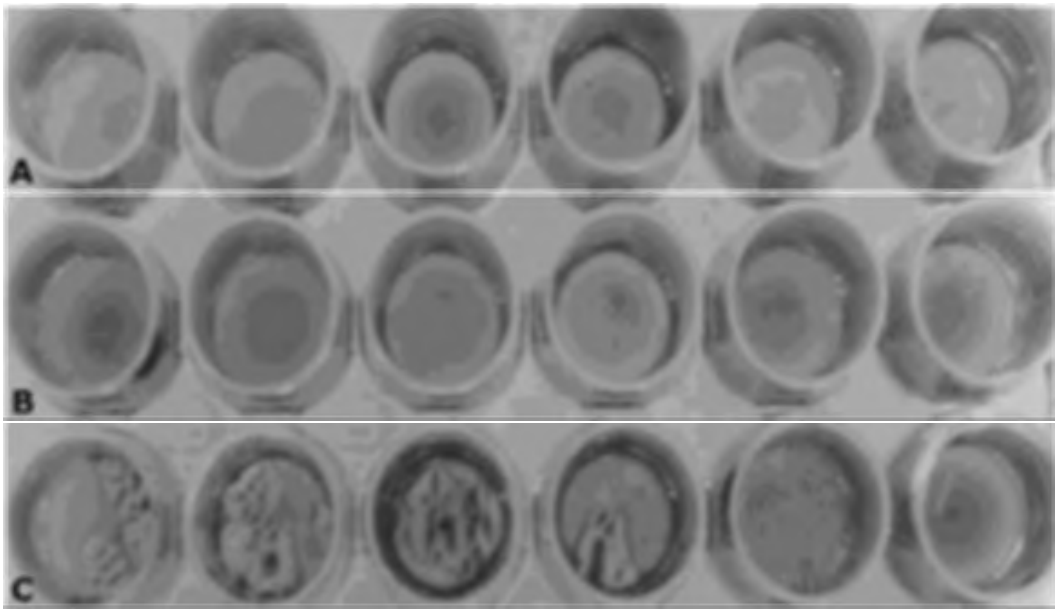

Figure 1. Crystal violet assay to see the formation of biofilm, a. Polymicrobial biofilm by adminitration of eugenol compounds; b. Polymicrobial biofilm by adminitration of thymol compounds; c. Polymicrobial biofilm without adminitration of test compound

RESULT AND DISCUSSION

Crystal violet assay for staining biofilm

Crystal violet staining is commonly used for quantification of biomass biofilm formation in various types of microorganisms. Crystal violet binds the negative charge on the surface of the molecule and polysaccharide to EPS so that crystal violet remains attached to the biofilm after being washed with distilled water (Peeters *et al.,* 2008). Crystal violet was used to show the quantity of biofilm mass (Stepanovic *et al.,* 2000). Crystal violet is bound to molecular surface negative ions and polysaccharides present in the extracellular matrix (Li *et al.,* 2003).

Biofilm formation can be seen in the microplate base after administration of crystal violet (Figure 1). Figure 1.C shows that the intensity of crystal violet staining is very clear, this showed that the composition of biofilm numbers located in these wells is very thick and strong where the biofilm is not well formed.

Whereas in figure 1.B the intensity of crystal violet staining is not as close as in Figure 1c.This indicates that biofilm formation is not completely formed. This inhibiting mechanism is caused by thymol compounds that inhibit polymicrobial biofim. Therefore, one bacterium was unable to form a community with other bacteria.

In figure 1. A, the intensity of staining of violet crystals is very low indicating that the biofilms formed are less than in figure 8.C and 8.B. This showed the inhibition of biofilm formation because the eugenol compound can inhibit the formation of *S. aureus*, *P. aeruginosa*, *E. coli* and *C. albicans* to form complex biofilm communities.

Effectof thymol and eugenol against mono-speciesmid – phase biofilm (24h)

In this study we evaluated the antibiofilm potencies of thymol and eugenol, each against polymicrobial and mono-species biofilms. We observed a decline in the rate of biofilm formation along with the increased concentrations of thymol and eugenol. The formation of *C. albicans* biofilm begins with the attachment of cells to host cells which last between 0-2h continuing with hyphae formation (4-6h). The hyphae yarns form a monolayer (6-8h) that will proliferate (8-24h) to then maturate (24-48h) (Ramage *et al.*, 2001).

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Table I. Effect of thymoland eugenol against mono-species mid – phase biofilm (24h)

Compound	Bacterial Strains	% Inhibition	$MBIC_{50}$ v/v
Thymol 1%	*P. aeruginosa*	84.10±1.26*	0.13%
	E. coli	85.30±0.52*	0.29%
	C. albicans	84.40±1.85*	0.20%
	S. aureus	59.70±0.90*	0.51%
Eugenol 1%	*P. aeruginosa*	86.86±1.15*	0.51%
	E. coli	82.87±0.62*	0.054%
	C. albicans	81.73±1.45*	0.06%
	S. aureus	57.56±0.51*	0.206%
Chloramphenicol 1%	*P. aeruginosa*	88.76±0.73*	
	E. coli	77.95±0.83*	
	S. aureus	59.02±1.10*	
Nystatin 1%	*C. albicans*	70.67±0.36*	

Table II. Effect of thymol and eugenol against mid – phase polymicrobial biofilm (24h)

Compound	% Inhibition	$MBIC_{50}$ v/v
Thymol 1%	84.05±0.25*	0.10%
Eugenol 1%	89.20±0.25*	0.31%
Chloramphenicol 1%	69.82±1.96*	
Nystatin 1%	55.70±0.72*	

The results of this study showed that the formation of mid-phase biofilms of *P. aeruginosa, E. coli, C. albicans* and *S. aureus* decreased with increasing concentrations of thymol compounds (Table I and Figure 2). Eugenol showed inhibitory activity against mid-phase mono-species and polymicrobials biofilm. The formation of mid-phase biofilms of *P. aeruginosa, E. coli, C. albicans* and *S. aureus* decreased with increasing concentrations of eugenol compounds (Table I and Figure. 3).

Effect of Thymol and Eugenol against mid – phase polymicrobial biofilm (24h)

The biofilm tested consisted of Gram-positive bacteria i.e *Staphylococus aureus* and Gram-negative bacteria i.e *Pseudomonas aeruginosa* - *Escherichia coli* and yeast *Candida albicans*. Previous study found that bacteria synergistically can form biofilms with other bacterial species that difficult to penetrate by antibiotics compared to planktonic cells (Andersson *et al*., 2008). EPS matrices in biofilms may help cells survive longer by providing protection layers against antibiotics (Anderson *et al*., 2008; Leriche *et al*., 2003).

Thymol 1% and eugenol 1%, each showed higher activity against Nystatin and Chloramphenicol of the same concentration. It was observed a concentration dependent antibiofilm activity towards a mid-phase polymicrobial biofilm (Table II and Figure 4). This value showed that the power of inhibiting activity of thymol and eugenol compound was strong and had potential as anti-biofilm medication's candidate.

Effect of Thymol and Eugenol against mono-speciesbiofilm maturation phase (48h)

In the maturation phase, antimicrobial agents will have more difficulties to penetrate the biofilm and eugenol compounds have the potential to be antibiofilm. We observed decreasing in biofilm growth with increasing concentration of thymol and eugenol compounds, as described in (Table III, Figure 5 and 6).

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Table III. Effect of thymol and eugenol against mono-species biofilm maturation phase (48h).

Compound	Bacterial Strains	% Inhibition	$MBIC_{50}$ v/v
Thymol 1%	*P. aeruginosa*	84.82±0.30*	0.22%
	E. coli	80.34±0.78*	0.45%
	C. albicans	72.63±1.41*	0.43%
	S. aureus	55.21±1.70*	0.52%
Eugenol 1%	*P. aeruginosa*	84.36±1.05*	0.26%
	E. coli	74.50±0.60*	0.51%
	C. albicans	74.91±0.55*	0.51%
	S. aureus	56.31±0.41*	0.62%
Chloramphenicol 1%	*P. aeruginosa*	79.66±0.20*	
	E. coli	81.84±0.56*	
	S. aureus	65.31±0.78*	
Nystatin 1%	*C. albicans*	71.49±0.41*	

Table IV. Effect of thymol and eugenol against polimicrobial biofilm phase (48h).

Compound	% Inhibition	$MBIC_{50}$ v/v
Thymol 1%	82.27±0.36 *	0.26%
Eugenol 1%	71.66±0.58 *	0.50%
Chloramphenicol 1%	74.72±0.26 *	
Nystatin 1%	50.98±3.71 *	

Thymol caused 50% damage in maturation phase of the mono-species *P. aeruginosa, E. Coli, C. albicans* and *S. aureus*. Antibiotic (chloramphenicol) and antifungal (nystatin 1%) that used as control showed a lower biofilm inhibition compared to thymol and eugenol compound. In biofilm inhibition of mono-species *P.aeruginosa* and *C. albicans*, thymol 1% showed higher activity against Chlorampenicol and nystatin of the same concentration (Table III).

In this phase, the microbes that formed biofilm were already adhesive to the substrate, so those thymol and eugenol compounds were harder to kill the biofilm compared to the mid-phase. In this phase, microbes were forming a strong biofilm defense system, and built a communication cell mechanism called quorum sensing. These made the antibiotics were hard to kill and damage the bacteria that formed biofilm.

Effect of Thymol and Eugenol against polimicrobial biofilm phase (48h)

Our results in figure 7 showed that thymol and eugenol with 0.5% concentration can damage the polymicrobial biofilm defense system for 50 %. On the concentration of 1% thymol and eugenol had inhibiting activites for 82.27±0.36% and 71.66±0.58%, while in antibiotic (chloramphenicol) and antifungal (nystatin 1%) showed a smaller inhibiting activity (Table IV). We reported that the eugenol activity on maturation phase of the polymicrobial biofilm was better compared to chloramphenicol. This showed that eugenol is potential to be developed and improved as the candidate for anti-biofilm. Eugenol at sub-inhibitory concentrations inhibited the produ-ction of virulence factors, including violacein, elastase, pyocyanin, and biofilm formation (Zhou *et al.*, 2013)

$MBIC_{50}$ values for polymicrobial biofilm maturation phase were 0.26% v/v (Thymol) and 0.50% v/v (Eugenol). This value showed that thymol and eugenol compounds had strong inhibiting activity, but eugenol $MBIC_{50}$ value on the middle-phase was better compared to the maturation phase, because in the maturition phase, the heterogeneous pattern was found in the biofilm, that interacted one and another and had more complex structure.

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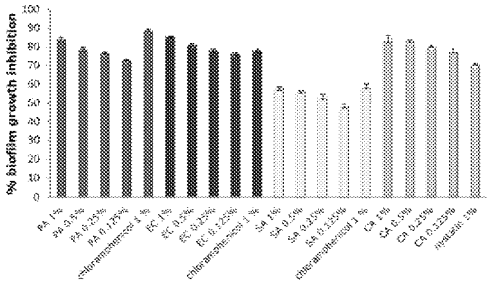

Figure 2. Effect of thymol against mono-speciesmid – phasebiofilm. Blue= *P. aeruginosa,* Red= *E.coli,* Yellow= *C.albicans,* Green= *S. aureus*

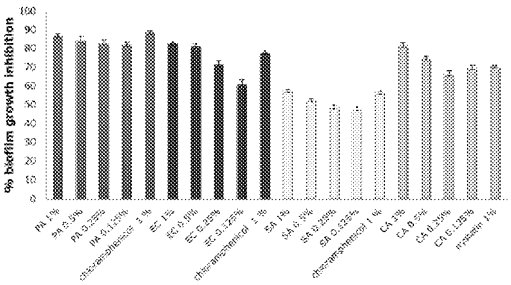

Figure 3. Effect of eugenol against mono-speciesmid – phase biofilm. Blue= *P. aeruginosa,* Red= *E.coli,* Yellow =*C.albicans,* Green= *S. aureus.*

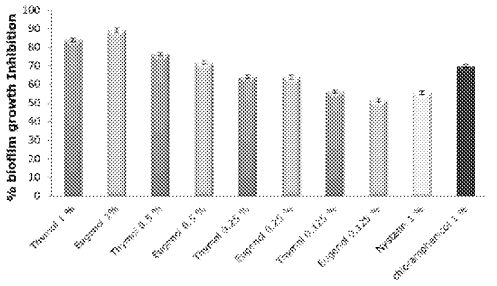

Figure 4. Effect of thymol and eugenol against polymicrobial mid – phasebiofilm. Brown = *Thymol,* Green= *Eugenol,* Yellow=*Nystatin,* Red= *Choloramfenicol.*

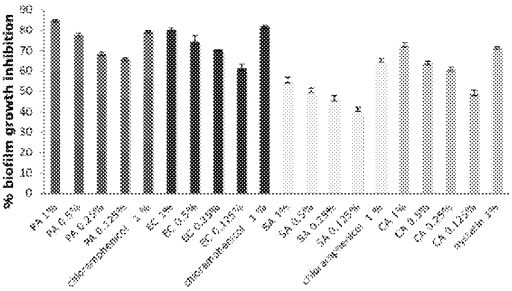

Figure 5. Effect of Thymol against mono-species maturation biofilm. Blue = *P. aeruginosa,* Red =*E. coli,* Yellow =*C. albicans,* Green = *S. aureus.*

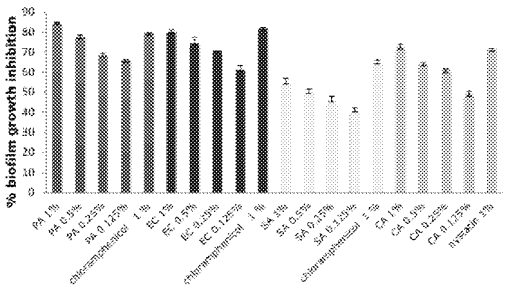

Figure 6. Effect of eugenol against mono-species maturation biofilm. Blue= *P. aeruginosa,* Red=*E. coli,* Yellow=*C. albicans,* Green = *S. aureus.*

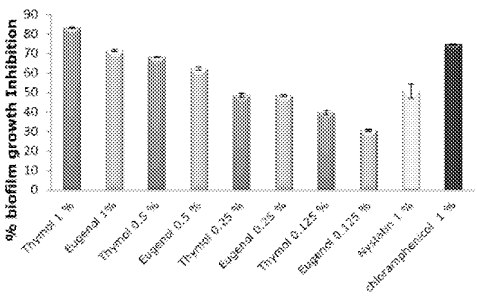

Figure 7. Effect of thymol and eugenol against polymicrobial maturation biofilm. Brown = *Thymol,* Green= *Eugenol,* Yellow =*Nystatin,* Red = *Choloramfenicol.*

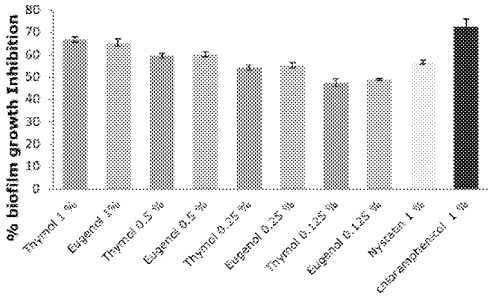

Figure 8. Effect of thymol and eugenol against polymicrobial eradication biofilm. Brown = *Thymol,* Green= *Eugenol,* Yellow =*Nystatin,* Red = *Choloramfenicol* Green

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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This is in accordance with Hamzah (2017) statement that interactions in biofilm bacteria can improve the ability of other bacterial species to survive and grow in aquatic environments that trigger rapid responses and result in complex biofilm formation.

Effect of Thymol and Eugenol against polimicrobial biofilm phase eradication

In polymicrobial biofilm *P. aeruginosa* rapidly triggered *E. coli* growth, making it possible to form a boarder biofilm area. The interaction with biofilm bacteria such as *P. aeruginosa* increased the ability of *E. coli* to survive and grow in an aquatic environment. In polymicrobial biofilm, they were well-organized in order to ful fill each others' nutrition. We reported that thymol and eugenol degraded 50% formation of *C. albicans*, *P. aeruginosa*, *E. coli* and *S. aureus* biofilm (Figure 8).

It was harder to damage the microbes that formed biofilm compared to microbes that formed biofilm in a middle and inhibition phase. This caused by the longer growth time of biofilm, lead toformation of strong bacteria community so that antibiotics are difficult to penetrate. Matrices extracellular polymer subtances (EPS) in biofilms may help cells survive longer than if a set of conditions because EPS bound with water in an abundance amount so the microbes form a strong biofilm that had resistance toward drought, nutrients' deficiency, anti-microbial substance and other conditions that brought disadvantages to the microbes' growth. The EPS matrix on biofilms can help microorganism cells last longer than when they are in planktonic conditions, so it can help to microcortium various species of microorganisms in the degradation process (Donlan, 2002).

In this study, we reported that thymol and eugenol compound had activity of biofilm damaging. The $MBEC_{50}$ value of thymol and eugenol are 0.17 and 0.24 *(*P<0.05)* respectively. According to this study, it can be reported that the inhibition activities of thymol and eugenol compound in biofilm degradation phase were more potent compared to the control such as nystatin 56.66 % ± 0.96 %; while in chloramphenicol, the inhibition activitiesof thymol and eugenol compound in biofilm degradation phase were found almost similar 72.63±3.33%.

Therefore effectiveness of thymol and eugenol against polymicrobial biofilm is an interesting thing to the discovery of new antibiofilm compounds as a therapeutic option for biofilm polymicrobial related infections.

CONCLUSION

Thymol and Eugenol potential as potential sources of novel antibiofilm candidates against polymicrobial biofilms *C. albicans – P. aeruginosa - E. coli* and *S. aureus*.

ACKNOWLEDGEMENT

Authors acknowledge Faculty of Pharmacy UGM for research financial support.

REFERENCES

Andersson S., Kuttuva Rajarao G., Land CJ., and Dalhammar, G., 2008. Biofilm formation and interactions of bacterial strains found in wastewater treatment systems: Biofilm formation and interactions of bacterial strains. *FEMS Microbiology Letters*, 283: 83–90.

Burmølle M., Ren D., Bjarnsholt T., and Sørensen, S.J., 2014. Interactions in multispecies biofilms: do they actually matter?. *Trends in Microbiology*. 22: 84–91.

Cowan SE., Gilbert E., Liepmann D., and Keasling, JD., 2000. 'Commensal Interactions in a Dual-Species Biofilm Exposed to Mixed Organic Compounds, *Applied and Enviromental Microbiology*. 66: 4481-4485.

Donlan RM., 2002. *Biofilm:* Microbial Life on Surfaces. *Emerging Infectious Diseases* 8: 881–890.

Dorman HJD., Deans S. G., 2000. Antimicrobial agents from plants: antibacterial activity of plant volatile oils. *J Appl Microbiol.* 88: 308–316.

Furukawa WF., Bryers JD., Robbins J., 2006., Biomaterial-centered infection: *microbial adhesion*. Science.

Hamzah H., 2017, The Effect of C-10 *Massoialactone* to The Culture Multispecies of Biofilm, Thesis, Universitas Gadjah Mada, Indonesia.

Kim YG., Lee JH, Gwon G, Kim SI, Park JK, Lee J., 2016. Essential Oils and Eugenols

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-9067; Released by CDRH on 05-23-2024

Inhibit Bioflm Formation and the Virulence of *Escherichia coli* O157:H7. *Scientific reports*. 6 : 363777.

Leriche V., Briandet R., dan Carpentier B., 2003. Ecology of mixed biofilms subjected daily to a chlorinated alkaline solution: spatial distribution of bacterial species suggests a protective effect of one species to another. *Environmental Microbiology*. 5: 64–71.

Li X., 2003. Quantitative variation of biofilms among strains in natural populations of Candida albicans. *Microbiology*, **149**: 353–362.

Liu H., Xu L., Zeng J., 2000. Role of Corrosion Products in Biofilms in Microbiologically Induced Corrosion of Carbon Steel. *British Corr J*. 35: 131-135.

Nestro A., Blanco A. R., Cannatelli MA., Enea V., Flamini G., Morelli I., Sudano Roccaro SA., Alonzo V., 2004. Susceptibility of methicillin-resistant staphy lococci to oregano essential oil, carvacrol and thymol. *FEMS Microbiol Lett*. 230: 191–195.

Peeters E., Nelis, HJ., and Coenye T., 2008. Comparison of multiple methods for quantification of microbial biofilms grown in microtiter plates. *Journal of Microbiological Methods*, **72**: 157–165.

Pierce CG., Uppuluri P., Tristan AR., Wormley FL., Mowat E, Ramage G., 2008. A Simple and Reproducible 96 Well Plate-Based Method for The Formation of Fungal Biofilms and Its Application to Anti-fungal Susceptibility Testing. *Nat Protoc*. 3: 1494-1500.

Pratiwi SUT., Lagendijk EL., de Weert S., Hertiani T., Idroes R., Van Den Hondel CAMJJ., 2015. Effect of *Cinnamomumburmannii* Nees ex Bl. and *Massoiaaromatica* Becc. Essential oils on planktonic growth and biofilm formation of *Pseudomonas aeruginosa* and *Staphylococcus aureus* in vitro. *International Journal of Applied Research in Natural Product*.8: 1-13.

Ramage G., VandeWalle K., Wickes BL., Lopez-Ribot JL., 2001. Standardized Method for In Vitro Antifungal Susceptibility Testing of *Candida albicans* Biofilms. *Antimicrobial Agents and Chemotherapy*. 45: 2475–2479.

Stepanović S., Vuković D., Dakić I., Savić B., and Švabić-Vlahović M., 2000. A modified microtiter-plate test for quantification of staphylococcal biofilm formation. *Journal of Microbiological Methods*, **40**: 175–179.

Zhou L., Zheng H., Tang Y., Yu W., Gong Q., 2013. Eugenol inhibits quorum sensing at sub-inhibitory concentrations. *Biotechnol Lett*. 35: 631–637.

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U.S. FOOD & DRUG ADMINISTRATION

K220635
LivaNova Deutschland GmbH
Trade/Device Name: (b)(4) Heater-Cooler System 3T
Contact Name: Julia Leslie

This document is being communicated via e-mail as an attachment. The date on which FDA sent this e-mail is the official date of this correspondence.

We have reviewed your submission K220635 and have determined that additional information is required. Your file is being placed on hold pending a complete response to the attached deficiencies.

Please submit your response, referencing the submission number K220635 to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Please refer to the eCopy guidance at https://www.fda.gov/media/83522/download for current information on eCopy requirements.

Your response is due within 180 days from the date of this request, which is the hold date plus 180 days. If a complete response is not received in CDRH's Document Control Center by this date, we will consider this submission to be withdrawn, and we will delete it from our review system.

You may not market this device until you have received a letter from FDA allowing you to do so. If you market the device without FDA clearance, you will be in violation of the Federal Food, Drug, and Cosmetic Act.

If you would like a meeting or teleconference with the review team and management to discuss your planned approach for responding to the attached deficiencies, please submit your request for feedback as a Submission Issue Q-Submission (Q-Sub). Please note that a Submission Issue Q-Sub does not take the place of a formal response to this email notification. As noted above, FDA will consider this submission to be withdrawn if FDA does not receive, in a submission to the Document Control Center, a complete response to all of the attached deficiencies within 180 calendar days of the date of this request.

This request for additional information has undergone supervisory review to ensure that the deficiencies cited are least burdensome and relevant to the marketing decision. Please see the revised guidance "Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions" issued on September 29, 2017 (https://www.fda.gov/media/71735/download) for clarification regarding major and minor deficiencies.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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MAJOR DEFICIENCY LIST

The Agency has identified major deficiencies that if not adequately resolved, may preclude a favorable decision on the marketing application.

(b)(4)

FDA is offering a teleconference within 10 calendar days from the date on this letter to address any clarification questions you may have pertaining to the deficiencies. If you are interested in a teleconference, please provide (1) proposed dates and (2) a list of your clarification questions via email at least 48 hours before the teleconference to the lead reviewer assigned to your submission. We would like to emphasize that

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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the purpose of the meeting is to address specific clarification questions. Please note that if the specific clarification questions are not received at least 48 hours before the teleconference, the review team might not be able to provide feedback. The teleconference is not intended for review of new information, test methods or data; these types of questions could be better addressed via a Submission Issue Q-Submission (Q-Sub). For additional information regarding Q-Subs, please refer to the Guidance for Industry and FDA Staff on Medical Devices: Requests for Feedback and Meetings for Medical Device Submissions at https://www.fda.gov/media/114034/download.

Least Burdensome (LB) Flag

The LB flag is an approach to allow submitters the opportunity for the informal review by or on behalf of Division management of an issue raised in an FDA request for additional information (i.e., a deficiency letter). The goal of the LB flag is to quickly address FDA requests that submitters do not believe are least burdensome or when submitters believe they are being held to a different standard than their legally marketed predicate device. The LB flag is not intended to clarify deficiencies, is not an appeal under 21 CFR 10.75, and is not intended to provide a review of a proposed response to deficiencies.

If you would like to throw the LB flag, FDA has several criteria that should be met before you submit your request:

- You should have tried to address your concern by discussing it with Division management before attempting to throw the LB flag. This discussion with Division management may take place as part of a teleconference (such as the voluntary teleconference held within 10 days following transmission of an Additional Information letter to clarify deficiencies), email, or a Q-Submission Submission Issue Request.
- Your flag should generally be limited to two topic areas. Topic areas are common premarket review deficiency categories that apply to many device types across multiple reviewing Divisions. Examples of topic areas include biocompatibility, sterility, reprocessing, software, electromagnetic compatibility, wireless, electrical safety, clinical, and non-clinical performance testing.
- If you would like to discuss issues pertaining to more than two topic areas, you should contact OPEQSubmissionSupport@fda.hhs.gov for more information.
- You should throw the LB flag within 60 calendar days of the date that FDA sent the deficiency letter.

Upon meeting the criteria, you should send a short email (e.g., 1-2 page) that includes: 1) a summary of the deficiencies under disagreement, 2) a summary of relevant communications with Division management, and 3) a proposed path forward. The LB flag should be sent to the lead reviewer and their Assistant Director. You should also copy OPEQSubmissionSupport@fda.hhs.gov on your LB flag email request. Within two business days of your email, your request will be acknowledged by the reviewing Division. If you do not meet the criteria for the LB flag, you will be notified in this acknowledgement email.

Your LB flag should contain sufficient information to determine whether the deficiency letter was not least burdensome, or you are being held to a different standard than your predicate device. FDA may request a phone call with you to discuss your concern further and intends to communicate feedback from Division management on LB flags through email no later than 21 calendar days of their receipt. Please note that the LB flag does not change the deadline for your response to the Document Control Center. If you have any questions, please contact OPEQSubmissionSupport@fda.hhs.gov.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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8.0 FINANCIAL DISCLOSURES

LivaNova is not submitting clinical data in support of this 510(k) notice. For this reason, FDA's regulation regarding clinical investigators' financial interests and arrangements, i.e., 21 C.F.R. § 54.4, do not apply. Thus, the Company is not providing a disclosure or certification to the absence of any disclosable financial interests or arrangements.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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U.S. FOOD & DRUG ADMINISTRATION

Food and Drug Administration
CDRH/OPEQ/OHTII/DHTIIB
AWL RMONR
Global Work Location
Silver Spring, MD 20705

Premarket Notification 510(k) Review

Date: April 26, 2022

Reviewer: Jacob Morand

510(k)# K220635 Subject: Traditional

Applicant: LivaNova Deutschland GmbH	**Device Trade Name:** (b)(5) Heater-Cooler System 3T
Contact Name: Julia Leslie	**Contact Title:** Senior Director, Regulatory Affairs CS
Correspondent Firm: LivaNova Deutschland GmbH	**Phone:** 49 (89) 323-01141 **Email:** julie.leslie@livanova.com
Received Date: March 4, 2022	**Due Date:** June 2, 2022
Pro Code(s): DWC **Class:** II **Reg #:** 870.4250	**Reg Name:** Cardiopulmonary Bypass Temperature Controller

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K191402	DWC	Heater-Cooler System 3T	LivaNova Deutschland GmbH

Recommendation

(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(5)

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(b)(5)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approved: OMB No. 0910-0120
Expiration Date: June 30, 2023
See PRA Statement on last page.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(If known)*
10/12/2022	(b)(4)	K220635

SECTION A — TYPE OF SUBMISSION

PMA & PDP
- ☐ Original
- ☐ Modular Submission
- ☐ Amendment
- ☐ Report (annual or PAS)
- ☐ Report Amendment
- ☐ Other:
  - ☐ Premarket Report (reprocessed SUD)
  - ☐ Licensing Agreement

PMA/PDP Supplement
- ☐ 180 day - PAS protocol or labeling change, location change, trade name change
- ☐ 180 day - Design or labeling change
- ☐ Special CBE
- ☐ Panel Track
- ☐ 30-day Notice
- ☐ Real-time Review
- ☐ Amendment to PMA/PDP Supplement

510(k)
- ☐ Original Submission:
  - ☐ Traditional
  - ☐ Special
  - ☐ Abbreviated
  - ☐ 3rd Party Traditional
  - ☐ 3rd Party Special
  - ☐ 3rd Party Abbreviated
  - ☐ Dual Track (Dual 510(k) and CLIA Waiver by Application)
- ☐ Amendment
- ☒ Supplement

CLIA

CLIA Categorization Record (CR)
- ☐ Original
- ☐ Amendment

CLIA Waiver by Application (CW)
- ☐ Original
- ☐ Amendment
- ☐ Supplement

Q-Submission
- ☐ Pre-Submission
- ☐ Informational Meeting
- ☐ Submission Issue Meeting
- ☐ Day 100 Meeting
- ☐ Agreement Meeting
- ☐ Determination Meeting
- ☐ Study Risk Determination
- ☐ Other *(Specify below)*

IDE
- ☐ Original IDE:
  - ☐ Amendment to Original IDE
- ☐ Supplement:
  - ☐ Amendment to Supplement
- ☐ Report:
  - ☐ Amendment to Report

HDE
- ☐ Original Submission
- ☐ Amendment to Original
- ☐ Report
- ☐ Report Amendment
- ☐ HDE Supplement:
  - ☐ 75-day Supplement
  - ☐ 30-day Notice
  - ☐ Special CBE
  - ☐ Amendment to Supplement

Class II Exemption Petition
- ☐ Original Submission
- ☐ Additional Information

Emergency Use Authorization
- ☐ Original
- ☐ Supplement
- ☐ Amendment
- ☐ Report

De Novo
- ☐ Original:
  - ☐ Direct
  - ☐ Post-NSE
- ☐ Amendment
- ☐ Supplement

Pre-Emergency Use Authorization
- ☐ Original
- ☐ Supplement
- ☐ Amendment

Other Submission
- ☐ 513(g)
- ☐ Appeal
- ☐ Other *(Briefly describe submission below)*

Expanded Access to Devices
- ☐ Compassionate Use Request **NOT associated with an IDE**
- ☐ Follow-up Report for Compassionate Use **NOT associated with an IDE**
- ☐ Emergency Use Follow-up Report **NOT associated with an IDE**

SECTION B — APPLICANT / SPONSOR

Company/Institution Name		Establishment Registration Number/FEI *(if known)*
LivaNova Deutschland GmbH		9611109
Street Address		City
Lindberghstrasse 25		Munchen
State/Province	ZIP/Postal Code	Country
BY	80939	Germany

Contact Name	Contact Title
Julia E. Leslie, PhD	Senior Director, Regulatory Affairs CP
Division Name *(if applicable)*	Phone Number *(including area code)*
Cardiopulmonary	+49 89 323 01 141
Fax Number *(including area code)*	Contact Email Address
	julie.leslie@livanova.com

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SECTION C OFFICIAL CORRESPONDENT (e.g., may be a consultant and/or 510(k) Third Party) (if different from Section B)

Company/Institution Name		Establishment Registration Number/FEI *(if known)*
Street Address		City
State/Province	ZIP/Postal Code	Country

Contact 1 Name	Contact 1 Title
Contact 1 Division Name *(if applicable)*	Contact 1 Phone Number *(including area code)*
Contact 1 Fax Number *(including area code)*	Contact 1 Email Address
Contact 2 Name	Contact 2 Title
Contact 2 Division Name *(if applicable)*	Contact 2 Phone Number *(including area code)*
Contact 2 Fax Number *(including area code)*	Contact 2 Email Address
Contact 3 Name	Contact 3 Title
Contact 3 Division Name *(if applicable)*	Contact 3 Phone Number *(including area code)*
Contact 3 Fax Number *(including area code)*	Contact 3 Email Address

To add another set of Section C items, please click on the button to the right. May be repeated as needed. Add Section C

SECTION D INTENDED USE POPULATION

Check all that apply.

- ☐ Adults Only (greater than 21 years of age)
- ☒ Adults and Pediatrics
- ☐ Neonate/Newborn (birth through 28 days)
- ☐ Infant (from 29 days to 2 years of age)
- ☐ Child (from 2 years to 12 years of age)
- ☐ Adolescent (from 12 years to 18 years of age)
- ☐ Transitional Adolescent A (18 through 21 years of age)
- ☐ Transitional Adolescent B (18 through 21 years of age)
- ☐ Other *(Specify below)*

SECTION E PRODUCT INFORMATION – APPLICABLE TO ALL SUBMISSIONS

	Trade Name
1	(b)(4) Heater-Cooler System 3T
2	
3	
4	
5	

Common/Generic Name *(Include if no Trade Name)*
Cardiopulmonary bypass temperature controller

Records processed under FOIA Request 2023-9067; Released by CDRH on 05-23-2024

SECTION F PRIOR RELATED SUBMISSIONS FOR THIS DEVICE OR STUDY

FDA document numbers of all prior related submissions *(regardless of outcome)* or state no prior submission in box 1.

1 K052601	2 (b)(4)	3 K191402
4	5	6
7	8	9
10	11	12

SECTION G PRODUCT CLASSIFICATION – APPLICABLE TO ALL SUBMISSIONS

Product Code(s) *(when applicable) (If more than one, please separate with commas.)*

DWC

C.F.R. Section *(If applicable)*	Classification Panel/Medical Specialty
21 CFR 870.4250	

Device Class

☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

SECTION H1 REASON FOR APPLICATION – PMA, PDP, OR HDE

☐ New Device
☐ STED

☐ Post-approval Study Protocol

☐ HDE Request for Annual Distribution Number (ADN)

☐ Change in Design, Component, or Specification:
- ☐ Software/Hardware
- ☐ Color Additive
- ☐ Material
- ☐ Specifications
- ☐ Other *(Specify below)*

☐ Location Change:
- ☐ Manufacturer
- ☐ Sterilizer
- ☐ Packager

☐ Report Submission:
- ☐ Annual or Periodic
- ☐ Post-approval Study

☐ Process Change:
- ☐ Manufacturing
- ☐ Packaging
- ☐ Sterilization
- ☐ Vendor/Supplier Change
- ☐ Other *(Specify below)*

☐ Labeling Change:
- ☐ Indications
- ☐ Instructions
- ☐ PAS update
- ☐ Performance Characteristics
- ☐ Shelf Life
- ☐ Trade Name
- ☐ Other *(Specify below)*

☐ Amendment:
- ☐ Withdrawal
- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Address
- ☐ Request for Extension
- ☐ Response to FDA Correspondence
- ☐ Other *(Specify below)*

☐ Bundle Submission – *If this is selected, list in the spaces below any PMAs in the Bundle.*

1	2	3
4	5	6
7	8	9

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SECTION H2 REASON FOR APPLICATION – IDE

☐ Original IDE

☐ Supplement:
- ☐ New Study/New Protocol
- ☐ Change in Correspondent
- ☐ Change in Manufacturer
- ☐ Change in Sponsor
- ☐ Change in Design
- ☐ Change in Informed Consent
- ☐ Change in Manufacturing
- ☐ Change in Protocol
- ☐ 5-Day Notice – Device or Manufacturing
- ☐ 5-Day Notice – Protocol
- ☐ Compassionate Use Request (under an IDE)
- ☐ Live Case Request
- ☐ Request Deviation from Protocol
- ☐ Expansion of Study (Study/Sites)
- ☐ Extension of Time to Submit Annual Report or Respond to FDA Letter

Supplement *(Continued)*
- ☐ Request for Waiver
- ☐ IRB Certification
- ☐ Request for CMS Recategorization
- ☐ Study Resumed
- ☐ Study Suspension
- ☐ Other *(Specify below)*

☐ Report:
- ☐ Adverse Effect
- ☐ Final, Study Completed
- ☐ Annual Progress
- ☐ Interim Progress
- ☐ Semiannual Investigator List
- ☐ Failure to Obtain Informed Consent
- ☐ Compassionate Use Follow-up
- ☐ Emergency Use
- ☐ Live Case Follow-up
- ☐ Completion of Patient Enrollment
- ☐ Completion of Patient Follow-up
- ☐ Other *(Specify below)*

☐ Amendment to Original IDE:
- ☐ Amendment Before Final Decision
- ☐ Response to Refuse to Accept
- ☐ Response to Disapproval
- ☐ Response to Approval with Conditions
- ☐ Withdrawal
- ☐ Other *(Specify below)*

☐ Amendment to Supplement:
- ☐ Response to Disapproval
- ☐ Response to Approval with Conditions
- ☐ Withdrawal
- ☐ Amendment Before Final Decision (additional Information)
- ☐ Other *(Specify below)*

☐ Amendment to Report:
- ☐ Response to Deficiency Letter
- ☐ Withdrawal
- ☐ Amendment Before Final Decision (additional Information)
- ☐ Other *(Specify below)*

SECTION H3 REASON FOR SUBMISSION – Q-SUBMISSION

☐ Pre-Submission:
- ☐ Request Face-to-Face Meeting
- ☐ Request Teleconference
- ☐ Request Email Response
- ☐ Submit Meeting Minutes
- ☐ Request Meeting Minutes Disagreement T-con

☐ Submission Issue Meeting:
- ☐ Request Face-to-Face Meeting
- ☐ Request Teleconference
- ☐ Request Email Response
- ☐ Submit Meeting Minutes
- ☐ Request Meeting Minutes Disagreement T-con

☐ Additional Information

☐ Change in Legal Entity:
- ☐ Change in Correspondent
- ☐ Change in Sponsors
- ☐ Change in Manufacturer
- ☐ Other *(Specify below)*

☐ Agreement Meeting:
- ☐ Request Face-to-Face Meeting
- ☐ Request Teleconference

☐ Determination Meeting:
- ☐ Request Face-to-Face Meeting
- ☐ Request Teleconference

☐ Informational Meeting:
- ☐ Request Face-to-Face Meeting
- ☐ Request Teleconference
- ☐ Submit Meeting Minutes
- ☐ Request Meeting Minutes Disagreement T-Con

☐ Other *(Specify)*:

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SECTION H4 REASON FOR SUBMISSION – 510(k)

- ☐ Original
- ☐ Withdrawal of Original
- ☐ Amendment Before Final Decision:
  - ☐ Change in Ownership
  - ☐ Change in Correspondent
  - ☐ Withdrawal
- ☐ Amendment After Final Decision
- ☒ Supplement:
  - ☐ Response to Refuse to Accept (RTA)
  - ☒ Response to Additional Information Request
  - ☐ Withdrawal
- ☐ Reprocessed SUD
- ☐ Corrective Action
- ☐ STED
- ☐ Third Party *(Complete Section C)*
- ☐ Other Reason *(Specify)*:

Information on devices to which substantial equivalence is claimed *(If known)*

	510(k) Number	*Trade Name*	*Submitter*	*Product Code*
Primary Predicate (A)	K191402	Stöckert Heater-Cooler System 3T	LivaNova Deutschland GmbH	DWC
Predicate or Reference Device (B)				

To add another Predicate or Reference Device (B) entry row, please click on the button to the right. May be repeated as needed. Add Device Information

SECTION H5 DE NOVO SUBMISSIONS

- ☐ Post NSE De Novo: Number of the 510(k) that was NSE'd in the past 30 days:
- ☐ Withdrawal

SECTION H6 REASON FOR APPLICATION – CLIA

Includes CLIA Parent Document number, CR number, or CW number.

- ☐ **CLIA Categorization Record (CR):**
  - ☐ CLIA Categorization of marketed device (include marketing submission number)
  - ☐ CLIA Categorization of device exempt from premarket review
  - ☐ Additional information regarding an open CR (include CR number)
- ☐ **CLIA Waiver by Application (CW):**
  - ☐ Request for CLIA Waiver by Application for marketed device (include marketing submission number)
  - ☐ Request for Dual 510(k) Clearance and CLIA Waiver by Application (include Pre-submission number)
  - ☐ Response to FDA correspondence
  - ☐ Additional information regarding an open CW (include CW number)
- ☐ **Other Reason** *(Specify)*

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SECTION I MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

Applicable only to IDEs

Note: Submission of this information does not affect Registration and Listing.	FDA Document Number *(if known)*

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager/Relabeler

Company/Institution Name		Establishment Registration Number/FEI *(if known)*
Street Address		City
State/Province	ZIP/Postal Code	Country

Contact 1 Name	Contact 1 Title
Contact 1 Division Name *(if applicable)*	Contact 1 Phone Number *(including area code)*
Contact 1 Fax Number *(including area code)*	Contact 1 Email Address

Contact 2 Name	Contact 2 Title
Contact 2 Division Name *(if applicable)*	Contact 2 Phone Number *(including area code)*
Contact 2 Fax Number *(including area code)*	Contact 2 Email Address

Contact 3 Name	Contact 3 Title
Contact 3 Division Name *(if applicable)*	Contact 3 Phone Number *(including area code)*
Contact 3 Fax Number *(including area code)*	Contact 3 Email Address

To add another set of Section I items, please click on the button to the right. May be repeated as needed. Add Section I

SECTION J UTILIZATION OF STANDARDS

Note: Please see guidance document titled "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices" for details on the Declaration of Conformity.

How to fill out this section:

Recognition Number: State the FDA recognition number. If the standard is not recognized, write **NR**.

Declaration of Conformity or General Use: Select 'Declaration of Conformity' if including a "Declaration of Conformity to a Recognized Standard" statement. For all other uses, select 'General Use' and indicate if you have made deviations from the Recognized/Non-recognized standard.

Standard: State the Standards Development Organization (SDO), the Designation Number (including year), and the Title.

Location: State the section and/or the page number(s) in the submission where the standard is applied.

Examples

	Recognition Number	Declaration of Conformity or General Use		Standards Development Organization (SDO), Designation Number-Year, and Title	Location
1 X	8-185	Declaration of Conformity	*If General Use,* Deviation?	ASTM F451-08, standard specification for acrylic bone cement.	Section 3, p. 15
2 X	3-44	General Use	*If General Use,* Deviation? Yes	AAMI ANSI BP22:1994 (R) 2011 Blood Pressure Transducers	Section 4, p. 32

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Entries for Utilization of Standards

	Recognition Number	Declaration of Conformity or General Use		Standards Development Organization (SDO), Designation Number-Year, and Title	Location
1 X	19-4	General Use	*If General Use*, Deviation? No	IEC 60601-1 2005 A1:2012	Section 9
2 X	19-8	General Use	*If General Use*, Deviation? No	IEC 60601-1-2 Edition 4.0 2014	Section 9
3 X	5-125	General Use	*If General Use*, Deviation? No	ISO 14971 Third Edition 2019	Section 9
4 X	NR	General Use	*If General Use*, Deviation? No	EN 55011/CISPR 11 2009+A1:2010	Section 9
5 X	NR	General Use	*If General Use*, Deviation? No	IEC 61000-3-2 2005+A1:2008+A2:2009	Section 9
6 X	NR	General Use	*If General Use*, Deviation? No	IEC 61000-4-2 2008	Section 9
7 X	NR	General Use	*If General Use*, Deviation? No	IEC 61000-4-3 2006+A1:2007+A2: 2010	Section 9
8 X	NR	General Use	*If General Use*, Deviation? No	IEC 61000-4-4 2012	Section 9
9 X	NR	General Use	*If General Use*, Deviation? No	IEC 61000-4-5 2005	Section 9
10 X	NR	General Use	*If General Use*, Deviation? No	IEC 61000-4-6 2013	Section 9
11 X	NR	General Use	*If General Use*, Deviation? No	IEC 61000-4-8 2009	Section 9
12 X	NR	General Use	*If General Use*, Deviation? No	IEC 61000-4-11 2004	Section 9
13 X	14-530	General Use	*If General Use*, Deviation? No	EN ISO 11607-1 2009+A1:2014	Section 9
14 X	19-36	General Use	*If General Use*, Deviation? No	IEC 60601-1-2 Edition 4.1: 2020	Section 9

To add another row for Section J, please click on the button to the right. May be repeated as needed.
(To remove a particular row, please click on the "X" button at the beginning of the row.)

Add Row/Standard

SECTION K UTILIZATION OF CDRH GUIDANCE DOCUMENTS

How to fill out this section:

Title: Enter the title of the guidance documents used in the preparation of your premarket submission. CDRH guidance documents can be found at ***http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm***.

Entries for Utilization of CDRH Guidance Documents

	Title of Guidance Document
1 X	Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices (2018)

To add another row for Section K, please click on the button to the right. May be repeated as needed.
(To remove a particular row, please click on the "X" button at the beginning of the row.)

Add Row/Document

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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U.S. FOOD & DRUG ADMINISTRATION

November 16, 2022

LivaNova Deutschland GmbH
Julia Leslie
Senior Director, Regulatory Affairs CS
Lindbergh Strasse 25
Munchen, BY 80939
Germany

Re: K220635
Trade/Device Name: Heater-Cooler System 3T
Regulation Number: 21 CFR 870.4250
Regulation Name: Cardiopulmonary bypass temperature controller
Regulatory Class: Class II
Product Code: DWC
Dated: October 12, 2022
Received: October 14, 2022

Dear Julia Leslie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Nicole M. Gillette -S

Nicole Gillette
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Heater-Cooler System 3T

Indications for Use *(Describe)*

The Heater-Cooler 3T System is used to circulate water through heat exchangers to warm or cool a patient during cardiopulmonary bypass procedures lasting 6 hours or less.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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510(k) SUMMARY

I. SUBMITTER

Name:	LivaNova Deutschland GmbH
Address:	Lindberghstrasse 25 D-80939 München, Germany
Establishment Registration Number	9611109
Contact Person:	Julia E. Leslie, PhD
Phone:	+49 89 323 01 141
Email:	julie.leslie@livanova.com
Secondary Contact:	Florian Goetz
Phone:	+49 89 323 01 236
Email:	florian.goetz@livanova.com
Date Prepared:	February 28, 2022

II. DEVICE

Proprietary Name:	Heater-Cooler System 3T
Common Name:	Cardiopulmonary bypass temperature controller
Classification Name:	Controller, Temperature, Cardiopulmonary Bypass
Regulation Number:	21 CFR 870.4250
Product Code:	DWC
Device Class:	Class II

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III. PREDICATE DEVICE INFORMATION

Heater-Cooler System 3T with the Deep Cleaning service is substantially equivalent in function and intended use to **Heater-Cooler System 3T (K191402).**

IV. INDICATIONS FOR USE

The Heater-Cooler System 3T is used to circulate water through heat exchangers to warm or cool a patient during cardiopulmonary bypass procedures lasting 6 hours or less.

V. DEVICE DESCRIPTION

The Heater-Cooler System 3T is an independent (i.e., independent of the water supply) 3-circuit heating/cooling base unit that includes three water circuits (two circuits for the patient supplied by one tank (for the heating/cooling blanket, the oxygenator) and one interchangeable heating/cooling circuit for cardioplegia. If required, patient and cardioplegia circuits can be switched off separately, in order to increase the activated functional group's heating and/or cooling performance.

The following optional components and accessories are also available for the Heater-Cooler System 3T:

1. Heating-cooling blankets;
2. Water circuit tubing; and
3. Various cables.

The Heater-Cooler System 3T includes a disposable aerosol collection set that consists of a canister connected to the Heater-Cooler System 3T and the user facility's vacuum source that captures emissions that are drawn from the tank using negative pressure created by the user facility's vacuum.

The changes proposed in the current 510(k) include the offering of a Deep Cleaning service by LivaNova to customers. The safety of the Heater-Cooler System 3T is ensured by the regular disinfection and cleaning, monitoring of the bacteria levels and by the aerosol collection set, as described in the Operating Manual that was cleared in K191402. The Deep Cleaning service is intended to address cases where heavily contaminated devices cannot meet the acceptable level described in section 6.5.2 of the Operating Instructions. In this situation, to allow the device to return to clinical use, the customer may choose to return the device for the Deep Cleaning service. The Deep Cleaning service is intended to reduce bioburden levels within the water circuit, thereby reducing the risk of NTM Aerosolization in the clinical setting. There are no changes to design or intended use.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Heater-Cooler System 3T and its predicate have the same intended use, clinical setting, target user, target patient population, and principle of operation.

VII. PERFORMANCE DATA

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The following non-clinical testing was performed to support the substantial equivalence of the Heater-Cooler System 3T, with the Deep Cleaning service, to its legally marketed predicate device:

- Process Validation of Deep Cleaning service
  - Installation Qualification
  - Operational Qualification
  - Process Qualification

Animal testing was not required to demonstrate the substantial equivalence of the Heater-Cooler System 3T to its predicate device and is not included as part of this premarket notification.

Clinical testing was not required to demonstrate the substantial equivalence of the Heater-Cooler System 3T to its predicate device and is not included as part of this premarket notification.

VIII. CONCLUSION

Based on the indications for use, technological characteristics, results of non-clinical testing, and comparison to predicate devices, the Heater-Cooler System 3T with the Deep Cleaning service is substantially equivalent to its predicate device (K191402).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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11.0 EXECUTIVE SUMMARY

11.1 SCOPE AND LAYOUT OF 510(K) NOTICE

LivaNova Deutschland GmbH is submitting the attached premarket notification ("510(k) Notification") for its proposed service of Deep Cleaning for the 3T Heater Cooler.
General information for the subject device is provided in the table below.

This 510(k)submission follows the format of a traditional 510(k) submission and conforms with FDA's September 13, 2019, Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s.

11.2 DEVICE DESCRIPTION

The Heater-Cooler 3T System is used to circulate water through heat exchangers to warm or cool a patient during cardiopulmonary bypass procedures lasting 6 hours or less.

There are no proposed changes to the intended use environment.

Proprietary Name:	Heater-Cooler 3T System
Common Name:	Cardiopulmonary bypass temperature controller / Heater Cooler
Classification Name:	Controller, Temperature, Cardiopulmonary Bypass
Regulation Number:	21CFR870.4250
Product Code:	DWC
Device Class:	Class II

Table 11.2-1: General device information

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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11.3 INDICATIONS FOR USE

The Heater-Cooler 3T System is used to circulate water through heat exchangers to warm or cool a patient during cardiopulmonary bypass procedures lasting 6 hours or less.

11.4 SYSTEM COMPONENTS

The 3T System is a stand-alone, heating/cooling base unit that allows for the attachment of three (3) water circuits:

- One water circuit is for connection to the heat exchanger of an oxygenator, an accessory device.
- One water circuit is for connection to a heating/cooling blanket, an accessory device.
- One water circuit is for connection to the cardioplegia heat exchanger, an accessory device.

The Heater-Cooler 3T contains three (3) internal water tanks.

- One of the internal water tanks supplies both the oxygenator and the heating/cooling blanket circuits. This tank temperature can be set from (b)(4) degrees Celsius.
- One of the internal water tanks supplies cold water to the cardioplegia circuit. This tank temperature can be set from (b)(4) degrees Celsius.
- One of the internal water tanks supplies warm water to the cardioplegia circuit. This tank temperature can be set from (b)(4) degrees Celsius.

The vacuum canister and internal sealing solution maintains negative air pressure inside the 3T System's water tanks in order to direct aerosols and the potential NTM accompanying these aerosols away from the operating environment and into the Aerosol Collection Set.

The following components and accessories are also available for the 3T System (a further description of these components is provided below):

1. Heating-cooling blankets
2. Various cables and water circuit tubing:
   - 25 meter length (b)(4) tube to allow the user to set up the three circuits (oxygenator, blanket and, cardioplegia).
   - Three (3) metal tubing connectors (½ inch, 90° angle) and three (3) metal tubing connectors (½ inch, straight) for connecting the water circuit tubing with the tubing for the oxygenator or other accessories (such as heating-cooling blankets).
   - Potential equalization cable (grounding cable).
   - Optional Controller Area Network (CAN) cable for communicating with heart-lung machines.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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11.5 OPERATING PRINCIPLE

The changes proposed in the current 510(k) include the offering of a Deep Cleaning service by LivaNova to customers. The Deep Cleaning process was approved for implementation under 21 CFR 806 by the FDA in April 2018. This 510(K) requests FDA clearance of offering the Deep Cleaning service outside of 21 CFR 806 conditions.

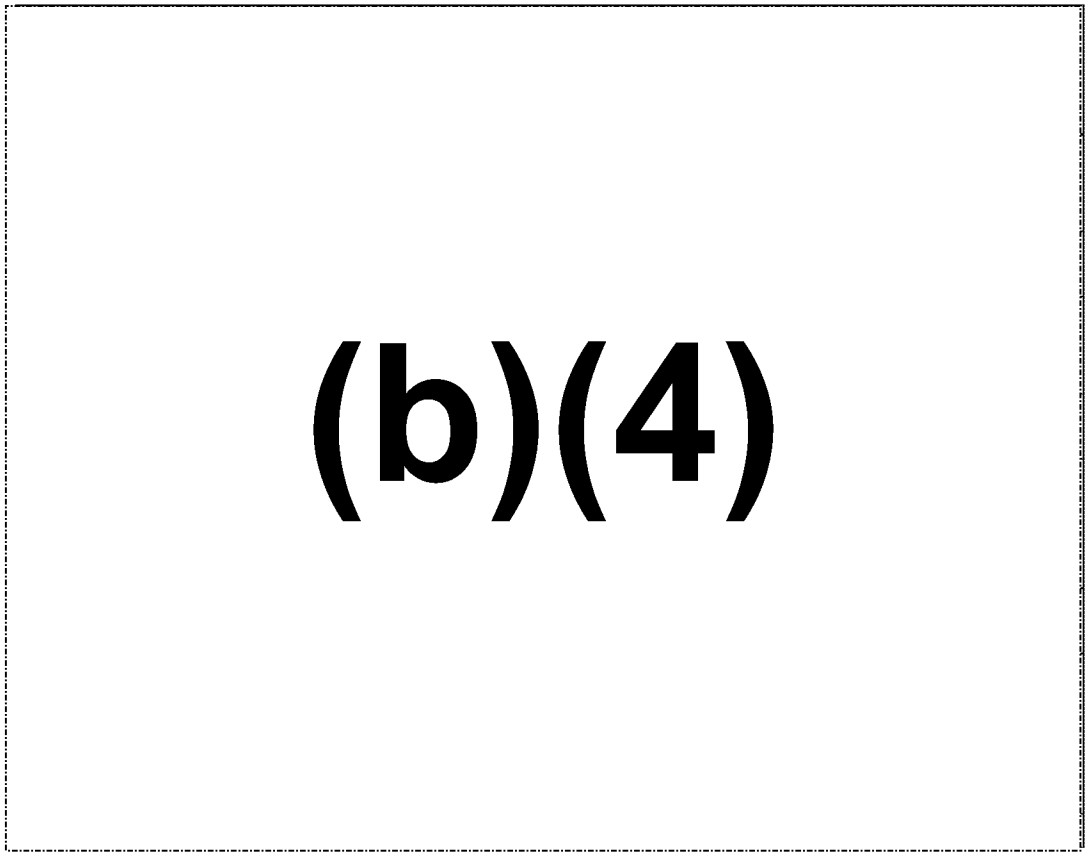
The safety of the 3T Heater Cooler device is ensured by the regular disinfection and cleaning, monitoring of the bacteria levels and by the aerosol collection set, as cleared in K191402.

The Deep Cleaning service is intended to address cases where heavily contaminated devices cannot meet the acceptable level described in section 6.5.2 of the Operating Instructions. In this situation, to allow the device to return to clinical use, the customer may choose to return the device for Deep Cleaning service. The Deep Cleaning service is intended to reduce biofilm levels within the water circuit, thereby reducing the risk of NTM Aerosolization in the clinical setting.

There are no changes to design or intended use.

The Deep Cleaning Process in place at LivaNova Deutschland, proposed for US customer devices, is described below.

Process Overview



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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11.6 PREDICATE COMPARISON

3T Heater Cooler, with the proposed optional Deep Cleaning Process, is proposed to be substantially equivalent to its predicate, 3T Heater Cooler (K191408). LivaNova has made the determination based on the intended use/ indication for use, operational characteristics, fundamental design characteristics, and fundamental technological characteristics.

Substantial Equivalence Chart

	3T System with Optional Deep Cleaning Process	**Cleared 3T System (K191408)**	**Difference**
Indications for Use	The 3T System is used to circulate water through heat exchangers to warm or cool a patient during cardiopulmonary bypass procedures lasting 6 hours or less	The 3T System is used to circulate water through heat exchangers to warm or cool a patient during cardiopulmonary bypass procedures lasting 6 hours or less	No change
User Population	Clinical personnel (e.g., qualified perfusionists) and Maintenance personnel (e.g., biomedical engineers/technicians who may perform maintenance on the 3T System)	Clinical personnel (e.g., qualified perfusionists) and Maintenance personnel (e.g., biomedical engineers/technicians who may perform maintenance on the 3T System)	No change
Primary Technological Characteristics	An independent (i.e., independent of the water supply) 3-circuit heating/cooling base unit that includes three water circuits (two circuits for the patient supplied by one tank (for the heating/cooling blanket, the oxygenator) and one	An independent (i.e., independent of the water supply) 3-circuit heating/cooling base unit that includes three water circuits (two circuits for the patient supplied by one tank (for the heating/cooling blanket, the oxygenator) and one	No change

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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	3T System with Optional Deep Cleaning Process	**Cleared 3T System (K191408)**	**Difference**
	interchangeable heating/cooling circuit for cardioplegia	interchangeable heating/cooling circuit for cardioplegia	
Accessories	Optional components and accessories include heating-cooling blankets and various cables and tubing	Optional components and accessories include heating-cooling blankets and various cables and tubing	No change
Dimensions (W x H x D(depth))	50 x 97.5 x 68 cm	50 x 97.5 x 68 cm	No change
Input Voltage	208V/ 60 Hz 120V/ 60 Hz	208V/ 60 Hz 120V/ 60 Hz	No change
Operation	Stand alone and optional remote operation feature as part of cleared S5/C5 heart-lung machine	Stand alone and optional remote operation feature as part of cleared S5/C5 heart-lung machine	No change
Software	**(b)(4)**		
Sterilization	Intended as non-sterile and for use in the non-sterile area of the user's facility	Intended as non-sterile and for use in the non-sterile area of the user's facility	No change

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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11.7 PERFORMANCE DATA

The following non-clinical testing was performed to support the substantial equivalence of the 3T System with the Deep Cleaning service to its legally marketed predicate device:

- Deep Cleaning Process Validation

(b)(4)

The following chemical disinfection approaches used within the Deep Cleaning service were already approved for inclusion in the US Operating Instructions:

- (b)(4)

The verification and validation of these chemical disinfection approaches was cleared in K191402.

Animal testing was not required to demonstrate the substantial equivalence of the 3T System to its predicate device and is not included as part of this premarket notification.

Clinical testing was not required to demonstrate the substantial equivalence of the 3T System to its predicate device and is not included as part of this premarket notification.

11.8 SUBSTANTIAL EQUIVALENCE

The discussion of the substantial equivalence of the device to its predicate devices is provided in Section 12, Substantial Equivalence.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Operating principle and technological characteristics

The 3T Heater Cooler, with the proposed Deep Cleaning Process, has the same operating principles and technological characteristics as its predicate. There are no changes to intended purpose, design, or functionality.

Conclusion

Based on the information provided, LivaNova has determined that the 3T Heater Cooler, with the proposed Deep Cleaning Process, is substantially equivalent to the 3T Heater Cooler and that any differences are minor and raise no new issues of safety or effectiveness.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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March 16, 2022</br></br>

Acceptance Review Notification - Accepted

An administrative acceptance review was conducted on your submission K220635, and it was found to contain all of the necessary elements and information needed to proceed with the substantive review. We will contact you should we require any additional information during the course of the substantive review.

The lead reviewer assigned to your submission is me, Jacob Morand. The file is being reviewed in Office of Health Technology 2, Division of Health Technology 2 B. The first line supervisor is the Assistant Director, Circulatory Support Devices. You may contact me at any point during the review if you have questions or concerns. You can provide valuable support for CDRH to continue to improve our programs by raising to the attention of management relevant issues that arise during the course of this review. If you feel there is an unresolved issue or a matter that requires additional attention, you should contact the Assistant Director. If your concern or issue is not addressed by the Assistant Director, you should contact the Division Director or OHT Director. The contact information for each management level can be found in the CDRH Management Directory.

We will contact you should we require any additional information during the course of the substantive review. FDA aims to apply the least burdensome principles when requesting additional information.

If you have general questions about the review process for your submission, you should contact OPEQSubmissionSupport@fda.hhs.gov.

 *** This is a system-generated email notification ***

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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LivaNova

Health innovation that matters

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Signature Manifest

Document Number: (b)(4) **Revision:** (b)(4)

Title: Deep Disinfection Process HC-3T

All dates and times are in Central European Time.

(b)(4) **Deep Disinfection Process HC-3T**

(b)(4)

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PROCESS VALIDATION PLAN (PVP)

HEATER COOLER 3T DEE P DISINFECTION PROCE SS

(b)(4)

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INSTALLATION QUALIFICATION (IQ)

(b)(4)

(b)(4)

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U.S. FOOD & DRUG ADMINISTRATION

Food and Drug Administration
CDRH/OPEQ/OHTII/DHTIIB
AWL RMONR
Global Work Location
Silver Spring, MD 20705

Premarket Notification 510(k) Review

Date: November 10, 2022

Reviewer: Jacob Morand

510(k)# K220635/S001 Subject: Traditional

Applicant: LivaNova Deutschland GmbH	**Device Trade Name:** (b)(5) Heater-Cooler System 3T
Contact Name: Julia Leslie	**Contact Title:** Senior Director, Regulatory Affairs CS
Correspondent Firm: LivaNova Deutschland GmbH	**Phone:** 49 (89) 323-01141 **Email:** julie.leslie@livanova.com
Received Date: October 14, 2022	**Due Date:** November 17, 2022
Pro Code(s): DWC **Class:** II **Reg #:** 870.4250	**Reg Name:** Cardiopulmonary Bypass Temperature Controller

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K191402	DWC	Heater-Cooler System 3T	LivaNova Deutschland GmbH

Recommendation

(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: Taddese, Biniyam
To: Morand, Jacob
Subject: RE: K220635-S001 Consult Request
Date: Wednesday, October 19, 2022 5:05:17 PM
Attachments: image001.png

Hi Jacob,

(b)(5)

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Sincerely,
-Bini

Biniyam Tesfaye Taddese, Ph.D.
Electrical Engineer

THT3A1: Renal and Transplantation Devices Team
DHT3A: Division of Renal, Gastrointestinal, Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration
10903 New Hampshire Ave, Silver Spring, MD 20993
WO66, Room 2544
Tel: 240-402-6570
biniyam.taddese@fda.hhs.gov

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From: Morand, Jacob <Jacob.Morand@fda.hhs.gov>
Sent: Monday, October 17, 2022 1:48 PM
To: Taddese, Biniyam <Biniyam.Taddese@fda.hhs.gov>
Subject: K220635-S001 Consult Request

Hello Bini,

Hope all is well with you. Reaching out today as LivaNova provided S001 for K220635 in which you identified **(b)(5)** **(b)(5)** Let me know if this timeline works for you and thank you!

Best,
Jacob

Jacob Morand
Lead Reviewer

Center for Devices & Radiological Health
U.S. Food and Drug Administration
White Oak Bldg 66, New Hampshire Ave, Silver Spring, MD 20993
Phone: 1 (301) 796-1127
Jacob.Morand@fda.hhs.gov

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Heater-Cooler System 3T

Indications for Use *(Describe)*

The Heater-Cooler 3T System is used to circulate water through heat exchangers to warm or cool a patient during cardiopulmonary bypass procedures lasting 6 hours or less.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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EMC – TEST REPORT

Type / Model Name : Heater-cooler system 3T

Product Description : Heater-cooler system 3T

Applicant : LivaNova Deutschland GmbH

Address : Lindberghstr. 25

80939 München, GERMANY

Manufacturer : LivaNova Deutschland GmbH

Address : Lindberghstr. 25

80939 München, GERMANY

(b)(4)

Test Report No. :	(b)(4)	28. September 2022 Date of issue

ilac-MRA DAkkS Deutsche Akkreditierungsstelle D-PL-12030-01-01

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

The test report merely corresponds to the test sample. It is not permitted to copy extracts of these test results without the written permission of the test laboratory.

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From: DCCLetters@fda.hhs.gov [DCCLetters@fda.hhs.gov]
Sent: 3/4/2022 7:38:26 PM
To: julie.leslie@livanova.com
CC: DCCLetters@fda.hhs.gov
Subject: K220635 Acknowledgement Letter
Attachments: K220635-Acknowlegement Letter.pdf

March 4, 2022

Thank you for your submission. We have attached your acknowledgement letter for your records. If you have any questions about your acknowledgement letter, please contact us at DCCmailroom@fda.hhs.gov. Please do not reply to this email.

*** This is a system-generated email notification ***

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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U.S. FOOD & DRUG ADMINISTRATION

Acknowlegement Letter

03/04/2022

Julia E. Leslie, Senior Director, Regulatory Affairs CS, Cardiopulmonary
LivaNova Deutschland GmbH
Lindbergh Strasse 25
Munchen,
BY 80939 GERMANY

Dear Julia E. Leslie:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the address listed below. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please contact the Office of Product Evaluation and Quality (OPEQ) submission support at (301) 796-5640 or OPEQSubmissionSupport@fda.hhs.gov .

Submision Number: K220635
Received: 03/04/2022
Applicant: LivaNova Deutschland GmbH
Device: (b)(4) Heater-Cooler System 3T

We will notify you when the review of this submission document has been completed or if any additional information is required.If you are submitting new information about a submission for which we have already made a final decision, please note that your submission will not be re-opened. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm .

Sincerely yours,

Center for Devices and Radiological Health

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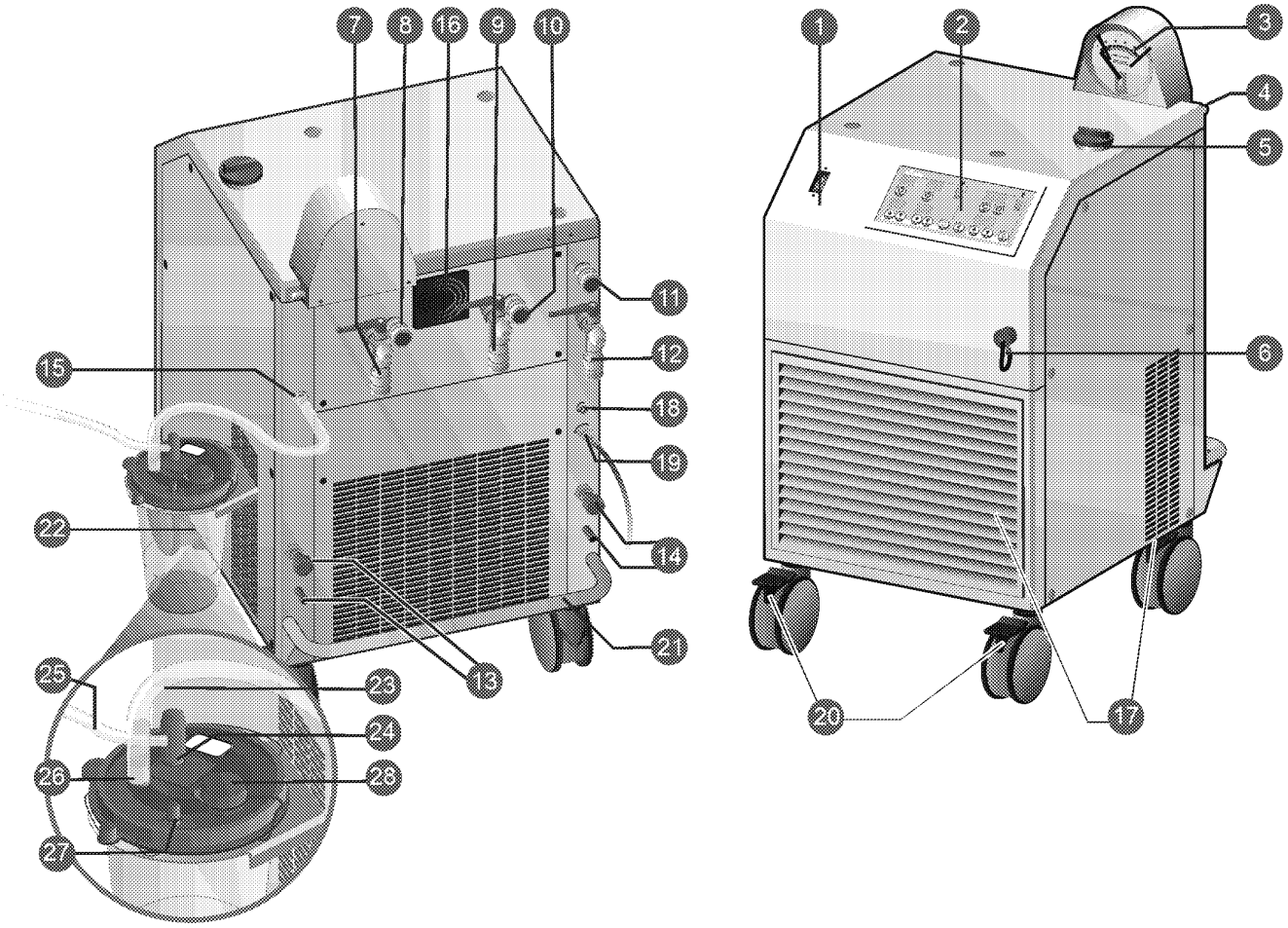
System Description

IMPORTANT: Read full IFU for complete details

Heater-cooler



1. Main Power Switch
2. Control Panel
3. Vacuum gauge with scale
4. Vacuum gauge service port
5. Filler neck with cap
6. CAN jack with cover
7. Patient 2 circuit outlet
8. Patient 2 circuit inlet
9. Patient 1 circuit outlet
10. Patient 1 circuit inlet
11. Cardioplegia circuit inlet
12. Cardioplegia circuit outlet
13. Patient circuits drain valve
14. Cardioplegia circuit drain valve
15. Overflow outlet
16. Fan
17. Ventilation grills
18. Potential equalization point
19. Power cable
20. Castors
21. Bumper
22. Aerosol collection canister
23. Connection line (short line)
24. Vacuum port (V)
25. Vacuum source line
26. Patient port (P)
27. Tandem port (T)
28. Pour spout (S)

Continue on reverse side ▶

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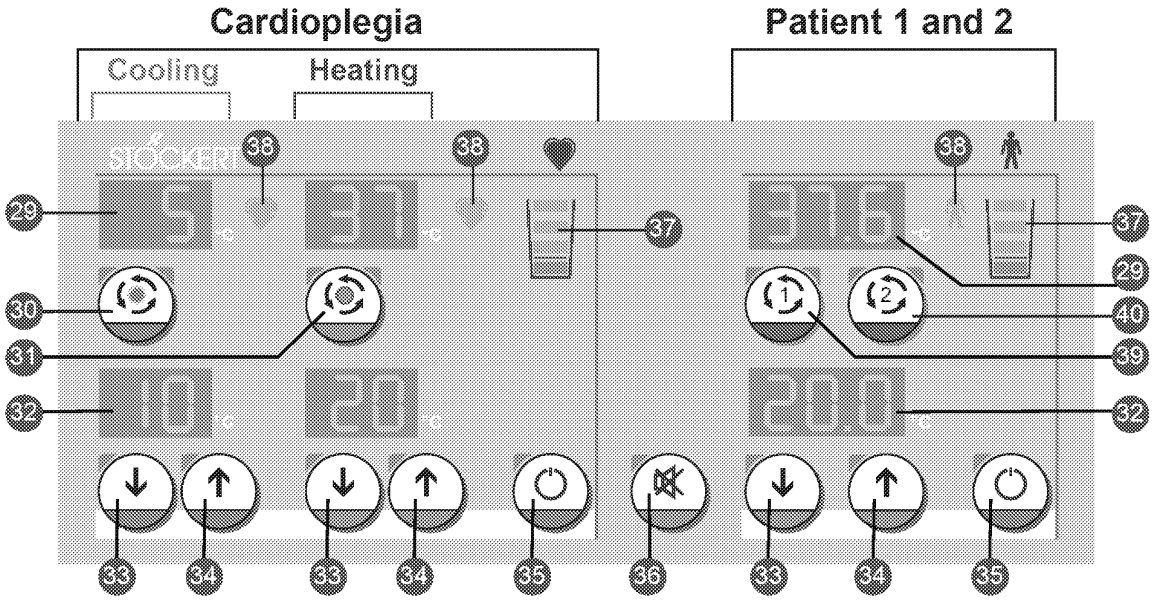
Control Panel



29 Actual tank temperature indicator

30 Cold cardioplegia circuit Start/Stop button

31 Warm cardioplegia Start/Stop button

32 Set temperature indicator

33 Set value down button

34 Set value up button

35 Standby button

36 Pause audio button

37 Water level display

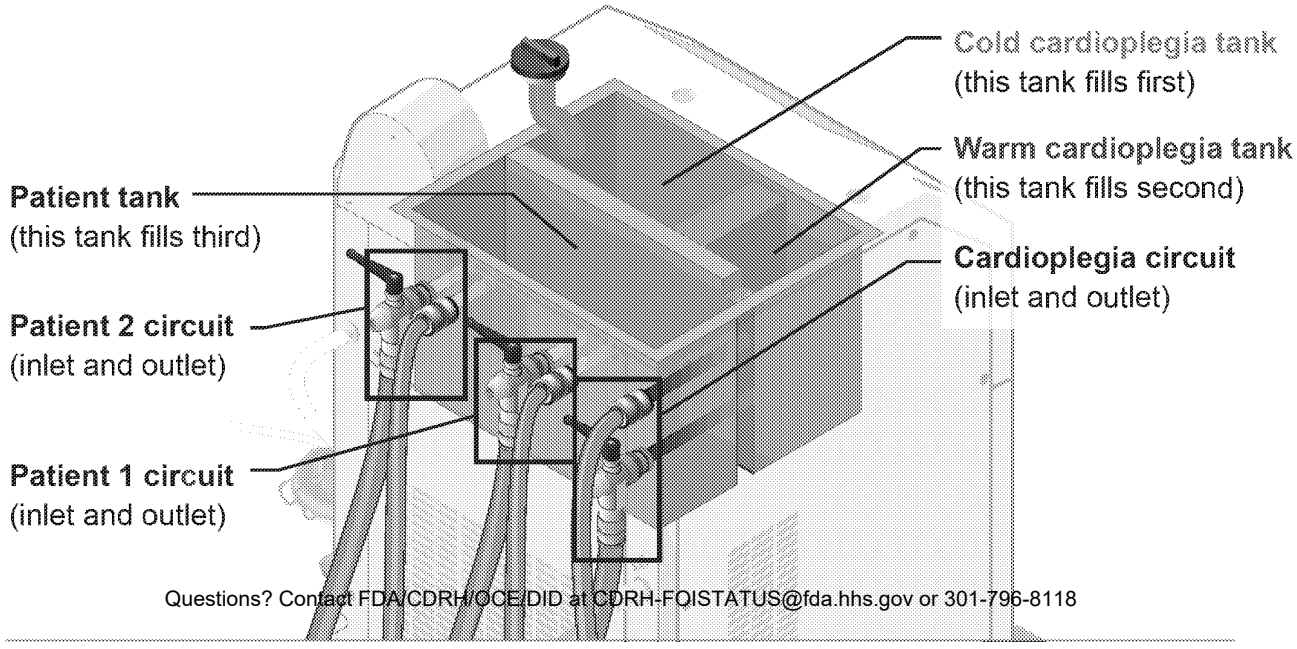
38 High temperature indicator Display

39 Patient 1 circuit Start/Stop button

40 Patient 2 circuit Start/Stop button

Tanks and Circuits

The Patient 1 and 2 circuits draws water from the Patient tank. The Cardioplegia circuit draws water from either the cold or warm cardipoplegia tank.



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Maintenance Calendar

IMPORTANT: Read full IFU for complete details

Before FIRST use Before storing	**Clean and disinfect external surfaces, connectors, and fittings**	Chapter 6.3
	Disinfect the water circuits	Chapter 6.4
Every Connection	**Disinfect connections and fittings**	Chapter 6.3.2 Chapter 6.3.3
After every Use	**Clean and disinfect external surfaces**	Chapter 6.3.1
Storing/Before use Daily	**Monitor the hydrogen peroxide concentration**	Chapter 6.5.1
After 7 Days	**Replace the aerosol collection set**	Chapter 5.7.2
Every 7 days	**Change the water and add hydrogen peroxide**	Chapter 6.6
Every 14 days	**Disinfect the water circuits**	Chapter 6.4
Every Month	**Monitor the water for total bacteria** **Monitor the water for NTM**	Chapter 6.5.2
Every Year	**Replace procedural tubing**	Chapter 6.9

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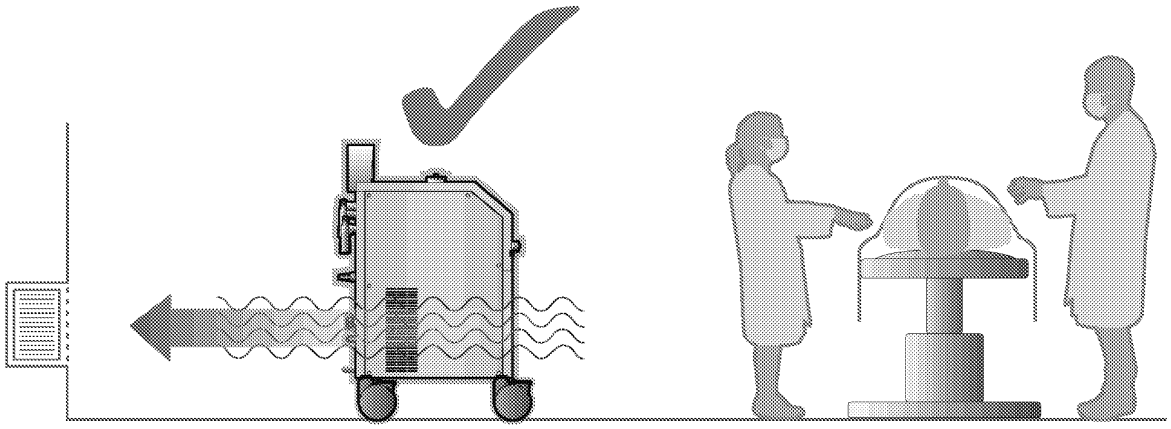
Pre-procedure checklist

IMPORTANT: Read full IFU for complete details

Set up and position

- ☑ Machine air exhaust aimed away from the sterile field



⚠ WARNING

Do not position the heater-cooler's and portable vacuum source's (if applicable) exhaust flow toward the operating field. Position the exhaust flow away from the operating field and toward the exhaust vent system.

- ☑ Castor brakes locked
- ☑ Aerosol collection set installed
- ☑ Vacuum regulator set to full
- ☑ Reading greater than 50Pa on HC3T vacuum gauge

Circuits and water level

- ☑ Procedural tubing secured in circuit connectors
- ☑ Circuit valves opened
- ☑ Circuits primed and water levels adjusted if required
  (To adjust the water level, create a mixture with 10 ml of H_2O_2 and 910 ml of filtered tap water and fill the tanks)

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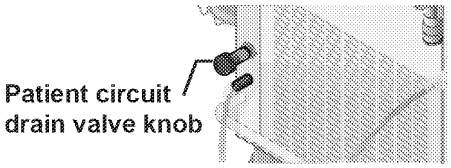
Every Day

Monitor the hydrogen peroxide

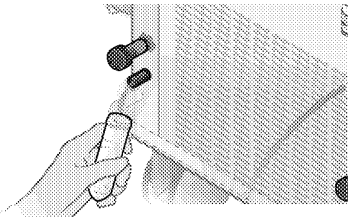
IMPORTANT: Read full IFU for complete details

1 Check hydrogen peroxide concentration

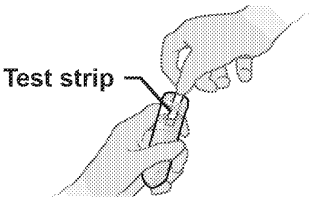
a) Drain at least **100 ml** of solution from the Patient drain valve and discard.



b) Drain at least **5 ml** of solution into the sterile sample container.



c) Immerse the test strip in the sample container according to the test strip instructions.



2 Correcting the hydrogen peroxide concentration

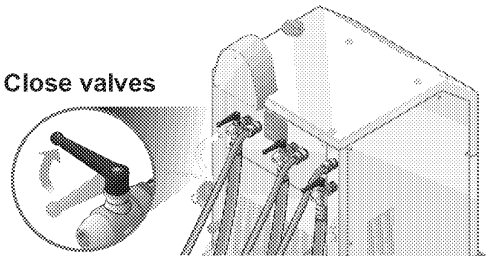
Acceptable concentration: greater than or equal to 100 mg/L H_2O_2

There is no additional action to be taken other than to monitor the concentration daily.

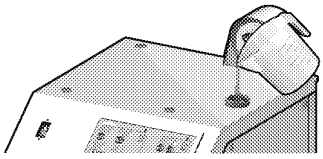
Unacceptable concentration: less than 100 mg/L H_2O_2

Proceed to next steps:

a) If the procedural tubing is connected: Close the circuit valves, run the circuit pumps, then stop running the circuit pumps once the tubing is drained.



b) Pour **100 ml** of medical grade 3% hydrogen peroxide into the tank.



c) Mix tank contents for **5 minutes**.

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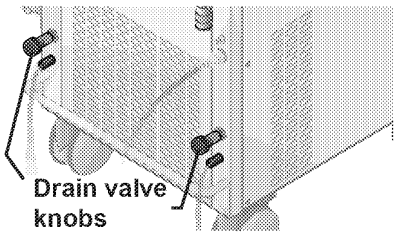
Every 7 days

Change water and add hydrogen peroxide

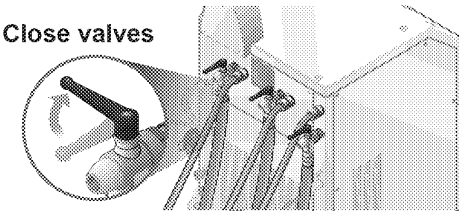
IMPORTANT: Read full IFU for complete details

1 Drain tanks

a) Drain the patient and cardioplegia tanks, then close the drain valves.

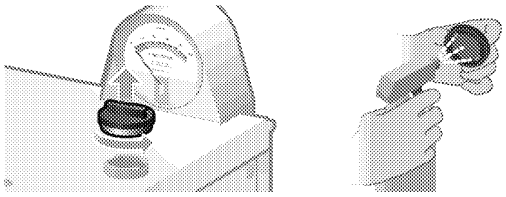


b) Drain and disconnect the procedural tubing (if applicable), and close the red valve levers.



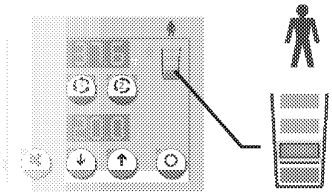
2 Disinfect filler neck cap

Remove and disinfect the filler neck cap.

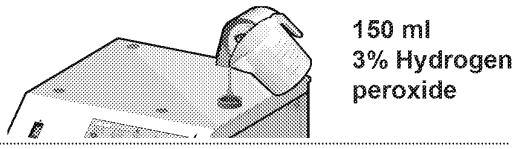


3 Fill tanks

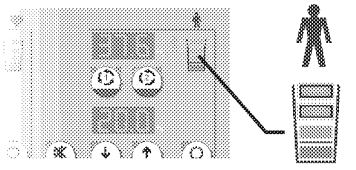
a) Fill the water tanks with filtered tap water to the orange segment on the patient circuit water level.



b) Pour **150 ml** of medical grade 3% hydrogen peroxide solution into the tank.



c) Continue filling the tanks with filtered tap water until the second green segment of the **patient circuit** water level display lights up.

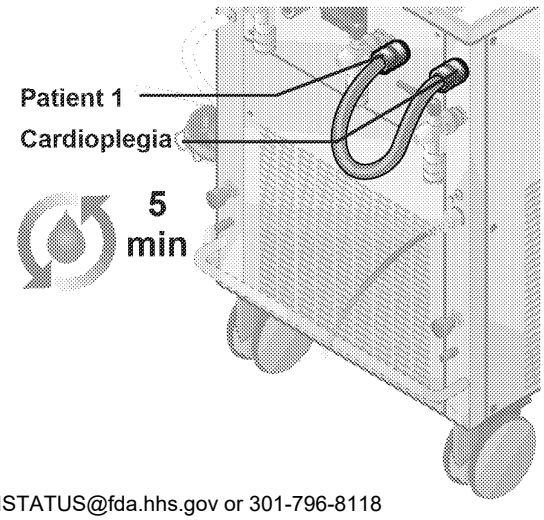


4 Mix tanks

a) Connect short-circuit tubing between the Cardioplegia circuit inlet and the Patient 1 circuit inlet.

b) Run the cold cardioplegia circuit for **5 minutes**.

c) Disconnect the short circuit between the cardioplegia circuit inlet and the patient circuit inlet.



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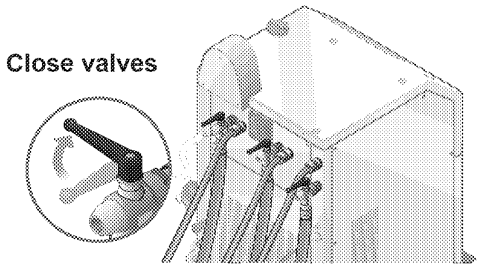
Every 14 days

Disinfect the water circuits

IMPORTANT: Read full IFU for complete details

1 Drain tanks

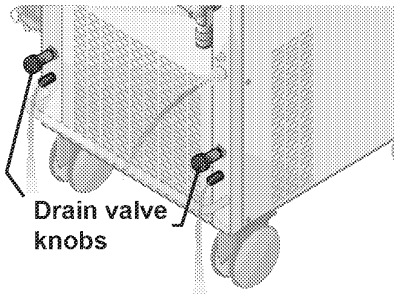
a) If the procedural tubing is connected: close the circuit valves, run the circuit pumps until the tubings is drained. Then stop the circuit pumps and disconnect all procedural tubing.



b) If you are monitoring the water for bacteria or NTM today, take water samples before draining the system.

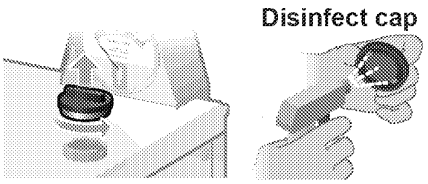
c) Fully drain the patient and cardioplegia tanks.

d) Twist both drain valve knobs clockwise until drain valves are fully closed.

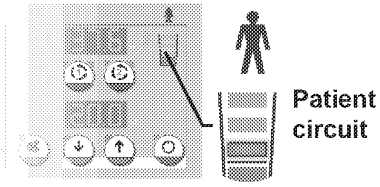


2 Fill tanks and add disinfectant

a) Remove and disinfect the filler neck cap.



b) Fill the water tanks with filtered tap water until the orange segment on the patient circuit water level display lights up.



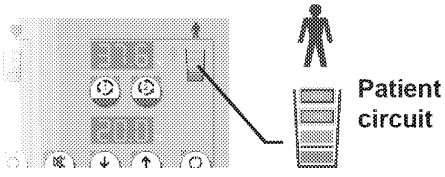
c) Add one disinfectant to the tank contents using the appropriate amount:

⚠ WARNING

- **Use only one disinfectant**. The use of both products will potentially result in a dangerous chemical reaction.
- Use of a higher volume of disinfectant might damage the heater-cooler.

Option 1: 450 ml of Minncare Cold Sterilant or Puristeril 340 or Peresal
OR
Option 2: 180 ml of Clorox® Germicidal Bleach (8.25%)

d) Continue filling the tanks with filtered tap water until the second green segment of the **patient circuit** water level display lights up.



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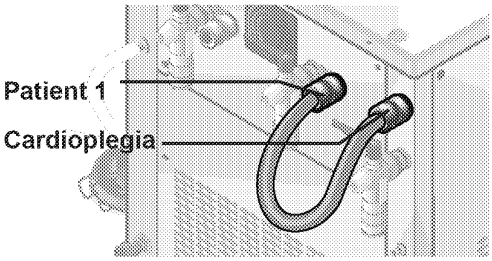
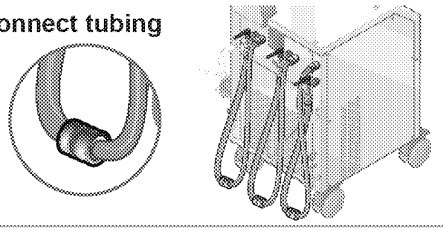
3 Run disinfectant through system

a) Connect **short-circuit tubing** between the cardioplegia circuit inlet and the Patient 1 circuit inlet.

b) Run the cold cardioplegia circuit for **5 minutes**.

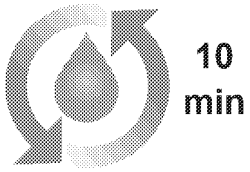


c) Connect procedural tubing between circuits using a suitable short-circuit adapter (part number 73-300-160). **NOTE**: If needed, bridge any unused circuits with short-circuit tubing.



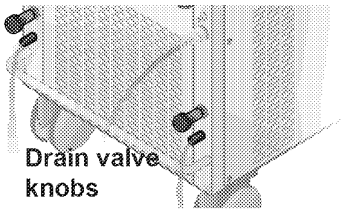
d) Run the disinfectant through the system:

- Open venting valves
- Run the **Patient 1, Patient 2**, and warm cardioplegia circuit for **10 minutes**.
- Close the venting valves before stopping the circuit pumps to drain tubing.

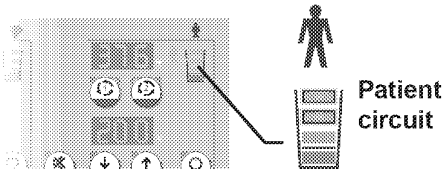


4 Drain, refill, rinse TWO (2) times

a) Drain the patient and cardioplegia tanks, then twist both drain valve knobs clockwise until drain valves are fully closed.



b) Using filtered tap water, fill the water tanks until the second green segment of the patient circuit water level display lights up.



c) Rinse tanks and tubing:

- Open the venting valves
- Run the **Patient 1, Patient 2**, and Warm cardioplegia circuit for **3 minutes**.
- Close the venting valves before stopping the circuit pumps to drain tubing.

d) **Repeat steps a) through d)** so that the system is rinsed **two (2) times**.

5 Final steps

a) Replace the aerosol collection set (including tubing).

b) Fill the water tanks per the water change procedure, as required.

c) If you are monitoring the water for bacteria or NTM today, take water samples after disinfecting and filling the system.

Records processed under FOIA Request 2023-9067; Released by CDRH on 05-23-2024

Aerosol collection set

After **7 days**

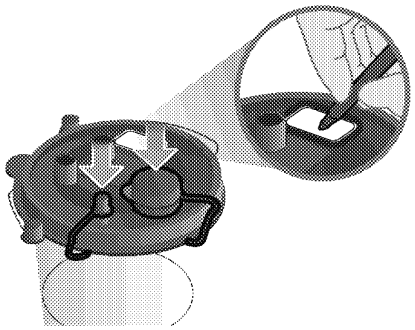
IMPORTANT: Read full IFU for complete details

1 Installation procedure

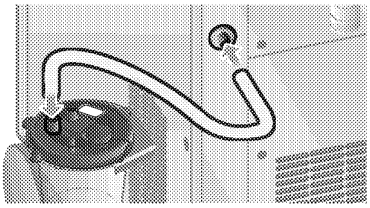
a) Place lid on canister

b) Place caps on Tandem port (T) and Pour spout (S)

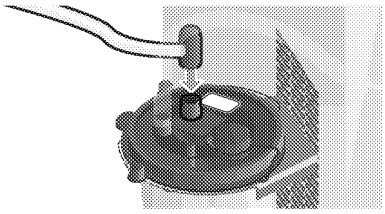
c) Write installation date on label



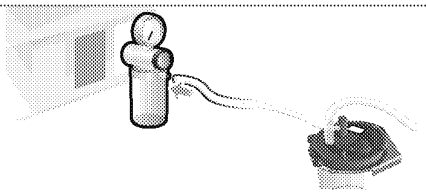
d) Connect Patient port (P) to the HC3T Overflow using the short tube.



e) Connect Vacuum port (V) to the vacuum regulator using the long tube (90° connector on Port V).



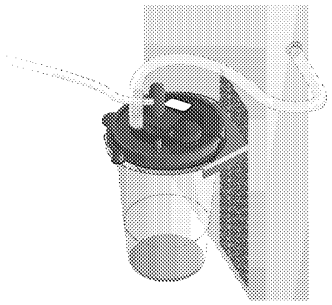
f) Connect the long tube's other end to the external vacuum source.



1 In-procedure use

a) Verify connections

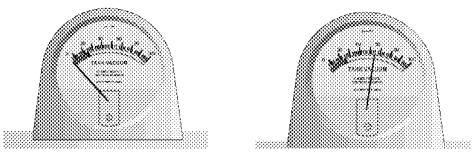
- Patient port (P) to heater-cooler
- Vacuum port (V) to the vacuum source
- All other ports are capped



b) Verify vacuum regulator is set to zero or off

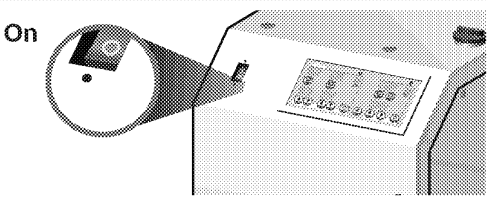
c) Check zero point on HC3T vacuum gauge

d) Set vacuum regulator to **maximum**



e) Verify vacuum gauge reads **> 50Pa**

f) Turn on heater-cooler



Continue on reverse side ▶

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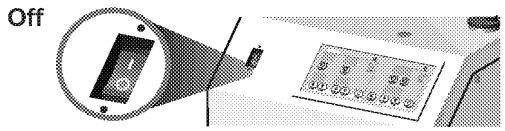
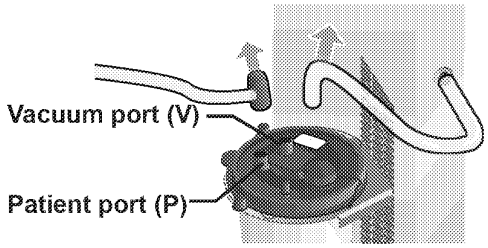
3 Emptying (if less than 7 days use)

a) Turn off heater-cooler (as required).

b) Set vacuum regulator to off (or turn off portable source).

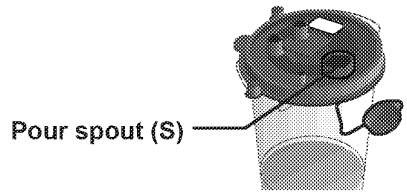


c) Disconnect tubes from Patient port (P) and Vacuum port (V).



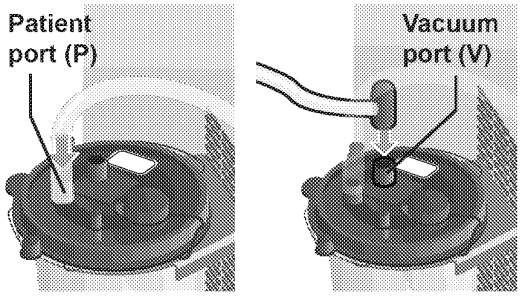
d) Lift canister from holder.

e) Uncap Pour spout (S) and pour contents of canister into appropriate drain.



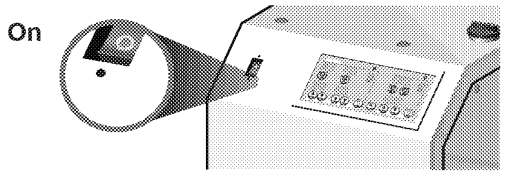
f) Recap Pour spout (S), and place canister back into holder.

g) Reconnect Patient port (P) to heater-cooler and Vacuum port (V) to the vacuum regulator.



h) Set vacuum regulator to maximum

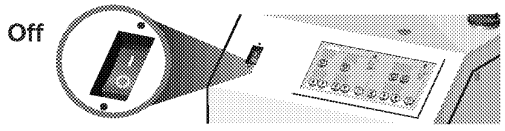
i) Turn on heater-cooler (as required)



4 Disposal (after 7 days)

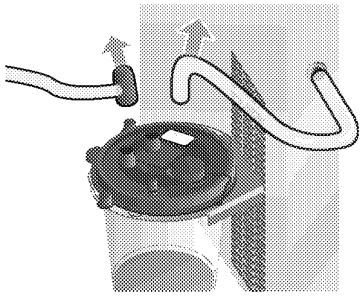
a) Turn off heater-cooler (as required)

b) Set vacuum regulator to off (or turn off portable source)



c) Disconnect tubes from Patient port (P) and Vacuum port (V), and from HC3T and vacuum source.

d) Remove collection canister from holder, and discard all aerosol collection set components according to hospital policy.



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Every Month

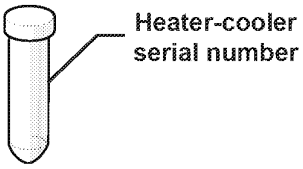
Monitor for bacteria and NTM

IMPORTANT: Read full IFU for complete details

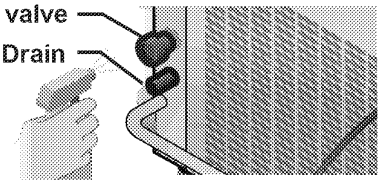
1 Preparation

a) Gather required sample containers

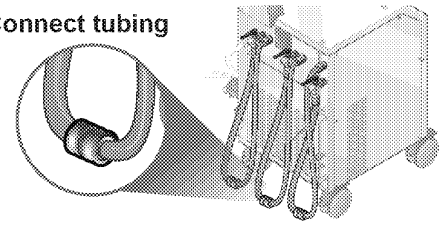
- **2 x 50 ml** for total bacteria
- **4 x 50 ml** or **2 x 100 ml** for NTM



b) Disinfect patient drain valve

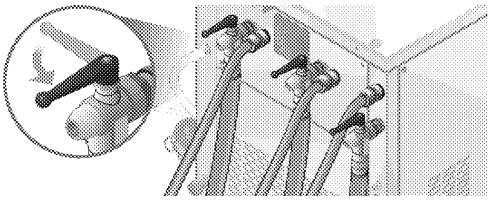


c) Connect procedural tubing between circuits using a suitable short-circuit adapter (part number 73-300-160)



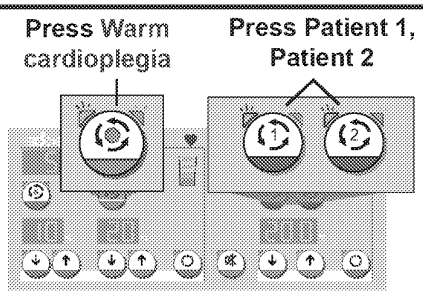
IMPORTANT: Do not connect tubing to any circuits not used during procedures.

d) Open red valves for circuits with tubing connected.

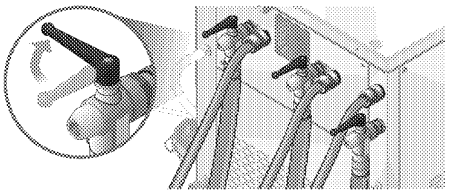


2 Run Circuits

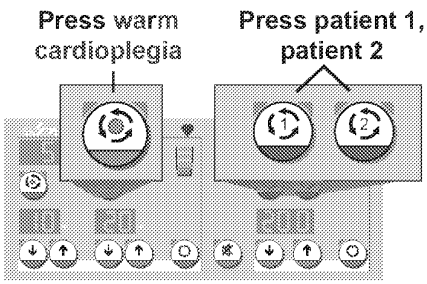
a) Press the Start/Stop buttons for **Warm** cardioplegia, **Patient 1**, and **Patient 2** circuits.



b) Run the circuits for **5 minutes**, then close the venting valves and drain the tubing.



c) Stop the circuit pumps.



Questions? Contact FDA/CDRH at DOD at CDRH-FOIA-STATUS@fda.hhs.gov or 301-796-8110

Continue on reverse side ►

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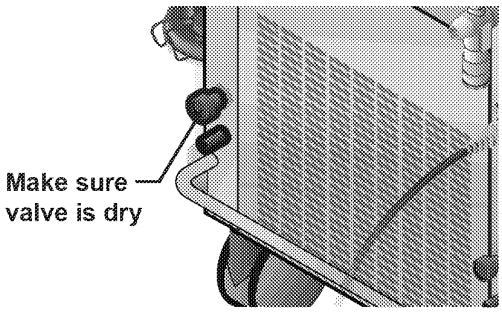
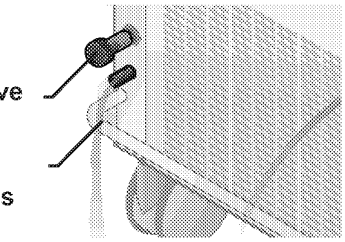
3 Collection

a) Check the patient drain valve and make sure the disinfectant is dry.



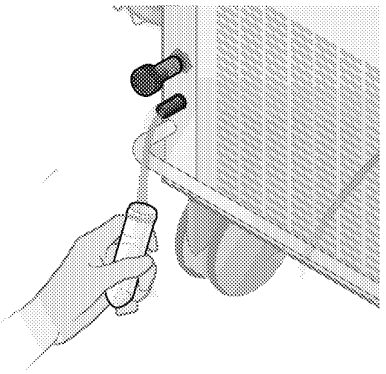
b) Fully open patient drain valve

c) **Drain for at least 5 seconds and discard**

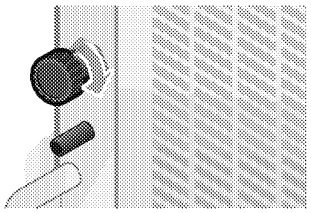


d) Collect samples:

- Total Bacteria: **50 ml** of water in one sample container
- NTM: **100 ml** of water in one or two sample containers



e) Close the drain valve.



f) Disinfect heater-cooler, then **repeat steps 1 to 3** of this quick reference guide to collect a second set of samples.

Disinfect heater-cooler, then repeat steps: 1 2 3

g) Interpret results according to the IFU Chapter 6.5.2, step 4.

Interpret results, Chapter 6.5.2, Step 4

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Document Number: (b)(4) **Revision:** (b)(4)

Title: 3T Aerosol Collection Set

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(b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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3T Aerosol Collection Set

POR – Português

Estas instruções descrevem a instalação, verificações durante o processo e esvaziamento e eliminação do conjunto de recolha de aerossóis 3T (050900100). Para informações detalhadas, consultar o manual de instruções do Sistema de hipo-/hipertermia 3T.

Importante: o conjunto de recolha de aerossóis deve ser substituído 7 dias consecutivos após a sua data da instalação. O conjunto de recolha de aerossóis deverá ser igualmente substituído após a desinfeção do sistema de hipo-/hipertermia.

1 Instalação
2 Verificações durante o processo
 2.2 Com o vácuo completamente fechado e o sistema de hipo-/hipertermia desligado, a pressão do sistema de hipo-/hipertermia é igual a 0 pascais
 2.3 Com o vácuo completamente aberto, a pressão do sistema de hipo-/hipertermia é superior a 50 pascais
3 Esvaziar o recipiente de recolha de aerossóis de acordo com as políticas do hospital.
4 Eliminar o conjunto de recolha de aerossóis de acordo com os regulamentos ambientais locais e a política hospitalar.

Fabricante
Data de fabrico
Número de catálogo
Consultar as instruções de utilização
Data
Código de lote
Data de validade
Eliminar num período de 7 dias consecutivos
Perigo biológico

RUS – Русский

В данной инструкции представлено описание установки, опорожнения и утилизации системы сбора аэрозолей 3T (050900100), а также сопутствующих проверок. Дополнительные сведения представлены в руководстве по эксплуатации аппарата для гипотермии 3T.

Важно. Замену системы сбора аэрозолей необходимо проводить через 7 календарных дней после даты установки. Замену системы сбора аэрозолей также необходимо проводить после дезинфицирования аппарата для гипотермии.

1 Установка
2 Сопутствующие проверки
 2.2 При полностью закрытом клапане вакуумной установки и отключенном аппарате для гипотермии давление в нем должно быть равно 0 Па.
 2.3 При полностью открытом клапане вакуумной установки давление в аппарате для гипотермии должно составлять более 50 Па.
3 Опорожнение канистры для сбора аэрозолей необходимо проводить в соответствии с правилами медицинского учреждения.
4 Утилизацию системы сбора аэрозолей необходимо проводить в соответствии с местным природоохранительным законодательством и правилами медицинского учреждения.

Производитель
Дата изготовления
№ по каталогу
Обратитесь к указаниям по применению
Дата
Код партии
Использовать до
Утилизировать в течение 7 календарных дней
Биологическая опасность

SLV – Slovenščina

V teh navodilih so opisani namestitev, preverjanja med postopki, praznjenje in odstranjevanje kompleta za zbiranje aerosola 3T (050900100). Za dodatne podrobnosti glejte navodila za uporabo grelno-hladilnega sistema 3T.

Pomembno: Komplet za zbiranje aerosola je treba zamenjati v roku 7 dni po dnevu namestitve. Komplet za zbiranje aerosola morate zamenjati tudi po razkuževanju grelno-hladilnega sistema.

1 Namestitev
2 Preverjanja med postopki
 2.2 Ko je vakuum povsem zaprt in grelno-hladilni sistem izklopljen, je tlak v grelno-hladilnem sistemu 0 paskalov
 2.3 Ko je vakuum povsem odprt, je tlak v grelno-hladilnem sistemu večji od 50 paskalov
3 Izpraznite zbiralno posodo aerosola v skladu s pravilniki bolnišnice.
4 Komplet za zbiranje aerosola odstranite v skladu z lokalnimi okoljskimi predpisi in pravilniki bolnišnice.

Proizvajalec
Datum proizvodnje
Kataloška številka
Glejte navodila za uporabo
Datum
Številka serije
Uporabno do
Odstranite v roku 7 koledarskih dni
Bioloska nevarnost

SWE – Svenska

Dessa anvisningar beskriver installationen, processkontrollerna samt tömningen och kasseringen av 3T-aerosolinsamlingssatsen (050900100). Mer information finns i bruksanvisningen till hypotermienheten 3T.

Viktigt! Aerosolinsamlingssatsen måste bytas ut inom 7 kalenderdagar från installationen.
Aerosolinsamlingssatsen måste även bytas ut efter att hypotermienheten har desinficerats.

1 Installation
2 Processkontroller
 2.2 Med helt stängt vakuum och hypotermienheten avstängd är hypotermienhetens tryck 0 pascal
 2.3 Med helt öppet vakuum är hypotermienhetens tryck högre än 50 pascal
3 Töm aerosolinsamlingsbehållaren enligt sjukhusets regler.
4 Kassera aerosolinsamlingssatsen enligt lokala miljöföreskrifter och sjukhusets regler.

Tillverkare
Tillverkningsdatum
Katalognummer
Läs bruksanvisningen
Datum
Partikod
Utgångsdatum
Kassera inom 7 kalenderdagar
Biologisk risk

RON – Română

Aceste instrucțiuni descriu instalarea, verificări în timpul procesului, golirea și eliminarea setului de colectare aerosoli 3T (050900100). Pentru detalii suplimentare, vă rugăm să consultați instrucțiunile de utilizare ale aparatului hipotermie 3T.

Important: Setul de colectare aerosoli trebuie înlocuit în decurs de 7 zile de la instalare. Setul de colectare aerosoli trebuie de asemenea înlocuit după dezinfectarea aparatului hipotermie.

1 Instalarea
2 Verificări în timpul procesului
 2.2 Cu vidul complet închis și aparatul hipotermie oprit, presiunea din aparat este de 0 Pascali
 2.3 Cu vidul complet deschis, presiunea din aparat hipotermie depășește 50 de Pascali
3 Goliți recipientul de colectare aerosoli în conformitate cu politicile din spitalul dvs.
4 Eliminați setul de colectare aerosoli conform reglementărilor locale de mediu politicii spitalului.

Producător
Data de producție
Număr de catalog
Consultați instrucțiunile de utilizare
Data
Număr lot
Utilizați până la data
Eliminați în decurs de 7 zile calendaristice
Pericol biologic

SLK – Slovenčina

Tieto pokyny popisujú inštaláciu, kontroly počas postupu, vyprázdnenie a likvidáciu súpravy na zachytávanie aerosólu 3T (050900100). Ďalšie podrobnosti nájdete v pokynoch na prevádzku systému ohrevu a chladenia 3T.

Dôležité: Súpravu na zachytávanie aerosólu je potrebné vymeniť do 7 dní od dátumu jej inštalácie. Súpravu na zachytávanie aerosólu je potrebné vymeniť tiež po dezinfekcii systému ohrevu a chladenia.

1 Inštalácia
2 Kontroly počas postupu
 2.2 Keď je vákuum úplne zatvorené a systém ohrevu a chladenia vypnutý, tlak v systéme ohrevu a chladenia sa rovná 0 Pascalov
 2.3 Keď je vákuum úplne otvorené, tlak v systéme ohrevu a chladenia je väčší ako 50 Pascalov
3 Nádobu na zachytávanie aerosólu vyprázdnite v súlade so zásadami vašej nemocnice.
4 Súpravu na zachytávanie aerosólu zlikvidujte v súlade s miestnymi predpismi na ochranu životného prostredia a zásadami nemocnice.

Výrobca
Dátum výroby
Katalógové číslo
Pozrite si návod na použitie
Dátum
Kód šarže
Použite do
Zlikvidujte do 7 kalendárnych dní
Biologické nebezpečenstvo

SPA – Español

Estas instrucciones describen la instalación, las comprobaciones durante el proceso, el vaciado y la eliminación del juego de recogida de aerosol 3T (050900100). Para obtener detalles adicionales, consulte las instrucciones de uso del aparato de hipotermia 3T.

Importante: El juego de recogida de aerosol debe sustituirse en un plazo de 7 días después de la fecha de instalación. El juego de recogida de aerosol también debe sustituirse tras desinfectar el aparato de hipotermia.

1 Instalación
2 Comprobaciones durante el proceso
 2.2 Con el vacío totalmente cerrado y el aparato de hipotermia apagado, la presión del aparato de hipotermia equivale a 0 Pascales.
 2.3 Con el vacío totalmente abierto, la presión del aparato de hipotermia es superior a 50 Pascales.
3 Vacíe el recipiente de recogida de aerosol de conformidad con la política del hospital.
4 Elimine el juego de recogida de aerosol según la normativa medioambiental local y la política del hospital.

Fabricante
Fecha de fabricación
Número de catálogo
Consulte las instrucciones de uso
Fecha
Código de lote
Fecha de caducidad
Eliminar en un plazo de 7 días naturales
Riesgo biológico

TUR – Türkçe

Bu talimatlarda, 3T Aerosol Toplama Setinin (050900100) Kurulumu, Proses İçi Kontrolleri, Boşaltılması ve Atılması açıklanmaktadır. Ek bilgi için Isıtma Soğutma Sistemi 3T Çalıştırma Talimatlarına bakınız.

Önemli: Aerosol toplama seti, kurulum tarihinden sonra 7 gün içinde değiştirilmelidir. Aerosol toplama seti ayrıca ısıtma soğutma sistemi dezenfekte edildikten sonra değiştirilmelidir.

1 Kurulum
2 Proses İçi Kontroller
 2.2 Vakum tam kapalıyken ve ısıtma soğutma sistemi çalışmadığında, ısıtma soğutma sisteminin basıncı 0 Pascal'a eşdeğerdir
 2.3 Vakum tam açıkken, ısıtma soğutma sisteminin basıncı 50 Pascal'dan büyüktür
3 Aerosol toplama kabını hastanenizin kurallarına uygun şekilde boşaltın.
4 Aerosol toplama setini yerel çevre düzenlemelerinize ve hastane kurallarınıza uygun şekilde atın.

Üretici
İmalat tarihi
Katalog numarası
Kullanım talimatlarına başvurun
Tarih
Grup kodu
Son kullanma tarihi
7 takvim günü içinde atın
Biyolojik tehlike

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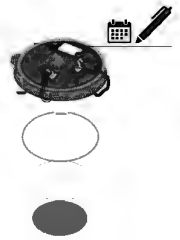
3T Aerosol Collection Set

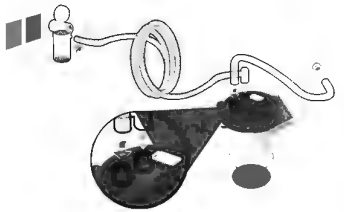
These instructions describe the Installation, In-Process Checks, Emptying & Disposal of the 3T Aerosol Collection Set (050900100). For additional detail, please refer to the Heater-Cooler System 3T Operating Instructions. The aerosol collection set must be replaced within 7 days of its installation date. The aerosol collection set must also be replaced after the heater-cooler is disinfected.

1 Installation

1.1

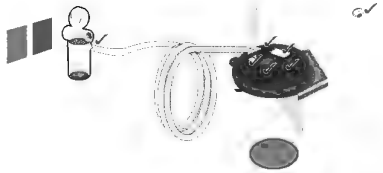


1.2

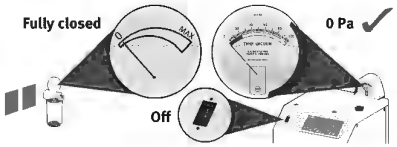


2 In-Process Checks

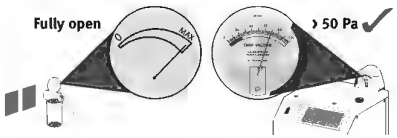
2.1



2.2



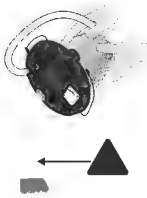
2.3



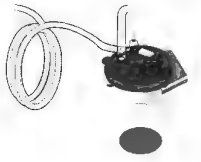
3 Emptying

3.1

3.2



3.3



4 Disposal

Dispose of the aerosol collection set according to your local environmental regulations and hospital policy.

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3T Aerosol Collection Set

BUL – Български

Тези инструкции описват инсталирането, проверките по време на процес, изпразването и изхвърлянето на набора за събиране на аерозол 3T (050900100). За допълнителни подробности, моля, вижте ръководството за експлоатация на системата нагревател/охладител 3T.

Важно: Наборът за събиране на аерозол трябва да бъде заменен в рамките на 7 дни от датата на инсталиране. Наборът за събиране на аерозоли също трябва да се замени след дезинфекция на нагревател/охладителя.

1 Инсталиране
2 Проверки по време на процес
- 2.2 При напълно затворен вакуум и изключване на нагревателя/охладителя, налягането на нагревателя/охладителя е равно на 0 Pa
- 2.3 При напълно отворен вакуум налягането на нагревателя/охладителя е по-голямо от 50 Pa

3 Извадете касетата за събиране на аерозол в съответствие с правилата на Вашата болница.
4 Изхвърлете набора за събиране на аерозол в съответствие с Вашите местни екологични разпоредби и болнична политика.

Производител
Дата на производство
Каталожен номер
Консултирайте се с инструкциите за употреба
Дата
Партиден код
Годно до
Изхвърлете в рамките на 7 календарни дни
Биологична опасност

CZE – Čeština

Tyto pokyny se týkají instalace, průběžných kontrol, vyprázdnění a likvidace soupravy pro sběr aerosolu 3T (050900100). Další podrobnosti naleznete v návodu k obsluze zařízení pro ohřev a chlazení 3T.

Důležité: Soupravu pro sběr aerosolu je nutné vyměnit do 7 kalendářních dnů od data instalace. Soupravu pro sběr aerosolu je rovněž nutné vyměnit, pokud bylo zařízení pro ohřev a chlazení dezinfikováno.

1 Instalace
2 Průběžné kontroly
- 2.2 Když je podtlakový systém zcela zavřený a zařízení pro ohřev a chlazení je vypnuté, tlak v zařízení pro ohřev a chlazení je 0 pascalů.
- 2.3 Když je podtlakový systém zcela otevřený, tlak v zařízení pro ohřev a chlazení je vyšší než 50 pascalů.

3 Vyprázdněte kanystr pro sběr aerosolu podle zásad platných v nemocnici.
4 Soupravu pro sběr aerosolu zlikvidujte podle místních předpisů pro ochranu životního prostředí a zásad platných v nemocnici.

Výrobce
Datum výroby
Katalogové číslo
Přečtěte si návod k použití
Datum
Kód šarže
Použít do
Zlikvidujte do 7 kalendářních dnů
Biologické riziko

DAN – Dansk

Disse instruktioner indeholder en beskrivelse af installation, løbende proceskontroller, tømning og bortskaffelse af 3T opsamlingssæt til aerosoler (050900100). Yderligere oplysninger fremgår af brugsanvisningen til hypothermiapparat 3T.

Vigtigt: Opsamlingssættet til aerosoler skal skiftes inden for 7 dage efter dets installationsdato. Opsamlingssættet til aerosoler skal også skiftes efter desinfektion af hypothermiapparatet.

1 Installation
2 Løbende proceskontroller
- 2.2 Når vakuummet er fuldt lukket, og hypothermiapparatet er slukket, er hypothermiapparatets tryk lig med 0 pascal
- 2.3 Når vakuummet er fuldt åbent, er hypothermiapparatets tryk større end 50 pascal

3 Bortskaf kanisteren til opsamling af aerosoler i henhold til politikken på dit sygehus.
4 Bortskaf opsamlingssættet til aerosoler i henhold til de lokale miljøforskrifter og politikken på dit sygehus.

Producent
Fremstillingsdato
Katalognummer
Se brugsanvisningen
Dato
Batchkode
Holdbarhedsdato
Bortskaffes inden for 7 kalenderdage
Biologisk fare

DUT – Nederlands

Deze instructies bieden een beschrijving van de installatie, de controles tijdens het gebruik, evenals het legen & afvoeren van de 3T Aerosol Collection Set (050900100). Raadpleeg de gebruiksaanwijzing van het Heater-Cooler System 3T voor meer informatie.

Belangrijk: De Aerosol Collection Set moet binnen 7 kalenderdagen na de installatiedatum worden vervangen. De Aerosol Collection Set moet ook worden vervangen nadat de heater-cooler is gedesinfecteerd.

1 Installatie
2 Controles tijdens het gebruik
- 2.2 Bij volledig gesloten vacuüm en uitgeschakelde heater-cooler bedraagt de druk van de heater-cooler 0 Pascal
- 2.3 Bij volledig open vacuüm bedraagt de druk van de heater-cooler meer dan 50 Pascal

3 Maak de zuigpot van de Aerosol Collection Set leeg volgens de richtlijnen van uw ziekenhuis.
4 Voer de Aerosol Collection Set af volgens de plaatselijke milieu- en ziekenhuisvoorschriften.

Fabrikant
Productiedatum
Catalogusnummer
Gebruiksaanwijzing raadplegen
Datum
Partijcode
Te gebruiken vóór
Binnen 7 kalenderdagen afvoeren
Biologisch gevaar

ENG – English

These instructions describe the Installation, In-Process Checks, Emptying & Disposal of the 3T Aerosol Collection Set (050900100). For additional detail, please refer to the Heater-Cooler System 3T Operating Instructions.

Important: The aerosol collection set must be replaced within 7 days of its installation date. The aerosol collection set must also be replaced after the heater-cooler is disinfected.

1 Installation
2 In-Process Checks
- 2.2 With vacuum fully closed and heater-cooler off, heater-cooler pressure equals 0 Pascal
- 2.3 With vacuum fully open, heater-cooler pressure is greater than 50 Pascal

3 Empty the aerosol collection canister in accordance with your hospital's policies.
4 Dispose of the aerosol collection set according to your local environmental regulations and hospital policy.

Manufacturer
Date of manufacture
Catalog number
Consult instructions for use
Date
Batch code
Use by
Dispose within 7 calendar days
Biological hazard

EST – Eesti

Need suunised kirjeldavad 3T aerosooli kogumiskomplekti (050900100) paigaldamist, protsessi-siseseid kontrolle, tühjendamist ja kõrvaldamist. Täiendavate üksikasjade teada saamiseks vaadake soojendi-jahutisüsteem 3T kasutusjuhendit.

Oluline: aerosooli kogumiskomplekt tuleb välja vahetada 7 kalendripäeva jooksul pärast paigaldamist. Aerosooli kogumiskomplekt tuleb asendada pärast soojendi-jahuti desinfitseerimist.

1 Paigaldamine
2 Protsessi-sisesed kontrollid
- 2.2 Kui vaakum on täielikult suletud ja soojendi-jahuti välja lülitatud, on rõhk 0 paskalit.
- 2.3 Kui vaakum on täielikult avatud, on soojendi-jahuti rõhk suurem kui 50 paskalit.

3 Tühjendage aerosooli kogumise kanistrit vastavalt oma haigla eeskirjadele.
4 Kõrvaldage aerosooli kogumiskomplekt vastavalt kohalikele keskkonnanormidele ja haigla eeskirjadele.

Tootja
Tootmiskuupäev
Kataloogi number
Järgige kasutusjuhendit
Kuupäev
Partii kood
Kasutada enne
Kõrvaldage 7 kalendripäeva jooksul
Bioloogilised ohud

FIN – Suomi

Näissä ohjeissa kuvataan 3T-aerosolinkeräyssarjan (050900100) asennus, menettelynaikaiset tarkistukset sekä tyhjentäminen ja hävittäminen. Lisätietoja on 3T-lämmönvaihtimen käyttöohjeissa.

Tärkeää: Aerosolinkeräyssarja on vaihdettava 7 kalenteripäivän sisällä sen asennuspäivästä. Aerosolinkeräyssarja on vaihdettava myös sen jälkeen, kun lämmönvaihdin on desinfioitu.

1 Asentaminen
2 Menettelynaikaiset tarkistukset
- 2.2 Kun alipaine on täysin suljettu ja lämmönvaihdin pois päältä, lämmönvaihtimen paine on 0 pascalia.
- 2.3 Kun alipaine on täysin auki, lämmönvaihtimen paine on yli 50 pascalia.

3 Tyhjennä aerosolinkeräysastia sairaalan käytäntöjen mukaisesti.
4 Hävitä aerosolinkeräyssarja paikallisten ympäristömääräysten ja sairaalan käytäntöjen mukaisesti.

Valmistaja
Valmistuspäivämäärä
Luettelonumero
Katso käyttöohjeet
Päivämäärä
Eräkoodi
Käytettävä viimeistään
Hävitä 7 kalenteripäivän kuluessa
Biologinen vaara

FRA – Français

Ces instructions décrivent l'installation, les contrôles en cours d'utilisation, le vidage et la mise au rebut du dispositif de collecte d'aérosols 3T (050900100). Pour plus de détails, reportez-vous au mode d'emploi du générateur thermique 3T.

Important : le dispositif de collecte d'aérosols doit être remplacé dans les 7 jours suivant sa date d'installation. Le dispositif de collecte d'aérosols doit également être remplacé après la désinfection du générateur thermique.

1 Installation
2 Contrôles en cours d'utilisation
- 2.2 Lorsque le système de vide est entièrement fermé et que le générateur thermique est hors tension, la pression du générateur thermique équivaut à 0 Pascal.
- 2.3 Lorsque le système de vide est entièrement ouvert, la pression du générateur thermique est supérieure à 50 Pascal.

3 Videz le récipient de collecte d'aérosols conformément au protocole en vigueur dans l'hôpital.
4 Mettez le dispositif de collecte d'aérosols au rebut conformément à la réglementation environnementale locale et au protocole en vigueur dans l'hôpital.

Fabricant
Date de fabrication
Référence
Consulter le mode d'emploi
Date
Code de lot
À utiliser avant
Mettre au rebut dans un délai de 7 jours calendaires
Risque biologique

GER – Deutsch

Diese Anleitung beschreibt die Installation, die Checks während der Verwendung, die Vorgehensweise beim Leeren und die Entsorgung des Aerosol Auffangsystems 3T (050900100). Weitere Einzelheiten finden Sie in der Gebrauchsanweisung des Hypothermiegeräts 3T.

Wichtiger Hinweis: Das Aerosol Auffangsystem muss innerhalb von 7 Tagen nach der Installation ausgetauscht werden. Nach der Desinfektion des Hypothermiegeräts muss das Aerosol Auffangsystem ebenfalls ausgetauscht werden.

1 Installation
2 Checks während der Verwendung
- 2.2 Bei vollständig geschlossenem Vakuum und ausgeschaltetem Hypothermiegerät beträgt der Druck des Hypothermiegeräts 0 Pascal.
- 2.3 Bei vollständig geöffnetem Vakuum beträgt der Druck des Hypothermiegeräts über 50 Pascal.

3 Entsorgen Sie den Aerosol Auffangbehälter gemäß den Vorschriften in Ihrer Klinik.
4 Entsorgen Sie das Aerosol Auffangsystem umweltgerecht und gemäß den Vorschriften in Ihrer Klinik.

Hersteller
Herstellungsdatum
Katalognummer
Gebrauchsanweisung beachten
Datum
Chargenbezeichnung
Verwendbar bis
Innerhalb von 7 Kalendertagen entsorgen
Biologische Gefahr

GRE – Ελληνικά

Αυτές οι οδηγίες περιγράφουν την εγκατάσταση, τους ελέγχους εντός της διεργασίας, καθώς και την εκκένωση και απόρριψη του σετ συλλογής αερολυμάτων 3T (050900100). Για πρόσθετες λεπτομέρειες, ανατρέξτε στο εγχειρίδιο λειτουργίας της συσκευής υποθερμίας 3T.

Σημαντικό: Το σετ συλλογής αερολυμάτων θα πρέπει να αντικαθίσταται εντός 7 ημερών από την ημερομηνία εγκατάστασής του. Το σετ συλλογής αερολυμάτων πρέπει επίσης να αντικαθίσταται έπειτα από απολύμανση της συσκευής υποθερμίας.

1 Εγκατάσταση
2 Έλεγχοι εντός της διεργασίας
- 2.2 Με το κενό τελείως κλειστό και τη συσκευή υποθερμίας απενεργοποιημένη, η πίεση της συσκευής υποθερμίας ισούται με 0 Pascal
- 2.3 Με το κενό τελείως ανοικτό, η πίεση της συσκευής υποθερμίας είναι μεγαλύτερη από 50 Pascal

3 Εκκενώστε το δοχείο συλλογής αερολυμάτων σύμφωνα με τις πολιτικές του νοσοκομείου σας.
4 Απορρίψτε το σετ συλλογής αερολυμάτων σύμφωνα με τους τοπικούς περιβαλλοντικούς κανονισμούς και την πολιτική του νοσοκομείου σας.

Κατασκευαστής
Ημερομηνία παραγωγής
Αριθμός καταλόγου
Συμβουλευτείτε τις οδηγίες χρήσης
Ημερομηνία
Κωδικός παρτίδας
Να χρησιμοποιηθεί έως
Απορρίπτετε προϊόντα εντός 7 ημεραλγιακώνημερών
Βιολογικός κίνδυνος

3T Aerosol Collection Set

HUN – Magyar

Ez az útmutató a 3T vízpáragyűjtő készlet (050900100) beszerelését, használat közbeni ellenőrzéseit, ürítését és ártalmatlanítását mutatja be. További információkért lásd a 3T fűtő-hűtő rendszer használati útmutatóját.

Fontos: A vízpáragyűjtő készletet a beszerelés napjától számított 7 napon belül ki kell cserélni. A vízpáragyűjtő készletet akkor is ki kell cserélni, ha fertőtlenítették a fűtő-hűtő rendszert.

1 Beszerelés
2 Használat közbeni ellenőrzések
- 2.2 Amikor a vákuum teljesen el van zárva és a fűtő-hűtő rendszer ki van kapcsolva, a fűtő-hűtő rendszer nyomása 0 pascal.
- 2.3 Amikor a vákuum teljesen ki van nyitva, a fűtő-hűtő rendszer nyomása 50 pascal.

3 A vízpáragyűjtő tartályt kiürítését a kórház irányelvei szerint végezze el.
4 A vízpáragyűjtő készlet ártalmatlanítását a helyi környezetvédelmi előírások és a kórház irányelvei szerint végezze el.

Gyártó
Gyártás dátuma
Katalógusszám
Lásd a használati útmutatót
Dátum
Tételkód
Felhasználható
Ártalmatlanítsa 7 naptári napon belül
Biológiailag veszélyes hulladék

ITA – Italiano

Queste istruzioni descrivono le procedure di installazione, controllo operativo, svuotamento e smaltimento del Set di raccolta di aerosol 3T (050900100). Per ulteriori dettagli, consultare le istruzioni per l'uso del Sistema Generatore Termico 3T.

Importante: il set di raccolta di aerosol deve essere sostituito entro 7 giorni dalla data di installazione. Sostituire il set di raccolta di aerosol anche dopo aver disinfettato il Generatore Termico.

1 Installazione
2 Controlli operativi
- 2.2 Con l'aspirazione completamente spenta e il Generatore Termico spento, la pressione del Generatore Termico deve essere di 0 pascal
- 2.3 Con l'aspirazione completamente aperta, la pressione del Generatore Termico deve essere maggiore di 50 pascal

3 Svuotare il serbatoio per la raccolta di aerosol in base alla politica della struttura ospedaliera.
4 Smaltire il set di raccolta di aerosol in conformità alla politica della struttura ospedaliera e alle normative locali in materia di tutela ambientale.

Produttore
Data di fabbricazione
Numero di catalogo
Consultare le istruzioni per l'uso
Data
Numero di lotto
Utilizzare entro
Smaltire entro 7 giorni
Rischio biologico

JPN – 日本語

本書では、3T エアロゾル回収セット（050900100）の取り付け、インプロセスチェック、水捨て、廃棄について説明します。詳細については、ヒータークーラーシステム 3T 取扱説明書を参照してください。

重要：エアロゾル回収セットは、取り付け後 7 日以内に交換する必要があります。また、ヒータークーラーを消毒した後にも交換する必要があります。

1 **取り付け**
2 **インプロセスチェック**
- 2.2 **真空を完全に閉じ、ヒータークーラーをオフにした状態で、ヒータークーラーの圧力が 0 パスカルを示す**
- 2.3 **真空を完全に開くと、ヒータークーラーの圧力が 50 パスカルを超える**

3 **院内規定に従ってエアロゾル回収キャニスターを空にします。**
4 **使用地域の環境規制と院内規定に従ってエアロゾル回収セットを廃棄します。**

製造元
製造日
カタログ番号
使用説明書を参照
日付
バッチコード
有効期限
7 層日以内に廃棄
バイオハザード

LAV – Latviešu

Šajos norādījumos ir apraksīta 3T aerosola savākšanas ierīces (050900100) uzstādīšana, pārbaudes procesu izpildes laikā, iztukšošana un utilizācija. Papildinformāciju, lūdzu, skatiet apsildes-dzesēšanas sistēmas 3T lietošanas pamācībā.

Svarīgi! Aerosola savākšanas ierīce ir jānomaina 7 dienu laikā kopš uzstādīšanas brīža. Aerosols savākšanas ierīce ir jānomaina arī pēc apsildes-dzesēšanas sistēmas dezinfekcijas.

1 Uzstādīšana
2 Pārbaudes procesu izpildes laikā
- 2.2 Kad vakuums ir pilnībā noslēgts un apsildes-dzesēšanas sistēma ir izslēgta, apsildes-dzesēšanas sistēmas spiediens ir 0 paskālu.
- 2.3 Kad vakuums ir pilnībā atvērts, apsildes-dzesēšanas sistēmas spiediens ir augstāks par 50 paskāliem.

3 Iztukšojiet aerosola savākšanas tvertni saskaņā ar jūsu slimnīcas politiku.
4 Utilizējiet aerosola savākšanas ierīci atbilstoši vietējiem vides noteikumiem un slimnīcas politikai.

Ražotājs
Izgatavošanas datums
Numurs katalogā
Skatiet lietošanas pamācību
Datums
Partijas kods
Izlietošanas beigu termiņš
Utilizējiet 7 kalendāro dienu laikā
Bioloģisks apdraudējums

LIT – Lietuviškai

Šiose instrukcijose aprašytas 3T aerozolio surinkimo prietaiso (050900100) įrengimas, tikrinimai per procesą, ištuštinimas ir utilizavimas. Papildomos informacijos žr. Šildymo-vėsinimo sistemos 3T naudojimo instrukcijose.

Svarbu: praėjus 7 dienoms po surinkimo, aerozolio surinkimo prietaisą reikia pakeisti. Aerozolio surinkimo prietaisą taip pat būtina pakeisti šildytuvą-vėsintuvą dezinfekavus.

1 Įrengimas
2 Tikrinimas per procesą
- 2.2 Visiškai užsukus vakuumą ir išjungus šildytuvą-vėsintuvą, šildytuvo-vėsintuvo slėgis lygus 0 paskalių.
- 2.3 Iki galo atsukus vakuumą, šildytuvo-vėsintuvo slėgis yra didesnis nei 50 paskalių.

3 Aerozolio surinkimo kanistrus ištuštinkite laikydamiesi ligoninėje nustatytų reikalavimų.
4 Aerozolio surinkimo prietaisą utilizuokite laikydamiesi vietinių aplinkosaugos taisyklių ir ligoninėje nustatytų reikalavimų.

Gamintojas
Pagaminimo data
Katalogo numeris
Žr. naudojimo instrukcijas
Data
Partijos kodas
Sunaudoti iki
Utilizuoti per 7 kalendorines dienas
Biologinis pavojus

CHI – 中文

本说明介绍 3T 气溶胶收集套件 (050900100) 的安装、过程中检查、清空和处置。有关其他详细信息，请参阅 3T 心肺流转热交换水箱操作说明。

重要提示：气溶胶收集套件必须在安装后 7 日内更换。在对热交换水箱进行消毒之后，也必须更换气溶胶收集套件。

1 **安装**
2 **过程中检查**
- 2.2 **在真空完全封闭及热交换水箱关闭的情况下，热交换水箱压力等于 0 帕**
- 2.3 **在真空完全打开的情况下，热交换水箱压力大于 50 帕**

3 **根据医院制度清空气溶胶收集罐。**
4 **根据当地环保法规和医院制度处置气溶胶收集套件。**

制造商
生产日期
目录编号
参阅使用说明
日期
批号
失效日期
在 7 日内处置
生物性危害

NOR – Norsk

Denne bruksanvisningen beskriver hvordan du installerer, utfører kontroller under bruk, tømmer og kasserer 3T-aerosoloppsamlingssettet (050900100). Du finner mer informasjon i bruksanvisningen for hypotermienhet 3T.

Viktig: Aerosoloppsamlingssettet må skiftes ut innen 7 kalenderdager etter installeringsdatoen. Aerosoloppsamlingssettet må også skiftes ut når hypotermienheten har blitt desinfisert.

1 Installering
2 Kontroller under bruk
- 2.2 Når vakuum er helt lukket og hypotermienheten er av, er trykket i hypotermienheten lik 0 pascal.
- 2.3 Når vakuum er helt åpent, er trykket i hypotermienheten større enn 50 pascal.

3 Tøm aerosoloppsamlingsbeholderen i henhold til sykehusets retningslinjer.
4 Kasser aerosoloppsamlingssettet i henhold til lokale miljøforskrifter og sykehusets retningslinjer.

Produsent
Produksjonsdato
Artikkelnummer
Se bruksanvisningen
Dato
Partikode
Brukes innen
Kasser innen 7 kalenderdager
Biologisk fare

POL – Polski

Niniejsza instrukcja opisuje instalację, kontrole w trakcie procesu, opróżnianie i utylizację zbiornika na aerozol 3T (050900100). Dodatkowe szczegóły można znaleźć w instrukcji obsługi systemu grzewczo-chłodniczego 3T.

Ważne: Po 7 dniach od zamocowania konieczna jest wymiana zbiornika na aerozol. Zbiornik na aerozol musi również zostać wymieniony po dezynfekcji grzejniko-chłodziarki.

1 Instalacja
2 Kontrole w trakcie procesu
- 2.2 Jeżeli źródło podciśnienia jest całkowicie zamknięte, a grzejniko-chłodziarka jest wyłączona, ciśnienie grzejniko-chłodziarki wynosi 0 paskali
- 2.3 Jeżeli źródło podciśnienia jest całkowicie otwarte, ciśnienie grzejniko-chłodziarki jest wyższe niż 50 paskali

3 Pojemnik do zbierania aerozolu należy opróżniać zgodnie z zasadami obowiązującymi w szpitalu.
4 Zbiornik na aerozol należy utylizować zgodnie z lokalnymi przepisami dotyczącymi ochrony środowiska oraz zasadami obowiązującymi w szpitalu.

Producent
Data produkcji
Numer katalogowy
Zapoznać się z instrukcją obsługi
Data
Kod partii
Data przydatności
Poddać utylizacji w ciągu 7 dni kalendarzowych
Zagrożenie biologiczne

产品名称：	心肺流转热交换水箱
型号规格：	3T
组件名称：	气溶胶收集套件
注册人 / 生产企业名称：	LivaNova Deutschland GmbH 理诺独德国有限责任公司
注册人 / 生产企业住所：	Lindberghstr. 25 80939 Munchen Germany
生产地址 / 原产地：	Lindberghstr. 25 80939 Munchen Germany
注册人 / 生产企业联系方式：	+49/(0)89/32301-0
代理人 / 售后服务机构名称：	理诺钛（中国）医疗科技有限公司
代理人 / 售后服务机构住所：	中国（上海）自由贸易试验区美盛路 56 号 2 层 218 室
代理人 / 售后服务机构联系方式：	021-23569551
产品注册证编号：	国械注准 20172102137
产品技术要求编号：	国械注准 20172102137
生产日期：	见英文标签 YYYY-MM-DD 项内容
失效日期：	见英文标签 YYYY-MM-DD 项内容
注意：	产品适用范围和产品结构及组成以如下信息为准。

适用范围：该产品用于配合人工心肺机系统使用，在体外灌注手术中控制水循环的冷却或加热。

该产品配套使用的心肺机系统的型号为 S5/C5/S3/SC。

产品结构及组成：该产品由水循环系统（包括 3 个水桶和 5 个泵）、1 套制冷系统、2 套加温系统、6 个温度传感器、2 个液平面探头、负压表、气溶胶收集套件组成。

说明书编制或修订日期： 请见第 1 页！

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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INSTALLATION QUALIFICATION (IQ)

(b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Document Number : (b)(4)

Document Revision : (b)(4)

Document Title : 3T Aerosol Collection Set

Effective Date: 17 Nov 2020

Expiration Date:

Notes :

(b)(4)

Previous Number: **Change Number:** (b)(4)

Document Type: (b)(4)

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19.0 PERFORMANCE TESTING – ANIMAL

This section does not apply because 3T Heater Cooler with Deep Cleaning process did not require animal data to demonstrate substantial equivalence.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Contains Nonbinding Recommendations

Print Form

510(k) Acceptance Checklist

Not for use with Third Party 510(k)s

Choose Submission Type: ☒ **Traditional** ☐ **Abbreviated** ☐ **Special**

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k) #: K220635 Date Received by DCC:

Lead Reviewer: Jacob Morand

Center: CDRH Office: OHT 2 Division: DHT2B

Decision:

◉ Accept. If Accept, notify submitter.

○ Refuse to Accept. If Refuse to Accept, notify submitter electronically and include a copy of this checklist.

Is an Addendum attached?: ○ Yes ◉ No Click paperclip icon on the left panel if Addendum is attached.

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during substantive review.

IMPORTANT - Many checklist elements include additional details regarding information to address the element that can be seen by hovering over the element (Example - Element 4 in Section A of the checklist).

Preliminary Questions **Answers in the shaded blocks indicate consultation with a Center advisor is needed. (Boxes checked in this section represent FDA's preliminary assessment of these questions at the time of administrative review.)**	**Yes**	**No**	**N/A**
1 Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product (per 21 CFR 3.2(e)), or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action, and inform management. *Provide a summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* If the product does not appear to be a device or such a combination product, mark "No."	☒	☐	
Comments:			
2 Is the submission with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the submission is not with the appropriate Center or you are unsure, consult with the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide a summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* If submission should not be reviewed by your Center mark "No."	☒	☐	
Comments:			

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3 If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: **a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?** **b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?** If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide a summary of Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* If the answer to either question above is no, mark "No." If there was no RFD, mark "N/A."	☐		☒
Comments:			
4 Is the submission for a combination product that contains as a constituent part a drug that has the same active moiety as an approved drug with exclusivity as described in 21 USC 503(g)(5)(C)(ii)-(v) (section 503(g)(5)(C)(ii)-(v) of the FD&C Act)? If "Yes," then contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide the summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.*	☐	☒	☐
Comments:			
5 Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), consult with the appropriate CDRH or CBER staff during the acceptance review, provide a summary of the discussion with them, and indicate their recommendation/action in the comment section below. If 510(k) is not the appropriate regulatory submission, mark "No."	☒	☐	
Comments:			
6 Is there a pending PMA for the same device with the same indications for use? If "Yes," consult your management and CDRH Office of Product Evaluation and Quality/Office of Regulatory Programs/Division of Regulatory Programs 1 (Submission Support) (OPEQ/ORP/DRP1) or appropriate CBER staff to determine the appropriate action.	☐	☒	
Comments:			
7 If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If "Yes," consult with the CDRH Office of Product Evaluation and Quality/ Office of Clinical Evidence and Analysis/Division of Clinical Science and Quality (OPEQ/OCEA/DCEA1) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action, provide a summary of the discussion with them, and indicate their recommendation/action. If no clinical studies have been submitted, mark "N/A." Check on the AIP list at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/application-integrity-policy/application-integrity-policy-list.	☐	☐	☒
Comments:			

- If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.
- If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.
- If the answer to 4 is "Yes," then contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer, provide a summary of the discussion with them, and indicate their recommendation/action.
- If the answer to 5 is "No," the lead reviewer should consult management and other Center resources to determine the appropriate action.
- If the answer to 6 is "Yes," then stop review of the 510(k), contact the CDRH/OPEQ/ORP/DRP1, or appropriate CBER staff.
- If the answer to 7 is "Yes," then contact CDRH/OPEQ/OCEA/DCEA1 or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with DCEA1 or BMB Staff, and indicate their recommendation/action.

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Organizational Elements

Failure to include these items should not result in an RTA designation.

*Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	*Page #
1) Submission contains a Table of Contents	☒	☐	
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	☒	☐	
3) All pages of the submission are numbered. *All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2…).*	☒	☐	
4) Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special). *If type of 510(k) is not designated, review as a Traditional 510(k).*	☒	☐	
Comments:			

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during RTA review.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
A. Administrative					
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	☒	☐		☐	
2) Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form (Form 3514, available at https://www.fda.gov/media/72421/download)):				☐	
a) Device trade/proprietary name	☒	☐			
b) Device class and panel OR Classification regulation OR Statement that device has not been classified with rationale for that conclusion	☒	☐			
3) Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance "Alternative to Certain Prescription Devices Labeling Requirements," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/alternative-certain-prescription-device-labeling-requirements.) *See recommended* format (https://www.fda.gov/media/86323/download).	☒	☐		☐	
4) Submission contains a 510(k) Summary or 510(k) Statement.	☒	☐		☐	
5) Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(l) *See recommended format (https://www.fda.gov/medical-devices/premarket-notification-510k/premarket-notification-truthful-and-accurate-statement).*	☒	☐		☐	
6) Submission is a Class III 510(k) device.	☐		☒	☐	
7) Submission contains clinical data	☐		☒	☐	
8) The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Q-Submission, IDE, PMA, etc.). **OR** States that there were no prior submissions for the subject device.	☒	☐		☐	
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed.	☒	☐	☐		
9) The submission utilizes voluntary consensus standard(s) (See section 514(c) of the FD&C Act). *This includes both FDA-recognized and non-recognized consensus standards.*	☒		☐	☐	
a) The submission cites FDA-recognized voluntary consensus standard(s).	☒		☐		
i) The submission includes a Declaration of Conformity (DOC) as outlined in FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices. **OR** If citing general use of a standard as noted in FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," the basis of such use is included along with the underlying information or data that supports how the standard was used.	☒	☐			

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
b) The submission cites non-FDA-recognized voluntary consensus standard(s).	☒		☐		
i) The basis of use is included along with the underlying information or data that supports how the standard was used.	☒	☐			
Combination Product Provisions - Per 503(g) of the FD&C Act. Select "N/A" if the product is not a combination product. 21 CFR 3.2(e). The remaining criteria in this section will be omitted from the checklist if "N/A" is selected. If you are unsure if the product is a combination product, consult with the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.			☒		
B. Device Description					
12) The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding the device description that is applicable to the subject device.	☐		☒	☐	
13) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).	☒	☐		☐	
14) The submission includes descriptive information for the device, including the following:				☐	
a) A description of the principle of operation or mechanism of action for achieving the intended effect.	☒	☐			
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	☒	☐	☐		
c) A list and description of each device for which clearance is requested.	☒	☐	☐		
d) Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. **OR** Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device).	☒	☐			
15) Device is intended to be marketed with accessories and/or as part of a system.	☒		☐	☐	
a) Submission includes a list of all accessories to be marketed with the subject device.	☒	☐			
b) Submission includes a description (as detailed in item 14(a), 14(b) and 14(d) above) of each accessory.	☒	☐	☐		
c) A 510(k) number is provided for each accessory that received a prior 510(k) clearance. **AND** A statement is provided that identifies accessories that have not received prior 510(k) clearance.	☒	☐			
C. Substantial Equivalence Discussion					
16) Submitter has identified a predicate device(s), including the following information:				☐	

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
a) Predicate device identifier provided (e.g., 510(k) number, De Novo number, reclassified PMA number, classification regulation reference, if exempt (e.g., 21 CFR 872.3710), or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online (https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/preamendment-status).*	☒	☐			
b) The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing).	☒	☐			
17) Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] *See the FDA guidance document "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k for more information on comparing intended use and technological characteristics.*				☐	
a) Indications for Use	☒	☐			
b) Technology, including technical specifications, features, materials, and principles of operation	☒	☐			
D. Proposed Labeling (see also 21 CFR part 801 and 809 as applicable)					
18) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).	☒	☐		☐	
a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).	☒	☐			
b) Labeling includes: - Statements of conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) **AND** - Includes adequate directions for use (see 21 CFR 801.5) **OR** - Submission states that device qualifies for exemption per 21 CFR 801 Subpart D	☒	☐			
19) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	☒	☐		☐	
20) Labeling includes the prescription statement [see 21 CFR 801.109(b)(1)] or Rx Only symbol (see also Section 502(a) of the FD&C Act and FDA's guidance "Alternative to Certain Prescription Device Labeling Requirements," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/alternative-certain-prescription-device-labeling-requirements.	☒	☐	☐	☐	
21) The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding labeling that is applicable to the subject device.	☒		☐		

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
a) The submission addresses labeling recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.	☒	☐	☐		
b) The submission includes labeling information that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	☒	☐	☐		
22) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.	☐	☐	☒	☐	
E. Sterilization					
If an *in vitro* diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.			☐		
☐ Provided sterile, intended to be single-use					
☒ Requires processing during its use-life					
☐ Non-sterile when used (and no processing required)					
☐ Information regarding the sterility status of the device is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ Sterility status not needed for this device (e.g., software-only device)					
☐ Sterility status needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *Please refer to the FDA guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling, for additional information.*					
23) Assessment of the need for cleaning and subsequent disinfection or sterilization information				☐	
a) Identification of device and/or accessories, if applicable, that are provided sterile.	☐	☐	☒		
b) Identification of device and/or accessories, if applicable, that are end user sterilized or disinfected.	☐	☐	☒		
c) Identification of device, and/or accessories, if applicable, that are reusable.	☒	☐	☐		
24) If the device and/or accessories, if applicable, are provided sterile:			☒	☐	
25) If the device and/or accessory, if applicable, is reusable or end user sterilized or disinfected:			☐	☐	
a) Cleaning method is provided in labeling for each device and/or accessory, if applicable.	☒	☐	☐		

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b) Disinfection method is provided in labeling for each device and/or accessory, if applicable.	☒	☐	☐		
c) Sterilization method is provided in labeling for each device and/or accessory, if applicable.	☒	☐	☐		
d) Device types in this submission are listed in the Federal Register (FR) Notice entitled "Validated Instructions for Use and Validation Data Requirements for Certain Reusable Medical Devices in Premarket Notifications" (Reprocessing FR Notice, available at https://www.federalregister.gov / documents/2017/06/09/2017-12007/medical-devices-validated-instructions-for-use-and-validation-data-requirements-for-certain-reusable).	☒		☐		
i) If device types in this submission are included in the Reprocessing FR Notice, the submission includes protocols and test reports for validating the reprocessing instructions.	☒	☐	☐		
26) The device has a device-specific guidance document, special controls, and/or requirement in a device-specific regulation regarding sterility and/or reprocessing that is applicable to the subject device.	☒		☐	☐	
a) The submission addresses sterility and/or reprocessing recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.	☒	☐	☐		
b) The submission includes sterility and/or reprocessing information that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	☒	☐	☐		
F. Shelf Life					
27) Proposed shelf life/expiration date stated **OR** Statement that shelf-life is not applicable because of low likelihood of time-dependent product degradation	☒	☐	☐	☐	
28) For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf life.	☐	☐	☒	☐	
29) Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH, osmolality, etc.). **OR** Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.	☒	☐		☐	
G. Biocompatibility					
If an vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.			☐		
Submission states that there: (one of the below must be checked)		☐		☐	

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☐ Are direct or indirect tissue-contacting components.					
☒ Are no direct or indirect tissue-contacting components.					
☐ Information regarding tissue contact status of the device is not provided (if this box checked, please also check one of the two boxes below).					
☐ Tissue contact information not needed for this device (e.g., software-only device)					
☐ Tissue contact information needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
H. Software					
Submission states that the device: (one of the below must be checked)		☐		☐	
☒ Does contain software/firmware					
☐ Does not contain software/firmware					
☐ Information on whether device contains software/firmware is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ Software/firmware information not needed for this device (e.g., surgical suture, condom)					
☐ Software/firmware information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
33) Submission includes a statement of software level of concern and rationale for the software level of concern.	☒	☐		☐	
34) All applicable software documentation provided based on level of concern identified by the submitter, as described in "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-submissions-software-contained-medical-devices, or the submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has identified an alternate approach with a rationale).	☒	☐		☐	
I. Cybersecurity					
Submission states that the device: *(one of the below must be checked)*		☐		☐	
☒ Does contain any external wired and/or wireless communication interfaces (Wired: USB, ethernet, SD, CD, RGA, etc. or Wireless: Wi-Fi, Bluetooth, RF, inductive, Cloud, etc.)					
☐ Does not contain external interfaces as described above					
☐ Information on whether device has external interfaces is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ Cybersecurity information not needed for this device (e.g., surgical suture, condom)					
☐ Cybersecurity information is needed or need unclear					
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35) All applicable documentation identified by the submitter, as described in "Guidance for the Content of Premarket Submissions for Management of Cybersecurity in Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-management-cybersecurity-medical-devices-0. **OR** Submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has identified an alternate approach with a rationale).	☒	☐		☐	
J. Electrical Safety and EMC					
Electrical Safety Submission states that the device: *(one of the below must be checked)*		☐		☐	
☒ Does require electrical safety evaluation					
☐ Does not require electrical safety evaluation					
☐ Information on whether device requires electrical safety evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ Electrical safety information not needed for this device (e.g., surgical suture, condom)					
☐ Electrical safety information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
36) Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, a device-specific standard), **OR** Submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	☒	☐		☐	
EMC Submission states that the device: (one of the below must be checked)		☐		☐	
☒ Does require EMC evaluation					
☐ Does not require EMC evaluation					
☐ Information on whether device requires EMC evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ EMC information not needed for this device (e.g., surgical suture, condom)					
☐ EMC information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
37) Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, the device-specific standard) **OR** Submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	☒	☐		☐	
K. Performance Data - General					
If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from checklist if "N/A" is selected. Performance data criteria relating to IVD devices is addressed in Section K.			☐		
38) Summaries of the non-clinical laboratory studies and full test reports* are provided. *Summary and full test report content recommendations can be found in FDA's guidance "Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket. If a submitter chooses to declare conformity to a voluntary consensus standard that FDA has recognized, submission of a full test report may not be necessary. Refer to 9a. See FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices.	☒	☐	☐	☐	
a) Submission includes an explanation of how the data generated from each test supports a finding of substantial equivalence (e.g., comparison to predicate device testing, dimensional analysis, etc.).	☒	☐			
39) The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding performance data that is applicable to the subject device.	☐		☒	☐	
40) If literature is referenced in the submission, submission includes:			☐		
a) Legible reprints or a summary of each article.	☒	☐			
b) Discussion of how each article is applicable to support the substantial equivalence of the subject device to the predicate.	☒	☐			
41) For each completed animal study, the submission provides the following:			☒	☐	
L. Performance Characteristics - In Vitro Diagnostic Devices Only **(Also see 21 CFR 809.10(b)(12))**					
Submission states that the device: (one of the below must be checked)				☐	
☐ is an in vitro diagnostic device.					
☒ is not an in vitro diagnostic device.					
If "is not" is selected, the performance data-related criteria below are omitted from the checklist.					

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Digital Signature Concurrence Table

Reviewer Sign-Off	Jacob Morand -S	Digitally signed by Jacob Morand -S Date: 2022.03.16 13:28:37 -04'00'
Management Sign-Off (digital signature optional)*		

* Management review of checklist and concurrence with with decision required.

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4.0 INDICATIONS FOR USE STATEMENT

The Company's Indications for Use statement for Stöckert Heater-Cooler System 3T is provided on the following page.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

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CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Response

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Form Approved: OMB No. 0910-0511 Expiration Date: August 31, 2022. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4)
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/ucm370879.htm

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

LivaNova Deutschland GmbH
Lindbergh Strasse 25
Munchen
80939
DE

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)

2. CONTACT NAME
Valentina Rollo
2.1 E-MAIL ADDRESS
valentina.rollo@livanova.com
2.2 TELEPHONE NUMBER (include Area code)
89-32301236
2.3 FACSIMILE (FAX) NUMBER (Include Area code)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] 30-Day Notice
[ ] De Novo Request

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of your establishments have registered and paid the fee, or this is your first device and you will register and pay the fee within 30 days after entering into an operation that requires you to register and submit device listing information.)
[ ] NO (If you currently market a medical device and your establishment is required to register and submit device listing information, FDA will not accept your submission until you have paid all fees due to FDA. See http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).
[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT
Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4) 24-Jan-2022

Form FDA 3601 (08/19)

"Close Window" Print Cover sheet

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OPERATIONAL QUALIFICATION REPORT

(b)(4)

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PERFORMANCE QUALIFICATION REPORT

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As presented in the 510(k) Cover Letter, LivaNova is providing responses to close FDA's questions received in (b)(4), regarding Deep Cleaning.

(b)(4)

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5.0 510(k) SUMMARY

The Company's 510(k) Summary is provided on the following pages.

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510(k) SUMMARY

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April 29, 2022</br></br> We have reviewed your submission. Please see attached.

If you have any questions, please contact the lead reviewer assigned to your submission, Jacob Morand.

 *** This is a system-generated email notification ***

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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6.0 TRUTHFUL AND ACCURATE STATEMENT

[As Required by 21 CFR 807.87(l)]

I certify that, in my capacity as Director, Regulatory Affairs, Cardiac Surgery, LivaNova, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(b)(6)

Julia E. Leslie, PhD
Director, Regulatory Affairs, Cardiac Surgery

March 3, 2022
Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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U.S. FOOD & DRUG ADMINISTRATION

November 16, 2022

LivaNova Deutschland GmbH
Julia Leslie
Senior Director, Regulatory Affairs CS
Lindbergh Strasse 25
Munchen, BY 80939
Germany

Re: K220635
Trade/Device Name: Heater-Cooler System 3T
Regulation Number: 21 CFR 870.4250
Regulation Name: Cardiopulmonary bypass temperature controller
Regulatory Class: Class II
Product Code: DWC
Dated: October 12, 2022
Received: October 14, 2022

Dear Julia Leslie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for

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devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Nicole M. Gillette -S

Nicole Gillette
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

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Operational Qualification Plan

(b)(4)

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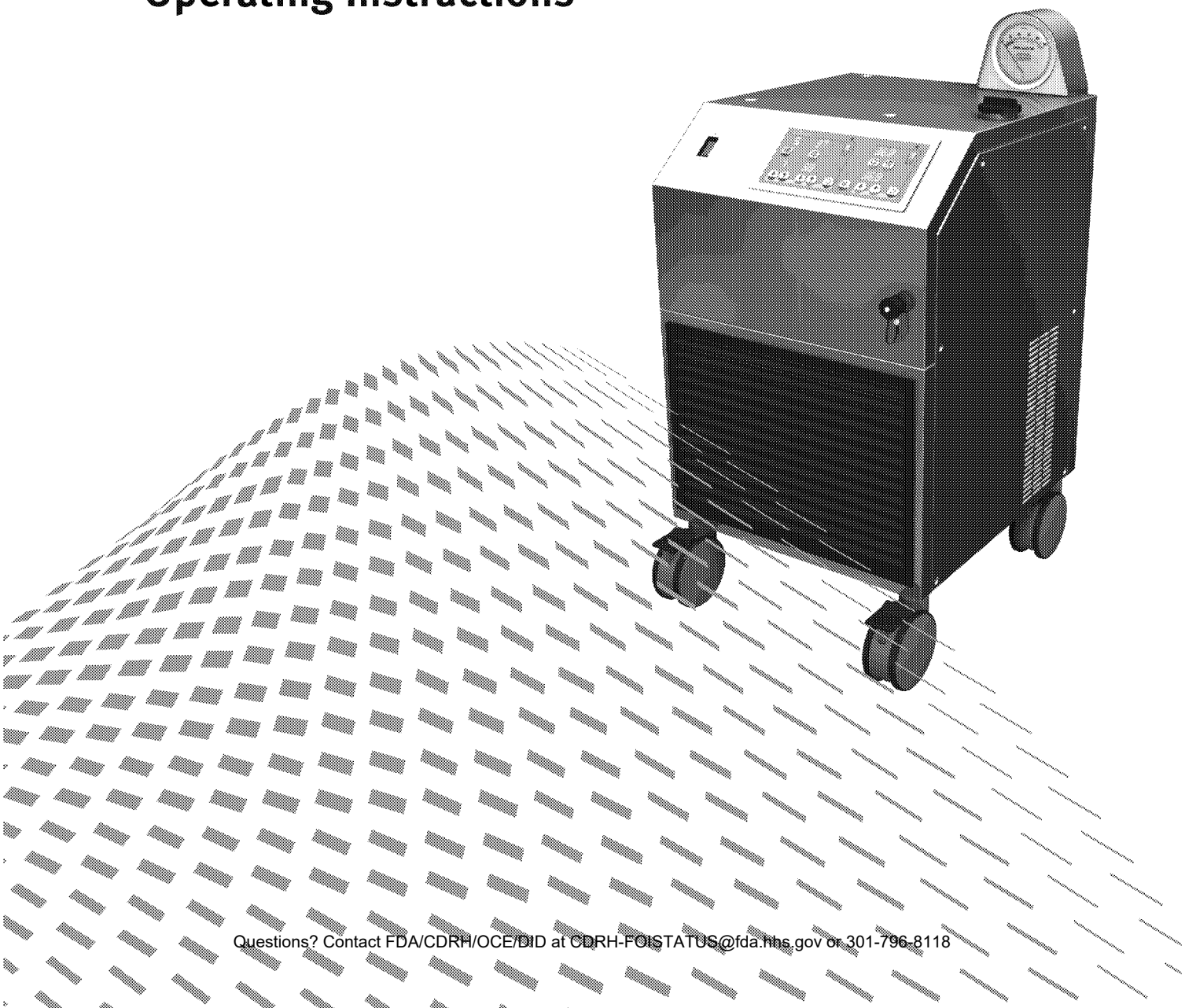
LivaNova

Health innovation that matters

Heater-Cooler System 3T
Operating Instructions



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Indications for use

The Heater-Cooler System 3T is used to circulate water through heat exchangers to warm or cool a patient during cardiopulmonary bypass procedures lasting 6 hours or less.

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Distributed in the U.S.A. by:

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Operating Instructions
Version 11/2022 - CP_IFU_16-XX-XX_USA_022

Firmware version No. 2.07

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1 Introduction

This chapter provides an overview of the device, including indications for use and contraindications. This chapter also provides an explanation of each chapter, technical terms and symbols used in this operating manual, and a definition of the filtered water required for use in the heater-cooler.

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1.1 Introduction

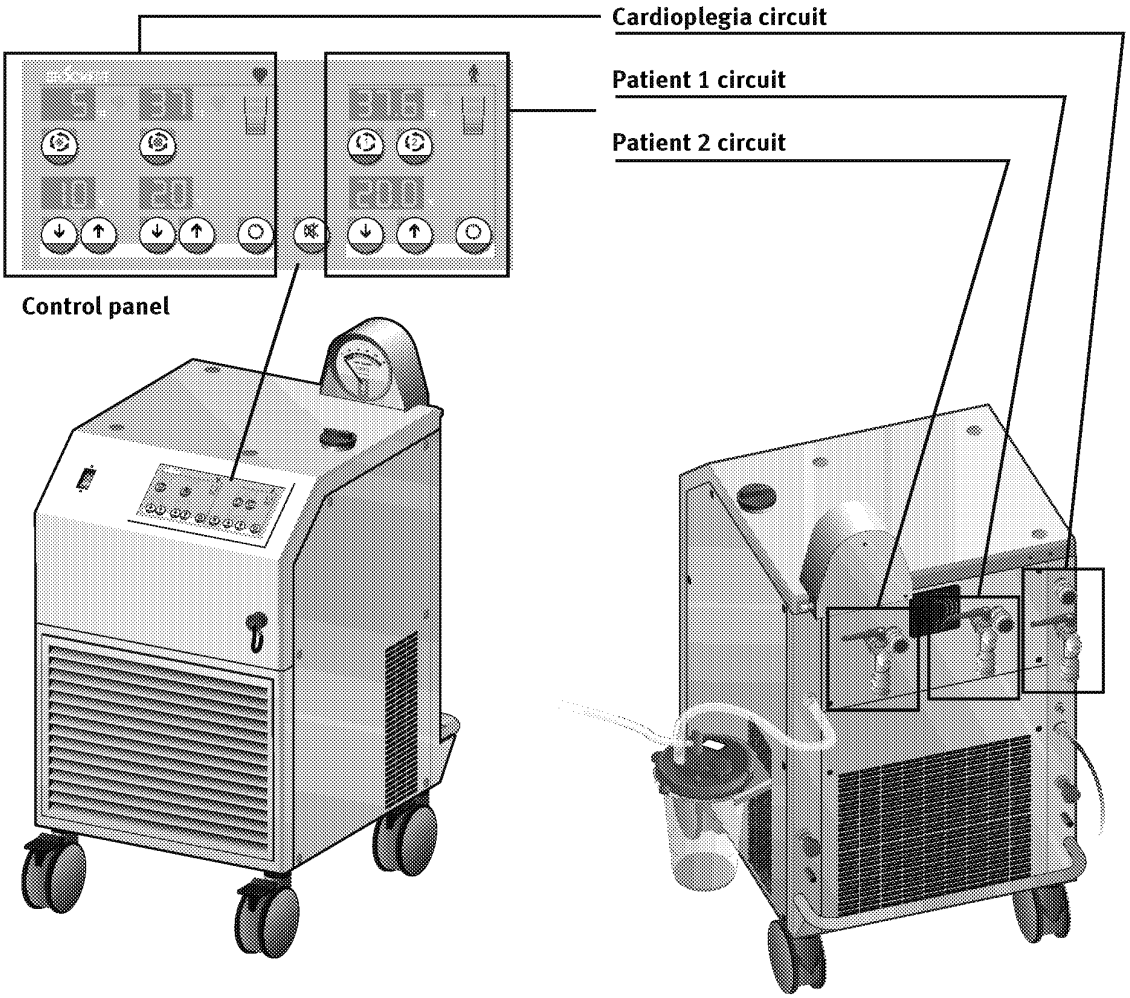
1.1.1 Device summary

The Heater-Cooler System 3T is an independent 3-circuit-heating/cooling system which is suitable for continuous use.

The heater-cooler has three circuits that you control from the control display panel:

- **Cardioplegia circuit**, whose temperature can be controlled from independent heating and cooling tanks.
- **Patient 1 circuit** and **patient 2 circuit**, which can be used with the oxygenator and/or the single-use heating/cooling blanket. The temperature for these two circuits can be controlled from one heating/cooling tank.

The heater-cooler is a non-sterile device. No part of the heater-cooler is provided sterile or can be sterilized.



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1.1.2 Indications for use

The Heater-Cooler System 3T is used to circulate water through heat exchangers to warm or cool a patient during cardiopulmonary bypass procedures lasting 6 hours or less.

1.1.3 Contraindications

There are no known contraindications for the Heater-Cooler System 3T. The attending physician is solely responsible for the use of the system.

1.1.4 Legal disclaimer

LivaNova Deutschland GmbH will not assume any liability for any injuries and/or damage to property caused by failure to observe the safety or operating instructions or by failure to exercise due care. This also applies even if the duty to exercise due care has not been expressly stated.

1.1.5 About these operating instructions

- These operating instructions are intended for clinical and maintenance personnel, and provide instructions for using, operating, and maintaining the Heater-Cooler System 3T.
- To ensure the safety of patients and the operators, read these operating instructions thoroughly before using the heater-cooler for the first time.
- These operating instructions provide valuable information. They describe operational steps and also contain information on how to avoid dangerous situations and errors. These operating instructions also provide troubleshooting instructions.

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1.1.6 Symbols used in these operating instructions

WARNING

Indicates a hazardous situation that, if not avoided, could result in death or serious injury.

CAUTION

Indicates a hazardous situation that, if not avoided, could result in minor or moderate injury.

NOTICE

Indicates a hazardous situation that, if not avoided, may result in damage to the device or other property.

Important

Indicates information considered important but not hazard related.

NOTE: Provides additional information that can help you better understand a specific instruction of function.

☑ Checkmark: Used to indicate an item to check before or after completing a task. These items are for reference and do not replace detailed instructions.

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1.1.7 The chapters in these operating instructions

1 Introduction

This chapter provides an overview of the device, including indications for use, contraindications. This chapter also provides an explanation of each chapter, technical terms and symbols used in this operating manual, and a definition of the filtered water required for use in the heater-cooler.

2 Safety

This chapter provides general safety information that you must follow to ensure safe and effective use. Additional safety information, such as Warnings and Cautions, are included throughout the instructions in this manual.

3 System description

This chapter describes the system's features and components, and the controls that you will use to control the system's circuits.

4 Preparing the heater-cooler for a procedure

This chapter provides instructions for preparing the heater-cooler for use.

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5 Using the heater-cooler during a procedure

This chapter provides instructions for positioning the heater-cooler in the OR and using the heater-cooler's controls during a procedure. This chapter also provides the basic steps you will conduct after a procedure.

6 Maintaining the heater-cooler

This chapter provides instructions for the routine maintenance that is part of the operating conditions for the heater-cooler. This applies to the routine maintenance performed by the responsible organization as defined in IEC 60601-1 or the equivalent national standard, as well as to the preventive maintenance and safety checks performed by LivaNova representatives or competent service personnel.

7 Technical specifications

This chapter provides technical specifications including information about the heater-cooler's physical characteristics, labeling, part numbers, accessories, and electromagnetic compatibility. This chapter also includes warranty information.

8 Troubleshooting

This chapter provides troubleshooting for warnings and error codes you might see on the control panel, and troubleshooting related to the aerosol collection set.

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1.1.8 Terminology and abbreviations

Terminology

Abbreviated term	Full term
Heater-cooler	Stöckert Heater-Cooler System 3T
S5 System	Stöckert S5 System, modular heart-lung machine
C5 System	Sorin Compact 5 System, compact heart-lung machine
Aerosol collection set	3T Aerosol Collection Set

Abbreviations

Abbreviated term	Full term
ACS	Aerosol Collection Set 3T
AL	Allowable Limit
CAN	Controller Area Network (CAN bus)
cc	Cubic centimeter (cm^3)
CFU	Colony Forming Unit
EMC	Electromagnetic Compatibility
EPA Reg. No.	Registration number of the United States Environmental Protection Agency (applies to the United States only)
HC3T	Heater-Cooler System 3T
HLM	Heart-Lung Machine
L	Liters
LPM	Liters per minute
mL	Milliliters
NTM	Non-tuberculous Mycobacteria
OR	Operating Room
Pa	Pascal
kPa	Kilopascal
ppm	Parts per million
RF	Radio Frequency
UDI	Unique Device Identifier

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1.1.9 Requirement for filtered tap water

Tap water used to fill the heater-cooler must be filtered using the following filter and specifications:

Disposable Pall-Aquasafe water filter with an 0.2 µm membrane (Pall part reference in the U.S.: “AQINA”; “AQIN” in other countries) or a filter of equivalent performance that meets the requirements for bacterial retention of Brevundimonas diminuta to ≥ 10^7 CFU/cm^2 of effective filtration area.[1]

For instructions on filter management and disposal after the specified use period please refer to the manufacturer’s instructions for use.

1 American Standard Test Method F838-15ae1 “Determining Bacterial Retention of Membrane Filters Utilized for Liquid Filtration”

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2 Safety

This chapter provides general safety information that you must follow to ensure safe and effective use.

Additional safety information, such as Warnings and Cautions, are included throughout the instructions in this manual.

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2.1 Safety information

2.1.1 General safety

- Read and understand the instructions for use before operating the heater-cooler.
- Disinfect the external surfaces and water circuits per chapter 6 prior to first use.
- Do not place any objects (including the portable vacuum source) on top of the heater-cooler.
- Maintain at least 70 cm clearance from walls and other devices while operating the heater-cooler to prevent the heater-cooler from overheating.
- Do not operate the heater-cooler in the presence of explosive substances.
- Do not modify any of the mechanical or electrical systems of the heater-cooler.
- Do not remove the side or rear panels of the heater-cooler. Contact with the internal components can cause serious injury or death.
- A list of approved accessory devices is contained in chapter 7. Do not use any unapproved accessory devices with the heater-cooler.
- Do not use self-closing tubing connectors or connectors that incorporate a valve. These connectors can reduce water flow to the external circuits.
- Drain heater-cooler water tanks outside the OR.
- Do not replace the aerosol collection canister in the OR environment.
- Avoid splashing heater-cooler water in the OR environment during use and when making water circuit connections.
- Remove water spills from the OR floor using suitable disinfectants as recommended by hospital procedures.
- Do not perform any maintenance activities while the heater-cooler is in use or connected to an oxygenator or other heat exchanger device.

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2.1.2 Information on diffusion of hydrogen peroxide through the oxygenator heat exchanger

The water in the heater-cooler contains approximately 330 ppm of hydrogen peroxide when prepared per these operating instructions. Contact the manufacturer of the disposable oxygenator for information specific to the hydrogen peroxide permeability of the heat exchanger for concentrations at or below this level.

Do not use the heater-cooler with disposable oxygenators that have a heat exchanger with a permeability rate that exceeds the daily allowable limit (AL) as defined in the following table:

Duration of exposure to H_2O_2	Allowable limit (AL) in mg/day per kg of patient body weight	Allowable mass of hydrogen peroxide (H_2O_2) in mg/day the can be transferred in patient blood for:	
		An adult (typical body weight is 60 kg)	A neonate (typical body weight is 3 kg)
Up to 6 hours	0.21	12.60	0.63
Over 6 hours	0.034	2.02	0.10

Although allowable limits (AL) for hydrogen peroxide diffusion are provided, actual performance may vary in individual cases. Monitor and manage all patients.

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2.1.3 Procedural safety

- The heater-cooler does not monitor the temperature of the patient's blood or the cardioplegia solution.
- Do not empty the external circuits until the patient has been discharged from the OR.
- LivaNova recommends always having a replacement heater-cooler available in case the heater-cooler in use is no longer functional (e.g., due to a total system failure). The replacement heater-cooler must have compatible connectors.

2.1.4 Electrical safety

- Do not modify any of the electrical systems of the heater-cooler.
- The heater-cooler should only be connected to a hospital-quality power source with an integrated protective conductor (ground).
- To avoid the risk of electric shock, the heater-cooler must only be connected to a supply mains with protective earth.
- Check the condition of the power cable and plug regularly and do not use the heater-cooler if the cable or plug shows signs of wear or damage.
- Do not position the heater-cooler where it will block access to the mains power plug. Removing the mains plug from the receptacle isolates the heater-cooler from mains voltage and the plug must remain accessible at all times.

2.1.5 Integrating the HC3T into your facility

As part of the integration of the Heater-Cooler System 3T into your facility, LivaNova strongly recommends the following:

- Ensure that all operators and maintainers of the heater-cooler read the instructions and familiarize themselves with the use and maintenance of the device (chapters 4, 5 and 6), with special emphasis on the critical tasks listed in the table below.
- Integrate all maintenance activities listed in chapter 6.2.1 into your facility's preventative maintenance scheduling system. This includes the cleaning and disinfection of the heater-cooler before first use. Failure to perform the maintenance tasks as indicated can lead to bacterial growth inside the device and an increased risk of exposing the patient to harmful bacteria.
- Implement regular bacterial sampling of the water in the heater-cooler into your preventative maintenance scheduling system. This testing is critical to understanding if the disinfection and water preservation activities are being completed effectively. This testing can also indicate if an external source of contamination (e.g. a contaminated water hose) is present.

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If you have any questions about the integration of the Heater-Cooler System 3T into your facility, please contact your LivaNova sales representative.

Human Factors Testing and clinical experience have shown that operators are most likely to have issues understanding or performing the critical tasks in the following table. This table provides the task description, where to locate the instructions related to this task, and the consequences of failing to perform the task correctly.

Task	Location of instructions	Potential consequences of incorrect task performance or omission
Do not use the HC3T without the ACS attached.	Chapter 4.5	Failure to use the ACS may result in the emission of aerosol.
Cap unused ports on the ACS.	Chapter 4.5 Task 3, ▶ 3	Failure to cap the tandem and pour ports may lead to a loss of vacuum in the ACS, potentially reducing the effectiveness in preventing the emission of aerosol.
Write the installation date on the ACS.	Chapter 4.5 Task 4, ▶ 7	Failure to write down the installation date can lead to use of the ACS beyond 7 days, potentially clogging the filter and reducing the effectiveness in preventing the emission of aerosol.
Replace the ACS after the disinfection procedure.	Chapter 6.4.2 Task 11	Failure to replace the ACS after the disinfection procedure could lead to disinfectant vapor entering the vacuum system.
Clean and disinfect the HC3T prior to first use.	Chapter 6.2.1	Bacteria may be present on or in the heater-cooler if the packaging was damaged during transport or storage.
Disinfect the connectors and tubing fittings prior to each connection.	Chapter 6.3.2 Chapter 6.3.3	Failure to disinfect the connectors and/or fittings could lead to bacterial growth that can be transferred to other parts of the heater-cooler or the OR.
Drain water tanks prior to adding disinfectant.	Chapter 6.4.2 Task 2	Failure to drain the tanks prior to adding disinfectant could reduce the disinfectant's effectiveness.
During disinfection, fill the water tanks to the Patient level second green LED after adding disinfectant.	Chapter 6.4.2 Task 4, ▶ 4	Failure to completely fill the tanks during disinfection could lead to a low level in one tank, potentially resulting in incomplete disinfection.
Circulate disinfectant by pressing the WARM CP, Patient 1, and Patient 2 buttons.	Chapter 6.4.2 Task 8, ▶ 1	Failure to circulate disinfectant using Patient 1, Patient 2, and the WARM CP buttons could lead to incomplete disinfection of one or more tanks.

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Task	Location of instructions	Potential consequences of incorrect task performance or omission
Do not use disinfectant during a procedure.	Chapter 6.4.1	Use of disinfectant in the water during a procedure could lead to failure of the heater-cooler and the attached accessory devices.
Mix chemicals (disinfectant or hydrogen peroxide) by connecting a tube between the INLET of the CP circuit and the INLET of the Patient 1 circuit.	Chapter 4.7 Task 3 & 4 Chapter 6.4.2 Task 6 Chapter 6.6 Task 4 & 5	Failure to properly connect the tubing prior to mixing could lead to one or more tanks not being exposed to the correct amount of the chemical, potentially reducing the effectiveness of the water preservation process.
Mix chemicals (disinfectant or hydrogen peroxide) using the COLD CP button.	Chapter 6.4.2 Task 6, ▶ 1 and Task 6, ▶ 2	Failure to use the COLD CP button to mix disinfectant could result in insufficient exposure of one or more tanks to the required quantity of disinfectant.
Change the water in the heater-cooler every 7 days.	Chapter 6.2.1 Section 6.6	Failure to change the water can lead to ineffective prevention of bacterial growth.
Add 150 ml of 3% medical-grade hydrogen peroxide when filling the heater-cooler.	Chapter 4.7 Task 2, ▶ 3 Chapter 6.6 Task 3, ▶ 3	Failure to add hydrogen peroxide when filling the water tanks can lead to ineffective prevention of bacterial growth.
Performing the monthly bacterial monitoring procedure.	Chapter 6.5.2	Failure to properly sample the water in the heater-cooler can lead to an inability to identify potentially harmful levels of bacterial growth in the device.

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3 System description

This chapter describes the system's features and components, and the controls that you will use to control the system's circuits.

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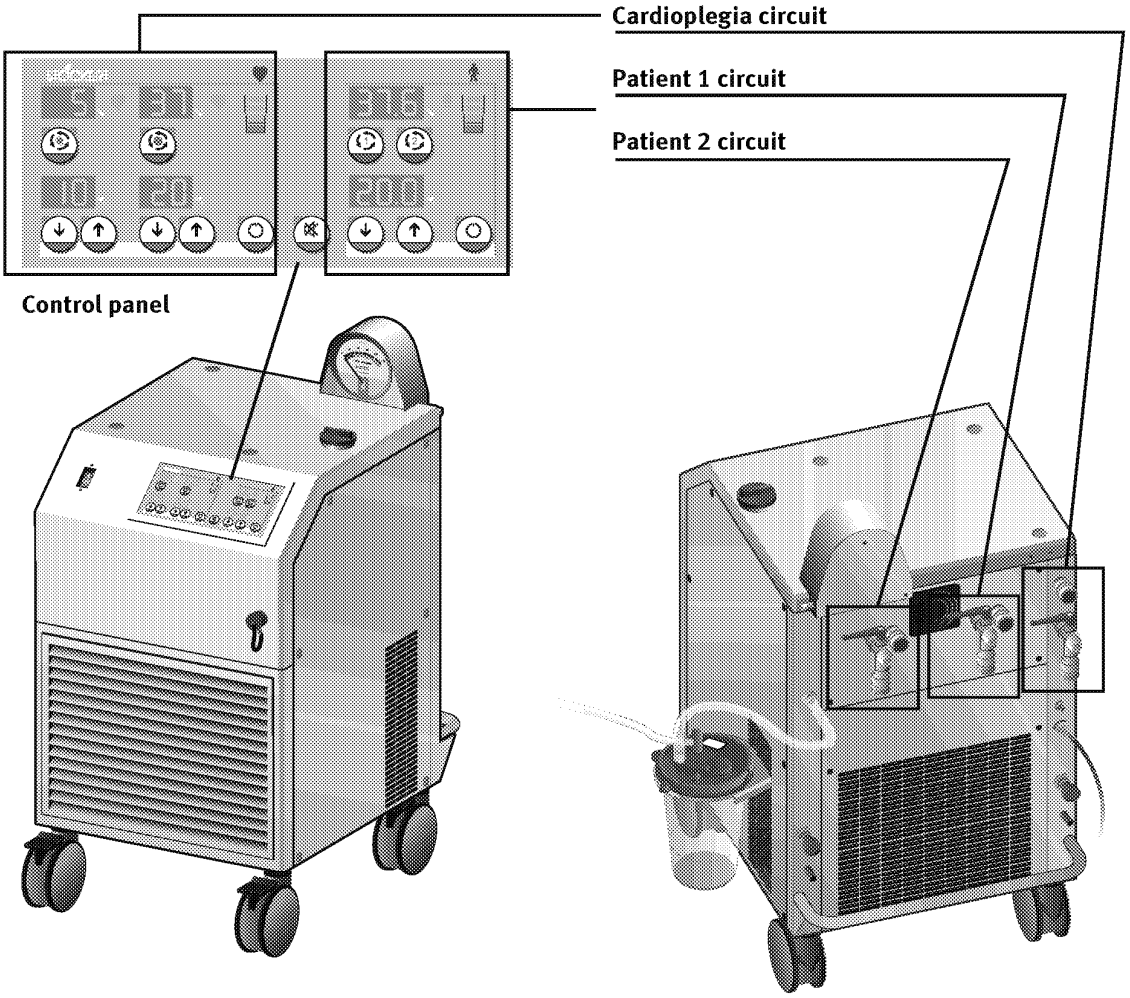
3.1 General description

3.1.1 Device summary

The Heater-Cooler System 3T is an independent 3-circuit-heating/cooling system which is suitable for continuous use.

The heater-cooler has three circuits that you control from the control display panel:

- **Cardioplegia circuit**, whose temperature can be controlled from independent heating and cooling tanks.
- **Patient 1 circuit** and **patient 2 circuit**, which can be used with the oxygenator and/or the single-use heating/cooling blanket. The temperature for these two circuits can be controlled from one heating/cooling tank.



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3.1.2 System components

Below are lists of standard components, mandatory components, and optional components that can be used with the heater-cooler. To obtain additional components, contact LivaNova Deutschland GmbH or your local LivaNova distributor.

Standard components (included in delivery)

- Heater-Cooler System 3T
- Aerosol collection container holder
- 1/2" tubing connectors, straight (3 pieces)
- 1/2" tubing connectors, 90° angle (3 pieces)
- CAN cable for connection to the S5/C5 System
- Potential equalization cable
- Screwdriver for zeroing the vacuum gauge
- Operating instructions

Mandatory components (not included in delivery)

- 3T Aerosol Collection Set

Optional components (not available from LivaNova)

- Tubing sets and/or adapters for connecting single-use heating/cooling blankets
- Single-use heating/cooling blankets for adults (55 x 150 cm)

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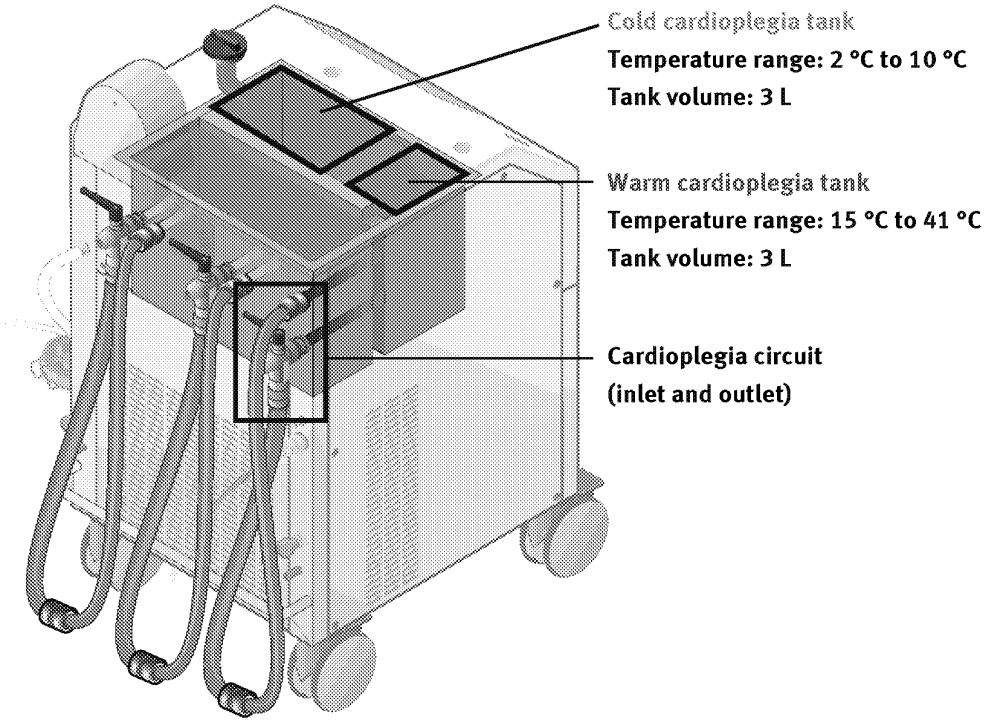
3.1.3 Explanation of the heater-cooler circuits and tanks

The heater-cooler has three circuits: the cardioplegia circuit, the patient 1 circuit, and the patient 2 circuit.

See chapter 3.2.2 for more details on the control panel which you will use to control each circuit.

The cardioplegia circuit uses two tanks

- There is one cardioplegia circuit, accessed from the inlet and outlet valves on the back of the heater-cooler.
- This circuit can be switched between either the heating tank or the cooling tank inside the heater-cooler. The heating and cooling tanks are separate so that water can be kept at desired temperatures even when not being accessed:



- The cardioplegia circuit can only be circulating from one of these tanks at a time. For example, if the warm cardioplegia pump is running and you power on the cold cardioplegia pump, the heater-cooler will circulate water from the cold cardioplegia tank and stop circulating water from the warm cardioplegia tank.

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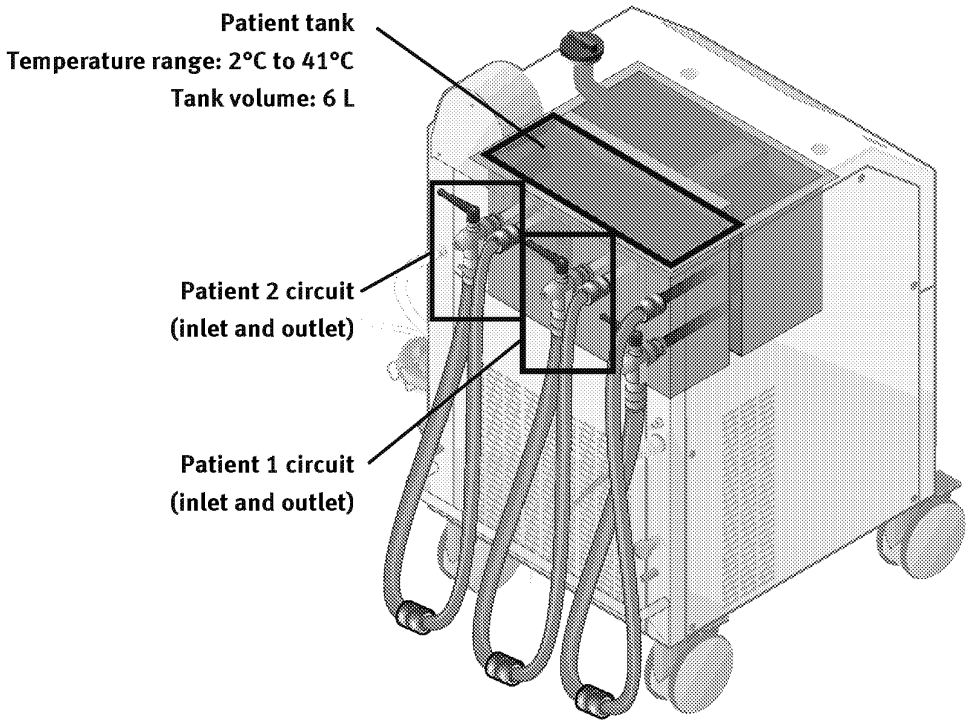
The two patient circuits use one tank

- There are two patient circuits, accessed from the patient 1 and patient 2 inlet and outlet valves on the back of the heater-cooler. These circuits can be used with the oxygenator and/or the single-use heating/cooling blanket.
- The patient 1 and patient 2 circuits can be run at the same time or one at a time.
- Both patient circuits access the same tank (i.e., one tank) inside the heater-cooler. As such, both patient circuits will always be set to the same temperature.



- The circuits for the patient and the circuit for cardioplegia can be switched off separately to increase the heating and cooling performance of active circuit(s). See chapter 5.6 for details.

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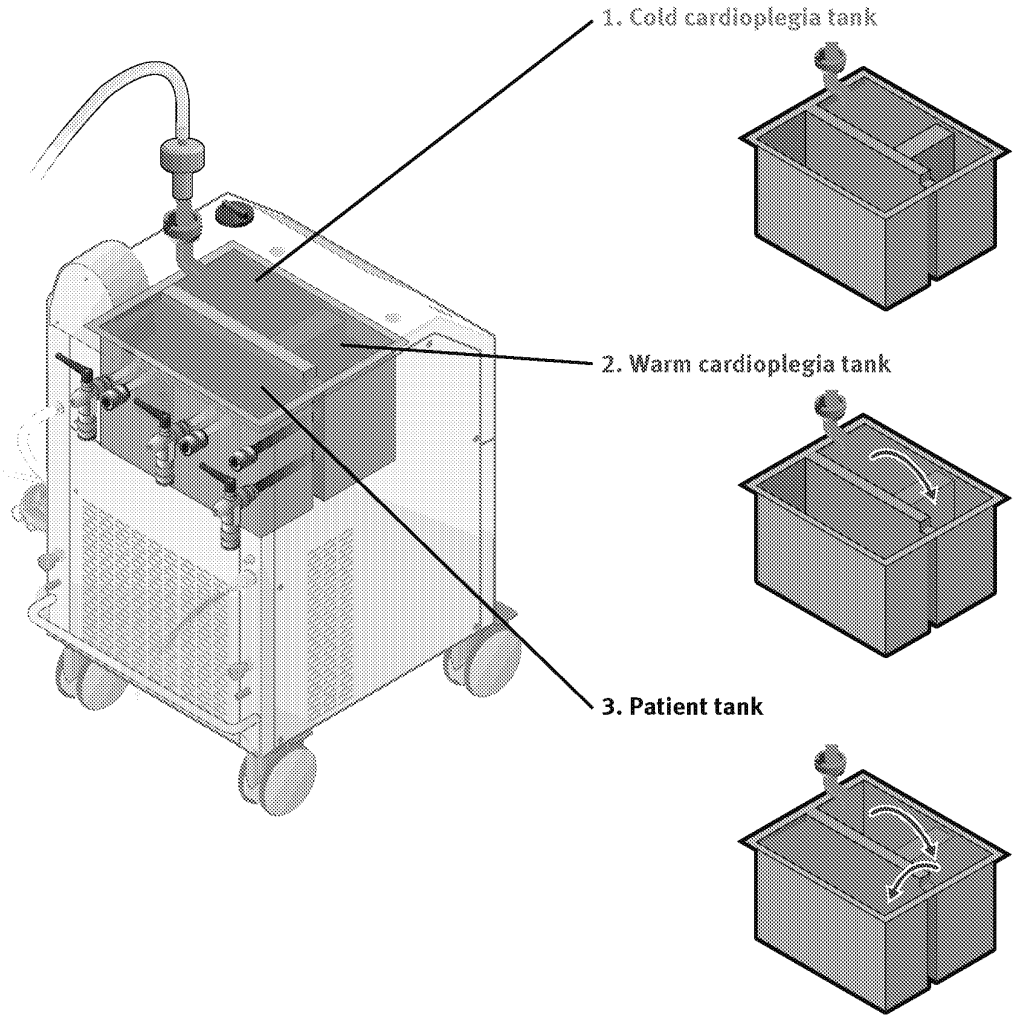
How the heater-cooler's three tanks fill

As you pour water into the single filler neck, all three tanks will fill in the following order:



Additional information about water tank levels:

- The cardioplegia tanks must fill completely before the patient tank begins to fill.
- After filling, and during operation, the system will equalize the water levels between the two cardioplegia tanks. Therefore, running one pump (i.e., the warm or cold pump) will reduce the water level in both tanks.

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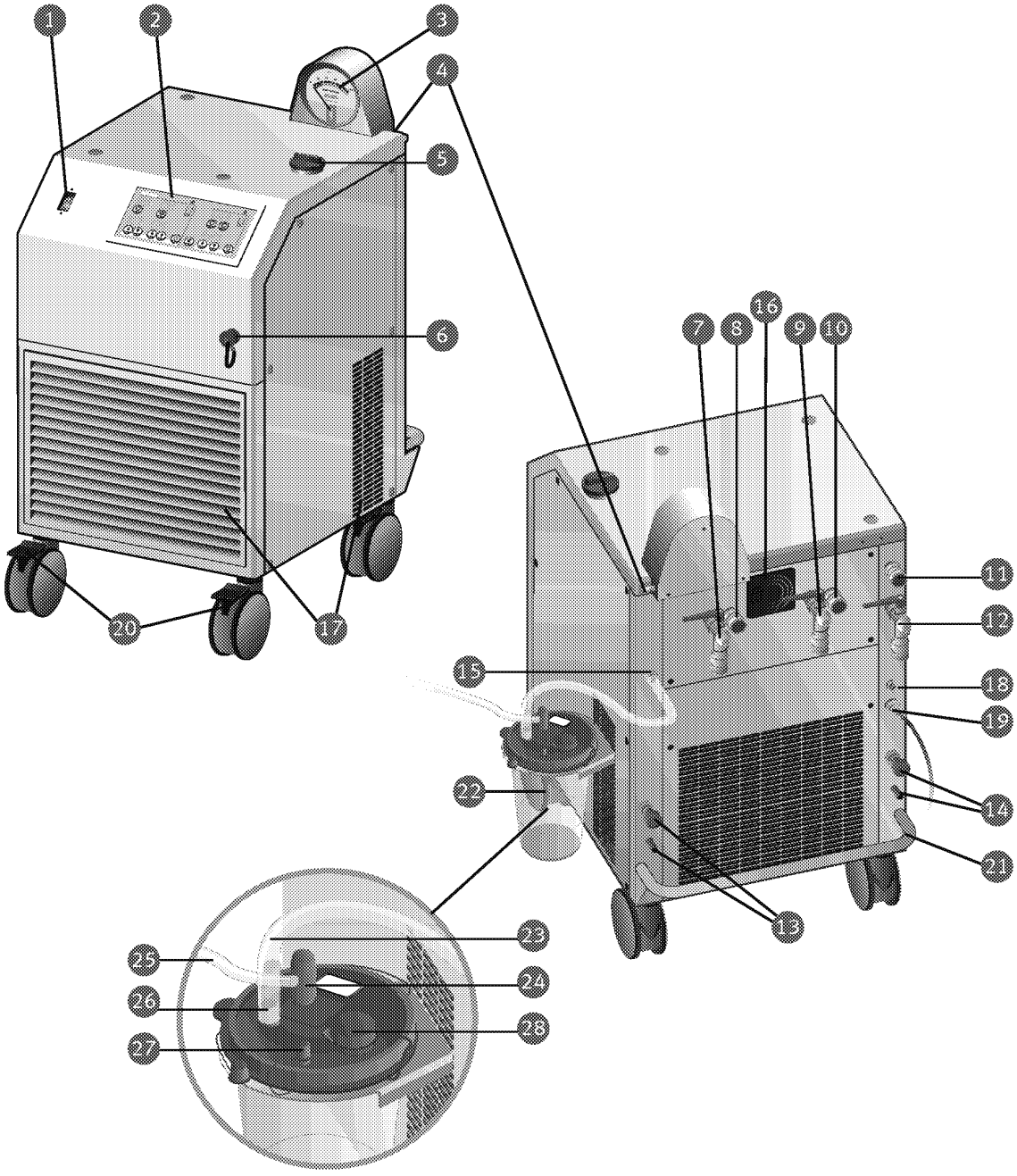
3.2 Structure of the heater-cooler

3.2.1 Heater-cooler overview



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Items depicted in heater-cooler overview

Item	Name	Function
1	Mains power switch	• For powering the heater-cooler on/off • Integrated automatic circuit breaker
2	Control panel	For separated operation and configuration of the three circuits • Two patient circuits • One cardioplegia circuit
3	Vacuum gauge with scale	Indicates the vacuum level inside the tanks
4	Vacuum gauge service port	For removing potential obstructions within the internal pressure monitoring line
5	Filler neck with cap	For filling all tanks with filtered tap water
6	CAN jack with cover	For connecting the heater-cooler to the S5/C5 System
7	Patient 2 circuit outlet connector with valve lever	For connecting the tubing, all inlets and outlets with 1/2" tubing connectors
8	Patient 2 circuit inlet connector	
9	Patient 1 circuit outlet connector with valve lever	
10	Patient 1 circuit inlet connector	
11	Cardioplegia circuit inlet connector	
12	Cardioplegia circuit outlet connector with valve lever	
13	Patient tank drain valve	For emptying the tanks
14	Cardioplegia tank drain valve	
15	Overflow outlet	For draining excessive water from the tanks and for connecting the aerosol collection container
16	Fan	For ventilation of the heater-cooler
17	Ventilation grill	
18	Potential equalization point	For connecting the potential equalization cable
19	Power cable	Power supply of the heater-cooler
20	Castors	Castors with brakes
21	Bumper	Protects the valves, drains, etc. against accidental crashes
22	Aerosol collection set (with tubing)	For collecting aerosol

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Items depicted in heater-cooler overview (continued)

Item	Name	Function
23	Connection line (short line)	For connecting the aerosol collection container to the heater-cooler
24	Vacuum port (V)	Connection point on the aerosol collection container for the vacuum source line
25	Vacuum source line (long line)	For connecting the aerosol collection container to the external vacuum source
26	Patient port (P)	Connection point on the aerosol collection container for the connection line
27	Tandem port (T)	Unused (capped at all times)
28	Pour spout (S)	Port for emptying the aerosol collection container (capped during normal use)

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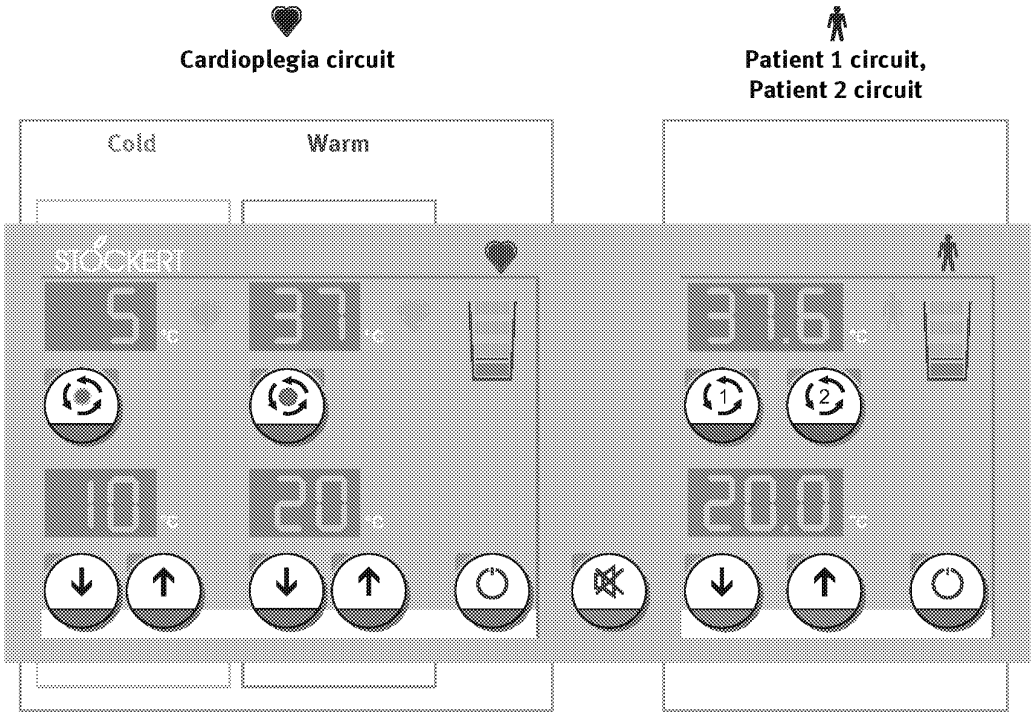
3.2.2 Heater-cooler control panel overview

The control panel manages all control and monitoring functions of the heater-cooler. Specifically, the control panel:

- Is used to adjust the temperature set values
- Is used to start and stop the circuit pumps
- Displays all set and actual temperatures
- Displays water level in the three tanks

The control panel is divided into two sections:

- Cardioplegia circuit controls, which include the warm tank and the cold tank.
- Patient 1 and patient 2 circuit controls, which includes one tank for the two patient circuits.



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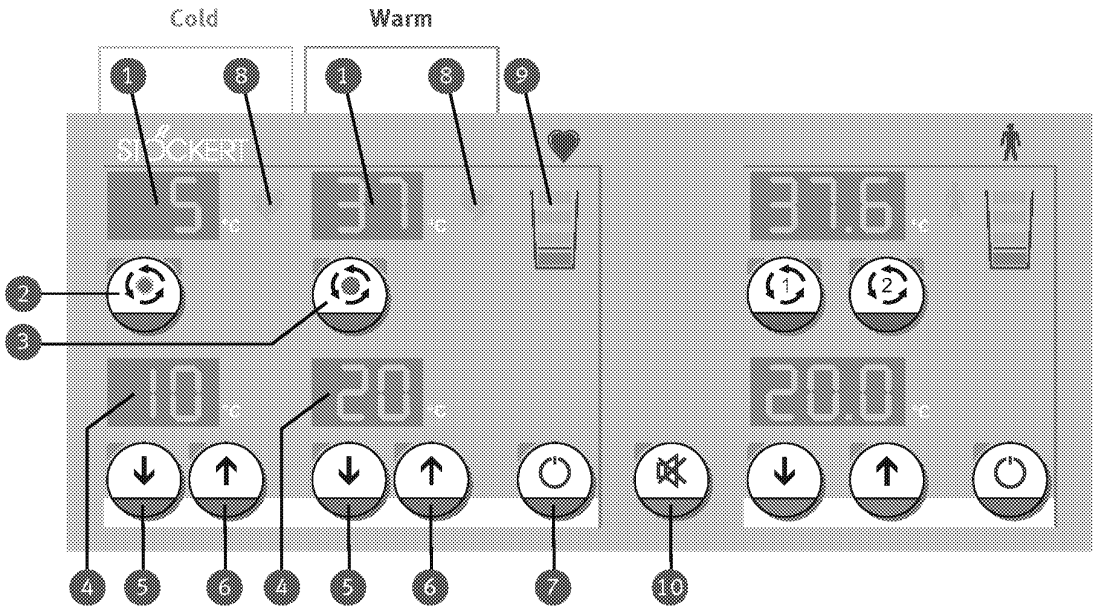
Cardioplegia circuit controls



Item	Name	Function
1	Actual temperature display	Display the actual tank temperatures
2	Cold cardioplegia circuit Stop/Stop button	For starting and stopping the circuit and for switching from the warm to the cold tank
3	Warm cardioplegia circuit Stop/Stop button	For starting and stopping the circuit and for switching from the cold to warm tank
4	Set temperature display	Displays the tank set temperatures
5	Set value down button	For decreasing the set temperature
6	Set value up button	For increasing the set temperature
7	Standby button	For switching the cardioplegia circuit on and off
8	High temperature indicator	Illuminates red if high tank temperature detected
9	Water level display	Displays the water level in the tanks
10	Pause audio button (global control)	Pauses the audible tone for a maximum of 2 minutes. Pressing the button again switches the audible tone back on.

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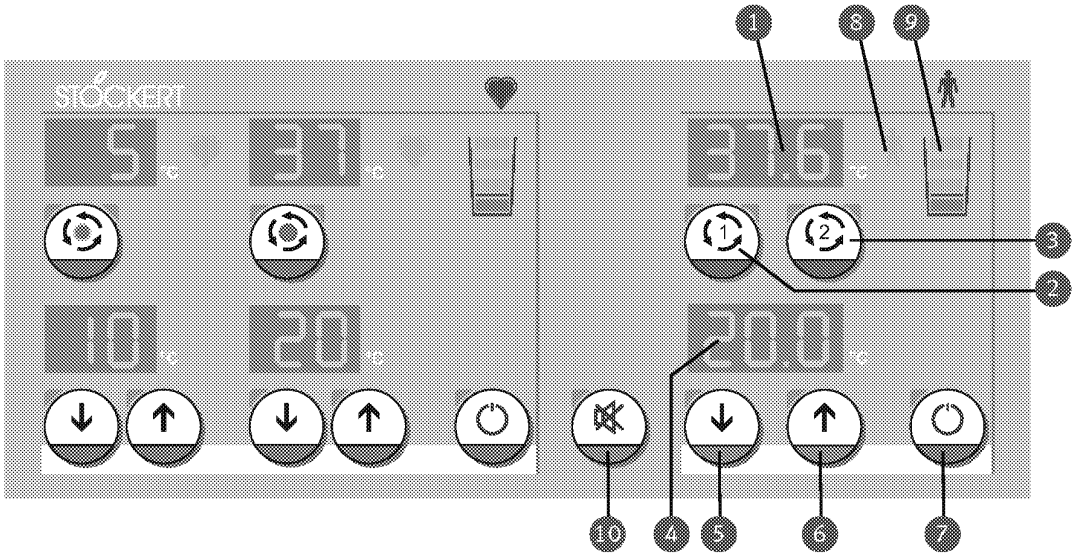
Patient 1 and patient 2 circuit controls



Item	Name	Function
1	Actual temperature display	Display the actual tank temperatures
2	Patient 1 circuit Start/Stop button	For starting and stopping the patient 1 circuit
3	Patient 2 circuit Start/Stop button	For starting and stopping the patient 2 circuit
4	Set temperature display	Displays the set temperatures
5	Set value down button	For decreasing the set temperature
6	Set value up button	For increasing the set temperature
7	Standby button	For switching the patient 1 and patient 2 circuits on and off.
8	High temperature indicator	Illuminates red if high tank temperature detected
9	Water level display	Displays the water level in the tanks
10	Pause audio button (global control)	Pauses the audible tone for a maximum of 2 minutes. Pressing the button again switches the audible tone back on.

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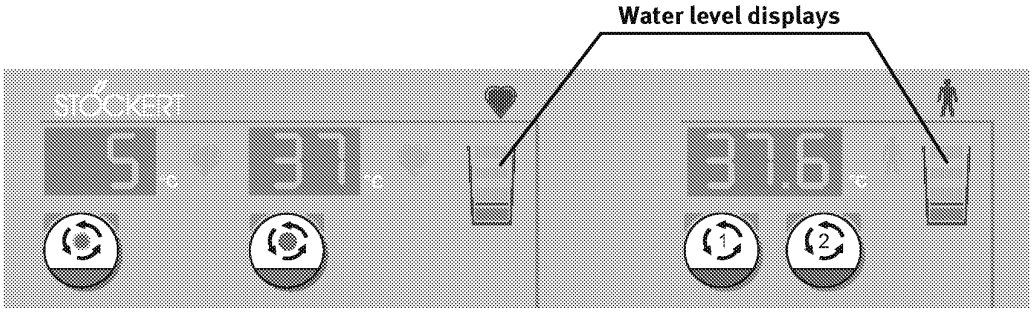
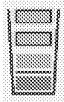
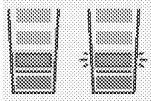
Explanation of the water level display



Display	Segment color	Water level meaning
	Second green	Maximum capacity
	First green	Full
	Orange	Solid: Low level Blinking: Low level warning. Refill recommended.
	Red	Must be refilled. Pump(s) and heating/ cooling functions stop until refilled. **Circuit will not operate**.

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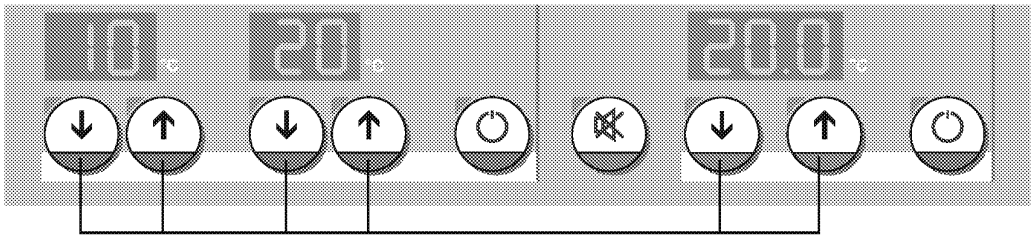
Explanation of special Set value button operations



Set value buttons

- For the cardioplegia Set values, pressing and holding a Set value button changes the temperature value by 1°C. Continuing to hold the Set value button will increase or decrease the set value more rapidly.
- For the patient set value, pressing and holding a Set value button initially changes the temperature value by 0.1 °C, then changes the temperature value by 1 °C. If you then release the Set value button and immediately press it once, the temperature value will still change by 1 °C.
- You can increase the temperature value change increment by pressing and holding one Set value button and pressing its counterpart (i.e., up or down) once.

3.2.3 Control panel S5/C5 System

The CAN port allows the heater-cooler to be connected to an S5 or C5 HLM. Operating the heater-cooler with the S5/C5 System does not require additional remote control modules. You do not need to make additional connections or perform additional steps besides connecting the CAN cable between the heater-cooler and the S5/C5 System.

You may control the heater-cooler with the S5/C5 System menu or directly on the base unit of the heater-cooler.

NOTE: Do not connect the heater cooler's CAN port to any other device. The heater-cooler is only compatible with the S5/C5 System.

Refer to the S5/C5 System's operating instructions for information about the heater-cooler's displays when in use with the S5/C5 System.

Important
The length of water circuit tubing between the heater-cooler and accessory devices **must not exceed 5 m.**

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4 Preparing the heater-cooler for a procedure

Read the following chapter thoroughly before operating the heater-cooler for the first time.

This chapter provides instructions for preparing the heater-cooler for use.

See chapter 5 for detailed instructions for positioning and using the heater-cooler during a procedure.

See chapter 6 for detailed instructions for conducting scheduled maintenance activities.

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4.1 General technical requirements

4.1.1 General use requirements

- Operate the heater-cooler only at ambient temperatures between 10 °C and 30 °C.
- Operate the heater-cooler in a spacious area. The heater-cooler can overheat if operated in a confined space. Maintain a separation of at least 70 cm between the ventilation grills and walls or other devices.
- Do not position the heater-cooler where it will block access to the mains power plug. Removing the mains plug from the receptacle isolates the machine from mains voltage and the plug must remain accessible at all times.
- The heater-cooler must be connected to a potential equalization point for the safety of operators and patients.
- Electrical installations must abide by the requirements stated in IEC 60364-7-710, or the corresponding equivalent local regulations.
- A central hospital vacuum source or a portable vacuum source must be available for operating the 3T Aerosol Collection Set.
  - Operate the heater-cooler with an applied vacuum source. Aerosol will not be collected from the water tanks without a vacuum source.
  - The vacuum source must be capable of a flow of 20 LPM or greater (ISO 10079-1 for Medical Suction Equipment).
  - Portable vacuum sources must be specified for medical applications and meet the requirements of IEC 60601-1 and IEC 60601-1-2.
  - The power supply for the vacuum source must be connected to a back-up power generator to avoid power loss during use.

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4.1.2 Materials you will need (not provided with the heater-cooler)

- Tubing sets compatible for connecting:
  - the oxygenator
  - the cardioplegia heat exchanger
  - a single-use heating/cooling blanket, if used
- 3T Aerosol Collection Set (part number 050900100)

Important

LivaNova recommends always having a replacement heater-cooler available in case the heater-cooler in use is no longer functional (e.g., due to a total system failure). The replacement heater-cooler must have compatible connectors.

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4.2 Conducting any required disinfection and maintenance

1 Before first-time use of the heater-cooler

Complete the following procedures per the maintenance schedule in chapter 6.2.1 “Schedule: Disinfection and maintenance”:

- ☑ Disinfect the external surfaces
- ☑ Disinfect the water circuits

2 Before each use of the heater-cooler, verify that device maintenance is up to date

Verify that, if necessary, the following maintenance procedures have been completed per the maintenance schedule in chapter 6.2.1 “Schedule: Disinfection and maintenance”:

- ☑ Disinfect the external surfaces
- ☑ Monitor the hydrogen peroxide concentration
- ☑ Replace the aerosol collection set
- ☑ Change the water and add hydrogen peroxide
- ☑ Disinfect the water circuits
- ☑ Monitor the water quality for total bacteria count
- ☑ Monitor the water quality for NTM
- ☑ Replace the tubings used with the heater-cooler

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4.3 Connecting the procedural tubing

Important

- Follow your hospital's policies regarding the use of personal protective equipment (PPE).
- Before connecting any tubings to the heater-cooler:
  - Disinfect all heater-cooler connectors, tubing fittings, and tubing connectors.
  - Disinfect all connectors and fittings on the tubings as well as the connectors for the water circuits.
- Do not use self-closing connectors. They will reduce water flow.
- Check all tubings, connectors, and accessories to ensure all water connections are properly sealed. Replace damaged components immediately.
- Check that all tubings are free of bends and kinks.
- Close inactive circuits with short-circuit tubing.

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1 Connect tubing to the water circuits

1 Before connecting any tubing to the heater-cooler, disinfect the following items:
- all heater-cooler connectors
- all tubing fittings and connectors

Important
Disinfect connectors and fittings every time you make a connection according to chapter 6.3.2 and chapter 6.3.3.

Continue step on next page ►

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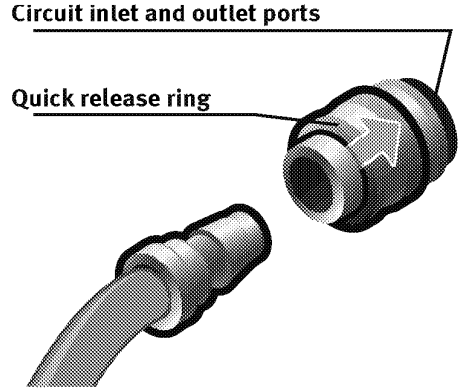
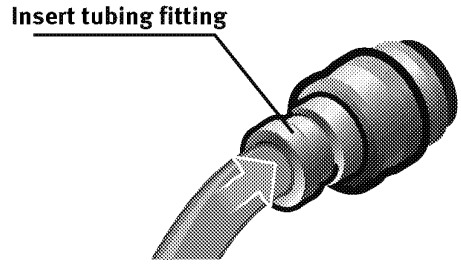
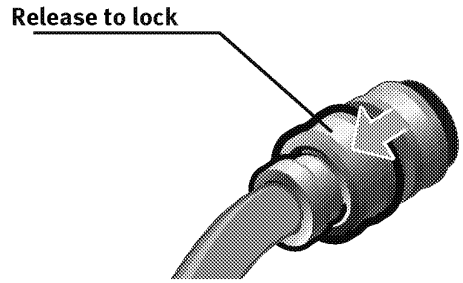
2 Connect the procedural tubing to the circuit inlet and outlet ports:

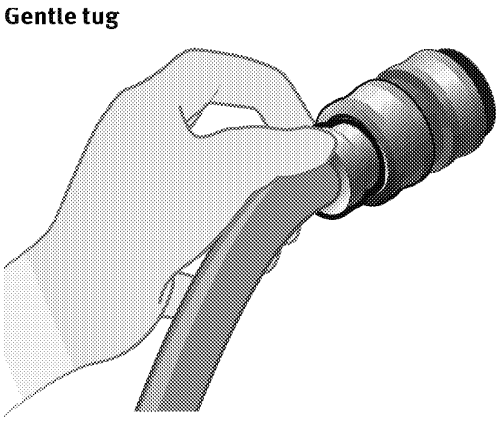
- Push and hold the quick release ring back.
- Insert the tubing fitting into the quick release ring.
- Release the quick release ring which will click back into place and lock the tubing.







3 Check that the connection is secure by gently pulling on the tubing fitting.



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4.4 Connecting the potential equalization cable and the power supply

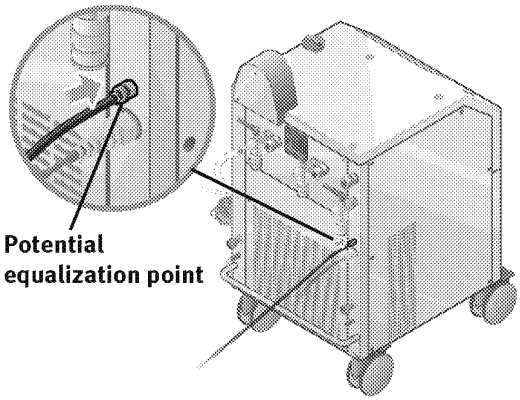
Summary of steps you will complete in this section

1 **Connect the potential equalization cable**

2 **Connect the power cable**

1 Connect the potential equalization cable

- ▣ 1 Connect the potential equalization cable to the heater-cooler's potential equalization point.
- ▣ 2 Connect the potential equalization cable's other end to the potential equalization point at the OR's central ground.



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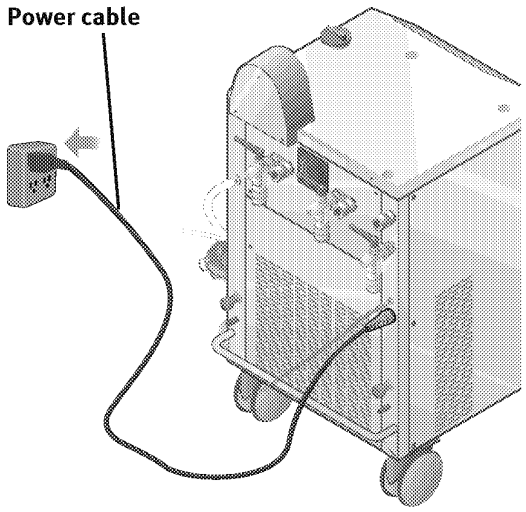
2 Connect the power cable

▶ 1 Connect the AC power cable to an appropriate outlet.



⚠ WARNING

Do not connect the heater-cooler to a heart-lung machine's auxiliary outlet. The heater-cooler should be connected to a separate dedicated AC line.

To avoid the risk of electric shock, the heater-cooler must only be connected to a supply mains with protective earth.

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4.5 Connecting the aerosol collection set

WARNING

Operation of the heater-cooler without an applied vacuum source will stop the collection of aerosol from the water tanks.

Summary of steps you will complete in this section

1. **Dispose of the aerosol collection set after 7 days**
2. **Prepare the heater-cooler**
3. **Prepare the aerosol collection canister**
4. **Connect the aerosol collection set to the heater-cooler**

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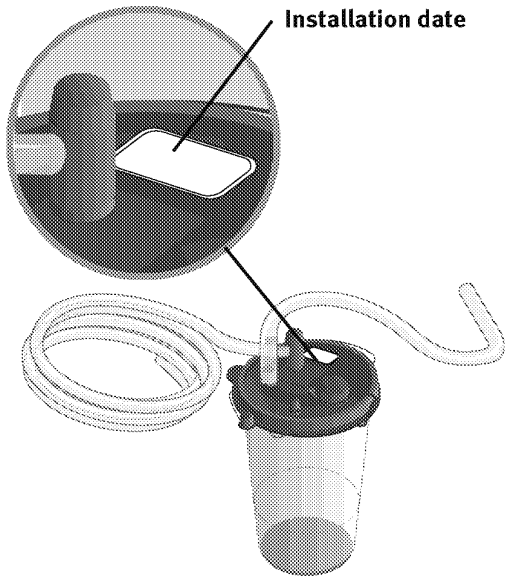
1 Dispose of the aerosol collection set after 7 days

If an aerosol collection set is already attached to the heater-cooler (e.g., from a previous procedure), check the installation date written on the aerosol collection canister lid:

- If the aerosol collection set is more than 7 days old, bring the aerosol collection set to the disposal area, and dispose of in accordance with your hospital's policies. Be sure to dispose of all components:
  - Canister
  - Canister lid
  - Heater-cooler connection line
  - Vacuum source line
  - Vacuum source extension line (if applicable)
- If the aerosol collection set is less than 7 days old, you may empty the canister according to chapter 5.7.2 and reconnect the emptied canister following the applicable steps in this chapter. Or, you may replace the entire aerosol collection set.



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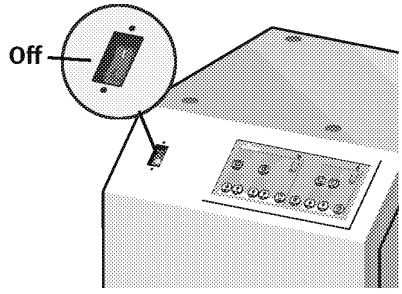
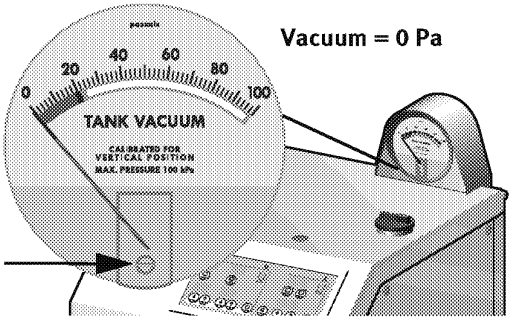
2 Prepare the heater-cooler

☐ 1 Make sure that the heater-cooler is powered off.



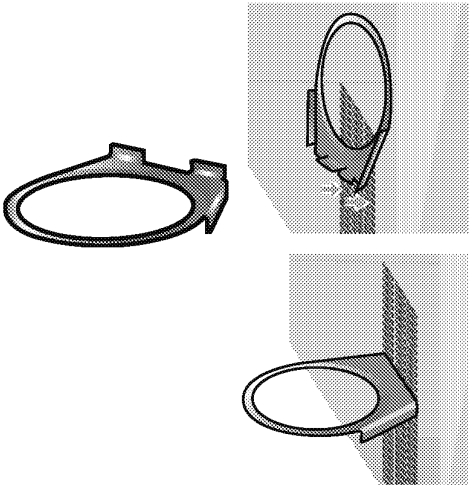
☐ 2 Verify that the vacuum gauge reads 0 Pa.

If the vacuum gauge does not read 0 Pa, use the provided screwdriver to turn the adjustment screw near the bottom of the gauge. Turn the adjustment screw until the indicator needle is set to 0 Pa.



☐ 3 Attach the aerosol collection canister holder to the heater-cooler by inserting the two top tabs of the holder into the vent slots on the heater-cooler. Release the holder and allow it to rest in a horizontal position.

NOTE: Make sure that the holder is positioned such that the aerosol collection canister does not touch the floor or any part of the heater-cooler.



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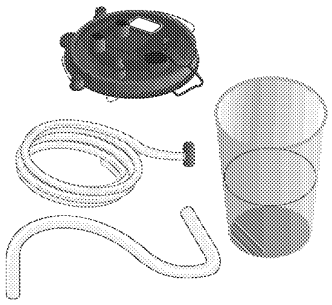
3 Prepare the aerosol collection canister

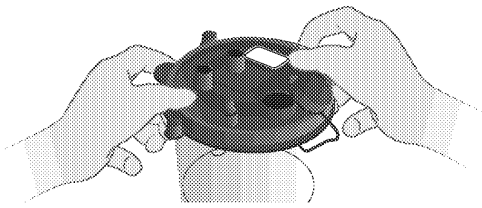
☐ 1 Gather a new aerosol collection set, and remove the components from the packaging:
- o Aerosol collection canister
- o Canister lid
- o Vacuum source line (with right-angle connector)
- o Heater-cooler connection line



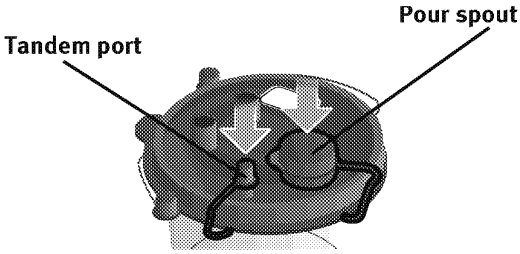
⚠ **CAUTION**

Prior to use, visually inspect the 3T Aerosol Collection Set to ensure that connections, seals, and components were not damaged during shipment. Do not use the 3T Aerosol Collection Set if any defects are found.

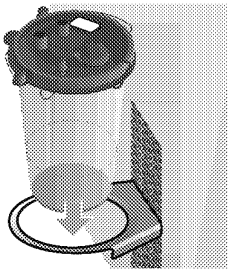
☐ 2 Place the lid on the aerosol collection canister, and secure the lid around the entire perimeter.



☐ 3 Apply the following caps over their respective openings:
- o Pour spout
- o Tandem port



☐ 4 Place the aerosol collection canister into the holder.



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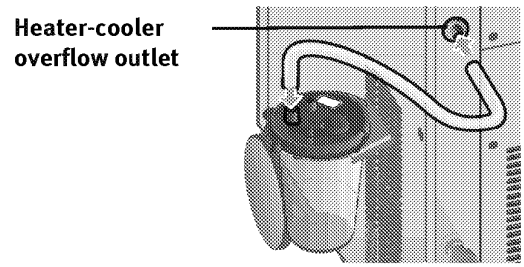
4 Connect the aerosol collection set to the heater-cooler

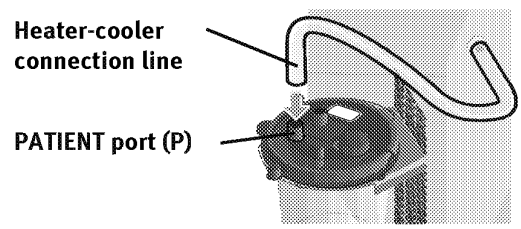
1 Connect the heater-cooler connection line (the short line) to the heater-cooler overflow outlet.



CAUTION

Do not connect the heater-cooler connection line to the vacuum service port or the drain valve. This will limit the vacuum flow to the aerosol collection canister.

2 Connect the other end of the heater-cooler connection line (the short line) to aerosol collection canister lid's PATIENT port (P) .

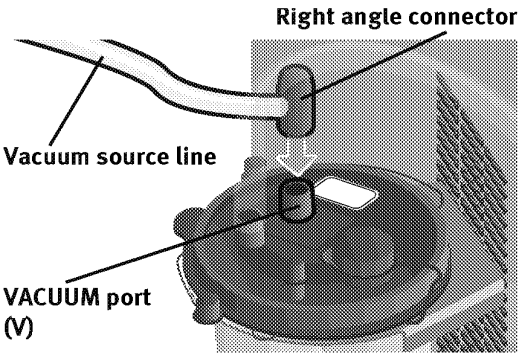


Important

Pushing the connection line too far onto port will make the line very difficult to remove later.

3 Connect the vacuum source line's (the long line) right angle connector to the aerosol collection canister lid's VACUUM port (V).

4 Check that the vacuum source line is free of kinks.



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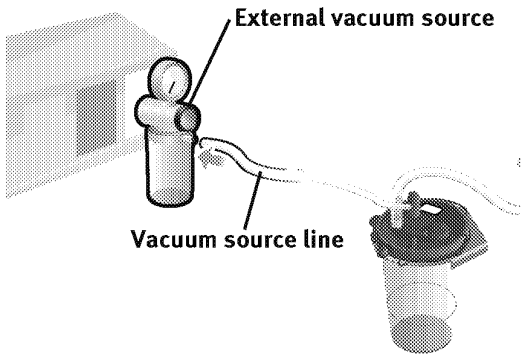
5 Connect the vacuum source line's (the long line) other end to the external vacuum source.



NOTE: LivaNova recommends connecting an overflow safety trap to the external vacuum source. This will avoid liquid introduction into the external vacuum source's system.

NOTE: If additional length is needed to access the external vacuum source, attach a vacuum extension line to the vacuum source line. Order this part separately (part number 050900111).

CAUTION

You must connect the vacuum source line to a vacuum regulator. This will control and adjust the flow to the aerosol collection canister.

Continue step on next page ▸

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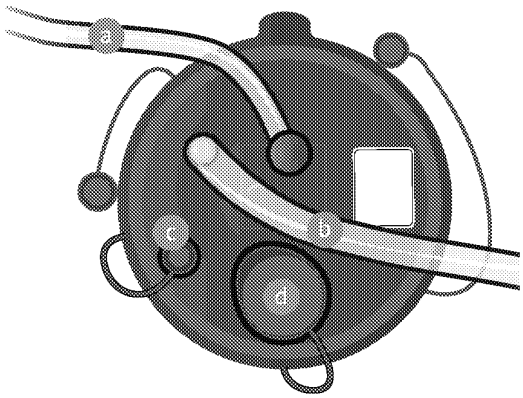
▶ 6 Check that all lid caps and connections are secure:

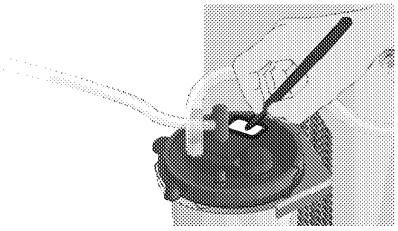
- ☑ Vacuum source line (a)
- ☑ Heater-cooler connection line (b)
- ☑ Tandem port cap (c)
- ☑ Pour spout cap (d)
- ☑ Vacuum source extension line (if applicable)

Top view of lid



▶ 7 Write the date of installation on the lid's label.

▶ 8 The aerosol collection set is now ready for use.



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4.6 Connecting to the S5/C5 System (if applicable)

1 Connect the heater-cooler to the S5/C5 System

Connect the heater-cooler to the S5/C5 System according to the separate S5/C5 System's operating instructions.

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4.7 Filling and mixing water tanks

Important

- Follow your hospital's policies regarding the use of personal protective equipment (PPE).
- Do not use de-ionized or reverse osmosis processed water. These types of water can cause deterioration of the refrigeration system.

Summary of steps you will complete in this section

1. **Prepare for filling**
2. **Fill the water tanks**
3. **Prepare for mixing**
4. **Mix the tank contents**

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1 Prepare for filling

▶ 1 Make sure that you have access to filtered tap water that has been filtered using the following filter and specifications:

Important

Disposable Pall-Aquasafe water filter with an 0.2 µm membrane (Pall part reference in the U.S.: "AQINA"; "AQIN" in other countries) or a filter of equivalent performance that meets the requirements for bacterial retention of Brevundimonas diminuta to ≥ 10^7 CFU/cm^2 of effective filtration area.*

(*American Standard Test Method F838-15ae1 "Determining Bacterial Retention of Membrane Filters Utilized for Liquid Filtration")

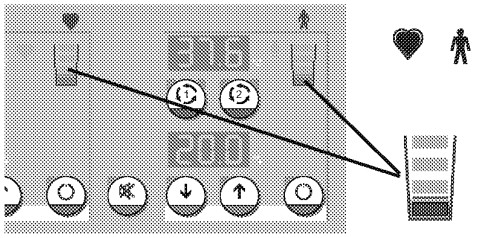
▶ 2 Gather the following materials:

- 150 mL of medical grade 3% hydrogen peroxide solution
- Measuring cup

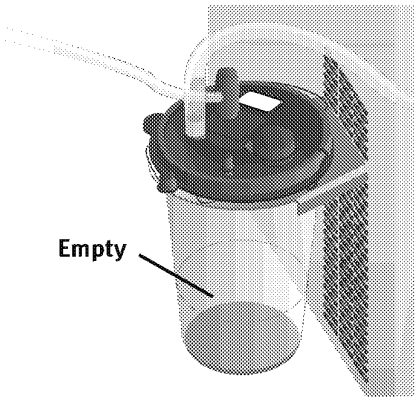
▶ 3 Check to ensure that hydrogen peroxide solution is not expired.

▶ 4 If the water tanks have been drained (i.e., are empty), the red segment on both water level displays will be illuminated.

NOTE: Confirm that the water level displays function correctly after performing a water change or disinfection.



▶ 5 Make sure that the aerosol collection canister is empty. Refer to chapter 5.7.2 for instructions on emptying the aerosol collection canister.



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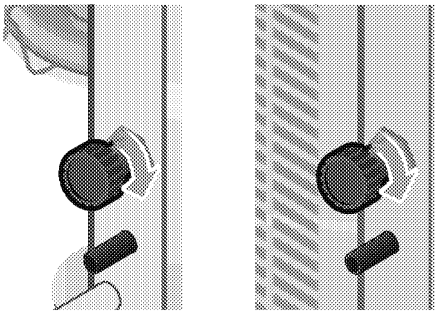
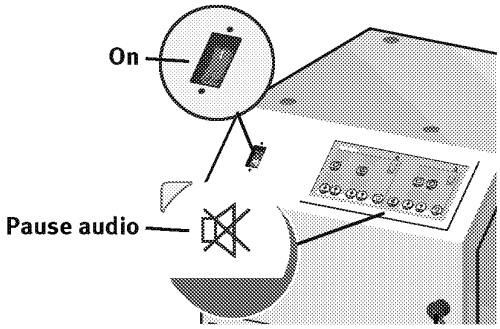
6 Make sure that both drain valves are fully closed so that water does not flow out when filling the water tanks.

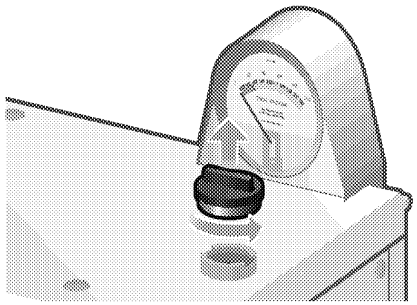


7 Press the mains power switch to power on the heater-cooler.

NOTE: A tone will sound indicating that the heater-cooler tanks are empty. You can press the Pause Audio button to pause the tone.



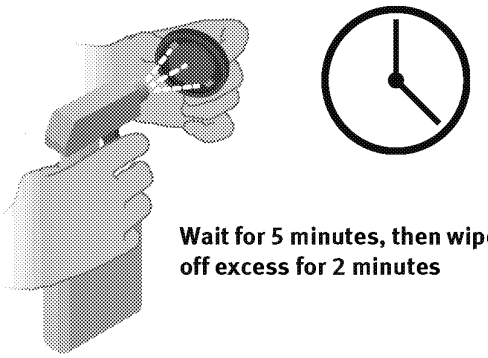
8 Turn the filler neck cap counterclockwise to remove.



9 Apply four sprays of disinfectant on the cap until all surfaces are wet, including the cap's underside and sealing surface.

10 Wait for 5 minutes. Ensure that all surfaces remain wet with disinfectant during this time. Apply additional disinfectant if necessary.

Wipe all surfaces with a disinfectant wipe for 2 minutes to remove excess disinfectant.



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2 Fill the water tanks

Important

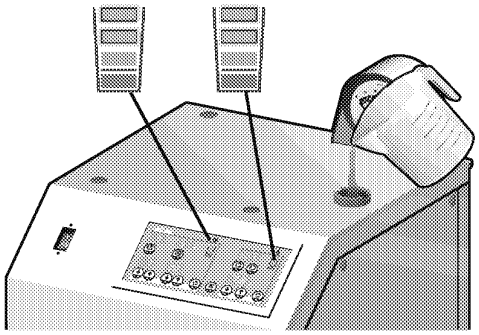
As you pour water into the single filler neck, all three tanks will fill in the following order:

- Cold cardioplegia tank
- Warm cardioplegia tank
- Patient tank

If the water tanks are not empty:

- Prepare a mixture of hydrogen peroxide and filtered tap water at a ratio of 1:91. For example: 10 mL of hydrogen peroxide and 910 mL of filtered tap water
- Fill the water tanks with the mixture until the second green segments of both circuit water level displays light up.
- Continue to step 3, *Prepare for mixing*.

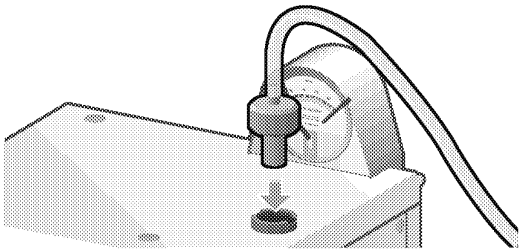
1:91 mixture hydrogen peroxide to filtered tap water



If the water tanks are empty, complete the rest of step 2:

▶ 1 Begin filling the water tanks with filtered tap water.

NOTE: The use of any other liquid is not recommended.



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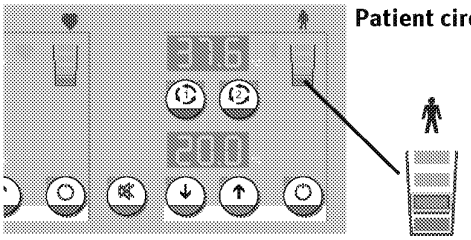
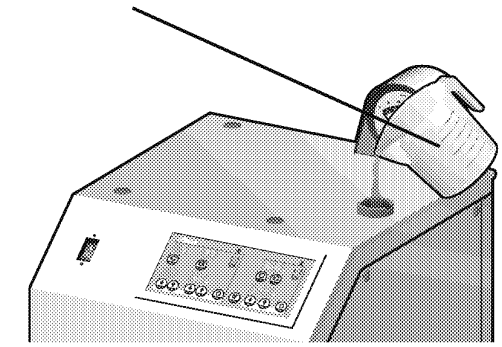
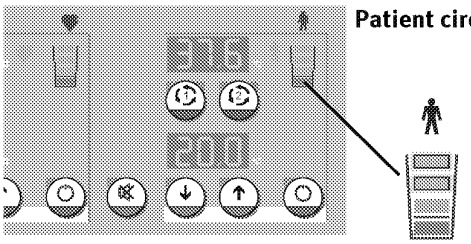
☐ 2 Pause filling when the orange segment on the **patient circuit** water level display lights up.



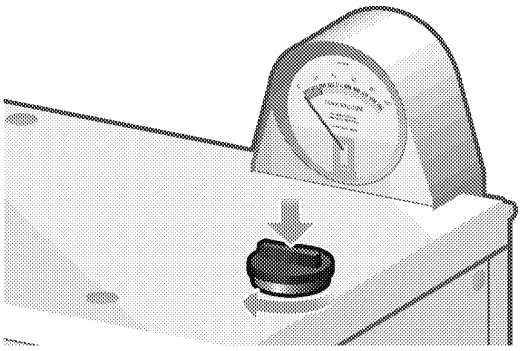
☐ 3 Pour 150 mL of medical grade 3% hydrogen peroxide solution into the tank.



☐ 4 Continue filling the tanks with filtered tap water until the second green segment of the **patient circuit** water level display lights up.



☐ 5 Attach the filler neck cap, and turn clockwise to secure.



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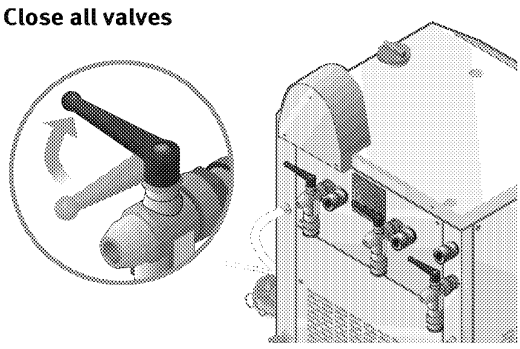
3 Prepare for mixing

1 On the back of the heater-cooler, make sure that the three red valve levers are closed. Turn clockwise to close.

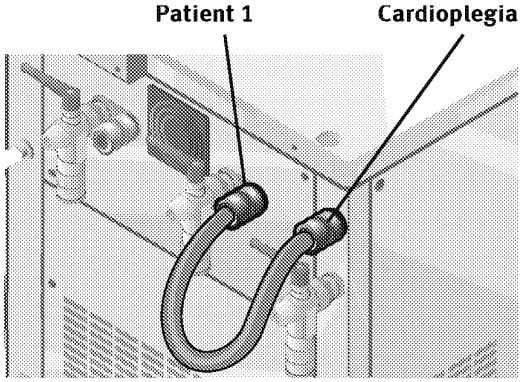
2 Disinfect the heater-cooler connectors and short-circuit tubing fittings.



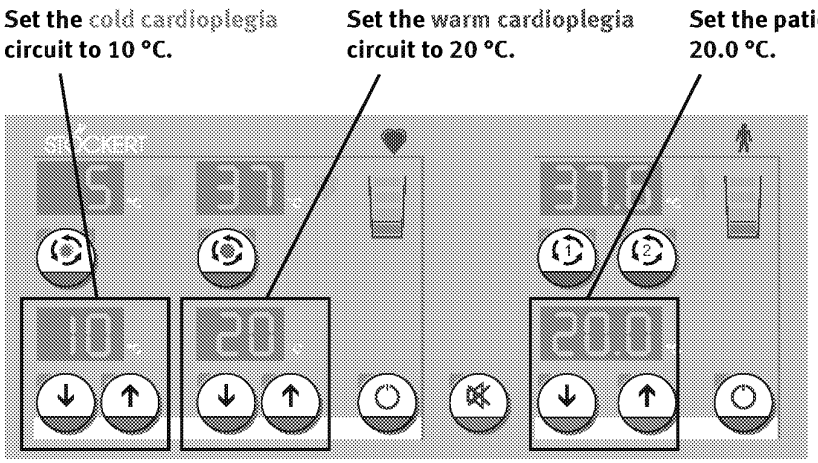
Important

Disinfect connectors and fittings every time you make a connection according to chapter 6.3.2 and chapter 6.3.3.

3 Connect short-circuit tubing between the cardioplegia circuit inlet and the patient 1 circuit inlet.



4 To avoid triggering a high temperature warning while mixing:



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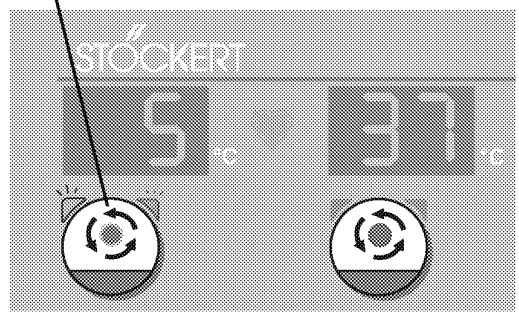
4 Mix the tank contents

1 Press the cold cardioplegia circuit Start/Stop button to start mixing.

NOTE: The green LEDs will flash alternately to indicate the circuit is running.

Press cold cardioplegia to start



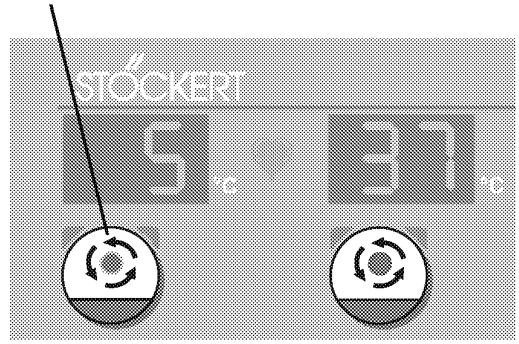
CAUTION

Operate ONLY the cold cardioplegia circuit to ensure proper mixing.

2 After 5 minutes, press the cold cardioplegia circuit Start/Stop button again to stop mixing.

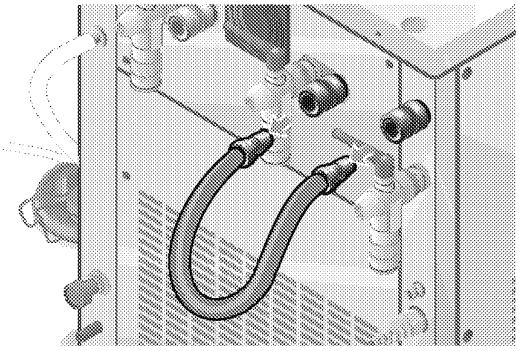
The mixing process is now complete.

After 5 minutes, press to stop



3 Disconnect the short-circuit tubing.

Tank filling is now complete.



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5 Using the heater-cooler during a procedure

Read the following chapter thoroughly before operating the heater-cooler for the first time.

This chapter provides instructions for positioning the heater-cooler in the OR and using the heater-cooler's controls during a procedure.

See chapter 4 for detailed instructions for preparing the heater-cooler for use.

This chapter also provides the basic steps you will conduct after a procedure.

See chapter 6 for detailed instructions for conducting scheduled maintenance activities.

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5.1 Positioning the heater-cooler in the OR

Important

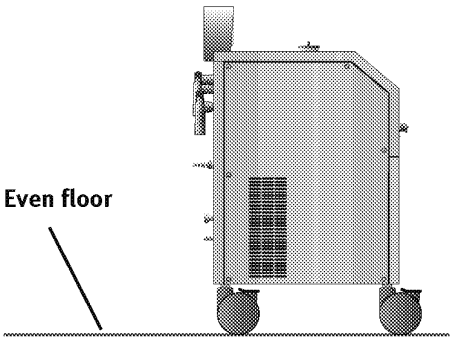
- Do not cover the ventilation grills.
- Maintain at least 70 cm clearance from walls and other devices to prevent the heater-cooler from overheating.
- The length of water circuit tubing between the heater-cooler and accessory devices must not exceed 5 m.

Summary of steps you will complete in this section

1. **Bring the heater-cooler into the OR**
2. **Place the heater-cooler in a safe position**
3. **Connect a portable vacuum source, if needed**

1 Bring the heater-cooler into the OR

1. If the heater-cooler is not already in the OR, bring the heater-cooler to the OR.
2. Place the heater-cooler on a level, even floor.



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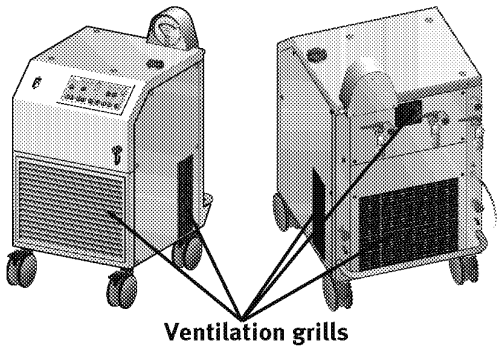
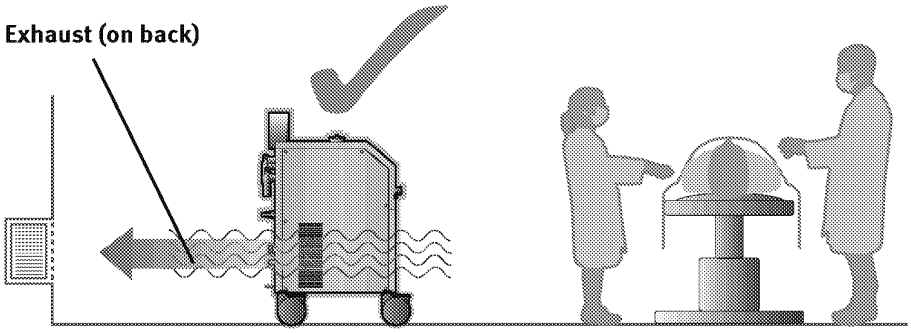
2 Place the heater-cooler in a safe position

1 Place the heater-cooler at a sufficient distance (at least 70 cm) from walls and other devices.

Make sure that the ventilation grills are not covered.

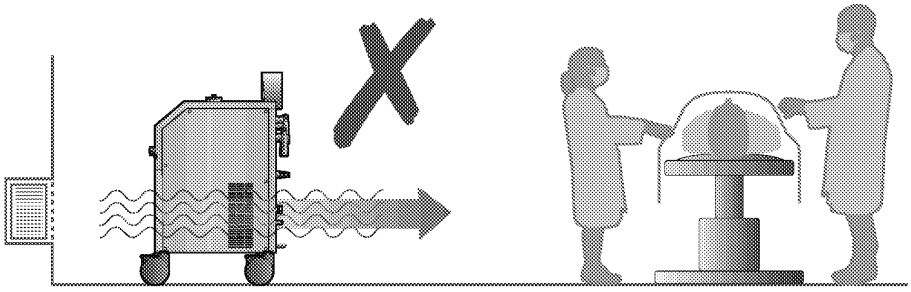


2 Position the heater-cooler's and portable vacuum source's (if applicable) exhaust flow away from the operating field and toward the exhaust vent system.



WARNING

Do not position the heater-cooler's and portable vacuum source's (if applicable) exhaust flow toward the operating field. Position the exhaust flow away from the operating field and toward the exhaust vent system.



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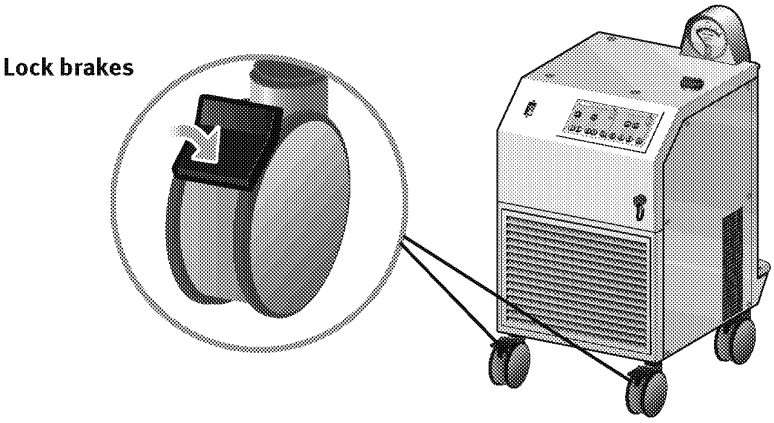
3 Step down on the brakes and lock the castors.



3 Connect a portable vacuum source, if needed

If you are using a portable vacuum source, mount and operate the device according to its instructions for use. Pay special attention to the instructions related to use of the vacuum source in the OR.

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5.2 Connecting the procedural tubing to external devices

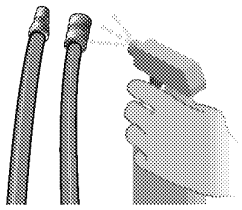
Summary of steps you will complete in this section

1 **Connect the procedural tubing to the external devices**

2 **Check the procedural tubing and connections to all devices**

1 Connect the procedural tubing to the external devices

▶ 1 Before making any connections, disinfect the connectors on the procedural tubing.



Important

- Disinfect the connectors and fittings every time you make a connection according to chapter 6.3.2 and chapter 6.3.3.
- **Do not** apply disinfectant to the fittings on the external devices.

▶ 2 Connect the procedural tubing to the external devices.

2 Check the procedural tubing and connections to all devices

▶ Inspect the heater-cooler procedural tubing and make sure:

- Tubing is free of kinks
- Tubing is not damaged
- Connections to devices in the OR are secure

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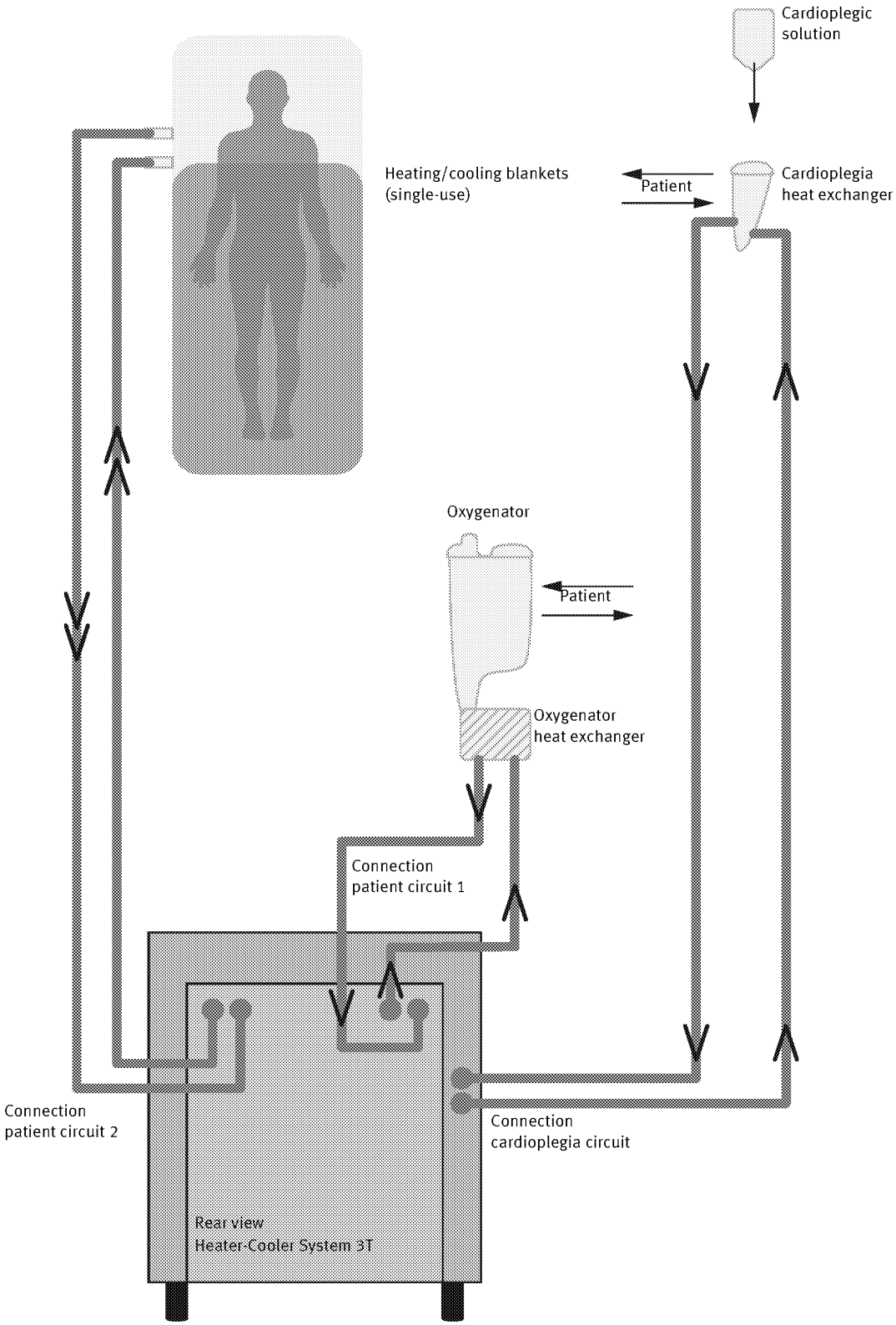
Overview of a typical circuit



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5.3 Powering on and checking the panel

WARNING

Operation of the heater-cooler without an applied vacuum source will stop the collection of aerosol from the water tanks.

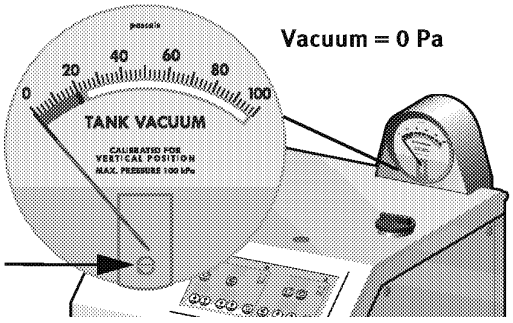
Summary of steps you will complete in this section

1. **Connect the vacuum source**
2. **Power on the heater-cooler and observe the self-test**
3. **Check the control panel to confirm the heater-cooler is ready for use**

1 Connect the vacuum source

1 Verify that the vacuum gauge reads 0 Pa.

If the vacuum gauge does not read 0 Pa, use the provided screwdriver to turn the adjustment screw near the bottom of the gauge. Turn the adjustment screw until the indicator needle is set to 0 Pa.



Continue step on next page ►

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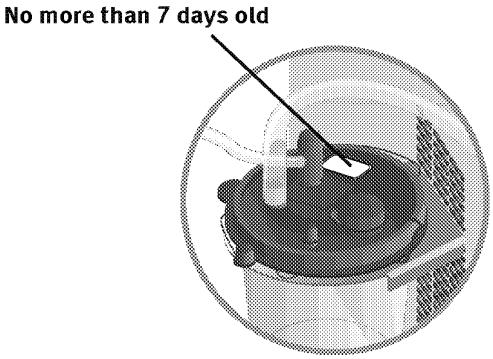
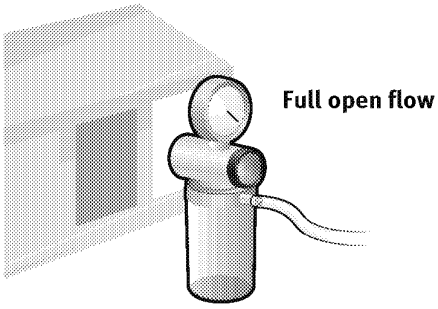
☐ 2 Check the installation date on the aerosol collection canister.

If more than 7 days have passed since the installation date, dispose of the aerosol collection canister and install a new one according to chapter 4.5.

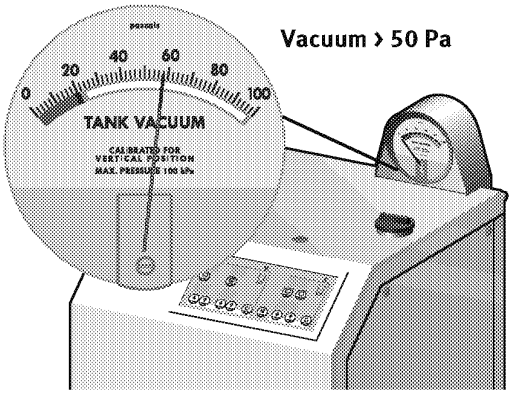


☐ 3 Power on the external vacuum source and set the vacuum regulator to full open flow.



☐ 4 Make sure that the heater-cooler's vacuum gauge reads greater than 50 Pa.

NOTE: With full open vacuum flow, the heater-cooler's vacuum gauge might read greater than 100 Pa. The vacuum gauge can accept full vacuum flow.



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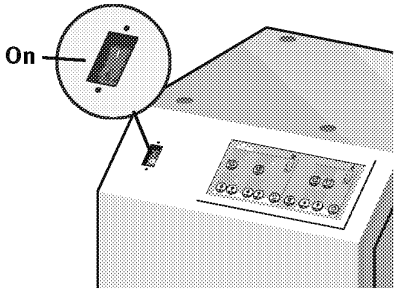
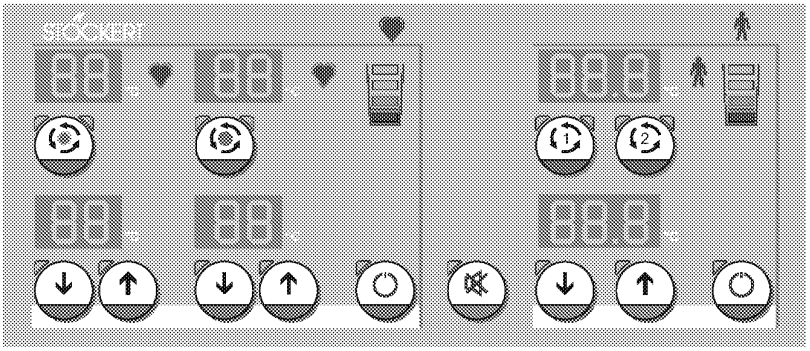
2 Power on the heater-cooler and observe the self-test

1 Press the mains power switch to power on the heater-cooler.



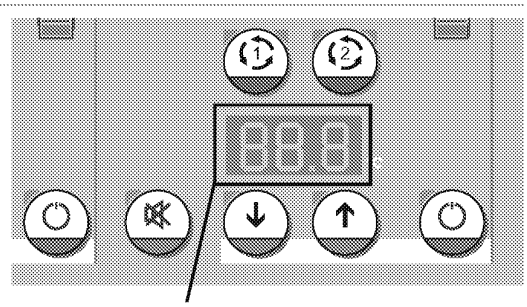
2 The heater-cooler will run a self-test while powering up. All of the control panel's LEDs and 7-segment displays will illuminate for 2 seconds, and a tone will sound.

Check that all LEDs and 7-segment displays are properly illuminated before use.



3 After the control panel lights up, the device's software version number (EPROM) will display for 1 second in the patient circuit display.

4 The heater-cooler is now finished powering on and will display the last set temperature values. The heater-cooler is now actively controlling the tank temperatures, but the circuit pumps are not running.



Version number appears in patient circuit display

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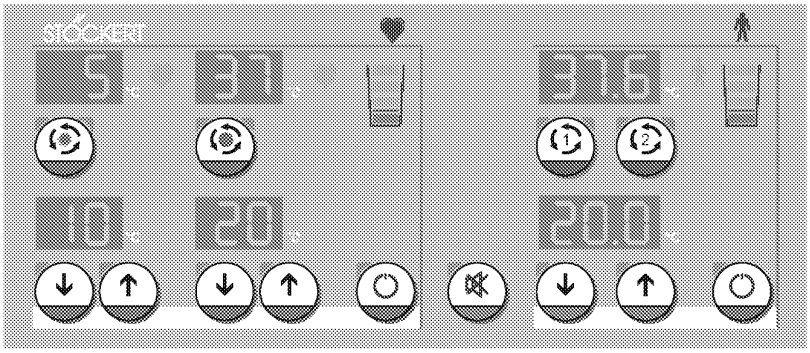
3 Check the control panel to confirm the heater-cooler is ready for use

Important

Do not use the heater-cooler if the elements on the control panel are flashing. If the control panel is flashing, the heater-cooler is in service mode. Power off the heater-cooler and power it on again to exit service mode.

1. Once the self-test is complete, confirm the following:
   - The green LEDs of the Standby buttons are not illuminated (i.e., the circuits are not in standby mode).
   - The control panel displays the last set temperature values.
   - Both circuit water level displays are illuminated to the second green segment.
2. The heater-cooler is ready for use.



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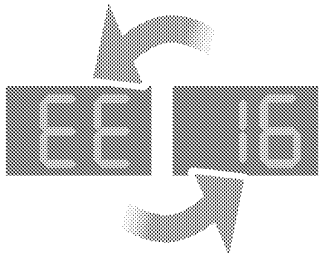
If errors EE(E) appear on control panel

If a circuit's set point display flashes between "EE(E)" and a number, this is an error code:

- Error code E08, E19, or E23 might display during priming, but should clear when priming completes (all air is removed from the circuit).
- Do not use a circuit if an error code remains after priming. Refer to chapter 8.1.4 for error code definitions, and notify your authorized service technician as soon as possible.

NOTE: You may use the unaffected circuits even if one circuit displays an error code.



Flashes between error and code number

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5.4 Performing a functional check prior to operation

Important

- Perform the steps outlined in this chapter before every time you use the heater-cooler.
- Address any error codes immediately. Depending on the error code, you might not be able to use a particular circuit, or you might not be able to use the heater-cooler at all. Refer to chapter 8.1.4 for error code descriptions.
- The heater-cooler is ready for operation after you have performed the functional check.

Summary of steps you will complete in this section

1 **Check the setup**

2 **Check when first switching power on**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1 Check the setup

- ☑ Confirm the heater-cooler's and portable vacuum source's (if applicable) exhaust is pointed away from the operating field.

⚠ WARNING

Do not position the heater-cooler's and portable vacuum source's (if applicable) exhaust flow directed toward the operating field. Position the exhaust flow away from the operating field and toward the exhaust vent system.

- ☑ Confirm that the heater-cooler is positioned on a level, even floor.
- ☑ Confirm that the castor brakes are locked.
- ☑ Confirm that the power cable and potential equalization cable have been connected according to applicable regulations.
- ☑ Confirm that the mains plug is completely dry.
- ☑ Confirm that the power cable is free of damage.
- ☑ Confirm that all tubing connectors are secure and locked.
- ☑ Confirm that all procedural tubings are free of damage and leaks.
- ☑ Confirm that the aerosol collection set is less than 7 days old.
- ☑ Confirm that the aerosol collection canister is holding less than 0.5 L of fluid.
- ☑ Confirm that the heater-cooler's vacuum gauge reads greater than 50 Pa with full open vacuum flow applied.
- ☑ Confirm that a replacement heater-cooler with compatible connectors is available.
- ☑ Confirm that the CAN cable is properly connected (if you are operating the heater-cooler with a S5/C5 System).

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2 Check when first switching power on

- ☑ Confirm that all LEDs and temperature displays on the control panel are illuminated.
- ☑ Confirm that a tone sounded.
- ☑ Confirm that the control panel is reflective of a functioning heater-cooler (i.e., the heater-cooler is not in service mode and does not display errors). If the heater-cooler displays an error, refer to chapter 8.1.4 for error code descriptions.
- ☑ Confirm that the water level indicators on the patient and cardioplegia circuit displays are not blinking orange or solid red.

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5.5 Priming the complete circuit

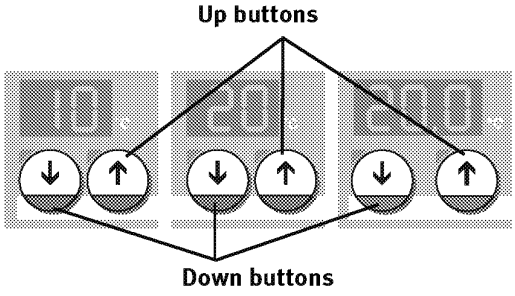
Summary of steps you will complete in this section

1. **Adjust the set values as needed**
2. **Place unused circuits in standby mode**
3. **Prime the external circuits**

1 Adjust the set values as needed

Important
The heater-cooler will begin adjusting temperatures to the set values 2 seconds after the last Set value button press.

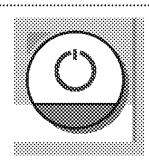
- To adjust the set values:
  - Press the Set value up button to raise the circuit temperature.
  - Press the Set value down button to lower the circuit temperature.



2 Place unused circuits in standby mode

- If not being used, press the circuit's Standby button to place the circuit on standby.

  NOTE: The other circuit will continue to function and the heating/cooling performance will be increased.



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3 Prime the external circuits

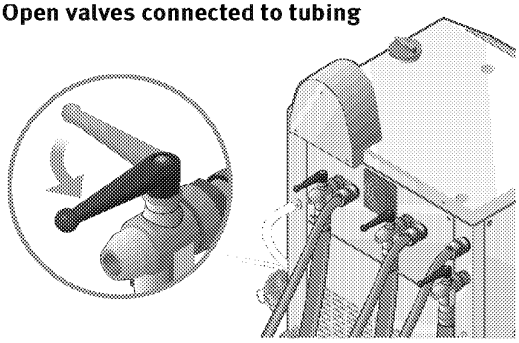
Important

Prime the circuits' tubings and heat exchanger before using the heater-cooler.

- When you power on a circuit for the first time, an error code might appear indicating that air is present in the tubings.
- Do not use the heater-cooler until you have resolved the errors by completely priming the external circuits.

☐ 1 On the back of the heater-cooler, for any circuits with tubing connected, turn the red levers counterclockwise to open the valves.

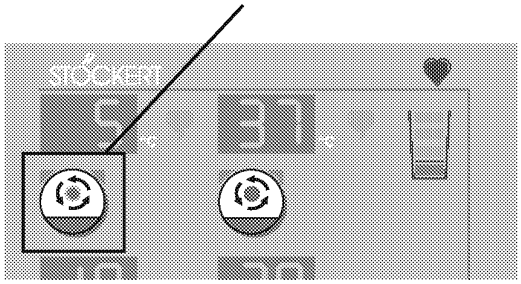
Open valves connected to tubing



☐ 2 Prime the cardioplegia circuit using the cold cardioplegia tank.

NOTE: Do not use the warm cardioplegia tank to prime. This will trigger an error code and stop the circuit pump.

Use cold cardioplegia circuit to prime



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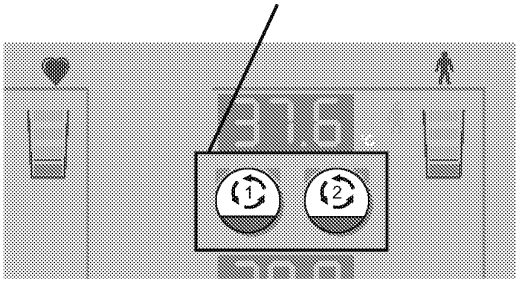
3 Prime the patient circuit(s) using the associated pump(s).

NOTE: Do not run a pump if there is no tubing connected.

Prime patient 1 and patient 2 circuits

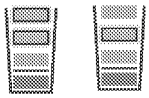


4 Depending on the volume of the circuit tubing, you might need to refill the water tanks after priming. Check the water level displays:

- Make sure the first or second green segments on both water level displays are illuminated.
- If not, refill the water tanks before use according to chapter 4.7, step 1 and step 2.

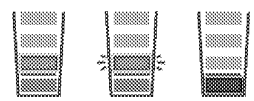
Acceptable volume

Cardioplegia or patient circuits



Unacceptable volume

Cardioplegia or patient circuits



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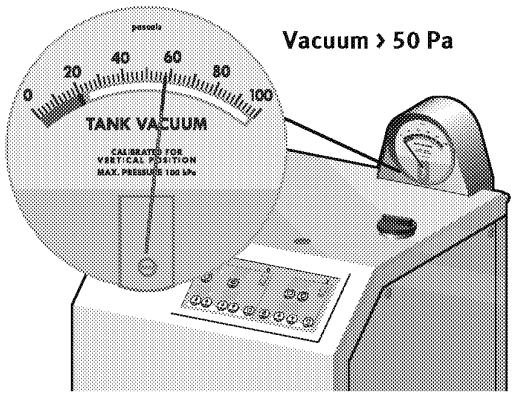
5.6 Using the device controls during a procedure

5.6.1 Checking the vacuum

Checking the vacuum

Adjust the external vacuum source to full open vacuum flow to check that the heater-cooler operates at vacuum levels greater than 50 Pa.



WARNING

Operating the heater-cooler with the vacuum level indicated on the tank vacuum gauge in the red solid zone limits the aerosol collection set's ability to collect aerosol from the water tanks. Refer to chapter 8.2.1 for possible remedies.

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5.6.2 Opening and closing the circuit valves

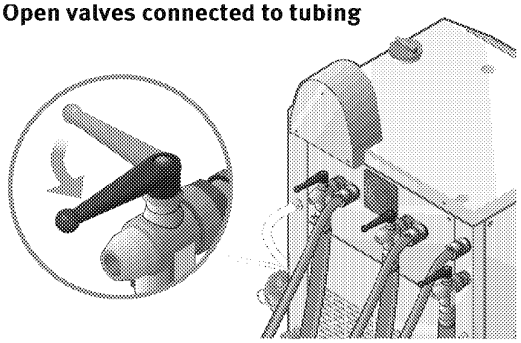
Important

- To fill the tubing and to run water through the circuits, the valves must be open.
- To drain tubing, the valves must be closed.

Opening a valve

On the back of the heater-cooler, for any circuits with tubing connected, turn the red levers counterclockwise to open the valves.

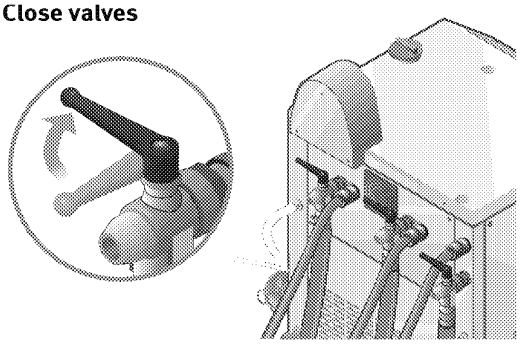
Open valves connected to tubing



Closing a valve

On the back of the heater-cooler, turn the red valve lever clockwise to close the valve.

Close valves



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5.6.3 Using the circuit controls

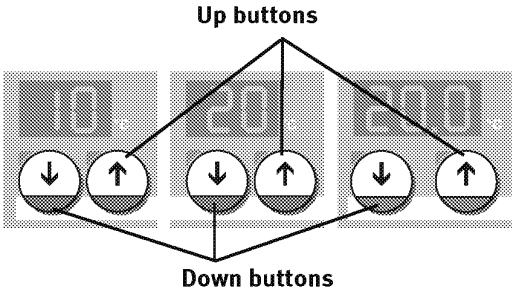
Adjusting the set values

Important

The heater-cooler will begin adjusting temperatures to the set values 2 seconds after the last Set value button press.

To adjust the set values:

- Press the Set value up button to raise the circuit temperature.
- Press the Set value down button to lower the circuit temperature.



Special Set value button operations:

Cardioplegia: Pressing and holding a Set value button changes the temperature value by 1 °C. Continuing to hold the Set value button will increase or decrease the set value more rapidly.

Patient: Pressing and holding a Set value button initially changes the temperature value by 0.1 °C, then changes the temperature value by 1 °C. If you then release the Set value button and immediately press it once, the temperature value will still change by 1 °C.

You can increase the temperature value change increment by pressing and holding one Set value button and pressing its counterpart (i.e., up or down) once.

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Using the device controls during a procedure

Operating the cardioplegia circuit

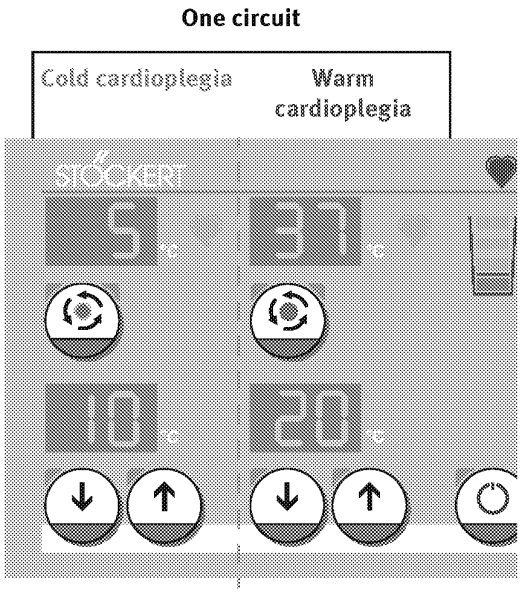
How the cardioplegia circuit works:

The cardioplegia circuit has two tanks: a warm tank and a cold tank. The warm and cold cardioplegia tanks operate using a single circuit. Only one cardioplegia circuit (warm or cold) can run at a time.

You can control each tank's temperature independently so that warm and cold water sources are available on demand during a procedure.

The temperature range for the cold cardioplegia tank is: 2 °C to 10 °C.

The temperature range for the warm cardioplegia tank is: 15 °C to 41 °C.

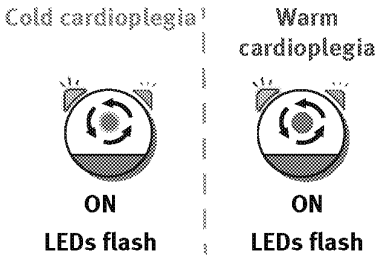


Starting the cardioplegia circuit:

Press the Start/Stop button of your desired cardioplegia circuit to run the circuit.

The water from the selected cardioplegia circuit's tank (warm or cold) will fill the cardioplegia circuit.

NOTE: The green LEDs will flash alternately to indicate the circuit is running.



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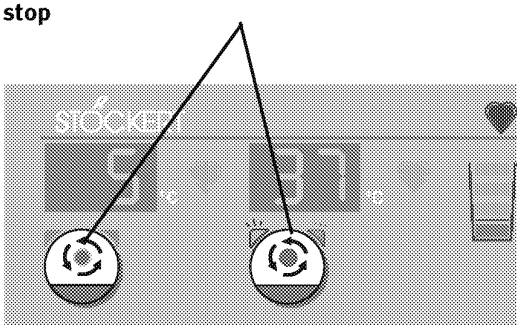
Switching between cardioplegia tanks (warm or cold):

Press the Start/Stop button of the inactive cardioplegia tank to run the circuit.

Within 5 seconds, the active cardioplegia circuit will stop running, and the water from the selected cardioplegia circuit's tank (warm or cold) will fill the cardioplegia circuit.

NOTE: The green LEDs will flash alternately to indicate the circuit is running.

Start one cardioplegia circuit and the other will stop

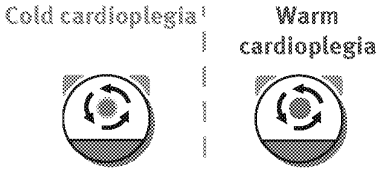


Stopping the cardioplegia circuit:

Press the Start/Stop button of the active cardioplegia circuit to stop the circuit.

The cardioplegia circuit will stop running.

NOTE: The green LEDs will go out when the cardioplegia circuit stops running.

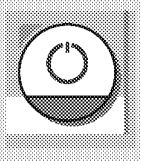


OFF
LEDs off

OFF
LEDs off

Important

Put the cardioplegia circuit in standby when it is not in use. Leaving the cardioplegia circuit active reduces the patient circuits' heating/cooling performance.



Cardioplegia Standby button

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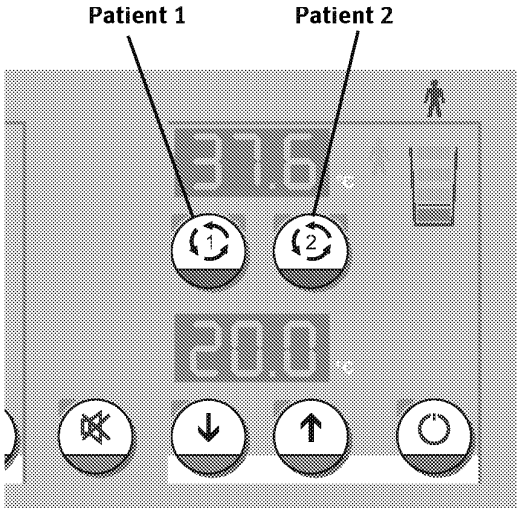
Operating the patient circuits

How the patient circuits work:

The patient 1 and patient 2 circuits operate using separate circuit valves and pumps. Both patient circuits can run at the same time.

The patient 1 and patient 2 circuits use the same water tank. The temperature of both patient circuits will always be the same.

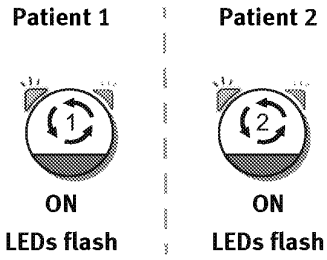
The temperature range for the patient tank is 2 °C to 41 °C.



Starting the patient circuit(s):

Press the Start/Stop button of your desired patient circuit to run the circuit.

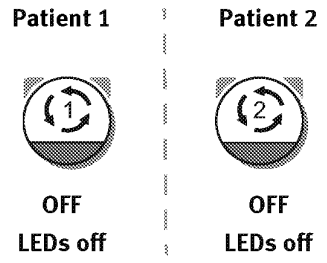
NOTE: The green LEDs on the patient(s) circuit(s) will flash alternately to indicate the circuit is running.



Stopping the patient circuit(s):

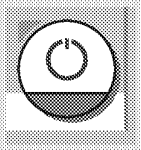
Press the Start/Stop button of the active patient circuit(s) to stop the circuit(s).

NOTE: The green LEDs will go out when the patient(s) circuit(s) stops running.



Important

Put the patient circuits in standby when they are not in use. Leaving the patient circuits active reduces the cardioplegia circuits' heating/cooling performance.



Patient Standby button

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5.7 Completing a procedure

WARNING

Do not empty the external circuits until the patient has been discharged from the OR environment to reduce the potential of exposure to aerosol.

5.7.1 Drain and disconnect tubing

Summary of steps you will complete in this section

1. **Confirm the patient is not in the room**
2. **Prepare the heater-cooler for draining**
3. **Drain the external circuits**
4. **Disconnect the tubing from the external devices**
5. **Power off the heater-cooler**

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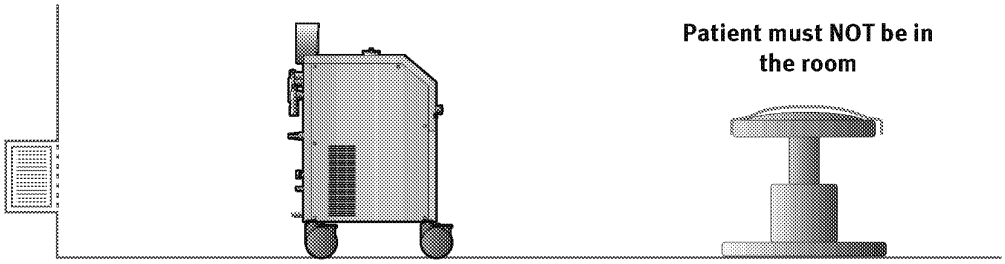
1 Confirm the patient is not in the room

- Confirm that the patient has been discharged from the OR before conducting any further steps.



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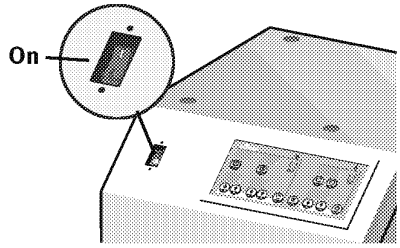
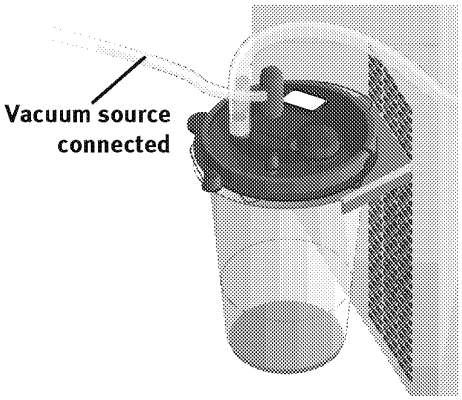
2 Prepare the heater-cooler for draining

1 Make sure that the heater-cooler is powered **on** when draining. If needed, press the mains power switch to power on the heater-cooler.



2 Make sure that the aerosol collection set is connected and the vacuum source is connected and set to maximum.



WARNING

Do not shut off the applied vacuum source until you have drained the circuits and powered off the heater-cooler. Operate the heater-cooler with an applied vacuum source to ensure that aerosol continues to be collected from the water tanks.

Important

If you are draining longer tubes with high volumes, there is a potential for overflowing the aerosol container. If the volume in the container exceeds 0.5 L, pause the draining of the circuit and empty the aerosol container according to chapter 5.7.2, then continue draining.

Continue step on next page ►

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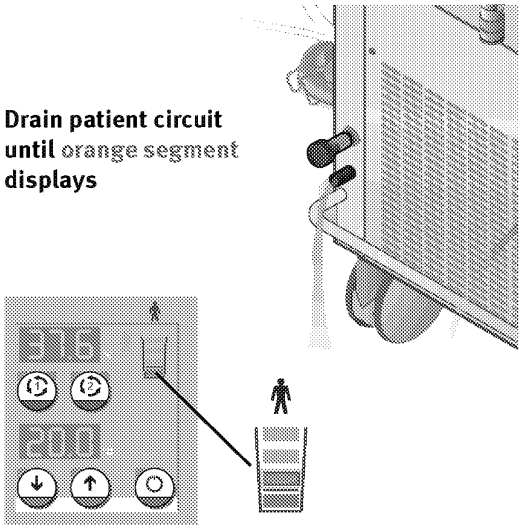
3 To prevent excess overflow, drain water from the patient circuit tank until the orange segment on the patient circuit water level display flashes.

Close the drain valve after draining this amount from the tank.



3 Drain the external circuits

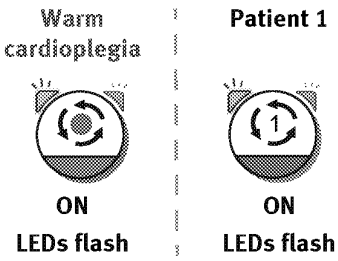
WARNING

Do not close all valves at once when draining water circuits. Always close one circuit valve at a time. Failure to close the external water circuit valves in the order specified below may result in increased levels of aerosol emission.

1 Make sure that the circuit pumps are running on any circuits that are connected. Press the Start/Stop buttons if needed.

NOTE: The green LEDs will flash alternately to indicate the circuit is running.

Example of Start/Stop buttons:



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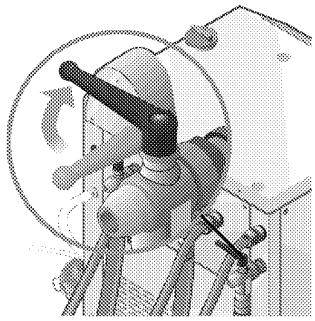
☐ 2 With either cardioplegia pump running, turn the **cardioplegia circuit's** red valve lever clockwise to close the valve.

Allow the external water circuit volume to enter the tank before closing the next valve.

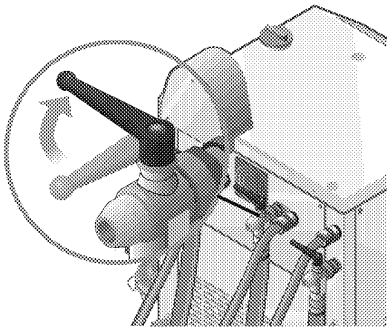
Close cardioplegia valve, wait to drain



☐ 3 Turn the **patient 1** circuit's red valve lever clockwise to close the valve.

Allow the external water circuit volume to enter the tank before closing the next valve.

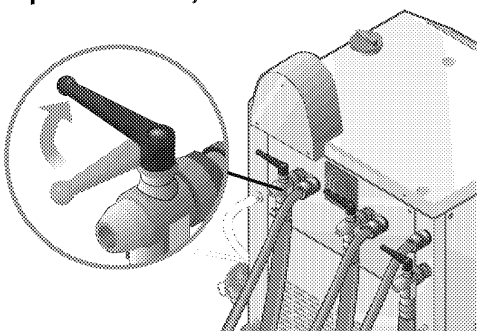
Close patient 1 valve, wait to drain



☐ 4 If in use, turn the **patient 2** circuit's red valve lever clockwise to close the valve.

The water from the external circuit will return to the patient circuit tank.

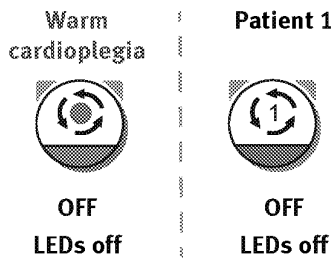
Close patient 2 valve, wait to drain



☐ 5 Press the Start/Stop button of the active circuit(s) to stop the circuit(s).

NOTE: The green LEDs will go out when the circuit(s) stops running.

Example of Start/Stop buttons:



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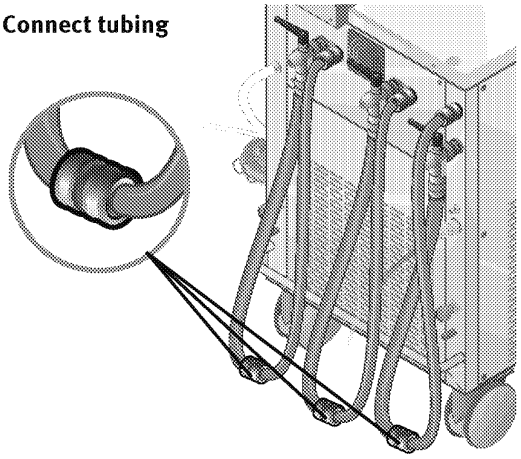
4 Disconnect the tubing from the external devices

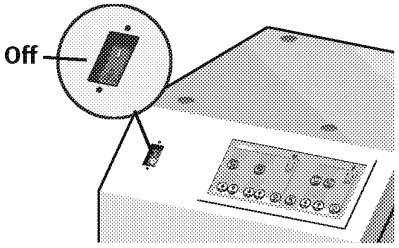
1. Make sure that the circuits are drained before disconnecting any tubing.
2. Disconnect all procedural tubing from external devices.
3. Disconnect the procedural tubing from the heater-cooler
   OR
   Disinfect the tubing connectors and suitable short-circuit connectors (part number 73-300-160). Then, short-circuit the procedural tubing.



Important
Disinfect the connectors and fittings every time you make a connection according to chapter 6.3.2 and chapter 6.3.3.

5 Power off the heater-cooler

- Press the mains power switch to power off the heater-cooler. The vacuum source may now be shut off and/or disconnected.



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5.7.2 Emptying and/or disposing of the aerosol collection set

Summary of steps you will complete in this section

1 **Empty the aerosol collection canister**

2 **Dispose of and replace, or reconnect the aerosol collection set based on the date it was installed**

1 Empty the aerosol collection canister

⚠ WARNING

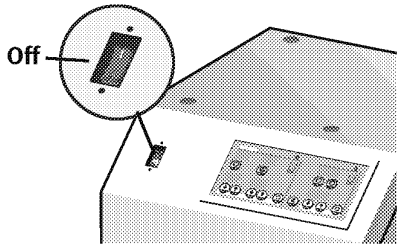
The aerosol collection canister contents are potentially hazardous due to collection of bacteria. Use appropriate Personal Protection Equipment (PPE), and handle the contents accordingly.

⚠ CAUTION

Do not expose the aerosol collection canister's hydrophobic lid filter to the water inside the aerosol collection canister. This will seal the filter, which will stop vacuum flow and limit the aerosol collection canister's ability to collect aerosol from the heater-cooler's water tanks.

If the hydrophobic lid filter has been exposed to water, replace the aerosol collection set according to the steps in this chapter.

▣ 1 Make sure that the heater-cooler is powered **OFF**. If needed, press the mains power switch to power off the heater-cooler.



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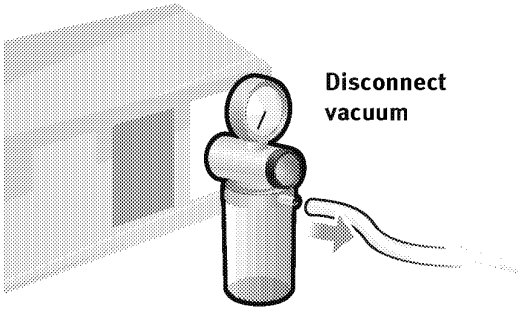
CAUTION

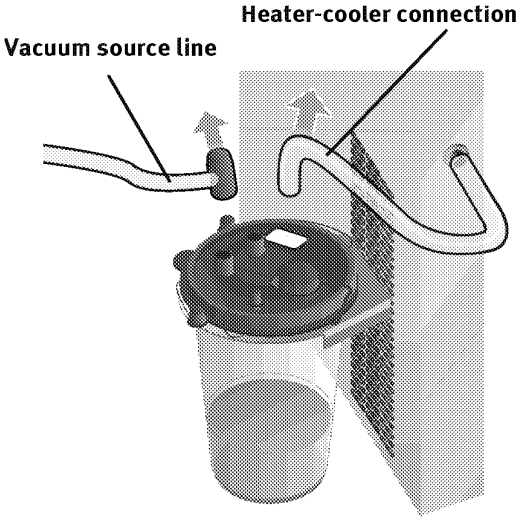
Do not disconnect the vacuum source if the heater-cooler is powered on.

2 Disconnect the **vacuum source line** (the long line) from the vacuum regulator.



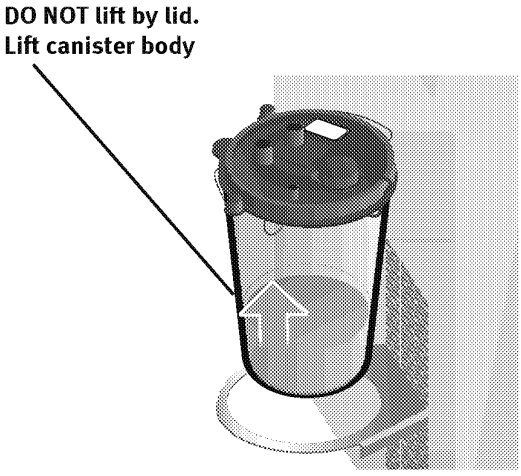
3 Disconnect the **heater-cooler connection** line and **vacuum source** line from the canister lid.

4 If you are disposing of the aerosol collection set (instead of only emptying), also disconnect the **heater-cooler connection** line from the back of the heater-cooler.



5 Lifting from the canister body, carefully remove the aerosol collection canister from the holder.

NOTE: Do not lift the aerosol collection canister by the lid, as the weight of the contents might cause the lid to separate from the aerosol collection canister.



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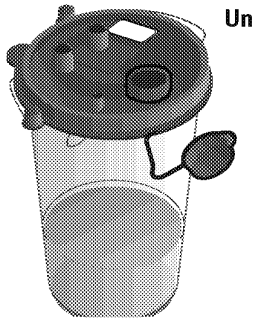
☐ 6 Uncap the **pour spout** on the aerosol collection canister.

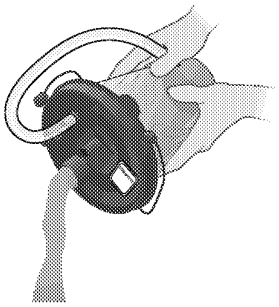


CAUTION

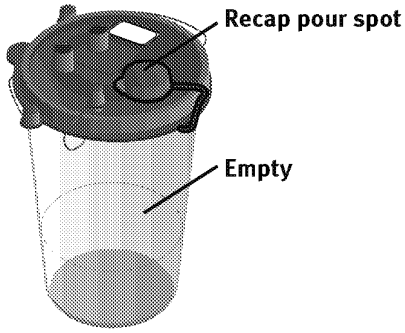
Do not expose hydrophobic filter in Canister Lid to water when emptying the canister. Exposure to water will block filter and cause it to not function.

☐ 7 Empty the aerosol collection canister in accordance with your hospital's policies.

NOTE: Empty the aerosol collection canister outside of the OR, if possible.



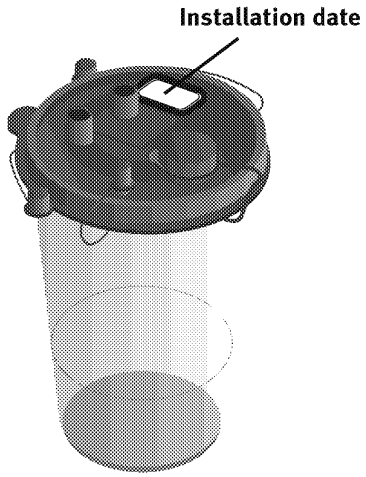
☐ 8 Recap the **pour spout** on the aerosol collection canister.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

2 Dispose of and replace, or reconnect the aerosol collection set based on the date it was installed

1. Check the installation date written on the aerosol collection canister lid:
   - **If the aerosol collection set is less than 7 days old**, you may reconnect the emptied canister using the same heater-cooler connection line and vacuum source line. Or, you may replace the entire aerosol collection set.
   - **If the aerosol collection set is more than 7 days old**, replace the entire aerosol collection set including all its components and lines.
2. Follow the applicable steps in chapter 4.5 to connect a new or emptied aerosol collection set to the heater-cooler.



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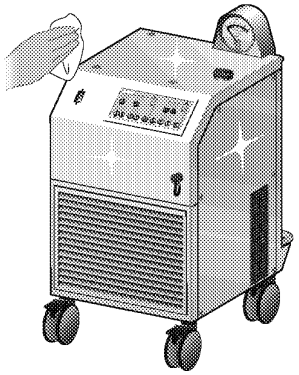
5.7.3 Conducting any required maintenance according to schedule

1 Clean and disinfect the heater-cooler surfaces after every use

- Clean and disinfect the heater-cooler surfaces after every use according to the instructions in chapter 6.3.



2 Review the schedule for disinfection and maintenance

- Review the schedule for disinfection and maintenance in chapter 6.2.1 to determine if any additional maintenance, cleaning, and/or disinfection tasks are required.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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6 Maintaining the heater-cooler

Regular maintenance is an important factor for the operation of the heater-cooler as it results in operational safety, reliability and increased service life.

This chapter provides instructions for the routine maintenance that is part of the operating conditions for the heater-cooler. This applies to the routine maintenance performed by the responsible organization as defined in IEC 60601-1 or the equivalent national standard, as well as to the preventive maintenance and safety checks performed by LivaNova representatives or competent service personnel.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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6.1 General maintenance precautions

6.1.1 Safety instructions for routine maintenance

⚠ WARNING

It is important to follow the cleaning and disinfection process described in these operating instructions to help reduce the risk of contamination.

Personnel and preparation:

- Only individuals trained to use the heater-cooler should perform maintenance on the heater-cooler.
- Only service technicians authorized by LivaNova may repair the heater-cooler system.
- Only refrigerant systems experts are authorized to repair the cooling circuit.
- Do not service the internal components of the heater-cooler. Only LivaNova representatives — or other service personnel deemed qualified by LivaNova — are authorized to maintain, service, and repair internal components of the heater-cooler.

Materials and protective equipment:

- When performing any maintenance activities on the heater-cooler, follow your hospital's personal protection equipment (PPE) policy to protect against exposure to hazardous materials, such as bacteria and/or disinfectant chemicals.

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CAUTION

Materials and protective equipment:

- Use only cleaning agents and disinfectants that are approved for use in the concentrations specified in chapter 6.3 and 6.4.1. Deviating from the labeling could cause damage to the heater-cooler.

Timing:

- Conduct regular maintenance of the heater-cooler. Doing so will result in operational safety, reliability, and increased service life.
- Perform all cleaning and disinfecting procedures according to the maintenance schedule provided in chapter 6.2.
- Disinfect the heater-cooler before using it for the first time. Disinfect the heater-cooler before storage.

NOTICE

- Adhere to local regulations related to documenting all maintenance procedures, as required by European Directive 93/42, and any operating failures in a medical device log. The medical device log should be presented to authorized service personnel upon request.

NOTE: LivaNova recommends documenting this information regardless of local regulations. Providing this information to LivaNova will assist with maintenance and support activities.

- Exposing the heater-cooler to disinfectant for longer than its intended exposure time will increase the wear on the device and might lead to premature failure of the heater-cooler.
- All ventilation grills must be cleaned at regular intervals to avoid contamination. Detailed information on this subject is provided in chapter 6.8.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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6.2 Maintenance schedule and checklists

This chapter includes a schedule of maintenance tasks and several checklists you should use to make sure that the heater-cooler is properly maintained, disinfected, and functioning.

6.2.1 Schedule: Disinfection and maintenance

Timing	Task	Chapter
Before first-time use, before storing	Clean and disinfect external surfaces, connectors, and fittings	6.3
	Disinfect the water circuits	6.4
Upon every connection	Disinfect connections and fittings	6.3.3
After every use	Clean and disinfect external surfaces	6.3.1
Daily, before use Daily, when in storage	Monitor the hydrogen peroxide concentration	6.5.1
Every 7 days	Replace the aerosol collection set	5.7.2
Every 7 days	Change the water and add hydrogen peroxide	6.6
Every 14 days (including when in storage)	Disinfect the water circuits	6.4
Once a month	• Monitor the water quality for total bacteria count • Monitor the water quality for NTM **NOTE:** Conduct **before and after** disinfecting the water circuits	6.5.2
Once a year	Replace the tubings used with the heater-cooler	6.9
Once a year or 1,000 hours (which ever comes first)	Schedule a maintenance check after every 1,000 operating hours or at least once every 12 months, whichever comes first.	6.2.4

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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6.2.2 Checklist: Daily or with every use

1 Perform these checks daily or every time you use the heater-cooler

- Check the maintenance schedule in 6.2.1 to determine whether any maintenance activities are due. Perform the required maintenance activities according to their corresponding instructions.
- Make sure that the daily monitoring of the hydrogen peroxide concentration has been completed per 6.5.1.
- Dispose of used single-use items according to local environmental regulations and the manufacturer's instructions.
- Check the installation date on the aerosol collection canister.
  - If more than 7 days have passed, replace the aerosol collection canister. Refer to chapter 5.7.2 for instructions on replacing the aerosol collection set.
  - If 7 days or fewer have passed, check the fill level on the aerosol collection set and empty it if needed, according to instructions in chapter 5.7.2.
- Contact LivaNova if the heater-cooler or any of its components are defective or damaged.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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6.2.3 Checklist: Mechanical checks

- **Perform regular checks** to ensure that the heater-cooler is in proper working condition, and to reduce or eliminate the chance of malfunction.
- **Do not use** the heater-cooler if the heater-cooler does not meet all the conditions listed in this chapter.
- **Contact LivaNova** if the heater-cooler or any of its components are damaged or require service.

1 Check the heater-cooler's main power, potential equalization, and CAN cable

▶ Make sure:

- ☑ The cables are free of damage (e.g., cracks, cuts, kinks) along the entire length of the cable
- ☑ All contacts are clean
- ☑ The plugs are free of mechanical damage (e.g., no damage to housing and no bent pins)
- ☑ The mains power connection to the heater-cooler is secure with no movement between cable and strain relief

2 Check the water circuits

▶ Make sure:

- ☑ Water tubing is free of damage and leaks
- ☑ Water circuit connections are free of damage and leaks
- ☑ Water circuit connectors lock and unlock smoothly

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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6.2.4 Checklist: Regular maintenance from LivaNova

You/your organization is responsible for scheduling maintenance checks from a LivaNova service technician.

Only LivaNova representatives — or other service personnel deemed qualified by LivaNova — are authorized to perform maintenance checks of the heater-cooler.

Maintenance checks by LivaNova service technicians include, but are not limited to, the following:

- Status checks
- Electrical safety checks
- Operational safety checks
- Status of the water circuits/tanks for calcification and biofilm
- Status of cooling coils for corrosion
- Decalcification and/or disinfection

Important

As a preventive measure, contact LivaNova service personnel to schedule a maintenance check of the water tank cooling coils if you observe either of the following:

- Dark gray liquid is observed during the water circuit disinfection process.
- Excessive hydrogen peroxide consumption is observed during the daily monitoring of hydrogen peroxide concentration.

Note: The rate of decrease in hydrogen peroxide concentration is expected to vary by device, and depends on several factors such as age or overall condition of the device, past maintenance practices, and local water conditions.

Important

The expected service life of the Heater-Cooler System 3T is 10 years. Use of the device beyond the expected service life, improper maintenance practices, or the incorrect use of disinfection and water preservation chemicals may lead to excessive corrosion damage of the water circuit components.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1 Record or estimate the operating hours

- ☑ Where required by local regulations, record the operating hours of the heater-cooler.[1]
- ☑ If local regulations do not require tracking of operating hours, LivaNova recommends estimating the operating hours.

2 Schedule a maintenance check

- ☐ Schedule a maintenance check with a LivaNova service technician every 1,000 operating hours or every 12 months, whichever comes first.

6.2.5 Checklist: Proper disposal

1 Dispose of the heater-cooler and/or accessories according to your local environmental regulations and hospital policy

- ☑ Dispose of used single-use items according to local environmental regulations and the manufacturer's instructions. Wear appropriate personal protection equipment (PPE) while disposing of these items.
- ☑ The heater-cooler must not be disposed of in accordance with Directive 2012/19/EU or its national transpositions as the system is to be regarded as potentially infectious at the end of its service life.
- ☑ Dispose of all heater-cooler accessories according to your hospital's policy, local environmental regulations, and the accessories' instructions.
- ☑ Only refrigerant systems experts are authorized to dispose of the cooling circuit's refrigerant (CFC-free HFC-[hydrofluorocarbons]) refrigerant. The refrigerant system service information is contained on the refrigerant system label.

1 As required by European Directive 93/42 and/or local regulation

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-9067 - Released by CDRH on 01-04-2024

6.3 Cleaning and disinfecting external surfaces, connectors, and fittings

Cleaning and disinfecting schedule

- **After every use**, clean and disinfect the device surfaces
- **Upon every connection**, disinfect the tubing connectors on the heater-cooler
- **Upon every connection**, disinfect the fittings and connectors on the tubing

Important

- Make sure the CAN jack cover is closed before cleaning and disinfecting.
- Use only disinfectant wipes and sprays that are approved for use with the heater-cooler. See the table below for a list of approved cleaning supplies.

Approved pre-soaked disinfectant wipe

Product name	Manufacturer
CaviWipes	Metrex

Approved disinfectant spray

Product name	Manufacturer
CaviCide	Metrex

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Released under FOIA Request 2023-9067; Released by CDRH on 05-23-2024

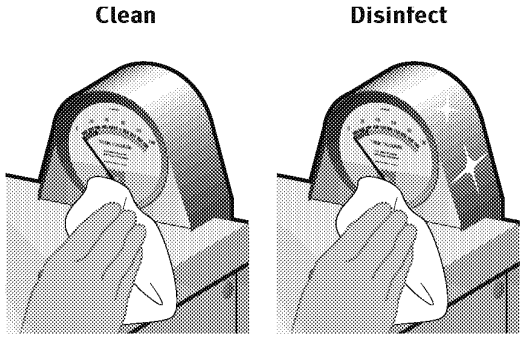
6.3.1 Cleaning and disinfecting heater-cooler external surfaces

Summary of steps you will complete in this section:

1. **Clean and disinfect the vacuum gauge**
2. **Clean all accessible device surfaces**
3. **Disinfect all accessible device surfaces**

1 Clean and disinfect the vacuum gauge

1. Using **only approved disinfectant wipes**, clean the vacuum gauge, removing any surface contamination and liquid spills.
2. Using **only approved disinfectant wipes**, disinfect the vacuum gauge.



Important
Using other disinfectants may result in damage or a shortened lifetime of the gauge face.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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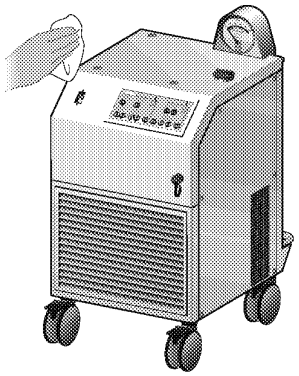
2 Clean all accessible device surfaces

- 1 Remove liquid spills (such as blood) from the device surfaces as quickly as possible.
- 2 Remove any surface contamination using pre-soaked disinfectant wipes.
- 3 Dispose of used disinfectant wipes in accordance with your hospital's policies.

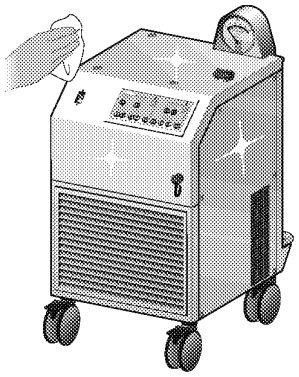
Clean all surfaces



3 Disinfect all accessible device surfaces

- 1 Thoroughly wipe all devices surfaces using pre-soaked disinfectant wipes per the wipes' instructions for use and your hospital's policies.
- 2 Wait for the exposure time specified by the disinfectant wipes you are using.
- 3 Dispose of used disinfectant wipes in accordance with your hospital's policies.

Disinfect all surfaces



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

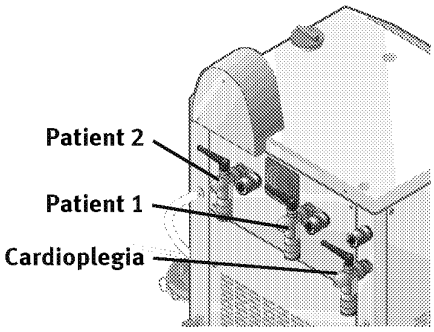
Processed under FOIA Request 2023-6067. Released by CDRH on 05-23-2024

6.3.2 Disinfecting the tubing connectors on the heater-cooler

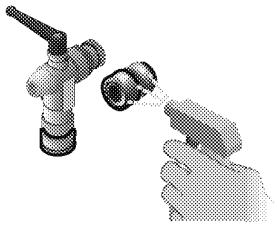
1 Disinfect tubing connectors on the heater-cooler

Important
Make sure that no liquids enter the housing of the heater-cooler when spraying disinfectant.

▶ 1 Conduct steps ▶ 2 and ▶ 3 on all tubing connector inlets and outlets:
- **Patient 2** connectors
- **Patient 1** connectors
- **Cardioplegia** connectors



▶ 2 Apply four sprays of disinfectant on the exterior of each connector. Push and hold the quick release ring back and apply four sprays of disinfectant to the interior of each connector.



▶ 3 Wait for 5 minutes. Ensure that all connector surfaces remain wet with disinfectant during this time. Apply additional disinfectant if necessary.

Wipe all connector surfaces with a disinfectant wipe for 2 minutes to remove excess disinfectant.

Wait for 5 minutes, then wipe off excess for 2 minutes

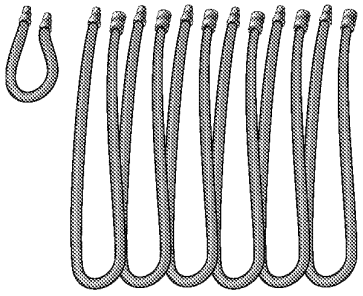
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-9067 - Released by CDRH on 10-31-2023

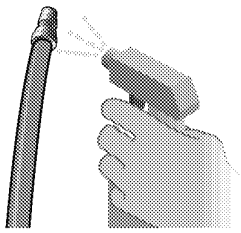
6.3.3 Disinfecting the fittings and connectors on the tubing

1 Disinfect all connectors and fittings on the tubing

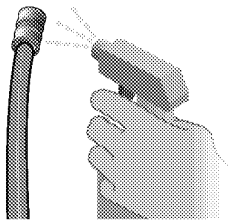
▶ 1 Conduct steps ▶ 2 through ▶ 4 on all fittings and connectors on short circuit and procedural tubing.



▶ 2 Apply four sprays of disinfectant on the male fitting.



▶ 3 On the other end of the tube, apply four sprays of disinfectant on the exterior of the female connector. Push and hold the quick release ring back and apply four sprays of disinfectant to the interior of each connector.



▶ 4 Wait for 5 minutes. Ensure that all surfaces remain wet with disinfectant during this time. Apply additional disinfectant if necessary.

Wipe all surfaces with a disinfectant wipe for 2 minutes to remove excess disinfectant.

Wait for 5 minutes, then wipe off excess for 2 minutes

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Recorded from Freedom of Information Request 2023-9067; Released by CDRH on 05-23-2024

6.4 Disinfecting the water circuits every 14 days

Water circuit disinfecting schedule

- Disinfect the water circuits every 14 days, regardless of water changes.
- Take water samples before and after disinfecting the system if you are scheduled to monitor the water for bacteria and/or NTM.
- Disinfect the water circuits before using the heater-cooler for the first time and before storing the heater-cooler.

Important

- Be sure to disinfect the procedural tubing typically used with the heater-cooler.
- Follow your hospital's policies regarding the use of personal protective equipment (PPE).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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6.4.1 Supplies and materials for disinfection

WARNING

Do not use disinfectants in the water circuits during a surgical intervention. Only use disinfectants preoperatively and postoperatively.

Important

- Use only LivaNova-approved disinfectants to disinfect the water circuits. The use of any other disinfectant is explicitly not recommended. Other disinfectants could contain different additives that might influence the material compatibility, even if they have the same peracetic acid or sodium hypochlorite concentration.
- Refer to your disinfectant's instructions for use for details related to your specific disinfectant.
- Refer to your disinfectant's safety data sheet for information regarding personal protection measures.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Reading processed under FOIA Request 2023-6067. Released by CDRH on 05-23-2024

List of the approved disinfectants

Product name	Manufacturer	EPA Reg. No.
Clorox Germicidal Bleach (8.25% sodium hypochlorite)	Clorox Company	5813-100-67619
Minncare Cold Sterilant	Minntech Corporation	52252-4

Check the availability of the recommended disinfectants in your country, if applicable.

Materials you will need

Materials to fill the water tanks

- Tap water filtered according to chapter 1.1.9
- Tubing required to connect the filter to your hospital's faucet or water supply

Materials to disinfect the water circuits

- Tap water filtered according to chapter 1.1.9
- Short-circuit tubing for mixing
- Procedural tubing used during procedures
- A measuring cup with at least 500 mL volume
- An approved disinfectant, as listed in the table above

Materials to drain the water tanks

- 1-2 collection buckets for drained water, each with at least 8 L volume[1]
- Cellulose tissues for removing liquid spills

1 Only required if you will not drain the solution directly into floor drains.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-9067 - Released by CDRH, 3T Medical, Inc.

6.4.2 Disinfecting the water circuits

Important

- During the disinfection procedure, leave the used 3T Aerosol Collection Set connected to the heater-cooler.
- Make sure procedural tubing is disconnected from the heater-cooler prior to beginning the disinfection procedure.

Summary of steps you will complete in this section:

1. **Prepare for the disinfection procedure**
2. **Drain the water tanks**
3. **Prepare for filling**
4. **Fill the water tanks and add disinfectant**
5. **Prepare for mixing**
6. **Mix the tank contents**
7. **Prepare to run the disinfectant solution through the system**
8. **Run the disinfectant solution through the system**
9. **Drain the disinfectant from the water tanks**
10. **Rinse the tanks and tubing two (2) times**
11. **Replace the aerosol collection set**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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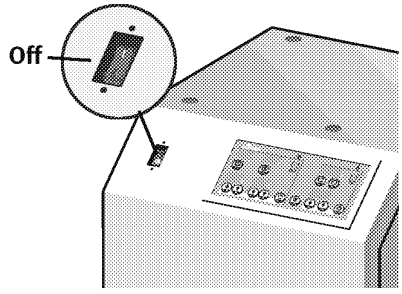
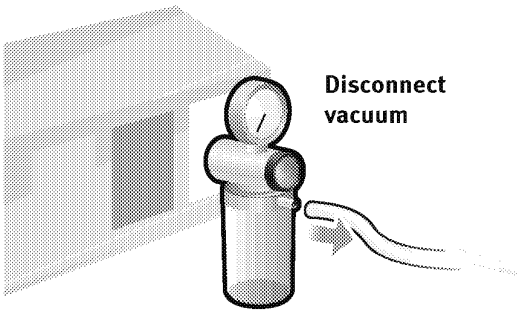
1 Prepare for the disinfection procedure

☐ 1 Press the mains power switch to power off the heater-cooler.

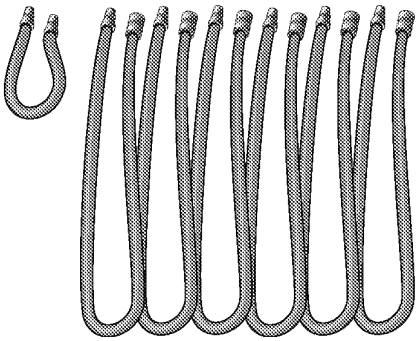


☐ 2 Disconnect the aerosol collection canister's vacuum line from the external vacuum source.



☐ 3 Gather the following tubing:

- Tubing used for mixing (short-circuit tubing)
- Tubing used during procedures (procedural tubing)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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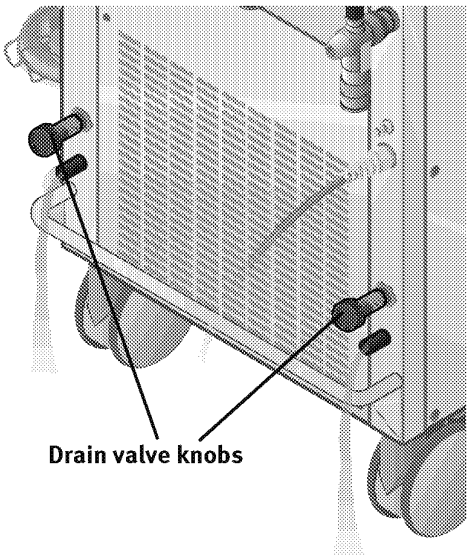
2 Drain the water tanks

Important
When draining the water tanks, drain the solution into buckets or directly into floor drains.

1. Twist both drain valve knobs counterclockwise until the drain valves are fully open.
2. Drain the tanks until the solution stops flowing from the drain valves.
3. Twist both drain valve knobs clockwise until the drain valves are fully closed.
4. Dispose of the solution in accordance with your hospital's policies.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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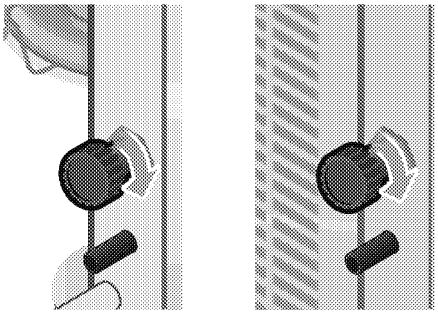
3 Prepare for filling

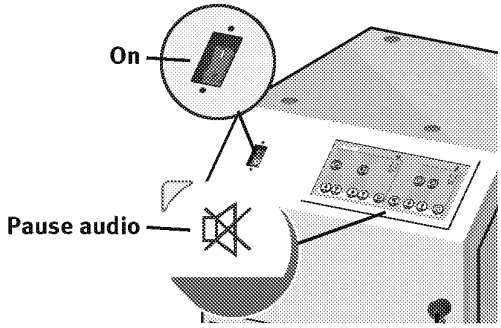
☐ 1 Make sure that both drain valves are fully closed so that water does not flow out when filling the water tanks.



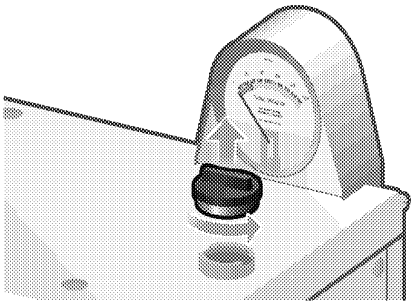
Important
Make sure to completely drain the water tanks prior to filling with water and disinfectant. Failure to do this can lead to incomplete disinfection of the tanks.

☐ 2 Press the mains power switch to power on the heater-cooler.

NOTE: A tone will sound indicating that the heater-cooler tanks are empty. You can press the Pause Audio button to pause the tone.



☐ 3 Turn the filler neck cap counterclockwise to remove.



Continue step on next page ▸

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
CP_IFU_18-XX-XX_USA_022

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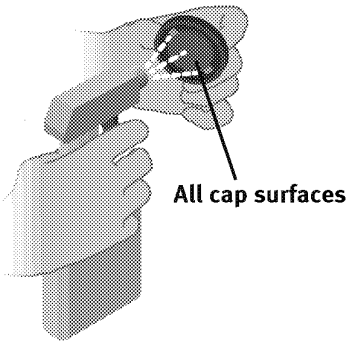
4 Apply four sprays of disinfectant on the cap until all surfaces are wet, including the cap's underside and sealing surface.



5 Wait for 5 minutes. Ensure that all surfaces remain wet with disinfectant during this time. Apply additional disinfectant if necessary.

Wipe all surfaces with a disinfectant wipe for 2 minutes to remove excess disinfectant.

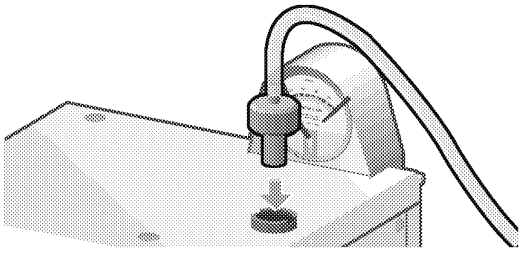
4 Fill the water tanks and add disinfectant

Important

As you pour water into the single filler neck, all three tanks will fill in the following order:

- Cold cardioplegia tank
- Warm cardioplegia tank
- Patient tank

1 Begin filling the water tanks with filtered tap water.



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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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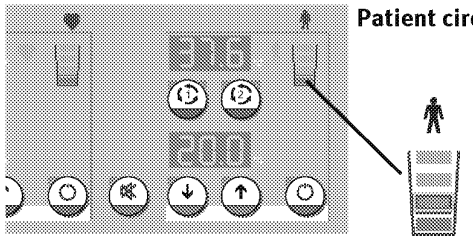
☐ 2 Pause filling when the orange segment on the **patient circuit** water level display lights up.



☐ 3 Add one disinfectant to the tank contents using the appropriate amount:

WARNING

Use only one disinfectant. The use of both products will potentially result in a dangerous chemical reaction.

CAUTION

Use of a higher volume of disinfectant might damage the heater-cooler.

- **Option 1: Use 450 mL of Minncare Cold Sterilant.**
  Note: This amount of disinfectant mixed with filtered tap water to the second green level of the patient indicator results in a mixture ratio of 1:30.

OR

- **Option 2: Use 180 mL of Clorox Germicidal Bleach (8.25%).**
  Note: This amount of disinfectant mixed with filtered tap water to the second green level of the patient indicator results in a mixture ratio of 1:77.

Continue step on next page ►

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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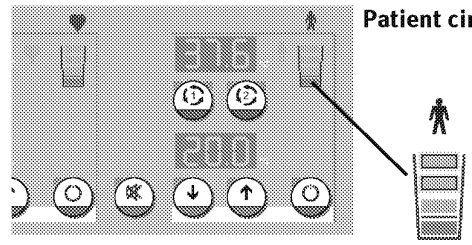
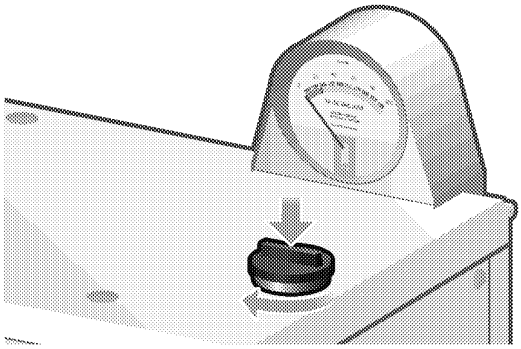
4 Continue filling the tanks with filtered tap water until the second green segment of the **patient circuit** water level display lights up.



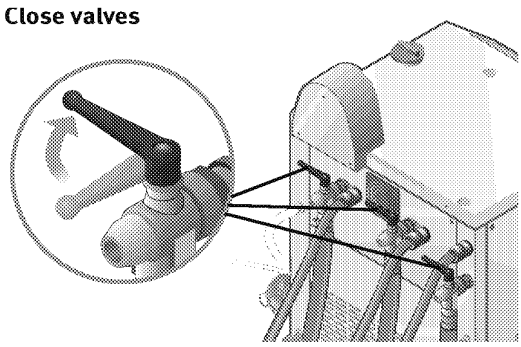
5 Attach the filler neck cap, and turn clockwise to secure.



5 Prepare for mixing

1 On the back of the heater-cooler, make sure that the three red valve levers are closed. Turn clockwise to close.

2 Disinfect the heater-cooler connectors and short-circuit tubing fittings.



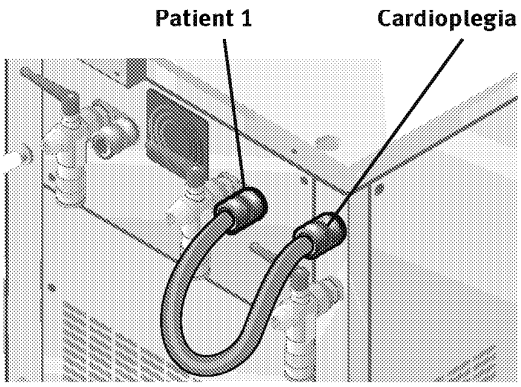
Important
Disinfect connectors and fittings every time you make a connection according to chapter 6.3.2 and chapter 6.3.3.

Continue step on next page ►

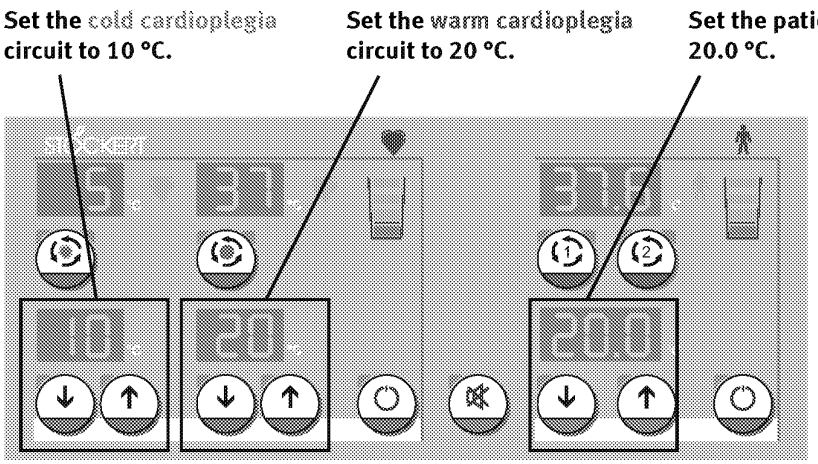
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Reprocessing Under FDA Request 2023-0007. Released by CDRH on 05-23-2024

3 Connect the short-circuit tubing between the cardioplegia circuit inlet and the patient 1 circuit inlet.



4 To avoid triggering a high temperature warning while mixing:



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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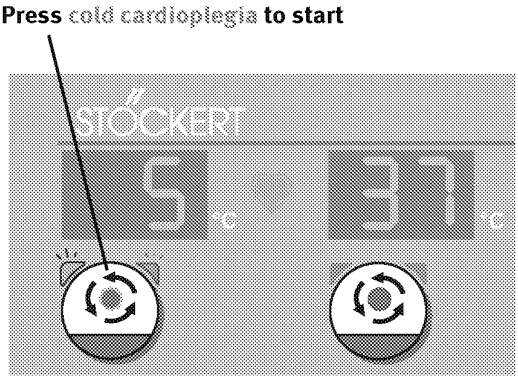
6 Mix the tank contents

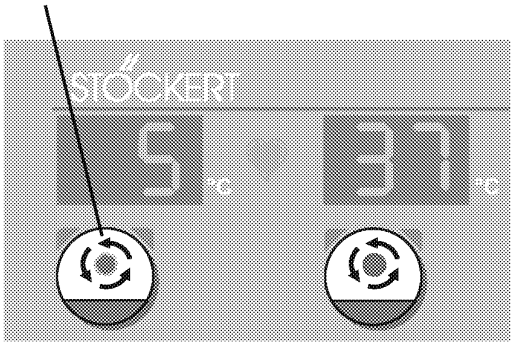
1 Press the cold cardioplegia circuit Start/Stop button to start mixing.

NOTE: The green LEDs will flash alternately to indicate the circuit is running.



2 After 5 minutes, press the cold cardioplegia circuit Start/Stop button again to stop mixing.

The mixing process is now complete.



CAUTION

Mixing for more than 6 minutes might damage the heater-cooler.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records from Case Number FOIA Request 2023-9067; Released by CDRH on 05-23-2024

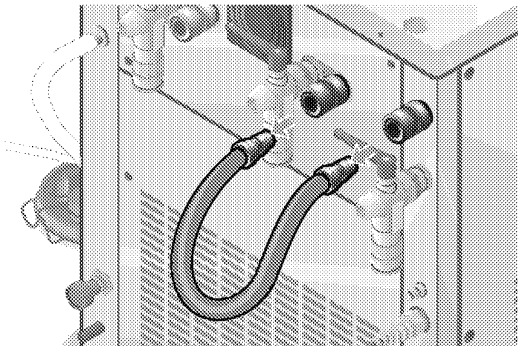
7 Prepare to run the disinfectant solution through the system

Important

All circuits, including those not used during procedures, must be connected to tubing in order to disinfect the system:

- Make sure to connect procedural tubing to any circuits that are used during procedures.
- If any circuits are not used during procedures, connect these circuits using short-circuit tubing.

1 Disconnect the short-circuit tubing between the cardioplegia circuit inlet and the patient 1 circuit inlet.



2 Disinfect all procedural tubing connectors and suitable short-circuit connectors (part number 73-300-160).

Important

Disinfect the connectors and fittings every time you make a connection according to chapter 6.3.2 and chapter 6.3.3.

Continue step on next page ►

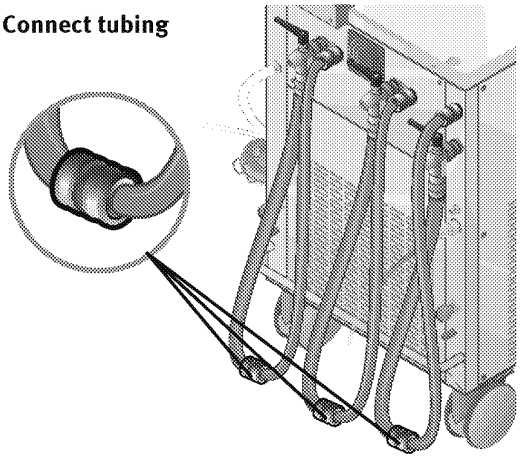
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-9067 - Released by CDRH on 07-06-2023

3 Connect the procedural tubing between the circuits using the suitable short-circuit connectors:
- Cardioplegia circuit's inlet and outlet
- Patient 1 circuit's inlet and outlet
- Patient 2 circuit's inlet and outlet

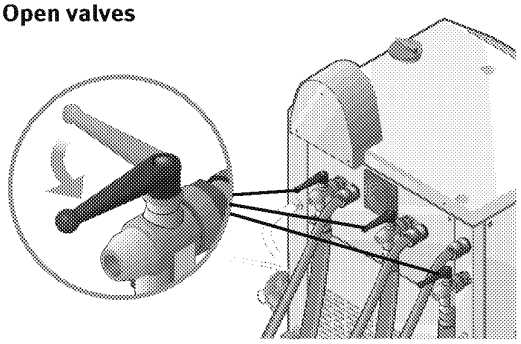
NOTE: If needed, bridge any circuits not used in procedures with short-circuit tubing.

Connect tubing



4 On the back of the heater-cooler, turn the three red levers counterclockwise to open the valves.

Open valves



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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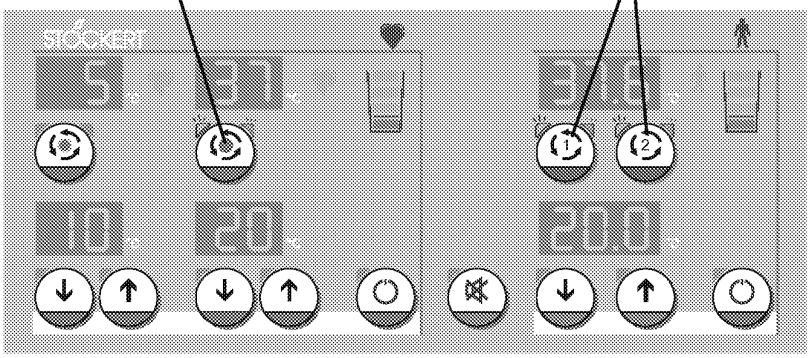
8 Run the disinfectant solution through the system

1 Start running the circuit pumps:

Press the warm cardioplegia circuit Start/Stop button.

Press the patient 1 and patient 2 circuit Start/Stop buttons.



The green circuit button LEDs will flash alternately to indicate the circuit is running.

2 Monitor the water level displays.

If the **orange** segment on either water level display flashes, add the specified amount of filtered tap water premixed with one of the following disinfectants:

WARNING

Use only one disinfectant and make sure it is the same one you added when filling the tanks for disinfection. The use of both products will potentially result in a dangerous chemical reaction.

- **Option 1: Premix 930 mL of filtered tap water** with 30 mL of Minncare Cold Sterilant.

OR

- **Option 2: Premix 1,150 mL of filtered tap water** with 15 mL of Clorox Germicidal Bleach (8.25%).

Continue step on next page ►

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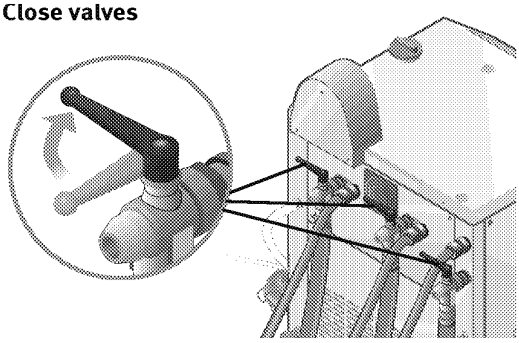
3 After 10 minutes, turn the three red valve levers clockwise to close the valves. Allow the circuit pumps to run until the tubing is drained.

Close valves



CAUTION

Running the circuit pumps with disinfectant solution for more than 11 minutes might damage the heater- cooler.

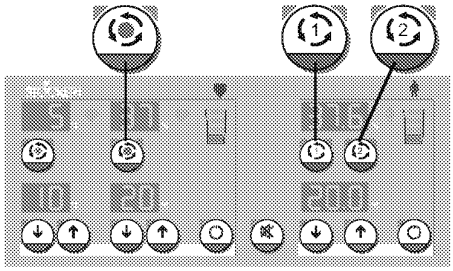
4 Stop running the circuit pumps:

- Press the warm cardioplegia circuit Start/Stop button
- Press the patient 1 and patient 2 circuit Start/Stop buttons.

The green circuit button LEDs will go out when circuit pumps stop running.

Press warm cardioplegia

Press patient 1, patient 2



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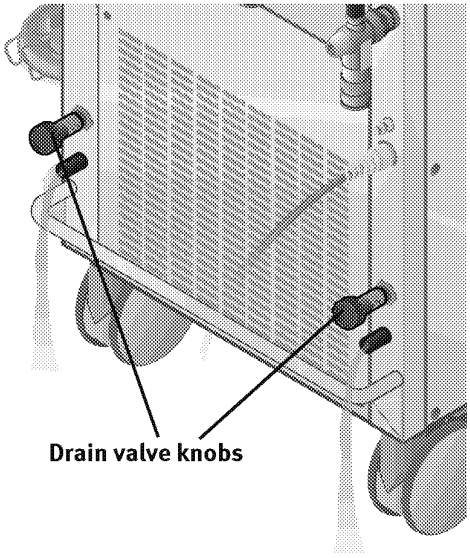
9 Drain the disinfectant from the water tanks

Important
When draining the water tanks, drain the solution into buckets or directly into floor drains.

- 1 Twist both drain valve knobs counterclockwise until the drain valves are fully open.
- 2 Drain the tanks until the solution stops flowing from the drain valves.
- 3 Twist both drain valve knobs clockwise until the drain valves are fully closed.
- 4 Dispose of the solution in accordance with your hospital's policies.



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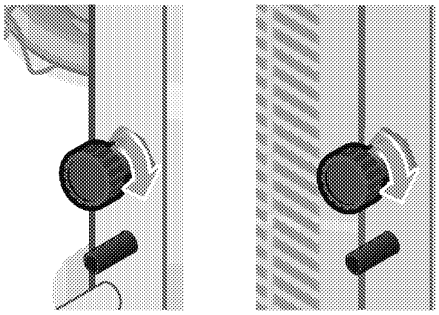
10 Rinse the tanks and tubing two (2) times

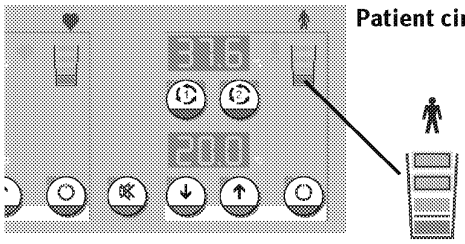
CAUTION

To remove residual disinfectant solution from the system, rinse the tanks and tubing after every disinfection cycle two (2) times as described below.

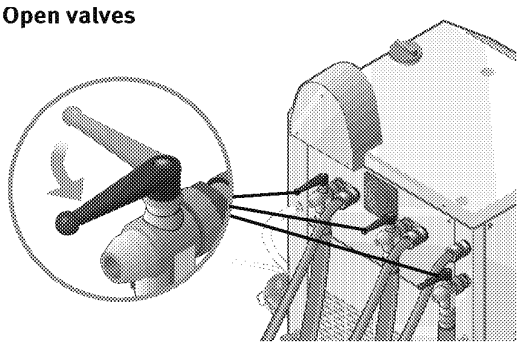
1 Make sure that both drain valves are fully closed so that water does not flow out when filling the water tanks.



2 Using filtered tap water, fill the water tanks until the **second green segment** on the patient circuit water level display lights up.



3 On the back of the heater-cooler, turn the three red levers counterclockwise to open the valves.



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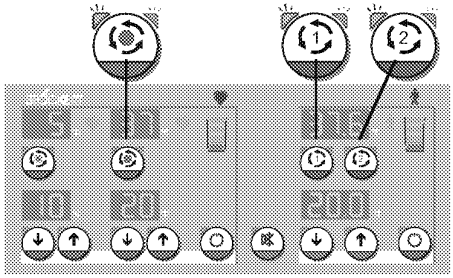
☐ 4 Start running the circuit pumps:

- Press the **warm cardioplegia** circuit Start/Stop button
- Press the patient 1 and patient 2 circuit Start/Stop buttons.

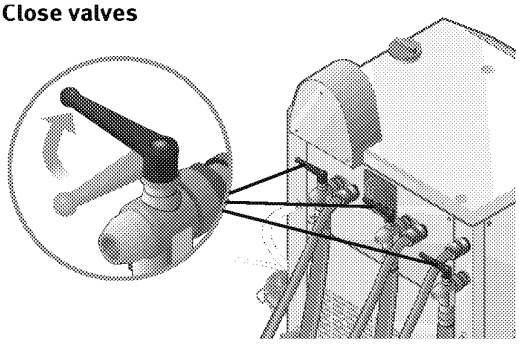
The green circuit button LEDs will flash alternately to indicate the circuit is running.

Press warm cardioplegia **Press patient 1, patient 2**



☐ 5 After 3 minutes, turn the three red valve levers clockwise to close the valves. Allow the circuit pumps to run until the tubing is drained.

Close valves

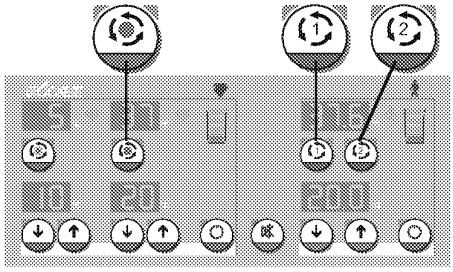


☐ 6 Stop running the circuit pumps:

- Press the **warm cardioplegia** circuit Start/Stop button
- Press the patient 1 and patient 2 circuit Start/Stop buttons.

The green circuit button LEDs will go out when circuit pumps stop running.

Press warm cardioplegia **Press patient 1, patient 2**



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Important

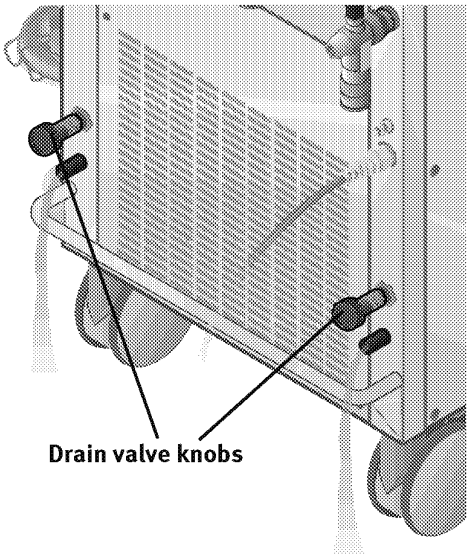
When draining the water tanks, drain the solution into buckets or directly into floor drains.

7 Twist both drain valve knobs counterclockwise until the drain valves are fully open.

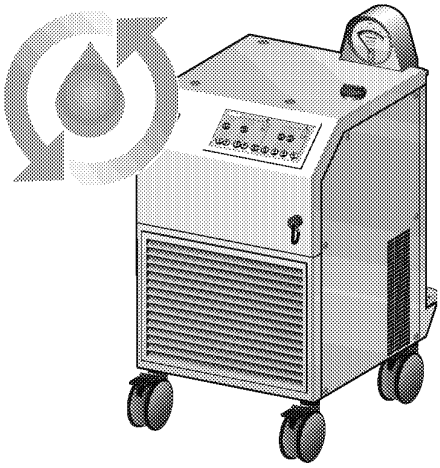
8 Drain the tanks until the solution stops flowing from the drain valves.

9 Twist both drain valve knobs clockwise until the drain valves are fully closed.

10 Dispose of the solution in accordance with your hospital's policies.



11 **Repeat sub steps 1 through 10** (Step 10,"Rinse the tanks and tubing two (2) times") so that the system is rinsed two (2) times.



CAUTION

Rinsing two (2) times helps to ensure the system is rinsed of disinfectant solution.

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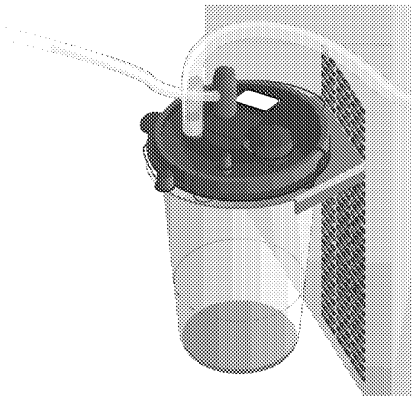
11 Replace the aerosol collection set

☐ Replace the aerosol collection set according to chapter 5.7.2.

The disinfection procedure is now complete. The heater-cooler may now be prepared for a procedure (see chapter 4) or placed in storage (see chapter 6.7).



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6.5 Monitoring the tank water

6.5.1 Monitoring the hydrogen peroxide concentration daily

Hydrogen peroxide monitoring schedule

- Check hydrogen peroxide concentration daily, before heater-cooler use.
- Check daily, even if the heater-cooler is not in use.

Important

- Do not disinfect the drain valve prior to monitoring the hydrogen peroxide concentration because the disinfectant chemical may affect the test results.
- If you do not wish to monitor the hydrogen peroxide concentration daily when the heater-cooler is not in use, drain the water tanks before storing.
- In addition to the instructions in this chapter, refer to your hydrogen peroxide test strips for specific use instructions.
- Follow your hospital's policies regarding the use of personal protective equipment (PPE).

Materials you will need:

- Empty container with at least 100 mL volume
- Sterile sample container with at least 5 mL volume
- Hydrogen peroxide (H_2O_2) test strips (MQuant, Peroxide Test, Method: colorimetric with test strips, 100 - 1,000 mg/l H_2O_2, Reference 1.10337.0001, or equivalent)

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Summary of steps you will complete in this section:

1. Collect a sample
2. Interpret the hydrogen peroxide concentration
3. Take action based on the hydrogen peroxide concentration
4. Make sure the water tanks are full

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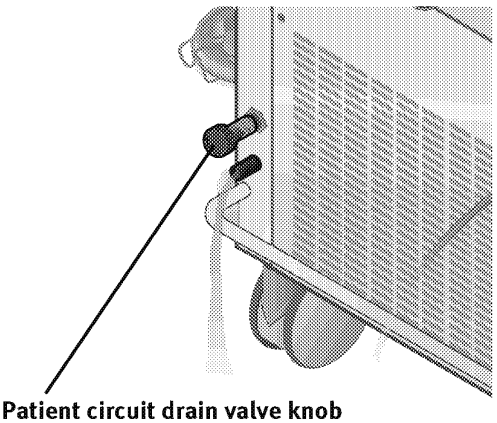
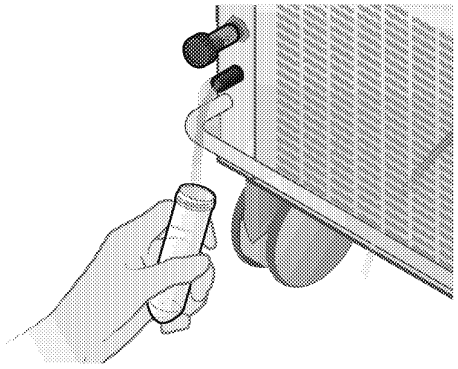
1 Collect a sample

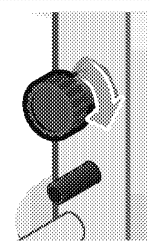
1. Twist the patient circuit drain valve knob counterclockwise to open the patient circuit drain valve.
2. Drain at least 100 mL of solution from the drain valve and discard.



3. Before closing the drain valve, drain at least 5 mL of solution into the sterile sample container.



4. Twist the patient circuit drain valve knob clockwise until the drain valve is fully closed.



Important

The patient circuit water level might be low. Do not add volume to the tanks until you complete the hydrogen peroxide test and adjustment procedures.

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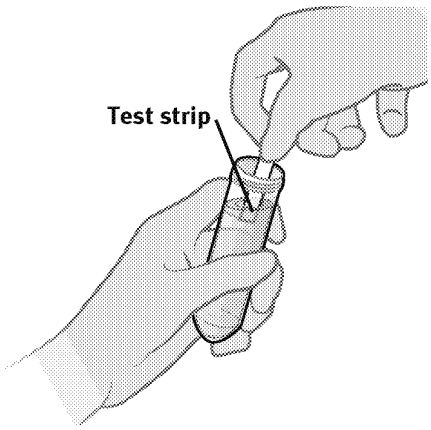
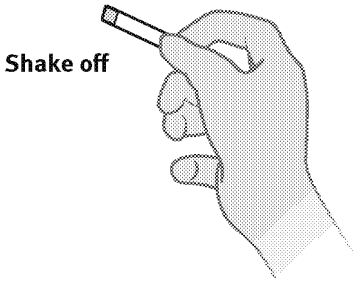
2 Interpret the hydrogen peroxide concentration

☐ 1 Immerse the test strip in the sample container for the time specified in the test strip instructions.



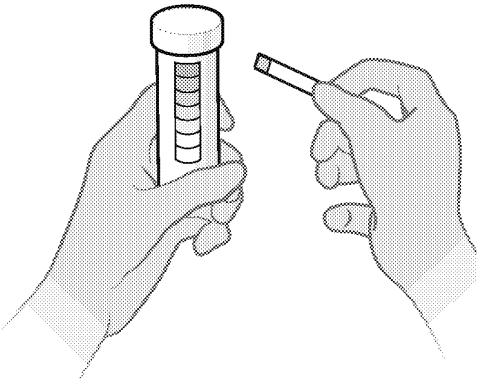
☐ 2 Then, remove the strip and shake any excess liquid from the test strip.



☐ 3 Determine the hydrogen peroxide concentration using the color key supplied with your test strips.

☐ 4 Document the hydrogen peroxide concentration according to your hospital's policies.

☐ 5 Determine whether the hydrogen peroxide concentration is acceptable and take action as described in the next step.



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3 Take action based on the hydrogen peroxide concentration

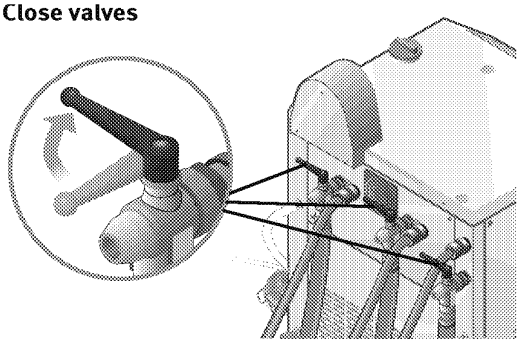
Acceptable concentration:
greater than or equal to 100 mg/L H_2O_2

There is no additional action to be taken other than to monitor the concentration daily.

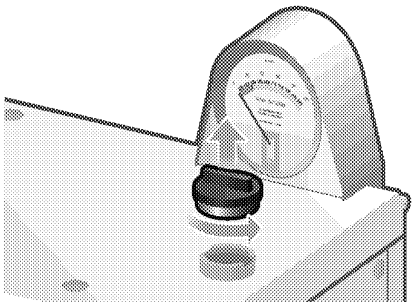
Unacceptable concentration:
less than 100 mg/L H_2O_2

Adjust hydrogen peroxide concentration according to adjustment steps below:

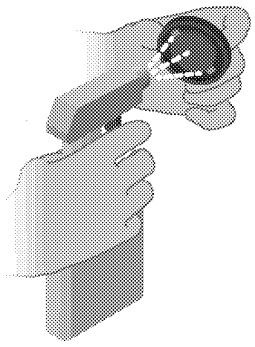
1. Make sure the circuit valves are closed, and any connected tubing is drained.



2. Turn the filler neck cap counterclockwise to remove.



3. Apply four sprays of disinfectant on the cap until all surfaces are wet, including the cap's underside and sealing surface.



Continue step on next page ►

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(Continued)
Unacceptable concentration: less than 100 mg/L H_2O_2

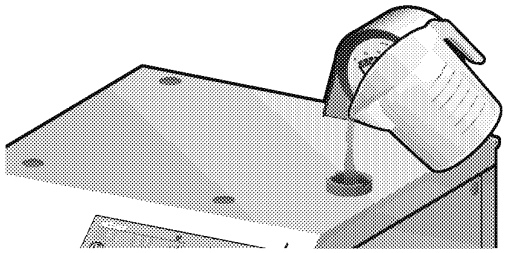
☐ 4 Wait for 5 minutes. Ensure that all surfaces remain wet with disinfectant during this time. Apply additional disinfectant if necessary.

Wipe all surfaces with a disinfectant wipe for 2 minutes to remove excess disinfectant.

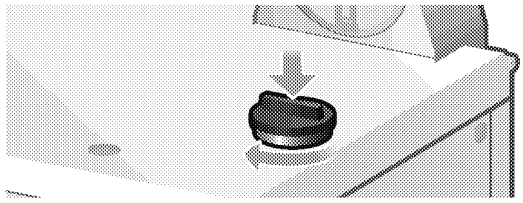
NOTE: You may proceed to the next step during the disinfectant's exposure time.

Wait for 5 minutes, then wipe off excess for 2 minutes

☐ 5 Pour 100 mL of medical grade 3% hydrogen peroxide into the tank.



☐ 6 Attach the filler neck cap and turn clockwise to secure.

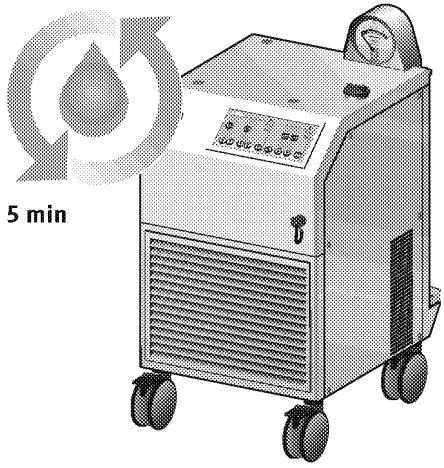


☐ 7 After adjusting the hydrogen peroxide concentration, mix the heater-cooler's solution:

- Attach short-circuit tubing between patient 1 inlet and cardioplegia inlet.
- Run cold cardioplegia pump for 5 minutes.
- Disconnect short-circuit tubing.

(See chapter 6.6 steps 4 and 5 for complete instructions on mixing).

The H_2O_2 adjustment procedure is now complete.



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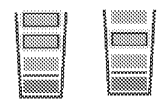
4 Make sure the water tanks are full

Important
Do not add volume to the tanks until you complete the hydrogen peroxide test and adjustment procedures.

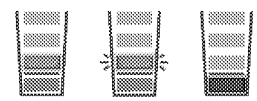
▶ 1 Determine if the water tank volume is acceptable by checking both circuit's water level displays.

- If the second green segments on both displays are illuminated, the volume is acceptable, and no action is needed.
- If the second green segments on either display are not illuminated, the volume is unacceptable. Add volume to the water tanks. Proceed to Step ▶ 2.

Acceptable volume
Cardioplegia or patient circuits



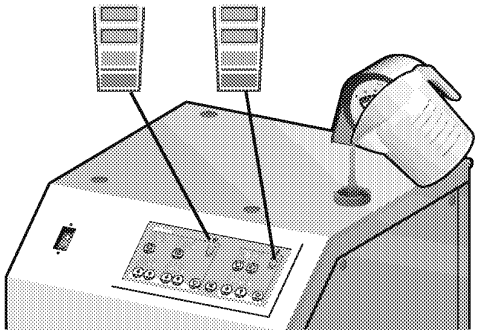
Unacceptable volume
Cardioplegia or patient circuits



▶ 2 If you need to add volume to the tanks:

- Prepare a mixture of hydrogen peroxide and filtered tap water at a ratio of 1:91. For example: 10 mL of hydrogen peroxide and 910 mL of filtered tap water
- Fill the water tanks with the mixture until the second green segments of both circuit water level displays light up.

1:91 mixture hydrogen peroxide to filtered tap water



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6.5.2 Monitoring the water for bacteria and NTM

Bacteria and NTM monitoring schedule

- At least once a month, monitor the tanks' water for bacteria and NTM.
- When you monitor the tanks for bacteria and NTM, do so when you are disinfecting the system. Take water samples before and after the disinfection procedures.

Important

- Samples can be stored in a refrigerator at temperatures from 2 °C to 8 °C. Do not store samples for more than 24 hours.
- Pay attention to hand hygiene and protective barriers by disinfecting your hands and using gloves.

Materials you will need:

- Sterile containers for bacteria sampling: 2x 50 mL
- Sterile containers for NTM sampling: 2x 50 mL or 1x 100 mL
- Disinfectant spray and/or wipes
- 1-2 collections bucket for drained water, each with at least 1 L volume.
  NOTE: You may drain the solution into the collection buckets or directly into floor drains.
- Supplies to identify and track samples based on your hospital's policies (e.g., sample labels and permanent markers)

Summary of steps you will complete in this section:

1. **Prepare to collect a water sample**
2. **Collect the sample**
3. **Disinfect the heater-cooler, then collect a second set of samples**
4. **Interpret the results**

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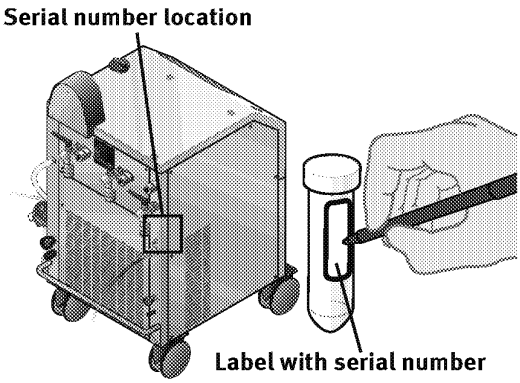
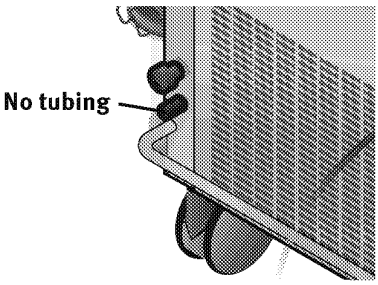
1 Prepare to collect a water sample

1 Label the samples with the serial number or internal identification number of the heater-cooler based on your hospital's policies.

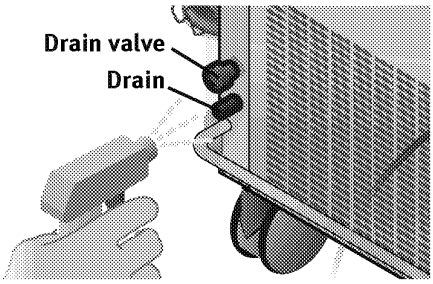


2 Disconnect any tubing connected to the patient drain.



3 Spray disinfectant on the patient circuit drain and patient circuit drain valve until wet, including the opening of the drain.

Wait for the exposure time specified by the disinfectant you are using.



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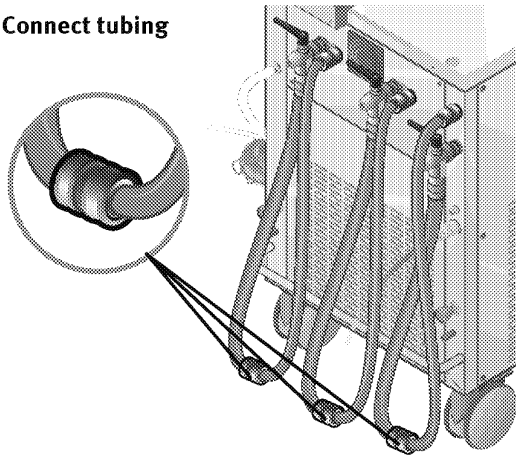
4 Disinfect the procedural tubing connectors and a suitable short-circuit connector (part number 73-300-160).

Important
Disinfect the connectors and fittings every time you make a connection according to chapter 6.3.2 and chapter 6.3.3.

5 Connect the procedural tubing between the circuits using the short-circuit connector.

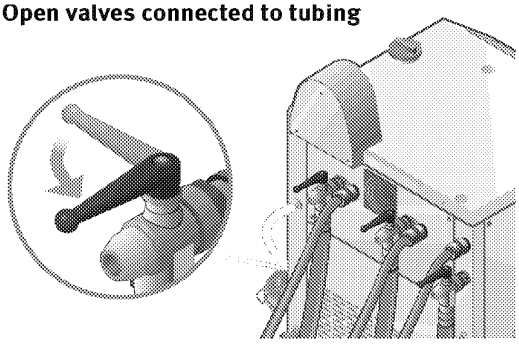
Connect tubing



Important
Do not connect tubing to any circuits not used during procedures.

6 On the back of the heater-cooler, for any circuits with tubing connected, turn the red levers counterclockwise to open the valves.

Open valves connected to tubing



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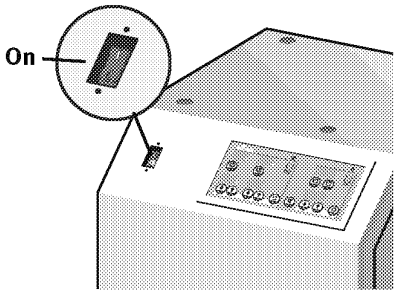
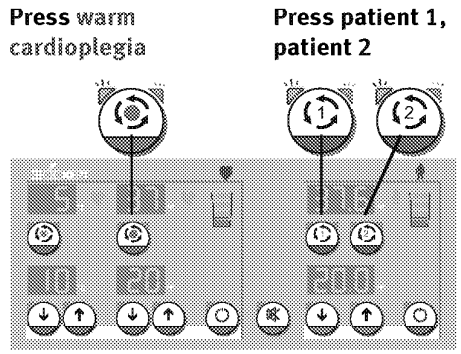
7 If the heater-cooler is powered off, press the mains power switch to power on the heater-cooler.

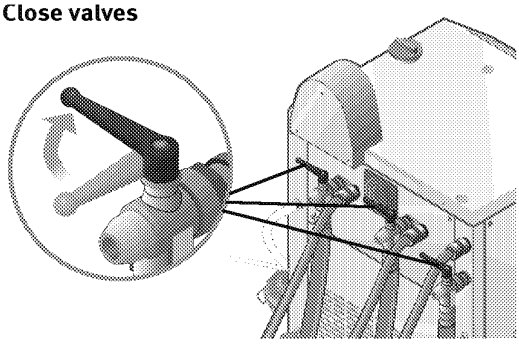


8 Start running the circuit pumps:
- Press the **warm cardioplegia** circuit Start/Stop button
- Press the patient 1 and patient 2 circuit Start/Stop buttons.

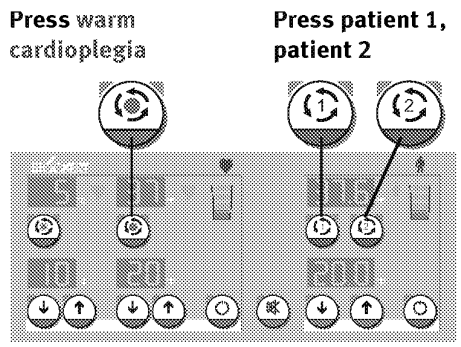
NOTE: Run all three circuits even if tubing is not connected.



9 After 5 minutes, turn the red valve levers clockwise to close the valves. Allow the circuit pumps to run until the tubing is drained.



10 Stop running the circuit pumps:
- Press the **warm cardioplegia** circuit Start/Stop button
- Press the patient 1 and patient 2 circuit Start/Stop buttons.



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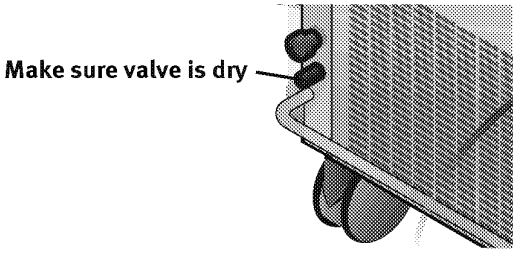
2 Collect the sample

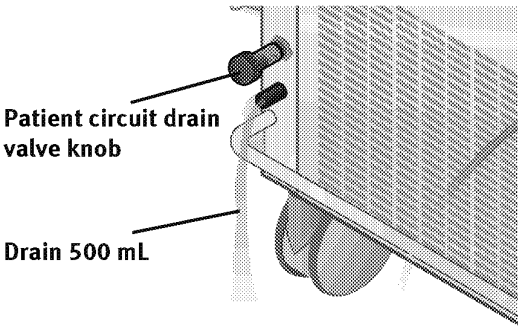
☐ 1 Check to make sure the disinfectant is completely dry. Do not take water samples until the disinfectant has completely dried.



Important
When draining the water tank, drain the solution into buckets or directly into floor drains.

☐ 2 Twist the patient circuit drain valve knob counter clockwise to fully open the patient circuit drain valve.

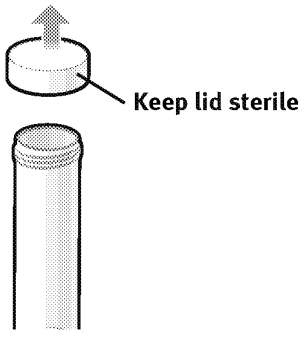
☐ 3 Drain the solution for **at least 5 seconds** and discard.



☐ 4 Keeping the lid of the sample container away from non-sterile surfaces, remove the lid from the sample container.

Do not place the lid on a non-sterile surface.

Do not touch the upper rim of the sample container.



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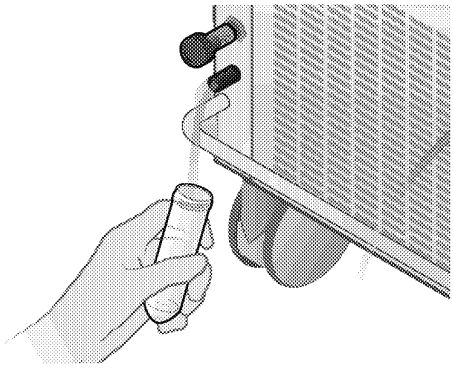
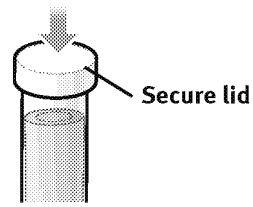
5 Before closing the drain valve, fill each sample container needed for the test you are running.

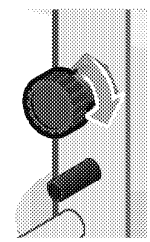
- **Bacteria check, every month:** Fill one 50 mL container.
- **NTM check, every month:** Fill two 50 mL containers, or one 100 mL container.



6 Secure the lid on each container.



7 Twist the patient circuit drain valve knob clockwise until the drain valve is fully closed.



3 Disinfect the heater-cooler, then collect a second set of samples

1 Disinfect the water circuits according to chapter 6.4.2.

2 Repeat this monitoring procedure (steps 1 and 2) to collect sample(s) after water circuit disinfection.

Important

If the water samples cannot be immediately forwarded to the testing laboratory, store the samples in a refrigerator at 2 °C to 8 °C for up to 24 hours.

Potential contract laboratory resources: Nelson Labs, NAMSA, MICROBAC, Toxikon, Microchem Laboratory, Eurofins Scientific.

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4 Interpret the results

Bacteria results

Determine whether the bacteria count is acceptable and take action as described below:

Acceptable bacteria count:	**Less than 100 CFU/mL** There is no additional action to be taken other than to monitor the bacteria count monthly.
Unacceptable bacteria count:	**Greater than or equal to 100 CFU/mL** **System may not be used.** Remove the system from service and analyze to determine possible causes. Contact your hygiene officer and your authorized service technician. LivaNova can provide an optional Deep Cleaning service for the system. Please contact your service technician or sales representative to request this service.

Continue step on next page ►

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NTM results

Determine whether the NTM count is acceptable and take action as described below:

Acceptable NTM count:	**Less than 1 CFU/100 mL** There is no additional action to be taken other than to monitor the bacteria count monthly.
Unacceptable NTM count:	**Greater than 1 CFU/100 mL** **System may not be used.** Remove the system from service and analyze to determine possible causes. Contact your hygiene officer and your authorized service technician. LivaNova can provide an optional Deep Cleaning service for the system. Please contact your service technician or sales representative to request this service.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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6.6 Changing the water and adding hydrogen peroxide

Water change schedule:

- At least once a week

Important

- Follow your hospital's policies regarding the use of personal protective equipment (PPE).
- Do not use de-ionized or reverse osmosis processed water. This water can cause deterioration of the refrigeration system.
- Change the water in the heater-cooler at least once a week, whether the heater-cooler is used or not.

Materials you will need

- Tap water filtered according to chapter 1.1.9.
- 1-2 collection buckets for drained water, each with at least 8 L volume.
  NOTE: Only required if you will not drain the solution directly into floor drains.
- At least 150 mL of medical grade 3% hydrogen peroxide solution that is not expired.
- A measuring cup with at least 150 mL volume for hydrogen peroxide.

Summary of steps you will complete in this section:

1. **Drain the water tanks**
2. **Prepare for filling**
3. **Fill the water tanks**
4. **Prepare for mixing**
5. **Mix the tank contents**

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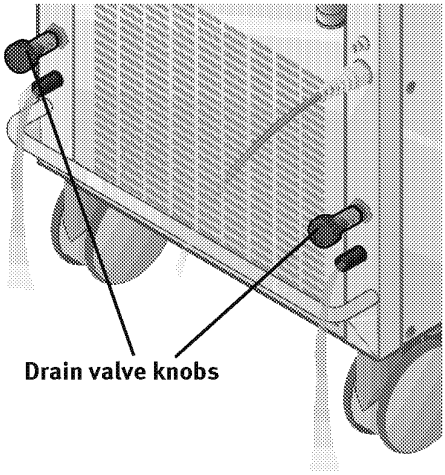
1 Drain the water tanks

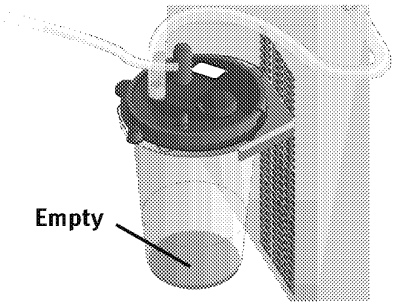
Important
When draining the water tanks, drain the solution into buckets or directly into floor drains.

1. Twist both drain valve knobs counterclockwise until the drain valves are fully open.
2. Drain the tanks until the solution stops flowing from the drain valves.
3. Twist both drain valve knobs clockwise until the drain valves are fully closed.
4. Dispose of the solution in accordance with your hospital's policies.



2 Prepare for filling

1. Make sure that the aerosol collection canister is empty. Refer to chapter 5.7.2 for instructions on emptying the aerosol collection canister.



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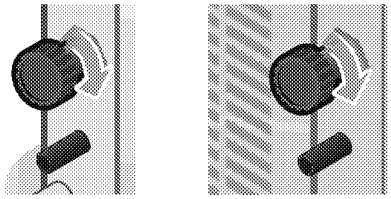
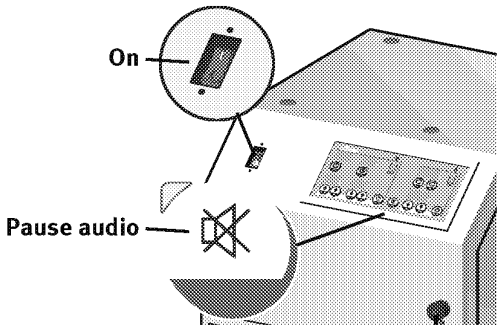
2 Make sure that both drain valves are fully closed so that water does not flow out when filling the water tanks.

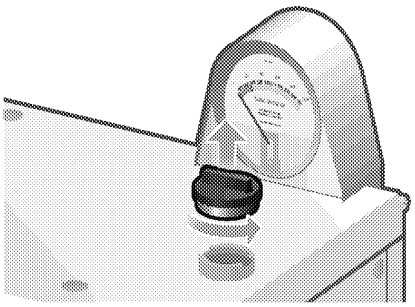


3 Press the mains power switch to power on the heater-cooler.

NOTE: A tone will sound indicating that the heater-cooler tanks are empty. You can press the Pause Audio button to pause the tone.



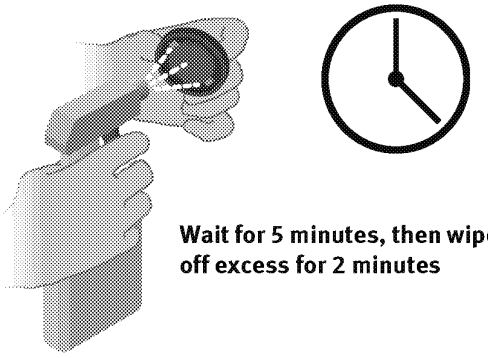
4 Turn the filler neck cap counterclockwise to remove.



5 Apply four sprays of disinfectant on the cap until all surfaces are wet, including the cap's underside and sealing surface.

6 Wait for 5 minutes. Ensure that all surfaces remain wet with disinfectant during this time. Apply additional disinfectant if necessary.

Wipe all surfaces with a disinfectant wipe for 2 minutes to remove excess disinfectant.



Wait for 5 minutes, then wipe off excess for 2 minutes

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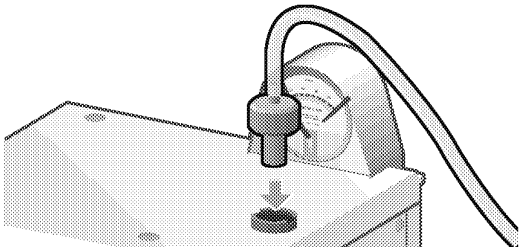
3 Fill the water tanks

Important

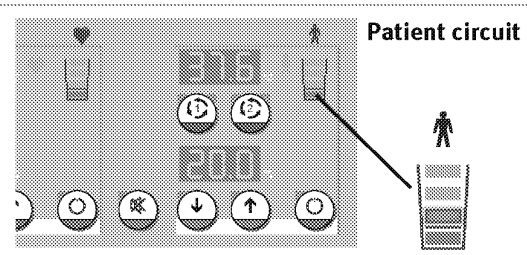
As you pour water into the single filler neck, all three tanks will fill in the following order:

- Cold cardioplegia tank
- Warm cardioplegia tank
- Patient tank

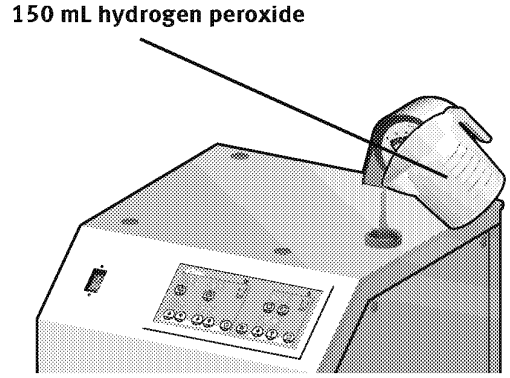
1 Begin filling the water tanks with **filtered tap water.**



2 Pause filling when the orange segment on the **patient circuit** water level display lights up.



3 Pour 150 mL of medical grade 3% hydrogen peroxide solution into the tank.



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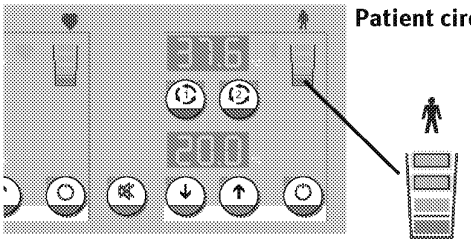
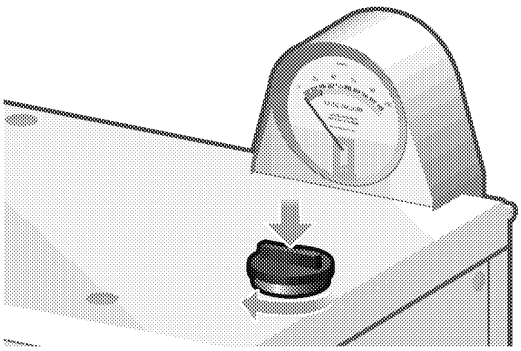
4 Continue filling the tanks with filtered tap water until the second green segment of the **patient circuit** water level display lights up.

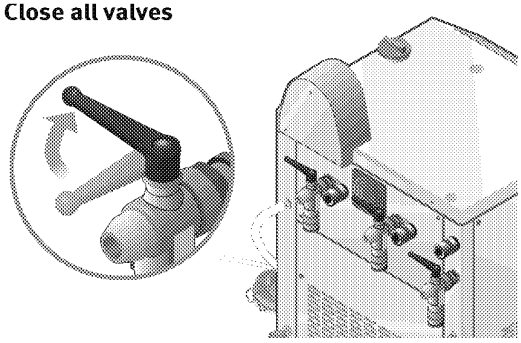


5 Attach the filler neck cap, and turn clockwise to secure.



4 Prepare for mixing

1 On the back of the heater-cooler, make sure that the three red valve levers are closed. Turn clockwise to close.



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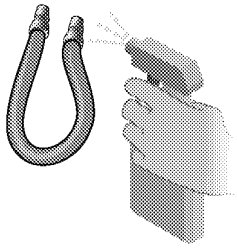
▶ 2 Apply four sprays of disinfectant on the short-circuit tubing's male connectors until all surfaces are wet.

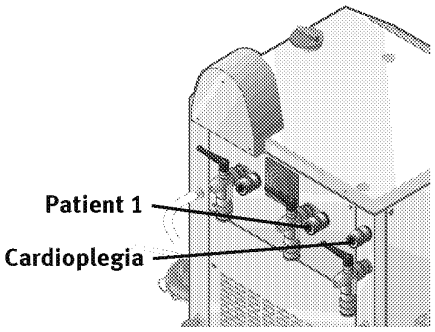


▶ 3 Wait for 5 minutes. Ensure that all surfaces remain wet with disinfectant during this time. Apply additional disinfectant if necessary.

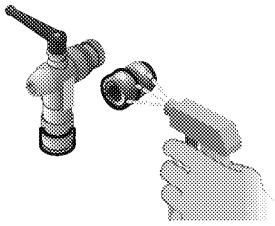
Important
Make sure that no liquids enter the housing of the heater-cooler when spraying disinfectant.

▶ 4 Conduct steps ▶ 5 and ▶ 7 on these tubing connectors:

- **Patient 1** inlet connector
- **Cardioplegia** inlet connector



▶ 5 Apply four sprays of disinfectant on the exterior of the female connector. Push and hold the quick release ring back and apply four sprays of disinfectant to the interior of each connector.



▶ 6 Wait for 5 minutes. Ensure that all surfaces remain wet with disinfectant during this time. Apply additional disinfectant if necessary.

Wipe all surfaces with a disinfectant wipe for 2 minutes to remove excess disinfectant.

Wait for 5 minutes, then wipe off excess for 2 minutes

Continue step on next page ▸

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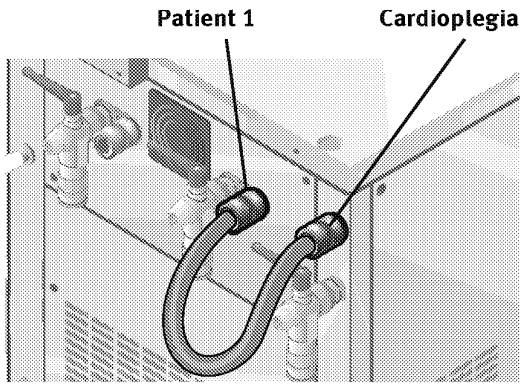
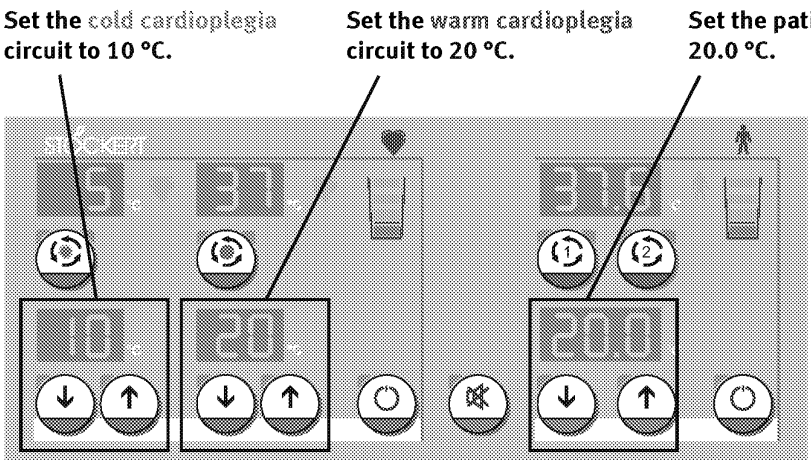
7 Connect the short-circuit tubing between the cardioplegia circuit inlet and the patient 1 circuit inlet.



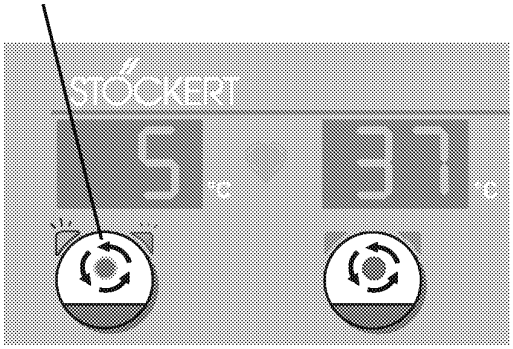
8 To avoid triggering a high temperature warning while mixing:



5 Mix the tank contents

1 Press the cold cardioplegia circuit Start/Stop button to start mixing.

NOTE: The green LEDs will flash alternately to indicate the circuit is running.



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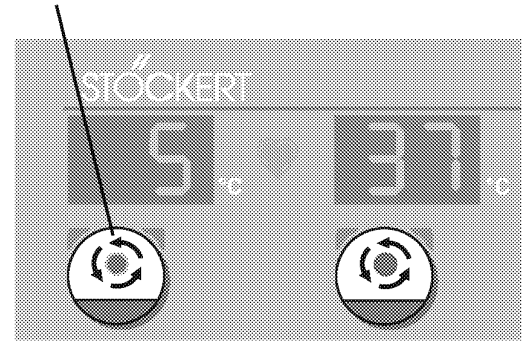
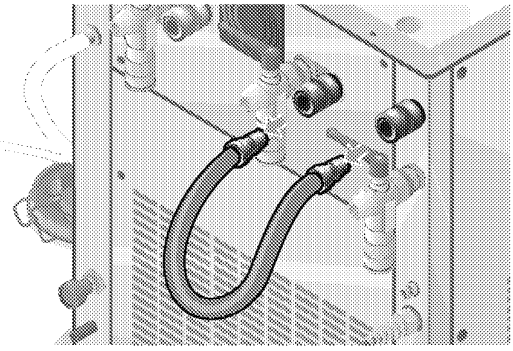
▶ 2 After 5 minutes, press the cold cardioplegia circuit Start/Stop button again to stop mixing.



▶ 3 Disconnect the short-circuit tubing between the cardioplegia circuit inlet and the patient 1 circuit inlet.



You can now connect the procedural tubing and use the heater-cooler.

Refer to chapter 4.3 for instructions on selecting and connecting the tubing.

Important

Check the heater-cooler's hydrogen peroxide concentration daily, even if the heater-cooler is not in use. Daily checks must be performed before heater-cooler use. Refer to chapter 6.5.1 for instructions on checking the hydrogen peroxide concentration.

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6.7 Preparing the heater-cooler for storage

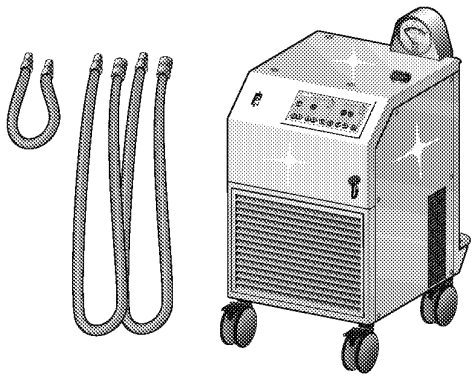
Important
Disinfect the heater-cooler every 14 days during storage.

Summary of steps you will complete in this section:

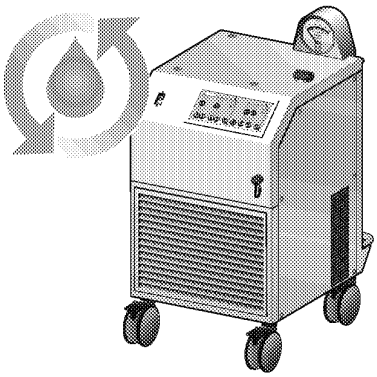
1. **Clean and disinfect the entire system**
2. **Make sure all tanks are drained**
3. **Disconnect and store all tubings**

1 Clean and disinfect the entire system

▷ 1 Clean and disinfect external surfaces, connectors, and fittings according to chapter 6.3.



▷ 2 Disinfect the water circuits according to chapter 6.4.



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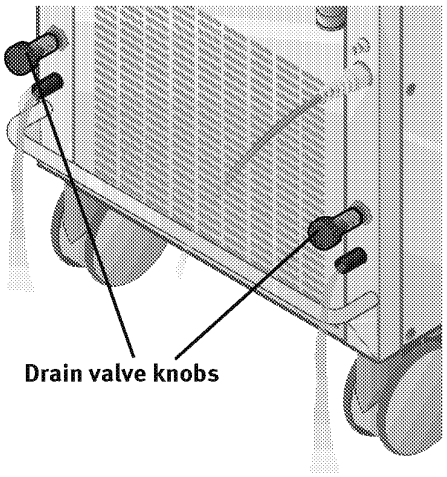
2 Make sure all tanks are drained

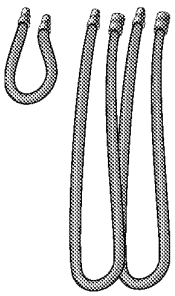
Important
When draining the water tanks, drain the solution into buckets or directly into floor drains.

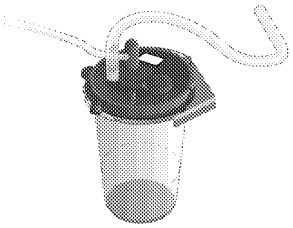
1. Twist both drain valve knobs counterclockwise until the drain valves are fully open.
2. Drain the tanks until the solution stops flowing from the drain valves.
3. Twist both drain valve knobs clockwise until the drain valves are fully closed.
4. Dispose of the solution in accordance with your hospital's policies.



3 Disconnect and store all tubings

1. Disconnect all tubings attached to the heater-cooler. This includes:
   - Short-circuit tubing
   - Procedural tubing
   - Aerosol collection set tubing
2. Store all tubings such that:
   - They are in a dry location that is free of dust
   - They are in an orientation that will enable any residual water to drain





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6.8 Cleaning the heater-cooler interior

Important

Clean the interior of your heater-cooler regularly or if the fan behind the front ventilation grill is running too quickly and/or too loudly. Cleaning the interior of the heater-cooler will eliminate any dust that has collected inside the heater-cooler and has inhibited air circulation.

If excessive dirt is present or if the non-accessible interior surfaces require cleaning, contact your authorized service technician.

Summary of steps you will complete in this section:

1 **Disconnect from the power supply**

2 **Clean the accessible areas behind the front grill**

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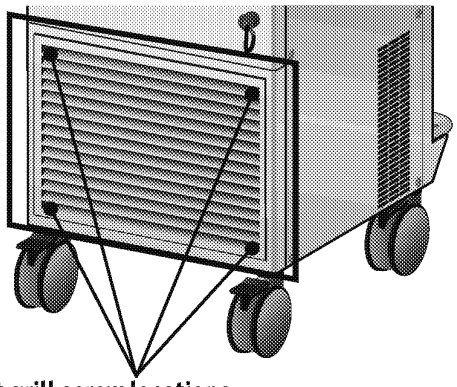
1 Disconnect from the power supply

- Disconnect the heater-cooler's power cable from the power supply outlet.

2 Clean the accessible areas behind the front grill

1. Unscrew the four screws on the front ventilation grill.
2. Remove the front ventilation grill only. Do not remove the side and rear ventilation panels.
3. Using a vacuum cleaner or pressurized air, clean the accessible areas of the heater-cooler's interior.
4. Reattach the ventilation grill and secure the four screws.


Front grill screw locations

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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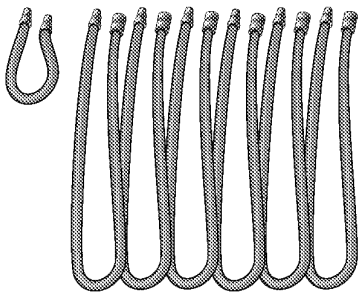
6.9 Replacing the tubings once a year

1 Replace the procedural tubing at least once a year

- Use only tubing that is approved for use with the heater-cooler (i.e. part number 75-510-218).



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7 Technical specifications

This chapter provides technical specifications including information about the heater-cooler's physical characteristics, labeling, part numbers, accessories, and electromagnetic compatibility. This chapter also includes warranty information.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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7.1 Specifications

7.1.1 Dimensions and weights

Heater-cooler

Width	500 mm
Height	975 mm
Depth	680 mm
Weight (when empty)	100 kg
Max. weight of equipped device	125 kg

7.1.2 Operating, storage and transport conditions

Operating conditions

Operating temperature	10 °C through 30 °C Note: Cooling performance might be reduced at operating temperatures greater than 25 °C.
Relative humidity	30% through 75%
Operating altitude (atmospheric pressure)	0 ... 2,000 m (700 hPa ... 1,060 hPa)

Storage conditions

Storage temperature	-10 °C through 60 °C
Relative humidity	0% through 80%
Atmospheric pressure	500 hPa through 1,060 hPa (7.3 psi through 15.4 psi)

Transport conditions

Transport temperature	-10 °C through 60 °C
Relative humidity	0% through 85%
Atmospheric pressure	500 hPa through 1,060 hPa (7.3 psi through 15.4 psi)

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7.1.3 Electrical specifications

Heater-cooler

Drip-proof	IPX1		
Input current	16 A 13 A for devices with a BS 1363 (type G) mains plug		
Input voltage (variants are device-specific)	Mains Voltage, Nominal (V)	Mains Frequency, Nominal (Hz)	Maximum Current Draw (A)
	120[1]	60	16
	127	60	16
	200	50	16
	200	60	16
	208[1]	60	16
	220	50	13[2] / 16
	220	60	13[2] / 16
	230	50	13[2] / 16
	230	60	13[2] / 16
	240	50	13[2] / 16
	240	60	13[2] / 16
Allowed voltage tolerance	± 10% max		
Fuse protection	T6A3 250 V (serviced by authorized service technicians only)		

1 Available in the U.S.
2 Heater-coolers utilizing a BS 1363 (Type G) mains plug are limited to 13 A

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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7.1.4 General performance data

General data

Heating element performance (2 x patient, 1 x cardioplegia)	3 x 650 W (input voltage 120/127 V ~) 3 x 900 W (input voltage 200 V ~) 3 x 1,000 W (input voltage 200/208 V ~) 3 x 1,150 W (input voltage 220 V ~) 3 x 1,250 W (input voltage 230 V ~) 3 x 1,350 W (input voltage 240 V ~)
Cooling performance	› 1,500 W at an ambient and tank temperature of 20°C
Noise level at 1 m	≤ 63 dB (A)

Volume and flow

Minimum level patient tank	4.5 L (11.6 L total tank volume)
Maximum level patient tank	6.5 L (13.8 L total tank volume)
Water flow patient circuits	13.0 - 16.4 liters per minute (circuit outlet) 10.8 – 12.6 liters per minute (5 m + 5 m circuit)
Water flow cardioplegia circuit	7.5 – 9.8 liters per minute (circuit outlet) 7.4 – 8.7 liters per minute (5 m + 5 m circuit)
Water pressure in patient circuits	0.63 – 0.79 bar
Water pressure in cardioplegia circuits	0.65 – 0.72 bar

Temperature ranges

Normal range patient circuits	2.0 °C through 41.0 °C ± 0.5 °C
Normal range cool cardioplegia circuit	2 °C through 10 °C ± 2 °C
Normal range warm cardioplegia circuit	15 °C through 41 °C ± 1 °C

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Cleaning and disinfection process

Disinfection Effectiveness Devices were inoculated with at least 10^6 CFU/ml or greater levels of organisms prior to executing the disinfection process described in chapter 6.4 of the operating instructions.	Test devices achieved the following results: • **P. aeruginosa**: 99.9999% reduction • **M. chimaera**: 99.9% reduction • **M. avium**: 99.9% reduction
Water Preservation Effectiveness Devices were studied over a 58 week period as follows: • Positive controls which did not adhere to chapter 6.6 of the operating instructions (e.g., no use of hydrogen peroxide). • Test devices which did adhere to chapter 6.6 of the operating instructions.	Test devices achieved the following results: • **Heterotrophic Plate Counts**: ≤ 100 (CFU) per 1 ml of water • **M. chimaera**: < 1 CFU per 100 ml of water • **P. aeruginosa**: < 1 CFU per 100 ml of water **Biofilm formation**: Devices maintained per the labeling showed statistically lower viable plate count and qualitatively less surface microbial adhesion than those not maintained per the labeling.

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Aerosol collection set effectiveness

Physical Assay Devices with the Aerosol Collection Set were studied using aerosol particle sizing (APS) methodology to determine the effectiveness of the ACS and whether it remains functional after 7 days of continued twenty-four (24) hour simulated use.	Aerosol Collection Sets reduced particle emission in excess of 99.0% during the water warming phase and water circuit valve closure phase in the following tests: • **Vacuum Range Testing**: When tested at a range of negative pressures inside the device from 50 Pa to approximately 150 Pa. • **ACS Functional Testing**: Throughout the 7-day use period.
Microbiological Testing Devices with the Aerosol Collection Set were inoculated with at least 10^6 CFU/ml of M. chimaera to determine the effectiveness of the ACS in reducing microbial aerosol emissions. Testing was performed to assure the ACS was effective for 7 days of continued use.	Aerosol Collection Sets reduced NTM emission in excess of 99.9% in the following tests: • **Vacuum Range Testing**: When tested at a range of negative pressures inside the device from 50 Pa to approximately 150 Pa. • **ACS Functional Testing**: Throughout the 7-day use period. • **Filter Testing** also demonstrated a › 99.9% reduction of aerosols after passing through the ACS.

Note: To mitigate the potential risks of aerosolization during use:

1. Always use the Aerosol Collection set;
2. Confirm that the heater-cooler vacuum gauge reads greater than 50 Pa with full open vacuum flow applied;
3. Do not empty the external circuits until the patient has been discharged from the OR environment;
4. Always close the external circuits one valve at a time in the order specified.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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7.1.5 Information about global warming potentials

The cooling circuit of the heater-cooler is filled with a CFC-free HFC-(hydrofluorocarbons) refrigerant. Refer to the device label and chapter 7.2 for further information about the type and volume of the refrigerant.

Global warming potentials

Refrigerant	R-134/HFC-134a The mixture of the refrigerant may vary.
GWP	1,300 GWP According to IPCCIII (2001/Appendix I): Baseline data in EU F-gas regulation
Active life span	100 years According to IPCCII (1996) source document for the Kyoto protocol

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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7.2 Icons and labels

7.2.1 Icons and designations on the nameplates

Regulatory symbols and quality marks

CE 0123	This device complies with the requirements of EU Directive 93/42/EEC of the European Council for Medical Devices.
TÜV SÜD C US	Only applies in the U.S.A. and Canada: Certification according to NRTL for Canada (C) and the U.S.A. (US)
	Only applies in Russia: Certification according to GOST

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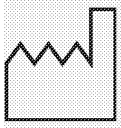
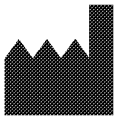
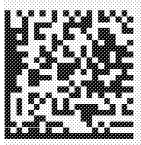
Additional icons and designations

	Purchase order number
	Serial number
	Date of manufacture
	Manufacturer
	Unique Device Identifier (UDI)
125 kg	Maximum permitted load: A primed and filled heater-cooler must not exceed a total weight of 125 kg.
Rx ONLY	Only applies in the U.S.A.: Sale (and prescription) is restricted to physicians
	Degree of protection against electrical shock: type B
	Protection class I
IPX1	Drip-proof: protected against vertically falling water drops
V ~	Voltage (alternating current)
Hz	Frequency
A	Ampere
kPa	Kilopascal

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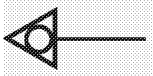
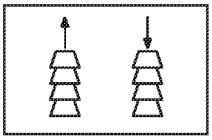
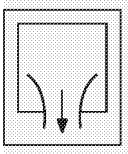
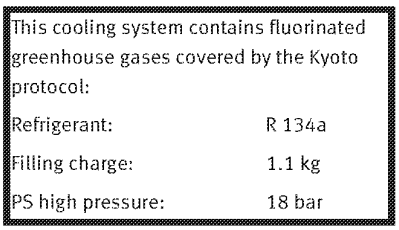
7.2.2 Icons and additional labels on the housing

	Follow instructions for use
	General warning sign
	Potential equalization point
	Outlets and inlets of the patient circuits and cardioplegia circuit
	Drain valve of the patient circuits Drain valve of the cardioplegia circuit
	This cooling system contains fluorinated greenhouse gases covered by the Kyoto protocol: Refrigerant (R 134a) (hydrofluorocarbons) Filling charge Pressure switch high pressure

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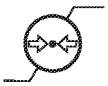
7.2.3 Icons on the packaging

	Fragile item Packaged item is extremely sensitive. Handle with care.
	This side up Always keep in upright position.
	Keep dry Keep out of precipitation.
	Temperature limitation Transport and store within the permissible temperature range.
	Relative humidity limitation Transport and store within the permissible relative humidity range.
	Atmospheric pressure limitation Transport and store within the permissible atmospheric pressure range.

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7.3 Part numbers

Refer to chapter 6 in these operating instructions for the cleaning and disinfection instructions of reusable products manufactured by LivaNova.

Additionally, refer to chapter 6 for disposal instructions for disposables products manufactured by LivaNova.

For other products that are delivered with separate instructions for use, refer to the manufacturer's instructions on the cleaning and disinfection of reusable accessories and/or for the disposal of specific single-use accessories.

Heater-Cooler System 3T and electrical components

Part name	Part number	Manufacturer	Use type
Heater-Cooler System 3T (240 V ~ / 60 Hz)	16-02-81	LivaNova	Reusable
Heater-Cooler System 3T (208 V ~ / 60 Hz)	16-02-82	LivaNova	Reusable
Heater-Cooler System 3T (120 V ~ / 60 Hz)	16-02-85	LivaNova	Reusable
CAN cable for connection to the S5/C5 System (including blocking ferrite)	45-12-16	LivaNova	Reusable
Potential equalization cable (5 m)	45-10-50	LivaNova	Reusable

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Other parts

Part name	Part number	Manufacturer	Use type
Tubing connector ½", 90° angle	16-10-17*	LivaNova	Reusable
Tubing connector ½", straight	73-300-019*	LivaNova	Reusable
Water tubing ½", blue (25 m)	75-510-218*	LivaNova	Reusable
Hansen coupling ⅜" for oxygenator, straight, with ½" tubing connector	73-300-089*	LivaNova	Reusable
Hansen coupling ⅜" for oxygenator, 90° angle, with ½" tubing connector	73-300-090*	LivaNova	Reusable
Short circuit tubing bridge for ⅜" Hansen couplings	73-300-160*	LivaNova	Reusable
3T Aerosol Collection Set	050900100	LivaNova	Disposable with specified use period
¼" Vacuum extension line with connector	050900111	LivaNova	Disposable with specified use period
Holder for aerosol collection container	005-21-0039	LivaNova	Reusable

* Applied part according to IEC 60601-1. An applied part is that part of the medical electrical equipment (ME equipment) which in normal use necessarily comes into physical contact with the patient. When the Heater Cooler System 3T is used during an extracorporeal circulation blood is exposed to temperatures from 2°C to 41°C. To prevent damage to the blood by hemolysis, denaturation of proteins and activation of triggers of inflammatory response the temperature during heating shall not exceed 43°C.[1] The blood's resistance to cold temperatures, especially that of the red blood cells, is much higher. Temperatures of 1°C to 4°C are frequently used for blood storage in blood banks.[2]

1 Poder TG, Nonkani WG, Tsakeu Leponkouo É. Blood Warming and Hemolysis: A Systematic Review With Meta-Analysis. Transfus Med Rev 2015;29:172-80
2 Yoshida T, Prudent M, D'Alessandro A. Red blood cell storage lesion: causes and potential clinical consequences. Blood Transfus 2019;17:27-52

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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7.4 Tested accessories

Compatibility of the Heater-Cooler System 3T with the products listed in the table below has been tested by LivaNova Deutschland GmbH and is thus guaranteed.

The products listed below must be used in compliance with the separate instructions for use provided by the manufacturer. Please refer to the specific products' separate instructions for use for details on the cleaning and disinfection of reusable accessories and/or for the disposal of specific single-use accessories.

Part name	Manufacturer	Use type
Pall-Aquasafe water filter	Pall	Disposable with specified use period
3T Aerosol Collection Set	LivaNova	Disposable with specified use period
¼" Vacuum extension line with connector	LivaNova	Disposable with specified use period

7.5 Warranty

The contractually agreed warranty conditions apply.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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7.6 Information on electromagnetic compatibility (EMC) according to IEC 60601-1-2 (4th edition)

7.6.1 Guidance and manufacturer's declaration

Medical electrical equipment needs precautions regarding electromagnetic compatibility and has to be installed and put into service according to the EMC information provided in the following guidance and the manufacturer's declaration.

Portable and radio frequency (RF) equipment can affect medical electrical equipment.

Essential performance characteristics of the Heater-Cooler System 3T

Heating and cooling of water:

- Patient tank: 2.0 °C to 41.0 °C
- Cold cardioplegia tank: 2 °C to 10 °C
- Warm cardioplegia tank: 15 °C to 41 °C

The Heater-Cooler System 3T can have a performance degradation, but the basic safety and essential performance will not be influenced.

If the Heater-Cooler System 3T is operated outside the EMC environment specified here, basic safety as well as essential features might fail. In this case, the operator should be aware of a possible risk to the patient.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Guidance and manufacturer's declaration – electromagnetic emission

The Heater-Cooler System 3T is intended for use in the professional healthcare facility environment specified below. In order to prevent adverse advents to the patient and operator due to electromagnetic disturbances, the Heater-Cooler System 3T must not be operated outside its intended EMC environment. Furthermore, the Heater-Cooler System 3T must not be operated if the enclosure, cables or measures for electromagnetic shielding are damaged.

Table 1: Emission limits

Phenomenon	Professional healthcare facility environment	Electromagnetic environment – guidance
Conducted emissions	CISPR 11	Note: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR11 classB is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the equipment.
Radiated RF emissions	CISPR 11	
Harmonic distortion	IEC 61000-3-2	
Voltage fluctuations and flicker	IEC 61000-3-3	

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Guidance and manufacturer's declaration – electromagnetic immunity

The Heater-Cooler System 3T is intended for use in the professional healthcare facility environment specified below. In order to prevent adverse advents to the patient and operator due to electromagnetic disturbances, the Heater-Cooler System 3T must not be operated outside its intended EMC environment. Furthermore, the Heater-Cooler System 3T must not be operated if the enclosure, cables or measures for electromagnetic shielding are damaged.

Table 2: Enclosure port

Phenomenon	**Basic EMC standard or test method**	**Immunity test levels** **Professional healthcare facility environment**
Electrostatic discharge	IEC 61000-4-2	± 8 kV contact ±2 kV, ±4 kV, ±8 kV, ± 15 kV air
Radiated RF EM fields	IEC 61000-4-3	3V/m 80 MHz – 2.7GHz 80% AM at 1kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See Table 3
Rated power frequency magnetic fields	IEC 61000-4-8	30A/m 50 Hz or 60Hz

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Test specifications for enclosure port immunity to RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380–390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430–470	GMRS 460 FRS 460	FM ±5 kHz deviation 1 kHz sine	2	0.3	28
710 745 780	704–787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
810 870 930	800–960	GSM 800/900 TETRA 800 iDEN 820 CDMA 850 LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
1720 1845 1970	1700-1990	GSM 1800 CDMA 1900 GSM 1900 DECT LTE Band 1,3,4, 25 UMTS	Pulse modulation 217 Hz	2	0.3	28
2450	2400-2570	Bluetooth WLAN 802.11 b/g/n RFID 2450 LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9

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Note: If necessary to achieve the immunity test level, the distance between the transmitting antenna and the Heater-Cooler System 3T may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

Note: Portable radio frequency (RF) communications equipment (including peripherals such as antenna cables and external antennas) as well as cables specified by the manufacturer should be used no closer than 30 cm to any part of the Heater-Cooler System 3T. Otherwise this could result in performance degradation of this equipment.

Table 4: Input AC power port (1 & 2)

Phenomenon	**Basic EMC standard**	**Immunity test levels** **Professional healthcare facility environment**
Electrical fast transients/ bursts	IEC 61000-4-4	± 2 kV 100 kHz repetition frequency
Surges Line-to-line	IEC 61000-4-5	± 0.5 kV, ± 1 kV
Surges Line-to-ground	IEC 61000-4-5	± 0.5 kV, ± 1 kV, ± 2 kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V 0.15 MHz – 80 MHz 6V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz
Voltage dips	IEC 61000-4-11	0% U_T; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
		0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0°
Voltage interruptions	IEC 61000-4-11	0% U_T; 250/300 cycle

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 5: Patient coupling port

Phenomenon	Basic EMC standard	Immunity test levels Professional healthcare facility environment
Electrostatic discharge	IEC 61000-4-2	± 8 kV contact ±2 kV, ±4 kV, ±8 kV, ± 15 kV air
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V 0.15 MHz – 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz

Table 6: Signal input ports/signal output ports

Phenomenon	Basic EMC standard or test method	Immunity test levels Professional healthcare facility environment
Electrostatic discharge	IEC 61000-4-2	± 8 kV contact ±2 kV, ±4 kV, ±8 kV, ± 15 kV air
Electrical fast transients/ bursts	IEC 61000-4-4	± 1 kV 100 kHz repetition frequency
Surges Line-to-ground	IEC 61000-4-5	±2 kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V 0.15 MHz – 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz

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The emissions limits, IEC 60601 test levels and tests specified by this collateral standard do not address electromagnetic compatibility of electrical equipment at very close distances.

Unless all electrical equipment is compatible with respect to both electric fields and magnetic fields at very close distances over the entire range of expected frequencies, separation is prudent.

If it is essential to use the Heater-Cooler System 3T very close to other electrical equipment, it is prudent to determine, by observation, if the performance of either product is affected by unintended electromagnetic coupling. If this happens, the user is encouraged to try to correct the interference by one or more of the following measures:

- re-orient or relocate the equipment
- increase the amount of space between the equipment
- connect the equipment to separate power sources

Note: If the Heater-Cooler System 3T is operated directly next to other high frequency (HF) surgical devices such as electrocautery and diathermy, this can lead to EMC interference and potentially to:

- Display of wrong data or state (temperature, pump or water level status)
- Remote connection down or disturbed
- Components (partly) damaged
- Electrical safety impaired

The use of the Heater-Cooler System 3T along with HF surgical devices must be observed with increased attention. When unusual behavior is observed, please follow the measures listed above to increase the distance between equipment and cables and restart the device.

In case an error code is displayed, refer to the troubleshooting section in chapter 8.1.4 to identify the impaired functionality and how to restore it.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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7.6.2 Technical description

Note: The use of cables other than those specified below may result in increased emissions or decreased immunity of the heater-cooler and/or the heart-lung machine.

For detailed information about cables that may be used for the overall system, please refer to the relevant HLM operating instructions.

Use of cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Cables/sensors	Length	Part number
Potential equalization cable	5 m	45-10-50
CAN connection cable for the S5/C5 System	6 m	45-12-16

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8 Troubleshooting

This chapter provides troubleshooting for warnings and error codes you might see on the control panel, and troubleshooting related to the aerosol collection set.

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8.1 Control panel warnings and error code displays

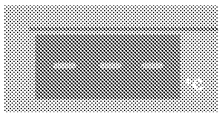
WARNING

Do not use the heater cooler if the control panel is flashing. This means the heater-cooler is in service mode. Power off the heater-cooler and power it on again to exit service mode.

NOTE: LivaNova recommends documenting all maintenance procedures and any operating failures in a medical device log regardless of local regulations. Provide this information to LivaNova when they perform service activities.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

8.1.1 General errors

Display	Possible cause(s)	Effects	Corrective measures
Display is dark	• Defective fuse D 31 (F3) • Defective mains transformer • Defective power pack • Ring main to the display drivers defective • Control system not working	Affected circuit cannot be operated	Have the heater-cooler checked by your service technician as soon as possible.
Three dashes on one of the actual temperature indicator 7-segment displays 	None	Incorrect or no actual temperature measurement. The affected circuit will not function.	Have the heater-cooler checked by your service technician as soon as possible.

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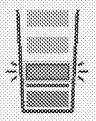
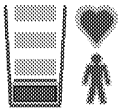
8.1.2 Low water level display

NOTE: Refilling the water tanks to maximum water level will have a brief influence upon the actual temperature of all circuits (dependent on the temperature of the refilled water).

Display	Possible cause(s)	Effects	Corrective measures
Water level display's orange segment blinks. 	Preliminary stage of low water level.	This preliminary warning has no direct effect on operation.	Refill solution as quickly as possible. A further decrease of the water level will stop the water circuits.
The water level display's red segment lights up and an audible tone sounds. The corresponding circuit's symbol flashes. 	The minimum water level has been reached.	The corresponding circuit's pump stops.	Refill solution immediately. The water circuit must be restarted manually.

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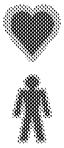
8.1.3 High temperature display

Display	Possible cause(s)	Effects	Corrective measures
The symbol of the corresponding patient circuit lights up and an audible tone sounds.	Maximum deviations between the patient tank's temperature and the water temperature during heating/cooling have been exceeded.	The pumps of the corresponding circuit stop.	You can keep the water circuit running (if necessary) by continuously pressing the corresponding Circuit Start/Stop button. You may wait until the deviation drops within the normal tolerance range again. Then, start the pumps again.
The symbol of the corresponding circuit lights up and an audible tone sounds.  The actual value temperature display shows 41 °C or more.	• Temporary temperature deviation during operation. • Excess temperature, defective temperature control.	The pumps of the corresponding circuit stop.	• Wait a short time until the temperature stabilizes at its set temperature, restart the pumps. • You may re-operate the circuit shortly by opening the overflow valve, allowing the water of the corresponding circuit to run out and by refilling it with cold water. However, the temperature control is out of order; for this reason this solution is only suitable for an interim period and if no replacement unit is available. • Contact your service technician and do not use the heater-cooler until repaired.

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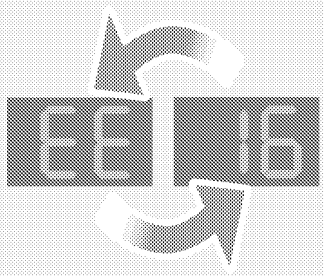
8.1.4 Error code displays

An error code consists of a series of the capital letter “E” followed by a two-digit number. An error code is usually displayed in the Set Temperatures display of the circuit in which the error has occurred and will stop the function of that circuit. Some error codes are associated with failures affecting all circuits. If such a failure has occurred, the device stops functioning and the corresponding error code is displayed in the Set Temperatures display of the patient circuit.

How an error code is displayed

Display	Effects
“EE(E)” flashes on one or several 7-segment displays, alternately with an error code. Example: 	Depending on which circuit the error code is displayed in and depending on the error code number, the error has an impact on the function of the respective circuit or on the entire heater-cooler.

Important

During priming, E08, E19, and E23 error codes are normal: During priming, if you receive error code E08 on the cold cardioplegia circuit display and E19 and E23 on the patient circuit displays, this is normal. These errors appear because air is still in the tubing system (see the full list of error codes below for the exact error code definition). The errors will be resolved once you complete the priming process.

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How to resolve an error code:

To try to clear an error code, perform a “cold start” by powering the heater-cooler off for at least 10 seconds and then powering it back on.

- If the error code is cleared, you may complete the current procedure, but LivaNova strongly recommends the heater-cooler be taken out of service and checked by an authorized service technician as soon as possible.
- If the error code persists, there is a defect and the heater-cooler should not be used. Notify your authorized service technician as soon as possible if you receive error codes other than those present during priming (E08, E19, and E23). All other error codes require attention from an authorized service technician.

Full list of error code numbers

Display	Description of error cause
E00	• Short circuit at control temperature sensor(s) • Short circuit at warm cardioplegia/cold cardioplegia/patient tank
E01	• Interruption at control temperature sensor(s) • Interruption at warm cardioplegia/cold cardioplegia/patient tank
E02	• Short circuit at safety temperature sensor(s) • Short circuit at warm cardioplegia/cold cardioplegia/patient tank
E03	• Interruption at safety temperature sensor(s) • Interruption at warm cardioplegia/cold cardioplegia/patient tank
E04	The temperature difference between the control and safety systems is too great in one or more tanks (warm cardioplegia tank, cold cardioplegia tank, patient tank).
E05	Power consumption is too low. Pump might not start. The affected component will vary depending on which display presents the error: • Patient tank display: stirring mechanism • Cold cardioplegia display: cold cardioplegia pump • Warm cardioplegia display: warm cardioplegia pump
E06	Pump (stirring mechanism) uses too much power. The affected component will vary depending on which display presents the error: • Patient tank display: stirring mechanism • Cold cardioplegia display: cold cardioplegia pump • Warm cardioplegia display: warm cardioplegia pump

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Display	Description of error cause
E07	Pump (stirring mechanism) is blocked. The affected component will vary depending on which display presents the error: • Patient tank display: stirring mechanism • Cold cardioplegia display: cold cardioplegia pump • Warm cardioplegia display: warm cardioplegia pump
E08	• Pump (stirring mechanism) is not immersed in liquid. The affected component will vary depending on which display presents the error: o Patient tank display: stirring mechanism o Cold cardioplegia display: cold cardioplegia pump o Warm cardioplegia display: warm cardioplegia pump • There is still air in the external circuit • Incorrect pump configuration of one or more tanks (warm cardioplegia tank, cold cardioplegia tank, patient tank)
E09	The set temperatures of the control system and safety system are not identical. This error can apply to one or more tanks (warm cardioplegia tank, cold cardioplegia tank, patient tank).
E16	Patient circuit 1 pump does not start (power consumption is too low)
E17	Patient circuit 1 pump uses too much power
E18	Patient circuit 1 pump is blocked (too slow)
E19	• Patient circuit 1 pump is not immersed in liquid (rpm is too high) • There is still air in the external circuit
E20	Patient circuit 2 pump does not start (power consumption is too low)
E21	Patient circuit 2 pump uses too much power (patient circuit 1)
E22	Patient circuit 2 pump is blocked (too slow)
E23	• Patient circuit 2 pump is not immersed in liquid (rpm too high) • There is still air in the external circuit
E24	Short circuit: Temperature sensor on the liquefier
E25	Interruption: Temperature sensor on the liquefier

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Display	Description of error cause
E26	Cooler: defective fan cooler or defective rpm sensor (= Hall sensor) • Fan: defective motor Symptoms: Fan is not running or is too slow; fan voltage ≥ mains voltage • Hardware activation: error (e.g. Triac) Symptoms: Fan is not running or is too slow; fan voltage ≥ mains voltage • No or incorrect speed measurement: (e.g. Hall sensor) Symptoms: Defective Hall sensor; fan speed too high (1,300 ... 1,500 rpm)
E27	Cooler: Pressure switch tripped (part of the compressor circuit) If the pressure is too high, the compressor is switched off.
E28	Cooler: Excess temperature switch tripped (Klixon, located in the compressor junction box). If the temperature of the compressor is too high, compressor is switched off.
E29	Start test: Stuck key detected
E30	Safety system: Program run error; communication problems between the control and safety systems
E31	Start test: No supply synchronization possible
E32	EEPROM module: Defective or cannot be accessed
E33	Start test (control system): Data in the EEPROM is defective
E34	Start test (safety system): Data in the EEPROM is defective
E35	Safety system: EEPROM write test failed
E36	Start test: Cannot access CAN controller
E37	Start test: Cannot access display drivers
E38	Start test (control system): ROM checksum error
E39	Start test (control system): RAM error
E40	Start test (control system): CPU error
E41	Start test (safety system): ROM checksum error
E42	Start test (safety system): RAM error
E43	Start test (safety system): CPU error
E44	Safety system: Control system does not respond
E45	Safety system: 5 V control system not within the tolerated range
E46	Control system: Safety system does not respond
E47	Control system: 5 V safety system is not within the tolerated range
E48	Start test: All relays and Triacs are open, current too high
E49	Start test (warm cardioplegia): Relay does not open

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Display	Description of error cause
E50	Start test (warm cardioplegia): Triac does not open
E51	• Start test (warm cardioplegia): Relay or Triac does not close • Start test for warm cardioplegia heating interrupted
E52	Start test (warm cardioplegia): Heating uses too much power
E53	Start test (patient tank): Relay does not open
E54	Start test (patient tank): Triac 1 does not open
E55	• Start test (patient tank): Relay or Triac 1 does not close • Start test (patient tank): Heating 1 interrupted
E56	Start test (patient tank): Heating 1 uses too much power
E57	Start test (patient tank): Triac 2 does not open
E58	• Start test (patient tank): Relay or Triac 2 does not close • Start test (patient tank): Heating 2 interrupted
E59	• Start test (patient tank): Heating 2 uses too much power • Pumps operate with a continually fluctuating rotational speed

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8.2 Troubleshooting or returning the 3T Aerosol Collection Set

8.2.1 Troubleshooting for the aerosol collection set

Problem	Possible cause(s)	Corrective measures
Vacuum does not exceed 50 Pa when vacuum is first applied	Vacuum regulator not set to maximum	Adjust vacuum regulator to full open vacuum
	Vacuum source line is detached or kinked	Reconnect and/or unkink vacuum line
	HC3T connection line is detached or kinked	Reconnect and/or unkink HC3T connection line
	ACS lid filter is blocked	Replace ACS according to chapter 5.7.2
	ACS caps are not tight	Secure caps over the pour spout and tandem port
	ACS lid is not tight	Secure ACS lid to canister around the entire perimeter of the lid
	Filler neck cap is removed or loose	• Secure filler neck cap • Check filler neck and cap sealing surfaces for debris • Contact LivaNova for a replacement cap
	Circuit tanks are empty (allowing air to enter via the circuit inlets)	• Fill tanks and recheck vacuum • Connect procedural tubing and recheck vacuum

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Problem	Possible cause(s)	Corrective measures
Continued: Vacuum does not exceed 50 Pa when vacuum is first applied	Internal vacuum line is blocked	☐ 1 Remove service port cap (white Luer fitting) on the side of the vacuum gauge ☐ 2 Set vacuum regulator to maximum ☐ 3 Replace service port cap ☐ 4 Set vacuum regulator to off ☐ 5 Remove service port cap (white Luer fitting) on the side of the vacuum gauge ☐ 6 Apply air pressure through the service port using a 30 cc or larger sterile syringe ☐ 7 Replace service port cap
	Vacuum gauge failure	Contact your LivaNova service technician
Vacuum drops below 50 Pa during the procedure	Overflow safety trap (“water trap”) in the vacuum line is full	Empty the overflow safety trap Replace overflow safety trap with a larger unit (i.e. Ohio Medical 275 mL Collection Bottle with ⅛" NPT Locking Gland)
	ACS is completely filled with water	Empty the ACS per chapter 5.7.2
	Vacuum source line is detached or kinked	Reconnect and/or unkink vacuum source line
	HC3T connection line is detached or kinked	Reconnect and/or unkink HC3T connection line If vacuum is still low, the lid filter may be blocked. Replace the ACS per chapter 4.5.
Excessive condensation in the safety overflow trap	Operation in humid climates increases the volume of condensation	Contact LivaNova for information on a larger safety overflow trap

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8.2.2 Returning a used aerosol collection container

For customers within the United States

1 Obtain a returned goods authorization (RGA) number from LivaNova USA, Inc. prior to returning the 3T Aerosol Collection Set.

2 Clean and disinfect the aerosol collection container if it has been in contact with blood or body fluids.

CAUTION

Do not return products that have been exposed to blood-borne infectious diseases. It is the responsibility of the healthcare institution to adequately prepare and identify the product for return shipment.

To ship the aerosol collection container:

1 Package the aerosol collection container in either the original carton or an equivalent carton to prevent damage during shipment

2 Label the carton with the RGA number and an indication of the biohazardous nature of the contents of the shipment.

3 Ship the aerosol collection container to the following address:
LivaNova USA, Inc.
Returned CV Products
14401 West 65th Way
Arvada, CO 80004-3599

Instructions for cleaning and materials, including appropriate shipping containers, proper labeling, and an RGA number may be obtained from the LivaNova USA, Inc. Returned Goods Coordinator, Quality Assurance Department (phone: 800-650-2623).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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For customers outside the United States:

Contact your sales representative for specific instructions.

Clean and disinfect the aerosol collection container if it has been in contact with blood or body fluids.

CAUTION

Do not return products that have been exposed to blood-borne infectious diseases. It is the responsibility of the healthcare institution to adequately prepare and identify the product for return shipment.

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