

**California Department of Public Health (CDPH)  
Center for Health Care Quality  
Healthcare-Associated Infections (HAI) Program**

**Infection Control Checklist for Sorin 3T Heater-Cooler Devices**

September 20, 2016

The CDPH HAI Program developed this checklist for hospitals with a Sorin 3T heater-cooler device. The checklist includes all infection control-related requirements in the September 2015 Sorin 3T operating instructions, the most current manual that should be used by all hospitals with a Sorin 3T despite when the device was acquired.

Infection preventionists, epidemiologists, perfusionists, surgery technicians, and other personnel can use the checklist to evaluate adherence with the manufacturer's recommended maintenance, cleaning, and disinfection processes. The required infection control procedures limit the growth of biofilms and reduce the risk of contaminated aerosols in the operating room. The Sorin 3T operating instructions emphasize, "It is essential for the safe operation of the heater-cooler device that the hygiene measures (cleaning and disinfection) are carried out regularly and completely."

If the results of your evaluation indicate items on the checklist have not been done regularly, completely, or as recommended, the device may be contaminated with biofilm and further evaluation indicated. The U.S. Food and Drug Administration (FDA) recommends to "Immediately remove from service heater-cooler devices that show discoloration or cloudiness in the fluid lines/circuits, which may indicate bacterial growth. Consult your hospital infection control officials to perform the appropriate follow up measures and report events of device contamination to the manufacturer." The FDA also requests that healthcare providers submit "reports describing difficulty following the manufacturers' instructions for use" via the [Medical Device Reporting \(MDR\)](#) process. See FDA Safety Communication, October 15, 2015, for additional recommendations and details.

Additional considerations when using this checklist to evaluate Sorin 3T from an infection control perspective:

- Internal components cannot be accessed for physical cleaning. The manufacturer states, "The heater-cooler has no user-serviceable internal components. All service must be performed by SORIN GROUP or qualified personnel."
- Disinfection of the water circuit is defined to include internal device components (the pump and heating and cooling tanks) and external device components (fittings and all interconnecting tubing).
- These instructions apply to all Sorin 3T heater-cooler devices. However, if your facility purchased and used a Sorin 3T prior to September 2014, be aware the device may have been shipped from the factory contaminated with *Mycobacteria chimaera*. If cleaning and disinfection instructions in such a device were not adhered to in the past, there may be an increased likelihood of biofilm growth with *M. chimaera*. Please refer to FDA Safety Communication, June 1, 2016, for additional recommendations.

Please contact the CDPH HAI Program for more information or if questions at [HAIProgram@cdph.ca.gov](mailto:HAIProgram@cdph.ca.gov).

---

*Please refer to the complete Sorin 3T operating instructions manual for many additional operational and maintenance requirements not related to infection control and therefore not included in this checklist.*

*The Sorin 3T operating instructions manual used to produce this infection control checklist was downloaded from the LivaNova Sorin website on September 7, 2016, at <http://www.livanova.sorin.com/products/cardiac-surgery/perfusion/hlm/3t>.*

**CDPH HAI Program**  
**Infection Control Checklist for Sorin 3T Heater-Cooler Devices**

Page numbers for each item reference the Sorin 3T operating instructions available at  
<http://www.livanova.sorin.com/products/cardiac-surgery/perfusion/hlm/3t>.

✓ if YES		Page #
<b>Operating Instructions</b>		
<input type="checkbox"/>	Sorin 3T operating instructions in use are dated 09/2015	<i>back of cover page</i>
<input type="checkbox"/>	Current, complete, legible operating instructions are available close to the heater-cooler device at all times.	2.3
<b>Water Use and Changes</b>		
<input type="checkbox"/>	Hand hygiene is performed and gloves are worn when filling water tanks.	5.2
<input type="checkbox"/>	Only filtered tap water is used (for device use, re-filling, and disinfection and rinse cycles).	2.4, 5.2
<input type="checkbox"/>	Water is filtered using a disposable Pall-Aquasafe water filter with a 0.2 µm membrane.	2.4, 5.2
<input type="checkbox"/>	Demineralized water is used if available.	2.4
<input type="checkbox"/>	De-ionized or reverse osmosis processed water is NOT used.	5.2, 6.12
<input type="checkbox"/>	5 oz. medical grade 3% hydrogen peroxide solution is added to the tank to help prevent microbial growth.	5.2, 6.12
<input type="checkbox"/>	Hydrogen peroxide is not used past its expiration date.	5.2
<input type="checkbox"/>	After refilling water (i.e., "topping off"), 4 oz. of 3% hydrogen peroxide mixed with 34 oz. of <b>filtered</b> tap water is added to the tank.	5.2
<input type="checkbox"/>	Device is run through a 5 min. mixing process each time the tank is refilled to ensure hydrogen peroxide solution gets to all water in the tanks.	5.3-5.5
<input type="checkbox"/>	Water is completely changed every 7 days.	6.3, 6.12
<input type="checkbox"/>	Hand hygiene is performed and gloves are worn when changing water.	6.12
<input type="checkbox"/>	Test strips are used to measure hydrogen peroxide concentration between water changes. Concentrations should not be below 100 ppm. (Optional?)	6.12
<b>Disinfection of Water Circuits</b>		
<input type="checkbox"/>	New device is disinfected prior to first use.	2.6, 6.2
<input type="checkbox"/>	Device is disinfected prior to placing in storage.	2.6, 6.2
<input type="checkbox"/>	Disinfection of water circuits is performed every 14 days for devices in use.	6.2
<input type="checkbox"/>	Disinfection of water circuits is performed every 14 days for devices in storage.	6.2
<input type="checkbox"/>	Only Clorox Regular Bleach (8.25% sodium hypochlorite) or Minncare Cold Sterilant is used to disinfect water circuits.	6.6
<input type="checkbox"/>	Protective gloves are worn for cleaning and disinfecting the system.	6.2
<input type="checkbox"/>	Protective goggles are worn during the disinfection process.	6.2
<input type="checkbox"/>	Tubings normally used with the device are connected to the device during the water circuit disinfection procedure.	6.15
<input type="checkbox"/>	35-step water circuit disinfection procedure is followed every time (referring to instructions).	6.8-6.11
<input type="checkbox"/>	Only filtered tap water is used during the disinfection procedure (0.2 µm filter).	6.7
<input type="checkbox"/>	6 oz. of Clorox Regular Bleach (or 15 oz. of concentrated Minncare cold sterilant) is added to the water tanks for disinfection of the water circuits.	6.8
<input type="checkbox"/>	Bleach or Minncare solution is added according to instructions, i.e., after water tanks are filled until orange light displays, but before filling again until green light displays.	6.8
<input type="checkbox"/>	Disinfection cycle is run for 5 min. in the cold cardioplegia circuit.	6.11
<input type="checkbox"/>	Disinfection cycle is run for 10 min. in the warm cardioplegia circuit and 2 patient circuits.	6.11
<input type="checkbox"/>	After draining the bleach or Minncare solution, the device is refilled with filtered tap water (0.2 µm filter) and run for a 3 min. rinse cycle to remove residual disinfectant solution.	6.11
<input type="checkbox"/>	Rinse cycle is performed two (2) times after every disinfection cycle.	6.11

## Infection Control Checklist for Sorin 3T Heater-Cooler Devices - continued

Page numbers for each item reference the Sorin 3T operating instructions available at  
<http://www.livanova.sorin.com/products/cardiac-surgery/perfusion/hlm/3t>.

✓ if YES		Page #
<b>Surface Cleaning and Disinfection</b>		
<input type="checkbox"/>	Protective gloves are worn for cleaning and disinfecting.	6.2
<input type="checkbox"/>	External device surfaces are disinfected after every use.	6.3, 6.5
<input type="checkbox"/>	External surface disinfection is done using ready-to-use disinfectant wipes approved by Sorin, specifically Bacillol, CaviWipe, Super Sani Cloth, Meliseptol HBV, or Mikrozyd AF.	6.5
<input type="checkbox"/>	Ventilation grills are cleaned at regular intervals or when contaminated.	6.2
<input type="checkbox"/>	Overflow water bottle is emptied after every device use (or at least daily).	6.17
<input type="checkbox"/>	Overflow bottle is run through an automatic washer-disinfector every 7 days.	6.17
<b>Tubing</b>		
<input type="checkbox"/>	Only tubings certified for drinking water systems are used.	6.2, 6.15
<input type="checkbox"/>	Connectors and tubing fittings are disinfected before connecting them to the heater-cooler device.	4.3
<input type="checkbox"/>	Hand hygiene is performed and gloves are worn when connecting tubings to the water circuit.	4.3
<input type="checkbox"/>	Protective gloves are worn when disconnecting used tubing.	6.2
<input type="checkbox"/>	Tubings certified for drinking water systems are used for connecting heating blankets and other accessory devices.	4.1
<input type="checkbox"/>	Single-use heating blankets are not reused (can contaminate the device if reconnected).	6.2
<input type="checkbox"/>	All tubings used with the device are replaced once/year.	6.15
<b>Device in Use</b>		
<input type="checkbox"/>	Device is placed at least 2.5 ft. from walls and other devices.	4.2
<input type="checkbox"/>	Device is placed so that exhaust flow is not directed toward the operating field.	4.2
<input type="checkbox"/>	Device is set up in an adjoining room/space and controlled remotely. (OPTIONAL)	4.2
<input type="checkbox"/>	Length of tubing between the heater-cooler and heat exchangers and heating blanket does not exceed 16.4 ft.	4.2
<input type="checkbox"/>	Covering is not placed over device ventilation grills and fan	4.2
<input type="checkbox"/>	Routine maintenance checks are performed (by hospital personnel) daily or every time device used.	6.17
<input type="checkbox"/>	Routine safety checks are performed (by hospital personnel) regularly.	6.16
<input type="checkbox"/>	Preventive maintenance is performed by a Sorin-authorized service technician every 1000 operating hours or annually, whichever comes first.	2.3, 6.17
<b>Device in Storage</b>		
<input type="checkbox"/>	Prior to storage, device water circuits are disinfected, tanks drained, and tubings disconnected, dried, and stored in a dust-free area.	6.13
<input type="checkbox"/>	During storage, device water circuits are disinfected every 14 days (i.e., 35-step process)	6.13
<input type="checkbox"/>	Preventive maintenance is performed by Sorin-authorized service technician annually.	6.17

**Notes and observations:**