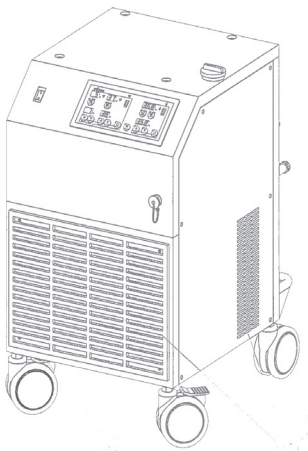


Testing Sorin Heater Cooler Instruments



Sorin Heater-Cooler T-3

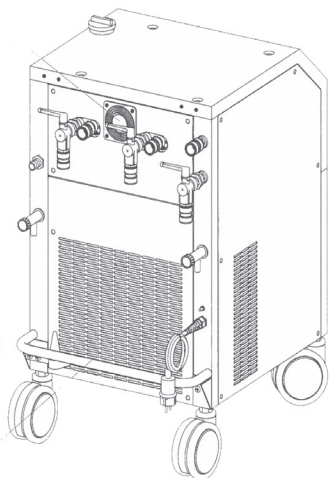
Background

Since 2011, cases of invasive cardiovascular infection caused by *M. chimaera* have been reported in patients having previously undergone cardiac surgery. Most of these have occurred in Switzerland, Germany, the Netherlands and the UK.

- In October 2015 WellSpan hospital in York Pa., reported eight patients contracted nontuberculous mycobacterium infections following cardiac surgery; four patients died.
- Sorin heater-cooler instruments have been identified as a source of surgical site infections caused by *M. chimaera*.
- Most infections have been prosthetic valve infections (endocarditis) or coronary artery bypass grafts.
- More than 250,000 heart bypass procedures using heater-cooler devices are performed in the US every year.
- Approximately 60% of these surgeries included the use of Sorin devices.
- The CDC estimates the risk of developing an infection was between 1 in 100 and 1 in 1000.
- The bacteria associated with infection and the Sorin heater-cooler device (HCD) is *Mycobacterium chimaera*, a nontuberculous mycobacterium (NTM).
- *M. chimaera* is often found in soil and water and rarely causes infections in humans.
- Symptoms of infection may take 5 months to 5 years after exposure.
- Instruments that are not maintained properly become colonized with a wide variety of microorganisms forming a protective biofilm.
- Mycobacterium sp. can be found in biofilm and along with their thick waxy cell wall, they are protected from harsh environmental conditions including disinfectants.



Testing Sorin Instruments



Sorin Heater-Cooler T-3

Sorin Device

The Sorin heater-cooler (HTC) contains a tank with two main compartments: one for warming water and one for cooling water. The warm water circuit controls the patient's blood temperature and the cold water circuit cools the cardioplegia solution.

Although water in the circuits does not come in direct contact with the patient, there is the potential for contaminated water to enter parts of the device and transmit bacteria through the air.

A fan within the instrument ensures a constant airflow through the instrument and because it is not airtight, aerosols are generated which can then contaminate the sterile operative field.

To date the Sorin HCT is the only device that has been implicated with patient infections and *M. chimaera* is the only pathogen that has been recognized. There most likely have been many cases of *M. chimaera* infections that have gone undiagnosed. Mycobacterium is such an unusual pathogen, the surgeon would not have asked the laboratory to test for it.

Investigations have determined that the Sorin HCD's were shipped to the states already colonized with *M. chimaera*.

Total Legionella Control

Special Pathogens Laboratory is dedicated to Total Legionella Control, through an integrated platform of evidence-based solutions:

- Pathogen Testing
- Consulting & Education
- ZEROutbreak Protection

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SpecialPathogensLab.com



July 2014

June 2015

Aug. / Sept. 2015

Oct. 2015

Dec. 2015



Federal Office of Public Health Switzerland reports Mycobacterium chimaera infections with exposure to contaminated heater-cooler devices.

Sorin Group issues Field Safety Notice

FDA inspects two Sorin facilities: Munich, Germany and Arvada, Colorado.

- Two hospitals in Pennsylvania report deadly heater-cooler infection outbreaks.

- FDA publishes a Safety Communication. Heater-cooler devices were linked to 32 reported NTM infections between January 2010 and August 2015.

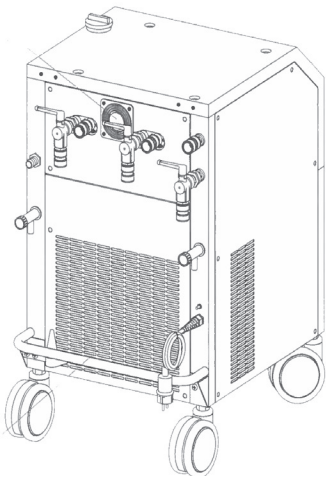
- FDA issues warning Letter to Sorin Group stating that Sorin did not adequately verify or validate the new cleaning procedures.

- FDA blocks imports of the Sorin heater-cooler and warns that instructions for sterilization may be inadequate.

Sorin Recommended Testing

- Heterotrophic Plate Count (HPC): less than 500 cfu/ml
- Pseudomonas aeruginosa: not detectable in 100ml
- Coliform bacteria: not detected in 100 ml
- Nontuberculous mycobacterium: not detected in 100 ml

Testing Sorin Instruments



Sorin Heater-Cooler T-3

Special Pathogens Laboratory Sorin Testing

Special Pathogens Laboratory provides testing recommended by Sorin.

- Heterotrophic Plate Count – Test code 103, Cost \$25
- Pseudomonas aeruginosa – Test code 102, Cost \$30
- Coliform/E.coli – Test code 106, Cost \$50
- Nontuberculous mycobacterium – Test code 108, Cost \$150
- Legionella pneumophila and other Legionella sp. have been recovered from the Sorin instruments. Test code – 101, Cost \$110

Collection Instructions

- Collect water samples from both the hot and cold tanks.
- Run the device for five minutes, then collect a separate sample from each of the hot and cold circuits.
- Sample both before and after disinfection.
- Samples of at least 100 ml is required for each test ordered.
- When testing for all of the above tests a total of 500 ml is required, so it is important to fill the bottle completely.
- Sterile bottles containing sodium thiosulfate as well as ice packs can be obtained free of charge from SPL.

Shipping instructions

The HPC, Pseudomonas aeruginosa, and the Coliform/E.coli tests are both time and temperature sensitive. The water samples must be shipped overnight with frozen ice packs. You can use the same box the collection bottles were shipped in. This box contains an insulated liner which helps prevent drastic temperature changes during shipping. Be sure to fill out and include the Chain of Custody (COC) form with the water samples. The COC should include the test codes, time and day of collection, water sample description that matches the description on the bottles and the submitting company information. Special Pathogens Laboratory does not perform these tests on weekends or holidays. Mail the samples "next day overnight delivery" Monday through Thursday.

Nontuberculous mycobacterium test

The Nontuberculous mycobacterium (NTM), test code 108, is a presence/absence test. The isolates can only be identified to species using 16S DNA sequencing. This test is not done at SPL, however, the isolate can be sent out for sequencing at a cost of \$200 per isolate. If you are only interested in knowing if isolates are *M. chimaera*, our microbiologists can select those isolates for sequencing that are suspicious based on colony morphology and growth rate. If mycobacteria are recovered our microbiologist will notify you to discuss if sequencing is desired. If so, we will e-mail a form for you to sign and return authorizing SPL to send the isolate or isolates for sequencing.

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