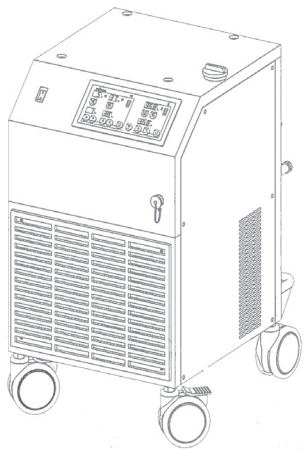


NTM Prevention

Heater Cooler Instruments



Sorin Heater-Cooler T-3

“... bacteria can become aerosolized when the heater cooler device is operated and serve as a source of contamination.” Sorin Field Safety Notice, June 2015:

In October 2015, the FDA issued a safety communication on **non-tuberculosis mycobacterium (NTM) infections** associated with heater-cooler devices. Heater-cooler devices are commonly used during cardiac surgeries to warm and cool a patient's blood. Recent reports have shown that the sterile surgical field can be compromised through aerosolization from contaminated water in these instruments. Endocarditis and other serious cardiovascular infections with *Mycobacterium chimaera* have occurred when these devices were used during cardiothoracic surgery. The CDC is promoting increased vigilance for NTM infections by healthcare providers.



Sorin recommends testing

Sorin Group Deutschland voluntary Field Safety Notice provides instructions for disinfection, maintenance procedures and testing. European reports also show the presence of Legionella in these devices. Testing includes:

- Heterotrophic Plate Count (HPC): is less than 500 cfu/ml
- Non-Tuberculous Mycobacterium: is not detectable in 100 ml
- Coliform bacteria: is not detectable in 100 ml
- Pseudomonas aeruginosa: is not detectable in 100 ml

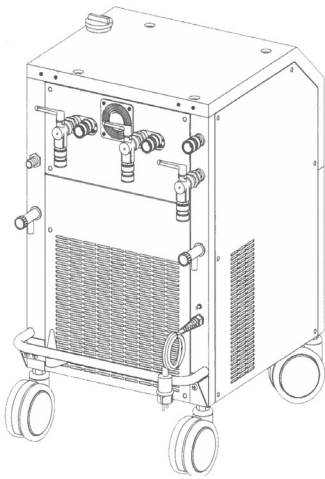
**Due to European reports and SPL testing results for Sorin instruments, we recommend testing for Legionella: is not detectable in 100 ml.*



Special Pathogens Laboratory provides testing services for heater-cooler instruments. Our clinical microbiologist, an expert in mycobacterium, will assist you in testing, recommended disinfection protocols and developing a quality monitoring plan. Contact Jack Rihs, jrihs@specialpathogenslab.com



Mycobacterium chimaera infections



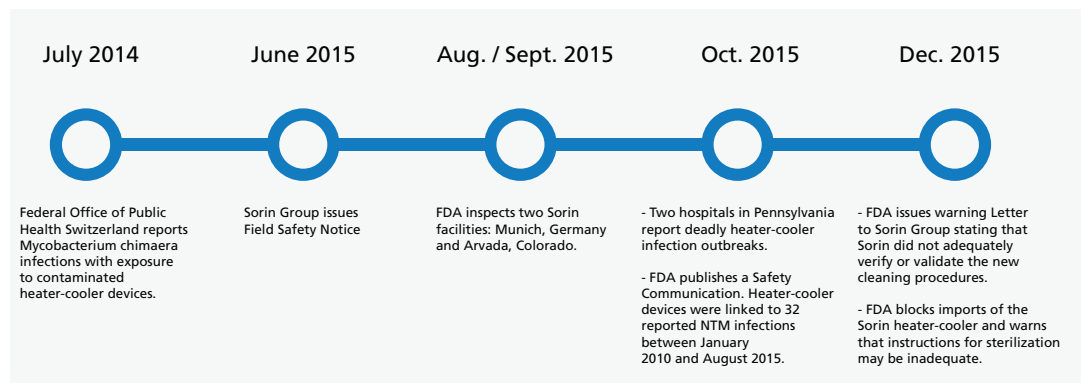
Sorin Heater-Cooler T-3

Heater-cooler devices like LivaNova (formerly Sorin) HT 3 are linked to the majority of reported NTM infections in the United States.

Mycobacterium chimaera

Mycobacterium chimaera is a slow growing non-tuberculosis mycobacterium belonging to the M. avium complex.

- First reported by Tortoli et al. in 2004
- Requires molecular testing for identification
- Widely distributed in nature and can be found in soil and water, including chlorinated water
- Opportunistic pathogen and on rare occasions can cause infections in the very ill or immunocompromised individuals.
- 1.5 to 3.5 years for clinical manifestations to appear



We need your feedback.

heater-cooler survey: <https://www.surveymonkey.com/r/RPXDG5J>

Help Special Pathogens Laboratory investigate the efficacy of disinfection in heater-cooler instruments to find out if:

- cleaning and disinfection effectively eradicates NTM in colonized devices
- cleaning and disinfection is effective in preventing colonization
- heterotrophic plate count can predict the presence of NTM
- instruments sold in the US were already colonized with NTM

Total Legionella Control

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

- Pathogen Testing
- Consulting & Education
- ZERO outbreak Protection

P: 877.775.7284

SpecialPathogensLab.com



The FDA recommends implementing a quality control program. Special Pathogens Laboratory provides testing required to detect NTM and other bacteria found in heater-cooler devices, which includes: heterotrophic plate count, coliform bacteria, Pseudomonas aeruginosa, NTM, and Legionella.