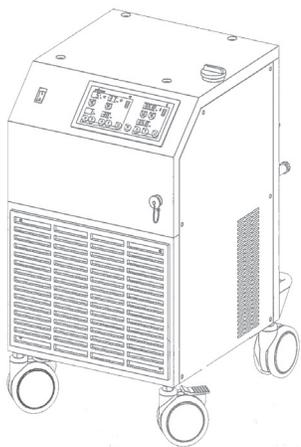


# NTM Prevention

## 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

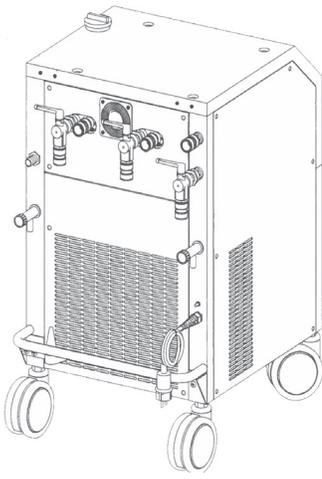
*\*Due to European reports and SPL testing results for Sorin instruments, we recommend testing for Legionella: is not detectable in 100 ml.*



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](mailto:jrihs@specialpathogenslab.com)



# Mycobacterium chimaera infections



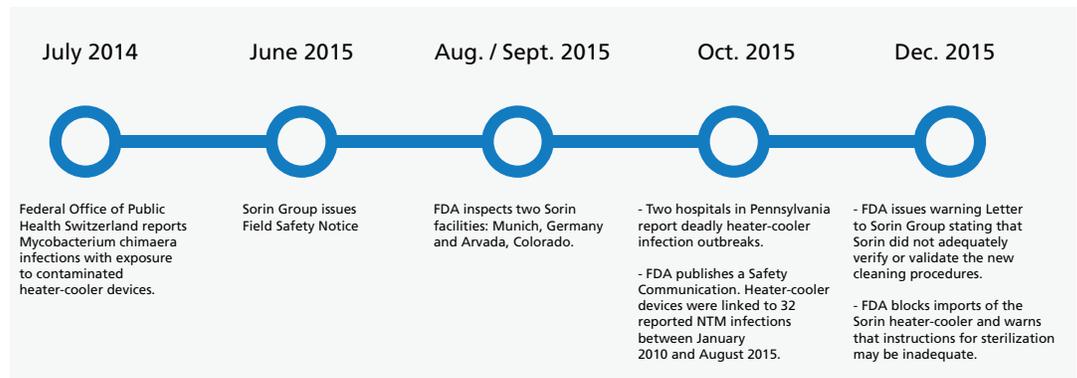
Sorin Heater-Cooler T-3

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://goo.gl/yIWSE6>

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](http://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.*