Circulatory System Devices Panel of the Medical Devices Advisory Committee

June 2 and 3, 2016

Mission

Our Mission is to deliver world class temperature management solutions to our customers right the first time.

Vision

Our Vision is to create innovative temperature management solutions to improve life.

Cincinnati Sub-Zero Products, LLC

- **The CSZ Hemotherm® 400 series of products have been in distribution since 1981 (35 years).**

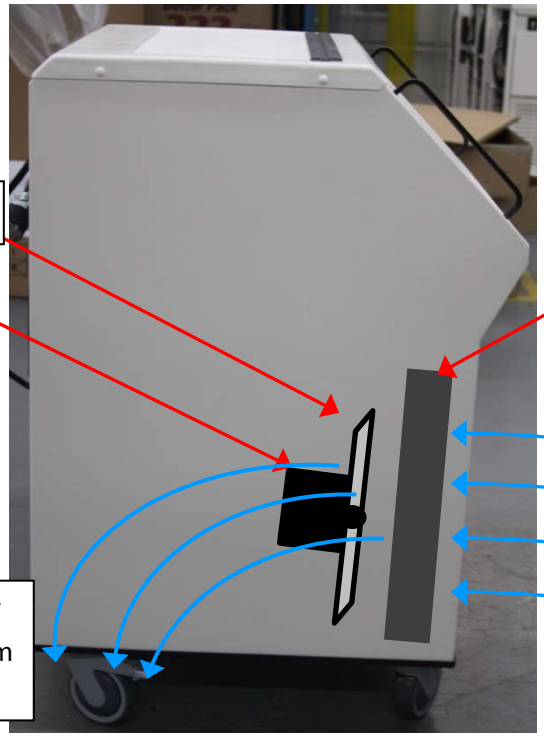
Hemotherm® 400

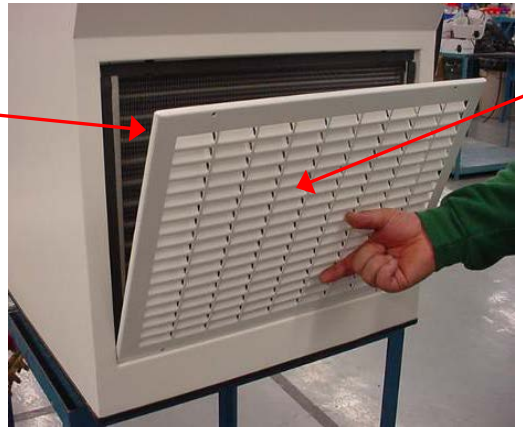
- **“Safety first” design to prevent aerosolization**
  - Air flow directed away from sterile field at a rate of less than 185 CFM
  - Water reservoirs isolated from operating room environment by two separate barriers
  - Closed loop fluid management system
  - Excess capacity available in reservoir to handle overflow
  - Reservoir lid and covers are accessible for easy cleaning

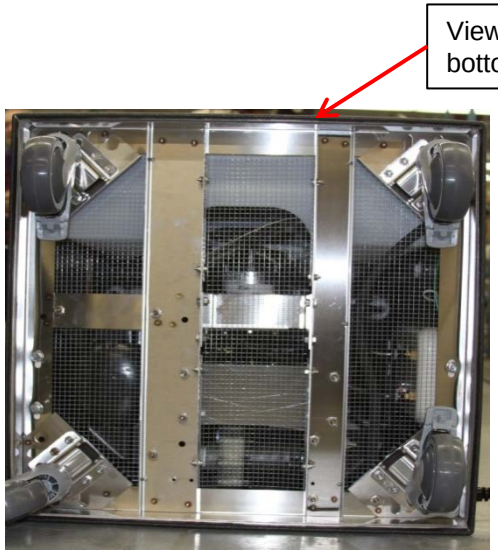
Hemotherm® Air Flow Path

- **Air is expelled through the bottom of the device not directed towards the sterile field. No exposed water is within the expelled airstream to become contaminated.**

Hemotherm® Air Flow Path

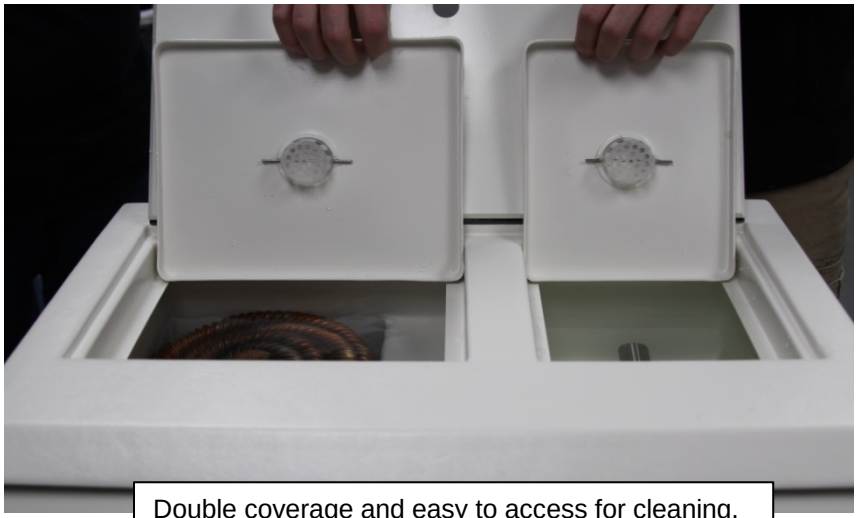




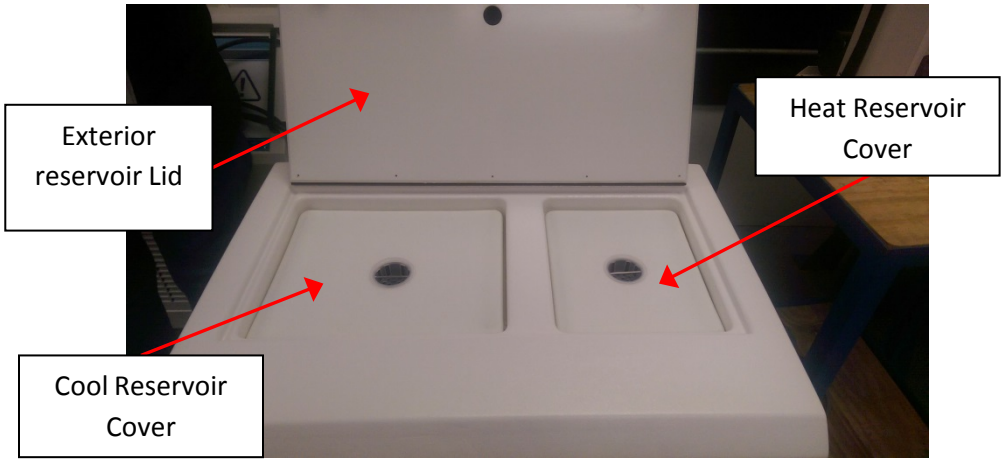


Hemotherm® Reservoir

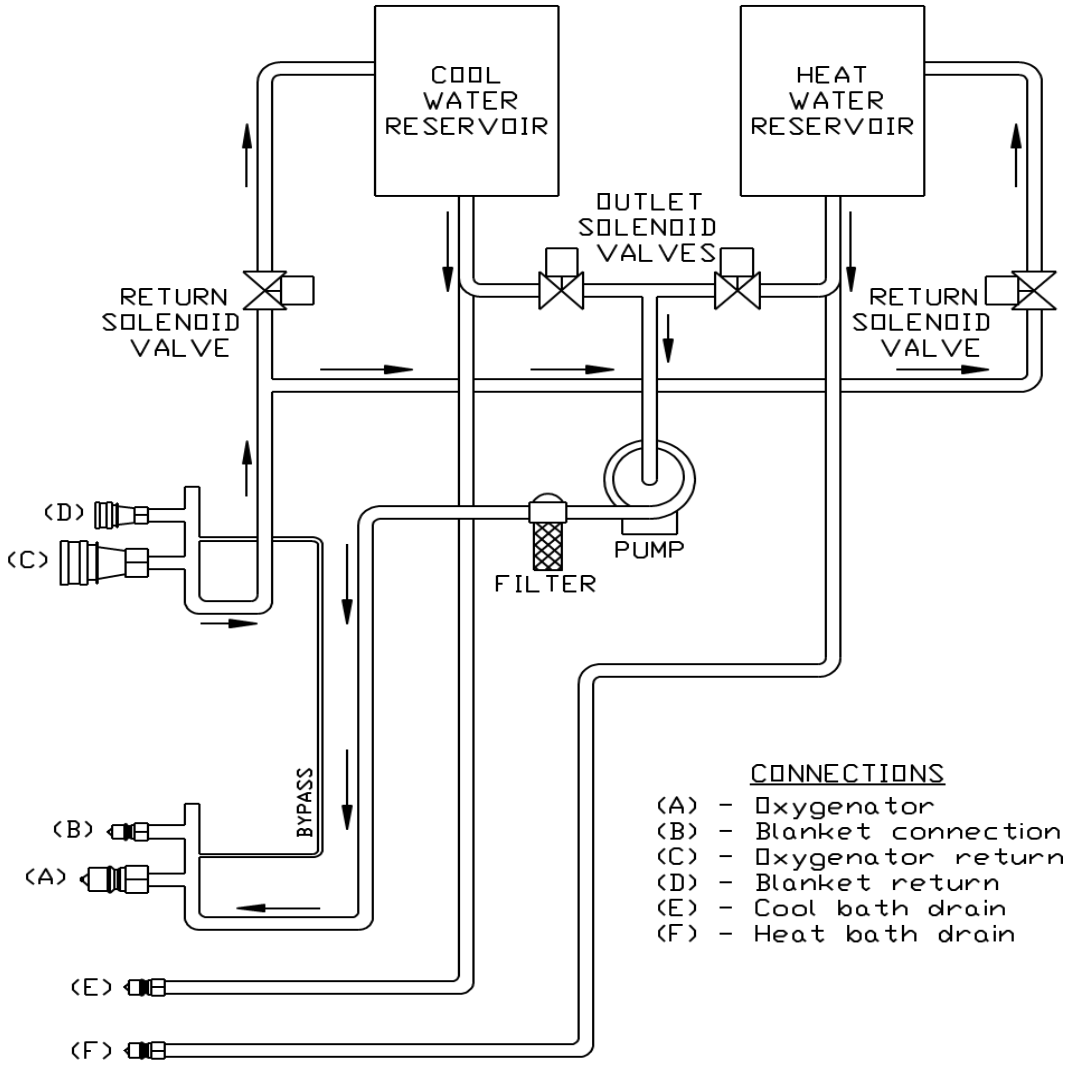
- **Water is isolated from the OR environment by a reservoir cover and an exterior reservoir lid.**
- **Excess capacity available in reservoir to handle overflow.**
- **Reservoir lid and covers are accessible for cleaning.**



Double coverage and easy to access for cleaning.



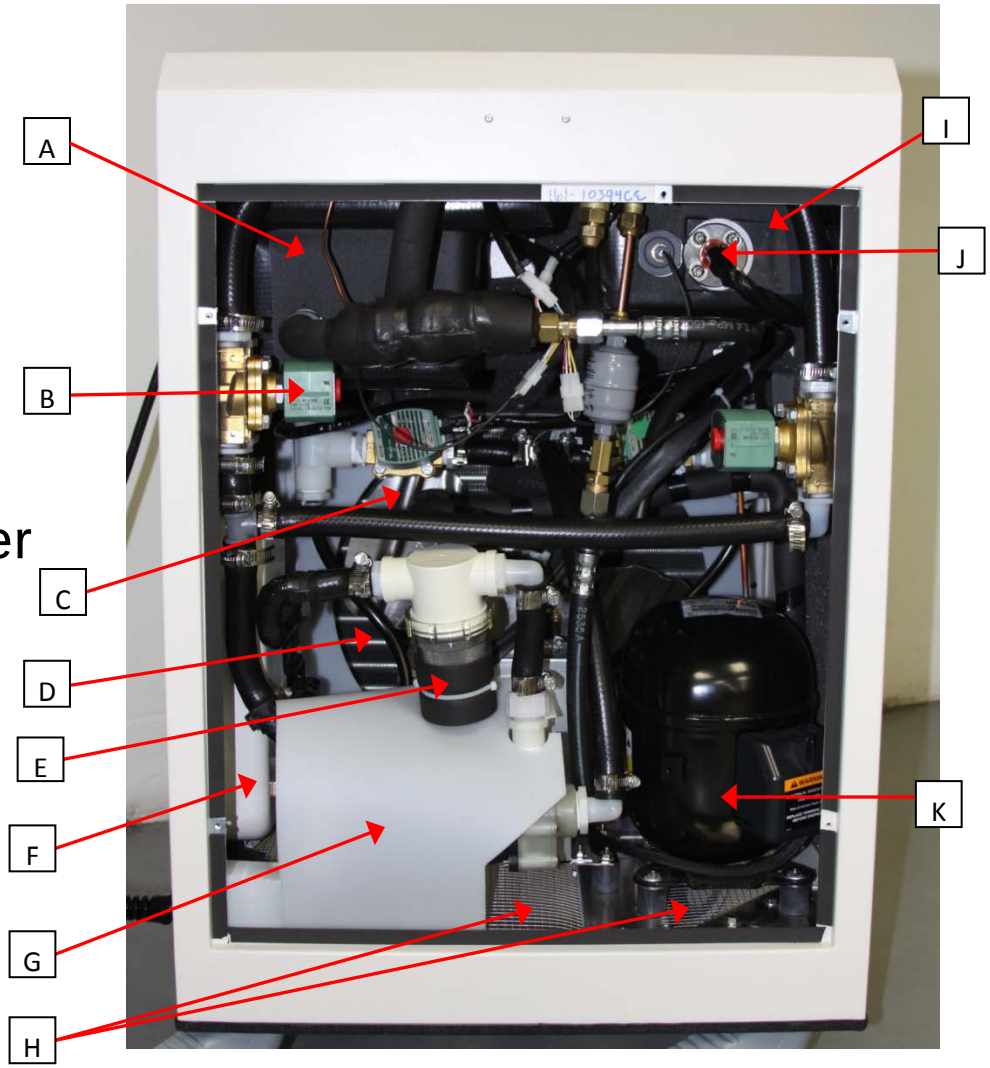
Hemotherm® Water Flow Path



Hemotherm®

(Design & Schematics)

- A. Cooling Reservoir
- B. Solenoids (Qty. 4)
- C. Fan
- D. Condenser
- E. Water Filter/Strainer
- F. Manifold
- G. Pump with Shroud Cover
- H. Wire Mesh Bottom
- I. Heating Reservoir
- J. Heater
- K. Compressor

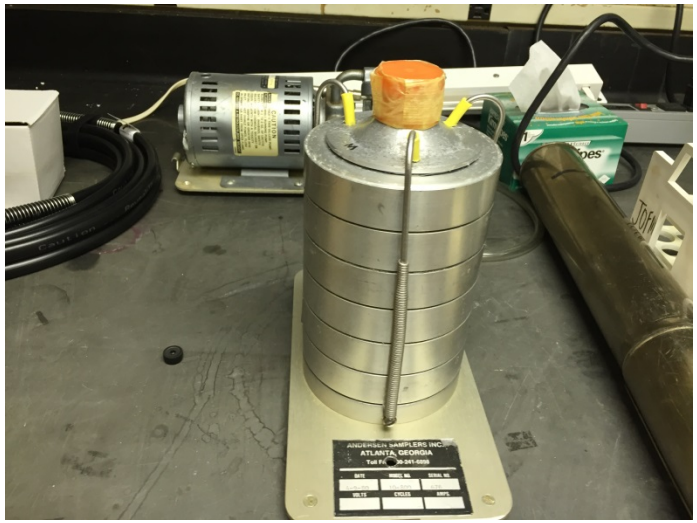


Mitigations

- **CSZ has been working closely with Dr. Joseph O. Falkinham, III Professor of Microbiology at Virginia Polytechnic Institute and State University.**
  - Dr. Falkinham focuses on NTM and is assisting CSZ with our cooler/heater instructions for cleaning and disinfecting as they relate to Nontuberculous Mycobacteria (NTM).
  - Dr. Falkinham measured the aerosolization potential of NTM during use of CSZ's cooler/heater devices using high-volume Andersen 6-Stage Cascade Samplers.
  - Characterization studies indicate that the Hemotherm does not generate any aerosols containing NTM.

Aerosolization

- **An inoculated Hemotherm and two Andersen 6-Stage Cascade Samplers were placed in an unventilated and sealable room of 30m³ volume.**



- **No *Mycobacterium* spp. were recovered from possible aerosols in the room in which the Hemotherm was operating.**

Water System Cleaning Procedure

- **Use Only Distilled Water**
- **Change Water Monthly**
- **Preventive Maintenance Quarterly**
  - Drain and clean reservoirs
  - Clean water system
  - Clean water filter
  - Refill reservoirs with distilled water
  - Clean condenser and grille

Adverse Event Investigation

- **Re-examination of the product risk file for incremental risks associated with aerosolization of microflora.**
- **Heighten scrutiny in complaint handling process to detect and evaluate possible contamination incidents.**
- **Established a cross-functional team and enlisted outside experts to take a deep dive into the risk assessment and provide CSZ with recommendations and expertise to execute them.**

Improving Communications

- **Recommend FDA involvement in education initiatives in collaboration with CDC/NIH and user facilities to promote improvement of infection control procedures.**
- **Communication with Health Care Facilities could be improved by creating an environment to facilitate open communication between manufacturers and hospital risk managers.**

CSZ's Conclusions

- **Characterization studies indicate that the Hemotherm does not generate any aerosols containing NTM.**
- **CSZ is voluntarily revalidating the current cleaning procedures by a 3rd party expert as they relate to NTM.**
- **None of the existing data suggests that the Hemotherm is a source of any nosocomial infection, including NTM.**

spirit of innovation