Overview
Cardiopulmonary bypass is a technique used to perform the oxygenation and circulation functions of the heart during surgery. Patients at PSHMC have been acquiring infections after being placed on cardiopulmonary bypass. These infections were traced back to the Sorin 3T Heater/Cooler units by a specific strain of nontuberculous mycobacteria (NTM). Once these bacteria colonize inside the heater/cooler units, they are aerosolized and ejected into the operating room via the cooling fan where they infect patients.

Objective
Create a cleaning protocol that will eliminate and prevent further growth of NTM within the Sorin 3T Heater/Cooler System units used at Penn State Hershey Medical Center (PSHMC) for cardiopulmonary bypass.

Approach
- A site visit was completed to gather customer needs
- An external search was performed to identify existing models
- Two rounds of brainstorming were conducted to develop a list of potential solutions
- Engineering specifications were developed based on customer needs
- All possible options were researched to assess pros and cons of each potential solution
- A master list of ideas with analysis of each option was generated
- Concept selection and analysis were performed based on pros and cons list
- A 3-step cleaning solution emerged as the potential solution
- Each step of the cleaning method was further investigated
- A step-by-step protocol for parts 1 and 2, coolant replacement, and regular cleaning was developed
- Collaboration with a PSU graduate student led us to develop the concept for step 3
- Testing was not performed due to limitations imposed by Sorin and PSHMC
- Dr. Knecht and PSHMC will continue the testing for step 3, plasma sterilization
- A 3-step comprehensive cleaning protocol was finalized for future implementation by PSHMC

Outcomes
We present a multi-step cleaning protocol to eliminate nontuberculous mycobacteria from the heater/cooler units at PSHMC:
- Ethylene glycol (25%) will replace water as the coolant due to its ability to reduce condensation, kill NTM, and conduct heat
- Orthopthalaldehyde (OPA) will be used as a regular cleaner due to its non-toxic properties and action against NTM
- Plasma sterilization will be used as a deep-cleaning method due to its species-independent effect against bacteria