MCH Water Path & Airflow Design

Cleanability, Compatibility, Compliance, Communication
Presenters

- **Douglas E. Platt, Partner**
  - 25+ years experience servicing & refurbishing perfusion equipment
  - Two patents in cooler-heater design

- **Jon L. Gardner, Chief R&D Engineer**
  - 8 years experience with perfusion equipment
  - One patent in cooler-heater design
  - Fifth-generation medical professional
CardioQuip MCH-1000

- Same hardware, software, & design
- Different tank sizes for different cooling needs
Open vs. Closed Water Path
Open Water Path Design

- No inaccessible airspace to harbor microbes
- Water-borne disinfectants contact all wetted components
- Tank is easy to inspect & clean
Cleaning Protocol

- Regular inspection
- Add disinfectant & circulate
- Wipe/scrub the tank
- Flush & fill twice
- Wipe down external surfaces
Cleaning Protocol Validation

- Fill device with contaminated water
- Sample water for HPC testing (pre-cleaning)
- Perform cleaning procedure
- Sample water for HPC testing (post-cleaning)
- Evaluate “cleanability”
  - Objective: time required, inspection results
  - Subjective: ease of inspection & cleaning
Validation Results

- The MCH is easy to clean
- The cleaning protocol is effective

<table>
<thead>
<tr>
<th>Disinfectant</th>
<th>CFU/mL (Pre)</th>
<th>CFU/mL (Post)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PineSol™</td>
<td>15,100</td>
<td>4.0</td>
</tr>
<tr>
<td>Chlorine Bleach (5%)</td>
<td>2,570</td>
<td>60.0</td>
</tr>
<tr>
<td>Hydrogen Peroxide (3%)</td>
<td>1,770,000</td>
<td>9.3</td>
</tr>
<tr>
<td>MinnCare™ (22% H₂O₂, 5% Peracetic Acid)</td>
<td>195,000</td>
<td>&lt;200</td>
</tr>
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Why Use Water?

- Regulatory history
- Materials compatibility
- Similarity to blood
- Superior performance
Water Risk Mitigations

- Valved connectors
- Dripless hose kits
- Anti-microbials
- Education
The Other Factor to Mitigate: Airflow
Surgical Ventilation System

Filtered air flows from the top center of the room, toward the perimeter. Exhaust grilles are located at two or more corners of the room. Pushes airborne microbes & particulates away from the patient. Specifications governed by international standards.

20x30x10’ room (6,000 ft³)

- 2,000 CFM
- 1,000 CFM
- 1,000 CFM

20 ACH from AHU

Touchscreen Control Panel

Return Pre-filter

Blowers (Heating/Cooling Coils Optional)

Point-of-Delivery HEPA Filtration
Factors for Airflow Validation

- Analyze with respect to Surgical Ventilation System standards (ASHRAE 17-2008, ISO 14644-3 et al)
- Consider airflow & history of similar devices
Airflow Validation

- Standard unit: ~50 CFM fan, bottom intake/exhaust
- Optional Refrigeration Module: front/rear intake, side exhaust, ~300 CFM (~150 CFM per side), smoke tested
Airflow Validation

- Compact unit: ~50 CFM fan, bottom intake, side/rear exhaust
- Optional Thermo-Electric Cooling Module, front/rear intake, side exhaust, ~100 CFM (~50 CFM per side)
Summary

Water Quality
Airflow

“Cleanability”
Effectiveness

Risk Assessment
Mitigation

Communication
Education
Contact Info

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