MCH Water Path & Airflow Design

Cleanability, Compatibility, Compliance, Communication

CardioQuip

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

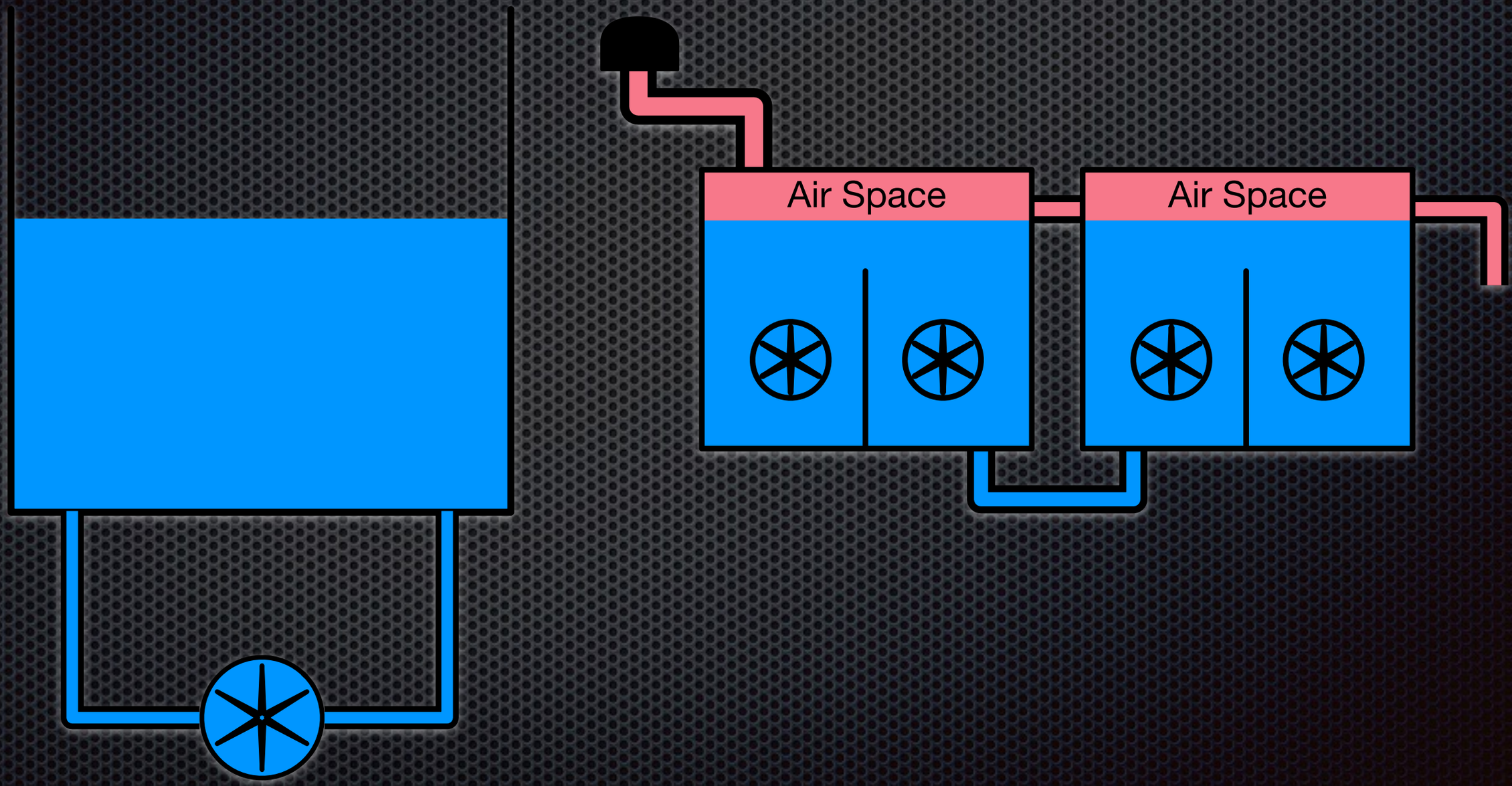
CardioQuip MCH-1000

MCH-1000(i)

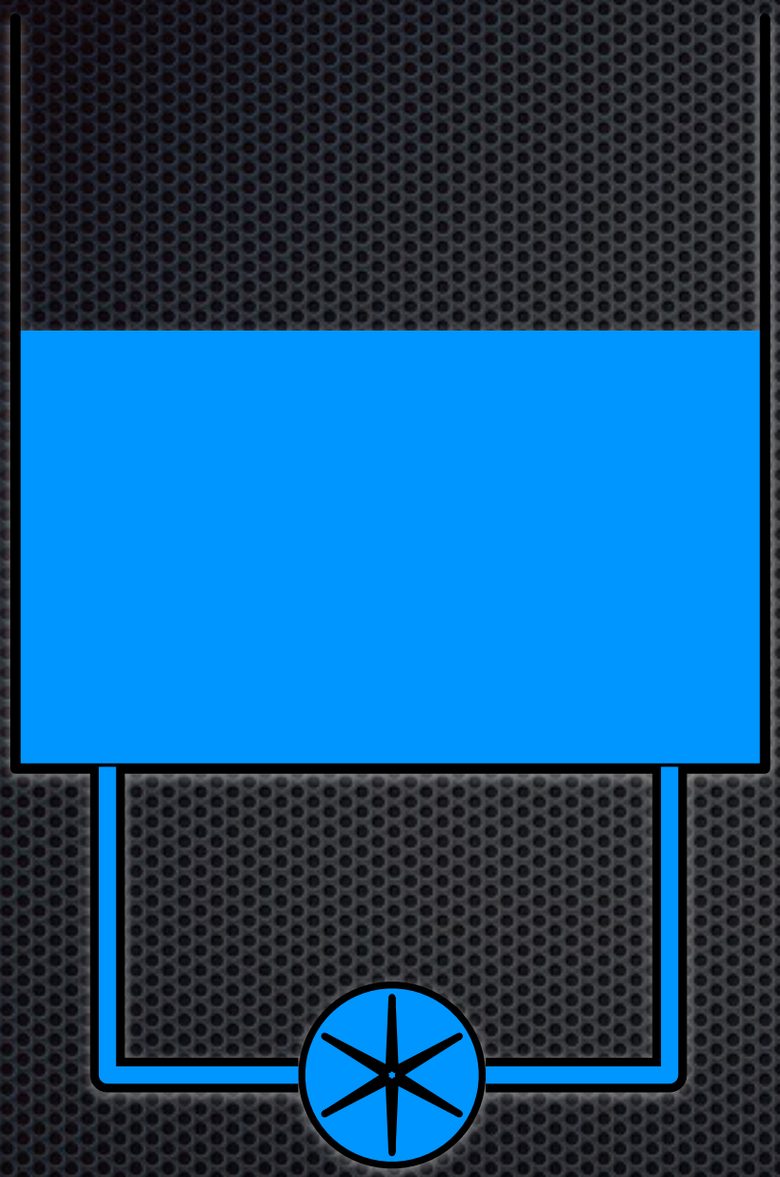
MCH-1000(m)

- 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

Disinfectant	CFU/mL (Pre)	CFU/mL (Post)
PineSol™	15,100	4.0
Chlorine Bleach (5%)	2,570	60.0
Hydrogen Peroxide (3%)	1,770,000	9.3
MinnCare™ (22% H_2O_2, 5% Peracetic Acid)	195,000	<200

Why Use Water?

- Regulatory history
- Materials compatibility
- Similarity to blood
- Superior performance

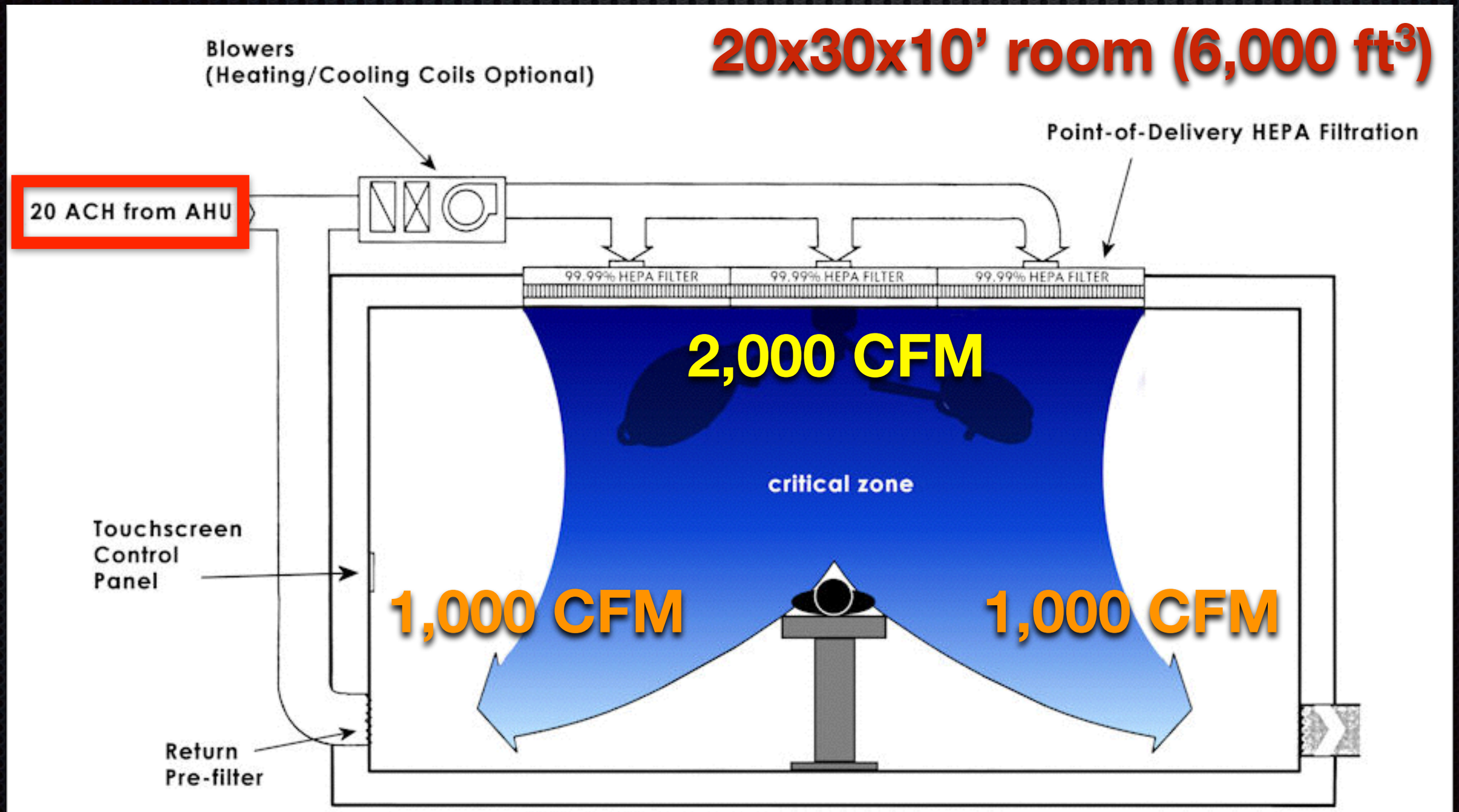
Water Risk Mitigations

- Valved connectors
- Dripless hose kits
- Anti-microbials
- Education

The Other Factor to Mitigate:

Airflow

Surgical Ventilation System



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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