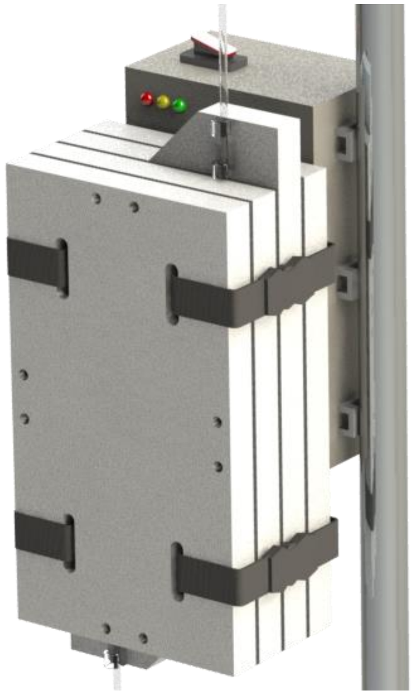
OpenFluidWarmer
Preliminary Design Review



John Opsahl
October 5th, 2020

Current State of Accessible Fluid Warming

"Commercial fluid warmers are either cost prohibitive in many contexts or not available for purchase" (Field Ready Fluid Warmer Open Challenge, Hackaday Prize 2020).

Hacked together, unproven designs are sometimes the only option.

*Images of fluid warmer at Annapurna Neurological Institute from “Low Cost Fluid Warmer Thesis by Marjolein van der Male”

OpenFluidWarmer Concept

- Industry standard safety features
- Common-off-the-shelf components
- Built using widely accessible manufacturing techniques
- Flexible design that can accept multiple alternative components
- Simple operation
- User feedback guided development
- Open-source

How It Is Used

- Cold fluid from IV bag at the inlet, warm IV fluid for the patient delivered at outlet
- Mounted on an IV pole
- IV tubing is routed through device

Use-Cases

- Hospitals with few financial resources and/or medical device sourcing options
- Mobile medical care, provides a solution that can be maintained with only a few tools on hand
- Disaster zone medical care, provides a flexible solution that can work with locally available components

Progress to Date

- Working proof-of-concept prototype
- Design and development documented on OpenFluidWarmer Hackaday.io page

Requirements Tracking

Req 1	Req 7	Req 13	Req 19
Req 2	Req 8	Req 14	Req 20
Req 3	Req 9	Req 15	Req 21
Req 4	Req 10	Req 16	Req 22
Req 5	Req 11	Req 17	
Req 6	Req 12	Req 18	

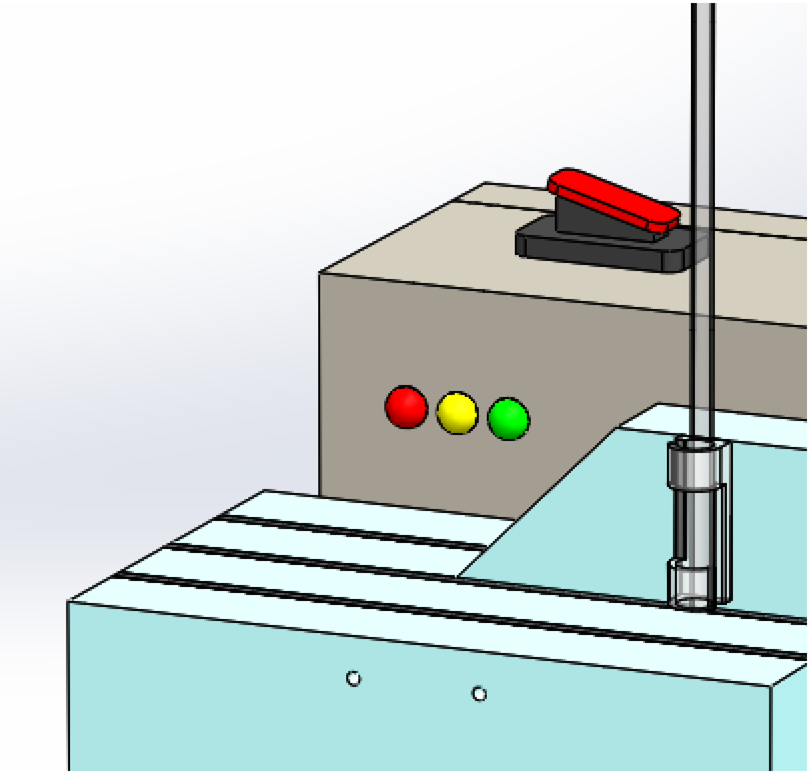
compliant

not compliant, in development

not compliant

Req 1: never fail without alerting the user

- Indicator lights and buzzer are current method to alert user of a fault
- Biggest challenge is when device loses power while in use (i.e. indicator lights and buzzer do not work without power)
- Currently, no clear strategy on how to measure fluid temperature through the IV tubing. Possible that this may not be necessary.
- Electrical current sense on the heaters has been considered to detect heater short or open circuit (minimal cost add).

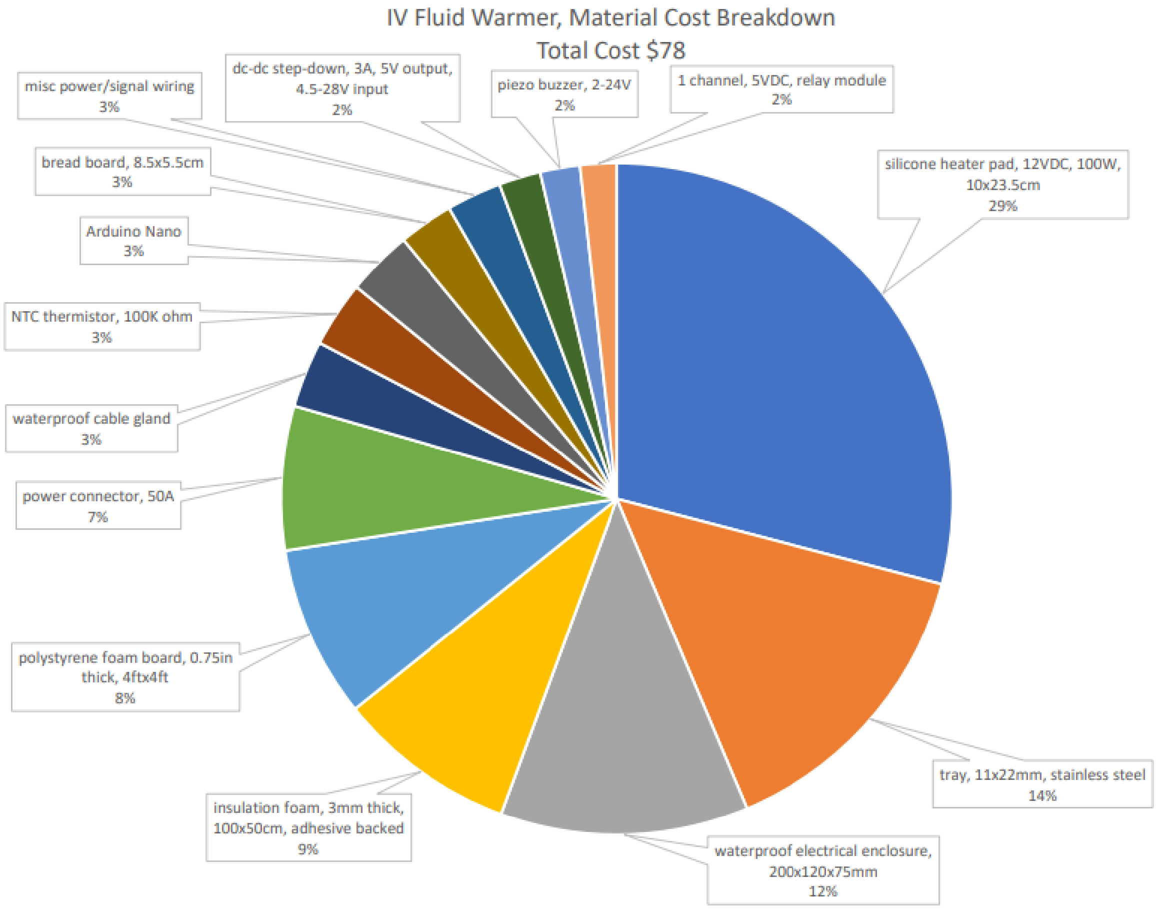


Req 2: shall cost less than $100 USD
Req 3: should cost less than $80 USD

- Current material cost is less than $80
- Small (<$10) cost increase expected
- Potential for larger cost increase to add all safety features

The five most expensive components being:

1. heaters -> 29%
2. stainless steel trays -> 14%
3. electronics enclosure -> 12%
4. adhesive backed foam -> 9%
5. polystyrene foam -> 8%



Req 4: shall warm fluid to 38 +/- 2°C at a flow rate of at least **20**mL/min

- Currently able to warm 6°C fluid to only 26°C at 20mL/min. Modifications to hot plates is expected to close this gap.

Req 5: shall warm fluid to 38 +/- 2°C at a flow rate of at least **80**mL/min

- If 20mL/min is a challenge with this current design, 80mL/min is unlikely.

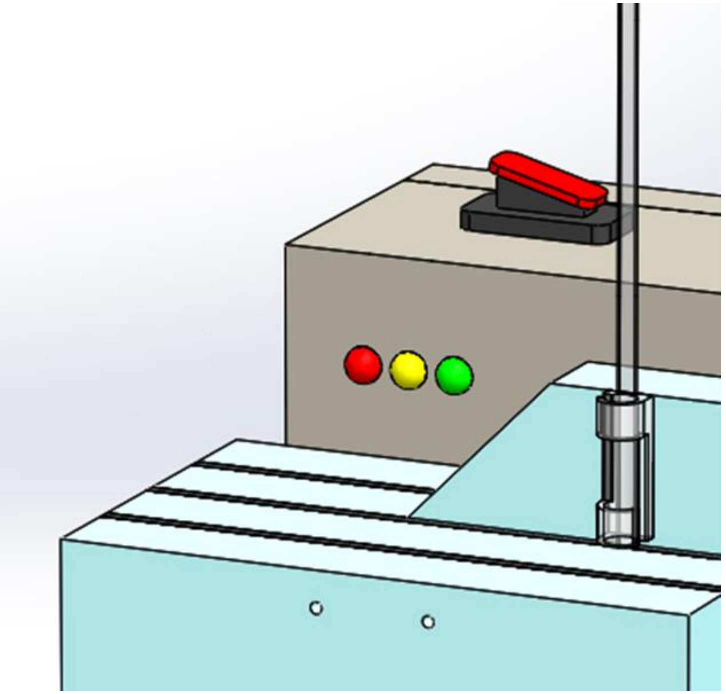
Req 6: turn off the heaters and alert the user when fluid is at risk of exceeding 42°C
Req 7: alert the user when fluid temperature is at risk of dropping below 36°C

- Requires ability to measure fluid temperature through IV tube or predict IV fluid temperature; no strategy developed yet to achieve this
- Instead of measuring IV fluid directly, may be possible to detect other system conditions that result in these fluid temperature conditions (heater current for example)

Req 8: warm up upon startup in less than 2 minutes from 4 to 36°C and in less than 45 seconds from 20 to 36°C

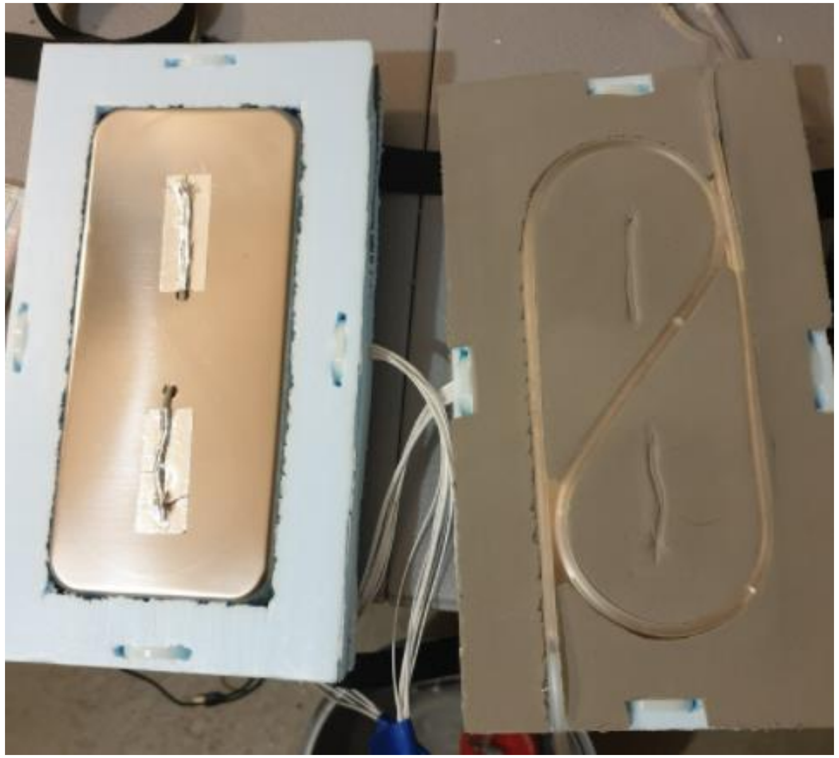
- Prototype can warm from 25°C to 105°C in less than 50 seconds

Req 9: one button operation



Req 10: be easy to clean contact surfaces after each use

- Not clear whether is it correct to say that the adhesive backed foam on the rear hot plate can be considered "easy to clean"
- Device does not need to be sterilized



Req 11: operate continuously when powered

- More testing is required, but prototype has operated continuously for over an hour and a half without issue

Req 12: meet or exceed IP54 ingress protection

- automotive silicone pad heaters are waterproof
- IP68 chord grips
- IP65 electronics enclosure
- marine grade waterproof rocker switch
- sealant may be required on polystyrene foam to prevent water absorption

- should incorporate a hot plate water drain hole

Req 13: meet IEC electrical shock protection Class I (chassis connected to electrical earth)

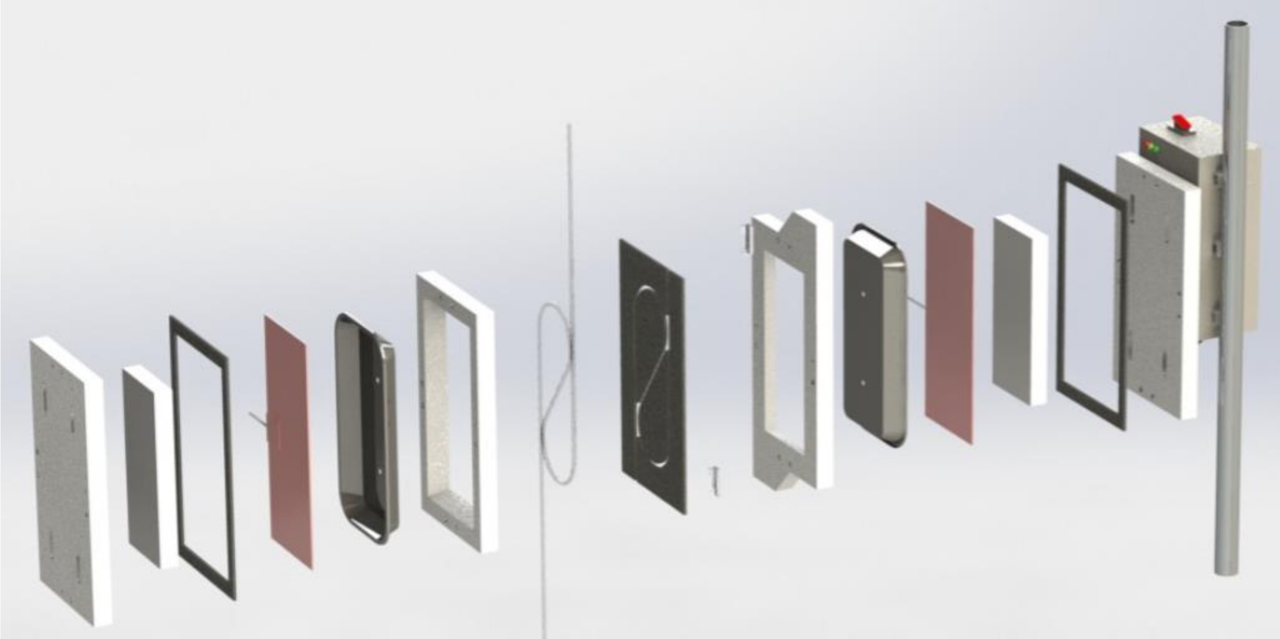
- Pertains to earth grounding conductive surfaces that user may come in contact during operation. Stainless instrument trays are currently not grounded

Req 14: include protections against defibrillation voltages per IEC 60601-1

- Dielectric breakdown study needed between IV fluid and electronic components. Low risk of being unable to meet.

Req 15: be constructed of common off the shelf components

Req 16: be constructed using common tools and manufacturing methods



Req 17: assume that the assembler has little knowledge of standard electronics assembly or troubleshooting methods

- Detailed assembly and user manual will be developed once design has been finalized

Req 18: track total time that device has been in operation
Req 19: include a fault history log

- Software features that are not difficult to implement. Other development has been prioritized for the first build

Req 20: display set point temperature on the device

- Currently anticipating this as a single set point device. A label on the outside of the device.

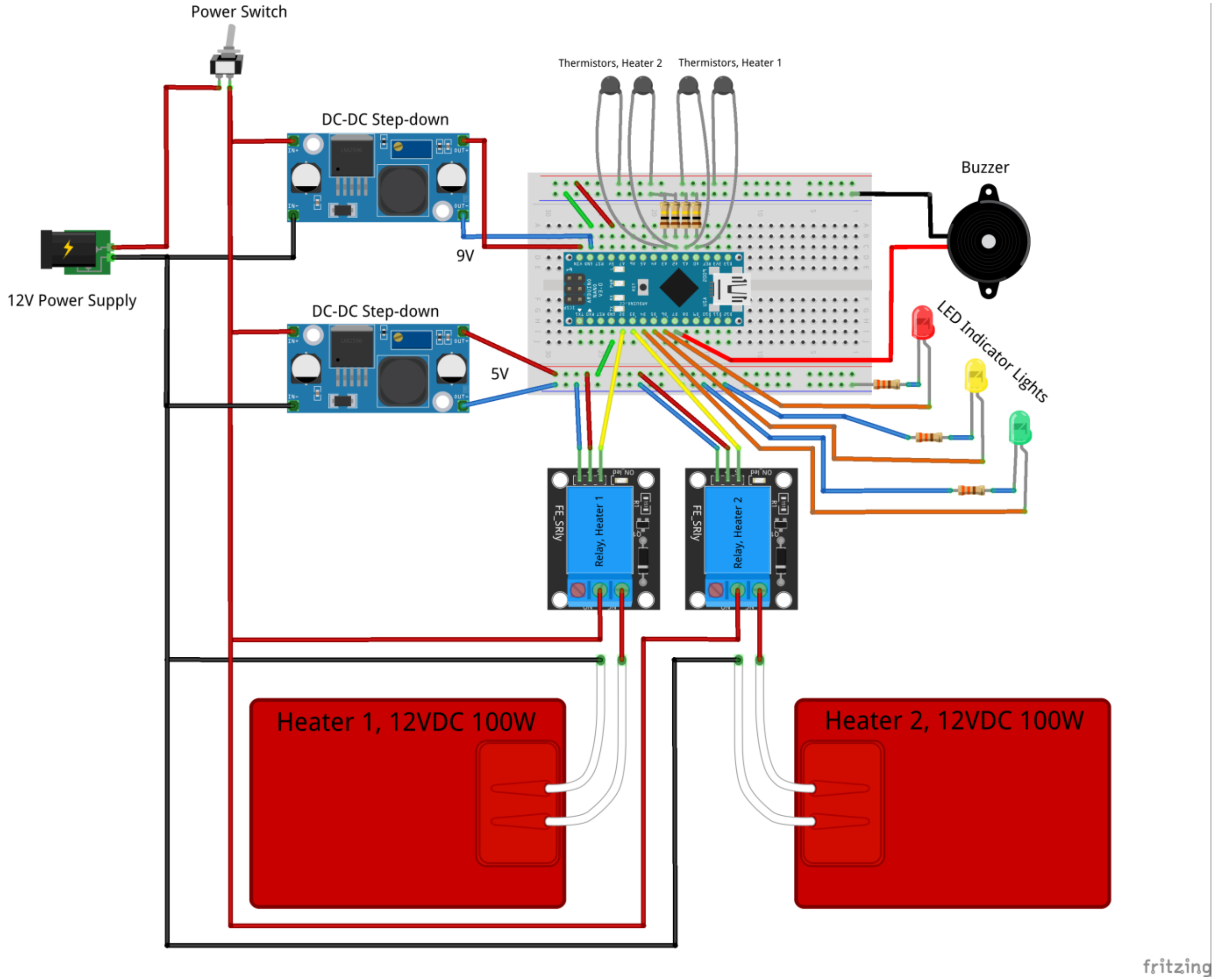
Req 21: display applicable safety hazard warnings on the device

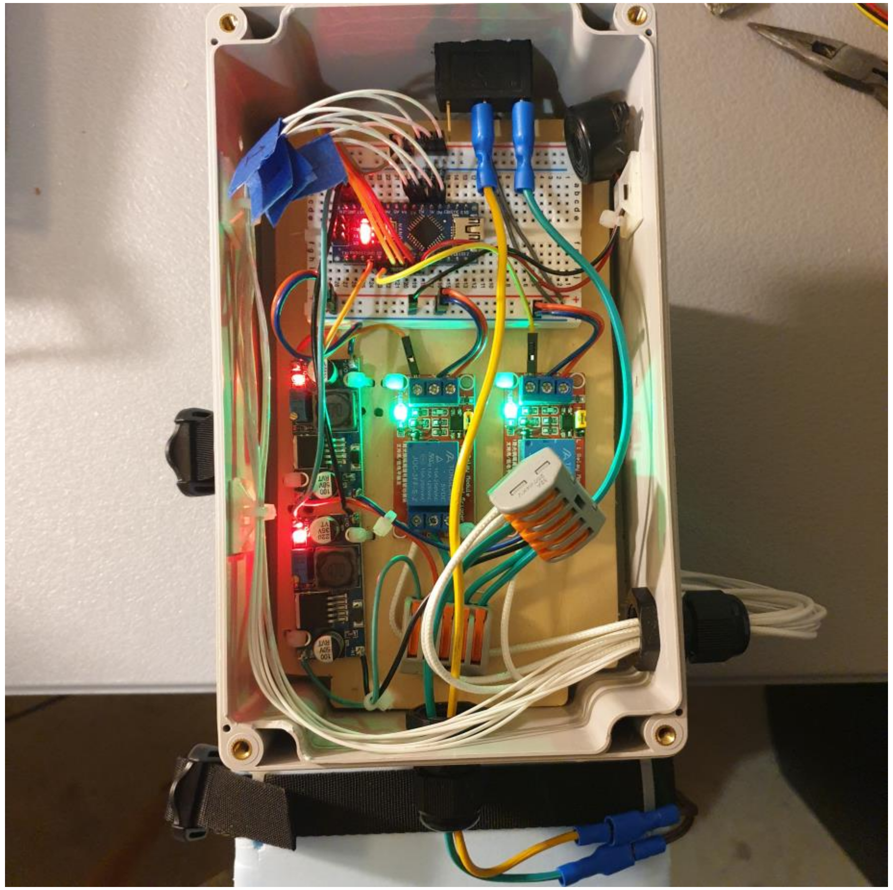
- A label on the outside of the device will display the safety hazards. In-depth safety hazard analysis needs to be performed.

Req 22: meet or exceed ASTM F2172 Standard Specification for Blood/Intravenous Fluid/Irrigation Fluid Warmers

- Requires payment to access this document. Waiting on initial outside investment before purchasing.
- Likely to have impact on the current safety strategies.

Wiring Diagram





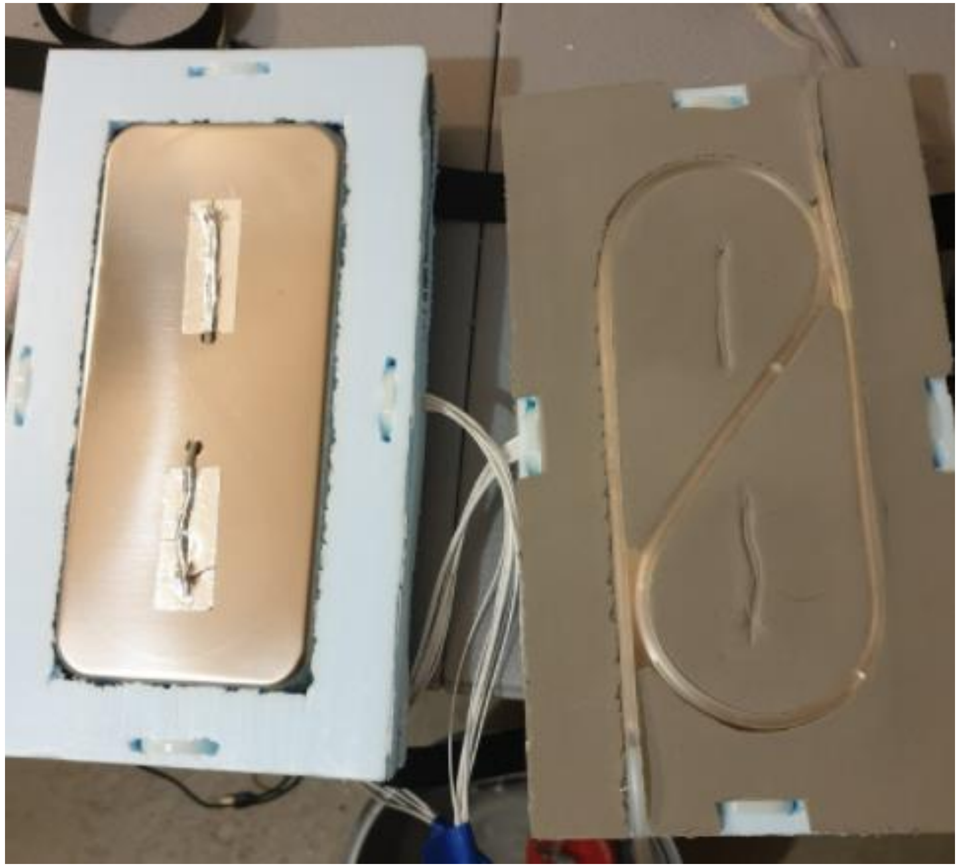
Biggest Technical Challenges

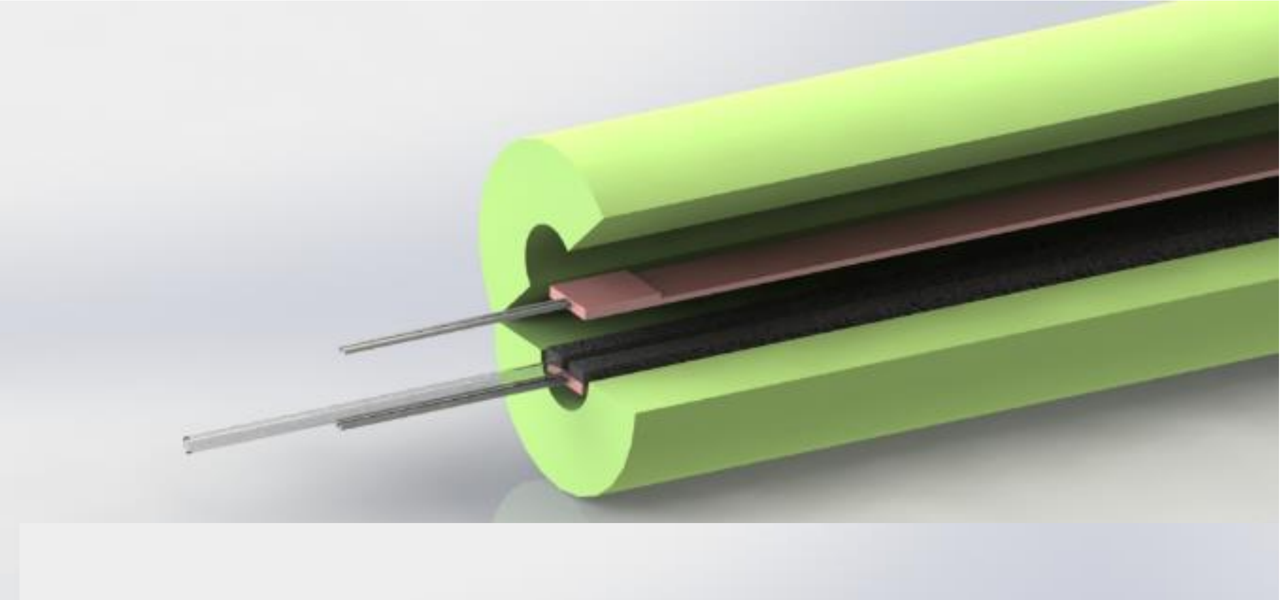
- Heat transfer strategy to achieve 38 +/- 2°C outlet temperature with 6°C inlet temperature at 20mL/min
- Approach to meet safety requirements. Cost impact of the approach.

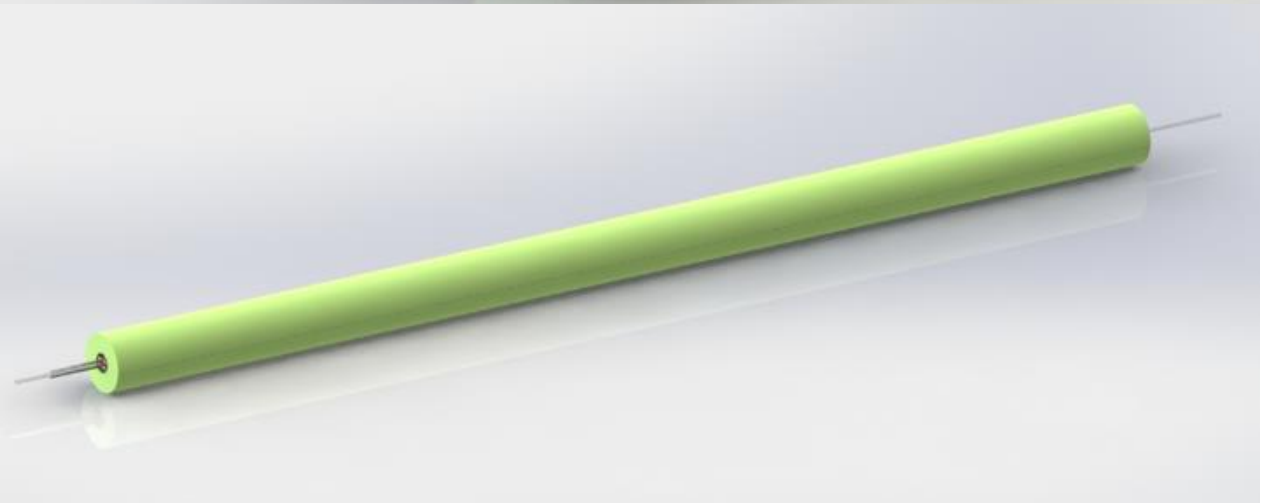
Hot Plate Design

- Heat transfer to fluid is dependent on:
  - Fluid flow rate (presumably laminar flow at 20mL/min in 3mm inside diameter tube)
  - Temperature differential between hot plate and fluid
  - Thermal resistance between heaters and fluid
    - Contact area between tubing and stainless steel tray
- PVC IV tubing (0.5mm wall thickness, 3mm inside diameter) is largest resistance in thermal network
- Ideally design would use no longer length of IV tubing than current design uses (24in total, takes up 14in of usable length)

Hot Plate Design Cont.







Future Improvements

- Custom PCB option (with hardware faults)
- Selectable set point temperature
- Optimize cost with two models - high flow and low flow
- Assembler and operator training materials