

Product Design Specifications (PDS)

Project: Cooling device for a transesophageal 3-D ultrasound probe (probe_cooling)

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Problem Statement:

Our client has been using a prototype of a new 3-D transesophageal ultrasound probe in pigs to image an injection catheter in the left ventricle. The injection catheter and imaging method are being tested as a method to deliver stem cells to damaged heart tissue. The continuous imaging that is required to determine the placement of the injection catheter and the stem cells causes the probe to overheat and turn off until it has cooled down enough to prevent any tissue damage. Our client would like a device to cool the ultrasound probe so that he could image for a longer period of time without tissue damage. This project would have commercial potential as this is a novel use of 3-D ultrasound. The cooling device could be as simple as using cold saline to flush the probe to a more sophisticated electronic cooling device.

Client Requirements:

- A continuous method of cooling the ultrasound probe
- Prevent probe from heating to 42 degrees Celsius where shutdown occurs
- Cool at a steady state temperature for up to 2 hours
- The cooling device must be waterproof
- The cooling device must withstand conditions in the esophagus
- Preferred the probe is not permanently attached to the probe

Design requirements:

Physical and Operational Requirements

a. *Performance Requirements* – The cooling device should be able to keep the probe at a steady state under 42 degrees Celsius for a minimum of two hours

b. *Safety* – The unit should not harm the animal in any way by being too bulky to be inserted down the esophagus, by being too rough or by being toxic.

c. *Accuracy and Reliability* – The unit should keep the temperature of the probe within 10-42 degrees Celsius.

d. *Life in Service* – The unit should be able to withstand frequent use in a controlled, clinical environment for a long duration. It should be able to withstand conditions within the esophagus.

e. *Shelf Life* – The unit should not degrade while in storage.

f. *Operating Environment* – The unit should be able to withstand acid and chemicals in the esophagus of the pig. It must not be affected by the ultrasound imaging process.

g. *Ergonomics* – The unit should not interfere with the insertion of the probe into the esophagus.

It should not protrude more than 1 cm total from the device (no more than 0.5 cm on each side if it surrounds the probe).

h. *Size* – The unit must be able to fit inside a pig's esophagus (see g).

i. *Weight* - The weight should be minimal (at least under 5 lbs).

j. *Materials* – Plastic is likely to be used. Materials should not interfere with ultrasound or kill

the animal (no toxic chemicals).

k. *Aesthetics* – The unit should integrate well with the probe.

Product Characteristics

- a. *Quantity* – Only one cooling device is required because the client only has one ultrasound probe.
- b. *Target Product Cost* – Budget will be adequate for the manufacturing of these units, although cost should be kept under \$150.

Miscellaneous

- a. *Standards and Specifications* – The unit will fit within the client's current testing protocol, thus no further board approval is necessary.
- b. *Customer* – It is okay if the animal is slightly harmed during the procedure, the primary goal is to keep the probe from shutting down.
- c. *Patient-related concerns* – Not applicable
- d. *Competition* – Other cooling devices exist but none made specifically for a 3-D transesophageal ultrasound probe