

Product Design Specification

Barostat To Measure Esophageal Strictures

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Function: A device to measure the size of the stricture (the percent reduction in radius of the stricture) and the compliance of the tissue (the stress-strain behavior).

Client requirements:

- Allow for easy and quick of interpretation of information of device

Design requirements:

Physical and Operational Characteristics

- Performance requirements:* If cost and time effective, device would be used in every procedure. Must measure size of stricture and compliance of tissue during the procedure.
- Safety:* Can't be toxic in body. Needs to be small enough to fit down esophagus and be of a flexible material as not to puncture esophageal walls. Must not have parts that may fall off into esophagus.
- Accuracy and Reliability:* Must measure within 1mm of actual size. Must be able to measure the size of a structure between 2mm to 25 mm.
- Life in Service:* Dependent upon cost
- Shelf Life:* 2-5 years
- Operating Environment:* Inside esophagus-approx 37 degrees C, wet, acidic environment. Also in typically hospital environment.
- Ergonomics:* Easy to learn and use, not complicated.
- Size:* Needs to fit through opening in camera tube and down the esophagus of patient. As small as possible is best in order to allow for maximum comfort of patient.
- Weight:* Must not put unneeded pressure on esophageal walls.
- Materials:* Non-toxic materials, safe to use in body. Flexible material, can alter size, volume (like balloon). Blunt as not to puncture balloon or esophagus.

- k. *Aesthetics, Appearance, and Finish*: Smooth edges. It will be similar to other instruments currently used in the esophagus (such as balloons or guidewires).

Production Characteristics

- a. *Quantity*: One per procedure room in hospital.
- b. *Target Product Cost*: approx. \$150-pressure transducers \$60, extra syringe and tubing \$20, device to interface from transducers to computer \$80

Miscellaneous

- a. *Standards and Specifications*: Must follow current human testing guidelines.
- b. *Customer/Patient-related concerns*: : Reasonable cost, small as possible, no added procedure.
- c. *Competition*: none known