

Product Design Specification

Device to Measure Esophageal Strictures

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FUNCTION:

The goal of our project is to develop a safer method of treating esophageal strictures. An esophageal stricture is a collection of scar tissue partially blocking the esophagus pathway limiting food flow and giving the patient a choking sensation. Currently, a pressurized balloon dilation method is used to break the strictures, but can lead to tearing of the esophagus. We intend to instrument the esophageal dilation device to obtain accurate measurements of balloon pressure and volume and examine tissue compliance during dilation. The instrumented system and a computer-readout of the results would be available to the surgeon during the dilation. By measuring the pressure on the esophagus, the surgeon may avoid over-pressurization and prevent the tearing of the esophagus tissue.

CLIENT REQUIREMENTS:

The device must be easy to use by the doctor, safe, low cost, reusable, durable, and capable of transmitting accurate graphical data that can be used to measure tissue compliance in the esophagus. It must also be approved for use on animals and humans.

DESIGN REQUIREMENTS:

1. Physical and Operational Characteristics
 - a. Performance Requirements
 - i. Reusable
 - ii. Easily interpreted data
 - iii. Withstand sterilization by common household cleaner
 - iv. Non-invasive
 - v. Must not affect dilation procedure
 - b. Safety
 - i. Non-toxic and non-allergenic materials
 - ii. Durable
 - iii. No risk of electrical shock
 - iv. No sharp edges
 - c. Accuracy and Reliability
 - i. Measure pressure within 0.1atm of actual pressure
 - ii. Measure volume within 0.5mL
 - d. Shelf Life: 2-5 years
 - e. Operating Environment
 - i. Sterile hospital environment
 - ii. 25°C, standard room temperature
 - f. Ergonomics
 - i. Easy to use
 - ii. Low force required to operate device
 - g. Size
 - i. Sensors must fit on syringe or handgun

- ii. Wires must not interfere with balloon catheter
- h. Weight
 - i. Light
 - ii. Must not add stress to user's hand
- 2. Production Characteristics
 - a. Quantity: 1 unit
 - b. Target Product Cost: minimal
- 3. Miscellaneous
 - a. Standards and Specifications
 - i. Must meet human testing guidelines (FDA)
 - ii. Research Animal Resources Center (RARC) certification and approval
 - b. Customer/Patient Related Concerns
 - i. Easy to use
 - ii. Minimal training needed
 - iii. Reasonable cost
 - iv. Safe
 - c. Competition
 - i. Low Compliance Pneumohydraulic Perfusion System
 - 1. Amdorfer Medical Specialities, Greendale, WI
 - 2. Digital signal to computer from Model D1200AC
WinDaq Acquisition from DATAQ Instruments
 - 3. Volume inputted manually
 - ii. Barostat, Manometric Catheters, and Paper Polygraph
 - 1. Polygraph Model 1600, MFE, from Salem, NH
 - 2. Pressure collected via pneumohydraulic system
 - 3. Barostat measures volume of air in a bag maintained at constant pressure
 - iii. No designs measured pressure and volume while sending data to a computer *during* the dilation