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Device for Dilating Esophageal Strictures

Function: The current prototype is designed to measure the tissue compliance of an esophageal stricture during balloon dilation. A syringe gun is used to inject saline in a balloon. As the syringe is depressed, a sensor attached to the side of the gun and to the top of the syringe measures the change in volume. The potentiometer measures the change in volts as the arm of the sensor gets shorter. The pressure sensor is attached at a T-joint at the end of the syringe. Saline is then able to go into the pressure sensor and the balloon. The two sensors are attached to a computer, which can store the data. The data is collected, analyzed, and displayed in real time using the LabView software. The graph measures pressure versus volume which is tissue compliance.

Client Requirements: The client has three goals for the project. The first goal is to gain approval for human testing. This requires writing an IRB protocol and gaining approval from the IRB board. The second is to design an alarm program that will accompany the software to alert the doctor and nurses of perforation of the esophagus. The last is to make the design aesthetically pleasing. This will get the device ready to be used in a hospital setting. This includes putting the sensors in a plastic casing and binding the wires into a single wire.

Design Requirements:

1. Physical and Operational Characteristics

a. *Performance requirements:* The data recording will be added on to a device that is already in common use in hospitals. The addition of the sensors must not interfere with the procedure and should be capable of being implemented in any GI procedure room in the country. The device must measure the full volume of the syringe, which is 60 mL. The device must also read up to 10 atm of pressure.

b. *Safety:* The sensor device is essentially a no risk addition to the procedure. The operation is already being done and the device only measures the surgery and does not change it.

c. *Accuracy and Reliability:* The pressure and volume sensors need to be able to make a smooth graph that is readable to the operating team. The device should be significant to 1 significant figure after the decimal.

d. *Life in Service:* The sensors will be good for the lifetime guaranteed by the manufacture. The syringes are replaced as needed readily from hospital supply. A new balloon dilator is used with every patient.

e. *Ergonomics:* The only restriction on the device is the length of the wires connecting it to the computer and the force needed to pull the trigger of the syringe gun.

f. *Size:* The device has to be able to be held in one hand or mounted and capable of being moved around the operating room.

g. *Aesthetics, Appearance, and Finish:* The final product should be similar in color and texture to the syringe gun the sensor is mounted on.

2. Production Characteristics:

a. *Quantity:* The current goal is to produce one prototype. The future goal is to have the device available and in every GI procedure room in the country.

b. *Target Product Cost:* The materials for the sensors cost around $100. The syringe gun is the most expensive of the prototype at around $500. The syringe and balloon dilator are bought in mass quantities and are disposable.

3. Miscellaneous

a. *Standards and Specifications:* With one of the goals to begin human testing, approval from the UW-Madison Institutional Review Board will be necessary to incorporate the device into the procedure.

b. *Patient-related Concerns:* All team members will need to be HIPAA certified to work with the data collected. Each patient will be assigned a number and the list of the names and numbers will be kept inside a locked box where only the doctor can access it. People working with the data will only be able to see the number of the patient.