

Appendix A

Product Design Specifications for BME 400 Group 47: Surgical Simulator

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Problem Statement:

The methods to practice surgical procedures have begun to change in the medical field. Instead of using expensive cadavers to practice, many surgeons are starting to practice on simulators. Our objective this semester is to design a simulator for endoscopic carpal tunnel surgery by using a life-like physical hand model to interface with a virtual 3-D representation of the wrist and hand.

1. Design Requirements:

The device must meet all of the client requirements

- a. Performance requirements: Hand model should feel as close to a regular hand as possible. Signaling device should potentially be able to detect motion within all six degrees of freedom without detectable delay.
- b. Safety: Device should not cause any harm to the surgeon or other connected devices involved with the simulator
- c. Accuracy and Reliability: Signaling device should be able to detect position of the endoscope within 1 mm. Device should maintain accuracy of position throughout single and multiple simulations.
- d. Life in Service: Simulator should be able to withstand repeated uses by surgeons practicing the surgery for at least a year.
- e. Operating Environment: Device will be used in a hospital setting at room temperature and standard humidity.
- f. Ergonomics: The hand model should look and feel like a real hand. The hardware should be arranged in a way that does not get in the way of the surgery. The method of signaling should not change the physical components of the endoscope.

- g. Size: Hand model should be life size and the simulated incision should be anatomically similar to what is seen during surgery.
- h. Materials: Hand material feel, look and act like regular tissue. Material should also have similar mechanics involving structure that is similar to tissue of the hand.

2. Production Characteristics:

- a. Quantity: One reproducible working prototype is necessary.
- b. Target Product Cost: \$400

3. Miscellaneous:

- a. Standards and Specifications: No specific standards because prototype is only used in simulation, not actual surgery
- b. Customer: Client is currently working on creating the virtual environment. Client also specified the need for a signaling device that will track position of endoscope accurately and precisely. The feel of the hand model should also be similar to a normal hand so that practicing surgeons can get used to the feel of the surgery. The only anatomy specified by the client is the restrictions of the carpal tunnel.
- c. Patient-related Concerns: None
- d. Competition: A current device involving minimally invasive surgeries called TrEndo. It creates a physical connection between the tracking element and the surgical device.