

## Product Design Specification Report Sensing Forceps

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**Problem Statement**

Our client Dr. Michael Zinn of the UW-Madison Dept of Mechanical Engineering is looking for a forceps that can display the applied force. Currently there is no way to measure the force exerted by the forceps. Forceps that can measure and display real time forces are needed for research and surgical use in pediatrics; particularly on neurological, bowel, and artery tissue. The force display needs to be straightforward, clearly readable, and does not encumber the user.

**Client requirements**

- Able to withstand autoclave sterilization
- Display is able to withstand current flow through forceps
- Ideally wireless components
- LabView compatible
- Real-time display and feedback
- Low cost
  - Max of \$500.00
- Universally compatible with all forceps design
- Does not hinder surgeon's ability to perform the surgery
  - Max weight of 250 grams
- Holds up to contact with blood and other body fluids
- Continuous force value not just a threshold
- Material must be non-toxic
- Display must be easily viewable but not obstructive
- Must hold up to vigorous use
- Must be able to withstand long-term storage at room temperature
  - Lifetime of 10 years minimum
  - Approximately 25°C
  - 50% humidity

## Design requirements:

### 1. Physical and Operational Characteristics

- a. *Performance requirements:* The forceps will be used to measure the force exerted on bodily tissues. The given measurement will be displayed on a digital display. At least the component of the forceps physically used on tissue will be sterilization-capable. The display should be able to run off a watch battery for a minimum of 10 hours.
- b. *Safety:* The forceps and display will not endanger or contaminate the tissue or entire patients on which it is being used; therefore, sterilization will be necessary for direct usage on tissue. Safety aspects relating to both the mechanical and electrical components of the instrument will be labeled.
- c. *Accuracy and Reliability:* The forceps will measure the applied force to the nearest 0.01 N. The range capable for display will be from 0.00 N to 20.00 N.
- d. *Life in Service:* The forceps and electrical components will not degrade or become unreliable for up to 10 years of usage, assuming the correct precautions are taken in sterilization and the protection of the electronics.
- e. *Shelf Life:* The forceps and user interface should not degrade over time in storage for at least 10 years as long as the device is stored properly and at room temperature or slightly below.
- f. *Operating Environment:* The forceps will be used by one surgeon at a time, at a variety of temperatures ranging from 25<sup>0</sup>C-40<sup>0</sup>C, and at high humidity. The forceps will be exposed to blood and other bodily fluids. The forceps may be used on animals or humans. The user interface will be used at 25<sup>0</sup>C and at between 30% and 50% humidity but should not be exposed to large amounts of liquid.
- g. *Ergonomics:* The display that shows the force should be at least 7.5 cm from the eye and no more than 1 m away. The display will fit comfortably on the surgeon or in the surgery room. The interface and its connections will not obstruct or obscure the use of the forceps.
- h. *Size:* The forceps may vary in length from 10cm-25cm in length. The user interface may vary in size but the display should be visible to the user and easy to read.
- i. *Weight:* The display should not exceed 250 grams and the forceps should not exceed 50 grams. The other equipment needed to use the surgical device must be portable and easy for one person to carry.

j. *Materials*: Materials used must be safe for use around humans. Any material used should not pose a health risk or be abrasive when the device is handled. Non-radioactive, non-flammable, and non-corrosive materials should be used. Materials for the non-electronics should be durable with the ability of being sanitized through either autoclaving or gas sterilization.

k. *Aesthetics, Appearance, and Finish*: The device should be pleasing to the eye and users should be comfortable reading the display naturally. The finish should be smooth and clean looking.

## 2. Production Characteristics

a. *Quantity*: One model is required at this time. However, if the product is to be produced on a large scale in the future, additional models will have to be manufactured.

b. *Target Product Cost*: The target manufacturing cost for the product is no more than \$500, which includes the initial cost of forceps, strain gauges and user interface.

## 3. Miscellaneous

a. *Standards and Specifications*: The forceps as a whole will need FDA approval because they are a medical device that has the possibility to be used on humans. The device will adhere to client specifications.

b. *Customer*: The product should follow the customer's basic requirements for the user interface option: a suitable method to communicate the measured force levels to the physician. The client's requirements will be addressed in producing the interface.

c. *Patient-related concerns*: This device will come in direct contact with the patient. Because of this, the device must be sure not to: cause damage to the patient's tissue, infect or poison the patient in any way, or leave debris after use. This device should not endanger the surgeon using it.

d. *Competition*: There are currently no force sensitive forceps on the commercial market. There is research being done on methods of sensing force that would be suitable for use with forceps. Creating a user interface using microcontrollers has been done before; however, there are no programs readily available for our purpose.