

Sensing Forceps

BME 201
University of Wisconsin-Madison
Department of Biomedical Engineering
May 3, 2011

Team:

Alan Meyer – *Team Leader*
Hope Marshall – *Communicator*
Spencer Strand – *BSAC*
Michael Scherer – *BWIG*

Client:

Dr. Michael Zinn, University of Wisconsin: Madison – Department of Mechanical
Engineering

Dr. Carter Smith, University of Wisconsin: Madison – Department of Surgery

Advisor:

Professor Paul Thompson
University of Wisconsin-Madison Department of Biomedical Engineering

Table of Contents

Abstract.....	2
Background.....	3
Motivation	3
Problem Statement.....	4
Client Requirements.....	4
Ethics	4
Ergonomics.....	4
Design Proposal Overview.....	4
Design 1: Glasses, Speed Change, Flashing.....	5
Design 2: Monitor, Pitch Change, Color Change.....	5
Design 3: Armband, Volume Change, Color Change.....	6
Design Evaluation	6
Final Design	8
Testing.....	8
Future Work	10
Works Cited.....	12
Appendix A: Product Design Specification Report.....	13
Appendix B: Wireless Component.....	16
Appendix C: Test Results.....	17
Appendix D: Java Code.....	19
Appendix E: Cost and Labor.....	20

Abstract

Body tissues have different force thresholds before damage begins to occur. In order to discovering what these threshold values are, a specialized forceps needs continued development to measure this force and give real-time feedback to the user. The data received from the forceps (through attached strain gauges) will be brought into a developing computer program via a microcontroller and processed into useable data. The data will then be outputted to a display. Currently, there are three alternative designs in progress to meet this objective. The first design consists of a heads up display mounted to a pair of glasses with flashing LEDs to alert the user that a threshold has been reached. The second design uses a monitor to display the feedback along with a tone change to warn the user of the current force. Finally, the third design implements an armband with a display with a changing volume to indicate an approaching threshold. Based on relevant evaluation criteria, a final design will be chosen that best meet our clients' needs.

Background

All surgeries require a precise application of force on a given tissue. Depending on the type of tissue being handled, there are various thresholds of force that can be applied before damage occurs. Currently these thresholds are unknown. Because of this, surgeons currently base the amount of force that should be applied to the tissues on previous experience.

Current technologies used to measure forces include piezoresistive thick-film technology and strain gauges. Piezoresistive technology is inexpensive and effective. However, research has shown that piezoresistive technology has not been effectively used with the metals used in surgical instruments. No effective adjustments have been attempted in order to make this technology compatible with any surgical instruments [1]. There is technology that could be used to measure the force applied to a tissue, but none of this technology has been applied to create a sensing forceps that can be used in a clinical setting.

Strain gauges have been used with surgical instruments in the past [2, 3] and were chosen by Stephen Young, Tanner Marshall, Kelsey Hoegh, Karin Rasmussen, and Vinodh Muthiahto to be used in their design from the 2010 Fall semester. A USB amplifier was also used in last semester's design to relay information from the strain gauges to the computer in Java.

Displays for surgical instruments mostly consist of monitors and screens on handheld instruments. Since there have been no forceps designs that display numeric values, there have been no displays made for forceps to be viewed during surgery.



Figure 1: Strain gauges on forceps

Motivation

The need for force sensing forceps in the 2011 medical world is for new surgeons to quickly learn the force limits in which they can exert on certain tissues. It is very difficult for beginning surgeons to learn the amount of pressure in which each type of tissue can withstand. Currently, surgeons gain their ability to handle tissues through years of practice. The goal of the force sensing forceps is to streamline the education of these future surgeons in order to make the entire process more efficient.

In addition to teaching new surgeons, the forceps are also capable of determining what the specific thresholds are for each type of tissue. Presently, there is no documented data describing the amount of force tissues can withstand. The forceps would measure the force exerted by surgeons and give tissue-damaging thresholds for tissues. Overall, the device will be capable of discovering the strength of various bodily tissues and modernizing surgical teaching tools.

Problem Statement

Our client, Dr. Michael Zinn of the UW-Madison Department of Mechanical Engineering, wants a forceps that can display the applied force. Currently there is no way to measure the force exerted by the surgeon on 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 not encumber the user.

Client Requirements

The final device should be Java compatible, have a real-time display and feedback of the force exerted on the tissue, cost less than \$500, and be universally compatible with all forceps designs. The device must not hinder the surgeon's ability to perform an operation and it must not weigh more than 500 grams. The device must be able to withstand exposure to blood and other bodily fluids as well as vigorous use. The display must show a continuous force, not just a threshold and it must be easy for the surgeon to read during an operation. The device must be made out of non-toxic materials that are biocompatible and must last more than 5 years. The device must be able to withstand high humidity of 80%.

Ethics

The ethical concerns involved with improving a current surgical device for clinical use are directly related to patient care. The new device needs to be just as patient friendly as the current design, and should not endanger the patient through any means. Materials of choice must not be toxic, radioactive, flammable, or corrosive in any way. To use this device clinically, it would need to be reviewed and approved by the FDA.

Ergonomics

The force sensing forceps need to be able to assist a surgeon in measuring the force he or she is exerting on a tissue. It should not damage the tissue if used properly in surgery. The surgeon must be free of any optical-related stress or damage due to the display. In addition, the entire device (forceps, wiring, and display) should not be a distraction to the user.

Design Proposal Overview

The sensing forceps function as a tool for both research and a useable tool for surgery. Along with the actual forceps, a user interface needs to be developed that can constantly display the force currently being exerted on the tissue by the forceps, as well as warning the user when he or she is reaching a threshold force that will begin to damage the tissue. To do this, we will need to receive the deflection reading from the forceps' strain gauges via the USB microcontroller, process the data so that it is relevant to the user, and send the data to an external

display that can be easily accessed by the user. To process the data we will use a program such as Java to read the analog input, convert the input to a digital signal, filter out any noise, and display the data. The coding that will need to be done to display the data will vary based on the design that is chosen. Each design will require code to numerically display the real-time force being applied as well as indicated threshold values that will trigger the design specific warning mechanisms. Three designs for possible prototypes for the sensing forceps display are described below.

Design 1: Glasses, Speed Change, Flashing

The glasses design focuses on ease of use during clinical procedures, providing the surgeon with real time feedback viewable by simply glancing to the right. This will allow the user to maintain maximum attention on the procedure at hand. The design consists of a small LED force display located at the back of the device, near the ear of the wearer. To provide adequate ability to be sterilized, the display will be removable. The rest of the device will consist of a real-time numerical force display along with a special LED designated to flash at increasing frequency when a predetermined threshold is breached. There will be two thresholds that will be set to ensure that minimal tissue damage occurs. When the first threshold is breached, the flashing begins. The second threshold represents a danger region where tissue damage can occur. When this threshold is breached, the LED will flash fervently.

This display will be held in a sturdy yet lightweight plastic enclosure with its display facing forward. At the front of the device, the display will be reflected across the face of the user by a mirror, and then again, into the eye of the user by a semi-reflective yet semi-transmissive material to ensure the surgeon can both read the display and see through the film. A wire framework will surround the film to support it and provide additional durability. Along the inner length of the design will be plastic clips to secure the device to the frame of a pair of glasses to be worn by the user.



Figure 2: HUD on glasses [4]

Design 2: Monitor, Pitch Change, Color Change

The monitor design gives a constant visual indication of the force being applied by the forceps and both audio and visual warnings if the tissue damage threshold is reached. This design will be centered around a mounted monitor (Figure 3). This monitor will be mounted on a mobile cart to allow for easy transportation. The monitor will also be mounted on a swinging arm, giving added mobility. To make sure the monitor is visible from a distance, a 17 to 23 inch monitor will be used. This size



Figure 3: Monitor

range allows for clear visibility 8 to 12 feet away while maintaining a respectively low cost.

Along with a constant numerical visual reminder of the applied force, this design incorporates an audio and color warning. The audio warning will consist of a change in pitch. When the forceps' user breaks the threshold of force at which tissue damage will occur, a 500 Hz tone will sound as a warning. If the user exceeds a second threshold, a 1000 Hz tone will sound as a stop notification. This range is within the 200-2000 Hz range to which the human ear is the most sensitive [5]. Coupled with this warning will be a stoplight display. If the force being applied is under the first threshold, the light will be green. If the force is between the first and second threshold, the light will be yellow. If the force exceeds the third threshold, the light will be red. These various methods of feedback allow for a range of communication to the user as well as create back-ups for colorblind and hearing-impaired users.

Design 3: Armband, Volume Change, Color Change

The armband design gives a constant visual display of the force being applied by the surgeon to the forceps and both audio and visual cautions if a threshold is broken. The display will be secured on an armband. The forceps will be wired to a computer to be processed, and then the output will be on the armband display. To ensure the display is visible from 1 to 2 feet, a 3 to 4 inch display will be used.

Apart from the visual display, the design implements a volume and color system to alert the user. When in use, the device will provide a single pitch at a constant tempo, similar to a metronome. If the user approaches a threshold for a certain tissue, then the metronome volume will increase. If another threshold is reached, the metronome volume will increase to a final warning level. To complement this feedback system, there will also be a stoplight display. If the force being applied is under the first threshold, the light will be green. If the force is between the first and second threshold, the light will be yellow. If the force exceeds the third threshold, the light will be red. These various methods of feedback allow for a range of communication to the user as well as create back-ups for color blind and hearing-impaired users.



Figure 4: Armband design [6]

Design Evaluation

Table 1 lists evaluation criteria for the different designs for a user interface to be used with the sensing forceps. The evaluation criteria for the three designs are as follows: Feasibility, Cost, Durability, Sterilization, Ubiquitous, and Cumbersome. Using these criteria, a final design was selected. The designs were assigned a score between 1 and 5 for each category and then the total score was summed. Feasibility evaluates the probability of building the design over the period of one 14-week semester. Cost evaluates the overall price of materials that will be

required to build the design. Durability evaluates how the design will hold up over multiple uses. Sterilization evaluates the ability of components of the design to be autoclaved. Ubiquitous evaluates if everyone can use the design or if there is a limited group of users. Finally, Cumbersome evaluates how awkward the design is to use.

The Glasses Design scored a 19 overall. It scored a 3 in feasibility because while the design itself is relatively straightforward, constructing it to be useful while still not cumbersome would be difficult. In addition, attaining a semi-reflective and semi-transmissive material that would work could prove to be a challenge. A 3 was awarded for cost due to the price of the material used in front of the glasses lens. The design scored a 2 for durability because some sort of plastic or metal would be needed to support the film fixed in front of the surgeon's eye around its perimeter. Even with this added support, the film structure would still be fairly flimsy and breakable. The design scored a 4 for Sterilization because depending on the film of choice, the force display could easily be removed to leave just the film, plastic container and mirror to be sterilized. The Ubiquitous score of 5 is because the design offers the easiest way for a surgeon to view the display while keeping most of his attention on the work at hand. Finally, a 2 was awarded for cumbersome because if the weight of exceeds 500 grams, which is a strong possibility, the device was become too heavy to be useful.

The Monitor Design scored a 26 overall. Because this design would only require buying a monitor with built in speakers and connecting the monitor to the computer output, this design scored a 5. Because this design only requires buying a monitor and some cables, the design scored a 4 in cost. This design scored a 5 in durability because monitors have a long life of use if not abused. Since the monitor can be distanced away from the actual surgery, there is no need to use autoclave sterilization. Because of this, the design scored a 5 for Sterilization. Because this design uses audio and color visual feedback, it will not be as useful to someone who is color blind or hearing impaired and therefore, reducing the ubiquitous score to a 3. This design is also the least cumbersome design at a score of 4. The reason for this score as that while the monitor will not encumber the user, it still takes up space and requires a wired connection.

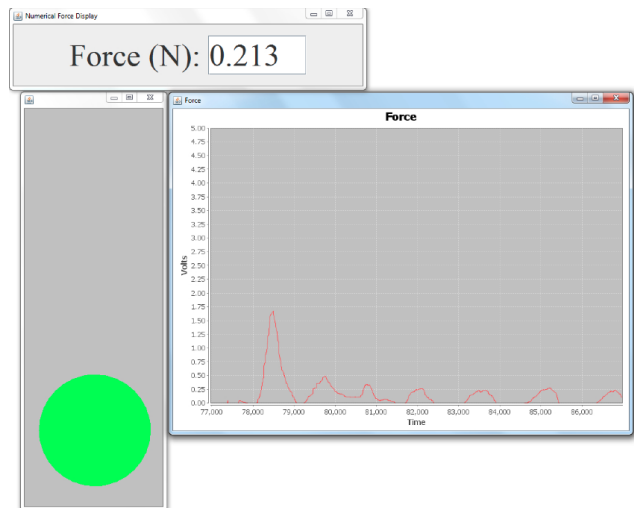
The Arm Band Design scored a 22 overall. This design only requires the purchase of a small digital display, a holster, and some wires, giving it a feasibility score of 5 and a cost score of 4. This design scored a 5 in durability since both the digital display and the holster have long life-of-use if not abused. Because this device will be close to the actual surgery, it will need to be sterilized. However, since you cannot autoclave the digital monitor (a disposable skin would be need) or the holster (a disposable skin would not work here) this design scored a 3 in ability to sterilize. This design scored a 3 in ubiquitous because it relies on audio and color visual feedback, making it difficult to use for the color blind and hearing impaired. Finally, this device scored a 2 in cumbersome. This low score is because the device is attached to the surgeon's arm, weighing it down, and because of the added wires that would be surrounding the user.

Table 1: Matrix for design evaluations

Design	Feasibility	Cost	Durability	Sterilization	Ubiquitous	Cumbersome	Total score
Glasses Design	3	3	2	4	5	2	19
Monitor Design	5	4	5	5	3	4	26
Arm Band Design	5	4	5	3	3	2	22

Final Design

The final design consists of a combination of elements from the alternative designs. A USB microcontroller transmits the electrical output from the strain gauges on the forceps. A four-pin connector is attached to the microcontroller and forceps, allowing for interchangeable forceps. Java was chosen as the compiler program, because it is readily available and cost effective. The final program allows for the threshold to be input by the user. It takes the stream of data converted to serial by the microcontroller and reads it through the USB port. The display consists of a laptop computer monitor for simplicity and cost-effectiveness. The monitor renders the real-time numerical force exerted on the tissue. A line graph is also displayed to convey the force over time. Next to the numeric and graphical displays is a vertical computerized stoplight. When the user exerts a force less than the first imputed threshold, the stoplight is green, illustrating the operator is applying an acceptable amount of force on the tissue. When the user exerts a force greater than or equal to the first imputed threshold but less than the second imputed threshold, the stoplight is yellow, notifying the user he or she is in a cautionary zone. When the user exerts a force greater than or equal to the second imputed threshold, the stoplight is red, warning the user he or she is in the tissue-damaging zone. In addition to the visual indicators, an audible alert system is used. If the user applies an acceptable amount of force, no sound is heard. If the user is in the cautionary zone, a quiet constant tone is heard. If the user is in the tissue-damaging zone, a noticeably louder and higher-pitched tone is heard. For more specifics on the Java code, see Appendix D.

**Figure 5:** Final Design [7]

Testing

The final design was put through a series of tests to assure accuracy and reliability. The first series of test were designed to make sure the strain gauges were attached properly. These tests consisted of hanging varying weights from the end of the forceps and recording the corresponding voltage output. Once the data points were recorded, the points were plotted on a graph (Figure 6) to verify that the strain gauges maintained a linear relationship ($R^2 = 0.9997$).

Using the data collected in the calibration test, the conversion factor ($CF = 1.995 \text{ N/V}$) from volts to Newtons was found by converting the mass values to Newtons and taking the slope of the corresponding line (Figure 6).

Before the second set of tests was performed, the inert variability of the strain gauges was measured. We found that when there is no force being applied to the forceps, there is variable output of ± 0.02 Newtons. With this variation accounted for, the second set of tests was designed to evaluate how the feedback affects a non-surgeon's ability to hold a pencil with the forceps at a constant force. Once this variability was found, each subject performed this test twice, once without any feedback (blind test), and once with both audio and visual feedback (normal test). The standard deviation of the data points output by the user-interface was found for each test. Comparing the standard deviations from the subject's blind and normal tests showed that there was no significant improvement and in some cases even a decline in ability to maintain a constant force.

The final two tests employed resident surgeons from the UW Madison Hospital. These tests were designed to qualitatively evaluate the ergonomics of the forceps as well as the effectiveness of the design as a teaching tool. In the first task, quantitative data was collected showing the forces subjects exerted during trials of an enterotomy. Each surgeon performed a blind and normal test. Figure 7 shows multiple tests from one surgeon, where there are different magnitudes of force at the same point during different trials. In the second task data was collected showing the forces each subject exerted on plastic beads when picking them up with the forceps and placing them on a pegged-board. Figure 8 shows the results from one set of trials. In the normal test the peak heights are noticeably lower and less variable than in the blind test. The improvements between the blind and normal tests show that the device aids in a significant improvement in a surgeon's ability to perform tasks using minimal force. The differences between the blind and normal tests can be seen in Appendix C.

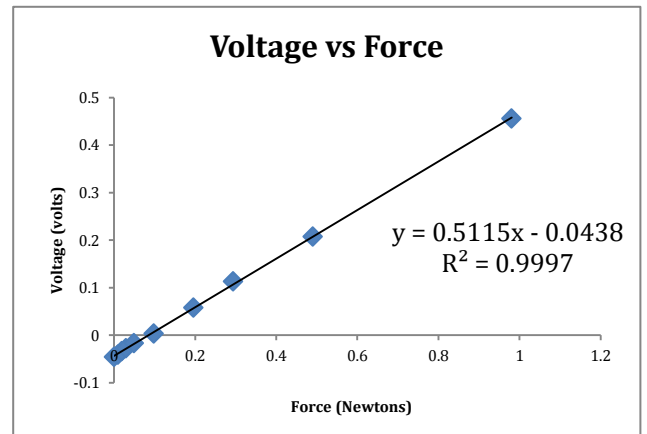


Figure 6: Voltage vs Force

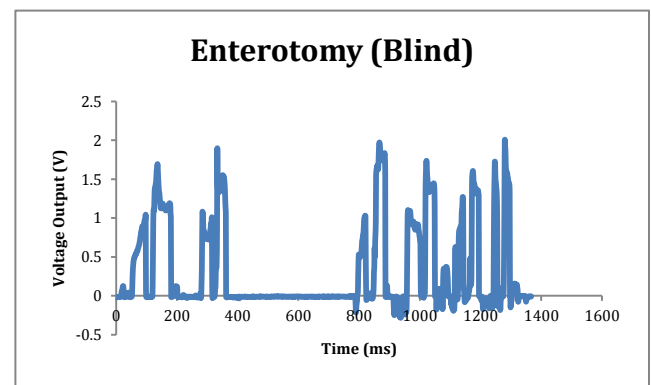


Figure 7: Enterotomy stimulation. For the trial with the interface feedback, the thresholds were set to 90% the max force and the max force.

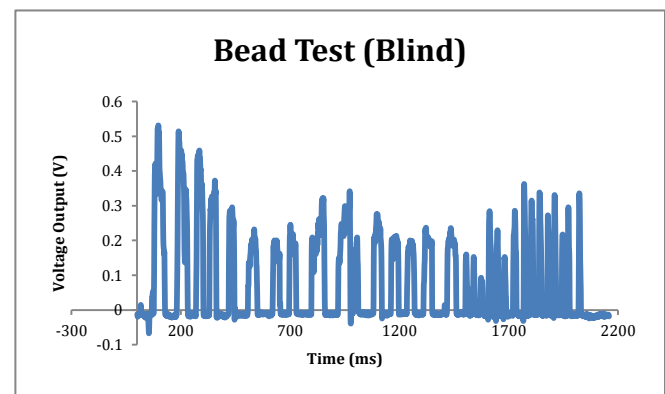


Figure 8: Bead Test. For the trial with the interface feedback, the thresholds were set to 90% the max force and the max force.

Future Work

While the current design meets the requirements and specifications determined by our client, there are many additions that could be made to increase marketability and improve ergonomics of the device. Two major improvements are making the device autoclave-capable and developing a wireless design. Other minor improvements include making the code more robust and improving aesthetics.

Autoclave Capabilities

To successfully withstand autoclave sterilization, the forceps must withstand temperatures higher than 135 °C (275 °F). An epoxy that doesn't degrade at this temperature is needed for strain-gauge attachment to the forceps. J-B WELD [6] epoxy can withstand a constant temperature of 260 °C (500 °F), and the maximum temperature threshold is approximately 316 °C (600 °F) for 10 minutes.

It is important to realize that epoxies react with acids, bases and strong oxidizing agents, all of which are found in the body. Therefore, the forceps with J-B WELD epoxy must be tested on the human body and on animals for biocompatibility before they are used for surgeries or surgical training. Also, the epoxy may release carbon monoxide, carbon dioxide, aldehydes, carboxylic acids, and other organic substances over time, which may be harmful to the body.

Wireless components

The wireless system must have a battery that operates for an hour before recharge/change, communicate the data effectively to a computer that is at most 12 feet away from the forceps, not inhibit the surgeon or off-balance the forceps, and weigh less than 30 grams. See Appendix B for the list of components as well as their specifications including weight, dimensions, product number, voltage and power capabilities, and price. Using the chosen components the weight of the add-ons would be less than 26.2 grams. This wireless system can be assembled in the in-house bioinstrumentation lab at a cost of approximately \$300 including 10 batteries.

Modifications would have to be made to the programming if a Bluetooth module is used to communicate data from the strain gauges to the computer. Disadvantages would include no possibility of autoclaving the wireless device.

Other improvements

Along with these additional add-ons, there are several other possible improvements that could be made to the design. Currently, the surgeon can choose to switch out different types of forceps. However, the new forceps must be re-calibrated (re-zero and recalculate the Voltage to Force conversion) with every switch by manually manipulating the Java code. To improve the design, a feature that automatically re-calibrates the new forceps when attached could be added. Additionally, a pause feature could be added to the program. This way, the user would have the option to pause the program (especially during down time in a surgery) in order to reduce the number of irrelevant data points.

Currently, as data is collected, the program displays it in the console. The user must then copy and paste the data into a program (such as Excel) that can process the data. In order to avoid this extra step, an additional class in Java could be written to reformat, save and graph the data directly. Along with the data processing feature, it would be beneficial for the surgeon to have an auditory alert in the form of a sound gradient in addition to the threshold notifications to communicate an approaching threshold.

The current forceps are capable of measuring compressive force between the two prongs (shown as positive force on the graph) and compressive force that is not between the two prongs (shown as negative force on the graph). However, the forces that are not between the two prongs may not be accurately represented on the graph because the forceps have not been designed to accurately measure these forceps. The forceps also do not have the capability of properly identifying and measuring torsional forces.

Finally the current device lacks aesthetics and robust components that would make the design more marketable. The USB connector on the current device is handmade, so a commercial USB connector is needed. Also, the aesthetics of the strain gauge attachments could be improved.

The device would have to go through extensive testing to be certified by the FDA for use on human patients. One of the primary deterrents for use of this device on living patients is the lack of capability for sterilization. However, the current design could be used effectively in a research setting and for training using artificial tissues.

Works Cited

- [1] Jacq, C., T. Maeder, and P. Ryser. "Load Sensing Surgical Instruments." Pubmed. Web. 05 Aug. 2005. <<http://www.ncbi.nlm.nih.gov/pubmed/18679770>>.
- [2] Hanna, Drew, Arnold, Fakhry, and Cuschieri. "Development of Force Measurement System for Clinical Use in Minimal Access Surgery." Pubmed. Web. 11 July 2007. <<http://www.ncbi.nlm.nih.gov/pubmed/17623237>>.
- [3] Trejos, Javaraman, Patel, Naish, and Schlachta. "Force Sensing in Natural Orifice Transluminal." Pubmed, 18 June 2010. Web. <<http://www.ncbi.nlm.nih.gov/pubmed?term=Force%20sensing%20in%20natural%20orifice%20transluminal.>>.
- [4] Gadget Review. 2008. *Retinal Display System Makes HUD Glasses Obsolete*. Retrieved from <http://www.gadgetreview.com/2008/04/retinal-display-system-makes-hud-glasses-obsolete.html>
- [5] Hass, J. (2003). *An Acoustics Primer*, Chapter 12. Retrieved on February 13, 2011 from: <http://www.indiana.edu/~emusic/acoustics/pitch.htm>
- [6] "J-B Weld Company - J-B WELD Product Information." *J-B Weld Company - World's Finest Cold Weld - Don't Scrap It! J-B Weld It!* Web. 02 May 2011. <<http://www.jbweld.net/products/jbweld.php>>.

Appendix A: Product Design Specification Report
Product Design Specification Report
Sensing Forceps

Date: 30 January 2011

Team:

Alan Meyer-Team Leader
Hope Marshall-Team Communicator
Spencer Strand-BSAC
Michael Scherer-BWIG

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
- 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 500 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 5 years minimum
 - Approximately 25°C
 - 80% 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 5.00 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 25⁰ C-40⁰ 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 25⁰ 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 the forceps 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.

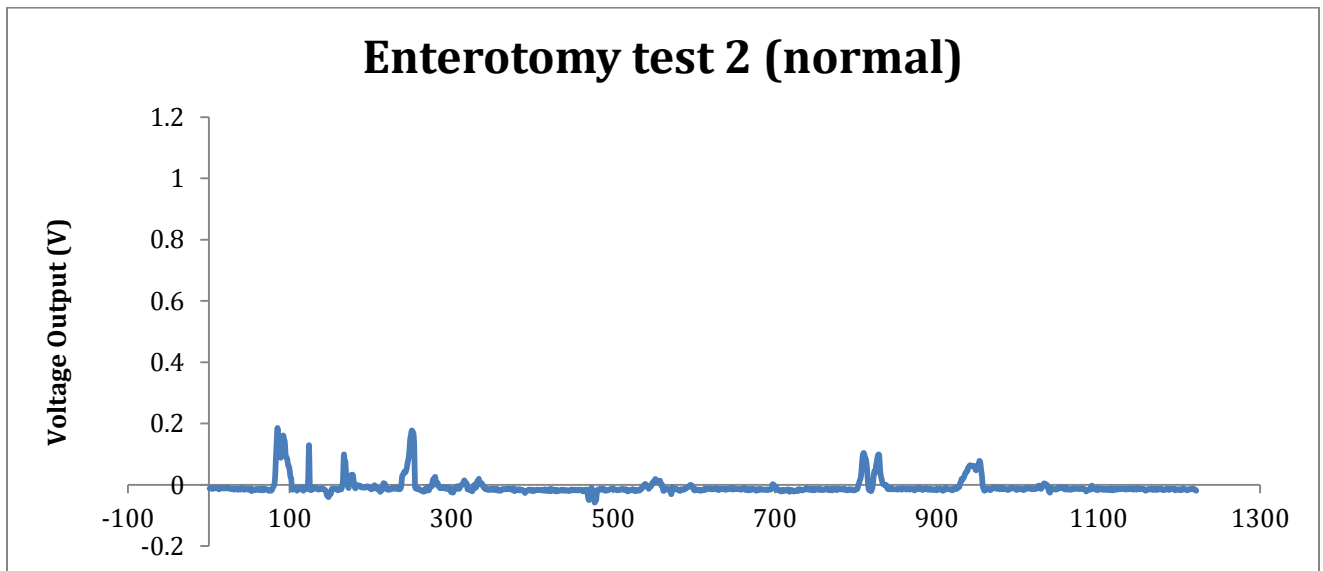
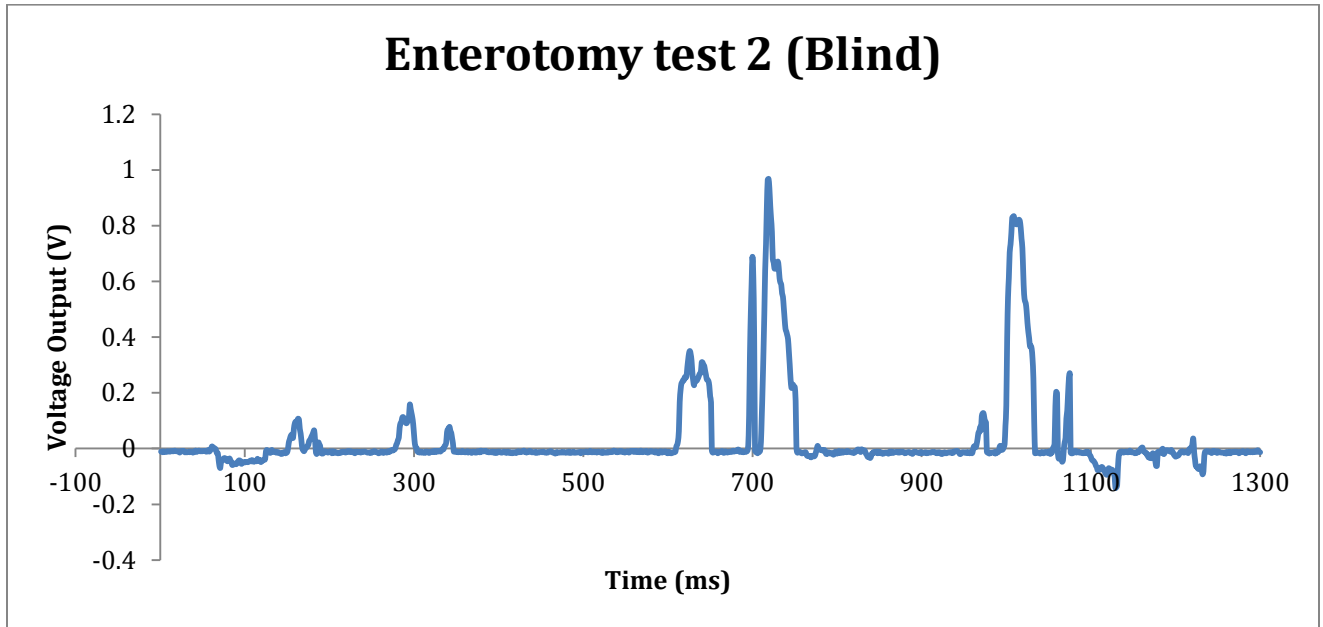
c. *Patient-related concerns:* This device will come in direct contact with the patient. Because of this, the device must be sure not to: cause damage to the patient's tissue, infect or poison the patient in any way, or leave debris after use. This device should not endanger the surgeon using it.

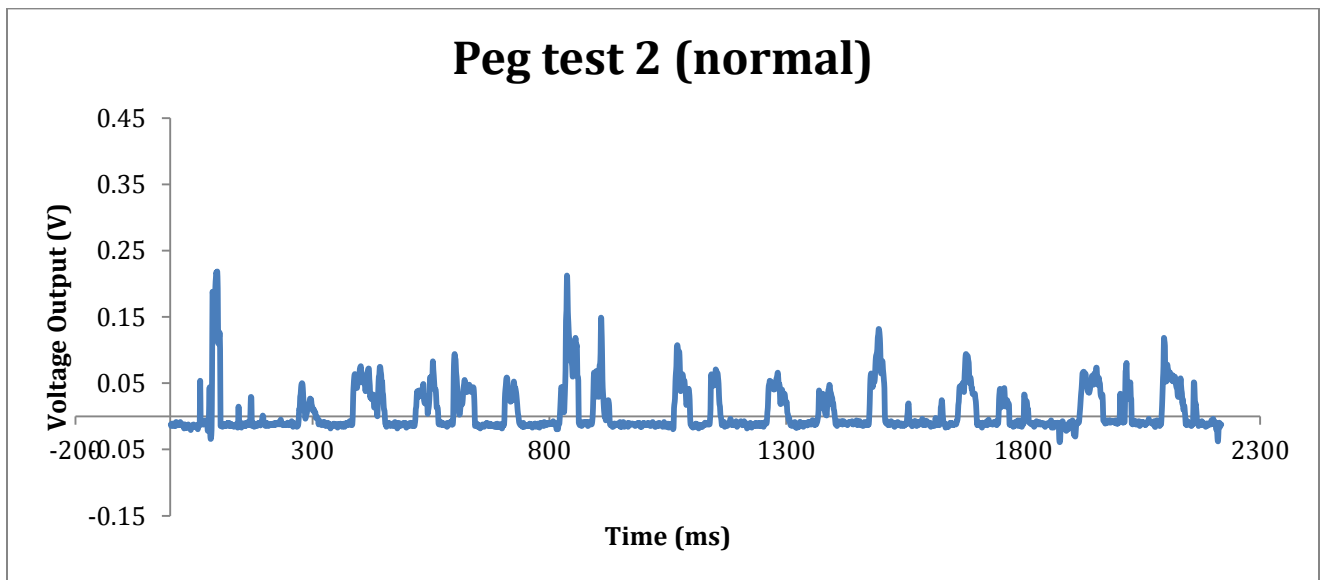
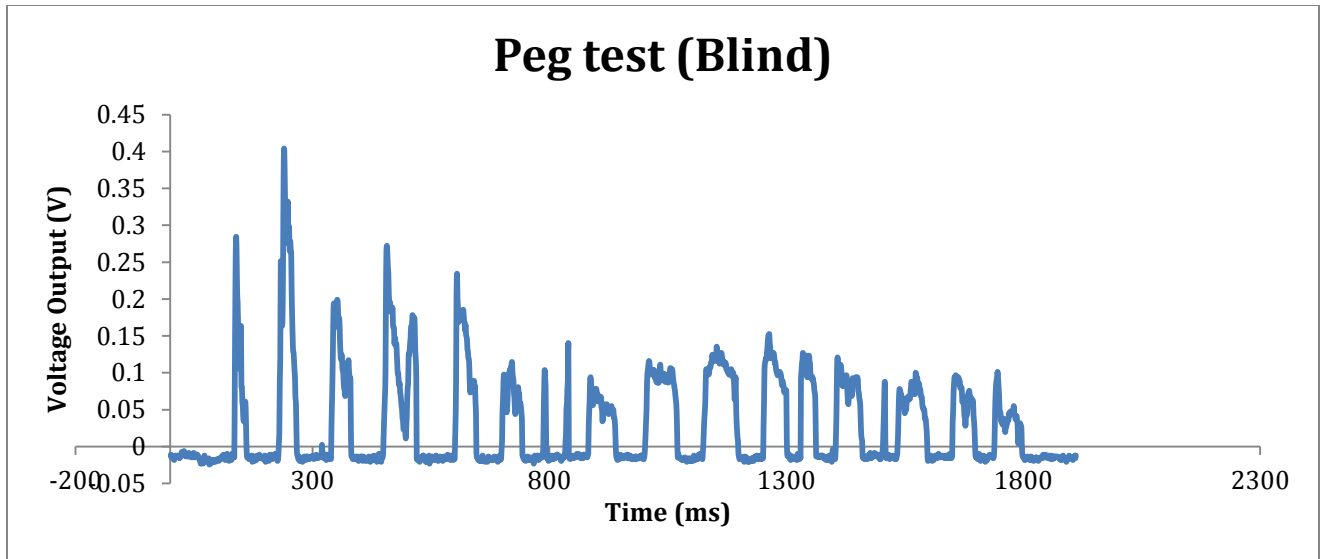
d. *Competition:* There are currently no force sensitive forceps on the commercial market. There is research being done on methods of sensing force that would be suitable for use with forceps. Creating a user interface using microcontrollers has been done before; however, there are no programs readily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

Appendix B: Wireless Components

1. Bluetooth Module: The chosen model is made by Roving Networks, part number DS-RN41-V3.1 and can be found at [6]. The dimensions of the module are 13.4mm x 25.8 mm x 2mm and the module weighs 3.2 grams. The module works in environments with temperatures ranging from -40 to 85 degrees Celsius and can transmit data to a Bluetooth compatible device up to 100 m away. 3.3 V and 30mA of power are needed to power the module. The cost of the Bluetooth module is \$32.
2. Microcontroller: in house design. Dimensions will vary and weight will vary but will be less than 20 grams. 5 V needed to power the microcontroller. The cost of the microcontroller is about \$200.
3. Battery: The chosen battery is manufactured by Panasonic and distributed by Digikey, part number P143-ND. The circular 6V battery has a diameter of 23mm and weighs 3.2 grams. The battery will power the wireless forceps device for much longer than 1 hour, and will cost \$3.22 per battery if 10 are ordered. The battery supplies 625 mA of power. The battery is not rechargeable and will eventually have to be changed.

Appendix C: Test Results





Appendix D: Java Code

README file for Sensing Forceps

This file contains information on:

- 1 Instillation
- 2 Setup
- 3 Audio File Location setup
- 4 USB port setup
- 5 Run
- 6 Changing Audio Sounds

1 Instillation

Start by unzipping DataAcquisition.rar to a location of your chose

If eclipse is not already installed on the computer:

Unzip eclipse-SDK-3.6.2-win32 for 32-bit OS or eclipse-SDK-3.6.2-win32-x86_64 for 64-bit OS.

Run eclipse.exe to begin installation of eclipse

Open eclipse and set up a workspace in a location of your choosing

2 Setup

Once eclipse is installed:

copy and paste the folder DataAcquisition into your workspace

In eclipse:

File >> New >> Java Project >> Create Project from existing source

Selected DataAcquisition from your workspace and select finish

3 Audio File Location setup

To Locate the Audio files used for the warnings, open:

DataAcquisition >> src >> da >> Audioapp.java

On line 31 contains the code: `songPath = new URL("..." + filename);`

the ... needs to be changed to the audio files new location.

If you used the default location to set up the workspace all you should have to do is change Alan to your user name.

If you did not use the default location for the workspace, you will need to change the address more completely.

The audio files will be located under `workspace/DataAcquisition/bin/` if you right click on the audio file and select properties, you can get the URL

4 USB port setup

In order to use the forceps, you must designate which USB port you have the microcontroller plugged into.

If you run the program without designating the USB port, it will indicate which ports are available.

To designate which port you wish to use go to:

Run >> Run Configurations >> (x)= Arguments

Under Program arguments type `COM#` where # is the port number you've selected

It may take some trial and error to select the correct port if you are not sure of the port number.

***Note: make sure under the Main table the Project is DataAcquisition and Main class is `da.DataAcquisition`**

5 Run

Once everything is set up you can start the program:

Run >> run as >> 1 Java Application

-or-

Open/select DataAcquisition class and hit the green button with a triangle

Once the program is started, you will be prompted by the console to enter the threshold values that you want to use.

After you have input the values, the program will begin.

To stop the program, either close the Numerical or Graph Display or click the red square above the console

6 Changing Audio Sounds

If you wish to change the audio sounds that are used simply replace the .wav files under DataAcquisition >> src

beep-1.wav is used for the yellow alarm

beep-2.wav is used for the red alarm

Appendix E: Cost and Labor

Strain Gauge Attachment	\$165.00
4-pin Connector	\$ 7.56
Microcontroller Case	\$ 3.00
USB Microcontroller	<u>\$300.00</u>
Total Cost	\$475.56

Team Member	Time (Hrs)
Alan Meyer	41.0
Hope Marshall	33.5
Spencer Strand	26.0
Michael Scherer	24.0
Entire Team	24.0