A DEVICE FOR MEASURING THE SEVERITY OF PERIPHERAL EDEMA

A Major Qualifying Project Report:

Submitted to the Faculty of

WORCESTER POLYTECHNIC INSTITUTE

In partial fulfillment of the requirements for the

Degree of Bachelor of Science

by

Stephanie LeGare

Charles Gammal

Erika Hall

Rachelle Horwitz

Submitted on: April 27, 2007

Approved:

Prof. Kristen Billiar, PhD

Prof. Y Mendelson, PhD

Dr. Raymond Dunn, MD

1. peripheral edema 4. medical device
2. tonometer 5. electrical device
3. swelling 6. viscoelasticity
ABSTRACT

Peripheral edema causes swelling in extremities and often indicates the presence of a serious medical condition. The subjective methods that clinicians currently use to assess edema lead to inconsistencies in medical treatment. To eliminate this subjectivity, we have developed a handheld device that uses a manually depressed probe to measure the depth of tissue displacement and the force required to depress the tissue. These measurements allow clinicians to objectively monitor a patient's progress over time.
ACKNOWLEDGEMENTS

We would like to thank Prof. Kristen Billiar, Prof. Yitzhak Mendelson, Prof. John McNeill, and Dr. Raymond Dunn for advising the project. We would also like to thank Alexander Camilo and Robert Weir for aiding us with programming the TI MSP430, Col. Kenneth Stafford and Mr. Brad Miller for recommending the linear encoder from U.S. Digital, Neil Whitehouse for helping us cut the memory foam, and Michael O’Donnell for machining the prototype. Special thanks also go to Dr. Howard Fixler, Melissa Blatt, and others at Fairlawn Rehabilitation Hospital for their help in assessing our edema models and for feedback on our device. In addition, we would like to thank Tim Roth for assisting us in preparing paperwork submitted to the Institutional Review Board at UMass.
EXECUTIVE SUMMARY

This report describes the development and design of a device to measure the severity of pitting edema. Current edema assessments made by clinicians are subjective and vary between medical professionals. The subjectivity of measurements makes them hard to compare over time in a single patient, making it difficult to make accurate diagnoses. An objective means of assessment, such as the medical device described in this report, makes it possible for clinicians to monitor changes in edema severity over time for one patient, and to compare measurements taken by different clinicians.

While many investigators have proposed other objective assessment methods for edema assessment, the methods are often too expensive or complicated to incorporate into routine medical examinations. In addition, these methods provide limited information about tissue properties. Lack of convenient and inexpensive method for edema assessment leads most medical professionals to assess pitting edema using their thumb and fingers to push into the patient’s tissue and observe its response to indentation.

Our edema measurement device mimics clinicians’ assessments to depress areas of edema, just as a clinician does his thumb or finger. To obtain a measurement, the examiner holds the device against the patient’s tissue and uses his thumb to depress a tissue indenter, creating an indentation. The device measures and displays the depth of indentation on a display screen as the primary indicator of edema severity. The microprocessor program outputs the distance measured when the force increases rapidly and the displacement of the tissue indenter ceases to increase. The device also displays the force required to reach maximum displacement, and the return time of the tissue following displacement. Return time is an indicator of whether edema
is or is not present in a patient. A clinician can collect the values from this device over time to determine whether a patient’s swelling is increasing or decreasing.

The complete device is compact, ergonomic, and has a base cost of less than $500. It consists of a handheld component that makes contact with the patient’s tissue, and contains force and distance transducers. A remote display box contains batteries and a microprocessor.

To test the effectiveness and consistency of the device, we developed models using viscoelastic memory foam soaked in vegetable oil to simulate pitting edema. We collected data from several clinicians who rated the models according to their own pitting edema scales. We then assessed the same models using the edema measurement device. Comparing the data sets from subjective assessments with those obtained using the device, it is apparent that the device provides a much more reproducible measurement between users.
# TABLE OF CONTENTS

ABSTRACT ................................................................................................................................. i
ACKNOWLEDGEMENTS .......................................................................................................... ii
EXECUTIVE SUMMARY ...................................................................................................... iii
TABLE OF CONTENTS .......................................................................................................... v
TABLE OF FIGURES.............................................................................................................. ix
TABLE OF TABLES ................................................................................................................ xi

1 INTRODUCTION............................................................................................................. 1
2 BACKGROUND ON PERIPHERAL EDEMA ............................................................. 3
  2.1 Causes of Edema.............................................................................................................. 4
  2.2 Treatment of Peripheral Edema ....................................................................................... 6
  2.3 Ideal Measurement for the Severity of Peripheral Edema ............................................... 7
  2.4 Diagnostic Tools for Assessing the Severity of Peripheral Edema ................................. 7
  2.5 Traditional Method for Assessing the Severity of Peripheral Edema............................ 11
  2.6 Translating Subjective Measurements into Objective Measurements........................... 13
  2.7 Reducing Subjectivity in Edema Assessments .............................................................. 14
3 DESIGN APPROACH: An Edema Measurement Device .......................................... 16
  3.1 Goal and Specific Aims ................................................................................................. 16
  3.2 Stakeholders................................................................................................................... 17
  3.3 Original/Revised Client Statement ................................................................................ 17
  3.4 Objectives to Accomplish Goal ..................................................................................... 18
  3.5 General Device Constraints ........................................................................................... 20
  3.6 Evaluation of a Previous MQP: A device to quantify lower extremity edema.............. 21
  3.7 Potential problems in an edema measurement device ................................................... 22
4 DEVICE DESIGN........................................................................................................... 24
  4.1 Design focus areas for the edema device....................................................................... 24
  4.2 Measured parameters to indicate edema severity .......................................................... 27
    4.2.1 Device Functions .................................................................................................. 27
    4.2.2 Survey of clinicians to determine important parameters for edema severity...... 30
    4.2.3 Final Measurement Parameters............................................................................. 32
  4.3 Components and Means Research ................................................................................. 32
    4.3.1 Force Transducer .................................................................................................. 33
    4.3.2 Displacement Transducer...................................................................................... 34
    4.3.3 Data Processing and Time Sensing....................................................................... 35
    4.3.4 Power Requirements ............................................................................................. 36
5 DEVICE HOUSING ....................................................................................................... 37
  5.1 Preliminary Housing Designs ........................................................................................ 37
    5.1.1 Cuff Design........................................................................................................... 37
    5.1.2 Dual Cylinder Design ........................................................................................... 39
    5.1.3 Value Analysis for Final Housing Design ............................................................ 39
6 FINAL DESIGN.............................................................................................................. 41
  6.1 Final Housing Design .................................................................................................... 41
    6.1.1 Indenter Design..................................................................................................... 46
    6.1.2 Anticipated User Error with Device Design......................................................... 47
    6.1.3 Market Analysis .................................................................................................... 49
## TABLE OF FIGURES

<table>
<thead>
<tr>
<th>Figure</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Pitting edema in two patients</td>
<td>3</td>
</tr>
<tr>
<td>2</td>
<td>Circumference (a) and water displacement (b) to monitor swelling</td>
<td>8</td>
</tr>
<tr>
<td>3</td>
<td>Perometer for infrared limb volume sensing</td>
<td>9</td>
</tr>
<tr>
<td>4</td>
<td>Common location and method for peripheral edema assessment</td>
<td>11</td>
</tr>
<tr>
<td>5</td>
<td>Objectives for the edema measurement device</td>
<td>17</td>
</tr>
<tr>
<td>6</td>
<td>Potential issues with device design</td>
<td>23</td>
</tr>
<tr>
<td>7</td>
<td>Black Box Conceptualization</td>
<td>25</td>
</tr>
<tr>
<td>8</td>
<td>Interrelationship of Design Areas</td>
<td>26</td>
</tr>
<tr>
<td>9</td>
<td>Device features that clinicians identified as “very important”</td>
<td>31</td>
</tr>
<tr>
<td>10</td>
<td>Relationship between distance depressed and edema severity (a), Time constant for edematous and healthy issue (b)</td>
<td>32</td>
</tr>
<tr>
<td>11</td>
<td>Preliminary Housing Cuff Design</td>
<td>38</td>
</tr>
<tr>
<td>12</td>
<td>Preliminary Housing Dual Cylinder Design</td>
<td>39</td>
</tr>
<tr>
<td>13</td>
<td>Final Housing Design</td>
<td>42</td>
</tr>
<tr>
<td>14</td>
<td>Final prototype with control box, microcontroller, and batteries</td>
<td>42</td>
</tr>
<tr>
<td>15</td>
<td>Housing Assembly - Isometric View</td>
<td>43</td>
</tr>
<tr>
<td>16</td>
<td>Housing - Top View</td>
<td>43</td>
</tr>
<tr>
<td>17</td>
<td>Housing Assembly - Back View</td>
<td>44</td>
</tr>
<tr>
<td>18</td>
<td>Housing - Cover</td>
<td>45</td>
</tr>
<tr>
<td>19</td>
<td>Demonstrated use of prototype for edema in the lower leg</td>
<td>46</td>
</tr>
<tr>
<td>20</td>
<td>Circuit diagram for distance measurement</td>
<td>53</td>
</tr>
<tr>
<td>21</td>
<td>Channel A - linear encoder (green), input to P1.7 of the microcontroller (yellow)</td>
<td>54</td>
</tr>
<tr>
<td>22</td>
<td>Channel B from the linear encoder (green), and input to P1.6 of the microcontroller (yellow), when tissue indenter is moving out</td>
<td>54</td>
</tr>
<tr>
<td>23</td>
<td>Channel B from the linear encoder (green), and input to P1.6 of the microcontroller (yellow), when tissue indenter is moving in</td>
<td>55</td>
</tr>
<tr>
<td>24</td>
<td>Circuit diagram for the load cell</td>
<td>55</td>
</tr>
<tr>
<td>25</td>
<td>Output from load cell</td>
<td>56</td>
</tr>
<tr>
<td>26</td>
<td>Microcontroller display provides instructions to user</td>
<td>62</td>
</tr>
<tr>
<td>27</td>
<td>Simplified flowchart of the microcontroller program</td>
<td>62</td>
</tr>
<tr>
<td>28</td>
<td>Detailed flowchart of the microcontroller program</td>
<td>63</td>
</tr>
<tr>
<td>29</td>
<td>Different thicknesses of foam in vegetable oil represent edema severities</td>
<td>68</td>
</tr>
<tr>
<td>30</td>
<td>Testing setup for edema device on foam models</td>
<td>70</td>
</tr>
<tr>
<td>31</td>
<td>User variability in &quot;pitting&quot; measurements on foam models</td>
<td>74</td>
</tr>
<tr>
<td>32</td>
<td>Clinician severity ratings on foam models</td>
<td>75</td>
</tr>
<tr>
<td>33</td>
<td>Device variability in &quot;pitting&quot; measurements on eight additional models</td>
<td>77</td>
</tr>
<tr>
<td>34</td>
<td>Distance vs. time while indenting a 1&quot; foam model</td>
<td>78</td>
</tr>
<tr>
<td>35</td>
<td>Force vs. time while indenting a 1&quot; foam model</td>
<td>79</td>
</tr>
<tr>
<td>36</td>
<td>Force vs. distance while indenting a 1&quot; foam model</td>
<td>80</td>
</tr>
<tr>
<td>37</td>
<td>Conceptual analysis of the 2004 MQP</td>
<td>103</td>
</tr>
<tr>
<td>38</td>
<td>Frequency that clinicians assess edema</td>
<td>123</td>
</tr>
<tr>
<td>39</td>
<td>Methods clinicians use to assess edema</td>
<td>124</td>
</tr>
<tr>
<td>40</td>
<td>Clinician rating of relative importance of different parameters related to edema</td>
<td>125</td>
</tr>
<tr>
<td>41</td>
<td>Parameters identified as “very important” for assessing edema</td>
<td>125</td>
</tr>
</tbody>
</table>
TABLE OF TABLES

Table 1: Primary Weighted Objectives
Table 2: General Device Constraints
Table 3: Decision Matrix for Force Transducer
Table 4: Decision Matrix for Displacement Transducer
Table 5: Device Power Requirements
Table 6: Value Analysis of Housing Designs
Table 7: Potential User Error
Table 8: Cost Breakdown: Base Price
Table 9: Cost Breakdown: Bulk Price
Table 10: Descriptive statistics for unconstrained distance testing with the prototype
Table 11: Future recommendations for the edema measurement device
Table 12: Pairwise comparison chart (PCC) of device design objective
Table 13: Types of Force Transducers
Table 14: Value Points for Metrics Related to Force Transducer Technologies
Table 15: Types of Displacement Transducer
Table 16: Value Points and Metrics for Assessing Displacement Transducer Technologies
Table 17: Bill of Materials
Peripheral edema, or swelling in the extremities, is caused by an excess of interstitial fluid that builds up in the extravascular space. Over 4 million people in the United States of all ages and races suffer from this type of edema. The presence of peripheral edema is usually an indicator of more serious medical conditions, such as left ventricle heart deficiency, congestive heart failure, liver or kidney disease, or venous stasis disease. Because peripheral edema is a side effect of these serious diseases, it is important to quantify the severity of edema so medical professionals can monitor the condition and assess a patient’s improvement over time.

The excess interstitial fluid buildup from edema changes the properties of the tissue. Edematous tissue is characterized by an increase in resistance to pressure, as well as a severe reduction of elasticity, which gives the tissue a putty-like quality. When pressure is applied to edematous tissue, it may remain depressed for several minutes before returning to its original state. This phenomenon is known as “pitting.” One of the primary ways to evaluate peripheral edema is to observe the response of edematous tissue to depression. Medical professionals classify the level of edematous severity using a scale ranging from 1 (least severe) to 4 (most severe). Because clinicians determine the severity of edema only through visual and tactile observations, the evaluation is subjective and often inconsistent between measurements. Subjective measurements such as these are difficult to communicate to other medical professionals and reduce the accuracy of the diagnosis.

Ideally, an edema measurement would be simple, fast, quantifiable, and easily communicated between medical professionals. A device for evaluating edema should reduce subjectivity to make the diagnosis of severity more accurate. There are a number of complex ways to quantify the properties of edematous tissue, and the United States Patent and
Trademark Office has issued several patents covering such devices. These devices, however, have not been widely adapted in the medical community as a means to evaluate edema because they are inconvenient to use or too expensive. In 2004, a group of students developed a device for their Major Qualifying Project that examined means to obtain a quantitative measurement of the severity of edema using a convenient, handheld device (Weindling and Fontaine, 2004).

Our goal in this project was to develop a device that can objectively monitor the severity of edema in extremities. The primary use of the device will be to collect a patient’s edema measurements for a comparison over time to determine if any increase or decrease in swelling has occurred. The most important objectives for the device are to improve accuracy and objectivity by reducing user-dependence and minimizing individual bias in measurements. Our team evaluated past designs and identified the most important parameters for measuring edematous pitting, such as depth of pitting, relaxation time, and force needed to depress the tissue. We incorporated these objectives into a convenient and easy-to-use device that measures parameters associated with edema and outputs a simple and communicable measurement that specialists can track to determine a the patient’s condition over time.

Our device will improve the accuracy of medical diagnoses for the benefit of both medical professionals and patients. Objective, quantitative diagnoses allow for improved patient care, increased communication among medical professionals, and reduced costs for healthcare.
2 BACKGROUND ON PERIPHERAL EDEMA

Edema, or swelling, is an excess of interstitial fluid that is present in the extravascular space (Terry, 1998). Edema can affect individuals of all ages; however, pregnant women and the elderly are more susceptible to edema than the general population (American Family Physician, 2005). There are several different types of edema and they can occur in any part of the body, such as the lungs, brain, abdomen, and peripheral extremities. Peripheral edema, which affects the body’s extremities, such as the arms, hands, legs, feet, and ankles, is the most common type of edema (Noah, 2006; Owens, 2005). Peripheral edema is often characterized by a phenomenon known as pitting (Cho, 2002). When an individual presses on non-edematous tissue and releases his finger, the tissue immediately returns to its original state. When an individual applies pressure on edematous tissue and releases the pressure, the tissue remains depressed for a variable amount of time and returns to a normal position slowly depending on the severity of the edema, as shown in Figure 1. The depression may remain for several minutes if an individual suffers from severe edema (Lehrer, 2006).

![Figure 1: Pitting edema in two patients](Used with permission from Charles Goldberg and Ghatak, 2006)
2.1 Causes of Edema

Edema afflicts more than 4.4 million individuals in the United States, and is a symptom of numerous diseases and conditions ("Basic summary for edema," 2006). Medical professionals diagnose and gauge the severity of edema because it allows them to diagnose the underlying cause of the edema and monitor a patient’s condition over time (Cho, 2002). There are four general causes of peripheral edema: low concentrations of plasma proteins, increased permeability of the capillary walls, blockage of lymph vessels, and increased venous pressure.

Peripheral edema may occur when there is a lower concentration of plasma proteins than normal. The plasma-colloid osmotic pressure, or osmotic pressure, decreases due to a higher concentration of proteins and lower concentration of water in plasma than in interstitial fluid. The result is that excess fluid leaks through the capillary pores, and less fluid is re-absorbed into the capillaries. Several diseases and conditions may cause a reduction in the number of plasma proteins. These conditions include kidney disease, in which the number of plasma proteins in urine increases; liver disease, which results in a reduction number of synthesized plasma proteins; a protein-deficient diet; and burns. Burns can result in edema because the patient suffers from a loss of proteins from tissue trauma (Sherwood, 2004).

Another cause for peripheral edema is the increase of the permeability of the capillary walls, causing an increased number of plasma proteins that pass from capillaries into the interstitial fluid. This also reduces the plasma-colloid osmotic pressure because there are fewer plasma proteins that remain in the plasma and more plasma proteins in the interstitial fluid. Conditions that increase the permeability of capillary walls are allergic reactions and trauma, such as blisters (Sherwood, 2004).
Blocked lymph vessels also cause peripheral edema. One of the consequences of a blocked lymph vessel is that the interstitial fluid, normally delivered to the blood via the lymphatic system, is unable to enter the lymph vessels. The result is that the interstitial fluid accumulates in interstitial spaces. Removal of lymph nodes and elephantitis, a condition caused by a mosquito-borne parasitic worm that infects lymph vessels, are two conditions that can cause edema due to blockage of lymph vessels (Sherwood, 2004). Peripheral edema caused by compromised lymphatic circulation is referred to as lymphedema. While pitting edema is characterized by a putty-like quality, lymphedema causes the tissue to become tough and fibrous due to the growth of fatty tissue. Lymphedema can start out as pitting edema, but over time, it can become harder (Bates, 1994).

The last main cause of edema is an increase in venous pressure, which occurs when blood accumulates in veins. Increased venous pressure results in an increase in capillary pressure because all veins eventually drain into capillaries. There are several causes of increased venous pressure, including pregnancy, congestive heart failure, and venous stasis disease (Sherwood, 2004). Pregnancy can cause an increase in venous pressure because the uterus can compress the veins in the lower extremities (Sherwood, 2004). Congestive heart failure occurs when the heart does not pump efficiently. When left heart failure occurs, a back up of blood materializes in the lungs, resulting in pulmonary edema. When right heart failure occurs, blood pools in the periphery systems resulting in peripheral edema (Dunn, personal communication, 2006). Venous insufficiency, or a loss of venous function because of improperly functioning valves, accounts for ninety percent of all edema cases (Nicolaides, 2005). In the early stages, the edema due to venous insufficiency is soft and pitting (Cho, 2002).
2.2 Treatment of Peripheral Edema

Edema is most often a symptom or a side effect of a more serious condition that clinicians must treated directly. Edema can become a primary concern if it causes discomfort for the patient, and clinicians often treat its symptoms to minimize the effects of edema. Some methods of treating edema symptoms include reducing dietary sodium intake, taking diuretics, applying compression to edematous tissue, and elevating the afflicted area.

Reducing dietary sodium is beneficial to patients who suffer from edema because sodium reduces fluid retention. Medications such as diuretics are beneficial because diuretics induce the elimination of fluids through urination. Clinicians prescribe different types of diuretics depending on the disease that is causing edema. Compression stockings are another treatment method for edema. They reduce edema by applying pressure to the edematous area, therefore decreasing the amount of fluid that collects in the legs and ankles (O’Brien, 2006). Elevating the afflicted limb above the height of the heart aids in alleviating edema because gravity drains the fluid from the afflicted area, reducing the volume of the swelling (Bodor, R., 1999).

If edema is left untreated, extreme discomfort, leg ulcers, and infections may develop because the cells in the edematous tissue are undernourished (Lehrer, 2003). Tissue undernourishment occurs because edema increases the distance between blood and cells of the tissues, reducing the amount of nutrients that are exchanged (Sherwood, 2004). The tissue can become tough and dry and may exhibit some discoloration without proper nutrition. Venous ulcers are usually found directly above the ankle on the inside of the leg, and can be very painful. Every year, between 500,000 and 600,000 people in the United States suffer from venous ulcers, which comprise 90% of all leg ulcers (Lower extremity ulcers, 2006).
2.3  Ideal Measurement for the Severity of Peripheral Edema

Because edema is characterized by many changes in the tissue’s properties, it is important to consider as many characteristics of edematous tissue as possible when assessing its severity. An ideal measurement would account swelling changes in the limbs due to the leakage of interstitial fluid, the amount of fluid leaked into interstitial spaces, and the mechanical response of the affected tissues to manipulations. Clinicians would compare the measurements over time to a control value of the patients’ limbs when in a normal, unaffected state.

Although there are several complex ways to measure the ideal properties of edema, it is also important to remember that edema is often a side effect of a more serious medical condition. Thus, an edema assessment is merely one of the factors representing a patient’s overall condition and may not always be a clinician’s primary concern. For that reason, a device to measure edema should be quick, efficient, and should provide results that are easy to record and analyze. Additionally, an ideal edema measurement device would be portable and usable at any location that patients, nurses, and clinicians may need to take an edema measurement, including away from the clinicians office. The measurement must be easily communicable and comparable between patients and various medical professionals for a long-term analysis of the condition (Dunn, personal communication, 2006).

2.4  Diagnostic Tools for Assessing the Severity of Peripheral Edema

The United States Patent and Trademark Office cites several patents for devices that clinicians can use to assess the severity of edema. Some means for assessing edema measure the external and internal properties of the edematous tissue, while other devices measure the response of edematous tissue to manipulation. All of the measurements for assessing edema must be repeated several times over time and used to compare to a control measurement of unaffected
tissue, or to track the patient’s progress from day-to-day to determine improvement.
Practitioners take edema measurements according to a schedule in the same way and area to try
to maintain consistency in edema severity measurements.

Assessing edema by measuring the external properties of the tissue can be as simple as
taking repeated circumference or volume measurements of the swollen area and comparing the
measurements over time to determine whether the swelling increases or decreases. Measuring
the volume of the leg through displacement in a known volume of water or other media (Figure
2) is another measurement that changes with the amount of swelling in the tissue (US Patent
#6077222, 2000). Both circumference and volume measurements address swelling as an
external manifestation of edema, but cannot determine the severity of the condition related to
the leakage of fluid into the interstitial spaces of tissue. These measurements cannot measure
the properties of the affected tissue and are only an indicator of whether the patient’s swelling
is increasing or decreasing over time.

(a)  (b)
Figure 2: Circumference (a) and water displacement (b) to monitor swelling
(Reprinted with permission from MediGraph Software and Alere Medical, Inc.)
The Perometer, shown in Figure 3, is a more accurate device that scans the limb with infrared sensing and calculates limb volume. Unfortunately, this device is very expensive, ranging from $15,000 to $30,000 for newer models, making it infeasible to use in most hospitals. In addition, this device requires the patient to be mobile to sit or stand in the sensing area, making it not ideal for patients with more severe conditions or limited mobility.

Figure 3: Perometer for infrared limb volume sensing
(Reprinted with permission from peromedenver.com)

Measuring the internal properties of tissue, such as the water content, impedance, thermal energy (US Patent # 6488677, 2002), or ultrasound or magnetic resonance imaging of the tissue can provide a more accurate, quantitative representation of edema severity in tissue. Many of these measurements, however, are expensive or non-patient-friendly, reducing or eliminating the ability to complete the measurement on a consistent basis or compare measurements over time. For example, measurements of impedance in tissue are proportional to the amount of current-conducting fluid in the leg and can yield a ratio of intra-cellular to extra-cellular water content (US Patent # 6714813, 2004). An impedance measurement, however, requires a device to pass a high frequency current through the affected tissue via electrodes, and has a more limited patient compliance than other more simplistic methods. In
addition, ultrasound and magnetic resonance elastography (MRE) measurements can provide specific and accurate pictures of internal tissue composition, but are too expensive and unwieldy for using on a regular basis to assess edema (Wu, 2001).

Because edematous swelling changes tissue properties, the tissue response to physical manipulation also differs from the response of unaffected tissue. Recent devices have been proposed to measure parameters related to this change in response, such as the force response of the tissue as it returns to normal over time (Patent # 6186962, 2001), the time it takes for tissue to return after indentation, as well as the depth of pitting when force is applied. In a 2004 Major Qualifying Project, two WPI students developed a device that used light to measure the relaxation time, or the time it takes the tissue to return to its original position after indentation (Weindling and Fontaine, 2004). The device described in this report is a continuation of their work to develop a device that can quantify the severity of edema.

Since there is very little information about clinical studies that characterize edema, it is difficult to relate any measurement of the properties of edematous tissue to the severity of edema. The measurements can, however, be related to a scale of severity based on traditional diagnosis and used as a basis of comparison for edema severity assessment over time. Despite many patents and devices created to achieve that goal, few have reached the stage of manufacturing and medical professionals have not adopted these devices to replace the traditional clinician-patient examination to assess the severity of edema (Dunn, personal communication, 2006). For nearly all methods available, edema measurements are either inaccurate or inconvenient, or too expensive for everyday use in a clinical setting; thus, clinicians currently use a manual method to assess edema.
2.5 Traditional Method for Assessing the Severity of Peripheral Edema

Measurements of force, distance, and return time of the tissue are closely related to the traditional method medical professionals currently use to diagnose the severity of edema. The method, termed digital manipulation, requires a medical professional to press a thumb or forefinger into the patient’s tissue at a point above the tibia on lower extremities and the above the radius for upper extremities. The clinician continues pressing into the tissue until meeting significant resistance from the bone, at which point he releases the pressure and observes the behavior of the tissue. Throughout the evaluation, the clinician pays close attention to the depth of pitting, the resistance of the tissue to depression, the force it takes to reach the bone while applying pressure to the tissue and the relaxation of the tissue after indentation. The specialist uses his observations to assess the severity of edema on a scale of 1 (slight edema) to 4 (severe edema) (Dunn, personal communication, 2006).

There is little, if any, direct correlation between clinical intervention and severity of edema (Fixler, personal communication, 2006). An edema assessment by itself is irrelevant without information regarding the greater context of the patient’s condition. Thus, clinicians look at
factors such as patient history and medical condition in addition to the physical properties of the edematous tissue. Two patients with the same level of edematous severity do not necessarily require the same treatment. For this reason, a medical device could measure edema severity but could not replace a clinician for diagnoses. The device would not be useful independent of an expert opinion, and would be a tool to help assess edema.

The primary problem with using digital manipulation for diagnosing edema is that it is very subjective. Each clinician bases the diagnosis on his own personal evaluation of the edema, which may vary greatly. For example, some clinicians base their evaluation on the return time of the pitted tissue, while others simply look at the depth of pitting or the resistance of the tissue to depression. Thus the measurement, if repeated by several different clinicians, may be inconsistent. It is difficult for the clinician to take quantitative notes describing the patient’s condition so he can compare one day’s measurements to the next; thus, assessment of the patient’s condition over time is more difficult. Because the severity scale for digital manipulation is limited, it does not allow for a more specific assessment of the changes in edema over time after treatments. Despite these disadvantages, digital manipulation remains the primary means of assessment for edema today and no other devices on the market are not commonly used in clinical setting to assess pitting edema conditions because they are too expensive, unwieldy, inaccurate, or not widely available to clinicians (Dunn, R. and Fixler, H. personal communication, 2006).
2.6 Translating Subjective Measurements into Objective Measurements

Medical professionals routinely perform subjective evaluations similar to those made with current edema assessments. Examples of similar subjective measurements include using photometric observations to diagnose jaundice in infants (Sanpavat, 2004) or body size to diagnose severity of obesity. Subjective measurements can be beneficial because they allow the examiner to determine a patient’s condition based on a wide range of factors, which are often unquantifiable. This is important because each patient is different and has a unique set of circumstances that contribute to their overall medical condition.

Nevertheless, comprehensive evaluations that consider unquantifiable factors contain biases based on the subjective opinion of the examiner. Such evaluations impair communicability of data since individual biases can negatively affect the accuracy of the data and make it difficult to compare measurements between different medical professionals. Advancements in communication and information sharing have made it possible for medical professionals to monitor a variety of medical conditions from remote locations. Minimizing the subjectivity of measurements can help medical professionals draw more accurate conclusions regarding a patient’s condition and help communicate assessments to other specialists even if they are not in direct contact with the patient.

Advancement in technology has made it possible to eliminate the user bias that has previously characterized a medical assessment. For example, optical devices have been developed to assess the level of jaundice in infants, a condition previously evaluated by a subjective visual evaluation. However, sophisticated technology can be difficult to implement in medical settings because it can be disruptive to standard practice and clinicians must be
taught to implement new devices. Additionally, new technology often requires a high initial financial investment (Dunn, personal communication, 2006).

2.7 Reducing Subjectivity in Edema Assessments

In the case of edema assessments, many other factors besides the physical characteristics of the edematous tissue influence the clinician’s assessment. These factors may include whether or not the patient has suffered an injury, whether the patient usually elevates their legs during the day or how much walking the patient has done. If the edema is a “2” because of severe congestive heart failure, it is a much different situation than if the edema is “2” because the patient has a poor diet and does not elevate their feet. For the first condition, the edema may naturally become worse due to compromised circulation. For the latter condition, the edema can improve through very simple modifications. Thus, a comprehensive evaluation of edema is beneficial in determining the severity of the patient’s medical condition.

An edema assessment device should be able to quantify objectively several of the factors medical professionals use to determine the presence and severity of pitting edema. To avoid the complications associated with subjectivity, the device should reduce variability whenever possible. One way to reduce variability is to standardize the measurement procedure such that the operator plays a minimal role in the information gathering. Clinicians should use the device as one part of their comprehensive assessment of a patient’s condition. The device cannot replace clinicians, but can assist them by providing objective measurements.

Since the properties and characteristics of edematous tissue have not been extensively researched, it is difficult to establish exact conditions for the severity levels represented in the 1 to 4 edema assessment scale. However, an edema assessment device is ideal for monitoring a patient’s condition over time by recording changes in tissue parameters. Another important
application of the device is further investigation into the parameters that are associated with the severity of edema. Establishing a correlation between changes in tissue parameters and edematous severity levels would allow us to standardize the 1-4 edema assessment scale for all edema patients. Regardless, if the device could objectively assess edema levels, a clinician would still need to assess a patient's overall condition to make a diagnosis.

The development of an edema assessment device parallels that of a scleroderma sensor developed by Takei et al (Takei, 2004). In the past, the severity of scleroderma was subjectively determined by means of external tissue palpitation and ranked according to the Modified Rodnan Tissue Thickness Score (MRSTS). Simplified scoring methods were to reduce variability due to measurement bias (Kahaleh, 1986). The scleroderma sensor device measures tissue hardness using a tactile sensor and correlates measurements to the MRSTS. This process of collecting subjective information and ranking it according to a standard scale is similar to digital manipulation and the 1-4 scale associated with edema measurements.
3 DESIGN APPROACH: An Edema Measurement Device

The main objective of this project was to build a device that can objectively monitor the severity of a patient’s edema over time. Current edema assessments are highly subjective, and depend solely on the interpretation of the examiner. Variations among medical professionals in measurement technique and assessment criteria result in edema measurements that contain bias. Because of their subjectivity, clinicians cannot easily compare measurements objectively over time, making day-to-day progress for one patient difficult to monitor. Other quantitative edema measurement devices have not been widely adopted to reduce the subjectivity of edema measurements due to cost, inconvenience, or inaccuracy of the measurements.

3.1 Goal and Specific Aims

Our goal was to reduce or eliminate the subjectivity of current edema assessment methods by building a prototype device that measures the same parameters as those assessed by medical professionals during digital manipulation of edematous tissue. We then designed and built a prototype device that accurately measures this parameter and displays a clinically relevant value that will be meaningful to clinicians and convenient to implement in a medical setting. To test this device, we used foam models of different thicknesses to represent edematous tissue of varying severity and collected data to determine whether we could obtain consistent results with varying users on foam models.

- Identify a measurable parameter that corresponds to edematous severity
- Simulate models of edematous tissue
- Collect information regarding the specific objectives, needs, and preferences of medical professionals who assess edema
- Design a prototype device that reproducibly measures and displays the identified parameter
- Design a device housing that is ergonomic and adaptable for a variety of patients
- Verify the efficacy of the device through clinical testing on actual patients at UMass with clinicians in a hospital setting
3.2 Stakeholders

To understand the scope of this project, it is important to identify all of the stakeholders and their specific requirements. The stakeholders in this project can be categorized into four groups: designers, manufacturers, users, and clients.

Our MQP design team represents the designers and our objectives were to implement and test a prototype device that meets anticipated user and client objectives, which can be manufactured efficiently. Manufacturing considerations include using easily procured and inexpensive, unmodified components and incorporating standard dimensions where possible.

The device users consist of both clinicians who monitor and assess edema, and patients who suffer from edema. The team conducted interviews and surveys to help determine user objectives. In addition, our clinical sponsor, Dr. Raymond Dunn, suggested that it would be ideal for patients who suffer from edema to be able to use the device on themselves to communicate a level of severity to their clinicians.

The clients are project advisors Professor Kristen Billiar, Professor Yitzhak Mendelson, Professor John McNeill, and Dr. Raymond Dunn. We incorporated feedback and input from various stakeholders throughout the design process as the basis for developing the main objectives for the device.

3.3 Original/Revised Client Statement

The problem statement in the project description served as the original client statement; however, specific objectives for developing the device were unclear.

Poor venous circulation in the leg, a condition called "venous stasis disease," often results in constant lower leg swelling (edema) and ultimately skin breakdown and chronic ulceration. Clinicians need a tool to measure the pressure in the leg that will objectively show efficacy of treatments for reducing edema (e.g., wrapping, elevation, and topical dehydrants). Students will design
a device for measuring the viscous return following indenting of the leg and reduce the design to practice by developing a working device to be used in the clinic. This project requires a multidisciplinary team with students interested in electrical, mechanical, and clinical areas.

Our goal was to design a device that quantitatively assesses the severity of edema. To expand this problem statement, and to identify some of the objectives and constraints for the device, we interviewed our primary client, Dr. Dunn. The revised client statement reflects feedback from Dr. Dunn. We made specific additions to the client statement based on Dr. Dunn’s input and our understanding of what he envisioned for the final device.

Develop a device to aid medical professionals in quantitatively assessing peripheral pitting edema in extremities. Clinicians will primarily use the device to monitor changes in the severity of a patient’s edema over time. The output of our device will correspond to a severity level index, similar to that used by clinicians for digital manipulation. The device must be inexpensive, non-invasive, safe, adaptable for a variety of patients, consistent, accurate, and easy to operate.

In our revised statement, we did not limit ourselves to measuring the viscous return of the tissue because our preliminary research indicated that other parameters might be more relevant to assessing edema. In addition, we included key objectives for our device that would allow it to be appealing and useful to clinicians who would use it.

3.4 Objectives to Accomplish Goal

To understand the client’s objectives for the device, we conducted background research and interviewed several medical professionals. This helped us understand the types of clinical settings in which clinicians would use the device, as well as the specific desires and preferences that determine the objectives of the users. From this information, we determined several specific objectives and sub-objectives shown in Table 1. To calculate the relative
weight for each main objective, we used the pairwise comparison chart (PCC) shown in Appendix Error! Reference source not found.. The percentages in parentheses next to each main objective indicate its weight in relation to the overall project.

Table 1: Primary Weighted Objectives

<table>
<thead>
<tr>
<th>Objectives</th>
<th>Related Sub-Objectives</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repeable (20%)</td>
<td>- Consistent within users when collecting measurements related to edema</td>
</tr>
</tbody>
</table>
| Convenient (33.3%) | - Minimally time consuming  
                        | - Simple to operate  
                        | - Ergonomic  
                        | - Easy to incorporate into daily routine  
                        | - Relatable to current practice  
                        | - User-friendly |
| Robust (23.3%) | - Reproducible measurements between users  
                        | - Independent of testing conditions |
| Adaptable (6.7%) | - Useable on a variety of patients  
                        | - Useable on multiple areas of the body |
| Durable (10%) | - Long lasting  
                        | - Reliable after repeated usage |
| Expandable (6.7%) | - Capable of providing multiple relevant outputs |

Overall, convenience, robustness, and accuracy are the most highly weighted objectives, with convenience being the most important. For the device to be useful to clinicians, it should be as easy as or easier than current methods employed for assessing edema. Thus, the device should fit into a clinician’s medical routine by being compact, portable, ergonomic, and requiring minimal setup and measurement time. Additionally, the device should provide an output that is clinically relevant and easily communicated to others. Accuracy implies that the device outputs a value that corresponds to the true level of edema in a patient. The robustness of the device is inversely related to the subjectivity of the measurement. A highly robust device outputs consistent, repeatable measurements, regardless of user or measurement environment. A robust device is minimally user-dependent, such that any user could obtain the
same numeric results on the same patient. Adaptability ensures that clinicians can use the
device on multiple patients despite variations in patient anatomy and condition. The device
should be able to monitor edema in a variety of locations on the patient’s body, with the most
common locations to measure edema being the lower leg and ankle. Durability of the device
refers to the sturdy, physical construction of the device. The device must remain sturdy and
output accurately calibrated measurements after repeated usage. Expandability ensures that
there is a possibility for future device improvements. These may include adapting the device
so it is suitable for taking measurements on many different locations on the patient.

3.5 General Device Constraints

In addition to fulfilling the objectives discussed in section 3.4, the device must also conform
to several general constraints. Budget and time constraints dictate that we minimize the
number of components and avoid over complicated circuitry if possible. Other constraints are
determined by the clients, users and the clinical nature of the device (Table 2).

<table>
<thead>
<tr>
<th>Constraint</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time</td>
<td>We must complete the research, design, and construction of the device by the end of D-term 2007</td>
</tr>
<tr>
<td>Project Budget</td>
<td>The allotted budget from the Biomedical Engineering department for the design and the construction of the device is $610</td>
</tr>
<tr>
<td>Test time</td>
<td>The time to set up the device and take the measurement should not exceed the current assessment method (approximately 20 seconds)</td>
</tr>
<tr>
<td>Safety</td>
<td>The device cannot cause any pain or physical harm to the patient or physician</td>
</tr>
<tr>
<td>Materials</td>
<td>All materials used in the device must be readily available and FDA approved for use in a medical device</td>
</tr>
<tr>
<td>Size</td>
<td>The device must be portable and the use must be comfortable using the device as an alternative to digital manipulation</td>
</tr>
</tbody>
</table>
3.6 Evaluation of a Previous MQP: A device to quantify lower extremity edema

Before starting the design of the edema measurement device, we evaluated a previous solution developed by an MQP team in 2004 (Weindling and Fontaine, 2004). The MQP group developed an edema assessment device based on a light detection system. The device measured the time constant for the relaxation of edematous tissue after indentation. The time constant was the time it took for the tissue to move from maximum indentation back to 63% of its initial position. The group’s basic assumptions were that the return time constant corresponds to the level of edematous severity and that the amount of light collected by a light detector can be used to represent the linear displacement of the tissue.

Our research determined that it is unclear whether the return time constant directly corresponds to edematous severity. Although we can verify a clear difference in the return time of healthy and edematous tissues, the exact relationship between return time and severity requires clinical research and characterization of edematous tissue, which is beyond the scope of this project. In light of this consideration, our group decided not to proceed with the return time constant as our final measurement parameter. Because of the uncertainty of the measurement that best indicates the severity of edematous tissue, we conducted research to determine the most effective measurement method. Section 4.2 provides further explanations of the parameters our device will measure.

The 2004 MQP used optical technology as a non-contact method to measure displacement. In the device, a thin barrier moves up and down with the indenter positioned between a light emitting diode (LED) and a photoreceptor to measure displacement (see Appendix 0 for more detail). Thus, the photoreceptor is saturated when the indenter is at its initial displacement, and fully blocked by the barrier when the indenter is at maximum indentation. Varying severities
of edema will correspond to varying distances the barrier will have to move, however, the
dimensions of the LED are constant. Once the LED has been completely blocked, the device
no longer collects data. If the clinician has not pushed through all of the edematous tissue, the
measurement will be inaccurate. Based on this analysis, we decided not to pursue this method
of measuring displacement.

3.7 Potential problems in an edema measurement device

The insight we gained through our research on the related background for edema assessment
enabled us to anticipate several potential problems that may be associated with the
implementation of an edema assessment device as indicated in Error! Reference source not
found..
Potential Problems

Problems with the device
- Unable to measure different levels of severity
- Complicated device operation
- Flimsy device construction

User-controlled error
- Inconsistencies among clinicians in performing the measurement
- Subjectivity in the measurement

Patient or environment variability
- Variability of environment
- Patient-to-patient variability

Inconvenience
- Set-up time is too long
- Output not relatable to current practice

Figure 6: Potential issues with device design
Each of the issues indicated in Error! Reference source not found. can affect the accuracy and consistency of our measurements when measuring the severity of edema. The presence of any of these problems in our final design may cause the device to be inoperable, or unlikely for medical professionals to adopt it for the measurement of edema in clinical settings. The final design of our device should address each problem and minimize or eliminate the associated complications. By minimizing these potential problems in our final design, we will develop a device that meets our goals to create a convenient and clinically relevant device that can accurately monitor the severity of pitting edema.
4 DEVICE DESIGN

We divided the design process into three different areas, measurement parameters, internal components, and housing and worked on each of these design areas simultaneously to reach our final design.

4.1 Design focus areas for the edema device

We implemented a black box scenario to describe our approach to the overall design of the edema measurement device. In the early stages of the design process, we had not yet determined what parameters to measure, how to perform the measurement, and how to house the device. To define these aspects of the device more clearly, we identified the overall functions of the device in terms of inputs and outputs (Figure 7), as well as three specific design areas that determine the device parameters. The input to the device is the contact with a tissue of a certain edematous severity. The output is a measurement value indicating the level of severity of the input. This output should be clinically relevant and useful to medical professionals. Figure 7 shows the three specific design areas comprise the overall design of this device. The first design criteria relates to the parameters which the device measures. The second design area encompasses the internal components, which physically calculate the output value. The device housing and user interface comprise a third design area.
One of the aims of this project is to determine parameters that characterize edematous tissue. The parameters we select have a direct influence on the overall design of the device, since they determine what the device must measure. If we select return time as a parameter of interest, the device must have some way of measuring displacement and time. We determined those parameters through theoretical research, computer simulations, and lab tests.

The internal components also influence the device design because they dictate how the device will measure the selected parameter or set of parameters. The device must house all necessary components. The design for a device that houses a motor and automated depressing mechanism may differ significantly from a device that merely measures displacement manually. We selected device components based on extensive means research, which provided us with options for components that work together to provide the desired output measurement.

The device housing, which encompasses both the user and patient interfaces, influences the overall design. The device housing should be convenient for the user and should interface safely and comfortably with the patient. The housing should also be durable and reliable after many uses. Through interviews, surveys and research of other clinically approved devices, we
were able to define desired device characteristics, as well as specific constraints and limitations that ensure that the device meets these requirements. The device housing itself should also facilitate robust measurements, which are independent of patient and user movement.

While we will research and analyze each area separately, the design areas are interdependent, as shown in Figure 8. The interrelationship between design areas necessitated that we develop each area simultaneously. Ultimately, each design area must work together to fulfill the objectives discussed in section 3.4.

![Figure 8: Interrelationship of Design Areas](image)

The arrows connecting the gray boxes illustrate the interrelationship of three design areas that impose requirements on the overall design. The white boxes represent various means of determining parameters for each design area.
4.2 Measured parameters to indicate edema severity

One of the aims of this project was to determine parameters a device could use to characterize edematous tissue. The parameters we selected have a direct influence on the overall design of the device, since they determine what the device must measure. For example, a device that measures the response of the tissue to an indentation must incorporate a probe as well as a mechanism that controls the depression of the probe. If we select return time as a parameter of interest, the device must have some way of measuring displacement and time. We determined the parameters to measure through theory research, computer simulations, and lab tests.

4.2.1 Device Functions

Before identifying types of measurement parameters, we developed a list of general functions that the device must perform to fulfill the client’s goal. The overall function of the device is to produce an output that indicates the severity of a patient’s edema. The device must create a displacement, measure the displacement, measure the resistance of the tissue, measure the time required for the tissue to return to its original state before depression, process the data collected throughout the measurement, and display the output. The output of the device must correspond with the severity level, and the device itself must interface comfortably with the patient.

Edematous tissue, like most biological tissues, has varying inhomogeneous mechanical and physiological tissue properties. To explore possible parameters that might indicate the level of severity for edematous tissue, we explored viscoelasticity theory and applied it to biological tissues and edema. The primary measurements used to determine the mechanical properties of a tissue are creep and creep recovery tests, stress relaxation, and oscillatory tests. In addition to these, we explored force loading profiles and depth of tissue indentation as possible parameters that might accurately indicate the severity of edema.
We hypothesized that as severity of edema increased, the material properties of the tissue would also change enough to differentiate between varying levels of severity. To test this hypothesis, we used MATLAB to model tissue responses using constitutive equations for a linear viscoelastic material. Appendix 12.2 provides specific equations and more detailed explanations of viscoelasticity theory applied biological tissue and edema testing. Although we modeled the theoretical responses of tissue with equations, the actual tests needed to derive the parameters from edematous tissue were infeasible to implement.

Oscillatory tests, for example, require repeated cyclical probing of the tissue at a fast rate to derive mechanical properties. These types of tests are designed for tissues that have an immediate return response and will rebound quickly after being indented by a probe. Because pitting edema is characterized by a very slow tissue response, oscillatory tests are difficult to do on edematous tissue. In addition, repeated cyclical probing may be uncomfortable and invasive for a patient. For these reasons, we did not consider oscillatory tests a plausible means to assess edema for our device.

Stress relaxation and creep tests are difficult to test because parameters can only be calculated if the total thickness of the tissue is known, which varies between patients and is unknown before testing begins. These measurements rely on the response of the tissue after it is indented, meaning that the total time to obtain measurements will take several minutes, making our device much less convenient and less ideal compared to the current manual measurement that clinicians make. Our team determined that stress relaxation and creep tests could not be incorporated into a quick and easy device to quantify the severity of edema. The remaining tests that we explored to indicate the severity of edema were measurements of the force response profile, the depth of pitting, and the return time of the tissue upon indentation.
We estimated that as the severity of edema increased, a greater force would be required to depress edematous tissue. Thus, the force response vs. time and the depth of the tissue to depression may be able to indicate different levels of severity. Mathematical simulations of tissue response, however, indicated that the differences in force versus time were very small, and did not become highly differentiated unless the tissue was under large forces or depressed at large depth, much greater than the scale of edema would allow. For this reason, our device does not rely solely on a measurement of force over time as a primary indicator of edematous severity. Our final device, however, will include the capability of measuring force versus time. Thus, investigators may use our device as a diagnostic tool to help characterize edema, and will provide information in clinical testing that will help improve future iterations of the device.

Measuring the force the indenter probe applies is essential because we must set a maximum threshold of force to prevent injury to the patient. The measurement of force will prevent the probe from indenting at a force that may injure the patient.

The 2004 Edema MQP used the time constant for the return of edematous tissue after indentation to indicate edema severity. The time constant was the time it takes for the tissue to move from maximum indentation to 63% of its initial position. Clinical research is necessary to verify that the return time differs for different severities in a predictable way. Simulations using MATLAB demonstrated that the time constant was not significantly different for different thicknesses of edematous tissue based on edema models we modified from the 2004 MQP. Our models, however, are limited, and cannot mimic the true response of biological tissue. Although the time constant for edematous tissue of different severities may vary significantly, we cannot verify those differences without extensive clinical testing and characterization of edematous tissue, which is beyond the scope of this project. We do know
that the time constant is quite different between non-edematous and edematous tissue. Healthy, normal tissue has a very small time constant and returns instantly upon depression. Edematous tissue, on the contrary, has a slower response and a much larger time constant. Our team decided to use the measurement of time constant as an indicator of whether there is edematous tissue in the area the device measures (Bates, Levick and Mortimer, 1994).

The measurement of the pitting depth is the same as most clinicians use to assess edema manually. Our interviews indicated that clinicians are most comfortable relying on depth to indicate the severity of edema, and that they would be most willing to adopt a device that measures edema in a similar manner. Our team chose the measurement of pitting depth as the primary indicator of the severity of edema. This measurement is easy to collect, and will allow clinicians to objectively measure the depth of edema pitting.

4.2.2 Survey of clinicians to determine important parameters for edema severity

To determine what parameters were most important for assessing edema severity we conducted a survey asking clinicians to identify what parameters they used to assess edema and to specify what device features they would find valuable in an edema measurement device. We obtained 16 completed surveys from medical professionals whose titles ranged from registered nurses (RN) to medical clinicians (MD), and whose specialties were cardiac or rehabilitation care. None of the respondents indicated that they were aware of other edema assessment devices.

Figure 41 is a pie chart showing the ‘most important’ parameters that clinicians identified for edema assessment. Most participants felt that the depth of indentation was “very important” for edema assessment. This result helps us verify that assessment of tissue displacement is clinically significant and meaningful to medical professionals.
Figure 41: Parameters clinicians identified as “very important” for assessing edema

Our survey also questioned clinicians about the importance of a variety of device features. Figure 54 represents the ‘most important’ device features in a pie chart. As we predicted, set-up time, cost and duration of measurement had the highest percentage of respondents who indicate that these features are “very important.” Overall, clinicians responded that set-up time was the most important device feature, with more than half of the responses indicating that it is very important. Cost was the second most important device feature. The administered survey and more detailed survey results are available in APPENDIX B: Edema Survey.

Figure 9: Device features that clinicians identified as “very important”
4.2.3 Final Measurement Parameters

Our final device will measure three aspects of edema; the depth of pitting, the time constant for return of tissue, and the force required to depress the tissue. The depth of pitting is the primary indicator of edema severity; the thicker the tissue, the greater the severity (Figure 5). Healthy tissue, however, will also have a depth of indentation. The return time will differentiate whether the tissue has a fast or slow time constant, corresponding to healthy and edematous tissue (Figure 6). Finally, the measurement of force versus time is included as a diagnostic tool to determine if force profiles vary between different severities of edema, as well as a safety measure to prevent clinicians from injuring patients by a forceful depression of the probe.

![Diagram illustrating the relationship between distance depressed and edema severity, and time constant for edematous and healthy issue.](image)

Figure 10: Relationship between distance depressed and edema severity (a), Time constant for edematous and healthy issue (b)

4.3 Components and Means Research

Once we determined what type of measurement and parameters correlate to the severity of edema, we determined what components would be necessary to achieve each measurement. The relevant parameters we identified for edema measurement were the force required to depress the tissue, the total distance displaced, and the recovery time for the tissue after being
A microcontroller will collect the process the data for each parameter, with an LCD to display the results that indicate edema severity.

For each component, we developed metrics to evaluate the feasibility for using the component. We used metrics to assign a value point to each component depending on its ability to fulfill each requirement and gave each metric a weight depending on its importance in the overall design. A higher weight indicated a more important objective. After a comprehensive research of components compatible with our device, we evaluated the devices with a decision matrix to determine which component was optimal for our device.

4.3.1 Force Transducer

Appendix 14.3.1 provides a list of force transducers that fell within the required metrics. Table 3 provides the decision matrix used to evaluate the six best force transducers we researched.

<table>
<thead>
<tr>
<th>Force Transducer</th>
<th>Market</th>
<th>CUI</th>
<th>Measurement Specialties</th>
<th>Tekscan</th>
<th>Honeywell</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Weight</td>
<td>Value point</td>
<td>Total</td>
<td>Value point</td>
<td>Total</td>
</tr>
<tr>
<td>1 Cost</td>
<td>50</td>
<td>1</td>
<td>50</td>
<td>2</td>
<td>100</td>
</tr>
<tr>
<td>2 Size &amp; Weight</td>
<td>60</td>
<td>4</td>
<td>240</td>
<td>5</td>
<td>300</td>
</tr>
<tr>
<td>Range &amp; Resolution</td>
<td>90</td>
<td>5</td>
<td>450</td>
<td>5</td>
<td>450</td>
</tr>
<tr>
<td>4 Interface</td>
<td>40</td>
<td>3</td>
<td>120</td>
<td>3</td>
<td>120</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td>860</td>
<td></td>
<td>970</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Force Transducer</th>
<th>Market</th>
<th>HBM</th>
<th>Sensortechnics</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Weight</td>
<td>Value point</td>
<td>Total</td>
</tr>
<tr>
<td>1 Cost</td>
<td>50</td>
<td>1</td>
<td>50</td>
</tr>
<tr>
<td>2 Size &amp; Weight</td>
<td>60</td>
<td>1</td>
<td>60</td>
</tr>
<tr>
<td>Range &amp; Resolution</td>
<td>90</td>
<td>1</td>
<td>90</td>
</tr>
<tr>
<td>4 Interface</td>
<td>40</td>
<td>2</td>
<td>80</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td>280</td>
</tr>
</tbody>
</table>
The load cells by Measurement Specialties and Sensortechnics scored similarly in the decision matrix. Because the two components are nearly identical in design, the team chose to use the load cell manufactured by Measurement Specialties because it was less expensive than the Sensortechnics sensor.

### 4.3.2 Displacement Transducer

The displacement transducer that the team chose was a linear encoder made by U.S. Digital. Appendix 14.3.2 provides the list of possible displacement transducers and an evaluation of each, including metrics and the decision matrix (Table 4). The metrics we used for the selection of a distance transducer were cost, size & weight, range & resolution, interface, and contact/non-contact. We created the contact/non-contact metric to quantify the method by which the displacement transducer measured a change in distance. For example, a capacitive sensor emits an electric field and detects changes in the field to measure changes in displacement. Thus, the capacitive sensor measures displacement without making direct contact with the surface of interest, which is ideal. Alternatively, a linear encoder contains a plunger, which needs to move up and down to detect changes in displacement. Thus, the linear encoder measures changes in displacement using a contact measurement. The reason for the selection of the various metrics was the same as the reasons provided for the force transducer and thus the weights that we assigned were the same.

The reason that this metric is of interest to the team pertains to the development of the final device. The final device has an indenter that makes the depression into the edematous tissue. If the linear displacement transducer makes a non-contact measurement, the device could be mounted on the indenter. If the displacement transducer makes a contact measurement, a
connection between the displacement transducer and the indenter would ensure that motion of
the indenter corresponds to the motion of the displacement transducer.

4.3.3  Data Processing and Time Sensing

The edema measurement device must measure force against time, distance against time, and force against distance. In addition, it will take a distance measurement at the peak rate of change of force. Lastly, the device measures the tissue return time to indicate the presence of edematous tissue. An embedded microcontroller processes the data and measures time.

There are dozens of different companies that manufacture microcontrollers; however, since we were only familiar with the PIC and the MSP430 microcontroller, we decided to eliminate all other types of microcontrollers. We decided to research microcontrollers in the MSP430 family because they contain 16 working registers, compared to the PIC, which has only one working register. Additionally, the MSP430 consumes less power.

Table 4: Decision Matrix for Displacement Transducer

<table>
<thead>
<tr>
<th>Displacement Transducer</th>
<th>Market</th>
<th>U.S. Digital</th>
<th>Solatron Metrology</th>
<th>BEI</th>
<th>Omron</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Weight Value point</td>
<td>Total</td>
<td>Value point</td>
<td>Total</td>
</tr>
<tr>
<td>1 Cost</td>
<td></td>
<td>50 1 50 1</td>
<td>50 2 100 2 100</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 Size &amp; Weight</td>
<td></td>
<td>60 3 180 3</td>
<td>180 4 240 4 240</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 Range &amp; Resolution</td>
<td></td>
<td>90 5 450 1</td>
<td>90 3 270 3 270</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4 Interface</td>
<td></td>
<td>40 2 80 2</td>
<td>80 2 80 2 80</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 Contact or Non-Contact</td>
<td></td>
<td>40 0 0 0</td>
<td>0 0 0 0 1 40</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>760</td>
<td>760</td>
<td>400</td>
<td>690</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Displacement Transducer</th>
<th>Market</th>
<th>Schaevitz</th>
<th>Honeywell</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Weight Value point</td>
<td>Total</td>
</tr>
<tr>
<td>1 Cost</td>
<td></td>
<td>50 1 50 5</td>
<td>5 250</td>
</tr>
<tr>
<td>2 Size &amp; Weight</td>
<td></td>
<td>60 1 60 5</td>
<td>5 300</td>
</tr>
<tr>
<td>3 Range &amp; Resolution</td>
<td></td>
<td>90 1 90 1</td>
<td>1 90</td>
</tr>
<tr>
<td>4 Interface</td>
<td></td>
<td>40 1 40 1</td>
<td>1 40</td>
</tr>
<tr>
<td>5 Contact or Non-Contact</td>
<td></td>
<td>40 0 0 0</td>
<td>0 0 0 0</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>240</td>
<td>240</td>
</tr>
</tbody>
</table>
Before we decided which microcontroller in the MSP430 family we could use, we realized that we needed a development board that would contain an LCD, physical pins for input and output, and push buttons so that the clinician would be able to scroll through the information displayed on the LCD. The WPI Electrical and Computer Engineering Department uses and supports Olimex’s MSP430-449STK2 development board, which contains an LCD, push buttons, and LED, and a buzzer. Because we are familiar with the TI MSP430, we decided to purchase it for prototyping purposes. The TI MSP430F449 contains the features that we need: ultra-low power consumption, an ADC, 60KB of flash memory, 2KB of data memory, and 48 I/O pins. If the device was manufactured on a large scale, we would scale down by using a less powerful microcontroller that would contain less memory and fewer digital input/output (I/O) ports.

4.3.4 Power Requirements

The components in the edema measurement device are powered by an external source. Table 5 displays the maximum voltage and current requirements for each device in our system. The team would like to avoid the use of an AC wall outlet to provide ultimate portability for using the device. After researching several types of batteries, we concluded that the rechargeable lithium ion battery was the most feasible power source. Specifications for various types of batteries are available in Appendix 14.3.3.

<table>
<thead>
<tr>
<th>Device</th>
<th>Voltage</th>
<th>Current</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microcontroller</td>
<td>3.6V</td>
<td>420 μA</td>
</tr>
<tr>
<td>Linear Optical Encoder</td>
<td>5.0V</td>
<td>27 mA</td>
</tr>
<tr>
<td>Load Cell</td>
<td>5.0V</td>
<td>20 mA</td>
</tr>
</tbody>
</table>
5 DEVICE HOUSING

Although the internal components of the device are crucial for measuring and processing data, perhaps more important is the development of the device housing and user interface. The device must be easy to understand, efficient, compact, and durable to be successful in a fast-paced medical environment. Our team brainstormed preliminary housing designs that would facilitate a comfortable user interface for the patient and an efficient and convenient setup for the clinician. The design of our housing strives to eliminate many of the potential problems that we identified in Section 3.7. For example, one of the primary problems with the 2004 MQP device was that it lacked immunity to user error, making the device produce incorrect or subjective measurements. Our final design works to eliminate these errors and creates a reliable way to measure edema severity. We designed the device housing so clinicians would feel that the benefits of using our team’s device would outweigh those of digital manipulation.

5.1 Preliminary Housing Designs

We brainstormed four different user interfaces, including a modification of 2004 MQP interface. Appendix 15.1 provides an in-depth analysis of our preliminary designs. We chose the final housing design by using a value analysis to evaluate two possibilities: the cuff design and the dual cylinder design.

5.1.1 Cuff Design

The cuff design consisted of attaching a cuff, similar to a blood pressure cuff, to a tissue indenter as shown in Figure 11. The cuff would offer greater device stability because clinician would push on the probe without needing to stabilize the probe solely with his hands. There were two serious disadvantages related to the cuff. Clinicians would not be able to use it on
different locations on the patient’s body, such as hands or feet, and there is a possibility the cuff could compress the tissue and skew pitting depth measurements. If a clinician wanted to measure edema severity on a patient with a venous ulcer the leg, the clinician would be unable to quantify the edema with the device because the cuff would touch the ulcer. If a patient had edema in his hand or foot, the cuff could be inconvenient to wrap around the hand or foot and would be unstable during measurement. Although the cuff eliminates some user error by maximizing stability, there is increased room for user error if the clinician secures the cuff too tightly on a patient. The cuff could compress edema out of the area being measured and the distance that the probe would measure would be inaccurate.

Figure 11: Preliminary Housing Cuff Design
Top: Cuff design when the cuff is open. Bottom: Cuff design when the cuff is closed. We would place a box containing the probe and device controlling components on top of the cuff with the display.
5.1.2 *Dual Cylinder Design*

The dual-cylinder design, conceptualized in Figure 12, was similar to that of the 2004 MQP, but requires only a single button to activate the measurement, where the previous design required two buttons to activate the measurement (Weindling and Fontaine, 2004). Some of the advantages of the dual-cylinder design are that it is the smallest of our housing designs, it could be used anywhere on the body, and setup time would be minimal. In addition, the microcontroller and the battery for the device are separate from the probe portion of the device, making it smaller and more convenient to hold during measurements.

![Figure 12: Preliminary Housing Dual Cylinder Design](image)

5.1.3 *Value Analysis for Final Housing Design*

Table 6 provides a value analysis for the cuff and dual-cylinder and lists the primary objectives for our housing design in order of importance. We believe that the ability of the device to assess edema anywhere on the body is the most important objective because edema can occur anywhere on the body; when we visited the wound clinic, we observed pitting edema in the foot, front of the knee, side of the knee, and calf. If we created a device that could assess
edema on only one part of the body, we would be limiting the number of potential users. We assigned weights ranging from 10 to 80 for each of the objectives. Appendix 0 provides the metrics that we used to rate the cuff and dual-cylinder design are given in Table 6.

<table>
<thead>
<tr>
<th></th>
<th>Cuff</th>
<th></th>
<th>Dual Cylinder</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Weight</td>
<td>Value point</td>
<td>Total</td>
<td>Value point</td>
</tr>
<tr>
<td>1  Manufacturing time</td>
<td>10</td>
<td>2</td>
<td>20</td>
<td>4</td>
</tr>
<tr>
<td>2  Inexpensive</td>
<td>20</td>
<td>4</td>
<td>80</td>
<td>5</td>
</tr>
<tr>
<td>3  Short set-up time</td>
<td>30</td>
<td>3</td>
<td>90</td>
<td>5</td>
</tr>
<tr>
<td>4  Size (volume)</td>
<td>40</td>
<td>2</td>
<td>80</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5  Ability to eliminate error due to motion of clinician's hand or wrist</td>
<td>50</td>
<td>5</td>
<td>250</td>
<td>1</td>
</tr>
<tr>
<td>6  Easy to interface with transducers and probe</td>
<td>60</td>
<td>2</td>
<td>120</td>
<td>3</td>
</tr>
<tr>
<td>7  Possibility of non-probe section pressing on edema</td>
<td>70</td>
<td>1</td>
<td>70</td>
<td>5</td>
</tr>
<tr>
<td>8  Ability to assess edema anywhere on body</td>
<td>80</td>
<td>1</td>
<td>80</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>790</td>
<td></td>
<td>1430</td>
</tr>
</tbody>
</table>
6 FINAL DESIGN

The final design of this device has components that measure displacement and force while depressing a probe into edematous tissue. A microcontroller and batteries control the system and yield a measurement that indicates edema severity. This section details the final ergonomic device housing, circuitry and microcontroller programming for the edema device.

6.1 Final Housing Design

We used the dual cylinder design as the starting point for the final housing design and selected a mechanism to indent the tissue of the edematous patient. We constructed the final model around the geometry of the linear encoder and force transducer and took preliminary prototypes to Dr. Dunn for approval. Figure 13 shows the final housing, which contains the linear encoder, force transducer, thumb depressor, indenter, and associated wires. A wire leaves the housing and terminates in the control box, which contains the microcontroller, associated circuitry, and batteries.

We manufactured the final housing out of Delrin, a polymer sold as a metal substitute. We chose Delrin because it was lightweight, had a low coefficient of friction, wear-resistant, and has been approved for use by the FDA for medical devices. The dimensions of the components determined the geometry of the final housing, which we also designed to fit the contours of a hand, and to be ergonomically pleasing. The base of the device is flat and allows the clinician to make solid contact with the edematous tissue. To use the device, the clinician places his thumb around the front of the device over the thumb depressor. We designed the thumb depressor (.75” diameter) to be comfortable for an average thumb size based on anthropometric data. The indenter, the piece that makes contact with the tissue, is .5” in
diameter. We chose the sizes based on the amount of pressure required for the clinician to make an indentation into the tissue.

Figure 13: Final Housing Design

Figure 14: Final prototype with control box, microcontroller, and batteries
Figure 15 displays an isometric view of the final housing. The thumb depressor is inserted into a hole on the front of the device and connected to an internal indenter. The smaller hole on top of the device is an outlet for the linear encoder probe. The slot on the side of the device is an outlet for the wires to the microcontroller.

Figure 16 displays a top view of the housing with the thumb depressor removed. From this view, the ½-inch diameter tissue indenter outlet is visible though the ¾ in. diameter thumb depressor hole.
When assembled, the thumb depressor sits on top of the load cell, which connects to the tissue indenter. Pressing on the thumb depressor into the tissue results in a force measurement that corresponds to the stress the clinician applies to the depressor. The depressor moves smoothly up and down 1 ¼ in. which represents the full range of motion of the linear encoder.

Figure 17 displays a back view of the housing assembly. This figure shows the relationship between the depressor, indenter, and load cell. The linear encoder (blue) fits snugly into the back of the device with the plunger of the encoder close to the bottom of the device. The depressor (pink) makes contact with the top of the load cell (green) which is sandwiched between the depressor and the indenter. The indenter connects to the plunger of the linear encoder so that relative motion of the encoder corresponds to relative motion of the indenter, load cell, and depressor unit. The user will notice the plunger of the linear encoder poking out the top of the device as the plunger moves up and down.
Figure 18 displays the cover for the housing. The cover fits snugly into the back of the device. There are two tabs on the top and bottom of the cover that fit into the back of the housing after the components are inserted in the back of the device.

The microcontroller, additional circuitry, and batteries are located in a separate control box connected to the main housing by one wire. The control box contains an LCD that displays the output values for edema severity and has buttons for the clinician to begin and clear measurements on the microcontroller. The clinician may place the control box to the side during measurement and reference once the measurements are complete.

The final device requires a minimum number of components and is easy to assemble. All of the parts are inserted without modification directly from the manufacturer. For assembly drawings with detailed dimensions please refer to 16.3.
6.1.1 Indenter Design

Because the final measurement in our device will incorporate the return time, it is important that the device indenter is lightweight and as frictionless as possible so the tissue will be able to return to its original position without much opposition from the indenter. The size of the indenter needs to be optimal so that the person using the device can deliver enough force to push the probe towards the bone without hurting the patient. The indenter cross-sectional area needs to be large enough so that the thumb of a clinician can push on it with ease and large enough to house the force transducer. The indenter must also be smooth and not have sharp edges to ensure that the patient interface is comfortable and causes no irritation to the tissue. We chose a cylindrical shape for the indenter to simulate the size and shape of a thumb.

These constraints limit the materials we can choose for the indenter design. The material chosen is Delrin™, which is often used as a metal substitute. It is a lightweight, low-friction,
and wear-resistant plastic. The FDA has approved Delrin™ for use in the food industry. Delrin’s resistance to liquids and low coefficient of friction has made it useful as a bearing-replacement in casters and wheels.

6.1.2 *Anticipated User Error with Device Design*

Even with an ideal housing design, the device is still susceptible to user error, particularly if the device includes a manual input. Manual input describes situations in which the user plays a direct role in acquiring measurements. Manual inputs for our device include setup of the device, stabilization of the device and depression of the probe. If the device is not properly designed, manual inputs can vary significantly from user to user. This variation can introduce bias or user-related error into the measurement. One way to minimize bias is to make the device user independent or automatic. In this case, the user’s only role would be to place the device on the patient and the device would collect the measurement automatically. However, automation can be expensive and requires additional components that increase the size and weight of the device. Thus, we decided on a manual design to simplify our design.

Table 7 shows a user error matrix that reflects various scenarios that could potentially produce error. During measurement, there are three times when the user can introduce error. These areas are prior to measurement, indenting, and creep recovery. The second column of the user error matrix provides an explanation of the user error and the third column addresses what the team has done to remedy the error.
# Table 7: Potential User Error

<table>
<thead>
<tr>
<th>PRIOR TO MEASUREMENT</th>
<th>EXPLANATION</th>
<th>SOLUTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poor contact with tissue</td>
<td>Indenter not flush with tissue surface</td>
<td>-Red marker -Instructions: place device against tissue</td>
</tr>
<tr>
<td>Compression</td>
<td>Casing depresses tissue</td>
<td>-Instructions</td>
</tr>
<tr>
<td>Device angled</td>
<td>Indenter not perpendicular to tissue surface</td>
<td>-Instructions: ensure that the indenter is perpendicular to tissue surface</td>
</tr>
<tr>
<td>Failure to initialize</td>
<td>Start button not pressed</td>
<td>-Clearly marked “start” button</td>
</tr>
</tbody>
</table>

| DURING MEASUREMENT
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>INDENTING</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rate of depression too fast</td>
<td>Rate of depression too fast</td>
<td>-LED -Instructions: depress slowly -Monitor with microcontroller: buzzer or display “fast”</td>
</tr>
<tr>
<td>Device angled</td>
<td>Indenter not perpendicular to tissue surface</td>
<td>-N/A</td>
</tr>
<tr>
<td>Lift up</td>
<td>Casing loses contact with tissue</td>
<td>- Increasing distance, decreasing force – output error message</td>
</tr>
<tr>
<td>Compression</td>
<td>Casing depresses tissue</td>
<td>-Instructions</td>
</tr>
<tr>
<td>Release indenter (a little)</td>
<td>User releases pressure on indenter a little</td>
<td>-None - does not affect measurement</td>
</tr>
<tr>
<td>Release indenter (a lot)</td>
<td>User releases pressure on indenter a little</td>
<td>Microcontroller outputs “error” and user must restart measurement</td>
</tr>
<tr>
<td>Failure to reach force threshold</td>
<td>User does not press enough into tissue to reach threshold</td>
<td>No output</td>
</tr>
<tr>
<td>Failure to reach dx/dt ~ 0</td>
<td>User does not press far enough to cause minimal change in distance</td>
<td>-No output unless FS is exceeded</td>
</tr>
<tr>
<td>Exceed safety threshold</td>
<td>User exceeds a safe force level</td>
<td>-Microcontroller outputs warning</td>
</tr>
</tbody>
</table>

| **CREEP RECOVERY** | | |
| Tissue does not push probe back | Tissue does not push probe back | Lightweight components |
| Device angled | Indenter not perpendicular to tissue surface (tau is skewed) | N/A |
| Lift up | Casing loses contact with tissue (tau is skewed) | Microcontroller recognizes change in direction of indenter and outputs error |
| Compression | Casing depresses tissue | |
| Prematurely stop measurement | User removes device before tau is measured | Output “error” message |
| Movement | User causes device to move | |
| Patient Movement | Patient causes device to move | N/A |
6.1.3 Market Analysis

Currently there is no device on the market that clinicians are willing to use to assess the severity of peripheral edema. Other methods of assessment are either inaccurate or too expensive. For example, many clinicians could potentially assess the severity of edema using water displacement; however, his method is inconvenient and not widely used. There is currently a device on the market called the Perometer, which is highly accurate and uses infrared sensing to measure the volume of a limb; however, this device costs $30,000 and is only on the wish list of hospitals. The edema assessment device produced by this MQP fulfills a need that has not yet been satisfied by a medical device.

The base price of our edema measurement device is less than $500 (Table 8), making it ideal for mass manufacturing and affordable for clinicians to use every day in edema assessment. The cost of the housing includes the Delrin™ and manufacturing the part. We obtained the cost of the plastic from Plastics Unlimited in Worcester, MA and the estimated cost of manufacturing from Northern Manufacturing. U.S. Digital and Measurement Specialties provided the cost of the Linear Encoder and Load cell. Included in the cost of the linear encoder is the associated circuitry and cabling. The cost of the indenter, depressor, and microcontroller housing was estimated after talking with the Lab Machinist, Michael O’Donnell at WPI. The microcontroller cost was obtained from Olimex. Included in the cost of the microcontroller is the associated circuitry required. The costs of the batteries were obtained from Duracell. Included in the cost of the batteries is the associated battery holder.
Table 8: Cost Breakdown: Base Price

<table>
<thead>
<tr>
<th>Quantity</th>
<th>Description</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Housing</td>
<td>$50</td>
</tr>
<tr>
<td>1</td>
<td>Linear Encoder</td>
<td>$189.73</td>
</tr>
<tr>
<td>1</td>
<td>Load Cell</td>
<td>$65</td>
</tr>
<tr>
<td>1</td>
<td>Indenter</td>
<td>$.50</td>
</tr>
<tr>
<td>1</td>
<td>Depressor</td>
<td>$.50</td>
</tr>
<tr>
<td>1</td>
<td>Microcontroller</td>
<td>$100.90</td>
</tr>
<tr>
<td>5</td>
<td>Batteries</td>
<td>$12</td>
</tr>
<tr>
<td>1</td>
<td>Microcontroller Housing</td>
<td>$6</td>
</tr>
</tbody>
</table>

Total $424.63

In estimated bulk pricing, the edema assessment the device would cost approximately $165 each (Table 9), a value based on manufacturing 3,000 of the device if all the major hospitals in New England purchased no more than 25 of the device. The current iteration of the device assumes that the potential buyers would be hospitals for use by the clinicians. The device that we constructed is not at a point where patients could assess the severity of their own edema.

Table 9: Cost Breakdown: Bulk Price

<table>
<thead>
<tr>
<th>Quantity</th>
<th>Description</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Housing</td>
<td>$5</td>
</tr>
<tr>
<td>1</td>
<td>Linear Encoder</td>
<td>$80</td>
</tr>
<tr>
<td>1</td>
<td>Load Cell</td>
<td>$20</td>
</tr>
<tr>
<td>1</td>
<td>Indenter</td>
<td>$0.1</td>
</tr>
<tr>
<td>1</td>
<td>Depressor</td>
<td>$0.1</td>
</tr>
<tr>
<td>1</td>
<td>Microcontroller</td>
<td>$45</td>
</tr>
<tr>
<td>5</td>
<td>Batteries</td>
<td>$2</td>
</tr>
<tr>
<td>1</td>
<td>Microcontroller Housing</td>
<td>$1</td>
</tr>
</tbody>
</table>

Total $163.20
The potential clients are receptive to the device because current clinicians understand that their assessment of edema means nothing in comparison to another clinician’s assessment of edema. Said another way, a clinician in Boston could not call a clinician in Worcester and be able for the clinician in Worcester to understand what a “3” means to the clinician in Boston. One way clinicians can communicate an objective measurement is through a qualitative description. The device developed by the MQP provides an objective way for that clinician in Boston to be able to communicate the measurement to a clinician anywhere in the world. Clinicians recognize this value and are excited about the product. From the device, the users can obtain an assessment that includes the depth of pitting, force required to achieve said depth, and return time of the edematous tissue.

6.2 Circuitry

The purpose of the circuitry for both the distance measurement and the force measurement was to scale the maximum voltage down from 5V to 2V from the load cell and 3V from the linear encoder. We needed to scale down the voltage from the load cell to 2V because the maximum voltage that the analog-to-digital converter (ADC) would convert was 2.5V. Since any voltage greater than 2.5V would be interpreted as 2.5V, we chose to use a 0.5V margin to prevent the voltage from exceeding approximately 2V. The maximum voltage that could be input to the microcontroller was 3.3V, so we chose to scale down the voltage from the linear encoder to 3V, which provided us with a 0.3V margin. This proved to be sufficient.
6.2.1  **Power**

Eight AA batteries power the linear encoder, LS 7184, and load cell. Since this voltage is greater than 5V and the maximum recommended voltage to power the load cell is 5V, the group used a voltage regulator, the 7805A, to protect the components from voltages that are higher than 5V.

6.2.2  **Circuitry for the Distance Measurement**

The cable that connects the linear encoder to the protoboard contains four wires connected to four of the five pins on the linear encoder. Pin 1 on the linear encoder is connected to the brown wire on the cable, which goes to ground on the protoboard. Pin 2 is unconnected. Pin 3, connected to the blue wire, carries Channel A from the linear encoder to Pin 4 on the LS 7184. Pin 4 on the linear encoder is hooked up to the orange wire of the cable, and it carries the +5V DC signal from the output of the voltage regulator to the linear encoder. The last pin, Pin 5, carries Channel B and is connected to Pin 5 on the LS 7184.

One of the output signals from the LS 7184 indicates the distance that the plunger is traveling. This output comes from Pin 8 of the chip, and it is a series of $5V_{peak}$ digital square pulses, each of which represents $1/250^{th}$ of an inch.

The other output signal from the LS 7184 indicates the direction in which the plunger is moving. This output comes from Pin 7 of the chip, and is either a 0V DC signal or a 5V DC signal, depending on whether the plunger is moving out or in (down or up), respectively.

Since the maximum voltage that can be an input to a microcontroller is 3.3V, we used two identical voltage dividers, shown in Figure 20, to scale the voltages down to a range of 0-3V. Each of these voltage dividers consisted of a 2kΩ resistor, which was connected to the output of the chip, and a 3kΩ resistor, connected to ground. The inputs to the microcontroller came
from the nodes between the 2kΩ and 3kΩ resistors. The output from the voltage divider from Pin 7 on the LS 7184 connects to P1.6 on the microcontroller, or Pin 11 on EXT, as shown in Section Error! Reference source not found.. Pin 8 connects to P1.7 on the microcontroller, or Pin 9 on EXT, as shown in Section Error! Reference source not found.. It was necessary to place an 8.2MΩ resistor between Pin 1 and ground because the 8.2MΩ resistor adjusts the width of the square pulses to 120µs.

Figure 20: Circuit diagram for distance measurement

Figure 21 shows Channel A, the upper waveform, and the input to P1.7 of the microcontroller, the lower waveform. Whenever Channel A transitions from low to high over a 0V to 5V range, the input to P1.7 is a square pulse that ranges from 0V to 3V. The frequency of the signals in Channel A and the input to P1.7 correspond to the rate at which the plunger of the linear encoder is moving; the faster the plunger moves, the higher the frequency of the pulses. When the plunger is not moving, Channel A and the input to P1.7 are DC signals.
Figure 21: Channel A - linear encoder (green), input to P1.7 of the microcontroller (yellow)

Figure 22 and Figure 23 show Channel B and the input to P1.6 of the microcontroller when the plunger is moving out (Figure 22), and in (Figure 23). The maximum voltage in Figure 23 is 3V, showing that the voltage divider is working properly. When the plunger changes moving directions, the input to P1.6 transitions from low to high or from high to low.

Figure 22: Channel B from the linear encoder (green), and input to P1.6 of the microcontroller (yellow), when tissue indenter is moving out
6.2.3 *Circuitry for the Force Sensor*

Theoretically, the load cell outputs an analog signal that ranges between 1V and 4V, where 1V would correspond to 0 lbs and 4V would correspond to 10 lbs. Since 4V is too large to input to the microcontroller, we again used a voltage divider, which consisted of a 100kΩ resistor and a 100kΩ potentiometer that was set to 71kΩ, to scale the voltage down to a maximum of 2V. Figure 24 shows the schematic for the force sensor circuit. The output from the voltage divider goes to P6.7 on the microcontroller, or Pin 1 on AEXT, as shown in Section *Error! Reference source not found.*.

![Figure 24: Circuit diagram for the load cell](image)
Figure 25 shows the output from the load cell when an individual applied pressure, released, and continued to apply pressure and release the pressure several more times. We measured the maximum peak-to-peak voltage to be 1.61V, and measured the voltage when no force was applied to be 0.408V. We calculated the maximum voltage that the force sensor can output to be 2.02V. This is close to the predicted maximum voltage output of 2V.

6.3 Microcontroller Program

The goals of the program for the microcontroller were to determine the distance the probe moved, determine the force applied to the sensor, determine the rate of change of the applied force, calculate the velocity at which the probe was moving, and measure tau. The outputs of the microcontroller were the maximum depth of indentation in two-hundred-fiftieths of an inch, the maximum force on a scale between 0 and 4095, and tau in hundredths of seconds. We accomplished these goals by writing a program in C that took advantage of the capabilities of the microcontroller. Many of the basic functions we used had been adapted or copied from
a program called demo.c, written by Jose Brache. The code for demo.c is widely available and given to all students who take ECE 2801 at WPI.

6.3.1 Clock Frequency

The frequency of the clock is 8MHz. Although this might appear excessive, a high frequency clock was necessary because at a lower clock frequency, we were not obtaining an accurate distance measurement. This was due to one of the interrupt service routines (ISRs) containing a significant amount of code, and we found that it was difficult to reduce the amount of code in that ISR. When we increased the frequency of the clock to 8MHz, this problem disappeared.

6.3.2 Measurement of Distance

The LS 7184 outputs two signals: digital square pulses, each of which indicates 1/250th of an inch, and a DC signal that changes voltage depending on whether the plunger of the linear encoder is moving up or down. There were two methods we could employ to measure distance: polling or interrupts. We decided to use interrupts because the microcontroller calculates distance by continuously adding or subtracting the number of square pulses. If the microcontroller neglected to detect a square pulse, our value for the distance would be wrong for the duration of the measurement. Another reason for using interrupts is that we knew that we could configure the pins to fire an interrupt whenever the microcontroller detected a rising edge on one of the pins. This simplified the program; instead of writing code that would detect an edge, we could take advantage of the capabilities of the microcontroller.

When an interrupt is generated by a rising edge on P1.7, the pin attached to the square pulses from the LS 7184 that indicate distance, the microcontroller checks the voltage on P1.6, the pin that is attached to the directional signal from the LS 7184, to determine whether it is
high or low. If the voltage is high on P1.6, it means that the plunger is moving down, so the value for the variable that keeps track of distance, dist, is incremented. If the voltage is low on P1.6, the plunger is moving up, so the value for dist is decremented. Because an interrupt is generated only when there is a rising edge on P1.7, the value for counter remains constant when P1.7 does not detect square pulses, and this occurs when the plunger of the linear encoder is not moving.

At the end of each measurement, the value of dist will always be between 0 and 274, unless the user moves the probe up. If the probe moves up, the value of dist will be negative. To convert this measurement into inches, we divide each measurement by 250.

6.3.3 Measurement of Force

We decided to use polling to obtain the force instead of using interrupts because interrupts compromise the speed of the program. Our algorithm requires that both of the following conditions be satisfied: the velocity at which the probe moves must be approximately zero and the force must be larger than a threshold force. By using polling to obtain the force, we would be obtaining the force more frequently than necessary. Unlike counter, the force variable, force, does not depend on previously obtained values of force.

6.3.4 Calculation of the Velocity of the Probe

The velocity of the probe dx/dt, is calculated every 10ms. Because the compiler does not allow slashes in variable names, we called dx/dt dxdt. An array called samples of size SIZE contains the most recent value for dist, which is stored in the first element, as well as the previous (SIZE-1) values for dist. Every 20ms, an interrupt is fired by Timer A. In the
body of the interrupt service routine, each of the elements in an array called distSamples is moved up to the next highest index. The most recent value of counter is stored into the first element of distSamples. By taking the difference between the value of the most recent counter value and the value of counter at time (SIZE-1)*10 ms before, dxdt can be found. Because we want to know when dxdt is approximately zero and we do not care about the direction, to make the comparisons easier, we assigned dxdt to the absolute value of the previously mentioned difference.

Because SIZE is a constant whose value is defined in the beginning of the program, we can easily change its value while we are calibrating the device. If SIZE is too large, dxdt will be calculated over too many data points. If SIZE is too small, dxdt will be calculated over too few data points.

Every time dxdt is smaller than the thresholds for dxdt, DXDTTH, a second counter called distCounter is incremented. The variable distCounter must be above a threshold, VALTH, in order for the microcontroller to know that the probe is no longer moving. If dxdt is ever larger than DXDTTH, distcounter is reset to zero. It is necessary that we also use this variable to know when dxdt has reached its threshold because if dxdt is below the threshold only once, the microcontroller will think the clinician reached the bone too soon. If VALTH is set to be too high, the microcontroller will not think the velocity had become zero until a significant amount of time after it had already occurred.

6.3.5 Calculation of dF/dt

To calculate dF/dt, we calculated the differences between each of the points in each of the array for force samples, which was called forceSamples[]. The difference between
each point was stored in an array called $\text{dFdtArray}$. The size of $\text{dFdtArray}$ needed to be one element smaller than the size of $\text{forceSamples}$. After taking the difference between each point in the array, we shifted each of the samples by one element to make room for the most recent element. We then added each of the elements in $\text{dFdtArray}$ together. The next step was to set the first element in $\text{forcenames}$ to the current value of force to set up for the next calculation of $\text{dFdt}$. Finally, we set $\text{dFdt}$ to be equal to the negative sum of each of the elements in $\text{dFdtArray}$. The code is provided below:

```c
for (j=(FORCEARRAYSIZE-1); j>0; j--)
{
    \text{dFdtArray}[j-1]=\text{forceSamples}[j]-\text{forceSamples}[j-1];
    \text{forceSamples}[j]=\text{forceSamples}[j-1];
    \text{sum} += \text{dFdtArray}[j-1];
}
\text{forceSamples}[0] = \text{force};
\text{dFdt} = -\text{sum};
\text{sum} = 0;
\text{interruptFired}='0';  // clears interruptFired
```

It is important to note that the units of $\text{dFdt}$ are meaningless; they are proportional to units of lbs/sec, but because the ADC provides force in arbitrary units, the only way to obtain the force in lbs/sec is to determine what one ADC unit corresponds to in lbs.

6.3.6 Measurement of Tau

The microcontroller knows the clinician has reached the bone when both of the following conditions are met: $\text{distCounter}$ is greater than $\text{VALTH}$ and the $\text{dFdt}$ is greater than the force threshold, $\text{DFDTTH}$. When both of these conditions are met simultaneously, the microcontroller stores the value of $\text{dist}$ at that moment, which corresponds to the maximum distance, $\text{maxDist}$. The distance at which tau occurs, $\text{tauDist}$, is calculated by multiplying
0.63 by maxDist. After the 0.75-second window in which the clinician continues to press passes and the clinician stops applying force, the variable timerb restarts and counts the number of hundredths of seconds that have passed since the clinician stopped applying force. When tauDist is reached, the value of the variable timerb corresponds to tau in hundredths of seconds.

6.3.7 Program Flow

Figure 28 shows the flowchart for the program. The measurement of the distance traveled is not included in the program because it occurs whenever the microcontroller detects a rising edge on P1.7, and the calculation of $\frac{dx}{dt}$, force, and $\frac{dF}{dt}$ are not included because they occur every 10ms throughout the program. When the program starts, “START” is written to the LCD. Until the clinician presses Button 4, the rightmost button, he can move the probe, but the distance the probe moves will not be saved. When the clinician presses Button 4, the value of dist is reset to zero. Once the clinician presses Button 4, as he pushes on the probe, the distance is measured is displayed on the LCD in two-hundred-fiftieths of an inch. When dx/dt is less than a threshold for a specified number of samples and dF/dt is greater than a specified threshold, DFDTTH, the clinician has reached maximum compression, so a buzzer is sounded. The microcontroller simultaneously stores the maximum distance, calculates tauDist, and displays “HOLD” on the LCD. “HOLD” is displayed on the LCD for 0.75 seconds, and during this time, if the probe moves a distance that is greater than the value of COUNTERMOVE, a constant that is defined in the beginning of the program, the microcontroller alerts the clinician that the measurement is invalid by displaying “DOAGAIN” on the LCD, and later, instead of providing the clinician with the maximum distance, maximum force, and tau, it displays “INVALID” on the LCD. If the probe does not move a distance that is greater than the value
of COUNTERMOVE, after 3 seconds, the microcontroller displays “RELEASE” on the LCD. When the force the clinician is applying drops below FTHWAIT, another constant defined in the beginning of the program, the timer resets to zero and the LCD displays “RETURN.” When \( \text{tauDist} \) is reached, the value for \( \text{tau} \) in milliseconds and the value of \( \text{maxDist} \) are displayed on the LCD.

Figure 26: Microcontroller display provides instructions to user

![Microcontroller display](image)

Figure 27: Simplified flowchart of the microcontroller program

![Flowchart](image)
Main Program Flowchart

Figure 28: Detailed flowchart of the microcontroller program
6.4 Calibration of the Load Cell

To calibrate the load cell, use the program `datalogging.c` to output the force on a scale of 0-4095 into the left column of the text in HyperTerminal. See Appendix 0 for instructions that specify how to open HyperTerminal and obtain data from the microcontroller.

First, record the force on the 0-4095 scale when no external force is applied to the load cell. This corresponded to the baseline force. Using the EXTECH 475044 force gauge, apply different amounts of force that range between 1lb and 10lbs. During each measurement, store the largest force recorded from the force gauge and plot it against the largest force on the 0-4095 scale from the ADC that is observed in HyperTerminal. After obtaining 20 data points, we plotted the points in Excel and created a best-fit line.

\[
f_{\text{lbs}} = \frac{f_{\text{ADC}} - 1095}{447}
\]

where \(f_{\text{lbs}}\) is the force in lbs and \(f_{\text{ADC}}\) is the force on the 0-4095 scale from the ADC.

6.5 Device Specifications

- Outputs: Depth of pitting, force required to reach said depth, return time of edematous tissue
- Power Requirements: 5V, 28mA
- Batteries Required: 5 AA
- Ergonomic grip
- Low friction, non-binding, indenter
- Distance resolution: .002 in.
- Force resolution: .0025lb/V
- Contains: Linear encoder, load cell, indenter, depressor, microcontroller
- 12 seconds per measurement
- Easy to remove cover
- LCD screen displays measurement
- Lightweight Delrin housing
- Buzzer & LCD screen provide measurement cues
- Cost: $200
- Stabilizing base
- Pain free
6.6 Device Safety

We designed the device to interface safely with both the examiner and the patient. The data-collecting algorithm will sound a buzzer prior to reaching high forces that could hurt a patient. The diameter of the indenter base mimics the size of a thumb, and is large enough prevent the kind of tissue stress that would result from depressing a smaller indenter into the patient’s tissue. Both of these safety precautions help to protect the patient from experiencing pain because of the tissue depression.

To ensure the safety of the patient, we recommend that users sterilize the bottom of the device with sterilizing spray after each use. This will help to avoid the potential spread of harmful tissue conditions between patients.

The device is not waterproof, and electric shock could result if the device is submerged in water. Although the circuitry is not openly exposed, the device should never be used in conditions where there is a chance of liquid getting inside the device.
7 DEVICE EVALUATION AND TESTING

We tested our device on foam models that mimicked the response of edematous tissue. Our testing allowed us to determine if our device could accurately measure parameters that represented edema. Testing helped identify and account for areas of user error in measurement. The initial tests performed here lead to clinical testing of our device on patients who suffer from edema.

7.1 Model Assessment and Development

We developed models that accurately represented different severities of edema because it was desirable to compare and contrast the properties of edema at different severity levels. This was helpful because we could gauge the approximate return times, forces required to create an indentation in the tissue, and distances for the different model severities of edema. We assumed that we could use viscoelastic memory foam of varying thicknesses to model edema of different severities by saturating it with vegetable oil. The vegetable oil and foam model the consistency of edematous tissue, while greater thicknesses of foam were used to model edema of greater severity. The validity of the foam models was confirmed by our advisor, Dr. Raymond Dunn, Chief of the Division of Plastic Surgery at UMass Medical School as well as Dr. Howard Fixler, Chief of Internal Medicine at Fairlawn Rehabilitation Hospital, Melissa Blatt, lymphedema specialist, and other members of the Fairlawn hospital staff.

7.1.1 Initial Models

Initially, we developed our models based on those described by the 2004 MQP group (Weindling and Fontaine, 2004). Their models consisted of pieces of memory foam that were saturated in no liquid, vegetable oil, and motor oil. The dry memory foam represented the least
severe edema, and the memory foam in motor oil represented the most severe edema. Because
the 2004 MQP group did not state that the thicknesses of the memory foam changed, we
assumed the thicknesses were constant. Without knowing the thickness of the memory foam
the 2004 MQP group used, we decided that the thickness of our initial models should be
between 1” and 1.5” because according to Dr. Dunn, if a patient has pitting edema, the depth of
the pit rarely exceeds 1”. We decided to use four liquids that we hoped would represent 1, 2, 3,
and 4 edema. According to the 2004 MQP group, return time constant was proportional to the
severity of the edema, so the different liquids in which the memory foam was saturated would
provide the different time constants. The 2004 group stated that the time constant of dry
memory foam was 0.8 seconds, the time constant of memory foam saturated with vegetable oil
was 9.5 seconds, and the time constant of the motor oil was 11.2 seconds. We wanted to add a
liquid whose properties would make the time constant between that of the dry memory foam
and vegetable oil. The liquid that appeared to have this property was Master of Mixes: Piña
Colada. Once we identified the liquids that we used, we prepared the models in the manner as
shown in APPENDIX F: Modeling Edema.

When we asked Dr. Dunn and Dr. Fixler to assess the severity of the representative edema
in each of the models, they both said that our models were inaccurate; the return time of the
water was too short to accurately represent edema, and the return time of the piña colada mixer
was too long. They added that the severity of the edema of the vegetable oil and motor oil was
4+ because the thickness was large. We concluded that we needed to improve our models by
changing the thickness of the memory foam instead of changing the liquid with which the
memory foam was saturated.
7.1.2 Final Models

Our final models consisted of memory foam of five thicknesses: 0.25”, 0.5”, 0.75”, 1”, and 1.25”, each saturated with vegetable oil. Appendix 17.1 contains protocols for model fabrication. Dr. Dunn and Dr. Fixler stated that memory foam saturated with vegetable oil feels similar to edematous tissue.

To confirm our new models, we interviewed Melissa Blatt, an edema specialist, and asked her to assess the severity of the “edema” in three different thickness of memory foam saturated with vegetable oil: 0.5”, 0.75”, and 1”. Melissa stated that with our models, the 0.5” corresponded to level 2 edema, 0.75” corresponded to level 3 edema, and 1.25” corresponded to level 4 edema. Therefore, we concluded that when we saturate memory foam with vegetable oil at different thicknesses, it modeled different severities of edema.

![Figure 29: Different thicknesses of foam in vegetable oil represent edema severities](image)

7.2 Lab Testing on Foam Models

Data for tests was collected using the TI MSP430 microcontroller and the program datalogging.c, provided in Section 12.16. To control the microcontroller, we used IAR Embedded Workbench. The data was sent from the microcontroller to the PC via a serial port. We used HyperTerminal to receive the data and Excel to format the data. Section 12.15 includes a description of how to collect the data.
The data in HyperTerminal was displayed in two columns: force on the left and distance on the right. If a force and distance measurement were on the same row, they were sampled in the same 20ms period. The values for force could range between 0 and 4095. To convert values into recognizable units, such as pounds, we determined the relationship between the two, described in Section 6.4.

The values for distance ranged between 0 and 65535. To normalize this data, we converted the distances to values between 0 and 274 converting any numbers above 60000 to negative numbers; i.e. 65535 corresponded to a distance of -1, 65534 corresponded to a distance of -2, and so on. We then searched for the smallest number, took the absolute value, and added it to each of the distances. The result was a series of numbers that started at 0 and never exceeded 274. We divided each entry by 250 to obtain the distance traveled in inches.

7.2.1 Protocols for Testing

We instructed five users to depress the probe slowly into the edema models until they felt they could press no further. At that point, the team collected the maximum distance and force that the user pressed into the model. Each user repeated the test five times on each of the four different thicknesses of foam (0.25”, 0.5”, 0.75”, 1”), for a total of 20 tests per user. Between each test, the user ensured that the foam model returned to its original state and was no longer indented. We instructed the users to be careful not to compress the tissue with their hand or the device before measuring.

We performed additional tests where the user first depressed as slow as possible into the foam model, and then, after the model foam returned to normal, to depress again into the tissue as fast as possible. The purpose of this test was to determine how the rate of depression into
the tissue affected the measurements of the depth of pitting, the force applied to the model, and the profiles of force and distance over time.

![Figure 30: Testing setup for edema device on foam models](image)

7.2.2 Testing Results

Our testing objectives were to first verify that our device had high repeatability within users, meaning that the same person could repeat a measurement several times in the same place and the device would produce similar outputs. Then, we verified reproducibility between users by having several users test the device and examining the variation in the data. We wanted to verify that our device could distinguish between several different thicknesses of foam as well as reduce user variability in measurements of distance. We also tested our device on foam models and compared them to evaluations that clinicians performed on the same models to show how our device could be more consistent in edema measurements. Additional tests verified the consistency of force, return time measurements between users, and investigated the effect of rate of depression on the overall measurement.
Our first objective for testing was to verify that each user was consistently pressing to the same distance in each piece of foam and identify how much variation there was in measurement within a single user. For these tests, each individual user depressed the probe to a constant distance for each of their five tests on a single piece of foam. The users tested in four different thicknesses of foam (0.25”, 0.5”, 0.75”, 1”). The measurements were collected with a prototype version of the device and did not use the microcontroller algorithm. Instead, the user depressed until she felt she could no longer press into the foam and then stopped the measurement. We found the means and standard deviations of five trials using SPSS (v 14.0) to show that each user consistently measured a single thickness of foam.

Our data contained some outliers and missing data in each group. For an initial analysis, we left outliers in the data and considered them a source of user error. Outliers occur less frequently as the user gains more experience using the device. By identifying where outliers occur in this testing, we will be able to program algorithms that alert the user if their measurement is invalid. With outliers in the data, the largest standard deviation of that data is near ±20, or 20% deviation from the mean, with a maximum coefficient of variance of 30%. We can decrease this error by removing and analyzing our data without outliers, reducing the standard deviation to ±0.12, or 12% deviation from the mean and reducing coefficient of variance to less than 20%. Our goal is to refine our device to each user can measure each thickness of foam within a standard deviation of ±0.1, or less than 10% deviation from the mean measurement and a coefficient of variance of the same. This data shows that an individual user consistently presses into foam models with the device, even without audio or visual clues to indicate that a measurement is complete. As shown in late data, the consistency
of measurement within a single user increases when the microcontroller algorithm instructs the user to complete the measurement at a consistent point.

Table 10: Descriptive statistics for unconstrained distance testing with the prototype

<table>
<thead>
<tr>
<th>Thickness</th>
<th>User</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 INCH</td>
<td>Erika</td>
<td>.62080</td>
<td>.071240</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Rachelle</td>
<td>.66560</td>
<td>.101414</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Stephanie</td>
<td>.63600</td>
<td>.025820</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Mark</td>
<td>.78240</td>
<td>.036508</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Chuck</td>
<td>.97280</td>
<td>.193812</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>.74800</td>
<td>.162566</td>
<td>24</td>
</tr>
<tr>
<td>0.75 INCH</td>
<td>Erika</td>
<td>.39280</td>
<td>.036813</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Rachelle</td>
<td>.48880</td>
<td>.067729</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Stephanie</td>
<td>.50320</td>
<td>.047615</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Mark</td>
<td>.49680</td>
<td>.046853</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Chuck</td>
<td>.77360</td>
<td>.068373</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>.53104</td>
<td>.139748</td>
<td>25</td>
</tr>
<tr>
<td>0.5 INCH</td>
<td>Erika</td>
<td>.30880</td>
<td>.026442</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Rachelle</td>
<td>.29500</td>
<td>.061741</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Stephanie</td>
<td>.38300</td>
<td>.056131</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Mark</td>
<td>.35920</td>
<td>.079770</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Chuck</td>
<td>.40440</td>
<td>.054229</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>.35104</td>
<td>.067769</td>
<td>23</td>
</tr>
<tr>
<td>0.25 INCH</td>
<td>Erika</td>
<td>.17360</td>
<td>.039659</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Rachelle</td>
<td>.15760</td>
<td>.020900</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Stephanie</td>
<td>.21000</td>
<td>.018903</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Mark</td>
<td>.16000</td>
<td>.037417</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Chuck</td>
<td>.28333</td>
<td>.056226</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>.18845</td>
<td>.053386</td>
<td>22</td>
</tr>
<tr>
<td>Total</td>
<td>Erika</td>
<td>.37400</td>
<td>.172166</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td>Rachelle</td>
<td>.40737</td>
<td>.211039</td>
<td>19</td>
</tr>
<tr>
<td></td>
<td>Stephanie</td>
<td>.44894</td>
<td>.177986</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>Mark</td>
<td>.44960</td>
<td>.237341</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td>Chuck</td>
<td>.64467</td>
<td>.295937</td>
<td>18</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>.46221</td>
<td>.237573</td>
<td>94</td>
</tr>
</tbody>
</table>

We next determined whether users were consistently measuring to the same distance in each model. In one test, five users tested the device on four different thicknesses of foam (0.25", 0.5", 0.75", 1"). Using SPSS, we analyzed the data using an analysis of variance (ANOVA) to identify if there was a difference between users. The ANOVA indicated that
there was no significant difference between users and all of the data from individual users was combined into one group of data for each foam thickness (p<0.05).

We also used SPSS to conduct an additional ANOVA with blocking to determine whether the device could detect four distinct thicknesses of foam despite user variability (α=0.05). In SPSS, the user was counted as a random factor and variability between users was accounted for when calculating the ANOVA for different thicknesses of foam. The ANOVA indicated that there was a difference between individual thicknesses of foam. A Tukey’s post hoc test indicated that the measured values for each thickness of foam were distinctly different from each other (p<0.001). This indicated that our device could detect at least four different thicknesses of foam despite user variability.

Figure 31 shows the maximum distance depressed for four different thicknesses of foam (0.25”, 0.5”, 0.75”, 1”). The maximum distances depressed are lower than the actual distance due to the maximum compressibility of the foam. The error bars indicate one standard deviation on both sides of the mean and are representative of user variability in the data for five users. Because these measurements are unconstrained by the algorithm, we expected user variability to decrease once we implemented the microcontroller algorithm.
In a second test, we asked eight clinicians to assess the edema severity in foam models with eight different thicknesses (0.26”, 0.40”, 0.54”, 0.73”, 0.78”, 0.90”, 0.96”). We asked clinicians to rate edema severity on a scale from 1 to 4, with 1 being the least severe and 4 being the most severe, using their own method of manual edema assessment. Figure 32 shows boxplots that show the median response (black line) within the blue box, which contains 50% of all the data between the first and third quartile. The error bars represent the maximum and minimum data point for each data set. This data shows how clinicians will rate edema severity very subjectively. In some cases, they even rated models on the full range of 1-4. This occurred because each clinician used a varying method to assess edema severity. While some clinicians measured depth of pitting, others counted return time or felt the resistance of the
tissue. Although clinicians normally make assessments based on the entire condition of a patient and not just a piece of foam, this test represents the wide range of responses that often occurs in clinical practice of edema assessments.

Two users measured the same eight thicknesses of foam with our edema device, using the microcontroller algorithm to indicate to the users when to complete each measurement. In this experiment, there were a low number of users able to test on the same eight pieces of foam as the clinicians tested; however, the results of the tests from this experiment were consistent with the other data we gathered. Figure 33 shows boxplots with the maximum, minimum, and median values of the data gathered with the device from the models. The data showed
repeatability within users, with a maximum standard deviation within ±6% of the mean value after five tests, and a maximum coefficient of variance of 16% within individual users. The device also showed reproducibility between users, with a maximum standard deviation of ±2% for two users, with a maximum coefficient of variance of 7% between users. We expect that this percentage would increase for a greater sample of users but would not exceed ±6% based on our previous tests with the device.

In addition, our device shows that it can consistently measure within an 1/8 inch thickness of foam, meaning that it is highly sensitive (ANOVA, \( \alpha = 0.05 \), \( p < 0.01 \)). It would be difficult for clinicians to measure small differences in swelling changes with their current method. Our device detected differences in thicknesses of foam up to approximately one inch. At one inch of foam, the device could not distinguish between small differences in foam because the algorithm prevented the user from pressing harder into the foam for the patient’s comfort and safety. This is acceptable because clinicians have expressed that conditions with more than one inch of edematous tissue are very serious and are rarely seen in practice (Dunn, Fixler, personal communication, 2006).
We also collected representative data samples from the device, recording force vs. time, distance, vs. time, and force vs. distance to see if the profiles had a consistent shape and behavior between users. We discovered that the profiles looked like we predicted.

A representative distance vs. time profile (Figure 34) shows how the distance the microcontroller measures as the user presses the probe increases linearly until reaching the maximum compression of the foam. At that point, the distance vs. time steadies at approximately zero. We use this assumption to help us determine when the user has depressed completely through all of the edematous tissue. Figure 34 marks in red the point on the graph where the user reached maximum compression.
As the user depresses the probe, the force on the tissue also increases, particularly as the user begins to reach the point of maximum compression. At this point, the force increases at a greater rate than previously. The force increases exponentially until the user releases the thumb depressor. Figure 17 marks the same point where distance vs. time reached zero. At this point, the graph shows how the force vs. time increases exponentially because the user has reached the bottom of the point where he can depress. By monitoring force vs. time, we can ensure that the user has not stopped pressing before reaching the maximum compression point.
Combining the two primary values of our measurements, we graphed force vs. distance to show an easily defined point where we can identify that distance has reached a maximum, and force is increasing exponentially. Figure 18 shows how the graphs remains relatively constant until the point where distance and force reach their peak, at the red x. The red X corresponds to 2.5 seconds where distance and force were marked in Figures 16 and 17. By programming the algorithm in our microcontroller to monitor force and distance over time simultaneously, we can identify the point has depressed though all of the edematous tissue and collect a maximum distance. This value will correspond to the severity of edema in each patient.
Finally, we completed testing to determine if rate of depression affected the overall measurement of edema severity. We instructed one user to press with the device into the tissue as fast as possible for five tests, as slow as possible for five tests, and at a normal testing speed for five tests. We discovered that slower rates do not affect the measurement; however, faster rates of depression reach higher forces more quickly than normal or slow testing speeds. Nonetheless, the distance the device depresses into the tissue remains constant within ±10%. We determined that rate of depression does not affect measurements enough to be a concern in the initial iteration of the device. In the operating manual, we advise users to depress slowly into the tissue. The microcontroller also monitors rate of change of force and will now collect a measurement of the rate of change of force is too great for the algorithm to process.

7.2.3 Discussion and Future Implications for Testing

Testing with the edema models showed some limitations in our models of edematous tissue, despite the fact that clinicians had verified them. For example, a clinician normally assesses the entire condition of the patient when assessing edema. With our models, only the feel and
touch are available for the clinician to observe, independent of patient statistics. This caused the range of assessments from clinicians to be greater than it might be if they were assessing an actual patient. It is difficult to create an entire physiological model of edematous tissue, and thus, we must corroborate our data with human clinical studies to verify the large range of subjectivity and the validity of our device for testing on edematous tissue.

Although we cannot directly correlate the thicknesses of foam to actual edema severity in patients, we do know that we can more consistently measure at least one parameter that clinicians often measure, depth of pitting in edema. Our device, despite who uses it, will provide a consistent output for depth of pitting that will allow clinicians to compare measurements over time with more confidence that the assessment was performed objectively.

Additional testing must also be done with the device to verify that the user variability is as small as was represented in our tests. For this, we need to test with a greater sample size. The tests should allow clinicians to assess different thicknesses of foam manually, and then have the clinicians test with the device after minimal instruction on how to use it. This would allow us to compare clinicians’ manual measurements to measurements with the device.

### 7.3 Human Clinical Studies

The team felt that the best way to verify the efficacy of the device and to investigate whether results obtained using the foam models corresponded to results obtained with edematous tissue would be to conduct a clinical study. The justification for performing a clinical study lies in the beneficial information that we can obtain through testing the device on human subjects. Although foam testing has provided a preliminary basis for saying that the device provides reproducible and accurate results, human testing is required to verify that these results translate to human patients. Through human clinical studies, the team would expect to verify the
efficacy of the new device and to observe aspects such as ease of use, comfort of patient interface, adaptability to different locations on the patient and logistical considerations related to the separate handheld and display components.

The team applied to conduct a clinical study at UMass, with Dr. Dunn acting as the primary investigator (PI). To conduct a clinical study at UMass, the paperwork requirements included submission of an Institutional Review Board (IRB) application, a Health Insurance Portability & Accountability Act (HIPPA) form, and a patient consent form. The IRB application includes detailed information regarding the study and its purpose, as well as the researchers’ intended activity throughout the study. The IRB application also requires verification of the PI, and other persons involved in the study. The HIPPA form allows the subject to authorize that specified portions of their medical records may be released to the researchers for the purposes of the study. The consent form includes a comprehensive summary of the testing procedure and requires that the patient sign before participating in the study. We submitted all of these forms to UMass for review along with a formal project abstract.

The clinical study would involve using the device on several different patients at the wound clinic at UMass. The patients would be selected at random from the population of patients who arrive for outpatient care. To participate in the study, patients would have to be over 18 years of age and have peripheral, pitting edema. The team recommends a two-stage human clinical study, with the first stage being a preliminary investigation of efficacy, convenience, and reproducibility. For this stage, we would ask different clinicians would to use the device on patients. A qualitative assessment of device usage would include observations regarding convenience, patient and user comfort and reproducibility among different clinicians.
Once the efficacy and reproducibility of the device is demonstrated through human testing, the device could be used as an investigative device in further research on characterizing edema. Thus, the second stage of the study would involve many patients, and would look at measurements as they relate to the severity and type of edema. Specifically, investigators would attempt to characterize the exact relationship between different edemas and parameters such as depth of pitting, tissue resistance, and return time. It would also be possible to determine the effect of patient size on measured parameters.

Potential risks of using the device in clinical studies may include momentary discomfort due to the indenter pushing against the patient’s tissue. It is important to note that this discomfort would be identical to the effects of a medical professional indenting the tissue to create a depression. Medical history from a patient’s medical history file would be obtained. However, there would be no need to specifically identify patients and their identity could remain undisclosed. Expected benefits of conducting clinical studies far outweigh the potential risks to the patient, which are minimal to nonexistent.

7.4 FDA Regulations and Patenting Process

The Food and Drug Administration (FDA) has specific standards and regulations that must be fulfilled before marketing any medical device. All medical devices are subject to general controls of the Federal Food Drug & Cosmetic (FD&C) Act. Title 21 Code of Federal Regulations (CFR) identifies all of the requirements that are necessary for the marketing of medical devices. These regulations pertain to proper labeling, marketing, and monitoring of the device once it is on the market.

To determine what level of regulatory control is necessary to safely manufacture and market the device, the device must be classified based on the risk that it presents to the user
and patient. The classification, which ranges from Class I (low risk) to Class III (high risk) also determines what paperwork is necessary to receive approval from the FDA. The edema measuring device, is most likely a Class I device because it presents a very low risk to the user and the patient. Class I means that the device is not life supporting or life sustaining and does not present a potential risk of illness or injury.

About 74% of Class I devices are exempted from the premarket notification process and/or parts of the good manufacturing practices set forth in the quality system regulations in Title 21, Part 820. If the edema-measuring device was deemed to be a Class I medical device, the manufacturing facility would simply have to register with the FDA, and all products would have to be listed prior to introduction of the device into interstate commerce.

Our device received contingent approval from the Institutional Review Board (IRB) at UMass Medical. The Committee determined the device to be a non-significant risk device.
8 DISCUSSION

Throughout the development of the edema measurement device, we looked for ways to minimize the subjectivity of measurements by standardizing the output so that it would be the same for any patient, regardless of the examiner. We did this by writing an algorithm that detects the point in the measurement where the clinician can no longer push into the tissue, and by outputting the depth of the swelling, maximum force required to press into the tissue, and return time constant. Our results indicate that our device can differentiate among different thicknesses of foam based on the depth of the indentation in the foam models. The variability from the users who tested the device was significantly lower than the variability from the doctors who used digital manipulation to assess the severity of the edema on the same models.

There are two primary points of variability that remain in the device measurements, the rate at which the clinician presses on the skin and the location on the patient’s body where the clinician takes a measurement.

Currently, the program requires that the user press slowly on the thumb depressor to indent the tissue. If the user does not press slowly enough, the microcontroller will not collect a measurement; however, the exact depression rate remains subjective and may have a slight impact on the output.

Another measurement variability is the location on the patient’s body where the clinician takes a measurement. It is important to collect measurements in the same place over time to provide an accurate assessment of the patient’s progress. If examiners collected measurements at different locations on the patient, the measurements would not necessarily represent the patient’s progress because the swelling could be more severe in some sections of the body than
in others. This issue can be solved by standardizing the measurement location through a small body marker or by indicating a standard measurement location on the patient’s charts.

The measurement algorithm prevents the device from lifting off the patient’s tissue during measurement by monitoring the direction of motion of the indenter. This prevents data collection from taking place if the user moves or shakes the device during the measurement. The algorithm also limits the speed at which the user can depress into the tissue. We addressed these issues in the operating instructions so that users are aware of the necessity to keep the device in contact with the tissue and to depress at a slow rate. Error in measurements related to lifting up on the device decreases as the user becomes accustomed to manipulating the device.

The measurement technique is resistant to small movements of the patient and examiner. Larger movements do not present much of a problem during tissue depression, as long as the device remains in contact with the tissue and the indenter continues to move downward against the patient’s tissue; however, large movements could affect the return time measurements. For this reason, the operating instructions clearly state the necessity to remain still when collecting the return time. Our testing was not able to fully evaluate the range of return times the device can measure because the probe on our prototype device was too heavy and return times were inconsistent between models. Future recommendations for our device address these issues and will allow return time measurements to become more consistent in future design iterations.

It is important to note that the device does not preclude the “hands on” examination associated with digital manipulation. When using our device, the clinician is encouraged to support the patient’s leg for pre-tibial and other lower extremity edema assessments. The device allows the examiner to depress the tissue indirectly in a manner very similar to digital
manipulation. Because the indenter mimics the size of a thumb, it requires a similar amount of force to depress the patient’s tissue.

At this point, the device is suitable for comparing one patient’s measurements over time to monitor their edema. Because the device is intended for use on one patient over time, measurements of edema severity are not comparable between patients. Refining the measurement algorithm so that measurements are comparable between different patients would require extensive clinical studies that relate the values of pitting depth, force, and tissue return time to different types of edema and different patient sizes. The ability to compare measurements among different patients would not necessarily be useful because edema levels do not necessarily correlate directly with diagnoses or treatment.

The results of the foam testing are very important because they demonstrate that the device can distinguish between different thicknesses of foam, suggesting that the device can also detect different depths of pitting in edematous tissue. Using the foam, we were also able to obtain preliminary data for time constants and force of depression. Although the foam testing was necessary to demonstrate the repeatability and reproducibility of the device output, it is insufficient for developing relationships between force, distance and return time for actual human tissue and the edema severity scale. Human clinical studies are required to characterize the exact relationships between the measured parameters and the severity and type of edema.

Our investigations are consistent with research and other devices that have been recommended for edema assessment. Our device improves upon previous patents for edema or swelling related devices (Patent # 6186962, 2001) by incorporating depth of pitting measurements in addition to force and return time as measures of edema severity. In addition, Bates et al. developed a tonometer that objectively provides the depth and rate of pitting of
edema by attaching resting a plunger on the skin and attaching the other end to a lever, which deflects a strain gauge. The tonometer applied a weight to a plunger and recorded the indentation versus time, where the time was several minutes. The tonometer was tested in vitro on sponges in liquids of varying viscosities and on patients whose upper arms were swollen due to breast cancer treatment. Data showed no significant difference in the initial quasi-instantaneous deformation between the normal and swollen arms, but the spring constant of the swollen arms during the slow deformation was 23% less than that of the normal arms. The depth of the slow deformation was significantly larger in the swollen arms than in normal arms, and that the time constant was longer in swollen arms than in normal arms (Bates, 1994). The device developed by Bates et al was not feasible for use in routine clinical examinations and was not adapted to do clinical assessments of edema on a regular basis. Data by Bates et al confirms that parameters of deformation time and depth of pitting are significant when comparing edematous tissue to healthy tissue.

Another use of our device is that researchers can use it as an investigative tool if there is a need for an objective measurement of the severity of edema. Some drugs are directly related to the development of peripheral edema, such as thiazolidinediones, which can cause peripheral edema in patients who have type 2 diabetes (Mudaliar, Chang, Henry, 2003). A study conducted by Mudaliar et al, concluded that thiazolidinediones are related to peripheral edema based on the frequency patients who had peripheral edema; however, this study could not objectively determine the severity of edema caused by the drug. The use of our device in a similar study would enable researchers to more specifically examine the severity of the patients’ edema in relation to the use and dosage of drugs.
Understanding the need for convenience, we concentrated on making the device quick and easy to use. Thus, the setup and measurement times are minimal, and the device operation is straightforward. The device outputs measurements that are clinically relevant to edema and easily communicated among clinicians. All of these considerations make the device a viable alternative to digital manipulation.
## 9 FUTURE RECOMMENDATIONS

Currently, our device can be used without modification for assessing edema. However, before manufacturing, we recommend a few modifications to facilitate easier measurements and more accuracy over long-term use. There are many enhancements that can be made to the current iteration of the device to improve the robustness of the measurement and enhance its market appeal. These modifications are summarized in Table 11 and described in detail in this section.

### Table 11: Future recommendations for the edema measurement device

<table>
<thead>
<tr>
<th>Cosmetic</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>- Add an LED/buzzer to housing to eliminate control box</td>
<td></td>
</tr>
<tr>
<td>- Eliminate development board and incorporate a smaller microcontroller once program is refined</td>
<td></td>
</tr>
<tr>
<td>- Manufacture housing with injection molding to facilitate bulk production and additional ergonomic features</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Functional</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>- Reduce size and weight of the circuitry</td>
<td></td>
</tr>
<tr>
<td>- Include calibration kit with final device</td>
<td></td>
</tr>
<tr>
<td>- Include an expandable program for investigative studies</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>User Error</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>- Control rate of depression</td>
<td></td>
</tr>
<tr>
<td>- Eliminate compression of tissue</td>
<td></td>
</tr>
<tr>
<td>- Prevent device angling during measurement</td>
<td></td>
</tr>
<tr>
<td>- Prevent device housing from loosing contact with the skin</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Program</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>- Display standard units related to the edema severity scale</td>
<td></td>
</tr>
<tr>
<td>- Provide a more accessible reset button</td>
<td></td>
</tr>
<tr>
<td>- Include maximum force threshold to prevent patient injury</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Testing</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>- Conduct extensive clinical studies to characterize edema</td>
<td></td>
</tr>
<tr>
<td>- Refine the relationship between parameters and the severity scale that clinicians currently use</td>
<td></td>
</tr>
<tr>
<td>- Test for additional sources of user error and how they affect edema measurements</td>
<td></td>
</tr>
</tbody>
</table>
9.1 Cosmetic Modifications

Some improvements can be made cosmetically to our device to make it easier for the user to perform measurements. We recommend that future iterations of the device include a start button and buzzer on the primary housing of the device, rather than on the additional control box kept to the side. This would allow the user to start the device and measure edema without needing to refer to the control box until after completing the measurement, when the LCD displayed the final values. This modification would require minimal rewiring from the microcontroller to the main housing of the device, and could be incorporated into a final design for manufacturing.

The microcontroller used in this project comes with a large development board that has additional A/D converters, buttons, buzzers, and many other accessories that are unnecessary. Eliminating extra components and reducing the size of the microcontroller would eliminate need for cords to travel to a separate display box. The microcontroller could be incorporated into the handheld portion of the device. This modification would reduce the number of components in the device as well as reduce size and cost of the device for manufacturing.

The device currently uses eight AA batteries to power the device. Although the performance of the batteries is sound, a smaller watch type battery could easily be used to power the device and reduce bulk. Lastly, the linear encoder uses some additional circuitry to provide signal conditioning. This circuitry is small enough that it could be made on an small IC. Additional components can be miniaturized and incorporated into the main housing so that the device is one piece.

To enhance the robustness of the return time measurement, the weight of the indenter, load cell, depressor unit, and external housing should be reduced. The device can capture the return
time; however, the weight of the load cell assembly provides enough resistance to prevent the time measurement from being as accurate and consistent. Currently, the indenter and depressor are made out of Delrin rod. Alternative, lightweight materials could replace Delrin or the current Delrin rods could be hollowed to reduce the weight of the assembly.

The selection of a distance-measuring device smaller than the linear encoder would reduce the overall weight and size of the device considerably. The linear encoder is the largest component and therefore the largest constraint on the housing design. Selecting a component that is smaller and lighter would allow the overall size of the device to be reduced dramatically. A size reduction would allow more flexibility in the design of the housing, ultimately leading to a more ergonomic design.

The device housing can be made more ergonomic by using injection molding in place of machining. An injection-molded design has a greater capability to form to the contours of the hand; the housing of the device should have more curved surfaces that provide ergonomic grips for the user when holding the device. The reason that injection molding was not considered in this iteration is because the mold costs about $5,000. Housing for the final device may be injection molded for manufacturing in bulk. The control box, also injection molded, should contain an indentation to serve as a storage base for the housing device when not in use.

9.2 Functional Modifications

Although the analog circuitry is functional, several improvements could be made, such as replacing the 100kΩ potentiometer with a resistor; replacing the protoboard with a PCB; using surface mount parts; and replacing the development board with two buttons, an LCD, the TI MSP430F449, a buzzer, and I/O pins. The 100kΩ potentiometer is heavy; a resistor is
significantly smaller and lighter. This would reduce the size and weight of the device. A PCB would make the circuit more reliable, durable, and longer lasting. Like replacing the potentiometer with a resistor, replacing the current components with surface mount parts would reduce the size and weight of the circuit. Replacing the development board with buttons, and LCD, the microcontroller, a buzzer, and I/O pins would also have the same effect.

If the device will be used long-term in hospitals, it may be necessary to calibrate the device after repeated uses. The device should include a calibration mode that allows the clinician to depress the thumb depressor to a known force to recalibrate the load cell with a calibration program. In addition, the device should require yearly maintenance to maintain functions and ensure the device is working properly.

The program for the device used in hospitals will provide an output of maximum distance depressed, maximum force, and a value of tau. When purchasing the device, the user should also have the option of adding additional programming that allows them to do data logging with the device and download force and distance values from the microcontroller for data analysis. These files can then be analyzed using standard software such as Microsoft Excel, MATLAB, or SPSS. This will allow the device to be expandable for investigative research as well as for edema assessment in a medical environment.

9.3 Future Recommendations Related to User Error

One of the potential problems with our current device is that it does not sufficiently reduce user error. Some of the sources of user error are pressing too quickly, compressing the skin with the casing, angling the device, and lifting the device.
9.3.1 *Pressing Too Quickly*

If the user presses too quickly, measurements are not accurate because there is a limit to the rate at which the microcontroller can detect rising edges to determine the distance traveled. Currently, the microcontroller signals the user with the LCD if a measurement is invalid from pressing too quickly. An alternative method for indicating this error is to use a series of LEDs. The number of LEDs that illuminate would be directly proportional to the rate at which the clinician presses. The device would identify the range of acceptable pressing speeds. If the clinician were pressing too fast, he/she would be able to look at the number of LEDs that are illuminated and recognize when the depression rate is too high.

9.3.2 *Compressing the Skin with the Casing*

Compressing the skin with the casing before or during the measurement would cause the maximum pitting distance to be smaller than it should be. If compression of the skin with the casing occurred while the skin was returning to its normal state, tau would be larger than the actual value. Currently, there is no measure to alert the user that he/she is pressing on the skin with the casing. To accomplish this, two small force sensors could be placed on the bottom of the device, so they would contact the patient’s skin and measure the force. If the force exceeded a threshold on both of them, the microcontroller would alert the user that he/she is pressing on the patient’s skin by displaying a message on the LCD such as “COMPRESS” and by sounding the buzzer at a low frequency.
9.3.3  *Angling the Device*

Angling the device before or during the measurement would cause the maximum distance to be higher than the actual value. This is because instead of taking a vertical path, the probe would be taking a diagonal path from the bottom of the casing to the patient’s bone. If angling occurred while the skin was returning to its normal state, tau would be greater than it should be for the same reason that the distance would be higher than the actual value. Currently, the flat base of the device discourages the user from angling the device, provided that the base remains in contact with the skin. To prevent further angling, the device could incorporate the same two force sensors that would be used to detect compression of the patient’s tissue. If the force detected by one force sensor were significantly greater than the force detected by the other force sensor, the device would indicate that it was not flush with the skin. The microcontroller would alert the user that he/she is angling the device by displaying a message on the LCD such as “ANGLING” and by sounding the buzzer at a low frequency.

A problem with using only two force sensors is that it would be able to detect angling in only one direction. Ideally, a ring-shaped force sensor could be placed on the bottom of the casing to detect angling in an infinite number of directions; however, the number of force sensors that would be needed to adequately detect angling is unknown. It is possible that four force sensors would suffice. Even without these modifications, the effects of compression and device angling were minimal in the overall use of the device.

9.3.4  *Lifting the Casing*

Lifting the casing during the measurement would cause the distance to be larger than it should be, and lifting the casing during the skin’s return to its normal state would cause tau to be shorter than it should be. To prevent this from occurring, the same force sensors used to
prevent compressing and angling could be used; if the sensors detected that the force was too low, the LCD could display “LIFTING” and a low-frequency buzzer tone could be sounded. Occurrences of the casing lifting from the tissue decrease as the user becomes more accustomed to using the device.

9.4 Recommendations to Improve the Program

Improvements to the program include displaying distance, force, and tau in units that are more easily communicated and related to the edema severity scale, providing an easily accessible reset button that, and including a maximum force threshold.

9.4.1 Displaying distance, force, and tau in standard units

One of the problems with the program is that the distance is displayed in two-hundred-fiftieths of an inch, the maximum force is displayed in arbitrary units, and tau is displayed in hundredths of seconds. A better way to display the distance, force, and tau is to display the distance in inches, force in lbs, and tau in seconds as well as to relate them to the current edema severity scale of 1-4. This would require floating-point math, which is a computationally expensive process. Additional programming is necessary to convert and display the distance, force, and tau in inches, lbs, and seconds, respectively. Relating these values to the clinical severity scale requires further clinical testing to characterize the properties of edematous tissue.

9.4.2 Providing an Easily Accessible Reset Button

Although a reset button is provided on the development board, it is small and difficult to access compared to the four large buttons below the LCD on the development board. Currently, the
user can reset the program only when the results are being displayed. It would be beneficial for the user to be able to reset the program at any time in case he/she does not want to continue with the measurement. Additional programming will allow the device to incorporate a more accessible reset button.

9.4.3 Including a Maximum Force Threshold

Currently, there is no safety measure in the program to alert the clinician that he/she is pressing too hard on the patient’s skin. If a maximum force threshold were included, if the clinician were to reach the threshold, the buzzer could sound a high-pitched tone and the LCD could display “TOOHARD.” Implementing this maximum force threshold would not be difficult; the most challenging part would be determining what the maximum force threshold is to prevent injury to a patient. Once a value for the maximum force threshold is known, the microcontroller would constantly monitor the force to ensure that it is below the threshold. Clinical testing based on the dimensions of our tissue probe is necessary to determine a maximum force threshold to prevent pain when using this device.

9.5 Further Testing and Evaluations

Extensive clinical testing is necessary to characterize different types of edema in relation to depth of pitting, return time, and force required to depress the tissue and create a more accurate correlation for the values our device outputs and the severity of edema. This characterization will allow medical professionals to relate a measurement scale output on the device to the levels of edema they are currently familiar with in medical diagnoses.

Because of the limited amount of time available to work on this project, there are numerous changes that could be made to improve the device; however, the current iteration is
still valuable for objective assessments of edema. Even without modifications, this device has the potential to greatly reduce subjectivity in edema assessment and help to standardize measurements among clinicians.
CONCLUSION

Our device is simple to use and provides a repeatable, reproducible, and quantifiable measurement that outputs values related to the severity of edema. We verified device principles on models that mimic the response of edematous tissue and our data indicates that our edema measurement device has the potential to reduce the subjectivity of edema measurement between clinicians who use the device. The device provides a consistent, quantifiable output with less inherent subjectivity that medical professionals can communicate easily to relay edema severity.

Furthermore, the final design of our device is simple, portable, and inexpensive, making it easy to manufacture, distribute, and use among hospitals across the country. The device can expand with additional programming to allow completion of investigative trials that characterize the properties of the different types of edematous tissue and how they respond to indentation. The device may not only be used for assessment of patients and to facilitate more accurate diagnoses, but also in clinical drug studies, or other investigations related to edematous swelling.
REFERENCES


Dunn, R. (personal communication, September 14, 2006) discussed edema and the process of measuring the severity of edema.


Shepro, D. (personal communication, October 1, 2006) discussed the relationship among venous insufficiency, venous stasis disease, and edema.


12 APPENDIX A: Background Research

Prior to designing our device, we conducted background research to expand our understanding of the design problem, including client needs, previous solutions and relevant engineering theory and principles. These appendices provide information gathered from the 2004 MQP, interviews and edema assessments.

12.1 Analysis of a previous Major Qualifying Project (2004)

The set up involves a light emitting diode (LED) and a photoresistor (PR), which are separated from each other by a thin, opaque barrier. The barrier moves up and down with the central indenter. The user controls the rate of depression as he pushes the indenter into the patient’s tissue with his thumb. During return, the indenter rides back towards its original position on top of the returning tissue. The light intensity, which passes to the PR, is a function of the displacement of the barrier. In its original position before depression, the PR is fully saturated by the light of the LED. As the barrier depresses into the tissue the barrier moves downward between the LED and PD, such that the amount of light collected by the PD is decreased. At maximum indentation, the barrier is blocking the PR from receiving any light.

![Diagram of LED and PR in different positions](image)

Figure 37: Conceptual analysis of the 2004 MQP
12.2 Viscoelasticity Theory

We used viscoelastic theory to model the behavior of edematous tissue because many properties of edematous tissue are similar to those of viscoelastic materials. The following section discusses relevant viscoelastic theory; however, many of the theoretical concepts of tissue viscoelasticity were difficult to apply to clinical test on patients. Traditional tissue characterization methods such as testing stress relaxation, creep response, and oscillatory tests are not feasible in a clinical environment. We explored these concepts to better understand the final measurement parameters in our edema measurement device.

12.2.1 Viscoelasticity Background

The purpose of looking at viscoelasticity is to understand the different ways that edematous tissue may potentially be measured and then selecting a robust method grounded in theory.

STRESS ANALYSIS

*Stress* – The stress is the force that acts on a body divided by the cross-sectional area.

\[ \sigma = \frac{F}{A}. \]

*Strain* – The deformation of an object is described as the change in length over the original length.

\[ \epsilon = \frac{\delta \ell}{\ell_0} \]

VISCOELASTICITY

*Viscoelastic material* – characterizes by possessing both *viscous* and *elastic* behavior. Some of the energy stored is recovered upon removal of the load and the rest is dissipated in the form of heat.

Ex.) Skin is a nonlinear viscoelastic material

Properties are influenced by:

- Frequency
- Temperature
- Dynamic strain rate
- Static pre-load
- Creep
- Stress relaxation
**Damping** – the conversion of mechanical energy in a structure to thermal energy

**Elastic material** – a purely elastic material is one which all the energy stored in the sample during loading is returned when the load is removed.

As a result, the stress strain curves for elastic materials move completely in phase. The relationship between stress and strain is given through Hooke’s Law:

\[
\sigma = E \varepsilon
\]

**Viscous material** – the complete opposite of an elastic material that is the material does not return any of the energy stored during loading. All energy is lost as thermal energy. In this case, the stress is proportional to the strain and the ratio of stress to strain is viscosity.

\[
\frac{\sigma}{\varepsilon} = \eta
\]

\[
\phi = \tan^{-1}\left(\frac{\omega}{\omega}ight)
\]

Phi measures the damping level. The larger the angle the greater the damping.

**MEASUREMENT METHODS**

*Stress relaxation, strain, and hysteresis (oscillatory) are features of viscoelasticity.*

**Stress relaxation** – deform a body a specific amount (holding a certain displacement level) and measure the stress in the material over a period of time. A viscous material will relax (stress...
decrease) as time progresses; however, a purely elastic material will maintain the stress until the deformation is removed.

This can be explained by the fact that pressure is proportional to tension divided by radius. If the tension decreases with time (which is what happens if you apply a strain and hold it), then the pressure (stress) will also decrease.

**Creep** – apply a known constant load to a body and measure the deformation at specific time intervals.

**Creep Recovery** – apply a known load to a body, release the load and measure how fast the tissue recovers

**Oscillatory** – apply an oscillatory stress to the body and monitor the corresponding strain. A viscoelastic material is a material whose current state depends upon its immediate history.

**MODELING**

To model the behavior of the above measurement methods we use *springs* and *dashpots*.

**Spring** – produces an **instantaneous deformation** that is proportional to the load. Stress is proportional to strain. A spring resists displacement.

\[ \sigma_s = E \varepsilon \]

**Dashpot** – produces a velocity proportional to the load at any instant **opposing motion** and absorbing energy. (Force = (rate of strain) * (coefficient of viscosity)). The dashpot cannot deform instantaneously.

\[ \sigma_D = \eta \frac{d\varepsilon}{dt} \]

Three models are used: *Maxwell, Voigt, and Kelvin body (standard linear solid)*

**Maxwell** – The Maxwell model is a viscoelastic liquid.

**Voigt** – The Voigt model is a viscoelastic solid.

**Kelvin Body** – The Kelvin body is a standard linear solid.

**Out of the three models, the Kelvin body most closely approximates edematous tissue.**
12.2.2 Viscoelasticity evaluation in relation to testing

**Goal:** To determine what tests should be simulated with keeping in mind that these tests should be realizable in our final device.

**Issue:** How to measure these parameters on foam with tools at hand? Capabilities of Instron and how we can translate that to testing? Other machines on campus that have better capabilities → hardness machine

**MODEL**

**CREEP:** Apply a constant stress, measure strain

\[
\varepsilon(t) = \frac{\sigma_0}{E_2} \left[ \left( \frac{E_1 + E_2}{E_1} \right) - e^{-\left( \frac{E_1}{\eta} \right)t} \right]
\]

It should be noted that we are approximating the response with one major time constant although there could very well be many.

In addition, if we change the indenter size between patients this is not good.

1. Apply load as fast as possible (instantaneous) [Force: .5 lbs to 5lbs]
   The ramp loading is not an assumption but a good approximation because we are ensuring that it is not the same magnitude as Tau.

**Limits of Ramping**

a. **Question:** How fast until the probe becomes unsafe or uncomfortable?
   This is something that we will need to determine.

b. **Question:** How slow can we depress until it affects the creep curve (instantaneous is no longer an appropriate assumption)
   If the rate of depression is the same order of magnitude as Tau. In addition, on a healthy person there is no way you can ramp faster than the time constant because the response is so fast. This may lead to a limitation on the final device. That is, the device could only be used with people who have a certain level of edemas tissue.
The doctor may have to “feel” the patient first to see if there is “X” level of edema before the device’s measurement can be considered valid.

1. Not measuring any time or stresses during depression

2. Extracting the change in strain (distance)
   a. Question: Do we need to know total thickness to determine strain? Can we measure change in distance divided by final distance?

   We need to know the total thickness to determine strain. Also, the strain for an indentation is a complex strain field. This is because the shape of the hole we are indenting is irregular. The conclusion is that we do NOT want to try to measure strain at all. Rather the strain in the equation should be converted to displacement (x). This would also mean a change from strain to force (F).

Problem: If probe has a fixed displacement, how can it “follow” the creep of the skin to measure strain?

Don’t want to measure strain at all. It’s not going to follow the creep of the skin!

So if we are not doing strain at all, what can we do? Maybe there is some significance to a force v distance profile. The problem here is the use of an expensive force transducer. This could be tested by ramping at a certain displacement rate and measuring force until the force gets to be so high that you are hitting bone.

**CREEP RECOVERY** - Measure recovery response of tissue after applying a known load

\[
x = x_{\text{max}} (1 - e^{-t/\tau})
\]

The equation for the creep response can be derived by looking at the equation for creep. The initial value is the value of the final value of the creep curve. Tau is the same on the way up as it is on the way down. The tissue will decay back to 0 instead of a steady state.

The first part of the creep curve is approximately linear and defines E1. The “creeping” part of the curve above represents the behavior of E2 and η.
1. Apply a load as fast as possible to a known stress (instantaneous)
   a. **Question:** Do we have to allow time for it to creep first?
      *Yes, but the more you let it creep the bigger recovery you will get. The
       “dashpot” or viscous fluid needs time to move. If you do not let the skin time to
       creep you are just getting the elastic behavior of the skin and will not see the
       exponential decay. You should check to see that TAU should not change
       depending on how much you let it creep because TAU is a material property.*

2. Remove load (immediately???) and record time it takes to return to normal or to an
   offset value (measuring distance too)
   *Either can be done. We should model and see what looks good.*

3. Extracting Tau (time constant)
4. **Question:** Measuring Tau more robust in this experiment?
   *Billiar’s hunch is that it is more robust and the more you let it creep the more recovery
   you will get. However, patient compliance will decrease the longer you let it creep.*
5. **Question:** Does amount of force applied affect tau? (Old MQP assumed no)
   *No. The more force you apply the more creep you will get. Tau will not change it is a
   material parameter.*
6. **Question:** Does the distance force is applied affect tau?
   *Applying a constant rate of displacement so no.*
7. **Question:** Does the rate the force is applied affect tau?
   *No but the displacement of the tissue will be different.*
8. **Question:** Is tau different on the way down?
   *Not for creep. It is for stress relaxation!*

Another option
1. Indent probe to tibia (when stress plateaus and becomes “constant”)
2. Measure total distance to tibia and time to get there
3. Release probe to 63% of total distance
4. Measure time it takes for skin to return to 63%

**2004 MQP**
1. Apply a load to a predetermined distance (tibia). (Assume force applied doesn’t
   matter)
2. Hold for three seconds (for what reason?)
3. Release and measure time to return to normal (probe moving with skin?)
4. Extract tau
5. **Question:** Possible to repeat this with the Instron device.
STRESS RELAXATION - Apply a known strain and measure resulting stress

\[ \sigma(t) = \varepsilon_0 \frac{E_1 E_2}{E_1 + E_2} \left[ 1 + \frac{E_1}{E_2} e^{-\frac{(E_1 + E_2)}{\eta} t} \right] \]

1. Indent probe to a known strain.
   a. **Question:** How can we determine strain? *Can’t.* However, you can substitute force for sigma and displacement for strain. The units of force are \(N\). The units of displacement are \(m\). The units of \(k\) are \(N/M\). The units of the damping are \((N/M)*S\). Force/displacement = structural stiffness. Structural stiffness should tell you something about the viscoelastic properties of the material.
   b. **Question:** How do we determine the total thickness of the tissue? Is it possible to determine it without indenting and remeasuring? *No.*
   c. **Question:** Is it possible to get a strain value without knowing anything (initially) about deformation? *No.*
   d. **Note?** Relaxation is independent of strain in viscoelastic material. *Yes.*
   e. **Question:** Can we indent and measure resulting stress without measuring the strain? If so, how to we know when to “stop” indenting so it is consistent (distance or force) between severities? Does it need to consistent or will the profile be the same? *Should stick to the displacement and force instead of stress and strain.*
   f. Extracting stress change over time.

2. Indent probe to tibia (based on reaching a known strain) *Can’t do known strain.* If you are working with displacement you can’t do that either because displacement depends on how severe the edema is.

3. Measure distance to tibia
4. Return probe to X percentage of total distance (for known strain).
5. Measure force profile starting when skin reaches probe until constant.
6. **Question:** How does initial percentage strain affect profile? *A better signal to noise ratio.*
7. **Question:** If relaxation is independent of strain, how does simplified relaxation profile look between different foam models?
8. Extracting what value from simplified relaxation profile?

RAMP LOADING - Apply ramp loading at different rates to determine properties

\[(E_1 + E_2) \sigma + \eta \dot{\sigma} = E_1 E_2 \varepsilon + E_1 \eta \dot{\varepsilon}\]

*The downside of ramping is that you will need a force transducer. CAN do two ramps on someone BECAUSE if you ramp really fast you will get the instantaneous elastic behavior of the tissue and it will come back immediately. Then you can ramp down again and watch it come back.*

1. Indent probe “instantaneously” (fast rate) and measure stress profile during indentation.
2. Wait for tissue to return to normal.
3. Indent probe at a slow rate and measure stress profile
4. Extracting what? Creep time
5. Question: Will the purely elastic portion of the different foam models always be the same? (If so can eliminate fast loading) Not sure.

Question: How are rates of displacement affecting these measurements? Need to test these.
Question: If rate of displacement is slower than tau, how will it affect the measurement?
Question: How does shaking foam affect these measurements?

- Theoretical modeling might not be as applicable if we cannot test in lab
- We can do tests using stain on our foam because we will know the thickness of our models, but thickness in patients will vary.

12.3 Interviews and Edema Assessments

To help us understand the scope of our problem we visited several hospitals to observe edema assessments and to interview medical professionals who conduct edema assessments on a regular basis. The information we received from the interviews informed the development of our models, the measurement we chose for the final design, and our housing design. Throughout the design process, we asked for feedback from these medical professionals to ensure that our device fit closely with the daily routines and expectations of clinicians who might use the device to assess edema.

We conducted three interviews at Fairlawn, a rehabilitation hospital in Worcester, MA. Fairlawn is a rehabilitation hospital. Many of the patients at this hospital have some form of compromised mobility that increases their risk of edema. We observed that many of the patients wore compression stockings because of their propensity toward edematous conditions. We interviewed three specialists at Fairlawn: Melissa Blatt, Lymphedema Specialist; Dr. Howard Fixler, Chief of Internal Medicine; Nurse Letty Wheelock, RN. Additionally, we conducted several interviews with our primary client, Dr. Raymond Dunn, Head of Cosmetic Surgery at UMass. We also briefly interviewed two clinicians, Dr. Savoie and Dr. Chelley, from the Wound Clinic at UMass.

12.3.1 Depth of Pitting is Primary Consideration

A common theme throughout all of the interviews was that most clinicians base edema assessments primarily on the depth of pitting. Although the properties or the texture of the
tissue may change between different levels of severity, these parameters are secondary factors and not the main basis for assessment of edema. Interviewees described sensing the creep response of the tissue upon depression, but did not indicate that different creep responses corresponded to different levels of severity. Dr. Fixler indicated that many of the patients seen at Fairlawn experience a mixture of pitting edema and lymphedema. Thus, the resistance of tissue to depression could be more a factor of the type of edema than the severity of edema.

All interviewees indicated that return time of the tissue to its pre-depressed state is irrelevant to their determination of edematous severity. We were unsure whether this was because they do not have the capabilities to accurately monitor this parameter or whether it is simply not important to the overall assessment of edema. We determined that return could be important as a Boolean value, which merely indicates the absence or presence of pitting edema.

12.3.2 Likelihood of Using Edema Assessment Device

When asked about the likelihood of using an edema measurement device, all interviewees stated that it would be helpful to have a device that could provide an objective measurement regardless of the operator. Currently, Nurse Wheelock indicated that she would not rely on someone else’s subjective assessment on a scale of 1-4. Instead, she would perform the assessment herself. She indicated that it would be helpful if an admitting nurse could record edema levels to compare values collected by another individual at a later time. Ms. Melissa Blatt, an edema specialist, also indicated that it would be helpful for insurance purposes to have a device that could quantify the patient’s progress. She discussed how clinicians measure wounds objectively in centimeters. Objective measurements in centimeters would allow medical professionals to rely on information obtained by other individuals and eliminate errors due to different measurements techniques.

12.3.3 Clinical Relevance of Edema Assessments

Dr. Fixler emphasized that there is little correlation between edematous severity and clinical intervention. An edema assessment by itself is irrelevant without information regarding the overall patient condition. Nurse Wheelock explained that an edema assessment is merely one small indicator of the patient’s overall condition. Thus, the same level of edematous severity on two patients does not necessarily mean that they require the same treatment.
12.3.4 Regarding Device Parameters

Ms. Blatt cautioned that the stabilizing features of the device must not compress the tissue before or during the measurement because it could lead to skewed measurements. Several interviewees indicated that patients with edema might be sensitive to pressure on the affected area. Compression could cause pain for the patient. Thus, if we were to use a cuff design, we would have to ensure that it did not cause compression of the tissue, which could lead to discomfort or skewed results. Additionally, the probe should be comfortable for the patient, and should not contain sharp edges, which might hurt the tissue. Ms. Blatt suggested a “roll-on deodorant” approach to the probe tip.

As far as size and time constraints, Ms. Blatt indicated that she would prefer a compact device with less range of displacement over a larger device with greater range. This is consistent with feedback from other interviewees, who expressed the importance of a quick and easy device. Nurse Wheelock emphasized that although she spends as much time as is required to fully examine the extent of the edema, a device measurement should be quick and easy to implement the device practically. Ms. Blatt also talked about identifying the best location for edema measurements. She said edema tends to be less in areas over the muscle belly, since muscle activity tends to prevent too much fluid buildup.

12.4 Edema Assessment Observations

Three edema assessments at Fairlawn Hospital illustrated that similar levels of edema can represent very different patient conditions. The first patient observed had unilateral pitting edema in one leg due to a blood clot that was a complication of hip surgery. For this patient, unilateral pitting edema indicated a very dangerous condition that required constant monitoring and careful administration of medication. A second patient had a similar level of edema due to a recent toe amputation. His edema was a natural result of the recent surgery and was being treated with compression stockings. Doctors were monitoring his edema as an indicator of his healing. A third patient suffered from congestive heart failure, which resulted in pitting edema in both lower extremities. The appropriate intervention was, again, compression stockings to minimize the swelling.
In the three assessments at Fairlawn, the edema was a secondary symptom of the patient’s condition, which was of primary concern. At UMass, we observed a case in which the edema itself had become a primary concern, as it resulted in ulcers and necrotic tissue. A patient observed at the wound clinic in UMass had severe pitting edema due to congestive heart failure. This patient’s legs and feet were affected by edema that varied with location. On the outside of her knee, the swelling was assessed as a 3, whereas it was a 2 inside the tibia. The edema caused a large, painful ulcer on the back of the lower leg. In this case, it was important to treat the edema to ensure healing of the ulcer.

Another patient at UMass had compromised circulation in his lower leg, which resulted in unilateral pooling of fluid around one ankle. Pitting edema in the affected ankle was assessed to be a 3+. In this case, the edema was a chronic condition, treated through rest, elevation of the limb and massaging. The edema only had to be kept under control. We noted that the return time for this patient’s 3+ pitting edema seemed to be much greater than that for the 2+ pitting edema on the patient with congestive heart failure.

12.4.1 Conclusion: Assist—not replace

From this wide range of patients with different levels and causes of edema, it is clear that edema by itself is not indicative of the severity of the patient’s condition. Thus, our edema measurement device will not replace the clinicians who assess the severity of edema based on many factors including the patient’s history and medical condition. Rather, our device will assist medical professionals in monitoring the progress of edema regardless of the severity or the cause. The clinician determines the severity of the condition that causes edema and whether or not clinical intervention is necessary.
13 APPENDIX B: Edema Survey

We conducted a survey of 16 clinicians to determine what features they would find most useful for an edema measurement device.

13.1 Development survey questions and anticipated results

Before developing the questions, the group identified the target audience: medical professionals who assess edema on a regular basis. This includes physicians and nurses with a broad range of specializations, including plastic surgery, cardiology, vascular surgery, geriatrics, and wound healing. The survey sent to the clinicians is found in Appendix 13.2.3.

The goals of the first question, “How often do you assess the severity of peripheral, pitting edema in a patient's lower extremities,” were to gauge the importance of our device and to enable us to weigh different clinicians’ and nurses’ responses differently. Showing that there are some clinicians who assess edema daily corroborates the statement that an objective edema measurement device would be used regularly. If the group found that medical professionals who do not assess edema on a regular basis responded to our survey and their responses differed from those who assess edema frequently, the group would place more weight on the responses from the clinicians who measure edema often. The group expected that most clinicians who responded to the survey would say that they assess edema daily, but this would vary, depending on the clinician’s specialty.

Asking medical professionals to indicate how they currently assess edema is necessary because if they indicate that they do not use an edema assessment device or another objective measurement, their assessment will be highly subjective. The group expects that visually inspecting the tissue and depressing the edematous tissue will be the most common responses, both of which are subjective methods. Knowing whether a large percentage of medical professionals use subjective methods will be helpful because it will support our hypothesis that the device is an improvement over current methods.

The third question is essential because it will indicate which parameters the group will need to measure to properly assess edema: distance, force, and/or time. The group expects that the depth of the tissue depression, time for the tissue to return to its pre-depressed state, and the
volume of the limb will be very important, and the physical resistance of the tissue to depression will be either somewhat important or important.

The fourth question is to help us develop the housing and user interface for the housing. If it were helpful for patients to assess the severity of their own edema, the design should contain two separate units: the depressor and the actuator, which would be applied directly on the leg; and the LCD and the controls, which the patient would hold in his/her hands. The group expects that the ability for patients to assess their own edema would be somewhat helpful.

The group has not yet encountered inexpensive, commercially available devices that accurately and objectively assess the severity of edema. If medical professionals affirm that they know of inexpensive, commercially available devices that accurately and objectively assess the severity of edema, the group will research the commercially available edema assessment devices and compare those devices to the final design.

One of the major design decisions regarding our device is whether it should be automatically or manually actuated. If it were automatically actuated, the user would only need to push a button; the device would contain a unit that would depress a probe into the tissue and measure the distance, force, and time constant. If the device were manually actuated, the user would use his/her thumb to push on the probe, and an LED would indicate when to stop applying pressure to the probe. The group expects that most medical professionals would prefer an automatic device.

Another design decision is how to hold the device against the patient’s tissue. Because the group eliminated all of the housing options except for the cuff and the handheld, two-cylinder design that is similar to the housing proposed by the 2004 MQP group, these were the only two options presented to the survey takers. The group also allowed the medical professionals to provide another idea for housing. Because the two-cylinder design can be used anywhere on the body, we expect that it will be preferred over the cuff design.

It is essential to know how clinicians feel about importance of set-up time, duration of the measurement, cordlessness, weight, cost, and size of the device. The responses guide design decisions such as how to power the device, the size and weight of the materials, and the approximate cost. The group expects that set-up time, duration of measurement, and cost will be very important; and cordless design, compact size, and weight will be somewhat important.
The purpose of Question 9 is to gauge the likelihood that medical professionals would use the device. If the responses show that medical professionals would be interested in the device, it would strengthen the argument that an edema measurement device will be useful and accepted in clinical settings.

Because the group is likely to continue to have questions for medical professionals throughout the remainder of the project, the last question asks the survey takers to provide information about themselves if they feel comfortable doing so.

13.2 Survey Distribution

The group distributed the survey by using surveymonkey.com. Once the survey was finalized in surveymonkey.com, the group created a Microsoft Word version of the survey that could be sent through the postal service. The group also wrote a cover letter, which introduced the survey. There were three clinicians to whom the group sent the electronic version of the survey: Dr. Raymond Dunn, Dr. Howard Fixler, and Dr. David Shepro. Dr. David Lyons received a paper copy of the survey. The instructions for each of the clinicians were to complete the survey and encourage their colleagues to do the same.
Biomedical Engineering Department  
Edema Monitor MQP  
100 Institute Road  
Worcester, MA 01609  

November 2006  

The authors of this survey are students at Worcester Polytechnic Institute. We are currently working on a senior-level engineering design project in collaboration with Dr. Raymond Dunn, of UMass Medical School. The project encompasses the design and construction of a new device that quantitatively assesses the severity of a patient's edema* over time.

The purpose of this brief, ten-question survey is to collect information from medical professionals regarding their views on a new edema assessment device. When you have finished the survey, please mail it to:

Rachelle Horwitz  
WPI Box 1616  
100 Institute Rd.  
Worcester, MA 01609

If you have any questions, the group may be contacted via email at tono@wpi.edu or via phone at (508) 414-4220.

Thank you for your time and support.

Sincerely,

Rachelle Horwitz  
Erika Hall  
Charles Gammal  
Stephanie LeGare
Biomedical Engineering Department  
Edema Monitor MQP  
100 Institute Road  
Worcester, MA 01609

November 2006  
Dear Colleagues,

I am collaborating with a group of students from Worcester Polytechnic Institute (WPI) whose senior project is to develop a device to monitor the severity of pitting edema. The catalyst for the project lies in the fact that most edema assessments are highly subjective and, consequently, the severity of edema is difficult to monitor quantitatively. The students are designing a device that will quantitatively measure the level of severity of pitting edema over time and eliminate the subjectivity characteristic of current edema measurements.

The students have developed a brief online survey to help them determine the preferences of clinicians who assess edema on a regular basis. Your participation in this survey will greatly assist them in developing their edema monitoring device.

The Edema Monitoring Device Survey is found at the following URL:  
<http://www.surveymonkey.com/s.asp?u=650372905040>

Thank you for your time and support.

Sincerely,

Dr. Raymond Dunn

WPI Students  
Erika Hall  
Rachelle Horwitz  
Charles Gammal  
Stephanie LeGare
13.2.3 Survey Questions

*Please note that, for the purposes of this survey, "edema" refers to peripheral, pitting edema in the lower extremities.

1) How often do you assess the severity of peripheral, pitting edema in a patient's lower extremities?
   a. Less than once per month
   b. Once or twice per week
   c. Several times per week
   d. Several times per day

2) How do you currently assess the severity of edema? Indicate all that apply.
   a. Inspect visually
   b. Depress tissue on the patient's leg using your finger or thumb
   c. Use an edema assessment device
   d. Measure volume of limb
   e. Other (please specify below)

3) How important are the following parameters for proper assessment of edema? Please circle your response.

   Physical resistance of the tissue to depression:
   Unimportant Somewhat important Important Very important

   Time for the tissue to return to its pre-depressed state:
   Unimportant Somewhat important Important Very important

   Depth of tissue depression:
   Unimportant Somewhat important Important Very important

   Volume of the limb:
   Unimportant Somewhat important Important Very important

4) How helpful would it be to you if patients had the ability to assess the severity of their own edema?
   a. Not helpful
   b. Somewhat helpful
   c. Helpful
   d. Very helpful

5) Are you aware of any commercially available devices that quantify the severity of edema?
   a. No
   b. Yes (please specify below)
6) Assuming that a new edema assessment device takes measurements by depressing the patient's tissue, do you have a preference regarding whether the device is depressed by a clinician or is depressed automatically?

a. Yes, the device should be depressed by a clinician
b. Yes, the device should be depressed automatically
c. No, I have no preference

7) Assuming edema measurements are made on the patient's lower leg; please indicate the optimal way for the device to remain in contact with the patient.

a. The device is held against the patient's leg by a clinician while the measurement is being taken
b. The device is secured by a cuff (similar to a blood pressure cuff) that wraps around the patient's leg
c. Other (please specify below)

8) How important are the following device features for a device that is convenient and usable?

<table>
<thead>
<tr>
<th>Feature</th>
<th>Unimportant</th>
<th>Somewhat important</th>
<th>Important</th>
<th>Very important</th>
</tr>
</thead>
<tbody>
<tr>
<td>Set-up time</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duration of measurement</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cordless design</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weight</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cost</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Compact size</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

9) Assuming there is a new edema assessment device which conveniently and accurately monitors the severity of a patient's edema over time, how likely would you be to use such a device?

a. Very likely
b. Likely
c. Somewhat likely
d. Not likely
e. I would not use such a device
10) Thank you for taking the time to participate in this survey. In the event that we are interested in obtaining clarification regarding your survey responses, please use the space provided below to provide contact information that would allow us to contact you.

Specialization: ______________________________________________________________
Title (e.g. RN, MD, etc.): ____________________________________________________
Name: ____________________________________________________________________
Phone number: _____________________________________________________________
Extension: _________________________________________________________________
Email address: ______________________________________________________________
13.3 Survey Results

The group analyzed the data by comparing the percentage of medical professionals who chose different answers to the same questions. Because surveymonkey.com displays the percentages for the test administrator, we did not need to perform any calculations. We obtained 16 completed surveys from medical professionals whose titles ranged from registered nurses (RN) to medical clinicians (MD), and whose specialties were either cardiac or rehabilitation care. None of the survey respondents indicated that they were aware of an edema assessment device.

The first question investigated the frequency with which survey participants assess edema as shown in Figure 38. Of those who responded to this question, there was only one person who assessed edema less than once per month.

![Figure 38: Frequency that clinicians assess edema](image)

The second question requires participants to indicate their method of edema assessment. As seen in Figure 39, all participants indicated that they assess edema via visual inspection and/or digital manipulation. No participants indicated otherwise. This is important because it verifies that an objective means of edema assessment would be an improvement over current subjective means indicated by participants.
We included the third question to investigate the importance of certain characteristics of edematous tissue in determining the severity of edema. Figure 40 shows the results for this question. A pie chart showing the ‘most important’ parameters is shown in Figure 41. Most participants felt that the depth of indentation was “very important” for edema assessment. This result corresponds with our survey results in verifying that assessment of tissue displacement is clinically significant and meaningful to medical professionals.

About half of the responses indicated that physical resistance to depression is also “very important,” while about 40% indicate that it is “important.” The exact relationship between resistance to depression and edematous severity is yet to be determined. However, our edema measurement device has the capability of measuring force, and is suitable for further investigation of this relationship.

Limb volume was deemed mostly “important” or “somewhat important.” Return time showed the most disagreement between respondents, as responses were almost evenly distributed between “unimportant” to “very important.” This result can perhaps be explained by the fact that no clinical studies showing a relationship between return time and severity of edema have been conducted.
The third question was designed to investigate how helpful it would be to medical professionals if patients had the ability to assess their own edema. As seen in Figure 42, roughly half of the respondents indicated that patient self-assessment would be “very helpful,” while the other half were distributed between “somewhat helpful” and “helpful.” No participants indicated that it would not be helpful if patients could assess their own edema. These results indicate that there was high level of interest in a marketed device that is patient friendly and suitable for self-assessment.
The next question investigated the feelings of medical professionals regarding whether the device was manually or automatically depressed. Figure 43 shows the results for this question. Roughly half of the participants indicated that they had no preference regarding the method of depression. Of the remaining half, about 70% indicated that they would prefer automatic depression. The group expected that a greater number of medical professionals would prefer automatic depression. The large number of responses indicating no preference is perhaps because the device is still in a conceptual stage at this point.

Figure 44 shows responses to the survey question regarding the optimum method of maintaining contact between the patient and the device. The majority of respondents indicated that they would prefer if the device were held in contact with the patient via a cuff design. This preference was taken into consideration in the final design of the device, however the
group decided against using the cuff design because the dual cylinder allows for more variation in the location of the measurement.

Figure 44: Method of maintaining contact with skin in an edema device

Figure 45 shows responses to the next survey question, which examined the importance of a variety of device features. The ‘most important’ device features are represented in a pie chart in Figure 46. As we predicted, set-up time, cost and duration of measurement had the highest percentage of respondents who indicate that these features are “very important.” Overall, set-up time was deemed by respondents to be the most important device feature, with more than half of the responses indicating that it is very important. Cost was the second most important device feature. A large majority of the responses for weight and compact size indicate that these features are “important.” Duration of measurement and cordless design show the most discrepancy in their results, with importance levels evenly distributed between “very important,” “important” and “somewhat important.”
Most of the respondents indicated that they would be “very likely” to use an edema assessment device. No respondents indicated that they would not use or would not be likely to use such a device. These results not only strengthen our prediction that an edema measurement device would be accepted and viewed as useful in a clinical setting, but they also indicate that the device would be welcomed and adopted into use by medical professionals.
Lastly, our survey tracked the professional titles of the respondents. A majority of the survey participants were MD’s and RN’s, with a specialty in cardiology.
14 APPENDIX C: Design Process

Our device underwent a detailed design process and several iterations before arriving at the final design. These appendices provide detail regarding the design approach, and how we determined our overall objectives, basic functions, and requirements for the device. The design appendices contain an attributes list, decision charts, methods for weighting criteria and other decision charts relating to our initial design process.

14.1 Attributes List

The attributes list includes functions, objectives, and constraints for the device. The attributes list serves as an outline of the criteria the device should meet when completed.

1.0 Functions
   1.1 Depress tissue
   1.2 Measure resistance of tissue to depression
   1.3 Measure time
   1.4 Measure displacement
   1.5 Correspond measured parameter with severity level
   1.6 Display severity level
   1.7 Interface comfortably with patient

2.0 Objectives
   2.1 Accurate: Measures the true level of severity for one patient
   2.2 Convenient: Easier than or as easy as the current method
      2.2.1 Simple device operation
      2.2.2 Easily fits into daily routine
      2.2.3 Minimal set up time
      2.2.4 Output relatable to current practice
   2.3 Robust: Consistent/repeatable
      2.3.1 User-independent
      2.3.2 Independent of testing conditions
   2.4 Adaptable: Can be used for a variety of patients
   2.5 Durable: Sturdy
      2.5.1 Long lasting
      2.5.2 Repeated usage
   2.6 Expandable: Suitable for future improvements/development
      2.6.1 Other areas of the body
      2.6.2 Inclusion of multiple relevant measurements

3.0 Constraints
   3.1 Time
   3.2 Project budget
   3.3 Device budget
   3.4 Range of linear displacement
   3.5 Test time
   3.6 Safety
   3.7 Materials
14.2 Pairwise Comparison Chart and Objectives Tree

The pairwise comparison chart (PCC), shown in Table 12, is a means to evaluate our primary objectives and to assign weights to each objective to determine which carry the greatest weight within the device design. The PCC chart lists objectives vertically and horizontally so each block of the PCC represents a comparison between two objectives, one on the vertical axis, and one on the horizontal axis. An “X” is used in the blocks that compare the same objective. For each comparison, a “1” denotes that the objective on the vertical axis is more important than that on the horizontal axis. A “0” denotes that the horizontal objective is more important, while a “0.5” indicates that both objectives have the same importance. Numbers from each block are totaled in the “total” column, divided by the total number of points, and multiplied by 100% to yield the weight.

The primary objectives for this project were to be robust, convenient, accurate, and repeatable in measurements. The majority of our resources were expended to achieve these goals. Figure 49 shows a weighted objectives tree, which summarizes the results of the PCC analysis. The weighted objective tree makes it clearer what detailed sub-objectives we need to achieve to complete each objective. We assigned sub-objectives to each weight based on their comparative importance.
Table 12: Pairwise comparison chart (PCC) of device design objective

<table>
<thead>
<tr>
<th>OBJECTIVES</th>
<th>Robust</th>
<th>Durable</th>
<th>Adaptable</th>
<th>Convenient</th>
<th>Accurate</th>
<th>Expandable</th>
<th>Total</th>
<th>Weight [%]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Robust</td>
<td>X</td>
<td>1</td>
<td>0.5</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>3.5</td>
<td>23.3</td>
</tr>
<tr>
<td>Durable</td>
<td>0</td>
<td>X</td>
<td>0.5</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1.5</td>
<td>10</td>
</tr>
<tr>
<td>Adaptable</td>
<td>0.5</td>
<td>0.5</td>
<td>X</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>6.7</td>
</tr>
<tr>
<td>Convenient</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>X</td>
<td>1</td>
<td>1</td>
<td>5</td>
<td>33.3</td>
</tr>
<tr>
<td>Repeatable</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>X</td>
<td>1</td>
<td>3</td>
<td>20</td>
</tr>
<tr>
<td>Expandable</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>X</td>
<td>1</td>
<td>6.7</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>15</strong></td>
<td><strong>100%</strong></td>
<td><strong>100%</strong></td>
<td><strong>100%</strong></td>
<td><strong>100%</strong></td>
<td><strong>100%</strong></td>
<td><strong>100%</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

**Expandable** - Device can incorporate additional features and/or be used on multiple limbs or for assessing various types of edematous swelling.

**Robust** - Variability of user measurements are within a range of accuracy regardless of the user implementing the device.

**Repeatable** - Device controls for four types of measurement accuracy:
- a) accuracy within the device - the device consistently records measurements in the same manner, at the same angle, resulting in consistent values with repeated measurements.
- b) accuracy of repeated measurements on a patient - measurements taken on the same patient over several days are consistent and accurate.
- c) accuracy among a population - measurements of the same level of edema of different patients return consistent measurements.

**Adaptable** - Easy to use, possibly self automated, readouts self explanatory, few calculations or thinking required to use.

**Convenient** - Looks appealing, looks easy to use, looks comfortable to the patient.

**Durable** - Device can be used repeatedly with minimal maintenance, breakage, or malfunction. External and internal components withstand wear and tear of use.

**Key:**
- 0 = Less Important
- ½ = Equally Important
- 1 = More Important
14.3 Components and Means Research

To identify the means available to accomplish the desired device functions, we researched components to measure force and distance and to power the device. The results of our component research are explained in the following sections.

14.3.1 Force Transducer Selection

There are an uncountable number of force transducers on the market to choose for our device. To organize the priorities for selecting a force transducer, the team developed a list of metrics and weights. The metrics used for the selection of a force transducer are cost, size & weight, range & resolution, and interface. Cost is a metric due the limited budget for the project; however, the team did not feel it was the most important metric and thus it received a weighting of 50. The size & weight of the device were important because our goal is to develop a device that is small and lightweight, making it easy for the clinician to use. Thus,
the metric for size and weight received a weighting of 60. The range & resolution of the
device were critical because the transducer needs to be able to detect the range of forces (1-5lbs) that the clinician will be applying to the patient. This was the team’s most important
criterion and received a weight of 90. Lastly, the device needs to be able to interface easily
with the processing component of the assessment device. We also considered what additional
components we needed to interface between the processing component and the force
transducers. We considered interface the least important metric and assigned a weight of 40.

Table 13 provides the nomenclature for these devices and lists the types of force
transducers we evaluated. Table 14 provides the metrics and value points assigned to each
component. Finally, this appendix also provides a detailed description of the final devices that
we evaluated in the Force Transducer Decision Matrix. Many of the devices listed in this
appendix are similar or identical in operation, but many have different names depending on the
manufacturer.

<table>
<thead>
<tr>
<th>Device</th>
<th>Cost</th>
<th>Interface</th>
<th>Range &amp; Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pressure transducer</td>
<td>$10 - $20</td>
<td>Excellent</td>
<td>Excellent</td>
</tr>
<tr>
<td>Load cell</td>
<td>$20 - $50</td>
<td>Very Good</td>
<td>Very Good</td>
</tr>
<tr>
<td>Strain gauge</td>
<td>$50-$80</td>
<td>Good</td>
<td>Good</td>
</tr>
<tr>
<td>Piezoelectric sensor</td>
<td>$80-$150</td>
<td>Fair</td>
<td>Fair</td>
</tr>
<tr>
<td>Force transducer</td>
<td>$150+</td>
<td>Poor</td>
<td>Poor</td>
</tr>
<tr>
<td>Force transducer</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Digital pressure gauge</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pressure transducer</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pressure controller</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Capacitive pressure sensor</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 14: Value Points for Metrics Related to Force Transducer Technologies

<table>
<thead>
<tr>
<th>Cost</th>
<th>Interface</th>
<th>Range &amp; Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>$10 - 20</td>
<td>Excellent</td>
<td>Excellent</td>
</tr>
<tr>
<td>$20 - $50</td>
<td>Very Good</td>
<td>Very Good</td>
</tr>
<tr>
<td>$50-$80</td>
<td>Good</td>
<td>Good</td>
</tr>
<tr>
<td>$80-$150</td>
<td>Fair</td>
<td>Fair</td>
</tr>
<tr>
<td>$150+</td>
<td>Poor</td>
<td>Poor</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Size &amp; Weight</th>
<th>Range &amp; Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excellent</td>
<td>Excellent</td>
</tr>
<tr>
<td>Very Good</td>
<td>Very Good</td>
</tr>
<tr>
<td>Good</td>
<td>Good</td>
</tr>
<tr>
<td>Fair</td>
<td>Fair</td>
</tr>
<tr>
<td>Poor</td>
<td>Poor</td>
</tr>
</tbody>
</table>
Figure 50 shows the CUI force transducer, which is 2.5 inches long and can sense up to 1.5kg of force. The device produces a resistance that is proportional to the load applied. A cost was not readily available however; an inquiry to the company provided the team with a $150 quote on the transducer. One potential drawback of the CUI device is that it contains lead. However, it can be easily mount or bent to curved surfaces.

![Figure 50: CUI Force Transducer](http://www.cui.com/srchresults.asp?catky=560054&subcatky=895884)

Figure 51 shows the Measurement Specialties solution is the selection that the team made for a force transducer. The device is approximately 1 in. x .5 in. The standard range is 1-5lbf and that input produces an output that spans 1-4VDC. The cost of the device is $120, which is a relatively low cost for force transducers. The output of the device is amplified and can readily be attached to a processing component.

![Figure 51: Measurement Specialties Load Cell](http://www.meas-spec.com/myMeas/sensors/senseElements.asp)

Tekscan offers a force transducer that looks very similar to that offered by CUI (Figure 52). The difference is that the Tekscan transducer is slightly longer (4 in.) and has a wide range of sensing capabilities. There are three versions of the device available, the 1lb, 25lb, and 100lb. The 1lb version is too small for the team whereas the 25lb version may be overkill. The team received a $180 quote from the company on the 25lb version. The interface for the device is very poor because it requires a lot of output drive circuitry to condition the output signal.

---

1 http://www.cui.com/srchresults.asp?catky=560054&subcatky=895884
2 http://www.meas-spec.com/myMeas/sensors/senseElements.asp
The Honeywell force transducer solution is very similar to that of Measurement Specialties in size and in cost. The cost of the device is $120 and the size is 1 in. x .5in. The sensing area is considerably smaller and higher than that of the Measurement Specialties device as shown in Figure 53. The output and input of the device are separated on two different sides of the transducer. This was a drawback because wires would have to come out of all sides of the device rather than one on the Measurement Specialties device.

The Sensortechnics device was also very similar to the Measurement Specialties device. The load range and resolution is the same and the size is approximately the same. The sensing area has a negligible difference and the input and output is featured on three pins on the right side of the device (Figure 54). The only difference between the two options is the price differential. The Sensortechnics device costs $155.

---

3 http://www.tekscan.com/flexiforce/specs_flexiforce.html  
4 http://content.honeywell.com/sensing/prodinfo/force/  
5 http://www.sensortechnics.com/index.php?fid=300&fpar=YToxOntzOjQ6InBjaWQiO3M6MjoiNzMiO30%3D&isSSL=0&aps=0&blub=ca3ce97247d32d04ca3c15435363d1a3
The Measurement Specialties force transducer scored 970. The closest competitor was the Sensortechnics device, which is identical in function and differed in cost. The other devices fell short of the Measurement Specialties device.

14.3.2 Displacement Transducer Selection

Displacements transducers were also very abundant and had a wide range of nomenclature. Table 8 provides a list of the types of displacements transducers we evaluated with metrics and the decision matrix. Table 9 indicated the value points and metrics we used to evaluate displacement transducers. This appendix also describes the displacement transducers we used in the decision matrix to come to a final decision.

<table>
<thead>
<tr>
<th>Table 15: Types of Displacement Transducer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Device</strong></td>
</tr>
<tr>
<td>Encoder</td>
</tr>
<tr>
<td>Linear potentiometer</td>
</tr>
<tr>
<td>Linear variable differential transformer</td>
</tr>
<tr>
<td>Laser micrometer</td>
</tr>
<tr>
<td>Inductive</td>
</tr>
<tr>
<td>Magneto</td>
</tr>
<tr>
<td>Ultrasonic</td>
</tr>
<tr>
<td>Variable Reluctance</td>
</tr>
<tr>
<td>Capacitive</td>
</tr>
<tr>
<td>Eddy Current</td>
</tr>
<tr>
<td>Fiber Optic</td>
</tr>
<tr>
<td>Magnetostrictive</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 16: Value Points and Metrics for Assessing Displacement Transducer Technologies</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cost</strong></td>
</tr>
<tr>
<td><strong>$20 - $50</strong></td>
</tr>
<tr>
<td><strong>$50-$80</strong></td>
</tr>
<tr>
<td><strong>$80-$150</strong></td>
</tr>
<tr>
<td><strong>$150+</strong></td>
</tr>
<tr>
<td><strong>Contact/Non Contact</strong></td>
</tr>
<tr>
<td><strong>Weight &amp; Size</strong></td>
</tr>
<tr>
<td><strong>Very Good</strong></td>
</tr>
<tr>
<td><strong>Fair</strong></td>
</tr>
</tbody>
</table>
U.S. Digital’s linear encoder, the device chosen by the team, costs $178 and is 3.8 in. long by 1.5 in. wide. The device the team chose is the first of the four devices displayed in Figure 55. The resolution of the device is .002 inches and it can measure up to 1 in. of displacement. Our interviews with clinicians indicated that if a person had 1-1.5 inches of edema, they would need immediate attention and an edema assessment device would be irrelevant. Although U.S. Digital’s device cannot measure the full spectrum of edematous patients, its range would be appropriate for an edema measurement device. There are a number of external components that need to be purchased with the encoder. To interpret the signals coming out of the device the manufacturer suggests purchasing an integrated circuit, which costs $12. In addition, an $8 cable is needed to interface with the quadrature output of the device. The team could acquire a device that measures up to 2 in. of displacement; However, the device becomes almost 50% larger, which makes the device unattractive from a size & weight standpoint.

Figure 55: U.S. Digital Linear Encoder

Figure 56 shows a linear encoder manufactured by Solatron Metrology that is very similar to that offered by U.S. Digital. The device is 3 in. long and 1 in. wide. The device makes

---

6 http://www.usdigital.com/products/pe/
contact measurements using a plunger. The range of the device is 1 in. and the resolution is approximately a micron. The resolution of this device is far too precise for the device that our team needs and this is one of the reasons why it was inferior to the U.S. Digital solution. The micron accuracy of the device leads to a cost of $300.

Figure 56: Solatron Metrology Linear Encoder

Figure 57 shows BEI’s linear motion position transducer is slightly larger than U.S. Digital’s linear encoder, 4 in. x 1.5 in. The device comes in three different models, the .5 in., 1.5 in., and 2.5 in. The models represent the range of distance that the device can measure. The .5 in. model is too small for our application and the 1.5 in. model is too large for our application. The device makes contact measurements using the plunger and interfaces to external components using the three metal prongs that protrude from its surface. The three prongs is an awkward setup compared to the compact quadrature output of U.S. Digital’s device. However, the device costs $85, significantly cheaper than the U.S. Digital solution.

Figure 57: BEI linear motion position transducer

Figure 58 is a non-contact capacitive sensor manufactured by Omron, which is 1.34 inches in diameter and has a range of .98 in and a resolution of .2 in. The device comes with a

---

mounting bracket and costs $115. A non-contact solution is ideal for an edema measurement device but a capacitive solution is not.

![Figure 58: Omron capacitive sensor](http://rocky.digikey.com/scripts/ProductInfo.dll?Site=US&V=236&M=E2K-C25ME1)

Schaevitz Sensors sells an LVDT (linear variable differential transformer) solution. The device costs $181 and is displayed in Figure 59. At a first glance, the product is ruled out due to its immense size (10.5 in.). The device measures up to 2 in. of linear movement and makes a contact measurement. The 1 in. device is still very large (6 in.).

![Figure 59: Schaevitz Sensors linear variable differential transformer](http://rocky.digikey.com/scripts/ProductInfo.dll?Site=US&V=356&M=02560546-000)

Honeywell offers a magnetic solution that costs $6.15. The device makes a non-contact measurement using a magnetic field and the dimensions of the device are .2 in. x .15 in. The fault in the device is that it can only measure .3 in. of movement. The concept and size are ideal but the range of measurement could not be found rendering this solution unviable.

14.3.3 Power Requirements Selection

Although the final decision for powering the device is listed in section 4.3.4, several options were considered for power, which are listed in these sections.

---

Nickel Cadmium

The Nickel Cadmium battery (Ni-Cd) is a very popular type of rechargeable battery and has been used extensively in numerous portable electronics and toys. Ni-Cd batteries use nickel hydroxide as the positive electrode and cadmium as the negative electrode. In general, Ni-Cd batteries make use of the metal nickel (Ni) and cadmium (Cd) as the active chemicals. Ni-Cd cells have a nominal voltage of 1.2V, which is lower than the 1.5V of many primary cells. However, Ni-Cd batteries are able to provide a constant voltage through their service life.

Advantages
- Long cycle life
- Inexpensive
- Easy to use
- Suited for high current applications

Disadvantages
- Durability
- Memory effect
- Low energy density
- Low nominal cell voltage

Nickel Metal Hydride

The Nickel Metal Hydride battery (Ni-MH) is a type of rechargeable battery similar to a Nickel Cadmium (Ni-Cd) battery. Ni-MH batteries are manufactured with nickel hydroxide for the positive electrode and hydrogen-absorbing alloys for the negative electrode. Ni-MH batteries have become predominant over Ni-Cd batteries because of their high capacity and insignificant memory effect.

Advantages
- Inexpensive
- Higher capacity than an equivalent size NiCad
- Memory effect is not significant
- Easy to use

Disadvantages
- Low energy density
- Lower cycle life than NiCad
- Low nominal cell voltage
- Higher self-discharging rate than NiCad

Lithium Ion

The Lithium Ion battery (Li-on) is also a type of rechargeable battery. Today, lithium-ion is the fastest growing and most promising battery chemistry. However, Li-on batteries require a protection circuit to maintain safe operation. Lithium ion batteries produce 3.6V, approximately three times the voltage of rechargeable Ni-Cd or Ni-MH batteries. Because of
Its lightness and high energy density, Li-on batteries are excellent for portable electronics devices, such as notebook computers.

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>- No memory effect</td>
<td>- Expensive</td>
</tr>
<tr>
<td>- Light weight and small size</td>
<td>- Lower cycle life than NiCad and NiMH</td>
</tr>
<tr>
<td>- High energy density</td>
<td></td>
</tr>
<tr>
<td>- High nominal cell voltage</td>
<td>- Safety concern</td>
</tr>
<tr>
<td>- Lower self-discharge rate compared to NiCad</td>
<td></td>
</tr>
<tr>
<td>and NiMH</td>
<td></td>
</tr>
</tbody>
</table>
15 APPENDIX D: Device Housing

Our device housing went through several iterations before reaching the final design. These iterations are described in detail in the following appendices.

15.1 Preliminary Housing Designs

The 2007 MQP group brainstormed four different user interfaces, including a modification of 2004 interface. Our preliminary designs included a miniature table that would sit above the patient’s leg, a single cylinder that would indent into the leg, adjustable finger-like grips placed around the patient’s leg, a cuff that would be similar to a blood pressure cuff, and a dual cylinder design similar to that developed by the previous MQP. The Table Design and the Gripper Design were eliminated. A table that summarizes the advantages and disadvantages of each design is provided in Appendix 15.3.

15.1.1 Table Design

The table design implements a miniature, four-legged table with a downward-protruding probe that originates from the center of the surface of the table, as shown in Figure 4.

![Figure 60: Preliminary Housing Table Design](image)

The table design provides outstanding stability for measurement because the clinician would not be holding the device, and would only need to push on the probe with a finger to take the measurement. The table would need to be positioned over the patient’s leg or arm on a parallel surface; thus, the physician would be limited to taking edema assessments on a patient
who was either lying down or who was sitting up with his arm or leg parallel to the floor. Dr. Raymond Dunn indicated in an interview that he performs nearly all of his edema assessments on patients who are sitting upright and whose legs are perpendicular to the floor. In these instances, the physicians would need to adjust the position of the patient’s legs or arms to use the device. Not only would this require a large amount of preparation time to use the device, it might also be uncomfortable for the patient. Therefore, we eliminated the table idea as a convenient means for housing our device.

15.1.2 Grip Design

The grip design consisted of attaching curved, finger-like grips to the probe, as shown in Figure 61. The curved design allows the user to attach the device to an arm or leg despite whether the original position of the leg is horizontal or vertical. The design would also allow for stability for probe measurements because the grips would secure the probing device against the limb. Unfortunately, the grip design was also eliminated because it would limit edema assessment to only the arm or the leg, and may difficult and time-consuming to adjust the curvature of the grips to accommodate limbs of different sizes. In addition, the grips might cause compression of the tissue.

Figure 61: Preliminary Housing Gripper Design
15.1.3 *Cuff Design*

The cuff design consisted of attaching a cuff, similar to a blood pressure cuff, to the probe as shown in Figure 62. The cuff would offer greater stability because the clinician would push on the probe without the need to stabilize the probe solely with his hands. However, there were two serious disadvantages related to the cuff: its inability to be used on different locations on the patient’s body, such as hands or feet, and the possibility of it compressing edematous tissue before the clinician pushes on the probe. In addition, if a clinician wanted to measure the severity of edema on a patient with a venous ulcer on one side of his leg, the clinician would be unable to quantify the edema on the other side of the leg because the cuff would touch the ulcer. In addition, if a patient had edema in his hand or foot, the cuff could be inconvenient to wrap around the hand or foot and would be unstable during measurement. Although the cuff eliminates some user error by maximizing stability, there is increased room for user error if the clinician secures the cuff too tightly on a patient. The cuff could compress edema out of the area being measured and the distance that the probe would measure would be inaccurate.

![Figure 62: Preliminary Housing: Cuff Design](image)

Top diagram shows the cuff and the bottom shows the device when the cuff is closed.
15.2 Device Housing Metrics

Short Manufacturing Time
Objective: Minimize the time to manufacture the housing
Units: Rating the estimated time to manufacture the housing, including machining time, on a scale of 5 (best) to 1 (worst)
Metric: Estimate the amount of time required to manufacture the housing
On a scale from 1-5, assign the following ratings to range of the displacement transducer:
5 – Less than 1 hr
4 – 1-2 hours
3 – 2-3 hours
2 – 3-4 hours
1 – More than 4 hours

Inexpensive
Objective: Minimize the cost of the housing
Units: Rating the estimated cost of the housing on a scale of 5 (best) to 1 (worst)
Metric: Estimate the cost of the housing
5 – Less than $10
4 – $10-$20
3 – $20-$30
2 – $30-40
1 – More than 4 hours

Short Set-Up Time
Objective: Minimize the time required to set up the device before taking the measurement
Units: Rating the estimated time to set up the designs on a scale of 5 (best) to 1 (worst)
Metric: Estimate the time required to set up the device
5 – Less than 5 seconds
4 – 5 sec-10sec
3 – 10sec-30sec
2 – 30sec-1min
1 – More than 1min

Small volume
Objective: Minimize the size of the device
Units: Rating the estimated volume of the designs on a scale of 5 (best) to 1 (worst)
Metric: Estimate the volume of the devices
5 – Less than 0.25ft³
4 – 0.25ft³-0.5ft³
3 – 0.5ft³-0.75ft³
2 – 0.75ft³-1ft³
1 – More than 1ft³

Stable
Objective: eliminate error due to motion of the clinician’s hand or wrist
Units: Rating the estimated percentage of user error that is eliminated by the physical device housing
Metric: Estimate the percentage of user error that is eliminated by the physical device housing
5 – Completely eliminates the error
4 – Eliminates 75%-100% of the error
3 – Eliminates 50%-75% of the error
2 – Eliminates 25%-50% of the error
1 – Eliminates less than 25% of the error

Easy to Interface with Sensors and Probe
Objective: Be easily connected to the displacement transducer, force transducer, and probe
Units: Rating the ability of the housing to interface with the sensors and probe on a scale of 5 (best) to 1 (worst)
Metric: Estimate the amount of time required for the group to interface the device housing with the sensors and probe. This includes machining time.
5 – More than 4 hours
4 – 3-4 hours
3 – 2-3 hours
2 – 1-2 hours
1 – Less than 1 hour

Unlikely for Non-Probe Section to Press on Edema
Objective: to eliminate the possibility that a part of the device that is not the probe will press on the edematous tissue and introduce error into the measurement
Units: Rating the likelihood of the none-probe section to press on the edematous tissue on a scale of 5 (best) to 1 (worst)
Metric: As a percentage, estimate the likelihood that the non-probe section of the housing will press on the edematous tissue. Assume that a medical professional who is unfamiliar with the device will be taking the measurement.
5 – Greater than 50%
4 – 30%-50%
3 – 20%-30%
2 – 10%-20%
1 – Less than 10%

Able to Assess Edema Anywhere on the Body
Objective: Enable clinicians to assess edema on any part of the body.
Units: Rating the ability of clinicians to assess edema on any part of the body on a scale from 5 (best) to 1 (worst), where 5 and 1 are the only options.
Metric: Answer whether the clinician will be able to assess edema anywhere on the body.
5 – Yes
1 – No
## 15.3 Pros and Cons of the Housing Designs

<table>
<thead>
<tr>
<th>Table Design</th>
<th><strong>Pros</strong></th>
<th><strong>Cons</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Can measure edema anywhere on the body</td>
<td>The patient must be lying down</td>
</tr>
<tr>
<td></td>
<td>Eliminates inaccuracy due to motion from the medical professional’s hand or wrist</td>
<td>Long set-up time due to time to align probe and ensure that it is perpendicular to the tissue</td>
</tr>
<tr>
<td></td>
<td>Very easy to interface with probe and transducers</td>
<td>Very easy to interface with probe and transducers</td>
</tr>
<tr>
<td></td>
<td>Easy to manufacture</td>
<td>Easy to manufacture</td>
</tr>
<tr>
<td></td>
<td>Expensive</td>
<td>Expensive</td>
</tr>
<tr>
<td></td>
<td>Large volume and weight</td>
<td>Large volume and weight</td>
</tr>
<tr>
<td></td>
<td>Difficult to manufacture</td>
<td>Difficult to manufacture</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Grip Design</th>
<th><strong>Pros</strong></th>
<th><strong>Cons</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Relatively short set-up time</td>
<td>Unable to conform to legs of different circumferences</td>
</tr>
<tr>
<td></td>
<td>Eliminates inaccuracy due to motion from the medical professional’s hand or wrist</td>
<td>Difficult to manufacture</td>
</tr>
<tr>
<td></td>
<td>Patient can be in any position</td>
<td>Patient can be in any position</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Moderately large volume and weight</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Somewhat difficult to interface with probe and transducers</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cannot measure edema anywhere on the body</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Difficult to manufacture</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cuff Design</th>
<th><strong>Pros</strong></th>
<th><strong>Cons</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Patient can be in any position</td>
<td>Long set-up time</td>
</tr>
<tr>
<td></td>
<td>Eliminates inaccuracy due to motion from the medical professional’s hand or wrist</td>
<td>Difficult to manufacture</td>
</tr>
<tr>
<td></td>
<td>Easy to manufacture</td>
<td>Difficult to manufacture</td>
</tr>
<tr>
<td></td>
<td>Easy to interface with probe and transducers</td>
<td>Difficult to manufacture</td>
</tr>
<tr>
<td></td>
<td>Can measure edema anywhere on the body</td>
<td>Moderately large volume and weight</td>
</tr>
<tr>
<td></td>
<td>Easy to manufacture</td>
<td>Somewhat difficult to interface with probe and transducers</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cannot measure edema anywhere on the body</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Dual-Cylinder Design</th>
<th><strong>Pros</strong></th>
<th><strong>Cons</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Patient can be in any position</td>
<td>Does not eliminate inaccuracy due to motion from the medical professional’s hand or wrist</td>
</tr>
<tr>
<td></td>
<td>Short set-up time</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Easy to interface with probe and transducers</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Can measure edema anywhere on the body</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Easy to manufacture</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Relatively easy to interface with probe and transducers</td>
<td></td>
</tr>
</tbody>
</table>
16 APPENDIX E: Final Design

Materials in this appendix pertain to the final design of our edema measurement device.

16.1 Bill of Materials

The bill of materials in Table 17 represents all reimbursed expenses during the development of this MQP. Some minor expenses for supplies such as tape, screws, glue, and other small items were not included on the bill of materials for reimbursement.

Table 17: Bill of Materials

<table>
<thead>
<tr>
<th>BILL OF MATERIALS</th>
<th>LOCATION/COMPANY</th>
<th>DESCRIPTION</th>
<th>AMOUNT ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2/18</td>
<td>Plastics Unlimited</td>
<td>Delrin</td>
<td>$47.80</td>
</tr>
<tr>
<td>3/24</td>
<td>Radioshack</td>
<td>Battery Holder &amp; Clips</td>
<td>$12.45</td>
</tr>
<tr>
<td>1/18</td>
<td>Radioshack</td>
<td>Project Box, Batteries, Clips</td>
<td>$27.89</td>
</tr>
<tr>
<td>10/31</td>
<td>Foamorder.com</td>
<td>Memory Foam</td>
<td>$68.45</td>
</tr>
<tr>
<td>12/19</td>
<td>Amazon.com</td>
<td>Serial to USB converter</td>
<td>$15.74</td>
</tr>
<tr>
<td>2/7</td>
<td>U.S. Digital</td>
<td>Linear Encoder IC</td>
<td>$27.29</td>
</tr>
<tr>
<td>11/28</td>
<td>U.S. Digital</td>
<td>Linear Encoder</td>
<td>$189.73</td>
</tr>
<tr>
<td>11/28</td>
<td>Measurement Specialties</td>
<td>Load Cells</td>
<td>$140.50</td>
</tr>
<tr>
<td>12/14</td>
<td>U.S. Digital</td>
<td>Linear Encoder Accessories</td>
<td>$49.20</td>
</tr>
<tr>
<td>2/16</td>
<td>Radioshack</td>
<td>Resistors, wires, capacitors</td>
<td>$1.45</td>
</tr>
<tr>
<td>11/12</td>
<td>Price Chopper</td>
<td>Shampoos (Housing bottles)</td>
<td>$19.69</td>
</tr>
<tr>
<td>2/17</td>
<td>Radioshack</td>
<td>Resistors, wires, capacitors</td>
<td>$1.88</td>
</tr>
<tr>
<td>11/10</td>
<td>Linens 'N Things</td>
<td>Memory Foam Mattress</td>
<td>$73.49</td>
</tr>
<tr>
<td>11/17</td>
<td>Price Chopper</td>
<td>Housing containers</td>
<td>$5.49</td>
</tr>
<tr>
<td>12/15</td>
<td>WPI Bookstore</td>
<td>Lab Notebooks</td>
<td>$28.22</td>
</tr>
<tr>
<td>1/8</td>
<td>WPI Bookstore</td>
<td>Lab Notebook</td>
<td>$16.28</td>
</tr>
<tr>
<td>1/20</td>
<td>Home Depot</td>
<td>Plastic Wheel</td>
<td>$6.20</td>
</tr>
<tr>
<td>11/29</td>
<td>Price Chopper</td>
<td>Vegetable Oil, Motor Oil</td>
<td>$11.82</td>
</tr>
<tr>
<td>11/14</td>
<td>Price Chopper</td>
<td>Plastic Wrap, Motor Oil</td>
<td>$13.84</td>
</tr>
<tr>
<td>12/14</td>
<td>Price Chopper</td>
<td>Vegetable Oil</td>
<td>$5.49</td>
</tr>
<tr>
<td>11/29</td>
<td>Price Chopper</td>
<td>Gladware</td>
<td>$2.63</td>
</tr>
<tr>
<td>2/7</td>
<td>Radioshack</td>
<td>Connectors</td>
<td>$4.27</td>
</tr>
<tr>
<td>1/22</td>
<td>WPI ECE Shop</td>
<td>BNC Connector</td>
<td>$1.80</td>
</tr>
<tr>
<td>2/5</td>
<td>Microcontroller Pros Corporation</td>
<td>Microcontroller</td>
<td>$81.90</td>
</tr>
<tr>
<td>11/28</td>
<td>Microcontroller Pros Corporation</td>
<td>Microcontroller &amp; Development Board</td>
<td>$100.90</td>
</tr>
<tr>
<td>4/01</td>
<td>WPI ECE Shop</td>
<td>Single pull single throw on-off rocker switch</td>
<td>$2.00</td>
</tr>
<tr>
<td>4/01</td>
<td>WPI ECE Shop</td>
<td>100k ohm potentiometer</td>
<td>$1.00</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td></td>
<td></td>
<td><strong>$957.40</strong></td>
</tr>
</tbody>
</table>
16.2 Operating Manual

1. Turn the device on by moving the switch into the “on” position. Turn the development board on by attaching the battery pack to the development board. If the LCD on the development board does not display “START,” the development board is off.

2. Place the device in the desired location so that it is resting firmly against the patient’s tissue. Avoid compressing the tissue.

3. When you are ready to take the measurement, press the rightmost button on the display box. Immediately after pressing the rightmost button, the device should display “00000000.”

4. Keeping the device level against the tissue, use your thumb to push the indenter into the patient’s tissue at a constant, reasonably slow rate (depression should take approximately 4 seconds). Make sure that the base of the device remains in contact with the patient’s tissue throughout the measurement. Avoid lifting the device off the patient’s tissue.

5. Continue pushing the indenter further into the patient’s tissue until you hear an audible alarm and the device displays “HOLD.”

6. Hold the device on the patient’s skin until the LCD displays “RELEASE.”

7. Make sure that the base of the device remains in contact with the patient’s skin and remove your thumb from the indenter. Hold the device still until the measurements appear on the display screen. If you moved the device during this period, “INVALID” will appear on the LCD instead of the measurements.

8. To reset the device, press the second leftmost button.

9. Sanitize the base of the device after each use.
16.3 Assembly Drawings for Device

Figure 63: Thumb depressor drawing (CAD)
Figure 64: Device housing drawing (CAD)
Figure 65: tissue probe drawing (CAD)
Figure 67: Device assembly drawing (CAD)
17 APPENDIX F: Modeling Edema

The development of our models changed throughout the course of this project based on interviews with clinicians and interactions with patients who have edema. This section describes the protocols for developing appropriate models for testing.

One of the primary results of the interviews was feedback relative to our edema models. Every person we interviewed indicated that they relied on the depth of pitting to assess the severity of edema. Thus, it was difficult for interviewees to assign different levels to models of the same thickness even though the viscosity varied between models. Dr. Fixler, Nurse Wheelock and Dr. Dunn all indicated that the two models with the lowest viscosities did not feel like biological tissue. The vegetable and motor oil felt similar because their thicknesses were identical and their viscosities were similar.

Based on this assessment, we corrected our models to represent different thicknesses. We saturated the new models with vegetable oil, with thicknesses ranging from 0.25 inch to 1.25 inches. Melissa Blatt assessed the models and was able to assign different severity levels to each model based on the thickness and depth of pitting.

17.1 Final Protocol for Model Fabrication

Supplies

High Density Viscoelastic Memory Foam
   Brand: Homedics
   Name: Thera P Memory Foam Mattress Topper
   Model #: TPT-T
   Store: Linens N Things
   Cost: $69.99
   Size: twin
   Material: 100% viscoelastic polyurethane foam
   Thickness: 1.25”

Tupperware Soaking Containers
   • Five 25oz GLAD plastic storage containers with interlocking lids
   • Dimensions: ~5” x ~5” x ~1.5”
   • Shape: square with rounded edges

Vegetable Oil (~34.6cP)\textsuperscript{11}

\textsuperscript{11} http://www.engineeringtoolbox.com/dynamic-absolute-kinematic-viscosity-d_412.html
Foam Preparation

1) Cut three 4” x 4” pieces of memory foam from the mattress topper. When they are initially cut from the mattress topper, their thickness is 1.25”
2) Cut one piece of memory foam into two pieces. The first piece should be 4”x4”x0.50,” and the second piece should be 4”x4”x0.75.” This can be done by using a band saw.
3) Cut another piece of memory foam into two pieces. The first piece should be 4”x4”x0.25,” and the second piece should be 4”x4”x1.”
4) Place one piece of memory foam into each of the five containers.
5) Pour vegetable oil into each container. Submerge the memory foam in the liquid, pressing out all of the air. Repeat until the memory foam is completely saturated. The foam should not float in the liquid.
6) Ensure that the top of each piece of saturated memory foam is no more than a couple of millimeters below the vegetable oil.
7) Cover each container.
8) Wait between four and six hours before testing the memory foam.
9) Immediately before testing, ensure that the memory foam is saturated.

17.2 Initial Protocol for Model Fabrication

Supplies

Viscoelastic Memory Foam
- Brand: Homedics
- Name: Thera P memory foam mattress topper
- Price: $69.99
- Model #: TPT-T
- Store: Linens N Things
- Size: Twin
- Color: White
- Thickness: 1.5”

Tupperware Soaking and Testing Containers
- 4 plastic containers
- Brand: Glad
- Size: 25oz

Saran Wrap

Liquid Substances of Varying Viscosity
- Water (1 cP)
- Vegetable oil (34.6cP) (http://www.engineeringtoolbox.com/dynamic-absolute-kinematic-viscosity-d_412.html)
- Master of Mixes: Piña Colada (viscosity unknown)
Foam Preparation

1. Cut foam into four 4”x4” squares
2. Pour the four liquids into the four containers until the containers are half-full.
3. Place one square of memory foam into each container.
4. Saturate memory foam with liquid by squeezing and releasing the memory foam while it is submerged in the liquid.
5. Add more liquid into each container until the containers are approximately ¾ filled.
6. Repeat the saturation process by squeezing and releasing the memory foam while submerged in the liquid. If the memory foam is no longer floating in the liquid, it is saturated.
7. Cover each container with a lid.
8. Wait approximately 6 hours before testing.
Testing the output of the device was necessary for verifying that it provided accurate and repeatable measurements. The following appendices provide a summary of protocol to be used for a thorough assessment of device function.

18.1 Foam Testing Protocol

** Protocol altered in this step

During experimentation:

1. Take notes of any problems, inconveniences, quirks, or difficulties you have in measuring and any “special” positions, tweaks, or adjustments you feel yourself making to compensate for a “good” measurement.
2. Do additional testing in areas that problems arise. See if you can fix a problem through troubleshooting, and observe and note what ways you might be able to fix these problems (even minor ones).
3. Try to keep everything consistent except the variable you are trying to measure.
4. Make note of any modifications you make to the protocols.

Test Measurement of distance:

1. Use 4 pieces of foam at 0.25 in, 0.5 in, 0.75 in, 1 in and 1.25 inches of thickness
2. Place foam on table (in container if vegetable oil).
3. Hold device on foam surface. Be sure probe is flush with casing. Try not to compress the foam.
4. Depress probe slowly into foam until you cannot press anymore. Do not worry about “pain threshold” or anything. Do your best NOT to lift up on the casing while taking the measurement. Check distance reading and record.
5. Repeat 3 times on each thickness of foam.
6. Change person doing the testing and repeat. If there is someone you can snag who knows nothing about our project, have him or her do it a third time.
7. Check calculations to see if distance corresponds to the expected thickness of the foam.

Test Measurement of distance with lifting up:

8. Use 4 pieces of foam at 0.25 in, 0.5 in, 0.75 in, 1 in and 1.25 inches of thickness
9. Place foam on table (in container if vegetable oil).
10. Hold device on foam surface. Be sure probe is flush with casing. Try not to compress the foam.
11. **Depress probe slowly into foam until you cannot press anymore. Do not worry about “pain threshold” or anything. While depressing foam, lift casing approximately 0.25 inches (not in contact with tissue). Use ruler to estimate. Check distance reading and record.
12. Repeat 3 times on each thickness of foam.
13. **Repeat test but lift casing ~0.5 inches. Use ruler to estimate.
14. Change person doing the testing and repeat. If there is someone you can snag who knows nothing about our project, have him or her do it a third time.
15. Check calculations to see if distance corresponds to the expected thickness of the foam.

Test Measurement of distance with poor contact:
16. Use 4 pieces of foam at 0.25 in, 0.5 in, 0.75 in, 1 in and 1.25 inches of thickness
17. Place foam on table (in container if vegetable oil).
18. **Hold device above foam surface (hand in contact with foam but device is NOT in contact by ~0.25 inches). Try not to compress the foam (with your hand).
19. **Depress probe slowly into foam until you cannot press anymore. Do not worry about “pain threshold” or anything. Do your best NOT to lift up on the casing while taking the measurement, and try to maintain the device NOT in contact with the foam. Check distance reading and record.
20. Repeat 3 times on each thickness of foam.
21. Change person doing the testing and repeat. If there is someone you can snag who knows nothing about our project, have him or her do it a third time.
22. Check calculations to see if distance corresponds to the expected thickness of the foam.

Test Measurement of distance with an angle:
23. Use 4 pieces of foam at 0.25 in, 0.5 in, 0.75 in, 1 in and 1.25 inches of thickness
24. Place foam on table (in container if vegetable oil).
25. **Hold device on foam surface. Tilt device to only one side is in contact with the foam and the device is at approximately a 20-40 degree angle. Try not to compress the foam.
26. **Depress probe slowly into foam until you cannot press anymore. Do not worry about “pain threshold” or anything. Do not move the housing to compensate for where of how the probe exits, just keep device at an angle. Check distance reading and record.
27. Repeat 3 times on each thickness of foam.
28. Change person doing the testing and repeat. If there is someone you can snag who knows nothing about our project, have him or her do it a third time.
29. Check calculations to see if distance corresponds to the expected thickness of the foam.
30. → Note: In this case, the measurements might seem accurate for larger thicknesses (i.e. the linear encoder says 1 inch, but the probe did not necessarily enter the foam for a full inch. If the foam is truly 1 inch, we will not be able to tell whether the encoder measured “correctly” or whether the device angling did affect it. We can only tell if the measurements for distance are greater than they should be i.e. measuring 0.75 inches for a 0.5-inch foam.

Test Measurement of distance with compression:
31. Use 4 pieces of foam at 0.25 in, 0.5 in, 0.75 in, 1 in and 1.25 inches of thickness
32. Place foam on table (in container if vegetable oil).
33. **Hold device on foam surface. Be sure probe is flush with casing. Compress the device into the foam “a little.” Just try to hold the device “firm” against the tissue, feeling that you are compressing into the foam.

34. Depress probe slowly into foam until you cannot press anymore. Do not worry about “pain threshold” or anything. Do your best NOT to lift up on the casing while taking the measurement. Check distance reading and record.

35. Repeat 3 times on each thickness of foam.

36. **Repeat measurement pressing into the foam with the device as much as possible.

37. Change person doing the testing and repeat. If there is someone you can snag who knows nothing about our project, have him or her do it a third time.

38. Check calculations to see if distance corresponds to the expected thickness of the foam.

Test Measurement of distance with a fast depression rate:

39. Use 4 pieces of foam at 0.25 in, 0.5 in, 0.75 in, 1 in and 1.25 inches of thickness

40. Place foam on table (in container if vegetable oil).

41. Hold device on foam surface. Be sure probe is flush with casing. Try not to compress the foam.

42. *Depress probe as fast as you can into the foam and stop when you feel you have reached the end. Do not worry about “pain threshold” or anything. Do your best NOT to lift up on the casing while taking the measurement. Check distance reading and record.

43. Repeat 3 times on each thickness of foam.

44. Change person doing the testing and repeat. If there is someone you can snag who knows nothing about our project, have him or her do it a third time.

45. Check calculations to see if distance corresponds to the expected thickness of the foam.

46. ➔ In this experiment, I assumed that all of the other tests were done at a “slow” rate, so this test does not need to be repeated for a “slow” rate. (See test #1)

47. ➔ Also note observations: What affect does depressing fast seem to have? Did you notice yourself lifting up when you reached the end, and could you control that at all?

Test Measurement of distance while moving device:

48. Use 4 pieces of foam at 0.25 in, 0.5 in, 0.75 in, 1 in and 1.25 inches of thickness

49. Place foam on table (in container if vegetable oil).

50. Hold device on foam surface. Be sure probe is flush with casing. Try not to compress the foam.

51. **Depress probe slowly into foam until you cannot press anymore, but while pressing rock the device back and forth slowly a small amount >20 degree angle. Do not worry about “pain threshold” or anything. Do your best NOT to lift up on the casing while taking the measurement. Check distance reading and record.

52. Repeat 3 times on each thickness of foam.

53. Change person doing the testing and repeat. If there is someone you can snag who knows nothing about our project, have him or her do it a third time.
54. Check calculations to see if distance corresponds to the expected thickness of the foam.

Test Measurement of distance **while lifting thumb:**

55. Use 4 pieces of foam at 0.25 in, 0.5 in, 0.75 in, 1 in and 1.25 inches of thickness
56. Place foam on table (in container if vegetable oil).
57. Hold device on foam surface. Be sure probe is flush with casing. Try not to compress the foam.
58. **Depress probe slowly into foam until you cannot press anymore. Do not worry about “pain threshold” or anything. Do your best NOT to lift up on the casing while taking the measurement. Halfway through measurement, lift thumb off depressor, then continue pressing to end. Check distance reading and record.**
59. Repeat 3 times on each thickness of foam.
60. Change person doing the testing and repeat. If there is someone you can snag who knows nothing about our project, have him or her do it a third time.
61. Check calculations to see if distance corresponds to the expected thickness of the foam.
62. \( \rightarrow \) Note you may want to repeat this experiment lifting the thumb off by different amounts depending on how it affects the measurement.

Test Measurement of distance **with shaking:** (this may be best done with dry foam)

63. Use 4 pieces of foam at 0.25 in, 0.5 in, 0.75 in, 1 in and 1.25 inches of thickness
64. Place foam on table (in container if vegetable oil).
65. Hold device on foam surface. Be sure probe is flush with casing. Try not to compress the foam.
66. **Depress probe slowly into foam until you cannot press anymore, but while pressing, have someone shake or wiggle the container with the foam. Do not worry about “pain threshold” or anything. Do your best NOT to lift up on the casing while taking the measurement. Check distance reading and record.**
67. Repeat 3 times on each thickness of foam.
68. Change person doing the testing and repeat. If there is someone you can snag who knows nothing about our project, have him or her do it a third time.
69. Check calculations to see if distance corresponds to the expected thickness of the foam.

Test Measurement of distance with **correct positioning:** (can only be done with dry foam)

70. **Use 4 pieces of DRY foam at 0.25 in, 0.5 in, 0.75 in, 1 in and 1.25 inches of thickness.
71. **Tape foam pieces to someone’s leg near tibia.
72. Hold device on foam surface. Be sure probe is flush with casing. Try not to compress the foam.
73. **Depress probe into foam until you cannot press anymore. Let the “patient” tell you if they are hurting, but otherwise press as far as you can. Do your best NOT to lift up on the casing while taking the measurement. Check distance reading and record.**
74. Repeat 3 times on each thickness of foam.
75. Change person doing the testing and repeat. If there is someone you can snag who knows nothing about our project, have him or her do it a third time.
76. Check calculations to see if distance corresponds to the expected thickness of the foam.
77. **Make note of any positioning issues you come across: Is it easy to hold and complete the measurement at that position? Are you having trouble holding the device flush with the foam or is there a gap? Are you holding it at an angle? Is the device torqueing or twisting as you press?

Testing summary ideas (only a few):
1. What errors affect an accurate distance measurement the most?
2. What error affected low levels of edema? Were any that affected the accuracy of higher levels of edema?
3. What were the greatest difficulties you encountered while measuring?
4. If there are errors in these measurements, are they consistent (like nose or bias that can be subtracted) or are they random and unpredictable.
5. What are recommendations for future improvement?

18.2 Clinical Testing Protocol

Stage I

Purpose
To demonstrate the efficacy of the device in differentiating between areas of pitting and non-pitting, as well as reproducibility and repeatability of the measurement as reflected in small standard deviations (SD’s) for sets of measurements.
To determine the convenience, comfort and adaptability of the device in a medical setting.

Procedure
Clinicians perform 3 edema assessments within the same vicinity on a patient’s edematous tissue using the device*. The examiners then conduct the same number of assessments on a healthy portion of the patient’s tissue using the device.
Observe and record the clinicians’ usage of the device to determine the extent to which the device is intuitive and easy to use. Researchers should ask all clinicians a set of interview questions pertaining to the comfort and convenience of the device and record responses.

Data Analysis
Analyze data for individual clinicians and among different clinicians, calculating standard deviations and means separately for edematous and healthy tissue measurements. Perform statistical analyses of data sets for each clinician. Group observations and feedback from clinicians into positive and negative feedback to develop future suggestions for device design.

**Interpretation**

SD’s for each individual user should be small, indicating that the device can provide repeatable results for one user. In addition, a statistical analysis of the difference among clinicians should reveal that they are not statistically significant, meaning that the device also provides reproducible measurements among different clinicians. The mean return times for edematous and normal tissue should be significantly different, given the different return times expected from the different tissues.

* Note that pitting resulting from prior assessments may affect subsequent measurements. Thus, we recommended that the user leave sufficient time between measurements to allow the tissue to return to its normal condition.
APPENDIX H: Microcontroller Code

The code enabled us to write our own data collection algorithm for the microprocessor. The following appendices include the schematic for the MSP430, instructions for logging data in hyperterminal and the code.

19.1 Schematic for the MSP430-449STK2 Development

These schematics were obtained from the Olimex website: [http://olimex.com/dev/pdf/msp430-449stk2-a.PDF](http://olimex.com/dev/pdf/msp430-449stk2-a.PDF). This website contains the complete schematic for the MSP430-449STK2 development board.

![Figure 68: Pins on EXT](image1)

![Figure 69: Pins on AEXT](image2)

![Figure 70: Buttons on development board](image3)
19.2 Logging Data in HyperTerminal

1) Connect the TI MSP430 to the PC by using a serial cable.
2) Go to Start All Programs → Accessories → Communications → HyperTerminal.
3) Type anything for “Name.” Click OK.
4) Connect using COM1. Click OK.
5) For the port settings, set “bits per second” to 9600, “data bits” to 8, “parity” to “none,” “stop bits” to 1, and “flow control” to “none.” Click OK.
6) Open IAR Kickstart and datalogging.c. Click on “Debug,” and then on “Go.” You should see a menu on the LCD of the microcontroller.
7) Press Button A to log data. As soon as you press A, you should see data in HyperTerminal.
8) When you have finished, press Button C. The data should have stopped transferring into HyperTerminal.
9) In HyperTerminal, go to Transfer → Capture Text.
10) Name the file and save it as a “.xls”
11) Open Excel and select the file you want to open.
19.3 Code for Data Logging Program

```c
#include "msp430x44x.h"      // Definitions, constants, etc for msp430F449
#include <string.h>
#include <stdio.h>
#include <stdlib.h>
#include <math.h>
#include <in430.h>

void init_sys(void);                  // MSP430 Initialization routine
void swDelay(unsigned int max_cnt);   // simple SW delay loop
void clearLCD(void);                  // Clears LCD memory segments so that LCD is blank
void initLCD(void);                   // Setup code to interface LCD with MSP430F449
void writeLetter(int position,char letter);  // display single character on LCD
void writeWord(const char *word);    // displays words upto 7 chars on LCD. Can also display numbers passed as text
void buzzerOn(void);    // turns buzzer on
void buzzerOff(void);   // turns buzzer off

char *LCD = LCDMEM;          // pointer to LCD Memory Segments

// From Muneeb Shahriar's LCD driver code from Olimex.com
#define     a      (0x80)    // definitions for LCD segments on the Olimex LCD. 4-Mux operation is assumed
#define     b      (0x40)    // For more details on 4-Mux operation, gather your LCD datasheet,
#define     c      (0x20)    // TI's MSP430F449 User Guide (look for LCD Controller, then 4-Mux),
#define     d      (0x01)    // and MSP-449STK-2 schematic. You will need ALL these 3 when defining
#define     e      (0x02)    // each number or character. Remember, the Olimex LCD doesn't use a LCD driver!
#define     f      (0x08)    // You tell the LCD what characters to display. It's very time consuming!!
#define     g      (0x04)
#define     h      (0x10)

void brsDelay(unsigned int delay); // software delay
void clearFlash(void);  // clears the flash
void SendData(void);  // sends data from MSP430 to PC
void RS232_OUT(unsigned char* pointer); // send data out from microcontroller
void RS232_INIT(void); // initialization routines for RS232
```

---

167
void RS232_OUT_CHAR(unsigned char letter);  // send a character out
void flash_write(unsigned int sample);
void Datalog(void); // log data
void getForce(void); // get the force
void setUpDistPins(void); // set up pins used for counting
void writeNum(long int timerTemp); // converts an int to ASCII
void clearFlash(void);  // clears flash
void config_timerA(void); // sets up timer A
void scrollWord(char string[]); // scrolls words on LCD

/***************************** datalogging.c Globals ***************************/
unsigned char RS232_RX_BUFFER[256]; // buffer to send to computer
unsigned char flash_full=1; // indicates when flash is full
unsigned char *RS232_RX_WRITE_POINTER;
unsigned char *RS232_RX_READ_POINTER;
unsigned int *data_pointer = (unsigned int*)0xFdff;
unsigned int *data_read = (unsigned int*)0xFdff;
long int timer;  // counts ms
long int timera;  // counts ms too
char LCDarray[7];  // array to print on LCD
int dist=0; // distance
int force=0;  // force

/******************** MAIN FUNCTION ********************
void main(void)
{
  /* The following functions are part of initializing the program */
  WDTCTL = WDTPW + WDTHOLD;   // Stop watchdog timer
  init_sys();                 // Initialize the MSP430
  setUpDistPins();            // Set up the pins for measuring displacement
  config_timerA();
  _BIS_SR(GIE);               // enable interrupts

  /* The menu scrolls through and allows the user to log data, erase flash,
  or dump the logged data into the computer*/
  while(1) // loop forever in here
  {
    scrollWord("       A LOG DATA       B ERASE FLASH       C DUMP LOGGED DATA       ");

    /* If button A is pressed, log data */
    if(P3IN==0xe0) // if button A is pressed
    {
      writeWord("LOG DAT");
      while(P3IN !=0xF0){} // wait for the user to let go of the button
      Datalog(); // log data. The user pushes the probe into the foam and the
      // program records the distance and force
      writeWord("DONE"); // When the user has finished logging data, write “DONE”
      while(P3IN !=0xF0){} // Wait for the user to press another button
    }

    /* If button B is pressed, erase the contents in flash*/
    if(P3IN==0xd0) // if button B is pressed
    {
      while(P3IN !=0xF0){} // wait for user to release
      scrollWord("    TO ERASE FLASH. PRESS B      ");
      while(P3IN ==0xF0){} // get out of this loop when the user presses another button
      // CALL FUNCTION
      if (P3IN==0xd0) // if the user presses B again
      { // clearFlash();
        clearFlash();
        scrollWord("       FLASH EMPTY       ");
      }
      else // if a button other than B is pressed
      {
        scrollWord("      FLASH ERASE ABORTED      ");
      }
    }

    while(P3IN !=0xF0){} // wait for the user to press another button
}
/* If button C is pressed, dump the data from flash to the computer*/
if(P3IN==0xB0) // if button C is pressed
{
while(P3IN !=0xF0){} // wait for user to release button
scrollWord("TELL YOUR TERMINAL TO SAVE THE FILE AND THEN PRESS ANY KEY");
while(P3IN ==0xF0){} // wait for the user to press any button
while(P3IN !=0xF0){} // wait for the user to let go of the button
SendData();
while(P3IN !=0xF0){} // wait for the user to press any button
}
}

/**************************************************************/
/********************** setUpDistPins() **************************/
/**************************************************************/
/* This function configures P1.6 and P1.7 to get information from
the linear encoder */
void setUpDistPins(void)
{
P1DIR &= ~(BIT7|BIT6);    // P1.7-6 are inputs, so they are set to 0
P1SEL &= ~(BIT7|BIT6);    // P1.7-6 are I/O, so they are set to 0

// Enable interrupts on P1.7, which will be the counted signal
P1IE = 0x80;   // enable interrupt on P1.7, which is Pin 9 on EXT
P1IES = 0x00;  // generate interrupt on rising edge
P1IFG = 0x00;  // clear interrupt flag
}

/**************************************************************/
/********************** config_timerA() ****************************/ 
/**************************************************************/
/* This function configures timer A so that it fires an
interrupt every 20ms */
void config_timerA(void)
{
TACTL = TASSEL_1 + CNTL_0 + MC_1 + ID_0; // ACLK 16 BIT, UP MODE, DIV=1
TACCR0 = 655; // fire an interrupt every 20ms
TACCTL0 = CCIE; // ENABLE INTURPTS
}

/**************************************************************/
//************************************************************/ 
//************************* ISR for counting *****************/ 
//************************************************************/
/* This ISR fires off whenever there is a rising edge
on P1.7 */
#pragma vector = PORT1_VECTOR
__interrupt void P1count(void)
{
if(P1IN & 0x40) // if Channel B on P1.6 is high, increment dist
{
dist--;
}
else // if Channel B on P1.6 is low, decrement dist
{
dist++;
}
P1IFG = 0x00; // clear interrupt flag. If not, it will keep firing
}

/**************************************************************/
//************************************************************/ 
//************************* ISR for timer A ************************/ 
//************************************************************/
/* This ISR fires off every 20ms, during which the timera
is incremented.*/
#pragma vector = TIMERA0_VECTOR  // sets location
__interrupt void Timer_A0(void)
{
timera++;
_BIS_SR(LPM0_EXIT+GIE);
return;
}

/*********************************************************/
/**************** writeNum() *****************************/
/*********************************************************/
/* This function converts an integer to an ASCII character
so it can be written to the LCD */
void writeNum(long int toPrint)
{
  long int pows[] = {1, 10, 100, 1000, 10000, 100000}; // lookup table
  int i=6; // counter
  long int power;
  LCDarray[7] = 0;
  for(i=6; i>0; i--)
  {
    power=pows[i-1];
    LCDarray[6-i] = toPrint/power + '0';
    toPrint = toPrint % power;
  }
}

/*************************************************************/
/************************** getForce() **********************/
/*************************************************************/
/* This function gets the force from the ADC and converts it
to a number between 0 and 4095. It is heavily based on the code
from "Embedded Systems Design Using the Ti Map430 Series" by Chris Nagy */
void getForce()
{
  ADC12CTL0 = SHT0_6 + SHT1_6 + REFON + REF2_5V + ADC12ON;
  ADC12CTL1 = SHP;
  ADC12MCTL0 = INCH_7 + SREF_1;
  ADC12CTL0 |= ADC12SC + ENC;
  P6SEL |= 0x01; // Always P6 because ADC is tied to P6. We are using P6.7
  // Stick-up thing on AEXT labeled "1" corresponds to Pin 7
  while (ADC12CTL1 & 0x80); // 1000 0000, where the 1 corresponds to Pin 7
  force = ADC12MEM0 & 0x00000fff; // OUTPUTS LEVEL BETWEEN 0 AND 4095
}

/*************************************************************/
**********             datalogging.c functions               **********
/*************************************************************/
*************  ISR for Alex Camilo's Circular Serial Buffer  *****************/
/* Write and read data in a circular motion. Stores data until
you can actually read it. */
#pragma vector=UART1RX_VECTOR
__interrupt void usart1_rx(void) // Fires off when 430 receives a byte from UART1
  //, which is connected to the serial port.
  // In other words, fires off whenever the 430
  // receives a byte over the serial port
  // This is an unused function, but it's here
  // for expandability. It came with the others.
{
  *RS232_RX_WRITE_POINTER=*RXBUF1;
  if (RS232_RX_WRITE_POINTER==&RS232_RX_BUFFER[255]) // if we've reached the end of the buffer
  {
    RS232_RX_WRITE_POINTER=&RS232_RX_BUFFER[0]; // then loop back to the beginning of the buffer
  }
  else
  {
    RS232_RX_WRITE_POINTER++; // otherwise, keep going until we reach the end.
  }
}
/* This function sends a string over the serial port */
void RS232_OUT(unsigned char* pointer)
{
    int i=0;
    while(pointer[i]) // loops through the buffer
    {
        while (!(IFG2 & UTXIFG1));    // USART1 TX buffer ready?
            TXBUF1= pointer[i];
        i++;
    }
}

/* This function writes data to flash */
void flash_write(unsigned int sample)
{
    // write to flash
    if (*data_pointer==0xffFF) // if the value in the memory location is FFFF, it’s
        // empty, so you can write to it
    {
        flash_full=1;
        *data_pointer = sample;
        while (FCTL3 & BUSY){}
        data_pointer--; // decrement the data pointer
    }
    else
    {
        flash_full=0; // flash is full
    }
}

/* This function sends a byte over the serial port */
void RS232_OUT_CHAR(unsigned char letter)
{
    while (!(IFG2 & UTXIFG1)); // USART1 TX buffer ready?
        TXBUF1= letter; // put the letter into the buffer
}
/** Scroll a word across the LCD */
void scrollWord(char word[])
{
    // wait for them to let go of whatever key they are pressing
    while(P3IN != 0xF0){};
    // s is the 'slice' string
    // get the length of our message
    int len=strlen(word);
    // the place to stop slicing. (slice is 7 long. any more and we would be including memory
    // locations that are not part of our string.)
    int max=len-6;
    // start display loop
    // take a slice, display, shift slicing box to the right... repeat.
    for(int i=0; i<max; i++)
    {
        clearLCD();
        // display our slice
        for(int j=1; j<8; j++)
        {
            // write our 7 chars to the LCD display
            // -6 so it's not displayed on the LCD screen backwards.
            // screen goes from right to left. we read from left to right.
            writeLetter(j,word[(6-(j-1))+i]);
            if(P3IN != 0xF0)
            {
                clearLCD();
                return;
            }
        }
        // delay before writing the next slice (so organic life forms can read the message)
        brsDelay(2000);
    }
}

/************************************************************************
******************************* brsDelay ********************************/
/*************************************************************************
void brsDelay(unsigned int delay) // like swDelay, but briefer
{
    int i=1;
    for(int j=0; j<delay; j++)
    {
        for(int k=0; k<10; k++)
        {
            while(i>0)
            {
                i++;
            }
        }
    }
}

/*************************************************************************
******************************** clearFlash() ******************************/
/***************************************************************************/
/* This function clears flash. It was adapted from "Embedded Systems Design
Using the Ti Msp430 Series" by Chris Nagy */
void clearFlash(void)
{
    char *ptr = (char*)0xfdff;
    while ((ptr++)[0x2000]) // iterate through sectors in memory
    {
        FCTL2=FWKEY + FSSEL_1 + 12; // set up timing generator for MCLK and a clock divisor of 12
        FCTL3=FWKEY;
        FCTL1=FWKEY + ERASE;
        *ptr=0xFF;
        ptr=ptr-512;
        while(FCTL3&0x001){}; // wait for BUSY flag to clear
    }
}
writeNum(((unsigned int)ptr/512)-20);
writeWord(LCDarray);
}
data_read = (unsigned int*)0xFdff; // reset pointer
return;
}
**************************************************************************
***************************** Datalog() **********************************
**************************************************************************
/* This function logs data */
void Datalog(void)
{
while(flash_full==1 && P3IN == 0xF0) // this while loop gets run at the sampling rate
{
    writeNum(((unsigned int)data_read/512)-20);
    writeWord(LCDarray);
    getForce();
    flash_write(force);
    flash_write(dist);
    writeNum(dist);
    writeNum(*data_read);
    data_read--;
    RS232_OUT_CHAR(0x09);
    writeNum(*data_read);
    RS232_OUT_LCDarray();
    data_read--;
    RS232_OUT_CHAR(0x0d);
    RS232_OUT_CHAR(0x0a);
    _BIS_SR(LPM0_bits + GIE); // go to sleep. Acts like a delay
    // Makes the sampling rate constant.
    // If you didn't have this, it would sample at a
    // rate that's not constant. It would be as fast
    // as the chip could go.
}
}
**************************************************************************
************************************** SendData() **************************
**************************************************************************
/* This function sends data from the microcontroller to the computer */
void SendData(void)
{
data_read=(unsigned int*)0XFdff;
while(data_read != data_pointer)
{
    writeNum(*data_read);
    RS232_OUT_LCDarray();
    data_read--;
    RS232_OUT_CHAR(0x09);
    writeNum(*data_read);
    RS232_OUT_LCDarray();
    data_read--;
    RS232_OUT_CHAR(0x0d);
    RS232_OUT_CHAR(0x0a);
}
/******** The following are from demo.c by Jose Brache********/

void initSys(void)
{
    initLCD();  // Setup LCD for work
    clearLCD();  // Clear LCD display
    RS232_INIT();
}

void swDelay(unsigned int max_cnt)
{
    unsigned int cnt1 = 0, cnt2;
    while (cnt1 < max_cnt)
    {
        cnt2 = 0;
        while (cnt2 < 65535)
            cnt2++;
        cnt1++;
    }
}

void initLCD(void)   // initialize the various registers for LCD to work
{
    // (code obtained from sample demos of MSP430F449)
    // Initialize LCD driver (4Mux mode)
    LCDCTL = LCDSG0_7 + LCD4MUX + LCDON; // 4mux LCD, segs16-23 = outputs
    BTCTL  = BT_fLCD_DIV128;             // set LCD frame freq = ACLK
    P5SEL  = 0xFC;                       // set Rxx and COM pins for LCD
}

void clearLCD(void) // makes the LCD blank
{
    unsigned int iLCD;
    for (iLCD =0; iLCD<20; iLCD++)  // clears all 20 LCD memory segments
    {
        LCD[iLCD] = 0;
    }
}

void writeLetter(int position,char letter) // writes single character on the LCD.
{
    // DO NOT PLAY WITH THE CODE BELOW -----------------------------------------
    if (position == 1)  // this is position adjustment for compatibility
        position = position + 6;
    else
        if ( (position > 1) &  (position < 8) )
            position = ((position * 2) - 1) + 6;  // adjust position
    switch(letter)
case 'A': LCD[position-1] = a + b + c + e; LCD[position] = b + c + g;
break;
case 'B': LCD[position-1] = c + h + e; LCD[position] = b + c + g;
break;
case 'C': LCD[position-1] = a + h; LCD[position] = b + c;
break;
case 'D': LCD[position-1] = b + c + h + e; LCD[position] = c + g;
break;
case 'E': LCD[position-1] = a + h + e; LCD[position] = b + c + g;
break;
case 'F': LCD[position-1] = a; LCD[position] = b + c + g;
break;
case 'G': LCD[position-1] = a + c + h + e; LCD[position] = b + c;
break;
case 'H': LCD[position-1] = b + c + e; LCD[position] = b + c + g;
break;
case 'I': LCD[position-1] = a + h + f; LCD[position] = d;
break;
case 'J': LCD[position-1] = b + h + c; LCD[position] = c;
break;
case 'K': LCD[position-1] = d + g; LCD[position] = b + c + g;
break;
case 'L': LCD[position-1] = h; LCD[position] = b + c;
break;
case 'M': LCD[position-1] = b + c + g; LCD[position] = b + c + f;
break;
case 'N': LCD[position-1] = b + c + d; LCD[position] = b + c + f;
break;
case 'O': LCD[position-1] = a + b + c + h; LCD[position] = b + c;
break;
case 'P': LCD[position-1] = a + b + e; LCD[position] = b + c + g;
break;
case 'Q': LCD[position-1] = a + b + c + h + d; LCD[position] = b + c;
break;
case 'R': LCD[position-1] = a + b + d + e; LCD[position] = b + c + g;
break;
case 'S': LCD[position-1] = a + c + h + e; LCD[position] = b + g;
break;
case 'T': LCD[position-1] = a + f + b; LCD[position] = d + b;
break;
case 'U': LCD[position-1] = b + c + h; LCD[position] = b + c;
break;
case 'V': LCD[position-1] = g; LCD[position] = b + c + e;
break;
case 'W': LCD[position-1] = b + c + d; LCD[position] = b + c + e;
break;
case 'X': LCD[position-1] = d + g; LCD[position] = e + f;
break;
case 'Y': LCD[position-1] = b + c + h + e; LCD[position] = f;
break;
case 'Z': LCD[position-1] = a + h + g; LCD[position] = e;
break;

END

// number // LCDM7

case '0': LCD[position-1] = a + b + c + h; LCD[position] = b + c;
break;
case '1': LCD[position-1] = b + c; LCD[position] = d & a;
break;
case '2': LCD[position-1] = a + b + e + h; LCD[position] = c + g;
break;
case '3': LCD[position-1] = a + b + c + e + h; LCD[position] = g;
break;
case '4': LCD[position-1] = b + c + e; LCD[position] = b + g;
break;
case '5': LCD[position-1] = a + c + h + e; LCD[position] = b + g;
break;
case '6': LCD[position-1] = a + c + h + e; LCD[position] = b + c + g;
break;
case '7':  LCD[position-1] = a + b + c;          LCD[position] = d & a;
break;
   case '8':  LCD[position-1] = a + b + c + e + h;  LCD[position] = b + c + g;
break;
   case '9':  LCD[position-1] = a + b + c + e ;     LCD[position] = b + g;
break;
   // others
   case '.':                                        LCD[position] = h;
break;  // decimal point
   case '^':                                        LCDM2 = c;
break;  // top arrow
   case '!':                                        LCDM2 = a;
break;  // bottom arrow
   case '>':                                        LCDM2 = b;
break;  // right arrow
   case '<':                                       LCDM2 = h;
break;  // left arrow
   case '+':                                        LCDM20= a;
break;  // plus sign
   case '-':                                        LCDM20= h;
break;  // minus sign
   case '&':                                        LCDM2 = d;
break;  // zero battery
   case '*':                                        LCDM2 = d + f;
break;  // low battery
   case '(':                                        LCDM2 = d + f + g;
break;  // medium battery
   case ')':                                        LCDM2 = d + e + f + g;
break;  // full battery */
 }

// **************************** writeWord *****************************
void writeWord(const char *word)  // displays a word upto 7 characters -- why 7?
// words must be in upper case (why?){
   unsigned int strLength = 0;   // variable to store length of word
   unsigned int i;               // dummy variable
   strLength = strlen(word);     // get the length of word now
   for (i = 1; i <= strLength; i++) // display word
   {
       writeLetter(strLength - i + 1,word[i-1]);  // displays each letter in the word
   }
}

// buzzerOn() ******************
void buzzerOn(void){
   FLL_CTL0 |= XCAP10PF;                 // Configure load caps
   P1DIR |= BIT2|BIT0;                   // P1.2,0 output
   P1SEL &= ~BIT2;                       // P1.2 I/O option
   P1OUT &= ~BIT2;                       // P1.2 output = 0
   P1SEL |= BIT0;                        // P1.0 TA0 option
   CCTL0 = OUTMOD_7;                     // CCR0 reset/set
   CCR0 = 0x0f;                          // PWM Period
   TACTL = TASSEL_1 + MC_1 + ID_0;       // ACLK, up mode, 1 divider
}

// buzzerOff() ******************
void buzzerOff(void){
   TACTL = MC_0;                       // Stop Timer
   P1DIR |= BIT2|BIT0;                  // P1.2,0 output
   P1SEL &= ~(BIT2|BIT0);               // P1.2,0 I/O option
   P1OUT &= ~(BIT2|BIT0);               // P1.2,0 output = 0
}
void LEDOff(void)
{
    P2DIR |= (BIT7|BIT6|BIT5|BIT4);       // Set P2.7-2.4 to output direction
    P2SEL &= ~(BIT7|BIT6|BIT5|BIT4);    // P2.7-2.4 I/O option
    P2OUT |= (BIT7|BIT6|BIT5|BIT4);     // P2.7-2.4 output = 1 (LEDs off)
}

void LEDdisplayHex(unsigned char num)
{
    unsigned char   tmp_num;
    tmp_num = (~num)<<4;
    // P2DIR |= (BIT7|BIT6|BIT5|BIT4);       // Set P2.7-2.4 to output direction
    // P2SEL &= ~(BIT7|BIT6|BIT5|BIT4);    // P2.7-2.4 I/O option
    P2OUT = tmp_num & 0xF0;
}

19.4 Programming for mainProgram.c

/********************************************************************************
************* Main Program for the Edema Monitoring Device *************/
/********************************************************************************
************* Written by Rachelle Horwitz *************
/********************************************************************************
******** Some functions have been written by Alex Camilo and Jose Brache
from WPI, and by Muneem Shahriar from Texas Tech University. *************/
/********************************************************************************
*******************************************************************************/

/* For calibration, the user can change the modifiable constants listed
under "Modifiable Constants."
It is important to note that dx/dt should be dx/dt, but because the compiler
does not accept dx/dt, I used dxdt to represent dx/dt */

#include "msp430x44x.h"
#include <string.h>
#include <stdio.h>
#include <stdlib.h>
#include <math.h>
#include <in430.h>

/*********** Functions from demo.c by Jose Brache **************/
**** Comments written by Jose Brache, modified by Rachelle Horwitz *****/
/*************************************************************************/
void init_sys(void);                  // MSP430 initialization routine, modified by Rachelle
Horwitz
void swDelay(unsigned int max_cnt);   // simple software delay loop
void clearLCD(void);                  // Clears LCD memory segments so that LCD is blank
void initLCD(void);                   // Setup code to interface LCD with MSP430F449
void writeLetter(int position,char letter);  // display single character on LCD
void writeWord(const char *word);    // displays words upto 7 characters on LCD.
   // Can also display numbers passed as text
void buzzerOn(void);    // turns buzzer on
void buzzerOff(void);   // turns buzzer off

*********** Functions by Rachelle Horwitz and Alex Camilo *************/
******** These functions are used when transferring data from
the microcontroller to the PC and when modifying the flash. *************/
婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳婳(Paint)

void config_timerB(void); //
void clearAll(void); // resets the variables to their initial states
void setUpDistPins(void); // set up pins used for determining the distance
void configForce(void); // set up ADC and the pin used for determining the force
void writeNum(signed int x); // displays a number on the LCD
void getForce(void); // outputs a level between 0 and 4095. This number
   // directly corresponds to the force being applied;
   // the higher the number, the greater the force
void toSerial(void); // for debugging purposes, writes data out to serial port
void writeResults(); // after the measurement has been taken, this function  
// displays the distance, force, and tau on the LCD

void checkMovement(void); // while the clinician is holding the device on the  
// patient's skin after he has finished pushing, this  
// function checks to see if the distance has changed  
// from maxDist.

void update(void); // displays distance on LCD, increments distCounter if  
// necessary, calculates moving average of force

void alertThatDone(void); // sound buzzer, calculate maxDist and maxForce

void makeHold(void); // display "HOLD" on LCD for 3/4 of a second

void monitorTau(void); // calculate the distance at which tau is measured,  
// wait until clinician releases to start measuring tau

void pollswDelay(unsigned int max_cnt); // same as swDelay by Jose Brache,  
// but polls button B to see if the clinician  
// wants to reset the device

 señor

 /************************************************************************/  
 /******* Global variable declarations from demo.c by Jose Brache  *******/  
 /************************************************************************/  
 char *LCD = LCDMEM; // pointer to LCD Memory Segments  
 unsigned char cntr=0; // counter for swDelay  
 long int cnt=0; // another counter for swDelay

 /************************************************************************/  
 /*********** Global variable declarations by Alex Camilo ***************/  
 /************************************************************************/  
 unsigned char RS232_RX_BUFFER[256];  
 unsigned char *RS232_RX_WRITE_POINTER;  
 unsigned char *RS232_RX_READ_POINTER;  
 unsigned int *data_pointer = (unsigned int*)0xFdff;  
 unsigned int *data_read = (unsigned int*)0xFdff;  
 unsigned char flash_full=1;  

 /************************************************************************/  
 /************************ LCD CONSTANTS ***********************************/  
 // From Muneem Shahriar's LCD driver code from Olimex.com  
 #define a (0x80) // definitions for LCD segements on the Olimex LCD. 4-Mux  
 operation is assumed  
 #define b (0x40) // For more details on 4-Mux operation, gather your LCD datasheet,  
 #define c (0x20) // TI's MSP430F449 User Guide (look for LCD Controller, then 4-  
 Mux),  
 #define d (0x01) // and MSP-449STK-2 schematic. You will need ALL these 3 when  
 defining  
 #define e (0x02) // each number or character. Remember, the Olimex LCD doesn't use  
 a LCD driver!  
 #define f (0x08) // You tell the LCD what characters to display. It's very time  
 consuming!!  
 #define g (0x04)  
 #define h (0x10)  

 /************************************************************************/  
 /************************** Modifiable Constants **************************/  
 /************************************************************************/  
 #define DISTARRAYSIZE 5 // takes the derivative of distance samples that are  
 // DISTARRAYSIZE*10ms away from each other  
 #define FORCEARRAYSIZE 10 // Number of force samples to average together. The  
 // larger the number, the smoother the average  
 #define VALTH 22 // Number of times dx/dt has to be less than DXDTTH
```c
#define DXDTTH 2 // Threshold for change in distance
    // Not the absolute derivative
#define DFDTTH 120 // threshold for change in force. This is a proxy for measuring
    // df/dx.
#define FTHWAIT 800 // force when clinician release. Program does not begin to
    // calculate tau until force is less than FTHWAIT
#define DISTMOVE 10 // maximum distance the probe can move after maxDist has been calculated

/********************* Edema global variables ***************/
long int timerb; // gets incremented every 10ms = 1/100th of a second
char LCDarray[8]; // array to print on LCD
int distSamples[DISTARRAYSIZE]={0}; // holds dist values to calculate dxdt
int forceSamples[FORCEARRAYSIZE] = {0}; // holds force values to calculate dFdt
int dFdtArray[FORCEARRAYSIZE-1] = {0}; // holds dFdt values for the moving average
unsigned int dxdt=1000; // dx/dt. Not an "absolute" dx/dt
signed int dFdt = 0; // dF/dt. Not an "absolute" dF/dt
signed int dist = 0;  // distance. Varies between 0 and 274, but can be negative
int tauDist=0;  // distance at which tau occurs
int force=666;  // force on a scale of 0 to 4095. Initialized to 666 because
    // this is the approximate value of force when no pressure is
    // being applied
signed int maxDist=0; // maximum distance. Varies between 0 and 274.
int distCounter=0;  // number of dxdt's to hold
    // gets incremented every time that dxdt > dxdtTh
int tau=0;  // tau
char done = 'n'; // dummy variable
int valid=1; // is set to 1 if the measurement is valid or has the potential to be valid
int clkdiv=0; // effectively makes the ISR fire every 10ms instead of every 1ms
char interruptFired = '0';  // if 0, an interrupt has not been fired since
    // the last time this variable has been checked.
    // if 1, an interrupt has been fired
int maxForce = 0; // maximum force applied

/************************** MAIN ****************************/
/* The actual program is found in mainProgram(). After
mainProgram() has been run, clearAll() is called to reset
everything so that the user can start the program again. */
void main(void)
{
    while(1)
    {
        mainProgram();
        clearAll();
    }
} // end main

/************************** MAIN PROGRAM **********************/
void mainProgram()
{
    /* Initialization routines */
    WDTCTL = WDTPW + WDTHOLD; // Stop watchdog timer
    init_sys();  // Initialize the MSP430
    setUpDistPins(); // Set up the pins for measuring displacement
    config_timerB(); // set up timer B so that it runs at 8MHz
    configForce(); // configure the ADC and the pin used to measure force

180```
RS232_INIT(); // initialize RS232
_BGR(GIE); // enable interrupts

/* Loop through this */
while(valid==1)
{
toSerial(); // send data through the serial port
writeWord("START");
if(P3IN==0x70) // 0x70 = 0111 0000 --> P3.7 = button D
{
    while(P3IN != 0xF0) // while the clinician holds on the button
    {
        _BIS_SR(LPM0_bits + GIE); // go to sleep. Reduces power consumption
    }
    dist = 0; // resets dist in case doc started pushing
    clearLCD();
    done = 'n'; // not done yet
    while(done == 'n') // loop through this
    {
        update(); // write the current distance on the LCD
        if((distCounter>VALTH)&&(dFdt>DFDTTH)) // if the clinician has reached the bone
        {
            alertThatDone(); // alert the clinician that he has reached the bone
            makeHold(); // make the clinician hold for a specified period of time
            clearLCD();
            writeWord("RELEASE"); // when the clinician stops applying pressure to
            // the probe, "RELEASE" is written to the LCD
            monitorTau(); // determine the distance at which tau occurs and and
            // check to see whether the doctor has reached it yet
            buzzerOn(); // when the doctor has reached the distance at which
            // tau occurs, turn the buzzer on
            while(1) // display results until clinician pushes reset or turns device off
            {
                writeResults(); // write the max distance, max force, and tau to the LCD
            }
        }
    } // end inner while(done == 'n')
} // end if button D;
_BGR(LPM0_bits + GIE);
} // end while(done == 'n');

/***************************************************************************/
/********************** clearAll()*************************/
/***************************************************************************/
/* This function resets the variables to their initial values */
void clearAll()
{
    buzzerOff();
timerb=0; // counts ms

    for(int i = 0; i < DISTARRAYSIZE; i++) // set each element in distSamples to 0
    {
        distSamples[DISTARRAYSIZE]=0;
    }

    for(int i = 0; i < FORCEARRAYSIZE; i++) // set each element in forceSamples to 0
    {
        forceSamples[FORCEARRAYSIZE] = 0;
    }

    for(int i = 0; i < FORCEARRAYSIZE-1; i++) // set each element in dFdtArray to 0
    {
        dFdtArray[FORCEARRAYSIZE] = 0;
    }
dxdt=1000;
dFdt = 0;
dist = 0;
tauDist=0;
force=0;

181
maxDist=0;
distCounter=0; // number of dxdt's to hold
    // gets incremented every time that dxdt > dxdtTh
tau=0;
done = 'n';
valid=1;
clkdiv=0;
interruptFired = '0';
}

/**********************************************************/
/******************* pollswDelay() ************************/
/**********************************************************/
/* This function polls the reset button (button B) during the
software delay. It is adapted from Jose Brache's code for
swDelay() */
void pollswDelay(unsigned int max_cnt)
{
    unsigned int  cnt1=0, cnt2;
    while (cnt1 < max_cnt)
    {
        cnt2 = 0;
        while (cnt2 < 65535)
        {
            if (P3IN==0xd0) // button B
            {
                clearAll();
                mainProgram();
            }
            cnt2++;
        }
        cnt1++;
    }
}

/**********************************************************
/******************** toSerial() ****************************/
/**********************************************************/
// A lot has been commented out because it was previously used, but
// is not used in the final version. However, it is still here.
void toSerial()
{
    //writeNum(dxdt);
    //RS232_OUT(LCDarray);
    //RS232_OUT_CHAR(0x09);
    //writeNum(dFdt); // convert dFdt to ASCII
    RS232_OUT(LCDarray); // send it out through RS232
    RS232_OUT_CHAR(0x09); // tab
    //writeNum(dist);
    //RS232_OUT(LCDarray);
    //RS232_OUT_CHAR(0x09);
    //writeNum(force);
    //RS232_OUT(LCDarray);
    //RS232_OUT_CHAR(0x09);
    //writeNum(maxDist);
    //RS232_OUT(LCDarray);
    //RS232_OUT_CHAR(0x09);
    //writeNum(tauDist);
    //RS232_OUT(LCDarray);
    //RS232_OUT_CHAR(0x09);
    //writeNum(tau);
    //RS232_OUT(LCDarray);
    RS232_OUT_CHAR(0x0d); // tab
    RS232_OUT_CHAR(0x0a); // new line
return;
}

/**************************************************************/
/********************** setUpDistPins() ***********************/
/**************************************************************/
/* This function configures the pins that are used to determine the distance */
void setUpDistPins(void)
{
    P1DIR &= ~(BIT7|BIT6); // P1.7-6 are inputs = 0
    P1SEL &= ~(BIT7|BIT6); // P1.7-6 are I/O = 0

    // Enable interrupts on P1.7, which will be the counted signal
    P1IE = 0x80;   // enable interrupt on P1.7, which is Pin 9 on EXT
    P1IES = 0x00;  // generate interrupt on rising edge
    P1IFG = 0x00;  // clear interrupt flag
}

/**************************************************************/
/************************* ISR for counting *****************/
/**************************************************************/
/* This ISR fires off whenever there is a rising edge on P1.7. When this occurs, the value for the distance in two-hundred-fiftieths of an inch is either incremented or decremented, depending on whether P1.6 is high or low. P1.6 corresponds to the directional channel from the linear encoder.*/
#pragma vector = PORT1_VECTOR
__interrupt void P1count(void)
{
    if(P1IN & 0x40)  // if Channel B is high, decrement dist
    {
        dist--;
    }
    else  // if Channel B is low, increment dist
    {
        dist++;
    }

    P1IFG = 0x00; // clear interrupt flag. If this is not done, it will keep firing
}

/**************************************************************/
/**************** config_timerB() ***********************/
/**************************************************************/
/* This function configures timerB. It is running 8MHz, and an interrupt is being fired every 1ms */
void config_timerB(void)
{
    TBCCR0 = 0x1F40; // 8mhz/ 1000hz --> fires every 1ms
    TBCTL = TBSSEL_2 + CNTL_0 + MC_1 + ID_0;
    TBCCTL0 = CCIE; // ENABLE INTERRUPTS
}

/**************************************************************/
/**************** ISR for Timer B **********************/
/**************************************************************/
/* This is the interrupt service routine for timer B. It gets fired every 1ms, but because we want to take samples of the distance and force every 10ms, we have to effectively divide the frequency at which the ISR is fired by a factor of 10*/
#pragma vector = TIMERB0_VECTOR       // sets location
__interrupt void Timer_B0(void)
{
    if (clkdiv>=10) // if clkdiv is >= 10, actually do everything in this ISR/
        // The purpose of clkdiv is to divide make the good stuff
        // in the ISR happen 10 times less frequently than how often
// the ISR is fired
{
    clkdiv=0; // reset clockdiv
timerb++; // fires off every 10ms
P2OUT &= 0xfe; //debug make pin low

/* The following lines calculate dxdt. It is unnecessary to find
a moving average for dxdt because the output from the linear encoder
is digital. However, dxdt is still a little choppy, but it’s manageable*/
for (int i=(DISTARRAYSIZE-1); i>0; i--) // DISTARRAYSIZE determines
    // how many ms will be between the // points to calculate dxdt.
    // dt will be // DISTARRAYSIZE*10ms
    distSamples[i]=distSamples[i-1]; // shift everything over by one element
}
distSamples[0]=dist; // put the most recent value of dist into the array
dxdt=abs(distSamples[(DISTARRAYSIZE-1)]-distSamples[0]); // get dxdt

getForce(); // read the force
interruptFired = '1'; // and interrupt was fired
    _BIS_SR(LPM0_EXIT+GIE); // exit low power mode
} else // if clkdiv is < 10, just increment clkdiv.
{
    clkdiv++; // increment clkdiv
}

/***********************************************************/
/******************** update() ***************************/
/***********************************************************/
/* This function is implemented after the clinician pressed
the start button, while he/she is pressing into the tissue.
This function writes the current value of dist to the LCD;
determines whether dxdt is less than the threshold, DXDTTH;
adjusts the variable distCounter accordingly; and, if the ISR
that includes getting the force was just fired, it calculates
the moving average for dFdt. */
void update()
{
    toSerial();
    writeNum(dist);
    int j = 0;
    int sum = 0;
    writeWord(LCDarray);
    if(dxdt < DXDTTH) // if dxdt is less than DXDTTH, increment
        // distCounter. If not, reset distCounter.
    {
        distCounter++;
    }
    else
    {
        distCounter=0;
    }
    if(interruptFired == '1') // if a new value of force was obtained
    {
        for (j=(FORCEARRAYSIZE-1); j>=0; j--) // calculate the moving average
            // of dFdt
        {
            dFdtArray[j-1]=forceSamples[j]-forceSamples[j-1];
            forceSamples[j]=forceSamples[j-1];
            sum += dFdtArray[j-1]; // add everything together
        }
        forceSamples[0] = force;
        dFdt = -sum; // We are not doing any division to get the "absolute"
            // dFdt because it requires floating point math. Because
            // the program needs to move quickly, floating point math
            // is not a good idea. The current method of calculating
// dFdt is proportional to the actual dFdt, so there is no
// need to use floating point math.
sum = 0; // reset sum
interruptFired='0'; // clears interruptFired
}
}

/*************************************************************/
/********************** alertThatDone() *********************/
/*************************************************************/
/* This function alerts the clinician that he/she can no longer
push any harder. A buzzer is sounded, maxDist and maxForce are
obtained. */
void alertThatDone()
{
buzzerOn();
maxDist = dist;
maxForce = force;
clearLCD();
swDelay(3);
buzzerOff();
clearLCD();
}

/*************************************************************/
/****************** makeHold() *******************************/
/*************************************************************/
/* This function is implemented immediately after the clinician
has reached the bone. This function makes the clinician hold
the probe onto the patient's skin for 0.75 seconds. 75 was chosen
arbitrarily; it was a number that we thought would allow the tissue
to set, but not long enough to induce frustration in the clinician
and patient. */
void makeHold()
{
timerb=0; // reset timerb
while(timerb <= 75)  // during the 0.75 seconds, write "HOLD" on the LCD
// and check to see if the distance has changed significantly.
// To see if the distance has changed significantly,
// call the checkMovement() function
{
  writeWord("HOLD");
  checkMovement();
}
timerb=0; // reset timerb again after the 0.75 seconds
}

/*************************************************************/
/*********************** monitorTau() **********************/
/*************************************************************/
/* This function calculates the distance at which tau occurs,
tauDist, which is 63% of the maximum distance the probe
traveled. When the clinician stops applying pressure,
timerb is reset so that it can measure tau. As the probe moves
up, "RETURN" is written on the LCD. When tauDist is reached,
the value of tau is set to the current value of timerb. */
void monitorTau()
{
tauDist = (0.63*maxDist);
//getForce();
while(force >= FTHWAIT) // wait until clinician releases
{
  getForce();
toSerial();
}
timerb=0; // reset timer
while(dist >= tauDist)
{
clearLCD();
writeWord("RETURN");
toSerial();
}
tau = timerb;
}

/**************************************************************************/
/**************** writeNum() ****************************/
/**************************************************************************/
/* This function converts an integer to an ASCII value */
void writeNum(signed int toPrint)
{
    // Check to see if the number is positive or negative
    if(toPrint < 0)
    {
        toPrint = ~(toPrint) + 1; // two's complement because it's negative
        LCDarray[6] = '-';
    }
    else
    LCDarray[6] = '+';
    long int pows[] = {1, 10, 100, 1000, 10000, 100000}; // lookup table
    int i=6; // counts
    long int power;
    LCDarray[7] = 0; // set end of string to zero
    for(i=6; i>0; i--)
    {
        power=pows[i-1];
        LCDarray[6-i] = toPrint/power + '0';
        toPrint = toPrint % power;
    }
}
/**************************************************************************/
/************************* writeResults() ***************************/
/**************************************************************************/
/* If the measurement is valid, this function displays the max distance, max force, and tau on the LCD. The max distance is displayed in units of two-hundred-fiftieths of an inch, the max force is displayed in the units that the ADC provides, and tau is displayed in hundredths of seconds. This function is exited when the user presses the reset button or when he/she turns the microcontroller off. */
void writeResults()
{
    if(valid==1) // if the measurement is valid, meaning that if the probe // did not significantly move while the clinician was told // to hold the probe...
    {
        clearLCD();
        writeWord("DIST");
        pollswDelay(2); // poll the buttons while providing a software delay
        clearLCD();
        writeNum(maxDist);
        writeWord(LCDarray);
        pollswDelay(3);
        clearLCD();
        pollswDelay(2);
        buzzerOff();
        writeWord("FORCE");
        pollswDelay(2);
        clearLCD();
        writeNum(maxForce);
        writeWord(LCDarray);
        pollswDelay(3);
        clearLCD();
        swDelay(2);
        buzzerOn();
        writeWord("TAU");
        pollswDelay(2);
        clearLCD();
        writeNum(tau);
    }
}
writeWord(LCDarray);
pollswDelay(3);
done = 'y';
}
else // if the measurement is invalid, "INVALID" is written to the LCD
{
clearLCD();
writeWord("INVALID");
buzzerOff();
}
}

/***********************************************************/
/************************** checkMovement() ****************/
/***********************************************************/
/* This function is implemented when the clinician is told to
hold the probe on the patient's skin. If the probe moves
significantly, "DOAGAIN" is written to the LCD and the variable
valid is set to 0.*/
void checkMovement()
{
if((-dist-DISTMOVE)>(maxDist)) || ((dist+DISTMOVE)<(maxDist))) // if probe moves
{
clearLCD();
writeWord("DOAGAIN");
swDelay(2);
valid=0;
}
}

/***********************************************************/
/************************** getForce() ************************/
/***********************************************************/
/* This function converts the number from the ADC into a level
between 0 and 4095.*/
void getForce()
{
force = ADC12MEM0 & 0x00000fff; // outputs a level between 0 and 4095
}

/***********************************************************/
/************************** configForce() **********************/
/***************************************************************/
// Based on "Embedded Systems Design using the TI MSP430 Series", by Chris Nagy
/* This function sets up the ADC so that it continuously samples
the incoming signal on P6.7 at 5MHz. The highest voltage that
it reads is 2.5V.*/
void configForce()
{
ADC12CTL0 = SHT0_6 + SHT1_6 + REFON + REF2_5V + ADC12ON + MSC;
// Reference voltage is 2.5V
ADC12CTL1 = SHP+CONSEQ_2;
ADC12MCTL0 = INCH_7 + SREF_1;
ADC12CTL0 |= ADC12SC + ENC;
P6SEL |= 0x00; // Always P6 because ADC is tied to P6. We are using P6.7
// Stick-up thing on AEXT labeled "1" corresponds to Pin 7
}
void initSys() {
    WDTCTL = WDTPW + WDTHOLD;
P2DIR = 0xff;
P2SEL = 0x00;
    initLCD();  // Setup LCD for work
    clearLCD();  // Clear LCD display

    // Stop watchdog timer
    // FLL_CTL0 |= DCOPLUS + XCAP10PF;  // DCO+ set, freq = xtal x D x N+1
    // SCFT0 |= FN_4;  // x2 DCO freq, 8MHz nominal DCO
    // SCFQCTL = 121;  // (121+1) x 32768 x 2 = 7.99 MHz
    FLL_CTL1 = SELS+SELM_XT2;
    unsigned char i=1;
    while(i>0){ i++; }
    RS232_INIT();
}

void swDelay(unsigned int max_cnt) {
    unsigned int  cnt1=0, cnt2;
    while (cnt1 < max_cnt) {
        cnt2 = 0;
        while (cnt2 < 65535)
            cnt2++;
        cnt1++;
    }
}

void initLCD(void) {  // initialize the various registers for LCD to work
    // (code obtained from sample demos of MSP430F449)
    FLL_CTL0 = XCAP10PF;  //set load capacitance for 32k xtal
    // Initialize LCD driver (4Mux mode)
    LCDCTL = LCDSCG0_7 + LCD4MUX + LCDON;  // 4mux LCD, segs16-23 = outputs
    BTCTL = BT_LCD_DIV128;  // set LCD frame freq = ACLK
    PSSEL = 0xFC;  // set Rxx and COM pins for LCD
}

void clearLCD(void) {  // makes the LCD blank
    unsigned int iLCD;
    for (iLCD =0; iLCD<20; iLCD++)  // clears all 20 LCD memory segments
    {  
        LCD[iLCD] = 0;
    }
}
// *************************************  writeLetter *************************************
void writeLetter(int position, char letter) // writes single character on the LCD.
{
    // User can specify position as well
    // DO NOT PLAY WITH THE CODE BELOW ----------------------------------------------------------
    if (position == 1) // this is position adjustment for compatibility
    position = position + 6;
    else
    if ( (position > 1) & (position < 8) )
    position = ((position * 2) - 1) + 6; // adjust position
    //-------------------------------------------------------------------------------

    switch(letter)
    {
    // letter  // LCDM7                          // LCDM8                          // End
    case 'A': LCD[position-1] = a + b + c + e;      LCD[position] = b + c + g;
        break;
    case 'B': LCD[position-1] = c + h + e;          LCD[position] = b + c + g;
        break;
    case 'C': LCD[position-1] = a + h;              LCD[position] = b + c;
        break;
    case 'D': LCD[position-1] = b + c + h + e;      LCD[position] = c + g;
        break;
    case 'E': LCD[position-1] = a + h + e;          LCD[position] = b + c + g;
        break;
    case 'F': LCD[position-1] = a;                  LCD[position] = b + c + g;
        break;
    case 'G': LCD[position-1] = a + c + h + e;      LCD[position] = b + c;
        break;
    case 'H': LCD[position-1] = b + c + e;          LCD[position] = b + c + g;
        break;
    case 'I': LCD[position-1] = a + h + f;          LCD[position] = d;
        break;
    case 'J': LCD[position-1] = b + h + c;          LCD[position] = c;
        break;
    case 'K': LCD[position-1] = d + g;              LCD[position] = b + c + g;
        break;
    case 'L': LCD[position-1] = h;                  LCD[position] = b + c;
        break;
    case 'M': LCD[position-1] = b + c + g;          LCD[position] = b + c + f;
        break;
    case 'N': LCD[position-1] = b + c + d;          LCD[position] = b + c + f;
        break;
    case 'O': LCD[position-1] = a + b + c + h;      LCD[position] = b + c;
        break;
    case 'P': LCD[position-1] = a + b + e;          LCD[position] = b + c + g;
        break;
    case 'Q': LCD[position-1] = a + b + c + h + d;  LCD[position] = b + c;
        break;
    case 'R': LCD[position-1] = a + b + d + e;      LCD[position] = b + c + g;
        break;
    case 'S': LCD[position-1] = a + b + d + e;      LCD[position] = b + c + g;
        break;
    case 'T': LCD[position-1] = a + c + h + e;      LCD[position] = d + g;
        break;
    case 'U': LCD[position-1] = b + c + h;          LCD[position] = b + c;
        break;
    case 'V': LCD[position-1] = g;                  LCD[position] = b + c + e;
        break;
    case 'W': LCD[position-1] = b + c + d;          LCD[position] = b + c + e;
        break;
    // number  // LCDM7                              // LCDM8                          // End
    case '0': LCD[position-1] = a + b + c + h;      LCD[position] = b + c;
        break;
    case '1': LCD[position-1] = b + c;              LCD[position] = d & a;
        break;
    case '2': LCD[position-1] = a + b + e + h;      LCD[position] = c + g;
        break;
    case '3': LCD[position-1] = a + b + c + e + h;  LCD[position] = g;
        break;
    
    // number    // LCDM7                              // LCDM8                          //
    case '0': LCD[position-1] = a + b + c + h;      LCD[position] = b + c;
        break;
    case '1': LCD[position-1] = b + c;              LCD[position] = d & a;
        break;
    case '2': LCD[position-1] = a + b + e + h;      LCD[position] = c + g;
        break;
    case '3': LCD[position-1] = a + b + c + e + h;  LCD[position] = g;
        break;
    
    END
}
case '4': LCD[position-1] = b + c + e; LCD[position] = b + g; break;
case '5': LCD[position-1] = a + c + h + e; LCD[position] = b + g; break;
case '6': LCD[position-1] = a + c + h + e; LCD[position] = b + c + g; break;
case '7': LCD[position-1] = a + b + c; LCD[position] = d & a; break;
case '8': LCD[position-1] = a + b + c + e + h; LCD[position] = b + c + g; break;
case '9': LCD[position-1] = a + b + c + e; LCD[position] = b + g; break;

// others
case '+': LCDM20 = a; break; // plus sign
case '-': LCDM20 = h; break; // minus sign
break;
}

/******************************  writeWord ***********************************/
void writeWord(const char *word) // displays a word upto 7 characters
// words must be in upper case (why?)
{
    unsigned int strLength = 0; // variable to store length of word
    unsigned int i; // dummy variable
    strLength = strlen(word); // get the length of word now
    for (i = 1; i <= strLength; i++) // display word
    {
        writeLetter(strLength - i + 1, word[i-1]); // displays each letter in the word
    }
}

/***************** buzzerOn() ****************************/
void buzzerOn(void)
{
    PLL_CTL0 &= XCAP10PF; // Configure load caps
    P1DIR |= BIT2|BIT0; // P1.2,0 output
    P1SEL &= ~BIT2; // P1.2 I/O option
    P1OUT &= ~BIT2; // P1.2 output = 0
    P1SEL |= BIT0; // P1.0 TA0 option
    CCTL0 = OUTMOD_7; // CCR0 reset/set
    CCR0 = 0x0f; // PWM Period
    TACTL = TASSEL_1 + MC_1 + ID_0; // ACLK, up mode, 1 divider
}

/***************** buzzerOff() ****************************/
void buzzerOff(void)
{
    TACTL = MC_0; // Stop Timer
    P1DIR |= BIT2|BIT0; // P1.2,0 output
    P1SEL &= ~(BIT2|BIT0); // P1.2,0 I/O option
    P1OUT &= ~(BIT2|BIT0); // P1.2,0 output = 0
}

void LEDOff(void)
{
    P2DIR |= {BIT7|BIT6|BIT5|BIT4}; // Set P2.7-2.4 to output direction
    P2SEL &= ~(BIT7|BIT6|BIT5|BIT4); // P2.7-2.4 I/O option
    P2OUT |= {BIT7|BIT6|BIT5|BIT4}; // P2.7-2.4 output = 1 (LEDs off)
}

***************************************************************************/
/****** The following functions were written by Alex Camilo from WPI ******/
/-----------------------------------------------------------------------------/
* Author Details : Alex Camilo
Electrical and Computer Engineering (Sophomore)
WPI
Email: kamiro87@wpi.edu
* ----------------------------------------------------------------------------------- */
#pragma vector=UART1RX_VECTOR // incoming RS232 from PC to microcontroller.
// Fires off whenever something has been received
__interrupt void usart1_rx(void)
{
*RS232_RX_WRITE_POINTER=RXBUF1;
if (RS232_RX_WRITE_POINTER==&RS232_RX_BUFFER[255])// if we've reached the end of the buffer
{RS232_RX_WRITE_POINTER=&RS232_RX_BUFFER[0]; // then loop back to the beginning of the buffer
} else
{
RS232_RX_WRITE_POINTER++; // otherwise, keep going till we reach the end.
}
}

******************* RS232_OUT *******************
void RS232_OUT(unsigned char* pointer) // outputs a string over RS232
{
int i=0;
while(pointer[i])
{
  while (!(IFG2 & UTXIFG1)); // USART1 TX buffer ready?
    TXBUF1= pointer[i];
i++;
}
}

******************* RS232_INIT *******************
void RS232_INIT(void) // initialization routines for RS232
// Heavily based on code from the TI website.
//(www.ti.com)
{
WDTCTL = WDTPW + WDTHOLD; // Stop WDT
FLL_CTL0 |= XCAP18PF; // Configure load caps
P4SEL |= 0x03; // P4.0,1 = USART1 TXD/RXD
ME2 |= UTXE1 + URXE1; // Enable USART1 TXD/RXD
UCTL1 |= CHAR; // 8-bit unsigned character
UMCTL1 |= SSEL1; // UCLK = SMCLK
UBR01=0x56; // used MSP GCC baud rate calculator.
  // Used a baud rate of 9600
UBR11=0x03;
UMCTL1 = 0x00;
UCTL1 &= ~SWRST; // Initialize USART state machine
IE2 |= URXIE1; // Enable USART1 RX interrupt
_EINT();
}

******************* RS232_OUT_CHAR *******************
void RS232_OUT_CHAR(unsigned char letter)
{
while (!(IFG2 & UTXIFG1)); // USART1 TX buffer ready?
TXBUF1= letter;
APPENDIX I: Files included with the CD

Additional related files that are not included in this report are available on the CD.

1. Testing Data.zip – Includes data from tests completed with the prototype device on viscoelastic memory foam

2. Data Sheets.zip – Includes manufacturer data sheets for relevant components.

3. SolidWorks (CAD).zip – CAD drawings and modeling for the final prototype developed in SolidWorks v.6