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Pressure Ulcer Prevention Device

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A Major Qualifying Project proposal to be submitted to the faculty of Worcester Polytechnic Institute in partial fulfillment of the requirements for the Degree of Bachelor of Science

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ABSTRACT

Pressure ulcers cost billions of dollars annually. Complications often arise leading to infection, amputation, and even death. Pressure ulcers occur when the tissue has capillary occlusion leading to necrosis and ultimately an ulcer. To minimize the risk of ulceration a wired detection system was created. This was done with the use of pressure and relative humidity sensors placed underneath the patients' body at the sites of high ulceration risk. An incorporated computer program which reads data in real-time alerts the caregiver when and what part of the body to move. Experiments tested the threshold of ischemia in the tissue through the indication of pain. These tests resulted in the development of an algorithm that is similar to the golden standard of repositioning a patient every two hours. In conclusion, it is recommended that testing be conducted on a wider demographic and that the patch be made wireless. In respects to the marketability of the device, there needs to be research on obtaining FDA approval.

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EXECUTIVE SUMMARY

Pressure ulcers cost billions of dollars annually. There are many problems which can arise from pressure ulcers such as infection, amputation, and in worst cases, death. The sequences of events which lead to ulceration are not conclusive, yet through the compilation of research the team developed their own progression. Pressure ulcers occur when the tissue lacks oxygenation which leads to cell deformation and cell apoptosis. Pressure ulcers can also occur through capillary occlusion at 35mmHg which causes ischemia. It is through the onset of ischemia that a healthy individual would feel pain and move their body part; however the lack of movement leads to necrosis and ultimately an ulcer.

To minimize the risk of ulceration a prevention system was created. This was done with the use of a patch underneath the patients' body at the sites of high ulceration risk combined with a program that reads real-time data and alerts the caregiver of when and what part of the body to move. The patch consists of sensors that measure pressure and moisture in an adhesive bandage. To measure pressure, the Tekscan A401 force sensor was selected due to its thin and large surface area and high weight tolerance. To measure moisture, the Honeywell HIH4000 relative humidity (RH) sensor was selected due to its small size. The algorithm was programmed using LabVIEW and interfaced with the sensors in the wired patch through the National Instruments 6009 DAQ. The program uses lights indicators and sounds to alert the caregiver when to attend to the patient. The program does not allow the caregiver to ignore the warning until the situation is properly resolved.

Initial tests were performed to determine the relationship between the applied force and voltage output for the force sensor. To test the RH sensor, the sensor was introduced to water to determine the voltage reading that corresponds to a moist environment. The RH sensor was also tested to see if it is compatible with other types of moisture such as sweat by placing it the armpits of the researchers and observing a change in voltage. Preliminary evaluation of this device was performed on the heel, which has the highest prevalence in hospitals (U.S department of Health and human services, 2010). Experiments determined the threshold of ischemia in the tissue through the indication of pain. The next step was to test the efficacy of the device on group members. During testing, individuals were placed at a 90 degree angle and were instructed not to move. Additional tests were performed on a standard mattress with the subject lying in the supine position. During each of the described tests the patch was placed under the subject's heel and data were collected by the computer.

The initial tests confirmed a linear relationship between sensor readings and voltage readings. The data collected from the human trials displayed a negative correlation between the amount of pressure applied and the amount of time the participants were able to maintain their position. In conclusion, with the preliminary testing performed, our device can be seen as effective in preventing pressure ulcers. It is recommended that testing be conducted on a wider demographic and that the patch be made wireless. In respects to the marketability of the device, there needs to be research on obtaining FDA approval.

1 INTRODUCTION

A pressure ulcer is defined as the breakdown of skin due to compromised blood flow. More commonly known as bed sores or pressure sores, pressure ulcers occur at bony prominences on the body when pressure is applied for long periods of time. Most ulcers are found on the sacrum (backbone), shoulders, heels and elbows. Ulceration can vary in severity due to the depth through the skin and often results in open sores on the body. These sores can easily become infected and can take anywhere from months to years to heal; requiring constant medical attention (Linder-Ganz, et. Al., 2009).

Pressure ulcers have become a major issue to the health care industry. The cost of pressure ulcers generally become the responsibility of the hospitals due to secondary diagnosis. Secondary diagnosis refers to an ulcer formed in the hospital, as opposed to the primary reason the patient is admitted. Therefore, it is evident to the caregivers that it is important to develop a better way of preventing pressure ulcers. According to Center of Medicare and Medicaid Services (CMS), in 2007 there were 257,412 reported preventable pressure ulcers as secondary diagnoses (US Department of Health & Human Services, 2010).

It was estimated that a single pressure ulcer costs about $43,180 for a stage III and the cost for just a stage IV ulcer can reach more than $70,000. These values do not include the cost of surgery if the patient is eligible (US Department of Health & Human Services, 2010). Ulcers can be prevented with adequate care and efficiency in detecting such formation. If such technology existed it would greatly alter the current preventive measures of pressure ulcer formation and would lower the money spent on pressure ulcers annually.

Regardless, it is not entirely about the money needed to treat and prevent pressure ulcers but more importantly about the quality of life of a person. There are many people who have limited mobility and are not able to move independently when they feel the intense pain which indicates pressure ulcer formation. There are also those with limited sensory perception who do not feel when they have to move and are unaware of pressure ulcer formation (Allman, et al., 1995). Patients with untreated pressure ulcers eventually may need amputation if the ulcer becomes large enough surgery or any other treatment becomes ineffective. Ulcers in locations that cannot be amputated may lead to death.

The goal of this project is to solve the problem of pressure ulcers by creating a wired patch system with patches which are placed over the bony prominences. The system will alert caregivers when ulceration is about to occur and alert him or her when pressure needs to be relieved or when the moisture of the patient's skin needs to be adjusted.

2 BACKGROUND

2.1 What is a Pressure Ulcer?

A pressure ulcer is simplistically defined as a breakdown of skin due to blood flow being compromised. Pressure is the major cause of blood flow blockage but can be exacerbated by the effects of factors such as shear, friction, and moisture. The effects of pressure are most observed at the areas of the body where bones are most prominent. These areas include, but are not limited to, the heels, the hips, the spine, and the shoulders (Linder-Ganz, et. Al., 2009). Figure 1 (obtained from orthonurse.org) displays the high risk areas of ulceration and their percentage of occurrence.

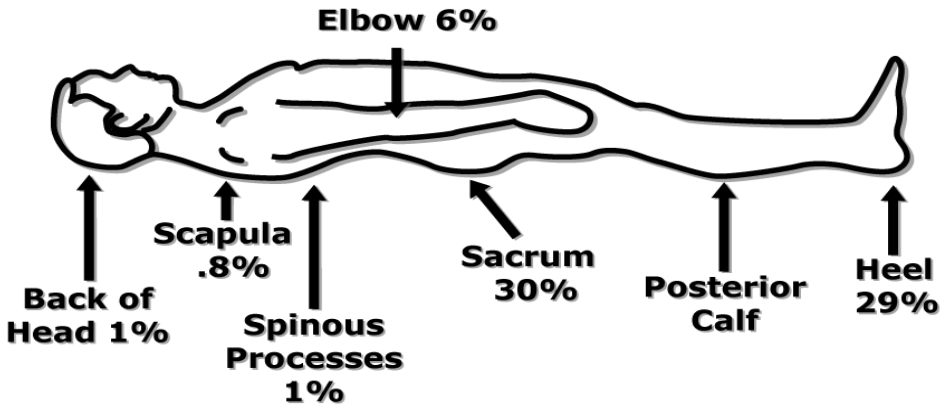

Figure 1: High risk areas distributed by percentage of incidence rate.

Biological factors can also encourage pressure ulcer production. Medical conditions such as ischemia and medications which influence blood flow can directly cause pressure ulcers. Nutritional deficits which hinder skin healing can increase the risk of pressure ulcers and their severity. Medical conditions which limit the ability of the patient to move or to feel sores on the skin make a patient far more reliant on care providers and far more likely to develop pressure ulcers. Other factors which can affect pressure ulcer formation can include the skin thickness, age, and body type of the individual (Papanikolaou, 2007).

Pressure ulcers vary in severity and will become gradually worse if left untreated. The severity of pressure ulcers is ranked by the National Pressure Ulcer Advisory Panel (NPUAP). The scale ranks pressure ulcers from stage I to stage IV; I being an acute ulcer and IV being a severe ulcer as described in Table 1.

Table 1: NPUAP Staging System for Pressure Ulcers

Stage	Description
Suspected deep-tissue injury	Purple or maroon localized area of discolored, intact skin or blood-filled blister caused by damage to underlying soft tissue from pressure or shear; the discoloration may be preceded by tissue that is painful, firm, mushy, boggy, or warmer or cooler compared with adjacent tissue
I	Intact skin with nonblanchable redness of a localized area, usually over a bony prominence; dark pigmented skin may not have visible blanching, and the affected area may differ from the surrounding area; the affected tissue may be painful, firm, soft, or warmer or cooler compared with adjacent tissue
II	Partial-thickness loss of dermis appearing as a shallow, open ulcer with a red-pink wound bed, without slough; may also appear as an intact or open/ruptured serum-filled blister; this stage should not be used to describe skin tears, tape burns, perineal dermatitis, macerations, or excoriations
III	Full-thickness tissue loss; subcutaneous fat may be visible, but bone, tendon, or muscle is not exposed; slough may be present, but does not obscure the depth of tissue loss; may include undermining and tunneling*
IV	Full-thickness tissue loss with exposed bone, tendon, or muscle; slough or eschar may be present on some parts of the wound bed; often includes undermining and tunneling*
Unstageable	Full-thickness tissue loss with the base of the ulcer covered by slough (yellow, tan, gray, green, or brown) or eschar (tan, brown, or black) in the wound bed

*— The depth of a stage III or IV pressure ulcer varies by anatomic location. Because the bridge of the nose, ear, occiput, and malleolus do not have subcutaneous tissue, ulcers on these areas can be shallow. In contrast, areas of significant adiposity can develop extremely deep stage III or IV ulcers. In stage IV ulcers, exposed bone or tendon is visible or directly palpable.

The sequences of events which lead to a pressure ulcer remain undefined. Pressure ulcers may form due to increased pressure on an area of bony prominence which causes blood occlusion to the area (Boutens & et. Al., 2003). This can cause ischemia when the tissue is deprived of oxygen which decreases metabolic processes. Cellular apoptosis would then occur causing cell and tissue death which would then lead to necrosis of the skin. Figure 2 represents a proposed sequence of events that occur after pressure is applied to the body (Stekelenburg, et. Al., 2008).

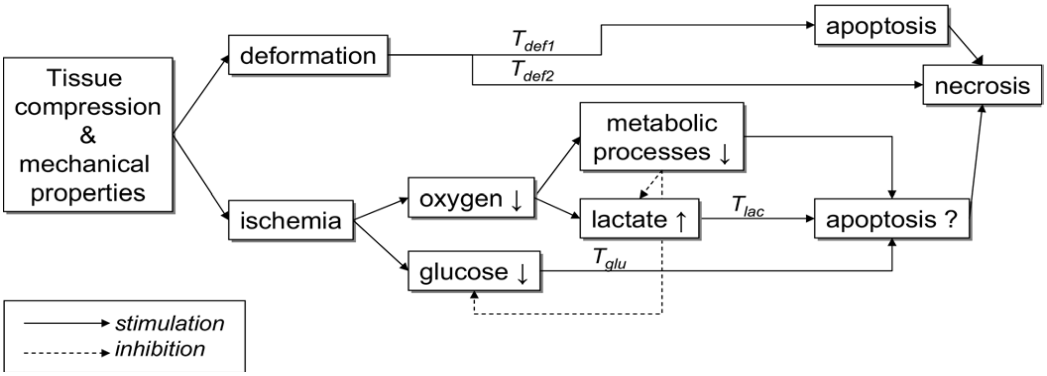

Figure 2: Proposed sequence of events during tissue compression.

Through the collective research the group members proposed a sequence of events which would be taken into consideration for this project. Figure 3 demonstrates the cycle of a pressure ulcer which will be used and referred to in the progression of this Major Qualifying Project (MQP).

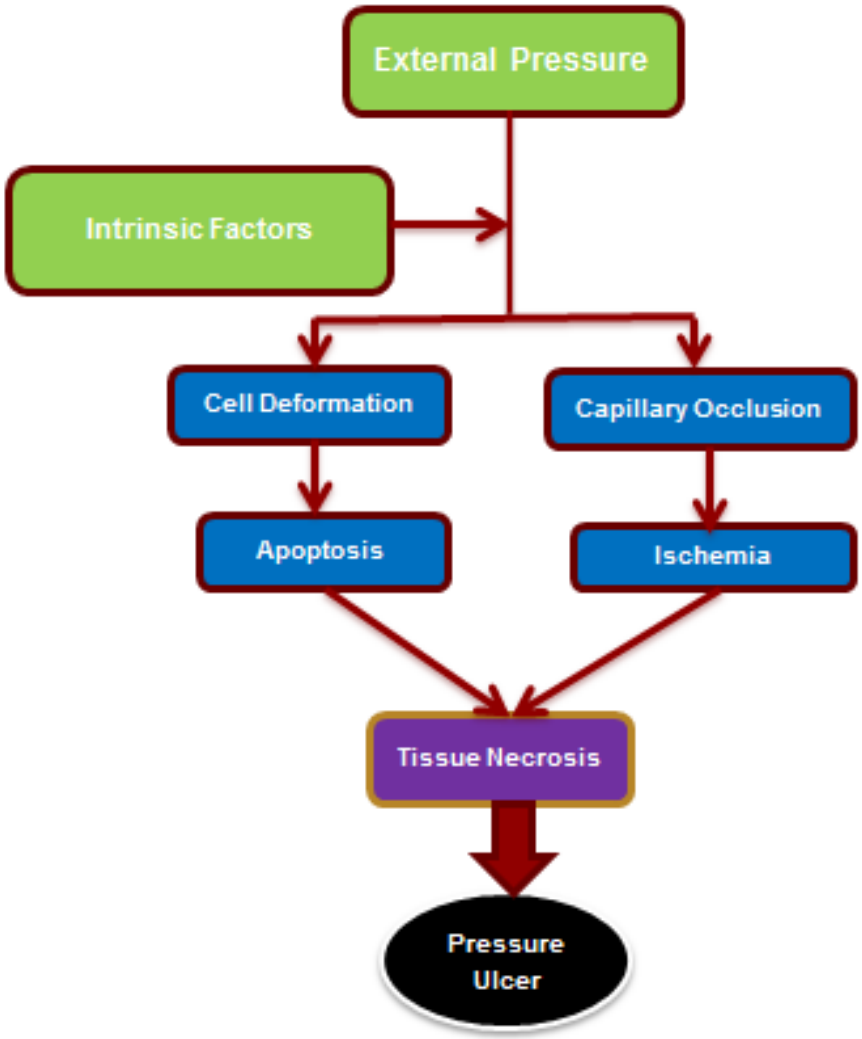

Figure 3: Proposed sequence of events by the group members based on collective research.

2.2 Patient Types

There are many patient characteristics which affect pressure ulcer formation. These factors include age, gender, skin color, weight loss, illness, sensory perception, length of stay, mobility, incontinence, medications, and nutrition (Papanikolaou, 2007).

Age, gender, and skin color have been seen to be contributing factors to the risk of developing pressure ulcers. However, there are many conflicting studies with regards to these areas. There are some sites and articles which report males are at a higher risk than females or vice versa, but there is no

conclusive information. In another study, it states that patients 64 years and under were at a higher risk of pressure ulcer formation than the older patients in a nursing home. This is contradicting information since it is estimated by many other articles that the older a patient is the more likely he/she is of developing pressure ulcers. In regards to skin color, there are studies which show there are no differences, but there are others which state that people with a darker skin color are at a higher risk of pressure ulcer formation. Using age, gender, and skin color therefore are inconclusive factors which would need to be intrinsically studied and researched (Park-Lee, et al., 2009).

In a study, weight loss was analyzed as a factor that significantly increases the risk of pressure ulcer formation. Weight loss was evaluated only if the patient had 5% or more of weight loss in the last 30 days or 10% in the last 180 days. This risk could have increased because when a person losses weight there can be excess skin with a loss of elasticity making the skin weaker (Park-Lee, et al., 2009).

Patients who have lack of mobility are at a higher risk of forming pressure ulcers. The risk of pressure ulcers increases when people are not able to move or walk. Being in a bed, chair, or wheelchair for a long period of time causes blood to cut off in specific areas. The weight of the person concentrates against these bony areas and causes the formation of ulcers. In addition to immobility patients who experience incontinence can also have an increased risk of forming pressure ulcers. In addition, patients whose skin has excess moisture are at a higher risk of forming ulcers because the moisture causes the skin to break down faster (Allan, et al., 1995).

2.3 Risk Assessment Scales

Many risk assessment scales have been developed to evaluate the risk of a patient in developing a pressure ulcer. The three most common scales are the Norton scale, Waterlow scale and the Braden scale. Risk assessment scales evaluate a range of factors and give a numerical value according to the patient's condition. The values achieved within each risk factor are summed to derive the total score. Threshold values are set to indicate the level of vulnerability to pressure ulcer development. The total score is generally used with clinical judgment. One study reveals that the estimated predictive validity varies considerably within the same scale, across different scales, and when used across different clinical care settings and/or patient populations (Papanikolaou, Lyne, & Anthony, 2007).

2.3.1 Norton Scale

In this scale, the total risk score is a linear function of five risk factors considered important by Dr. Norton.

SN = X1 + X2 + X3 + X4 + X5

Dr. Norton set the score of 16 or below to be the critical cut-off point as the onset of risk. The scale is easy and convenient to use but does not include nutrition as a risk factor. The difficulties with using this scale as a tool to predict how inclined a patient is to developing a pressure ulcer is that it does not provide descriptions of risk components and it is restricted to the use of better-trained health care professionals (Papanikolaou, 2007).

2.3.2 Waterlow Scale

This scale was designed to serve three purposes; to provide an assessment of the risk of pressure ulcer damage, to make recommendations for preventive measures across different risk circumstances and to deliver a pressure classification system. This assessment takes 2 minutes to complete and is fairly easy. The following equation was used to create a pressure ulcer formation score.

$$SW = Q1 + Q2 + Q3 + Q4 + Q5 + Q6 + Q7 + d1W1 + d2W2 + d3W3 + d4W4,$$

SW is the Waterlow total score indicating the risk of pressure ulcer development; Q1 is the build/weight for height (a body mass index assessment) score; Q2 is the continence score; Q3 is the skin type score; Q4 is the mobility score; Q5 is the gender score; Q6 is the age score; Q7 is the appetite score; W1 is the tissue malnutrition score (condition-specific); W2 is the neurological deficit score (condition-specific); W3 is the major trauma/surgery score (condition-specific); W4 is the medication score (treatment-specific), and dj indicates the presence or absence of the special risk in consideration. Hence, it takes on the value one if the particular risk is present (dj = 1) and zero if that risk is not there (dj =0). Q1 through Q4 scores, range from zero (most favorable) to three. If SW is greater than 10, then the patient is at risk of developing a pressure ulcer. With this scale there were many issues found. One of them is that pain was not treated as a separate risk factor and gender risk put women in a higher risk position than males. This is a problem because there is no definite proof of this. Another problem with this assessment, like others, is that it did not provide description of risk components and it is also restricted to better trained professionals. In Comparison to the Norton scale, the Waterlow scale is a more advanced and comprehensive system (Papanikolaou, 2007).

2.3.3 Braden Scale

The Braden scale focuses primarily on nutrition. Braden noticed that poor nutrition was the principal contributing factor in ulcer formation. The following equation was used to create a pressure ulcer formation score.

$$SB = Z1 + Z2 + Z3 + Z4 + Z5 + Z6$$

Where SB is the Braden total score indicating the risk of pressure ulcer development; Z1 is the sensory perception; Z2 is the activity score; Z3 is the mobility score; Z4 is the nutrition score; Z5 is the moisture score; and Z6 is the friction and shear score. The first three are what might cause the pressure and the last three are what could affect the tissue tolerance for pressure. The issues that occur with this scale is that detailed information on the patient's dietary intake is needed, as well as information on the patient's ability to move and frequency of the skin being moist.

With all of these risk assessment scales, it has inadequate reliability and insufficient predictive performance. In the review of assessments, it was found too simplistic to use the equal weighting scoring technique to calculate the risk of pressure ulcer formation (Papanikolaou, 2007).

2.4 Current Treatment

Through the research for current treatments and preventive measures for pressure ulcer care, it was evident that these practices are still very simple. In order to prevent the pressure ulcer formation, the current gold standard includes having a nurse or caregiver reposition the patient every two hours in a different position (Thomas, et al., 2006). This can be effective if the patient has a very efficient caregiver(s) and is moved every two hours. However, there are many problems with this method and its effectiveness in a larger setting. Human error increases its inadequacy in lowering the risk of pressure ulcer formation (Jones, et al., 2007).

There are many locations where patients are at risk of developing pressure ulcers. This includes hospitals, nursing homes, clinics, home-care facilities, etc. In addition to the wide variety of settings of pressure ulcer formation, there are many caregivers that must be factored in the prevention of ulcer formation; these include nurses, nursing aides, physicians, physical therapists, and nutritionists (Berlowitz, et al., 2007). It is a very complex process that requires a lot of time and people and therefore is costly.

There is no innovative technology available to prevent pressure ulcer formation. The most that can be seen in the market are beds and mattresses with alternating pressure settings. However, these are not accurate and are not specific to either prevention of ulcers or patient characteristics. During a tour at UMass Memorial Medical Center University Campus it was seen that at-risk patients were placed on an inflatable bed but no other technology was utilized.

In the absence of technology, many techniques have been attempted. There has been research done to see the efficiency of using maggots for treating pressure ulcers. The maggots are placed in the ulcer and are left to remove the necrotic tissue and to clean the wounds (Sherman 2002). In this study it was evident that the use of maggots improved healing rate, however, this was a great method for treating rather than preventing the ulcers.

In addition, some hospitals have tried to implement management practices to improve their efficiency in taking care of patients. This includes management involvement and commitment, cultural change, organization infrastructure, training, project management skills, and project prioritization (Antony et al., 2002; Gorenz et al., 2003). This improves upon existing practices and ensures the procedures are utilized correctly, such as two hour repositioning of the patient.

Hence, it is evident that there is no technology that can help prevent the formation of pressure ulcers and this is why many ulcers lead to surgery. Surgery is performed on ulcers of class 3 and 4, and it can include direct closure, skin grafting, local flaps, and other advanced and unconventional procedures (Sorensen, et al., 2004). The surgery, however, can take a toll on the patient and not everyone can withstand such procedure. Surgery can also mean amputation of severely damaged limbs which can be very expensive and leave the patient in an emotional turmoil.

2.5 New Technology

Various technology and patents have been created to tackle the problem of pressure ulcers. Many of these technologies have not been release to market, nor been tested but the ideas and schematic drawings have been documented. In the search for patents that involve pressure ulcers, many items were found to deal with devices that prevented ulcers rather than sensing. The few that did claim to sense when a pressure ulcer was forming only looked at one risk factor, pressure. The following are summaries of the inventions that claimed to prevent or detect pressure ulcers and there description of how they alleviate pressure ulcers as well as a few inventions that sense some of the risk factors of pressure ulcers.

Patent 7,141,032 - Apparatus and methods for Preventing and/or Healing Pressure Ulcers

An apparatus was developed to prevent and aid the healing of pressure ulcers. It has been documented that pressure ulcers occur more frequently in certain areas of the body such as the heel, ankle, the trochanter, the sacrum, the scapulae, elbows, knees and etc. The invention protects these parts of the body by attaching separate padding and cushions between the body and the support surface. This is to reduce the pressure between the bone-soft tissue interfaces to these areas. The inventors recognized that in these high risk areas there only is a thin layer of soft tissue between the bony prominence and the outer skin layer. The way that the prosthesis works is by increasing the area over where the weight of the body part is being distributed. By adding thickness to the soft tissue, there is a decrease in pressure at the interface. The prosthesis is made of soft foam-like material to provide good weight distribution. One thing that was analyzed was that the softer the foam was the thicker it had to be to provide the right amount of protection. The soft foam was able to conform to the shape of the body part that needed to be protected. The design of the device can be seen in figure 4. (Flam, Bodine, & Schanzer, 2006)(Patent 7141032).

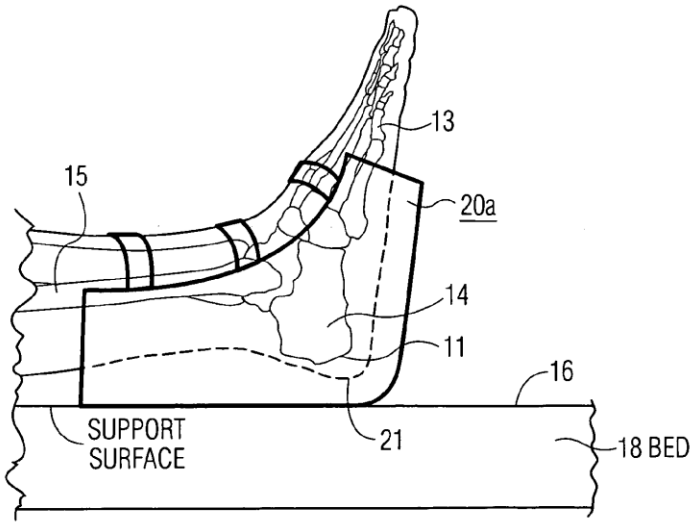

Figure 4: Schematic Drawing of device.

Patent 7,222,625 – Pressure Ulcer Prosthesis and Method for Treating and/or Preventing Pressure Ulcers

Another invention that prevents formation of pressure ulcers and is similar to the previous invention is a device that evaluates pressure ulcers that form around the calcaneus (heel bone) and lateral malleolus of the foot. The basic formation of the invention is a prosthesis that fits around the lower leg and ankle that support the patient's limb. With the prosthesis design, there is a latitudinal and a longitudinally extending support and has a cross section that is acute and concave. It was important to develop this invention in a shape that allows the patient to lie horizontally on a bed. Within the design of the prosthesis, there is at least one hole to provide ventilation and the liner is formed from high density foam. Further, there is plurality of reinforcement structures on the outer surface also fitted with fitting straps. One benefit of the device is that it is anti-hyperextension. Meaning that the patient can't experience extension pressure and that there knee is at the relatively same height as their foot, as seen in figure 5 (Huber & Andrews, 2005).

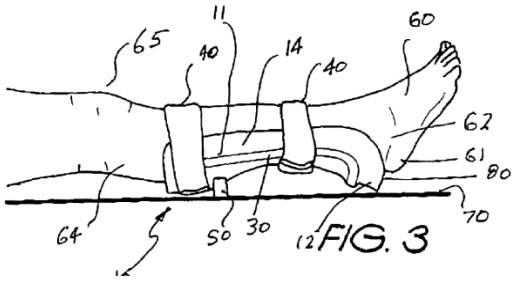

Figure 5: Schematic drawing of device.

Patent 6,287,253 - Pressure Ulcer Condition Sensing and Monitoring

This invention, seen in figure 6, is a pressure ulcer condition and sensing device. The invention is a device that monitors one or more pressure sensitive areas on the body. Other pressure sensing and monitoring systems have been developed that are similar to this invention. Those sensors are different because they can be very complicated and expensive as well. This invention creates a simple and improved device for sensing and monitoring pressure ulcers. This invention provides a novel and a better approach to medical sensing and methods of monitoring pressure sensitive areas. It provides real-time monitoring of the status of the pressure area over time, which allows for quick identification of pressure ulcer formation and allows immediate response to the patients. Also this invention provides an advantage of being relatively inexpensive compared to other designs and also has the benefit of having disposable sensors that measure exposure time to pressure. Even though these sensors are disposable, they can be reused. The sensors in this device are wireless, thin and flexible and do not require additional handling by the care giver which presents many benefits. There are no wires extending from

the patient and is not significantly adding bulk to the patient. From the sensing device, local warnings can be given and continuous monitoring. (Ortega, Schwabe, & Sabaolich, 2001).

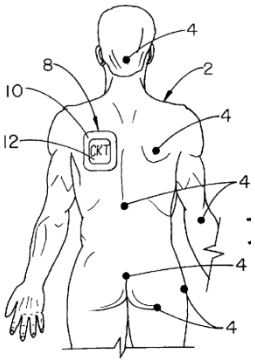

Figure 6: Schematic drawing of sensor on one of the key areas where pressure ulcers form.

WoundVision's Bedside Thermographic Imaging System

One of the newer technologies found that senses pressure ulcers is a device created by the company called WoundVision. WoundVision has developed a device, that they claim can predict and track pressure ulcers and other wounds. The WoundVision imaging system will help detect pressure ulcers, malnutrition, dehydration, infection, vein thrombosis and other medical conditions. With the imaging system, caregivers can perform a full body, non-contact scan. This system has been in development for nearly four and a half years and has not made it to the public yet. Substantial information has not been released to the public market. (WoundVision introduces bedside thermographic imaging system.2010).

Patent 4,554,930 - Pressure sensing device and method for preventing pressure ulcer formation

This invention is a monitoring device that records the pressure on the skin and the elapsed time period during which the skin has been exposed to that certain pressure. An alarm sounds when the pressure and the time has reach a predetermined dangerous level, as documented in figure 7, in order to prevent damage. Each pressure sensor may be in direct contact with the surface of the skin at the interface where the pressure is to be measured or may be implanted just beneath the surface of the skin (Kress, 1985).

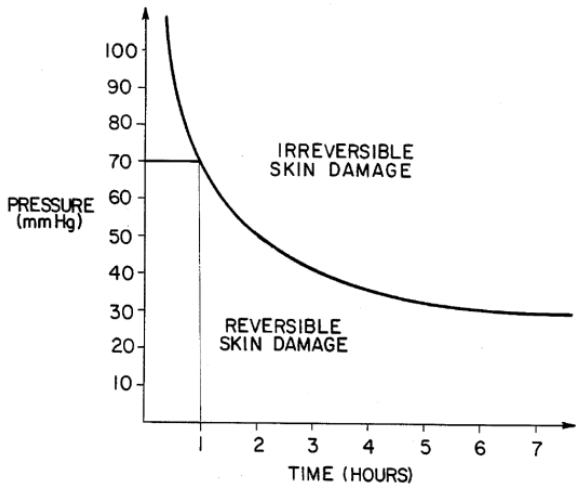

Figure 7: Graph showing the relationship between pressure, elapsed time, and skin damage.

Patent 5,642,096 – Device for Prevention of Ulcers in the Feet of Diabetes Patients

This invention, seen in figure 8, is a device created to prevent ulcers on the feet of diabetic patients. This device is an article of footwear that senses both pressure condition and temperature condition on the feet and signals the patient. This device would ideally be inexpensive and would be available to almost all diabetic patients. The device includes a sensor suspended in a contained liquid mass of a hydrocell carried in the shoe inner sole. This senses and signals an adverse pressure condition to a patient or caregiver (Leyerer, Schaff, & Wetter, 1996).

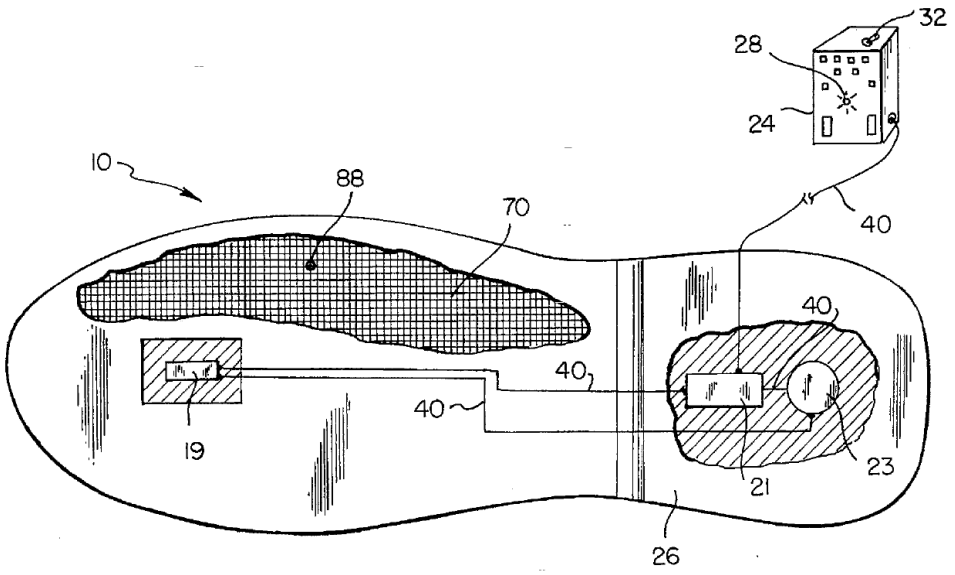

Figure 8: Schematic view of the innersole of the shoe. The depiction shows the device being carried on the innersole.

The following is a comparison chart that looks at the pros and cons of the aforementioned technologies. In Table 2, the benefits and drawbacks of each technology is summarized. It also demonstrates that some technologies do not prevent pressure ulcers but only detect.

Table 2: Comparison Chart of New Technology

Patent/ Technology	Purpose	Pros	Cons	Prevent	Detect
Patent 7,141,032	increase area where body weight is distributed	alleviate pressure target area	bulky material	yes	no
Patent 7,222,625	prosthesis	alleviates pressure anti-hyperextension	bulky material	yes	no
Patent 6,287,253	monitoring device	real time monitoring alarm system wireless thin sensor target area inexpensive	only monitors pressure and time	yes	yes
Thermo graphic Imaging system	imaging system	detects pressure ulcers, malnutrition, dehydration, infection, etc. Full body non-contact scan	not continuous monitoring	yes	yes
Patent 4,554,930	monitoring device	alarm system	only monitors pressure and time	yes	yes
Patent 5,642,096	sensing device	senses both temperature and pressure	only for feet	yes	yes

In conclusion of researching new and innovative technology related to the detection of pressure ulcers, it can be seen that there is nothing readily available to the market. This shows us as designers that there is a need to create a simple and innovative device that detects and prevents the formation of pressure ulcers.

2.6 Pain

Pain was used as an indication of the development of ischemia and the physiological trigger of the beginning of ulceration. There are several forms of pain, including nociception, inflammatory pain, neuropathic pain and functional pain. In addition, the body produces pain using different mechanisms, including nociception, peripheral sensitization, central sensitization, ectopic excitability, decreased inhibition structural reorganization and facilitation (Gan et al., 2003).

One of the pain forms useful for the purposes of this project is nociceptive pain. This type of pain is meant to protect the body and serve as a warning system to the brain. It makes the body aware of intense, potentially dangerous stimulus from the environment. Patients unable to properly perceive nociceptive pain are prone to pressure ulcers because they are unable to feel the pressure and the pain associated with developing ulcers. As a result, they do not move when it is necessary to restore blood flow. This can be caused by an interrupt in any step of the complex pain perception process. In this process, pressure is translated into an electrical signal which propagates along the nervous system, making its way to the brain where it can be perceived (Gan et al., 2003).

Another important pain form in ulcer formation is inflammatory pain. Most situations of inflammatory pain involve the nociceptive pain system becoming overwhelmed, resulting in tissue damage. This system only responds to intense tissue damaging stimuli. Unfortunately by the time this pain is felt, major damage has already occurred to the tissues. For experimental purposes, the nociceptive pain was triggered in normal participants to discover the proper ranges of time and pressure needed to keep a patient safe (Gan et al., 2003).

The pain scale, as revised by Hicks et al., was used in the study and can be seen in figure 9 below. This scale is currently used effectively for small children or people who cannot verbally express their pain (Hicks et. Al., 2001). The scale is used by asking the patient their perceived level of pain and showing them the scale where the patient can point to respond. It can oftentimes be paired with a 0-10 number system as well when dealing with more vocal patients. This scale was chosen due to its ease of use and universal communication of pain. During testing it is expected, as time elapses, ischemia will be produced.

Figure 9: Faces Pain Scale.

2.7 Contributor Functional Factors

There are many factors involved in pressure ulcer formation. To create a cohesive device which meets the design objectives, the factors were evaluated. The factors that were analyzed include pressure, time, skin thickness, moisture, pH, blood flow, shear stresses, friction, and skin temperature. These factors were assessed in how well they could be measured, their significance in pressure ulcer formation and how well they could be implemented into the design ideas.

2.7.1 Pressure

Pressure is one of the most important based on the premises that an ulcer forms as pressure is applied to a bony prominence. Pressure is also the namesake of the pressure ulcer. Pressure cuts off the blood supply to the cells at certain areas causing apoptosis and ultimately tissue death or necrosis. Commercially produced pressure sensors are thin, light weight, highly accurate and easily available (Pressman, et al., 1963).

2.7.2 Moisture

Skin moisture has been found to increase the prevalence of pressure ulcers. Skin moisture can be caused by many different factors such as fecal or urinary incontinence, wound drainage and sweating due to fever. A moist environment increases the risk of pressure ulcer development by breaking down skin tissue (Keller, 2002). Several studies have shown that patients have higher pressure ulcer incidence when associated with moisture due to urinary incontinence and fecal incontinence, especially when both are involved. When moisture is absent the skin, it leads to cracking and splitting of the tissue. Moisture can be measured using relative humidity sensors, which are commercially available in small sizes (Baumgarten, 2005).

2.7.3 Blood flow

Blood flow is the most prominent contributor to pressure ulcer formation but is a secondary factor because it is restricted as a result of pressure. In order for skin tissues to be resilient and able to heal, they must be able to receive necessary nutrients and dispose of waste properly. When blood flow is restricted, even slightly, cells begin to die. As blood flow becomes more restricted and for longer periods of time, there are greater impacts upon the surrounding tissues, ultimately leading to ulceration (Bluestein, 2008). Small commercial blood flow sensors are available.

2.7.4 Time

Time can easily be measured with a clock, stopwatch, or any other type of time monitor. The problem with time is that the time required to form a pressure ulcer is variable based upon the other factors involved. For example, a middle-aged, Caucasian male will take a different amount of time to develop a pressure ulcer than an older African American male. There were two independent studies conducted for the evaluation of time and pressure ulcers which provided useful information for the development of the design. The research was done to correlate the time it would take to develop a pressure ulcer at specific pressure increases, using animal models (Sacks, 1989; Defloor, 1999). In order to use this factor, an algorithm needed to be incorporated into the device and could be a good indication of when the device should alert physicians to reposition the patients (Livesley, et al. 2002).

2.7.5 Shear

Shear is caused by sheet or clothing pulling against the surface of the skin. The seemingly gentle pulling is actually abrasive against the outer layers of skin and slowly degrades the surface. This exposes the under layers of the dermis which are more easily broken down by external forces, creating open wounds. Shear is typically measured using multi-directional force transducers (Bluestein, 2008).

2.7.6 Skin Thickness

It has been researched that different types of skin can influence the prevalence of pressure ulcers. The thicker the skin the longer it takes for necrosis of the tissue to occur and delays ulceration. This could be due to the fact that with thicker skin the complete deoxygenation of cells in the tissues occurs over a longer period of time. Skin thickness can be measured using ultrasound technology (Alexander, et al., 1979; Eisenbeiss, et al., 2001). However, this technique would require some invasiveness and constant attention from caregivers or specialized technicians. Another technique used for measuring skin thickness is a Harpenden Skinfold caliper (Dykes, et al., 1977). This technique, however, can be considered somewhat invasive and would also require additional nurse attention in order to make the measurement of the skin-fold with the caliper.

2.7.7 Friction

Friction is the rubbing of the body against surfaces which is found in most normal movements of a patient. Friction wears down the outer layers of skin and can contribute to the restriction of blood flow in the epidermis. The effects of friction become more important as patients become limited in their ability to move. Decreased strength and fatigue can lead to dragging of the body during major self-repositioning and increases the amount of friction on the body (Bluestein, 2008). Friction is measured using a multi-directional force transducer.

2.7.8 Temperature

Temperature above basal temperature can mean infection, inflammation or analogous symptom indicative of need for immediate action. Temperatures below basal temperature can be indicative of loss of blood flow to the affected area. Temperature is also a secondary factor as other symptoms occur before significant temperature change can be detected (Leyerer et al., 1996). Temperature can be measured through small thermometers which also can be wireless.

2.8 Decision Risk Factor Assessment

The following diagram, table 3, displays all the risk factors, how they can be measured, and the pros and cons of the measuring tool. This table allowed the design team to decide upon which risk factors could be incorporated into the device and which factors were possible to measure. It can be seen that some of the risk factors were not ideal to incorporate in the design because of the difficulties to include it into a patch.

Table 3: Decision Risk Factors

Risk Factor	Measuring Methods	Comments
Pressure	Transducer	Non-invasive
	Force Sensor	
	Pressure Sensor	
Time	Graphs	There are too many factors
	Patient Characteristic Assessment	
Skin Thickness	Ultrasound	Needs constant recording
		Can't be done without a caregiver
Moisture	Relative Humidity Sensor	Non-invasive
		Can be simply added to the pressure sensor
PH	Blood Sample	Invasive
Blood Flow	Ultrasound	Non-invasive
		Bulky
	Laser Doppler	Non-invasive
		Can be used in a patch
Shear Stresses	Multi-Directional Pressure Sensors	Non-invasive
Friction		Difficult to build
Temperature	Thermometer	Non-invasive
		Wireless
		Can be used in a patch

In addition, the risk factors were assessed for their noninvasive measurability and their importance in ulcer formation. As seen in table 4, each factor was assessed if it could be measured noninvasively. It was then assessed how easy it is to obtain the measurement with 1 being the easiest, 3 being the most difficult and 0 being not possible for our system. Each factor was then ranked in order of importance in pressure ulcer formation with 1 being a primary factor, present in all pressure ulcer cases, 3 being a factor which exacerbates the process but is not seen in all cases and 0 is a factor that would not be measured.

Table 4: Decision Risk Factor Comparison

Risk Factor	Measurable	Measuring Rank	Rank	Notes
Pressure	yes	1	1	
Moisture	yes	1	1	
pH	no	0	0	Invasive
Blood Flow	yes	2	1	
Time	yes	1	2	Too general and needs various contributing factors
Shear	yes but dif.	3	3	
Skin Thickness	yes but dif.	3	3	Easy to measure but only by ultrasound. Can be used for algorithms
Friction	yes but dif.	2	3	
Temperature	yes	1	2	Not conclusive

MR
1 easy, 2 medium, 3 hard

Rank importance
1-most 3- least

The factors that were deemed unimportant and that wouldn't be used in the design include pH, shear, skin thickness, and friction. These factors were ranked either immeasurable in a non-invasive manner or immeasurable for the design purposes of using sensor pads for the parts of the body prone to pressure ulcers in a supine position.

Although time and temperature were ranked high, they were not conclusive and were in need of various contributing factors. By this it is suggested that in order to accurately use both in a pressure pad design, the device would have to be able to factor in the different patient characteristics to make it more effective. As stated previously, the rate and risk of pressure ulcers can vary according to patient's skin color, skin thickness, age, gender, nutrition, etc. Pressure, moisture, and blood flow were deemed the most important measurable risk factors that could be well-fitted into the pressure pad design. There is potential for all three factors to be measured non-invasively and for them to be accurate factors of assessing the risk of pressure ulcer development.

3 PROBLEM ANALYSES

3.1 Initial Problem Statement

The initial client statement given to the team was to "design and develop a wireless sensor based pressure ulcer prevention system". Through the research conducted and the needs of the clients a list of objectives and constraints was developed.

3.2 Objectives & Constraints

Along with risk factor analysis, the objectives and constraints pertaining to the design were evaluated. The objectives tree in figure 10 demonstrates some of the requirements and wishes that the clients' had for the device. The objectives can be seen within circles and the constraints within rectangles. These factors were taken into consideration when trying to build upon the initial problem statement.

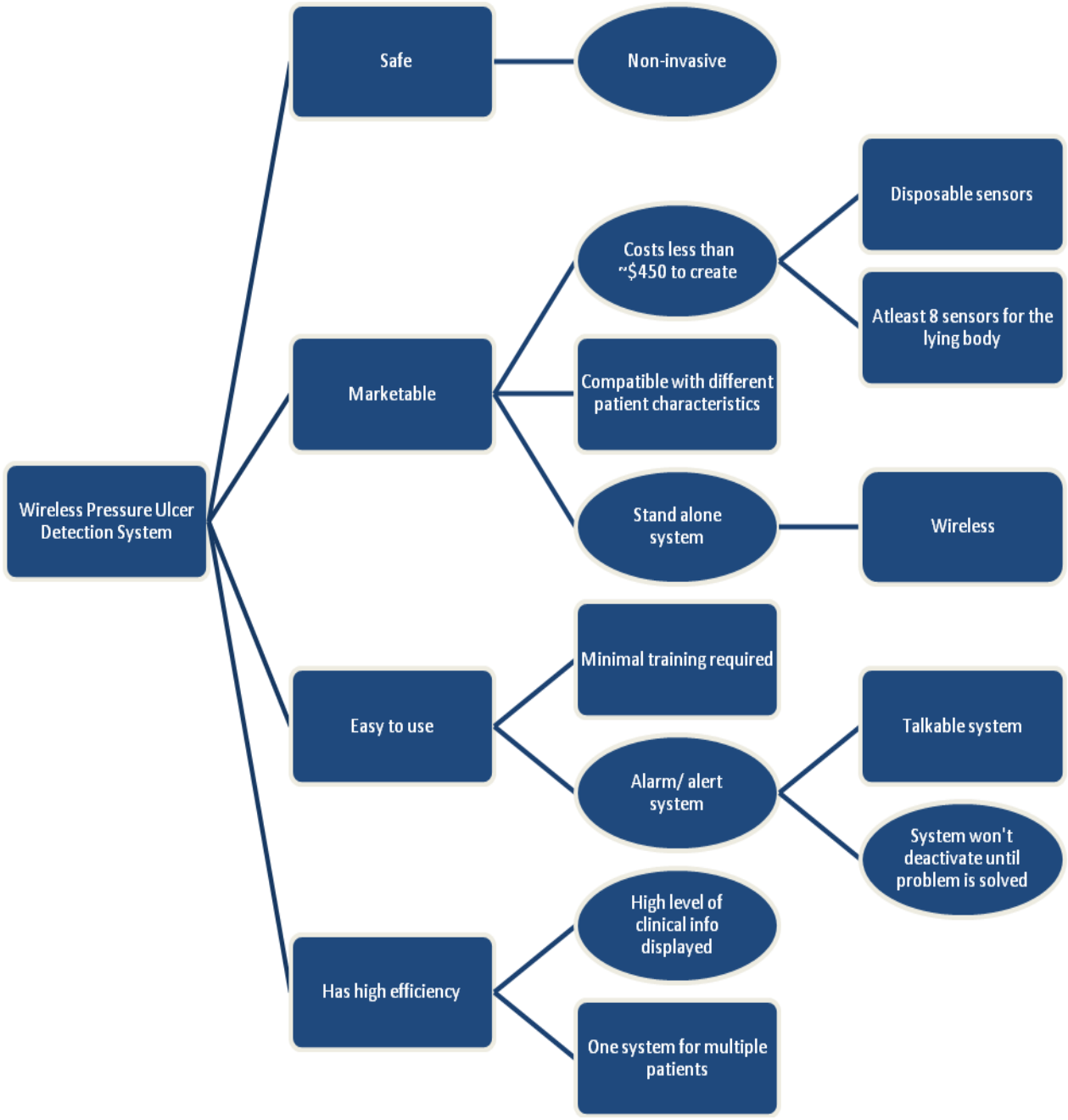

Figure 10: Combined Objectives and Constraints Tree.

In order to further define the needs of the clients, the main objectives were assembled into a pairwise comparison chart, seen in table 5, and the clients were asked to rank them accordingly. The objectives included the device's safety, cost effectiveness, user friendliness, portability, durability, and marketability. This was done in order to determine which factors the clients were more willing to see within their device. Through this it was found that safety, user friendliness, and the marketability of the device were the most important objectives.

Table 5: Pairwise Comparison Chart

Goals	Safety	Cost Effective	User Friendly	Portability	Durability	Marketability	Score
Safety		1	0.5	1	1	1	4.5
Cost Effective	0		0	1	1	0	2
User Friendly	0.5	1		1	1	0	3.5
Portability	0	0	0		1	0.5	1.5
Durability	0	0	0	0		0	0
Marketability	0	1	1	0.5	1		3.5

3.3 Revised Problem Statement

After thorough revision and additional research a new problem statement was developed. The goal of the MQP is to develop a standalone computer-based system to prevent the onset of pressure ulcers on the heels by monitoring pressure and moisture on the patient's skin. The moisture sensor will measure 0 to 100% humidity. The pressure sensor will measure from 0-25lbs. These sensors will be integrated into a patch which will be affixed to the calcaneus region of the patient's heel. The patch will be no more than 35mm in diameter and 6mm in thickness. The patch will be part of a wired system, placed next to the patient's bed. The device should be easy to use, accessible to anyone and it should be portable.

The sensors on the patches will be interfaced to a computer using a LabVIEW based data acquisition system. A program will allow the user to interact with the system in real time. The program will include an alert system for the user to warn the caregiver when the potential of pressure ulcer formation occurs. The readings from the pressure sensor will be monitored in real time and compared against a series of thresholds using an algorithm. When pressure has surpassed a threshold for a specified period of time, the alert system will activate. The program will also alert the caregiver when the relative humidity sensor reading is outside of the 40-95% range. The alert system will display a visual of the location of the problem area, and will describe the problem in written format, which is intuitive and easily comprehensible. The caregiver will not be able to deactivate the alerts until the problem is resolved.

4 DESIGN APPROACH

4.1 Design Focus Areas for Pressure Ulcer Formation

The device that was designed initially included the measurement of pressure, moisture, and blood flow. These were in the form of sensors that were created to be attached to the patient at the pressure points where the risk of pressure ulcer formation is the highest. The sensors can be placed in a lying (supine), side-lying, and sitting position. In the supine position the shoulder, ischium, and heel would require two sensors on either side of the body and one sensor for the head and the sacrum. On the sitting position, the scapula, ischium, heel, and ball of foot would count each as two sensors for either side of the body.

Taking into consideration hospital conditions, the optimal characteristics of the sensors would be that they are disposable and that their lifetime be at least 24 hours. The sensor will measure no more than 35mm in any direction and will measure no more than 6mm in thickness. The range and materials are more open-ended; based on the actual sensors that are obtained and the parameters of the design overall.

4.2 Components and Means Research

The sensors will measure three factors: pressure, moisture and blood flow. The following is a description of how they will be measured.

4.2.1 Force Sensor

The maximum allowable weight of a person for medical devices was found to be 1000 lbs. (William 2009). Therefore in terms of pressure the average weight of person through segmentations was researched. The following is the percent body weight contribution per segmentation as part of the whole body. This study was conducted with cadavers and the average of their results is in table 6 (Clauser, et al., 1969). Knowing the weight and proportion of body segments was important in order to assess the pressure that needed to be recorded and supported by the sensor to be incorporated into the design.

Table 6: Weight percentage according to a 1000 lbs. patient.

	% of Whole Body Weight	Segment Weight for a 1000lb patient
Head	7.55 %	75 lbs.
Torso	46.87 %	468.7 lbs.
Entire Arm, Right	5.36 %	53.6 lbs.
Entire Arm, Left	5.21 %	52.1 lbs.
Upper Arm, Right	2.9 %	29 lbs.
Upper Arm, Left	2.8 %	28 lbs.
Forearm + Hand, Right	2.47 %	24.7 lbs.
Forearm +Hand, Left	2.38 %	23.8 lbs.
Forearm, Right	1.73 %	17.3 lbs.
Forearm, Left	1.66 %	16.6 lbs.
Hand, Right	0.715 %	7.15 lbs.
Hand, Left	0.717 %	7.17 lbs.
Entire Leg, Right	16.59 %	165.9 lbs.
Entire Leg, Left	16.485 %	164.85 lbs.
Thigh, Right	10.26 %	102.6 lbs.
Thigh, Left	10.215 %	102.15 lbs.
Calf + Foot, Right	6.22 %	62.2 lbs.
Calf + Foot, Left	6.23 %	62.3 lbs.
Calf, Right	4.61 %	46.1 lbs.
Calf, Left	4.58 %	45.8 lbs.
Foot, Right	1.58 %	15.8 lbs.
Foot, Left	1.61 %	16.1 lbs.

Pressure will be measured with a chip or sensor that senses changes in pressure. This can include a transducer or element that has the ability to produce an electrical signal proportional to pressure or changes to pressure. This sensor or chip will measure from 0-25 lbs; this range was chosen so that the design could have the greatest accuracy.

There are various sensors and chips that can be used to measure pressure. Most of these pressure sensors can be custom made by ordering them from certain companies with a list of specifications. However, the most promising technology for measuring pressure in the device includes a pressure chip called F-Socket Edge that is currently used in prosthetics devices and it is paper thin and can measure up to 10psi. The schematics are shown in figure 11.

MAP AND SENSOR MODEL NUMBER: 9811E
SENSOR NAME: *F-SOCKET*™ EDGE

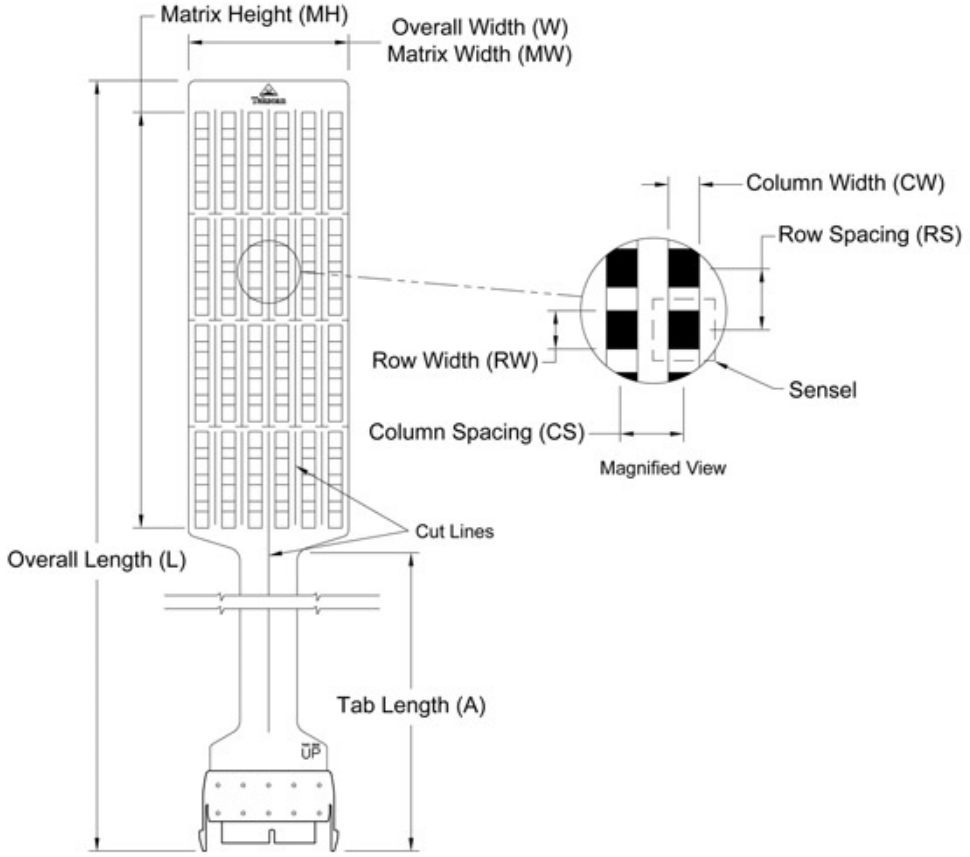

Figure 11: Schematics of F-Socket Edge.

The dimensions of the F-Socket Edge are 7.43inches in width, 8.00inched in length, and 0.0070inches in thickness. The dimensions, in greater detail, can be seen in table 7.

Table 7: Dimensions of F-Socket Edge.

	General Dimensions			Sensing Region Dimensions								Summary	
Model	Overall Length L	Overall Width W	Tab Length A	Matrix Width MW	Matrix Height MH	Columns CW	Columns CS	Columns Qty.	Rows RW	Rows RS	Rows Qty.	Total No.of Sensels	Sensel Spatial Resolution
US	(in)	(in)	(in)	(in)	(in)	(in)	(in)		(in)	(in)			(sensel per sq-in)
9811E	14.48	3.00	5.61	3.00	8.00	0.250	0.5	6	0.310	0.500	16	96	4.0
Metric	(mm)	(mm)	(mm)	(mm)	(mm)	(mm)	(mm)		(mm)	(mm)			(sensel per sq-cm)
9811E	367.8	76.2	142.5	76.2	203.2	6.4	12.7	6	7.9	12.7	16	96	0.6

Application Examples: Prosthetic assessment, handgrips, clothing fit, diaper and pressure garments

Special Features: Can be slit into six independent strips of 16 sensing cells each; External vents

Requirement: *VersaTek*® Cuff

4.2.2 Relative Humidity Sensor

The patch will also have a moisture sensor. Moisture will be measured by using a sensor that detects when the moisture is present on the skin. Many different products were analyzed under these criteria and with thoughts of future purchase. Many different types of tools were found to measure moisture. One of those methods can be found in bedwetting devices that use a sensor to alert the child when they have urinated. These alarms come in many different types: wearable alarms, wireless alarms, and pad-type alarms. Although varying in styles, all have the same component of a moisture sensor and an alarm component. In the wearable alarms, the system detects moisture immediately.

There are a few moisture sensing devices in the cosmetic field as well. The most common methods of measuring the skin moisture content are the Bioimpedance Analysis (BIA) and the capacitance method. In the BIA method it measures the impedance to calculate water content in the outer most layer of skin. This is a small device that has a transducer at the tip that supplies a small electrical current that runs between electrodes through the skin and then measures the impendence. A BIA can be seen in figure 12 (Truong, 2009).

Figure 12 -BIA system

In the capacitance method, water content is treated in the skin as a dielectric material and it gives higher accuracy compared to the BIA method. A capacitance method device can be seen in figure 13.

Figure 13 –Capacitance Method

4.2.3 Blood Volume Sensor

Initially blood flow was to be measure with a blood volume sensor. Through thorough research, blood flow was removed from the design. The blood volume sensor added a difficulty level in the patch design due to the bulkiness of the sensor and the increased risk that it could create additional pressure. Eventually the monitoring of blood flow was discontinued from the overall design due to the high cost and complexity of implementation into the device. The blood volume sensor can be seen in preliminary designs 1 & 2 but was removed in the following designs.

4.3 Block Diagram of Design

The device consists of patches affixed to the patient's skin in areas of interest. These patches are connected to the receiver which will gather and interpret the data. These results would theoretically be presented on both the screen of the receiver and would be wirelessly transmitted from the receiver to computers at the nurses' station. Figure 14 is a crude representation of ideal placement of patches.

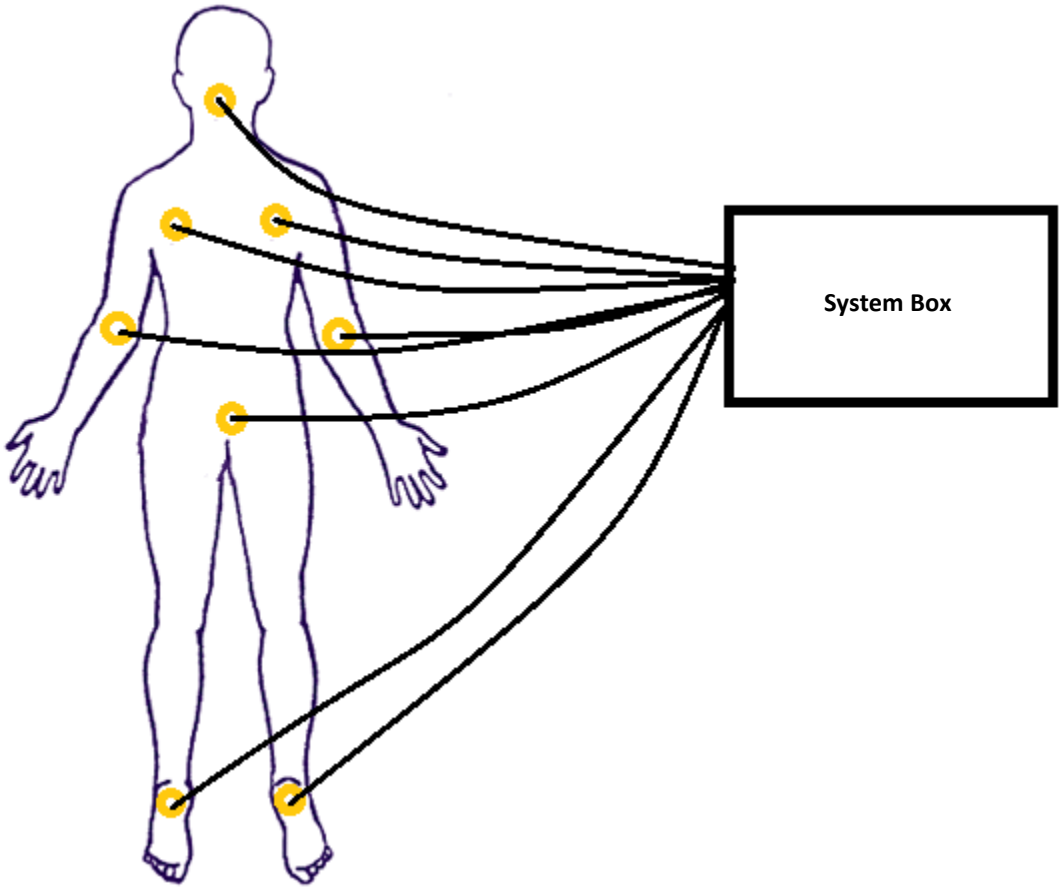

Figure 14: Schematic Drawing of Patch Attachment to the Body.

4.4 Choosing the Design

The design for the device was chosen based on the comfort of the patient. Since the patch will be placed underneath the patient, the design will be such that it doesn't increase the risk of ulceration and is efficient. The design of the patch will conform to the size of the sensors; allowing the smallest patch to be created.

4.5 Choosing the Sensors

Through the analysis of objectives, constraints, and the optimal design parameters, guidelines were created for the evaluation of each independent sensor. Many different approaches were considered for all three initial sensors. At the beginning of C term the team had chosen a pressure, relative humidity, and blood volume sensor. The blood volume sensor was removed from the design due to the complicated nature of the sensor and its redundancy with the pressure sensor. It could be suggested that the pressure sensor would always have to alert the program before the blood volume sensor. The following is a thorough description of the final pressure sensor and relative humidity sensor that were chosen for the final design and their explanations.

4.5.1 Final Pressure Sensor

The pressure sensor was purchased from Tekscan, Inc. and is called Flexiforce, model A401. This sensor measures a range of 0 – 25 lbs. and has a sensing diameter of one inch. The original sensor choice was Flexiforce model A201, which had a smaller sensing surface and measured a range of 0-100 lbs. The change of sensor was prompted due to the need for a larger sensing area and a more focused range of measurement. Flexiforce model A401 can be seen in figure 15.

Figure 15: Flexiforce sensor model A401.

The specifications of this sensor can be seen in table 8. They show the physical parameters and internal qualities of the sensor.

Table 8: Specifications of Flexiforce sensor model A401

	A401 MODEL
PHYSICAL PROPERTIES	
Thickness	
Length	2.24 in. (56.8 mm)
Width	
Sensing Area	1.0 in. diameter (25.4 mm)
Connector	2-pin male square pin
TYPICAL PERFORMANCE	
Linearity Error	<±3%
Repeatability	<±2.5% of full scale
Hysteresis	<4.5% of full scale
Drift	<5% per logarithmic time scale
Response Time	<5 microseconds
Operating Temperatures	15°F to 140°F (-9°C to 60°C)
Force Ranges	0-25 lb (110 N)***
Temperature Sensitivity	Output variance up to 0.2% per degree F

4.5.2 Final Relative Humidity Sensor

The relative humidity sensor was acquired from Honeywell Sensing and Control. Based on the available information, it was chosen to use a capacitance humidity sensor for our design. Based on ideal dimensions and specifications the Honeywell humidity 1000-01 was selected. It was then decided to use the Honeywell 4000 model, seen in figure 16, because the output is given in voltage and the circuit was easier to create.

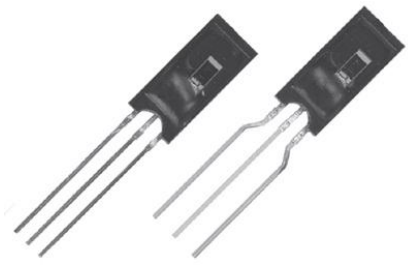

Figure 16: Honeywell RH 4000 sensor

The specifications of the relative humidity sensor can be seen below in table 9.

Table 9: Specifications for Relative Humidity Sensor

Specifications	
Description	integrated circuit
Output	analog voltage
Package type	SIP (2,54 mm [0.100 in] or 1,27 mm [0.050 in] lead pitch)
Response time	5 s 1/e in slow moving air
Operating temperature range	-40 °C to 85 °C [-40 °F to 185 °F]
Operating humidity range	0 % RH to 100 % RH
Moisture/dust filter	no
Cover/case	no
Calibration and data printout	yes (some listings)
Accuracy	±3.5 % RH
Voltage supply	4 Vdc to 5.8 Vdc

4.6 Choosing the Target Area

Given the fact that the body has many areas that have high risk of pressure ulceration, one specific area was chosen for evaluation. As mentioned above some of these areas include the cranium, shoulder blades, ischium, elbows, and heels. From this list the heels were chosen as the area of research due to the high incidence recorded in this area in comparison to other bony prominences. Although, the sacrum is the area of most incidences, the heel has a better ease of detection and analysis (Meaume, 2008).

The heel is one of two most common areas were ulcers form. In hospitals, it is the number one occurring area. In a study, a biomechanical model was developed to calculate internal soft tissue pressures at the heel when in a supine position. This model demonstrated that a typical foot that is heavy weighted, has a sharp posterior calcaneus and thin soft tissue padding are more prone to heel ulcers. These variables have the most effect on whether a patient will develop ulceration on the heel.

Also, diabetes and edema at the feet will create additional risks for heel ulcers. An example of a heel ulceration can be seen in figure 17 (Gefen, 2010).

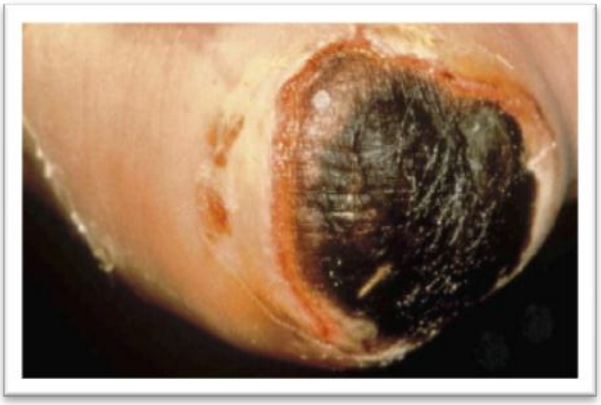

Figure 17 - Typical deep tissue damage on heel.

For the accuracy of research, a control area was chosen; the posterior calf. Through research and recommendations of Dr. Dunn it was suggested that a pressure ulcer formation in this area would be unlikely. This area has a higher content of fat and muscle over the bone. Pressure ulcers are prone to bony areas perhaps due to the higher pressure and therefore it was concluded that an area such as the calf would not have pressure ulcerations and could be an effective control for the experimental trials.

4.7 Choosing the Program

The initial design for the system included a program with an embedded algorithm to monitor sensor readings in real time through a data acquisition unit (DAQ) and alert the caregiver when necessary. This program would have an attractive and intuitive graphical user interface (GUI). The GUI was to be created in the programming language JAVA, which is known for its portability between platforms and familiarity in the tech sector.

The team had access to two data acquisition systems; National Instruments LabVIEW and BioPac Systems. The BioPac system was not appropriate for use in this application because it is unable to operate without specific connectors and can only be read by specific programs. The LabVIEW system can better accept a wider range of inputs and while it has a specific platform for use, that platform can be embedded into other programs. Naturally, the LabVIEW system became the DAQ of choice.

Upon further research, it was discovered that while the LabVIEW platform could be integrated with other programs, a premade software package was needed to achieve this aim. Unfortunately, this software package was not currently at our disposal and to purchase it would cost approximately five times the total budget for the project. Fortunately, the LabVIEW platform can be used to create

programs to analyze data in real time and produce a simple GUI. This feature was utilized to create an initial prototype of the team's final vision for the program.

5 ALTERNATIVE DESIGNS

5.1 Needs Analysis

Through research and discussion it was decided a patch including three sensors would be ideal. The sensors would detect pressure, moisture and blood volume, respectively, and their readings would be analyzed over time. In order to read the data over time, a computer equipped with a data acquisition system (DAQ) and LabVIEW software would be used. To affix the patch to the patient, a material with adhesive would house the sensors and keep them properly positioned against the skin for the duration of their use. The DAQ and the sensor patch were connected using a length of wire. Additionally, some circuitry was assembled to facilitate the connection between the sensors and the DAQ.

5.2 Preliminary Designs

At the beginning of C term there were two patch designs which included a blood volume, pressure, and relative humidity sensor. An additional two patch designs followed the removal of the blood volume sensor. The latter of these two is deemed the final patch design.

5.2.1 Preliminary Design 1

After the individual evaluations of each independent sensor, the actual patch containing all three sensors was analyzed. The design of the patch had to incorporate the use of the sensors in optimal locations for their independent measurements and had to be integrated in a way that their performance would not be hindered. The pressure sensor was placed in the center since it was considered that pressure would be at its highest at this point. Both the blood volume and the relative humidity sensor were placed to the side. Figure 18 is a CAD drawing of this preliminary patch design.

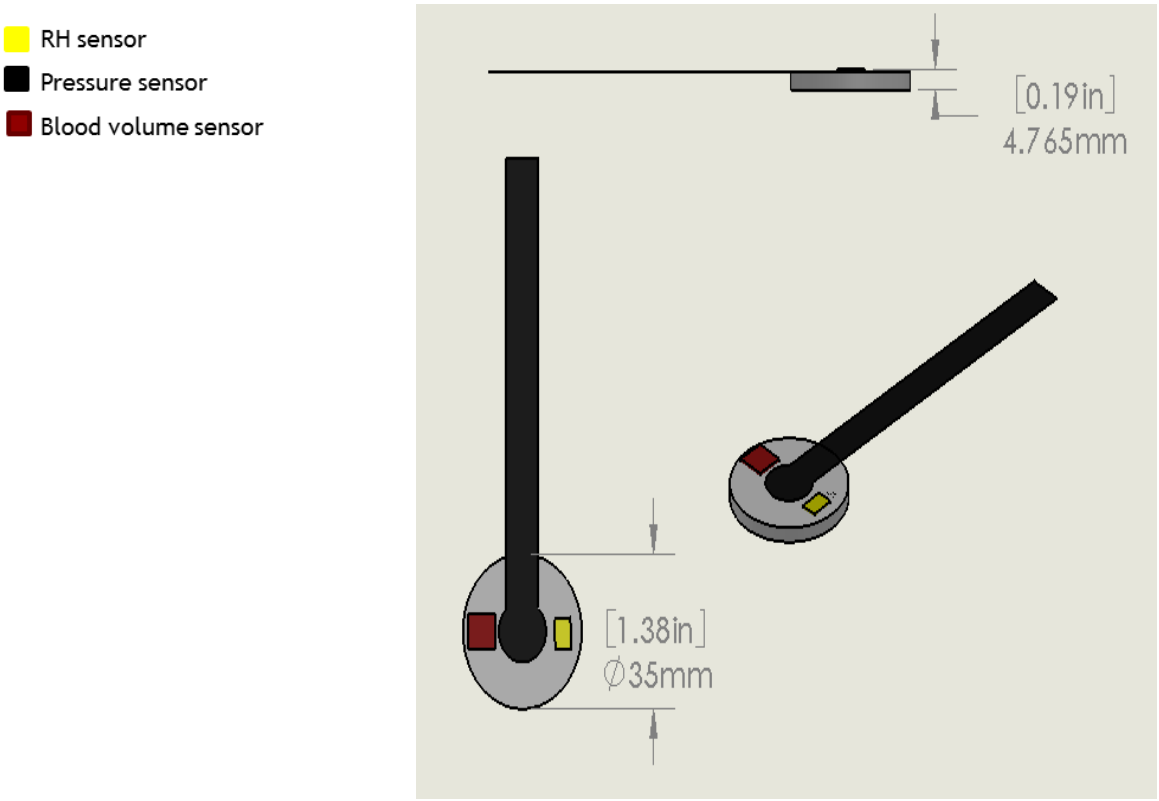

Figure 18: Preliminary patch design 1.

5.2.2 Preliminary Design 2

The second patch design was developed in the same time frame as the first. This design featured a pressure sensor, moisture sensor and blood volume sensor as the previous patch. The difference involved the shape of the patch itself. The patch would be a suction cup shape, with the pressure sensor along the rim of the patch where it would receive the most possible pressure. The moisture and blood volume sensors are affixed to the inside of the patch where they will be protected from light and outside moisture causing elements, reducing noise and creating the best possible measurement conditions for these devices. This design can be seen in figure 19.

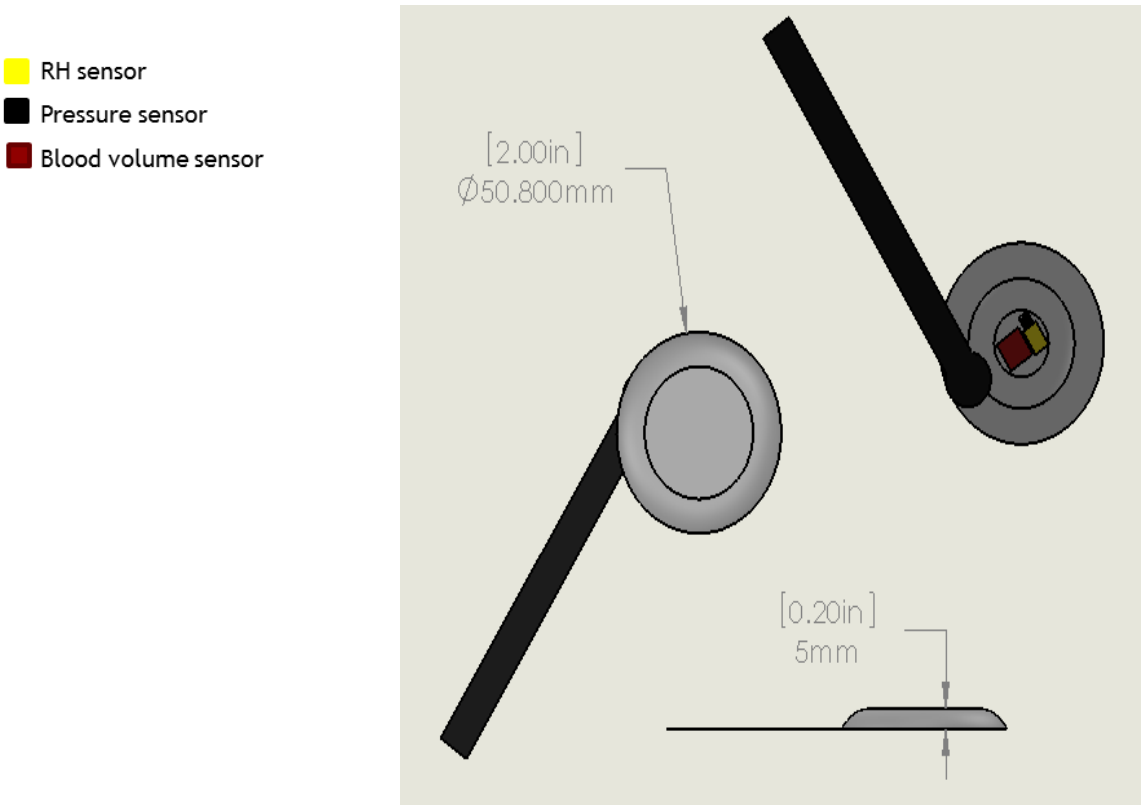

Figure 19: Preliminary patch design 2.

5.2.3 Preliminary Design 3

The third patch design was developed at the beginning of C term. This patch concept involved the same design as described previously. However, the difference rested on the conclusion that the blood volume sensor was deemed unimportant and taken out of the final sensor decisions. In addition, the pressure sensor was changed from the A201 model to the A401 model of the Flexiforce sensors as mentioned above. The relative humidity sensor was placed to the side. Since this patch involved only two sensors, it was designed to be much smaller. Figure 20 is a CAD drawing of this sensor. It can be seen that the pressure sensor takes up most of the patch space and that the relative humidity sensor is placed to the side, right underneath the tail of the pressure sensor.

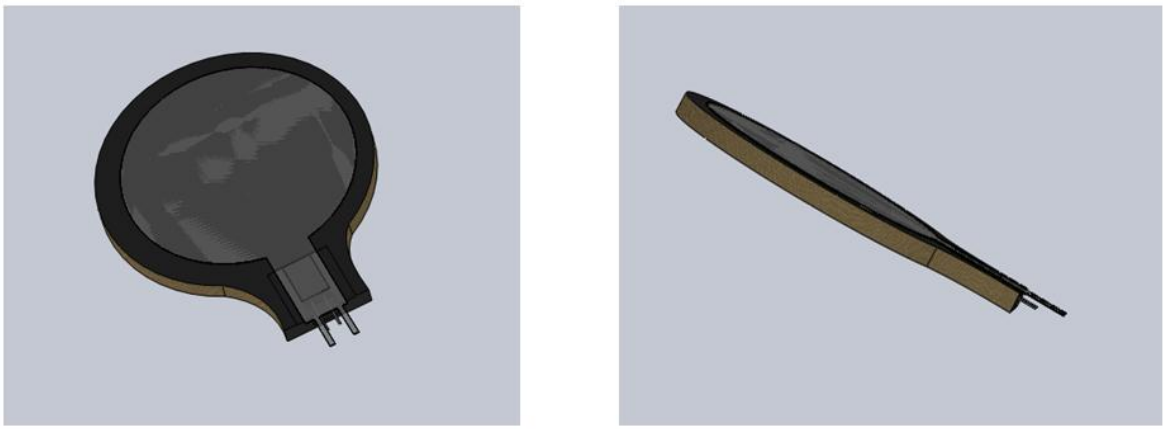

Figure 20: CAD drawings of the preliminary patch design 3.

5.2.4 Final Solution

The final patch design involves a pressure and relative humidity sensor with a similar design to preliminary patch design three. The difference relies on the thickness of the patch considering only the thickness of the pressure sensor rather than the thickness of the relative humidity sensor. The relative humidity sensor would be placed to the side of the pressure sensor but not underneath the heel so that its larger thickness does not influence the formation of ulcers on the patient.

6 FINAL DESIGN

6.1 Overview of Final Design

6.1.1 Circuitry

The relative humidity sensor which was purchased came with the circuit below in figure 21 provided. Since this was a simple circuit and suited the needs of the device, it was used in the creation of the prototype. The resistor selected and used was 75kΩ as the distributor noted a typo in the figure, where the maximum load should be 80kΩ, rather than the minimum load being 80kΩ.

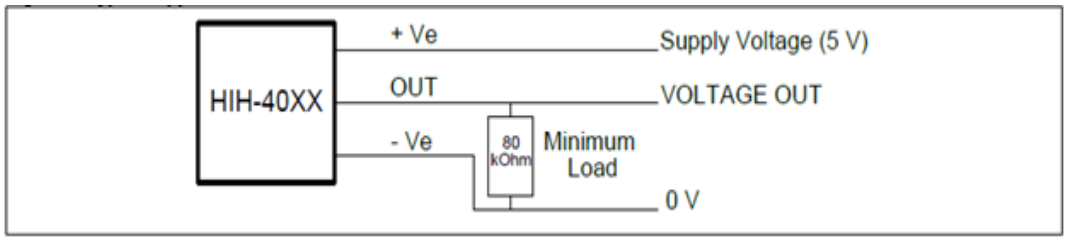

Figure 21: Humidity Sensor Circuit

Since the device is to be run using battery power, specifically 9V batteries the RH sensor became a concern. The RH sensor can only run using a maximum of 6 volts of power, so a circuit was developed to

be able to convert the 9 volts of power provided by a standard 9V battery into 4.5 volts as can be seen below in figure 22.

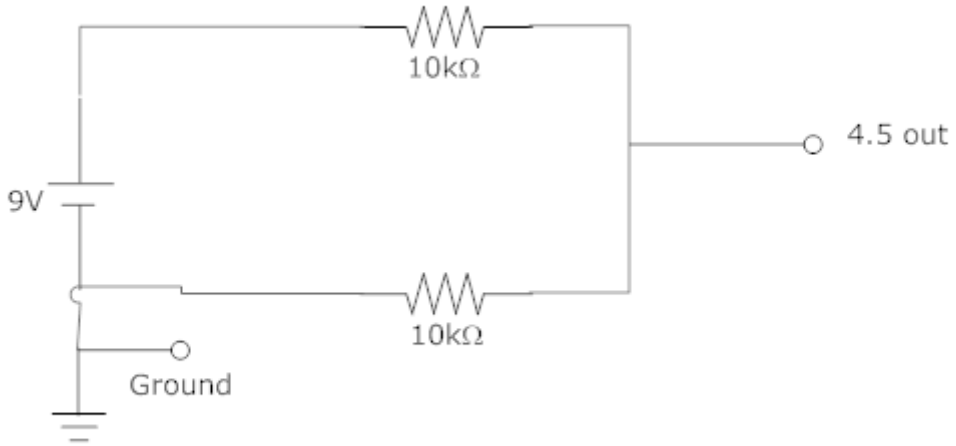

Figure 22: Voltage Conversion for RH Sensor

The pressure sensor also came with a circuit provided as can be seen below in figure 23. This circuit involved a dual power supply and provided little information about the size of resistors and power supplies necessary.

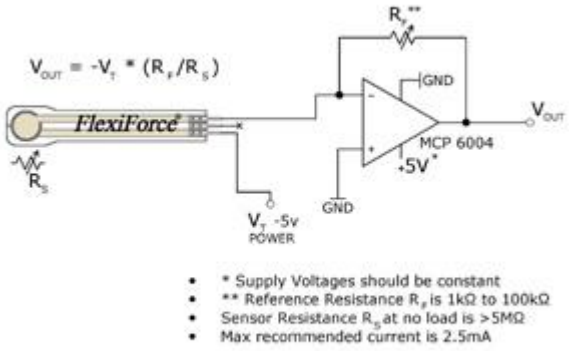

Figure 23: Pressure Sensor Circuit Supplied From Company

The circuit was then adapted to the needs of the device by finding an optimal resistor for the range of measurements the device needed and adjusted to run off of two 9V batteries. The final circuit for the pressure sensor used in the device can be seen below in figure 24.

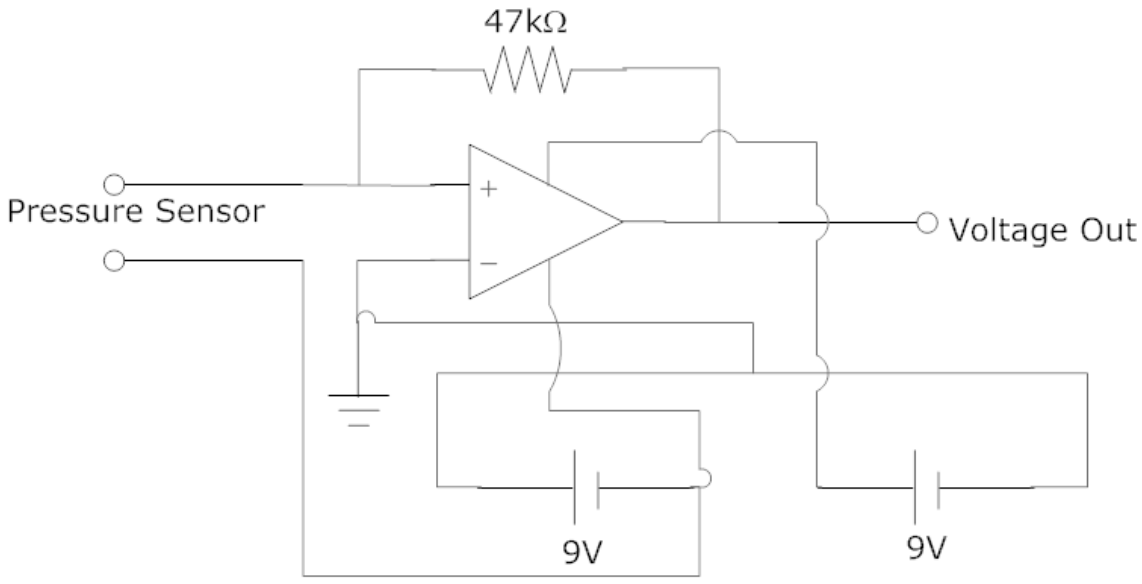

Figure 24: Pressure Sensor Circuit Used in Device

6.2 Design Components

Table 10 displays the materials necessary to create this device. It outlines the quantities of each material and provides individual cost of each item.

Table 10: Bill of Materials

Material	Description	Quantity	Cost
Pressure Sensor	Teskan A201	1 for each patch	$78/4
Humidity Sensor	HIH 4000	1 for each patch	$16.68
Wire	32 AWG (7/40) SPC	100 ft.	$42.00
Wire coating	used IV tubing	100 ft.	Donated
9 Pin connector female	D-sub miniature, gold contact	16	7.90/10
9 pin connector male	D-sub miniature, gold contact	2 for each patch	7.90/10
Hammond Project Box	grey 6x3"	1	$12.90
Philmore DB9 Hood		2 for each patch	7.90/10
Punchboard			$14.25
Resistors			Donated
silicone sealant	to seal around plugs	1	5.97
screws		32	.98/10
LED	red	8	Donated
9V battery		3	4.99
9V battery connectors		3	Donated
Band-Aid		1 for each patch	
vinyl decals			Donated
DAQ			
soldering equipment			
masses for testing			

6.3 Building the Device

The construction of the device began with attaching long wires to the sensors. These wires were at least 3 feet in length to make the patch easier to use. These wires were then attached to appropriate pins on a 9-pin male plug. The connection of the sensors to the plug remained consistent throughout the process so the plugs could easily be interchanged between the ports of the device. Initially the circuits required for the sensors were assembled on a breadboard. Using a female 9-pin plug and attaching an oscilloscope to the circuit, each sensor was tested to ensure the connections were stable.

A 13 x 7 cm box was drilled so that eight 9-pin female plugs could be inserted in the two long sides of the box in two rows of four. At the same time, the eight holes in the lid of the box were drilled to fit the LEDs. Punchboard was trimmed, creating eight pieces which were able to fit inside the box and hold the necessary circuits for the sensors. The circuit from the breadboard was copied onto each piece of punchboard and soldered in place. For the assembly of the prototype, only two sets of circuits were created. The prepared boards were then inserted into the box and the necessary lead wires were

threaded out the holes for the plugs. All of the wires to attach to the sensors went to one side and the wires to and from the DAQ went to the corresponding hole on the opposite side. These wires were attached to 9-pin female plugs, in a standardized manner, reflecting the way which the sensors were attached to the male plug. The wires which needed to be connected to power were attached to another perforated board in the box which had been equipped with the necessary circuit to feed power to the sensors using 9-volt batteries.

The 9-pin female plugs were assembled on each side of the project box, securing them in place with small bolts. A seal was created around the plugs by applying silicone caulk around the edges and filling in any gaps. The boards inside the box were adjusted as needed to create a secure fit. Another piece of perforated board was cut to fit the lid of the box, and the LEDs were attached in the proper pattern to fit the shape on the lid. The wires were attached to the appropriate plugs inside the box and the LED board was suspended in the lid using adhesive tape. The box was then closed and secured with screws and the decals were added to the sides. Unfortunately the box obtained for the prototype had a surface which would not allow the prepared vinyl decals to be adhered. The use of permanent marker was also tried for this application to give an idea of design, but the permanent marker did not stay on the surface well either. The final device can be seen in figure 25.

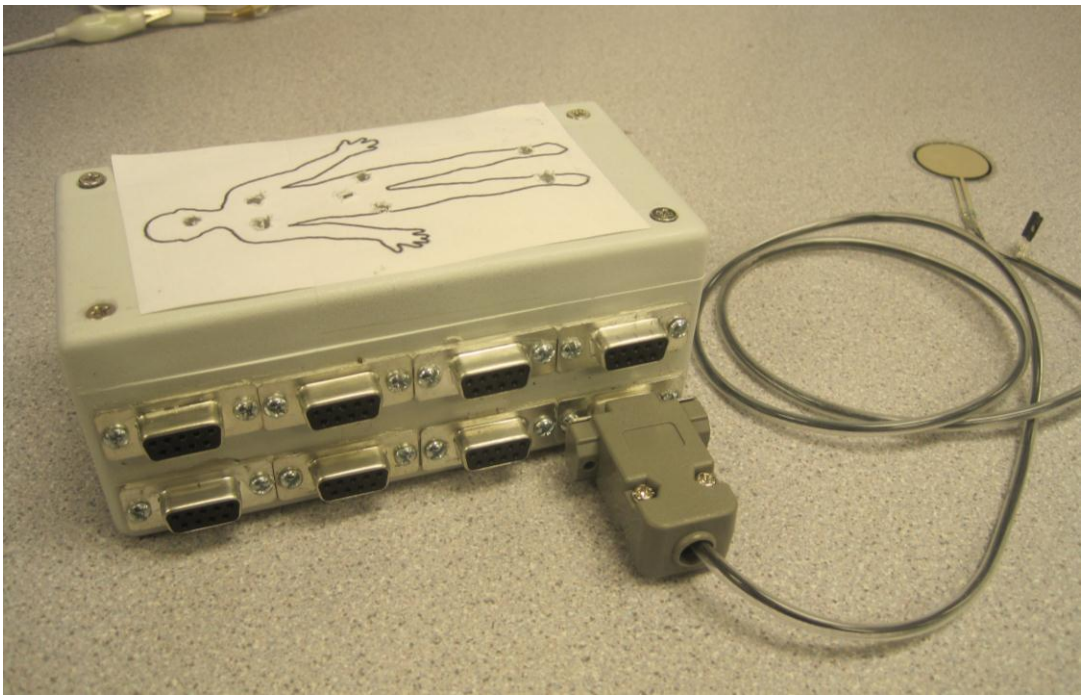

Figure 25: Final Device with sensor

6.4 Pressure and Moisture Thresholds

An important feature of this device is a program which can alert the caregiver when conditions prone to pressure ulcer formation occur. These conditions are found through comparing the measured values from the sensors against a series of thresholds and initiating a response accordingly. The thresholds

used in the program were found through a combination of research and tests with the sensors. From the research, certain key points for observation were found. Patients were most prone to pressure ulcers when their skin was wet, 100% humidity, and when their skin contained below 40% relative humidity of moisture. A key pressure number which appeared in the research was 35mmHg when capillary occlusion is thought to occur.

Taking the above numbers, their voltage equivalents were found from the sensors in the lab. The humidity testing (seen in the sections below) provided that 100% relative humidity was 0 volts and the room humidity of 47% corresponded to 1.996 volts. The threshold for 100% relative humidity was adjusted to 0.2 volts in the program to account for noise. Using the points obtained, the value for 40% relative humidity was extrapolated to be 2.3 volts. This value was adjusted for noise to become 2 volts in the program.

Through the weight testing described n the sections below it was found 35mmHg correlated to 2.04 volts from the pressure sensor. This value was only achieved during the test to failure trials, indicating there were other values of interest. Utilizing the data, from the group trials, three major thresholds were found; 0.2, 1 and 2 volts. These thresholds were taken from the low end of the average of the major trials.

6.5 Device Safety

It is important that the device upholds certain standards of safety so as not to place the users in any added risks to their health. An important part of this safety is the device design. Hence the design was chosen so that the relative humidity would be placed to the side since it is the bulkiest sensor with the thin pressure sensor being placed directly underneath. The patch itself will provide additional comfort with thin padding. In addition, the device will be powered using batteries so that it removes the risk of shock through an electrical connection.

7 SOFTWARE DESIGN

7.1 Program Overview

The system would not be a complete solution to our problem without a program to monitor the factor of time and to provide an interface for the user. The goal of the program was to include an algorithm which would be structured around the gold standard of repositioning every two hours. This procedure, used effectively has been shown to reduce pressure ulcers, but human error prevents this practice from being completely effective. Human error would be reduced by alarms every two hours which could not be ignored. Additionally, the alert system should be an intuitive system which provides the user with a high level of information.

Some patients are able to move themselves to an extent. This idea prompted an addition to the program which would monitor the pressure applied to the sensor. If the patient moved during the two

hour phase, the caregiver's intervention would be unnecessary, an inefficient use of the caregiver's time and a possible disruption to the patient's other treatments. There is also a known correlation between the intensity of the pressure applied and the time in which an ulcer develops. Since the pressure would already be monitored by the system, it was a logical step to include a progression of thresholds which would reduce the amount of time between alerts as the intensity of the pressure increased. The values for the thresholds were ultimately determined using the data from the group member testing in later sections.

Moisture values would also be monitored. The trigger for the moisture alert would be more of a toggle switch; either moisture is in range, or it is not. The moisture alert would be immediate when the condition is sensed because moisture problems do not only create a risk to pressure ulcers, but they can also be dangerous to other conditions.

7.2 Program Design

The program required the ability to measure data in real time. This required the direct link to the DAQ channel using an I/O channel for each sensor. Pressure data is read and reported as a value to the system. This value is compared against the thresholds of 2 volts, 1 volt and 0.2 volts. If there is no pressure on the system, the value will be 0. As pressure passes a threshold, the time is noted and the program continues to compare the current time to the time of initialization. Once the difference between the two times exceeds the acceptable value programmed, the indicator LED is changed to red, and the pressure text warning is prompted. If at any time the pressure value drops below the threshold, the time is reset. The program measures time in milliseconds, so the time which the pressure goes into the danger zone is more accurate than a human keeping an eye on the clock.

The moisture value is also read and compared against the given values. If the moisture is outside the acceptable range, the indicator LED is automatically changed to red and the appropriate moisture warning text is prompted. Below are two figures which show the workings of the program in all the possible paths which can be taken for one patch. Figure 26 shows all the paths if all the values are true and figure 27 shows the path if all the values are false. For the entire system to function, the program in the figure below needs to be included once for every patch used.

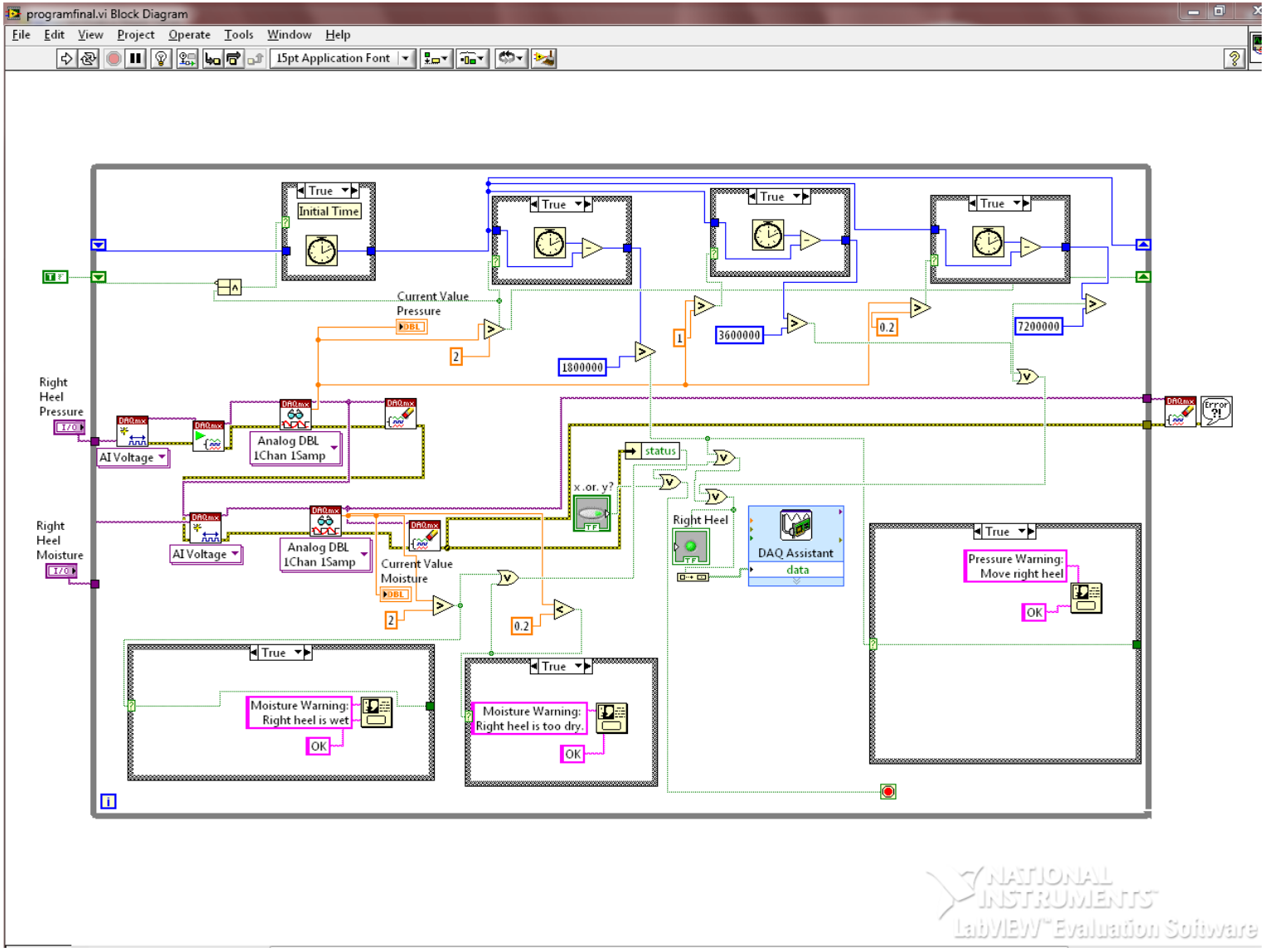

Figure 26: Program view 1

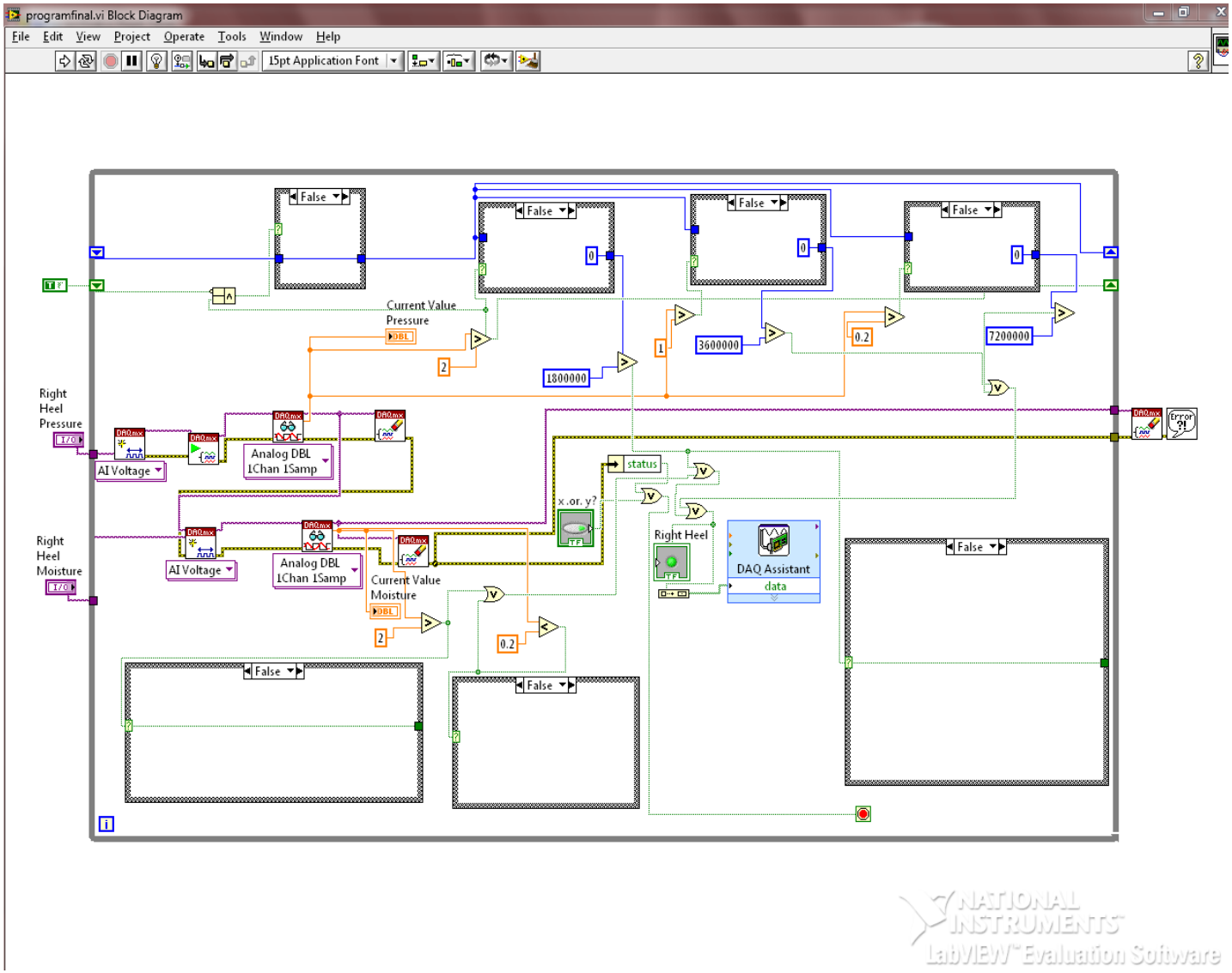

Figure 27: Program View 2

7.3 User Interface Design

The system of loops and connections in the prior section are far too complicated for a caregiver to analyze in a matter of moments to produce the appropriate care quickly. A simple GUI was created to display the information needed. It consists of a series of indicator lights aligned upon the outline of a supine patient for reference, which are green in normal status and red in alert status. Additionally a simple but informative text box appears with each warning. In figure 28 is a picture of the GUI in normal status and figure 29 displays a pressure alert status in the right heel.

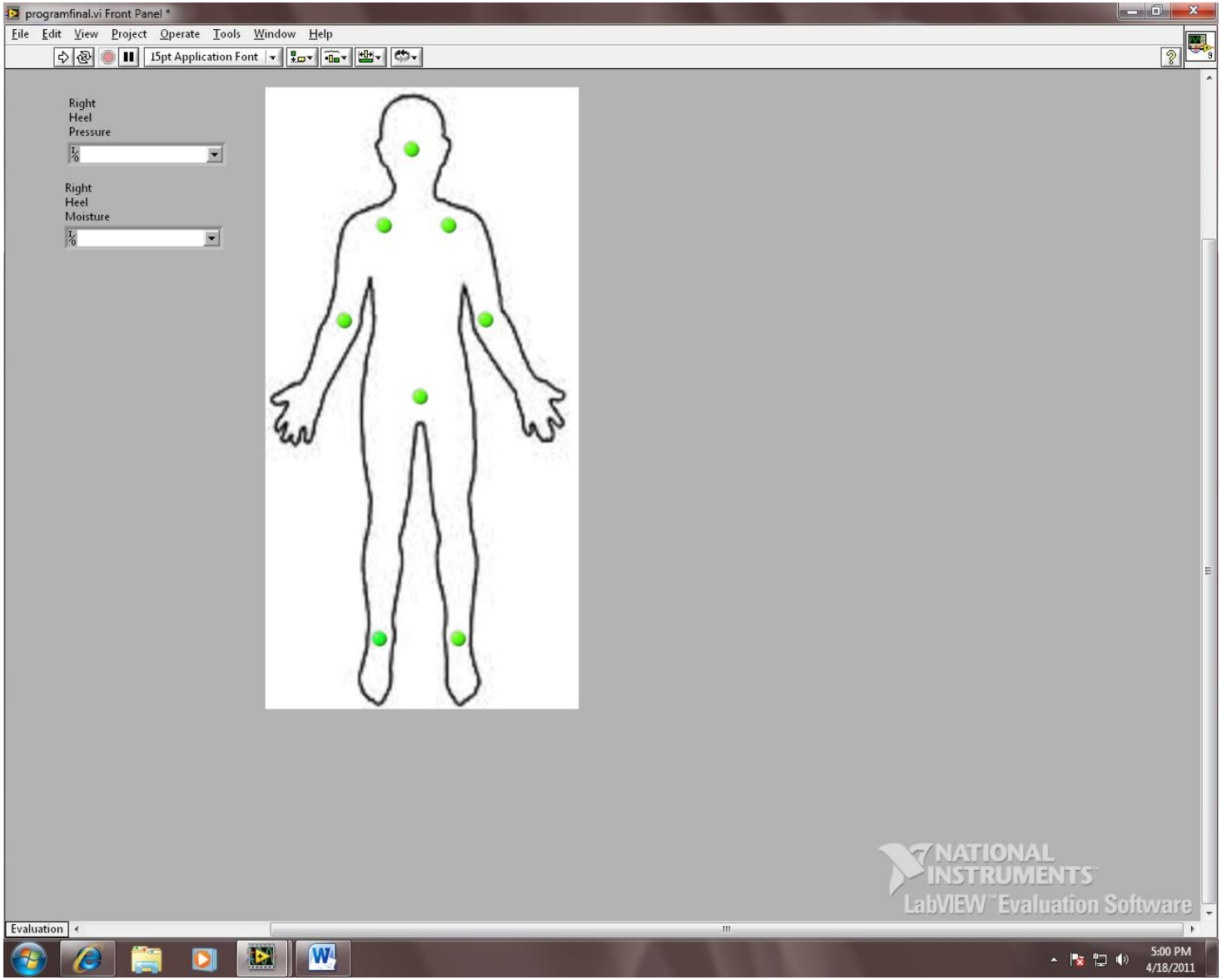

Figure 28: GUI normal view

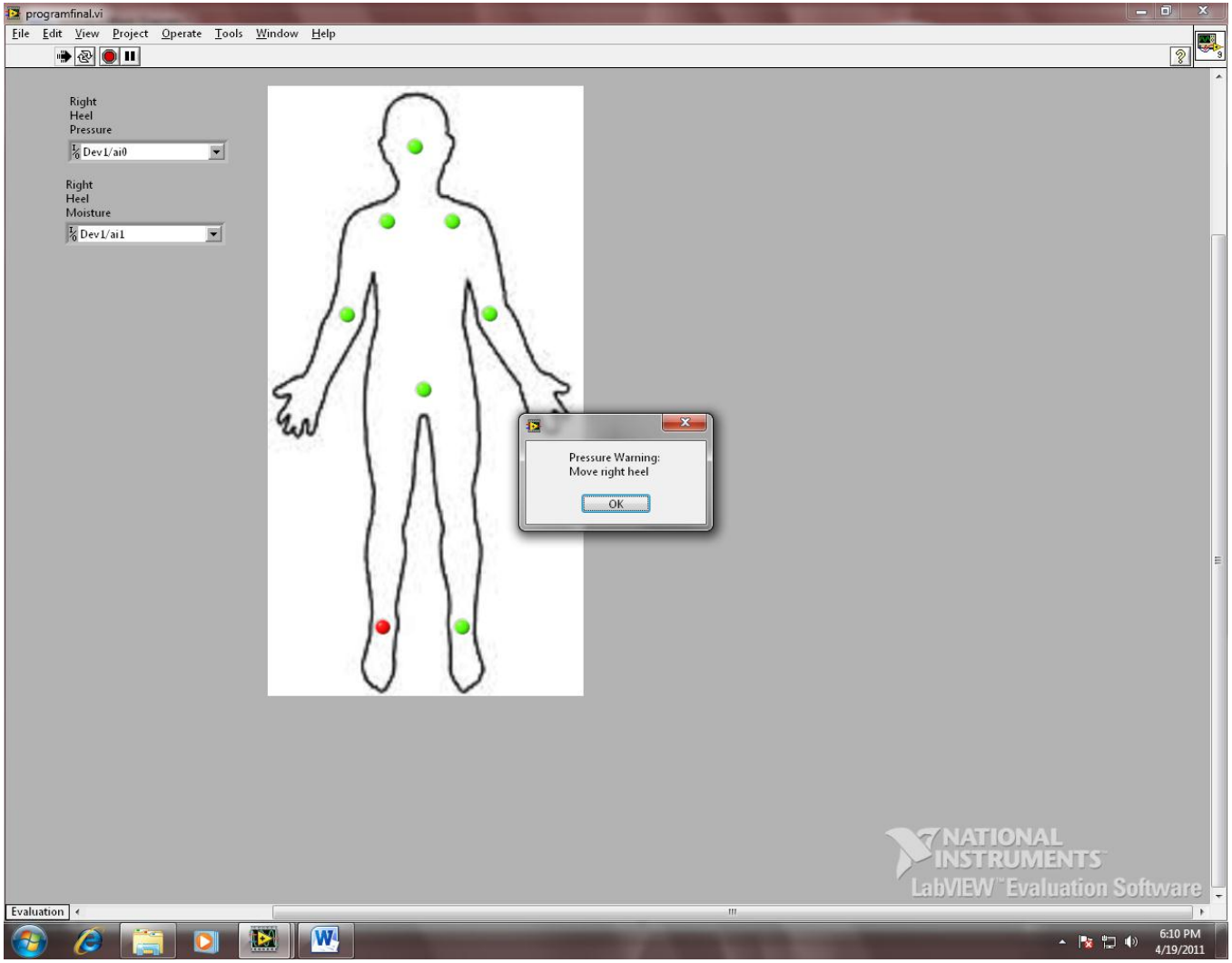

Figure 29: GUI Pressure warning view

8 DESIGN VALIDATION

8.1 Design Verification

In order to test the efficacy of the system, different aspects were evaluated. The setup, calibration, sensor testing, LabVIEW, and the patch were thoroughly analyzed with a variety of experiments. Table 11 is the summary of testing procedures that were performed and why they were performed.

Table 11: Testing Procedures

	Test	Procedure	Expected Results	Reason
Setup & Calibration				
	Circuitry testing	Set up sensors to bread board according to their schematics. Determine the adequate readings.	Output in voltage. Continuous signal without interference.	These tests are important to ensure correct setup and calibration
	Range testing	Test the necessary ranges for each sensors to give ideal readings		
	DAQ testing	Set up sensors to DAQ. Test if sensor are giving the necessary output with ranges	Gives readings on graphs.	
LabVIEW& Sensor testing				
	Functionality testing	Manual entry of data into program and observe expected results, test thresholds for the ulcer formation indicator.	When threshold is met the system is triggered. When pressure is relieved the timer is reset. When moisture is removed, the indicator turned green again.	To determine if the program is working correctly
	Sensor Accuracy test	Pressure sensor, accuracy testing will be accomplished by simulating inputs. Pressure will be increased using free weights. Moisture sensor: How does it perform with barrier? How does it perform with various levels of humidity and given readings?		To determine if we are getting the correct inputs
	User friendly testing	Is the program user friendly?		To determine if the program is intuitive
Patch evaluation				
	comfort	Is the patch comfortable to be worn for long periods of time? Rate comfort level from 1-10		Is the patch patient friendly?
	Durability/Fail test	Test the maximum inputs that the sensor can with stand and function correctly under.		To determine failure rate and durability of the patch

8.1.1 Initial Sensor Testing

Most of the testing of the sensor was done with a bread-board version of the design. Using LabVIEW, a simple program was written to read the signals from the sensor prototype display them with a moderate filter and determine correct settings. Once the signals are into the computer, a simple LabVIEW program processes the information. This is to test the connectivity of the NI-6008 to the computer using LabVIEW. This involves creating a waveform display window and then connecting it to a DAQ Manager. This gave us the ability to determine the data type and the sampling rate.

Since this is a basic test, the default setting of voltage and 1 kHz sampling were chosen respectively. Once the LabVIEW program was set up, leads from a DC power supply were connected to the NI-6008. Voltage was then supplied to the DAQ while the LabVIEW program was running. The output from the power supply and the LabVIEW reading was determined to be accurate with each other.

8.1.1.1 Pressure Sensor

The following calibration and conditioning of the sensor was provided and recommended by Teskan, inc.

Part 1: Conditioning the Sensor

Before using the sensors it is recommended that you condition the sensors. This process will "break in" the sensor, and should be done before calibration and before every use for best results. To condition the sensor, place 110% of the maximum test load onto the sensor for approximately 3 seconds. For this sensor, the maximum test load is 25 lbs.; place 27.5 lbs. onto the sensor. Remove the load from the sensor. Repeat 4-5 times. When finished, proceed to **Part 2: Calibration of the Sensor.**

Part 2: Calibration of the Sensor for Static Forces

1. Place 1/3 of the test weight on the sensor. Leave the weight on the sensor the same amount of time (before recording the output) as you will in your actual experiment. This helps minimize the drift error. Record the output, and then remove the weight from the sensor.
2. Place 2/3 of the test weight on the sensor, again waiting the approximate amount of time. Record the output. Remove weight from the sensor.
3. Place the full test weight on the sensor. Wait the approximate amount of time again, and record the output. Remove the weight from the sensor.
4. Gather each set of data (Sensor Output vs. Force Applied) and plot the data on a graph. Sensor output is plotted as Voltage vs. Force. This gives a linear plot. You can then draw a line of best fit, or calculate one with MS Excel.
5. Use the equation for the line of best fit and the sensor output to determine the force of unknown loads on the sensor during the experiment.

Results:

The initial program design was to include an alert system for the user when the pressure sensor reading exceeds 35mmHg for 2.5+ hours. The pressure was translated into about 3 pounds of force on

the sensor. When this force is felt on the sensor for 2 hours, the alert system will be activated. Below is table 12 that shows how the pressure is translated into voltage.

Table 12: Pressure to voltage

Pressure	Diameter	Area	Force	Amplitude
35mmHg	1 inch	4.93 in^2	3.336 lbs.	2.04 volts

A linear relationship was confirmed through initial testing between force and voltage readings. The data can be seen in Figure 30. Weights of 1.1, 2.2, 3.3, 6.1, 8.3 and 10.2 pounds were placed on the center of the sensor for ten seconds. From these measurements a linear forecast trend line was created and a linear equation was populated. The linear equation will allow us to determine the threshold input of the system.

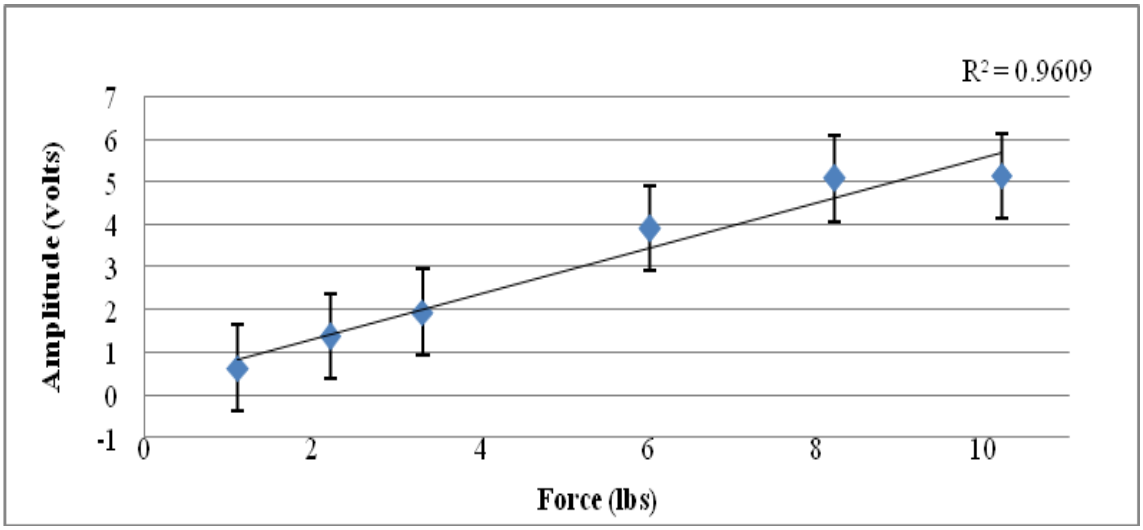

Figure 30: Pressure Sensor Readings

Linear equations were developed for each sensing area size. The r values displayed shows that the linear equation is very fitting to the data point. The closer the r value is to 1, the better the fit is. This can be seen in table 13.

Table 13: R values

	Linear equation	R-value
Big	y=.1887x+.3038	0.9971
Med	y=.4308x-.0908	0.9986
Small	y=.509x-.145	0.9974
nothing	y=.3021x+.2097	0.9954

As seen in figure 31, as the weight increases the greater the difference in amplitude is found between measurements. This correlates to what occurs clinically. The larger the area in which the force is applied, the smaller the voltage reading and vice versa. This correlates to what occurs clinically and mathematically. Even though the sensor does not measure pressure, it is in line of what the device should be measuring.

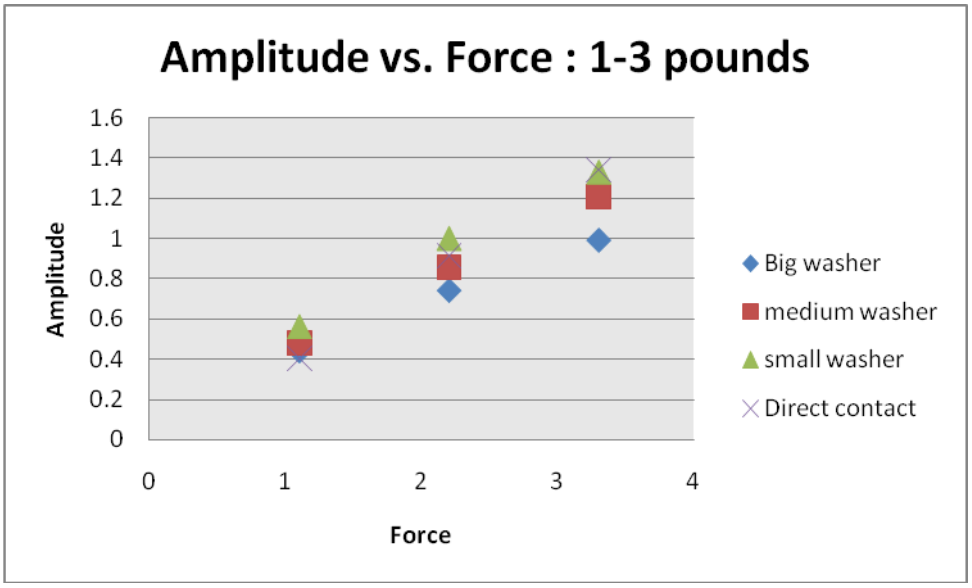

Figure 31: Forces of 1-3 pounds

Several different data points were collected to determine the standard deviation of the force sensor reading. The weight was applied in several different areas of sensors. Locations included: center, off to the side and touching the perimeter. The standard of deviation was calculated to be .104 from this sample of data and can be seen as error bars in figure 32. This demonstrates that the sensor has the ability to read force in various locations on the sensor. This accuracy is beneficial to our device because the force will not always be placed at the center of the sensing area.

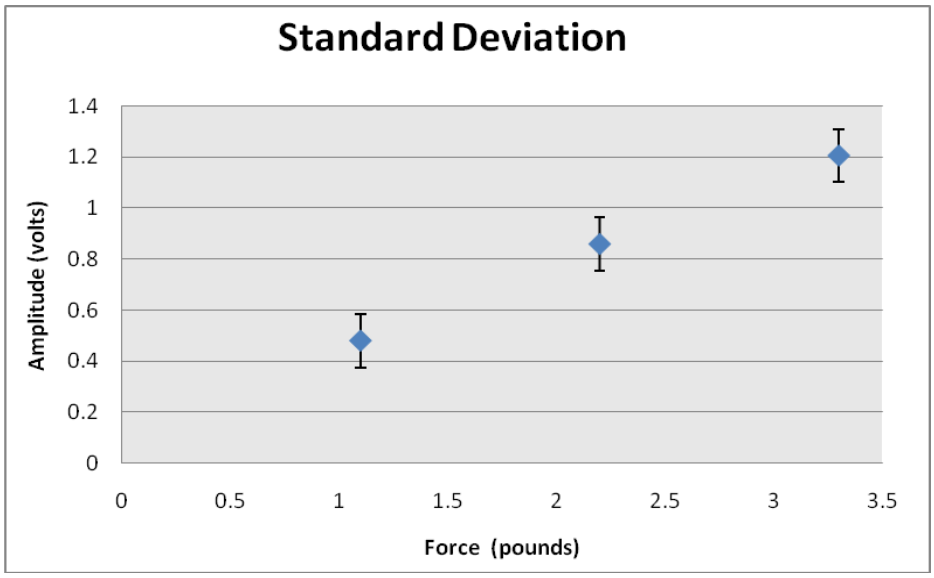

Figure 32: Standard Deviation of Force Sensor

8.1.1.2 Moisture Sensor Testing

Part 1: Calibration of the Sensor for Relative Humidity

1. Put sensor into an environment with a humidity generator at specified humidity
2. Leave the sensor in environment for the same amount of time for each test. This helps minimize the drift error. Record the output, and then remove the sensor from the environment.
3. Place the full humidity on the sensor. Wait the approximate amount of time again, and record the output. Remove the sensor from the given environment.
4. Gather each set of data (Sensor Output vs. Humidifier reading) and plot the data on a graph. Sensor output is plotted as RH% (humidifier) vs. RH % (Sensor). This gives a linear plot.
5. Repeat procedure with weight place on top of sensor. This will determine how the sensor functions under force.

Results:

Figure 33 displays the correlation between humidity and voltage as humidity was altered between the humidity of the room (47%) and saturation (100%). The results were consistent and were in line with manufacture specification. It was also observed that when introduced to sweat the humidity sensor read the same as it was introduce to water. It was also noted that applying force to the sensor did not affect the readings.

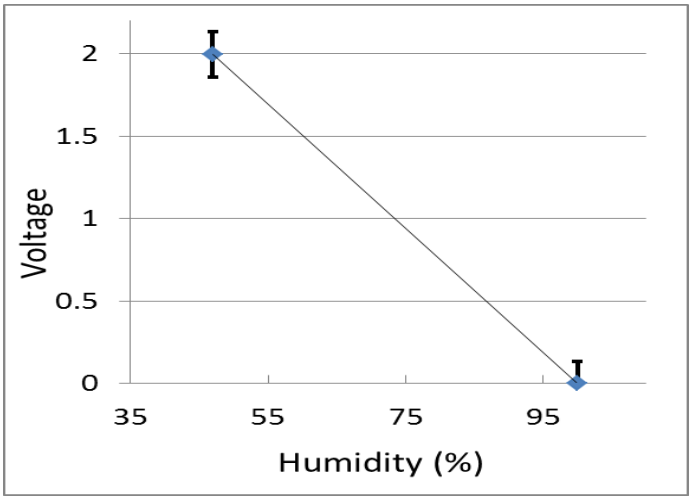

Figure 33: Voltage vs. Humidity

When comparing our results to the manufacture specifications, shown in figure 34, it can be seen that the results are comparable. The trend line is inversed based on building the circuit of the sensor differently but the line equation is the same.

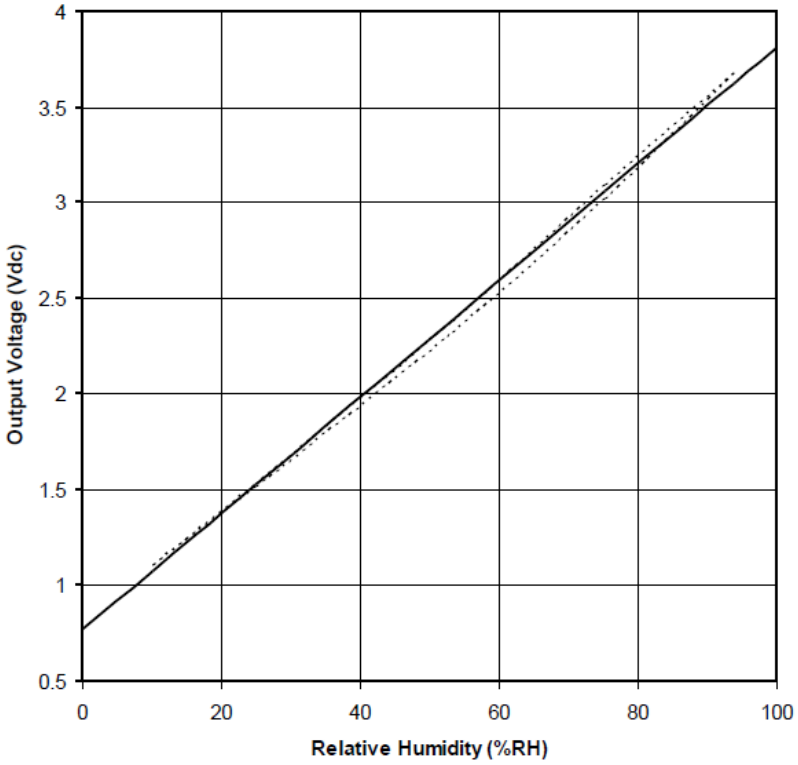

Figure 34: Manufacturer's Output Voltage vs. Relative Humidity (At 25C and 5V)

8.1.2 Program Testing

The program was tested for accuracy in three ways. The first test determined the ability of the system to function overall as expected. The second test determined the ability of the system to properly read data from the sensors. The third test determined the accuracy of the timing functions of the program.

The first test was performed by observing the actions taken by the program when expected sensor use occurred. This process included applying pressure over the programmed threshold to the pressure sensor for the duration of the timer, removing the pressure before the timer had completed its iteration and applying pressure below the programmed threshold for the times above. Water was also added and dried from the humidity sensor to observe the results. From this testing it was confirmed there was no human error inhibiting the program and overall it functioned as expected.

The second test was done by simultaneously connecting the sensor to the DAQ and a digital storage oscilloscope. Pressure and moisture were applied to the sensors respectively and the readings produced by the program were compared to those of the oscilloscope. The program and the oscilloscope had consistent readings to 0.001 Volts, which was the maximum obtainable tolerance of the oscilloscope.

The third test was done by applying a series of constant forces to the pressure sensor which would surpass each triggered threshold. When the force was applied to the pressure sensor a timer was started. When the program reached the point at which the alert was activated, the timer was stopped. The time from the timer was compared to the expected time frame from the program. The times were consistent within 1-2 seconds which is an acceptable margin of human error while operating a stopwatch.

8.1.3 Patch Evaluation

It was made clear at the beginning of the design process the patch should be lightweight, comfortable, easy to wear, easy to use, non-restrictive, and allow the system to function properly. Through our validation of the system as a whole, the patch was proven to be effective and allowed the system to work as intended. The utilization of small sensors allowed for the patch to be lightweight and compact. Overall, the patch can be considered comfortable because while using the patch, the sensors cannot be felt. The only foreseen discomfort from the patch would be a result of the adhesive bandage used, especially in populations with sensitivity to such bandages. Due to the adhesive bandage, the patch is easy to wear, with minimal fear of sensor displacement. The patch itself is non-restrictive due to its small size, but the wires do restrict overall patient movement and comfort.

The use of the patch is slightly complicated, due to the need to center the patch on the targeted area. Currently there is no means to ensure proper alignment. Additionally, the shape of the adhesive bandage used can increase or decrease the difficulty of applying the patch due to the various shapes and sizes of human body parts. It may be best suited in the future to provide varying shapes and sizes of patches for such purposes. However, the ability of the patch to be quickly interchanged due to the standardized connection to the circuit box adds efficiency and ease of use.

8.2 Preliminary Testing with Group Members

8.2.1 Methodology

The experimental procedures were evaluated on the three group members. There were three trials conducted per each of the three members. The trials were repeated if there were inconsistencies or human error. There were additional trials to the three if the data reported was thought to have error or if it did not support the expected results from research. There were various experiments created to test both the accuracy of the pressure and relative humidity sensors within the final patch design.

8.2.1.1 Pressure Sensor Experiments

There were a total of four different experiments that were created in order to test the efficiency of the pressure sensor. Half of the tests were conducted on the heel and the other half were conducted on the calf as a control experiment. Table 14 was used as a means to accurately record the data for each experiment.

Table 14: Blank Sample Table of Data Collection.

Group Member _____: Trial #		
Time	**Degree of Pain**	**Additional Observations**
0 minutes		
5 minutes		
10 minutes		
15 minutes		
20 minutes		
25 minutes		
30 minutes		
35 minutes		
40 minutes		
45 minutes		
50 minutes		
55 minutes		
60 minutes		

The tests for the efficiency evaluation for the pressure sensors that were held include experiments in the heels and in the calf. The first scenario for the experiments involved the group member in a 90° angle between the upper and lower body. The group member was suspended between two chairs with hard surfaces; heel on the edge of one chair and ischium on the edge of the other. The group member rested their heel on the patch, as seen in figure 35, and used pain as an indication of ischemia. There were general and pain observations gathered in increments of 5 minutes until the pain was so unbearable that the group member had to remove their foot.

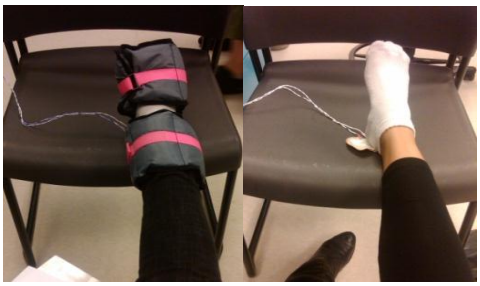

Figure 35: Testing of the sensor patch on the heel.

The same experiment was conducted on the calf since this area was used as a control for the experiments. The group member was still suspended between the two chairs with their ischium at the edge on one but with their calf on the edge of the other. The group member placed their calf on the patch and again recorded all observations in increments of 5 minutes until the maximum time of 60 minutes or unbearable pain was reached.

In order to test to failure, the body was placed in the same angle as the scenario described above with the only difference of an additional weight of five pounds added to the heels. This additional weight would increase the pressure on the heel and theoretically decrease the time of the development of ischemia. This was also repeated using the calf.

In order to mimic hospital settings, testing was continued on a standard mattress surface. The group member laid in a supine position with the patch placed beneath the heel. Pain was measured every five minutes until levels became unbearable.

Results:

The data recorded from the human trials displayed a negative correlation between the amount of pressure applied and the amount of time the participant was able to maintain their position. This can be seen in Figure 36 where the average voltage of each trial was compared to the total time the participant was able to remain in their position. All experiments ended at a maximum of 60 minutes to prevent injury.

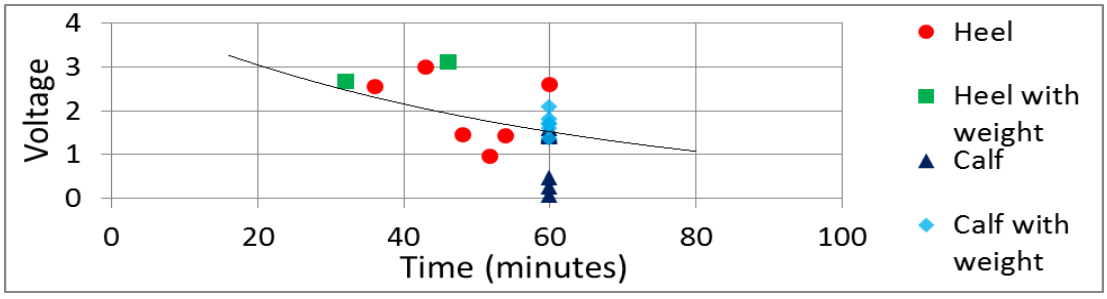

Figure 36: Pressure vs. Time Graph

Pain level was recorded through all tests. Pain was used as an indication that ischemia is occurring and as a signal that ulceration can occur. It was determined that the heel on a hard surface displayed a higher pressure reading then on the mattress testing. With the higher amounts of pressure applied in the pressure prone area, pain levels escalated at a much faster rate than when pressure readings were lower. The fastest rise in pain level occurred in testing when pressure was the most on the heel (weight on heel test). Test results showed that pain levels remained at a minimum for the control area of the calf, signifying no ischemia was occurring. It was also seen that pressure readings remain very low in this area. Results can be seen in figure 37.

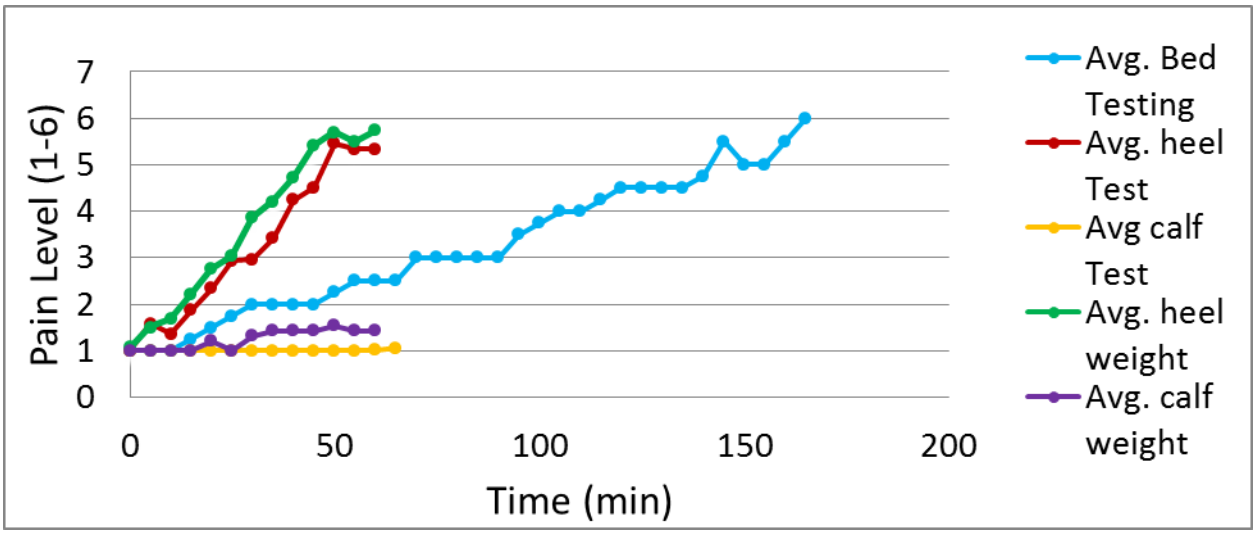

Figure 37: Pain level vs. Time

8.3 Expert Opinion Meeting Summary

To obtain a thorough evaluation, we took our device to the UMASS Residents of plastic surgery to gain useful information and feedback. We first demonstrated our device and explain how it could be applied in a hospital setting. There were 6 participants who we asked to survey our device in different areas.

Overall, they really like the device and all agreed that it should be wireless because the patients already have so many wires hooked up to them. A suggested application for our device is to put it into casted patients. This way the doctors know if the pain that the patient is experiencing is from pressure ulcers or from other causes. The doctors would prefer not to remove the cast unless necessary. Another recommendation included a larger sensing area. Some also wanted to see it demonstrated on an actual patient.

Below are the results of the survey:

How would you rate the overall device (1 being the lowest, 10 being the highest):

- Four **10**'s and two **8**'s

How would you rate the response time of the device? (1 being the lowest, 10 being the highest):

- Four **10**'s and one **8**, one **7**

(The person who gave a 7 stated that 10 seconds was too short, misunderstood that time set was just for demonstration purposes)

How would you rate the ease of use for this device (1 being the lowest, 10 being the highest)?

- Four **10**'s and two **8**'s

How would you rate the alarm system (1 being the lowest, 10 being the highest)?

- Four **10**'s and two **8**'s

From this meeting, it can be concluded that our device can be seen in the hospital setting. The next step is to gain more feedback on the device, then taking it to the nurses and caregivers. Their perspective will give a new light on the device and will allow us to improve the system.

9 DISCUSSION

Although, the sensor patch created can be proven to detect and efficiently warn the caregiver as to when to reposition the patient, there is still room for improvement. First and foremost, additional testing with a wider demographic would be beneficial in order to confirm the accuracy of the device. It is recommended that the patch be made wireless for increased ease of use to the caregiver and comfort to the partially mobile patient. Other developments can include the optimization of the device so that it could be included as an integral part in the care and welfare of patients in the health care industry.

In addition, in respects to the marketability of the device, there needs to be research on obtaining FDA approval. This would include that the alert system be compliant with hospital standards and to determine its longevity. Patches would need to be made disposable, cheaper, and sterile for hospital use which could happen in a combination of bulk manufacturing and advanced processing techniques rather than work by hand.

10 CONCLUSIONS AND FUTURE RECOMMENDATIONS

10.1 Future Implications for Testing

Although, the sensor patch created can be proven to detect and efficiently warn the caregiver as to when to reposition the patient, there is still room for improvement.

10.1.1 Human Clinical Trials

Additional testing with a wider demographic would be beneficial in order to attest the accuracy of the device. The additional trials would increase the statistical significance of the device. The trials could be conducted in a more normal setting rather than testing to failure. A normal setting is one in which the patient would find themselves to be within a hospital such as in a supine position.

10.1.2 FDA Regulations

In respect to the marketability of the device, there needs to be research on obtaining FDA approval. This would involve that the alert system be compliant with hospital standards and to determine its longevity. The color of the alert system would also have to be compliant with the hospital rules for FDA approval. Patches would need to be made disposable, cheaper, and sterile for hospital use which could happen in a combination of bulk manufacturing and advanced processing techniques rather than work by hand.

10.2 Functional Modifications

It is recommended that the patch be made wireless for an increased ease of use to the caregiver and comfort to the partially mobile patient. Other developments can include the optimization of the device so that it could be included as an integral part in the care and welfare of patients in the health care industry.

10.3 Cosmetic Modifications

The device that has been created could also allow for cosmetic modifications. For example, the patch would preferably have a circular design around the pressure sensor with the relative humidity sensor placed to the side. For purposes of this project the design was made according to the bandages that were commercially available. With further hospital setting testing then the optimal size for the patch could be accurately evaluated and reconstructed to be more efficient.

10.4 Recommendations to Improve Program

The program as it stands is extremely simple. The algorithm is functional and reliable, but needs rigorous testing in order to be approved by the FDA and useful in medical settings. Due to the restrictions of LabVIEW, the user interface is not customizable, nor is it highly visually appealing. In order to improve the user interface, a program must be developed to produce the GUI. Ideally, the program would accept and display data from multiple patients to one interface. The ideal program would also include multiple preset patch layouts (supine, sitting) and allow for the user to customize the patch placement to their own needs. Another feature which should be incorporated into the program is sound to accompany the alerts which could not be added in this iteration of the device.

Additional tests would include a questionnaire for people without an engineering background. These questions would ask about the programs user interface and its ease of use. This will provide information about the users' ability to work with the device efficiently.

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