

Wireless Pressure Ulcer Prevention Device

A Major Qualifying Project 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 are a common problem in current hospital settings. This project created a system to detect the early onset of pressure ulcers and alert a caregiver. Three different physiological factors, known to contribute to the formation of pressure ulcers, can be continuously measured via a disposable adhesive patch and wirelessly transmitted to a computer interface. The user interface instructs a clinician to input additional physiological factors, not locally measured, which indicate the risk of local ulcer formation.

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2 Literature Review	Alexandra Hause, Amber Truhanovitch, Mikkal Williams
3 Problem Analysis	Amber Truhanovitch
4 Design Approach	Mikkal Williams, Alexandra Hause, Amber Truhanovitch
5 Final Design	Mikkal Williams, Alexandra Hause, Amber Truhanovitch
6 Design Verification	Alexandra Hause, Amber Truhanovitch, Mikkal Williams
7 Conclusions	Alexandra Hause
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Appendix C: Proof of Concept Testing	Alexandra Hause, Mikkal Williams, Amber Truhanovitch
Appendix D: IRB Approval	Alexandra Hause
Appendix E: ADC and Wireless Transmit	Mikkal Williams
Appendix F: Wireless Receive and UART Transmission Code	Mikkal Williams, Alexandara Hause

Executive Summary

Pressure ulcers are a serious injury and problem in society today. They form on patients in hospitals, nursing homes, wheel chairs, patients with prosthetic limbs and even patients in home care. Society needs a way to predict the early formation of pressure ulcers in all patients varying in gender, age, race, weight, mobility and many other physiological factors (Metler, 2010). In October of 2008, Medicare decided they would no longer reimburse hospitals for the treatment of pressure ulcers. They classified pressure ulcers as preventable and a result of improper care by the hospital (Dorner, 2009).

The main intrinsic risk factors that affect the development of pressure ulcers include: high blood pressure, a lack of local blood flow, a lower blood saturation oxygen, CO₂, blood glucose, skin thickness, skin color, patient weight, patient age, patient nutrition and patient mobility levels. In 2010, a team of Worcester Polytechnic Institute (WPI) undergraduate students set out to develop a standalone computer-based system to prevent the onset of pressure ulcers by monitoring pressure and moisture on the patient's skin. The team developed a successful prototype and completed preliminary testing on themselves (Gutierrez et al., 2011).

Our project improved upon the previous project by creating a wireless reusable multi patch system for the accurate long-term monitoring of pressure ulcers. The system combines the use of a temperature, pressure, and relative humidity sensors incorporated into a disposable patch to set off an alarm and alert clinicians in advance of a potential condition that can lead to the formation of a pressure ulcer. These alarm conditions are dependent upon additional physiological factors entered by the clinician to a data acquisition program controlled by LabVIEW. The factors considered in this algorithm include age, weight, systemic blood pressure, nutrition and mobility levels. A clinician can be alerted, via an alarm on a user interface, when the pressure exceeds 35 mmHg for a prolonged set period of time, the temperature of the area underneath the patch increases by 1.2 °C over 24 hours or the relative humidity is between 40% to 50%.

To measure pressure, an array of Interlink® sensors were used based on their sensitivity and large surface area. A Honeywell 5030 relative humidity sensor was chosen due to its low voltage and current requirements in addition to its low profile. A MAX 6612 analog temperature sensor IC was chosen for its low power consumption and input voltage, high sensitivity, and simple integration with our system. A TI-CC430 microcontroller was used to sample the sensor outputs and transmit the digital signals. The receiving controller converts these values to voltages, and inputs them into the LabVIEW signal analysis program through a UART USB connection. The wireless transmission frequency chosen was 915 MHz. This band provides the advantage of a balance between energy consumption, transmission distance, minimal protocol overhead and reduced likelihood of interference from adjacent devices.

The initial tests of the individual sensors displayed an expected linear relationship based on the sensor's data sheets. There were slight deviations throughout each trial. However, these deviations were within the sensitivity specifications for each sensor, within the region of interest, and would be compensated by rounding. Human trials demonstrated the successful detection of increase in skin temperature, and relative humidity changes on the three members of the team. The changes in temperature and humidity were externally simulated using a heating pad and humidifier. Pain was used as an indicator of the early formation of a pressure ulcer in health test subjects. The purpose of the pressure testing on human subjects was to demonstrate that the subject's pain was greater when the pressure array was outputting a larger voltage. Testing confirmed the hypothesis, and demonstrated that pressure was less on the chosen control area, the calf, compared to the heel, an area prone to pressure ulcers.

1 Introduction

There are 5.2 million cases of pressure ulcers a year in the world. In 2007, Wild Iris Medical Education recorded 2.4 million cases in the United States alone, only four years ago. Pressure ulcers are a serious injury and problem in society today. They form on patients in hospitals, nursing homes, wheel chairs, patients with prosthetic limbs and even patients in home care. Society needs a way to predict the early formation of pressure ulcers in all patients varying in gender, age, race, weight, mobility and many other physiological factors.

A pressure ulcer, commonly referred to as a bed sore, is defined as a breakdown of the skin due to a lack of blood flow, often brought on by an increase in pressure on bony prominences. The most common locations of pressure ulcers are on the back of the heels, the backbone, and the shoulder blades (Metler, 2011).

It can cost a hospital up to \$70,000 for the treatment of one pressure ulcer. In 2008, the cost of a 14 day stay in the hospital for the treatment of a pressure ulcer ranged anywhere from \$16,755 to \$20,430 just for the stay. The cost of treating an acute pressure ulcer for a 9-10 day stay is \$43,180. Unfortunately, in older patients, pressure ulcers are not acute but much more severe, leading up to that \$70,000 mark (Domer, et. al, 2009).

There are currently no widely used innovative methods for preventing pressure ulcers. Clinicians take preventative measures to help decrease the likelihood of forming pressure ulcers based on various clinical practice guidelines. When these measures do not work, ulcers are diagnosed and treated based on the scale of severity. The problem with this method is that the preventative measures are not effective enough to completely prevent pressure ulcers at an early enough stage, and the treatment of the ulcers is costly and painful to the subjects (Tomas, 2010).

In 2010 a team of undergraduate students at Worcester Polytechnic Institute (WPI) set out to develop a standalone computer-based system to prevent the onset of pressure ulcers by monitoring pressure and moisture on the patient's skin. The team was able to develop a successful prototype and complete preliminary testing on themselves.

The goal of this project was to improve upon the previous project by creating a wireless reusable patch system for the accurate long-term monitoring of pressure ulcers. The system combines the use of a temperature, pressure and relative humidity sensors placed inside a disposable patch to set off an alarm and alert clinicians of a potential condition that can lead to the formation of a pressure ulcer. These alarm conditions depend upon additional physiological factors entered by the clinician to the data acquisition program including age, weight, systemic blood pressure, nutrition and mobility levels.

2 Background

2.1 What is a Pressure Ulcer

The National Pressure Ulcer Advisory Panel (NPUAP, 2007) defines a pressure ulcer as a:

“localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear and/or friction. A number of contributing or confounding factors are also associated with pressure ulcers; the significance of these factors is yet to be elucidated.”

2.1.1 Clinical Need for a Prevention System:

Hospital costs are important, but more importantly, pressure ulcers can have long-term consequences for patients. Bedsores are very uncomfortable and when increased in severity they become very painful. Pressure ulcers can also form all over the body leaving patients feeling vulnerable and possibly embarrassed. These pressure ulcers are

not something quickly and easily taken care of, and not only can it lead to emotional distress, but it can also lead to long-term hospitalization. If an ulcer becomes infected, the patient is at risk for serious surgery, amputation and even death. In 2007 there were roughly 60,000 reported cases that resulted in the death of the patient. Even if a patient does not have a more serious ulcer, once an ulcer forms they are more likely to form repeatedly. The prevention of pressure ulcers is a clinical need in our society and the world. Humans are living longer, making them more susceptible to forming these ulcers. A way is needed to identify and stop the dangers of pressure ulcers before they cause a loss to patients and hospitals (Metler, 2011).

2.1.2 Demographics

Pressure ulcers are commonly known as bedsores. They are prominent in patients with limited mobility. Roughly 70% of pressure ulcers occur in patients 65 years or older and the other 30% of pressure ulcers are common in younger patients with severe illnesses or diseases (Bluestein et al., 2006). Even semi mobile patients in wheel chairs are extremely susceptible because they sit in one position for long periods of time without shifting their body's weight. To this day the most vulnerable patients are paralyzed, meaning that they have a communication or sensory problem that does not allow them to either feel the discomfort and/or inform them of pain. Their caregivers would have to be very thorough administering daily exams to identify any possible ulcer formations. Some of the common sites of pressure ulcer formation are included in Figure 1 below. In 2010, the US Census report showed that there were 40.3 million people in the United States 65 years and older. This makes up 13% of our population. Between 2000 and 2010, the 65 years and older group grew by 15.1%. This data illustrates that the number of older individuals is increasing, which in turn means the number of people that are at risk for pressure ulcers increases as well.

2.1.3 Causes

It is commonly thought that pressure ulcers form from an irritation or constant force applied to the body over a long period of time. Although this is true, pressure ulcers can also come from a large, sharp force over a short period of time (Bluestein et al., 2006). The force needed to produce a pressure ulcer simply must be large enough to impede local blood flow to the tissues and capillary system, meaning a force greater than the mean arterial blood pressure of 35 mmHg (Thomas, 2010). This force is disruptive and can cause severe tissue damage by impeding the transport of oxygen or other important nutrients to the tissue.

Excessive pressure exerted on the skin is one of the main reasons for the formation of pressure ulcers, but there are also a number of other leading physiological factors that can increase the risk of developing a pressure ulcer that will be described in the next section.

2.1.4 Common Location for Pressure Ulcer Formation:

The areas identified in Figure 1 represent those mostly likely to form pressure ulcers. These sites are exposed to increased amounts of pressure when a patient is in the supine or seated position. These sites also are typically the bonyest and lack adipose deposits.

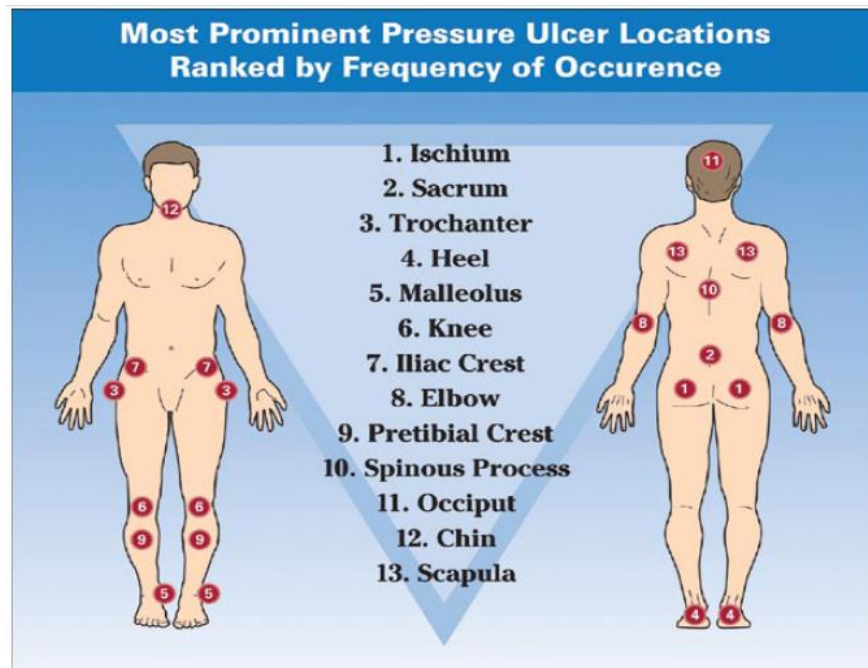


Figure 1 The common locations of pressure ulcers in order of ranked frequency (Shoemaker et al., 2007).

2.1.5 Etiology: Causation of Pressure Ulcers

The main intrinsic risk factors that affect the development of pressure ulcers include: high blood pressure, a lack of local blood flow, a lower blood saturation oxygen, CO₂, blood glucose, skin thickness, skin color, patient weight, patient age, patient nutrition and patient mobility levels.

2.1.5.1 Blood Pressure

The human cardiovascular system is a closed loop system that doesn't allow blood to leave the long network of blood vessels. As oxygenated blood is pumped away from the heart to the rest of the body, oxygen and nutrients diffuse across blood vessel to cells. During this process CO₂ and metabolic waste products are carried away.

Arteries supply blood to our major organs while arterioles supply smaller vessels with blood that travels directly through muscle walls into capillary beds. Within the capillaries are endothelial cell walls that allow the nutrients and oxygen to exchange with waste products and CO₂. Veins take over from here carrying the oxygen-depleted blood and metabolic wastes products back to the heart.

The body works by pushing blood through our system at a steady flow to supply energy and oxygen as needed. The pushing force of blood against the walls of veins, arteries, arterioles and capillaries is quantified as blood pressure. There are two kinds of blood pressures throughout the body, systemic and local. Systemic blood pressure is the blood pressure throughout our entire cardiac cycle¹. Local blood pressure is the pushing force on the walls of a particular area. For instance, if we are interested in localized blood pressure on the palm we would be measuring the localized blood pressure of the capillaries. But if we wanted to measure localized blood pressure on the arm we would measure systemic arterial blood pressure (Thomas, 2010).

¹ The cardiac cycle is the process of blood flow in one heartbeat. Deoxygenated blood is returned to the right atrium to the right ventricle and is then pumped through the pulmonary artery to the lungs. In the lungs the blood releases CO₂ and is re-oxygenated. The re-oxygenated blood from the lungs and pulmonary vein is then passes through the left atrium and onto the left ventricle that pumps the oxygenated blood out the aorta throughout the body.

Localized blood pressure is a risk factor in the formation of pressure ulcers because it signifies if there is proper blood circulation in that particular area. Systemic blood pressure fluctuates above or below the normal range. The most common attribution to poor circulation is the narrowing of arteries and blockages in the veins causing high blood pressure. Low blood pressure, due to the dilating of blood vessels, causes circulation to slow down. In turn, the transport of oxygen-rich blood and nutrients to muscles, tissues, capillaries and skin diminishes. In the absence of oxygen and nutrients, tissues are not able to prevent the formation of pressure ulcers (Thomas, 2010).

2.1.5.2 Blood Flow

Blood flow is affected greatly by blood pressure. If a person is in hypotension, meaning their blood pressure is below the normal range, blood flow decreases. This results in arterial blood not being transported quickly enough to the capillary bed in the tissue. Blood perfusion decreases as external pressure increases in the body over a long period of time. As soon as the external pressure surpasses systolic arteriolar pressure, blood flow to that region will completely stop. This is referred to as “localized ischemia” (Thomas, 2010). After the tissue has entered ischemia, necrosis, or cell death, will occur.

There is a strong correlation between blood flow and temperature as well. When the skin is presented with colder surroundings, blood flow decreases, but when there is an increase of heat and activity in certain parts of the body, blood flow increases. With the increase of temperature the body requires a higher blood flow to support metabolism (Hagblad, 2011).

Another important factor in the skin is the rate of blood flow in different areas of the body. For example, sacral blood flow is higher than over the Gluteus Maximus (Thomas, 2010). This is important because when blood flow is decreased from an increase in external pressure there is more damage to the sacral; thus correlating to more incidences of pressure ulcers in the sacral region than the gluteus maximums (Thomas, 2010).

Blood flow to the skin is particularly important. Tissue below the skin breaks down due to anoxia (the lack of oxygen) and lack of blood flow. The process of Skin break down is described in Table 1, section 2.1.4.5. With added moisture the skin will also start to increasingly break down and degrade the epidermis and underlying tissue, increasing the risk and severity of a pressure ulcer (Lawrence, 2006).

Blood flow is one of the biggest contributing factors to the formation of pressure ulcers. When blood flow is reduced, even by a small amount, oxygen cannot get through the capillary bed and tissues. In turn, tissue and skin breaks down the longer oxygen are lacked. Nutrients are directly related because the majority of them diffuse through the layers of tissue with oxygen. Without oxygen getting into the tissue, nutrients do not have the ability to get to the tissue to help them heal. Pressure directly affects blood flow, but there are many other factors that we have gone through that also affect blood flow including: temperature, moisture, and medicines that thin blood and reduce blood flow.

2.1.5.3 Blood O₂ and CO₂

Oxygen is a key factor in all processes of the human body, namely for the absorption of nutrients and cellular respiration, an extremely vital process for all aerobic organisms. Once the blood in the lungs absorbs oxygen, it attaches to the heme group and travels through the blood stream to tissue. Nutrients are oxidized by the enzyme mono oxygenase within the cells and create the energy our body needs called in a process called metabolism. The products formed when enzymes oxidize the nutrients are H₂O and CO₂, which are then transported back to the lungs (Hagblad, 2011). This has a direct correlation with the formation of pressure ulcers as seen in Figure 2. Metabolism is extremely important because it is the process that converts food and nutrients into a usable form of energy. It also removes unnecessary waste products. Our main interest in metabolism is where cells and tissue are reproduced, grown and healed (Franklin Institute, 2011).

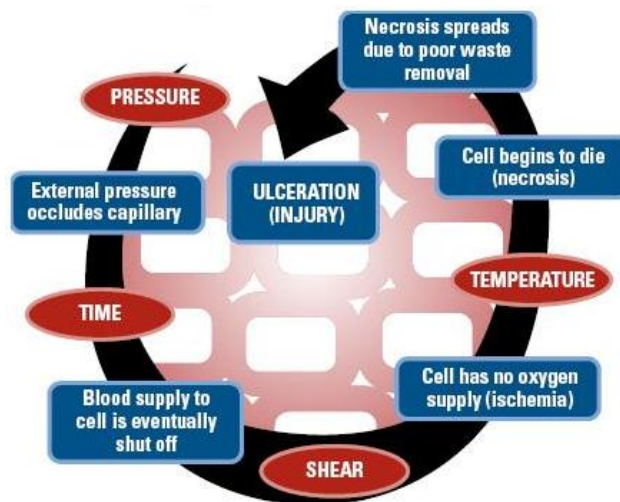


Figure 2 The development of a pressure ulcer over time (Shoemaker, et al., 2007).

Pressure, time, shear and temperature lead to the formation of ulcerations. Shear stress is when two objects slide up against each other, in this case the body and sheets or the body and the mattress.

Oxygen levels in the tissues that supply the capillaries are extremely important. Without sufficient blood flow, cells are deprived of oxygen, which is called ischemia. Without oxygen, cells can no longer perform the functions of metabolism. When there is a halt in the oxidation of nutrients, waste products build up and CO₂ cannot be transported back to the lungs. Without nutrients there is no energy for cells to reproduce or heal. The buildup of waste and bad cells leads to necrosis (cell death) and ulcerations begin to form, eventually showing through the skin. Hence, a decreased level of oxygen or increased level of CO₂ would be a useful early indication of the formation of pressure ulcers.

2.1.5.4 Capillary Blood Supply to Cells

Some of the primary causes of pressure ulcers relate to the presence of blood in the tissue under specific bony prominences, specifically local blood flow, blood volume and blood pressure. As previously mentioned, there are both systemic and local measurements of these three factors. In the specific application of the sensors used for pressure ulcer prevention, the local measurements are of importance. For this application the local measurement of these factors refers to the capillary level.

The typical blood pressure in the capillaries is 35 mmHg, and when the externally applied pressure exceeds this limit there will be no blood in the capillaries (Thomas, 2010). Local blood flow refers to the amount of blood flowing through the capillaries over a period of time. When an external pressure is applied and occludes the capillaries, the blood flow slows almost to a complete stop.

Local blood volume is the amount of blood in an area of tissue. During a normal cardiac cycle, the local blood volume will fluctuate with the heartbeat. When the capillaries are occluded for a small period of time this pulsatile component will disappear. If the capillaries are occluded for a long period of time the constant level of blood volume will also decrease (Naslund, 2006).

Blood volume seems to be the best indicator for determining when a tissue is no longer in contact with blood. Blood volume will change values starting when external pressure is applied and the diameter of the capillary initially decreases. Also blood volume is the only factor that decreases as external pressure increases and eventually occludes the capillaries completely.

2.1.5.5 Iron Levels

Another factor in the lack of oxygen to parts of the body is anemia, or a decreased number of red blood cells and/or a decreased amount of hemoglobin. Oxygen binds to the hemoglobin to travel to different parts of the body such as muscles, tissue, capillary beds and the skin. When there is a lack of hemoglobin, which is found in the RBCs, the organs and tissues have a lack of oxygen supply resulting in similar effects mentioned in the section above (University of Maryland Medical Center, 2011).

2.1.5.6 Patient Age & Skin

Another risk factor for older patients is their mobility. When patients get older their mobility decreases greatly. They become weaker, more fragile and cannot get around as easily. Decreased mobility lowers the chance that a patient is able to move and relieve pressure in an area of concern.

Patients over 65 are much more susceptible to pressure ulcers and it has a great deal of correlation with the skin (Metler, 2011). Table 1 discusses this relationship in further detail. The skin is composed of three main layers. The epidermis is the outer layer that contains skin cells, pigment and proteins. The middle layer is the dermis that holds blood vessels, nerves, glands and hair follicles. The inner layer is the subcutaneous layer that holds blood vessels, fats and glands. The dermis provides nutrients to the epidermis (NIH, 2011). When humans age the epidermis thins, pigment decreases, elasticity decreases as the connective tissue between layers of skin and the fat layer in the subcutaneous thins. This thinning results in skin that is weaker. When our tissue is weaker there is a decrease in blood flow, in turn less nutrients are delivered and the breakdown of blood vessels and capillaries occur (Lawrence, 2006). This weakness also allows the skin to tear, bruise and become injured much easier.

Not only is the skin vulnerable when it is too dry and weak, it is extremely vulnerable to damage with a build up in moisture. Increased moisture can be due to increase in sweat but in older patients it is more common that build up of moisture is from an inability to control the release of bodily functions. Patients that are aging and have a lack of mobility often cannot control their release of urine and fecal matter (often being diarrhea). Urine and feces are toxic to the epidermal skin. The toxins are bacteria that release ammonia. The added perspiration increases the skin's pH level and expedites cell deterioration (Click, 2009).

Table 1 Correlation between age and pressure ulcer onset (Metler, 2011).

AGING SKIN AND PRESSURE ULCERS
Obvious changes in both skin structure and function occur with aging. These changes contribute to the occurrence of skin and wound problems.
<ul style="list-style-type: none">• Flattening of the epidermal-dermal junction decreases the overall strength of the skin, which increases the risk for skin tears and blistering.• Decrease in the melanocytes and Langerhans cells increases the risk for allergic reactions and sensitivity to sunlight.• Decreased blood flow decreases skin temperature.• Decreased production of oil and sweat contributes to dryness and flaking.• Decreased subcutaneous tissue, especially fat, decreases the body's natural insulation and padding.• Decline in the reproduction of the outermost layer of the epidermis may lead to the skin's inability to absorb topical medications.
These changes in skin structure and function, together with the risks that occur with a change in overall health and functional ability, put the aged patient at very high risk for the formation of a pressure ulcer.

In bony areas of the skin, pressure ulcers can be identified when the skin becomes blanched. The pink rosiness disappears when the blood flow is cut off. It has been theorized in varying sources that patients with darker skin are more susceptible to the formation of a pressure ulcer. However, this may be attributed to an increased difficulty to identify the first signs of pressure ulcers and treatment is prolonged (Lawrence, 2006).

2.1.5.7 Skin Temperature

Human skin is very susceptible to changes that can affect underlying tissue, strongly influencing the formation of pressure ulcers. The contact between the body and the surface of a bed or chair creates a local increase in skin temperature. When skin temperature increases around pressure ulcers, oxygen consumption rates increase, as well as the productions of CO₂ and metabolic waste. When skin temperature increases in healthy individuals, their skin blood flow increases to reduce the heat and minimize the accumulation of metabolic waste. But patients that are susceptible to pressure ulcers do not have full control over blood flow to specific regions and are unable to respond adequately to the effects of the temperature increase (Sae-Sia et al., 2003). Studies have shown that a skin temperature increase of ~1.2°C over a 24-48 hour time period increase a patients risk of forming an ulcer. If the temperature increase is still present even after the patient has changed positions then it is more likely to be an intrinsic factor representing tissue inflammation and potential damage.

When the body's skin temperature increases it interacts with sweat gland functions. When the body sweats it increases moisture on the damaged skin. When pressure is added to the body, skin tolerance decreases, increasing the patient's risk of forming a pressure (Gefen, 2011).

2.1.5.8 Patient Weight

A patient's weight is a concern for doctors and nurses monitoring for pressure ulcers. Malnourished patients with lower weights have less fat on their body. Bedsores already occur in areas where there is little tissue and fat between the bone and skin. If a person is malnourished, there is less cushioning between the bony surface and the skin. A common expression used for a person who is very thin and doesn't weigh enough is "they are just skin and bone" which is nearly a direct correlation with the formation of pressure ulcers (Lawrence, 2006).

2.1.5.9 Patient Nutrition

Nutrition is a complex factor in the formation and even healing of pressure ulcers. It is not to say if someone has poor nutrition, like eating fatty foods etc., they will develop a pressure ulcer, but rather if a patient does not get the right amount and source of nutrients and vitamins their immune system will weaken. Poor nutrition leads to increased inflammation throughout the body and results in the slowing of a cells ability to receive oxygen. An example of an important vitamin the body uses to keep the skin fresh and prevent breakdown is vitamin C (Lawrence, 2006).

An important part of nutrition includes hydration. Dehydration throws the body's pH and chemical balance off. This also contributes to pressure ulcers in a similar way as malnutrition. There is a significant decrease blood circulation throughout the body. Again, without adequate blood circulation, skin, tissue, and capillaries do not get enough oxygen and nutrients, preventing them from fighting off ulcers.

2.1.5.10 Mobility

There are different degrees of mobility and the more severe and less mobile a person is the greater the risk for a pressure ulcer to develop. Mobility ranges from having problems with full range of motion to coma. When patients have a lack of mobility and feeling, they cannot sense when there is pain, or when there is stiffness and they need to move. Some patients simply can't move and rely completely on their health care professionals to try to relieve the pressure and restore the blood circulation (Lawrence, 2006) (Melter, 2011).

2.1.5.11 Formation of Pressure Ulcer Wrap Up

We separated the risk factors into two different groups as shown in Table 2. Appendix A and B compares these factors in a pairwise comparison chart. Scores above 7 were considered “Primary Causes” (Appendix B) and scores below 7 were considered “Secondary Causes” (Appendix C).

Table 2 List of the primary and secondary causes of pressure ulcers

Primary Causes	Secondary Causes
Pressure	Systemic Blood Pressure
Mobility	Local Blood Pressure
Blood Flow	Patient Weight
Blood Volume	Skin Thickness
Age	Iron Levels
Blood O ₂	Blood CO ₂
Shear Stress	Nutrition
Skin Temperature	
Moisture	

An important consideration between the pairwise charts and the final decision for the primary vs. secondary causes was *age* as a risk factor. Age had a very low score of 3. That is simply because it is almost like a given primary factor. Age consideration is not more important than pressure and oxygen getting into the skin. But the majority of pressure ulcers occur in older patients due to all of the other risk factors, like circulation and mobility issues. So in the end we made the executive decision that *age* is a primary factor that we will take into account in determining pressure ulcers.

These charts helped to rank the risk factors against each other to illustrate which risk factors are the most important and therefore need to be tested. The sections below show the pairwise charts comparing different sensor testing techniques for these primary factors.

2.2 Current Methods for Management of Pressure Ulcers

There are currently no widely used innovative methods for preventing pressure ulcers. Clinicians take preventative measures to help decrease the likelihood of them based on various clinical practice guidelines, and when these measures do not work ulcers are diagnosed and treated based on the scale of severity. The problem with this method is that the preventative measures are not effective enough to completely prevent pressure ulcers at an early enough stage, and the treatment of the ulcers is costly and painful to the subjects (Tomas, 2010).

2.2.1 Preventative Measures

In October of 2008, Medicare decided they would no longer reimburse hospitals for the treatment of pressure ulcers. They classified pressure ulcers as preventable and a result of improper care by the hospital. The first step in the process of prevention is determining the risk the patient is at for developing a pressure ulcer. Based on this, the nurses are able to account for the increased risk of ulcer formation by repositioning patients more frequently and using specially designed surfaces to decrease pressure on sensitive areas (Thomas, 2010). There are multiple scales that have been developed to give a numerical value that helps determine how at risk a patient is for developing a pressure ulcer.

The three most common are the Braden, Norton and the Waterloo scales. The Braden scale (Appendix A) is the most commonly used and based on the patient's nutrition. It offers the best sensitivity and specificity balance between the three scales, but requires intensive monitoring of a patient's dietary intake, which is not reasonable in

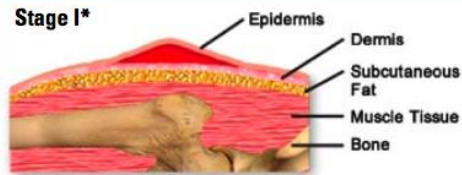
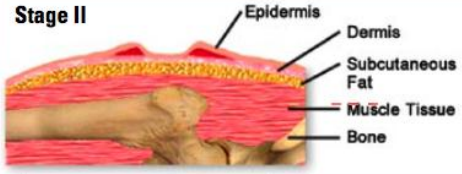
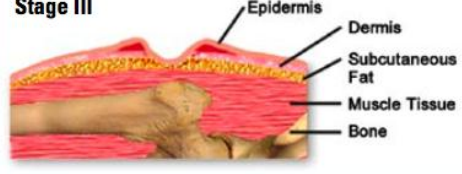
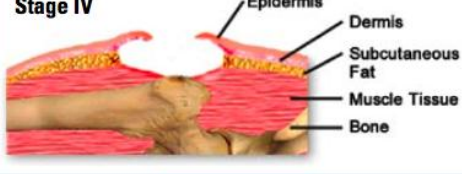
some applications (Pancorbo-Hidalgo, 2006). The Norton scale does not include nutrition as a factor and offers high specificity between patients. The Waterlow scales uses ten factors to assess the current damage due to a pressure ulcer and then makes preventive recommendations. The draw back to the second two methods is the lack of a proper description, which leads to clinician confusion in assessing each factor. Multiple studies propose that the linear and equal weighing of each risk factor is too simplistic and suggest the implementation of a more data-driven method (Pananikolaou, 2007).

At risk patients are repositioned every four hours to redistribute the pressure applied to specific areas and increase air circulation around sensitive sites. One study showed that patients moved every two to three hours were just as likely to develop pressure ulcers as patients that were moved every four hours (Thomas, 2010). The problem with this method of prevention is that it is highly dependent on frequent intervention of an outside party. Inflatable beds and other mechanical solutions are also implemented to decrease the amount of pressure applied to specific areas, however none are completely effective at ulcer prevention, see subsequent sections for specific applications. Although there has been extensive research and work done on preventative methods and technologies, in 2010 there were 5.2 million pressure ulcers in the world requiring treatment (Advanced Wound Care Management, 2011).

2.2.2 Diagnosis of Pressure Ulcers

There are some promising technologies to aid in the diagnosis of pressure ulcers such as ultrasound and thermographic imaging, which are discussed in the new technologies section, but the primary diagnosis of pressure ulcers is still done by clinicians. Pain is a useful indicator of pressure ulcers, specifically in the early stages. However, many patients are not conscious or lack feeling in the affected areas and are unable to verbally communicate discomfort (Qurinio, 2004). After the onset of a pressure ulcer a clinician visually assess the wound site and classifies it as stage I-IV (Bergman, 1994). A brief description of each of these stages can be seen in Table 3.

Table 3 Pressure Ulcer stages and corresponding criteria (Shoemake, 2007)

Ulcer Stage	Criteria
Stage I* 	Non-blanchable erythema of intact skin; the heralding lesion of skin ulceration. May also include changes in skin color, skin temperature, skin stiffness and/or sensation (pain)
Stage II 	Partial thickness skin loss involving epidermis and/or dermis. The ulcer is superficial and presents clinically as an abrasion, blister or shallow crater.
Stage III 	Full thickness skin loss involving damage or necrosis of subcutaneous tissue; may extend down to but not through underlying fascia. Presents clinically as a deep crater with or without undermining of adjacent tissue.
Stage IV 	Full thickness skin loss with extensive destruction, tissue necrosis or damage to muscle, bone and/or supporting structures, e.g., tendon, joint capsule.

2.3 Potential New Technology for Pressure Ulcer Prevention

Due to the large clinical need and lack of effective treatment on the market today, there are many efforts to develop new technologies that could aid in the early detection and prevention of pressure ulcers. This particular section focuses primarily on recent discoveries assuming the newer technologies will likely encompass older discoveries as well. Although each of these technologies and methods provide improvements for the existing treatment of pressure ulcers, none have been accepted as a standard of care.

2.3.1 Mechanical Solutions

There are various technologies that claim to aid in the prevention of pressure ulcers by distributing the force exerted on specific problem areas, or supportive surfaces that move the patients after a set period of time. These solutions do not have any type of feedback system for each patient's specific contributing physiological factors, such as pressure exerted or moisture content of the sample area. Another disadvantage is that these methods are meant purely for prevention based on time rather than prevention based on physiological factors.

2.3.1.1 Dynamic Supportive Surface

Apparatus and Methods for Preventing Pressure Ulcers in Bedfast patients (Patent # 7,761,945: 2010)

This mattress features a temperature control system that can be used to prevent the early onset of pressure ulcers. The two chambers of the mattress can be pressurized at independent times to shift the weight distribution. Each chamber can either be filled with gasses or liquids, which allow airflow between the patient and the surface of the pad to cool the skin and remove moisture (Butler, 2010). This method of preventing pressure ulcers is bulky, non-portable, and expensive. It also only applies to bed-ridden patients and does not factor in the difference between these patients. The invention can be seen below in Figure 3.

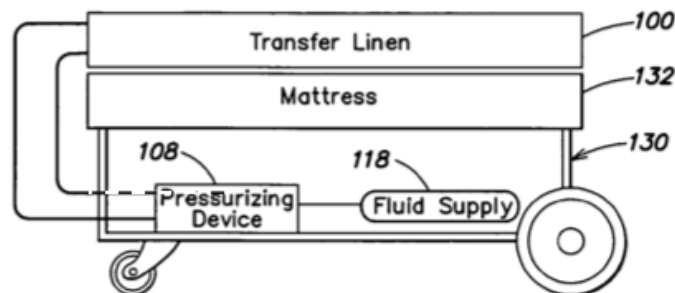


Figure 3 Dynamic mattress system for bed-ridden patients (Butler, 2010)

2.3.1.2 Site Specific Prosthetic Interventions

Pressure Ulcer prosthesis and Method for Treating and/or Preventing Pressure Ulcers (Patent # 7,798,150:2010)

This apparatus prevents pressure ulcers that form on the lateral malleolus and back of the calf by attaching to the patients leg, shown in Figure 4. The device features strategic holes for proper ventilation and prevents hyperextension of the legs. Through the support of the calf, the foot should be left suspended in the air preventing any contact with the sensitive lateral malleolus (Huber et al., 2010). This method only applies to bed-ridden immobilized patients, and only prevents pressure ulcers on the feet.

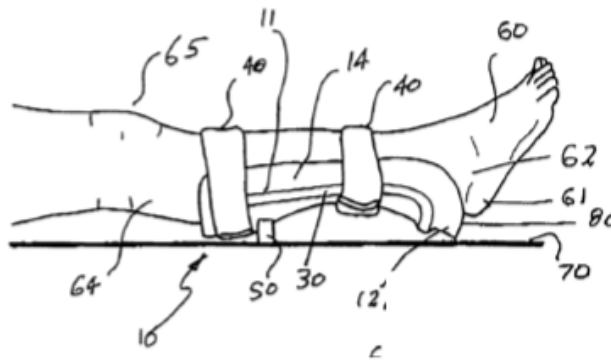


Figure 4 Prosthetic fixture for bed-ridden patients (Huber et al., 2010)

2.3.1.3 Angiosome Based Mobile Padding

Decubitus Ulcer Prevention and Treatment (Patent # 7,823,219: 2010)

This device alleviates pressure on specific areas of the body based on the distribution of the angiosomes. The device is a portable garment with a pump and inflatable channels to relieve the pressure shown in Figure 5 (Freund, 2010). Angiosomes are “three dimensional tissue blocks supplied by a single source artery” some of which can be seen in the figure below. This technology is unique because it takes into account the location of the angiosomes in the body, the theory behind this is that by alleviate pressure on the angiosomes blood flow can continue throughout the body. Although the device is portable it is difficult to put on completely immobilized patients and does not allow the physician access to the body.

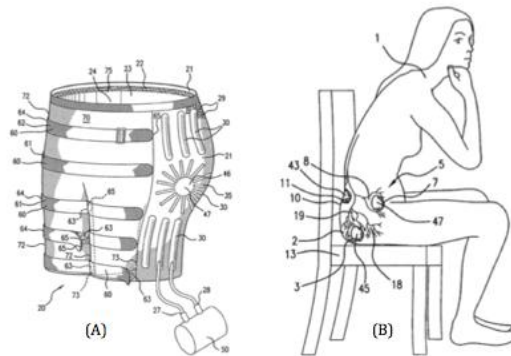


Figure 5 Left: inflatable textile to reduce pressure. Right: Select angiosomes in the distal region (Butler, 2010)

2.3.2 Systems with Feedback

The following technologies take measurements of various contributing physiological factors from each subject. These systems are more accurate because they are tailored to each patient. While the previously discussed mechanical systems purpose was to prevent pressure ulcers, the following technologies are used to detect the early onset of pressure ulcers and notify someone.

2.3.2.1 Supportive Surface with Multiple Sensors

Method and System for Determining a Risk of Ulcer Onset (Patent # 10,508,002: 2005)

This system detects pressure ulcers in bed-ridden patients through strategic sensors placed over various points on the surface where the patient lies. Combinations of seven different areas measure the pressure and temperature, and can be seen below in Figure 6. The pressure is measured using a FlexiForce® sensor and converted to voltage

using an operational amplifier (LM 324). Both signals are controlled through an analog PDI controller for increased accuracy. The temperature is measured using a thermocouple and filtered before going through an A/D converter. The digital signals are then analyzed in the program LabVIEW, which also supports the user interface (Gefen, 2005). While this system provides a cost effective and somewhat accurate solution, it is tailored for a specific demographic (bed ridden patients) and is not portable due to the wires connected to the system.

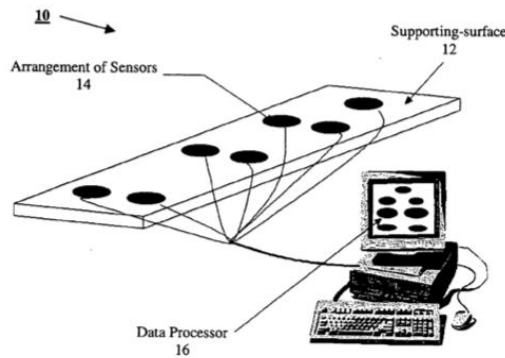


Figure 6 Block diagram of pressure based mattress sensor (Gefen, 2005)

2.3.2.2 Capacitive Based Pressure Sensor

System and Method of Reducing Risk and/or Severity of Pressure Ulcers (Patent # 12,761,156: 2010)

A wired pressure sensitive pad that indicates a threshold pressure has been breached for a specified amount of time and a patient should be moved. Previous designs made use of the flexi force sensor. However, pressure sensitive capacitive contacts were used in this application. The predetermined threshold of pressure used in this system is 35 mmHg, which is the universally accepted critical threshold pressure in the development of pressure ulcers. This system is dependent on the amount of time the pressure has been applied, which has to be determined by a medical professional. The pads are adhesive and small, and wired to a portable touch screen monitor, shown below in Figure 7. This means the system could be used for patients in wheel chairs. This monitor features a memory card slot to retain historical data. While the device is currently a wired system, the patent notes that wireless connections are possible (Drennan et al., 2010). This device is interesting in that it determined the FlexiForce® sensor was not necessary for this application, and a custom more simple force sensor could be used. Also a custom touch screen monitor was developed to increase portability without making the system wireless.

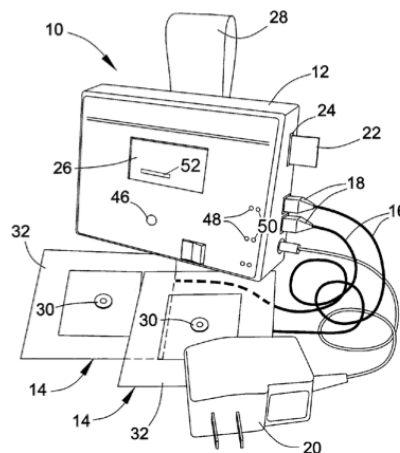


Figure 7 Capacitive based wired portable sensors (Drennan et al., 2010)

2.3.2.3 Wireless Matt Pressure Sensor

Method and Apparatus for Mitigating the Risk of Pressure Sores (Patent # 7,378,975: 2008)

Bed Check Corporation in Tulsa Oklahoma patented this technology in 2008. The system uses a position sensor as the only indicator of pressure ulcer risk, and bases its calculation on the last sensed patient movement to minimize the alarms set off shown below in Figure 8. If the patient has not moved for a predetermined amount of time an alarm notifies the nursing staff to reposition the patient. This signal analysis is done primarily through a local microprocessor within the mat itself. The sensor uses wireless communication, and is a compact size which makes it portable and able to be used in a wheelchair in addition to a hospital bed (Smith et al., 2008). While this system uses pressure it is based on the time of patient immobility. The use of only one parameter (time of immobility) is a major disadvantage to this method; however the microprocessor and wireless communication are a strong advantage. An additional advantage to a mat style sensor is its ability to be used to help lift and reposition the patient.

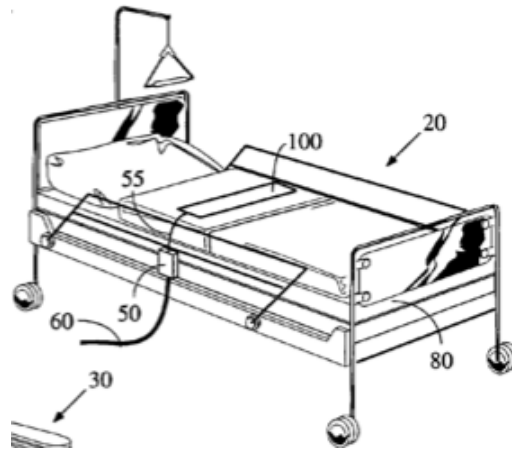


Figure 8 Patient position detection mat (Smith et al., 2008)

2.3.2.4 Wireless Shear Stress Adhesive Sensor

Bedsore Main-Factor Measuring Device (Patent # 7,090,647: 2006)

This system is a small pressure sensor that is cable of measuring both shear and tensile stress based on a strain gauge. The sensor itself, shown in Figure 9, was designed in three sheets of marginally flexible material with a strain gauge to measure the distortion of each of these sheets relative to each other in order to determine the amount of pressure exerted on the site of the potential pressure ulcer. The device is wireless and communicates with a custom designed simple hand held monitor (Mimura et al., 2006). This technology is unique in that it can detect shear stress in addition to tensile stress. Also it is extremely portable and could be used in a variety of settings. The custom made simple monitor does not leave much room for future improvements or compatibility with existing medical equipment.

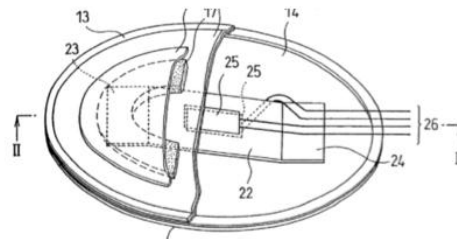


Figure 9 Wireless sensor with shear stress detector (Mimura et al., 2006)

2.3.2.5 Wireless Pressure Humidity Sensor with Comprehensive Database

Active On-Patient Sensor, Method and System (Patent # 11,934,054: 2008)

This product was developed by a large prosthetic company in Seattle Washington. However, the company has shown no intention of bringing the product to the market in the near future. This product measures pressure and moisture by adhering to the body and using sensors that employ electromagnetic induction. The system, shown in Figure 10, is wireless and uses a transmitter antenna to communicate with an external monitor database system. The patent claims that the system has a low profile to ensure it is not causing more pressure to be applied to the patient, which is partially made possible by the low power requirements of the sensors and a flexible printed circuit technology. The external monitor is unique in that it has a database feature, and which allows the pressure ulcer formation to be calculated based on more physiological factors than those that are measured by the sensor. The database will also keep track of specific patients and past pressure ulcers, which increase the risk of developing a pressure ulcer. The wireless technology is more advanced than other similar sensors and can be used on a larger scale due to differently responsive antennas. These antennas also feature a notification for when the sensor is out of range (Ortega et al, 2008).

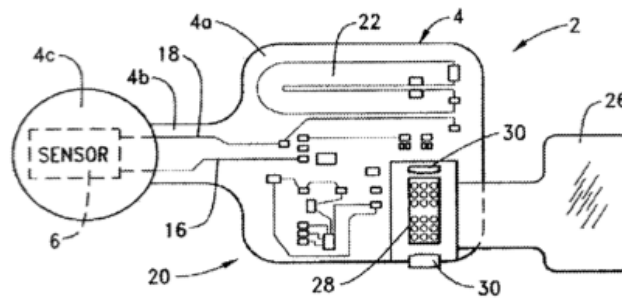


Figure 10 Wireless pressure and humidity temperature diagram (Ortega et al, 2008).

2.3.2.6 The M.A.P System

Commercial Device made by WellSense

The M.A.P. system is a commercial product that uses a pressure array to indicate to a clinician when which areas of the body are under the most pressure. A large mat is placed on a patient's bed, and a standalone graphical user interface can be placed on the bedside (shown below in Figure 11). Areas that appear in red have the most pressure, and those that are blue have the least. "The colors are intended to act as a guide to the proper repositioning and do not indicate the formation of a pressure ulcer" (M.A.P System, 2011). The system will alert a clinician if a patient has not been repositioned before their scheduled time interval. The system does not currently record data.



Figure 11 M.A.P Graphical User Interface (M.A.P System, 2011)

2.3.3.7 Thermographic Imaging System

WoundVision (2009)

Woundvision entered beta testing in 2009 for their thermographic imaging system. The device, shown in Figure 12, is hand held and claims to be able to detect pressure ulcers at an early stage based on optical technology. The beta tests had 198 subjects, and the results were promising. As of August 25, 2011 WoundVision released a press statement that the device would be brought to market by the end of 2011. There is currently no information on the specific technology or operation of the device. However it is hand held and presents some similar drawbacks as the previous technology that it requires a trained operator to manually check at risk patients on a consistent basis (WoundVision, 2009).



Figure 12 WoundVision hand held thermographic imaging system (WoundVision, 2009)

Although each of these new technologies improves the outcome for at risk patients, none are cost effective or accurate enough to be widely used on the market today. A summary of all of these new technologies can be seen below in Table 4.

Table 4 New Technology Comparison Summary

Device	Cost	Accurate	Universal	Portable	Physiological Factors	Physician Intervention
Mechanical Solutions	Low	Less Reliable	Variable	Variable	Variable	Low
Dynamic Supportive Surface	High	Low	Only Bed Ridden	Low	Pressure	Low
Site Specific Intervention	Low	Low	Only Bed Ridden	Low	Pressure	Low
Angiosome padding	High	Moderate	All patients	High	Pressure	Low
Systems with Feedback	Moderate	High	Variable	Variable	Variable	Moderate
Supportive Surface	Low	Moderate	Only Bed Ridden	Low	Multiple	Moderate
Capacitive Based Pressure	Low	Moderate	All patients	High	Pressure	Moderate
Wireless Matt Pressure	Moderate	Moderate	Only Bed Ridden	Low	Pressure	Moderate
Wireless Adhesive Sensor	Low	High	All patients	High	Shear Stress	Moderate
M.A.P System	High	High	Only Bed Ridden	Low	Pressure	High
Thermographic Imaging	High	High	All patients	Moderate	Blood Flow	High

2.4 Previous Accomplishment Review

In 2010, a team of undergraduate students at Worcester Polytechnic Institute (WPI) set out to develop a standalone computer-based system to prevent the onset of pressure ulcers by monitoring pressure and moisture on the patient’s skin. The team developed a successful prototype and completed preliminary testing on themselves. Overall, the project accomplished what it set out to, but was limited by the technical background of the team (Gutierrez et al., 2011).

The team determined through literature research which physiological factors were the most critical to the formation of a pressure ulcer. They also considered the method, size, and cost of measurement for each of these factors. Ultimately, pressure and humidity were the two most reasonable factors to consider in this application of determining the onset of pressure ulcer formation. As seen in Figure 13, pressure was measured using a FlexiForce® transducer. This sensor was chosen based on its pressure range. Humidity was measured using a Honeywell 4000 sensor, which was chosen based on its relative simplicity and specific voltage output. The final design including DAQ is shown below (Gutierrez et al., 2011).

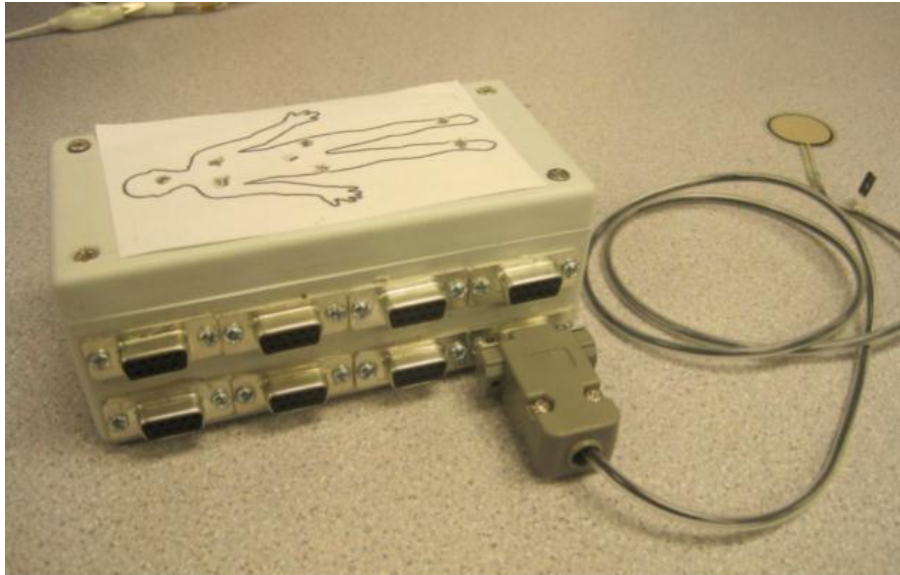


Figure 13 Final Design with Sensor (Gutierrez et al., 2011)

The sensors were interfaced with a computer running a LabVIEW program. The threshold pressure voltage and humidity output voltage were determined experimentally and these threshold voltages were compared to the real time voltages of each sensor. If the threshold was exceeded for a specific amount of time, a visual alarm is set off in the form of an LED on the hardware and indicator light on the GUI program.

The team verified through testing the set up and calibration, the LabVIEW and sensor functionality, and the patch comfort and durability. After preliminary testing were performed on members of the team, the design was proven to be successful based on their testing criteria. Feedback from UMASS plastic surgeons confirmed a successful response time, ease of use and alarm system of the device (Gutierrez et al., 2011).

Upon review of the project, the team suggested the following improvements of the device:

1. A wider demographic should be tested to confirm the accuracy.
2. The patch should be wireless to increase the mobility of the patient. The alarm system should be altered for FDA compliance.
3. The patches should be made disposable and cheap.
4. A more compatible and user friendly program than LabVIEW was recommended.

2.5 Measuring Physiological Factors

Based on the major contributing physiological factors to pressure ulcers, reasonable measurement methods for detecting these factors are discussed in this section. Various methods for measuring these factors are discussed in each section, and used to determine which factors could be measured for this application.

2.5.1 Pressure

Pressure is typically the foremost concern when addressing the detection and prevention of a pressure ulcer. The application of pressure in the area of a bony prominence is universally agreed upon as the primary cause of a pressure ulcer. Because of this, research into methods of quantifying the application of pressure became of immediate importance. Several options are available on the market, and have been for a number of years. One important consideration in choosing a pressure sensor for this application is that it must be thin.

2.5.2 Temperature

Temperature increase in an area of applied pressure has the tendency to decrease the amount of time it takes a pressure ulcer to form. It also increases the severity of deep tissue damage (Iaizzo, 2004). The reasoning behind this being that temperature increases elevate levels of tissue metabolism and the rate of oxygen consumption. However, due to the compression present on the surface of the skin, and the resulting ischemia, the availability of nutrients is greatly diminished (Kokate, 1995). This research made the addition of a temperature sensor beneficial to our design. Measuring temperature increase presents us with an even wider range of options for collecting data. Also important to this application would be limiting the sensor's size in order to avoid creating any additional pressure on the measurement area. There are several devices suitable for the measurement of skin temperature.

The skin temperature of a normal human rests just around 32°C. However, a person resting on a surface such as a bed can expect this temperature to increase. In order to account for this change in temperature, it would be reasonable to design for a temperature sensor with the ability to measure temperatures reliably from 30°C to 40°C (Chen et. al, 2011).

Some technologies that would work in our application due to compact size and relative simplicity are integrated circuit sensors, thermocouples, resistance temperature detectors and thermistors. Each of these presents benefits and drawbacks (Basic Sensors and Principles, 2011).

2.5.3 Relative Humidity

Relative humidity is described as being the ratio of specific humidity to the saturated level at that particular temperature and pressure. This measurement differs from that of absolute humidity, which is simply the overall amount of water vapor in the air (Dessler & Sherwood, 2009).

A humid environment is said to greatly increase the chance of pressure ulcer development. Increased humidity of the skin can be attributed to a variety of reasons. Regardless, excess moisture on the skin can increase the risk of a pressure ulcer developing by over five hundred percent. Excessively moist skin will weaken its consistency, increasing the overall effect of pressure. On the other hand, excessive dryness will increase the effect of shearing, again making the formation of a pressure ulcer more likely (Keller et. al, 2002). This makes the inclusion of a simple humidity sensor a worthwhile endeavor. Humidity sensors are relatively small and inexpensive, making their addition simple and cost effective.

2.5.4 Skin Thickness

Skin thickness is a measurable variable that may also prove useful in our design, given that the thickness and quality of skin naturally proves indirectly proportional to the amount of time it would take a pressure ulcer to form. Its method of measurement, called ultrasonography, uses an ultrasound scanner at 20MHz to provide fairly accurate measurements (Jasaitiene et. al, 2010). However, this technology is currently expensive, with systems often priced at thousands of dollars, and therefore cannot be used towards our application.

2.5.5 Blood Oxygen

There are two forms of noninvasive blood oxygen measurements that can be done on the extremities. The first measures the oxygen saturation in the tissue, and can be measured through transcutaneous oxygen measurements and the second measures the oxygen in the hemoglobin and is measured through pulse oximetry.

Transcutaneous oxygen measurements, $tcpO_2$, were taken into consideration as a method to assess the oxygen tension in the skin. $TcpO_2$ gives a direct indication of microvascular function, as it relays the actual oxygen supply available for skin tissue cells located under the measuring electrode. However, there are several factors that make this type of measurement impractical for our application. In order to make these readings, the electrode is fitted with a heating element, increasing the temperature of the area it takes its readings from. This heating is

undesirable in our application, due to the adverse effect that increased temperatures have in the formation of pressure ulcers. In addition, the sensors used in these measurements are bulky, which may prove detrimental in our design (Wirth, 2009).

Pulse oximetry is a noninvasive method of determining the oxygen in arterial blood, or SpO₂. Most commonly, it is measured using two light sources, infrared and red LED. The reflection off of the skin, blood and additional tissue is then measured by a photodetector. The oxygen level of the blood can then be estimated using an algorithm that factors in the difference between the two sources of light measured (Severinghaus et al., 1987). Due to the nature of pressure ulcers, using pulse oximetry would be a great addition to our design. Reflective pulse oximetry would be suited towards our objective (Yocum et al., 1989).

The problem with measuring blood oxygen levels with pulse oximetry as a method to detecting pressure ulcers is that the blood perfusion in the sites that typically form pressure ulcers is not large enough for the change between the two light sources being measured to get a reading for the blood oxygen content.

2.5.6 Local Blood Volume

Photoplethysmography (PPG) is an optical technique, similar to pulse oximetry, that can be used to measure changes in blood volume in a microvascular region of tissue (Allen, 2007). It uses an infrared light source that propagates through a region of the skin and analyzing the light returned. As blood fills the capillaries their overall volume increase. This increase modifies the absorption, reflection, and scattering of light. The change in light propagation then allows for a fairly accurate measurement of the change in blood volume (Webster, 2010). This method also allows for relative changes in blood volume to be measured specifically in the skin as opposed to the underlying tissues (Nasulund et al, 2006).

2.5.7 Blood Flow

Laser Doppler flowmetry is another noninvasive method of measuring blood perfusion in tissue. This method utilizes a low powered laser, illuminating a section of the skin and measuring light that returns due to reflection. Because moving blood has a tendency to scatter light in this practice, the amount of blood flowing through a localized area can be assessed using the amount of light measured upon return (Shepard & Oberg, 1990). The use of this practice would present us with the ability to directly measure the change in blood flow of a local tissue area. Research and development presented by MIT has expressed that this practice can be used in small scale, precision based applications (Ansari et. al, 2009). Although, the widespread clinical availability of devices that use this principle would allow for greater flexibility within our design, market available technology is expensive for our purpose.

Doppler ultrasound is another method of measuring blood flow in a localized area. It utilizes an ultrasonic wave which is projected through the skin to blood vessels. This ultrasonic wave is then reflected back with a change in pitch proportional to blood flow (Gibson, et al., 1994). Despite being noninvasive, Doppler ultrasound methods used to measure blood flow are unable to measure low levels of blood flow, such as those present within the capillaries, making it non-ideal for our design (Rajan et. al, 2009).

2.5.8 Systemic and Local Blood Pressure

Clinically today, systemic blood pressure measurements are generally taken using a sphygmomanometer, which operates by using a cuff to constrict the circulation of the blood. Digital blood pressure monitors also exist, using the classic measurement scheme yet removing the need for a stethoscope to be used by a clinician. This allows for untrained individuals to attain blood pressure measurements without the need for clinician. Our application will benefit from the knowledge of an individual's systemic blood pressure (Xuegang 2010). Figure 14 shows potentially applicable blood pressure transducers.

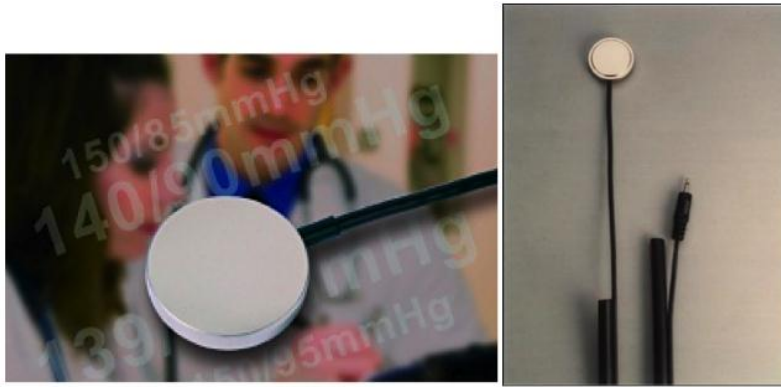


Figure 14 Left: Arterial Pressure Transducer (Morgan electroceramics, 2011). Right: Piezoelectric Pressure Sensor (Prowave, 2011)

3 Problem Analyses

3.1 Initial Problem Statement

The team was originally tasked with “developing a wireless pressure ulcer prevention system”. After researching the key physiological factors leading to the formation of pressure ulcers and the different methods of measuring these factors, a list of project goals was generated and ranked against one another in the following table. A score of 0 means that the goal down the row is NOT more significant than the corresponding goal cross the top row. A score of 1 means that the goal down the row is more significant than the corresponding goal across the top row.

3.2 Project Goals

Our design team decided on goals for the project, which could then be expanded into design objectives and constrains. Design objectives are attributes the design must accomplish. Design constraints are attributes the design must include and adhere to. Table 5 shows the ranking of these project goals to determine which were the most important.

Table 5 Overall Project Goals Ranked By Importance

Goals:	Cost Effective	Safe	User Friendly	Long-Term Monitoring	Wireless	Size/Patch	Alarm
Cost Effective	1	1	0	1	1	1
Safe	0	0	0	0	0	0
User Friendly	0	1	0	0	1	1
Long-Term Monitoring	1	1	1	1	1	1
Wireless	0	1	0	0	1	1
Size/Patch	0	1	0	0	0	0
Alarm	0	1	1	0	0	1
Totals	1	6	3	0	2	5	4

3.3 Objectives and Constraints

Our four main goals of the project are constraints which include cost, user friendliness, safety and functionality (meaning the device must detect pressure ulcers before formation). Figure 15 shows the overall project objectives and constraints.

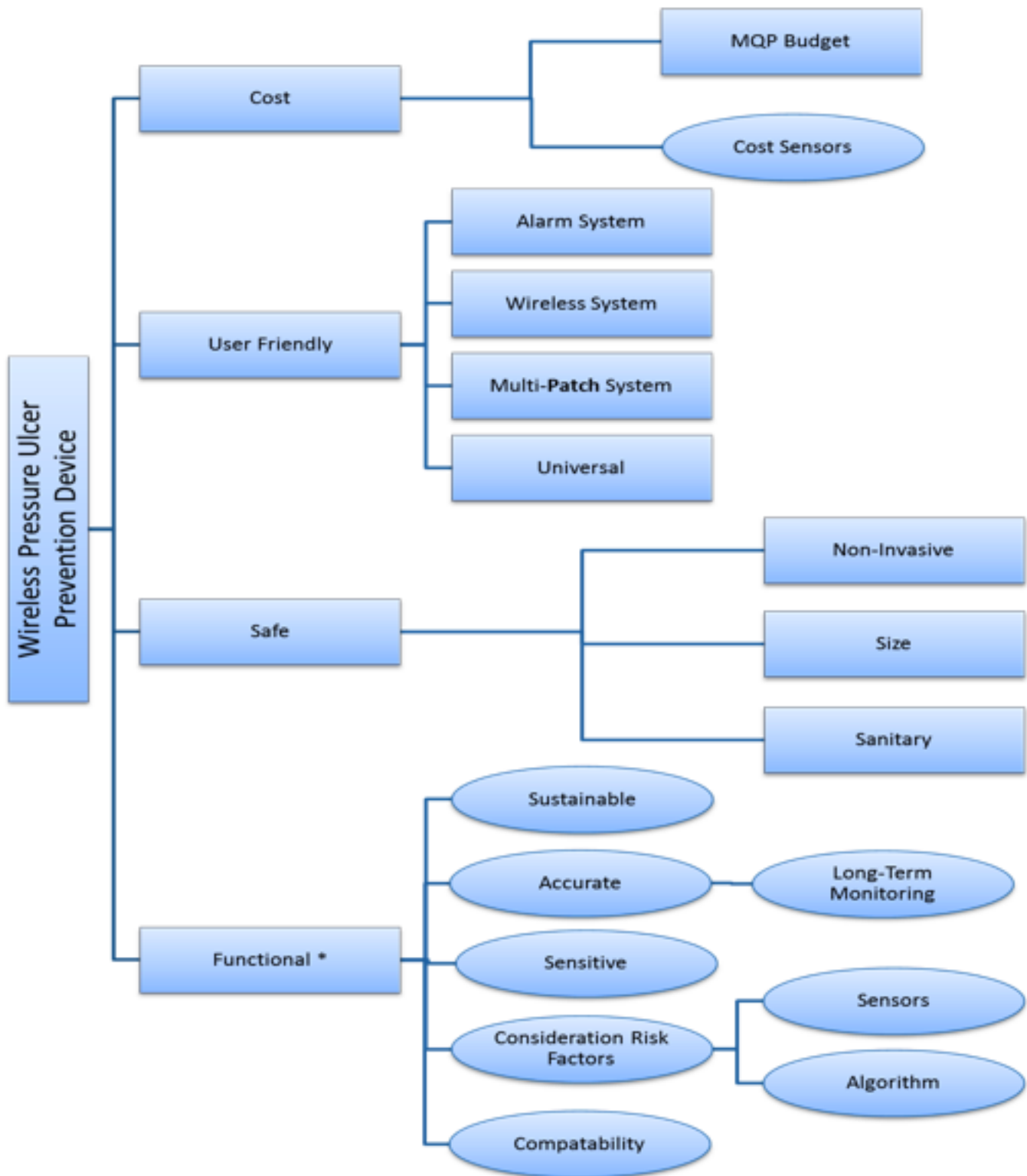


Figure 15 Objectives and Constraints Tree

3.4 Revised Problem Statement

A revised client statement was written based on further revisions, discussion with the advisors, and additional research. Accordingly, the goal of this project is to create a wireless reusable multi patch system for the accurate long term monitoring of pressure ulcers. The system will combine the use of a temperature, pressure, relative humidity and blood volume sensor in a patch to set off an alarm and alert clinicians of a potential pressure ulcer. These alarm conditions will be dependent upon additional physiological factors entered by the clinician into a data acquisition program implemented using LabVIEW software. The factors considered in this algorithm include age, weight, skin thickness, hematocrit, systemic blood pressure, nutrition and mobility levels.

The clinician will be alerted when the pressure exceeds 35 mmHg for a prolonged period of time, the temperature of the area underneath the patch increases by 1.2 °C over 24 hours, the relative humidity increases 40% to 50% or there is a decrease in blood volume for a prolonged period of time. The amount of time for both increase pressure and decreased blood flow will change in the algorithm based on the patient’s risk for developing a pressure ulcer which is based on the clinician’s input of the previously listed physiological factors.

4 Design Approach

4.1 General Design

The physiology of each patient is very different so the output of the sensor will vary greatly with each subject. In order to compensate for this, the physiological measurements taken will not be compared to a set value but relatively compared to previous patient data. At the initial application of the patch, a baseline or normal temperature and relative humidity are established. The data gathered after this point is then referenced to this initial baseline. This allows the measurements to be independent of factors such as age, weight and skin thickness because these factors are not changing during the time of monitoring.

An additional way to get a “baseline” reading is to use a reference sensor, applied in a location that is not at risk of developing a pressure ulcer but also has low blood perfusion, such as the chest plate on a patient lying in a supine position. This would make the baseline reference time independent. However, the problem with the approach is that not all locations will have similar blood flow characteristics and temperatures.

There are multiple ways to detect pressure ulcers. Choosing the most significant physiological factors are important. Different measurement options for the keys physiological factors are presented in the Components Means Chart in Table 6.

Table 6 Components means chart displaying the different means of measuring each physiological factor

Measurement	1	2	3	4
Pressure	Flexiforce® (resistive)	Pressure sensor arrays
Skin Temperature	Thermocouples	Integrated Circuit Sensors	Resistive Temperatu	NTD Thermisters
Relative Humidity	Capacitive RH sensor	Resistive RH Sensor	Absolute Humidity	...
Blood Oxygen	Transcutaneous	Pulse Oximetry
Blood Flow	Laser Doppler Flowmetry	Doppler Ultrasound
Local Blood Volume	PPG
Blood Pressure	Sphygmomanometer	Digital BP monitor

4.2 Sensor Components

In order to attain the measurements we deemed necessary, our final design employed a variety of sensors in order to measure pressure, temperature, humidity and blood volume. The following pairwise comparison chart ranks the different considerations in order of importance. These criteria were used to choose each of the components as can be seen below in Table 7.

Table 7 Sensor Comparison Pairwise Comparison Chart

Means	Accessibility	Sensitivity	Size	Compatibility	Relevance	Safety	Durability	Totals
Accessibility	...	1	1	1	0	0	1	4
Sensitivity	0	...	0	0	0	0	1	1
Size	0	1	...	0	0	0	1	2
Compatibility	0	1	1	...	0	0	1	3
Relevance	1	1	1	1	...	0	1	5
Safety	1	1	1	1	1	...	1	6
Durability	0	0	0	0	0	0	...	0

4.2.1 Pressure Sensor

Because pressure in the capillary beds is our primary concern, the pressure sensor chosen must have the ability to accurately display pressures upwards of 35mmHg. The reasoning behind this being that 35mmHg is the pressure at which most capillary systems undergo occlusion. Being able to detect this pressure gives the ability to reliably determine whether or not an area experiencing pressure has undergone capillary occlusion (Bush, 2009). In the selection of a pressure sensor, it was important to keep in mind that use of a large or unnaturally protruding device would focus pressure further on a specific area, increasing the effects of pressure and aiding in the formation of a pressure ulcer. Because of this concern, thin film sensors prove the most applicable to our design, as they can greatly reduce this effect. For this reason, pressure sensor research moved more in this direction.

4.2.1.1 Tekscan's Flexiforce® Single Sensor

Tekscan offers a variety of thin film force sensor options suitable to our application, as shown in Figure 16. Shown below is a standard single resistive pressure sensor. In order to detect changes in applied pressure, it uses pressure sensitive ink which produces a change in resistance inversely proportional to the level of applied pressure.



Figure 16 Tekscan A401 Force Sensor (Tekscan, 2011)

4.2.1.2 Pressure Mapping Array

Also available are pressure sensor arrays, which give the ability to map pressure distribution over a wider area. Although generally more expensive, such an option may become useful given concerns about the accuracy of a single sensor. These can be created by overlaying piezoresistive material in the configuration of an array, as shown in Figure 17. Afterwards, using positioning software, the area of applied pressure can be detected using the readings from the individual layouts.

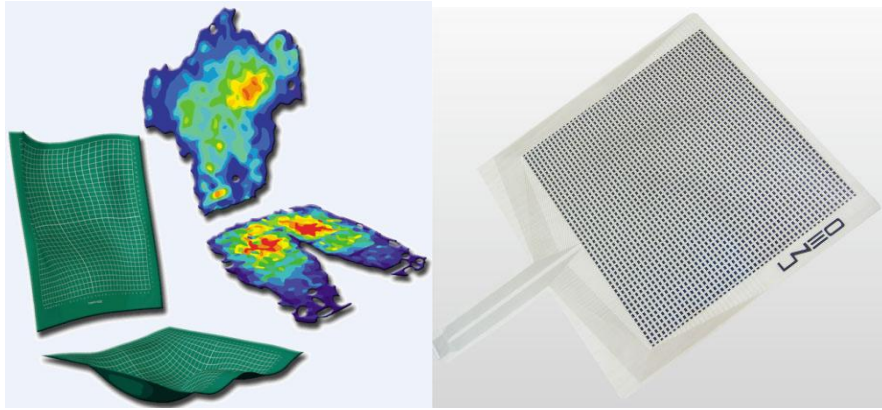


Figure 17 Left : Tekscan CONFORMat system(Tekscan, 2011) Right : UNEQ Force Imaging Array(Uneotech, 2011)

However at this time, pressure-mapping technology is far too expensive for our use, as available technology can reach upwards of one thousand dollars.

4.2.1.3 Fabric Pressure Sensor

This approach uses two pieces of neoprene material separated by sheets of Velostat™. Four conductive pads are sewn into the neoprene with conductive thread, as shown in Figure 18. As pressure is applied, there is an overall decrease in resistance measured between the conductive pads. The change in resistance was specified to range from 200 Ohms to 2K Ohms. As pressure was applied, a change of resistance could be seen on an ohmmeter, however these changes were extremely inconsistent with the expected results. The protocol for this testing was modeled after the testing of the pressure sensor array discussed in a subsequent section.

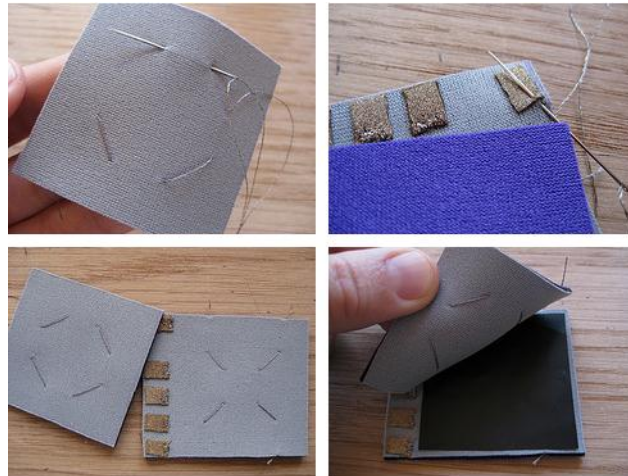


Figure 18 Fabric Pressure Sensor (Satoni, 2012)

4.2.1.4 Gel Filled Pouch

This method of pressure sensing uses a method similar to a blood pressure cuff. Air is displaced when there is an increase in pressure applied. This change in pressure can be measured using an air pressure gauge with an analog output. In order to decrease the likelihood of puncture, the pouch could be filled with a viscous material rather than air. The primary benefit of this design is the flexibility of the size of the pouch. The materials would all be custom made, rather than purchased from an outside manufacturer.

4.2.1.5 Array of Piezoelectric Sensors

If a single piezoelectric sensor was used (with a 1 in diameter), the pressure might not be accurately measured if part of the weight is displaced relative to the edge of the sensor. By using a larger array of these sensors with an

increased surface area, the pressure sensors will more accurately measure the pressure across the specific boney prominences.

In order to obtain a more uniform pressure sensor array, square sensors were used (seen in Figure 19) rather than the circular Interlink sensors. These sensors are 1.5 X 1.5 inches, and four individual sensors were arranged to form a square array covering an area of 3 by 3 inches.

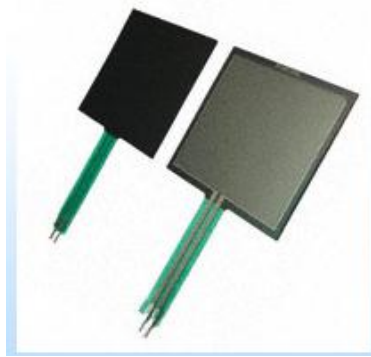


Figure 19 Interlink electronics force sensor resistor (Digikey, 2012)

4.2.1.6 Choosing a Pressure Sensor

The advantages and drawbacks of each sensing technique are outlined in Table 8 which highlights the advantages and drawbacks of each sensor design. Overall, an array of piezoelectric sensors was chosen. The table ranks each of these options based on their compliance with the original project objectives. The highest rating a sensor can have is a 3 and the lowest a 0.

Table 8 Pressure Sensor Comparison based on project objectives

	Single Sensor	Pressure Mapping	Pressure Sensor Array	Fabric Sensor	Gel Filled Pouch
Size	Small [0]	Large [3]	Large [3]	Large [3]	Large [3]
Cost	Low [0]	High [3]	Moderate [2]	Moderate [2]	Low [0]
Accuracy	High [3]	High [3]	High [3]	Low [0]	Moderate [2]
Compatibility	High [3]	Low [0]	High [3]	Low [0]	Low [0]
Sensitivity	High [3]	High [3]	High [3]	Low [0]	Low [0]
Total	9	12	15	5	5

The final pressure sensors chosen from Interlink Electronics were very similar to the FlexiForce® sensors from Tekscan, but they are square instead of circles. This allows the edges of each sensor to line up and creates a 3 x 3 inch square patch. The setup of the four pressure sensors with the humidity and temperature sensors were all encased as can be seen in Figure 25.

4.2.2 Temperature Sensor

Temperature is a concerning factor over a number of different fields. After determining the importance of including a temperature sensor into our design, several methods of measuring temperature were considered. Some technologies that could work in our application due to compact size and relative simplicity are integrated circuit sensors, thermocouples, resistance temperature detectors and thermistors. Each of these presents its own benefits and drawbacks (Basic Sensors and Principles, 2011).

Temperature measuring IC sensors are commonly used methods and offer a variety of operating ranges. These devices are generally great for low power applications and are also inexpensive. The LM135 series from National Semiconductor provide good flexibility (Childs, 2000).

Thermistors are another low cost option for measuring temperature in our application. These devices produce a change in resistive properties depending on their temperature. This change can then be measured, giving users the ability to estimate temperature. This resistive property, along with their exceptionally small size and great accuracy, allows for added flexibility (Childs, 2000).

Resistance Temperature Detectors (RTDs) are another type of temperature measuring device which rely on changes in resistance to provide accurate temperature measurements. Although these devices are very accurate, they are generally more suited to applications where high temperature changes are likely (Childs, 2000).

Thermocouples are devices based upon two different metal alloys joined together in order to produce a voltage difference at their junction proportional to the temperature difference at either end. Although generally not very sensitive, they are exceptionally robust in comparison to other devices used for the same purpose, and are therefore commonly found in high temperature and hazardous environments (Childs, 2000). Table 9 shows a pairwise comparison chart used to determine which sensor would be best suited for our application. The table is scaled 1 to 5: 5 being the best and 1 being the worst.

Table 9 Temperature Sensor Pairwise Comparison Chart

	Thermocouple	Resistive Detector	NTC Thermistors	<i>Integrated Circuit (IC)</i>
Accessibility	5	2	4	4
Sensitivity	3	2	4	4
Size	3	3	4	3
Compatibility	1	2	3	4
Relevance	3	2	3	4
Safety	5	5	5	5
Durability	1	2	2	3
Totals	21	18	25	26

Table 10 includes more detailed information used to determine the ranking in Table 9, the values and information are based off of information from digikey.com. The temperature sensor we have decided to use for our application is a Temperature Sensing IC. The size isn't as small as the negative temperature coefficient (NTC) Thermistors but it provides a number of other benefits.

Table 10 Specifications of various temperature sensors

	Thermocouple	Resistive Detector	NTC Thermistors	Integrated Circuit (IC)
Cost	Very High 30\$ - 75\$	High 3\$ - 30\$	Low 1\$ - 5\$	Low 1\$ - 6\$
Sensitivity	10-40 $\mu\text{V} / \text{C}$	3.85m Ω /C	Varied -4.4% / C Typical	Variable Sensitivity
Size	Small	Small/thin	Very small	small
Compatibility	Digital needed, V output, Self-Powered	Resistive output, constant I/V source	Resistive output, constant I/V source, high	V output, >4 V power source
Relevance	Δ Temp not ABS Temp	Amplification needed	Usable	Useable, easier manipulation
Safety	Non-Invasive	Non-Invasive	Non-Invasive	Non-Invasive
Durability	Very Durable / No Self Heating	Fragile	Fragile, somewhat self heating	Durable, some self heating
Totals	21	18	25	26

The temperature sensor ultimately decided upon was the MAX 6612 analog sensor IC. This sensor provides an optimal balance between low power consumption and input voltage, high sensitivity, and simple integration with an ADC, causing less space to be needed for a conversion circuit.

4.2.3 Relative Humidity Sensor

After determining the usefulness of including a humidity sensor within our design, research into choosing this sensor was performed. Relative humidity sensors operate in a range of 0 - 100% RH. It's not uncommon for skin to reach both extremes given favorable conditions.

Capacitive relative humidity sensors are currently a popular choice among a variety of applications where humidity measurements are needed. This type of sensor measures the effect of moisture on a dielectric constant of either a polymer or metallic oxide, using the change in capacitance to provide a measure on relative humidity (Roveti, 2001).

Resistive humidity sensors operate by measuring the change in the resistance of a material as it comes under the effect of moisture. These types of sensors are not as popular, given that they require additional amplification due to having a relatively lower sensitivity when compared to capacitive humidity sensors (Roveti, 2001).

Absolute humidity sensors are designed to measure the absolute water content in air. They are generally very durable, having the ability to operate at very high temperatures. However, their non-linear output forces them to rely on microcontrollers to produce accurate readings.

Table 11 shows the pairwise comparison chart used to determine which type of humidity sensor should be used for this application. The table has a scale from 1 to 5: 5 being the best and 1 being the worst.

Table 11 Humidity Sensor Pairwise Comparison Chart

Measuring Techniques	Capacitive Humidity	Resistive Humidity	Thermal Conductivity (AH)
Cost	5	3	2
Sensitivity	4	4	2
Size	4	4	2
Compatibility	4	4	3
Relevance	4	4	2
Safety	5	5	5
Durability	2	2	4
Totals	28	26	20

Table 12 includes more detailed information gathered and used to determine the ranking for different humidity sensors in Table 11. The best Humidity sensor for our application is a Capacitive Humidity Sensor.

Table 12 information on various humidity sensors

	Capacitive Humidity	Resistive Humidity	Thermal Conductivity (AH)
Cost	Low Cost 11\$ -30\$	Low Cost 17\$ - 25\$	50\$
Sensitivity	.2-.5pF / 1%RH (Good)	150 Ω / 1%RH (Good)	Fair Temperature Dependent
Size	Small	Small	Small but Bulky
Compatibility	Capacitance output	Resistive or DC output, easily calibrated	DC output Low Temps, Calibration needed
Relevance	Usable	Useable	Temp. dependent unreliable
Safety	Non-Invasive	Non-Invasive	Non-Invasive
Durability	Fair	Fair	Durable

4.2.4 Blood Volume Sensor

Through a literary review, it was determined that blood volume could be measured using a method called photoplethysmography (PPG). There are two components to the PPG signal: average amplitude of the signal, or the “DC offset”, and a periodic signal resulting from the heartbeat “AC component”. The “DC offset” can be used to estimate the blood volume in a specific area and remains fairly constant with time. A common application of PPG is to use the “AC component” as an indicator of the blood volume in areas of high blood proliferation, such as the fingertip. When the blood supply is cut off from the tissue the pulsatile waveform will disappear. Additionally, the overall “DC offset” of the waveform will decrease as a result of decreased blood volume. In areas of low blood perfusion the “AC component” signal may be difficult to measure even when the blood flow is not occluded (Nauslund, 2006). The team hypothesized that changes “DC offset” can be used to indicate if blood flow has been occluded in the capillaries.

4.3 Sensor Encasing

The three relevant options the team identified for encasing the sensors used to directly measure the physiological factors contributing to pressure ulcers were: (1) a surface that would lie under the entire body of the patient, (2) a

pad that would be placed under specific areas of concern, and (3) an adhesive patch that could be adhered to the areas of concern. For each possible encasing we compare the important objectives including size, portability, cost, number of sensors needed for the design, accuracy, ease of placement of the encasing and the encasing that contributes the least amount of additional pressure on the patient when used. Table 13 compares these pros and cons of each design with a scale from 1 to 5: 5 being the best and 1 being the worst.

Table 13 Comparison of the three methods to encase the sensors

Encasing/objectives	Size	Portability	Cost	Accuracy / Placement	Decrease Pressure	Number of sensors needed	Totals out of 30
Mattress	2	2	2	2	5	1	14
Pad	3	3	3	3	5	2	19
Patch	5	4	4	5	1	4	23

Based on the design objective and constraints, a mattress would not be ideal in this application. While an adhesive patch would be an ideal solution, a pad would also be an option for this application. The use of a pad would include the additional benefit of decreasing externally applied pressure. The patch formation accurately meets the group objective of portability and cost effectiveness and additionally provides increased accuracy by taking measurements from a consistent location.

An additional consideration for the sensor encasing is the potential for reusable parts. Reusable medical sensors require more durability due to their increased life cycle and need for frequent sterilization in-between patients. By making the sensor reusable, the system becomes more cost effective for hospitals and thus more marketable. For example, pulse oximeter sensors come in both disposable and reusable sensors and hospitals typically opt for the more durable reusable sensors (Shariq, 2004).

In order to make the sensor more marketable, the sensor will be encased in a disposable adhesive patch. This adhesive patch will need to be changed with each patient, but the circuitry inside can be used for multiple patients. This disposable encasing will ideally be water resistant for additional durability. The exact dimensions of the patch will be adjusted in conjunction with the sensor assembly. Simple adhesive wound care bandages, 3M Tegaderm™ film dressing, were used for concept testing.

In conjunction with the redesign of the pressure sensor, the layout of the patch and patch encasing were revised to ensure all sensors would still receive accurate signals from the subject. Based on the overall project objectives the team determined that the most accurate and user friendly encasing would be in a disposable, adhesive patch.

Adhesive:

- **Marketability:** The device should be able to accurately detect the early formation of pressure ulcers on wide patient demographics.
 - The patch should be adhesive so that it will remain accurately positioned on semi mobile patients. For example, if a person were to sit up and lie back down, the sensor should not have to be reapplied to the area of concern.
- **User Friendly:** Single application by the clinician, should not have to be replaced.
- **Accurate:** The sensors will remain in the same position to accurately acquire signals.

Disposable:

- Cost Effective: The cost of the internal sensors and the microprocessor would not make it cost effective to dispose of the entire sensor between patients. A disposable encasing would ensure sterility, and still make the product marketable.

Internal Layer:

- Durability: For increased durability, there should be an internal layer that surrounds the sensors and other circuitry. A tight fitted hole will be left for the humidity sensor because it needs to be in contact with the skin. This will fit tightly around the sensor so it will not allow moisture into the surrounding circuitry. This layer will not be disposable and will increase the overall patch durability.

4.4 Power Requirements

The power requirements for the device as a whole were carefully considered throughout each stage of the design. As each component to be used in the design was selected, it was carefully checked against the low power constraints previously established by the power supply. This was done in order to assure that individual components would not exceed the limits of what the power supply could support.

The power supply considered was a 3.6V lithium battery rated at 550mAh @ .5mA. This is currently the highest rated coin battery available commercially. Despite being somewhat pricey at \$5.32, it is a promising component for powering the current sensors selected in our design. Table 14 below shows the power requirements for the three sensors used in the patch.

Table 14 Power requirements for currently selected components are as follows.

Device	Voltage Requirement	Current Requirement
Honeywell 5030 (RH)	2.7V(min) - 5.7V(max)	.2mA(typical) - .5mA(max)
Maxim 6612 (Temperature)	2.4V(min) - 3.3V(typical)	.035mA(max)
Interlink (Pressure)	Variable	Variable

4.5 Microcontroller

One of the main design objectives was to make the system wireless. Due to the added complexity of wireless transmission, and multiplexing the multiple input channels, the team made the decision to use a microcontroller or and MCU.

4.5.1 Wireless Transmission

There were several attributes to consider in selecting a wireless option in this system. The factors considered were: the number of members participating in the network and network complexity, the expected range between these members, the distinct requirement of low power, and regulatory RF standards present for both country and medical RF use.

4.5.1.1 Frequency Band Selection

The selection of a radio frequency to use in our application was based upon a few factors. Due to the inverse relationship between transmission frequency, and both distance and output power, a lower frequency would be ideal. However, not including the 2.4GHz ISM frequency band, which is available to be used without a license in most countries, the ISM bands under 1 GHz are more restricted. As shown below in Figure 20, in the USA, the ISM bands under 1 GHz available to be used without licenses are the 915MHz, 433MHz, and 315MHz bands. The 915MHz band is the primary frequency band in the US, with the lower bands being available with more limited use.

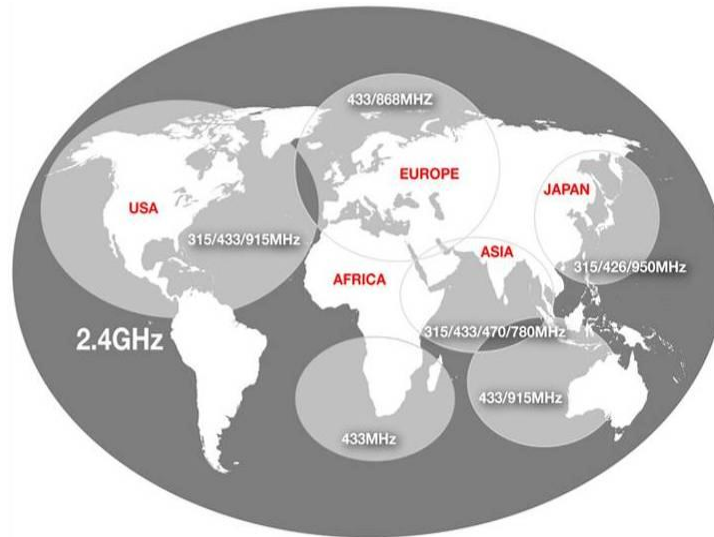


Figure 20 Unrestricted Frequency Bands by Country (Texas Instruments, 2009)

Use of a lower frequency band provides a number of advantages when compared to higher frequency bands. Generally, lower frequencies provide improved range with the same output power and current consumption on the transmitter. These frequencies are more resistant to interference and have a greater ability to penetrate walls and obstructions in the environment. Unfortunately, lower frequency bands generally require larger antennas to provide reliable transmission. On the other hand, the 2.4GHz band is much more widely used and accepted transmission band. This comes with the advantage of having more advanced transmission protocols readily available.

With increased popularity, however, there is a greater probability of saturation in the frequency band. The popularity of higher frequency bands also means that experiencing interference from other signals is more likely, detracting from the channel selectivity of the device. Although these limitations can be, to some degree, compensated for by the protocol used, higher-level transmission protocols require additional memory and add complexity to the design.

Taking these factors into account, the choice was made to use the 915 MHz frequency band. This band provides the advantage of a balance between energy consumption, transmission distance, minimal protocol overhead and reduced likelihood of interference from other devices. It will also require a smaller antenna size.

4.5.1.2 Network

Wireless considerations for future developments of this project may require the inclusion of multiple nodes on a network, including not only the device on the patients' connection to the receiver, but the receiver's connection to a central hub such as a nurse's station. A sample of the different potential network topologies can be seen in Figure 21. For the purpose of this round of development, however, a simple point-to-point topology was sufficient, allowing for reliable communication between a single device and a receiver.

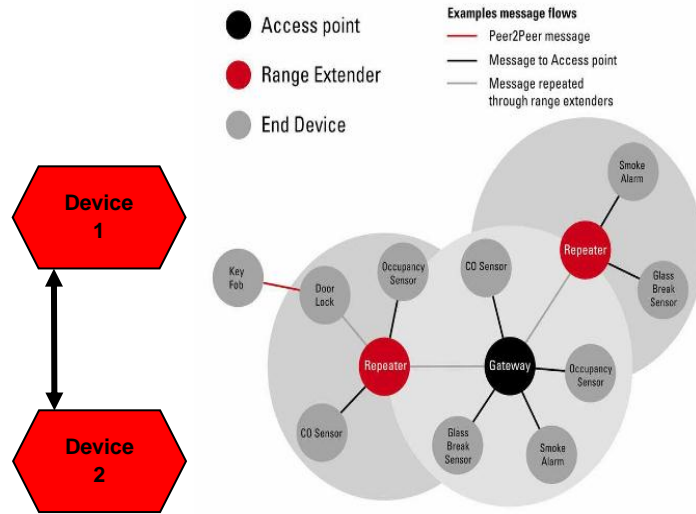


Figure 21 Point to Point and Star Network Topology Examples (Texas Instruments, 2009)

4.5.1.3 Range

The range requirement of our device is closely related with the need for a low power transmission. The relationship of the transmission distance can be estimated using Friis' transmission equation for free space propagation, which is described below in Equation 1.

$$P_r = \frac{P_t G_t G_r}{(4\rho)^2 d^2} \quad (1)$$

Where P_t and P_r are the transmitted power and received power, respectively, G_t and G_r are the transmitter and receiver antenna gains, respectively, d is the distance between the transmitter and receiver, and λ is the wavelength. Looking at this relationship, we determine that factors such as transmission and receiving power, as well as antenna gains, are directly proportional to the distance in which a wireless signal can be transmitted reliably, whereas the transmission frequency is inversely proportional.

4.5.1.4 Antenna

The antenna is a vital component and a key part of a wireless system. Its purpose is not only to convert electrical current into the form of radio waves for transmission, but also to receive these waves, converting them into small changes in voltage, which can in turn be amplified and read as a meaningful signal. As a general rule, reducing the frequency by half will double the range of signal transmission. In addition, larger frequencies require larger antennas to propagate correctly. Looking at three frequencies available within the United States, we can compare their relative antenna sizes shown in equation 2, 3 and 4.

$$\lambda/4 \text{ at } 433 \text{ MHz is } 17.3 \text{ cm (6.81 in)} \quad (2)$$

$$\lambda/4 \text{ at } 915 \text{ MHz is } 8.2 \text{ cm (3.23 in)} \quad (3)$$

$$\lambda/4 \text{ at } 2.4 \text{ GHz is } 3.1 \text{ cm (1.22 in)} \quad (4)$$

Due to there being no specific direction for signal propagation, the antenna used was a dipole antenna. The directional transmission of a dipole antenna can be modeled as a donut, with respect to an isotropic antenna, which is a theoretical antenna that emanates signal indiscriminately in all directions. The dipole sacrifices transmission in the Z plane to further propagation in the X-Y plane. A dipole antenna is by far the most commonly used in wireless systems. Several types of antennas are shown in Figure 22.



Figure 22 PCB (left), Whip (middle), and Chip antennas (right) (Texas Instruments, 2009)

Each antenna type has its own advantages and disadvantages, and shown in Table 15. A number of the preliminary assessments made into the choice of an antenna are detailed below.

Table 15 Potential Antenna Comparisons

	PCB Antenna (left)	Whip Antenna (middle)	Chip Antenna (right)
Cost	No additional Cost	Low (2.10\$ - 20\$)	Very low (.50\$ - 5.00\$)
Gain	Mid (0 dBi - 6.1 dBi)	Large (0dBi - 8.1dBi)	Lower (0dBi - 4.4dBi)
Size	Very small	Large (17.6 - 209mm)	Small (1.1mm - 4mm)
Implementation	Requires additional software	No additional factors	No additional factors

4.5.1.5 Data Rate and Transmission Frequency

The data rate at which information is transmitted is also inversely proportional to its transmission range. Figure 23 provides a very rough estimate of line-of-sight (LOS) transmission range in free space when both data rate and transmission frequency are factored. Increasing data rate in free space transmission also lowers the sensitivity on the receiving end due to less energy being used per bit, which in turn forces the use of a wider receiving filter bandwidth. This presents a tradeoff between transmission range and energy consumption that should be closely monitored going forward.

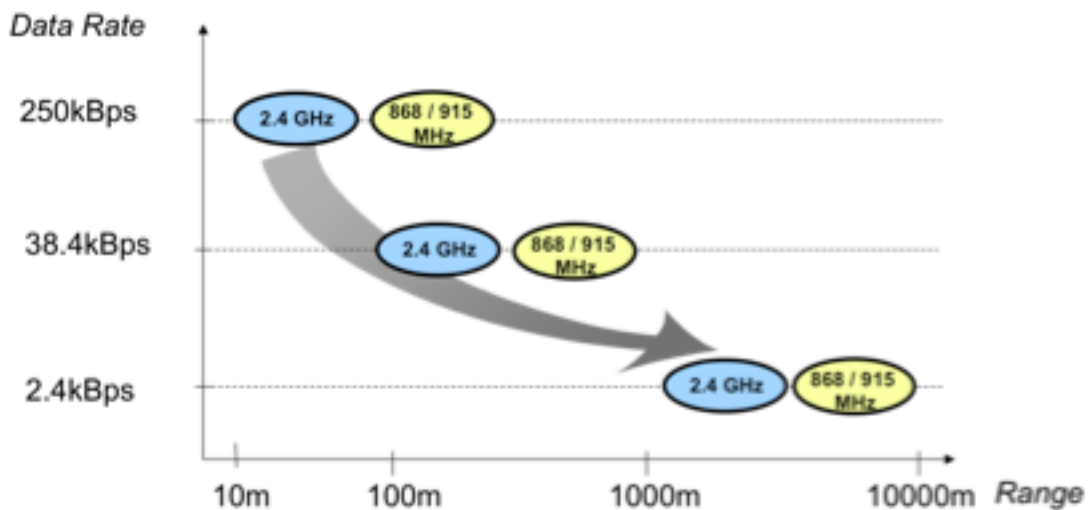


Figure 23 Range, Data Rate and Frequency Relationship (Texas Instruments, 2009)

Other factors influencing the distance a signal can be transmitted reliably include environmental factors, such as being able to maintain a direct line of sight between the receiver and transmitter, the presence of obstructions in

the environment, reflections, refractions and multiple-path fading, which result from refracted radio signals reaching the receiver from more than one path. The channel selectivity of the device represents its ability to operate reliably in an environment with interference and therefore also affects transmission range.

4.5.2 Choosing a Microcontroller

In our particular application, power supply requirement is a major factor to be accounted for in the design of the system. With this in mind, the selection of both the wireless transceiver and its operational parameters, such as output power, data rate, and transmission frequency, must be considered. These considerations become even more paramount due to this area of the design being the most power intensive. For this reason the primary research done on wireless transceivers focused on chips that offered low power operation.

The CC1101 offers current consumption as low as 14.6 mA in transmission. The chip offers programmable frequencies from 300mHz to 900MHz, as well as programmable data rates from 0.6 to 600kbps. The tradeoff for using the lower power settings is that the range is decreased, however range is not a major issue since the bedside monitors (receiving end of the data transmission) are typically only 2 meters away.

The MSP430 is the model name of Texas Instruments ultra-low power 16-bit microprocessor. This microcontroller comes with 16 registers and arithmetic can be performed directly on the values in the memory, which could potentially allow for some kind of averaging of the signals over time. It is widely used in electrical engineering applications, and for student projects at WPI. Due to the low power of the MSP430, and student familiarity with the programming platform, this chip was chosen for the design.

After some research, the team was actually able to identify a chip that combined the MSP 430 and the CC1101 into one chip, called the CC430F513x. This chip allows for a uniform platform to program both the AD conversion and then wirelessly transmit within the same chip. The ADC allows for up to 8 channels of input which allows room for future sensors to be implemented within the patch. This IC has one active mode, and five programmable low-power modes which are important for the patch application. In order to design the system, a development board was used, specifically the EM430F5137RF900, which included two wireless target boards, two wireless antennas and additional hardware (including LEDS and pushbuttons) to aid in troubleshooting.

4.6 Serial to USB Communication

In order to increase the marketability, a USB connection is an ideal interface between the receiving microcontroller and the CPU. A USB connection is a universal connection compatible with most computers. There is currently a wireless transceiver called the EZ340 Chronos that is entirely compatible with our current microcontroller and code that would allow a USB interface. To keep the project on budget, the current receiving microcontroller was interfaced with the CPU through a USB to UART converter called a CP2103. This specific hardware connection is from USB to the microcontroller through a connection with the UART communication system.

In order to interface the receiving microcontroller with the LabVIEW signal analysis and pressure ulcer risk algorithm, the real time signal must be read into LabVIEW. This requires functions to initialize the connection and access the memory registers at specific addresses determined through testing, both of which are available through Texas Instruments. These functions are written in C programming language and must be integrated into LabVIEW.

4.7 Software

The signals from the three sensors on the patch are then transmitted wirelessly to a Data Acquisition system (DAQ). The program we chose for this is National Instrument's LabVIEW platform. LabVIEW offers a visual basic style of programming, which simplifies the design and allows easy transmission of data between the sensor and the algorithm. Algorithm inputs will be requested in the form of patient mobility, blood pressure age, weight and

nutrition levels. These factors are recognized by the algorithm software and help to trigger an alarm given exceeded parameters, which are measured by the sensors.

5 Final Design

Figure 24 displays a general overview of the final design. The system includes the three sensors, their output amplification and signal conversion from current to voltage (not shown), conversion into digital form, wireless transmission and reception into the software interface. Not including the humidity and temperature sensors, which have inherent voltage outputs, each pressure sensor produces an output in the form of current. These current outputs require both conversion to voltage and amplification before conversion to a digital format. Following digital conversion, data read by the sensors is then transmitted via radio frequencies to the software interface.

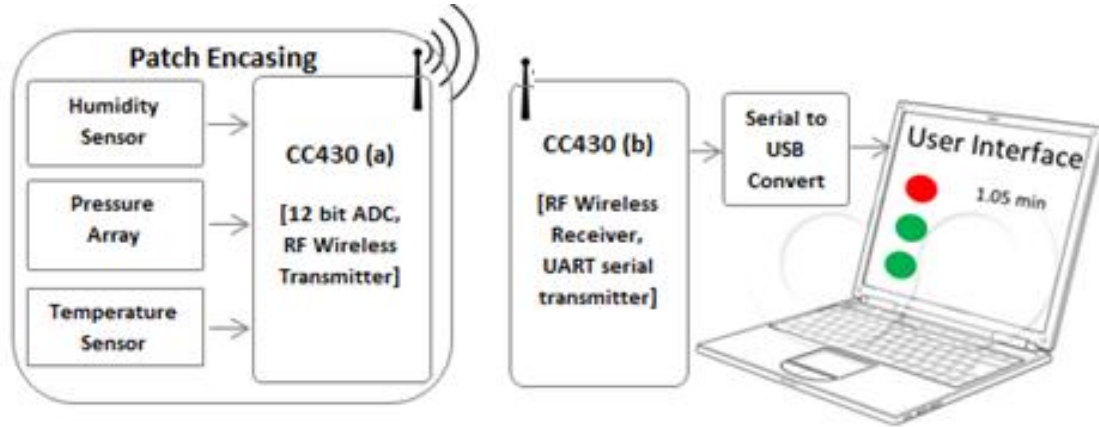


Figure 24 A general overview of the final design

5.1 Patch Layout

The redesign of the pressure sensing system and elimination of blood volume sensors has changed the layout of the patch. The patch must facilitate the placement of the sensors to allow accurate measurements. Based on Table 16, the patch must be placed in direct contact with the skin and not placed on the outside of the clothing due to the humidity sensor.

Table 16 Necessary sensor proximity to skin to ensure accurate measurements

Sensor	Proximity to skin
Pressure	Can be measured through clothing
Humidity	Must be in contact with the skin
Temperature	Must be either in contact with the skin or in contact with the skin via a conductive material

The temperature/humidity sensor surface area should be increased to maintain compatibility with the pressure sensor array.

- The temperature sensor could be placed in contact with a conductive material to increase its sensing surface area. Thermally conductive material to distribute the temperature evenly, for example conductive kapton polyimide film tape, could be incorporated within the internal encasing layer to distribute the temperature more evenly.

- The humidity sensor measures the relative humidity of the skin, which should not vary significantly over the three inches of the patch.

Due to time limitations, the wiring within the patch was done using quick wire technique. Figure 25 shows a diagram of the sensor layout of that final design.

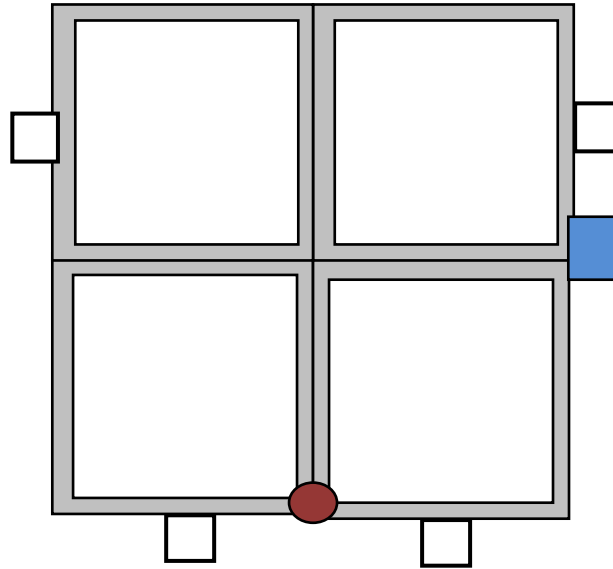


Figure 25 Sensor layout top views. Pressure sensor-grey squares (electrical edge connections, red-temperature, blue humidity). The drawing is to scale, the entire sensor area is 3 square inches.

The output signals of all the sensors required minimal amplification and no filtering. The output of the pressure sensors required minimal amplification using an inverting op-amp, the optimal dynamic range was achieved using a $3\text{k}\Omega$ resistor, which was determined through testing. The humidity sensor required a current to voltage conversion through a $1\text{k}\Omega$ resistor. Figure 26 below shows the detailed circuit diagram of all the front-end electronics.

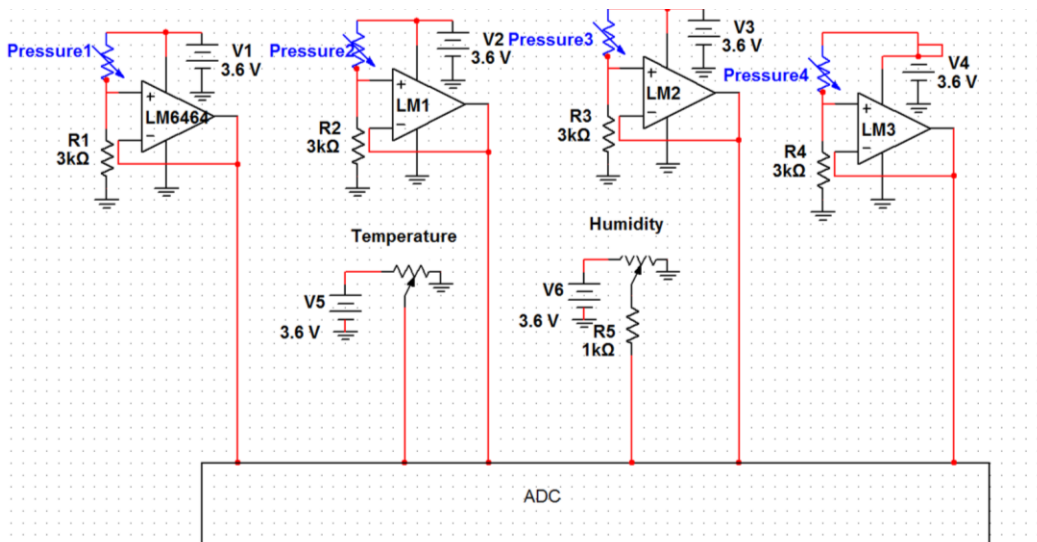


Figure 26 Signal Amplification Circuit Diagram

5.2 Programming the Microcontrollers

5.2.1 Analog to Digital Conversion

An ADC samples external voltages and converts them into binary numbers by comparing them to a reference voltage, typically the voltage that is supplying power to the converter. The output binary number is determined by the ratio of the input signal to the reference signal. Each ADC has a specific voltage range that it can specifically convert, which typically relates to the power supply. For this application, this is extremely important because the system runs on a 3.6V battery. The three main considerations of the ADC were the bit resolution, the required sampling frequency and the power requirements.

5.2.1.1 Bit Resolution

The precision of an ADC is determined by the amount of bits it converts each sample to. The chip used in this application includes a 12-bit ADC. In order to determine the resolution of the ADC, the discrete steps must be compared to the voltage range of the ADC as determined in equation 5 and 6.

$$\text{Quantization} = 2^N \quad (5)$$

$$2^{12} = 4096 \text{ discrete steps} \quad (6)$$

The voltage range is typically set externally by the power supply, however the MSP430 offers an internal preset voltage supply of 3 volts. By using this internal voltage as the ADC range, there is no need to supply an external voltage regulator. This greatly improves the accuracy of the ADC demonstrated in Equations 7 and 8.

$$\frac{\text{voltage range}}{\text{discrete steps}} = \text{Bit Resolution} \quad (7)$$

$$\frac{3.0V}{4096} = 0.805mV \text{ resolution} \quad (8)$$

This resolution is more than sufficient for this application because the highest level of accuracy required is for the temperature sensor; both the pressure and humidity sensors are less sensitive than the temperature sensor. The temperature sensor has a sensitivity of 19.53mV/ °C and can measure temperature changes accurately to the 0.2 °C. This means that each 0.2 °C will result in a change of 4mV, which is well within the bit resolution of the ADC included with the MSP430.

5.2.1.2 Sampling Rate

The lowest acceptable sampling rate of an ADC depends on the frequency of the signal it is acquiring. The Nyquist theorem states that the sampling frequency must be at least twice the frequency of the signal being sampled. In this case the signals being acquired change so slowly that they are almost DC. The fastest rate necessary to monitor these physiological factors is once per second. Therefore, by the Nyquist sampling principle, the fastest sampling rate necessary is 2Hz, or once every 0.5 seconds.

5.2.2 Minimizing Power Consumption

Good power management is an important concern in the design of our system. Several steps were taken to maximize battery life. Some of the considerations involve RF transmission as detailed below.

- Using the lowest possible duty cycle.
 - This includes minimizing the number of transmissions that need to be made in order to maintain an accurate reading on a patient.
- Using the highest data rate

- Adherence to this must be closely monitored however, as data rate also contributes to a devices max range.
- Using the lowest possible voltage
 - This is due to the fact that RF chips in general draw less current at lower voltages.

Continuous data transmission would cause too much current draw, and drain the battery in less than 5 hours. In order to minimize power consumption, the CC430 enters a low power mode when not sampling or transmitting signals. Low power modes disable the CPU and various clocks, and maintain the RAM memory. Activation of an interrupt service routine, which occur every 30 seconds, brings the MCU into active mode. The header file specifies a variety of low power modes; the mode we chose was low power mode 3. This mode disables the CPU and all clocks other than the ACLK, which controls the interrupt service routine.

In low power mode 3, the current consumption of the chip is 7.1 μ A. The normal power consumption in active transmission mode is 18 mA. The microcontroller is transmitting 3.3% of the time (twice per second) and in low power mode the remaining time. The average life of a typical coin cell battery is 100mAHr. Equations 9 and 10 demonstrate the anticipated battery life.

$$Life\ Cycle = \frac{100mAHr}{(3.3\% \text{ active} * 18mA) + (96.7\% \text{ low power} * 0.0071mA)} \quad (9)$$

$$Life\ Cycle \cong 166Hours \sim 7days \quad (10)$$

5.3 Software Development

5.3.1 Signal Analysis

The signal analysis and alarms were created in LabVIEW. Voltages are entered into LabVIEW via the NI 6004 DAQ and are split based on their respective sensors. Each sensor output voltage is compared to a set threshold voltage; if the voltage is larger than this threshold voltage, an alarm sounds. When the voltages go over the defined threshold values, the alarms (red buttons) begin to blink. The block diagram that shows how the front panel was created is seen in Figure 27.

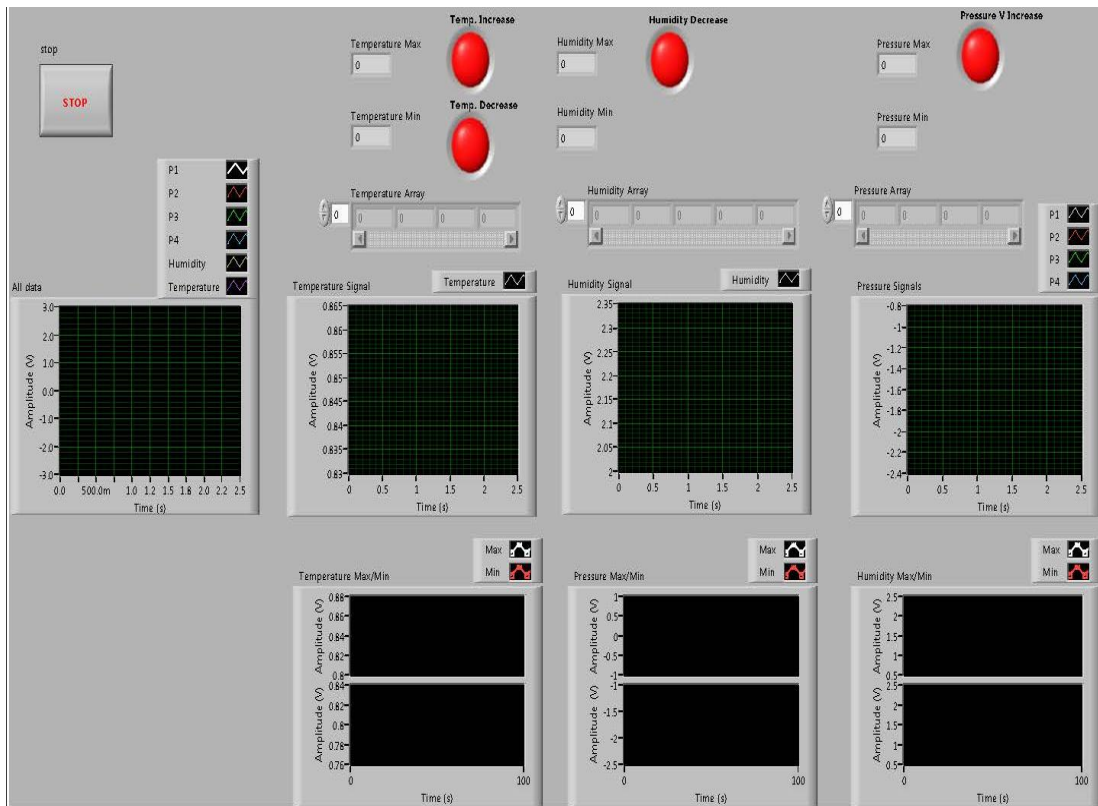


Figure 27 LabVIEW front panel used for signal analysis

Figure 28 shows the GUI that allows the operator to view the trend of each signal, record the maximum and minimum values and compare these results to the individual sensor testing.

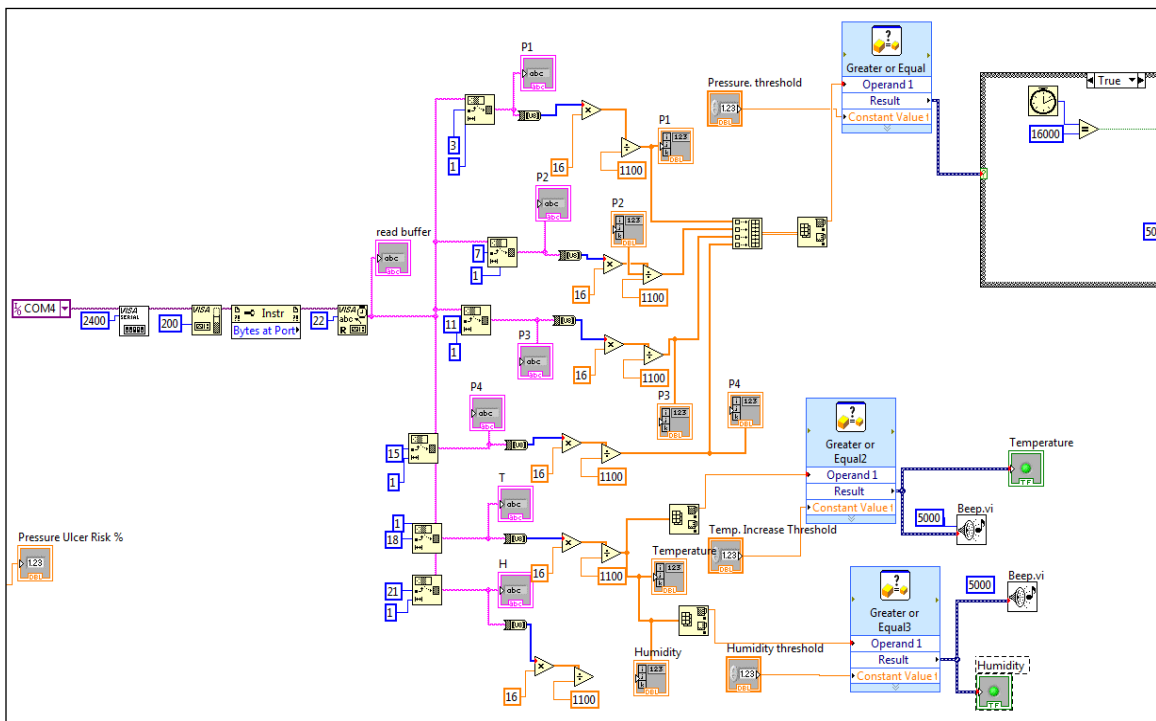


Figure 28 LabVIEW block diagram used for signal analysis.

5.3.2 Algorithm Development

The algorithm factors in 6 physiological factors that commonly contribute to pressure ulcers. These factors are determined and entered by the caregiver. Once the caregiver enters the information into the LabVIEW program, the algorithm goes through a series of calculations to determine the risk of developing a pressure ulcer. The input parameters include age, mobility level, weight, nutrition level, blood pressure, iron level, O₂ levels, and CO₂ levels.

5.3.2.1 Age

Age percentage is simply the patient's age. Literary review shows, the majority of pressure ulcers develop in older subjects. Patients 65 years old and above were found to develop pressure ulcers more commonly. Therefore, the risk percentage of a person getting a pressure ulcer depending on their age increases linearly as they get older. For instance, a person that is 50 years old has a 50% chance of getting a pressure ulcer, whereas a 20 year old patient has a much smaller chance at 20%.

5.3.2.2 Mobility Levels

The caregiver also enters mobility levels, based on a scale explained on the user interface. A scale from 1 to 5 has been set up to evaluate the patient's mobility level. The scale developed takes into account the major mobility levels that affect pressure ulcers and can be seen in Table 17 below.

Table 17 Patient Mobility Levels

Mobility levels	Patient Characteristics
1	Minimal problems or normal mobility levels
2	Paraplegic or quadriplegic
3	Problems with sensory communication (unable to feel pain or discomfort)
4	Bed ridden
5	Comatose

5.3.2.3 Weight

The weight of the patient is entered into the user interface. The risk % for this particular cause is calculated based on if the patient is too thin or over weight for their height. The user interface includes a guide that easily allows the caregiver to determine the patients weight based on a scale. This was done instead of using the actually weight number because a patient might be very tall with wide shoulders and weigh 300 lbs. and still be average or only slightly overweight. A rating of 4 is given to both patients that are significantly underweight and a patient that is obese because they both have a greater risk of forming a pressure ulcer.

5.3.2.4 Nutrition

Nutrition is important factor in the formation of pressure ulcers. Nutrition refers to vitamin intake and hydration. This is why a 1 to 4 scale was set up for the caregiver to assign a nutrition level that is very similar to the weight scale. 1 is a score representing the patient's vitamin levels are good and they are comfortably hydrated. A score of 2 is simply when a patient's vitamin intake is a bit lower than it should be and they are slightly dehydrated but these can be easily be addressed. When a patient has a significantly lower vitamin intake and dehydration that affects their health they are rated a 4. And finally a score of 5 is dangerously ill and an unmanageably low amount of vitamins in their system and deathly dehydrated.

5.3.2.5 Blood Pressure

Poor circulation throughout the body increases the risk for pressure ulcers. The most common attribution to poor circulation is the narrowing of arteries and blockages in the veins causing high blood pressure. Low blood

pressure, due to the dilating of blood vessels, causes circulation to slow down. According to the National Heart Lung and Blood Institute, to have high blood pressure, the diastolic pressure does not need to be high. 140/90 mmHg is considered high. Pre-hypertension is between 120/80 mmHg and 139/89 mmHg. This allows us to determine the risk by setting the high pressure concerned value at 125 mmHg systolic blood pressure. Low blood pressure is usually systolic blood pressure below 90 mmHg. Therefore, a 100% risk was set at 80mmHg and 145 mmHg at 100% risk (both 20 mmHg off from the concerned values). The algorithm works by taking the systolic BP value the user enters and subtracting 125 and 90 (our concerned values). This algorithm calculation can be seen in Table 18.

Table 18 Algorithm calculation risk for blood pressure.

Systolic Blood Pressure	Sys. BP - 125	Sys. BP - 90	Smaller #/20	Risk %	Adjusted Risk %
60	65	30	1.5	150	100
65	60	25	1.25	125	100
70	55	20	1	100	100
75	50	15	0.75	75	75
80	45	10	0.5	50	50
85	40	5	0.25	25	25
90	35	0	0	0	25
95	30	5	0.25	25	25
100	25	10	0.5	50	50
110	15	20	0.75	75	75
115	10	25	0.5	50	50
120	5	30	0.25	25	25
125	0	35	0	0	25
130	5	40	0.25	25	25
135	10	45	0.5	50	50
140	15	50	0.75	75	75
142	17	52	0.85	85	85
145	20	55	1	100	100

The algorithm in LabVIEW changes the zeros and other percentages over 100 to their respective value as seen in the adjusted risk.

5.3.2.6 Low Oxygen Saturation Levels

Low oxygen levels are also a concern for the formation of pressure ulcers because there is not enough oxygen getting around the body. Blood oxygen levels are most commonly taken through noninvasive pulse oximetry. The user entered blood oxygen level is subtracted from 90 and then divided by 10 to give a risk percentage. The algorithm calculation is seen in Table 19.

Table 19 Algorithm calculation risk for blood oxygen.

Blood Oxygen Level	90- O ₂	#/10	Risk %	Adjusted Risk %
75	15	1.5	150	100
80	10	1	100	100
85	5	0.5	50	50
90	0	0	0	25
95	5	0.5	50	50
110	20	2	200	100

The algorithm in LabVIEW changes the zeros and other percentages over 100 to their respective value as seen in the adjusted risk. Figure 29 shows the LabVIEW block diagram of the inputs into the formula described previously.

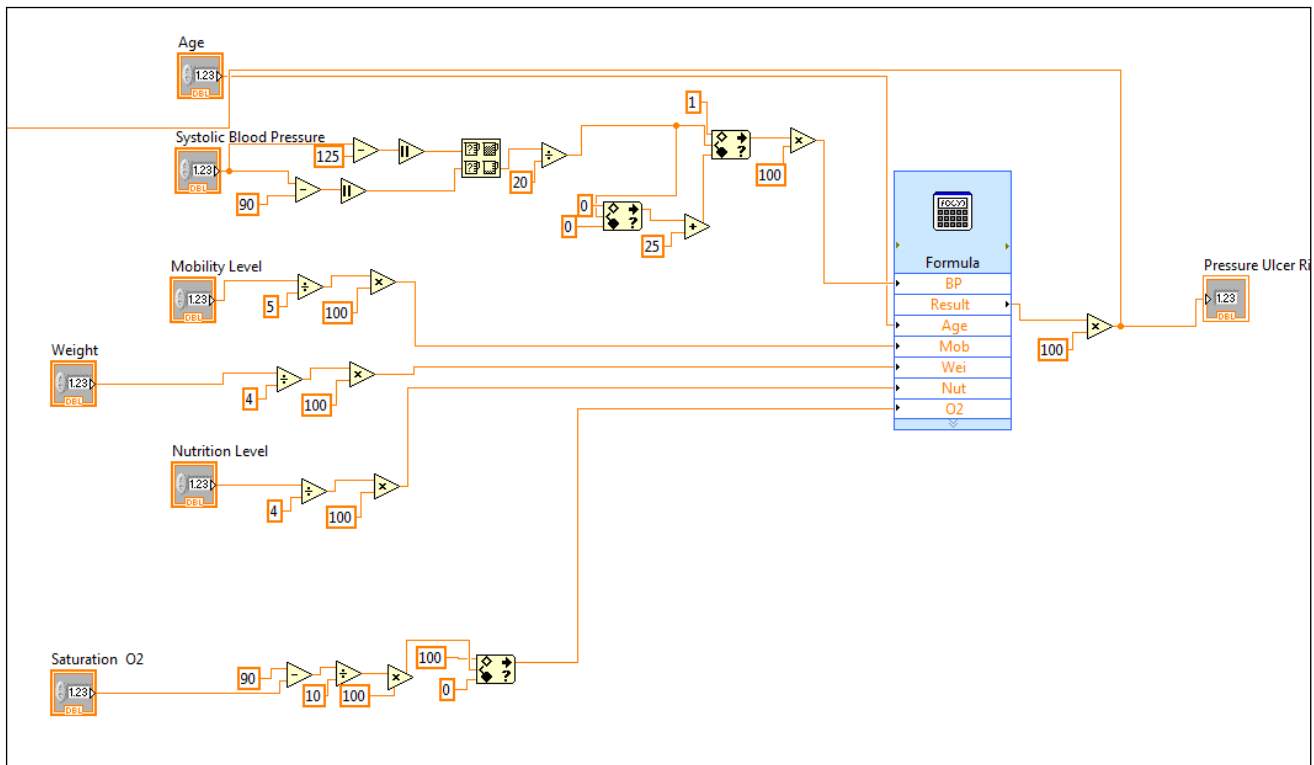


Figure 29 Algorithm development in LabVIEW

5.3.3 User Interface

The LabVIEW user interface for the algorithm that is currently being used can be seen in Figure 30.

The figure shows a LabVIEW user interface with a grid background. On the left side, there are several input fields: 'Age' with the value 45, 'Weight' with 1, 'Mobility Level' with 1, 'Nutrition Level' with 1, 'Systolic Blood Pressure' with 137, and 'Saturation O2' with 29. In the center, there is a section titled 'Selection Information' with three sub-sections: 'Weight: Please choose the most appropriate' with options 1 (Average weight for age and body size), 2 (Slightly over or under weight for age and body size), 3 (Significantly over or under weight for age and body size), and 4 (Unmanagably over or under weight for age and body size); 'Mobility: Please choose the most appropriate' with options 1 (No problems), 2 (Hard time moving/walking needs help), 3 (Wheel chair but patient is relatively mobile), and 4 (Sensory/communication problems and can't identify pain/); and 'Nutrition: Please choose the most appropriate' with options 1 (Good level of vitamin and comfortably hydrated), 2 (Slightly low amount of vitamin intake and slightly dehydrated), 3 (Significantly low amount of vitamin intake and dehydration), and 4 (Dangerously low amount of vitamin intake and dehydration). On the right side, there are three green circular indicators labeled 'Pressure', 'Temperature', and 'Humidity'. At the bottom center, there is a 'Pressure Ulcer Risk %' field with the value 75.

Figure 30 LabVIEW user input interface to calculate the total patient risk of forming a pressure ulcer

This information is used within the signal analysis and setting the alarms. When the patient's overall risk percentage in forming a pressure ulcer increases, the amount of time before an alarm sounds proportionally decreases. If the patient is over 60% at risk to form a pressure ulcer, the threshold values begin to decrease. If the patient's risk percentage continues to rise, the threshold values that set off the alarms will continue to decrease. This allows the caregivers to monitor the patients that are at a higher risk in forming a pressure ulcer more frequently.

6 Design Verification

Throughout the build process each component was tested individually. After each sensor was tested individually, they were tested with the signal analysis program and user interface. The wireless transmission and ADC were tested individually and then integrated with the front-end sensors and verified.

6.1 Individual Sensor Testing Protocol

The purpose of this testing was to determine the relationship between the voltage output and the temperature, pressure and humidity inputs. There are manufacturers specifications that indicate expected relationships between each of these factors (pressure, humidity, and temperature) and the output voltages. In order to ensure proper operation of each of these sensors, each sensor was tested with a custom protocol described in this section.

6.1.1 Pressure Sensor Array

The force sensors were individually calibrated based on the same protocol used to test the FlexiForce® sensors. The manufacturers specifications for output resistance compared to force in grams was used to determine an appropriate RM value for the circuit diagram shown in Figure 31. The resistor that offered the largest dynamic range in the region of interest was a 3k resistor.

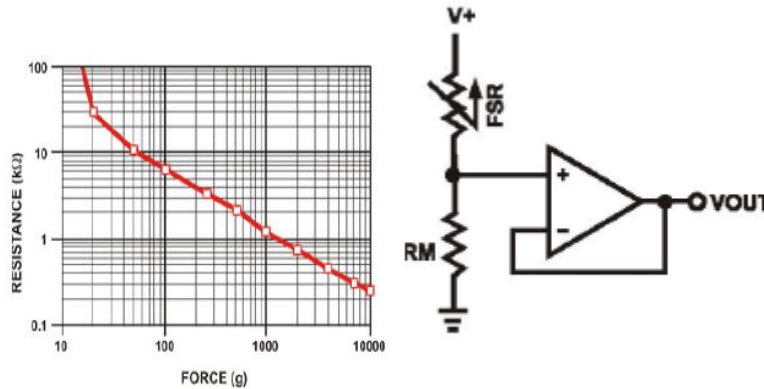


Figure 31 Manufacturers specification force vs. output resistance and suggested circuit diagram (Interlink)

6.1.1.1 Pressure Array Testing

1. The voltage of the pressure sensor array was read into a LabVIEW algorithm that recorded the data in real time. This testing was performed after the DAQ verification, and signal analysis verification was completed.
 - a. This program recorded the output voltages from each sensor independently and also recorded the sum of these voltages.
2. The weight was concentrated in specific locations of the sensor using a quarter with a diameter of 2.42cm weighing 5.67 grams.
 - a. The pressure was focused on an area of 15.24 cm² (the area of the quarter)
3. Metal blocks were used to gradually increase the weight to determine the voltage output of the pressure sensor array. The weight was tested using a National Controls, Inc. scale, Model # 3820 (capacity of 50 lbs.).
 - a. Weights vary from 0.4 lbs. to 25 lbs.
4. The output was recorded with no weight, and weight was gradually increased to 10 pounds.
5. The tests were repeated with the weight being focused on different locations around the sensor array including:
 - a. Centered on all 4 pressure centers
 - b. Centered on a single pressure sensor
 - c. Offset evenly between 2 pressure sensors
 - d. Offset between 3 pressure sensors

6.1.1.2 Array Results

Alarm should be set at a pressure threshold of 35 mmHg, the pressure at which people become at risk for developing a pressure ulcer. One mmHg corresponds to 1.359 g/cm², and in the case the weight is being distributed over the area of a quarter (15.24 cm). Therefore the threshold should be set to the output voltage that corresponds to 663.12 grams or 1.46 pounds. Figure 32 below shows the results of these three tests, the blue marker shows the results of centralized pressure testing, the red shows the voltage output across two sensor, and the green shows the voltage output focused on one sensor.

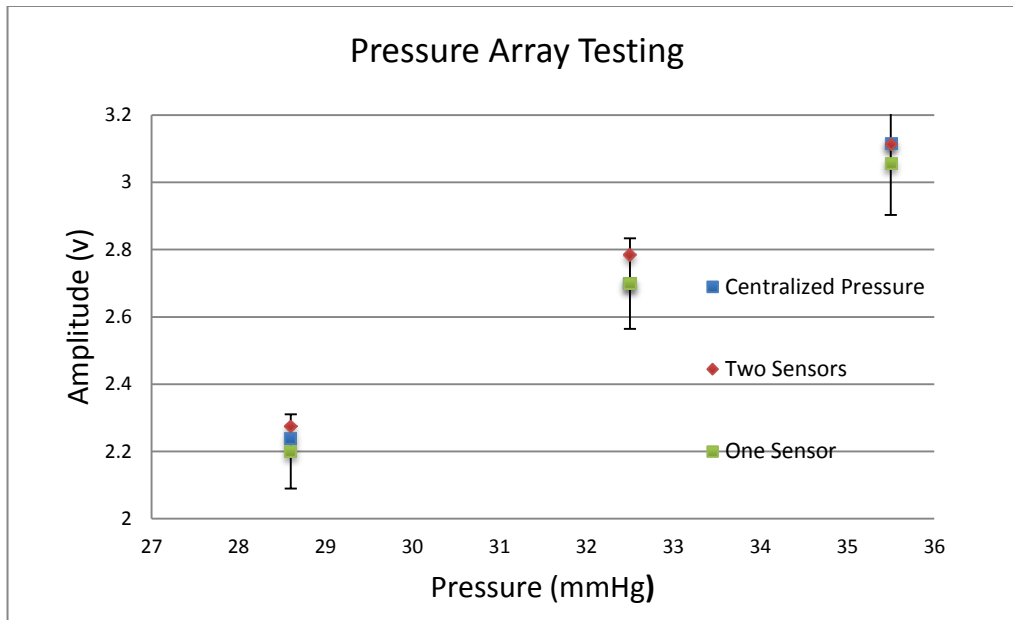


Figure 32 Pressure array tested at various locations on the sensor

6.1.2 Temperature Sensor

The temperature sensor was calibrated and tested with a digital heating pad, an infrared thermometer and a digital multimeter. The data were recorded over time and plotted according to the following protocol:

1. The voltage output was measured at standard room temperature.
2. The temperature was measured with an infrared thermometer.
3. The temperature controlled blanket was placed on the temperature sensor at approximately 3 °C warmer than room temperature.
4. At the time of recording, the actual temperature of the sensor was measured using the infrared thermometer to ensure proper conduction from the blanket to the temperature sensor.
5. The digital heating pad was increased at a rate of 1 °C, and a data point was taken a minute later.
6. This process was repeated to 60 °C. At 55 °C human skin would feel sharp discomfort, and the patch should not be exposed to such extreme temperatures. However, the manufacturers specifications that temperatures can be measured accurately up to 150°C.

6.1.2.1 Temperature Sensor Results

The temperature sensor operated in a nearly linear fashion as shown in Figure 33. At some measured temperatures, the voltage output was not accurate to the manufacturers specifications. However, within the range of physiological interest, the relationship between temperature and output voltage is nearly linear.

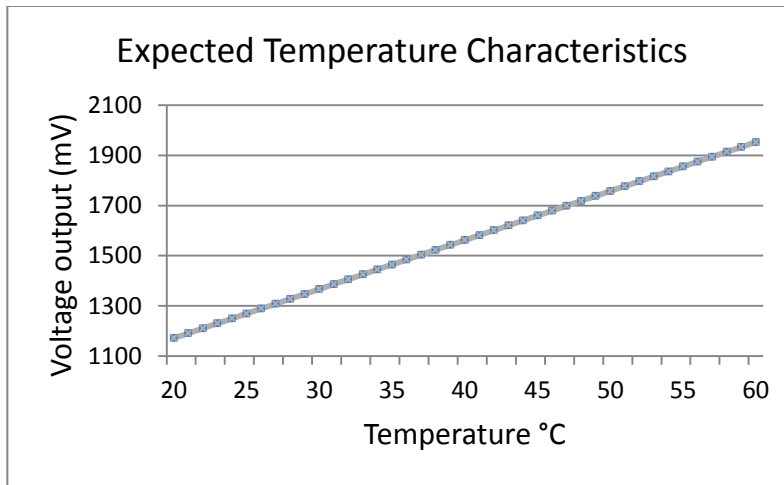


Figure 33 Expected temperature characteristics based on the manufacture specifications

The actual observed temperature characteristics were linear for the most part, and within the range of interest the output voltage increased linearly. The range of interest is the typically temperature of human skin, 30-40°C. Figure 34 below shows the results of one of the three trials conducted.

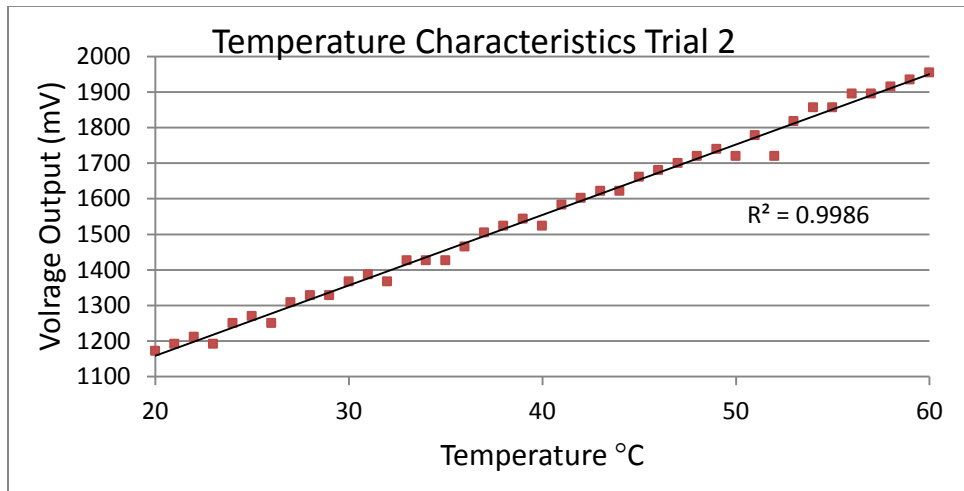


Figure 34 Temperature characteristics trial three, the high r value indicates a linear relationship

Table 20 shows the results of the three trials conducted. The high R values indicate a linear relationship between temperature and voltage output, as expected.

Table 20 R square values for Temperature Collection

	Linear Equation	R ²
Trial 1	$y = 19.559x + 780.57$	0.9921
Trial 2	$y = 19.267x + 755.42$	0.9986
Trial 3	$y = 18.676x + 744.31$	0.9938

Temperature Sensor Repeatability:

It was necessary for the temperature sensor to be accurate to 1.2°C (the change in temperature that indicates the formation of a pressure ulcer), based on Table 20 above, that corresponds to a change in 19mV. The standard

deviation should be below 9.5 mV in order to obtain the necessary accuracy. Figure 35 shows the standard deviation at each temperature reading over the range of interest based on the readings taken for the 3 trials.

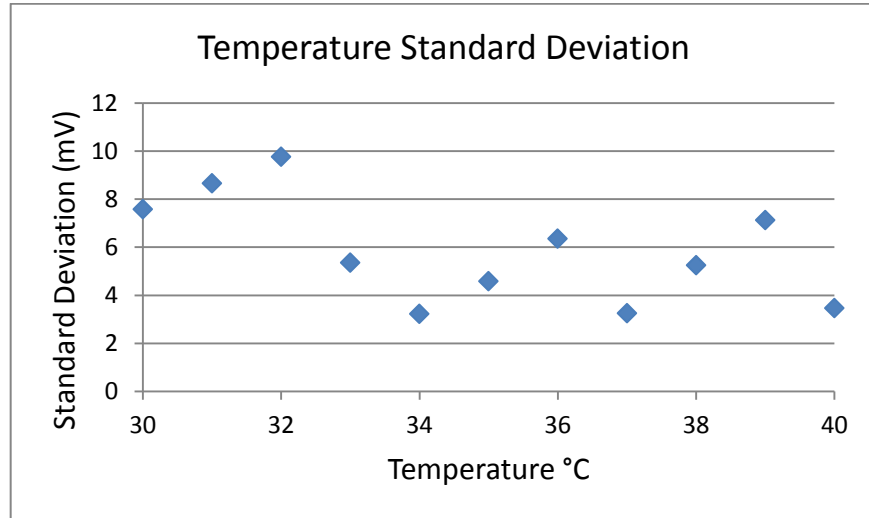


Figure 35 Temperature reading standard deviation

The chart indicates that the standard deviation is below 9.5 mV in each case, and therefore the temperature will be accurate to at least 1.2°C.

6.1.3 Humidity Sensor

1. The Vicks Personal Steam inhaler V1200 was used to regulate humidity in a closed container.
2. A standard temperature humidity thermometer was used to measure temperature and humidity inside the closed container.
3. The humidity sensor on a small prototyping board was placed inside the container.
4. The Vaporizer was then turned on and as the water boiled, the steam increases the humidity level.
5. As time elapsed (every minute), humidity and temperature level were recorded at the given time together with the voltage reading from the multimeter.
6. Humidity (horizontal axis) vs. Voltage (vertical axis) was then plotted as seen in Figure 37 below.

6.1.3.1 Results

The humidity sensor follows the sensor’s design specifications shown in Figure 36.

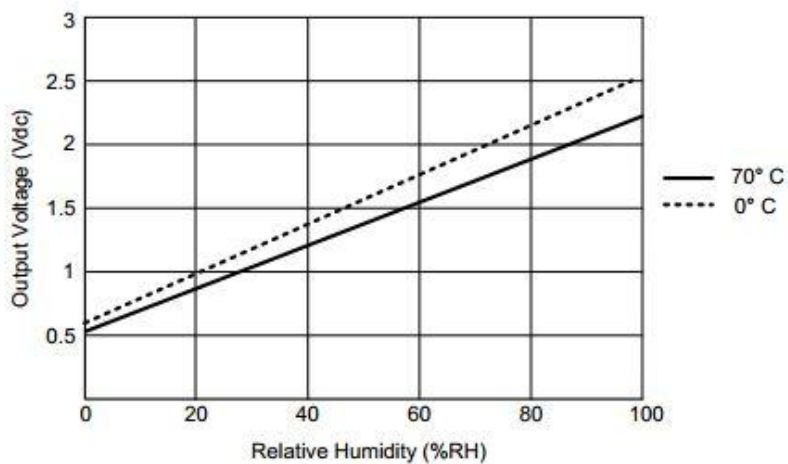


Figure 36 Humidity vs. Voltage output for the HIH5030 given by the manufacturer

The humidity sensor was calibrated, and testing showed that the expected voltage output was repeatable at consistent humidity values. The results of these tests can be seen in Figure 37. This allowed the team to pick a relative humidity that is considered dangerous and set the corresponding threshold voltage according to the testing.

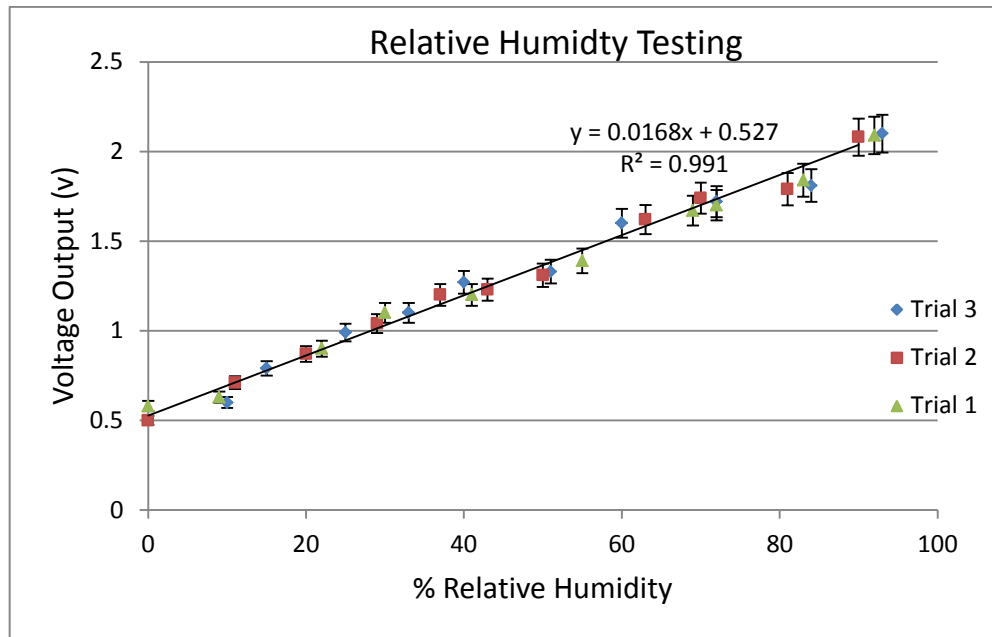


Figure 37 Results of the relative humidity sensor testing

The high R-squared value indicates a linear relationship between relative humidity and voltage output, as expected from the sensor data sheet.

6.2 Software Compatibility Testing

In order to verify proper integration of the sensors and the signal analysis program, the alarm threshold and response time were tested using a DC power source. Each sensor was individually tested to ensure alarms sounded when the pressure, temperature and humidity thresholds were exceeded. This testing was done through wired analog means due to delays in programming the wireless transmission. This compatibility testing was beneficial for subsequent stages of testing. However, the final interface with the software will not use the NI 6004 DAQ but UART/USB interface.

6.2.1 Alarm Thresholds and Response Time

The NI 6004 DAQ was tested with the signal analysis program to ensure that if known voltages were exceeded, an alarm would sound within a reasonable amount of time. A laboratory DC power supply across a 1kΩ resistor was used to generate a voltage on each of the input channels to ensure the values being analyzed corresponded to the readings taken with the digital multimeter. On each channel the DC power supply was set at 1V below the alarm threshold and gradually increased until the threshold was exceeded. The response time was then recorded using a stopwatch. The results of this testing can be seen below in Table 21.

Table 21 Basic analog alarm testing

Channel	V _{thresh} (mV)	Response Time (sec)	Successful Alarm Activation
Pressure Array	2500	4.3	Yes
Humidity	490	4.3	Yes

The analysis of the skin temperature is more complex, and therefore was tested with a DC power supply set to a typical output voltage of the temperature sensor. The temperature algorithm takes an average of the temperature readings for one minute, stores that reading for 5 minutes, and then compares the current temperature to the previous baseline temperature.

6.2.2 Sensor Compatibility with LabVIEW

Compatibility between the sensor configuration and the software was tested through a wired connection with the NI 6004 DAQ. This required that all data were input into LabVIEW at a rate of 500 samples at 200 Hz. The results of the digital multimeter, placed on the sensor output, were compared to the values read by LabVIEW. The results can be seen below in Table 22. This test was used to ensure that the individual sensors are compatible with their respective signal analysis and threshold alarms were activated as expected.

Table 22 Pressure array alarm testing

	Pressure (mmHg)	LabVIEW (mV)	Alarm Activation
Centralized Pressure			
	35.5	3056	Yes
	28.6	2200	No
	32.5	2699	No
Pressure Across Two Sensors			
	35.5	3114	Yes
	28.6	2276	No
	32.5	2785	No
Pressure focused on One Sensor			
	35.5	3116	Yes
	28.6	2240	No
	32.5	2699	No

The minimal delay can be attributed to a wait function in the algorithm that acts as a filter so alarms are not sounded unnecessarily.

6.3 Analog to Digital Conversion

The analog to digital conversion accuracy was tested using two sources, a simple ramp up DC power source and interfaced with the sensors at known voltage outputs.

6.3.1 DC Power Source

The initial set up and testing was done using a steady DC power source. The signals being acquired are nearly DC and therefore the sensors could be tested with a simple DC power source. Known voltages were input into the ADC and the corresponding hex values were viewed through the watch register in IAR and recorded into Excel. These values were compared to the expected conversion values based on Equations 11 and 12.

$$\frac{3.0V}{4096} = 0.805mV \text{ resolution} \quad (11)$$

$$V_{converter} = 0.805 * \text{memory register value} \quad (12)$$

The voltage was tested from 0-3V in increments of 10 mV. As expected, the ADC correctly converted these DC values to the expected hex code with an accuracy of at least 1 mV. This showed that the ADC was configured correctly; see Appendix C for full microcontroller code and conversion characteristics.

ADC testing was performed in order to verify linear conversion of the ADC present within the CC430. By verifying its linear nature, the accuracy of the system was confirmed. Testing was performed by applying a test voltage through a 1kΩ resistor to an ADC input pin of the CC430F5137. Vcc used for conversion was a simulated battery input at 3 V with Vss of 0V. Figure 38 shows that the ADC is working correctly. Minor deviations are the result of measurement error.

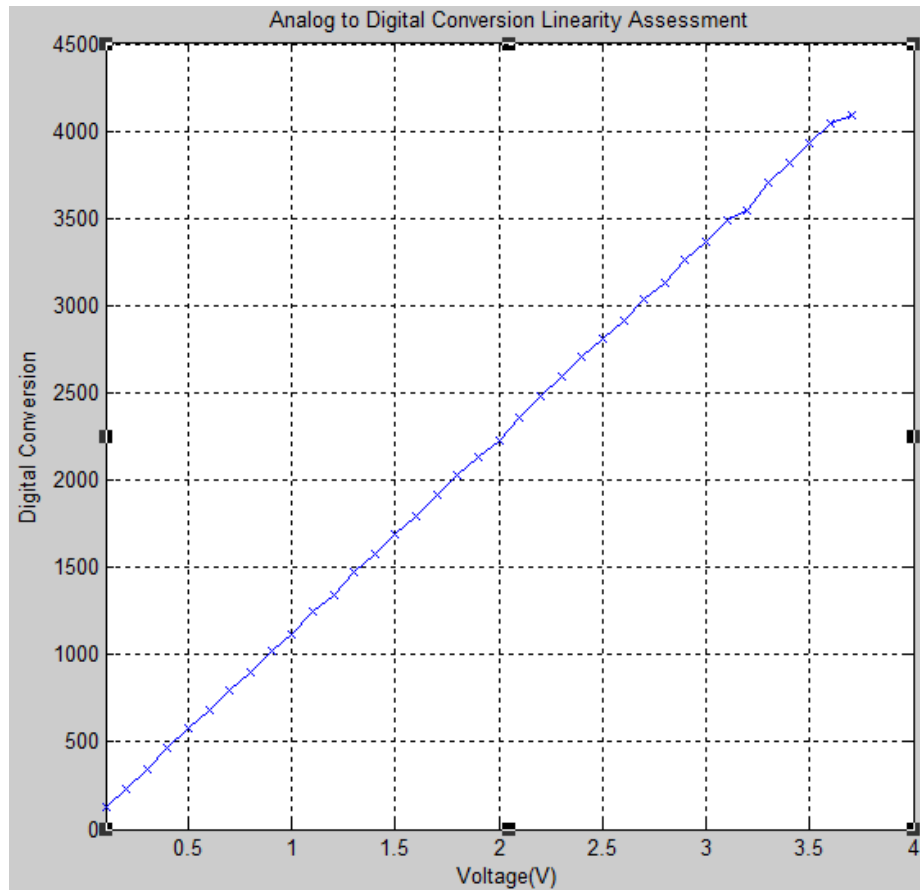


Figure 38 ADC Verification Test Results

6.3.2 Sensor Inputs

One at a time each of the sensors was connected to their respective channels of the ADC. The voltage conversion was done through the main function, and the converted voltage was compared to the expected voltage based on the parameter input. An oscilloscope verified the actual sensor output voltage. The method of parameter variations and measurement was the same as in previous stages of testing (small weights applied to the sensor, temperature applied by a digital heating pad). Humidity was varied by blowing on the sensor due to difficulties with the humidifier. These tests were conducted 5 times with different parameter values chosen each time. Table 23 shows sample results from one of these trials.

Table 23 Trial 2 Sensor Compatibility with Analog to Digital Converter

	Parameter Value	Expected Output Voltage (V)	Measured Output Voltage (V)	Hex code	Conversion Value (V)
Pressure	35 mmHg	3.11±0.1	3.056±0.01	0xD9	3.1
Temperature	25.1°C	1.27±0.01	1.31±0.01	0x5C	1.29
Humidity	50% RH	1.42±0.1	1.41±.01	0x63	1.41

6.4 Wireless Transmission

Transmission distance was again recorded, looking this time at the power seen by the receiving end. This value was calculated as RSSI (Received Signal Strength Indicator) and is given in units of dBm. Measuring in continuous asynchronous transmission mode at 915kHz, 38.4kBauds and 0dBm of Tx power, unobstructed transmission was made between the receiving and transmitting devices. Table 24 and Figure 39 detail the relationship between distance and received strength.

Table 24 Transmission distance to RSSI relationship

Distance (meters)	RSSI (dB)	Calculated
0.1	-21	-15.7
0.5	-27	-29
1	-33	-35.7
2	-41	-41.7
3	-48	-45.2
4	-50	-47
5	-52	-49.7

Previous testing confirmed a noise floor of approximately -100dBm. The following Figure 39 depicts the results of line of sight testing performed on our system, with a measure of received signal strength in dBm on the Y axis, against distance in meters on the X axis. Extraneous data points have been removed in order to better represent the overall trend of the device. Testing was performed using a 0dB Tx power, 38.4kBaud rate and 915MHz carrier frequency. The tests were performed on a football field, granting a flat service with limited noise. Using two prototyping boards of the CC430, measurements were taken by moving the boards away from each other across an even plane. As the graph depicts, the received signal strength diminishes as the distance between the boards increase. More importantly however is the RSSI at the max distance. We see that the noise floor of -100dBm has not been reached at approximately 90 meters. This denotes that signal reception is still possible at this range.

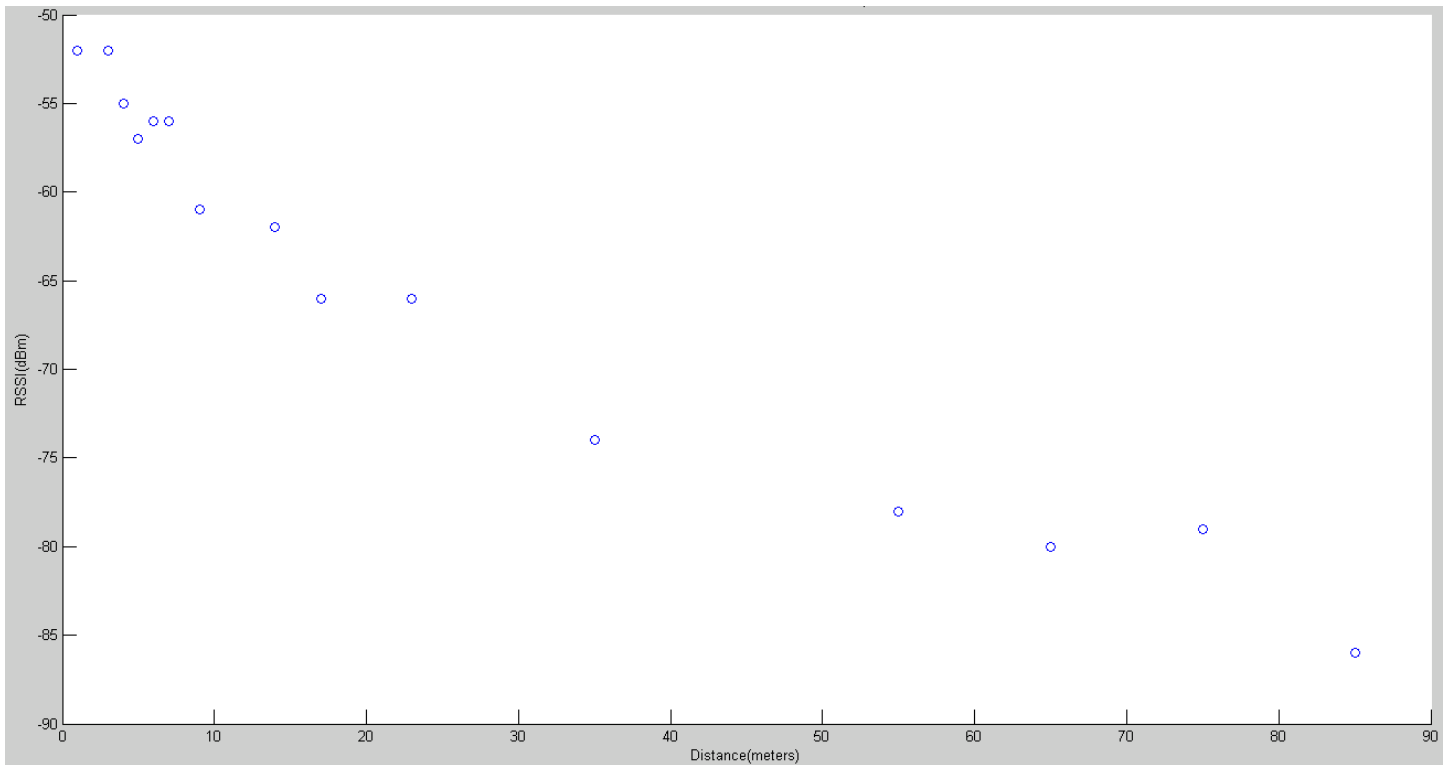


Figure 39 Wireless Gain to Distance Relationship

Measurements comprising the above figure were taken methodically to minimize obstruction between transmission points and in order to detail the effect of free space loss on this transmission band. Approximating an antenna gain of +2dBm, a fairly standard value, we can estimate the expected RSSI over the 915kHz frequency with regards only to free space loss and using Equation 13.

$$\text{FreeSpaceLoss(dB)} = 20\log_2 \frac{4\pi d}{\lambda} \quad (13)$$

The relationship between distance and RSSI is fairly consistent with our calculations and expected values. This allows us to further extrapolate the effect of free space loss as distance increases.

6.5 Patch Encasing Material

The disposable material encasing the patch was chosen for its adhesive properties, relatively low cost (\$4), and durability. In order to ensure the temperature sensor could achieve an accurate reading, the thermal properties of the material were tested.

The adhesive patch material was placed over the top of a beaker containing hot water. The beaker was then placed in a Styrofoam box to ensure the heat was escaping through the patch. The temperature inside the container was measured using an infrared thermometer and compared to the temperature outside of the material. This process was repeated every 2 minutes and the results can be seen below in Figure 40.

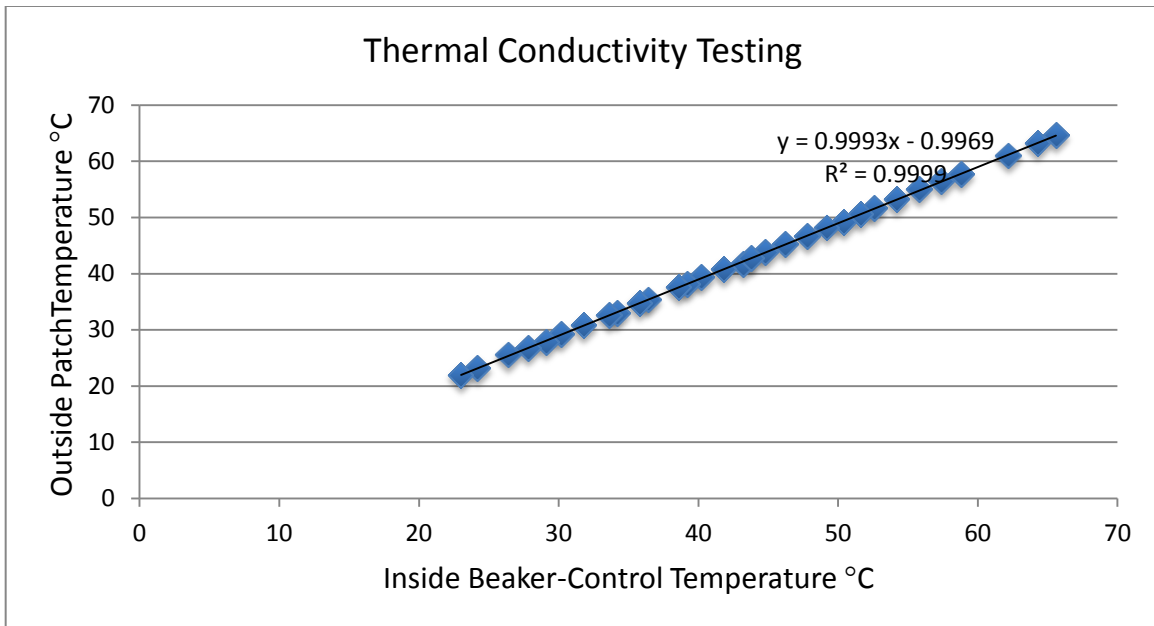


Figure 40 Results of the thermal properties of the patches

There was a difference of about 1°C between the inside of the sensor encasing, and the outside (patients skin). The software analysis records a baseline temperature, and compares this to values in real time. The program is using relative changes in temperature rather than absolute values, and the encasing material has a linear temperature gradient. Although there is a slight difference in temperature, the material will still work as a sensor encasing.

6.6 Power Consumption

In order to help determine the data rate and Tx power which would be most suitable for operation, current consumption was measured during several different configurations. The measured values appear in Table 25.

Table 25 Current Consumption with Varying Data Rate and Tx Power

Rate (kBaud)	Tx Power (dBm)	Current (mA)
1.2	10	33.6
	0	17.3
	-6	17.6
	-12	14.2
38.4	10	32
	0	17.6
	-6	17.2
	-12	14.2
175	10	31
	0	17.4
	-6	17
	-12	13.9
250	10	29.7
	0	17.1
	-6	16.7
	-12	13.6

Measurement results dictate an overall decrease in Tx current when both data rate increases and Tx power decreases.

Figure 41 represents the total power profile of our device over a transmission or reception cycle. Starting from the left, the first box demonstrates the initiation and settling of the external crystal oscillator, followed by a box to the right, representing the calibration of the frequency synthesizer. The major power spike for 7.5 ms can be attributed to packet transmission. The smaller box next represents the brief transition from the radio's idle state, to low power mode 3 (LPM3) in the box directly afterwards. The Tx/Rx cycle consumes about 46.15µAhrs of current in total, not including LPM3.

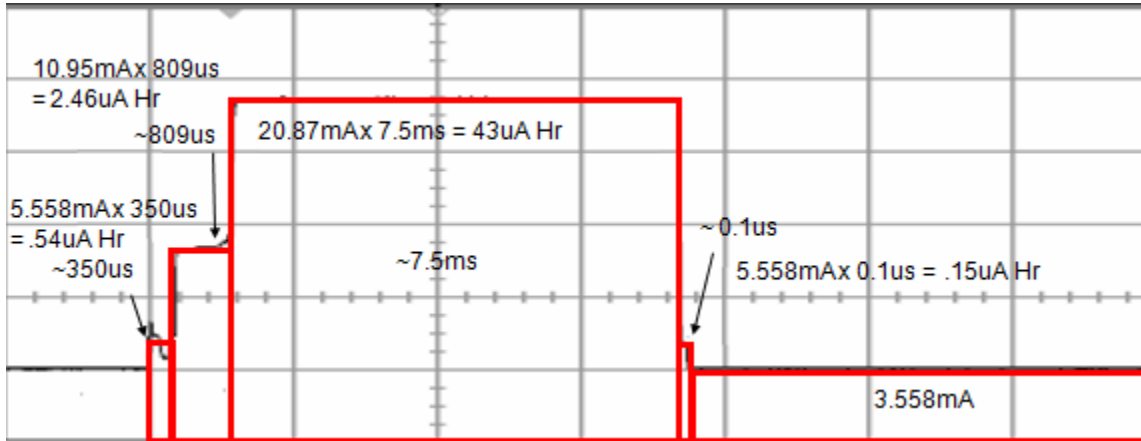


Figure 41 Power Profile Over Tx Cycle

Quiescent operation of the system during LPM3 included the concurrent operation of circuitry and sensors. This state consumes an average of 3.558mAhr, and can be broken down by individual device as seen in Table 25.

Table 26 Current Consumption by Device

Device	Classifier	Current Consumption [mA]
LM6464	Op-Amp	0.14
HIH 5031	Humidity	0.4
MAX6612	Temperature	0.016
CC430F5137	MCU (LPM3)	0.002
I.E. FSR	Pressure	3 (Average)
Total		3.558

Current consumption attributed to the Interlink force sensors is variable due to the nature of the device, as it consumes more energy based upon how active the sensors are. The average value displayed above represents an exaggerated scenario where all 4 sensors are acting at approximately 75% of their maximum load.

The duty cycle chosen to provide an accurate assessment of the physiological changes of the patient was 2 readings per minute. With this configuration, we calculate

$$120 * 46.15\mu AH = 5.538mAH \tag{16}$$

Added to the 3.558mAH consumed by the sensors gives a total of 9.096mAH. Using a conservative estimate of the .55AH Tadiran TL-2450 battery gives a safe estimate of our total battery life.

$$\frac{.5AH}{9.096mAH} = 55 \text{ Hours} \tag{17}$$

6.6 Design Validation

In order for the final patch design to be tested and verified, all sensor components must be encased and tested on human subjects. Due to time constraints, the wireless transmitter was not integrated into the system in time to perform proof of concept testing. Therefore, a prototype patch enclosure was assembled and wired to a NI 6004 DAQ.

6.6.1 Test Sensor Encasement

Each of the sensors was wired using simple copper tape and quick wire. Although this testing was conducted on a basic prototype, the electrical connections were durable enough to withstand multiple trials. Table 27 shows a list of the materials used for the prototype sensor encasing.

Table 27 Prototype sensor encasing bill of materials

Component	Model	Quantity	Price
Quick Wire		1 roll	Donated
Electrical Tape	3M 6134-BA-10	1 roll	\$3
Adhesive Encasing	3M Tegaderm™ Dressing 9001	Box of 5	\$20.30
Saran wrap	Reynolds	1 poll	Donated

Figure 42 below shows the final front end design and arrangement of sensors. Under the sensors is the patch encasing, which easily allows the sensors to slide in and out of. The wireless transmitter, power supply, and signal conditioning are housed in a small container approximately 6 inches to the right of the patch.



Figure 42 Final sensor encasement

6.6.2 IRB Testing Approval Application

In order to conduct tests on human subjects an International Review Board (IRB) must approve the test protocol. WPI has its own review board, and regimented application process. The approval process is often lengthy and was not realistic with the time constraints of this project, but a completed application form is included in Appendix D along with team member's online clinical credentials through the National Institute of health or NIH.

6.6.3 Testing Protocol

Human subject testing was performed on the three members of the team. The purpose of this testing was to demonstrate the operation of each of the sensors. Data were collected and stored using a modified LabVIEW VI. Statistical analysis was performed using Excel software.

6.6.3.1 Pressure Testing

In order to improve upon last year's project, their test protocol was reviewed and considered in the design of this year's testing protocol. To quantify the effects of pressure, the group used a degree of pain scale as an early indicator for ischemia and maintained pressure until the pain was unbearable, or an hour of testing had occurred. This limit was set for safety reasons. The following conditions were used to test the pressure portion of the sensor. The source document shown in Table 28 was filled out during testing.

1. Back of the heel in a sitting position
2. Shoulder blade on a hard surface with the patient in a supine position
3. Additional locations and orientations can be added as needed base on testing results

Table 28 Sample source document use to record pressure testing

Pressure Testing		
Team Member: _____ Foot Weight: ____ Date: _____		
Time (min)	Degree of Pain	Comments:
0		
5		
10		
15		
20		
25		
30		

6.6.3.1.1 Pressure Testing Results

Figure 43 shows a comparison of the subject's pain levels over a period of 30 min showing that an increased level of pain was achieved by maintaining a stationary position on top of a hard surface.

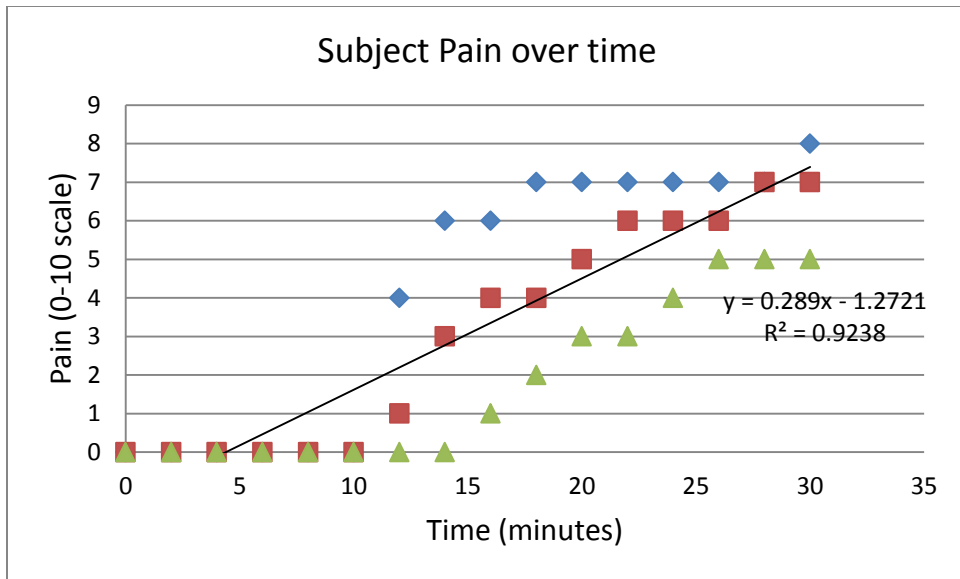


Figure 43 Results showing increased pain over time

Figure 44 shows the sample results from one test trial. The voltage output of the pressure sensor array was recorded on the y-axis over time. These results showed that after a period of 20 min the test subject subconsciously began moving their limb in order to alleviate pressure. This indicates that testing should be performed on immobile patients in order to achieve a higher accuracy.

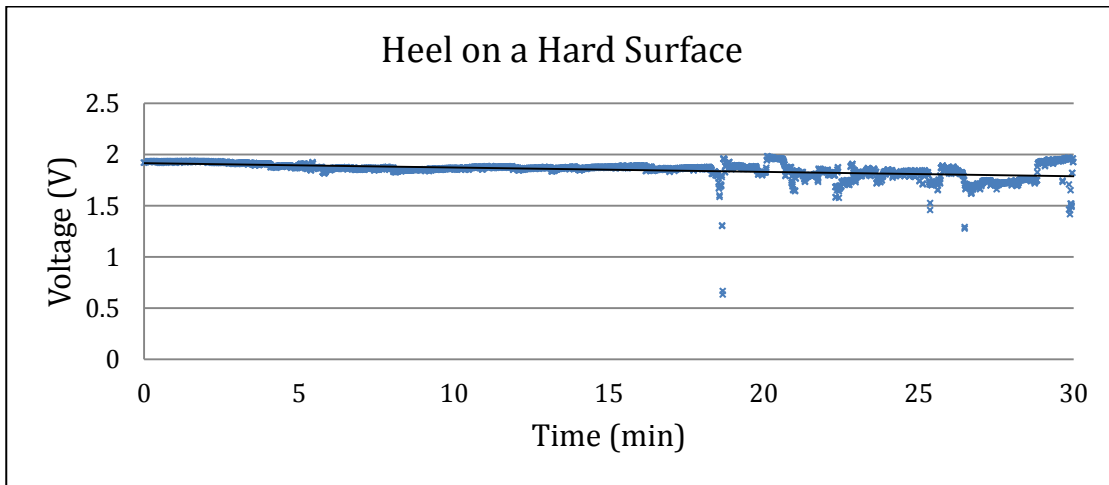


Figure 44 Trial 1 results of the heel tested on a hard surface

Overall, the voltage output of the sensors was larger with an increased level of pain. A summary of the average test results can be seen below in Figure 45.

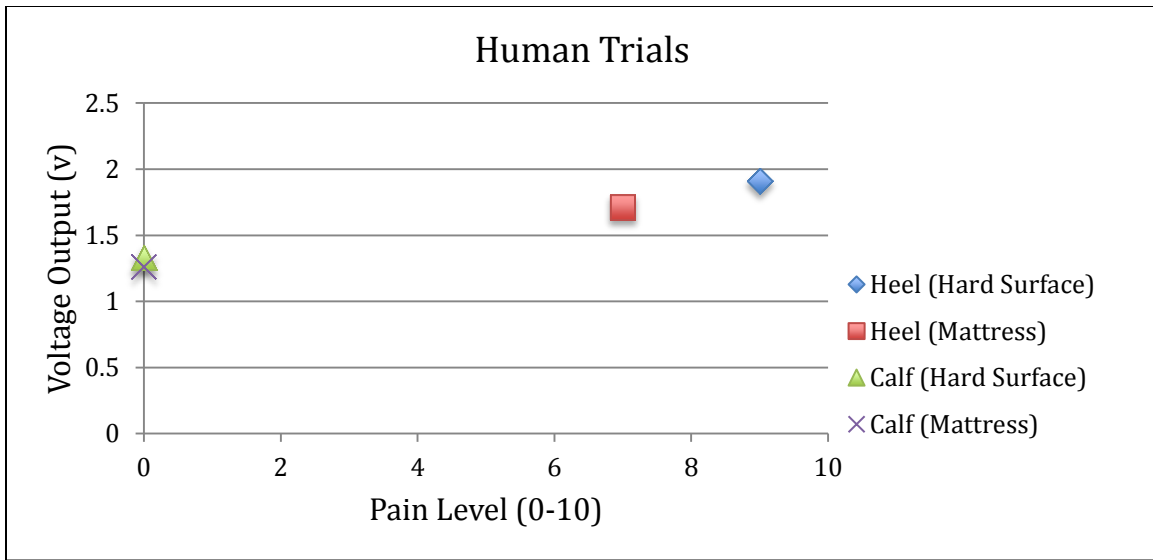


Figure 45 Summary of the results from human testing

6.6.3.2 Humidity

A change in temperature occurs when a patient is at an extremely high risk for developing a pressure ulcer, and hence, it would be impractical to test team members for breaking this specific parameter threshold. Therefore, relative humidity was tested by artificially increasing it by placing a wet sock on the test subject's foot.

1. Skin moisture increase
 - a. The subject placed their foot into a damp sock.
 - b. The subject then placed their foot on top of the patch, and the voltage output of the humidity sensor was recorded.

6.6.3.2.1 Results of the Relative Humidity Testing

Figure 46 shows the results of the relative humidity testing. The voltage output was recorded using a LabVIEW VI, and the relative humidity was measured using an omega OM-71 relative humidity sensor. The average output for each test subject can be seen below. The variations in relative humidity are due to different moisture levels in the socks.

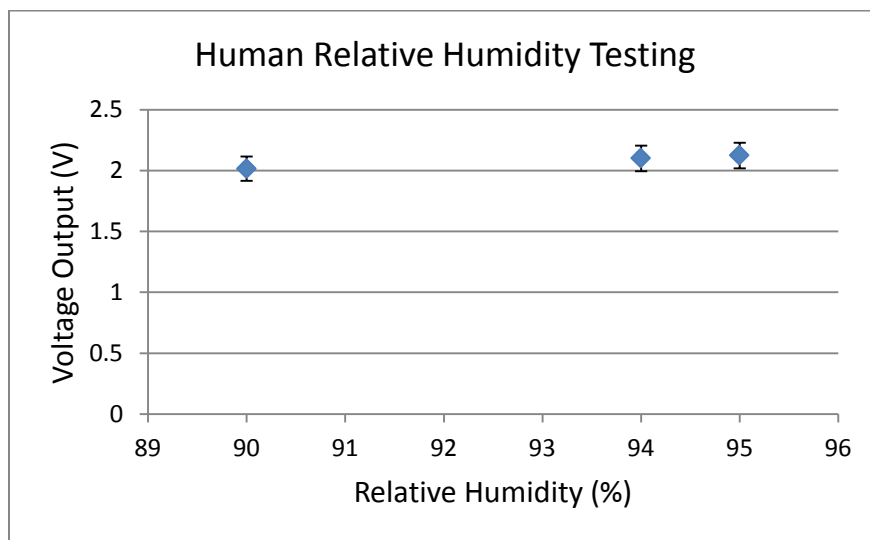


Figure 46 Results of the Relative Humidity Testing on Human Subjects

These results indicate that the relative humidity sensor can detect increased relative humidity on the skin. Additionally, the alarms did sound successfully after a period of 15 minutes (as set by the algorithm for this testing).

6.6.4 Expert Opinion Meeting

In order to assess the overall user friendliness of the graphical user interface, and marketability of the system, the team interviewed a clinician at UMass medical center. The meeting focused on opinion based questions and typically lead into a discussion about potential improvements that could be made to the system.

6.6.4.1 User Friendliness

The system is a good start for a prototype, but when thinking about a commercialized device, the user interface should be made more resilient to user entry errors. To address this feedback, it was recommended to use pop-up windows to enter physiological factors for the patient.

6.6.4.2 Ease of Use

The physiological factors required by the algorithm are simple and intuitive, and caregivers would be able to make an accurate assessment based on the descriptions provided on the interface itself. The additional visual effects and the pop-up windows for inserting physiological factors added to the current user interface would make the product easy to use for most all caregivers. The expert advised that the patch should be made completely disposable to allow the best ease of use.

6.6.4.3 Marketability

It is easier than most of the current technology on the market, like full mattress pads. The system is wireless, which is valuable in places like the critical care unit. The system would be more marketable if the patches were completely disposable and smaller for ankles, elbows, and the sacral. The increased demographic of use by patients in a wheelchair also makes the system much more marketable.

6.6.4.4 Compatibility with a Hospital Setting

The device would work in a hospital setting according to the clinician. It would be easier to integrate it if the overall system was programmed in something like Java or C+ because it is more commonly used, and visually appealing. The concept of the wireless patch increases the devices compatibility of the system because the patients are currently hooked up to many devices with wires and tubes everywhere. The wireless design puts fewer burdens on the caregiver and the patient.

7 Conclusion and Future Recommendations

This chapter discusses the improvements made to the previous Major Qualifying Project, and future improvements that would help make the system more marketable. Overall, the project met the original goals including: cost, user friendly, safety and functional. The reusable hardware, and disposable encasing make the system cost effective. Expert opinion interviews show that the system is more user friendly because it is wireless. The patch is not bulky, and therefore will not increase the risk for a pressure ulcer. The system is sustainable for a period of at least 24 hours, and the accuracy of the system is better due to the inclusion of global risk factors.

7.1 Improvements to Previous Major Qualifying Project

Improvements in the front end sensor arrangement/encasing, wireless transmission, and consideration of additional physiological factors increased the accuracy and aesthetics of the system.

7.1.1 Additional Physiological Factors

Algorithm development allowed for increase accuracy by considering additional physiological factors such as: age, mobility level, weight, nutrition, oxygen saturation, and systemic blood pressure. Additionally, a temperature sensor was included as another indication of the formation of pressure ulcers.

7.1.2 Larger Surface Area

Increased surface area size allowed for the patch to be used on additional locations on the body, particularly the ischium, sacrum and scapula areas. The increased size of the patch allows for a more accurate pressure measurement, and does not require the caregiver to place the patch as accurately on the patient.

7.1.3 Adhesive Patch Encasing

The adhesive encasing of the patch made the system compatible with a wider demographic, including semi mobile patients. The encasing also allows for the sensor to be reused on multiple patients to increase the cost effectiveness of the system.

7.1.4 Wireless Transmission

Wireless transmission increased the ease of use by the caregiver and comfort of the patient.

7.2 Future Recommendations

The following section outlines the improvements that could be made to make the system more marketable.

7.2.1 Human Clinical Trials

The systems should be tested on a wider demographic of patients, specifically those more prone to pressure ulcers, as outline in the IRB approval form shown in Appendix D. Additional clinical trials would attest to the accuracy of the system, and increase the statistical significance of our initial findings.

7.2.2 FDA Regulation Compliance

Additional research should be conducted into making the system compliant with current hospital standards. The current LabVIEW code can be validated to comply with current Good Manufacturing Practice, by using software models available from National Instruments. Additional testing should be performed with instruments calibrated by approved companies per 21 CFR 820.

The alarm system needs to be altered to comply with ICE 60601-1-8. The current system uses standard audible alarms from LabVIEW. Based on the ICE standard, an alarm to indicate a pressure ulcer should be assigned a low priority, with increasing priority if the injury is ignored. The condition for a low priority alarm is 1 burst and then 2 slow pulses with a fundamental frequency between 150-1000 Hz. The most low cost option to accomplish these sounds is acoustically, or through a transducer/speaker combination (O'Brien et. al, 2010).

7.2.3 Software

The user interface should be made simpler for use in a clinical setting. Clinician inputs should be asked sequentially by popup windows at program initialization to decrease potential user entry errors. Additionally the program should be made compatible for more than one patch, and alert a clinician as to which part of the body should be moved. The program in general should be compatible with more than one patient at a time to allow a caregiver to monitor multiple patients from a single station.

All components encased in the patch are portable and could be used by a mobile patient. The software should be made compatible with mobile devices, such as iPads, for personal use on patients with prosthetics and in wheelchairs.

7.2.4 Wireless Improvements

The current wireless system utilizes point-to-point communication, and should be made compatible with a mesh network to allow multiple patients to be monitored with one receiver. The wireless transmission should be tested in a clinical setting to ensure this particular interference does not affect the data quality. If needed additional error checking in the wireless code, such as cyclic redundancy, could be implemented to make the connection more robust.

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Appendix A: Braden Scale

BRADEN SCALE FOR PREDICTING PRESSURE SORE RISK

Patient's Name _____

Evaluator's Name _____

Date of Assessment _____

<p>SENSORY PERCEPTION ability to respond meaningfully to pressure-related discomfort</p>	<p>1. Completely Limited Unresponsive (does not moan, flinch, or grasp) to painful stimuli, due to diminished level of consciousness or sedation OR limited ability to feel pain over most of body.</p>	<p>2. Very Limited Responds only to painful stimuli. Cannot communicate discomfort except by moaning or restlessness OR has a sensory impairment which limits the ability to feel pain or discomfort over ½ of body.</p>	<p>3. Slightly Limited Responds to verbal commands, but cannot always communicate discomfort or the need to be turned OR has some sensory impairment which limits ability to feel pain or discomfort in 1 or 2 extremities.</p>	<p>4. No Impairment Responds to verbal commands. Has no sensory deficit which would limit ability to feel or voice pain or discomfort.</p>				
<p>MOISTURE degree to which skin is exposed to moisture</p>	<p>1. Constantly Moist Skin is kept moist almost constantly by perspiration, urine, etc. Dampness is detected every time patient is moved or turned.</p>	<p>2. Very Moist Skin is often, but not always moist. Linen must be changed at least once a shift.</p>	<p>3. Occasionally Moist Skin is occasionally moist, requiring an extra linen change approximately once a day.</p>	<p>4. Rarely Moist Skin is usually dry; linen only requires changing at routine intervals.</p>				
<p>ACTIVITY degree of physical activity</p>	<p>1. Bedfast Confined to bed.</p>	<p>2. Chairfast Ability to walk severely limited or non-existent. Cannot bear own weight and/or must be assisted into chair or wheelchair.</p>	<p>3. Walks Occasionally Walks occasionally during day, but for very short distances, with or without assistance. Spends majority of each shift in bed or chair.</p>	<p>4. Walks Frequently Walks outside room at least twice a day and inside room at least once every two hours during waking hours.</p>				
<p>MOBILITY ability to change and control body position</p>	<p>1. Completely Immobile Does not make even slight changes in body or extremity position without assistance.</p>	<p>2. Very Limited Makes occasional slight changes in body or extremity position but unable to make frequent or significant changes independently.</p>	<p>3. Slightly Limited Makes frequent though slight changes in body or extremity position independently.</p>	<p>4. No Limitation Makes major and frequent changes in position without assistance.</p>				
<p>NUTRITION usual food intake pattern</p>	<p>1. Very Poor Never eats a complete meal. Rarely eats more than ½ of any food offered. Eats 2 servings or less of protein (meat or dairy products) per day. Takes fluids poorly. Does not take a liquid dietary supplement OR is NPO and/or maintained on clear liquids or IVs for more than 5 days.</p>	<p>2. Probably Inadequate Rarely eats a complete meal and generally eats only about ½ of any food offered. Protein intake includes only 3 servings of meat or dairy products per day. Occasionally will take a dietary supplement OR receives less than optimum amount of liquid diet or tube feeding.</p>	<p>3. Adequate Eats over half of most meals. Eats a total of 4 servings of protein (meat, dairy products) per day. Occasionally will refuse a meal, but will usually take a supplement when offered OR is on a tube feeding or TPN regimen which probably meets most of nutritional needs.</p>	<p>4. Excellent Eats most of every meal. Never refuses a meal. Usually eats a total of 4 or more servings of meat and dairy products. Occasionally eats between meals. Does not require supplementation.</p>				
<p>FRICTION & SHEAR</p>	<p>1. Problem Requires moderate to maximum assistance in moving. Complete lifting without sliding against sheets is impossible. Frequently slides down in bed or chair, requiring frequent repositioning with maximum assistance. Spasticity, contractures or agitation leads to almost constant friction.</p>	<p>2. Potential Problem Moves feebly or requires minimum assistance. During a move skin probably slides to some extent against sheets, chair, restraints or other devices. Maintains relatively good position in chair or bed most of the time but occasionally slides down.</p>	<p>3. No Apparent Problem Moves in bed and in chair independently and has sufficient muscle strength to lift up completely during move. Maintains good position in bed or chair.</p>					
<p>Total Score</p>								

Appendix B: Primary Factors

Risk Factors	Pressure	Mobility	Blood Flow	Blood Volume	Age	Blood O ₂	Shear Stress	Skin Temperature	Moisture	Systemic Blood Pressure	Local Blood Pressure	Patient Weight	Skin Thickness	Iron Levels	Blood CO ₂	Nutrition	Totals
Age	0	0	0	0	0	1	0	0	0	0	1	0	0	0	1	3
Shear Stress	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	1
Systemic Blood Pressure	0	0	0	0	1	0	1	0	0	...	0	1	0	1	0	1	5
Local Blood Pressure	0	1	0	0	1	0	1	0	0	1	1	0	1	0	1	7
Patient Weight	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Skin Thickness	0	0	0	0	1	0	1	0	0	0	0	1	0	0	0	3
Iron Levels	0	0	0	0	1	0	1	0	0	0	0	1	1	0	0	4
Nutrition	0	0	0	0	0	0	1	0	0	0	0	1	1	1	0	4

Appendix C: Secondary Factors

Risk Factors	Pressure	Mobility	Blood Flow	Blood Volume	Age	Blood O ₂	Shear Stress	Skin Temperature	Moisture	Systemic Blood Pressure	Local Blood Pressure	Patient Weight	Skin Thickness	Iron Levels	Blood CO ₂	Nutrition	Totals
Pressure	1	1	1	0	1	0	1	1	1	1	1	1	1	1	1	13
Mobility	0	0	0	1	0	1	1	0	1	0	1	1	1	0	1	8
Blood Flow	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	14
Blood Volume	0	1	0	1	1	1	1	1	1	1	1	1	1	1	1	13
Blood O ₂	0	1	0	0	1	1	1	1	1	1	1	1	1	1	1	12
Skin Temperature	0	0	0	0	1	0	1	1	1	1	1	1	1	0	1	9
Moisture	0	1	0	0	1	0	1	0	1	1	1	1	1	0	1	9
Blood CO ₂	0	1	0	0	1	0	1	1	1	1	1	1	1	1	1	11

Appendix D: Proof of Concept Testing

As discussed in the background, the idea of using PPG to measure blood flow in areas of low perfusion was not used in the final system. Preliminary tests were done using the BioPac system with preassembled PPG sensors to investigate whether the concept could be used to detect the potential formation of a pressure ulcer. The tests performed were done on both the finger (an area of relatively high blood perfusion) and the elbow (an area of relatively low blood perfusion).

Lack of AC component with increased external pressure (finger)

The first test was on the finger to demonstrate that the PPG signal would no longer have an identifiable AC component when enough external pressure was applied to cut off local blood circulation. This can be seen in Figure 47 after 20 seconds.

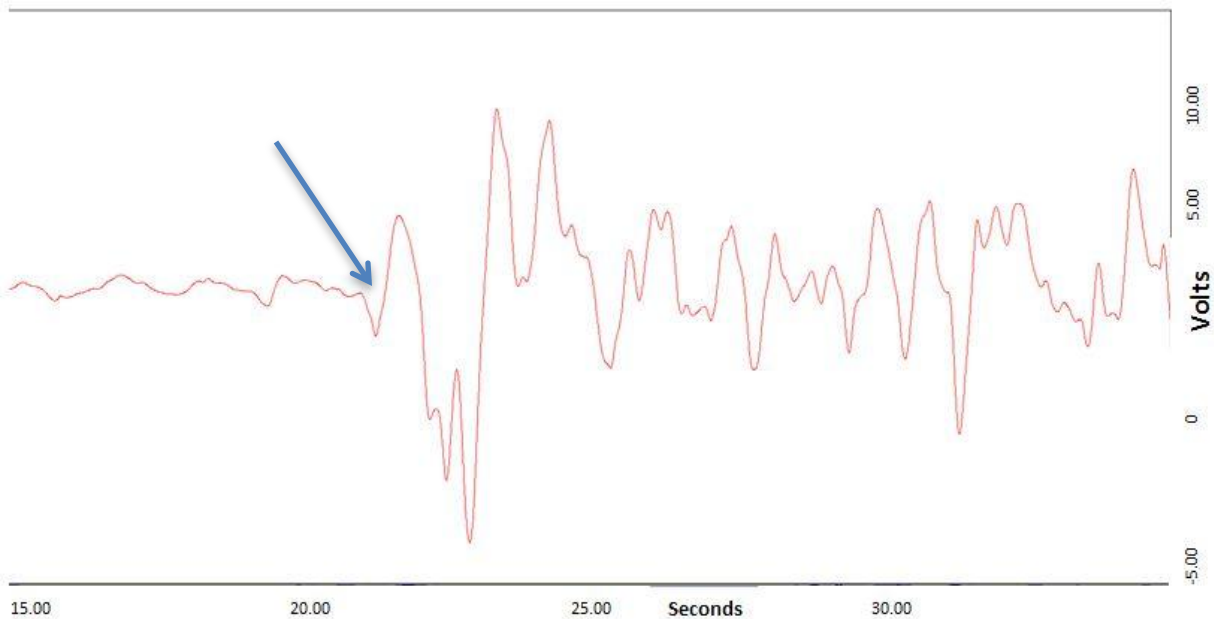


Figure 47 Pressure occluding blood flow in the finger

Design of a custom PPG sensor

When the team tried to see the DC portion of the signal using the BioPac system, the built in high pass filtering prohibited them from seeing any changes in this DC component of the PPG waveform. This filtering is necessary in the standard use of the PPG sensor when measuring heart rate, which is only concerned with the AC component of the PPG signal. In order to see changes in the DC offset for different amounts of external pressure, a custom circuit, shown in Figure 48, had to be designed that did not use the BioPac system.

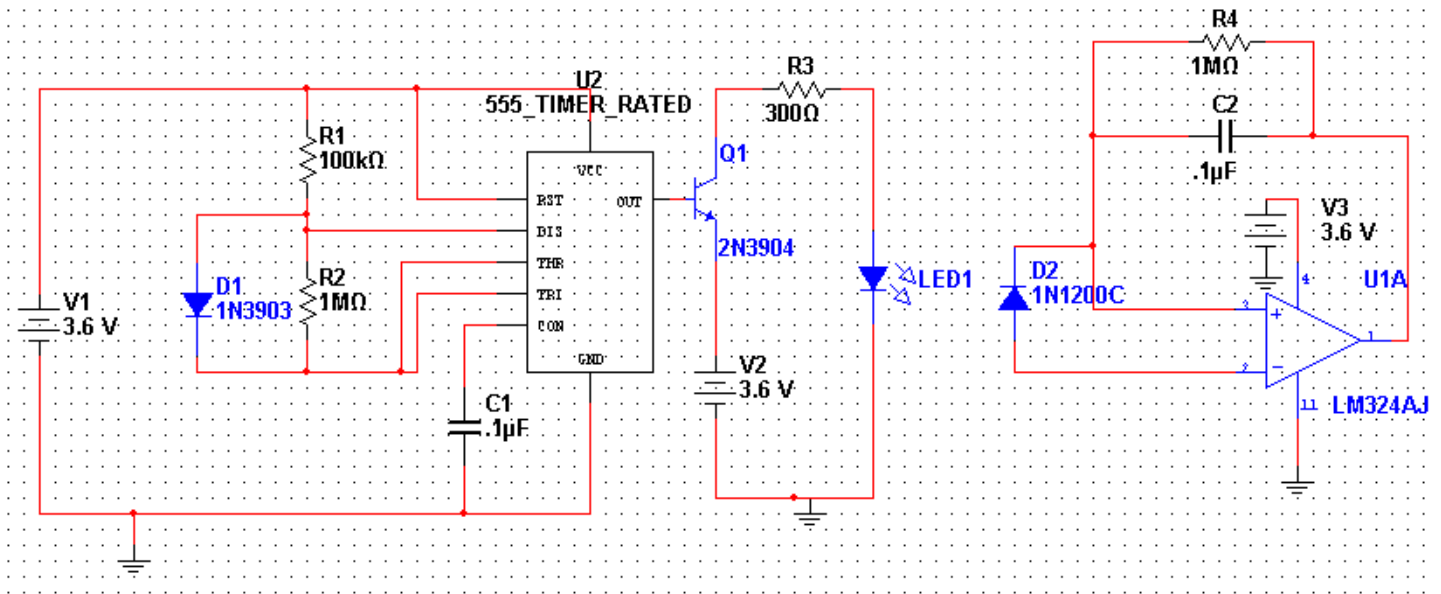


Figure 48 Circuit Diagram for testing PPG sensor

The PPG circuit utilizes a 555 timer to pulse the LED. This was done to both reduce the average energy used by the LED to a fraction of its original value, as well as provide a baseline with which to judge the impact of ambient light. When the LED is turned off, any signal seen on the photodiode can be attributed to external ambient light, and should be nulled out. Using a combination of the bypass diode D1, the resistor R3 and capacitor C2, a duty cycle of 1.8% was achieved, along with a frequency of 13Hz. This duty cycle was used to activate the transistor Q1, allowing the activation of the subsequent LED1. At this point, the photodiode, represented by D2, produced a current, which was then amplified by the operational amplifier U2A, producing an analog output voltage.

This circuit includes a first order low pass filter with a cutoff frequency calculated by Equation 14. The cutoff frequency was chosen based on external noise measured during initial testing.

$$\frac{1}{2\pi R_2 C_1} = 10.6 \text{ HZ} \quad (14)$$

This attenuated the AC waveform from the PPG and only shows the DC component of the signal because of the inclusion of the low pass filter, with an extremely low cut off frequency. This stage also provided significant noise reduction incurred from outside sources, such as ambient light interference.

Increase of DC offset-areas of high blood perfusion

The AC signal cannot be used to determine when the blood flow has been cut off to the tissue in the area of interest because they do not have a large amount of blood perfusion. The PPG is not sensitive enough to measure the minor changes in blood volume when the amount of blood perfusion is low to begin with. The change in DC offset is simply a measure of the light being reflected back to the photodiode, which typically changes more significantly with changes in blood volume. Therefore, the DC level of light returned back to the photodiode should indicate that blood flow has been cutoff by changing in amplitude. This concept was proven in an area of high blood perfusion (the finger). The increase in this DC signal was more gradual than the change in the AC signal. In multiple tests, the average increase in DC offset was 200mV when blood flow to the finger was cut off, with a standard deviation of 5mV. This proved that the DC signal increases when blood flow is cut off in this area of high blood perfusion.

Increase in DC offset-areas of low blood proliferation

The changes in DC amplitude were then tested in an area of low blood perfusion such as the heel where pressure ulcers are commonly formed. An oscilloscope was used to measure the changes in DC offset. A measurement was taken before pressure was applied; another was taken after pressure was applied (and blood volume was decreased). The difference between these measurements is displayed in Table 29 below. The tests were repeated ten times for three different subjects. The results were extremely variable, about half of the time the change in DC offset was negative rather than positive.

Table 29 PPG output signal with ambient lights on

	Subject 1	Subject 3	Subject 3
Voltage Change (mV)	44	64	24
	72	50	116
	0	56	100
	104	100	32
	104	112	108
	172	80	172
	64	124	64
	20	64	0
	124	83	64
	Average	78.22	81.44
ST Dev.	53.78	25.83	57.28
%Error	68.75	31.72	74.39

The standard deviation in each case shows large changes in offset between tests. The percent error is inconsistent between subjects, and also much too large to indicate successful test conditions. The team also tried testing with the lights turned off because ambient lighting could be a major factor. This did change the results (the average change did decrease), however the results were still inconsistent as can be seen by the large variation in the standard deviation shown in Table 30.

Table 30 PPG output signal with ambient lights on

	Subject 1	Subject 2	Subject 3
Voltage Change (mV)	88	108	112
	32	108	100
	108	88	24
	32	0	12
	40	108	44
	124	44	32
	112	44	80
	20	0	44
	0	112	44
	Average	61.78	68.00
ST Dev.	46.14	46.82	34.64
%Error	74.68	68.85	63.37

The major issue with the variability of the results is that the changes may not necessarily be due to the obstruction of blood flow. The change in DC offset is simply a measure of the light being reflected back to the photodiode, which typically changes more significantly with changes in blood flow. However, if other tissues than blood are absorbing the light, then any changes in the signal to the photodetector may not be due to changes in blood flow. These changes are likely representing the reflection back from the bone and the tissues being compressed rather than an actual change in blood flow.

Due to time constraints, the team decided to focus more on the other three sensors. This particular aspect did not seem feasible to complete by the deadline given. Some of the proposed modifications include:

1. Better adhesion, to make sure the PPG sensor remained attached to the skin
2. Increasing light intensity to increase light propagation throughout the skin and underlying tissues

Appendix E: IRB Approval

This application is for: <i>(Please check one)</i> <input checked="" type="checkbox"/> Expedited Review <input type="checkbox"/> Full Review				WPI IRB use only
Principal Investigator (PI) or Project Faculty Advisor: <i>(NOT a student or fellow; must be a WPI employee)</i>				
Name: <u>Yitzak Mendelson</u>	Tel No: <u>(508) 831-5103</u>	E-Mail Address: <u>YM@wpi.edu</u>	<input type="checkbox"/>	
Department: <u>Biomedical Engineering</u>				
Co-Investigator(s): <i>(Co-PI(s)/non students)</i>				
Name: <u>Raymond Dunn</u>	Tel No: <u>508-334-1000</u>	E-Mail Address: <u>Raymond.Dunn@umassmemorial.org</u>	<input type="checkbox"/>	
Name: _____	Tel No: _____	E-Mail Address: _____	<input type="checkbox"/>	
Student Investigator(s):				
Name: <u>Alexandra Hause</u>	Tel No: <u>(303) 717-8769</u>	E-Mail Address: <u>ARHause@wpi.edu</u>	<input type="checkbox"/>	
Name: <u>Amber Turhanovitch</u>	Tel No: <u>(508)873-9835</u>	E-Mail Address: <u>ATurhanovitch@wpi</u>	<input type="checkbox"/>	
Check if: <input checked="" type="checkbox"/> Undergraduate project <i>(MQP, IQP, Suff., other)</i> <u>MQP-Wireless Pressure Ulcer Detection</u> <input type="checkbox"/> Graduate project <i>(M.S. Ph.D., other)</i> _____				

Has an IRB ever suspended or terminated a study of any investigator listed above?
 No Yes *(Attach a summary of the event and resolution.)*

Vulnerable Populations: The proposed research will involve the following (Check all that apply):
 pregnant women human fetuses neonates minors/children prisoners
 students individuals with mental disabilities individuals with physical disabilities

Collaborating Institutions: *(Please list all collaborating Institutions.)*
UMass Medical Center

Locations of Research: *(If at WPI, please indicate where on campus. If off campus, please give details of locations.)*
UMASS Medical Center

Project Title: Wireless Detection of Pressure Ulcers

Funding: *(If the research is funded, please enclose one copy of the research proposal or most recent draft with your application.)*

Funding Agency: _____ WPI Fund: _____

Human Subjects Research: *(All study personnel having direct contact with subjects **must** take and pass a training course on human subjects research. There are links to web-based training courses that can be accessed under the Training link on the IRB web site <http://www.wpi.edu/offices/irb/training.html>. **The IRB requires a copy of the completion certificate from the course or proof of an equivalent program.**)*

Anticipated Dates of Research:

Start Date: 2/15/2012 Completion Date: 3/2/2012

Instructions: Answer all questions. If you are asked to provide an explanation, please do so with adequate details. If needed, attach itemized replies. Any incomplete application will be returned.

1.) Purpose of Study: *(Please provide a concise statement of the background, nature and reasons for the proposed study. Insert below using non-technical language that can be understood by non-scientist members of the IRB.)*

The purpose of this study is to ensure the level of accuracy of the device. The device is a 3in by 3 in patch applied underneath a patients heel to test for the formation of pressure ulcers, This information will be sent wirelessly to a CPU for data logging and signal analysis. The intended subject demographic are individuals who are semimobile, or bed ridden in a hospital setting.

2.) Study Protocol: *(Please attach sufficient information for effective review by non-scientist members of the IRB. Define all abbreviations and use simple words. Unless justification is provided this part of the application must not exceed 5 pages. Attaching sections of a grant application is not an acceptable substitute.)*

A.) For **biomedical, engineering and related research**, please provide an outline of the actual experiments to be performed. Where applicable, provide a detailed description of the experimental devices or procedures to be used, detailed information on the exact dosages of drugs or chemicals to be used, total quantity of blood samples to be used, and descriptions of special diets.

B.) For applications in the **social sciences, management and other non-biomedical disciplines** please provide a detailed description of your proposed study. Where applicable, include copies of any questionnaires or standardized tests you plan to incorporate into your study. If your study involves interviews please submit an outline indicating the types of questions you will include.

C.) If the study involves **investigational drugs or investigational medical devices**, and the PI is obtaining an Investigational New Drug (IND) number or Investigational Device Exemption (IDE) number from the FDA, please provide details.

D.) Please note if any **hazardous materials** are being used in this study.

E.) Please note if any **special diets** are being used in this study.

3.) Subject Information:

A.) Please provide the exact number of subjects you plan to enroll in this study and describe your subject population. *(eg. WPI students, WPI staff, UMASS Medical patient, other)*

Males: 5 Females: 5 Description: UMASS Medical Patient

B.) Will subjects who do not understand English be enrolled?

No Yes *(Please insert below the language(s) that will be translated on the consent form.)*

C.) Are there any circumstances under which your study population may feel coerced into participating in this study?

No Yes *(Please insert below a description of how you will assure your subjects do not feel coerced.)*

If patients fully understand that the study is completely voluntary there would be no reason for them to feel coerced

D.) Are the subjects at risk of harm if their participation in the study becomes known?

No Yes *(Please insert below a description of possible effects on your subjects.)*

The device under test is proposed purely for testing purposes

E.) Are there reasons for excluding possible subjects from this research?

No Yes (If yes, please explain.)

The subject qualification will be based on their level of mobility, the purpose of this study is to test patients that are immobile for the most part

F.) How will subjects be recruited for participation? (Check all that apply.)

Referral: (By whom) UMASS nursing staff

Other: (Identify) _____

Database: (Describe how database populated) _____

Direct subject advertising, including: (Please provide a copy of the proposed ad. All direct subject advertising must be approved by the WPI IRB prior to use.)

Newspaper

Bulletin board

Radio

Flyers

Television

Letters

Internet

E-mail

F.) Have the subjects in the database agreed to be contacted for research projects? No Yes N/A

G.) Are the subjects being paid for participating? (Consider all types of reimbursement, ex. stipend, parking, travel.)

No Yes (Check all that apply.) Cash Check Gift certificate Other: _____

Amount of compensation _____

4.) Informed Consent:

A.) Who will discuss the study with and obtain consent of prospective subjects? (Check all that apply.)

Principal Investigator Co-Investigator(s) Student Investigator(s)

B.) Are you aware that subjects must read and sign and Informed Consent Form prior to conducting any study-related procedures and agree that all subjects will be consented prior to initiating study related procedures?

No Yes

C.) Are you aware that you must consent subjects using only the IRB-approved Informed Consent Form?

No Yes

D.) Will subjects be consented in a private room, not in a public space?

No Yes

E.) Do you agree to spend as much time as needed to thoroughly explain and respond to any subject's questions about the study, and allow them as much time as needed to consider their decision prior to enrolling them as subjects?

No Yes

F.) Do you agree that the person obtaining consent will explain the risks of the study, the subject's right to decide not to participate, and the subject's right to withdraw from the study at any time?

No Yes

G.) Do you agree to either 1.) retain signed copies of all informed consent agreements in a secure location for at least three years or 2.) supply copies of all signed informed consent agreements in .pdf format for retention by the IRB in electronic form?

No Yes

(If you answer No to any of the questions above, please provide an explanation.)

5.) Potential Risks: (A risk is a potential harm that a reasonable person would consider important in deciding whether to participate in research. Risks can be categorized as physical, psychological, sociological, economic and legal, and

include pain, stress, invasion of privacy, embarrassment or exposure of sensitive or confidential data. All potential risks and discomforts must be minimized to the greatest extent possible by using e.g. appropriate monitoring, safety devices and withdrawal of a subject if there is evidence of a specific adverse event.)

A.) What are the risks / discomforts associated with each intervention or procedure in the study?
The patient may indicate discomfort due to the adhesive covering on the patch. The patient may experience discomfort due to the semimobile nature of the study, however the study will not ask the patients to remain still

B.) What procedures will be in place to prevent / minimize potential risks or discomfort?

A member of the clinical staff will check in with the patient each hour to ensure there is no discomfort.

6.) Potential Benefits:

A.) What potential benefits other than payment may subjects receive from participating in the study?

A potential decreased risk for detecting pressure ulcers

B.) What potential benefits can society expect from the study?

An improved method for early detection and prevention of pressure ulcers

7.) Data Collection, Storage, and Confidentiality:

A.) How will data be collected?

Data will be collected through three noninvasive sensors placed below the extremities

B.) Will a subject's voice, face or identifiable body features (*eg. tattoo, scar*) be recorded by audio or videotaping?

No Yes (*Explain the recording procedures you plan to follow.*)

C.) Will personal identifying information be recorded? No Yes (*If yes, explain how the identifying information will be protected. How will personal identifying information be coded and how will the code key be kept confidential?*)

No identifying information be recorded

D.) Where will the data be stored and how will it be secured?

No identifying information will be recorded.

E.) What will happen to the data when the study is completed?

At completion of the study, the data will be analyzed to test for proper device functionality. After which it will be stored in the project records

F.) Can data acquired in the study adversely affect a subject's relationship with other individuals? (*i.e. employee-supervisor, student-teacher, family relationships*)

The data will remain anonymous and their study involvement will not be disclosed or published

G.) Do you plan to use or disclose identifiable information outside of the investigation personnel?

No Yes (*Please explain.*)

All patient identities will remain confidential, and subjects will be identified by an enrolment number that will not be associated with their name

H.) Do you plan to use or disclose identifiable information outside of WPI including non-WPI investigators?

No Yes (Please explain.)

8.) Incidental findings: *In the conduct of information gathering, is it possible that the investigator will encounter any incidental findings? If so, how will these be handled? (An incidental finding is information discovered about a subject which should be of concern to the subject but is not the focus of the research. For example, a researcher monitoring heart rates during exercise could discover that a subject has an irregular heartbeat.)*

All information collected about subjects health status will be collected by a nurse practitioner, as part of their standard clinical measurements. Incidental findings shall be dealt with according to UMASS standard nursing procedures.

9.) Deception: *(Investigators must not exclude information from a subject that a reasonable person would want to know in deciding whether to participate in a study.)*

Will the information about the research purpose and design be withheld from the subjects?

No Yes (Please explain.)

All information about the design of the device and the academic purposes of the study will be fully disclosed to patients

10.) Adverse effects: *(Serious or unexpected adverse reactions or injuries must be reported to the WPI IRB within 48 hours using the IRB Adverse Event Form found out at <http://www.wpi.edu/offices/irb/forms.html>. Other adverse events should be reported within 10 working days.)*

What follow-up efforts will be made to detect any harm to subjects and how will the WPI IRB be kept informed?
Upon completion of the study subjects will have a follow up meeting to determine if any adverse events occurred. The IRB will be immediately informed of any adverse events

11.) Informed consent: *(Documented informed consent must be obtained from all participants in studies that involve human subjects. You must use the templates available at <http://www.wpi.edu/offices/irb/forms.html> to prepare these forms. **Informed consent forms must be included with this application.***

Investigator's Assurance:

I understand that I have ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulations imposed by the WPI IRB.

I agree to comply with all WPI policies, as well all federal, state and local laws on the protection of human subjects in research, including:

- ensuring the satisfactory completion of human subjects training.
- performing the study in accordance with the WPI IRB approved protocol.

Signature of Principal Investigator _____ Date _____

Print Full Name and Title _____

Please return a signed hard copy of this application to the WPI IRB c/o Ruth McKeogh 2nd Floor Project Center
Or email an electronic copy to irb@wpi.edu

Protocol #:	010
Study Title:	Wireless Pressure Ulcer Prevention System
Study Sponsor:	Worcester Polytechnic Institute, UMASS medical
Study Objectives:	<ul style="list-style-type: none"> • Verification of design concept • Alarm management and algorithm weighing optimization • Clinical feedback user friendliness
Study Design:	<ul style="list-style-type: none"> • Un blinded, preliminary study • Up to ten subjects • Volunteers will be enrolled based on inclusion exclusion criteria and demographic goals • Medical history will be performed for device operation (age, weight, blood pressure, general nutrition, mobility level assessment) • Patch will be placed under the subjects right heel and data will be transmitted wirelessly to a recording test station that will only record information, and have no user interface • Subject will be asked to leave the patch on for the next 10 hours, without behavioral modifications • At completion of the measurement time the patient and clinical staff will be asked to rank the patch for comfort
Study Methods:	<p>Primary Focus: Verify the design accuracy</p> <p>Secondary Focus: Determine compatibility with real world clinical applications.</p>
Study Conduct:	<p>In accordance with:</p> <ul style="list-style-type: none"> • Principles of Good Clinical Practice (GCP) • The Medical Research Council's Code of Ethical Conduct for Research Involving Humans • Title 21 Parts 50, 54, 56 and 812 of the Code of Regulations • Principles of Declaration of Helsinki (1989) • All federal and local laws of the regulatory authorities
Subject Selection:	<p>Inclusion Criteria:</p> <ul style="list-style-type: none"> • Must be between the ages of 19-65 • Must be semi mobile and remain mostly bed ridden • Must be at a high risk for developing pressure ulcers as determined by the nursing staff <p>Exclusion Criteria:</p> <ul style="list-style-type: none"> • Must not have known vascular diseases in the lower extremities
Study Plan:	<p>Study length of time:</p> <ul style="list-style-type: none"> • Baseline- twenty days • Testing period- ten hours • Follow up within twenty four hour

Appendix F: Analog to Digital Conversion and Wireless Transmission Code

/******

* CC430 Transmission End Code

* Original Code Created By

* M. Morales/D. Dang

* Texas Instruments Inc.

* June 2010

* Built with IAR v4.21 and CCS v4.1

*****/

```
#include "cc430x513x.h"
```

```
#include "RF_Toggle_LED_Demo.h"
```

```
#define PACKET_LEN    (0x06)                // PACKET_LEN <= 61
```

```
#define RSSI_IDX      (PACKET_LEN) // Index of appended RSSI
```

```
#define CRC_LQI_IDX   (PACKET_LEN+1) // Index of appended LQI, checksum
```

```
#define CRC_OK        (BIT7) // CRC_OK bit
```

```
#define PATABLE_VAL   (0x51) // 0 dBm output
```

```
extern RF_SETTINGS rfSettings;
```

```
unsigned char packetTransmit;
```

```
unsigned char TxBuffer[PACKET_LEN];
```

```
unsigned char buttonPressed = 0;
```

```
unsigned int i = 0;
```

```
unsigned char transmitting = 0;
```

```
volatile unsigned int results[6]; // Needs to be global Otherwise, the compiler removes it because it is not used for anything.
```

```
unsigned int Gcount = 0; //Gcount - global count variable
```

```
void main( void )
```

```
{
```

```
    // Stop watchdog timer to prevent time out reset
```

```
    WDTCTL = WDTPW + WDTHOLD;
```

```
    P2SEL = 0x0F;
```

```
    // Enable A/D channel inputs
```

```
    ADC12CTL0 = ADC12ON + ADC12MSC + ADC12SHT0_2; // Turn on ADC12, set sampling time
```

```
    ADC12CTL1 = ADC12SHP + ADC12CONSEQ_1; // Use sampling timer, single sequence
```

```
    ADC12MCTL0 = ADC12INCH_0; // ref+=AVcc, channel = A0
```

```
    ADC12MCTL1 = ADC12INCH_1; // ref+=AVcc, channel = A1
```

```
    ADC12MCTL2 = ADC12INCH_2; // ref+=AVcc, channel = A2
```

```
    ADC12MCTL3 = ADC12INCH_3; // ref+=AVcc, channel = A3
```

```
    ADC12MCTL4 = ADC12INCH_4; // ref+=AVcc, channel = A4
```

```
    ADC12MCTL5 = ADC12INCH_5+ADC12EOS; // ref+=AVcc, channel = A5 and EOS
```

```
    ADC12IE = 0x08; // Enable ADC12IFG.3 //IFG.3!///
```

```
    ADC12CTL0 |= ADC12ENC; // Enable conversions
```

```
    /*Initialize Timer A*/
```

```
    P1DIR |= 0x01; // P1.0 output
```

```
    TA1CCTL0 = CCIE; // CCR0 interrupt enabled
```

```
    TA1CCR0 = 50000; //10 Seconds
```

```
    TA1CTL = TASSEL_2 + MC_2 + TACLR + ID_3; // SMCLK, contmode, clear TAR, clk divider = 8
```

```
    while(1) // Loop Timer A indefinitely
```

```
    {
```

```
        __bis_SR_register(LPM0_bits + GIE); // Enter LPM0, enable interrupts
```

```
    }
```

```

}

// Timer A0 interrupt service routine
#pragma vector=TIMER1_A0_VECTOR
__interrupt void TIMER1_A0_ISR(void)
{
    if(Gcount == 20)                // Check global count at 20
    {

        //Conversion and Interrupt
        ADC12CTL0 |= ADC12SC;        // Start convn - software trigger
        __bis_SR_register(LPM4_bits + GIE); // Enter LPM4, Enable interrupts

        for (i = 0; i <=5 ; i++)
        {
            TxBuffer[i]= (results[i]/16);           //Send results to TxBuffer
        }

        //Transmission
        SetVCore(2);                // Reset core voltage for proper transmission
        ResetRadioCore();
        InitRadio();

        P3OUT |= BIT6;              // Pulse LED during Transmit
        buttonPressed = 0;          // Reinitialize button press
        P1IFG = 0;

        Transmit( (unsigned char*)TxBuffer, sizeof TxBuffer);
        transmitting = 1;
        P1OUT ^= 0x01;              // Toggle LED to signify Transmit
        P1IE |= BIT7;              // Re-enable button press
        Gcount = 0;                // Reset the global count
        TA1CCR0 += 50000;          // Add Offset to CCR0
    }

    else
    {
        Gcount ++;                // Increment the global Count
        TA1CCR0 += 50000;          // Add Offset to CCR0
    }

}

//ADC Interrupt

#pragma vector=ADC12_VECTOR
__interrupt void ADC12ISR (void)
{
    switch(__even_in_range(ADC12IV,34))
    {
    case 0: break;                // Vector 0: No interrupt
    case 2: break;                // Vector 2: ADC overflow
    case 4: break;                // Vector 4: ADC timing overflow
    case 6: break;                // Vector 6: ADC12IFG0
    case 8: break;                // Vector 8: ADC12IFG1
    case 10: break;              // Vector 10: ADC12IFG2
    case 12:                      // Vector 12: ADC12IFG3
        results[0] = ADC12MEM0;    // Move results, IFG is cleared
        results[1] = ADC12MEM1;    // Move results, IFG is cleared
        results[2] = ADC12MEM2;    // Move results, IFG is cleared
        results[3] = ADC12MEM3;    // Move results, IFG is cleared
        results[4] = ADC12MEM4;    // Move results, IFG is cleared
        results[5] = ADC12MEM5;    // Move results, IFG is cleared
        __bic_SR_register_on_exit(LPM4_bits); // Exit active CPU, SET BREAKPOINT HERE
    case 14: break;              // Vector 14: ADC12IFG4
    case 16: break;              // Vector 16: ADC12IFG5
    case 18: break;              // Vector 18: ADC12IFG6
    case 20: break;              // Vector 20: ADC12IFG7
    case 22: break;              // Vector 22: ADC12IFG8
    case 24: break;              // Vector 24: ADC12IFG9
    case 26: break;              // Vector 26: ADC12IFG10
    }
}

```

```

case 28: break;           // Vector 28: ADC12IFG11
case 30: break;           // Vector 30: ADC12IFG12
case 32: break;           // Vector 32: ADC12IFG13
case 34: break;           // Vector 34: ADC12IFG14
default: break;
}
}

void InitButtonLeds(void)
{
    // Set up the button as interruptible
    P1DIR &= ~BIT7;
    P1REN |= BIT7;
    P1IES &= BIT7;
    P1IFG = 0;
    P1OUT |= BIT7;
    P1IE |= BIT7;

    // Initialize Port J
    PJOUT = 0x00;
    PJDIR = 0xFF;

    // Set up LEDs
    P1OUT &= ~BIT0;
    P1DIR |= BIT0;
    P3OUT &= ~BIT6;
    P3DIR |= BIT6;
}

void InitRadio(void)
{
    // Set the High-Power Mode Request Enable bit so LPM3 can be entered
    // with active radio enabled
    PMMCTL0_H = 0xA5;
    PMMCTL0_L |= PMMHPMRE_L;
    PMMCTL0_H = 0x00;

    WriteRfSettings(&rfSettings);

    WriteSinglePATable(PATABLE_VAL);
}

#pragma vector=PORT1_VECTOR
__interrupt void PORT1_ISR(void)
{
    switch(__even_in_range(P1IV, 16))
    {
        case 0: break;
        case 2: break;           // P1.0 IFG
        case 4: break;           // P1.1 IFG
        case 6: break;           // P1.2 IFG
        case 8: break;           // P1.3 IFG
        case 10: break;          // P1.4 IFG
        case 12: break;          // P1.5 IFG
        case 14: break;          // P1.6 IFG
        case 16:                 // P1.7 IFG
            P1IE = 0;           // Debounce by disabling buttons
            buttonPressed = 1;
            __bic_SR_register_on_exit(LPM3_bits); // Exit active
            break;
    }
}

void Transmit(unsigned char *buffer, unsigned char length)
{
    RF1AIES |= BIT9;
    RF1AIFG &= ~BIT9;         // Clear pending interrupts
    RF1AIE |= BIT9;           // Enable TX end-of-packet interrupt

    WriteBurstReg(RF_TXFIFOWR, buffer, length);
}

```

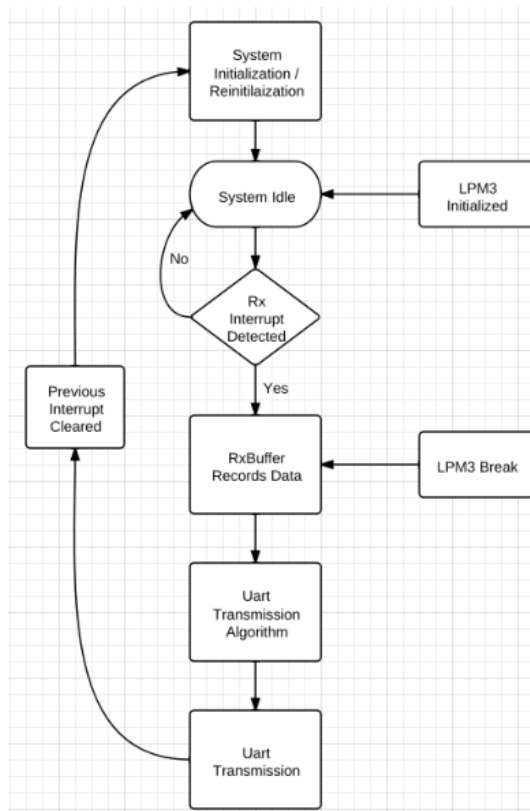
```

Strobe( RF_STX );           // Strobe STX
}

#pragma vector=CC1101_VECTOR
__interrupt void CC1101_ISR(void)
{
switch(__even_in_range(RF1AIV,32)) // Prioritizing Radio Core Interrupt
{
case 0: break;           // No RF core interrupt pending
case 2: break;           // RFIFG0
case 4: break;           // RFIFG1
case 6: break;           // RFIFG2
case 8: break;           // RFIFG3
case 10: break;          // RFIFG4
case 12: break;          // RFIFG5
case 14: break;          // RFIFG6
case 16: break;          // RFIFG7
case 18: break;          // RFIFG8
case 20: break;          // RFIFG9

if(transmitting)         // TX end of packet
{
RF1AIE &= ~BIT9;        // Disable TX end-of-packet interrupt
P3OUT &= ~BIT6;         // Turn off LED after Transmit
transmitting = 0;
}
else while(1);          // trap
break;
case 22: break;          // RFIFG10
case 24: break;          // RFIFG11
case 26: break;          // RFIFG12
case 28: break;          // RFIFG13
case 30: break;          // RFIFG14
case 32: break;          // RFIFG15
}
__bic_SR_register_on_exit(LPM3_bits);
}

```



Appendix G: Wireless Receive and UART Transmission Code

```
/******  
* CC430 Receiving End Code  
  
* Original Code Created By  
* M. Morales/D. Dang  
* Texas Instruments Inc.  
* June 2010  
* Built with IAR v4.21 and CCS v4.1  
*****/  
  
#include "RF_Toggle_LED_Demo.h"  
  
#define PACKET_LEN    (0x05) // PACKET_LEN <= 61  
#define RSSI_IDX      (PACKET_LEN) // Index of appended RSSI  
#define CRC_LQI_IDX   (PACKET_LEN+1) // Index of appended LQI, checksum  
#define CRC_OK        (BIT7) // CRC_OK bit  
#define PATABLE_VAL   (0x51) // 0 dBm output  
  
extern RF_SETTINGS rfSettings;  
  
unsigned char packetReceived;  
  
unsigned int RxBuffer[PACKET_LEN+1];  
unsigned int RxBufferLength = 0;  
unsigned int i = 0;  
unsigned char receiving = 0;  
unsigned int l;  
float conversion[6];  
unsigned int gcount;  
  
void main( void )  
{  
    // Stop watchdog timer to prevent time out reset  
    WDTCTL = WDTPW + WDTHOLD;  
    PMAPPWD = 0x02D52; // Get write-access to port mapping regs  
    P2MAP6 = PM_UCA0RXD; // Map UCA0RXD output to P2.6  
    P2MAP7 = PM_UCA0TXD; // Map UCA0TXD output to P2.7  
    PMAPPWD = 0; // Lock port mapping registers  
  
    P2DIR |= BIT7; // Set P2.7 as TX output  
    P2SEL |= BIT6 + BIT7; // Select P2.6 & P2.7 to UART function  
  
    UCA0CTL1 |= UCSWRST; // **Put state machine in reset**  
    UCA0CTL1 |= UCSSEL_1; // CLK = ACLK  
    UCA0BR0 = 0x0D; // 2400 (see User's Guide)  
    UCA0BR1 = 0x00; //  
    UCA0MCTL |= UCBRS_6+UCBRF_0; // Modulation UCBRSx=6, UCBRFx=0  
    UCA0CTL1 && ~UCSWRST; // **Initialize USCI state machine**  
  
    // Increase PMMCOREV level to 2 for proper radio operation  
    SetVCore(2);  
    ResetRadioCore();  
    InitRadio();  
    InitButtonLeds();
```

```

ReceiveOn();
receiving = 1;

while(1) // Loop Timer A indefinitely
{
  __bis_SR_register(LPM3_bits + GIE); // Enter LPM3, enable interrupts
  __no_operation();

  /* Transmit 4 Pressure Sensor Readings Via Uart */
  for(l = 0; l < 4 ; l++) // Loop For Simplified Pressure Marking
  {
    while(!(UCA0IFG&UCTXIFG)); // USCI_A1 TX buffer ready? (Not sure why ; at the end)
    {}
    UCA0TXBUF = '$'; // Tx -> $ Sign
    while(!(UCA0IFG&UCTXIFG)); // USCI_A1 TX buffer ready?
    {}
    UCA0TXBUF = 'P'; // Tx -> Sensor Marker
    while(!(UCA0IFG&UCTXIFG)); // USCI_A1 TX buffer ready?
    {}
    UCA0TXBUF = '1'; // Tx -> Pressure Sensor Marker
    while(!(UCA0IFG&UCTXIFG)); // USCI_A1 TX buffer ready?
    {}
    UCA0TXBUF = RxBuffer[l]; // TX -> Sensor Conversion Value
  }

  /* Transmit Temperature Sensor Reading Via Uart */
  while(!(UCA0IFG&UCTXIFG)); // USCI_A1 TX buffer ready?
  {}
  UCA0TXBUF = '$'; // Tx -> $ Sign
  while(!(UCA0IFG&UCTXIFG)); // USCI_A1 TX buffer ready?
  {}
  UCA0TXBUF = 'T'; // Tx -> Sensor Marker
  while(!(UCA0IFG&UCTXIFG));
  {}
  UCA0TXBUF = RxBuffer[4]; // TX -> Sensor Conversion Value

  /* Transmit Humdiity Sensor Reading Via Uart */
  while(!(UCA0IFG&UCTXIFG)); // USCI_A1 TX buffer ready?
  {}
  UCA0TXBUF = '$'; // Tx -> $ Sign
  while(!(UCA0IFG&UCTXIFG)); // USCI_A1 TX buffer ready?
  {}
  UCA0TXBUF = 'H'; // Tx -> Sensor Marker
  while(!(UCA0IFG&UCTXIFG));
  {}
  UCA0TXBUF = RxBuffer[5]; // TX -> Sensor Conversion Value

  ReceiveOn(); //Clear previous interrupt
}
}

void InitButtonLeds(void)
{
  // Set up the button as interruptible
  P1DIR &= ~BIT7;
  P1REN |= BIT7;
  P1IES &= BIT7;
  P1IFG = 0;
  P1OUT |= BIT7;
  P1IE |= BIT7;

  // Initialize Port J

```

```

PJOUT = 0x00;
PDIR = 0xFF;

// Set up LEDs
P1OUT &= ~BIT0;
P1DIR |= BIT0;
P3OUT &= ~BIT6;
P3DIR |= BIT6;
}

void InitRadio(void)
{
// Set the High-Power Mode Request Enable bit so LPM3 can be entered
// with active radio enabled
PMMCTL0_H = 0xA5;
PMMCTL0_L |= PMMHPMRE_L;
PMMCTL0_H = 0x00;

WriteRfSettings(&rfSettings);

WriteSinglePatable(PATABLE_VAL);
}

#pragma vector=PORT1_VECTOR
__interrupt void PORT1_ISR(void)
{
switch(__even_in_range(P1IV, 16))
{
case 0: break;
case 2: break;           // P1.0 IFG
case 4: break;           // P1.1 IFG
case 6: break;           // P1.2 IFG
case 8: break;           // P1.3 IFG
case 10: break;          // P1.4 IFG
case 12: break;          // P1.5 IFG
case 14: break;          // P1.6 IFG
case 16:                  // P1.7 IFG
P1IE = 0;                 // Debounce by disabling buttons
__bic_SR_register_on_exit(LPM3_bits); // Exit active
break;
}
}

void ReceiveOn(void)
{
RF1AIES |= BIT9;         // Falling edge of RFIFG9
RF1AIFG &= ~BIT9;        // Clear a pending interrupt
RF1AIE |= BIT9;          // Enable the interrupt

// Radio is in IDLE following a TX, so strobe SRX to enter Receive Mode
Strobe( RF_SRX );
}

void ReceiveOff(void)
{
RF1AIE &= ~BIT9;         // Disable RX interrupts
RF1AIFG &= ~BIT9;        // Clear pending IFG

// It is possible that ReceiveOff is called while radio is receiving a packet.
// Therefore, it is necessary to flush the RX FIFO after issuing IDLE strobe
// such that the RXFIFO is empty prior to receiving a packet.

```



```

Strobe( RF_SIDLE );
Strobe( RF_SFRX );
}

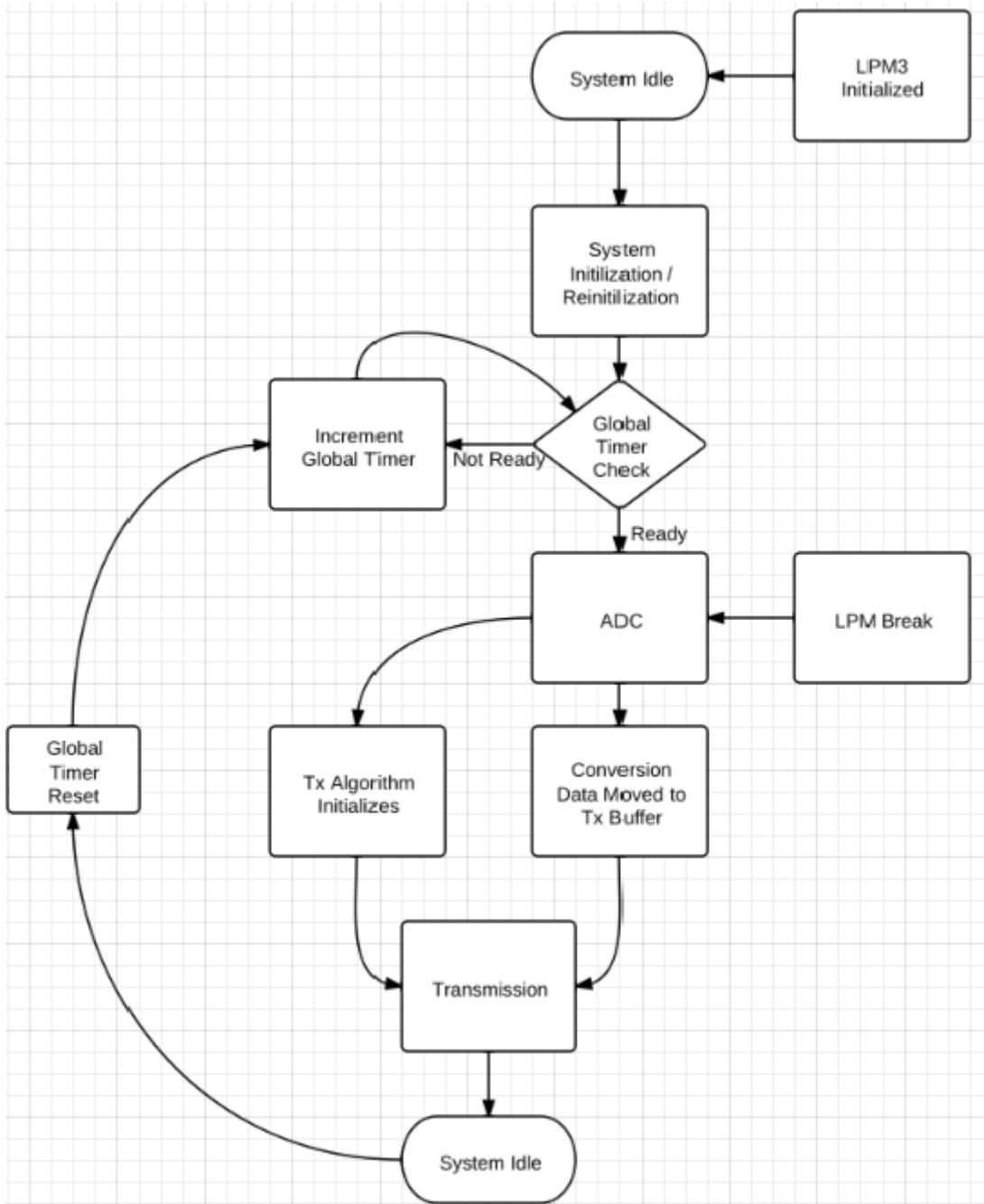
#pragma vector=CC1101_VECTOR
__interrupt void CC1101_ISR(void)
{
switch(__even_in_range(RF1AIV,32))    // Prioritizing Radio Core Interrupt
{
case 0: break;           // No RF core interrupt pending
case 2: break;           // RFIFG0
case 4: break;           // RFIFG1
case 6: break;           // RFIFG2
case 8: break;           // RFIFG3
case 10: break;          // RFIFG4
case 12: break;          // RFIFG5
case 14: break;          // RFIFG6
case 16: break;          // RFIFG7
case 18: break;          // RFIFG8
case 20:                 // RFIFG9
if(receiving)            // RX end of packet
{
// Read the length byte from the FIFO
RxBufferLength = ReadSingleReg( RXBYTES );
ReadBurstReg(RF_RXFIFORD, RxBuffer, RxBufferLength);

// Stop here to see contents of RxBuffer
__no_operation();

// Check the CRC results
if(RxBuffer[CRC_LQI_IDX] & CRC_OK)
P1OUT ^= BIT0;          // Toggle LED1
}

else while(1);           // trap
break;
case 22: break;          // RFIFG10
case 24: break;          // RFIFG11
case 26: break;          // RFIFG12
case 28: break;          // RFIFG13
case 30: break;          // RFIFG14
case 32: break;          // RFIFG15
}
__bic_SR_register_on_exit(LPM3_bits);
}

```



Appendix H: Supplementary Universal Code

Code for hal_pmm

```

//*****//
// Function Library for setting the PMM
// File: hal_pmm.c
//
// Texas Instruments
//
// Version 1.2
// 11/24/09
//
// V1.0 Initial Version
// V1.1 Adjustment to UG

```

```

// V1.2 Added return values
//*****//

#include "msp430.h"
#include "hal_pmm.h"

#define _HAL_PMM_DISABLE_SVML_
#define _HAL_PMM_DISABLE_SVSL_
#define _HAL_PMM_DISABLE_FULL_PERFORMANCE_

//*****//
#ifdef _HAL_PMM_DISABLE_SVML_
#define _HAL_PMM_SVMLE SVMLE
#else
#define _HAL_PMM_SVMLE 0
#endif
#ifdef _HAL_PMM_DISABLE_SVSL_
#define _HAL_PMM_SVSLE SVSLE
#else
#define _HAL_PMM_SVSLE 0
#endif
#ifdef _HAL_PMM_DISABLE_FULL_PERFORMANCE_
#define _HAL_PMM_SVSFP SVSFP
#else
#define _HAL_PMM_SVSFP 0
#endif
//*****//
// Set VCore
//*****//
unsigned int SetVCore (unsigned char level)
{
    unsigned int actlevel;
    unsigned int status = 0;
    level &= PMMCOREV_3; // Set Mask for Max. level
    actlevel = (PMMCTL0 & PMMCOREV_3); // Get actual VCore

    while (((level != actlevel) && (status == 0)) || (level < actlevel)) // step by step increase or decrease
    {
        if (level > actlevel)
            status = SetVCoreUp(++actlevel);
        else
            status = SetVCoreDown(--actlevel);
    }
    return status;
}

//*****//
// Set VCore Up
//*****//
unsigned int SetVCoreUp (unsigned char level)
{
    unsigned int PMMRE_backup,SVSMHCTL_backup;

    // Open PMM registers for write access
    PMMCTL0_H = 0xA5;

    // Disable dedicated Interrupts to prevent that needed flags will be cleared
    PMMRE_backup = PMMRE;
    PMMRE &= ~(SVSMHDLIE | SVSMLDLYIE | SVMLVLRIE | SVMHVLRIE | SVMHVLRIE);
    // Set SVM highside to new level and check if a VCore increase is possible
    SVSMHCTL_backup = SVSMHCTL;
    PMMIFG &= ~(SVMHIFG | SVSMHDLYIFG);
    SVSMHCTL = SVMHE | SVMHFP | (SVSMHRRLO * level);
    // Wait until SVM highside is settled
    while ((PMMIFG & SVSMHDLYIFG) == 0);
    // Disable full-performance mode to save energy
    SVSMHCTL &= ~_HAL_PMM_SVSFP;
    // Check if a VCore increase is possible
    if ((PMMIFG & SVMHIFG) == SVMHIFG){ //-> Vcc is to low for a Vcore increase

```

```

// recover the previous settings
PMMIFG &= ~SVSMHDLYIFG;
SVSMHCTL = SVSMHCTL_backup;
// Wait until SVM highside is settled
while ((PMMIFG & SVSMHDLYIFG) == 0);
// Clear all Flags
PMMIFG &= ~(SVMHVLRIFG | SVMHIFG | SVSMHDLYIFG | SVMLVLRIFG | SVMLIFG | SVSMLDLYIFG);
// backup PMM-Interrupt-Register
PMMRIE = PMMRIE_backup;

// Lock PMM registers for write access
PMMCTLO_H = 0x00;
return PMM_STATUS_ERROR;          // return: voltage not set
}

// Set also SVS highside to new level          // -> Vcc is high enough for a Vcore increase
SVSMHCTL |= SVSHE | (SVSHRVLO * level);
// Set SVM low side to new level
SVSMLCTL = SVMLE | SVMLFP | (SVSMLRRL0 * level);
// Wait until SVM low side is settled
while ((PMMIFG & SVSMLDLYIFG) == 0);
// Clear already set flags
PMMIFG &= ~(SVMLVLRIFG | SVMLIFG);
// Set VCore to new level
PMMCTLO_L = PMMCOREV0 * level;
// Wait until new level reached
if (PMMIFG & SVMLIFG)
while ((PMMIFG & SVMLVLRIFG) == 0);
// Set also SVS/SVM low side to new level
PMMIFG &= ~SVSMLDLYIFG;
SVSMLCTL |= SVSLE | (SVSLRVLO * level);
// wait for lowside delay flags
while ((PMMIFG & SVSMLDLYIFG) == 0);

// Disable SVS/SVM Low
// Disable full-performance mode to save energy
SVSMLCTL &= ~( _HAL_PMM_DISABLE_SVSL + _HAL_PMM_DISABLE_SVML + _HAL_PMM_SVSFP );

// Clear all Flags
PMMIFG &= ~(SVMHVLRIFG | SVMHIFG | SVSMHDLYIFG | SVMLVLRIFG | SVMLIFG | SVSMLDLYIFG);
// backup PMM-Interrupt-Register
PMMRIE = PMMRIE_backup;

// Lock PMM registers for write access
PMMCTLO_H = 0x00;
return PMM_STATUS_OK;          // return: OK
}

//*****//
// Set VCore down (Independent from the enabled Interrupts in PMMRIE)
//*****//
unsigned int SetVCoreDown (unsigned char level)
{
    unsigned int PMMRIE_backup;

// Open PMM registers for write access
PMMCTLO_H = 0xA5;

// Disable dedicated Interrupts to prevent that needed flags will be cleared
PMMRIE_backup = PMMRIE;
PMMRIE &= ~(SVSMHDLYIE | SVSMLDLYIE | SVMLVLRIE | SVMHVLRIE | SVMHVRPE);

// Set SVM high side and SVM low side to new level
PMMIFG &= ~(SVMHIFG | SVSMHDLYIFG | SVMLIFG | SVSMLDLYIFG);
SVSMHCTL = SVMHE | SVMHFP | (SVSMHRRLO * level);
SVSMLCTL = SVMLE | SVMLFP | (SVSMLRRL0 * level);
// Wait until SVM high side and SVM low side is settled
while ((PMMIFG & SVSMHDLYIFG) == 0 || (PMMIFG & SVSMLDLYIFG) == 0);

// Set VCore to new level
PMMCTLO_L = PMMCOREV0 * level;

```

```

// Set also SVS highside and SVS low side to new level
PMMIFG &= ~(SVSHIFG | SVSMHDLYIFG | SVSLIFG | SVSMLDLYIFG);
SVSMHCTL |= SVSHE | SVSHFP | (SVSHRVL0 * level);
SVSMLCTL |= SVSLE | SVSLFP | (SVSLRVL0 * level);
// Wait until SVS high side and SVS low side is settled
while ((PMMIFG & SVSMHDLYIFG) == 0 || (PMMIFG & SVSMLDLYIFG) == 0);
// Disable full-performance mode to save energy
SVSMHCTL &= ~_HAL_PMM_SVSFP;
// Disable SVS/SVM Low
// Disable full-performance mode to save energy
SVSMLCTL &= ~(_HAL_PMM_DISABLE_SVSL+_HAL_PMM_DISABLE_SVML+_HAL_PMM_SVSFP);

// Clear all Flags
PMMIFG &= ~(SVMHLRIFG | SVMHIFG | SVSMHDLYIFG | SVMLVLRIFG | SVMLIFG | SVSMLDLYIFG);
// backup PMM-Interrupt-Register
PMMRIE = PMMRIE_backup;
// Lock PMM registers for write access
PMMCTLO_H = 0x00;

if ((PMMIFG & SVMHIFG) == SVMHIFG)
    return PMM_STATUS_ERROR; // Highside is still to low for the adjusted VCore Level
else return PMM_STATUS_OK; // Return: OK
}

```

Code For RF1A

```

#include "RF1A.h"
#include "cc430x513x.h"

// *****
// @fn Strobe
// @brief Send a command strobe to the radio. Includes workaround for RF1A7
// @param unsigned char strobe The strobe command to be sent
// @return unsigned char statusByte The status byte that follows the strobe
// *****
unsigned char Strobe(unsigned char strobe)
{
    unsigned char statusByte = 0;
    unsigned int gdo_state;

    // Check for valid strobe command
    if((strobe == 0xBD) || ((strobe >= RF_SRES) && (strobe <= RF_SNOP)))
    {
        // Clear the Status read flag
        RF1AIFCTL1 &= ~(RFSTATIFG);

        // Wait for radio to be ready for next instruction
        while( !(RF1AIFCTL1 & RFINSTRIFG));

        // Write the strobe instruction
        if ((strobe > RF_SRES) && (strobe < RF_SNOP))
        {
            gdo_state = ReadSingleReg(IOC2G2); // buffer IOC2G2 state
            WriteSingleReg(IOC2G2, 0x29); // chip-ready to GDO2

            RF1AINSTRB = strobe;
            if ( (RF1AIN&0x04)== 0x04 ) // chip at sleep mode
            {
                if ( (strobe == RF_SXOFF) || (strobe == RF_SPWD) || (strobe == RF_SWOR) ) {}
                else
                {
                    while ((RF1AIN&0x04)== 0x04); // chip-ready ?
                    // Delay for ~810usec at 1.05MHz CPU clock, see erratum RF1A7
                    __delay_cycles(850);
                }
            }
            WriteSingleReg(IOC2G2, gdo_state); // restore IOC2G2 setting

            while( !(RF1AIFCTL1 & RFSTATIFG) );
        }
    }
}

```

```

else // chip active mode (SRES)
{
    RF1AINSTRB = strobe;
}
statusByte = RF1ASTATB;
}
return statusByte;
}

// *****
// @fn    ReadSingleReg
// @brief  Read a single byte from the radio register
// @param  unsigned char addr  Target radio register address
// @return  unsigned char data_out  Value of byte that was read
// *****
unsigned char ReadSingleReg(unsigned char addr)
{
    unsigned char data_out;

    // Check for valid configuration register address, 0x3E refers to PATABLE
    if ((addr <= 0x2E) || (addr == 0x3E))
        // Send address + Instruction + 1 dummy byte (auto-read)
        RF1AINSTR1B = (addr | RF_SNGLREGRD);
    else
        // Send address + Instruction + 1 dummy byte (auto-read)
        RF1AINSTR1B = (addr | RF_STATREGRD);

    while (!(RF1AIFCTL1 & RFDOUTIFG));
    data_out = RF1ADOUTB; // Read data and clears the RFDOUTIFG

    return data_out;
}

// *****
// @fn    WriteSingleReg
// @brief  Write a single byte to a radio register
// @param  unsigned char addr  Target radio register address
// @param  unsigned char value  Value to be written
// @return  none
// *****
void WriteSingleReg(unsigned char addr, unsigned char value)
{
    while (!(RF1AIFCTL1 & RFINSTRIFG)); // Wait for the Radio to be ready for next instruction
    RF1AINSTRB = (addr | RF_SNGLREGWR); // Send address + Instruction

    RF1ADINB = value; // Write data in

    __no_operation();
}

// *****
// @fn    ReadBurstReg
// @brief  Read multiple bytes to the radio registers
// @param  unsigned char addr  Beginning address of burst read
// @param  unsigned char *buffer  Pointer to data table
// @param  unsigned char count  Number of bytes to be read
// @return  none
// *****
void ReadBurstReg(unsigned char addr, unsigned char *buffer, unsigned char count)
{
    unsigned int i;
    if(count > 0)
    {
        while (!(RF1AIFCTL1 & RFINSTRIFG)); // Wait for INSTRIFG
        RF1AINSTR1B = (addr | RF_REGRD); // Send addr of first conf. reg. to be read
        // ... and the burst-register read instruction
        for (i = 0; i < (count-1); i++)
        {
            while (!(RFDOUTIFG & RF1AIFCTL1)); // Wait for the Radio Core to update the RF1ADOUTB reg
            buffer[i] = RF1ADOUT1B; // Read DOUT from Radio Core + clears RFDOUTIFG
            // Also initiates auto-read for next DOUT byte
        }
    }
}

```

```

}
buffer[count-1] = RF1ADOUT0B;    // Store the last DOUT from Radio Core
}
}

// *****
// @fn    WriteBurstReg
// @brief  Write multiple bytes to the radio registers
// @param  unsigned char addr    Beginning address of burst write
// @param  unsigned char *buffer  Pointer to data table
// @param  unsigned char count    Number of bytes to be written
// @return  none
// *****
void WriteBurstReg(unsigned char addr, unsigned char *buffer, unsigned char count)
{
    unsigned char i;

    if(count > 0)
    {
        while (!(RF1AIFCTL1 & RFINSTRIFG));    // Wait for the Radio to be ready for next instruction
        RF1AINSTRW = ((addr | RF_REGWR)<<8) + buffer[0]; // Send address + Instruction

        for (i = 1; i < count; i++)
        {
            RF1ADINB = buffer[i];    // Send data
            while (!(RFDINIFG & RF1AIFCTL1));    // Wait for TX to finish
        }
        i = RF1ADOUTB;    // Reset RFDOUTIFG flag which contains status byte
    }
}

// *****
// @fn    ResetRadioCore
// @brief  Reset the radio core using RF_SRES command
// @param  none
// @return  none
// *****
void ResetRadioCore (void)
{
    Strobe(RF_SRES);    // Reset the Radio Core
    Strobe(RF_SNOP);    // Reset Radio Pointer
}

// *****
// @fn    WriteRfSettings
// @brief  Write the minimum set of RF configuration register settings
// @param  RF_SETTINGS *pRfSettings  Pointer to the structure that holds the rf settings
// @return  none
// *****
void WriteRfSettings(RF_SETTINGS *pRfSettings) {
    WriteSingleReg(FSCTRL1, pRfSettings->fsctrl1);
    WriteSingleReg(FSCTRL0, pRfSettings->fsctrl0);
    WriteSingleReg(FREQ2, pRfSettings->freq2);
    WriteSingleReg(FREQ1, pRfSettings->freq1);
    WriteSingleReg(FREQ0, pRfSettings->freq0);
    WriteSingleReg(MDMCFG4, pRfSettings->mdmcf4);
    WriteSingleReg(MDMCFG3, pRfSettings->mdmcf3);
    WriteSingleReg(MDMCFG2, pRfSettings->mdmcf2);
    WriteSingleReg(MDMCFG1, pRfSettings->mdmcf1);
    WriteSingleReg(MDMCFG0, pRfSettings->mdmcf0);
    WriteSingleReg(CHANNR, pRfSettings->channr);
    WriteSingleReg(DEVIATN, pRfSettings->deviatn);
    WriteSingleReg(FREND1, pRfSettings->frend1);
    WriteSingleReg(FREND0, pRfSettings->frend0);
    WriteSingleReg(MCSM0, pRfSettings->mcsm0);
    WriteSingleReg(FOCCFG, pRfSettings->foccfg);
    WriteSingleReg(BSCFG, pRfSettings->bscfg);
    WriteSingleReg(AGCCTRL2, pRfSettings->agcctrl2);
    WriteSingleReg(AGCCTRL1, pRfSettings->agcctrl1);
    WriteSingleReg(AGCCTRL0, pRfSettings->agcctrl0);
    WriteSingleReg(FSCAL3, pRfSettings->fscal3);
}

```

```

WriteSingleReg(FSCAL2, pRfSettings->fscal2);
WriteSingleReg(FSCAL1, pRfSettings->fscal1);
WriteSingleReg(FSCAL0, pRfSettings->fscal0);
WriteSingleReg(FSTEST, pRfSettings->fstest);
WriteSingleReg(TEST2, pRfSettings->test2);
WriteSingleReg(TEST1, pRfSettings->test1);
WriteSingleReg(TEST0, pRfSettings->test0);
WriteSingleReg(FIFOTHR, pRfSettings->fifothr);
WriteSingleReg(IOCFG2, pRfSettings->iocfg2);
WriteSingleReg(IOCFG0, pRfSettings->iocfg0);
WriteSingleReg(PKTCTRL1, pRfSettings->pktctrl1);
WriteSingleReg(PKTCTRL0, pRfSettings->pktctrl0);
WriteSingleReg(ADDR, pRfSettings->addr);
WriteSingleReg(PKTLEN, pRfSettings->pktlen);
}

// *****
// @fn WritePATable
// @brief Write data to power table
// @param unsigned char value Value to write
// @return none
// *****
void WriteSinglePATable(unsigned char value)
{
while( !(RF1AIFCTL1 & RFINSTRIFG));
RF1AINSTRW = 0x3E00 + value; // PA Table single write

while( !(RF1AIFCTL1 & RFINSTRIFG));
RF1AINSTRB = RF_SNOP; // reset PA_Table pointer
}

// *****
// @fn WritePATable
// @brief Write to multiple locations in power table
// @param unsigned char *buffer Pointer to the table of values to be written
// @param unsigned char count Number of values to be written
// @return none
// *****
void WriteBurstPATable(unsigned char *buffer, unsigned char count)
{
volatile char i = 0;

while( !(RF1AIFCTL1 & RFINSTRIFG));
RF1AINSTRW = 0x7E00 + buffer[i]; // PA Table burst write

for (i = 1; i < count; i++)
{
RF1ADINB = buffer[i]; // Send data
while( !(RFDINIFG & RF1AIFCTL1)); // Wait for TX to finish
}
i = RF1ADOUTB; // Reset RFDOUTIFG flag which contains status byte

while( !(RF1AIFCTL1 & RFINSTRIFG));
RF1AINSTRB = RF_SNOP; // reset PA Table pointer
}

```

Code For RfRegSettings

```

#include "RF1A.h"

#ifdef MHZ_915

// Chipcon
// Product = CC430Fx13x
// Chip version = C (PG 0.7)
// Crystal accuracy = 10 ppm
// X-tal frequency = 26 MHz

```



```

// RF output power = 0 dBm
// RX filterbandwidth = 101.562500 kHz
// Deviation = 19 kHz
// Datarate = 38.383484 kBaud
// Modulation = (1) GFSK
// Manchester enable = (0) Manchester disabled
// RF Frequency = 914.999969 MHz
// Channel spacing = 199.951172 kHz
// Channel number = 0
// Optimization = -
// Sync mode = (3) 30/32 sync word bits detected
// Format of RX/TX data = (0) Normal mode, use FIFOs for RX and TX
// CRC operation = (1) CRC calculation in TX and CRC check in RX enabled
// Forward Error Correction =
// Length configuration = (0) Fixed packet length, packet length configured by PKTLEN
// Packetlength = 61
// Preamble count = (2) 4 bytes
// Append status = 1
// Address check = (0) No address check
// FIFO autoflush = 0
// Device address = 0
// GDO0 signal selection = ( 6) Asserts when sync word has been sent / received, and de-asserts at the end of the packet
// GDO2 signal selection = (41) RF_RDY
RF_SETTINGS rfSettings = {
    0x08, // FSCTRL1 Frequency synthesizer control.
    0x00, // FSCTRL0 Frequency synthesizer control.
    0x23, // FREQ2 Frequency control word, high byte.
    0x31, // FREQ1 Frequency control word, middle byte.
    0x3B, // FREQ0 Frequency control word, low byte.
    0xCA, // MDMCFG4 Modem configuration.
    0x83, // MDMCFG3 Modem configuration.
    0x93, // MDMCFG2 Modem configuration.
    0x22, // MDMCFG1 Modem configuration.
    0xF8, // MDMCFG0 Modem configuration.
    0x00, // CHANNR Channel number.
    0x34, // DEVIATN Modem deviation setting (when FSK modulation is enabled).
    0x56, // FREND1 Front end RX configuration.
    0x10, // FREND0 Front end TX configuration.
    0x18, // MCSM0 Main Radio Control State Machine configuration.
    0x16, // FOCCFG Frequency Offset Compensation Configuration.
    0x6C, // BSCFG Bit synchronization Configuration.
    0x43, // AGCCTRL2 AGC control.
    0x40, // AGCCTRL1 AGC control.
    0x91, // AGCCTRL0 AGC control.
    0xE9, // FSCAL3 Frequency synthesizer calibration.
    0x2A, // FSCAL2 Frequency synthesizer calibration.
    0x00, // FSCAL1 Frequency synthesizer calibration.
    0x1F, // FSCAL0 Frequency synthesizer calibration.
    0x59, // FSTEST Frequency synthesizer calibration.
    0x81, // TEST2 Various test settings.
    0x35, // TEST1 Various test settings.
    0x09, // TEST0 Various test settings.
    0x47, // FIFOTHr RXFIFO and TXFIFO thresholds.
    0x29, // IOCFG2 GDO2 output pin configuration.
    0x06, // IOCFG0 GDO0 output pin configuration. Refer to SmartRF® Studio User Manual for detailed pseudo register explanation.
    0x04, // PKTCTRL1 Packet automation control.
    0x04, // PKTCTRL0 Packet automation control.
    0x00, // ADDR Device address.
    0x05 // PKTLEN Packet length.
};

```