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# An Improved Method for Hospital Acquired Pressure Ulcer (HAPU) Prevention

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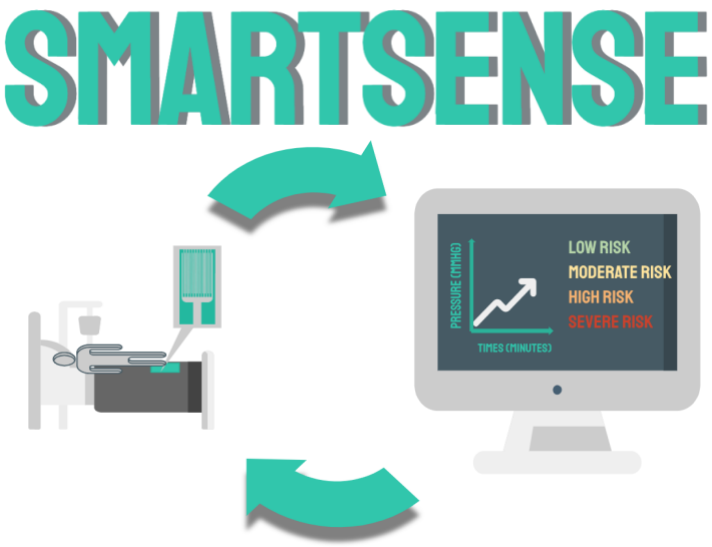


# An Improved Method for Hospital Acquired Pressure Ulcer (HAPU) Prevention

By

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ABSTRACT

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Hospital acquired pressure ulcers (HAPUs), also called bedsores, are damage to the skin and/or underlying tissue caused by prolonged pressure on the bony areas of the body, with around 20% of pressure ulcers occurring in the heel region. Currently, the most common practice for HAPU prevention is arbitrary manual repositioning of patients by nurses every 1-2 hours. The goal of our project was to address HAPUs in the heel region of low mobility patients through an ulceration risk sensing system. Our team has created a wearable ulceration risk assessment system that combines individual patient risk data with real time pressure data to determine overall HAPU risk level. This system includes a pressure sensor system embedded within a silicone foam dressing, which can be strapped around the heel. The pressure data is wirelessly sent to a computer display and combined with scores from the current risk assessment scale (Braden Scale) to create a real time HAPU risk assessment tool for clinicians. Based on our validation testing, the system accurately reads pressure at the heels and creates an accurate ulceration risk assessment tool. This tool, when fully developed, could lead to faster recovery time for patients, a decrease in the overall cost of patient treatment, and a decreased burden on nurses, allowing them to better optimize their time.

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## Background

Pressure ulcers are areas of localized damage to the skin and underlying tissue death [1]. This localized soft tissue death, or necrosis, is a result of prolonged pressure between a bony region and an external surface. These bony regions, or prominences, have an increased risk of pressure ulcer development because the bone is less padded by the surrounding tissue, causing it to be closer to the external surface than other regions of the body. The compression between the bony prominence and external surface results in the occlusion of capillaries, causing ischemia, or restriction of blood flow to tissues [2], which can cause the underlying and surrounding tissues to become oxygen deprived, or anoxic [3]. Over time, this can lead to cell death. Muscle and subcutaneous fat are particularly susceptible to compression, which often results in internal pressure-induced injuries prior to visible skin damage. Ischemia induced pressure ulceration can occur between the first hour and 4 to 6 hours of sustained pressure [4][5].

Risk Factors:

While pressure ischemia is commonly identified as one of the most prevalent causes of ulceration, there are several other external and internal ulceration risk factors. External risk factors include: shear, friction, moisture, abnormal posture, and impaired mobility [6]. Internal risk factors include: altered consciousness, decreased or absent sensations, nutrition, anemia, edema, medications, and emotional stress [6]. Typically, ulceration occurs due to a combination of external and internal factors.

One particularly relevant external risk factor is shearing. Shearing occurs when skin and subcutaneous tissue remain stationary, while the body moves across a surface [6]. This differential movement of the underlying tissue results in the stretching and tearing of blood

vessels, which reduces blood flow and can lead to ulceration. In hospital or rehabilitation settings, where pressure ulcers commonly occur [1], shearing is often a result of a patient being moved without being fully lifted off the surface. While manual patient readjustment is a common method to redistribute force, it can also cause shearing, which can cause the patient to become more susceptible to pressure ulcers.

Additionally, friction at the skin/external surface interface can result in a breach in the epidermis [6]. If the breach occurs at a site where the underlying tissue is already presenting with ischemia, infection can rapidly occur. The presence of moisture from perspiration, urine, feces, discharge, etc. can cause the skin to become macerated, which weakens the skin barrier and can cause the skin to be more susceptible to the external factors of pressure, shear, and friction [6].

In terms of internal risk factors, sensory perception and nutrition play an important role in ulceration risk. Sensory perception is divided into two categories: physical and mental. Mental sensory perception refers to the ability of an individual to communicate pain status or respond to painful stimuli [6]. Physical sensory perception refers to the ability of an individual to feel pain. A decrease in either one or both forms of sensory perception can result in a failure to make necessary postural adjustments in response to prolonged pressure, which can result in the formation of pressure ulcers. Nutrition also plays a critical role in prevention, as nutrition can contribute to the condition of the skin and can determine the rate at which it breaks down [7]. Nutrition can impact the body's hemoglobin levels, which can impact tissue oxygenation and can precipitate tissue necrosis.

Risk Assessment:

The Braden Scale is a common method used to determine the extent of which an individual is at risk of developing pressure ulcers. The Braden Scale ranks the aforementioned risk factors of sensory perception, moisture, activity, mobility, nutrition, and friction and shear [1]. Each factor is ranked from 1-4 based on severity, with the exception of friction and shear, which is ranked from 1-3, with 1 being high risk and 4 being low risk [1]. The scale has a maximum possible score of 23, with a score of 18 or lower indicating pressure ulceration risk [1]. For detailed information on how the Braden Scale works, see A-1 [8].

Stages:

There are four primary stages of pressure ulcers that are based on severity, and two stages that do not fall into those categories [2]. Stages I and II present themselves on the surface of the skin, while stages III and IV are deeper, as seen in A-2 [9]. In a stage I pressure ulcer, the skin is intact, with nonblanchable redness serving as a warning sign, while in stage II there is an initial break in the surface of the skin, and blisters begin to form [2]. In stage III, the pressure ulcer has gone deeper, reaching the layer of subcutaneous fat, while in stage IV the ulcer has reached bone [2]. The other case is a suspected deep tissue injury between stages II and III, where the ulcer is between partial and full ulcer thickness [1]. The last stage is when the ulcer is deemed unstageable, meaning there is a scab covering the pressure ulcer, which hides its depth [1].

Pressure Ulceration at the Heels:

There are specific locations on the body where a patient is at risk of developing pressure ulcers, known as bony prominences, as shown in A-2 [10]. These locations include the back of

the head, heel, ear, scapulae, elbows, breasts and genitalia, sacrum, knees, and heels, with 20% of pressure ulcers occurring in the heel region [11].

The posterior surface of the heel is particularly susceptible to ulceration as it is not adapted to resist forces in the way that the plantar surface is [12]. The posterior region of the heel does not present with fat-filled fascial spaces that help absorb compressive forces generated by prolonged pressure or shear forces generated during movement [12]. Additionally, the blood supply in this region is poor and there is no underlying muscle to help cushion the bone or redistribute pressure [12]. As an individual rests in a supine or lying position, the resulting pressure from the weight of the lower leg and foot are concentrated at the posterior region of the heel, causing pressure ulceration [12].

Hospital Acquired Pressure Ulcers:

Pressure ulcers are a prevalent concern for patients with limited mobility, as they are unable to readjust themselves to redistribute pressure. Specific regions of the hospital where pressure ulceration is a concern are Intensive and General Care Units, as limited patient mobility is common in these units. Pressure ulceration that occurs during hospitalization is referred to as Hospital Acquired Pressure Ulcers (HAPUs) and are of serious concern, with an approximate prevalence of 2.5 million HAPUs per year [13]. HAPUs can form between the first hour and 4 to 6 hours of sustained pressure [5]. If left untreated, HAPUs can cause serious complications and even death, with 60,000 deaths directly linked to HAPUs each year [14]. The current method of prevention is arbitrarily repositioning the patient every 1-2 hours [1]. Due to the arbitrary nature of the current method of prevention, nurses are often unable to accurately redistribute the

pressure off the bony prominences of the body. Hospitals often use wedges and cushions to offload pressure on bony prominences, especially at the heels.

Stages III, IV, and unstageable HAPUs are currently designated as one of 29 "never events" by the National Quality Forum (NQF). A "never event" is an adverse event that is serious and preventable. The Centers for Medicare and Medicaid Services (CMS) announced in August 2007 that Medicare would no longer pay for additional costs associated with many preventable errors, including those considered "never events" [15]. The cost of treatment per ulcer is between $2,000- $20,000 depending on severity and stage [16]. An increase in stage or severity of an ulcer can increase the cost significantly, pushing the cost into the higher end of the range. When cost of patient care is included, prices can range from $20,900 to $151,700 per ulcer [14]. The high cost of treatment for a condition that is preventable, highlights the need to create a device that increases accuracy in prevention of HAPUs.

Prior Art:

Although the current method for preventing HAPUs is primarily manual arbitrary repositioning, there are some pressure ulcer prevention devices currently on the market that eliminate this arbitrary nature. There are two categories of prevention devices currently out there: automatic pressure redistributing devices and sensor systems.

In terms of automatic pressure redistributing devices, there are mattresses that use alternating pressure and low air loss technology to prevent pressure ulcers. These systems constantly alter the pressure under the patient to prevent pressure ulcers, and are seen to be very effective. However, these systems are not readily used by hospitals because they are too expensive, costing hundreds to thousands of dollars per mattress [17][18].

There are a limited number of devices currently on the market that use sensing systems for pressure ulcer prevention. These devices are not readily implemented in hospitals due to their high cost. These systems are able to track certain risk factors including mobility, pressure distribution, and skin temperature, in real-time and give alerts on the patient's status. One example of a sensor system that is used to prevent pressure ulcers is adhesive and wireless accelerometers. These types of devices track the patient's orientation, position, movement, and activity to determine the patient's mobility and pressure ulcer risk [19]. The Leaf sensor is an example of this technology and can be found in Appendix B-1 [19].

Another example of a sensor system is temperature sensing devices like the temperature sensing socks found in Appendix B-1 [20]. It has been shown that increased skin temperature can be a sign of tissue inflammation, which is indicative of tissue degradation or infection. That is why pressure ulcer development could be indicated by an increase in skin temperature [21]. These socks are embedded with temperature sensors that monitor changes in skin temperature of the feet.

The final type of sensor system is pressure visualization systems, which utilize mattress pads fitted with pressure sensors to relay real-time pressure data to a user interface. This interface displays a pressure map and gives real-time feedback about the success of repositioning [22]. An example of a pressure visualization system, the BodiTrak2, is shown in more detail in B-2 [22].

Current Patents:

Current patents tend to generally outline how sensors and sensor systems should be set up. An example of this is the patent in B-2, which outlines how sensors should be embedded

within a supporting surface and how these sensors should connect to a data processor [23]. Another patent found in B-3 outlines how pressure sensors would connect to a microcontroller and an alarm would be sounded when a certain pressure over time threshold was met [24]. However, the general pool of patents does not discuss how to create an accurate risk algorithm through the incorporation of the Braden Scale. Our product goes beyond the general pool of patents and current pressure visualization systems through the incorporation of a risk algorithm which takes into account risk factors of the Braden Scale, such as nutrition and sensory perception, which are often left out of patented devices.

**Problem Statement**

Hospital acquired pressure ulcers (HAPUs), also called bedsores, are damage to the skin and/or underlying tissue caused by prolonged pressure on the bony areas of the body [1]. There are 2.5 million occurrences of HAPUs costing hospitals $9.1-$11.6 billion per year in the US [13]. Regions of the body that are particularly susceptible to pressure ulcers include the back of the head, sacrum, and heels, with around 20% of pressure ulcers occurring in the heel region [11]. Common places of occurrence are intensive and general care units, where patients often have decreased mobility for extended periods of time [13]. Risk factors for HAPUs, as outlined by The Braden Scale, include: prolonged pressure, patient communication, degree of moisture, patient activity level, mobility level, nutrition, and degree of friction caused by movements [1]. Currently, the most common practice for preventing HAPUs is manual repositioning of patients every 1-2 hours arbitrarily by nurses [1]. **Addressing the prevalence of hospital acquired pressure ulcers in the heel region of low mobility patients through an ulceration risk**

**sensing system could lead to faster recovery time, a decrease in the overall cost of treatment, and a decreased burden on nurses, allowing them to better optimize their time.**

## Design Objectives

To address the problem of HAPUs, we needed to establish the main goals of our design. Our team chose to break up our design into the electrical system and form factor, as we wanted each component to accomplish different objectives. Table 1 outlines the key objectives for both design components. The full objective trees can be found in C-1.

*Table 1. Highlights the main objectives of the two parts of the device, the electrical system component and the form factor.*

| | **Electrical System** | **Form Factor** |
|---|---|---|
| **Main Objectives** | **Accurate** | **Biocompatible** |
| | **Simple** | **Comfortable** |
| | **Affordable** | |

Electrical Component:

For the electrical component of our design, we aimed to focus on accuracy, simplicity, and affordability, as shown in Table 1. Our team chose accuracy, as we wanted our system to eliminate the arbitrary nature of the current prevention method of repositioning the patient every 1-2 hours. Accuracy refers to the validity of our sensor, as well as the user interface of our design, which assists nurses in helping relieve pressure more effectively. We would also like our system to be real-time, which will allow the patient to be continuously monitored and as a result improve accuracy.

Our second major goal was to emphasize simplicity and ease of use in our design. This would allow us to better assist nurses by giving them guidance on pressure conditions at the heels and the current ulceration risk level of the patient, in order to assess when shifting is necessary. This objective is addressed by the user interface of our design.

Our third objective is to make the device affordable. The products currently on the market are often expensive, costing hundreds to thousands of dollars, and for that reason are not frequently seen in the hospital setting [18]. Making our design a more affordable option for hospitals will make our device more marketable.

While electrical safety is important to our design, the device would remain outside of the body, which would therefore pose a smaller risk to the patient than an internal device would. Other design objectives that our team identified include durability and customizability for all risk categories and body types, though these are not part of our main objectives.

Form Factor:

The second part of our design is our form factor, which houses the electrical system and is in contact with the patient. The main goal of the design format is to provide an interface between the electrical components and the skin of the patient that does not cause any harm to the patient. For this reason, we emphasized biocompatibility to ensure that our design format would not cause any irritation of the skin, and would not worsen the overall skin condition, which could increase a patient's susceptibility to HAPUs.

Keeping patient needs in mind, we also wanted the design format to be comfortable for the patient's heels to rest on. To optimize marketability, the design should also be affordable. We wanted the design to be simple, so the nurses can easily and effectively use the device. The

design must also be durable to protect the electrical system from general wear and tear. Having our design be reusable would benefit our design, but is not a necessity. Keeping both parts of the design in mind, these objectives allowed us to prioritize our main goals of each design component, as well as create an innovative design.

**Design Functions and Specifications**

Keeping in mind our main objectives, we broke our functions into three main categories: detect, track, and interpret, as shown in Table 2.

*Table 2. Summary table of main functions.*

| **Main Functions** | | |
|---|---|---|
| **1. Detect** | **2. Track** | **3. Interpret** |
| Pressure | Pressure over time | Categorize pressure ulcer risk |
| Braden Scale User Inputs | | Display pressure over time visual |

Detection focuses on pressure, as well as the user input for the Braden Scale risk factors. User input for risk factors will allow for optimal patient risk assessment. The second main function, tracking, gives real-time data tracking for the sensor inputs. Tracking pressure over time allows us to record pressure at the heels and show changes in pressure over time. The final function, interpret, involves combining data from the detection and tracking stages, and categorizing pressure ulcer risk into specified risk levels. The output is the user interface of our product, which involves a visual displaying ulceration risk and a graph of pressure vs. time.

Many of these functions are binary. For example, the device will either have a visual display or not, and it will either receive Braden Scale inputs or not. D-1 includes an in depth view of our teams functions and a corresponding specifications chart. Through these functions,

our device works to overcome the shortcomings of current devices on the market by incorporating pressure ulceration risk factors from the Braden Scale. These functions also provide a viable method for accurately and effectively determining ulceration risk.

**Design Requirements**

Table 3 outlines the top three design requirements for our HAPU prevention system. We chose these as our top design requirements, as their functionality is crucial to our system performance and its ability to accurately prevent HAPUs.

*Table 3. Top three design requirements.*

| Function | Metric | Unit | Marginal Value | Ideal Value | Specification Type |
|---|---|---|---|---|---|
| Detect pressure | Pressure | mmHg | 0-500 [25] | 0-700 [25] | Objective & Numeric |
| Track pressure over time | Time | Hours | 1 [5] | Continuous | Objective & Numeric |
| Categorize pressure ulcer risk | Risk Level | N/A | 3 Levels | 5 Levels | Objective |

The first requirement is that the device must detect pressure. Ideally, our device will be able to detect pressure levels up to 700 mmHg, and marginally up to 500 mmHg. We chose this as a top requirement because it is the most important indicator of pressure ulceration risk. These pressure values are based on the values given by the Reswick and Rogers curve, which predicts ulceration risk [25].

The second requirement is that our device tracks pressure over time. Ideally, our device will continuously track pressure over time, or marginally every hour. This requirement is crucial

for our device as it informs how accurately our system is at determining HAPU risk and dictates whether our device is informing the user of real-time events. For example, if the system only updated the user every few hours, a pressure ulcer could have already developed within that time period.

Our final design requirement is that our device must accurately categorize the HAPU risk into marginally 3 risk levels, and ideally 5 risk levels. This requirement informs whether the risk algorithm is accurately identifying pressure ulceration risk and whether or not it has good sensitivity. A greater number of risk levels would mean that our device could differentiate between smaller changes in pressure and other risk factors.

**Documentation of Proposed Design**

Our final design solution is a pressure sensing system that utilizes real-time sensing data and user inputs to give an accurate real-time ulceration risk assessment. The sensor is embedded within a silicone foam heel cup that is secured to the patient's heel, and a user interface is used to communicate ulceration risk to patient caregivers.

Risk Algorithm:

In order to determine the real-time ulceration risk level of a patient, our team developed a risk algorithm that incorporates 1) real-time pressure data sent wirelessly over Bluetooth from a force sensitive resistor (FSR) to MATLAB on the computer and 2) Braden Scale values directly inputted into our system by the nurse. FSRs use conductive film and conductive print to change resistance as an external force or pressure is applied, i.e. as more pressure is applied to the

system, the conductive layers have increased contact, which causes the resistance to decrease. Figure 1 shows the general overview of how the algorithm works.

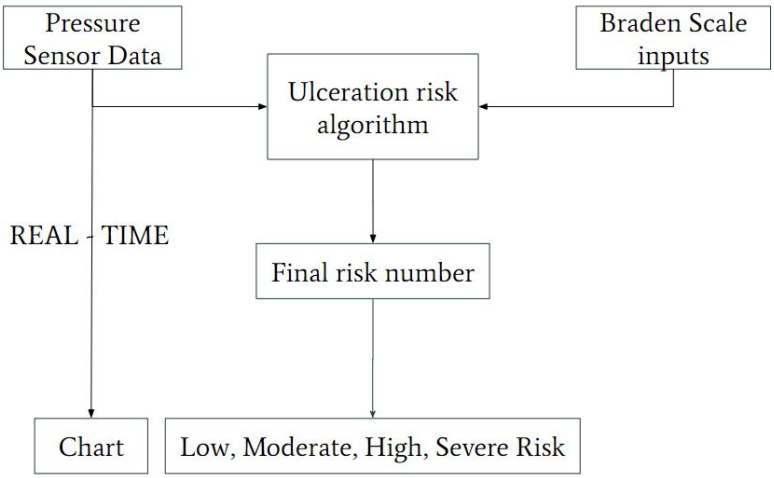


*Figure 1. Risk algorithm flow chart for our pressure ulcer prevention system.*

The risk algorithm serves as an advanced version of the Braden Scale evaluation, as it takes into account individual patient risk factors, as well as real-time pressure readings. The nurse will provide inputs for the Braden Scale into the user interface. The values are then totaled, giving the Braden Scale risk number, which is categorized as low, moderate, high, or severe risk based on the pre-established Braden Scale ranges (Figure 2).

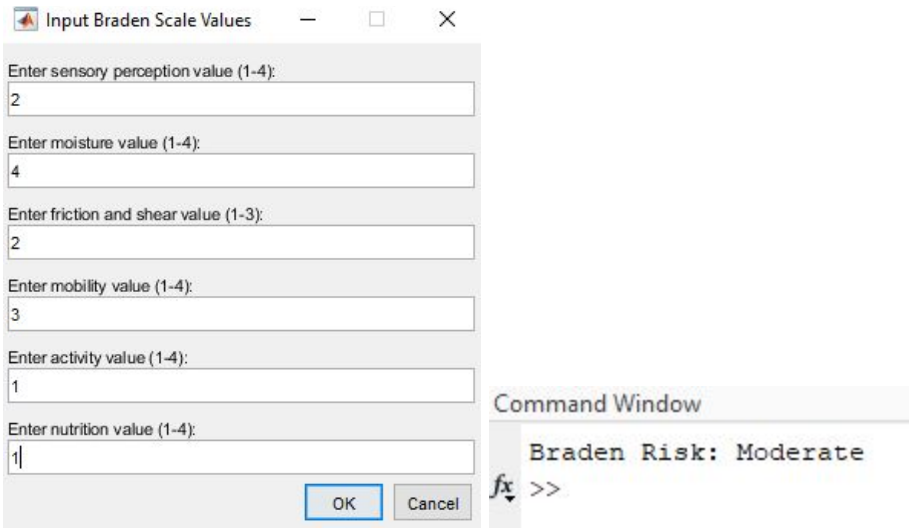


*Figure 2. Current algorithm allows input of Braden Scale values into a dialog box and outputs the Braden Scale risk in the command window of MATLAB.*

Simultaneously, the incoming force value is converted into pressure in mmHg, based on the FSR sensing area, and is compared against the Reswick and Rogers curve. The Reswick and Rogers curve is an established curve demonstrating pressure over time tolerance for developing a pressure ulcer. The original Reswick and Rogers curve is broken into three categories: acceptable, marginal, and unacceptable (Figure 3).

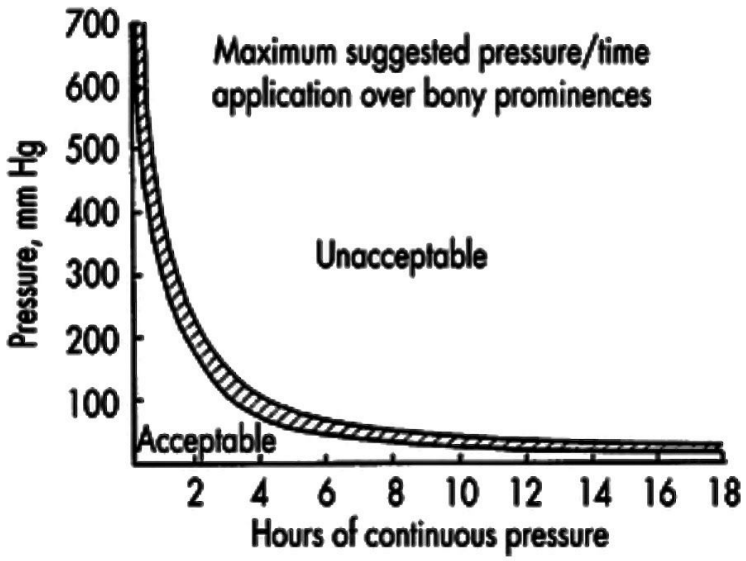


*Figure 3. Reswick and Rogers Curve. Guidelines for sitting duration. This graph provides guidelines on sitting tolerance based on the magnitude of localized pressure [24].*

We felt that the range of acceptable pressures over time was too large, so we chose to further divide the curve into 4 categories: low, moderate, high, and severe (Figure 4). Depending on the sampling time, each pressure data sample is compared to the modified curve and is designated a pressure risk value.

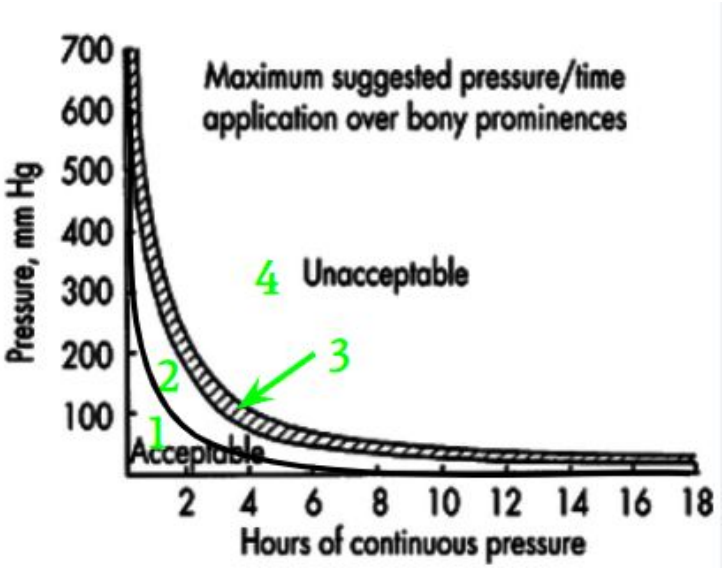


*Figure 4. Our modified Rewick and Rogers Curve which breaks the curve into four sectors ranging from 1-4 corresponding to low, moderate, high, and severe ulceration risk.*

Once the Braden Scale and pressure versus time values have been categorized, they are compared to each other and are placed into a final risk level using our risk combination table, which ranges from low to severe, with each level indicating an increased risk of ulceration (Table 4). With further testing, this table could be modified and refined and our system could be used as a data collection tool since there is very little data currently available on pressure over time values for pressure ulcer formation.

*Table 4. Risk Combination Table.*

| | | **Braden Scale Risk Categories** | | | |
|---|---|---|---|---|---|
| **Real-time Pressure Risk Categories** | | **Severe** | **High** | **Moderate** | **Low** |
| | **Severe** | Severe | Severe | Severe | High |
| | **High** | Severe | High | High | Moderate |
| | **Moderate** | High | Moderate | Moderate | Low |
| | **Low** | Moderate | Moderate | Low | Low |

Along with risk level, our user interface displays a real-time plot of pressure versus time overlayed with our modified Reswick and Rogers curve (Figure 5). The plot resets whenever the pressure reading is zero, which simulates the patient being repositioned. Upon further development, this resetting command could be refined to reset when the pressure experiences a significant drop but does not go down to zero, representing a patient shifting on their own without fully lifting their heel. Further data collection would need to be conducted to determine what change in pressure assures that the patient has sufficiently repositioned to avoid forming a pressure ulcer.

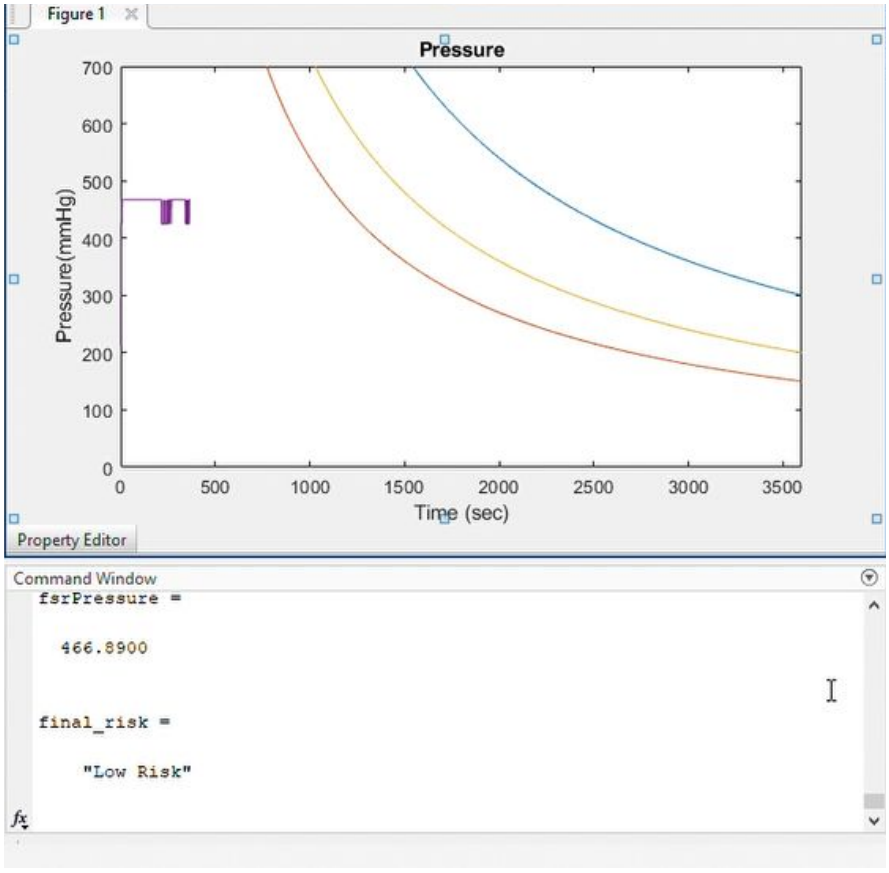


*Figure 5. Snapshot of real-time pressure data in mmHg over time in seconds from the heel plotted over our modified Reswick and Rogers curve. Command window displays the current pressure reading and the final ulceration risk level in MATLAB.*

Sensor System:

In order to record the FSR data and send it to the MATLAB risk algorithm, we first had to develop our circuit. Figure 6 shows our current circuit diagram. Our Interlink 402 FSR is attached through a voltage divider to the Arduino Uno microcontroller. In order to send the FSR data wirelessly to the computer, we used an HC-05 BLE module. We also used a 5V battery pack to power the circuit. In the future, ideally, a smaller microcontroller with BLE and a battery would be implemented in order to embed the circuit within the form factor. An important factor that our team considered was wireless data transfer. Mitigating the use of wires is helpful in the clinical setting as wires tend to get in the way and there are already so many machines with wires in the patient's room or attached to the patient. This idea was supported by nurse clinician Kathleen Capone from Albany Medical Center.

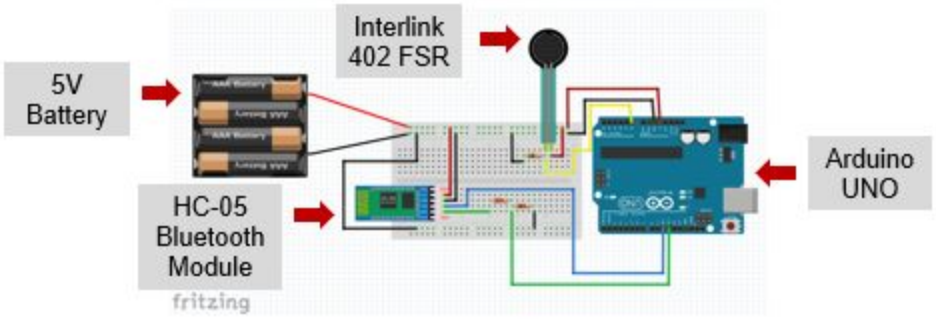


*Figure 6. Fritzing diagram of our current circuit.*

Design Format:

In terms of mechanical format, this design focuses on the heels of at-risk patients, where approximately 20% of HAPUs form. The design features a force sensitive resistor (FSR) contained within a silicone foam dressing that is fitted to the heel, with a VELCRO strap connected to the dressing (Figures 7 & 8).

An FSR was chosen over other force sensors due to its flexibility and size. The FSR featured in our design is circular with a half inch diameter sensing area, which best approximates the area of the heel that is in contact with an external surface. The FSR is flanked by a silicon insert which eliminates direct contact between the sensor and the skin by sandwiching it between the silicone foam dressing and the insert.

Silicone foam was chosen as the bulk form factor material, as it has been shown to reduce the incidence of pressure ulcers by preventing them from reaching Stage I [26]. The material helps to decrease pressure over an area, as well as prevent shearing. A study of silicone foam dressings suggests that they should be part of the standard protocol for pressure ulcers at the heel [26]. Silicone foam is also a low cost material, with an individual heel dressing costing around $10 [27]. It is also a common material used in Intensive and Wound Care Units, meaning it would be familiar to nurses.

The VELCRO strap serves two main functions: securing the dressing to the heel and containing the microcontroller. The former function is necessary because it eliminates the necessity of an adhesive, which could potentially increase skin degradation, as well as allows the device to be used on both mobile and immobile patients. With a secure connection, the device will move as the patient moves, eliminating the possibility of the patient moving off the sensing area, resulting in a false pressure reading. Containing the electronics within the VELCRO strap keeps the design compact and eliminates external components that may interfere with clinical practices.

The final form factor works to incorporate both HAPU prevention and risk detection. The design addresses varying patient mobility levels, can fit around any sock or existing dressing,

and utilizes silicone foam to decrease pressure ulcer incidence. Additionally, as this device is smaller than other sensor system devices on the market such as the BodiTrak2, it is cheaper, which increases its marketability. Our team aims to make this product accessible to all hospitals, rather than only larger hospitals with more money, which is something that the other products on the market do not offer.

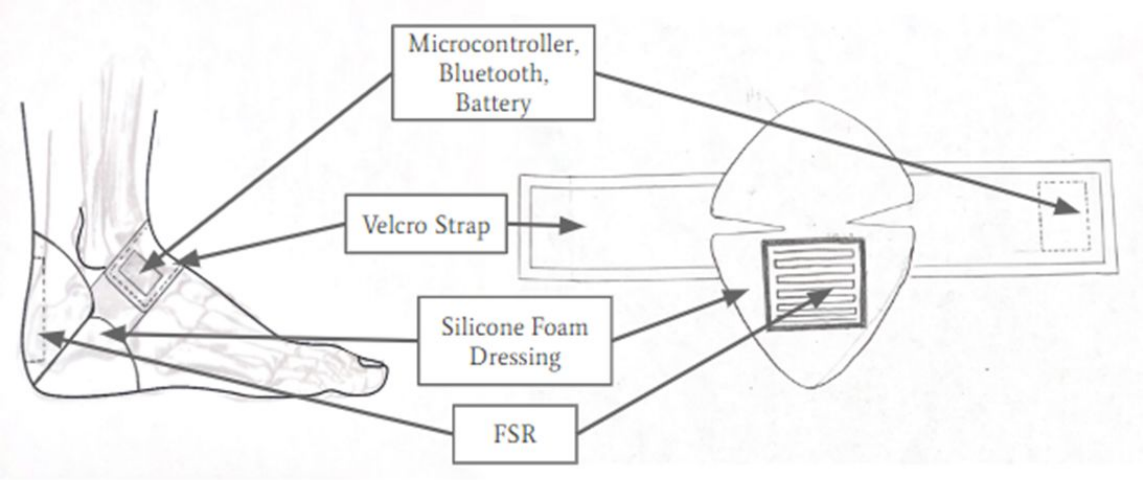


*Figure 7. Diagram of form factor.*

*Figure 8. Form factor prototype using silicone foam dressing designed for the heel.*

User Interface:

An important aspect of our prototype was the development of a user interface for nurses and clinicians. The interface must be easy to interpret, as well as easy to use. Our team developed an app using MATLAB (Figure 9) to allow nurses to input Braden Scale values, connect to the device, and interpret the risk level generated by our algorithm. On the left panel, the nurse can update the Braden Scale input values to evaluate or re-evaluate the patient at any point in time. When the "Braden Scale Risk Level" button is pressed, the Braden Scale score is determined and displayed in the "Braden Scale Risk" box below the button. The user input selection for the Braden Scale categories, shown in Figure 9, is limited to the relevant Braden Scale values which accounts for user input validation. This ensures that the Braden Scale output will stay within the expected range of values.

To operate the system, the "Connect to Device" button is used to connect to the device's Bluetooth in order to read in pressure values. On the right panel, the "Plot Pressure" button displays the pressure vs. time graph on the app interface, and the "Final Risk Evaluation" button populates the final risk value, as determined by the most recent Braden Scale inputs and the real-time pressure values, into the box beneath the button. This design has minimal buttons to create an interface that is simple to work with and can be used as a quick tool to assess the patient. This interface allows the nurse to visually observe pressure values at the heel, while taking in all the different risk factors of the patient in order to guide the nurse on when to reposition the patient.

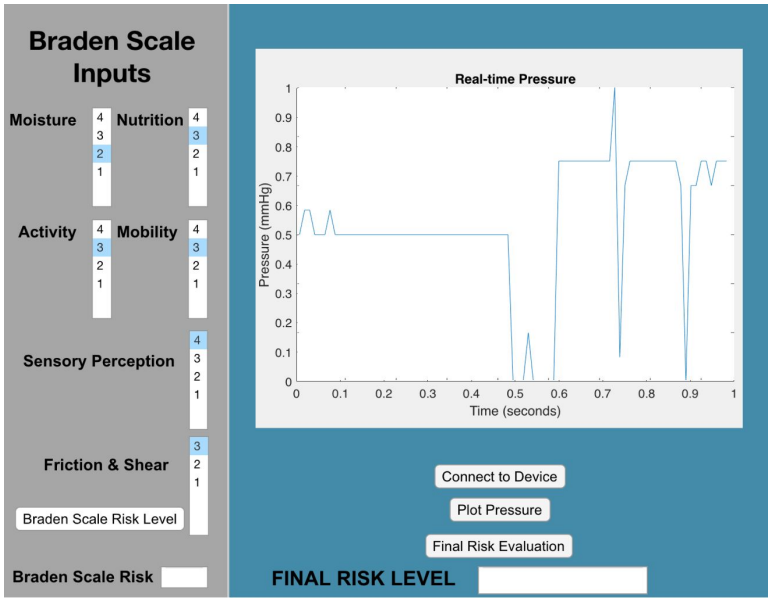


*Figure 9. MATLAB app design for user interface.*

## Validation of Design

To validate the functionality of our device, according to our design requirements, we wanted to test the accuracy of the sensor and pressure readings, as well as address practicality of our form factor and user interface. We wanted to validate both our small circular FSR (1.69cm$^2$ sensing area) and our large square FSR (15.68cm$^2$ sensing area) to determine which was more accurate and more applicable to the required heel sensing area. Our team implemented four different tests to validate our design, which included: sensor testing with weights, heel testing, practicality assessment of our form factor, and device cost breakdown.

Sensor Testing with Weights

The first type of testing was validating each FSR using weights. With both FSRs, we used known weights to compare the expected pressure values with the FSR pressure values. Pressure is the normal force applied over the area the force is distributed. The weight provides a

known force placed over the known sensing area of the FSR, which gives a known pressure value. We then compared this known value to the output of the FSR.

The quantitative results were inconclusive, leading us to favor the qualitative/observational results. The known weights were not the shape of either FSR, which meant the force was not evenly distributed over the area as a heel would be. The smaller FSR was difficult to validate with weights due to the small sensing area, which only allowed for small weights. There was also an issue when stacking weights where the higher the weights the higher the error and fluctuation. We speculate the FSR could not capture the force far away from the FSR and the force was not getting distributed over the area effectively. These results were not very useful in fully validating our FSR choice and design, leading us to move forward with more realistic pressure scenarios using heel testing.

Heel Testing

The next step in validation testing was performing human subject tests with actual heel pressure values rather than weights, as allowed by the Union College Human Subjects Review Committee [27]. We conducted tests on six different subjects using the PASCO force plate and both FSRs to calculate the normal force at the heel. For both the force plate and the FSRs, we followed the protocol detailed in Figure 10.

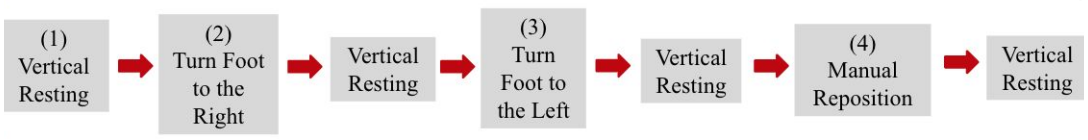


*Figure 10. Protocol for heel testing with PASCO force plate and FSR with subjects.*

The force plate allowed us to collect data illustrating normal forces occurring at the heels of subjects lying down on their backs, in supine position, with and without the foam dressing (set

up shown in E-1). This data allowed us to generate benchmark pressure values that will be a useful comparison tool for the future of our product and for those who want to understand forces at the heel. Table 5 shows the results for average pressure at the heel in a resting supine position.

*Table 5. Pressure data of subjects in a resting supine position with and without silicone foam dressing.*

| Subjects | Pressure without foam (mmHg) | Pressure with foam (mmHg) | Change in Pressure (mmHg) |
|---|---|---|---|
| 1 | 462.18 | 446.42 | 15.76 |
| 2 | 582.38 | 519.15 | 63.23 |
| 3 | 432.51 | 412.68 | 19.84 |
| 4 | 434.20 | 396.48 | 37.72 |
| 5 | 499.15 | 482.91 | 16.24 |
| 6 | 512.12 | N/A | N/A |
| | | Average | 30.56 |
| | | STDEV | 20.36 |

The results show that the resting position results in pressure values within the range of 400-580 mmHg. This data allowed us to better understand pressure at the heel when an individual is lying down. The results also address how silicone foam dressings provide pressure relief. This is shown by a decrease in pressure at the heel when the silicone foam dressing was applied. Moving forward, this was helpful in benchmarking these values against our FSRs.

In comparing the FSR pressure values to the force plate pressure values, we found that the large square FSR fluctuated greatly and gave pressure values that were significantly different from those determined from the force plate. As shown in Figure 11, the smaller FSR had comparable pressure values to those given by the force plate, and both the force plate and FSR registered changes in pressure as the subject readjusted. When the patient follows the protocol, this can result in a positive or negative change in pressure depending on how the heel is moved. This is not consistent over each time the protocol is performed and can vary between subjects.

The important aspect of the peaks shown in Figure 11 is that both the force plate and the FSR can sense changes in pressure. While the peaks do not perfectly match up as a result of timing differences in the protocol, both curves show a significant change in pressure, which is what is required for the functionality of our system. This validates that our device can accurately sense pressure values, as well as change in pressure at the heel, which is the primary objective of our design.

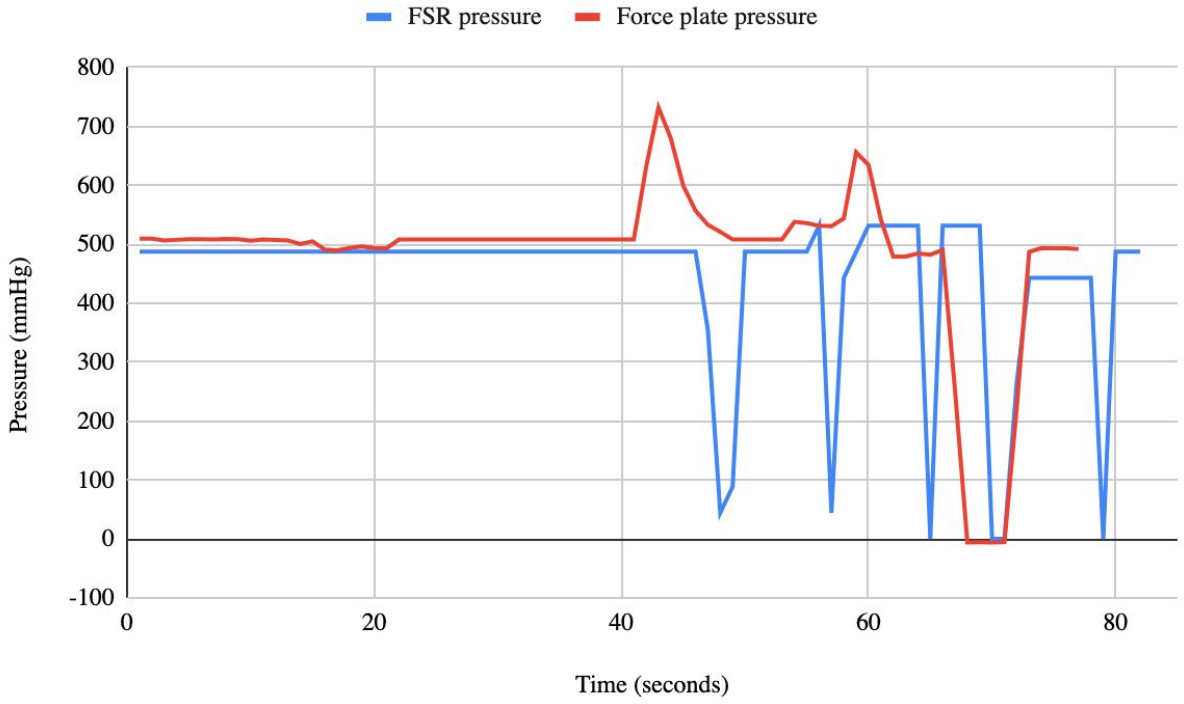


*Figure 11. Using the testing protocol, the FSR pressure was compared to the force plate pressure of the same test subject without foam.*

Through testing, we also wanted to quantify the area of the heel where force is being distributed when in a supine position. After force plate testing, we used ink to stamp the heel of the subjects as they rested in a supine position to determine the average sensing area. We also measured the width of the largest part of the subject's heel with calipers to determine the required width of the form factor. The results, shown in Table 6, provide information to help

address the necessary sensing area of the heel we are working with. This will allow for more customizable heel sensing options in the future, where FSR sensing area is optimized.

*Table 6. Measurements of heel sensing area using ink blots and callipers on 6 subjects.*

| Subjects | Heel Width (cm) | Total Area (cm^2) |
|---|---|---|
| 1 | 5.10 | 25.13 |
| 2 | 5.00 | 20.73 |
| 3 | 5.18 | 17.91 |
| 4 | 6.04 | 32.99 |
| 5 | 4.90 | 26.70 |
| 6 | 4.50 | 24.13 |
| Average | **5.12** | **24.60** |
| STDEV | **0.47** | **4.74** |

Practicality Testing: Form Factor

To validate our form factor design, we met with Kathleen Capone, the AMC nurse we had previously met with, to help assess the practicality of our form factor and user interface in the clinical setting. Kathleen assessed our form factor and thought the VELCRO strap was extremely easy to work with and helpful for getting the device on and off a patient. She also stated that a strap that holds the device firmly in place is useful for patients with increased mobility. She also addressed the benefit of having a wireless connection and said she knew many nurses who would love that the device is completely wireless due to hospital rooms being constantly overtaken by wires. She also validated our user interface app on it's easy to interpret display and integration into their work routine. She also acknowledged that the silicone foam dressing is commonly used and is a great material for the form factor. Although this is one nurse's opinion, we found her feedback to be very useful for validating our design format.

Device Cost Breakdown:

As previously mentioned, other sensor system devices on the market like the BodiTrak2 cost upwards of $1,000 [18]. As shown in Table 7, the bulk cost for 30 units of our device would be $1,085.95 with a unit price of $36.18. The bulk cost of our device is similar to the cost of a single BodiTrak2 device, which highlights the cost benefit of our system in comparison to other devices on the market.

*Table 7. Cost breakdown of our device.*

| | Unit Price | Bulk Price (30) |
|---|---|---|
| Foam Dressing [27] | $7.66 | $230.00 |
| VELCRO strap [29] | $1.73 | $52.00 |
| FSR [30] | $6.30 | $189.00 |
| Silicone Insert [31] | $1.49 | $44.95 |
| Microcontroller with Bluetooth [32] | $19.00 | $570.00 |
| Total | $36.18 | $1,085.95 |

**Anticipated Regulatory Pathway**

The Leaf Patient Monitoring System, which was previously mentioned in the prior art section, went through the 510(k) clearance process in 2014. This device's regulatory pathway would be very similar to that of our device. The Leaf system's 510(k) number was K141877 and the applicant was Leaf Healthcare Incorporated (755 N Mathilda Avenue, Suite 100 Sunnyvale, CA 94085). Its classification product code was KMI with regulation description of bed-patient monitor and it was considered a Class I device. The review panel was General Hospital with a

Regulation Number of 21 CFR 880.2400 [33]. The identification description for the Leaf system was: "A bed-patient monitor is a battery-powered device placed under a mattress and used to indicate by an alarm or other signal when a patient attempts to leave the bed." The classification description was: "Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in 880.9 [34]."

In 2014, the Leaf system was deemed substantially equivalent to the predicate device DynaSense System by Centauri Medical, Inc [35]. The Leaf sensor is a continuous patient monitoring for pressure ulcer prevention and it notifies when movement deviates from set parameters and is used in medical, nursing, and long term care facilities. The Leaf sensor is attached to the patient with an adhesive on the chest [19].

Our device might encounter different pathways to be cleared by the FDA. Since our device does not use an adhesive and does not demonstrate patient movement, it may require less controls than the Leaf sensor. For example, the BodiTrak2 system, mentioned in the prior art section, is 510(k) exempt and is just FDA listed [22]. Our system is very similar to the BodiTrak2 except for the fact that our device is enclosed in a heel cup and has a different risk algorithm. Overall, our device would be considered Class I and require either 510(k) clearance or even be exempt considering the noninvasive nature of our device.

**Conclusion**

We have developed a low-cost individual pressure ulceration risk system that integrates existing hospital procedures with an easy to interpret user interface and a form factor with simple

implementation. We also validated that our design gives accurate pressure readings for the heel region of 6 subjects and that our design would be practical in a hospital setting based on nurse feedback.

Our project has many possible future directions. One would be miniaturization of electrical components so that they fit seamlessly into the heel cup form factor. Another would be modularizing our design. This would involve the one time purchase of our reusable electrical component and buying the form factors repeatedly. We could also expand our scope to include form factors for multiple bony prominences. Eventually, we would also like to improve the usability of our user interface app. Finally, we could do human trials to assess the validity of our risk algorithm.

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# Appendix A

## BRADEN SCALE – For Predicting Pressure Sore Risk

**SEVERE RISK**: Total score ≤ 9 **HIGH RISK**: Total score 10-12
**MODERATE RISK**: Total score 13-14 **MILD RISK**: Total score 15-18

| RISK FACTOR | SCORE/DESCRIPTION | | | | DATE OF ASSESS ➡ | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | 1 | 2 | 3 | 4 |
| **SENSORY PERCEPTION** Ability to respond meaningfully to pressure-related discomfort | **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 surface. | **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. | **3. SLIGHTLY LIMITED** – Responds to verbal commands but cannot always communicate discomfort or need to be turned, **OR** has some sensory impairment which limits ability to feel pain or discomfort in 1 or 2 extremities. | 4. **NO IMPAIRMENT** – Responds to verbal commands. Has no sensory deficit which would limit ability to feel or voice pain or discomfort. | | | | |
| **MOISTURE** Degree to which skin is exposed to moisture | 1. **CONSTANTLY MOIST**– Skin is kept moist almost constantly by perspiration, urine, etc. Dampness is detected every time patient is moved or turned. | 2. **OFTEN MOIST** – Skin is often but not always moist. Linen must be changed at least once a shift. | 3. **OCCASIONALLY MOIST** – Skin is occasionally moist, requiring an extra linen change approximately once a day. | 4. **RARELY MOIST** – Skin is usually dry; linen only requires changing at routine intervals. | | | | |
| **ACTIVITY** Degree of physical activity | 1. **BEDFAST** – Confined to bed. | 2. **CHAIRFAST** – Ability to walk severely limited or nonexistent. Cannot bear own weight and/or must be assisted into chair or wheelchair. | 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. | 4. **WALKS FREQUENTLY**– Walks outside the room at least twice a day and inside room at least once every 2 hours during waking hours. | | | | |
| **MOBILITY** Ability to change and control body position | 1. **COMPLETELY IMMOBILE** – Does not make even slight changes in body or extremity position without assistance. | 2. **VERY LIMITED** – Makes occasional slight changes in body or extremity position but unable to make frequent or significant changes independently. | 3. **SLIGHTLY LIMITED** – Makes frequent though slight changes in body or extremity position independently. | 4. **NO LIMITATIONS** – Makes major and frequent changes in position without assistance. | | | | |
| **NUTRITION** Usual food intake pattern<br>[1]NPO: Nothing by mouth.<br>[2]IV: Intravenously.<br>[3]TPN: Total parenteral nutrition. | **1. VERY POOR** – Never eats a complete meal. Rarely eats more than 1/3 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[1] and/or maintained on clear liquids or IV[2] for more than 5 days. | **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. | **3. ADEQUATE** – Eats over half of most meals. Eats a total of 4 servings of protein (meat, dairy products) each day. Occasionally refuses a meal, but will usually take a supplement if offered, **OR** is on a tube feeding or TPN[3] regimen, which probably meets most of nutritional needs. | 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. | | | | |
| **FRICTION AND SHEAR** | 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. | 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. | 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 at all times. | | | | | |
| **TOTAL SCORE** | **Total score of 12 or less represents HIGH RISK** | | | | | | | |

| ASSESS | DATE | EVALUATOR SIGNATURE/TITLE | ASSESS. | DATE | EVALUATOR SIGNATURE/TITLE |
|---|---|---|---|---|---|
| 1 | / / | | 3 | / / | |
| 2 | / / | | 4 | / / | |

| NAME-Last First Middle | Attending Physician | Record No. | Room/Bed |
|---|---|---|---|
| | | | |

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**BRADEN SCALE**



Figure 1. Braden scale evaluation sheet [8].

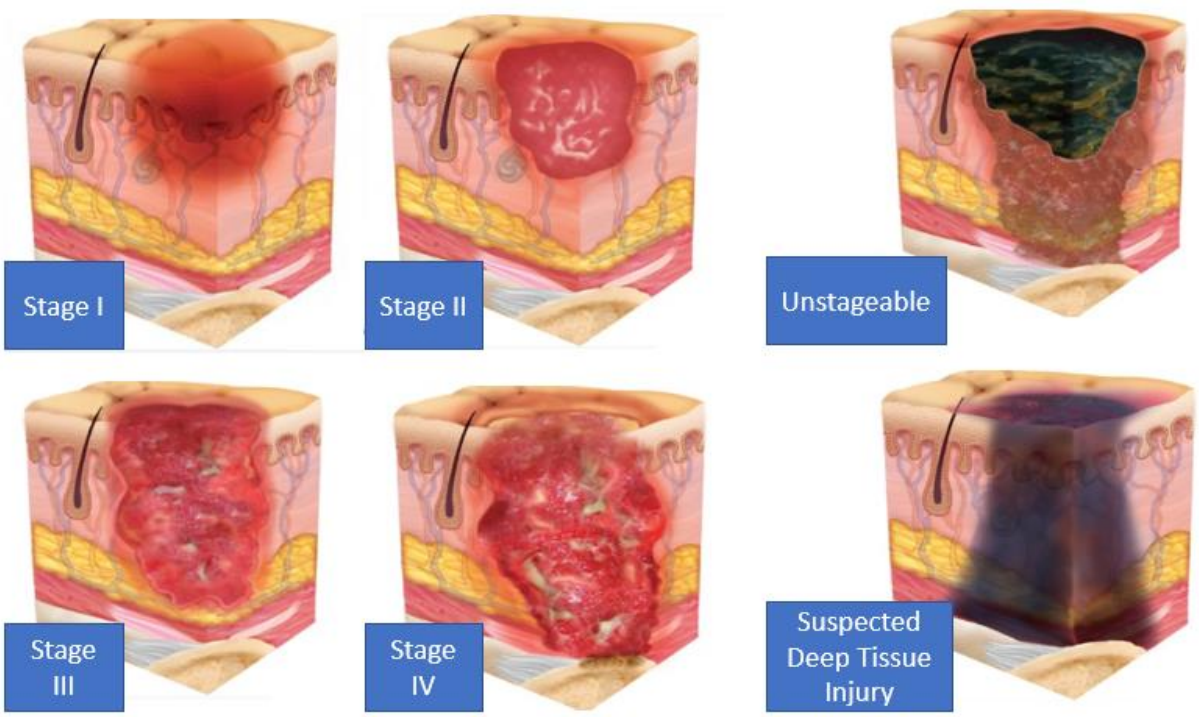


Figure 2. Pressure ulcer stages I-IV, unstageable, and suspected deep tissue injury [9].

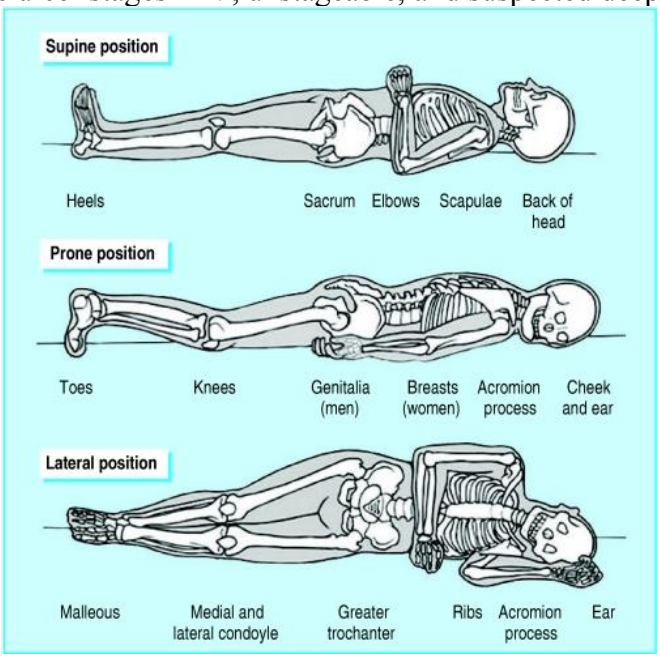


Figure 3. Bony prominences where pressure ulcers commonly occur due to the close proximity of bone to the skin [10].

## Appendix B

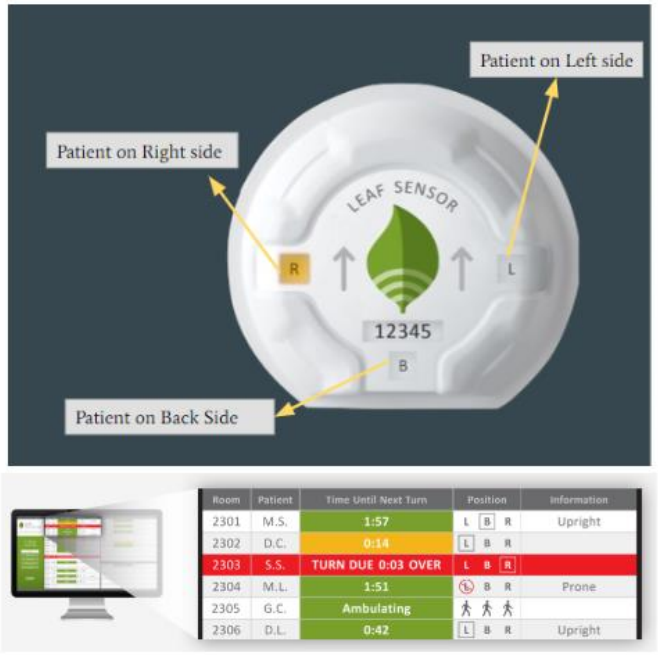


Figure 1. The Leaf sensor is a disposable, wireless stick on sensor that provides information about the patient's mobility to a computer interface [19].

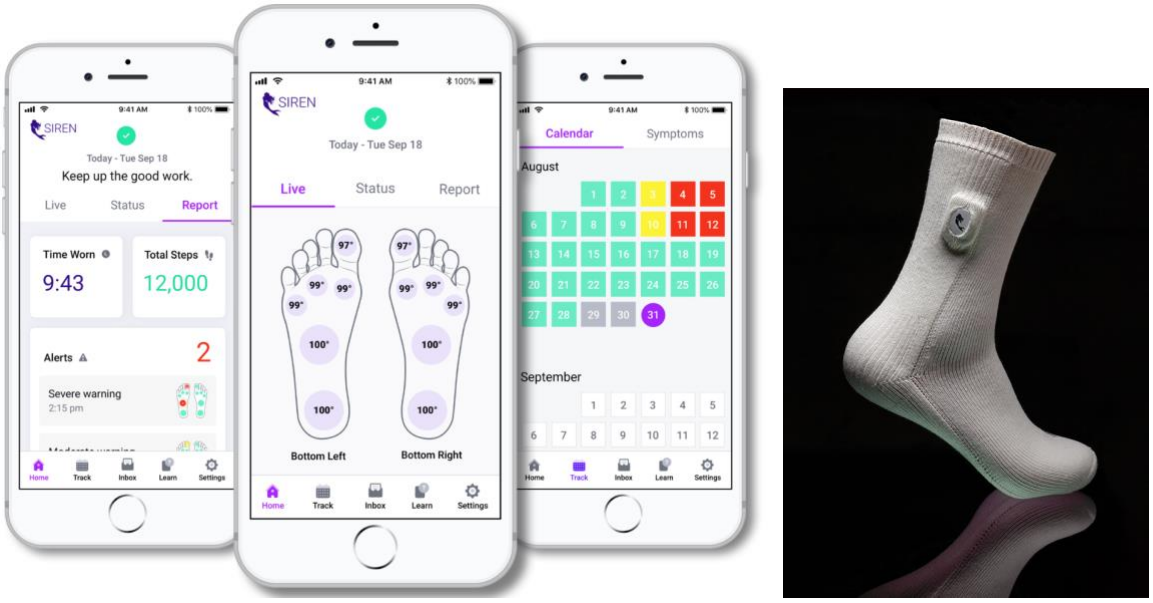


Figure 2. Siren socks are one brand of temperature sensing socks that monitor inflammation, thereby assessing the risk of pressure ulcer formation [20].

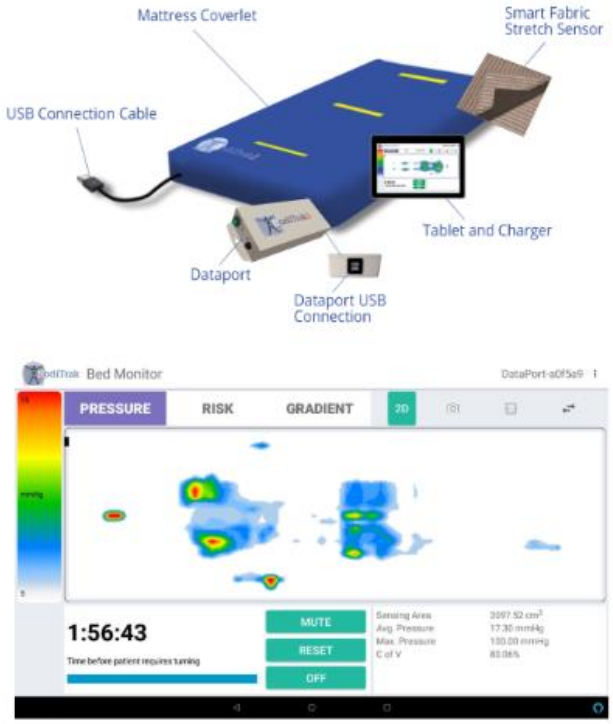


Figure 3. The Boditrack2 bed system provides real-time pressure readings to assist caregivers in correctly repositioning patients who are at risk of developing pressure ulcers [22].

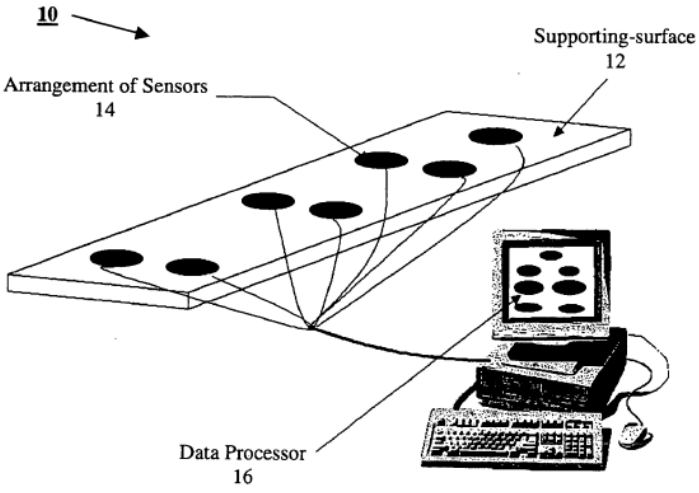


Figure 4. Method and System for Determining a Risk of Pressure Ulcer Onset [23].

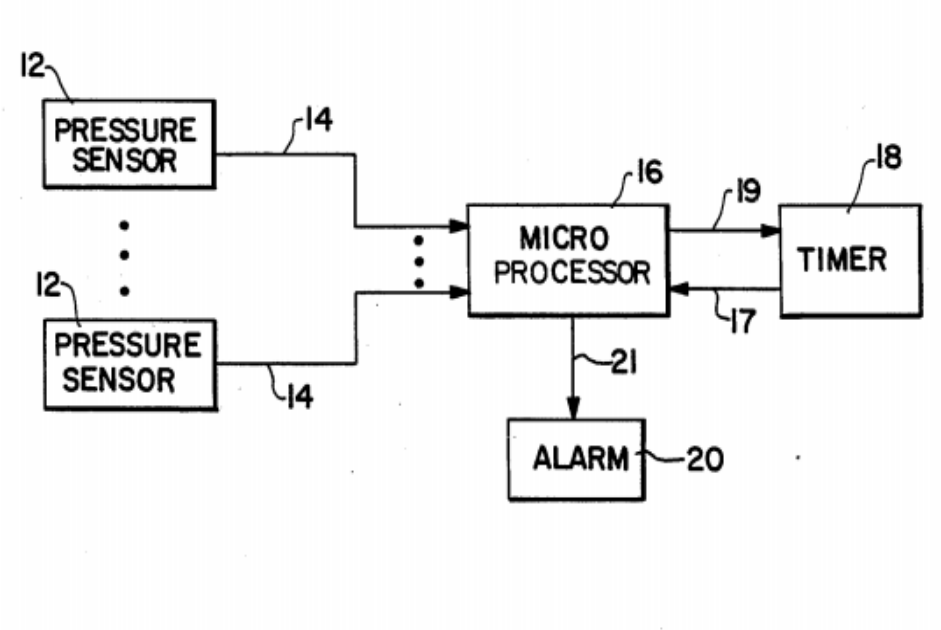


Figure 5. Pressure Sensing Device and Method for Preventing Ulcer Formation [24].

## Appendix C

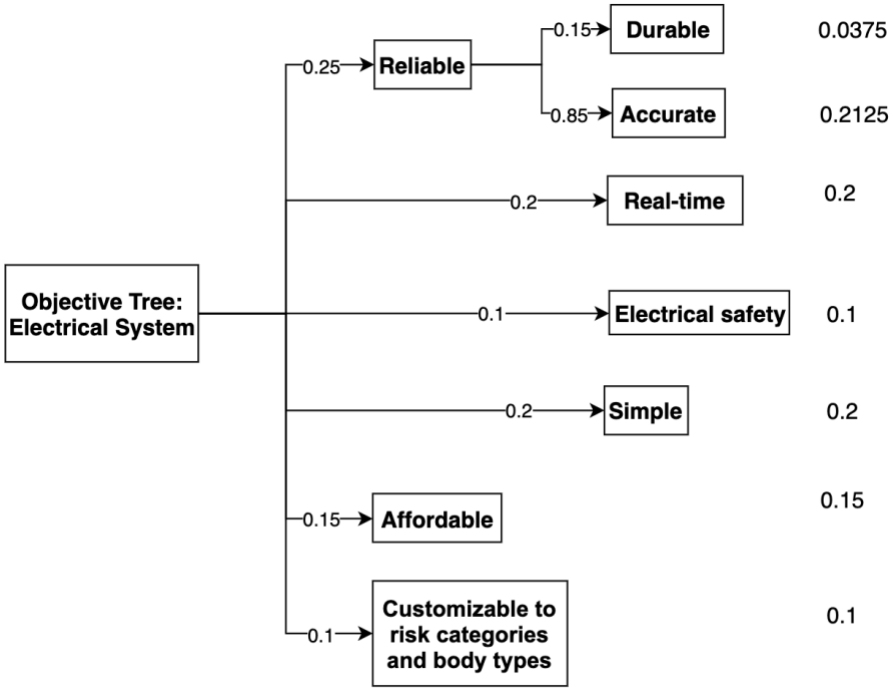


Figure 1. Entire objective Tree with weights for the electrical system component of the pressure ulcer prevention system.

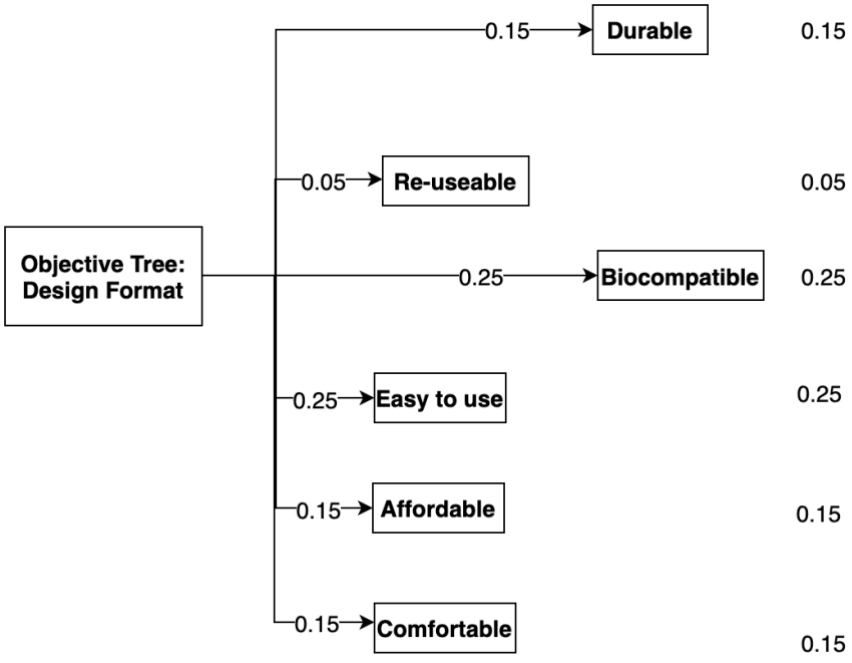


Figure 2. Entire objective Tree with weights for the design format component of the pressure ulcer prevention system.

**Appendix D**

Functions:

1. Detect pressure ulcer risk
    a. Receive Braden Scale inputs
    c. Detect pressure at heels
    d. Track pressure over time
2. Display visual of pressure over time
3. Combine Braden Scale inputs and pressure over time to determine the overall risk of developing a HAPU
4. Categorize risk into risk levels
5. Display final ulceration risk level

| Function | Metric | Unit | Marginal Value | Ideal Value | Specification Type |
|---|---|---|---|---|---|
| Receive Braden Scale inputs | Input Raw Data | Binary yes or no | N/A | N/A | Binary |
| Detect pressure | Pressure Range | mmHg | 0-500[25] | 0-700[25] | Objective & Numeric |
| Track pressure over time | Time | Hours | 1 [5] | Continuous | Objective & Numeric |
| Display visual of pressure over time | Displays visual | Binary displays or does not display | N/A | N/A | Binary |
| Categorize pressure ulcer risk | Risk Level | N/A | 3 Levels | 5 Levels | Objective |
| Display Ulceration Risk | Notification mode | Binary yes or no | N/A | N/A | Binary |

**Appendix E**

Figure 1. Heel testing set up showing a subject in a supine position.