Smart Cushion: A Device to Reduce the Risk of Pressure Ulcer Formation

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Abstract

Pressure ulcerations, a result of tissue ischemia, are a serious medical condition affecting over 2 million individuals in the US every year and incur costs of approximately $11 billion[1,2]. Among those individuals at high risk are the elderly and wheelchair bound. This proposed device is a wheelchair cushion that is intended to reduce the risk of pressure ulcer formation based on an algorithm to regulate interface pressure at discrete points and temperature via a feedback mechanism. Currently, there are no commercially available wheelchair cushions with these capabilities. Recent studies indicate that tissue ischemia has a higher probability of occurring when prolonged or excessive interface pressure is accompanied by an increase in skin surface temperature. This device will consist of an array of temperature and pressure sensors implemented within a cushion composed of individual fluid-filled bladders. The sensors will collect temperature and pressure data in real time. This information will be sent to a microprocessor to drive actuators that adjust local pressure and activate a thermoregulation system, thereby reducing the user's overall pressure ulcer formation risk.

Introduction

A. *Pathology of Pressure Ulcers*

Infections from pressure ulcers directly result in the hospitalization of approximately 65,000 individuals per year [3]. Traditionally, pressure ulcers are defined as a localized injury of the skin over a bony prominence, resulting from pressure in combination with shear stresses and friction [4]. When in the sitting position, the two areas of maximum interface pressure applied to the gluteal tissue are the ischial tuberosities.

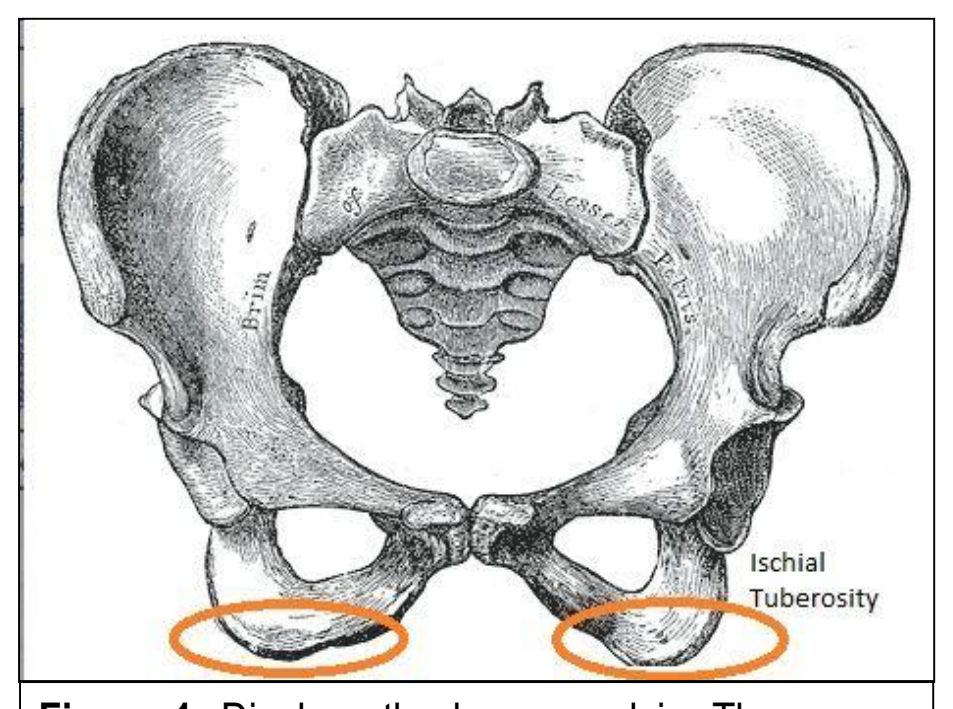


Figure 1. Displays the human pelvis. The orange circles used to highlight two bony protrusions are indicating the location of the ischial tuberosities. The ischial tuberosities is where the most max pressure points are located in a seated individual. Image retrieved from: https://s-media-cache-ak0.pinimg.com/736x/bc/b0/27/bcb027dbc2e4c674 58ba59024371dcc3.jpg

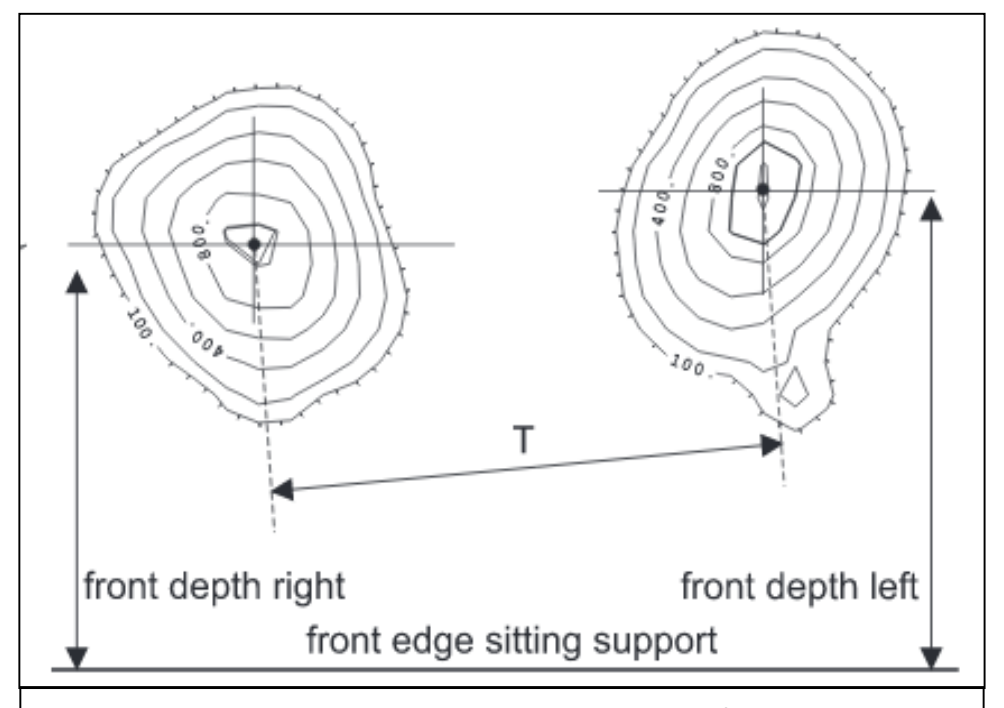


Figure 2. Displays the general interface pressure gradient under the ischial tuberosities when an individual is seated. T, the distance between the two max pressure points is 12.4 cm. A 1 cm distance is the average distance between pressure lines which in indicates a statistically significant increase in pressure moving away from the max pressure point. Image retrieved from Lauchenbruch et al.

A recent study conducted by Lauchenbruch et al., has correlated tissue ischemia to subsequent ulcer formation [5]. Their research shows that two of the most influential factors affecting the level of tissue ischemia are increased skin surface temperature and interface pressure at the surface of the skin.

B. *Ideal conditions for Tissue Ischemia*

Measurements of reactive hyperaemia via doppler flowmetry that Lauchenbruch et al. used in their study determined that at temperatures above 32ºC in conjunction with the application of pressure up to 13.3 kPa, there was a statistically significant increase in the level of tissue ischemia observed. Additionally, the research found that a 1ºC increase in temperature has the same effect on tissue ischemia formation as a pressure increase of up to 15 mmHg, and the risk for pressure ulcer formation begins to increase at an interface pressure of 115 mmHg [6].

Overview of Methods & Materials

Figure 3. Smart Cushion device mounted on a standard wheelchair. Due to limited budget a prototype displaying proof of concept was constructed. The bladders are only present in the defined area where max interface pressure occurs. A stiff foam encompasses the areas around the maximum pressure to support the rest of the gluteus and legs. The slits in the cushion are to ensure ventilation so the air flow generated thermoregulation

Bladder:
- 30 MIL flexible PVC
- Bonded via Oatey X15 Adhesive

Foam:
- High Density Foam Upholstery Foam Padding
- 55lb Compression

Pressure Sensors:
- Piezoresistive FlexiForce sensor
- One on top of each bladder

Temperature Sensosr:
- Digital non-contact thermopile
- Melexis MLX90614

Base Frame:
- Aluminum alloy 6061

Specifications & Requirements

#	Requirements	Specification	Justification
1	Device must measure interface pressure of the gluteal tissue.	Pressure sensors must measure interface pressure in range of 0-250 mmHg ± 1 mmHg.	Current commercially available PU pressure redistribution devices contain sensors that measure in this range. Studies shows that ulcers form at the gluteal-seat interface at a pressure of 115 ± 15 mmHg [6].
2	Device must measure surface temperature of gluteal tissue.	Temperature sensors must be able to measure surface temperatures from -30 to 50ºC with an accuracy of ± 0.5ºC.	Average skin surface temperature is 24ºC ± 1.2. A study determined that tissue temperatures of −30 ° C and colder were always associated with complete necrosis. Another study found that at 50° C, cell death occurs within 2–3 min.
3	Device must adjust pressure at discrete regions of the gluteal tissue.	Device must adjust pressure for an area of 5.0 cm ± 0.2 cm by 5.0 cm ± 0.2 cm inside IT area and 10.0 cm ± 0.2 cm by 10.0 cm ± 0.2 cm outside IT area	An assumption was made that the pressure reading at the sensor is valid for a uniform distance of 2.5 cm (inside IT area) and 5 cm (outside IT area) in any direction, creating 5 cm by 5 cm or 10 cm by 10 cm square regions. This is an overestimation of pressure, which will ensure more readjustment, thereby reducing likelihood of entering the Risk Zone.
4	Device must adjust surface temperature of the gluteal tissue.	Device must decrease the temperature at areas of skin contact to below 32 ºC or by 1 ºC based on baseline temperature within 20 minutes from when the skin temperature reaches 32 ºC or higher.	The relative contributions of interface pressure, shear stress, and temperature on tissue ischemia indicate that a 1.0° C increase in temperature has 14.33 times as much of an effect on pressure ulcer formation as a 1 mm Hg increase in interface pressure.

Device Design Features

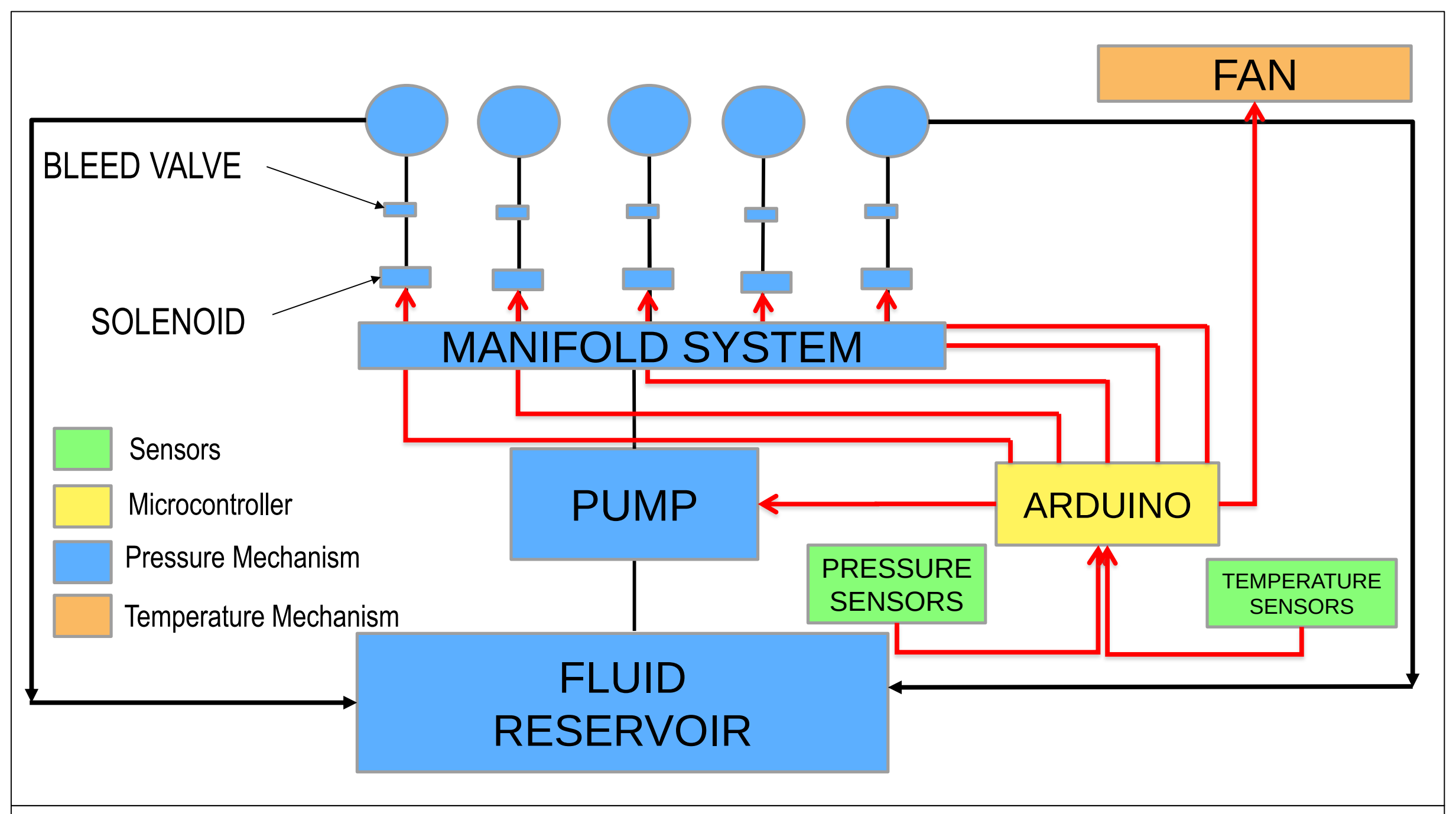


Figure 4. Displays a schematic outlining the integration of the pressure mechanism, temperature mechanism, and the microcontroller. At rest, each bladder with be filled to an internal pressure of 25 psi in order to support the maximum device rated weight of 200 pounds. If the gluteal-bladder interface pressure becomes too high as predefined by the risk zone at a specific bladder(s) then the exist solenoid corresponding to the bladder will open allowing for fluid to flow out at rate controlled by the outlet solenoid. To refill the bladders, the inlet solenoid will open allowing the pump to push fluid into the bladder(s), returning the bladder(s) to their original volume . A 12V battery will be used to power all of the device components.

Pressure & Thermoregulation Algorithms

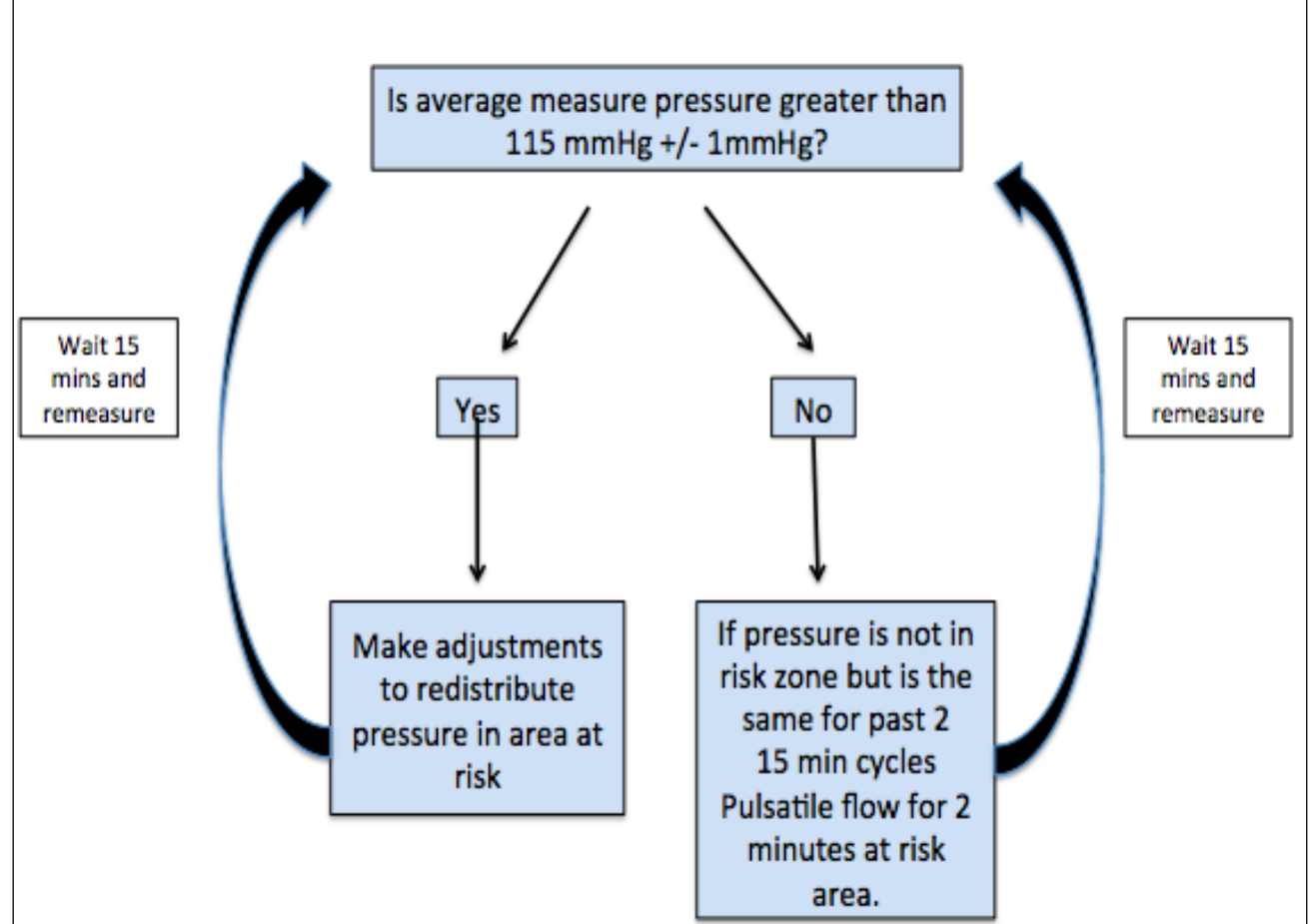


Figure 5. Displays the algorithm developed for control of the pressure regulation. Risk of pressure ulcer formation significantly increases at a pressure of 115 ± 15 mmHg, for a duration of 15 minutes or longer [6]. Piezoresistive pressure sensors will send signals to the microcontroller, where software will implement the algorithm diagrammed. If the pressure readings indicate an increased risk for ulcer formation, the fluid reservoir, pump, and manifold system, in conjunction with solenoid will be activated to displace fluid and thereby regulating pressure at discrete points.

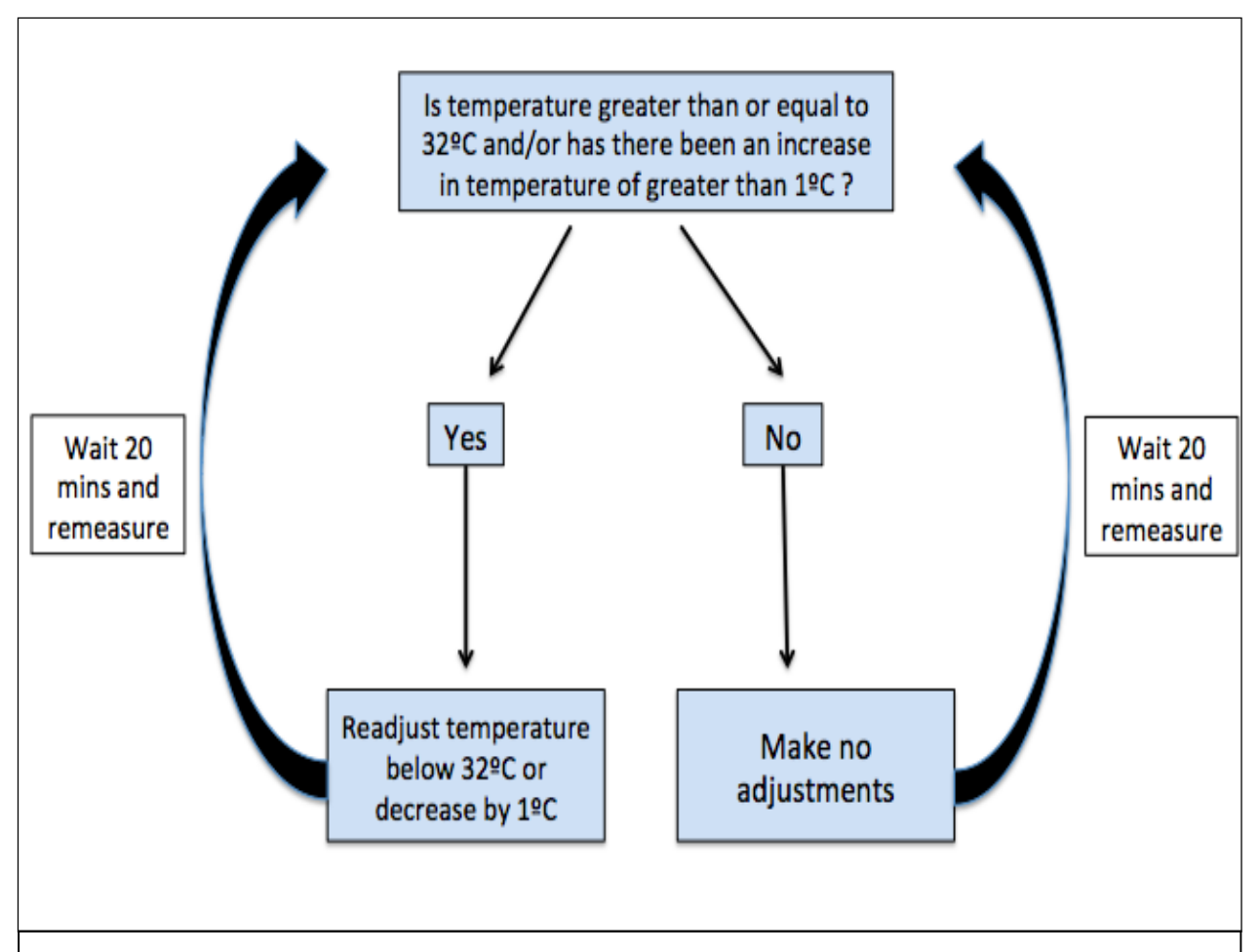


Figure 6. Displays the algorithm developed for control of the thermoregulation mechanism. The Smart Cushion is specified to maintain skin surface temperature below 32ºC and prevent a 1ºC increase from the user's baseline skin temperature. If the temperature readings indicate that the user is at an increased risk for pressure ulcer formation, the thermoregulation mechanism will be activated. This system incorporates a fan and nozzle; it will generate airflow across the cushion, and dissipate heat radiating from the skin.

Integrated Circuitry

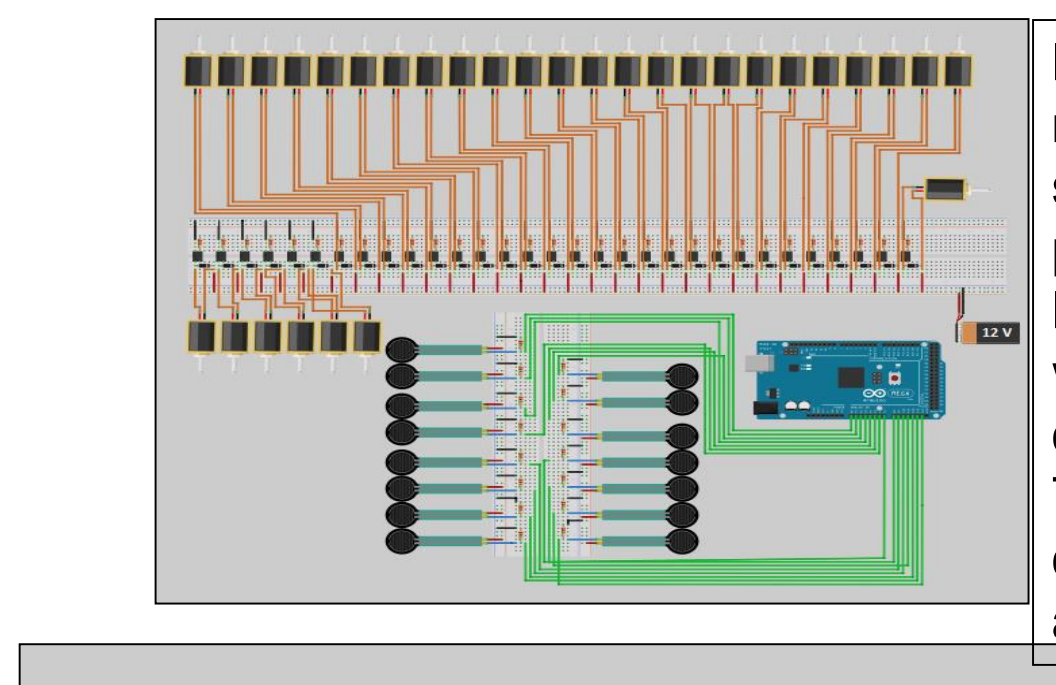


Figure 7. Displays the circuitry for the pressure regulation mechanism. 15 peizoresistive FlexiForce sensors are implemented in the cushion device. The pressure sensors are part of a voltage divider with 2.2 MΩ resistors voltage is taken between the two resistors via analog pins. A solenoid driver was needed for each of the 30 solenoids to supply the needed 12V of power. They are activated when their corresponding Arduino digital pin outputs high and turn off when the pin outputs are low.

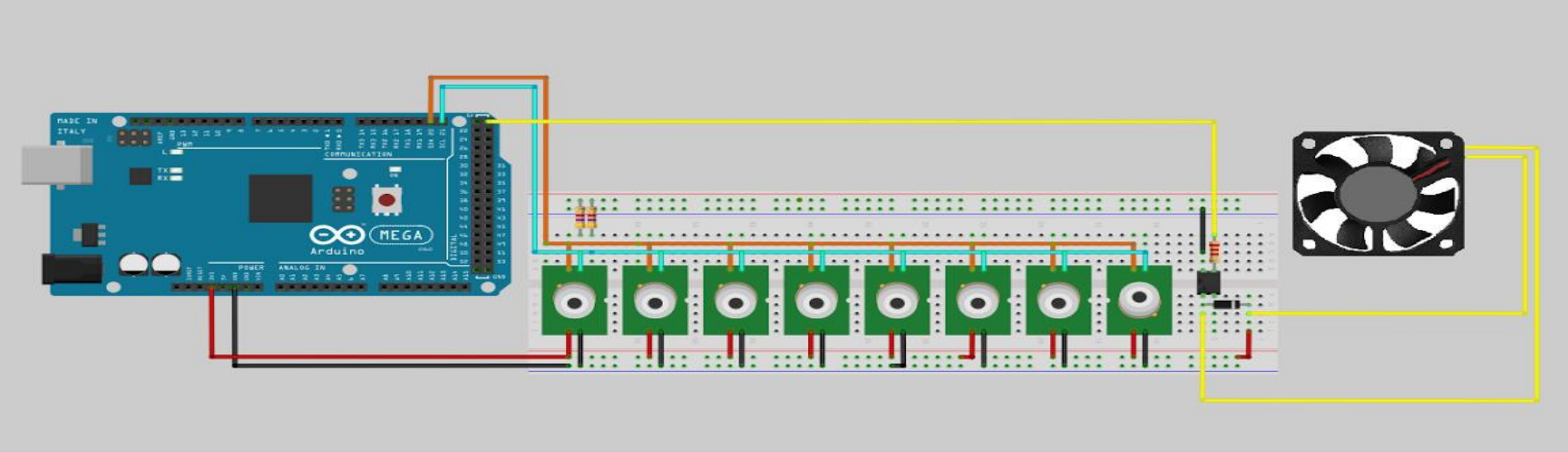


Figure 8. This schematic shows the circuitry for the. The bottom box are the 8 infrared temperature sensors. They are implemented using i2c. Each of them have their own i2c address to read temperature from each one of them.

Manufacturing & Testing

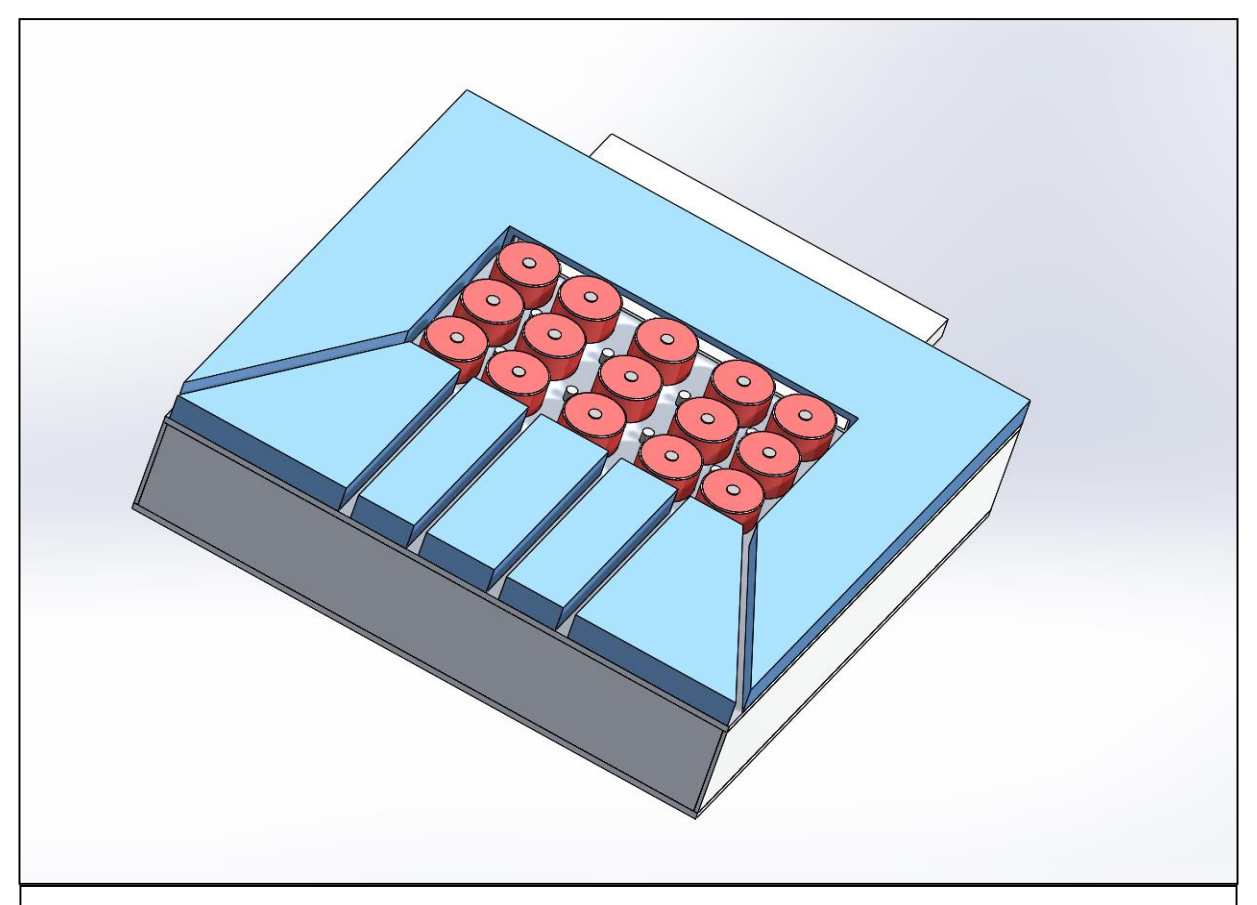


Figure 9. Displays a solid works representation of the Smart Cushion Device. Using a Vacuum Former to manufacture the bladders, sheets of flexible was heated, then pressed down on a mold of the desired bladder shape. Suction was applied for 30 seconds to form the bladders. Threaded Hex PVC pipe bushings were friction welded to the PVC shower pan liner at 1200 rpm create a bladder-frame interface. Oatey X15 PVC adhesive was used to adhere the top final bladder configuration. The seam failure stress, tested using an Instron mechanical testing frame was 50 psi ± 1.8.

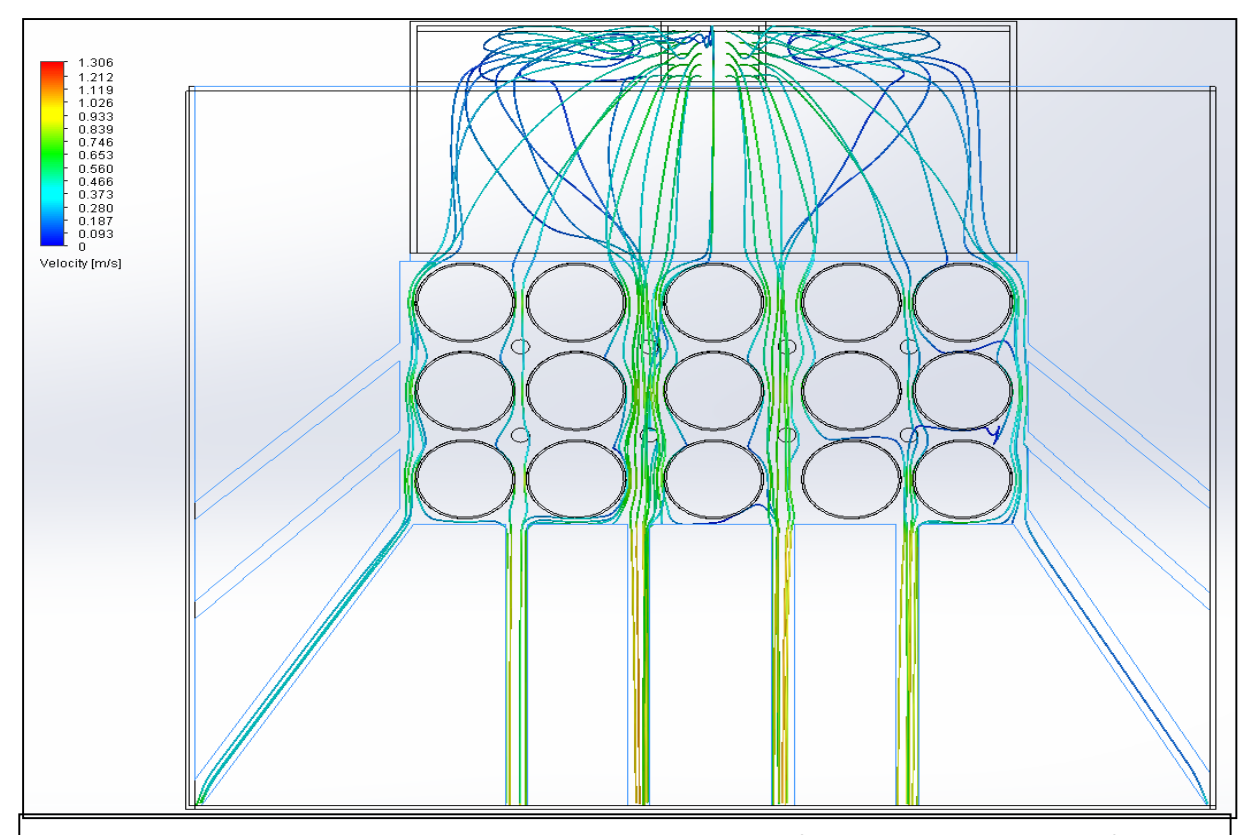


Figure 12. A diagram displaying airflow analysis of the thermoregulation mechanism. Using SolidWorks' FloXPress Analysis wizard, an investigation was performed to determine the air velocity traveling around the water bladders from the air nozzle that is connected to the fan. At a fan speed of 2 CFM, one-fifth of its maximum volumetric airflow rate, an airflow velocity between approximately 0.280 m/s and 0.746 m/s was generated This is about 2 to 5 times that of the maximum anticipated air velocity required to cool the skin surface temperature by 1ºC.

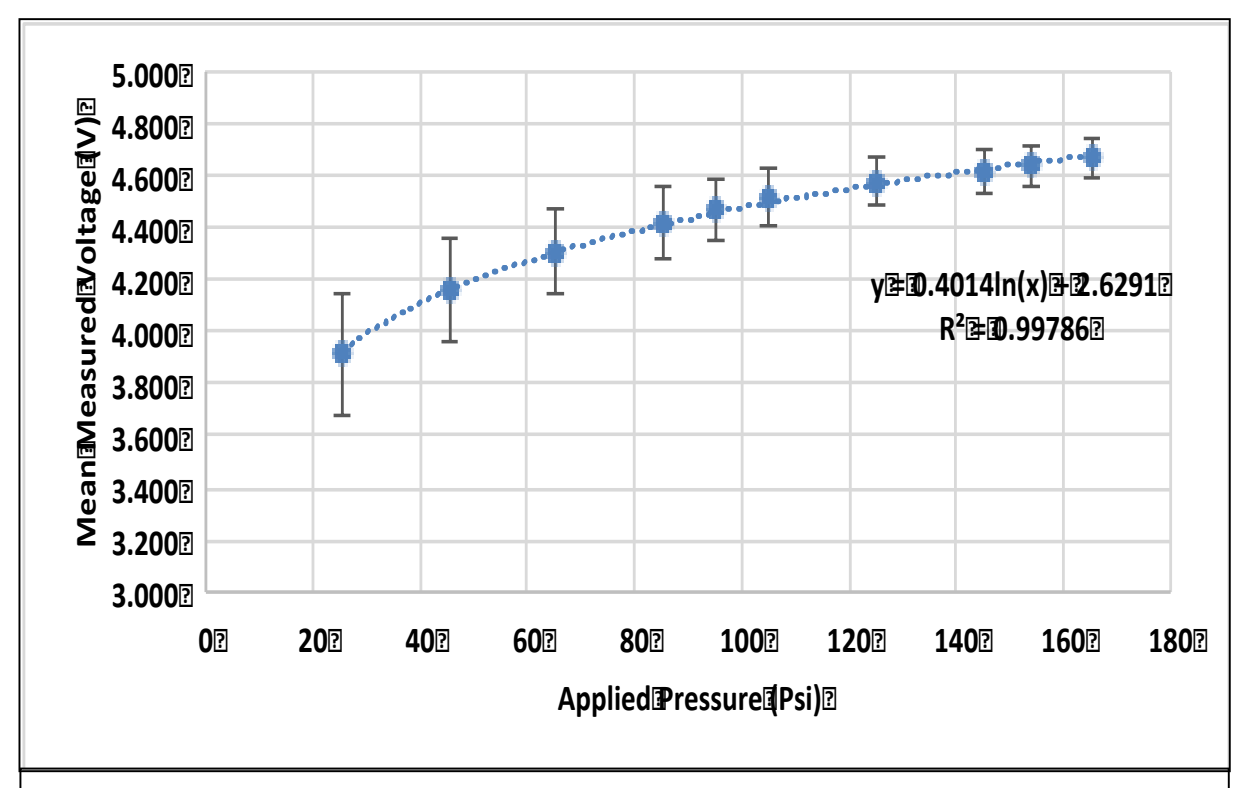


Figure 13 Displays a pressure sensor calibration curve. Corresponding voltage values obtained from this testing are used in the coding for the algorithm used for pressure regulation in order to actuate the pressure redistribution system when the applied load is within the "Risk Zone". A logarithmic trend line was used via Microsoft Excel to fit the data, with an R squared value of 0.9979.

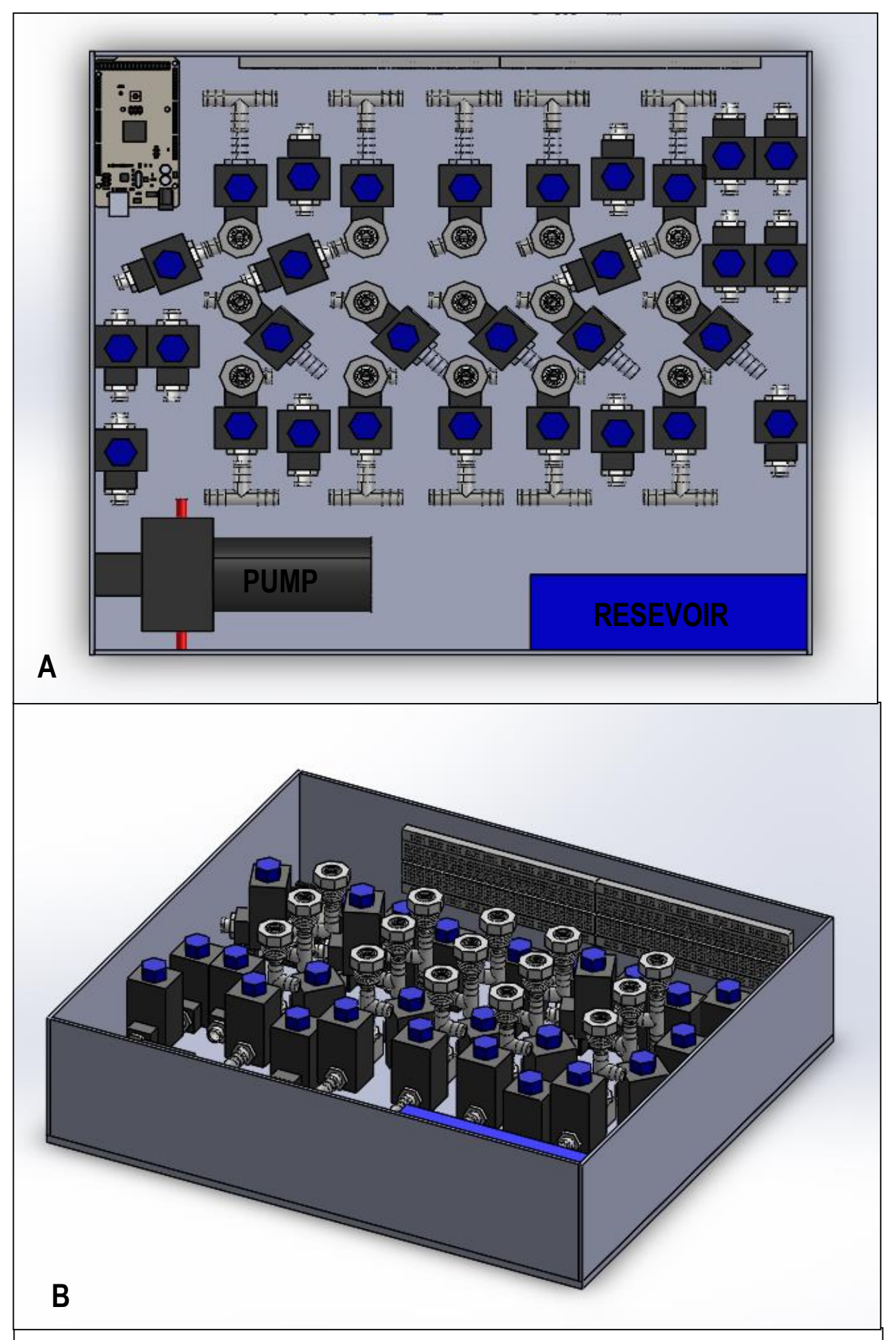
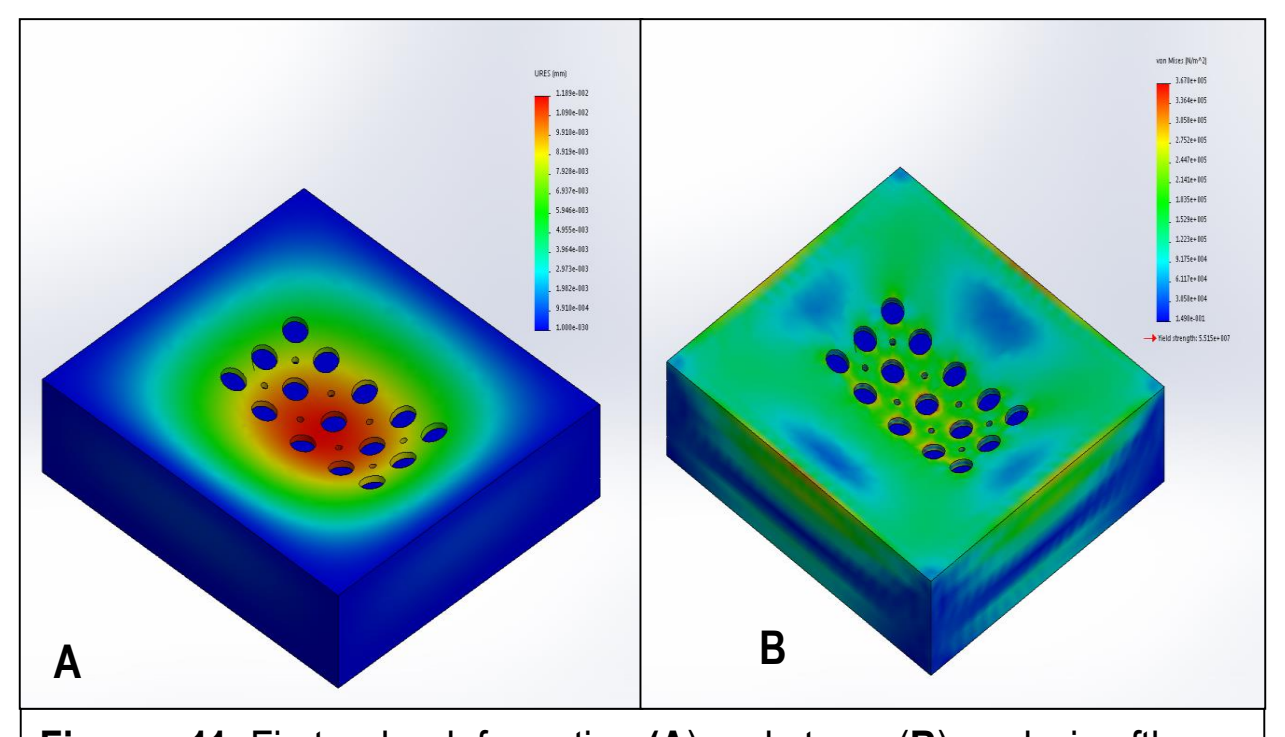


Figure 10. Shows the solenoid, pump, fluid reservoir, and microcontroller placement in the interior of the Smart Cushion Device. For visual purposes the wires and tubing connecting the individual components is not included in this image.



Figures 11. First order deformation (**A**) and stress (**B**) analysis ofthe Aluminum Alloy 6061 device mainframe using SolidWorks simulation.

Thermocouple thermometer skin surface (°C)	Infrared temperature (°C)	Abs. value of the temperature difference
32.78	32.89	0.11
32.78	33.11	0.33
32.78	32.67	0.11
32.78	32.83	0.05

Table 1. Research conducted to test the effectiveness of an emissivity value of 0.73 when measuring skin surface temperature beneath jean fabric with IR sensors. True skin surface temperature was recorded via a thermocouple. A two-sample t-test (α=0.05) determined there was no statistically significant difference between the methods of measurement (p-value =0.37).

Verification of the device's pressure sensing capabilities will be accomplished by placing sandbags of known weights concentrated over predefined areas to simulate interface pressure. To verify temperature-sensing abilities saturated sponges with various known temperatures will be applied to the device. Validation of the device's pressure and temperature redistribution mechanisms will involve human subject testing to ensure activation of the redistribution mechanisms, namely a decrease in the individual fluid-filled bladder's stiffness and the activation of a cooling air flow.

Conclusion

Pressure ulcers currently impose a significant, financial burden on the US health-care system and reduce the quality of life of bedridden and wheelchair bound individuals. Similar commercially available devices attempt to address this problem; however they rely on manual user adjustment, and only address either interface pressure or surface temperature independently. The aim for this project is to provide an innovation including an active feedback-system that monitors and adjusts interface pressure and temperature for the reduction of pressure ulcer risk formation. The innovation being implemented into the design will allow for autonomous control via continuous evaluation and storage of data.

References & Acknowledgements

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A special thank you to Joseph Zanetti and Christopher Collins of TCNJ for their guidance throughout the manufacturing and building processes.