Weight Bearing Sensor

Section 306

Preliminary Report

10/08/2025

Team:

Nikolai Hess (nphess@wisc.edu) Team Lead

Jetzu Thao (<u>ithao27@wisc.edu</u>)

BSAC

Cassity Dechenne (<u>dechenne@wisc.edu</u>) Communicator

Keira Ferrigan (kferrigan@wisc.edu) BPAG

Norah Greer (<u>nigreer2@wisc.edu</u>) BWIG

Client:

Daniel Kutschera, PT

Advisor:

Professor David Dean (ddean8@wisc.edu)

Abstract

Many people, especially those in physical therapy, can only safely put a certain amount of weight on either one or both of their legs. This can be a significant problem for patients trying to adjust to these restrictions, particularly when the patients are learning how much weight they can safely put onto their legs. These weight restrictions are very common among patients with or recovering from a myriad of disease states and conditions. Some rudimentary ways to monitor this exist, but none that are easily used by physical therapists while remaining low in cost. In order to address these issues, the device designed will need to accurately and quickly display the amount of weight placed on a sensor, which will need to be easily placed in the sole of a shoe or under the foot of a patient, to record the weight in one leg.

Table of Contents

Abstract	1
Table of Contents	1
Introduction	2
Background	3
Preliminary Designs	3
Criteria Descriptions	4
Sensor Designs	5
Sensor Design Matrix	7
Table 1: Sensor Design Matrix	7
Circuit Designs	9
Circuit Design Matrix	12
Table 2: Circuit Design Matrix	12
Circuit Design Scorings	12
Fabrication/Development Process	13
Materials:	13
Methods	13
Testing	14
Future work	15
References	16
Table of Contents	15
Background	16
Function	16
Design requirements	17
Physical and Operational Characteristics	17
a. Performance requirements:	17

b. Safety:	17
c. Accuracy and Reliability:	17
f. Operating Environment:	18
g. Ergonomics:	18
h. Size:	18
i. Weight:	19
j. Materials:	19
k. Aesthetics, Appearance, and Finish:	19
2. Production Characteristics	19
a. Quantity:	19
b. Target Product Cost:	19
3. Miscellaneous	20
a. Standards and Specifications:	20
b. Customer:	20
d. Competition:	20

Introduction

Partial weight-bearing is a common and critical component of rehabilitation following lower limb injuries, fractures, joint replacements, etc. aiming to speed up the healing process by allowing early motion [1]. Achieving the prescribed weight bearingness is essential for patients' healing, however these prescribed amounts (20%, 50%, etc.) can be hard to accurately gauge and put into practice. Most of the time, patients apply more weight than prescribed [2], which can slow the healing process significantly [3]. Partial weight-bearing is prescribed for people of all ages, from elderly populations who may be recovering from falls or joint replacements, to obese patients that may be re-learning how to walk, to pediatric patients who are overcoming broken bones or sports injuries [4]. With this large variation in size between patients, the main unmet need is versatility.

The market offers several devices designed to provide partial weight-bearing feedback, but they are limited in patient size. The main category in these sensors is a shoe-based design such as the Beeper Boot, and the Stappone Rehab Insole [5]. However, these are severely lacking in versatility. They require the patient's foot to be enclosed in a specific size of footwear or a shoe-like device, and would require physical therapy facilities to stock a range of sizes. To accommodate this wide range of demographics that may be working in physical therapy, this will be a highly adjustable device that is able to be used on everyone. In addition to these devices, other methods of testing partial weight-bearing exist, such as stepping on a generic bathroom scale, and physical therapist subjective assessments. However, biofeedback devices have been

proven to increase patient compliance in non-weight-bearing, as these more analog techniques lack accuracy and the ability to ensure the correct force is applied throughout the session [6].

Current technology and clinical methods are insufficient for consistently ensuring patient adherence to prescribed partial weight-bearing limits during physical therapy sessions. The primary gap lies in the lack of a single, versatile, real-time feedback device that can accurately measure applied force regardless of patient foot size, obesity, swelling, or the absence/presence of typical footwear. This deficiency creates a risk of suboptimal healing, and unnecessary costs to the rehabilitation facility.

Background

During rehabilitation after a leg or foot injury or surgery, percent weight bearing refers to the amount of body weight a patient is allowed to place on the affected limb while standing or walking. This weight bearing percentage helps control the stress placed on healing tissues, bones, or surgical repairs. Physical therapists often guide patients through stages such as non-weight bearing (0%), partial weight bearing (25–50%), weight bearing as tolerated, and full weight bearing (100%) [7]. As a patient progresses through physical therapy, gradually increasing the percent weight bearing helps restore strength, balance, and mobility while minimizing the risk of re-injury or delayed healing. The client for this project, Physical Therapist Daniel Kutschera, recognized the challenge patients face in accurately gauging and practicing partial weightbearing. Mr. Kutschera requested this device to help patients visualize and successfully apply their prescribed load, and asked that it be comfortable during use, and largely adjustable to fit all of his patients regardless of foot size or swelling.

Preliminary Designs

Criteria Descriptions

1. Safety: The safety criterion addresses the device's ability to be used for the duration of a physical therapy (PT) session. The device should not be dangerous to the foot, no matter the weight placed on it. Any amount of weight should not cause physical discomfort or damage to the skin or foot, even if rubbed, moistened, or damaged. The wiring should also avoid being sharp or exposed, and avoid risk of tearing or breaking as much as possible, to mitigate safety concerns. The device should also avoid causing an allergic or chemical reaction, even if rubbed, moistened, or damaged.

- **2. Ergonomics/Comfort**: Ergonomics and comfort relate to the ability of the device to be used for extended periods of time without causing discomfort to the user. The device should be small, with a thin, flat profile, and be made of a soft material in order to disturb the foot as little as possible. The sensor inside should be as small and lightweight as possible in order to ensure it does not interfere with this. The wiring connecting the sensor and the circuit should also be as small and inconspicuous as possible, so as not to hurt the user. The device should also avoid causing an allergic or chemical reaction, even if rubbed, moistened, or damaged.
- **3. Versatility**: Versatility encompasses both how easy it is to use the device for different parts of the foot and slightly different uses, as well as how well the design can be used for in-shoe vs out-of-shoe applications. The device should work both in the shoe of a patient as well as attached to the foot in some way, and it should be easy to switch modalities.
- **4. Ease of Use**: Ease of use encompasses the ability of the device to be quickly and unobtrusively used in a PT session. This section encompasses the inobtrusiveness of wires, ease of getting the device into a shoe and onto the foot of a patient, and ease of using the readout. This section will encompass most of the day-to-day use tasks, such as positioning, cleaning, and adjusting the sensor.
- **5.** Cost: The cost criterion relies only on the budget given to us by the client, as this design is primarily meant to be a tool to aid a physical therapist during sessions. The design ideally would be as low cost as possible, in order to save money for the client and have competitive pricing were it to ever go to the market, but the primary requirement is costing less than \$500.

Sensor Designs

Design 1: The Built in Strap

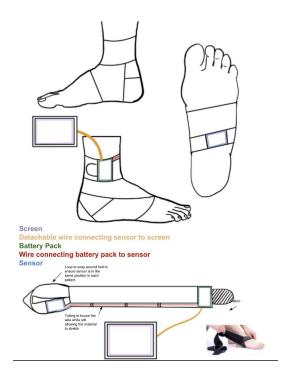


Figure 1: Built in Strap Design

This device uses an ankle-brace like strip of elastic that can be adjusted to fit any patient. The loop at the end ensures that the sensor will sit in the same spot on each person's foot. The wiring will be fed through a tube of fabric to allow it to stay contained while the strap stretches. The battery pack will be fixed to the end of the strap, near the velcro strip. The wire connecting the battery pack/sensor to the readout will be detachable to prevent tangling when putting the device on.

Design 2: The Wrap-Around

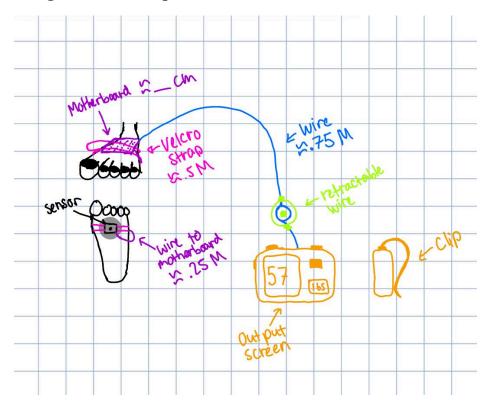


Figure 2: Wrap-Around Design

This device incorporates the sensor being placed at the bottom of a foot and for it to be strapped around the foot itself. The straps will be velcro to accommodate the different sized and shaped feet. This device also has the motherboard strapped to the top of the foot so that it can stay near the sensor and still out of the way of the patient's gait. A wire will then be run from the motherboard to the display screen, however the wire will be retractable so that no excess wire will be in the way of the physical therapist of the patient. This display screen will also have a clip on it so that it can be easily read by the patient and the pt while it is attached to the walker.

Design 3: The Cloth Pocket

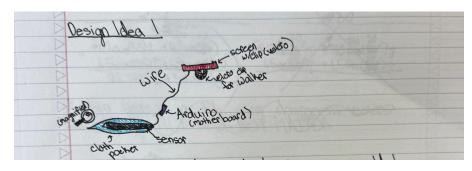


Figure 3: Cloth Pocket Design

In this design, the weight bearing sensor would be resting in a cloth pocket. This would be placed under the client's foot. It would be attached with a wire to the Arduino circuit, which could rest in the shoe/boot. This wire would also attach to the screen that would display the weight data. This screen would be able to clip onto a patient walker if needed with a velcro strap.

Sensor Design Matrix

			Design 1		Design 2		Design 3
Criteria	Weighted Score	Score	Weighted Score	Score	Weighted Score	Score	Weighted Score
Safety	35	4.5	31.5	4	28	4	28
Ergonomics	25	5	25	4	20	4	20
Versatility	20	4	16	5	20	5	20
Ease of use	15	4	12	3	12	4	12
Cost	5	3	3	4	4	4.5	4.5
Total	100	Sum	87.5	Sum	84	Sum	84.5

Table 1: Sensor Design Matrix

Sensor Design Scorings

Design one scored highly in safety, ergonomics, and ease of use. The design scored highly in safety due to avoiding the need to step on the electrical components, and the number of safety features that could be included in the strap. The device scored highly in ergonomics due to the form-fitting nature of the strap, and the padding and comfort features which could be included in the design. The ease of use was also ranked the highest, due to the fact that once attached, the strap would stay in place and not need to be moved/adjusted in any way. While the versatility of the design was slightly lower due to the slight difficulty in using the device in different locations on the foot, with the proper design features it could be used for any part of the foot. The cost would also be slightly higher than other designs due to the fact that the strap materials would be higher than simple foam, and would include some more elements to ensure it stayed in place. This design scored highest out of the three due to its overall benefits and high scoring in most sections.

Design two scored the highest in versatility due to the ability for the sensor to be wrapped around the patient's foot and the ability to be adjusted based on the size of the patient's foot. Another factor that contributed to the high versatility score is the ability for the sensor's location to be changed easily. It also ranks relatively high in the safety and ergonomics criteria due to how the location of the electrical components are located at a safe distance and the form fitting nature of the wrap. However, it did not rank as highly as other designs due to how the wrap with the sensor only goes around the foot and leaves the ankle unsupported. This design scores lower than others in the ease of use criteria due to the possible difficulties of putting the sensor onto the heel. The cost scores relatively highly due to simple design. This design scored highest in versatility and scored similarly to the others in other categories, but falls short of the other designs.

Design three scored the highest in versatility, ease of use, and cost. The design had high scores in ease of use and cost due to its simplicity, remaining very easy to assemble, and low in cost due to not needing extra components beyond the basic parts of the circuit and the pad. The device also scored the highest in versatility, tied with design two, because the simplicity of the design allows it to be used at any part of the foot, and could be used both in and out of a shoe, as well as for toe touch sensing. While the design scored highly in three sections, it scored lower in safety and ergonomics. Due to the need to step on a pad with the sensor in it, and the difficulty in ensuring that safety features implemented aside from foam padding would be effectively used, this design scores lower in safety. The ergonomics of the design also scored lower due to the pad having a more difficult time adhering to the foot than other designs, and this leading to potential discomfort with the pad sliding around either in the shoe or on the foot. While the design scored highly in some sections, it scored lower in the two highest ranked sections than other designs, and due to this scored just barely second overall.

Circuit Designs

Design 1: Base Circuit

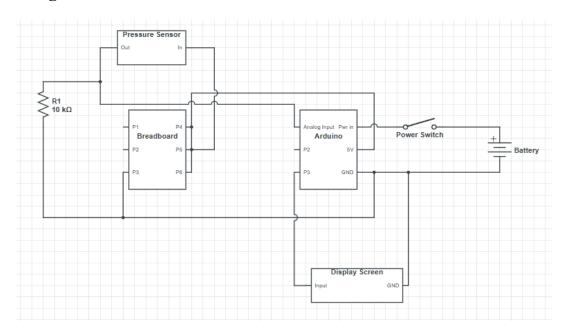


Figure 4: Base Circuit Design

This design utilizes a basic circuit with a battery pack and power switch powering an arduino, which powers both the load cell sensor used to measure the patient's weight, as well as the display. The design utilizes a resistor in the sensor's ground connection in order to stabilize the signal. It would use as few extra components as possible, keeping the device both as simple and easy to assemble as possible. The battery pack would power the arduino, which would power a breadboard feeding into the sensor, which would send a signal directly back to the arduino, which would then send the required data to the display. This design would be both the simplest, most cost effective, and the easiest to assemble out of all the designs, however the design suffers from a lack of accuracy, and the wired connection to the display could be intrusive and potentially get in the way of the patient.

Design 2: Base Circuit With Bluetooth

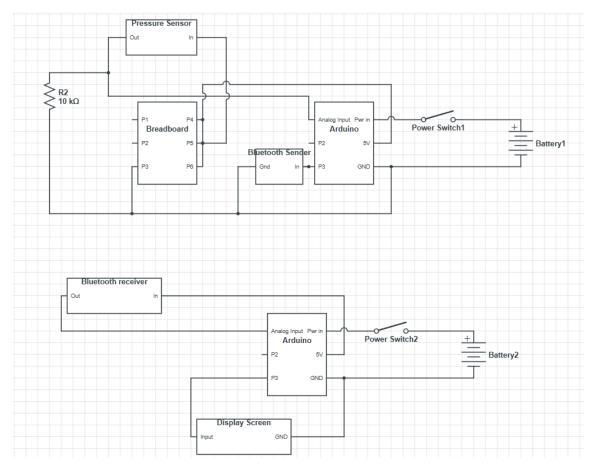


Figure 5: Base Circuit with Bluetooth Design

This design utilizes a similar base design to the base circuit, with an arduino, power switch, load cell sensor, and display, however it uses two separate arduino, battery pack, and switch circuits, both with a bluetooth device. One of the circuits would power and receive a signal from the load sensor, and project data through the bluetooth device to the other half of the circuit. The second half of the circuit would receive data from the first half through the bluetooth device, and feed that signal back into the arduino, which would then project the data required to the display. The separate display circuit would allow the display to be clipped to a walker or set in a separate location in order to avoid interrupting the PT sessions or hindering the patient's movements. This design benefits from its compactness and safety, avoiding extra wires and obtrusiveness by not having a directly wired display screen, however the cost would be significantly higher, and the design still suffers from a lack of accuracy.

Design 3: Base Circuit With Amplifier

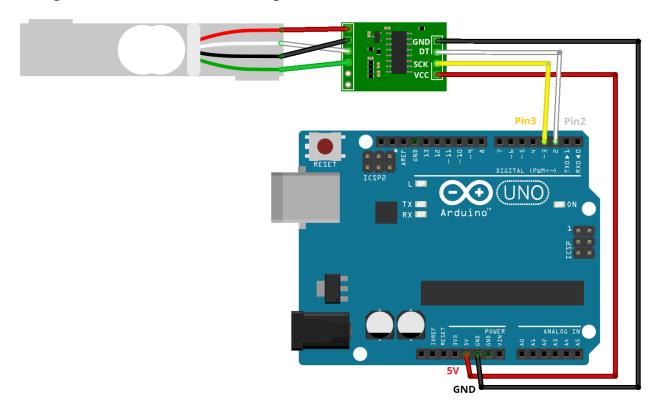


Figure 6: Base Circuit with Amplifier Design

This design utilizes a similar base circuit, with an arduino, power switch, load cell sensor, and directly wired display, however uses an amplifier after the output of the sensor to increase the signal output. This design would still have a directly wired display screen, and the same base components, but would utilize the amplifier in order to increase the accuracy, as the output of the load cells would be very low. The benefits of this design are that it would remain quite simple and easy to assemble, while still remaining quite cheap and significantly increasing the accuracy of the output, however the design would still suffer from the lack of compactness due to the wired display.

Circuit Design Matrix

		Basic Circuit		Basic Circuit with bluetooth		Circuit with amplifier	2000
Criteria	Weighted Score	Score	Weighted Score	Score	Weighted Score	Score	Weighted Score
Safety	30	4.5	27	5	30	4.5	27
Accuracy	25	4	20	4	20	5	25
Compactness	20	4	16	4.5	18	4	16
Simplicity	10	5	10	3	6	4.5	9
Cost	5	4.5	4.5	3.5	3.5	4	4
Total	100	Sum	77.5	Sum	77.5	Sum	81

Table 2: Circuit Design Matrix

Circuit Design Scorings

The first design, including nothing but the base circuit, scored the highest out of the three in terms of simplicity and cost, remaining the simplest, and easiest to assemble out of all of the options. This is due to the lack of extra components needed to make the circuit work, without an amplifier or bluetooth required. While it scored the highest in these two categories, the wired display causes it to score lower in both compactness and safety, as the long and potentially obtrusive wiring could lead to tripping hazards, and would take up quite a bit of space. The accuracy for this design was also on par with the second design, having only the sensor readout, with no increase to the signal. While this design scored decently overall, the benefit of its simplicity and low cost were not enough to put it in the lead, and overall it scored identically to design 2.

The second design, including the base circuit and bluetooth integration, scored the highest out of the three in terms of compactness and safety due to not having a wired display, and instead using a separate circuit to receive the signal and output data to the display. Avoiding this long wire to the display allows the design to avoid any potential tripping hazards, and significantly reduces both the profile of the circuit, and the risk of wiring heating up or hurting the patient. While this design benefits from safety and compactness, due to its complexity and the additional cost of the additional components this design scored the lowest in both simplicity and cost.

The third design scored higher than the others in terms of accuracy, and was very similar to other designs that scored highest in many other categories. The accuracy for this design was the highest out of the three, and while it didn't score the highest in any of the other categories, the compactness and safety was similar to the base design, and the simplicity and cost were both comparable. Because the third design scored so well in most categories, and had the highest accuracy out of all of the designs, the third design scored the highest overall and was selected. This design won in terms of our criteria due to its overall favorable attributes and the significantly higher accuracy.

Fabrication/Development Process

Materials:

This product will consist of two main elements, the sensor and the strap. The sensor will consist of a load cell capable of reading up to 100kg which will be surrounded by a cushioning foam, and housed within the strap. The strap will be made of an antibacterial and waterproof material that is able to be wiped down [8]. The strap will be secured on the patient via Velcro.

The sensor element will consist of a 100kg load cell, an Arduino, and an amplifier. This will be powered by batteries, housed in a lightweight, 3D printed box, and strapped around the patient's ankle with skin-safe Velcro [9]. This will then be attached to an LED screen with a 3D printed walker clip.

Methods

The strap will be sewn using the chosen material, ensuring it is long enough to wrap around even the largest patient's foot. Then the load cell will be surrounded in foam, glued in place, and inserted into the strap before sewing it shut, leaving a small channel for the wiring. Then, loop and hook ends of velcro, and the plastic loop will be sewn onto the strap.

The wiring from the load cell will be attached to the arduino and the battery pack. The battery pack will be enclosed in a 3D-printed box, and a velcro strap will be added to secure it around the ankle.

The LED screen will be attached to the 3D-Printed walker clip, and the wiring from the sensor/strap to the screen will be connected.

Testing

Test 1: Accuracy

To test the device's accuracy outlined in the PDS, varying weights (100-150lb) will be placed on the sensor. The readout will be ensured to display a weight that is correct within our allowed margin of error outlined in the PDS (1-2lbs for every 150lbs of force). If the displayed weight doesn't match our expected weight, an attempt will be made to calibrate the sensor and re-run this test.

Test 2: Accuracy Over Time

Once the initial accuracy test is complete, the sensor's accuracy will be tested to ensure it remains accurate both over the entirety of a physical therapy session (~1 hour) and over repeated use (~1 day). To complete this test, the desired weight (150lb) will be left on the sensor, and it will be ensured that the weight remains within the allowable margin of error at the end of 1 hour and 1 day. If the sensor does not pass the test, the durability will be worked on and the test re-run.

Test 3: Moisture

To ensure the device's integrity under normal use conditions, (humidity, dampness, etc.) a damp paper towel will be placed between the sensor and the applied weight, and the Accuracy Over Time test will be re-run. After the test is complete the device will be evaluated for any water damage.

Test 4: Disinfection

The device will be put to use on an actual person, having them walk around/exercise. After they have used the device, the strap will be wiped down with a sanitizing wipe, similar to that used in a physical therapy office. To check if the strap's material is able to be fully disinfected, a UV light will be shown on the surface, ensuring there is no sweat remaining (would glow under UV light).

Test 5: Patient Interaction

To test how the device interacts with patients people will be asked to put on the device and walk around in it. After they use the device, they will be asked to rate (Scale of 1-10) the ease of putting the device on, the comfort of the device on their foot, and their ability to maintain their natural gait. If any of the scores average below a 7/10, the design will be reevaluated and an attempt will be made to improve patient interaction with the device.

Discussion

This device will be used to assist in physical therapy for patients with weight bearing limitations. Thus, the device should be able to effectively and safely measure and display weight for the physical therapist and patient to monitor proper weight bearing restrictions. The device should require minimal setup and training and be simple for the physical therapist to use in session and easy for patients to read and understand the displayed weight. Manufacturing of this device should remain to a minimal cost, while maintaining a quality of design and data collection, as it will be a single unit. The device should be reusable, meaning that it should also be able to be easily sanitized between sessions by the provider. Testing should be conducted ethically, responsibly, and standardized in order to validate accuracy, safety, and durability.

The device should also avoid utilizing materials that may cause allergic reactions for patients, and it is critical that patients are fully informed about material properties and possible risks from using the device.

Conclusions

The goal for this project is to accurately and safely monitor weight distribution on patients with weight bearing restrictions on one of their legs in a way that aligns with our client's wishes. The built-in strap design including a base circuit with an amplifier became the clear best way to do so. This circuit design reduces tripping hazards and increases accuracy compared to the other designs, though it is not the most compact. The built-in strap design for the sensor is safer and easier to use with a variety of patients than the other circuit designs, though more costly. The few drawbacks these designs do have in cost and size are considered worth having the product perform better in areas that are most important, such as safety and accuracy. Moving forward with the designs, they will be tested in order to ensure their accuracy and safety. The product will then be set up to culminate in a useful initial product that may be further worked on and improved during future semesters.

Future work

Future work for this device will include prototype fabrication, where the circuit and software will be assembled and developed, and fine tuning this prototype design to the client's specifications. Once the prototype is finalized, testing for accuracy and durability will begin. Further issues that are found during testing will need to be addressed before moving onto further additions such as bluetooth or an application to go alongside the device.

References

- [1] A. J. DiStasio, F. R. Jaggears, L. V. DePasquale, F. J. Frassica, and C. H. Turen, "Protected early motion versus cast immobilization in postoperative management of ankle fractures," Contemp Orthop, vol. 29, no. 4, pp. 273–277, Oct. 1994.
- [2] "Accuracy of Bathroom Scales to Measure Weight-Bearing eOrthopod.com," Oct. 26, 2015. Available:
- https://eorthopod.com/news/accuracy-of-bathroom-scales-to-measure-weight-bearing/, https://eorthopod.com/news/accuracy-of-bathroom-scales-to-measure-weight-bearing/.
- [3] A. M. Eickhoff, R. Cintean, C. Fiedler, F. Gebhard, K. Schütze, and P. H. Richter, "Analysis of partial weight bearing after surgical treatment in patients with injuries of the lower extremity," Arch Orthop Trauma Surg, vol. 142, no. 1, pp. 77–81, 2022, doi: 10.1007/s00402-020-03588-z. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8732824/.
- [4] "Obesity May Affect Foot Size." Available: https://www.newtampafootandankle.com/patient-education/blog/obesity-may-affect-foot-size.
- [5] "STAPPONE Rehab," stappone. Available: https://www.stappone.com/en/products/partial-weight-bearing-management/stappone-rehab/.
- [6] J. W. Hustedt, D. J. Blizzard, M. R. Baumgaertner, M. P. Leslie, and J. N. Grauer, "Is it possible to train patients to limit weight bearing on a lower extremity?," Orthopedics, vol. 35, no. 1, pp. e31-37, Jan. 2012, doi: 10.3928/01477447-20111122-14
- [7] contributors Physiopedia, "Weight bearing," Mar. 16, 2023. Available: https://www.physio-pedia.com/Weight_bearing
- [8] "Medical Fabrics: A Reservoir of Pathogenic Bacterium?," Infection Control Today, Dec. 31, 2008. Available:

https://www.infectioncontroltoday.com/view/medical-fabrics-reservoir-pathogenic-bacterium.

[9] "What is Skin-Safe Velcro Strap?," https://anmyda.com/. Available: https://anmyda.com/what-is-skin-safe-velcro-strap/.

Weight Bearing Sensor

Section 306

Product Design Specifications

09/18/2025

Team:

Nikolai Hess (nphess@wisc.edu)

Team Lead

Jetzu Thao (<u>ithao27@wisc.edu</u>) BSAC

Cassity Dechenne (<u>dechenne@wisc.edu</u>) Communicator

Keira Ferrigan (kferrigan@wisc.edu)

BPAG

Norah Greer (nigreer2@wisc.edu)

BWIG

Client:

Daniel Kutschera

Advisor:

Professor David Dean (<u>ddean8@wisc.edu</u>)

Table of Contents

Table of Contents	1
Background	2
Function	2
Client requirements	2
Design requirements	3

1. Physical and Operational Characteristics	3
a. Performance requirements:	3
b. Safety:	3
c. Accuracy and Reliability:	3
d. Life in Service:	3
e. Shelf Life:	3
f. Operating Environment:	4
g. Ergonomics:	4
h. Size:	4
i. Weight:	4
j. Materials:	4
k. Aesthetics, Appearance, and Finish:	5
2. Production Characteristics	5
a. Quantity:	5
b. Target Product Cost:	5
3. Miscellaneous	5
a. Standards and Specifications:	5
b. Customer:	6
c. Patient-related concerns:	6
d. Competition:	6
References	7

Background

Patients with, or in recovery from, many conditions have restrictions on how much weight they can safely put onto their legs without causing themselves further injury. While there are some ways to attempt to ensure this requirement is met, they are difficult to implement, do not work as well as desired, or do not provide as much feedback as would be helpful to patients and those assisting them. The goal of this project is to design a low-profile, user-friendly device to measure and record the weight applied to a patient's legs, providing feedback to both the patient and care providers to ensure their safety precautions are being met.

Function

The device should be designed to assist a physical therapist (PT) in actively measuring the amount of weight put onto the legs of an individual they are working with. The device will use a weight sensor and a wired output to show the weight put onto a patient's legs, one at a time. The device will consist of a small sensor that could be placed in a shoe or strapped to a foot, and a digital display to read out the amount of weight registered. This design will allow the PT to know exactly when a patient is putting too much weight on a leg, and help them to correct.

Client requirements

- The device should be as close to wireless as possible, with minimal wiring.
- The device should have a visible readout that can be clipped to a walker.
- The device should be small, thin, and soft, so as not to cause discomfort or injury to a patient.
- The device has a somewhat flexible budget limit of \$500.

Design requirements

1. Physical and Operational Characteristics

a. Performance requirements:

The sensor will transmit data about the percentage of weight distributed on a patient's foot at a given point in time. It will transmit this weight data via a wire to a screen that will output whether the patient is putting more weight than recommended on their foot. This screen will be able to clip onto a walker and be small enough to hold in a hand. The product will be designed to be used in a rehabilitation center in which a PT will be present at the time of use. This means that both the PT and the patient should be able to tell whether the patient is putting excess weight on their foot.

b. Safety:

The device must have clear instructions for operation and detailed descriptions of potential hazards and storage measures to avoid confusion and prevent harm. The device should not be altered in any way after purchase, and the electrical components should be properly secured and covered to prevent exposure. In addition, it should be kept away from water, though it can withstand minimal moisture.

c. Accuracy and Reliability:

The device shall measure and accurately display weight within ± 1 pound from the actual measured pressure onto a screen or monitor. The sensor must be able to work properly in conditions under stress, and in warmer and humid environments (37-40°C), such as inside the patient's shoe or boot. The device should be able to be used several times and provide accurate and similar readings for each use.

d. Life in Service:

The sensor must be able to withstand heat, moisture, and pressure throughout the duration of a physical therapy session for potentially several hours. The screen must also not run out of battery throughout a physical therapy session. The device should be able to withstand this for as many usages as possible. Its main area of usage will be in the rehabilitation center, not at the patient's home.

e. Shelf Life:

Given this device is stored in a location that will not damage or alter the electrical components, this product can have a shelf life of many years and be used to assist many patients through their recovery. The material used will be sturdy and reliable; however, depending on how repeatedly the device is used, the sensor and reader can slowly wear down after a few years of use.

f. Operating Environment:

During use, this device will be at the base of the patient's shoe and will likely be in a warm and moisture-filled environment. It should be sanitized and/or be placed in a plastic wrapping during every use. When not in use, it should be stored at room temperature (between 20 and 22 degrees celsius).

g. Ergonomics:

The device should fit snugly in a patient's shoe, no matter the size of the foot. It will also have a velcro strap attached to it to wrap around the foot if the patient's foot can no longer fit in a shoe. In addition, we will provide disposable covers to be changed out between each use. The sensor will not have any sharp corners or edges to prevent discomfort and injury during use.

h. Size:

The sensor should be small enough to fit within a patient's shoe without causing discomfort to the patient and the supporting strap and exterior parts should be adjustable and able to fit on all patients no matter the size required. This means that the sensor should be able to fit in patients' shoes of varying sizes and should be between ~1 to 5 inches in width, less than three inches in height, and smaller than twelve inches in length. [1]

i. Weight:

The device is intended to be as unobtrusive as possible, and as such, should weigh as little as possible. While the circuit and other components may weigh slightly more, an ideal goal for the sensor recording the weight and any attached padding would be under 1 pound, as this would put them in the range of lighter-weight insoles that are currently on the market. [2]

j. Materials:

These materials are required to be safe for the patient and should not cause any irritation or damage to the skin or feet of the patient as well as avoiding materials that are common allergens. Materials that may be considered unsafe for this device are: nickel, chromium, cobalt, adhesives, or common allergens such as latex. Electronic materials should also adhere to proper safety standards and shall be safe for use for the physical therapist along with the patient. The materials used would also be preferred to be lightweight as it'll be easier for the patient and physical therapist to use and maneuver. [3]

k. Aesthetics, Appearance, and Finish:

Functionality and ease of use are the most important characteristics. However, the device should have a compact and sleek look with neutral color, and all internal components out of view (no exposed wiring or motherboards). The wire connecting the sensor to the reader should not have excess wiring when being used. To improve the finished look, the battery pack and wires will be as enclosed and hidden as possible on an ankle band.

2. Production Characteristics

a. Quantity:

Only one device needs to be made, as it is intended to help one PT assist one patient in gauging how much weight they are putting on a leg, one at a time. This amount was also decided on with input from the client.

b. Target Product Cost:

The device is not primarily intended for production for a wider population than the patients in the rehabilitation hospital. As such, the limiting factor in terms of cost is simply the provided budget of \$500 from the client and \$50 from the design program. The target total cost is under \$550.

3. Miscellaneous

a. Standards and Specifications:

The device will be legally considered a "Force measuring platform" [4] as opposed to a medical insole, as it is not intended to relieve any symptoms of athlete's foot. [5] This allows for exemption from market notifications if the device were to ever be sold, decreasing the work of selling it if patented. While this specific legal categorization has little influence on the scope of this project, the device should also need to adhere to the codes listed in NIST handbook 44, "Specifications, Tolerances, and Other Technical Requirements for Weighing and Measuring Devices". [6] This handbook provides extensive information and regulations, including that the scale shall not display more than one unit of measurement, shall have a zero indication, and shall have a method of zeroing the scale, as well as displaying weight to one, two, or five decimal points. The device will also need to adhere to ASTM E74 and F3109, which provide detailed specifications on the calibration and accuracy of the device.

b. Customer:

The primary customers of this device are PTs working in rehabilitation facilities with patients recovering from lower limb injuries. It will be designed according to average measurements,

while also accounting for the possibility of large amounts of swelling. The device will provide patient data after each session, and provide real-time feedback to the user and PT via a vibration or digital cue on the screen.

c. Patient-related concerns:

The device will be easy to use and include use and cleaning instructions. The device's battery and sensor will be able to withstand several hours of continuous use, with the surface temperature not exceeding 100.F. The product will be small, thin, and soft, to avoid any irritation to the foot, and the strap will be long enough to account for any swelling that may be present. The product should be disinfected between uses.

d. Competition:

There are multiple other weight bearing sensors out on the market, but their readings can be unreliable, and their capabilities are not ideal for rehab usage. The Engineering Rehabilitation nCounters company has a weight bearing sensor for \$599. [7] The device will differ from their design as it will consist of an inserted sensor into the patient's shoe and give live feedback on the weight placed on the sensor.

References

- [1] *Shoe Width Measurement Chart* HealthyFeetStore.com, https://www.healthyfeetstore.com/pages/width-sizing-chart?srsltid=AfmBOooKyExUymib8d5y HaJcTAppGIITAPRf7-1rMZUi3F22Mz3xorzQ.
- [2] Form ultra-thin maximum support insoles Insoles.com, https://insoles.com/products/form-ultra-thin-maximum-support-insole?srsltid=AfmBOoqq2R_tV gZEImaS-nMdru1rFkMwtTd1DPojcoawrkNv5Ud1jHsv.
- [3] K. Pachenko and J. Thyssen *Contact dermatitis from biomedical devices, implants, and metals-trouble from within* The journal of allergy and clinical immunology. In practice, https://pubmed.ncbi.nlm.nih.gov/39067854/.
- [4] (2008, June 23) Code of federal regulation, Title 21, chapter 1, subchapter H, part 890, subpart B, 890.1575,

https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-890/subpart-B/section-890.157

- [5] (2008, June, 23) Code of federal regulation, Title 21, chapter 1, subchapter H, part 880, subpart g, 880.6280,
- https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-880/subpart-G/section-880.628 0.
- [6] (2024) *NIST handbook 44*, National Institute of Standards and Technology, https://www.nist.gov/system/files/documents/2024/04/09/NIST%20HB44%202024%20Section %202-24-24%202.24.%20Automatic%20Weighing%20Systems.pdf.
- [7] P. Barrett. (2024, June 17). *Portable Limb Load Monitor_Touch (PLLM_Touch) How it Works* NCounters Engineering Biofeedback Rehabilitation Products, https://ncountersonline.com/portable-limb-load-monitor?srsltid=AfmBOorgs17z_IRzwpqhIDLD VsmhdjpraP52KHlSWBttH-hSM0nHljNG.