Weight Bearing Sensor

Section 306

Product Design Specifications

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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℃), 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=AfmBOooKyExUymib8d5yHaJcTAppGIITAPRf7-1rMZUi3F22Mz3xorzQ.

[2] *Form ultra-thin maximum support insoles* Insoles.com, https://insoles.com/products/form-ultra-thin-maximum-support-insole?srsltid=AfmBOoqq2R_tVgZEImaS-nMdru1rFkMwtTd1DPojcoawrkNv5Ud1jHsv.

[3] [1] 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-890.1575.

[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-880.6280.

[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_IRzwpqhIDLDVsmhdjpraP52KHlSWBttH-hSM0nHljNG.