

**BME Design**  
**The Product Design Specification (PDS)**  
of  
**The Stair Assist Bench**  
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**Function:**

In the field of neuro-rehabilitation, physical therapists encounter a significant obstacle when assisting patients with weight-bearing restrictions to transition back to their homes. The primary challenge revolves around negotiating steps, which often proves to be an arduous task due to various constraints. Ramps, typically considered a solution, are frequently deemed impractical due to cost implications and compliance with rise-to-run criteria. As an alternative, patients are advised to use garden benches from hardware stores, which lack adjustability and medical design. This makeshift solution is frustrating for healthcare providers, as it is not purpose-built and poses issues with bench availability.

To address this gap within the next three months, there is a clear need for a specialized, medically designed bench tailored for step use, offering safety and adjustability to improve the mobility and independence of patients in neuro-rehabilitation.

**Client requirements**

The client has requested the following specifications made to the design:

- The project must not exceed a budget of \$400.
- The device should be reliable and safe throughout the non-weight bearing period.
- The device must be usable without the need for assistance from another individual.
- The device's dimensions must conform to international standard codes for stairs, including minimum width and tread depth, while accommodating the individual's foot on the stair.
- The weight limit should be up to 300 lbs.
- It should incorporate handles for lifting the bench, providing support and the ability to withstand a substantial weight.
- It should securely attach to the step to prevent tipping.

- Ergonomic comfort features should be included to ensure the non-weight bearing leg can comfortably rest on the bench.

## 1. Physical and Operational Characteristics

### a. *Performance requirements:*

- i. The device will offer support to the non-weight bearing limb as the individual goes up and down stairs.
- ii. The device should be easily moved up stairs with one hand, using a handle, without requiring assistance from another person.
- iii. The handle should be able to withstand a significant amount of weight to assist the individual as they can use it as a crutch to ascend the stairs.
- iv. The device must be capable of sustained daily use throughout the non-weight bearing period, which may range from several weeks to several months, without any compromise in its functionality or safety.
- v. The device should be able to withstand weight distribution and movement on its surface, supporting a maximum weight of up to 300 lbs.

### b. *Safety:*

- i. The device must have a defined weight capacity that ensures it can safely support users. This information should be clearly communicated to users.
- ii. The device must follow ISO 11334-1:2007 international standards pertaining to assistive products for walking manipulated by one arm [1]. This covers various aspects of designing and testing to ensure safety and performance.

### c. *Accuracy and Reliability:*

- i. The device must withstand repeated loads of up to 300 lbs with no permanent structural damage.
- ii. The device must easily adjust its height in 1 inch increments without compromising its structural integrity.
- iii. The device must secure to the stairs to prevent tipping while also being easily lifted without resistance to reach the next step.
- iv. The device must conform accurately to stairs in accordance with Wisconsin state construction standards, which specifies a riser height of less than 8 inches and a tread depth of 9 inches, with the tread depth being the primary criterion [2].

### d. *Life in Service:*

- i. As this device is used for patients with a non-weight bearing leg, according to American Orthopedic Foot and Ankle Surgeons, these injuries could last as short as 1 week and as long as 14 weeks, thus the device should be able to last at least 14 weeks [3].
- ii. The device will remain in use every day until the patient's leg is no longer classified as non-weight bearing.

- e. ***Shelf Life:***
  - i. The device will be able to remain in storage without compromising its integrity for 5 - 10 years as it will be composed of durable materials that will not decay or deteriorate rapidly over time.
  - ii. The device should undergo testing before patient use following extended periods on the shelf.
  
- f. ***Operating Environment:***
  - i. The device will primarily be used indoors in homes and only occasionally outside, so it must withstand typical household conditions of temperatures ranging from 60 to 80 degrees Fahrenheit, exposure to sunlight, and humidity levels between 25% and 55% [4].
  
- g. ***Ergonomics:***
  - i. The device should take into consideration the physical capabilities of individuals and the specific geometry of the human body it comes into contact with, such as the tibia bone and the palm of the hand.
  - ii. The device should mitigate potential discomfort that may arise from loading points of contact, such as the wrist, shin, and knee, through the use of inclusive design.
  
- h. ***Size:***
  - i. The bench must have a width of less than 36 inches and a tread depth of less than 9 inches, in accordance with the minimum stairway code standards [2]. The width should exceed the mean male diameter of 7 inches [5].
  - ii. The bench height should be adjustable to accommodate the length of the human tibia. On average, the tibia ranges from approximately 13 to 20 inches [6].
  - iii. The bench handle should not exceed the height of the ranges of the human femur, approximately 17 to 21 inches [6].
  
- i. ***Weight:***
  - i. The device should be lightweight enough to be lifted with one arm to a height of at least 8 inches, which is the maximum stair riser height [2]. The bench should not exceed 10 lbs to meet this requirement.
  
- j. ***Materials:***
  - i. The foundation of the device should be fabricated with lightweight and strong materials that are able to withstand up to 300 lbs without deforming.
  
- k. ***Aesthetics, Appearance, and Finish:***
  - i. The device should appear simple in nature and relatively easy to use.
  - ii. All edges of the device should have fillets, and all surfaces should be smooth to touch.

- iii. Depending on the material, all surfaces should be professionally finished; either being matte or gloss.

## 2. Production Characteristics

### a. *Quantity:*

- i. The device will initially be produced in one iteration for testing and proof of concept purposes.
- ii. The device is an adjustable, standalone product that does not require multiple devices or configurations so it only requires a quantity of one.

### b. *Target Product Cost:*

- i. There are two constraints governing the product cost, firstly our budget of \$400 and second the target consumer space.
- ii. The budget of \$400 gives us plenty of resources to experiment and try several prototypes.
- iii. Most importantly, the target consumer space for the product is to satisfy the need for a cheap alternative for long-term built-in products such as elevators or chair stair assist machines.
- iv. To properly fill this space, the product should be manufactured for less than \$40 in order to keep retail cost less than \$100.

## 3. Miscellaneous

### a. *Standards and Specifications:*

- i. This assist device is a class 1 low risk medical device and will need to be approved by the FDA to be sold. This product needs to adhere to FDA code 21CFR890.5050 detailing the requirements for a daily assist device for recreational activity. Additionally the stair assist bench needs to follow FDA code 21CFR890.3790 for regulation of cane, crutch, walker tips and pads [7]. For this movable bench, ISO 11334-1:2007 needs to be followed which details assistive products for walking manipulated by one arm [1]. Lastly, there will be a testing process for the safety, stability, of the product with clinical applications for the device that is regulated by the FDA [8].

### b. *Customer:*

- i. The client, Dan Kutschera, a physical therapist, is asking for a stair assist device for patients with weight bearing restrictions as they return back to their homes. Our target customers are neurological and trauma rehab patients that require mobility assistance. Having a specialized, medically designed bench that offers safety and adjustability would improve mobility and independence of patients rehabilitation.

c. ***Patient-related concerns:***

- i. Our product must be safe to use as our customers are recovering from an injury and this product will be used during rehabilitation. Often patients will stay in the hospital for 4-6 weeks of rehabilitation before being discharged where they face the obstacle of stairs during reintegration [9].
- ii. This product must be adjustable. Customer height varies which will require the product to adjust between 15.75 inches and 26.38 inches according to average knee height and anthropometric measures [10]. The base of this product must be adjustable for different stair tread lengths.

d. ***Competition:***

- i. iWALK Crutch [11]: The iWALK Crutch is a hands free crutch that attaches to the thigh and shin to secure and brace the leg at a 90 degree angle. iWALK Crutch provides support for below the knee injuries while removing the fatigue caused by standard crutches. This product was designed to allow more mobility while having weight bearing restrictions. The downside of this product is that it is cumbersome to strap on before going up and down stairs. This product is FDA approved and retailing for \$159.
- ii. Shower bench [12]: A shower bench is a moveable chair with handles that is placed in a shower or tub. This assist device allows for non weight bearing patients to have the independence of showering. Shower benches are a seated option to provide strength and stability over a longer period of time. The drawbacks of this design are that it wouldn't be stable on the stairs and doesn't allow for adjustments or single leg support. Shower benches retail for between \$40 and \$300 [13].

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