DEPARTMENT OF
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Dynamic Balance Device

BME 200/300 - Preliminary Report

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Abstract

Patients who have suffered from strokes often develop Unilateral Stroke Neglect (USN) syndrome and sustain long-lasting subsequent symptoms such as a deficit of awareness of one side of their bodies and a lack of static and dynamic balance, leading to injuries and falls. The client, Mr. Daniel Kutschera, is a physical therapist who focuses on patients who suffer from such post-stroke conditions and seeks to develop a professional tool to improve the current method of performing dynamic balance training. The current tool used in his practice is a yardstick with a yellow dot attached to the end which allows patients to visually scan the target and attempt to reach it. He has also tried to develop a customized prototype using PVC pipe and cardboard but he seeks a more professional and interactive design that displays different colors and shapes, and that contains a scalable measurement system to evaluate patient performance and improvement. The device should be lightweight, stable, and easy to use in clinical settings on a daily basis. To reach a final design, design matrices were made for each of the three components of the device: the handle, the shaft, and the display. The different design options were rated and classified based on different criteria considering what is most important to the client. At the end of this analysis, the chosen design was a regular handle grip with a carbon fiber shaft and an RGB LED Matrix display. For future work, a prototyping plan must be developed, the required materials must be ordered, and any testing protocols must be drafted. At the end of the semester, a final prototype must be delivered to the client following the design specifications [see Appendix A], with the goal of successfully assisting post-stroke patients with dynamic balance training.

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Introduction

Motivation

This device seeks to address the lack of affordable rehabilitation equipment that is necessary for efficient recovery from neurological conditions, primarily Stroke Spatial Neglect Syndrome in post-stroke patients. Many of these patients neglect the input from one of their eyes and cannot see out of it, while other patients have difficulty recovering their balance while moving and distort the size and shape of objects. As one may expect, the primary age of these patients is sixty-five and older. One of the most effective ways to test patient recovery and balance is testing a patient's visual scanning through their peripheral vision, and having them reach out to touch an object to analyze balance and flexibility. Many neurological rehabilitation hospitals can afford expensive and specialized equipment to test this, however, once a patient begins a transition back to daily life, this equipment is too expensive for local doctors at outpatient centers to acquire. The goal of this project is to create an affordable and professional device that allows doctors to test their patient's visual scanning, balance, and flexibility while staying in a position to allow the doctor to assist should the patient need help stabilizing.

Current Methods

The primary device associated with this method of recovery is the Bioness Integrated Therapy System (BITS) which is an integrated and interactive system that utilizes a wise touchscreen and a board that is placed beneath the patient. After a doctor initiates the system, the display will begin lighting up with different shapes and colors, and the patient has to recognize and touch them, which the screen responds to with an audio queue. Depending on the patient's condition and stage in therapy, the board beneath them will shift and test their balance while they continue to recognize shapes and colors in front of them. The BITS system will record the patient's performance for the doctor to review, ideally allowing them to better tailor a recovery plan for the patient.

Another method to resolving problems with visual scanning is to make a homemade version. While there is no formal documentation or patenting for this, it is an effective method that can be tailored to fit the clinician's needs. Current versions of this include purchasing piping from a local store and attaching red and green paper on opposite sides of one end. The clinician can then flip the pipe to test the patient's response to different colors while varying their grip to see what patients can reach. This homemade design is easy to use, and allows the clinician to stand directly behind the patient, allowing them to assist should the patient begin falling.

Problem Statement

Many elderly people–especially those who have suffered from strokes–sustain lasting neurological and mobility problems as they attempt to recover and return to "everyday" life. Currently, treatment methods and equipment that physicians use are too expensive to easily acquire, or are inadequate in allowing the physician to give sufficient attention and support to the patient while maintaining a professional and entertaining environment for patients. Physicians have attempted to create solutions to these issues themselves, and have succeeded in creating an effective alternative, but have fallen short in creating a professional device. The goal of this project is to provide a solution that remedies the issues of cost and unprofessionalism with current designs. Additionally, there is potential to expand beyond a prototype and provide instructions to outpatient centers detailing how to affordably produce this device, or to simply produce more of these devices and sell them to smaller clinics at an affordable cost of around two hundred to three hundred dollars. .

Background

Relevant Biology and Physiology

A primary motivation for this type of rehabilitation therapy are post-stroke patients–specifically those suffering from Stroke Spatial Neglect Syndrome [1], which occurs in about forty percent of stroke patients at some point. It's most often caused by damage to the trunk of the right cerebral hemisphere, causing the left-hemisphere to become more active and the right-hemisphere to fade, shifting the brain's overall attention toward their right eye and the images they receive from there. This is typically associated with individuals who have experienced a right brain stroke (though left sphere neglect occurs as well) and lose awareness over what is happening with half their body. Patients suffering from this often have trouble balancing and moving around as their brain amplifies the signaling received from one eye compared to the other, distorting the shape and size of objects along with their distance relative to it. Compounding this fact is that seventy-five percent of strokes occur to those sixty-five and older [2], who are more likely to have preexisting conditions that limit mobility and balance. This necessitates care in neurological rehabilitation hospitals that specialize in treating brain, spinal-cord, and orthopedic injuries. These hospitals help a patient recover from their initial trauma, but follow-up visits to smaller clinics are often required, which cannot afford large and expensive specialized equipment. Different stimuli provoke different responses from patients [3], including different colors, distances from the eyes, shapes, activities (such as putting on a shirt), and movement. These stimuli will not all be tested by the device, but the goal is to capture as many as possible.

In addition to the above motivation for the project, it is also important that the device is easy to use in everyday care. The solution to this problem is in an ergonomic design that allows the client to easily use the product without tiring and without having to move from his positioning to assist should a patient lose their balance. Considering that the client may have to use this device many times a day and for extended periods of time, the device should be lightweight so as not to cause shoulder damage and allow him to easily wield it. This will factor into the weight distribution of the device, as the weight should be distributed more towards the user due to simple torque mechanics. While the device should never be close to the threshold that is possible for an average person to hold, it should be comfortable, which means the device's weight threshold should be set (relatively arbitrarily) at five pounds.

Client Information

Mr. Daniel Kutschera is a clinician specializing in neurological rehabilitation therapy at the

Children’s Hospital of Wisconsin-Fox Valley and the Theda Clark Medical Center. He has requested a professional and affordable device to assist in treating his patients suffering from Spatial Neglect Syndrome, providing guidelines that it should be lightweight, ergonomic, and easy to use with easily identifiable shapes and colors.

Design Specifications

This device focuses on assisting post-stroke patients with spatial neglect syndrome in performing dynamic balance and visual scanning training and must follow the Product Design Specification guidelines [see Appendix A]. It should contain a target displaying different colors and shapes and a scalable difficulty measurement system to register and analyze patient performance and improvement. The weight of the power source for the target display should be well-balanced to ensure ease of use, preferably located at the bottom, inside of the handle. The overall device must be lightweight, stable, easy to use, and safe, featuring round edges and safely-guarded electronic components. It must be accurate and withstand one year of daily use and three years of storage with no major calibration or maintenance adjustments. The device must have a professional design, display bright and clear colors, and be made of durable materials that are easy to sterilize with a wipe. In terms of measurements, the device should weigh no more than 5 pounds, and be approximately 3-ft long, with a 3-in target.

Initially, only one final prototype is required by the client, with a target cost of production of $200. It must adhere to regulations set by the Federal Food and Drug Administration (FDA) as well as the IEC code 62353 for medical devices. The client desires this product to be used in everyday therapy, making both ease of use and durability high priorities. The current competition involves significantly larger and more expensive equipment–including the Bioness Integrated Therapy System, as well as a homemade version made out of piping and laminated cardboard, which is effective in purpose but has room for improvement when it comes to professionalism and engaging features.

Preliminary Designs

Shaft Designs

For the shaft of the device, the group came up with three different designs that each contained different structural features: the Carbon Fiber Shaft Design, the Aluminum Shaft Design, and a PVC Pipe Shaft Design. The Carbon Fiber Shaft Design allows for the shaft to be extremely strong and durable, which is a key component since the device will be used daily [4]. Additionally, carbon fiber is extremely lightweight which is crucial since the client will be extending the device for extended periods of time. The main downside of carbon fiber is how expensive it is. The second design is the Aluminum Shaft Design [5]. This design allows for the shaft to be extremely strong which is beneficial to holding up the display screen at the end and increasing the lifespan of the device. On the other hand, aluminum’s strength results in an extremely heavy weight which would be unmanageable for our client. The third design is the PVC Pipe Design [6]. The PVC pipe shaft allows for the shaft to be extremely lightweight and easy to use. The PVC pipe is also extremely customizable and cheap to manufacture. The main disadvantage behind the use of PVC pipe is that it is not very strong nor durable and it would struggle to support the weight of the display screen, while maintaining a solid structure.

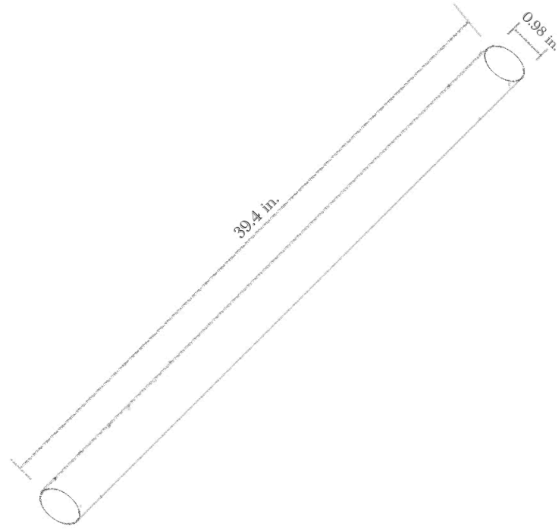


Figure 1: Shaft Design

Display Screen Designs

For the display mechanism, several different panels were evaluated along with several alternative methods of displaying the target. The final designs considered used an 8x8 RGB LED Matrix, an LCD Touchscreen, and a substantially larger 32x32 LED Panel. The 8x8 LED Matrix Design offers the most flexibility out of any of these options, being easily foldable and moldable to a specific shape. Additionally, the size is perfect for a 3x3 inch target at the top of the handle, while being lightweight, non-power intensive, and easily wireable [7]. The main disadvantage of the 8x8 matrix is the low image resolution, potentially limiting the recognizability of shapes that may be displayed, especially in older patients who may already have limited vision. The second design is the LCD Touchscreen Design. The LCD Touchscreen remedies the greatest problem with the LED matrix, with a 320x480p screen resolution [8]. The size of the touch screen would fit well into a box on the end of the shaft, and there is potential for audio queues with an additional sound box wired to the touchscreen. The drawback with the Touchscreen comes with weight and battery drain. While the weight is not a massive issue, its placement at the end of the rod will compound any weight related issues, and the display method may cause a large drain on the battery, requiring a heavier battery to be installed in the handle, or the implementation of an easy way to recharge the battery. The third design for the display screen is the LED Matrix Panel Design. The LED Matrix panel offers the best mix of resolution and power conservation, with a 32x32 light grid that can be programmed to display any object or image desired [9]. However, this panel has significant concerns associated with its weight and the distinctiveness of its colors. These panels are primarily used in larger displays or to be seen from a distance. Additionally, the panel requires a Raspberry Pi to operate, and the wiring associated with a Raspberry Pi may be complicated to implement through the piping to the handle, as well as the team having limited experience working with Raspberry Pi.

Handle Designs

For the handle of the device, the design team came up with three different options containing different ergonomic features: the Regular Handle, the Finger Grip Handle, and a Support Band Handle. The Regular Handle Design consists of a flashlight-style handle grip with a compartment inside to accommodate the power source and a lid to open it up. It also contains buttons to turn the display on and off and change colors and shapes. This option is efficient, easy to fabricate, and easy to attach to the other components of our device, although it may not have the most ergonomic design. The second design is the Finger Grip Handle Design. This design is similar to the regular handle in its features, but contains ergonomic finger contours that provide a more comfortable and secure grip. It is easy to use and ergonomic, but slightly harder to fabricate from scratch due to its shape. The Support Band Design is also very similar to the other handle designs but features a curved profile aiming for an anatomical design. It also contains a band attached to both ends allowing for secure attachment to the user's hand. It is ergonomic and provides a more stable handling wen compared to the other options, hen compared to the other options, but it may be inconvenient to set up or adjust to the hand. Also, depending on the material of the band, the size and weight may be slightly higher than desired.

Preliminary Design Evaluation

Design Matrix

The design matrix is a tool that is used by the design team to determine which preliminary design is the best fit for their implemented criteria. The design team broke their design up into three separate matrices: shaft, screen, and handle. Each matrix consists of their own criteria that applies to the specific portion of the total design. The criteria was selected based on the clients requirements and the prior knowledge possessed by the design team.

	Design 1: Carbon Fiber 		**Design 2:** Aluminum 		**Design 3:** PVC Pipe 	
Weight (40)	5/5	40	2/5	16	5/5	40
Durability (25)	5/5	25	4/5	20	3/5	15
Ease of Engraving (15)	3/5	9	4/5	12	2/5	6
Cost (10)	2/5	4	3/5	6	5/5	10
Ease of Fabrication (10)	3/5	6	1/5	2	5/5	10
Total (100)	84		56		81	

Table 1: Shaft Design Matrix

The criteria for the shaft matrix consists of five categories, with each category contributing a certain point total towards the total percentage. The first category is weight, which is weighted the highest of all categories at forty percent. The weight is extremely important since the client needs to hold out the device for extended periods of time, and he has specified that it is critical to the project that it be easy to use. The second category is durability, which is weighted at twenty five percent. The shaft durability is crucial as the client will use the device multiple times a day and sanitize the device after every use. While none of these materials have huge durability concerns, it is still an important consideration in which shaft we decide to use. The third category is ease of engraving, which is weighted at fifteen percent and assesses how easy the material is to engrave during the production of the prototype. This is important as it’s the hardest part of the design process as it relates to the shaft, and it’s important to keep in mind how we could mass produce these as that is one of the end goals down the line for this product.The last two categories are ease of fabrication and cost, which are weighted the lowest at ten percent. Cost assesses how expensive the shaft material is and ease of fabrication assesses how easy the shaft is put together. Both of these categories ranked the lowest due to the client's needs being the most important factor, but are important considerations in any engineering project, and still deserve to be factored into our selection process.

The design matrix uses the criteria above to determine the best design. For weight, both carbon fiber and PVC pipe scored full points since they are both extremely lightweight. For durability, carbon fiber scored full points since its chemical composition makes it much stronger than its counterparts, and aluminum scored well due to its status as a metal, PVC scored the lowest due to simply being less durable than the others, although this is on a scale relative to the other materials evaluated. The ease of engraving category awarded full points to the aluminum shaft since metal is the easiest material to engrave compared to the other designs. Finally, the cost and ease of fabrication categories both went to the PVC pipe shaft since it is very cost effective and easy to construct when considering it can be purchased from any local store. Carbon fiber needs to be custom made and fitted for each pipe, which makes it harder to acquire and significantly more expensive, and depending on the make of aluminum it can become very pricey.

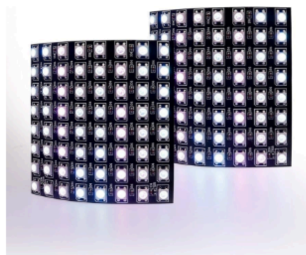
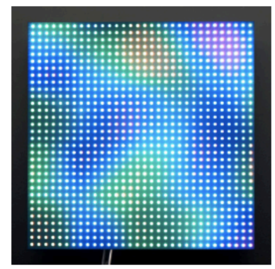
	Design 1: RGB LED Matrix Display		**Design 2:** TFT LCD Touch Screen Display		**Design 3:** LED Matrix Panel	
Criteria (weight)						
Distinctiveness of Colors (25)	5/5	25	4/5	20	3/5	15
Weight (20)	5/5	20	3/5	12	4/5	16
Size (20)	5/5	20	5/5	20	3/5	12
Power Source (15)	4/5	12	2/5	6	3/5	9
Ease of Fabrication (10)	5/5	10	3/5	6	4/5	8
Cost (10)	4/5	8	5/5	10	4/5	8
Total (100)	95		74		68	

Table 2: Display Screen Design Matrix

The display screen design matrix has 3 previous criteria categories and 3 new criteria categories. The previous criteria categories are weight, which is weighted lower at twenty percent due to the lower weight of the display in comparison to the shaft. Cost and ease of fabrication are both weighted at ten percent for this matrix as well. The first new criteria category is distinctiveness of color, which is weighted the highest at twenty five percent. The color is very important as the clients' patients need to view primary colors that are easy to distinguish for effective recovery, and the patients respond differently to different color stimuli. The second new criteria category is size, which is weighted at twenty percent. The size of the screen is rated highly since the clients' patients need a large enough screen in order to react to the display. Additionally, the display has to easily show different shapes, and fit into the casing made for it effectively so the device doesn't become hard to use. The last new criteria category is power source, which is weighted at fifteen percent. The power source of the display screen needs to be small and have the ability to move around easily. This is included in the display matrix as the battery will be chosen based on the power needs of the display, which is variable, and the device should not drain overly quickly.

The design matrix uses the criteria above to determine the best design. For distinctiveness of color, the RGB LED Matrix Display scored full points since it produces vibrant, bright colors, while the Touch Screen produces slightly more muted colors and the 32x32 matrix panel is primarily designed to be viewed at a distance, sometimes emitting colors too brightly for comfort. For weight, the RGB LED Matrix Display scored full points since it is the lightest out of all of the designs due to its flexibility. While the larger 32x32 panel is heavier, it is not as much of a concern as it is for the touchscreen, as its weight may introduce the need for a counterweight in the handle, increasing the weight of the full design. For size, both the RGB LED Matrix Display and the TFT LCD Touch Screen Display scored full points. These designs are both the client's desired display screen size, while the larger matrix would need to be cut down. The power source category awarded full points to the RGB LED Matrix Display since it has the easiest power source to move around. The other two's larger displays may provide a clearer view for the patient, but also require a much higher current, necessitating a larger battery or a quickly rechargeable battery. The ease of fabrication category awarded full points to the RGB LED Matrix Display as well since the displays are relatively trivial to construct and add together. The larger matrix requires Raspberry Pi and pins to effectively operate, which would pose a challenge to wire and code. Additionally the touch screen will be harder to effectively wire and code, as the image display system is different from the other two. The last category was cost and it awarded full points to the TFT LCD Touch Screen Display since it was the cheapest design option. The only cost evaluated was for the display itself, not a corresponding power source, as it was determined to not be a large contributing factor to the overall budget.

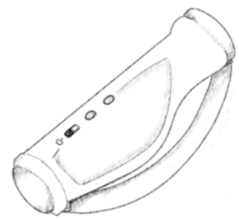
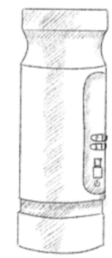
	Design 1: Finger Grip		**Design 2:** Support Band		**Design 3:**	
Criteria:						
Ergonomics (30)	4/5	24	5/5	30	4/5	24
Ease of Use (20)	5/5	20	4/5	16	5/5	20
Size (15)	4/5	12	5/5	15	4/5	12
Ease of Fabrication (15)	3/5	9	4/5	12	5/5	15
Cost (10)	5/5	10	5/5	10	5/5	10
Weight (10)	5/5	10	4/5	8	5/5	10
Total (100)	85		91		91	

Table 3: Handle Design Matrix

The handle matrix has 4 previous criteria categories and 2 new criteria categories. The previous criteria categories are size and ease of fabrication, which are both weighted at 15 percent, and cost and weight, which are both weighted at 10 percent. The first new criteria category is ergonomics, which was weighted the highest at 30 percent. The ergonomics of the handle assess how comfortable it is which is very important for the client since the device will be used multiple times a day for extended periods of time. The last new criteria category was ease of use, which was weighted at 20 percent and assesses how easy it is for the client to use the handle.

The design matrix uses the criteria listed above to determine the best design. For ergonomics, the Support Band Handle scored full points because it offered a hand strap and design that was most comfortable. For ease of use, both the Finger Grip and Flashlight Handle scored full points as they are simple handle designs. The size criteria category awarded full points to Support Band Handle since it was slightly smaller than the other designs. The ease of fabrication category awarded full points to the Flashlight Handle since the design had no complex features. For cost, all three handles received full points since they are all extremely cheap to produce. Lastly, the weight category awarded full points to the Finger Grip and Flashlight Handle since they don't have any extra components weighing them down.

Final Design

The final design consists of the standard flashlight-style handle, with a carbon fiber shaft and an RGB LED Matrix display. The handle will contain an internal compartment for storage of the power source, as well as buttons to turn the display on and off and change colors and shapes. It will also contain a lid to allow for maintenance and replacement of the power source. The carbon fiber shaft will connect the handle to the display and be either engraved or wrapped with a scalable system for patient performance and improvement analysis. It will also be empty inside to minimize weight and accommodate the wires. Finally, the target will be made of an RGB LED matrix, which displays clear and bright colors and is compatible with the Arduino microcontroller, allowing for easy programming. The target should be small enough to minimize weight but large enough to accommodate the microcontroller. Overall, the device will prioritize light weight, ergonomics, stability, affordability, and ease of use, being ideal for clinical settings that perform visual and balance training with patients.

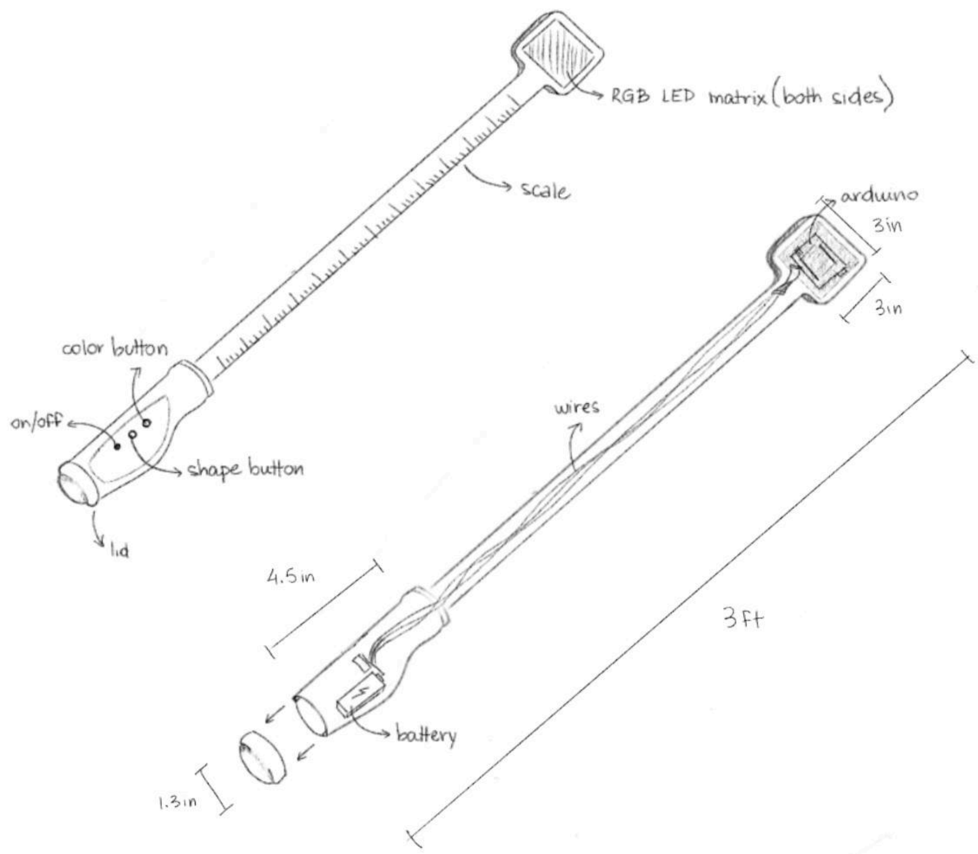


Figure 2: Final design.

Fabrication

Materials

The material that was chosen for our shaft was carbon fiber. Carbon fiber allows for extreme durability and strength while maintaining a super lightweight with a density of around 2 g/cm^3 [10]. Carbon fiber's extreme strength and durability come from weaving together thousands of carbon strings and then epoxying them together. Its chainlike bonds allow for a super strong connection between the bonds and keep the product extremely lightweight [11]. This meets the criteria of being strong enough to withstand daily use and sanitation while maintaining a lightweight.

The material for the handle of the device is going to be a 3D printer plastic, such as thermoplastic polyurethane (TPU). TPU is extremely lightweight and has an average density of 1.14 g/cm^3 [12]. TPU is also extremely durable with a tensile strength that ranges from 25-50 MPa and can stretch 300-600 percent of its original length before it breaks [13]. This durability allows for continuous use without abrasions or cracking, while still providing premium slip resistance. 3D printing allows for the criteria to be met since the handle will be fully customizable.

The material for the case around the display screen is going to be a 3D printer plastic, such as polycarbonate. Polycarbonate is lightweight with a density of 1.2 g/cm^3 while remaining extremely strong by having a tensile strength of 72MPa [14]. It is also extremely impact resistant [14] which is beneficial for protecting the display screen from accidental damage if the device were dropped. 3D printing allows for the criteria to be met since the case will be lightweight and fully customizable.

The display screen will function through the use of an arduino. The specific type of arduino is not known at this point in the design process.

Methods

The carbon fiber shaft can be purchased and will not require any additional fabrication. Since the carbon fiber shaft determines the width of the device, a method to fit the shaft dimensions would be to design the handle in OnShape, then 3D print it. The handle can be attached via a glue adhesive. For the case that holds the display, one method of construction would be to design the case in OnShape and 3D print it to fit the display screen comfortably, while easily attaching to the carbon fiber shaft via a glue adhesive. The display screen and arduino will be purchased which will eliminate the need for fabrication, however, it will be necessary to create the code to control the display screen.

Testing and Results

Throughout the design process, the team plans to test the device to ensure the product meets the specifications outlined in the product design specifications (PDS) document. One of the predominant design requirements laid out in the PDS was that the device must be ergonomic and easy to use. The client will be holding the device in one hand for long periods of time. In order to ensure the device is ergonomic and easy to use, it is essential that the device be lightweight and have a center of mass close to the handle. In order to test the ergonomics and ease of use specifications, the team will have 30 participants hold and use the device for 2 minutes. During the two minutes of testing, the participants will hold the device in one hand while moving it around and using the buttons on the handle. Afterward, the participants will rate both the ergonomics, or how easy the device was to hold, on a scale of 1-10 with 10 being the most ergonomic. The participants will also rate the ease of use, or how easy it was to use the buttons on the handle, on a scale of 1-10. Using the data collected in the tests, two one-sided hypothesis tests will be performed to determine if the ergonomics and ease of use specifications were met. The null hypothesis states that the population mean is 5 and the alternative hypothesis states that the population mean is above 5. The significance level used for the test will be 0.05. A p-value will be calculated and compared to the significance level. If the p-value is less than the significance level of 0.05, the null hypothesis will be rejected. This would mean that the test provided significant evidence to support the alternative hypothesis that the population mean is above 5, meaning the specification is met. Additionally, the weight and size of the device will be tested. As stated in the PDS, the device must be under 5 lbs and under 3 feet long. A weight test will be performed to determine if the device weighs under 5 lbs. If the device weighs less than 5 lbs, the specification will be met. A size test will be performed to determine if the device is under 3 feet long. Additionally, the PDS states that the display screen is clearly visible and at least 3 in x 3 in. In order to test this, a display screen size test will be performed to determine if the display screen is of adequate size.

Discussion

After the previously outlined tests are performed on the device, the results will be analyzed through statistical significance tests and pass or fail tests. If any test is failed, the team will reassess and rework the design. If the ergonomic test fails, the team will reassess the weight distribution of the prototype and work to move the center of mass closer to the handle. This will make the device more comfortable to hold for long periods of time. In the case that the ease of use test fails, the team will rework the handle design to ensure the user can easily use the buttons on the handle while holding the device. If the weight test fails, the team will reassess the design and work to replace components with lighter materials. If the size test fails, the team will shorten the length of the carbon fiber shaft. In the case that the display screen size test fails, the team will either add additional pieces to the display screen LED matrix or look into different options for the display screen. If the design is reworked and improved, the device will be retested with the previously stated tests. Once all the tests are passed and the specifications of the PDS are met, the device will provide an efficient and ergonomic solution to our client's problem. Additionally, the device could be useful to other physical therapists, as there are very limited competing designs on the market.

Possible sources of error could arise from the ergonomic test due to a time limitation. For this test, a participant will use the device for two minutes and rate the ergonomics device afterwards. This test will be used to determine if the device is comfortable to carry in one hand for long periods of time. However, we will not have adequate time to have each participant use the device for long periods of time, so the test will be limited to two minutes. This could cause a source of error because the longer a subject holds the device, the harder and less comfortable it is to hold the device. This means that a subject holding the device for two minutes might not accurately represent the ease of using the device for long periods of time.

Conclusion

The client, Mr. Daniel Kutschera, requests a device to assist in treating his patients by stimulating neurological rehabilitation. The device should feature a display that can show various colors. The device should be designed so that the display can be held a few feet away from the user. This allows for the client to hold the device and test the visual scanning of the client's physical therapy patients. In order to provide a solution to this problem, the team created a design for a device that features a display screen attached to a carbon fiber shaft with a handle on the other end of the shaft. The display screen will be programmed to display solid green, blue, and red colors. The control of the display screen will be located in the handle of the device, making it easy to change the color of the display screen while holding the device. The device is designed so that the majority of the weight is located in the handle of this device. This makes the center of mass closer to the handle, making the device easy to hold with one hand for long periods of time. This allows the client to use the device while also assisting the patient if needed.

In the future, the team will order the materials for the design, including the display screen, the carbon fiber shaft, the handle, and components for the electronic portion of the design. Next, the team will begin creating a fabrication plan. The fabrication plan will include creating a 3D printed display screen box, attaching the various components to the shaft, and adding measurements onto the shaft portion of the design. Additionally, the fabrication plan will include a plan to program the microcontroller and create the electronic circuit to power the display screen. After the fabrication plans are completed, the team will begin production of the device. The team will test various components of the device throughout the production process, changing and improving the design if necessary.

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Appendix

A. Product Design Specifications

Project Function

Patients who have suffered from strokes often sustain long-lasting subsequent symptoms such as a deficit of awareness of one side of their bodies and a lack of static and dynamic balance, leading to injuries and falls. Currently, the solutions for physicians to use in addressing this issue are either too expensive to easily acquire, or inadequate and difficult to use, failing to provide sufficient attention and support to the patient. The goal of this project is to design a convenient and reliable tool to assist post-stroke patients in performing visual scanning training and functional reach tests for regaining dynamic balance. As opposed to the existing yardstick with a yellow dot attached to the end, our device must be professional and contain a target as well as display different colors and shapes. Ultimately, the product should be convenient, affordable, and multifunctional across different therapies for patients suffering from post-stroke conditions.

About the client

Mr. Daniel Kutschera is a physical therapist based in Neenah, WI, and affiliated with the Children's Hospital of Wisconsin-Fox Valley and Theda Clark Medical Center. He works with patients who suffer from post-stroke conditions and seeks to develop a professional tool to improve the current method of performing dynamic balance training.

Design Requirements

Physical and Operational Characteristics

a. *Performance Requirements:* The device must help post-stroke patients improve their balance and visual scanning in the case of hemispatial neglect syndrome. It should contain a target for patients to reach and display different colors and shapes for visual scanning. It must also include a scalable difficulty system, whether automated or manually driven, to register and analyze patient performance and improvement. Lastly, the power source should be located at the bottom to act as a counterbalance to the weight of the display and weight of the general rod to make it easy to hold and manipulate. Additional counterbalancing may be required as well.
b. *Safety:* The device must be stable and lightweight to prevent strain or fall during use. The doctor must be near the patient and have a free hand to assist with balance, which must factor into the design specifications while creating this device. All electronic components must be safely guarded and sealed away to prevent hazards or accidental electrical failures. Any sharp corners should be rounded, as should edges. The design should prioritize ergonomic handling

to prevent injury. This device should not cause physical strain to the doctor or patient using it so as to focus on the effectiveness of the actual test itself.

c. *Accuracy and Reliability:* The device should have a long-lasting calibration mechanism to ensure consistent target positioning and color and shape display. Also, the difficulty grading system should accurately measure and keep track of patient performance and improvement and display it in real time.
d. *Life in Service:* The device should withstand daily use (8 hours a day, 5 days a week) and function effectively for at least 1 year with minimal maintenance, excluding major components such as the rod, the light disk, and the electronics.
e. Shelf Life: The device should be able to last up to 3 years in storage with no change in functionality or deterioration of components, including the battery and the touchscreen, as well as any adhesives used to bring the device together.
f. Operating Environment: The device will be used for physical therapy in indoor clinical environments and as thus should not have to withstand arduous conditions.. The device should however be waterproof, and the electronics should be able to withstand gentle cleaning, as it will be sanitized often due to the age of the patients this hospital services.
g. Ergonomics: The device will be used by a physical therapist to aid in the neurological rehabilitation of patients who have experienced a stroke. The device must be easily held and controlled in one hand, allowing the user to be able to aid the patient if necessary. Additionally, the colored target portion of the device should be easily adjusted by a control panel near the handle. The weight distribution of the device should be balanced and make the device easy to wield, as the client has complained of current solutions failing to meet this criteria and being unwieldy. For this reason, it may be prudent to implement a counterweight or distribute the pisces of the
h. Size: The size of the stick portion should be a maximum of 3 feet in length, which may be adjustable depending on the client's need. The display needs to be a target with at least a 3-inch diameter and be reachable by a patient.
i. Weight: The device needs to be under 5 pounds with the majority of the weight located in the handle of the device to prevent fatigue from accumulating while the device is in use.
j. Materials: The materials for this device need to be able to withstand multiple cleaning wipes along with daily usage, and be lightweight. The screen materials need to be lightweight as well and need to have the ability to portray all three primary colors. Ideally the display should have a greater range of colors to choose from as well, and the screen should easily display different shapes for patients to recognize. These materials must all be lightweight and not impose too much of a power drain onto the battery, as it would be ideal if the device only had to recharge overnight, or had a battery panel implemented to replace used batteries.
k. Aesthetics, Appearance, and Finish: The device should have a professional and high-quality appearance, as it is designed to be used in a medical setting and professional appearance is important to the client. The device must be easily wiped down and cleaned by an alcohol wipe on a regular basis without harm to the aesthetics of the device. The light-up portion of the device must display various bright colors to assist with patient treatment, and must not display as too close to each other. The product should also prevent an element to allow colorblind individuals to see at least two different color sets. Additionally, the design will include measurement markings engraved onto the shaft so the user is easily able to determine

how far the patient can reach. These markings must be professional and easy to see from behind the patient.

Production Characteristics

l. *Quantity:* One prototype of the device is all that is currently needed. More devices can be made after further product development and client testing and approval in clinical use.
m. *Target Product Cost:* The target cost of the product is within $200.

Miscellaneous

n. *Standards and Specifications:* The product should adhere to regulations set by the Federal Food and Drug Administration. Since the product does not have a chemical/drug component, it is expected that the product should pass unhindered. Additionally, it may need to adhere to IEC code 62353, a set of electronic regulations related to medical equipment. All electrical equipment should be safely insulated from incidental access and fire risk that may stand to harm the client and his patients. Lastly, the battery pack should be installed in a manner to minimize clunkiness.
o. *Customer:* The client is a doctor specializing in neurological rehabilitation and desires this product to be used in everyday therapy, making both ease-of-use and durability high priorities. Similarly, the device should be professional-looking and operate on the same level, if not better than current devices on the market. The client specifically requested that in an ideal-world the device should have features such as noise-makers or light up pods built-in to make the product more fun for patients. The client has also requested a balanced and easy to wield device, as current options are unwieldy. Ergonomics is a main concern for the client, as he has a current version of the device which is simply too heavy and cannot be easily used, severely limiting how much it is used in his practice. Eventually, the product may be produced by smaller outpatient clinics on their own within a reasonable budget, or sold to them, to be used for a similar purpose.
p. *Patient-related concerns:* The device should be designed to test the range of how far a patient can reach when used by the client while allowing an attending doctor to maintain a position where they can easily help the patient recover should they lose their balance. The device should also be easily sterilizable with an alcohol sanitizing wipe, as it will be regularly used by different patients who may be especially susceptible to pathogens. The product should require on;y one hand to be used by an attendant doctor, and should be easily adjustable in length so the patient can test their reach and balance effectively at different positions.
q. *Competition:* Current competition involves a homemade version of the product made out of piping and laminated cardboard, as well as significantly larger and more expensive equipment–including the Bioness Integrated Therapy System. The homemade version of the product is effective in purpose yet unprofessional and could use upgrades designed at making the product more fun for patient use. The Bioness device is a touchscreen that lights up with different targets for the patient paired with a board to pivot beneath patients, testing their dynamic balance. While it is effective, it is tedious for the client to activate, and prohibitively expensive for smaller clinics. Likewise, there are similar neurorehabilitation devices such as Hocoma's Balance Rehabilitation System, however they are also expensive and serve a slightly different function than the product is meant to.

B. Proposed Materials Purchasing

(Not materials purchased yet, though these are the materials that will be purchased should the project move forward in its present state.

Item	**Description**	**Manufacturer**	**Mft Pt#**	**Vendor**	**Vendor or Cat#**	**Date**	**QTY**	**Cost Each**	**Total**	**Link**
8x8 LED Matrix	Lightweight and Flexible 2 pack of LED panels. Can be programmed using an Arduino, and has an 8x8 display that has an area of 3 inches by 3 inches	Loamlin	WS2812B	Amazon.com	7174281805 89	10/9/2024	1	$12.51	$12.51	8x8 Link
Carbon Fiber Wrapped Piping	Strong, Lightweight, and Flexible Carbon Fiber Piping that is 25mmx23mmx1m long. 2 mm thick, 23mm radius from center to inside edge. Blue wrap, which also adds extra flair and fun to the design.	Carbon Kevlar Supply	843728109361	Amazon.com	8437281093 61	10/9/2024	1	$47.46	$47.46	Carbon Link
									$0.00	
								TOTAL:	**$59.97**	

Additionally, there will be costs associated with producing a handle or purchasing one, but the method through which that will happen has not been decided upon yet.