

## **Appendix A: PDS**

### **Function**

Design, develop, and build a brace or support that can be worn to aid in holding a person in an upright position when standing or sitting, while also facilitating increased mobility. The client, Linda Oberstar, is a 65-year-old petite female who has suffered from Parkinson's disease for over 15 years and has developed a common complication called camptocormia. Camptocormia has caused Mrs. Oberstar to have abnormal flexion in her trunk that occurs when standing or sitting but disappears when lying down. Due to this abnormal trunk flexion, Mrs. Oberstar has lost the ability to perform every day movements due to a significant reduction in her mobility. The brace or support device must hold Mrs. Oberstar in an upright position so that she is able to comfortably perform everyday tasks, especially cooking in her kitchen.

### **Client Requirements**

- Brace must fit a petite sized woman weighing 556.03 N (125 lbs.) with average strength.
- Device must be less than 44.48 N (10 lbs.), as per patient request.
- Originally, a weight of 13.34-22.24 N (3-5 lbs.) on her mid-section is enough to hold her upright.
- New measurements show the amount needed to hold her as closer to 160.14N (36 lbs.) applied above the breast line.
- Manageable from the front of the body, to ensure independent use.
- Device should be able to fit over and underclothing; adjustable for differing daily conditions.
- Brace must be able to withstand and work with body functions including walking, minor twisting or arm movement, and using the restroom.
- Device must be quickly and easily put on/removed—to enable simple and independent dressing and undressing.
- Device must have a quick release, in case of emergency or bathroom usage.
- Provide adjustable mechanical settings, to facilitate an upright position while both standing and sitting.
- Must replace lack of lower lumbar strength, in order to straighten spine.
- Must be comfortable enough for client to wear for most of the day.
- Facilitate activities such as kitchen and garden usage.

### **Design Requirements**

#### **1. Physical and Operational Characteristics**

- a. *Performance requirements:* The device will be used as needed throughout the day when the client is not lying down or sleeping, and allow for comfortable sitting, standing and minor twisting. The device must apply a load of at least 13.34-22.24 N (3-5 lbs.) to patient's midsection to effectively pull spine

upright, and be comfortably worn all day. However, as of November 10<sup>th</sup>, force measurements via a handheld dynamometer on the patient indicate that the force required is much closer to 160.14N (36 lbs.) when applied above the breast line.

- b. *Safety*: Material must be breathable in order to prevent skin irritations such as bedsores. Device must be able to be removed quickly and easily, in case of emergency. For the sake of retaining muscle strength, the patient should not be able to become completely reliant on it upon use.
- c. *Accuracy and Reliability*: Device must apply necessary forces in correct locations and amounts—which are unique to patients—in both standing and sitting position. An adjustable system will provide this benefit for patient wearing different clothing. Device should be usable over a lifetime.
- d. *Life in Service*: The device will be used seven days a week, 10 hours a day, for approximately 20 years.
- e. *Shelf Life*: Device is not assumed to be “on shelf” unless patient is sleeping. In that case, conditions will be the same as those endured when brace is being used.
- f. *Operating Environment*: Operating environment constraints include situations where the Aluminum used would corrode such as in contact with chemicals. Furthermore the steel plates may be subject to rust if the brace frequently comes into contact with water. Lastly, large heavy should not be picked up considering this will cause for higher force and stress on the cam mechanism.
- g. *Ergonomics*: The brace should ideally have no restrictions of motion for the patient. It should allow for both extension upward (to reach high cabinets) and to sit/bend (to garden). Patient expressed interest in being able to twist to approximately 60° left and right. Device should be comfortable enough to wear throughout life in service.
- h. *Size*: Device should be less than 44.48 N (10 lbs.) and fit to the patient’s unique body type. Should be portable.
- i. *Weight*: Less than 44.48 N.
- j. *Materials*: Device materials should not be flammable, as device will be used often in a kitchen environment. Material should be stiff, assuming that it will provide support. Device should be washable, and not rust/tarnish over time. Material should be durable for the life in service, 20 years.
- k. *Aesthetics, Appearance, and Finish*: Disguisable, if possible. Potentially hidden beneath some clothing. However, patient expressed interest in function over fashion.

## **2. Production Characteristics**

- a. *Quantity*: One device is needed, two if financial means are available.
- b. *Target Product Cost*: Yet to be discussed, assumed to be as low-cost as possible, yet still effective. With BME Funding for Rehabilitation Project, a cost of less than \$500 was predicted to be realistic.

### 3. Miscellaneous

- a. *Standards and Specifications*: Thus far, aware of none. (EC Medical Device Directive)
- b. *Customer*: Utmost, stressed completion. Disappointed multiple times from others pursuing project—including WI orthoist currently in process of designing such braces as a new business venture. Desire function over fashion, but disguisable would be an added bonus.
- c. *Patient-related concerns*: Does not want to be “a robot”—wants to garden and use kitchen, twist and bend.
- d. *Competition*: Mechanical engineering student and outside private orthoist are both working on a device for patient as well. There are surprisingly few articles, patents, and devices aimed towards camptocormia patients, or other patients experiencing trouble straightening and maintaining normal gait.

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- Shelf Life:* Device is not assumed to be “on shelf” unless patient is sleeping. In that case, conditions will be the same as those endured when brace is being used.
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