

Appendix A: Product Design Specifications

Measuring Exercise Systolic BP Using Finger Doppler in Kids

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Function: A simple auscultatory-cuff method is currently used to measure blood pressure (BP) during treadmill stress testing in adults and kids. With children between the ages of six and twelve, it is often difficult to hear the peak systolic sound that defines systolic pressure. Laser Doppler sampling from the first finger or thumb at rest reads this pressured signal nicely so that it can be used with blood pressure cuffs to find peak systolic BP equivalent. The problem is that laser Doppler signals are motion sensitive. Luckily, when the BPs of kids are exercised, their arms are held off the treadmill. A stabilizing device that holds a laser Doppler probe in place on that first finger or thumb, while stabilizing it from movement that causes artifact on laser Doppler signal, is needed.

Client requirements:

- The Perimed Probe 457 Small Angled Thermostatic Probe is the preferred probe for usage
- Device must provide oscilloscope with steady BP signal
- Material should be lightweight
- Device should not interfere with stress treadmill testing
- Device should not infringe upon previous patents
- Device should preferably applied onto patient's right hand

Design requirements:

1. Physical and Operational Characteristics

a. Performance requirements: This device will be worn by pediatric patients and must be able to resist movement of probe. It must be unaffected by sweat and movement of the child.

b. Safety: This garment or glove should not restrict blood flow and should not in any way irritate the wearer while in use.

c. Accuracy and Reliability: This device must restrict movement of probe in reference to the finger/thumb to a level that provides a clear signal on the oscilloscope. It must also must maintain this level of accuracy regardless of the age or hand size of the wearer.

d. Life in Service: It must be able to maintain its function for one hour each time a test is being performed and must be able to be used repeatedly for different patients over a lifespan of five years.

e. Shelf Life: While there are no perishable items, any materials that include fabric or elastomeric components should last five years from date of manufacturing.

f. Operating Environment: The device will be mainly used for patients while exercising on a treadmill in hospitals due to arrhythmias.

g. Ergonomics: The setup for attaching and removing the device onto the right hand should take no longer than thirty seconds. When the patient is walking with the device on, the acceptable max operation of the thumb when worn is less than 23 kg.

h. Size: The size of the device should wrap to the patient's extremity as a glove would. The material of the glove should at least slip on top of the thumb or first finger. Anthropometric data will be used to determine the average dimensions of children's' fingers between the ages of six and twelve.

i. Weight: To prevent inhibition of the patient's exercise, the weight of the device should be no greater than 2.5 kg.

j. Materials: The material used needs to be both lightweight and comfortable for patient to wear while running on the treadmill. Also, the material of the device should be hypoallergenic.

k. Aesthetics, Appearance, and Finish: The device is not required to be a specific color. The texture should not be uncomfortable when applying to the hand, and should integrate well with the laser Doppler Dr. Wilson will provide.

2. Production Characteristics

a. Quantity: One device will originally be made to hopefully accommodate a range of children's hand sizes.

b. Target Product Cost: The client has a set budget of \$1000. This design, however, will most likely spend significantly less when fabricating.

3. Miscellaneous

a. Standards and Specifications: The device must adhere to FDA standards for Class I devices such as general controls to assure quality, suitability of use, and proper labeling. Specific regulatory standards for laser Doppler related devices can be found in Code of Federal Regulations Title 21. 21 CFR 1040.10 and 1040.11 discuss the performance standards for light-emitted products.

b. Customer: The device will be made to ensure that customer satisfaction is prioritized. This will be achieved through comfortable materials, elasticity and durability of fabrics, and simplistic design concepts for ease of use.

d. Competition: Currently, Dr. Wilson's blood perfusion methods using a laser Doppler are novel, so no competitors exist.

