Device for Measuring Arterial Stiffness: Product Design Specifications

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Date: May 4, 2016

Function

The device must function as a diagnostic tool to assess arterial stiffness by measuring peripheral pulse wave velocity at the location of a pediatric patient's hand using two laser Doppler probes, one placed on the index finger tip and the other on the wrist. Pulse wave velocity measurements must be obtained noninvasively and must be precise. Two pieces of equipment are necessary in order to obtain the measurements: a laser Doppler flowmeter with two probes as well as an oscilloscope. The device must output the pulse wave traces for analysis in Excel, and analysis should be simple enough to perform so that the patient can be notified at the point of care whether or not his or her arterial stiffness is outside of the normal range.

Client requirements

- Obtain repeatable values of peripheral pulse wave velocity
- Inform the patient at the point of care whether or not his or her arterial stiffness is within the normal range
- Laser Doppler probe is to be incorporated into the design

Design Requirements

1. Physical and Operational Characteristics

a. Performance requirements: The device will be used daily by pediatric cardiologists on multiple patients, and access to a power supply is needed.

b. Safety: There are no safety concerns for this device.

c. Accuracy and Reliability: The device must output repeatable values of pulse wave velocity that are consistently within 0.5 m/s of each other.

d. Life in Service: Since the device relies on an external power supply and consists of a laser Doppler flowmeter and an oscilloscope, its operation will only be limited by functional problems with these two pieces of equipment. Otherwise, the device will be able to operate indefinitely.

e. Shelf Life: Shelf life is unlimited provided that the equipment is protected from water damage.

f. Operating Environment: The pressure probes may be exposed to a variety of pressures by the patient's hand.

g. Ergonomics: The device must be easy to use for practitioners: a cumbersome setup or data analysis method must be avoided.

h. Size: The device components must all be able to easily fit on a desk in a doctor's office.

i. Weight: The operator of the device must be able to lift all components easily, so all components must weigh less than 10 pounds.

j. Materials: No material restrictions.

k. Aesthetics, Appearance, and Finish: Equipment must not appear obtrusive or intimidating to pediatric patients.

2. Production Characteristics

a. Quantity: One device containing a laser Doppler flowmeter, oscilloscope, and computer for data analysis is needed.

b. Target Product Cost: The product will not cost a pediatric cardiologist any money to obtain provided that he or she already has an oscilloscope, laser Doppler flowmeter, and computer.

3. Miscellaneous

a. Standards and Specifications: FDA approval is not required as all components used have already been deemed to meet national standards.

b. Customer: The device should be able to give patient a diagnosis of arterial stiffness within ten minutes after obtaining a pulse wave trace on the oscilloscope.

c. Patient-related concerns: Patients must be comfortable while measurements are being taken.

d. Competition: Existing devices include the following:

- Vicorder: Test is three minutes long, has optional export of xls files, device is one size fits all for adults, not children, cost: $5,000
- SphygmoCor system - Measure blood pressure/PWV on almost any area of the body, one size fits all for adults, not children, cost: $3,000