

October 26, 2006

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Blood Flow PDS

Problem Statement

Current instruments used in the measurement of pulse transit time are inefficient for home use. An existing product with working ECG and pulse wave circuits along with software to analyze the data has been provided. The primary goal will be to optimize the existing setup for use at home. This will be performed by miniaturizing the circuit, reducing the signal to noise ratio, and improving of the already existing software. These tasks will attempt to be rectified by numerous design additions.

Client Requirements

- Optimized for use with children
- Integrate with previously designed system
- Write program to deal with skipped heart beat
- Integrate flash memory to make device more compact
- Improve signal to noise ratio

Design Requirements

1. Physical and Operational Characteristics

- a. *Performance requirements:* The probe needs to be small enough to stay fixed to children's fingers. More over, the probe needs to stay attached to the finger during sleep. The monitoring system needs to be non-evasive and not interfere with sleep patterns. The monitoring software needs to record the signals from the finger probe and EKG leads while filtering out skipped beats.
- b. *Safety:* Because the device will be used while children are sleeping, the chords must not present a strangling hazard. Also circuits must be made to minimize electrical hazards.
- c. *Shelf life:* The device must be operated by batteries to allow it to be compact. The adhesive needs to be reusable.
- d. *Accuracy and Reliability:* The device should be accurate within 10 ms to accurately relate peaks of signals and accurate transit time can be given.

- e. *Life in Service*: The device should be able to be used for multiple uses by a single patient and then repeated for many more patients.
- f. *Operating Environment*: Ideally, the device will be able to be used in the patient's home while they are sleeping. If optimal minimization is achieved, it could be worn on the wrist.
- g. *Ergonomics*: The functionality of the device is our top concern. The look of the device is of secondary importance.
- h. *Size*: The device needs to be small enough to fit on a bed size table, or optimally, attached to the wrist of the patient to allow the chords to be non-obtrusive.
- i. *Weight*: The device needs to be as light as possible so it will not be felt while sleeping.
- j. *Materials*: Plastic would be used for the casing of the device.

2. Product Characteristics

- a. *Quantity*: For the time being, only one device is necessary. If the device is successful, multiple units may be made in the future.
- b. *Target Product Cost*: The device should be as inexpensive as possible so not to burden families when the device is taken home.

3. Miscellaneous

- a. *Standards and Specifications*: The device must meet FDA medical device specifications.
- b. *Customer*: Christopher Green, M.D. Dept. of Pediatrics UW Medical School
- c. *Patient-related concerns*: The patient's personal information will not be stored in the device. No sterilization of the device will be needed in-between uses aside from the application of new EKG patches at every use.
- d. *Competition*: Probe devices with LED are on the market but there are no devices that measure blood flow and pulse transit time.