

Pulse Transit Time

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Function: The device must detect and measure the vasoconstriction phase in sleep apnea, a function of pulse transit time. The device will be a software program capable of detecting and measuring changes in pulse transit time caused by vasoconstriction. The device will interface with the physiological signals being measured as well as the other equipment currently being used in the sleep laboratory.

Client requirements (itemize what you have learned from the client about his / her needs):

- “box” which can detect Pulse Transit Time (Digital Signal Processing)
- Device must interface with Flaga system (Use ECG and Oximeter signals and output to Flaga)
- Create an algorithm to detect PTT and also determine the correlation of PTT to sleep disorders
- Design budget of \$1,000-\$2,000
- Lead up to a small portable device that can be used by patients at home

Design goals: The goal for this semester is to create an algorithm which will detect Pulse Transit Time and notifies the user when an arousal in sleep occurs due to a sleeping disorder. This design could be strictly software but may lead into a separate “box” which contains the digital signal processing. This design should also interface with the currently used Flaga System. The long term goal is to produce a separate lightweight portable device which has the same features.

Physical and Operational Characteristics

a. Performance requirements: The device will be used in combination with the sleep study equipment, Flaga. It must have the capability to perform during an entire sleep study, 10-12 hours at least twice a week. The design must process real time data and produce a real time output.

b. Safety: The device must not shock the patient or cause interference with the already existing lab equipment. The device must be checked by hospital engineering if it is to be used anywhere in the hospital and would need to be reviewed by a hospital review board if it were to be used in sleep studies. Additionally, the device would need to be FDA approved if it were to be used in a commercial setting.

c. Accuracy and Reliability: The device must record pulse transit time of 250ms +/- 25ms. It must be able to capture accurately and differentiate the stage in sleep

apnea where there is vasoconstriction. In addition, if a sampling technique is used, the sampling frequency must accurately capture the desired signal.

- d. Life in Service:** The device will be used for up to 4 years. It will remain in the hospital sleep laboratory and will be handled by the technicians, nurses and doctors operating the sleep lab.
- e. Shelf Life:** When not in use the device will be stored in the sleep laboratory. It will be stored for up to a maximum of 3 days. It will be in a dry room, away from sunlight, and traffic that could possibly destroy it.
- f. Operating Environment:** The device will be used at room temperature, typical pressure, and average humidity conditions. The device will be used in the sleep laboratories and handled by hospital staff. It may need to be dusted as needed.
- g. Ergonomics:** Device must not interfere with other measurements of the Flaga system and be tailored for pediatrics. Also if time permits to create a stand alone device the device should be comfortable for the child to wear during sleep. Materials which directly come in contact with the patient should be hypoallergenic.
- h. Size:** The eventual size of the design should be lightweight, compact, and portable.
- i. Weight:** The final design of use in a home setting should be extremely light in weight so that it is easily transportable, approximately 5lbs. However, given the time restraints for this semester this value is flexible, the design must not exceed 20 lbs.
- j. Materials:** Materials which come into contact with the patient must be carefully chosen as to some patients have allergic reactions to certain materials. Latex is one such material that can not be used.
- k. Aesthetics, Appearance, and Finish:** Digital signal processing would ideally be down with a small box shaped device which could be connected to the ECG and Oximeter as well as the Flaga system. It should be lightweight and portable. The color should be visually appealing to the eye.

Product Characteristics

- a. Quantity:** For manufacturing purposes, a national supply of approximately 5,000 units would be needed.
- b. Target Product Costs:** Based on devices that offer similar functionality, a portable device could cost \$1,000-5,000 commercially.

Miscellaneous

- a. *Standards and Specifications:*** FDA approval would be needed, and the device would need to pass such tests as EMC emissions, vibrational, and drop testing to be sold commercially. For hospital trials, human subject approval would need to be obtained and the device would need to be approved by hospital engineering.
- b. *Customer:*** The client would prefer that the final device be portable so that patients would be able to take it home with them overnight. It should also minimize connections to patient for ease of use.
- c. *Patient-related Concerns:*** Any parts of the device that directly touch the patient should be non-latex.
- d. *Competition:*** Currently, there are no competing commercial products.