Paul Cyr

Earlobe Heart and Sleep Monitor

Senior Project Proposal

ETEC 471

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- <u>Summary</u>

  I am designing a sleep monitor that logs data based on the users sleeping patterns. This is an ideal device for those who are suspicious that they either snore or toss and turn too much during the night, preventing them from getting a good night's sleep. This device connects to the patient's ear where it monitors their heart rate. If their heart rate goes outside an acceptable range, it will log what time the event occurred. The Earlobe Heart and Sleep monitor is also equipped with a microphone and an accelerometer to record what time the user snores and/or becomes overly restless.

- <u>Benefits</u>

  There is a lot of expensive equipment on the market aimed to help sleep related issues such as snoring, sleep apnea and other airway obstruction problems. While some products like the CPAP may cost over $500, other pricy operations such as the uvulopalatopharyngoplasty (UPPP) to stop snoring by removing the uvula costs thousands of dollars. The Earlobe Heart and Sleep Monitor is a device that will help doctors see what is going on during a patients sleep at an affordable price before trying out something a bit more drastic.

  Since the Earlobe and Heart Rate Monitor is designed specifically for people who are having difficulty sleeping well, it accordingly only needs to be worn for about 8-10 hours. This greatly reduces the demand for a large battery since it may be charged during the daytime hours. The nature of this device also makes it low power, and therefore less demanding on batteries still. Some heart rate specific medical devices such as the Holter Monitor require many leads and patches to be worn for up to 48 hours.

  When someone is using a piece of medical equipment, especially while sleeping, it is very important that they remain as unaware of its presence as possible. A very appealing feature of this device is its small overall physical footprint in comparison to the previously mentioned Holter Monitor which has 5-7 leads attached to the chest.

- <u>Constraints</u>
  - Economic

    The Earlobe Heart and Sleep Monitor is an intermediate medical device that doctors will use to evaluate patients before moving on to a more expensive alternative. Therefore, it will be designed as cost efficiently as possible.

  - Health and Safety

    My product is an electrical device that a patient will be wearing while sleeping, so the microcontroller and all of the wires will be insulated and protected for safety. The FDA is in charge of the standards for medical devices. This will be further covered under the list of standards.

  - Manufacturability

    This project will be designed for manufacturability. All of the parts used will be traceable and it will be simple to manufacture.

- Detailed product description

    o Product sketch
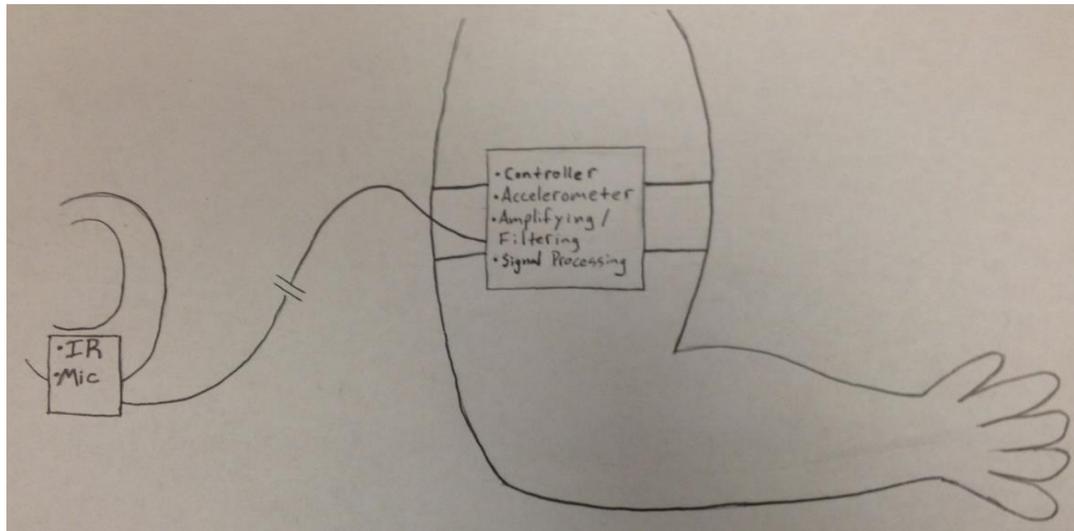
The Earlobe Heart and Sleep Monitor will be a two part system. The main station will house the microcontroller as well as all of the small signal filtering, amplifying and the accelerometer. This portion will be battery powered and ideally strapped to the arm as shown in the picture above. From here communication wires will connect to the ear piece that contains the different sensors. Data will be acquired through IR LEDs and an electret microphone. This information will either be filtered and amplified or sent to the microcontroller for processing and storage. If an event is detected by any of these three sensors, it will be time stamped and saved to a SIM card. From here the results can be viewed by plugging the controller into the computer. A block diagram that visually describes this process is provided below.

    o Block diagram
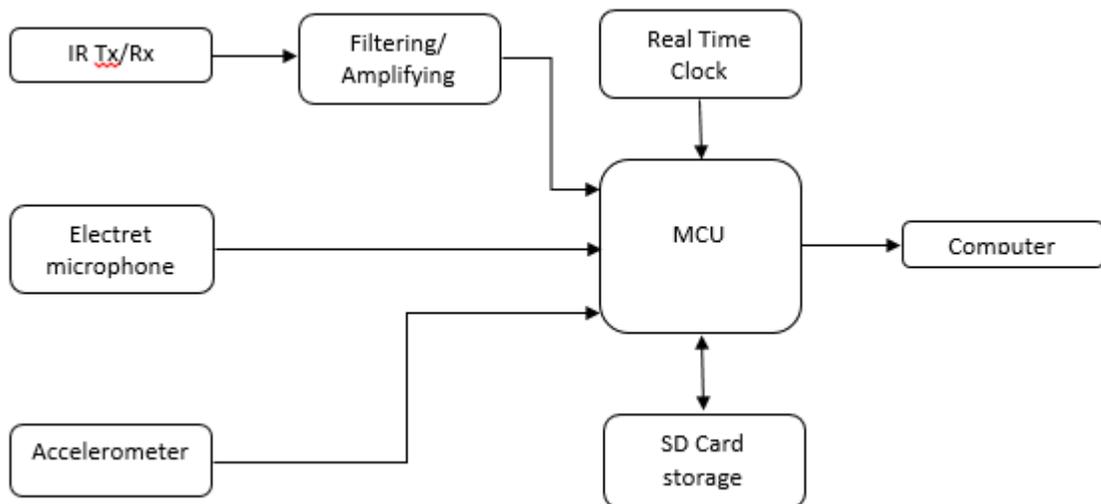
- o Prioritized list of features
    1. My first priority on this project is the photoplethysmograph module. I anticipate this to be the trickiest part of the design, due to the amount of work that will have to be done to filter out and amplify the small signal provided by the infrared sensor.
    2. My second priority on this project is the accelerometer module. Using the accelerometer to detect if someone moves too much during their sleep, and at what time, is the next most valuable piece of information.
    3. My third priority on this project is the microphone module. This electret microphone will be used to see if a threshold decibel level is breeched, implying snoring. This should be the most simple part, so I will leave it to the end if there is enough time.

- Preliminary list of standards

    The FDA is in charge of the standards for both medical devices and electronic radiation-emitting products. The code of Federal Regulations Title 21 is the list of regulations on medical devices from the FDA.

    - o Subpart C- section 820.30   (Design controls)
    - o Subpart F- section 820.65   (Traceability)
    - o Subpart K – section 820.130   (Labeling and Packaging Control)

- Development plan

    The Earlobe Heart and Sleep monitor will be developed with a combination of the measuring/test equipment in the WWU EE labs and parts purchased online. Some of the parts that the labs don't offer include a microcontroller, IR LEDs, electret microphone, SD card, accelerometer and a project box. When looking up microcontrollers I have to keep in mind how many GPIO ports it has, as well as data storage capabilities. Many of the Kinetis boards have an accelerometer on them.

    This device will be battery powered so that the patient may wear it without the cumbersomeness of a power cord. This project will be build and mounted to a project box that can be easily strapped to the arm. The communication wires will run from here to a clip that will hold the IR LEDs comfortably on the earlobe and the microphone close to the user's mouth. For demonstration, I will be wearing the device to show how it looks and what it does. I will need a computer so the results of the monitor can be viewed.

- Bibliography

  - Sleep Apnea Treatment Cost. (2008, January 12). Retrieved October 31, 2014, from http://health.costhelper.com/sleep-apnea.html
  - Holter Monitor. (2013, April 13). Retrieved October 31, 2014, from http://health.costhelper.com/sleep-apnea.html
  - http://www.ecfr.gov/cgi-bin/text-idx?SID=5ec411a9322d6e8a8fac3d482b09254b&node=pt21.8.820&rgn=div5