BME 200/300
Pulse Oxitelemetry
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Product Design Specifications

Function:
The pulse oxitelemetry sensor will collect real time blood oxygen saturation data from patients in a variety of environments made accessible by wireless data transmission. These unprocessed signals will be periodically stored in a base-station 'agnostic' database for analysis and evaluation by healthcare providers. Contemporary technologies are most often wired instruments, which cause mobility limitations that make real time data collection unrealistic for patients.

Client requirements:
- Wireless transmission from device to base station at predetermined intervals
- Comfortable design that will not burden day to day activities
- Battery life beyond 1 week for discontinuous monitoring
- Ability to customize data collection intervals and signal threshold notifications

Design requirements:

1. Physical and Operational Characteristics
a. *Performance requirements*: Primarily 24/7 home monitoring, during day to day activities and while sleeping. Monitoring will consist of wireless signal transmission from the device to the base station and vice versa. Clinical and ambulatory settings would also be desirable.
b. *Safety*: The thermal state of the device cannot cause discomfort to the patient. Patients cannot be exposed to any harmful currents or voltages from the device. Waterproofing the device to limit the likelihood of these events is strongly preferred. Needs to be safely sterilized. Safety warnings will be included and Continua Healthcare Alliance standards will be considered.
c. Accuracy and Reliability: Precision and accuracy should very closely resemble the signal outputs of contemporary pulse oximetry devices. A specific signal tolerance from the wireless output relative to the wired output has not yet been determined.
d. *Life in Service*: Signals must be transmitted by the device at least every 15 minutes, 24 hours a day, 365 days per year. Battery life must last longer than one week supporting these transmission intervals.
e. *Shelf Life*: Shelf life and life cycle of usage should be a minimum of 1 year.
f. *Operating Environment*: The device should not be exposed to temperature ranges, pressure ranges, humidity, shock loading, dirt or dust, corrosion from fluids, noise levels, insects, or vibration beyond those of clinical outpatients.
g. *Ergonomics*: The device usages will be restricted to the heights, reach, forces, and operation torques standard to clinical outpatients.

h. *Size*: Device size will ideally be comparable to or smaller than standard hearing aids, in order to fit comfortably on the ear to allow for minimal lifestyle disruption.
i. *Weight*: Device weight will ideally be comparable to or smaller than standard hearing aids, in order to fit comfortably on the ear to allow for minimal lifestyle disruption.
j. *Materials*: Any materials used cannot irritate skin, or be functionally disrupted by bodily fluids and oils.
k. *Aesthetics*, *Appearance, and Finish*: The device should be as close to the patients skin color as possible, in shape that snugly fits behind the ear, with a smooth, comfortable, soft texture and finish.

2. Production Characteristics

a. *Quantity*: 1.
b. *Target Product Cost*: Less than $100.00 to purchase, manufacture, and distribute each device.

3. Miscellaneous

a. *Standards and Specifications*: FDA approval is required, IEEE wireless transmission certification is beneficial, and the Continua Healthcare Alliance certification is also beneficial.
b. *Customer*: Comfortability, mobility, reliability, device should be discrete as possible.
c. *Patient-related concerns*: Device will need to be sterilized on a monthly basis. Unprocessed patient pulse oximetry frequency responses must be transmitted over a secure network.
d. *Competition*: Masimo and Nonin pulse oximeters.