

Product Design Specifications

Function:

This pulse oxitelemetry device will automatically collect and transmit patient's blood oxygen saturation data from any location with 3G cellular coverage, to one or more physicians simultaneously. The device will also be interfaced with a front end system, which will allow for the pulse oximeter data to be stored and viewed in real-time on a web interface. In doing so, the device improves patient quality of life by providing freedom of mobility, a hands-free lifestyle, and reducing hospital readmissions.

Client requirements:

Device:

- 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

Front End System:

- Ability to store large amount of patient biometric data
- Synchronized with patient medical records
- Real-time data visualization
- Intuitive user interface for ease of patient health assessment
- User adjusted alarm set points

Design requirements:

1. Physical and Operational Characteristics

- Performance requirements:* Primarily 24/7 monitoring, during day-to-day activities and while sleeping. Monitoring will consist of wireless signal transmission from the device to the cellular network and vice versa. Clinical and ambulatory settings would also be desirable.
- 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. The RF exposure guidelines will be taken into account. Waterproofing the device to limit the likelihood of these events is strongly preferred. It needs to be thoroughly sterilized. Safety warnings will be included and Continua Healthcare Alliance standards will be considered.
- 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 will be determined.
- 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. Therefore the device should be encased.

g. *Ergonomics*: The device usages will be restricted to the heights, reach, forces, and operation torques standard to clinical outpatients. The user interface should be easy to use and provide the most important data in an efficient web layout.

h. *Size*: Device size and 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.

i. *Materials*: Any materials used cannot irritate skin, or be functionally disrupted by bodily fluids and oils.

j. *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. The user interface will be built with bootstrap, which provides modern template styling for an aesthetically pleasing design.

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. Before trials, IRB approval will be requested.

b. *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.

c. *Competition*: Masimo, Nonin, and Phillips pulse oximeter