

**BME 200/300 Design**  
**Remote Patient Postpartum Monitoring App**  
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**Preliminary Design Specifications**

**Function:**

The device will consist of a mobile app in conjunction with a bluetooth-enabled blood pressure cuff and heart rate monitor to measure outpatient vitals and transfer those readings to a nurse database. Ideally, this will decrease or eliminate patient readmission postpartum, especially relating to hypertension. The app will provide a medium for physician-patient interaction, patient monitoring and video conference with healthcare specialists (nurses, doctors, etc.).

**Client requirements:**

- The application will be bluetooth enabled.
- The application will automatically read in monitor values without internet connection.
  - Data could possibly be uploaded to Epic databases.
- The application will connect to the internet to allow for other features with the primary concern being data sharing.
- The application will sync with the A&D UA-767-PBT-Ci blood pressure monitor.
- The application will work with the patient's existing smart phones and tablets.
- The app will allow the freedom to record measurements in the order of their choosing.
- The app may utilize Fuze, a mobile communication platform for communication between physicians, nurses and patients. It is currently used by Meriter Hospital.

**Design requirements:**

1. Physical and Operational Characteristics

a. *Performance requirements:*

The app will be used daily for six weeks post-discharge. Patients will monitor their blood pressure and heart rate twice daily. The app can be used offline for data collection, but will be synced to the internet to share the collected data with healthcare staff.

b. *Safety:*

The device will require a warning that app and video conference on the app do not replace mandatory scheduled visits with a medical professional and prescribed medications may not provide full treatment for postpartum disorders. In order to protect private patient information, the app will adhere to HIPAA standards and requirements [1].

c. *Accuracy and Reliability:*

The app will read in measurements from several bluetooth devices to the smallest degree allowed by the device. For example, if the scale reads 125.635 kg, the program will read the same number. It will not round to 126 kg or 125.64 kg. Measurements read on the program will always reflect those taken by the connected devices.

d. *Life in Service:*

The app will work for the entirety of a patient's six-week monitoring period. Furthermore, the app will ideally be updated to run effectively with new operating systems soon after they are available. Features such as video nurse conferences and physician consultations will be limited to hospitals hours, but measurements can be taken and uploaded at any time of the day.

e. *Operating Environment:*

The app will run on major smartphones including iOS mobile devices and Android Devices. Ideally, the app will be able to output data directly into spreadsheets the nurses are using, as the current product requires all data to be manually input into the system from a report that is formatted poorly and not useful.

f. *Ergonomics:*

The app will be user friendly and simple to navigate for smartphone users of all abilities.

g. *Aesthetics, Appearance, and Finish:*

The app will have professional yet uplifting look that makes users trust in the ability of the app and comfortable using it. Colors will follow a UW theme (red and white) and users, physicians, and nurses will all have avatars.

## 2. Production Characteristics

a. *Target Product Cost:*

Ideally, there will be minimal cost associated with the development of this app. Prospective costs could include licensing fees and hardware procurement. Total system costs will include the mobile device and associated bluetooth hardware. The user is responsible for the cost of the mobile device while the hospital will provide the necessary monitoring equipment.

## 3. Miscellaneous

a. *Standards and Specifications:* international and /or national standards, etc.

Our app and bluetooth device would fall under the jurisdiction of the sub committee of the FDA, center for devices and radiological health (CDRH). It is necessary that all medical devices are registered with the FDA[2]. However, our device will most likely fall under the class I category and will likely be exempt from premarket notification as our product falls under the medical device data systems.

HIPAA compliance [1] will be necessary in transferring patient information to the nurse database. This private information can range from vital sign readings to patient names and addresses. The app must be password protected and encrypted with accordance to HIPAA standards. Recommended and hospital-issued monitoring equipment used in conjunction with the app will be FDA approved.

b. *Customer:*

Customer requests and needs will be analyzed with data from the client once the information is readily available.

c. *Patient-related concerns:*

Patient privacy is the utmost priority of this project. HIPAA standards [1] and regulations will be followed to ensure no patient information is made public or used commercially. Furthermore, information will not be shared with anyone to whom the patient has not given consent.

d. *Competition:* Are there similar items which exist (perform comprehensive literature search and patents search)?

Currently, the client and a team developed an existing program that was successful in reducing patient readmission. There also are existing blood pressure monitoring apps that do not fulfill all client-specified requirements, especially relating specifically to pregnancy. These home blood pressure monitoring apps are also targeted for patient blood pressure monitoring needs [3], rather than developed with a health provider-to-patient relationship in mind as desired by the client. These top apps also use email to export data [4], which doesn't fulfill the client's goal of eliminating manual data entry by the nurses. Many of the top blood pressure monitoring apps [3] - Family Lite [4], Blood Pressure Companion [5], Smart Blood Pressure Tracker [6], and Blood Pressure Watch [7] - are available for iOS devices, supporting the idea that an iOS app will reach a majority of the intended users.

[1] State of California. (2017, July 24). *What is HIPAA* [Online]. Available: <http://www.dhcs.ca.gov/formsandpubs/laws/hipaa/Pages/1.00WhatisHIPAA.aspx>

[2] U.S Food and Drug Administration Code of Federal Regulations, Title 21, Part 801, 2017.

[3] K. Nouse. (2016, August 19). *Top Four Blood Pressure Monitoring Apps* [Online]. Available: <https://www.engadget.com/2016/08/19/top-4-blood-pressure-monitoring-apps/>

[4] Taconic System, LLC. (2012). *BPMonitor Lite* [Online]. Available: <http://www.taconicsys.com/app/bpmonitor-lite.html>

[5] Maxwell Software. (2016). *BPCompanion* [Online]. Available: [http://www.maxwellapps.com/apps\\_16\\_bp\\_companion.html](http://www.maxwellapps.com/apps_16_bp_companion.html)

[6] Evolve Medical Systems, LLC. (2012). *Smart Blood Pressure (SmartBP)* [Online]. Available: <http://www.evolvemedsys.com/faq>

[7] (2017). *Blood Pressure (BP) Watch* [Online]. Available: <https://play.google.com/store/apps/details?id=com.boxeelab.healthlete.bpwatch&hl=en>