

EE93 / Comp 50 – Medical Mobile Devices and Apps Semester Project Description

Instructors: Ming Chow and Ron Lasser

Jumbo Medical is a Boston-based company started several years ago by a Tufts engineering alum. *Jumbo Medical* manufactures medical monitoring measurement equipment for in-hospital and small clinical use. Their products are used worldwide with major revenue coming from domestic sales. While small, and just coming out of their start-up adventure, the company sells three products: PM-101 – a low-acuity patient monitor supporting fast, quality care decisions for the critical vital signs: blood pressure (systolic/diastolic); pulse rate, SpO₂, and temperature; the Dart 73 – a lightweight monitor with 8.8-inch display on a 4-wheel pole for mobile patients in all rehab situations requiring acuity level care; and the Aerial – 2000 a bedside wall-mounted monitor providing core vital signs, advanced cardiac real-time data analysis and display, and ventilation, a high-acuity patient monitor for a broad set of clinical measurements adaptable to varying patient environments. These products implement several patented technologies to secure error reduction biological measurements, in sync with the company's mission statement – *measurements you can believe*.

Although *Jumbo Medical* has won several new product awards at major medical technology conferences, they recently missed a key opportunity to move into portable and mobile products. The assessment in a public statement by their CEO to investors stated, "...we did not believe the app market, especially the tablet infiltration into medical would explode the way it did. I don't want to say it caught us off guard, as we have been moving in this direction, but, and no apologies here, I believe it was the small sensor integration with the tablets that we really messed up on." The miss has dropped revenues by 10% causing a hiring freeze at the company. The existing Engineering team is focused on supporting current products to maintain their technological competitive edge.

Recently, *Jumbo Medical* obtained a competitor's brochure and user manual for a monitoring product line. Physicians and nurses use the manual for training and learning about the comprehensive features available for measurement display. *Jumbo Medical* desires to design and sell a mobile medical patient monitor with a distinct sensor handheld. The sensor handheld is connected via Wi-Fi to a tablet that acts as the patient monitor. This provides ambulatory or bedside, and possibly remote, care. Remote would be a breakthrough product. The Vice President of Marketing has stated emphatically to the Marketing team: "We've obtained a user manual from a competitor: for an older portable product, we would like to have a lot of the features from that product but much more compact, and mobile, and in an app. Packing the competitor's features into a mobile transducer and app—that's the product we want to deliver."

Your team is being asked to help the Tufts alum. Your team will need to demonstrate a reasonably comprehensive set of measurements provided by their competitor's portable monitor. As a minimum, your solution must display and react to signals for the vital signs providing acute care: blood pressure (systolic/diastolic); pulse rate, SpO₂, and temperature. However, you are only being asked to implement in hardware real-time temperature, pulse, and electrocardiogram (ECG) measurements. All other features are to be simulated and appear on the display as real-time measurement. The expectation is that your demo prototype will be taken to a medical trade show and shown privately to potential customers, rather than in the booth on the show floor. Your team will need to construct dummy real-time patient data for the simulated patient measurements. The dummy data will need to provide good vital signs and vital signs that trigger alerts and alarms.

Caregiver intervention is necessary to reset the signal measurement causing the alarms in such a way as to not compromise the other measurements. However, alarms and other indicators are to excite the patient. The user interface and other parts of the app need to be intuitive to nurses, medical technicians, and physicians.

As the Vice President of Sales states your job as "I consider the importance of providing units that have low weight, small, sleek packaging, not the breadboard stuff that gets packaged quickly to meet a deadline. No, the look and feel and size and weight all need to be thought about at the same time as the hardware and software. It is a trade show prototype that I want to be able to sell. I know several hospital administrators who will be coming to the show. That's the market. I want to sell to them. Actually, I want them to see the demo and want to buy it with me having to make the sale. To be sure, initially for the US, but there is a bonus if the internationalization of the units is well conceived, implemented, and delivered."

An interview with *Jumbo Medical* Product Marketing and Sales departments identified several critical features:

- Real-time – Dropped data ± 2 data cycles
 - Testing must explicitly demonstrate this specification
- Wi-Fi from sensor to iPad – Data transmission is direct, no intermediate server communication is acceptable.
- Medical privacy – Patient data must not be compromised for any accidental eavesdropping.
- Recovery from fault – Sensor failure, loose connection, reset, unit must have soft recovery, must not require reboot.
- Signal display equal to or better than competitor
 - Signal must not introduce a medical anomaly or irregularity in patient data signal. Accuracy of data trace is critical within 4 pixels.
- Under arm temperature -- Temperature is measured under the arm. Arm will be held vertical at patient side. Transducer will be held in place by patient squeezing arm gently against torso. Temperature measurement reaches steady-state measurement within 20 seconds with audible/visual

- indicator.
- Pulse at the finger – pulse measurement reaches steady-state measurement within 3 seconds with audible/visual indicator.
 - 3-lead EKG (two shoulder leads, on leg/ankle lead for ground) – EKG measurement reaches steady-state measurement within 6 seconds with audible/visual indicator.

Key Consultant Deliverable & Demonstration Dates to Jumbo Medical Marketing and Sales Staffs – Some deliverable dates may change as sales team canvas potential customer prior to the January trade show.

Date	Week	Thursday Deliverables
7 & 9 Oct	Week 6	Problem Definition
14 & 16 Oct	Week 7	Patient Monitor Customer Requirements
21 & 23 Oct	Week 8	Block diagram of major modules Task List: task, duration, deliverable, who responsible
28 & 30 Oct	Week 9	Project Status Update
4 & 6 Nov	Week 10	User Interface Demo of Major Functionality
11 & 13 Nov	Week 11	Hardware/Software Design Review
18 & 20 Nov	Week 12	Wifi Data Transfer Demonstration
25 Nov & No Class	Week 13	Project Status Update
2 & 4 Dec	Week 14	Patient Monitor Demonstration& Presentation

Customer Interviews

Customer interviews were held with potential customers from January 2014 to August 2014 to understand the customer requirements for the mobile device and app. The summary represents a significant number of similar statements from multiple interviews. The comments were redacted from audio recordings by the sales team during their on-site visits.

Customer Interview Summary

27 potential in-hospital customer were interviewed to obtain next generation customer input into the design of the new gazelle 100 – mobile medical patient monitor and app. Customer types: doctors, in-room care nurses, central station nurses, network IT; chiefs of medicine, intensive care staff, hospital maintenance and repair staff. An aggregate of the input is described below.

“We need high-performance monitoring for critical and intermediate care settings. It is imperative. We are driven by quality care of patients, and cost. Look, we need to have the patients recover quickly. We can do that if we can tell clearly some thing is amiss quickly and respond.

No matter what the patient monitors must be designed to match the pace of activity around here. We dart, listen to this, we dart, my people are like bees in a hive, they don’t stop. They are like sharks continually in motion. They need the information now, they need it while they are on their way to the patient, and they need it when they are not here for critical care”

“Each patient has unique needs. The needs of adult, pediatric, and neonatal intensive care are different and crucial. The refresh must be immediate, no glitches, no drops, no rests; a drop is deadly for anesthesia and peri-operative care; and cardiac care environments, a mobile device for bed and ambulatory care. I need to see it without my glasses. I need to see the monitor from close where I set it on a table or desk, to across the room – a hospital room is fine”

“Don’t rest on your heritage in patient monitoring. The Dart is fine, but the technology is moving. We need a product that is ahead of us, so we can catch up. I’ll be honest, doctors move slow, but care does not. Patients want to see the monitor, so don’t scare them. Inform. A blip is an issue. It takes us from something important or life threatening to wasting time on a nuisance. I need see the sweep. I need to read the numbers. The nurse needs to call out the numbers or describe the wave.”

“A highly flexible screen configuration; an extensive clinical measurements menu; built-in clinical support tools such as event surveillance and notification. You do that, I’ll buy a hundred. One for each member on my staff.”

“No new fangled gizmos, I want a conventional diagnostic 3-lead ECG, and multi-lead arrhythmia analysis; and the other features, I don’t need.

“Easy to use. What does that mean to me? It means this; in less than five steps, I can turn the thing on, and immediately know what to do. I don’t have to waste my time learning. It is just obvious. If I need help, I press here and help appears, in context, not like some computer manufacturers where you search on how to delete a file and it shows you unrelated crap. I can’t waste time.”

“The sensors are independent of the box. Long battery life for the transducer. Operates on a networked platform that can span the hospital enterprise or be local if required. Patient privacy. Security. Cost effective. Small. Fits in the palm of a small petite nurse who will not drop it. Very light in weight, but heavy enough so you can feel it. But here’s the thing: after you carry this around all day, you don’t want your arm to be sore so you can’t do the same thing the next day.”

“I need it to be able to be configured to suit patient acuity, department protocols, or specific procedure requirements. I don’t want it to fit every hospital on the planet. Just mine. Or I want you to make think you did it just for me. Do you understand? Let me make myself clear: our hospital makes money. We make money because we provide excellent care. We provide excellent care because we have systems and procedures that work for us, and are a cut above all the others. That is way patients choose to come here: for emergencies, for electives, and for hangnails if they need it. I don’t want some piece of technology to put a black mark on all that we have achieved. Your equipment when we buy doesn’t look and work like your equipment, it looks and works like our equipment. We can make it do what we need it to do. Do you understand?”

“It must be compatible with the range of SpO2 technologies and sensors from all other manufactures. We mix and match probes all time. Wireless is fine, but it has to work with all the probes.”

“Patient monitoring and clinical analysis – the patients need to be connected to their doctor and vice versa at all times. That is the next wave.”

“As a nurse my thing is the user interface. Please improve visibility of patient data, make it easier to use, and to be compatibility with standard software. As to user interface—the doctors need the information without error, my staff needs to provide it; I have nurses who are part-time, work at several hospitals, and use different technology all the time. I need them to come here and use the technology and not screw up because they are confusing it with a tech monitor they used yesterday somewhere else. Standard. I have nothing more to add there.”

“Make it automatically adjust in size depending on the number of waves or data being configured and viewed.”

"If we configure it, it must go back to the default with one touch and return to our user interface with another touch."

"For me the capture and review of diagnostic 3-lead ECGs at the monitor before sending them to the the DIG (Diagnostic Information Center) is a necessity. Able to print cardiograph-type, diagnostic 3-lead ECG reports from the bedside."

"I need to review 3-lead interpretation and the patient's previous 3-lead ECGs directly at the bedside and trigger 3-lead export to an ECG archive. Will it do that?"
"Each NBP (non-invasive blood pressure) measurement must produce a data series for storage in the patient's trending vital signs table. Other acuity measurements must be able to be added for a comprehensive vital signs data set for any non-invasive measurement."

"I am tired of the alarms going off here and there over stupid things that happen. Can you make the alarm smart? Maybe if there is a problem, it takes three heartbeats before it sends alarm. I know there is a patient monitor someone sells, they call it a delay algorithm. What is great is it reduces the number of pulse oximetry nuisance alarms. My staff can stay focused on the patient's real problem."

"The transducer doesn't need to control the mobile, just send data to it. I don't want controls everywhere and accidentally getting pushed. Any thing that touches the patient, just collects data."

"No cables. None."

"It has to be all touchscreen operation. The transducer functionality must be set by the base station."

"Let's see, what do I want. Hmm, not more than a one-button keypad, one-touch, get it, no hunting around for what to press. Easy to read display, an LED to let me know the transducer is good, broken, bad, what condition the thing is in. If it is a stand alone, some diagnostics to report on what I need to do. Oh and battery level. That is critical. Rechargeable is essential or runs on standard AAA batteries. Auto power shutdown after 8 seconds on no use. Did I say a low battery indicator. The outside of the transducer needs to be able to take a high-impact. It cannot break or be damage if it is dropped from under someone's arm onto a linoleum cover concrete floor."

"Size, for me, well my palm is small. I'm petite. The electronics part, the package, that's what the engineers call, no more than three inches by three inches by about 2 inches tall. And the transducer part: well that can be like a pretzel stick size. That would be okay. No bigger. Maybe half that size if think about it. So, maybe about three-eighths to a half-inch in diameter and about this long. So about the size of my palm, maybe three, four inches. Most of my nurses would agree with this too."

“Simple, one-touch commands.”

“Easy patient information input and navigation of features.”

“Customized viewing options—I won’t buy one if it doesn’t customize to me.”

“Okay, the data. Here’s my list: I want to view and analyze data in graphical or numerical formats. I want to juxtapose real-time measurements and trended data. I want to organize every onscreen element. I don’t care what the onscreen thing is—from waveforms to data labels—I want pre-sets for the screen. Color. Bright waveforms seen from 20 feet. At least 4 waveforms. Quiet, able to dim for night, but still seen, starts quickly. I don’t like these long boot ups or reboots.”