Respirage:

A Respiratory Rate Measurement Device for Emergency Department Triage

Final Report
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1. ABSTRACT

To improve medical decision-making in the emergency department (ED) of hospitals, we have developed a novel respiratory rate (RR) measurement device for use in ED triage. The current standard of care for respiratory rate (RR) measurement in ED triage is manual measurement, often for 15 or 30 seconds. Due to this, and nurse under-appreciation of RR, nurses rarely measure RR accurately, if at all. Although a broad range of RR measurement technology exists, few devices are both cost-effective and suited for the transient nature of triage. Our device is designed to measure RR in 15 seconds or less, with an accuracy of ±2 breaths per minute (bpm) of the World Health Organization's (WHO) gold standard. It consists of a sensor to be clipped on the patient's clothing over the abdomen or taped to the skin on the patient's stomach. A data acquisition system records motion of the sensor due to breathing, and translates that to a RR frequency for nurse to record. Incorporating this technology into the triage workflow does not increase the average time it currently takes to measure vitals, 160 seconds. The device is designed to cause little to no discomfort to the patient, so as not to interfere with the patient's true RR.

2. INTRODUCTION

2.1 The Clinical Problem

Every year, there are 129.8 million visits to emergency departments (EDs) in the US.[1] The assessment of vital signs – pulse rate, oxygen saturation, RR, blood pressure, and body temperature – during ED triage plays a fundamental role in medical decision-making and determines how quickly a patient can receive the appropriate level and type of care. During the progression of disease, changes in RR are of a greater magnitude relative to other vital signs and typically appear earlier.[2] As a result, RR is most effective in indicating the onset of conditions in various body systems, such as cardiac arrest, heart attack, severe acidosis, sepsis, and increased intracranial pressure.[2,3]

Both RR and tidal volume depend on the exchange of carbon dioxide and oxygen between the lungs and the rest of the body. This gas exchange relies on the body's metabolic demands and adjusts with physical activity or in disease states such as infection. In life-threatening diseases like metabolic acidosis, the body attempts to correct hypoxemia and hypercarbia through respiratory compensation. As a result, both RR (tachypnea) and alveolar ventilation (hyperventilation) increase significantly.[3] Since the magnitude of an individual's metabolic demand is reflected in the RR, patients with an elevated RR often have a more serious illness.[6] Conditions including hypoxemia, acidosis, sepsis, increased intracranial pressure, and hypotension are capable of inducing tachypnea, and they all also have the potential to lead to arrest.[4] Decreased RR (bradypnea), which can result from life-threatening conditions such as renal failure, brain tumors, or high intracranial pressure, not only limits supplies of oxygen, but also endangers other organ systems in the body.[7] In effect, RR is an important indicator of a severe abnormality in not only the respiratory system but also many other body systems, and is therefore a key predictor of adverse events.[3]

Triage scoring systems (Figure1) in the ED use abnormal RR cutoffs of less than 12 and greater than 20 breaths per minute (bpm) in defining a patient's priority level. In fact, a RR of 27 bpm has been shown to single-handedly predict cardiac arrest up to three days before it occurs, with a sensitivity of 54% and a specificity of 83%.[3] If triage scoring systems are to work effectively, all vitals measurements – especially RR – must be accurate.

2.2 The Need

Unfortunately, RR is the only vital sign that is measured inaccurately, if at all. While all other vitals are measured by the press of a button on single, multi-parameter machines like GE Healthcare's Dinamap®, RR is still measured manually by nurses in triage, often for 15 or 30 seconds. Manual measurement is performed through careful visual monitoring of chest movement. The team at Emsol Health has surveyed ED physicians and nurses (Figure 3), as well as observed the measurement of vital signs during ED triage. Nurses must completely stop what they are doing to accurately measure RR, which is inconvenient and intrusive compared to measuring other vitals. Because manual measurement interrupts the fast-paced workflow of triage, nurses often completely neglect the RR. Thus, nurse measurements of RR are inaccurate and tend to cluster around 16 bpm (Figure 2), which misleadingly falls in the normal RR range.[4]

Eight out of ten nurses that Emsol Health spoke with admitted that they often neglected RR measurement, citing inconvenience as the primary reason for doing so.

The problem of inadequate RR measurement transcends the hospital. Today, 49% of Americans are at risk of heart disease, and nearly 2,000 cardiac arrests occur in the US every day.[5] The risk factors for heart disease are the same as those for cardiac arrest, which more often than not leads to death. Members of this at-risk population, particularly those above the age of 45, need to know in advance when an adverse event may be imminent, so that they can seek appropriate preventive care in a timely manner. Treatment of early heart disease symptoms through oxygen therapy and administration of nitroglycerin would be less costly than treatment following a heart attack or cardiac arrest. More importantly, preventative treatment would thwart irreversible damage, and the likely death that follows. Earlier detection of the onset of such conditions in healthcare and home settings will improve medical decision-making and ultimately reduce the likelihood of adverse outcomes. Thus, there is a need to quickly and reliably measure RR.

2.3 Design Specifications

After carefully weighing our need criteria, we adopted the following goals and constraints:

DESIGN GOALS
1. Measure RR in ≤ 15 sec.
2. Must be convenient & easily applied; must be user-friendly, simple, & intuitive[19]; ≥ 7/10 nurses must prefer our device over manual measurement.
3. Measure RR accurately with error ≤ ±2 bpm w.r.t. WHO gold standard.[2]
4. Provide visual feedback that displays real-time RR.
5. Minimize cost to ≤ $60 per device.
6. Minimize discomfort to patient; device does not cause pain.
7. Must be easy to be trained to use (proficiency after a 5-minute instructional video).

DESIGN CONSTRAINTS
1. Safety Considerations: • If device contacts skin, it must be disposable or contain a disposable interface. • If device is non-contact, it must not pose harm to the patient (such as dangerous radiation levels).
2. The total time required to take all vitals must not exceed 160 seconds.

3. DESIGN

3.1 Device Overview

Respirage (Figures 4.1, 14) aims to solve the RR measurement problem with a simple, reusable device that can be quickly clipped to the patient's clothing to measure RR with an accuracy of ±2 bpm. Respirage's combination of speed, ease of use, and comfort, as well as its ultimate reduction of downstream healthcare costs makes it ideal for use by triage nurses in the ED and at-risk patients in the comfort of their own home.

- Respirage works quickly, allowing real-time RR to be measured by a sensor, calculated by a microprocessor, and then displayed on a small LCD screen on the front of the device, in just 15 seconds. Respirage will not increase the total time required to measure vitals in triage and will allow home users to quickly measure RR.

- Respirage is convenient (Appendix F). Ease of use is critical for ensuring that triage nurses actually use the device to measure RR. Once the nurse begins data collection of the other vital signs, she can simply clip Respirage onto the patient's clothing, press a button to start data collection, transcribe the number displayed on the device after 15 seconds, and then unclip the device from the patient's clothing for reuse later. This process is simple and will easily fit into the triage workflow. For users measuring RR at home, application of the device will be intuitive, and the simple option of using a disposable adhesive option to attach Respirage under clothing will allow the user to carry out other tasks while their RR is being measured.

- Respirage is comfortable and noninvasive, with no cumbersome parts. This is important because discomfort could affect RR and produce an unreliable measurement.

The typical triage workflow consists of attaching the pulse oximeter to the patient, followed by a blood pressure cuff. Immediately after, the temperature is taken and the nurse observes the patient to determine RR. Modifying this workflow to incorporate the Respirage is simple. An integrated workflow (Figure 5) is as follows:

Step 1: The patient enters the triage room with a chief complaint and is seated in a chair.
Step 2: Place the pulse oximeter onto the patient's finger to measure pulse.
Step 3: Place the blood pressure cuff onto the patient's arm.
Step 4: Attach the Respirage to the patient's clothing near the upper stomach/lower chest.
Step 5: Place the thermometer into the patient's mouth to measure temperature.
Step 6: Record the RR displayed on the Respirage after 15 seconds.

3.2 The Measurement Mechanism

Throughout our design process we have tested various RR measurement mechanisms, including piezoelectric sensors, thermistors, and acoustic sensors. However, a common problem with each of these sensors was a low signal-to-noise ratio, due to high sensitivity to other internal and

external noise sources, such as pulse sounds and vibrations, movements of the patient, as well as various external sound frequencies that are easily picked up.

Our team has ultimately chosen a tri-axial accelerometer (Figure 7; Appendix A) to serve as the hardware responsible for direct measurement of respiration. Displacement of the chest and abdomen is a common indication of respiration. Such displacements are significant enough to be detected by the eye of a nurse, especially since the standard of care requires counting the number of chest displacements of a patient through visual observation. Based on this standard, a tri-axial accelerometer is an appropriate device to use to measure displacement.

3.3 Signal Processing & Filtering

The output of the device (Figure 8) is an array of three voltage signals (referred to as 'points'), each of which is converted into a digital signal with integer values from 0 to 4095. Each point is stored with the sampling time. The team wrote a collection of Java classes (Figure 9; Appendix D) to read, analyze, and plot the data from the microcontroller (Figure 6) to make testing and design more visual. The code used to analyze the signal is the same algorithm used on both the microcontroller and computer. One important aspect of the code is the establishment of a baseline for each component. For about 1-2 seconds after the device is placed and switched on, the code finds the average of each component, which is labeled as a baseline. All values read from the device hereafter can then be interpreted as deviations from this baseline.

In Figure 10, the red line corresponds to the "*X*" axis, the green is the "*Y* "axis, and the blue is the "*Z*" axis of the accelerometer. The baseline for the *X* axis is about 2175, and it hardly deviates from this. The *Y* and *Z* signals, however, do visibly deviate from their respective baselines during a breath. Because there is likely to be too much noise in the raw component signals, a fourth value (*L*) was added. *L*, shown as the orange line, represents the combination of the three signals from the microcontroller as the magnitude of the vector sum of the three components multiplied by two. The orange values are not measurements from the microcontroller; rather, they are calculations based on the microcontroller data that have been plotted on the same graph for comparison.

With this method, any deviation of any of the components from its respective baseline will contribute to a positive increase in the orange magnitude plot. If the whole device were to be rotated any number of degrees about any axis (not even an *X*, *Y*, or *Z* one), then it is possible that there would be deviations of varying magnitude from any of the component axes. This is taken into account by finding the magnitude of all three components. Furthermore, the constant scaling factor of two ensures that even small deviations from the baseline are noticeable. Thus, the device has a robust response to inexact placement on the abdomen. As long as there is a reasonable degree of displacement on the spot where the device is placed, then the magnitude calculation can generate distinct peaks for each breath. A dynamic baseline has been incorporated into the device to account for sudden, unexpected movements or sounds of the patient. Since the RR will ideally be taken as the nurse measures the patient's temperature, patient movements should be minimal.

The counting algorithm simply counts the number of peaks. It does so by setting a threshold value about 100 points above the baseline for the orange axis, which would be about 390 on the graph above. If the orange values cross that threshold (from below to above) and then cross it again (from above to below) within a reasonably short time, then that situation is referred to as a breath, and a counter keeps track of how many breaths have occurred since the device was turned on.

3.4 The Display & Power Source

This number is then read by OLED display (Figures 6, 14). The code to control the OLED display is open source. The only user input anticipated so far is an on/off switch and a visual display. When the device is turned on, there will be a small delay to allow the user to remove his/her hands. This will be necessary because the accelerometer is very sensitive to sudden jerks, such as pressing a switch. Then the device will start the program to establish baselines, count breaths, etc. After 15 seconds, the program will end and display the breaths counted to the screen, and beep or blink lightly so that the nurse is aware that the measurement is complete. Before that time, the display will read a message that says "counting."

Two 110mAh polymer lithium ion batteries (Figure 6) currently serve as the power source for Respirage. They can easily be charged with a micro-USB charger. Because the power requirement for Respirage will ultimately be very low and require infrequent charging, our team plans to reduce the battery to an even smaller size. A standard toggle switch is used to power Respirage on or off, but the team plans to upgrade it to a standard on/off push-button switch.

3.5 The Outer Casing & Base Isolation

All of the hardware and software is housed within the outer casing (Figures 6, 11), which has consists of slots for the OLED display, the toggle switch, and the battery charging port. In order to assemble the outer casing, the manufacturer will produce two separate parts (Figure 11), the chief housing for the electronics, as well as the lid that constitutes one face of the box. Currently, the outer casing is made of polylactic acid, a durable, cost-efficient thermoplastic that is easily 3-D printed. Unlike most thermoplastics, such as polyvinyl acetate, which can be degraded by base hydrolysis and microorganisms such as algae, yeast, and bacteria, this thermoplastic is resistant to many real-world defects. However, since Respirage will likely make skin contact, our team is currently investigating various medical grade plastics, such as Bayer's Texin thermoplastic polyurethane (TPU) resin, as well as their Desmopan TPU resin, which are commonly used in medical devices, and can vary from flexible to rigid. This offers the additional advantage of comfort for the patient.

Neoprene foam sheets (Figure 6) that have been pasted inside the outer casing currently serve as base isolation and shock absorbance for Respirage. The foam allows the OLED to displace with a damped response, and acts as a constrained layer damper for flexural vibrations. ISODAMP grommets are used for the accelerometer and microcontroller, and the case is protected by urethane elastomer bumpers.

3.6 The Attachment Mechanism

Respirage will be attached to the patient in one of three ways: a clip-on to the clothing, an adhesive for the clothing, or an adhesive for the skin. The clip mechanism (Figure 12) is currently being developed as a money-clip-like mechanism, which would be positioned horizontally on the back of the case. With a clip-on mechanism, the nurse could easily slip the patient's clothing into the clip to ensure that the device stays attached to the patient. An additional consideration for clipping Respirage onto the patient is that it must remain flush against the patient's abdomen or chest, so that interferences like baggy clothing do not affect the signal.

The adhesive mechanisms have been finalized, as the team began the project as an adhesive to the neck. A Pedifix moleskin (Figure 13) has been selected and tested for adequate and comfortable adhesion to both the skin and clothing. This adhesive would have to be replaced after each use, as its adhesive properties degrade after making contact with surfaces. The Pedifix adhesive can withstand up to 1.33 Newtons of force, and because we do not expect our device to exceed 130 grams.

3.7 Competitive Landscape

The main competition for Respirage (Figure 4) is the variety of RR measurement devices on the market. Currently, almost all RR measurement devices have been designed for postoperative settings or long-term bedside monitoring. As a result, although many of these devices are highly accurate, they are 1) invasive and inefficient for fast-paced situations like triage, 2) bulky and complicated to use, or 3) too expensive. Thus, while these attributes may be acceptable in a slow-paced emergency room setting where the patient stays in one room for an extended period of time, these devices are not suitable for the ED triage setting.

In triage, a nurse simply needs to get a quick, accurate reading of the patient's RR in order to accommodate the large inflow of patients in the ED at any given time. In addition to a RR measurement, the nurse also has to measure the rest of the patient's vital signs as well as ask the patient questions regarding his or her medical history. Since the current standard of care consists of visual measurement of RR, there is no additional setup time required for the measurement of RR in comparison to the other vital signs. As a result, for a successful implementation of an automated RR measurement device in triage, both speed and accuracy are the most important criteria. Respirage is easy to use such that setup and measurement time of the device is minimal and does not interfere with the other processes of triage. Current existing RR measurement technologies (See chart in Appendix B) not designed for triage involve a lengthy setup and measurement time that could lead to interference with the triage workflow and subsequently prolong the time it takes for a patient to receive appropriate care. In addition, measurement devices that are too invasive would contribute to added discomfort to patients in the ED already in an agitated state. For example, the Respir8 is a RR measurement device that utilizes a mask that the patient has to wear around his or her face, and the BioHarness requires the patient to remove his or her clothing in order to place a belt strap device tightly around his or her chest. Carrying out these setup procedures could be difficult for nurses depending on the severity of the patient's condition.

Currently, Respirage's most direct competitor that has been designed for ED triage is Kai Medical's Kai Spot Model KMS 200, which is a non-contact RR measurement device. As a radar-based device, however, it 1) requires specific positioning of a patient for accurate RR acquisition, 2) is bulky and requires placement on a table, and 3) currently costs approximately $600. In contrast, the costs of other vital sign monitoring devices are much lower than that of the Kai Spot. A pulse oximetry monitor, blood pressure cuff, and temperature probe all range from $20-$70 in price, and thus the cost of a RR measurement device (Appendix B) for ED triage should fall within the same range in order to remain cost-effective.

Portability and adaptability are rooted in Respirage's sustainable competitive advantage against other RR measurement devices currently on the market. An all-in-one device, Respirage can be easily attached and removed from the patient's stomach using no additional monitor or wires, with convenient display of the patient's RR on the device itself. These attributes allow the device to be easily integrated by nurses into the triage workflow as it can be used in conjunction with devices that measure the remaining vital signs of the patient. Existing RR measurement devices would have to undergo significant rescaling, redesign, or possible technological change in order to become adoptable for ED triage and the wide variety of customers that Respirage targets. In addition, Respirage's convenient, portable design and low costs prevent the device's usability from being limited to only ED triage environments, as the device can be expanded for use in home environments as well with only a few minor adjustments.

4. RESULTS

4.1 Types of Testing Required

There are three types of tests required for quality assurance of Respirage. The first is performance verification testing (Figure 15), in which an accuracy of ±2 bpm of the W.H.O. gold standard and a measurement speed of 15 seconds is ensured. This testing will be conducted through simultaneous measurement of RR with Respirage and manually by a certified healthcare provider. Testing will be done on healthy volunteers in controlled settings, as well as on hospital patients in the triage setting.

The second type of testing is usability validation testing (Figure 16), in which we ensure that Respirage is simple, user-friendly, and intuitive, as well as easy to teach and easy to be trained to use. This testing will solely be conducted in ED triage, where nurses will perform the normal steps of triage, but will measure RR with Respirage. As RR is measured, a witness will measure the gold standard RR, time the overall triage process and device setup time, and compare the Respirage results with the manual measurement results. Afterwards, a nurse survey will be conducted to determine whether our device was efficient for the nurses, and to obtain feedback from the nurses on improving the device to better incorporate it into the workflow.

The third type of testing required is physical parameter testing, in which we ensure that Respirage is durably built to withstand drops and other unexpected physical forces. Additionally, parameter testing includes testing on clip mechanisms and adhesives to determine the maximum amount of weight they can sustain on a patient's chest.

4.3 Testing Results

Because our team spent a large amount of time on in-depth experimentation with a number of RR measurement mechanisms and only recently settled on the accelerometer, there has been little time for testing. However, we have conducted some preliminary testing that we plan to expand upon in the next few weeks. We have done performance testing with Respirage on each of our team members and compared it with accurate RR measurement counted manually by a certified emergency medical responder. Through a Bland-Altman analysis, we determined that Respirage measurements highly correspond to true RR measurements, and much more so than nurse measurements, as seen in Figure 17. Currently, the accuracy of our device is ±3 bpm under controlled circumstances. Under less controlled circumstances, such as ED triage, the device will have less accuracy, so our team will accommodate such situations after bringing the controlled setting accuracy level to ±2 bpm.

Additionally, we have done adhesive force testing (Figures 18, 19, 20), in which different weights were attached to a person's bare, as well as clothed, abdomen using different adhesives. The Pedifix self-adhesive silicone moleskin was determined to be the strongest adhesive, withstanding 1.33 Newtons.

4.4 Conclusion

Ultimately, we slightly adjusted the speed goal of our original proposal (Appendix G) from 30 seconds to 15 seconds of RR measurement. While our device has not completely met the desired accuracy standard, we are working to improve its accuracy through alterations to the code.

The design of Respirage has been finalized, with a functional electronic prototype complete but not yet wholly integrated with its form factor. The current prototype can collect data, count respirations and display the RR on a computer. A simple embedded system streams the analog voltage data from the sensor to the computer, allowing for development of the algorithm on a computer and visualization of the data. The collection of Java classes described earlier performs the same function as a stand-alone unit, but with the added features of plotting the data in real time to evaluate performance. Using this responsive testing environment, the algorithm has been tested on several different people and it has been tuned to work in many situations. So far, the results have been very accurate under the following circumstances: the patient does not make sudden movements, the user does not readjust position or angle significantly when data is being read, and the user takes breaths that are not unreasonably shallow. After noticing that some individuals exhibit more movement in the chest than in the stomach region when breathing, our device is being optimized for that scenario as well. Preliminary results of the prototype with the exact same algorithm show a promising level of accuracy, and the device could very well be optimized for both locations.

The next steps of Respirage development will focus on improving the code to become more accurate and robust. Improving accuracy consists of programming Respirage to better accommodate various external interferences such as patient movement or talking, while enhancing robustness would allow the nurse to be less specific about where he or she must place Respirage to obtain a strong signal. Because certain patient conditions can compromise abdominal breathing, an alternative must be determined so that the nurse can still accurately measure a patient's RR.

In terms of physical design, our team plans to design an improved clip mechanism that allows Respirage to stay flush against the patient's abdomen or chest. Additionally, we are exploring various medical grade plastic options for the exterior casing, as well as smaller electronics to reduce the overall size of Respirage. Alternative power supply options, such as solar power, are also being investigated to minimize the need for nurses to charge the battery.

Future work involves developing a custom electrical system instead of a developer kit, allowing the device to be integrated into one package. Beyond developing the electrical printed circuit board, the existing codebase has been ported to C for an embedded chipset. Currently the chipset is the Arduino as described, but ideally it would be smaller than the typical Arduino board, which is mainly used for prototyping. There are several microcontrollers that fit the technical, financial, and geometric specifications of Respirage. Battery technology is currently being researched to provide long battery life with minimal charging time. Additionally, Respirage will be tested against ASTM standards to verify and validate base isolation criteria such as durability and shock absorbance by the International Organization of Standards. ASTM standards are in place to ensure that the device is well-built, and not easily tampered with, taken apart, or

damaged. Verification testing of the device will be conducted once the full prototype has been completed.

We plan to submit a completed IRB for verification and validation studies by June 2014, so that we can proceed to test Respirage on both healthy volunteers and hospital patients. The intellectual property of Respirage will be protected through both a copyright and patent. A provisional patent has been filed. Investors can expect a copyright of the source code used to acquire and process data to be granted in the next seven to ten months. Additionally, Emsol Health is looking into avenues for patenting specific features of the unique approach of Respirage to the triage workflow which allow Respirage to sustain a competitive advantage over other RR measurement devices. In particular, patentable features in Respirage include a unique filtering algorithm that creates a very high confidence interval in measuring breath peaks. Electrocardiograms (ECGs), which are more difficult to digitally filter than accelerometers, employ a variety of algorithms called QRS detection algorithms that rigorously filter the noise out of a signal. For example, the MAC 5500 HD ECG, by GE Healthcare, was able to patent its own P-Wave Signaling Averaging Algorithm because of how accurate it was able to detect heart arrhythmias. By applying the same amount of rigor in filtering the signals in the accelerometer, we can create very high confidence intervals in counting breath peaks. Other areas that have patent potential are features of the device that can affect target implementation and signal fidelity, such as a unique clip that keeps the RR measurement device in place on the patient's abdomen.

5. APPENDICES

Appendix A: Prototype Materials

The Measurement Mechanism: Triple Axis Accelerometer Breakout - MMA8452Q SEN-10955

Signal Processing & Filtering: DEV-11303 Arduino Mini 05 1 $33.95 $33.95

The Display: LCD-11676 Serial Miniature OLED Module - 1.5" (?OLED-128-G2-GFX)

The Power Source:

- PRT-00731 Polymer Lithium Ion Battery - 110mAh
- PRT-10217 LiPo Charger Basic - Micro-USB
- Toggle Switch COM-09276

The Outer Casing: Polylactic Acid

Shock Mitigation Material: Sponge Neoprene 1/8” thick x 54” wide x 1’

The Attachment Mechanism:

- Stainless Steel Money Clip
- Pedifix Moleskin Medical Grade Silicone Self-Adhesive

Appendix B: Prototype Budget

Component/Material	**Cost (Dollars)**
Triple Axis Accelerometer Breakout - MMA8452Q, SEN-10955	9.95
DEV-11303 Arduino Mini 05	33.95
LCD-11676 Serial Miniature OLED Module - 1.5" (OLED-128-G2-GFX)	49.95
PRT-00731 Polymer Lithium Ion Battery - 110mAh (x2)	13.90
PRT-10217 LiPo Charger Basic - Micro-USB	7.95
Toggle Switch COM-09276	1.95
Polylactic Acid	2.00
Sponge Neoprene 1/8” thick x 54” wide x 1’	1.25
Stainless Steel Money Clip	7.95
Pedifix Moleskin Medical Grade Silicone Self-Adhesive	0.62
Total	129.47

Although our current prototyping cost is $129.47, we plan to reduce the price to a manufacturing cost of $8 per unit, and sell it for $60 per unit.

Appendix C: Figures, Photos, & Sketches

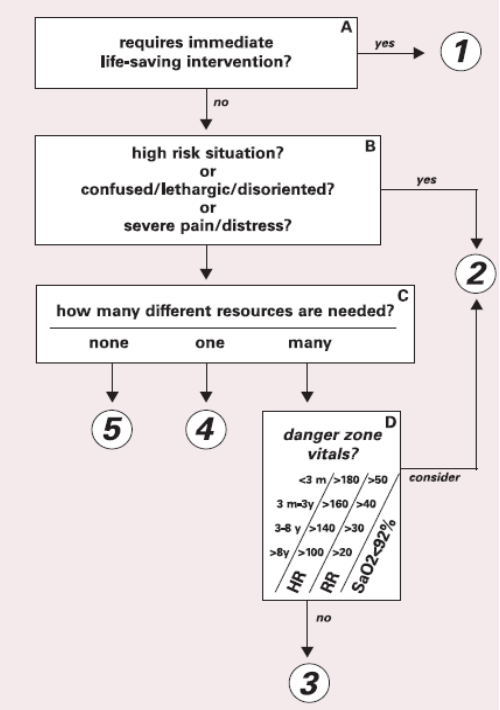


Figure 1. *Emergency Severity Index (ESI) Triage Algorithm. Note the role of RR in determining an acuity level of 2 or 3.* [17]

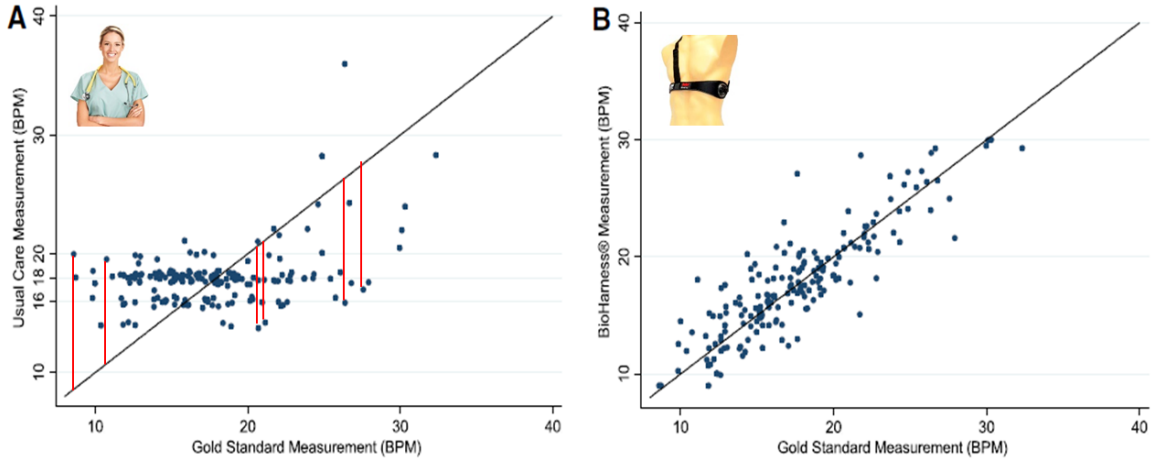
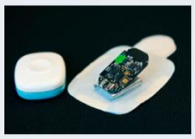


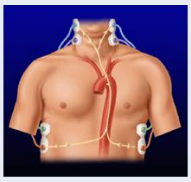
Figure 2. *Nurse measurement of respiratory rates (A) tended to cluster around 16 or 18 breaths per minute, whereas BioHarness measurement of respiratory rates (B) seemed to have a more distributed range of respiratory rates.* [14]

“It’s not that important.”
RR is measured only when it “appears to be abnormal”
Other vitals require the “the press of one button”
“Disposability may be time-consuming”
Display of only real-time RR is necessary; “no need for an alerting system”

Figure 3. *Nurse feedback on the clinical problem of inaccurate RR measurement.*

Device	**Masimo Rainbow Acoustic Monitoring**	**Anaxys RespiR8**	**Speckled Computing RESpeck**	**Zephyr BioHarness**
				
Primary Mechanism	Acoustic sensor	Electrochemical sensor	Tri-axial accelerometer	ECG

Device	**Respirion Omnicap**	**Vernier Respiration Monitor Belt**	**Transcutaneous CO2 Monitoring**	**BCI Capnocheck**
				
Primary Mechanism	Capnography (not IR Spec)	Gas pressure sensor	Electrochemical sensor	Capnography (IR Spectroscopy)

Device	**EverOn**	**Transthoracic Impedance**	**AQWave Photoplethysmograph**	**Scanadu Scout**
				
Primary Mechanism	Piezoelectric sensor	Aluminum-coated plastic electrodes	LED absorption	Near-IR LED sensor, ECG sensor, far-IR sensor, **microphone**

	Kai Spot Respiratory Rate Spot Check	Thermal Imaging
Device		
Primary Mechanism	Doppler radar	IR thermography

Figure 4. *Examples of existing devices that measure respiratory rate, as well as their primary mechanisms.*

Figure 4. *The full form factor of Respirage.*

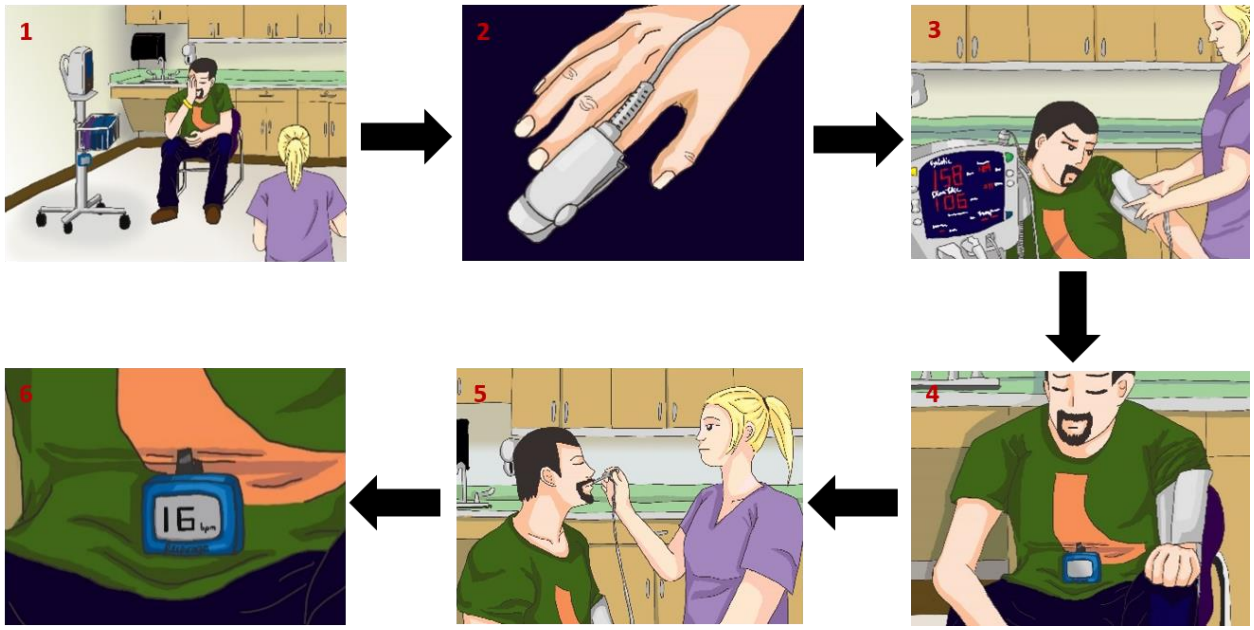


Figure 5. *Steps of the triage workflow, with Respirage integrated in Step 4.*

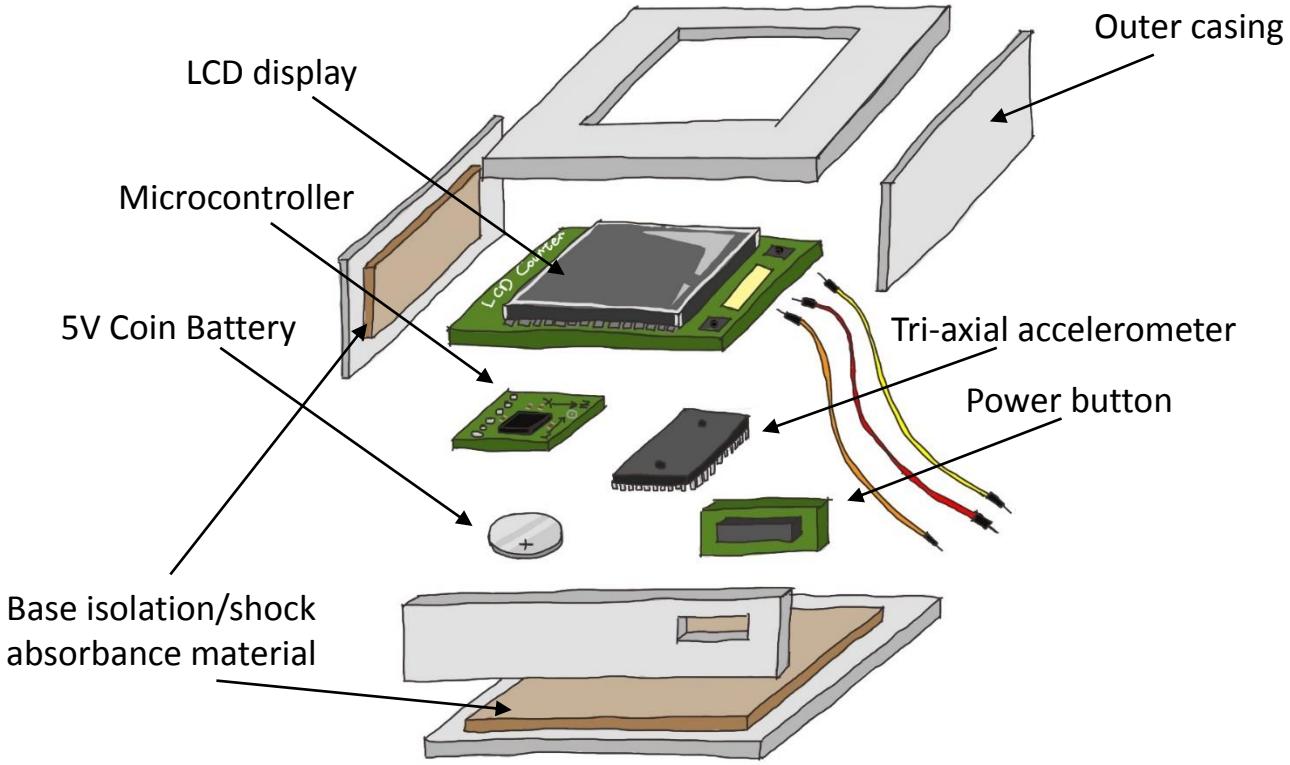


Figure 6. *An exploded view of the current Respirage prototype.*

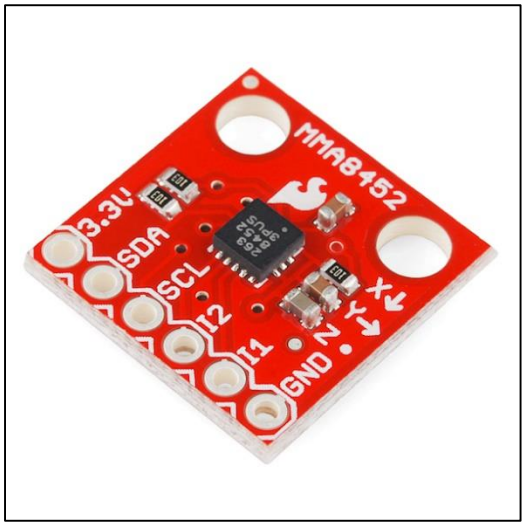


Figure 7. *The tri-axial accelerometer used in Respirage to measure displacements.*

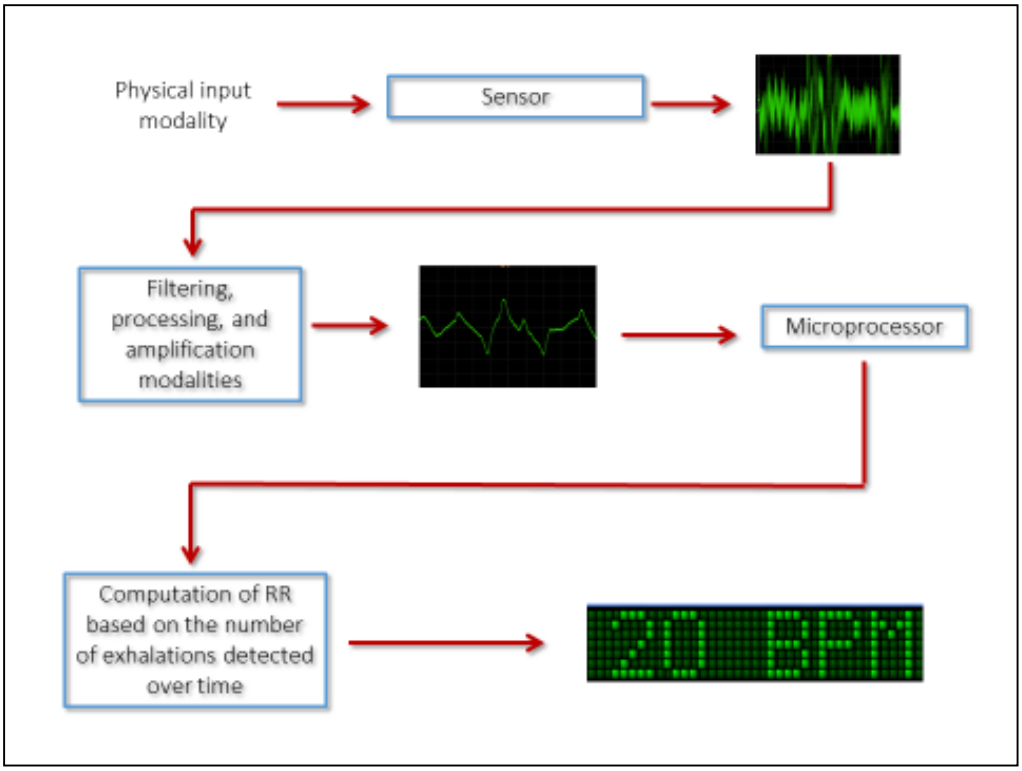


Figure 8. *A block diagram depicting how our device transforms a physical input, displacement of the abdomen, into a numerical respiratory rate measurement (in breaths per minute).*

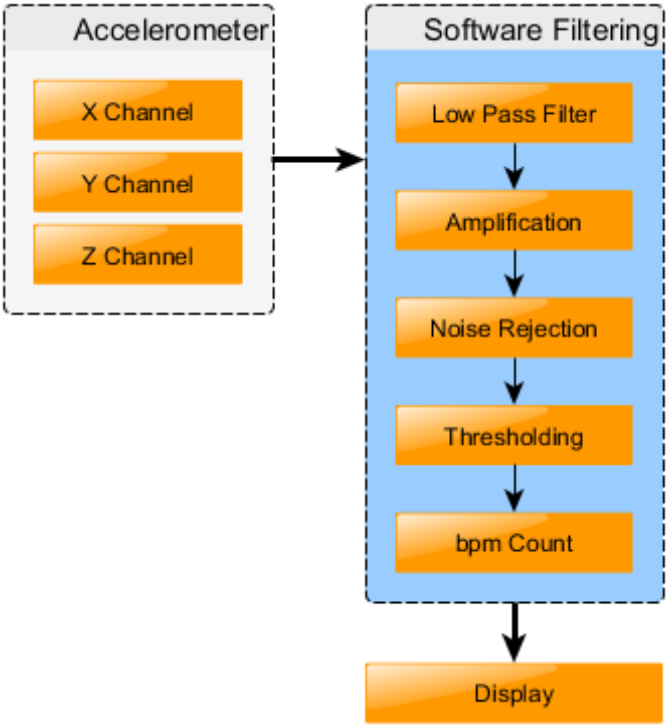


Figure 9. *A block diagram of our filtering algorithm.*

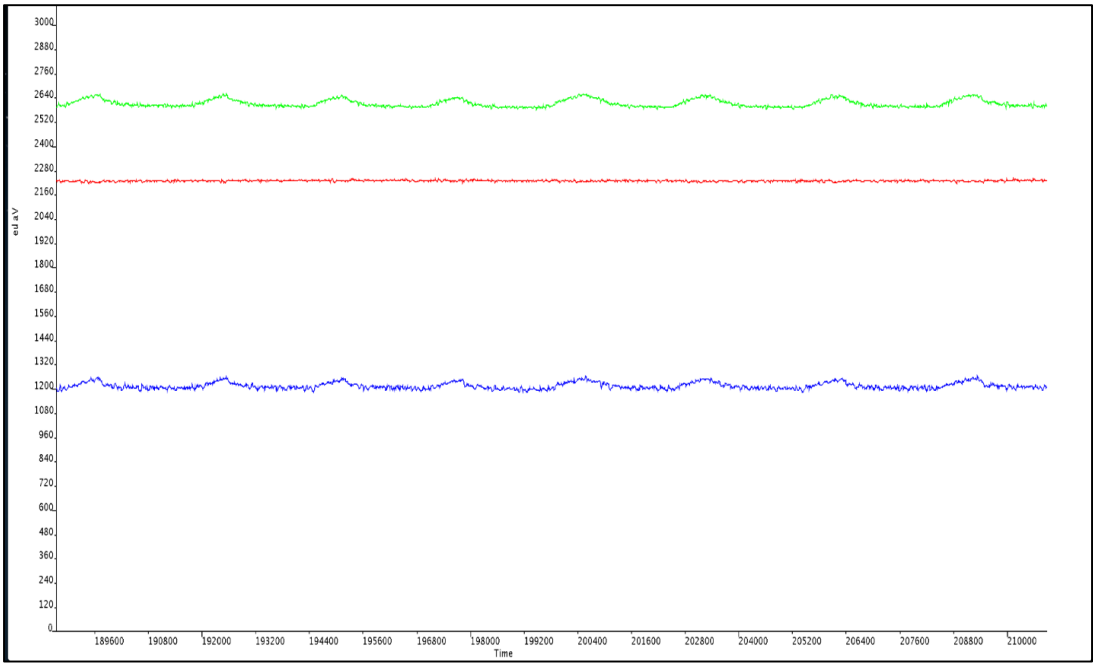


Figure 10. *Waveforms from the tri-axial accelerometer that depict breath peaks detected from measurement.*

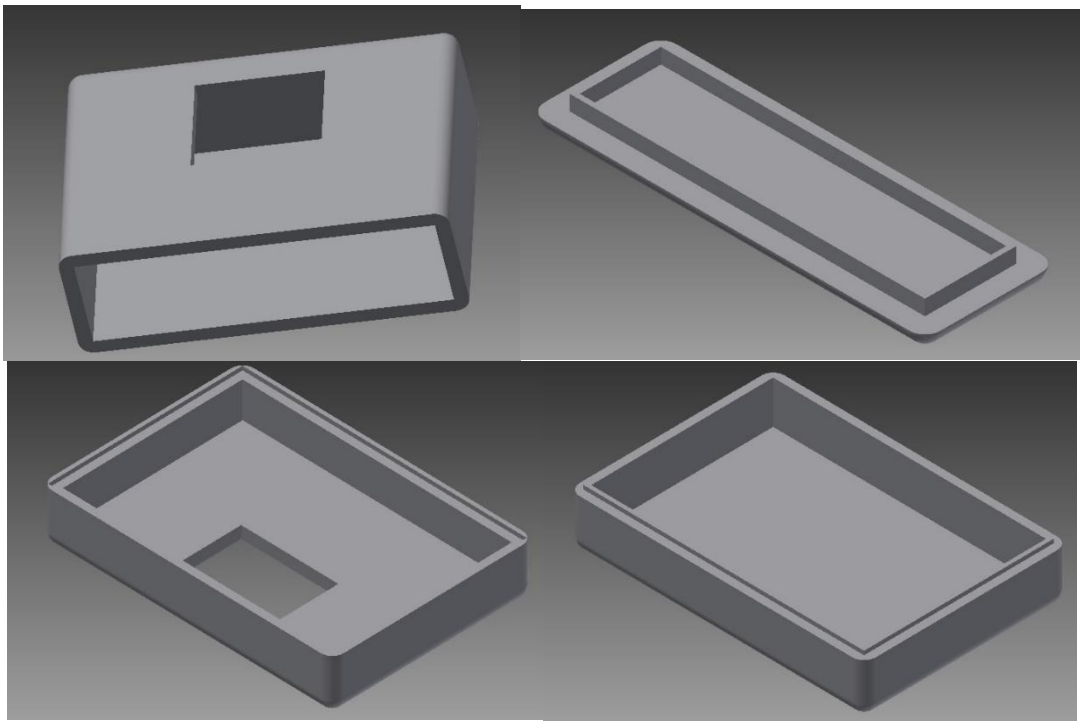


Figure 11. *The outer casing form factor.*

Figure 12. *A money clip mechanism that we envision for the clip-on component of our device for clothing.*

Figure 13. *The Pedifix silicone self-adhesive moleskin that will be used for adhesion to both clothing and skin.*

Figure 14. *An image of our final prototype.*

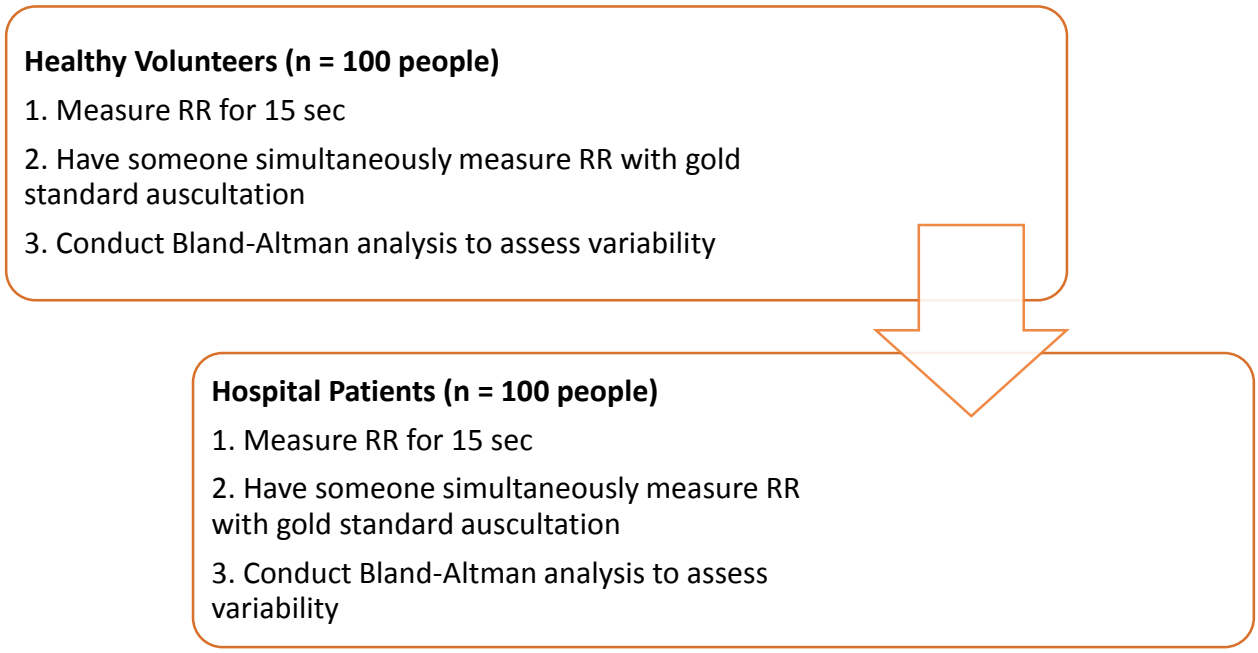


Figure 15. *The protocol for performance verification testing.*

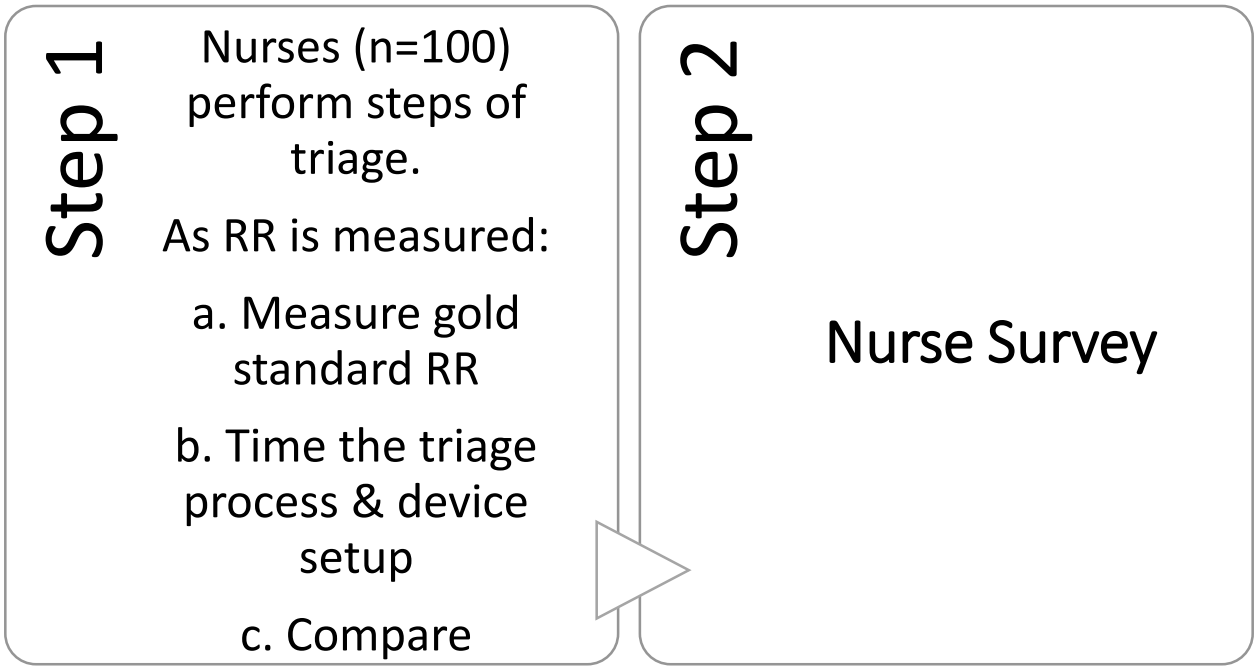


Figure 16. *The protocol for usability validation testing.*

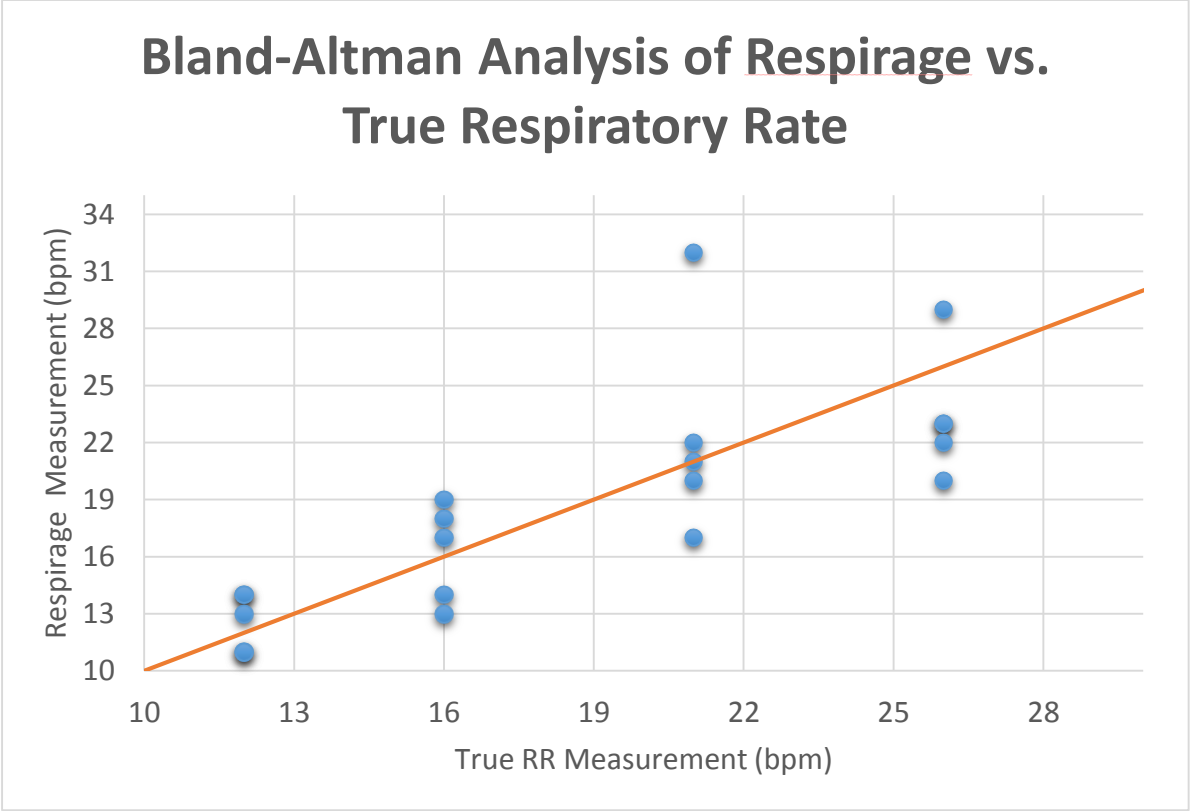


Figure 17. *A Bland-Altman analysis of Respirage measurements on our team members vs. true RR measurements done by an EMR-certified individual.*

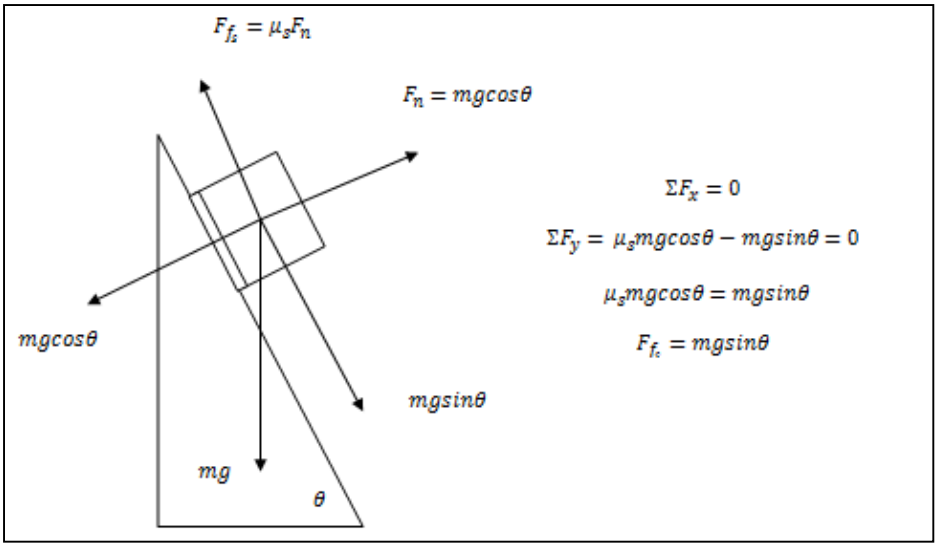


Figure 18. *The testing setup for the adhesive attachment component.*

Trial	Total Weight	Slip?
1	150.2	No
2	168.3	No
3	208.6	No
4	259.0	No
5	248.7	No
6	615.1	No
7	1101.5	No
8	1566.4	Yes, but after 30 seconds

Figure 19. *Testing results for the Pedifix adhesive.*

$$\theta = 58\ arcdegrees$$
$$F_{f_s} = (1566.4)\sin(58)$$
$$F_{f_s} = 1.3286\ N$$

The moleskin has an adhesive strength that can resist 1.3286 Newtons (135.6 grams) of force.

Figure 20. *Testing results for the Pedifix adhesive.*

Appendix D: Calculations

As a review, the overall functionality of the algorithm that counts the number of respirations is as follows:

> **Step 1:** Spend 1-2 seconds establishing a baseline for each axis.
> **Step 2:** Establish the baseline of the magnitude, which is L_{base} = SQRT($(x_{base})^2$ + $(y_{base})^2$ + $(z_{base})^2$, and establish the breath threshold as 100 points above L_{base}.
> **Step 3:** Start calculating the magnitude L(x, y, z) for each data point (x, y, z) using formula [1].
> **Step 4:** If the magnitude is above the breath threshold for at least 0.1 seconds, and then falls below it within another 0.5 seconds, then a breath has occurred and the breath counter is incremented.
> **Step 5:** Repeat steps 3 and 4 until program terminated.

Specifically:

$$L = 2(x - x_{base})^2 + 2(y - y_{base})^2 + 2(z - z_{base})^2 \qquad [1]$$

The following code consists of the algorithm we developed for the detection, filtering, counting, and display of a patient's respiratory rate:

```
#include <Wire.h> // Used for I2C
#include <SoftwareSerial.h>

#define txPin 2
#define resetPin 2

short COLOR_WHITE = 0xFFFF;
short COLOR_YELLOW = 0xFF00;
short COLOR_BLUE = 0xFF;

//#include <math.h>

// The SparkFun breakout board defaults to 1, set to 0 if SA0 jumper on the bottom of the board is set
#define MMA8452_ADDRESS 0x1D  // 0x1D if SA0 is high, 0x1C if low

//Define a few of the registers that we will be accessing on the MMA8452
#define OUT_X_MSB 0x01
#define XYZ_DATA_CFG  0x0E
#define WHO_AM_I   0x0D
#define CTRL_REG1  0x2A

#define GSCALE 2 // Sets full-scale range to +/-2, 4, or 8g. Used to calc real g values.
//our accelerometer has sensitivity of +/- 1.5 g we think

int timeOffset;

const int CALIBRATION_NUM_POINTS = 200; //how many points needed to establish baseline
unsigned long int baseline[4];
unsigned long int PREbaseline[4];
int howManyAbove = 0;
int howManyAbovePlus = 0;
int howManyBelow = 0;
int State = 0;
int BREATHS = 0;
int magnitude = 0;
int calibrationPoint[4];
boolean BaselineAlreadySet[4];
int lastval[4];
long startTime = 0;
int numPointsRead[4];
const long NUM_POINTS_READ = 500; //every 500 pts, say, reestablish baseline;
long timeAtLastBreath = 1000;
int letItSlidePoints = 0;
int commandDelay = 10;

SoftwareSerial LCD(4, 3);

void setup()
{
  //timeOffset = millis();
  Serial.begin(9600);
  LCD.begin(9600);
  pinMode(resetPin, OUTPUT);
```

```
  Serial.println("Resetting");
  reset();
  Serial.println("Done");

  pinMode(txPin, OUTPUT);
  Wire.begin(); //Join the bus as a master

  updateLCD(0, 0);
  Serial.println("Initializing");
  updateStatus("Initializing", 12);
  initMMA8452(); //Test and intialize the MMA8452
  updateStatus("Done", 4);
  for (int i = 0; i < 4; i++) {
    calibrationPoint[i] = 0;
    BaselineAlreadySet[i] = false;
    lastval[i] = 0;
    baseline[i] = 0;
  }
}

void loop()
{
  int accelCount[3];  // Stores the 12-bit signed value
  readAccelData(accelCount);  // Read the x/y/z adc values

  // Print out values
  /*for (int i = 0 ; i < 3 ; i++)
  {
    Serial.write(170);
    Serial.write((i << 6)+(accelCount[i] >> 6));
    Serial.write(accelCount[i] & 0b111111);
  }*/
  dataRead(accelCount);
  delay(10);  // Delay here for visibility
}

void readAccelData(int *destination)
{
  byte rawData[6];  // x/y/z accel register data stored here

  readRegisters(OUT_X_MSB, 6, rawData);  // Read the six
raw data registers into data array

  // Loop to calculate 12-bit ADC and g value for each axis
  for (int i = 0; i < 3 ; i++)
  {
    int gCount = (rawData[i * 2] << 8) | rawData[(i * 2) + 1];
//Combine the two 8 bit registers into one 12-bit number
    gCount >>= 4; //The registers are left align, here we
right align the 12-bit integer

    // If the number is negative, we have to make it so
manually (no 12-bit data type)
    if (rawData[i * 2] > 0x7F)
    {
      gCount = ~gCount + 1;
      gCount *= -1;  // Transform into negative 2's
complement #
    }

    destination[i] = gCount + 2047; //Record this gCount
into the 3 int array
  }
}

// Initialize the MMA8452 registers
// See the many application notes for more info on setting
all of these registers:
//
http://www.freescale.com/webapp/sps/site/prod_summa
ry.jsp?code=MMA8452Q
void initMMA8452()
{
  byte c = readRegister(WHO_AM_I);  // Read WHO_AM_I
register
  if (c == 0x2A) // WHO_AM_I should always be 0x2A
  {
    Serial.println("MMA8452Q is online...");
    updateStatus("Accel Online", 12);
  }
  else
  {
    updateStatus("Accel Error", 11);
    Serial.print("Could not connect to MMA8452Q: 0x");
    Serial.println(c, HEX);
    while (1) ; // Loop forever if communication doesn't
happen
  }

  MMA8452Standby();  // Must be in standby to change
registers

  // Set up the full scale range to 2, 4, or 8g.
  byte fsr = GSCALE;
  if (fsr > 8) fsr = 8; //Easy error check
  fsr >>= 2; // Neat trick, see page 22. 00 = 2G, 01 = 4A, 10
= 8G
  writeRegister(XYZ_DATA_CFG, fsr);

  //The default data rate is 800Hz and we don't modify it in
this example code

  MMA8452Active();  // Set to active to start reading
}

// Sets the MMA8452 to standby mode. It must be in
standby to change most register settings
void MMA8452Standby()
{
  byte c = readRegister(CTRL_REG1);
  writeRegister(CTRL_REG1, c & ~(0x01)); //Clear the active
bit to go into standby
}

// Sets the MMA8452 to active mode. Needs to be in this
mode to output data
```

```
void MMA8452Active()
{
  byte c = readRegister(CTRL_REG1);
  writeRegister(CTRL_REG1, c | 0x01); //Set the active bit
to begin detection
}

// Read bytesToRead sequentially, starting at
addressToRead into the dest byte array
void readRegisters(byte addressToRead, int bytesToRead,
byte * dest)
{
  Wire.beginTransmission(MMA8452_ADDRESS);
  Wire.write(addressToRead);
  Wire.endTransmission(false); //endTransmission but
keep the connection active

  Wire.requestFrom(MMA8452_ADDRESS, bytesToRead);
//Ask for bytes, once done, bus is released by default

  while (Wire.available() < bytesToRead); //Hang out until
we get the # of bytes we expect

  for (int x = 0 ; x < bytesToRead ; x++)
    dest[x] = Wire.read();
}

// Read a single byte from addressToRead and return it as
a byte
byte readRegister(byte addressToRead)
{
  Wire.beginTransmission(MMA8452_ADDRESS);
  Wire.write(addressToRead);
  Wire.endTransmission(false); //endTransmission but
keep the connection active

  Wire.requestFrom(MMA8452_ADDRESS, 1); //Ask for 1
byte, once done, bus is released by default

  while (!Wire.available()) ; //Wait for the data to come
back
  return Wire.read(); //Return this one byte
}

// Writes a single byte (dataToWrite) into addressToWrite
void writeRegister(byte addressToWrite, byte
dataToWrite)
{
  Wire.beginTransmission(MMA8452_ADDRESS);
  Wire.write(addressToWrite);
  Wire.write(dataToWrite);
  Wire.endTransmission(); //Stop transmitting
}

//receives raw data in form of array[3] from the other
readData method above
void dataRead(int *d) {
  float data[3];
  long time = millis();
  /*for (int i = 0; i < 3; i++) {
    Serial.print(data[0]);
    Serial.print(" ");
    Serial.print(data[1]);
    Serial.print(" ");
    Serial.print(data[2]);
    Serial.println();
  }*/
  for (int i = 0; i < 4; i++) {
    if (i < 3) {
      data[i] = d[i];
      numPointsRead[i]++; //once this reaches
NUM_POINTS_READ, it will recalculate baseline (which is
called in Smooth())
      Smooth(time, data[i], i);
    }
    //the baselines of x, y, and z must be set before the
baseline for
    //the total magnitude can be set, see the definition of
magnitude
    //below.
    else if ( BaselineAlreadySet[0] && BaselineAlreadySet[1]
&& BaselineAlreadySet[2]) {
      numPointsRead[3]++;

      //AMPLIFY SIGNAL BY TAKING VECTOR MAGNITUDE,
MULTIPLY IT BY SCALAR 12
      if (startTime == 0) {
        startTime = millis();
      }
      //magnitude shouldn't be allowed to be sent to smooth
unless other three baselines have been established
      //so why da fuk is this happening?
      //Serial.println("magnitude being calculated");
      int oldMag = magnitude;
      magnitude = (int) (12 * (sqrt(pow(abs(data[0] -
baseline[0]), 2) + //
                               pow(abs(data[1] - baseline[1]), 2) +
                               pow(abs(data[2] - baseline[2]), 2))));
      magnitude = (int)(oldMag * .8 + magnitude * .2);
      magnitude = abs(magnitude - baseline[3]) +
baseline[3]; //make all deviations positive
      //Serial.print("Magnitude: ");
      //Serial.println(magnitude);
      Smooth(time, magnitude, i);
    }
  }
}
//only for adding data points to baseline calculations
void addDataPoint(long time, int val, int k) {
  if (BaselineAlreadySet[k] && val < baseline[k] + 650)
PREbaseline[k] += val; //don't include things too high
    else if (!BaselineAlreadySet[k]) PREbaseline[k] += val;
//include everything if baseline not already set
    calibrationPoint[k]++; //need at least 200 of these

  if (calibrationPoint[k] > CALIBRATION_NUM_POINTS) {
```

```
      PREbaseline[k] /= CALIBRATION_NUM_POINTS; //avg
value
      if (BaselineAlreadySet[k] && PREbaseline[k] >
baseline[k] + 100) baseline[k] = PREbaseline[k] - 20;
      else baseline[k] = PREbaseline[k]; //correction factor:
reduce baseline by 20 or so to offset when baseline is
      //calculated during a breath, meaning it would be
higher than it should. using adaptive filtering should take
care of this
      PREbaseline[k] = 0;
      BaselineAlreadySet[k] = true;
      calibrationPoint[k] = 0;
      numPointsRead[k] = 0;
      /*Serial.print("*");
      Serial.print("Baseline ");
      Serial.println(k);
      Serial.println(" is set at ");
      Serial.println(baseline[k]);
      */
   }
  else if (k == 3 && (calibrationPoint[3] % 15 == 0 ||
calibrationPoint[3] >= CALIBRATION_NUM_POINTS)) {
   float percent = 100 * (float)calibrationPoint[k] /
(float)CALIBRATION_NUM_POINTS; //purely for updating
screen on status of initial baseline measurements
  }
}
void Smooth(long time, int val, int k) {
  if ( k == 3) {
   //Serial.println("Smooth, k = 3");
   val = (int)(.4 * val + .6 * lastval[k]);
   lastval[k] = val;
   countBreaths(time, val); //only calculate breaths from
the magnitude data, not from x, y, or z individually
  }
  if (!BaselineAlreadySet[k] || numPointsRead[k] >
NUM_POINTS_READ) { //set baseline at beginning and
every 500 pts
   addDataPoint(time, val, k);
  }

}
void countBreaths(long time, int val) {
  if (State == 1 && howManyAbove >= 8 /*&&
howManyAbovePlus >= 2 */&& howManyBelow > 50 &&
(millis() - timeAtLastBreath > 1000)) { //baseline[3] is
baseline of the magnitude graph
   BREATHS = BREATHS + 1;
   timeAtLastBreath = millis();
   if (BREATHS >= 3) {
    long time = millis() - startTime;
    float rate = (float)BREATHS / (float)(time /
(float)60000);
    updateLCD(BREATHS, (int)rate);
   }
   else {
    updateLCD(BREATHS, 0);
    updateStatus("Reading...", 10);
   }
   State = 0;
   howManyAbove = 0;
   howManyBelow = 0;
   letItSlidePoints = 0;
   howManyAbovePlus = 0;
  }
if (val > baseline[3] + 600) { //state where we are too high,
reset everything.
    State = 0;
   howManyAbove = 0;
    howManyBelow = 0;
    //Serial.println("TOO HIGH");
  }
  if (howManyBelow > 50 && (val > baseline[3] + 50)) {
//state where we are high enough to record a breath
     //
     State = 1;
     howManyAbove++;
     //give more leeway if many points have been above
     if (howManyAbove >= 6) letItSlidePoints = 0;
     else if (letItSlidePoints >= 1 && howManyAbovePlus >=
6) letItSlidePoints--;

     if (val > baseline[3] + 100) howManyAbovePlus++;
     //Serial.print("      ---above: ");
     //Serial.print(howManyAbove);
     //Serial.println();
  } else if (State == 1 && letItSlidePoints < 10 && val <=
baseline[3] + 50 && val > baseline[3] + 20) {
    //state where we are in between, could be due to noise
    letItSlidePoints++;
    //Serial.print("let it slide is: ");
    //Serial.print(letItSlidePoints);
    //Serial.println();
  } else if (val < baseline[3] + 45){ //state where we are too
low to record a breath
     State = 0;
     howManyBelow++;
     //Serial.print("below ");
     //Serial.print(howManyBelow);
     //Serial.println();
     howManyAbove = 0;
  }

}

//4d LCD

void updateLCD(int breaths, int bpm) {
 Serial.println("Updating LCD");
 scaleText(3);
 setTextColor(COLOR_YELLOW);
 moveCursor(0, 0);

 putInt(bpm);
 setTextColor(COLOR_BLUE);
 moveCursor(1, 0);
```

```
  putInt(breaths);

  scaleText(1);
  setTextColor(COLOR_WHITE);
  moveCursor(1, 10);
  putString("bpm", 3);
  moveCursor(4, 10);
  putString("cts", 3);

  if (bpm > 0) {
    if (bpm < 12) {
      updateStatus("LOW", 3);
    }
    else if (bpm > 21) {
      updateStatus("HIGH", 4);
    }
    else {
      updateStatus("GOOD", 4);
    }
  }
  delay(10);
}

void updateStatus(char* str, int len) {
  setTextColor(COLOR_WHITE);
  moveCursor(7, 0);
  putString("           ", 13);
  moveCursor(7, (12 - len) / 2 + 1);
  putString(str, len);
}

void putString(char* chars, int len) {
  LCD.write((byte)(0x00));
  LCD.write(0x06);
  for (int i = 0; i < len; i++) {
    LCD.write(chars[i]);
  }
  LCD.write((byte)0x00);
  delay(commandDelay);
}

void putInt(int i) {
  LCD.write((byte)(0x00));
  LCD.write(0x06);
  LCD.print(i);
  LCD.write((byte)0x00);
  delay(commandDelay);
}

void clearScreen() {
  LCD.write((char)0xFF);
  LCD.write((char)0xD7);
  delay(commandDelay);
}

void moveCursor(short line, short column) {
  LCD.write(0xFF);
  LCD.write(0xE4);
  LCD.write((byte)0x00);
  LCD.write((char)(line));
  LCD.write((byte)0x00);
  LCD.write((char)(column));
  delay(commandDelay);
}

void scaleText(short multiplier) {
  //Change width
  LCD.write(0xFF);
  LCD.write(0x7C);
  LCD.write((char)(multiplier >> 8));
  LCD.write((char)(multiplier & 255));
  delay(commandDelay);
  //Change height
  LCD.write(0xFF);
  LCD.write(0x7B);
  LCD.write((char)(multiplier >> 8));
  LCD.write((char)(multiplier & 255));
  delay(commandDelay);
}

void setTextColor(short color) {
  LCD.write(0xFF);
  LCD.write(0x7F);
  LCD.write((char)(color >> 8));
  LCD.write((char)(color & 255));
  delay(commandDelay);
}

void reset() {
  digitalWrite(resetPin, LOW);
  delay(150);
  digitalWrite(resetPin, HIGH);
  delay(3000);
}
```

Appendix E: References

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Appendix F: User Manual

Device Operation

Use of the Respirage consists of the following steps:

Step 1: Remove heavy clothing such as a jacket or sweatshirt from the patient.
Step 2: Clip the Respirage on to the patient's shirt in the stomach region.
Step 3: Wait for about a minute while Respirage collects data.
Step 4: When a number is displayed, record the respiration rate.
Step 5: Unclip the Respirage and continue with triage.

Not only are these steps simple to remember and perform, but most importantly, they do not interfere with the current triage workflow. Calculation of the RR is done automatically to compute RR with minimal interaction from the nurse. For at-home use, the device can be clipped onto the patient's clothing and left on for a long amount of time. Analysis of signal confidence will allow the omission of incorrect or irrelevant measurement periods, such as when the patient is talking. A continuous measurement of RR will be recorded and sent to the patient's mobile device for easy access.

Operation Workflow

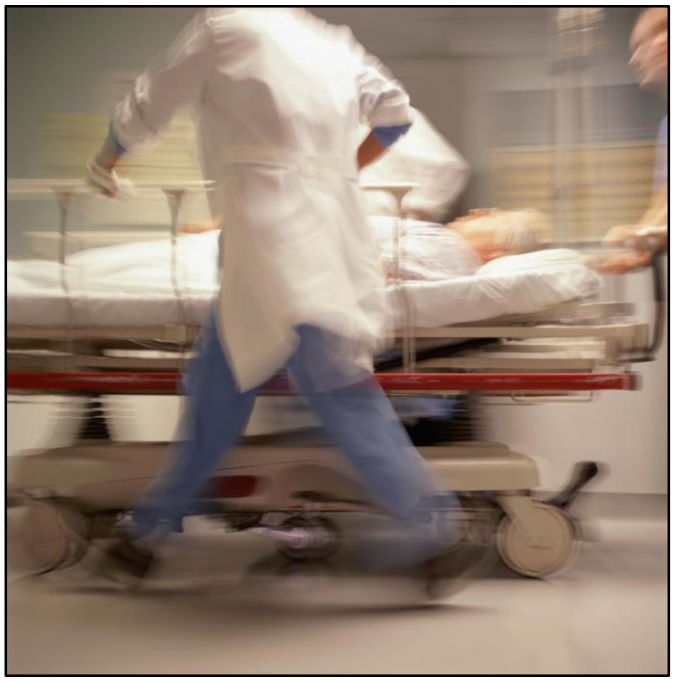
The typical triage workflow consists of attaching the pulse oximeter to the patient, followed by a blood pressure cuff. Immediately after, the temperature is taken and the nurse observes the patient to determine RR. Modifying this workflow to incorporate the Respirage is simple. An integrated workflow is as follows:

Step 1: The patient enters the triage room with a chief complaint and is seated in a chair.
Step 2: Place the pulse oximeter onto the patient's finger to measure pulse.
Step 3: Place the blood pressure cuff onto the patient's arm.
Step 4: Attach the Respirage to the patient's clothing near the upper stomach/lower chest.
Step 5: Place the thermometer into the patient's mouth to measure temperature.
Step 6: Record the RR displayed on the Respirage after 15 seconds.

Appendix G: Proposal

Respiratory Rate Measurement Device for Emergency Department Triage

Project Proposal



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Sponsors: *Edbert Hsu, M.D., M.P.H.; Samuel Yang, M.D.*[2]
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TABLE OF CONTENTS

1. ABSTRACT

To improve medical decision-making in the emergency department (ED) of hospitals, we plan to design, develop, and test a novel respiratory rate measurement device for use in ED triage. We will design our model to accurately measure respiratory rate to within ±4 breaths per minute of the World Health Organization's (WHO) gold standard of observation or auscultation for 60 seconds. The model will feature a user interface that displays real-time respiratory rate and alerts the user of dangerously high or low respiratory rates. Incorporation of our device into triage workflow will not increase the average time it currently takes to measure vitals, 160 seconds. The device should cause little to no discomfort to the patient, so as not to interfere with the patient's true respiratory rate. We will conduct accuracy tests on healthy volunteers, as well as volunteer patients in ED triage and a variety of other clinical settings. Bland-Altman analyses will be conducted to ensure that measurements are accurate in comparison to the WHO gold standard. We will also conduct usability studies on triage nurses.

2. INTRODUCTION

2.1 Background

The assessment of vital signs (pulse rate, oxygen saturation, respiratory rate, blood pressure, and body temperature) plays a fundamental role in medical decision-making. Vital signs objectively indicate the immediate well-being and level of physical functioning of patients, and have long been considered an imperative component of patient assessment and management.[1] Respiratory rate, in particular, plays an important role in the early recognition of diverse illnesses, such as pulmonary embolus, pneumonia, congestive cardiac failure, and toxicologic and metabolic emergencies.[2]

Respiratory rate has been proven to be the best predictor of cardiopulmonary arrest, even up to three days before arrest occurs.[1, 3, 4] A prospective observational study of 1025 ED patients found that a respiratory rate greater than 20 breaths per minute was predictive of cardiopulmonary arrest within 72 hours, with an odds ratio* of 3.93, and death within 30 days, with an odds ratio of 3.56 (**Figure 1**).[1] Similarly, a separate evaluation of general medicine inpatients found that a respiratory rate of greater than 27 breaths per minute was predictive of cardiopulmonary arrest within 72 hours, with an odds ratio of 5.56 (**Figure 2**).[4] In another prospective observational study of 1695 acute medical admissions, patients with a composite outcome of cardiopulmonary arrest, intensive care admission, or death within 24 hours had a mean respiratory rate of 27 breaths per minute, compared to controls who had a mean respiratory rate of 19 (**Figure 3**). While changes in pulse rate and blood pressure are comparatively small and could potentially be clinically missed, relative changes in respiratory rate are of a much greater magnitude and are therefore better at discriminating between stable patients and patients at risk of cardiopulmonary arrest.[5]

*Odds ratio: the odds that a patient has cardiac arrest given that he/she falls in a specific range of respiratory rate, divided by the odds that a patient has cardiac arrest given that he/she does not fall in a specific range of respiratory rate. If the odds ratio is greater than 1, then there is a high correlation.

Both respiratory rate and tidal volume depend on the exchange of carbon dioxide and oxygen between the lungs and the rest of the body (**Figure 4**). This gas exchange relies on the body's metabolic demands and adjusts with physical activity or in disease states such as infection. In life-threatening diseases like metabolic acidosis, the body attempts to correct hypoxemia and hypercarbia through respiratory compensation. As a result, both respiratory rate (tachypnea) and alveolar ventilation (hyperventilation) increase significantly.[3] Since the magnitude of an individual's metabolic demand is reflected in the respiratory rate, patients with an elevated respiratory rate often have a more serious illness.[6] Conditions including hypoxemia, acidosis, sepsis, increased intracranial pressure, and hypotension are capable of inducing tachypnea, and they all also have the potential to lead to arrest.[4] Decreased respiratory rate (bradypnea), which can result from life-threatening conditions such as renal failure, brain tumors, or high intracranial pressure, not only limits supplies of oxygen, but also endangers other organ systems in the body.[7]

In effect, respiratory rate is an important indicator of a severe abnormality in not only the respiratory system but also many other body systems, and is therefore a key predictor of adverse events.[3]

2.2 Standard of Care

Respiratory rate is measured manually by nurses in ED triage, often for 15 or 30 seconds. Manual measurement can be performed either with or without contact. Contact methods include tactile observation or estimation, via the use of one's hand or a stethoscope (auscultation) to feel for chest movement. Non-contact methods include visual monitoring of chest movement or estimation.[8] Various long-term monitoring devices (see **2.4 Existing Technology**) are often used to measure respiratory rate in other settings, like the intensive care unit (ICU) and post-surgical operations, but few devices are designed for the transient purposes of triage.

2.3 Clinical Problem

Every year, there are approximately 129.8 million ED visits in the US.[9] Of 209,000 yearly in-hospital cardiopulmonary arrests,[10] approximately 12% occur in the ED, and 50% occur in the ICU (**Figures 5, 6**).[11, 12] Although our focus is on ED triage, up to 55% of hospital patients (depending on the hospital) are admitted into an ICU within 24 hours of entry into triage.[13] As stated earlier, respiratory rate can predict cardiopulmonary arrest up to 72 hours before it occurs; thus, with proper respiratory rate measurement, ICU in-hospital arrests can also potentially be predicted and avoided, even before admission to the ICU.

Cardiopulmonary arrest is only one of several life-threatening diseases that is seen in the ED and is indicated by respiratory rate. Unfortunately, respiratory rate is rarely measured accurately, if at all. According to a study by Lovett et. al., triage nurses' measurements of the respiratory rates of 159 patients showed low sensitivity in detecting bradypnea and tachypnea, poor agreement with criterion standard measurements of respiratory rate (WHO recommendation of auscultation or observation for 60 seconds), as well as poor interobserver agreement. Variability of their measurements was also low (standard deviation of 3.3) compared with criterion standard measurements (standard deviation of 4.1). A lower variability indicates that

their measurements are more clustered than criterion standard measurements of respiratory rate, which might suggest conscious or unconscious result selection, even though the nurses were aware that their respiratory rate measurements were being collected for this study.[2]

In another study with 191 patients, Bianchi et. al. found that nurse measurements of respiratory rate tended to cluster around 16 or 18 breaths per minute (**Figure 7A**), with 144 patients falling within this range, when in actuality there were only 39 patients who fell within this range. Similar clustering is demonstrated in **Figure 8**, from another study. Bianchi et. al. also found that of the 191 patients, 44 were actually tachypnic (>20 breaths per minute), but the nurses identified only 10 of the 44 as being tachypnic.[14] In a study done between two careful observers, Edmonds et. al. found that independent measures of respiratory rate may differ by more than 35%, which implies that a measured respiratory rate of 16 breaths per minute may actually represent a rate anywhere between 10 (bradypnic) and 22 (tachypnic) breaths per minute.[15] With more casual observers, respiratory rate measurements made in a fast-paced setting are likely to show even more variation from a carefully taken measurement, and therefore are highly unreliable.[15] Finally, Philip et. al. recently discovered that nurses themselves have very low confidence in the reliability of their own respiratory rate recordings.[16]

The purpose of ED triage is to provide incoming patients in the ED with a brief but informative acuity rating of his or her medical state that will determine how long the patient can safely wait for medical screening and treatment.[17] The most commonly used triage scoring systems, the Emergency Severity Index (ESI) and the National Early Warning Scores (NEWS), both use abnormal respiratory rate cutoffs of less than 12 and greater than 20 breaths per minute (**Figures 9, 10**) in defining a patient's priority level.[17, 18] Therefore, respiratory rate and other vitals measurements must be sufficiently accurate if these triage scoring systems are to work effectively.

2.3.1 Problem Statement

Respiratory rate is one of the most sensitive markers of a patient's condition and is often one of the first indicators of physiological deterioration, yet it is often recorded inaccurately in ED triage.

2.3.2 Need Statement

In order to detect the onset of certain illnesses earlier and to improve medical decision-making, there is a need to reliably measure respiratory rate in ED triage.

2.4 Existing Technology

A broad range of technology exists for measuring respiratory rate in various settings (See **Figures 11, 12**). These devices can be inadequate for several reasons: they are not 1) efficient for fast-paced situations like ED triage, 2) accurate enough, 3) easy to use, or 4) cost-effective. There are several general methods used for respiratory rate measurement, as seen in **Figures 11 & 12**, and they can be classified into contact and non-contact methods. For example, Masimo's Rainbow Acoustic Monitor, which was designed for post-operative settings, is a contact device

that uses an acoustic sensor attached to the patient's neck, and takes approximately 40 seconds to get a reading. However, a Masimo-specific pulse oximeter flap must be attached to the patient's finger prior to measuring the respiratory rate, which requires extra effort from the nurse. Additionally, Masimo's device is expensive, as each acoustic sensor is on the order of hundreds of dollars and each monitor is on the order of thousands of dollars.

The most common mechanisms used in respiratory rate measurement devices are various types of sensors, ranging from acoustic to electrochemical. Several existing devices also employ IR spectroscopy, which monitors the partial pressure of carbon dioxide in respiratory gases, but does not measure actual respiratory rate. Plethysmography is also a common method, but it is often inaccurate.

2.5 Mission Statement

Our mission is to develop technology that will allow for more informed medical decision-making in the ED, more accurate diagnoses, and ultimately, improved treatment of hospital patients.

2.6 Goals & Constraints

After carefully weighing our need criteria (**Figure 13**), we adopted the following goals and constraints.

Goals
1. Create a device that is safe to use.
2. Measure respiratory rate accurately with an error tolerance that does not exceed ±2 bpm with respect to the WHO gold standard, 95% of the time.[2]
3. Provide audiovisual feedback to the user that displays real-time RR and audibly alerts the user of bradypnea & tachypnea.
4. Measure respiratory rate in ≤ 30 seconds.
5. Minimize the production cost to ≤ $50 per patient.
6. Minimize discomfort to the patient, so that the device does not cause any pain and is non-invasive & minimally noticeable.
7. Must be convenient and easily applied during use; must be user-friendly, simple, & intuitive[19]; at least 7/10 nurses must prefer use of the device over gold standard auscultation.
8. Must be easy to teach others to use, and easy to be trained to use. Nurses should be proficient in its use after a 10-minute instructional video.

Constraints
1. The solution to the clinical problem should be a tangible device, and not merely an alteration to the fundamental triage procedure.
2. Safety considerations: If the device is a *contact* device, it must be disposable or contain a disposable interface to avoid cross-contamination. If the device is a *non-contact* device, it must not pose any harm, such as a dangerous level of radiation, to the patient.
3. The total time it required to take all vitals must not exceed 160 seconds.
4. The final design of the device must be determined by May 2014.

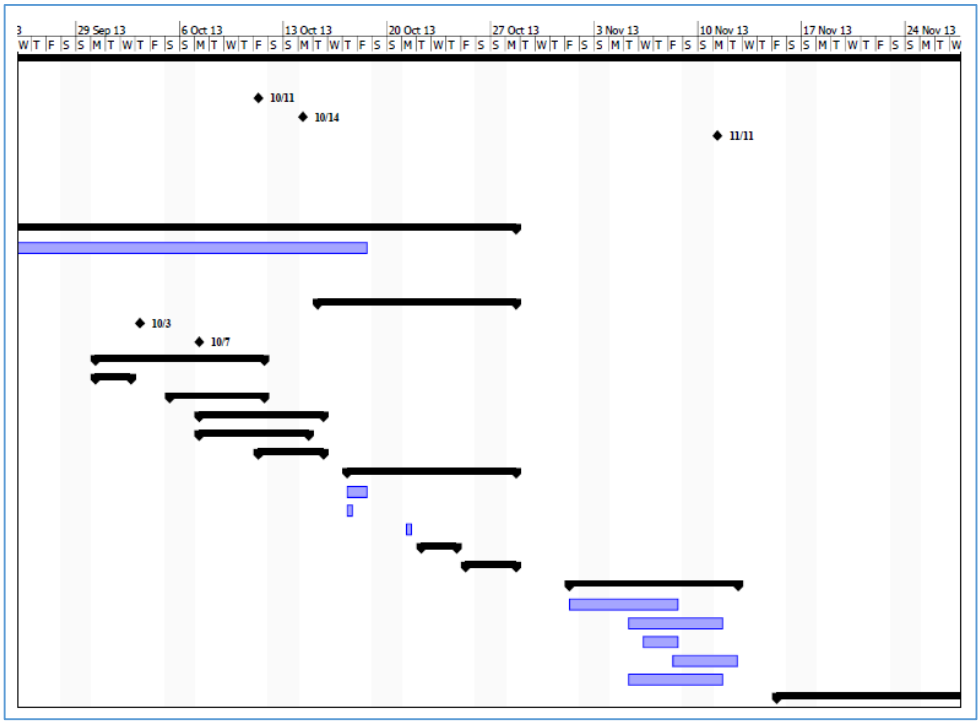
2.7 Anticipated Impact

Stakeholders	Primary Benefits	Primary Costs	Net Impact
Patients	▪ Increased accuracy of respiratory rate results in more accurate diagnoses, which results in better care and treatment overall ▪ Decreased anxiety ▪ Reduced healthcare costs resulting from fewer misdiagnoses	▪ Device administration could possibly result in discomfort	Positive
Doctors	▪ More accurate diagnoses and treatment of patients	▪ None known	Positive
Nurses	▪ More accurate triage ▪ More time to spend on other patients	▪ May require training (minimal)	Positive
Hospitals	▪ A standard by which accurate respiratory rate measurement can be provided in triage ▪ Less manpower required ▪ Fewer in-hospital adverse events; increased quality of care and treatment for patients	▪ Large-scale purchases of respiratory rate measurement device (costs money)	Positive
Medical Device Companies	▪ Device function could be incorporated into an all-inclusive vitals measurement device; can open doors to even further innovation ▪ Device function could be further incorporated into other environments, such as disaster triage or at-home use	▪ None known	Positive

3. PROJECT TIMETABLE

3.1 Fall Semester Gantt Chart

	Name	Duration	Start	Finish
1	**Milestones**	**60 days**	**9/17/13 8:00 AM**	**12/10/13 8:00 AM**
2	Reverse Engineering Presentation	0 days	9/17/13 8:00 AM	9/17/13 8:00 AM
3	Project Proposal	0 days	10/11/13 8:00 AM	10/11/13 8:00 AM
4	Midterm Presentation	0 days	10/14/13 8:00 AM	10/14/13 8:00 AM
5	Committee Meeting	0 days	11/11/13 8:00 AM	11/11/13 8:00 AM
6	Final Presentation	0 days	12/2/13 8:00 AM	12/2/13 8:00 AM
7	Final Report	0 days	12/6/13 8:00 AM	12/6/13 8:00 AM
8	IRB, ACUC Completed	0 days	12/6/13 8:00 AM	12/6/13 8:00 AM
9	Fall Innovation Showcase	0 days	12/10/13 8:00 AM	12/10/13 8:00 AM
10	**Clinical Problem Research**	**106 days?**	**6/3/13 8:00 AM**	**10/28/13 5:00 PM**
11	Individual research & team discussions	100 days	6/3/13 8:00 AM	10/18/13 5:00 PM
12	Nurse shadowing	2 days	6/22/13 8:00 AM	6/25/13 5:00 PM
13	Meeting with Masimo	0 days?	9/19/13 8:00 AM	9/19/13 8:00 AM
14	**Nurse Survey**	**10 days**	**10/15/13 8:00 AM**	**10/28/13 5:00 PM**
18	Problem & need fully defined	0 days	10/3/13 8:00 AM	10/3/13 8:00 AM
19	Research presentation to Drs. Yang & Hsu; proposal edits	0 days	10/7/13 8:00 AM	10/7/13 8:00 AM
20	**Brainstorming**	**10 days**	**9/30/13 8:00 AM**	**10/11/13 5:00 PM**
21	**Idea Generation**	**3 days**	**9/30/13 8:00 AM**	**10/2/13 5:00 PM**
24	**Idea Classification**	**5 days**	**10/5/13 8:00 AM**	**10/11/13 5:00 PM**
27	**Solution Landscaping**	**7 days**	**10/7/13 8:00 AM**	**10/15/13 5:00 PM**
28	**Research Potential Solution**	**6 days**	**10/7/13 8:00 AM**	**10/14/13 5:00 PM**
31	**Generate Solution Landscape**	**3 days**	**10/11/13 8:00 AM**	**10/15/13 5:00 PM**
36	**Secondary Brainstorming**	**8 days**	**10/17/13 8:00 AM**	**10/28/13 5:00 PM**
37	Check Previous Ideas with New Perspectives	2 days	10/17/13 8:00 AM	10/18/13 5:00 PM
38	Needs criteria method analysis	1 day	10/17/13 8:00 AM	10/17/13 5:00 PM
39	Eliminate mechanisms that do not fit need criteria	1 day	10/21/13 8:00 AM	10/21/13 5:00 PM
40	**Additional Idea Generation**	**3 days**	**10/22/13 8:00 AM**	**10/24/13 5:00 PM**
43	**Narrow Down Ideas**	**2 days**	**10/25/13 8:00 AM**	**10/28/13 5:00 PM**
47	**Systems Design**	**8 days**	**11/1/13 8:00 AM**	**11/12/13 5:00 PM**
48	Systems identification	6 days	11/1/13 8:00 AM	11/8/13 5:00 PM
49	Establish system parameters	5 days	11/5/13 8:00 AM	11/11/13 5:00 PM
50	Preliminary sketching & designing	3 days	11/6/13 8:00 AM	11/8/13 5:00 PM
51	Assess and simplify	3 days	11/8/13 8:00 AM	11/12/13 5:00 PM
52	Expert consultation	5 days	11/5/13 8:00 AM	11/11/13 5:00 PM
53	**Detailed Design**	**11 days**	**11/15/13 8:00 AM**	**11/29/13 5:00 PM**



3.2 Detailed Gantt Chart through November 12, 2013

	Name	Duration	Start	Finish
1	**Milestones**	**60 days**	**9/17/13 8:00 AM**	**12/10/13 8:00 AM**
2	Reverse Engineering Presentation	0 days	9/17/13 8:00 AM	9/17/13 8:00 AM
3	Project Proposal	0 days	10/11/13 8:00 AM	10/11/13 8:00 AM
4	Midterm Presentation	0 days	10/14/13 8:00 AM	10/14/13 8:00 AM
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13	Meeting with Masimo	0 days?	9/19/13 8:00 AM	9/19/13 8:00 AM
14	**Nurse Survey**	**10 days**	**10/15/13 8:00 AM**	**10/28/13 5:00 PM**
15	Complete nurse survey IRB	10 days	10/15/13 8:00 AM	10/28/13 5:00 PM
16	Administer nurse survey	4 days	10/21/13 8:00 AM	10/24/13 5:00 PM
17	Analyze nurse survey results	2 days	10/23/13 8:00 AM	10/24/13 5:00 PM
18	Problem & need fully defined	0 days	10/3/13 8:00 AM	10/3/13 8:00 AM
19	Research presentation to Drs. Yang & Hsu; proposal edits	0 days	10/7/13 8:00 AM	10/7/13 8:00 AM
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22	Individualbrainstorming	2 days	9/30/13 8:00 AM	10/1/13 5:00 PM
23	Groupbrainstorming	1 day	10/2/13 8:00 AM	10/2/13 5:00 PM
24	**Idea Classification**	**5 days**	**10/5/13 8:00 AM**	**10/11/13 5:00 PM**
25	Classify brainstorming ideas by mechanism	1 day	10/5/13 8:00 AM	10/7/13 5:00 PM
26	Discuss pros & cons	5 days	10/6/13 8:00 AM	10/11/13 5:00 PM
27	**Solution Landscaping**	**7 days**	**10/7/13 8:00 AM**	**10/15/13 5:00 PM**
28	**Research Potential Solution**	**6 days**	**10/7/13 8:00 AM**	**10/14/13 5:00 PM**
29	Patent search	1 day	10/8/13 8:00 AM	10/8/13 5:00 PM
30	Expert inquiry	6 days	10/7/13 8:00 AM	10/14/13 5:00 PM
31	**Generate Solution Landscape**	**3 days**	**10/11/13 8:00 AM**	**10/15/13 5:00 PM**
32	Check novelty of ideas	1 day	10/11/13 8:00 AM	10/11/13 5:00 PM
33	Assess fulfillment of needs criteria	1 day	10/11/13 8:00 AM	10/11/13 5:00 PM
34	Eliminate mechanisms that do not fulfill criteria	1 day	10/11/13 8:00 AM	10/11/13 5:00 PM
35	Confirm preliminary design solution	2 days	10/12/13 8:00 AM	10/15/13 5:00 PM

	Name	Duration	Start	Finish
36	**Secondary Brainstorming**	**8 days**	**10/17/13 8:00 AM**	**10/28/13 5:00 PM**
37	Check Previous Ideas with New Perspectives	2 days	10/17/13 8:00 AM	10/18/13 5:00 PM
38	Needs criteria method analysis	1 day	10/17/13 8:00 AM	10/17/13 5:00 PM
39	Eliminate mechanisms that do not fit need criteria	1 day	10/21/13 8:00 AM	10/21/13 5:00 PM
40	**Additional Idea Generation**	**3 days**	**10/22/13 8:00 AM**	**10/24/13 5:00 PM**
41	Individualbrainstorming	2 days	10/22/13 8:00 AM	10/23/13 5:00 PM
42	Groupbrainstorming	2 days	10/23/13 8:00 AM	10/24/13 5:00 PM
43	**Narrow Down Ideas**	**2 days**	**10/25/13 8:00 AM**	**10/28/13 5:00 PM**
44	Discuss pros & cons	2 days	10/25/13 8:00 AM	10/28/13 5:00 PM
45	Assess fulfillment of needs criteria	2 days	10/25/13 8:00 AM	10/28/13 5:00 PM
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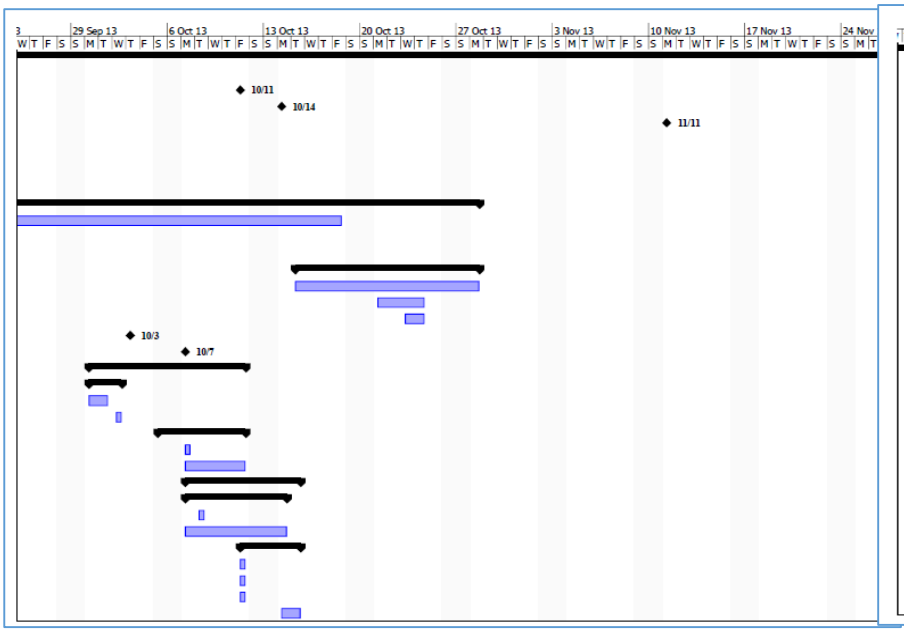
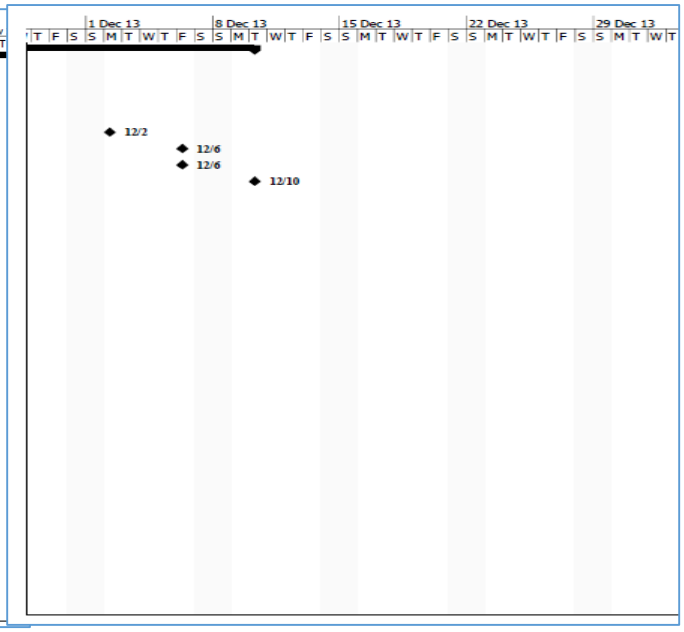
52	Expert consultation	5 days	11/5/13 8:00 AM	11/11/13 5:00 PM
53	**Detailed Design**	**11 days**	**11/15/13 8:00 AM**	**11/29/13 5:00 PM**
54	Systems expert consultation	5 days	11/15/13 8:00 AM	11/21/13 5:00 PM
55	Detailed sketching & designing	7 days	11/20/13 8:00 AM	11/28/13 5:00 PM
56	CAD sketches	5 days	11/23/13 8:00 AM	11/29/13 5:00 PM





4. APPENDIX

A. Figures

Table 2 Odds ratios and 95% confidence intervals of various vital sign parameters and three hospital outcomes in univariate analysis

	Clinical outcomes								
	Cardiac arrest within 72 h			Death within 30 days			ICU admission		
Vital Signs	OR	95% CI	*P*-value	OR	95% CI	*P*-value	OR	95% CI	*P*-value
PR/min									
N: 60–100 (reference)	1	–	–	1	–	–	1	–	–
<60	0.71	0.16–3.07	0.642	0.78	0.27–2.24	0.640	2.25	1.32–3.81	0.003
>100	1.93	1.08–3.44	0.025	1.80	1.15–2.81	0.010	0.95	0.68–1.32	0.752
SBP/mmHg									
N: 90–140 (reference)	1	–	–	1	–	–	1	–	–
<90	0.71	0.29–1.73	0.449	1.34	0.72–2.48	0.357	0.95	0.57–1.56	0.824
>140	0.35	0.18–0.70	0.003	0.60	0.36–0.98	0.040	0.74	0.53–1.03	0.076
DBP/mmHg									
N: 60–95 (reference)	1	–	–	1	–	–	1	–	–
<60	1.61	0.84–3.06	0.148	1.65	1.00–2.73	0.050	1.00	0.67–1.49	0.998
>95	0.92	0.41–2.05	0.837	0.93	0.50–1.73	0.822	1.13	0.76–1.70	0.537
RR/min									
N: 12–20 (reference)	1	–	–	1	–	–	1	–	–
<12	27.50	1.68–450.26	0.020	NC	–	–	NC	–	–
>20	3.93	2.19–7.05	<0.001	3.56	2.23–5.68	<0.001	1.06	0.70–1.60	0.778
SaO_2/%									
N: ≥95 (reference)	1	–	–	1	–	–	1	–	–
<95	2.28	1.22–4.26	0.010	2.39	1.46–3.90	0.001	1.32	0.88–1.97	0.180
GCS									
N: 15 (reference)	1	–	–	1	–	–	1	–	–
<15	2.96	1.60–5.49	0.001	5.16	3.23–8.23	<0.001	2.41	1.63–3.55	<0.001

CI, confidence interval; DBP, diastolic blood pressure; GCS, Glasgow Coma Scale; *N*, normal; NC, not computable because of small cell count; OR, odds ratio; PR, pulse rate; RR, respiratory rate; SBP, systolic blood pressure; SaO_2, oxygen saturation.

Figure 1. *Respiratory rate greater than 20 breaths per minute was predictive of cardiopulmonary arrest within 72 hours, with an odds ratio of 3.93, and death within 30 days, with an odds ratio of 3.56.*[1]

TABLE 2

Sensitivity, Specificity, Odds Ratio (OR), and 95% Confidence Limits (CL) for Selected Vital Sign Thresholds

	Group %					
Vital Sign	Arrest (n = 59)	Control (n = 91)	Sensitivity	Specificity	OR	95% CL
Respiratory rate (breaths per minute)						
>21	0.86	0.66	0.86	0.34	3.29	1.39–7.81
>23	0.83	0.54	0.83	0.46	4.20	1.94–9.22
>25	0.58	0.24	0.58	0.76	4.27	2.11–8.61
>27	0.54	0.17	0.54	0.83	5.56	2.67–11.49
>29	0.44	0.11	0.44	0.89	6.38	2.77–14.64
>31	0.42	0.08	0.42	0.92	8.82	3.53–22.24
Pulse rate (beats per minute)						
>100	0.51	0.44	0.51	0.56	1.32	0.69–2.55
>110	0.41	0.25	0.41	0.75	2.83	1.35–5.90
>120	0.22	0.11	0.22	0.89	2.29	0.93–5.64
>130	0.12	0.09	0.12	0.91	1.40	0.48–40.8
Systolic blood pressure (mm Hg)						
>139	0.53	0.43	0.53	0.57	1.48	0.75–2.92
>149	0.42	0.31	0.42	0.69	2.34	1.13–4.86
>159	0.40	0.23	0.40	0.77	1.35	0.65–2.80
>169	0.24	0.16	0.24	0.84	1.58	0.70–3.56
>179	0.12	0.09	0.12	0.91	1.40	0.48–4.08

Figure 2. *Respiratory rate greater than 27 breaths per minute was predictive of cardiopulmonary arrest within 72 hours, with an odds ratio of 5.56, sensitivity of 0.54, and specificity of 0.83. Sensitivity represents the proportion of patients with a particular range of respiratory rate that have cardiopulmonary arrest, whereas specificity represents the proportion of patients with no particular respiratory range that do not show cardiac arrest. The greater overall relative sensitivity, specificity, and odds ratio of respiratory rate compared to that of pulse rate and blood pressure demonstrates that respiratory rate is indeed better at predicting cardiopulmonary arrest than the others.* [4]

Parameter	On admission	24 h prior to event	6 h prior to event	Last set of observations prior to event
Systolic blood pressure; mmHg (SD)	135 (30) *n* = 259	120 (16) *n* = 24	120 (31) *n* = 46	128 (35) *n* = 176
>Δ; mmHg (%), p-values	5 (−4%) p < 0.005	20 (−14%) p < 0.001	20 (−15%) p < 0.001	12 (−9%) p < 0.001
Mean systolic blood pressure of 'stable' patients: 140 mmHg	94 (26) *n* = 262	106 (20) *n* = 24	102 (20) *n* = 42	101 (27) *n* = 178
Pulse rate; beats.min^{-1} (SD)	94 (26) *n* = 262	106 (20) *n* = 24	102 (20) *n* = 42	101 (27) *n* = 178
Δ; beats.min^{-1} (%), p-values	10 (+ 12%) p < 0.001	22 (+ 26%) p < 0.001	18 (+ 21%) p < 0.001	17 (+ 20%) p < 0.001
Mean pulse rate of 'stable' patients: 84 beats.min^{-1}	24 (8) *n* = 252	27 (6) *n* = 21	27 (7) *n* = 39	27 (9) *n* = 172
Respiratory rate; breaths.min^{-1} (SD)	24 (8) *n* = 252	27 (6) *n* = 21	27 (7) *n* = 39	27 (9) *n* = 172
Δ; breaths.min^{-1} (%), p-values	5 (+ 27%) p < 0.001	8 (+ 44%) p < 0.001	8 (+ 42%) p < 0.001	8 (+ 41%) p < 0.001
Mean respiratory rate of 'stable' patients: 19 breaths.min^{-1}	36.3 (1) *n* = 258	36.6 (0.8) *n* = 25	36.2 (1.2) *n* = 39	36.4 (1.3) *n* = 170
Temperature; °C (SD)	36.3 (1) *n* = 258	36.6 (0.8) *n* = 25	36.2 (1.2) *n* = 39	36.4 (1.3) *n* = 170
Δ; °C (%), p-values	0.3 (−0.7%) p < 0.001	0 (0%) p = 0.961	0.4 (−1%) p < 0.056	0.2 (−0.5%) p < 0.052
Mean temperature of 'stable' patients: 36.6 °C.				

Figure 3. *A study of 1695 acute medical admissions. Patients with a composite outcome of cardiopulmonary arrest, intensive care admission, or death within 24 hours had a mean respiratory rate of 27 breaths per minute, compared to controls who had a mean respiratory rate of 19.*[5]

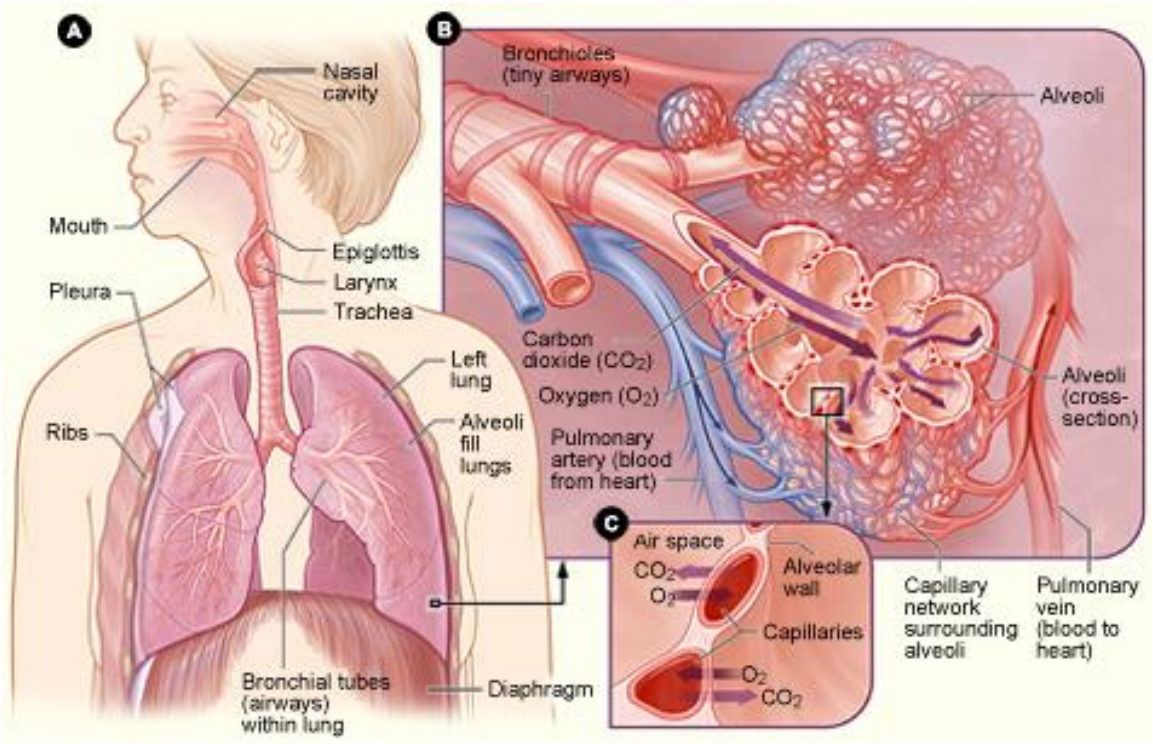


Figure 4. *The human respiratory system and its dependence on the exchange of carbon dioxide and oxygen between the lungs and the rest of the body.*[21]

Table 2 Event characteristics by location

Event characteristics (n = 60,852)	Missing data (n/%)	ED (n = 7435)		ICU (n = 30,476)		Floor (n = 9806)		Telemetry (n = 13,135)	
		%	95%CI	%	95%CI	%	95%CI	%	95%CI
First pulseless rhythm	327/0.54								
Asystole		33.0	[31.9, 34.1]	35.4	[34.8, 35.9]	53.2	[51.8, 54.5]	40.0	[39.2, 40.9]
PEA		36.6	[35.4, 37.7]	40.9	[40.3, 41.4]	33.6	[32.3, 34.9]	34.7	[33.9, 35.6]
Ventricular tachycardia		8.1	[7.5, 8.8]	8.9	[8.6, 9.3]	3.7	[3.3, 4.3]	7.4	[7.0, 7.9]
Ventricular fibrillation		22.2	[21.3, 23.3]	14.8	[14.4, 15.2]	9.5	[8.7, 10.3]	17.8	[14.1, 18.5]
Predisposing cause	5/0.008								
Arrhythmia		58.4	[57.2, 59.5]	66.5	[66.0, 67.0]	44.5	[43.5, 45.5]	55.7	[54.8, 56.5]
Hypotension/shock		38.5	[37.4, 39.6]	51.5	[50.9, 52.1]	25.7	[24.8, 26.6]	24.5	[23.8, 25.2]
Myocardial infarction		19.4	[18.5, 20.3]	9.8	[9.4, 10.1]	3.6	[3.2, 3.9]	6.7	[6.3, 7.1]
Acute pulmonary edema		3.0	[2.6, 3.4]	2.2	[2.0, 2.3]	1.0	[0.81, 1.2]	1.5	[1.3, 1.7]
Acute pulmonary embolism		1.8	[1.5, 2.1]	1.7	[1.5, 1.8]	2.7	[2.4, 3.0]	2.2	[1.9, 2.4]
Invasive airway displace		0.2	[0.09, 0.28]	0.5	[0.43, 0.59]	0.2	[0.09, 0.25]	0.1	[0.08, 0.21]
Acute respiratory insufficiency		42.2	[41.0, 43.3]	35.1	[34.6, 35.7]	44.0	[43.0, 45.0]	38.3	[37.5, 39.1]
Metabolic/electrolyte		9.2	[8.6, 9.9]	14.1	[13.7, 14.4]	6.8	[6.3, 7.3]	6.1	[5.7, 6.6]
Toxicological problem		1.9	[1.6, 2.3]	0.8	[0.73, 0.93]	0.7	[0.55, 0.88]	0.5	[0.37, 0.6]
Inadequate natural airway		1.6	[1.3, 1.9]	1.1	[1.0, 1.2]	3.6	[3.2, 4.0]	2.3	[2.0, 2.5]
Inadequate invasive airway		0.5	[0.38, 0.72]	1.2	[1.1, 1.3]	0.5	[0.34, 0.61]	0.4	[0.32, 0.54]
Malfunction of device		0	–	0.0	[0.002, 0.02]	0.0	[0.002, 0.06]	0	–
Conscious sedation		0.2	[0.08, 0.26]	0.2	[0.16, 0.26]	0.0	[0.01, 0.09]	0.0	[0.02, 0.09]
Acute stroke		0.2	0.13, 0.35]	0.3	[0.22, 0.34]	0.4	[0.25, 0.48]	0.1	[0.08, 0.21]
Status epilepticus		0.2	[0.09, 0.28]	0.1	[0.06, 0.13]	0.2	[0.1, 0.26]	0.1	[0.05, 0.16]
Hypothermia		0.3	[0.18, 0.43]	0.3	[0.25, 0.37]	0.1	[0.09, 0.25]	0.1	[0.03, 0.11]
Acute pneumothorax		0.3	[0.17, 0.42]	0.2	[0.17, 0.28]	0.0	[0.02, 0.1]	0.1	[0.03, 0.11]
Unknown/not documented		9.8	[9.1, 10.5]	5.6	[5.3, 5.8]	23.1	[22.2, 23.9]	16.4	[15.8, 17.1]
Interventions in place									
None	7/0.01	13.5	[12.8, 14.3]	0.5	[0.44, 0.61]	8.8	[8.3, 9.4]	3.8	[3.5, 4.2]
Vascular access	7/0.01	79.2	[78.3, 80.1]	96.5	[96.3, 96.7]	86.2	[85.5, 86.9]	91.4	[90.7, 92.0]
ECG monitor	7/0.01	76.9	[76.0, 77.9]	94.9	[94.6, 95.1]	17.3	[16.6, 18.1]	70.1	[69.3, 70.9]
Pulse oximeter	7/0.01	57.5	[56.4, 58.6]	86.2	[85.8, 86.6]	15.8	[15.1, 16.6]	25.6	[24.8, 26.3]
Invasive airway	7/0.01	27.3	[26.3, 28.3]	48.8	[48.2, 49.3]	4.1	[3.7, 4.5]	4.3	[3.9, 4.6]
Mechanical ventilation	7/0.01	24.5	[23.5, 25.4]	47.6	[47.0, 48.1]	3.6	[3.2, 4.0]	3.6	[3.3, 3.9]
Pacemaker	0/0	4.1	[3.7, 4.6]	9.4	[9.0, 9.7]	3.4	[3.0, 3.8]	6.4	[6.0, 6.9]
ICD	7/0.01	0.86	[0.68, 1.1]	1.7	[1.5, 1.8]	0.7	[0.57, 0.91]	2.1	[1.8, 2.3]
IABP	7/0.01	0.09	[0.05, 0.19]	2.8	[2.6, 3.0]	0.0	[0.006, 0.07]	0.0	[0.008, 0.07]
Intra-arterial catheter	7/0.01	1.0	[0.82, 1.3]	15.3	[14.9, 15.8]	0.3	[0.19, 0.4]	0.4	[0.34, 0.57]
PA catheter	7/0.01	0.19	[0.11, 0.32]	9.2	[8.8, 9.5]	0.2	[0.12, 0.3]	0.2	[0.14, 0.29]
IV vasoactive agents	7/0.01	14.5	[13.7, 15.3]	47.2	[46.6, 47.8]	2.0	[1.7, 2.3]	5.4	[5.0, 5.8]
IV antiarrhythmics	7/0.01	3.4	[3.0, 3.9]	9.7	[9.3, 10.0]	0.5	[0.35, 0.63]	2.0	[1.7, 2.2]
Dialysis treatment	7/0.01	0.51	[0.37, 0.7]	5.3	[5.1, 5.6]	2.4	[2.1, 2.7]	2.3	[2.0, 2.6]
Chest tube	7/0.01	1.3	[1.0, 1.6]	5.6	[5.3, 5.9]	0.6	[0.44, 0.74]	0.8	[0.67, 0.98]
Conscious sedation	7/0.01	0.39	[0.27, 0.56]	1.1	[0.95, 1.2]	0.1	[0.03, 0.13]	0.1	[0.04, 0.13]
Supplemental oxygen	7/0.01	13.1	[1.3, 13.9]	13.5	[13.1, 13.9]	11.8	[11.2, 12.5]	8.9	[8.4, 9.4]
Other	7/0.01	8.5	[7.8, 9.1]	13.7	[13.3, 14.0]	4.4	[4.0, 4.8]	5.3	[4.9, 5.7]

Figure 5. *A study of 60,852 patients with in-hospital cardiopulmonary arrest at various hospitals in National Registry of Cardiopulmonary resuscitation. Approximately 12% of in-hospital arrest occurred in the ED, while 50% occurred in the ICU.*[11]

Index event characteristics	
Event location	
ICU	48%
Inpatient	32%
ED	11%
Diagnostic area	4%
Operating room	2%
PACU	0.5%
Outpatient	0.4%
Other	2.1%
First pulseless rhythm	
VF/VT	25%
PEA	30%
Asystole	36%
Unknown by documentation	9%
Discovery status at time of event	
Witnessed and/or monitored	86%
Witnessed and monitored	66%
Witnessed and not monitored	11%
Monitored and not witnessed	9%
Not witnessed or monitored	14%
Immediate cause(s) of event (present within 1 h before arrest)	
Arrhythmia	49%
Acute respiratory insufficiency or compromise	37%
Hypotension	32%
Acute myocardial infarction or ischemia	10%
Metabolic/electrolyte disturbance	10%
Acute pulmonary edema	3%
Acute pulmonary embolism	2%
Airway obstruction	2%
Toxicological problem	1%

Figure 6. *Results from a study of 14,720 cardiopulmonary arrests that occurred in hospitals.*[12]

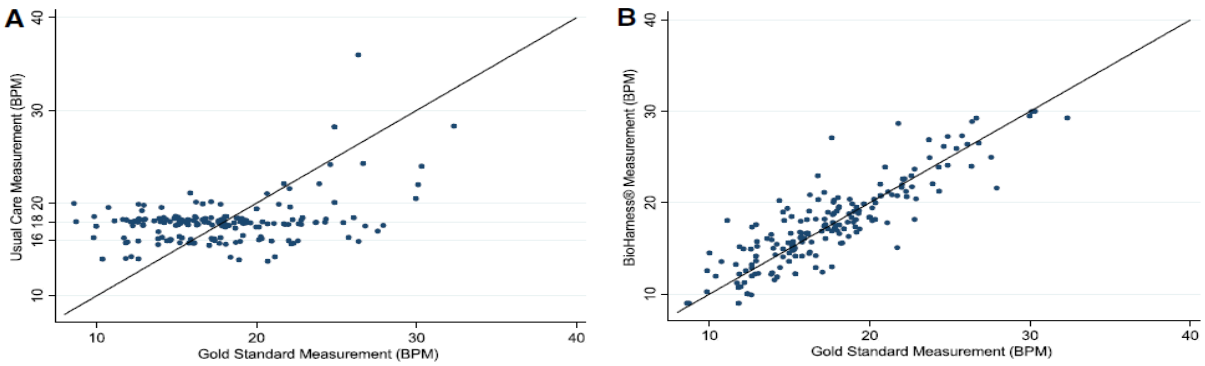


Figure 7. *Nurse measurement of respiratory rates (A) tended to cluster around 16 or 18 breaths per minute, whereas BioHarness measurement of respiratory rates (B) seemed to have a more distributed range of respiratory rates.* [14]

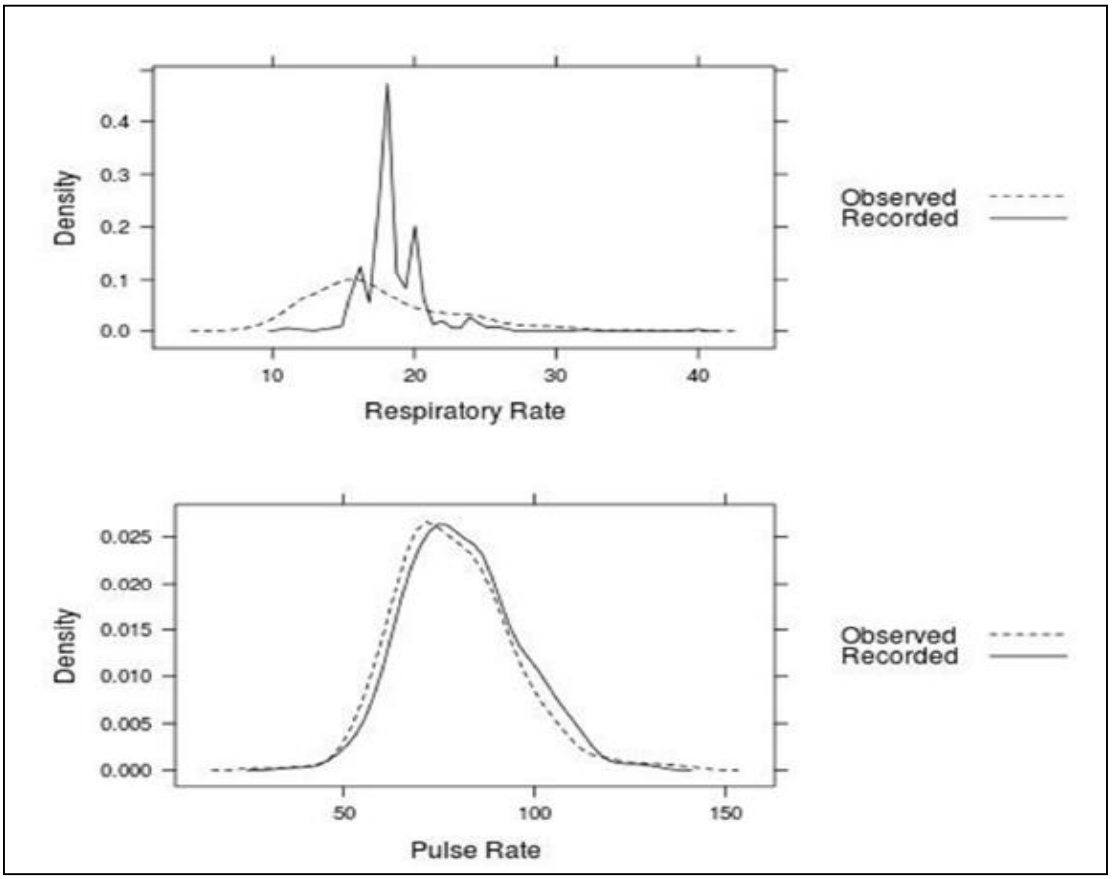


Figure 8. *Results of a study that demonstrate clustering of recorded respiratory rate measurements. Such clustering is hardly a problem with other vitals measurements, such as pulse rate.*[22]

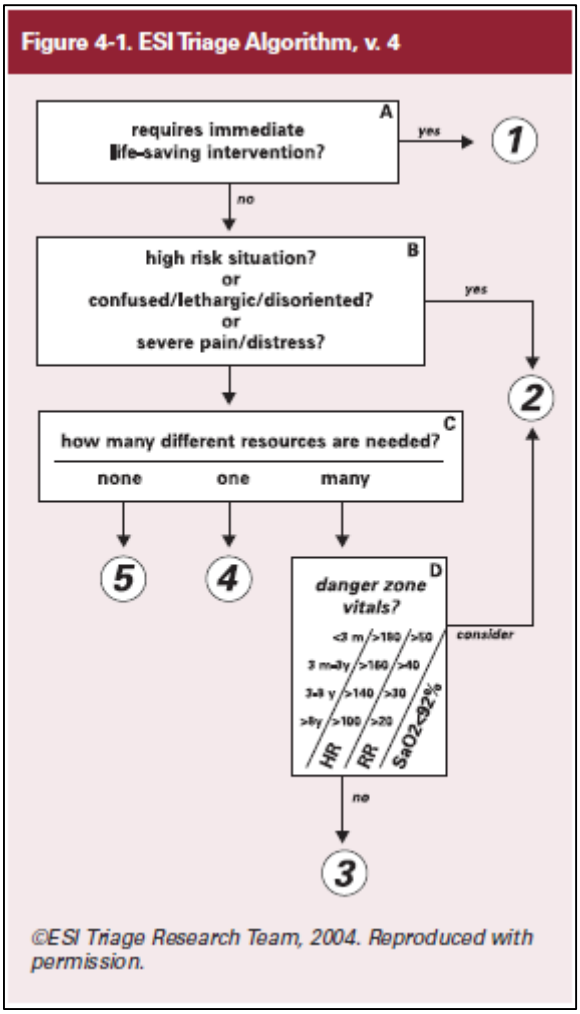


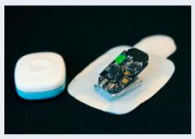
Figure 9. *Emergency Severity Index (ESI) Triage Algorithm. Note the role of vital signs in determining an acuity level of 2 or 3.* [17]

The National Early Warning Score (NEWS).

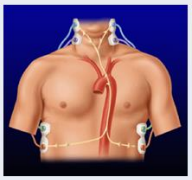
Physiological parameters	3	2	1	0	1	2	3
Respiration Rate (breaths per minute)	≤8		9–11	12–20		21–24	≥25
S_pO_2 (%)	≤91	92–93	94–95	≥96			
Any supplemental oxygen?		Yes		No			
Temperature (°C)	≤35.0		35.1–36.0	36.1–38.0	38.1–39.0	≥39.1	
Systolic BP (mmHg)	≤90	91–100	101–110	111–219			≥220
Heart/pulse rate (beats per minute)	≤40		41–50	51–90	91–110	111–130	≥131
Level of consciousness using the AVPU system				A			V, P or U

Level of consciousness: A – alert; V – responds to voice; P – responds to pain; U – unresponsive. Modified from National Early Warning Score (NEWS): Standardising the assessment of acute-illness severity in the NHS. Report of a working party. Royal College of Physicians, London, 2012.[12]

Figure 10. *Physiological parameters that define the National Early Warning Score (NEWS) triage prioritizing system.* [18]

	Masimo Rainbow Acoustic Monitoring	Anaxys RespiR8	Speckled Computing RESpeck	Zephyr BioHarness
Device				
Primary Mechanism	Acoustic sensor	Electrochemical sensor	Tri-axial accelerometer	ECG

	Respirion Omnicap	Vernier Respiration Monitor Belt	Transcutaneous CO2 Monitoring	BCI Capnocheck
Device				
Primary Mechanism	Capnography (not IR Spec)	Gas pressure sensor	Electrochemical sensor	Capnography (IR Spectroscopy)

	EverOn	Transthoracic Impedance	AQWave Photoplethysmograph	Scanadu Scout
Device				
Primary Mechanism	Piezoelectric sensor	Aluminum-coated plastic electrodes	LED absorption	Near-IR LED sensor, ECG sensor, far-IR sensor, **microphone**

	Kai Spot Respiratory Rate Spot Check	Thermal Imaging
Device		
Primary Mechanism	Doppler radar	IR thermography

Figure 11. *Examples of existing devices that measure respiratory rate, as well as their primary mechanisms.*

Table 2 Methods and devices for respiratory monitoring using detection of movement, volume and tissue composition as reported in literature

Method/device	Measuring parameter	Sensor type and placement	References
Transthoracic impedance	Transthoracic impedance	Skin electrodes on chest	ALLISON *et al.* (1964); ASHUTOSH *et al.* (1974); COHEN *et al.* (1997); DRUMMOND *et al.* (1996); HAMILTON *et al.* (1967); HOFFMAN *et al.* (1986)
Inductance plethysmography	Abdomen and thoracic circumference	Embedded coils around abdomen and chest	COHEN *et al.* (1997); SEMMES *et al.* (1985)
Fibre-optic plethysmography	Abdomen and thoracic circumference	Fibre-optic strain gauge around abdomen and chest	DAVIS *et al.* (1997)
Strain-gauge transducers	Abdomen and thoracic circumference	Resistive strain gauge around abdomen and chest	ERIKSSON *et al.* (1986)
Mutual inductance	Thorax volume	Magnets on chest	ASHUTOSH *et al.* (1974)
Magnetometer	Thorax volume	Magnets on chest and magnetometer	ASHUTOSH *et al.* (1974); ROLFE (1971)
Capacitance on distance	Thorax volume	Capacitance measurement	BARROW *et al.* (1969)
Microwave radiation	Thorax volume	Waveguide termination	FRANKS *et al.* (1976); LIN (1975)
Sensors in mattress	Thorax volume	Pressure or flow sensors in mattress	FRANKS *et al.* (1976); SIIVOLA (1989); WAAG-CARLSON *et al.* (1999)
Electromyography	Muscle activity	Skin electrodes	COP (1988)
Photoplethysmography	Venous return	Fibre-optic sensor	BARSCHDORFF and ZHANG (1994); JOHANSSON and ÖBERG (1999*a*; *b*); LINDBERG *et al.* (1992); NAKAJIMA *et al.* (1996); NILSSON *et al.* (2000); VEGFORS *et al.* (1993)

Figure 12. *More examples of existing respiratory rate monitoring devices. These devices specifically use detection of movement, volume, and tissue composition as their parameters of measurement.*[23]

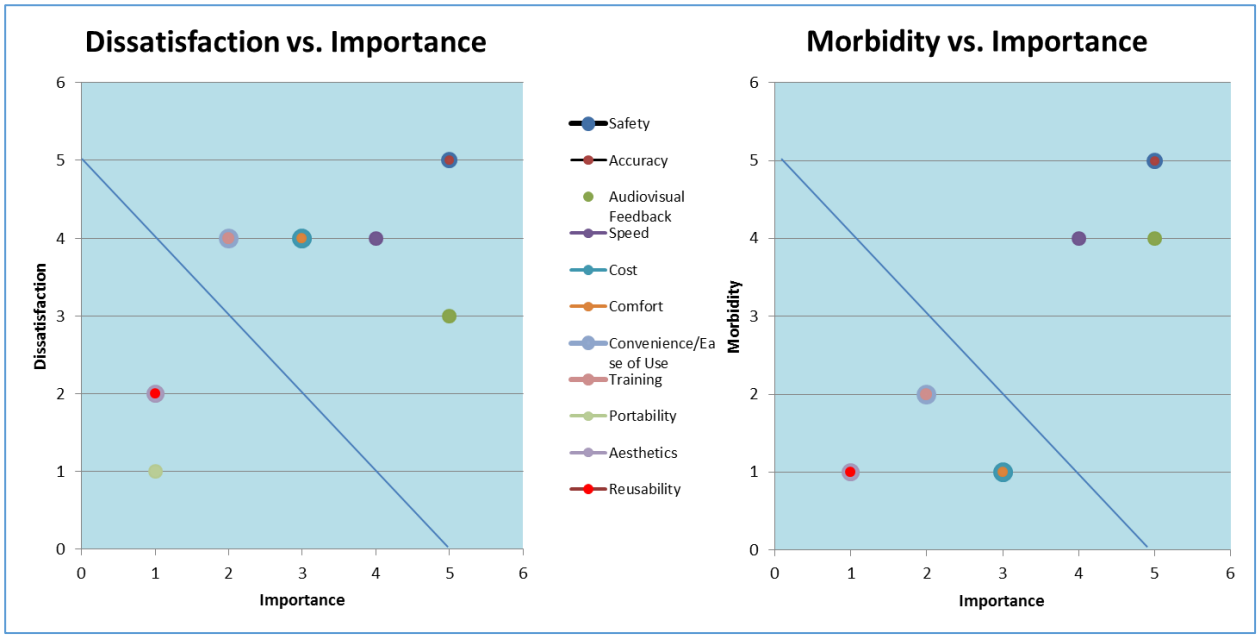


Figure 13. *Weighing of need criteria in terms of dissatisfaction vs. importance and morbidity vs. importance.*

B. References

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