Qualcomm Wireless Innovation Prize Competition
Burrell Business Plan Competition Business Plan

pulseMobile

Designed and Developed by Mindful Health

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Executive Summary

Part 1: Value Proposition

Ongoing management of CHF patients is time consuming and complex for care teams, and also poses a substantial financial burden to their healthcare institution as a whole. In 2013, Medicare levied $227 million in fines against 2,225 hospitals, from every state but one, as mandated by the Readmission Reduction Act (RRA) [2]. The RRA is one component of the Affordable Care Act (ACA), and aims to reduce the number of heart failure patients readmitted to hospitals within one month of release.

Even so, over 30% of the adults discharged from a hospital did not see a healthcare professional in the 30 days following [3]. These patients, that neglect to adhere to their recommended follow up appointments, account for the majority of avoidable readmission costs.

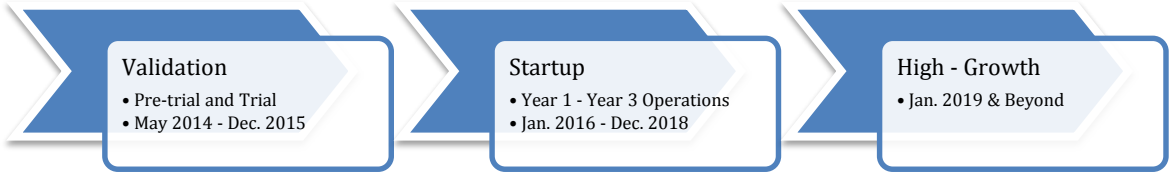
Telehealth systems pose a significant opportunity to improve compliance with physician instructions, improve patient wellness outcomes, and to reduce the sizable economic waste of avoidable readmissions. These systems have not been widely adopted by major healthcare providers, citing a significant disruption to workflow and increased care team inefficiency as the primary barrier to adoption.

As such, the efficiency and effectiveness of CHF outpatient management will be improved through the use of wearable health tracking devices that input data directly into the EHR using a method that ensures that this platform becomes a fluid and integral part of the care team workflow, while supplementing the benefit of improved care team efficiency with the value of truly objective, accurate, and reliable patient data.

Patient outcomes would also greatly benefit from fully automated analytics reports on patient vitals and trends, which enable deeper insight into outpatient conditions for both individual patients, as well as the healthcare provider's CHF patient population as a whole.

PulseMobile is a software as a service (SaaS) product that aims to address the three the 3 core opportunities to provide value for outpatient CHF management care teams and healthcare providers; reduce the cost of care for CHF patients, increase the efficiency of outpatient management processes, and improve patient health outcomes. The pulseMobile platform is comprised of two components; a high convenience wearable remote monitoring device and a cloud based, EHR connected clinical decision support application.

Part 2: Mindful Health's Future



Required Funding

Stage	Validation	Startup	High-Growth
Funding Need	$ 185,940.00	$ -	$ > 1,000,000

Expected Cash Flows

The Problem

While the electronic health record (EHR) has gained widespread adoption among major healthcare providers, a significant portion of those institutions have not experienced the improvements in quality and efficiency of care delivery those systems are expected to bring. Moreover, according to a study in the Journal of the American Medical Informatics Association, using bedside or point-of-care systems increased documentation time of physicians by 17.5%, while the use of computerized central-station desktops increased the physician's time per working shift from 98.1% to 328.6% [1].

One very narrow application of the EHR that our team focuses on is its use for documenting and tracking the condition of severe chronic patients, specifically congestive heart failure (CHF) patients, while they are at home. Ongoing management of CHF patients is especially time consuming and complex for care teams, and also poses a substantial financial burden to their healthcare institution as a whole.

In 2013, Medicare levied $227 million in fines against hospitals in every state but one, as mandated by the Readmission Reduction Act (RRA) [2]. The RRA is one component of the Affordable Care Act (ACA), and aims to reduce the number of heart failure, acute myocardial infarction, and pneumonia patients readmitted to hospitals within one month of release. In total, Medicare identified 2,225 hospitals that will have payments reduced, including 87% of major teaching hospitals. Furthermore, Medicare will increase the maximum penalty to a 3% payent reduction for all patient stays in October 2014 [2]. These financial punishments have been introduced for a clear reason; in a large portion of cases, these 30 day readmissions are fully avoidable.

On average, 1 in 12 patients are readmitted to the hospital within the first 30 days after discharge, and 4 in 12 are re-hospitalized within 1 year. The 2008 US expenditure for hospital readmissions within 30 days of discharge was $16.3 billion, and $97.2 billion for readmissions up to one year after [3]. While rehospitalizations are preventable, the underlying causes can only detected and addressed if patients follow up with physicians within the highly recommended 30 day time frame. Even so, over 30% of the adults discharged from a hospital in 2008 did not see a healthcare professional in the 30 days following, while 17.6% still had not followed up 90 days after discharge [3]. These patients, that neglect to adhere to their recommended follow up appointments, account for the majority of avoidable readmission costs, and pose a substantial risk to their own health.

Telehealth systems pose a significant opportunity to improve compliance with physician instructions, improve patient wellness outcomes, and to reduce the sizable economic waste of avoidable readmissions. A telehealth device is defined by the UK Department of Health as equipment that monitors vital health signs remotely, and automatically makes these readings available to an appropriately trained health professional, outside of the clinic. The economic value of these technologies lies primarily in the impact that out-of-clinic patient data can have on chronic disease management. These data enable physicians to make clinical decisions and interventions without seeing the patient directly. In doing so, potentially catastrophic episodes can be addressed earlier and more quickly.

In a study published in the International Journal of Medical Informatics, patients with severe respiratory illnesses were remotely-monitored using telehealth devices. The results of this study showed a 50% decrease in hospital admissions, a 55% decrease in acute home exacerbations, and a 17% reduction in hospitalization costs, even after the costs of monitoring are included [5]. Similarly, in a two year study by the UK Department of Health involving 6191 CHF, chronic obstructive pulmonary disorder, diabetic, and other HF patients, the telehealth device equipped population demonstrated significant reductions in 3 types of inpatient admissions, bed days, and tariff costs. Most strikingly, a 45% lower mortality rate was observed

in the telehealth equipped population versus the control. [4] These data can be found in figure 1.

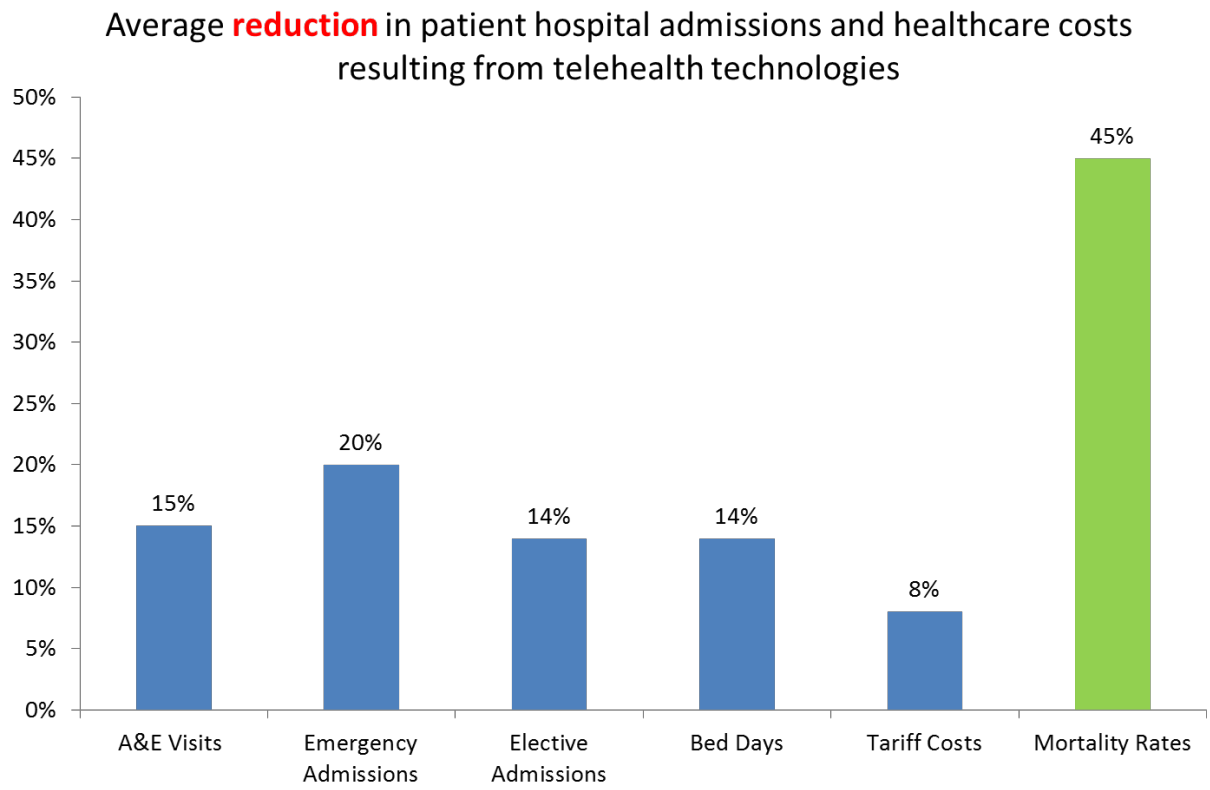


Figure 1. Graphical Representation of WSD Program Results. The telehealth equipped population demonstrated significant reductions in A&E clinic visits, emergency room admissions, patient elective admissions, average bed days, tariff costs, and mortality rate [4]

While the remote monitoring's efficacy in reducing avoidable costs and readmissions has been established, these systems have yet to be widely utilized by major healthcare providers. The primary barrier to implementation is the disruption to physician and nurse workflow caused by current technologies. As the vast majority of remote monitoring devices connect with stand-alone applications, care teams are highly deterred from using them as they commonly have to stop work on their current system, switch to the stand alone application, and in many cases, reenter patient data into their primary EHR. Coupled with the inefficiencies to care team workflow already introduced by the EHR itself, the lack of adoption of these systems is easily understood.

As a result, current CHF outpatient management processes most commonly involves nurses calling patients, talking through verbal wellness surveys, and manually inputting data into the EHR. This practice is neither an effective use of time, nor does it produce data of the same reliability, objectivity, or granularity as those acquired by remote monitoring devices. Furthermore, It is very challenging, if not impossible, to perform various analysis on individual patient or patient population databases in the market leading EHR systems. Because of this reality,

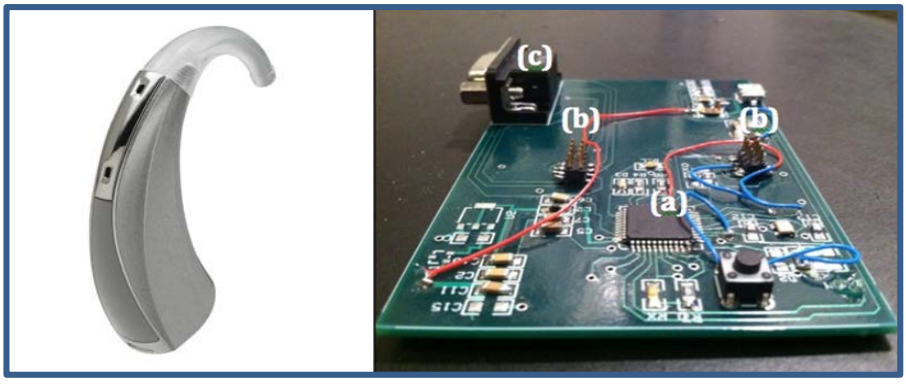
much of the data that is collected by the EHR is not utilized to its fullest potential; to improve patient outcomes through data analytics and augmented decision support.

As such, we believe the efficiency and effectiveness of CHF outpatient management will be improved through the use of wearable health tracking devices that input data directly into the EHR in a fully automated way. In doing so, faster and bigger data is available automatically, freeing care teams to spend less time on data entry and more time caring for their patients. In addition, our method of EHR connectivity ensures that this platform becomes a fluid and integral part of the care team workflow, while supplementing the benefit of improved care team efficiency with the value of truly objective, accurate, and reliable patient data. We also believe patient outcomes would greatly benefit from fully automated analytics reports on patient vitals and trends, which enable deeper insight into outpatient conditions for both individual patients, as well as the healthcare provider's CHF patient population as a whole.

While effective and efficient outpatient CHF management is one of the most complex and costly problems facing healthcare today, the Mindful Health team believes it's solution should be neither; we have developed an innovative solution that is both low-cost and elegantly simple – introducing, pulseMobile.

Mindful Health Technology's Solution

PulseMobile is a software as a service (SaaS) product that aims to address the three the 3 core opportunities to provide value for outpatient CHF management care teams and healthcare providers; reduce the cost of care for CHF patients, increase the efficiency of outpatient management processes, and improve patient health outcomes. The pulseMobile platform is comprised of two components; a high convenience wearable remote monitoring device and a cloud based, EHR connected clinical decision support application.



Figures 2a (left) The pulseMobile device encasing concept. [10] A concept model demonstrating the targeted form factor of the pulseMobile and **2b (right) The pulseMobile hardware,** highlighting the processor (a), OEM pulse oximetry access points (b), and sensor

The pulseMobile device collects patient blood oxygen saturation and heart rate, and transmits it into the platform cloud databases directly through the cellular network (figures 2a and 2b). This device was designed with the goal of minimizing the need for any patient compliance to the greatest extent possible. With this in mind, number of novel features have been incorporated to achieve maximized simplification of the patient experience. First, the device was designed into the form factor of a hearing aid. To date, no commercially available pulse oximeter devices can be exclusively worn behind the ear, out of sight and out of mind for patients.

While Bluetooth enabled wrist oximetry devices, like the Fitbit or Basis watch, are gaining popularity in consumer markets, the underlying oximetry technology and data quality is not suitable for critical clinical applications. These devices also suffer from long periods without any data uploads, resulting from inconsistent Bluetooth synchronization with their smartphones. In addition, when individual's phones run out of battery or when they are greater than 10 meters away, it is generally not possible for the device data to be collected. To avoid these sources of risk, the pulseMobile device is integrated with GSM cellular technology, so patient data can be sent directly to cloud servers on an hourly basis, using a fully automated process that requires no thought or interaction from the patient. In doing so, clinicians can expect high quality vital data to be updated consistently, reliable, and frequently, in a way that would not be possible with Bluetooth or wrist worn oximetry devices.

As such, the only thing patients need to do in order to utilize this device is simply just to wear it. The device's lightweight, unobtrusive form factor, fully automated data collection and transmission processes, and cellular network connectivity culminates in a patient experience that requires less time, effort, and action on their part than any other clinical grade modern remote monitoring system. Furthermore, this ease of use allows care teams to set the expectation that patients wear the device all day while they are awake. By continuously monitoring patients, data becomes available in greater volume and velocity, allowing for a much deeper understanding of patients heart conditions and exacerbations than was previously possible.

Next, the pulseMobile clinical decision support application displays patient data visualizations and trends, automatically prioritizes patients by severity based on vitals, and frequently updates the EHR with these data (figure 3). This software also provides a number of features that reduce or remove previous barriers of adoption, allowing the platform to become a fluid and integral part of the care team workflow. As previously mentioned, the pulseMobile software will input all patient data into the Electronic Health Record in a fully automated way, allowing care teams to spend significantly less time on manual data entry. In many cases, phone surveys will be unnecessary, as the current state of patient wellness is known, or alternatively, they can be more specific and productive, as critical patients can be given more attention and consideration. Furthermore, these severe patients can be prioritized in a fully automated way, based on vital thresholds set by the care team

itself, allowing care teams fast and clear insight any time the application is referenced.

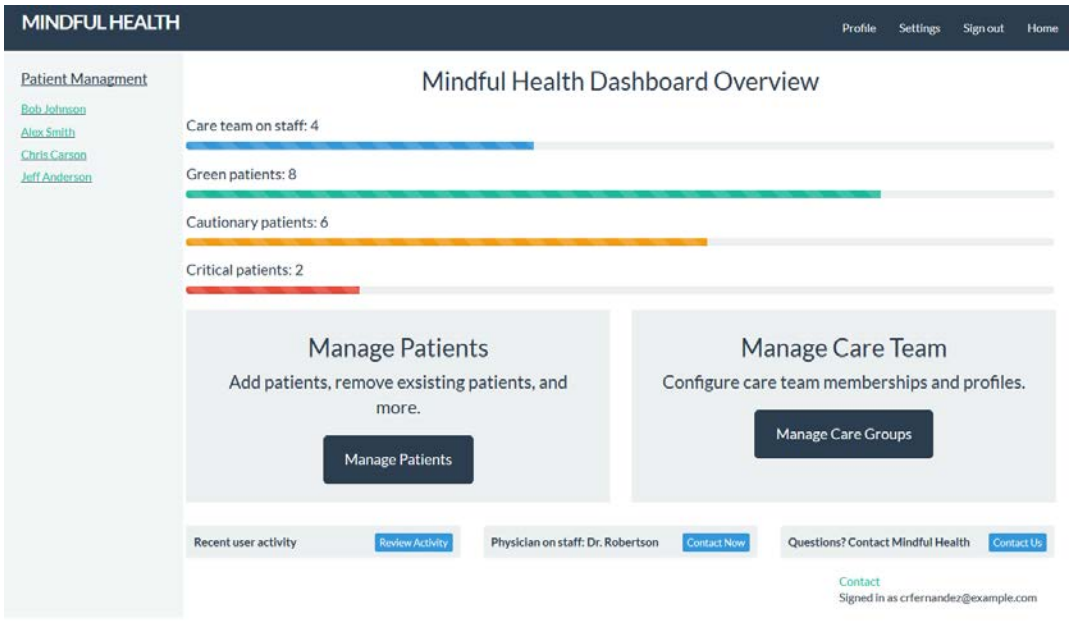


Figure 3. The pulseMobile application dashboard. This dashboard provides an overview of the current condition of all patients managed by one care group of physicians and nurses. Patients and care team members can be added using forms on this page. Individual patient profiles are accessed using the Patient Management sidebar.

One significant benefit of utilizing the cloud infrastructure is that the application is available on any desktop, tablet, or mobile device, with any operating system, as long as it has web accesses. This is distinct from the previously mentioned bedside point-of-care systems and central-station desktops, in that nurses and physicians can check up on patients using the pulseMobile application from almost anywhere at any time, encouraging more frequent and convenient outpatient health tracking.

Finally, the pulseMobile software leverages fully automated data analytics to allow physicians and nurses to embolden care teams with greater objectivity and confidence when considering a serious outpatient intervention (figure 3). According to a systematic review of 70 studies published in the British Medical Journal, decision support systems significantly improved clinical practice in 68% of trials. The pulseMobile application does not aim to replace physician's decision making, make any diagnoses, or recommend specific courses of action, but more accurately

to augment the existing expertise of care teams with dynamic, quantified report son patient conditions and deterioration for more informed and agile decision making.

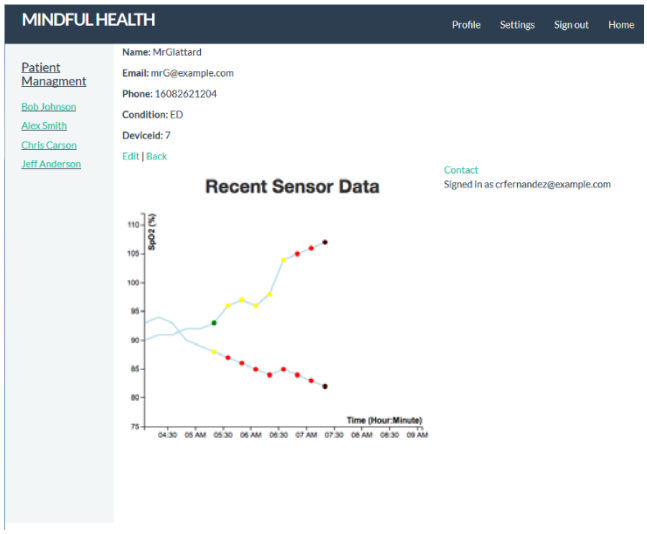
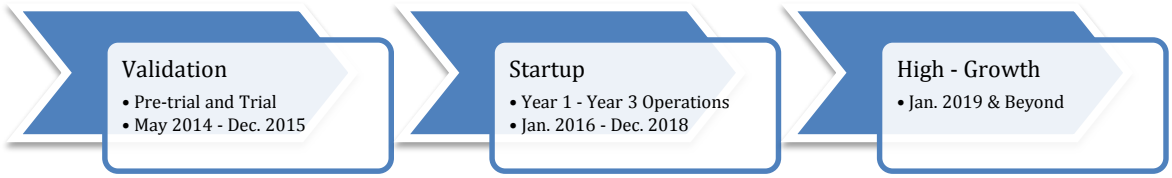


Figure 4. pulseMobile application analytics for a single patient. The Patient Management page shows recent patient vital data, color coded by the vital threshold levels set by care teams. Relevant patient contact information is used as needed for rapid intervention.

In summary, the pulseMobile platform will address the largest opportunities to provide value to CHF outpatient care teams. First, cost of care will reduced by minimizing the number of avoidable patient readmissions. This is accomplished by thorough and accurate tracking of patient heart conditions, and more targeted, strategic treatments and interventions for severe patients, augmented by objective, data supported care decisions. This will significantly improve healthcare provider's ability to avoid the very costly Readmission Reduction Programs financial penalties. Next, the efficiency of the outpatient management processes is improved through the automated collection, transmission, storage, and analysis of data in the ERH, freeing clinicians to spend more time working to improve the health of patients who need it most. The device agnostic nature of the pulseMobile cloud application allows for frequent and convenient outpatient check-ins, allowing the value of this platform to be maximized through rapid and focused outpatient interventions. Lastly, the pulseMobile platform culminates in improved patient outcomes. By leveraging the sophisticated features of this advanced pulseMobile technology, we expect to reduce CHF patient mortality rates equal to or greater than than those achieved by the UK Department of Health in their 2006 study.

Financial Forecast



Validation Phase

May 2014 – December 2015 Projections

Project Cash Flows Through Trial	
Before Trial Cost	
pulseMobile Redesign	$ (30,000.00)
Device MFG Cost	$ (101,250.00)
Total Pre-trial Expenses	$ (131,250.00)
Anticipated Trial Monitoring Cost	
Patient Incentive	$ (18,750.00)
Web Hosting	$ (4,968.00)
Data Storage	$ (972.00)
Trial Monitoring Expense	$ (24,690.00)
Total Trial Expenses	$ (155,940.00)
Potential Sources of Funding	
Burrell 1st Prize	$ 10,000.00
Burrell AARP Prize	$ 5,000.00
Qualcomm Innovation Prize	$ 15,000.00
Grant Money	$ 155,940.00
Friends, Family & Angel	???
Total Trial Funds	$ 185,940.00
Net Cash Flows Through Trial	$ 30,000.00

Assumptions

1. Receipt of [INSERT NAME OF GRANT] Grant
    a. 55% of applicants receive their requested grants.
    b. Grant are given in amounts up to $250,000
    c. Mindful Health's trial is well within the realms of the type of research that typically receives funding
2. Device redesign and testing will cost $30,000

a. This is a conservatively high estimate. It will most likely cost between $10,000 - $20,000

3. No salaries or labor expenses will be incurred over the course of the study because the founding team will still be in school, and will support Mindful Health's research study along with their degree studies

Startup Phase

Conservative Case (No Payer Reimbursements Authorized)[1]

	Projected Annual Income		
Year Ending Dec.	2016	2017	2018
Revenue	$ 576,000.00	$ 1,728,000.00	$ 2,880,000.00
COGS	$ (250,300.80)	$ (502,934.40)	$ (755,568.00)
Gross Profit	$ 325,699.20	$ 1,225,065.60	$ 2,124,432.00
Gen Admin Expense	$ (325,000.00)	$ (325,000.00)	$ (325,000.00)
Selling Expense	$ (33,600.00)	$ (33,600.00)	$ (33,600.00)
Sales & Admin Expense	$ (358,600.00)	$ (358,600.00)	$ (358,600.00)
EBITA	$ (32,900.80)	$ 866,465.60	$ 1,765,832.00
Other Income (Expense)	$ -	$ -	$ -
Earnings Before Taxes	$ (32,900.80)	$ 866,465.60	$ 1,765,832.00
Provisions for Income Tax	$ -	$ (346,586.24)	$ (706,332.80)
Earnings After Tax	$ (32,900.80)	$ 519,879.36	$ 1,059,499.20

Key Assumptions (Addressed Independently in Respective Appendix)

1. Revenue
    a. 3 Sales per year (3 new hospitals)
    b. 200 patients (devices) per hospital in their first year as a customer and 400 for each year after
    c. $80 per month per device
2. Cost
    a. Customer acquisition costs

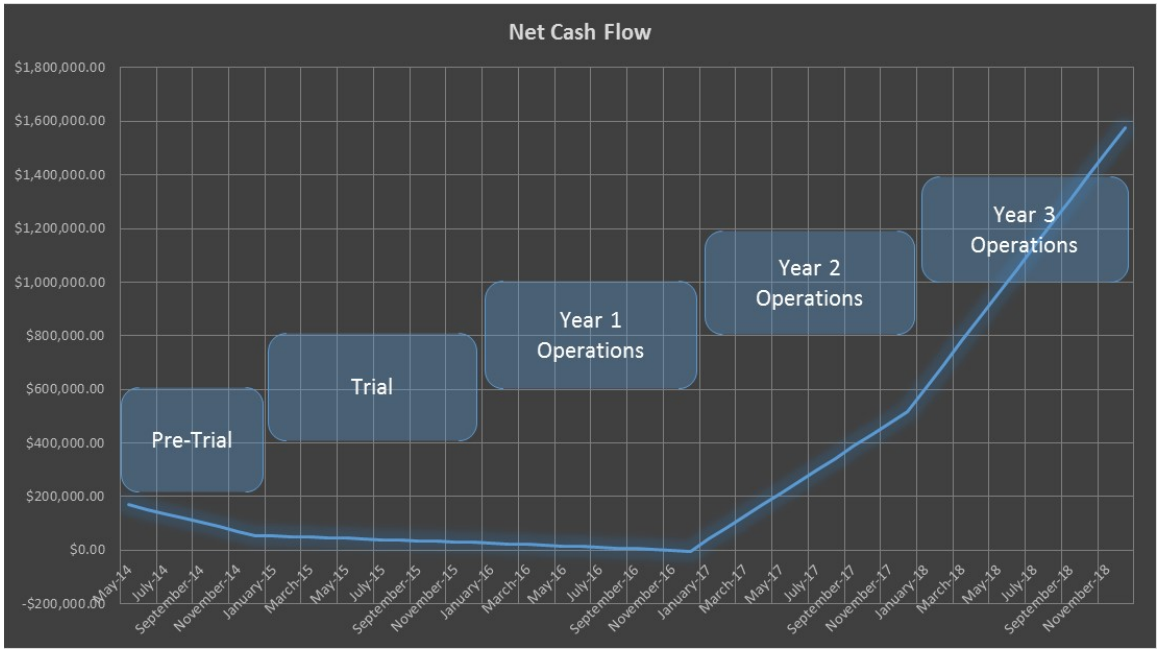
[1] These projections were derived from a series of other models available for review in the appendices. See Customer 2-year Value, Device Cash Flows and Device Cost

Fortunate Case (Payer Reimbursements Authorized for Device MFG Costs)

	Projected Annual Income		
Year Ending Dec.	2016	2017	2018
Revenue	$ 576,000.00	$ 1,728,000.00	$ 2,880,000.00
COGS	$ (250,300.80)	$ (502,934.40)	$ (755,568.00)
Gross Profit	$ 325,699.20	$ 1,225,065.60	$ 2,124,432.00
Gen Admin Expense	$ (325,000.00)	$ (325,000.00)	$ (325,000.00)
Selling Expense	$ (33,600.00)	$ (33,600.00)	$ (33,600.00)
Sales & Admin Expens	$ (358,600.00)	$ (358,600.00)	$ (358,600.00)
EBITA	$ (32,900.80)	$ 866,465.60	$ 1,765,832.00
Payer Reimbursements	**$ 243,000.00**	**$ 486,000.00**	**$ 729,000.00**
Earnings Before Taxes	$ 210,099.20	$ 1,352,465.60	$ 2,494,832.00
Provisions for Income Tax	$ (84,039.68)	$ (540,986.24)	$ (997,932.80)
Earnings After Tax	$ 126,059.52	$ 811,479.36	$ 1,496,899.20

It is extremely likely that Mindful Health would be authorized for pay reimbursements because the pulseMobile fits the specifications of technology that payers will cover (see appendix Payer Reimbursement Authorization for more details).

Net Cash Flow



High-growth Phase

It is December 2018. Mindful Health's pulseMobile has proven effective and profitable in 5 to 10 hospitals. There are a few things that need to be addressed for Mindful Health to be successful in the high-growth phase. At this stage, Mindful Health intends to raise Series A venture funding to address:

1. Its largest cost center, OEM pulse oximeter, representing 65% of overall costs for Year 3 operations (40% in Year 1, 56% in Year 2)
    a. Mindful Health will develop and clear for use its own pulse oximetry technology leading to a more ergonomic product and potential cost savings of up to 50% of overall costs.
2. Lack of professional sales force.

Chance of success

The Team

The highly cross-functional, motivated, and passionate Mindful Health team is at the core of the pulseMobile development, and moreover, its future implementation. Chris Fernandez, Nick Glattard, and Brandon Jonen, who comprise the core hardware development team, are biomedical engineers focused on medical instrumentation and computing. Chris and Nick will both attend graduate school at UW – Madison for biomedical engineering next year. Olivia Rice and Jared Buckner is a biomedical engineer and computer science student respectively, and lead development of the pulseMobile software applications. Olivia will be expanding her CHF expertise next year as she begins medical school. Geoff Cohn is a business student with a CS minor, and leads the teams business and customer development endeavors. This summer, Geoff will gain hands on experience in Venture Capital in Tel Aviv that will be directly applicable to the progress of Mindful Health. Finally, the team is advised by Dr. Fred Robertson, who has extensive experience in business and medicine ranging from serving as CEO of Tomotherapy, GE Marquette Medical Systems, and a Board Member of Massimo and the UW Foundation. While the team could greatly benefit from professionals with industry experience, Mindful Health believes it has one of the most qualified and determined undergraduate student teams at the University.

Barriers to Entry

FDA 510K (Future Threat)

FDA 510k approval is not necessary at this point in time. Mindful Health is using an FDA approved oximetry technology, therefore, does not need to pursue FDA equivalence (510K) for the first commercial version of the pulseMobile.

When Mindful Health enters the high-growth stage, it will need their pulse oximetry technology to be stamped by the FDA as, "Substantially equivalent," to already approved pulse oximetry technology. Bluntly, this is not a matter of, "if," this is a matter of, "how much," and, "how long." Mindful Health estimates the upper bound of the cost to be $200,000 and the duration to be a year and a half.

Reimbursement Approval – Health Technology Assessment (Current Opportunity)

It is likely that Mindful Health's pulseMobile will qualify for reimbursement, and that Mindful Health will be able to push the costs of qualifying onto the hospitals it partners with. By charging care providers, Mindful Health encourages them the seek reimbursements from payers. It is unclear how long qualifying will take or precisely how much data is needed to substantiate coverage. The requirement for reimbursement approval are summarized by the phrase: the technology must be both, "Necessary and effective." See Appendix for more details.

HIPPA Compliance (Current Threat)

At the present time, no data requiring HIPA compliance is transmitted from the device to the cloud platform. Commutated data packets contain a custom device ID, present vital values, and a timestamp, with all data encrypted prior to transmission. Identifiable patient information exists in the cloud database, which will need to be HIPPA compliant prior to the first commercial version of pulseMobile. Fortunately, there are an increasing number of HIPPA-as-a-service compliant backends. Mindful Health is currently exploring opportunities to collaborate with Catalyze.io, a Madison based HIPPA compliant backend provider. If successful, the pulseMobile cloud application will be HIPPA compliant prior to completing the pilot study.

Appendices

Revenue Assumptions

Sales Per Year

The year 1 operating models include the assumption that Mindful Health will a) begin year 1 operations with 3 customers and b) the sales force will be able to acquire 3 new customers each year.

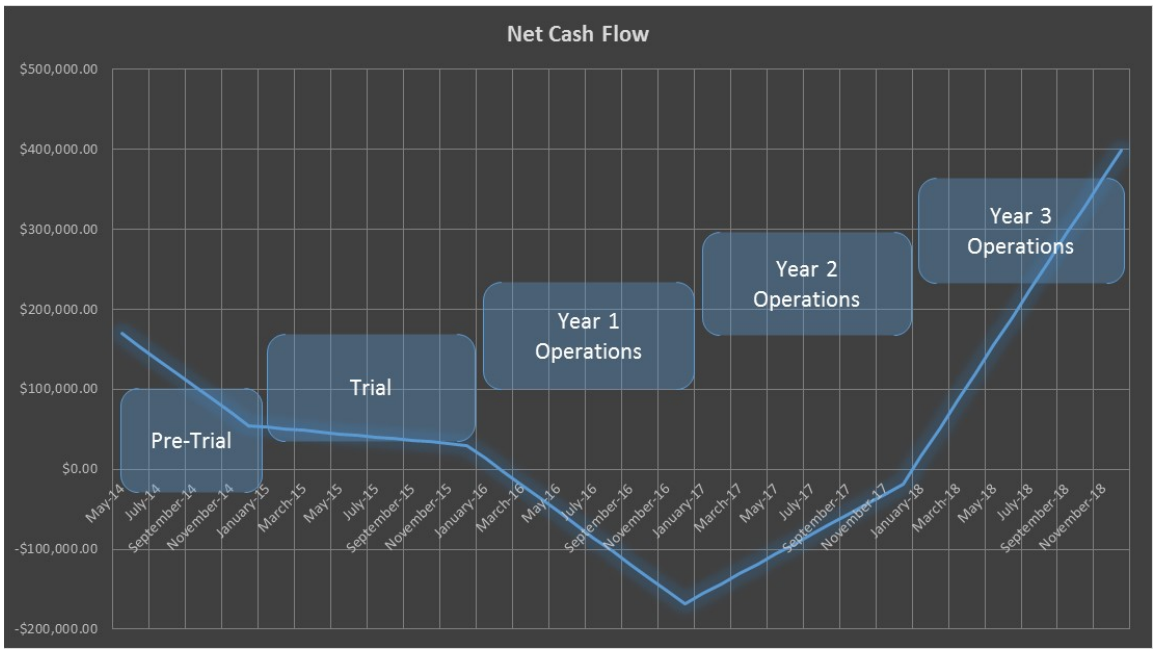
a) Mindful Health's trial will be a 3 clinic trial. If the trial goes as anticipated it will be extremely likely that the 3 trial clinics immediately become Mindful Health's first customers because, by definition of, "going as anticipated," the trial clinics would be economically better off purchasing the pulseMobile.
b) Fred Robertson, former CEO of TomoTherapy, will mentor the sales team in the early years. In years 1 through 3, the sales force will consist of founders Chris Fernandez, Geoff Cohn and Mr. Glattard. It is reasonable to assert that

each founder will be able to make at least 1 sale under the tutelage of Dr. Robertson

Patients Per Hospital

The models assume Mindful Health will be serving 200 patients in the first year of contracting with a health care organization and 400 patients for every year after that. The models also assume a 100% retention rate for health care institutions. The 200 → 400 number is derived as follows:

1. The American Hospital Association asserts there are 4,999 hospitals in the US. [6]
2. The CDC estimates that there were 1 million hospitalizations due to CHF in the year 2000 and 2010 [7], thus 1 million CHF caused hospitalizations per year in the US is a robust estimate for all years.
3. Mindful Health made the simplifying assumption that it will serve "average" hospitals. In this context, on average each hospital has roughly 200 CHF related hospitalizations per year (1 million / 5,000 = 200)
    a. Mindful Health recognizes the dangers of averages and completed a sensitivity analysis presuming Mindful Health partners only with hospitals 50% below average (100) CHF caused hospitalization a year (see chart below).



4. Mindful Health made the simplifying assumption that all new patients for a year are admitted and equipped with a mobilPulse on January 1st of that year. Although this assumption is clearly flawed it, it does not jeopardize the integrity of the model. A more complex model would have the same start and end point (on an income statement, however not a cash flow statement).

Cash flows, though different, would not be materially different because the most significant cost, device MFG, costs would be delayed at the exact same rate as revenue.

5. Patients are assumed to wear the device for 24 months. Some patients will wear this device until their death, others might wear the device for less than a year. 24 months seemed to be a reasonable average.
6. After 24 months the device is assumed to have no salvage value. This is not true and may represent an significant opportunity for cost savings

$80 Per Patient (Device) Per Month

Selling a medical device using a SaaS model is not common place (yet). In light of this, Mindful's Health's used two Value-Based Pricing models and the philosophy, "Find something reasonable," to derive the $80/patient/month price.

Model 1: Life-saving prescription drug

- Mindful Health hypothesized that a life-saving prescription drug could reasonably and ethically command at least $50-$100 per month ($600-$1200 per year)
- As noted earlier, remote monitoring technologies have been shown to improve patient life expectancies by 45%; therefore, the ***pulseMobile*** offers a similar value as a life-saving prescription
- $80/month is within this range and leads to $960 a year

Model 2: % of Yearly Care Costs (to the health care system)

- $80/month represents 11% of average per patient monitoring, which, represents a reasonable percentage of current given that Mindful Health is based on significantly reducing these costs.
    - Currently yearly average costs of care for CHF patients is $8500 [7]
        - 960 / 8500 = 11%
    - Mindful Health will aid hospitals in reducing costs of care by 25% +

Payer Reimbursements

The following is a direct quote of Blue Cross Blue Shields Health Technology Assessment criteria. Meeting this criteria would mean Blue Cross Blue Shield would cover the costs of a medical device. There are over 40 payers in the US with different, but similar, requirements. Ensuring reimbursement eligibility would require approval from all 40 [8]. The Blue Cross Blue Shield materials are available at http://www.bcbs.com/blueresources/tec/ .

The Blue Cross and Blue Shield Association uses the five criteria below to assess whether a technology improves health outcomes such as length of life, quality of life and functional ability.

1. The technology must have final approval from the appropriate governmental regulatory bodies.

- This criterion applies to drugs, biological products, devices and any other product or procedure that must have final approval to market from the U.S. Food and Drug Administration or any other federal governmental body with authority to regulate the technology.
- Any approval that is granted as an interim step in the U.S. Food and Drug Administration's or any other federal governmental body's regulatory process is not sufficient.
- The indications for which the technology is approved need not be the same as those which Blue Cross and Blue Shield Association's Technology Evaluation Center is evaluating.

2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.

- The evidence should consist of well-designed and well-conducted investigations published in peer-reviewed journals. The quality of the body of studies and the consistency of the results are considered in evaluating the evidence.
- The evidence should demonstrate that the technology can measure or alter the physiological changes related to a disease, injury, illness, or condition. In addition, there should be evidence or a convincing argument based on established medical facts that such measurement or alteration affects health outcomes.
- Opinions and evaluations by national medical associations, consensus panels, or other technology evaluation bodies are evaluated according to the scientific quality of the supporting evidence and rationale.

3. The technology must improve the net health outcome.

- The technology's beneficial effects on health outcomes should outweigh any harmful effects on health outcomes.

4. The technology must be as beneficial as any established alternatives.

- The technology should improve the net health outcome as much as, or more than, established alternatives.

5. The improvement must be attainable outside the investigational settings.

- When used under the usual conditions of medical practice, the technology should be reasonably expected to satisfy TEC criteria #3 and #4.

Cost Assumptions

Customer Acquisition Costs

1. Making the sale
    a. Only $2000 are allocated for making each sale. This is because the sales team will be the founding team who is salaried at $50,000 per year. The $2000 are only intended to cover necessary travel and other related expenses.
2. Implementing pulseMobile
    a. Mindful Health assumes implementation will be simple and cheap. Mindful Health might even be able to do it themselves.
        i. pulseMobile uses a web application and does not require integration with any hospital electronic systems. It requires only that the users (patient care teams) have access to the internet.
    b. Just in case, the financial include 1 week of consulting fees that come from national averages.

Device Cost

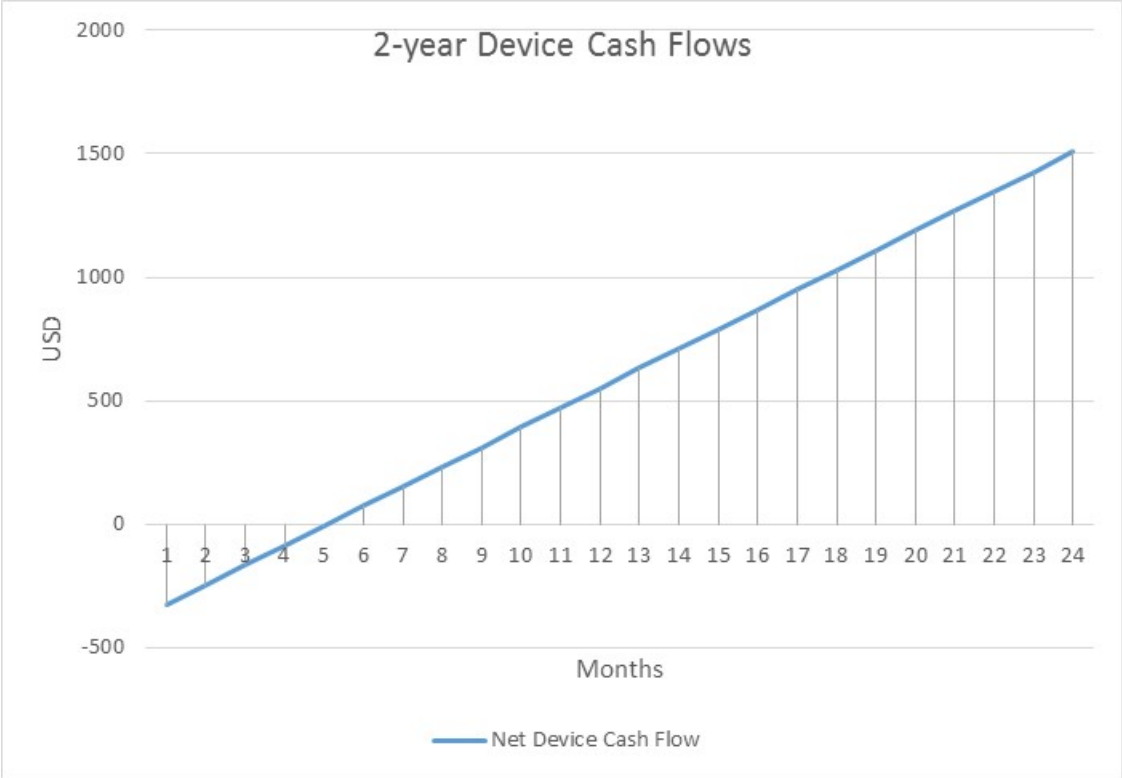
Device Cost	Amount
Procurement Costs	$ 405.00
Operating Costs	7.78
2-year Total	412.78

2-Year Customer Value

year by year hospital cashflows

	Year 1 (200 Patients)	Year 2 (400 Patients)	Year 3 (400 Patients)
Revenue	$ 192,000.00	$ 384,000.00	$ 384,000.00
Expenses			
Aquiisition	$ (11,200.00)	$ -	$ -
Hosting	$ (1,656.00)	$ (1,656.00)	$ (1,656.00)
Device MFG & Dist.	$ (81,000.00)	$ (81,000.00)	$ (81,000.00)
Device Maintenance	$ (777.60)	$ (1,555.20)	$ (1,555.20)
net cashflow	$ 97,366.40	$ 299,788.80	$ 299,788.80
	0	0	0

Device Cash Flows



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