VioSense

A Noninvasive Glucometer

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Executive Summary

Diabetes affects hundreds of millions of people and this number is expected to increase over time. There can be a lot of complications associated with Diabetes and there are many deaths that are linked to the condition. Diabetics need to regularly monitor their blood glucose levels to manage their condition. The most common tool for this is test strip technology, which requires patients to prick their finger each time. This can be burdensome for the patient since they need to take several measurements a day over the course of their lives.

Our device, VioSense can alleviate some of that burden by giving patients accurate and safe results without the prick of a finger. Our device makes use of the photoplethysmography (PPG), the same technology used in pulse oximetry and pairs this with machine learning to predict a measurement of blood glucose concentration. With the use of two LEDs, we are able to obtain a biosignal from patients. From there we have an activity detector that ascertains if the device is picking up a proper signal. Afterwards, the data goes to a signal processing module that can pull relevant features from the shape of the curve, which will be sent to the machine learning module to get a prediction. The signal is obtained from a finger scanning piece, which contains the two LEDs connected to a base that features a LCD interactive display In order for patients to understand their readings, VioSense's BGguru offers results summaries over time and communicates with users about trends in their results.

The VioSense manufacturing process utilizes an electric injection molding machine and an automatic motor assembly machine. ABS plastic resin is injection molded into three steel molds that produce the pieces of our device enclosure. These pieces are combined with sets of electronic components at different stages of the assembly machine, including the PPG unit, circuit board, and screen placement assemblies. These machines are fully automated and can efficiently meet the demands of our production scale up. The final product is a VioSense glucometer equipped with our desired features: a hinged scanner that can comfortably fit the user's finger, a capacitive touch interface overlaying a beautiful LCD screen, and bluetooth/WiFI capabilities for remote updates and data transfer.

VioSense will require 5 years of development and regulation, as well as an investment of $5.7 million. At the start of year 6, we expect our product to be available to the general public and revenues to begin. Each year post startup, our manufacturing is scaled up, resulting in lower production costs and higher revenue. In less than 3 years after startup, we expect our net present value with the time value of money to turn positive and the company to break even. By the end of year 10, VioSense can generate $38 million in revenue if we are able to manufacture and sell 50,000 VioSense devices. As the business is scaled up in subsequent years after startup, we expect our devices readings to become more accurate, production costs to decrease, and self-monitoring blood glucometer market share to increase.

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Introduction

As of 2019, there were 463 million people in the world living with diabetes.[1] Since then, this number has increased and is expected to continue growing, therefore it is a major health concern. Diabetes is a disease characterized by high fasting blood glucose levels. When the glucose levels in the blood remain high, it can lead to many complications, namely kidney, nerve, and eye damage, as well as poor circulation leading to heart attack and stroke. In 2016, Diabetes was linked to 1.6 million deaths.[2] Unmanaged diabetes can be quite dangerous, which is why the most common treatment for diabetes is self-monitoring of blood glucose (SBGM). The goal of SBGM is to maintain a relatively reasonable level of blood glucose in the blood by regularly monitoring blood glucose levels and taking actions to return blood glucose to appropriate levels.

Current devices that aid diabetics in this mission are typically invasive. The current market for SBGM devices is saturated with devices that use test strip technology. These require diabetics to prick their finger to obtain a blood sample for blood sugar testing. We propose a new noninvasive device that allows patients to test their blood sugar and other vital signs. Other noninvasive devices exist/are in development, but our device will utilize an optical technique to obtain blood glucose concentrations among other vital signs, such as blood oxygenation, blood pressure and heart rate. The main selling point of our device is that it allows people to get accurate and reliable results without piercing their skin. The added information that the device provides gives patients the ability to track other elements of their health. This is especially important because some of the comorbidities of diabetes concern heart health.

[1] "Worldwide Toll of Diabetes." 2019, *IDF Diabetes Atlas 9th Edition 2019*, International Diabetes Federation

[2] "Diabetes." *World Health Organization*, World Health Organization, 8 June 2020

Background

Market Information

The existing market for monitoring blood glucose levels is worth multiple billions of dollars. Specifically, the current market estimates put the value at 13.7 billion US dollars.[3] This is split into two main groups, professional and personal. Our device VioSense falls into the second market, which makes up the vast majority at 87%, or roughly $11.9 billion US dollars.[3] In addition, there is a subsection to the self-blood glucose monitoring market (SBGM), known as the noninvasive market. Valued at 140 million dollars, the noninvasive market is much smaller due to the currently limited available options for purchase.[4] VioSense seeks to both thrive in the existing noninvasive market and to expand into the invasive market, which are both expanding with an estimated 5.9% compound annual growth rate (CAGR) and a 10.0% CAGR respectively.[3,4]

The people who are the target for VioSense are those with diabetes. Current estimates for the United States Department of Health and Human Services believe that 9.3% of all adults age 20 – 79 have diabetes, and 88 million American adults have a condition known as pre-diabetes that may develop into diabetes in the future. These same estimates also show that age is a major factor in the development of diabetes, with only 4.2% of adults 18 - 44 years of age having diabetes, while 26.8% of adults older than 65 years suffering from the same ailment.[5]

Existing and developing technology that our device would compete with fall into a few categories, test strip based, continuous, or noninvasive. These first two make up the majority of all invasive glucose measuring devices, as they directly measure the blood of the user. Test strips systems use a small amount of blood applied to a single use strip which is analyzed by the main system to determine the blood glucose concentrations. Continuous blood glucose monitors have a similar process by always giving the device direct access allowing for constant, consistent reading in exchange for discomfort. The final group, noninvasive, is our direct competition. These devices are in the development and testing phases currently, but analysis based on

[3] "Global $13.7 Bn Blood Glucose Monitoring Market Study, 2020-2025." *GlobeNewswire News Room*, "GlobeNewswire", 19 Mar. 2020

[4] "Healthcare." *Absolute Reports® - Global Non Invasive Glucose Meter Market,* Absolute Reports, 1 Feb. 2019

[5] "National Diabetes Statistics Report, 2020." *Centers for Disease Control and Prevention*, CDC, 28 Aug. 2020

currently released information from a set of chosen devices, DiaMonTech, GlucoWatch GlucoTrack, and GlucoWise, shows that the devices each have some combination of rapid measuring, portability, and competitive pricing, but not all three.[6,7,8,9] VioSense stands apart by providing a midpoint between the other devices, being small enough to be easily portable, affordable enough for the common person, and fast enough to avoid being a detriment to daily life.[10]

Technical Background

VioSense leverages the technology that is used by pulse oximetry. This technology, photoplethysmography, uses spectroscopy to measure the absorbance of blood at different wavelengths. In pulse oximetry, the absorbance is used to find blood oxygenation from empirical calculations. With respect to glucose readings, the same approach cannot be taken because of complications that arise with respect to the measurement of glucose in Diabetic patients. For this reason, we utilize machine learning to obtain features from the absorbance of the blood among other factors to predict a blood glucose reading.

Spectroscopy is well-known technology and widely used for biosensors. Photoplethysmography is an optical technique that relies on spectroscopy to obtain a waveform which can be used to determine bioinformation. Spectroscopy has to do with the interaction of matter and light. When matter absorbs light, there is an energy change, which depends on the amount of energy that both the light/photon and matter carry. Absorbance is the amount of energy that the photon loses to the molecule when it passes through it.[11] The Beer-Lambert law is used to determine the absorbance which is the ratio of the intensity of the light that is shone on the sample and the measurement of the light intensity after that absorption. It is a function of the wavelength of light that is shone on the sample, the concentration of the molecule that absorbs it and a constant, the molar absorption coefficient which is based on the probability of a molecule to be excited by the light.

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6 Mendosa, David. "The GlucoWatch Biographer." *Mendosa*, 31 Oct. 2007

7 *GlucoTrack*

8 "Nicht-Invasive Blutzuckermessung." *DiaMonTech*

9 "GlucoWise™." *GlucoWise™ : Meet the New Non-Invasive Glucose Monitor That Helps You Take Control of Your Life*

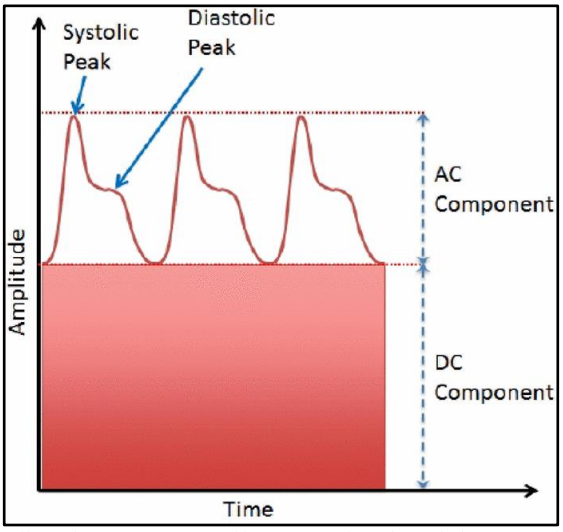
10 Hughes, Mark D. "The Business of Self-Monitoring of Blood Glucose: a Market Profile." *Journal of Diabetes Science and Technology*, Diabetes Technology Society, 1 Sept. 2009

11 Libretexts. "10.1: Overview of Spectroscopy." *Chemistry LibreTexts*, Libretexts, 11 Aug. 2020

$$A = \log_{10}\left(\frac{I_o}{I}\right) = \epsilon l c$$

Equation 1: Beer-Lambert's Law

Photoplethysmography utilizes a light source and a light detector to determine the absorbance of light through the finger over a period of time. There are two main features to the absorbance that is measured, the AC and DC waveform. The AC waveform, named after alternating current, is based on the light that is absorbed by the blood, which is pulsatile due to the change in blood volume from the heartbeat. The DC waveform is essentially the background reading and gives an indication of the light that is absorbed by the tissue and for the most part remains a constant value. It is often measured as the trough of the wave from the AC wave as seen in Fig.1 below.[12] The photoplethysmograph is used in clinical settings to observe the wave and its effects on oxygen saturation. As seen in the diagram below the curve that is represented by the absorbance can give an indication of the heart's rhythm. From this wave we can measure the blood pressure and the heart rate.[13]



Saquib et al. "Measurement of heart rate using photoplethysmography"

Figure 1: A schematic of a PPG curve, annotated to show the components of the wave

[12] Alian, Aymen A., and Kirk H. Shelley. "Photoplethysmography." *Best Practice & Research Clinical Anaesthesiology*, Baillière Tindall, 9 Sept. 2014

[13] Saquib, et al. Measurement of heart rate using photoplethysmography. *2015 International Conference on Networking Systems and Security (NSysS)*, Dhaka, 2015, pp. 1-6.

Product Concept

VioSense is a noninvasive glucometer. It uses photoplethysmography as a sensing technique and machine learning to get a measurement. Consumers will be able to insert their finger into an opening of the device. The device will take approximately one minute to obtain the reading and to predict a value for the blood glucose concentration. The device can also offer results for heart rate, blood pressure and oxygen saturation.

User Interface

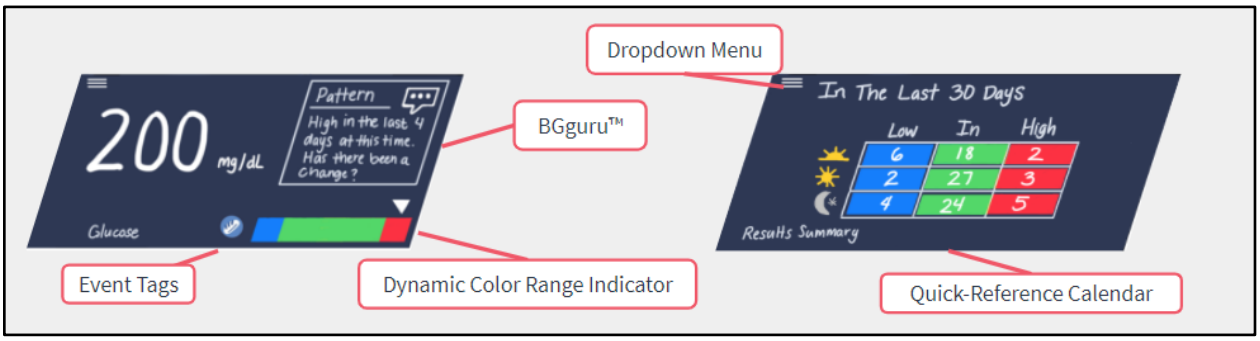


Figure 2: An overview of the key features VioSense offers to the user.

The VioSense user interface employs several features that have been shown to be effective in patient self-management of diabetes. This is based on an international survey of healthcare professionals.[14] The dynamic color range indicator, or DCRI, makes it quick and easy to understand a user's glucose reading simply based on the color their reading falls into. Green for in range, blue for low, and red for high. This same color scheme is also used in the quick-reference calendar where the user can get a feel for results trends at different points in the day or after certain events.

Perhaps the most significant feature is the blood glucose guru (BGguru) which provides personalized support for the user. It detects trends in results based on the time of day or event tag and then informs the user. It also provides tips for getting back within the user's target range and then messages of encouragement when the user is in range and meets their goals. The user can find additional analytics and statistics upon a Bluetooth or USB connection to a device, whether that be a smartphone, tablet, or computer. Users can take advantage of event tag readings for

[14]Greenwood D., Grady, M.. Healthcare Professional Perceptions of Blood Glucose Meter Features That Support Achievement of Self-Management Goals Recommended by Clinical Practice Guidelines. *Journal of Diabetes Science and Technology*. 10 August 2020.

things like: before meal, after meal, high carbs meal, exercise, stress, illness, medication and also set goals for number of readings per day and target range. For the other vitals that VioSense measures, the user can easily and quickly navigate from the main blood glucose reading screen to either the blood pressure or oxygen saturation/HR screens.

Product Design

Product Mechanism

In the preliminary design of our glucometer, we had to consider our desired electronic functions and the necessary mechanisms and components to achieve them. We created a system block diagram to encapsulate these functions. The back-end mechanism contains the modules required to take and process our photoplethysmography (PPG) measurements into blood glucose readings and other vital signs. This includes the LEDs, photodiode and sensor module that make up the PPG system. The rest of the mechanism is composed of our information processing modules, to be designed and programmed onto a printed circuit board. A microcontroller interfaces the measurements taken by the back-end with the remainder of the device. The information modules can be accessed and programmed through a microUSB port wired to the controller. The battery charger for the proposed lithium-ion battery is also wired through this port. In determining our product concept, we wanted to ensure our device had a simple-to-access, comprehensive touch screen as well as Bluetooth and Wi-Fi capabilities for remote updates and data transfer. The corresponding blocks were incorporated into the system block diagram to reflect these functions.

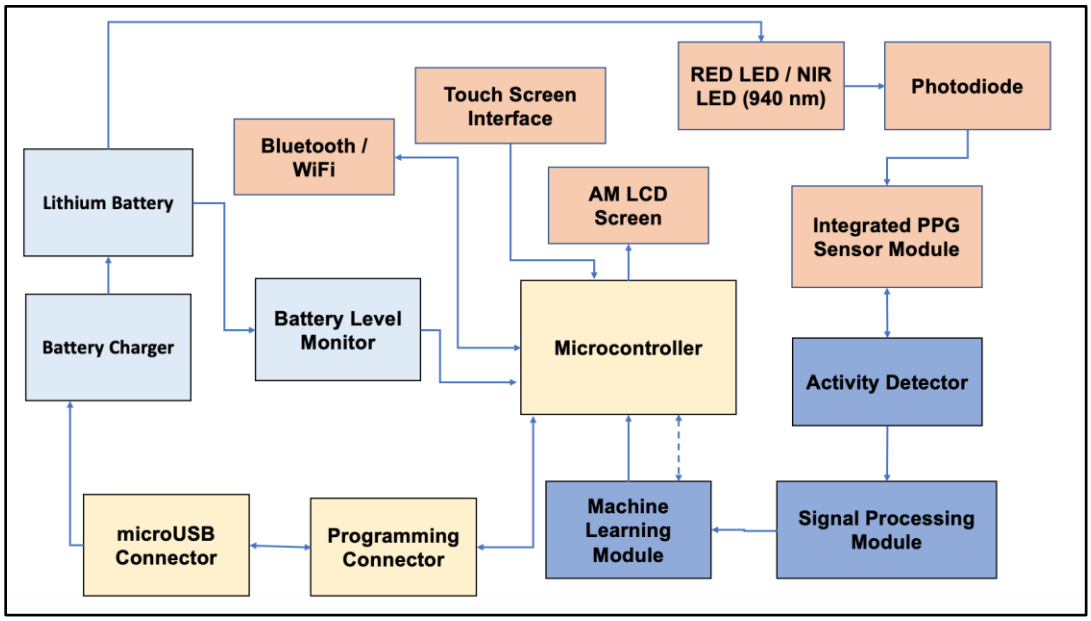


Figure 3: System Block Diagram for VioSense Glucometer. This diagram outlines the electronic functions of the device and how the functional components interconnect. Arrows represent system-level connectivity. The goal of the diagram was to layout the functions of the device before selecting production components.

The system block diagram served as a preliminary guide in transitioning the idea of taking blood glucose measurements with pulse oximetry readings from a concept to production. The decisions made at the functional level would help us determine the production components necessary to achieve the user interface and device functionality we are targeting. Prior to modeling the physical components, we needed to develop and model the back-end measurement mechanism that will perform our primary function.

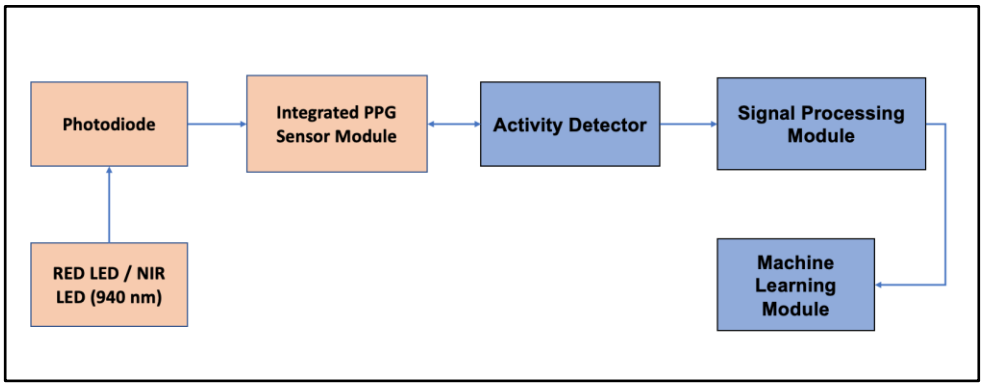


Figure 4: Information flow diagram for VioSense back-end mechanism. The LED, photodiode, and sensor module work together to generate a PPG signal from passing light through the user's fingertip. The activity detector filters the signal for the signal processing module to be able to extract features (signal properties) that the machine learning module then interprets to determine BGL, BP, SpO2, HR.

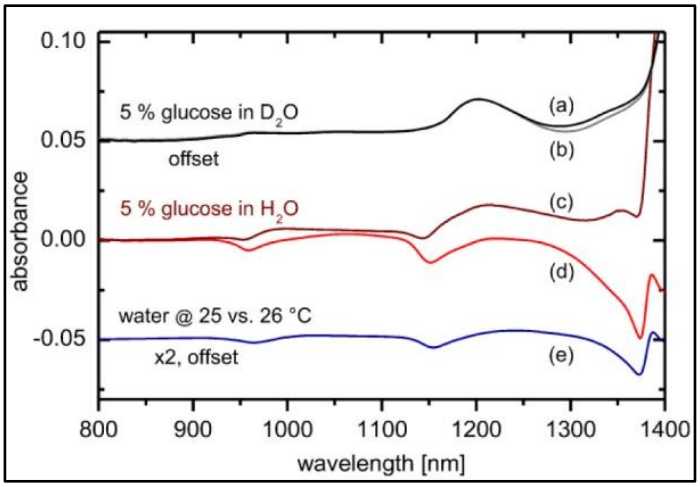
Photoplethysmography (PPG) - Signal Generation

VioSense uses the PPG signal to measure blood oxygenation and glucose concentration. In order to do this, we use two different LEDs. From Fig. 5 we can see that an optimal wavelength for glucose measurements lies in the 930-980 nm range. For this reason we have chosen to use a near-infrared (NIR) LED that has a wavelength of 940 nm which lies within this optimal range. We also use an LED at 660 nm which in combination with the NIR LED allows us to measure for blood oxygenation or SpO2. This is the same methodology used for pulse oximetry. The molecule of interest here is hemoglobin, which carries oxygen. The red light at 660 nm is used to determine the absorbance of deoxygenated hemoglobin and the NIR light can also be used as a proxy for the oxygenated hemoglobin, so the NIR LED is doing double duty. The ratio of these absorbances is determined by the following equation, where the absorbance is measured as the amplitude of the PPG wave:

$$R = (A_{\text{red,AC}}/A_{\text{red,DC}})/(A_{\text{IR,AC}}/A_{\text{IR,DC}}),$$

Equation 2: Modulation Ratio, ratio of the absorbances used in SpO_2 calculations.

Traditionally, this value of R is then used to determine the SpO_2 by using a calibration curve determined from empirical calculations.[15] Either/both of the wavelengths can be used to give us a measurement for heart rate and blood pressure.



Vahlsing, Thorsten, et al. "Noninvasive Monitoring of Blood Glucose…"

Figure 5: This figure shows the absorbance of water and water with glucose at varying wavelengths.

[15] Chan, Chan, Chan. Pulse oximetry: Understanding its basic principles facilitates appreciation of its limitations. *Respiratory Medicine.* Vol. 107, No. 6. Pp. 789-799. June 2013.

These calibration curves are determined by using data from a "normal", healthy population of people. For individuals that deviate from the norm, the calculated SpO2 can sometimes be inaccurate. This can happen particularly in people who have issues with blood perfusion, which can be common among diabetics. Other aspects of the signal generation can contribute to inaccurate calculations. The PPG curve of each individual should theoretically be different. There are a lot of factors that affect the reading that we get from absorbance. Those factors are ambient light, hemodynamics, finger thickness, amount of melanocytes, fat, muscle, hemodynamics of the person and more.[15] These factors can be accounted for by using a machine learning algorithm. The algorithm can use known information about the blood glucose measurement to determine a prediction that is accurate based on features of the PPG wave. This methodology allows us to obtain accurate measurements for a wider set of individuals.

Activity Detection Module (ADM) - Signal Filtration

Both during and following signal generation by the PPG unit, an activity detection module (ADM) verifies and cleans the signal. The goal of the AD module is to ensure that what is output to the signal processing module (SPM) is clean and accurate data by removing corruptions and artifacts. It first confirms that the input it is receiving is a PPG signal and discards what it determines to be corrupt signals. Then, it amplifies and fits that signal to different windows and timeframes, capturing different subsections of multiple pulses (heartbeats), to find the highest quality window from the total sample. To stabilize the signal and remove noise, the ADM uses a moving average filter and a Savitzky-Golay filter. The moving average filter corrects for a wandering or variable baseline and the Savitzky-Golay filter uses a digitally smoothening polynomial fit to remove noise and artifacts.[16] Artifacts are errors or variations in the signal measurement due to user error like movement during a reading or environmental interferences like the presence of high frequencies. These filtering techniques are extremely simple and can be simply modeled in Matlab as shown in the appendix. The combination of these filters makes the device reading derivations more robust, meaning that the device can withstand imperfect measurement conditions that might otherwise corrupt a signal.

[16] Habbu, S., Dale, M. & Ghongade, R. Estimation of blood glucose by non-invasive method using photoplethysmography. *Sādhanā* 44, 135 (2019).

There are still limits to this robustness, so VioSense is not really a glucometer for extreme conditions, but rather, precise and accurate in the user's everyday life.

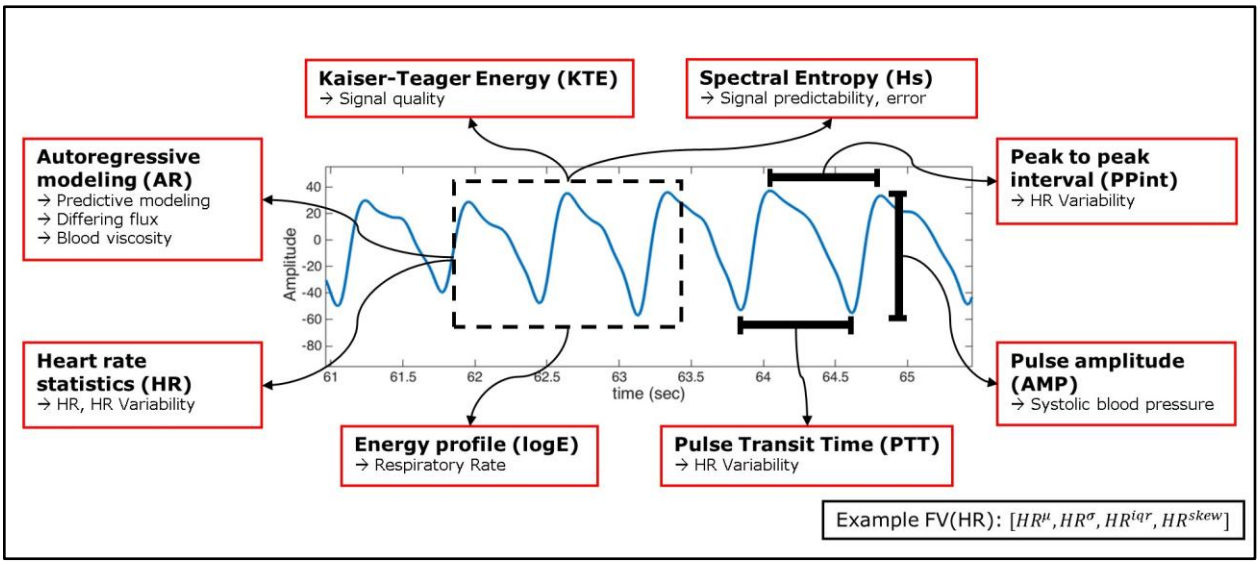


Figure 6: The signal processing module extracts relevant features based on the PPG curve. Features can either be statistics that describe certain properties like pulse amplitude or frequency or they can be coefficients for a polynomial fit.

Signal Processing Module (SPM) - Feature Extraction

The signal processing module derives various relevant features or statistics based on the shape of the PPG curve input from the ADM. The goal of these features is to accurately model how the individual user's personal hemodynamic conditions affect the signal, allowing the machine learning module (MLM) to correct for these conditions and give an accurate reading. A given feature output looks either like the example feature vector shown in Fig. 6 with mean, variance, interquartile range, and skewness for various curve properties like amplitude, peak to peak interval, or pulse. Alternatively, some feature vectors are coefficients for a polynomial fit. This is for the autoregressive modeling and Kaiser-Teager Energy profile. Features can be extracted on a 'global' scale using the entire sample or on a 'local' scale using a frame extracted from the sample. These two scales are referenced as $S_{window}(t)$ and $S_{frame}(\tau, n)$, respectively, where τ is the length of a frame and n is the number of samples within that selected frame. We will briefly discuss the features shown in Fig. 6 and their physiological and photoplethysmographical significance:

Assuming the general shape of a signal pulse, the autoregressive (AR) model allows for predictive modeling of the signal as well as the personalized pulse and blood viscosity of the

user. Blood passes through vessels of varying thickness and diameter and how that affects the overall flux of blood varies person-to-person. AR modelling helps determine this property, known as vessel compliance, as well as blood viscosity to have a better sense for the user's personal blood flux properties and how they, in turn, alter the PPG pulse.[16,17]

Heart rate (HR) variability is one of the most important physiological features to take into account and several extraction methods work in tandem to derive the statistics for it. Each heart rate is determined by when the PPG curve passes through amplitude = 0, which has been shown to be a more reliable technique than using the bases or peaks of the pulses. The time between these *zero crossings* is used to derive HR statistics (mean value, variance, interquartile range, skewness). The SPM also uses pulse transit time (PTT) and peak to peak interval (PPint), the time between each onset and peak of the pulses, respectively, as additional considerations in determining HR variability.[16,17]

Respiratory rate is another important factor that we are accounting for. The SPM approximates the user's respiratory rate by taking the log-energy profile of the signal. Log-energy is easy and fast to calculate at the expense of precision. Expanding the size of the window in which the device takes determines the log-energy profile of the signal can result in more precise estimation of respiratory rate, but this might not be necessary depending on how significantly the precision of this estimate affects overall device accuracy.[16]

$$LogE_n = Log\left(\sum_{\tau=1}^{L_{frame}} S^2_{frame}(\tau, n)\right)$$

Equation 3: Log-Energy profile derivation for a given PPG signal frame.

Pulse amplitude, also known as systolic amplitude, is a useful measure in estimating blood pressure, looking at how changes in blood flow affect the properties of the PPG curve.[16]

The Kaiser-Teager energy (KTE) profile is used to verify signal quality, detecting noise and artifacts similar to the ADM. KTE is computed at both the global and local level using the same equation shown below. A high KTE value indicates a cleaner signal for a given frame or sample.[16,17]

[17] Monte-Moreno. Non-invasive estimate of blood glucose and blood pressure from a photoplethysmograph by means of machine learning techniques. Artificial Intelligence in Medicine. 2011 (53): pp. 127-138.

$$KTE(t) = S(t)^2 - S(t+1) * \quad S(t-1)$$

Equation 4: Kaiser-Teager energy (KTE) profile derivation. The PPG signal can either be global or local.

The spectral entropy sequence (Hs) is also used to determine the signal quality of a given sample at the local level with a lower value corresponding to a cleaner frame. The calculations for determining are more involved than some of the other features. First, we take the fast Fourier transform (FFT) of a signal frame. The FFT will yield several frequency bins. For each bin, we square the absolute value and normalize. Finally, we perform operations on $P_X^n$to get H_n^S.[17]

$$X^n = FFT(S_{frame}(\tau, n), L_{FFT})$$

$$P_X^n[k] = \frac{|X^n[k]|^2}{\sum_{j=1}^{L_{FFT}} |X^n[j]|^2}, k = 1,2,\ldots, L_{FFT}$$

$$H_n^S = \sum_{k=1}^{L_{FFT}} P_X^n[k] Log(P_X^n[k])$$

Equations 5,6,7: Derivations for determining the spectral entropy sequence for a given PPG signal frame.

Machine Learning Module (MLM) - Reading Derivation

The machine learning module uses a random forest (RF) algorithm to determine the biometrics of interest. Essentially, the RF algorithm will learn how to fit the information from the feature vectors generated by the SPM to BGL, SBP, DBP, SpO2, and HR levels. Random forests have been found to be the most effective regression tool for this application, showing an improved correlation to measured blood glucose compared to linear regression, neural networks, and support vector machines.[17] A random forest is a set of independently trained decision trees where the training of each tree involves artificial or implemented randomness that provides improved control on the overall bias and variance of the algorithm. The final output of the forest is an aggregate of the output of all of the trees. By taking the average of independently trained sets, the method reduces the inherent bias and variance in each tree, which means the final estimate will have a lower error rate than otherwise. The training of this module involves an n=500 study, taking 3-minute PPG signals that we then extract 1-minute windows from and

bootstrap to inflate the sample size. We split this sample of windows into different training sets and then also a test set.[17] We will tune the random forest parameters by optimizing correlation during our training trial.

Physical Product Design

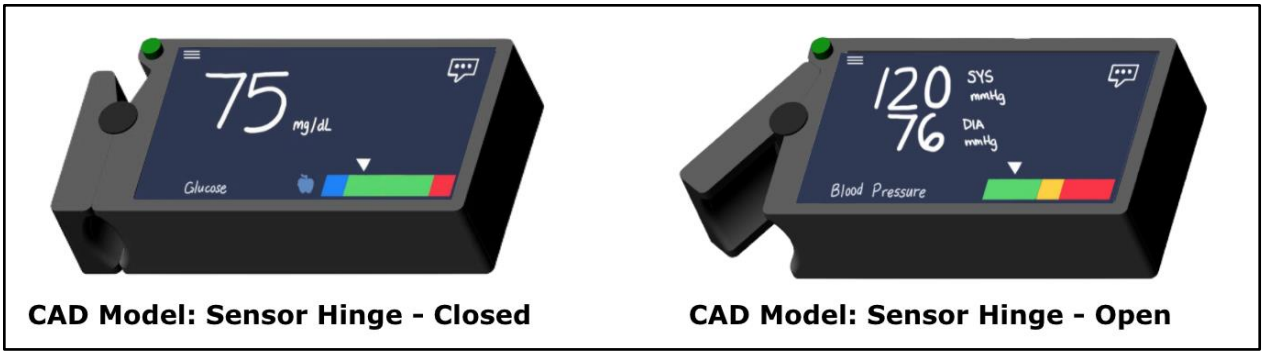


Figure 7: 3D Model of VioSense Device created in AutoCAD. The overall dimensions of the model are 5.5''x2.7''x1.25''. Separately designed images displaying the user interface have been superimposed onto the model. A model with the PPG sensor in both the closed and open configurations is shown.

Using measurements taken on a physical pulse oximetry device, and keeping other discussed design goals in mind, we developed a 3D model of a VioSense device in AutoCAD 2019. The device is 5.5'' long and 2.7'' tall, small enough to fit in a pocket and producing space for a 4.81'' across screen. We considered navigational buttons to control the interface, but with the spatial requirements of the sensor hinge, we opted to make the interface a touch screen (see Manufacturing Process). Instead, the device features a green power button in the top left corner of the front face. The thickness of the device is 1.25''; this leaves a rounded opening .975'' across for the user's finger, consistent with the sampled pulse oximeter and larger than the average width of a human finger. The main corners were rounded with a 0.1'' radius to smooth the physical appearance of the device. The hinge has a radius of .25'' and the angle opening of the hinge is 36.8°. Excess material was removed from that area of the model to allow for the 36.8° opening. Fully detailed 2D engineering drawings can be found in Fig.10. Completion of the model was essential to visualizing our product and determining manufacturing requirements of the glucometer.

Intellectual Property and Literature

There are two pieces of literature that the concept of VioSense is based on. They both use photoplethysmography and machine learning to derive blood glucose levels in a similar manner to VioSense. The first paper, written by Enric Monte-Moreno in 2010, is the source for much of the technical foundation of VioSense as we are able to skip some of the research Monte-Moreno conducted for things like the specific machine learning technique we will use and what features we are looking for in the PPG data. The key difference between VioSense and Monte-Moreno's device is the PPG unit. VioSense uses an independent dual-frequency LED pulse oximeter while Monte-Moreno used an iPod digital oximeter.[17] This results in a higher fidelity PPG signal for VioSense that includes additional information that can be interpreted by the machine learning module to derive additional biometrics like blood oxygen saturation. More information on VioSense's PPG unit can be found in the *Product Design* Section.

A more recent paper based on Monte-Moreno's work was published in 2019 by Habbu, Dale, and Ghongade.[16] It covers much of the same material but includes additional features to extract in the SPM. Our ADM model is also based on the filtering techniques outlined in this paper. Once again, the main difference lies in signal generation. While this group used a more advanced PPG module than Monte-Moreno, they still only measured the PPG signal at one wavelength. It is worth noting that Habbu, Dale, and Ghongade were able to achieve FDA compliance in reading accuracy. The signal processing techniques employed by VioSense are a mosaic of the most effective methods discussed in these two papers so it will likely be even more accurate. Beyond the back-end mechanism of the device, VioSense owes very little to these papers. Our device design, interface, and manufacturing plans were independently devised.

Regarding patented technology in the United States, there are a handful of patents pertaining to using some form of spectroscopy to determine biometrics. In our research, we erred on the side of caution, making note of any patent that was remotely similar to our device. In reality, there is likely very little overlap with any of these patents, but that is difficult to determine without experience in patent law. Many of these patents we found to be related to VioSense simply present the possibility of non-invasively measuring blood glucose, but have minimal concrete evidence or plans for how to do so.

These patents include:

- ➢ *Determining standard uptake value (SUV) in emission tomography imaging using SUV-related data and event data*[18]
    - Wearable device, presents the potential to determine SpO2, blood glucose
- ➢ *Motion-activated display of message on an activity monitoring device*[19]
    - Physiological parameter monitoring (blood glucose)
- ➢ *Personal health data collection*[20]
    - Personal hand-held monitor that measures blood flow to determine blood pressure
- ➢ *Multiple wavelength sensor emitters*[21]
    - Used LEDs to "noninvasively measured physiological parameters." Presents the potential to measure blood glucose
- ➢ *Wearable monitor with arrhythmia burden evaluation*[22]
    - A wearable device that estimates physiological conditions from a PPG/ECG signal. The patent presents minimal information beyond the look of the device and what it *could* possibly do. It also does not mention blood glucose or pressure.
- ➢ *Biomedical parameter probabilistic estimation method and apparatus*[23]
    - Systems and methods for measurement of heart rate and other heart-related characteristics from PPG signals using collision computing.

[18] Yuen, et al. Portable monitoring devices and methods of operating same. United States Patent US 10,856,744. United States Patent and Trademark Office. 8 Dec. 2020.

[19] LeBoeuf, et al. Wearable audio device. United States Patent US 10,842,389. United States Patent and Trademark Office. 24 Nov. 2020.

[20] Kwon, et al. Apparatus for detecting bio-information. United States Patent US 10,349,847. United States Patent and Trademark Office. 16 July 2019.

[21] Samec, et al. Augmented reality display system for evaluation and modification of neurological conditions, including visual processing and perception conditions. United States Patent US 10,332,315. United States Patent and Trademark Office. 25 June 2019.

[22] Poeze, et al. Multi-stream data collection system for noninvasive measurement of blood constituents. United States Patent US 10,299,708. United States Patent and Trademark Office. 28 May 2019.

[23] Park, et al. Wireless portable activity-monitoring device syncing. United States Patent US 9,655,053. United States Patent and Trademark Office. 16 May 2017.

Manufacturing Process

In determining our required manufacturing process and its associated costs, we considered VioSense's electronic component makeup and the design of its enclosure. VioSense will follow a manufacturing process similar to many other electronic devices. We have sourced competitive retailers for all our acquired components and raw materials. The enclosure was designed as three separate molds, which are injection molded using ABS plastic on our production floor. The smallest mold is sent to be incorporated with LEDS and a sensor for the PPG unit. The remaining two ABS molds make up the device housing; these are combined with the Printed Circuit Board, printed in bulk off site, and our PPG unit in an Automatic Motor Assembly Machine, programmed to complete the construction of the device. After the capacitive touch screen and LCD display have been arranged within the housing, the molds are sealed together and our VioSense glucometer is complete. A simplified visualization of this process can be found below.

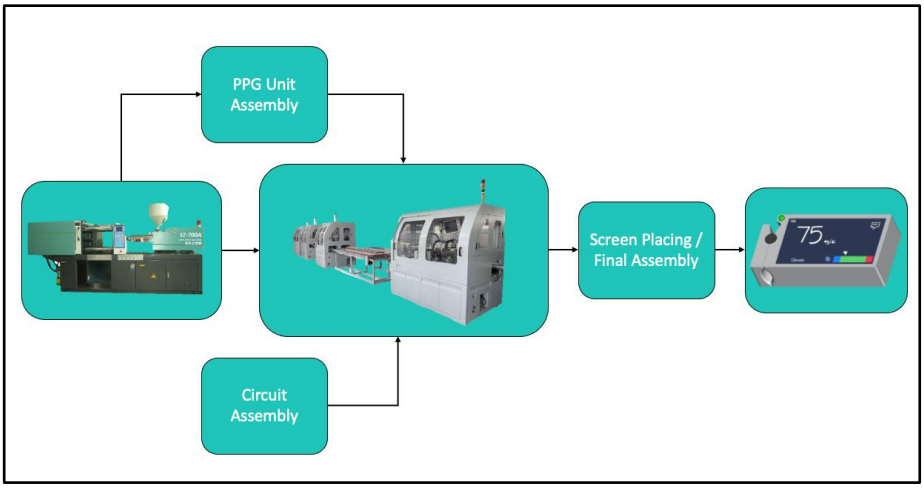


Figure 8: Manufacturing Block Diagram for the VioSense glucometer. This diagram has been simplified to the physical processes that will occur onsite and does not represent any of the materials/components required.

Acquisition of Electronic Components and Raw Materials

To construct the list of electronic components required to achieve our desired device functions, we assessed our system block diagram and compiled the components necessary to perform each function. Details from the 3D model and selected product attributes served as guides to balance cost and quality in selecting product components and their sources.

The PPG Unit entails a Red LED, an NIR LED at 940nm, a photodiode, and an integrated PPG sensor module for capturing the raw data. The NIR LED was specified to 940 nm because of the wavelength's higher absorbance selectivity to glucose.[15] These components are quite inexpensive, with the exception of the integrated PPG sensor module, costing $5.66 per unit at its lowest wholesale price.[24] The three information processing modules (ADM, SPM, MLM) will be programmed onto a printed circuit board, specifically designed during Phase I of development to account for the modules, controller, and remainder of electronic components. We selected Pcbcart as our circuit board manufacturer due to competitive pricing and options corresponding to different stages of device development.[25] In selecting a battery, we followed the standards set by cell phones and other small electronic devices. We selected a small lithium-ion battery with an 1150 mAh capacity and 3.7 V voltage and an inexpensive battery level monitor to work in tandem with it.[26] Bluetooth and Wi-Fi capabilities are met with corresponding receivers to be integrated into the circuitry. A microUSB port, the proper wiring, and a microcontroller that can interface between all the components make up the parts left to complete the circuit assembly diagrammed above. The microUSB connector and microcontroller were both competitively sourced and selected. Exact costs for circuit wiring could not be determined without the PCB and circuit design to be completed during Phase I development.

After selecting electronic components for VioSense's internal design, the external structure, including the screen and device housing, was considered. As mentioned in the *Physical Product Design* section, the available space on the front of the device after adding the hinge called for a touch screen over navigational buttons. Aligning with other small electronic devices, VioSense has a thin film transistor liquid crystal display (TFT LCD). The thin film transistor improves upon the active-matrix LCD design to produce higher quality images; the structure of a TFT LCD can be seen in Fig. 9. These advanced screens are used in televisions, computer monitors, and cell phones so we felt it would be the best option to display our user interface.[27] To enable the touch screen capabilities of the display, a capacitive overlay would need to be included on the screen. Capacitive touch screens respond to the current in the finger, while

[24] Integrated PPG & ECG Bio-Sensor Module. *Newark*.
[25] Standard PCB Manufacturing Cost Calculator. *Pcbcart*.
[26] Replacement Battery for Samsung SGH-A987. *BatteriesFactoryOutletStore.com*.
[27] LCD Basics. *Japan Display Inc*. 2020.

resistive touch screens respond to pressure.[28] We decided a capacitive touch screen would allow us to maximize our user experience. A retailer was sourced for a TFT LCD screen at 4.81'' across, with a capacitive overlay already included. At bulk pricing, this screen will cost us about $7 per device.

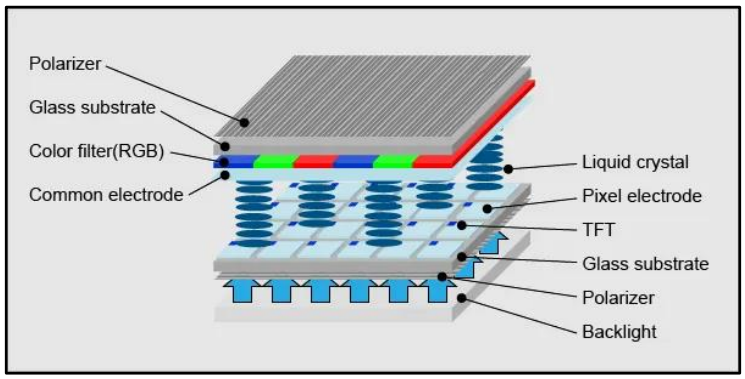


Figure 9: Diagram explaining the structure of a Thin Film Transistor Liquid Crystal Display. The transistors are produced from a thin film of amorphous silicon deposited onto the glass substrate. *LCD Basics - Japan Display Inc.*[27]

The final consideration in the Bill of Materials was the raw material selection for the device housing. We desired a plastic that could be injection molded into a durable, sleek, and protective enclosure for VioSense's internals. Upon analyzing materials used for protecting similar sensitive electronics, including desktop electronics and medical devices, Acrylonitrile-Butadiene Styrene (ABS) was selected as our raw material. ABS enclosures offer durable performance at an affordable price and are highly impact resistant. We found a retailer for general purpose ABS resin sold in batches of 1000 lbs. ABS plastic with IZOD Impact ratings 3-5 are available, the price increasing with higher impact ratings.[29] Balancing cost and impact protection, we selected black IZOD 4 ABS as the raw material to be injection molded into the VioSense housing. A complete table of device pricing at different wholesale quantities is available in Appendix 3A.

Enclosure Design

While a majority of components on VioSense's Bill of Materials are sold by units, the ABS plastic resin is sold in pounds. To determine the cost of raw material per device, we had to quantify the amount of plastic resin required for injection molding for one device with a

[28] Understanding Your Options: Capacitive vs. Resistive Touchscreens. *TouchDynamic*. 29 Oct. 2015.
[29] ABS|Black ABS GP Resin|4 IZOD - Gen Purpose - 1000 LB. *ProfessionalPlastic.com*.

thickness of 0.08”. A series of geometric volume calculations were completed based on the drawings in Fig. 10, shown below.

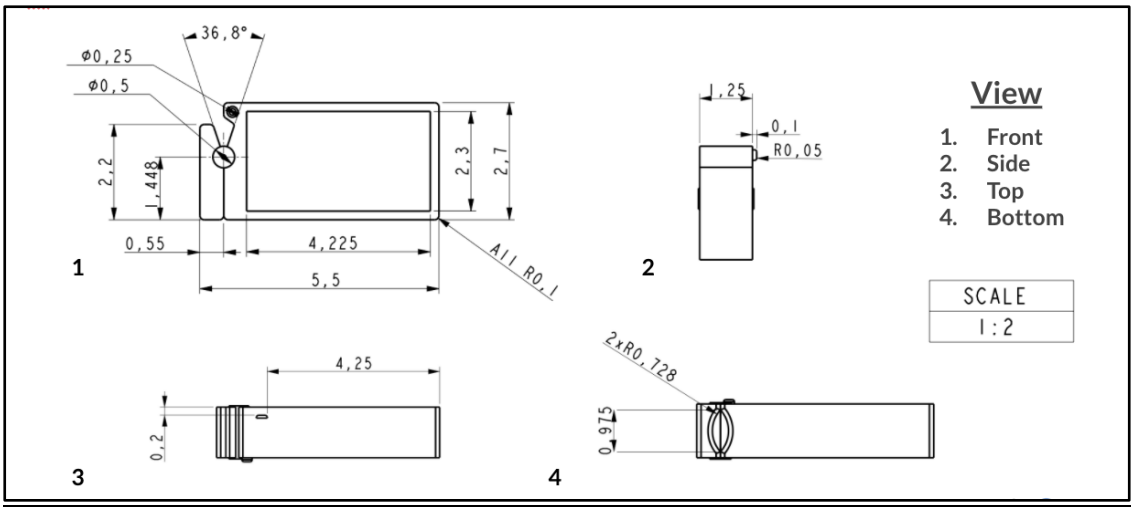


Figure 10: 2D Detailed Engineering Drawings of the AutoCAD VioSense Device Model. 4 Faces of the device are displayed and measurements are shown in inches. The ϕ represents the diameter of the hinge and power button. R, followed by a measurement in inches, represents the radius of the rounded corners.

To calculate a volume of ABS for our device, we determined the housing could be produced in three molds, the top half of the device with an opening for the screen, the bottom half of the device, and the scanning finger piece to be attached with the hinge. For calculations, the mold of the scanning piece was further divided into two sections to produce volumes from the areas calculated using the schematics. Drawings of our volumetric calculations are available in Appendix 3B. With our selected thickness, the outer coverage of our three molds was calculated to be 3.568 in^3. Since the thickness used in this calculation does not account for the internal structure of the mold that may be required to hold electronic components in place, we decided to scale up this calculation. An overhead scaling factor of 1.5 was applied to the summed volume of the molds to ensure we did not underestimate the amount of ABS necessary for injection molding or the associated cost. Our final calculation was 5.35 in^3 of ABS plastic per device. Applying a density of 0.0376 lb/in^3 ABS and a retail cost of $2.658/lb of ABS, the cost of raw material per device was estimated at $0.5347.

On-site Manufacturing

Manufacturing of the VioSense glucometer can be completed with injection molding of the device enclosure and several assembly steps, completely detailed in Fig. 11. To achieve these

processes, two advanced pieces of equipment are required. First is an electric injection molding machine.[30] After steel molds of our designed enclosure pieces are constructed, the injection molding machine selected can produce device molds efficiently and with flexibility. We selected an electric molding machine over a conventional hydraulic molding machine. Benefits of this choice include lower maintenance costs and an overall cleaner manufacturing facility. The machine can be fully automated to produce device molds at a set rate, and because it is completely electric, there is less efficiency loss and cost associated with machine start-up and shutdown.[31]

The second necessary piece of equipment is an automatic motor assembly machine. The machine has several modules for the different assembly steps our device requires. The specific machine we selected has programmable control and auto-generated production statistics, so that the machine can be fully automated. The equipment is capable of handling throughputs higher than our ultimate manufacturing goal, so we believe it will be sufficient to meet our production requirements at each stage of scale up.[32] Using the enclosure molds from the injection molding machine and the required electronic components, the automatic motor assembly machine will be able to handle all of our assembly steps: PPG Unit Assembly, Circuit Assembly, Device Assembly, and Screen Placing/Final Assembly. Visuals of the selected machines are available above in Fig. 8. A fully detailed manufacturing block diagram, showing stages at which different components are incorporated can be found in Fig. 11. The injection molding machine has an estimated cost of $20,000 and the assembly machine has an estimated cost of about $60,000, not including installation.[32,33]

[30] Full-auto/All electric/ABS injection molding machine. *Alibaba.com.*

[31] Midstate Mold. Plastic Injection Molding Machines: Types and Benefits. *Midstate Mold & Engineering*. 25 May 2017.

[32] Full Automatic Motor Assembly Machine. *Alibaba.com.*

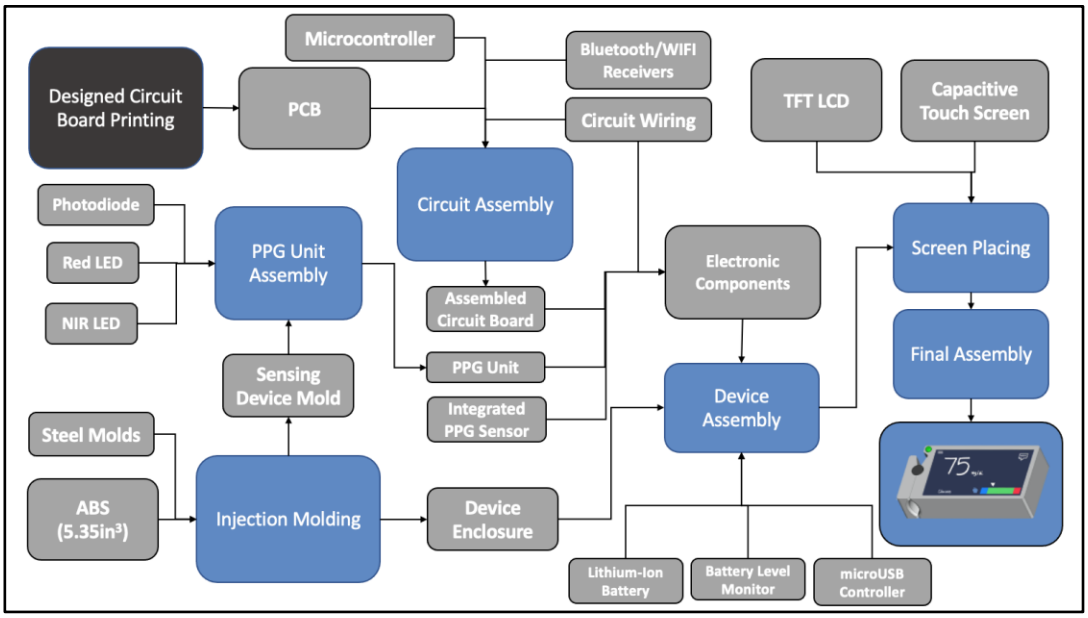


Figure 11: Full Manufacturing Block Diagram for VioSense Glucometer. This representation of our manufacturing process includes raw materials / electronic components. Blue blocks represent processes that occur on-site. The black block represents an off-site process.

Safety and Regulation

We believe that regulating VioSense will take approximately five years. The first couple of years will consist of the research and development of the device. We believe that in this time we can develop a prototype and conduct preliminary studies to determine the safety and efficacy of our product. During this phase of development, we will have to take into account the radiating aspects of our device given the spectroscopy aspect and the Bluetooth capability. Given that our device is classified as a Class 2 device, we can apply for Investigational Device Exemption Status. This gives us the ability to conduct studies as required by the Food and Drug Administration (FDA) so that we can achieve 510(k) status.[33] This phase of the study will be monitored by the FDA and ensures that with respect to other devices on the market, our device is safe and performs similarly. This route to regulation is faster. After the study is complete, we can apply for the 510(k) and after we get clearance, we will be able to take our product to market.

There are several costs associated with the regulation process, these costs are all accounted for in the development costs. The costs of these applications are in the figure below. There are other costs in terms of certifications, clinical studies, and unexpected costs that may come from consultations with FDA regulators. These costs have also been accounted for in development, either explicitly or in overhead.

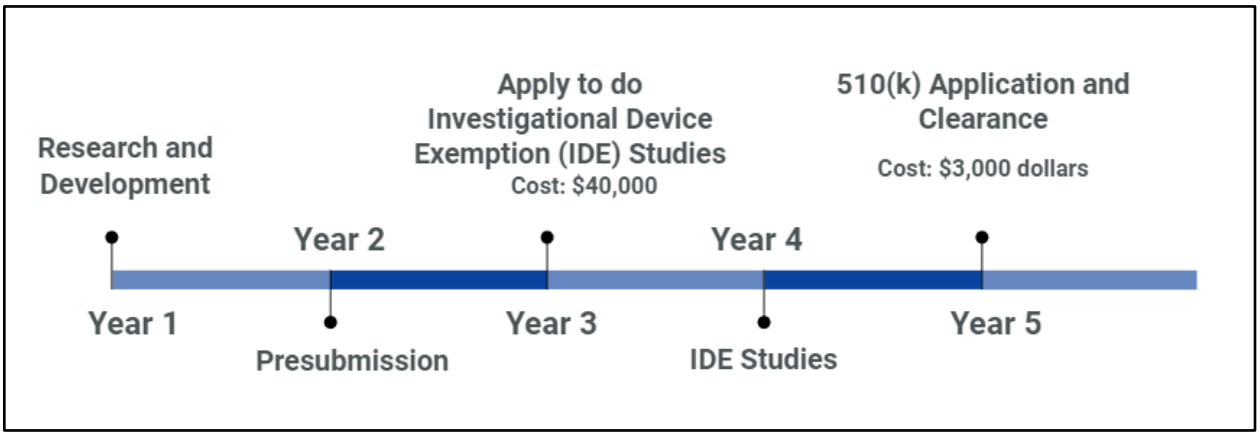


Figure 12: This timeline shows a brief summary of the expected FDA regulation of VioSense.

[33] Overview of Device Regulation. *FDA.gov*. 4 Sept. 2020.

Economic Analysis

Development Costs

Because of the long approval timeline for the FDA, we have split development into 2 phases to minimize unnecessary costs. In phase 1, we will build the prototype and perform the training trial in which we will optimize the random forest configuration and the clinical trial required by the FDA to prove device precision and accuracy. Phase 2 is mostly paperwork and downtime due to FDA procedures. In our cost estimation, we applied great caution and used conservative estimates within reason. Development costs can be categorized neatly as shown below:

Development Costs

Patent Acquisitions	$135,000
Lab Space	$360,000
Trial Costs	$20,000
Parts & Raw Materials	$7,700
Salaries	$1,750,000
Overhead	$1,600,000
FDA Applications	$43,000
Total	**$3,910,000**

Figure 13: Comprehensive cost projection for the development of a working VioSense prototype approved by the FDA. Overhead costs are 75% of the total costs for lab space, trials, parts and raw materials, and salaries.

Based on a search of US patents that involve PPG to find biometric data, we found 9 relevant patents, but this would likely decrease upon a legal consultation, which would help avoid redundant patent acquisitions. Lab space costs are based on an upper estimate for a large private lab space in Baltimore provided by Johns Hopkins.[34] We are assuming this includes utilities and lab materials. Trial costs are for subject compensation and materials. Parts and raw materials costs are based on buying the parts to build 100 devices. This will be a much slower process than when we move into manufacturing because these devices will either be built by hand or outsourced for assembly as we do not have the manufacturing machinery at this point.

[34] Hopkins Hopes Latest Incubator, Fastforward 1812, Spurs Commercialization. *Science and Technology Park at Johns Hopkins.* 11 Apr. 2017.

Personnel during development includes 2 PhDs (biologist, ML developer), 4 engineers (computer manufacturing engineer, computer programmer, software developer, and a microsystems engineer), and 3 clinical technicians. When the prototyping and trials are finished, we will only need the technicians to continue working during phase 2. We will re-hire the PhDs and engineers during manufacturing startup. We are assuming salaries will be consistent with the occupational employment statistics from the Bureau of Labor Statistics.[35] Overhead (75%) covers employee benefits as well as unexpected/unaccounted costs. From all this we calculated a development cost of about $4 million.

Capital Costs

Capital Costs

Equipment (Injection molding, automatic assembly, installation)	$160,000
Facility Costs (3.1x lang factor -- buildings, electrical, controls, etc.)	$500,000
Off-Site Costs (Storage, distribution facilities, utilities)	$130,000
Total	**$790,000**

Figure 14: Cost projection for the fixed capital of VioSense. In other words, the cost of the facility startup to begin manufacturing and distributing VioSense devices.

The bulk of our fixed capital is from the manufacturing machinery, facility, storage, and distribution. Equipment costs are based on the cost of acquisition and installation of the injection molding machine and the auto assembly machine with an assumption that shipping and installation will cost approximately one third the value of the machinery.[30,32] Facility costs are based off of a Lang factor multiplier for a solid-processing plant (3.1x) applied to equipment costs.[36] Off-site costs include things like material storage, distribution, and utilities. We used a 0.2x multiplier on the equipment and facility costs. We also applied a 50% contingency factor on everything to account for uncertainty and additional unexpected costs.

[35] Occupational Employment and Wages, May 2019, 17-2041 Chemical Engineers: *U.S. Bureau of Labor Statistics*. May 2019.
[36] Wolf T. E. Lang Factor Cost Estimates. *Capital Project Management Support.* 2013.

Operating Costs

Operating costs are presented as a range because we will scale up the manufacturing process overtime from 5,000 units in our first year of production to 50,000 by our 5th year, resulting in higher overall but lower unit costs for parts and raw materials. These are also annual or recurring costs rather than fixed costs like for development and capital because operation is and will continue to be an ongoing process.

Operating Costs (Annual)

Parts & Raw Materials	$181,000 - $1,800,000
Utilities	$10,000
Maintenance	$79,000
Salaries	$822,00
Lab Costs	$247,000
Capital Charges, Taxes, Insurance	$110,000
Total	**$1,450,000 - $3,070,000**

Figure 15: The annual manufacturing operating costs for VioSense once we have reached the manufacturing phase. This does not include administrative or business costs for the production of VioSense devices.

Utilities costs are based off of the electric consumption rates of our machinery and a 6,000 square foot lab space -- which is likely much larger than we would actually need -- using the average cost of electricity in Maryland.[37] Maintenance as well as capital charges, taxes, and insurance are based off of our fixed capital, assuming multipliers of 10%, 10%, 2% and 2%, respectively. The manufacturing personnel is similar to that of development with the microsystems engineer being replaced by an extra manufacturing engineer and then an additional software developer for keeping the device updated and competitive. Lab costs were then calculated assuming they would be 30% of operating salaries.[38]

[37] Jiang, Jess. The Price of Electricity in Your State. *Npr.org.* 28 Oct. 2011.

[38] Estimation of Operating Costs. *Chemical Engineering Projects.* 11 May 2014.

Business Costs

The estimated business costs will vary over time as we scale up from an initial start of 5,000 to 50,000 units produced annually. The increase in costs will be motivated by this change in production and this is reflected in the start up and ongoing costs.

Business Costs (Start-Up)

Website	$20,000
Search Engine Optimization	$15,000
Advertisements	$130,000
Total	**$165,000**

Figure 16: Cost projection for the marketing and advertising of VioSense upon facility startup. These are one time costs integral to establishing VioSense as a new player in the noninvasive glucometer market.

Our initial startup business costs are based off of the initial advertising for our device and preparation for sales when the product is released. This includes the construction of a Website to be used for both information and access to the product, and advertisements used to inform the market about the existence of our product through either search for relevant keywords, or direct advertisements.[39]

Business Costs (Production, Annual)

Website	$5,000
Search Engine Optimization	$10,000
Shipping & Packaging	$40,000 - $400,000
Advertisements	$20,000
Marketing Salaries	$60,000
Total	**$135,000 - $495,000**

Figure 17: Cost projection for the ongoing marketing and advertising of VioSense as well as unit shipping and packaging and marketing personnel. The scaling-up of manufacturing results in increasing costs for shipping and packaging as we will be distributing more devices.

[39] Digital Marketing Pricing: How Much Does Digital Marketing Cost in 2020? *WebFX.com.* 2020.

Business costs include both general maintenance for the website and the search optimization, as well as continuing advertisements for our product that include print and online forms. In addition, our annual costs accounts for a small part time marketing team, either directly hired or acquired through an existing marketing firm, that would manage our advertising budget and any sort of social media presence that our company would require. The final portion of our annual budget would go directly to the packaging and shipping of each VioSense device. We are currently budgeting and estimate $8 dollars per device to account for both the physical specifications of the product as well as shipping it worldwide if necessary.[39]

Product Pricing

In determining the price of VioSense, we had two criteria. The price had to be competitive with other noninvasive glucometers on the market and it had to provide savings for people switching from conventional invasive glucometers. A quick survey of the noninvasive market found that upfront prices vary drastically, due to the nature of the products still being tested and developed and the various manners used to take the readings used by each device. Of the devices with released price estimates, they ranged from $700-$2,000 per device.[40] However, the less expensive devices used disposable components or sensors, which leads to annual costs of up to $5,000 for the consumer, making them uncompetitive when compared to invasive devices.

We felt that a reasonable middle ground in this market was a price of $1,500 with an optional payment plan. This plan would include 0% financing over a 5-year payment period, meaning that a VioSense would only cost the average user just $25/month for 5 years. When compared to the cost of using test strips, which may mean using 5 to 8 strips daily that range anywhere from $.40 to $1 each in price, VioSense provides a more affordable option to both

[40] Young, Emma. Non-invasive glucose monitoring for diabetes: five strategies under development. *The Pharmaceutical Journal*. 12 Oct. 2017.

invasive and noninvasive devices.[41,42] Compared to the minimum $750/year spent on test strips, based on the lowest estimates of using 5 test strips costing $.40 each daily, VioSense costs over 60% less each year for the consumer to use.[42] Taking into account the amount saved each year by using VioSense over traditional devices that use disposable additions like test strips, a VioSense will have paid for itself in a little as 5 years. Given that our device only costs about $36 to produce, our profit margin is still considerably high.

Profitability Analysis

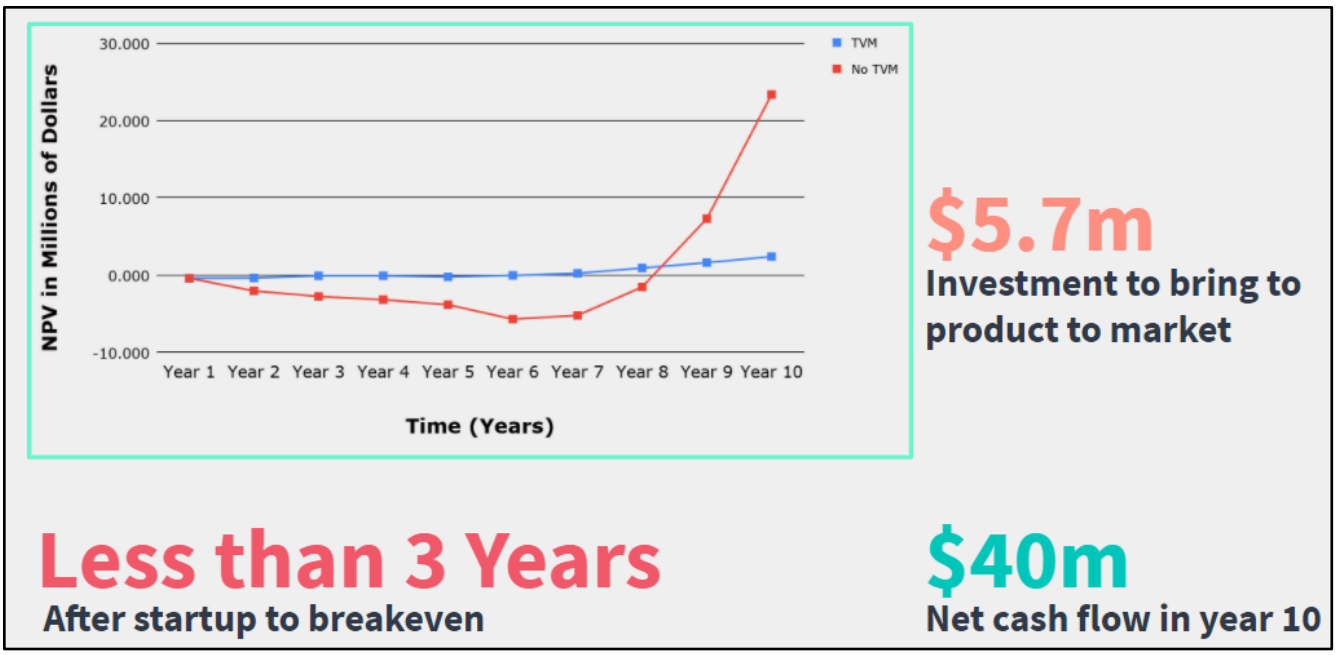


Figure 18: A brief financial summary for VioSense. The graph shows the net present value projections both with and without the time value of money. They break even in years 6 and 8, respectively. Additional financial statistics of interest are shown as well.

From our cost and revenue estimations, we were able to derive a net present value graph over the first 10 years of operation both with and without the time value of money with a 10% discount rate. Important metrics are also shown in the figure above. We estimate a cost of $5.7 million dollars, including R&D, initial production, business startup, and overhead. At the start of year 6, we expect our product to be available to the general public and revenues to begin. Each year after startup, our manufacturing is scaled up, resulting in lower production costs (at the unit level) and higher revenue. In less than 3 years after startup, producing around 16,000 devices, we

[41] How often do I need to test my blood glucose? *Diabetes.co.uk.* 15 Jan. 2019.
[42] Gebel, E. The Cost of Test Strips. *DiabetesForecast.org.* July 2012.

expect our net present value with the time-value of money to go positive and our business to break even. At the end of year 10, we expect approximately $40+ million dollars in net cash flow conditional on the production and sale of 50,000 VioSense devices.

Conclusion

VioSense uses photoplethysmography and machine learning to determine blood glucose measurements among other vitals, putting accurate health information into the hands of those who need it. By removing the need to constantly buy test strips and taking a thumb prick every time one needs a reading, VioSense removes the barriers for patients to get the treatment they need. Just 18% of people with diabetes report testing themselves the recommended frequency of at least 8 times a day while over 55% say they would if testing were painless and convenient.[9] VioSense has the potential alongside other noninvasive glucometers to reshape how we view the burden of living with diabetes. Treatment should not be expensive, painful, or inconvenient. It is time that society shifts the focus away from excessive monetization to a patient-oriented model that actually works. We believe the continuous improvement of our product's measurements and clinically desired features will blossom into an incredibly successful business, and we'd love your support delivering this new age convenience to the hands of diabetes patients.

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Appendix

Appendix 1: User Interface Displays

A

B 

C 

D 

E 

Fig A shows options for event tags: after meal, stressed, other, exercise, before meal, sick, carbs, and medication. Fig B indicates a drop-down menu. Fig C and D represent example reading for the blood pressure, oxygen saturation and heart rate. Fig E shows an example of BGguru interacting with the user.

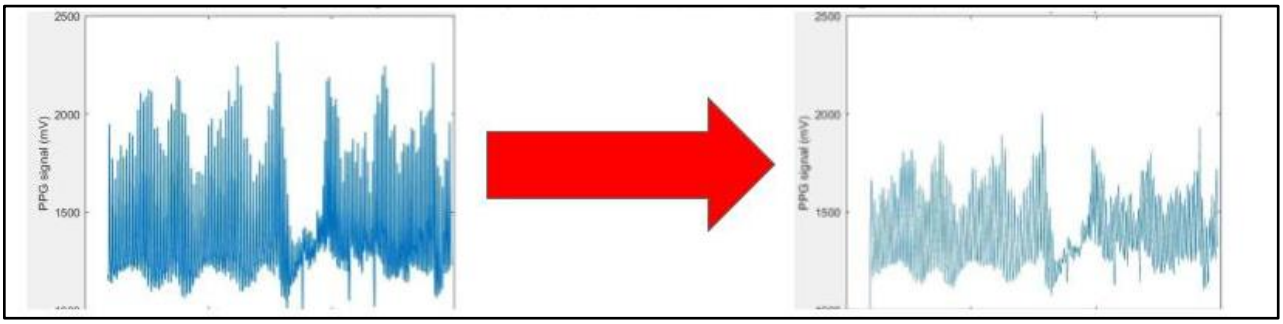
Appendix 2A: Our Matlab model for the activity detection module. The PPG signal passes through a moving average filter and a Savitzky-Golay filter.

Editor - adModel.m

hw11.m | adModel.m

```
clear
[num,txt,raw] = xlsread('noisyPPG.xlsx');
t = num(:,1);
sig = num(:,7);


%MOVING AVERAGE FILTER (11 POINT)
B = (1/51)*ones(51,1);
sig_MA = filter(B,1,sig);

%SOVITZKY-GOLAY FILTER
order = 14;
framelen = 21;
sig_SGF = sgolayfilt(sig_MA,order,framelen);

figure(1)
plot(t,sig,'LineWidth',1)
axis([4.21786605*10^4 4.2178662*10^4 1000 2500])
xlabel('t'),ylabel('PPG signal (mV)'),title('Raw PPG')

figure(2)
plot(t,sig_SGF)
axis([4.21786605*10^4 4.2178662*10^4 1000 2500])
xlabel('t'),ylabel('PPG signal (mV)'),title('Filtered PPG (MA/SG)')
```

Appendix 2B: The figure below shows the effect these two filters have on an example PPG signal. Much of the extreme noise has been removed. Note that this AD model is a simplified version of what would actually be used. The filter parameters have also not been optimized/would be optimized for each sample based on certain criteria (i.e Kaiser-Teager Energy profile, spectral entropy profile).



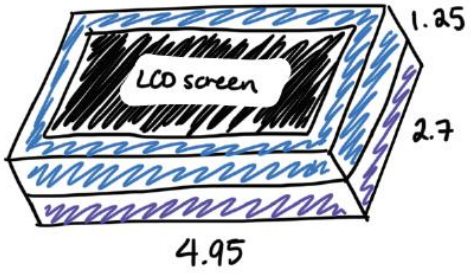
Appendix 3A: Cost of Materials for Increasing Quantities.

Component	Price for Various Quantities							
NIR (940 nm) LED	1-9	10-49	50-99	100-249	250+			
Unit Price	$0.60	$0.57	$0.56	$0.51	$0.48			
Red LED	1-9	10-49	50-99	100-499	500-999	1000-4999	5000-9999	10000+
	$0.611	$0.495	$0.369	$0.321	$0.303	$0.257	$0.233	$0.222
Photodiode	1-24	25-99	100-249	250-499	500-999	1000-2499	2500+	
	$0.54	$0.51	$0.49	$0.46	$0.44	$0.42	$0.40	
Integrated PPG Bio-Sensor Module	1-9	10-24	25-49	50-99	100-249	250+		
	$7.57	$6.83	$6.52	$6.10	$5.67	$5.66		
Printed Circuit Board **(+$500)**	50+	100+	250+	500+	1000+	2000+	5000	10000+
	$16.13	$12.53	$7.09	$5.91	$5.22	$4.88	$4.67	$4.60
Micro Controller	1+	25+	100+					
	$1.76	$1.60	$1.45					
Battery Level Monitor	1+	25+	100+	1000+				
	$0.59	$0.49	$0.45	$0.43				
Lithium Ion Battery	1	3+						
	$7.95	$5.95						
microUSB Connector	1+	50+	100+	250+	500+	1000+		
	$2.991	$2.726	$2.648	$2.563	$2.486	$2.417		
TFT LCD Touch Screen	1+	500+	1000+	3000+				
	$8.00	$7.80	$7.70	$7.50				
WiFi Receiver	50+							
	$1.665							
Bluetooth Receiver	1+	25+	100+	1000+	2000+			
	$7.57	$6.23	$5.64	$4.00	$3.86			
Device Housing - ABS Plastic	1000 lbs.	$/Device						
	$2,658	$0.535						

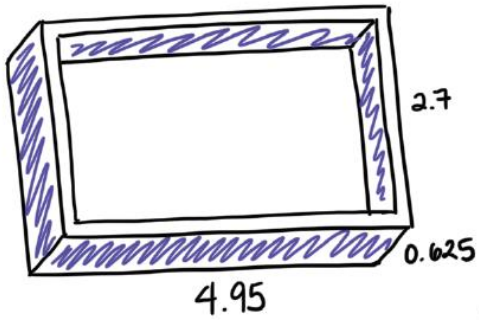
Appendix 3B: Written Enclosure Design

Injection Molding : 0.08 in thickness

Main Piece



Bottom



Bottom panel:

$4.95 \times 2.7 \times 0.08 = 1.0692$

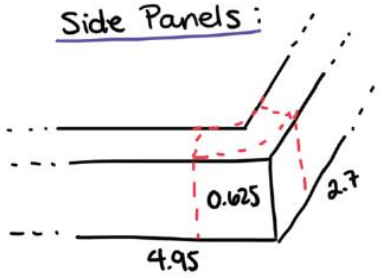
$-$ corners $(6.87 \times 10^{-4}) = \underline{1.0685 \text{ in}^3}$

subtract rounded corner

$$\frac{0.1^2 - \pi(0.1^2)}{4}$$

$$4\left[\frac{0.1^2 - \pi(0.1^2)}{4}\right] 0.08 = 6.87 \times 10^{-4} \text{ in}^3$$

Side Panels:



lengths: $2(4.95 \times 0.625 \times 0.08) = 0.495 \text{ in}^3$

widths: $2(2.7 \times 0.625 \times 0.08) = 0.27 \text{ in}^3$

lengths + widths $-$ edges $= \underline{0.759 \text{ in}^3}$

subtract rounded edge $0.1^2 - \frac{\pi(0.1^2 - 0.02^2)}{4}$

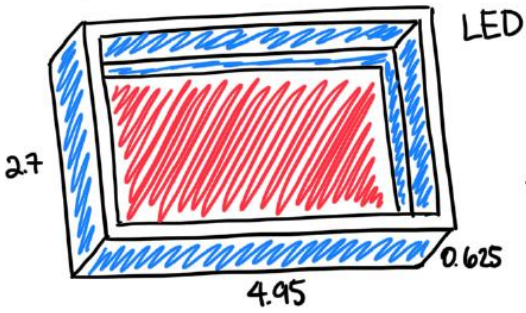
$$\left[4 \times 0.1^2 - \pi(0.1^2 - 0.02^2)\right] 0.625$$

$$= 0.00615$$

Total amount needed for bottom of main piece:

1.827 in^3

Top



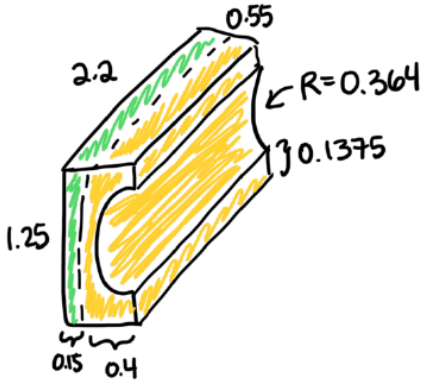
LED Screen: $4.225 \times 2.3 \times 0.08 = 0.774$

$1.0685 - 0.774 = 0.2945\ in^3$

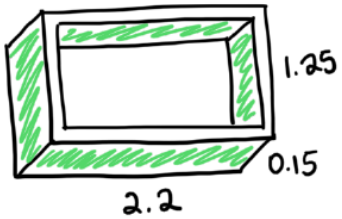
+ side panels: $0.7589\ in^3$

Total amount for top of main piece: $1.053\ in^3$

Scanning Finger Piece



Right



Bottom Panel:

$2.2 \times 1.25 \times 0.08 = 0.22\ in^3$

$-$ Corners (6.87×10^{-4})

$= 0.2193\ in^3$

Side panels

lengths: $2(2.2 \times 0.15 \times 0.08)$

$= 0.0264 in^3$

widths: $2(1.25 \times 0.15 \times 0.08)$

$= 0.015\ in^3$

lengths + widths - edges

$= 0.07296\ in^3$

Total amount needed for outside part of finger scanning piece: $0.292\ in^3$

Left

$$2\left[1.25 \times 0.4 \times 0.08 - \frac{\pi(0.364)^2}{2} \times 0.08\right]$$

$$= \underline{0.0483\ in^3}$$

$$\frac{\pi(or^2 - ir^2)h}{2}$$

$$\frac{\pi(0.364^2 - 0.284^2)(2.2)}{2}$$

$$= \underline{0.1791\ in^3}$$

$$2(2.2 \times 0.4 \times 0.08)$$

$$= \underline{0.1408\ in^3}$$

$$2(2.2 \times 0.1375 \times 0.08)$$

$$= \underline{0.0484\ in^3}$$

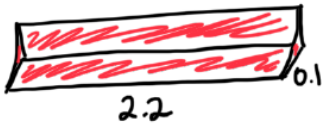
Total amount for inner part of finger scanning piece:

$$0.0483 + 0.1408 + 0.0484 + 0.1791 - 0.00172 - 0.0189 = \boxed{0.396\ in^3}$$

To take out for rounded edges

$$2\left[0.4 \times 0.1^2 - \frac{\pi}{4} 0.1^2 \times 0.4 = 0.4 \times 0.1^2 \left(1 - \frac{\pi}{4}\right)\right]$$

$$= \underline{0.00172}$$



$$2\left[2.2 \times 0.1^2 (1 - \pi/4)\right] = 0.0189$$

Outer Coverage

$$1.827 + 1.0534 + 0.292 + 0.396 = 3.568\ in^3$$

Scaling Factor of 1.5 to account for internal design of molds

Full amount: 1.5 x outer coverage = $\boxed{5.35\ in^3}$

Appendix 4A: Economic timeline with (NPV) and without (Net Cash Flow) time value of money. Additional financial tables are attached in an .xlsx file.

($Million)	Year 1	Year2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Development	-1.636	-1.027	-0.417	-0.417	-0.417	0.000	0.000	0.000	0.000	0.000
Start-up	0.000	0.000	0.000	0.000	-0.952	0.000	0.000	0.000	0.000	0.000
Production	0.000	0.000	0.000	0.000	-0.792	-1.584	-2.069	-2.551	-3.039	-3.521
Revenue	0.000	0.000	0.000	0.000	0.000	1.395	5.929	13.601	24.413	38.363
Cash flow	-1.636	-1.027	-0.417	-0.417	-2.161	-0.189	2.509	7.183	13.893	22.647
NPV (TVM)	**-0.381**	**-0.088**	**-0.080**	**-0.073**	**-0.469**	**-0.027**	**0.330**	**0.858**	**1.508**	**2.235**
Net cash flow	**-1.636**	**-2.663**	**-3.080**	**-3.497**	**-5.659**	**-5.847**	**-3.338**	**3.845**	**17.737**	**40.384**