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AbStats: From Concept to Market

A thesis submitted in partial satisfaction
of the requirements for the degree
Master of Science in Electrical Engineering

by

Andrew Nicolas Kotite

2016

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2016

Abstract of the Thesis

AbStats: From Concept to Market

by

Andrew Nicolas Kotite

Master of Science in Electrical Engineering

University of California, Los Angeles, 2016

Professor William J. Kaiser, Chair

Clinical grade electronics is a highly challenging and competitive field. Creating high volume reliable systems involves many complex design considerations. *AbStats*, a digestive monitoring system, was designed from the ground up to incorporate these design considerations to bring a clinical device to market. Built to diagnose postoperative ileus, *AbStats* is able to monitor symptoms and aid physicians in treating patients. Early prototypes defined system specifications, and after a proof of concept was established, a production ready version of *AbStats* was needed to bring the technology to market. The system comprised of two main parts, the gateway and the sensors. The gateway comprised of a user interface for the physician, as well as electronics to enable the sensors and algorithms. The sensors were designed to be noninvasive, and provide the interface to the patient. Creating high quality inexpensive sensors was the most challenging aspect of the design. Quality assurance is a critical part of the design as end of line testing is integral in any consumer facing product. Taking cues from the consumer electronics space, design considerations were made to quickly develop the system and push to production. Contract manufacturing and rapid prototyping influenced the development and enabled a rapid push to market. Currently, *AbStats* has received FDA 510(k) and IEC 60601-1 certifications. *AbStats* is currently ramping up production to satisfy the needs of many hospitals and clinics in the Los Angeles area. *AbStats* has created a new space in gastrointestinal monitoring and is proving to be successful in the market.

The thesis of Andrew Nicolas Kotite is approved.

Robert N. Candler

Gregory J. Pottie

William J. Kaiser, Committee Chair

University of California, Los Angeles

2016

To my loving parents . . .

who have always supported me in all my endeavors.

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Finally, I want to thank my family for their love and support. Through their guidance, they have enabled me to accomplish my goals and have given me the opportunities that make me into the individual that I am today.

CHAPTER 1

Introduction

Post operative ileus is a condition of the digestive tract that can impact patients who have undergone abdominal surgery. Symptoms – including nausea, constipation, dehydration, and vomiting – exacerbates the condition of the patient after surgery. However not life threatening, post operative ileus can lengthen the hospital stay of patients, increasing the likelihood of developing secondary conditions. In addition to the side effects, the increase in stay is costly to the patient as well as the hospital [1].

The human digestive tract is where post operative ileus impacts the patient. During normal digestive function, the intestine contracts and relaxes to move chyme, a semifluid mass of partly digested food, in a process called peristalsis. These events are key indicators of a healthy and functioning gastrointestinal tract – the lack of these strong muscle contractions are indicative of ileus. Currently there is no way diagnose or monitor postoperative ileus easily prior to exhibiting symptoms.

The main diagnostic method for physicians to diagnose post operative ileus is through auscultation, the method of listening to internal sounds of the body, typically using a stethoscope. However, it is not practical for physicians to constantly monitor for peristalsis events. As a result a vast majority of cases go unnoticed until serious side effects present themselves, leading to a physician to recommend the patient abstain from solid foods and liquids.

AbStats, a novel biomedical device, is aimed to aid physicians in the diagnosis of ileus and the monitoring of patients who are at risk of developing the condition. With long term use, hospitals are able to monitor and track patients' digestive health remotely, akin to how ECG and SPO2 machines monitor and track patients in clinics around the world.

This thesis focuses on the design and manufacturing of the two main components of the *AbStats* system, the sensors and the gateway. The sensors act as a mechanism to couple sound from the patient and traduce that physical signal into an electrical one. This electrical signal then is relayed to the gateway by an auxiliary cable. The gateway houses all the electronics including power management, audio conditioning, motor control, signal processing, and a touch display. This configuration allows the device to collect signals from the patient, interpret these signals, and relays information to the physician. A high level diagram is below in Figure 1.1.

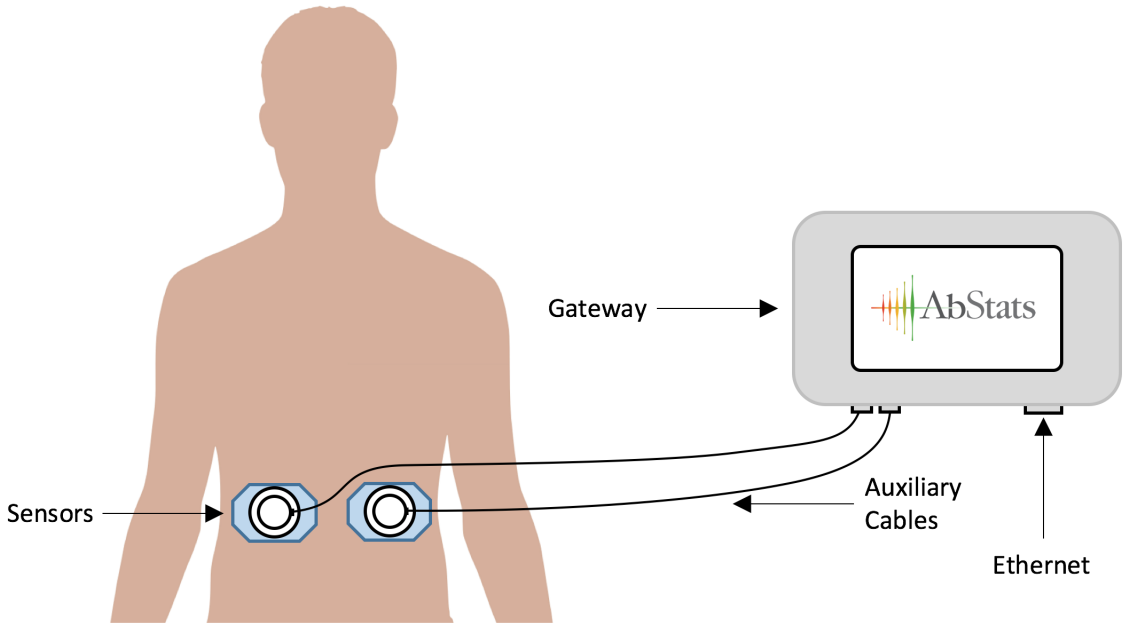


Figure 1.1: *AbStats* System

AbStats is a combination of existing and new technologies that create a novel product. Developing new methods to couple the acoustic noise of the abdomen to electronic sensors proved to be a challenge, as well as ensuring the quality of the signal over many use cases. Signal processing, audio conditioning, communication protocols, and power consumption were all integral to bringing the technological advances from the consumer space into the medical field.

As this device is intended to go to market the cost, form factor, quality, and manufac-

turability all play a role in the design. This thesis will walk through the design methodology of each component of the device and how the system functions. Working with different contract manufacturers we were able to implement a production line ensuring our product had a clear path to be constructed. In addition, end of line testing was implemented to aid in manufacturing to ensure operational devices were being shipped. In effect, design methodologies from the consumer electronics industry were applied to create a cost effective and high quality product.

CHAPTER 2

Sensors

2.1 Introduction

The sensors used in the *AbStats* system are one of the major components of the design. These sensors have a number of functions in the system to ensure proper operation. They act as the only interface between the subject and the gateway. The ability of these sensors to couple with the low frequency signals of the digestive track is key to the overall implementation of the system. Proper acoustic coupling allows an electronic transducer to convert a vibrational signal into an electrical one. In addition, the sensors include a vibration motor to test that the coupling between the sensor and patient is properly formed. The use of the vibrational motor will be discussed further in later sections.

These sensors are designed to operate similarly to a stethoscope to allow monitoring of the digestive tract. As a peristalsis event occurs, the rapid movement of the muscles cause a low frequency vibration to propagate to the surface of the skin. As it reaches the surface, the vibrations need to be coupled to the sensor, and this interface is key to the effectiveness of the sensor. You can see the different parts of the sensor system in Figure 2.1. An acoustically coupled signal and motor-control line go into the sensor, while an electrical signal goes out to the gateway. This section will describe the design methodology used to develop these sensors from enclosure and electronics design, to acoustic coupling.

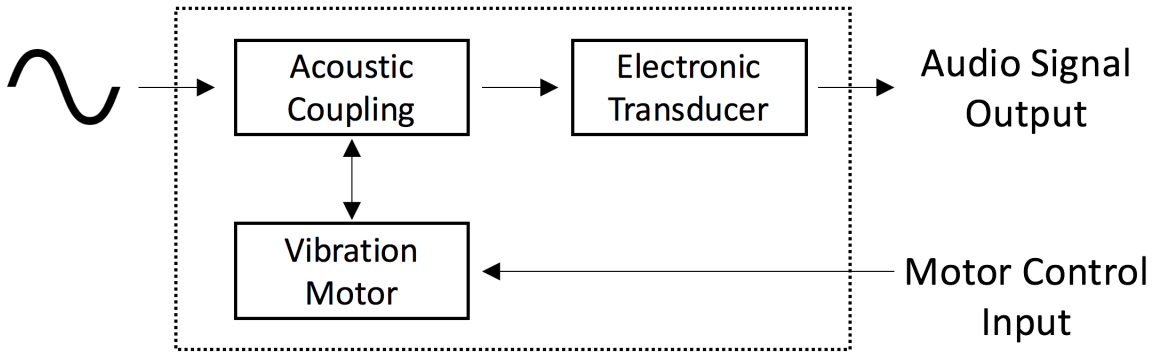


Figure 2.1: Sensor Block Diagram

2.2 Sensor Housing Specifications

As these sensors are going to be in contact with patients, it is critical to meet the specifications that were set out to implement a safe and effective system. When designing any system, it is important to set a list of specifications in order to ensure the design goals are met. There are three major considerations that went into designing the sensor housing outlined below.

2.2.1 Acoustically Coupled Design

The first major design consideration is how the housing couples to the patient. Creating a simple sensor that provides good contact to the patient allows for the signals at the surface of the skin to couple to the transducer. The housing must be able to conform to different patient body types to ensure proper contact. This flexibility allows the sensor to be applied to the abdomen without many considerations to the exact positioning.

2.2.2 Form Factor

The form factor of the device impacts the overall aesthetic of the sensor as well as how the device is interacted with. Being able to create a small device with a minimalistic footprint allows the sensor to be more user friendly. Everything from the feel in the hand, to weight

distribution, to how you attach it to the cabling, falls under this category. Many markets move to cleaner and more professional feeling products. As a result, customers have come to expect the attention to detail that goes into a good industrial design. Also the behavior of the sensor while attached to the patient must be taken into consideration as this is meant as a long term monitoring device.

2.2.3 Cost and Disposable Sensors

Being a disposable sensor impacts the design in a number of ways. Because the sensor will be single-use, the cost-per-sensor must be reduced. The material the housing is made of must be robust and reliable, but at the same time inexpensive. This was a challenging aspect of the design as cost usually goes hand in hand with quality, which is a goal of the sensor design.

2.3 Housing Design

2.3.1 3D Printed Housing

Designing an enclosure for the sensor hardware is an iterative process. Being able to design different shapes, adjust dimensions, and changed overall aesthetics is important to hone in a perfect design. To be able to iterate quickly on the housing designs we utilized a Makerbot 5th Generation 3D printer. A 3D printer takes an electronic model and converts it to a physical one. We used an additive 3D printer that prints layer by layer until the entire model is complete. The material we chose for our prototyping is polylactic acid (PLA). PLA is a perfect prototyping material because it is light, inexpensive, and has high structural rigidity. For the housing, we wanted to adhere to our three main goals of creating an acoustically coupled design, having a slim and compact form factor, and reducing the cost to make disposable sensors feasible. By using a 3D printer, we were able to refine our design so it has a sleek aesthetic that uses a small amount of plastic, and supports the acoustic needs

of our system.

In Figure 2.2 below you can see the modeled housing. On the left hand side of the housing you can see the port for the audio jack we use to connect to the sensor. You can also see the overall shape and aesthetic of the design which is minimalistic to reduce the complexity of manufacturing. The chamfered edges are meant to allow fabric to slide over its surface smoothly. The low profile design aids in the feel of the sensor as the patient can not notice it easily under clothing.

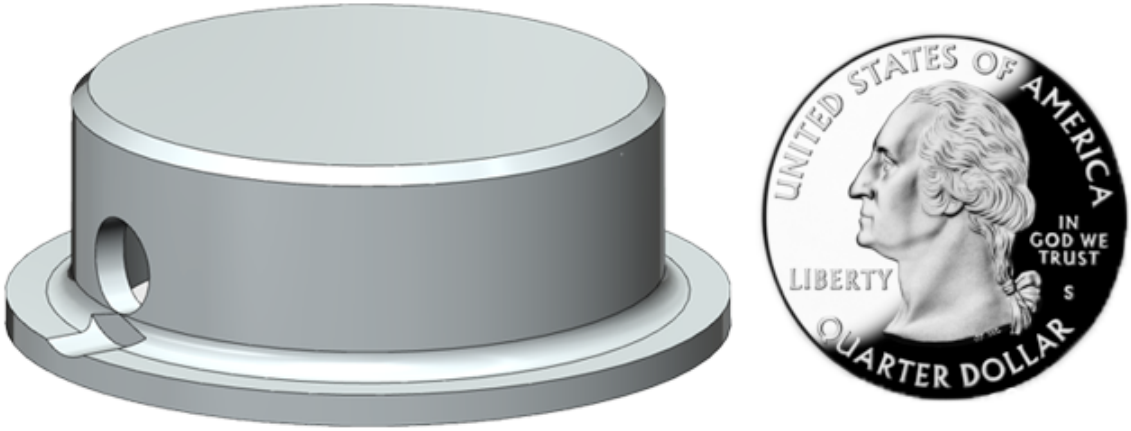


Figure 2.2: Housing Design



Figure 2.3: Housing Cross Section

2.3.2 Acoustically Coupled Design

This design was also implemented with acoustic coupling in mind. The ring that surrounds the main body is meant to support the adhesive tape that is used to attach the sensor to the abdomen. This structure allows the main body seen in Figure 2.4 to be sealed. To create this seal in the housing, a ring of VHB tape was used along the perimeter of the ring. From this adhesive ring Tegaderm was attached to seal the opening in the bottom of the sensor. Tegaderm was used because it is a thin adhesive film commonly used in hospital settings. The natural elasticity of the tape acts as a diaphragm coupling the vibrations on the skin to changes in pressure inside the housing. As a peristalsis event occurs, and the vibrations propagate to the skin, the Tegaderm interface allows the inner chambers pressure to vary as a direct result. In addition, the walls of the housing act as a ridged support allowing the Tegaderm to be an effective diaphragm.

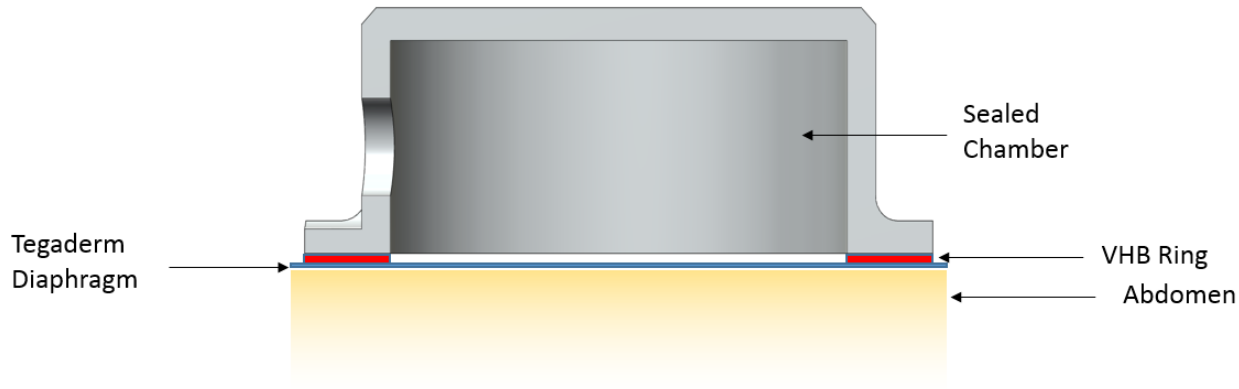


Figure 2.4: Acoustically Coupled Sensor Cross Section

2.3.3 Printed Circuit Board Mechanical Design

The final part of the sensor housing is the electronics inside the enclosure. There are four major components to the electronics inside, an electret microphone, a vibration motor, an audio jack, and a printed circuit board (PCB). All these parts come together to form the necessary electronics for the sensor to operate.

The printed circuit board in the housing is what supports all the internal components in the sensor. The PCB was designed to fit snugly in the enclosure so a friction seal would hold it in place. The PCB also connects all the electronics together. The PCB has a structural center layer made of an epoxy and plated on both sides with copper. Etching the copper layers with different patterns allows for electrical connections to be made between different components that attach to the PCB.

The vibration motor is mounted behind the PCB as seen in Figure 2.5. The motor is soldered onto the PCB and securely glued to the housing, this translate the vibrational waves coming from the motor to the sensor. The vibration motor will be used for coupling tests discussed in later sections.

The audio jack is mounted towards one edge of the PCB and extends through the housing. This allows the jack to be accessible outside of the housing and provides the interface between the sensor and the rest of the system. A small amount of adhesive surrounds this port to ensure a sealed enclosure.

The final mechanical consideration on the PCB is the electret microphone. This microphone is what translates the physical waves from the sealed enclosure into an electrical signal. The placement was important as it had to be far enough back from the moving diaphragm to not come into contact with the Tegaderm. The microphone's aperture also had to be relatively centered in the enclosed space. The surrounding structure could dampen the signal if the microphone were to come into contact.

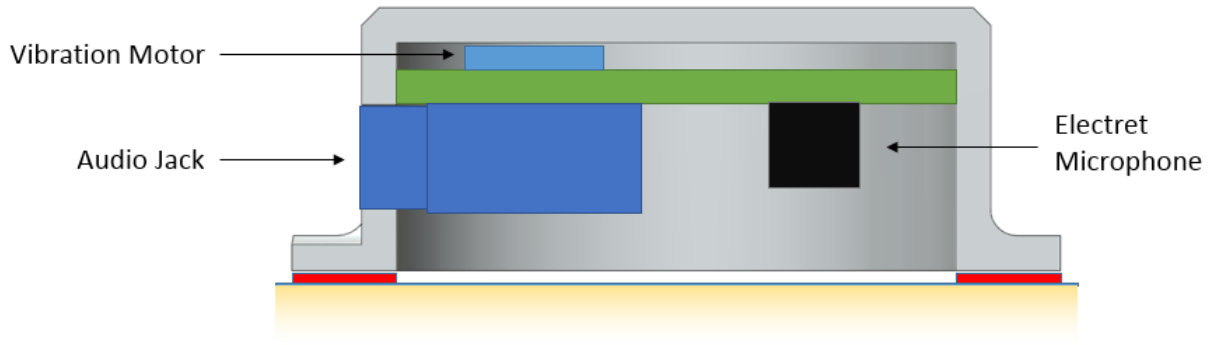


Figure 2.5: Sensor Electronics Cross Section

2.4 Electrical Design Specifications

The performance of the sensor was a major design consideration for the overall system to function property. Being able to efficiently translate the entire frequency range of interest to an electrical signal allows for a simple design. Part selection of the components in the sensor was important to minimize the size and optimize performance of the sensor.

2.4.1 Electret Microphone

The electret microphone used in the sensor needed to meet a number of factors. It needed to have the proper frequency response for our application, be cheap enough to create disposable sensors, as well as be small enough to fit in the sensor housing.

Peristalsis events are audible signals that can be heard by physicians. The critical frequencies of these events fall between the 80Hz to 200Hz frequency range, and our sensor needs to be able to pick up this frequency range. Using microphones meant to mimic human hearing, which is within the 20Hz to 20kHz frequency range, would cover the frequency spectrum of interest for this design. Once the frequency range of the sensor was established the remaining key factors were cost and size.

After careful consideration, the XCM6035 from SPL was chosen as the electret micro-

phone for the sensor [2]. At a size of 6mm wide by 3.5mm tall, it would fit the designed enclosure as well as provide a robust frequency response. We can see the microphone pictured below in Figure 2.6. Note the two terminals, which are GND and signal, are to connect to the sensor to a PCB.



Figure 2.6: Electret Sensor

The frequency response of the microphone is very important to get the signal of interest from the sensor. The frequency response of this device encompasses the range we need for our system. In Figure 2.7 the frequency response of the microphone is shown, which ranges from 20Hz to 20kHz.

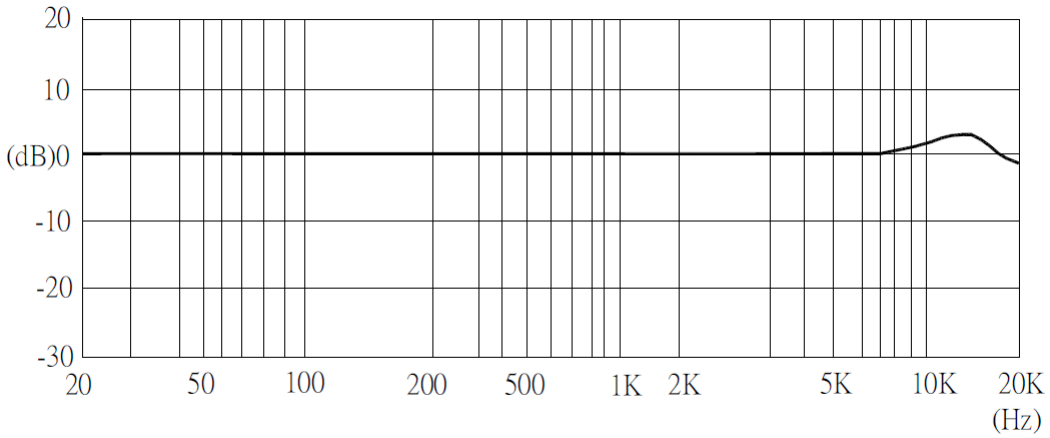


Figure 2.7: Electret Sensor Frequency Response Curve

In addition to the microphone, there needs to be supporting circuity to properly use this transducer. In Figure 2.8 you can see the electret microphone as well as a resistor and capacitor. This provides biasing to the microphone to operate properly. As this design is meant to be inexpensive and compact, adding these extra components into the housing did not seem like a sound decision. Instead, the biasing circuitry is included in the gateway where the data processing is occurring. This also allowed the sensor to remain a three terminal device as we do not need an extra reference voltage.

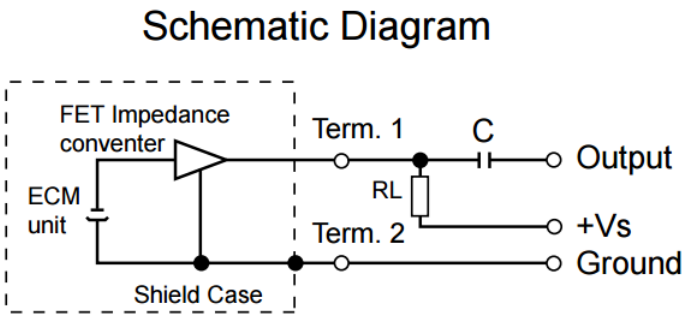


Figure 2.8: Electret Sensor Schematic Diagram

2.4.2 Vibration Motor

Another component in the sensor is a vibration motor. This motor is important as it is used in coupling tests to ensure proper attachment of the sensor. When the system starts, the vibration motor in one of the sensors vibrates as the other listens, and vice versa. If the sensor is properly attached, the microphone on the non-vibrating sensor will pick up the vibrations. Using this method, we can ensure that both sensors are attached to the patient and are properly coupled. The vibration motor chosen is from Parallax pictured below in Figure 2.9 [3].

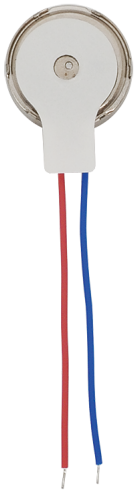


Figure 2.9: Vibration Motor

This vibration motor runs off of 3V provided by the gateway. When 3V is applied across the terminals the weight inside the motor begins to spin at 9,000 RPM. This moving weight causes a vibration that can be seen if another sensor is attached to the same patient. To provide a comfortable experience for the patient these vibration motors are only turned on for 100ms. This is enough time for the motor to spin up and take an audio sample from the other sensor. These coupling tests are performed on a number of occasions. One case is the start of a recording when the sensors are expected to be attached. Another is when the gateway recording is paused or resumes. The final case is if there is a sharp spike in the acoustic signal received from the microphone, indicative of rapid movement.

This coupling test is important as the interface between the patient and the sensors need to be robust to receive a signal from any peristalsis event. If the sensors are not attached properly during certain peristalsis events there could be an issue in the algorithm used to detect post operative ileus [8].

2.4.3 Printed Circuit Board

The remaining component in the sensor is the printed circuit board. This part electrically connects all the components in the sensor including the microphone, the audio jack, and the vibration motor. To be able to create the board we utilized a computer aided design software called Eagle. This software allows for the creation of Gerber files that can be used for the fabrication of a PCB.

The first part in the printed circuit board process can be seen below in Figure 2.10. This image shows the schematic for the sensor PCB. The schematic shows the connections that need to be made between all the different components in the system. A critical part in the creation of the schematic is to correctly choose the components. Each part in Eagle, and most CAD tools, have a corresponding footprint that is reflected on the PCB. If the footprint does not correspond to the part you intend to install on the board, then your design would not work. The *AbStats* sensor only has a few components which resulted in a simple schematic. On the left hand side there are through hole connections meant to connect the motors leads into the PCB. Below that is the microphone with its corresponding leads to bring its signal and GND lines out. On the right hand side there is an audio jack that is connected to all the parts in the sensor as denoted by the signal names. In Eagle you can give wires (nets) the same name and they will be connected on the board. This naming structure allows for clean schematics where it is clear where everything is connected.

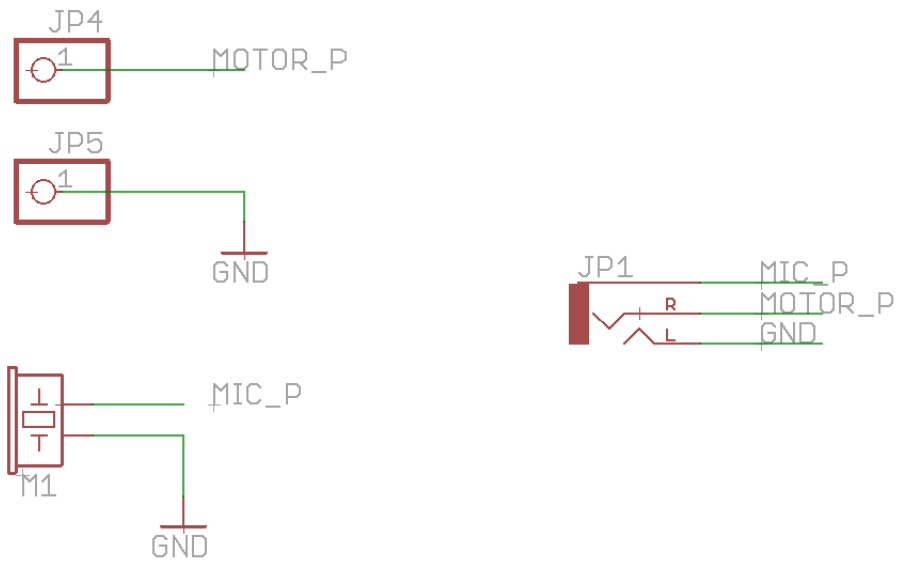


Figure 2.10: Sensor PCB Schematic

Once the schematic is complete all the parts are generated in an empty layout. A layout of a schematic is the physical representation of the board. By moving parts around and connecting them we can finish the design that was created in the schematic. The first step was creating the outline so we know the dimensions of the board. After that we needed to make sure that each of the parts are in the correct position. The audio jack had to be towards the side of the PCB to enable a connection through the housing. The microphone needed to be isolated from the other components so they do not physical interfere when mounting the actual hardware. The terminals for the motor also needed to be placed in such a way that is easy to attach. Once the placement is done connections can be made between the parts. Traces are made in the surface of the PCB which can either be on the top or bottom of the board. As this is a two layered board we can route these wires on either side to create the electrical connections.

You can see the top layer in Figure 2.11. On this layer of the board you can see the audio jack and the mounting holes for the vibration motor and microphone. The lines you see on the surface are the traces mentioned before that electrically connect these components.

Below that in Figure 2.12 you can see the bottom of the board where the vibration motor is mounted. You can also see the trace connecting the microphone to the audio jack.

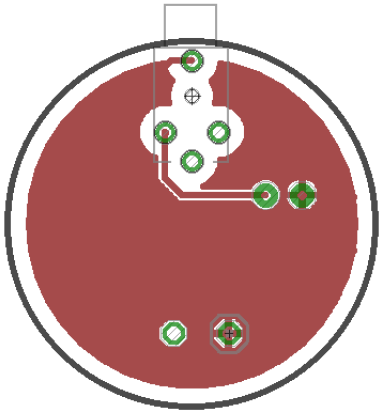


Figure 2.11: Sensor PCB Top Layer

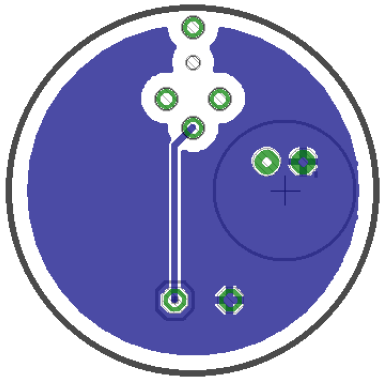


Figure 2.12: Sensor PCB Bottom Layer

Once the schematic and board layout was complete we sent the board out to be manufactured in bulk to reduce the cost of each PCB. You can see the resulting final design in the finished PCB below in Figure 2.13 and Figure 2.14.

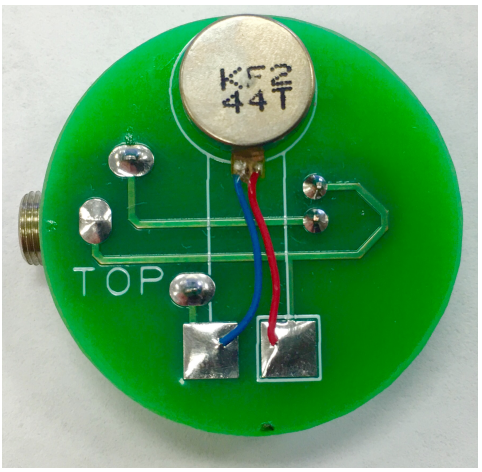


Figure 2.13: Sensor PCB Top Side

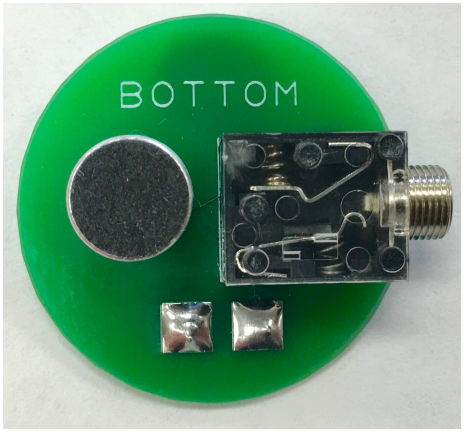


Figure 2.14: Sensor PCB Bottom Side

2.5 Sensor Results

The sensor that was designed for the *AbStats* system met the goals set out in the initial design. The housing in addition to the PCB created a solution that is easy to assemble, and is mechanically and electrically sound. Below in Figure 2.15 you can see a set of six completed sensors.

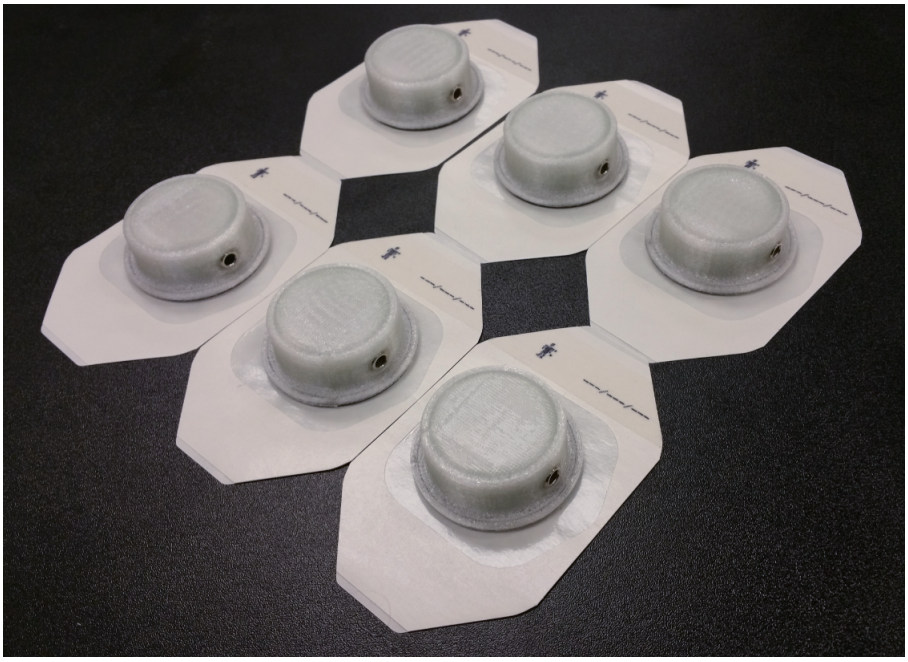


Figure 2.15: Finished Sensors

CHAPTER 3

Gateway

3.1 Introduction

The gateway serves many functions that lead to the overall operation of the sensors. Signal acquisition, data processing, motor control, and conveying information to physicians are all functions that are housed in the gateway. Below in Figure 3.1, you can see the overall block diagram for the gateway.

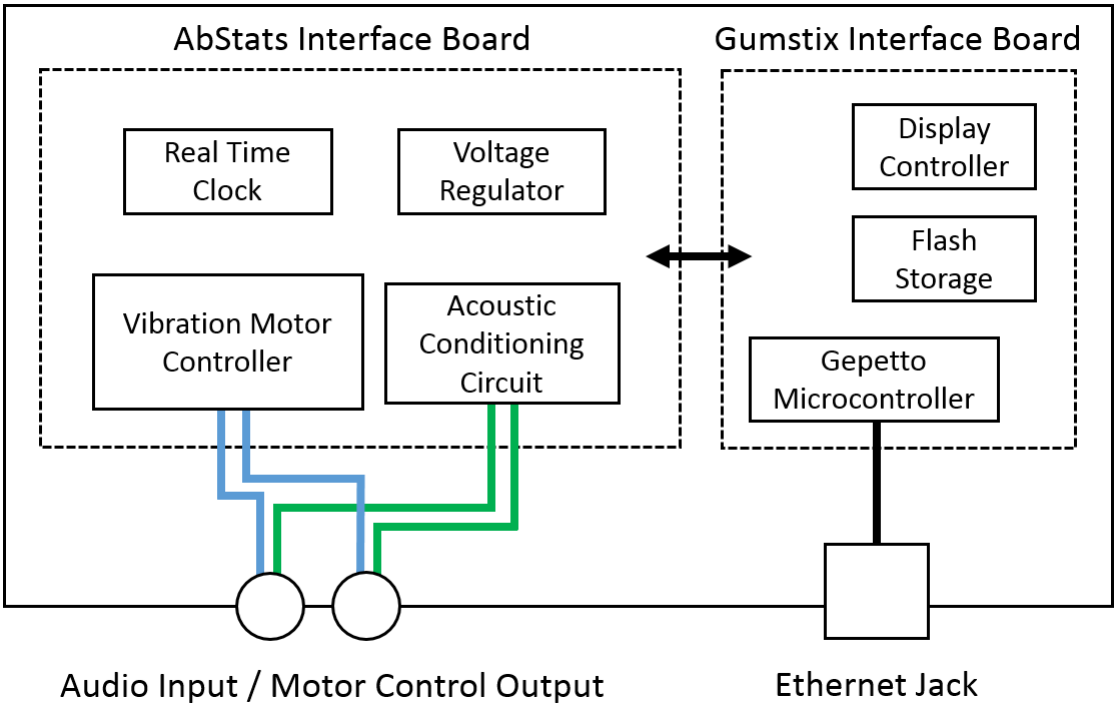


Figure 3.1: Gateway Block Diagram

In this diagram there are two main components inside, the AbStats Interface Board as

well as the Gumstix Interface Board. Each one of these custom PCBs provide a large variety of functionality, and they are both necessary for the overall design. Both boards are housed in an aluminum framed enclosure that allows for an interface between the outside world and the electronics inside. Audio jacks, an ethernet port, a power connector, and a 5 inch touch screen are the only interfaces that the gateway has to the outside world. The design of both the housing and the electronics are described in this chapter.

3.2 Gateway Housing

3.2.1 External Interfaces

To be able to design a housing that can contain the electronics and bulk head connectors requires careful planning. Everything from the PCB layout to the part selection is key to ensure a proper fit and robust design. Considerations to how the physicians and end user will interact with the device is also a consideration to make the final product compelling to use. The current design of the gateway is illustrated in the Figure 3.2 below.

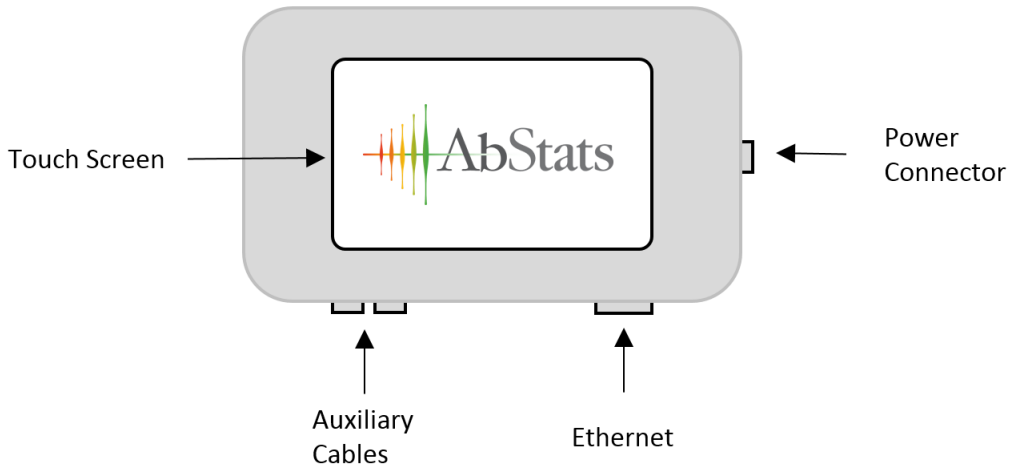


Figure 3.2: Gateway External Features

As seen in the representation of the gateway above there are a number of external features

on the device. There is a capacitive touch screen mounted in the top panel of the aluminum enclosure, as well as a number of ports around the sides. These ports provide a way to power and connect peripherals to the device. There are two audio jacks located close together on the front left of the housing that are used to attach the custom *AbStats* sensors. There is also an ethernet jack on the right side of the front panel to plug into a router or switch, this enables certain internet based services. Towards the right side panel there is a barrel jack where a 5V AC to DC converter would attach to power the device. Overall the external options on the device enable the user to place the device on its back, while still gaining access to all the ports and touch screen.

3.2.2 Internal Layout

The internal layout of the components allow the bulk head connectors to easily interface with the electronics. To be able to attach to each board without straining any connectors was key to make the device robust. Below in Figure 3.3 you can see the different components and how they mount inside the enclosure.

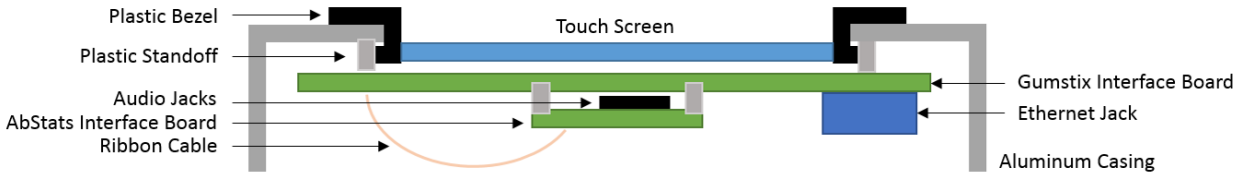


Figure 3.3: Gateway Cross Section Layout

In the figure it is clear how the different boards and the screen are mounted in the aluminum casing. The black bezel in combination with standoffs support the Gumstix Interface board to the screen and housing. From this board more standoffs attach the AbStats Interface Board. A ribbon cable from the AbStats Interface Board connects to the Gumstix Interface Board allowing for communication and power to be passed between them. A short ethernet cable from the ethernet jack on the Gumstix Interface Board is connected to the bulk head connector in the casing. In addition, short auxiliary cables attach the

bulkhead audio connectors to the connectors on the AbStats Interface Board. Not pictured in the diagram above is the barrel jack connector which is wired to the AbStats Interface Board. This connector brings in 5V from an external 5V AC to DC converter. In Figure 3.4 below you can see both interface boards mounted together, as well as the audio cables leading away from the AbStats Interface Board. In addition you can note the 20 pin connectors on both boards which are linked by a ribbon cable.

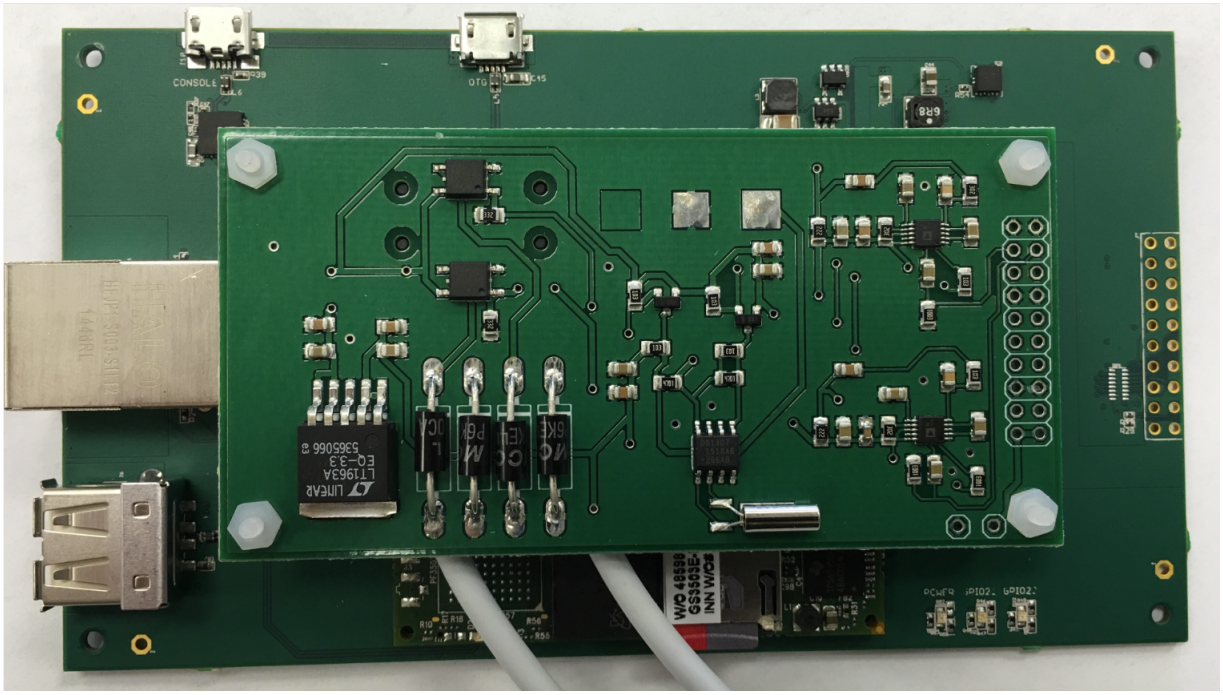


Figure 3.4: Gateway Board Stack-Up

3.3 Gateway Electronics

The electronics in the gateway are critical to enable key functionality. Having a custom electrical solution allows for the design to be specifically tailored for the objectives that needed to be met. For the gateway there are two main components that form the electronics, the AbStats Interface Board, and the Gumstix Interface Board. These two PCBs each take separate roles in the system, coming together to form a coherent solution. The AbStats Interface Board acts as the analog front end to the gateway, while the Gumstix Interface

Board houses all the processing and communication aspects of the device. This section describes the design and implementation of each of these boards and the functionality they provide.

3.4 AbStats Interface Board

The AbStats Interface Board is a completely custom solution designed for the *AbStats* system. It contains the analog front end and extra periphery devices that are not housed on the Gumstix Interface Board. There are three major components to the AbStats Interface Board, audio condition circuits, a real time clock, and motor controllers. In addition there are three headers on the board to connect to. Two of them are the audio jacks that pass through the housing and attach to the sensors. The other one is a 20 pin connector that attaches the AbStats Interface Board to the Gumstix Interface Board via a ribbon cable. These subsystems on the board create the PCB and allow the electronics to function.

3.4.1 Audio Conditioning

When creating the AbStats Interface Board the main function was to properly bias and condition the signal coming from the sensor. The biasing circuitry was left out of the disposable sensor to reduce cost, so the supporting circuitry is in the gateway. This conditioning circuit biases the internal MOSFET in the microphone allowing it to function. To be able to condition the signal the SSM2167 audio preamp from Analog Devices was used [4]. This part allows for the microphone to be properly biased as well as add extra functionality. In addition to biasing the microphone it can noise gate the signal, as well as provide amplification. These two features allow us to simplify the analog electronics on board packing all this functionality into one IC.

In Figure 3.5 below you can see the SSM2167 used in the schematic for the board. In the schematic there are passive components used in conjunction with the IC to enable certain functionality. By changing the values of these passive components the gain as well as the

frequency response of the circuit can change. In this particular application the noise gate was set to -55dB and the gain component of the circuit acted as a buffer. In the schematic you can see the audio signal coming in on the left hand side as "CH1AUDIO", and it leaves the IC on the right as "LINEOUT1". There are two of these chips on the AbStats Interface Board as there are two sensors that need the supporting circuitry.

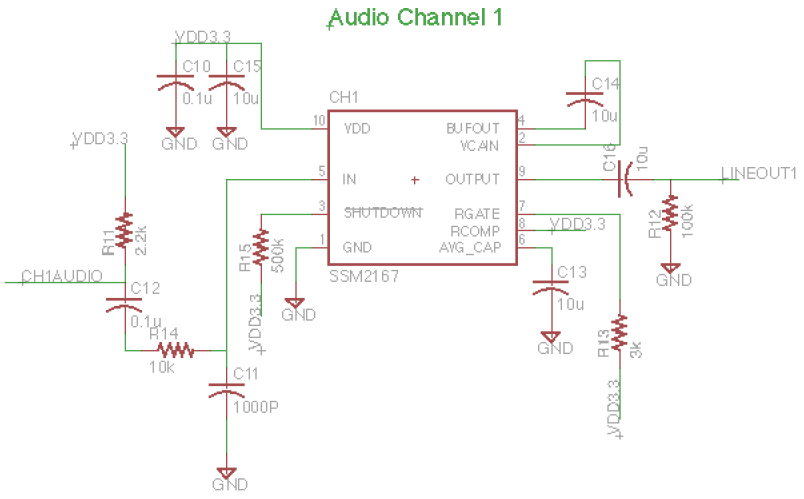


Figure 3.5: Audio Conditioning Circuit

3.4.2 Real Time Clock

In order to keep accurate records of recordings they must be time stamped. Being able to know when a recording was taken is important, and the gateway needs to remember the time even if the device is no longer powered. To be able to keep track of time a real time clock was added to the board. A real time clock is an IC that keeps track of time for an extended duration. These devices are usually powered from a secondary source like a coin cell battery. In the case of this system we used the DS1307 from Maxim Integrated [5]. This IC uses an external crystal and a button cell battery to keep track of the time for up to 11 years after it has been preprogrammed. In Figure 3.6 below you can see the DS1307 used in the schematic for the board. This IC once programmed can communicate back to the Gumstix Interface Board via I2C. I2C is a two wire interface that is commonly used in electronics.

This allows the IC to communicate back to the Linux platform so the time is always known when the device boots up. In the figure you can see the I2C lines on the right hand side of the schematic.

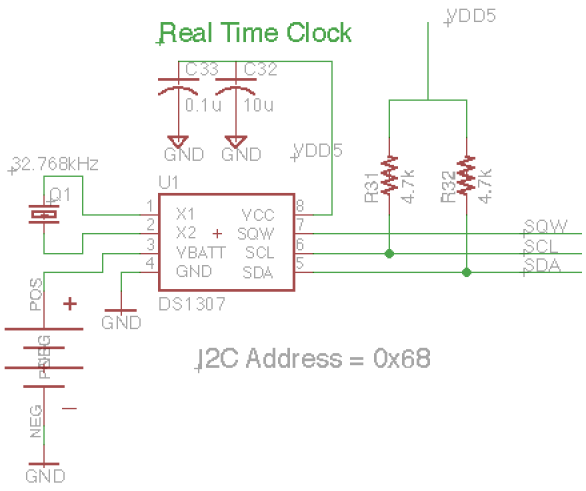


Figure 3.6: Real Time Clock Circuit

3.4.3 Motor Controllers

The final major component of the AbStats Interface Board is the control circuity for the vibration motors. To control the motors a photo relay is used. This device operates by receiving an electrical signal on its control pin and then shorting its other two pins. If a voltage source and the motor are connected to the output pins the motor can be provided with power. The relay chosen to be used in the system is the AQY21 [6]. This relay electrically isolates the input and output of the chip by communicating the status of the input over light. This allows for isolation so if an external voltage is applied to the sensor or connector the electronics inside the gateway are protected.

In addition to the protection gained from the photo relays zener diodes were added to the system as well. These diodes will allow current to flow between its terminals if the voltage between them is too high. This means that if a high voltage is present on the relay or audio signals the diode will sink current to ground so the electronics do not get damaged.

The final aspect of the motor controller is the pull up resistor. The relay is controlled by the microcontroller in the Gumstix Interface Board via a general purpose input output pin (GPIO). This pin can be in an unknown state when the device initializes, and thus could turn the relay on. The pull up resistor ensures that the voltage of the control line is known, and can only be pulled down after the device has properly been configured. In Figure 3.7 you can see the relay, the zener diode, and the pull up resistor.

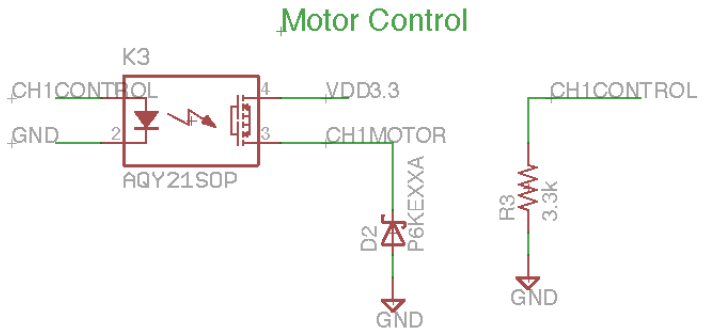


Figure 3.7: Motor Controller

3.4.4 Board Layout

Once the functionality and the components of the board were determined the schematic had to be turned into a PCB layout. Figure 3.8 below shows the layout for the top of the two layered PCB. You can see where the different components described in the previous sections are located. On the board there is also a 3.3V linear regulator to provide clean voltage to the board from the external barrel connector. The placement of the parts as well as the mounting holes were carefully considered to fit into the overall system. The 20 pin connector located at the bottom of the board attaches to a ribbon cable that connects it to the Gumstix Interface Board. This connector relays power as well as signals between the two boards.

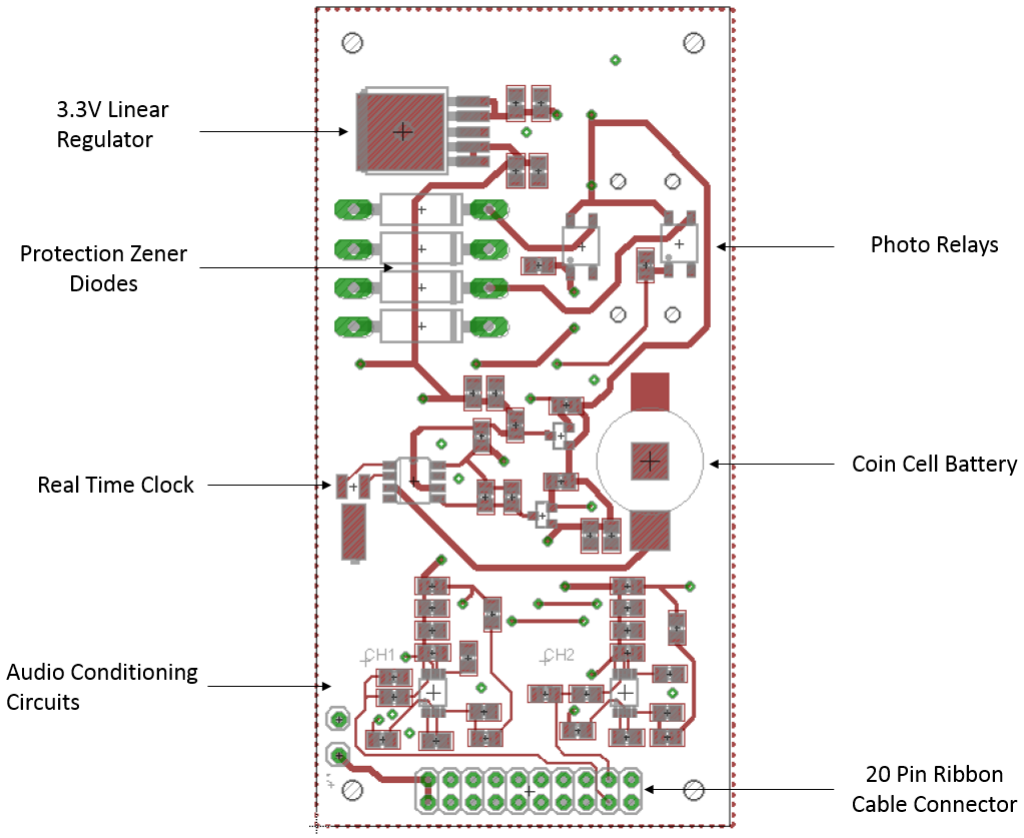


Figure 3.8: AbStats Interface Board Top Side

In Figure 3.9 you can see the bottom side of the PCB. This side only houses the audio jack connectors. They are oriented in a way to connect directly to the external bulk head audio connectors. By placing the audio jacks on the bottom it leaves a clean route to plug in the cables, as well as reduces the overall height of the board in the stack up show in Figure 3.3 above.

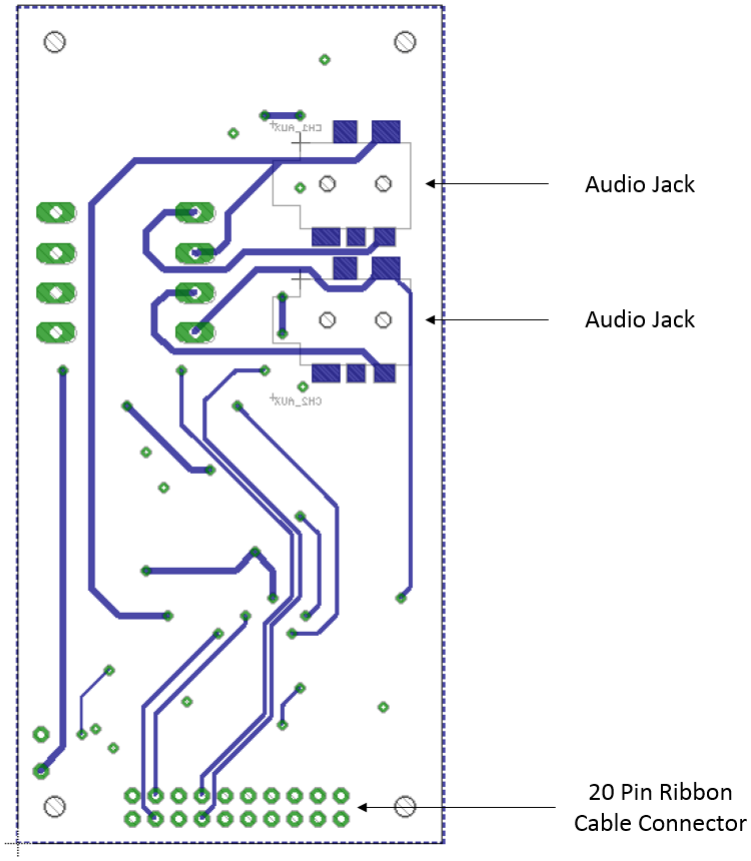


Figure 3.9: AbStats Interface Board Bottom Side

3.5 Gumstix Interface Board

The second major component in the gateway is the Gumstix Interface Board. This PCB connects to the display as well as the AbStats Interface Board. It houses major components such as the Linux Kernel, the ethernet port, the display controller, as well as the on board storage. To construct this board we hired an external vendor that utilizes a web based design tool to create a custom solution. The design time to create a custom display controller as well as a Linux platform would have been excessive with the resources available. Thus using Gumstix as a vendor we designed the solution seen below in Figure 3.10 and 3.11.

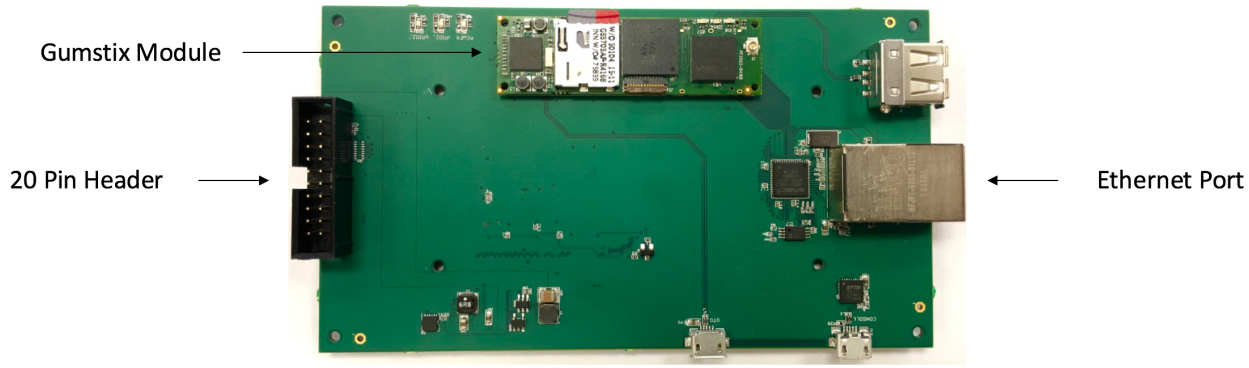


Figure 3.10: Gumstix Interface Board Top Side

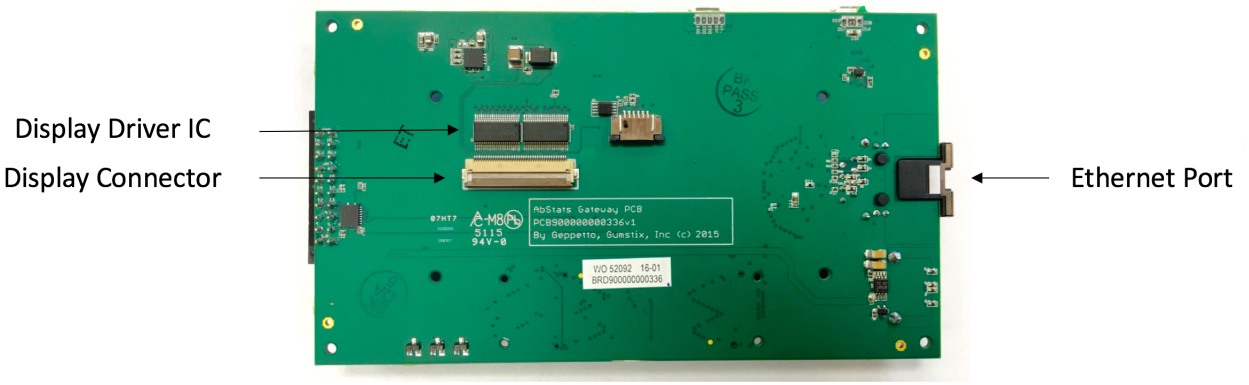


Figure 3.11: Gumstix Interface Board Bottom Side

There are two main portions to this board, the Interface Board and the Gumstix Module. The Interface Board houses the supporting circuitry to allow different periphery devices to work. It contains the circuitry for the ethernet port, the display driver, as well as the 20 pin connector to the AbStats Interface Board. The Gumstix Module houses the Linux platform that controls the system. It has an ARM Cortex A9 microcontroller, a Wi-Fi chip, and SD card slot. This module attaches to the Interface Board providing the Linux platform a way to connect to the system. Together these modules create the Gumstix Interface Board.

3.5.1 Gumstix Module

The Gumstix Module is a small custom PCB that mounts to the larger Gumstix Interface Board [7]. This board can be seen in Figure 3.12 below. This module houses the ARM Cortex A9 microcontroller, a Wi-Fi chip, and a SD card slot. There are two 90 pin board to board connectors on the bottom that mount it mechanically and electrically to the Interface Board. A custom Linux Kernel runs on the ARM Cortex A9 microcontroller. This Linux platform communicates with all the hardware in the system, as well as enables our algorithms [8]. This ARM based board allows for data acquisition with an on board ADC, as well as digital interfaces to communicate with other peripherals. As the brains of the system this module manages all the functionality.

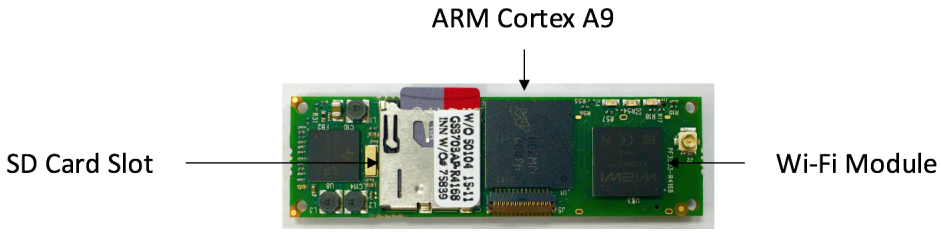


Figure 3.12: Gumstix Module

3.5.2 Ethernet Interface

The ethernet connection in the *AbStats* gateway is the main interface between the physician and the device. Connected to the hospitals network, the gateway communicates with our servers providing a back end that physicians can access. Seen in Figure 3.10 this port connects to an ethernet bulk head connector, which is then connected to an ethernet jack in the hospital room. This ensures constant connection to the network regardless of Wi-Fi connectivity.

The Wi-Fi aspect on the Gumstix Module is only used for over the air updates or diagnostics, and is disabled once the device is shipped.

3.5.3 Display Controller

The other main component of the Gumstix Interface Board is the display controller. Using libraries in the Linux Kernel we can communicate over SPI to the display drivers. These display drivers manage the images to the screen, and control the 5 inch touch screen mounted in the top of the gateway. By knowing where the user is pressing on the screen we can easily create a user interface that requires no additional hardware.

3.6 Gateway Results

The *AbStats* gateway brings together the entire system to meet the goals set out in the initial design. The housing in addition to the custom PCBs created a solution that is easy to use, as well as supports the sensors. Below in Figure 3.13 you can see the completed gateway.



Figure 3.13: *AbStats* Gateway

CHAPTER 4

Manufacturing and Quality Control

4.1 Introduction

Once the design of the early prototypes of the *AbStats* system were completed, we shifted focus to mass manufacturing. This involved finding vendors and creating design documentation to ensure we could produce gateways and sensors at scale. Working with contract manufactures we were able to get the gateway and sensor to vendors who could produce the product per our instructions. Once built the last stage of manufacturing needed to determine if the devices were properly built. To accomplish this, two end of line (EOL) testers were developed for the sensor as well as the gateway. This chapter will dive into the details of bringing the device through manufacturing, as well as how we ensured a working product.

4.2 Manufacturing

To create the *AbStats* system multiple vendors were used to create different parts of the device. Once the different subcomponents of the system were built they were sent to a final contract manufacturer for final assembly and test. Three main manufacturers were used in the *AbStats* system each providing key parts to the overall system.

4.2.1 Advanced Circuits

Advanced Circuits is a printed circuit board part manufacturer and assembler. They take CAD designs to create PCBs and then populate them with components. We worked closely

with them to produce all of our custom circuit boards present in the sensor as well as the gateway. The AbStats Interface Board, and the sensor PCB are both manufactured by Advanced Circuits.

In working with this company we learned many key factors to ensure smooth builds. Proper documentation and communication is key to ensure fast turn times and assembly. Clear communication on turn and assembly times result in clear expectations between the vendor and the group. Ensuring a proper build of materials as well as correct PCB footprints also goes a long way in terms of reducing road blocks in the manufacturing process. Part mismatch to layout footprints could delay boards from shipping on time and adds cost to the build. Knowing the PCB capabilities of the fabrication facility also adds another layer of checks to ensure the design can be produced within the tolerances of the manufacturer.

Keeping these factors in mind we were able to produce large batch runs with Advanced Circuits lowering the cost per PCB, and establishing a method for electronics assembly. Once the PCBs were completed they were shipped to the final contract manufacturer for assembly.

4.2.2 Stratasys

To create the housing for the sensor enclosures we used a large 3D print manufacturer Stratasys. As we are building sensors on the scale of thousands and not tens of thousands, injection molding was too costly looking at price per sensor. Instead using a 3D print house we were able to create large batch builds that provided us with the housings at a break point to be produced at a low cost.

Working with Stratasys was straight forward as we provided the 3D model and worked with them to match the price point we were targeting. It was important to communicate with the vendor to ensure the proper materials and tolerances were used to match our 3D printed prototypes. You can see the finished manufactured housing in Figure 4.1 below. Once produced we shipped the finished housings to the final contract manufacturer for assembly.



Figure 4.1: Sensor Housing

4.2.3 AER Technologies

The final aspect of the build process was to take the materials created by the other manufactures, and off the shelf parts, and assemble it. To do this we worked with AER Technologies to create a manufacturing line to assemble gateways and sensors. Providing them with the raw materials and comprehensive build instructions, we were able to guide them on how to assemble the *AbStats* system. It was key to make the documentation very clear as any step that is not stated can not be guaranteed to be done on the assembly line. Working with their engineers we guided them through the assembly process making sure both the gateway and sensors were assembled correctly.

The final step for AER Technologies once the systems were assembled was to test them. To do this we provided them with two end of line testers described in the next section.

4.3 Quality Control

As *AbStats* is a biomedical device, it is especially important that each aspect of the system is tested. To test the system two end of line testers were built and used to validate the operation of the sensor as well as the gateway.

4.3.1 Sensor End of Line Tester

To test the sensors we needed to simulate an enclosure that mimics the human torso, and ensure that the sensor can operate within specifications. To do this a tester was constructed to see if the sensor could correctly identify a signal source over a specific frequency range. We used LabView to control a NI myDAQ, which is a low cost data acquisition device. This device is able to generate a signal that is amplified and sent to a speaker in an acoustic enclosure. From there the enclosure couples the sound generated by the speaker to the sensor attached to it. The sensor is also connected to the NI myDAQ which interprets the signal coming from the sensor. By performing a fast fourier transform and looking at RMS values we were able to determine if the sensor correctly picked up on different frequencies the speaker goes through. Figure 4.2 shows the system block diagram for this end of line tester.

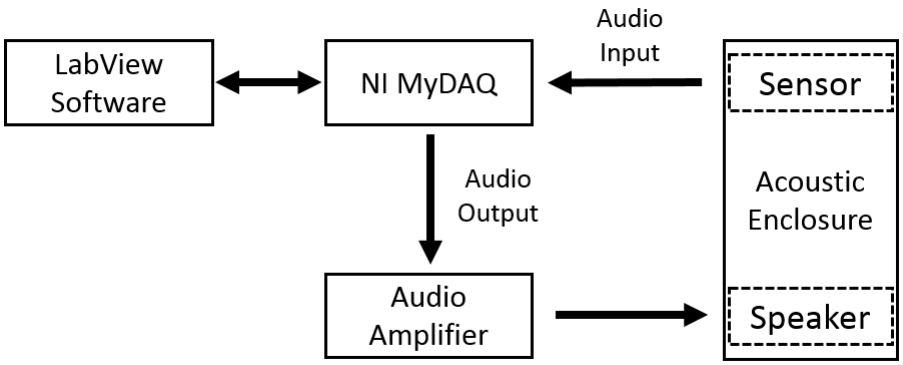


Figure 4.2: EOL Sensor Block Diagram

In this diagram we can see the different components of the system and how they interact. To incorporate this design in the manufacturing line a front end GUI was developed to aid technicians. A technician would place a sensor in the device, hit run, and a green or red light would flash indicating a pass or a fail. If a sensor passes it is packaged and shipped to a customer, if it fails parts are recycled and the faulty sensor is disposed. Below in Figure 4.3 you can see the EOL Sensor tester and where the sensor would slot into the acoustic enclosure.

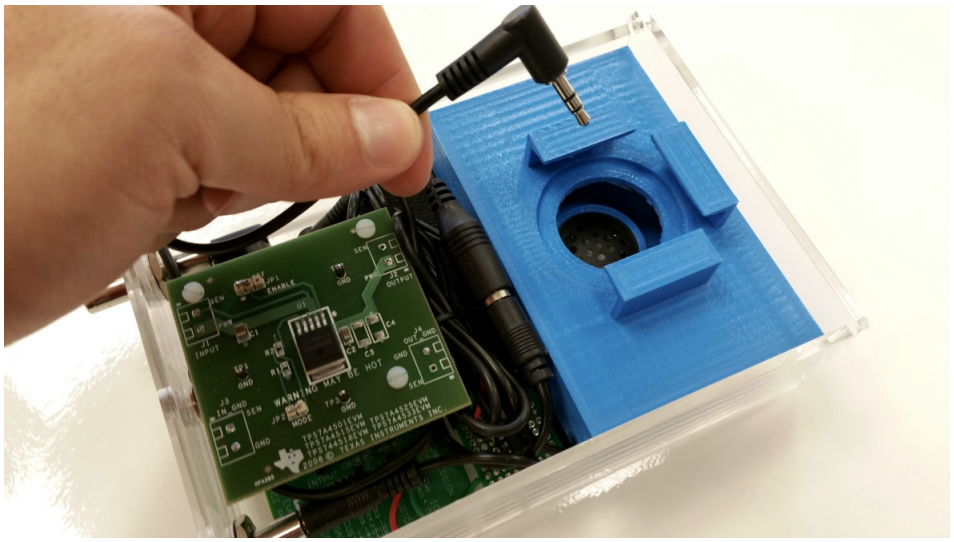


Figure 4.3: EOL Sensor Tester

4.3.2 Gateway End of Line Tester

To test the gateway a sample stimulus is needed as an input. Generating a similar waveform as to what would be seen with a sensor allows our Linux Kernel to diagnose issues if a specific part in the gateway does not function. To accomplish this the EOL tester was built to be able to generate different waveforms. A 555 timer, an IC commonly used for signal generation, was used to create a square wave which can then be filtered into a sine wave. By changing the resistor and capacitor values in the schematic we can alter the frequency, amplitude, and type of wave that is generated. In Figure 4.4 you can see the schematic for the gateway EOL tester.

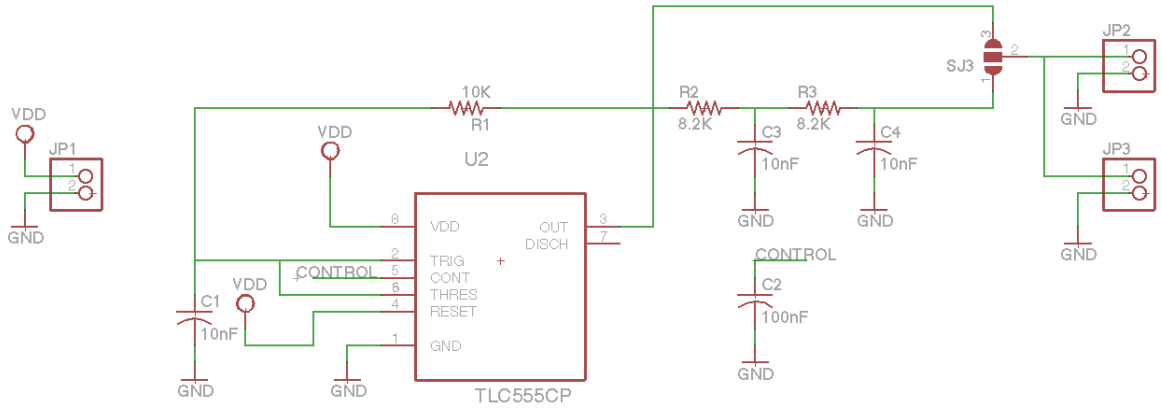


Figure 4.4: EOL Gateway Tester Schematic

Once the schematic for the tester was created the layout needed to be finished with considerations to the testing environment. As this system was going to be used on a manufacturing line the overall layout needed to be small, easy to work with, and reliable. Taking these factors into account the layout was designed as seen in Figure 4.5 and Figure 4.6. In Figure 4.5 you can see through hole headers for a 5V USB plug as the input, and a set of through hole headers for two audio jacks as the outputs. The board draws 5V from the USB plug and is able to generate signals to the two audio jacks. On the other side of the board, as seen in Figure 4.6, there are passives and a solder bridge signal selector. Replacing the resistors and capacitors in this part of the board allows for the frequency to be adjusted. Also by shorting the solder bridge the user can choose to bypass the low pass filter. This allows the tester to generate both sine and square waves. The silkscreen on the board makes using it very clear as each part is labeled and indicates its function.

Once the board has been constructed the audio jacks are plugged into the gateway. Test firmware then confirms the functionality of the device by testing different subcomponents in the system. If an error returns we can pin-point where in the system a fault is occurring.

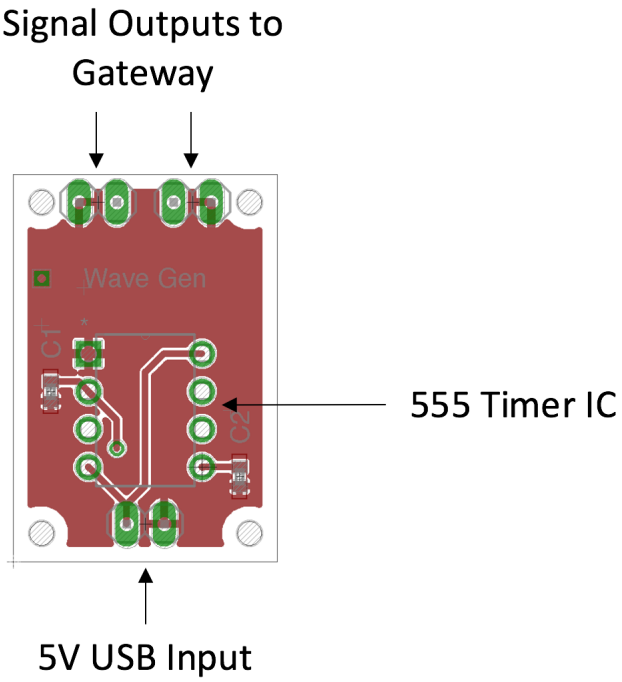


Figure 4.5: EOL Gateway Tester PCB Top Side

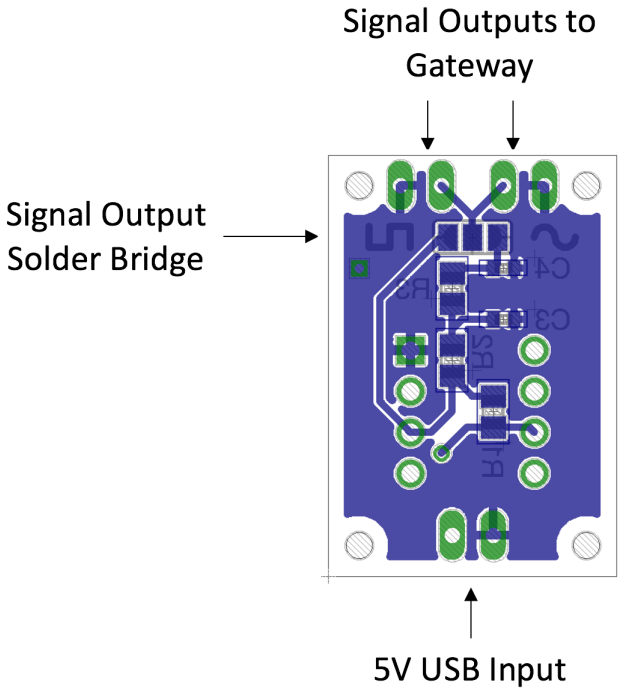


Figure 4.6: EOL Gateway Tester PCB Bottom Side

4.4 Manufacturing and Quality Control Results

Proper manufacturing and quality control are very important aspects of a medical device. By working with contract manufactures and creating a quality control system *AbStats* is able to be produced reliably and quickly at scale. By ensuring proper manufacturing techniques and including EOL testers we could control the quality of the final product. These extra steps in the production line enabled us to ship many *AbStats* systems to hospitals with confidence in their build quality and operation.

CHAPTER 5

Conclusion and Future Work

This thesis presents the development of *AbStats* through its design to final manufacturing. Using custom sensors and electronics *AbStats* is able to detect peristalsis events aiding physicians in their diagnosis of post operative ileus. Through extensive design work and contract manufacturing *AbStats* is currently on the market.

Recently *AbStats* has passed FDA 510(k) certification which ensures that the device is safe and effective. Currently *AbStats* is used in many hospitals in the Los Angeles area such as the VA West Los Angeles Healthcare Center, Cedars-Sinai Medical Center, and Ronald Reagan UCLA Medical Center. This version of *AbStats* aids these physicians in difficult cases where long-term monitoring is a must.

The *AbStats* platform is currently only deployed in clinical settings. Future work includes developing a wearable *AbStats* system that encompass all the functionality of the clinical version. Currently in early prototypes this device would allow patients to be monitored remotely from the comfort of their own homes. Remote monitoring will allow for reduced hospital stays and faster patient recovery, as the patient returns to normal daily activities.

As the medical field moves towards long term monitoring, systems such as *AbStats* prove to be a compelling solution. The design methodology described here illustrates the process of how this novel idea can be implemented into a compelling product.

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