SQVID:

Simplified Quad-Vitals Integration Device

UCF Senior Design Group 1

Sponsored by Philips

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1.0 Executive Summary

The Simplified Quad-Vitals Integration Device, or SQVID, project is a proposed solution to a problem the Philips Company is facing with regards to existing magnetic resonance imaging (MRI) patient connections. Currently, patients facing an MRI scan are monitored for various vital signs both during a scan and during their hospital stay. They are subjected to an array of wires and cablings which are unnecessarily large and only complicate an already uncomfortable situation. In an effort to improve the wellbeing and comfort of patients, Philips seeks a clean remedy to replace the existing spider's-web of cabling that presently exists for their healthcare customers and patients' alike.

There are four vital signs typically monitored during a patient's stay in the hospital, before, during, and after an MRI scan. The signals that are of concern include: electrocardiography (ECG), spot oxygen saturation (SpO2), carbon dioxide (CO_2), and non-invasive blood pressure (NiBP). Two of these have already been converted into a wireless reading device by Philips, however each one goes to a separate battery-powered hand-held, which still adds to unnecessary clutter, as the individual hand held devices simply lay at the patient's side and must be adjusted with every movement of the patient. The SQVID cable solution will incorporate these two signals, with the main objective of converting the others into a similar wireless signal, and all four will converge into a central location at the bottom of the patient's bed. This convergence point will be a single housing device, containing all the electronics necessary to take the signals and wirelessly transmit them to the main software system nearby for the needed manipulation and display.

This central connection box is designed to be no larger than a 1'x1'x1' cube. It is imperative that it be extremely mobile, for it will be traveling with the patient wherever he or she goes. The housing device will have individual connection slots for each vital sign, as the main cable splits into the four signals approximately one foot from its terminating end. All materials used in the construction and prototyping of the connection box and any vital sign cabling used will be subject to Philips' approval and proprietary manufacturing techniques: The Philips Company already has an existing "secret recipe" for their cable fabrication which has been incorporated into the team's design.

The necessary software system is designed with a "plug-and-play" architecture in mind, and is known as the Intelligent Navigation Controller, or "INC". The software system is designed as a simple User Datagram Protocol (UDP) listener capable of graphing and displaying incoming data numerically. Expansion capabilities for multiple signals are endless using this simple structural design. Because not all four vital signs are always necessary, the system could be easily programmed to detect which are connected and thus which need to be monitored. The goal of this architecture is to reduce errors or the accidental misreading of information that is currently caused by human negligence or lack of knowledge regarding the system. The software system can run from a tablet, laptop, or desktop computer based on the needs of the physician monitoring the patient. Within the scope of this project the software system only serves to demonstrate that the newly designed hardware is capable of wireless functionality. It is imperative that all vital

sign data received from the individual monitoring microcontroller within the connection box is accurate and reliable. The software system ensures that these two requirements are fulfilled, in addition to adding consumer appeal and functionality.

While the main objective of the SQVID project is to provide the Philips Company with an alternative, innovative approach to wireless data transfer, the central connection hub has begun to fulfill the cable consolidation requirement. It was designed to house all electronics and all four vital signal connection points in the hopes that future revisions of SQVID will evolve into a marketable product.

2.0 Project Description

2.1 Motivation and Goals

The Philips Company is a leader in the health industry and continually seeks to utilize the latest technology and improve the lives of their customers and patients. In an effort to innovate and ease the stress placed upon patients facing an MRI scan, the already wireless ECG and SpO2 signals served as a model to follow and starting point for a more robust wireless solution as part of the SQVID Project. While these two signals were an improvement over their predecessors, the remaining vital signs, non-invasive blood pressure (NiBP), and CO2, still involved a spiders-web of cabling which hindered patient transport and comfort. The SQVID Project incorporated the existing wireless signals into a more complete system with the NiBP signal fully functional, and the CO2 signal left for future expansion. A prototype software system provided a proof of concept demonstration of the controller's capabilities.

The pre-existing vital signs (ECG and SpO2) were monitored via a battery powered handheld. While this approach provided a portable, effective, and comfortable way to observe a patient's condition, converting the other two necessary vital signs in the same way would have only contributed to unnecessary clutter. It was imperative that the SQVID Project take into consideration extreme mobility with regards to cable consolidation, as well as reliable data transfer with regards to wireless data transmission. These two factors were the driving force for the final design: a small enclosure which resides at the bottom of a patient's bed where each vital sign connects and is transmitted wirelessly to the necessary software system.

The software system is a simple UDP listener with the ability to receive data transmitted from the microcontroller. It displays the vital signs in a familiar waveform manner, with accompanying textual data. It has a user-friendly design which can be easily run on a touch screen interface, allowing health care professionals to get to the information they need effortlessly. It has the ability to run from any Windows device, whether it a tablet interface, a laptop, or a desktop computer, making it easy to customize for a specific need or environment.

Due to the dangers associated with the strength of the MRI magnet, extreme precaution and excessive testing would be required to prove that the SQVID prototype is safe to be used on hospital patients. While this testing was part of the original scope of the project, Philips suggested that only a proof-of-concept device should be of primary concern, and instead the company would take the device and conduct their own testing at a later date, pending the success of the team's finished product. Still, all materials used during development and construction were approved and fabricated by Philips to ensure the quality of their products and to maintain their high standards.

2.2 Project Objectives and Constraints

2.2.1 Cable Fabrication: MRI Safety and Compliance

Within the initial scope of this project a single cable which would encompass all four vital signs was to be used to fulfill half of the consolidated cabling requirement (with the remaining half being fulfilled by the electronics enclosure). The team, unfortunately, did not have adequate time to pursue this goal. The following objectives in **Table 2-1**. are associated with the safety of all patients and healthcare professionals involved in an MRI procedure as well as the accuracy of data obtained from the vital signs being monitored by the SQVID device. These standards would be required for further enhancement of the consolidated cabling system.

Table 2-1: Cable Fabrication Objectives

Objective	Requirement Description
CF-001	All cables used to monitor the four required vital signs cannot interfere with the MRI image. The cable(s) must aim for minimum noise, conductivity, magnetism, etc.
CF-002	All cables must meet Philips' approval and their personal requirements for manufacturing and production.
CF-003	Cable(s) cannot bunch, loop, or perform any other unanticipated movement that would disrupt the clarity of the signal being monitored.
CF-004	Cable length can be no longer than 8 feet.

2.2.2 Connector Choice

The following goals illustrated in **Table 2-2** regard the choice of the connectors used for each vital sign necessary for the SQVID Project. The final SQVID product used Philips' proprietary connectors and thus met all these requirements.

Table 2-2: Connector Choice Objectives

Objective	Requirement Description
CC-001	All connectors must take into consideration the magnetic field associated with an MRI scan and thus cannot interfere with the MRI image. The connectors must strive for minimum noise, conductivity, magnetism, etc.
CC-002	All cables must meet Philips' approval and their personal requirements for manufacturing and production.
CC-003	All connectors must be as small as possible to prevent additional bulk to the central connection box.

2.2.3 Connection Box

The following objectives found in **Table 2-3** address the central connection box or housing device designed to be located at the bottom of a patient's bed and provide connection points for all vital signs that require monitoring.

Table 2-3: Connection Box Objectives

Objective	Requirement Description
CB-001	The central connection box must take into consideration the magnetic field produced by the MRI scan and cannot allow this interference to disrupt the MRI image. The box must be designed for minimum noise, conductivity, magnetism, etc.
CB-002	The central connection box must take into consideration the magnetic field produced by the MRI scan and cannot allow this interference to disrupt the MRI image.
CB-003	The design and functionality of the box must have Philips' approval and meet their personal requirements for manufacturing and production.

Table 2-3: Connection Box Objectives

CB-004	The connection box must be designed for maximum portability. Handles or other additions to ease the transport of the box are of high importance.
CB-005	The connection box must not be larger than a 1x1x1 foot cube.
CB-006	The connection box must be structurally stable and sit at the bottom of a patient's bed without interfering with that patient's comfort or mobility.
CB-007	The connection box must be easily moved, thus weighing as little as possible, capable of traveling with the patient throughout the hospital and never hindering bed transfers or other non-stationary processes.

2.2.4 Embedded System for Central Connection Box

The following requirements in **Table 2-4** address the electrical functionality and programming of the electronic components located in the central connection box.

Table 2-4: Embedded System Objectives

Objective	Requirement Description
ESCB-001	The connection box embedded system must take each signal and perform analog-to-digital and/or digital-to-analog conversion as required for each individual signal.
ESCB-002	The connection box embedded system will handle the to-wireless conversion of each signal and the transmitting of this signal as necessary.

2.2.5 Software

The following objectives in **Table 2-5** address the software system, Intelligent Navigation Controller, or INC, associated with the SQVID Project.

Objective	Requirement Description
S-001	The software system must provide a user-friendly, easy to understand and manipulate interface for healthcare professionals or other users involved in its operation.
S-002	The software system must do any necessary calculations and/or modifications to accurately depict the signal as required for all users operating the system.
S-003	The software system must acquire and display the data with minimal to no user intervention.
S-004	The software system must be extremely reliable and display data accurately.

2.3 Project Requirements and Specifications

2.3.1 Hardware Requirements and Specifications

The following, **Table 2-6,** depicts the SQVID Project hardware requirements and specifications, all of which must also meet the needs and approval of Philips as the sponsor and consumer.

Table 2-6: Hardware Requirements and Specifications

Hardware Requirements Specification	Description
HRS-001	All cabling materials used will be MRI safe.
HRS-002	All materials used in manufacturing the central connection box will be MRI safe (no ferro-magnetic materials).
HRS-003	The central connection box and/or any other devices requiring power will utilize an approved (by sponsor) DC supply.
HRS-004	The central connection box will be a maximum of 1ft. in length by 1ft. in height by 1ft. in width.

HRS-005	The central connection box will not exceed 10lbs in weight.
HRS-006	Each connector used will have a small (that is, no bigger than a 2in. by 3in. rectangle) footprint.
HRS-007	Any and all connectors used will be MRI safe.
HRS-008	The consolidated cable length will be no longer than 8ft.
HRS-009	The central connection box will allow for up to four connections, and will operate with as little as one.
HRS-010	All cabling will resist bending or looping.
HRS-011	All cabling will be robust, that is, able to withstand the typical use of such a cable.
HRS-012	All materials used will be subject to sponsor approval due to the safety of others involved in the final product.

2.3.1.1 **Software Requirements and Specifications**

The following (**Table 2-7**) shows the SQVID INC software requirements and specifications. The "software system" refers to the user's GUI interface, while the "embedded system" is in reference to the programming of the microcontroller.

Table 2-7: Software Requirements and Specifications

Software Requirements Specification	Description
SRS-001	The software system will be a standalone program with a user-friendly interface for healthcare professionals and all other users.
SRS-002	The software system will perform all necessary calculations and/or modifications to the signal received with little-to-no user intervention.

Table 2-7: Software Requirements and Specifications

SRS-003	The software system will perform in real-time.
SRS-004	The software system will display reliable, accurate data, in a familiar and/or easily understood way for all users.
SRS-005	The software system will attain the wireless data sent from the central control box electronics/embedded system.
SRS-006	The software system will be reliable, that is, completely functional without errors or performance interruptions.
SRS-007	The embedded systems software will convert from analog-to-digital or digital-to-analog as necessary.
SRS-008	The embedded systems software will handle the converting and transmitting of the wireless signal(s) to the software system.

3.0   Research Related to Project Definition

3.1   MRI Background Information

3.1.1   Sensors Utilized

NiBP – Blood pressure monitoring is the process of recording data about a patient's arterial pressure and, in turn, data about the patient's heart. There are two categories of monitoring a patient's blood pressure; invasively and non-invasively. Within those, there are multiple methods of acquiring the data. See **Figure 3-1**.

Invasive blood pressure (IBP) monitoring means the patient's skin must be breached and a device is directly interacting with a patient's blood. This is, of course, a more critical procedure when dealing with patient safety in the chaotic environment of a hospital. This method would not be advised if other safer options are available or blood pressure is not of concern during the patient's care. Fortunately, a safer non-invasive method is available and usually more appropriate to use for most patients.

Non-invasive blood pressure (NiBP) monitoring is the most commonly practiced category of blood pressure monitoring. "Non-invasive" means that the data is recorded from outside the patient's body. Nothing is required to break skin or enter the patient's body to get a reading. To monitor a patient's blood pressure non-invasively, a cuff is placed around the patient's bicep and is filled with air, cutting off circulation of blood through the brachial artery. The pressure of the cuff is slowly released and at a certain

pressure, blood will push past the tourniquet. The point at which blood first pulses past the tourniquet is called the systolic pressure and it is important that this value be recorded accurately. The blood is slowly released into the artery and, as the heart pumps, distinct pulses of blood pressure can be measured. As the cuff deflates, it loses force against the artery and pressure waves become less prominent. The point of the last measurable wave of pressure is called the diastolic pressure and it is also an important figure that should be recorded accurately. With both systolic and diastolic pressures measured, a doctor or trained physician can make an assessment of the patient's heart and its health.

Figure 3-1: Sample NiBP Signal
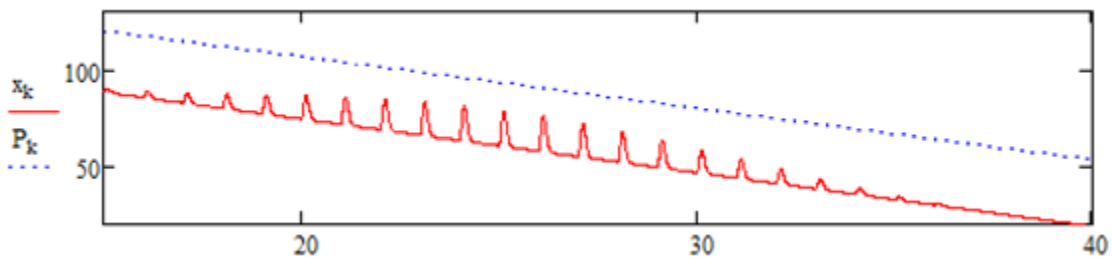
Within the non-invasive category of blood pressure monitoring, two methods of gathering data are most commonly practiced. The first, a very manual and judgment based method, requires the physician to listen for the first pulse of blood to pass the tourniquet with the use of a stethoscope. The turbulent initial spurt of blood makes a sound, referred to as the first Korotkoff sound, and this marks the systolic pressure. The physician then continues listening and marks the last audible pulse (fifth Korotkoff sound) as the diastolic pressure. This technique's accuracy is reliant on the physician's judgment and this is not the technique our project will encompass, but testing the accuracy of our design may require the use and comparison of this method.

The second method uses the same pressure cuff but reads changes in the cuff pressure by way of a pressure transducer. With proper signal analysis and computation, the patient's blood pressure can be monitored precisely, accurately, and, most importantly, remotely. A physician does not need to physically interact with the patient (aside from applying the cuff) to obtain the data. This is the preferred method of monitoring most patients' blood pressure. With the data being read into a computer, the pulses can be visualized and past data can be stored to show changes in behavior over time. This data can be very useful in patient care. Our project will be implementing this technique of blood pressure monitoring.

ECG--An electrocardiogram (ECG) is a non-invasive recording of a heart's electrical activity. The monitoring of a patient's heart and its behavior is crucial and can provide physicians with a lot of information about its health. See **Figure 3-2**.

With every muscle contraction, there's a system of nerves instructing it to do so. These nerves, as do all nerves, use cellular and extra-cellular ion concentrations to create potential differences on the scale of millivolts. These potential changes are propagated down the nerves, to and from the muscle. The human heart uses a lot of muscles to pump blood throughout our bodies and these muscles are being controlled by a lot of nerves. The ECG leads read the signals from these nerves and, with this data, a visual representation of the heart's activity can be produced and analyzed. Physicians often need to know how a patient's heart is behaving to diagnose any complications or be sure a procedure is going smoothly. A heart's muscle contraction is a time sensitive cycle so differently timed contractions can mean a heart is operating correctly or not.

A cardiac cycle can be broken into three distinct waves. The P-wave marks beginning of the cycle and occurs over approximately 80 milliseconds. Next, the QRS-complex is the most prominent feature of the cardiac cycle and the heart rate is usually calculated based off its peaks. The QRS-complex lasts about 100 milliseconds, but can vary from patient to patient. The last distinct wave is the T-wave and it can reveal a lot of information about the heart's condition. The T-wave is the period where the heart's ventricles are recovering, or repolarizing, back to restart the cycle. The shape of the T-wave is particularly important to preserve.

Figure 3-2: Sample ECG Signal
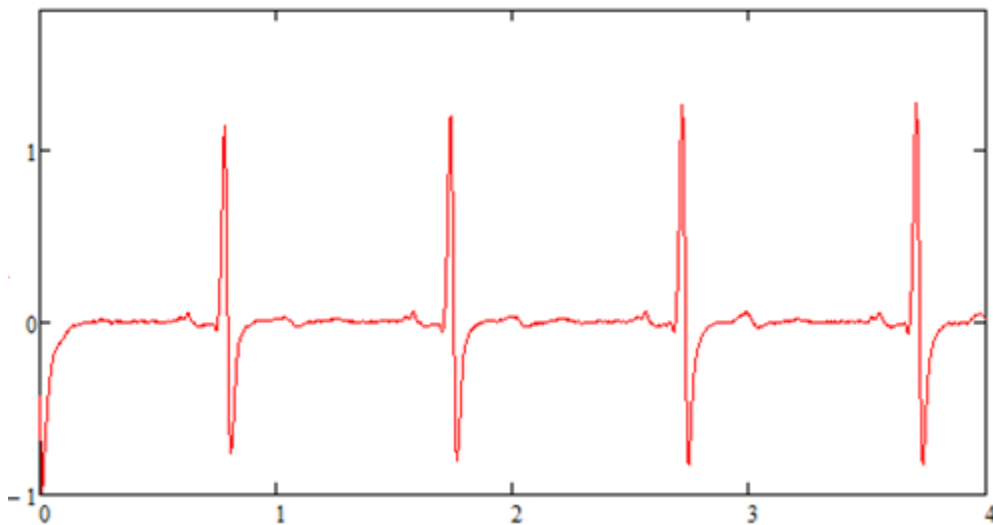
Since the signal corresponds to the motion of the heart, the shape of the graph is an important aspect to preserve and provide to the physician as accurately as possible. This means extra efforts may be required to prevent noise from entering the system and to filter out the noise that does become present. An ECG requires a number of electrodes (two may suffice, but five is common) to be placed on the surface of the patient's skin in certain locations around the torso. These electrodes are sensitive enough to pick up the electrical activity of local nerves, so, in turn, they are sensitive enough to pick up a lot of noise. Noise can be an even larger problem when monitoring within an MRI.

SpO2--Pulse oximetry measures a patient's saturation of peripheral oxygen (SpO2). This is a non-invasive method of measuring the concentration of oxygen in a patient's bloodstream. Lack of oxygen in the bloodstream leads to organ failure and possibly death, so it is important for physicians to be notified when saturation levels drop. Healthy levels of oxygen saturation are around 95-100 percent. See **Figure 3-3**.

The device used to monitor SpO2 is called a pulse oximeter. The oximeter clips, non-invasively, onto the patient's fingertip or earlobe and records oxygen saturation via photosensors (typically infrared or near-infrared). Inside the clip are two LEDs and the photodiode. The LEDs use different wavelengths that interact with blood-saturated oxygen differently (one is absorbed more so than the other). The light is shined into the clipped appendage, may it be a finger or ear, and the photodiode receives the levels of the two wavelengths and sends the data to a small processor. Little processing is required to give an accurate SpO2 reading; the signal just needs analog-to-digital conversion and those values can correspond to a lookup table. The processor is located within the clip in some models, but it is best to keep the processor out of the magnetic field when being used in an MRI environment so the data is run to a small device away from the patient.

Figure 3-3: SpO2 Sensor
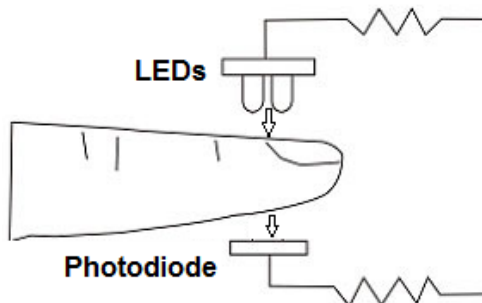
Since the magnitudes of light sources are the values being measured, optical fiber can be used to carry the signal to a photodiode away from the magnetic field. Using an optical fiber is ideal because it is not conductive and will not interfere with the MR imaging.

CO2--A capnogram measures the CO2 concentration in a patient's respiration. Its measurements are based off the partial pressure of carbon dioxide versus other gases in a patient's exhale. The electronics used consists of an infrared LED and a photodiode along with the processing tools. A mask is placed over the patient's mouth and nose to contain the respiratory gases and the gases make their way to the sensor as the patient breathes.

Similar to an SpO2 monitor, the LEDs pass their light through a material (in this case, respiratory gas) and the photodiode picks up the intensity of light that has not been absorbed by the material. Carbon dioxide is known to absorb infrared radiation and the

partial pressure can be calculated from the amount of infrared radiation absorbed by the gas.

3.1.2 Signal Paths and Systems

3.1.2.1 Multiple Sensor Environment

When a patient is in such a condition that requires four vitals (ECG, SpO2, NiBP, and CO2) to be monitored simultaneously, the mess of cables running from patient to monitor can become bothersome and even hazardous. This is especially so if the patient needs to be moved through the hospital or into an MRI. These vitals used to each require a hard connection to the monitor, which could easily get tangled or caught on something. Currently, though, two of these vitals can be monitored remotely. Philips has wireless solutions in place for ECG and SpO2 monitoring and both are MRI safe. The remaining two vitals, NiBP and CO2, are still using hard connections running to the monitor. Even though half of the troublesome cables are eliminated from the equation at this point, the monitor still has to be physically attached to the patient and it's still a hassle for nurses or physicians to work around in an emergency situation. Our goal, as stated before, is to completely eliminate the hard connections to the monitor so vitals can be supervised from anywhere.

With such critical information at stake, it is important that each monitor's data transmits cleanly to the display and is calculated correctly. This becomes increasingly trickier to ensure with the more signals being received at the monitor. If each signal were to be transmitted independently and received at a sole monitor, their frequencies would have to not interfere with one another.

In the case of this project, consolidating the sensors to a common hub, many other factors could become an issue with multiple signals needing independent transmission. For example, the added hardware for each RF transmitter inside the hub requires space to be mounted, which takes away from the concept of consolidation. One possible perk to having each signal transmit through separate hardware would be that, in the event of some hardware component failing, the other signals could remain intact while the malfunctioning hardware could be swapped for a backup. The idea of keeping each vital's signal separate was a consideration for the convenience of troubleshooting. However, our goal is consolidation so that's what our design will be: one consolidated and portable device.

As a matter of scope, our primary consolidation efforts will be focused on the transmission of the two soon-to-be wireless signals, NiBP and CO2. The merging of the signals will take place in the microcontroller after the post-sensor analog waveforms are passed through the analog-to-digital conversion program coded into the microcontroller. Once both signals are converted to digital information, they can be transmitted through one channel by way of time-division multiplexing. Time-division multiplexing is essentially transmitting one signal at a time over one channel but taking turns doing so.

Each signal is transmitted for a certain duration and gets cycled through at a rate dependent upon the number of signals to be transmitted. At the receiving end, a synchronized receiver separates the signals and passes them to their desired destination in chunks. Each additional signal slows the overall data transfer rate of a single signal by a proportion of 1/N with N being the number of signals. Since we're multiplexing two signals, the overall data transfer rate for one of the signals would be one half of that if it had a channel to itself. The data should be sending and receiving fast enough to where even half its potential speed would be close enough to real-time for physicians to react in a timely manner.

As the scope of the project grows, more facets of the system will become consolidated. Ideally, we would like all four signals to be integrated into one device and transmitted together but the wireless solutions currently in place operate just fine so there's no need to rework them. The next step up consolidation-wise would be to combine the physical cables into either an organized grouping or to actually fabricate a new all-in-one cable that bundles everything into a single bus.

3.1.2.2 Cable Requirements and Usage

In order to be useful in an MRI environment, all cables must be:

- invisible to the MRI if used inside the imaging area
- adequately shielded from magnetic field if housing a conductor
- sufficient length for patients of various height
- managed in a way that avoids forming loops
- unable to accumulate uncomfortable/hazardous levels of heat from RF radiation

The materials that cannot be used or that are highly advised against using are: Iron, nickel, cobalt, chromium, gadolinium, dysprosium, steel, and some medical grades of stainless steel. Some non-magnetic forms of stainless steel can be made magnetic if altered slightly, including aluminum, tin, titanium, gold, and lead. This is because most metals are not purely made and have impurities that can only be found through the use of a permanent magnet to test how it affects the material before using it in a MRI.

3.1.3 Electromagnetic Field Environment

Other than the strong magnetic field that the MRI causes, it also sends out strong Radio Frequency (RF) pulses that can be built up in conductive materials and cause burns [2]. The MRI's strong magnetic field can pull any metallic item towards the center of the magnetic bore of the MRI [1]. "Metal devices also absorb RF energy and make become hotter than the surrounding tissue" some lead problems to keep in mind are some that

were filed with the FDA [3]. The sections below cover a list of factors that need to be considered before devices enter the MR Field.

3.1.3.1 Static Magnetic Field Spatial Gradient

A strong magnetic field constantly permeates throughout the room reaching levels of three Teslas or 30,000 Gauss. As the distance from the bore of the MRI machine increases the magnetic field strength greatly reduces and that yields a sizeable spatial gradient. In addition, things may want to align with the poles produced by the magnetic field, just like playing with two bar magnets, and thus induce a torque on various ferromagnetic materials introduced into the room of the MRI machine. The motion induced by the magnetic field can be hazardous not only to people, but small materials in devices, because if they are not secured properly, they could spin in and/or be ripped from the device they inhabit. Also, materials that are usually inert in a magnetic field may have their properties changed when bent or geometrically changed; therefore, care should be taken to all materials that have been changed from raw state because they could start out inert and become magnetic after that change.

The Static Magnetic Field and Spatial Gradient created from the static field can also induce dizziness and/or nausea, reminiscent of vertigo, when a person's head moves quickly near a powerful three Tesla, or higher, field near the magnetic bore of the MRI machine since electrical currents may be induced in the brain because of the high speed movement [6].

3.1.3.2 Pulsed Gradient Magnetic Fields

This is used for signal localization, and when it is applied the magnetic field intensity changes quickly which results in a magnetic field varying by time. This change resulting in a time-varying magnetic field induces a voltage in electrical conductors which could be hazardous to several types of equipment used in the MRI room on in the bore of the machine. Such as the analog to digital converter, if not properly shielded, then converted results may come out faulty due to incorrect voltage measurements that may have been skewed by the added voltage noise induced from this pulsed gradient.

Pulsed Gradient Magnetic field also generates high acoustic noise levels that are extremely strong in the center of the bore of the MRI machine. This strong noise could cause many ailments ranging from a ringing noise in the ear, tinnitus, or causing permanent hearing loss [6]. Ways to prevent these ailments are listed in the Risk Management section.

3.1.3.3 **Pulsed Radio Frequency**

Used to induce Magnetic Resonance signals from tissue in patients; however, in medical equipment, it can induce electrical currents in conductive materials. This induced current could heat up materials and cause surrounding material, if it has a low melting point, to melt or warp. This induced current could ultimately destroy equipment, like melting a printed circuit board or warping the board permanently, which could cut off connections, ruin results or stop result collecting all together.

Operating a device in the MRI machine room results in noise production not conducive to electrical systems, not only distorting the MRIs signals but the device itself. The noise could prove hazardous for patients and the device by giving incorrect results to both which leads to incorrect assumptions.

3.1.4 **Potential Hazards**

The FDA showed some incidents with horrific results when factors were not considered in the MRI. They are all shown below in **Table 3-1**.

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Table 3-1: MRI Incidents

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MDR-701219
A patient received blistered burns on the finger where a pulse oximeter was attached during MR scanning. A skin graft was required to treat the affected area. (2/27/95)
MDR-591457
A child was burned on their right hand because of an ECG cable on the bare skin of the patient while the patient was under anesthesia. Since the patient was under the effects of the anesthesia they could not move, and thus a skin graft was done in order to repair the affected area. (1/26/95)
MDR-175218 [4]:
Another patient with an implanted cardiac pacemaker died; however, the reason of death was discovered to be due to an interruption by the MR system. (9/18/89)
MDR-100222 [4]
An iron filing in a patient's eye was moved during an MR scan that concluded with the patient losing appropriate vision in the eye which held the filing. (1/8/85)

Table 3-1: MRI Incidents

MDR-405200 [4]:
A nurse brought a pair of scissors into the magnet room that was pulled from her grasp and pulled into a patient's head causing a cut on the patient's head. (8/2/93)
MDR-19168 [4]:
Two Forklift tines, 80 lbs each, were accelerated, by the magnet, towards a technician and the impact of the interaction between the tines and the technician propelled the technician over 15 feet resulting in grave wounds to the technician. (6/5/86)
MDR-183981 [4]:
RF noise was present in the MRI room which yielded incorrect data acquisition for a patient, and it resulted in a surgery being performed on the patient based off of faulty data. (1/30/90)

3.1.5 Risk Management

There are certain measurements that can be taken to prevent things from going wrong during an experiment. As this environment involves a gigantic magnet that is continually running the room that could cause multiple incidents ranging from propelled ferromagnetic materials to heat conductive materials that can get as hot or hotter than/as curling irons. Listed below are steps to take in order to prevent incidents from occurring:

Concerning the pulsed gradient magnetic field which causes high acoustic noise in the MR environment, Work Safe in Victoria, Australia has suggested that the following exposure levels in **Table 3-2** be followed to prevent hearing loss and other hearing related injuries [6]:

Table 3-2: MRI Exposure Levels

Exposure Level dB (A)	**Exposure Time**
85	8 hours
88	4 hours
91	2 hours

Table 3-2: MRI Exposure Levels

94	1 hour
97	30 minutes
100	15 minutes
103	7.5 minutes
106	3.8 minutes
112	57 seconds
115	28.5 seconds
124	3.6 seconds
130	0.9 seconds

Some solutions to increase the time to tolerate being in a high noise MR environment would include wearing noise cancelling headphones (non-magnetic) and to carefully follow the chart above to prevent hearing loss or potentially worse injuries.

To ensure that dizziness does not happen to a patient, technician, or others involved in the MRI procedure, all who are near the machine should be cautious. Especially if close to the bore of the machine, all should beware of moving their head or body too quickly in the MRI machine area. Sensitivities may differ from person to person so it is possible that even a two and a half Tesla environment could cause a person making rapid movement within range of the machine to experience vertigo.

To guarantee that metal "missile" projectiles do not occur in the MR environment, personnel should be screened for ferromagnetic materials before entering the area. If any metallic or ferromagnetic materials are detected, any and all material must go through a test to resist at least 1000 Gauss to be declared MRI SAFE or MRI CONDITIONAL [6] if the individual wishes to continue into the environment. Otherwise, no magnetic material should be allowed into the MR environment.

Also, any ferromagnetic implants such as cardiac pacemaker, dental implant(s), or bone replacement alternative should not be allowed into the MR environment due to the Static Magnetic Field and the Spatial Gradient. Implants can be dislodged from personnel and cause internal ruptures, bleeding, bruising, other serious injuries, and in some cases death. The Radio Frequency Field can cause heat to build up in the implant if it is conductive which could result in internal burns ranging from first, second, and third degree.

3.2 Existing and Similar Projects

3.2.1 Shared Resources

There are many resources available for projects of a similar nature. Make magazine has published an article on a do it yourself blood pressure monitor which gives good insight into the signal filtering and amplification before passing into the microcontroller. The project described in this article differs in that the processor used was a PIC microcontroller, and the processor to be used for the SQVID is a MSP430 microcontroller.

Additionally, there are a few carbon dioxide sensor projects though none seem to be based on the same hardware as used in the SQVID. The challenge will be to integrate both sensed values into a single multiplexed data stream.

To start as a base platform for the signal analysis, the blood pressure circuit used in the project named above is examined. The initial filter and amplification stage will follow a very similar technique.

3.2.2 Content Similarities

The similarities of the blood pressure project published in Make magazine to the SQVID system are within the signal acquisition and amplification process. Because the microcontrollers are different, the signal handling beyond acquisition will follow a different process. The amplification and filtering process will be studied and modified to suit this project.

Because the CO2 sensor does not have as many readily available resources, a more unique approach must be used to successfully integrate the signal. The sensor will sit at the end of the consolidated cable system in order to make the cable system non-disposable. The tubing must then extend from the patient to the sensor. The unique approach for the handling of this signal then will produce new knowledge and prove a viable method for signal communication.

3.2.3 Consolidated Cable Systems

Consolidation of the various cables in this project is a major focus, and a custom cable will be developed to meet the needs of this project. The availability of resources for cable consolidation is wide, and no difficulty is expected in obtaining a set of specifications for the cable system.

3.2.4 **Wireless Systems**

There are some systems that already have wireless solutions to some of the sensors. Philips has wireless solutions for the ECG in the MR environment along with the SpO2 sensor. Philips says the leads are nearly invisible to the MRI machine when on patients and thus they are perfectly suitable for utilization in the SQVID project.

BIOPAC Systems, Incorporated have a wireless solution for the non invasive blood pressure (NiBP) sensor that is also useable in an MR environment. BIOPAC Systems, Inc. calls the system NiBP-MRI; It is a monitoring system that tracks the blood pressure of a patient utilizing pulse-decomposition analysis (PDA) technology and it also monitors heart rate. During the MRI scan, this device will give beat-to-beat results in real-time. The basic features of the NiBP-MRI are listed in **Table 3-3** below [11]:

Table 3-3: NiBP Wireless Features

NiBP-MRI Main Features [11]	Description
Feature 1	Utilizing WiFi technology, the device sends blood pressure data from Care Taker blood pressure processing unit to the computer.
Feature 2	The real-time data is used to create systolic and diastolic values which are available from two D/A channels.
Feature 3	The device can also be used in conjunction with MRI machine recordings.

The NiBP-MRI comes with many more features which range from hardware advantages to software advantages listed in **Table 3-4**:

Table 3-4: NiBP Other Features

NiBP-MRI Basic Features [11]	Description
Feature 1	USB D/A converter and Bluetooth dongle
Feature 2	Automatic blood pressure calibration unit
Feature 3	There is also a HLT100C High-level transducer module that interfaces with an INISO optically isolated input adapter to the MP

	150
Feature 4	Utilizes a PC computer with Windows 7 operating system and sends analog signals back to a BIOPAC MP device or third-party A/D converter.
Feature 5	The device weighs approximately 114 grams
Feature 6	The device can operate for approximately 12 hours on a single battery charge
Feature 7	Experiments have been performed which lead to the result that this device may be used for detecting hemorrhages or the technology may be harvested and utilized in conjunction with something else for the detection of hemorrhages. Results that were concluded because of the properties of the PDA in which it is good for tracking pulse pressure, which is a marker for central hypovolemia (a state of decreased blood plasma).

Even though BIOPAC's NiBP-MRI may be a semi-perfect fit for this project, in addition to the property rights, this device has not been certified by the FDA for clinical use and can thus not be used for medical distribution [11]. However, the significance of this device shows that it is possible to find a solution to the wireless MRI NiBP sensor problem.

Philips has also found a wireless solution to the NiBP; the IntelliVue CL NBP Pod or NBP Pod for short. There are also other wireless solutions in this cable package that Philips covers. The NBP's features are labeled in **Table 3-5** below [12]:

Table 3-5: Philips NBP Intellivue Features

IntelliVue CL NBP Pod Features	Description
Feature 1	Communicates utilizing short range radio (SRR) to an IntelliVue patient monitor or a telemetry transceiver, TRx4841A (x4851A also).
Feature 2	There also a charging station used to charge the pod
Feature 3	The support tool is a PC USB interface that allows access for the

Table 3-5: Philips NBP Intellivue Features

	support tool Mark2 at the charging station.
Feature 4	The IntelliVue CL Transmitter Base Station is used to connect the device for the purposes of upgrading, cloning, or configuring the device and can be connecting via USB cable to a PC that utilizes the IntelliVue Support Tool Mark2. Therefore, the Transmitter Base Station can be powered via a USB or with an external supply station.
Feature 5	Noninvasive solution to wirelessly detect blood pressure on a patient.

A block diagram of the NBP Pod is presented in **Figure 3-4**.

Figure 3-4: Philips NBP Pod
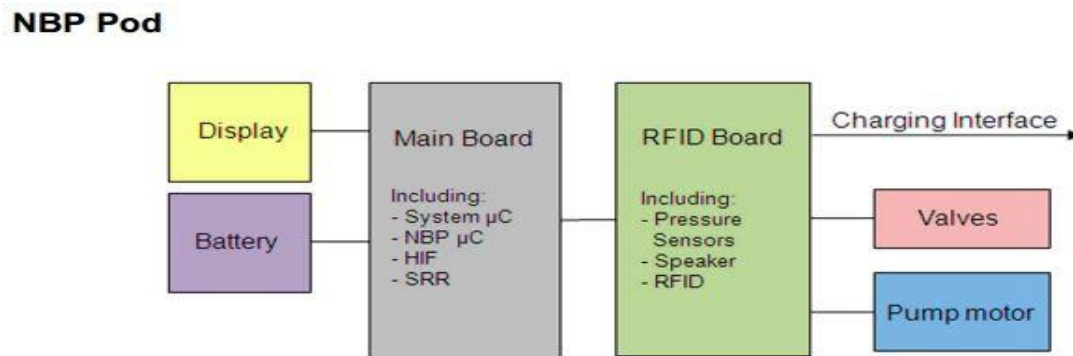
Although this is a wireless solution provided by Philips, it cannot be exposed to strong magnetic fields and thus cannot be used in the Magnetic Resonance Imaging machine environment [12].

3.3 Design-Critical Components and Hardware

3.3.1 MRI-Safe Qualification of Hardware

Not all materials can enter an MR environment. There are tests that must be done in order for materials/devices to be marked safe or acceptable in a MR environment. Tests should address all factors that are present in the environment of the MRI machine (e.g., magnetically induced torque on objects, magnetically induced displacement on objects, heating in conductive materials, etc). Visibly marking the materials or devices should never compromise the purpose of the material/device no matter its size. Some come in varying sizes and shapes, and for those that are not big enough or properly shaped to withstand a sticker or stamp, they should still have some form of safety marking that would indicate whether the material/device is allowable in the MR environment and what precaution to take when operating it. When materials pass these tests they are marked a certain way depending on which tests they pass. This marking system is shown in the figures below [7]:

Figure 3-5: MR SAFE Filled square w/ color

Background color should be green while the letters are capitalized Arial font 'MR' in white with the size that is large as possible without touching the edges of the square.

Figure 3-6: MR SAFE Filled square w/o color

Background color should be black while the letters are capitalized Arial font 'MR' in white with the size that is large as possible without touching the edges of the square.

Figure 3-7: MR SAFE Hollow square w/ color

 Background color should be white while the letters are capitalized Arial font 'MR' in green with the size that is large as possible without touching the edges of the square; the edges will be a frame with a visible thickness, approximately 10% of the side length of the square, the same color as the letters.

Figure 3-8: MR SAFE Filled square w/o color

Background color should be white while the letters are capitalized Arial font 'MR' in black with the size that is large as possible without touching the edges of the square; the edges will be a frame with a visible thickness, approximately 10% of the side length of the square, the same color as the letters.

Figure 3-9: MR Conditional w/ color

The shape should be an equilateral triangle with a background color of yellow and letters 'MR' capitalized in black Arial font with a black frame and letters that are large as possible within the frame without touching the edges of the frame.

Figure 3-10: MR Conditional w/o color

The shape should be an equilateral triangle with a background color of white and letters 'MR' capitalized in black Arial font with a black frame and letters that are large as possible within the frame without touching the edges of the frame.

Figure 3-11: MR Cond. Supplemental w/ color

The shape should be rectangular, have a black frame with a yellow background and black arial font text. The background color yellow which indicates the caution needed for this elected material/device should always cover at least 50% of the total area of the icon.

Figure 3-12: MR Cond. Supplemental w/o color
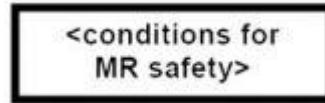
Rectangular black frame with a white background and black arial font text.

Figure 3-13: MR Unsafe w/ color

Circular background of white icon with a, 45 degree inclined from horizontal, red slash through the black Arial font capitalized 'MR' letters that are not touching the frame but are large as the frame can possibly hold, the frame is red and encapsulates the entire circular icon.

Figure 3-14: MR Unsafe w/o color

Circular background of white icon with a, 45 degree inclined from horizontal, black slash through the black Arial font capitalized 'MR' letters that are not touching the frame but are large as the frame can possibly hold, the frame is black and encapsulates the entire circular icon.

It should be quantifiably noted within the markings of what safety tests the material/device passed or did not pass because all MR environments differ in strength, size, magnetic field, etc. Therefore, some materials/devices may behave differently and may or may not work properly in one MR environment even if the device/material originally did work well in a different MR space.

3.3.2   **Availability of Components**

Philips sponsored SQVID and provided most materials needed for the project . They have a secret chemical technique for insulating the leads of the ECG, SpO2, CO2, and NiBP sensors. Almost everything was available for us to sample and test, including two wireless solutions that have already been created for the ECG and SpO2. Access to the CO2 and NiBP sensors was also available to our group including the transducers in the machine that converts the air from the CO2 and NiBP into electrical signals. They had a couple MRI machines for us to run tests off of. Those tests would have ranged from making sure that our devices and materials would not have been magnetized in the MRI room when testing for temperature increases that may be susceptible to RF energy absorption, for example, coiled conductive materials like copper. Overall, a lot of materials, sensors, and devices were provided for our group, leaving only the matter of taking everything that is available and putting it together in a portable solution that is sensitive to the factors of the MR environment and patient comfort.

3.3.3   **Limitations**

In order to be useful in an MR environment, all cables must meet a certain requirements. The requirements are listed in the following subsections, and if not followed could result in problematic situations when designing the consolidated SQVID cable:

3.3.3.1 **Requirements for Cables**

The original requirements were that (requirement 1) they were invisible to the MRI if used inside the imaging area, so the material must be made near completely magnetically porous in order for it to be nigh undetectable in the MRI bore. The second requirement was that they were adequately shielded from magnetic field if housing a conductor, and must do this while still satisfying the first requirement. The third requirement was that sufficient length for patients of various heights, while being shielded from absorbing too much RF energy which could have resulted in heating and thus burning patients. The fourth requirement was that the cables be managed in a way that avoids forming loops while still satisfying requirement 3, so a solution to requirement 3 could not be synonymous to winding of a water hose. The fifth requirement was that the cables be unable to accumulate uncomfortable/hazardous levels of heat from RF radiation

3.3.3.2 **Material Limitations**

Some materials have a high disadvantage in a MR environment, and can change properties or have completely different properties from what they are usually believed to have.

A few highly disadvantageous materials are: Iron, nickel, cobalt, chromium, gadolinium, dysprosium, steel, and some medical grades of stainless steel. Additionally, some non-magnetic forms of stainless steel can be made magnetic if altered slightly: Aluminum, tin, titanium, gold, and lead are just some examples, and this is only because most metals are not made purely and have impurities that could only be found out through the test of using a permanent magnet and seeing how it affects the material before use in a MRI. This does not mean that these materials could not have been used; however, it did mean that extreme caution should have been exercised if we were going to use them inside the MR environment.

4.0 Project Hardware and Software Design Details

4.1 Overall Design Architecture and Diagrams

The system is designed using a modular approach, as the details of equipment provided for integration were not made readily available at the beginning of this project. Initially, we consider signal acquisition process using the sensors named below in **Table 4-1.**

Table 4-1: Sensor Signal Acquisition

Sensor	Measurand	Existing Process
SpO2	Blood Oxygen Saturation	Sensor connects to wireless handheld, transmit to base station.
ECG	Heart Electrical Activity, Pulse Rate	Sensor connects to wireless handheld, transmit to base station.
NiBP	Blood Pressure	Cable directly to base station
CO2	Carbon Dioxide Respiration	Cable directly to base station

The signals are passed into a central hub under the patient's bed, through the SQVID consolidated cable assembly. A major component of this project is the design and construction of this SQVID cable. The requirements of the system specify that the hub should provide plug and play capability, in that it should detect which sensors are attached through different cable sets and respond accordingly.

4.1.1 System Interconnect Diagram

The interconnect diagram for the system is given below in **Figure 4-1.** Of the four sensors, two (ECG and SpO2) will have a pre-existing wireless module that will be integrated into the signal acquisition unit. The other two sensors will use a newly developed platform similar to what is already in place. On the base station/receiver side, the signals will be received and demodulated, before passing the values into the software platform at the patient monitoring terminal.

Figure 4-1: System Interconnect Diagram
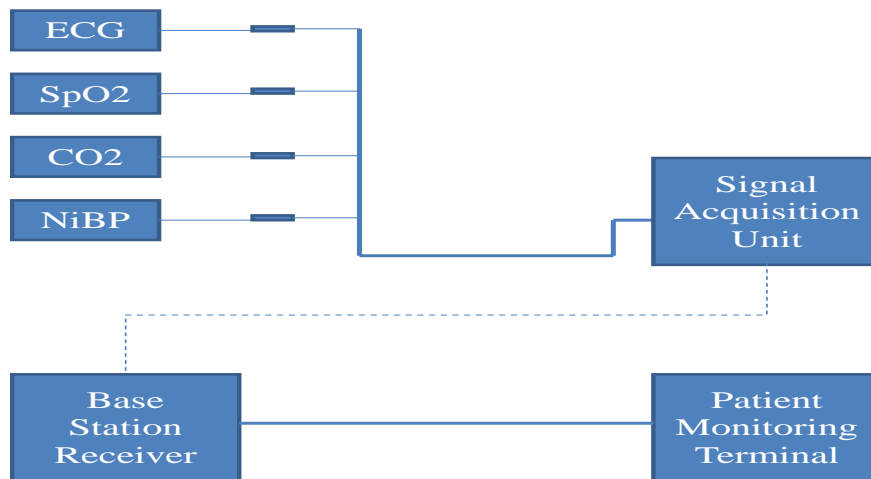
4.1.2 Design Tree and System Flow Down

The design tree for this project can be observed in **Figure 4-2** below. The process of development on the project will follow the top down order of the design tree, with equal effort divided throughout the project amongst the three main subcategories; the SQVID cable assembly, the data acquisition unit, and the base station.

Figure 4-2: System Design Tree
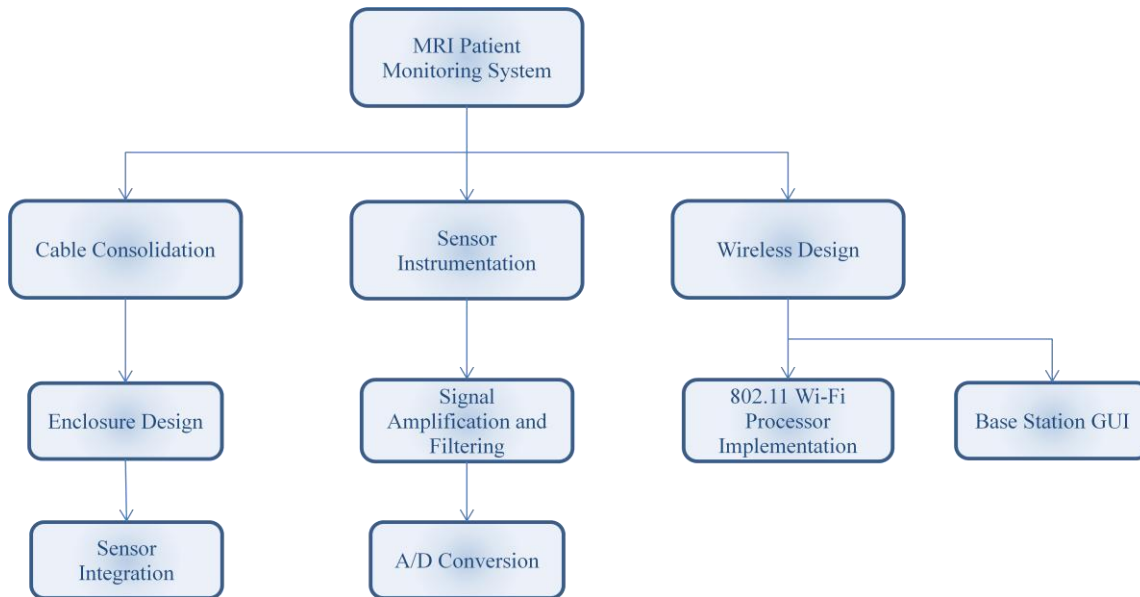
4.1.3 Functional Block Diagrams

4.1.3.1 Hardware

The initial development of the system has been considered as a general feedback controlled bioinstrumentation platform. The system will be designed as detailed below in **Figure 4-3**.

Figure 4-3: Hardware Block Diagram

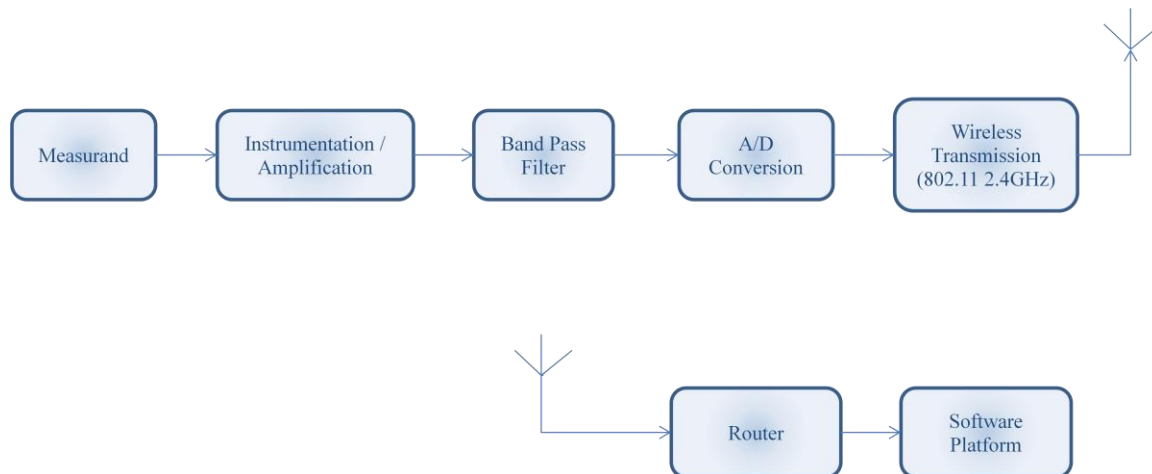Note that the critical path in the above block diagram does not include a wireless component. This shall be considered as Block 0 in development, and the primary goal of this stage is to successfully pass the signals from the sensors to the monitoring platform.

The Block 1 stage of development will most likely be incorporated into the final design, assuming an integration of the developed wireless platform with what is currently in place is possible. Technical details of the current wireless implementation of two signals are currently unavailable.

4.1.3.2 Software

The following block diagram (**Figure 4-4**) gives a basic overview of the functionality of the software program.

Figure 4-4: Software Block Diagram
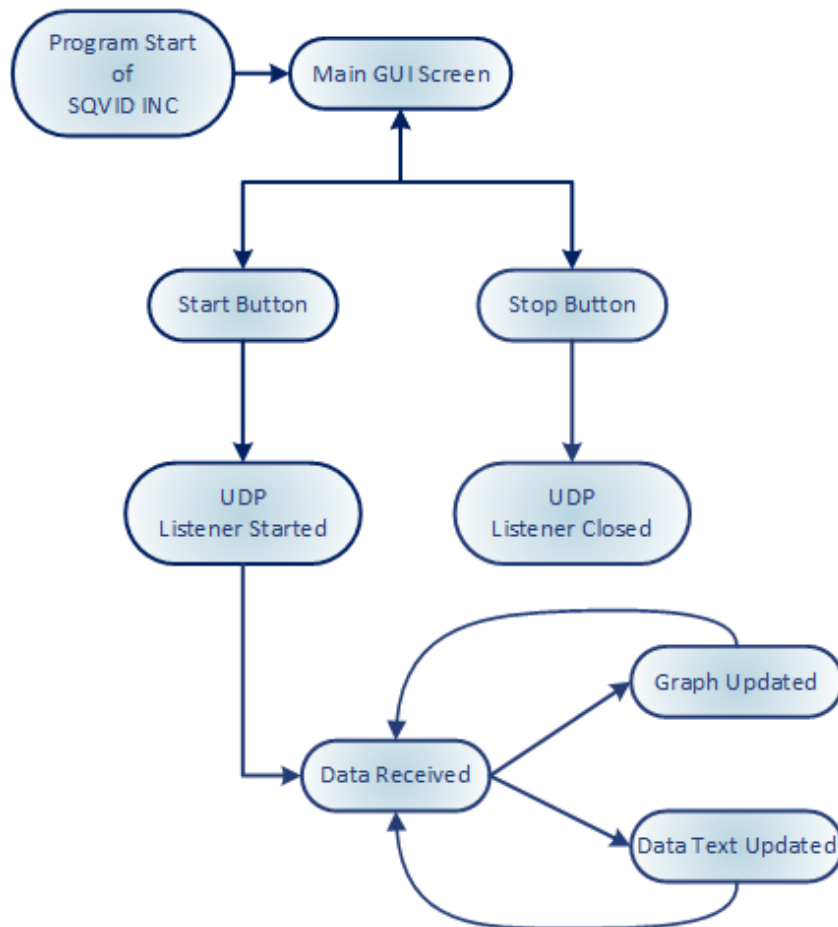
4.1.4 Schematic Drawings

The schematic drawings for the system are in development, and are not yet fully functional. Some of the Philips hardware technical data to be provided for integration has yet to be disclosed and will result in changes to the following design as new developments occur.

The main focus of this project is now on the development of a wireless solution for the non-invasive blood pressure and exhaled carbon dioxide sensors. In order to achieve this end a pressure transducer and carbon dioxide sensor must be used to collect the signal. The signal is amplified and filtered, then digitized and multiplexed before wirelessly transmitting to the receiver.

Using a pressure transducer will require signal conditioning with a band-pass filter, using operational amplifier (op-amp) circuits. The op-amp selected for this purpose is the LM324 Quadruple Operational Amplifier. The circuit for each amplifier within the IC is given below in **Figure 4-5**.

<div align="center">Figure 4-5: Op-Amp Circuit</div>
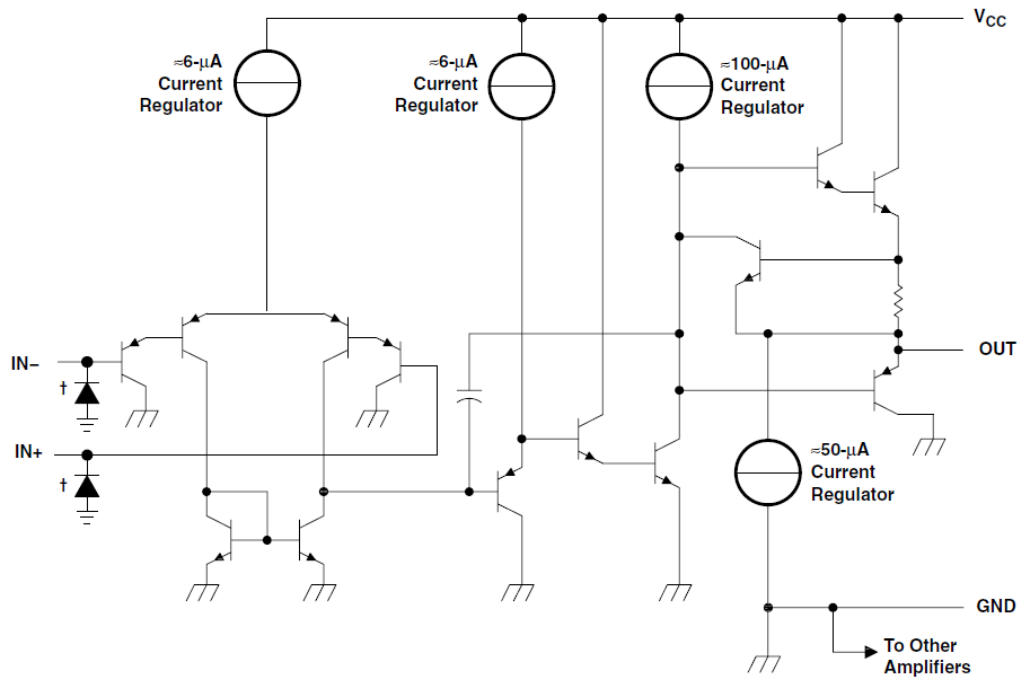
COMPONENT COUNT (total device)	
Epi-FET	1
Transistors	95
Diodes	4
Resistors	11
Capacitors	4

† ESD protection cells - available on LM324K and LM324KA only

Courtesy of Texas Instruments

4.2   Block 0 System Design

4.2.1   Cabling System Materials and Design

The SQVID cable is designed to meet the requirements and specifications of the all-up-round system as listed in **Section 2.3 – Requirements and Specifications**, and follows the particular set of requirements given below in **Table 4-2.**

<center>Table 4-2: SQVID Cable Requirements</center>

Requirement	Description
HRS-UC-001	The cable shall have shielding to reduce interference and data loss
HRS-UC-002	The main SQVID connector shall have a small footprint
HRS-UC-003	The cable shall not exceed 8 feet in length, or be allowed to coil or bunch.
HRS-UC-004	The cable must be durable and able to withstand frequent mating/de-mating and transportation.
HRS-UC-005	No ferromagnetic materials may be used for the cable or connectors

In an effort to meet the above criteria and provide a good fit for the project, a few types of connectors are reviewed below in **Table 4-3.**

<center>Table 4-3: Connector Options</center>

Option	Name	Description
A	**Micro-D Connector**	Very small footprint Difficult to mate Limited plug cycles
B	**ODU Medi-Snap Connector**	Very small footprint

Table 4-3: Connector Options

		Easy to mate
		Proprietary connector type, procurement issues
C	**Hypertronics Clearimage Connector**	Extremely nonmagnetic
		Low contact resistance
		Easy to mate
		Proprietary connector type, procurement issues
D	**Non-magnetic D-Sub mini Connector**	Readily available from various suppliers
		Familiar interface
		Easy to mate
		Low cost

4.2.1.1 **Reduced-Risk Cable Systems**

The SQVID cable fabrication is a proprietary process to Philips, and is not disclosed. The specifications for the cable have been noted and will be used to develop a cable that meets this standard. In order to reduce risk related to cable systems, the following items in **Table 4-4** are observed. To mitigate these risks, the cable is designed to meet the sets of given requirements in **Section 2.3 – Requirements and Specifications** and **Section 4.2.1 – Cabling System Materials and Design**, paying close attention to the following details:

Table 4-4: Cable Risk Factors

Risk Factor	Description	Mitigation
Looped Cable	Even a single coil in the cable can induce a large current in an MRI environment. The powerful magnetic flux can create a current that can burn a patient or destroy equipment.	All materials used in cable construction including connectors must be non-magnetic. The Shielding shall be semi-rigid and resist coiling or bunching.
Excess Length of Cable	Excess length of cable causes clutter and could potentially cause a safety hazard, such as an individual getting tangled or tripping over a cable.	The cable shall be no longer than required, or 8 feet, whichever is shorter. The cable shall be routed such that it is safely out of the way.

4.2.1.2 MRI Compatibility of Cable Systems

The cable and connectors must be made of non-magnetic materials. A few non-magnetic metals that could be used in the construction of this system are:

- Aluminum

- Platinum

- Copper

- Lead

The majority of materials to be selected from in this design fall into the "safe" category, as most cables and connectors are made using the above listed materials. The cables used, however, will be fabricated by Philips using a proprietary process and will not be subject to disclosure. The technicians responsible for the cable fabrication are to be aware of the restrictions for cabling materials and requirements for cable resilience. The connectors will be selected so as to provide the most seamless integration with the current system, while maintaining a modular and efficient design.

4.2.1.3 Cable-Sensor Interface Design

The modular approach to this project allows for a custom setup of different sensor combinations as needed. In order to receive maximum utility from the SQVID cable assembly, an interface for each of the sensors will be included in the final cable build. The signal acquisition unit will discern which sensors are being used by which are plugged into the other end of the SQVID cable, and respond accordingly.

4.2.1.4 Cable-Platform Interface Design

The SQVID cable interface with the platform could be arranged such that integration with the existing platform is possible through a shared connector between all of the sensors. The SQVID enclosure houses the current wireless solution for the ECG and SpO2 sensors, and a similar wireless platform has been developed for the CO2 and NiBP sensors and is housed in the unit as well. The data acquisition unit is capable of taking in the signals and transmitting them in a multiplexed data stream to a receiver base station outside of the MRI room. The design of the connector is governed by the requirements set forth in this document with the overriding principle of MRI compatibility taking precedent.

4.2.2 Cable Consolidation Solutions

The current system relies on four separate cables, which creates clutter and presents safety concerns. To consolidate the cabling systems, a custom cable solution is under development by Philips following our design specifications and hardware suggestions. The chosen connectors and cable shielding are incorporated into Philips' fabrication process, which is proprietary information and may not be disclosed.

4.2.3 Component Selection

The hardware to be used in the initial signal collection and processing stages has not yet been entirely decided. As new components are chosen, they are weighed against other current options and exchanged if necessary. As mentioned previously, the extent of integration will be limited to the non-invasive blood pressure and exhaled carbon dioxide signals. The other two signals (electrocardiogram and pulse oximetry) have existing wireless monitors that will be mounted on the outside of the SQVID system, sitting flush against the surface with the cables routed internally and connected to the SQVID cable port.

The sections below cover the various hardware selections that have been made in development of this system. Options for each component are researched and compared

(where applicable), and reasonable justification is given towards the selection of each component in the final design.

4.2.3.1 **Voltage Regulator**

Many different options for a DC voltage regulator exist for this design. The options were narrowed down by power requirements, and specific output voltages limited to a small range. Some options are listed below in **Table 4-5**.

Table 4-5: Voltage Regulator Options

Option	Name	Description
A	**LD1117 V33 Fixed**	Fixed to 3.3V output Provides a low dropout voltage of about 1V. Provides up to 800mA output current. Various packages available.
B	**uA7800 Series 7805**	Fixed output to 5V. High power dissipation capability. Output current up to 1.5A Internal thermal overload protection
C	**LT1121-3.3**	Fixed output at 3.3V. Very low dropout voltage of 0.4V. 150mA output current and 30uA quiescent current. 8-pin DIP package.
D	**ADM7150**	Fixed output at 3.3V or 5V. Ultra low noise operation. High power supply rejection ratio (PSRR).

Table 4-5: Voltage Regulator Options

		Dropout voltage or 0.6V. 800mA output current and 4.3mA quiescent current.

4.2.3.2 Microcontroller

There are a few microcontroller brands to compare as well. The focus was narrowed by the requirements for low power consumption and ease of integration with the sensors. The first line of comparison is with the different brands of processors available. A short description is provided as **Table 4-6** takes a look at the best options for microcontroller brands.

Table 4-6: Microcontroller Options

Option	Name	Description
A	**TI MSP430**	Well suited to low power and bioinstrumentation solutions. Familiarity with the architecture from embedded systems laboratory. Low cost and easy prototyping.
B	**ST ARM**	More powerful and ubiquitous platform. Newer microcontrollers from this family have increased performance with decreased power consumption.
C	**Atmel AVR**	High availability of resources and open source support. Low-power and wireless capabilities in the zigbee wireless standard.
D	**Microchip PIC**	8-bit microprocessors available for very small low power applications.

		Robust third-party support and development kits.
		Larger and more powerful units available as well.

For this project, the Texas Instruments MSP430 line of processors was deemed the best fit. The familiarity with the platform gained in the embedded systems laboratory, as well as the extensive community support and reference material resulted in this choice.

Specifically, the MSP430G2553 microcontroller was selected for development during this project. The launchpad development platform was used in the initial evaluation of this module, as shown below.

Figure 4-6: MSP430G2553 LaunchPad

Courtesy of Texas Instruments

4.2.4 **Microcontroller Analog to Digital**

The MSP430 G2 series has some types of analog-to-digital and digital-to-analog modules. The ones that will be focused on are the 10-bit and 12-bit analog-to-digital module and a 12-bit digital-to-analog module. **Table 4-7** below will be the start of the benefits of using the ADC10 module, which is a 10-bit analog-to-digital converter (ADC) [13].

<p style="text-align:center">Table 4-7: Microcontroller ADC10 Benefits</p>

Perks of the ADC10 Module	Description
Benefit 1	Greater than 200 kilo-samples per second maximum conversion rate.
Benefit 2	Software selectable on-chip reference voltage generation with selections of 1.5 volts or 2.5 volts.
Benefit 3	Sample-and-hold with programmable sample periods
Benefit 4	Up to 8 external input channels.
Benefit 5	Selectable conversion clock source.

The ADC10 module's block diagram provided by Texas Instruments (**Figure 4-7**) shows the structure of the module:

Figure 4-7: TI ADC10 Block Diagram

Courtesy of Texas Instruments
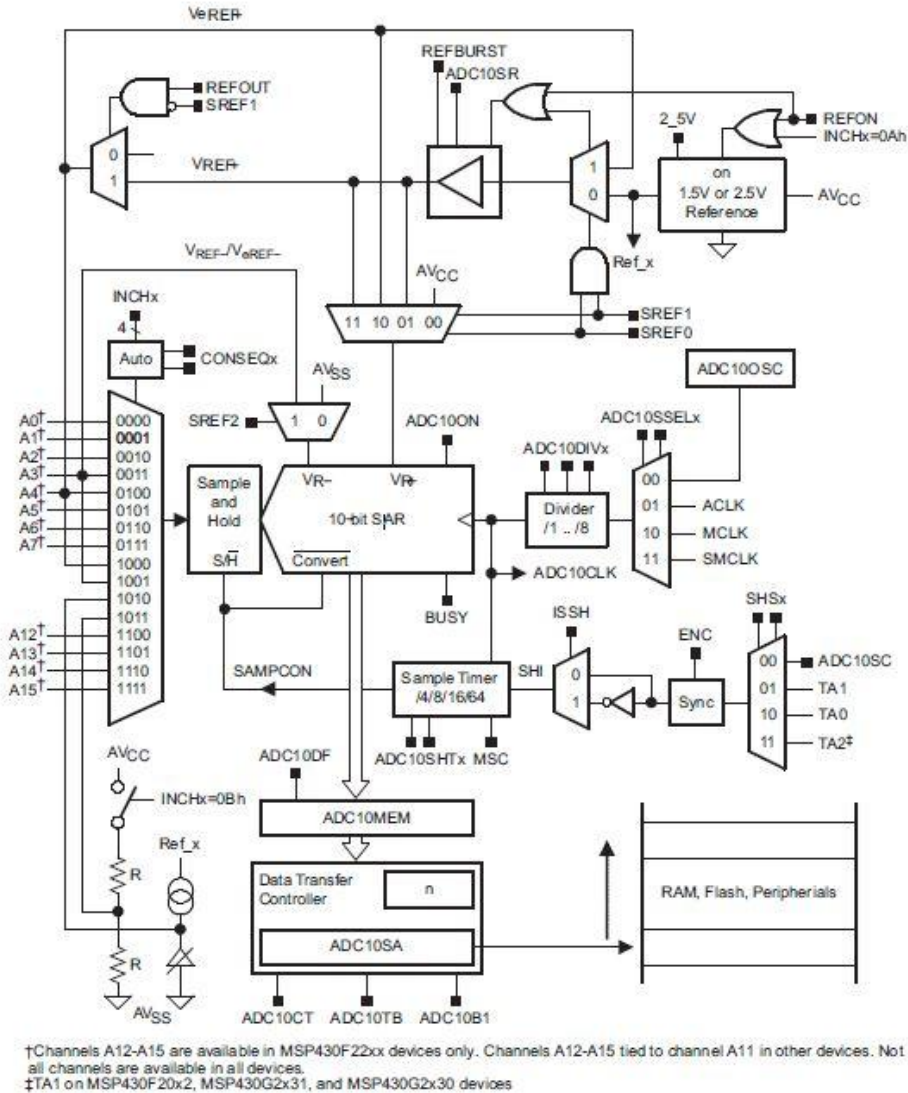
Considering how the ADC10 is dependent upon software to be configured to the user's specifications, there are a lot of functions available to meet this project's particular needs. Some features of the ADC module are detailed in the following sections.

4.2.4.1 **10-Bit ADC Core**

The ADC core converts the analog signal and then changes the signal into its 10-bit digital representation and stores the result in the ADC10MEM register. However, before any conversion can take place, the Enable conversion (ENC) register must be set to 1.

The core uses two distinguishable voltage levels, V_{R+} and V_{R-}, which are completely programmable/selectable to define the upper and lower limits of the conversion from analog to digital. The digital output (N_{ADC}) is full scale (03FFh or 1023_{10}) when the $V_{IN} \geq V_{R+}$ and zero when $V_{IN} \leq V_{R-}$. The conversion formula for the ADC when in binary format is:

$$N_{ADC} = 1023 \text{ x } \frac{VIN - VR-}{VR+ - VR-}$$

The ADC10 core must be enabled with the ADC10ON bit when configuring the two control registers, ADC10CTL0 and ADC10CTL1, and they can only be modified when ENC = 0.

4.2.4.2 Conversion Clock Selection

The ADC10CLK is used for both conversion clock purposes and to generate the sampling period, the source clock is selected using ADC10SSELx bits and can be divided from 1 to 8 using the ADC10DIVx bits, and possible source clocks for the ADC10CLK are SMCLK, MCLK, ACLK, and internal oscillator ADC10OSC (however, there are a lot of variables that must be considered first when using the ADC10OSC, so caution must be taken while using the ADC10OSC).

The user must ensure that the clock chosen for ADC10CLK remains active until the end of a conversion or the operation will not complete and any result will be invalid.

4.2.4.3 Analog Port Selection

The ADC10 external inputs Ax, V_{eREF+}, and V_{REF-} share terminals with general purpose input and output ports, which are digital CMOS gates. When using the CMOS gates, parasitic current can flow from VCC to ground, so the port pin buffer must be enabled with the ADC10AEx bits in order to eliminate parasitic current flow and reduce current consumption.

4.2.4.4 Voltage Reference Generator

The ADC module has an internal voltage reference that must be turned on via the REFON register by setting it to 1. It can be used internally, REFOUT = 0, or externally, pin V_{REF+} = REFOUT = 1. The internal reference voltages are 2.5V when REF2_5V is set to 1 and 1.5V when REF2_5V is set to 0.

4.2.4.5 Auto Power-Down

Since the ADC10 is meant for low power applications, the core is automatically disabled and re-enabled when needed depending on whether the ADC10 is actively converting or not.

4.2.4.6 Sample and Conversion Timing

An ADC is initiated with a rising edge of input signal sample SHI, for which the source is selected with the SHSx bits and includes the following registers: the ADC10SC bit, Timer_A Output Unit 1, Timer_A Unit 0, and Timer_A Unit 2. The polarity SHI signal can be inverted with the ISSH bit, the SHTx bit selects the sample period t_{sample} to be 4,8,16, or 64 ADC10CLK cycles, and the sampling timer sets the SAMPCON high for the selected t_{sample} after synchronization with the ADC10CLK. The conversion and cycles are shown in the **figure 4-7** below with the high-to-low SAMPCON transition as the starter for the analog-to-digital conversion:
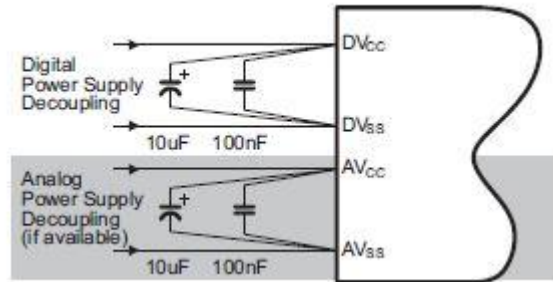
Figure 4-7: TI ADC10 Sample Timing Graph
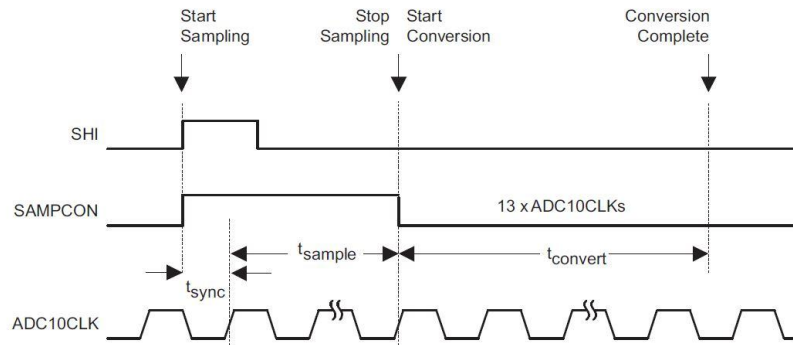
Figure 22-3. Sample Timing
Courtesy of Texas Instruments

4.2.4.7 ADC10 Grounding and Noise Considerations

Certain configurations can be made in order to keep from creating ground loops and other noise complications because ground loops are formed when return current form the A/D travels via paths that analog and digital circuitry share. The current can generate differentiations than expected in the reference voltages or input voltages of the A/D converter. In addition to grounding, the conversion result can be skewed due to ripple and noise spikes being induced over the supply lines from changing power supply lines (digitally or manually).

Fix for noise and grounding issues that can affect the internal reference voltage results:
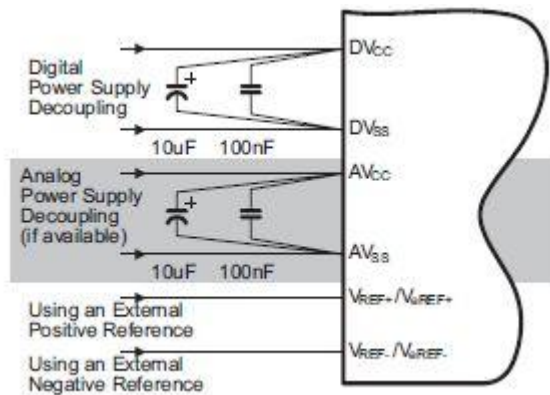
Figure 4-8: TI ADC10 Sample Timing Graph

Courtesy of Texas Instruments

Fix for noise and grounding issues that can affect the external reference voltage results:

Figure 4-9: TI ADC10 Sample Timing Graph

Courtesy of Texas Instruments

4.2.4.8 Using the Integrated Temperature Sensor

The analog input channel must be set with the INCHx register to 1010. When using this sensor, the sample period must be greater than 30 micro-seconds. Since the temperature sensor's offset error is large, calibration is necessary for accurate results.

4.2.4.9 CONSEQx Modes in ADC10

In CONSEQ0, A single channel is selected by INCHx, sampled, converted once, and the result is written in ADC10MEM. Setting the ADC10 to CONSEQ1 will allow a sequence of channels to be sampled and converted once, beginning with INCHx selection in conjunction with decrementing channel A0. CONSEQ2 works by taking a single channel selection, selected by the INCHx bit, and sampling and converting continuously by repeatedly rewriting into the ADC10MEM register with each ADC result. Finally, CONSEQ3 is a combination of all modes, such that a sequence of channels are taken in and rewritten to the ADC10MEM register and may be the best mode for this experiment as the MRI machine will be outputting several signals in a sequence that will need to be converted all at once (4 to be exact) for optimizing this code as much as possible.

Table 4-8: ADC10 Registers

Register	Description (all ADC10)	Register Type	Address	Initial State (POR = Power-on-reset)
ADC10AE0	Input enable register 0	Read/Write	04Ah	Reset with POR
ADC10AE1	Input enable register 1	Read/Write	04Bh	Reset with POR
ADC10CTL0	Control register 0	Read/Write	01B0h	Reset with POR
ADC10CTL1	Control register 1	Read/Write	01B2h	Reset with POR
ADC10MEM	Memory	Read	01B4h	Unchanged
ADC10DTC0	Data transfer register 0	Read/Write	048h	Reset with POR
ADC10DTC1	Data transfer register 1	Read/Write	049h	Reset with POR
ADC10SA	Transfer start address	Read/Write	01BCh	Reset with POR

Table 4-9 below illustrates some of the benefits if using the ADC12 module, which is a 12-bit analog-to-digital converter (ADC) [13].

Table 4-9: Microcontroller ADC12 Benefits

ADC12 Benefits	Description
Benefit 1	Greater than 200 kilo-samples per second maximum conversion rate.
Benefit 2	Software selectable on-chip reference voltage generation with selections of 1.5 volts or 2.5 volts.
Benefit 3	Sample-and-hold with programmable sample periods
Benefit 4	Up to 8 external input channels.
Benefit 5	Selectable conversion clock source.
Benefit 6	16 conversion-result storage registers (word conversion-and-control buffer).

The ADC12 module's block diagram provided by Texas Instruments is shown in **Figure 4-8**, illustrating the structure of the module:

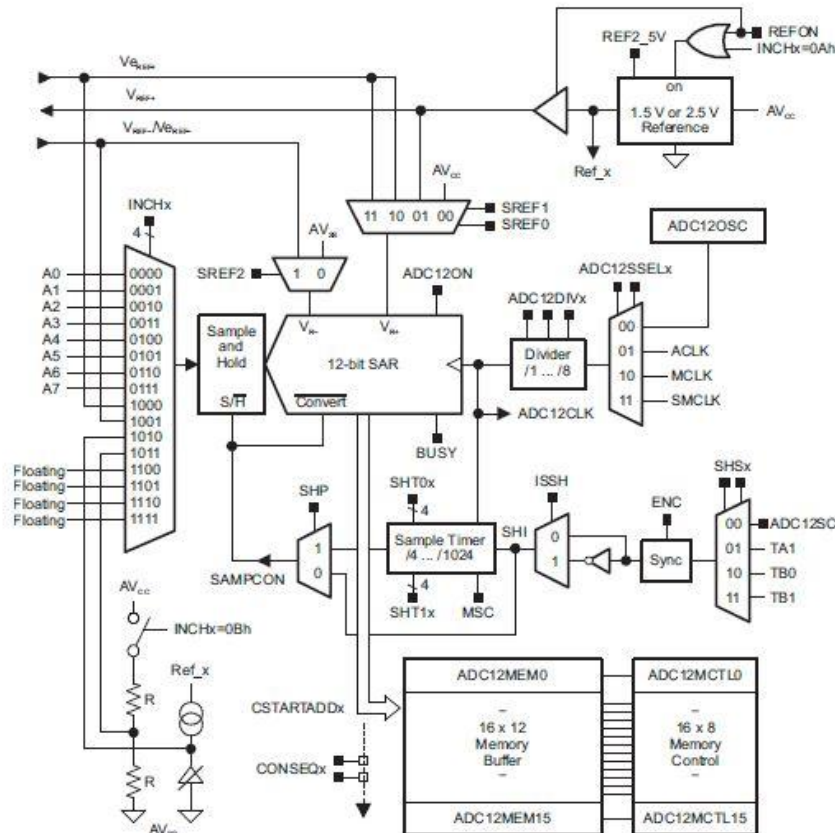**Figure 4-8: TI ADC12 Block Diagram**

Figure 23-1. ADC12 Block Diagram

Courtesy of Texas Instruments

The ADC12 is software dependent for configuration. There are a lot of functions available to meet the user's particular needs. Features of the ADC12 module are listed the sections below:

4.2.4.10 **12-Bit ADC Core**

The ADC core converts the analog signal and then changes the signal into its 12-bit digital representation and stores the result in the conversion memory. However, before any conversion can take place, the Enable conversion (ENC) register must be set to 1. The core uses two distinguishable voltage levels, V_{R+} and V_{R-}, which are completely programmable/selectable to define the upper and lower limits of the conversion from

analog to digital. The digital output (N_{ADC}) is full scale (0FFFh or 4095_{10}) when the $V_{IN} \geq$ V_{R+} and zero when $Vin \leq V_{R-}$. The conversion formula for the ADC when in binary format is:

$$N_{ADC} = 4095 \text{ x } \frac{VIN - VR-}{VR+ - VR-}$$

The ADC12 core must be enabled with the ADC12ON bit when configuring the two control registers, ADC12CTL0 and ADC12CTL1, and they can only be modified when ENC = 0.

4.2.4.11 **Conversion Clock Selection**

The ADC12CLK is used for both conversion clock purposes and to generate the sampling period, the source clock is selected using ADC12SSELx bits and can be divided from 1 to 8 using the ADC12DIVx bits, and possible source clocks for the ADC12CLK are SMCLK, MCLK, ACLK, and internal oscillator ADC12OSC (however, there are a lot of variables that must be considered first when using the ADC12OSC, so caution must be taken while using the ADC12OSC).

The user must ensure that the clock chosen for ADC12CLK remains active until the end of a conversion or the operation will not complete and any result will be invalid.

4.2.4.12 **Analog Port Selection**

The ADC12 inputs are multiplexed with port P6 pins, which are digital CMOS gates that can cause parasitic current to flow from VCC to GND when taking in analog signals. This extra current consumed can be avoided by disabling the port pin buffer, the P6SELx bits.

4.2.4.13 **Voltage Reference Generator**

The ADC12 module has an internal voltage reference that must be turned on via the REFON register by setting it to 1. The internal reference voltages are 2.5V when REF2_5V is set to 1 and 1.5V when REF2_5V is set to 0.

4.2.4.14 **Sample and Conversion Timing**

s An ADC is initiated with a rising edge of input signal sample SHI, for which the source is selected with the SHSx bits and includes the following registers: the ADC12SC bit, Timer_A Output Unit 1, Timer_B Unit 0, and Timer_B Unit 1.The high-to-low SAMPCON transition is the starter for the analog-to-digital conversion for the ADC12CLK and two different time sampling methods can be chosen with control bit SHP:
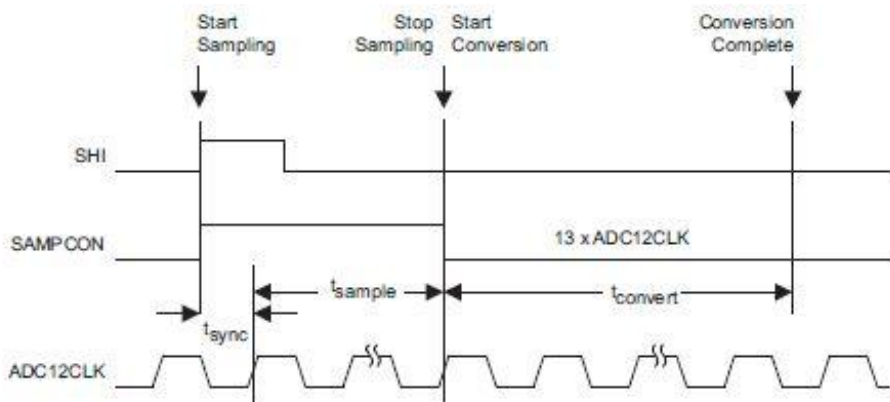
Figure 4-11: Extended Sample Mode
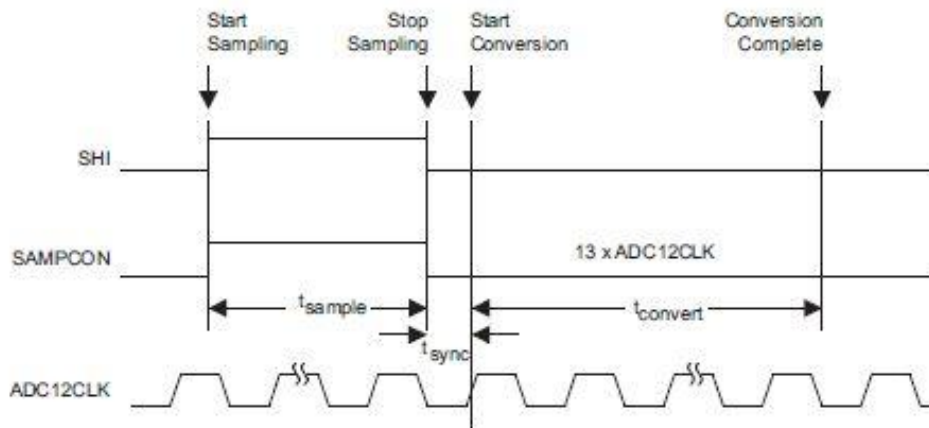
Courtesy of Texas Instruments

Selected when SHP = 0. The SHI signal directly controls the SAMPCON and defines the length of the t_{sample} period.

**Figure 4-12: Pulse Sample Mode**

Courtesy of Texas Instruments

Selected when SHP = 1. The SHI signal is used to start the timer of the sampling while the SHT0x and SHT1x bits in ADC12CTL0 control the variables that make up SAMPCON's sample period $t_{sample} = t_{sample} + t_{sync}$.

4.2.4.15 **ADC12 Grounding and Noise Considerations**

Certain configurations can be made in order to keep from creating ground loops and other noise complications because ground loops are formed when return current form the A/D travels via paths that analog and digital circuitry share. The current can generate differentiations than expected in the reference voltages or input voltages of the A/D converter. In addition to grounding, the conversion result can be skewed due to ripple and noise spikes being induced over the supply lines from changing power supply lines (digitally or manually). Fix for noise and grounding issues that can affect the reference voltage results by using separate analog and digital ground planes with a single-point connection:

Figure 4-13: Pulse Sample Mode

Courtesy of Texas Instruments

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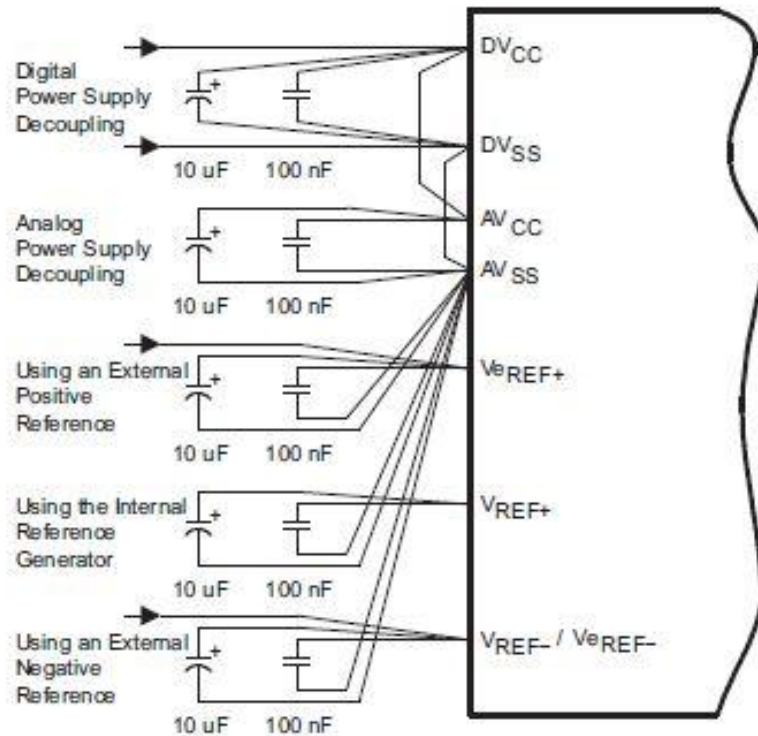
Each of the 16 ADC12MEMx conversion memory registers store conversion results and have a ADC12MCTLx control register associated to it for configuration purposes. SREFx bits define voltage reference, INCHx bits select input channel, EOS bit defines end of sequence for sequential modes (discussed later) used, and when the EOS bit is not set, a sequence will roll over from ADC12MEM15 to ADC12MEM0. The CSTARTADDx bits define the first ADC12MCTLx when used for any conversion and points to specific x's when the mode conversions are single or repeat-single.

The corresponding flag in the ADC12IFG register is set when conversion results are written to the ADC12MEMx.

4.2.4.16 **Using the Integrated Temperature Sensor**

The analog input channel must be set with the INCHx register to 1010. When using this sensor, the sample period must be greater than 30 micro-seconds. Since the temperature sensor's offset error is large, calibration is necessary for accurate results.

4.2.4.17 **CONSEQx Modes in ADC12**

Below are conversion modes that are chosen by the CONSEQx bits within the ADC12.

CONSEQ0:   A single channel is selected, sampled, converted once, and the result is written in ADC12MEMx defined by the CSTARTADDx bits. Successive conversions can also be triggered by the ADC12SC bit when the ADC12SC triggers a conversion.

CONSEQ1:   Sequence of channels are sampled and converted once, beginning with writing the ADC results into the ADCMEMx defined by the CSTARTADDx bits and ending when the EOS bit is reached with its set standard.

CONSEQ2:   A single channel is selected, sampled and converted continuously by repeatedly rewriting into the CSTARTADDx bit defined ADC12MEMx after it has been read (read so it won't just be continually written over without acquiring the previous results).

CONSEQ3:   A combination of all modes in a sequence of channels are taken in and rewritten to the CSTARTADDx bit defined ADC12MEMx and may be the best mode for this experiment as the MRI machine will be outputting several signals in a sequence that will need to be converted all at once (4 to be exact) for optimizing this code as much as possible.

Table 4-10: ADC12 Registers

Register	Description (all ADC12)	Register Type	Address	Initial State (POR = Power-on-reset)
ADC12CTL0	Control register 0	Read/write	01A0h	Reset with POR
ADC12CTL1	Control register 1	Read/write	01A2h	Reset with POR
ADC12MEM0	Memory 0	Read/write	0140h	Unchanged
ADC12MEM1	Memory 1	Read/write	0142h	Unchanged
ADC12MEM2	Memory 2	Read/write	0144h	Unchanged
ADC12MEM3	Memory 3	Read/write	0146h	Unchanged
…	…	…	…	…
ADC12MEM13	Memory 13	Read/write	015Ah	Unchanged
ADC12MEM14	Memory 14	Read/write	015Ch	Unchanged
ADC12MEM15	Memory 15	Read/write	015Eh	Unchanged
ADC12MCTL0	Memory control 0	Read/write	080h	Reset with POR
ADC12MCTL1	Memory control 1	Read/write	081h	Reset with POR
ADC12MCTL2	Memory control 2	Read/write	082h	Reset with POR
ADC12MCTL3	Memory control 3	Read/write	083h	Reset with POR
…	…	…	…	…
ADC12MCTL13	Memory control 13	Read/write	08Dh	Reset with POR
ADC12MCTL14	Memory control 14	Read/write	08Eh	Reset with POR
ADC12MCTL15	Memory control 15	Read/write	08Fh	Reset with POR

4.2.5 NiBP System Design

This section covers the specifics of the non-invasive blood pressure system we implemented and its analog signal from the input at the cuff up until it passes into the microcontroller for analog-to-digital conversion. The NiBP sensor circuit (minus the transducer) is pictured in **Figure 4-9**.

Figure 4-9: NiBP Sensor Circuit
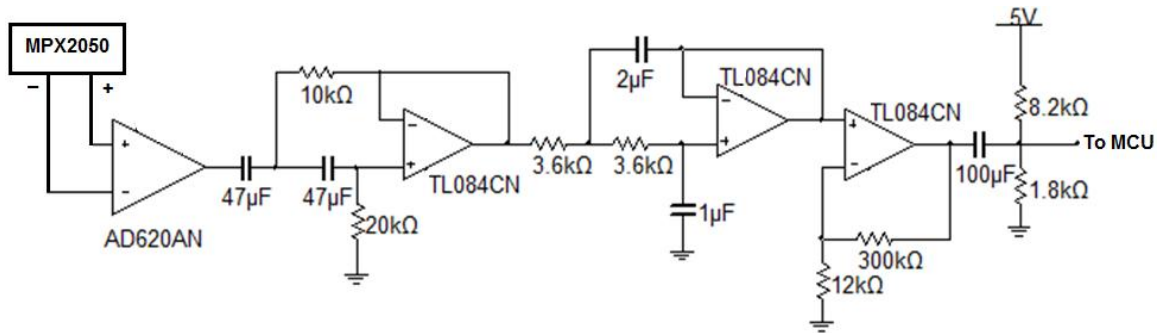

4.2.5.1 Pressure Cuff

Starting at the cuff, we used a standard adult sized blood pressure cuff (Part #: M1574A) manufactured and provided by Philips. All of Philips' standard cuffs use the same size tubing, so any other model will be compatible with the adaptor we build. The reason we chose this cuff over other cuffs is for testing purposes; the M1574A is an appropriate size for all our group members whom will be performing the testing procedures.

4.2.5.2 Pressure Transducer

The pressure transducer we have decided to use is Motorola's MPX2050 with the 344C type casing (See **Figure 4-10**). Motorola is a company we are familiar with and we have been satisfied with the quality level of parts we've used in the past so we had confidence in using them again. As far as pressure sensors go, the MPX2050 has a good reputation among certain engineering communities and forums.

Aside from trusting the manufacturing quality, the MPX2050 (specifically, the MPX2050DP with the type 344C case) has some practical features that appealed to our intended use. The orientation of the intake nozzles, relative to the designed mounting orientation, is ideal for easy access to the nozzles when the transducer is surface mounted and for structural durability. Effectively, the force from attaching the cuff tubing is applied parallel to the surface it will be mounted to (i.e. along the same axis the nozzles are facing). The majority of the load applied to the mounting joints will be split between shear force acting on the bolt (along the plane where surface and casing meet) and the static friction (between the case and the surface) reinforced by the tightened nut/bolt. The benefit here is that the bolted joint is known to be one of the most structurally stable configurations to handle forces being applied as it is here. This should prolong its structural lifetime and prevent shifting after repeated use.
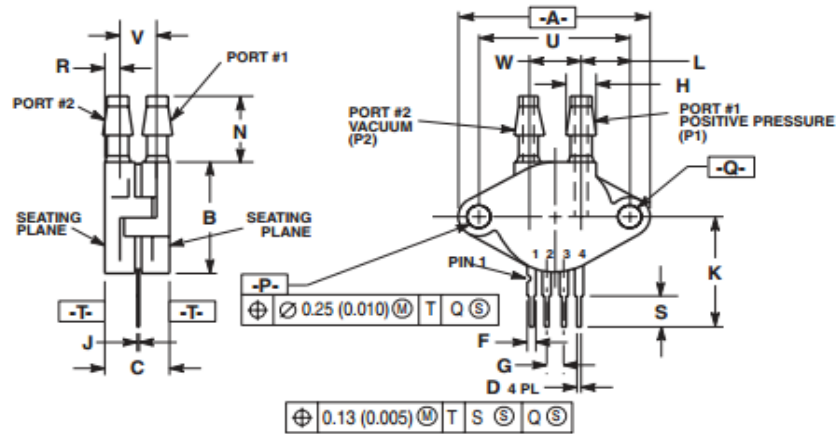
Another potentially useful feature of the MPX2050DP is that there are actually two pressure sensitive transducers in the one package. Each transducer has a nozzle of its own. Though rarely, if ever, is more than one pressure cuff being used at a time to monitor a patient. One potential benefit for having an extra transducer is that one can be used to read pressure from the cuff while the other could remain open to the atmosphere and record a value corresponding to the ambient atmospheric pressure. To take advantage of the control ambient pressure, we measured the difference in the two transducers instead of referring the input signal to ground. Doing this could have, theoretically, given us a more accurate signal relating cuff pressure to the ambient pressure. However, no tests were run analyzing this property so we are unsure if our intentions were satisfied. Also, since the transducers are very close to each other, physical noise sources (loud sounds, temperature change, etc.) affect both transducers in a similar manner which means an otherwise problematic noise source could be reduced to negligible magnitudes. With MRI rooms having potential to be very loud, this could make a difference. In practice, sudden ambient pressure changes (i.e. sound) would likely be entering the system at different locations; one directly into the open ambience sensor and the other, most prominently, through the actual cuff.

The transducer's electrical properties agreed with our intended application; the response to change in pressure is very linear and precise over a large range relative to our maximum operating range. Blood pressure cuffs generally don't require more than 160mmHg of applied pressure to act as a proper tourniquet and blood pressure higher than 180mmHg indicates an extreme case of arterial hypertension. However, the maximum pressure a cuff is ever inflated to in practice is 300mmHg. Converting kilopascals to millimeters of Mercury (following the conversion factor: $1\,kPa \cong 7.5\,mmHg$), the documented maximum input pressure for the MPX2050, 50 kilopascals, is equal to ~375mmHg. This is well above any input foreseeable in practice.

Figure 4-11: MPX2050 Output Voltage vs. Input Pressure
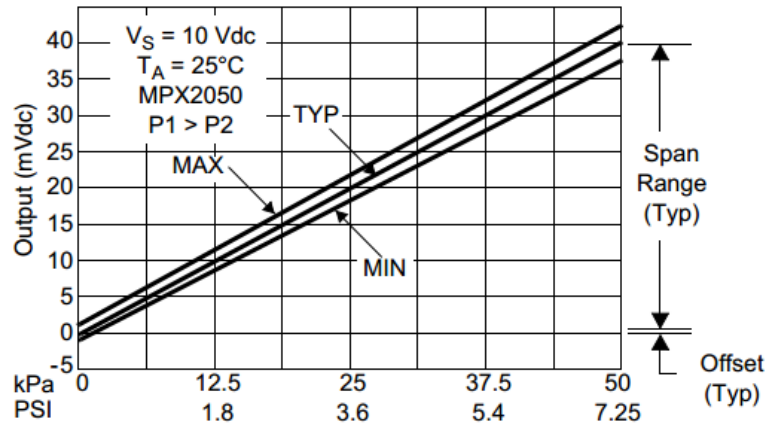
The practical input range of the transducer used to measure blood pressure has extremes of a 180mmHg systolic pressure and a 60mmHg diastolic pressure shown in **Table 4-11**. Anything higher or lower than this range is classified as a hypertensive emergency or hypotension, respectively. The desired systolic and diastolic pressures altogether range from 119mmHg to 60mmHg. From this information, we can get an idea of what to expect from our analog electrical signal.

Table 4-11: Blood Pressure Classifications

Patient State	Systolic (mmHg)	Diastolic (mmHg)
Hypotension	< 90	< 60
Desired	90 - 119	60 - 79
Hypertensive Emergency	≥ 180	≥ 110

The highest pressure we were concerned about reading accurately from a patient's cuff was 180mmHg. Giving a 20mmHg (~11%) margin, the highest pressure we wanted to read was 200mmHg (~26.7kPa). Using the sensitivity 0.8mV/kPa, given in the MPX2050 datasheet (Appendix B), we calculated the sensor's output to be 21.36mV at 26.7kPa and used this as the maximum voltage we cared to measure accurately.

Applying the same procedure to the lowest pressure we were concerned about reading accurately, 60mmHg, we used the same margin as before and set our floor to 40mmHg

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(~5.33kPa). At 5.33kPa, the sensor's output is approximately 4.26mV. This isn't the absolute minimum the output can be, the sensor's output still produces a 0 V signal if there's no pressure being read. The target minimum is simply the lowest voltage we want to be distinct; which means we couldn't allow any noise at the transducer to become comparable to 4.26mV.

Table 4-12: Key Sensor Outputs

Max. Output (mV)	40
Max. Target Output (mV)	21.36
Min. Target Output (mV)	4.26
Min. Output (mV)	0

4.2.5.3 Instrumentation Amplifier

Once we obtained the raw signal coming from the sensor, it needed to be amplified because its amplitude was very low compared to what the microcontroller performing the analog-to-digital conversion was capable of handling. The larger the signal passing into the A/D converter is (without exceeding the controller's input restraints), the clearer the digital signal is because it makes use of more samples. If the step in voltage required to increase one increment in the digital signal's amplitude is 5mV, an analog signal peaking at 20mV will cover 4 increments whereas a signal peaking at 4V will encompass 800 increments. The resolution is proportional to the analog amplitude.

The output signal from the pressure transducer was capable of spanning a peak-to-peak amplitude of 40mV under typical conditions. However, we were not concerned about values over 21.36mV. So our sensors' output was considered to have a peak-to-peak amplitude of 21.36mV, unless exceeding any following input limitations is a concern and it is not in this case.

In order to use the second pressure transducer as a reference signal and find the cuff's difference in pressure from the ambient atmosphere, we needed to subtract the reference signal from the cuff's signal. To find the difference in signals, we decided to use an instrumentation amplifier. Analog Devices' AD620 Instrumental Amplifier was the amplifier we chose to handle the initial stage of amplification. Choosing to use the AD620 over other options was simply a matter of being content with a prior experience using the AD620.

Running the cuff's post-sensor signal P_1 to the V$^+$ pin on the AD620 and the reference signal P_2 to the inverting pin, we established an output proportional to P$_1$-P$_2$. The actual output depends on the gain of the amplifier stage, which is controlled by the resistance of R$_G$. Since R$_G$ lies outside the AD620's packaging, the value of R$_G$ can be defined by the user (as is the case with many instrumentation amplifiers).

The AD620 is not used as the primary amplifying stage in the circuit, however, because the unfiltered signal is carrying a lot of noise. Amplifying this noise would draw extra unnecessary power, so the signal noise is filtered out before the majority of the amplification takes place. Some amplification from the AD620 is applied to make the signal more readily observable from an oscilloscope and distinguish the signal from potential noise at the op amps. Using the gain equation provided in the AD620 datasheet,

$$G = \frac{49.4k\Omega}{R_G} + 1, \qquad\qquad (1)$$

the instrumentation stage provides a gain of 10.7 when using the designed gain resistor value of 5.1kΩ. However, a 10kΩ potentiometer is used in place of the gain resistor to allow easy tweaking, if necessary, after the PCB was finalized.

4.2.5.4 Bandpass Filter

Pressure signals from an NiBP cuff have a large low frequency component due to the relatively slow, steady release of cuff pressure throughout the monitoring cycle. Thermal noise and other noise sources can vary in frequency but it is advisable to eliminate it as best as you can regardless of whether you know at which frequencies it's located or not. Since the scope of the project was simply proof of concept and not to spend time designing a polished filter, we did not run any RF analysis ourselves on the MRI environment. So, aside from the 60Hz mains hum, the key frequencies we were aware of are those of human hearts and we designed around passing these frequencies and their harmonic components.

A cycle of blood pressure monitoring records a series of blood pressure pulses. These spikes in blood pressure are caused by your heart contracting and releasing periodically, or beating. If we know how fast our heart is beating, we know how fast these pressure spikes are occurring. Or in other words, the frequency of the target pressure signal is the patient's current heart rate.

Table 4-13 holds a few key values of heart rates. A person's approximate maximum heart rate is commonly estimated by subtracting their age (in years) from 220. If this is the case, then 220bpm must be close to the absolute maximum possible heart rate. An average heart rate lies somewhere between 60 and 100bpm. 50bpm is considered a very low resting heart rate so the minimum is set at 40bpm out of judgment. These heart rate values have been converted to frequencies in Hertz and they correspond to possible spectrum components of the blood pressure signals. For example, a heart rate of 60bpm is equal to 1Hz, which means the fundamental component in that signal's frequency

spectrum is located at 1Hz. So, the range from minimum to maximum frequency in **Table 4-13** (0.667-3.667Hz) is the range where one would expect to find the fundamental frequency component of any patient's blood pressure signal. The likelihood is higher near the average values we, but we accommodated for some more extreme cases and for testing purposes we pushed the upper corner frequency to 6Hz.

Table 4-13: Estimated Heart Rate Values

	Heart Rate (bpm)	Frequency (Hz)
Maximum	220	3.667
Average	60 - 100	1 – 1.667
Minimum	40	0.667

With this information, we designed a second-order Butterworth bandpass filter to fit around the frequency range 0.667-6Hz. Through prior experience dealing with NiBP frequency spectrums, the lower edge of the frequency range, 0.667Hz, is noticeably close to the unwanted low frequency component. Doubling the filtering order is advisable to mitigate the low frequency component and flatten the baseline.

Designing active filters requires the selection and use of an operational amplifier. The amplifier we had the most experience using is Texas Instrument's TL084 and there are no parameters in the filter design that disagree with the use of the TL084 so it is the amplifier we chose to use.

When designing circuits, it's advisable to use values of single components that are commonly manufactured. It is possible to create almost any custom resistance out of multiple resistors, but it is not nearly as clean as using a single resistor. The capacitor and resistor values determine the passband corner frequencies. So with limited options of capacitances and resistances, the options for corner frequencies were limited as well.

**Figure 4-12: Second-Order Butterworth Highpass Filter**
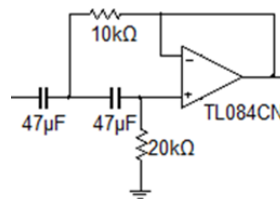
Figure 4-13: Second-Order Butterworth Lowpass Filter
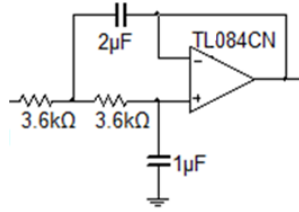
The second-order Butterworth bandpass filter was designed, with corner frequencies at 0.24 and 31 Hz, to isolate the frequency components found in typical NiBP readings, ranging from 0.67 to 30 Hz. The highest considered heart rate of 6Hz (360 bpm) has a fifth harmonic at 30Hz. Thus, the corner frequencies of 0.24 and 31 Hz should pass all frequency components attributed to the blood pressure reading we would expect to see from a patient.

The use of inductors and electrolytic capacitors near an MRI is not recommended due to the strong magnetic field and RF pulses, so this filter will be strictly RC and use only ceramic capacitors. For the sake of simplicity and tunability, the bandpass is divided into lowpass and highpass stages (as opposed to two cascaded single-order bandpasses) and a Sallen-Key topology is used for both. The Sallen-Key configuration allows corner frequency tuning with the adjustment of only two components (per stage) sharing a common value. However, these filter stages are both unity-gain so another op amp stage was needed to provide sufficient post-filter amplification.

Figure 4-14: Bandpass Filter Frequency Response
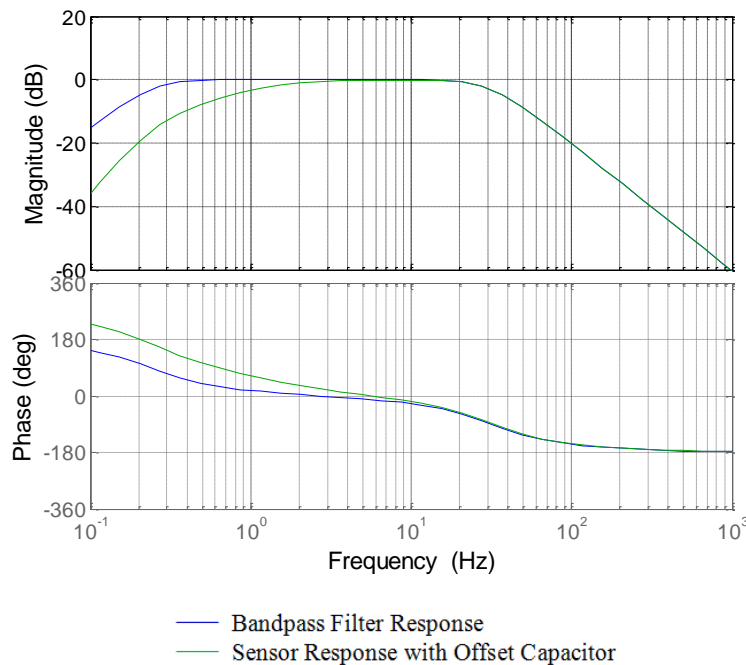
The filtered analog signal is passed through a non-inverting amplifier stage that brings the signal amplitude to the maximum amplitude desired entering the microcontroller. With the signal's baseline at 0V, the waveform would've included negative voltages which the MSP430 microcontroller being used for A/D conversion will not accept.

4.2.5.5 DC Offset

A DC offset of 0.9V was added to the signal after this amplifier stage and the reference voltage for the A/D conversion is set to 2.5 V, so the max peak amplitude fell around 1.5V. The negative peaks of the waveform were generally not comparable to the positive peaks so a 0.9V offset was sufficient to ensure no negative values, though errant negative voltage spikes wouldn't damage the system or achieve high enough potential to cause problems with the microcontroller.

The 0.9V DC offset was implemented using a capacitor and a voltage divider supplied by Vcc at 5V. The filtering effect of the capacitor-resistor configuration imposes a highpass filter with a cutoff under 1Hz, so it does not significantly affect the passband established by the Butterworth filters. The combined response is shown in **Figure 4-14.**

4.2.5.6 NiBP Output

The final signal output by the sensor, shown in **Figure 4-15,** gets read into the microcontroller for A/D conversion. It has a baseline at 0.9V and stays constrained from 0 to 2.5V. All the signal components necessary to read a patient's blood pressure are present aside from the reference pressure the pump would be exerting. The implemented sensor can observe the where the systolic and diastolic pressures occur, and referring to the pump pressure at those points identifies the actual pressure values.

Figure 4-15: NiBP Sensor Output with Manual Pressure Input
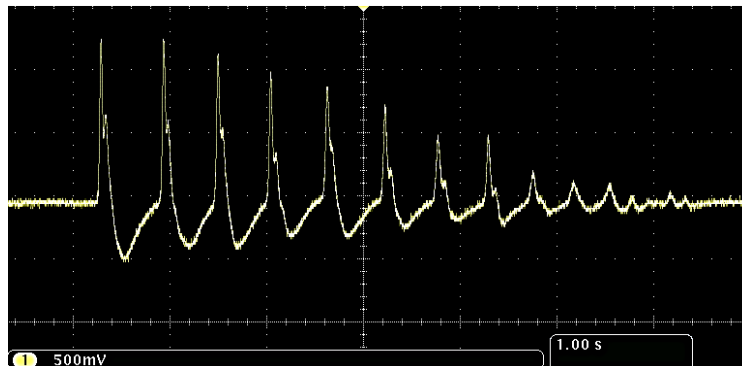
4.2.6 Signal Multiplexing

The concept of the project was/is to combine all four sensors into one unit. We did that physically, but not electronically. Our completed project only transmitted one sensor's signal wirelessly, though the design was left open to readily accept the other three signals if we had time to integrate them.

The sensed signals would be collected in the data acquisition unit, digitized, and then down a multiplexed data stream using Wi-Fi to the base station/receiver. The current system implementation by Philips has two sensors with independent wireless handhelds. The objective was to integrate the two current handheld wireless systems with the data acquisition unit by dismantling the handhelds and embedding their components into the unit. The two other sensed signals would've been digitized within the unit and sent wirelessly in the same fashion.

4.2.6.1 Cable Management

The SQVID cable will consolidate the separate sensor cables into one, but even with the reduced amount of cables some risk is still present. To minimize the chances that the cable will become a hazard, cable management must be considered. Following the system requirements, the cable must not bunch or loop, and must be as short as possible while still allowing seamless patient transfer from the MRI chamber to a recovery area. The data acquisition unit will be located under the patient's bed, and will be easily transferred from one location to another. Along the underside of the bed, and anywhere the cable must be routed, a series of cable clips will be installed in order to ensure the cable slack is well managed and will not present a safety hazard.

4.2.7 Limitations

The system design is subject to limitations present in the high magnetic field of an MRI environment such as the need for non-ferromagnetic metals in cable and connector design. The sensitivity of the system to noise must be considered and appropriate shielding used where applicable. Any interference must be filtered out before transmitting the signal to the receiver base station. The information available on the current platform is limited and has resulted in a large portion of the proposed system upgrade to be based upon speculation and may be altered to comply with new requirements as they are formed.

4.3　Block 1 System Design

4.3.1　Wireless System Materials and Design

An existing wireless platform is used by Philips to monitor and transmit two of the four signals from the sensors. Integration with this platform is the goal, in which the two sensors without wireless solutions (CO_2 and NiBP) will be passed through an extension to the current wireless system and transmitted in the same manner to a receiver/base station.

For the proposed system upgrade, the signals must all be collected in the data acquisition unit located under the patient's bed, and transmitted in a multiplexed data stream to the receiver base station.

If the platform is to be designed with an open-ended approach, a wireless module would be included to pass the signals to the receiver. A few options for wireless modules are listed below in **Table 4-14**.

Table 4-14: Wireless Modules

Option	Name	Description
A	TiWi-uB2 Bluetooth Module	Bluetooth 2.1+EDR and BLE 4.0 Integrated Band-Pass Filter Miniature Footprint: 7 mm x 7 mm
B	XBee Pro 60mW Wire Antenna - Series 1 (802.15.4)	250kbps Max data rate 6 10-bit ADC input pins 128-bit encryption Built-in antenna 1 mile (1500m) range

Table 4-14: Wireless Modules

C	XBee Pro 900 XSC RPSMA	Up to 2000 ft Indoor range with high-gain antenna 10 Kbps data rate Up to 24 dBm (250 mW) Transmit Power Receiver Sensitivity of -109 dBm at 9600 baud
D	TI CC2560	Supports Bluetooth 4.0 dual-mode (BR/EDR/LE) protocols Support of up to 6 simultaneous connections Flexibility for Easy Stack Integration and Validation Into Various microcontrollers, Such as MSP430 and ARM Cortex M3 and M4 MCUs
E	TI CC3000	IEEE 802.11 b/g Embedded IPv4 TCP/IP stack Works with low MIPS and low-cost MCUs with compact memory footprint Integrated crystal and power management

Of the above options, the TI CC3000 is likely the most viable. Some of the reasons for justification of this decision are listed below:

- Compatibility and ease of integration with the MSP430 architecture.

- Large amount of available resources on development with CC3000.

- 802.11 b/g WIFI preferred connection method by Philips.

4.3.1.1 **CC3000 Wireless Module**

The CC3000 module was selected for the wireless communication requirements of this project. The device communicates with serial peripheral interface (SPI) to the host microcontroller following the general wiring diagram provided below.
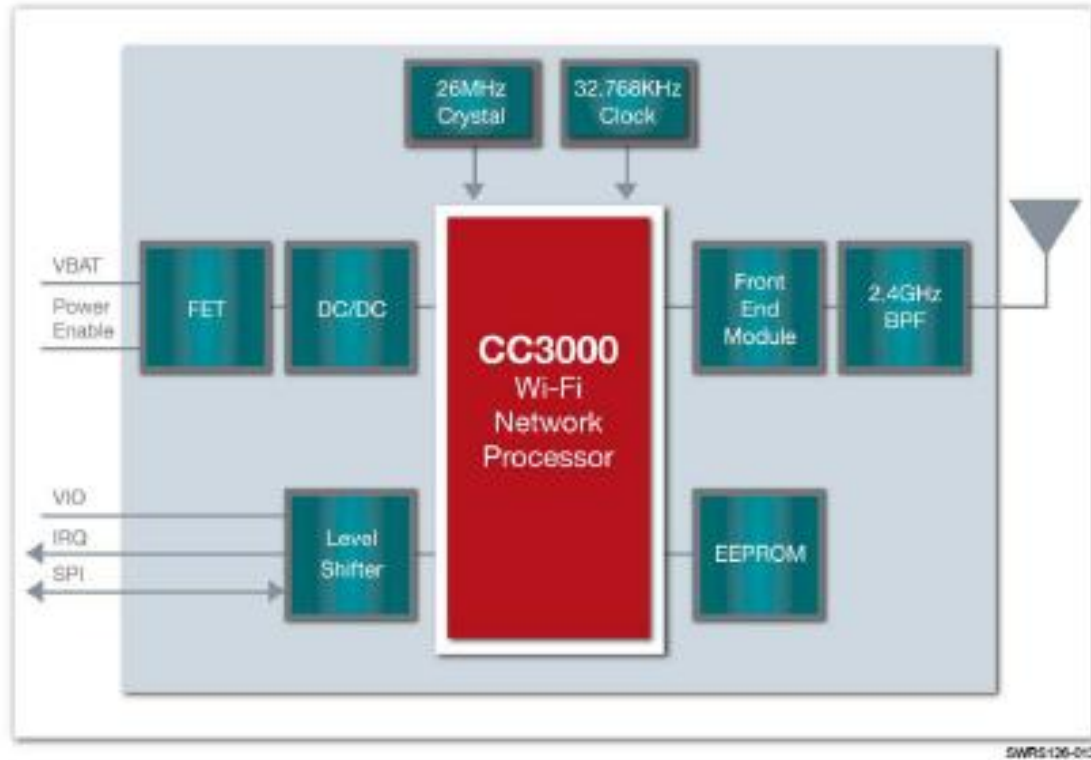
Courtesy of Texas Instruments

The initialization of the wireless module is covered in the embedded system coding plan, in section 6.0 of this document. Printed circuit board design considerations are also provided in section 6.0, under hardware design criteria.

4.3.1.2 **Integration with Existing Hardware**

The wireless platform used by Philips was studied in order to mimic the current design. The provided platform gives a base for which to build the wireless platform of the CO2 and NiBP sensors. If the system is unable to be built upon or seamlessly incorporated into the final design, the two above named sensors will use a new platform similar but separate to the current wireless solution.

 The level of integration is limited to embedding the existing two wireless monitors into the exterior of the SQVID cube. The two monitors will sit flush on the surface and their

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cables routed alongside the two internal cables. The routing of the cable are handled internally and an extension will be used from each wireless monitor to the connector of the SQVID cable. The connector at the other side of the SQVID cable interfaces with the sensor and pass the signal back to the wireless monitor.

4.3.1.3 **Operational Frequency/Spectrum**

For the wireless signal to retain as much information as possible while being subject to as little interference as possible, a certain wireless spectrum must be adhered to. **Table 4-15** lists the different ranges of the industrial, scientific, and medical (ISM) frequency bands.

Table 4-15: ISM Frequency Bands

Frequency Range		Bandwidth	Center Frequency	Description
6.765 MHz	6.795 MHz	30 kHz	6.780 MHz	Subject to local acceptance
13.553 MHz	13.567 MHz	14 kHz	13.560 MHz	Worldwide
26.957 MHz	27.283 MHz	326 kHz	27.120 MHz	Worldwide
40.660 MHz	40.700 MHz	40 kHz	40.680 MHz	Worldwide
433.050 MHz	434.790 MHz	1.74 MHz	433.920 MHz	Region 1 only and subject to local acceptance[1]
902.000 MHz	928.000 MHz	26 MHz	915.000 MHz	Region 2 only (with some exceptions)[2]
2.400 GHz	2.500 GHz	100 MHz	2.450 GHz	Worldwide
5.725 GHz	5.875 GHz	150 MHz	5.800 GHz	Worldwide
24.000 GHz	24.250 GHz	250 MHz	24.125 GHz	Worldwide
61.000 GHz	61.500 GHz	500 MHz	61.250 GHz	Subject to local acceptance

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[1] Region 1 includes Europe, Africa, the Middle East west of the Persian Gulf including Iraq, the former
[2] Region 2 includes the Americas, Greenland, and some of the eastern Pacific islands.

| 122.000 GHz | 123.000 GHz | 1 GHz | 122.500 GHz | Subject to local acceptance |
| 244.000 GHz | 246.000 GHz | 2 GHz | 245.000 GHz | Subject to local acceptance |

Overall, the 2.4 GHz frequency ranges are the most desirable as to provide a standardized wireless system that is used for multiple sensor environments and minimal interference. Development resources are widely available, and the ubiquitous nature of the 2.4 GHz spectrum ensures greater availability and lower cost of parts.

4.3.2 Software Platform

The software system, the Simplified Quad-Vitals Integration Device Intelligent Navigation Controller (SQVID INC), works in conjunction with the connection box to attain and display the wireless data in realtime. The standalone program runs on any standard Windows operating system with the 4.0 .Net Framework and has the ability to utilize a touch screen interface if necessary. The Windows operating system was chosen due to its universal acceptance and current use in the Philips industry. Due to the prototype nature of this project, app development was not of concern and thus it was decided that an iOS or Android application was not needed.

4.3.3 Existing System

In conjunction with their cableless measurements solutions, Philips uses IntelliVue Guardian Software, the accompanying system which receives the wireless signals and processes them. Philips' entire IntelliVue Guardian Solution includes the software, patient monitor, cableless measurement devices, and mobile management support, in addition to more sophisticated and advanced services. The core of the system, IntelliVue Guardian Software, analyzes a patient's vital signs for deviations, is highly configurable, and connects to a hospital's enterprise system. Due to the scope of this project as well as its proprietary nature, it was decided that the new system would be a dramatically simplified version of this software, only providing the necessary functions to ensure proper functionality and demonstration of the newly designed hardware. **Table 4-16** displays the main features of the current Philips system in comparison to the new program written for this project.

Table 4-16: IntelliVue Guardian vs. SQVID INC

IntelliVue Guardian Software	SQVID INC
Acquires and Displays Vital Signs	✅
Smoothes Workflows, Reduces Human Errors	✅
Automatically Verifies the Accuracy of Data	❌
Aids in Early Detection of Deterioration by Analyzing Data	❌
Highly Configurable	❌
Configurable Action List with Recommended Care	❌
Aligns with Clinical Practices	❌
Automates Early Warning Scoring	❌
Connects to a Hospital's Enterprise System	❌
Several Additional Services Available	❌

4.3.3.1 **User Interface**

Various user interface designs were considered for this project. The first option considered was a similar layout to Philips current IntelliVue Guardian system, as seen below on the IntelliVue bedside monitor in **Figure 4-17**. This approach, while it would have been familiar to current users of Philips' software, was essentially an unreachable goal for the Senior Design Team due to time constraints and limited resources. The team felt that choosing such a layout would have overcomplicated the software and robbed focus from the hardware design and functionality, which was not only the biggest challenge of this project but the greatest victory. A cleaner design was thus drafted and followed to help highlight the hardware's operation and to demonstrate the accuracy in the data attained from the microcontroller and software pairing.

Figure 4-17: IntelliVue Bedside Monitor

*Image Reprint Courtesy of Philips*

With the main concerns being simplicity and functionality, a basic elementary design was chosen. It was decided that a touch screen interface would be a great feature to add for demonstration purposes as well as portability, and thus the design could easily be run on a touch screen device. This particular feature is becoming more and more commonplace in the professional industry, and will soon be expected rather than desired. The recent versions of the Visual Studio IDE make writing a program compatible with tactile input too manageable to be ignored. Combined with the popularity of the Windows 8/8.1 operating system and its versatility among tablets and desktop computers alike, implementing a design that was touch screen friendly became a trivial decision.

The user interface displays the single NiBP reading being received from the blood pressure sensor mounted on the microcontroller. The data is displayed both graphically and numerically, automatically updating in real-time as information comes in. The graph scrolls automatically to accommodate the real-time display, and clears each time the "Stop"-"Start" buttons are pressed in sequence.

It was determined that due to the scope of this project units of measurement were irrelevant, and therefore the GUI graph is given a generic scale, but can be easily customized if development of SQVID continues.

Figure 4-18 shows SQVID INC operating in real-time.

Figure 4-18: User Interface Design for SQVID INC
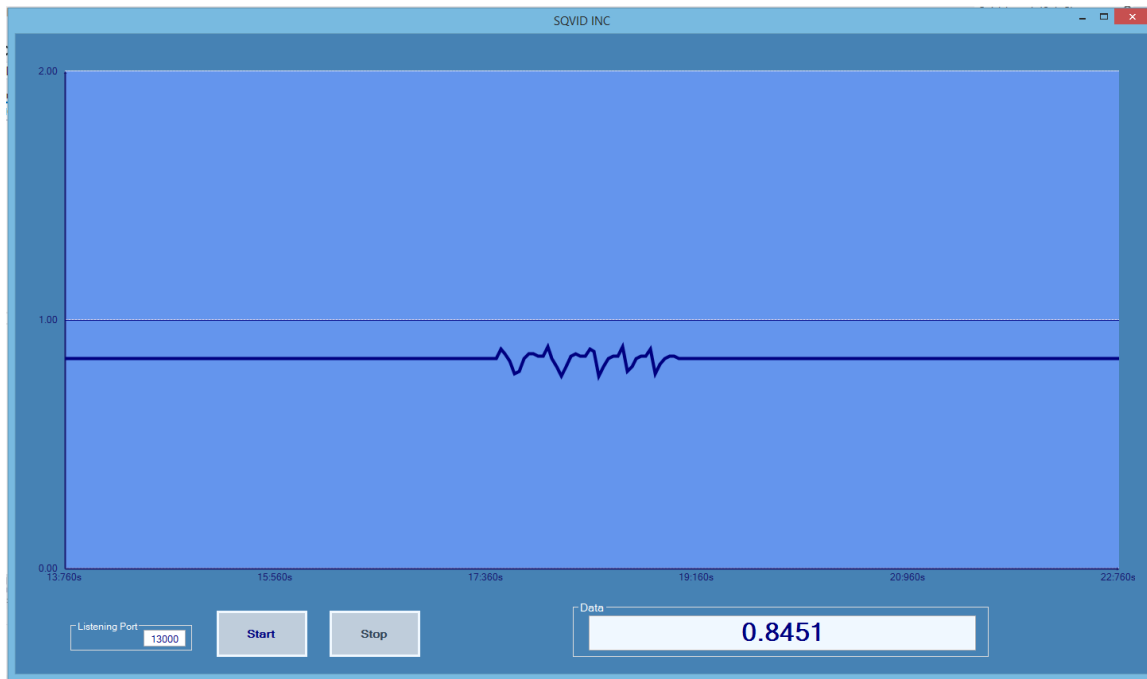
4.3.3.2 Coding Language

Two coding languages were considered for the graphical user interface: object oriented Pascal using Embarcadero RAD Studio/Delphi 2010 and C# using Visual Studio 2012. Pascal was only considered because of the main programmer's extensive experience with the language and pre-existing code that could be of use. The pre-existing code already had the ability to take in digital and analog signals and graph them, using TCP/IP and UDP messaging protocols. However, while a versatile language with many capabilities, Delphi Pascal is not necessarily a common coding choice and is not widely used in a professional environment. It is one of the oldest languages still in existence with very few open-source resources in comparison to newer languages like C++, Java, and C#. In addition, only recent versions of the IDE, such as Delphi XE2, have gesturing and touch screen interface support comparable to what Visual Studio has to offer. Delphi XE2 is an expensive and license-only product, inaccessible to the typical hobby coder. Visual Studio 2012, however, is offered for free to students studying a related programming field. The C# language was thus explored further, and even with very little experience with the language, the opportunity to learn it was appealing to the programmer.

The language provided the real-time data acquisition capabilities necessary for the system, while yielding simplicity and power, as well as seemingly nonexistent limitations. Microsoft Visual Studio was chosen as the coding IDE due to its comfortable and familiar environment. The software system takes advantage of the .NET framework and the language enables easy UI design and touch interface features to be effortlessly integrated. The diverse open source libraries available to the language allow for various

features to be added with a few lines of code both during initial coding of the program as well as at a later time to enhance the performance of the program if necessary. While the system is intended for use on a touch screen device running Windows 8/8.1, it is also capable of running on any standard Windows operating system yielding the 4.0 .Net framework.

4.3.3.3 Signal Acquisition and Processing

The two main methods discussed for transferring data between the connection box and the software program were Bluetooth and wireless TCP/IP communication. Inital research into the IntelliVue Guardian software as well as previous programming experience led the team to contemplate using TCP/IP protocol communication. This method was considered not only to mimic Philips' current software system but because of its reliability and ease of use. However, during the actual development stage of the project and research into the embedded wireless transmitter, TCP/IP began producing problems. User Datagram Protocol (UDP) was then considered and proved to be not only more efficient but simpler to implement and thus was chosen over the previous method.

UDP communication is used to handle the data exchange between the CC3000 wireless module and the actual software program. The CC3000 module and the receiving software system each possess their own unique IP address, both residing on the same network. A configurable port number is set on both sides to ensure proper data packet transmission. Once started, the software program begins its UDP server/listener and awaits data from the microcontroller. When the controller is powered on, it automatically attains its IP address and awaits the user to press a button to begin data transfer. Once this button is pressed a UDP socket is automatically opened with the necessary information and data is sent to SQVID INC. Due to the nature of this protocol, packet loss is never visible to the user and was not of great concern due to the prototype nature of this project. If the connection between client and server is lost data display is stopped until the problem is acknowledged and/or fixed. Testing showed that this was very rare, only occurring when the power supply of the microcontroller and sensor ran too low or was depleted completely.

4.3.3.4 Scalability

Due to the coding choice as well as the IDE, the final software program will possess countless options for improvement at very little cost. Apps can be created if necessary for the Windows 8/8.1 environment, depending on what is needed. For instance, a version compatible with Windows 8.1 can be created while maintaining a version of the app compatible with Windows 8 all from within Visual Studio 2012. However, a developer license is needed to develop and test Windows Store apps before the Windows store can certify them.

Further development to include all four vital signs would also be extremely feasible. Using the same communication protocol and assuming the same wireless processor, each signal could easily be programmed to include one-to-two bytes of data indicating the nature of the signal (i.e. ECG, SpO2, CO2). And thus, through simple parsing on the side of the software system, these signals could be handled and displayed differently. An alternative approach would be to have separate wireless processors each with their own unique IP address sending to the same software system. Each signal could then be handled accordingly by using their IP address as identification.

Being designed to run on Microsoft's latest operating system, compatibility and legacy support should not be of great concern for several years. Many features were considered when drafting the design of this program, and those that weren't considered vital to the prototype nature of this project could easily be added with the necessary information from Philips and some time to make the changes. A few of these features and what would be required to include them are summarized in **Table 4-17** below, with details of each feature and steps for implementation described afterward.

Table 4-17: Additional Feature Requirements

Feature	Required Information
Early Detection of Patient Deterioration	Philips' proprietary data analysis techniques
Hospital Enterprise System Integration	Philips' permission and detailed network information
Advanced Configurability	Access to Philips' current software system to analyze and mimic existing code functionality
Multiple Patient Profiles	No information needed, just time to make the change and test its functionality

Early Detection of Patient Deterioration: One of the most powerful tools integrated into Philips' IntelliVue Guardian Software system is the analysis of a patient's vitals automatically with the intention of predicting if the patient's health is or will be deteriorating. Philips refers to this as "EWS", Early Warning Score, which is the first of its kind to provide assistance and recommendations to caregivers based on their hospital's policies, all from a spot-check monitor with the patient. The system is completely customizable and can be adjusted for varying vital sign collection periods. To duplicate this feature within this project's scope the algorithms and calculations Philips uses to detect variances in a patient's vital readings would have to be shared with the team. Lots of time would be required for implementation as well as thoroughly testing the system to ensure it performed correctly, consistently, and was up to Philips' high standards.

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Hospital Enterprise System Integration: Philip's IntelliVue Guardian Solution enables connectivity to a hospital's enterprise system using IntelliBridge Enterprise. This provides interoperability between the Philips clinical systems and the facility's enterprise information systems, with efficient connection points, secure data transferring, and incredible reliability. This feature was not considered appropriate or necessary for the main objectives of this project as it did not relate to the construction or demonstration of the SQVID cable. To add this feature to SQVID INC would require a significant amount of research into the development and functionality of IntelliBridge Enterprise, and how a typical hospital's enterprise system works, all before any code could be changed within the program.

Advanced Configurability: It was determined that only a minimum amount of configuration options would be necessary to properly demonstrate the functionality of the SQVID cable and hardware system. In fact, an objective of the program, as stated in Section 2.2.5, is that the INC software obtains the vital signals and does the necessary manipulations to properly display the waveform data automatically, with preferably no human intervention to prevent accidental human error. To enhance INC with advanced customization features comparable to that provided in IntelliVue Guardian, a deeper understanding to how the software is used by Philips' customers would need to be attained. Taking into consideration only the four signals being monitored, a lot more research would need to be done with regards to filtering techniques for each waveform and how manipulation would affect the data. While adding aesthetic customization features for the user's benefit may be trivial, enhancing INC with the sophisticated techniques used by Philips to provide accurate, reliable, and detailed patient information would prove to be quite the challenge.

Multiple Patient Profiles: This feature would be most applicable in an instance where multiple SQVID boxes and their cables were in circulation. The feature would allow for multiple patients to be saved into the INC program's database, each with their own individual IP address linking them to their respective SQVID box. This information could be accessed and edited from the main screen of the program, and a "Connect to Patient" option could be added to control the servers currently active. That is, only selected patients, known to be using their SQVID box, would have a server awaiting client connections. The most difficult part of implementing this feature would be the production of multiple SQVID boxes and their cables for thorough testing, assuming SQVID INC would be running as a stand-alone program separate from a hospital's network or Philips' existing software system as written to do so for this project.

Unfortunately, full integration into the existing Philips system is nearly impossible due to not only to the proprietary nature of this project and Philips' understandable discrepancy to relay specific details of their existing system to members of the team, but because of the sheer scope and amount of work that would be involved in such an undertaking. The INC program written to interface with the new SQVID cable is purely for demonstrational purposes, and while features were added to enhance the functionality and emphasize design aspects of the hardware, it was never intended to be installed and used in a professional, hospital setting as a replacement or even an accompanying system for Philips' IntelliVue Guardian Software.

The scalability of the hardware will be limited by the level of integration allowed with the current system provided by Philips. If the two existing wireless sensors are integrated using Philips' proprietary wireless solution, the system will have plenty of remaining input/output space for future sensor integration. The wireless nature of the device will allow for greater system expansion without the associated bulk of additional cable connections. Expanding upon the wireless capabilities, the system may be used to connect to a larger mesh network and communicate between multiple base stations and peers on the network.

4.4   Enclosure Design

The main concept behind designing a consolidated system is reducing the number parts the user has to manage. So, the ideal system would have all four sensor leads reconstructed into one cable that plugs into a single unit at the foot of the bed. Unfortunately, the reconstruction of MRI-safe sensor leads is beyond the scope of this project. However, the idea of consolidation stays alive with the sensor hub. The case is designed to be as close to one part with one switch as possible.

The general layout of the case and configuration of sensors is to lay the four modules side-by-side and keep the case as flat-packed as possible. Taking the smallest area the sensors could fit into securely and allotting additional space for power supply and miscellaneous electronics (indicator LEDs, switches, etc.) resulted in a case footprint of roughly 12"x10" with a cozy 2" ceiling. For ease of access and assembly, the modules are mounted to a tray (**Figure 4-#**) that slides into the front of the outer shell (**Figure 4-#**) and is secured with an external screw.

Figure 4-19: CAD Drawing of Enclosure's Outer Shell
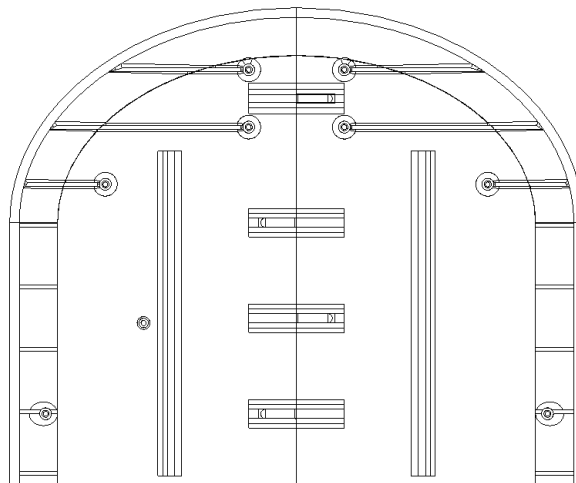
For the production of the housing, Philips has made available the use of their rapid prototyping lab, complete with a 3D printer. With 3D printing capabilities, the model was designed using CAD sketches and 3D modeling software. The software of choice was PTC Creo 2.0, particularly Creo Parametric.

Being able to create custom parts contributed greatly to the unifying theme. Though, relying on the use of the 3D printer imposed a few constraints on the model's dimensions and mechanics. One of which is the printer's 7.8"x11" printing stage with a 5" maximum height required the 12"x10"x2" model be split into smaller parts in order to be printed. The case being split into parts, as opposed to a solid single-cut shell, is inherently less structurally sound but this problem was alleviated by adding extra support bridging the seams along the outermost shell and ribbing throughout the inside (visible in **Figure 4-###**).

Figure 4-20: CAD Drawing of Service Tray
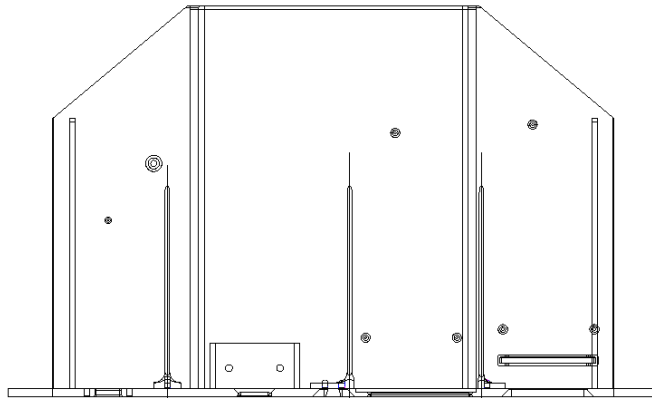
The other main factor taken into consideration was the amount of material being used. The plastics used in the printer are a substantial expense, so it is good practice to conserve material as much as possible without sacrificing too much strength. As mentioned earlier, ribbing along the hollow insides is an efficient and sturdy support.

With STEP files containing dimensions for the SpO2, ECG, and EtCO2 sensors and the known dimensions of the PCB and battery packs, the model shown in **Figure 4-20** was tailored to secure all the parts in as small a space as possible. The STL (stereolithography) files were then sent to the printer and the model was realized.

Figure 4-21: 3D Model of Enclosure (section removed to reveal inside)
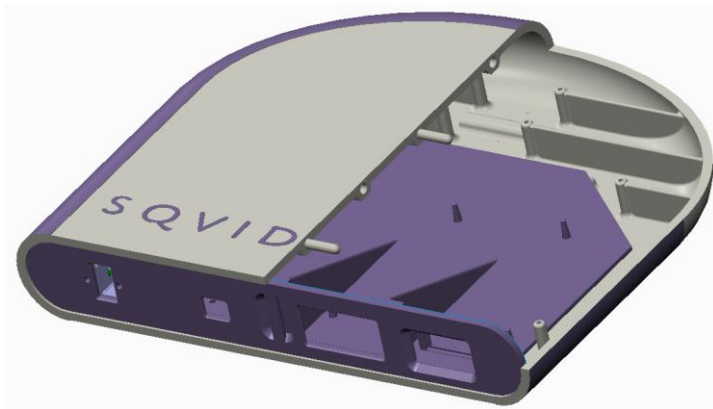
5.0   Design Summary of Hardware and Software

5.1   Hardware Design Summary

The primary goal in designing the hardware for the SQVID, as is with most designs, is functionality; the device does what it needs to do in the conditions it will be used in. So, we designed the device as simply as possible using parts that will operate in and not interfere with an MRI environment. Once that is achieved, we can move to other aspects like reliability and consolidation.

Knowing the sensor cables running from the patient to the SQVID will be provided to us by Philips, we started our design at the hub where the cables will all connect. The ECG and SpO2 sensors already had wireless transmission solutions, so we were left with NIBP and CO2 to handle. NIBP sensors are relatively straightforward so we designed our own. Capnography is not as simple, so we may need to use Philips' current CO2 sensor design. However, no schematic for the CO2 sensor has been provided. The NIBP and CO2 sensors run to a microcontroller (TI MSP430) for A/D conversion and multiplexing. Then an RF transmitter sends the data wirelessly to a monitoring display.

5.2   Software Design Summary

The accompanying software system, the Simplified Quad-Vitals Integration Device Intelligent Navigation Controller, uses wireless UDP communication to acquire the various vital signs connected to the SQVID connection box. The vital sign is shown graphically and numerically for the user through a simple GUI. The program is written to have minimal human intervention during operation and is designed with simplicity in mind.

The INC software program runs on any standard Microsoft Windows operating system with the 4.0 .Net Framework. Its design is touch-screen friendly with large buttons, which makes it possible to run the program on a tablet device for easy portability.

6.0 Project Prototype Construction and Coding

6.1 Final Hardware Design

6.1.1 Objective Summary

The main objectives of the final hardware design for the SQVID are to successfully integrate the NIBP and CO2 sensors into a wireless-capable platform alongside the two existing wireless sensors. The cable consolidation and management aspect of the project are included within the enclosure design and custom connector concepts. These goals and concepts are listed below in **Table 6-1**.

Table 6-1: Hardware Plan Objectives

Objective	Requirement Description
H-001	Successfully integrate NIBP and CO2 sensors into wireless capable platform.
H-002	Allow for future expansion and development on the hardware platform by available connections to unused host controller GPIO pins.
H-003	Achieve cable consolidation and management through enclosure development efforts.
H-004	The operation of the system should remain as simple as possible, allowing for ease of use by the end customer.

6.1.2 Schematic Capture

Final schematics for the SQVID were produced using EAGLE CAD software, following suggested design specifications to reduce noise and increase reliability. Bypass capacitors were inserted along each power trace for each IC, on both input and output sides. Nets were linked from sheet to sheet to allow greater traceability when reading the schematic, and reduce ambiguity resulting from multiple traces spanning multiple pages.

Although EAGLE CAD does not provide a circuit simulation aspect, the visual appearance of the completed schematic is very clean and easy to read. Additionally, the circuit can be exported for use in simulation software, though for the purpose of this project this step was not performed. The circuit was tested in the laboratory using physical components on a proto-board and utilizing laboratory power supplies and oscilloscopes.

6.1.3 Printed Circuit Board (PCB) Design

The design of the PCB took a four layer design approach, as suggested by the sponsor, Philips. This allowed for greater flexibility when routing the traces. The required trace thickness was calculated using a max current well above what is expected for this device, in order to provide confidence in the robustness of the design. The calculations for trace thickness can be observed in **Figure 6-1**.

Figure 6-1: PCB Trace Width Calculation

Inputs:

Current	.5		Amps
Thickness	.035		mm

Optional Inputs:

Temperature Rise	10	Deg C
Ambient Temperature	25	Deg C
Trace Length	5	cm

Results for Internal Layers:

Required Trace Width	11.8	mil
Resistance	0.0840	Ohms
Voltage Drop	0.0420	Volts
Power Loss	0.0210	Watts

Results for External Layers in Air:

Required Trace Width	4.55	mil
Resistance	0.219	Ohms
Voltage Drop	0.109	Volts
Power Loss	0.0546	Watts

6.1.3.1 RF Trace Considerations

Special attention was given to the CC3000 module and accompanying antenna design. Using miscrostrip trace impedance calculations, the ideal trace width was determined to be 34 mils for 50Ω impedance matching based on other board design criteria including substrate thickness, relative permittivity, and trace thickness.

Figure 6-2: RF Trace Width Calculation

Select the units for all dimensions: ⦿ mm ○ mils

H (Dielectric thickness) :	.5	⦿ mm	○ mils
T (Trace thickness) :	.035	⦿ mm	○ mils
W (Trace width) :	34	○ mm	⦿ mils
ε_r (Relative permittivity) :	4.7		

Zo (Characteristic impedance): 49.8 ohms

6.1.3.2 PCB Routing and VIA placement

The four layer stack is arranged in the following order from top to bottom: Signals, Ground, Signals, Signals. Originally, there was to be a VCC plane. Due to the nature of our board, however, this layer was converted to allow for general signal trace routing. The board utilizes positive and negative 5V regulators, as well as a 3.3V regulator. This makes a single VCC plane impractical. The layer stackup is pictured below.

Figure 6-3: PCB Layer Stackup

Design Rules (SparkFun_4layer *)

File | Layers | Clearance | Distance | Sizes | Restring | Shapes | Supply | Masks | Misc

Nr	Copper	Isolation
1	0.035mm	
		0.5mm
2	0.035mm	
		0.5mm
3	0.035mm	
		0.5mm
16	0.035mm	

Total: 1.64mm

Setup (1*2+3*16)

Layers are combined through either *core* or *prepreg* material. **a*b** combines layers *a* and *b* with a *core*, while **a+b** does the same with *prepreg*.
Buried and **through** vias are defined by writing (...).
Blind vias are defined by writing [t:...:b], which defines a blind via from top to layer *t* and from bottom to layer *b*.
Example: [2:1+((2*3)+(4*16))] is a multilayer setup with two cores, combining layers 2/3 and 4/16, respectively, with buried vias going through both cores. The cores are combined through a prepreg and buried vias are produced through the resulting stack. Finally layer 1 is added, with blind vias going from layer 1 to 2.

OK | Cancel | Apply

Vias were placed as needed for passing signals between layers, via stitching was used throughout the board to provide many paths to ground, reducing noise and increasing thermal dissipation.

In particular, the RF Trace was lined with vias and the CC3000 included many vias for the benefits listed above. This was suggested by the PCB design considerations document for the CC3000 module, provided by TI. This reference was consulted and adhered to in the design process. Additionally, the RF trace is impedance matched 50 ohms, as detailed above. The silkscreen layer and all traces are shown in **Figure 6-4**.

Figure 6-4: PCB Layout and Routing
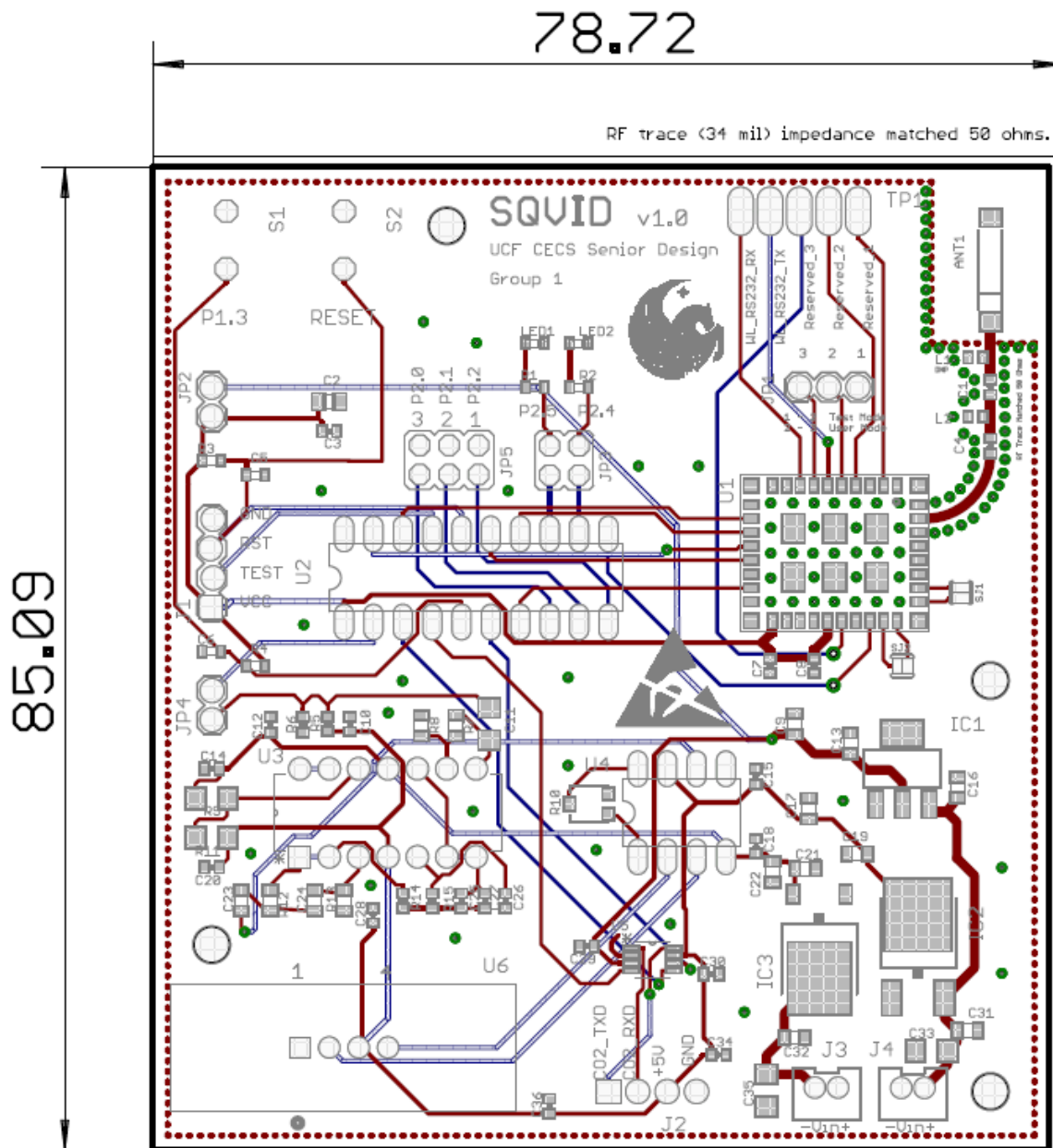
6.2 Final Coding Plan

6.2.1 Objective Summary

The main objectives the SQVID INC software was designed to accomplish are found in Section 2.2.5 and the table is reprinted below (**Table 6-2**) for convenience.

Table 6-2: Coding Plan Objectives

Objective	Requirement Description
S-001	The software system must provide a user-friendly, easy to understand and manipulate interface for healthcare professionals or other users involved in its operation.
S-002	The software system must do any necessary calculations and/or modifications to accurately depict the signal as required for all users operating the system.
S-003	The software system must acquire and display the data with minimal to no user intervention.
S-004	The software system must be extremely reliable and display data accurately.

Objective S-001 is met through the designed GUI as described in Section 4.3.3 The touch screen friendly interface and intuitive layout provide the user or healthcare professional with important and accurate displays of vital sign data both graphically as well as numerically, and easy to use operation that assists in data analysis and enhances patient care.

Objective S-002 would be more accurately met through the use of the Philips Company's custom, proprietary algorithms. However, as a proof of concept project no complex filters were added on the GUI side. The raw data is displayed both graphically and numerically for the user to reflect the functionality of the hardware.

Objectives S-003 and S-004 are met through the use of a UDP communication initiated with the start of the program. Clicking the "Start" button of the program begins a UDP listener which waits for open socket connections and data transmission. Throughout testing the program displayed no signs of malfunction. Only when the sending hardware experienced problems did the software demonstrate a small lack of performance. This included noise in the data signal as well as severe lag in real-time display due to the lack of DC power being supplied to the module.

6.2.2 **Communication**

As previously stated, communication between the wireless CC3000 module and the accompany software system, SQVID INC, uses User Datagram Protocol. This decision was made during the actual production phase of this project when it became clear that the originally proposed TCP/IP communication protocol would have overcomplicated the wireless data transfer. The following sections outline the reasoning behind the design modification as well as the proper IP address configuration procedures used to accomplish the data exchange between the microcontroller and SQVID INC.

The host controller (MSP430) communicates with the CC3000 module over serial peripheral interface, and the CO2 sensor communicates with the controller over standard UART communication protocol. The CO2 port is also used for hyperterminal communication and debugging of the microcontroller.

6.2.2.1 **UDP Communication Details**

User Datagram Protocol, or UDP, was chosen as the method of data exchange for the SQVID project. While the main reason for its implementation was pure simplicity, it also proved to be well suited for the purposes of this project. Due to the prototype nature of this project it was not vital that data be received in a certain order, but instead that the data be received and transmitted in as close to real-time as possible. The frequency of data sampling was handled on the embedded system's side and therefore the only real concern was that the communication protocol chosen could operate at the same speed. No handshaking was necessary or of importance, and only two bytes of data were being transmitted at a time, a very small amount easily managed by UDP. **Table 6-3** showcases differences in greater detail between TCP and UDP which were of concern for the SQVID project.

Table 6-3: TCP vs. UDP

TCP (Transmission Control Protocol)	UDP (User Datagram Protocol)	Details and Relevance to SQVID
Connection-Oriented, Handshaking Required	Connectionless, No Handshaking	Handshaking would have been required to accomplish TCP. With SQVID being a "proof-of-concept" project and data transmission being one-way, handshaking would have unnecessarily complicated programming.

Table 6-3: TCP vs. UDP

Highly Reliable, Order Specified	Not as reliable, No Inherent Order	Reliability was not of great concern, neither was the order packets were received. The sampling frequency rate (and thus the speed of which data was being sent) was more important.
Slow(er) due to Error Checking of Packets	Faster than TCP	The speed of data reception was extremely vital for SQVID. Data needed to be received and displayed in realtime to prove that the wireless transmission could be used in a medical environment with existing hardware.
Needs three packets to set up a socket connection – 12 fields for successful transmission	Extremely Simple – 4 fields for successful transmission	All that was required for the sending of data on the microcontroller side was an IP, port number, and the length of data, along with the method of transmission (UDP). This would have been much more complicated had TCP been chosen.
Acknowledgement when data received	No Acknowledgment when data received	Due to the speed of which data was being sent, if a packet was lost it was not visible to the user. Therefore, an acknowledgement was not of concern.
Flow Control	No Flow Control	Flow control was not of concern due to the prototype nature of the project.

For scalability purposes UDP also exhibited many benefits over the originally considered TCP/IP communication protocol. Assuming the same hardware configurations, that is, that a CC3000 would be used as the wireless data transfer device, different listening ports could easily be of use to distinguish between various transmitted information. If multiple CC3000 modules were involved, unique IP addresses could be used as well if necessary.

6.2.2.2 **CC3000 Initial Configuration**

The CC3000 requires an initial configuration process to connect to a designated access point. This is a one-time-only procedure required when connecting for the first time to a specific wireless network. As a TI product the CC3000 can use Smart Config, an application designed to work with the device to automatically connect it a network. Smart Config comes in the form of an iOS app, Android app, or a Java Applet capable of running on any computer and launched from a web browser. The application automatically gathers the network's SSID, IP address, and allows the user to enter the network's password and/or key if applicable. Configuration of the host controller follows the general process outlined below:

- Host driver initializes general purpose input/output (GPIO) pins and clock source/frequency.
- SPI communication is established with CC3000 wireless processor.
- UART communication is enabled to aid in debugging the processor.

The team chose to use the CC3000 Software Development Kit available from the TI official website to assist in configuring the CC3000 module correctly. The SDK includes the Basic Wifi Demo application, which can run in TI's Code Composer Studio or the IAR Embedded Workbench environment. The demo program enables the use of a HyperTerminal to communicate with the device using the proper opcodes and is capable of running with the chosen microcontroller, the MSP430g2553. This open-source application was used because of the specific drivers and firmware that were necessary for the CC3000's operation and these were not only included in the CCS project, but downloaded and run automatically. The opcodes found in Table 6-3, below, were provided by TI for use in the WiFi Demo. Many were used for testing purposes in addition to the Smart Configuration process.

Table 6-3: TI Basic WiFi Demo Opcodes

Function	Opcode	Arguments
Smart Configuration	01	None
CC3000 Connect	02	SSID, SSID Length
Socket Open	03	None
Send Data	04	Destination Port, IP Address with Data
Receive Data	05	None
Bind	06	Port To Bind
Socket Close	07	None
IP Configure	08	Local IP Address, Default Gateway
CC3000 Disconnect	09	None
CC3000 Delete Policy	0a	None
CC3000 Send mDNS Advertisements	0b	None

The WiFi Demo application allowed for the Smart Configuration process to be completed almost effortlessly. Both the iOS App and the Java Applet were tested during SQVID's construction and programming and both worked without any error. By sending the "01" opcode command to the device and running the Smart Config tool, the CC3000 was automatically connected to our designated AP and an IP address was assigned based on the network's subnet. This address can also be manually set if desired, but wasn't necessary for this project. Pinging of the device was frequently used to ensure that connection was successful. **Figures 6-1** and **6-2** show TI's Smart Config Application for iOS as well as the Java Applet, respectively.

Figure 6-5: Smart Config for iOS   **Figure 6-6: Smart Config Java Applet**

6.2.2.3 UDP Specific Configuration

For proper functionality, both the CC3000 and the receiving software system need to be on the same wireless network. This is automatically done for the CC3000 after using Smart Config. SQVID INC is programmed to listen for any IP address so long as the port

number configuration is correct. Therefore, the only concern is that the CC3000 is on the desired network and is not in possession of an IP address that's already in use.

In order for the microcontroller to know where to send data the IP address of the receiving software system needs to be programmed. This is best done by first configuring a static address for the receiving computer based on the wireless network's subnet and then carrying this address over into the programming of the microcontroller. **Table 6-4** displays the IP address and port configuration chosen and used for the SQVID system. A portable NetGear wireless router was used during demonstrations and testing to prevent from having to reconfigure the CC3000 unnecessarily. The subnet mask was assumed to be "255.255.255.0" for all devices as documented by TI for the CC3000.

Table 6-4: IP Address and Port Configuration

Device	IP Address	Port Number	Details
Wireless Router	192.168.1.1	N/A	A NetGear WirelessN Router was used during demonstration and testing to prevent the team from having to constantly reconfigure the CC3000 to connect to a different AP. Its IP address was automatically assigned and a simple password was used for connection.
Device Running SQVID INC	192.168.1.12	N/A	The computer running INC was configured to have a static IP address such that it could be easily programmed for the CC3000.
SQVID INC Software System	N/A	13000 (configurable)	The software system itself did not require an IP address but a port number. This was configurable via a textbox on the interface but needed to correspond to the programmed port number for the CC3000.
CC3000	192.168.1.X	13000	The team allowed Smart Config to assign the IP address of the CC3000, which often resided between ".2" and ".5". The port number was programmed to correspond with the default value assigned for INC.

After power-up the CC3000 automatically initializes its driver and attains its IP address, displaying a green LED to indicate it is ready to begin sending data. Pressing switch P1.3 sets the designated port, IP address, and opens and binds the necessary socket. The UDP sending procedure then begins, taking data from the ADC10MEM register of the MSP430 microcontroller. These bytes of data are placed into a temporary array, and a data pointer is used to pass this information to the UDP sending procedure. Figure 6-3

highlights the important segments of code used to complete this process. The "sendto" procedure is part of the host driver for the CC3000 and was included with TI's SDK.

Figure 6-4: UDP Communication Code for CC3000

```
volatile long ulSocket;

// Destination Port: 13000 – Hex
tSocketAddr.sa_data[0] = ascii_to_char('3', '2');
tSocketAddr.sa_data[1] = ascii_to_char('c', '8');

// Destination IP Address: 192.168.1.12 – Hex
tSocketAddr.sa_data[2] = ascii_to_char('c', '0');
tSocketAddr.sa_data[3] = ascii_to_char('a', '8');
tSocketAddr.sa_data[4] = ascii_to_char('0', '1');
tSocketAddr.sa_data[5] = ascii_to_char('0', 'c');

ulSocket = socket(AF_INET, SOCK_DGRAM, IPPROTO_UDP);
bind(ulSocket, &tSocketAddr, sizeof(sockaddr));

data = ADC10MEM;

// Conversions for proper place values
tempArray[4] = (data/10) + 0x30;
tempArray[5] = (data%10) + 0x30;
pcData = (char *)&tempArray[4];

sendto(ulSocket, pcData, ulDataLength, 0, &tSocketAddr,
        sizeof(sockaddr));
```

6.2.2.4 **SQVID INC Communication Details**

SQVID INC operates as a simple UDP listener. When the "Start" button is clicked from the GUI an instance of the .Net UDP Client Class is created and a receiver is run, awaiting any data that might be sent to the specific IP address and port number that has been configured. This is a multi-threaded procedure to ensure proper data handling. As soon as data is received it is converted to the proper string for display, and then parsed into the proper integer format for graphing. The relative code for this procedure is found below in **Figure 6-4**. The UDP client listener is then closed when the "Stop" button is clicked.

Figure 6-5: SQVID INC UDP Code

```
private void startButton_Click(object sender, EventArgs e)
{
    listenPort = Convert.ToInt32(portTextbox.Text);
    listener = new UdpClient(listenPort);

    System.Threading.Thread t = new System.Threading.Thread(runReceiver);
    t.Start();
}

public void runReceiver()
{
    byte[] bData;
    string sData1, sData2, sData;
    float iData1, iData2;
    double dData = 0;

    IPEndPoint end = new IPEndPoint(IPAddress.Any, listenPort);
    bData = listener.Receive(ref end);

    sData1 = bData[0].ToString();   //Conversions needed for byte array
    sData2 = bData[1].ToString();
    sData = sData1 + sData2;

    iData = Convert.ToSingle(sData);
    iData2 = iData / 10000;         //Conversions for proper place values
    sData = iData2.ToString();      //sData will be displayed as text

    Double.TryParse(sData, out dData); //dData will be displayed on graph
}
```

6.3 Enclosure Construction

The raw construction of the SQVID enclosure was the 3D printing done at Philips Invivo's rapid prototyping lab. We provided the STL files to be printed and a few engineers at Philips sent them through the printer and were kind enough to clean the filler material off the parts as they came out. The filler material is a water soluble plastic that supports the modeling plastic as it is printed.

With the parts printed, the only construction left for us to complete manually should have been just assembling and gluing the appropriate parts together. However, the service tray had some slight warping to it and this caused a great deal of friction between it and the rails it fits to. The modeling plastic was very brittle and applying too much force on one piece could easily break that piece and this did happen for two of the pegs bridging the middle seam in the shell. With the service tray not fitting into case, we had to sand down the rails to give it some extra room. Sanding down the rails manually with sandpaper

would have taken a full day or more, but we were fortunate enough to have a Dremel tool lying around in a garage. The tray, finally, fit in the case with a tolerable amount of force and the only other manual construction was installing the LED and power switch, and then fitting all the sensors into the case.

The service tray was designed to fit all four sensors with a small amount of error margin. There were also measures taken to allow mechanical fastening of each sensor, but time became an issue and we resorted to taping/gluing the sensors in their desired locations. A layer of tape was applied to the device surface and its contacting surface on the tray and the two taped surfaces were glued together. This seemed like the sturdiest temporary solution.

Figure 6-7: Photo of Final Assembled SQVID

7.0 Project Prototype Testing

7.1 Hardware Testing Environment

7.1.1 Faraday Cage

The primary testing environment we are concerned with is an MRI room, but we will not have free access to an MRI. Trips to the MRI must be scheduled and not as frequently as we please. So it is important we have our RF signals analyzed as best as we can before we visit the MRI room. We do have access to a Faraday cage in the Invivo labs, so we will make more frequent trips there to do signal testing before testing at the MRI.

7.1.2 MRI Testing Considerations

When testing devices inside the MRI chamber, they must be strained in locations where readings are the most extreme and reach the highest peak value. The following sections describe tests for making devices MRI safe.

7.1.2.1 Static Magnetic Field and Spatial Gradient

The field is strongest at the central bore of the MRI machine and thus all components need to be measured inside the bore for complete safety checks. Also objects need to be tested at varying distances to ascertain that no changes occur while moving through the spatial gradient of the magnetic field. All materials should be tested in finalized forms because their change in geometry may change their reluctance to magnetic pulls.

7.1.2.2 Pulsed Gradient Magnetic Field

Since this is sent out in pulses it is time varying and it induces a voltage on electrical conductors, during the rise-time of the magnetic field. So this can ultimately be tested anywhere in the MRI chamber. If there is a place where the highest voltage induced is greatest, then all devices need to be tested in that area to make sure that the voltage noise will not affect the machines' electronics.

7.1.2.3 Pulsed Radio Frequency Fields

This induces currents on electrical devices and induces noise which materializes as static or distortion on screens. So electrical devices should be tested where the temperature in the devices is highest and in that field, the temperatures should be recorded and an

insulator made to match that maximum temperature. In the place with the highest distortion, the device should be tested in the area of highest noise and then variably filtered out with that maximum result as a foundation for the filter. Prerecorded results should be acquired before testing in high noise level areas so proper tests can be performed.

Below are specific tests to that can be performed in order to determine MR environment safety for various factors. One test cannot necessarily determine if a device is MR safe; however, it does absolve if the device is safe for that particular factor in the MR environment.

7.1.2.4 MRI Force Test

Objective: To measure the magnetic induced displacement force on an object when exposed to the static magnetic field gradients with comparison to the object's weight.

Equipment: A fixture that is nonmagnetic and capable of supporting the weight of the suspended device properly. The fixture should have a protractor attached to it, with one degree increments, with the string being attached at the zero degree mark or any location that is convenient to the tester. The string should have an almost negligible weight, approximately within one percent of the tested device's weight, and should allow the device to hang freely in space. A nonmagnetic scale should also be attached between the string and the device to be tested.

Test Summary: Device is suspended by a string at a specific point in a magnetic field that will induce the greatest pull on the object. If the object deflects less than 45 degrees from its original position, than the objects gravitational pull to the earth is greater than the magnetic pull towards the MRI; however if it is greater than the opposite may be true and the object may not be safe for the MR environment.

Procedures:
Step1: After the apparatus has been set up, the device's weight should be recorded.
Step2: The device should be placed in the MR environment where the magnetic pull is the greatest (Usually near the bore of the MRI machine).
Step3: Hold the device until it reaches the zero degree mark and the string is completely vertical.
Step4: Let the string go and record the greatest degree difference from the zero degree mark to the nearest degree.
Step5: Repeat steps 3 and 4 about three to four times.

Calculations: Compute/Calculate the mean angle from zero for the device and document the results, record the mean degree for how far the device was repelled or attracted to the main magnetic structure. Compute the induced displacement force based off of the mean deflection angle.

Report: This should include the device's description: importance and performance, diagram of the test, equipment used to perform the test, mean force, tabulated results, mean deflection angle, displacement force, and conclusion based off of various recorded and observed results of experiment.

7.1.2.5 MRI Torque Test

This next test observes the effects that the static magnetic field induces on a device in relation to the torque that the field can impose on some objects present in the MR environment.

Objective: To measure the induced torque on an object when exposed to the static magnetic field produced by an MR environment. If the maximal torque is less than the product of the dimension of the device and its weight then the product may be acceptable for use in a MR environment.

Equipment: The test apparatus is illustrated in the figure below:

Figure 7-1: MRI Torque Test Apparatus
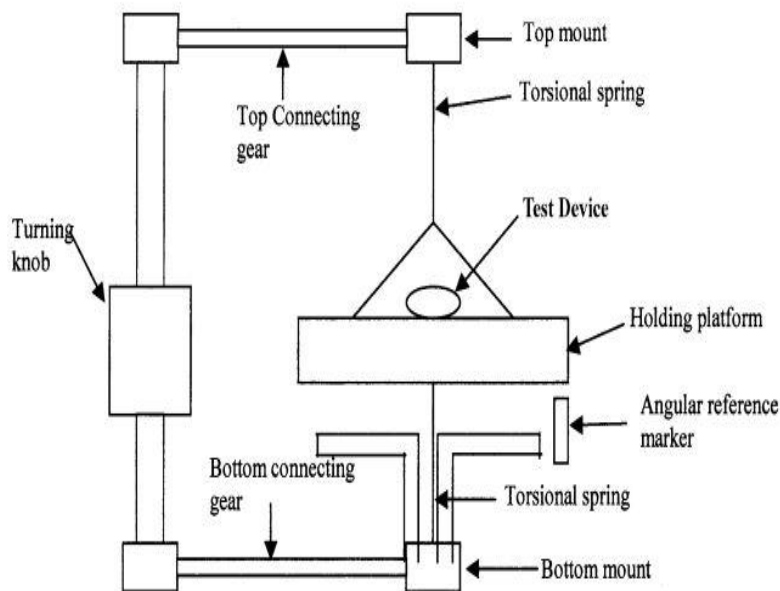
In this apparatus, materials should be non-ferromagnetic and the holding platform should be very sturdy and have torsional springs attached to it connecting the holding platform to the structure. The torsional springs' diameter should also be chosen so that the maximal deflection angle does not exceed nor equals 25 degrees. The device to be tested should be tied, taped, or however it can be, attached to the holding platform usually in some sort of basket holding cell. There should be a protractor, with at least one degree measuring tabs,

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attached to the structure that is rotated with a turning knob and a marker attached to the holding platform, where the device is housed, so that the angle between the holding platforms held device and the structure can be measured and recorded.

Test Summary: When in the static field of the MR environment, devices susceptible to magnetism try to align along the axis of the magnetic field that is projected from the source. The device shall be tested by a basic torsional pendulum method. The torsional pendulum method works by a device being placed in a holder suspended by a torsional spring and the difference in the deflection angle of the holder from its equilibrium position, the difference being created by the device being placed within the static magnetic field, shall be used to calculate the maximum magnetic torque and the gravity torque. The maximum recorded magnetic torque and maximum gravity torque shall be compared and used to determine the safety of the device with regards to its induced torque in relation to its own weight.

Procedures:
Step1: The device to be tested is set up as the equipment section specifies and is then placed in an area with the greatest uniform magnetic field. Rotate the structure and record the deflection angle between the structure and the rotating platform as the structure rotates from zero to 360 degrees until at equilibrium again. Measure the rotating platform at 10 degree increments of the structure being rotated.
Step2: Repeat step 1 two to three times for acquiring data to compute an average.
Step3: Lead wires should be arranged in a manner that represents *in vivo* set-up and should carry the currents that are applicable to an *in vivo* configuration, if practical.

Calculations: Torque, $\tau = k\Delta\theta$, is calculated using the deflection angle, theta, which represents the difference in angle between the marked device and the base structure. The variable k, is the spring constant.

Report: The report should include the following: all tabulated data, a description of what the device is and what it does and why this test was necessary for it, materials used and their properties, weight of the device. It should also include, dimensional diagram of the whole apparatus configuration. There should also be a photo of the equipment set-up with labels for each major equipment part detailing its importance. A description of strength and type of magnetic field that the device was subjected to is another factor to include in the report. The calculations used in the experiment using the tabulated results and a mean torque calculated; and there should be a conclusion drawn utilizing all results to support initial hypothesis and to determine device's safety concerning induced torque within a magnetic field.

7.1.2.6 MRI RF Heating Test

This test checked for the safety of the patients within the MRI. Some devices are affected by RF energy in the form of an induced current occurring in the wires and then a

dissipation of heat into the tissue of the patient's body which is measured in the form of specific absorption rate (SAR). Patients can be badly burned in a MR environment ranging from first to third degree burns. However, because the main focus of this test was for implants within the patient's body, the test would have had to be edited in order to focus more on the device itself heating up and how it will be affected in relation to if a patient was in the vicinity of the device itself.

Objective: The purpose of this experiment is to measure the effects of radio frequency (RF) on conductive materials that can be subjected to induced heat as a result of being exposed to RF energy during magnetic resonance imaging (MRI), and as a result, leads to patient burning and injury. The amount of RF-induced heat transfer is measured in the form of specific absorption rate (SAR) and will depend on the frequency of RF that is dependent upon the static magnetic field strength. Since the base of this experiment is based on devices that are assumed to be entirely inside the body, this experiment shall be edited for the purpose of devices that may be outside or near the patient's body.

Equipment: The testing apparatus will be composed of a phantom and a MR system or any type of MR system that will replicate the effects of a RF field induced from a MRI machine. The phantom, device, and MR system should completely emulate the same type of scenario in which a patient is exposed to an MRI machine. The scenario should basically establish the heating behavior of a device on top of a phantom in an MR environment. For the purpose of not being affected by the MR environment, the temperature sensor should be a fiber-optic, a fluoroptic thermometry probe, or some technology similar to these and resistant or impervious to the MR environment's effects to measure the temperature versus time in the vicinity of the device on the phantom during the RF exposure. The temperature sensor specifications should vary within, but no more than, 0.1 degrees Celsius, the diameter should be no more than one mm and the results of the test for temperature measurement should be able to be obtained within four seconds of application of the temperature sensor device.

Test Summary: In the original experiment, the device was to be placed in a phantom material, materials that simulate tissue of the human body, that simulated the electrical and thermal properties of the human body; but in this experiment, the device will be placed on top of the same type of phantom material instead. The device will be placed in a location with the highest exposure results for severest case scenarios to be recorded. The local SAR will be used to determine how severe the device could be if placed on the patient in that location. The phantom material shall be composed of a gelled saline mimicking the human body's properties of water make-up. Temperature probes will be placed at the locations where the induced device heating is going to be at its peak. The phantom body should be placed in an RF field that will be outputting a SAR of about 2 W/kg averaged over the volume of the phantom body for a period of at least 15 minutes.

The test will be divided into two sections. Section one will test the device in multiple areas on the phantom using fiber-optic thermometry probes, or an equivalent to this type of technology, during approximately 15 minutes of RF application. The temperature should be measured from a reference location in this first section. Section two will be

when the device is removed and the same RF application is repeated as in section one. The measurements will be recorded in the same spots of the device.

Procedure, Part I:
Step1: The house of the phantom should be composed of nonferromagnetic materials and non-metallic materials. The phantom house should also be built with the same or similar dimensions as shown below:

The phantom material as shown in **Figure 7-1** above should have a volume of approximately 24.6 L. The phantom material including the dotted portion (basically optional) lifts the volume to a 28.2 L. For larger devices, look into increasing the depth of the phantom house in order to get consistent results as shown in this experiment.

Step2: The phantom material simulating the tissue of a patient should fall in line with the following specs with little deviation:

The conductivity of the gelled saline at test temperature should be 0.47 ± 10% S/m.

The dielectric constant, relative electric permittivity (ε_r), should be 0.8 ± 20 at the frequency of 64 or 128 MHz for testing.

The thermal properties should mimic the human body as closely as possible by being within the specifications of a diffusivity of precisely 1.3E-7 m^2/s and a heat capacity of 4150 J/kg°C (which is approximately the heat capacity of water).

The viscosity should be of a gelled nature so that it does not allow bulk transport or convection currents.

Step3: The properties in step 2 can be attained by having 1.32 g/L NaCl and 10 g/L golyacrylic acid (PAA) in water, in which the air conductivity would be 0.47 S/m, and a viscosity adequate enough to not have convective heat transport. The recipe should satisfy all phantom properties that the experimenter is looking for. However, the solution is very sensitive to the environment, so it should be sealed in an airtight container to avoid evaporation because even evaporation can change the properties of the solution. The solution's properties can also be changed through various other factors, so the solution should be changed/re-made if there are any changes in volume, conductivity, color, or viscosity.

Step3.1: The ingredients of the PAA gelled saline are: deionized or distilled water with a conductivity less than 1 mS/m, 99% pure reagent grade sodium chloride (NaCl), and Aldrich product number 436364, 'polyacrylic acid partial sodium salt.

Step3.2: The PAA should be prepped by adding the NaCl to the water and stirring until the NaCl is completely dissolved into the water. The conductivity should be verified to a 10% deviation of 0.26 at 25 degrees Celsius measured at frequencies lower than 15 kHz.

Step3.3: Add PAA and stir until everything is well mixed and thick. (Suspension polymerization)

Step3.4: After one hour, blend the suspension into slurry in a kitchen grade blender with a blade for 20 min to remove all lumps. Any blender with the same power could be used as long as it removes all lumps of any and most sizes.

Step3.5: Stir occasionally, and after 24 hours, the slurry should be complete and look semi-transparent, free of bubbles, and free of lumps.

Step3.6: Check the conductivity to be at 10% of variation from 0.47 at 20 degrees Celsius to 25 degrees Celsius when measured at frequencies lower than 15 kHz.

Step4: The device needs to be tested in the worst case configuration and orientation so that the greatest heating scenario can be acquired while the device is on top of the phantom. Try various configurations if one has not already been found during previous tests, and show the worst case configuration and provide the evidence that lead to the specific orientation being the worst case placement.

Step4.1: The location of maximum induced heat can be found by experimentally using multiple temperature probe locations and finding all locations of high heat in different device configurations. The locations of maximum heating can be found computationally by using thermal and electromagnetic simulation tools to calculate the E-field, B-field, SAR and/or temperature distribution on the surface of the device. These methods must also include sound experimental validation data. The best formations may be large loops that can be formed, on the sharp edges of the device, in thin devices with high length to diameter ratios, points, and/or corners.

Step5: For the device holder, it should be comprised of materials that are resistant to the MR environment (such as non-ferromagnetic and non-metallic devices). The holders should also be oriented such that they do not disturb the original temperature of the area in which it is placed. Since the temperature probes will cause SAR variances, they should be placed within twice the diameter length apart from each other (e.g., if the diameter is 5 mm, then the probe should be placed 10 mm apart from each other).

Step6: When you know the E-field gradients, choose a location where the E-field and SAR is known to heat the device-less phantom's temperature 10 times the original amount (e.g. if the precision of the temperature probe is 0.1 degrees Celsius, then

you want the area where the probe's temperature is increased to 1 degree Celsius). Also choose an area where the E-field is unchanging.

Step7: Find the device's maximal heating positions, which may be done computationally or experimentally. Locate and label at least three to four temperature probes on those locations where the experiment can be done numerous of times and the precision is within a deviation of 0.5 mm between the sensor and the device. In addition, a reference temperature point should be found in order to not disturb the fields near the device; the point should be adequately far from the device while the E-field should be high.

Step8: Take pictures and provide dimensions on the device within the photo relative to the temperature sensors while on the phantom. Fill the phantom with the saline solution and visually make sure that there are no position differences before and after the heating experiment begins because even smallest of changes can give high variations in temperature readings. Try to turn off the MRI bore patient fans if possible and limit air flow through the MRI bore because you do not want air flow to vary the temperature readings too much. If the fans cannot be turned off and no obstruction cannot be placed to prevent free airflow through the bore of the MRI then a way to cover the phantom while the device is place on top of it should be implemented in order to mitigate the variable damage that free airflow could cause to the experiment's results.

Step9: Use a system in which when the RF field is applied the power of the RF will achieve the results as stated in step 6, while having a SAR of precisely 2 W/kg or higher.

Step10: Prior to the application of the RF energy, up to four temperature probes should be used to record the temperature to make sure everything is uniform and no additional heating is taking place before the application of the RF energy. The temperature in the MR environment should be stable within a standard deviation of no more than 1 degree Celsius.

Step11: If the values could be, record the MR environment's whole body averaged SAR, local SAR, peak SAR, partial body SAR, flip angle(s), the number of RF pulses applied per unit time, the bandwidth of the RF pulses, the RMS average applied to the B1 field, total time/duration over which the field was applied, and the total average power that was transferred to the phantom material.

Step12: Begin recording the temperature from each probe once every five seconds at least two minutes before the start of the scan, 15 minutes during the scan, and two minutes after the supply of RF energy is terminated.

Step13: Repeat steps 6 through 12 until a plethora of results are acquired enough to create a mean.

Procedure, Part II:

Step1: Section 1 must be split into two parts. The first part is with the device on top of the phantom device and the second part is without the phantom device on top. Record and properly label all results for preparation of the lab report.

Step2: When the device is removed, using the same RF energy applied in step 9, measure the local heat utransference at the temperature probe locations and make sure that there are minimal bubbles or air pockets formed in the phantom so results are no skewed.

Step3: SAR can be calculated by the following equation without the device present:

$$SAR = c \, (\Delta T/\Delta t).$$

Where **c** is 4150 J/(kg°C), specific heat of phantom, **T** is temperature in degrees Celsius, and **t** is the time in seconds. Record the temperature increase over 15 minutes and plot a fitted curve onto the SAR results.

Step4: For the purpose of being able to label the device with some MR conditions, for safety qualification in the MR environment, this section will give a walkthrough of how to calculate the whole body averaged SAR (WB-SAR) using the calorimetric method on the phantom.

Step5: Repeat all of Section 1 except this time the phantom body will be covered up when exposed to the MRI scan. The temperature probes will be within the precision of 0.05 degrees Celsius and the device will not be in the vicinity of the phantom.

Calculations:

Step 2 has of the calculations used for the phantom without the device present.

A similar equation could be used for the first section, except the specific heat of the material would be needed.

All the code for the calculation of the various fields within the MRI machine, if it was needed, in order to find the maximum points where the device's heating would be peaked.

Report:

A description of the device should be included as to what the device's function is within the MR environment, its importance, along with a photo of the device.

List of materials used throughout the experiment.

Pictures taken of the overall experiment done with the device on the phantom and the other done without the device on the phantom during the MRI scan and while the phantom is out of the MRI scanner.

Pictures should have dimensions of all objects with a role in the experiment from the temperature sensors to the actual holder of the phantom.

Provide all information on the type of MRI machine used to conduct this test.

Show any code, the programming environment and or any type of analysis tool(s) used to calculate the electrical field gradient in the phantom.

The RF output power should be included in the report and also the specifications of the phantom in relation to the output.

Graphs should be provided for the temperature probe's recordings in which it is temperature vs. time.

The SAR calculated in Section 2 should be included also.

Tell of why each temperature probe was placed where it was placed in/on the phantom.

Give the WB-SAR that was calculated in Section 2 of the experiment which utilized the same SAR equation shown in Section 2.

Give the temperature recordings of the minutes before the RF application, during the application, and after the application has been terminated on the phantom body.

Tell of any modifications to the test and provide justifications as to why any modifications were needed for this experiment (e.g., this test needed to be modified for our experiment because the "implant" in question will actually be a device that may lay across the patient and it needs to be tested in case it causes any burns while on the patient in the MRI machine).

This test would have exposed the worst case scenario in which a nurse or technician may leave the device on the patient while the patient is in the MR environment. And inversely, it would have also told if the device was safe to be left on the patient while in the MR environment or in the bore of the MRI machine. The test could have been edited to be applied for testing for devices to be placed into the patient and devices placed on top/outside the patient's body. For the purpose of this project, since the scope narrowed, this test was not done.

7.1.3   RF-Noisy Environment

Another concern for performance was the SQVID's clarity in an environment polluted with RF noise, such as a hospital hallway. Patients may be transported from room to room throughout a hospital and it is important to keep a strong connection between the SQVID and the receiving end monitor. Other wireless devices, perhaps even other SQVIDs, may be communicating nearby and we need to be sure those signals will not interfere with one another.

Fortunately, we will not need to use a hospital to simulate this environment. Many public places have wirelessly communicating devices broadcasting a bunch of RF signals. A lot of options are available to us for testing in this environment and we can test frequently. The procedure for testing will simply be to communicate simulated signals to our wireless monitor and record the results.

7.2 Hardware Specific Testing

We will be running through these checklists throughout construction and will be performing a finalized test on our completed prototypes. More specifications will arise as construction proceeds, but these are the qualities and methods we expect we will need to identify and control.

7.2.1 Microcontroller A/D

The MSP430G2 series original utilization plan in coding the ADC was described by **Table 7-1** below.

Table 7-1: Analog to Digital Test

Steps	Process/Question
1	How many signals coming in? Is it 0, 1, 2, etc…?
2	ECG – 0001, SpO2 – 0010, CO2 – 0100, NiBP – 1000, or NONE – 0000.
3	Display LED that a signal was received. Example: Display LED in binary format (1 is on and 0 is off) 0001 or 1000 for ECG or NiBP respectively, etc…
4	Store signal in register(s), like R4, R5, R#
5	Push data in register onto stack, s0, s1, s2, s#
6	Change signal in s# from analog to digital using subroutine
7	Flicker LED for corresponding changing signal. Example, if ECG is changing then 0001 should flicker.
8	Pop data off of s# onto corresponding R#

Table 7-1: Analog to Digital Test

9	Stop Flickering of LED, to indicate data converted, for approximately 5 seconds until returning to step 4 and completing until all signals converted.

LEDs do not have to be used in order to test if the signal is received, there is also built-in UART, as an option, on the MSP430 and thus a HyperTerminal could also be used to show that the signal is received using the same binary format or using ASCII characters. There are also multiple code templates on Texas Instruments' website to start from as the foundation of the ADC code, and everything is fully open enough to modify all code. Assembly language code may be the best choice for this job because of its direct setup and style of code; however, the C language code is always an option too when using the MSP 430G2 series.

7.3   Software Testing Environment

The following sections pertain to properly testing the Simplified Quad-Vitals Integrated Device Intelligent Navigation Controller software and ensuring correct functionality.

7.3.1   Proximity to SQVID Connection Box

Due to wireless signal strength variances it is necessary that the SQVID connection box be no more than 100 feet away from the computer running the INC software. This estimate is based on the typical ranges of a standard 802.11b/g/n router's signal strength. This estimate takes into consideration the layout of a typical hospital setting as well as an MRI examination room, as seen in **Figure 7-2a** and **Figure 7-2b**, below. Due to the prototype nature of this project the INC software system is ideally running off of a mobile tablet or laptop, capable of staying within range of the wireless signals being transmitted to the program as the connection box follows its patient. However, if run from a stationary desktop or laptop computer, the scopes depicted in the figures have also been taken into consideration.

Figure 7-2a: Hospital Setting

Figure 7-2a: Hospital Setting
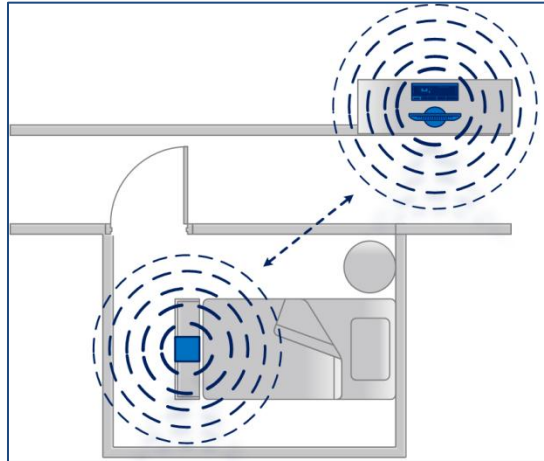
Figure 7-2b: MRI Exam Setting
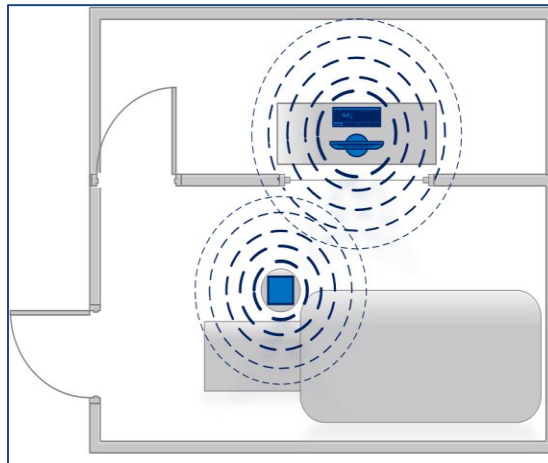
7.3.2 **Operating System**

The software is to be run from any Windows environment with the 4.0 .Net Framework installed. The operating system may be on a desktop, laptop, or tablet computer. Only machines with tactile functionality will demonstrate the touch screen capabilities of the software. The INC program has been tested on a Windows 7 desktop and laptop, as well as a Windows 8 laptop and Windows 8.1 laptop.

7.4 Software Specific Testing

7.4.1 Preliminary Testing for CC3000 Communication

The preliminary testing with the CC3000 wireless module began before the actual SQVID prototype circuit board was completed. The team used the TI MSP430 LaunchPad with a CC3000 BoosterPack running the TI Basic WiFi Demo application for the MSP430g2553 microcontroller. Testing procedures are outlined in Table 7-6 and then explained in detail in the sections that follow. All these tests were completed using TI's provided opcodes and a HyperTerminal. These opcodes are described in Table 6-3 in section 6.1.2.3. It is important to note that each test builds upon the previous one and thus were conducted in the described order.

Table 7-2: Preliminary Testing for CC3000 Communication

Test	Description and Purpose
AP Connection	To ensure that the CC3000 can be connected to a specified access point/wireless network.
Static IP Configuration	Manual configuration of the IP address for the CC3000 to ensure that it can be set it needed.
Socket Creation and Port Binding	Creation of a socket as per the correct IP and port settings, then binding the port it in preparation for data transmission.
UDP Data Packet Transmission	Sending data in the form of a string as entered through a HyperTerminal to the receiver to prove UDP communication is functional.
Socket Closing	Closing and destroying the previously created socket to end UDP data transmission.

7.4.1.1 AP Connection

The first test was to ensure that the device was capable of connecting to a designated access point. This was done using TI's Smart Config Java applet included in the CC3000 SDK as provided by the Texas Instruments website. A standard 802.11n wireless network was established using a NetGear WirelessN router. Connection was done without any security settings, and to test for a successful connection the device was pinged based on its assigned IP address. Once a HyperTerminal was properly established, the exact procedural steps were as follows:

1) Connect computer running CCS and the Basic WiFi Demo to desired AP

2) Launch CC3000 Smart Config Application as provided by TI's SDK download
   a. Enter the password for the wireless network (all other fields fill in automatically)
   b. Begin the Smart Config process by clicking the "Start" button
3) Download and Run the Basic WiFi Demo on the CC3000+MSP430g2553
4) Send the "01" opcode command to the device using the HyperTerminal
   a. If successful, "Smart Config Done" followed by an IP address echo the "01" command
5) Ping the assigned IP from the command prompt to ensure the connection was truly successful.

7.4.1.2 Static IP Configuration

The static IP Configuration test was to show that the CC3000 could have a programmable IP. This could be useful if multiple devices were required or they resided on a network with very specific configuration requirements. The command as entered through the HyperTerminal was an eighteen-digit string command and assumed that the network subnet mask was "255.255.255.0". Once a HyperTerminal was properly established, the required AP connected to, and the WiFi Demo running in CCS, the following steps were used to test the static IP configuration:

1) Execute the command "08XXYYZZUUAABBCCDD" via the HyperTerminal where…
   a. XXYYZZUU is the desired IP address in hexadecimal form.
   b. AABBCCDD is an IP address of the default gateway in hexadecimal form.
2) If successful "Done" echos the previous command. Test the connectivity by attempting to ping the device.

7.4.1.3 Socket Creation and Port Binding

It was very important to test that the CC3000 could properly create a socket and bind the specified port. This was done using a HyperTerminal and the "Socket Open" and "Bind" opcodes provided by TI. Once the module was connected to the designated AP, a HyperTerminal was configured, and the WiFi Demo was running in CCS, the following steps were followed to test that a socket could be created and the specified port bound:

1) Execute the "03" opcode command via the HyperTerminal. If the socket opened correctly, "Done" appears.
2) Execute the "06" opcode command followed by the port number in hex. If successful, "Done" appears.

100

7.4.1.4 **UDP Data Packet Transmission**

The most important test was designed to prove that a UDP packet could be transferred from the microcontroller and CC3000 to a receiver. This required that SQVID INC be running on the same network, listening for incoming traffic. This could also have been monitored via a network packet sniffer, such as Wireshark, but INC was used instead. This test also served to prove that INC functioned correctly. After the CC3000 was connected to the correct network, a HyperTerminal was set up, a socket had been opened and the proper port bound, the following steps were conducted while running the WiFi Demo in CCS:

1) Execute the "sendto" command, using the opcode string "04AAX…Y02BCDEFGHIKLMN" where…
    a. "AA" is the hexadecimal representation of the length of data.
    b. "X…Y" is the actual data being sent (note that the length must match "AA").
    c. "02" is the family type ("02" corresponds to AF_INET which is the only one supported).
    d. "BCDE" is the hexadecimal representation of the destination port number.
    e. "FGHIKLMN" is the hexadecimal representation of the destination IP address.
2) If successful, the sent data string would appear on the SQVID INC GUI.

7.4.1.5 **Socket Closing**

To test that the socket would properly close the "07" opcode was executed from within the HyperTerminal. Assuming the device was connected to the correct AP and the WiFi Demo was running in CCS, "Done" would appear upon success. This test was done to prove that a switch (P1.3) could be used to perform this action.

7.4.2   **Intermediate Testing for CC3000 Communication**

After testing was done using the Basic WiFi Demo provided by TI, it was time to eliminate as much of the HyperTerminal interface as possible. While the prototype board was being developed, the external temperature sensor built into the LaunchPad was used to experiment with how data from the ADC10MEM register would be sent and received. This also served to exercise all functions of the GUI for SQVID INC and ensure that data was properly displayed.

To eliminate the need for multiple HyperTerminal-entered opcodes, a new opcode was created which would trigger the socket creation, port binding, and data sending all consecutively. In order to retrieve valid data from the temperature sensor, example code was used to properly configure the ADC10 memory register on the MSP430 and then

convert this figure into a temperature reading. This code was provided by TI as part of the LaunchPad demo, included with the purchase. The code used to configure the ADC and interpret the temperature data is displayed below for reference, in Figure 7-2.

Figure 7-3: Temperature Sensor Example Code

```
main(void)
{
        volatile int temperature;

        //Initialize the ADC -- for Temperature reading
        ADC10CTL0 = SREF_1 + REFON + ADC10ON + ADC10SHT_3;
        ADC10CTL1 = INCH_10 + ADC10DIV_3;

        temperature = tempOut();


}

int tempOut()
{
        int t = 0;
        __delay_cycles(1000);
        ADC10CTL0 |= ENC + ADC10SC;
        while (ADC10CTL1 & BUSY);
        t = ADC10MEM;
        ADC10CTL0&=~ENC;
        return(int) ((t*27069L - 18169625L) >> 16);
}
```

7.4.3 Final Testing for CC3000 Communication

Once the prototype SQVID board was assembled, all the previous testing procedures were followed again to guarantee that there were no errors with the board's construction and that the CC3000 module incorporated into the design was fully functional. To test the previously written temperature sensor code, the LaunchPad was connected to the SQVID board and a debugging cable was used to enable HyperTerminal communication and the ability to step through the code in Code Composer.

Unfortunately, errors were encountered during this phase of testing. It was determined that the latest firmware and driver updates from TI were incompatible with the CC3000 module included in the SQVID circuit board. While one UDP packet would send successfully, the program would get caught in a host communication interface event awaiting acknowledgement that the packet was sent. It would never receive this signal and thus would loop forever in a single function. This problem was well documented in

the virtual community of TI users, and it was determined that by removing the addition made by the upgraded driver all problems were solved.

Once the temperature example code was functioning with the SQVID prototype board, successfully sending data continuously to SQVID INC, testing began on the actual NiBP sensor. At this stage of development, only the working temperature sensor code was tested. The only change required was to eliminate any conversions specific to the temperature reading, and it quickly became clear that sending raw ADC10MEM register data was more than adequate to demonstrate the functionality of SQVID. This code was shown in Figure 6-3 of section 6.1.2.3. A blood pressure cuff attached to the NiBP sensor was used to yield realistic pulses of data.

8.0   Administrative Content

8.1   Milestone Discussion

8.1.1   Research

The major research milestones for this project came along in the form of component selections near the end of the first phase. The process was chosen based on widely available known resources for the MSP430 architecture and previous experience with the processor in the embedded systems laboratory. The analog filtering and amplification circuits were derived from material covered in the electronics classes as well. The analog to digital conversion was a relatively new concept and specific software for the MSP430 was studied for this end.

8.1.2   Design

8.1.2.1 Hardware

The hardware design of this project was focused mainly on the signal acquisition from the pressure transducer and carbon dioxide sensor along with the amplification and filtering of said signal, and then finally multiplexing and wirelessly transmitting to the base station. This milestone in research focus came along once the decision was made to no longer attempt integration of the two existing wireless systems present for ECG and SPO2 signals. The extent of the integration was to allow for the implanting of the two wireless devices onto the exterior of the SQVID cube, allowing for full functionality as before while still satisfying the requirement of cable management.

The range of options available for this focus was wide, as there are many different processers and wireless boards to choose from on the market. Of the various options which were covered in **Section 4.3.1 Wireless System Materials and Design**, the TI CC3000 was chosen based on its compatibility with the MSP430 architecture, the wide

availability of resources for configuring and troubleshooting the device, and most of all because the preferred method for wireless communications in this project as requested by Philips is IEEE 802.11 2.4 GHz WIFI. The major milestone in this selection is the type of wireless communication protocol and the specific board to be used.

The processer selected for this purpose was the MSP430, more specifically the MSP430F5529. This microcontroller was linked to in the cc3000 product page. This not only ensures compatibility with the wireless device, but also the same breadth of resources available for development.

8.1.2.2 Software

The software design aspect of this project focused on the program that communicates with the embedded system board located in the SQVID connection box. Deemed the "Intelligent Navigation Controller" or "INC", the main milestone with regards to this software system was how it would interface with the embedded system board. Research done into Philips' current software used by their clients in the professional industry with their current cableless measurement devices led the team to first consider TCP/IP communication protocol. However, once into the development stage it became clear that UDP communication was not only easier, but more suited to the prototype nature of the project, while still providing numerous opportunities for enhancement.

However, the software system's main objective is to prove that the hardware design is fully functional, as well as accurate and reliable. By achieving communication between the CC3000 module transmitting the NiBP sensor data from the MSP430 microcontroller, and INC, SQVID demonstrates an innovative and efficient way to enhance the comfort of a patient facing an MRI scan or undergoing medical observation.

8.1.3 Prototype and Testing

The prototyping and testing schedule is given in a rough form below in **Table 8-1**.

<div align="center">Table 8-1: Prototype and Test Schedule</div>

Jan. 6 - 12	Receive custom cables from Philips; have them ordered and ready before semester starts.
	Have all parts ordered, if not delivered already
	Begin programming A/D converter on the MSP430 microcontroller
	Begin adapting NiBP and CO2 hoses to sensors.

Table 8-1: Prototype and Test Schedule

	Test both CO2 and NiBP sensors' functionality.
Jan. 13 – 19	Test both sensors' input/output properties. (lag, max frequency, max input, power, etc.)

Test sensor output with input via hoses.

Begin assembly of power supply unit |
| **Jan. 20 – 26** | All remaining NiBP parts acquired

Begin assembly of NiBP rough prototype

A/D conversion program finished

Test microcontroller for proper A/D conversion

Begin programming WiFi module |
| **Jan. 27 – Feb. 2** | All remaining CO2 parts acquired

Begin assembly of CO2 rough prototype |
| **Feb. 3 - 9** | Rough NiBP prototype assembled

Begin assembly of wireless receiver

Wireless communication software finished |
| **Feb. 10 - 16** | Rough CO2 prototype assembled

Power supply unit complete

Wireless receiver built

Test wireless receiver's functionality

Test power supply separately for stability and proper temperature

Test power supply on NiBP sensor, then CO2, and then both together |
| **Feb. 17 – 23** | Connection between SQVID and receiver established; test for accuracy and reliability of transmission

Test receiver with multiple signals |
| **Feb. 24 - Mar. 2** | Begin construction of consolidation shell |
| **Mar. 3 - 9** | Flex week - Spring Break |

Table 8-1: Prototype and Test Schedule

	Possible Gainesville MRI testing	
Mar. 10 - 16	Mount NiBP and CO2 components into consolidation shell Test structural soundness of NiBP and CO2 devices alone and their mounting	
Mar. 17 - 23	Mount SpO2 and ECG into consolidation shell Test structural soundness of SpO2 and ECG devices alone and their mounting	
Mar. 24 - 30	Mount power supply into consolidation shell Test structural soundness of power supply	
Mar. 31 - Apr. 6	Final Gainesville MRI testing Test complete SQVID on human subject if allowed	
Apr. 7 – 13	Complete testing Final product/finishing touches	
Apr. 14 – 20	Flex week	

8.2 **Budget and Finance Discussion**

8.2.1 **Budget Allocation**

The budget allocation for this project is divided in the manner displayed in (**Table 8-2**) below.

Table 8-2: Project Budget Allocation

Sensor Leads	25%	All cables used on patients to monitor vitals are manufactured and supplied by Philips.

Table 8-2: Project Budget Allocation

SQVID	55%	The allotted percentage of Total Budget is broken down as follows		
		ECG	15%	Provided by Philips. Known to be slightly more expensive than other sensors.
		SpO2	10%	Provided by Philips.
		NIBP	10%	Custom built.
		CO2	10%	Sensor may be provided by Philips. Integration into wireless solution is our responsibility.
		MCU	5%	Microcontroller purchased from third-party. Relatively low required processing power is expected to greatly reduce the cost.
		Wireless	5%	Wi-Fi module purchased from third-party.
		(percentages here are in reference to the total budget):		
Miscellaneous	20%	Entails small components (resistors, capacitors, etc.), gas used in trips to Gainesville MRI center for testing, materials used in SQVID casing, cable adaptors, etc.		

8.2.2 Parts List

The parts list is a work in progress, and the currently selected components are subject to change at any time. The final documentation for this project will include a complete and accurate list of parts. See **Table 8-3** and **Table 8-4** below.

Table 8-3: Parts List 1

	Part	Qty.	Price (USD)	Link
ECG	Expression MRI Monitoring System - ECG component	1	(Provided)	http://www.invivocorp.com/ monitors/monitorinfo.php?id =7

Table 8-3: Parts List 1

SpO2	Expression MRI Monitoring System – SpO2 component	1	(Provided)	http://www.invivocorp.com/monitors/monitorinfo.php?id=7
NiBP	Pressure cuff	1	(Provided)	http://www.healthcare.philips.com/main/products/supplies/Products/patient_monitoring/
	MPX2050 Pressure Transducer	1	12.20	http://www.digikey.com/product-detail/en/MPX2050DP/MPX2050DP-ND/2186536
	AD620 Instrumentation Amplifier	1	9.43	http://www.digikey.com/product-search/en?wt.z_cid=ref_hearst_0211_buynow&site=us&mpart=AD620AN&v=505
	TL084 Operational Amplifier	2	0.68	http://www.digikey.com/product-detail/en/TL084CN/296-1784-5-ND/277429
CO2	CAPNO2 mask	1	(Provided)	http://capno2mask.respironics.com/default.asp
	CAPNOSTAT CO_2 Sensor	1	(Provided)	http://capnostat.respironics.com/
Microcontroller	MSP430F5529	1	12.99	http://www.ti.com/tool/msp-exp430f5529lp
Wireless	SimpleLink Wi-Fi CC3000	1	9.99	http://www.ti.com/product/cc3000

Table 8-4: Parts List 2

Part	Value	Device	Package	Description
A1	ANTENNA2SMD2	ANTENNA2SMD2	ANTENNA-CHIP3	Antenna

Table 8-4: Parts List 2

C1	2.2pF	CAP0402-CAP	0402-CAP	Capacitor
C2	10uF	C_0805	805	
C3	.1u	CAP0402-CAP	0402-CAP	Capacitor
C4	10pF	CAP0402-CAP	0402-CAP	Capacitor
C5	1nF	C_SMD0603	603	
C6	100nF	C_SMD0603	603	
C7	1u	CAP0402-CAP	0402-CAP	Capacitor
C8	1u	CAP0402-CAP	0402-CAP	Capacitor
C9	.1u	CAP0805	805	Capacitor
C10	.1u	CAP0402-CAP	0402-CAP	Capacitor
C11	100u	CAP1206	1206	Capacitor
C12	.1u	CAP0402-CAP	0402-CAP	Capacitor
C13	1u	CAP0805	805	Capacitor
C14	.1u	CAP0402-CAP	0402-CAP	Capacitor
C15	.1u	CAP0402-CAP	0402-CAP	Capacitor
C16	2.2u	CAP0805	805	Capacitor
C17	.1u	CAP0805	805	Capacitor
C18	.1u	CAP0402-CAP	0402-CAP	Capacitor
C19	1u	CAP0805	805	Capacitor
C20	.1u	CAP0402-CAP	0402-CAP	Capacitor
C21	.1u	CAP0805	805	Capacitor
C22	1u	CAP0805	805	Capacitor
C23	47u	CAP0805	805	Capacitor
C24	47u	CAP0805	805	Capacitor

Table 8-4: Parts List 2

C25	1u	CAP0402-CAP	0402-CAP	Capacitor
C26	1u	CAP0402-CAP	0402-CAP	Capacitor
C27	1u	CAP0402-CAP	0402-CAP	Capacitor
C28	.1u	CAP0402-CAP	0402-CAP	Capacitor
C29	.1u	CAP0402-CAP	0402-CAP	Capacitor
C30	.1u	CAP0402-CAP	0402-CAP	Capacitor
C31	2.2u	CAP0805	805	Capacitor
C32	2.2u	CAP0805	805	Capacitor
C33	10u	CAP1206	1206	Capacitor
C34	.1u	CAP0402-CAP	0402-CAP	Capacitor
C35	10u	CAP1206	1206	Capacitor
C36	.1u	CAP0402-CAP	0402-CAP	Capacitor
IC1	LM7811	V_REG_LM1117SOT223	SOT223	Voltage Regulator LM1117
IC2	LD117ADT50TR	LD117ADT50TR	DPACK	Low drop fixed and adjustable positive voltage regulators 1 A
IC3	MC79M05CDTG	MC79M05CDTG	DPACK_3	500 mA Negative Voltage Regulators
J1		M04LOCK	1X04_LOCK	Header 4
J2		M041X04_NO_SILK	1X04_NO_SILK	Header 4
J3	M02JST-PTH-VERT	M02JST-PTH-VERT	JST-2-PTH-VERT	Standard 2-pin 0.1 header. Use with"
J4	M02JST-PTH-VERT	M02JST-PTH-VERT	JST-2-PTH-VERT	Standard 2-pin 0.1 header. Use

Table 8-4: Parts List 2

				with"
JP1	JUMPER-3PTH	JUMPER-3PTH	1X03	
JP2		JUMPER-2PTH	1X02	Jumper
JP3		JP2QE	JP2Q	JUMPER
JP4		JUMPER-2PTH	1X02	Jumper
JP5		JP3QE	JP3Q	JUMPER
L1	NL	INDUCTOR0402	C0402	Inductors
L2	2.2nH	INDUCTOR0402	C0402	Inductors
LED 1	red	LED_0603D0603	DIODE0603	
LED 2	green	LED_0603D0603	DIODE0603	
R1	470R	R_SMDR0603	603	
R2	270R	R_SMDR0603	603	
R3	47K	R_SMDR0603	603	
R4	47K	R_SMDR0603	603	
R5	8.2k	RESISTOR0402-RES	0402-RES	Resistor
R6	1.8k	RESISTOR0402-RES	0402-RES	Resistor
R7	300k	RESISTOR0805-RES	805	Resistor
R8	12k	RESISTOR0805-RES	805	Resistor
R9	500k	RESISTOR1206	1206	Resistor
R10	5.1k	TRIMPOTSMD	TRIMPOT-3MM	Various small potentiometers for set-and-forget" applications"
R11	500k	RESISTOR1206	1206	Resistor

Table 8-4: Parts List 2

R12	10k	RESISTOR0805-RES	805	Resistor
R13	20k	RESISTOR0805-RES	805	Resistor
R14	3.6k	RESISTOR0402-RES	0402-RES	Resistor
R15	3.6k	RESISTOR0402-RES	0402-RES	Resistor
S1		PB	PBTH	OMRON SWITCH
S2		PB	PBTH	OMRON SWITCH
SJ1	SOLDERJUMPER NO	SOLDERJUMPERNO	SJ_2S-NO	Solder Jumper
SJ2	SOLDERJUMPER NO	SOLDERJUMPERNO	SJ_2S-NO	Solder Jumper
TP1	TP5P5-25-13	TP5P5-25-13	P5-25-13	Test pad
U1	CC3000	CC3000	CC3000	TI SimpleLink CC3000 Module - WiFi 802.11b/g Network Processor
U2		DIL20	DIL20	Dual In Line / Socket
U3	TL084BCN	TL084BCN	DIP254P762X508-14	OPERATIONAL AMPLIFIERS
U4	AD620N	AD620N	DIL08	Low Cost, Low Power, Instrumentation Amplifier
U5	TXS0102DCTT	TXS0102DCTT	SOP65P400X130-8N	BIDIRECTIONAL VOLTAGE-LEVEL TRANSLATOR

Table 8-4: Parts List 2

U6	MPX2050DP	MPX2050DP	FREESCALE_CASE_3 44C-01	IC, PRESSURE SENSOR, 0 TO 50KPA, SIP-4

List of Tables

List of Figures

Appendices

Appendix A – References

[1]   http://science.howstuffworks.com/mri6.htm

[2]   http://www.mrisafety.com/safety_article.asp?subject=17

[3]   http://www.biac.duke.edu/research/safety/tutorial.asp#RF_2

[4]   http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm107721.htm#general

[5]   http://www.biac.duke.edu/research/safety/tutorial.asp#SF_1

[6]   http://www.swinburne.edu.au/lss/bpsyc/neuroimaging/documents/MRI-09.pdf

[7]   http://enterprise.astm.org/filtrexx40.cgi?+REDLINE_PAGES/F2503.htm

[8]   http://enterprise.astm.org/SUBSCRIPTION/filtrexx40.cgi?REDLINE_PAGES/F2052.htm

[9]   http://enterprise.astm.org/SUBSCRIPTION/filtrexx40.cgi?+REDLINE_PAGES/F2213.htm

[10]   http://enterprise.astm.org/SUBSCRIPTION/filtrexx40.cgi?+REDLINE_PAGES/F2182.htm

[11]   http://www.biopac.com/Noninvasive-Blood-Pressure-MRI

[12]   http://incenter.medical.philips.com/Default.aspx?tabid=729   (publication   #: 453564219221)

[13]   http://www.ti.com/product/msp430g2553

Appendix B – Datasheets

-MPX2050

Operating Characteristics

Table 1. Operating Characteristics
(V_S = 10 Vdc, T_A = 25°C unless otherwise noted, P1 > P2)

Characteristics	Symbol	Min	Typ	Max	Unit
Pressure Range[1]	P_{OP}	0	—	50	kPa
Supply Voltage[2]	V_S	—	10	16	Vdc
Supply Current	I_o	—	6.0	—	mAdc
Full Scale Span[3]	V_{FSS}	38.5	40	41.5	mV
Offset[4]	V_{off}	-1.0	—	1.0	mV
Sensitivity	$\Delta V/\Delta P$	—	0.8	—	mV/kPa
Linearity[5]	—	-0.25	—	0.25	%V_{FSS}
Pressure Hysteresis[5] (0 to 50 kPa)	—	—	±0.1	—	%V_{FSS}
Temperature Hysteresis[5] (-40°C to +125°C)	—	—	±0.5	—	%V_{FSS}
Temperature Effect on Full Scale Span[5]	TCV_{FSS}	-1.0	·	1.0	%V_{FSS}
Temperature Effect on Offset[5]	TCV_{off}	-1.0	·	1.0	mV
Input Impedance	Z_{in}	1000	·	2500	Ω
Output Impedance	Z_{out}	1400	·	3000	Ω
Response Time[6] (10% to 90%)	t_R	—	1.0	—	ms
Warm-Up	—	—	20	—	ms
Offset Stability[7]	—	—	±0.5	—	%V_{FSS}

1. 1.0 kPa (kiloPascal) equals 0.145 psi.
2. Device is ratiometric within this specified excitation range. Operating the device above the specified excitation range may induce additional error due to device self-heating.
3. Full Scale Span (V_{FSS}) is defined as the algebraic difference between the output voltage at full rated pressure and the output voltage at the minimum rated pressure.
4. Offset (V_{off}) is defined as the output voltage at the minimum rated pressure.
5. Accuracy (error budget) consists of the following:
    Linearity:Output deviation from a straight line relationship with pressure, using end point method, over the specified pressure range.
    Temperature Hysteresis:Output deviation at any temperature within the operating temperature range, after the temperature is cycled to and from the minimum or maximum operating temperature points, with zero differential pressure applied.
    Pressure Hysteresis:Output deviation at any pressure within the specified range, when this pressure is cycled to and from the minimum or maximum rated pressure, at 25°C.
    TcSpan:Output deviation at full rated pressure over the temperature range of 0 to 85°C, relative to 25°C.
    TcOffset:Output deviation with minimum rated pressure applied, over the temperature range of 0 to 85°C, relative to 25°C.
6. Response Time is defined as the time for the incremental change in the output to go from 10% to 90% of its final value when subjected to a specified step change in pressure.
7. Offset stability is the product's output deviation when subjected to 1000 hours of Pulsed Pressure, Temperature Cycling with Bias Test.

Maximum Ratings

Table 2. Maximum Ratings[1]

Rating	Symbol	Value	Unit
Maximum Pressure (P1 > P2)	P_{max}	200	kPa
Storage Temperature	T_{stg}	-40 to +125	°C
Operating Temperature	T_A	-40 to +125	°C

1. Exposure beyond the specified limits may cause permanent damage or degradation to the device.

On-Chip Temperature Compensation and Calibration

Figure 3 shows the minimum, maximum and typical output characteristics of the MPX2050 series at 25°C. The output is directly proportional to the differential pressure and is essentially a straight line.

The effects of temperature on Full-Scale Span and Offset are very small and are shown under Operating Characteristics.
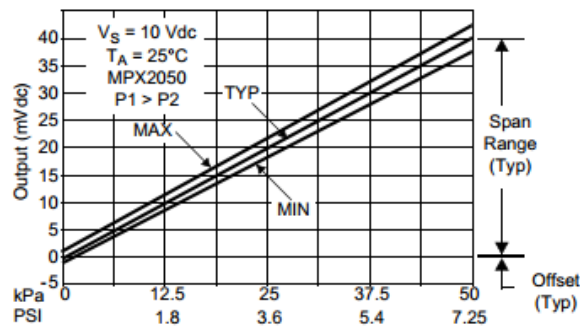
Figure 3. Output versus Pressure Differential
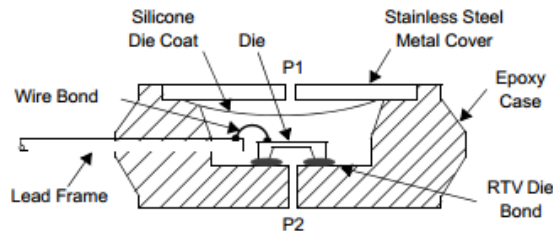
Figure 4. Cross-Sectional Diagram (not to scale)

Figure 4 illustrates the differential or gauge configuration in the basic chip carrier (Case 344). A silicone gel isolates the die surface and wire bonds from the environment, while allowing the pressure signal to be transmitted to the silicon diaphragm.

The MPX2050 series pressure sensor operating characteristics and internal reliability and qualification tests are based on use of dry air as the pressure media. Media other than dry air may have adverse effects on sensor performance and long term reliability. Contact the factory for information regarding media compatibility in your application.

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PACKAGE DIMENSIONS
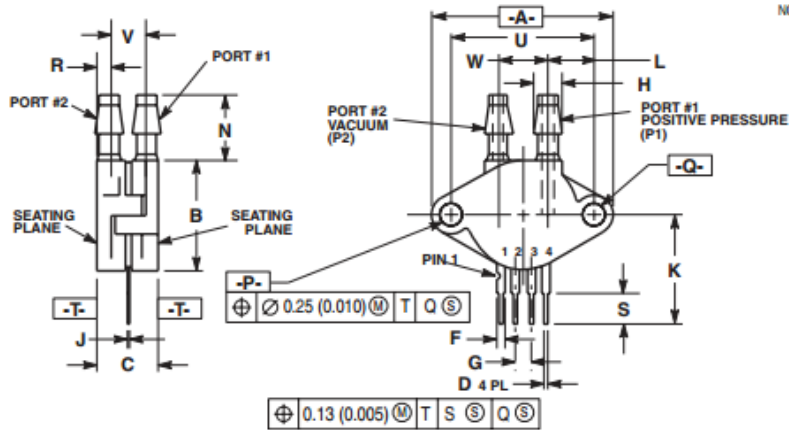
DIM	INCHES		MILLIMETERS	
	MIN	MAX	MIN	MAX
A	1.145	1.175	29.08	29.85
B	0.685	0.715	17.40	18.16
C	0.405	0.435	10.29	11.05
D	0.016	0.020	0.41	0.51
F	0.048	0.064	1.22	1.63
G	0.100 BSC		2.54 BSC	
H	0.182	0.194	4.62	4.93
J	0.014	0.016	0.36	0.41
K	0.695	0.725	17.65	18.42
L	0.290	0.300	7.37	7.62
N	0.420	0.440	10.67	11.18
P	0.153	0.159	3.89	4.04
Q	0.153	0.159	3.89	4.04
R	0.063	0.083	1.60	2.11
S	0.220	0.240	5.59	6.10
U	0.910 BSC		23.11 BSC	
V	0.248	0.278	6.30	7.06
W	0.310	0.330	7.87	8.38

STYLE 1:
PIN 1. GROUND
2. + OUTPUT
3. + SUPPLY
4. - OUTPUT

CASE 344C-01
ISSUE B
UNIBODY PACKAGE

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Appendix C – Permissions

<u>Texas Instruments</u>

<u>Freescale Semiconductor</u>

Appendix D – Flow Charts and Diagrams

Figure 3-4: Philips NBP Pod
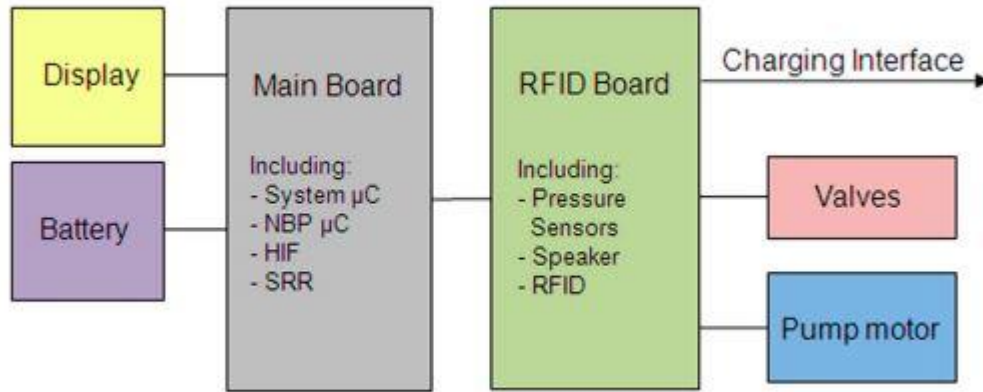
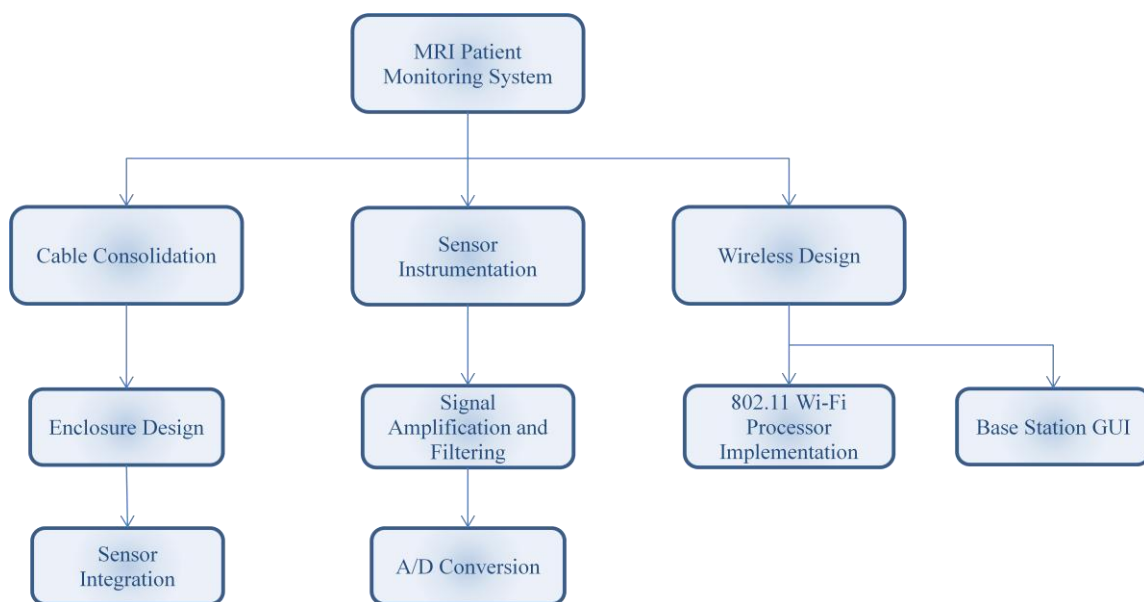Figure 4-1: System Interconnect Diagram
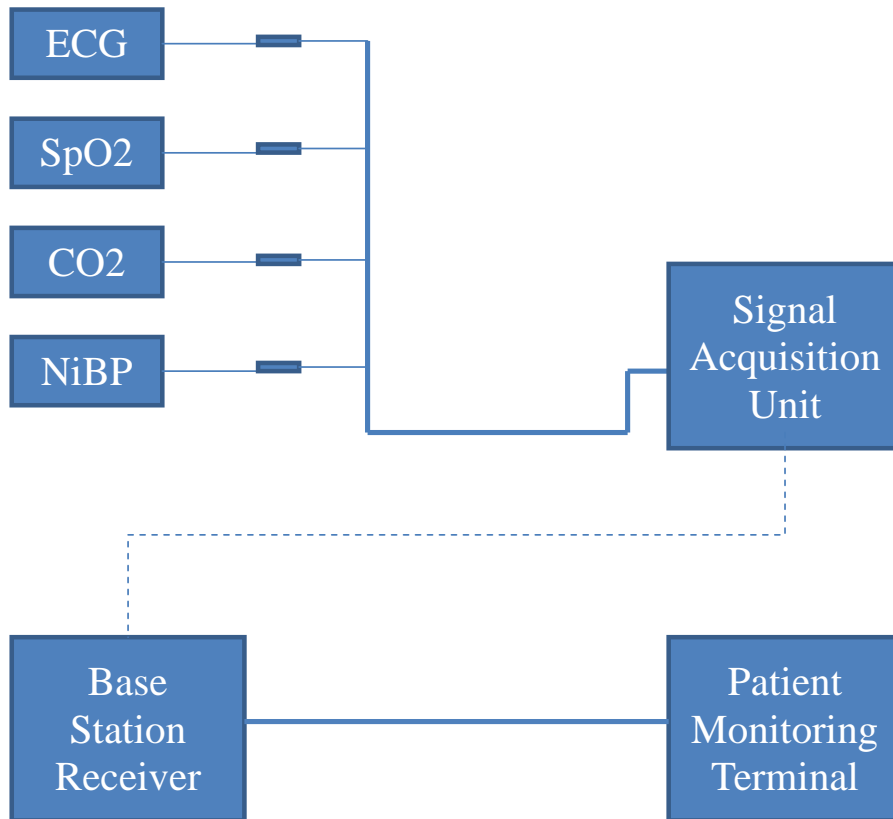
Figure 4-2: System Design Tree

Figure 4-4: Hardware Block Diagram

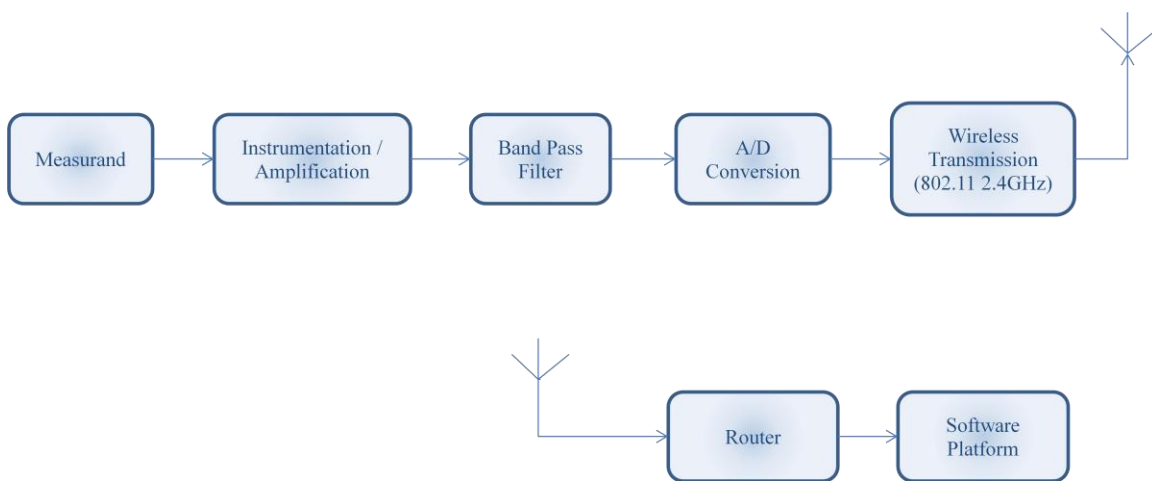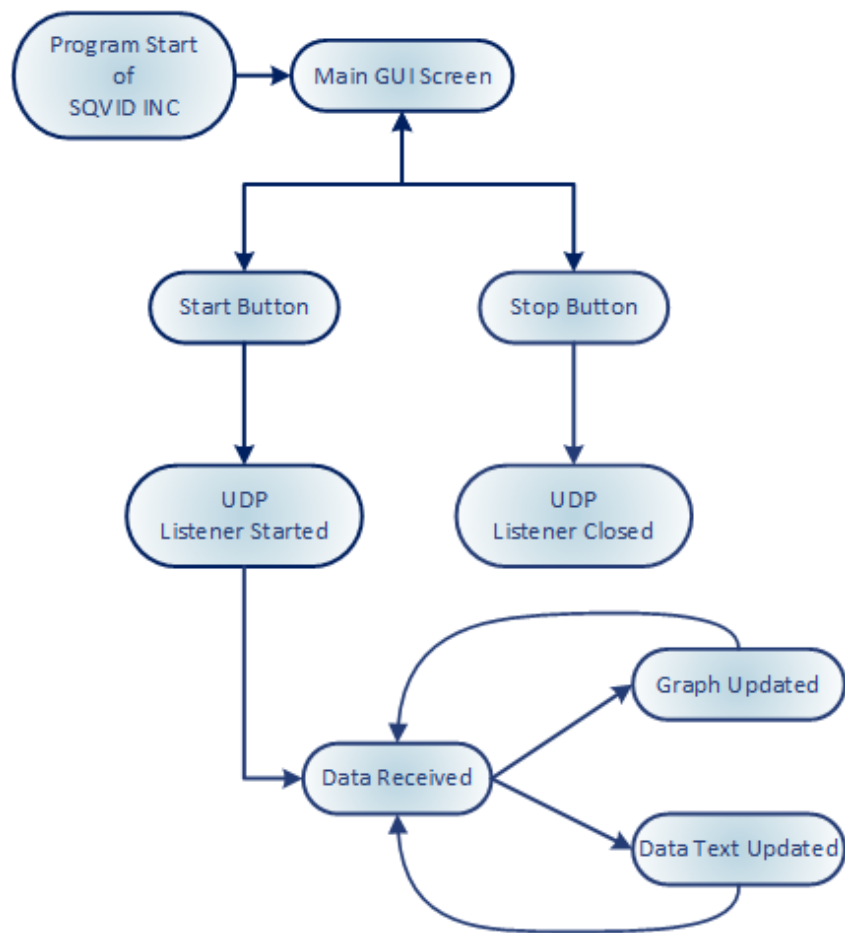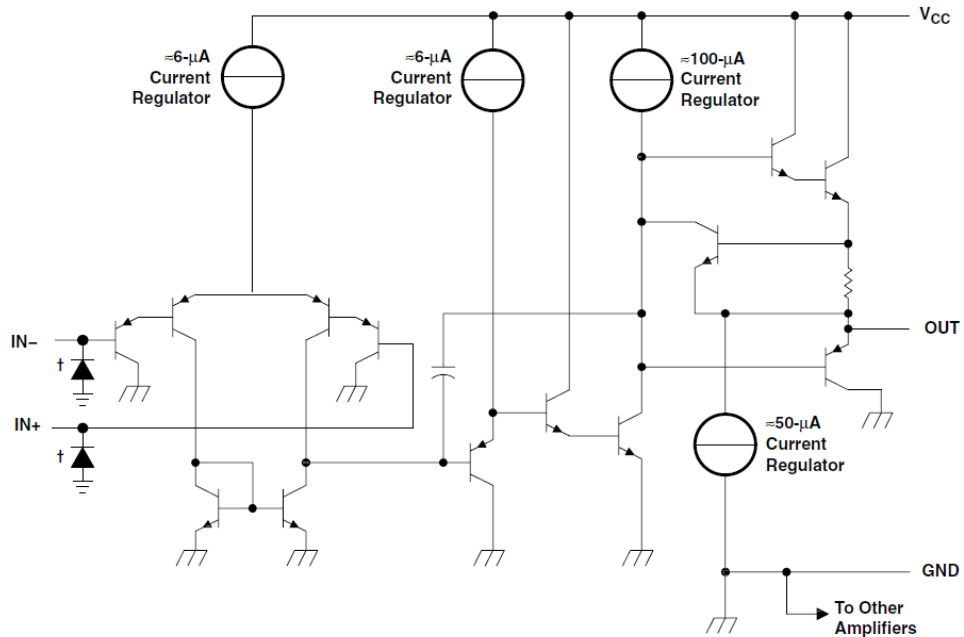**Figure 4-10: Software Block Diagram**

Appendix E – Schematics
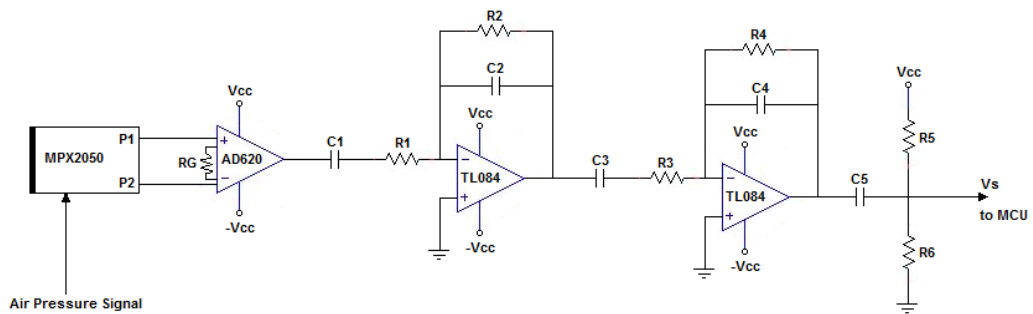
Figure 4-16: Op-Amp Circuit

COMPONENT COUNT (total device)	
Epi-FET	1
Transistors	95
Diodes	4
Resistors	11
Capacitors	4

† ESD protection cells - available on LM324K and LM324KA only

Figure 4-17: NiBP Sensor Circuit
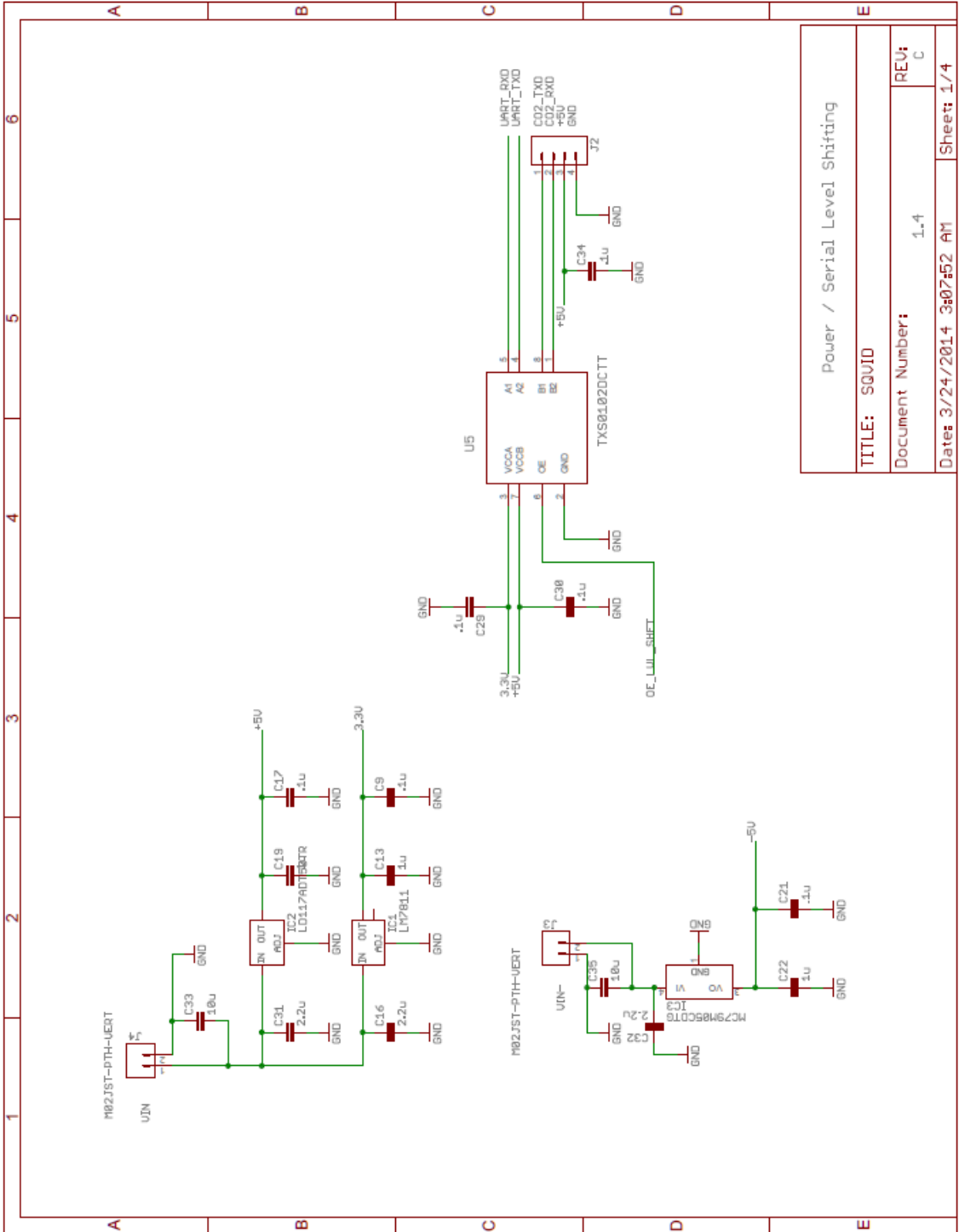
Power / Serial Level Shifting

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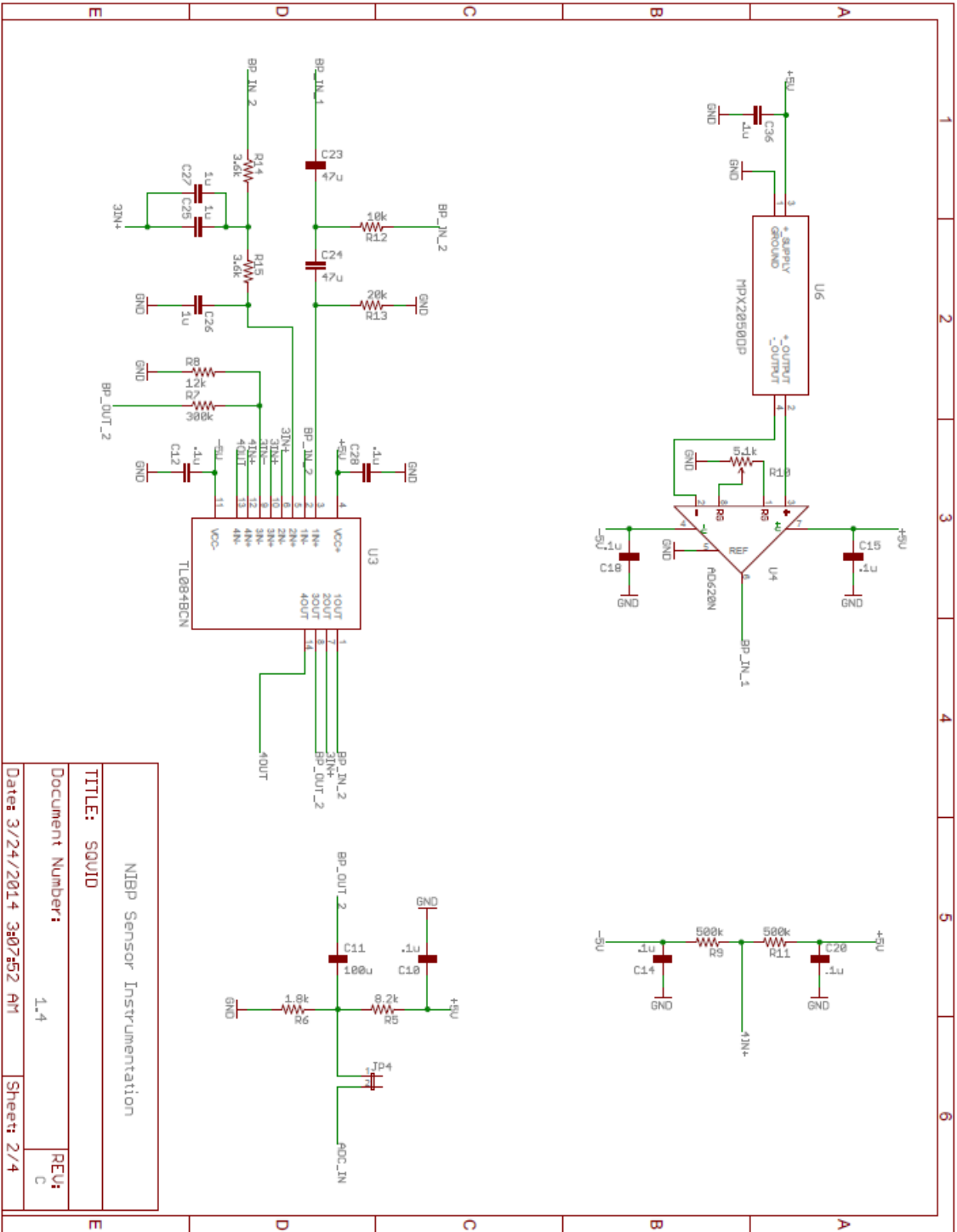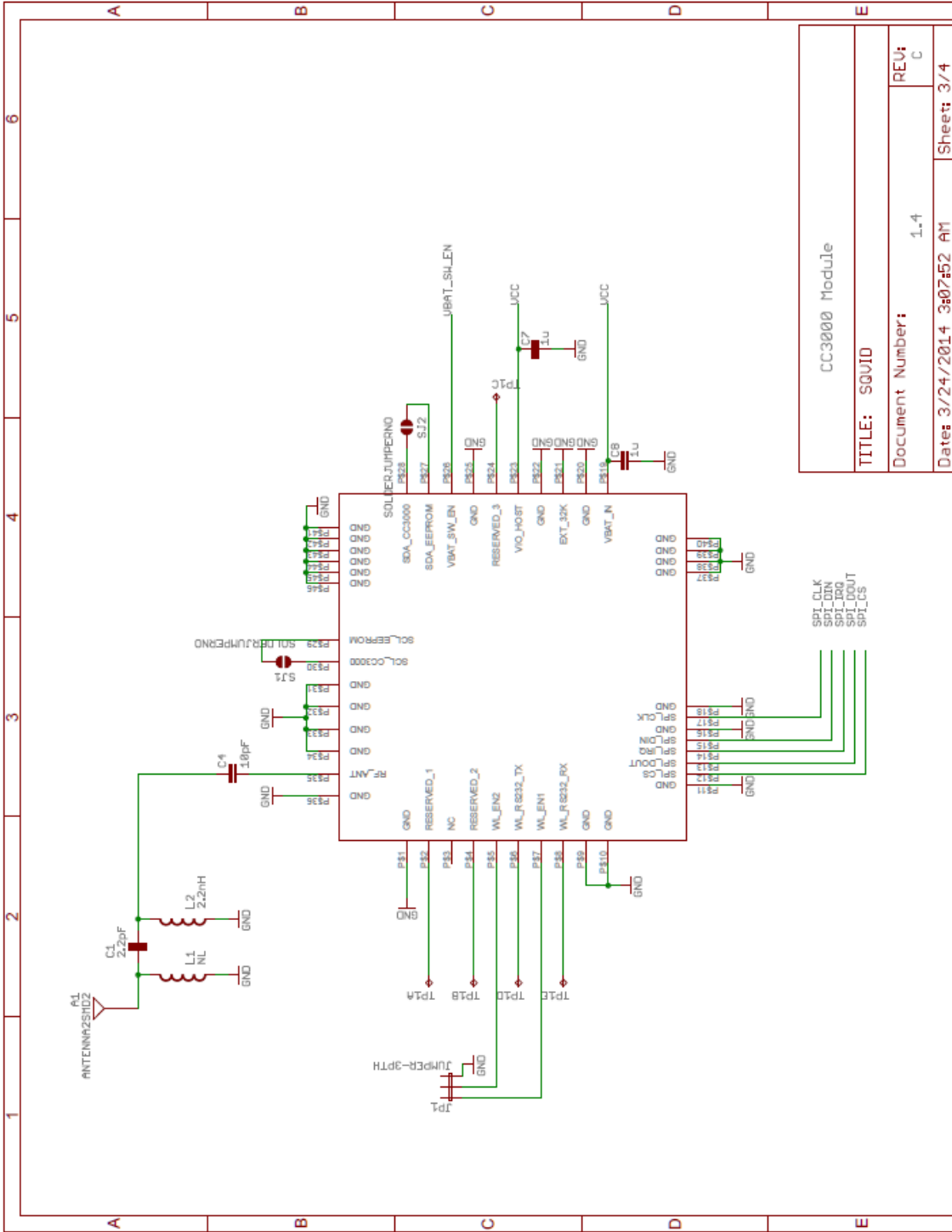
NIBP Sensor Instrumentation
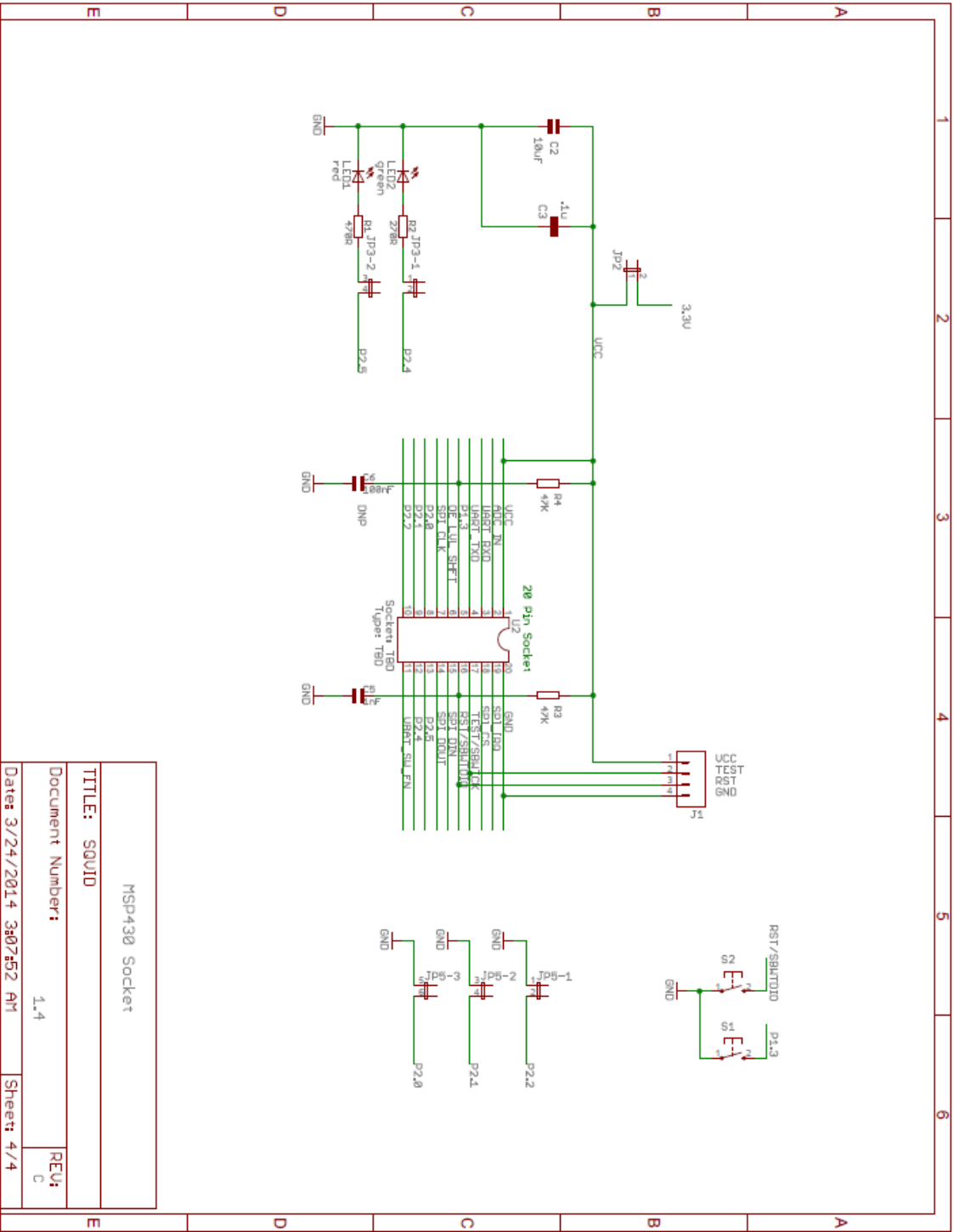
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