Alternative Design #2 Report

Expert Anesthesiology Monitoring System

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# Table of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Alternative Design No.2</td>
<td>3</td>
</tr>
<tr>
<td>1.1. Introduction</td>
<td>3</td>
</tr>
<tr>
<td>1.2. Subunits</td>
<td>5-21 (ATM)</td>
</tr>
<tr>
<td>1.2.1. Labview Program</td>
<td>5-8</td>
</tr>
<tr>
<td>1.2.1.1. Front panel</td>
<td>5-6</td>
</tr>
<tr>
<td>1.2.1.2 Block Diagram</td>
<td>7-8</td>
</tr>
<tr>
<td>1.2.2 Signal Familiarization</td>
<td>9-13</td>
</tr>
<tr>
<td>1.2.2.1 Electrocardiograph (ECG)</td>
<td>9</td>
</tr>
<tr>
<td>1.2.2.2 Electroencephalograph (EEG)</td>
<td>10</td>
</tr>
<tr>
<td>1.2.2.3 Blood Pressure</td>
<td>10-12</td>
</tr>
<tr>
<td>1.2.2.4 Volumetric Capnography</td>
<td>12-13</td>
</tr>
<tr>
<td>1.2.2.5 Patient’s Prior Information</td>
<td>13</td>
</tr>
<tr>
<td>1.2.3 Material Requirements</td>
<td>13-15</td>
</tr>
<tr>
<td>1.2.3.1 Case</td>
<td>13-14</td>
</tr>
<tr>
<td>1.2.3.2 Interface Screen</td>
<td>14-15</td>
</tr>
<tr>
<td>1.2.3.4 Transducers</td>
<td>15-18</td>
</tr>
<tr>
<td>1.2.4. Electric Circuit</td>
<td>15-16</td>
</tr>
<tr>
<td>1.2.4.1. Low-Pass Filter</td>
<td>16-17</td>
</tr>
<tr>
<td>1.2.4.2. High-Pass Filter</td>
<td>17-18</td>
</tr>
<tr>
<td>1.2.4.3. Band-Pass Filter</td>
<td>18</td>
</tr>
<tr>
<td>1.2.4.4. Leakage Current</td>
<td>19-20</td>
</tr>
<tr>
<td>1.2.5. Testing</td>
<td>19-21</td>
</tr>
<tr>
<td>1.2.5.1. Labview Testing</td>
<td>19</td>
</tr>
<tr>
<td>1.2.5.2. Circuit Testing</td>
<td>19-20</td>
</tr>
<tr>
<td>1.2.5.3. Total Testing</td>
<td>20</td>
</tr>
<tr>
<td>1.2.6. Integration</td>
<td>20-21</td>
</tr>
<tr>
<td>1.3. Realistic Constraints</td>
<td>21-23</td>
</tr>
<tr>
<td>1.4. Safety Issues</td>
<td>23-24D</td>
</tr>
<tr>
<td>1.5. Impact of Engineering Solutions</td>
<td>22-23</td>
</tr>
<tr>
<td>1.6. Life-Long Learning</td>
<td>23-24</td>
</tr>
<tr>
<td>1.7. References</td>
<td>25-26</td>
</tr>
</tbody>
</table>
**Figures and Tables**

*Figure 1:* Flow chart for Device Operation 3  
*Figure 2:* Example front panel of the anesthesia monitoring system 4  
*Figure 3:* Bis Vista monitor. 6  
*Figure 4:* Example of a well designed block diagram. 7  
*Figure 5:* Basic elements of the ECG signal and heart anatomy 8  
*Figure 6:* Data acquisition and result examples. 9  
*Figure 7:* A patients’ systolic and diastolic pressures are determined. 10  
*Figure 8:* Patient’s blood pressure will be displayed in LabVIEW. 11  
*Figure 9:* Volumetric Capnography equipment and terminals. 12  
*Figure 10:* Volumetric Capnography as used in a surgical setting. 12  
*Figure 11:* Example case for the monitor. 13  
*Figure 12:* 8”x 8” LCD monitor. 14  
*Figure 13:* Information on the LCD screen. 15  
*Figure 14:* The circuit schematic of a lowpass filter. 16  
*Figure 15:* Low-pass Bode Plot. 16  
*Figure 16:* The circuit schematic of a highpass filter. 17  
*Figure 17:* High-pass Bode Plot. 17  
*Figure 18:* The circuit schematic of a Bandpass filter. 17  
*Figure 19:* Function generator and Oscilloscope setup  
*Table 1:* EEG and ECG filtering parameters. 18  
*Table 2:* Potential Budget 22
Alternative Design Project #2:

1.1 Introduction:

The following proposal is an in depth explanation of how a specialized unit for determining the consciousness level of a patient to help the anesthesiologist maintain a vigilance can be designed. Chief of trauma anesthesiology at Hartford hospital, Dr. Joseph McIsaac, is the main client and his needs will be considered for all aspects of this design. The principles of engineering will be followed in determining the best cost efficient design encompassing all of the needs of the client. An informative description of the project’s goals are outlined which includes the device requirements and its overall abilities. Possible programs and components will be highlighted for use as well.

This device is going to use measurements of a four vital signs to determine the level of consciousness of a patient under anesthesia. Mainly the monitor will focus on the patient’s physical condition, medical conditions and prior exposures. During the process of anesthesia the patients ECG, volumetric capnography, blood pressure and their EEG signal will be recorded and analyzed.

The development of new software and hardware has given anesthesiologists hope for additional improvements on the current anesthesiology monitoring systems. LabView is the new data acquisition software that will be used in this project to create measurements and a calculated level of consciousness on a clear front panel. This device should be reliable and easily used throughout a surgical endeavor. The settings should be easily managed allowing any level technician to update them. The front panel will display clear graphs with the corresponding numerical values and appropriate labels. The device should be able to withstand a great deal of time in the surgical rooms and be durable enough to withstand every day use. The device should have a clean and purposeful appearance in the fact that there should not be any wasted space as the device will be in close proximity of patients while maintaining accessibility without compromising the surgery.

The device will then be in such a way which minimizes noise through using analog filtering and amplifications built and after the signal manipulations the data will be sent to the Labview program. In the final product the program will be transferred to a data chip, which will allow the chip to control the functions of the LabView program without a personal computer which optimizes the device’s functionality in the surgical environment. The components necessary for this device consist of a screen, mother board, microprocessor, and a box to contain the internals. Figure 1 shows a block diagram of the operations of the anesthesia monitoring system.
Figure 1: Flow chart for Device Operation
1.2 Subunits:

1.2.1 Labview Program

National Instruments Labview Style Guide

“To create a successful VI, consider who needs to use the VI and for what reasons. Remember the following:
• Users need a clear front panel.
• Developers need an easy to read block diagram.
• Users and developers need thorough documentation.”

1.2.1.1 Front panel

The front panel for this design has a few preliminary aspects that need to be addressed. The main focus of the front panel is to have a clear graphical and numerical display of the most important data. The graphs will display as close to real time as possible the patients ECG, volumetric capnography, blood pressure and their EEG signal. Each graph will have separate alert levels that will set off the visual and audio alarms to warn the anesthesiologist that the patient is becoming conscious or beginning to fall into an unrecoverable state. These graphs will be colorful in a way that will allow for color segregation between graphs. The numerical values that will be displayed to show the level of consciousness of the patients will be large and clearly displayed next to their corresponding graph. Figure 2 shows a rough estimate of the visual appeal of the front panel. This new design allows the anesthesiologist to only focus on the signal of choice as well on the overall level of consciousness. However the combo box and the new emergency system allow the anesthesiologist to pin point the problem immediately and quickly access the appropriate graphs by using the source of problem box and the vital signal drop down menu.

The patient’s information must be easily manipulated on the front panel by the anesthesiologist. These factors consist of the patient preliminary statistics based on their prior resistance, acute and chronic disease states, age, weight, gender, exercise tolerance, medication usage, and habits such as smoking, drug and alcohol use. These will all have to be configured neatly and clearly on the front panel so that the anesthesiologist can alter these during the procedure if necessary. There is a chance that a patient may lie to the doctors and the information given maybe wrong for one reason or another. This is why it is necessary to make the preliminary statistics easily manipulated, and ensure the program is not completely dependent on these factors.
“Front panels must be well-organized and easy to use because users see the front panel first when working with a VI. When designing a front panel, keep in mind two types of users, the end user and the developer. End users work with user interface VIs, which have front panels that only the end user sees, and developers work with subVIs, which have front panels that only developers see.”

The main model for the front panel is being compared to the Aspect Medical Systems BIS VISTA or GE anesthesia machine the BIS monitor as displayed in figure 3. The BIS monitor relies on a clear graph of an Electroencephalogram (EEG) to determine the level of consciousness of a patient at a moments notice by the anesthesiologist and then displays a number between 1 and 100 that corresponds to their consciousness. The BIS monitor also highlights an acceptable region to which the patient is within the correct level of consciousness for the surgery to continue without amnesia, analgesia, and immobility becoming a factor. There is also an alarm that will sound if the patient exceeds the previously determined range to alert the anesthesiologist of the patient approaching brain damage or a wakening state.
1.2.1.2 Block Diagram

The block diagram for the program will be aimed to meet the code followed by national instruments programmers, which consists of common rules to pursuing a proper program. The program should be clear and easily manipulated. The titles of all the different parts of the program are necessary when working with the program and problem shooting. The DAQ must be used in a manner that allows the program to take different inputs and apply them all to one block diagram.

The block diagram is going to have a case structure that will allow for the calculations of each of the vital signs and then the calculation of the level of consciousness produced from them. Each vital sign will have its own portion of the block diagram. The case structures will allow the anesthesiologist to use individual portions of the program and disconnect others if the surgery is interfered with by the sensors.

The block diagram will include global variables that will be placed outside the main loops. This will allow for the numbers to be manipulated at any point in the device’s process. Each of these separate loops can be recalled and used in multiple places in the program making the information easy to work with.

An example of a block diagram that fits the requirements that we are looking to pursue is shown as figure four. This diagram is clear, well labeled, and organized in an easily followed manner. This is extremely important in creating a good environment for fixing and accessing
problems that may arise during testing or even during later uses. There are flaws that tend to escape the grasp of the testing atmosphere and are only discovered when the device is used in the actually application it was designed for. These errors will have to then be examined and corrected after the device has been cleared for use. This might mean someone unfamiliar with the design may have to navigate the block diagram, find the error, and reprogram the section. If the block diagram is impossible to follow this job becomes immensely more difficult.

**Figure 4:** Example of a well designed block diagram.

**National Instruments Block Diagram Style**

“The block diagram is the primary way for others to understand how a VI works; therefore it is often worth the effort to follow a few simple steps to make block diagrams more organized and easier to read. Style is as important on the block diagram of the VI as on the front panel. Users may not see the block diagram, but other developers do. A well-planned, consistent block diagram is easier to understand and modify.”
1.2.2 Signal Familiarization

1.2.2.1 Electrocardiograph (ECG)

The electrocardiograph has specific characteristics that are essential for analyzing the acquired data because of what each electrical impulse corresponds to. The electrocardiogram is a display of the electrical impulses during a heart contraction. The ECG is dependent on variables such as age, weight, height, and personal habits, but is also dependent on different stimuli such as physical activity or the resting state of the heart.

![Figure 5: Basic elements of the ECG signal and heart anatomy](image)

Each fluctuation represents an element of the heart contraction and each interval is dependent on the depolarization and polarization durations within the cardiac muscle. Changes in intervals correlate to the rate at which the heart beats while the amplitude correlates to the strength of the contraction. This means that by monitoring the electrocardiogram the anesthesiologist can monitor the status of the patient’s heart.

By examining the PQRST expressed in fig. 5 which shows waves exhibited by the heart during this process the pulse created by the heart can be used to determine the R to R interval, which will give the patients heart rate and can be used to understand the level of consciousness of the patient. Also by examining the T to P portion of the PQRST wave, the extension of the time between them would also display the decreased blood flow to the body and the lowered level of consciousness.
1.2.2.2 Electroencephalograph (EEG)

Electroencephalography measures the electrical activity of the brain. Fluctuations are attributed to a variety of stimuli ranging from awake and resting states to brain disorders such as tumors or epilepsy. For this system the application of interest will be monitoring the changes which occur due to an anesthetically induced resting state of the brain. The purpose of monitoring the patient’s EEG is because of the possibility of over sedation. Over sedation can produce a flat EEG meaning there is zero brain activity. The EEG is made up of four different types of wave forms: Alpha, Beta, Delta, and Theta waves. Each wave form is influenced by different stimuli. Alpha wave are influenced by visual or mental concentration. Beta waves have frequencies appear in patients who are alert they also appear in the presents of seizure medication. Delta waves and theta waves are most apparent in sleeping adults and children.

![EEG waves](image)

**Figure 6**: Data acquisition and result examples.

National Instruments has a head piece used to measure the EEG waves that is compatible with Labview, which will be used by our devise. This devise should be able to display the alpha, beta, theta, and delta waves that are needed to judge the level of consciousness of the patient. When this part is received and attached to the program, tests can be run to determine the levels of the average person and then they can be applied to the alarm offsets on the Labview program. This head piece will need to be connected using a DAQ assistant and will pass the signals to the Labview program, which will then show similar wave forms to the ones expressed in fig. 6.

1.2.2.3 Blood Pressure

The blood pressure monitoring device will be an automated non-invasive transducer to accurately obtain data about the patient’s blood pressure. The transducer obtains the data by inflating the sphygmomanometer cuff until the artery of focus collapses. The point at which the artery collapses is the systolic arterial pressure but pin pointing the exact value is difficult with the increasing pressure due to its varying rate. To eliminate this problem the cuff is inflated past the systolic pressure and then released at slow and constant rate. The return of blood flow is associated with two characteristics; the first sound of Korotkoff and pulsations. The diastolic
pressure is associated with the discontinuation of the sound of korotkoff and pulsations. Normally blood pressure is measured with a sphygmomanometer and stethoscope, however this application requires

The idea is to prevent any unnecessary stress for the patient as well as to allow the anesthesiologist to monitor the overall condition of the patient rather than using a sphygmomanometer. When a patient’s blood pressure is measured, the goal is to determine the systolic and diastolic pressures. These values vary with age, physical health and personal habits. A typical adult human has 120 mmHg systolic and 80 mmHg diastolic pressures. However children tend have lower values while the elderly tend to have higher values. This change is proportional to the change in arterial flexibility.

![Figure 7: A patient’s systolic and diastolic pressures are determined](image)

Systolic pressure is defined as the maximum cuff pressure where blood flow returns to the artery. Diastolic pressure is the least amount of pressure that still influences the arterial blood flow. Figure 8 gives a visual explanation of how a patient’s blood pressure is determined using Korotkoff sounds. The system will display the systolic and diastolic data points along a time axis using an ambulatory blood pressure measurement graph (ABPM). This display gives the anesthesiologist a means to make clear correlations between drug administration and blood pressure fluctuations blood pressure.
Figure 8: An example of how the patient’s blood pressure will be displayed in LabVIEW.

The range for blood pressure can be observed for patients under anesthesiology to determine a relative level of consciousness. While the patient falls into an unconscious state the systolic and diastolic pressure maximums and minimums fall as presented in fig. 8. If the maximum comes over the top of the estimated level given to an unconscious patient then the anesthesiologist knows the patient is waking up and if it goes below then they can tell that the patient maybe falling to deep into the coma.

1.2.2.4 Volumetric Capnography

Volumetric capnography is the measurement of CO$_2$ concentration inhaled and exhaled through the respiratory process as well as the volume of air respired. A capnograph measures the carbon dioxide concentration in a sample of air by means of infrared light absorption. The amount of absorbed light depends on the concentration of CO$_2$ in the air sample. The capnograph provides valuable information about respiratory patterns and oxygen absorption rate. The blood CO$_2$ concentration can be indirectly determined based on the concentration in and concentration out of the lungs. In addition to CO$_2$ concentration, a volumetric capnograph measures respiratory flow rate. This gives valuable information regarding the respiratory state of the patient, and aids in early detection of any sort of respiratory trauma or failure during anesthesia.
Figure 9: Volumetric Capnography equipment and terminals.

Using these volumetric capnography sensors as shown in fig. 9 is used to judge the level of consciousness of a patient can be helpful in that it will allow the anesthesiologist to see exact oxygen intake of the patient under anesthesia. These designs are highly specific for determining the exact respiration of CO$_2$, which can be translated into oxygen consumption. Knowing the amount of O$_2$ that is being processed by the body allows the anesthesiologist to determine the activity of the body. Figure 10 is a great example of the amount of space that will be consumed by the volumetric capnography equipment.

Figure 10: Volumetric Capnography as used in a surgical setting.

1.2.2.5 Patient’s Prior Information
While considering prior resistance, acute and chronic disease states, age, weight, gender, exercise tolerance, medication usage, and habits such as smoking, drug and alcohol use a patient has had prior to the anesthesia the average range for vital signs will be much more readily available. These estimates will increase or decrease the alarm levels of the patient by determining the amount that the person’s vital signs will be affected by these prior experiences. For example if the patient is between a certain age range the upper limit will be lowered because the anesthesia drugs will have a stronger effect on them. Some of the personal information used will have a stronger effect then others, such as weight and prior drug use. The main problem with using information given by the patient is that the patient may lie about some information due to a fear of punishment. If a patient has prior experiences with pain killers they may be more likely to need more drugs to keep them at the correct consciousness level but they may not tell the anesthesiologist for fear of persecution. When the anesthesiologist realizes that the drugs are not causing the amount of anesthesia that they are supposed to, it maybe appropriate to change the prior drug usage to a higher level to account for this resistance during the procedure.

1.2.3 Material Requirements

1.2.3.1 Case

The casing structure that will be used to house the monitor and the electrical components should be a durable, protective and light material. The best choice is going to be a polymer based purely on its mechanical strength and its light weight. The polymer should be soft enough to absorb some of the force if the device is dropped or tipped over. This exterior covering should be large enough to encompass all the materials necessary to run the monitor, while maintaining a small size as to not get in the way of other devices in the room. The monitor box will have to be able to support the front weight of the LCD touch screen. This means that there will have to be some weight in the rear of the box to support and balance the container. There will have to be good ventilation that will allow for the monitor to run without over heating.

![Figure 11: Example case for the monitor.](image)

Figure 11 is an example of a case that would be able to support the monitoring system. This specific box is 12.5 pounds and made of Aluminum. This cube is approximately 18”x18”x18” with 9 fan holes. This box supports a mother board and enough room that the monitor could be inserted into one of the sides with ease. There are pre drilled switch holes and enough accessibility to have room to spare.
1.2.3.2 Interface Screen

The flat screen panel being used for the monitoring system should be large enough to have a clear display of the visual graphics that need to be displayed for quick reference by the anesthesiologist. Figure 12 shows an LCD monitor that would fit the requirements for the project perfectly. This model has visual enhancements available on the frame of the screen. This screen is clear and will allow for a good picture quality for clear numerical values and clear graphs. The eight by eight inch screen should be large enough display all the graphs that will be needed for the anesthesia monitor. The informational specifications of the LCD screen displayed in fig. 12 are described in detail in fig. 13, including weight, resolution, and display size.

Figure 12: 8”x 8” LCD monitor.
1.2.3.4 Transducers

The choice of transducers is an important because there are many variables that need to be considered. Firstly, the hospital’s position on purchasing new transducers if they refuse to buy new equipment the monitoring device will need to be adapted to their current transducers. If hospital is willing to spend the money to buy new transducers the device will be made to use the National Instrumentation transducers to minimize complications.

1.2.4. Electric Circuits

1.2.4.1. Low-Pass Filter

The Expert anesthesiology monitoring device will require a variety of electrical components. The most important components will be the active filters that will provide voltage amplification and signal isolation. To acquire the most accurate data, a second order filter will be used to obtain close information to ideal characteristics which creates a more effective filter.
There are two general types of active filters; a low-pass and a high-pass. The purpose of the low-pass filter is to effectively attenuate all of the undesirable high frequency noises. Figure 14 is an example of a second order low-pass filter. The cutoff frequency is determined with this equation: \( f_{oc} = \frac{1}{2\pi R_1 C_1} \). The distinguishing features that make it second order filter is the second set of resistor/capacitor combination connected to the positive terminal. The low-pass filter is shown in figure 15 through the graphical interpretation of using the bode plot method.

![Figure 14: The circuit schematic of a low-pass filter.](image)

1.2.4.2. High-pass Filter

The high-pass filter is created with a similar setup to the low-pass filter. However, the C1, C2 and R1, R2 positions are switched. Opposed to the low-pass filter this setup attenuates low frequencies reducing any noise with a frequency below the cutoff frequency to be
eliminated. Figure 16 displays the High-pass filter. The cutoff frequency is determined in the same way as the low-pass. The equation relating the filter with the circuit is \( f_{oh} = \frac{1}{2\pi R_f C_1} \).

The cutoff equations can be used to adjust the filtering parameters to accommodate the individual vital signals for the expert anesthesiology monitoring device. The graphical display of a high-pass filter is shown in figure 17.

**Figure 16:** The circuit schematic of a high-pass filter.

**Figure 17:** High-pass Bode Plot.

These filters also provide an amplifying effect creating clearer output and will allow for easy analysis. The amplification is influenced by ratio between resistors RG and RF. The equation relating these resistors is \( A_v = 1 + \frac{R_F}{R_G} \). Depending on the type of signal the specific circuit is dealing a different combination of resistors will be used for applying the correct amplification.
1.2.4.3. Band-pass Filter

These filters can be combined into circuits in series to produce filters effect that are know in industry as a band-pass filter and a stop band filter. Each is used for it’s inherit filtering characteristics. The band-pass filter is the combination of a high-pass and low-pass filter producing a filter that an effect of an inverted parabola. Any frequencies exceeding the upper and lower cutoff frequencies will be attenuated eliminating any back ground noise. The band-stop filter used when there is a need for eliminated a noise spike. An example of a common noise spike present in most vital signals is the power line noise.

![Figure 18: The circuit schematic of a Band-pass filter.](image)

Determining the specific values of each circuit element will determine using preexisting information about the electroencephalogram, electrocardiogram, Volumetric Capnography and Blood pressure. The current filtering parameters for the EEG and ECG are displayed in Table 1 and are also mentioned in sections 1.2.2.2 and 1.2.1.2.

<table>
<thead>
<tr>
<th>EEG waves</th>
<th>EEG Signal</th>
<th>ECG Signal</th>
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<tbody>
<tr>
<td>Alpha</td>
<td>$f_{OH}$ 0.0833Hz, $f_{OL}$ 0.125Hz</td>
<td>$f_{OH}$ 0.05Hz, $f_{OL}$ 40/100/150Hz</td>
</tr>
<tr>
<td>Beta</td>
<td>0.0333Hz, 0.077Hz</td>
<td></td>
</tr>
<tr>
<td>Delta</td>
<td>0.143Hz, 0.25Hz</td>
<td></td>
</tr>
<tr>
<td>Theta</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 1: EEG and ECG filtering parameters.

1.2.4.4. Leakage Current

Another electrical concern is the current leakage. Current leakage is described as the current that flows from the internal device through the grounding conductor and then into the hospital ground. Leakage current could shock nearby individuals near the monitoring device. This would severely hinder the surgical procedure and may have fatal results for the individual who received the shock. Leakage current the in range of 3mA can easily create shock and possible pain for the individual making contact. Current meeting or exceeding 8mA causes cardiac arrhythmia and if the current is great enough fatalities will result. To ensure that leakage
current does not occur, proper grounding and insulation should be implemented into the design. Designers commonly use protective earth grounds connected to the case to maximize the device’s safety. This is accomplished by connecting a leakage current tester to a ground then testing the external metal components of the device. If the components carry amperage above a certain safety level, the device is leaking current. Also, the power cord must be tested for leakage. This is done by connecting the device directly to the leakage current detector. If when the cord is moved the milliamp current reading fluctuates, the cord is leaking current.

1.2.5. Testing

1.2.5.1 Labview Testing

The testing of Labview will involve a break down of the program into smaller portions to make sure that all the parts work independently before combining them into one program. The program will mostly be broken down into each individual component. After each of the signals are working independently and the errors or deciphered and fixed, the program will be consolidated into and will be run through one Data Acquisition or DAQ assistant. This is where most of the problems in the program should be experienced. When combining multiple working signals into one, there is an error rate that has to be accounted for. The chance that multiple programs can be combined without interference is implausible.

The testing without the circuits attached can be done with programmer installed data. Instead of using the circuits to input the data from the patient, signals can be simulated and applied to the program to make sure that the program can process and display the data correctly without error. At this point the filters can be tweaked and the noise will be separated from the signal and can be filtered out. This will allow for the most precise measurements. Knowing the signal that should be outputted will allow for a proper diagnosis of noise and error in the outputted signal and graph.

1.2.5.2 Circuit Testing

Testing the electrical hardware will be done in two ways. First using PSpice the circuit build and simulated with the calculated resistive and capacitive components. Once the board has gone through extensive virtual trouble shooting it will be translated into electronic hardware. This hardware will be required to undergo additional tests to check whether or not there were errors incurred during fabrication and soldering of the components.

Each of the signals will require specialized components to meet their amplification and filtering needs. First the circuitry will be verified by testing the amplification and filtering. Given that each signal requires a unique set of filtering and amplifying parameters the circuitry components will be customized set their requirements.

For example the EEG amplitudes and frequency components vary from 10-100 μV and from 0.5-30Hz respectively and within these general parameters there are sub parameters correlating to the different periodicity’s which compose the EEG signal. Each of these periodicities is characterized by a more specific frequency and amplitude as well as the conditions which they are most apparent. The filtering of this design will be completed solely in analog domain.
The approach to verify the functionality of the circuit will be to connect a function generator to the input of the circuit board and to channel 1 of an oscilloscope and connect channel two of the oscilloscope to the output. This will provide an easy way to compare the inputted signal to the outputted signal. The input signal will be attenuated by the same scale that that output signal is amplified by which will reproduce the un attenuated signal. To manually test the filtering of the circuit board the frequency of the created signal will be move around each cutoff frequency. As the frequency exceeds a cutoff frequency the signals should be attenuated to about zero. Figure 19 displays a general setup for a function generator and oscilloscope.

![Function Generator and Oscilloscope Setup](image)

**Figure 19:** function generator and oscilloscope setup

1.2.5.3 Total Testing

The total testing of the Labview program and the circuits once they are all set up will involve using biopack equipment for the ECG and blood pressure. For the other signals, sensors will have to be bought, tested and applied to the corresponding signal before combination. There will be sensors set up and attached to the Labview program where the sensors will be attached to a patient, or a test subject. The program will be run while the test subject is in a physically active state, or has just completed physically straining activity, which should allow a spike in the level of consciousness monitor. Then at a separate time the patient will be totally relaxed or even asleep while the next test is taken. If the patient is attached to the sensors and the device while they are falling asleep, it will be possible to watch the signals and observe the level of consciousness decrease. This will be a simulation of the application of the drugs used in an anesthesiology case. The effects of sleep will not be as strong as the effects of the drugs, but it should be possible to lower most of the signals at a level that will allow for a proper test.

1.2.6. Integration

The total monitor will have to integrate the Labview program to the circuits and to the sensors. The sensors should input the data from the patient or test subject to circuit, where it will be amplified and filtered and then it will be sent to the Labview program to clearly display the patient’s current status through the use of graphs and numeric values. The circuit board will
include all of the filtering and amplification. The advantages to using all electrical hardware for the signal manipulations once the circuit is built is more robust and analog filtering and amplification provides better results. However, the downfall to manipulating in the analog domain is that all the filtering and amplification parameters are fixed, which eliminates any possibility of adjusting the parameters to optimize the displayed signal. The data is then converted to the digital domain where the signals are compiled into one DAQ assistant allowing the program to have one collaborative final output and will be able to analyze each signal simultaneously. The signal transducers will be implemented into circuit board where the data will be manipulated to reduce the noise. After the acquisition stage the input will then be ready for the Labview program that is installed onto a blackfin chip. Then the display screen will have to be attached to the circuit board to allow for a clear presentation of the signals. The Labview program will have to be either applied to a PIC chip or a blackfin chip to control the function of the monitoring system. The blackfin chip will allow for a more complex display, which will allow for more alterations on the site. The PIC chip will be more difficult to use due to its less capable abilities.

1.3 Realistic Constraints:

There are a number of organizations that specialize in developing and maintaining engineering standards for which projects must meet or exceed. Organizations such as the International Organization of Standardization (ISO), the International Electrotechnical Commission (IEC), and the Association for the Advancement of Medical Instrumentation (AAMI) are the ones responsible for these standards that all engineers must take into consideration when developing a device such as an expert anesthesiology monitoring device.

These standards are not only put in place for the patient’s safety but also as guidelines for the engineering developers. They set a level of quality for each product which ultimately reduces the number of incompatible components when using a variety of different manufacturers; they also prevent unintentional misuse, and promote proper safety and effectiveness evaluations for each device. Before production medical devices are compared to three different groups of standards all of which must be met before production continues. The three groups are process standards, standard test methods, and performance standards.

Process standards provide a systematic way of accomplishing goals with a certain level of confidence. The most important process standard according to Kunst and Goldberg is the ISO 9001:2000 Quality Management Systems – Requirements which provides systematic methods for managing all aspects of manufacturing a device. This standard includes steps needed in purchasing raw materials, quality control, maintenance of manufacturing equipment, product servicing, and methods for training all users. For the expert anesthesiology monitoring system the design control section will provide the most applicable information because it deals with developing new devices. This section is relevant to product development because of the requirements it sets forth regarding establishing and documenting the product’s design requirements, the evaluations of possible design hazards, final device specifications as well as establishing a correct method for transferring the design to the final large scale product.
Other relevant process standards are EN 1441:1997 Medical Devices – Risk Analysis, ISO 11135:1994 Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization, and BS 5295:1989 Environmental Cleanliness in Enclosed Spaces. EN 1441:1997 outlines the procedure that is performed throughout the development process. It investigates the safety of the medical device by identifying hazards and estimating the risks associated with the hazards. ISO 11135:1994 provides development teams with procedures for validating their product’s sterilization status and ensure the product will be sterile for field implementation. BS 5295:1989 sets regulation regarding the manufacturing environment to assure the final product will maintain a certain level of cleanliness suitable for medical applications.

Standard test methods are strict protocols for analyzing the physical properties or performance levels of the medical devices. Part of these standards only provide guidelines for testing allowing for comparisons based on complete and accurate data. Others provide specific test methods and criteria before the results will be considered acceptable. Two examples of Standard test methods are ISO 10993-1:1997 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing and ISO 10993-7:1995 Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals. ISO 10993-1:1997 specifies material safety tests and acceptance criteria which must be met before the device is considered to be biocompatible. ISO 10993-7:1995 lists special tests that the device must pass to assure the product does not contain toxic by-product during the sterilization.

Performance Standards accurately describe all performance attributes of the medical device. These protocols are unique for each device category, for example pacemakers, wheelchairs, vascular catheters, and medical aids such as the expert anesthesiology monitoring device. These standards commonly reference other previously created standards when describing the qualities a device must possess which requires extensive background information. This way of intertwining the standards aids the development team with learning all of the standards relevant to their project.

A few examples of performance standards that are relevant to the expert anesthesiology are EN 980:1999 Graphical Symbols for Use in the Labeling of Medical Devices, EN 868-1:1997 Packaging Material and Systems for Medical Devices Which are to be Sterilized – Part 1: General Requirements and Test Methods, and EN 1041:1998 Information Provided by the Manufacturer with Medical Devices. EN 980:1999 provides a set of international symbols that eliminate the need for producing multilingual products. EN 868-1:1997 standardizes packaging to make it compatible with the sterilization process as well as storage. EN 1041:1998 requires the producers to provide a specific list of information which minimizes the risk and maximizes safety and effectiveness.

Economically the automated anesthesia monitoring system will require enough funding to purchase all of the probes and adapters for each vital sign. The amount of funding we receive will be proportional to the quality of devices. Top of the line devices will guarantee the minimum possible noise in the received signals; translating into a safer monitoring system due to more precise readings. Once system is complete, maintenance checks should occur on a regular basis to ensure the functionality of each probe. Even if the probes are correctly functioning there an expiration date will limit their functioning duration to minimize failures during operation.
Configuring the monitor system for each patient requires a controlled environment to prevent any abnormal conditions that may alter the patient’s normal vital signs. Any change in mental or physical state may jeopardize the patient’s life. Minimizing the all stimuli is required for correct configuration of the system. Maintaining room temperature, eliminating any air contaminations, and ending any drug use prior to configuration are all possible factors that may influence the patient’s vitals in such a way that will result in an incorrect configuration.

There are some serious ethical issues that must be considered to create a device that will be able to function in our society. The device must first off do no harm. This means that this device must not hinder the anesthesiologist’s diagnosis of patient consciousness. Ethically this device may not be used unless it maintains a constant enhancement of performance of the anesthesiologist.

Politically the device has to be approved for use by the FDA’s Quality System. This encompasses regulatory affairs, quality assurance, process development or manufacturing to maximize the performance of the mechanism. Before a medical device can be put on the market it must first meet all electrical safety requirements. The FDA 510(k) states that before introducing a device into the market, there must be a pre-market notification submitted, which allows the FDA to see if there is an equivalent device already on the market, to ensure effectiveness and safety. Ninety percent of all devices fail product certification testing the first time, due to rules that are unseen without total understanding of the testing process.

Socially we have to consider the patient’s reaction of placing their life in yet another automated system. As our society advances, we are relying on less human performance and more computer controlled devices. This is somewhat unsettling for the human psyche. Making sure that the device looks clean, simple and clear may help to settle the patients.

1.4. Safety Issues:

The safety of the patients as well as the hospital employees is a top priority. For the Expert anesthesiology monitoring device electrical, mechanical, thermal, biocompatibility and decontaminations are all important elements that need to be taken into consideration. If any element is overlooked there could be fatal consequences.

When formulating the electrical components great care must be taken to prevent electrical failure. Failure of these components can directly result in electrical fires and electrical injuries. Different failures can produce different types of injuries. Arc-Flash is a term used when heat and light energy emitted during an electrical fault. This arc-flash is caused by the break down of insulation between two energized components or these components and ground. Electrical contact refers to the nonfatal flow of electrical current through the near-by victim. The most serious result in electrical failure is electrocution which is an increased flow of electrical current through a human being that results in the death of the patient. The prevention and or resolution of electrical failures can occur only through full understanding and correct probing and analyses of the components under consideration.
Mechanical failure can also prove to be a serious problem for the monitoring device. The case enclosing the electrical circuit and interface screen could experience wear over time. This would increase the probability of failure if indeed the case no longer provides the protective enclosure it initially had. Other aspects of this system that could experience mechanical failure are the female and male adapters for each transducer. After a number of field trials these components may experience abnormal stresses. For example in-between surgical procedures the monitoring device may need to be repositions depending on the upcoming. During one of these repositions an accidental collision may occur. A step to increase the longevity of the system would be to include a replaceable barrier between the system and its external environment for additional protection.

Integrating thermal dissipation units will aid in preventing thermal failure and will be an essential factor in creating a successful device. Before selecting materials to aid in thermal dissipation the amount of thermal heat produced but the device should be estimated. This step will ensure the selected material is optimal. Selecting the correct material to withstand the thermal dissipation is helpful when deciding between heat spreading devices and/or cooling systems to maintain a static environment within the monitoring device.

Ensuring the monitoring device is biocompatibility with the patients is only applicable to the signal transducers because these elements will be the only components directly in contact with human tissue. To maximize the biocompatibility of these transducers the patient will have to list any allergies they may have. This safety issue is not a fatal problem but can create an uncomfortable environment for the patient before and after the surgery.

Decontamination of the monitoring device between patients will need to occur after each surgical procedure. This is applicable to all components that are in direct contact with the patient. After each procedure the signal transducers sterilized and the electrodes will need to be replaced. During manufacturing the device will need to be produced using a certain protocol to ensure the device is initially up to the engineering standards even before the device enters field applications.

1.5. Impact of Engineering Solutions

Our project is an automatic expert anesthesia monitoring system which will provide a surgeon or anesthesiologist with an accurate reading of the patient’s consciousness level. The expert anesthesia monitoring system will positively impact the medical device market globally, economically, environmentally, and socially. The differences between our device and others on the market will be substantial in the field of anesthesiology monitoring. Our design is unique in that it uses four different vital signals instead of the typical single signal used by most current devices. While most devices on the market use just an electroencephalogram (EEG) signal, our design uses the addition of blood pressure, an electrocardiogram (ECG), and volumetric capnography. With the addition of these three new signals this device provides a more accurate and dynamic interpretation of the patient’s level of consciousness than previous devices. The device itself is intuitive, accurate, and cost efficient. It is small enough to be placed in an operating room unobtrusively, but large enough so it can be easily used.
The global impact of this device will be seen in the changes to anesthesiology monitoring. This device is in essence a medical device that is constantly being upgraded in order to reduce the amount of error, both human and mechanical, that results from the use of such a device. The basic purpose of a medical device is to make the job of whoever is using it easier by doing a portion of their work for them. Our monitoring system removes a good deal of the human element from consciousness monitoring by reducing the error inherent in the device. The tasks that an anesthesiologist must perform are simplified as a result of the more accurate and easy to use device. The prospect of an easier to use and more accurate device will be extremely appealing to corporations, hospitals, and especially doctors.

The economic impact of this device can affect consumers of the product, both doctors and patients. At this point in time, the budget has been estimated to be between $590 and $2155. Aside from the device itself, the only equipment required by the hospital is the electrode/lead sets for the four signals. This is a relatively low cost to pay for a device that has such a high benefit. Every operating room has an anesthesia monitoring system, and generally all hospitals try to update their equipment as much as possible. With the introduction of this new and improved device, the demand will inherently be high. Table 2 shows an estimated parts list and cost for each part.

<table>
<thead>
<tr>
<th>Pricing for Hardware and Software Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>EEG Sensor</td>
</tr>
<tr>
<td>Wiring</td>
</tr>
<tr>
<td>Electrodes</td>
</tr>
<tr>
<td>Blood Pressure Cuff</td>
</tr>
<tr>
<td>LCD Screen</td>
</tr>
<tr>
<td><strong>Total</strong></td>
</tr>
</tbody>
</table>

Table 2: Potential Budget.

The environmental impact on the operating room will be minimal. Since the device will only be used in an operating room, and is relatively the same size and shape as current products, there will not be any change to the actual operating room environment as a result of the use of the new device. With the addition of the new signals, there are a number of new wires that need to be used, and could result in clutter that was not previously present. This could theoretically create a danger for doctors and nurses moving around an operating room. However, the device will be able to turn off certain inputs in order to customize the monitor for different types of surgeries.

Disposal of this device does not carry any direct environmental risks. There are no rechargeable batteries or hazardous materials that are not typically found in such a device so eventual disposal of the unit will be in the same manner as any other similar electric device.

The societal response of this device could have mixed reactions. With each new medical device that reaches the market, control is taken from the doctor and given to the new device. The prospect that a person’s life is put in the hands of yet another automated machine could be discouraging to some people. At the same time, this could be a positive thing in the eyes of
some people in that the element of human error will be removed. In general, most people will welcome a device that allows the operating room staff to focus more on the task at hand while their safety is automatically maintained.

The automatic anesthesia expert monitor will make the job of a surgeon or anesthesiologist much easier in the operating room. The device itself is basically an improvement on a current concept, and uses a compilation of already existing technologies. Ultimately, this device will be an accurate, easy to use, low cost anesthesia monitor.

1.6. Lifelong Learning

The design of this device requires a vast array of knowledge to build and program. Most of the technologies in the device, such as electric circuits and LabVIEW have been covered to a certain extent in our classes, but more was required of us. We needed to learn new software and concepts. This is where lifelong learning became important.

We needed to learn Microsoft Visio for schematic drawings early on in the design process. This program was crucial for writing reports since they involve the use of diagrams and figures. We needed to diagram circuits and physical designs of the device, and Visio was a program that could do both.

This design requires a level of understanding of the LabVIEW software that has not been taught in classes before this point. Our experience with LabVIEW has been spaced between several classes and has been fairly general. We were required to apply what we had already learned about the software while learning brand new techniques and ideas in order to create an original program that is specific to our device.

Our team needed to learn a great deal about electronic circuits for the project. We have had some background in electric circuits, but had never had any experience designing….By building the ECG device early on in the semester we learned the necessary soldering skills that we would need in creating the anesthesia monitor. We needed to learn how to check for leakage current in an electronic device to ensure that no current is emanating from the device through any of its external metal components or through the power cord. This was an important skill to learn since it could have devastating effects to either the patient or the operating room staff if it is not detected.

One very important thing that our team has learned is teamwork and time management. Very quickly we realized that is important to quickly and effectively delegate each person’s role in the project. It is very important to have a sense of diplomacy in order to ensure the project is completed on time. Each team member must be able to communicate well with the rest of the team and do their share of the work. We have all had experience in teamwork before, but never to this extent. Time management was another extremely important lifelong learning experience. College itself is a lesson in time management, and this project furthers our knowledge in how to effectively manage our time.
In general, our team learned about research and design at a level that had previously not been experienced. This portion of the learning process is perhaps the most important. We must interact with our client at Hartford Hospital, and ensure that our design is appropriate for the client’s needs. We needed to learn how to order parts and communicate with vendors, all while staying under budget.

This project as a whole requires learning new skills, and sharpening previously learned skills. From learning a new program to re-learning how to work as part of a team, this project has been a lifelong learning experience.

1.7. References


