PROJECT PROPOSAL

Expert Anesthesiology Monitoring System

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**EXECUTIVE SUMMARY:**

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, 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.

Other anesthesiology models have been considered and the Aspect BIS monitor which displays the EEG will be used as a reference, as determined by the client. The engineering design team discovered another monitoring system, the SNAP II, which may be used for ideas as well. The patents for these devices will be considered and examined in the proposal so as not to infringe on them. The budget has been discussed with the client and outlined to maintain a firm understanding of design limitations. Throughout this proposal a full description of the intended design, methods, and goals will be laid out, which should meet the goals of the client and display an effective plan of engineering. This design should supply a more efficient and precise estimation of the level of consciousness for patient under anesthesia with little to no time delay, creating a much safer environment for patient and anesthesiologist alike.

**INTRODUCTION:**

1.1 **BACKGROUND:**

The client Joseph McIsaac, chief of trauma anesthesiology at Hartford Hospital, is looking to enhance his ability as an anesthesiologist by proposing the development of an anesthesiology monitoring system that will more accurately judge the consciousness of patients. Our client is interested in the education of students and the advancement of his ability to become a better anesthesiologist. This project creates a chance for the client to support students in learning and simultaneously create a safer environment in the operating room for patient and surgeon alike.

As an anesthesiologist judging the level of consciousness of each patient is difficult because of the uniqueness of each case. To aid them they use differential equations and precise calculations of fuzzy logic as described by Joseph McIsaac. He explained the procedure as an educated guess and check that has to be monitored and then reconsidered through the full time that the patient is under anesthesia. The anesthesiologist must also consider each individual patient 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. The doses that are applied take time to affect the patient so as more medicine is added to the patient one must wait till they are sure the “poison” has taken its effects on the consciousness of the patient.
Doctor McIsaac suggested that the BIS monitoring system by GE should be considered as the basis for our project. He supplied the project with a manual and some background information that may help direct the project more efficiently.

1.2 PROJECT PURPOSE:

This project’s main objective is to develop a device that will act as an “Automatic Anesthesia Expert System”. With this device the anesthesiologist should be able to see all of the patient’s relevant information such as specific vital signs and a calculated level of consciousness based on these vital signs. The main function is to aid the anesthesiologist in accurately predicting the patient’s level of consciousness using more than just the EEG signal. This will be accomplished by examining the ECG, volumetric capnography, and blood pressure in addition to the EEG signal.

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 with the 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.

PRIOR WORK DONE BY OTHERS:

1.3.1 PRODUCTS:

Considering that there are previously designed anesthesia monitoring systems on the medical market, there must be significant advances in this new design for anesthesiologists to invest additional funds. The client has pointed out that the BIS monitoring system is available and is the model that is being used as an example. The SNAPP II is another anesthesiology monitoring system that is also on the market that has been researched.

The main model that will be examined and used as a guide is the Aspect Medical Systems BIS VISTA or GE anesthesia machine the BIS monitor. The BIS monitor relies on an Electroencephalogram (EEG) to determine the level of consciousness of a patient 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.
Another model that is available on the market is Everest Biomedical Instruments anesthesia monitoring system called the SNAP II. This device is similar to the BIS monitor in that it mainly focuses on the level of consciousness of the patient relevant to their electroencephalogram wave and supplies a level of consciousness numerical value between 1 and 100. The SNAP II also has alarm limit bars that will show exactly whether the patient is within acceptable range of consciousness or not. There is also an elapsed time clock that shows exactly how long the patient has been under anesthesia. There is also a battery symbol which shows exactly how much longer the device will work before the battery runs out.

![SNAP II](image1)
![BIS-Vista](image2)

**Figure 1: SNAP II (left), designed by Everest Biomedical Instruments and BIS-Vista, designed by Aspect Medical Systems (right).**

### 1.3.2 Patent Search Results:

Thoroughly searching for current United States patents is an essential part of beginning a project design. If there are any similar designs that may be infringed upon, the design team must know about them and make sure to either find their own method or honor the patent. Intellectual property rights are formed by a patent which gives exclusive rights by the state to a patentee for a certain period of time in exchange for the right to regulate public disclosure of certain details of a device, method or composition of matter which is new, inventive, and useful for industrial applications.

The first patent was the Vital signs monitoring system patent number 4,705,048 in November 10, 1987. This patent includes the first sensor unit including a microphone for mounting on the patient’s chest for picking up breath and heart sounds with a filter and automatic gain control circuit. There was also a second sensor unit which positioned a microphone beneath the blood pressure cuff for picking up the korotkoff sounds used to determine blood pressure. There were also earphones for monitoring the selected sounds by the physician on hand.
The next patent is a continuation of the first one with a number of 5,010,890 in April 30, 1991. This patent has one altercation that allows for continuation of the patient. The patent now includes a switch selector which allows the physician to move freely throughout the operating room while still maintaining the portable receiver that allows the physician to hear the monitoring system.

The next patent consists of an anesthesia machine with a head worn display which includes the gas delivery system control and a patient monitor system in full cooperation. This patent is the anesthesia machine with head worn display which was passed on July 9, 2002. The measured values of the sensor can be displayed on the head-worn display device which has stereoscopic capabilities. The monitor includes communication ports for selectively monitoring the sensors of a similar anesthesia machine which can be remotely positioned and the other port can be saved for downloading patient’s medical records from a hospital medical record computer. This entire system is wireless and can facilitate the anesthesiologists movement throughout the operating room.

The fourth patent that was found is closer to the design that will be used to suit the needs of this monitoring system. This monitor patent is an EEG operative and post-operative patient monitoring method approved on May 23, 2000 and was designed mainly to focus on the electroencephalograph (EEG) of the patient involved in the surgery. This patent suggests that by modeling the brain waves, both ongoing and evoked by stimuli, are amplified, digitized and recorded. The brain waves of the patient prior to the surgery are used and compared to the brain waves during the procedure to maintain vigilance over the patient’s consciousness. This method focuses mainly on the relative power in the theta band which indicates blood flow, and prolongations of the latency periods under brain stem stimuli as indicated by the patient’s ability to feel pain.

The last patent that was found to be relevant was the EEG operative and post-operative patient monitoring system and method passed on December 23, 1997. This method focused on the electroencephalograph (EEG) system monitors patients during and after medical operations to make sure that sufficient anesthetics are being used to attain the desired level of anesthesia. This device functions by examining the brain waves of a patient and determining whether or not additional anesthesia is required.

**PROJECT DESCRIPTION**

2.1 **OBJECTIVE**

While considering the already existent anesthesia modeling systems the ability to use an electroencephalograph to determine a level of consciousness is already prevalent in the field of anesthesia. This means that there is a need for more precision using more information to diagnose the level of consciousness more accurately. To come up with a more influential anesthesiology design other vital signs will have to be considered. The most important vital signs have to be considered and applied to judge a level of consciousness. This monitor will
completely transform the ability that anesthesiologists have on determining to what degree a patient really is anesthetized. The monitor is going to make all of the vital signs easily read and will be totally inclusive.

While considering the fact that a more inclusive design is required, the idea that the operating staff has to be able to access the patient without too many monitors cluttering the surgery room puts restrictions on the device. This brings about the point that the monitor needs to be either wireless or centralized to a smaller area on the patient. At minimum the patient will need a brain wave monitoring pad on their forehead, a sensor on the neck for pulse and blood pressure, and another sensor over the mouth to determine tidal volume and pace of breath. These are just the initial vital signs that apply to the level of consciousness of the patient.

All of these measurements are being taken to accomplish the task of relieving the patient of consciousness, supplying amnesia, analgesia, and immobility during surgery. The main goal of this device is to find a perfect method of applying precision calculations using fuzzy logic to determine an individual treatment that depends on the patients prior resistance, acute and chronic disease states, age, weight, gender, exercise tolerance, medication usage, habits such as smoking, and drug and alcohol use. These important factors all have to be assessed but can not be factored in too much because there may be false information given that could ruin the diagnoses of consciousness. This means that these should all be factors, but should not be relied on primarily for any judgment of consciousness.

The idea behind this anesthesia monitoring system is to assist an anesthesiologist in his diagnosis of consciousness with precision. There is no way that this device could be 100 percent accurate at all times for many reasons. The objective is to make the monitor as accurate as possible and to function on its own in order to give the anesthesiologist more confidence in their evaluation of the patient.

2.2 METHODS

This project requires a conglomeration of technology to effectively monitor the patient’s level of consciousness. The key elements in this system are the vital signals and their parameters which they are configured for. The vital signals pertaining to anesthesia are electrocardiogram, electroencephalogram, blood pressure, and volumetric capnography. For each signal there will be a corresponding signal transducer which will be incorporated into the user interface. LabVIEW will be used for the system’s data acquisition and the user interface. The project will be developed in different stages. Stage one will be the development of the individual signal acquisitions. Stage two unifies the signals into a single LabVIEW program. Stage three is the incorporation of the signal parameters which will alarm the anesthesiologist if the patient exceeds the determined range of safe consciousness levels. Stage four, if time permits, will entail developing the system further to a point where it will induce and maintain surgical anesthesia based on each signal and its corresponding parameters.

**Stage One**

Each signal has specific characteristics and they 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 2: Basic elements of the ECG signal and heart anatomy

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.

Producing a distinguishable ECG wave requires filtering of the initial data acquired from the transducer. A general a band-stop filter must be applied at 60Hz because there is significant power line noise creating a voltage spike at this frequency. This noise is universal making the band-stop filter a requirement in all data acquisition. Specifically for the ECG a high-pass filter set at 0.05Hz and a low-pass filter of 40, 100, or 150Hz are used to eliminate any wandering baseline and any high frequency interference.

The blood pressure monitoring device will be an automated non-invasive measuring device. 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.
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 2 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.

Figure 3: A patient’s systolic and diastolic pressures are determined.

Figure 4: An example of how the patient’s blood pressure will be displayed in LabVIEW.
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 brain 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 forms have frequencies between 0.0833Hz and 0.125Hz and are influenced by visual or mental concentration. Beta waves have frequencies between 0.0333Hz and 0.077Hz and commonly appear when seizure medication as been taken. Delta waves are around 0.33Hz and are most apparent in sleeping adults and children. Theta waves are between 0.143Hz and 0.25Hz and are analogous to Delta waves.

Data acquisition amplifiers with gains ranging from one thousand to one hundred thousand are required to obtain reasonable signals. After, the amplification filters will be applied to remove the skin to electrode interference and polarization and depolarization of muscle tissue. These are receptivity signals, referred to as electrogalvanic and electromyographic signals. Their cutoff frequencies are commonly attenuated at 0.5Hz and 35-70Hz.

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.
Stage Two
Once all three signals are established, they must be combined together in a useful way using LabVIEW. Each of the signals contains valuable information about the patient's level of consciousness and must be interpreted by the software. Using while loops in the LabVIEW software, the EEG, ECG, and volumetric capnography data will be combined together into an easy to use system and filtered in order to reduce unwanted noise.

Stage Three
Once the signals are conditioned and transferred into LabVIEW, alarms must be programmed in order to alert the surgeon when any of the signals get outside a desirable range. Both audio and visual alarms will prompt fast action by the anesthesiologist, nurses, or surgeons as a result of any undesirable response by the patient to the anesthetic. This will all be displayed on a LabVIEW front panel that is easy to read and offers straightforward manipulation. A possible design for the resulting LabVIEW front panel is as follows:

![Figure 6: An example of a possible front panel design](image)

This initial version of the front panel clearly displays the vital signals involved in the determination of the level of consciousness, as well as a display of total consciousness. Each vital signal is enclosed by an upper and lower limit to indicate the acceptable range of the signal. The emergency indicator on the right portion of the front panel will flash along with an audible alarm to indicate that one of these signals has gone outside of the predetermined allowable range. The inputs on the left side of the front panel are user defined parameters including age, weight, and gender. The rest of the inputs, such as exercise tolerance and medication usage, are defined...
on a scale of 1 – 100 based on the frequency or extent to which each of these conditions has been met. These initial parameters along with the data from the signals coming from the patient combine to determine the patient’s total consciousness level, which is displayed at the bottom of the screen.

**Stage Four**

Time permitting, the system will be configured to distribute anesthesia to the patient and maintain an induced state automatically based on their vital signs. Since this stage actually uses anesthetic drugs it will require a new set of equipment. Syringes, anesthetics, and potentially test subjects would be needed in order to test the system at this stage.

### 3.0 BUDGET

The budget for this project is limited at this point. National Instruments is backing the project with software and possibly some extra hardware. National Instruments is going to be the primary source for software, and a large portion of the needed hardware. The budget for the equipment that will be used via National Instruments will be assessed by a National Instruments consultant who will be able to help determine the hardware that will coordinate with the LabVIEW software being used.

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<tr>
<th>Pricing for Hardware and Software Components</th>
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<tr>
<td>EEG Sensor</td>
<td>$45-65</td>
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<tr>
<td>Wiring</td>
<td>$5-10</td>
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<tr>
<td>Electrodes</td>
<td>$10-20</td>
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<tr>
<td>Blood Pressure Cuff</td>
<td>$30-60</td>
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<tr>
<td>LCD Touch Screen</td>
<td>$500-2000</td>
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<tr>
<td><strong>Total</strong></td>
<td><strong>$590 – 2155</strong></td>
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*Table 1: Potential Budget*

Joseph McIsaac also has some access to software and hardware that would be applicable to this project such as old BIS interface software. The equipment that he will supply to the engineering design team will be primarily for testing and comparison. The client has a great deal of experience in the medical field and is willing to help find old equipment that will help the engineering portion of the design.

Hartford hospital will also be an ally for the engineering of this design because the client is well known by the organization. Hartford Hospital should be an extremely valuable tool in that they have a great deal of old equipment that must be updated regularly. This means that they most likely have old equipment that they would part ways with to help the endeavors of the engineering design team. With the vast use of anesthesia in Hartford Hospital, there should be a surplus of old monitors that can be salvaged and used to help with the design of the optimal anesthesia monitoring system. The maximum budget will mostly depend upon the amount of equipment that is either salvaged from Hartford hospital or what is provided by Dr. McIsaac.
Assuming all equipment will be purchased the maximum possible budget will be between $500 - $2155.

4.0 CONCLUSION

This anesthesia delivery system is intended to make the job of an anesthesiologist or surgeon much easier in the operating room. Most current consciousness monitoring systems on the market just use data from an electroencephalogram. This system is unique in that it uses not only data from brain activity, but electrocardiography and capnography data as well. The addition of these signals will alert the surgical staff to any respiratory or cardiac trauma due to anesthesia before it would have presented in an EEG. The result is a more accurately defined level of consciousness with minimal human input. Alarms will alert the anesthesiologist to any dramatic change in the patient’s consciousness level so prompt action can be taken. This improvement upon current systems will make the anesthesiologist’s tasks easier and more intuitive.

At this point in time the budget does not have a definite value, and with the addition of an as of yet unconfirmed level of support from Dr. McIssac and Hartford Hospital, approximating a final cost of the project is difficult. Assuming that each part needs to be purchased, the final cost should be in the range of $500 - $2155 for the supplies needed, but some fluctuation will be expected based on the amount of donated materials. Most of the equipment required is either already owned by the university, or will be acquired from Dr. McIssac or Hartford Hospital, so the final cost could potentially be much less than this estimate.

This product will certainly encounter issues in a market that is currently dominated by Aspect Medical Systems. There are many devices on the market that perform a very similar function. In order for this device to gain any sort of marketability it must perform functions that other current products can not. The prospect of a device that, if perfected, could virtually eliminate the need for an anesthesiologist is groundbreaking. However, the fact that a person’s life would be put entirely in the hands of a machine could potentially be unsettling for a patient. For this reason, the alarm systems and eventual delivery system must be accurate and foolproof. If these obstacles can be overcome the resulting product should be one that is an improved version of current anesthesia monitoring systems.
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