Title: INTEGRATED ULTRASOUND IMAGING DEVICE WITH PULSE OXIMETER WAVEFORM DISPLAY FOR APPLICATION OF REGIONAL ANESTHESIA

Abstract: The various embodiments of the present invention provide an integrated ultrasound imaging device with pulse oximeter waveform display for application of regional anesthesia. The device has an ultrasound probe (11) and a Saturation of Hemoglobin with Oxygen as measured by Pulse Oximeter (SpO2) probe (12) connected to a display unit (15) through a beam former (13) and a pulse oximeter (14) respectively. A processor (40) is connected to the ultrasound probe (11), the SpO2 probe (12) and the display unit (15) to receive the output signals from the ultrasound probe (11) and the SpO2 probe (12) to display a real time ultrasound image of the scanned area and the measured SpO2 values on the same display unit (15). It provides a color doppler imaging mode to differentiate between the nerves and blood vessels to avoid puncture the blood vessel.
INTEGRATED ULTRASOUND IMAGING DEVICE WITH PULSE OXIMETER
WAVEFORM DISPLAY FOR APPLICATION OF REGIONAL ANESTHESIA

TECHNICAL FIELD
The present invention generally relates to imaging devices and particularly to ultrasound based imaging device used for the application of regional anesthesia.

BACKGROUND OF THE INVENTION
Anesthesia has traditionally meant the condition of having sensation including the feeling of pain blocked or temporarily taken away. This allows patients to undergo surgery and other procedures without the distress and pain they would otherwise experience. Another definition for anesthesia is a "reversible lack of awareness".

There are several forms of anesthesia. The anesthesia may be a total lack of awareness such as general anesthesia or a lack of awareness of a part of the body like local anesthesia such as spinal anesthesia.

The following forms refer to the states achieved by anesthetics working on the brain:

General anesthesia corresponds to drug induced loss of consciousness during which patients are not aroused, even by painful stimulation. Patients undergoing general anesthesia can often neither maintain their own airway nor breathe on their own. While usually administered with inhalational agents, general anesthesia can be achieved with intravenous agents such as propofol.

The deep sedation/analgesia condition corresponds to the drug induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. In this state, the patients may sometimes be unable to maintain their airway and breathe on their own.
The Moderate sedation/analgesia or conscious sedation condition corresponds to drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. In this state, patients can breathe themselves and need no help in maintaining an airway.

Minimal sedation or anxiolysis condition corresponds to drug induced state during which patients respond normally to verbal commands. Though concentration, memory, and coordination may be impaired, patients need no help in breathing or maintaining an airway.

The level of anesthesia achieved ranges on a continuum of depth of consciousness from minimal sedation to general anesthesia. The depth of consciousness of a patient may change from one minute to the next.

In modern anesthesia, a wide variety of medical equipment is desirable depending on the necessity for portable field use, surgical operations or intensive care support. Anesthesia practitioners must possess a comprehensive and intricate knowledge of the production and use of various medical gases, solutions, anesthesia agents and vapors, medical breathing circuits and the variety of anesthesia machines (including vaporizers, ventilators and pressure gauges) and their corresponding safety features, hazards and limitations of each piece of equipment, for the safe, clinical competence and practical application for day to day practice.

The patients being treated under general anesthetics must be monitored continuously to ensure the patient's safety. In general, the anesthetists have set minimum monitoring guidelines for General and Regional Anesthesia.

For minor surgery, this generally includes monitoring of heart rate (via ECG or pulse oximetry), oxygen saturation level (via pulse oximetry) blood pressure in non invasive manner, inhaled and exhaled gases (for oxygen, carbon dioxide, nitrous oxide and volatile agents).
For moderate to major surgery, monitoring may also include temperature, urine output, invasive blood pressure measurements (arterial blood pressure, central venous pressure), pulmonary artery pressure and pulmonary artery occlusion pressure, cerebral activity (via EEG analysis), neuromuscular function (via peripheral nerve stimulation monitoring) and cardiac output. In addition, the operating room's environment must be monitored for temperature and humidity and for buildup of exhaled inhalational anesthetics which might impair the health of operating room personnel.

Regional anesthesia is anesthesia affecting only a particular portion of the body. It is administered by injecting the anesthetic drug near the nerve supplying that particular portion. The usual method followed for giving regional anesthesia is to locate the nerve by using the knowledge of anatomy and then the anesthesia drug will be given. Multiple trial-and-error attempts to locate the target nerve can lead to operator frustration, unwarranted patient pain, and time delay in the operating room, especially in patients with difficult anatomical landmarks.

Another method is the Peripheral Nerve Stimulation (PNS) guidance which is useful only when a motor response is elicited. The currently available method helps in locating the nerve indirectly. The indirect evidence of nerve location and the evidence of proper needle placement (i.e. motor response) disappear after injection of 1-2 ml of local anesthetic itself. The motor response achieved at < 0.5 mA does not guarantee a successful or complete block. This method does not prevent intravascular, intraneural or pleural puncture.

Currently the regional anesthesia is provided by injecting the anesthesia dose by the anesthetist based on his/her anatomical knowledge. The dosage is validated by seeing the level of consciousness of the patient by mechanical or electrical stimulation. But the dosage can be more regulated by actually viewing the location of the injected dose with respect to the nerve being desensitized. This can be achieved by using an ultrasound scanner as an
imaging device during the administration of the anesthetic agent. This would involve the
anesthetist using his dominant hand for the injection while probing with his other hand. The
entire procedure may last around 5 minutes. AU through the process it is required to monitor
the hemodynamics of the patient. This is routinely done by using a separate
equipment/monitor.

Thus the anesthetist needs to look at two displays during the entire procedure. As well as two
equipments have to be present for the procedure. A general-purpose ultrasound imaging
scanner usually a cart based one is used for this purpose. The currently available general-
purpose scanner is redundant for this application, as many of the options available in the
scanner would not be used at all. It would be user friendly if a scanner having minimum
number of keys is developed particularly for this application based on the options required
for this application. The software would also be trimmed down to suit this application to
make it user friendly.

Moreover the scanner is typically owned by the clinics/hospitals and the anesthetist uses it
for the duration of this application. A group of the anesthetists are freelance professional
moving from one hospital to the other. Some of them carry a pulse oximeter
equipment/monitor to make them partly independent and distinguish themselves from other
anesthetists.

Hence there is a need to develop an integrated device or composite device or multifunction
device built in with Ultrasound scanner and pulse oximeter exclusively for the application of
regional anesthesia. Also there is a need to develop a portable anesthesia monitoring and
controlling device for this application.

OBJECTS OF THE INVENTION

The primary object of the present invention is to develop an integrated anesthesia monitoring
and imaging device built in with an ultrasound scanner and pulse oximeter having a single
common display to exhibit the oximeter values and waveform along with the real time ultrasound scan image.

Another object of the present invention is to develop an integrated anesthesia monitoring and imaging device built in with an ultrasound scanner and pulse oximeter to detect a specific nerve for injecting anesthesia at desired location effectively and efficiently.

Yet another object of the present invention is to develop an integrated anesthesia monitoring and imaging device built in with an ultrasound scanner and pulse oximeter to provide a real time imaging guidance during the needle advancement and the real time oximeter waveform.

Yet another object of the present invention is to develop an integrated anesthesia monitoring and imaging device built in with an ultrasound scanner and pulse oximeter to monitor the condition of the patient administered with anesthesia easily, efficiently and effectively.

Yet another object of the present invention is to develop an integrated anesthesia monitoring and imaging device built in with an ultrasound scanner and pulse oximeter to provide a color Doppler image to differentiate between the nerves and the blood vessels to prevent the puncturing of the blood vessel by the needle during the needle advancement process.

Yet another object of the present invention is to develop an integrated anesthesia monitoring and imaging device built in with an ultrasound scanner and pulse oximeter to provide a real time image to reveal the nerve location and the surrounding vascular, muscular, bony and visceral structures.

Yet another object of the present invention is to develop an integrated anesthesia monitoring and imaging device built in with an ultrasound scanner and pulse oximeter to provide a real time imaging guidance during the needle advancement to enable necessary needle movement and proper adjustment of the needle in its direction and depth.
Yet another object of the present invention is to develop an integrated anesthesia monitoring and imaging device built in with an ultrasound scanner and pulse oximeter to provide a real time imaging to exhibit the local anesthesia spread pattern during the injection of anesthesia agent.

Yet another object of the present invention is to develop an integrated anesthesia monitoring and imaging device built in with a ultrasound scanner and pulse oximeter to provide a real time imaging to control the administration of the anesthesia agent to improve the quality of the sensory block, the onset time and the success rate compared to nerve stimulation techniques.

Yet another object of the present invention is to develop an integrated anesthesia monitoring and imaging device built in with an ultrasound scanner and pulse oximeter to provide a real time imaging of needle advancement to reduce the number of needle attempts for nerve localization thereby reducing patient discomfort and the risk of injury to nearby structures.

Yet another object of the present invention is to develop an integrated anesthesia monitoring and imaging device built in with an ultrasound scanner and pulse oximeter thereby eliminating the need for using the patient monitoring system and the ultrasound scanner separately.

Yet another object of the present invention is to develop an integrated anesthesia monitoring and imaging device built in with an ultrasound scanner and pulse oximeter to display the ultrasound image as well as the oximeter waveform, values and alarm conditions in a single display thereby eliminating the need for the anesthetist to look at different screens during the entire process and avoiding the need for using two different equipment.

Yet another object of the present invention is to develop an integrated anesthesia monitoring and imaging device built in with an ultrasound scanner and pulse oximeter to communicate
the alarm related conditions pertaining to the oximeter visually and audibly using a single equipment.

Yet another object of the present invention is to develop an integrated anesthesia monitoring and imaging device built in with an ultrasound scanner and pulse oximeter thereby reducing the size of the device to improve the portability of the device to enable the anesthetist to carry the device from one place to another easily.

These and other objects and advantages of the present invention will become readily apparent from the following detailed description taken in conjunction with the accompanying drawings.

**SUMMARY OF THE INVENTION**

The above-mentioned shortcomings, disadvantages and problems are addressed herein and will be understood by reading and studying the following specification.

The various embodiments of the present invention provide an integrated anesthesia monitoring and controlling system built in with ultrasound scanner and pulse oximeter to display the real time imaging of the location in which the anesthesia agent is injected, along with the measured saturated oxygen level, pulse oximeter wave form, and alarm conditions in the same display screen. According to one embodiment of the present invention, an integrated ultrasound-imaging device with pulse oximeter waveform display has an ultrasound probe to scan the area to be desensitized to provide a real time ultrasound image of the area to detect a nerve for administering an anesthetic agent. Saturation of Hemoglobin with Oxygen as measured by Pulse Oximetry (SpO2) probe is provided to measure the saturated oxygen level in hemoglobin in the scanned area in real time. A processor is connected to the ultrasound probe and the SpO2 probe. A display unit is connected to the processor. The processor receives the output signals from the ultrasound probe and the SpO2
probe to display a real time ultrasound image of the scanned area and the measured SpO2 values and waveform on the same display unit.

According to one embodiment of the invention, the system has an ultrasound scanner to capture and display the real time image of the nerve location and the surrounding vascular, muscular, bony and visceral structures to provide real time imaging guidance during the needle advancement for manually controlling the needle movement along a proper direction and the depth level to prevent unnecessary needle movement thereby reducing the risk of nerve injury. The ultrasound image indicates the local anesthesia spread pattern during injection of anesthesia solution to enable the anesthetist to control the dosage. A color Doppler imaging mode is used for the better differentiation of the nerves from the blood vessels to prevent the puncturing of the blood vessel by the needle. A pulse oximeter is provided in the system to measure the saturated oxygen level in the blood. The pulse oximeter values are used as reference to monitor the functional oxygen saturation in the body of the patient. A single display screen is provided to project the scanned real time image of the nerves, the measured saturated oxygen values, pulse oximeter waveform, alarm conditions. The system may also be provided with other hemodynamic parameter modules like ECG, EtCO2 in addition to the pulse oximeter module.

According to one embodiment of the present invention, the integrated anesthesia monitoring and controlling system built in with ultrasound scanner and pulse oximeter has a display screen to project the scanned real time image of the nerves, the measured saturated oxygen values, pulse oximeter waveform alarm conditions. The display screen is provided with windows to display the general information regarding the patient, the thumbnail image, the ultrasound image, ultrasound parameters along with the values, message box, the measured SpO2 values along with the alarm limits, pulse rate values along with alarm limits, the SpO2 waveform and the soft keys menu. The system may also be provided with other hemodynamic parameter modules like ECG, EtCO2 in addition to the pulse oximeter module.
According to one embodiment of the present invention, a regional anesthesia monitoring system is provided to identify a nerve location, to control the needle movement to inject anesthesia at a desired location and to observe the flow of the anesthetic solution to control the quantity of anesthesia to be injected. According to one embodiment of the present invention, the system is provided with an ultrasound probe to scan the area to be desensitized to provide real time imaging guidance during the anesthesia administration process. A processor is connected to the ultrasound probe through a beam former to display the real time image of the scanned area to identify a nerve for injecting an anesthetic agent on a display.

The processor activates a display unit to display the spread of the anesthetic solution in the scanned area to provide a real time imaging guidance to control the movement of the needle and to control the amount of anesthetic solution injected, when an anesthetic agent is injected into the detected nerve. An interface module is connected to the processor to provide the user inputs. The interface module includes plurality of tactile keys, atleast one multifunctional knob, a track ball with set and skip keys and an on/off key. The system is powered either by the mains or by the battery supply.

According to another embodiment of the invention, a regional anesthesia monitoring process is provided. The area to be desensitized is scanned with an ultrasound scanner to obtain a real time image of the desired area to identify a nerve for injecting the anesthetic solution. A needle is inserted near the identified nerve to inject the anesthetic solution and the movement of the needle is adjusted along the direction and depth using guidance of the real time ultrasound image. The needle is removed after confirming the flow of the anesthetic solution and the saturated oxygen level obtained from the pulse oximeter provided in the integrated system is useful for monitoring the condition of the patient before during and after the entire process.

Thus the various embodiments of the invention provide an integrated system built in with ultrasound image scanner and pulse oximeter to display the real time image along with the
measured oximeter values and waveform to reveal the nerve location and the surrounding vascular, muscular, bony, and visceral structures. The system provides real-time imaging guidance during the needle advancement to enable the anesthetist to control the needle movement direction and depth of movement. The system images the local anesthesia spread pattern during injection to improve the quality of sensory block and the onset time thereby reducing the number of needle attempts for nerve localization and the risk of nerve injury. The system helps to differentiate extra-vascular injection from unintentional intravascular injection and extra-neural injection from unintentional intraneural injection.

10 **BRIEF DESCRIPTION OF THE DRAWINGS**

The other objects, features and advantages will occur to those skilled in the art from the following description of the preferred embodiment and the accompanying drawings in which:

FIG. 1 shows a block diagram of the integrated ultrasound scanner with built-in pulse oximeter according to one embodiment of the present invention.

FIG. 2 shows a display screen of the integrated ultrasound scanner with built-in pulse oximeter according to one embodiment of the present invention.

FIG. 3 shows a look-up table provided with the functions assigned to multifunctional keys arranged in the display window of the integrated ultrasound scanner with built-in pulse oximeter according to one embodiment of the present invention.

FIG. 4 shows a detailed functional block diagram of the integrated ultrasound scanner with built-in pulse oximeter according to one embodiment of the present invention.

FIG. 5 illustrates a flow chart explaining the regional anesthesia process performed using the integrated ultrasound scanner with built-in pulse oximeter according to one embodiment of the invention.
Although specific features of the present invention are shown in some drawings and not in others. This is done for convenience only as each feature may be combined with any or all of the other features in accordance with the present invention.

5 DETAILED DESCRIPTION OF THE INVENTION

In the following detailed description, reference is made to the accompanying drawings that form a part hereof, and in which the specific embodiments that may be practiced is shown by way of illustration. These embodiments are described in sufficient detail to enable those skilled in the art to practice the embodiments and it is to be understood that the logical, mechanical and other changes may be made without departing from the scope of the embodiments. The following detailed description is therefore not to be taken in a limiting sense.

The various embodiments of the present invention provide an integrated equipment built-in with ultrasound scanner and pulse oximeter to display the real time imaging of the location in which the anesthesia solution is injected, along with the measured saturated oxygen values, pulse oximeter waveform, and alarm conditions in the same display screen.

According to one embodiment of the present invention, an integrated ultrasound-imaging device with pulse oximeter waveform display has an ultrasound probe to scan the area to be desensitized to provide a real time ultrasound image of the area to visualize a nerve for administering an anesthetic agent to reduce the risk of nerve injury. Saturation of Hemoglobin with Oxygen as measured by Pulse Oximetry (SpO2) probe is provided to measure the saturated oxygen level in hemoglobin at that time. The ultrasound probe is connected to a processor through a beamformer. The SpO2 probe is connected to the processor through a pulse oximeter processing module. The processor is connected to the display unit.
The processor receives the output signals from the ultrasound probe and the SpO2 probe to display a real time ultrasound image of the scanned area and the measured SpO2 values on the same display unit. The processor is provided with an application which is executed to display both the real time ultrasound image and the measured SPO2 values on the same display unit. The system is provided with a color Doppler imaging mode for the better differentiation of the nerves and the blood vessels in the displayed real time image of the area scanned by the ultrasound probe.

According to one embodiment of the present invention, the system includes an ultrasound scanner module to capture and display the real time image of the nerve location and the surrounding vascular, muscular, bony and visceral structures to provide real time imaging guidance during the needle advancement to control the needle movement along a proper direction and the depth level to prevent unnecessary needle movement thereby reducing the risk to nearby structures. The ultrasound image indicates the local anesthesia spread pattern during injection of anesthesia solution agent to enable the anesthetist to control the dosage. A color Doppler imaging mode is used to differentiate the nerves from the blood vessels to prevent the puncturing of the blood vessel by the needle. The ultrasound scanner module has an ultrasound probe to scan the desired nerve area with ultrasound energy waves during the injection of anesthesia solution. The output of the probe is fed to a beam former and processed using a processor to project a real time image of the scanned area on a display monitor.

According to one embodiment of the present invention, a regional anesthesia monitoring system is provided to identify a nerve location, to control the needle movement to inject anesthesia at a desired location and to observe the flow of the anesthetic solution to control the quantity of anesthesia to be injected. According to one embodiment of the present invention, the system is provided with an ultrasound probe to scan the area to be desensitized to provide real time imaging guidance during the anesthesia administration process. A
processor is connected to the ultrasound probe through a beam former to display the real time image of the scanned area to identify a nerve for injecting an anesthetic agent.

The processor displays the spread of the anesthetic solution in the scanned area to provide a real time imaging guidance to control the movement of the needle and to control the amount of anesthetic solution injected, when an anesthetic agent is injected near the detected nerve. An interface module is connected to the processor to provide the user inputs. The interface module includes plurality of tactile keys, at least one multifunctional knob, a track ball with set and skip keys and an on/off key. The system is powered either by the mains or by the battery supply.

According to another embodiment of the invention, a regional anesthesia monitoring process is provided. The area to be desensitized is scanned with an ultrasound scanner to obtain a real time image of the desired area to identify a nerve for injecting the anesthetic solution. A needle is inserted near the identified nerve to inject the anesthetic solution and the movement of the needle is adjusted along the direction and depth. The flow of the anesthetic solution is observed to control the amount of the anesthetic solution injected in the desired area. The needle is removed after confirming the flow of the anesthetic solution.

FIG. 1 shows a block diagram of the integrated ultrasound scanner with built in pulse oximeter according to one embodiment of the present invention. As shown in FIG. 1, the ultrasound scanner and the pulse oximeter is integrated in a single unit to display the real-time imaging of the location in which the anesthesia solution is injected. The ultrasound scanner module includes an ultrasound probe to scan the desired nerve area with ultrasound energy waves during the injection of anesthesia solution. The output of the probe is fed to a beam former to project a real time image of the scanned area on a display monitor. A pulse oximeter is provided in the system to measure the saturated oxygen level in the blood. The pulse oximeter includes an SPO2 probe to measure the saturated oxygen level in the blood. The pulse oximeter values are used as reference to monitor the
functional oxygen saturation in the body of the patient. The ultrasound scanner and the pulse oximeter are integrated to display the real-time image on the single display screen 15.

FIG. 2 shows the display screen 15 of the integrated ultrasound scanner with built in pulse oximeter according to one embodiment of the present invention. A single display screen 15 is provided to project the scanned real-time image of the nerves, the measured pulse oximeter values, pulse oximeter waveform, alarm conditions. The display screen 15 is provided with windows to display the general information regarding the patient 21, the thumbnail images 22, the ultrasound images 23, ultrasound parameters along with the values 24, message box 25, the measured SpO2 waveform 26, pulse rate values along with alarm limits 27, the SpO2 values along with alarm limits 28 and the soft keys menu 29. The system may also be provided with other hemodynamic parameter modules like ECG, EtCO2 in addition to the pulse oximeter module.

The general information window 21 on the display screen 15 shows the details of the patient such as name of the patient, ID of the patient, age of the patient and gender of the patient. In addition to the details of the patient, this window 21 also provides information about the selected preset values, hospital name, date and time etc.

The message box 25 window on the display screen 15 provides the status of the operation that is currently done. For example, when the user presses save cine by using the functional key, a cine state message such as "saving cine" is displayed on the message box.

The display unit 15 also includes a window 24 to display the ultrasound parameters along with their values. Depending on the type of the imaging mode selected such as brightness mode (B-mode), color mode (C-mode), the parameters such as frequency, dynamic range, gain, power, frame filter, edge enhancement, Pulse Repetition Frequency (PRP), Wall filter, persistence along with their current values are displayed in this window area 24.
The display unit 15 further includes a soft keys menu 29 in which multifunctional keys are provided. Soft key menu is contextual and hence very easy to operate. The multifunctional keys on the menu are assigned with different functions depending on the imaging mode selected. The functions assigned to each soft key under different imaging mode are listed below.

FIG.3 shows a look up table provided with the functions assigned to multifunctional keys arranged in the display unit of the integrated ultrasound scanner with built in pulse oximeter according to one embodiment of the present invention. The multifunctional keys are provided in the soft key menu window in the display unit. This makes the system easy to operate. The multifunctional keys on the menu are assigned with different functions as shown in FIG.3 depending on the imaging mode selected.

FIG.4 shows a detailed functional block diagram of the integrated ultrasound scanner with built in pulse oximeter according to one embodiment of the present invention. With respect to FIG. 4, the ultrasound scanner and pulse oximeter is integrated in a single unit to display the real time imaging of the location in which the anesthesia agent is injected. It also displays the measured saturated oxygen values, pulse oximeter waveform and alarm conditions in the same display screen 15.

The ultrasound scanner includes an ultrasound probe 11 to be used for scanning a patient to be anesthetized. The ultrasound probe 11 scans the desired nerve area with ultrasound energy waves during the injection of anesthesia solution. The ultrasound probe 11 is connected to a motherboard processor 40 through a beamformer 13 to project a real time image of the scanned area on a thin-film transistor (TFT) display 15. The ultrasound probe 11 captures and displays the real time image of the nerve location and the surrounding vascular, muscular, bony and visceral structures to provide real time imaging guidance during the needle advancement to control the needle movement along a proper direction and depth. The ultrasound image indicates the local anesthesia spread pattern during injection of anesthesia.
solution to enable the anesthetist to control the dosage. A color Doppler imaging mode is used to differentiate the nerves from the blood vessels to prevent the puncturing of the blood vessel by the needle.

A SpO2 probe 12 is connected to the motherboard processor and to a SpO2 waveform and audio amplifier 41 through a SpO2 module 14. The SpO2 probe 12 measure the saturated oxygen level in the blood. The pulse oximeter values are used as reference to monitor the functional oxygen saturation in the body of the patient. The output of the SpO2 module 14 is fed to the SpO2 waveform and audio amplifier 41 and to the motherboard processor 40. The audio signals corresponding to the measured SpO2 values are output through the speaker 42. The TFT display unit 15 projects measured pulse oximeter waveforms. The system may also be provided with other hemodynamic parameter modules like ECG, EtCo2 in addition to the pulse oximeter module.

The ultrasound probe 11 and the SpO2 probe 12 are connected to the TFT display unit 15 through the motherboard processor 40. The motherboard processor 40 receives the output signals from the ultrasound probe 11 and the SpO2 probe 12 to display the real time ultrasound image of the scanned area and the measured SpO2 values on the common TFT display unit 15. The TFT display unit 15 projects the scanned real time image of the nerves, measured saturated oxygen values, pulse oximeter waveform and alarm conditions. The multifunctional keys are provided in the soft key menu window of the TFT display unit 15 to enable the user to input data easily. The multifunctional keys on the menu are assigned with different functions.

The switched mode power supply unit (SMPS) 43 provides power supply to the motherboard processor 40, beam former 13 and audio amplifier 41. The SMPS unit 43 regulates the input voltage and dissipates the required output voltage. The input to the SMPS unit 43 is supplied by mains supply system 46. The main supply system 46 provided with fuses and switches is connected to an equipotential ground 47. A battery 44 is also connected to the SMPS unit 43
to provide a battery back up to the device so that the physicians can use the device even during power failure and emergency conditions. A battery charger 45 is connected to the battery 44 to charge the battery 44 when the device is powered through the mains. A solid state drive (SSD) 48 is interfaced with the motherboard processor to store the operating system, application software, patient related data etc.

An inverter 49 is connected between the mother board processor and the TFT display device to provide power to the backlight of the TFT display unit 15. A video adapter 50 is integrated with the motherboard processor 40. It allows the TFT display unit 15 to display the images from the computer. It provides video output in a format compatible to that of video graphics printer/ other peripheral devices.

A multifunction keyboard 52 is connected to a keyboard controller 51 which is interfaced with the motherboard processor 40. The controller on the motherboard interfaces with a controller inside the keyboard using a serial communication to receive the data corresponding to the keys pressed in the keyboard 52. An alphanumeric key board 29 is also connected to the motherboard processor 40 to enable the user to input data to the patient monitoring device.

FIG.5 illustrates a flow chart explaining the regional anesthesia monitoring process in a regional anesthesia monitoring system according to one embodiment of the invention. With respect to FIG.5, the regional anesthesia monitoring system continuously scans the area to be anesthetized using an ultrasound scanner (61). The monitoring system is provided with an ultrasound scanner to image the desired area to locate and identify the nerve for injecting anesthesia solution (62). A needle is inserted near the identified nerve and the movement of the needle is controlled along the direction and the depth based on the displayed real time image so that the tip of the needle is in the desired location (63). Then an anesthesia solution is injected through the needle into the desired location (64). The spread pattern of the anesthetic solution is observed on the real time image near the nerve (65). The amount of the
anesthetic solution injected in the desired area is controlled based on the displayed spread pattern and the needle is removed after confirming the anesthetic condition in the desired area (66).

Thus the various embodiments of the invention provide an integrated system built in with ultrasound image scanner and pulse oximeter to display the real time image along with the measured oximeter values and waveform to reveal the nerve location and the surrounding vascular, muscular, bony, and visceral structures. The system provides real-time imaging guidance during the needle advancement to control the needle movement direction and the depth of movement. The system images the local anesthesia spread pattern during the injection of anesthetic agent to improve the quality of the sensory block and the onset time thereby reducing the number of needle attempts for nerve localization and the risk of nerve injury. The system helps to differentiate extra-vascular injection from unintentional intravascular injection and extra-neural injection from the unintentional intraneural injection.

ADVANTAGES OF THE INVENTION
The various embodiments of the invention provide an integrated system built in with ultrasound image scanner and pulse oximeter to display the real time image along with the measured oximeter values and waveform to reveal the nerve location and the surrounding vascular, muscular, bony, and visceral structures. The system provides real-time imaging guidance during the needle advancement to control the needle movement direction and the depth of movement. The system images the local anesthesia spread pattern during the injection of anesthetic agent to improve the quality of sensory block and the onset time thereby reducing the number of needle attempts for nerve localization and the risk of nerve injury. The system helps to differentiate an extra-vascular injection from the unintentional intravascular injection and an extra-neural injection from unintentional intraneural injection. The system uses color Doppler imaging mode to differentiate between the nerves and the blood vessels so that the needle does not puncture the blood vessel. The system displays the ultrasound image, the oximeter waveform along with values and alarms pertaining to
oximeter values on a single display screen thereby eliminating the need for using the patient monitoring system and ultrasound scanner separately. The system eliminates the need for the anesthetist to look at two displays during the entire procedure to regulate the dosage of anesthesia solution and to probe the area to be desensitized. The system provides both the visual and audio alarms to communicate the alarm conditions related to oximeter. The system is compact and portable thereby enabling the freelance anesthetists to carry the system easily or they can move the equipment easily from one OT to another in a big hospital.

Although the invention is described with various specific embodiments, it will be obvious for a person skilled in the art to practice the invention with modifications. However, all such modifications are deemed to be within the scope of the claims. For example it is possible to integrate other critical patient monitoring parameters like ECG, EtC02 on similar lines.

It is also to be understood that the following claims are intended to cover all of the generic and specific features of the present invention described herein and all the statements of the scope of the invention which as a matter of language might be said to fall there between.
CLAIMS

1. An integrated ultrasound imaging device with pulse oximeter waveform display for regional anesthesia comprising:
   An ultrasound probe;
   A Saturation of Hemoglobin with Oxygen as measured by Pulse Oximetry (SpO₂) probe;
   A processor connected to the ultrasound probe and the SpO₂ probe; and
   A display unit connected to the processor.

2. The device according to claim 1, wherein the processor receives the output signals from the ultrasound probe and the SpO₂ probe to display a real time ultrasound image of the scanned area and the measured SpO₂ values and waveform on the same display unit.

3. The device according to claim 1, further comprising a beam former connected to the ultrasound probe to provide real time image of the area scanned by the ultrasound probe on the display unit.

4. The device according to claim 1, wherein the ultrasound probe scans an area to be desensitized to provide a real time ultrasound image of the area to visualize a nerve for administering an anesthetic agent.

5. The device according to claim 1, wherein the SpO₂ probe measures the saturated oxygen level in hemoglobin in the body during the scanning process.

6. The device according to claim 1, further comprising a pulse oximeter connected to the SpO₂ probe to exhibit the measured SpO₂ values on the display unit.
7. The device according to claim 1, wherein the processor is provided with an application which is executed to display both the real time ultrasound image and the measured SpO₂ values on the same display unit.

8. The device according to claim 1, wherein the display unit is provided with a color Doppler imaging mode to differentiate the nerves and the blood vessels in the displayed real time image of the area scanned by the ultrasound probe.

9. A regional anesthesia monitoring system comprising:
   - an ultrasound probe;
   - a beam former connected to ultrasound probe;
   - a processor connected to the beam former;
   - an interface module connected to the processor; and
   - a display unit connected to the processor.

10. The system according to claim 9, wherein the processor activates the display unit to display the ultrasound image of an area to be monitored to detect a nerve for inserting a needle to inject an anesthetic agent.

11. The system according to claim 9, wherein the processor activates the display unit to display the spread of the anesthetic solution through the detected nerve to provide a real time imaging guidance to control the movement of the needle, when an anesthetic agent is injected into the detected nerve.

12. The system according to claim 9, wherein the ultrasound probe scans an area to be monitored to display the real time image of the area to be monitored to identify a nerve for injecting an anesthetic agent.
13. The system according to claim 9, wherein the interface module includes plurality of tactile keys, at least one multifunctional knob, a track ball with set and skip keys and an on/off key.

14. The system according to claim 9 further comprising battery to supply power to the ultrasound probe, the beam former, the processor, the display and the interface console.

15. The system according to claim 9 further comprising a mains power supply to supply power to the units in the system.
FIG. 1
FIG. 2
<table>
<thead>
<tr>
<th>State</th>
<th>F1</th>
<th>F2</th>
<th>F3</th>
<th>F4</th>
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FIG. 3
FIG. 5

61 Continuously scan the area using ultrasound scanner

62 Locate and identify nerve

63 Insert needle and advance needle tip to desired location

64 Inject the anesthetic solution

65 Observe the spread pattern of anesthetic solution

66 Remove the needle
## INTERNATIONAL SEARCH REPORT

### A. CLASSIFICATION OF SUBJECT MATTER

**INV.** A61B5/00 A61B8/08

According to International Patent Classification (IPC) or to both national classification and IPC

### B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

### C. DOCUMENTS CONSIDERED TO BE RELEVANT

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Further documents are listed in the continuation of Box C

See patent family annex

Special categories of cited documents

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
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Date of the actual completion of the international search

1 February 2010

Date of mailing of the international search report

09/02/2010

Name and mailing address of the ISA/

European Patent Office, P B 5818 Patentlaan 2 NL - 2280 HV Rijswijk

Tel (+31-70) 340-2040,

Fax (+31-70) 340-3016

Authorized officer

Messmer, Melitta
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