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(54) **SYSTEM, METHOD, AND COMPUTER ALGORITHM FOR MEASURING, DISPLAYING, AND ACCURATELY DETECTING CHANGES IN ELECTROPHYSIOLOGICAL EVOKED POTENTIALS**

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(52) **U.S. Cl.**

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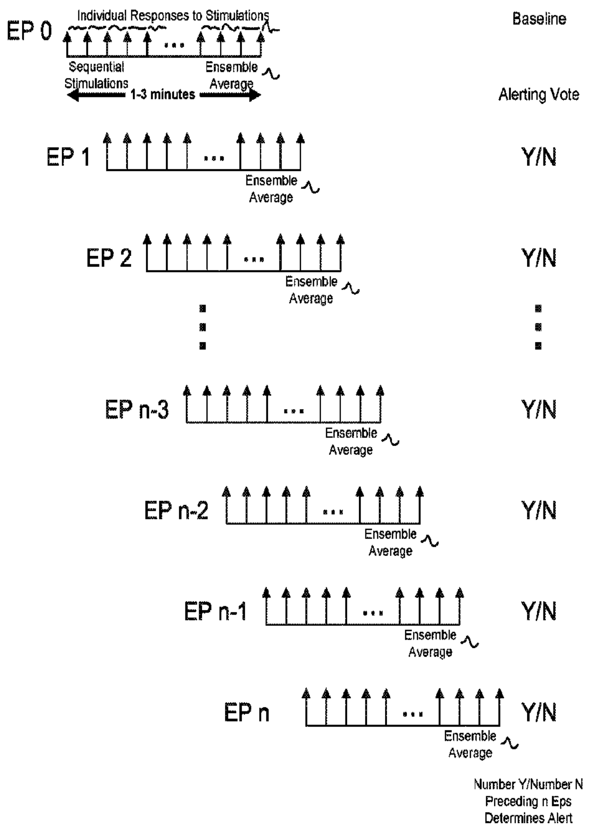
(57) **ABSTRACT**

An automated evoked potential analysis apparatus for improved monitoring, detecting and identifying changes to a patient's physiological system is described. The apparatus includes an input device for obtaining electrical potential data from the patient's physiological system after application of stimulation to a patient's nerve and a computing system for receiving and analyzing the electrical potential data. The computing system includes a processing circuit configured to: generate a plurality of evoked potential waveforms (EPs) based on the electrical potential data, measure changes or trends in the generated EPs utilizing a sliding window of analysis, display incremental changes in waveforms between full subsets of EPs, and determine an alert vote for each subset, representative of changes to the physiological system generating the EPs.

Sliding Window EP Acquisition and Display



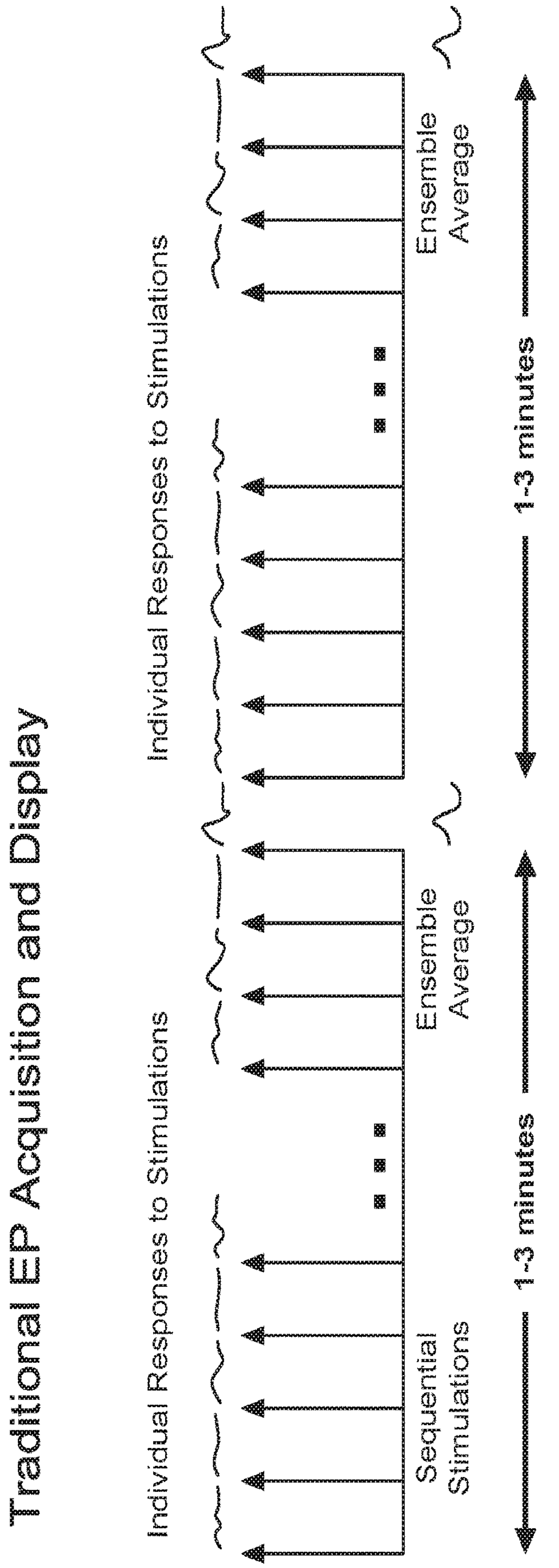

Traditional EP Acquisition and Display
Individual Responses to Stimulations
Sequential Stimulations
Ensemble Average
1-3 minutes
Individual Responses to Stimulations
Ensemble Average
1-3 minutes

FIG. 1

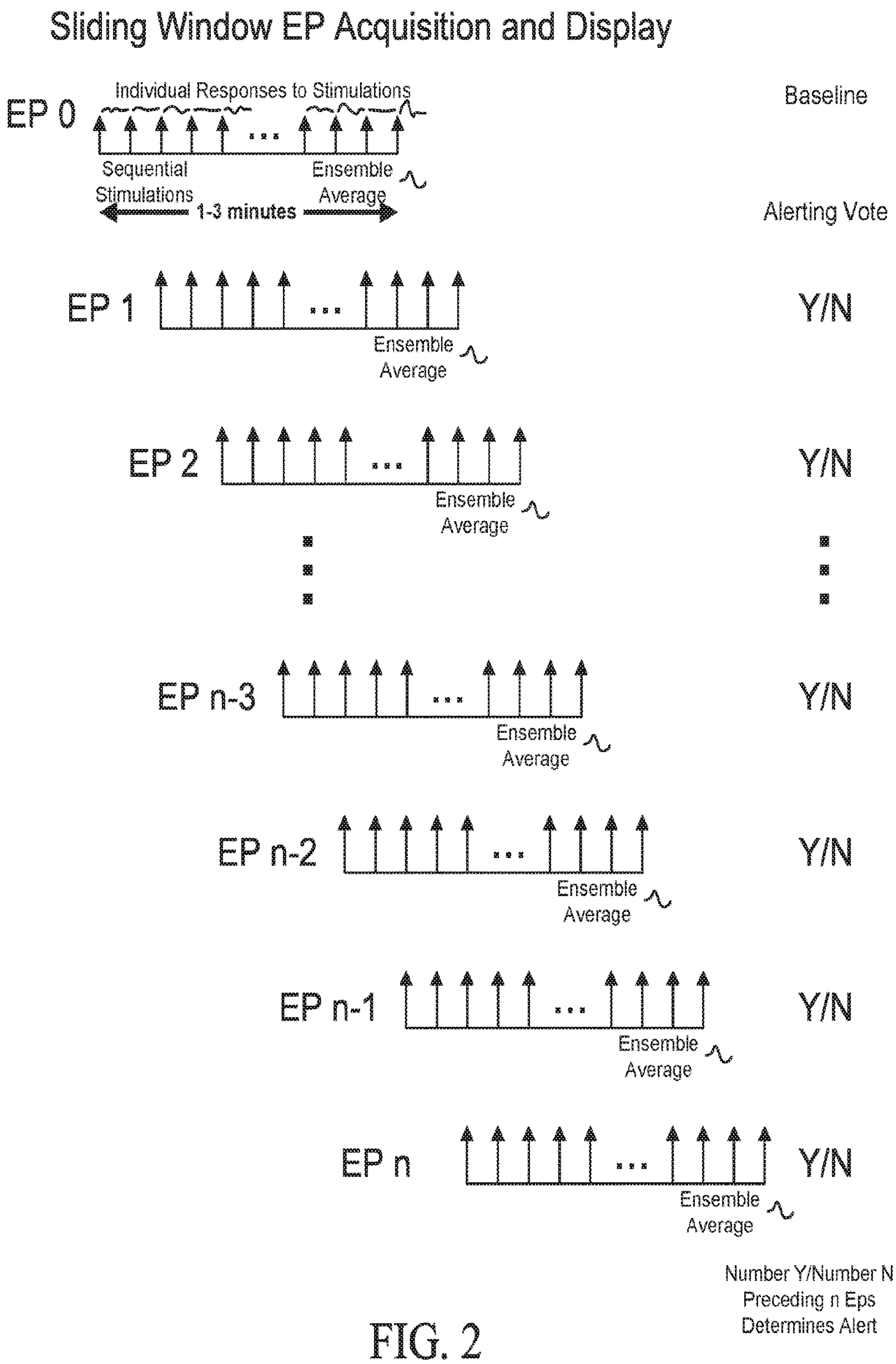

Sliding Window EP Acquisition and Display
EP 0
Individual Responses to Stimulations
Baseline
Sequential Stimulations
Ensemble Average
1-3 minutes
Alerting Vote
EP 1
Ensemble Average
Y/N
EP 2
Ensemble Average
Y/N
EP n-3
Ensemble Average
Y/N
EP n-2
Ensemble Average
Y/N
EP n-1
Ensemble Average
Y/N
EP n
Ensemble Average
Y/N
Number Y/Number N Preceding n Eps Determines Alert

FIG. 2

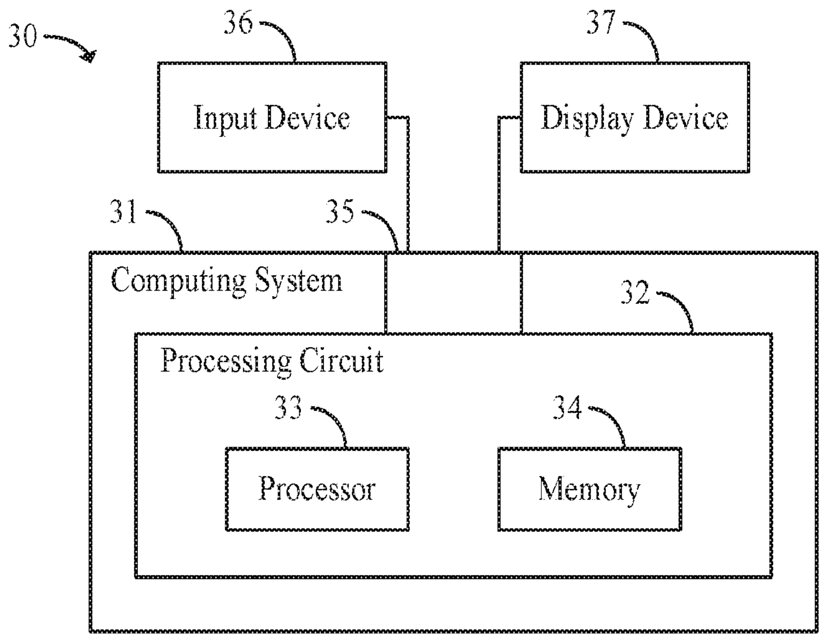

30
36
37
Input Device
Display Device
31
35
Computing System
32
Processing Circuit
33
34
Processor
Memory

FIG. 3

# SYSTEM, METHOD, AND COMPUTER ALGORITHM FOR MEASURING, DISPLAYING, AND ACCURATELY DETECTING CHANGES IN ELECTROPHYSIOLOGICAL EVOKED POTENTIALS

## RELATED APPLICATIONS

**[0001]** This application claims priority from Provisional Application U.S. Application 62/156,874, filed May 4, 2015, entitled "SYSTEM, METHOD, AND COMPUTER ALGORITHM FOR MEASURING, DISPLAYING, AND ACCURATELY DETECTING CHANGES IN ELECTROPHYSIOLOGICAL EVOKED POTENTIALS" incorporated herein by reference in its entirety. This application is also related to U.S. patent application Ser. No. 13/874,867 (published as U.S. Patent Publication 2014/0020178), filed May 1, 2013, entitled "SYSTEM, METHOD, AND COMPUTER ALGORITHM AND CHARACTERIZATION AND CLASSIFICATION OF ELECTROPHYSIOLOGICAL EVOKED POTENTIALS," which is hereby incorporated by reference in its entirety.

## BACKGROUND

**[0002]** The present invention relates generally to computer programs and methods for detecting changes in evoked potential (EP) waveforms, and more particularly to systems, methods, and computer-readable medium, which use a mathematical algorithm to assess and display EP waveforms, and calculate alerts to waveform changes.

### Standard Attended Intraoperative Monitoring

**[0003]** Somatosensory evoked potentials are summated electrical potentials usually recorded from the head or neck area and a peripheral nerve after repeatedly stimulating a peripheral nerve. Monitoring patients using somatosensory evoked potentials during surgery has been shown to allow early identification of impending injury, particularly nerve injury.

**[0004]** Such monitoring generally requires highly trained technologists under physician supervision with sophisticated, multichannel amplifier and display equipment. Unfortunately, such personnel and equipment are limited in their availability, require pre-booking, and are costly. In addition, such monitoring is fraught with difficulties due to the small size of potentials and ongoing noise which make recognizing significant changes, and alerting of these changes, difficult. In current systems that are used to generate alerts automatically, substantial noise and variability can cause false alerts.

**[0005]** Embodiments described herein relate to improved, systems, methods and devices for accurately detecting changes in electrophysiological evoked potentials. Improvements to existing systems include reduction in false positive/false negative alerts due to signal noise. Accordingly, the improved systems, methods, and devices generate more accurate alerts. Reducing the number of false positive alerts also creates more efficient systems, methods, and devices compared to known systems.

## SUMMARY OF THE INVENTION

**[0006]** Embodiments described herein relate to methods, devices, systems, apparatuses, and/or means to automatically detect and display changes to the evoked potential waveforms (EPs) in real time while showing incremental changes between completed ensemble averages. Embodiments described herein also relate to producing alerts with reduced or eliminated influence of variable noise and bias, while minimizing or eliminating false negative and false positive errors. The present disclosure generally relates to the computer signal processing and display algorithms for the characterization and classification of changes to EPs in real-time. The disclosed embodiments can be used in lieu of expert analysis typically provided by the technologist and physician. Further, various embodiments can be used in conjunction with other equipment. For example, upon detecting a change in EPs, an operating room table can be moved or adjusted. Such movement allows the patient to be automatically moved to ameliorate or avoid patient injury. Thus various embodiments herein extend the benefit of such equipment by automatically controlling the equipment based upon the EPs.

**[0007]** When seeking to accurately monitor or detect somatosensory evoked potentials (SSEPs), the waveforms can require acquisition at specific frequencies and/or averaging together to help eliminate random and cyclical noise. Even a few aberrant waveforms heavily affected by noise can markedly change the apparent amplitude (height) or latency (time of onset) of a waveform of interest when averaged together. While this is partly avoided by careful choice of stimulation frequencies and filtering of the waveforms, such methods cannot be complete as the waveforms of interest fall within the frequency range of the background noise and the cyclical background noise varies somewhat in frequency. In addition, these methods require producing a complete average (Ensemble Average or EA) of 100-300 stimulations and resultant waveforms, and then confirming any suspected change based on comparison with another EA, each taking up to **3** minutes to collect.

**[0008]** There is presently no way of observing slow onset incremental changes or discounting aberrant epochs affected by noise. The cost of having professionals fully engaged in interpreting these waveforms results in limiting of the service to only the most high risk surgeries. In addition, interpretation may be biased by human factors such as prior negative patient outcomes.

**[0009]** Thus, embodiments herein generally relate to systems, methods, devices and computer algorithms for measuring, displaying, and accurately detecting changes in electrophysiological evoked potentials. In some aspects the embodiments can automatically detect and display changes to the EPs in real time, including while showing incremental changes between completed ensemble averages. Also, in some aspects the embodiments can provide alerts free of the influence of variable noise and bias, including while minimizing or eliminating false negative and false positive errors. Embodiments described herein generally relate to the computer signal processing and display algorithms for the characterization and classification of changes to EPs in real-time implemented on specialized devices and systems. This systems and devices utilizing the algorithms may substitute for the expert analysis typically provided by the technologist and physician.

**[0010]** In an exemplary embodiment of the present invention a system, method, and computer algorithm for measuring, displaying and accurately detecting changes in electrophysiological evoked potentials is disclosed. In this disclosure, an EP is defined as a voltage versus time signal obtained by ensemble averaging of the electrophysiological responses to repetitive stimulation of a specific neural system, detected using suitable electrodes. Examples of EPs are somatosensory, auditory or visual EPs. The algorithms are applied to a time sequence of EPs acquired over the course of an ongoing clinical procedure. The algorithms establish changes to the characteristics of an EP relative to the baseline/normal EP, as well as to any previous EPs to determine if the functioning of the underlying neural system has been significantly affected by the ongoing clinical procedure. The algorithms communicate with ancillary hardware and algorithms developed to acquire the sequence of EPs and provide suitable feedback to ensure a safe and effective clinical workflow. The algorithms provide the basis for a clinically effective application such that false positives and false negatives are minimized.

**[0011]** Further features and advantages of the invention, as well as the structure and operation of various embodiments of the invention, are described in detail below with reference to the accompanying drawings.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[0012]** The foregoing and other features and advantages of the invention will be apparent from the following, more particular description of a preferred embodiment of the invention, as illustrated in the accompanying drawings.

**[0013]** FIG. **1** illustrates the traditional method evoked potential waveform (EP) acquisition and display.

**[0014]** FIG. **2** illustrates a sliding window method of EP acquisition, display, and alerting, according to an exemplary embodiment of the present invention.

**[0015]** FIG. **3** is a block diagram of a model EP analysis apparatus according to an exemplary embodiment.

## DETAILED DESCRIPTION

**[0016]** Various exemplary embodiments of the invention including preferred embodiments are discussed in detail below. While specific exemplary embodiments are discussed, it should be understood that this is done for illustration purposes only. A person skilled in the relevant art will recognize that other components and configurations can be used without parting from the spirit and scope of the invention.

**[0017]** FIG. **1**. illustrates a traditional way in which EPs are acquired and displayed. Using this method, a series of stimulations are applied and the resultant individual waveforms are displayed either as each is acquired, or as an evolving average of the ongoing average until a final ensemble average is acquired and displayed. The clinical interpretation is based on this ensemble average. If the user is satisfied with the average they may set that average as the 'baseline' to which all others are compared, or repeat it to confirm the presence and morphology of the waveform of interest. The whole process is then repeated with the next series of stimulations. Comparison of that series is then made to the preceding one that is chosen to be the baseline.

**[0018]** Since as few as five or six noisy individual waveforms that escape filtering can cause the waveform morphology, amplitude, and latency to widely vary, applying this method in an electrically noisy environment may lead to erroneous alerting of potential, imminent injury if an automated alerting system is used. This generally requires expert interpretation of the individual waveforms that takes into account the clinical situation, expected waveform and general trend in the waveform pattern over time.

**[0019]** An embodiment of the present invention relates to the computer signal processing and algorithms for the display of EP waveforms, calculation of alerts to waveform changes, and minimization of false positive and false negative alerts. This algorithm may substitute for the expert analysis typically provided by the technologist and physician. The computer algorithm running in software installed on an EP machine may be used in any surgery or situation where a patient is at risk, in order to detect, alert, and ameliorate positioning effect, or any nerve injury or abnormality.

**[0020]** FIG. **2**. illustrates an exemplary depiction of a sliding window of analysis and alerting using metadata from automatically calculated alerts that takes into consideration variation in noise and automatically looks back at the trend of the waveform over time, according to the present invention.

**[0021]** After collection of one or more sets of EPs, an Ensemble Average (EA) is created and a baseline of the waveform of interest is calculated. The baseline waveform may be identified by any standard technique including for example wavelet analysis, curve fitting etc.

**[0022]** For the next "n" number of stimulations, a new EA is created using similar waveforms as the previous one but from which a number of EPs are removed from the beginning of the average and a similar number is added to the end. For example, as shown on FIG. **2**, EP**2** does not incorporate the first two EPs of EP**1**, and includes two additional EPs at the end. Thus achieving a "sliding window" selection of EP data on which to create the new EA for the ongoing stimulation series. In certain preferred embodiments, a new EA is created for every epoch, i.e. the "window" slides forward only one EP, eliminating the first and adding an additional one to the end, relative to the previous EP selection for the previous EA.

**[0023]** The overall average can be updated and displayed with every overlapping epoch allowing a slow change in the morphology to evolve for the viewer. In this way, the viewer observes a real-time, incremented change in the EP waveform morphology over time, similar to viewing a live event or motion picture. In an exemplary embodiment of the invention, the generated overlapping EAs allows display of the effect of incremental consequence on the baseline average caused by newly collected waveforms in between non-overlapping EAs.

**[0024]** Each new EA waveform is identified and the salient characteristic (for example amplitude or latency) is measured and recorded. The new values are compared to the baseline value of the characteristic and it is determined whether an alert vote is to be generated. An alert vote is generated if the characteristic reaches a change threshold, i.e., a degree of change the user has set to trigger an alert. This process is repeated. Each new EA generates a vote as to whether an alert should be triggered or not. When the number of EAs reaches a specific number (n), typically when the initial stimuli of the EA no longer overlap the baseline EA, the votes are tallied and, in preferred embodiments, only then can an alert be triggered depending upon the ratio of yes to no (Y/N) alert votes required to trigger an alert. The user may alter the ratio of alert votes (Y/N) required depending upon their wish for specificity of the alerting process. In other embodiments, the votes may be continuously tallied and an alert triggered once the yes (Y) votes reach a certain predetermined number, or the ratio reaches a predetermined value.

**[0025]** In an exemplary embodiment of the invention, since the voting process may be asymmetrical, different ratios of voting may be used for triggering (onset) and releasing (offset) a final alert to the user that nerve injury to the patient is possible or imminent.

**[0026]** The alerting process examines the meta-data (the alerting vote) for the individual overlapping epochs. Since any real change in data will be sustained and always eventually deliver 100% (or close) Y/N votes for alert, the specificity of the alerting process can now be manipulated independent of the sensitivity of the system on the basis of the voting. For example, the user may alter the ratio to be less specific, requiring only 30% or 50% of votes vs 80% of votes for more specificity. In this way, there can be a reduction in the number of false alerts without really altering the sensitivity of the process to detecting real sustained change. In currently used systems, substantial noise and variability can cause false alerts, whereas the voting ratio used according to the present invention lessens the impact of the noisy signals. In an exemplary embodiment of the invention, EAs with wildly variant waveform values can be discarded from the voting process, eliminating intermittent noise that escapes the frequency filters. Thus, embodiments have an improved way of handling the effects of noise in EPs. The effect of this noise is further nullified by the voting process itself

**[0027]** Going forward the process is repeated, the voting using the last 'n' number of EAs to decide if an alert is triggered and displaying each EA or an averaged group of EAs as a progressively changing waveform which can easily be compared to baseline visually. In various embodiments, when an alert is triggered other actions can also occur. For example, information leading to the alert trigger can be sent to other equipment. As another example, a command to move a portion of an operating room table can be sent to the operating room table. Upon receipt, the operating room table can move and thus move the position of the patient. The movement reduces the patient's risk of nerve injury.

**[0028]** In an exemplary embodiment of the invention, once the process is established, a smooth ongoing generation of overlapping EAs can identify gradual changes that are due to processes such as cooling or depth of anesthesia that are not due to more abrupt onset injuries.

**[0029]** Referring to FIG. **3**, according to an exemplary embodiment, the EP analysis described above is implemented with an EP analysis apparatus **30**. The EP analysis apparatus **30** includes hardware and software for operation and control of the system. According to an exemplary embodiment, the EP analysis apparatus **30** includes a computing system **31**, an input device **36**, and a display device **37**. The computing system comprises a processing circuit **32** having a processor **33** and memory **34**. Processor **33** can be implemented as a general purpose processor, an application specific integrated circuit (ASIC), one or more field programmable gate arrays (FPGAs), a group of processing components, or other suitable electronic processing components. Memory **34** (e.g., memory, memory unit, storage device, etc.) is one or more devices (e.g., RAM, ROM, Flash-memory, hard disk storage, etc.) for storing data and/or computer code for completing or facilitating the various processes described in the present application. Memory **34** may be or include volatile memory or non-volatile memory. Memory **34** may include database components, object code components, script components, or any other type of information structure for supporting the various activities described in the present application. According to an exemplary embodiment, memory **34** is communicably connected to processor **33** and includes computer code for executing one or more processes described herein. The memory **34** may contain a variety of modules, each capable of storing data and/or computer code related to specific types of functions.

**[0030]** Referring still to FIG. **3**, the computing system **31** further includes a communication interface **35**. The communication interface **35** can be or include wired or wireless interfaces (e.g., jacks, antennas, transmitters, receivers, transceivers, wire terminals, etc.) for conducting data communications with external sources via a direct connection or a network connection (e.g., an Internet connection, a LAN, WAN, or WLAN connection, etc.).

What is claimed is:

**1**. An automated evoked potential analysis apparatus for monitoring, detecting and identifying changes to a patient's physiological system, wherein the apparatus comprises:

an input device for obtaining electrical potential data from the patient's physiological system after application of stimulation to a patient's nerve;

a computing system for receiving and analyzing the electrical potential data, and comprising a processing circuit configured to:

generate a plurality of evoked potential waveforms (EPs) based on the electrical potential data;

measure changes or trends in the generated EPs utilizing a sliding window of analysis;

display incremental changes in waveforms between full subsets of EPs; and

determine an alert vote for each subset, representative of changes to the physiological system generating the EPs.

**2**. The apparatus of claim **1**, wherein measuring changes with a sliding window of analysis comprises:

calculating an ensemble average waveform (EA) of a first subset of the plurality of EPs;

displaying the EA;

calculating a second EA of a second subset of the plurality of EPs, wherein the second subset eliminates at least one initial EP from the first subset of EPs and includes at least one additional EP from after the termination of the first subset, and wherein the first and second subsets comprise the same number of EPs and represent a sliding window for generating a plurality of EAs; and

displaying the second EA to display incremental changes between the first and second subset of EPs.

**3**. The apparatus of claim **1**, wherein a positive alert vote is created if the acquired EP waveforms in a subset of EPs reach a change threshold in latency, amplitude or morphology compared with a previous subset of EPs.

**4**. The apparatus of claim **1**, wherein said apparatus is further configured to integrate into other devices in a surgical environment.

**5**. The apparatus of claim **1**, wherein said computing system is further configured to feed information to other devices in the surgical environment that allows these devices to manually or automatically ameliorate or mitigate the physiological changes and improve subsequently acquired EP waveforms.

**6**. The apparatus of claim **5**, further comprising an operating table, wherein the operating table is configured to be adjustable to ameliorate or mitigate the physiological changes by causing an adjustment of the patient's position, in response to the information from the computing system.

**7**. The apparatus of claim **1**, wherein said apparatus computing system is further configured to:

obtain information from an anesthesia or blood pressure machine; and

determine when changes in EP waveforms are due to anesthesia or blood pressure changes.

**8**. A method of automatically identifying potential injury to peripheral nerve structures comprising:

stimulating a peripheral nerve with electrical pulses;

recording resultant electrical waveforms (EPs) generated by the nervous system, wherein the resultant EPs are collected through electrodes placed over the nerve pathway;

measuring changes in the acquired EPs utilizing a sliding window of analysis;

displaying incremental changes in waveforms between full subsets of EPs; and

alerting the user to the changes utilizing alert voting from overlapping subsets of the EPs.

**9**. The method of claim **8**, wherein measuring changes utilizing a sliding window of analysis comprises:

calculating an ensemble average waveform (EA) of a first subset of the plurality of EPs;

displaying the EA;

calculating a second EA of a second subset of the plurality of EPs, wherein the second subset eliminates at least one initial EP from the first subset of EPs and includes at least one additional EP from after the termination of the first subset, and wherein the first and second subsets comprise the same number of EPs and represent a sliding window for generating a plurality of EAs; and

displaying the second EA to display incremental changes between the first and second subset of EPs.

**10**. The method of claim **9**, wherein a positive alert vote is created if the second EA waveform reaches a change threshold in latency, amplitude or morphology.

**11**. The method of claim **10**, wherein an alert is triggered when a ratio of positive to negative alert votes for a determined number of EAs exceeds a threshold value.

**12**. The method of claim **8**, further comprising passing information related to alerts to an automated operating room table and readjusting patient position through adjustment of the table.

**13**. The method of claim **9**, wherein adjustment of the operating room table is performed automatically or semi automatically.

**14**. The method of claim **8**, further comprising passing information related to alerts to other devices or processes.

**15**. The method of claim **8**, wherein the electrodes are placed at the neck or head.

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|---|---|---|---|
| 专利名称(译) | 用于测量，显示和准确检测电生理诱发电位变化的系统，方法和计算机算法 | | |
| 公开(公告)号 | US20180078220A1 | 公开(公告)日 | 2018-03-22 |
| 申请号 | US15/569367 | 申请日 | 2016-05-03 |
| [标]申请(专利权)人(译) | 赛佛欧普手术有限公司 | | |
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| 当前申请(专利权)人(译) | SAFEOP外科INC. | | |
| [标]发明人 | JOHNS GREGG<br>OBRIEN RICHARD<br>SNOW ROBERT | | |
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| 外部链接 | Espacenet USPTO | | |


摘要(译)

描述了一种用于改进监测，检测和识别患者生理系统变化的自动诱发电位分析装置。该装置包括用于在对患者的神经施加刺激之后从患者的生理系统获得电势数据的输入装置和用于接收和分析电势数据的计算系统。该计算系统包括处理电路，该处理电路被配置为：基于电势数据生成多个诱发电位波形（EP），利用分析的滑动窗口测量所生成的EP中的变化或趋势，显示完整子集之间的波形的增量变化EP，并确定每个子集的警报投票，代表生成EP的生理系统的变化。