



(19) **United States**

(12) **Patent Application Publication**
Eide

(10) **Pub. No.: US 2002/0161304 A1**

(43) **Pub. Date: Oct. 31, 2002**

(54) **MONITORING PRESSURE IN A BODY CAVITY**

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(21) Appl. No.: **09/843,702**

(22) Filed: **Apr. 30, 2001**

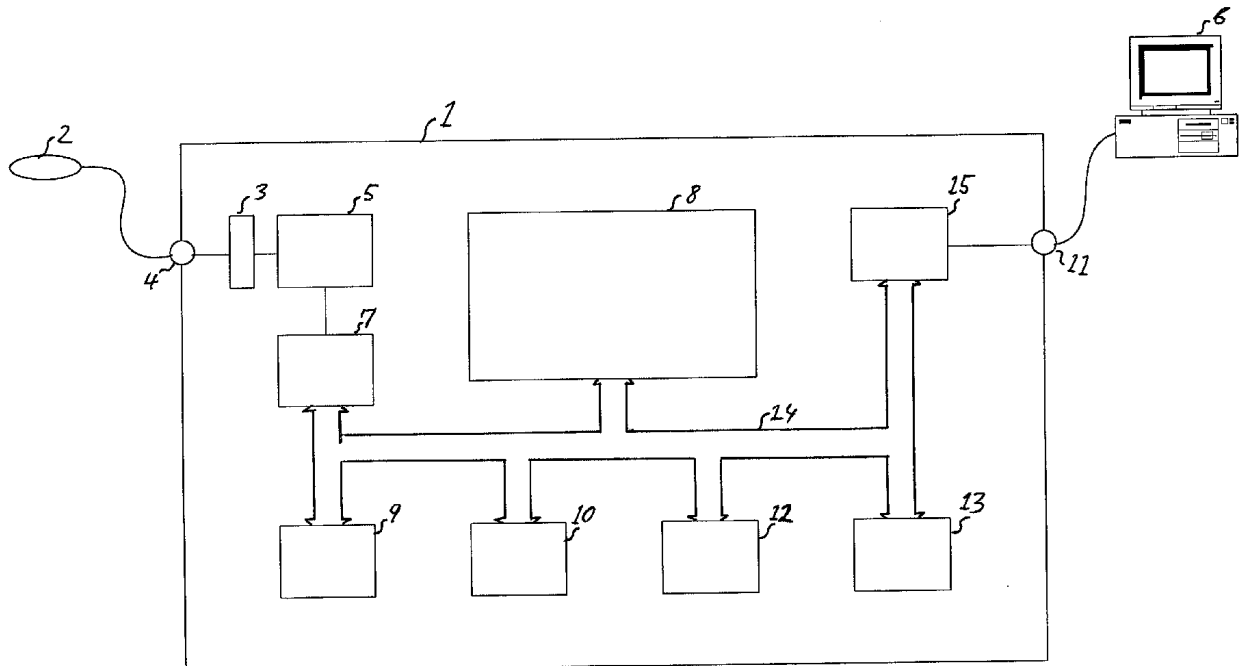
Publication Classification

(51) **Int. Cl.⁷** **A61B 5/02; A61B 5/103; A61B 5/117**

(52) **U.S. Cl.** **600/485; 600/500; 600/561; 600/587**

(57) **ABSTRACT**

The present invention relates to an apparatus for monitoring, sampling and storing pressure in a body cavity or blood pressure of a patient. The apparatus is a small portable recording unit for pressure assessment, including software for analysis of pressure recordings. A pressure transducer implanted e.g. in the skull of a patient senses the pressure and outputs a signal indicative of the pressure in the patients skull. The signals indicative of the pressure are converted to digital signals and sampled and stored by the microcomputer. The apparatus is sufficiently small to allow the patient to move freely around and not be bedridden during pressure recording. Intracranial pressure is sampled and stored by the apparatus several times a second for several days. After the end of pressure sampling, the data is transferred to a computer or network station for analysis. The invention includes a new method for analysis of pressure as well as software for performing the analysis. The computer software provides different quantitative presentations of pressure curves as a matrix of the number of intracranial pressure elevations of different levels or durations, a matrix of pressure changes of different levels and durations, or a matrix of the number of single pulse pressure waves with preselected characteristics.



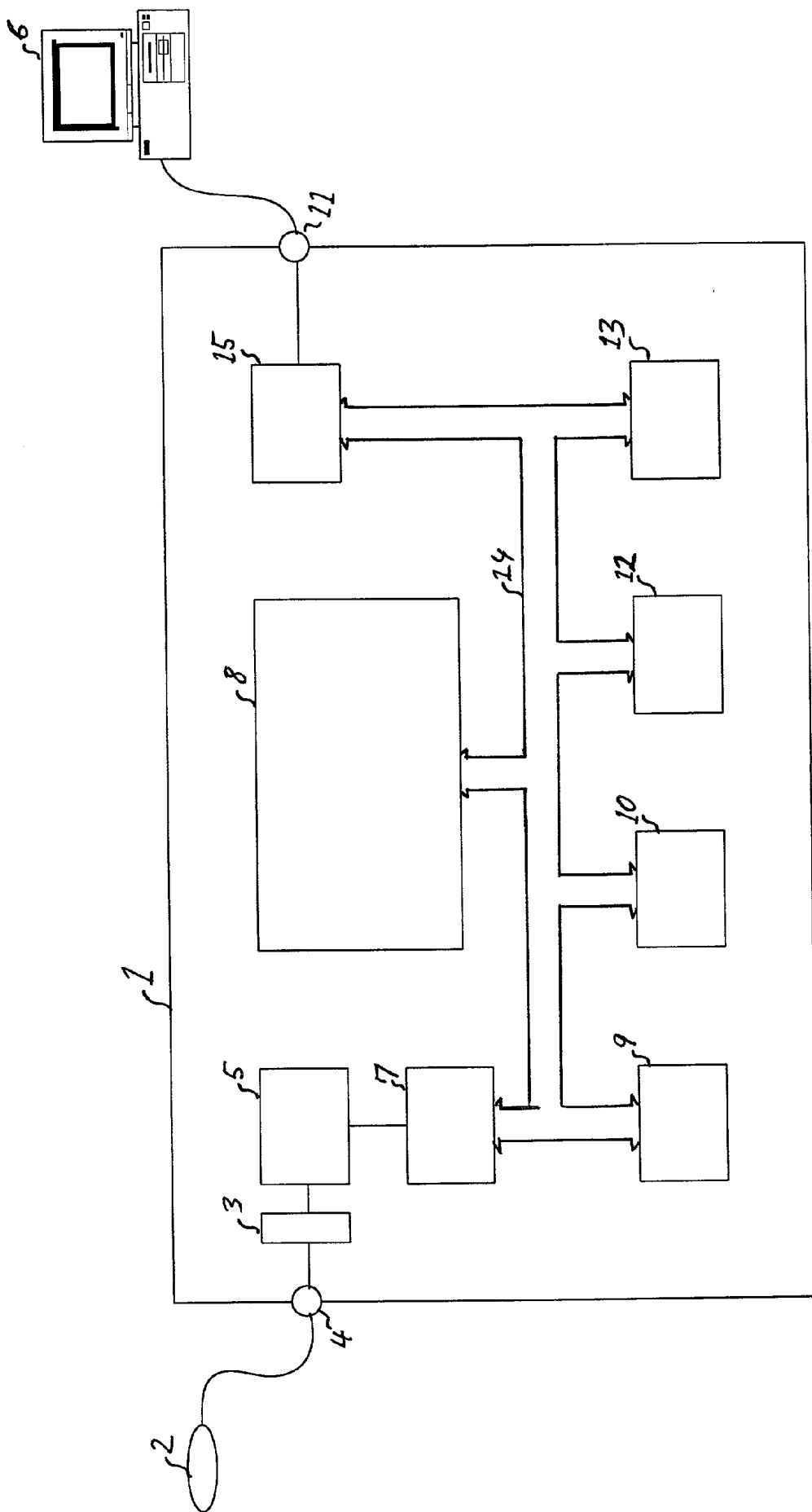


Fig. 1

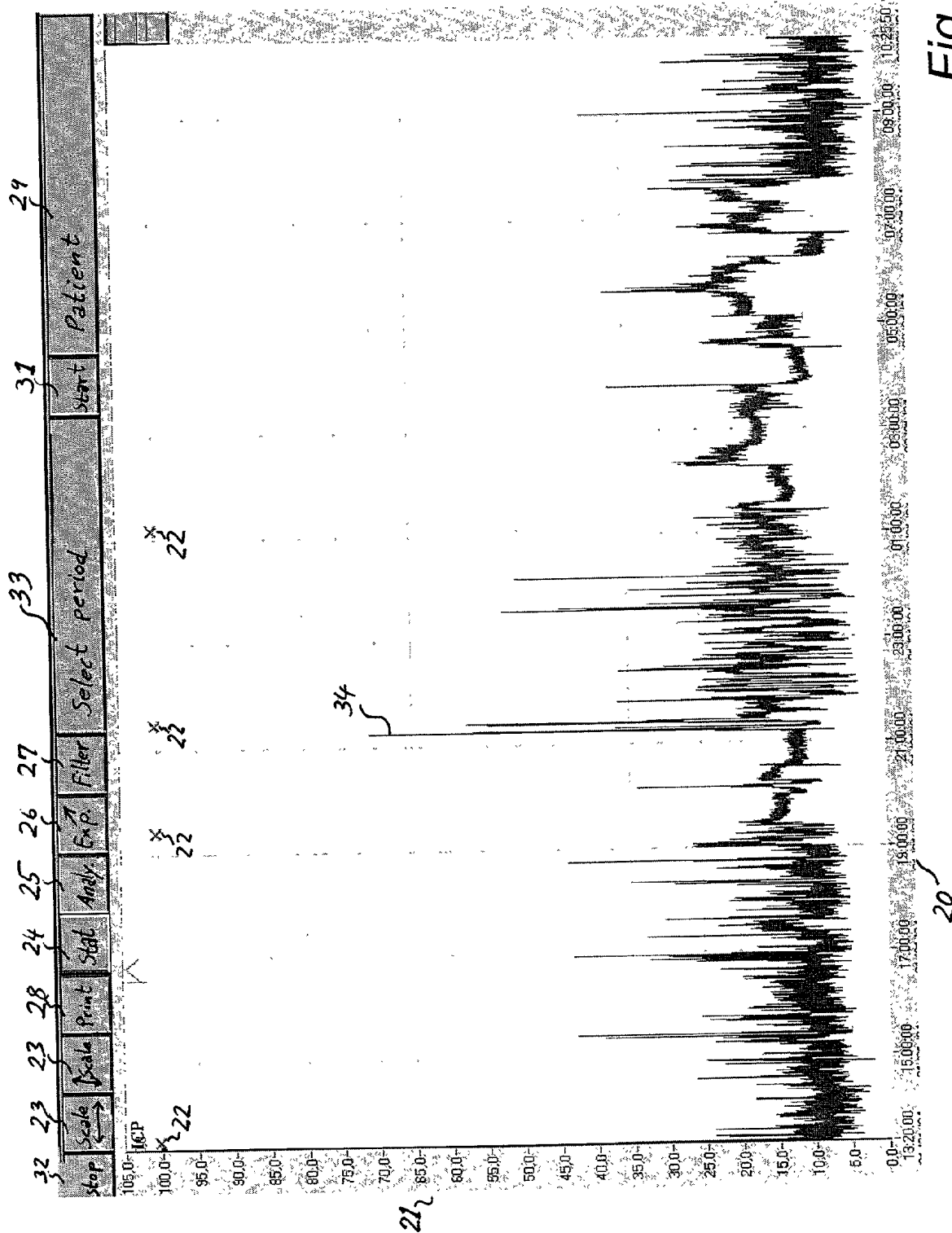


Fig. 2

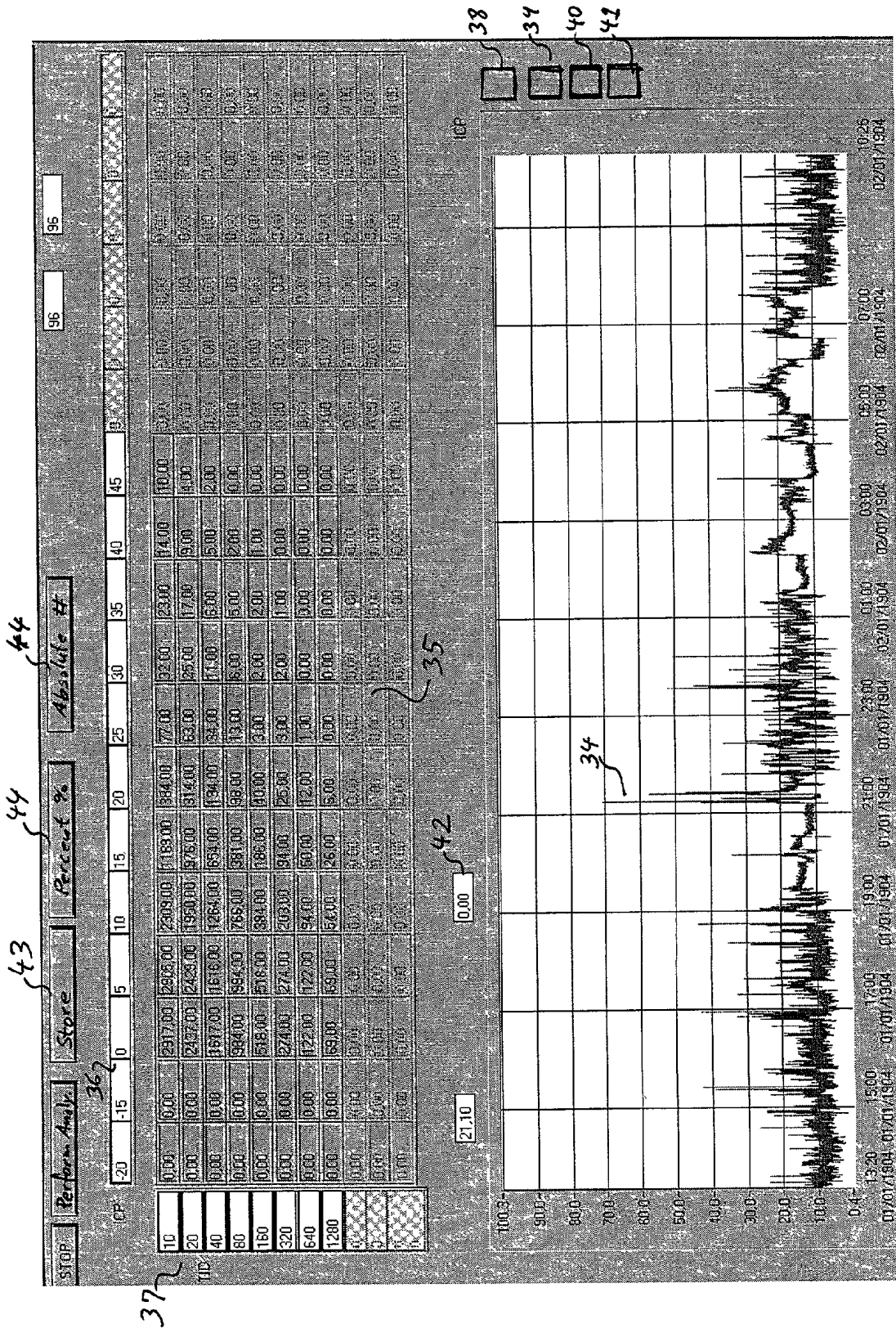


Fig. 3

MONITORING PRESSURE IN A BODY CAVITY

BACKGROUND OF THE INVENTION

[0001] 1. Field of the Invention

[0002] The present invention relates to an apparatus and method for monitoring the pressure within a cavity in a patient, and more specifically, but not by way of limitation, to devices and methods for monitoring and analysis of intracranial pressure and blood pressure. The invention includes an apparatus for sampling, recording and storing pressure measurements, and a method and computer software for quantitative analysis of the pressure.

[0003] 2. Related Art

[0004] The clinical use of intracranial pressure monitoring was first described by Janny in 1950 and Lundberg in 1960. During the last two decades the clinical application of continuous intracranial pressure monitoring has increased dramatically after the introduction of new intracranial pressure microtransducers in the 1980's. Intracranial pressure monitoring has been most extensively used in the monitoring of critically ill patients with brain damage (e.g. due to head injury or intracranial haemorrhage). It is well recognised that abnormal increases in intracranial pressure may lead to brain damage and even death. In these cases a pressure transducer is implanted within the skull of the patient, the transducer is connected to a pressure recorder that in turn is coupled to the monitoring system of the patient.

[0005] A number of intracranial pressure microtransducers are commercially available, both solid and fibreoptic transducers. The most commonly used invasive transducers include the Codman® Micro Sensor ICP Transducer (Codman & Shurtlef Inc., Randolph, Mass.) and the Camino®-110-4B (Camino Laboratories, San Diego, Calif.). Others are ICP Monitoring Catheter Kit OPX-SD (InnerSpace Medical, Irvine), Epidyn® (Braun Melsungen, Berlin), Gaeltec® ICT/B (Novotronic GmbH, Bonn), HanniSet® (pvh medizintechnik gmbh, Kirchseeon), Medex® (Medex medical GmbH, Ratingen) and Spiegelberg® (Spiegelberg KG, Hamburg). The microtransducers give an analog signal that is sent to the apparatus. Commonly used equipment's for intracranial pressure monitoring include: Codman ICP Express (Codman & Shurtlef Inc., Randolph, Mass.) and Camino OLM 110-4B (Camino Laboratories, San Diego, Calif.). These equipment's may be connected to other neurointensive monitoring systems. The equipment's presently available are developed for on-line intracranial monitoring in critically ill patients staying in the intensive care unit, that is patients with head injury or intracranial haemorrhage. Intracranial pressure is recorded on-line, providing the opportunity for acute interventions in order to reduce abnormal rises in intracranial pressure. For the individual case, the storing of pressure values for analysis later on has limited clinical value.

[0006] In not-critically ill patients outside the intensive care unit, continuous intracranial pressure monitoring has been less extensively used. Indications for this type of intracranial pressure monitoring include childhood hydrocephalus or craniosynostosis, adult hydrocephalus (including so-called normal pressure hydrocephalus), as well as childhood and adult shunt failure. In these patients intracranial

pressure monitoring is performed in awake patients either sitting or lying in the bed and the intracranial pressure curve is analyzed off-line after the intracranial pressure monitoring has been terminated. In these cases the primary object with intracranial pressure monitoring is to detect abnormal high intracranial pressure and abnormal elevations of intracranial pressure. The results of the analysis may be used in the preoperative assessment to select patients for surgery (e.g. extracranial shunt treatment, shunt revision or cranial expansion surgery). Only a few neurosurgical departments perform this type of intracranial pressure monitoring, and then usually in connection with research, not the daily clinical activity. There are several reasons for this situation: Invasive intracranial pressure monitoring provides a small but definitive risk of complications. It has been very difficult to analyze the intracranial pressure curve in a reliable and accurate way.

[0007] Accordingly, it has been difficult to justify a procedure with some risk of complication when the outcome of the procedure is uncertain. The currently available equipment's for intracranial pressure monitoring designed for use in patients within the intensive care unit, do not fulfil the needs for monitoring patients that are not bed-ridden. The apparatuses that are available requires the patient to be bedridden, thereby providing a less physiological monitoring of intracranial pressure. The currently available equipment's for this type of monitoring does not include portable apparatuses that may be carried by the patient. In particular, the evaluation of shunt failure patients should be performed in freely moving patients as over-drainage is a common problem in these cases.

[0008] Another reason for the less widespread use of continuous intracranial pressure monitoring in not critically ill patients is that there are still no generally accepted methods for analyzing intracranial pressure. The methods used so far include evaluation of the mean intracranial pressure, recordings of plateau waves (e.g. the Lundberg's A- and B-waves), as well as calculating the frequency of B-waves in percentage of the recording time. The morphology of the waves including assessment of latency, amplitude and wavelength of the waves, has also been described. There are, however, major limitations of the currently used methods of analyzing intracranial pressure. In the daily clinical practice the ICP curves usually are assessed by calculating mean ICP and a descriptive evaluation of plateau waves.

[0009] There is a close relationship between blood pressure and intracranial pressure as the intracranial pressure waves are built up from the blood pressure waves. Simultaneous assessment of intracranial pressure and blood pressure provides several advantages, for instance by calculation of the cerebral perfusion pressure (that is mean arterial pressure minus intracranial pressure). The assessment of cerebral perfusion pressure represents a critical parameter in the monitoring of critically ill patients. Assessment of blood pressure per se also has a major place in daily clinical practice, including both assessments of diastolic and systolic pressures.

[0010] Normal mean intracranial pressure has not been defined, and depends on age. In children most authors consider mean intracranial pressure of 10 mmHg or below as normal, mean intracranial pressure between 10 and 15 mmHg as borderline and mean intracranial pressure above

15 mmHg as abnormal. In adults a mean intracranial pressure of 12-15 mmHg or below usually is considered as normal. However, the mean intracranial pressure represents only one facet of an intracranial pressure curve that may include elevations of intracranial pressure of various duration's. Obviously, for different intracranial pressure curves equal mean intracranial pressure's may include different proportions of pressure elevations and depressions. Furthermore, the description of plateau waves may be inaccurate as the A, B and C waves may be differently defined by the various physicians, as the different waves usually is identified on the basis of the morphology of the intracranial pressure curve. This is illustrated by the fact that different authors report a large variation in the frequency of B-waves that they consider normal. Attempts also have been made to differentiate B waves into different types on the basis of the morphology of the waves. Thus, the interpretation of an intracranial pressure curve will be very observer dependent. Since the consequences of pressure monitoring is so important (surgery or not) accurate and reliable conclusions of intracranial pressure monitoring are needed for this method to be of interest in daily clinical activity.

[0011] On this background the applicant developed a new method for the quantitative analysis of the intracranial pressure curve as well as blood pressure curves. Instead of describing the morphology of the intracranial pressure curve with calculation of mean intracranial pressure and the observer-dependent identification of apparent plateau waves, the intracranial pressure curve was quantified in different ways: The pressure recording were either presented as a matrix of numbers of intracranial pressure elevations of different levels (e.g. 20, 25 or 30 mmHg) and duration's (e.g. 0.5, 1, 10 or 40 minutes), or a matrix of numbers of intracranial pressure changes of different levels and durations, or a matrix of numbers of single pressure waves of certain characteristics. Similar analysis was made for blood pressure and cerebral perfusion pressure. In order to simplify the analysis, new windows compatible software was developed for this analysis. The applicant has shown in a not yet published study including 127 patients that the calculation of mean intracranial pressure is an inaccurate measure of intracranial pressure. There was a weak correlation between mean intracranial pressure and the number of intracranial pressure elevations. A high proportion of abnormal intracranial pressure elevations may be present despite a normal mean intracranial pressure. In another study including 16 patients undergoing continuous intracranial pressure monitoring before and after cranial expansion surgery, the applicant found that calculation of numbers of intracranial pressure elevations of different levels and duration's in a sensitive way revealed changes in intracranial pressure after surgery. These changes were not revealed by comparing mean intracranial pressure before and after surgery. Accordingly, this type of quantitative analysis of the intracranial pressure curve represents a far more accurate and reliable way of analyzing intracranial pressure than the classical ways of analyzing mean intracranial pressure and describing Lundberg's A, B or C waves.

SUMMARY OF THE INVENTION

[0012] One object of the present invention is to provide an apparatus for measuring pressure in a body cavity such as intracranial pressure, with or without simultaneous blood pressure measurement, in freely moving individuals that are

not bed-ridden. Therefore the apparatus is small and may be driven by a rechargeable battery.

[0013] Another object of the present invention is to provide an apparatus for recording and storing a large number of intracranial pressure recordings, that is pressures sampled at least 10 times a second, and more preferably 100 to 150 times a second, for at least 24-48 hours. Preferably the frequency by which pressure is sampled may be selected by the physician, ranging from about 10 to 150 Hz. The data may be transferred via the serial port to a personal computer or network connection for further analysis.

[0014] Another object of the present invention is to provide an apparatus that may record signals indicative of the intracranial pressure or blood pressure from various sources of signals, that is invasive implanted microtransducers and non-invasive devices using acoustic or ultrasonic signals.

[0015] Another object of the present invention is to provide an apparatus that may serve as an interface between the patient and a monitor/network station allowing online monitoring of the intracranial pressure.

[0016] Another object of the present invention is to provide a new method of analyzing pressure samples such as intracranial pressure, blood pressure or cerebral perfusion pressure, including quantitative presentations of the various pressure curves.

[0017] Yet another object of the present invention is to provide software for the quantitative analysis and presentation of pressure curves representing e.g. intracranial pressure, blood pressure and cerebral perfusion pressure. The software has several options for quantitative description of the data, including calculation of a matrix of pressure elevations of different levels and durations, or a matrix of pressure changes of different levels and durations, or a matrix of number of single pulse pressure waves with selected characteristics.

[0018] The main objectives of the invention are related to intracranial pressure and blood pressure, but this is not a limitation on the scope of the invention. The invention can also be utilized in connection with pressure sensors measuring pressure in other body cavities.

[0019] In light of the above mentioned objectives, a method has been developed for measuring and analyzing pressure in a patient. According to this method one or more pressure sensors are applied to a patient and the pressure signals from the sensors are sampled at selected intervals. The sampled signals are converted to digital form and stored along with a time reference that makes it possible to evaluate the change of pressure over time. The time reference may be stored as part of the digital value, or it may be associated with the memory position, or memory address, at which the pressure value is stored. The stored sample values are then, according to this embodiment of the invention, analyzed in order to generate a presentation of at least one of the following: number of pressure elevations with any selected combination of level and duration; number of pressure changes with any selected combination of level difference and duration of change; and number of pulse pressure waves with preselected characteristics regarding minimum, maximum, amplitude, latency and rise time. The method allows for various sampling rates and duration of measuring periods.

[0020] According to one aspect of the invention, an apparatus for performing the information gathering according to the method has been developed. The apparatus is small enough to be carried by a patient, so the patient will be free to move about during the measuring period. The apparatus comprises means for connecting to one or more sensors, a converter for producing the digital measuring values, a processor controlling the sampling of the measuring signals and storing the digital values in a data memory. The apparatus also comprises a connector for connecting the apparatus to external computing means in order to upload values stored in the data memory or to deliver sampling values in real time to said external computing means.

[0021] Another aspect of the invention concerns a system for performing the analysis according to the method. The system may be in the form of a suitably programmed computer, or dedicated equipment particularly designed for performing this analysis. The system includes a communication interface for receiving a set of digital pressure sample values, a memory for storing these values, and a processor for performing the analysis described above. The system further includes a video interface that is controlled by the processor and that is capable of generating a visual presentation of the result of any analysis performed by the processor. The visual presentation will be presented on a display. The system also comprises input means for allowing a user to change the parameters of the performed analysis.

[0022] Finally the invention includes a computer program product for controlling a computer performing the analysis described above. The computer program may be installed on a computer or carried on a carrier such as a CD ROM a magnetic storage device, a propagated signal carrying information, or in any other manner known in the art.

[0023] The particular features of the invention are described in the attached independent claims, while the dependent claims describe advantageous embodiments and alternatives.

BRIEF DESCRIPTION OF THE DRAWINGS

[0024] FIG. 1 is a block diagram of the various components of a system according to the inventions

[0025] FIG. 2 is a graphical user interface used for presenting pressure sampling results.

[0026] FIG. 3 is a graphical user interface for presenting and controlling the analysis of a pressure curve.

[0027] FIG. 4 shows a part of the graphical user interface of FIG. 3 for different levels and durations.

[0028] FIG. 5 is a graphical user interface for presenting pressure sampling results.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

[0029] FIG. 1 illustrates in a block diagram a system for measuring pressure in a body cavity of a patient. The main components of this system includes a pressure sensor 2, a portable apparatus for measuring and storing pressure values 1, and a network station such as a personal computer 6 for receiving and processing registered pressure values. The apparatus 1 is a digital system with a central processing unit 8 for sampling and storing pressure measurements in a

patient, such as intracranial pressure, blood pressure or pressure in other body cavities or blood pressure. In the following example an embodiment for measuring intracranial pressure will be described, but it must be understood that this is not a limitation on the scope of the invention.

[0030] As a result of its compact construction and light weight, the apparatus 1 can easily be carried by a patient. The apparatus may be fastened to the belt of the patient or kept in a carry pouch with straps. Alternatively, the apparatus may be used as an interface for connecting the network station or personal computer 6 to the pressure sensor. This allows real time online monitoring of pressure so that the pressure curve may be displayed on a display.

[0031] A microtransducer 2 for sensing the intracranial pressure is implanted within the body cavity within which pressure is to be measured, such as the skull of the patient. The sensor may be a small pressure transducer with a small sensor in the distal end and a connector connecting the sensor to the apparatus 1 in the other. Various microtransducers for continuous intracranial pressure monitoring are already on the market.

[0032] The apparatus 1 may be constructed in a number of ways. The embodiment described below is based on a unit with a central processing unit operating in accordance with instructions stored in memory and communicating with the various parts of the apparatus over a common data bus. However, a number of variations are possible. Instead of using a central processing unit and instructions stored in memory, the functionality of the apparatus could be constructed directly in hardware, e.g. as ASICs.

[0033] The main components of the apparatus 1 are the analog to digital converter 7, which converts the received analog measuring signals to digital, the data memory 9, which receives the digitized values from the analog to digital converter 7 and stores them, and an input/output interface 15 allowing data stored in the memory 9 to be transferred to the network station or personal computer 6 for processing. In addition the apparatus preferably includes a galvanic element 3 protecting the patient from the electric circuitry of the apparatus, a signal conditioner 5 either to the input or the output of the analog to digital converter 7, an input control 10 for controlling operation and adjusting settings of the apparatus, a display unit 12, and an alarm unit 13. Input control 10, display 12 and alarm unit 13 are connected to and in communication with the central processing unit 8 and/or other parts of the apparatus such as ASICs, display drivers, and power sensors (not shown).

[0034] After being received by the apparatus over a connector 4 to which the pressure transducer 2 is connected, analog measuring signals are sent to a signal conditioner 5. Signal processing modifies the signal-to-noise ratio. This is required since a high degree of noise can be expected for instance during walking. The signal conditioner 5 may be an analog filter. Alternatively, the signal conditioner 5 may be a digital filter operating under control of the central processing unit 8. The signal conditioner will then be positioned following the conversion of the sampled signal from analog to digital.

[0035] Preferably a galvanic element 3 is positioned between the interface 4 and the signal conditioner 5, representing a security element preventing electrical energy from

being sent retrograde to the patient. After the analog signals have been processed by the signal conditioner **5**, the analog signals are converted to digital signals within an analog to digital converter **7**. The central processing unit **8** controls the operation of the various elements of the apparatus **1**. The central processor is in communication with the analog to digital converter **7**, and is capable of reading out samples of the digitally converted pressure measurements and storing them in a data memory **9**. The data memory **9** may be in the form of electronic circuits such as RAM, or some form of magnetic storage, such as a disc, or any other convenient form of data memory known in the art.

[0036] As has already been mentioned, the apparatus is here described as receiving signals indicative of the intracranial pressure from sensors implanted within the skull. However, the apparatus may also incorporate a signal conditioner **5** for processing signals from non-invasive devices such as acoustic, ultrasonic or Doppler devices. Whether the entire apparatus must be constructed with a signal conditioner **5** for a specific purpose or whether the same signal conditioner **5** allows for different usage, with or without re-programming, is dependent on implementation and specific needs. If the apparatus is intended to work with various sensors with various levels of sensitivity, the signal conditioner should be adjustable in a manner that allows operation with the desired sensors and to adapt the output range to the various sensors to the input range of the analog to digital converter **7**. In this case the signal conditioner **5** must obviously be connected between the input of the apparatus and the analog to digital converter **7**.

[0037] The apparatus is programmable including an input control **10**, with a simple key board for entering a few commands. The input control has a calibration function that allows calibration of the pressure sensor against the atmospheric pressure, before the sensor is implanted within the skull of the patient. Thereby the intracranial pressure monitored actually is the difference between the atmospheric pressure and the pressure within the skull of the patient. The input control also contains a function for selecting the interval of pressure recordings. The pressures may be recorded with variable sampling frequency, e.g. from about 10 Hz up to 100 Hz or preferably from 10 Hz up to 150 Hz. The minimum memory space should then allow storing of recordings at least 150 times a second for at least 48 hrs (26 920 000 recordings). Via a connector **11**, data may be transferred to a personal computer **6** for analysis. The connector **11** may be a serial port, and the apparatus will preferably comprise an input/output interface **15** converting the internal signal format for the apparatus **1** to a format for communication over said connector **11**. The input control **10** preferably also has a function for adjusting the real time clock, since each pressure sample should include a time reference indicating when the sample was made.

[0038] Functions on the input control **10** for the physician preferably include the following: On/Off, calibration, protocol (frequency rate of pressure sampling), start and clock adjustments. Functions for the patient or the nurse may include: Day/Night and Events.

[0039] A display **12** shows on-line the digital pressure signals as well as the real-time time. The display is preferably controlled by the central processing unit **8**.

[0040] The apparatus is powered by an internal battery (not shown) that preferably is rechargeable, but with input for external power supply (not shown).

[0041] In a preferred embodiment, the apparatus has an alarm function that indicates shortage of memory capacity or reduced battery capacity. This alarm may be displayed visually on the display **12**, but may also include a unit **13** emitting an audible alarm signal.

[0042] In addition to the battery that powers the apparatus while in use, the apparatus may include an additional battery that serves to maintain data in the volatile part of the memory when the main battery runs low or is removed. Alternatively, or in addition, the alarm function described above may, upon detecting low power status of the main battery, trigger a routine that transfers any data in the volatile part of the memory to a non volatile part of the memory. The volatile part of the memory may be the working RAM of the apparatus, while the non-volatile part of the memory may be any combination of ROM, EEPROM, a magnetic storage medium or any other such memory known in the art. People skilled in the art will, however, realize that other configurations of memory are possible within the scope and spirit of the invention.

[0043] The apparatus may be connected to a personal computer **6** via the serial port **11**. Alternatively the apparatus may be connected to another digital computer-based monitoring system such as a network station. This gives the opportunity for on-line and real time monitoring of the pressure with real time graphic presentation of the recordings. In this situation the apparatus functions as an interface for a stationary personal computer or flat screen.

[0044] The apparatus is preferably controlled by software that is stored in a non-volatile part of the memory **9**, and that controls the operation of the central processor **8**. The various units of the apparatus are shown as communicating over a common data bus **14**, but it should be noted that the various components may be interconnected in other ways.

[0045] The apparatus has been described above with only one channel for receiving pressure signals from one pressure sensor. The apparatus may, however, include one or more additional channels for receiving signals from additional pressure sensors. According to a preferred embodiment of the invention the apparatus comprises two input channels, allowing the simultaneous recording of e.g. intracranial pressure and blood pressure. An embodiment with more than one input channel will comprise additional connectors **4** and galvanic elements **3**, and the signal conditioner **5** and analog-to-digital converter **7** may be similarly duplicated, or one signal conditioner **5** and/or one analog-to-digital converter **7** may operate the several pressure signal channels in a multiplexed manner, controlled by the central processing unit **8**. If the apparatus comprises several channels, the capacity of the data memory **9** must be increased accordingly.

[0046] The invention also relates to a method for measuring and analyzing pressure in a patient, using the apparatus described above. This method will now be described.

[0047] First, a pressure sensor **2** is applied to the patient. A signal from the sensor representative of said pressure, is sampled at selected intervals. This signal is converted to digital form and stored along with a time reference repre-

sentative of the time at which the sample was made. The time reference does not have to be a time reference value stored for every sample. Since the sample rate will be known, it will be sufficient to store an actual time reference for the start of the measuring period. The time reference for the individual samples will then be given by their relative address in memory.

[0048] The stored sample values may then be analyzed in order to generate a presentation of at least one of the following:

[0049] number of pressure elevations with any selected combination of level and duration,

[0050] number of pressure changes with any selected combination of level difference and duration of change,

[0051] number of single pulse pressure waves with preselected characteristics such as minimum, maximum, amplitude, latency and rise time.

[0052] In order to analyze number of pressure elevations with any selected combination of level and duration, the stored samples are simply analyzed in order to determine for how long the measured pressure has remained within a certain pressure interval. According to a preferred embodiment of the invention, the user performing the analysis will be able to set the pressure intervals defining the various levels and duration of pressure elevations manually and perform the analysis repeatedly with different values for these parameters. Level may be measured on a linear scale e.g. with intervals of 5 mmHg, while the time scale intervals should preferably increase with time, e.g. each interval being twice as long as the previous shorter interval.

[0053] An analysis of number of pressure changes with any selected combination of level difference and duration of change would involve an analysis of the stored samples in order to determine the size of a pressure change and the time over which the change takes place.

[0054] An analysis of pulse pressure waves will take into consideration not only elevations that remain within a certain time interval, but the transition of a wave from minimum to maximum and back to a new minimum or vice versa. Preselected characteristics may be the duration of the single pulse wave from minimum (maximum) back to minimum (maximum) combined either with minimum value, maximum value or amplitude of the single wave. Another preselected characteristic may be the rise time of the single wave combined with the amplitude of the wave.

[0055] The step of applying a pressure sensor may involve implanting the sensor in a body cavity of the patient, but it may also involve applying a non-invasive technique with a sensor using acoustic measuring signals, ultrasonic or Doppler, or even a pressure sensor for measuring blood pressure.

[0056] As a result of the small size of the apparatus, the sampling and storing of pressure signals may be made while the patient is free to move about. The analysis is preferably performed by transferring the aggregated data to a computer for analysis and graphical presentation. The presentation generated as part of this analysis may be in the form of absolute numbers, percentages or numbers per time unit.

[0057] According to a preferred embodiment, the sampling rate is at least 10 Hz, and the measurements may be

taken over a period of at least 24 hours. Even more preferably, the measurements may be performed with a sampling rate of 100 Hz, or even 150 Hz, and taken over a period of at least 48 hours. According to the preferred embodiment of the apparatus the physician can set the sampling rate through the input control 10.

[0058] The computer 6 performing the analysis of the aggregated pressure data may be a regular personal computer or a dedicated unit for performing the analysis and generating presentations of the results. The computer embodies a system for analysis of recorded pressure data in accordance with the invention.

[0059] The computer preferably includes a standard communication interface for receiving a set of digital pressure sample values from the apparatus described above, as well as data memory, such as a hard drive, for storing the received sample values and processing means, such as a microprocessor, with access to said data memory, and capable of analyzing said sample values in order to determine at least one of the following:—number of pressure elevations with any selected combination of level and duration,—number of pressure changes with any selected combination of level difference and duration of change,—number of single pulse pressure waves with preselected characteristics regarding minimum, maximum, amplitude, latency and rise time. The computer further includes a video interface in communication with said processing means and capable of, in combination with the processor means, generating a visual presentation of the result of any analysis performed on the pressure sample values together with a graphical user interface. The video interface may be a graphics card connected to a display for displaying the generated visual presentation. The computer will also include input means allowing a user of the system to enter and change parameters on which said analysis should be based. These input means will normally include a keyboard and e.g. a mouse, and the user will be assisted by a graphical user interface presented on the display.

[0060] The parameters on which the analysis should be based may include at least some of the following: pressure intervals defining a number of pressure elevations, pressure change intervals defining a number of pressure change step sizes, time intervals defining a number of durations, pressure wave characteristics including minimum, maximum, amplitude and latency, selection of type of analysis, and selection of presentation of numbers as absolute numbers, percentages or numbers per time unit.

[0061] The operation of the computer will preferably be controlled by computer program instructions stored in the computer and making the computer capable of performing the analysis. The program will preferably be able to perform the analysis based on default values in the absence of parameters input by a user. Such a computer program may be stored on a computer readable medium such as a magnetic disc, a CD ROM or some other storage means, or it may be available as a carrier signal transmitted over a computer network such as the Internet.

[0062] FIG. 2 illustrates the graphical user interface of the computer software used for presenting the results of the sampling described above. Various modules of the software generate output or can be invoked through this interface. After the end of intracranial pressure sampling, the intrac-

ranial pressure curve **34** may be presented in various windows. The X-axis shows the time of registration **20**, that is real time of intracranial pressure sampling (presented as hours: minutes: seconds). The Y-axis **21** shows the absolute intracranial pressure recordings (presented as mmHg). During the recordings, it is possible to mark events (e.g. sleep, walking, sitting) and these may be presented as symbols **22** along the X-axis above the pressure graph. There are functions **33** for selecting the recording periods, for instance selecting parts of the intracranial pressure curve during sleep, walking, sitting etc. There are functions for selecting different window sizes **23** both vertically and horizontally. A special function **24** allows simple statistical analysis of the data (with calculations of mean, std, median, ranges and time of recording). Another function **25** transfers control to a software module that performs quantitative analysis of the intracranial pressure curve in accordance with the invention. The results of this analysis is described below with reference to **FIG. 3**. Another function **26** allows export of intracranial pressure data from a selected window to files with a selected text format such as ASCII, that can be utilized by e.g. spreadsheet or word processing applications. The intracranial pressure curve may be smoothed by another function **27**. Another function allows printing of the intracranial pressure curve **28**. The software also includes a function for patient identification **29** also containing some data of the patient (such as tentative diagnosis and cause of examination). In addition, there are start **31** and stop **32** buttons. If the apparatus has collected pressure samples from several channels, e.g. intracranial and blood pressure, these may be simultaneously analyzed.

[0063] The functions referred to above and the software modules that perform them will not be described in detail as they are well known in the art and do not constitute a part of the invention as such.

[0064] Reference is now made to **FIG. 3** which shows the graphical user interface of the software module for analysis of the intracranial or blood pressure curve. The selected window of the intracranial pressure curve **34** is presented as a chart **35** of quantities of different types, derived through the invented method of analysis:

[0065] By clicking a first button **38**, the user can select a presentation of the data as a chart of numbers of intracranial pressure elevations with various combinations of level **36** and duration **37**. The intracranial pressure levels and durations may be selected in each case. According to a preferred embodiment, intracranial pressure is expressed as mmHg and duration as seconds and minutes.

[0066] A second button **39** allows the user to select presentation of the data as a chart of numbers of intracranial pressure changes of different levels and duration's. The changes may be differences between two recordings or differences between a recording compared to a given or selected value (e.g. mean pressure).

[0067] By clicking a third button **40**, the user selects presentation of the data as numbers of single pulse pressure waves with pre-selected characteristics. The users accesses an input dialog box for entering these characteristics by clicking a fourth button **41**. Each pulse pressure wave is identified by minimum, maximum, amplitude, latency and rise time.

[0068] The method for performing these analysis are described above, and the various buttons described above invokes software modules for performing the various steps of this method.

[0069] The presentation of the results of the analysis **35** may be toggled between absolute numerical quantities and percentages of recording time by clicking one of two buttons **44**.

[0070] The numbers may be standardized by presenting the data as numbers per time unit **42**. The time unit (e.g.) may be selected in each individual case.

[0071] Again, a special function **43** allows the analyzed data to be saved as text files with a selected text format such as ASCII, or other files compatible with applications for mathematical and/or statistical handling of the data or for generating presentations.

[0072] **FIG. 4** shows part of the graphical user interface of **FIG. 3** with a different set of parameters. In particular, the various time intervals of duration **37** have been changed, and the numbers of elevations **35** are now normalized as number of occurrences per time unit **42**.

[0073] The results shown in **FIG. 4** are the results of an analysis of number of pressure elevations with selected combinations of level and duration. The stored samples have been analyzed in order to determine for how long the measured pressure **36** has remained within a certain pressure interval, represented as -10, -5, 0, 5, 10, 15, 20, 25, 30, 35, 40 and 45 mmHg relative to atmospheric pressure, for certain periods of time. The various periods of time **37** are selected as 30, 60, 300, 600, 1200 and 2400 seconds, respectively. The results have been normalized to a period of 10 hours **42**. Among the results in the result matrix **35** it can be seen that intracranial pressure elevations of 45 mmHg with a duration of 30 seconds have occurred 8.88 times when normalized to a 10 hour measuring period. Similarly, pressure elevations of 30 mmHg with a duration of 600 seconds have occurred 2.22 times when normalized to a 10 hour period. In **FIG. 3**, where the results are not normalized, all the results are integers.

[0074] **FIG. 5** shows the same part of the graphical user interface as **FIG. 4**, but in this case the analysis is an analysis of number of pressure changes with selected combinations of level difference and duration of change. The stored samples have been analyzed in order to determine the number of pressure changes of certain sizes, represented as -20, -15, 0, 1, 2, 3, 4, 5, 6, 7, 8, 9 and 10 mmHg, respectively, and the duration over which these changes take place, given as 10, 15, 20, 25, 30, 35, 40, 45 and 50 seconds. Among the results given in the result matrix **35** it can be seen that a pressure change of 2 mmHg over 15 seconds has occurred on average 1.14 times per 10 hour period. Changes of 0 mmHg represents periods of time over which the pressure has remained constant.

[0075] The invention is intended for use on children or adults in whom there is a question of abnormally increased or reduced intracranial pressure and/or blood pressure. In a minor surgical procedure, the pressure transducer **2** is implanted within the skull of the patient. This is performed in general narcosis in children and in local anesthesia in adults. During the procedure, a small opening is made in the skull with a subsequent small opening in the dura. The

sensor is canalled subcutaneously to the surgical opening. The sensor is coupled to the apparatus **1** and calibrated against atmospheric pressure by means of the Input control **10**. Then the sensor is penetrated about one centimeter in the brain parenchyma. The surgical opening is closed and the sensor is fastened to the skin by sutures or by other means. By means of the Input control **10**, the frequency of pressure sampling is selected. Then pressure recordings are started. The patient should be bed-ridden the first 3-4 hours after the surgical procedure, but may then stand up and walk around, carrying the apparatus on the body. Prior to this procedure, it should be controlled that the battery is charged and that the apparatus has enough memory capacity. Otherwise the alarm functions **13** will inform the patient/physician. During continuous pressure recordings, the patient may move freely around. The Input control **10** contains a small keyboard with some functions that may either be controlled by the patient or the nurse. This control may indicate events such as walking around, sitting, sleeping, painful procedure that in turn may be displayed on the intracranial pressure curve. The intracranial pressure is monitored continuously for about 24-48 hrs. Then the apparatus is disconnected from the sensor. The sensor is removed from the patient (a procedure that does not require local anesthesia). The physician may connect the apparatus **1** to his or her personal computer **6** or network station via the serial port **11**. The digital pressure data is transferred from the memory **9** of the apparatus to either the hard disk, zip drive or network area for storage. Then the data may be analyzed by the software program described above. The intracranial pressure curve may be analyzed as described previously. As described above, the apparatus may have two channels allowing simultaneous recordings of intracranial pressure and blood pressure. Blood pressure recordings are sampled, stored and analyzed in the same way as intracranial pressure recordings.

[0076] The invention is intended used in several groups of patients: Adult patients with so-called normal pressure hydrocephalus. This syndrome includes dementia, unsteady gait as well as urinary incontinence, which often is associated with increased ventricles within the brain. A major problem so far has been to select the best candidates for surgery as the treatment (commonly extracranial shunting of the ventricular fluid to the peritoneum) since the treatment is not without risk and treatment is non-successful in many patients. In these patients intracranial pressure monitoring has not received widespread use due to the limited prognostic value. The methods used so far to analyze the intracranial pressure curves of these patients have been less accurate, as previously described. Other invasive tests (mainly various types of infusion tests) also have been of limited prognostic value. The present invention provides at least two advantages: Continuous intracranial pressure monitoring by means of a portable apparatus represents a more physiological situation than with the patient bed-ridden. A large number of intracranial pressure recordings may be sampled and stored by the apparatus. Second, the new apparatus and method provide a far more accurate assessment of the intracranial pressure recordings than the currently used methods provide.

[0077] The invention may also be used in children and adults treated with extracranial shunts in whom there is a question of shunt malfunction. It is well known that over-drainage and under-drainage may give similar symptoms that only may be properly diagnosed by intracranial pressure

monitoring. A major advantage with the present invention is that intracranial pressure monitoring may be performed in patients that are moving freely around. In these cases intracranial pressure monitoring in bed-ridden patients does not give reliable results. Proper treatment in these patients has major effect on the quality of life. The invention also may be used in children and adults with questions of increased intracranial pressure due to other disease states (e.g. pseudotumour cerebri, cerebral vein thrombosis, craniosynostosis, and hydrocephalus). In these cases continuous intracranial pressure monitoring provides invaluable information in addition to the clinical and radiological examinations.

[0078] The following examples are intended to illustrate various aspects of the present invention, and are not intended to limit the scope thereof.

EXAMPLE 1

[0079] Continuous intracranial pressure monitoring was performed in a girl aged 2 years and 11 months because of suspected shunt failure. In this girl an extracranial shunt was previously placed because of hydrocephalus. Shunt failure was suspected because of headache, lethargy and irritability. In fact, these symptoms may be caused by either increased, reduced or normal intracranial pressures. The results of intracranial pressure monitoring during sleep in this girl were as follows: Mean intracranial pressure 14.4 mmHg, range 0.1-67.3 mmHg, std 5.7 mmHg. The duration of intracranial pressure monitoring was 544 minutes. A mean pressure of 14.4 mmHg is by most physicians considered as borderline whereas a pressure above 15 mmHg is considered as abnormal. Therefore, no indication for surgery (shunt revision) was found on the basis of the intracranial pressure monitoring. The girl was not treated which resulted in lasting symptoms of headache and lethargy for more than 2 years. A retrospective analysis of the intracranial pressure curve was performed by means of the method according to the invention. FIG. 4 shows a matrix of intracranial pressure elevations of different levels and durations that was calculated, clearly demonstrating a high number of abnormal intracranial pressure elevations, for instance a high number of intracranial elevations of 25 mmHg or above. This case serves as an example of an intracranial pressure curve that was misinterpreted because the curve was interpreted on the basis of classical criteria. Mean intracranial pressure was within acceptable values. Application of the present software added significant new information that would have changed the decision making in this patient.

EXAMPLE 2

[0080] Continuous intracranial pressure monitoring was performed in a 3 years and 10 months old boy due to suspected premature closure of the cranial sutures. The boy had symptoms of increased intracranial pressure. During sleep the data of the intracranial pressure curve were as follows: Mean intracranial pressure 15.4 mmHg, range 0-57.1 mmHg, std 6.0 mmHg, and time of pressure recording 480 min. On the basis of the results of intracranial pressure monitoring, surgery was performed. A cranial expansion procedure which is a rather major procedure, was performed to increase the cranial volume and thereby reduce intracranial pressure. However, after surgery the patient still had symptoms of intracranial hypertension. Therefore it was

decided to repeat the intracranial pressure monitoring, that was undertaken six months after surgery. The data for this monitoring during sleep were as follows: Mean intracranial pressure 15.2 mmHg, range 5.5-39.4 mmHg, std 3.9 mmHg, and time of intracranial pressure recording 591 min. This new intracranial pressure monitoring was inconclusive because mean intracranial pressure was unchanged after surgery. In retrospect, the monitoring of intracranial pressure was without purpose since no conclusions could be drawn on the basis of the pressure recordings. Though the pressure was unchanged after surgery, it was decided not to perform a new operation though the results of intracranial pressure monitoring did not document any reduction of intracranial pressure after cranial expansion surgery. A "wait and see" policy was chosen on the basis of intracranial pressure monitoring. However, when the method according to the present invention was applied retrospectively to the intracranial pressure curves before and after surgery, it was found a marked and significant reduction of number of intracranial pressure elevations. The numbers of intracranial pressure elevations of different levels and duration's before and after surgery is presented in Table 1. The results documents that surgery had a major effect in reducing the number of intracranial pressure elevations despite an unchanged mean intracranial pressure. After surgery, there were no elevations of 40 or 45 mmHg, the number of elevations of 25, 30 or 35 mmHg were markedly and significantly reduced, whereas the number of intracranial pressure elevations of 20 mmHg were not significantly changed. Accordingly application of this method would have justified no re-operation in a stronger and more reliable way. The patient has been followed for an observation period of 2 years without surgery and has shown a satisfactory development in this period.

[0081] The invention described here is markedly different from the methods and equipment described in the prior art: (a) The apparatus is a minicomputer and may be powered by a rechargeable battery. Thereby the apparatus may be carried by the patient thus providing a more physiological monitoring of intracranial pressure. The currently available apparatuses for intracranial pressure monitoring are stationary apparatuses requiring the patient to be bed-ridden during monitoring. (b) The present apparatus allows the digital storage of a large number of intracranial and blood pressure recordings, different from the currently available apparatuses. (c) This invention is primarily designed for analysis of intracranial and blood pressure off-line, that is after the end of 24-48 hours continuous intracranial pressure monitoring. The currently available equipment for intracranial pressure monitoring are designed for on-line monitoring allowing immediate interventions to modify pressure in critically ill patients in the intensive care unit. (d) The method and software for analysis of intracranial pressure described here has not been previously described. The main advantage of the method is that the intracranial and blood pressure curves is presented in a very accurate way that in a reliable way indicate whether the intracranial pressure curve is normal or not. For the patients described here, accurate information from the intracranial pressure curve is obligatory since the results have major impact on the decision for major surgery or not. (e) The software allows standardizing the pressure data, something that facilitates comparison of pressure curves between different patients, as well as before and after treatment. This is required in some situations when it is questionable whether the effect of surgery has been

obtained. (f) The method and software provide an easily understandable presentation of the intracranial pressure curve that may be easy to use for the physician in his daily clinical work, not requiring time-consuming evaluation of the intracranial pressure curve.

[0082] While particular embodiments of the present invention have been described herein, it is to be understood that various changes, modifications, additions and adaptations are within the scope of the present invention, as set forth in the following claims.

1. Method for measuring and analyzing pressure in a patient, comprising the steps of

applying a pressure sensor to the patient,

sampling, at selected intervals, a signal from the sensor representative of said pressure,

converting the sampled signal to digital form and storing the digital sample value along with a time reference,

analyzing the stored sample values in order to generate a presentation of at least one of the following:

number of pressure elevations with any selected combination of level and duration,

number of pressure changes with any selected combination of level difference and duration of change,

number of single pulse pressure waves with preselected characteristics regarding minimum, maximum, amplitude, latency and rise time.

2. Method according to claim 1, wherein the step of applying a pressure sensor involves implanting the sensor in a body cavity of the patient.

3. Method according to claim 1, wherein the step of applying a pressure sensor involves applying a non-invasive technique with a sensor using acoustic measuring signals.

4. Method according to claim 1, wherein the step of applying a pressure sensor involves applying a sensor for measuring blood pressure.

5. Method according to claim 1, wherein the measurements are made while the patient is free to move about.

6. Method according to claim 1, wherein the presentation generated is in the form of absolute numbers, percentages or numbers per time unit.

7. Method according to claim 1, wherein the sampling rate is at least 10 Hz, and the measurements are taken over a period of at least 24 hours.

8. Method according to claim 7, wherein the sampling rate is at least 100 Hz.

9. Method according to claim 7, wherein the sampling rate is at least 150 Hz.

10. Method according to claim 7, wherein the measurements are taken over a period of at least 48 hours.

11. Apparatus for recording and storing pressure recordings from a pressure sensor applied to a patient, comprising

a first connector for connecting the apparatus to a pressure sensor,

an analog-to-digital converter for converting received pressure measurements to digital form,

processing means in communication with the analog-to-digital converter, capable of reading out samples of the

digitally converted pressure measurements and storing said measurements in a data memory connected to said processing means,

input/output interface in communication with the processing means and connected to a second connector for connecting the apparatus to external computing means, and

a power source for supplying the apparatus with power.

12. Apparatus according to claim 11, further comprising a galvanic circuit connected to the first connector for preventing the transfer of electrical energy from the apparatus towards the sensor.

13. Apparatus according to claim 11, further comprising a signal conditioner for removing noise from the received pressure measurement signals.

14. Apparatus according to claim 13, wherein said signal conditioner is an analog filter connected between the first connector and the analog-to-digital converter.

15. Apparatus according to claim 13, wherein said signal conditioner is a digital filter connected to the output of the analog-to-digital converter.

16. Apparatus according to claim 11, further comprising an input control for entering control and calibration signals.

17. Apparatus according to claim 11, further comprising a display connected to said processing means.

18. Apparatus according to claim 11, wherein said data memory further contains instructions controlling the operation of the processing means.

19. Apparatus according to claim 11, further comprising an alarm circuit capable of generating an audible or visual alarm upon detection of low memory capacity in the data memory or low power capacity in the power source.

20. Apparatus according to claim 11, wherein said data memory is a random access memory (RAM) circuit.

21. Apparatus according to claim 11, wherein said data memory is a magnetic storage device.

22. Apparatus according to claim 11, wherein the processor and the analog-to-digital converter in combination are capable of sampling the received pressure measurements with a sampling rate of at least 10 Hz.

23. Apparatus according to claim 22, wherein the sampling rate is at least 100 Hz.

24. Apparatus according to claim 22, wherein the sampling rate is at least 150 Hz.

25. Apparatus according to claim 11, wherein the processor is programmable through input control means to operate with a sampling rate between a minimum sampling rate and a maximum sampling rate.

26. Apparatus according to claim 11, wherein said data memory has a capacity which allows the storage of at least 24 hours of continuous sampling of the received pressure measurements at maximum sampling rate.

27. Apparatus according to claim 11, wherein said data memory has a capacity which allows the storage of at least 48 hours of continuous sampling of the received pressure measurements at maximum sampling rate.

28. Apparatus according to claim 11, comprising a plurality of input connectors and means for multiplexing pressure signals from said input connectors for the simultaneous recording of pressure signals from more than one pressure sensors.

29. System for the analysis of recorded pressure data, comprising

communication interface for receiving a set of digital pressure sample values;

data memory for storing the received sample values;

processing means with access to said data memory, capable of analyzing said sample values in order to determine at least one of the following:

number of pressure elevations with any selected combination of level and duration,

number of pressure changes with any selected combination of level difference and duration of change,

number of single pulse pressure waves with preselected characteristics regarding minimum, maximum, amplitude, latency and rise time;

video interface in communication with said processing means and capable of, in combination with the processor means, generating a visual presentation of the result of any analysis performed on the pressure sample values together with a graphical user interface;

a display for displaying the generated visual presentation; and

input means allowing a user of the system to enter and change parameters on which said analysis should be based.

30. System according to claim 29, wherein said parameters include at least some of the following:

pressure intervals defining a number of pressure elevations, pressure change intervals defining a number of pressure change step sizes, time intervals defining a number of durations, pressure wave characteristics including minimum, maximum, amplitude and latency, selection of type of analysis, and selection of presentation of numbers as absolute numbers, percentages or numbers per time unit.

31. Computer program product for controlling a computer on which is stored a set of values representing pressure samples with a time reference, comprising program instructions for causing the computer to perform the steps of

receiving from a user interface or as pre stored default values a set of parameters on which an analysis of said set of samples should be based;

analyzing said sample values in order to determine at least one of the following:

number of pressure elevations with any selected combination of level and duration,

number of pressure changes with any selected combination of level difference and duration of change,

number of single pulse pressure waves with pre-selected characteristics regarding minimum, maximum, amplitude, latency and rise time;

generating a visual presentation of said analysis.

32. Computer program product according to claim 31, stored on a computer readable medium.

33. Computer program product according to claim 31, carried on a propagated signal.

专利名称(译)	监测体腔内的压力		
公开(公告)号	US20020161304A1	公开(公告)日	2002-10-31
申请号	US09/843702	申请日	2001-04-30
[标]申请(专利权)人(译)	EIDE PER KRISTIAN		
申请(专利权)人(译)	EIDE PER KRISTIAN		
当前申请(专利权)人(译)	SENSOMETRICS AS		
[标]发明人	EIDE PER KRISTIAN		
发明人	EIDE, PER KRISTIAN		
IPC分类号	A61B5/00 A61B5/0215 A61B5/0245 A61B5/03 A61B5/02 A61B5/103 A61B5/117		
CPC分类号	A61B5/021 G06F19/3487 A61B5/031 A61B5/03 A61B5/02108 G16H15/00		
外部链接	Espacenet USPTO		

摘要(译)

本发明涉及一种用于监测，采样和存储患者体腔内的压力或血压的装置。该装置是用于压力评估的小型便携式记录单元，包括用于分析压力记录的软件。例如植入的压力传感器在患者的头骨中感知压力并输出指示患者头骨中的压力的信号。指示压力的信号被转换成数字信号并由微计算机采样和存储。该装置足够小以允许患者在压力记录期间自由移动并且不会卧床不起。通过该装置对颅内压进行取样和储存，每秒数次，持续数天。压力采样结束后，数据被传输到计算机或网站进行分析。本发明包括用于分析压力的新方法以及用于执行分析的软件。计算机软件提供压力曲线的不同定量表示，作为不同水平或持续时间的颅内压升高的矩阵，不同水平和持续时间的压力变化矩阵，或预先选择的单脉冲压力波数的矩阵特点。

