(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
7 November 2002 (07.11.2002)

PCT

(10) International Publication Number
WO 02/087435 A1

(51) International Patent Classification[7]: A61B 5/03 // 5/02

(21) International Application Number: PCT/NO02/00164

(22) International Filing Date: 29 April 2002 (29.04.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
09/843,702 30 April 2001 (30.04.2001) US

(63) Related by continuation (CON) or continuation-in-part (CIP) to earlier application:
US 09/843,702 (CIP)
Filed on 30 April 2001 (30.04.2001)

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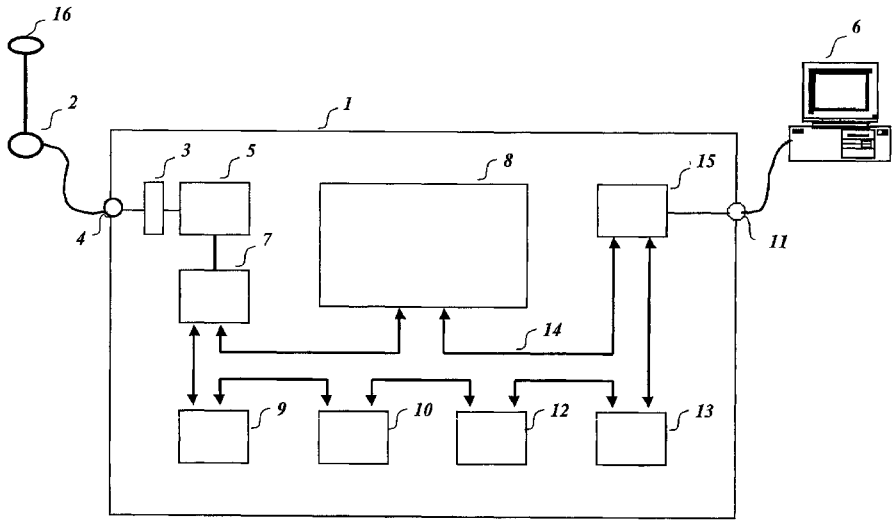
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

[Continued on next page]

(54) Title: DEVICE, METHOD AND SYSTEM FOR MONITORING PRESSURE IN BODY CAVITIES



(57) Abstract: The present invention relates to a system and method for digital sampling, quantitative analysis and presentation of pressures in a body cavity. The invention also relates to a portable apparatus for monitoring, sampling and storing pressure and a software for analysis of pressures. The invention includes an algorithm for analysis and presentations of pressures and a software for performing the analysis. The computer software may be integrated in the portable apparatus and in a variety of systems. The software provides different quantitative presentations of pressure curves as a matrix of numbers of intracranial pressure elevations of different levels and durations and a matrix of numbers of single pulse pressure waves with preselected characteristics. The parameters may be standardised according to recording time and heart rate variabiity. The data may be presented indifferent ways, both on-line and off-line after pressure monitoring.

WO 02/087435 A1

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DEVICE, METHOD AND SYSTEM FOR MONITORING PRESSURE IN BODY CAVITIES

BACKGROUND OF THE INVENTION

Field of the Invention

The present invention relates to a method, an apparatus, a system and a computer program product for monitoring and analyzing the pressure within a cavity in a patient, and more specifically, but not by way of limitation, apparatuses, methods and systems for monitoring and analyzing intracranial pressure and blood pressure, or pressures in other body cavities (e.g. cerebrospinal fluid space). The invention includes an apparatus for sampling, recording, storing and processing pressure measurements, a method, a system and computer software for quantitative analysis of the pressure. The invention aims at providing a technical solution for digital pressure monitoring in patients that are free to move about, as well as a technical solution for comparisons of continuously recorded pressures between patients and within patients. The computer software may be used in the portable apparatus described here or integrated in various computer systems or vital sign monitors.

Related Art

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. So-called infusion tests were introduced in 1970 by Katzman and Hussey. Infusion tests may be performed in a variety of ways, basically by measuring pressures in cerebrospinal fluid while a fluid is introduced into the cerebrospinal fluid cavity. 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 sensor is implanted within the skull of the patient, the sensor is connected to a pressure transducer that is connected to the monitoring system of the patient.

Intracranial pressures may be measured by different strategies. Solid or fibre-optic transducers may be introduced into the epidural or subdural spaces, or introduced into the brain parenchyma. Intracranial pressure also may be recorded directly by measuring pressure in the cerebrospinal fluid, requiring application of catheter to the cerebrospinal fluid space (most commonly in the cerebral ventricles or the lumbar spinal cavity). During infusion tests the pressure in the cerebrospinal fluid is recorded.

A number of intracranial pressure sensors and microtransducers are commercially available, both solid and fibre-optic transducers. The most commonly used invasive transducers include the Codman® Micro Sensor ICP Transducer (Codman & Shurtlef Inc., Randolph, MA) and the Camino® -110-4B (Camino Laboratories, San Diego, CA). Others are ICP Monitoring Catheter Kit OPX-SD (InnerSpace Medical, Irvine), Epidyn® (Braun Melsungen, Berlin), Gaeltec® ICT/B (Novotronic GmbH, Bonn), HanniSet® (pvb 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 equipments for intracranial pressure monitoring include: Codman ICP Express (Codman & Shurtlef Inc., Randolph, MA) and Camino OLM 110-4B (Camino Laboratories, San Diego, CA). The equipments may be connected to other monitor systems. The equipments 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.

In not-critically ill patients outside the intensive care unit, continuous intracranial pressure monitoring has been less extensively used. Such patient groups include children with potential intracranial hypertension caused by hydrocephalus, craniosynostosis, shunt dysfunction, or other problems. In adults, clinical entities such as normal pressure hydrocephalus are included. 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 pre-operative 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. 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 equipments 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 require the patient to be bedridden, thereby providing a less physiological monitoring of intracranial pressure. The currently available equipments for this type of monitoring are not 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. The development of non-invasive pressure transducers, as well as the development of pressure transducers that may be implanted within a human body cavity increases the need for portable apparatuses for pressure sampling and monitoring.

In the clinical setting, the question may be whether a continuous pressure recording of several hours is normal, borderline or abnormal. Continuous intracranial pressure curves usually are evaluated by calculation of mean intracranial pressure. With regard to rises in pressure most authors identify so-called pressure waves: Lundberg's A waves (50-10 mmHg lasting 5–20 minutes), B waves (up to 50 mmHg with a frequency 0.5-2/min), and C waves (up to 20 mmHg with a frequency 4-8/min). However, the description of such waves is quite subjective and based on a morphological description of the waves. Actually the various authors differently describe such waves.

The present invention deals with strategies to analyze single pulse pressure waves, and make analysis of these waves available to the daily clinical practice. The fluctuations of intracranial pressure arise from cardiac and respiratory effects. The intracranial pressure cardiac waves or cerebrospinal fluid pulse waves result from the contractions of the left cardiac ventricle. The intracranial pressure wave or the cerebrospinal fluid pulse wave resemble the arterial blood pressure wave, that is characterized by a systolic rise followed by a diastolic decline and a dicrotic notch. In addition, changes in pressures associated with the respiratory cycle affect the intracranial pressure wave. The morphology of the intracranial pulse pressure wave depends on the arterial inflow, venous outflow, as well as the state of the intracranial contents. The single pulse pressure waves of intracranial pressure include three peaks that are consistently present, corresponding with the arterial pulse waves. For a single pulse pressure wave the maximum peak is termed P1 or top of the percussion wave. During the declining phase of the wave, there are two peaks namely the second peak (P2), often termed the tidal wave, and the third peak (P3), often termed the dicrotic wave. Between the tidal and dicrotic waves is the dicrotic notch that corresponds to arterial dicrotic notch. In the present application, the amplitude of the first peak ($\Delta P1$) is defined as the pressure difference between the diastolic minimum pressure and the systolic maximum pressure, the latency of the first peak ($\Delta T1$) is defined as the time interval when pressures increases from diastolic minimum to systolic maximum. The rise time ($\Delta P1/\Delta T1$)) is defined as

the coefficient obtained by dividing the amplitude with the latency. The morphology of the single pulse pressure wave is intimately related to elastance and compliance. Elastance is the change in pressure as a function of a change in volume, and describes the effect of a change in volume on intracranial pressure. Compliance is the inverse of elastance and represents the change in volume as a function of a change in pressure. Therefore, compliance describes the effect of a change in pressure on craniospinal volume. Elastance is most useful clinically as elastance describes the effect of changes in intracranial volume on intracranial pressure. The relationship between intracranial pressure and volume was described in 1966 by Langfitt and showed an exponential curve, where the slope of any part of the curve resembles the rise time of a single wave (that is $\Delta P/\Delta T$ or change in pressure/change in volume). The curve is termed the pressure-volume curve or the elastance curve. The horizontal part of the curve is the period of spatial compensation whereas the vertical portion is the period of spatial decompensation. When elastance increases also the amplitude of a single pulse pressure wave increases due to an increase in the pressure response to a bolus of blood from the heart. It has, however, not been possible to take the knowledge of single wave parameters into daily clinical practice.

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. Though there are large amounts of experimental data concerning single pulse pressure waves and their relationship to the pressure volume curve, the clinical application of this knowledge has not been straightforward. During continuous intracranial pressure monitoring in clinical practice the single pulse pressure waves are not assessed and used in the decision making. An indirect approach has been Fast Fourier Transformation or spectral analysis to assess the frequency distribution of the various waves. Strategies to examine the pressure volume relationship in a single patient have involved infusion of fluid to the cerebrospinal fluid space or inflation of a balloon, but these strategies are invasive, and neither involve assessment of single pulse pressure waves. In the clinical context, methods to explore the pressure-volume relationships or elastance by analysis of the pressure curve are lacking. There are no strategies that make it possible to determine accurately where a single patient is on the elastance curve.

In the intensive care unit, continuous intracranial pressure monitoring usually presents the pressures as mean pressure in numerical values, or as a curve that has to be visually analyzed. Though single waves may be displayed on the monitor, strategies to explore trends in changes of single wave characteristics are lacking.

Furthermore, strategies to continuously examine compliance solely on the basis of the pressure curves have not been established.

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 durations. Obviously, for different intracranial pressure curves equal mean intracranial pressures 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 are 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 as 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 are 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. Similarly, accurate criteria for the normal variation of blood pressure are lacking. The current criteria are wide.

Strategies to accurately compare pressure recordings (either within or between individuals) are sparse. With regard to intracranial pressure, mean intracranial pressure may be compared or the distribution of plateau waves (A- or B-waves). With regard to blood pressure, systolic and diastolic pressure may be compared. Nevertheless, the strategies remain subjective and not very precise. Accurate comparisons of pressures within individuals might be useful for comparing pressures before and after treatment (for example blood pressure treatment), as well as detecting changes in pressure trends in patients undergoing continuous pressure monitoring. The ability to accurately compare pressure recordings between individuals might be helpful in establishing normative criteria for pressures within a human body cavity. For example, presently it is not possible to compare the pressures of an individual against a reference curve.

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.

SUMMARY OF THE INVENTION

On this background the applicant developed technical solutions for monitoring pressures in patients that are free to move about, for accurate digital sampling and analysis of pressure recordings, as well as a technical solution for comparing pressure recordings within or between individuals.

An apparatus was developed allowing direct communication between the pressure transducer and a computer (that is add-on to computers such as medical device computers, vital signs patient monitors, or as a stand-alone system for sampling of pressure recordings). Furthermore, a new algorithm for sampling, analysing and presenting pressure recordings was developed and incorporated in computer software. The computer software records, samples, analyses, and provides various outputs of the pressure recordings. The technical solution may be applied to a variety of pressures such as intracranial pressures (or cerebrospinal fluid pressures), blood pressures, or other body cavity pressures. Invasive or non-invasive sensors may record pressures.

According to the invention, the intracranial pressure curve is quantified in different ways. The pressure recordings may be presented as a matrix of numbers of intracranial pressure elevations of different levels (e.g. 20, 25 or 30 mmHg) and durations (e.g. 0.5, 1, 10 or 40 minutes), or a matrix of numbers of intracranial pressure changes of different levels and durations. The pressure recordings also may be presented as a matrix of numbers of single pulse pressure waves of certain characteristics. In this context, elevations are understood as rises in pressure above the zero level that is relative to the atmospheric pressure. An elevation of 20 mmHg represents the pressure of 20 mmHg relative to the atmospheric pressure. Pressure changes represent the differences in pressures at different time stamps. A pressure change of 5 mmHg over a 5 seconds period represents the differences in pressure of 5 mmHg over a 5 seconds measuring period. It should be understood that each pressure recording is measured along with a time stamp. All pressure signals are measured along a recording time. Similar analysis can be made for blood pressure and cerebral perfusion pressure.

With regard to sampling, analysis and presentation of single pulse pressure waves, relative differences in pressures and relative time differences are computed. The

analysis is not relative to the zero level or the atmospheric pressure, therefore the results of data analysis are not affected by the zero level or drift of zero level.

By means of the invention used as stated above, the applicant was able to show in a 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 durations in a sensitive way revealed changes in intracranial pressure after surgery. Comparing mean intracranial pressure before and after surgery did not reveal these changes. 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 Lundbreg's A, B or C waves.

With regard to single pulse pressure waves, the invention provides measurement and analysis of the following parameters:
a) Minimum is defined as the diastolic minimum pressure of the single wave, or as the valley of the wave.
b) Maximum is defined as the systolic maximum pressure of the single wave, or defined as the peak of the wave.
c) Amplitude is defined as the pressure difference between the systolic maximum pressure and the diastolic minimum pressures during the series of increasing pressures of the single wave.
d) Latency is defined as the time of the single wave when the sequence of pressures increases from minimum pressure to maximum pressure.
e) Rise time is defined as the relationship between amplitude divided by latency, and is synonymous with the rise time coefficient.
f) Wavelength is defined as the duration of the single pulse pressure wave when pressures changes from minimum and back to minimum, and reflects the heart rate.

As mentioned in the Related Art section, amplitude, latency and rise in the present invention is referring to the first peak (P1). This does not represent a limitation of the scope of the invention, however, as amplitude, latency and rise time also may be calculated for the second (P2) and third (P3) peaks as well.

By means of the invention the applicant showed that quantitative analysis of characteristics of single pulse pressure waves revealed important and new

information about the pressures. Both these latter parameters are important for assessment of abnormal pressures. The applicant has demonstrated (not published) that parameters of the single pulse pressure waves analyzed and presented quantitatively, provide information about compliance and elastance.

The quantitative method was developed for various pressures such as blood pressure, intracranial pressure (subdural, epidural, intraparenchymatous, or cerebrospinal fluid pressure), and cerebral perfusion pressure.

Furthermore, the quantitative method was developed for offering different types of data presentations:
a) matrix presentations of numbers or percentages of single pulse pressure waves with pre-selected characteristics during a recording period,
b) graphical presentations of single pulse pressure waves with the opportunity to compare single waves, either between individuals, against a reference material or within the same individual at different time intervals,
c) various types of statistical handling of the data are possible.

This invention relates to a method, an apparatus, a system and a computer program product for recording pressure in a human body cavity (invasively or non-invasively), sampling and processing the recorded pressure signals, performing mathematical analysis, and providing presentations of the recorded and analysed data (either via monitors, flat screens, or integrated in computer systems).

One object of the present invention is to provide a technical solution for continuous digital sampling of pressures 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.

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 at least 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 at least 150 Hz. The data may be transferred via the serial port to a personal computer or network connection for further analysis. During monitoring of single pulse pressure waves, a frequency of 100 Hz will be acceptable for monitoring single waves, with parameters related to the first peak (P1).

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, or other signals recorded by non-invasive devices. Thus, the algorithm for analysis of pressures may be used whether pressure signals are derived from invasive or non-invasive devices.

Another object with the invention is to provide a technical solution for monitoring intracranial pressures without being dependent on the zero level (i.e. calibration against the atmospheric pressure). This is particularly important for pressure sampling by means of non-invasive sensors. An object of the invention is to provide a solution for analysis and presentation of continuous intracranial pressure recordings obtained by non-invasive sensors.

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.

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. The different pressures may be monitored simultaneously.

Yet another object of the present invention is to provide software for the quantitative analysis and presentation of continuous pressure recordings 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 numbers of single pulse pressure wave parameters with selected characteristics.

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 (such as the cerebrospinal fluid cavities).

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. Assessment of single pulse pressure waves preferentially requires a sampling rate of 100 Hz or above. As an alternative to numbers, percentages may be computed. Any point of the single waves may be calculated, and different parameters of the waves may be computed. There is a fundamental difference between computation of number of pressure elevations with any selected combination of level and duration and number of pulse pressure waves with preselected characteristics regarding minimum, maximum, amplitude, latency and rise time. The first method computes pressures relative to a zero level (i.e. atmospheric pressure), whereas the latter method computes relative differences in pressures and time and therefore is independent on the zero level.

One object of the invention is to provide a system for handling single pulse pressure waves in a way that pressures from a single subject may be superimposed on the pressure-volume (elastance) curve providing information about the elastance. This solution provides one of several strategies of early detection of decompensation of pressures, before the conventional methods.

One object of the present invention is then to provide a system for quantitative and accurate comparisons of pressure recordings/curves when assessing pressure in a body cavity or blood pressure. Comparisons may be made between different continuous pressure curves that include different recording periods, different heart rates, as well as different zero levels. Comparisons of continuous pressure recordings may be made both between individuals and within individuals (that is before and after treatment or comparisons of pressure recordings at different time intervals). This system includes a new algorithm integrated in computer software. The algorithm includes quantitative approaches for analysis of the pressure recordings and strategies to present the recordings. The system may be integrated in commercially available pressure transducer devices, in computer servers or in medical device computers or in the portable apparatus for pressure monitoring described here.

The technical solution of comparing various continuous pressure curves involves standardisation procedures. The numbers/percentages during a given recording period may be standardized to numbers/percentages during a standardized recording period (e.g. one or 10 hours) and a standardized heart rate. For different individuals the quantitative data for a given recording period may be standardised to a selected recording period (for example numbers/percentages during one

minute, one hour or 10 hours recording period), as well as standardised to a selected heart rate (for example heart rate of 60 each minute). Thereby, continuous pressure recordings for different individuals may be compared. This strategy may provide the opportunity for development of reference curves, on the basis of recordings in several individuals. Comparisons of pressure curves for individual cases also become possible. During real time and on-line pressure monitoring, changes in pressure trends may be explored. For example, numbers of pressure characteristics during one hour of pressure recording may be compared at different time intervals.

As compared to the traditional monitoring of mean intracranial pressure, assessment of parameters of single waves may provide early warning of changes in brain compliance, allowing early intervention to reduce pressure.

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.

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. This implies that the system may be integrated in different computer servers, medical device computers or vital sign monitors. Therefore, the apparatus described here represents no limitation by which the invention may be applied.

The output computed by the software may be presented in a number of ways, including matrix of numbers, graphical presentations, and comparisons of pressures

in an individual against a reference material or against previous recordings of the individual.

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.

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

FIG. **1** is a block diagram of the various components of a system according to the invention.

FIG. **2** is a graphical user interface used for presenting pressure-sampling results.

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

FIG. **4** shows a part of the graphical user interface of FIG. **3** for different levels and duration's.

FIG. **5** is a graphical user interface for presenting pressure-sampling results.

FIG. **6** is a presentation of comparisons of pressure curves within an individual.

FIG. **7** is a presentation of the parameters measured during analysis of single pulse pressure waves.

FIG. **8** is parts of graphical user interfaces for presentation of single pulse pressure waves.

FIG. **9** is graphical user interfaces for presentation of pressure recordings and parameters of single pulse pressure waves during an infusion test.

FIG. **10** is a presentation of comparisons of parameters of different types of single pulse pressure waves.

FIG. **11** is a block diagram of different applications of the invention.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

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 **16**, a pressure transducer **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.

As a result of its compact construction and lightweight, a patient can easily carry the apparatus **1**. The apparatus **1** may be fastened to the belt of the patient or kept in a carry pouch with straps. Alternatively, the apparatus **1** may be used as an interface for connecting the network station or personal computer **6** to the pressure sensor **2**. This allows real time online monitoring of pressure so that the pressure curves may be displayed on a display. The different applications of the apparatus **1** as well as modifications in the construction of the apparatus **1** are further illustrated in FIG. **11**.

In an embodiment of the invention, the pressure sensor **16** is implanted within the body cavity within which pressure is to be measured, such as the skull of the patient. The sensor **16** is connected to a pressure transducer **2**, which in turn is connected to the apparatus **1** via a connector **4**. People known in the art would know that sensor and transducer are not identical in the sense that the sensor itself detects various types of physical forces, whereas the transducer converts the signal from the sensor to either a voltage or a current signal. There is no limitation of the type of pressure sensors that may be connected to the apparatus **1**. Various types of pressure sensors **16** and transducers **2** are commercially available, including transducers for non-invasive pressure assessment, using acoustic, or other types of signals. Other sensors **16** may detect pressure within a fluid space such as the cerebrospinal fluid space. Independent of the type of signals, the signals are converted from analogue to digital form in an analogue to digital converter **7**.

Most commercially available sensors **16** give an analogue signal on the basis of a mechanical action on the sensor. Within the pressure transducer **2** the signals from the sensor is converted to a signal that may either be a voltage or current signal. The pressure transducer **2** then produces a continuous voltage or current signal. The voltage or current signals from the transducer are further processed within the signal conditioner **5**. The analogue signals are converted to digital signals within the analogue to digital converter **7**. Certainly various modifications are possible.

When data are collected from for example a vital signs monitor both the pressure transducer **2** and the analogue to digital converter **7** may be built into the vital signs monitor. The digital signals are handled according to the invention.

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 **8** operating in accordance with instructions stored in memory **9** and communicating with the various parts of the apparatus over a common data bus **14**. However, a number of variations are possible. Instead of using a central processing unit **8** and instructions stored in memory **9**, the functionality of the apparatus **1** could be constructed directly in hardware, e.g. as ASICs. The apparatus represents no limitation for the use of the system for the analysis and presentation of pressures described here.

The main components of the apparatus **1** are then 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. An input/output interface **15** allows data stored in the memory **9** to be transferred to the network station or personal computer **6** for processing. 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).

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**. 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. Signal processing in the conditioner **5** 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 **5** will then be positioned following the conversion of the sampled signal from analog to digital.

Besides, the software computes the number of artifacts during a recording period, and the artifact ratio. The program includes an option for excluding recordings when the artifact ratio is above a selected level.

After the signal conditioner **5** has processed the analog signals, 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.

As has already been mentioned, the apparatus **1** is here described as receiving signals indicative of the intracranial pressure from sensors **16** 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 **1** must be constructed with a signal conditioner **5** for a specific purpose or whether the same signal conditioner **5** allows for different uses, with or without re-programming, is dependent on implementation and specific needs. If the apparatus **1** is intended to work with various sensors **16** 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 **1** and the analog to digital converter **7**.

The apparatus **1** is programmable including an input control **10**, with a simple key board for entering a few commands. The input control **10** has a calibration function that allows calibration of the pressure sensor **16** against the atmospheric pressure, before the sensor **2** 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. It should be noted, however, that this invention also describes a method for recording and analysis of relative continuous pressure recordings that are not related to the atmospheric pressure, and are independent of a zero level. The input control **10** also contains a function for selecting the interval of pressure recordings. The pressures may be recorded with variable sampling frequency, e.g. from about 1 - 10 Hz up to at least 150 Hz (most preferably between 100 and 200 Hz). When single pulse pressure waves are monitored, the sampling frequency preferentially is 100 Hz or above. 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). 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.

Functions on the input control **10** for the physician preferably includes 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.

Via a connector **11**, data may be transferred to the 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**.

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

An internal battery (not shown) powers the apparatus **1** that preferably is rechargeable, but with input for external power supply (not shown).

In a preferred embodiment, the apparatus **1** 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.

In addition to the battery that powers the apparatus **1** while in use, the apparatus **1** may include an additional battery that serves to maintain data in the volatile part of the memory **9** 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 **1**, 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.

As mentioned before, the apparatus **1** may be connected to a personal computer **6** via the serial port **11**. Alternatively the apparatus **1** may be connected to another digital computer-based monitoring system **6** 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 **1** functions as an interface for a stationary personal computer or flat screen. Different applications are illustrated in FIG. **11**.

The apparatus **1** 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.

The apparatus **1** has been described above with only one channel for receiving pressure signals from one pressure sensor. The apparatus may, as mentioned before, 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**. 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.

The invention also relates to a method for measuring and analyzing pressure in a patient. This method will now be described.

First a signal from a pressure sensor **16** and transducer **2** representative of pressure in a body cavity is received and sampled at selected intervals. This signal is converted to digital form **7** and stored along with a time reference representative of the time at which the sample was made **9**. 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.

The stored sample values may then be analyzed in order to generate a presentation regarding a time period 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 pre-selected characteristics such as minimum, maximum, amplitude, latency and rise time.

This type of analysis may be performed either on-line or off-line. During on-line analysis, analysis is performed repeatedly and presented repeatedly during real-time on-line monitoring. This allows for comparisons of pressure characteristics at

repeated intervals. Off-line analysis is performed after the recording period has been ended.

In order to analyze number of pressure elevations with any selected combination of level and duration occurring in a time period, 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.

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.

An analysis of single 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. Pre-selected characteristics identifying a pressure wave of interest 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 pre-selected characteristic may be the rise time of the single wave.

The pressure sensor **16** may be applied by implanting the sensor in a body cavity of the patient, but it may also be applied by a non-invasive technique with a sensor using acoustic measuring signals, ultrasonic or Doppler, or even a pressure sensor for measuring blood pressure. In general, a problem with non-invasive sensors recording intracranial pressure, is the lack of a zero level since intracranial pressure is calibrated against atmospheric pressure. The present invention solves this problem by computing the relative differences in pressure during single pressure wave analysis. Thereby the need for a zero level is excluded.

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 **6** 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.

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 at least 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**.

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.

The computer is not shown in detail. It 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.

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.

The operation of the computer **6** will preferably be controlled by computer program instructions stored in the computer **6** 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.

FIG. **2** illustrates the graphical user interface of the computer software used for presenting the results of the sampling described above. The software processes the digital pressure signals. Before the continuous pressure recordings are presented in the graphical user interface as shown in FIG. **2**, the pressure signals are sampled and averaged. With regard to FIG. **2**, the sample update rate was in the range 30 to 100 Hz and the update rate (average interval) was in the range 1 to 5 seconds. The update rates may vary between 1 – 10 Hz for low frequency sampling. Modern vital signs monitors may offer a computer interface producing this type of averaging. Various modules of the software generate output or can be invoked through this interface. The intracranial 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. The curve **34** presented in the window in FIG. **2** represents about 21 hours recording time (that is actual recording time). A special function **24** allows simple statistical analysis of the data presented in the window (with calculations of mean, standard deviation, median, ranges and time of recording). Another function **25** transfers to a software module that performs quantitative analysis of a single intracranial pressure curve in accordance with the invention. The results of this analysis are described below with reference to FIG. **3-6**. 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 smoothened 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 for controlling the sampling process. If the apparatus has collected pressure samples from several pressure transducers **2**, e.g. intracranial and blood pressure, these may be simultaneously

analyzed. The functions are linked up to the pressure recordings displayed in the window. Any type of pressure may be presented in this way.

The size of the window, that is the observation time may be changed to reveal the single pulse waves. Each single pulse wave is built up from a blood pressure wave. Comparable to the heart rate, during one minute of recording often about 50-70 single pulse waves may be recorded. There is, however, a large variation in heart rate both between and within individuals, accordingly there is a variation in the numbers of single pulse intracranial or blood pressure waves during one minute recording.

The graphical interface in FIG. **2** represents one example of presenting/displaying the various functions. Various modifications are possible. Simultaneous presentations of the continuous pressure recording curves of different pressures (e.g. intracranial pressure, blood pressure, cerebral perfusion pressure) may be presented in the same window. The continuous recordings are presented real time so that the different types of pressures may be compared. Modifications in the graphical interface may be performed whether the pressure monitoring is intended for on-line or off-line monitoring. During on-line monitoring, statistical analysis may be computed repeatedly, to allow comparisons between different time intervals. The real-time continuous pressure curve may be presented in one window, the absolute pressure parameters (such as mean pressure, standard deviation, and ranges) in another window and single waves in still another window.

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.

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, or other pressures in human body cavities. The selected window of the intracranial pressure curve **34** is presented as a chart or matrix **35** of quantities of different types, derived through the invented method of analysis. Any size of the recording period **33** represented by the window may be selected for the quantitative analysis. A similar user interface is used independent on the type of pressure measured.

The mathematical functions may be implemented in the software by various routes. One implementation is shortly described. The data needed for analysis of pressure elevations of different levels and durations include the pressure recordings and the corresponding time recordings. Two variables are selected, namely the threshold levels (pressures expressed in mmHg) and the width (time expressed in seconds). A search is made for both peaks (positive-going bumps) and valleys (negative-

going bumps), and the exact levels of peaks and valleys are identified. Peaks with heights lower than the threshold or valleys with troughs higher than the thresholds are ignored. For a threshold value less or equal to zero a valley search is performed. For threshold values greater than zero a search for peaks is performed. The peak/valleys analysis is performed for every with/threshold combination in the matrix. In short, the procedure is as follows. The part of the pressure curve **34** that is to be examined is selected **33**, the data is visualised in the user interface. A suitable width/threshold matrix is selected, specifying the with/threshold combinations. The units used are time in seconds (width) **37**, and pressure in mmHg (threshold) **36**, respectively. The software records the numbers of samples that fit a given width/threshold combination. The output from the analysis is a matrix containing the numbers of all the different width and threshold combinations. An example of such a matrix **35** is given in FIG. **3**. As shown in the matrix **35**, the width/threshold combination 20 seconds/25 mmHg (that is ICP elevations of 25 mmHg lasting 20 seconds) occurred 63.00 times during the actual recording time of 21.10 hours **45**. In this matrix the numbers were not standardised to a selected recording period **42**. The pressure elevations are relative to the zero level that corresponds to the atmospheric pressure.

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. Also blood pressure may be expressed as mmHg. Independent of the type of pressure measured the pressures may be presented in the same way.

A second button **39** allows the user to select presentation of the data as a chart of numbers of intracranial pressure intracranial pressure changes of different levels **36** and duration **37**. The changes may be differences between two recordings or differences between a recording compared to a given or selected value (e.g. mean pressure).

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 user accesses an input dialog box for entering these characteristics by clicking a fourth button **41**. Each single pulse pressure wave is identified by minimum, maximum, amplitude, latency and rise time. Further details about analysis and presentation of the parameters of single pulse pressure waves are given in FIG's. **7-10**.

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

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. The data presented in FIG. **3** was based on a recording time of 21.1 hrs (actual recording time **45**), and the recordings were not standardized in this case (represented by zero in standardization input box **42**). It should be noted that standardization may be performed to various time units, such as each one minute, one hour or even 10 hours. Since the calculation of single pulse pressure waves automatically also gives the heart rate it is possible to standardize the numbers according to a given heart rate (further details given in FIG. **7**). For example, the numbers may be standardized to a given heart rate of 60/min.

The opportunity to standardize the numbers presented in the matrix is important for comparisons of pressure recordings, either within or between individuals. Thus, two matrixes **35** may be compared, for example at two different times in one individual. For example, it may be possible to calculate the numbers of single waves with certain characteristics (defined by parameters such as rise time and amplitude) during a recording time.

During on-line presentation the matrix **35** may be compared repeatedly. The whole matrix **35** may not need to be presented but only certain width/threshold combinations. Differences between certain combinations at different time intervals may be revealed. For example, the numbers or percentages of intracranial pressures of 15, 20 and 25 mmHg lasting 5 minutes during 1 hour recording period may be computed and presented each hour during on-line presentation. Normalization of data to a standardized recording time **42** and heart rate allows for accurate comparisons between different time intervals for individual cases, as well as comparisons between individuals.

For example, for blood pressure, comparisons of pressure curves may be performed before and after treatment with medications in an individual. Alternatively, pressure recordings from an individual may be compared against a normal material. A normal material may be constructed on the basis of the recordings from a large group of individuals.

The method for performing these analyses is described above, and the various buttons described above invokes software modules for performing the various steps of this method.

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.

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 matrix **35** shows numbers of elevations normalized as number of occurrences per time unit **42**. In this case the numbers are derived from a standardized recording time of 10 hours **42**, with the actual recording period 9.01 hrs **45**.

The results shown in FIG. **3** are the results of an analysis of number of pressure elevations with selected combinations of level and duration. As indicated in FIG. **4**, the stored samples have been analyzed in order to determine for how long the measured pressure level **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 **37**. The various periods of time **37** are selected as 30, 60, 300, 600, 1200 and 2400 seconds, respectively. In FIG. **4**, the results have been normalized to numbers during a 10 hours recording period **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 hrs recording period. In FIG. **3**, where the results are not normalized, all the results are integers.

During the standardisation procedure, the numbers or percentages are adjusted to a given factor. The normalised time may be chosen in each individual. An example is given. If the actual recording time is 6 hours, a standardisation to 10 hours recording time implies that all numbers or percentages of pressure elevations are multiplied with a factor equal to 10/6 (that is 1.66666).

The following example is intended to illustrate various aspects of the present invention regarding related measurements of pressure waves described in FIG.'s **2-4**, but is not intended to limit the scope thereof.

EXAMPLE 1

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, increased, reduced or normal intracranial pressures may cause these symptoms. 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. During a standardized recording time of 10 hours, intracranial pressure elevations of 25 mmHg lasting 300 seconds occurred 6.66 times. Such elevations generally are considered as abnormal. 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.

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 with selected combinations of level difference **30** and duration of change **37**. The stored samples have been analyzed in order to determine the number of pressure changes of certain sizes **30**, represented as -20, -15, 0, 1, 2, 3, 4, 5, 6, 7, 8, 9 and 10 mmHg relatively, and the duration **37** 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 that takes place over a 15 seconds has occurred on average 1.14 times per 10 hour period. Changes of 0 mmHg represent periods of time over which the pressure has remained constant. Also in this matrix the numbers have been standardized to numbers during a 10 hours recording period. The standardization procedure gives the opportunity to compare pressure curves, either within individuals at different time intervals or between individuals.

Different strategies may be used to calculate numbers of changes over a given period of time. One implementation is described. If the signal represented by X has n samples, it is possible to find n-1 changes with a given interval (l). The changes represented by J_i will be equal to the sequence of elements represented by the sample number (X_i, X_{i+l}) for i=0,1,2,.. .n-1. The changes itself J_i will be

represented by X_{i+1}-X_i. After this procedure, the numbers from the latter analysis is then inspected for a given change. If this number is found a counter is increased with one. If a number of intervals and changes are put in a matrix where the rows represent time and the columns represented intervals. This procedure produces an easy-to-understand presentation of various changes of various intervals. If the matrix has a number of A rows, and B columns. The sequence J_i mentioned above has be done A x B times.

The procedure of comparing pressure curves **34** is further illustrated in FIG. **6**. The pressure curves before (left) and after (right) surgery are shown, and below the matrix **35** of numbers of pressure elevations. The numbers are standardized to a 10 hrs recording period **42**. More details are given in Example 2 below. This example is intended to illustrate various aspects of the invention described in FIG.'s **2-6**, but is not intended to limit the scope thereof.

EXAMPLE 2

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 (8.0 hrs). On the basis of the results of intracranial pressure monitoring, surgery was performed. A cranial expansion procedure that 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 (9.85 hrs). 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 matrix **35** of numbers of intracranial pressure elevations of different levels **36** and duration's

37 before and after surgery is presented in both Table **1** and FIG. **6**. In FIG. **6** both the intracranial pressure curve and the corresponding matrix **35** of intracranial pressure elevations of different levels **36** (20 – 45 mmHg) and durations **37** (0.5 – 40 minutes) are presented (before surgery at left and after surgery at right). The matrix **35** is presented as numbers during a standardised recording time of 10 hours **42** (actual recording time **45** before surgery 8 hours and after surgery 9.85 hours). 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. For example, during a standardized recording time of 10 hours, intracranial pressure elevations of 30 mmHg lasting 1 minute occurred 30 times before surgery (left matrix) and one time after surgery (right matrix). Various statistical methods may be applied to the data to identify statistically significant changes. 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.

As can be seen from the above mentioned examples the invention provides an accurate way of comparing pressure curves. The standardization procedure is crucial. For example it may be useful to compare pressures during sleep. The recording periods may be different, therefore it may be useful to standardize to a given recording time. It might not be representative to for example select one of 6 hours of recording.

In FIG's. **2-6** changes in the pressure curves of longer duration (30 seconds or above) have been illustrated. Though reference has been made to intracranial pressure, this represents no limitation of the invention. Pressures from other body cavities may be presented in the same way.

In the following FIG.'s **7-10** the invention applied to single pulse pressure waves is described. Analysis of single pulse pressure waves represents an even more detailed strategy for comparing pressures between and within individuals.

With regard to data collection, several steps are basically similar to the processes described for FIG.'s **2-6**. The signals from the sensor are converted to either a continuous current or voltage signal that is further processed in the apparatus **1** or modifications thereof. The continuous current or voltage signals are converted to digital signals within the analogue to digital converter. Another approach is to collect data from a vital signs monitor. Different from the data presented in FIG.'s

2 – 6 a higher sampling rate is required for analysis of single waves. With regard to single wave analysis the crucial point is to have a sufficient sample rate, as well as sufficient resolution order to reproduce the pressure waveform properly. According to the experience of the inventor so far a sampling rate of at least 100 Hz is sufficient to find maximum and minimum values an calculate latency, amplitude and rise time for the first peak (P1) (see FIG. 7). A higher sampling rate (at least 200Hz) is required to compute the latencies and amplitudes of the second (P2) and third (P3) peaks. It is required that the analogue to digital converter has a resolution of at least 12 bits. It is preferably to use 16 bits or higher.

Reference now is given to FIG. 7, demonstrating the parameters of a single pulse pressure wave that are analyzed quantitatively. All pressure signals are recorded, usually with a recording frequency of 100 Hz or above. The window with single pulse pressure waves is opened by pressing button **40** (FIG. **3**). The single waves are defined by the maximum **46** and minimum **47** values. By pressing another button **41** (FIG. **3**), the following parameters at any point on the single pressure curve may be computed: Amplitude **48**, latency **49**, and rise time **50**.

Latency **47** represents the time interval during which the pressure is changed from one pressure to another pressure. Each pressure signal may be identified on the time scale because pressures are recorded along with a time reference. The maximum **46** and minimum values **47** identify each single wave. The latency from one minimum **47** value back to another minimum **47** value is the heart rate and the duration of the wave. The latency from minimum **47** to maximum **46** is the time where the pressure of the single wave increases from the diastolic to the systolic pressure.

People skilled in the art would know that a single intracranial pressure wave contains three peaks, the first (P1), second (P2) and third (P3). The second peak (P2) also is termed the tidal wave and the third peak (P3) the dichrotic wave. Whether the waveform is reproduced properly or not depends on a sufficient resolution order and a sufficient sampling rate. The expressions amplitude **48**, latency **49** and rise time **50** are with reference to each of these peaks. The identification of the first peak (P1) is relative to maximum **46** and minimum **47**. The identification of the second peak (P2) also is relative to the first peak (P1), and the third peak (P3) is relative to the second peak (P2). In the present embodiment focus is given to amplitude, latency and rise time related to the first peak (P1), though this does not represent any limitation of the scope of the invention. References may also be to the second (P2) and third peaks (P3).

For the first peak (P1), the amplitude $\Delta P1$ represents the relative pressure difference between the diastolic minimum **47** and systolic maximum **46** pressures.

Latency ΔT1 is the time interval by which pressures increase from diastolic minimum **47** to systolic maximum **46**. Rise time ΔP1/ΔT1 is the quotient between difference in pressure divided by difference in time. The differences of pressures and time represent relative values. Any type of relationship may be calculated. The software allows the calculation of a matrix **53** of number of single pulse pressure waves with pre-selected wave characteristics of different amplitude **51** and latency **52**. Any kind of combinations of single wave parameters may be computed within the matrix **53**. The amplitudes **51** usually are expressed in mmHg and the durations **52** in seconds.

The results may be presented as absolute numbers or as percentages, and the results may be standardized to a selected recording time (for example each one minute, one hour, or even 10 hours recording time) **42**, as compared to the actual recording period **45**. During the standardisation procedure, the numbers or percentages of single waves with selected parameters are adjusted to a factor. The normalised time may be chosen in each individual. An example is given. If the actual recording time is 6 hours, and it is desired to standardise to 5 minutes recording time, the function implies that all numbers of single waves are divided with a factor equal to (6 x 60)/5 (that is 72.0).

Calculation of single pulse pressure waves automatically gives the heart rate because each intracranial single pulse pressure wave is built up from the blood pressure wave. Therefore the numbers of single waves with certain characteristics during a given recording time also may be standardized to a given heart rate **55**, as compared to the actual heart rate **54**. During the procedure of standardisation to a given heart rate, the heart rate must be selected beforehand. The recording interval also has to be selected, when an average of the heart rate must be computed. An example is given, though this is not intended to limit the scope of the invention. It is chosen to standardise the numbers or percentages of certain single waves to a heart rate of 60 beats a minute. Furthermore, it is chosen to average the heart rate to each 5-second recording period. During this recording period of 5 seconds the averaged heart rate is computed. Given that the total continuous recording period is 6 hours this standardisation analysis has to be repeated a total of 4320 times (x12/minute, x720/hour). Given that the actual average heart rate is 120 beats a second in a 5 seconds interval, the numbers or percentages of single waves during the period of 5 seconds must be divided by 2, to be standardised to a average heart rate of 60 beats a second. On the other hand, if the average heart rate is 30 during the 5 seconds interval the numbers or percentages of single waves during these 5 seconds has to be multiplied with a factor of 2, to be standardised to a heart rate of 60 beats a second. This approach also allows for on-line and real-time update of

standardised numbers or percentages to a given heart rate since such an update may be performed repeatedly every 5 seconds.

With regard to presentation of single wave parameters, a number of variations are possible. The matrix **53** of pre-selected characteristics of amplitude **51** and latency **52**, may be presented repeatedly and comparisons between matrixes **53** at different times may be performed. Only certain single wave parameters may be compared. The numbers/percentages of single wave parameters may be subject to any type of statistical analysis.

FIG. **8** illustrates the computation of single pulse pressure waves with certain pre-selected characteristics. The mathematical process of quantitative analysis of single wave parameters may be implemented in the software in various ways, one strategy of implementation is described here. The acquired signal is first run through separate detection of minimum **47** and maximum **46** values. The maximum threshold value is set to the lowest level in the signal, and width greater than pre-selected seconds. A variety such pre-selected seconds may be chosen, and the values may depend on age. In the first studies, durations of 0.1–0.2 seconds were used, but other durations may also be used. The minimum threshold is set to highest signal level, and the width is set to pre-selected seconds, as described above. After this analysis all maximums **46** and minimums **47** are represented with an amplitude value and a location value or time stamp. The locations are reported in indices from the start of processing. This procedure will result in a lot artificial maximum and minimum detections. In other words the maximum **46** and minimum **47** detection has to be refined. After this is done the result is a collection of approved maximum and minimum pairs, which in the next turn can be presented to the function handling the dynamic parameter analysis. First, grouping of the maximum values and minimum values is performed. For every maximum **46** the subsequent minimum **47** is found. This couple makes a maximum-minimum pair. The latter maximum-minimum pair is inspected for threshold level. The threshold value has to be larger than a given value. This is performed by subtracting the maximum amplitude and minimum amplitude. If this value is less than the threshold value the pair is discarded. Afterwards the pair is inspected for the rise time ($\Delta P1/\Delta T1$). The rise time is expressed as maximum amplitude minus minimum amplitude divided by maximum location minus minimum location. This will remove pairs caused by for example an artefact in the collected signal. All rise time values with a value equal or larger than a given value is discarded. A large variation is possible with regard to rise times that are discarded. The collection of maximums and minimum's contained now only approved values. All the dynamic values are calculated by using the approved maximum-minimum pairs. The values which are calculated are amplitude ($\Delta P1$) (delta intracranial pressure expressed in

mmHg) **51**, latency (ΔT1) **52**, and rise time (ΔP1/ΔT1) **59**, and heart rate **58**. All these values are quite forward to find using the information found in the approved maximum-minimum pairs. The collections of amplitude (ΔP1) **51** values give information constituting the matrix column information. The collections of latency (ΔT1) values **52** give the matrix row information. A matrix **53** of different amplitude **51** and latency **52** combinations is computed.

An important aspect with the computation parameters of single pulse pressure waves is that the invention computes the relative differences in pressures and time. These relative differences are not related to a zero level of pressure. Accordingly, the single wave analysis is not influenced by the zero level of pressure, neither of drift of the zero level of the sensor. It should be noted that the procedure of calculating pressure elevations of various durations FIG.'s **3-6** involves computation of absolute intracranial pressures (or other pressures in a human body cavity) relative to atmospheric pressure. The conventional methods of assessing intracranial pressure use calibration against atmospheric pressure. The present invention of computation of relative pressures of single pressure waves solves several problems of known in the art.

(a) The impact of inter-individual and intra-individual differences in pressure is reduced. When comparing continuous pressure curves between or within individuals, a source of error may be differences in the baseline pressure due to differences or drift of zero level. In the present invention, the accurate zero level does not affect the single wave parameters computed.

(b) A drift in the zero level of the pressure sensor usually is a problem with pressure sensors, particularly when pressure is monitored continuously for several days. Drift in zero level of pressure has no influence on the single wave parameters computed as described here.

(c) The major problem with continuous monitoring of intracranial pressure by means of non-invasive sensors is the problem of determining a zero level. Thereby relative differences in pressure must be computed, but the output give non-accurate data since it may be nearly impossible to suggest the intracranal pressure on the basis of such relative pressure assessments. In the present invention it has been possible to accurately compute the single waves with pre-selected characteristics of latency, amplitude and rise time. Since relative differences are computed, there is no need for a zero level. When single waves are computed by means of a non-invasive sensor, the present invention allows for determination of the intracranial pressures with a high degree of accuracy. On the basis of computing several hundred thousand of single waves and comparing the single wave parameters with the mean intracranial pressure, a

high degree of correlation between amplitude, rise time and mean intracranial pressure has been found. According to this invention, single wave analysis of signals from non-invasive sensors may both give information about relative changes in pressure and about the intracranial pressure, as the relationships between intracranial pressure and single wave characteristics are known beforehand, on the basis of a large number of comparisons. This process may be as follows. A non-invasive sensor **16** may be applied to the patient and connected to the transducer **2**, and the signals are processed in the apparatus **1** or modifications thereof. Such sensors **16** may use acoustic or other signals, for example by application of a sensor-device to the outer ear, sensing pressure in the middle ear indicative of the intracranial pressure. The signals are converted in the apparatus **1** and stored along with the time stamp. The computer software handles the digital signals and performs the quantitative analysis of the parameters of single pulse pressure waves described here. Without knowing the exact zero level of intracranial pressures, changes of single wave parameters may be followed continuously. This approach provides a simple approach to follow changes in intracranial pressure, and obtaining accurate information about the intracranial pressure.

(d) It is possible to implant permanently pressure sensors within the intracranial compartment, for example in conjunction with ventricular shunts. Telemetric devices may record pressures. Also with this type of pressure monitoring, drift of zero level remains a problem, hence it may be a question of whether the correct pressure is monitored. The present invention soles this problem as drift in zero level does not affect the pressures recorded.

Exploration of the single pulse pressure waves is started by pressing the button **40**, and the single wave parameters are selected by pressing the button **41**. The upper figures in FIG. **8** shows the single pulse pressure waves **57**, including the time recordings **20** along the X axis, and pressure levels **56** along Y axis. On the Y axis the absolute pressure values are shown, it should be noted, however, that the single pulse pressure waves are calculated by computation of relative pressure and time differences. As indicated in the upper figure to the left (FIG. **8**), the single waves are identified by the minimum **47** and maximum **46** values. For the first peak (P1), the amplitude (ΔP1) and latency (ΔT1) are both indicated.

In FIG. **8** is also indicated the process of computing numbers of characteristics of single pulse pressure waves. A graphical user interface reveals the curve of intracranial pressure **34**. A window revealing the pressure curve **34** along with the absolute intracranial pressure recordings **21** and the time of registration **20** is shown. The actual recording period **45** was 472.0 seconds, and the recording period

was not standardised **42** (0.00 in output box). During this period of recording the numbers of single pulse pressure waves with pre-selected characteristics where computed. The amplitudes of single waves **51** were selected to either 2.0, 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5 or 7.0 mmHg. The latencies of the single waves **52** were either selected to 0.23, 0.25, 0.26, 0.27, or 0.28 seconds. The numbers of single pulse pressure waves with these pre-selected characteristics were computed and presented in the matrix **53**. For example, during the recording period of 472.0 seconds, single pulse pressure waves with an amplitude of 5.5 mmHg and a latency 0.28 seconds (that is rise time of 5.5/0.28 = 19.64 mmHg/sec) occurred 43 times during this recording period. The results may be standardized **42** to a recording time of for example 600 seconds. In this situation all numbers must be multiplied with a factor of 600/472. The numbers also may be standardised to a selected heart rate, as described above. A number of variations are possible with regard to methods of data presentation.

The invention provides the option for comparisons of pressure curves. For example, during monitoring of intracranial pressure during sleep the numbers of single waves with certain pre-selected characteristics may be computed (for example amplitude 4 to 8 mmHg and latency 0.25-0.28 seconds). The numbers of such single waves may be computed during a standardized recording period (e.g. each one minute or each one hour) and a standardized heart rate (e.g. 70/min). The numbers of single waves may be computed within the same individual at different times (e.g. before and after treatment) and compared. Alternatively the numbers of single waves may be computed within an individual and the numbers may be compared against a normal material.

FIG. **9** demonstrates the recordings of intracranial pressure (cerebrospinal fluid which represent one of the compartments of the intracranial cavity) **34** while infusing a liquid into the cerebrospinal space. Pressures are presented as absolute values of mmHg on the Y axis **21** and time is expressed as seconds on the X axis **20**. The intracranial pressure **34** is measured simultaneously with infusion of physiological saline into the lumbar cerebrospinal space, which is termed infusion test. It is shown how the intracranial pressure curve **34** increases as liquid is infused. The increase of pressure is shown in the upper figure. The figure also demonstrates the simultaneous computation of rise time **59-60** and heart rate **58**. With regard to rise time, two parameters are computed simultaneously, namely $\Delta P1/\Delta T1$ **59** and $\Delta P1/\Delta T2$ **60**. It is shown that the rise times $\Delta P1/\Delta T1$ **59** and $\Delta P1/\Delta T2$ **60** increase with time. The heart rate **53**, on the other hand, declines as the pressure increases. This illustrates that the rise times may be calculated repeatedly and plotted against time (X-axis). Alarm functions may be incorporated for example alarming the occurrence of $\Delta P1/\Delta T1$ **59** above a given level. Rise time

may be an important predictor of abnormal pressure. The present technical solution allows for computation of the exact numbers or percentages of single waves with certain rise times during a given recording time. For example, the numbers or percentages of single waves with a rise time between for example 10 and 30 mmHg/seconds during 5 minutes of recording may be computed repeatedly, and presented graphically. FIG. **9** shows some examples of presentation of single wave characteristics, though the examples represent no limitation of the scope

It should be noted in FIG. **9** that heart rate declines as the rise time increases. This is a physiological effect in the way that heart rate declines as a result of increased decompensation related to increased pressure. Since the relative duration of each single wave corresponds to the heart rate, the heart rate may be automatically computed. The observation presented in FIG. **9** further illustrates the value of concomitant recording of heart rate. The parameter heart rate provides additional information about abnormality of intracranial pressure.

FIG. **10** shows strategies to compare pressure curves. The input box **40** (FIG. **3**) allows for comparisons of various single pulse pressure waves. In particular single pulse pressure waves of intracranial pressure and blood pressure may be compared, but any type of presure may be compared. The different pressure waves are revealed simultaneously during real time on-line monitoring, with the identical time reference. The output may be time on the X axis **20** and pressure **21** on the Y axis. For example, the curve of single arterial blood pressure waves **61** may be revealed simultaneously with the single intracranial pulse pressure waves **57**. For a given recording period **45** the numbers of single pulse pressure waves may be computed and the numbers may be standardised to a given recording period **42**. Furthermore the actual heart rate **54** may be standardised to a standardised heart rate **55**. The curves of single pulse intracranial **57** and arterial blood pressure **61** waves are presented in the upper figure to the right. The time reference **20** is identical, thus allowing comparisons of single pulse pressure waves at identical points of time. The Y axis reveals the absolute blood pressure **62** and intracranial pressure **56** values. As described for intracranial pressure, a matrix may be computed with the opportunity to define relationships between parameters of different single waves. In the lower figure to the left is shown a matrix **65** defining numbers of relationships between rise time for intracranial pressure waves (ΔP_I-1/ΔT_I-1) and rise time of blood pressure waves (ΔP_I-2/ΔT_I-2). This relationship (ΔP_I-1/ΔT_I-1)/ (ΔP_I-2/ΔT_I-2) has been computed and the matrix **65** presents the numbers by which this relationship was 1, 2, 3, or 4. This example represents no limitation concerning the relationships between single waves that may be computed.

FIG. **11** shows different applications of the apparatus according to the invention. As mentioned before, the invention includes a system and method for recording, sampling, analysis and presentation of pressure recordings. The invention also incorporates an apparatus for high frequency sampling of pressure recordings. It should be understood that a number of variations are possible for the system described here. Though this invention includes a portable apparatus **1** (see FIG. **1**) for sampling and recording pressure signals, the computer based method may be integrated in a number of systems and devices as indicated in FIG. **11**.

First, pressure signals may be derived from various pressure sensors **16** and transducers **2**, either invasive or non-invasive systems. For intracranial pressure, a number of pressure sensors **16** are commercially available. Intracranial pressure may be assessed from the epidural, subdural spaces, brain parenchyma, or from the cerebrospinal fluid space. Also for arterial blood pressure, a number of commercially available pressure sensors **16** are available. Pressure sensors **16** also may be implanted and recorded by means of telemetric or other devices. Non-invasive devices, utilising for example acoustic or Doppler or other signals may record pressures. The method described here may utilize pressure signals from any source.

The computer software may be integrated in the portable apparatus **1**, as well as in a network station, a personal computer, medical device computers **6**, computer servers **6** connected to vital signs monitors, or incorporated directly in vital signs monitors. Output from the quantitative analyzes may be presented on the monitor screen, flat screen or other devices known in the art.

Various modifications of the apparatus **1** are possible. Components of the apparatus **1** may be integrated in the pressure transducer **2** or in various types of computers including medical device computers **6**.

(I) In one situation the pressure signals are transmitted from a commercially available pressure sensor **16** and transducer **2** to a commercially available vital signs patient monitor. In this situation the invention **1** may be incorporated in the vital signs patient monitor, or in a computer server that is connected to the vital signs patient monitor, for example via network. The output of data processing may be displayed on a flat screen or on the vital signs patient monitor.

(II) In another situation the apparatus **1** is integrated in other commercially devices. Such situations are described below, though these examples do not represent a limitation by which the apparatus may be integrated in other systems. Commercially available pressure sensors **16** may be used for

assessment of intracranial pressure (e.g. Micro Sensor ICP Transducer coupled to Codman ICP Express; Codman & Shurtlef Inc., Randolph, MA) or cerebrospinal fluid pressure (Baxter Monitoring Kit). These pressure transducers **2** are connected via the portable apparatus **1** directly to a medical device computer **6**. In this situation the portable apparatus **1** is modified so that commercially available equipments is used instead of the transducer **2**. Furthermore, the portable apparatus **1** may include the galvanic element **3**, signal conditioner **5**, analogue to digital converter **7**, central processing unit **8**, and eventually an output-input unit **15**. Other functions such as data memory **9**, input control **10**, display **12**, and alarm unit **13** are incorporated in the medical device computer. In this situation, pressure signals are transferred directly from a commercially available pressure transducer **2** to a commercially available medical device computer **6**, and the invention **1** is used as an interface. The pressure transducer **2**, interface, and medical device computer may be placed on a rack allowing the patient to walk about, providing the opportunity to assess pressure in patients that are free to walk about.

(III) In yet another situation pressure signals are monitored and sampled by the apparatus **1** for a selected period. In this situation the apparatus 1 may be constructed in a number of ways and with a small size and light weight, thus allowing the patient to carry the apparatus in his/her pocket. After the period of monitoring has been ended, the apparatus is connected to a computer and the signals analyzed and presented.

(IV) In another situation the whole apparatus **1** is integrated in a medical device computer.

The invention may not exclusively be used in humans but may as well be used in animals, both in the clinical practice and in scientific experiments.

The invention is intended used in several groups of patients with various clinical problems. Some examples are given though these should not be understood as limitations of the scope of the invention.

Continuous intracranial or cerebrospinal fluid pressure monitoring according to the invention described here may be used in adults and children. (a) In children intracranial hypertension may be questioned on the basis of hydrocephalus, craniosynostosis, pseudo-tumor cerebri and questions of. (b) In children and adults either intracranial hypo- or hypertension may be questioned on the basis of shunt failure. (c) In adults with questions of so-called normal pressure hydrocephalus intrcaranial hypertension or abnormal absorption of cerebrospinal fluid may be

questioned. (d) In individuals in the intensive care unit, a vital aspect is to follow abnormal changes in intracranial and blood pressures.

Continuous blood pressure monitoring according to present invention may be used in (a) assessment of blood pressure medications, and in (b) children and adults in the intensive care unit in whom continuous blood pressure monitoring is used as part of the patient monitoring.

Though focus is given to intracranial pressure (including cerebrospinal fluid pressure), blood pressure, and cerebral perfusion pressure, any type of pressure in a human body cavity may be assessed according to the invention described here.

In all cases the invention described here may be used in (a) on-line monitoring of pressures revealing real-time changes in pressure characteristics, and (b) assessment of pressure curves after the end of pressure monitoring, that is off-line.

The following examples are intended to illustrate various applications of the present invention, and are not intended to limit the scope thereof.

When the invention is used in children or adults in whom there is a question of abnormally increased or reduced intracranial pressure and/or blood pressure, the procedure may be as follows. In a minor surgical procedure, the pressure sensor **16** is implanted within the skull of the patient. During the procedure, a small opening is made in the in the skull with a subsequent small opening in the dura. The sensor is canalled subcutaneously to the surgical opening. The sensor **16** is coupled to the transducer **2** and then to the apparatus **1** and calibrated against atmospheric pressure by means of the Input control **10**. Then the sensor **16** may be 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. 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 **1** 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 software program described above may analyse the data. 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. In these cases analysis and presentation usually is performed after the end of pressure monitoring. Usually it may be useful to compare pressures during sleep and the awake state. During the awake state it is important to differentiate whether pressure is monitored while the patient is lying in the bed or standing up. It may be useful to record changes in pressure from lying position to standing position or vice versa.

As described in FIG. **11** various modifications of this procedure may be done. The pressure transducer may be connected directly to the vital signs patient monitor and the pressure signals may be transferred via a network solution to another server or to personal computers. Alternatively, modifications of the apparatus may be used as an interface between the pressure transducer and the computer. Though an invasive method of recording pressures is described here various types of non-invasive sensors may be used.

In one example a patient is transferred to the hospital with an intracranial haemorrhage and question of increased intracranial pressure. If the hospital does not have the ability to install an invasive sensor, it may be useful to use a non-invasive sensor. A non-invasive pressure sensor sensing pressure via the outer ear canal may be coupled to the pressure transducer **2** and then to the apparatus **1** or modifications thereof. The software according to the invention handles the digital signals, intracranial pressure then may be presented in various ways.

The invention may also be used in children and adults treated with extracranial shunts in whom there are 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. The invention also may be used in conjunction with sensors permanently implanted within the cranial compartment, such as ventricular shunt systems.

The invention may also be used in 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) has a 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. The present invention provides at least two advantages: Continuous intracranial pressure monitoring by means of a portable apparatus **1** represents a more physiological situation than with the patient only 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. In such cases comparisons of continuous pressure recordings may be done between individuals and within individuals (before and after treatment). In these cases particularly intracranial pressure and cerebrospinal fluid pressure is of interest. In the assessment of normal pressure hydrocephalus, infusion tests also have been shown to be of value. During infusion tests pressure is measured within the cerebrospinal fluid space, either in the lumbar spinal cord or within the cerebral ventricles. The change in pressure also may be measured simultaneously with infusion of a liquid such as physiological saline. The present invention allows for calculation of single waves during the infusion test. The applicant has shown that changes in the infusion test are most accurately revealed by calculation of single wave parameters. During infusion testing, pressure within the cerebrospinal fluid space is recorded, a pressure transducer for assessment of liquid pressure is used. The pressure transducer is connected to a computer. In this situation the invention **1** may either be in the form of an analogue to digital converter. The software may be integrated within the computer allowing sampling, analysis and presentation of the data.

When pressures are measured in the cerebrospinal fluid during so-called infusion testing, a catheter is applied to the cerebrospinal fluid space, usually either within the cerebral ventricles or to the lumbar cerebrospinal fluid space. The catheter is connected to a commercially available sensor for sensing pressures within a liquid. This pressure sensor **16** may be connected via the apparatus **1** described here to a commercially available computer, or via a vital signs monitor to the computer. In this situation the apparatus **1** is modified, thus serving as an interface between the sensor and the computer. Pressure recordings are made while a fluid is infused to the cerebrospinal fluid space. The applicant has shown that recordings of single pulse pressure waves may be done simultaneously as the fluid is infused. According to this intervention the various parameters of the single pulse pressure waves may be calculated as well as the heart rate variability during infusion of

liquid. Various strategies of assessing single pulse pressure waves may be performed in this situation. The distribution of single waves during one minute of recording may be computed and related to the volume change that is known in this situation. The invention allows for standardisation of numbers or percentages to a given heart rate and a given recording period. For example, the matrix **53** of single waves with various amplitudes **51** and latencies **52** may be computed repeatedly during one minute of recording. Since the infusion rate and hence volume change is known a curve for each individual may be computed with percentage of pre-selected single wave on Y axis and volume change on X axis. When the curves of many individuals are known it is also possible to superimpose the recordings from one individual against a reference curve from several individuals. It has previously not been possible to superimpose the intracranial pressure recordings of a single subject on the pressure volume or elastance curve. The present invention may provide a technical solution for this problem. Since any types of single pulse wave parameters may be calculated by this invention, a variety of approaches may be possible.

With regard to on-line presentations, pressures (for example intracranial and blood pressures) may be presented by conventional means as real-time presentation of numerical values of mean pressure or as real-time presentations of intracranial pressure curves. The present invention provides a technical solution for continuous analysis and presentation of parameters of single pulse pressure waves. For example, the numbers or percentages of a certain rise times (for example 10 – 20 mmHg/sec) during a given recording period (e.g. 1 minutes) may be computed repeatedly and presented on a graph. Thereby changes in pressures may be detected before the conventional methods, thus providing early detection/warning of deterioration of pressures.

The invention also may be use to compare changes in blood pressure before and after interventions. Comparable to the situation described for intracranial pressure quantitative analysis and presentation of continuous blood pressures may be computed. Changes in numbers or percentages of single pulse pressure wave parameters may be compared. In the assessment of treatment of blood pressure, comparison of pressure curves before and after treatment is of interest. Single pulse pressure wave parameters may be calculated before and after treatment with blood pressure medications. The invention provides a detailed approach for assessment of these treatments. It should be noted that the invention may both be used in clinical practice and in scientific practice. Pressure may be monitored in both humans and animals. In particular, the invention may be used in animal experiments in which blood pressure medications are assessed.

This invention represents a new technical solution in various aspects, which now will be commented on:

(a) The invention provides a technical solution for digital recording of pressures in individuals that are free to move about. The apparatus is a minicomputer and may be powered by a rechargeable battery. Thereby the patient may carry the apparatus. This provide a more physiological monitoring of pressures, including single pulse pressure waves. 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 for digital storing of a large number of intracranial and blood pressure recordings, different from the currently available apparatuses. The important aspect in this context is high frequency sampling of pressure recordings, though the invention also allows for low frequency sampling. Thereby single pulse pressure waves may be calculated. The portable apparatus integrates standard components known in the art, therefore the systems for pressure recording and handling may also be integrated in various systems.

(c) This invention was 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. When assessing a continuous pressure curve off-line the problem is to define a representative part of the curve. Pressures change over time, therefore a misleading picture of the pressures may be provided by choosing only one part of the curve. The present invention provides several strategies of quantitative analysis of pressure recordings. Elevations of pressure of various levels and durations are accurately computed, thus providing an objective and quantitative description of the pressure curve. Single pulse pressure waves also are presented and analysed quantitatively. The standardisation procedure described here makes it possible to compare curves of different individuals, though the recording time for each individual may be different. Without this standardisation procedure, an alternative strategy might be to select pressure curves of identical duration from different individuals. Then it would be required to select one part of the curve, however, then it might be difficult to select a representative part of the curve. For example, if intracranial pressure or blood pressure is recorded continuously in one individual twice (one recording of 7 hours and one recording of 9 hours) and the two recordings are going to be compared, the problem is to compare representative portions of the curves. The present invention provides a technical solution to this

problem by means of standardising the recordings to a given recording period. Thereby the whole recording period may be utilised in the assessment.

(d) Though a major use with the present invention is off-line assessment of pressure recordings, the invention may as well be used for on-line and real-time monitoring of single pulse pressure waves (blood pressure, intracranial pressure, cerebral perfusion pressure, or other pressures in a human body cavity). The invention provides a technical solution for continuous calculation and presentation of single pulse pressure characteristics. Calculation of the accurate numbers or percentages of single pulse pressure parameters and comparisons of these parameters at different times, provide a technical solution for early detection/warning of changes in pressure. An example is given. The present invention allows for calculation of the exact numbers or percentages of single pulse pressure waves with amplitude 6 mmHg and latency 0.23 seconds (rise time 26 mmHg/sec) during one minute or 5 minute recordings. Given that the presence of 60% of such waves during a given recording period represents abnormality, it would be informative for the physician to have a graphical presentation of repeated computations of the percentage of this single pulse pressure wave. In fact, the invention allows for repeated computations of any combinations of single pulse wave parameters. A continuous and real time computation of the numbers or percentages of certain rise times (for example 26 mmHg/sec) during a given recording period represents an alternative presentation. Accordingly, this invention provides a technical solution for early warning of deterioration of pressures.

(e) The quantitative algorithms and methods of assessing pressures have previously not been described. Several authors have used methods to explore the frequency distribution of pressure waves. In particular spectral analysis or Fast Fourier Transformation (or spectral analysis) has been used. These methods are fundamentally different from the methods described here. The methods previously used have not gained ground in the clinic and have not been useful in daily clinical practice. The main advantage of the present invention is that the intracranial and blood pressure curves is presented in a very accurate way, that provide a reliable tool for examining normality and deviation from normality. The algorithms of assessing single pulse pressure waves described here particularly obtain this goal. 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. In particular assessments of the various parameters of the single pulse pressure waves provide new and detailed information.

(f) The invention provides a technical solution for monitoring intracranial pressure without the problem of zero drift of pressure sensors or the problem of identifying the zero level. The quantitative method of analysing single pulse pressure waves

utilises relative changes in pressures and time, and therefore not is dependent on the zero level of pressures. It is well known that drift of zero level of a pressure sensor represents a methodological problem, in particular with invasive sensors. When continuous monitoring is performed over time such as several days, drift of the zero level of the sensor may produce false pressure recordings. This is related to the fact that such sensors are calibrated against the atmospheric pressure. The same problem is seen with pressure sensors that are permanently implanted, for example implanted with a cerebral ventricular shunt system. These sensors may for example give a radio frequency signal that is recorded by a telemetric device. The present invention of signal handling eliminates the problem of zero drift. With regard to non-invasive sensors the problem is to define a zero level. For intracranial pressure, the establishment of a zero level requires calibration against the atmospheric pressure. The present invention computes the relative changes of single wave parameters. In this situation the zero level of pressure may not be known. By means of the present invention changes in parameters of single pulse pressure waves may be followed over time without the need for adjustment of zero level.

(g) The present invention provides a technical solution for comparisons of pressure curves within a body cavity, that is comparisons of waves in a wide sense of the word. Examples are comparisons of continuous pressure recordings within a single subject at different times, such as comparisons during a continuous monitoring of pressures. Alternatively continuous pressure recordings may be compared at different times, such as before and after treatment. Pressure curves may be compared between individuals or continuous pressure curves from an individual may be compared against a reference material. For example, continuous intracranial pressure is monitored for 12 hours in a single subject. The numbers of single pulse pressure waves with pre-selected characteristics concerning latency and rise time are computed. Since selection of only one portion of the curve would reduce the accuracy of the recordings, the numbers or percentages of the whole recording period may be standardised to a selected recording period. For example, the numbers or percentages of single waves with certain amplitudes and latencies during the actual recording period of 12 hours may be standardised to numbers of waves during one hour of recordings. This approach takes away the inaccuracy of selecting only one portion of the curve. In addition to computing the quantitative characteristics of high frequency fluctuations in pressure, quantitative analysis of the low frequency fluctuations in pressure may be computed, providing a more complete picture of the pressures. For low frequency pressure changes the normal distribution of pressure elevations of 20 mmHg lasting 10 minutes during for example one hour of recording may be computed. Due to some individual variation

in the normal distribution exact values may not be computed but rather a distribution with the median and percentile distribution.

(h) The invention provides a new technical solution for the clinical application of single wave analysis, when assessing continuous pressure recordings. Single pulse pressure wave parameters are calculated quantitatively, and the numbers or percentages of certain single waves may be computed. The numbers/percentages may be computed during a given recording period. Thereby the invention provides the unique opportunity to predict the placement of a continuous pressure recording in one individual on the elastance or pressure-volume curve. It has previously not been possible to superimpose the pressure recordings of an individual on the pressure-volume (elastance) curve because this curve is different for different individuals and the curve may vary over time. The effect of this inter- and intra-individual variation is markedly reduced by the present intervention. The present intervention provides a tool for computing a diagram of the normal variation of the pressure volume curve. For example the exponential pressure volume curve originally described by Langfitt in 1966 (volume on the X axis and pressure on the Y axis) may be presented as medians with percentiles. The present invention provides a tool for computing the distribution of certain single pulse pressure waves that may be considered as abnormal. For example, given that it is found that the presence of a single wave with amplitude 6 mmHg and latency 0.23 seconds in 60% of the recording time is abnormal, the invention provides the option to compute in a single patient the numbers and frequency of such single waves. During infusion testing pressure changes are known along with changes in volume because the rate of volume change is known. This situation provides the opportunity to compute the distribution of the different waves at different levels of the curve. For example, the distribution of a single wave with a rise time 30 mmHg/seconds may be computed at different pressures and volumes. During a recording time of 5 minutes these single waves may constitute 20% of single waves at one point of the horizontal part of the curve but may constitute 80% of single waves at one point of the vertical portion of the curve. Similar computations may be made for other single waves. Based on the recordings of many patients, normograms may a computed. Thereby the results from this single subject may be superimposed on the normogram of the pressure volume curve and an accurate description of elastance in this particular subject is given.

(i) The present invention presents an easy-to-understand presentation of quantitative characteristics of a pressure curve (high-frequency and low-frequency fluctuation in pressure), that is easy to understand for a physician not possessing detailed knowledge of pressures in a human body cavity. The data processing is

performed very fast, thus not requiring time-consuming evaluation of the intracranial pressure curve.

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.

Table 1. *Comparisons of intracranial pressure elevations before and after calvarial expansion in one case with craniosynostosis*

Duration (min)	ICP elevations (mmHg)									
	0	5	10	15	20	25	30	35	40	45
0.5	1028 (896)	1024 (896)	908 (865)	526 (480)	134 (143)	73 (21)*	45 (4)*	26 (1)*	6 (0)	1 (0)
1	704 (555)	701 (555)	613 (535)	340 (270)	89 (69)	45 (10)*	30 (1)*	11 (0)**	3 (0)	1 (0)
5	101 (151)	101 (151)	79 (140)	48 (67)	14 (20)	5 (3)	5 (0)	1 (0)		
10	39 (75)	39 (75)	38 (73)	31 (46)	11 (11)	9 (0)**	8 (0)	1 (0)		
20	19 (23)	19 (23)	19 (23)	16 (18)	8 (5)	5 (0)	1 (0)			
40	8 (17)	8 (17)	8 (17)	8 (16)	6 (1)	1 (0)				

Table 1

CLAIMS

1. Method for measuring and analyzing pressure in a body cavity in a patient, comprising the steps of:
a) measuring pressure by means of at least one sensor during a period of time (hereinafter called recording period) to provide at least one signal representative of the pressure,
b) sampling, at selected intervals, said signal representative of said pressure, converting the sampled signal to digital form and storing the digital sample value along with a time reference,
c) analyzing the stored sample values in order to generate a presentation of at least one of the following:
c1) number of pressure elevations with any selected combination of level and duration,
c2) number of pressure changes with any selected combination of level difference and duration of change,
c3) number of single pulse pressure waves with preselected characteristics regarding minimum, maximum, amplitude, latency and rise time or any other single pulse wave parameter,
wherein said numbers are related to a time period and
wherein the analysis performed in c3) includes computation of relative differences of pressure and time not involving a zero reference level and/or computation of absolute differences involving a zero reference level.

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

3. Method according to claim 1, wherein step a) involves applying a non-invasive technique with a sensor using acoustic or other measuring signals.

4. Method according to claim 1, where the at least one signal represents blood pressure, and other pressure signals subjected to steps c1)-c3) represent:intracranial pressure, blood pressure, cerebrospinal fluid pressure, and cerebral perfusion pressure.

5. Method according to claim 1, wherein step c) comprises:
c4) computation of the numbers of artifacts during a recording period,
c5) computation of the artifact ratio,
c6) exclusion of recording sequences of sampled values and time references when the artifact ratio is above a certain level.

6. Method according to claim 1, wherein the presentation in step comprises the steps of presenting the data in the form of absolute numbers, percentages or numbers per time period as follows:
- absolute numbers or percentages during the actual recording period,
-numbers or percentages during a standardized recording period (such as one minute, one hour or 10 hours)
- numbers or percentages standardized to a selected heart rate (for example a standardized heart rate of 60 per minute)
- numbers or percentages related to normative or reference data,
- numbers or percentages computed repeatedly during a continuous recording period.

7. Method according to claim 1, wherein the sampling rate in step b) is at least 10 Hz, and the recording period is at least 24 hours.

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

9. Method according to claim 7, wherein the sampling rate in step b) is at least 200 Hz.

10. Method according to claim 7, wherein the recording period is at least 48 hours.

11. Apparatus for recording and storing pressure recordings from a pressure sensor applied to a patient, comprising:
- a first connector (4) for connecting the apparatus to a pressure sensor,
- an analog-to-digital converter (7) for converting received pressure measurements to digital form,
- processing means in communication with the analog-to-digital converter (8), capable of reading out samples of the digitally converted pressure measurements and storing said measurements in a data memory (9) connected to said processing means along with a time reference,
- an input/output interface (10) in communication with the processing means and connected to a second connector (22) for connecting the apparatus to external computing means (6), 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 150 200 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
a) a communication interface for receiving a set of digital pressure sample values;
b) a data memory for storing the received sample values along with time references;
c) processing means with access to said data memory, capable of analyzing said sample values in order to determine at least one of the following:
c1) number of pressure elevations with any selected combination of level and duration,
c2) number of pressure changes with any selected combination of level difference and duration of change,
c3) number of single pulse pressure waves with preselected characteristics regarding minimum, maximum, amplitude, latency and rise time, or any other single pulse wave parameter,
wherein said numbers are related to a time period as follow:
- numbers or percentages of pressure elevations or changes or single wave parameters during an actual recording period,
- numbers or percentages of pressure elevations or changes or single wave parameters during a standardized recording period (for example 1 minute or 1 hour),
- numbers or percentages of pressure elevations or changes or single wave parameters during a recording time with a standardized heart rate,
wherein both real-time and on-line analysis/presentations are possible,
d) 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 capable of presenting the analyzed data:
- repeatedly during the recording period, with comparisons of the repeatedly analyzed data,
- along with normative or reference data,
e) a display for displaying the generated visual presentation; and

f) input means allowing a user of the system to enter and change parameters on which said analysis and said presentation 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/percentages during a standardized recording period or numbers/percentages with a given heart rate.

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:
1) number of pressure elevations with any selected combination of level and duration,
2) number of pressure changes with any selected combination of level difference and duration of change,
3) number of single pulse pressure waves with pre-selected characteristics regarding minimum, maximum, amplitude, latency and rise time,
where said numbers refer to a during a time period (recording period, standardized period, etc.) or a standardized heart rate.
- 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.

34. Computer program product according to claim 31, integrated in a portable apparatus or in different systems such as medical device computers, computer servers or vital signs monitors.

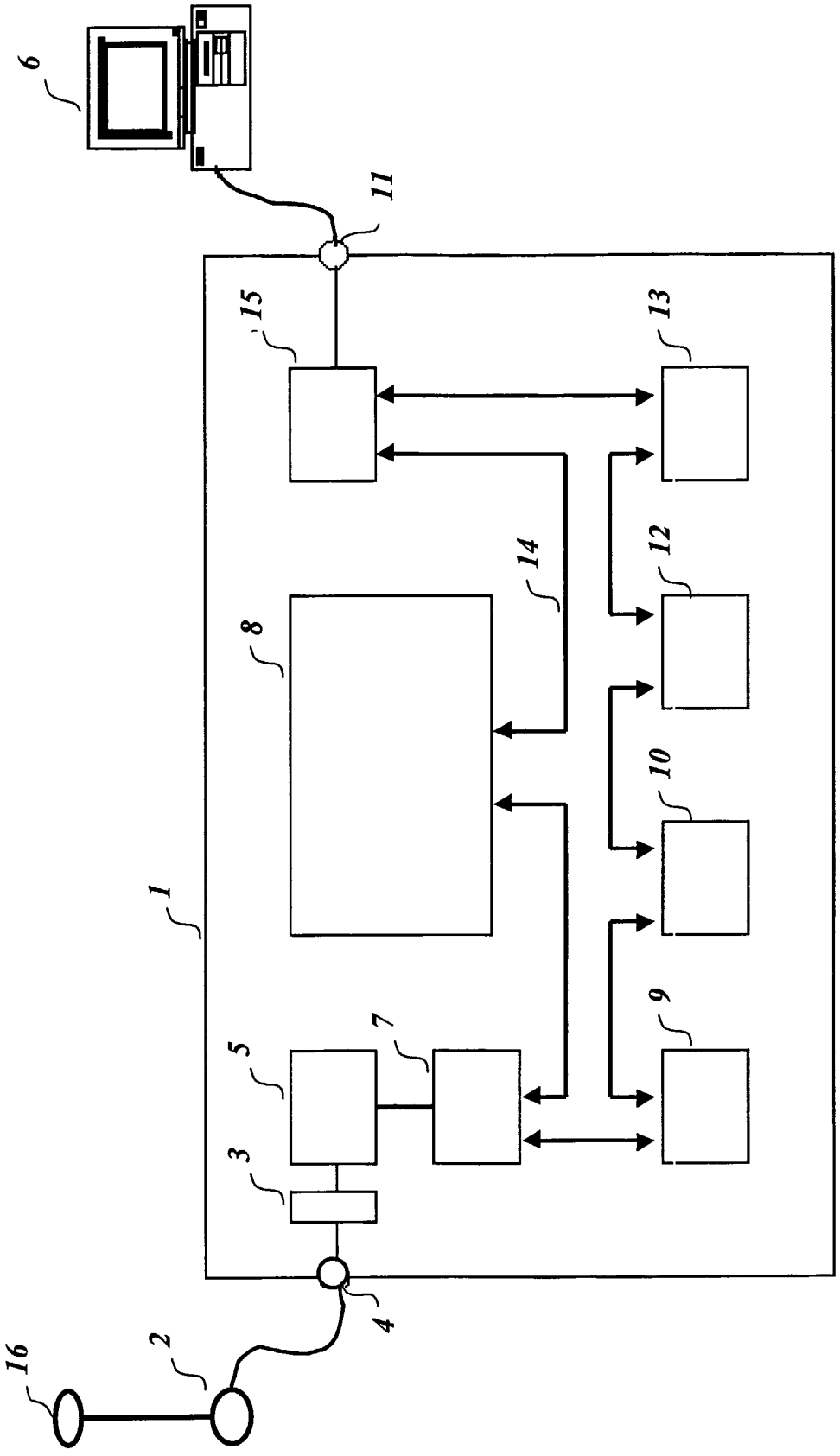
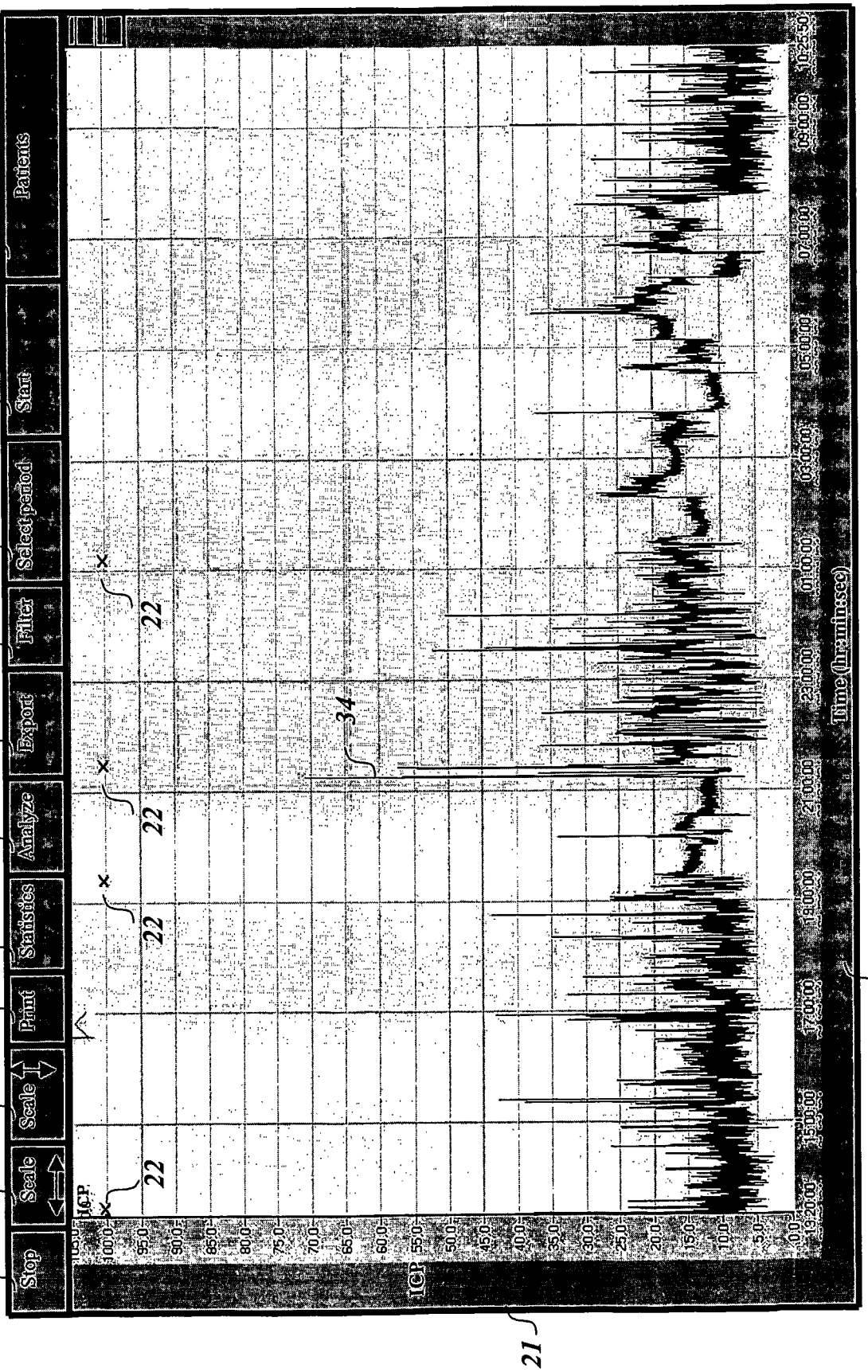


Fig. 1

Fig. 2


Stop
Scale
Scale
Print
Statistics
Analyze
Export
Filter
Select period
Start
Patients
ICP
Time (hr:min:sec)
22
34
20
21
23
24
25
26
27
28
29
31
32
33

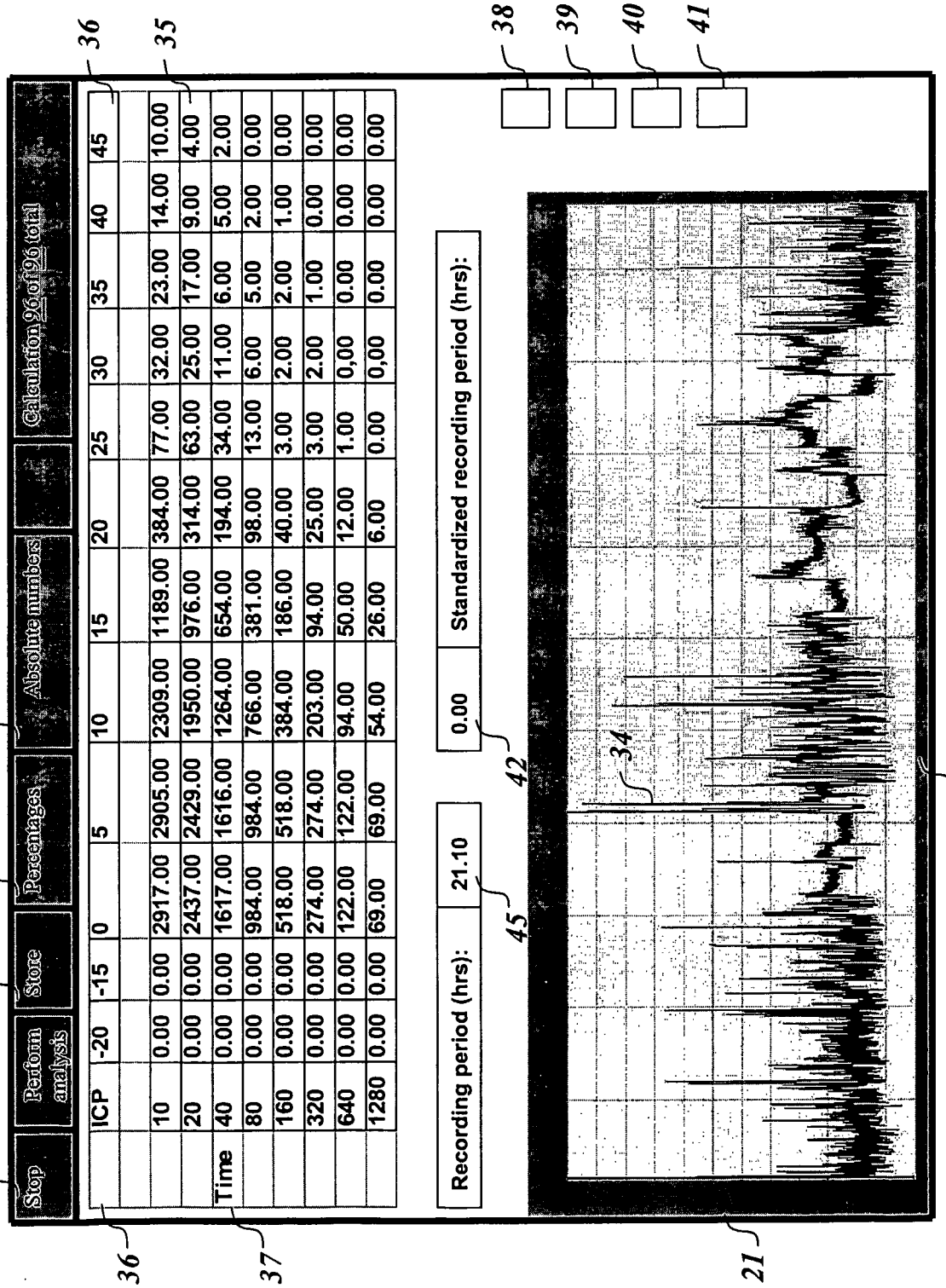

Stop
Perform analysis
Store
Percentages
Absolute numbers
Calculation 96 of 96 total
ICP
Time
-20
-15
0
5
10
15
20
25
30
35
40
45
10
20
40
80
160
320
640
1280
0.00
0.00
2917.00
2905.00
2309.00
1189.00
384.00
77.00
32.00
23.00
14.00
10.00
0.00
0.00
2437.00
2429.00
1950.00
976.00
314.00
63.00
25.00
17.00
9.00
4.00
0.00
0.00
1617.00
1616.00
1264.00
654.00
194.00
34.00
11.00
6.00
5.00
2.00
0.00
0.00
984.00
984.00
766.00
381.00
98.00
13.00
6.00
5.00
2.00
0.00
0.00
0.00
518.00
518.00
384.00
186.00
40.00
3.00
2.00
2.00
1.00
0.00
0.00
0.00
274.00
274.00
203.00
94.00
25.00
3.00
2.00
1.00
0.00
0.00
0.00
0.00
122.00
122.00
94.00
50.00
12.00
1.00
0,00
0.00
0.00
0.00
0.00
0.00
69.00
69.00
54.00
26.00
6.00
0.00
0,00
0.00
0.00
0.00
Recording period (hrs):
21.10
0.00
Standardized recording period (hrs):
32
43
44
44
36
35
38
39
40
41
36
37
45
42
34
20
21

Fig. 3

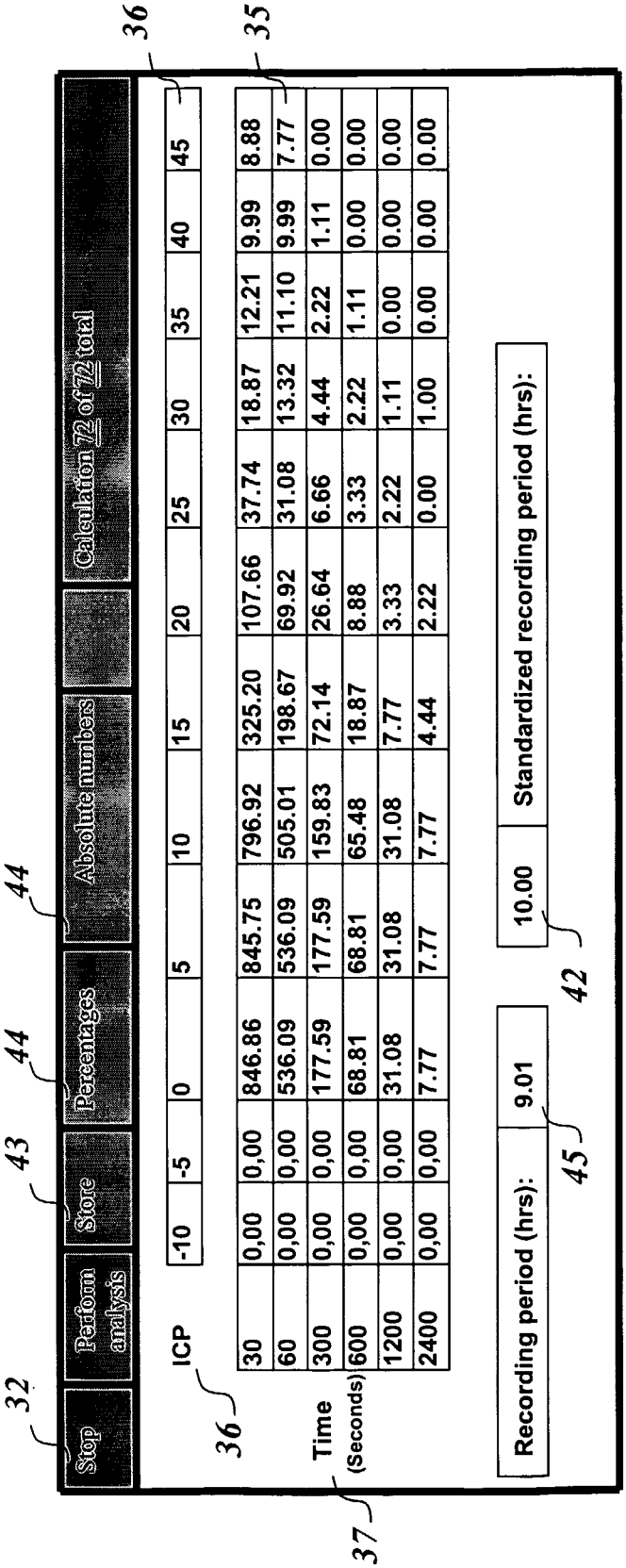

32
Stop
Perform analysis
43
Store
44
Percentages
44
Absolute numbers
Calculation 72 of 72 total
36
35
ICP
36
Time (Seconds)
37
-10
-5
0
5
10
15
20
25
30
35
40
45
30 0,00 0,00 846.86 845.75 796.92 325.20 107.66 37.74 18.87 12.21 9.99 8.88
60 0,00 0,00 536.09 536.09 505.01 198.67 69.92 31.08 13.32 11.10 9.99 7.77
300 0,00 0,00 177.59 177.59 159.83 72.14 26.64 6.66 4.44 2.22 1.11 0.00
600 0,00 0,00 68.81 68.81 65.48 18.87 8.88 3.33 2.22 1.11 0.00 0.00
1200 0,00 0,00 31.08 31.08 31.08 7.77 3.33 2.22 1.11 0.00 0.00 0.00
2400 0,00 0,00 7.77 7.77 7.77 4.44 2.22 0.00 1.00 0.00 0.00 0.00
Recording period (hrs): 9.01
45
10.00
42
Standardized recording period (hrs):

Fig. 4

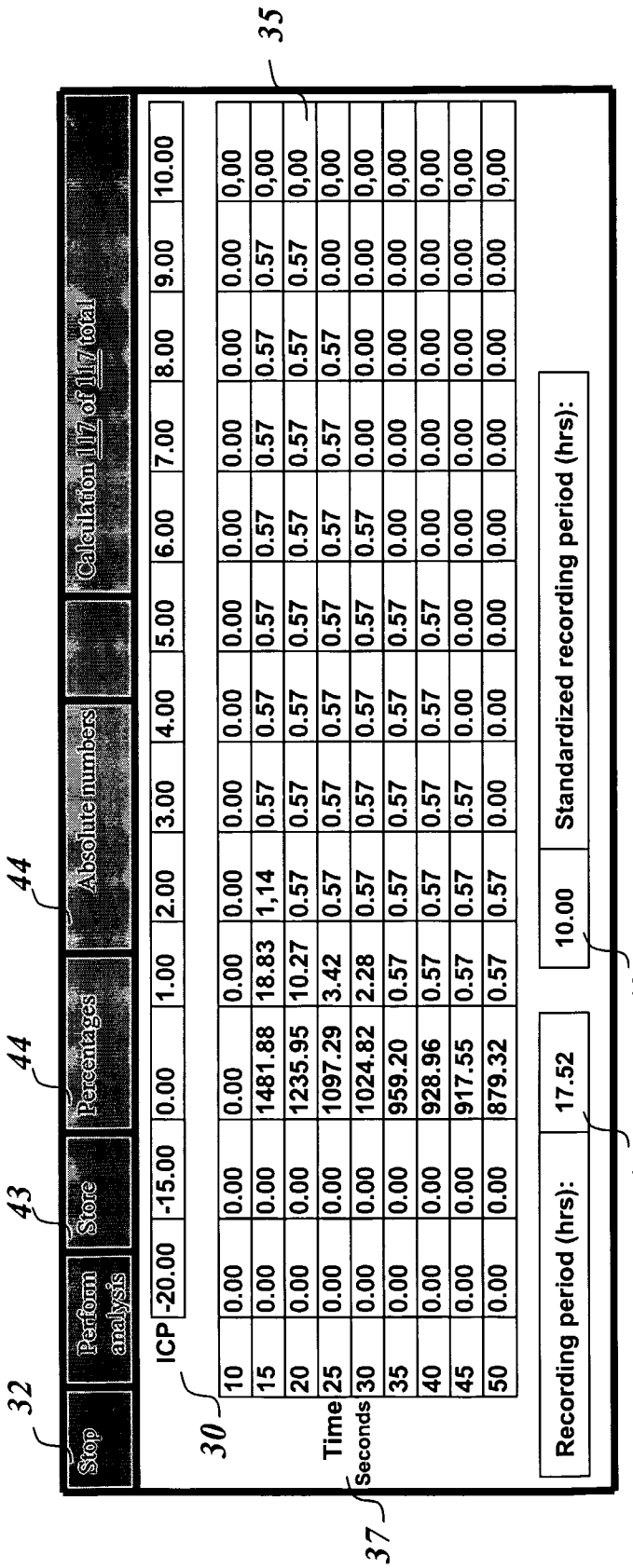
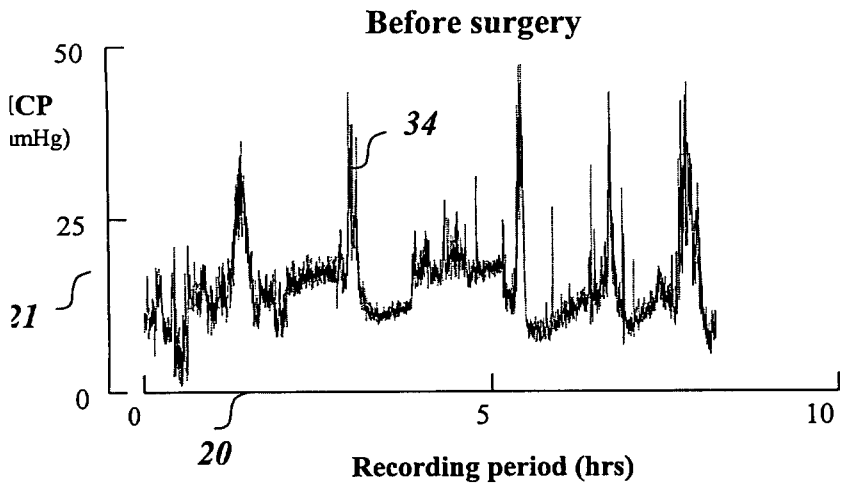
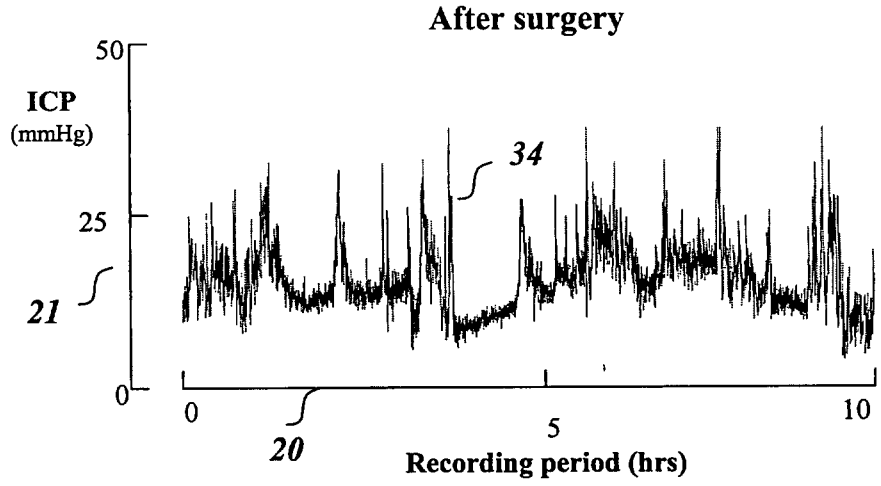

32
Stop
Perform analysis
43
Store
44
Percentages
Absolute numbers
Calculation 117 of 117 total
35
ICP
-20.00
-15.00
0.00
1.00
2.00
3.00
4.00
5.00
6.00
7.00
8.00
9.00
10.00
30
Time
Seconds
37
10
15
20
25
30
35
40
45
50
0.00
0,00
1481.88
1,14
1235.95
1097.29
1024.82
959.20
928.96
917.55
879.32
18.83
10.27
3.42
2.28
0.57
0.00
0.57
Recording period (hrs):
17.52
45
10.00
42
Standardized recording period (hrs):

Fig. 5





Duration (min)	ICP elevations					
	20	25	30	35	40	45
0.5	134	73	45	26	6	1
1	89	45	30	11	3	1
5	14	5	5	1		
10	11	9	8	1		
20	8	5	1			
40	6	1				

36, 37, 35

Recording period (hrs):	8.0
Standardised recording period (hrs):	10.0

45, 42

Duration (min)	ICP elevations					
	20	25	30	35	40	45
0.5	143	21*	4*	1*	0	0
1	69	10*	1*	0**	0	0
5	20	3	0	0		
10	11	0**	0	0		
20	5	0	0			
40	1	0				

36, 37, 35

Recording period (hrs):	9.85
Standardised recording period (hrs):	10.0

45, 42

Fig. 6

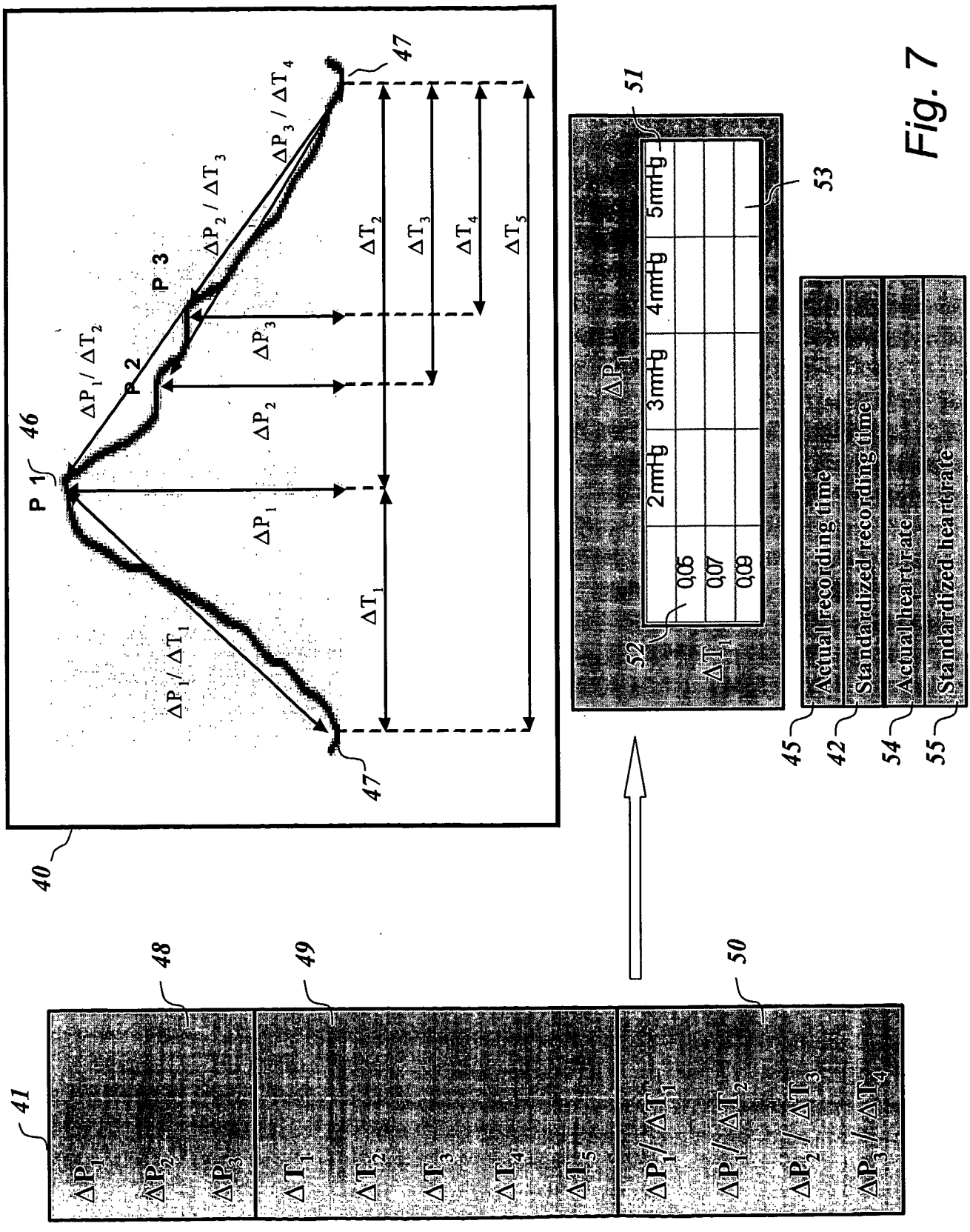
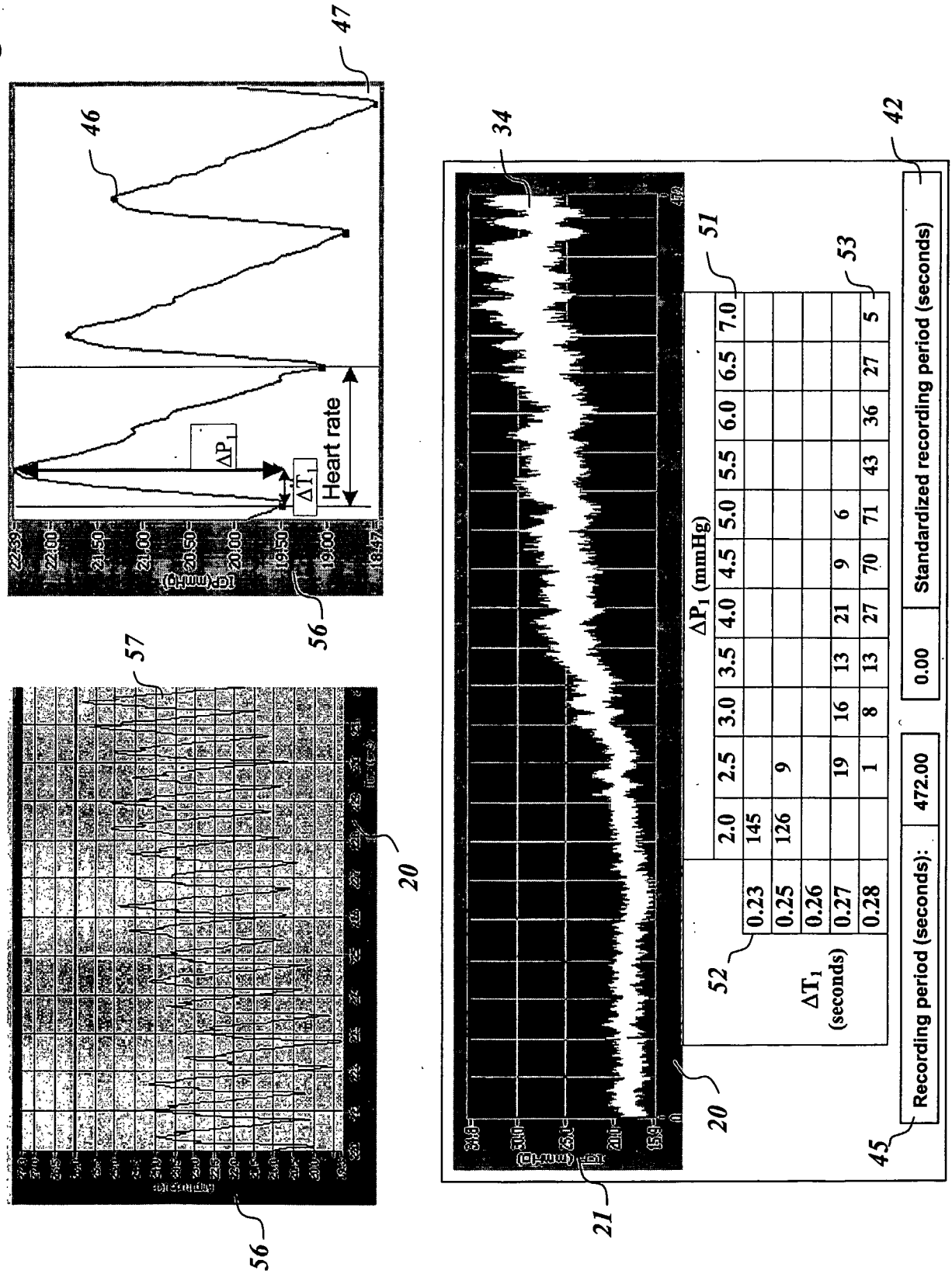

40
41
46
47
48
49
50
51
52
53
42
45
54
55
P 1
P 2
P 3
ΔP1 / ΔT2
ΔP2 / ΔT3
ΔP3 / ΔT4
ΔP1 / ΔT1
ΔP1
ΔP2
ΔP3
ΔT1
ΔT2
ΔT3
ΔT4
ΔT5
ΔP1
2mmHg
3mmHg
4mmHg
5mmHg
0,05
0,07
0,09
ΔT1
Actual recording time
Standardized recording time
Actual heartrate
Standardized heartrate

Fig. 7

Fig. 8


47
46
ΔP1
ΔT1
Heart rate
56
57
20
34
42
51
53
52
ΔP1 (mmHg)
ΔT1 (seconds)
2.0 2.5 3.0 3.5 4.0 4.5 5.0 5.5 6.0 6.5 7.0
0.23 145
0.25 126 9
0.26
0.27 19 16 13 21 9 6
0.28 1 8 13 27 70 71 43 36 27 5
20
21
45
Recording period (seconds): 472.00
0.00
Standardized recording period (seconds)

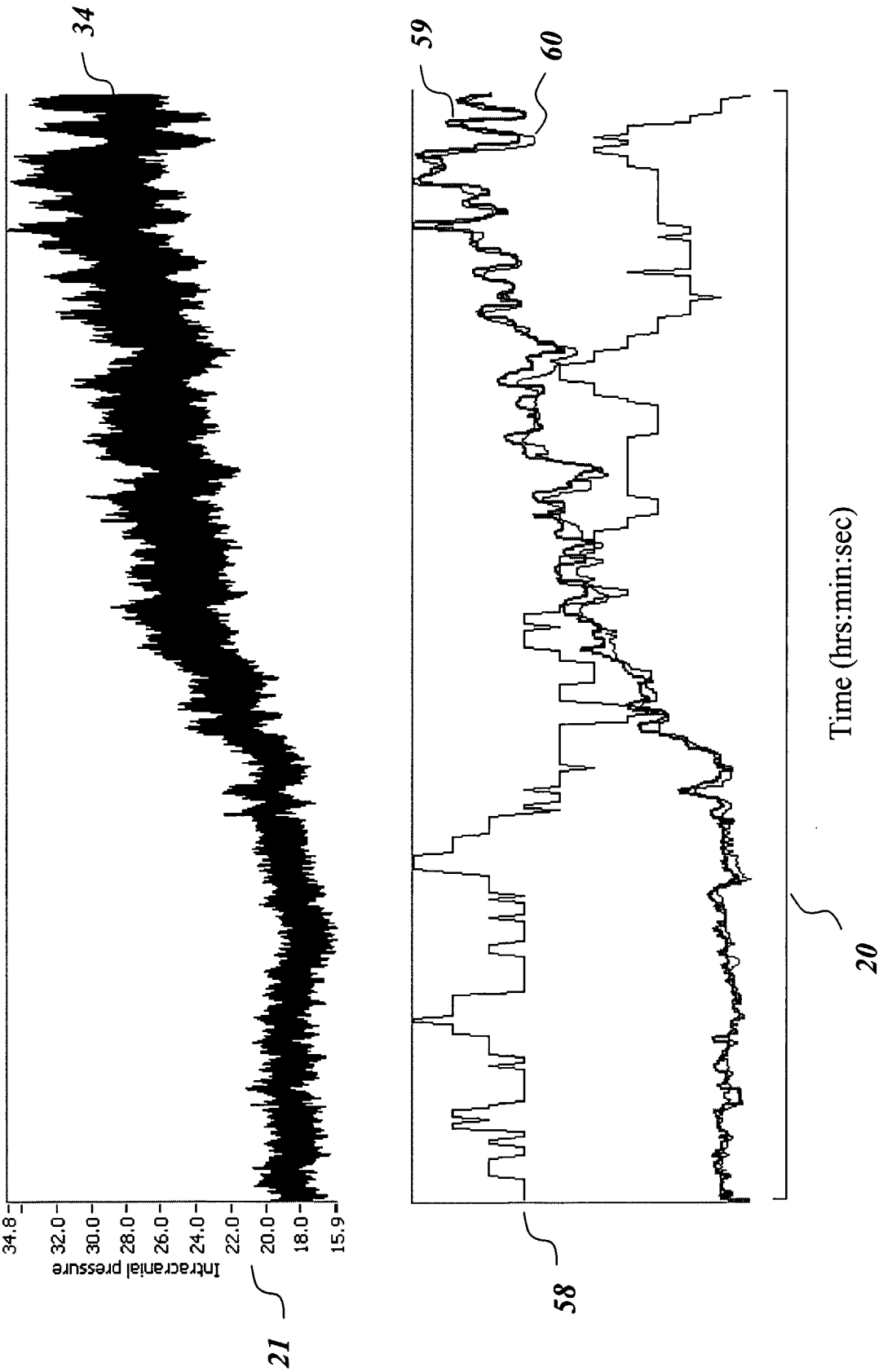

34
59
60
34.8
32.0
30.0
28.0
26.0
24.0
22.0
20.0
18.0
15.9
Intracranial pressure
21
58
Time (hrs:min:sec)
20

Fig. 9

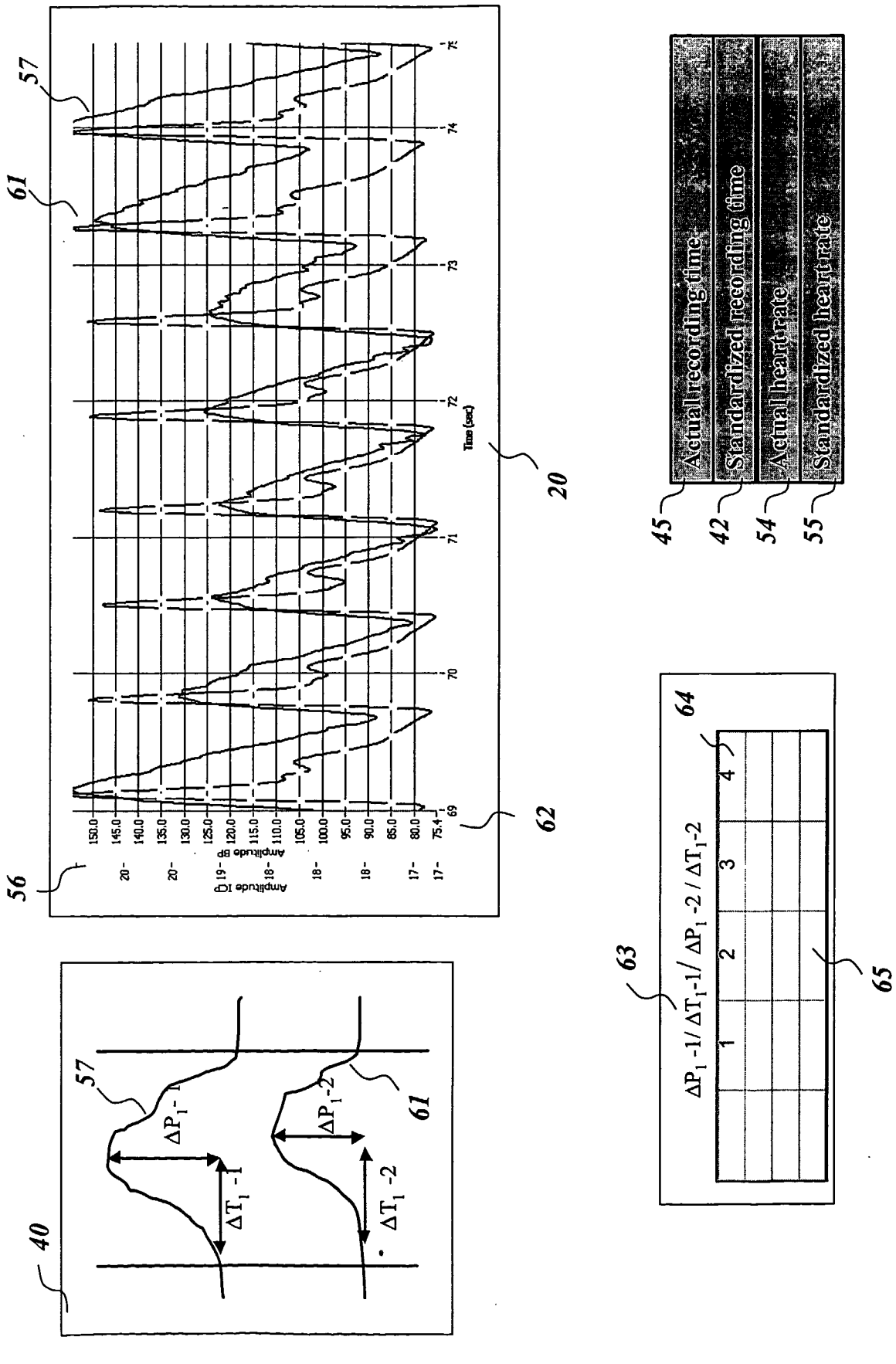
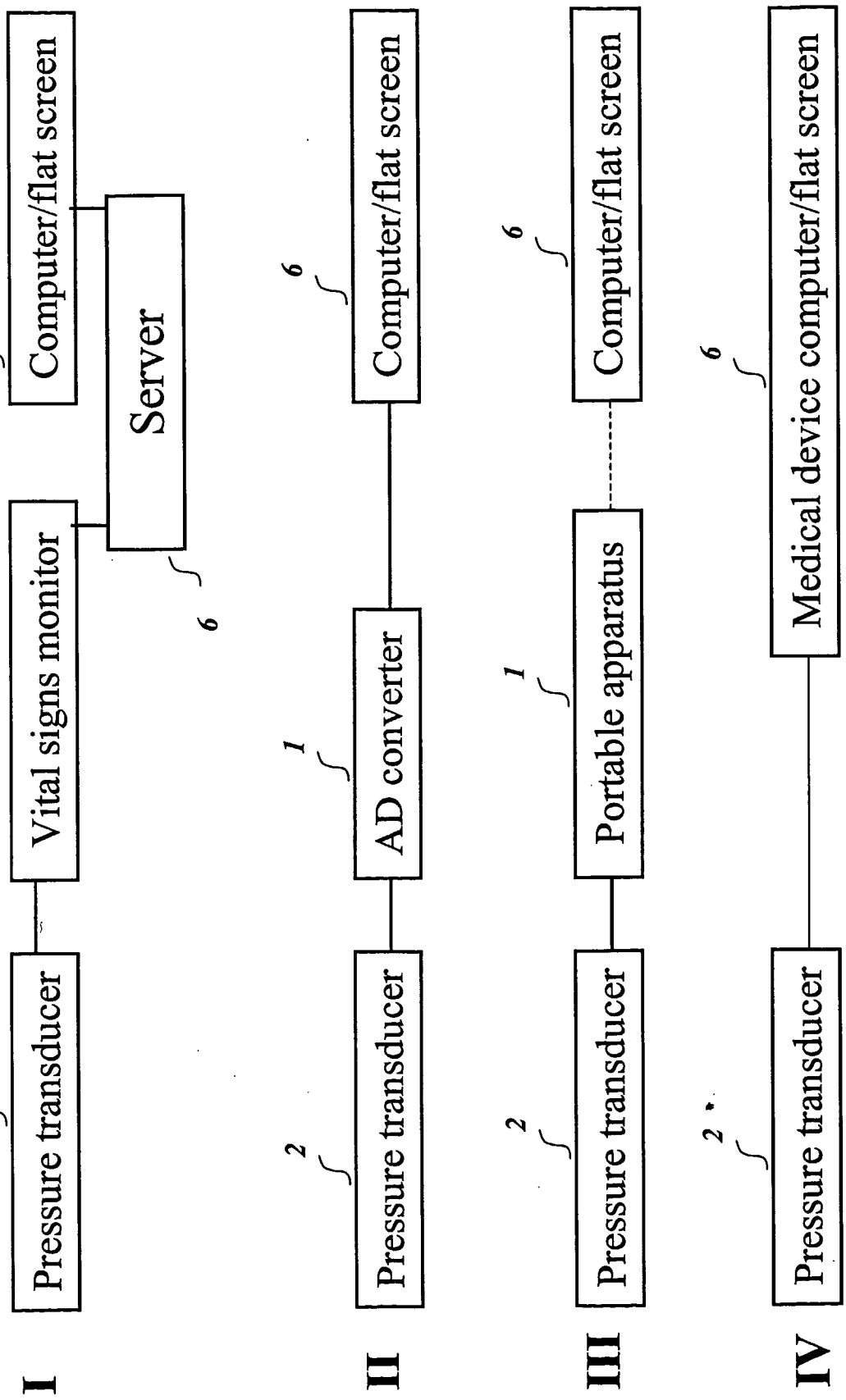

40
57
61
ΔP_1-1
ΔT_1-1
ΔP_1-2
ΔT_1-2
56
57
61
62
20
Amplitude IQ
Amplitude BP
Time (sec)
63
ΔP_1-1/ ΔT_1-1/ ΔP_1-2 / ΔT_1-2
64
65
1
2
3
4
45
42
54
55
Actual recording time
Standardized recording time
Actual heart rate
Standardized heart rate

Fig. 10

Fig. 11


I
Pressure transducer
2
Vital signs monitor
Server
6
Computer/flat screen
6
II
Pressure transducer
2
AD converter
1
Computer/flat screen
6
III
Pressure transducer
2
Portable apparatus
1
Computer/flat screen
6
IV
Pressure transducer
2
Medical device computer/flat screen
6

INTERNATIONAL SEARCH REPORT

Interna	Application No
PCT	02/00164

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/03 //A61B5/02

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)
IPC 7 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

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 080 653 A (BARNES JR RALPH W ET AL) 21 March 1978 (1978-03-21) column 1, line 26 -column 2, line 7	1-10, 29-34
A	---	11-28
X	D JOHN DOYLE ET AL: "Analysis of intracranial pressure." JOURNAL OF CLINICAL MONITORING, vol. 8, no. 1, January 1992 (1992-01), pages 81-90, XP002902599 page 85, column 1, line 7 -column 2, line 2	1-10, 29-34
A	---	11-28
	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in 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

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
5 August 2002	26. 08. 2002

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Frida Plym Forshell

INTERNATIONAL SEARCH REPORT

Intern	Application No
PCT	02/00164

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 893 630 A (BRAY JR ROBERT S) 16 January 1990 (1990-01-16) column 2, line 33 -column 3, line 62	11-28
A		1-10, 29-34

A	US 4 204 547 A (ALLOCCA JOHN A) 27 May 1980 (1980-05-27) column 2, line 51 -column 3, line 4	2-4

A	WO 84 01499 A (IVAC CORP) 26 April 1984 (1984-04-26) page 13, line 17 -page 14, line 31	5

A	US 4 295 471 A (KASPARI WILLIAM J) 20 October 1981 (1981-10-20) column 8, line 29 - line 64	5,7-10, 22-24

INTERNATIONAL SEARCH REPORT

In tional application No.
PCT/NO 02/00164

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 1-10
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.1

Claims Nos.: 1-10

Present claims 1-10 relate to a diagnostic method practised on the human body, namely a method for measuring and analysing pressure in a body cavity in order to detect a pathological state. Furthermore, when the method refers to invasive pressure measurement as suggested in claim 2, claims 1-10 also relate to a surgical method.

Thus, the International Searching Authority is not required to carry out an international search for these claims (PCT Rule 39.1.(iv)): Nevertheless, an international search has been executed for claim 1-10.

INTERNATIONAL SEARCH REPORT

rmation on patent family members

Inter Application No
PC 02/00164

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4080653 A	21-03-1978	NONE	
US 4893630 A	16-01-1990	CA 1230678 A1	22-12-1987
		GB 2156997 A ,B	16-10-1985
US 4204547 A	27-05-1980	EP 0020677 A1	07-01-1981
		WO 8000913 A1	15-05-1980
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		JP 59501895 T	15-11-1984
US 4295471 A	20-10-1981	AT 9056 T	15-09-1984
		CA 1161274 A1	31-01-1984
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		EP 0020110 A1	10-12-1980
		JP 56500599 T	07-05-1981
		WO 8002638 A1	11-12-1980

专利名称(译)	用于监测体腔压力的装置，方法和系统		
公开(公告)号	EP1383424A1	公开(公告)日	2004-01-28
申请号	EP2002720684	申请日	2002-04-29
申请(专利权)人(译)	SENSOMETRICS AS		
当前申请(专利权)人(译)	DPCOM AS		
[标]发明人	EIDE PER KRISTIAN		
发明人	EIDE, PER, KRISTIAN		
IPC分类号	A61B5/00 A61B5/021 A61B5/0215 A61B5/0245 A61B5/03 G06F19/00		
CPC分类号	A61B5/021 A61B5/02108 A61B5/03 A61B5/031 G06F19/3487		
优先权	09/843702 2001-04-30 US		
其他公开文献	EP1383424B1		
外部链接	Espacenet		

摘要(译)

本发明涉及用于数字采样，定量分析和体腔内压力呈现的系统和方法。本发明还涉及一种用于监测，采样和存储压力的便携式设备以及一种用于分析压力的软件。本发明包括用于分析和呈现压力的算法和用于执行分析的软件。计算机软件可以集成在便携式设备中和各种系统中。该软件提供压力曲线的不同定量表示，作为不同水平和持续时间的颅内压升高数量矩阵和具有预选特征的单脉冲压力波数量矩阵。可以根据记录时间和心率变化来标准化参数。在压力监测之后，数据可以以不同的方式呈现，在线和离线。