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Storm et al (2002), Skin Conductance correlates with Perioperative Stress"
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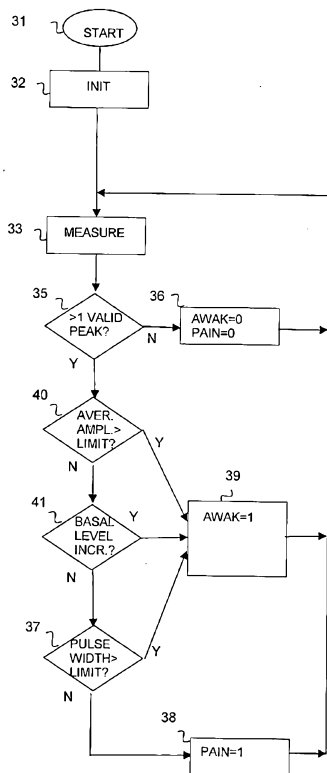
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(54) Title: METHOD AND APPARATUS FOR MONITORING A SEDATED PATIENT

(57) Abstract: A method and an apparatus for monitoring a sedated patient, the method comprising the steps of providing a skin conductance signal measured at an area of the patient's skin through a time interval, establishing the existence of at least two fluctuation peaks in the skin conductance signal through said time interval, considering if the amplitudes of fluctuation peaks in the skin conductance signal through said interval, the basal level of the skin conductance signal through said interval and the width of the fluctuation peaks in the skin conductance signal fulfils a predetermined criterion, activating a first output signal which indicates the state of awakening in the patient if said criterion is fulfilled, and activating a second output signal which indicates the state of pain in the patient if said criterion is not fulfilled.



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METHOD AND APPARATUS FOR MONITORING A SEDATED PATIENT

TECHNICAL FIELD

The invention relates in general to medical technology, and in particular to a method and an apparatus for monitoring patients during surgery and general
5 anaesthesia.

BACKGROUND OF THE INVENTION

During surgery it is very important to observe the patient's level of consciousness and awareness. Few reliable methods of observation exist today. In the field of medical technology there is a problem in producing physical measurements
10 representing the activity in an individual's autonomous nervous system, i.e. in the part of the nervous system, which is beyond the control of the will.

Particularly, there is a special need to monitor the autonomous nervous system of a sedated, non-verbal patient, e.g. a patient in anaesthesia or an artificially ventilated patient, in order to detect if the patient needs more hypnotics because of awakening
15 stimuli or more analgesia because of pain stimuli.

Tests have shown that the skin's conductance changes as a time variable signal which, in addition to a basal, slowly varying value (the so-called basal level or the average conductance level through a certain interval), also has a component consisting of spontaneous waves or fluctuations.

20 RELATED BACKGROUND ART

WO-03/94726 discloses a method and an apparatus for monitoring the autonomous nervous system of a sedated patient. In the method, a skin conductance signal is measured at an area of the patient's skin. Certain characteristics, including the average value of the skin conductance signal through a time interval and the number
25 of fluctuation peaks through the interval, is calculated. Based on these characteristics, two output signals are established, indicating pain discomfort and awakening in the patient, respectively. The awakening signal is established based on the number of fluctuations and the average value through an interval.

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SUMMARY OF THE INVENTION

The present invention seeks to provide a method and an apparatus for monitoring a sedated patient, which indicates a state of pain/discomfort in the patient and which also provides an indication of awakening of the patient.

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According to another example, the invention seeks to provide such a method and apparatus, which relies on the measurement of skin conductance variations due to emotional sweating.

10 In yet another example, the invention seeks to provide such a method and apparatus, which provides reliable output indications.

In a further example, the invention seeks to provide such a method and apparatus which overcomes disadvantages of the related prior art.

15

According to another example, the invention seeks to provide such a method and apparatus, which substantially differ from the related prior art.

20 In yet a further example, the present invention may be implemented by a method and an apparatus as defined in the appended claims.

Further advantages and characteristics of the invention can be found in the dependent claims.

25 BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be described by example with reference to the drawings, wherein

Figure 1 is a block diagram illustrating a preferred embodiment of an apparatus according to the invention, and

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Figure 2 is a flow chart illustrating a method according to the invention.

DETAILED DESCRIPTION OF THE INVENTION

Figure 1 illustrates a block diagram for a preferred embodiment of an apparatus according
5 to the invention. Substantial parts of the apparatus' hardware structure is previously
described in the Applicant's related patent application WO-03/94726, with particular
reference to the block diagram in fig. 1 and the corresponding,

detailed description. The disclosure of this publication, and the hardware structure and hardware components in particular, is hereby expressly incorporated by reference.

5 On an area 2 of the skin on a body part 1 of the patient, sensor means 3 are placed for measuring the skin's conductance. The measurement arrangement is disclosed in closer detail in WO-03/94726.

The apparatus comprises a measurement converter 4; which in a preferred embodiment may include a synchronous rectifier and a low pass filter; which converts the measured skin conductance signal into a voltage. This voltage is
10 further sent to control unit 5; which includes time discretization module 51 and analog-digital converter 52, which converts measurement data to digital form. The choice of circuits for time discretization and analog-digital conversion implies technical decisions suitable for a person skilled in the art. In the preferred embodiment, time discretization is done in an integrated circuit, which combines
15 oversampling, filtering and discretization.

In the same way as in the related patent application WO-03/94726, the control unit 5 also includes other data storage 54, 55 and data processing units 53 interconnected to a digital bus 59.

20 Data processing unit 53 analyses the measured and digitized signal coming from unit 52. The signal is then analysed in order to extract different types of information.

The control unit 5 is arranged to read time-discrete and quantized measurements for the skin conductance from the measurement converter 4, preferably by means of an executable program code, which is stored in the non-volatile memory 54 and which
25 is executed by the processing unit 53. It is further arranged to enable measurements to be stored in the read and write memory 55. By means of the program code, the control unit 5 is further arranged to analyze the measurements in real time, i.e. simultaneously or parallel with the performance of the measurements. The method or process performed by the control unit 5, in order to analyze the skin conductance
30 signal, is distinctive and substantially different from the method/process disclosed in WO-03/94726.

In this context, simultaneously or parallel should be understood to mean simultaneously or parallel for practical purposes, viewed in connection with the time constants which are in the nature of the measurements. This means that input, storage and analysis can be undertaken in separate time intervals, but in this case
5 these time intervals, and the time between them, are so short that the individual actions appear to occur concurrently.

The control unit 5 is further arranged to identify the fluctuations in the time-discrete, quantized measuring signal, by means of a program code portion which is stored in the non-volatile memory 54 and which is executed by the processing unit
10 53. The program code portion is substantially different from the program code portion disclosed in WO-03/94726.

The control unit 5 is advantageously also arranged to calculate the amplitude of the fluctuation peaks in the time-discrete, quantized measuring signal during a time interval, by means of a program code portion which is stored in the non-volatile
15 memory 54 and which is executed by the processing unit 53.

The processing unit 53, the memories 54, 55, the analog/digital converter 52, the communication port 56, the interface circuit 81 and the interface circuit 61 are all connected to a bus unit 59. The detailed construction of such bus architecture for the design of a microprocessor-based instrument is regarded as well-known for a
20 person skilled in the art.

The interface circuit 61 is a digital port circuit, which derives output signals 71, 72 from the processing unit 53 via the bus unit 59 when the interface circuit 61 is addressed by the program code executed by the processing unit 53.

An active state of the first output signal 71 indicates that the analysis of the skin
25 conductance measurement has detected that the patient is receiving awakening stimuli and may need more hypnotics. An active state of the second output signal 72 indicates the state of pain pain/discomfort in the patient.

In a preferred embodiment the display 8 comprises a screen for graphic visualization of the conductance signal, and a digital display for displaying the
30 frequency and amplitude of the measured signal fluctuations. The display units are preferably of a type whose power consumption is low, such as an LCD screen and

LCD display. The display means may be separate or integrated in one and the same unit.

The apparatus further comprises a power supply unit 9 for supplying operating power to the various parts of the apparatus. The power supply may be a battery or a
5 mains supply of a known type.

The apparatus may advantageously be adapted to suit the requirements regarding hospital equipment, which ensures patient safety. Such safety requirements are relatively easy to fulfill if the apparatus is battery-operated. If, on the other hand, the apparatus is mains operated, the power supply shall meet special requirements,
10 or requirements are made regarding a galvanic partition between parts of the apparatus (for example, battery operated), which are safe for the patient and parts of the apparatus, which are unsafe for the patient. If the apparatus has to be connected to external equipment, which is mains operated and unsafe for the patient, the connection between the apparatus, which is safe for the patient and the unsafe external
15 equipment requires to be galvanically separated. Galvanic separation of this kind can advantageously be achieved by means of an optical partition. Safety requirements for equipment close to the patient and solutions for fulfilling such requirements in an apparatus like that in the present invention are well-known to those skilled in the art.

20 Figure 2 illustrates a flow chart for a method for controlling a warning signal in an apparatus for monitoring the autonomous nervous system of a sedated patient, and especially for detecting stress or discomfort and awakening.

The method starts at reference 31.

The first process step 32 is an initial step, establishing initial values for use in the
25 remaining, repeated process steps.

In step 33, skin conductance signal or EDR (electrodermal response) signal is measured, preferably in microsiemens (uS), time-quantized and converted to digital form using the equipment described with reference to fig. 1. A time-series of a certain duration, typically between 5 seconds and 40 seconds, and more preferably
30 between 5 and 20 seconds, e.g. about 15 seconds, containing skin conductance data,

is acquired during this step. At 15 seconds, with a sampling rate of 20 – 200 samples per second, the time-series may contain 300 – 3000 samples.

In the test step 35, a test is performed in order to detect the existence of valid peaks in the time-series of the acquired skin conductance signal. If more than one peak is detected, the process continues at step 40. If one or no peak is detected, the process continues at step 36.

In step 36, both output signals 71 or 72 are set to passive state. Thus, if zero or one valid peak has been detected in step 35, the first output signal 71 indicates no awakening, and the second output signal 72 indicates no pain in the patient.

The existence of a valid peak is established in step 35 if the derivative of the signal changes sign through a small period in the interval. The derivative of the signal is calculated as the difference between two subsequent sample values. In addition, it is possible to use a simple digital filter that needs to see two or more subsequent sign changes before the sign change is accepted.

In the test step 35 it may be necessary to establish additional criteria for when a peak should be considered as valid. In their simplest form such criteria may be based on the fact that the signal amplitude has to exceed an absolute limit in order to be able to be considered a valid fluctuation. A recommended, such reference value for the conductance is between 0.01 μ S and 0.02 μ S, preferably 0.015 μ S.

Alternatively or in addition, it is an advantage to base the criteria on the fact that the signal actually has formed a peak that has lasted a certain time. The criteria may also be based on the fact that the increase in the skin conductance signal value as a function of time must remain below a certain limit, typically 20 μ S/s, if the maximum value is to be considered valid.

Another possible condition for establishing a valid peak is that the absolute value of the change in the conductance signal from a local peak to the following local valley exceeds a predetermined value, such as a value in the range [0.01 μ S, 0.02 μ S], e.g. 0.015 μ S.

Also, a maximum value appearing at the border of the interval, i.e. the starting point or ending point of the interval should preferably not be regarded as a valid peak.

The object is thereby achieved that artifacts, which can occur in error situations such as, e.g., electrodes working loose from the skin, or other sources of noise or disturbances, does not lead to the erroneously detection of peaks.

5 Step 40 is a test step wherein the amplitudes of fluctuation peaks in the skin conductance signal through the time interval is considered. An average value of the amplitudes through the interval is calculated. If the calculated average value exceeds a first limit value in the range [0,05 μ S, 0,20 μ S], preferably in the range [0,07 μ S, 0,13 μ S], or more preferably about 0,10 μ S, an awakening state in the patient is detected, and the process continues at step 39.

10 If the calculated average amplitude value does not exceed the first limit value, the process continues at step 41.

In step 41, the basal level of the skin conductance signal through said interval is considered. If the basal level has shown a recent significant increase, an awakening state in the patient is detected, and the process continues at step 39. More
15 particularly, this is the case if the basal level has increased more than a second limit value in the range [0,05 μ S, 0,3 μ S] during a recently elapsed time interval in the range [10 seconds, 30 seconds]. Preferably, the second limit value is within the range [0,08 μ S, 0,12 μ S] and the recently elapsed time interval is in the range [12 seconds, 18 seconds]. For instance, the second limit value may advantageously be
20 0,1 μ S and the elapsed time interval 15 seconds.

If the basal level has not shown such a significant increase, the process continues at step 37.

In step 37, the width of the pulses of the skin conductance signal is calculated, and the width is compared with a preset reference value. If the pulse width is above the
25 reference value, this indicates that the patient is receiving awakening stimuli and may need more hypnotics, thus the process continues at step 39. If the pulse width is below the second reference value, this indicates a state of pain/pain/discomfort. The process continues to step 38, where the output signal 72, indicating pain, is set. The process is then repeated from step 33.

The width of a pulse may be calculated as twice the time difference between the local minimum value and the local peak in one fluctuation. The width may also be calculated as the time difference between the local minimum values in the skin conductance signal. The width of a pulse may alternatively be calculated as the time difference between local peaks in the skin conductance signal. When several pulses are detected in the time series, the maximum width may advantageously be stored and used for the further processing. Another way of measuring the width of the pulses is to count the number of pulses during the time interval and calculating the width as the length of the time interval divided by the number of pulses during the time interval. Even another way of measuring the width of the pulses is to ensure that, during the time period, at least more than one pulse has a width above a preset reference value. Then, the average pulse width is calculated, based on the width of the pulses with a width above the preset value.

The reference value of the pulse width should be within the range [1 second, 5 seconds]. In order to obtain even better and more reliable results, the reference value should be within the range [1,5 seconds, 3 seconds], e.g. about 2 seconds.

In step 39, the output signal 71 is set or activated. The process is then repeated from step 33.

The process may be interrupted or terminated by an operating device (not shown) or by a command input from the communication port 56.

An improvement to the method illustrated in figure 2 will be described in the following:

In the embodiment in figure 2, a time-series is first acquired and subsequently analyzed. As an advantageous alternative, data acquisition and analysis are performed as separate, independent processes, concurrently executed by the processing unit 53.

A data acquisition process is then performed, which virtually continuously updates a portion of the memory 55 with the latest e.g. 15 seconds of skin conductance signal values.

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An analysis process is initiated e.g. every 1 second. This process will analyze the latest e.g. 15 seconds of skin conductance data, acquired by the concurrently executed data acquisition process. All the process steps 33-39 are performed by the analysis process, while the initial process step 32 is performed in advance, as initial step.

5

This solution leads to an even faster and more reliable indication of awakening, compared to the simpler method described with reference to figure 2.

The invention has been primarily described with reference to human patients. It should be appreciated that the invention also may be used with animals.

10

Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated integer or step or group of integers or steps but not the exclusion of any other integer or step or group of integers or steps.

15

Many modifications will be apparent to those skilled in the art without departing from the scope of the present invention.

The reference in this specification to any prior publication (or information derived from it), or to any matter which is known, is not, and should not be taken as, an acknowledgement or admission or any form of suggestion that that prior publication (or information derived from it) or known matter forms part of the common general knowledge in the field of endeavour to which this specification relates.

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The claims defining the present invention are as follows:

1. Method for monitoring a sedated patient, including the following steps, performed by a control unit that includes a processing unit:
 - 5 - providing a skin conductance signal measured at an area of the patient's skin through a time interval,
 - establishing the existence of at least two fluctuation peaks in the skin conductance signal through said time interval,
 - considering if the amplitudes of fluctuation peaks in the skin conductance signal through said interval, the basal level of the skin conductance signal through said interval and the width of the fluctuation peaks in the skin conductance signal fulfils the following predetermined criteria:
 - if the average of said amplitudes exceeds a first limit value in the range [0,05 μ S, 0, 20 μ S],
 - 15 - if said basal level has shown an increase of more than a second limit value in the range [0, 05 μ S, 0,3 μ S] during a recently elapsed time interval in the range [10 seconds, 30 seconds], and
 - if said width of the fluctuation peaks exceed a third limit valve of [1 second, 5 seconds],
 - 20 the method further including the steps of
 - activating a first output signal which indicates the state of awakening in the patient if one of said criteria is fulfilled, and
 - activating a second output signal which indicates the state of pain in the patient if none of said criteria is fulfilled.
 - 25
2. Method according to claim 1, further including the step of deactivating said first and second output signals if less than two fluctuation peaks in the skin conductance signal are detected through the time interval.
- 30 3. Method according to claims 1 or 2, wherein said first limit value is within the range [0,07 μ S, 0,13 μ S].

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4. Method according to any one of claims 1 to 3,
wherein said second limit value is within the range [0,08 μ S, 0,12 μ S] and said recently
elapsed time interval is in the range [12 seconds, 18 seconds].
5. Method according to any one of claims 1 to 4,
wherein said third limit value is within the range [1,5 seconds, 3 seconds].
6. Method according to any one of claims 1 to 5,
wherein said step of detecting the existence of at least two fluctuation peaks in the skin
conductance signal through said time interval includes
the substep of establish the existence of a valid peak if the derivative of the skin
conductance signal changes sign through a small period in the interval.
7. Method according to claim 6,
wherein said derivative is calculated as the difference between two subsequent sample
values.
8. Method according to any one of claims 6 to 7,
wherein an additional criterion is established for when a peak is considered valid,
including ensuring that the signal amplitude exceeds an absolute limit value selected from
the range [0.01 μ S, 0.02 μ S].
9. Method according to any one of claims 6 to 8,
wherein an additional criterion is established for when a peak is considered valid,
including ensuring that the increase in the skin conductance signal as a function of time
remains below a certain limit such as 20 μ S/s.
10. Method according to any one of claims 6 to 9,
wherein an additional criterion is established for when a peak is considered valid,
including ensuring that the absolute value of the change in the conductance signal from a

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local peak to a following local valley exceeds a predetermined value selected from the range $[0.01\mu\text{S}, 0.02\mu\text{S}]$.

11. Method according to any one of claims 6 to 10,
5 wherein an additional criterion is established for when a peak is considered valid, including ensuring that a starting point or an ending point of the interval is not regarded as a valid peak.

12. Method according to any one of claims 1 to 11,
10 wherein said step of providing a width value includes calculating twice the difference from a local minimum point to a local peak in the skin conductance signal.

13. Method according to any one of claims 1 to 11,
15 wherein said step of providing a width value includes calculating the time difference between local minimum points or between local peaks in the skin conductance signal.

14. Method according to any one of claims 1 to 11,
20 wherein said step of providing a width value includes counting the number of pulses during the time interval and calculating the width as the length of the time interval divided by said number of pulses.

15. Method according to any one of claims 1 to 14,
25 wherein more than one pulse width value is provided, and wherein the maximum pulse width is stored and used for the further processing.

16. Method according to any one of claims 1 to 15,
wherein data acquisition and data analysis are performed sequentially by a processing unit.
30

17. Method according to any one of claims 1 to 15,

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wherein data acquisition and data analysis are performed concurrently by a processing unit.

18. Apparatus for monitoring a sedated patient, including
- measurement equipment for providing a skin conductance signal measured at an
- 5 area of the patient's skin, and
- a control unit, arranged to perform the method according to any one of claims 1 to
- 17.

19. Method for monitoring a sedated patient, being substantially as hereinbefore
- 10 described with reference to the accompanying figures.

20. Apparatus for monitoring a sedated patient arranged to perform the method, substantially as hereinbefore described with reference to the accompanying figures.

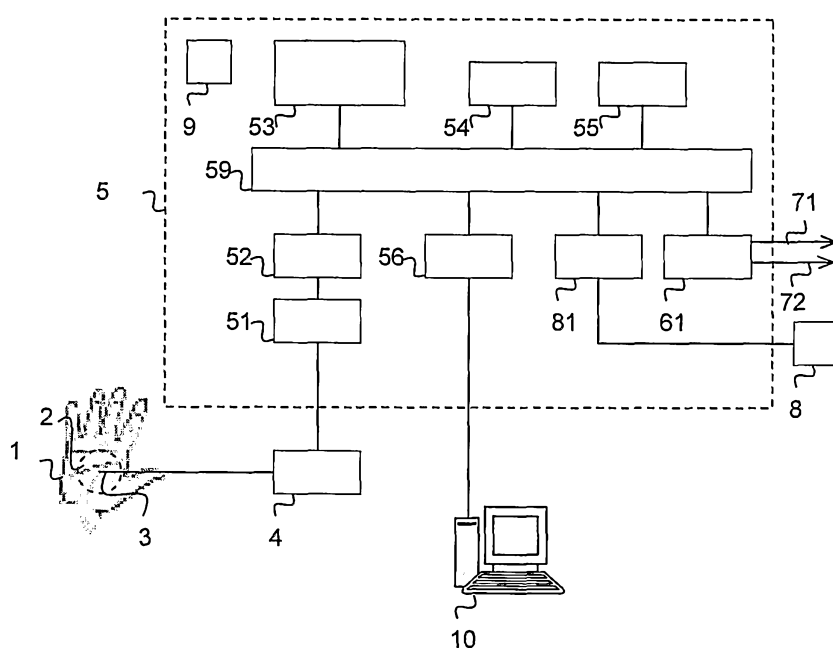


Fig. 1

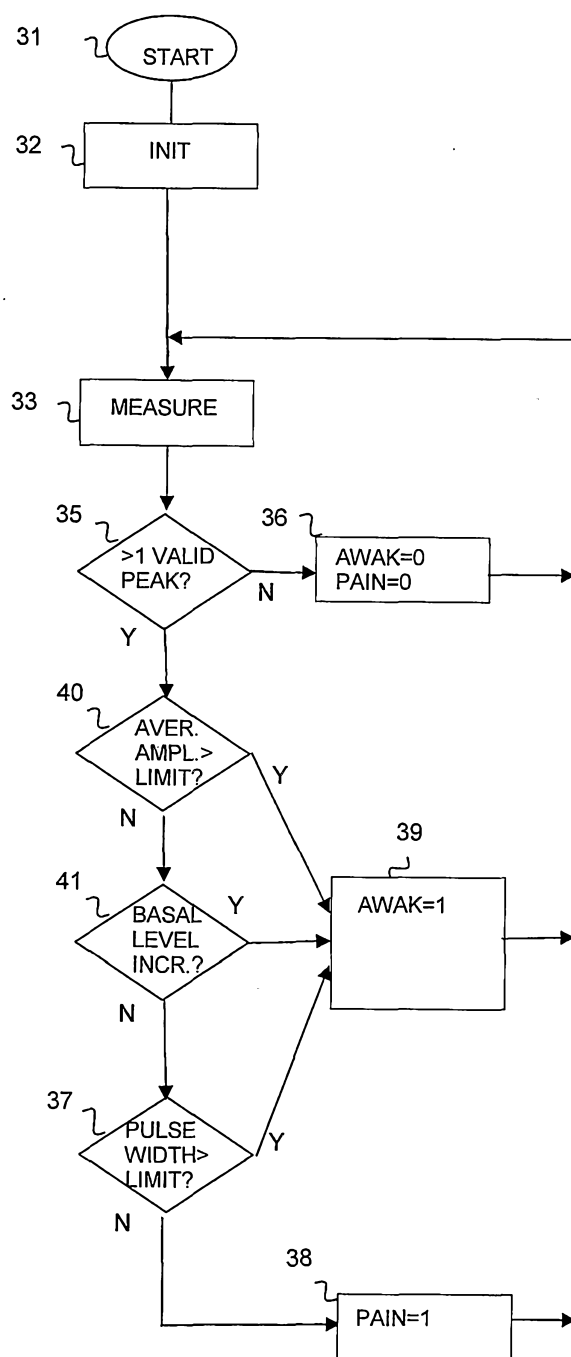


Fig 2