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(54) Title: APPARATUS FOR PROVIDING DIFFERENTIAL MEASUREMENTS OF A SENSATION

(57) Abstract: A sensation level measuring or analysing apparatus and method comprising the steps of delivering a varying physical stimulus to a person; detecting a sensation threshold value of said person by registering a first level of the physical stimulus upon actuation of said person; detecting a matched sensation value of said person by registering a second level of the physical stimulus upon actuation of said person; generating a matched processed parameter value (MPL) dependent on said detected sensation threshold (ST) and matched sensation values (MAL) of the physical stimulus according to a predetermined rule.

APPARATUS FOR PROVIDING DIFFERENTIAL MEASUREMENTS OF A SENSATION

Technical Field

The present invention relates generally to an apparatus for assessing the level of a sensation experienced by a person by providing a variable stimulus to the person until the applied stimulus matches the experienced sensation. More particularly, the present invention is directed to achieve such an apparatus that provides differential measurements of the sensation.

Background

When using sensation/stimulation matching for assessing changes in the level of a sensation, there are often physiological or psychological conditions that affect the measurement. These conditions may change as a matter of normal course or be due to pathological phenomena, and in both cases it is important to take account of these conditions in order to draw a correct conclusion from the result of a measurement.

Furthermore, the perception of sensations is to a high degree dependent on individual conditions, i.e. the perception may vary with the varying mood or possible pathological conditions of the person. Furthermore, the perception is sometimes different dependent on the sensation/stimulation intensity, i.e. the perception may vary dependent on the mode, the magnitude or the type of the sensation/stimulation.

In prior art, these facts have not been specifically addressed and the assessment level is usually assigned a value corresponding directly to the level of the applied stimulus and is often taken as an absolute measurement value. A more advanced interpretation of measurement values remains to be developed.

Prior Art

Examples of prior art sensation/stimulation matching is found in the patent publications:

DE G 92 04 961.3 (Gebrauchmuster) to Müller;
WO 97/24068 to Laserow;
WO 01/13793 to Cefar Painmatcher AB et al; and in
WO 01/13987 to Cefar Painmatcher AB et al.

The general structure of apparatuses and methods for sensation/stimulation matching is described in the mentioned pieces of prior art.

Object of the Invention

The general object of the present invention is to solve the problem of improving the comparability and interpretation of sensation level assessments with sensation/stimulation

matching apparatuses

Different aspects of the invention are directed to achieving a differential measurement and analysis of level values that inter alia:

- enables a more reliable interpretation of changes in sensations and changes in matched sensation levels.
- is individually adapted to each sensation assessing person and enables comparison between assessments at different occasions independent of the current personal condition; and
- enables comparison of assessments with different types of stimulation.

Summary of the Invention

The inventors have realised that improved assessments of a sensation or an experience by means of sensation/stimulation matching can be made by calculating and interpreting more complex measurement parameters. Such complex measurement parameters are for example derived from a sensation threshold, such as the perception threshold or the pain threshold, and a matched level of a sensation due to an affective or sensory experience such as pain.

The complex measurement parameters in accordance with different embodiments of the invention are for example:

- the sensation interval calculated as the difference between the sensation threshold and the matched sensation level, for one measurement and for comparison with subsequent measurements;
- the difference between sensation intervals in subsequent measurements;
- the relative level of sensation thresholds in subsequent measurements;
- the relative level of matched sensation level;
- combinations of the aforementioned parameters;
- the aforementioned parameters taken relative a corresponding normal level value for a specific person or for a group of persons;
- combinations and comparisons between the aforementioned parameters assessed by means of different stimulation types.

The invention is based on the fact that the sensitivity and the sensation threshold changes with changing conditions or mood of the patient. So, for example the same individual generally has a higher pain threshold when being in a normal condition than when already suffering from pain. The latter is due to the fact that the endogenous pain alleviating system gradually is breaking down, particularly when the person is suffering from a lingering pain. Therefore, relating the matched sensation value to the sensation interval as defined above enables a more reliable comparison between measurement values.

The parameter that is based on the difference in size between sensation intervals in

subsequent measurements gives information about how much the matched sensation level has changed between subsequent measurements.

Furthermore, the parameter based on the relative level of sensation thresholds in subsequent measurements entails information usable for indirect conclusions. For example, if a person has no pain but has a detectable lower pain threshold than normal, this is an indicator for a possible depression. The latter under the assumption that other pain threshold lowering factors, such as certain pharmaceuticals or drugs have been eliminated.

When for example specifically measuring and interpreting the level of pain, the invention is in one embodiment applied such that the pain threshold and the matched pain level are detected and stored in a first phase of the assessment. The numerical range or interval between the pain threshold and the matched pain level is thereafter calculated by subtracting the pain threshold level from the matched pain level. In a second phase of the assessment, the interval size is then presented in terms of an absolute level of stimulus or assigned a scale level in accordance with an appropriate scaling.

Experimental studies support the usability of these complex parameters. It has, for example, been shown that the sensation threshold in terms of an electrical pain threshold, i.e. pain induced by means of electrical stimulation, does not differ significantly between assessment occasions in healthy individuals or in individuals (patients) having pain. The electrical pain threshold can therefore in many such cases be regarded as being substantially constant for each individual. However, patients tend to have a general decrease in the pain threshold compared to healthy individuals.

The determined parameter levels are useful to store and compare between different assessment occasions, since further conclusions about the status of the person are possible to draw in the light of the changing parameters. Processing of input parameters resulting from assessments with different stimulation types, such as electrical stimulation or thermal stimulation with heat or coldness, enables further conclusions.

Different embodiments of the invention are applied in the sensation/stimulation matching apparatus itself as well as in a sensation level analysing apparatus. In the latter case the analysing apparatus comprises an input for the threshold levels and the matched sensation level. The processing of establishing the scale range and the scale is then typically performed in the analysing apparatus and the result may simply be presented or compared to other stored assessments for further analysis. The processing may also include automatically generated diagnosis and recommendations based on predefined rules. A convenient embodiment of the analysis apparatus would be realised by means of a specifically designed software program run on a general computer.

Brief Description of the Drawings

The invention will now be further described in conjunction with the drawings, wherein:

Fig 1 and 2 show block diagrams of the functional components of the inventive apparatus; and

Fig 3A and 3B show schematically diagrams of measurement parameters in accordance with the invention.

Detailed Description of Embodiments

Fig 1 shows a block diagram of the functional structure of embodiments of the invention. The functional structure of a sensation/stimulation matcher of this kind comprises a stimulus signal generator 102 coupled via means 106 for providing a pulsating stimulus to stimulus induction means 104, which in use are intended to be applied to the skin of a person for inducing a stimulus. A control unit 114, for example a control processor, is coupled to the stimulus signal generator 102 via an amplitude variation means 120 devised for varying the amplitude of the pulsating stimulus signal. The control unit is also coupled to the pulsating stimulus providing means 106 via a pulse width variation means 122 devised for varying the pulse width of the pulsating stimulus signal. The control unit is further coupled to a memory 116 for storing registered measurement values and control instructions for predetermined control schemes or analysing schemes, and a display 118 for the visual presentation of an obtained measurement value or other information. The control unit is also optionally coupled to a control switch 124, e.g. a button, for starting, stopping or halting a measurement sequence at for example a perception threshold, a sensation threshold, e.g. the pain threshold, or the tolerance threshold or a sensation level. In a preferred embodiment, the apparatus is devised to stop a variation of the pulsating properties of the stimulus in response to an actuation of the control switch 124, and the apparatus is devised to keep the pulsating property at its current level. So, for example, may the patient stop an increase in amplitude or pulse width at a level that seems to match the measured sensation and consider whether the level is correct. If the patient indeed considers the level to be correct, the patient releases his or her contact with the induction means 104. This leaves an open circuit that is detected by the apparatus, whereupon it is devised to automatically store the current value of amplitude and/or pulse width. A separate electrical circuit may be provided for the detection of an open circuit due to the patient's release of the contact with the induction means. If the halted level is not considered to be corrected, the patient may continue the increase, or variation, by releasing the button, resuming the contact or switch back to an initial switch position. In some embodiments the control switch is also used to actuate the registration of a matched sensation level, as an alternative to the open circuit detection.

In the embodiment as shown in Fig 1, the means 106 for providing a pulsating stimulus further comprises means 108 for providing a pulsed current stimulus intensity, e.g. in the shape of an oscillator, and/or means 110 for providing a square waved stimulus intensity, e.g. in the shape of a square wave or a triangle wave generator, either of the

means 108 and 110 being devised to provide a stimulus signal in the form of a pulsed current having a frequency in the range of 1-100 Hz. In Fig 1 is also shown a switching means, controllable by the control unit and being devised to switch between the different wave forms.

In addition to the general structure of a sensation/stimulation apparatus, the inventive apparatus further includes an analyser 130 communicatively coupled to the control unit 114 and devised for analysing the assessed levels of sensation or experience. The analyser 130 would typically in a communicatively coupled structure comprise a parameter processor, a storage structure for parameter processing rules and a storage structure for storing input parameters and processed complex parameters from different measurements. An alternative embodiment of the inventive apparatus would comprise an output 132 for outputting matched thresholds and levels in the shape of signals or data parameters, and a separate analysing apparatus.

Fig 2 shows a schematically an embodiment of the analysing apparatus by means of a functional block diagram. The analyser 201 thus comprises an input for a sensation threshold value ST and an input for a matched absolute level of a sensation. More specifically the sensation threshold ST would be a perception or sensation threshold value for a general sensation or experience, for example a pain threshold value PT. Furthermore, the analyser comprises an input for a matched absolute level value MAL of a sensation, for example a matched pain value. The sensation threshold value and the matched absolute level value are received in a parameter processor 202 devised to compare parameters and to derive or calculate complex parameters dependent or previously stored or pre-settable predetermined parameter rules and possibly dependent on stored previous parameter values. The parameter rules are preferably stored in a storage structure 203. Input parameter having absolute levels and calculated parameter levels from different measurement occasions are stored in a parameter storage structure 204. The analyser is also provided with an output for matched absolute levels and matched processed levels MPL that currently have been processed or taken from the parameter storage.

The input sensation threshold value and the matched absolute level are determined by means of sensation/stimulation matching and are indicated in some absolute unit of magnitude, for example electrical current amplitude or pulse width. The parameter processor is devised to carry out for example the following operations and calculations for generating the matched processed parameters MPL as shown in Fig 3A. The parameter processing is exemplified by a first and a second assessment of sensation values determined at two different occasions in time, here denoted by the index 1 and 2, being stored in the parameter storage 204.

The relative level of and the difference between the sensation thresholds T1 and T2 is determined as delta T= (T2-T1).

If delta T>0, then the person's perception threshold for the currently measured

sensation has increased and the person is less sensitive. For example in the case of pain, the pain threshold is higher which is an indicator for a better condition or a successful analgesic treatment.

- If delta T<0, then the person's perception threshold has decreased and the person is more sensitive. For example, the pain threshold has decreased which is an indicator for a worse condition or insufficient analgesic treatment.
- If delta T=0, then there is an indication of no change in sensitivity.
- The value of delta T provides an indication of the size of the change in sensitivity or perceptivity.

The level of the difference between the matched absolute value of the sensation MAL1 and MAL2 is determined as delta MAL=MAL2-MAL1.

- If delta MAL>0, then the person's matched absolute value indicates a stronger sensation.
- If delta MAL<0 then the person's matched absolute value indicates a weaker sensation.
- If delta MAL=0 then there is an indication of no change in sensation magnitude.
- The value of delta MAL provides an indication of the size of the change in sensation.

The sensation interval SI is determined as the difference between the sensation threshold and the matched sensation level in the same measurement SI=MAL-ST. The size of the sensation interval provides an improved measurement value for the actual strength of the sensation. This is due to the fact that both the sensation threshold and the actually perceived sensation level changes with changing conditions. Experimental studies verify the correctness and accuracy of these dependencies.

The difference between sensation intervals in subsequent measurements is determined as delta SI= SI2-SI1=(MAL2-ST2)-(MAL1-ST1).

- If delta SI>0, then a stronger sensation is indicated. For example a stronger pain.
- If delta SI<0, then a weaker sensation is indicated. For example less pain.
- If delta SI=0, then an unchanged size of sensation is indicated.

The SI and the delta SI parameters are currently believed to be important and decisive parameter values, since they are unaffected by conditions that may bias the sensation thresholds and the matched absolute levels. Furthermore, the differences in matched absolute levels and sensation thresholds between measurement occasions are often to small to draw a conclusion, whereas the SI and delta SI gives a more distinct indication. So, for example as shown in Fig 3B illustrating measurements of pain for two different persons, the first measurement of the pain threshold ST1=20 and the matched absolute level of experienced pain MAL1=30 indicated in some absolute or scaled unit of stimulation. Similarly, the second measurement has resulted in ST2=12 and MAL2=27. Superficially observed it seems that the second person has less pain than the first person, however with a fairly small difference. Now applying the inventive analysis thus generating the sensation intervals SI1=MAL1-ST1=30-20=10 and SI2=MAL2-ST2=27-

12=15, it is apparent that the pain experienced by the second person actually is quite considerably stronger. The extent of the difference is given by delta SI = SI2-SI1=15-10=5. A similar comparison can be carried out by comparing two timely spaced assessments for the same person. Assuming the same numerical values as in the previous example, the resulting conclusion is that the person actually indicates a worse pain at the second occasion of assessment. This is also supported by the parameter delta T=ST2-ST1=12-20=-8, which indicates worse pain or that the person has had a period of pain.

Taken alone or in combination with the absolute levels and other complex parameters the processed parameters form a basis for conclusions and diagnosis with the aid of sensation/stimulation matching. In the description the parameters have been exemplified by being directly derived from the absolute levels of the stimulation in some unit describing the stimulation intensity or energy. The different input parameters, processed parameters or output parameters can also within the inventive concept be scaled or transformed to other magnitudes, domains or units before, in or after the processing, however, being basically dependent on the described and similar parameter equations.

The functionality and the operating sequence of the sensation/stimulation matcher apparatus and the analysis apparatus is for example conveniently realised by means of computer program code devised to control a data processor to perform the steps of the inventive method.

Claims

1. A sensation level measuring apparatus comprising:
   - a stimulator (101) devised to deliver a varying physical stimulus;
   - a registration mechanism (114,116) devised to register a level of the physical stimulus;
   - a parameter processing mechanism (202) devised to generate a matched processed parameter (MPL) dependent on a first and a second registered level values (ST,MAL) of the physical stimulus according to a predetermined rule.

2. The apparatus as recited in the preceding claim, wherein the matched processed parameter level (SI) is generated dependent on a subtraction of the sensation threshold (ST) from the matched sensation value (MAL), i.e. dependent on SI=MAL-ST.

3. The apparatus as recited in any of the preceding claims, wherein the matched processed parameter level (delta SI) is generated dependent on a subtraction of the difference between a second matched sensation value (MAL2) and a second sensation threshold (ST2) from the difference between a first matched sensation value (MAL1) and a first sensation threshold (ST1), i.e. dependent on delta SI=(MAL2-ST2)-(MAL1-ST1).

4. The apparatus as recited in any of the preceding claims, wherein the matched processed parameter level (delta T) is generated dependent on the difference between the sensation thresholds T2 and T1, i.e. dependent on delta T= (T1-T2).

5. The apparatus as recited in any of the preceding claims, wherein the predetermined rules are stored in a storage structure (203).

6. The apparatus as recited in any of the preceding claims, wherein input parameters are stored in a storage structure (204).

7. The apparatus as recited in any of the preceding claims, wherein the processed parameters are stored in a storage structure (204).

8. A sensation level measuring method comprising the steps of:
   - delivering a varying physical stimulus to a person;
   - detecting a sensation threshold value of said person by registering a first level of the physical stimulus upon actuation of said person;
   - detecting a matched sensation value of said person by registering a second level of the

physical stimulus upon actuation of said person;

- generating a matched processed parameter value (MPL) dependent on said detected sensation threshold (ST) and matched sensation values (MAL) of the physical stimulus according to a predetermined rule.

9. The sensation level measuring method as recited in the preceding claim 8, further comprising the steps or stages of any of the preceding claims 1-7.

10. A computer program product for use in a sensation level measuring apparatus, comprising program code devised to perform the steps or functions of any of the preceding claims 1-9.

11. A sensation level analysing apparatus comprising:

- an input mechanism for receiving a level value of a physical stimulus;
- a parameter processing mechanism (202) devised to generate a matched processed parameter value (MPL) dependent on a first and a second level values (ST,MAL) of the physical stimulus according to a predetermined rule.

12. The apparatus as recited in the preceding claim, wherein the matched processed parameter level (SI) is generated dependent on a subtraction of the sensation threshold (ST) from the matched sensation value (MAL), i.e. dependent on SI=MAL-ST.

13. The apparatus as recited in any of the preceding claims 11-12, wherein the matched processed parameter level (delta SI) is generated dependent on a subtraction of the difference between a second matched sensation value (MAL2) and a second sensation threshold (ST2) from the difference between a first matched sensation value (MAL1) and a first sensation threshold (ST1), i.e. dependent on delta SI=(MAL2-ST2)-(MAL1-ST1).

14. The apparatus as recited in any of the preceding claims 11-13, wherein the matched processed parameter level (delta T) is generated dependent on the difference between the sensation thresholds T2 and T1, i.e. dependent on delta T= (T1-T2).

15. The apparatus as recited in any of the preceding claims 11-14, wherein the predetermined rules are stored in a storage structure (203).

16. The apparatus as recited in any of the preceding claims 11-15. wherein input parameters are stored in a storage structure (204).

17. The apparatus as recited in any of the preceding claims 11-16, wherein the processed parameters are stored in a storage structure (204).

18. A sensation level analysing method comprising the steps of:
- receiving as an input a sensation threshold value in the shape of a first level of a physical stimulus;
- receiving as an input a matched sensation value in the shape of a second level of the physical stimulus;
- generating a matched processed parameter value (MPL) dependent on said detected sensation threshold (ST) and matched sensation values (MAL) of the physical stimulus according to a predetermined rule.

19. The sensation level analysing method as recited in the preceding claim 18, further comprising the steps or stages of any of the preceding claims 11-17.

20. A computer program product for use in a sensation level analysing apparatus, comprising program code devised to perform the steps or functions of any of the preceding claims 11-19.

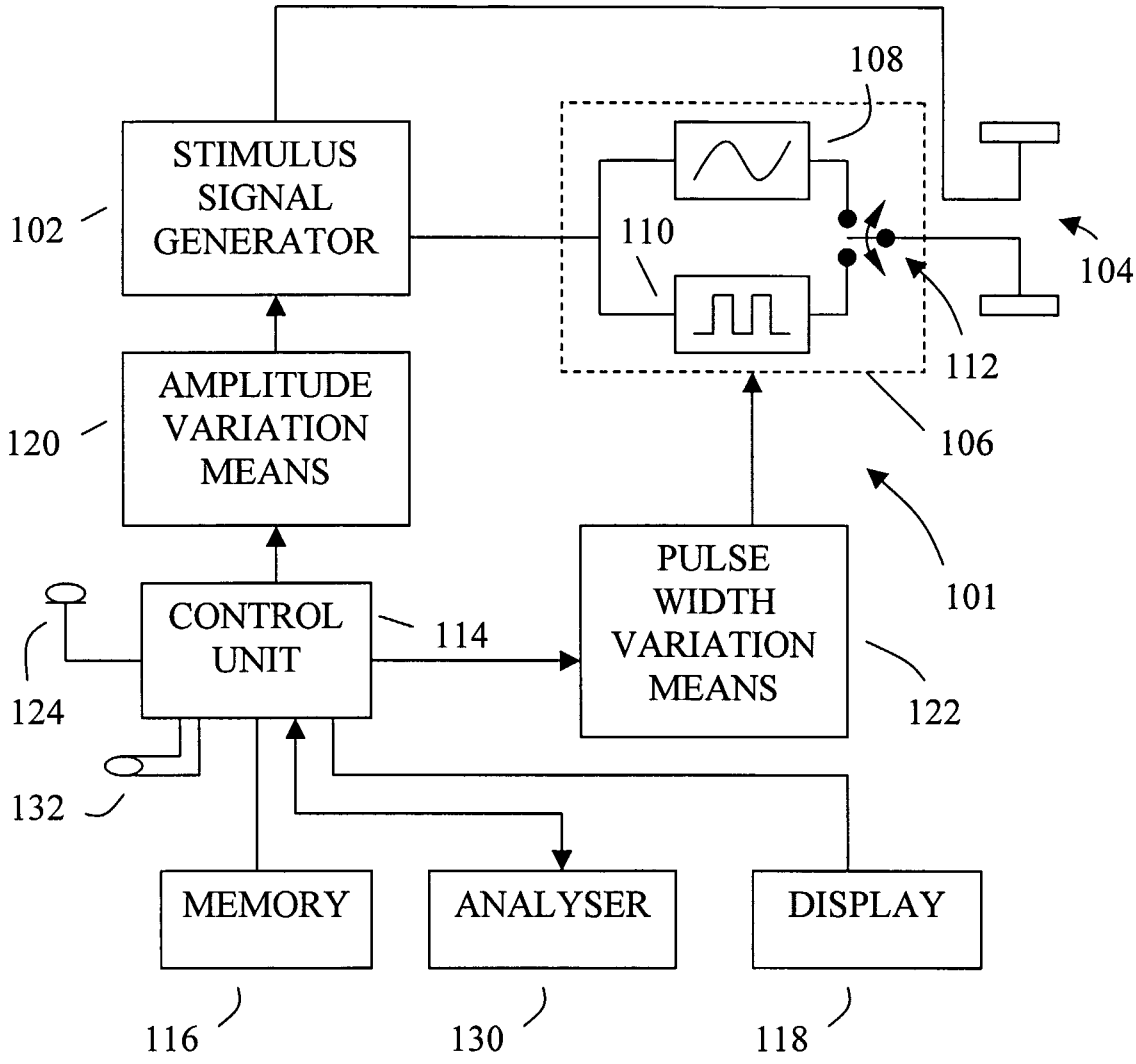
108
STIMULUS SIGNAL GENERATOR
102
110
104
112
AMPLITUDE VARIATION MEANS
120
106
PULSE WIDTH VARIATION MEANS
101
CONTROL UNIT
114
124
122
132
MEMORY
ANALYSER
DISPLAY
116
130
118

FIG. 1

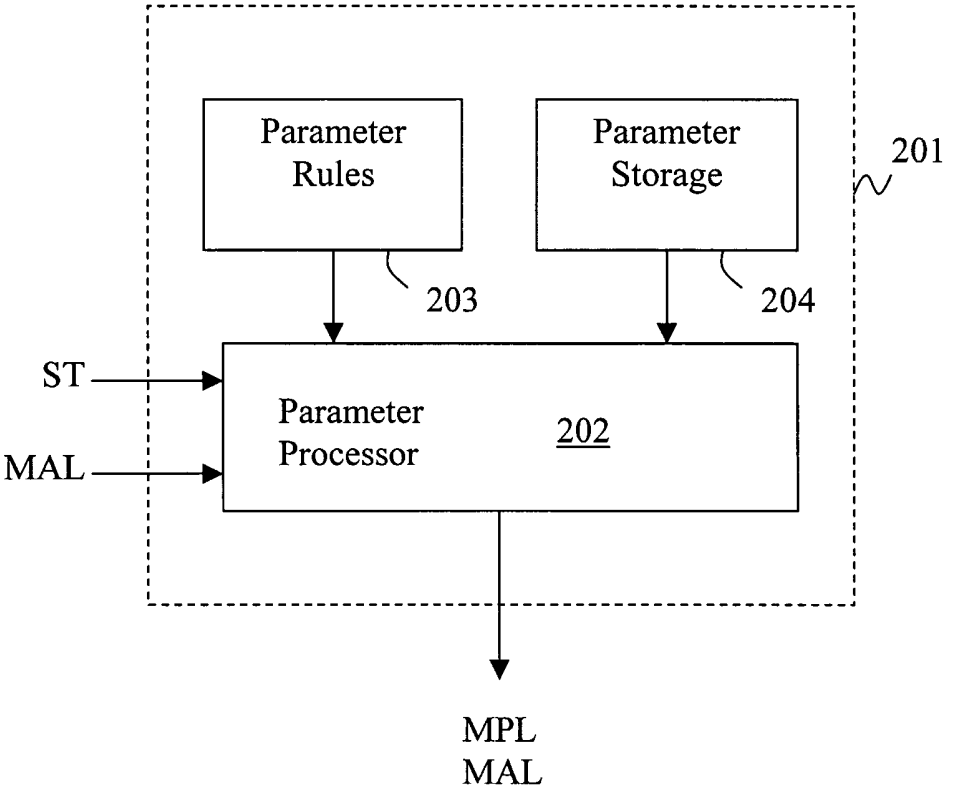
Parameter Rules
Parameter Storage
201
203
204
ST
MAL
Parameter Processor
202
MPL
MAL

Fig. 2

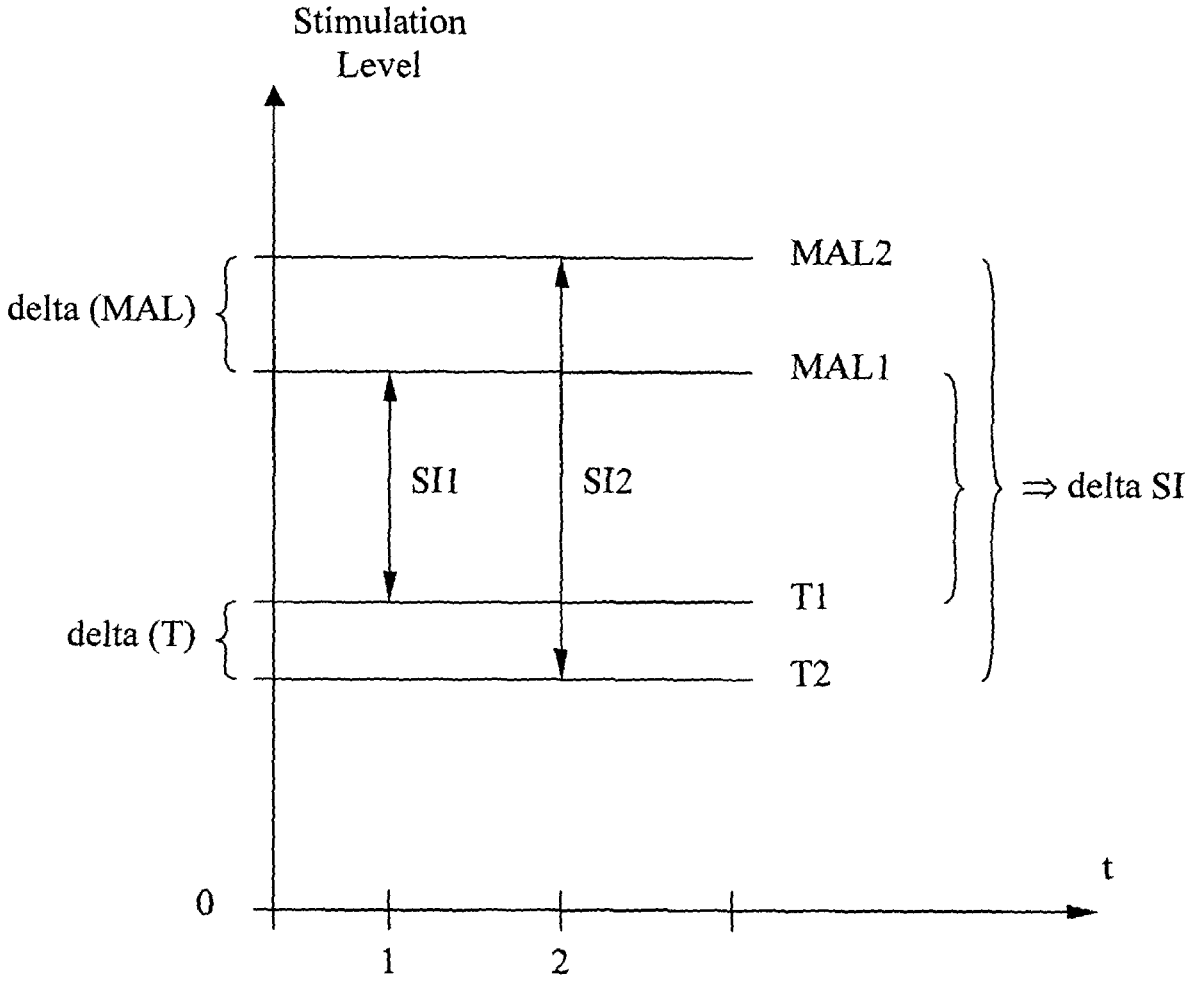
Stimulation
Level
MAL2
delta (MAL)
MAL1
SI1
SI2
⇒ delta SI
T1
delta (T)
T2
t
0
1
2

Fig. 3A

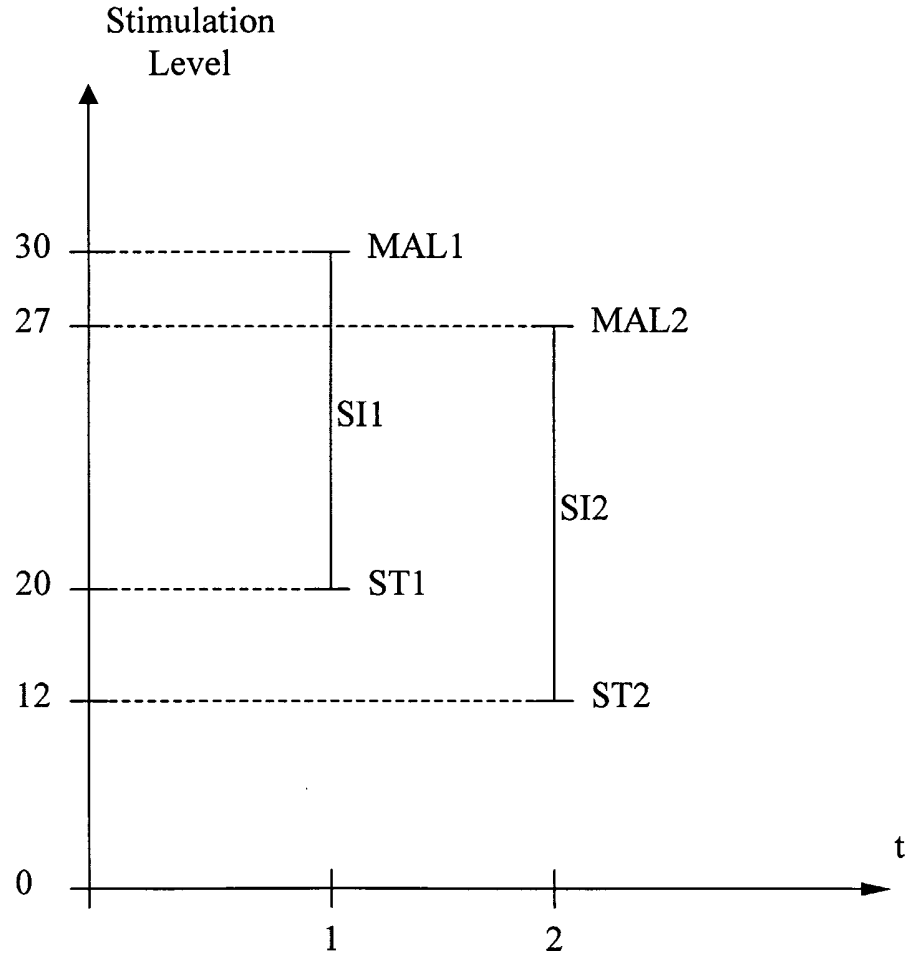

Fig. 3B

INTERNATIONAL SEARCH REPORT

International application No.
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A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61B 5/03, A61B 5/16 // A 61 N 1/18, A 61 B 5/05
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)

IPC7: A61B, A61N

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

SE,DK,FI,NO classes as above

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

EPO-INTERNAL, WPI DATA, PAJ, MEDLINE, BIOSIS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 0113793 A1 (CEFAR PAINMATCHER AB), 1 March 2001 (01.03.01), page 4, line 36 - page 5, line 17 --	1-20
A	WO 9724068 A1 (LASERROW, KAY), 10 July 1997 (10.07.97), page 6, line 19 - page 7, line 1 -- --------	1-20

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
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"P" document published prior to the international filing date but later than the priority date claimed
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"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
30 Sept 2002	02 -10- 2002
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Frida Plym Forshell/mj Telephone No. +46 8 782 25 00

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		JP 2000502579 T	07/03/00
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