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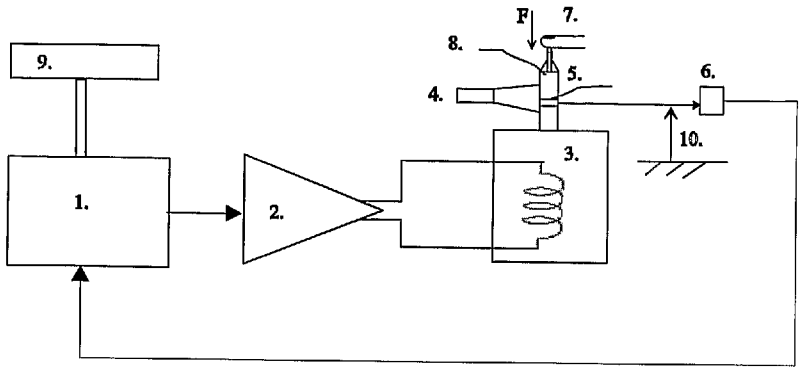
For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: VIBROTACTILE PERCEPTION METER



Force control system

(57) Abstract: An apparatus for testing or screening of peripheral neuropathies at a skin site of an object comprising: support means for supporting a body part containing said skin site of said subject to be tested, vibration generating means having a contact element for positioning in said skin site in a manner to control contact between said vibrating means and said skin site, said vibration generating means being vibrated at specific frequencies, frequency generating means connected to said vibration generating means for supplying a known discrete frequency signal to said vibration generating means, control circuit means modifying amplitude of said known frequency signal in an ascending and descending mode, switch means actuable by said subject to provide response signals to said control circuit means and responsive to an ascending and a descending amplitude of said known frequency signal, said control circuit means having processing means for obtaining a mean threshold signal value from said response signals defined by the means for keeping continuous contact force between said skin site and said contact within a predefined range; said means comprising a transmitter (4) and a receiver (6) for measuring the spatial position alteration (10) of said transmitted signal wherein the required DC-current (ic) is automatically adjusted by the Micro Computer System (1) so that zero offset is achieved for the spatial position (10).

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"Vibrotactile perception meter"

Field of invention

This invention relates generally to an apparatus for detecting sensory deficits in peripheral nerves and, in particular, to an apparatus for detecting sensory deficits associated with neuropathy in the fingers, or other parts of the body. The present invention relates to a method and a system for identifying vibrotactile perception thresholds of different mechanoreceptors at a skin site of a subject to assess sensory change in tactile sensory nerve function, and wherein the resultant threshold signals obtained by the method are substantially void of errors or inconsistencies.

Background of invention

Many provocative tests have long been used to detect the very early sensory impairment which usually occurs in diabetes neuropathy and neuropathy caused by vibration exposure. These tests include e.g. the "two-point discrimination" test for tactile gnosis and the monofilament test for touch/pressure. However, for various reasons, these tests have been found to be ineffective in early stages of neuropathy. On the contrary, the vibration sense of the hand is very early impaired in metabolic or vibration-induced neuropathy and various tests on vibration perception of the hand have therefore been developed. However the effectiveness of the vibratory tests is dependent on many test parameters, such as frequency, dimensions of the vibrating rod or probe area and very important, the probe contact force".

The measurement technique involves supporting the body part containing the skin site to be studied, and stimulating the skin surface with vibration under controlled contact conditions in such a way that a single mechanoreceptor population mediates the threshold at each frequency. Accordingly, it is a principal objective of the present invention to provide a screening or diagnostic system to measure the extent of sensory disturbances in neuropathies or any response to treatment of any such sensory disturbance. These objectives are attained generally, in a system to sense a body pressure sensitivity phenomenon of a patient, that includes a

vibratory stimulator to apply controlled and compensated vibratory force to a finger (or other body part) of the patient; a drive mechanism connected to effect vibration of the vibratory stimulator.

In US 5,002,065 (LaCourse et. al.) a method is described on how to achieve a well-controlled amplitude and acceleration on the probe by utilising a closed loop control system. However, this means that the amplitude and acceleration will be independent of the applied contact force on the vibrating probe. The used backpressure monitor measures the acceleration on the vibrating probe without any consideration to the applied contact force, which considerably degrades testing reliability.

In US 5,433,211 (Brammer et. al. the applied contact force on the vibrating probe is controlled by an external complex mechanical counter weight mechanism without actually measuring the applied contact force. This complexity increases the possibility of erroneous test set up conditions without any control of the test environment, i.e. the measured vibrotactile perception thresholds (VPT) may be recorded with incorrect applied contact force without any notice, which degrades testing reliability.

In Patent US 5,673,703, Fisher et. al. describes an apparatus for automatic testing of vibrotactile responses of a patient. In the preferred embodiment of the invention, a general-purpose computer functions to control the operation of the system and to record and store the patient's responses. Indentations and vibrations are produced by off-axis rotation of a stimulation probe. A frequency-modulated signal generated by the computer is used to control a motor, which drives the stimulation probe. This apparatus falls short since changes in the contact force will affect both the motor speed (frequency) and the amplitude for the stimulus probe. In fact the described principle for generating the probe movement will measure vibrotactile perception thresholds (VPT) with a very low precision and accuracy due to the inferior control mechanism and test set up. Thus the detected VPT will strongly vary depending on the applied contact force that is not controlled in any way and, accordingly, degrades testing reliability

In WO0059377A1 (LaCourse et. al.) the applied contact force is measured indirectly by measuring the applied force on a surround at which the finger rests during the test. This method requires more complex test equipment and the required applied contact force is much larger compared to when measuring without any surround. A higher contact force will also require a stronger (larger) vibrator that consumes more power which will further increase both the physical weight and the manufacturing cost for the Device (Instrument).

Disclosure of invention

To provide means to control and monitor the static and dynamic contact force between human skin and a vibrating probe. This is very important when measuring the Vibrotactile Perception Thresholds (VPT) in order to get accurate test conditions (set up) to achieve required measurement precision.

Brief description of the drawings

Figure 1; the Force control system which discloses a Micro Computer System (1) comprising a microprocessor and interface electronics with AD- and DA-converters; further is disclosed an amplifier (2) which amplifies an analogue signal from the Micro Computer System (1), the amplified signal drives the Electro Dynamic Vibrator (3). Said vibrator (3) is an electro dynamic device with an attached probe (8), which is moving when a current or a voltage is applied to said device. Transmitter (4); A transmitting device, which sends out some kind of signal. This signal may be an optical beam (light) or an electrical or a magnetic field. Aperture (5); A device, e.g. a hole or a lens, which limits or focuses the transmitted signal in space. The aperture is optional and is not required if the transmitted signal is narrow enough. Detector (6); A device that detects static or a dynamic spatial position of the Vibrating Probe (8) by measuring the transmitted signal from the Transmitter (4) in an appropriate manner. Human skin/body part (7); A human body part, e.g. a finger or a toe, which is pressed with the force F against the Vibrating Probe (8). Vibrating Probe (8); A probe that is fixed attached to the moving part, e.g. a membrane, in the Electro Dynamic

Vibrator (3). Human feed back Device (9); A device used by the Micro Computer System (1) to report the displacement in the position caused by the force F. Spatial position (10); Spatial position relative a fixed reference point, origin.

Figure 2; Shows forces and spatial position where $\mathbf{i_c}$ is the current through the Electro Dynamic Vibrator (3), $\mathbf{F_c}$ which is the Probe Force created by the current i_c supplied to the Electro Dynamic Vibrator (3), $\mathbf{F_s}$ shows the spring force created by the probe offset inside the Electro Dynamic Vibrator (3), **m** is the moving mass (probe + membrane) in the Electro Dynamic Vibrator (3), $\mathbf{F_m}$ which is the gravitation force on the moving mass (m), **F** is the external force caused either by a calibration force (weight) or by a pressure from a body part and x which is the spatial position (10) relative a fixed reference point, origin.

Figure 3; Shows the Required detector signal in an unbalanced system where $\mathbf{x_1}$ is the spatial position (10) for an unloaded system (x1) and $\mathbf{x_{cal}}$ which is the spatial position (10) when the calibration weight is mounted on the vibrating probe (8) without added DC-current (i_c), i.e. when i_c =0

Figure 4; Shows the required detector signal in a balanced system

Detailed description of the invention

Definitions, Abbreviations and Acronyms

In the context of the present application and invention the following definitions apply:

VPT	Vibrotactile Perception Threshold
RFD	Requested Force Displacement
RF	Requested Force
CF	Contact Force
SI	Sensibility Index
rms	Root Mean Square

Description

The invention is a screening or diagnostic testing apparatus, a system and a method of said screening for peripheral neuropathies. In its most basic form, the apparatus includes a surface having an opening, a surround disposed around the opening for a vibrating rod, disposed within said opening for contact with the pulp of a finger or other body part. The preferred apparatus includes a pressure sensor for sensing a pressure exerted by the body part upon the probe to ensure that pressure applied to the body part is within a specified range, means for ensuring said continuous contact with the body part.

Detection principle; the contact force (F) is created by the patient by pressing the body part to be examined (7) against the vibrating probe (8). The patient controls the applied force (F) by adjusting the force (F) in accordance to the reading on the output presented by the "Human feed back Device" (9). The correct force (F) is then applied when the "Human feed back Device" (9) presents a predetermined condition, e.g. correct colour, sound, numerical value etc.

The applied force (F) is measured indirectly by measuring the change of the spatial position (10) on the vibrating probe as a static displacement caused by the force (F). Since the vibrating probe is mounted in a spring supported

mechanical construction, any displacement corresponds to a specific force in a linear fashion. Therefore the displacement will be an indirect measure of the applied force, i.e. the force (F) may be calculated by measuring the occurred static displacement of the spatial position (10).

The unloaded Electro dynamic Vibrator (3), i.e. without an applied external force (F) may be calibrated by adding a well-known force, the Requested force (RF), e.g. a "calibration weight". The occurred displacement for the unloaded Electro dynamic Vibrator (3), i.e. the difference in the spatial position (10) of the probe with and without the "calibration weight" will then correspond to a specific force.

The displacement caused by the "calibration weight" is denoted as the "Requested Force Displacement" (RFD). During normal operation the RFD may be used as a requested absolute static offset which should be maintained during the complete test cycle.

A contact Force (F) below or above the RF will be presented on the "Human feed back Device" (9) as a "too low value" or a "too high value" respectively. On the "Human feed back Device" (9), the RFD may me visualised on e.g. a bar graph array as the centre value.

The displacement is measured by the Detector (6), which detects the signal emanating from the Transmitter (4) passing the optional Aperture (5). One or two of these items, i.e. the Transmitter (4) or the Aperture (5) or the Detector (6) may be located directly on the Vibrating Probe (8) whereas at least one item should be spatially fixed.

The output signal from the detector (6) corresponds to a spatial position (10) of the probe (8). This signal may be processed, e.g. filtered and then converted to a digital signal (DA-conversion) within the Micro Computer System (1). The digital signal is read by a microcomputer, which is a part of the Micro Computer System (1). The microprocessor compares read digital signal caused by the contact force (F) with a previously stored value for the signal caused by the calibrating force (RF) and outputs the difference on the "Human feed back Device" (9).

Instead of maintaining a calibrated static offset for the spatial position (10), the offset may be outbalanced by applying an overlaid calibrated DC-current (i_c) in the electrical current signal to the Electro dynamic Vibrator (3). This will create an opposite force (F_c), to out-balance the external applied force (F), which will render a zero static offset for the spatial position (10) when the correct static force (F) is applied by the human body part (7).

The calibrated DC-current (i_c) may be created within the Micro Computer System (1) where after the signal may be amplified by the Amplifier (2) to control the Electro dynamic Vibrator (3). The system is calibrated by first measuring the spatial position (10) when the system is unloaded, i.e. without any applied contact force (F). Then a "calibration weight" is mounted on the Probe (8) when the system still is unloaded, i.e. no additional force (F) asserted except for the calibration weight. The required DC-current (i_c) is automatically adjusted by the Micro Computer System (1) so that zero offset is achieved for the spatial position (10), i.e. when the spatial position (10) is the same as when no "calibration weight" is mounted on the probe (8). At zero offset the applied DC-current (i_c) is measured and the value is permanently stored in the Micro Computer System (1).

During normal operation the stored calibrated DC-current (i_c) is added to the electrical current signal to the Electro dynamic Vibrator (3). The contact force (F) created by the human body part (7) will cause a static displacement that is measured by the Detector (6), which detects the signal emanating from the Transmitter (4) passing the optional Aperture (5). One or two of these items, i.e. the Transmitter (4) or the Aperture (5) or the Detector (6) may be located directly on the Vibrating Probe (8) whereas at least one item should be spatially fixed.

The contact force (F) is equal to the calibration weight when the measured static displacement for the spatial position (10) is zero. A contact Force (F) below, at or above the calibration weight will then be presented on the "Human feed back Device" (9) as a "too low value", equal or a "too high value" respectively. On the "Human feed back Device" (9), the contact Force (F) may me visualised on e.g. a bar graph LED array

During normal operation, i.e. when the VPT's are recorded the spatial position (10) signal is measured from the Detector (6). This signal may be processed in any way in the Micro Computer System (1), e.g. low pass filtered. The filtered signal from the detector (6) will look something like either as in figure 3 or as in figure 4 below, depending of the selected method for monitoring the static skin force (F) applied by the patient (7). In these figures, x1 corresponds to the spatial position (10) for an unloaded system and x_{cal} to the spatial position (10) when the calibration weight is mounted on the vibrating probe (8) without added DC-current (i_c).

The VPT is preferably recorded by reading the real acceleration from an accelerometer sensor mounted directly on the vibrating probe (8). To enhance the accuracy it's also important to register the current skin temperature since the VPT vary with this parameter. The skin temperature may be measured continuously during the measurement or at least at the beginning, i.e. just before start of measurement. The temperature may be measured with e.g. a temperature sensor mounted on the vibrating probe (8) or in a separate place elsewhere on the measuring device.

Prior to a measurement the device shall perform a self-calibration to make sure that the required starting conditions prevails. This calibration shall at least include, a tare of the spatial position (10), a frequency control to make sure that the used frequencies run within certain limits and a measurement of background (vibration) noise. Additionally the maximum and minimum recordable amplitudes and accelerations may be measured during the self-calibration.

The "Human feed back Device" (9) is used to report the measuring status to both the Operator and the Patient to be tested. Prior to a measurement the device (9) should tell when the device is ready (calibration finished). During the measurement the device (9) should show the status for the applied skin contact force (F), i.e. if the force is too high, too low or within required limits. The used "feed back principle" may be e.g. as light by using a LED/lamp-array with different colours, a flashing lamp or a LED with different flashing frequencies or some kind of numerical or graphical display, to represent the status. An audible feedback signal (speaker or

headphones) may also be used as a "Human feed back Device" (9) where a combination of different frequencies and/or amplitudes are utilised to represent the status.

As an extra feature it is also possible to automatically compensate the registered VPT if the applied contact skin force (F) is outside the required limits, i.e. when the force is either too high or too low.

For this case, the actual spatial vibration amplitude (mean value), read via the Detector (6), is used to compensate for an erroneous contact force (F). If the applied contact skin force (F) is too low in a balanced system (fig 4) the measured mean value (X) of the spatial position (10) is larger than X1 in figure 4. The offset, X-X1 can then be converted to a specific acceleration offset value, which should be added to the read acceleration in order to get a compensated VPT. The same principle will also work if the applied contact skin force (F) is too high in a balanced system. In that case the read offset value (X-X1) will be negative which corresponds to a negative acceleration offset. The read acceleration should then be reduced with the corresponding converted negative acceleration offset in order to get a compensated VPT.

A full test cycle comprises the following steps:

1. The Operator starts a measurement by e.g. pressing a start button or entering a start command to the device.

2. The device starts with a self-calibration, which is displayed on the "Human feed back Device" (9). When the self-calibration is finished the "Human feed back Device" (9) reports a ready to measure condition.

3. The Patient to be examined applies the appropriate body part, e.g. a finger on the vibrating probe (8) whereas the "Human feed back Device" (9) reports the applied skin force (F). At this stage an integrated temperature sensor on the vibrating probe (8) may measure the skin temperature. Alternatively the temperature may measured in a different manner shortly before the body part is placed on the vibrating probe (8).

4. When the applied skin force is within the required limits, the probe starts to vibrate in a predetermined ascending sequence.

5. When the Patient feels a vibration he/she presses an external button, which will switch the vibration to a descending sequence. During the descending sequence the Patient continue to press the external button until he/she does not feel vibrations any more.

6. When the Patient releases the external button, i.e. when he/she does not feel any vibration, the device will switch back to an ascending sequence and the procedure jumps back to point 5 again and so on, until a full test sequence is completed. A completed test sequence includes changes in the vibration frequencies according to a well-defined scheme.

7. The vibration excitation stops when the VPT's has been registered for all required frequencies. The recorded VPT's may then be compared with normative data from healthy persons. The result may be reported to the Operator as e.g. a SI-value which is an absolute figure telling if the Patient is healthy or not, i.e. in terms of neuropathy.

During the test cycle according to point 5 and 6 above the applied skin contact force is monitored continuously by reading the spatial position (10). The read spatial position (10) is converted to a contact force (F), which is continuously displayed on the "Human feed back Device" (9). The Patient reads the output and adjusts the contact force (F) accordingly. The device may calculate an internal compensation to adjust the recorded VPT if the Patient does not make any adjustments or if made adjustments are insufficient. The VPT's are recorded as the mean value of the read max and min acceleration (rms values) during the ascending and descending cycle.

Unbalanced system:

When the correct contact force (F) is applied by the patient (7), the offset for the dc-component in the spatial position (10) signal shall be equal to (x_1 - x_{cal}). If the measured offset is higher then the patient must decrease the applied skin-force (F) and vice versa, i.e. increase the applied skin force (F) if the offset is to low. With this method no added DC-current component (i_c) is necessary in the electrical signal, which drives the Electro dynamic Vibrator (3).

Balanced system:

A dc-current (i_c) is added to the electrical signal, which drives the Electro dynamic Vibrator (3). When this current (i_c) is added and when the correct contact force (F) is applied by the patient (7), the dc-component in the spatial position (10) signal shall be equal to x_1, which corresponds to a zero static offset. If the measured spatial position (10) is less than x_1 then the patient must decrease the applied skin-force (F) vice versa, i.e. increase the applied skin force (F) the spatial position (10) is larger than x_1.

Spatial detection

The spatial position (10) can be measured in many ways, but the basic principle is that the vibrating probe (8) is moved when the human body part (7) applies a force (F) on the probe (8). The spatial position (10) and the subsequent movement will alter the signal from the transmitter (4) and the detector (6) measures this spatial alteration of the transmitted signal. In this respect the transmitter (4) can be mounted directly on the vibrating probe (8) while the detector (6) is fixed in space. Alternatively the detector (6) may be mounted directly on the vibrating probe (8) while the transmitter (4) is fixed in space. As a second alternative both the transmitter (4) and the detector (6) are fixed in space whereas the aperture (5) is mounted directly on the vibrating probe (8). The combination of the transmitter (4) and the detector (6) makes a matched pair that can use different techniques and some examples are:

Transmitter (4)	**Detector (6)**
Light Emitting Diode, LED	Position Sensitive Detector (PSD)
LASER Diode	Position Sensitive Detector (PSD)
Light Emitting Diode, LED	Photo detector
LASER Diode	Photo detector
Permanent Magnet	Magnetic field sensor
Electro Magnet	Magnetic field sensor

Patent claims

1. An apparatus for testing or screening of peripheral neuropathies at a skin site of an object comprising: support means for supporting a body part containing said skin site of said subject to be tested, vibration generating means having a contact element for positioning in said skin site in a manner to control contact between said vibrating means and said skin site, said vibration generating means being vibrated at specific frequencies, frequency generating means connected to said vibration generating means for supplying a known discrete frequency signal to said vibration generating means, control circuit means modifying amplitude of said known frequency signal in an ascending and descending mode, switch means actuable by said subject to provide response signals to said control circuit means and responsive to an ascending and a descending amplitude of said known frequency signal, said control circuit means having processing means for obtaining a mean threshold signal value from said response signals c a r a c h t e r i z e d by the means for keeping continuous contact force between said skin site and said contact within a predefined range; said means comprising a transmitter (4) and a receiver (6) for measuring the spatial position alteration (10) of said transmitted signal wherein the required DC-current (i_c) is automatically adjusted by the Micro Computer System (1) so that zero offset is achieved for the spatial position (10).

2. An apparatus according to claim 1 wherein said transmitter (4) operates either by light emitting or by transmitting an electromagnetic field and wherein said receiver (6) operates either by photo electric detection or by magnetic field sensing.

3. An apparatus according to claims 1-2 where the means for keeping continuous contact force between said skin site and said vibrating means is automated by a feed-back force compensation unit.

4. An apparatus according to claims 1-3 wherein said vibrotactile perception thresholds are recorded by reading the real acceleration from an accelerometer.

5. An apparatus according to claims 1-4 wherein the human feed-back device (9) uses a feed back principle based on light; such as LED or lamp arrays; flashing LED's or lights or some kind of graphical or numerical display.

6. An apparatus according to claims 1-5 where the temperature is measured at said skin site prior and during the entire test.

Figures

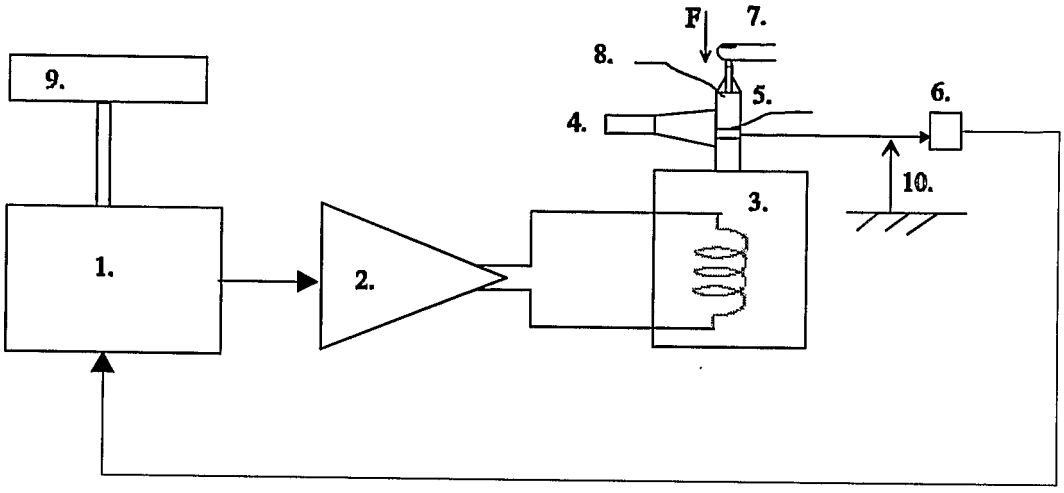

Fig. 1 Force control system

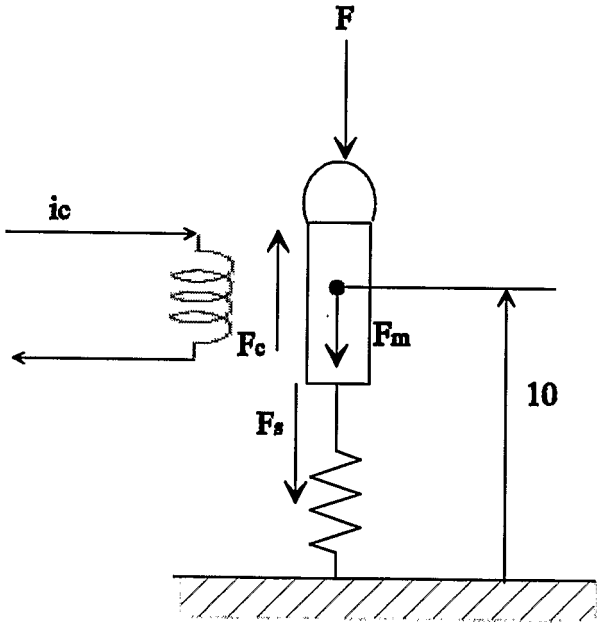

Fig. 2 Forces and spatial position

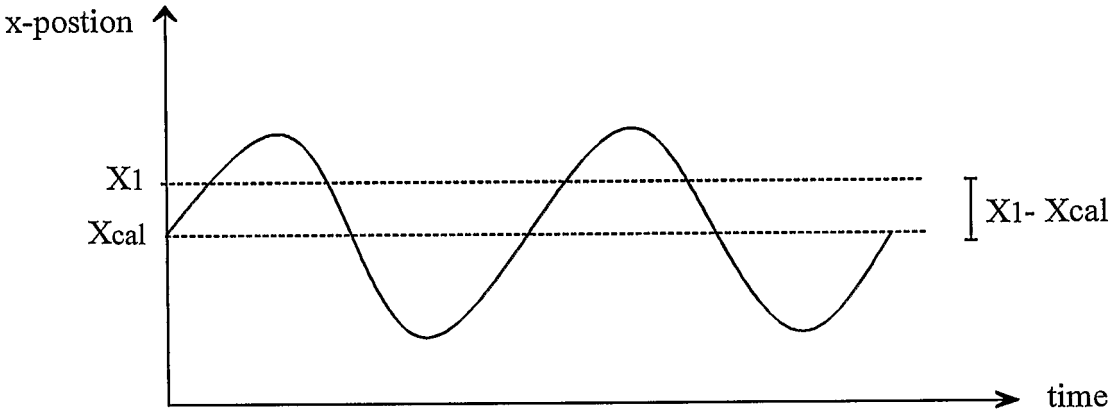

Fig. 3 Required detector signal in an unbalanced system

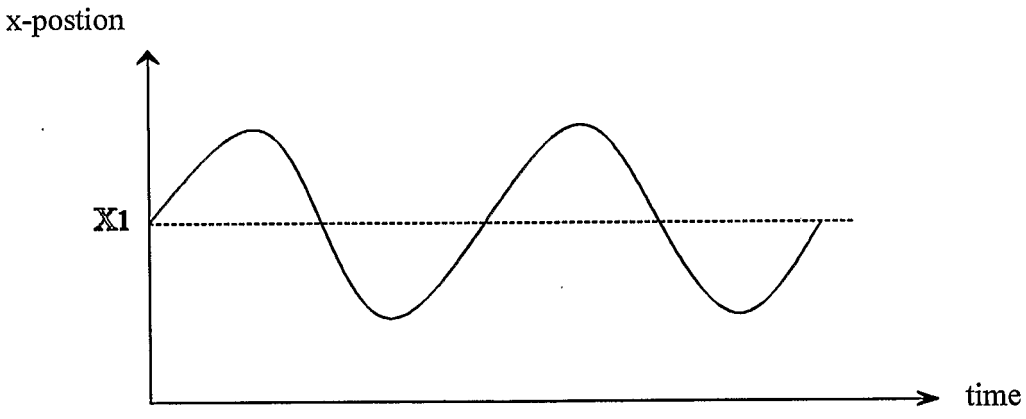

Fig. 4 Required detector signal in a balanced system

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 2005/001450

A. CLASSIFICATION OF SUBJECT MATTER

IPC: see extra sheet
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: A61B

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 0059377 A1 (BIOTHERAPEUTIC DEVICES, INC. ET AL), 12 October 2000 (12.10.2000), page 8, line 30 - page 10, line 8; page 12, line 23 - page 14, line 24 --	1-6
A	US 5433211 A (ANTHONY J. BRAMMER ET AL), 18 July 1995 (18.07.1995), column 2, line 17 - column 3, line 42 --	1-6

[X] Further documents are listed in the continuation of Box C. [X] 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
"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)
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"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
3 January 2006	05 -01- 2006
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 Ulrika Westman/MP Telephone No. +46 8 782 25 00

· INTERNATIONAL SEARCH REPORT

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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	NORIAKI HARADA et al: British Journal of Industrial Medicine; "Factors influencing vibration sense thresholds used to assess occupational exposures to hand transmitted vibration" Mars 1991, vol. 48, nr 3, page 185 - 192; whole document ISSN 0007-1072. -- --------	1-6

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WO	0059377	A1	12/10/2000	AU	4076200	A	23/10/2000
US	5433211	A	18/07/1995	CA	2100849	A	20/01/1995

专利名称(译)	Vibrotactile感知仪		
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摘要(译)

一种用于在物体的皮肤部位测试或筛查外周神经病的装置，包括：支撑装置，用于支撑包含所述待测对象的所述皮肤部位的身体部位，振动产生装置，具有用于定位在所述皮肤部位中的接触元件。一种控制所述振动装置和所述皮肤部位之间接触的方式，所述振动发生装置以特定频率振动，频率发生装置连接到所述振动发生装置，用于向所述振动发生装置提供已知的离散频率信号，控制电路装置修改所述已知频率信号在上升和下降模式下的幅度，开关装置可由所述对象致动，以向所述控制电路装置提供响应信号并响应所述已知频率信号的上升和下降幅度，所述控制电路装置具有处理装置用于从所述res获得平均阈值信号值由用于保持所述皮肤部位和所述接触部之间的连续接触力的装置限定的ponse信号在预定范围内;所述装置包括发射器（4）和接收器（6），用于测量所述发射信号的空间位置变化（10），其中所需的DC电流（ic）由微计算机系统（1）自动调节，使得零对于空间位置（10）实现偏移。