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# (54) DEVICE AND METHOD FOR ASSESSING THERMOALGESIC AND VIBRATORY SENSITIVITY

VORRICHTUNG UND VERFAHREN ZUR BEURTEILUNG VON WÄRMESCHMERZ- UND VIBRATIONSEMPFINDLICHKEIT

DISPOSITIF ET PROCÉDÉ D'ÉVALUATION DE LA SENSIBILITÉ VIBRATOIRE ET THERMOALGÉSIQUE

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## Description

### Object of the invention

**[0001]** The present invention patent application is comprised within the field of medicine and more specifically within the field of the assessment of thermoalgesic and vibratory sensitivity for the diagnosis and/or monitoring of diseases such as sensitive neuropathy, which registers the functional status of peripheral sensitive nerve fibres.

### Background of the invention

**[0002]** At present no appropriate devices are known for the rapid self-monitoring of the magnitude of sensitive loss as an indicator of the risk of foot ulceration, which are different from the ideal apparatus for the detection of subclinical changes in patients with a condition leading to neuropathy but that are still asymptomatic.

**[0003]** Distal sensitive neuropathy of the four limbs is present in multiple diseases with symptoms and/or signs that make up an initial presentation of the condition or as a consequence of complications of the base disease and/or the treatments thereof. Diabetes mellitus type 1, type 2; B1, B6 and B12 hypovitaminoses; malnutrition; leprosy; amyloidosis; vasculitis; collagen diseases; AIDS; Pierre-Marie-Toth disease; paraneoplasic diseases; post-chemotherapy; compressive radiculopathies; Friedrich's ataxia; hereditary motor-sensitive neuropathy type 1; Tangier's disease, ...

**[0004]** The clinical evaluation of sensitivity plays an important role during the neurological examination. By using simple methods with hand-held tools (disposable needles, brushes and/or cotton, glass tubes with hot or cold water, a 128-Hz tuning-fork, a qualitative guide, ...), examiners evaluate whether sensitivity is preserved or not. The examiner uses the comparative method on explored areas to identify differences between those that have been affected and those that have not.

**[0005]** Current diagnostic methods for sensitive impairment are semi-quantitative. They include tests for assessment on nerve fibres of heat, cold, vibration and thermal pain.

**[0006]** The tool equipment is based on thermal, thermoalgesic and vibratory stimulant devices, which are under the operation of a software programme that regulates stimulation, as well as a processor of the response conveyed by the patient that is being examined.

Specifically, Thermotest methods are used to assess the function of afferent pathways related to the sensitive submodalities of small-diameter fibres. It is an exploration method in which a temperature increase or decrease ramp is applied and the sensation thresholds are collected for the specific sensation, such as heat, cold or pain. As for the vibratory methods, these are used to assess the function status of medium-sized afferent nerve fibres that are sensitive to vibration differences.

Several programmes are used for forced-response choice, the yes/no paradigm and the yes/no response with a visual graded scale.

**[0007]** The complexity of each of these tools requires, for its diagnostic development, of sophisticated knowledge about software and medicine; hence they are conducted by medical staff who are specialized in this type of diseases (neurophysiologists).

**[0008]** The tool equipment is large in size (not portable), slow in test development (average time: 1.5 to 2 hours) and requires complex interpretations of its output and provides difficult-to-understand results; electrical installation is complex, with test calibrations requiring infrared thermometers, laser calibrators of distance and with great disadvantages when transporting it derived from its large size, installation and decalibration.

**[0009]** Some workers use a container with about 7 litres of water containing a disinfectant, from which the fluid is emitted through a system of 2 refrigerant hoses towards a large-sized Peltier plate, to allow its heating and cooling. In addition to a complex vibratory system composed of an engine arranged in a 800-g box with a 300-g sand cushion, a calibration system with a laser situated at a distance of 4 m and an alternator plus a computer connected to a box with the electronics of the Thermotest. Other elements are a number of boxes including pedalboards for both hands and/or feet with a vibration regulator, through an engine and connected to a data processor.

**[0010]** All the above said prevents implementation as a diagnostic approach method for quick and simple daily use in the clinic and/or as a monitoring test for non-medical healthcare personnel or for the patients themselves.

**[0011]** Other types of device for this kind of diagnostic test have the same characteristics than those described above and also carry out only one of the tests on the nerve fibre. The cost of this equipment is extremely high, as are the replacement parts, and also requires the continuous calibration for its maintenance. The prices of the various apparatus ranges between 6,000 and 24,000 euros. This situation impairs the required capacity for early detection of diseases allowing potential early treatment, and impairing its potential for determining the indicated treatments, worsening the condition and its extremely serious consequences, which imply high health costs.

**[0012]** Patent application JP2005052598A discloses a pen-type device with a clip for assessing vibratory, cold-hot, thermal pain and tactile sensitivity, wherein a vibration generation motor, a Peltier element and a fan are respectively

used. Once each stimuli is applied, the physician or professional carrying out the test asks the patient whether (s)he has detected each stimulus or not, thus obtaining useful information to determine a degree of sensity. Therefore, the technical solution disclosed in this application is not suitable for self-monitoring, but requires the presence of a professional who will receive feedback from the patient and then assess the results.

**[0013]** On the other hand, document US2009/082694A1 discloses a neuropathy monitor wherein neuropathy tests are carried out which comprise a heat test, a cold test, a vibration test or combinations thereof. Regarding the vibration test, however, no random stimuli with different intensities are applied, so that biasing of the patient cannot be avoided. This is an important point that is actually addressed by the present invention, thus ensuring reliability of the patient's data input received. Additionally, the invention disclosed in this document of the prior art is specially relevant for the testing of fingers or toes, as these are the points providing easiest access for said neuropathy monitor. In this regard, it would be specially advantageous to be able to test other parts or points of the body, for which the access for said monitor may actually be hindered, and for which a pivotable neuropathy device, such as the one covered by the present invention object of this application, is significantly advantageous due to its adaptability.

**[0014]** Because of all the above, the need has been identified of a device that can help to prevent the unchecked progress of neuropathies and provide a strong early indicator of risk of neuropathy on feet.

**[0015]** Said device can be used routinely by patients and/or healthcare personnel without prior health knowledge, with an aim to carrying out in a rapid manner a "Self-screen" for the early detection of distal sensitive perception impairment in each area explored when exposed to stimuli with different thresholds that have been pre-established from standard values of vibration, heat, cold and thermoalgesic pain.

**[0016]** This objective is achieved by the invention as defined in claim 1; the preferred embodiments of the invention are defined in the dependent claims.

**[0017]** The vibration generating means of the first unit may comprise: a tuning fork that has two arms converging on a central point, from which point an arm applying the vibrations projects, the end of which has a polyvinyl or Teflon button, the arm forming an angle of application of 30º with respect to the main axis of the first unit. Said applicator is connected to the outer casing of the first unit through a rubber washer and to the free end of each arm, a piezo-electrical system or a speaker with an inner coil generating vibrations is optionally fixed, the cables of the vibration generating means running through the central part of the first unit casing.

**[0018]** On the other hand, the means generating cold-heat of the first unit may comprise a Peltier cell with ventilators that will be rotatably connected according to an axis that is perpendicular to the turning axis of the casing, to an ejector arm that is parallel to said turning axis. Said arm is connected to the casing so it can move linearly with respect to it according to a direction parallel to the rotating axis, in such a way that, in the retracted position of the means that generate cold-heat, the Peltier cell with ventilators will be situated in parallel to the arm and in a deployed position the arm will protrude from the casing, and once extracted from it, the Peltier cell with ventilators will be able to rotate around the axis of the arm's end, adopting a certain tilt with respect to the axis of the casing.

**[0019]** The casing of the first unit can be tubular, of circular outline and can be made of a material of great hardness and resistance. On the tips it has a rubber washer, which dampens the impact in case of fall, and on the centre and ends is the rotation device, which is of the same material and has a power button for the first unit.

**[0020]** The means for data introduction of the second unit may comprise a button pad that is divided in two areas, a first area with a power button, and another area with two buttons for the input of data corresponding to the vibration generating means and for the input of data corresponding to the means generating cold-heat. The second area of buttons may comprise a first button that will be pushed when the patient identifies the vibration, and a second button that will be pushed when the patient identifies none.

**[0021]** The communication between the first unit and the second unit can take place by means of radiofrequency or infrared radiation, and alternative transmission means can be used allowing the bidirectional communication between the first and second units.

**[0022]** The first unit may comprise a skin temperature sensor and an ambient temperature sensor that will determine the coordinated temperatures to be able to carry out the assessment.

**[0023]** Additionally, the first unit may be coupled to the second unit through a slot made in the second unit (2) and a projection fitting into said slot, associated to the first unit, in such a way that both units are interconnected with each other, forming the device.

**[0024]** The first and second units may be powered through at least a rechargeable battery, which in the case of the first unit is located in one of its bases. The first unit may comprise on one of its bases, which rests on the ground during the use of the device, a rubber layer to prevent the transmission of vibrations from the ground to the arm of the vibration generating means, with an aim to said vibrations from the ground not being perceived by the patient and therefore, so they do not interfere with the assessment of vibration sensitivity.

**[0025]** The second unit may comprise visual and sound means of warning configured to indicate the end of the battery charge and may also have a port for communicating said second unit to a personal computer.

**[0026]** The indicator means of the second unit may comprise a plurality of different-colour leds, configured to light up

when the vibration generating and cold-heat means are on.

**[0027]** Finally, the means for data display of the second unit may comprise a screen located next to the first and second areas of buttons of the button pad, configured to display at least the following data: the date and time, the number and type of test being run, the score obtained in each test and in total, and the percentage of stimuli detected by the patient.

**[0028]** A second important aspect of the invention envisages a procedure for using the device and for assessing the sensitivity of the patient. Said procedure involves the following steps:

a).- switching on the first and second units
b).- implementation of a self-test by the first and second units, of at least the following parameters: battery charge, ambient temperature, skin temperature and radiofrequency or infrared communication status.
c).- deployment of the vibration applicator from one of the ends of the first unit casing.
d).- placement of the end of the vibration applicator on a localized area of the nail bed skin of the first toe of the right foot, continuing with the second toe until completing the foot, then continuing with the left foot and subsequently with the upper limbs.
e) placement under the ball of each explored finger of an insulating rubber plate.
f).- application of a plurality of vibrations of different intensity on each finger, said application being alternating within a limited period of time.
g).- pulsation by the patient, for each of the different vibrations, of the first button of the second unit if the vibration is felt, and of the second button of said unit if nothing is felt.
h).- quantification by the second unit of the percentage of vibrations detected by the patient, to determine a degree of sensitivity.
i).- deployment of the Peltier cell with ventilators from one of the ends of the casing of the first unit.
j).- placement of one of the sides of the Peltier cell with ventilators on the localized area of the skin of the back of the right foot, continuing with the left foot and subsequently with the upper limbs.
k).- application of a plurality of cold-heat stimuli to each limb, said application being alternating within a limited period of time.
l).- pulsation by the patient, for each of the different cold-heat/pain stimuli, of the first button if the stimulus is positively felt, or of the second button if it is not felt, after each stimulus.
m).- quantification by the second unit of the percentage of changes of temperature and pain induced by cold-heat correctly detected by the person, to determine a degree of sensitivity.

**[0029]** Considering the characteristics of the device for assessing the vibratory, thermal and thermoalgesic sensitivity object of the present invention, said device has the following advantages:

1. Compact size and light weight in more than 75% of existing devices (portable).
2.- Integration in a single unit for the assessment of the 4 tests in less than 15 minutes, with evaluation of small and medium-sized sensitive fibres using the same device.
3.- Absence of: replacement liquid coolants, manual controllers of liquids temperature, use of antiseptics for liquids.
4.- Simple-to-use software for a user without computer-specific and/or medical/health-related knowledge.
5.- Autonomy by rechargeable battery/non-rechargeable batteries.
6.- Reduced cost of device and tests.
7.- Instantaneous delivery of semi-quantitative/quantitative results with an interpretation for non-medical professionals.
8.- It allows the systematic self-monitoring of alterations and/or normality.
9.- Results response in visual and/or aural form for persons with visual deficit.
12.- Dispenses with the use of a PC, which is used in a supplementary, not compulsory, way.
13.- Applicable to all body surfaces.

Brief description of the designs

**[0030]**

Figure 1 represents a view of the device integrating the first and second units.
Figure 2 represents a perspective front view of the device integrating the first unit for assessing sensitivity, object of the present invention, said first unit being in retracted position. In figure 2b a lateral perspective view of said device is represented.
Figure 3 represents a perspective view of the first unit in deployed position.
Figure 4 represents a perspective view of the first unit forming part of the device for assessing sensitivity, object of

the present invention, said first unit being in partly deployed position.

Figure 5 represents a perspective view of the first unit forming part of the device for assessing sensitivity, object of the present invention, said first unit being in fully retracted position.

Figure 6 represents a perspective view of the second unit forming part of the device for assessing sensitivity, object of the present invention.

Figure 7 represents a perspective view of the vibration generating means forming part of the first unit of the device.

Description of a preferred embodiment

**[0031]** As can be seen in figure 1, the device for assessing the vibratory and thermoalgesic sensitivity, object of the present invention, is essentially made up of a first unit (1) and a second unit (2) that, when the device is being used, are mutually integrated thanks to a slot made in the second unit (2) and a protrusion or projection fitting perfectly inside said slot, said projection being made in the first unit (1).

**[0032]** The first unit (1) is made up of an outer casing (3) with a cylindrical configuration and that is divided into two parts (37) and (38), this unit having a sleeve on each of the two ends or a single sleeve (39) between the two parts, whereby thanks to a relative turn of both parts of the first unit (1) a vibration generating means (4) or a means generating cold-heat (4'), or both simultaneously if necessary, may be deployed.

**[0033]** In figure 3 the constitution of the first unit (1) is detailed, which in addition to the mentioned stimuli-generating means (4) and (4'), includes on/off and control (5) means, whose mission is, on one hand, to allow the switching on and off of the first unit (1) and, on the other hand, to control by means of an electrical circuit the intensity of the stimuli applied to the patient, both vibrations and cold-heat.

**[0034]** The vibration generating means (4) comprise a tuning fork (9), represented in detail in figure 7, which consists of arms (10) that converge on a central point (11) crossed by a stem (40) that makes up the vibration applicator (12), which has in its free end a Teflon button (13). In the connection area between said applicator (12) and the casing (3) is a rubber washer (14) to prevent the leakage of vibrations. On each end of the arms (10) the corresponding piezo-electric elements (248-125 Hz) or speakers that have an inner coil are arranged, which are responsible for generating the vibration, as they emit a vibratory discharge through the changes experienced by the piezo-electric unit in response to the electrical stimulus of this element, or through sound generating a vibratory effect in conjunction with the coil and with a frequency phase shift of 180º, leading to transmission through the arms of the tuning fork (9) to the applicator (12). The energy feeding the first unit (1), which is destined to said vibration generating means (4), is of 9 V, maintaining a vibration with a sinusoidal wave form of 4 milliseconds duration.

**[0035]** The vibration generating means (4) may be optionally displaced linearly with respect to the casing (3), being deployed from it through activation of the sleeve (39), enabling the means in the inside of the first unit that are appropriate for achieving said displacement.

For example, guides may be enabled (41).

**[0036]** On the other hand, the means generating cold-heat (4') have a Peltier cell with ventilators (16), in particular a Peltier thermode with ventilators, which is arranged on the end of an ejector arm (19), in parallel to the turning axis (18) of the casing (3), being rotatable with respect to said arm (19) according to an axis (17) perpendicular to the turning axis (18). In this way, in the idle state of the first unit (1), the casing contains a Peltier cell with ventilators (16) that by turning the sleeve (39) is extracted from the casing (3) projecting the arm (19), on the end of which the cell (16) lies in retracted position, because the diameter of the casing (3) is smaller than the necessary width for the Peltier cell with ventilators, as can be seen in figure 4. To be able to use the cell (16), it is retracted with respect to the arm's end (19) according to the rotational axis (17), resulting in it being completely deployed and ready for use.

**[0037]** In figure 5 the first unit (1) can be seen, in which the Peltier cell with ventilators (16) and the vibration applicator (12) have been completely deployed. A support element (42) of the first unit (1) can also be seen, which couples to the casing (3) through a hole made in it, said element (42) having a rubber base (34) to prevent vibrations from the ground transmitting to the first unit (1). The first unit (1) may have temperature sensors, a skin sensor (29) and an ambient temperature sensor (30) that are incorporated on the thermoalgesic unit containing the Peltier cell with ventilators.

**[0038]** In figure 6, the configuration of the second unit (2) is shown, which consists of means for data input (6), means for data display (7) and indicator means (8). The data input means are embodied in a button pad (20) that has a first area (21) of buttons comprising a button for the switching on and off and another area with two buttons for the input of data corresponding to the vibration generating means and for input of data corresponding to the means generating cold-heat, and a second area (22) of buttons having a first button (23) that will be pushed when the patient identifies a vibration and a second button (24) that will be pushed when the patient identifies none.

**[0039]** The main aim of the button pad is to register the detection of the different stimuli by the patient being assessed; thus the first button (23) corresponds to the capture of affirmative data (yes) regarding the identification of stimuli, while the second button (24) corresponds to the capture of negative data (no), or the lack of identification of the stimuli. Regarding the data display means (7), they comprise a screen (44) that can display at least the following data: the date

and time when the assessment or test is carried out, the number and type of test being run, the score obtained in each test and in total, and the percentage of stimuli detected by the patient.

**[0040]** The indicator means (8) are several leds (36) red and green in colour, whereby the led will light up red when the stimulus is being applied by the unit (1); it will subsequently stop lighting up and the green colour led will light up, indicating that at that moment the patient may proceed to pushing the buttons of the second unit (2).

**[0041]** Additionally, the second unit (2) will have visual warning means (35) that may appear on the screen itself, and/or aural, which indicate the battery charge (33) of the unit is near exhaustion and also may warn about the test results if they exceed certain predetermined values. In addition, it may have a connection port (27) for the second unit (2) to a personal computer with the aim of processing the data collected by said unit if necessary. This unit (2) may have emergency batteries that will activate in the case the battery (33) is exhausted during the assessment process.

**[0042]** The Peltier cell with ventilators (16) will have a dimension of 5 x 2.5 $cm^2$, and the tuning fork (9) a working frequency of 125 to 248 Hz. The increases or decreases of the stimulation temperatures used for the Peltier cell with ventilators (16) consist of pre-established random ramps ranging from 9º (pyramidal scale) for cold, 45º for the feeling of heat, to a limit of 49º (trapezoid scale) for the feeling of thermal pain. Each stimulus is maintained for a period of 10 seconds and 3 stimuli are repeated in one same period, except for the pain resulting from only one stimulus.

**[0043]** The responses to the five sensorial parameters assessed (cold, heat, thermal pain and vibration), are, in turn, registered in the second unit (2). Each response (pulsation of the appropriate button) should be given after application of the corresponding stimulus with a decision time of 10 seconds. Thus, each test (cold, heat, thermal pain and vibration) should provide data from 3 responses assigned to 3 stimuli of the same type but of different intensity. The thermal pain stimulus is applied only on one occasion, so it throws up a response result.

**[0044]** The covering material of units (1) and (2) is hard (not flexible) plastic, similar to metal, in the same way as the internal structure, for external protection and protection of components.

**[0045]** According to the disclosed configuration of the device, the assessment procedure is carried out in the following way.

**[0046]** The first (1) and second (2) units are switched on.

**[0047]** A self-test is carried out of said units, testing among other data, the battery charge (33), the date and operational status of radiofrequency or infrared communications between both units.

Assessment test for sensitivity to vibrations

**[0048]** Turning the sleeve (39) of the first unit (1) clockwise (the sleeve may be optionally located on the distal end, corresponding to the vibrator outlet) while holding fiexedly the shortest portion (38) of the casing (3), the vibrations applicator (12) is telescopically extracted from the first unit (1).

**[0049]** Then, the applicator (12) is placed in contact with the skin area just before the nail bed of the first toe of the right foot, then on the second toe, and continuing in the same way with the left foot. If necessary, one may proceed in the same way with the upper limbs. The contact between the surface of the applicator and the skin must be complete.

**[0050]** The insulating rubber plate is placed under the skin bed of each finger explored.

**[0051]** The vibration test session is initiated.

**[0052]** The complete examination of vibration stimuli is carried out, consisting of a total of 3 tests. Each test should generate 4 stimuli, i.e. a total of 12 stimuli and 12 responses.

**[0053]** The selected method for the assessment is: the "yes-no paradigm" ("two-interval forced choice", which has been included in the software installed in the units of the device).

**[0054]** The intensities of stimuli consist of: A) High intensity; B) intermediate intensity; C) low intensity, and D) null intensity. Each of these intensities is always characterized by presenting a vibration wave of sinusoidal form with a duration of 4 milliseconds and a wave width of +100 μm. a - 100 μm (125 to 248 Hz) with a constant intensity for A) 5.77 μm, B) 2.38 μm, C) 1.19 μm, and D) 0.01 μm.

**[0055]** The mode in which each test is carried out by the software programme is selected randomly as regards intensity and order of application of each stimulus according to the pre-established values in A), B), C) and D).

**[0056]** The time duration of each stimulus is 1.8 s and the pause interval between each stimulus is 13 s.

**[0057]** The beginning of the test is signalled by the lighting up of a red-colour led (36) in the second unit (2), and then the response must be decided (pulsation of the buttons on the second unit (2) by the patient), as the green-colour led (36) of the second unit (2) lights up. If the patient does not press any button after a stimulus, the response is interpreted as missed and is not given a value.

**[0058]** The stimulation programmes indicated are used randomly and distributed in different intensity gradation scales in the successive tests, using the described alternatives and in all cases with 6 non-consecutive null stimuli, such as, for example:

| 1º | 2º | 3º | 4º |
|---|---|---|---|
| A | D | B | D |
| A | D | C | D |
| B | D | A | D |
| B | D | C | D |
| C | D | A | D |
| C | D | B | D |

**[0059]** The patient must indicate to the second unit (2) the perception received of the stimulus. If the stimulus is identified, the affirmative (yes) button (23) will be pushed, and if the stimulus is not identified, the negative (no) button (24) will be pushed.

**[0060]** Each response is assessed in the quantification programme as:

Response 1: success (stimulus detected by the patient)
Response 0: error (stimulus not detected by the patient).

These results may be assessed in percentiles.

**[0061]** The test result is deemed abnormal if the group of responses gives a success rate lower than 75%.

**[0062]** If more than two null stimuli are given positive responses by the patient, the programme enters self-suspension, indicating on screen that the test has failed and the need to start again; if the error persists, the software will not allow continuation with tests until 48 hours have elapsed (the time needed to consult the error with the distributor and/or healthcare personnel).

**[0063]** After completing the test, the result in percentage of correct responses is shown on the screen of the response unit. If the result is 75% or less, a warning flashing red light will come on (optionally a sound alarm), indicating that the test result is not normal.

**[0064]** The results may be transferred to a personal computer and represented in numeric and/or graphical form. With these values one can identify for each area explored the stage at which the implemented tests are.

Assessment test for sensitivity to vibrations

**[0065]** By turning the sleeve (39) (or the sleeve located on the end with the Peltier plate with ventilators) counterclockwise and fixedly holding the longest portion (37) of the casing (3), the temperature and thermal pain stimulator (Peltier cell with ventilators (16)) one wishes to use are deployed.

**[0066]** By using the sensors of the unit an ambient temperature measurement is made.

**[0067]** By means of the sensors of the unit, a skin surface temperature measurement is made.

**[0068]** A similar measurement is made for the vibration stimulus, quantifying the response capacity to the stimulus of the patient.

**[0069]** In this case, the sensitivity and specificity of tests should be validated by contrasting against the method in CASE IV and with patient controls that are healthy or diseased, determining responses obtained according to sex, site explored, age and physical variables.

**[0070]** For a better understanding of the specification, the references used in drawings are listed below:

1. first unit
2. second unit
3. casing of first unit
4. vibration generating means of the first unit

4'. means generating cold-heat

5. on/off and control means of the first unit
6. data input means of the second unit
7. data display means of the second unit
8. indicator means of the second unit
9. tuning fork
10. arms of the tuning fork
11. central point of the tuning fork
12. vibration applicator

13. Teflon button
14. rubber washer
15. speaker of tuning fork - piezo-electrical element
16. Peltier cell with ventilators
17. rotational axis of Peltier cell
18. turning axis of the casing
19. ejecting arm
20. button pad
21. first area button pad
22. second area button pad
23. a first button
24. second button
27. port
29. skin temperature sensor
30. ambient temperature sensor
33. batteries first unit
34. base layer of rubber first unit
35. warning means of the second unit
36. leds indicator means of the second unit.
37. part of casing
38. part of casing
39. sleeve deployed
40. stem of the tuning fork
41. guides
42. support element

## Claims

**1.** Portable device for assessing thermoalgesic and vibratory sensitivity, comprising:

a first unit (1) configured to apply to localised points of the patient a plurality of stimuli comprising vibrations and temperature changes, the first unit (1) comprising:

an outer casing (3),
vibration generating means (4) and means for generating cold-heat (4') configured to act directly on the patient, which are arranged inside the outer casing (3),
on/off and control means (5) configured to activate the first unit (1) and to vary the intensity of both vibrations and temperature,
and
the device comprising a second unit (2) for gathering data communicating with the first unit, the second unit (2) comprising:
data input means (6),
data display means (7),
an affirmative (yes) button (23) and a negative (no) button (24) for indicating the perception received on each stimulus and
indicator means (8) of different operational stages of the first unit (1), wherein the communication between the first unit (1) and the second unit (2) takes place by means of a two-way wireless transmission means;
**characterised in that**
the vibration generating means (4) and means for generating cold-heat (4') are configured to move linearly with respect to the casing (3) in order to deploy from it at the moment when the stimulus is applied,
wherein the portable device is configured to perform a vibration test by applying a plurality of stimuli, each stimulus being a vibration of sinusoidal waveform of 125 to 128 Hz, having a duration of 1.8 seconds and the constant intensity of each stimulus is randomly selected from 5.77 μm, 2.38 μm, and 1.19 μm and followed by a stimulus of 0.01 μm, wherein a pause interval in the vibration test between each stimulus is 13 seconds.

**2.** Portable device of claim 1, wherein the vibration generating means (4) of the first unit (1) comprises a tuning fork

(9) that has two arms (10) converging in a central point (11), from which point a vibration applicator (12) projects, the end of which has a Teflon or polyvynil button (13), the arms forming an angle of application of 30° with respect to the main axis of the first unit (1), said applicator (12) being connected to the outer casing (3) through a rubber washer (14) and a piezo-electrical element of 125 to 128 Hz or a speaker with coil (15) generating vibrations being fixed to the free end of each arm (10), cables of the vibration generating means (4) running through a central part of the first unit (1) casing (3).

**3.** Portable device of claims 1 and 2, wherein the means generating cold-heat (4') of the first unit (1) comprise:

a Peltier cell (16) that is connected rotatably according to an axis (17) perpendicular to the turning axis (18) of the casing (3) to an ejector arm (19) that is parallel to said turning axis and that is connected to the casing (3) to move linearly with respect to it according to a direction parallel to the turning axis (18), in such a way that, in the retracted position of the means generating cold-heat (4'), the Peltier cell (16) is located in parallel to the arm (19), and in a deployed position the arm (19) projects from the casing (3) and, once deployed, the Peltier cell (16) turns with respect to the axis (17) of the arm's end (19) adopting an inclination with respect to the axis (18) of the casing (3).

**4.** Portable device of any of claims 1 to 3, wherein the data input means (6) of the second unit (2) comprise:

a pad of buttons (20) divided in two areas,

- a first area (2) of buttons for the input of the data corresponding to vibration generating means (4) and the data corresponding to the means generating cold-heat (4'), and
- a second area of buttons (22) comprising:

the affirmative (yes) button (23) and the negative (no) button (24).

**5.** Portable device of any of claims 1 to 4, wherein the first unit (1) remains coupled to the second unit (2) through a slot (31) made in the second unit (2) and a projection (32) that fits into said slot (31) associated to the first unit (1), in such a way that both units are coupled to each other, forming the device.

**6.** Device of claims 1 to 5, wherein the first unit (1) comprises on one of its bases, which it rests on the ground during use of the device, a rubber layer (34).

**7.** Portable device of claims 1 to 6, wherein the indicator means (8) of the second unit (2) comprises a plurality of leds (36) of different colours red and green, whereby a LED of red colour will light up when the stimulus is being applied by the first unit (1), then it will stop lighting up, and afterwards the LED of green colour will light up to indicate that the patient may proceed to push the buttons (23, 24) of the second unit (2) depending on whether he identifies a stimulus (23) or not (24).

**8.** Portable device of claims 1 to 7, wherein the data display means (7) of the second unit (2) comprises a screen (44) located next to the first (21) and second (22) areas of buttons of the button pad (20), configured to display at least the following data: the date and time, the number and type of test being carried out, the score obtained in each test and in total, and the percentage of stimuli detected by the patient.

**9.** Procedure for assessing the vibratory, thermal and thermoalgesic sensitivity by means of the portable device of claims 1 to 9, the procedure comprises the following steps:

a).- switching on the first (1) and second (2) units.
b).- deployment of the vibration applicator (12) from one of the ends of the first unit (1) casing (3).
c).- placement of the end of the vibration applicator (12) on a localized area of the nail bed skin of the first toe of the right foot, continuing with the second toe until completing the foot, then continuing with the left foot and subsequently with the upper limbs.
d).- placement under the ball of each explored finger of an insulating rubber plate.
e).- application of a plurality of stimuli of different intensity on each finger, wherein each stimulus is a vibration of sinusoidal waveform of 125 to 128 Hz, having a duration of 1.8 seconds, and the constant intensity of each stimulus is randomly selected from 5.77 μm, 2.38 μm, and 1.19 μm and followed by a stimulus of 0.01 μm, wherein a pause interval in the vibration test between each stimulus is 13 seconds.

f).- pulsation by the patient in the second unit (2), for each of the different vibrations, the affirmative (yes) button (23) if the stimulus is identified, and the negative (no) button (24) if the stimulus is not identified, after each stimulus.
g).- quantification by the second unit (2) of the percentage of vibrations detected by the patient, to determine a degree of sensitivity.
h).- deployment of a Peltier cell (16) from one of the ends of the casing (3) of the first unit (1).
i).- placement of one of the sides of the Peltier cell (16) on a localized area of the skin of the back of the right foot, continuing with the left foot and subsequently with the upper limbs.
j).- application of a plurality of cold-heat stimuli to each limb, said application being alternating within a limited period of time.
k).- pulsation by the patient in the second unit (2), for each of the different cold-heat/pain stimuli, the affirmative (yes) button (23) if the stimulus is identified, and the negative (no) button (24) if the stimulus is not identified, after each stimulus.
l).- quantification by the second unit of the percentage of changes of temperature and pain induced by cold-heat detected by the person, to determine a degree of sensitivity.

**10.** Procedure according to claim 9, wherein self-suspension is activated if at least 2 vibrations of 0.01 μm are given positive responses by the patient, and then indication is given on a screen that the test has failed and the need to start again.

**Patentansprüche**

**1.** Tragbare Vorrichtung zur Beurteilung von Wärmeschmerz- und Vibrationsempfindlichkeit, umfassend:

eine erste Einheit (1), dazu eingerichtet, um an örtlich begrenzten Punkten des Patienten eine Vielzahl von Impulsen anzuwenden, die Vibrationen und Temperaturänderungen umfassen,
wobei die erste Einheit (1) folgendes umfasst:

ein äusseres Gehäuse (3),
Mittel zur Vibrationserzeugung (4) und Mittel zur Erzeugung von Kälte-Wärme (4'), die dazu eingerichtet sind, direkt auf den Patienten einzuwirken, und die innerhalb des äusseren Gehäuses (3) angeordnet sind,
Mittel zum An- und Ausschalten und zur Steuerung (5), die dazu eingerichtet sind, die erste Einheit (1) zu aktivieren und die Intensität der Vibrationen sowie der Temperatur zu variieren, und
wobei die Vorrichtung eine zweite Einheit (2) umfasst, um Daten zu erfassen, die mit der ersten Einheit kommuniziert, wobei die zweite Einheit folgendes umfasst:

Mittel zur Dateneingabe (6),
Mittel zur Datenanzeige (7),
eine Taste (ja) zur Bejahung (23) und eine Taste (nein) zur Verneinung (24), um die auf jeden Impuls erfolgte Empfindung anzuzeigen, und
Mittel zur Anzeige (8) der verschiedenen Betriebsphasen der ersten Einheit (1),
wobei die Kommunikation zwischen der ersten Einheit (1) und der zweiten Einheit (1) durch Mittel zur drahtlosen Zwei-Wege-Übertragung vor sich geht;
**dadurch gekennzeichnet, dass**
die Mittel zur Vibrationserzeugung (4) und Mittel zur Erzeugung von Kälte-Wärme (4') dazu eingerichtet sind, sich linear in Bezug auf das Gehäuse (3) fortzubewegen, um sich davon abzulösen in dem Augenblick, in dem der Impuls angewendet wird,
wobei die tragbare Vorrichtung dazu ausgebildet ist, einen Vibrationstest durchzuführen, indem eine Vielzahl von Impulsen ausgegeben wird, wobei jeder Impuls eine Vibration mit einer sinusförmigen Wellenform von 125 bis 128 Hz darstellt, eine Dauer von 1.8 Sekunden hat und
die konstante Intensität jedes Impulses zufällig ausgewählt wird aus 5.77 μm, 2.38 μm, und 1.19 μm und von einem Impuls von 0.01 μm gefolgt wird, wobei die Pausenlänge im Vibrationstest zwischen jedem Impuls 13 Sekunden beträgt.

**2.** Tragbare Vorrichtung nach Anspruch 1, wobei die Mittel zur Vibrationserzeugung (4) der ersten Einheit (1) eine Stimmgabel (9) umfassen, die zwei Schenkel (10) aufweist, welche in einem zentralen Punkt (11) zusammenlaufen, von welchem ein Vibrationsanwender (12) absteht, dessen Ende eine Taste (13) aus Teflon oder Polyvinyl aufweist,

wobei die Schenkel einen Anwendungswinkel von 30º in Bezug auf die Hauptachse der ersten Einheit (1) bilden, wobei der besagte Anwender (12) mit dem äusseren Gehäuse (3) durch eine Gummischeibe (14) und ein piezoelektrisches Element von 125 bis 128 Hz verbunden ist, oder ein Vibrationen erzeugender Lautsprecher mit Spule (15) am freien Ende jedes Schenkels (10) befestigt ist, und die Kabel der Mittel zur Vibrationserzeugung (4) durch den zentralen Teil des Gehäuses (3) der ersten Einheit (1) verlaufen.

**3.** Tragbare Vorrichtung nach den Ansprüchen 1 und 2, wobei die Mittel zur Erzeugung von Kälte-Wärme (4') der ersten Einheit (1) folgendes umfassen:

eine Peltier-Zelle (16), welche drehbar in Bezug auf eine senkrecht zur Drehachse (18) des Gehäuses (3) befindliche Achse (17) mit einem Auswerfearm (19) verbunden ist, der parallel zu dieser Drehachse angeordnet ist und der mit dem Gehäuse (3) verbunden ist, um sich linear in Bezug auf dasselbe in einer zur Drehachse (18) parallelen Richtung fortzubewegen, und zwar derart, dass in der eingezogenen Position der Mittel zur Erzeugung von Kälte-Wärme (4'), die Peltier-Zelle (16) parallel zu dem Arm (19) angeordnet ist, während in der ausgefahrenen Position der Arm (19) aus dem Gehäuse (3) hervorsteht und, nach Implementierung, die Peltier-Zelle (16) sich in Bezug auf die Achse (17) des Armendes (19) dreht und eine Neigung bezüglich der Achse (18) des Gehäuses (3) annimmt.

**4.** Tragbare Vorrichtung nach einem beliebigen Anspruch von 1 bis 3, wobei die Mittel zur Dateneingabe (6) der zweiten Einheit (2) folgendes umfassen:

einen Tastenblock (20), der in zwei Zonen aufgeteilt ist,

- eine erste Tastenzone (2) zur Eingabe der Daten, die den Mitteln zur Vibrationserzeugung (4) entsprechen und der Daten, die den Mitteln zur Erzeugung von Kälte-Wärme (4') entsprechen, und
- eine zweite Tastenzone (22), die folgendes umfasst:

die Taste (ja) zur Bejahung (23) und die Taste (nein) zur Verneinung (24).

**5.** Tragbare Vorrichtung nach einem beliebigen Anspruch von 1 bis 4, wobei die erste Einheit (1) mit der zweiten Einheit (2) durch eine in der zweiten Einheit (2) angebrachte Kerbe (31) und einen Vorsprung (32) gekoppelt ist, der in die besagte, der ersten Einheit (1) zugehörigen Kerbe (31) passt, und zwar derart, dass beide Einheiten miteinander gekoppelt sind und die Vorrichtung bilden.

**6.** Vorrichtung nach den Ansprüchen 1 bis 5, wobei die erste Einheit (1) auf einer ihrer Grundflächen, welche während des Einsatzes der Vorrichtung auf dem Boden verbleibt, eine Gummischicht (34) aufweist.

**7.** Tragbare Vorrichtung nach den Ansprüchen 1 bis 6, wobei die Mittel zur Anzeige (8) der zweiten Einheit (2) eine Vielzahl von Leuchtdioden (36) verschiedener Farben von rot und grün aufweisen, wobei eine LED mit roter Farbe aufleuchtet, wenn der Impuls von der ersten Einheit (1) ausgegeben wird, und dann aufhört zu leuchten, wobei im Anschluss die LED mit der grünen Farbe aufleuchtet, um anzuzeigen, dass der Patient nun die Tasten (23, 24) der zweiten Einheit (2) drücken kann, je nachdem, ob er einen Impuls identifiziert (23) oder nicht (24).

**8.** Tragbare Vorrichtung nach den Ansprüchen 1 bis 7, wobei die Mittel zur Datenanzeige (7) der zweiten Einheit (2) einen Bildschirm (44) umfassen, der neben den ersten (21) und zweiten (22) Tastenzonen des Tastenblocks (20) angeordnet ist und dazu ausgebildet ist, zumindest die folgenden Daten anzuzeigen: das Datum und die Zeit, die Nummer und die Art des ausgeführten Tests, die Punktzahl, die in jedem Test und insgesamt erreicht wurde, und den Prozentsatz der vom Patienten erkannten Impulse.

**9.** Verfahren zur Beurteilung von Wärme-, Wärmeschmerz- und Vibrationsempfindlichkeit mittels der tragbaren Vorrichtung nach den Ansprüchen 1 bis 9, wobei das Verfahren die folgenden Schritte umfasst:

a).- Einschalten der ersten (1) und zweiten (2) Einheit.
b).- Ausfahren des Vibrationsanwenders (12) von einem der Enden des Gehäuses (3) der ersten Einheit (1).
c).- Positionieren des Endes des Vibrationsanwenders (12) auf einer örtlich begrenzten Fläche der Haut des Nagelbetts des ersten Nagels des rechten Fusses, fortfahrend mit dem zweiten Nagel, bis der Fuss komplettiert ist, dann Fortfahren mit dem linken Fuss und anschliessend mit den oberen Gliedmassen.
d).- Positionieren einer isolierenden Gummiplatte unter dem Ballen jedes untersuchten Fingers.

e).- Anwendung einer Vielzahl von Impulsen von verschiedener Intensität auf jedem Finger, wobei jeder Impuls eine Vibration mit einer sinusförmigen Wellenform von 125 bis 128 Hz darstellt, eine Dauer von 1.8 Sekunden hat und die konstante Intensität jedes Impulses zufällig ausgewählt wird aus 5.77 μm, 2.38 μm, und 1.19 μm und von einem Impuls von 0.01 μm gefolgt wird, wobei die Pausenlänge im Vibrationstest zwischen jedem Impuls 13 Sekunden beträgt.

f).- Betätigen, für jede der verschiedenen Vibrationen in der zweiten Einheit (2) und nach jedem Impuls, der Taste (ja) zur Bejahung (23) durch den Patienten, wenn der Impuls identifiziert wird, und der Taste (nein) zur Verneinung (24), wenn der Impuls nicht identifiziert wird.

g).- Quantifizierung durch die zweite Einheit (2) des Prozentsatzes an Vibrationen, die vom Patienten erkannt wurden, um einen Grad der Empfindlichkeit zu bestimmen.

h).- Implementierung einer Peltier-Zelle (16) von einem der Enden des Gehäuses (3) der ersten Einheit (1).

i).- Positionieren von einer der Seiten der Peltier-Zelle (16) auf einer örtlich begrenzten Fläche der Haut der Rückseite des rechten Fusses, Fortfahren mit dem linken Fuss und anschliessend mit den oberen Gliedmassen.

j).- Anwendung einer Vielzahl von Kälte-Wärme-Impulsen an jedes Körperglied, wobei diese Anwendung innerhalb eines begrenzten Zeitraumes alterniert.

k).- Betätigen, für jeden der verschiedenen Impulse von Schmerz und Kälte-Wärme in der zweiten Einheit (2) und nach jedem Impuls, der Taste (ja) zur Bejahung (23) durch den Patienten, wenn der Impuls identifiziert wird, und der Taste (nein) zur Verneinung (24), wenn der Impuls nicht identifiziert wird.

l).- Quantifizierung durch die zweite Einheit des Prozentsatzes von Temperaturänderungen und durch Kälte-Wärme ausgelösten Schmerz, die von der Person erkannt werden, um einen Grad der Empfindlichkeit zu bestimmen.

**10.** Verfahren nach Anspruch 9, wobei eine automatische Suspendierung aktiviert wird, wenn der Patient auf zumindest 2 Vibrationen von 0.01 μm positiv antwortet, wobei dann eine Anzeige auf einem Bildschirm erscheint, die besagt, dass der Test fehlgeschlagen ist und dass wieder von vorne begonnen werden muss.

**Revendications**

**1.** Dispositif portable pour évaluer la sensibilité vibratoire et thermoalgésique, comprenant:

une première unité (1) configurée pour appliquer à des points localisés du patient une pluralité de stimuli comprenant des vibrations et des changements de température, dans lequel la première unité (1) comprend:

une carcasse extérieure (3),
des moyens générateurs de vibrations (4) et des moyens pour générer du froid et de la chaleur (4'), configurés pour agir directement sur le patient, qui sont disposés à l'intérieur de la carcasse extérieure (3),
des moyens de contrôle et de marche/arrêt (5) configurés pour activer la première unité (1) et pour varier l'intensité tant des vibrations comme de la température, et
dans lequel le dispositif comprend une deuxième unité (2) pour recueillir des données qui communique avec la première unité, dans lequel la deuxième unité comprend:

des moyens de saisie de données (6),
des moyens d'affichage de données (7),
un bouton affirmatif (oui) (23) et un bouton négatif (non) (24) pour indiquer la perception reçue sur chaque stimulus et
des moyens indicateurs (8) de différentes phases opérationnelles de la première unité (1),
dans lequel la communication entre la première unité (1) et la deuxième unité (1) est effectuée par des moyens de transmission bidirectionnels sans fil;
**caractérisé en ce que**
les moyens générateurs de vibrations (4) et les moyens pour générer du froid et de la chaleur (4') sont configurés pour se déplacer de façon linéaire par référence à la carcasse (3) afin de se déployer d'elle dans le moment où le stimulus est appliqué,
dans lequel le dispositif portable est configuré pour réaliser un essai de vibration en appliquant une pluralité de stimuli, dans lequel chaque stimulus est une vibration en forme d'onde sinu-soidale de 125 à 128 Hz, qui a une duration de 1.8 secondes et où l'intensité constante de chaque stimulus est sélectionnée aléatoirement entre 5.77 μm, 2.38 μm, et 1.19 μm et suivie par un stimulus de 0.01 μm, dans lequel la pause d'intervalle dans l'essai de vibration entre chaque stimulus est 13 secondes.

**2.** Dispositif portable de la revendication 1, dans lequel les moyens générateurs de vibrations (4) de la première unité (1) comprennent une lyre (9) qui a deux branches (10) qui convergent dans un point central (11), à partir duquel fait saillie un applicateur de vibration (12), dont l'extrémité a un bouton de Téflon ou polyvinyle (13), les branches formant un angle d'application de 30º par rapport à l'axe principale de la première unité (1), ledit applicateur (12) étant connecté à la carcasse extérieure (3) par une rondelle en caoutchouc (14) et un élément piézoélectrique de 125 à 128 Hz ou un haut-parleur avec une bobine (15) qui génère des vibrations et est fixé à l'extrémité libre de chaque branche (10), dans lequel des câbles des moyens générateurs de vibrations (4) passent par la partie centrale de la carcasse (3) de la première unité (1).

**3.** Dispositif portable des revendications 1 et 2, dans lequel les moyens pour générer du froid et de la chaleur (4') de la première unité (1) comprennent:

une cellule Peltier (16) qui est connectée de manière rotative par rapport à un axe (17) perpendiculaire à l'axe de rotation (18) de la carcasse (3) à un bras éjecteur (19) qui est parallèle audit axe de rotation et qui est connecté à la carcasse (3) pour se déplacer de manière linéaire par rapport à celle-ci suivant une direction parallèle à l'axe de rotation (18), de telle manière que, dans la position rentrée des moyens pour générer du froid et de la chaleur (4'), la cellule Peltier (16) est située parallèle par rapport au bras (19), et dans une position déployée le bras (19) fait saillie de la carcasse (3) et, une fois déployée, la cellule Peltier (16) tourne par rapport à l'axe (17) de l'extrémité du bras (19) en adoptant une inclination par rapport à l'axe (18) de la carcasse (3).

**4.** Dispositif portable selon l'une des revendications 1 à 3, dans lequel les moyens d'entrée de données (6) de la deuxième unité (2) comprennent:

un tableau de boutons (20) divisé en deux zones,

- une première zone (2) de boutons pour l'entrée des données qui correspondent aux moyens générateurs de vibrations (4) et des données qui correspondent aux moyens pour générer du froid et de la chaleur (4'), et
- une deuxième zone de boutons (22) qui comprend:

le bouton affirmatif (oui) (23) et le bouton négatif (non) (24).

**5.** Dispositif portable selon l'une des revendications 1 à 4, dans lequel la première unité (1) reste couplée à la deuxième unité (2) par une rainure (31) réalisée dans la deuxième unité (2) et une projecture (32) qui s'adapte à ladite rainure (31) associée à la première unité (1), de telle façon que les deux unités sont couplées l'une avec l'autre, en formant le dispositif.

**6.** Dispositif des revendications 1 à 5, dans lequel la première unité (1) comprend sur une de ses bases, qui reste sur terre durant l'usage du dispositif, une couche de caoutchouc (34).

**7.** Dispositif portable des revendications 1 à 6, dans lequel les moyens indicateurs (8) de la deuxième unité (2) comprennent une pluralité de diodes lumineuses (36) de couleurs différents rouge et vert, dans lequel une diode lumineuse de couleur rouge s'allumera quand le stimulus est appliqué par la première unité (1), après l'allumage cessera, et après cela la diode lumineuse de couleur verte s'allumera pour indiquer que le patient peut commencer à appuyer sur les boutons (23, 24) de la deuxième unité (2), suivant le cas s'il identifie un stimulus (23) ou pas (24).

**8.** Dispositif portable des revendications 1 à 7, dans lequel les moyens d'affichage de données (7) de la deuxième unité (2) comprennent un écran (44) situé à côté de la première (21) et la deuxième (22) zone de boutons du tableau de boutons (20), configuré pour afficher pour le moins les données suivantes: la date et l'heure, le numéro et le type d'essai qui est effectué, le résultat obtenu dans chaque essai et au total, et le pourcentage de stimuli détectés par le patient.

**9.** Procédure pour évaluer la sensibilité vibratoire, thermique et thermoalgésique par le biais du dispositif portable des revendications 1 à 9, la procédure comprenant les étapes suivantes:

a).- mise en marche de la première (1) et la deuxième (2) unité.
b).- déploiement de l'applicateur de vibration (12) à partir d'une des extrémités de la carcasse (3) de la première unité (1).
c).- positionnement de l'extrémité de l'applicateur de vibration (12) sur une zone localisée de la peau du lit

unguéal du premier orteil du pied droit, en continuant avec le deuxième orteil jusqu'à compléter le pied, en continuant après avec le pied gauche et consécutivement avec les membres supérieurs.

d) positionnement d'une plaque isolante de caoutchouc en dessous de l'hypothénar de chaque doigt exploré.

e).- application d'une pluralité de stimuli de différente intensité sur chaque doigt, chaque stimulus étant une vibration d'une forme d'onde sinusoïdale de 125 à 128 Hz, ayant une duration de 1.8 secondes, et l'intensité constante de chaque stimulus est sélectionnée aléatoirement entre 5.77 μm, 2.38 μm, et 1.19 μm et suivie par un stimulus de 0.01 μm, dans lequel la pause d'intervalle dans l'essai de vibration entre chaque stimulus est 13 secondes.

f).- pression par le patient dans la deuxième unité (2), pour chacune des différentes vibrations et après chaque stimulus, sur le bouton affirmatif (oui) (23) si le stimulus est identifié, et sur le bouton négatif (non) (24) si le stimulus n'est pas identifié.

g).- quantification par la deuxième unité (2) du pourcentage de vibrations détectées par le patient, afin de déterminer un degré de sensibilité.

h).- déploiement d'une cellule Peltier (16) d'une des extrémités de la carcasse (3) de la première unité (1).

i).- positionnement d'un des côtés de la cellule Peltier (16) sur une zone localisée de la peau du dos du pied droit, en continuant avec le pied gauche et consécutivement avec les membres supérieurs.

j).- application d'une pluralité de stimuli de froid-chaleur à chaque membre, ladite application étant alternante pendant une période limitée de temps.

k).- pression par le patient dans la deuxième unité (2), pour chacun des différents stimuli de froid-chaleur/douleur et après chaque stimulus, sur le bouton affirmatif (oui) (23) si le stimulus est identifié, et sur le bouton négatif (non) (24) si le stimulus n'est pas identifié.

l).- quantification par la deuxième unité du pourcentage de changements de température et de douleur induits par froid-chaleur détectés par la personne, afin de déterminer un degré de sensibilité.

**10.** Procédure suivant la revendication 9, dans laquelle une suspension automatique est activée dans le cas où le patient donne des réponses positives à pour le moins 2 vibrations de 0.01 μm, et ensuite l'indication est donnée sur un écran que l'essai a échoué et qu'il faudra recommencer.

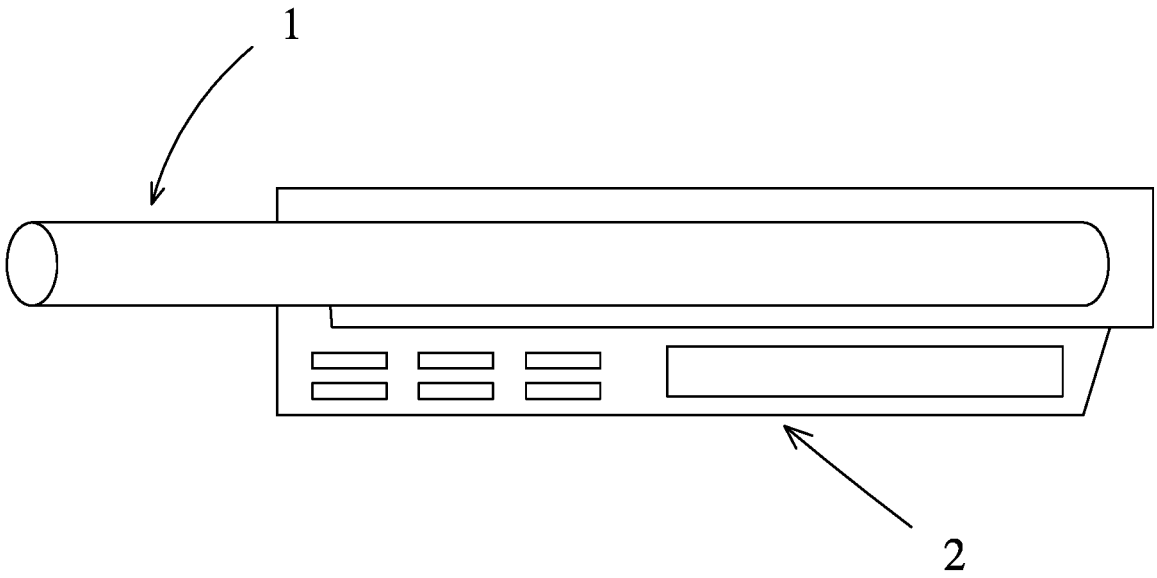



Figure 1

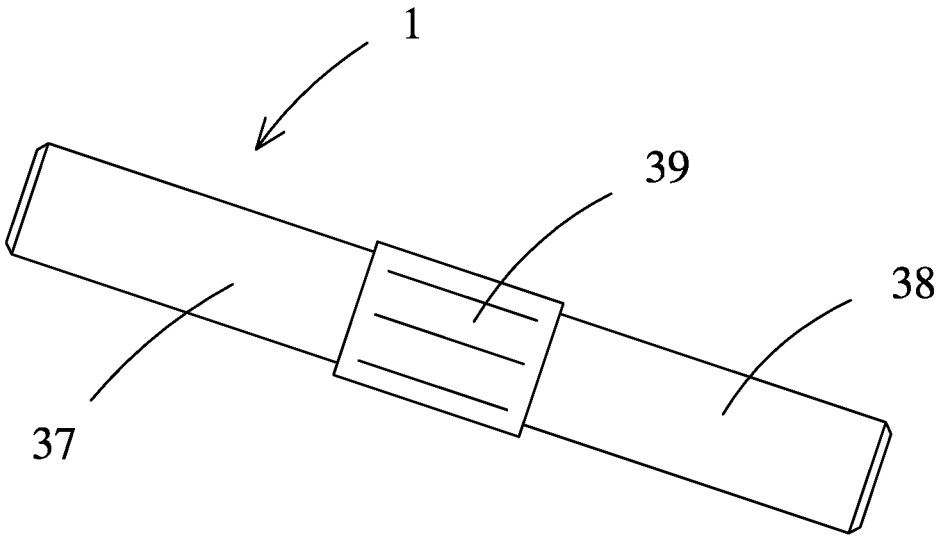



Figure 2

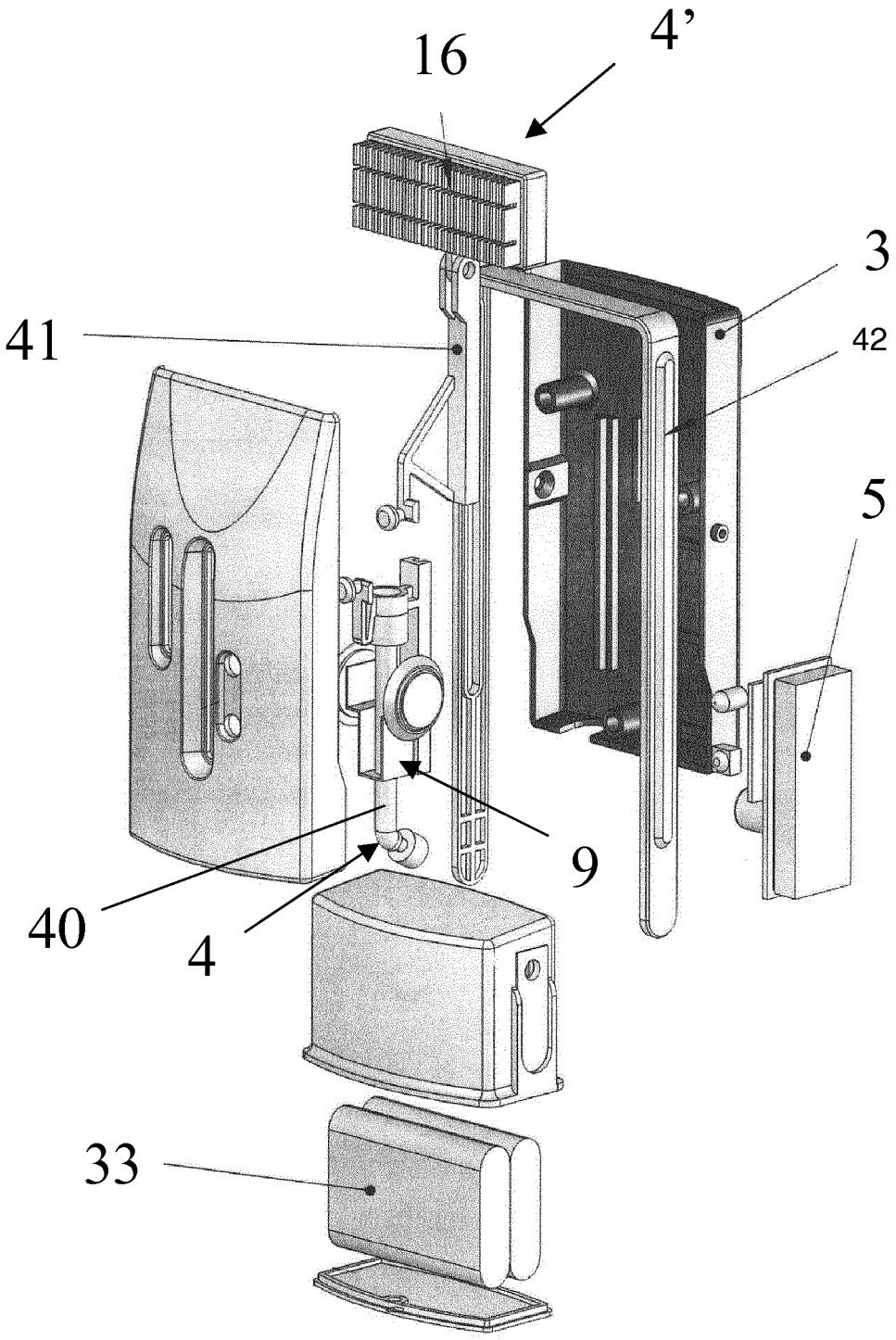
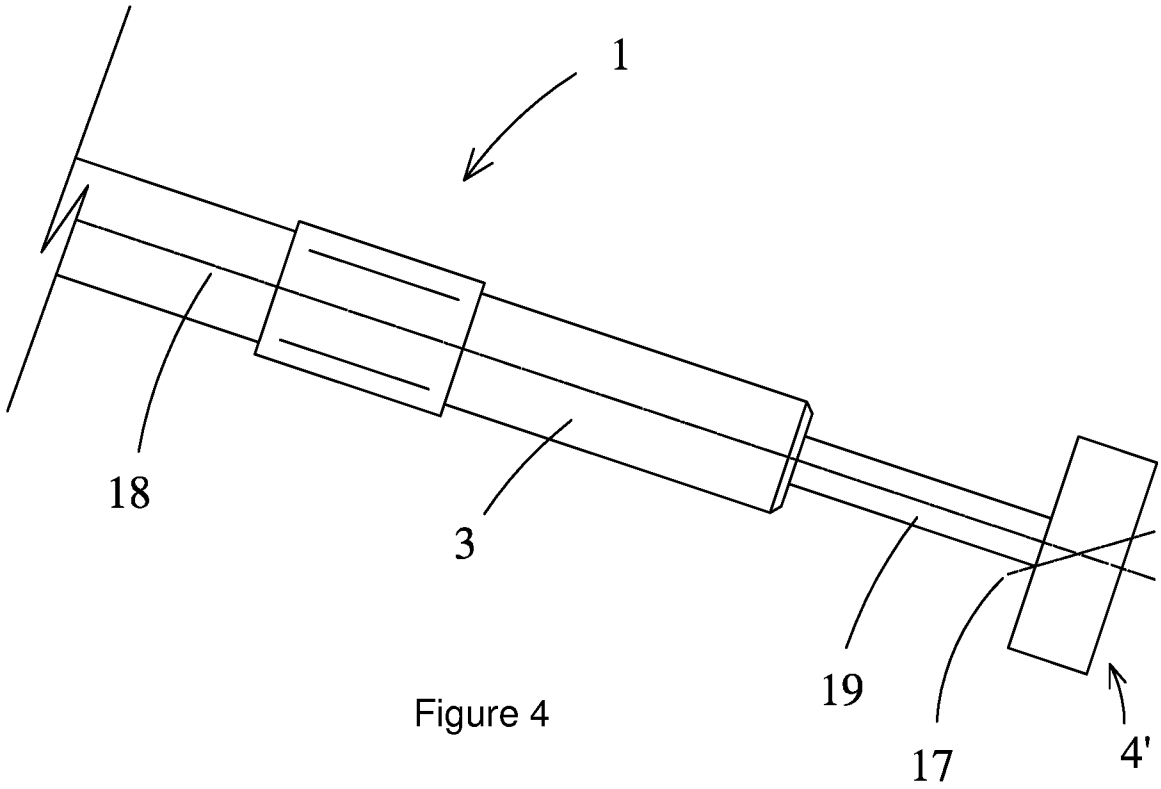



Figura 3

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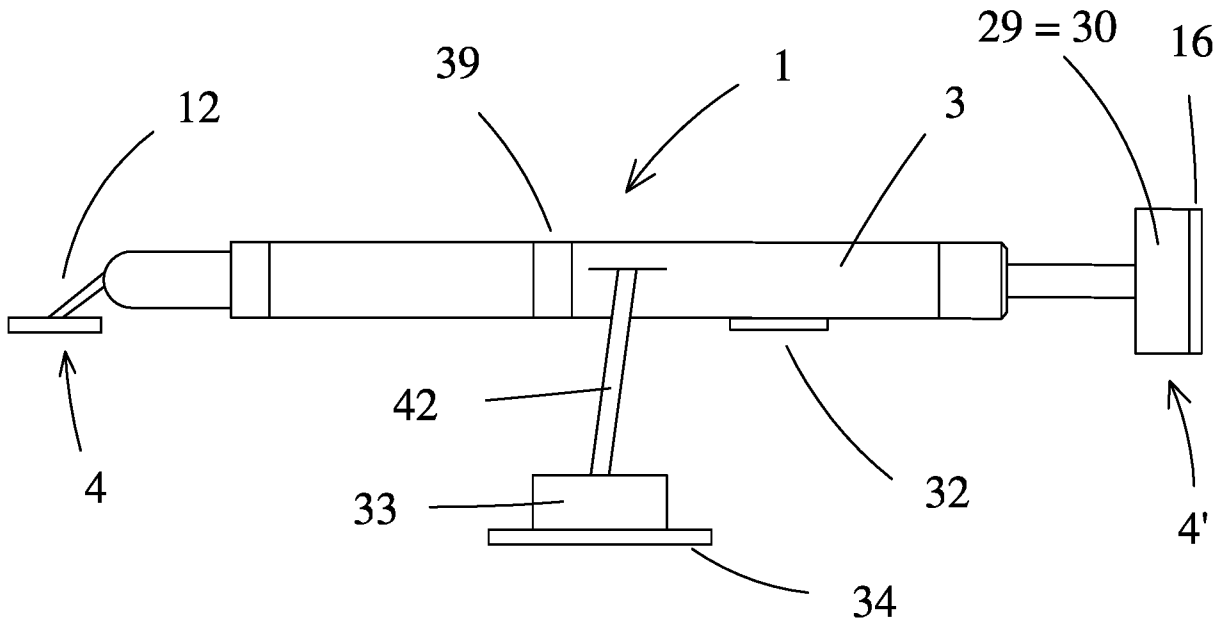


Figure 5

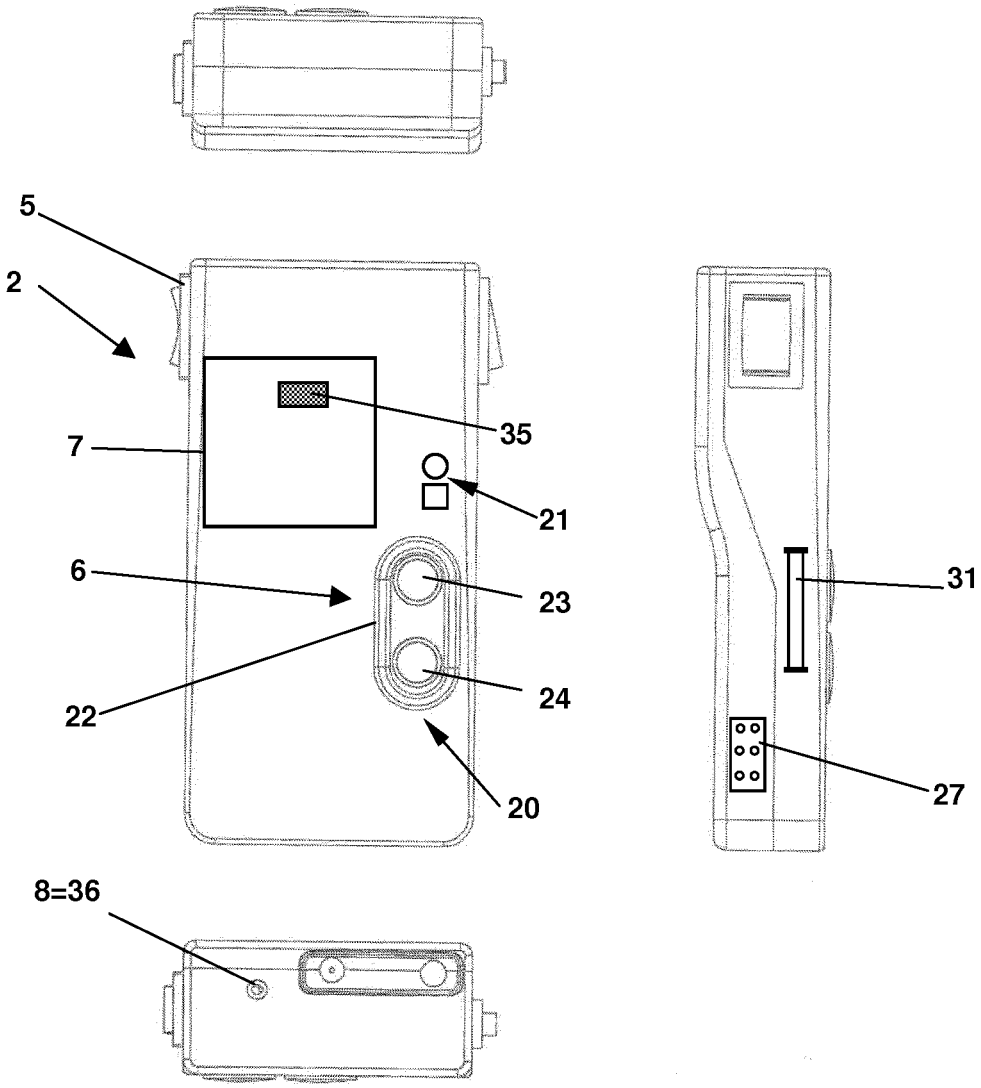


Figure 6

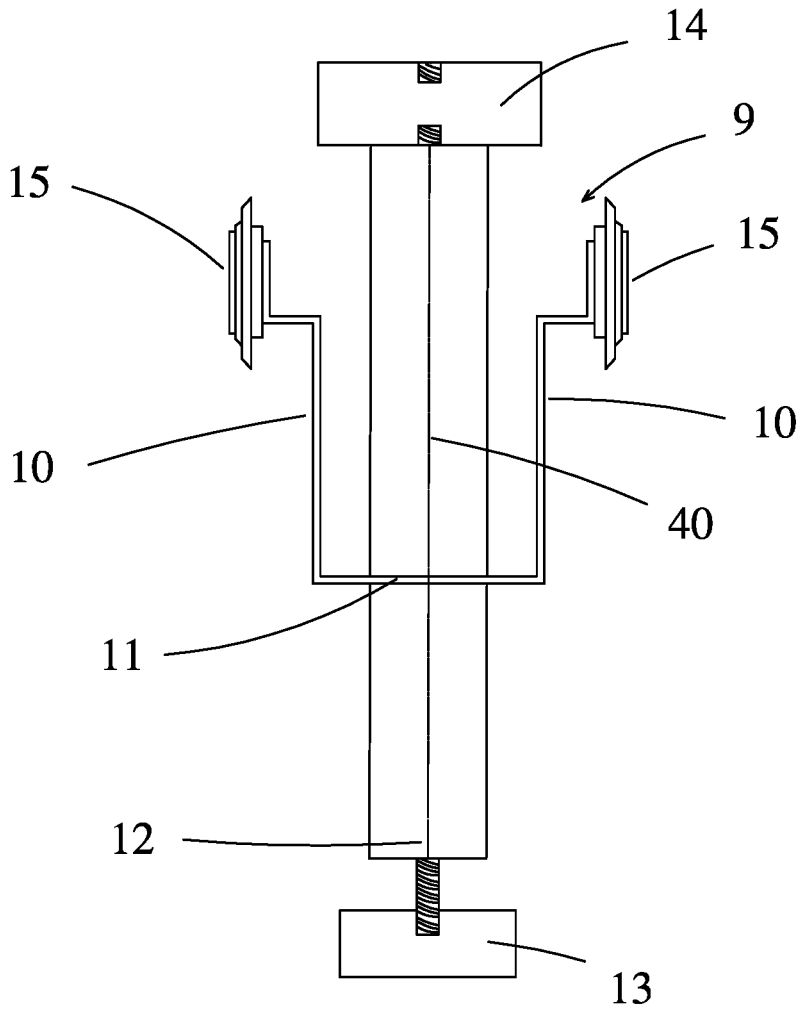


Figure 7

## REFERENCES CITED IN THE DESCRIPTION

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### Patent documents cited in the description


- JP 2005052598 A **[0012]**
- US 2009082694 A1 **[0013]**

| | | | |
|---|---|---|---|
| 专利名称(译) | 用于评估热痛觉和振动敏感性的装置和方法 | | |
| 公开(公告)号 | EP2425765B1 | 公开(公告)日 | 2018-02-14 |
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| IPC分类号 | A61B5/00 | | |
| CPC分类号 | A61B5/4827 A61B5/0024 A61B5/0051 A61B5/483 A61B5/7475 | | |
| 优先权 | 2009000890 2009-04-01 ES | | |
| 其他公开文献 | EP2425765A4<br>EP2425765A2 | | |
| 外部链接 | Espacenet | | |


摘要(译)

本发明涉及一种用于评估热痛和振动敏感性的装置，包括第一单元（1），其被配置为向患者的局部点施加包括振动和温度变化的多个刺激，用于收集数据的第二单元（2）与第一单元通信，其中第一单元（1）和第二单元（2）之间的通信借助于双向无线传输装置进行。本发明还涉及使用根据本发明的装置评估振动，热和热痛觉敏感性的方法。


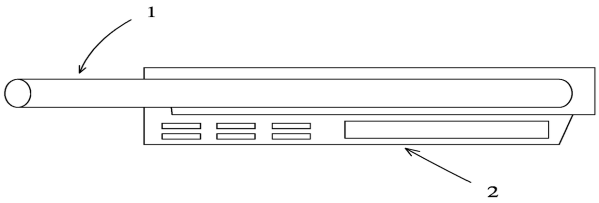

Figure 1

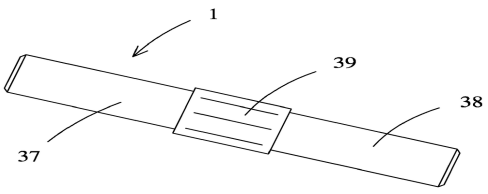

Figure 2