



(86) **Date de dépôt PCT/PCT Filing Date:** 2012/04/16
(87) **Date publication PCT/PCT Publication Date:** 2012/10/26
(85) **Entrée phase nationale/National Entry:** 2013/10/17
(86) **N° demande PCT/PCT Application No.:** EP 2012/001633
(87) **N° publication PCT/PCT Publication No.:** 2012/143111
(30) **Priorité/Priority:** 2011/04/19 (DE10 2011 018 228.4)

(51) **Cl.Int./Int.Cl.** **A61N 1/36** (2006.01),
A61H 39/00 (2006.01), **A61H 39/02** (2006.01),
A61N 1/04 (2006.01)

(71) **Demandeur/Applicant:**
CERBOMED GMBH, DE

(72) **Inventeurs/Inventors:**
ELLRICH, JENS, DE;
BECK, CHRISTOPH, DE;
FRENKEL, WOLF GERHARD, DE;
HARTLEP, ANDREAS, DE

(74) **Agent:** MARKS & CLERK

(54) **Titre : DISPOSITIF ET PROCEDE DESTINES A SOUMETTRE LA SURFACE D'UNE PARTIE DE L'OREILLE HUMAINE A UN SIGNAL DE STIMULATION ELECTRIQUE TRANSCUTANEE**
(54) **Title: DEVICE AND METHOD FOR APPLYING A TRANSCUTANEOUS ELECTRICAL STIMULATION STIMULUS TO THE SURFACE OF A SECTION OF THE HUMAN EAR**

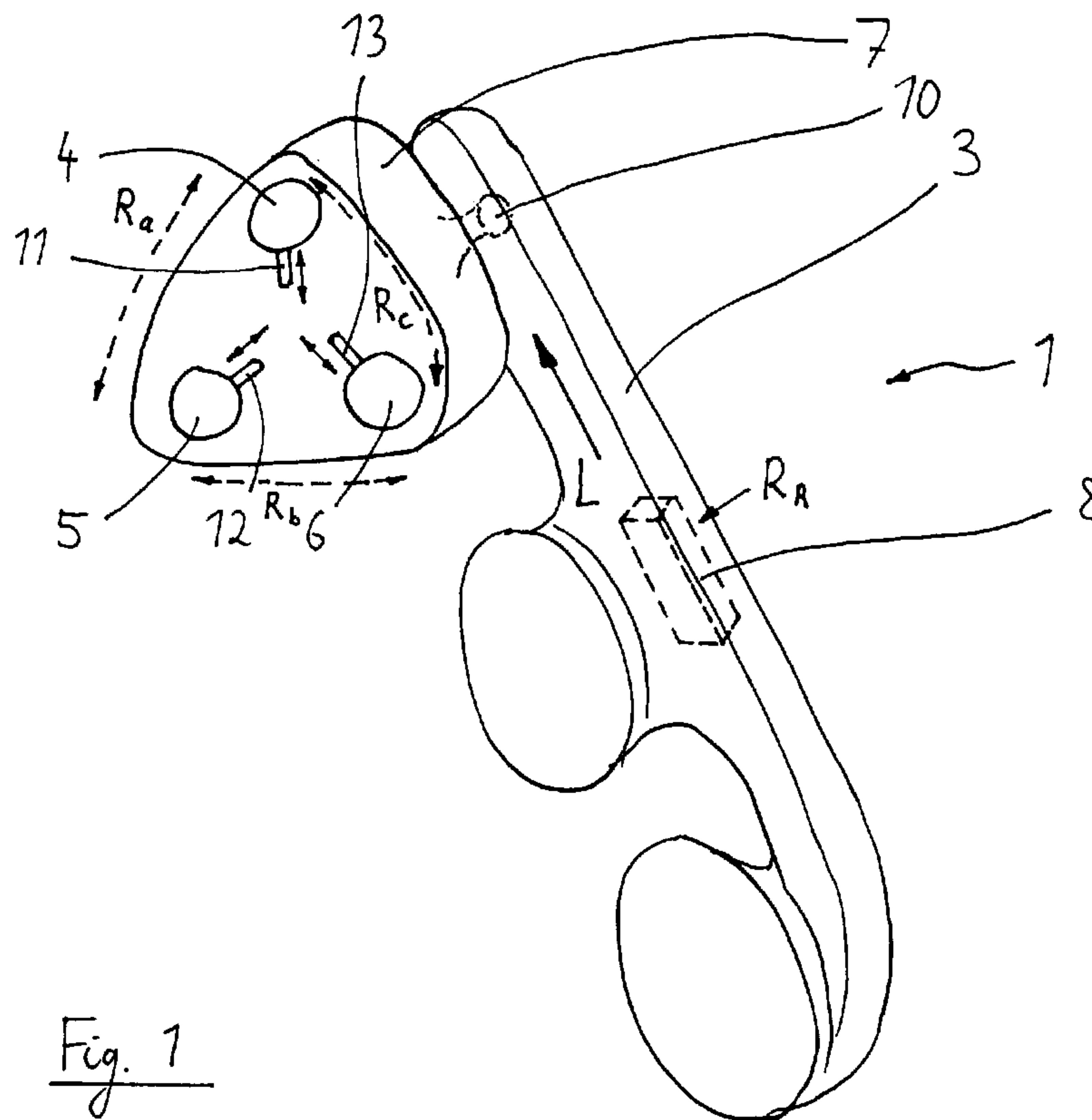


Fig. 1

(57) **Abrégé/Abstract:**

The invention relates to a device (1) for applying a transcutaneous electrical stimulation to the surface of a section of the human ear (2). The device comprises a retaining element (3) that is mountable on or in the ear and a number of electrodes (4, 5, 6) that are



(57) Abrégé(suite)/Abstract(continued):

arranged on or in an electrode carrier (7), wherein the device (1) comprises a control apparatus (8) that controls or regulates the generation of a potential difference between the electrodes (4, 5, 6). In order to permit an improved and safer transcutaneous stimulation, according to the invention at least three electrodes (4, 5, 6) are arranged on or in the electrode carrier (7), wherein the at least three electrodes (4, 5, 6) are located in one plane (E), wherein the position of at least one of the at least three electrodes (4, 5, 6) is adjustable on the electrode carrier (7) and wherein the at least one electrode (4, 5, 6) of which the position is adjustable is mounted such as to be displaceable in a translational manner in the plane (E). The invention further relates to a method for operating such a device.

5

Abstract

The invention relates to a device (1) for applying a transcutaneous electrical
10 stimulation stimulus to the surface of a section of the human ear (2), which
comprises a retaining element (3) which is mountable on or in the ear (2) and
a number of electrodes (4, 5, 6) which are arranged on or in an electrode
carrier (7), wherein the device (1) comprises a control apparatus (8) which
controls or regulates the generation of a potential difference between the
15 electrodes (4, 5, 6). In order to permit an improved and safer transcutaneous
stimulation the invention proposes that at least three electrodes (4, 5, 6) are
arranged on or in the electrode carrier (7), wherein the at least three electrodes
(4, 5, 6) are located in one plane (E), wherein the position of at least one of
the at least three electrodes (4, 5, 6) is adjustable on the electrode carrier (7)
20 and wherein the at least one electrode (4, 5, 6) of which the position is
adjustable is mounted such as to be displaceable in a translational manner in
the plane (E). Furthermore, the invention relates a method for the operation of
such a device.

25

Device and method for applying a transcutaneous
5 **electrical stimulation stimulus to the surface of a**
section of the human ear

The invention relates a device for applying a transcutaneous electrical stimulation stimulus to the surface of a section of the human ear, which
10 comprises a retaining element which is mountable on or in the ear and a number of electrodes which are arranged on or in an electrode carrier, wherein the device comprises a control apparatus which controls or regulates the generation of a potential difference between the electrodes, wherein at least three electrodes are arranged on or in the electrode carrier, wherein the at
15 least three electrodes are located in one plane. Furthermore, the invention relates a method for the operation of such a device.

It is generally known to take influence on the neurophysiological and neuroelectrical quality through invasive and non-invasive stimulation of the
20 nerves and thereby on the function of the simulated nerves. Hereby different conditions of sickness can be treated. Numerous devices exist both for the invasive and the non-invasive stimulation.

The present invention is basing upon the method of the transcutaneous
25 electrical stimulation of the nerves. At this method pulse currents of different current forms, amplitudes, pulse durations and frequencies are administered through the skin on different nerves and change their status parameter in an advantageous way.

AMENDED
SHEET

A device of the above mentioned kind is known from **WO 2010/032114 A2**. Here, an earphone is described which can be inserted into the ear channel, wherein electrodes are arranged at the earphone to carry out a transcutaneous electro stimulation. Other solutions are disclosed in **US 3 659 614**, in **US 6 341 237 B1** und in **WO 2009/137683 A2**.

Another device is known from **DE 10 2006 023 824 B1**. Here, a device for the transcutaneous stimulation of the vagus nerve of the human body is described which can be arranged in this concrete case in the pinna of the ear. The transcutaneous stimulation of the vagus nerve occurs after that parameters of the stimulation current have been pretended. Indeed, the data can be adjusted according to the individual needs. However, after the adjustment the data are fixed. The contact of the tissue which is to be stimulated takes place by two spherical electrodes, which are biased elastically against the skin surface.

It has been found out that the application of transcutaneous stimulation stimuli is beneficial, especially in the region of the Cymba conchae. Thereby, the region of the Cymba conchae is that region of the conchae of the ear which lies above the Crus helicis; it is also called Hemiconcha superior. The region of the Cavum conchae extends downwards below the Crus helicis.

However, in difference to the mentioned **DE 10 2006 023 824 B4** it is more difficult here to establish a perfect electrical contact between stimulation electrodes and skin surface. Here, in a specific manner a greasy skin surface or hairiness can exist which aggravates the establishment of a good electrical contact.

AMENDED
SHEET

Thus, it is an o b j e c t of the present invention, to provide a device of the mentioned kind as well as a corresponding method which allow in an improved manner to accomplish a safe transcutaneous stimulation. Thereby, it should be determined if applicable in a simple manner that the contact
5 relations of the electrodes on the skin are insufficient.

The s o l u t i o n of this object by the invention is characterized in that the position of at least one of the at least three electrodes is adjustable on the electrode carrier, wherein the at least one electrode of which the position is
10 adjustable is mounted such as to be displaceable in a translational manner in the plane, wherein the electrode carrier is arranged movable relatively to the retaining element so that the electrode carrier can swivel relatively to the retaining element in such a manner that all electrodes are in contact with the skin surface in the region of the Cymba conchae when the retaining element is
15 attached to the ear, wherein between the electrode carrier and the retaining element a spherical joint or a hinge joint is arranged or wherein between the electrode carrier and the retaining element a spring element (preferably designed as a connection section made from long-term flexible material) is arranged.

20

Preferably, exactly three electrodes are arranged at the electrode carrier.

The mentioned plane corresponds thereby especially at least approximately to the skin surface on which a transcutaneous stimulation stimulus has to be
25 applied.

Thereby, it is preferably provided that three electrodes are arranged triangular on or in an electrode carrier, especially in the form of an equilateral triangle.

AMENDED SHEET

Preferably all electrodes are adjustable arranged with respect to their position at the electrode carrier. The at least one electrode which is adjustable in its position is preferably arranged linear movable in a linear guide. Thereby, in adjustablility of all electrodes the linear guides are aligned preferably
5 radiating to another, i. e. the electrodes can be displaced radially. Also, at least one of the electrodes can be arranged movable in a guide which runs articulated around a virtual center point; so, this electrode can be moved along a circular path and can be approached and displaced respectively to or from the neighbor electrodes. Thereby, the position of the electrodes becomes
10 adjustable in an optimal way for each individual application.

Preferably, the ability to swivel of the electrode carrier relatively to the retaining element is prevented around a longitudinal axis of the retaining element.

15

Preferably, the electrodes are designed as hemispherical metal elements; but also other designs are possible.

The method for the operation of such a device for applying a transcutaneous
20 electrical stimulation stimulus onto the surface of a section of the human ear is characterized by the method steps:

- a) Measuring of the resistance between each pair of electrodes when the device is arranged at or in the ear for all possible pairs of
25 electrodes by the control apparatus;
- b) Comparison of the measured resistances between the pairs of electrodes and selection of the lowest resistance by the control apparatus;

30

AMENDED
SHEET

- c) Causing of a predetermined transcutaneous stimulation by the control apparatus via that pair of electrodes which have the lowest resistance between them.

5 Thereby, the control apparatus can compare the measured resistances with a stored reference resistance after carrying out of step a), wherein a signal is issued and/or the stimulation is prevented in the case that all measured resistances are above the stored reference resistance.

10 Thus, the proposed otoplastic (stimulation device) according to the invention has at least – preferably exactly – three punctual electrodes which are arranged in a plane. Preferably, it should be arranged in the Cymba conchae.

From the control apparatus the electrodes are charged with a stimulation
15 current.

The three punctual electrodes can be arranged like the corner points of a triangle. Thereby, a good rest of all three electrodes on the skin is obtained also with low pressure of the electrode carrier on the skin surface.

20

The electrode carrier can be equipped, as explained, with a flexible adjustment to the unevenness of the ground (analogue to a rail bogie with a center pivot point by which an adjustment to unevenness is possible). For doing so a solution with a hinge joint or spherical joint can be employed,
25 wherein preferably a restriction of the degree of freedom is provided in such a manner that no axial rotation around the longitudinal axis of the retaining element is possible.

Also, a long-term elastic buffer between electrode carrier and retaining
30 element (pressure bow) with a defined reset force is possible.

AMENDED
SHEET

The above mentioned method allows the measurement of the contact quality with a contact evaluation at all (three) electrodes; subsequently, an elimination occurs of the electrode which has the worst conductivity and a subsequent stimulation only with the two other electrodes with better
5 conductivity.

The mentioned contact evaluation can occur by means of a fix stored reference value which is stored in the control apparatus.

10 A possible mode of operation is basing on the simultaneous charging of the especially three electrodes with rotating changes of polarity clockwise or counter-clockwise or stimulation sequences.

Also, a variable arrangement of at least one of the at least three electrodes is
15 beneficial with respect to the distance relatively to the (two) other electrodes. Preferably, such adjustability can be provided for all electrodes. Therefore, the aim is to cover an optimal stimulation scope for each individual ear.

In the drawing an embodiment of the invention is depicted. It shows:

20

Fig. 1 schematically in a perspective view a stimulation device for the transcutaneous stimulation of the Cymba conchae of a human ear,

25 Fig. 2 schematically in a perspective view the stimulation device according to Fig. 1, seen from another perspective, and

Fig. 3 a human ear at which the stimulation device is arranged.

In Figure 1 and 2 a device 1 for the transcutaneous stimulation of a section of the human ear is depicted. The device 1 has a retaining element 3 which can be fixed at the ear (see also Fig. 3). The retaining element 3 extends substantially in the direction of a longitudinal axis L. An electrode carrier 7 is
5 arranged at the retaining element 3 which comprises at hand three electrodes 4, 5 and 6. The electrodes are at hand designed as hemispherical structures.

As far as in principle the construction of a vagus nerve stimulation device is concerned the described design corresponds to the pre-known solution
10 according to the above mentioned DE 10 2006 023 824 B4 of the applicant on which insofar explicitly reference is made.

The electrode arrangement is designed to be arranged at the ear of the person which uses the device 1 in the region of the vagus nerve. So, a transcutaneous
15 stimulation of the vagus nerve can be carried out.

As results from in the synopsis of Figure 1 and Figure 2 the three electrodes 4, 5, 6 lay in a plane E. They are arranged triangular. This has the benefit that a statically determined rest on the surface to be stimulated is given, whereby all
20 three electrodes 4, 5, 6 lay optimal on the skin surface.

The supply of the electrodes 4, 5, 6 with a stimulation current is caused by a control apparatus 8 which is only denoted schematically.

25 Furthermore, as can be seen by including of Figure 3 the device 1 is placed in such a manner in respectively at the ear 2 of a patient that the electrode carrier 7 with its three electrodes 4, 5, 6 lays in the region of the Cymba conchae. The electrode carrier 7 is arranged swivelling relatively to the retaining element 3 by means of a spherical joint 10 in such a manner that it can adapt

itself to the skin surface 9 of the ear 2 and the Cymba conchae respectively. Accordingly, the electrode carrier 7 can adapt itself in its position in such a manner that all three electrodes 4, 5, 6 lay optimal onto the skin surface 9.

- 5 An optimal adaption of the position of the electrodes 4, 5, 6 to the size of the Cymba conchae will be possible by the fact that the electrodes 4, 5, 6 are arranged adjustable in the direction of the double arrow (see Figure 1) by means of respective linear guides 11, 12 13. Thereby, the linear guides 11, 12, 13 need not necessarily allow an absolute linear displacement of the
10 electrodes 4, 5, 6; also possible is a slightly articulated displacement of the electrodes which is still substantially linear.

The control apparatus 8, which is in connection via not depicted wires with the electrodes 4, 5 and 6, is designed to identify that pair of electrodes
15 between which the lowest electrical resistance exists. Then, the stimulation occurs via this pair.

For doing so the control apparatus 8 measures the electrical resistance between the at hand three pairs of electrodes prior the actual stimulation, i. e.
20 between the electrodes 4 and 5 (resistance R_a), between the electrodes 5 and 6 (resistance R_b) and between the electrodes 4 and 6 (resistance R_c) – see therefore Figure 1. In the control apparatus 8 itself a reference resistance R_R is stored.

- 25 A proper electro stimulation is possible when in any case one of the resistances R_a , R_b and R_c respectively lies below the predetermined reference resistance R_R .

The control apparatus 8 is designed to compare after the measurement of the resistances R_a , R_b and R_c the values with the reference resistance R_R .

If all three measured resistances are higher than the reference resistance
5 inappropriate contact relations are given so that in this case the control apparatus 8 can issue a (warning) signal and/or the control apparatus 8 prevents (precautionary) the generation of a stimulation current. In this case the electrodes must be newly applied, e. g. after cleaning of the region of the Cymba conchae which should be electro stimulated.

List of References:

5	1	Device for transcutaneous stimulation
	2	Ear
	3	Retaining element
	4	Electrode
	5	Electrode
10	6	Electrode
	7	Electrode carrier
	8	Control apparatus
	9	Skin surface
	10	Spherical joint
15	11	Linear guide
	12	Linear guide
	13	Linear guide
	E	Plane
20	L	Longitudinal axis
	R_a	Resistance
	R_b	Resistance
	R_c	Resistance
	R_R	Reference resistance

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. Device (1) for applying a transcutaneous electrical stimulation stimulus to the surface of a section of the human ear (2), which comprises a retaining element (3) which is mountable on or in the ear (2) and a number of electrodes (4, 5, 6) which are arranged on or in an electrode carrier (7), wherein the device (1) comprises a control apparatus (8) which controls or regulates the generation of a potential difference between the electrodes (4, 5, 6), wherein at least three electrodes (4, 5, 6) are arranged on or in the electrode carrier (7), wherein the at least three electrodes (4, 5, 6) are located in one plane (E),

characterized in

that the position of at least one of the at least three electrodes (4, 5, 6) is adjustable on the electrode carrier (7), wherein the at least one electrode (4, 5, 6) of which the position is adjustable is mounted such as to be displaceable in a translational manner in the plane (E),

wherein the electrode carrier (7) is arranged movable relatively to the retaining element (3) so that the electrode carrier (7) can swivel relatively to the retaining element (3) in such a manner that all electrodes (4, 5, 6) are in contact with the skin surface (9) in the region of the Cymba conchae when the retaining element (3) is attached to the ear (2),

wherein between the electrode carrier (7) and the retaining element (3) a spherical joint (10) or a hinge joint is arranged or wherein between the electrode carrier (7) and the retaining element (3) a spring element is arranged.

2. Device according to claim 1, characterized in that the plane (E) corresponds at least approximately to the skin surface (9) on which a transcutaneous stimulation stimulus has to be applied.
3. Device according to claim 1 or 2, characterized in that three electrodes (4, 5, 6) are arranged triangular on or in an electrode carrier (7), especially in the form of an equilateral triangle.
4. Device according to one of claims 1 to 3, characterized in that all electrodes (4, 5, 6) are adjustable arranged with respect to their position at the electrode carrier (7).
5. Device according to claim 4, characterized in that the at least one electrode (4, 5, 6) which is adjustable in its position is arranged linear movable in a linear guide (11, 12, 13).
6. Device according to claim 5, characterized in that in adjustability of all electrodes (4, 5, 6) the linear guides (11, 12, 13) are aligned radiating to another.
7. Device according to one of claims 1 to 6, characterized in that the spring element is a connection section made from long-term flexible material.

8. Device according to one of claims 1 to 7, characterized in that the ability to swivel of the electrode carrier (7) relatively to the retaining element (3) is prevented around a longitudinal axis (L) of the retaining element (3).
9. Method for the operation of a device (1) for applying a transcutaneous electrical stimulation stimulus to the surface of a section of the human ear (2), wherein the device (1) comprises a retaining element (3) which is arrangable at or in the ear (2) as well as at least three electrodes (4, 5, 6) which are arranged on or in an electrode carrier (7), wherein the device (1) comprises a control apparatus (8) which controls or regulates the generation of a potential difference between the electrodes (4, 5, 6), wherein the method comprises the steps:
 - a) Measuring of the resistance (R_a , R_b , R_c) between each pair of electrodes (4, 5, 6) when the device (1) is arranged at or in the ear (2) for all possible pairs of electrodes (4, 5, 6) by the control apparatus (8);
 - b) Comparison of the measured resistances (R_a , R_b , R_c) between the pairs of electrodes (4, 5, 6) and selection of the lowest resistance by the control apparatus (8);
 - c) Causing of a predetermined transcutaneous stimulation by the control apparatus (8) via that pair of electrodes (4, 5, 6) which have the lowest resistance (R_a , R_b , R_c) between them.

10. Method according to claim 9, characterized in that the control apparatus (8) compares the measured resistances (R_a , R_b , R_c) with a stored reference resistance (R_R) after carrying out of step a) from claim 9, wherein a signal is issued and/or the stimulation is prevented in the case that all measured resistances (R_a , R_b , R_c) are above the stored reference resistance (R_R).

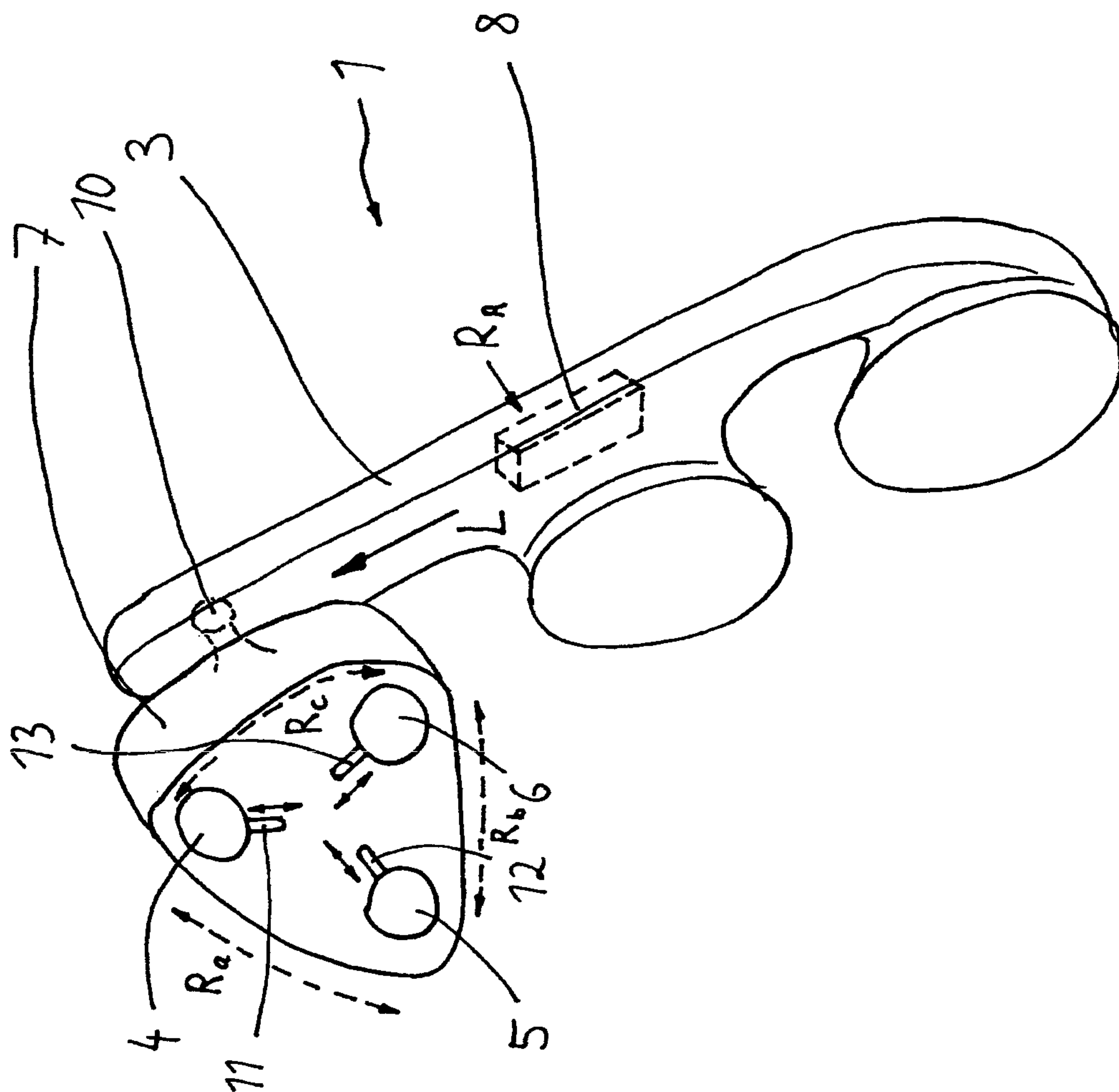
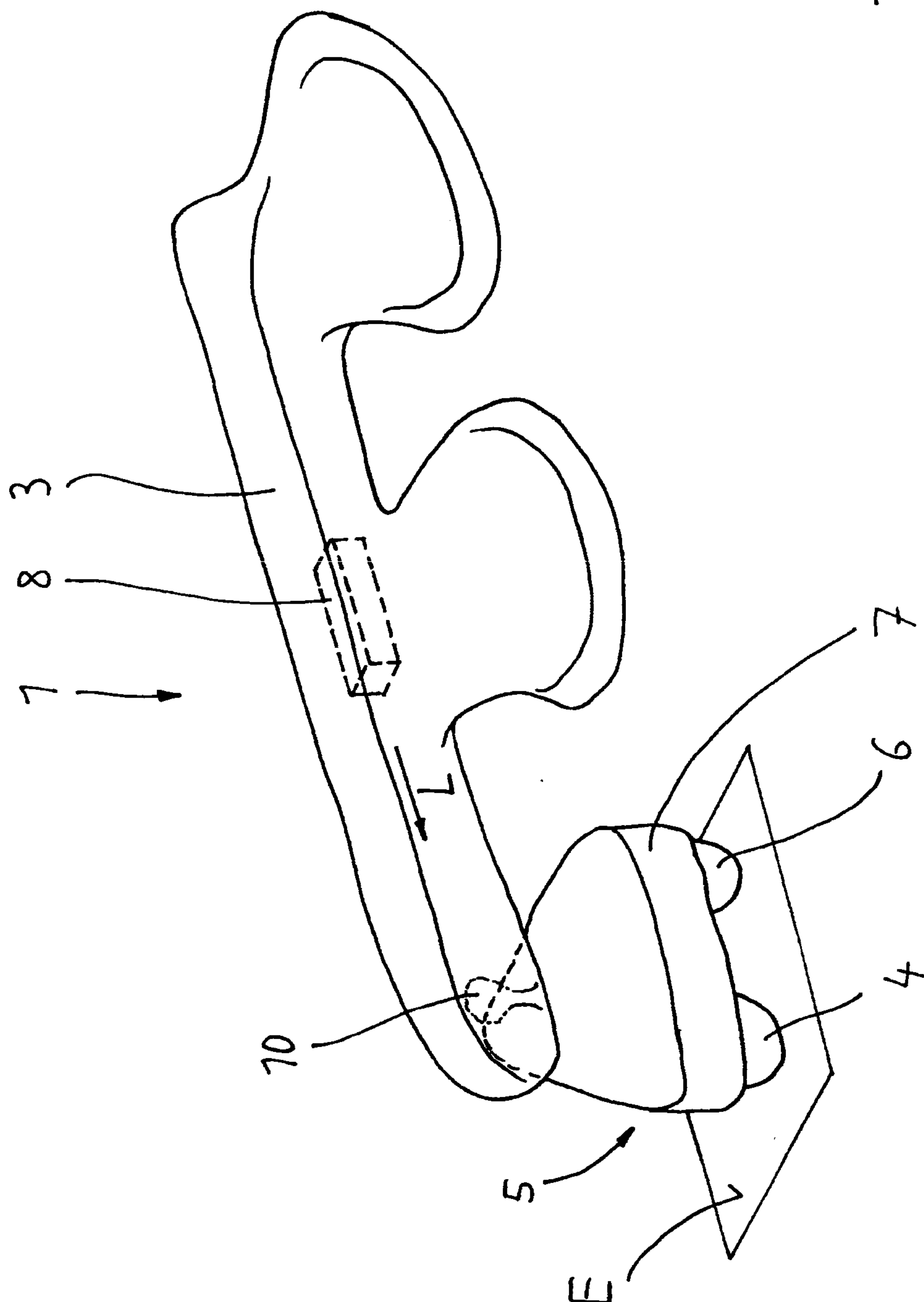


Fig. 7

Fig. 2



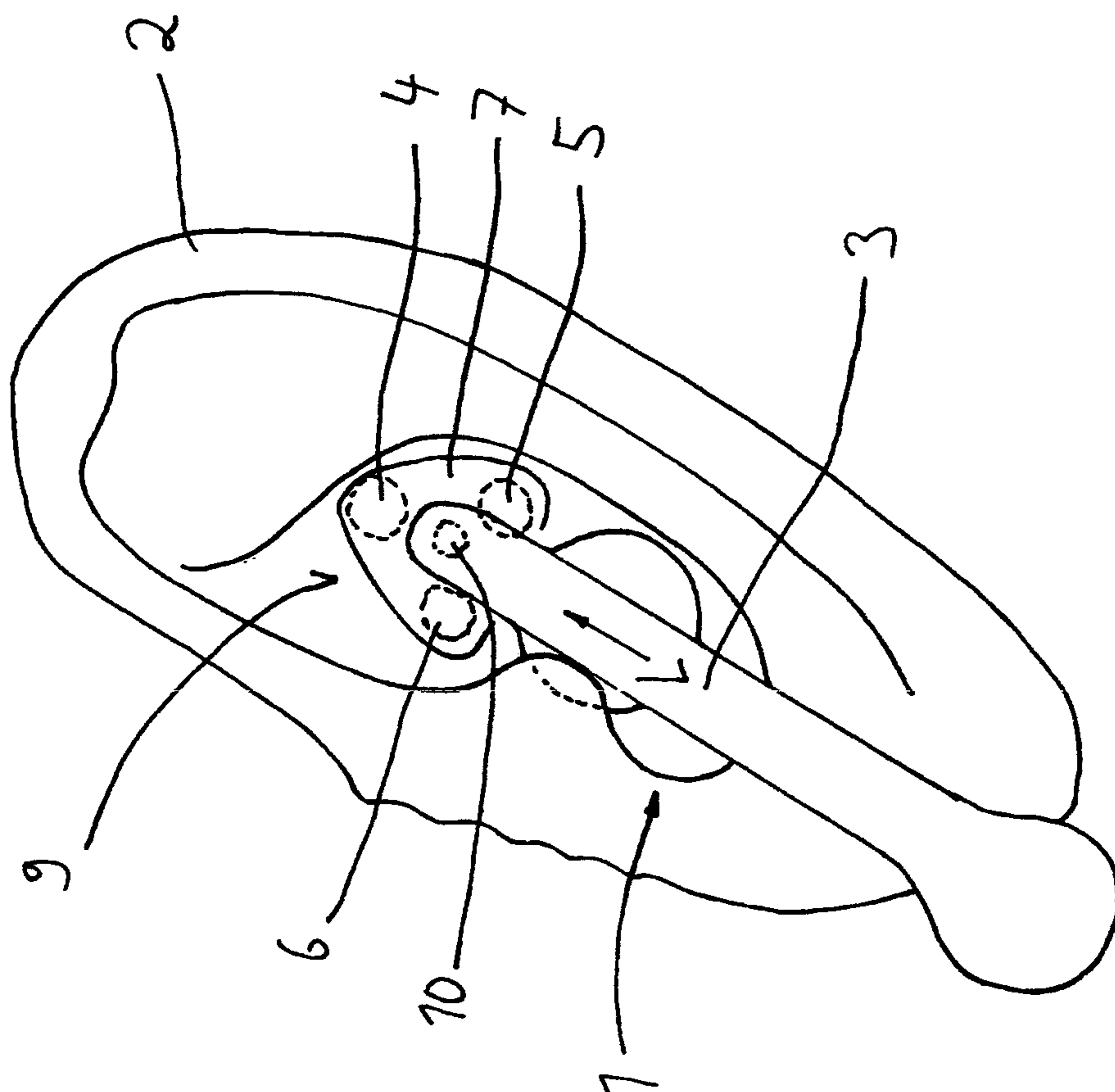


Fig. 3

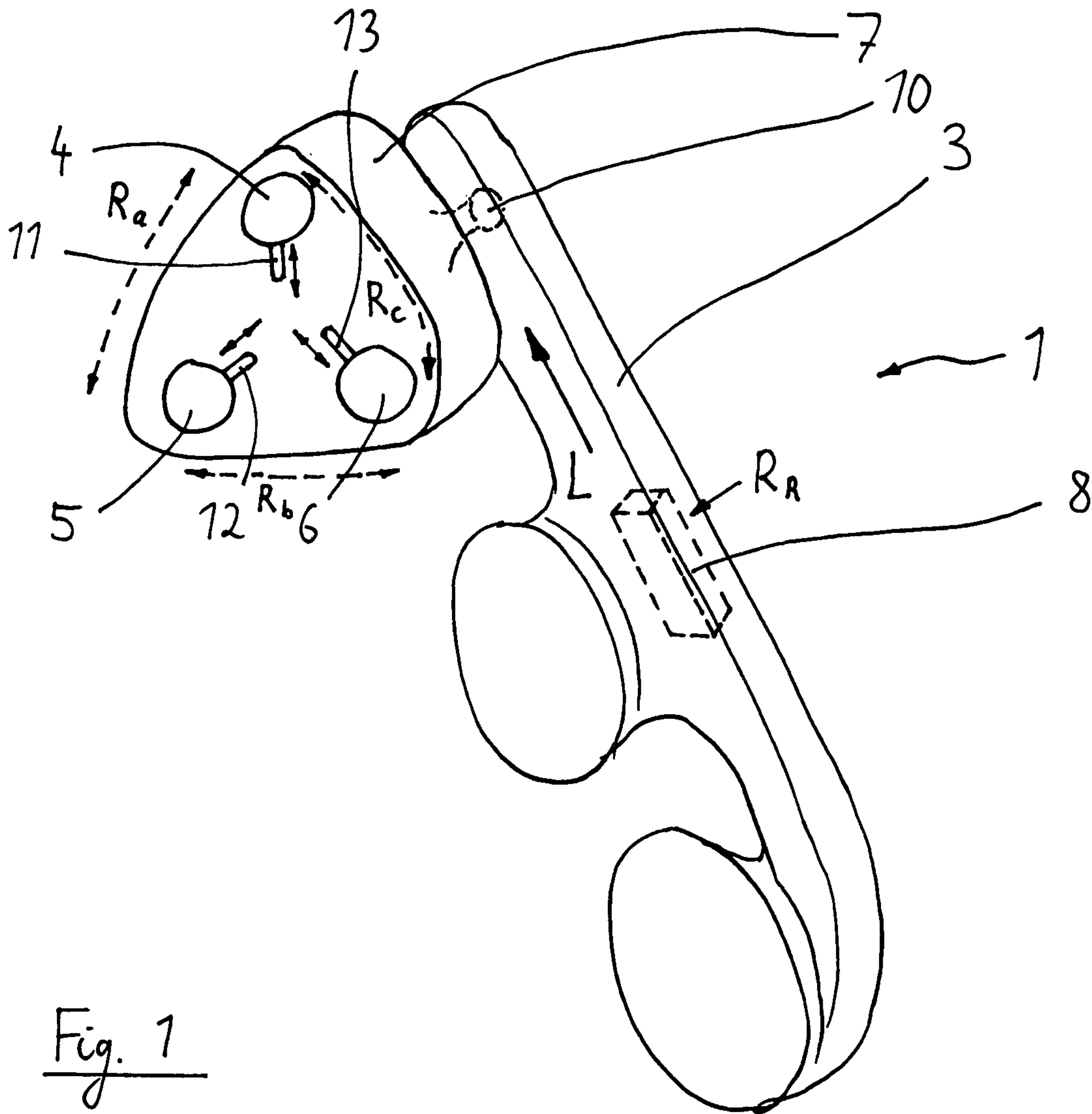


Fig. 1