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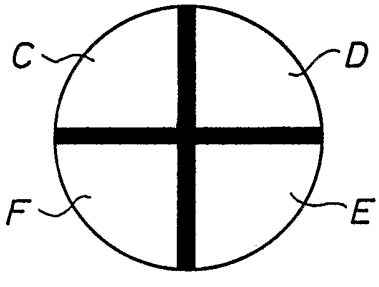
WO 2005/002668 A1

(54) Title: ELECTRODE WITH ALTERNATING POLES



(57) Abstract: An electrode comprising at least two poles, providing electrical contact with a patient's skin. The two poles (A, B) have alternating positive and negative polarity.

TITLE OF THE INVENTION: ELECTRODE WITH ALTERNATING POLES.

Technical Field

The present invention relates to an electrode, comprising at least two poles, for providing contact with a patients skin.

Background of the Invention

It is well known that activation of sensitive receptors may relieve pain. During the 70's and 80's, devices for transcutaneous electrical nerve stimulation (TENS) where developed with respect to this background. These TENS-electrodes includes, in one way or another, an electrode with a positive polarity and an electrode with a negative polarity.

However, the electrical field, which these TENS-electrodes developed, even though the amplitude and frequency are subjects to changes, is not changed by alternating polarity of the poles. When a nerve cell is subjected to a constant stimulation it is inclined to adapt to the stimulation

Thus, a problem in the prior art is adaptation. Adaptation is a process by which sensory receptors become accustomed to a sensation by a decline in the frequency of firing of a neuron, under conditions of constant stimulation. A constant electrical field yields constant stimulation which in turn yields a decline in the firing frequency of a neuron, and this phenomenon results in adaptation.

The Swedish patent application 9201453-9 discloses a device for relieving pain, which device comprises a flexible electrode plate through which a plurality of electrodes extends. Each electrode is terminated, at their respective free ends, by a electrode tip portion for shallow skin penetration. The electrode tip portion of each

electrode is surrounded by stop means, separating the electrode plate from the skin portion. The electrodes cooperate with a collector electrode of opposite electrical polarity to the electrodes. The collector electrode and the other active electrodes are electrically connected to a control unit, which is designed to activate the electrodes consecutively, so that when pressure is applied on the electrodes, the electrode tip portions will penetrate the isolating outer layers of the epidermis to stimulate the receptors of the skin. During a treatment process, according to this application, the polarity of electrodes and the polarity of the collector electrode remain constant.

The Swedish Patent Application No. 9201453-9 is mainly directed towards penetrating the outer layer of skin, thereby requiring lower amplitude of stimulation and thus lower consumption of energy. The plurality of active electrodes has negative polarity and the collector electrode has positive polarity. However, the device is space consuming and includes a lot of different parts, which are more prone to failure. Nowhere in SE 92014539 is mentioned poles with alternating polarity.

WO 91/19531 discloses a bipolar concentric electrode for medical treatment. During a treatment process, according to this application, the electrode configuration remains constant, i.e. the positive pole remains positive and the negative pole remains negative throughout the treatment process. Nowhere in WO 91/19531 is mentioned poles with alternating polarity.

WO 97/02861 discloses an apparatus for treating human pain. The treatment device electrode comprises preferably four electrodes, two of positive polarity and two of negative polarity, and each electrode comprise a magnetic flux generator. During a treatment process, according to this application, the electrode configuration remains

constant, i.e. the positive poles remain positive and the negative poles remain negative throughout the treatment process.

US 4,541,432 discloses an electric nerve stimulation device for suppressing organic pain. The device includes a pulse generator, which produces bipolar rectangular waveforms of a preselected repetition rate and of a preselected width. During a treatment process, according to this patent, the electrode configuration remains constant, i.e. the positive pole remains positive and the negative pole remains negative throughout the treatment process.

Summary of the Invention

It is an object of the present invention to provide an electrode, which circumvents the problem of adaptation.

It is another object of the present invention to provide an electrode system, which is easy to apply to a persons skin.

It is yet another object of the present invention to provide an electrode system, which is easy to use.

It is a further object of the present invention to provide an electrode system, which is easy and inexpensive to manufacture.

To achieve these objects the electrode according to the invention has the characteristic features according to claim 1.

Brief Description of the Drawings

Further objects, features and advantages of the invention will become apparent from the attached description of several embodiments of the invention, taken in conjunction with the appended drawings.

Fig. 1a is a plan view of an electrode, according to the invention, with two poles.

Fig. 1b is a plan of an electrode, according to the invention, with two concentric poles.

Fig. 1c is a plan view of an electrode, according to the invention, with a tetrahedron shape

Fig. 1d is a plan view of several electrodes, according to the invention, with other configurations.

Fig. 2 is a diagram of a rectangular/asymmetric biphasic waveform, with which the stimulation of an electrode, according to the invention, is applied.

Fig. 3 is a diagram of a rectangular/symmetric biphasic waveform, with which the stimulation of an electrode, according to the invention, is applied.

Fig. 4 is a diagram of a monophasic waveform, with which the stimulation of an electrode, according to the invention, is applied.

Fig. 5 is a plan view of an electrode, according to the invention, with four poles.

Fig. 6 is a plan view of an electrode, according to the invention, with four poles arranged linearly.

Fig. 7a is a side view of an electrode, according to the invention, with a control unit in an attached and unattached position, directly on the electrode.

Fig. 7b is a side view of an electrode, according to the invention, with a control unit attached via a cable.

Detailed Description of Embodiments

In a first embodiment of the present invention, the electrode system includes two integrated poles A and B, Fig 1a, where each pole may have alternating polarity. The poles in the electrode of the present invention are separated by an insulating material. This insulating material is intended to prevent a short-circuit between the poles and force the current to pass through the tissue of the patient. The width of this isolation material may vary,

such as between 1 mm to 50 mm. The poles are provided with pulses of electrical current.

A pulse configuration, with which the stimulation is applied, is normally an alternating current (A.C.). The structure of this pulse configuration may vary. Fig. 2 shows a rectangular/asymmetric biphasic waveform, Fig. 3 shows a rectangular/symmetric biphasic waveform and Fig. 4 shows a monophasic waveform, with which the stimulation of the poles of the electrode, according to the invention, is applied. An object of the pulse configuration is to compensate the ion charge from a negative rectangular pulse O with a positive pulse P, as shown in Fig. 2. When the integral of the pulse O is equal to the integral of the pulse P, the pulse O is electrochemically compensated by the pulse P. The width of the pulse O is between 0.05 to 10 ms, such as 0.1 ms to 0.5 ms, such as 0.2 ms to 0.4 ms.

The term "negative pole" refers to a pole, which is negative during the pulse O (Fig. 2, Fig. 3, Fig. 4), and the term "positive pole" refers to a pole, which is positive during a pulse O (Fig. 2, Fig. 3, Fig. 4). The term "a pole with negative polarity" refers to a pole, which is negative during the pulse O (Fig. 2, Fig. 3, Fig.4), and the term "a pole with positive polarity" refers to a pole, which is positive during the pulse O (Fig. 2, Fig. 3, Fig. 4). The terms "electrical field" and "direction of an electrical field" refers to the existing electrical field and the existing direction of an electrical field during the pulse O (Fig. 2, Fig. 3, Fig. 4). This is because the pulse P is for compensation of pulse O, as mentioned above, and normally has no treatment activity. Moreover, pulse P may be omitted in some cases, as indicated in Fig. 4.

The frequency, with which the alternating current is applied, is in the magnitude of 2 Hz to 200 Hz, such as 50 Hz to 150 Hz, such as 100 Hz.

Other kinds of currents exist, such as interference currents, which use frequencies in the magnitude of 4000 Hz, but the net stimulating frequency for these currents are in the magnitude of 10 to 200 Hz.

According to the invention the poles may be provided with electrical fields by stepwise alternating the negative current from one pole to the next pole.

The duration of each step may be modified as required by the treatment, provided that the duration of each step is larger than the inverted frequency of the applied waveform, such as larger than double the inverted frequency of the applied waveform. The duration of each step may for example be 20 ms to 5 minutes, such as 100 ms to 1 minute, such as 1 s to 30 s, such as 2 s to 10 s.

This causes two different areas to be stepwise treated by the electrode system; first the area that is covered by a pole A that, during the first induction, is negative, and then the area that is covered by a pole B that, during the second induction, is negative (the same pole that was positive during the first induction). This procedure may of course be performed with electrode systems which include two poles in another configuration than Fig. 1a, such as concentric, Fig. 1b, and electrode systems with another shape than round, such as tetrahedron, Fig. 1c, or any other amount of corners, such as 5,6,7, or 8, Fig. 1d.

In a second embodiment of the invention, the electrode system includes more than two poles, such as four poles, Fig. 5. When the electrode system according to the present invention includes four poles, the electrical field may move, for example by during the first step letting a pole C, Fig. 5, be of negative polarity and a pole D, Fig. 5, be of positive polarity. During the next step the pole D is of negative polarity and a pole E is of positive polarity. During the third step the pole E is of negative polarity and a pole F is of positive polarity. The fourth

step includes the pole F in negative polarity and the pole C in positive polarity. This procedure continues at the treated persons own discretion.

Since the action potential of the nerves is initiated mainly below the negative pole, the treatment seems to wander over the surface covered by the electrode in a circulating manner, according to the negative current applied to the different poles of the electrode. Such circulation from C, D, E, F and back to C will give a better treatment over the entire surface of the electrode. At the same time, adaptation of the nerve action is counteracted.

It is of less importance where the positive pole is situated. The above scheme may be modified by allowing the same pole to be the positive pole, except when it should be negative. For example, electrode C could be the positive electrode all the time, except the first time period in the sequence, when either of poles D, E, or F could be the positive electrode.

Another example of activation of the poles may be in the order C, E, D, F.

Still another example would be to allow pole C to always be positive and circulate the negative current to poles D, E, and F.

A third embodiment of the invention includes four poles K, L, M, N, which are linearly arranged, according to Fig 6. The electrical field may interchange in different patterns, where a treatment consists of a plurality of such patterns consisting of a plurality of steps, such as from K to M during the first step, L to N during the second step, M to K during the third step, and N to L during the fourth step, or from K to L during the first step, from L to M during the second step, from M to N during the third step, and from N to K during the fourth step. The interchange between the different poles is not limited to these

examples, but may follow any possible pattern. Other embodiments may include more than four poles aligned linearly, or less than four poles aligned linearly, such as 2 or 3.

The movement of the polarity of the poles in the electrode of the present invention is controlled by a control unit H, which may be connected directly to the electrode according to the present invention, Fig. 7a, via a electrode button I. The control unit H is supplied with energy via a battery G. The control unit H may alternatively be in contact with the electrode by a cable J, Fig 7b. It is also possible to supply energy by other means, such by a line driven power supply.

In the second embodiment with four poles, according to Fig. 5, the change between the different poles may follow different patterns. The interchange between the different poles may follow any possible pattern. The interchange may include two poles with positive polarity and two poles with negative polarity, or one pole with positive polarity and two poles with negative polarity, or two poles with positive polarity and one pole with negative polarity, at the same time.

In other embodiments of the invention the number of poles of the electrode system is at least 2, such as between 2 and 20, such as between 2 and 10, such as between 2 and 5, such as 3 or 4 poles, which have alternating positive and negative polarity. Also in these embodiments, the interchange between the different poles may follow any possible pattern, where a treatment consists of a plurality of such patterns consisting of a plurality of steps of different electrical fields. The interchange may include at least one pole with positive polarity and at least one pole with negative polarity, at the same time.

By changing the direction of the electrical field, the sensory receptors of the body do not become accustomed

to the stimulation and the decline in the frequency of firing a neuron, which accompanies adaptation under conditions of constant stimulation, does not occur.

The electrode system according to the invention is a one patch only application, in opposition to for example the electrode system in SE 9201453-9. The electrode system in SE 9201453-9 has cables connecting the positive pole, the negative pole, and the control unit. These cables may catch on to things in the vicinity of the patient, and thus disrupt the required electric circuit. In the electrode system according to the present invention, there is as few cables as possible, which are subjects to disruption of the electric circuit. This is a clear advantage for the patients freedom of movement.

The fact that the electrode system according to the present invention only has one electrode, including poles with alternating polarity, makes the electrode system according to the present invention easy to manufacture.

The electrode system according to the present invention may be attached to the patients skin by a layer of an adhesive, electrically conductive material. When the electrode is formable, the poles with alternating polarity may be incorporated in an adhesive, electrically conductive material to constitute the electrode according to the invention.

The size of the electrode according to the invention may vary. The main aspect to take into consideration is the convenience of the patient. The size of the electrode according to the present invention may range from about 4 cm^2 to 400 cm^2, such as from about 10 cm^2 to 200 cm^2, or else from about 25 cm^2 to 100 cm^2.

CLAIMS

1. An electrode, comprising at least two poles, providing electrical contact with a patient's skin c h a r a c t e r i s e d in that

said at least two poles (A, B) have alternating positive and negative polarity.

2. An electrode according to claim 1, c h a r a c t e r i s e d in that the number of poles is between 2 and 20, such as between 2 and 10, such as between 2 and 5, such as 3 or 4.

3. An electrode according to claim 1, c h a r a c t e r i s e d in that the shape of the electrode is round, circular, edged, or annular.

4. An electrode according to claim 1, c h a r a c t e r i s e d in that the shape of each of the poles is round, circular, edged, or annular.

5. An electrode according to claim 1, c h a r a c t e r i s e d in that the poles are aligned linearly.

6. An electrode according to claim 1, c h a r a c t e r i s e d in that the electrode comprises a layer of an adhesive, electrically conductive material for attachment thereof to a patient's skin.

7. An electrode according to claim 1, c h a r a c t e r i s e d in that the poles are incorporated in an adhesive, electrically conductive material.

8. An electrode according to claim 1, c h a r a c t e r i s e d in that the electrode is controlled by a control unit (H).

9. An electrode according to claim 8, c h a r a c t e r i s e d in that said control unit (H) is applied directly on the electrode.

10. An electrode according to claim 1, c h a r a c t e r i s e d in that the size of the electrode is ranging from about 4 cm^2 to 400 cm^2, or from about 10 cm^2 to 200 cm^2, or from about 25 cm^2 to 100 cm^2.

11. Method for operation of an electrode, comprising at least two poles, providing electrical contact with a patient's skin, c h a r c t e r i s e d by

repeatedly providing an electrical field between a pole and a another pole during consecutive time durations, where the pole with negative polarity shifts after each time duration.

12. Method according to claim 11, wherein the electrode comprises at least two poles c h a r a c t e r i s e d by

providing an electrical field between said poles with a first polarity for a first time duration,

providing an electrical field between said poles with a second polarity for a second time duration,

whereby said second polarity is opposite to said first polarity.

13. Method according to claim 11, wherein the electrode comprises at least three poles c h a r a c t e r i s e d by

applying an electrical field between a first pole and another pole for a third time duration,

applying an electrical field between a second pole and still another pole for a fourth time duration,

whereby said first and second poles are different poles and said another pole is any one of said at least three poles.

14. Method according to claim 11, wherein the electrode comprises at least three poles c h a r a c t e r i s e d by

applying an electrical field between a first pole and another pole for a fifth time duration,

applying an electrical field between a second pole and still another pole for a sixth time duration,

applying an electrical field between a third pole and still another pole for a seventh time duration,

whereby said first, second, and third poles are different poles and said another pole is any one of said at least three poles.

15. Method according to claim 11, wherein the electrode comprises at least four poles c h a r a c t e r i s e d by

applying an electrical field between a first pole and another pole for a eighth time duration,

applying an electrical field between a second pole and still another pole for a ninth time duration,

applying an electrical field between a third pole and still another pole for a tenth time duration,

applying an electrical field between a fourth pole and still another pole for a eleventh time duration,

whereby said first, second, third, and fourth poles are different poles and said another pole is any one of said at least four poles.

16. Method according to claim 11 to 15, c h a r a c t e r i s e d in that said time durations are larger than the inverted frequency of the applied waveform.

17. Method according to claim 11 to 15, c h a r a c t e r i s e d in that said time durations are larger than double the inverted frequency of the applied waveform.

18. Method according to claim 11 to 15, c h a r a c t e r i s e d in that said time durations are within 20 ms to 5 minutes, such as 100 ms to 1 minute, such as 1 s to 30 s, such as 2 s to 10 s.

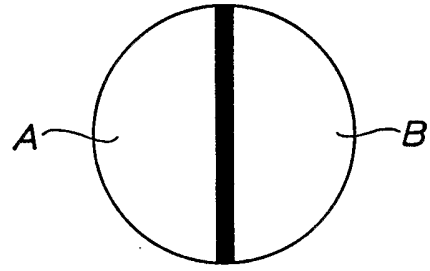


FIG. 1a

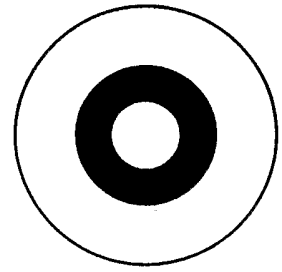


FIG. 1b

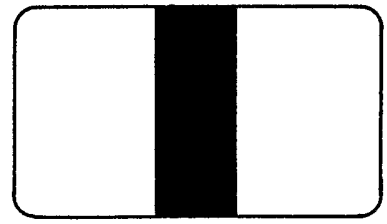


FIG. 1c

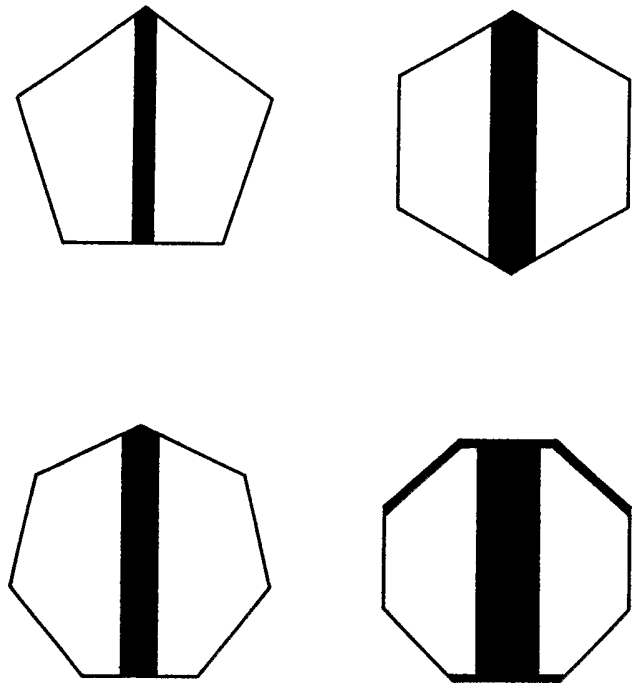


FIG. 1d

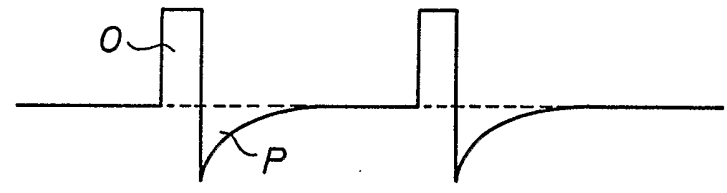


FIG. 2

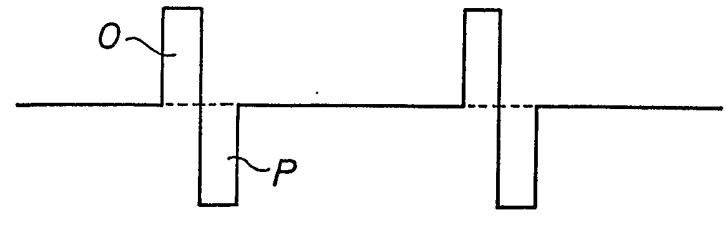


FIG. 3

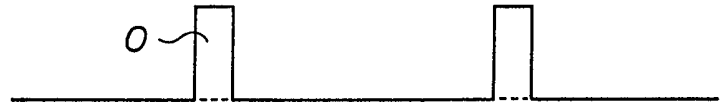


FIG. 4

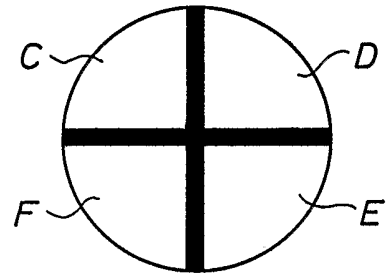


FIG. 5

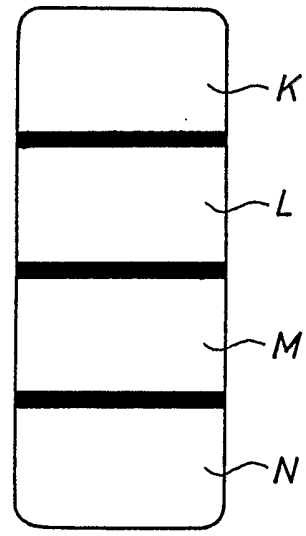


FIG. 6

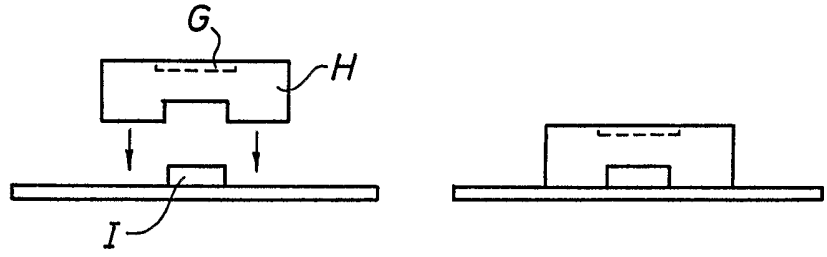


FIG. 7a

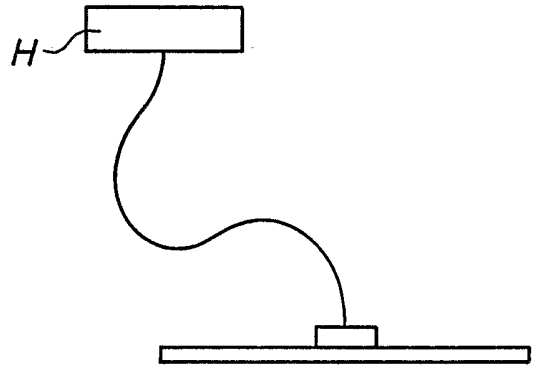


FIG. 7b

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 2004/001090

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61N 1/32, A61N 1/04
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61H, A61N

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

SE,DK,FI,NO classes as above

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 4228341 A1 (BREUNING, FRANZ), 3 March 1994 (03.03.1994), column 2, line 30 - line 49, figures 1-2	1-18
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X	US 4237899 A (NORMAN R. HAGFORS ET AL), 9 December 1980 (09.12.1980), column 3, line 4 - line 12; column 4, line 33 - line 54, figures 1,4, abstract	1-18
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E	EP 1457189 A1 (CHEN, YI-YING), 15 Sept 2004 (15.09.2004), paragraph (0008), (0015)-(0016), (0020); figures 1A, 2A-C; abstract	1-18
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[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)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"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
20 October 2004	01 -11- 2004
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 Anna Malmberg/MP Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 2004/001090

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4541432 A (PEDRO MOLINE-NEGRO ET AL), 17 Sept 1985 (17.09.1985), column 1, line 53 - line 62; column 2, line 12 - line 22; column 6, line 5 - line 32, figures 2A,4, abstract ---	1-18
A	US 4907601 A (KUNO FRICK), 13 March 1990 (13.03.1990), column 2, line 9 - line 57, abstract ---	1-18
A	WO 9702861 A1 (HOLCOMB, ROBERT. R.), 30 January 1997 (30.01.1997), page 3, line 22 - page 4, line 6; page 5, line 6 - page 7, line 1, figure 1, abstract --- --------	1-18

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 2004/001090

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 1-18
because they relate to subject matter not required to be searched by this Authority, namely:

See extra sheet

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

Claims 11-18 relate to a method of treatment of the human body by surgery or by therapy/ a diagnostic method practised on the human or animal body/Rule 39.1(iv). Nevertheless a search has been executed for this (these) claim(s). The search has been based on the alleged effects of the compound(s)/product/device.

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