THIS SHEET HAS BEEN REPLACED

A DEVICE FOR APPLICATION OF ENDERMIC ELECTROTHERAPEUTIC TREATMENTS TO A HUMAN BODY

The present invention relates to a device for application of electrotherapeutic treatments, in particular for treating pathologies such as cellulitis.

For curing a patient of these pathologies, several different treatments are now employed, which differ from each other based on the utilized operation principles.

One of these treatments is represented by electrolipolysis. It consists in creating a localized electric field, generally by driving needle-shaped electrodes into the skin. Passage of electric current through the cellulitis mass causes a local increase in the production of substances capable of promoting removal of fats from the inside of the cells.

Another treatment consists of iontophoresis utilizing the migration principle of ions from within an electric field of weak-intensity current to cause penetration of drugs and active ingredients until the deepest layers of the skin through capillaries, sweat glands and hair follicles. The electric field is applied locally by plate electrodes, wrapped into a spongy cloth saturated with an aqueous solution of the selected drug. Iontophoresis is generally employed as an alternative solution to mesotherapy which, on the contrary, consists in executing multiple microinjections of specific medicaments into the cellulitis mass. Often associated with iontophoresis is a

This Sheet Has Been Replaced

THIS SHEET HAS BEEN REPLACED

treatment phase providing application, by means of said electrodes, of the so-called Koltz waves, which deeply penetrate into the muscles causing the spontaneous contraction of same and therefore performing a sort of passive exercise.

Another typology of treatments against cellulitis is represented by ultrasonic hydrolipoclasis taking advantage of particular needle-shaped probes applied to the skin surface to utilize the lipolitic effect of ultrasonic waves.

It is apparent that during some of the above treatments (electrolipolysis, mesotherapy, ultrasonic idrolipoclasis) microtraumas may occur due to penetration of needles into the skin, in particular in the case of sensitive skin with fragile and superficial capillaries.

In addition, in the known art, electrotherapeutic treatments must be carried out by medical staff, at qualified centres.

Since many sessions spaced in time are necessary in order to achieve good results, this brings about the inconvenience that the patient must each time go to the session place to be submitted to treatment, which results in a temporary interruption of his/her working activity.

On the other hand, application of these treatments on one's own is of difficult accomplishment, due to the understandable difficulties encountered by the patient in preparing and positioning the electric-field generating circuit, in particular in the case in which the electrodes

This Sheet Has Been Replaced



consist of needles.

It is also to note that these sessions are generally expensive, so that the long-lasting therapy involves a very high total cost for the patient.

It is a general object of the present invention to obviate the above mentioned drawbacks by providing a device enabling a patient to be submitted to the application of endermic electrotherapeutic treatments without the intervention of medical staff and without any necessity to address to qualified centres.

It is a further object of the invention to provide a device enabling elimination of microtraumas and capillary breakings due to the needle penetration into the skin.

In view of the above objects, in accordance with the present invention, a device for carrying out endermic electrotherapeutic treatments has been devised which comprises a pulse-current generator and a garment to be worn by a patient, in which the garment is comprised of a plurality of electrically conductive discrete portions for contact with the patient's skin and connected to insulating portions intermediate between said conductive portions, the conductive portions being provided with respective terminals connected to the current generator by conductors.

It is apparent that a device in accordance with the invention, since it can be personally worn by the patient, enables treatments to be constant in time, offering improved results as compared with a series of individual

This Sheet Has Been Replaced.

application sessions, at a lower total cost. In addition, since cellulitis is a pathology that is likely to recur easily in time, the device of the invention can be reutilized on the occasion of subsequent therapeutic application cycles which the patient will be eager to execute, since all inconveniences and commitments connected with a treatment in a specialized centre are eliminated.

It is to note that the electrically conductive elements to be utilized for the conductive portion of the sheath garment being the object of the invention can be variously selected from those known per se. For example, fabrics in which the fibre is twisted with at least one conductive wire are known and they are used to make garments such as wollen underwear, shirts, etc. in order to attenuate potential differences taking place between the different parts of the human body, thereby creating a substantial equipotentiality.

Such an electrically conductive fabric can be used to form discrete portions of the garment being part of the device in accordance with the invention, that is to accomplish descrete electric-current application areas, intentionally creating between said areas potential differences to be utilized for therapeutic purposes.

In order to better explain the innovatory principles of the present invention and the advantages it offers over the known art, a possible embodiment applying said principles will be described hereinafter, by way of

example, with the aid of the accompanying drawings, in which:

- Fig. 1 is an elevation front view of the device in accordance with the invention;
- Fig. 2 is an elevation side view of the device in Fig. 1 seen from the right;
- Fig. 3 is a sectional view taken along line III-III in Fig. 2;
- Fig. 4 is a graph showing an example of a waveform of the electric current that can be utilized by the device of the invention.

A device 10 for executing endermic electrotherapeutic treatments is shown in Figs. 1 and 2. It comprises an element briefly identified as a garment 11, adapted to be worn by a patient, and a current generator 12. In this embodiment, the garment 11 is shown in a form adapted to cover the patient's abdomen, glutei and thighs by elastically wrapping them, for direct treatments to these parts of the human body.

According to the innovatory principles of the present invention, the garment or sheath 11 consists of a plurality of discrete portions having electrically conductive and insulating features, respectively. With reference to the preferred embodiment of the device shown in the drawings, electrically conductive portions are denoted by 13, 14 and 15 and are disposed at the patient's waist (sheath belt) and thighs (sheath leggings) respectively, whereas insulating sheath portions are

generally denoted by 16, and they separate the individual conductive portions from each other. In the example herein described three conductive poles or electrodes 13, 14 and 15 are shown. For particular requirements however, the sheath can be formed with a different number of conductive portions, disposed according to different configurations. At the conductive portions there are electrical contact means or strips 17, 18, 19 provided with a sticky surface for steady application or sewn. The electrodes are connected to generator 12 by respective clips and conductor wires 20, 21, 22.

The insulating portions 16 can be made of a common non-conductive fabric, such as cotton. The conductive portions 13, 14, 15 on the contrary, are made to advantage of a cotton yarn consisting of textile fibres and metal wire. A yarn that has offered excellent results is that known under the trade name "Kind Star" (Registered Trademark).

The contact means 17, 18, 19 can extend along the conductive fabric (as shown in broken lines in Fig. 1) so as to ensure a good electric contact with the conductive fabric forming the electrodes. It is therefore ensured also a good equipotentiality of the surface of each electrode, thus avoiding electrical breaks due to seams, breakings or ladders of the conductive fabric.

The use of a conductive fabric is surely advantageous, also due to its structural likeness with the non-conductive fabric to which it is connected for

obtaining the whole garment, so that the garment manufacture using machines of known type is facilitated. However, a material having behavioural features similar to those of a fabric, even with a different structure can be also used.

A garment having the disclosed structure allows a good wearableness and does not hinder the normal sweating, and thus can be used for a long time.

A non-woven fabric or a like film having features of electrical conductivity can be utilised for the purpose, which fabric must be in any case connected to the adjacent non-conductive portions of the garment following the most appropriate technologies based on the constituent material, and therefore by sewing, gluing, welding and the like.

Obviously the conductive material, typically a metal material in any case incorporated in the garment wall, is required to have high features in terms of being inoxidizable and resisting acid corrosion, also taking into account the electrolytic effect of the carried currents and the environment where treatment is executed.

The conductive and insulating portions of the sheath can be externally covered with an insulating coating layer 23, for example consisting of a fabric of the type known under the trade name "Lycra" (Registered Trademark), to give the garment the required consistency and elasticity. The coating layer 23, only partly represented in Figs. 1 and 2, can be clearly seen in Fig. 3 where, for the sake of

clarity, it has been shown without the section-indicating chain line. This coating layer promotes adhesion of the conductive fabric to the human body.

Generator 12 can be of reduced bulkiness (taking into account the weak currents involved), preferably of a portable type powered by an internal battery 25 or an AC/DC adapter. It can be of a known type in terms of circuits and adapted to generate electric currents characterized by waves known as "H waves", to create appropriate electric fields between the conductive portions of the sheath. Shown in Fig. 4 is a graph voltage-time of a current wave to be utilized with the device of the invention.

As can be viewed, the wave is formed of trains of alternating pulses having voltage output adjustable between ±20 ÷ ±80 volts, for example ±40 volts. The current output can be restricted at approximately 40 milliseconds.

With reference to the figure, experimental tests gave optimal characteristic values for time t1, t2, t3 corresponding to:

t1 = 1 millisecond;

t2 = 0.7-1 milliseconds;

t3 = 1000 milliseconds.

The initial edge of the pulses trains are spaced of t3 time. Each train consists of four positive/negative pulses. In that case, each train will last 15 milliseconds (with t2 = 1 millisecond).

A current with such a configuration has shown its capability of activating the blood and lymphatic microcirculations in a very satisfactory manner at the areas concerned with cellulitis pathologies, and of increasing the metabolic activity of the cells, resulting in a therapeutic action on cellulitis.

Generator 12 comprises a device 24 (e.g. a switch) for selection of the connections of the generator outputs to the three electrically conductive poles 13, 14, 15. In this way, different circuit configurations can be obtained and consequently different operating modes of the sheath. For example, the generator can be connected between the two electrically conductive poles of the sheath leggings (connected in parallel to each other) and the waist pole. As an alternative solution, the generator can be connected between the leggings poles, and the waist pole can be disconnected.

At this point it is apparent that the innovatory device of the invention enables achievement of the intended purposes.

Obviously, the above description of an embodiment applying the innovatory principles of the present invention is given for purposes of illustration only and is not to be interpreted as a limitation of the scope of the patent rights herein claimed.

For example, the sheath shape can be different than that herein shown and can vary depending on the body area concerned with treatment. In particular, it may comprise

other portions adapted to completely cover the patient's legs, thus taking the form of tights.

In addition, it is to note that the sheath in accordance with the invention, by generating appropriate electric fields between predetermined descrete portions of the sheath, enables application of treatments typical of electrolipolysis for stimulating the blood circulation and the production of given body substances, without excluding the possibility of using it for iontophoresis treatments for introduction of drugs and active ingredients through the skin.

Also solved are the problems of the prior art connected with the difficulty in conveniently positioning the electrodes by unskilled persons.

An essential advantage of the invention is represented by the fact that the patient, by merely wearing the garment, is automatically able to position the electrode conductive areas in a correct manner. For the above reason, every possibility of a wrong positioning is excluded and the patient is not required to have any ability and specific preparation, which qualities are on the contrary needed for positioning of free electrodes onto the human body, as provided by the known art.

The generator can be hung to the belt so as to allow an optimal freedom of movement.

THIS SHEET HAS BEEN REPLACED

* C L M S *

CLAIMS

1. A device for carrying out endermic therapeutic treatments, comprising a pulse-current generator (12) and a garment (11) adapted to be worn by a patient, in which the garment (11) comprises a plurality of electrically conductive discrete portions (13, 14, 15) for contact with the patient's skin and connected to insulating portions (16) intermediate between said conductive portions, the conductive portions (13, 14, 15) being provided with respective terminals (17, 18, 19) connected to the generator (12) by conductors (20, 21, 22).

2. A device according to claim 1, characterized in that the electrically conductive portions (13, 14, 15) are made of a cotton yarn fabric consisting of textile fibres and metal wire.

3. A device according to claim 1, characterized in that the discrete electrically conductive portions consist of a first conductive portion (13), or sheath belt disposed at the patient's waist, and second (14) and third (15) conductive portions or sheath leggings, disposed at the patient's thighs.

4. A device according to claim 1, characterized in that the conductive portions (13, 14, 15) and insulating portions (16) are externally covered with an insulating coating layer (23) giving the garment (11) the required mechanical features, in particular elasticity.

5. A device according to claim 1, characterized in that

This Sheet Has Been Replaced

the current generator (12) is adapted to generate electric currents with H waves, to create electric fields between the conductive portions (13, 14, 15) of the sheath.

6. A device according to claim 5, characterized in that the H wave is formed of trains of alternating pulses separated by 15 milliseconds and having maximum voltage values of ±80 volts and a duration of 1 millisecond each pulse, each train having four positive/negative pulses.

7. A device according to claim 3, characterized in that the current generator (12) comprises a device for selection of the outputs to the electrically conductive poles (13, 14, 15) so as to connect alternately the generator between the leggings or between the leggings and the belt.

This Sheet Has Been Replaced

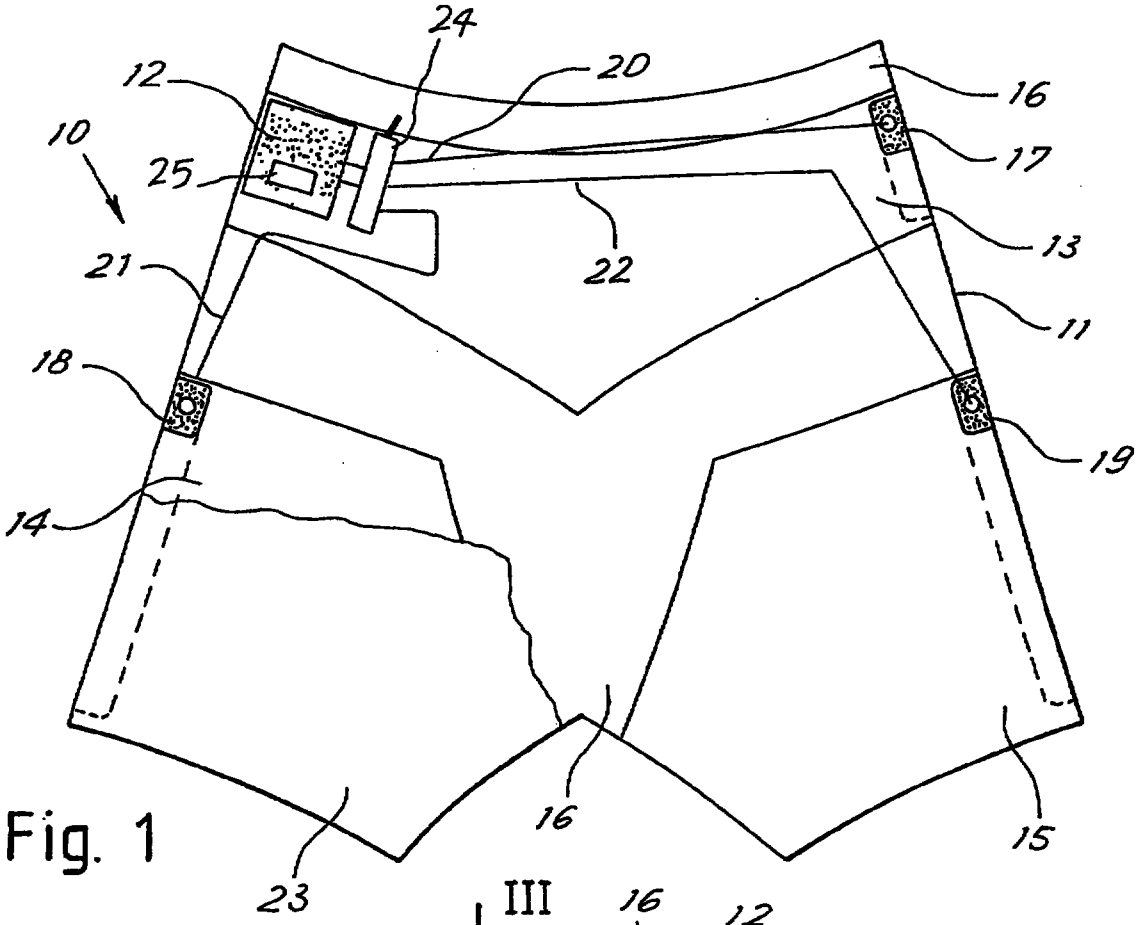

24
12
20
16
10
25
17
22
13
21
11
18
19
14
16
15
23

Fig. 1

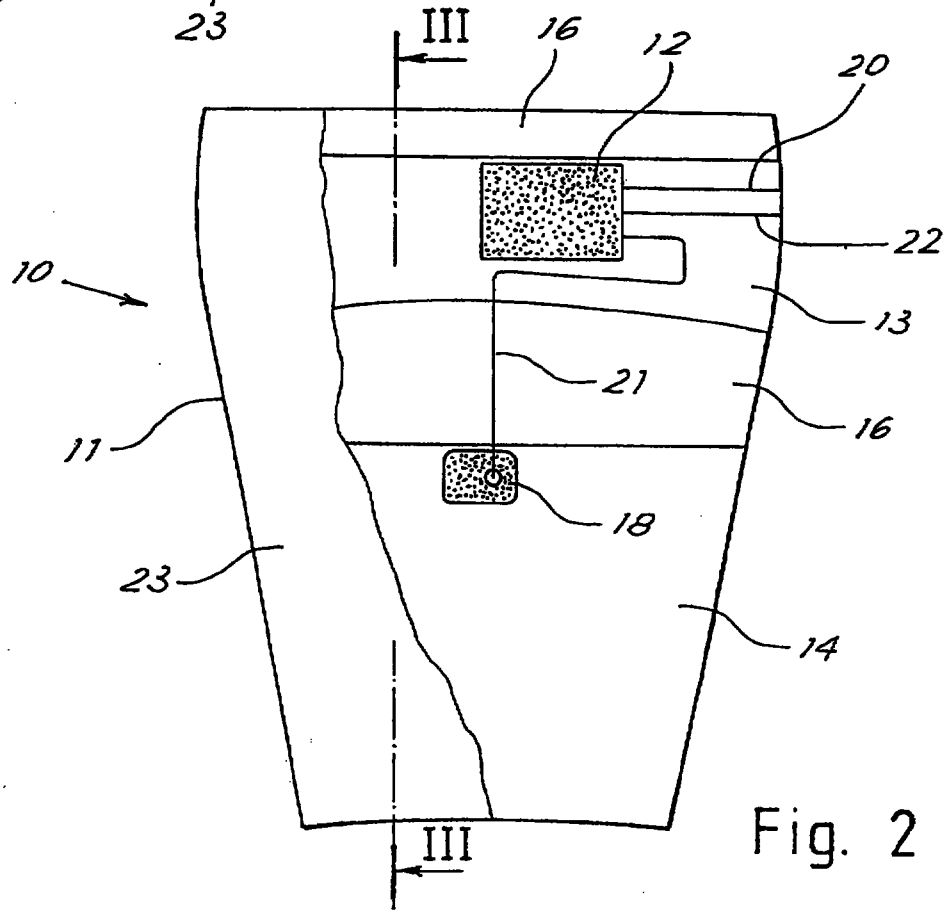

III
16
12
20
22
10
13
21
16
11
18
23
14
III

Fig. 2

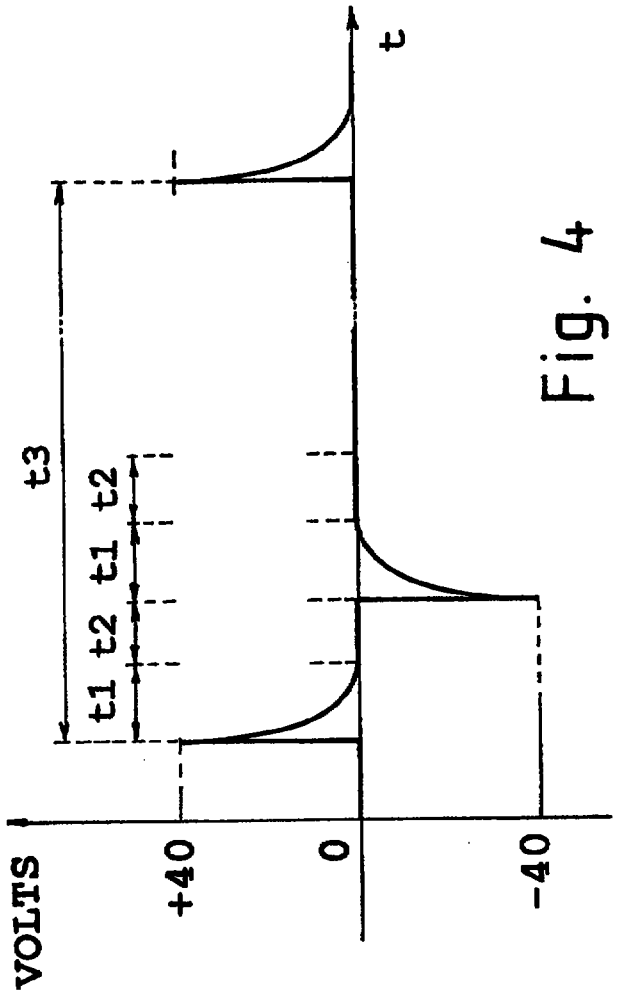


Fig. 4

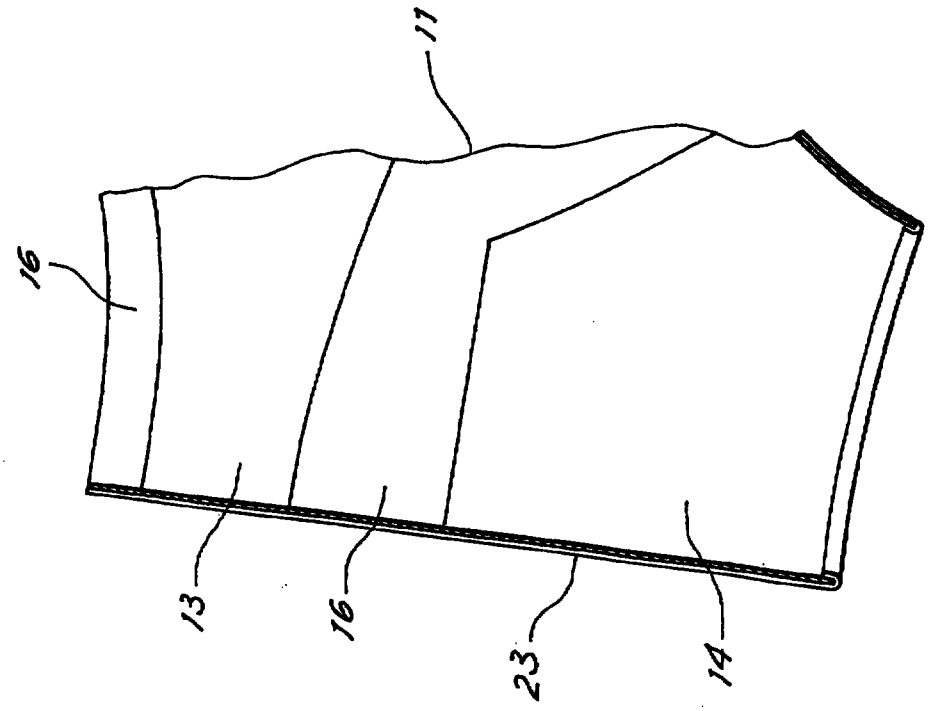


Fig. 3

<FR-A-2 502 015 discloses a iontophoresis treatment.>

A DEVICE FOR APPLICATION OF ENDERMIC ELECTROTHERAPEUTIC TREATMENTS TO A HUMAN BODY

The present invention relates to a device for application of electrotherapeutic treatments, in particular for treating pathologies such as cellulitis.

For curing a patient of these pathologies, several different treatments are now employed, which differ from each other based on the utilized operation principles.

One of these treatments is represented by electrolipolysis. It consists in creating a localized electric field, generally by driving needle-shaped electrodes into the skin. Passage of electric current through the cellulitis mass causes a local increase in the production of substances capable of promoting removal of fats from the inside of the cells.

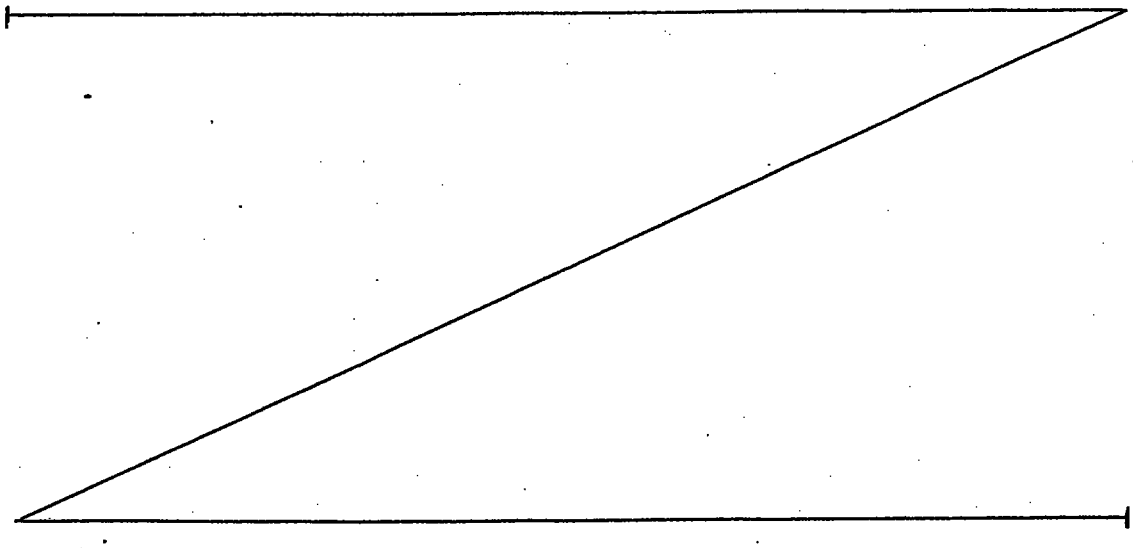
Another treatment consists of iontophoresis utilizing the migration principle of ions from within an electric field of weak-intensity current to cause penetration of drugs and active ingredients until the deepest layers of the skin through capillaries, sweat glands and hair follicles. The electric field is applied locally by plate electrodes, wrapped into a spongy cloth saturated with an aqueous solution of the selected drug. (<->) Iontophoresis is generally employed as an alternative solution to mesotherapy which, on the contrary, consists in executing multiple microinjections of specific medicaments into the cellulitis mass. Often associated with iontophoresis is a

treatment phase providing application, by means of said electrodes, of the so-called Koltz waves, which deeply penetrate into the muscles causing the spontaneous contraction of same and therefore performing a sort of passive exercise.

A device for carrying out these treatments can be of the kind disclosed in EP-A-0 128 103, wherein a plurality of small, well-localized electrodes are placed on the surface of a non-conductive garment, thus applying the current on the body in substantially punctiform areas.

Another typology of treatments against cellulitis is represented by ultrasonic hydrolipoclasis taking advantage of particular needle-shaped probes applied to the skin surface to utilize the lipolitic effect of ultrasonic waves.

Further treatments against cellulitis are known from FR-A-1 541 165. They use magnetic fields generated by the static electricity of the human body, circulating along electric circuits provided in a garment.



~~treatment phase providing application, by means of said~~ electrodes, of the so-called Koltz waves, which deeply penetrate into the muscles causing the spontaneous contraction of same and therefore performing a sort of passive exercise.

Another typology of treatments against cellulitis is represented by ultrasonic hydrolipoclasis taking advantage of particular needle-shaped probes applied to the skin surface to utilize the lipolitic effect of ultrasonic ~~waves.~~

It is apparent that during some of the above treatments (electrolipolysis, mesotherapy, ultrasonic idrolipoclasis) microtraumas may occur due to penetration of needles into the skin, in particular in the case of sensitive skin with fragile and superficial capillaries.

In addition, in the known art, electrotherapeutic treatments must be carried out by medical staff, at qualified centres.

Since many sessions spaced in time are necessary in order to achieve good results, this brings about the inconvenience that the patient must each time go to the session place to be submitted to treatment, which results in a temporary interruption of his/her working activity.

On the other hand, application of these treatments on one's own is of difficult accomplishment, due to the understandable difficulties encountered by the patient in preparing and positioning the electric-field generating circuit, in particular in the case in which the electrodes

consist of needles.

It is also to note that these sessions are generally expensive, so that the long-lasting therapy involves a very high total cost for the patient.

It is a general object of the present invention to obviate the above mentioned drawbacks by providing a device enabling a patient to be submitted to the application of endermic electrotherapeutic treatments without the intervention of medical staff and without any necessity to address to qualified centres.

It is a further object of the invention to provide a device enabling elimination of microtraumas and capillary breakings due to the needle penetration into the skin.

In view of the above objects, ~~/in accordance with the present invention/~~ a device for carrying out endermic electrotherapeutic treatments (according to claim 1) has been devised. ~~/which~~ comprises a pulse-current generator and a garment to be worn by a patient, in which the garment is comprised of a plurality of electrically conductive discrete portions for contact with the patient's skin and connected to insulating portions intermediate between said conductive portions, the conductive portions being provided with respective terminals connected to the current generator by ~~conductors.~~

It is apparent that a device in accordance with the invention, since it can be personally worn by the patient, enables treatments to be constant in time, offering improved results as compared with a series of individual

<so as to distribute the current onto the skin.>

This Sheet Has Been Replaced

CLAIMS

THIS SHEET HAS BEEN REPLACED

1. A device for carrying out endermic therapeutic treatments, comprising a pulse-current generator (12) and a garment (of fabric) (11) adapted to be worn by a patient, in which the garment (11) comprises a plurality of electrically conductive discrete ~~portions~~ areas (13, 14, 15) for contact with the patient's skin and connected to insulating ~~portions~~ areas (16) intermediate between said conductive ~~portions~~ areas, the conductive ~~portions~~ areas (13, 14, 15) being (made of wide portions of fabric) provided with respective terminals (17, 18, 19) connected to the generator (12) by conductors (20, 21, 22), <—>

2. A device according to claim 1, characterized in that the electrically conductive ~~portions~~ areas (13, 14, 15) are made of a cotton yarn fabric consisting of textile fibres and metal wire.

3. A device according to claim 1, characterized in that the discrete electrically conductive ~~portions~~ areas consist of a first conductive ~~portion~~ area (13), or sheath belt disposed at the patient's waist, and second (14) and third (15) conductive ~~portions~~ areas or sheath leggings, disposed at the patient's thighs.

4. A device according to claim 1, characterized in that the conductive ~~portions~~ areas (13, 14, 15) and insulating ~~portions~~ areas (16) are externally covered with an insulating coating layer (23) giving the garment (11) the required mechanical features, in particular elasticity.

5. A device according to claim 1, characterized in that

* C L M S *

AMENDED SHEET

the current generator (12) is adapted to generate electric currents with H waves, to create electric fields between the conductive ~~portions~~ areas (13, 14, 15) of the sheath.

6. A device according to claim 5, characterized in that the H wave is formed of trains of alternating pulses separated by 15 milliseconds and having maximum voltage values of ±80 volts and a duration of 1 millisecond each pulse, each train having four positive/negative pulses.

7. A device according to claim 3, characterized in that the current generator (12) comprises a device for selection of the outputs to the electrically conductive poles (13, 14, 15) so as to connect alternately the generator between the leggings or between the leggings and the belt.

980461-3
IPOS COPY.

* C L M S *

REPLACEMENT SHEET
08 JUL 1999

CLAIMS

1. A device for carrying out endermic therapeutic treatments, comprising a pulse-current generator (12) and a garment of fabric (11) adapted to be worn by a patient, in which the garment (11) comprises a plurality of electrically conductive discrete portions (13, 14, 15) for contact with the patient's skin and connected to insulating portions (16) intermediate between said conductive portions, the conductive portions (13, 14, 15) being made of wide portions of fabric provided with respective terminals (17, 18, 19) connected to the generator (12) by conductors (20, 21, 22), so as to distribute the current onto the skin.

2. A device according to claim 1, characterized in that the electrically conductive portions (13, 14, 15) are made of a cotton yarn fabric consisting of textile fibres and metal wire.

3. A device according to claim 1, characterized in that the electrically conductive discrete portions consist of a first conductive discrete portion (13), or sheath belt disposed at the patient's waist, and second (14) and third (15) conductive discrete portions or sheath leggings, disposed at the patient's thighs.

4. A device according to claim 1, characterized in that the conductive portions (13, 14, 15) and insulating portions (16) are externally covered with an insulating coating layer (23) giving the garment (11) the required 25 mechanical features, in particular elasticity.

5. A device according to claim 1, characterized in that

9804461-3
IPOE COPY

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61N 1/32 — A1

(11) International Publication Number: WO 97/28843

(43) International Publication Date: 14 August 1997 (14.08.97)

(21) International Application Number: PCT/EP97/00527

(22) International Filing Date: 4 February 1997 (04.02.97)

(30) Priority Data:
MI96A000217 7 February 1996 (07.02.96) IT

(71) Applicant *(for all designated States except US)*: INNUENDO S.R.L. [IT/IT]; Via Aurelio Saffi, 15, I-20123 Milano (IT).

(72) Inventor; and

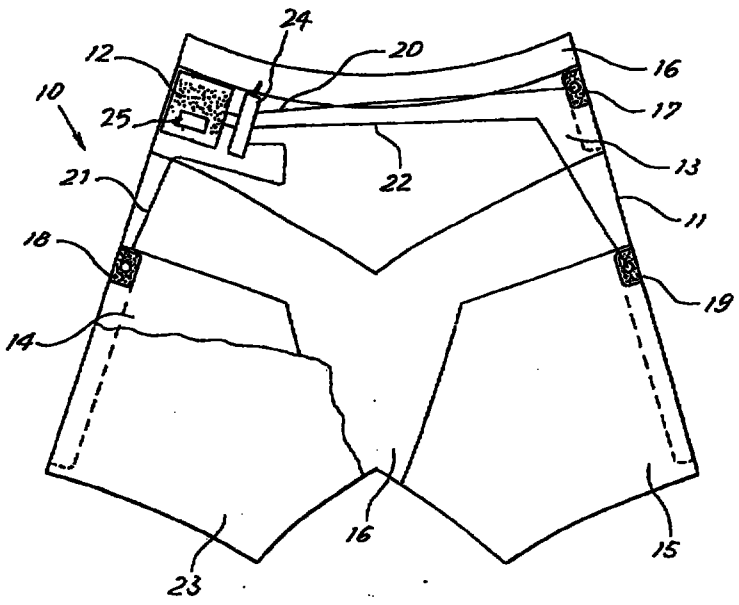
(75) Inventor/Applicant *(for US only)*: MAIDA, Massimo Maurizio [IT/IT]; Via Tornaboni, 2, I-54037 Marina di Massa (IT).

(74) Agent: FARAGGIANA, Vittorio; Ing. Guzzi e Ravizza S.r.l., Via V. Monti, 8, I-20123 Milano (IT).

(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published
With international search report.

(54) Title: A DEVICE FOR APPLICATION OF ENDERMIC ELECTROTHERAPEUTIC TREATMENTS TO A HUMAN BODY



(57) Abstract

A device for carrying out endermic electrotherapeutic treatments comprises a pulse-current generator (12) and a garment (11) adapted to be worn by a patient. The garment (11) is comprised of a plurality of electrically conductive discrete portions (13, 14, 15) for contact with the patient's skin, connected with insulating portions (16) intermediate between said conductive portions. The conductive portions (13, 14, 15) are provided with respective terminals (17, 18, 19) connected to the generator (12) by conductors (20, 21, 22).