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(71) Applicant *(for all designated States except US)*: **SELICOR, INC.** [US/US]; Second Floor, 7000 Mopac Expressway, F12, Austin, TX 78731 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **BEENS, Jason, A.** [US/US]; 7615 Creek Trail, San Antonio, TX 78254 (US). **HINSON, Scott, R.** [US/US]; 4112 Avenue H, Austin, Texas 78751 (US). **NESTHUS, Daniel, E.** [US/US]; 7146 Gallery Ridge, San Antonio, TX 78250 (US).

(74) Agent: **BAHLER, David, D.**; Fulbright & Jaworski L.L.P., Suite 2400, 600 Congress Avenue, Austin, TX 78701 (US).

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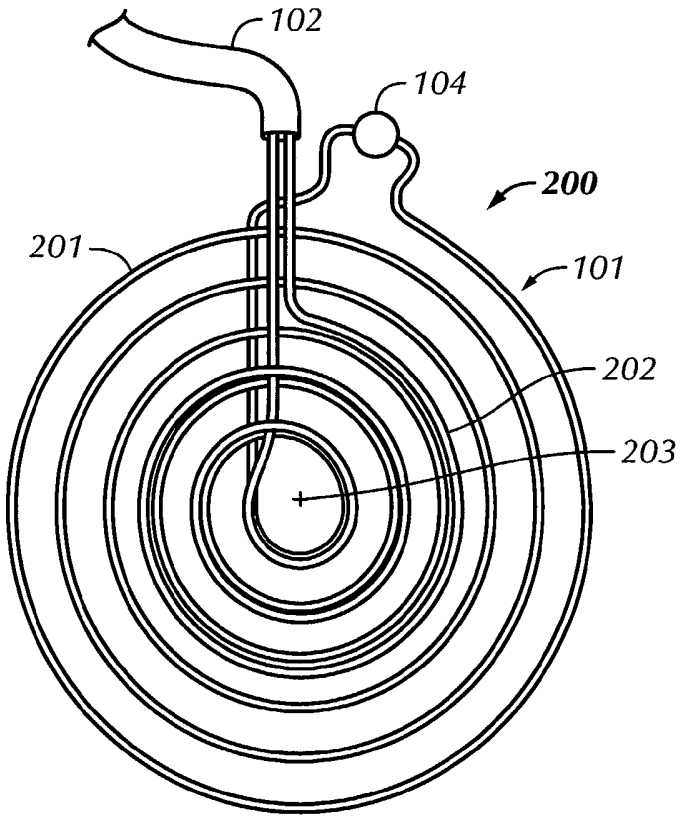
(54) Title: RADIO FREQUENCY DIATHERMY APPLICATION SYSTEM AND DEVICE



(57) Abstract: A radio frequency diathermy application device, including a flexible pad and a flexible coil structure coupled to and supported by the pad. The flexible coil structure has a flexible spiral-like primary winding and a flexible spiral-like secondary winding coupled to the primary winding, the primary and secondary windings each substantially lying in separate substantially parallel planes when the pad is in an unflexed state.

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DESCRIPTION

RADIO FREQUENCY DIATHERMY APPLICATION SYSTEM AND DEVICE

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to radio frequency diathermy application systems and devices.

2. Description of Related Art

Radio Frequency (RF) coil systems have been used to apply heat to various portions of a patient's body, including limbs. Such systems have provided therapeutic medical treatment, including muscle healing, wound healing, and warming of hypothermia victims.

For example, U.S. Patent No. 4,527,550 describes a coil designed for use under full-wave operation at coil-wire length resonance. This system is limited to operation in an electromagnetic shielded room in order to meet FCC requirements. U.S. Pat. No. 5,160,828 describes an apparatus for warming the extremities of a subject so that the subject can perform certain tasks in a cold environment. This apparatus can be operated in free-space, without shielding, while complying with environmental regulations.

U.S. Patent Nos. 6,094,599, and 6,853,865 (the disclosures of each of which are expressly incorporated herein by reference), each disclose RF diathermy apparatus for warming the extremities of a subject, including, for example, a hand, wrist, forearm, elbow, ankle, and/or knee. Such apparatus may also be operated in free-space, without shielding, while complying with environmental regulations. These devices may be used for treating slow or non-healing wounds due to vascular inefficiency, diabetic peripheral neuropathy, microangiography, microvascular disease, or compression neuropathies such as Carpal Tunnel Syndrome. However, prior apparatus for application of RF diathermy have been substantially

cylindrical in shape, or have required additional materials such as towels to provide for safe operation on large substantially planar muscle groups within the body, including, for example, the back, abdomen, chest, and/or neck areas. The absence of the additional material could result in overheating of the patient's subcutaneous fat layers and ultimately discomfort and injury.

SUMMARY OF THE INVENTION

The present invention solves the above-noted discrepancies existing in prior approaches, and in one embodiment provides a radio frequency diathermy application system and device, including a flexible pad; and a flexible coil structure coupled to and supported by the pad. The flexible coil structure has a flexible spiral-like primary winding and a flexible spiral-like secondary winding coupled to the primary winding, the primary and secondary winding each substantially lying in separate substantially parallel planes when the pad is in an unflexed state.

In accordance with one aspect of the invention, the primary and secondary windings may each be substantially two-dimensional spirals when the pad is in the unflexed state, with the two-dimensional spirals being, for example, Archimedean spirals.

In accordance with another aspect of the invention, the primary and secondary windings may each have a substantially common central axis with the windings being displaced from one another along the axis. In accordance with yet another aspect of the invention, a turns ratio of the secondary winding to the primary winding may be approximately 3:1.

In accordance with another aspect of the invention, the flexible pad structure has a thickness chosen to minimize the effects of stray electrical fields (E-fields) on the subcutaneous fat cells of the patient. In accordance with another aspect of the invention, the flexible pad structure is semi-rigid to prevent gross misshaping of the device so as to prevent

inadvertent tuning of the device to resonance. This also minimizes the use of the device on non-muscular tissue providing lower device temperatures and stress on the device. In accordance with another aspect of the invention, the frequency tuning capability of the device may be limited so as to only function when used on a patient.

The system of the present invention may include a radio frequency diathermy generator for driving the radio frequency diathermy application device

These, and other, aspects of the invention will be better appreciated and understood when considered in conjunction with the following description and the accompanying drawings. It should be understood, however, that the following description, while indicating various embodiments of the invention and numerous specific details thereof, is given by way of illustration and not of limitation. Many substitutions, modifications, additions and/or rearrangements may be made within the scope of the invention without departing from the spirit thereof, and the invention includes all such substitutions, modifications, additions and/or rearrangements.

BRIEF DESCRIPTION OF THE DRAWINGS

The drawings accompanying and forming part of this specification are included to depict certain aspects of the invention. A clearer conception of the invention will become more readily apparent by referring to the exemplary, and therefore nonlimiting, embodiments illustrated in the drawings, wherein like reference numerals (if they occur in more than one view) designate the same or similar elements. The invention may be better understood by reference to one or more of these drawings in combination with the description presented herein. It should be noted that the features illustrated in the drawings are not necessarily drawn to scale.

FIG. 1 is a radio frequency diathermy system and device in accordance with an embodiment of the present invention.

FIG. 2A is a schematic representation of a flexible coil structure usable in the device of **FIG. 1**.

FIG. 2B is cross-sectional view taken through section 2B-2B of **FIG. 1**.

FIGS. 3 and **4** are plan views of coils useable in the device of **FIG. 1**.

FIG. 5 is a representation of human musculature illustration a potential application of the present invention.

FIG. 6 is a block diagram of a short-wave diathermy generator (SWDG), representing an embodiment of the invention.

DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

The invention and the various features and advantageous details thereof are explained more fully with reference to the non-limiting embodiments that are illustrated in the accompanying drawings and detailed in the following description. It should be understood that the detailed description and the specific examples, while indicating specific embodiments of the invention, are given by way of illustration only and not by way of limitation. Various substitutions, modifications, additions, and/or rearrangements within the spirit and/or scope of the underlying inventive concept will become apparent to those of ordinary skill in the art from this disclosure.

The RF diathermy application device, representing an embodiment of the invention, facilitates application of RF diathermy to large, substantially planar, muscle groups within the body, including the chest, abdomen, back and/or neck.

Referring to **FIG. 1**, a functional block diagram of an RF diathermy application system and device is depicted. The system includes an RF diathermy application device **101**, in the form of a pad-shaped structure, which will be described in more detail below. Device **101** is connected to a RF generator **103** by a coaxial cable **102**. A tuning circuit **104** is

coupled to a flexible coil structure within device **101**, as will be described in more detail below. Attached to device **101** is securing strap **105**, including a fastening structure **106**, **107** for affixing device **101** to a patient under treatment. Fastening structure **106**, **107** may be, for example, a hook-and-loop type fastener, but other types of fasteners would also be acceptable.

RF diathermy application device **101** is a flexible structure which assumes a substantially planar form when in its unflexed state, as shown in **FIG. 1**. Device **101** is flexible so as to conform to the surface of an area to be treated, typically, large substantially planar muscle groups within the human body, including, for example, the back, abdomen, chest and/or neck areas.

RF generator **103** is described in detail with reference to **Fig. 6**. In one embodiment of the invention, generator **103** produces RF power at 27.12MHz (11.06 meters), however other RF frequencies may also be acceptable, including, for example, 13.56 MHz (22.12 meters).

Referring to **FIG. 2A**, a schematic representation of a flexible coil structure **200**, usable within device **101** is presented. Flexible coil structure **200** includes a flexible spiral-like primary winding **202** which is coupled to a flexible spiral-like secondary winding **201**. Tuning circuit **104** may include a tuning capacitor as shown. Primary winding **202** is connected to coaxial cable **102**, and to RF diathermy generator **103** (*see also*, **FIG. 1**).

Flexible spiral-like windings **201** and **202** are shown in **FIG. 2A** as they would appear when device **101** is in an unflexed state. In that unflexed state, windings **201** and **202** take the form of substantially two-dimensional spirals, each occupying a separate plane, with the separate planes being substantially parallel to each other. In addition, windings **201** and **202** may have a substantially common central axis **203** and may be displaced from one another along the central axis **203**. In one embodiment, windings **201** and **202** are flexible so they may flex with device **101**. In a specific embodiment, windings **201** and **202** are 18 gauge.

stranded silver-plated copper wire insulated with polytetrafluoroethylene (PTFE). Other types of wires and insulations would also be acceptable.

Tuning circuit **104** may be a variable capacitor as shown. However, other forms of tuning circuits may also be acceptable, including tuning circuits including inductive components or tuning circuits including both inductive and capacitive components. A matching circuit may also be included to match the unbalance coaxial cable **102** with the balanced coil structure **200**. The matching circuit may include a balun. The tuning range of the tuning circuit **104** may be selected so as to prevent resonance when muscle tissue is not coupled to the device. This is compatible with sensing circuitry in the RF generator **103** to prevent operator error. Additionally, limiting the tuning range provides easier operation in a manually controlled system. The appropriate tuning range depends on the specific embodiment, but is well understood in the art of RF diathermy. In one embodiment, tuning circuit **104** may be a high voltage PTFE trimmer capacitor with a tuning range of between 5 and 20 picoFarads. One acceptable trimmer capacitor includes a type NT25-6 trimmer capacitor available from Voltronics of Denville, New Jersey. Other types of variable capacitors and other types of tuning circuits would also be acceptable.

Referring now to **FIG. 2B**, represented is a cross-section through section 2B-2B of RF application device **101** of **FIG. 1** showing the mechanical configuration of windings **201** and **202**. Referring to **FIG. 2B**, secondary winding **201** is embedded within flexible pad **204** and primary winding **202** is embedded within flexible pad **205**. Primary winding **202** and secondary winding **201** are separated from each other by an insulating spacer **206**. Pads **204** and **205** and spacer **206**, incorporating windings **201** and **202** are bonded together to form a substantially unified structure, using an appropriate bonding method, such as, for example, adhesive or ultrasonic bonding. The unified structure provides stiffness that retards gross misshaping of the device and prevents inadvertent tuning to resonance other than through the

tuning circuit **104**. This feature also discourages application of the device to non-muscular tissue. Flexible pad **204** also provides space between the patient and the secondary winding **201** to reduce the effects of stray E-fields on subcutaneous fat in the patient as well as the immediate environment. The flexible coil structure including flexible primary winding **202** and flexible secondary winding **201** embedded within pads **204** and **205,** is enclosed by outer sheath **207**.

In one specific embodiment, pads **204** and **205** may be made from closed-cell polyethylene foams with thermo resistance, for example, type M200 Minicell brand material available from Voltek LLC, although other types of flexible material would also be acceptable. In addition, insulating spacer **206,** which serves to physically separate and electrically insulate primary winding **201** and **202**, may be made from any flexible insulating material with thermo resistance, for example, polyethylene. In one illustrative embodiment, barrier **206** is a flexible polyethylene sheet with a thickness of 160 millimeters, and flexible pads **204** and **205** may have a thickness of approximately 1.25 centimeters, however, other thicknesses and materials would also be acceptable.

Referring now to **FIGS. 3** and **4**, **FIG. 3** is a plan view of secondary winding **201** embedded within slotted pad **204**, and **FIG. 4** is a plan view of primary winding **202** embedded within slotted pad **205**. Each one of primary winding **202** and secondary winding **201** may assume a spiral-like shape such as the Archimedean spiral depicted in **FIGS. 3** and **4**. However, other spiral-like forms would also be acceptable, including, for example, square spirals, triangular spirals, logarithmic spirals, hyperbolic spirals, or parabolic spirals. Other forms of spirals would also be acceptable.

Regardless of the particular type of spiral, each of spiral-like windings **201** and **202** are substantially two-dimensional, and substantially lie in different spaced-apart parallel planes when RF diathermy application device **101** is unflexed.

As may be seen with reference to **FIGS. 3** and **4**, each of windings **201** and **202**, are formed about respective central axes **203** and **203'**. In some embodiments, axes **203** and **203'** may be the same, however, in other embodiments, there may be an offset between axes **203** and **203'**. In addition, the turns ratio of secondary **201** to primary **202** in the disclosed embodiment is 3:1 however, other turns ratios may also be acceptable.

Referring now to **FIG. 5**, depicted is a representation of the musculature of the human lumbar region **500**. Area **501** is depicted as an example of a large substantially planar muscle group within the human body, to which RF diathermy application device **101** may be applied. Of course, other substantially planar muscle groups elsewhere in the body, for example, other parts of the back, abdomen, chest and/or neck areas would also benefit from use of the present invention.

Referring to **FIG. 6**, a block diagram of a short-wave diathermy generator **103** is depicted that may be used in the embodiment of **FIG. 1**. It will be understood however that other RF generators may also be used without departing from the scope of the invention. An AC source **600** is coupled to a power switch **602** via a fuse **601**. The power switch **602** is coupled to a medical power supply **603**. The medical power supply **603** is coupled to an RF output power amplifier DC supply **604** and to a logic power supply **605**. The RF output power amplifier **604** may include a switching power supply that is coupled to a 27.12 MHz amplifier **608** and to a microcontroller **617** via an RF power output control circuitry **606**.

A 27.12 MHz generator **607** is coupled to a first impedance matching and harmonic suppression network **609** via the 27.12 MHz amplifier **608**. The first impedance matching and harmonic suppression network **608** is coupled to a 27.12 MHz output **611** via a VSWR bridge **610**. An RF diathermy garment lead **102** is coupled to the 27.12 MHz output connector **611,** and connects the short wave diathermy generator **103** to RF diathermy application device **101**. The VSWR bridge **610** is coupled to the microcontroller **617** via a

forward power line and a reflected power line. The microcontroller **617** is coupled to a treatment timer **618**, a warming delivery **619**, a power output selector **620**, a start of treatment switch **621**, and a sounder **622**.

The short-wave diathermy generator is powered from an AC source **600**, and is capable of producing RF power at 27.12MHz (11.06 meters). Other frequencies would also be acceptable, including, for example, 13.56 MHz (22.12 meters). In one embodiment, the short wave diathermy generator provides an indication of the RF power available and the RF power delivered. The generator may utilize the VSWR bridge **610** to measure the effects of the RF load on itself and automatically reduce power when the system is not coupled to a patient by detecting a change in impedance. The VSWR bridge **610** may also be used to control the front panel display and RF protection circuitry built into the generator.

The invention may include a device for RF diathermy treatment. The invention may also include an RF diathermy coil assembly.

The terms a or an, as used herein, are defined as one or more than one. The terms including and/or having, as used herein, are defined as comprising (i.e., open language). The term coupled, as used herein, is defined as connected, although not necessarily directly, and not necessarily mechanically.

All of the disclosed embodiments of the invention may be made and used without undue experimentation in light of the disclosure. The invention is not limited by theoretical statements recited herein. Although the best mode of carrying out the invention contemplated by the inventors is disclosed, practice of the invention is not limited thereto.

In addition, while the RF diathermy coil assembly described herein may be a separate module, it will be manifest that the RF diathermy coil assembly may be integrated into the system with which it is associated.

The appended claims are not to be interpreted as including means-plus-function limitations. Specific embodiments of the invention are differentiated by the appended dependent claims and their equivalents.

CLAIMS

1. A radio frequency diathermy application device, comprising:

a flexible pad; and

a flexible coil structure coupled to and supported by the flexible pad, including:

a flexible spiral-like primary winding; and

a flexible spiral-like secondary winding coupled to the primary winding, the primary and secondary windings each substantially lying in separate substantially parallel planes when the flexible pad is in an unflexed state.

2. The radio frequency diathermy application device of claim 1, the primary and secondary windings each comprising substantially two-dimensional spirals when the flexible pad is in an unflexed state.

3. The radio frequency diathermy application device of claim 2, the primary and secondary windings each comprising Archimedean spirals.

4. The radio frequency diathermy application device of claim 2, the primary and secondary windings each having a substantially common central axis, and being displaced from one another along the axis.

5. The radio frequency diathermy application device of claim 1, a turns ratio of the secondary winding to the primary winding being approximately 3:1.

6. The radio frequency diathermy application device of claim 1, at least one of the primary or secondary windings comprising a woven wire conductive coil.

7. The radio frequency diathermy application device of claim 6, the conductive coils flexing with flexing of the pad.

8. The radio frequency diathermy application device of claim 1, further comprising a tuning circuit coupled to the secondary winding.

9. The radio frequency diathermy application device of claim 8, the tuning circuit comprising a variable capacitor.

10. The radio frequency diathermy application device of claim 1, further comprising a radio frequency power source coupled to the primary winding.

11. The radio frequency diathermy application device of claim 10, wherein the radio frequency power source produces power at a frequency of approximately 27.12 MHz.

12. The radio frequency diathermy application device of claim 10, wherein the radio frequency power source produces power at a frequency of approximately 13.06 MHz.

13. The radio frequency diathermy application device of claim 1, the flexible pad having a thickness greater than a penetration distance of unintentionally generated electric fields.

14. The radio frequency diathermy application device of claim 1, the flexible pad having resistance to compression such that a compressed thickness of the flexible pad is greater than a penetration distance of unintentionally generated electric fields under normal use.

15. The radio frequency diathermy application device of claim 1, the flexible pad having sufficient rigidity to prevent gross distortions of the device.

16. The radio frequency diathermy application device of claim 8, the tuning circuit having a limited tuning range such that the device is incapable of resonating in the absence of a load.

17. A radio frequency diathermy application system, comprising:

a radio frequency application device, including, a flexible pad incorporating a flexible coil structure, the flexible coil structure having a flexible

spiral-like primary winding and a flexible spiral-like secondary winding coupled to the primary winding; and

a radio frequency power source coupled to the primary winding.

18. The radio frequency diathermy application system of claim 17, further comprising, a tuning circuit coupled to the secondary winding.

19. The radio frequency diathermy application system of claim 17, the primary and secondary windings each comprising substantially two-dimensional spirals when the flexible pad is in an unflexed state.

20. The radio frequency diathermy application system of claim 19, the primary and secondary windings each comprising Archimedean spirals.

21. The radio frequency diathermy application system of claim 17, a turns ratio of the secondary winding to the primary winding being approximately 3:1.

22. The radio frequency diathermy application system of claim 17, at least one of the primary or secondary windings comprising a woven wire conductive coil.

23. The radio frequency diathermy application system of claim 22, the conductive coils flexing with flexing of the pad.

24. The radio frequency diathermy application system of claim 18, the tuning circuit comprising a variable capacitor.

25 The radio frequency diathermy application system of claim 17, the flexible pad having a thickness greater a penetration distance of unintentionally generated electric fields.

26 The radio frequency diathermy application system of claim 17, the flexible pad being resistant to compression such that a compressed thickness of the flexible pad is greater than a penetration distance of unintentionally generated electric fields under normal use.

27 The radio frequency diathermy application system of claim 17, the flexible pad having sufficient rigidity to prevent gross distortions of the device.

28 The radio frequency diathermy application system of claim 18, the tuning circuit having a limited tuning range such that the device is incapable of resonating in the absence of a load.

29. The radio frequency diathermy application system of claim 17, the radio frequency power source producing power at a frequency of approximately 27.12 MHz.

30. The radio frequency diathérmy application system of claim 17, the radio frequency power source producing power at a frequency of approximately 13.06 MHz.

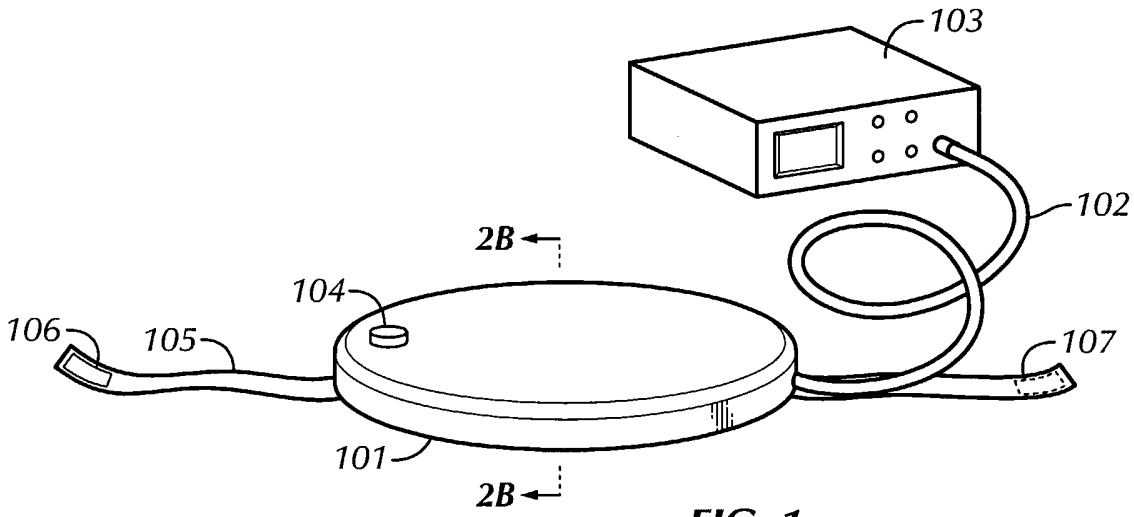

FIG. 1

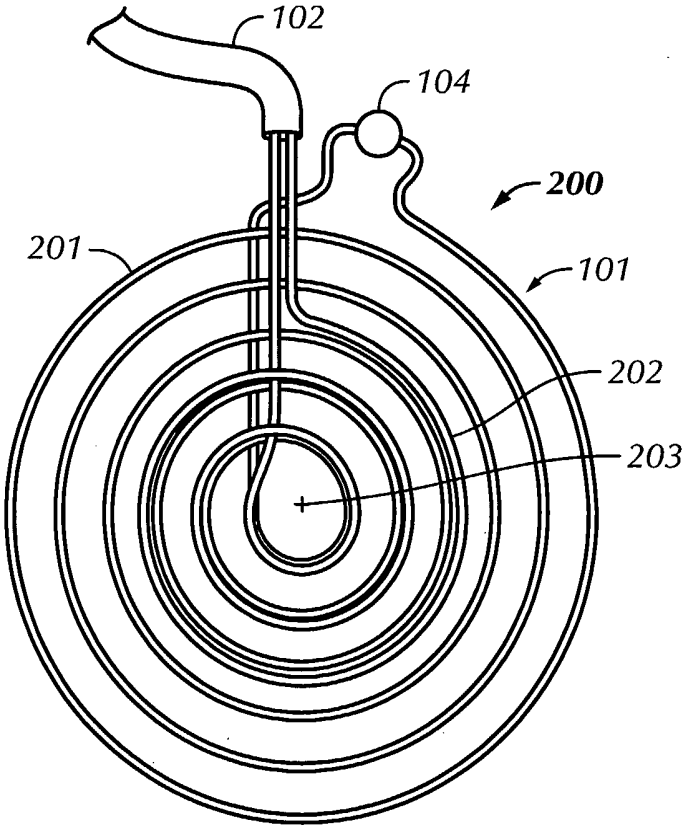

FIG. 2A

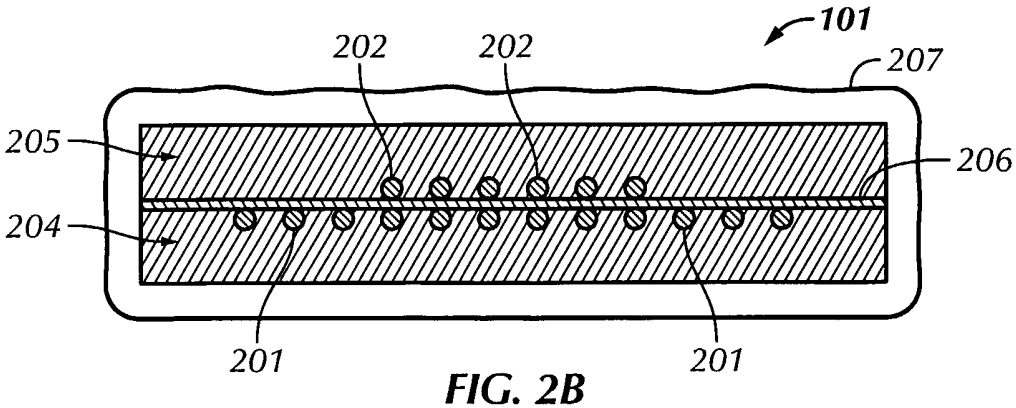

FIG. 2B

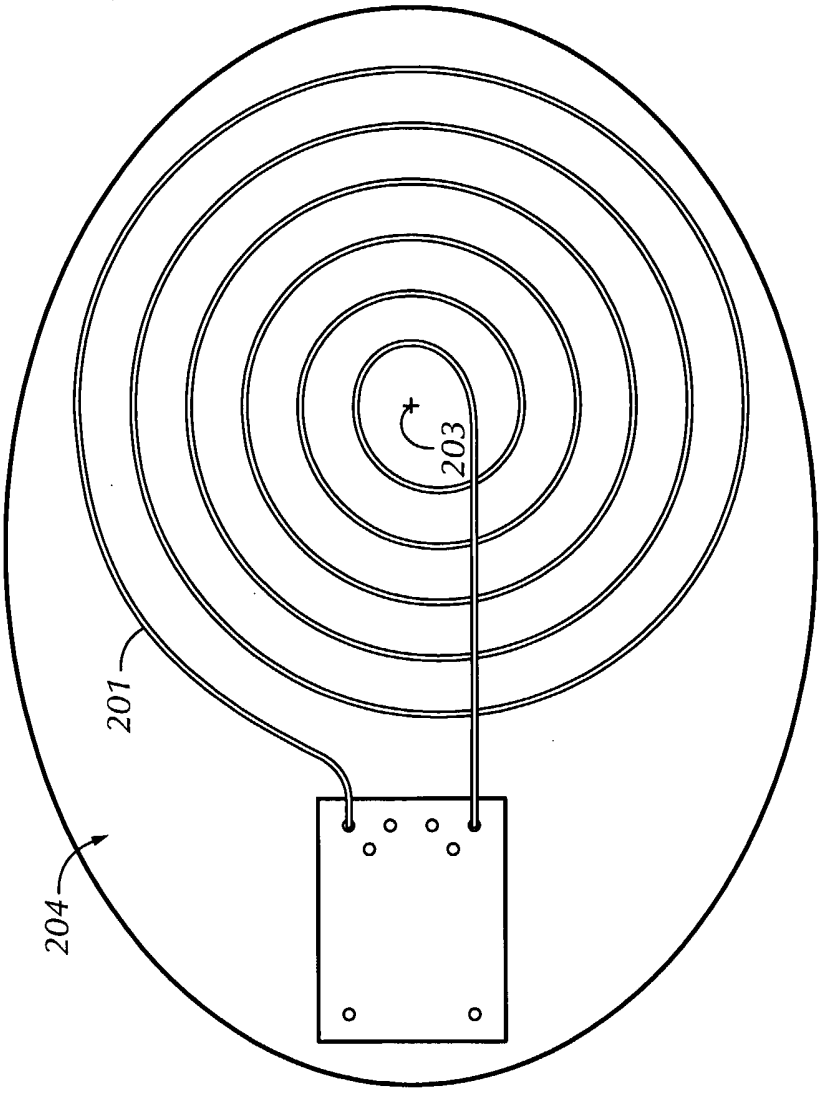

FIG. 3

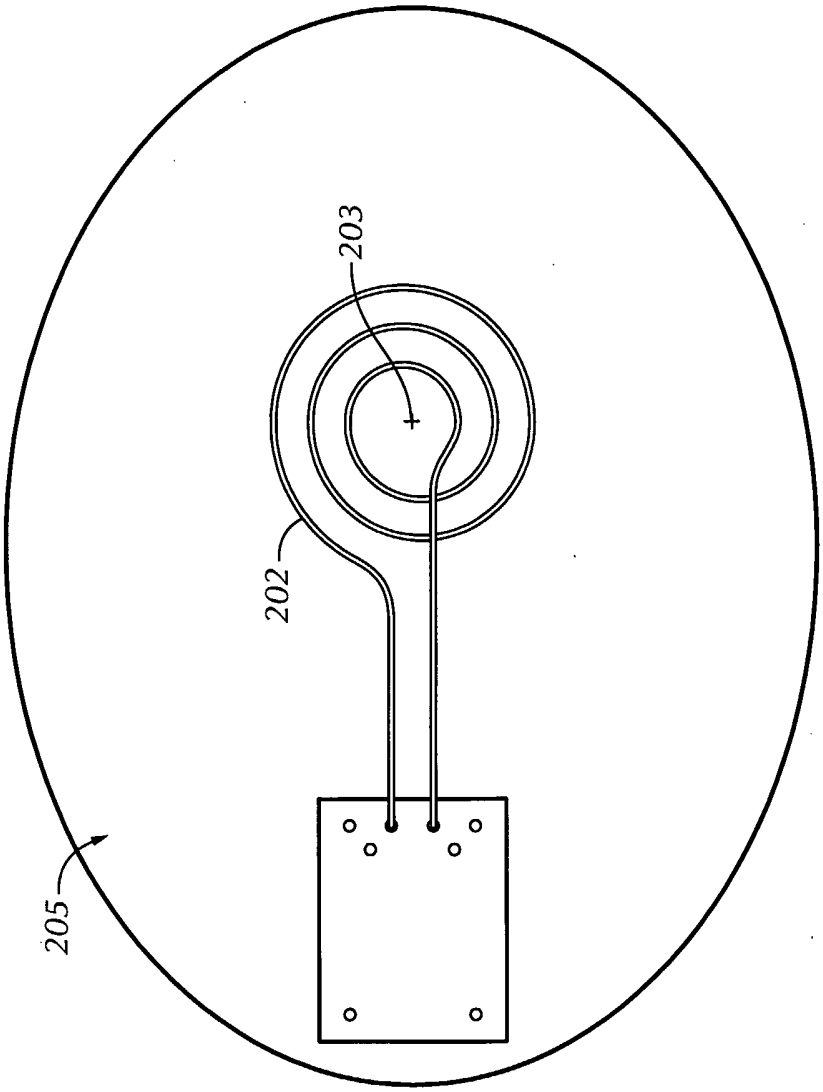

FIG. 4

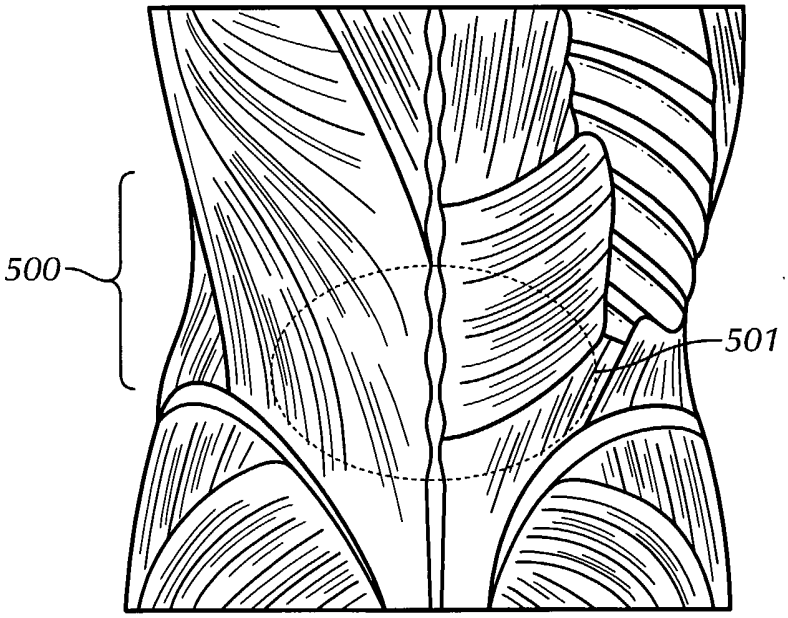

FIG. 5

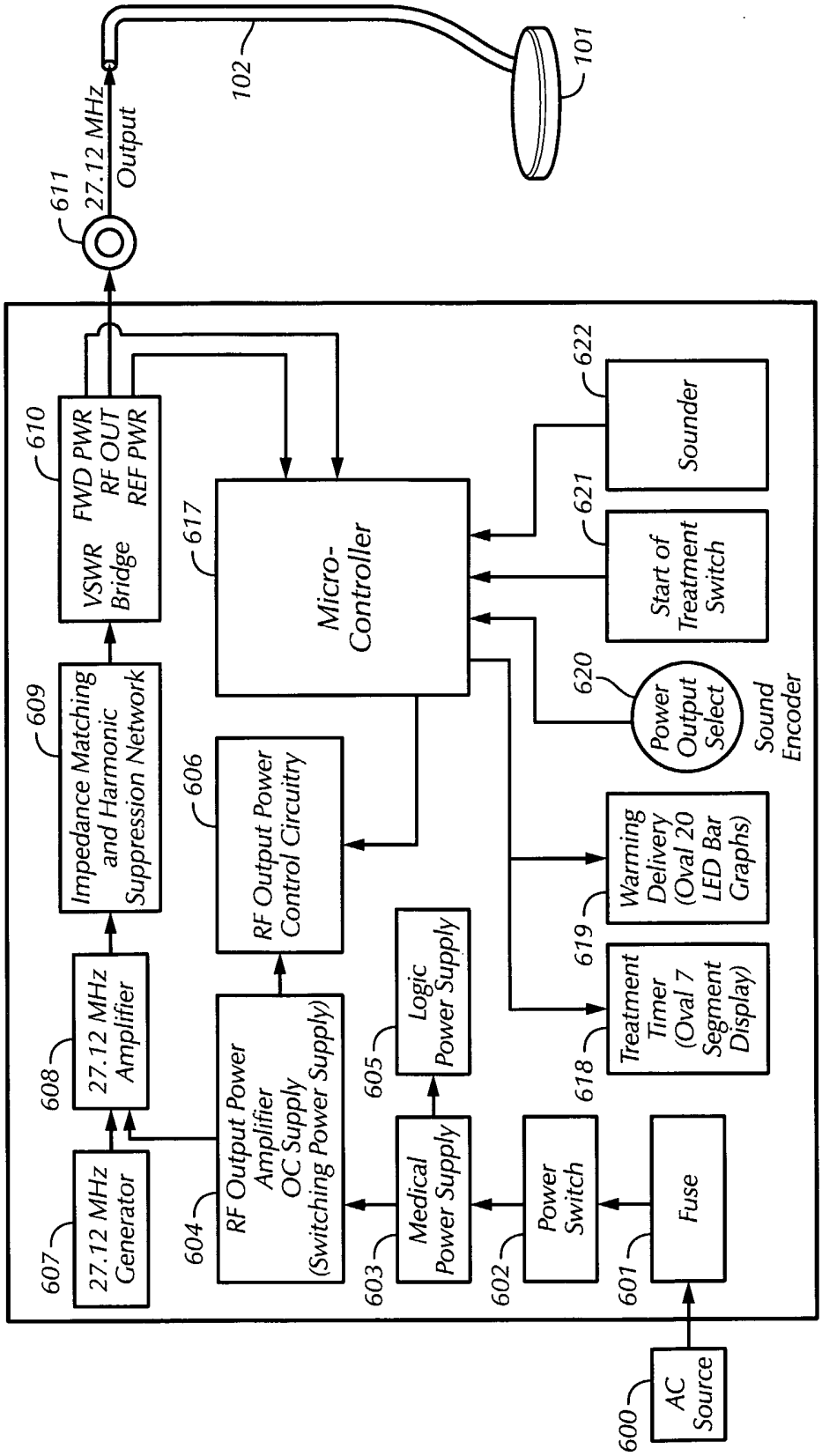
611
27.12 MHz
Output
102
101
610
FWD PWR
RF OUT
REF PWR
VSWR
Bridge
609
Impedance Matching
and Harmonic
Suppression Network
608
27.12 MHz
Amplifier
607
27.12 MHz
Generator
617
Micro-
Controller
606
RF Output Power
Control Circuitry
604
RF Output Power
Amplifier
OC Supply
(Switching Power Supply)
605
Logic
Power Supply
603
Medical
Power Supply
602
Power
Switch
601
Fuse
600
AC
Source
622
Sounder
621
Start of
Treatment
Switch
620
Power
Output
Select
Sound
Encoder
619
Warming
Delivery
(Oval 20
LED Bar
Graphs)
618
Treatment
Timer
(Oval 7
Segment
Display)

FIG. 6

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2005/043960

A. CLASSIFICATION OF SUBJECT MATTER
A61N1/40

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)
A61N

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 353 763 B1 (GEORGE FRANK R ET AL) 5 March 2002 (2002-03-05) column 3, line 29 - line 46 column 7, line 27 - line 34 column 8, line 13 - line 39 column 11, line 24 - line 32 column 16, line 36 - line 65 column 17, line 60 - line 67; figures 1,9,12,13	1-30
A	US 2004/230226 A1 (BINGHAM JAMES B ET AL) 18 November 2004 (2004-11-18) paragraphs [0007] - [0011]; figures	1-30
A	GB 283 236 A (GAYLORD WILSHIRE) 9 January 1928 (1928-01-09) page 1, line 84 - page 3, line 29; figures	1-30

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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

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Date of the actual completion of the international search	Date of mailing of the international search report
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Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Rakotondrajaona, C

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INTERNATIONAL SEARCH REPORT

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