(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
16 December 2010 (16.12.2010)

PCT

(10) International Publication Number
WO 2010/144548 A2

(51) International Patent Classification:
A61N 1/40 (2006.01) *A61N 5/06* (2006.01)
A61B 18/14 (2006.01) *A61N 1/06* (2006.01)

(21) International Application Number:
PCT/US2010/037933

(22) International Filing Date:
9 June 2010 (09.06.2010)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/185,393 9 June 2009 (09.06.2009) US

(71) Applicant (*for all designated States except US*): **REGEAR LIFE SCIENCES, INC.** [US/US]; 2000 Cliff Mine Road, Suite 450, Pittsburgh, Pennsylvania 15275 (US).

(72) Inventors; and

(75) Inventors/Applicants (*for US only*): **UNETICH, Robert, M.** [US/US]; 1811 Woodlands Circle, Pittsburgh, Pennsylvania 15241 (US). **HANLON, James** [US/US]; 1297 Royal Park Boulevard, South Park, Pennsylvania 15129 (US).

(74) Agents: **REZNICK, Paul, M.** et al.; The Webb Law Firm, 700 Koppers Building, 436 Seventh Avenue, Pittsburgh, Pennsylvania 15219 (US).

(81) Designated States (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

Published:

— *without international search report and to be republished upon receipt of that report (Rule 48.2(g))*

(54) **Title**: SHIELDED DIATHERMY APPLICATOR WITH AUTOMATIC TUNING AND LOW INCIDENTAL RADIATION

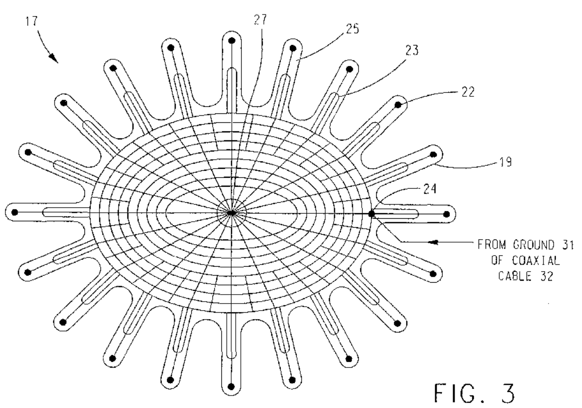


FIG. 3

(57) **Abstract**: An applicator supplying RF power for therapeutic diathermic treatment of a patient includes a radiation shielding device for shielding the applicator against misapplication of radiation to objects in the surroundings and unintended areas of the patient's body, and a coupling device for electrically coupling the radiation shielding device to at least one point of the body of a patient in a low impedance manner that reduces the potential drop from the grounded radiation shield to the body tissue.

WO 2010/144548 A2

SHIELDED DIATHERMY APPLICATOR WITH AUTOMATIC TUNING AND LOW INCIDENTAL RADIATION

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims priority from U.S. provisional application 61/185,393, entitled "SHIELDED DIATHERMY APPLICATOR WITH AUTOMATIC TUNING AND LOW INCIDENTAL RADIATION," filed June 9, 2009, which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0002] **Field Of The Invention**

[0003] This invention relates to the field of bioelectromagnetics, specifically, the conversion of radio frequency (RF) energy in human or animal tissue to achieve therapeutic purposes both thermal and athermal. It represents advancements in equipment design that substantially reduce the incidental radiation of energy, while improving the consistency of energy conversion within the desired target tissue.

[0004] **Description Of Related Art**

[0005] RF coil diathermy systems utilize coils to radiate both electric and magnetic fields. The proximity of the coils to the target tissue results in concentration of the electric and magnetic fields generated by RF excitation of the coils and energy conversion in the tissues near the coils. A problem with these coils is that significant fields can also exist at distances away from the coils, which can cause RF energy conversion within other tissue, exposure to workers nearby, and exposure to others in the general vicinity of the coils. It would, therefore, be desirable to provide an RF coil diathermy system that avoids the foregoing problems.

SUMMARY OF THE INVENTION

[0006] Disclosed is an applicator apparatus for supplying RF power for therapeutic diathermic treatment of a patient. The applicator includes radiation shielding for shielding the applicator against misapplication of radiation to objects in the surroundings and unintended areas of the patient's body, and a coupling device for electrically coupling the radiation shielding device to at least one point of the body of the patient in a low impedance manner.

[0007] The radiation shielding can include a conductive grid and at least one conductive pad electrically connected to the conductive grid to provide capacitive coupling to the body of the patient at least at one point. The periphery of the radiation shielding can curve or wrap around the non-applying areas of the applicator to form a curved conductive grid having radial spurs or fingers. The conductive pads can be circular in shape and can be connected at the electrical termination of each radial spur or finger of the curved conductive grid.

[0008] The conductive grid can include a substrate comprised of printed circuit material. The conductive grid can include an electrically conductive pattern disposed on a flexible, insulative substrate.

[0009] Also disclosed is a method of constructing a radiation shielded diathermy applicator device. The method includes providing a radio frequency diathermy applicator device including a first flexible coil structure, a second flexible coil structure, and a first non-conductive spacer between the first and second flexible coil structures. The method also includes providing a second non-conductive spacer disposed between the first flexible coil structure and a radiation shield that includes an electrically conductive grid pattern on a flexible, insulative substrate having radial fingers, wherein the electrically conductive grid pattern includes conductive pads on the radial fingers; and wherein said radial fingers can be curved around the first non-conductive spacer, the first flexible coil structure, and the second non-conductive spacer, and coupled to the first non-conductive spacer, wherein said conductive pads are positioned on the first non-conductive spacer on a surface thereof opposite the first flexible coil structure.

[0010] It should be understood that the following descriptions, while indicating various embodiments of the invention and numerous specific details thereof, are 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

[0011] **FIG. 1A** is an exploded perspective view of a flexible coil structure of a prior art radio frequency diathermy device;

[0012] **FIG. 1B** is a cross-sectional view of the radio frequency diathermy device of **FIG. 1A** in an assembled state;

[0013] **FIG. 2** is a cross-sectional view of a radiation shielded diathermy applicator in accordance with the present invention coupled to the body of a patient or treatment target;

[0014] **FIG. 3** is a radiation shielding device of the applicator of **FIG. 2**;

[0015] **FIG. 4** is an electrical schematic diagram of an RF diathermy device;

[0016] **FIG. 5** is a lumped series tuned circuit model of the tuning circuit of **FIG. 4**;

[0017] **FIG. 6A** is a plan view of the adjustable dielectric constant variable capacitor that can be used with the tuned circuit model of **FIG. 5**; and

[0018] **FIG. 6B** is a cross-sectional view of the adjustable dielectric constant variable capacitor shown in **FIG. 6A**.

DETAILED DESCRIPTION OF THE INVENTION

[0019] The invention and the various features and advantageous details thereof are explained more fully and illustrated by the accompanying drawings and detailed in the following description.

[0020] Referring to **FIG. 1A**, a prior art flexible coil structure **1**, like the one shown in U.S. 2006/0119462, which is incorporated herein by reference, includes a secondary flexible coil structure **5** having a flexible, spiral-like winding which is physically coupled or positioned in spaced relation to a primary flexible coil structure **3** that also has a flexible, spiral-like winding, and a non-conductive spacer **4** disposed between and in contact with both primary flexible coil structure **3** and secondary flexible coil structure **5.**

[0021] Referring to **FIG. 1B**, in an unflexed state, coil structures **3, 5** are two-dimensional spirals, each occupying a separate plane. Desirably, these separate planes are parallel to each other with spacer **4** disposed between and coupled to both coil structures **3, 5**. Desirably, coil structures **3, 5** have a common central axis **7** and are positioned in spaced relation along central axis **7.** In one, non-limiting embodiment, coil structures **3, 5** include 18-gauge stranded silver-plated copper wire disposed on a sheet or substrate of insulative polytetrafluoroethylene (PTFE). Other types of wires and insulative sheets would also be acceptable.

[0022] Referring to **FIG. 2**, a cross-sectional view of a radiation shielded diathermy applicator **9** coupled to a patient **12** or treatment target is depicted. The exterior of applicator **9** is a non-conductive, flexible pouch **11** which allows applicator **9** to conform to a patient's chest, abdomen, back, and/or neck. Desirably, pouch **11** is made from nylon. However, this is not to be construed as limiting the invention.

[0023] Applicator **9** is in the form of a pad-shaped structure that includes a non-conductive layer **13** that separates pouch **11** from secondary flexible coil structure **5** contained within the pad structure of applicator **9**. Applicator **9** also includes a non-conductive layer **14** that separates a radiation shield **17** (described hereinafter) from pouch **11**.

[0024] Secondary flexible coil structure **5** is embedded or disposed between layer **13** and spacer **4**. Primary flexible coil structure **3** is embedded or disposed between spacer **4** and a non-conductive radiation shield spacer **15.** Spacer **4** separates secondary flexible coil structure **5** from primary flexible coil structure **3**. Layer **13** provides space between patient **12** and secondary flexible coil structure **5** when applicator **9** is being used by patient **12.**

[0025] Desirably, layer **13**, layer **14**, spacer **4**, and radiation shield spacer **15**, are each made from closed-cell polyethylene foams with thermoresistance, although other types of flexible, insulative material would also be acceptable. In one embodiment, layer **13**, layer **14** and spacer **4** are made of foam having a thickness of 9.525 mm, and radiation shield spacer **15** is a foam layer having a thickness of 31.75 mm. However, other thicknesses and materials would also be acceptable.

[0026] With reference to **FIG. 3** and continuing reference to **FIG. 2**, radiation shield **17** covers the non-patient facing side of radiation shield spacer **15** and has radial fingers **19** that curve around radiation shield spacer **15**, primary flexible coil structure **3**, spacer **4**, and connect to the patient-facing side of spacer **4**. Desirably, Velcro® **21** is used to connect each radial finger **19** to spacer **4**. However, this is not to be construed as limiting the invention since it is envisioned that any other suitable and/or desirable means can be utilized to connect each finger to spacer **4**. At the end of each radial finger **19** is a conductive pad **22** that faces the body part of patient **12** under treatment when applicator **9** is worn by a patient. Desirably, each pad **22** provides capacitive coupling to the body of the patient **12**. Radiation shield **17** also includes a conductive pad **24** which is coupled to a ground reference, e.g., a ground **31** sheath of coaxial cable **32** (shown in Fig. 4) in use of radiation shield **17**.

[0027] Radiation shield **17** includes conducting tracks **23** formed on a flexible printed circuit material made of a flexible, insulative substrate **25**. Conducting tracks **23** are also disposed on substrate **25** and electrically coupled to conductive pads **22** and conductive pad **24.** Non-limiting examples of materials that can be used for this substrate include FR-4, G-10, or Kapton®. Kapton® is a registered trademark of E.I. du Pont de Nemours and Company. Desirably, radiation shield **17** has the grid-like pattern of conducting tracks **23** shown in **FIG. 3**. However, this is not to be construed as limiting the invention as it is envisioned that any suitable and/or desirable pattern having the same effect as the grid-like pattern shown in **FIG. 3** can be used. It should also be noted that other materials could be substituted for substrate **25** provided that any such material has sufficient flexibility and dielectric strength.

[0028] Desirably, radiation shield **17** adds only a small amount of stray capacitance across secondary flexible coil **5** while allowing electric field lines to terminate on the radiation shield conducting tracks **23,** which are coupled to a ground reference via conducting pad **24** coupled to the ground sheath **31** of coaxial cable **32**. Desirably, radial fingers **19** of radiation shield **17** remain constant in width as the radius of the radial fingers **19** increases radially from the center axis **27** of the radiation shield **17**. The pattern of radial fingers **19** on the periphery allows the fingers to be curved around shield spacer **15**, primary flexible coil structure **3**, and spacer **4**. The conductive pads **22** at the ends of radial fingers **19** define capacitive coupling elements that are positioned in spaced relation to the body tissue of patient **12** when applicator **9** is worn by the patient **12**. Each conductive pad **22** acts as one plate of a capacitor, with the body tissue of patient **12** acting as a second plate of a capacitor, and layer **13** acting as a dielectric between each pad **22** and the body tissue of patient **12**.

[0029] Conductive pads **22,** along with the body of patient **12** and layer **13**, form a capacitor which capacitively couples conductive tracks **23** to the patient's body **12**. More specifically, each conductive pad **22** spaced from the body of patient **12** by layer **13** acts as a separate capacitor in parallel with the combination of each of the other pads **22** spaced from the body of patient **12** by layer **13**. When multiple conductive pads **22** come into close proximity (spaced relation) with the body of patient **12** to form multiple parallel capacitors, these parallel capacitors act as a single large capacitor. Radiation shield **17** therefore avoids RF radiation fields from emanating to the surrounding environments by capacitively coupling these fields to the body of patient **12**.

[0030] Referring to **FIG. 4**, an electrical schematic diagram including supporting circuitry used with primary and secondary flexible coil structures **3**, **5** in an RF diathermy device **28** is shown. Resistor $\mathbf{R_p}$ is a representation of the body of patient **12**. Inductor $\mathbf{L_2}$ is a representation of secondary flexible coil structure **5** and inductor $\mathbf{L_1}$ is a representation of primary flexible coil structure **3**. Capacitor C_1 is a representation of the capacitance that exists by the spacing among patient **12**, primary flexible coil structure **3**, and secondary flexible coil structure **5**. The capacitance of capacitor C_1 may also include the capacitance of conductive pads **22** adjacent the body of patient **12**. Capacitor C_2 is a variable capacitor that can be connected in parallel with R_p and C_1. Capacitor C_2 enables tuning by matching the impedance of the combination of C_1, C_2, L_2, and R_p to the impedance of supporting circuitry so the same impedance can be realized throughout diathermy device **28** regardless of the patient **12** coupled to the device **28**. This impedance matching allows the resonant frequency of the combination of C_1, C_2, L_2, and R_p to be about the same for each patient **12** that uses the device. An isolation device **29** (*e.g.* a balun) transforms an unbalanced input signal on the **L3** side of device **29** into a balanced output signal on the **L4** side of device **29**, which output signal is supplied to primary flexible coil structure **3**. Isolation device **29** acts to electrical isolate primary and secondary flexible coil structure **3** and 5 from a ground reference, such as, without limitation, the ground **31** of a 75 ohm coaxial cable **32**, whereupon primary and secondary flexible coil structures **3** and **5** can "float" relative to said ground reference. Coaxial cable **32** connects the **L3** side of device **29** to an RF generator.

[0031] Referring to **FIG. 5**, a lumped, series tuned model circuit **33** is depicted. The schematic depicted in **FIG. 4** of RF diathermy applicator **28** can be reduced to create model circuit **33**. In model circuit **33**, resistor R_p represents patient **12;** variable capacitor **30** represents the lumped capacitance of applicator **28,** including variable capacitor C_2; variable inductor **29** represents the lumped inductance of applicator **28**, and resistor **35** represents the lumped resistance of applicator **28**. These elements are connected to an RF generator (not shown) via coaxial cable **32**. The tuning range of model circuit **33** may be selected so as to avoid resonance when body tissue is not coupled to applicator **9**.

[0032] In model circuit **33**, a resistive value R_s of resistor **35** changes with tissue loading. Specifically, resistive value R_s is lower when resistor **35** is unloaded and is higher when resistor **35** is "heavily loaded". Resistive value R_s changes over a range of about 2:1 in practice and the resulting currents and voltages across the tuning circuit elements can then also be expected to vary as much as 2:1 at resonance and even more at detuned conditions. When model circuit **33** is properly matched and resonated, resistor **35** simplifies into a 50 ohm resistor. With 35 watts present, this represents a voltage of about 42 Volts rms and a current of 42/50~0.84 Amps. These RF currents and voltages are significant values to apply to a tuning circuit, and when model circuit **33** is unloaded, the values increase significantly since the current flowing increases due to the lower load resistance value.

[0033] Referring to **FIGS. 6A-6B**, a non-limiting exemplary embodiment of variable capacitor $\mathbf{C_2}$, shown in **FIGS. 4** and **5**, is depicted. Variable capacitor $\mathbf{C_2}$ includes a moveable section of two low-loss dielectric materials **37, 39** that cause the average dielectric constant between the fixed metal plates (Contact A and Contact B) of capacitor $\mathbf{C_2}$ to vary over a two-to-one range as the moveable section is rotated or moved between Contact A and Contact B. The materials **37, 39** selected in this particular embodiment are Teflon® and Noryl®, with approximate dielectric constants of 2 and 4, respectively. Teflon® is a registered trademark of E.I. du Pont de Nemours and Company. Noryl® is a registered trademark of Saudi Basic Industries Corporation (SABIC). It should be noted that other materials could be substituted for either of materials **37, 39,** depending on the range of capacitance desired. Use of these materials avoids the need for the metal plates (i.e., Contact A and Contact B) to have a moveable electrical contact, greatly improving reliability and lowering cost. The construction of variable capacitor $\mathbf{C_2}$ in one embodiment is a circular design. It should be noted that other mechanical arrangements (for example a linear array) could be utilized without affecting the intended scope of this invention.

[0034] Variable capacitor $\mathbf{C_2}$ is used to tune the radio frequency of RF diathermy device **28** to resonance, the value of which depends upon stray capacitances across secondary flexible coil structure **5**. The transformed impedance caused by variable capacitor $\mathbf{C_2}$ varies from inductive to resistive and then to capacitive as the stray capacitances change and as variable capacitor $\mathbf{C_2}$ is adjusted.

[0035] Numerous characteristics and advantages of the invention covered by this document have been set forth in the foregoing description. It will be understood, however, that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of scope, size, and arrangement of parts without exceeding the scope of the invention. The invention’s scope is, of course, defined in the language in which the appended claims are expressed.

THE INVENTION CLAIMED IS:

1. An applicator apparatus supplying RF power for therapeutic diathermic treatment of a patient comprising:

a radiation shielding device for shielding said applicator apparatus against misapplication of radiation to objects in the surroundings and unintended areas of the patient's body; and

a coupling device for electrically coupling said radiation shielding device to at least one point of the body of said patient in a low impedance manner that reduces the potential drop from the grounded radiation shield to the body tissue.

2. The apparatus of claim 1, wherein said radiation shielding device comprises a conductive grid and wherein said coupling device comprises at least one conductive pad electrically connected to said conductive grid and providing capacitive coupling to the body of said patient at said at least one point.

3. The apparatus of claim 2, wherein said conductive grid adjacent its periphery comprises radially extending spurs or fingers curved around the non-radiation-applying areas of the applicator.

4. The apparatus of claim 3, wherein each pad is adjacent the distal end of one radial spur or finger.

5. The apparatus of claim 4, wherein each pad has a circular shape.

6. The apparatus of claim 2, wherein said conductive grid is comprised of a substrate comprised of printed circuit material.

7. The apparatus of claim 2, wherein said conductive grid is comprised of an electrically conductive pattern disposed on a flexible, insulative substrate.

8. The apparatus of claim 7, wherein said electrically conductive pattern is coupled to a ground reference.

9. The apparatus of claim 7, wherein said substrate is FR-4, G-10, or Kapton®.

10. A method of constructing a radiation shielded diathermy applicator device, comprising:

providing a radio frequency diathermy applicator device comprising a first flexible coil structure, a second flexible coil structure, and a first non-conductive spacer between the first and second flexible coil structures;

providing a second non-conductive spacer disposed between the first flexible coil structure and a radiation shield that includes an electrically conductive grid pattern on a flexible, insulative substrate having radial fingers, wherein the electrically conductive grid pattern includes conductive pads on the radial fingers; and wherein said radial fingers are curved around the first non-conductive spacer, the first flexible coil structure, and the second non-conductive spacer, and coupled to the first non-conductive spacer, wherein said conductive pads are positioned on the first non-conductive spacer on a surface thereof opposite the first flexible coil structure.

11. A method according to claim 10, wherein said flexible printed circuit material is FR-4, G-10, or Kapton®.

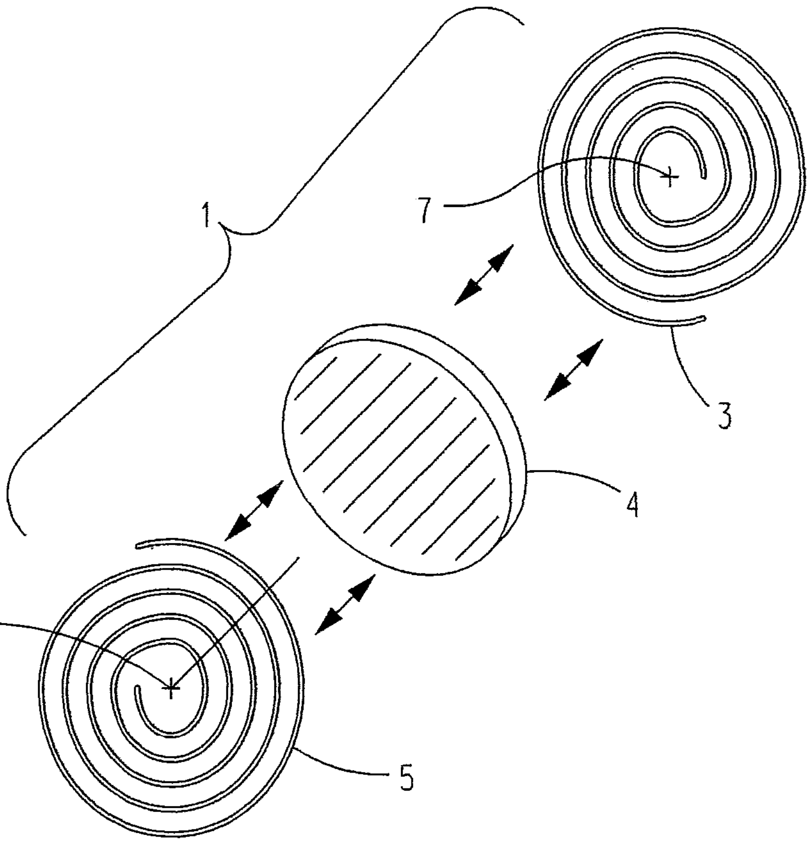


FIG. 1A
(PRIOR ART)

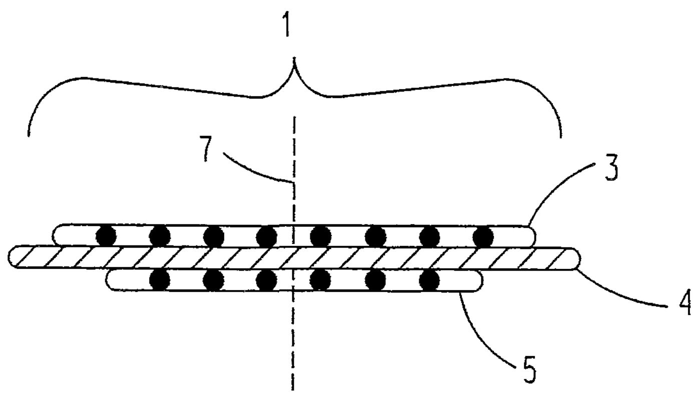


FIG. 1B
(PRIOR ART)

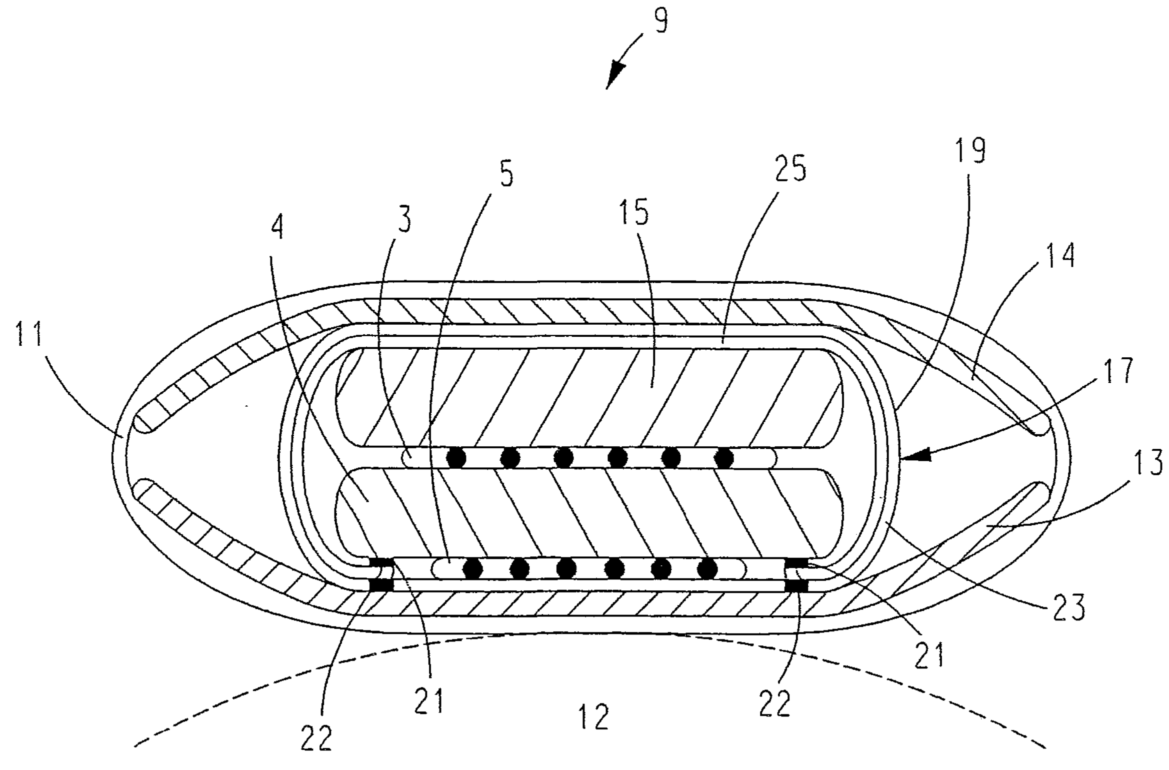


FIG. 2

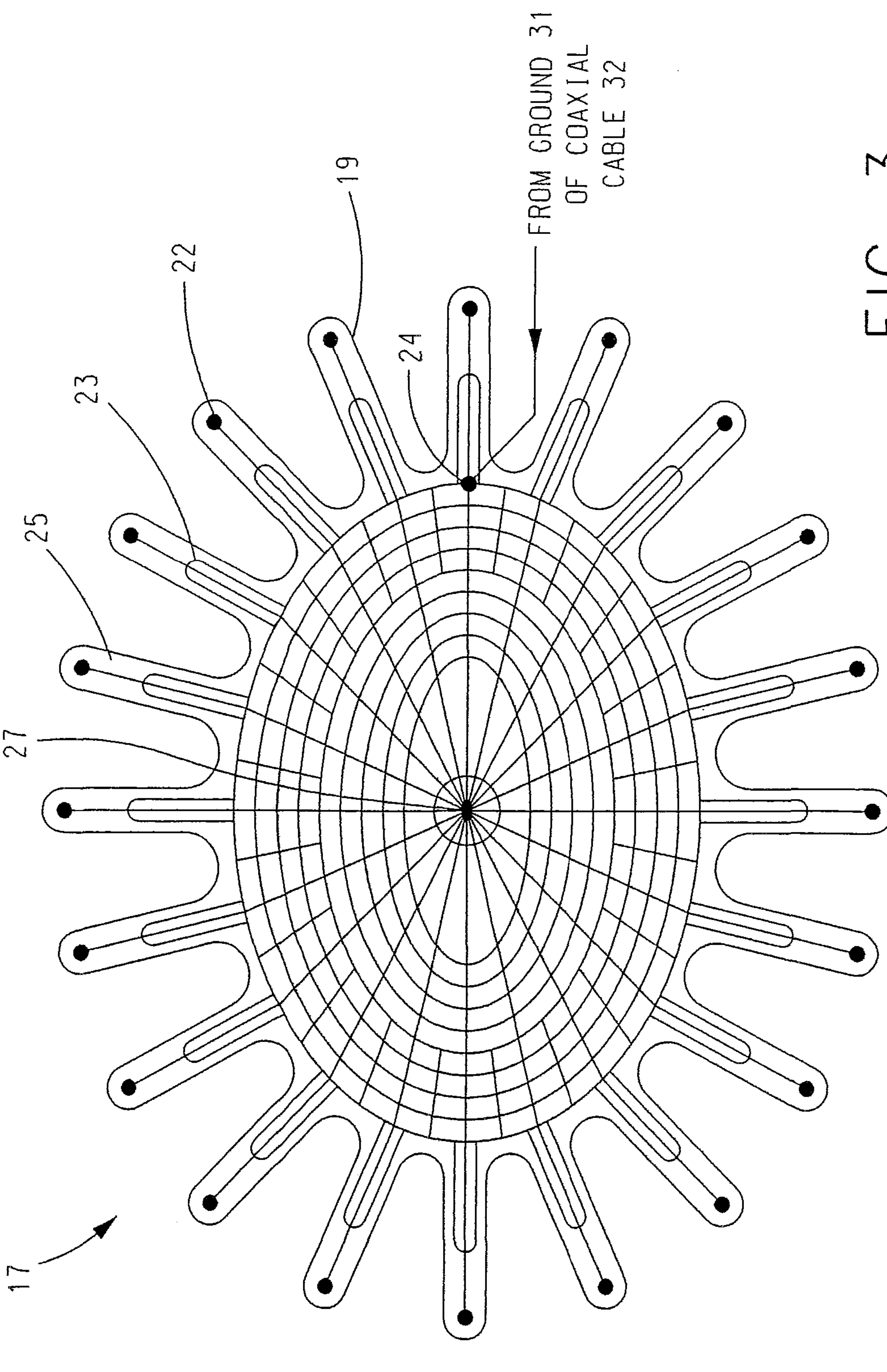


FIG. 3

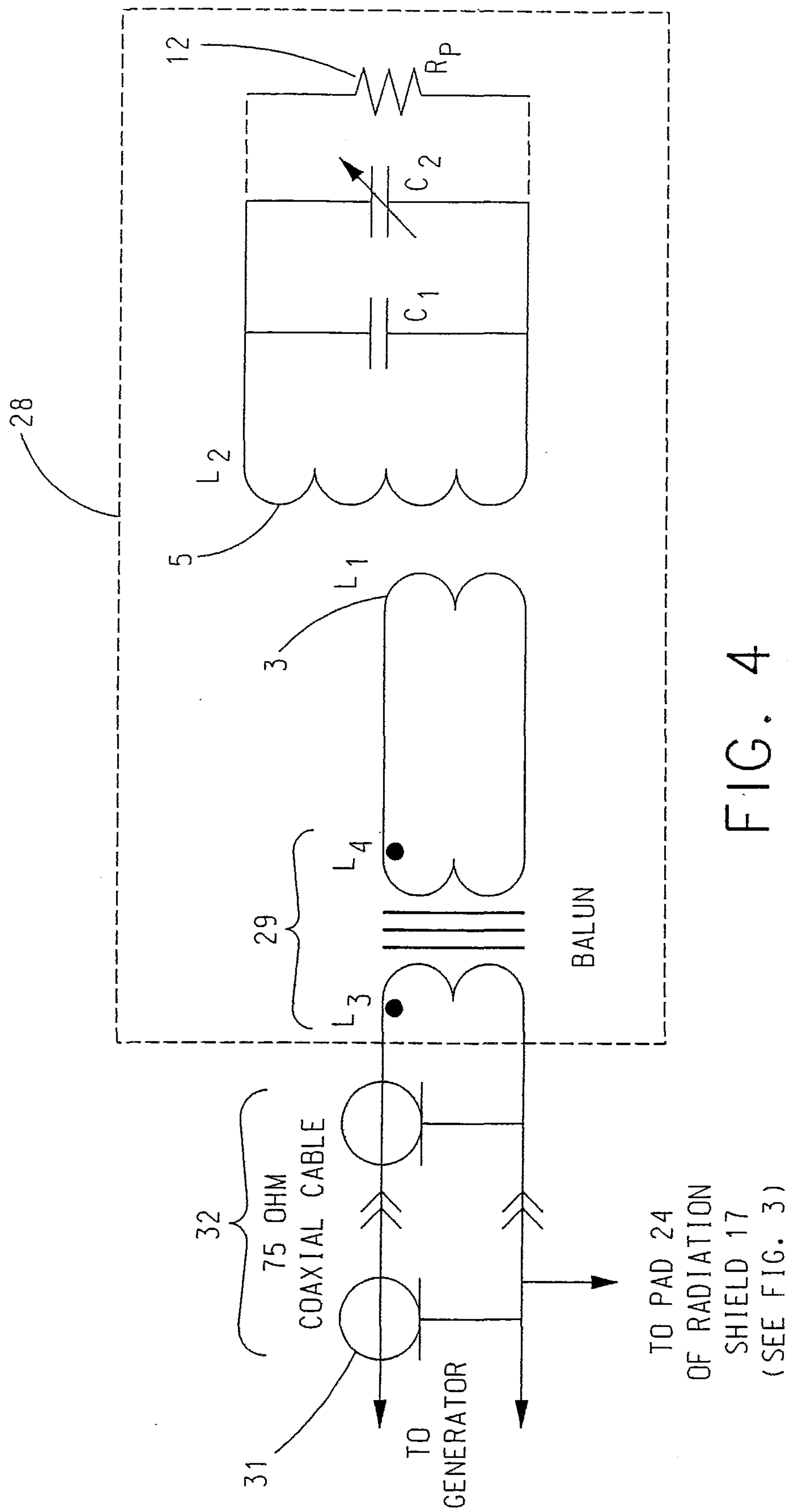
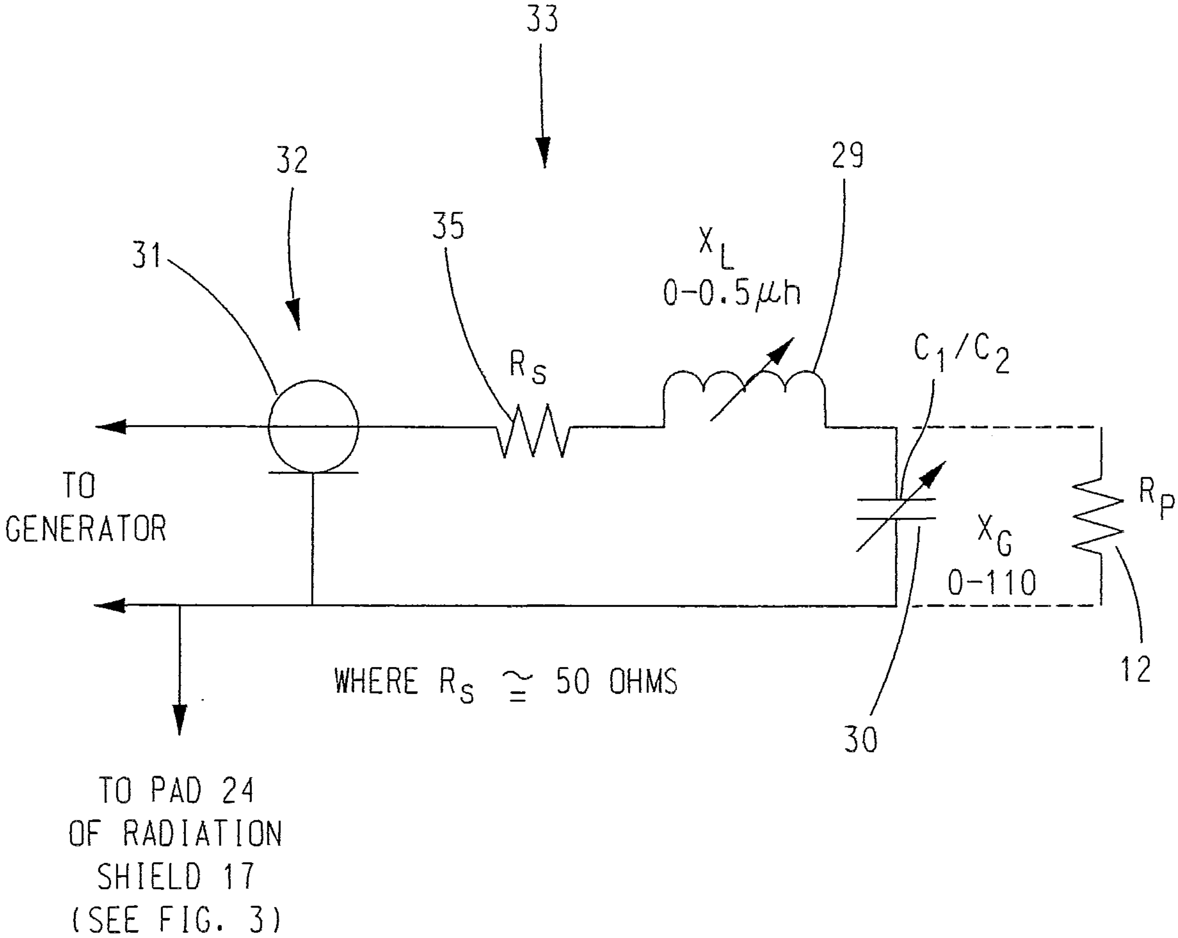

12
R_P
C_2
C_1
28
L_2
5
L_1
3
L_4
29
BALUN
L_3
32
75 OHM
COAXIAL CABLE
TO PAD 24
OF RADIATION
SHIELD 17
(SEE FIG. 3)
31
TO
GENERATOR

FIG. 4



33
32
29
35
31
X_L
0-0.5μh
R_S
C_1/C_2
TO
GENERATOR
R_P
X_G
0-110
12
WHERE $R_S \cong$ 50 OHMS
30
TO PAD 24
OF RADIATION
SHIELD 17
(SEE FIG. 3)

FIG. 5

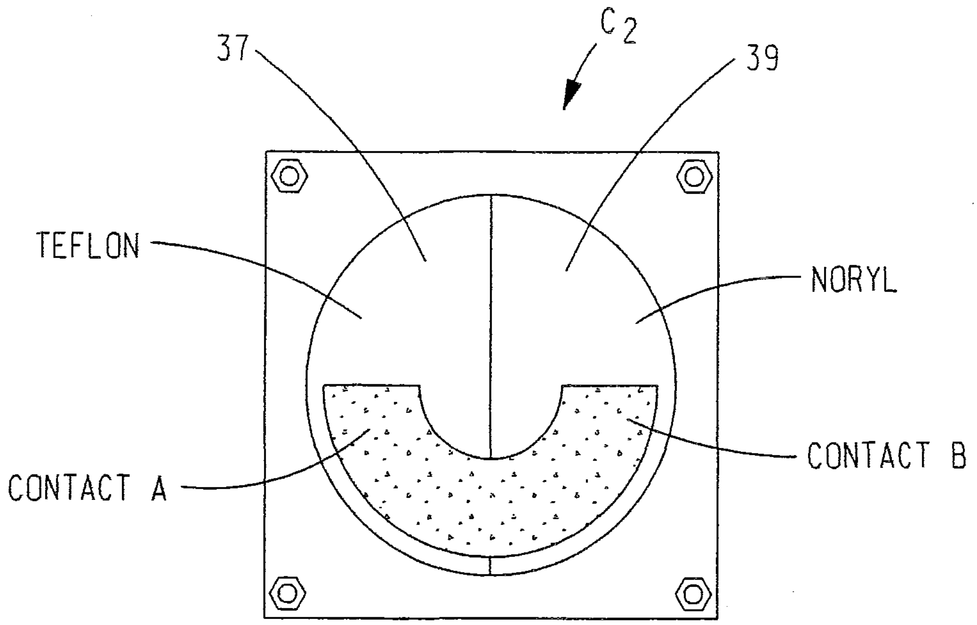

C2
37
39
TEFLON
NORYL
CONTACT A
CONTACT B

FIG. 6A

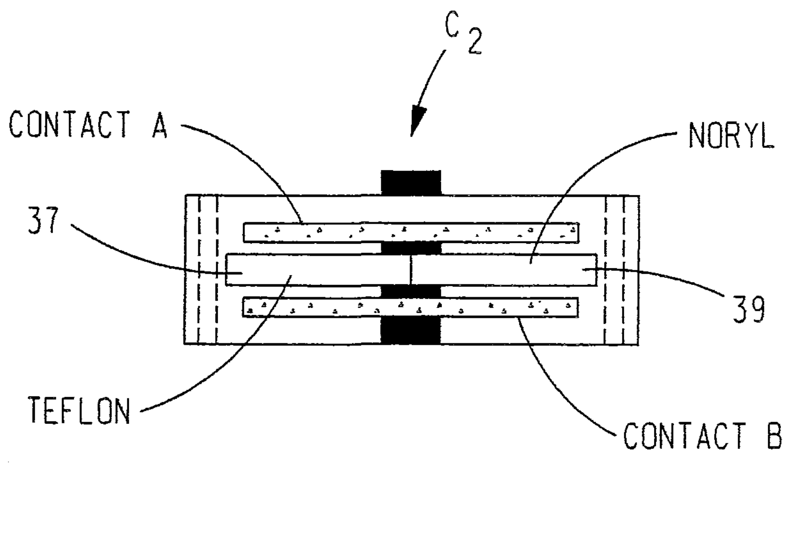

C2
CONTACT A
NORYL
37
39
TEFLON
CONTACT B

FIG. 6B