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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
15 September 2011 (15.09.2011)

PCT

(10) International Publication Number
WO 2011/111008 A1

(51) International Patent Classification:
H01Q 5/00 (2006.01) *H01Q 1/22* (2006.01)
H01Q 9/42 (2006.01) *H01Q 1/27* (2006.01)

(21) International Application Number:
PCT/IB2011/050991

(22) International Filing Date:
9 March 2011 (09.03.2011)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
00335/10 11 March 2010 (11.03.2010) CH

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(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, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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(54) Title: TELEMETRY SYSTEM FOR SENSING APPLICATIONS IN LOSSY MEDIA

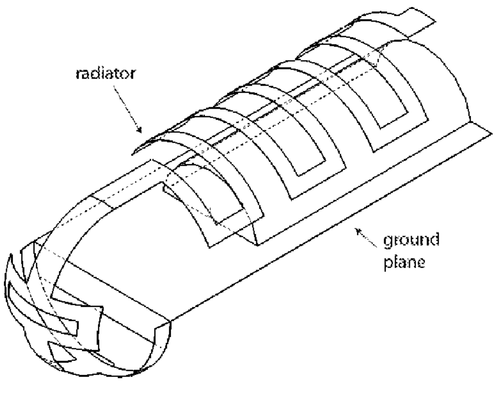

FIG. 4 (d)

(57) **Abstract**: Wireless communications in lossy media encounter growing interest, with applications as telemedicine, ground sensing, remote pipeline sensing, and food quality testing among others. As an application, an autonomous implantable Body Sensor Node for monitoring physiologic parameters or for controlling therapeutic devices is disclosed. The system is miniaturized and has been designed to be cylindrical so that it can be implanted into the patient in a minimally invasive way. The system may contain one or several self contained sensing devices or electronics necessary to control a therapeutic device. It consists of one or several analog and digital front ends to interface or control any kind of sensors or therapeutic devices, a programmable microcontroller or Digital Signal Processor, one or several secondary or primary batteries, a prospective battery recharge mechanism, a RF telemetry compliant with MedRadio band, a sealed biocompatible casing featuring an ergonomic shape and an anchoring mechanism to prevent the system to rotate or migrate, and an external control unit. The overall Body Sensor Node size may vary depending on the power consumption required by the application and on its recharging capabilities, but also depending on the sensor or therapeutic device interface size. As part of a network, several nodes may communicate and exchange information with the external control unit leading to complex biological application schemes.

WO 2011/111008 A1

Published:

— *with international search report (Art. 21(3))*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

Telemetry system for sensing applications in lossy media

Field of the invention

This invention relates generally to sensing devices and their components which are embedded in lossy media and wirelessly controllable.

Background of the invention

Wireless communications in lossy media encounter growing interest, with applications as telemedicine, ground sensing, remote pipeline sensing, and food quality testing among others. For instance,

telemedicine allows healthcare professionals to use “networked” and “connected” medical devices for the purposes of evaluating, monitoring, diagnosing and treating patients located in remote locations.

Remote patient monitoring is a branch of telemedicine that focuses on providing home health services using telehealth technologies. Currently focused on chronic disease management, it involves the use of technology that allows a remote interface to collect and transmit patient data between a patient and a healthcare care provider.

Chronic diseases occur across the wide spectrum of illness, mental health problems and injuries. They tend to be complex conditions that are often long lasting (over 6 months) and persistent in their effects. Chronic diseases can produce a range of serious complications and have a significant impact on a person’s life. They are also among the most costly and burdensome for the healthcare system. Management of chronic illnesses can help reducing the severity of the symptoms and the impact on the patient. The management of chronic diseases can involve medication and/or lifestyle modifications such as diet, exercise and attitude or stress management.

The chronic diseases that are currently believed to be the most amenable to remote patient monitoring technologies are:

- Diabetes;
- Congestive Heart Failure (CHF);
- Chronic Obstructive Pulmonary Disease (COPD) and Asthma;

- Hypertension.

But for instance pain management may also be concerned by remote monitoring.

For this purpose, special frequency bands have been allocated for implantable medical devices using RF telemetry, such as the MICS (Medical Implantable Communication Service) band ranging from 402-405 MHz and the MedRadio (Medical Device Radio communication Service) band that extends the range to 401-406 MHz. The limited battery capacity in implantable medical devices presents a challenge in operating a RF transceiver at such frequencies. However, the power consumed by the components of the implantable medical device can be optimized by keeping the components in a power off or low power "sleep" state when they are not being utilized.

The Body Sensor Node disclosed here makes use of this strategy.

Summary of the invention

An autonomous implantable Body Sensor Node as defined in claim 1 for monitoring physiologic parameters is provided.

The node may also perform therapeutic functions.

The node is miniaturized and has been designed to be cylindrical so that it can be implanted into the patient in a minimally invasive way.

The node may contain one or several self contained sensing devices or electronics necessary to control a therapeutic device.

The above mentioned features are achieved by a self contained implantable system which consists of one or several analog and digital front ends to interface or control any kind of biosensors or therapeutic devices, a programmable microcontroller or Digital Signal Processor, one or several secondary or primary batteries, a prospective battery recharge mechanism, a RF telemetry compliant with MedRadio band or any other Radio band dedicated to this aim, a sealed biocompatible casing featuring an ergonomic shape, an anchoring mechanism to prevent the system to rotate or migrate, and an external control unit.

The circuits, the sensing device(s), the batteries, a prospective battery recharge mechanism and the antenna are packaged together and sealed hermetically to the biologic environment. The control unit that is larger remains outside the body but close to the implantable system for minimizing communication distance, typically 2 to 3 meters.

The overall system size may vary depending on the power consumption required by the application and on its recharging capabilities.

As part of a network, several nodes may communicate and exchange information with the external control unit leading to complex biological application schemes.

Brief description of the drawings

FIG. 1 is a side, and front view of the Body Sensor Node and shows possible casing external shapes

FIG. 2 is an exploded view of the Body Sensor Node

FIG. 3 presents views of the flexible substrate circuit (unfolded and folded), of the assembly with the matching network circuit and of the chip-on-flip-chip assembly

FIG. 4 shows different radiators designs

FIG. 5 is an example of a pyramidal structure fitting the cylindrical casing

FIG. 6 is an example of a pyramidal structure (isometric view)

FIG. 7 is an example of insulating hollow cylinder whose internal surface is metalized to realize part of the ground plane

FIG. 8 is an example of antenna radiator shape

Detailed description

The Body Sensor Node may include one or more sensors for monitoring a variety of parameters, such as temperature, pressure, acceleration, strain or fluid flow and chemical, electrical or magnetic properties. It may also perform therapeutic functions such as drug delivery or electrical stimulation. Local digital signal processing will allow the node to act smartly and transmit only significant data in an autonomous manner, reducing its power needs and communication bandwidth. As part of a network, several nodes may communicate and exchange information with the external control unit leading to complex biological application schemes. The control unit may be placed on the patient’s skin (e.g. implemented into a wrist watch) or close to the patient (e.g. contained in a hand held device as a smart phone, a PDA…) or in the neighborhood of the patient (e.g. in the nightstand in his bedroom), and it will control and communicate remotely with the implanted nodes. Moreover, the control unit may be used as a data logger, which relays the recorded data from the body sensor nodes network, towards the patient's environment via cellular, Plain Old Telephone Service (POTS) or IP based networks (e.g. IEEE 802.15 Wireless PAN).

Two operational strategies depending on the application may be envisaged.

In the preferred one, the Body Sensor Node is intended to autonomously record every few minutes a physiologic parameter as for instance blood glucose levels in a diabetic patient. The node computes trends towards hyperglycemia and hypoglycemia, and alerts the patient through the external control unit when values are out of the normal glycemia range. Nevertheless, the Body Sensor Node may be waked-up and interrogated by the control unit at any time through the sniff mode described hereafter.

The second one is governed by very low power consumption in standby mode. It is ideally suited for applications requiring short measurement time and only few measurements per hours. To achieve the lowest power in standby mode, all components are turned off and the RF transceiver is kept in its lowest power state that consists in listening in the band dedicated to a wake-up signal (sniff mode). When this signal occurs, a measurement is triggered and the transceiver is waked-up that will further wake-up the other components. As soon as the measurement is performed, the node sends the data to the base station through its RF transceiver. After the transmission is complete, the microcontroller or the Digital Signal Processor sets the RF transceiver in standby mode that will result in powering off all the components of the node.

The telemetry circuit consists of a medical RF transceiver, a matching network, a single, dual or multiband antenna operating in the appropriate frequency bands e.g. the Medical Device Radio communication Service band (MedRadio, 401-406 MHz), the Medical Implantable Communication Service (MICS, 402-405 MHz) or the Industrial, Scientific and Medical band (ISM, 2.4-2.5 GHz). The implant is small in size so that it may be positioned to the desired location and implanted using a trocar or a catheter. It may also be implanted surgically by creating a small superficial incision.

The Body Sensor Node assembly is shown on FIG. 1 (a) and FIG. 2. The electronic components are assembled onto a two levels bended substrate that is fixed on the antenna structure. The antenna is composed of two parts: the radiator and the ground plane. The ground plane is part of the surface of the holder dimensioned here for up to four SR66 batteries. This results in an asymmetric positioning of the radiator, with respect to the casing axis, and in an enhancement of the directivity of the radiator from inside to outside the body. All the Body Sensor Node components are enclosed in an insulating biocompatible cylindrical housing hermetically sealed featuring an ergonomic shape and an anchoring mechanism to prevent the system to rotate or migrate (FIG. 1 (b)). Beside the batteries, a small empty volume is left free in the housing to place the sensing device(s).

The Body Sensor Node comprises two separate circuits. One contains the front end electronics, the programmable microcontroller or Digital Signal Processor and the RF transceiver (FIG. 3 (a)) while the other the matching network (FIG. 3 (b)). The two circuits, the sensing device(s), the batteries, the recharge mechanism, and the dual band antenna are packaged together and sealed hermetically to the biologic environment (FIG. 2). The larger control unit remains outside the body but close by the implantable system for minimizing communication distance.

The Body Sensor Node disclosed here is generic. As the flexible substrate circuit may support a wide variety of electronic components, some of them may be replaced depending on the application requirements. For instance, a microcontroller instead a Digital signal Processor may be implemented if the computation power required by the application is less demanding. In the same way, the number of primary or secondary batteries may be decreased if the application consumes less power. Changing the battery number will impact the battery holder surface that is also the ground plane of the antenna. The consequence is a little shift in the resonant frequency and a small reduction of the antenna gain. Nevertheless, the Body Sensor Node will still transmit data up to several meters if the battery holder length is not too reduced compared to the primary design. Otherwise, the matching network can be retuned and that is why it has been located on a separate circuit.

The two levels flexible substrate circuit is depicted on FIG. 3. The flexible circuit encompasses the front ends, the microcontroller or the Digital Signal Processor, the RF transceiver, the prospective recharge mechanism and the matching network circuit that encompasses the components to act as a filter separating the different working frequencies (e.g. MICS and ISM).

The two levels flexible substrate circuit assembly steps are as follows:

1) All the electronic components excepted for the RF transceiver and matching network circuit are mounted and soldered using a reflow oven;
2) The RF transceiver is then glued onto the flip-chip Digital Signal Processor and bonded. To protect the bonding, the chip-on-flip-chip assembly is covered by an epoxy (FIG. 3 (c));
3) The passive components of the matching network are mounted and soldered;

4) Then the matching network circuit is glued on the flexible substrate circuit and matching connection vias are soldered on the corresponding pads of the flexible substrate circuit;
5) The final assembly step consists in gluing the first level of the two levels flexible substrate circuit onto the antenna ground plane, in soldering the ground connection via and the antenna pin on the corresponding pad on the matching network circuit;
6) Then the two levels flexible substrate circuit is folded and glued to maintain in place the bending. The batteries can be inserted into the battery holder and wire connected to the flexible substrate circuit on its top connection pads;
7) Finally the resulting assembly is inserted into the biocompatible casing.

The antenna comprises three dimensional conductive elements combining, spherical, cylindrical, planar and vertical strips as illustrated in FIG. 4. This facilitates the current distribution over the structure resulting in an efficient electromagnetic radiation. Additionally, this 3-D metallization without a unique geometrical linear development (like monopoles, dipoles and patches antennas) results in an elliptical polarization of the antenna, which is much more favorable for multipath wireless communications than a linear polarization. This is crucial for the indoor communication with other devices (external or intra-body) as the polarization of the radiated/received electromagnetic field is affected by the presence of the external environment and by living body itself.

The antenna structure is formed by two main parts: the ground plane and the radiator as illustrated by the examples of FIG. 4. These two elements are separated by a dielectric (homogeneous or not) substrate. The ground plane comprises a planar and in a cylindrical hollow conformal design. Possible examples are indicated in FIG. 4. Its placement in the medical device, which is in between the radiator and that circuitry, fulfills four main purposes. First, it separates the radiating part from the circuitry, the power supply and sensor/device. This makes the performance of the antenna independent on the specific substrate circuit or batteries presence thus, improving the versatility of the design. Second, it improves the directivity of the radiation reinforcing the effect of the asymmetric placement previously explained. Third, it provides a mechanically robust structure for the circuitry, batteries and the desired sensor. Finally, it is conformal to the flexible substrate circuit, the selected batteries, the sensor and to the external casing optimizing the use of the available volume for the antenna. According to the latter characteristic, the ground plane as the ground plane can be described as double conformal.

The radiator part comprises a specific design, electrically connected to the ground plane, whose particular dimensions enable self-resonance at the desired single or dual working frequencies. Possible examples are indicated in FIG. 4. The single, dual or multi band capabilities improve the communication possibilities of the medical device providing different channels for the data communications (with different propagation properties) and/or allowing power saving modes [US/0229053]. Self-resonance allows an efficient radiation of the electromagnetic field and, at the same time, minimizes the use of a matching circuit for the connection to the necessary electronics or to any measurement setup.

The feeding of the antenna can be obtained by connecting a signal member to the radiator. The signal member may consist in a metallic stiff connected to the radiator and extending the ground plane (but without any contact with it) at a particular position [US/0216793].

In another arrangement, a metalized via can be realized in the dielectric substrate at the same position. The metalized via is in electrical contact with the radiator only. This alternative results in an efficient (and mechanically robust) feeding.

In another arrangement, the feeding of the antenna could consist of a signal member electromagnetically coupled to the antenna without galvanic connection.

A general advantage of the present invention, in particular of the implantable antenna, is that the radiator design can be arranged in order to obtain a single feeding point for two or more working frequencies. This simplifies and minimizes the circuitry for the connection between the antenna and electronics. Moreover, it is also possible to pre-set the area where the feeding point has to be located in order to minimize the circuitry and the printed circuit size.

In a preferred embodiment, the radiator consists of a multilayer stacked structure resulting in a peculiar pyramidal design to fit the available volume, as shown in FIG. 4 (c) and FIG. 5. Conductive lines, following a spiral design, are realized via chemical etching of metalized substrates with relatively high dielectric constant (such as alumina). The number of substrates is more than two and their pyramidal assembling fits the available volume as shown in FIGs. 5-6. Vertical metallic pieces, which could be made of brass, copper and copper-beryllium, provide connection among the metallic strips of each substrate and with the ground plane. Substrates and metallic strips dimensions are dependent on the dual band performances in order to obtain efficient radiation. The largest substrate is double face while the others are as well single face or even not metalized depending on the selected working frequencies.

In the aforementioned embodiment, the ground plane is formed by the bottom conductive surface of the largest substrate and the metallization (for instance with the use of a copper foil) of the internal surface of insulating hollow cylinder. The hollow cylinder, depicted in FIG. 7, hosts the required power supply.

In a second alternative preferred embodiment, the radiator consists in metallic lines conformal to a cylindrical surface, as shown in FIG. 4 (a-b). The conductive lines can follow different geometry such as spiral or meander in order to obtain self-resonance at the desired working frequencies. In this solution a single substrate, machined with the desired shape (examples are reported in FIG. 8) is the support for both the metallic part and the conformal ground plane. The substrate is fully metalized and, subsequently, the peculiar design is realized, for instance, with laser ablation techniques.

In another preferred embodiment, the radiator consists in a cylindrical and semi-spherical design as indicated in FIG. 4 (d). Similarly as the previously presented embodiment, a single substrate piece supports both the metallic part and the conformal ground plane (examples in FIG. 8). This embodiment might be preferable for implant locations that require a more omnidirectional radiation (depending on the performance of the wireless external network or on the implanted device location).

In another preferred embodiment, the ground plane comprises a closed geometry. It confines completely the circuitry and power supply exception made for the connections to the antenna and the sensor or therapeutic device.

A dedicated matching network circuit is included in the flexible substrate circuit to avoid any impedance discontinuity between the antenna input impedance and the RF transceiver.

The matching circuit acts as filter separating the working frequencies in a dual or multi band setup. Moreover, the matching circuit is placed on a separate circuit that is mounted on the main flexible substrate circuit. This improves the flexibility of the implantable telemetry device as the matching circuit characteristic can be modified independently of the main circuitry.

A general advantage of the present invention, and in particular of the implantable antenna, is the simple testing procedure of the antenna alone. In fact, despite the fact that the antenna is meant to work with the integrated electronics and power supplies, it is very useful to validate its performances avoiding costly full system measurements. This is performed with a feeding coaxial cable and the insertion of the radiator in a body phantom (that is a liquid, solid or fluid material with dielectric properties similar to those of the human tissues). The battery holder part of the ground plane is relatively less important for the electromagnetic radiation. Therefore, it is as easy as varying the deepness of the insertion of the antenna inside the body phantom to obtain correct validation of the performance of the radiator alone without suffering any feeding cable effect.

Thus, embodiments for GENERIC IMPLANTABLE BODY SENSOR NODE are disclosed. One skilled in the art will appreciate that the present invention can be practiced with embodiments other than those disclosed. The disclosed embodiments are presented for purposes of illustration and not limitation, and the present invention is limited only by the claims that follow.

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US/0229053

US2004206916

CLAIMS

1. An antenna suitable for a lossy environment, such as a biological or living environment, comprising :
   - multi-frequency self resonating capabilities for radio Frequency communication (RF) via far field electromagnetic radiation;
   - a single excitation for all working frequencies;
   - a metallic radiator part adapted to fit and/or follow the geometry of the sealed biocompatible dielectric casing;
   - a double conformal ground plane following the external geometry of said casing and designed to host internal elements such as electronics, sensing/acting device(s) and power source(s);

   wherein the said radiator consists in a conductive strip placed on different dielectric substrate arrangements comprising one of the following:
     - multilayered stacked structure consisting of a pyramidal assembling made of at least two substrates with relatively high dielectric constant (e.g. alumina);
     - cylindrical and/or semi-spherical structure realized on a single dielectric substrate with relatively high dielectric constant via, for instance, laser ablation.

2. An antenna according to claim 1 wherein said single excitation point is pre-set in a desired area allowing the minimization of the volume occupancy of the said internal elements.

3. An antenna according to claim 1 where the said radiator has a three dimensional metallic structure made of curved and/or planar conductive strips; the radiator dimensions and geometry enabling self-resonance for the desired frequency bands and thereby facilitating the communication when working at any given polarization.

4. An antenna according to claim 1 wherein said double conformal ground plane provides robust mechanically support for the circuitry, power supply and

sensing/acting device while preventing any electromagnetic interference between the said radiator and the said internal elements.

5. An antenna according to claim 1 wherein said double conformal ground plane and the said casing length is shortened/lengthened in order to fulfill the self-contained sensing/acting device and power source volumes requirements while not modifying the electromagnetics characteristics.

6. An antenna according to claim 1 wherein the said dielectric biocompatible casing properties (thickness and dielectric characteristics) are chosen to
   - enhance the electromagnetic radiation;
   - minimize the dissipated power by the RF communication in the lossy medium;
   - provide limited sensitivity of the antenna performances with the respect to the particular antenna location (for instance, in the human body).

7. A telemetry system according to claim 8 or 9 in the form of a modular arrangement comprising (but not limiting to):
   - a matching network circuit;
   - a circuitry to generate and receive the modulated RF signal;
   - a microcontroller or a DSP;
   - a generic analog and digital front-end;
   - a power supply to feed the system;
   - a flexible substrate circuit that is folded to assembly in a three dimensional fashion all the electronic components using chip-on-flip-chip techniques to reach the minimal achievable volume.

8. A telemetry system comprising an antenna as defined in any of the previous claims.

9. A telemetry system according to claim 8 wherein said system is implantable.

10. An antenna according to one of the previous claims wherein said casing being smaller than 7 % of the free space wavelength of the lowest working frequency.

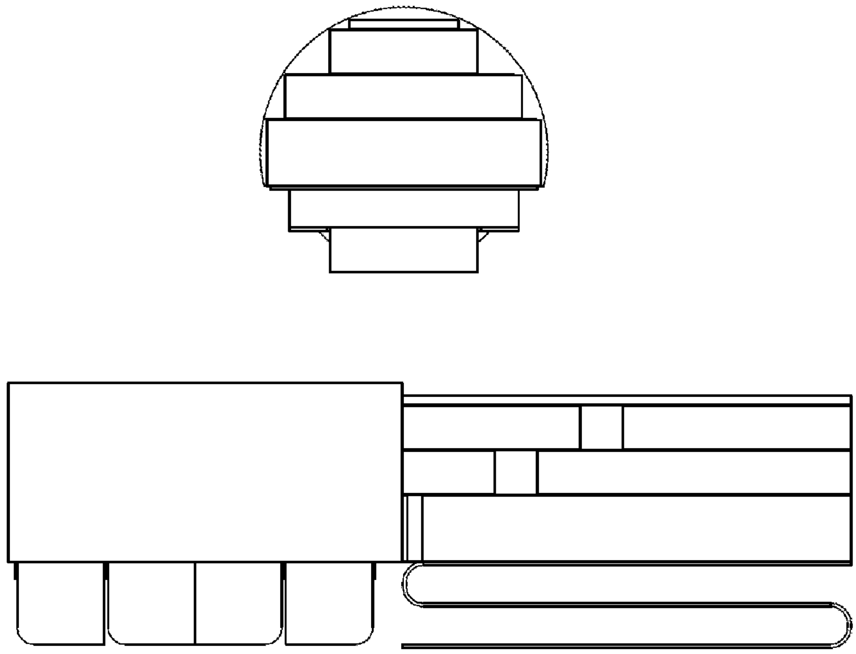

FIG. 1 (a)

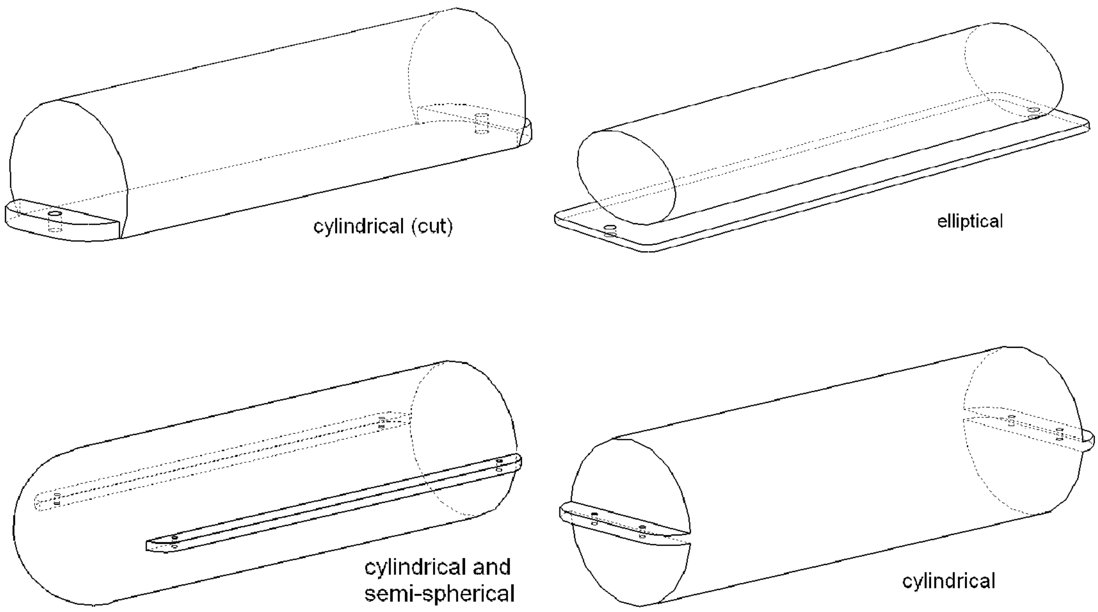
cylindrical (cut)
elliptical
cylindrical and
semi-spherical
cylindrical

FIG. 1 (b)

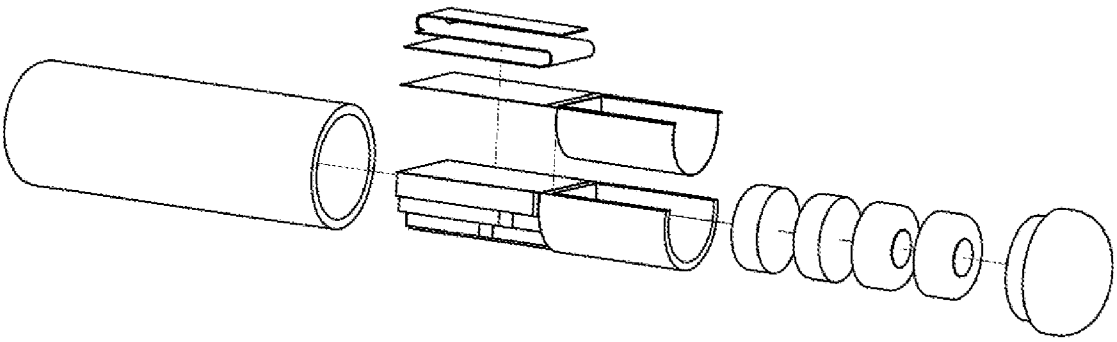

FIG. 2

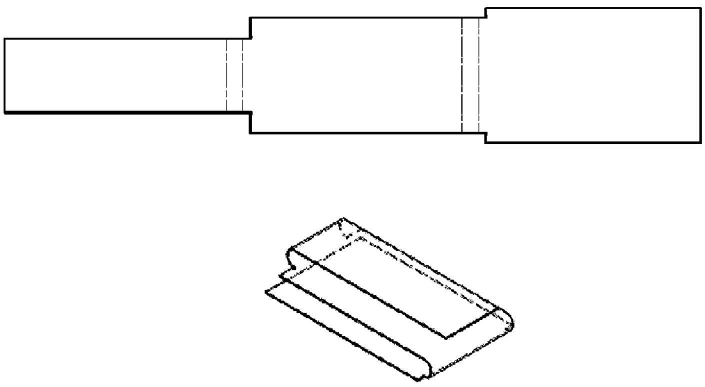

FIG. 3 (a)

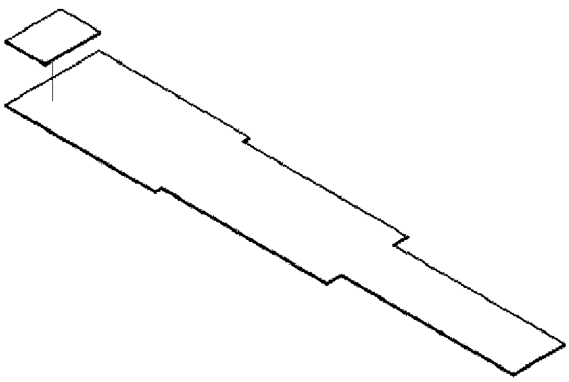

FIG. 3 (b)

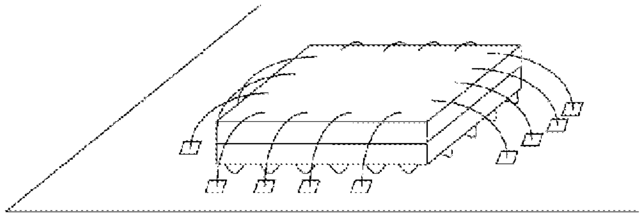

FIG. 3 (c)

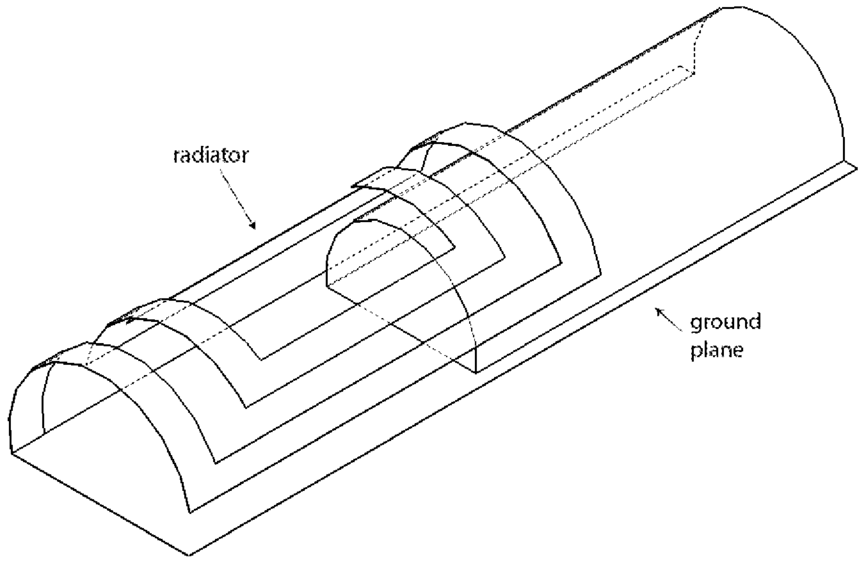

FIG. 4 (a)

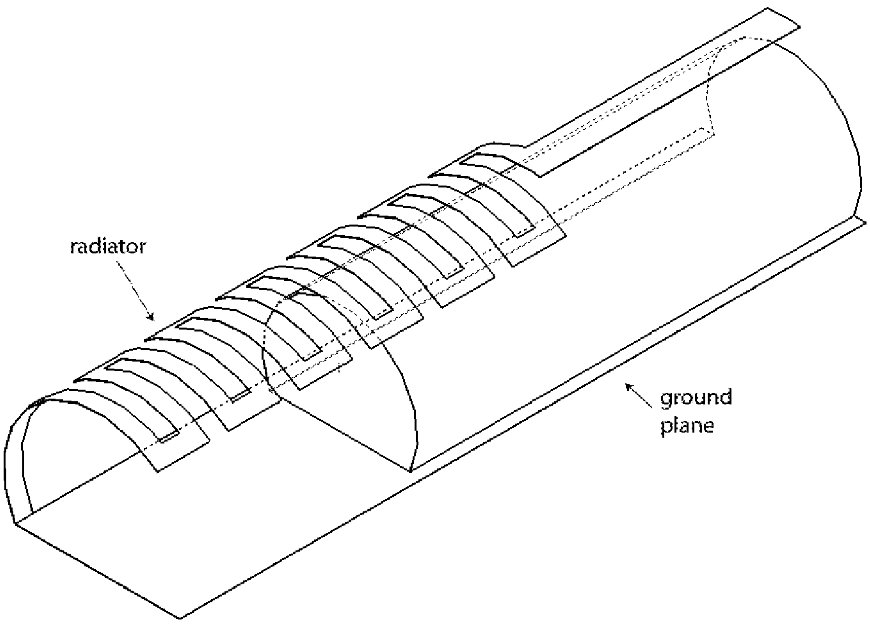

FIG. 4 (b)

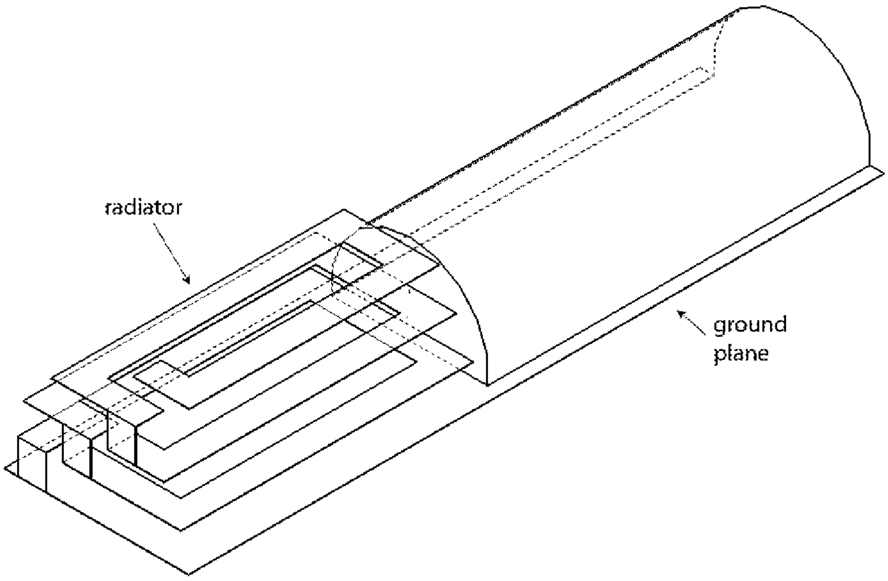

FIG. 4 (c)

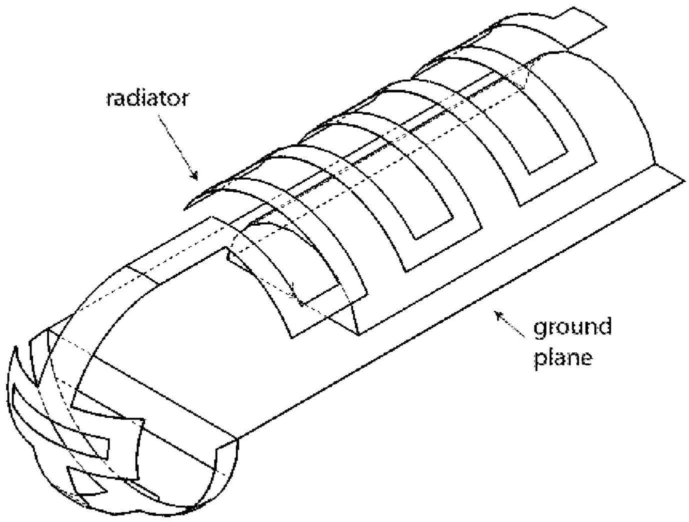

FIG. 4 (d)

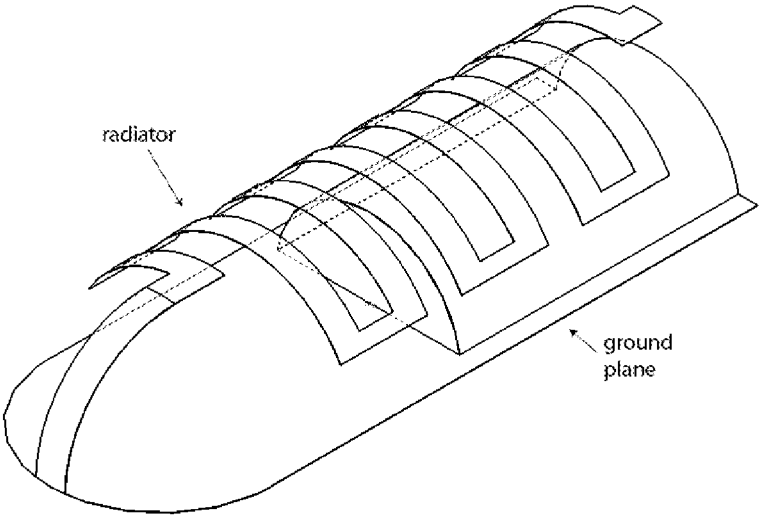

FIG. 4 (e)

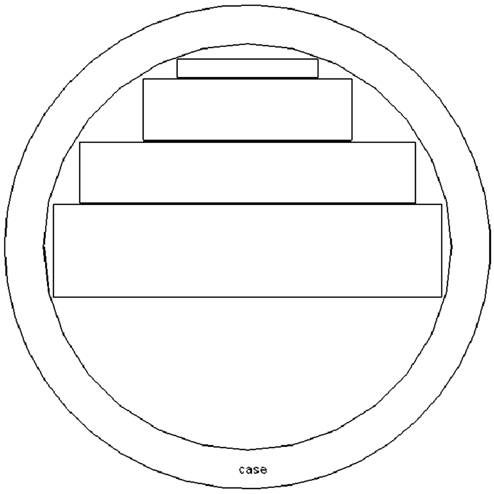

FIG. 5

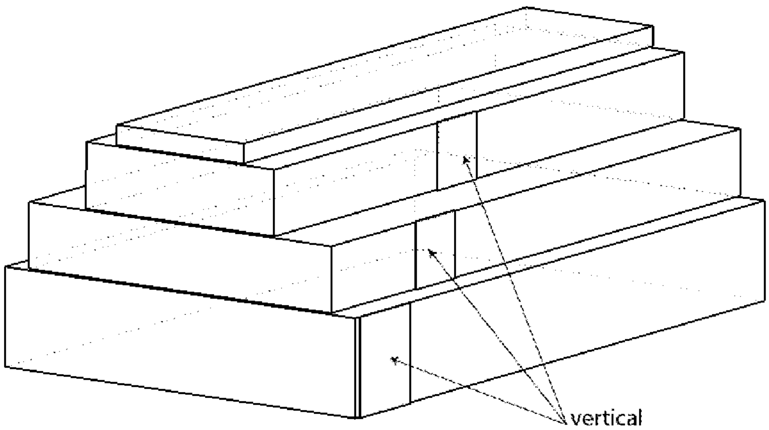

FIG. 6

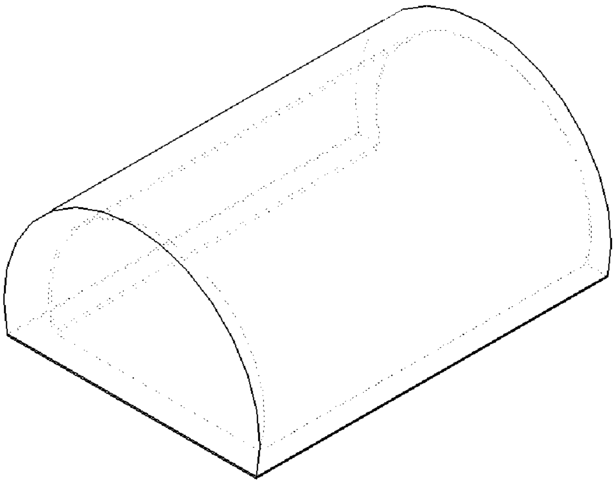

FIG. 7

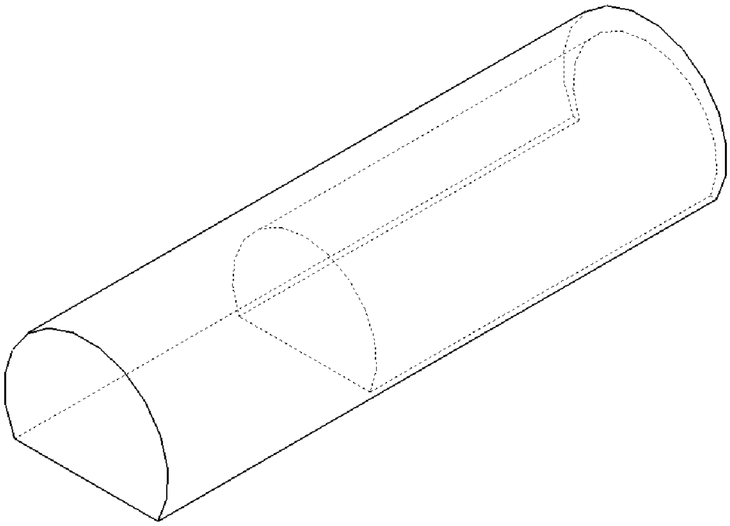

FIG. 8 (a)

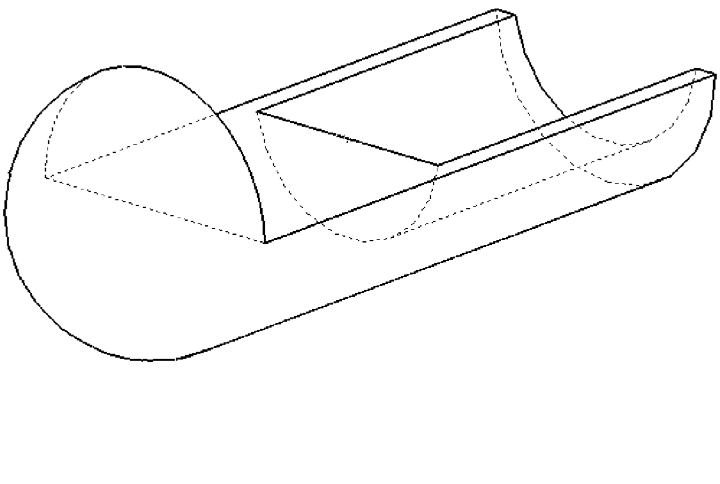

FIG. 8 (b)

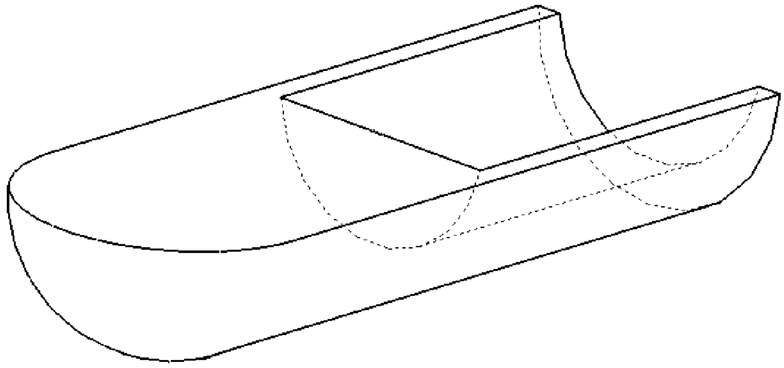

FIG. 8 (c)

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2011/050991

A. CLASSIFICATION OF SUBJECT MATTER
INV. H01Q5/00 H01Q9/42 H01Q1/22 H01Q1/27
ADD.

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)
H01Q

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.
Y	US 7 554 493 B1 (RAHMAN M MIZANUR [US]) 30 June 2009 (2009-06-30) abstract; figures 1-6 column 1, line 1 - column 8, line 12	1-10
Y	US 2009/228076 A1 (AMERI MASOUD [US]) 10 September 2009 (2009-09-10) abstract; figures 1-3,7-15 paragraph [0003] - paragraph [0143]	1-10

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
27 July 2011	04/08/2011

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, Fax: (+31-70) 340-3016	Hüschelrath, Jens

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2011/050991

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	MERLI F ET AL: "Implanted antenna for biomedical applications", ANTENNAS AND PROPAGATION SOCIETY INTERNATIONAL SYMPOSIUM, 2008. AP-S 2008. IEEE, IEEE, PISCATAWAY, NJ, USA, 5 July 2008 (2008-07-05), pages 1-4, XP031824104, ISBN: 978-1-4244-2041-4 the whole document -----	1-10
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A	WO 2009/052029 A1 (INTEL CORP [US]; CHOUDHURY DEBABANI [US]; SUH SEONG-YOUP [US]) 23 April 2009 (2009-04-23) abstract; figures 2,3,7 page 1, line 1 - page 5, line 28 -----	1-10
X,P	WO 2010/051249 A1 (MEDTRONIC INC [US]; MATEYCHUK DUANE N [US]; YAMAMOTO JOYCE K [US]; HIL) 6 May 2010 (2010-05-06) the whole document -----	1-10

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IB2011/050991

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