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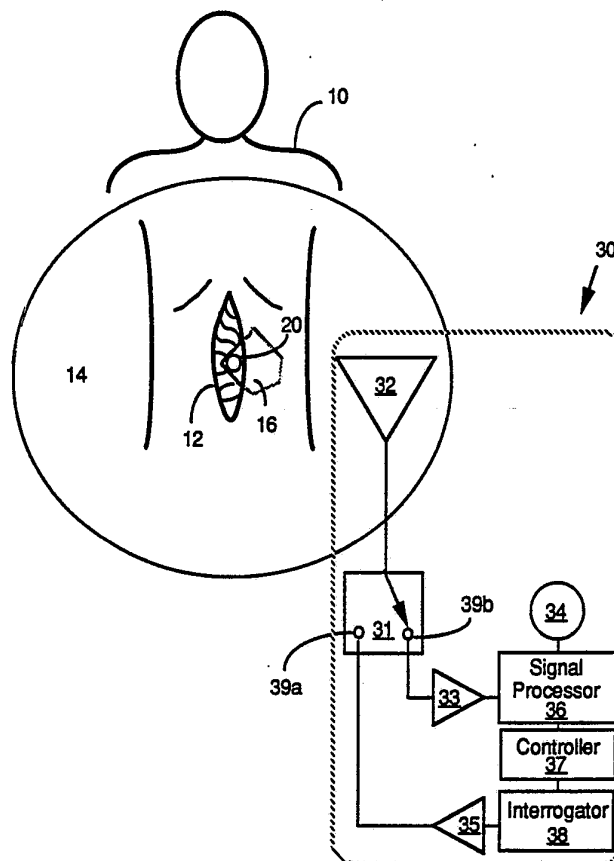
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(54) Title: SURGICAL IMPLEMENT DETECTOR UTILIZING A POWERED MARKER

(57) Abstract

An apparatus for detecting a surgical implement (16) in human or animal tissue has means for defining a transmitting zone (14) encompassing a surgical wound (12) in the tissue. A battery powered marker (20) is secured to a surgical implement (16) positioned within the wound (12). Field generating means (27) are provided for generating within the transmitting zone (14) an electromagnetic field having a predetermined frequency band. A signal generating (22) means generates a signal having a predetermined frequency band. The signal generating (22) means is operative to cause the field generating (27) means to generate the electromagnetic field, providing the marker (20) with signal identity. A detecting means (30) having an antenna (32) located within the transmitting zone (14) of the marker (20) detects the marker (20) signal irrespective of the marker's orientation therewithin.



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SURGICAL IMPLEMENT DETECTOR UTILIZING A POWERED MARKER

Background of the Invention

1. Field of the Invention

5 The present invention relates to a method for detecting a marked surgical implement such as a sponge, clamp, or a catheter within a surgical wound in human or animal tissue irrespective of its position or orientation therewithin.

2. Description of the Prior Art

10 During the course of a surgical operation it is frequently necessary for articles, such as surgical sponges, gauzes, instruments, needles, and the like, to be placed into a wound cavity. Notwithstanding rigorous precautions
15 attendant surgical procedures, such items are sometimes inadvertently lost during surgery and remain within the patient. When this happens, the patient can encounter serious consequences, including pain, infection, intestinal obstruction, and even death. The problem of retained surgical
20 implements has existed since the earliest days of surgery. Procedures conventionally employed to prevent post-surgical implement retention include a manual search of the wound by the surgeon prior to closure and a careful accounting for all materials inserted and removed from the wound. The accounting
25 function is customarily carried out by the operating room staff, usually the circulating nurse. Despite these precautionary measures the accidental retention of surgical implements continues to occur with disturbing regularity, even in prestigious institutions, and is regarded by surgeons
30 as a major unsolved problem.

At present, manual search and physical count remain the primary methods used in detection of retained surgical
implements. Most surgical instruments are composed of metal, and are easily detectable by x-ray. Sponges have been tagged
35 with radiopaque markers to make them also visible on x-ray, but x-rays are not routinely done before completion of the

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operation because of several disadvantages including inconvenience, expense, loss of operative time, and radiation exposure. Postoperative x-rays suffer from some of the same disadvantages. Moreover, even when postoperative x-rays are taken, retained items are occasionally overlooked; but even if detected, require a second operation to effect their removal.

To overcome the difficulty of detecting retained surgical implements, it has been suggested that the implements be provided with a radioactive tracer. This technique, disclosed by U. S. Patent 2,740,405 to Riordan, is subject to obvious hazards associated with use, storage and disposal of radioactive materials.

It has also been proposed that surgical sponges be marked with a flexible plastic impregnated with either paramagnetic or ferromagnetic materials in the form of powders. Detection of these marked sponges is accomplished by a metal detector. This method, taught by U. S. Patent 3,422,816 to Robinson et al., provides very small signals difficult to detect over the width of a patient's body. In addition, the Robinson et al. technique provides no discrimination against other metal objects, such as staples which, though present within the surgical wound, are appointed for retention therewithin.

Yet another proposal, advanced by U. S. Patent 3,587,583 to Greenberg, involves use of surgical sponges marked with magnetized particles whose presence is detectable with magnetodiodes. In practice, however, the magnetic field generated by these particles is too small to be readily detected by the diodes.

U. S. Patent 4,114,601 to Ables discloses the use of a small transponder fixed to a surgical sponge or instrument. This transponder exhibits gyromagnetic resonance at preselected frequencies. Detection is accomplished by nonlinear mixing of two frequencies impinging upon the transponder. The gyromagnetic resonance effect disclosed by

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Ables is a high frequency phenomenon, existing at frequencies of the order of about 5 gigahertz (5,000,000,000 cycles/sec). These frequencies, known as microwaves, are absorbed readily by animal tissue and are, in fact, used in microwave ovens for cooking. In use of the Ables type transponder, the energy developed goes primarily into heating tissue, rather than exciting the transponder into gyromagnetic resonance.

Summary of the Invention

The present invention provides a method and apparatus for accurately and reliably detecting surgical implements within animal or human tissue. The apparatus comprises a detector responsive to the presence, within a detection zone, of a surgical implement to which a marker is secured. The marker is adapted to produce identifying signal characteristics within the detection zone of the detector.

Generally stated the apparatus comprises means for defining a transmitting zone encompassing a surgical wound within human or animal tissue. A marker is secured to a surgical implement positioned within the wound, the marker being battery powered. The apparatus has a field generating means for generating an electromagnetic field having a predetermined frequency within the transmitting zone. A signal generating means is provided for generating a signal having a predetermined frequency band. The signal generating means is operative to cause the field generating means to generate the electromagnetic field, providing the marker with signal identity. A detecting means having an antenna located within the transmitting zone of the marker detects the marker signal irrespective of the marker's orientation therewithin.

More specifically, the marker comprises a miniature electronic transmitter enclosed within a water-tight case. The case is comprised of a plastic that remains inert to the body for the duration of the surgery. The transmitter is comprised of a battery and electronic circuit, and is adapted

to provide a unique identifying signal. A detector placed within the transmitting zone of the marker is adapted, irrespective of the orientation of such marker, to detect the marker signal and record such detection with visual and/or audio indicators.

Advantageously, the method and apparatus of the invention detect retention of surgical implements with far greater accuracy than methods and means involving a physical count of implements that enter and exit the wound. The apparatus is inexpensive to construct, safer for the patient than postoperative X-rays and avoids risk to the environment posed by radioactive tracers. Generation of a strong signal is effected in a highly reliable manner. The signal is more easily distinguished than signals generated by magnetic detection systems, and is generated without the heating of tissue caused by microwave detection systems.

Brief Description of the Drawings

The invention will be more fully understood and further advantages will become apparent when reference is made to the following detailed description of the preferred embodiment of the invention and the accompanying drawings in which:

Fig. 1 is a block diagram of a surgical implement detector incorporating the present invention;

Fig. 2 is a block diagram of a marker suited for use in the detector of Fig. 1;

Fig. 3 is a block diagram of a marker having an external tail antenna;

Fig. 4 is a diagram of a marker with a reed-switch starting means;

Fig. 5 is a side-view diagram of a wax-spacer starting means;

Fig. 6 is an isometric view of a shrink-tube starting means; and

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Fig. 7 is a schematic electrical circuit of a non-rechargeable marker therefore, and Fig. 8 is a block diagram of a surgical implement detector incorporating a coil antenna and a block diagram of a marker having a coil field generating means.

Description of the Preferred Embodiments

Referring to the drawings, there is shown in Fig. 1 a block diagram of a surgical implement detector incorporating the present invention. A marker 20 is secured to a surgical implement 16, such as a sponge, positioned within the wound. The marker 20 has means for defining a transmitting zone 14 encompassing a surgical wound 12 within patient 10. The marker, shown generally at 20 in Fig. 2, consists of a case 28 comprised of a material, such as ABS plastic, that will remain inert within the wound for the period of the surgery. Within the case 28 is housed a signal generating means 22, a field generating means 27, a starting means 26, a power means 24, and a recharging means 25. The configuration of field generating means 27 depends on the frequency of the signal produced by the signal generating means 22. Below 3 megahertz the field generating means 27 typically consists of a loop antenna comprised of one or more turns of enamel coated wire. Above 3 megahertz the field generating means 27 typically comprises a single lead, 2" or less in length, wound within the case and attached at one end to the signal generating means 22. Alternatively, as shown in Fig. 3, antenna 29 can be lengthened and connected through the case as a tail, thus enlarging the transmitting zone 14. In this case, the antenna 29 outside the case 28 is comprised of flexible, insulated wire. Upon being activated by a signal from the detector, shown generally at 30, the starting means 26 causes the power means 24 to be connected to the signal generating means 22 which, in turn, is connected to the field generating means 27. The resulting field is transmitted within zone 14 for a predetermined period of time. The starting means 26 is comprised of a narrow band receiver 26a tuned to receive said signal from detector 30, a timing circuit 26b, and a switch

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26c. Timing circuits are well known in the art and can be constructed from a type 555 timer, where a resistor and capacitor establish said predetermined time. Switch 26c is typically a simple transistor. The power means 24 is typically a rechargeable battery, such as NiCd, periodically refreshed by the recharging means 25. The recharging means 25 is comprised of a coil of wire connected to an ac to dc rectifier. An external ac source is inductively coupled via a coil to the coil in the recharging means 25. Alternatively, the recharging means 25 is comprised of two external contacts through the case 28. Recharging is accomplished by direct connection with an external dc source.

The detector 30 comprises an antenna 32, an electronic switch 31, a controller 37, an interrogator 38 and its amplifier 35, a signal processor 36 and its filtering preamplifier 33, and an indicator 34. The controller 37 acts as a common timing element for the processor 36, the interrogator 38, and the switch 31. The switch 31 connects the antenna 32 to either the processor preamp 33 or the interrogator amp 35 and contains the appropriate impedance matching elements for each connection.

When activated by operating room personnel, the controller 37 causes the switch 31 to connect antenna 32 to position 39a. The controller next causes the interrogator 38 to generate a single signal burst or, alternatively, a periodic signal burst, enhanced by amplifier 35 and transmitted through switch 31 and antenna 32 to the marker 20, thereby activating the marker's starting means 26 as described above. The signal transmitted into zone 14 by the marker 20 is received by the detector 30 through its antenna 32, placed within zone 14. The controller next causes switch 31 to connect antenna 32 to position 39b. After filtering and amplification by preamp 33 and verification of the received signal by the processor 36, the indicator 34 is activated. The indicator is comprised of visual and/or aural transducers, such as a light and/or a buzzer. The

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configuration of the detector antenna 32 depends on the frequency of the marker signal, as does the marker's field generating means 27. Typically, below 3 megahertz the antenna 32 is a coil and above 3 megahertz it is typically a single-
5 end lead or whip antenna.

Alternatively, the power means 24 is not rechargeable but comprises an alkaline or lithium battery. The signal transmitted by the marker 20 is of sufficiently long duration, at least $1/f$ milliseconds where f is the frequency
10 of transmission in kilohertz, to be detected by the detector 30. In this manner, power usage is minimized and battery life is maximized. The marker construction is simplified by elimination of the recharging means 25.

In a second embodiment of the invention, with reference
15 to Fig. 4, switch 31, interrogator 38 and amplifier 35 of detector 30 are eliminated. With this embodiment, the starting means 26 of marker 20 must be manually activated by operating room personnel before the marked implement 16 is placed within the wound 12. Marker 20 is rechargeable or,
20 alternatively, nonrechargeable as described in the previous embodiment. The starting means 26 is comprised of a normally-closed reed switch 42. A permanent magnet 44 placed on the outside of the case causes the switch 42 to be in the open position. Removing, demagnetizing, or reorienting magnet 44
25 by 90 degrees causes the switch 42 to close, thereby energizing the generating means 22. This, in turn, causes marker 20 to transmit a periodic signal. Detector 30, with the elimination of the interrogator 38, works as described in the previous embodiment. Replacing, remagnetizing or
30 reorientating the magnet 44 causes switch 42 to open and marker 20 to cease transmitting.

In a third embodiment of the invention, described with reference to Fig. 5, the starting means can be activated only once, the activation being accomplished by operating room
35 staff prior to the marker's first use. The marker's power means 24 is nonrechargeable and the recharging means 25 is

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eliminated. The starting means 26 is heat-activated and it is comprised of a spring-loaded battery contact 52 and an insulating wax spacer 54. Alternatively, battery 24 is coated with wax 54, thereby electrically insulating battery contacts 52 and 56 from battery 24. The wax 54 is selected to have a melting point, preferably at the standard operating point of gas sterilizers, approximately 140 degrees Fahrenheit. Beeswax and paraffin meet this criterion. Melting of the wax 54 causes the spring-loaded or cantilevered contacts 52 and 56 to close against battery 24 energizing the generating means 22, whereby marker 20 transmits a periodic signal. Alternatively, as shown in Fig. 6, starting means 26 is comprised of a sleeve of heat-shrink tubing 62 placed around two cantilevered contacts 63. Heat-shrink tubing typically requires temperatures of 100 degrees centigrade to activate and cannot therefore be in low temperature gas sterilizers but must be activated by steam or boiling water baths. Heating causes tubing 62 to contract and close the two cantilevered contacts 63, causing marker 20 to transmit a periodic signal. Detector 30 works as described in the previous embodiment.

EXAMPLE I

To further illustrate the present invention, a marker was constructed using the circuit shown in Fig. 7. Numerous other circuit configurations are viable, but the circuit specified in Fig. 7 was chosen for its simplicity. Inductors 76 and 78 were constructed as 1/4 inch diameter by approximately 1/3 inch length air-core coils each comprised of 10 turns of 24 gauge magnet wire. Resistor 74 was 200K ohms and capacitor 72 was a 10 mfd Tantalum. NPN transistor 70 was 2N2222. Battery 24 was a 1.5V button type EP675 and reed switch 42 was a normally closed type. The circuit was placed on a 3/4 inch diameter mounting board and housed within a water-tight case having a threaded lid. No antenna lead was used. A 1 inch bar magnet placed outside the case but parallel to reed switch 42 was sufficient to open switch

42 causing the marker to be inactive. On removing the magnet, switch 42 closes, causing marker 20 to emit a broad frequency signal having a range from about 15MHz to 30MHz and modulated at approximately 1Hz. The signal was received by an ordinary shortwave radio in the aforesaid frequency range at up to 10 feet with all orientations of the marker 20, even when the marker 20 was surrounded on all sides by at least 9 inches of water.

EXAMPLE II

The procedure of Example I was repeated except that the marker used was provided with a 3 inch tail antenna as illustrated in Fig. 3. The marker's transmit zone 14 increased by approximately 50 %.

EXAMPLE III

A marker was placed within a human cadaver. The marker used had the construction described in Example I, except that the starting means 26 was comprised of two contacts manually closed causing marker 20 to emit a broad frequency signal having a range from about 15MHz to 30MHz and modulated at approximately 1Hz. The detector comprised an ordinary shortwave radio with an insulated wire monopole antenna placed on the operating table along side the body. All orientations of the marker were detected.

Having thus described the invention in rather full detail, it will be understood that such detail need not be strictly adhered to but that various changes and modifications may suggest themselves to one skilled in the art, all falling within the scope of the invention as defined by the subjoining claims.

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What is claimed is:

1. An apparatus for detecting a surgical implement in
5 human
or animal tissue, comprising:

(a) means for defining a transmitting zone, encompassing
a surgical wound in said tissue;

(b) a marker secured to a surgical implement positioned
10 within said wound, said marker being battery powered;

(c) field generating means for generating an
electromagnetic field having a predetermined frequency band
within said transmitting zone;

(d) signal generating means for generating a signal
15 having a predetermined frequency band and being operative to
cause said field generating means to generate said
electromagnetic field, providing said marker with signal
identity; and

(e) detection means having an antenna located within
20 said transmitting zone of said marker.

2. An apparatus as recited in claim 1, wherein said
marker further comprises a starting means.

3. An apparatus as recited in claim 2, wherein said
starting means is adapted to connect said battery to said
25 signal generating means to cause said marker to be activated.

4. An apparatus as recited in claim 1, wherein said
detection means comprises a processor for detecting and
verifying said activation of said marker.

5. An apparatus as recited in claim 1, wherein said
30 detection means further includes an indicating means for
providing an audible or visible alarm when said marker is
activated.

6. An apparatus as recited in claim 1, wherein said
detection means comprises means for causing said starting
35 means to activate said marker.

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7. An apparatus as recited in claim 1, wherein said detection means further comprises an interrogator for generating a signal having a predetermined frequency band.

5 8. An apparatus as recited in claim 7, wherein said detection means further comprises a switch for connecting said antenna to either of said processor and said interrogator.

10 9. An apparatus as recited in claim 1, wherein said battery of said marker is rechargeable.

10 10. An apparatus as recited in claim 1, wherein said marker further comprises a recharging means.

15 11. An apparatus as recited in claim 10, wherein said recharging means of said marker is adapted to be inductively coupled to an external ac power source.

15 12. An apparatus as recited in claim 10, wherein said recharging means of said marker is adapted to be directly coupled to an external dc power source.

20 13. An apparatus as recited in claim 2, wherein said starting means of said marker comprises a magnetically activated reed switch.

14. An apparatus as recited in claim 3, wherein said starting means of said marker is adapted to be thermally activated.

25 15. An apparatus as recited in claim 3, wherein said starting means of said marker comprises two contacts within a sleeve of heat-shrink tubing.

16. An apparatus as recited in claim 3, wherein said starting means of said marker comprises two spring loaded contacts separated by wax.

30 17. An apparatus as recited in claim 1, wherein said field generating means of said marker comprises an external tail antenna.

18. A method for detecting a surgical implement in human or animal tissue, comprising the steps of:

35 (a) defining a transmitting zone, encompassing a surgical wound in said tissue;

(b) attaching a marker to a surgical implement appointed for disposition within said wound, the marker being battery powered;

5 (c) generating an electromagnetic field having a predetermined frequency band within said transmitting zone;

(d) generating a signal having a predetermined frequency band and being operative to initiate generation of said electromagnetic field, providing said marker with signal identity; and

10 (e) receiving said signal by an antenna located within said transmitting zone to detect said marker.

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Fig. 1

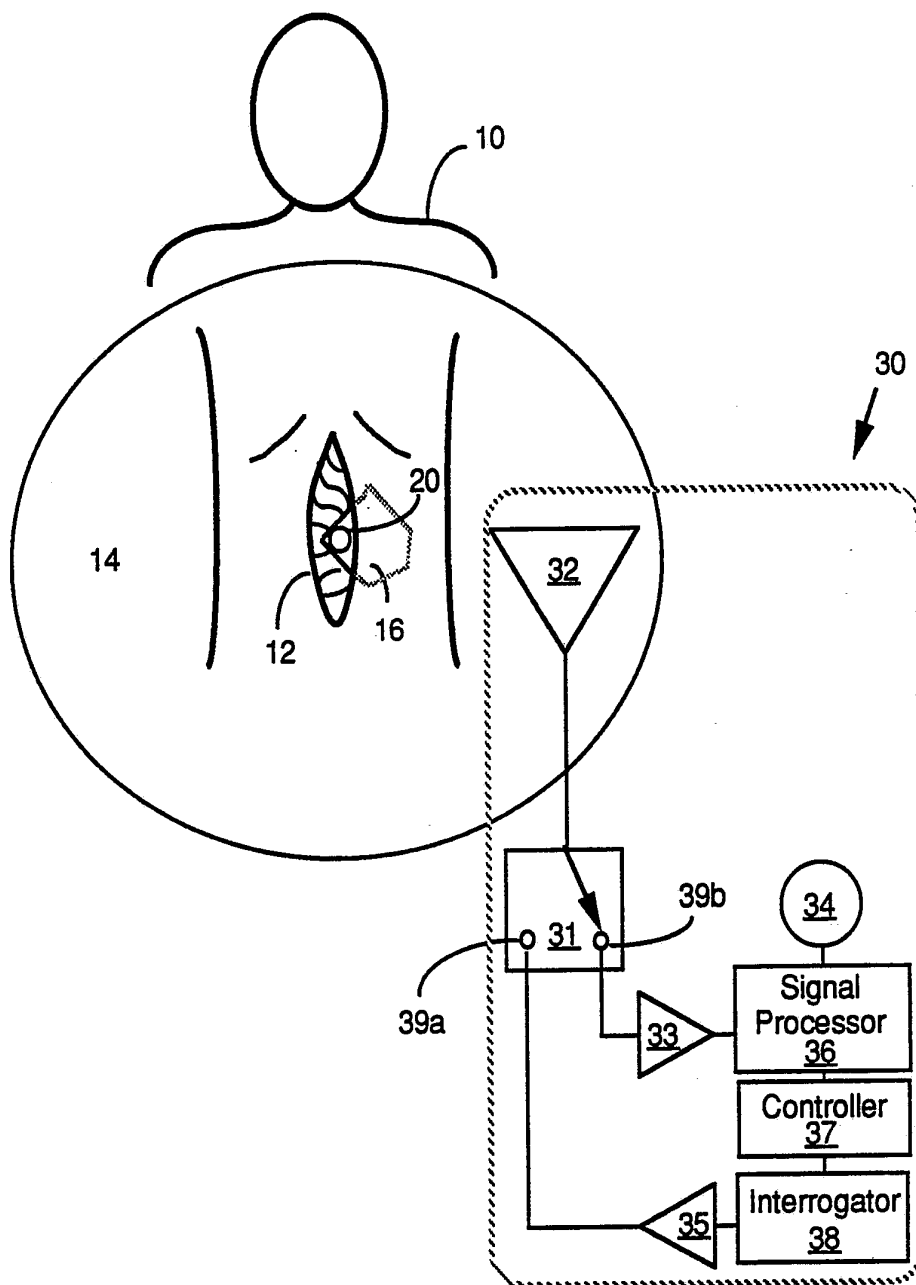


Fig. 2

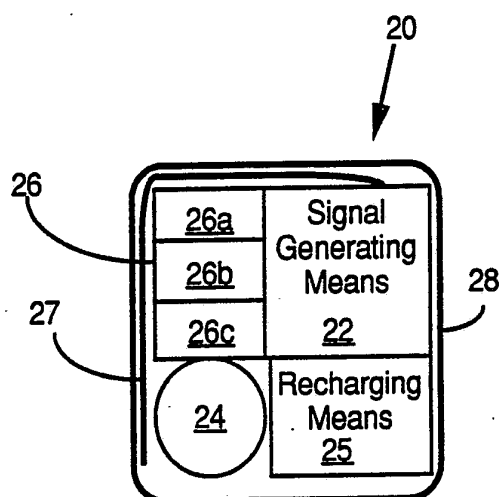


Fig. 3

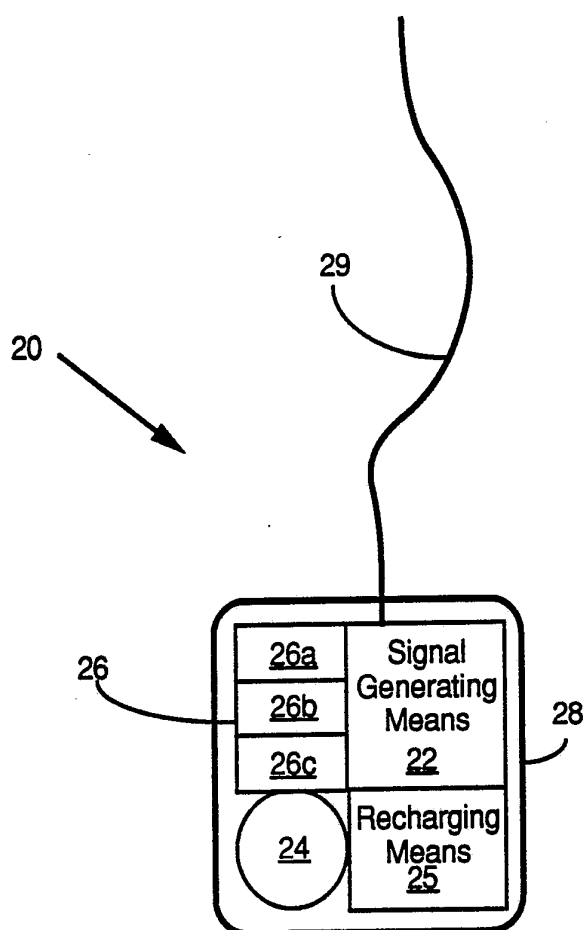


Fig. 4

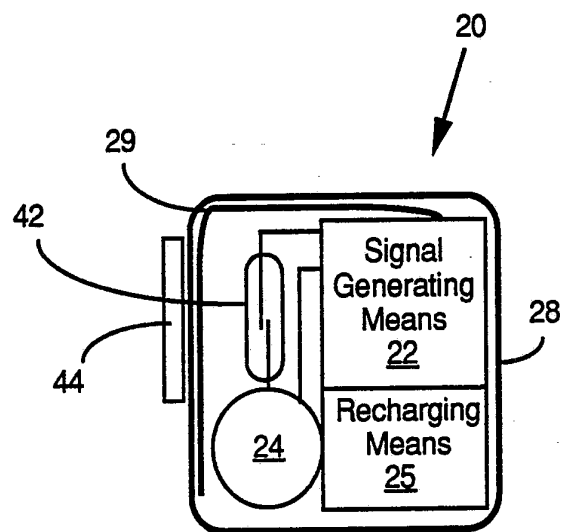


Fig. 5

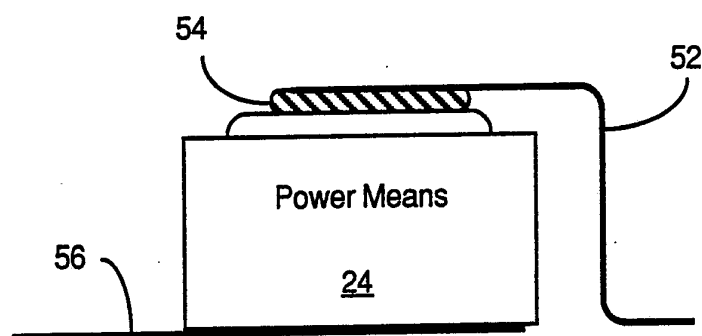


Fig. 6

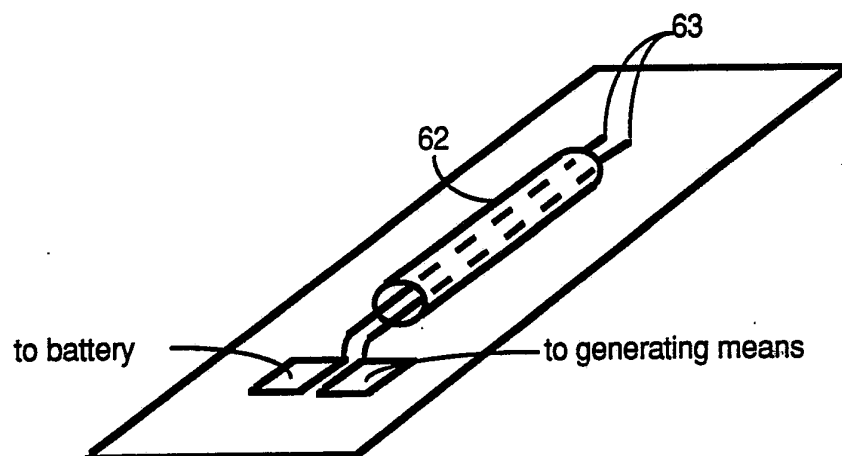


Fig. 7

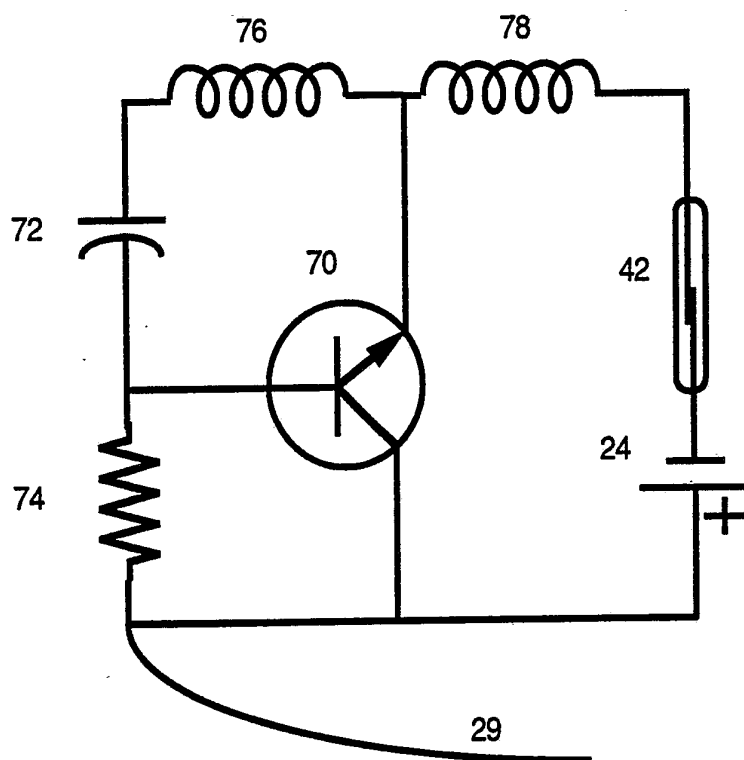
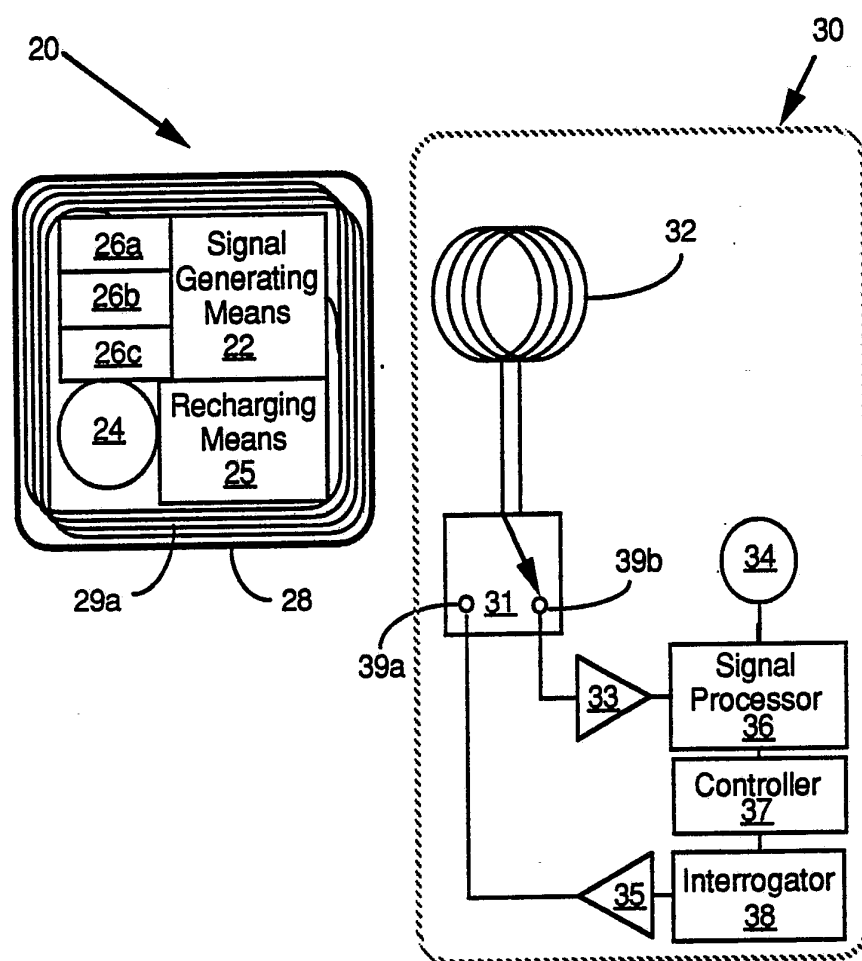


FIG. 8



INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 91/07125

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶		
According to International Patent Classification (IPC) or to both National Classification and IPC Int.Cl. 5 A61B5/06		
II. FIELDS SEARCHED		
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Classification System	Classification Symbols	
Int.Cl. 5	A61B ; A61F	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸		
III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹		
Category ¹⁰	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
X	EP,A,0 399 536 (MICRONIX PTY LTD.) 28 November 1990 see page 3, line 19 - page 4, line 35 see figures 1-4 ---	1,18
X	US,A,4 658 818 (MILLER, JR. ET AL) 21 April 1987 see column 3, line 16 - column 7, line 19 see figures ---	1,18
A	---	2,3
A	GB,A,1 284 941 (WARNER) 9 August 1972 see the whole document ---	1,5,7,18
A	US,A,4 706 689 (MAN) 17 November 1987 see column 3, line 52 - column 5, line 24 see column 6, line 5 - line 33 see figures 1-3 ---	1,9,10 12
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06 MAY 1992	03 JUN 1992	
International Searching Authority	Signature of Authorized Officer	
EUROPEAN PATENT OFFICE	CHEN A.H. <i>A Chen</i>	

**ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO.**

US 9107125
SA 52109

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP-A-0399536	28-11-90	None	
US-A-4658818	21-04-87	None	
GB-A-1284941	09-08-72	None	
US-A-4706689	17-11-87	GB-A- 2207786	08-02-89