

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
29 June 2006 (29.06.2006)

PCT

(10) International Publication Number
WO 2006/068896 A2

(51) International Patent Classification:
A61N 5/00 (2006.01)

(21) International Application Number:
PCT/US2005/045226

(22) International Filing Date:
13 December 2005 (13.12.2005)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
11/022,456 22 December 2004 (22.12.2004) US

(71) Applicant (for all designated States except US): **X-L SYN-
ERGY** [US/US]; 2000 Wyoming Avenue, El Paso, TX
79903 (US).

(72) Inventor; and

(75) Inventor/Applicant (for US only): **NEMIR, David, c.**
[US/US]; 1221 Baltimore Drive, El Paso, TX 79902 (US).

(74) Agent: **MYERS, Jeffrey, D.**; Peacock Myers, P.C., P.O.
Box 26927, Albuquerque, NM 87125-6927 (US).

(81) Designated States (unless otherwise indicated, for every
kind of national protection available): AE, AG, AL, AM,

AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN,
CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI,
GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE,
KG, KM, KN, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV,
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SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US,
UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every
kind of regional protection available): ARIPO (BW, GH,
GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM,
ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),
European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI,
FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT,
RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA,
GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declaration under Rule 4.17:

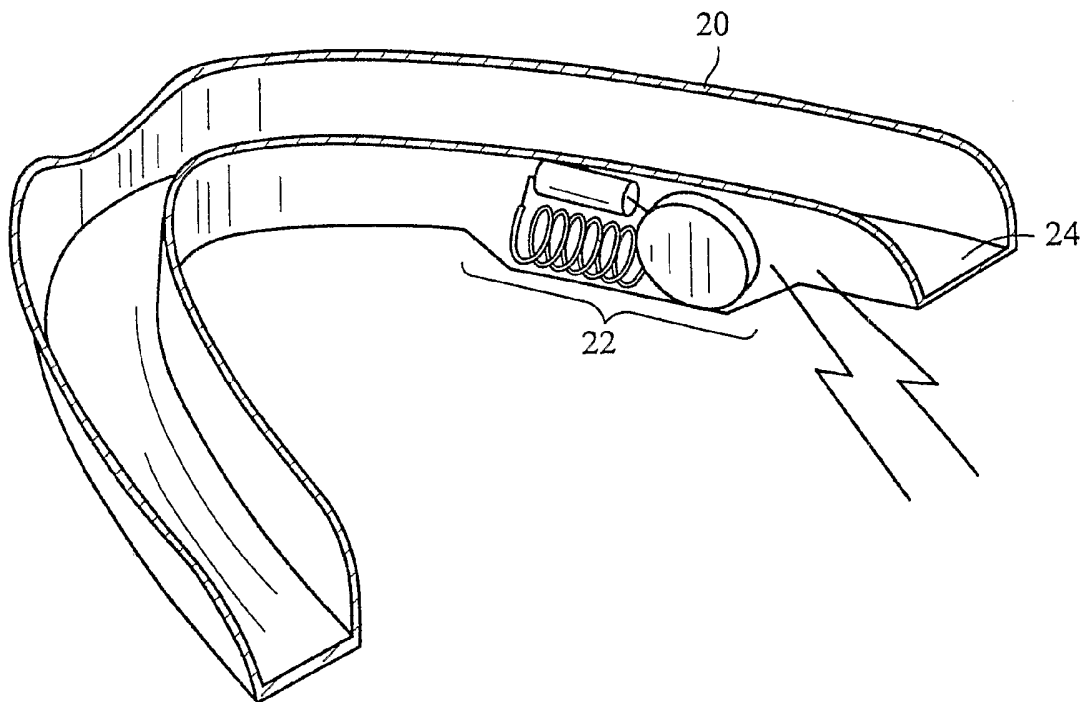
— of inventorship (Rule 4.17(iv))

Published:

— without international search report and to be republished
upon receipt of that report

For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.

(54) Title: APPARATUS FOR BODY CAVITY TELEMETRY



(57) Abstract: Apparatus and method for wireless transmission of biological information from within a body cavity comprising one or more sensors detecting one or more changes in biological state within the body; a signal processor encoding biological data received from the one or more sensors; a transmitter transmitting the encoded data; and a rechargeable power source storing power sufficient to permit substantially continuous detection in the body cavity by the one or more sensors.

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PCT APPLICATION

APPARATUS FOR BODY CAVITY TELEMETRY

5 CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority to U.S. Patent Application No. 11/022,456, entitled "Apparatus for Body Cavity Telemetry," filed December 22, 2004, and the specification is incorporated herein by reference.

10 BACKGROUND OF THE INVENTIONField of the Invention (Technical Field):

The present invention relates to a telemetry device for transmitting biological status information from a placement in a body cavity for the purpose of biofeedback. The use of a crystal controlled transmission oscillator/antenna combination minimizes the detuning that can occur from the changing environment in a body cavity. By utilizing a capacitive or secondary battery energy storage capability, off-line charging can be utilized to avoid the high dosage radiation required by passive transponder approaches.

Description of Related Art:

20 Telemetry is the wireless transfer of information between two points. Telemetering units may be active, in which case both the transmitter and the receiver contain a power source such as a battery. Alternatively, a telemetry system may comprise a passive transponder that receives its power from the radiated signal of a transceiver or interrogator and then either through loading down that signal, reradiating that signal, or transmitting an independent signal, serves to return useful data. Transponders have the advantage that they do not require an internal battery and can be inexpensively fabricated. However, transponders have the disadvantage that they generally must be located close to the interrogating transceiver and with an orientation that is favorable to power transmission. Furthermore, due to inefficiencies in transmission and losses in the system, the interrogator must often transmit power at levels that are many orders of magnitude greater than the

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signal that is returned. This can be a safety hazard in a continuous duty mode and can compromise pacemakers or other electronic equipment.

In biological systems, telemetry has found a home in applications as diverse as livestock indentifiers and data transfer from a heart pacemaker. In these environments, the telemetering device is implanted and is used infrequently. There are other applications where telemetry may play a role in the biofeedback treatment of an ailment and where it is part of a unit that is inserted into a body cavity for continuous use rather than implanted permanently into tissues for infrequent use.

Examples of body cavity telemetry applications are the biofeedback treatment of bruxism, temporomandibular joint dysfunction (TMJ) and myofascial pain dysfunction (MPD). Bruxism is the nonfunctional clenching or grinding of the teeth. It has been shown to cause or to contribute to occlusal tooth wear, muscle pain and spasm and headaches. TMJ disorders refer to problems associated with the mandible joint (the jaw joint) and can lead to debilitating local and referred pain and discomfort. MPD is a painful condition of the skeletal muscles, particularly the muscles of mastication. Bruxism, TMJ and MPD often exhibit similar symptoms and are often treated in a similar manner, so all three conditions are discussed herein as bruxism. Although bruxing behavior can occur by day or night, nocturnal bruxism is more serious and more difficult to treat since the sufferer is asleep and unaware of bruxing behavior.

A splint is a common dental appliance that is fabricated by dentists to treat various ailments including bruxism, TMJ and MPD. It is designed to cover the upper or lower teeth and is generally fashioned from a hard material such as acrylic. The inventor was the coauthor of a study of dental splint usage in the U.S. (Pierce et al, 1995). That survey of over five hundred dentists in the U.S. was made to assess the numbers of dental splints that were prescribed each year for the treatment of bruxism, TMJ dysfunction or myofascial pain dysfunction (MPD). When extrapolating the results to the total number of dentists in the U.S., it was estimated that over 3.6 million dental splints are fabricated each year. So, each year there are an estimated 3.6 million patients in the U.S. that see a dentist, are diagnosed with bruxism, TMJ or MPD, express a willingness to wear a splint, and pay a dentist to fashion one. By adding biofeedback to this treatment, the efficacy is improved.

U.S. Patent No. 4,995,404 (Nemir) discloses a bruxism treatment device that is encapsulated in a dental splint. Force sensing means on the biting surface of the splint is used to detect a bruxing event. Upon the occurrence of a sensed event, a radio transmitter is triggered, conveying the
5 bruxing information to a remotely located alarm unit. The patient is awakened and, in some embodiments, is forced to carry out an arousal contingency, thereby serving as an aversive conditioning stimuli. The patient thereby learns not to engage in bruxing behaviors.

Another body cavity application for telemetering devices is for the treatment of fecal
10 incontinence. Fecal incontinence is the impaired ability to control stool. Although not a life-threatening disease, symptoms are often distressing and socially incapacitating. Fecal incontinence is said to occur in approximately 7% of healthy, independent adults and between 32% to 47% of all nursing home residents. Parent U.S. Patent Application Serial No. 10/401,479 describes a treatment device for fecal incontinence consisting of a dam (a block) and a sensor device to detect
15 the presence of stool in the rectal vault. For those patients with nerve damage who are unable to sense the need for voiding, the sensor serves as patient feedback. Upon the detection of stool, the patient is notified of the need to void through a pager type of audio or vibratory alarm unit. The signal transmission from within the rectal vault to the external pager may take place via a wired connection or wirelessly via telemetry.

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U.S. Patent No. 4,494,545 (Slocum et al.) describes an implant telemetry system that receives data communications from a biomedical implant with specific applicability to cardiac pacemakers. Near field signal and power transmission is effected through a 16 KHz radio frequency carrier.

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U.S. Patent No. 5,211,129 (Taylor et al.) describes a syringe implantable transponder for animal identification. Described applications include the tracking of migratory habits in fish and the verification of domesticated animals (e.g., pets and racehorses). The transponder comprises a coil which receives the energy required for transmission by inductive coupling to an interrogator.

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One problem with biological telemetry is that it may be difficult to achieve alignment with transceiving antennas. The transmission power requirements increase substantially if either the transmitting antenna or the receiving antennas demonstrate transmission nulls that encompass the other antenna. This is purportedly solved in U.S. Patent No. 6,150,986 (Sandberg et al.) by using a plurality of antenna coils and dynamically switching to the antenna which has received the greatest energy.

U.S. Patent No. 6,285,342 (Brady et al.) describes a radio frequency tag with miniaturized resonant antenna. By the use of a loading bar and a tuning stub, various antenna configurations are proposed that give optimal power transfer.

There are at least four problems with prior art techniques as applied to continuous biological telemetry from devices deployed in a body cavity. First and foremost of these is safety. A telemetering device should be completely encapsulated in a biologically inert packaging. Because most telemetering devices, and, in particular, the bruxism treatment and fecal incontinence management devices contemplated herein, must be small and will be deployed for use over weeks or even months, they cannot rely upon a primary battery since a sufficiently small cell has limited power available for continuous transmission. A transponder approach is not appropriate because the radiating transceiver would have to broadcast substantial energy on a continuing basis. In particular, for deployments near the head of a bruxism patient, this could pose substantial health risks.

A second drawback of prior art telemetry techniques is that for a device that is inserted into a body cavity there are signal losses due to various interfaces through air, soft tissue and hard tissue. For a transponder, the signal attenuation occurs in both directions, first in the original RF power signal conveyed to the transponder, and then a second time, as the transponder signal leaves the body through the same interfaces (in a reverse direction) and through the same lossy materials.

A third problem with prior art telemetric techniques as applied to body cavity transmission relates to detuning by the changing environment. In the mouth, tongue positions can change in less

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than a second, leading to changes in capacitive loading on the telemetry transmission circuit. This makes it impossible to maintain an optimal transmission or reception profile. In a similar way, a transmitter situated within the rectal vault would be subject to a varying operating environment depending upon the fill amount and stool consistency surrounding the device.

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A fourth problem with prior art telemetry devices relates to antenna orientation. Because telemetry units must be small, they generally cannot provide an efficient coupling of electrical energy to radio frequency. The antennas must fit into a small form factor and generally have a sensitivity that is dependent upon orientation. A passive transponder implementation exacerbates the problem. The reason is that an external interrogator must transfer energy to the transponder which in turn must reradiate the data of interest. So, if the interrogator has a poor alignment, that is, the transponder lies in a transmission null of the interrogator, then the transponder will receive minimal energy for operation. If the interrogator uses the same antenna for reception as for transmission, then there will be a receiving null that is identical to the transmission null. Furthermore, if the transponder antenna also exhibits nulls in transmission/reception, then this accumulation of signal losses results in loss of data for some alignments.

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BRIEF SUMMARY OF THE INVENTION

In view of these drawbacks, it is an object of the present invention to address the specific requirements of transmitting information via telemetric units disposed in body cavities. The invention has the following objects and advantages:

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- a. It does not require a primary battery;
- b. It does not rely upon the real time reception of radio frequency energy from an interrogator;
- c. It has minimal orientation requirements between transmitting and receiving antennae;
- d. It accomplishes reliable short range transmission;
- e. It is not subject to disruption by changes in the body cavity;
- f. It is well suited to deployment in treatment apparatus for bruxism, TMJ or MPD; and
- g. It is well suited to deployment in treatment apparatus for fecal incontinence.

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When used with a splint based bruxism, TMJ or MPD treatment device, the present invention allows biofeedback treatment without the necessity for the patient to be connected to wires during sleep. When used in conjunction with a fecal incontinence management device, the present invention allows the patient maximum flexibility of motion and dress.

Perhaps the biggest problem with fashioning a biofeedback splint is to make it sufficiently unobtrusive that the patient will wear it. A splint must fit snugly to the biting surface in the mouth. In addition, the surface of the splint must have a proper occlusal fit or the patient will unconsciously engage it with tooth contact during sleep, trying to find a fit. Every mouth is different and the splint fabrication process has historically been largely manual. However, recent innovations in splint manufacture have resulted in a highly automated process that uses computer modeling. By generating a computer model of the patient's teeth, a splint can be fabricated to incorporate a telemetry device which is minimally invasive and which accomplishes the objectives outlined in the present invention.

Other objects, advantages and novel features, and further scope of applicability of the present invention will be set forth in part in the detailed description to follow, taken in conjunction with the accompanying drawings, and in part will become apparent to those skilled in the art upon examination of the following, or may be learned by practice of the invention. The objects and advantages of the invention may be realized and attained by means of the instrumentalities and combinations particularly pointed out in the appended claims.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

The accompanying drawings, which are incorporated into and form a part of the specification, illustrate one or more embodiments of the present invention and, together with the description, serve to explain the principles of the invention. The drawings are only for the purpose of illustrating one or more preferred embodiments of the invention and are not to be construed as limiting the invention. In the drawings:

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FIG. 1 depicts a biofeedback dental splint for the treatment of bruxism.

FIG. 2 depicts an overview of a biofeedback treatment approach for oral behaviors.

5 FIG. 3 depicts a biofeedback treatment device for the management of fecal incontinence.

FIG. 4 depicts the high dosage radiation situation when using a passive transponder with a dental splint based biofeedback.

10 FIG. 5 depicts a specific embodiment for the acquisition of information from a varying resistor and a circuit for the encoding and transmission thereof.

FIG. 6 depicts encoding protocols for amplitude shift keying and frequency shift keying.

15 FIG. 7 depicts a specific embodiment for acquiring information from a varying resistance and amplitude shift keying that information using a crystal controlled transmitter.

FIG. 8 depicts a design which incorporates a microcontroller to enable frequency shift keying of encoded information.

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FIG. 9 depicts a so-called Manchester protocol for data transmission.

FIG. 10 depicts a specific embodiment for a power supply recharging system for a fecal incontinence management device.

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FIG. 11 depicts a specific embodiment for a power supply recharging system for a bruxism treatment device.

30 FIG. 12 depicts a specific embodiment for a power supply recharging system that uses solar cells.

FIG. 13 depicts a specific embodiment for a power supply recharging system that uses transformer coupling.

5 FIG. 14 depicts a specific embodiment for a power supply recharging system as applied to a dental splint telemetry system.

FIG. 15 depicts a relay approach to body cavity telemetry.

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LIST OF REFERENCE NUMERALS

- 20 – Dental splint
- 22 – Transmitter
- 24 – Biting surface of splint
- 15 26 – Receiver unit
- 28 – Antenna
- 30 – Balloon
- 32 – Catheter
- 33 – Valve
- 20 34 – Anus
- 36 – Anorectal line
- 38 – Rectum
- 40 – Sensor/transmitter
- 42 – Stool
- 25 44 – Interrogator
- 46 – Bed
- 48 -- Patient
- 50 – Astable multivibrator
- 52 – Pulse stretcher
- 30 54 – Battery or charged capacitor
- 56 – Comparator
- 58 – Capacitor
- 60 – Noninverting input node
- 62 – Resistor

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- 64 – Resistor
- 66 – Comparator
- 68 – Resistor
- 70 – Capacitor
- 5 72 – Force sensing resistor
- 74 – Resistor
- 76 – Noninverting input node
- 78 – Pulse width modulated output
- 80 – Transmitter
- 10 82 – Capacitor
- 84 – Loop antenna
- 86 – Choke
- 88 – Feedback capacitor
- 90 – Emitter resistor
- 15 92 – Bypass capacitor
- 94 – NPN bipolar transistor
- 96 – Digital one
- 98 – Digital zero
- 100 – Crystal
- 20 102 – Antenna
- 104 – Resistor
- 106 – Capacitor
- 108 – Microcontroller
- 110 – Sensor
- 25 112 – Analog to digital input
- 114 – Control signal to enable frequency f1
- 116 – Control signal to enable frequency f2
- 118 – Electrodes
- 120 – Constant resistance in a voltage divider
- 30 122 – Steering diode
- 124 – Data processing and transmitter unit
- 126 – Measuring point for moisture proportional voltage
- 128 – Charging points
- 130 – Solar cells
- 35 132 – Capacitor
- 134 – Diode
- 136 – Diode

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- 138 – Transformer secondary
- 140 – Node A
- 142 – Node B
- 144 – Node C
- 5 146 – Center of transformer secondary
- 148 – Transformer secondary
- 150 – Transformer core
- 152 – Primary windings
- 154 -- Gap
- 10 156 – External AC power supply
- 158 – Slug
- 160 – Lower face of gap
- 162 – In body sensor/transmitter
- 164 – In body transmission antenna
- 15 166 – Relay transceiver
- 168 – Relay transceiver antenna
- 170 – Base receiver
- 172 – Receiver antenna

DETAILED DESCRIPTION OF THE INVENTION

20 The present invention is of a telemetry device and method for transmitting biological status information from a placement in a body cavity for the purpose of biofeedback. The use of a crystal controlled transmission oscillator/antenna combination minimizes the detuning that can occur from the changing environment in a body cavity. By utilizing a capacitive or secondary battery energy storage capability, off-line charging can be utilized to avoid the high dosage radiation required by

25 passive transponder approaches.

FIG. 1 depicts a biofeedback dental splint **20** as designed for the treatment of bruxism or other disorders. This device is adjusted by the dentist to fit tightly to the teeth and to provide a good occlusal fit on the biting surface **24**. One or more sensors (not shown) that are imbedded within the

30 splint **20** detect biting patterns and then convey this information to the outside world via transmitter **22**. Transmitter **22** serves to receive sensor information, process it, and to convey that data to the outside world. Transmitter **22** is small and preferably configured into the splint in such a way that it is unobtrusive to the wearer. The sensors can be based upon sensing biting forces or biting

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pressures or they can be optical or magnetic and sense either jaw position or tooth alignment. The biofeedback dental splint **20** is self-contained. There are no external wires connecting outside of the mouth.

5 FIG. 2 depicts the biofeedback dental splint **20** as worn by a patient. In this figure, the splint **20** is depicted as being worn over the upper teeth but in some embodiments, it might be preferable to configure the splint **20** for use over the lower teeth. Transmitter **22** serves to pass data to an external receiver unit **26** via a wireless transmission to antenna **28**. In some embodiments, receiver unit **26** will simply record data. In some embodiments, receiver unit **26** will trigger an alarm,
10 awakening the patient and teaching him through biofeedback not to engage in particular oral behaviors.

 FIG. 3 depicts a specific application for the transmitter of the present invention as applied to the treatment of fecal incontinence. A catheter **32** is inserted into the anus **34** so that a balloon **30** is
15 above the anorectal line **36**. Once in place, the balloon **30** is inflated to secure it within the rectum **38**. Inflation is carried out by means of a valve **33** which allows the balloon to be inflated and, for subsequent removal, deflated. A sensor/transmitter **40** serves to sense the presence or absence of fecal material **42** and then to transmit that data to an external receiver.

20 Normal bowel function is controlled by three things: anal sphincter pressure, rectal storage capacity and rectal sensation. For a continent individual, the anal sphincter muscle contracts to prevent stool from leaving the rectum. Rectal storage occurs when the rectum **38** stretches to hold stool. This storage can continue for some time after a person becomes aware that stool **42** is present, allowing the person to void the stool at a convenient time and place. For a continent
25 individual, rectal sensation tells the person that the stool **42** is in the rectum **38**. The fecal incontinence management catheter **32** is designed for patients who are unable to retain stool and/or unable to sense its presence. The balloon **30** assists the sphincter to prevent stool from exiting the rectum. Moisture from fecal matter that penetrates the sensor/transmitter **40** is sensed and this

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information is used to signal to the user or caregiver that fecal matter has entered the rectal vault and needs attention. Accordingly, the balloon **30** assists the sphincter in retaining stool and the sensor/transmitter **40** serves to give the feedback corresponding to rectal sensation. In most applications, the sensor/transmitter **40** sends out signals periodically, for example, every ten
5 seconds, giving the status of stool in the rectal vault. A receiver unit that would be preferably configured as a belt worn pager style of device receives this data and then alerts the patient or caregiver through audio, visual or vibratory means. This allows the patient or caregiver time to deflate the balloon **30**, remove the catheter **32**, and then to void the bowels at a convenient time.

10 Transponder technology is attractive for many applications. For radio frequency identification, or RFID applications, the transponder can be built at relatively low cost, leaving the expense and power requirements to the interrogator/receiver. In addition, in RFID applications, typically the antenna does not have significant size constraints and can be configured as a flat “patch” style of antenna. The distance between interrogator and transponder is typically short and
15 through air, and the transponder can be presented to the interrogator with an optimal orientation in order to receive maximum transmission efficiency. Unfortunately, such is not the case for a body cavity implementation.

FIG. 4 illustrates the potential problem with using transponder technology in association with
20 a biofeedback treatment splint. A patient **48** who is wearing a biofeedback splint is using the biofeedback approach while asleep in bed **46**. If a passive transponder is used in the biofeedback splint, it must receive its energy from an external interrogator unit **44** which might be located by the bedside. This interrogator **44** broadcasts a radiowave transmission at periodic interval from antenna
25 **28**. The radiowaves must penetrate into the oral cavity through air to tissue to air to acrylic before reaching a splint imbedded transponder. Sufficient energy must be passed to the transponder in this way to allow the reradiation of information regarding the bruxing behaviors and this reradiation must pass again through the various interfaces to reach the interrogator **44** which now functions as a receiver. Radiofrequency energy varies as the square of the distance from the transmitter. So, if the patient **48** changes position on the bed **46**, it can result in attenuation due to distance from the

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interrogator **44**. Furthermore, the orientation of the in-splint antenna may be critical to the efficient data transmission to an external interrogator **44**. Many antennas exhibit transmission nulls and these nulls can occur not only because of the antenna, but because of the interaction with the environment. Since the in-splint antenna is constrained to having a compact size, it will not have a high efficiency. Since there is no guarantee of the position of the patient **48** throughout the night, it is likely that poor antenna alignment will be experienced from time to time and that this will compromise transponder efficiency. Furthermore, the oral cavity is a changing environment with jaw movements and tongue movements causing changes in the loading of the antenna, presenting yet a further challenge to transponder function.

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Accordingly, in order to use a passive transponder to acquire data from a body cavity, the transmission energy must be substantial or there must be multiple interrogators. In particular, the biofeedback splint must be interrogated on at least one second intervals in order to obtain timely information regarding biting behaviors. This would result in a nearly continuous transmission of radio frequency power at a level that could disrupt electronic equipment or exceed recommended radiation exposure levels. Although this discussion has centered upon the bruxism treatment application, a similar analysis applies to other body cavity applications.

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FIG. 5 depicts a method for encoding data from a variable resistance **72** by generating a pulse width modulated output. In an application directed at the biofeedback treatment of bruxism, variable resistance **72** could be a force sensing resistor that was deployed onto the biting surface of a dental splint. In an application directed at the management of fecal incontinence, variable resistance **72** could be a moisture path induced by the presence of fecal matter. A direct current power supply, Vdc **54**, is supplied by a battery or charged capacitor. A square wave output is produced by astable multivibrator **50**. Comparator **56** compares the state of charge of a capacitor **58** to a reference point **60**. When the comparator **56** changes state, it charges or discharges capacitor **58** with a time constant that is proportional to the RC product given by capacitor **58** and resistor **62**. Resistor **64** provides hysteresis. With an RC time constant of 0.046 seconds, the output of first stage **50** is a square wave with frequency of 3 cycles per second. The pulse stretcher

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52 serves to adjust the duty cycle to yield an output with the same frequency as the output of astable multivibrator **50** but with a duty cycle that is related to the value of variable resistor **72**. An RC time constant given by resistor **68** and capacitor **70** serves to delay the voltage presented to the inverting input of comparator **66**. Comparator **66** changes state using the setpoint voltage at node **76** which is in turn, a function of the value of variable resistor **72**. Resistor **74** serves to compress the effective range of values of force resistance. When the variable resistor **72** has a value of 50K or above, the duty cycle is approximately 7%. When the variable resistor **72** has values of 15K, 6.8K, 2.2k and 1K, respectively, the duty cycles are 14%, 23%, 35% and 49%. Accordingly, the effect of the multivibrator **50** together with the pulse stretcher **52** is to convert the output of a relatively low impedance sensor (a variable resistor) into a pulse width modulated output.

Transmitter **80** serves to take the pulse width modulated output **78** and then transmit this as an amplitude shift keyed (ASK) signal. Transmitter **80** is turned on when line **78** has a high value and is turned off when line **78** has a low value. The radiating frequency is defined by capacitor **82** and loop antenna **84**. Inductor **86** serves as a choke. Capacitor **88** serves to provide base feedback to stabilize the transmission frequency. Resistor **90** is used to establish a DC operating point and capacitor **92** serves as a short path to ground for the high frequency AC to allow maximum gain. The combination of capacitor **82** and loop antenna **84** forms an LC tank circuit that governs the radio frequency carrier that is generated and transmitted. The loop antenna **84** acts as both an inductance and as a radiator. While this is referred to as a loop antenna, during manufacture, it may be configured as a loop and then folded back over itself to reduce size, without seriously impacting oscillation frequency. Transmitter **80** may be regarded as a free oscillator that oscillates (transmits a sinusoidal wave) with its own natural frequency when the input **78** is high and that turns off and does not oscillate (or transmit) when the input **78** is off. The transmitter **80** is not crystal controlled and its oscillation frequency may be a function of capacitance and inductance within the environment. In body cavity applications, in particular, these loading effects may be intermittent. For example, in a bruxism treatment application, as the patient moves his tongue into the vicinity of the transmitter, capacitive effects may cause a shift in the oscillation frequency by as much as 1%. In order to

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compensate for this, the radio wave receiver should be designed with a sufficiently wide reception frequency band for adequate signal acquisition.

FIG. 6 portrays the radiated output using two common transmission protocols. FIG. 6(a) portrays the data signal that represents the information to be transmitted. For example, referring to the FIG. 5 circuit, this would be the signal at the output **78** of the pulse stretcher and the information of interest would be the duty cycle of the waveform. FIG. 6(b) portrays the output that would be radiated from the transmitter **80** in FIG. 5. This means of encoding information for transmission is known as amplitude shift keying (ASK) since a carrier frequency is transmitted during the digital ones **96** and there is no transmission during the digital zeros **98**. One advantage to ASK transmission is that the encoded information can be extracted, or demodulated, using an envelope detector which is relatively simple to build. An alternative transmission technique is the so-called frequency shift keying (FSK) technique as depicted in FIG. 5(c). With FSK transmission, transmission is always taking place through the use of two distinct frequencies. One of these frequencies is used to represent one state (for example, a digital "one") and the second frequency is used to represent a second state (a digital "zero"). So in FIG. 6(c), the regions covering the time of low frequency transmission corresponds to a digital one and the regions corresponding to high frequency transmissions represent a digital zero. In this way, binary serial data can be transmitted by switching from one transmission frequency to another in a manner that is recognizable by an external receiver.

FIG. 7 portrays a second specific embodiment. This embodiment uses an astable multivibrator **50** and a pulse stretcher **52** to generate a pulse width modulated output **78**. Astable multivibrator **50** produces a square wave output with approximate 50% duty cycle with an oscillation frequency set by the product of the values of resistor **104** and capacitor **106**. Pulse stretcher **52** serves to change the duty cycle of the first stage multivibrator **50** according to the value of variable resistor **72**, to generate an output **78**. The transmitter **80** then serves to generate an amplitude shift keyed output which goes to antenna **102**. For a biofeedback splint, the antenna **102** might be the actual bruxism sensor or it might be a short monopole antenna, a loop antenna, a folded loop

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antenna, or an alternative profile. For a fecal incontinence treatment device, the antenna **102** might be a loop antenna or a dipole antenna or an alternative structure. The transmission carrier frequency of transmitter **80** is governed by crystal **100**. This crystal controlled transmitter gives a stable frequency output that is not sensitive to loading effects by a variable environment in the body cavity.

FIG. 8 depicts a microcontroller based telemetry module wherein a single chip microcontroller **108** serves to interface between one or more sensors **110** and a transmitter **80**. In the preferred embodiment, the sensors **110** will connect to analog to digital inputs **112**. The sensors **110** might correspond, for example, to strain, force or displacement sensing for a bruxism treatment device or they might correspond to moisture, resistance or light for a fecal incontinence management device. The analog values of the sensors will be converted to a digital value and then encoded for transmission through a transmitter **80**. Power supply **54** is a battery or charge storage capacitor and supplies power to the microcontroller **108**, the transmitter **80** and, possibly, to the sensor(s) **110**. The microcontroller **108** can easily implement an FSK scheme by simply controlling lines **114** and **116** so as to output either of two distinct frequencies. For example, when line **114** is high and line **116** is low, then the transmitter transmits carrier frequency f_1 , while a low on line **114** and a high on line **116** causes the transmitter to transmit at frequency f_2 . One transmission method would be the so-called Manchester encoded format.

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FIG. 9 depicts a Manchester encoded format. The signal includes a synchronization portion and a data portion. The synchronization portion includes a preamble with four identical bits then a low portion which is longer than the bit width, then a similar high portion and then a zero data bit. The purpose of the synchronization portion is to signal to the receiver the clock frequency to be used and when to look for data. For a binary "one", the transmission frequency changes from the higher frequency to either zero (for ASK transmission) or to the lower frequency (for FSK transmission) during the bit cell. For a binary "zero", the transmission frequency changes from zero frequency or the lower frequency, to the higher frequency during the bit cell.

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FIG. 10 depicts an electrical circuit for acquiring information from a biomedical sensor which also incorporates charging electrodes for off-line power restoration to a biomedical telemetry device. For example, in a management device for fecal incontinence, the sensing of moisture in stool is equivalent to the sensing of the electrical conductivity of the stool. This can be obtained by monitoring two electrodes **118** that serve as a leg in a voltage divider. The constant resistor **120** goes connects between one of the electrodes **118** to one side of the power source **54**. When a moisture path (which acts as a variable resistance) bridges electrodes **118**, it results in a voltage change on line **126** that can be digitized and transmitted by unit **124**. Unit **124** will include a transmitter and an antenna and may include a microcontroller and other components as discussed earlier.

FIG. 10 depicts a charging methodology for adding energy to a secondary (rechargeable) battery or cell, or to a capacitor. A secondary cell stores energy through a chemical process. As energy is extracted from the cell, the internal chemicals change state until the cell is completely depleted and unable to serve as a power source. The recharging process serves to reverse the chemical reaction so that the cell can deliver power. A capacitor is a charge storage device. In a capacitor, energy is stored through a separation of charge. The voltage difference between the two terminals of a capacitor serve to define the energy stored in the capacitor through the equation $E = \frac{1}{2} CV^2$, where C is capacitance in farads, V is the voltage in volts, and E is energy in joules. Capacitors with values of 0.1 farad or greater are available in a small size and often yield a higher energy capacity than the equivalently sized secondary cell. When the body cavity telemetry unit **128** is not in situ, the power source **54**, either a secondary cell or a capacitor, may be charged using the same two electrodes **118** that are used for sensing moisture. For example, for the fecal incontinence management application, when the device is removed from the rectum, it may be cleaned and then attached to an external charging system (perhaps designed for bathroom countertop use) that engages electrodes **118** and furnishes energy. When a polarity is applied to electrodes **118** using a voltage value that exceeds that of power source **54**, then energy goes into this power source **54**, allowing it to recharge. Optional steering diode **122** serves to allow a rapid

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charge to be delivered to power source **54** because it allows current flow to bypass resistor **120** during charge. Steering diode **122** is not an influence on circuit operation when the device is in situ because it blocks current flow in a reverse direction. Generally, resistor **120** would be chosen to be of relatively high value to avoid rapid discharge of power source **54**. However, having a high value
5 for resistor **120** can also limit the recharge rate. This is the reason for adding steering diode **122**.

Although both rechargeable cells and capacitors can be used for power source **54**, there are two factors that favor the use of a charged capacitor rather than a rechargeable cell for the power source of the body cavity telemetry unit. First, rechargeable cells are often limited in the number of
10 recharge cycles that they can sustain and their energy capacity declines over time. Second, rechargeable cells often require a lengthy amount of time for optimal recharge. In contrast, charge storage capacitors can generally be completely charged in under a minute and can withstand an order of magnitude more charge/discharge cycles than a rechargeable cell without the loss of energy storage capacity.

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FIG. 11 depicts a direct charging method that might be appropriate for a bruxism treatment implementation. A force sensing resistor **72** completes a voltage divider formed with resistors **72** and **120**. The force sensing resistor **72** would normally be disposed either on the biting surface of a dental splint or within the splint in such a configuration as to change in resistance in response to
20 changes in stress within the splint. The voltage on line **126** that goes into unit **124** is then encoded and transmitted to indicate the force or stress value within the splint. This gives an indication of tooth contact and pressures. Charge points **128** are used as a means to recharge the power source **54** when the bruxism treatment is not in use. During the integration of the telemetry and bruxism monitoring device into the dental splint, charge points **128** would be left exposed within recesses in
25 the splint. During oral use, these charge points **128** would be covered with dental wax or another saliva impermeable material. When not in use, the entire splint would be removed from the mouth and the charge points **128** would be used as a means to recharge power source **54** as described in conjunction with FIG. 10.

FIG. 12 depicts an alternative, off-line charging method whereby one or more solar cells **130** are used to generate the power for recharging power source **54**. Solar cells convert electromagnetic energy in the visible, ultraviolet or infrared range into electrical energy. For example, in a dental treatment splint, solar cells **130** could be assembled so that they are completely encapsulated in acrylic and are thereby protected from saliva. Steering diode **122** would ensure that the solar cells **130** did not discharge power supply **54** during use. When not in use, the dental splint would be removed from the mouth and placed into an ultraviolet (UV) charging unit. Since dental acrylic is translucent to UV, recharging of power supply **54** could take place by the very intense UV radiation of the UV lamp without the need for exposed charging electrodes. The UV source could simultaneously serve as a sterilizing means.

FIG. 13 depicts a recharging system that uses transformer coupling as a means of recharge and that uses a technique known as voltage multiplication to increase the effective voltage to allow better recharge of power source **54**. A transformer is a device that converts magnetic energy from a changing magnet flux into electrical energy. In FIG. 13, transformer secondary **138** receives energy from a transformer primary (not shown) to generate a sinusoidally varying voltage between node A **140** and node B **142**. When the voltage between nodes A and B is negative, diode **134** conducts to charge up capacitor **132**. Since there is no discharge path, capacitor **132** holds its charge until the next half cycle. Then, during the next half cycle, when the voltage between nodes A and B is positive, the voltage between nodes A and B sums with the voltage that was stored across capacitor **132** in the previous half cycle to develop a voltage at node C **144** that is greater than the peak voltage of the sinusoidal voltage generated between nodes A and B. If diodes **132** and **136** were ideal (no forward voltage drop) then the circuit depicted in FIG. 13 would serve to charge power source **54** to a value that is two times the peak voltage between nodes A and B. In practice, some allowance must be made for voltage drops across diodes **134** and **136** and it is preferable to use Schottky style diodes that have a lower drop. While FIG. 13 depicts a so-called "voltage doubler", in some applications, it may not be necessary to double the received voltage, in which case diode **134** and capacitor **132** may be omitted. In other applications, further degrees of voltage multiplication

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may be desirable and the construction of "voltage triplers" and higher orders of voltage multiplication are well known and will be obvious to one skilled in the art.

FIG. 14 depicts one specific embodiment for implementing the transformer coupling of energy from an external source into the telemetry power supply for a biofeedback splint **20**. This splint **20** is designed for wear over the upper teeth. Imbedded into splint **20** is a transformer secondary **148** comprising multiple turns of a wire conductor which is used for recharging. The remainder of the secondary side of the charging circuit, sensors and telemetry, would preferably be resident in the splint but are not depicted in FIG. 14. When worn by a patient, the transformer secondary winding **148** is disposed in the patient's palette. The transformer secondary **148** is entirely encased within the splint material. A hole **146** in the middle of transformer secondary **148** allows a ferrous core to be passed through the transformer secondary **148**. When the biofeedback splint **20** is not in service, its power source may be recharged using transformer coupling. Core **150** is made of a magnetic material to allow a low reluctance path for magnetic flux. Alternating current power supply **156** generates a high frequency sinusoidal wave. In the preferred embodiment, this might be in the range of 20 KHz to 100 KHz. The primary windings **152** are used to generate the magnetic flux that goes through core **150**. To achieve maximum coupling, the hole **146** in secondary **148** would be placed within the gap **154** in the core **150**. Then a slug **158** would be lowered through the gap and into the face **160** of the slot **154** to complete the magnetic circuit. For the bruxism treatment splint, for example, this configuration might be used during the daytime to recharge the power supply. At night, the splint **20** would be removed from the recharger and would be inserted into the mouth for nighttime use.

FIG. 15 depicts a relay device that ensures that reliable body cavity telemetry can be carried out at the absolute lowest signal level. The sensor/telemetry unit **162** is resident in a body cavity along with the attached antenna **164**. A relay transceiver **166** can be clipped on the pajamas for nighttime use or worn on a belt in the daytime to receive signals from the body cavity telemetry unit **162**. In some applications, this relay transceiver **166** may be able to accomplish all requirements of the telemetering device. For example, for a fecal incontinence management device, a belt worn

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pager type of alarm is sufficient to assist an ambulatory patient in managing incontinence. On the other hand, in a nursing home environment, it may be advantageous to send an alarm signal to a caregiver who may be many rooms away. In these cases, rather than require the sensor telemetry unit **162** to reliably transmit 100s of feet away, the belt worn relay transceiver can be used to receive
5 the local telemetry and then to relay that information to a remote base receiver **170**. The advantage is that the relay transceiver **166** need not be low power, may have an optimally designed antenna and, while it may operate continuously in a receive mode, it need only transmit upon the occurrence of an event needing attention by nursing staff.

10 In a similar way, for bruxism treatment, a relay transceiver can be clipped onto the pajamas to allow the receiver to be proximate to the splint based sensor/transmitter **162**. It can then either alarm directly or it can trigger a remote alarm when a bruxing event is sensed.

Although the invention has been described in detail with particular reference to these
15 preferred embodiments, other embodiments can achieve the same results. Variations and modifications of the present invention will be obvious to those skilled in the art and it is intended to cover in the appended claims all such modifications and equivalents. The entire disclosures of all references, applications, patents, and publications cited above are hereby incorporated by reference.

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CLAIMS

What is claimed is:

- 5 1. An apparatus for wireless transmission of biological information from within a body cavity, said apparatus comprising:
- one or more sensors detecting one or more changes in biological state
- within the body;
- a signal processor encoding biological data received from said one or more
- 10 sensors;
- a transmitter transmitting said encoded data; and
- a rechargeable power source storing power sufficient to permit substantially continuous detection in the body cavity by said one or more sensors.

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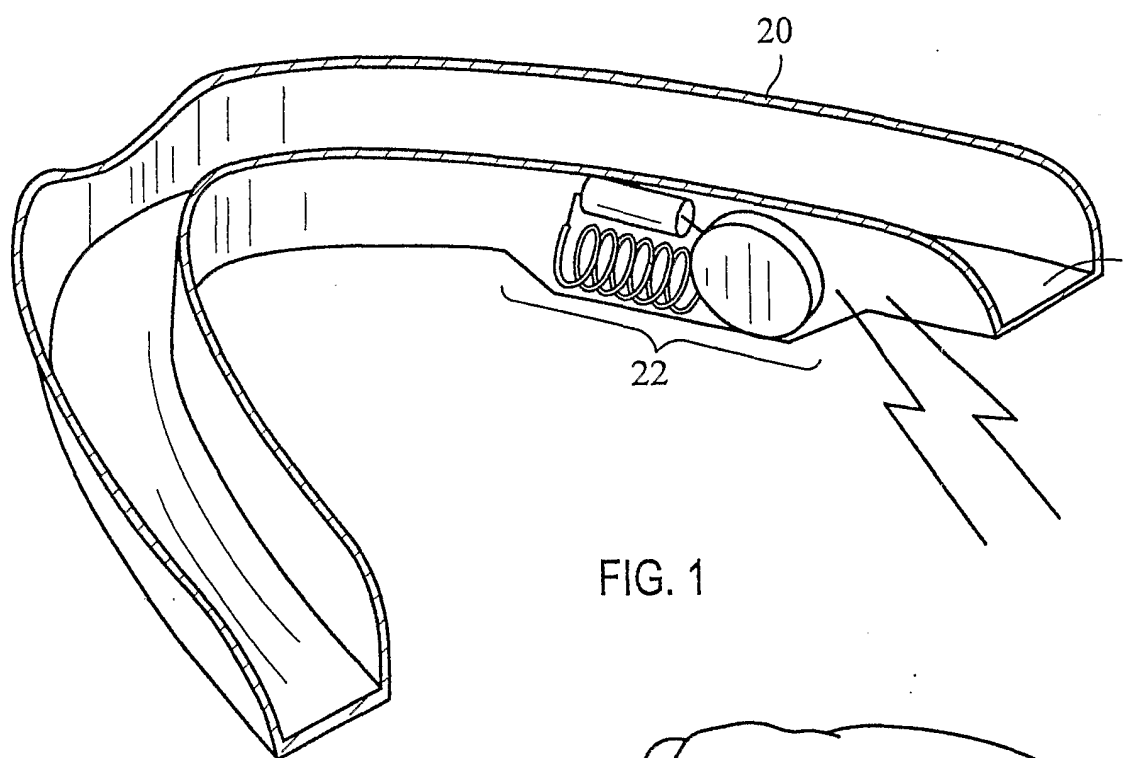


FIG. 1

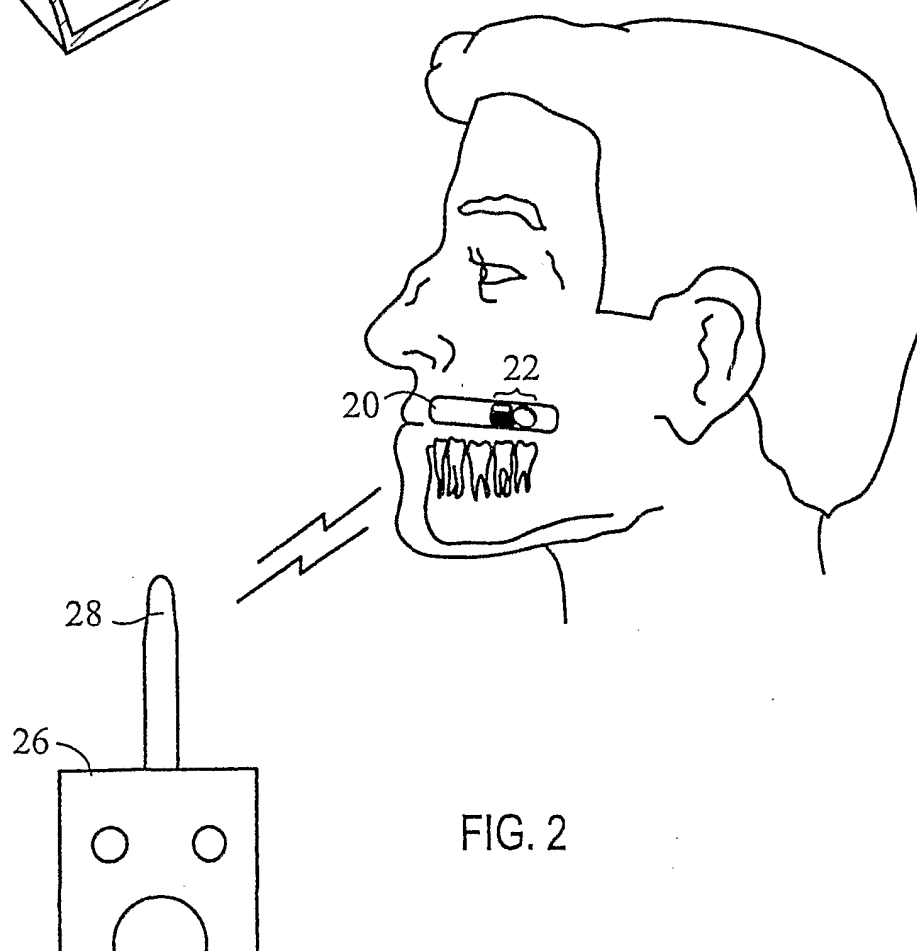


FIG. 2

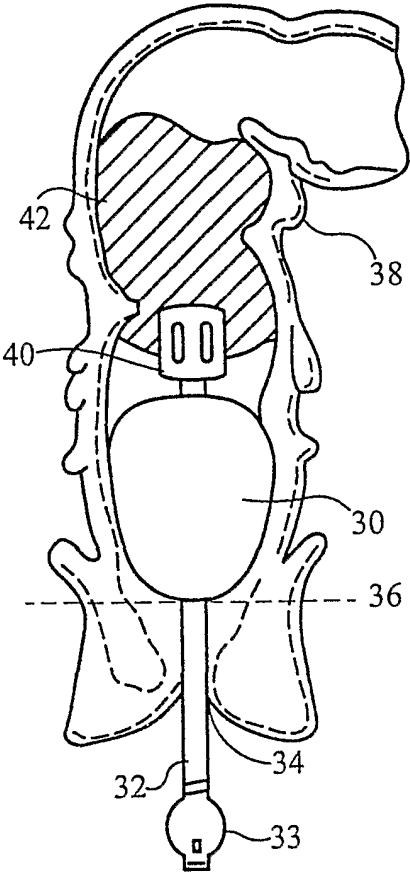


FIG. 3

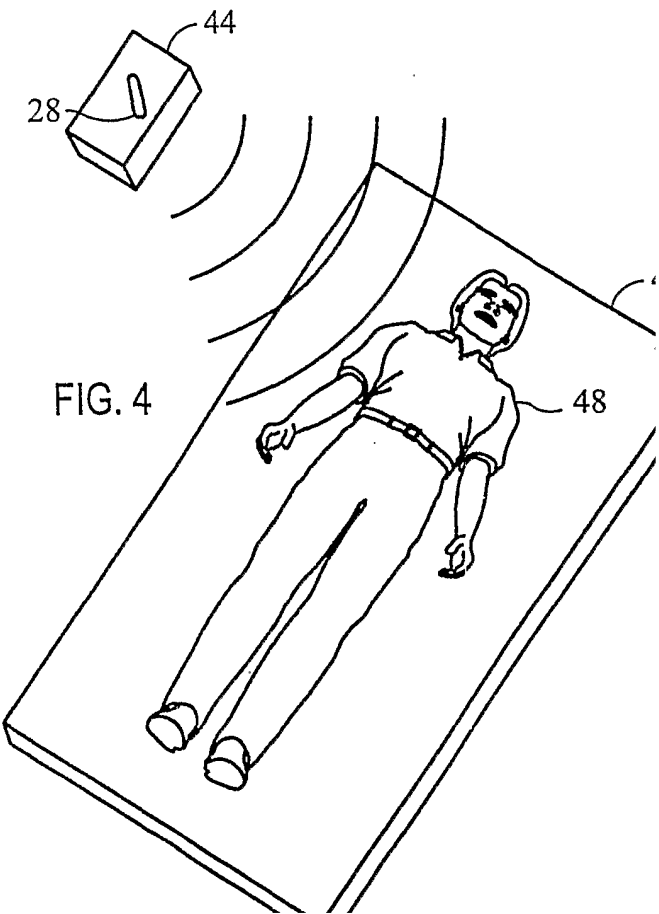


FIG. 4

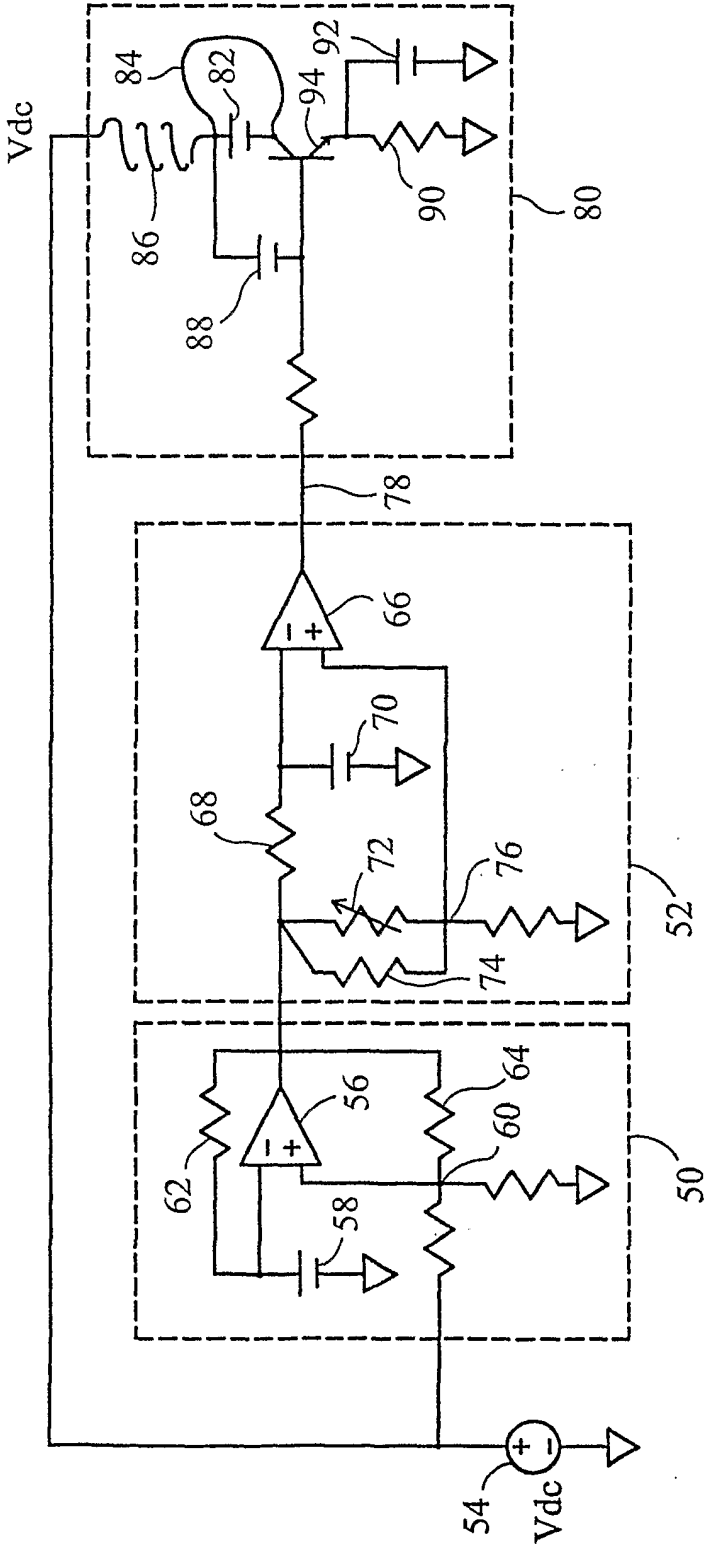


FIG. 5

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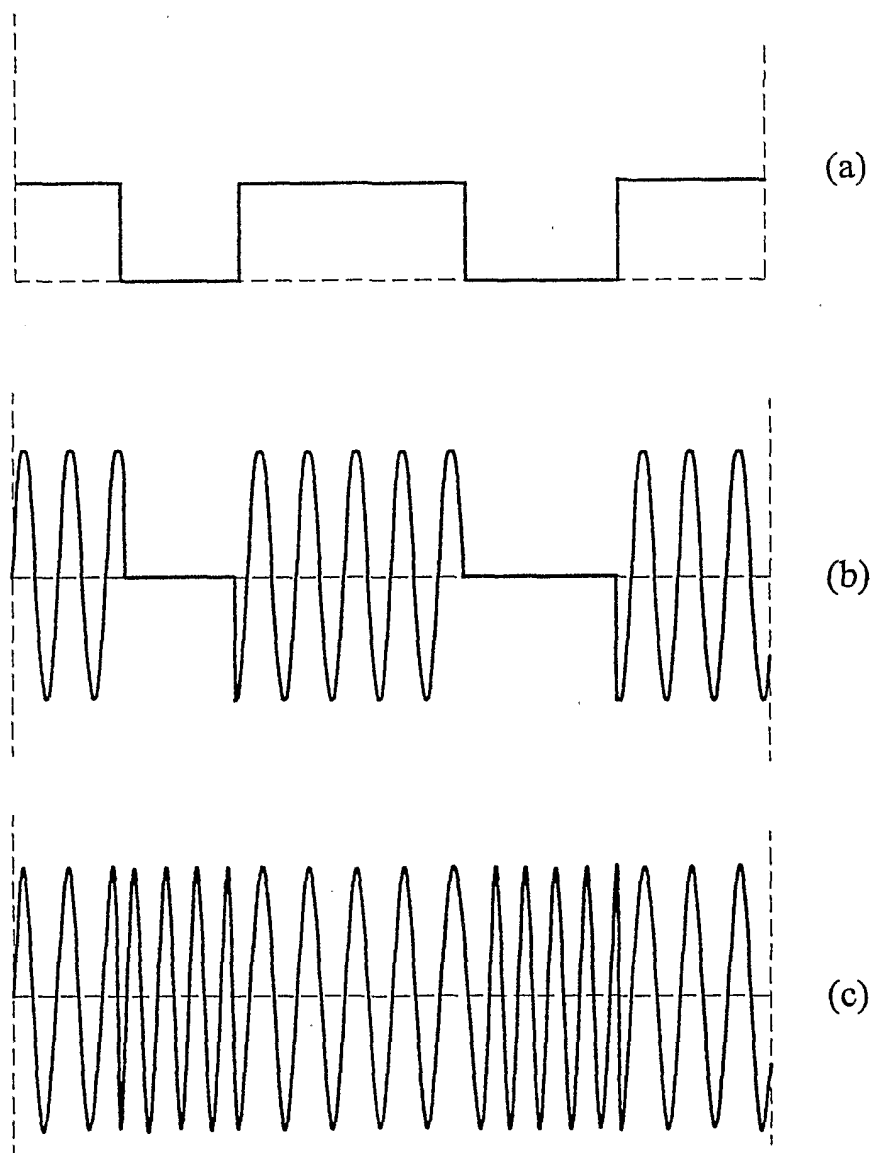


FIG. 6

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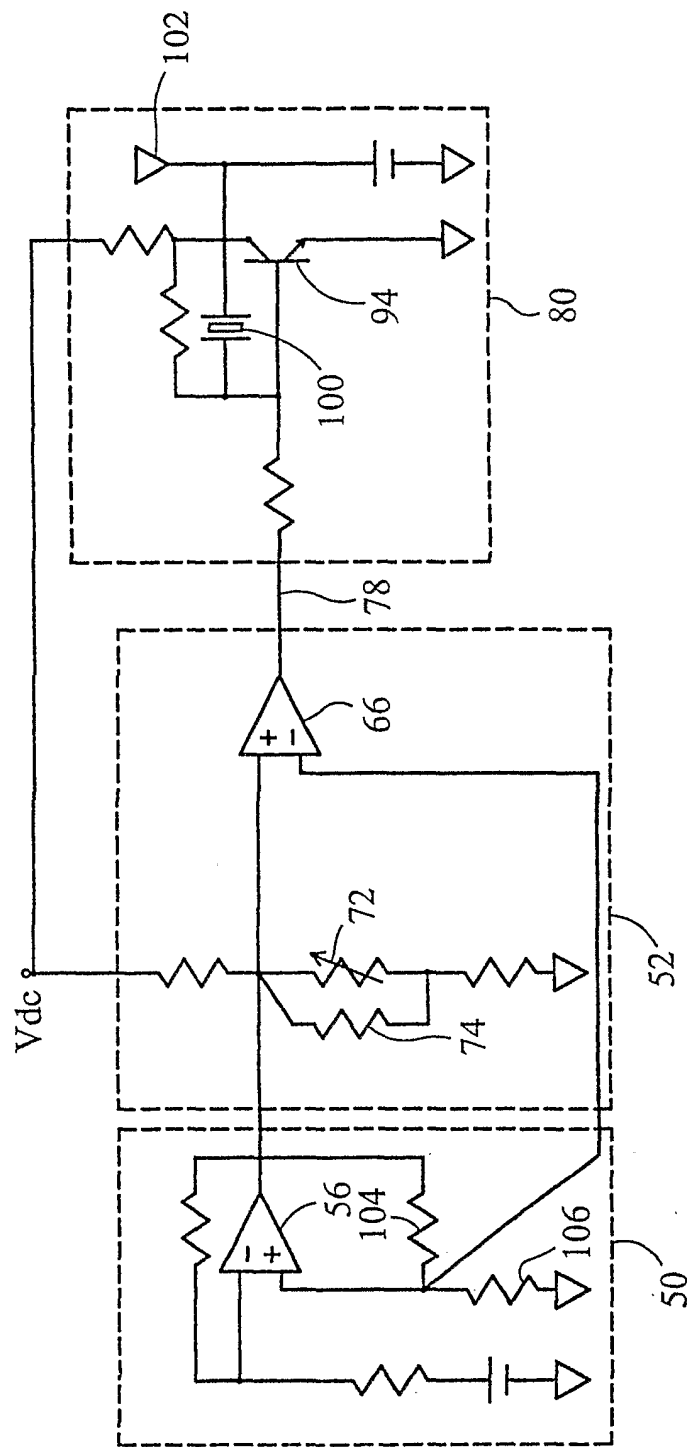


FIG. 7

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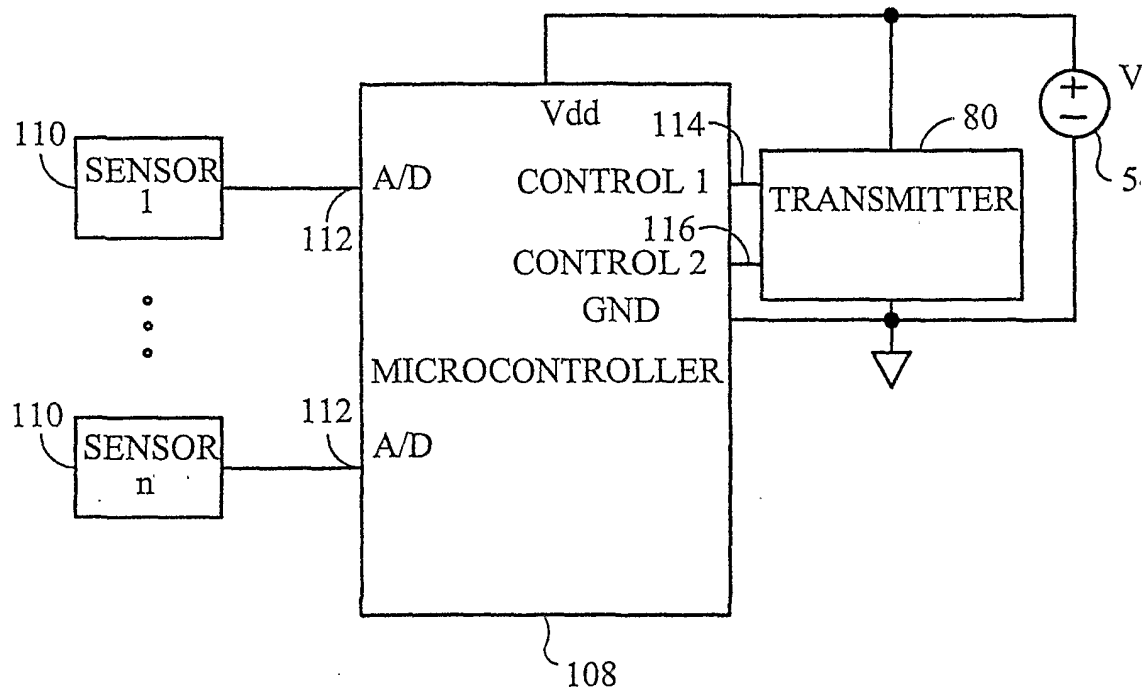


FIG. 8

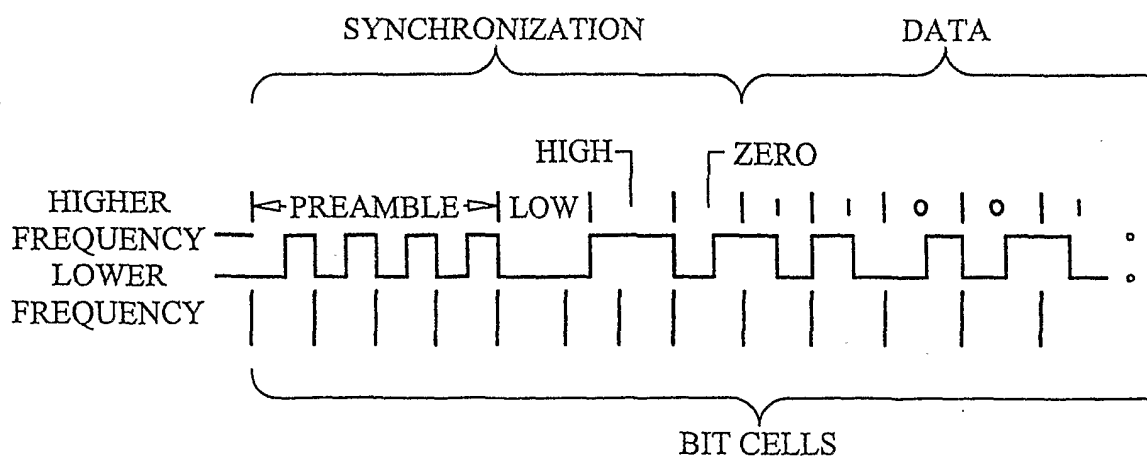


FIG. 9

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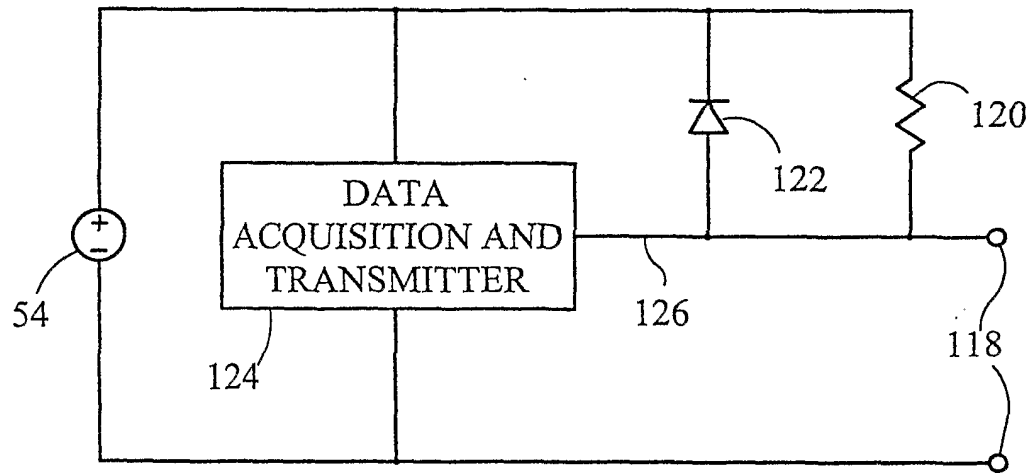


FIG. 10

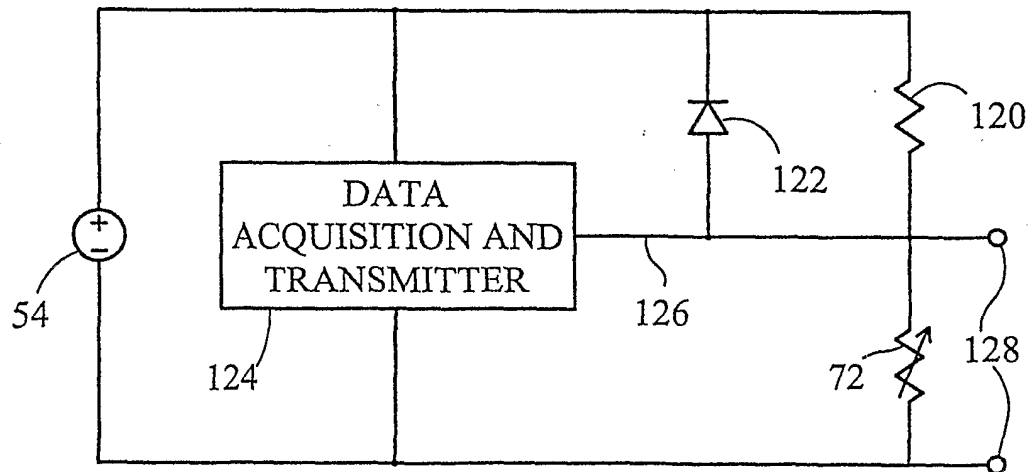


FIG. 11

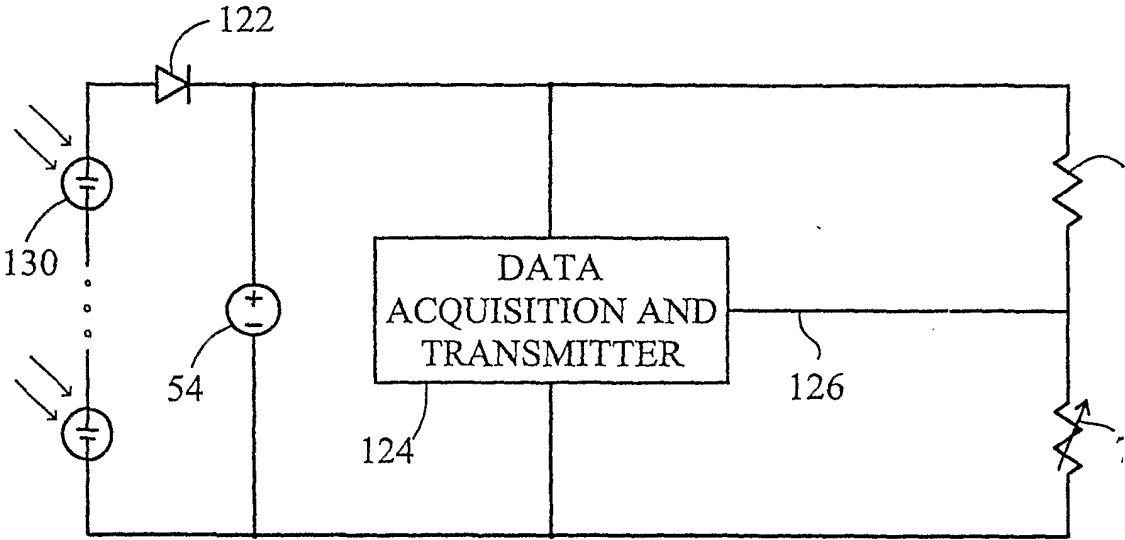


FIG. 12

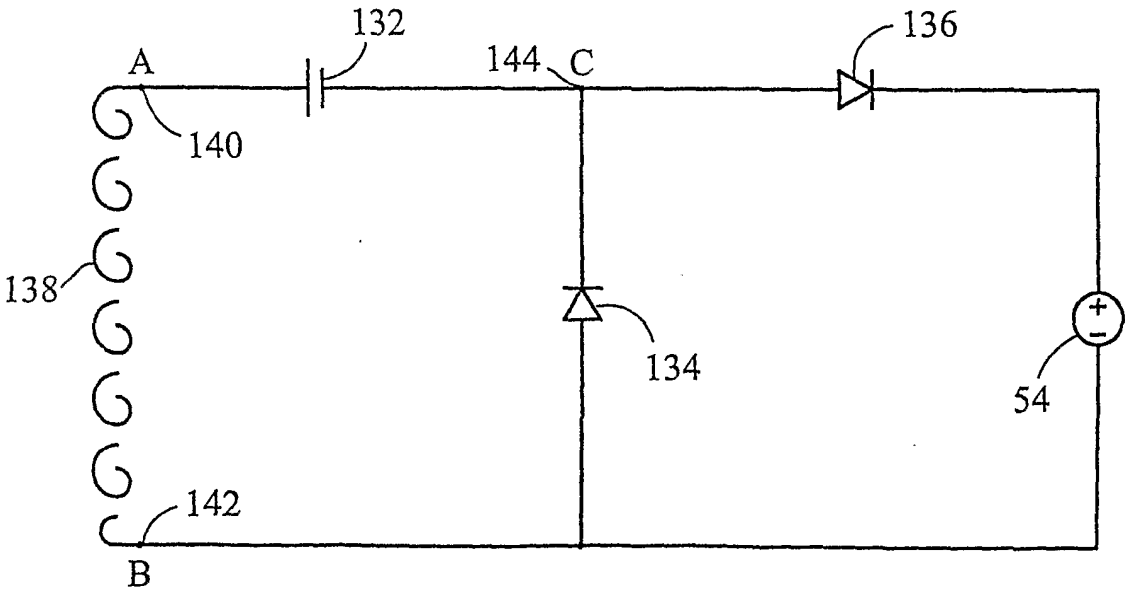


FIG. 13

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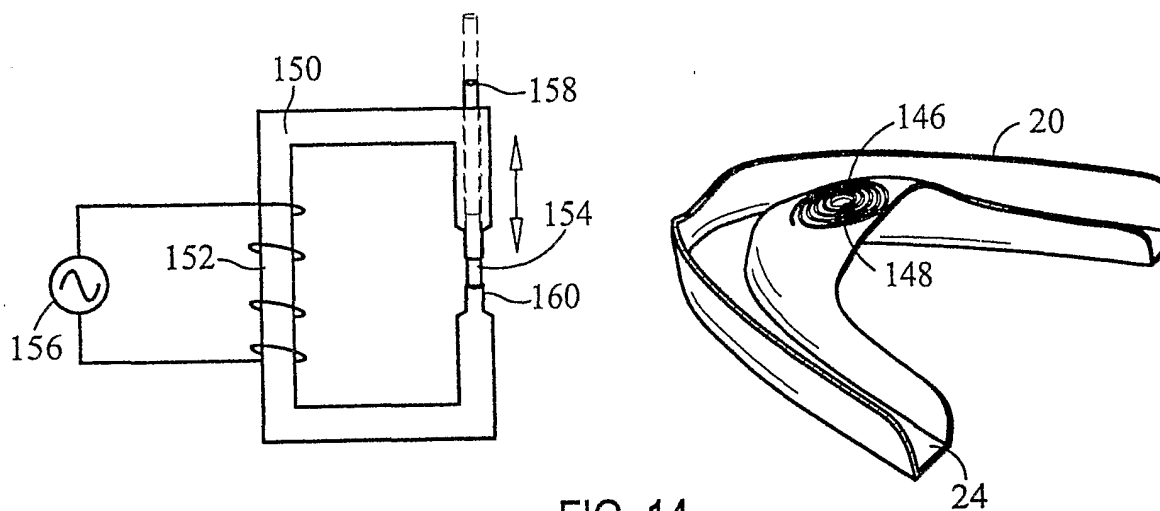


FIG. 14

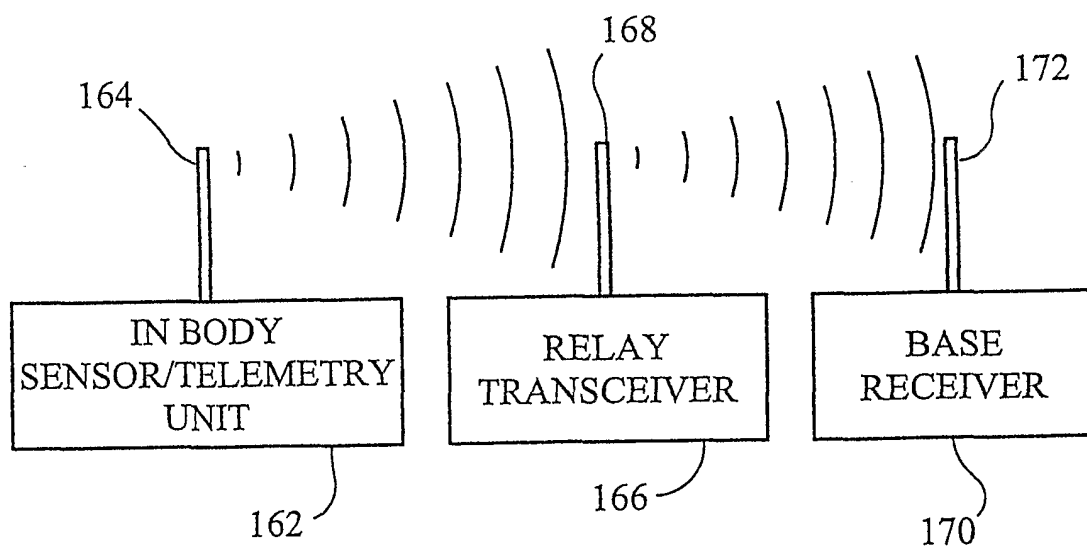


FIG. 15