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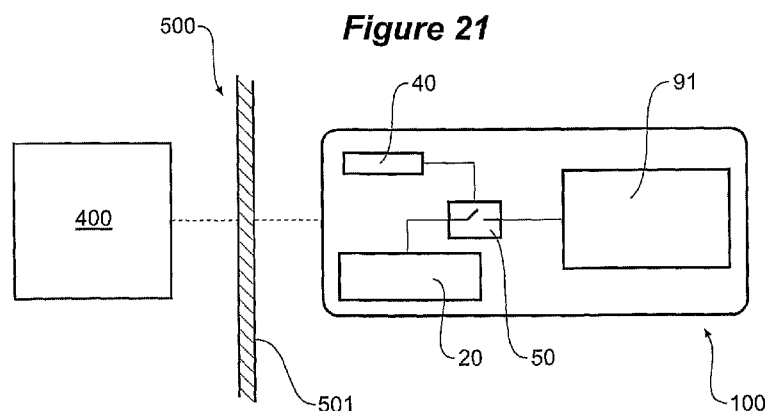
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(54) Title: MEDICAL IMPLANT WITH SAFETY FEATURE



(57) Abstract: A medical implant and system comprising a safety feature for reducing the likelihood of damage caused to a user of the implant system by exposure of body tissue and fluids to electrical energy from a power source of the implant. In one aspect, the medical implant comprises a disconnect switch which, upon actuation in response to an event, isolates the power source to prevent exposure to the user. In another aspect, there is provided a hermeticity failure sensor which, upon detection of a rupture in a hermetic casing of the medical implant, generates a detection signal.

MEDICAL IMPLANT WITH SAFETY FEATURE

TECHNICAL FIELD

The present invention relates to medical implants and to controlling power provided to the implant.

PRIORITY

This application claims priority from the following:

- Australian Provisional Patent Application No. 2008905254 entitled "Power Control For A Medical Implant" filed on 9 October 2008; and
- Australian Provisional Patent Application No. 2009901836 entitled "Medical Implant With Safety Feature" filed on 28 April 2009.

The entire content of each of these applications is hereby incorporated by reference.

INCORPORATION BY REFERENCE

The following documents are referred to in the present application:

- US Patent Application No. 2003/0171787 entitled "Cochlear Implant";
- US Patent No. 6,358,281 entitled "Totally Implantable Cochlear Prosthesis";
- International Patent Application No. PCT/AU96/00403 (WO97/01314) entitled "Apparatus And Method Of Controlling Speech Processors And For Providing Private Data Input Via The Same".

The entire content of each of these documents is hereby incorporated by reference.

BACKGROUND

Medical implants are used in a wide variety of applications, from regulating heart rhythm (e.g. a pace maker) to improving hearing in a user. Implantable hearing prostheses such cochlear implants are widely used in restoring a sense of hearing to profoundly deaf persons.

A cochlear implant allows for electrical stimulating signals to be applied directly to the auditory nerve fibres of the user, allowing the brain to perceive a hearing sensation

approximating the natural hearing sensation. These stimulating signals are applied by an array of electrodes implanted into the user's cochlea.

The electrode array is connected to a stimulator unit which generates the electrical signals for delivery to the electrode array. The stimulator unit in turn is operationally connected to a signal processing unit which also contains a microphone for receiving audio signals from the environment, and for processing these signals to generate control signals for the stimulator.

The signal processing unit is in practice, located externally to the user and the stimulator is implanted within the user, usually near the mastoid on the user's skull and underneath the surrounding tissue. The processor and stimulator may communicate by various wireless means including by a radio frequency link.

Despite the application of world's best practice in manufacture of such prostheses, there is always some risk of malfunction. Whilst these devices are designed to have minimal impact on user safety should they fail, the outcome of some failure modes is difficult to either control or predict. Until recently, cochlear implant hearing prostheses have been powered from energy that is electro-magnetically conveyed by external electronics systems located outside the body. Any user discomfort resulting from an electronics system or other failure is readily alleviated as soon the user removes this external part.

More recently however, such devices are provided with on-board power supplies that are also implanted within the user, as part of the implant.

A random semiconductor component failure within an implanted prosthesis may for example; cause localized unsafe heating of adjacent body tissue and potential user discomfort.

A strong impact to a user's head has the potential to damage the hermetic housing of an implanted hearing prosthesis sufficiently to allow ingress of body fluid. On bridging electrically powered circuitry, the ion rich, aqueous body fluids would be subject to electric current flow, electrolysis and subsequent production of toxic substances. Under

the pressure created by the electrolytic evolution of gaseous components, these toxic substances might be expelled into surrounding body tissue with dire effect to the user.

SUMMARY

According to one aspect of the present invention, there is provided a medical implant comprising:

- a disconnect switch interface for generating a disconnect signal in response to an event; and

- a power source disconnect switch for electrically isolating a power source from the medical implant in response to the disconnect signal.

In one form, the medical implant further comprises the power source.

In one form, the disconnect switch interface comprises an audio receiver and signal processor for receiving and processing the event in the form of an input audio signal to generate the disconnect signal if the input audio signal satisfies one or more criteria.

In one form, the one or more criteria comprise one or more of amplitude, frequency and spectral content.

In one form, the disconnect switch comprises a magnetic element and the disconnect switch interface comprises a magnet.

In another form, the disconnect switch and the disconnect switch interface are provided by an acceleration-activated switch.

In another form, the disconnect switch interface is provided by an implanted push-button.

In a further form, the disconnect switch interface is an external actuator.

In one form, the event is a rupture of a hermetic casing of the medical implant and the disconnect switch interface is a hermeticity failure sensor.

In one form, the hermeticity failure sensor comprises a pressure sensor.

In one form, the hermeticity failure sensor comprises a humidity sensor.

In another form, the hermeticity failure sensor comprises both a pressure sensor and a humidity sensor.

In one form, the medical implant is a cochlear implant.

According to a second aspect of the present invention, there is provided a medical implant system comprising:

- an external component; and

- a medical implant for implantation in a user, the medical implant comprising:

- a disconnect switch interface for generating a disconnect signal in response to an event; and

- a power source disconnect switch for electrically isolating a power source from the medical implant in response to the disconnect signal.

In one form, the medical implant system is a cochlear implant system and the external component is a sound processor and the medical implant is a cochlear implant.

According to a third aspect of the present invention, there is provided a power source module comprising a hermetically sealed casing having an internal pressure and housing a power source, at least a portion of the hermetically sealed casing comprising a flexible portion such that upon a change between the internal pressure and an external pressure, the flexible portion acts to isolate the power source.

According to a fourth aspect of the present invention, there is provided a medical implant comprising a hermetically sealed container having a first internal pressure, the power source module comprising:

- a second hermetically sealed container having a second internal pressure and housing:

- a power source;

- a first switch contact connected to the power source;
- a second switch contact for connection to a power drain;
- a coupling member operationally connected to one of either the first switch contact or the second switch contact; and
- a flexible portion operationally connected to the coupling member such that upon a change in differential pressure between the first pressure and the second pressure, the flexible portion acts on the coupling member to separate the first and second switch contacts, thereby isolating the power source.

According to a fifth aspect of the present invention, there is provided a medical implant system comprising:

- an external component; and
- a medical implant according to the fourth aspect.

In one form, the medical implant system is a cochlear implant system and the external component is a sound processor and the medical implant is a cochlear implant.

According to a sixth aspect of the present invention, there is provided a medical implant comprising:

- a hermetically sealed container housing;
- one or more hermeticity failure sensors for sensing a failure in hermeticity of the hermetically sealed container and for generating a detection signal in response to the one or more hermeticity failure sensors sensing a failure in the hermeticity of the hermetically sealed container.

In one form, the detection signal actuates a disconnect switch to isolate a power source from the medical implant.

In one form, the detection signal actuates an alarm warning of a hermeticity failure.

According to a seventh aspect of the present invention, there is provided a medical implant system comprising:

- an external component; and

a medical implant comprising a hermetically sealed container housing one or more hermaticity failure sensors for sensing a failure in hermaticity of the hermetically sealed container and for generating a detection signal in response to the one or more hermaticity failure sensors sensing a failure in the hermaticity of the hermetically sealed container.

In one form, the detection signal actuates a disconnect switch to disconnect a power source from the medical implant.

In another form, the detection signal actuates an alarm warning of a hermaticity failure.

In one form, the medical implant system is a cochlear implant system and the external component is a sound processor and the medical implant is a cochlear implant.

DRAWINGS

The various aspects of the present invention will now be described with reference to the following drawings in which:

Figure 1 – shows a schematic view of a medical implant according to one aspect of the present invention;

Figure 2A – shows one arrangement of the medical implant of Figure 1;

Figure 2B – shows another arrangement of the medical implant of Figure 1;

Figure 2C – shows yet another arrangement of the medical implant of Figure 1;

Figure 2D – shows a further arrangement of the medical implant of Figure 1;

Figure 3 – shows a power source disconnect interface according to one aspect of the present invention;

Figure 4 – shows a voltage waveform resulting from the interface of Figure 3;

Figure 5 – shows one arrangement of a part of a medical implant according to one aspect of the present invention;

Figure 6 – shows another arrangement of a part of a medical implant according to an aspect of the present invention;

Figure 7 – shows a circuit schematic of a power source disconnect switch;

Figure 8 – shows a schematic of a medical implant incorporating the arrangement of Figure 4;

Figure 9 – shows an alternative form of a power source disconnect interface;

Figures 10A and 10B – show yet a further alternative of a power source disconnect interface; and

Figure 11 – shows an application of the power source disconnect interface of Figure 10.

Figure 12 – shows a medical implant according to a first aspect of the present invention;

Figure 13 – shows the medical implant of Figure 1 with a rupture in the hermetically sealed casing;

Figure 14 – shows a power source module according to one aspect of the present invention;

Figure 15 – shows one form of the power source module of Figure 3;

Figure 16A – shows the power module of Figure 4 in use in a medical implant;

Figure 16B – shows the power source module of Figure 5A when the medical implant is ruptured;

Figure 17A – shows an alternative form of the power source module; and

Figure 17B – shows the power source module of Figure 6A when the medical implant is ruptured;

Figure 18A – shows an alternative arrangement in which a mechanical transducer is used to detect a failure in the hermeticity of the implant;

Figure 18B – shows the arrangement of Figure 7A with a rupture in one half of the implant;

Figure 18C – shows the arrangement of Figure 7A with a rupture in the other half of the implant;

Figure 19A – shows a further embodiment of the arrangement of Figure 2 using a plurality of sensors and logic circuits;

Figure 19B – shows a further variation of the arrangement of Figure 8A;

Figure 19C – shows yet a further variation of the arrangement of Figure 8A;

Figure 20 – shows an arrangement in which a detection signal is generated that may be used to actuate other functions in response to a detected failure in hermeticity;

Figure 21 – shows a medical implant system incorporating one or more features of the various aspects of the present invention;

Figure 22 – shows the system of Figure 10 as applied to one example of a cochlear implant system; and

Figure 23 – shows a medical implant system incorporating on or more aspects of the arrangement shown in Figure 20.

DETAILED DESCRIPTION

While the various aspects of the present invention are described in application to a cochlear implant, it will be understood that the various aspects are equally applicable to other medical implants including: ABI (Auditory Brainstem Implant, electrode for hearing, placed in the brainstem) such as Cochlear Corporation's Nucleus 24 [R] Multichannel Auditory Brainstem Implant (Multichannel ABI). The auditory brainstem implant consists of a small electrode that is applied to the brainstem where it stimulates acoustic nerves by means of electrical signals. The stimulating electrical signals are provided by a signal processor processing input sounds from a microphone located externally to the user. This allows the user to hear a certain degree of sound.

FES (Functional Electrical Stimulation) - FES is a technique that uses electrical currents to activate muscles and/or nerves, restoring function in people with paralysis-related disabilities. Injuries to the spinal cord interfere with electrical signals between the brain and the muscles, which can result in paralysis.

SCS (Spinal Cord Stimulator) - This system delivers pulses of electrical energy via an electrode in the spinal area and may be used for pain management. An example of a commercially available system is the RESTOREPRIME system by Medtronic, Inc, USA.

Figure 1 shows a schematic representation of a broad form of one aspect of the present invention. Shown there is a medical implant 100 with a hermetic housing or casing 10. The implant 100 is powered by power source 20. The power source 20 is illustrated schematically, and it will be appreciated that the power source 20 may provided either from outside the medical implant 100 (e.g. in a separate power module) or from within the implant 100 (e.g. from an internal battery or other internal power source).

Disposed between the power source 20 and any electrically conductive part of the medical implant 20, is a disconnect switch 50, which, when actuated, electrically isolates the power source 20 from the medical implant 100. The disconnect switch 50 actuates in response to a disconnect signal, which is generated from a disconnect switch interface 40 in response to an event as will be described in more detail below. Disconnect switch interface 40 is again shown schematically in Figure 1, to illustrate that disconnect switch interface 40 may be disposed either outside the medical implant 100 or inside the medical implant 100 as will be described in more detail below.

Figures 2A to 2D illustrate various possible combinations of the locations of the power source 20 and disconnect switch interface 40 in relation to the medical implant 100. In Figure 2A, the power source 20 is disposed inside the medical implant 100 and the disconnect switch interface 40 is disposed outside the medical implant 100. In Figure 2B, both the power source 20 and the disconnect switch interface 40 are disposed inside the medical implant 100. In Figure 2C, the power source 20 is disposed outside the medical implant 100, in one embodiment, in a separate power module 101, which may be implanted or located externally of the user. In Figure 2D, both the power source 20 and the disconnect switch interface 40 are located outside the medical implant 100. It will also be understood that further combinations may be possible, where for example, there are two or more disconnect switch interfaces 40, where one or more might be disposed inside medical implant 100 and one or more might be disposed outside medical implant 100.

It will also be appreciated that in some embodiments, the power source module 101 as shown in Figures 2C and 2D may itself be the medical implant, having the disconnect switch 50 and the power source 20 within the module 101. The module 101 may be used to power another medical implant 100, and upon detection of an event and subsequent disconnect signal as described further below, the disconnect switch 50 will actuate to electrically isolate the power source 20 from the medical implant being power module 101, as well as the other medical implant 100 which is being powered by power source 20.

In other examples, the medical implant 100 may be the combination of a primary medical implant such as cochlear implant 100 and a power source module 101.

In use, when disconnect switch 50 is actuated in response to the disconnect signal from the disconnect switch interface 40, power source 20 is electrically isolated from the medical implant 100. Thus, there is no part of the medical implant that is electrically live, which might then lead to the problems described above if tissue or body fluids of the user come into contact with any electrically conductive part of the medical implant.

Various examples embodying different embodiments will now be described in detail.

According to one aspect, the present invention provides a means whereby a user, experiencing discomfort due to malfunction or accidental misuse of the device, may temporarily or permanently interrupt the primary source or supply of electrical or other energy stored within the prosthesis such that any discomfort attributable to the supply of this stored energy is alleviated.

In one form, an emergency power disconnection system for use in a totally implantable hearing prosthesis can be configured by those skilled in the art, to use the audio signal as detected by the sound-receiving microphone of the prosthesis as a way of triggering the implanted battery or power source to be disconnected. In one example, three knocks of a finger knuckle joint upon a recipient's skull (one form of an event), as represented in Figure 3 can be converted to electrical signals by a microphone, then processed electronically, in any combination of analogue and or digital form, so as to trigger a break to the electrical connection between the battery and the electronics circuitry of an implanted prosthesis. In this example, the microphone and processing electronics act as the disconnect switch interface 40 to generate the disconnect signal to actuate the disconnect switch 50 as shown in Figure 1 for example.

Inadvertent operation of this emergency switch in response to normal incoming sounds is largely prevented through the use of frequency selective, band pass filters that reject all but the spectral components of head knocking. Electronic temporal discrimination is also applied to distinguish the repetitive transient characteristic of head knocking as well as to count the number of knocks. Activation of the emergency off switch, thus only occurs when just three knocks are detected within an acceptable time period spanning for example, 1 to 4 seconds. The relatively high loudness of the knocking sound, compared to

most other sounds further adds to the unlikelihood of inadvertent operation since the threshold level of sound required for activation can be set to levels seldom achieved by normal everyday sounds.

The low duty cycle transient nature of such head knocking signals is demonstrated in Figure 4 which shows a plot of output voltage versus time from an actual microphone implanted within the head of a person while their head was tapped as described. The signal displayed by this example is typical of the signal that would trigger the emergency off switch (or disconnect switch) to operate.

In an alternative arrangement, use could be made of a single tap, or two taps, to the skull (another form of an event), as is described in US Patent Application No. 2003/0171787 (previously incorporated by reference) which describes various means of providing a shut down function to parts of a control circuit. In accordance with one aspect of the present invention, the signal generated from this described arrangement could be used as a disconnect signal to cause the energy storage device or battery to disconnect from the remainder of the circuit.

In one embodiment, medical implant 100 is a cochlear implant. Figure 5 illustrates the main functional blocks of cochlear implant 100 according to this aspect of the present invention. Shown there is microphone 110, receiving sounds surrounding the user. Microphone 110 converts the received audio signals and converts these to an electrical signal. The electrical signal is provided to signal conditioner and filter 120 for discriminating specific audio signals having particular spectral and temporal characteristics (such as tapping). Signal conditioner and filter 120 then provides a signal to signal event detector and counter 130 for detecting and counting events meeting the specified criteria to be classed as a tap. Upon determining that the input sound results from three taps to the user's skull, a disconnect signal is generated by signal event detector and counter 130 and provided to disconnect switch 50, which then disconnects energy or power source or battery 20 from the rest of the implant 100. In one embodiment, the battery 20 and disconnect switch 50 may be encased in a high strength and hermetically sealed container 101. While in this embodiment, disconnect switch 50 is disposed inside battery casing 101 with the battery or power source 20, it will be appreciated that in other

embodiments, disconnect switch 50 may be disposed outside the battery casing 101 and within the medical implant 100 itself. In other embodiments, there may be no additional casing around battery or power source 20.

Battery charging and power distribution functions may be provided by block 140.

This configuration allows the implanted cell, battery of cells or energy or power source 20 to be disconnected and isolated from the medical implant 100 when the head is tapped three times. In this configuration, re-connection of the battery may be possible by the user. For example, in one embodiment, connection may be re-established by the user tapping their knuckle ten times (for example) on the side of their head over a period of, for example, 4 to 12 seconds. In this arrangement, the same signal processing will be conducted, generating a "connect signal" to re-connect battery 20 to the rest of the circuit.

In an alternative arrangement, re-connection may be accomplished by external means such as a wireless link 160, using RF signals or IR signals, as shown in Figure 6. Furthermore in Figure 6, there is shown resistor network 102, comprising high value resistors, that limits available battery current to a low and safe value, even in the event of a single component failure, yet sufficient to preserve the functionality of the sound-initiated disconnect system.

Figure 7 shows a more detailed arrangement of the disconnect switch 50 within casing 150, connected to battery 20. In this embodiment, use may be made of the principals of multiple redundancy to achieve partial immunity to component failure so as to achieve high reliability in disconnecting the battery supply of an implanted hearing prosthesis. In this regard, multiple banks of parallel resistors 7, 8, 9, 18, 11, 13 and 14 are used.

In this circuit the normal supply of battery power through the two series connected, field effect transistors (FETs) 1 and 2 results from their "switched on" low resistance state, caused by the application of a voltage to their gate terminal that is more negative than their source terminal. This gate to source voltage, supplied from the latching circuits, falls to almost zero when an appropriate negative going voltage, as initiated when battery disconnection is desired (via switch 12 provided in one embodiment, by signal event

detector and counter 130 from Figures 5 and 6), is conveyed to the input of both latch circuits 3 and 4. With almost zero, gate to source voltage, the internal source to drain resistance of both FETs 1 and 2 increases significantly to such an extent that the supply of battery current to other prosthesis circuitry beyond the barrier 150 (indicated by the dashed line) is virtually zero.

Power source de-coupling capacitors 15 and 16 are also shown in Figure 7.

Figure 8 illustrates the main functional blocks of a cochlear implant 100 incorporating one aspect of the invention. Shown there is implant 100, including microphone 110 for receiving sound (such as the sound of tapping on the user's skull). The converted sound signal is then applied to analogue to digital converter (A/D) 160 to convert the analogue electrical sound signal from microphone 110 (as conditioned by signal conditioner 120) in a digital signal, for input to electrode switching circuitry 180 which processes and applies stimulating signals to cochlear electrode array 230 for stimulation of the user's cochlea. The remaining blocks 190, 200, 210, 220 and 140 are part of a conventional cochlear implant as will be understood by the person skilled in the art.

As previously described, in accordance with this aspect of the present invention, signal conditioner 120, also applies a signal to signal event detector and counter 130, which, upon determination of the surrounding sound as three taps to the skull in this example, generates a disconnect signal to battery or power source disconnect switch 50. This will then disconnect battery 20 from the remainder of the implant 100 as previously described.

It will be understood that any other suitable user interfaces or means of generating a disconnect signal may be used in this aspect of the invention. For example, in US Patent Application No. 2003/0171787 (previously incorporated by reference), a control signal is generated to control various parts of the implant by various means. According to this aspect of the invention, this control signal could be used an event to generate the disconnect signal to disconnect the battery 20 from the remainder of the implant. In this US application, in one example, the control signal is generated upon the detection of a single, or two taps to the user's skull. In another example, the user interface is by way of a magnetic switch in the implant circuitry which may be activated by an external magnet, or

an implanted magnet. In other examples, the user interface could be a compliant membrane switch or a piezo electric switch, each as described in the incorporated US patent application.

US Patent No. 6,358,281 (previously incorporated) describes a number of other arrangements that could be used as a user interface for this aspect of the present invention. In particular, described therein is a pressure switch that can be actuated by the user (another example of an event), a magnetic switch that can be actuated by the user by way of an external magnet, and an external data transmitter that is able to generate instructions via various wireless links including radio frequency (RF) and infra red (IR).

In International Patent Application No. PCT/AU96/00403 (WO97/01314), (previously incorporated by reference), there is described a method of generating control signals within a cochlear implant using specific audio instructions, including voice commands from the user. Such an arrangement may also be used as the disconnect switch interface to generate the disconnect signal in response to the event of the audio instructions, for use in this aspect of the present invention.

Various other alternatives to the examples are described above are possible using a variety of manually- activated controls, switches and transducers to detect human intervention as examples of an event, intended to initiate the disconnection of energy or power sources such as batteries.

In the example shown in Figure 9, disconnect switch 50 is provided by a magnetically-actuated electrical switch, (in one example, a magnetically latching reed switch 51), which is used as a bi-stable element to break or interrupt the supply of battery power to the rest of the electronic circuitry of the implanted prosthesis 100, implanted in the user.

Alternatively a non-latching reed switch can be used to either interrupt or establish an electric current so as to trigger an electronic bi-stable circuit element such as a flip-flop into changing state so as to cause the conductivity of the electronic switching component to which it is connected to interrupt or disconnect the battery or energy source. Such a switching component may be a field effect transistor (FET), since the total electrical energy required to maintain this current controlling component in a state of electrical conduction

or insulation is small and thus has little impact on the period over which a battery powered prosthesis can operate per discharge cycle.

As shown in Figure 9, the proximity of a permanent magnet 49 applies a sufficiently strong magnetic field to the reed like contacts of the reed switch 51 so as to hold them together and in electrical contact. When an implanted user wishes to disconnect their battery, they have the option of momentarily pressing a finger 42 against their head at a position between the implant 100 and its associated magnet 49. This event causes the magnet 49 to move away from the implant 100, weakening the magnetic force applied to the reed switch 51 until its contacts open momentarily. This momentarily interrupts the supply of electric current to a flip-flop circuit, causing it and the switching device to which it is connected to interrupt the supply of battery energy to the implant circuitry.

By depressing the skin again, the user can trigger the flip-flop circuit into changing state so that the supply of battery energy is restored. Thus in this embodiment, disconnect switch interface 40 is provided by the combination of magnet 49 and finger 42.

Yet a further disconnect switch interface will now be described with reference to Figures 10A and 10B of Figure 10. In addition to allowing the battery or energy or power source of an implanted prosthesis to be disconnected at the discretion of the user, this variation automatically effects this disconnection when the medical implant is subjected to an event such as an impact or acceleration forces applied either manually by a user, or more importantly in this embodiment, due to an accident or misadventure likely to damage the implant 100.

While normal, everyday impacts to a user's head or implant site have little effect, a high impact event such as collision with a cricket, golf or baseball, or other serious impact such as in a bike or vehicle accident, will act as an automatic disconnect switch interface, to cause disconnection of the battery or energy or power source to the medical implant 100 automatically.

In one example, use is made of an inertial mass, which when acted upon by the acceleration forces that accompany an impact, applies a physical force that breaks or severs the electrical contact with the battery or energy supply circuit. This forms an

acceleration-activated switch. In this arrangement, both the disconnect switch interface and the disconnect switch are provided by the acceleration-activated switch.

A magnetically operated switch (such as a reed switch), can be optionally included as a means to temporarily bypass an already actuated emergency cut-out switch for diagnostic or other purposes.

In Figure 10A, there is shown switch 30 acting as the disconnect switch interface and disconnect switch. Switch 30 has electrical terminals 31 and 32, and a spring 33 supporting an electrically conductive mass 34. In this embodiment, surrounding terminal 32, is a mass receiving element 35 having a portion 36 which when receiving mass 34, allows electrical contact between mass 34 and terminal 32. Surrounding portion 36 is a second portion 37, which when mass 34 is received therein, prevents mass 34 from electrical contact with terminal 32, thus shutting off the switch. This is all housed within an electrically non-conductive housing 38.

Prior to activation, an electrical circuit is established between terminals 31 and 32 via electrically conductive helical compression spring 33 and ball/mass 34. The ball, which is confined within a shallow, electrically non-conductive recess, establishes the circuit by its direct contact with the conductor or terminal 32. When the switch housing is acted upon by sufficient lateral force such as that which is represented by the arrow as seen in Figure 10B, the housing 38 moves with respect to the ball or mass 34. This has the effect of relocating the ball 34 in electrically non-conducting recess or portion 37. This not only severs the electrical contact between the ball and the terminal 32, but the depth of the recess 37 captures and retains the ball 34. The force applied by the compression spring 33 provides further retaining force to ball 34 to keep it in recess 37, and thus keep the switch open/off.

In one embodiment, mass receiving element 35 would be shaped to have a circular portion 36 for receiving the ball 34 for electrical contact, and be surrounded by a circular portion forming non-conducting portion 37, in effect, forming two concentric "channels".

Figure 11 shows one possible embodiment using the acceleration switch of Figure 10. In this embodiment, there is shown cochlear implant 100 with disconnect switch interface 40

connected to battery 20, which supplies power to the remainder 90 of the cochlear implant 100. In this embodiment, three acceleration switches 30, 30' and 30'' as shown in Figure 10 are placed in series in the supply path of battery 20. These can be disposed orthogonally to the direction of expected impact force, or at least favourably aligned in such a manner as to be most sensitive to potentially damaging acceleration and intentional activation forces. Once the emergency cut-off switch has been activated, an optional glass encapsulated magnetically actuated reed switch 60, allows the circuitry to be reactivated using a permanent magnet 70 from outside the body for diagnostic or temporary emergency re-activation purposes.

It will be understood that any number of acceleration switches 30 could be used, including 1, 2, 3, 4, 5 or more. The use of more than one in series provides higher switch-off reliability.

According to another aspect of the present invention, disconnect switch 50 may be actuated upon the event of the hermetic casing of the medical implant 100 being ruptured or otherwise compromised, leading to the risk of biofluids entering the medical implant 100 and coming into contact with live elements. In one embodiment, the disconnect switch interface 40 may be provided by a hermeticity sensor 40.

Figure 12 shows a simplified schematic of a medical implant 100, in this case, a stimulator 100 of a cochlear implant system. Stimulator 100 comprises a hermetically sealed container 10, which houses functional electronics 91 for processing data and generating stimulation signals for stimulating nerve fibres in a recipient's cochlea by way of an electrode array (not shown). The hermetically sealed container 10 also houses a power source 20 for providing power to the functional electronics 30.

As previously described, if hermetically sealed container 10 ruptures (a further example of an event) while it is implanted within the recipient, surrounding biofluids will leak into the stimulator and come into electrical contact with electrical power through possibly the functional electronics 91 or directly with the power source 20. On bridging electrically powered circuitry, the ion rich, aqueous body fluids would be subject to electric current flow, electrolysis and subsequent production of toxic substances. Under the pressure

created by the electrolytic evolution of gaseous components, these toxic substances might be expelled into surrounding body tissue with dire effect to the user or recipient. Furthermore, the recipient may be further put at risk if there is provided a new, and undesirable current path to other parts of the recipients body, through biofluids now contacting electrical current.

Thus, according to one aspect of the present invention, and as shown in Figure 12, stimulator 100 also contains a hermeticity failure sensor, in this example, a pressure sensor 40, which is connected to a disconnect switch 50, connecting power source 20 to the rest of the implant 100.

In the case of traumatic event such as a significant impact to the recipient's head, hermetically sealed casing 10 may become ruptured as shown in Figure 13. This may then allow for the ingress of biofluids 600 into the casing or container 10, to allow contact with functional electronics 91 and/or power source 20.

In accordance with this aspect of the present invention, pressure sensor 40, acting as the disconnect switch interface, will detect a change in pressure and generate and send a disconnect signal to disconnect switch 50, which thereby disconnects and isolates any electrical power to the implant 100 to prevent any consequential damage. This will also act as a trigger to the recipient that there is a problem with his implant, and seek professional assistance.

The pressure change within the hermetically sealed container may be a sudden reduction in pressure as internal gases escape from the container 10, however, it is more likely that the pressure change detected will be a pressure increase within the container 10 as the biofluids seep into the container 10 through the rupture and begin generating gases upon contact with electrical power.

In one form, the power source disconnect switch may be provided by an arrangement as above with reference to Figure 7.

In one example, the pressure sensor 40 may be provided by a piezo resistive strain gauge. Combined with suitable electronics, such a system could provide a reliable pressure detection threshold of for example, 50 millibars for a fully implanted hearing prosthesis with an internal air or gas volume of about 1 cubic centimetre or 1 millilitre, yielding a leak detection threshold of about 50 micro litres.

In another form of the present invention, the pressure sensor 40 and disconnect switch 50 may be provided by, or as part of, a power source module 300 as shown in Figure 14. Power source module 300 has a power source module hermetically sealed container or casing 310, a first contact 320 connected to a power source 340 such as a battery, and a second contact 330 for connection to a power sink or drain such as the functional electronics 91 previously described. As can be seen, pressure sensor 40 may be provided as a part of power source module 300, to act on the first and/or second contacts 320,330 to disconnect the power source 340 from the rest of the implant. As previously described with reference to Figures 2C and 2D, power source module 300 in this arrangement, may be the medical implant 100 itself.

In one form, the pressure sensor 40 of the power source module 300 may be provided by a flexible or moveable portion 41, which, upon a differential pressure between inside and outside hermetically sealed casing 310 (another example of an event), will flex one way or another (outwardly if the internal pressure is greater than the external pressure and inwardly if the internal pressure is less than the external pressure). Figure 15 shows this arrangement with power source module 300 having hermetically sealed container 310, power source 340, pressure sensor 40 being provided by flexible portion 41 (in one example, a flexible membrane), and first and second electrical contacts 320 and 330. Also shown are corrugations 42, surrounding, or partially surrounding flexible portion 41. These may be optionally provided to enhance the action of the flexible portion. Flexible portion 41 and/or corrugations may for example, be provided by a flexible membrane made from 0.1 mm thick, sheet of biocompatible material such as surgical grade stainless steel or titanium metal, or may be provided by a flexible portion of the same material as the hermetically sealed casing which has been appropriately shaped, heat-treated or weakened, or a combination of both or other materials.

Also provided is a displacement or coupling member 350 which is disposed between flexible portion 41 and one of either first or second contacts 320, 330. The coupling member may, for example, be provided by an electrically non-conducting material such as a vitreous glass or ceramic or a polymer such as polyurethane, polyethylene or silicone elastomer.

The operation of power source module 300 will now be described with reference to Figure 16A, which shows power source module 300 located inside a hermetically sealed container 10 of a medical implant 100 such as a stimulator of a cochlear implant system. For clarity, the functional electronics 91 shown in Figures 1 and 2 has been omitted.

In Figure 16A, it can be seen that power source module is able to provide power to the rest of the device since contacts 320 and 330 are touching each other, providing for an electrical path. It will be appreciated that while the contacts 320 and 330 are shown "floating in space" and not connected to anything, that this is a schematic representation and that in practice, one of contact 320 or 330 will be connected to power source 340 and the other of the contacts will be connected to the rest of the circuit, including functional electronics 30.

As can be seen, because in this arrangement, during manufacture, the internal pressure of the power source module 300 has been made to be greater than the internal pressure within the hermetically sealed container 10 of the stimulator or medical implant 100, the flexible portion 41 is bowed outwards. The relative pressures may be controlled by controlling the pressure within the power source module or within the stimulator, or a combination of both. In one example, the internal pressure of the stimulator may be controlled to be about 0.5 Bar less than the internal pressure of the power source module, by setting of an air or gas pressure within the hermetically sealed casing of the stimulator. This is generally set to be about equal to the pressures of what would be expected in vivo.

In Figure 16B, there is shown the arrangement of Figure 16A, however, in this figure, hermetically sealed container 10 of the stimulator 100 has been ruptured, allowing the ingress of biofluids 200. As previously described, this will result in an increase in internal pressure of the hermetically sealed container 10, thus increasing the external pressure on the power source module 300. This in turn causes flexible portion 41 to push inwards, also

pushing down coupling member 350. This in turn pushes on second contact 330, pivoting this away from first contact 320, opening the circuit and effectively disconnecting or isolating power source 340. Accordingly, any biofluids within hermetically sealed container 10 will no longer be exposed to electrical power, reducing the propensity for consequential injury to the recipient. The subsequent interruption of electrical power and cessation of implant functionality are also of benefit in raising the malfunction to the attention of a user, who might otherwise remain unaware of a potentially hazardous, partial malfunction.

This arrangement of medical implant 100 with power source module 300 may be used in a medical implant system 500 comprising an external component and the medical implant. For example, in the case where the medical implant system 500 is a cochlear implant system, the external component 400 is a sound processor and the internal, medical implant 100 is a cochlear implant.

Figure 17A shows an alternative arrangement of power source module 300 within hermetically sealed container 10. In this arrangement, flexible portion 41 is provided in a different region such that an increase in pressure in the hermetically sealed container 10 (due to a rupture for example, as shown in Figure 17B) will result in the displacement of coupling member 350 upwards instead of downwards as previously described. In this arrangement, coupling member 350 is operationally connected to first contact 320 such it pulls first contact 320 away from second contact 330 to open the circuit, as shown in Figure 17B.

Figures 18A, 18B and 18C represent a cross sectional view of yet another alternative configuration whereby the interior volume of an implant 100 housing or casing 10, is pressurized to below ambient pressure within the body and is separated into two, approximately equal sized, gas tight sections 704 and 706, by a flexible dividing member 701. In these views, the functional electronics, the power source and the power source disconnect switch are not shown for clarity, but in one embodiment, are present.

One or more electrical conductors, cast into a block of electrically non-conductive material, form a hermetic electrical feed through member 705. This member allows electrical circuit

currents to pass between sections, while at the same time preserving a hermetic gas tight separation of both sections.

A mechanical transducer, in this case, piezo-resistive strain transducer 702 is attached or coupled to the surface of the flexible dividing member 701 such that a proportion of any mechanical strain applied to the flexible dividing member 701, will also be conveyed to the transducer 702. Electrical circuitry, (which has not been shown to aid clarity), constantly or periodically senses the electrical resistance of this transducer, and hence the strain force applied to the dividing member.

Under conditions of normal use, as illustrated by Figure 18A, this strain force is relatively small since the pressure of the gas filling both sections of the implant housing is largely equal, as represented by the more or less flat surface of the dividing member 701.

In Figure 18B, a rupture or breach 650 of the implant housing, is shown to have caused ingress of body fluid 600 and, a relative increase to the internal pressure within section 706 of the implant housing. The resultant pressure difference between sections 704 and 706, applies mechanical force to the dividing member 701 and a tensile force to the strain transducer, as suggested by the surface curvature of the dividing member 701.

On detecting the subsequent increase to the electrical resistance of the transducer, the electrical circuitry is configured to generate a signal to alert the implant user and isolate or disconnect the stored energy source.

A rupture 650 affecting the other section 704 of the implant housing, as shown in Figure 18C, creates a similar effect in that it too produces a pressure difference between sections, albeit in the reverse direction as illustrated by the reverse curvature of the dividing member 701. In this case the resulting strain applied to the transducer is compressive, and thus causes an equally detectable reduction to the electrical resistance of the strain transducer.

As those skilled in the art will appreciate, numerous other alternatives to the pressurization scheme and configuration illustrated in Figures 18A, 18B and 18C can be applied to detect and ameliorate the implant hermeticity failures.

It will also be appreciated that the internal pressure of the power source module may be manufactured to be less than the expected internal pressure of the hermetically sealed container of the implant in situations where a rupture in the hermetically sealed container of the implant might lead to a decrease in internal pressure.

In this case, the arrangement of flexible dividing member 701 and/or other equivalent elements and coupling member 350 would be adjusted or rearranged accordingly, such that a change in pressure will result in a disconnection of the power source.

It will also be understood that the flexible portion may be directly connected to one of the switch contacts, without a coupling member being disposed therebetween.

It will also be appreciated that the hermeticity failure sensor 40 need not be limited to a pressure sensing arrangement as provided in one form by the arrangement of Figures 16 - 18. A rupture in the hermetic container may be detected by sensing other parameters such as for example, the increase or reduction of a fluid or liquid in the container, an increase in light within the container, and increase in sound within the container. Accordingly, the hermeticity failure sensor 40 may be provided by any other suitable sensing arrangement to infer a hermeticity failure by other means such as, but not limited to; accelerometers to detect excess mechanical shock, humidity or surface moisture transducers that detect fluid ingress, gas sensors that detect loss of a specific gas incorporated within the hermetic protective member implant, transmitting and receiving acoustic transducers that detect internal volumetric changes due to fluid ingress, and one or more light sensitive photo PIN diodes that detect traces of ambient light leakage through any puncture or breach in an otherwise, normally opaque hermetic implant housing.

In some embodiments, more than one sensor may be used to detect failure of the hermetically sealed container. In Figure 19A, there is shown the implant 100 with hermetically sealed container 10, battery 20, functional electronics 91 and disconnect

switch 50. In this arrangement, two sensors or transducers 40, 41 are used to detect hermeticity failure. For example, sensor A (40) and sensor B (41) could both be moisture sensors, located at different places within the implant 100, to increase the likelihood of detection of fluid ingress. Alternatively, one or more moisture sensors could be used in combination with one or more gas sensors or gas pressure sensors.

Logic circuits 51, 52 may be used to control the result of the output of the various sensors used, as shown in Figures 19A, 19B and 19C. While the examples of Figures 19A, 19B and 19C use digital logic gates to combine or process transducer status signals to improve hermeticity failure sensitivity and reliability, those skilled in the art will appreciate that other forms of digital or analogue signal processing can be used with any combination or number of transducers or sensors, to similar effect.

The example shown in Figure 19A uses a digital logic AND gate circuit (52) to interrupt the supply of stored energy only when both two sensing transducers detect a failure in hermeticity. This combination might for example be used to reduce the probability of falsely detecting a hermeticity failure due to failure of one sensor or transducer.

The example shown in Figure 19B uses a digital logic OR gate circuit (51) to interrupt the supply of stored energy when either transducer detects a failure in hermeticity. In this example, the supply of stored energy would still be interrupted after a failure of hermeticity, despite a failure of either transducer.

The example shown in Figure 19C uses a combination of AND (52) and OR (51) gates to interrupt the supply of stored energy when sensor A (40) AND B (41) both detect a failure in hermeticity OR when sensor C (42) detects a failure in hermeticity.

It will be appreciated that any other combination and number of sensors, transducers and logic circuits or functions could be used to detect hermeticity failure and may be tailored for a particular application. It will also be appreciated that the logic functions may be provided by any means such as an integrated circuit or as a programmed function of a microprocessor.

In a further variation, there may be situations where one or more of the various aspects of the invention could be advantageously configured to allow the implant to continue stimulation for a short period during which an easily recognisable alarm is conveyed to the user before power is shut off. As one skilled in the art will appreciate, this alarm could take the form of neural stimulation representing or perceived as; a unique acoustic sound or series of tones or spoken language instructions.

It will also be appreciated that the arrangements described above may be used as hermeticity failure detectors 40, in their own right, with the detection signal being used for other functions not necessarily relating to power source disconnection. For example, the detection may be used simply to issue an alert or alarm. In other examples, the detection signal may be used to disconnect an external power source, for example provided by a battery in an externally-placed processor, providing power subcutaneously for example. In this case, a disconnect switch for the external power source may be provided in the external processor or in a pathway in the internal stimulator.

In other examples, the detection signal need not be used to disconnect a power source, but may rather be used simply to issue an alarm warning of a hermetic failure, may be used to shut off other parts of the circuitry, or may initiate any other function that may be deemed desirable in the event of a detected failure in hermeticity.

It will be understood that in another aspects of the present invention, some embodiments need not have the power source disconnect switch 50. In these embodiments, when the hermeticity failure sensor (whether this comprises a single sensor or a plurality of sensors) detects a rupture in hermetic casing 10, the result is a detection signal which may be used to actuate other functions, other than to actuate the disconnect switch 50.

Figure 20 shows the arrangement of Figure 19A without a battery disconnect switch. In this example, the output of the one or more sensors provides the detection signal (in this example the output is shown as the output of the AND gate, however, in an application with a single sensor, the output may come directly from the sensor itself). This detection signal may then be applied to actuate an alarm or any other desired function in response to the detected failure in hermeticity. For example, the actuated action may be to cause a

display external to the user to indicate the detection of a rupture in the medical implant, or in another example, to issue a set audio signal to the user, perhaps generating the words "Rupture detected". Methods and apparatus as described in International Patent Application No. PCT/AU96/00403 (WO97/01314), (previously incorporated by reference) may be able to be used in this application. In other embodiments, the detection signal may be used to generate a message for transmission to a remote monitoring station in the user's home or in the premises of the user's carer.

Figure 21 shows a general arrangement of a medical implant system 500 to which the various aspects of the present invention may be applied. In Figure 21 there is shown the medical implant system 500 with external component 400 and internal implant 100. Implant 100 as previously described includes functional electronics 91, power source disconnect switch 50, hermeticity failure sensor 40 and power source or battery 20.

External component 400 may provide user-interface or other processing functionality and may communicate with the internal implant 100 through tissue barrier 501 via any suitable method including a physical, hard-wired connection, or wireless means such as by induction or other RF means.

As previously described, if hermeticity failure sensor 40 detects a failure in hermeticity, it may generate a signal as a trigger for performing certain functions such as actuating power source disconnect switch 50 to disconnect power source or battery 20 from the rest of the implant, and/or for issuing an alert or performing some other function.

Figure 22 shows a medical implant system 500 being one example of a cochlear implant system, to which one embodiment of the present invention is applied.

In Figure 22, there is shown external component 400 being a sound processor, and internal implant 100 being a stimulator. Implant 100 is, in use, implanted within the implantee 9.

Chemical energy stored within a cell or battery of cells 420 supplies electrical energy via the wiring 418, to an electrical circuit 417. When incoming sound 15, impinges upon

microphone 416, an electrical audio signal is produced and conveyed to the electrical circuit 417.

Under discretionary control of the user, as captured by the user interface switches 425, this circuit uses various parameters and stored program instructions to extract audio information from the microphone signal. The extracted audio data is encoded for transmission and conveyed to an electromagnetic induction coil 411 via a short length of cable 414.

A significant proportion of the energy 520 radiated by the induction coil 411, is received by a second induction coil 113, associated with the implanted component 100. The received signal is conveyed to the functional circuitry or electronics 91 where the bulk of the electrical energy is extracted to power the implanted part and or to charge its battery 20 via the battery disconnect safety switch 50.

The extracted data component is decoded and processed to control the implanted part and the characteristics of the electrical currents that are delivered to the electrodes 8 that stimulate the neural centres of the implantee or user 9. As with the wiring of the induction coil, the wiring that connects the implant functional electronics 91 to the stimulating electrodes 8 pass through hermetically sealed electrical feed through insulators 7.

The outputs of two hermeticity failure detection transducers 40 and 41, are functionally combined by a logical gate circuit 52 (in this case an "OR" gate), whose output can be made to trigger the implanted circuit or functional electronics 91 to convey a warning of hermeticity failure to the user 9 either directly via an alarm consisting of a unique pattern of applied neural stimulation current or by firstly conveying data indicative of the hermeticity failure to the external control circuit 417 via the two inductions coils 113 and 411.

On receipt of this hermeticity status alert, the external circuit 417 in this example causes an acoustic alarm signal 21 to be emitted from a tiny speaker 422. The external circuit 417 may also produce a wireless transmission signal to be conveyed to a radiating antenna 424.

The electromagnetic energy 23, thus radiated and encoded with information of the hermeticity failure can be received by a nearby, Bluetooth™ like wireless device that too, can be made to sound an alarm or flash a light to alert the carer or guardian of a young infant user. For an adult user, circuit 417 can be optionally programmed to convey neural stimulation data back to the implanted part, which in turn invokes a neural response perceivable as a spoken message informing the user of the hermeticity failure.

The hermeticity failure detection signal output of the “OR” gate 52, may also pass to a time delay circuit 52A, which after the prescribed time delay designed or programmed into the delay circuit has elapsed, causes the battery isolation or disconnect switch 50 to sever the electrical circuit of the battery supply. The 30-second (for example) nominal time delay provided by 52A, allows the implant system to remain powered and functional whilst the various hermeticity failure alerts and alarms are processed and delivered as described.

Figure 23 shows a medical implant system 500 with medical implant 100 and external component 400, communicating through tissue 501 of a user. In the case of a cochlear implant system 500, the medical implant 100 is a cochlear implant and the external component is a sound processor, for example, as described above with reference to Figure 22.

In the arrangement in Figure 23, the medical implant system uses an embodiment similar to that described with reference to Figure 20, in which there is no power source disconnect switch. In this embodiment, upon hermeticity failure sensor 40 detecting a rupture in hermetic casing 10, a detection signal 40' is generated, which may then be used to actuate any other system as described above. In one form, of course, the detection signal may act as the disconnect signal in the embodiment of Figure 22.

Throughout the specification and the claims that follow, unless the context requires otherwise, the words “comprise” and “include” and variations such as “comprising” and “including” will be understood to imply the inclusion of a stated integer or group of integers, but not the exclusion of any other integer or group of integers.

The reference to any prior art in this specification is not, and should not be taken as, an acknowledgement of any form of suggestion that such prior art forms part of the common general knowledge.

THE CLAIMS:

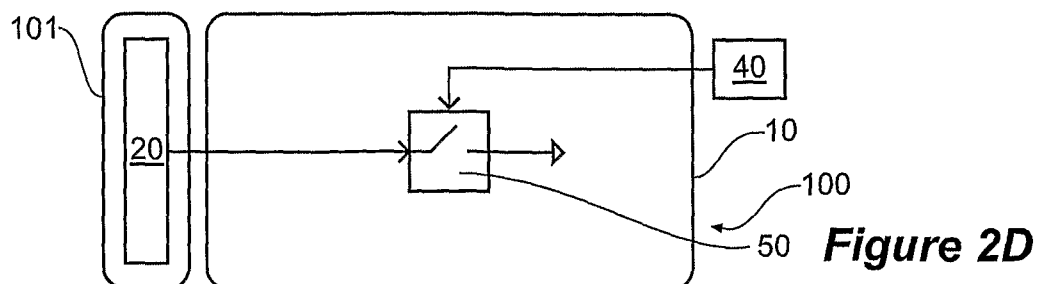
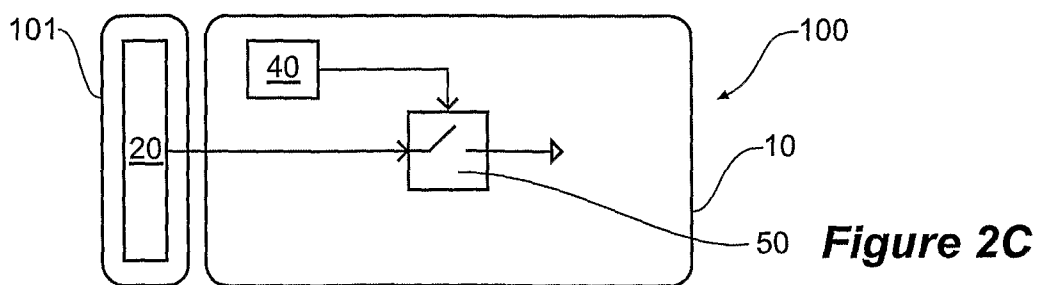
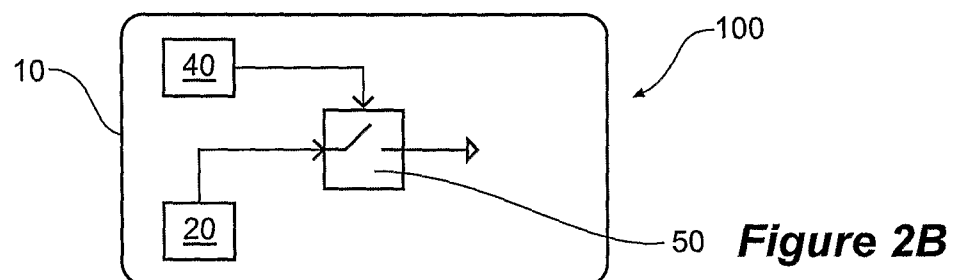
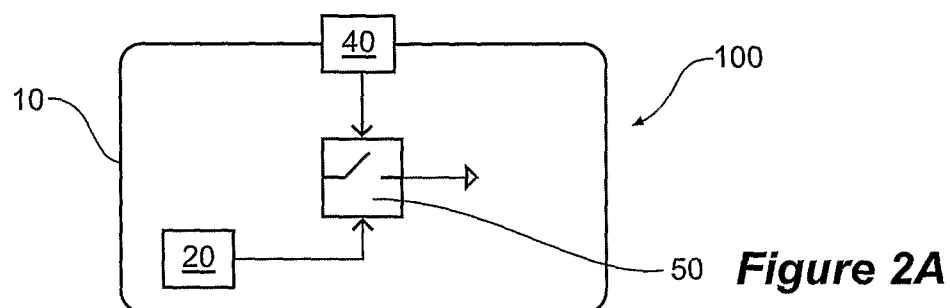
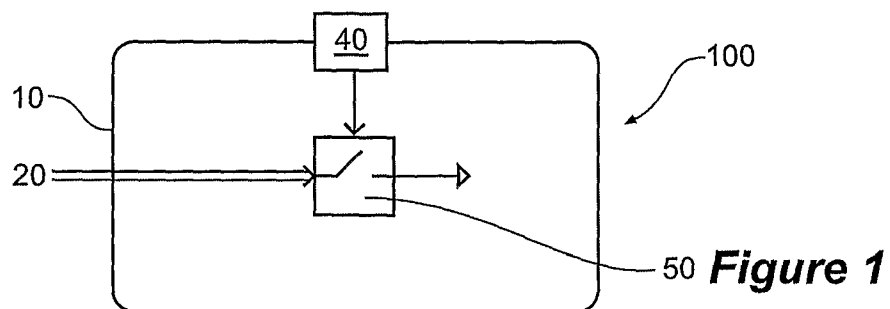
1. A medical implant comprising:
a disconnect switch interface for generating a disconnect signal in response to an event; and
a power source disconnect switch for electrically isolating a power source from the medical implant in response to the disconnect signal.
2. A medical implant as claimed in claim 1 wherein the medical implant further comprises the power source.
3. A medical implant as claimed in claim 1 or 2 wherein the disconnect switch interface comprises an audio receiver and signal processor for receiving and processing the event in the form of an input audio signal to generate the disconnect signal if the input audio signal satisfies one or more criteria.
4. A medical implant as claimed in claim 3 wherein the one or more criteria comprise one or more of amplitude, frequency and spectral content.
5. A medical implant as claimed in any one of claims 1 or 2 wherein the disconnect switch comprises a magnetic element and the disconnect switch interface comprises a magnet.
6. A medical implant as claimed in any one of claims 1 or 2 wherein the disconnect switch and the disconnect switch interface are provided by an acceleration-activated switch.
7. A medical implant as claimed in any one of claims 1 or 2 wherein the disconnect switch interface is provided by an implanted push-button.
8. A medical implant as claimed in any one of claims 1 or 2 wherein the disconnect switch interface is an external actuator.

9. A medical implant as claimed in any one of claims 1 or 2 wherein the event is a rupture of a hermetic casing of the medical implant and the disconnect switch interface is a hermeticity failure sensor.
10. A medical implant as claimed in claim 9 wherein the hermeticity failure sensor comprises a pressure sensor.
11. A medical implant as claimed in claim 9 wherein the hermeticity failure sensor comprises a humidity sensor.
12. A medical implant as claimed in claim 9 wherein the hermeticity failure sensor comprises both a pressure sensor and a humidity sensor.
13. A medical implant as claimed in any one of claims 1 to 12 wherein the medical implant is a cochlear implant.
14. A medical implant system comprising:
 - an external component; and
 - a medical implant for implantation in a user, the medical implant comprising:
 - a disconnect switch interface for generating a disconnect signal in response to an event; and
 - a power source disconnect switch for electrically isolating a power source from the medical implant in response to the disconnect signal.
15. A medical implant system as claimed in claim 14 wherein the medical implant system is a cochlear implant system and the external component is a sound processor and the medical implant is a cochlear implant.
16. A power source module comprising a hermetically sealed casing having an internal pressure and housing a power source, at least a portion of the hermetically sealed casing comprising a flexible portion such that upon a change between the internal pressure and an external pressure, the flexible portion acts to isolate the power source.

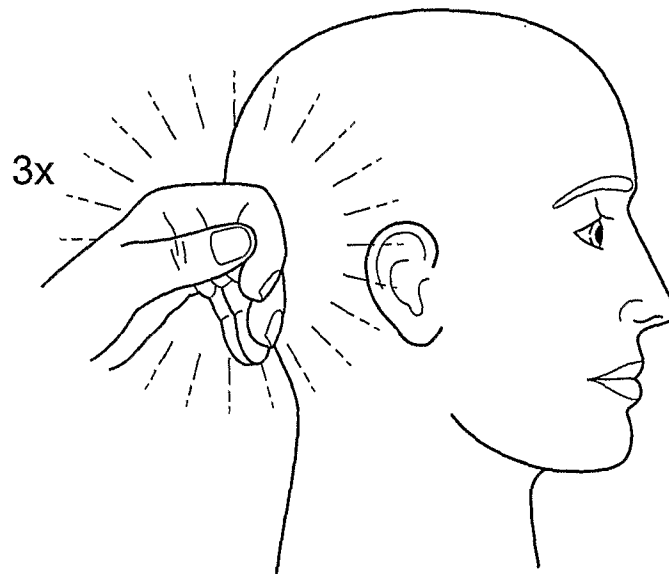
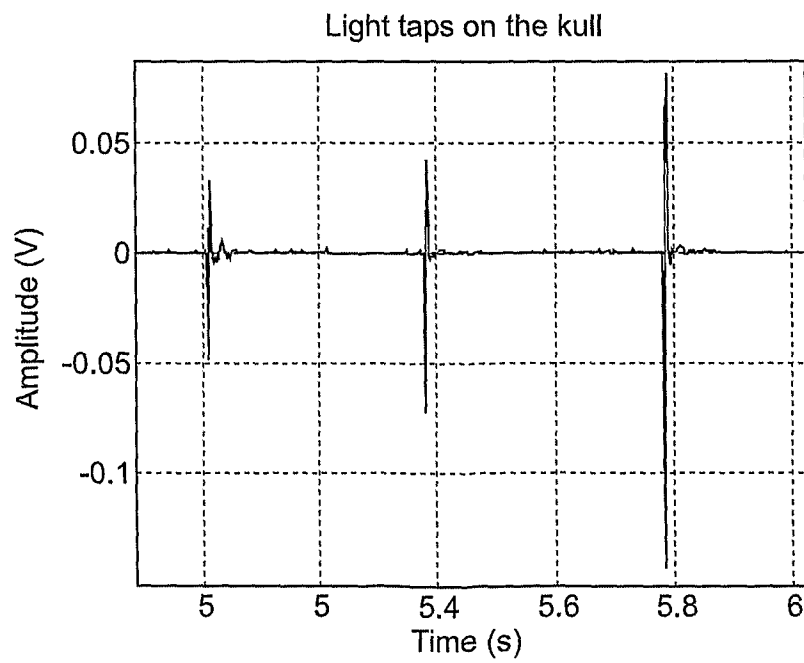
17. A medical implant comprising a first hermetically sealed container having a first internal pressure, the power source module comprising:
a second hermetically sealed container having a second internal pressure and housing:
a power source;
a first switch contact connected to the power source;
a second switch contact for connection to a power drain;
a coupling member operationally connected to one of either the first switch contact or the second switch contact; and
a flexible portion operationally connected to the coupling member such that upon a change in differential pressure between the first pressure and the second pressure, the flexible portion acts on the coupling member to separate the first and second switch contacts, thereby isolating the power source.
18. A medical implant system comprising:
an external component; and
a medical implant as claimed in claim 17.
19. A medical implant system as claimed in claim 18 wherein the medical implant system is a cochlear implant system and the external component is a sound processor and the medical implant is a cochlear implant.
20. A medical implant comprising:
a hermetically sealed container housing;
one or more hermeticity failure sensors for sensing a failure in hermeticity of the hermetically sealed container and for generating a detection signal in response to the one or more hermeticity failure sensors sensing a failure in the hermeticity of the hermetically sealed container.
21. A medical implant as claimed in claim 20 wherein the detection signal actuates a disconnect switch to isolate a power source from the medical implant.

22. A medical implant as claimed in claim 20 wherein the detection signal actuates an alarm warning of a hermeticity failure.
23. A medical implant system comprising:
an external component; and
a medical implant comprising a hermetically sealed container housing one or more hermeticity failure sensors for sensing a failure in hermeticity of the hermetically sealed container and for generating a detection signal in response to the one or more hermeticity failure sensors sensing a failure in the hermeticity of the hermetically sealed container.
24. A medical implant system as claimed in claim 23 wherein the detection signal actuates a disconnect switch to disconnect a power source from the medical implant.
25. A medical implant system as claimed in claim 23 wherein the detection signal actuates an alarm warning of a hermeticity failure.
26. A medical implant system as claimed in claim 23 wherein the medical implant system is a cochlear implant system and the external component is a sound processor and the medical implant is a cochlear implant.

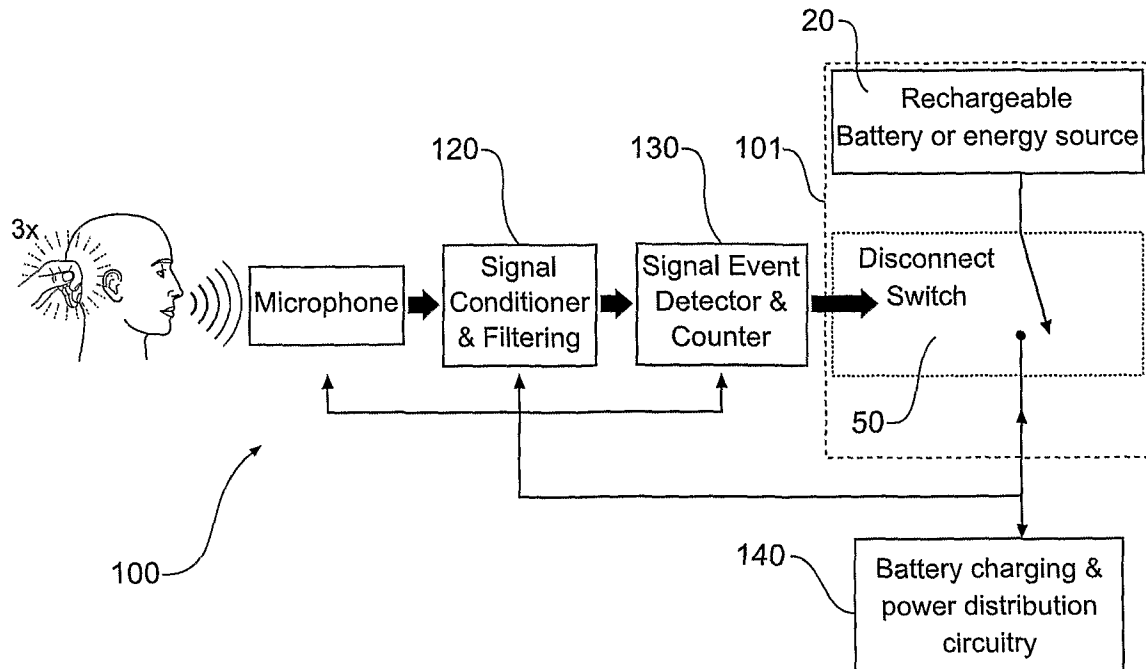
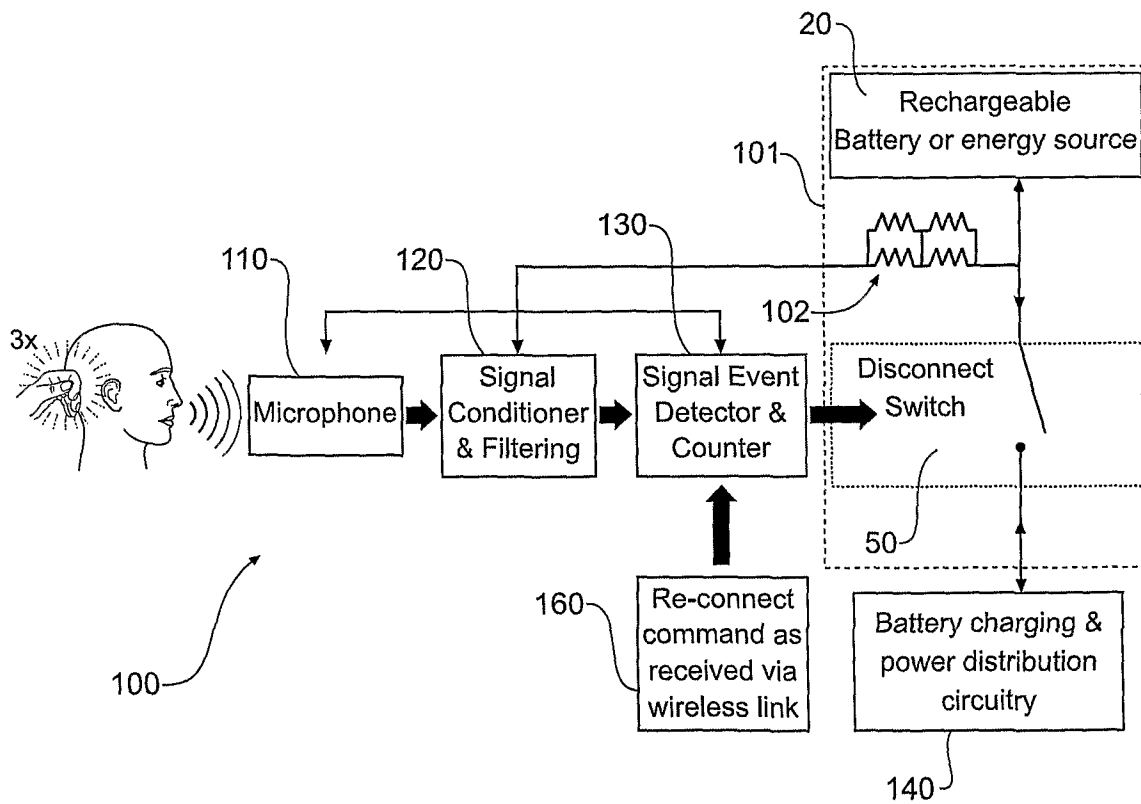
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**Figure 3****Figure 4**

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**Figure 5****Figure 6**

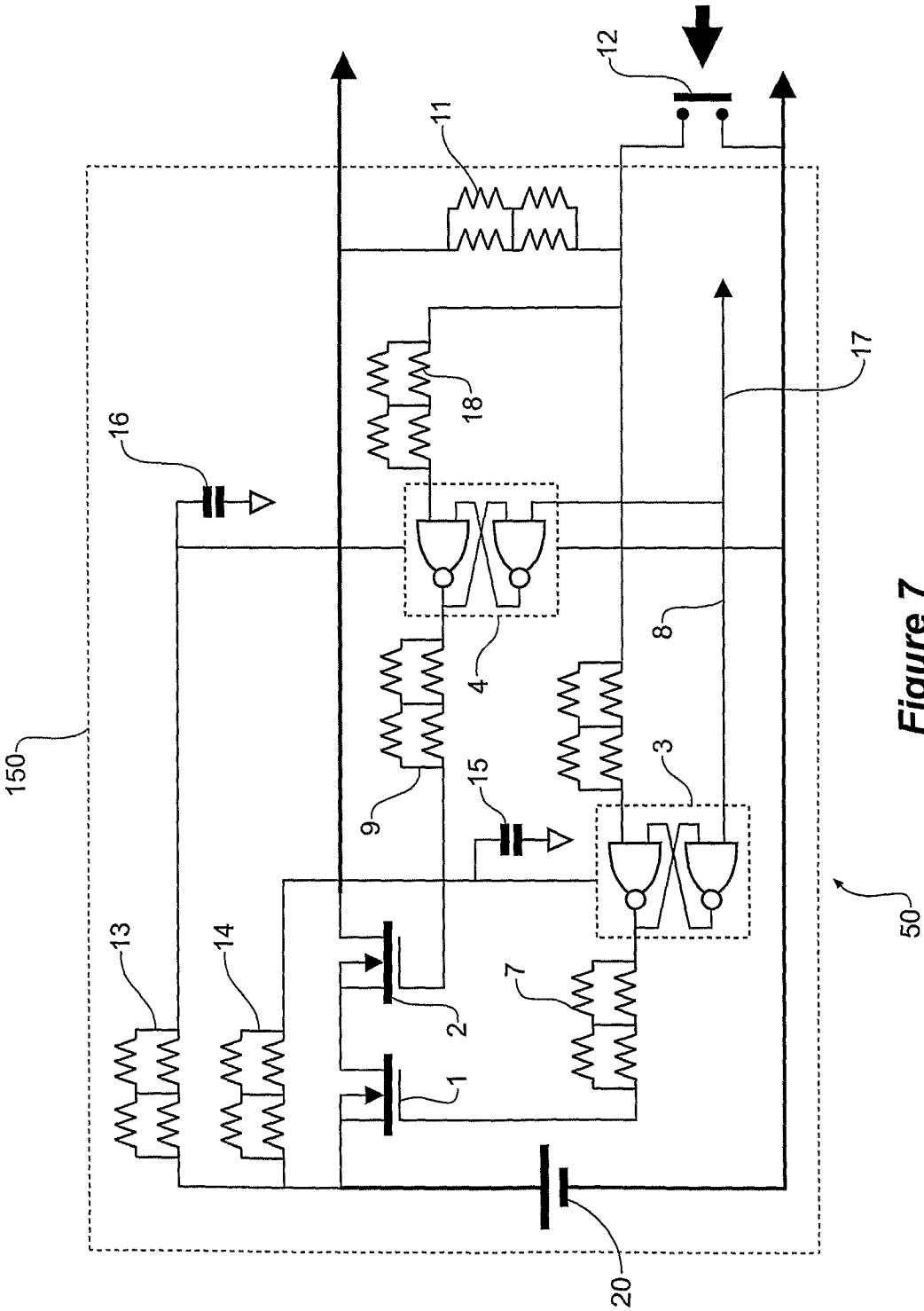


Figure 7

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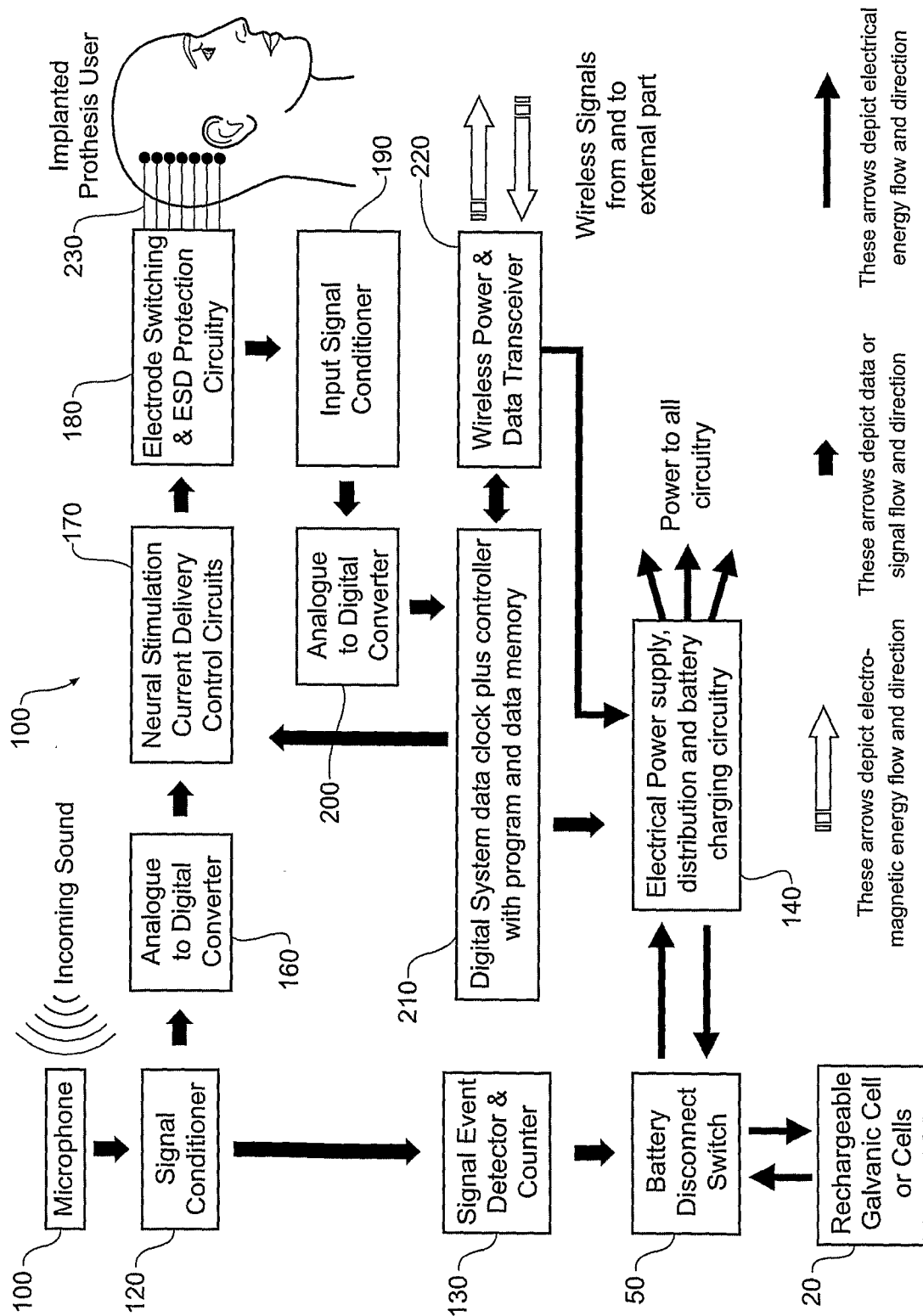
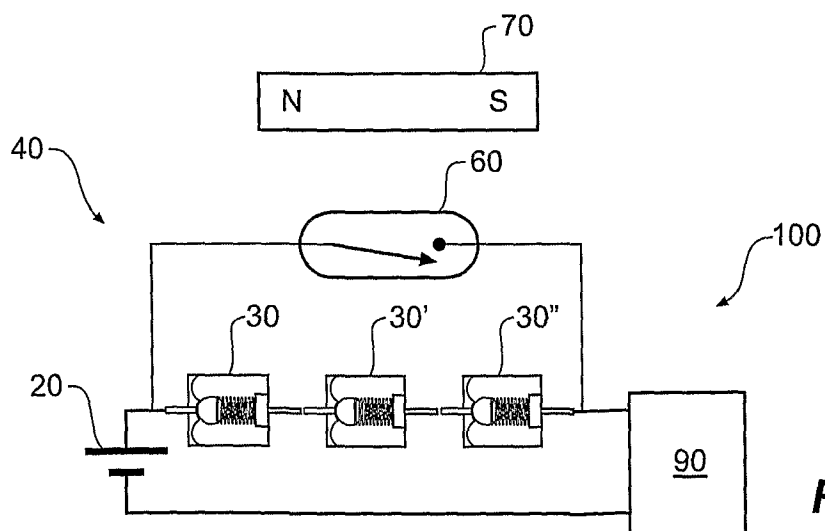
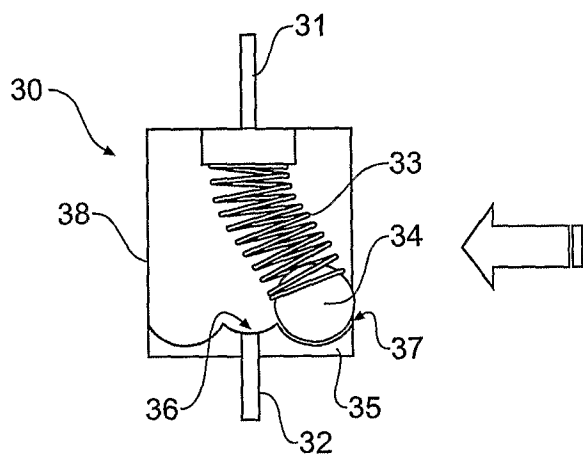
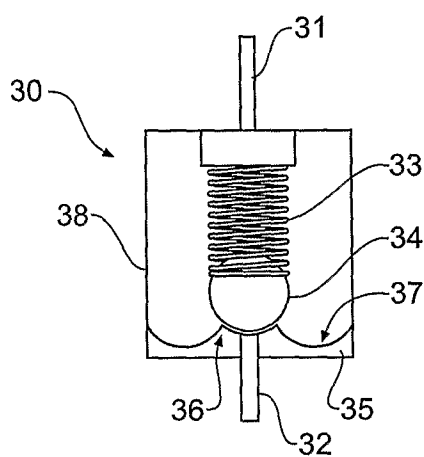
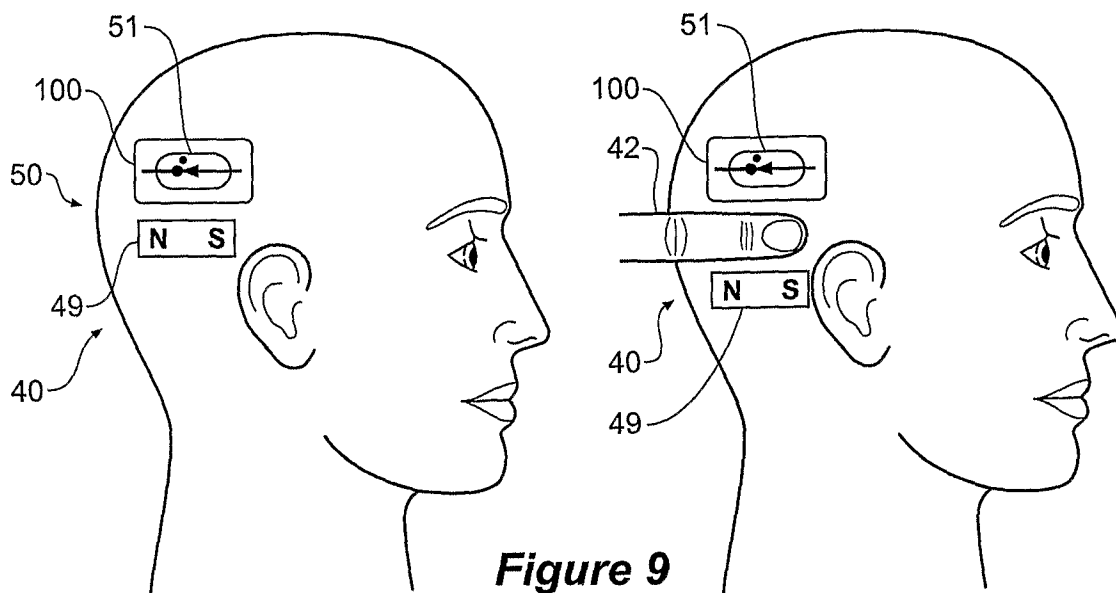


Figure 8

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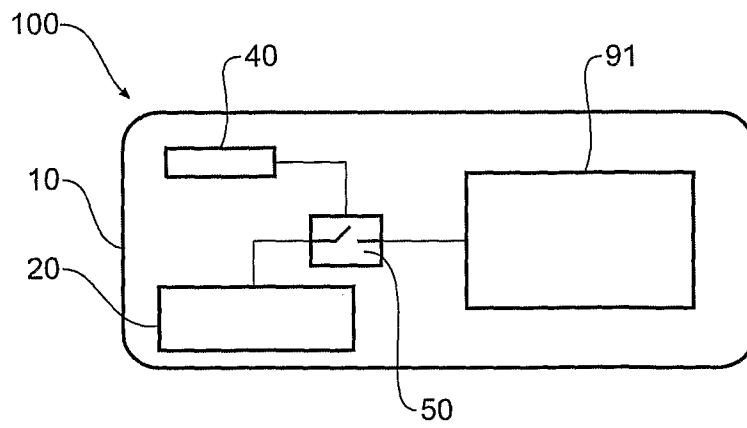


Figure 12

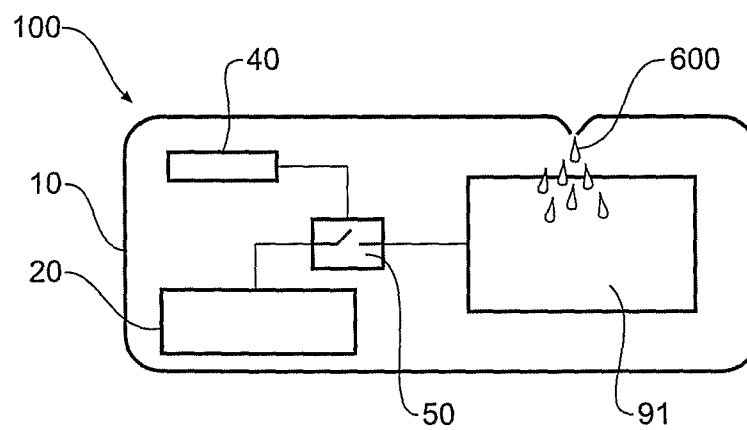


Figure 13

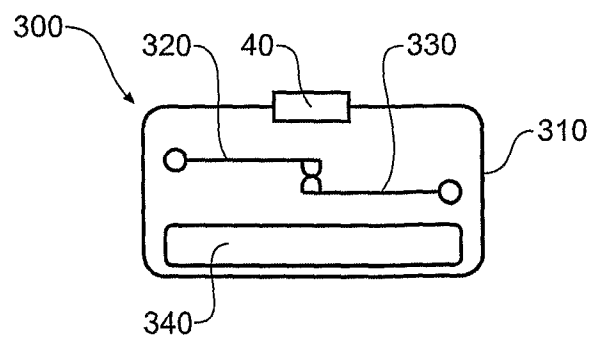


Figure 14

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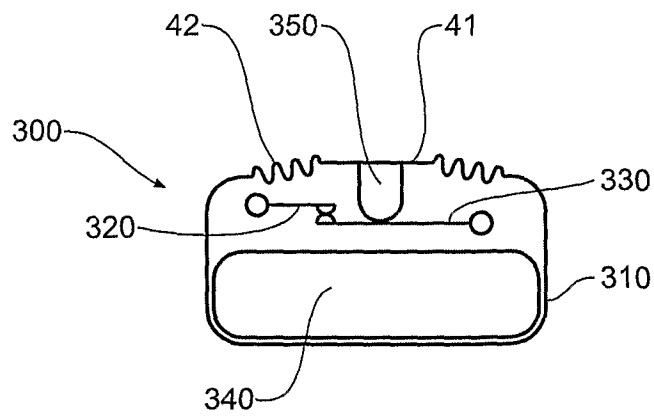


Figure 15

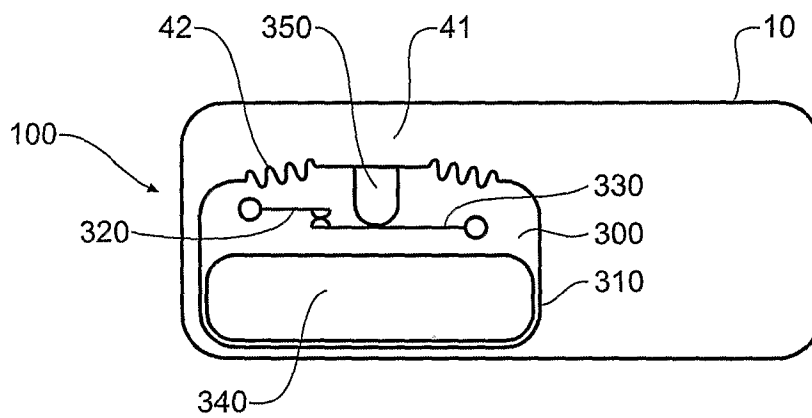


Figure 16A

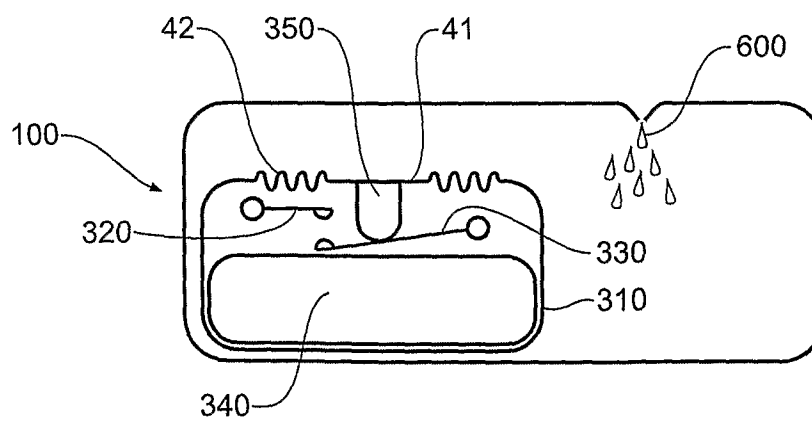


Figure 16B

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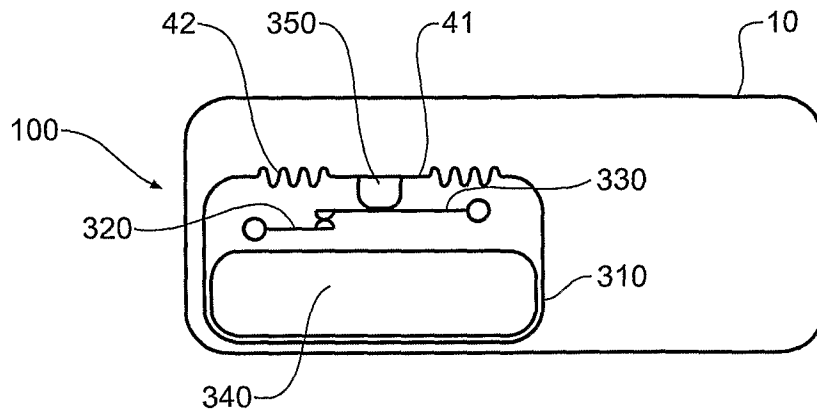


Figure 17A

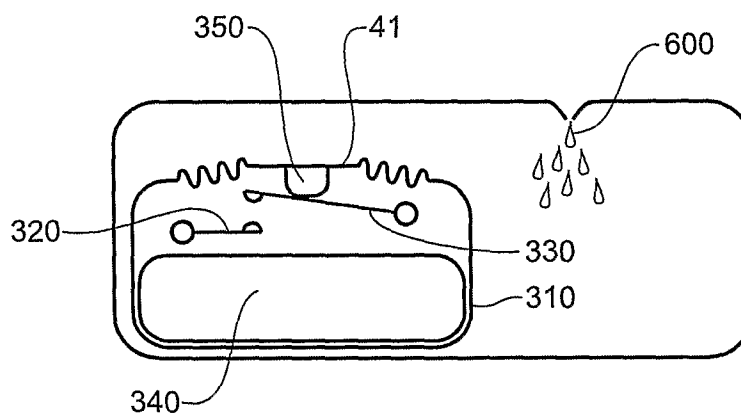


Figure 17B

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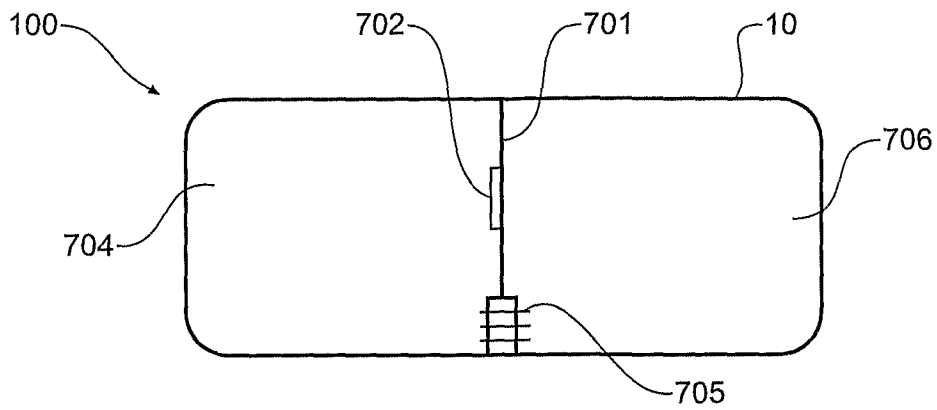


Figure 18A

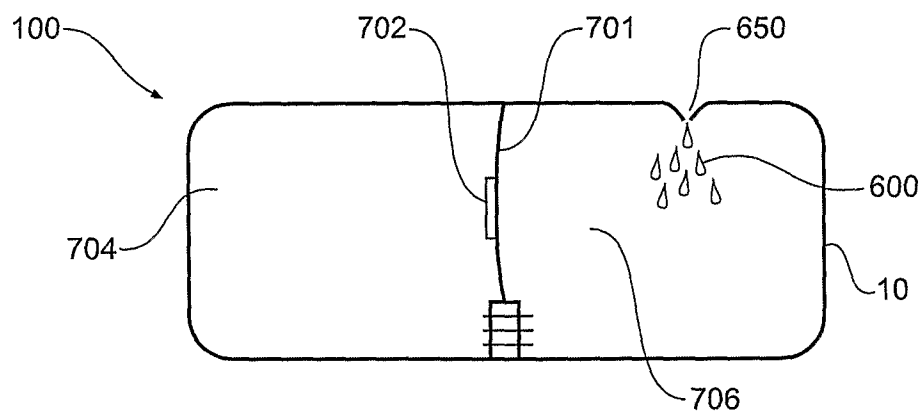


Figure 18B

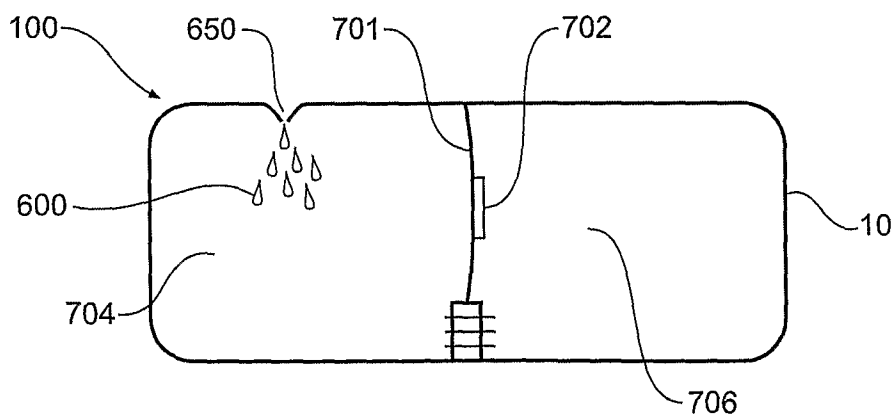


Figure 18C

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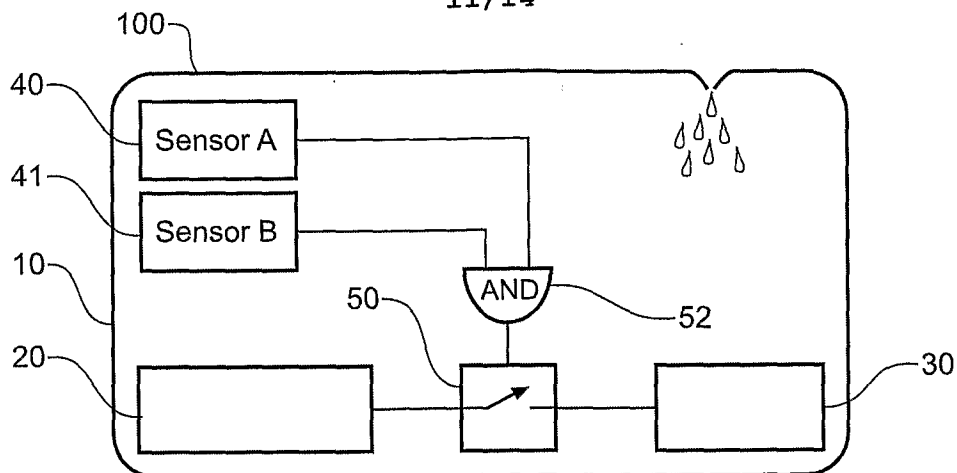


Figure 19A

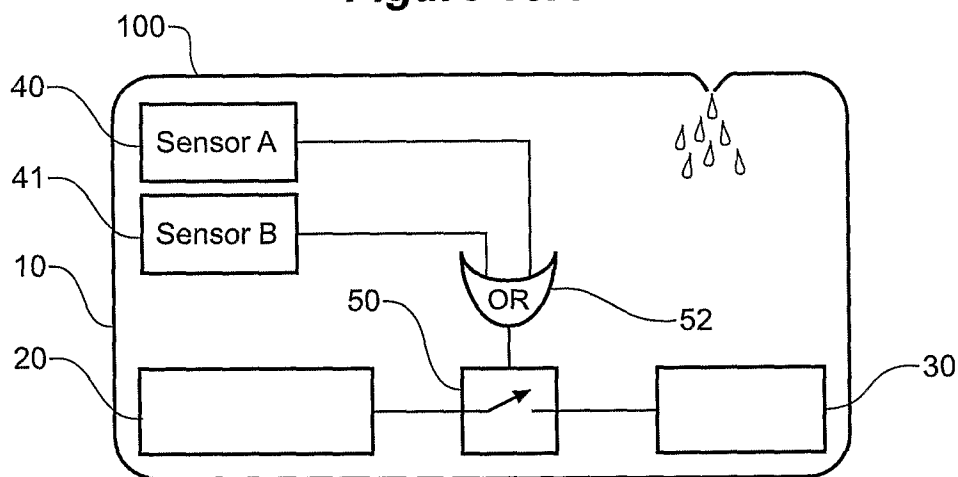


Figure 19B

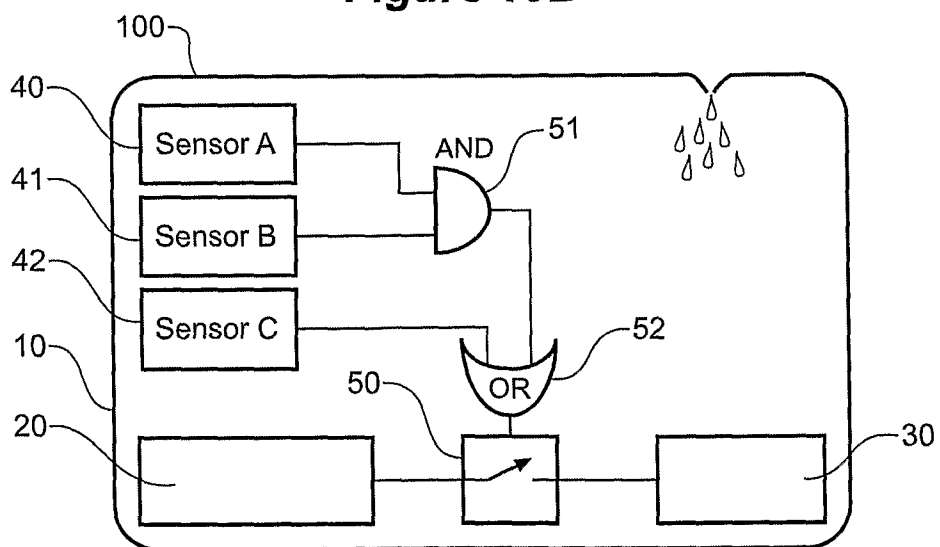
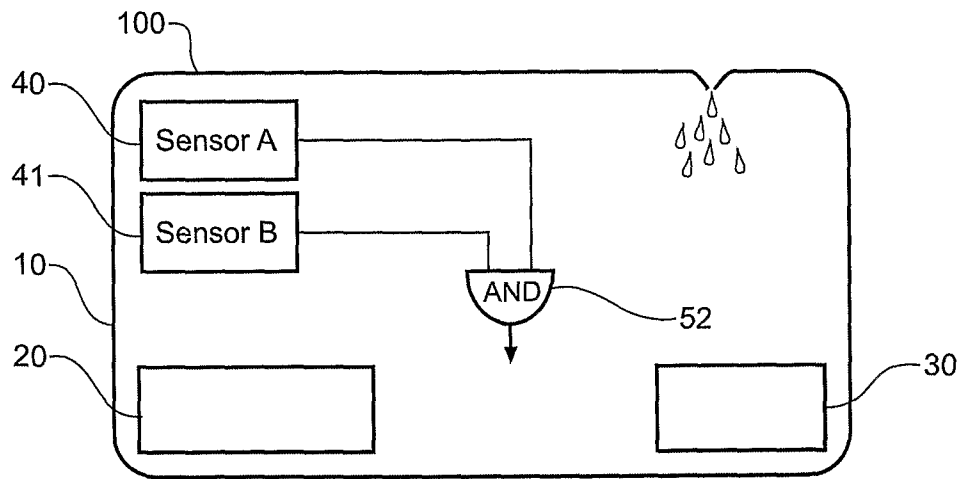
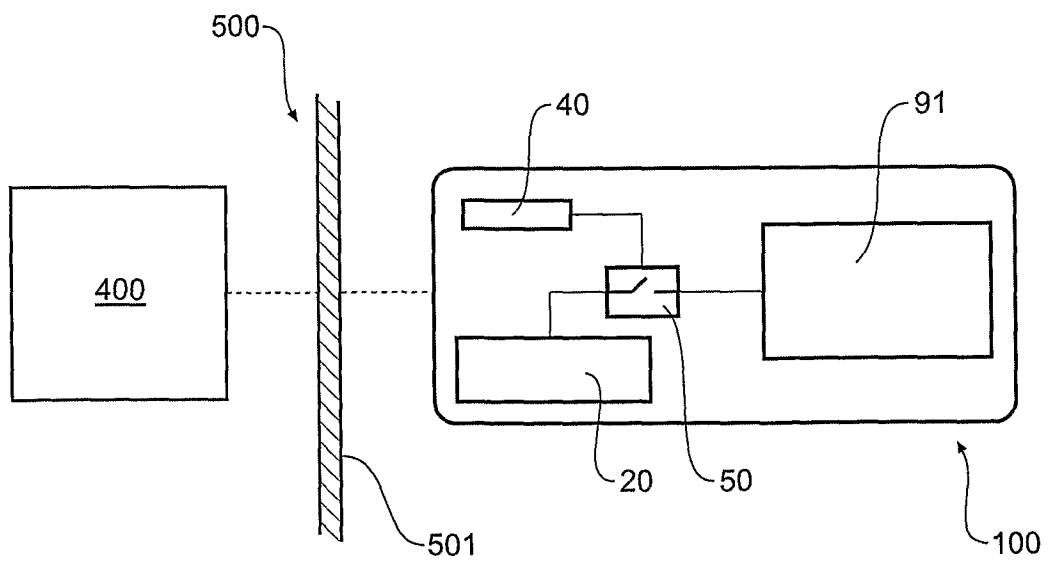
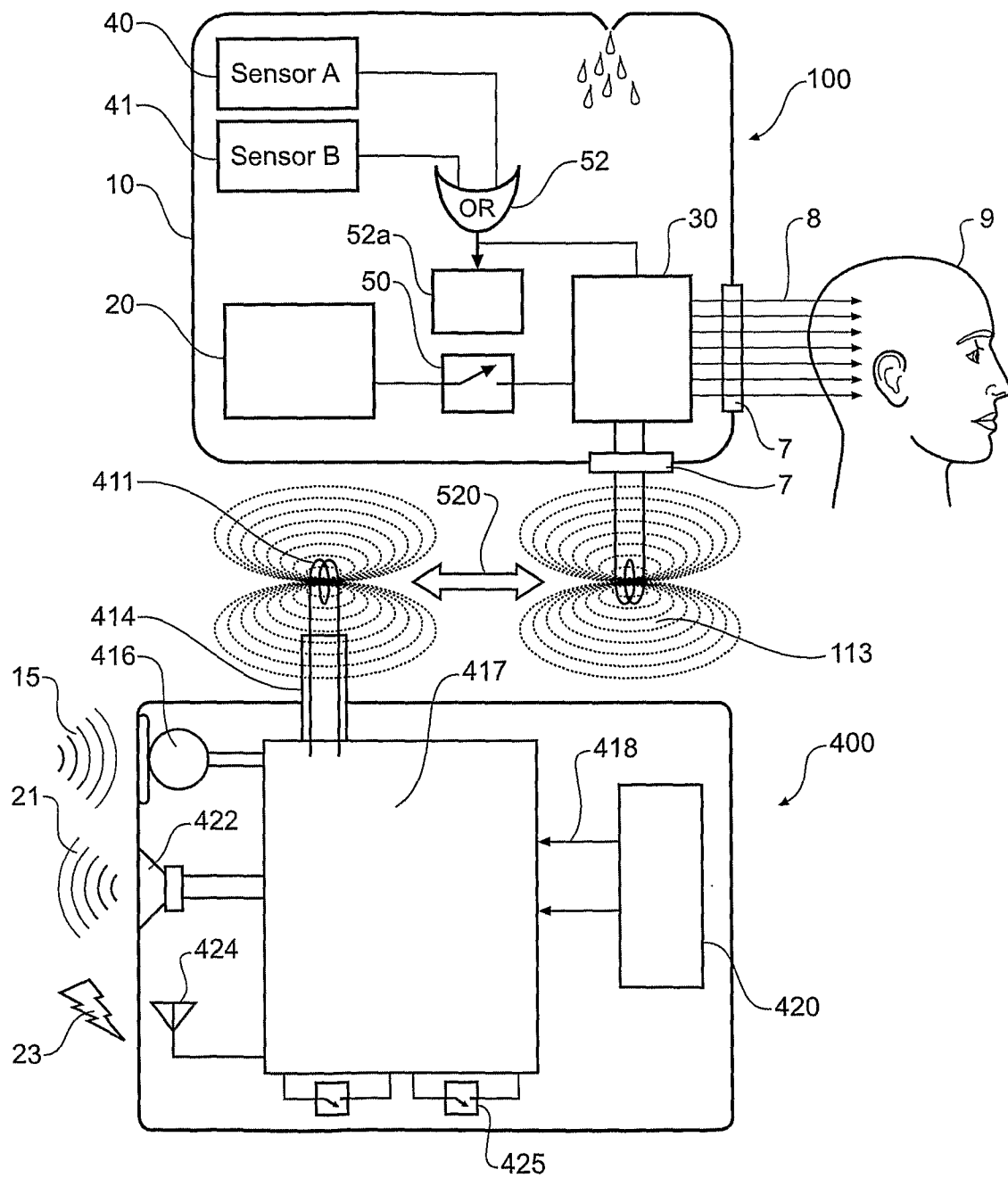


Figure 19B

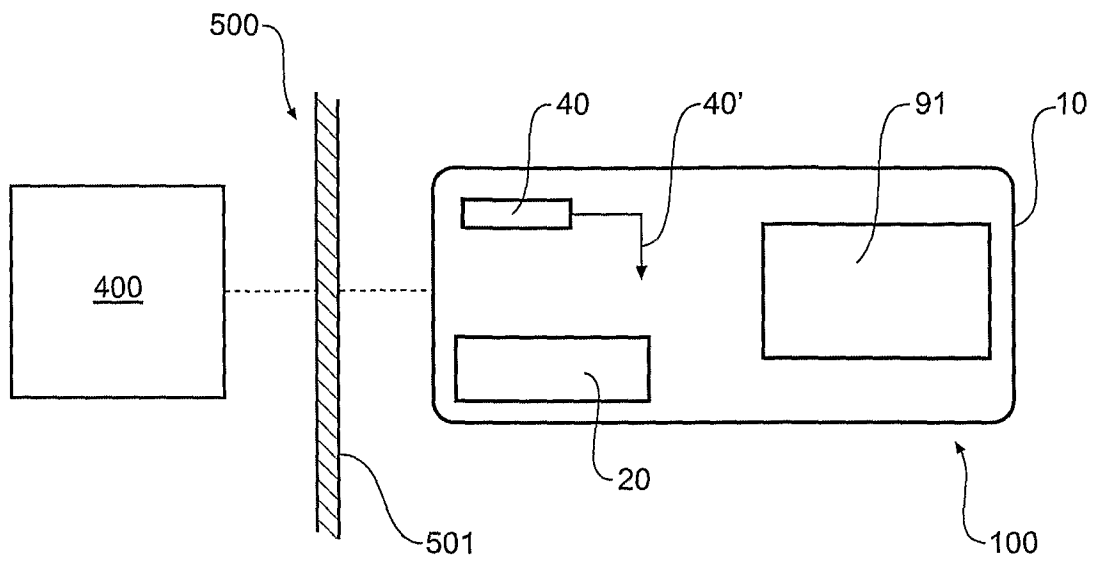
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**Figure 20****Figure 21**

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**Figure 22**

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**Figure 23**

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2009/001344

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. **A61F 11/04** (2006.01)

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)

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 practicable, search terms used)

WPI and EPODOC and IPC mark A61F, A61N and keywords: implant and power and malfunction and disconnect and similar terms.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2003/0171787 A1 (MONEY et al.) 11 September 2003 Paragraphs 158 to 178	1-4,7,13-15
X	US 2002/0019669 A1 (BERRANG et al.) 14 February 2002 Paragraphs 28 to 30	1,2,5,7,13-15
X	US 2008/0046018 A1 (VON HUBEN et al.) 21 February 2008 Paragraphs 21 to 33	1,2,6,8,14

☒ Further documents are listed in the continuation of Box C
 ☒ See patent family annex

* Special categories of cited documents:	
"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E" earlier application or patent but published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search
14 December 2009Date of mailing of the international search report **17 DEC 2009**

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2009/001344

C (Continuation).

DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2007/0255352 A1 (ROLINE et al.) 1 November 2007 Paragraphs 8 and 55 to 57	1,2,9
Y		11
Y	US 5606264 A (LICARI et al.) 25 February 1997 Column 1 lines 34 to 37	11

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2009/001344

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

See additional sheet.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1 to 19.

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2009/001344

Supplemental Box

(To be used when the space in any of Boxes I to IV is not sufficient)

Continuation of Box No: III

This International Application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept.

In assessing whether there is more than one invention claimed, I have given consideration to those features which can be considered to potentially distinguish the claimed combination of features from the prior art. Where different claims have different distinguishing features they define different inventions.

This International Searching Authority has found that there are different inventions as follows:

- Claims 1 to 19 directed to a medical implant which can isolate the power supply in response to an event. It is considered that isolating the power supply comprises a first distinguishing feature.
- Claims 20 to 26 directed to a medical implant with a hermetically sealed housing, including a sensor for detecting failure of the sealing of the housing. It is considered that detecting failure in the sealing of the housing comprises a second distinguishing feature.

PCT Rule 13.2, first sentence, states that unity of invention is only fulfilled when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. PCT Rule 13.2, second sentence, defines a special technical feature as a feature which makes a contribution over the prior art.

Each of the abovementioned groups of claims has a different distinguishing feature and they do not share any feature which could satisfy the requirement for being a special technical feature. Because there is no common special technical feature it follows that there is no technical relationship between the identified inventions. Therefore the claims do not satisfy the requirement of unity of invention a priori.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/AU2009/001344

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report				Patent Family Member			
US	2003171787	AU	68821/01	AU	2007202342	CA	2411782
		EP	1304017	US	7346397	US	2008147144
		WO	0205590				
US	2002019669	AU	18459/01	CA	2384248	EP	1233812
		US	6358281	US	6648914	WO	0139830
US	2008046018	AU	2007205767				
US	2007255352	US	2007255353	US	2007265662	US	2007265666
		US	2007265668	US	2007265669	US	2007265671
		US	2007265674				
US	5606264	NONE					
Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.							
END OF ANNEX							