Grounding of Implantable Medical Devices – A Tutorial

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The material in this tutorial is based on Design Considerations for Ground Refrencing in Multi-Module Neural Implant by Dorian Haciy, Yan Liuy, Sara S. Ghoreishizadehy, Timothy G. Constandinouy and my own research. For more information, please write to [hosseinniri@hotmail.com .](mailto:hosseinniri@hotmail.com)

Over the final six decades, implantable restorative gadgets have created through science and designing improvements, particularly in microelectronics, biotechnology, and materials. Jiang and Zhou say that 8 to 10 percent of the populace within the Joined together States and 5 percent of individuals in industrialized nations have experienced an implantable restorative gadget to restore bodily functions, accomplish distant better; a much better; a higher; a stronger; an improved">a much better quality of life, or amplify longevity. Most clinical IMDs are electrical stimulators. A great illustration is the heart rate, which employments discontinuous electrical beats as a implies of invigorating the heart to contract.

As of late, neuromodulation gadgets such as cochlear inserts for the hard of hearing and profound brain stimulators (DBS) for Parkinson's illness and fundamental tremor (ET) have appeared a critical affect on the quality of life of millions of patients. In expansion to these examples, implantable examples for the treatment of epilepsy have been illustrated as successful treatment methodologies, utilizing neurostimulation nerve inserts (VNS), of key role-playing. Such neuroprosthetics is as a rule embedded within the upper chest and mounted on dynamic gadgets housed in a metal or ceramic cage. Electrical conductivity is utilized as a implies to reach this region to fortify and contact anodes to transmit electrical beats to the target tissue.

History of IMDs:

From Zoll's first report on electrical heart incitement in 1952 to the primary marketed remote circulatory strain estimation framework presented via Cardiomems in 2010, clinical specialists have applied respectable endeavors to improve the nature of patients' lives with different clinical gadgets, for example, the implantable cardiovascular defibrillator, cochlear embed, embedded bladder trigger, and implantable remote weight sensor . Such implantable clinical gadgets were created to detect a physiological reaction in vivo or to incite physiological organs. As of late, with the superminiaturization of electronic circuits and mechanical structures, numerous analysts have concentrated on the improvement of implantable ongoing crucial observing frameworks, which are constantly worked in subsecond periods. The implantable continuous crucial observing gadgets may move clinical frameworks from helping occurrences after they happen to self-overseeing episodes before they happen.

For instance, the EndoSure of Cardiomems, which is embedded into the aorta to quantify intrasac pressure during endovascular stomach aortic aneurysm fix and during endovascular thoracic aortic aneurysm fix, can identify intraoperative holes of the stent join. After release from the emergency clinic, patients can check the intrasac pressure every day at home, which was generally observed by an angiographic strategy just at a medical clinic.

The primary completely implantable pacemaker was typified by araldite epoxy tar. Within the polymer epitome, a moo control utilization first-generation silicon transistor (OC460) coordinates with electrical circuits was bundled with two fixed 60 mAh nickel-cadmium battery cells. The electrical circuit was associated with an inductive coil for reviving the batteries. The electrical-pulse-generating framework was associated with electrodes via stainless steel wire covered with polyethylene. The whole measure of the primary implantable pacemaker was 55 mm in breadth and 16 mm in thickness, comparable to the measurements of a shoe clean can from British Kiwi.

The epoxy gum embodiment of the original pacemaker was created to shield the electronic circuits and batteries from body liquid infiltration and tissue intrusion to the framework. Likewise, the exemplification or lodging filled in as a boundary between the human body and unsafe batteries. In any case, the polymer-based epoxy pitch expand and broke down inside the human body. Hence, the lodging materials must be supplanted with earthenware production and titanium to secure the electrical frameworks. As of now, the electric components and a battery are bundled by a laser welding of titanium, which has a solid mechanical hardness, outrageous protection from erosion, biocompatibility, and sturdiness. Electrical associations between the metal-housed electronic framework and the lead wire of the pacemaker incited another fixing issue. Inferable from the metallic lodging, the electrical sign yield part, which is associated with the lead, ought to be passivated by a protector to forestall electrical association with the metal lodging. Along these lines, polymer or fired based electrical feedthrough was created with ideal division between the electronic framework and the human body condition.

The main activity for embedding a pacemakerwas finished by the specialist Ake Senning, who played out an open thoracotomy and stitching of 9 mm width anodes on the left half of the myocardium. A while later, the heart pace was electrically controlled for 3 hours. The following activity occurred on following day and the gadget labored for 7 days. As of now, the pacemaker embed method takes around 1 to 2 hours with 4-5 mm distance across cathodes fixed on the correct ventricle and the correct chamber. One day after the activity, the patient is discharged from the medical clinic and can make the most of their normal life again with the assistance of the pacemaker. The little size and lightweight principle body of the pacemaker permit the patient to maintain a strategic distance from open-heart medical procedure, and the adaptable platinum lead curls make a simple and short methodology conceivable.

This tutorial has been developed to help you understand what grounding in IMDs is, why it is important.

What is an Implantable Medical Device (IMD)?

A medical device is defined as implantable if it is either partly or totally introduced, surgically or medically, into the human body and is intended to remain there after the procedure.

Why grounding used in implantable medical devices?

1. Avoiding a DC voltage bias across the conductors in the implantable lead in Multi-Module Neural Implants.
2. Protection from electromagnetic Interference (Control EMI).

Ground Referencing in Multi-Module Neural Implants:

The requirement for both incitement and recording of the biosignal action, frequently a prerequisite in present day restorative strategies, have caused an ongoing flood in the age of shut circle neuroprostheses. This moderately new class of implantable gadgets, notwithstanding incitement, likewise presents the requirement for front end detecting, signal molding, and constant preparing. As of late FDA-affirmed and now clinically accessible instances of such gadgets incorporate the shut circle DBS Activa PC+S framework from Medtronic and the responsive neurostimulation (RNS) framework for headstrong halfway epilepsy executed by NeuroPace. Shut circle applications are currently requiring more interfacing channels (both for recording and incitement) and at different areas.

Also, surgical and security contemplations put extra necessities on performing certain capacities in certain areas. for case, a chest-mounted IMD can involve more volume (i.e. bigger battery) and disseminate more control (i.e. more capacity for on-board preparing) than one mounted within the head. To address this, a unused era of implantable restorative devices is presently developing. Rather than the centralized approach that employments a single dynamic implantable gadget, the framework is presently being apportioned and dispersed over numerous dynamic implantable gadgets each with particular capacities, and found at distinctive locales. This approach addresses a few of the restrictions of single-module inserts, in any case, it postures a modern set of challenges, basically related to inter-module network, useful unwavering quality, and quiet security. The implantable leads are presently furthermore utilized to encourage exchange control between modules and for bidirectional communication.

In addition, having particular dynamic modules suggests the require for electrical confinement from each other to maintain a strategic distance from coordinate current ways between them. This implies each implantable module has its possess control space, and thus distinctive reference possibilities between the electronic circuits (module grounds).

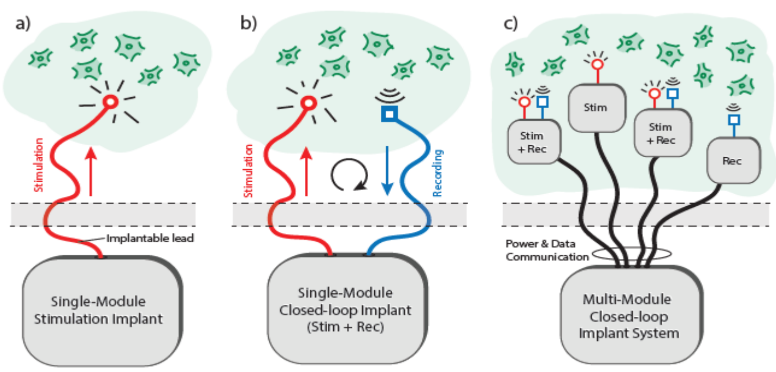

Fig. 1. Examination between various IMD ages: (a) solitary module pace-production incitement embed , (b) single-module shut circle incitement and recording insert, and (3) multi-module shut circle embed framework.

Multi-Module System Consept in Medical implant:

The normal setup comprises of one central embed, or central unit, and different littler fringe inserts, or fringe units, each found in near nearness to the target interface destinations. The previous incorporates the vitality source (battery), control administration circuitry, a control and preparing unit, and communication interfacing to transmit remote information remotely and to communicate with the fringe units through an intrabody arrange. In spite of the fact that there are a few investigate bunches examining distinctive strategies of actualizing remote intrabody systems, all clinically pertinent gadgets as of now require a wired association between the person modules. In addition, having unmistakable dynamic modules infers the require for electrical separation from each other to dodge coordinate current ways between them. This implies each implantable module has its claim control space, and thus distinctive reference possibilities between the electronic circuits (module grounds).

We'll hence focus only on a wireline association. Usually based on multi conductor implantable leads serving as communication channel (bidirectional) and control conveyance medium (from central to fringe). At the ‘receiving’ conclusion of this organize, the fringe units must moreover contain an intra-body communication interface, to associated with the arrange and to recover control. This will control up: (1) the front-end function-specific units, which can be both recording and incitement; (2) the information change circuitry (analog-to-digital and digital-to-analog); and (3) the advanced preparing unit (Fig. 2.c).

What is Ground?

'Ground' has ended up such a common term in electrical and electronic circuits that indeed in electronic gadgets which have no genuine contact with the physical soil, the ground plane on a PCB or a circuit (with reference to which all voltages on a PCB are measured) is called the 'ground' of the circuit. Typically a helpful way to tie all focuses with this circuit ground image together. voltage may be a differential amount. To degree the voltage of a single point, a reference point must be chosen to degree against.

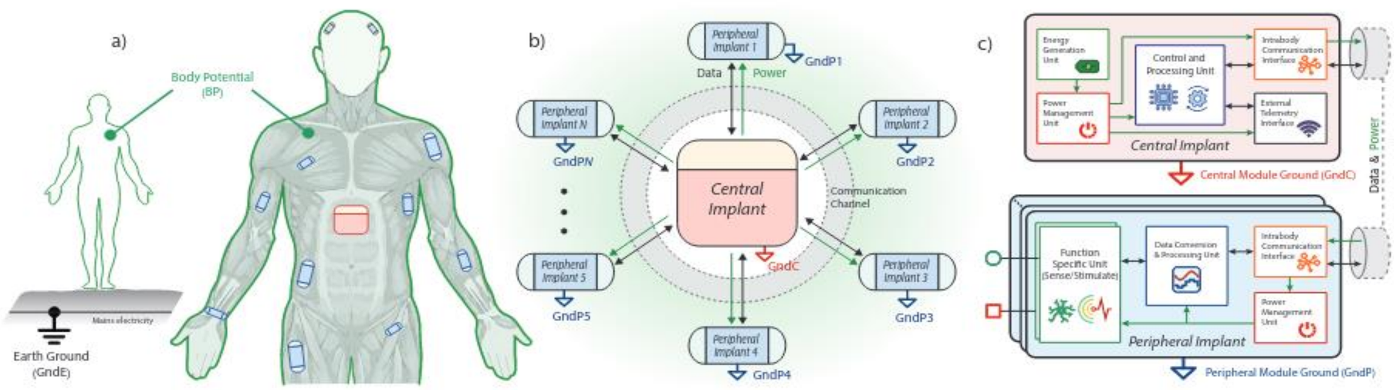

Fig. 2. Concept of the multi-module implantable system. (a) Conceptual body model with of a distributed implant system; (b) iter-module connectivity (one central implant, multiple peripheral implants) and; (c) block diagram of internal structure of both central and peripheral implants and their interfacing.

This common reference point is called "ground" and considered to have zero voltage. For secure voltage levels or protects walled in area, this does not ought to be Soil ground. There can be more than one circuit ground, due to limited conductance in wires.

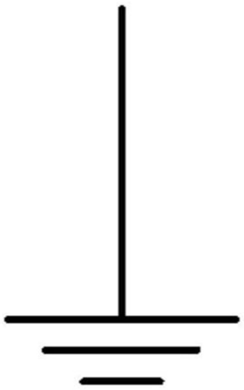

Fig. *3.* Common ground symbol*.*

Why it is necessary to common all the ground in circuit (groups of circuit need to interface with each other)?

It is fundamental when there are bunches of circuit got to interface with each other. Usually self-evident since ground is the reference. In case the grounds are not associated together, ground really loses its meaning.

Example for better understanding:

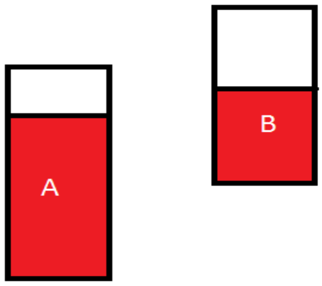

Fig. 4.

Consider this case, you've got fluid in jolt 'A' and jar 'B'. Level of fluid in Jostle B looks more isn't it? But the level of jolt A is higher. So the same thing happens with the potential distinction within the circuit. In case the reference isn't common, the comes about may be undesirable. So presently what to do to maintain a strategic distance from this?

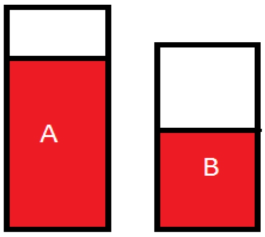

Fig. 5.

You bring both the jars at same level (You common the ground). Now can you say that the liquid level in Jar A is more than level in Jar B? You can compare it easily, in fact any other jar

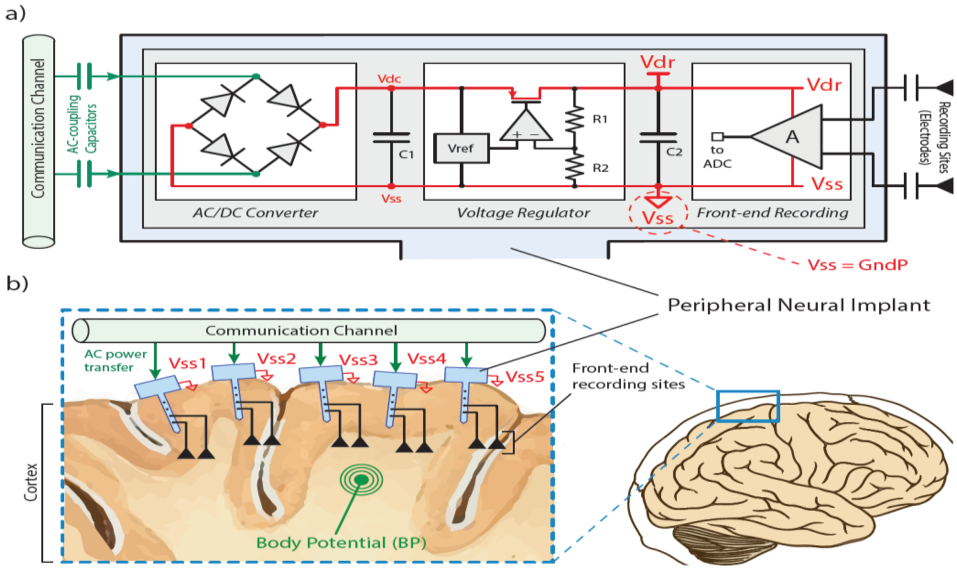

Fig. 6. Peripheral neural recording implant system: (a) power recovery and Vdr and Vss DC rail generation; (b) distributed multi-module brain

kept at same level, you can compare the levels with these 2 jars. the exact same logic applies with the level of potentials in the circuit.

Module Ground Referencing:

In arrange to maintain a strategic distance from a DC voltage predisposition over the conductors within the implantable lead, and in this way to preserve the charge adjust over time, control transmission plans based on AC coupling are regularly required in wired embed frameworks. This blocks undesirable current ways from being shaped between diverse modules in the event that the harm to the cover happens. Accordingly, AC/DC control space change is executed at the fringe side, producing a reasonable DC supply voltage for the front-end circuitry (Vdr - Vss), consequently, the module ground rail (GndP = Vss), has appeared in Fig. 6.a. This, in any case, creates DC segregation between central and fringe inserts, and so the electric potential of the module ground at the fringe embed N (GndPn) doesn't allude to the module ground at the central embed (GndC).

By definition, implantable neural frameworks are put interior the human body, consequently encompassed by natural tissue. Not at all like close to clinic hardware, they are not straightforwardly associated with the AC electrical control coming from mains (framework control), the instep gets the electrical vitality from a battery encased inside the embed or inductively from outside Control sources. Unless the body touches the mains, the produced potential rail is to be considered drifting and not referenced to the earth's ground. The human body, in any case, has it possess electric potential, Body Potential (BP), has appeared in Fig. 2.a. In electrical harmony (no current stream inside the body), such potential is considered the same over the entire body. BP must be taken into thought when managing with ground referencing within the neural embed framework, as the potential uprooting of GndC and GndP from BP may have a noteworthy effect on (1) security of the persistent (2) gadget unwavering quality, and (3) recording quality.

Grounding Impact on Recording Quality, Device Reliability and Patient Safety:

Implantable gadgets that sense biopotential signals, for case, neural recording frameworks, interface the detecting terminals that are in coordinate contact with the tissue, i.e. hence with BP, to tall impedance enhancer inputs. The watched biopotential in this way comprises of this huge pattern (BP) in expansion to a moderately frail AC flag (wanted action to be recorded). A differential front-end speaker is ordinarily utilized to record such signals, for case, in intracortical recording: this sense and intensifies the contrast in potential between two anodes, smothering the common potential (common-mode dismissal, CMR). In addition, to bargain with the obscure DC balanced between the BP and recording circuit (control rails Vdr and Vss/GndP), biopotential enhancer inputs are regularly AC coupled through capacitors.

This clears out the BP having a moderately tall impedance to the recording circuit control rail that viably makes the tissue an 'antenna' for picking up a common-mode commotion. It is in this way fundamental to preserve a general moo impedance association between the recording circuit control rails and BP to weaken the watched common-mode clamor (at the speaker inputs). Moreover, in terms of security, a noteworthy contrast in electric potential between GndC/GndP and BP (voltage) may lead to corrosion/failure of epitome that would result in the current stream into/from the tissue surpassing the security constraints characterized by the worldwide mandates on dynamic implantable devices. For these reasons, a suitable ground referencing conspire is required in arrange to guarantee great recording quality, but moreover gadget reliability and eventually understanding safety.

Body referencing circuit >> BRC

Ground Referencing Schemes:

Given that the central embed is encased inside a case serving as DC electrical screen from the body, with no coordinate contact between inside circuitry and body tissue, there's no requirement for GndC to be referenced to BP. On the other hand, the fringe inserts have a coordinate way to the tissue through the recording anodes (Fig. 6.b), subsequently, the requirement for legitimate referencing of the DC rails to the body potential.

The foremost common and basic ground referencing arrangement is the detached association of a fringe gadget control rail (either Vdr or Vss) to the body potential. In intense tests, the fringe module ground GndP is regularly shorted specifically to the BP through a ground terminal, so to reference the tissue to the most reduced potential of the module. The inactive conspire is spoken to in (Fig. 7.a) with a resistive divider. The 'short' is gotten from this when considering either R1 = 0, R2 = 1 (BP = Vdr), or vice-versa (BP = Vss). Depending on the starting esteem of the body potential, compared to the shorted rail, there will be a current stream from/to the tissue in arrange to equilibrate the potential between the two hubs. Within the situation of different fringe inserts near to each other, it is more often than not favored to brief the BP to all the fringe grounds (GndP1, …GndPN).

The second category of body referencing circuits (BRC) is composed of dynamic components. This may be encourage isolated into two topologies: (1) driving BRC; and (2) detecting BRC. The driving reference circuit is appeared in Fig.7.b comprising of a reference voltage era circuit (e.g. a resistor divider) and an yield buffer with a moo yield impedance to drive the BP. In both inactive and drive plans, there's a current stream between embed and tissue. This guarantees the voltage between BP and GndP to be settled, in this way lessening the common-mode flag at the input of the recording speaker, at the cost of money trade between the fringe module and body.

Not at all like for the inactive plot, the BRC with driver/buffer guarantees that the current is continuously infused into or out of the tissue giving a level of soundness to the source (fringe embed) from inalienable changes of the potential around BP.Fig. 7.c presents a third plot, based on a detecting BRC: this time, a front-end detecting circuit is utilized as a body reference circuit to degree the BP moment esteem and references the fringe rails level in like manner. The detected voltage (BP - GndP) can hence be sent to the recording speaker, which employments it to alter the input biasing point of the last mentioned. By doing so, the body potential vacillation itself, seen as a common mode from the recording input terminals, is utilized in truth as portion of the common-mode dismissal of the intensifier.

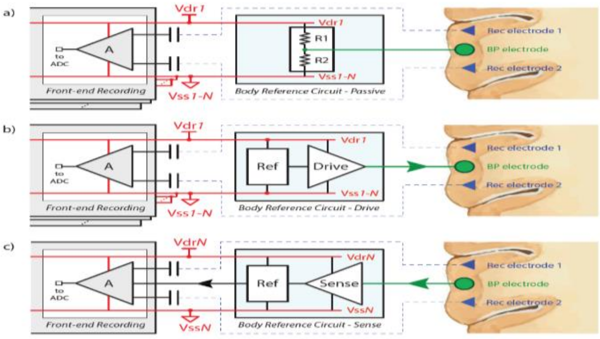

Fig. 7. Different grounding schemes: (a) passive; (b) drive; (c) sense.

ESD (Electrostatic Discharge):

Electrostatic discharge (ESD) is the sudden flow of electricity between two electrically charged objects caused by contact, an electrical short, or dielectric breakdown. A buildup of static electricity can be caused by tribocharging or by electrostatic induction. The ESD occurs when differently-charged objects are brought close together or when the dielectric between them breaks down, often creating a visible spark.

Fig. 8. ESD

ESD protection:

Protecting against the effects of ESD, **Electrostatic Discharge** is essential when dealing with electronic technology - from the home hobbyist to full scale manufacture ESD protection is very important.

ESD protection requirement:

With electronics devices used in today's electronics equipment being susceptible to electrostatic discharge, it is necessary to employ ESD design guidelines that ensure that devices used will be protected against its effects. The ESD design guidelines and the protection used is of particular importance where any connections are on the periphery of the equipment and may be accessed via the user.

When accessing external ports, users will not take any precautions against ESD, if they even understand about it. therefore it is necessary to provide full protection for any external ports that may exist.

Electronics devices manufactured today are often required to survive a discharge of 8kV contact discharge (i.e. where the 8 kV is discharged directly onto the pin via a metallic contact) or a 15 kV air discharge (where the 15 kV point is close to the pin and discharges across an air gap). While this is the aim, not all devices will survive this and in many cases the discharge may be greater than this. It is therefore wise to add additional protection.

ESD design methods:

The key to the ESD design guidelines for protecting the devices on any external Input / Output (I / O) lines, is to prevent the voltage rising above a level that will damage the interface device. This may be achieved using a circuit that clamps the maximum voltages to just outside the maximum operating extremes. typically this may be just above the rail voltage and just below the zero-volt line.

A typical circuit that can be used for clamping voltages employs reverse biased diodes from the input line to the voltage rail and to ground. This ESD protection circuit must ensure that the voltage excursions on the input line are limited. The diodes must also have a low level of residual current, and the capacitance must be low to ensure that the frequency response / data rate and other input parameters are not impaired.

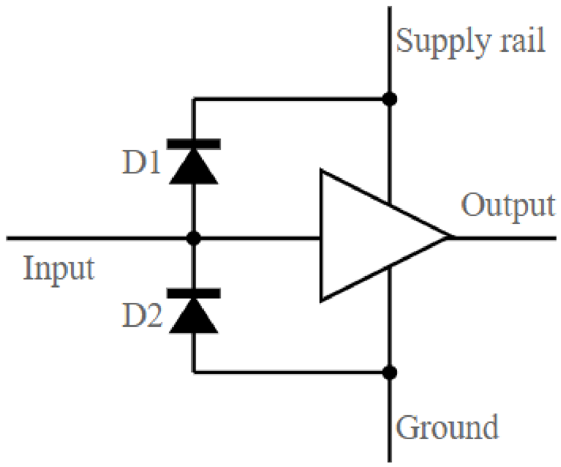

Fig. 9.- Diodes used on the circuit input for protection

The operation of the circuit is very simple in that the diodes, D1 and D2 are reverse biased under normal operating conditions. However if a pulse occurs that raises the input voltage above the rail voltage the top diode, D1, will conduct. Similarly if the voltage falls below the ground voltage, the other diode, D2, will conduct. Using ordinary signal diodes, the maximum voltage excursions that might expected on the input line in the first analysis may be +0.5V above the rail and -0.5V below ground. However this is not always the case as seen below.

The typical response curve for an electrostatic discharge is defined by IEC61000-4-5 and it simulates a typical electrostatic discharge curve. The waveform has a rise time of about 1 ns and the current level peaks at 30A. To suppress these voltages, very effective clamping circuits are required and ESD design guidelines need to specify acceptable components and performance limits.

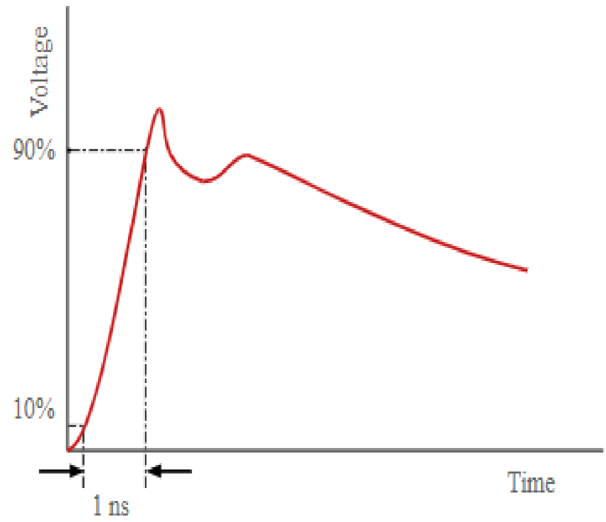

Fig. 10. - IEC 61000-4-2 pulse waveform used for ESD simulation

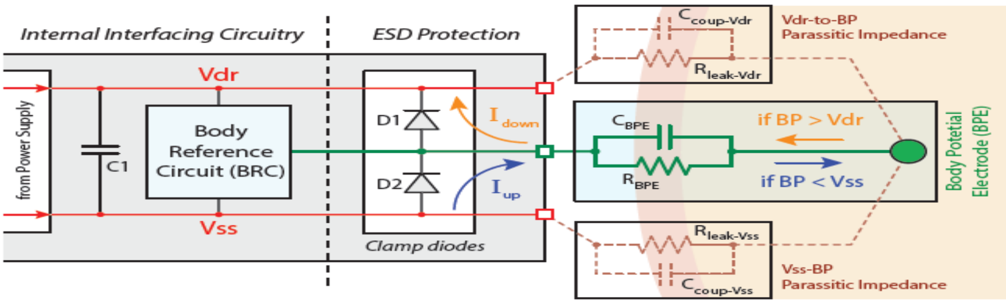

Fig. 11. Practical implementation interfacing of the body reference circuit (BRC) with the body potential (ESD, parasitic impedances, and BPE model).

Practical implementation of RBCs interfacing with the body potential:

Within the past segments, the middle between the RBCs and the body has been considered as perfect, with irrelevant parasitic components and considering a perfect body potential terminal (BPE). When for all intents and purposes actualizing the circuits in particular innovation and interfacing them to the natural tissue, modern challenges emerge due to (1) anode interface (metal-tissue) non-idealities and; (2) circuit usage limitations.

The electrical demonstrate of the terminal should be taken into consideration when assessing the effect of the ground referencing within the diverse plans, both for recording quality and security restrictions of current infusion. A streamlined demonstration is displayed in Fig. 11. Moreover, capacitive coupling and current spillage from the control rails, spoken to by R_{leak} and C_{coup} , influence the implant-tissue to meddle. This depends basically on epitome and circuit innovation.

The last-mentioned presents another meddle angle: ordinarily, in CMOS innovation, coordinates circuits require electrostatic release (ESD) assurance at the meddle cushions, in arrange to anticipate gadget glitch or breakdown. This can be more often than not actualized utilizing reverse-biased PN-junction diodes, which guarantee the potential at the cushion doesn't surpass the upper and lower limits of the control rails (V¬ss < Vp < Vdr). Such diodes (D1 and D2 in Fig. 5) include the parasitic impedances of the implant-tissue interface, all things considered, they demonstrate to be invaluable in clamping the body-potential inside the embed rail-to-rail extend by giving a 'weak' spillage path.

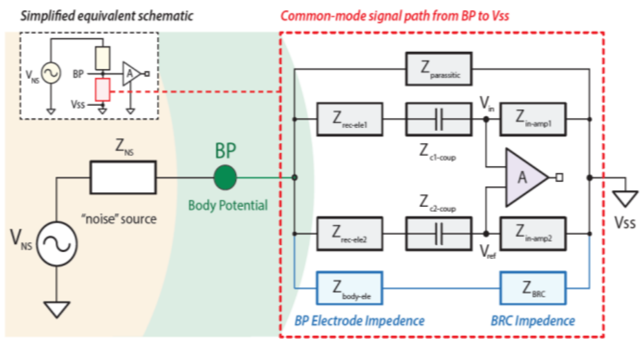

Fig. 12. Common-mode flag way in an test setup. Clamor sources (VNS) are watched at the recording intensifier inputs through stray commotion coupling impedance (ZNS). The reason of the body reference circuit is to shunt this common-mode flag to recording enhancer ground such that it is constricted at the recording enhancer input. There's basically a potential divider between ZNS and (ZBODY-ELE + ZBRC). It is therefore basic to preserve a moo impedance BP drive relative to the recording circuit ground.

Recording Performance:

The three ground referencing plans proposed within the past segment provide a diverse commitment to the neural recording execution depending on the RBC usage. As appeared in Fig. 12, where a schematic of BP to Vss way is outlined, the BRC and BPE impedances mediate within the alteration of such BP to Vss add up to impedance. By keeping up the last mentioned a moo impedance way, hence decreasing the BRC common-mode pick up A BRC-CM, the common-mode variance seen at the recording speaker inputs are minimized.

In any case due to the recurrence reaction of the RBC, ABRC-CM may increment with recurrence and conceivably reach its greatest hypothetical esteem of dB (open circuit), i.e. the common-mode commotion includes straightforwardly to the recording inputs (Vin and Vref) through the recording way. This is often spoken to within the case plot in Fig. 13 by the compelling CMRR at recurrence f2. On the other hand, a zero impedance BRC (brief circuit) would decrease the VNS potential division on BP, hence canceling out the common-mode flag. This situation is hypothetically conceivable, in any case, due to parasitic and terminal impedances, it remains a viable execution challenge.

Safety Considerations:

Other than modifying the neural recording execution, the chosen establishing conspire and the innovation highlights are key perspectives for body security necessities, since they characterize the electrical behavior at the implant-body interface (BP - GndP potential contrast and current stream). But for its aiming work, dynamic IMDs are required to be electrically unbiased when in contact with the body, and the greatest current thickness at the surface of a terminal is set to <0.75µA/mm¬¬2 agreeing to the mandate in. For this reason, current limiters are vital when utilizing driving ground referencing topologies, nearby with embed epitome and implant-to-implant electrical segregation.

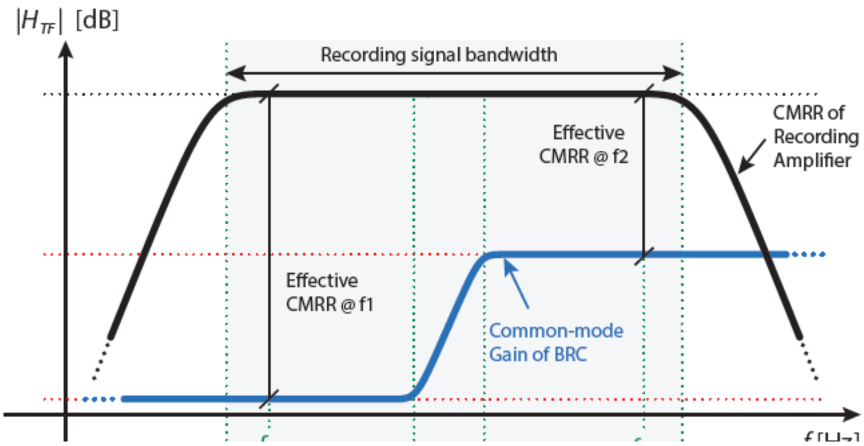

Fig. 13. Common-mode Dismissal Proportion (CMRR) of Recording Speaker and Common-mode pick up of Body Reference Circuit (BRC) with the compelling perceptible CMRR being the contrast between these reactions. The BRC setup, i.e. impedance/drivability of BP relative to recording intensifier ground, decides the size and recurrence reliance of the common-mode flag watched at the intensifier inputs (Vin and Vref). Usually basic for the exploratory plan.

EMI Definition: **Electromagnetic interference** (**EMI**), also called **radio-frequency interference** (**RFI**) when in the radio frequency spectrum, is a disturbance generated by an external source that affects an electrical circuit by electromagnetic induction, electrostatic coupling, or conduction.The disturbance may degrade the performance of the circuit or even stop it from functioning. In the case of a data path, these effects can range from an increase in error rate to a total loss of the data. Both man-made and natural sources generate changing electrical currents and voltages that can cause EMI: ignition systems, cellular network of mobile phones, lightning, solar flares, and auroras (northern/southern lights). EMI frequently affects AM radios. It can also affect mobile phones, FM radios, and televisions, as well as observations for radio astronomy and atmospheric science

What is EMI and Where Does It Come From?

EMI occurs when a device's function is affected by the electromagnetic fields generated by a nearby device. These fields can be traced to a wide variety of electrical and magnetic sources, as well as some non-electrical sources. Since EMI can be radiated, it can travel through the air and originate from many possible sources, including everyday consumer devices, such as cell phones, microwaves, radio frequency identification (RFID) equipment, anti-theft devices, and metal detectors. People also can be exposed to EMI in work environments and through industrial sources, such as arc welding, electric and combustion motors, radio towers, power supplies, and electron microscopes. Environmental factors, such as lightning and solar flares, also can generate EMI.

EMI generated by medical procedures is another concern. Dental equipment, transcutaneous electrical nerve stimulation (TENS), neurostimulation, magnetic resonance imaging (MRI), and defibrillators all can create EMI; the latter two, in particular, can cause intense EMI that is very difficult to guard against.

External defibrillation involves the administration of a 200+ volt shock to a patient's chest in an attempt to halt fibrillations and restart the heart with a normal rhythm. The shock is delivered in short pulses, which can travel through the patient's tissues and accidentally wreak havoc on any implanted devices. In the case of ICDs, this high-voltage spike actually stems from the device itself. By the same token, MRI equipment creates a magnetic field of up to three teslas (3T), equal to the strength of 600 common refrigerator magnets. Magnetic fields are dangerous to any kind of electronics, and can wipe out the digital memory of devices exposed to them. Thankfully, implantable devices can be designed to survive — and even continue operating normally — during intense voltage spikes and magnetic pulses.

How Can a Circuit Be Protected From EMI?

A conductive case, known as an EMI shield, can prevent radiated EMI from reaching a device. However, since medical devices are not closed systems, EMI shields must have openings that allow the shielded device to transmit signals or deliver treatment. Unfortunately, the wires used to transmit data and affect treatment can act as antennas, beaming harmful noise signals directly into devices, mixing with the intended signals, and resulting in potentially disastrous consequences.

Figure 14 — EMI shields, like this shield EMI shield for a power supply, are designed to prevent electromagnetic radiation (EMR) from escaping and acting as EMI in neighboring devices.

Implantable devices cannot be completely shielded from their environment, as many of them must interact with the body by sensing and distributing electrical impulses. Others even need the capability to interact with external devices. In some such cases, external adjustments to implantable devices are made using an external magnetic field or an electrical signal, so treatment can be adapted to the patient's needs. For example, some neurostimulators can be recharged wirelessly through the skin, and the frequency and strength of the pulses used to treat chronic pain can be controlled by patients using a handheld device.

Since implantable medical devices need to be both well-protected from EMI and able to send and receive signals from their environment, device engineers must employ EMI filters capable of separating the signals from the noise.

How Can We Filter EMI?

Filtering can either be active or passive. The simplest form of filtering, suitable for most of the high-frequency noise present in the environment, is passive filtering, generally achieved through the use of a capacitor.

A capacitor can filter electromagnetic noise by absorbing and smoothing out an incoming signal. High-frequency changes in voltage quickly charge and discharge capacitors and, in the process, cause the high-frequency noise to interfere with itself and cancel out the disruptive signal. Absorbing this energy to ground can neutralize or block certain frequencies from passing through a circuit.

When a capacitor is embedded in an EMI shield, feedthrough filters typically are the EMI filter of choice. A single feedthrough filter is usually round and shaped like a donut so that a lead, which carries the signal, can pass straight through the capacitor, while the capacitor's exterior is attached to the EMI shield. Filtered feedthroughs have a low equivalent series resistance (ESR) — one measure of the energy that the filter dissipates — and can be hermetically sealed and designed for high or low voltage, depending on the application.

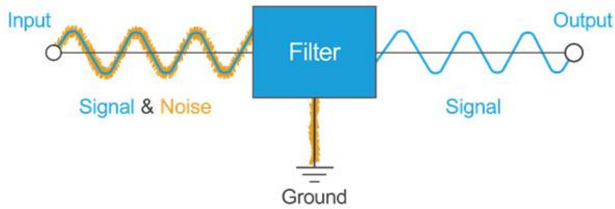

Figure 15— This diagram illustrates the basic concept behind passive EMI filtering: A low-frequency signal is passed through while high-frequency noise is removed.

Active filters comprise multiple active and passive circuit components, such as capacitors and operational amplifiers. Active filters, while suitable for many applications, require a power source to operate and can be limited in their upper frequency, so they are not commonly chosen for filtering in implantable medical devices.

Filtering also can be performed programmatically by initiating mathematical operations on the received signal to separate the signal from the noise. However, this can be computationally expensive and require larger circuitry and batteries to support the processing power. In addition, each signal line requires more computational processing, whereas multiple signal lines can be filtered through a single capacitor array. Often, a physical filter and computational filtering will be combined to optimize effectiveness and efficiency.

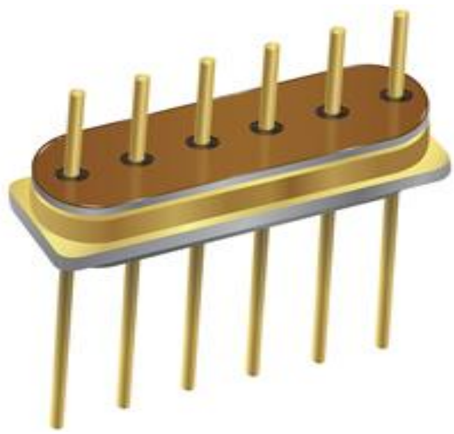

Fig. 16 — Six signal lines filtered with a capacitor array. Each line has its own separate capacitor built into the array so that each line can be filtered individually. The capacitor grounds are connected to the metal feedthrough surrounding the capacitor

Additional Concerns for Filtering in Implantable Devices:

Since many implantable devices are life-sustaining, they can be difficult to insert or remove, making the cost of device failure extremely high; and, if the device does fail, it is not easy to replace. This alarming concern brings to focus the issue of battery life. A dead or weakened battery can require removal of the current device and implantation of a new one, which can result in a lengthy, costly process in terms of both the number of doctor visits and overall patient health.

Selection of a feedthrough filter has an impact on battery life that can be twofold. To start, a very tiny amount of current always is flowing between the plates of a charged capacitor. Since one capacitor pole handles signal and the other is connected to a ground, leakage current can drain the battery over time. A strong dielectric of appropriate thickness has the ability to resist this flow of current as much as possible, significantly lessening battery drain.

In addition, filters in implantable medical devices should be designed to minimize loss of the intended signal. A filter's insertion loss measures how much a signal will be reduced or lost at each frequency. A good filter will have high insertion loss for noise frequencies and low insertion loss for the signal frequencies. Due to unavoidable effects, such as the internal resistance and inductance of the filter, some energy from the intended signal always will be lost, meaning device batteries need to work harder to achieve the same effect. However, careful design can minimize this energy loss. Less power dissipated means that less energy is demanded from the battery, extending battery life and improving efficiency.

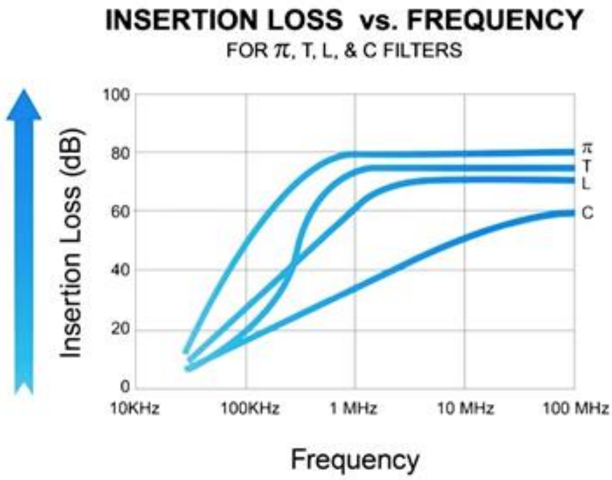

Fig. 17 — Example of insertion loss vs. frequency for several types of feedthrough filters. These filters are designed to have high insertion loss for high frequency signals, thereby blocking these signals (also known as radio frequency [RF] waves).

Through a combination of effective EMI shielding and filtering, implantable medical devices can be designed to withstand most daily exposure to EMI. If the protection is not implemented properly, the device will remain vulnerable to malfunction, damage, or a reduced lifespan. Careful EMI shield and filter selections and design-ins can optimize functionality and maximize the overall lifespan of the device.

Refrences

1- ESD Design Guidelines: for electronic circuits

2- Development of Implantable Medical Devices: From an Engineering Perspective

3- Protecting Implantable Medical Devices From Electromagnetic Interference

4- Design Considerations for Ground Referencing in Multi-Module Neural Implants

5- Why it is necessary to common all the ground in circuit?

6- Using Grounding to Control EMI

7- Electromagnetic interference