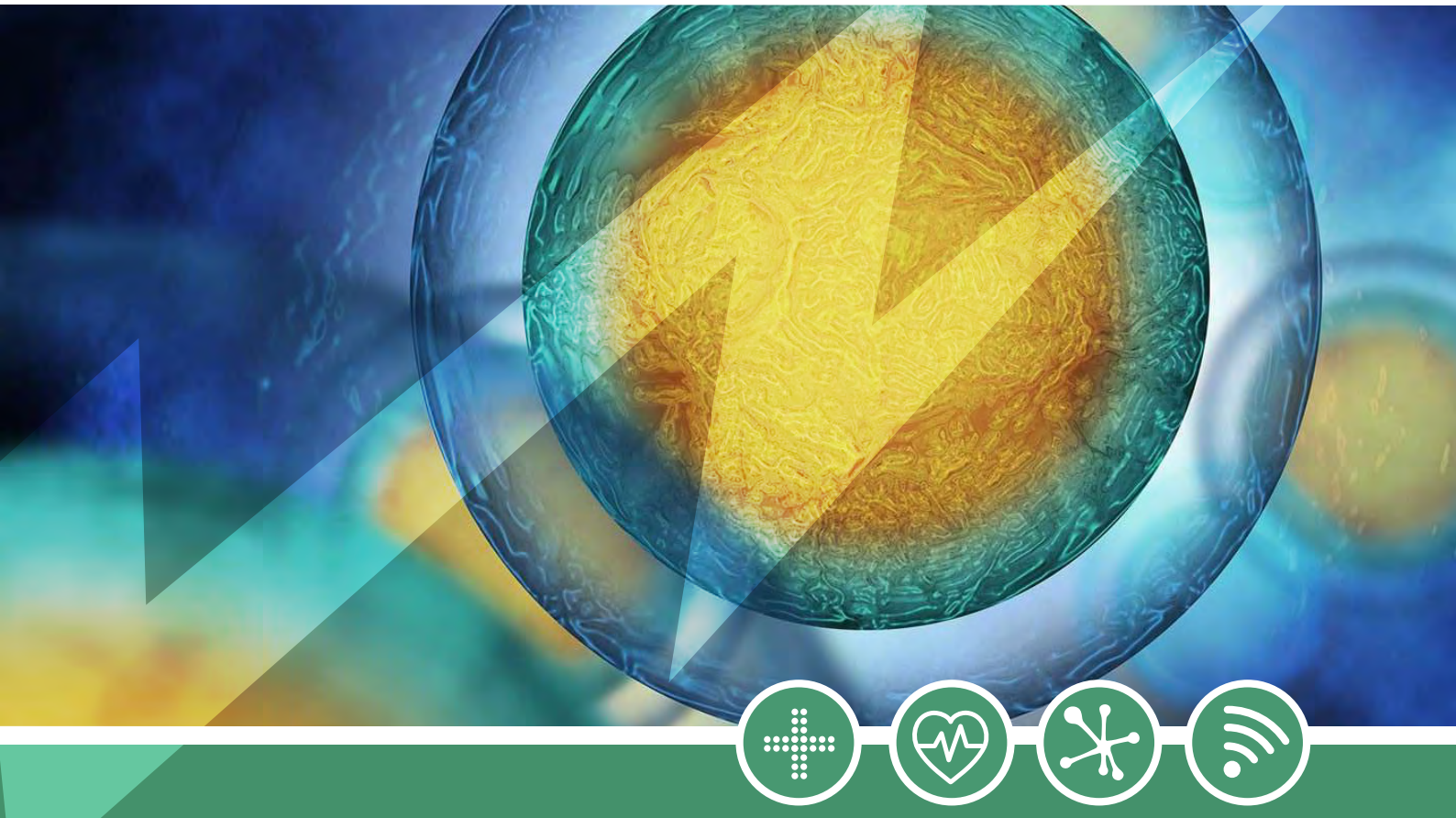
AFSEC

TECHNICAL GUIDELINES TO
ELECTROMAGNETIC COMPATIBILITY FOR MEDICAL DEVICES



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AN AFSEC GUIDE TO

ELECTROMAGNETIC COMPATIBILITY FOR MEDICAL DEVICES

Contents

A Brief History of Electromagnetic Compatibility

Electromagnetic Compatibility (EMC) may be a new term to some, though it first began to be an issue in the military environment earlier than World War II. The war encouraged the rapid development of Radio Frequency (RF) and microwave technology, which consequently, highlighted the necessity of EMC to lower the risk of practical failures.

In the 1880's, the German physicist Heinrich Hertz was searching experimental proof to find the light and electromagnetic reproductions equivalence. In 1887, Hertz performed a set of experiments to clearly show the existence of electromagnetic waves, confirming James Clerk Maxwell theory published two decades earlier.

He used two polished brass knobs as an oscillator (transmitting antenna), that were connected to the other end of an induction coil and separated by a tiny gap, in a small gap between two metal knobs he produced a spark which generated an oscillating current on the knobs resulting in electromagnetic waves generation during each spark. To further his assessments, he made a receiver consisting of a looped wire and sparked gap placed several yards from the transmitting antenna. According to the theory, if the oscillator sparks can spread electromagnetic waves, they would have sparks across the gap in receiving antenna. He turned on the oscillator and the theory occurred.

In the early 1890's, Guglielmo Marconi who learned of Hertz's experiments about radio waves began working on the idea of wireless telegraph. He made his first demonstration of his system to transport information using radio waves for the British government in July 1896. Although Marconi's system was a huge success, it introduced a whole new class of unexpected electromagnetic compatibility problems.

Electronic devices got the chance to interfere using radio technology even when they were located kilometers apart.

As commercial radio stations began to spread, a new phenomenon known as "intentional electromagnetic interference" appeared and by the time became more common in different countries. This led to establishing entities to regulate intentional radio frequency transmissions. In Europe, the International Special Committee on Radio Interference (CISPR) in 1933 and in the United State, the Federal Communications Commission (FCC) in 1934 set uniform restrictions on controlling electromagnetic interference supported by the International Electrotechnical Commission (IEC).

Later on, the U.S. Navy took an interest on Marconi's system to further improve communication with vessels at sea. The Navy started the first tests on board ships where many types of electronic equipment such as environment communication, navigation and data processing electronics had to successfully operate and function simultaneously in close proximity. Not surprisingly, they were not able to control the functioning of two transmitters simultaneously in the presence of strong radio frequency interference (RFI) fields. This early problem can be seen as the origin of the two major aspects of EMC, i.e. Emissions and Immunity.

Experiences with EMC problems during the war promoted many developments in this context and highlighted the importance of devices and systems compatibility. There are numerous examples in which EMC problems led to inefficient utilisation of weapons and defensive systems. *"As an instance, critical systems during the Vietnam War were often forced to shut down in order to avoid other systems to fail".*

The importance of measuring and problem solving of EMC, after the war were recognised by military organisations and around the world many engineers began giving more and more of their time and resources to diagnosing, solving or preventing electromagnetic compatibility problems.

Fortunately, since the early 90's engineers have had major developments in their attempts that can predict and correct EMC problems, using advanced electromagnetic modeling tools to predict worst-case scenarios in order to develop products to be liable and responsible for EMC issues. They also earned a deeper understanding of the coupling mechanisms to fulfill EMC requirements.

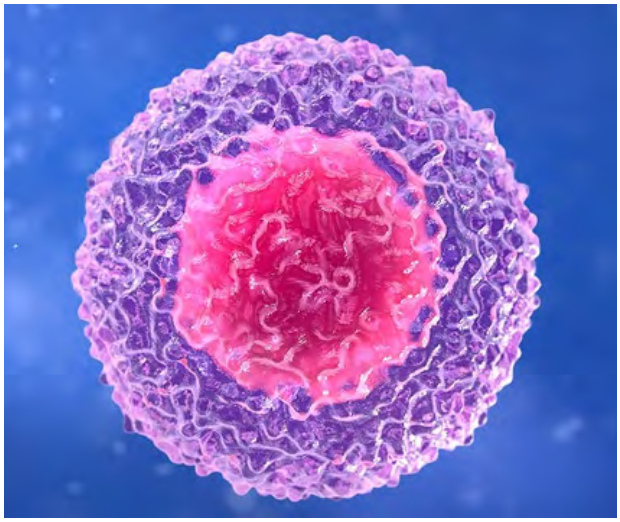
There has also been fast pace of technical novelty and innovation components available to minimize or completely remove undesirable electromagnetic coupling. *"Examples of these technological advancements include low-cost shielding materials employing nanostructures, thinner and more effective absorbing materials, smaller passive filter components and more sophisticated digital devices capable of reduced emissions and greater electromagnetic immunity."*

MEDICAL DEVICES

In non-military applications, EMC has become a source of concern due to the global popularity and proliferation electronic devices. These concerns are stemmed from an inevitable reliance on electronic devices: telephone, computers, smartphones, radios, medical devices, televisions etc. it is noteworthy that incompatibility is not only a threat to manufacturers, but also for those who install, use, modify or maintain such devices. All electronic devices controlled by microprocessor emit electromagnetic disturbance to varying degree and they are also susceptible to electromagnetic disturbance to varying degree. If precautions are not taken by manufacturers, it will result interference to other radio receivers and there will be degradation or malfunctioning in performance.

In medical devices, EMC is even more prominent because such deteriorations may entail drastic results. Consider medical devices actively used by emergency medical personnel. It is therefore crucial that all manufacturers of digital electronic devices have to ensure the safety and compatibility of their products. Such an approach helps achieve trouble free products and services. The result is improvement in quality and increased customer satisfaction. Medical equipment containing electronics are not excluded and they require passing the electromagnetic compatibility tests to guarantee that they can be used in the intended environment without failing or causing other devices to fail[1][2][3].

As electronics play a big role in healthcare and hospitals, the effect of electronic systems is becoming more apparent. Failure of electronic systems to perform their function may lead in many cases to catastrophic consequences involving potential loss of life. Many probable problems can be sorted out by ensuring sufficient separation of victims and sources of interference. It has been suggested in the literature that educating healthcare staff, visitors, contractors and patients including home-care patients about EMC helps minimise the risks of such unwanted phenomena.



Using cellular and radio communications phenomena in the vicinity of medical devices can increase the risks of EMI on the devices due to exposure to emissions from wireless technology which can be crucial and has become a potential problem. For example, when visitors in hospital use cell phone nearby patient monitoring equipment, there will be erroneous reading, this is an EMC issue. That is why many hospitals now prohibit the use of phones in certain patient care areas; EMC issues in medical devices can be fatal or have drastic effects. Imagine a machine used to operate humans that malfunction during a vital operation as a result of a mobile phone receiving call in the nearby entourage. Modern medical devices use sophisticated technologies based on radio wave propagation for control, automation, communications and all these aspect can be greatly affected by EMC.

To facilitate the manufacturing and employing EMC friendly medical devices, several protocols and standards has been evolved. For instance, IEC 60601[4] refers to a series of technical standards for the safety and effectiveness of medical electrical equipment that have published by the International Electro technical Commission first in 1977. These standards concentrate on EMC aspects of the medical device and its function.

However, there is still a clear need to develop unbiased information and tools to achieve our specific results in improving safety, reliability, effectiveness and security of wireless equipment in healthcare and developing the incorporation of wireless technology in healthcare.[5]

Although electrical interference in hospitals has often been a minor annoyance, there are recorded instances of failures of equipment due to electromagnetic interference (EMI) which have led to injury or death. Some examples are given below[6][7].

1. The powered wheelchair is a typical example: there are many stories of radio frequency interference (RFI) from police 'walkie talkies' or mobile phones causing the wheelchair to drive itself and its occupants into traffic or over a cliff[8].
2. Another appalling example happened in patients' monitoring systems: In 1987, patient monitoring systems failed to sound alarms because of interference; two patients died as a result[9].

FUNDAMENTAL DEFINITION AND CONCEPT

In this section, we explain specific terms and provide an outline for some concepts that are applicable to the subject matter. We begin with critical expressions related to electromagnetic theory and its practical use in electronics followed by some terms in biomedical engineering.

Emission: is the phenomenon by which electromagnetic energy emanates from a source [IEC 161-01-08].

Electromagnetic Disturbance (EMD): is any electromagnetic phenomenon which may degrade the performance of a device, equipment or system, or adversely affect living or inert matter. An electromagnetic disturbance may be an *electromagnetic noise*, an *unwanted signal* or a change in the propagation medium itself [IEC 161-01-05]

EN 55011[10] {CISPR 11} separates all equipment in two groups: Group 1 and Group 2. Additionally, each group is subdivided into two classes: Class A and Class B.

Group 1: contains all Industrial Scientific Medical (ISM) equipment in which there is intentionally generated and/or used conductively coupled radio-frequency energy which is necessary for the internal functioning of the equipment itself.

Group 2: contains all ISM equipment in which radio-frequency energy is intentionally generated and/or used in the form of electromagnetic radiation for the treatment of material, and EDM and arc welding equipment. Excluded from the testing requirements and limits of EN 55011 are components and subassemblies not intended to perform any stand-alone ISM function.

Class A: is equipment suitable for use in all establishments other than domestic and those directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.

Class B: is equipment suitable for use in domestic establishments and in establishments directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.

Electrocardiogram: a widely used medical device which aims to measure the electrical activity of the heart. It is commonly known as ECG and measure electrical activity of the heart muscle to determine heart conditions. As described in next chapters, the ECG signal is easily disturbed by the environmental interferences. Consequently, this may affect the patient heart beat data and even a small error might cause patient's death.

Therefore, it is extremely important to make sure it will not be affected by the surrounded signals.

Thoracic Electrical Bio-impedance (TEB): A non-invasive technique for monitoring of hemodynamic parameters. It is used to measure cardiac output, stroke volume, and cardiac index. The measurement occurs by placing four pairs electrodes at the neck and diaphragm and sending high frequency current into the chest.

Electromagnetic Waves: Movement and acceleration of an electron in atom caused by electric field creates electromagnetic radiation. Electromagnetic wave contains of an electric field (V/m) and a magnetic field (A/m) which are placed in two different directions with 90-degree angle beside each other.

Electromagnetic Interference (EMI): Is the degradation of the performance of an equipment, transmission channel or system caused by an electromagnetic disturbance (EMD) [IEC-01-06].

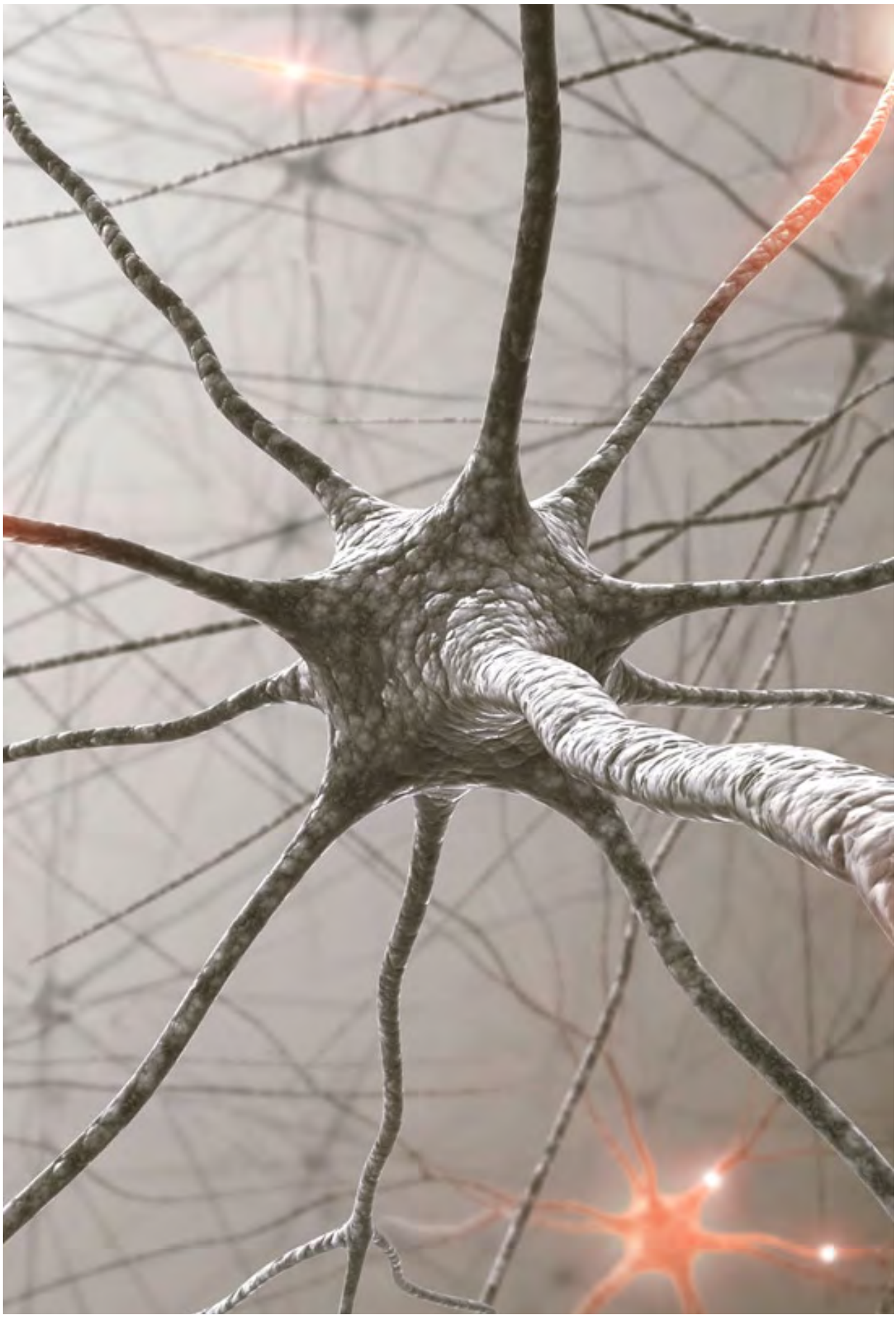
EMI Sink: can be defined as those devices characterised by negligible emission levels and whose operation may be affected by external electromagnetic disturbance. Consequently, EMC issues of such devices consist mainly of their immunity and susceptibility because conducted and radiated emissions can be safely ignored.

Electromagnetic Compatibility (EMC): The ability of an equipment or system to function satisfactorily in its *electromagnetic environment* without introducing intolerable *electromagnetic disturbance* to anything in that environment. Electromagnetic compatibility ensures equipment, device or more generally any electrical or electronic system functions satisfactorily in the presence of electromagnetic waves induced or generated by similar devices or natural causes in its vicinity.

EMC also requires the device to properly work without introducing or generating unacceptable electromagnetic disturbance to other equipment in the environment.

Electromagnetic disturbance is an ambiguous term but typically any degradation on the normal performance of a system that is resulted from electromagnetic waves is recognized as electromagnetic disturbance. Obviously, it will be nearly impossible to shield a device from any undesirable electromagnetic field. Therefore, any device should be tolerant to a level of disturbance. In other words, electronic devices are expected to demonstrate "immunity" and correctly operate even when some level of disturbance exists. Specific details on the level of tolerance and compatibility have attracted much attention and numerous protocols and standards have been defined to regulate such details about EMC.

An Operating Room Full of Medical Equipment



The ramification of electromagnetic disturbance on the functionality of medical devices can be beyond erroneous measurements and scale up to tragic incidents. In fact, a patient's safety may be largely compromised due to the malfunction of an electronic medical device implantable in patients. For example, in cardiac devices, such as defibrillators, EMD can mistakenly indicate an arrhythmia and result in adversary therapeutic actions or conversely, fail to detect arrhythmia yielding disastrous consequences. Other examples include equipment such as pacemakers and ECG monitors that have been drastically affected by EMD. Luca *et al*[11] describe two severe cases of EMI for the medical instruments:

1. A patient attached to a monitor-defibrillator in an ambulance passed away because of the interference from the ambulance radio that prevented the machine from working.

2. Another patient fitted with a pacemaker went into ventricular fibrillation in a little while the patient being scanned with a metal detector outside a courtroom.

With ever-increasing use of wireless technology applications in healthcare, the chance of EMI incidents has considerably increased which demands more attention to ensure the potential risks of these technologies are comprehensively assessed and examined[12]. Technologies such as Wi-Fi or RFID have become an essential part of any modern healthcare system and can be observed in conjunction with many medical devices[13]. Needless to say, that EMI is among the most crucial risk factors associated with this technology. This further promotes the necessity of the regulations for the Electromagnetic Compatibility (EMC) of medical devices[14]. This has been the motivation for many initiatives striving to define and impose the safety of medical devices. Tan *et al*[15] presented a detailed review of Health Canada's investigations to assure that the widely used medical devices would be minimally influenced by various types of electromagnetic interference. The project led to establishing compatibility requirements among other recommendations to lower the risk exposure for patients and guarantee the EMI safety.

EMI sinks in medical environments are of particular importance because their failure can lead to losing consciousness or, even, to death. Immunity of such devices are particularly critical because they are exposed to several IEMI and NEMI sources.[16] In this context, IEMI sources mainly consist of electronic medical equipment (Electro-surgery, Magnetic Resonance Imaging, pulsed Laser, etc.), information technology equipment (telemetry systems, computers, Wi-Fi network, RFID devices, mobile phones, etc.) and RF sources (FM radio, TV, base stations for mobile phones etc.). Whereas NEMI sources are represented by motors, fluorescent lights, elevators, switch gear and switching mode power supplies mostly.[17]

There are also some medical devices which have to be used outside medical environments, e.g. at home (pressure or ECG Holter, peritoneal dialysis equipment, etc.) or within the everyday environment (implantable medical devices). Particularly, an implantable medical device is fully or partially inserted into a human body for permanent use. It is supplied by its own power source (generally a battery), which does not exploit gravity or the energy produced by the human body itself. [18][19][20]

There are several kinds of implantable medical devices, such as cardiac, respiration and neuro stimulators, insulin and drug pumps, cochlea implants and other implantable monitors (ECG, pressure, etc.). Malfunctions of these devices may occur in presence of high-level magnetic fields within either extremely low frequency (ELF) or radio frequency (RF) ranges. Consequently, additional EMI sources should be taken into account in assessing immunity of implantable medical devices, like those easily present in the daily life of patients, such as electronic article surveillance (EAS) devices, metal detector devices (MDS), radiofrequency identification (RFID) systems and mobile phones.

Although international standards provide some procedures in order to determine EMC sensitivity of implantable medical devices, it is worth noting that these should be improved in order to account for their new usage.

IMPLANTABLE CARDIAC MEDICAL DEVICES

Implantable Cardiac Medical Devices (ICMDs) are nowadays commonly employed from even a very young age, allowing more people to live a normal life. Therefore, it is no longer unusual for people wearing an ICMD to work in environments characterised by high EMI levels, such as factories, where high-power machines and RF devices are extensively employed.

Referring to Fig. 1, ICMDs can be generally classified as Pacemaker (PMK) and Implantable Cardioverter Defibrillator (ICD), both of which have to support the heart for ensuring normal heartbeat. In fact, ICMDs operation consists of continuously monitoring the spontaneous heartbeat (sensing) and eventually stimulate the heart as needed (pacing) by means of appropriate electrical signals. Particularly, PMKs mainly aim to prevent the bradycardia, i.e. a rapid decrease of the heartbeat. Whereas ICDs are also able to deliver a certain amount of energy to the heart (up to 40 J) in order to cut off dangerous fast arrhythmias, such as ventricular tachycardia, flutter and fibrillation.

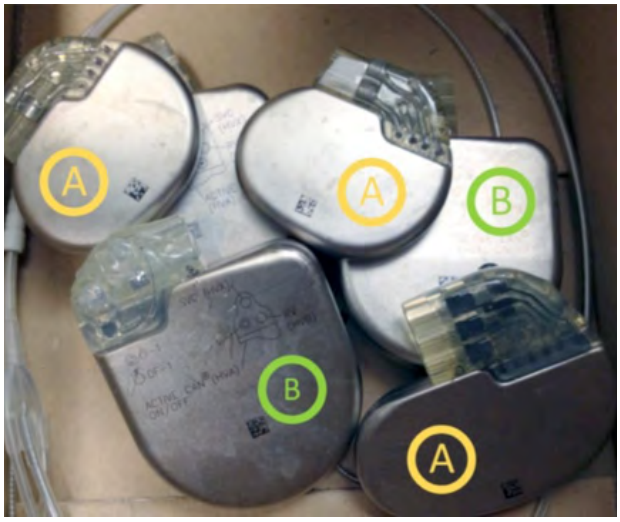


Fig. 1: Examples of ICMDs – (a) Pacemakers; (b) Implantable Cardiac Defibrillator

The electrical coupling between ICMD and the heart can be performed by means of appropriate leads, as shown in Fig. 2. They consist of multiple wires, appropriately covered by a silicone membrane, whose tails and tips are connected to ICMD and heart tissue respectively. Different leads can be employed for ICMDs, i.e. unipolar and bipolar. Unipolar leads exploit the titanium case of the device as the negative electrode, whereas bipolar leads are quite similar to coaxial cables.

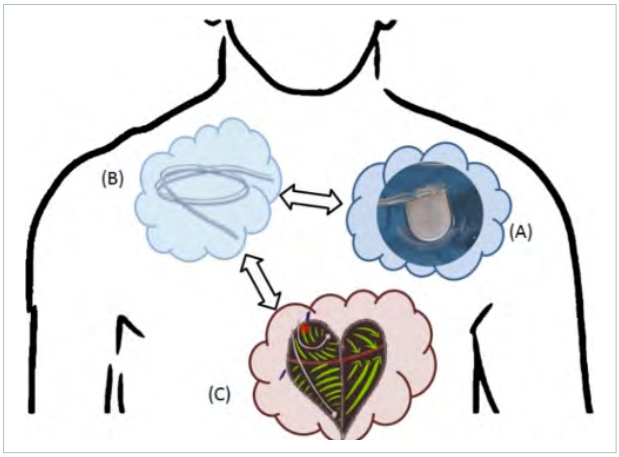


Fig. 2: (a) Implantable Cardiac Medical Devices; (b) Leads; (c) Human Heart

ICMDs may be exposed to EMI, especially through their leads, which can act as antenna for several external signals. Those signals are thus modulated and demodulated by ICMD, which can misinterpret them as heartbeat signals. Consequently, two different situations may occur: ICMD is not able to detect an abnormal heartbeat, thus no therapy is provided to the heart when needed. Alternatively, ICMD may provide inappropriate pacing, leading to unpredictable effects. Thus, EMI may cause inappropriate pacing inhibition and/or activation, permanent damages of the ICMD electronic circuitry, even a defibrillation shock. At the present time, the internationally recognised general safety standard for medical devices is the IEC 60601-1-2,

which includes EMI immunity requirements against RF emissions. This IEC standard defines two classes of electrical field strength: 3 V/m and 10 V/m. When carrying out EMI investigations in semi-anechoic environments, the IEC 61000-4-3[21] describes the test and measurement techniques.[22][23][24][25][26][27][28][29][30][31]

THE HEART

The heart is a muscle located in the thorax, whose size is that of a closed fist. Referring to Fig. 3, it is made up of four chambers, i.e. atriums (left and right) and ventricles (right and left). Each atrium is connected to its corresponding ventricle through a valve, i.e. tricuspid and mitral valve for right and left pair respectively, as shown in Fig. 4 too. There is also a semilunar valve interposed between right ventricle and pulmonary artery, as well as between left ventricle and the aorta. The heart is enclosed into the pericardial sac, filled in with the pericardial fluid, which lubricates the outer surface of the heart during its beat.

The heart is similar to a hydraulic pump, able to ensure an appropriate circulation of both venous and arterial blood in the body. This is accomplished by means of suitable polarisation and depolarisation of myocardial cells, which have to occur in a coordinated way by means of appropriate diffusion of electrical pulses throughout the heart. In particular, referring to Fig. 4, a cardiac heartbeat starts from right atrium depolarisation, which arises from Seno Atrial Node (NSA), which consists of the self-rhythmic cells known as natural pacemaker of the heart. The depolarisation wave then propagates from the NSA to the Atrioventricular Node (NAV), another bunch of self-rhythmic cells located near the bottom of the right atrium. From NAV, the depolarisation moves towards ventricles along atrioventricular bundles (AV bundles, also AV bundles are divided into right and left branches, both of which end with Purkinje fibers, which are smaller and, thus, able to conduct and transmit electrical signals very rapidly.

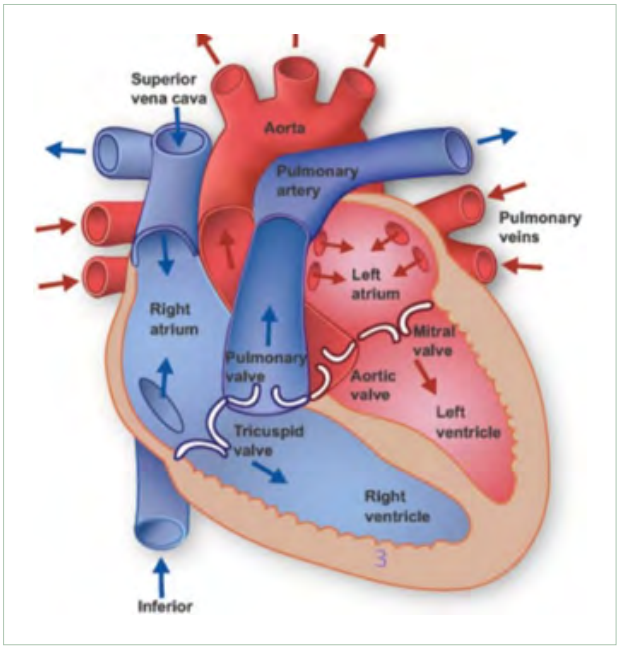


Fig. 3: Human Heart

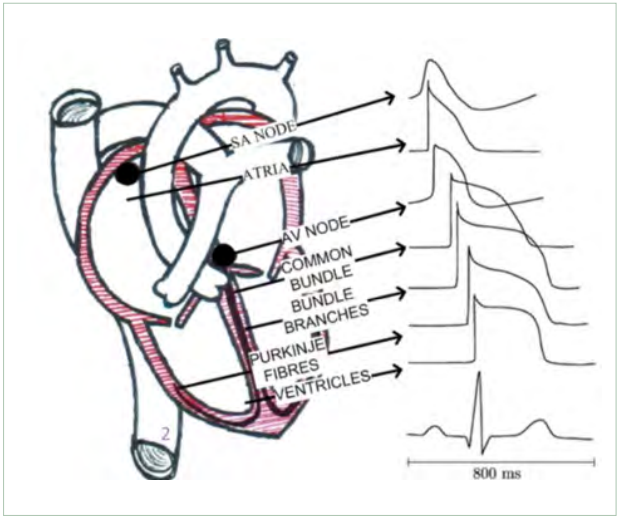


Fig. 4: The Heart and Its Impulse Propagation System

The electrical activity related to heartbeat is detectable by the Electrocardiogram (ECG). In particular, magnitude and orientation of the dipoles during depolarisation and re- polarisation of atriums and ventricles are represented by vectors. First of all, myocardial cells enter into polarisation phase during the first refractory period, at the end of which atrium depolarisation occurs[32][33][34]. Consequently, the P wave arises, which is the summation of the depolarisation of the atrial cells that result in blood flowing into the ventricle. The P wave is made up of low frequency signals, with a spectrum under 10 Hz. Subsequently, after another refractory period, ventricle depolarisation occurs, which is represented by the QRS complex that lasts about 0.1 s. During this stage, ventricles contract and pump blood through the human body, while atriums are relaxed. The highest signal level in the QRS complex corresponds to the peak of the R wave, which represents the depolarisation of all individual cells. Finally, another short refractory period occurs, after which ventricle re-polarisation starts. This is denoted by the T wave, which lasts approximatively 0.3 s.

A regular ECG is reported in Fig. 5. It is worth noting that QT interval depends on the heart rate, in particular it becomes shorter for increasing heartbeat frequency. Abnormal variations on the heartbeat are called cardiac arrhythmias, some of which are briefly described in this document.

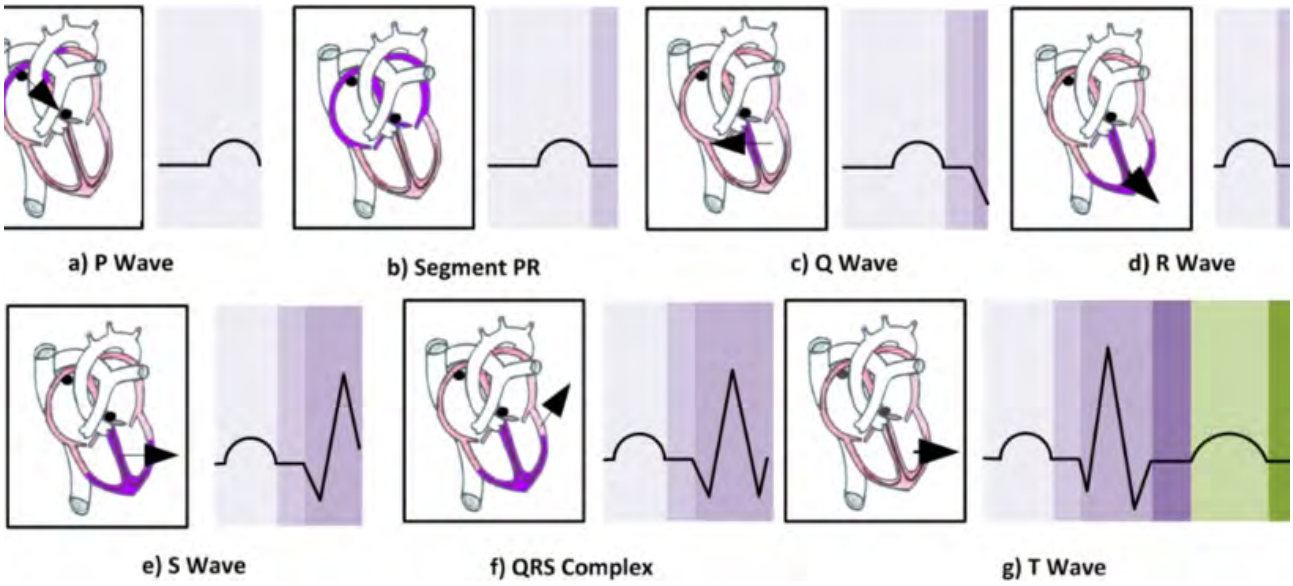


Fig. 5: An ECG recorded by an external electrode: (a) all cardiac cells at rest, (b) atrial depolarisation, (c) NAS to NAV, (d, e, f, g) ventricular depolarisation, (h) ventricular re-polarisation.

CARDIAC ARRYTHMIAS

Several kinds of cardiac arrhythmias may occur (bradycardia, tachycardia, heart block, atrial and/or ventricular fibrillation, etc.), each of which requires the assistance of the most suitable ICMD, i.e. PMK or ICD.[35]

Bradycardia refers to an abnormal slow heartbeat, in particular it indicates the decrease of heartbeat frequency below a given threshold, as a shown in Fig. 6. This arrhythmia causes fatigue, dizziness, light-headedness, fainting, extreme fatigue, poor exercise tolerance, and shortness of breath. In adults, bradycardia generally occurs when the Heart Rate (HR) is less than 60 beat per minute (bpm). There are three types of bradycardia, i.e. slight bradycardia (HR between 50 and 59 bpm), moderate bradycardia (HR between 40 and 49 bpm) or grave bradycardia (HR between 30 and 39 bpm). However, these intervals are subjective, they depending on age and physical activities of individuals. For example, normal heartbeat frequency of some athletes can be about 30 bpm.

Tachycardia is defined as an abnormal increase of HR, as shown in Fig. 7. Tachycardia threshold is generally assumed at 100 bpm in an adult, however it depends on the subject and on its state of health. A heart block is a disease of the heart electrical system, particularly it denotes a failure of the electrical conduction system, thus preventing electrical signals to reach the ventricles. Consequently, heart activity can decrease dramatically, as shown in Fig. 8. Heart blocks can cause dizziness, syncope (fainting), and palpitations.

Over atrial fibrillation, the regular electrical pulses generated by NAS are overcome by disorganised electrical pulses, as shown in Fig. 9. As a consequence, atrial fibrillation causes improper and reduced blood flows through the heart at the beginning of the cardiac cycle, leading to an irregular conduction of ventricular pulses that constitute the heartbeat. Atrial fibrillation may last for minutes to days, in particular it can be identified as a wave having a variable amplitude, duration and form. Its main symptoms are palpitations, fainting, chest pain, or congestive heart failure.

Unsynchronised electrical activity in the ventricles leads to a reduced or zero blood flow in the heart. This is the case of ventricular fibrillation, which appears as a particular wave characterised by the absence of the QRS complex, as shown in Fig. 10. Fibrillation begins when an electrical pulse stimulates the ventricle during the Ventricular Refractory Period (VRP) or during the falling edge of the T wave.

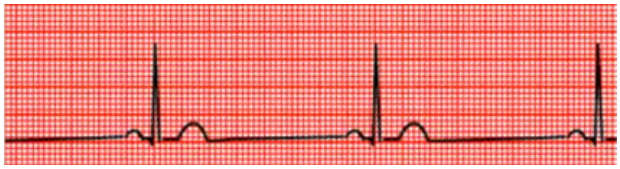


Fig. 6: Sinus Bradycardia

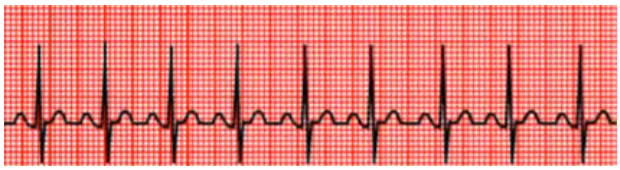


Fig. 7: Sinus Tachycardia

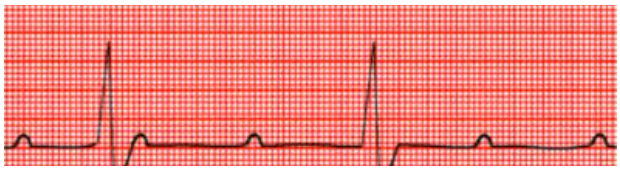


Fig. 8: Heartbeat Signal During Heart Block

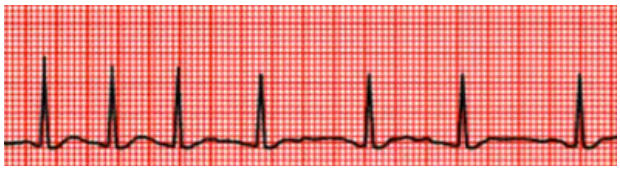


Fig. 9: Heartbeat Signal during Atrial Fibrillation

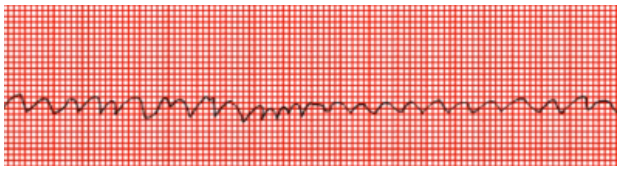


Fig. 10: Heartbeat Signal During Ventricular Fibrillation

PACEMAKER

PMK is a sophisticated electronic device that performs two basic functions: it monitors the electrical activity of the heart and provides electrical stimuli to suppress any abnormalities of the heartbeat. This device thus controls the heartbeat amplitude and frequency and coordinates the contraction of the heart. The principle of operation of PMK may be summarised in several phases: a phase of "sensing", during which the device detects any signs of spontaneous electrical activity of the heart, and a phase of "pacing", in correspondence of which the electrical pulses generated by the PMK are transmitted to the heart muscle. PMK is programmed for the first time in the operating room, in particular the most suitable configuration is set and verified during surgery. Sensing and pacing parameters can be appropriately adjusted or PMKs can be also reprogrammed in the subsequent checkups, based on patient feedbacks.

The first PMK was designed to provide a stimulus to the heart for patients subjected to severe bradycardia in order to restore normal heartbeat. The PMK is equipped with one or more leads, which are appropriately inserted into a vein and hooked to right ventricle and/or atrium by means of a surgical operation. PMKs used in the last twenty years operates in accordance with the "demand" algorithm; it consists of performing pacing therapy continuously, thus assuring constant frequency heartbeat. Modern PMKs are much more sophisticated.

When it detects an abnormal heartbeat, it starts appropriate procedures in order to support the spontaneous cardiac activity.

First models of PMK were manufactured by means of different types of material: mercury is used for some parts of their internal circuit, while alkaline batteries were employed as power supplies, which are encapsulated in epoxy resin. These PMKs were characterised by a short life (about 18 months), mainly due to the exhaustion of the batteries. More recent PMK instead resort to CMOS technology, together with improved batteries (Lithium-based), which ensure a theoretical life up to 12 years. The box of the pacemaker is now made up of titanium and the device is completely programmable via external telemetry. In addition, modern PMKs are equipped with a sophisticated sensing circuit in order to reduce the effects of any interference signals.[36][37]

A modern PMK, shown in Fig. 11, consist of:

a. **Sensing Circuit:** it is the "brain" of the device, since it has the task of elaborating the cardiac signals by appropriate recognition algorithms, selecting the most appropriate pacing therapy at the same time. These algorithms vary depending on PMK manufacturer and have to convert the analog cardiac signal into a digital one, which can be successfully processed by the sensing circuit. In addition, amplification and filtering are also required due to different amplitude of cardiac signal. The filtering system is constituted by band-pass filters, which allow the suppression of both low and high frequency signals, such as breathing and myopotentials. The filtering system covers a very important role in reducing the effect of EMI on both pacing and sensing.

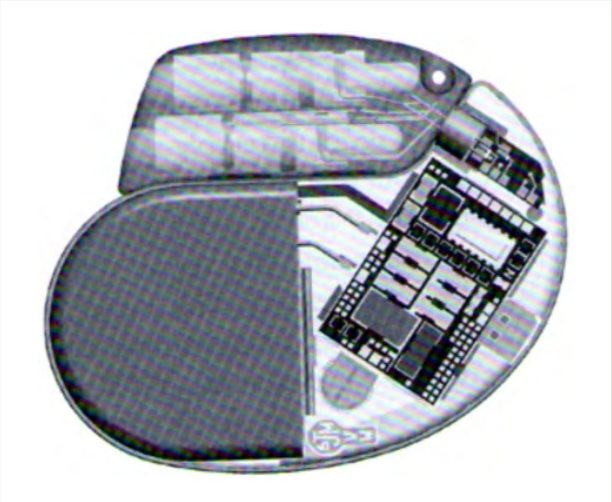


Fig. 11: Structure of a Pacemaker

b. **Battery:** it is the component that mostly contributes to PMK size and weight. In particular, referring to the PMK shown in Fig. 12, the battery corresponds to about 25 % of the total PMK volume. Today, almost all PMK batteries are Lithium-Ion, which is the most suitable

solution in terms of size, weight and lifetime (about 12 years). In particular, such a huge lifetime indicates that the Lithium-Ion battery voltage decays slowly, thus assuring appropriate supply current to the PMK in order to preserve all its functionality. Battery initial voltage is about 2.78 V, it being 2.65 V at the end of life. When the battery voltage reaches 2.55 V, which corresponds to about 95% of energy consumption, the decay forces the specialist staff to reliably anticipate replacement of the device. In some PMKs, the microprocessor is able to measure the amount of energy consumed, which helps to predict the time of elective replacement. Battery consumption is due to both the amount of energy consumed for pacing and to the current flowing at rest, which is also called cleaning current. Particularly, cleaning current is related to the amount of energy required by PMK operation (sensing, storing and recognition data, etc.), also when pacing is fully inhibited.

First generation PMK did not have complex functions, such as telemetry, programmability and diagnostic, thus their cleaning current was generally quite small. However, their overall energy consumption was very high due to their continuous pacing activity. Whereas modern PMK incorporate many advanced functions (inductive and/or RF telemetry, frequency-sensitive sensor, notifications, electro-grams, etc.), leading to significant cleaning current values. However, due to their selective pacing activity, they resort to smaller batteries, which last longer than first generation PMKs.

c. **Titanium case:** the sensing circuit and the battery are embedded into a special resin and locked to a titanium enclosure of small size. The use of this material is because it is biocompatible with the human body and represents a good shielding against EMI. PMKs can be classified based to the amount of heart chambers they can stimulate. Referring to Fig. 12, there are unicameral PMKs, which can stimulate one heart chamber only (right atrium or right ventricle) or bicameral PMKs, which can stimulate two chambers (right atrium and right ventricle). In addition, latest generation PMKs can also be able to stimulate three chambers simultaneously (right atrium and both ventricles). PMK functionalities are uniquely identified by a five-letter code, which was introduced by the North American Society of Pacing and Electrophysiology (NASPE), together with British Pacing and Electrophysiology Group (BPEG).

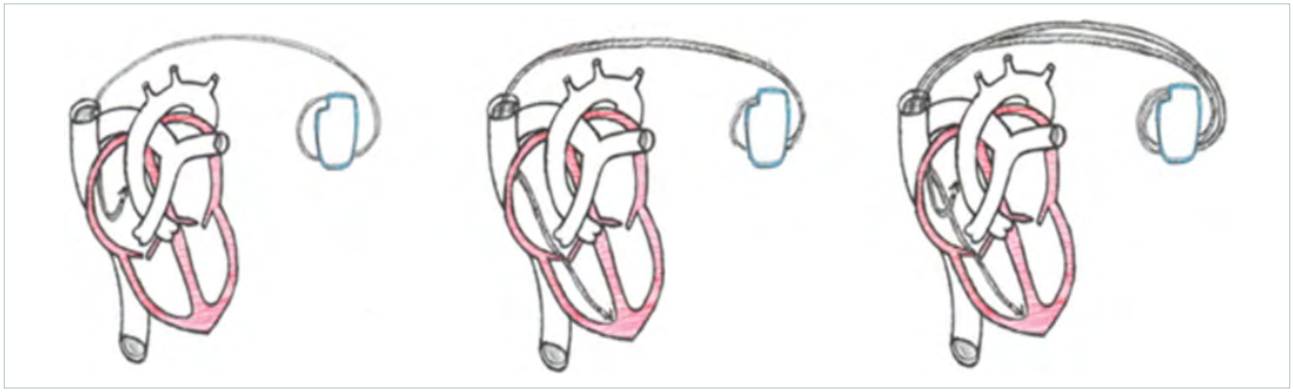


Fig. 12: Unicarmel and Bicarmel PMKs

Particularly, the five letters refer to the following aspects:

- Cardiac chamber stimulated (pacing);
- Cardiac chamber monitored (sensing);
- Response to detection (function type);
- Programmable and frequency response (R); andTachycardia function.

In this way, it is possible to identify the different types of PMKs currently available on the market, as shown in Table 1.

IMPLANTABLE CARDIOVERTER DEFIBRILLATOR

An ICD mainly consists of a pulse generator, a battery and appropriate input filters[38][39][40]. Differently from PMK, it is also equipped with a capacitor and a discharge resistor in order to accumulate and deliver the energy required by ventricular arrhythmias treatments. All these components are enclosed into a titanium case. Once implanted, the ICD can be programmed and monitored via telemetry, since the generator can interact with external tool control. Depending on heartbeat status, ICD can act as:

- Pacemaker, when the patient has a spontaneous abnormal heartbeat (e.g. bradycardia);
- Stimulator Antitachycardia, when it detects threatening and rapid arrhythmias; in such cases, ICD provides a very rapid cardiac pacing by stimulating the heart to a higher frequency than the arrhythmia itself;
- Defibrillator, either in case of potentially lethal arrhythmia or when antitachycardia pacing is ineffective; particularly, the ICD provides an electrical discharge (up to 40 J) in order to reset the heart and thus restoring the normal heartbeat.

There are two types of ICD: the first is single chamber ventricular ICD, which applies therapies as it detects dangerous arrhythmias occurring on the right ventricle. Whereas dual chamber ICD monitor both right atrium and ventricle, thus it is able to detect and suppress more kinds of arrhythmias.

I	II	III	IV	V
Chamber(s) Paced	Chamber(s) Sensed	Response de Sensing	Rate Modulation	Multisite Pacing
O = None	O = None	O = None	O = None	O = None
A = Atrium	A = Atrium	T = Triggered	R = Rate Modulation	A = Atrium
V = Ventricle	V = Ventricle	I = Inhibited		V = Ventricle
D = Dual (A+V)	D = Dual (A+V)	D = Dual (T+1)		D = Dual (A+V)

Table 1: Examples of ICD

LEADS

Leads connect PMK or ICD to the heart, having to guarantee appropriate communication over both sensing and pacing activities, as well as for providing electrical shock. Therefore, they are fundamental for proper operation of ICDMs. Signal transmission is accomplished through one or two electrodes, PMK leads can be classified based on multiple characteristics, among which the shape, i.e. straight or J-curved. In particular, referring to Fig. 13, straight leads are used for hooking ventricular tissue. Whereas J-curved leads, as shown in Fig. 14, are more appropriate for being hooked to the atrial wall. Leads can also be equipped with helical or anchor tips, mainly depending on the heart chamber to be stimulated. Referring to Fig. 15, the most important lead classification is based on polarities. Particularly, unipolar leads are characterised by a single electrode (cathode) located at their tip, while the other (anode) is represented by the titanium case of the implantable device. Whereas, in bipolar leads, both anode and cathode are located at lead tip. Consequently, bipolar leads have two coaxial spirals separated by a layer of insulating material (polyurethane). Both unipolar and bipolar leads are covered by a tube of plastic material (polyurethane or silicone), as shown in Fig. 16 [41][42][43][44].

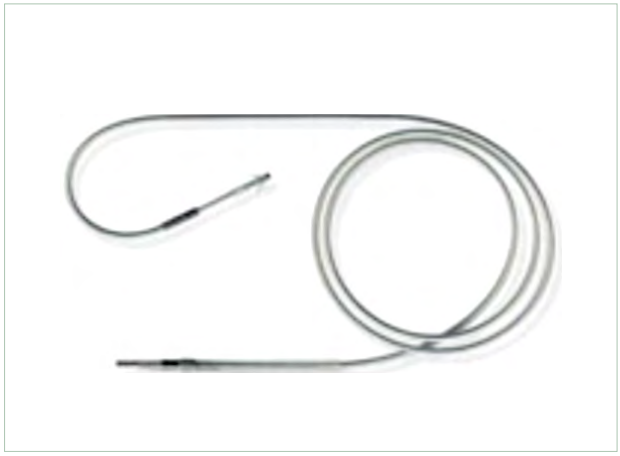


Fig. 13: Straight Lead

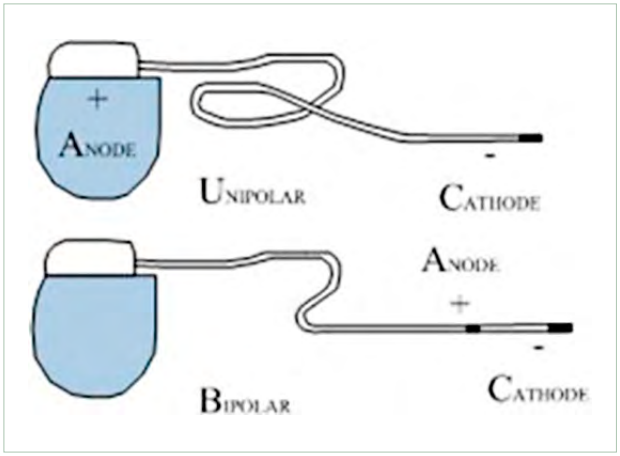


Fig. 15: Unipolar and Bipolar ~ Leads

Fig. 14: J-Curved Lead

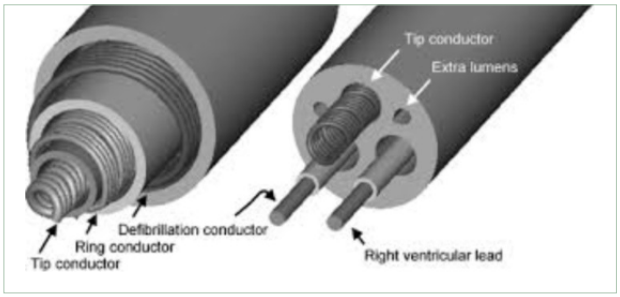


Fig. 16: An Example of an ICD Lead

In case of unipolar leads, the anode-cathode loop is quite huge (about 225 cm^2) because the closing path consist of the tissue interposed between the two electrodes, as shown in Fig. 17. In contrast, bipolar leads are characterised by much smaller loops (about 15–20 times less), both anode and cathode being placed within the heart, spaced 2–3 cm to each other. Consequently, unipolar leads are subjected to significant interference from skeletal muscle, as well as to EMI. However, the use of bipolar leads is not always possible due to their excessive outer diameter.

In addition, clinical experience reveals that bipolar leads are characterised by a higher replacement rates. Similar to PMK leads, ICD ones have a coaxial or multi-winding structure, as shown in Fig. 16. Coaxial structure is characterised by spiral conductors, each of which is covered by its own insulating layer. A spindle is also inserted for hooking the lead tip to the heart chamber. The main difference between PMK and ICD leads consists of the increased number of electrodes of the latter, which also have to provide electrical shock through appropriate shocking coils, as shown in Fig. 18.

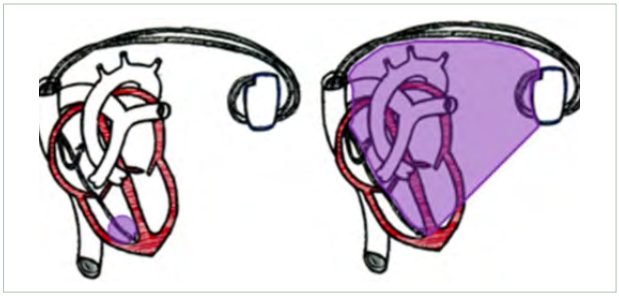


Fig. 17: Location of Electrodes for Unipolar (on the right) wand Bipolar Leads (on the left)

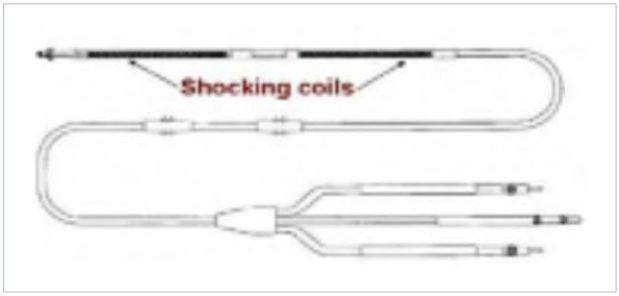


Fig. 18: ICD Lead with Shocking Coils

THE SENSING

The detection of heartbeat is a basic requirement for an implantable cardiac device, such as PMK or ICD. Particularly, referring to Fig. 19, refractory and vulnerable periods must be detected accurately, otherwise unsuitable therapies could be provided, which may cause severe arrhythmias in different parts of the heart[45][46].

Referring to Fig. 20, atrial and ventricular sensing must be considered separately, they are both based on an appropriate set of their corresponding sensing threshold. Particularly, proper ventricular sensing occurs when only the R wave is detected, whereas atrial sensing requires the detection of the P wave only. The sensing circuit must thus detect, amplify, filter and rectify the heartbeat signals so that P and R waves are readily recognisable, avoiding misunderstandings. These last may be due to several reasons, among which myopotentials, T wave variations, crosstalk between atrium and ventricle, atrial stimuli effects on ventricular channel and EMI. In this context, a very important role is covered by the low pass filter, which must suppress signals with frequency below 20 Hz and above 100 Hz, such as those ofT wave potential variations (< 20 Hz) and of myopotential (> 100 Hz).

Sensing tuning procedure is performed immediately after the lead is hooked to the heart. In particular, sensing threshold depends on lead type and hooking, it may also vary from patient to patient. In the case of unipolar lead, the anode is located in the tip, whereas the cathode is the case of the device, as above-mentioned. Consequently, sensing threshold is set at a high value in order to make sensing procedure unaffected by spurious signals. However, bipolar leads are highly recommended, both anode and cathode being placed in the lead tip. As a consequence, more information can be sent to the implanted device, which can also be transmitted and acquired more safely, thus opposing to antitachycardia more effectively. Another important difference between the two types of lead is hooking; unipolar leads suffer from inflammation in the wall of the heart chamber (atrium or ventricle), causing a period over which the measurements are staggered. Whereas bipolar leads are characterised by a floating node (anode), thus ensuring a highly accurate detection of cardiac signals.

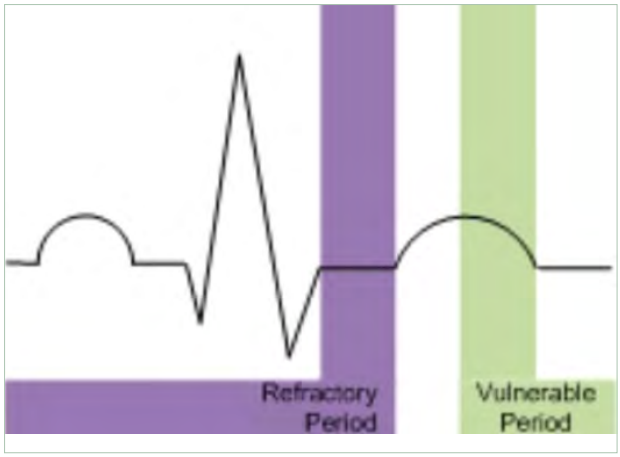


Fig. 19: Refractory and Vulnerable Period

Sensing thresholds are different for PMKs and ICDs, they ranging within 1.5–2.0 mV for PMKs. Whereas ICD values are much smaller (0.3–0.5 mV) because ICDs must extinguish cardiac arrhythmias rapidly, such as tachycardia and fibrillation. Consequently, low sensing thresholds assure a good detection of both P and R waves, as well as ventricular tachycardia, atrial and ventricular fibrillation.

In spite of the employment of appropriate filtering system and recognition algorithms, misunderstandings still occur, leading to wrong actions provided by the implanted device.In this context, under sensing occurs when detection of P or R wave is missed, as shown in Fig. 21. Particularly, atrial under sensing can cause stimulation in the vulnerable period, as well as prevent atrium contraction, leading to atrial or ventricular fibrillation respectively. Ventricular under sensing may occur due to wrong placement of lead tip, i.e. far from NAV, which significantly reduce R wave detection capability. Consequently, unsuitable pacing is provided, which may leads to dangerous and sometimes fatal arrhythmias.

Differently from under sensing, over sensing means that additional waves are detected, as shown in Fig. 22. Particularly, the device misinterprets spurious signals as threatening arrhythmias, consequently it inappropriately starts pacing activity or, in case of ICD, it may also provide a defibrillation shock. In such cases, the patient can experience a permanent heart block or device inhibition. Atrial over sensing is the most critical because the amplitude of the P wave is quite smaller than R wave. This requires an accurate placement of the ventricular lead, which should be quite far from the atrial one in order to avoid unsuitable crosstalk effects.

However, atrial over sensing may be also caused by myopotentials and other spurious body signals, such as those produces by contracting the two hands together or by coughing. In such cases, unipolar leads should be not employed, especially for patients with atrial arrhythmias. Atrial over sensing causes uncoordinated stimulation in some programming mode (AAI, DDI), fast and irregular heartbeat, and even atrial fibrillation. Ventricular over sensing is due mainly to myopotentials, T-wave detection and EMI, leading to device inhibition.

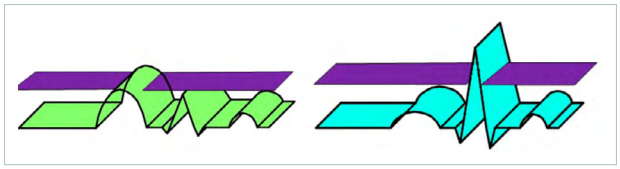


Fig. 20: Proper sensing: ventricular (on the left) and atrial (on the right).

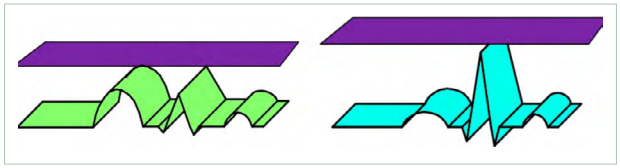


Fig. 21: Under sensing: ventricular (on the left) and atrial (on the right).

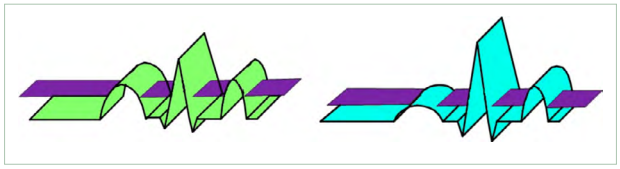


Fig. 22: Over sensing: ventricular (on the left) and atrial (on the right).

THE SENSITIVITY TEST

The Sensitivity Test is defined by EN 45502-2-1[47] and consists of measuring the sensing threshold of implantable cardiac medical devices. It thus must be performed in accordance with the setup shown in Fig. 23, which is made up mainly of:

- A Pulse Generator, i.e. the device under test;
- A Test Signal Generator (output impedance ≤ 1 kΩ), which has to emulate the human heartbeat;
- An impedance R_F in order to guarantee an appropriate coupling between the two generators;
- An impedance R_L for reproducing the cardiac tissue interposed between the lead electrodes; and
- A digital Oscilloscope in order to monitor the output waveforms.

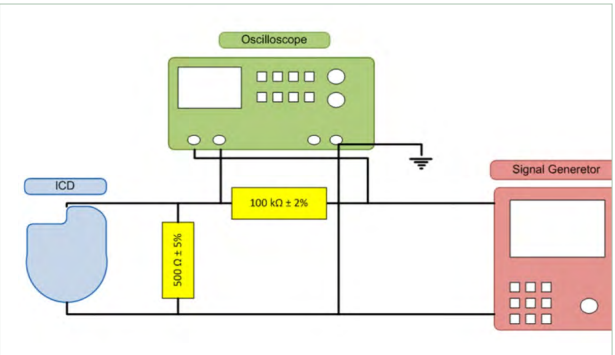


Fig. 23: Schematic representation of the Sensitivity Test in accordance with EN 45502-2-1[47]

More specifically, R_F and R_L must be chosen in accordance with the following relationships:

$$R_L = 500\Omega \pm 1\% \qquad R_F = 100k\Omega \pm 1\% \qquad (1)$$

In addition, the human heartbeat has to be emulated by a triangular wave, whose pulse width (T) has to be set to 15 ms, the leading edge (t) being equal to 2 ms, as shown in Fig. 24. The Sensitivity Test also requires a preliminary setting of both heartbeat amplitude and frequency, which are denoted by a and f respectively. In particular, a shall be set to zero, whereas f must be chosen in order to guarantee a period of the heartbeat signal at least 50 ms less than the basic pulse interval of the device under test (T_b). It is worth noting that, over such a starting condition, pacing always occurs due to the lack of heartbeat. Sensitivity Test can be thus started and carried on by slowly increasing a until pacing shall be consistently suppressed, leading to identify the positive sensing threshold $\sigma^{(+)}$ as follows:

$$\sigma^{(+)} = K \bullet \min\left\{A\,|_{\pi=0}\right\} \quad A, \frac{dA}{dt} > 0 \qquad (2)$$

Referring to (2), K denotes an appropriate scaling factor, π being the pacing status; in particular, π = 0 means that pacing is consistently suppressed, on the contrary π = 1. The above-mentioned procedure shall be repeated starting from the same initial condition, but slowly decreasing a. Consequently, as soon as pacing is consistently suppressed, the negative sensing threshold $\sigma^{(-)}$ is achieved as:

$$\sigma^{(-)} = K \bullet \max\left\{ A\,|_{\pi=0} \right\} \qquad A,\ \frac{dA}{dt} < 0 \qquad (3)$$

In conclusion, it is worth noting that the ICMD under test must be programmed in either VVI or AAI in accordance with international standards [48]. An alternative automatic sensing test procedure which aims to better characterise implantable cardiac medical devices in terms of sensing performance in detailed in performance in reference [49].

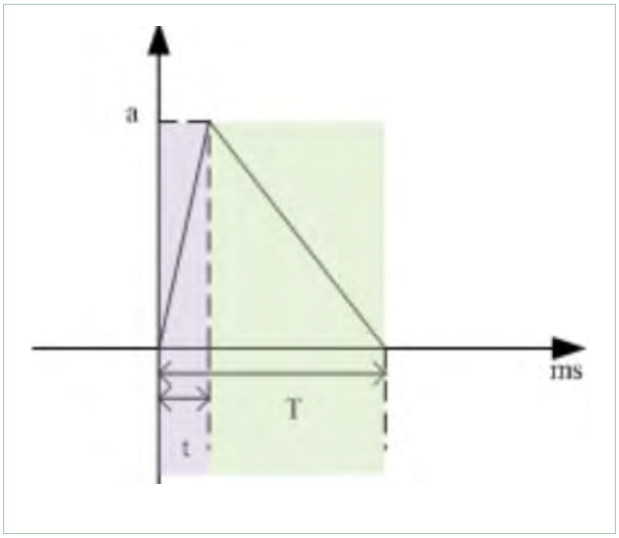


Fig. 24: The equivalent heartbeat signal required by EN 45502-2-1

EMC guidelines for medical devices

Perhaps the most common standard for medical electrical devices is IEC 60601 that is a series of technical standards which include a description of methods for the safety and effectiveness of medical electrical devices. It consists of a general standard, collateral and particular standards each briefly described below.

The general standard IEC 60601-1 broadly specifies requirements associated with the safety and performance of all medical electrical equipment. The collateral standards (60601-1-X) describe the requirements of safety and performance and pertains more to our main topic. In fact, the electromagnetic compatibility standard (IEC 60601-1-2) relates to this collateral since it intends to prevent any overriding of the requirements determined by the general standard. The particular standards (60601-2-X) describe the requirements for specific measurements for specific products. Nerve and Muscle Stimulators (IEC 60601-2-10) serve as an example here. Another pertinent standard is EN 55011 (2009) along with its first amendment which sketches the limits and techniques of measurement for radio frequency disturbance in Industrial Scientific and Medical (ISM) equipment. In nutshell, this standard deal with emission requirements related to RF disturbances.

CERTIFYING A MEDICAL DEVICE

Within Europe, a medical device or In Vitro Diagnostic product can not be placed on the market or taken into revenue service without having been CE Mark (the European Conformity mark). The CE mark is not a quality mark but indicates that the said devices complies with all applicable requirements of the appropriate European Union (EU) Directive, such as the Medical Devices Directives (MDD), In Vitro Diagnostic Device Directive (IVDD) and the Active Implantable Medical Device Directive (AIMD). In the USA, such medical device would need to comply with FDA requirements and approval process.

In addition to the above mentioned directives, other directives may apply such as the EMC Directive 2014/30/EU.

Within AFSEC Member States, the evidence of CE Marking and/or FDA approval should give confidence of that the medical device meets a basic level of conformity and EMC., however such should be reviewed in line with the environmental conditions applicable and the peculiarity of the installation environment available in Members States.

The process in Europe, requires the preparation of a Technical File, which consist of the evidence and/or justification in support of a claim of compliance to the applicable Directives. Such evidence includes test reports, from a qualified laboratory (or laboratories) for EMC, LVD, Chemical etc. The Technical File should also include a Risk Assessment performed in accordance with the requirements of ISO 14971[50]. The Technical File should also include a User Manual covering the Operation and Maintenance of the device. The certified medical device should be placed on the market with a Declaration of Conformity (DoC) issued by the manufacturer. The DoC is the written statement and a single declaration drawn up by the manufacturer to demonstrate the fulfilment of the EU requirements relating to a product bearing the CE marking he has manufactured.

The declaration shall be in respect of all Community acts applicable to the product containing all information required for the identification of Community harmonisation legislation to which the declaration relates.

EMC TEST

EMC testing is a way of demonstrating that an electronic/electrical equipment complies with the protection requirements of the EMC Directive. The protection requirements of the EMC Directive (in Annex 1 of [51]) states that:

"Equipment shall be so designed and manufactured, having regard to the state of the art, as to ensure that:

a. *the electromagnetic disturbance generated does not exceed the level above which radio and telecommunications equipment or other equipment cannot operate as intended;*

b. *it has a level of immunity to the electromagnetic disturbance to be expected in its intended use which allows it to operate without unacceptable degradation of its intended use."*

To this extend, medical devices are tested to demonstrate compliance with the requirements of IEC 60601-1-2. The test requirements are generally split into Emission and Immunity test. These test requirements are described below, followed by a summary of test data from an actual medical devices tested in an EMC TEST Laboratory of an AFSEC Member Stat.

EMISSION TEST

Emission is the phenomena by which energy emanates from a source. With respect to an electronic/electrical equipment, this is generally through cables attached to the equipment (conducted) and the enclosure (as well as cables acting as an antenna) of the equipment (Radiated).

Radiated Emission Test

The term radiated emission refers to the electromagnetic energy that radiates unintentionally from an electronic device into space. From the frequency around 30 MHz, EMD produced by the EUT (Equipment under test) starts to radiate out from the cables and after 300 MHz, the whole enclosure can radiate unwanted EMD. Measurement of radiated emission occurs in anechoic test chamber or Open Area test sites or depending on situation can be measured in situ.

To provide the correct measurement, ambient noise levels are measured and eliminated from the data and RF reflection from the EUT. Measurements are typically performed at either a test distance of 3 m or 10 m from the face of the EUT. Table 2, summarises the test limits.

Frequency Range (MHz)	Quasi Peak Limit at 3m (V/m)	Quasi Peak Limit at 10 m (V/m)
30 – 230	40	30
230 – 1000	47	37

Table 2: Radiated Emissions – Class B in accordance with EN 55011

Test Method

For measuring in an anechoic chamber an antenna, a receiver and a signal amplifier is needed. Measurements is to be taken in both horizontal and vertical polarisation. The center of the antenna is to be varied between 1 m and 4 m height for maximum indication at each test frequency. All cables are to be connected in the length and type specified by the manufacturer. If the cable has to be bundled, the bundled part is to have a length between 0.3 – 0.4 m.

Conducted Emission Test

EMD that is propagated via cables from the EUT (equipment under test) into other electronic devices is called conducted emission. This term refers to the radio frequency noise present in the physical wiring or traces of an electronic device.

As in the radiated emission limits, conducted emission limits are determined on a probabilistic basis to keep the suppression of disturbances within economically reasonable limits while still achieving an adequate level of radio protection and electromagnetic compatibility. The conducted disturbances in a particular conductor, emitted by one item of equipment, can couple directly into another item of equipment that is connected to the same conductor. Conducted disturbances can also be radiated from the conductors they travel along, as both electric and magnetic waves, and in this sense the conductor is acting as an 'accidental transmitting antenna'. Conducted disturbance can couple in either common mode or differential mode.

Test Method
Conducted emissions test on a main cable typically involves the use of an AMN (Artificial Mains Network) and a signal receiver. Table 3, summarises the limits associated with different configurations.

Frequency Range (MHz)	Quasi Peak Limit (dBuV)	Average Limit (dBuV)
0.15 – 0.50	66 – 56 (1)	56 – 46 (1)
0.50 – 5	56	46
5 – 30	60	50

Table 3: Conducted Emissions – Class B in accordance with EN 55011
(1): decreases with the logarithm of the frequency

Harmonics Distortion
IEC 60601-1-2 states that harmonics measurements are not applicable, in the case of equipment to be used in a professional healthcare environment unless the medical device is to be connected to a Public Mains Network.

Specifically, the requirements of IEC 61000-3-2 is applicable for medical device to be used either in a professional healthcare facility environment (if such a device is to be connected to a Public Mains Network) and mandatory for device to be used in a home healthcare environment. It is to be noted that Table 1 of IEC 60601-1-2, specifies applicable power input voltages and frequencies to be used during the test. The primary culprits of harmonics distortion are switch-mode or DC/DC power supplies, the source of noise being the rectifier circuitry. The level of distortion is directly related to the frequencies and amplitudes of the harmonics current. All harmonic current combine with the fundamental current to form the total harmonics distortion (THD). THD is expressed in as a % of the fundamental current and any THD value over 10 % is significant enough for concern.

The test report is expected to state the power input voltage and frequency used during the test.

Voltage Fluctuation and Flicker
IEC 60601-1-2 states that voltage fluctuation and flicker measurement is not applicable in the case of equipment to be used in a professional healthcare environment unless such a device is to be connected to a Public Mains Network.

Specifically, the requirements of IEC 61000-3-3 is applicable for medical devices to be used either in a professional healthcare facility environment (if such a device is to be connected to a Public Mains Network) and mandatory for devices to be used in a home healthcare environment.

IMMUNITY TEST

Immunity is the ability of a device, equipment or system to perform with degradation in the presence of an electromagnetic disturbance. The inability of a device, equipment or system to perform without degradation in the presence of electromagnetic disturbance is referred as susceptibility.

Radiated Immunity Test
IEC 60601-1-2 recognises three environments, namely professional healthcare facility, home healthcare and special environment, in which medical devices, equipment or systems may be used. IEC 60601-1-2 specifies radiated immunity test levels to suit. IEC 60601-1-2 through Tables 4 to 9 details the test levels for all applicable electromagnetic phenomena per device, equipment or system port. The manufacturer of such devices is however enabled to adjust the test levels based on previous experience. The justification in support of an amendment to the prescribed test levels is to be supported with the risk assessment. This process is particularly applicable to the "Special Environment".

It is not the intent of this guide to reproduce the content of IEC 60606-1-2 and thus the reader is referred to the standard for the full details of the applicable test levels, condition and assumptions.

Phenomenon	Basic EMC Standard or Test Method	Immunity Test Levels	
		Professional Healthcare Facility Environment	Home Healthcare Environment
Electrostatic Discharge	IEC 61000-4-2	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air	
Radiated RF EM Fields	IEC 61000-4-3	3 V/m 80 MHz–2,.7 GHz 80 % AM at 1kHz	10 V/m 80 MHz–2.7 GHz 80 % AM at 1 kHz
Proximity Fields from RF Wireless Comms Equip.	IEC 61000-4-3	Table 9 of IEC 60601-1-2 in accordance with IEC 61000-4-3	
Rated Power Frequency Magnetic Fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	

Table 4: Enclosure Port

Applicable EMC Standard for Implantable Medical Devices

The standards addressing the electromagnetic immunity of active implantable devices are to comply with the specific requirements of EN 45502-1[52], and its particular device-specific norms: EN 2745502-2-1 (for pacemakers)[53], EN 45502-2-2 (for defibrillators)[54], EN 45502-2-3 (for cochlear implants)[55].

The scope of the EN 45502 family of standards is to standardise the testing procedures to be used by manufacturers and notified bodies to assess the compliance to the applicable essential requirements. The essential requirements on EM immunity of implantable devices guarantees a high level of safety in several conditions, although, in a number of specific exposure conditions, interferences due to external EMF may occur. For example, appropriate mitigation and protective measures may be required in working environment.

Compliance is achieved if the device at all times functions in its set mode irrespective of the application of the EM signal. For frequency up to 1 kHz, however, compliance is achieved even if there are sensitivity settings causing malfunctioning, providing that an appropriate warning is given in the accompanying documentation. Immunity to radiated field requires compulsory testing up to 40 mW, and voluntary testing up to 8 W. The specified test requirement of a 40 mW emitted power ensures compatibility of implanted cardiac devices with handheld wireless and personal communication services phones when the transmitter is maintained a minimum of 15 cm from the implanted device, and it is consistent with the device labelling and patient guidance adopted by the manufacturer.

The voluntary testing level of 8 W is intended to ensure compatibility of implanted cardiac devices with handheld wireless phones that are operated without restrictions near the implantable device. The test for the radiated fields can be skipped if the PM is equipped with a feed-through filter with an attenuation of at least 30 dB. The rationale behind this clause is that for PM it is known that this solution is effective for radiated EMI in this band.

Protection from exposure to weak and strong static magnetic fields and to varying magnetic fields which patients may encounter in the general public environment is equally covered. A major difference between the electromagnetic and the magnetic tests concerns the mechanism of coupling with the device: the major influence of EMF is through induced voltages and currents in the leads; magnetic fields could cause malfunctions due to direct effects on the internal circuitry of the device.

Appendix A (Informative)

Test Data Summary of a Medical Device
This appendix summarises the test data of medical device, a Hemodynamic Monitor that was obtained in an EMC Test Laboratory of an AFSEC Member State. The test data is provided as is. The Hemodynamic monitoring devices currently exist to guide therapies designed to support the systems during times of circulatory instability. Monitoring hemodynamic events provides information with regards to the adequacy of a patients's circulation, perfusion and oxygenation of tissues and organs. The objective of hemodynamic monitoring is to ensure optimal tissue perfusion and oxygen delivery while maintaining adequate mean arterial blood pressure.

Hemodynamic monitoring can be accomplished using non-invasive and invasive methods. Non-invasive hemodynamic monitoring provides physiologic information without the risks associated with invasive monitoring (e.g. thrombosis, infections, air embolisms and trauma etc). The Equipment under Test (EUT), a hemodynamic monitor is a non-invasive type.

Test Standards
The EUT was tested to the following standards:

IEC 60601 Part 1-2	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
IEC 60601 Part 1	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
CISPR 11	Industrial, scientific and medical equipment – Radio- frequency disturbance characteristics – Limits and methods of measurement
EN 55011	
IEC 61000 Part 3-2	Electromagnetic compatibility (EMC) Part 3-2 Limits- Limits for Harmonic current EMISSIONS equipment input current ≤ 16 A per phase)
IEC 61000 Part 3-3	Electromagnetic compatibility (EMC) Part 3-3: Limits – Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16A per phase and not subject to conditional Connection
IEC 61000 Part 4-2	Electromagnetic Compatibility (EMC) – Part 4-2: Testing and Measurement Techniques – Electrostatic Discharge Immunity Test.
IEC 61000 Part 4-3	Electromagnetic Compatibility (EMC) – Part 4-3: Testing and Measurement Techniques – Radiated, Radio Frequency, Electromagnetic Field Immunity Test.
IEC 61000 Part 4-4	Electromagnetic Compatibility (EMC) – Part 4-4: Testing and Measurement Techniques – Electrical Fast Transient/Burst Immunity Test.
IEC 61000 Part 4-5	Electromagnetic Compatibility (EMC) – Part 4-5: Testing and Measurement Techniques – Surge Immunity Test.
IEC 61000 Part 4-6	Electromagnetic compatibility (EMC) – Part 4-6: Testing and measurement techniques – Immunity to conducted disturbances, induced by radio-frequency fields
IEC 61000 Part 4-8	Electromagnetic compatibility (EMC) – Part 4-8: Testing and measurement techniques – Power Frequency magnetic field immunity test
IEC 61000 Part 4-11	Testing and measurement techniques – Voltage dips, short interruption and voltage variations immunity tests

Table 5: EUT Demonstration of Compliance Standard List

Radiated Emissions Test Result

The EUT was set up as shown in Fig. 25 below and tested in accordance with the requirements shown in Table 2.

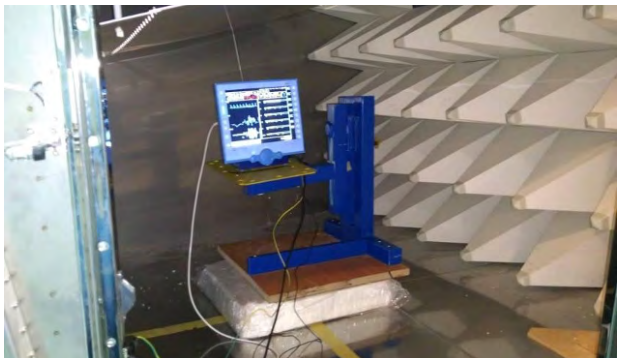


Fig. 25: Radiated Emission Test Set Up

Radiated Immunity Test Result

The EUT test setup is similar to that of Fig. 25 other than that rather than measure the non-intentional electromagnetic fields emanating from the EUT, the EUT is irradiated with a RF plane wave having the characteristic specified in IEC 61000-4-3 (refer to Table 4, pg 30 of this guide). For actual description of the test method, refer to the body of the guide.

Phenomenon	Basic Standard	Immunity Test Level
Radiated RF EM Field	IEC 61000-4-3	3 V/m, Performance Criteria B
During the test, the EUT worked as intended, temporary loss of function was observed, however the EUT self recovered. Low Signal Quality Index was observed during the test between the frequency range of 115 MHz – 2.7 GHz.		

Table 6: Radiated Immunity Test Result

Conducted Emission Test Result

The EUT was set up as shown in Fig. 27 and tested in accordance with the requirements shown in Table 3. Harmonics current emissions test on the AC power line, Phase L and Phase N, in accordance with the requirements of IEC 61000-3-2 was performed. Fig. 28 and 29, shows the compliance results of the test. As can be observed, the measured harmonics distribution is typical with the odd harmonics dominating and decreasing amplitude with increasing harmonics frequency, however these are well below the limit specified in IEC 61000-3-2.

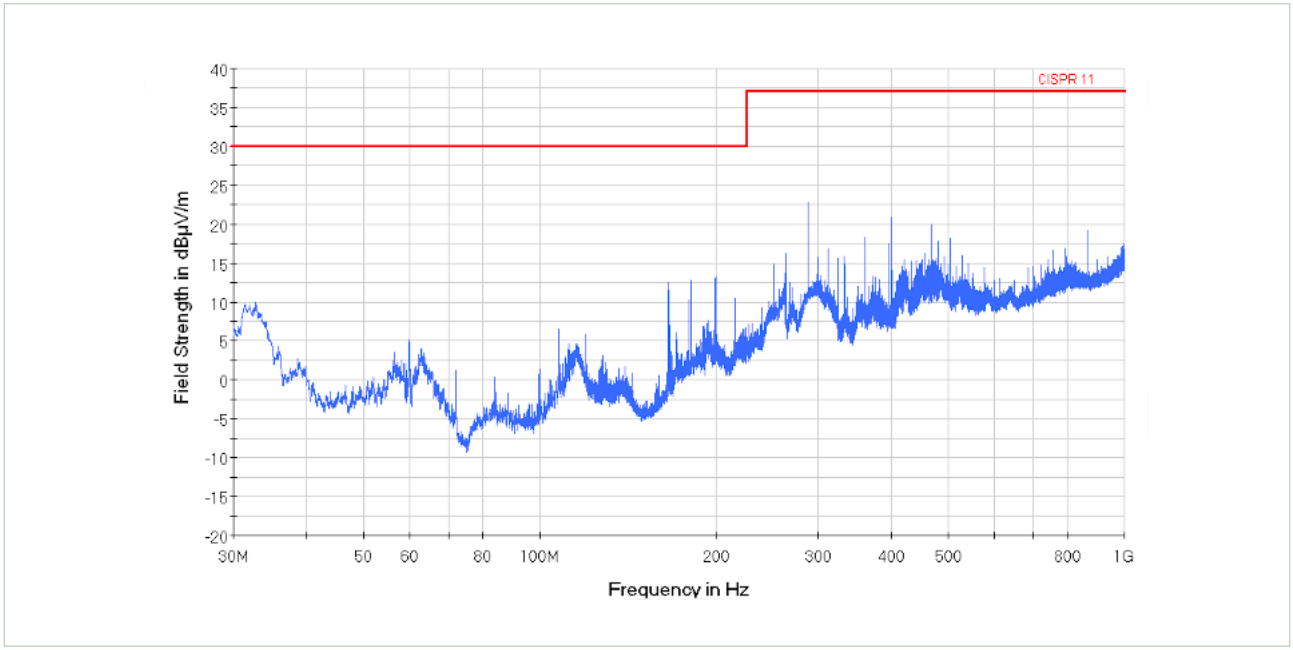


Fig. 26: Radiated Emission Test Results – Class B Compliance

Fig. 27: Harmonic Current Emission Test Setup

Voltage Fluctuation and Flicker Emissions
The EUT was setup as shown in Fig. 27 and tested in accordance with the requirements specified in IEC 60601 with reference to IEC 61000-3-3. Table 7, details the results of the compliance test.

Testconditions: EN 61000-3-3 / 240 V / 50 Hz / Phase L1 / Obs 8 x 15 min / Ztest (0.400+j0.2

FLICKER: Test PASS!

Time	Pmax	Pst	Sliding Plt	d(t)>3.30% [s]	dmax [%]	dc [%]	PASS	FAIL
11:00:33	0.000	0.0100	-.----	0.000	0.033	-.---	X	
11:15:33	0.000	0.0090	-.----	0.000	0.035	-.---	X	
11:30:33	0.000	0.0080	0.0091	0.000	0.035	-.---	X	
11:45:33	0.000	0.0080	0.0084	0.000	0.035	-.---	X	
12:00:33	0.000	0.0080	0.0080	0.000	0.036	-.---	X	
12:15:33	0.000	0.0080	0.0080	0.000	0.036	-.---	X	
12:30:33	0.000	0.0080	0.0080	0.000	0.038	-.---	X	
12:45:33	0.000	0.0080	0.0080	0.000	0.038	-.---	X	
Limits:		1.000	0.650	0.500	4.000	3.300		
Plt: 0.008435								
Evaluated: PST								

FLICKER: Source test PASS!

Time	Pmax	Pst	Sliding Plt	d(t)>3.30% [s]	dmax [%]	dc [%]	PASS	FAIL
11:00:33	0.000	0.0050	-.----	0.000	0.021	-.---	X	
11:15:33	0.000	0.0040	-.----	0.000	0.022	-.---	X	
11:30:33	0.000	0.0040	-.----	0.000	0.022	-.---	X	
11:45:33	0.000	0.0040	-.----	0.000	0.022	-.---	X	
12:00:33	0.000	0.0050	-.----	0.000	0.022	-.---	X	
12:15:33	0.000	0.0040	-.----	0.000	0.022	-.---	X	
12:30:33	0.000	0.0050	-.----	0.000	0.022	-.---	X	
12:45:33	0.000	0.0040	-.----	0.000	0.022	-.---	X	
Plt: 0.004429								
Evaluated: PST <= 0.4 dmax < 20% dmax1								

Table 7: FlickerTest Result

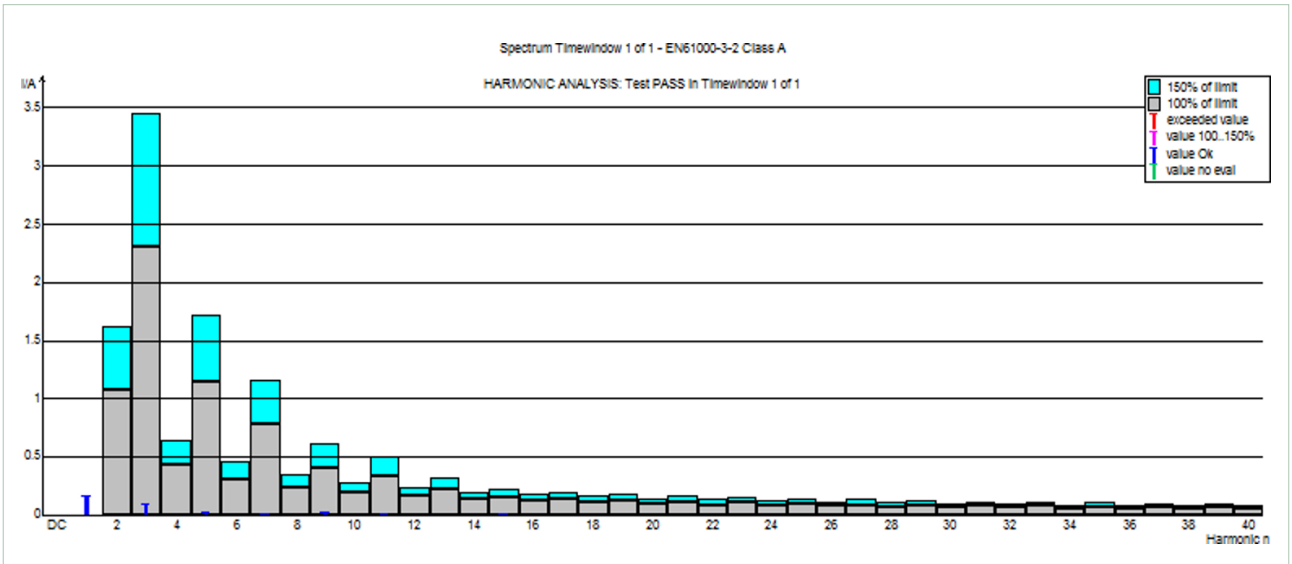


Fig. 28: Harmonic Current Emission Test Results – AC Power Phase L

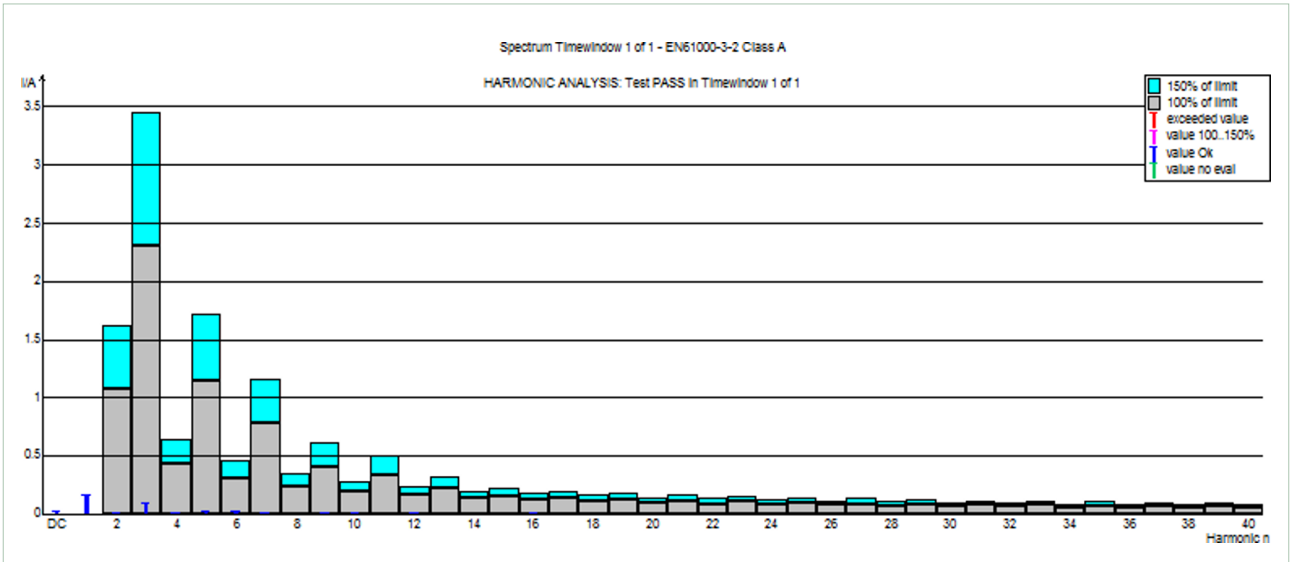


Fig. 29: Harmonic Current Emission Test Results – AC Power Phase N

Electrostatic Discharge Test Result

The EUT was setup as shown in Fig. 30 and tested in accordance with the requirements specified in IEC 60601 with reference to IEC 61000-4-2. The test result is summarised in Table 8.

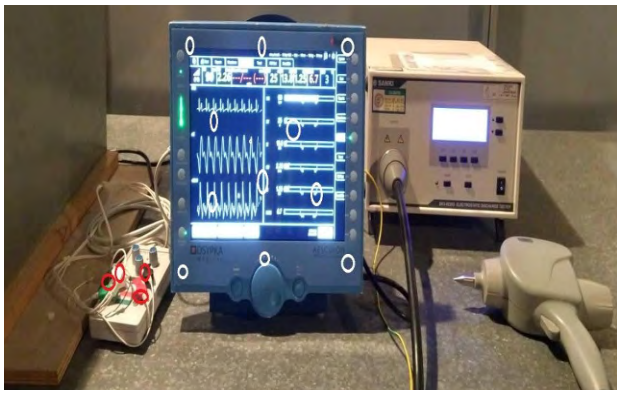


Fig. 30: Electrostatic Discharge (ESD) Test Setup

Phenomenon	Basic Standard	Immunity Test Level
Electrostatic Discharge	IEC 61000-4-2	±8kV contact discharge ±15kV air discharge
During the test, the EUT continued to perform as intended with no loss of function. The EUT passed at Performance Criteria A.		

Table 8: ESD Test Result

Electrical Fast Transient Test Result

The EUT was setup as shown in Fig. 31 and tested in accordance with the requirements specified in IEC 60601 with reference to IEC 61000-4-4. The test result is summarised in Table 9.

Fig. 31: Electrical Fast Transient (EFT) Test Setup

Phenomenon	Basic Standard	Immunity Test Level
Electrical Fast Transient	IEC 61000-4-4 Repetition frequency 100 kHz	±2kV
During the test, the EUT worked as intended, temporary loss of function was observed, however the EUT self recovered. Low Signal Quality was observed during the test.		

Table 9: EFT Test Result

Surge Immunity

The EUT was setup as shown in Fig. 32 and tested in accordance with the requirements specified in IEC 60601 with reference to IEC 61000-4-5. The test result is summarised in Table 10.

Fig. 32: Surge Immunity Test Setup

Phenomenon	Basic Standard	Immunity Test Level
Surge	IEC 61000-4-5	±1 kV (Line to Line) 5 positive and 5 negative surges applied at repetition rate of 1/min.
During the test, the EUT worked as intended, temporary loss of function was observed, however the EUT self recovered. Low Signal Quality was observed during the test. The EUT met performance criteria B.		

Table 10: Surge Immunity Test Result

Conducted Immunity

The EUT was setup as shown in Fig. 33 and tested in accordance with the requirements specified in IEC 61000-4-6. The test result is summarised in Table 11.

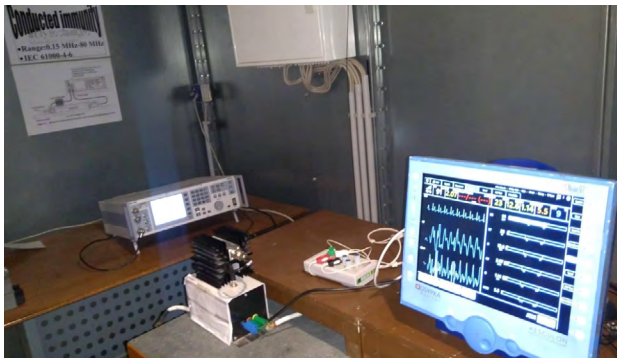


Fig. 33: Conducted Immunity Test Setup

Phenomenon	Basic Standard	Immunity Test Level
Conducted RF Disturbance	IEC 61000-4-6	0.15–80 MHz 3 V rms, 80 % AM, 1 kHz sine wave, 1 % step size
During the test, the EUT worked as intended, temporary loss of function was observed, however the EUT self recovered. Low Signal Quality was observed during the test. The EUT met performance criteria B.		

Table 11: Conducted RF Disturbance Immunity Test Result

Power Frequency Magnetic Field Immunity
The EUT was setup as shown in Fig. 34 and tested in accordance with the requirements specified in IEC 61000-4-8. The test result is summarised in Table 12.

Fig. 34: Power Frequency Magnetic Field Setup

Phenomenon	Basic Standard	Immunity Test Level
Power Frequency Magnetic Field	IEC 61000-4-8	30 A/m, 50Hz Continuous Field Class 4, X, Y and Z axis
During the test, the EUT worked as intended.		

Table 12: Power Frequency Magnetic Field ImmunityTest Result

Voltage dips / Short Interruptions
The EUT was setup as shown in Fig. 35 and tested in accordance with the requirements specified in IEC 61000-4-11. The test result is summarised in Table 13.

Fig. 35: Voltage dips and short interruptions Setup

Test conditions: EN 61000-4-11 voltage dips, short interruptions and variations test

Voltage / frequency:	240.0 V / 50.0 Hz
Test phase:	Single phase / L1-N
Executed test:	medical
Test description:	--
Disturbances per step:	3 (per phase angle) / 10.5 sec delay between

Step	Disturbance	TestLevel	Duration	Phase angle(s) (Ref.Ph.1)
1	Voltage dip / short interruption	0 %	0.5 periods	0°
2	Voltage dip / short interruption	0 %	0.5 periods	45°
3	Voltage dip / short interruption	0 %	0.5 periods	90°
4	Voltage dip / short interruption	0 %	0.5 periods	135°
5	Voltage dip / short interruption	0 %	0.5 periods	180°
6	Voltage dip / short interruption	0 %	0.5 periods	225°
7	Voltage dip / short interruption	0 %	0.5 periods	270°
8	Voltage dip / short interruption	0 %	0.5 periods	315°
9	Voltage dip / short interruption	0 %	1 period	0°
10	Voltage dip / short interruption	70 %	25 periods	0°
11	Voltage dip / short interruption	0 %	250 periods	0°

Table 13: Voltage dip and interruptionTest Result

RF Wireless Field Exposure to the Enclosure Port
A risk assessment was performed in accordance with the requirements of IEC 60601, in which the risk of exposure to RF fields generated to intentional transmitters was identified. The EUT was therefore assessed for its robustness against such fields. The EUT was set up as shown in Fig. 25. Table 14 shows the result of this test.

Phenomenon	Basic Standard	Immunity Test Level
Radiated RF EM Immunity	IEC 61000-4-3	28 V/m 385–2450 MHz PM 100 %, 50 % duty cycle
During the test, the EUT worked as intended, temporary loss of function was observed, however the EUT self recovered. Low Signal Quality was observed during the test. The EUT met performance criteria B. The immunity threshold at 745 MHz, PM 217 Hz was 9 V/m. At all the frequencies the immunity threshold was 28 V/m.		

Table 14: Radiated Emission Test result

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