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Experimental evaluation of electromagnetic compatibility of cardiac active implantable medical devices in the work environment of beauty and physiotherapy centers

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Abstract

Occupational health and safety framework identifies workers with active implantable medical devices (AIMD) as a particularly sensitive risk group that must be protected against the dangers caused by the interference of electromagnetic fields (EMF). Among the work environments in which EMF levels potentially exceed the Guidelines limits there are the beauty and physiotherapy centers. The aim of this paper is to investigate the potential risk for cardiac AIMD holders when exposed to four EMF sources that can be encountered in the work environment of aesthetic and/or physiotherapy centers.

1. Introduction

Pacemakers (PM) and implantable cardioverter/defibrillator (ICD) are active implantable medical devices (AIMD) needed in case of cardiac arrhythmias [1]. Over one million PM and over 200.000 ICD are implanted every year worldwide, and these numbers are expected to grow given the aging population and increasing clinical indications for pacing. Given their intrinsic structure and way of functioning, AIMDs are susceptible to electromagnetic fields (EMF). AIMD international technical product standards require AIMDs to be immune to certain EMF levels [2]. The immunity levels adopted in these standards are determined to protect implantable and patient-carried parts of an AIMD from the foreseeable electromagnetic environment based on the requirements for General Public of the ICNIRP (International Commission on Non-Ionizing Radiation Protection) Guidelines 1998 [3].

In cases of the work environment where the ICNIRP reference levels for the General Public can be exceeded, the safety for a worker who wears an AIMD is not guaranteed anymore. In addition, the AIMD technical standards take into account only the EMF sources that can be encountered in common-life scenarios (e.g., GSM/LTE cellular phones, WiFi transmitters), while the EMF sources in a work environment can be very specific in terms of modulation, pulse repetition time, etc., and can pose, as a matter of principle, a risk even at levels below the ICNIRP reference levels for the General Public. Consequently, the existing standards reasonably protect the General Public wearing AIMD, but are not sufficient to protect workers wearing AIMD. This is the reason why, in the context of occupational health and safety framework, workers with AIMD are identified as a particularly sensitive risk group that must be protected against the dangers caused by the interference of EMF.

Beauty and physiotherapy centers are among the work environments in which EMF levels potentially exceed the Guidelines limits. In these environments the devices used can emit EMF for the purposes of the treatments, but they can also disperse EMF into the environment whose value is not always under control. In Europe, a series of technical standards have been developed to support and guide the employer in the risk assessment of workers who wear AIMD [4-6]. The standards list a number of known sources (white list) whose effect on AMDs can be easily managed and propose risk assessment procedures for the other EMF sources. These procedures are not always straightforward involving several expertise such as occupational health and safety experts, occupational physician, AIMD-employee's responsible physician, manufacturer of the AIMD. Also it can require in-vitro measurement, calculation and the involvement of the AIMD employee in vivo-test.

The aim of this paper is to present four cases of risk assessment for four different EMF sources that can be encountered in the environment of beauty and/or physiotherapy centers (Velvet Skin, MyTone, Tecar Pharon, Magnetomed 8200).

2. Cardiac active implantable medical device

PM and ICD are small, battery-operated devices that help the heart beats in a regular rhythm. These devices are equipped with a battery and an electronic component that "senses" the heart and generates electrical impulses when needed. They are composed by a generator with a battery

and by a lead positioned inside the heart, which allows the AIMD to sense the electrical activity of the heart and to transmit electrical impulses to the heart. A PM sends electrical impulses to the heart when needed to aid in the proper pumping of blood in case of bradycardia. ICD is typically used to detect tachycardia and deliver a strong electrical shock to restore the heartbeat to normal. However, many ICD can also function as PM, delivering a weaker electrical pulses to correct bradycardia as well. The interaction between EMF and cardiac AIMD is an ongoing concern of patients, industry and regulators, given the potentially life-sustaining nature of these devices. The risks associated with such interactions include inhibiting the device or delivering inappropriate therapy which, in the worst case, could result in serious injury or death of the patient. In particular, exposure of the PM/ICD implant to an electromagnetic field can induce currents from the lead into the heart causing fibrillation and/or can induce voltages in the lead that prevent the device from correctly monitoring the intrinsic heart signal. The possibility of interference depends on several factors: the frequency content of the emitter, the type of modulation, the signal strength, the proximity to the patient, the coupling factors, and the duration of exposure.

3. Regulatory framework

The current regulatory framework for PM and ICD provides reasonable safety to electromagnetic fields up to the ICNIRP General Public Reference Levels [9-16]. The AIMD product standards take into account EMF up to 3GHz from handheld transmitters. Frequencies greater than 3 GHz are currently not considered in the product standards because of several aspects: the number and type of radiators at frequencies above 3 GHz; the increased device protection afforded by the attenuation of the enclosure and body tissue at microwave frequencies; the expected performance of EMI control features that typically are implemented to meet the lower-frequency requirements of this document; the reduced sensitivity of circuits at microwave frequencies. The product standards define the immunity levels of AIMD in terms of values of voltage (V) or current (A) directly injected into the device and of injected power (W) into a dipole antenna placed at 2.5 cm from the device. As far as EMF sources are concerned, in most Countries they must comply with the limits set by ICNIRP in 1998, while other countries enforce national laws that set even more stringent limits. The limits are expressed in terms of spatially and temporally averaged exposure expressed as the magnitude of electric field in units in V/m. These limits, however, do not take into account the possible effects of EMF on AIMD. First, since the value of electric field is averaged in time, power peaks of a few seconds are not excluded, which could lead to interference with the electronic circuitry of the implantable device. Second, it is not straightforward to correlate the electric field value (V/m) measured at a given point with the immunity value of AIMD (given in terms of voltage or current injected into the device, and injected power (W) into a dipole antenna placed at 2.5 cm from the device). Similar considerations can be made for the immunity levels of the magnetic fields, which are expressed in terms of A/m. According to European regulation, devices used in beauty and physiotherapy centers that emit EMF to treat the patient/subject must meet EMF emission requirements that follow the ICNIRP guidelines, except for EMFs used for treatment. However, devices must in any case be designed and manufactured in order to minimize the exposure of patients, users and other persons to the emission of incidental, isolated or diffuse radiation. In addition manufacturers are obliged to provide in the instructions for use detailed information regarding the nature, type, intensity and distribution of the radiation emitted. However, this information is often missing and it is therefore difficult to assess the risk of exposure.

4. Experimental protocol

The following equipment and instruments were used :

- a phantom in which the pacemaker implant was housed;
- an electrical signal recorder to monitor AIMD activity;
- 4 devices in use in beauty and physiotherapy centers as EMF field sources;
- One PM and one ICD which constitute a representative sample of current technological platform of these devices

For the measurement of the EMF:

- Microrad NHT 3DL with 02E probe (400kHz - 40MHz) and 33S probe (0Hz – 1MHz);
- Narda ELT 400 probe 100cm^2 (0Hz – 400kHz);
- Wavecontrol SMP2 with WP400 probe (0Hz – 400kHz);
- Narda EHP 200A analyzer (00kHz – 30MHz);
- PicoScope 5444D MSO 4 channel oscilloscope (0-200 MHz).

4.1 The phantom

An anthropomorphic phantom was used to mimic the human body and to host the PM (Figure 1). The phantom with the PM was then exposed to the EMF sources and the behavior of the implanted device was continuously monitored by a custom-made electrical signal recorder (logger). The phantom was filled with a saline solution at a concentration of 2.6 g/L (HI8733, Hanna Instruments™, Campanile, Italy), in order to simulate the dielectric properties of the human body at the frequency of the EMF sources. The PM was fixed inside the phantom over a graduated PVC grid (20 cm × 38 cm, Figure 1b) that allowed the leads to be arranged in loop paths with an easy-measurable area. In particular, the PM was connected to two leads, arranged to form an area of 165 cm^2 (atrial pacing/sensing lead) and 225 cm^2 (ventricular pacing/sensing lead), respectively (Figure 1b). The latter value (225 cm^2) is considered the maximum effective induction area in the EN50527-2-1 [5]. The PM were programmed at the most sensitive value (lowest voltage allowable) to mimic the worst case condition. The custom-made logger (based on the analog front end for ECG Applications ADS1291, Texas Instrument, Dallas, TX, USA) was placed in contact with the saline solution trough a couple of Ag/AgCl electrodes positioned on the chest of the phantom. The logger stored the voltage recorded between the two electrodes on a Secure Digital (SD) card.

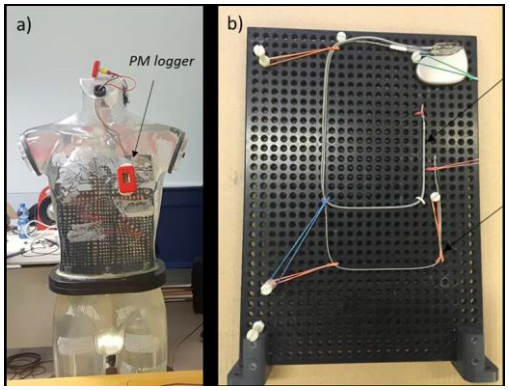

Figure 1. a) Anthropomorphic phantom and signal recorder; b) PM fixed over the PVC grid.

4.2 The EMF sources

Four sources of EMF were tested:

1. Velvet Skin (Top Quality Aesthetic.): certified as a medical device for facial skin rejuvenation and body reshaping. It uses RF signals at 500 kHz and 1 MHz. It can be use in resistive and capacity ways, with different handpieces.
2. MyTone (Biotec Aesthetic): device used for aesthetic purposes to tone the body, inducing muscle contractions by means of non-invasive applicators (1-100 Hz).
3. Tecar Pharon (Mectronic Medicale s.r.l): device used in the physiotherapy to carry out Tecar (Transfer Energy Capacitive And Resistive) therapy, fundamental frequency: 390kHz – 1MHz.
4. Magnetomed 8200 (Medical Italia): device used in the physiotherapy to carry out magneto therapy frequency range < 1kHz.

4.3 Experimental measures

The phantom was exposed to the EMF produced by the sources described in paragraph 4.2, bringing any handpieces/applicators and/or cables closer to the phantom. The characteristics of the signals emitted by the EMF sources in terms of waveform, frequency content and amplitude modulation were first analyzed using the Picoscope and Narda ELT400. Then the EMF field sources were evaluated in terms of EMF strength using Microrad NHT 3DL, Narda EHP200A and Wavecontrol SMP2. For each EMF source, the exposure conditions in terms of maximum electric and magnetic field coupling with the PM implant and of EMF source frequency modulation were identified and tested.

5. Results

Figure 2 shows the experimental conditions used for the 4 EMF sources. For the MyTone device, a 10-Ohm resistor was connected between the 2 applicators to mimic the proper load for the treatment. For the Tecar Pharon device, a conductive bowl filled with saline solution was used to mimic the human tissue under therapy. Both capacitive and resistive applicators were tested. For each EMF sources, many measurements were carried out in different use and measurement settings. Table 1 shows the highest electric field (V/m) and magnetic field (Tesla) measured, and the condition of such measurements (worst case condition).

Table 1.

EMF source	Highest Electric field (V/m)	Condition
Velvet Skin	141	Capacitive Handpiece; Probe in contact with handpiece; Device in multipolar mode
MyTone	25	Probe close to the applicator cable
Tecar Pharon	50	Capacitive; Distance between probe center cable and center 25 cm
	48	Resistive Distance between probe center cable and center 25 cm
Magnetic field (μT)		
Magnetomed	116	Probe positioned 20 cm from the side of the dummy with pacemaker
	121	Probe positioned in the neighboring room leaning against the wall adjacent to the device

Both the AIMD devices did not experience any malfunction in terms of pacing and sensing. No inhibition neither inappropriate stimulation occurred when the implants were exposed to the EMF sources tested.

6. Discussion and conclusion

Many devices used for aesthetic and physiotherapy purposes use EMF to carry out their treatments. The work environments in which these devices are used may therefore be characterized by EMF values higher than those expected for the general population and an employee wearing a AIMD could potentially be at risk. Since these devices use different frequencies, modulations and powers, an effective way to evaluate the potential damage on an AIMD is to carry out in vitro measurements. These measures are not trivial and require different skills and equipment. This paper presents the results of a measurement campaign carried out in 2023 in Italy, as part of the activities envisaged by projects financed by INAIL (Italian Workers' Compensation Authority).One of the aims of these projects is to carry out in vitro measurements on specific circumstances in worst case condition and to make the results of these assessments available in order to increase knowledge and information regarding this topic which is so alarming and difficult to study. This study demonstrates that it is possible to effectively monitor the behavior of an AIMD when subjected to EMF generated by various sources, and to measure the EMF values of these

Figure 2. Experimental conditions

sources. This monitoring and measurements require some AIMD devices and a phantom suitable for simulating interactions with the operator for the specific EMF sources of interest. The described procedure is general and it is performed in worst case conditions, but it can serve as a guide to carry out specific analyses, on a particular device with its specific system configuration and programming. No electromagnetic interference (EMI) occurred during the exposure of both implants to all the selected EMF sources. This result is not surprising since the maximum electrical and magnetic field generated by the EMF sources are below the ICNIRP reference levels for the general population and these levels are the basis for the immunity of the AIMD. No EMI occurred also for the Velvet Skin although the limit for the general population is exceeded (measured 141 V/m vs 87 V/m), but not the one for occupational environment (610 V/m).

7. Acknowledgement

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