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# Workers with Active Implantable Medical Devices Exposed to EMF: In Vitro Test for the Risk Assessment

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**Abstract:** The occupational health and safety framework identifies workers with an active implantable medical device (AIMD), such as a pacemaker (PM) or an implantable defibrillator (ICD), as a particularly sensitive risk group that must be protected against the dangers caused by the interference of electromagnetic field (EMF). In this paper, we describe the results of in vitro testing/measurements performed according to the EN50527-2-1:2016 standard, for the risk assessment of employees with a PM exposed to three EMF sources: (1) An electrosurgical unit (ESU); (2) a transcranial stimulator (TMS); and (3) an arc welder. The ESU did not affect the PM behavior in any of the configurations tested. For the TMS and the arc welder, interference phenomena were observed in limited experimental configurations, corresponding to the maximum magnetic field coupling between the EMF source and the implant. The in vitro measurements presented can be considered an example of how the specific risk assessment for a worker with a PM can be performed, according to one of the methodologies proposed in the EN50527-2-1:2016, and can be used as scientific evidence and literature data for future risk assessments on the same EMF sources.

**Keywords:** occupational safety; electromagnetic field; pacemaker

## 1. Introduction

### 1.1. The Regulatory Framework for Workers with AIMD

Workers who wear active implanted medical devices (AIMD), such as a cardiac pacemaker (PM) or an implantable cardioverter/defibrillator (ICD), have always been considered at particular risk if exposed to electromagnetic fields (EMF). The EU Directive 2013/35/EU on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) [1], stresses that “a system ensuring a high level of protection as regards the adverse health effects and safety risks that may result from exposure to EMF should take due account of specific groups of workers at particular risk and avoid interference problems with, or effects on the functioning of, medical devices such as PM and ICD”.

Practical indications for the risk assessment of workers with AIMD can be found in the non-binding guide to good practice for implementing Directive 2013/35/EU [2], which substantially adopts the same approach described in the EN50527 technical standards family [3–5]. The risk assessment starts from the knowledge of the electromagnetic immunity requirements that AIMD shall comply with

before entering the market. In particular, the new European Medical Device Regulation (MDR) [6] recognizes the electromagnetic immunity is an essential requirement for both non-implantable and implantable medical devices. Conformity to the requirements of the MDR can be demonstrated by applying the harmonized standards specific for each particular medical device [7]. The harmonized standards are not mandatory, but contain technical information on the test and the procedures that manufacturers can follow to obtain the presumption of conformity to the requirements of the MDR. The general standard that applies to the AIMD is the EN 45502-1 [8], together with all of the particular standards, specific for the different types of devices (EN 45502-2-1 [9] for the PM, EN45502-2-2 for ICD [10], etc.). The immunity levels adopted in these standards are determined to protect implantable and patient-carried parts of an AIMD from the foreseeable electromagnetic environment derived from the European Recommendation 1999/519/EC [11], which was based on the recommendations for General Public of the ICNIRP (International Commission on Non-Ionizing Radiation Protection) Guidelines 1998 [12]. Thus, if a worker who wears an AIMD is exposed to EMF levels below the ICNIRP reference levels for the General Public, the risks could be considered acceptable. However, in cases in the work environment where the ICNIRP reference levels for the General Public are exceeded, the safety for a worker who wears an AIMD is not guaranteed anymore. In addition, the 45,502 family standards take into account only the EMF sources that can be encountered in common-life scenarios (e.g., GSM/LTE cellular phones, WiFi transmitters). On the other hand, 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.

For these reasons, the EU has developed a series of technical standards to support the employer in the risk assessment of workers who wear AIMD: The general standard EN50527-1 with the particular standard EN50527-2-X for the different AIMD classes (e.g., EN50527-2-1 [4] for PM, EN50527-2-2 [5] for ICD).

### *1.2. General Procedure for the Risk Assessment Required for an AIMD Employee*

The EN50527-1 [3] and the non-binding guide to good practice for implementing Directive 2013/35/EU [2] provide a general procedure for the specific assessment required for workers with an AIMD: An initial simplified analysis is required, followed, when necessary, by a deeper specific risk assessment for the PM-employee. The initial simplified analysis starts from the identification of all the EMF sources active in the workplace and their comparison with a list of equipment reported in Table 1 (“whitelist”) of the EN50527-1 [3] (Table A.1 of the EN50527-2-1 [4]). A representative image of the “whitelist” is reported in Table 1 (the specific lines for medical workplaces and workplaces open to general public are reported). If all of the EMF sources are listed in the table, if they are used in accordance with the indication reported in the “exceptions and remarks” column, and if the AIMD employee has not received specific warnings from the responsible physician that the AIMD may be susceptible to electromagnetic interference (EMI) from one of the present equipments, further risk assessment is not necessary. Otherwise, a specific risk assessment shall be carried out, in accordance with the specifications provided in Annex A of the standard. The risk assessment should involve input from: (1) The employer and, if applicable, his occupational health and safety expert and/or occupational physician; (2) the AIMD employee and his responsible physician; and (3) experts (technical and medical), e.g., manufacturer of the AIMD. Then, two alternative methods to perform the risk assessment are proposed: The “non-clinical approach” and the “clinical approach”. The former bases the risk assessment on measurement, calculation, and/or information provided by the manufacturer of the AIMD, and does not involve directly the worker. The latter needs the AIMD employee to be exposed under clinical supervision for a significant duration in the workplace to the foreseeable exposure situations or in a laboratory simulating the workplace exposure situation. The behavior of the AIMD must then be checked by, e.g., telemetry during and after the exposure. The particular

standard EN50527-2-1 [4] follows the same approach of the general standard, providing the procedure for the specific assessment required for workers with implanted PM.

**Table 1.** Example from Table A.1—compliant workplaces and equipment with exceptions (“whitelist”) of the EN50527-2-1.

Designation of Workplace	Examples of Equipment	Exceptions and Remarks
Medical workplaces	All medical equipment not using RF sources	If medical workplaces include static or time varying magnetic or electric fields, then operational precautions may be necessary. For equipment used at medical workplaces listed elsewhere in this table look at the appropriate sub(clause).
Workplaces open to the general public (as covered by Article 4.3 of EMF Directive 2004/40/EC)	Places open to the public and in compliance with the exposure limits given in Council Recommendation 1999/519/EC are deemed to comply without further assessment provided that the compliance was assessed against the reference levels.	It is possible, under certain circumstances, to exceed the reference levels and still comply with the basic restrictions of Council Recommendation 1999/519/EC. Such circumstances are usually in localised areas, close to EMF emitting equipment, so transient exposure in those areas may be permitted. In case of doubt, further guidance may be obtained from device or emitter manufacturers, medical advisors or by the use of the appropriate device specific standard. An example for such equipment could be audio frequency induction-loop systems (AFILS following EN 60118-4) for assisted hearing where the system has been assessed against the reference levels.

In this paper, a practical example is presented, and the results of the joint project funded by INAIL (National Institute for Insurance against Accidents at Work—Ricerca BRIC ID 30/2016) are reported. The risk assessment for workers with PM was performed in an on-field experience on three EMF sources in the work environment: (1) An electrosurgical unit (ESU); (2) a transcranial stimulator (TMS); and (3) an arc welder. The three EMF sources evaluated in this work are not included in the whitelist of the EN50527-2-1 [4] and are widespread used in clinical (ESU and TMS) and industrial (arc welder) work environments. A specific risk assessment is thus needed for them. The non-clinical approach was adopted and, in particular, in vitro testing/measurements were performed for all the three sources. The aim of this paper was to describe a general approach that can help the employer in the risk assessment of workers with AIMD, following the in vitro testing/measurement approach suggested in the international standards.

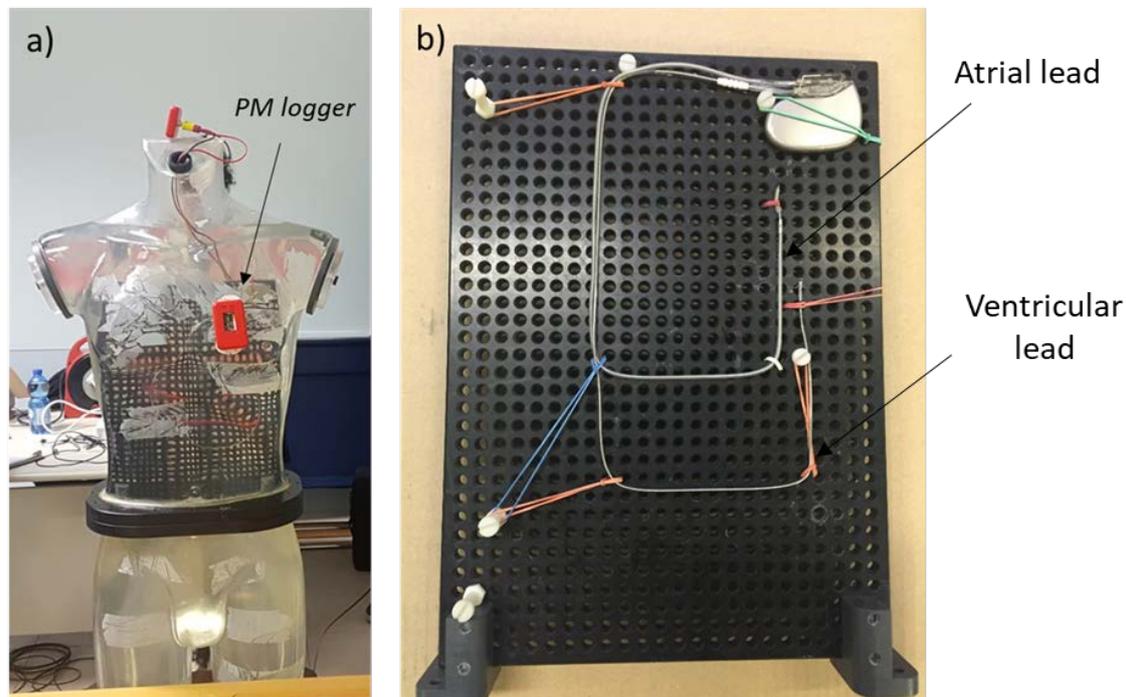
## 2. Materials and Methods

The methodology used in the construction of the model was directly derived from the indications of the EN50527-2-1 [4] for in vitro testing/measurements. A homogenous phantom was used to mimic the human body and to host the PM. The phantom with the PM was then exposed to the EMF source of interest and the behavior of the implanted device was continuously monitored by a custom-made electrical signal recorder. For each of the three EMF sources that were evaluated, the exposure conditions resulting in the maximum electric and magnetic field coupling with the PM implant were identified and tested.

### 2.1. The Human Torso-Shaped Phantom

The aim of in vitro testing was to mimic as close as possible the real in vivo situation: The possibility of interaction between a PM and the EMF sources under test was evaluated by placing the

PM and its leads inside a human torso-shaped phantom, mimicking a patient bearing it (Figure 1a). The phantom was designed and built at the Department of Cardiovascular, Endocrine-metabolic Diseases and Aging of the Italian National Institute of Health.



**Figure 1.** (a) The human torso-shaped phantom used for the in vitro testing/measurements. The custom-made logger used to monitor the pacemaker (PM) activity is shown by the arrow; (b) PM implant configuration.

It consisted of a transparent PVC (polyvinyl chloride) phantom that reproduced the trunk and the thighs of a 75 kg male, with an internal volume of about 50 L. In order to allow the movement of the phantom near the EMF source, the bottom of the phantom was fixed over a plastic stand provided with wheels. All of the metallic components were removed to prevent any unwanted modification of the exposure conditions. In order to simulate the dielectric properties of the human body, which vary as a function of the frequency of the EMF of interest, the tissue-weighted mean electrical conductivity was calculated from the database of the Italian National Research Council [13]: 0.3 S/m for the frequencies used by the arc welder and the TMS (~100 Hz and ~10 Hz, respectively), and 0.4 S/m for the ESU (~500 kHz). The torso simulator was then filled with a saline solution at a concentration of 1.9 g/L during the tests on the arc welder and the transcranial stimulator, and of 2.6 g/L during the tests on the electrosurgical unit. Before starting the tests, the conductivity of the saline solution was checked using a conductivity meter (HI8733, Hanna Instruments™, Campanile, Italy) and, if necessary, little adjustments of the Sodium Chloride (NaCl) concentration were made to match the desired values of conductivity.

The PM was fixed inside the phantom over a graduated PVC grid (20 cm × 38 cm) 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<sup>2</sup> (atrial pacing/sensing lead) and 225 cm<sup>2</sup> (ventricular pacing/sensing lead), respectively (Figure 1b). The latter value (225 cm<sup>2</sup>) is considered the maximum effective induction area in the EN50527-2-1 [4].

The PM was programmed at a sensitivity of 2.5 mV (default value for the PM under test) in unipolar sensing, that is, the sensing configuration most sensitive to electromagnetic disturbances [4].

## 2.2. The PM Activity Logger

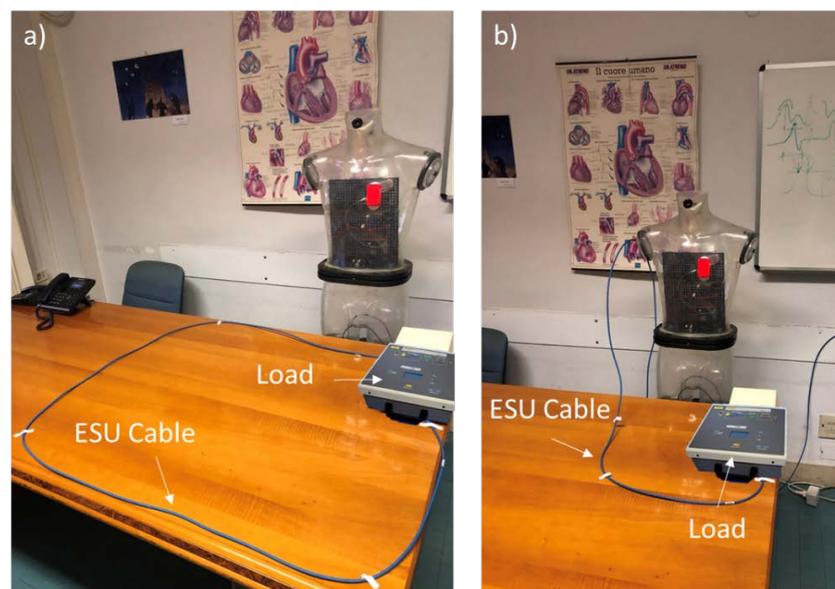
The activity of the PM during the test was monitored using a custom-made logger placed in contact with the saline solution through a couple of Ag/AgCl electrodes positioned on the chest of the phantom. The logger stored the voltage recorded between the two electrodes on a Secure Digital (SD) card. At the end of each measurement session, the data on the SD card were displayed and analyzed from a PC. The logger (based on the analog front end for ECG Applications ADS1291, Texas Instrument, Dallas, TX, USA, USA—supply = 3 V; gain = 12) had a resolution of 24 nV on a range of  $\pm 300$  mV and a sampling frequency of 500 S/s. Preliminary tests were performed to verify that the correct functioning of the logger was not affected by the EMF sources under test.

## 2.3. The Electrosurgical Unit

An ESU uses a high-frequency (100 kHz–1 MHz) electrical current to cut tissue and control bleeding by causing coagulation. Tests were performed on an ESU provided by the Policlinico “Le Scotte” (Siena, Italy) and both the cut and the coagulation modalities were investigated. For each modality, the potential effect on the PM was evaluated:

1. Leaving the ESU electrode open, not connected to any load (worst-case condition in terms of electric field);
2. Using a load of 50 Ohm at 250 W to maximize the current delivered (worst-case condition in terms of magnetic field);
3. Using a load of 400 Ohm at 400 W to simulate a more realistic scenario.

Two arrangements of the ESU cables were also tested: In the first configuration, the cable was placed as a loop on the surgical field, so to maximize the resulting magnetic field (Figure 2a); in the second one, the cable was placed parallel to the trunk of the phantom (parallel to the main segment of the PM leads—Figure 2b), in order to maximize the electrical coupling with the PM leads.



**Figure 2.** The experimental set-up adopted for testing the electrosurgical unit: (a) the electrosurgical unit (ESU) cable is arranged to maximize the resulting magnetic field; (b) the ESU cable is arranged to maximize the resulting electric field.

## 2.4. The Transcranial Stimulator

TMS are electric pulse generators connected to a magnetic coil that generate a changing electric current within the coil able to induce a high-intensity magnetic field (up to 3 T). Some TMS systems use

a positioning arm to fix the coil in the desired position, over the body region that has to be stimulated. If the positioning arm is not available, the transmitting coil can be placed next to the patient's head by using non-conductive headgear or elastic straps, which, however, can be rather uncomfortable to patients [14]. Thus, in many situations, the coil is hand-held by the health-care personnel, who stand behind the patient and place the coil near specific regions of the head. The coil can be very close to the operator's chest in such scenarios. The hospital provides two models of transcranial stimulators: The STM900 (ATES Medical Device, Colognola, Italy) and the Magstim®Bstim<sup>2</sup> (Magstim Company, Whiteland, UK). As shown in Figure 3a, beside the human torso-shaped phantom used to mimic the worker with the PM, also the head of the patient had to be simulated. A tank filled with a saline solution at the same concentration (2 g/L) used for the human torso-shaped phantom was adopted.



**Figure 3.** The experimental set-up adopted for testing the transcranial stimulators (TMS): (a) The STM900 (ATES Medical Device, Colognola, Italy) and (b) the Magstim®Bstim<sup>2</sup> (Magstim Company, Whiteland, UK). In both tests, beside the human torso-shaped phantom that simulates the health-care personnel holding the TMS coil, a tank filled with a saline solution at the same concentration (2 g/L) was adopted to simulate the patient's head.

The effect on the PM was evaluated in two configurations, which reproduced the typical placement of the coil for:

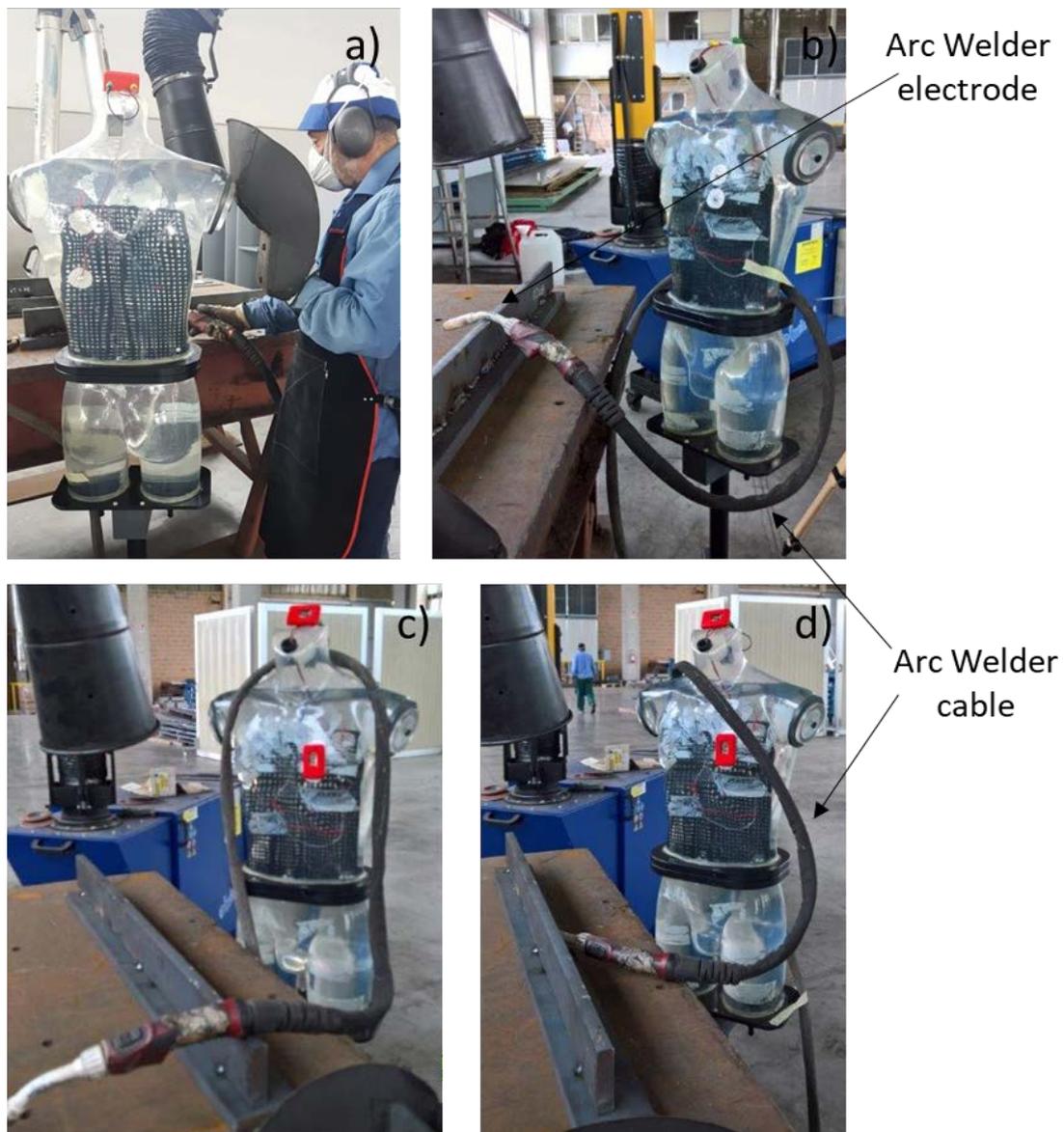
1. The stimulation of the parietal area, with the coil perpendicular to the trunk of the human torso-shaped phantom;
2. The stimulation of the occipital area, with the coil parallel to the trunk of the human torso-shaped phantom.

Both the stimulators were first set to deliver a single burst train with a duration ranging from 1 to 10 ms (minimum and maximum values allowed by the systems). Then, the effect of repeated burst trains was evaluated: Following the rationale of the international standard EN45502-2-1 [9], which defines the test conditions that shall be used to verify the electromagnetic immunity of PM, a repetition frequency of 2 Hz was adopted. Both monophasic and biphasic pulses were tested.

### 2.5. The Arc Welder

The measurements were conducted at the Toscana Lamiere Industries (Florence, Italy) where a fully-functioning arc welding system was made available for the test, and the support of a skilled worker was also granted. Realistic welding scenarios were tested and various arrangements of the welding system cable were reproduced, in order to find the configurations associated with the highest value of electric and magnetic field. Figure 4 shows the four configurations that were considered:

1. The cable raised from the floor next to the human torso-shaped phantom till reaching the worktable;
2. The cable was fixed around the belt of the phantom;
3. The cable was placed over both shoulders of the phantom;
4. The cable was placed over one shoulder of the phantom.



**Figure 4.** The four configurations adopted for testing the arc welder: (a) The cable raised from the floor next to the human torso-shaped phantom till reaching the work table; (b) the cable was fixed around the belt of the phantom; (c) the cable was placed over both shoulders of the phantom; (d) the cable was placed over one shoulder of the phantom. The support of a skilled worker (reported only in (a)) was granted during each configuration tested to operate the arc welder.

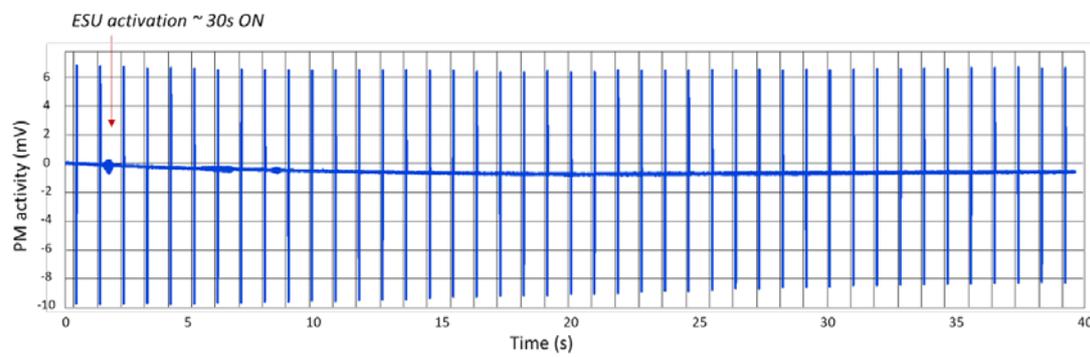
The first configuration represents the typical situation that should always be adopted according to the good-practice procedures for welding. The other configurations are worst-case scenarios and, even if should be avoided, are sometimes adopted also in real practice.

For each configuration, two welding modalities were reproduced: A continuous welding, with the arc always active for 5–10 s, and a pulsed welding, with the arc activated for a short period (<1 s) and repeated approximately twice per seconds (~2 Hz).

### 3. Results

#### 3.1. The Electrosurgical Unit

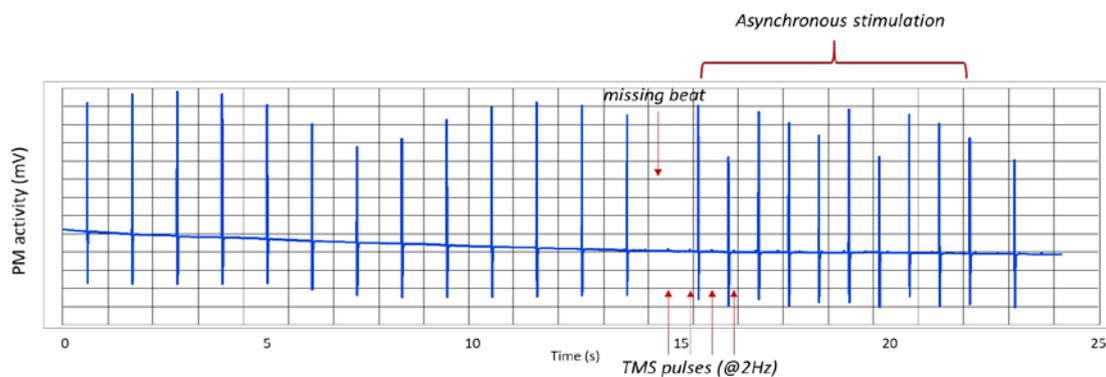
The in vitro testing/measurements conducted on the electrosurgical unit did not reveal any effect on PM activity, in any of the configurations tested. The electrical signals recorded during the test did not shown any evidence of the activation of the electrosurgical unit (an example is reported in Figure 5).



**Figure 5.** Example of PM activity recorded during the activation of the ESU (ON for about 30 s). No changes of the pacing rate or in the programmed parameters were observed.

#### 3.2. The Transcranial Stimulator

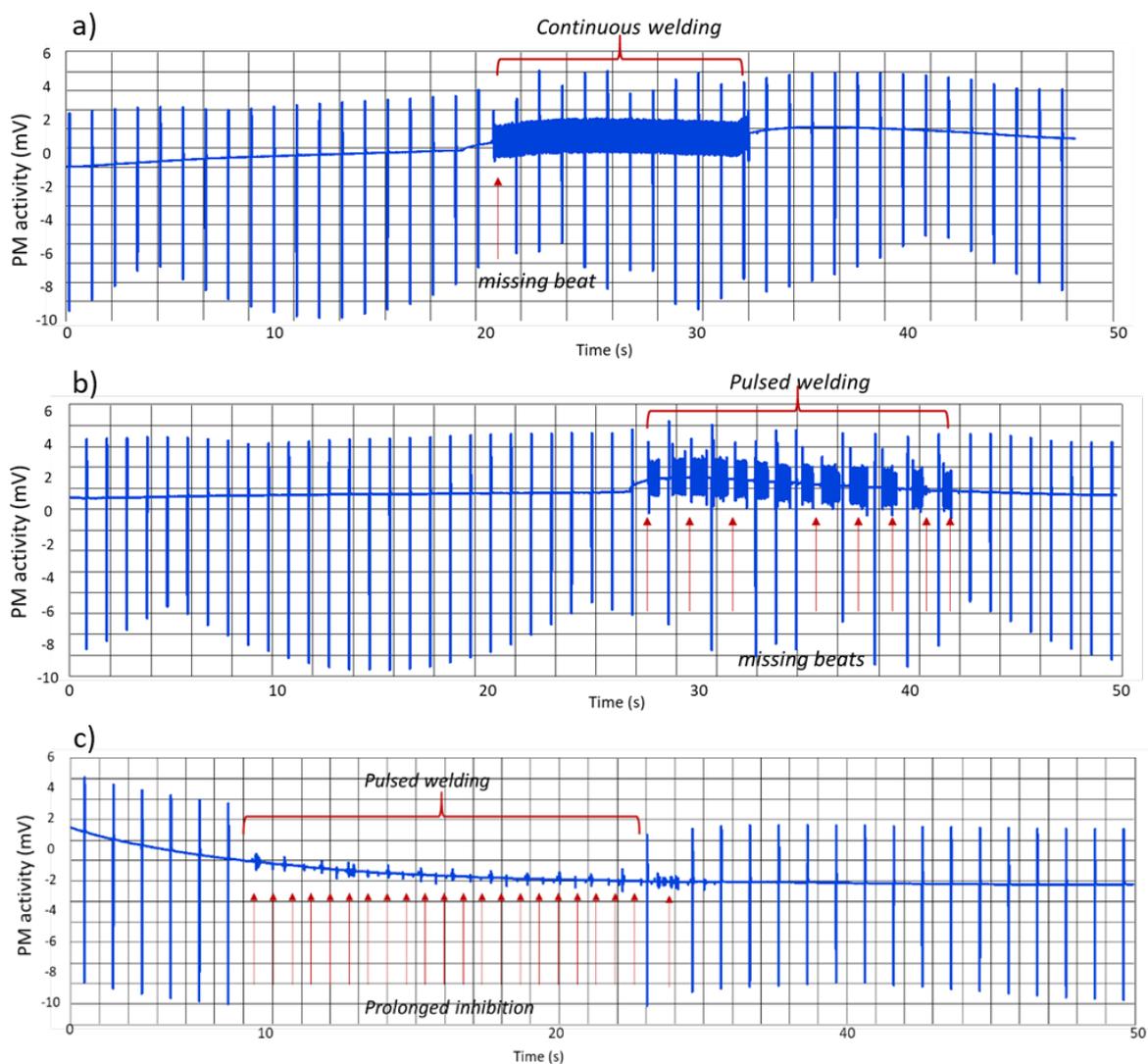
The TMS activation caused first the partial inhibition of the pacing activity (missing of one stimulation pulse) and then triggered the “noise reversion modality”; that is, a modality in which the PM switches from the programmed pacing rate to asynchronous stimulation (Figure 6). Such effects were observed for both the TMS systems under test, but only when the transmitting coil was placed parallel to the trunk of the human torso-shaped phantom (Figure 3) and with a 2 Hz repeated stimulation. In all of the other configurations, the PM activity remained unchanged.



**Figure 6.** Example of PM activity recorded during the activation of the TMS (from  $t \cong 14$  s to  $t \cong 24$  s), with the transmitting coil parallel to the trunk of the human torso-shaped phantom and with a repetition frequency of 2 Hz.

### 3.3. The Arc Welder

The PM activity was altered by the arc welder activation only when the cable of the welding system was placed over the shoulder of the phantom (Figure 4c,d). In such configurations, the EMI caused the inhibition of the pacing activity and did not trigger the “noise reversion modality”. For continuous welding, the inhibition consisted of just a single beat missed (Figure 7a). For pulsed welding, the inhibition was prolonged and, in some cases, lasted for the entire duration of the welder activation (Figure 7b,c).



**Figure 7.** Example of PM activity recorded during the activation of the arc welder. The cable of the welding system was placed over the shoulder of the phantom (one or both). (a) Single beat missed at the beginning of the continuous welding; (b,c) prolonged inhibition during pulsed welding.

## 4. Discussion

For the EMF sources that are not listed in the “whitelist” of the EN50527-2-1, the evaluation of the possible risk for the PM employee generally starts by measuring the field strength around the EMF source and comparing the measured values to the immunity levels stated in EN45502-2-1 standard [8]. For frequency, below 450 MHz, the radiated field emitted by the EMF source must be converted into the induced voltage at the PM input stage. This can be done using computational dosimetry or through the conversion formulas reported in the annex E of the EN50527-2-1 [4]. At frequency above 450 MHz, the radiated field strength can be immediately compared to the immunity level of the EN45502-2-1

standard [8]. If the immunity levels are exceeded, a specific risk assessment is required. If the measured field does not exceed the immunity levels, the PM can be expected to work uninfluenced. However, if there is not a history of uninfluenced behavior at the workplace, sufficient to exclude severe (clinically significant) interaction, a specific risk assessment is still required.

The results of the *in vitro* testing/measurements on the electrosurgical units, the transcranial stimulators, and the arc welders can be considered an example of how the specific risk assessment for worker with a PM can be performed, according to one of the methodologies proposed by the EN50527-2-1 [4]. The *in vitro* testing/measurements approach has been widely used to assess the electromagnetic compatibility of implantable medical devices: Different types of phantoms have been proposed to host the AIMD and to simulate the interactions with the EMF source of interest. When the wavelength of the interference signal is several times shorter than the dimensions of the human body (e.g., GSM, UMTS, LTE phones, WiFi transmitters, UHF RFID signals), the phantom can be limited to the size needed to host the AIMD [15–17]. At lower frequency (e.g., 1.5 T MRI scanner, LF—HF RFID, power supply lines), the dimensions of the phantom cannot be neglected and more realistic shapes are used [18–20]. Given the aim of this paper, that is, to describe a general procedure that can be adopted for the risk assessment of workers with AIMD, a realistic, human-shaped phantom was used.

The main advantages of *in vitro* testing/measurements are that they are safe, since the direct involvement of the workers is not needed, and they allow provocative testing, i.e., allow testing the performance of the device not only in realistic exposure conditions, but also in worst-case scenarios, which may be far from actual practice, but that enhance the interaction between the EMF source and the implanted device. As an example, the PM lead path can be arranged in a path that is not feasible as a clinical implant, but that maximizes the coupling with the electric or the magnetic field. Consequently, safety margins (in terms of power, distance) can be defined even when the EMF source does not produce any effect in standard conditions. However, this approach requires multiple and high-level expertise regarding the implantable device and the EMF source technology, and experimental set-up that could be rather complex and expensive. It is important also to underline that *in vitro* tests can be adopted for risk assessment only if a series of requirements are met:

- The workplace environment is such that a phantom, a monitoring device, and test personnel can be accommodated for the duration of anticipated testing;
- A fully functional pacemaker and leads of the same manufacturer and model as that implanted in the PM employee can be obtained from the manufacturer or the physician;
- A monitoring device to record and analyze the activity of the PM during the test is available.

In addition, the implant layout and the programmed parameters must be the same as in the PM employee.

The *in vitro* testing/measurement approach provides useful information not only on the occurrence of an unwanted effect on the AIMD behavior, but also on the clinical relevance of such an effect. Indeed, both these aspects must be considered in the general risk assessment procedure, and the consequent risk mitigation actions can point at reducing the occurrence of an unwanted event, its clinical relevance, or both, until the residual risk for the AIMD employee is considered acceptable.

The results presented in this paper are valid for the specific AIMD, EMF source, and environments that were investigated, and cannot be generalized to other scenarios, even if similar. A different programming of the AIMD or a different environment around the EMF source could modify the interactions and the consequent effects of the EMF on the AIMD. These results can be used to identify a general situation where the foreseeable risks for a worker with a PM exposed to a particular EMF source deserve a specific assessment.

To date, few studies have addressed the electromagnetic compatibility of PM with ESU or TMS [21,22]. These studies focused on the effects on a patient with a PM, but did not consider the case of healthcare personnel that use such EMF sources in the work environment. The exposure scenario

is definitely different for the two cases, and thus the results found for the patient are not valid for healthcare personnel. No specific studies are available on the possible effect of arc welders and AIMD.

The tests on the ESU did not show any changes in PM activity, even in the worst-case conditions (maximum electric and magnetic field coupling). Thus, it can be assumed that, for the PM and ESU models under test, no specific action must be taken to guarantee the PM employee safety.

The TMS systems caused the inhibition of the pacing activity (not for more than a single beat) and triggered the “noise reversion modality” in the PM. Such behavior was observed for the 2 Hz repeated stimulation and with the TMS coil placed parallel to the loop formed by the PM lead, close to the chest of the human torso-shaped phantom. Given the magnetic nature of the field generated by the coil, this configuration generated the maximum coupling between the coil and the implant. The noise reversion modality cannot be considered a malfunction of the PM, since it is a specific functionality that is activated when the PM recognizes at its input stage a high level of noise, which could interfere with its ability to sense the spontaneous activity of the heart. Thus, in this modality, the sensing activity is turned off and the PM starts stimulating at a fixed rate. Theoretically, an external stimulation concurrent with a physiological beat can induce a ventricular fibrillation. However, modern PM algorithms are able to prevent such risk, synchronizing the start of the asynchronous stimulation with the last sensed beat, and thus minimizing the actual risk for the PM-bearer. The initial pacing inhibition for no more than a single beat does not represent as well a clinical relevant effect for the employee safety. Thus, proper training of healthcare personnel on the particular configurations that should be avoided in the case of the PM employee and on the possible consequences on the PM behavior can be considered sufficient for the risk assessment.

The measurements on the arc welder when the typical good-practice procedures for welder workers were simulated (that is, with the cable raised from the floor to the worktable) did not reveal any effect on the PM behavior, both in the continuous and in the pulsed welding modality. The PM remained uninfluenced also when the cable was fixed to the phantom belt. Similarly to what observed for the TMS, the PM behavior was affected only in those configurations associated with the maximum magnetic field coupling. When the cable was placed over the phantom’s shoulders (one or both), it formed a loop almost parallel to the plane of the PM implant. In these configurations, the continuous welding caused partial inhibition of the pacing at the beginning of the arc activation, for no more than a single beat. For pulsed welding, a prolonged inhibition was observed: During the arc activation, a missing beat was recorded after almost each emitted pulse. In one test, the arc activation caused the complete inhibition of pacing activity, which was restored only when the arc was switched off. For a PM-dependent worker, such inhibition of the pacing activity can be dangerous and represents a serious hazard for his safety [23,24]. Consequently, the risk assessment shall lead to the definition of mitigation actions to limit as much as possible the occurrence of such unwanted events (e.g., proper training and information, safety distances, or even worker relocation).

The *in vitro* testing/measurements approach adopted in this study is just one of the possible approaches for the risk assessment of workers with AIMD. Other approaches, such as *in vivo* measurements [25] or numerical modeling [26], can be used as alternative methodologies or sources for complementary data. In any case, the EN45502 [3–5] standard family represents the main guidance that the employer shall follow to properly perform the risk assessment.

## 5. Conclusions

Workers who wear AIMD are considered at particular risk if exposed to EMF and, according to the EU Directive 2013/35/EU [2], need an in-depth and individual risk assessment. The non-binding guide to good practice for implementing Directive 2013/35/EU [3] and the EN50527 technical standard family provide the general procedures that the employer shall follow to carry on the risk assessment. The results of the *in vitro* testing/measurements presented in this study can be considered an example of how the specific risk assessment for a worker with a PM can be performed, according to one of the methodologies proposed in the EN50527-2-1 [4]. This methodology, although requiring multiple

and high-level expertise regarding the implantable device and the EMF source technology, allows provocative testing and the definition of safety margins, even when the effect of the EMF source does not produce any effect in standard conditions. The experimental data obtained for the TMS and the arc welder show that a real practical risk of interference, causing AIMD malfunctioning, exists and must be evaluated. The results presented in this paper can be used as scientific evidence and literature data to identify particular scenarios for which a specific risk assessment is necessary.

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**Conflicts of Interest:** The authors declare no conflict of interest.

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