

EVALUATION OF THE SAFETY OF USERS OF ACTIVE IMPLANTABLE MEDICAL DEVICES (AIMD) IN THE WORKING ENVIRONMENT IN TERMS OF EXPOSURE TO ELECTROMAGNETIC FIELDS – PRACTICAL APPROACH TO THE REQUIREMENTS OF EUROPEAN DIRECTIVE 2013/35/EU

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Abstract

Objectives: Electromagnetic fields (EMF) may cause malfunctions in electronic devices, in particular in active implantable medical devices (AIMD), along with discomfort or health hazards to users. The use of AIMD by workers is increasing (especially cardiac pacemakers, implantable cardioverter defibrillators and wearable insulin infusion pumps). Electromagnetic fields may be much stronger in the working environment than applied in basic immunity tests of AIMD (based on EN 60601-1-2:2015 and EN 50527-1:2016). European Directive 2013/35/EU regarding the safety of workers exposed to EMF considered the AIMD users to be “workers at particular risk” who need an individual evaluation of EMF hazards. The study aimed at evaluating the safety of users of AIMD in medical and industrial working environments exposed to EMF. **Material and Methods:** Near the common sources of strong EMF applied in medical and industrial use, the “standard safety distances” (SSD) for AIMD users were evaluated (i.e., distances from the EMF source, where exposure drops below limits from Recommendation 1999/519/EC and AIMD safety may be expected). The analysis is based on the results of measurements of magnetic and electric field strengths near 127 typical devices, in their normal use. **Results:** The longest electric field related SSD was identified near dielectric sealers (up to 180 cm), and the longest magnetic field related SSD – near induction heaters (up to 450 cm). **Conclusions:** Electromagnetic fields related AIMD malfunctions need to be considered up to several meters from EMF sources. The “individual safety distance,” that is sufficient to ensure the safety of a particular AIMD user may be significantly different (usually shorter) from the presented SSD, but needs to be considered in the context of detailed safety data from the AIMD manufacturer (if available). The labelling indicating the location of the area of a strong EMF increases safety of AIMD users in the work environment. *Int J Occup Med Environ Health* 2018;31(6):795–808

Key words:

Workers’ safety, Cardiac pacemakers, Implantable defibrillators, Exposure effects, Electromagnetic interference, Wearable insulin pump

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INTRODUCTION

Various dysfunctions of the human body, especially chronic ones, may be compensated by implantable medical devices, such as mechanical implants (e.g., orthopedic implants in joints, vascular stents, dental implants) and electronic implants (e.g., cardiac pacemakers, implantable cardioverter defibrillators (ICD), wearable insulin pumps or glucose monitors, cochlear implants – considered as active implantable medical devices (AIMD)). Patients are implanted at various ages – starting from children just a few years old (who may have cochlear implants, for example), up to seniors (who ever more frequently use implanted pacemakers and cardioverter defibrillators) [1–3]. Implants sufficiently compensate for health dysfunctions and users are able to continue work activities. The number of implant-treatments each year is increasing, and consequently the number of implant users in the working environment is rising.

It is well known that environmental electromagnetic fields (EMF) cause induced electric potentials inside any electrically-conductive structures, which may interfere directly with the body's functions, by causing thermal damage to tissue or nervous system dysfunctions due to electrostimulation [4]. However, currents induced in the structure of the implant or in adjacent tissues may also create malfunctions in electronic implants or effects in the adjacent tissue. Such effects are dependent on the EMF frequency, level, polarization and distribution in space and time. Consequently, in the vicinity of EMF sources, various hazards for implant users need to be identified and evaluated, especially for users of AIMD. In the systematic considerations, the EMF influence on AIMD functions may be split into the following groups (where it is not excluded that they will present together):

- influence on the electric circuit of the AIMD,
- influence on the internal memory of the AIMD,
- influence on mechanical structures – by heating, reposition, etc.,

- influence on tissues adjacent to the implant, e.g., by elevated heating or electrostimulation.

In result malfunctions in the AIMD activity may be observed when needed by the user or when not needed at all, and the lack of AIMD activity may be observed when needed by the user. Typical malfunctions caused by EMF influence are summarized in the Table 1, based on reports from extensive studies [5–39]. They may cause a dangerous situation for the safety and health of the AIMD user and, in the case of a working environment, also for any people and devices present near the worker who was disturbed by his AIMD malfunctions caused by the EMF. In some cases AIMD malfunction may even cause death, for example when the EMF causes a lack of electric cardiac stimulation in a user who is fully dependent on the cardiac pacemaker [40,41].

The need to apply safety measures to prevent these hazards for AIMD users is covered by European Directive 2013/35/EU, which sets out the minimum health and safety requirements regarding the exposure of workers to the risks arising from EMF of the frequency 0–300 GHz [42]. In Article 2 – “Definitions,” the interference with medical electronic equipment and devices, “including cardiac pacemakers and other implants or medical devices worn on the body” was included in the “indirect effects” from EMF exposure, defined as: “effects caused by the presence of an object in EMF, which may become the cause of a safety or health hazard.”

Special attention concerning the safety of AIMD users is also covered by the provisions of Article 4 of Directive 2013/35/EU – “Assessment of risks and determination of exposure.” It states that, in the process of a binding “risk assessment,” the employer must give particular attention, among other things, to any effects on the health and safety of “workers at particular risk” including: “workers who wear active or passive implanted medical devices, such as cardiac pacemakers; workers with medical devices worn on the body, such as insulin pumps, and pregnant workers.” The protection

Table 1. Variety of active implantable medical devices (AIMD) malfunctions observed through electromagnetic fields (EMF) exposure

Observed AIMD malfunctions	The source of EMF exposure	AIMD type*
Pacing inhibition (complete or temporary stop of pacing); the implant interprets electrical potentials from EMF electrodynamic interaction as the proper heart rate and stops the pacing, even in the absence of the intrinsic heart rate	EAS systems [5,6]; induction hobs (25–34 kHz) [7]; GSM [6,8–10]; vicinity of BTS [11,12]; MD gates [13]; MRI scanners (1.5 T) [6,14]; ESU [6,15]	CP
Triggering of rapid or premature pacing; triggering ventricular or atrial pacing in the case of voltage induction in the lead(s) of implants programmed in tracking mode, or triggering the reversion to noise mode	2.1. EAS systems [5,16]; 2.2. GSM handsets [6,8,17]; 2.3. ESU (non-cardiac or endoscopic treatment) [6,15,18]; 2.4. Vicinity of BTS [11,12]	2.1–2.3. CP, ICD; 2.4. CP
Reversion to noise mode; transient reversion to asynchronous pacing in the case of CP with protective algorithms against false signals	3.1. EAS systems [5]; 3.2. GSM handsets [8,10]; 3.3. Vicinity of BTS [11,12]; 3.4. 400 kV power lines [19]; 3.5. ESU [15,18]	3.1–3.4. CP; 3.5. CP, ICD
Activation of a magnetic switch; the magnetic switch of an implant switches off, usually in the case of exposure to a SMF of 1–3 mT and temporarily starts asynchronous pacing; in this time, tachycardia detection and treatment is switched off	permanent magnets emitting 1–3 mT SMF [20–22]; portable headphones [6,23]	CP, ICD
Electric reset; the induction of a high voltage peak in lead(s) system triggering the reset mode, only with basic factory preset	MRI scanners 1.5 T [24]	CP, ICD
Heating of the electrode tips; this can damage heart tissue in the vicinity of this tips, making the implant unable to pace	MRI scanners 1.5 T [24,25]	CP, ICD
Errors in electronic components (e.g., CPU, memory, transmission bus) triggering the reset mode only with the basic factory preset	induction hobs (20–50 kHz) [26]	CP, ICD
Damage to the CP's electronic components – permanent damage of the implant leading to its reimplantation	8.1. MRI scanners 1.5 T [24]; 8.2. ESU (cardiac vicinity treatment) [6,27]	8.1. CP, ICD; 8.2. CP
False arrhythmia detection; the implant interprets external signals as tachycardia or fibrillation and treats it	EAS systems [16]; MRI scanners 1.5 T [28,29]; 50 Hz [30]	ICD
Pump delivers insulin inaccurately or behaves erratically	GSM [31]; RFID [32,33]	IP
Failure of electronic components, e.g., CPU, memory, transmission bus	RFID [32]	IP
Temporary stoppage with restart with the basic factory preset	RFID [32]	IP
Heating or even damage of tissue in the vicinity of the conductive elements of implants	MRI scanners 0.5–1.5 T [34–36]	CI
Problems with sound quality – electric and magnetic components of EMF may predominate at the audio frequencies	mobile phones [37,38]	CI

Table 1. Variety of active implantable medical devices (AIMD) malfunctions observed through electromagnetic fields (EMF) exposure – cont.

Observed AIMD malfunctions	The source of EMF exposure	AIMD type*
Hearing distorted sound when passing near or through EAS systems	EAS systems, MD [36]	CI
Damage to the electrodes in the cochlea	dental instruments [36,39]	CI
Damage to the cochlear implants circuitry	ESU [36,39]	CI

* In the column: "AIMD type" the numbers from the column: "The source of EMF exposure" are referred.

AIMD – active implantable medical devices, EMF – electromagnetic fields, CP – cardiac pacemaker, SMF – static magnetic field, CPU – central processing unit, EAS – electronic article surveillance, MD – metal detectors, MRI – magnetic resonance imaging, ESU – electrosurgery units, BTS – mobile phone base station antenna, GSM – mobile phones handsets, RFID – radiofrequency identification, ICD – implantable cardioverter defibrillator, IP – insulin pump, CI – cochlear implant.

measures, workers training and information needs to comply with the results of such risk assessment. As a result, this directive requires that an individual EMF risk assessment be carried out for workers who are AIMD users.

The safety of AIMD users being exposed to EMF is also considered by international standards. In accordance with the EN 60601-1-2 standard (replicating IEC 60601-1-2) on electromagnetic compatibility (EMC) in EMF of frequency from 80 MHz to 2.7 GHz, medical equipment, including AIMD, should be manufactured to be resistant to electromagnetic interference from an electric field with a strength of up to 3 V/m when equipment is used in the environment of professional medical care, or up to 10 V/m when equipment is used in the environment of home medical care [43].

In addition, Appendix A to the European standard EN 50527-1:2016 (applicable to AIMD manufactured for the European Union (EU) market) provides recommendations on how to assess electromagnetic hazards for AIMD users in the workplace, with regard to the likelihood of clinically relevant effects from transient and long-term exposure [44]. This standard recommends that AIMD for use in the EU are manufactured so as not to be disturbed by EMF at a level within general public exposure limits provided by non-binding European Council Recommendation 1999/519/EC (based on published in 1998 guidelines from the International Commission on Non-ionizing Radiation Protection (ICNIRP)) [45,46]. It needs to be pointed out that E-field exposure limits provided by recommendation 1999/519/EC (of the level 28–61 V/m at 80 MHz–2.7 GHz frequency range) are many times higher than above mentioned immunity requirements set out by the mentioned European standard (3 V/m or 10 V/m). The Directive 2013/35/EU limits set out for workers exposure are even many times higher – 61–140 V/m at the discussed frequency range but are not relevant to the evaluation of exposure of mentioned “workers at particular risks”, who use AIMD.

MATERIAL AND METHODS

The subject of the study was the evaluation of AIMD users' safety in EMF near the most common sources of strong fields in medical and industrial working environments. Power installations and radiofrequency antennas were not considered in this work because they may be found in general public and work environment and therefore considerations regarding the safety of AIMD users near such EMF sources are available from other publications [30,47,48]. Magnetic resonance imaging (MRI) scanners were also omitted because of the wide availability of published results regarding possible AIMD malfunctions caused by MRI scanners in patients – with the general conclusion that such hazards exist only near MRI magnets located in the closed MRI chambers, with entrances usually labelled by signs warning against hazards to AIMD users [6,14,21,29,34–36].

In this study, the maximum distance from the EMF sources, where the EMF level drops so far that it does not exceed the exposure limit from Recommendation 1999/519/EC, has been evaluated [45]. This distance has been considered to be “a standard safety distance” (SSD) for AIMD users population (i.e., AIMD EMF-related malfunction is not expected in distance from EMF source longer than SSD, when AIMD is manufactured with respect to EN 50527-1:2016 recommendations [44], provided for devices made to be used in EU).

The assessment of hazards caused to the general public or workers because of thermal effects of radiofrequency EMF exposure, based on the provisions from Directive 2013/35/EU, ICNIRP 1998 guidelines or Recommendation 1999/519/EC, in the frequency range 0.1–6000 MHz requires the averaging the EMF over a 6-min period [42,45,46]. On the other hand, an assessment of AIMD immunity to electromagnetic interference following Standard EN 50527-1:2016 needs to be performed using electric field strength (E) and magnetic field strength (H) values that are non-averaged over time (peak values) [44]. So, it needs to be pointed out, that the SSD may be differ-

ent from safety distance evaluated with respect to the limits provided to protect against thermal effects of exposure when the level of EMF is changing within 6-min periods.

The evaluation of the environmental impact of EMF in the vicinity of medical and industrial devices included measurements of electric field strength (E), expressed in volts per meter (V/m), and magnetic field strength (H), expressed in amperes per meter (A/m). According to the requirements of regulations and standards, measurements of the spatial distribution of EMF near the sources were made without the presence of personnel operating particular devices (measurements of unperturbed fields) [42,45,46]. Measurements were performed in the vicinity of 127 devices emitting EMF, from various manufacturers (mainly of international brands), used in 35 enterprises/medical centers in Poland. Measurements were performed in the locations of the regular use of investigated devices, when they were equipped and set as for their regular use in industrial production or medical applications.

The EMF measurements were carried out using a broadband meters equipped with isotropic probes for measuring the root mean square (RMS) values of electric or magnetic field strength:

- EMR-300 (Narda, Germany); electric field range: 0.4–1400 V/m and 0.1–3000 MHz and magnetic field range: 0.02–16 A/m and 0.3–30 MHz,
- ELT-400 (Narda, Germany); magnetic field range: 8 mA/m–6.4 kA/m and 1 Hz–400 kHz,
- EFA-3 Field Analyzer (Wandel & Goltermann, Germany); electric field range: 0.5 V/m–100 kV/m and 5 Hz–30 kHz.

Taking into account principles of measurements by isotropic probes spatially averaging EMF, the investigated electric and magnetic fields were measured around the devices in the minimum distances of 10 cm from the source (i.e., no less than the diameter of measurement probe). The results of measurements (SSD) were taken to be the longest distance from the cover of each device

emitting EMF, where EMF of the defined level was found (i.e., EMF has been no higher than general public exposure limits provided by Recommendation 1999/519/EC). However, the measurement devices used in the study are RMS value calibrated, which means, among others, the indicated EMF level to be time-averaged. As a result, when evaluating the SSD for AIMD users exposed to modulated or pulsed EMF, the measured RMS value of the E or H field was converted to values non-averaged in time. This conversion was done applying correction factor K, derived from the RMS value measurements principle to be the inverse of the square root of the duty cycle in measured EMF (established for each individual case, based on the oscilloscope observation of the EMF wave over time). In the case of non-modulated EMF, the K factor is equal to one. The frequency and modulation of the assessed EMF were identified by the Fluke Scopemeter 199C oscilloscope equipped with EMF probes and fast Fourier transform (FFT) software. The accuracy of the used EMF meters was tested in an accredited calibration laboratory of the Central Institute for Labour Protection – National Research Institute (Centralny Instytut Ochrony Pracy – Państwowy Instytut Badawczy – CIOP-PIB) (accreditation certificate from the Polish Centre for Accreditation No. AP 061).

Statistical descriptive parameters (mean, standard deviation, median, interquartile and min.–max ranges) were applied to characterize the set of SSD values measured near each group of EMF sources, with the use of Statistica software version 9.0 PL (StatSoft, USA).

RESULTS

The presented results of investigations regarding the spatial distribution and wave-form over time of the EMF emitted by medical and industrial devices in common use covered sources of EMF from the frequency range 0 Hz–27 MHz. The results of measurements of SSD defined by magnetic and electric field strengths (H and E) in the vi-

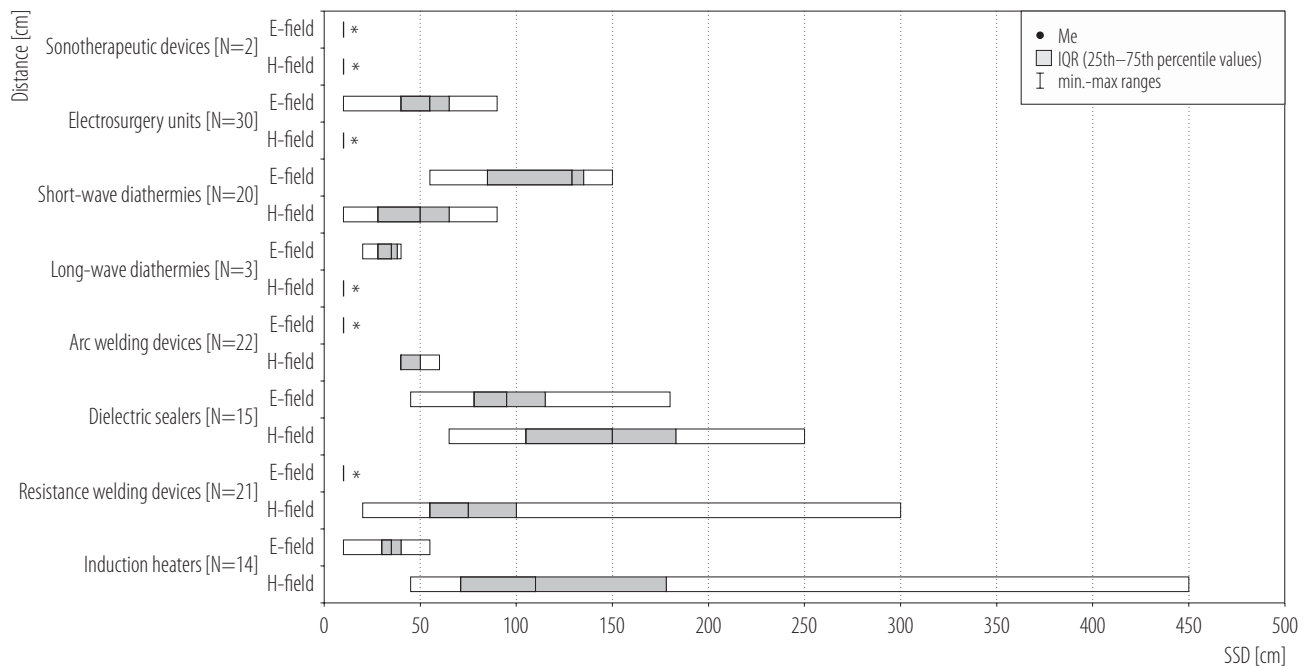
cinity of devices emitting EMF, performed at locations of their normal use in medical or industrial workplace, were analyzed and summarized in the Figure 1. The characteristics of selected EMF sources are shown in the Table 2 and 3.

The presented data covers SSD values identified near each group of devices emitting EMF, along with parameters characterizing their statistical distribution. In every group of investigated EMF sources, the mean and median values of SSD are comparable, which indicate the normal distributions in the analyzed data sub-sets.

The first step of analyzing the safety of AIMD users is the worst case considerations related to the maximum SSD. In the case of arc welding devices and induction heaters, SSD related to the electric field has not been found. Welding devices are low impedance sources in which the magnetic component of EMF is dominant and only SSD related to the magnetic field need assessment, similar the low frequency (kHz-range) induction heaters. On the other hand electrosurgery units and long-wave diathermies are high impedance sources in which the electric component of EMF is dominant and only SSD related to the electric field need assessment. Both magnetic and electric components of EMF should be evaluated in the vicinity of dielectric sealers.

The worst cases related to electric field (i.e., the longest SSD near electric field sources) are identified by dielectric sealers (SSD up to 180 cm from a device) and short-wave diathermies (SSD up to 150 cm) (Figure 1). The worst cases related to the magnetic field are identified by induction heaters (SSD up to 450 cm from the device), resistance welding devices (SSD up to 300 cm) and dielectric sealers (SSD up to 250 cm) (Figure 1).

In the case of sonotherapeutic devices SSD related to both magnetic and electric field was not found. Where SSD was not found, it meant that, at a distance 10 cm from the EMF source or longer, the level of EMF did not exceed general public exposure limits. An evaluation of EMF levels closer



* The SSD have not been found, i.e., electromagnetic field (EMF) not exceeded the general public exposure limits in the distance exceeding 10 cm from the source, where EMF were measured following the technical guidelines.

Me – median; IQR – interquartile range; E – electric field; H – magnetic field.

Fig 1. The range of standard safety distances (SSD) identified near medical and industrial devices [49,52,54]

than 10 cm to the source is not discussed because, following technical guidelines, EMF measurements should be taken at a distance exceeding 10 cm from the EMF source.

DISCUSSION

Directive 2013/35/EU advises an individual analysis of EMF hazards for each AIMD user. It needs to be pointed out that the EMF of investigated frequencies (0 Hz–27 MHz) are uncommon in the environment accessible to the general public (with the exception of the EMF of a power frequency – 50 Hz). Because of this, this frequency range is not covered by the general rules of testing the immunity to electromagnetic influence, e.g., provided by the standard EN 60601-1-2:2015, which advises an immunity test in EMF of frequency from 80 MHz to 2.7 GHz [43]. A wider approach is provided by the standard EN 50527-1:2016 regarding the assessment of EMF exposure of workers us-

ing AIMD – it recommends that manufacturers of implants dedicated for the use in the EU make them in such a way that the probability of EMF interference to implants is low in the case of exposure not exceeding the limits for the general public at any frequency of EMF [44–46]. However because of the above-mentioned uncommon exposure of the general public to EMF of the investigated frequencies, the experimental proof for such an approach is scarce.

However, it needs to be pointed out that many implants are not disturbed even in an EMF significantly exceeding the mentioned general public exposure limits. This is because many factors influence the response of implants to EMF exposure, such as: the type and model of AIMD, its operating settings, location in the body, the duration and spatial distribution of exposure of the user [42]. Because of that, Directive 2013/35/EU does not advise prohibiting the occupational EMF exposure to AIMD users.

Table 2. Common sources of strong electromagnetic fields (EMF)* applicable in medical treatment, covered by these investigations [4,49–54]

Devices emitting EMF	Dominant frequencies in emitted EMF	Wave-form	Dominant source of EMF in particular devices	Typical tasks nearby particular devices
Electrosurgery units	0.3–1.8 MHz	sinusoidal or modulated	cables connecting electrodes and generator, active electrode	the operator of the electrosurgery unit holds an active electrode in the palm; cables connecting the electrodes and generator are usually at a distance not exceeding 50 cm from the operator and other assisting personnel
Diathermy device long-wave	0.5–1 MHz	sinusoidal	cables connecting applicator with generator, applicator	the operator holds in the palm the applicator, which attaches to the patient's body; cables are usually at a distance of several centimeters from the operator and patient
short-wave	13.56 MHz or 27.12 MHz	sinusoidal or modulated	applicators and their supply cables	the operator's task is to set applicators at a selected part of the patient's body and to trigger treatment on the control panel (usually at a distance of at least 50 cm from applicators); during the treatment, the operator may stay away from the applicators
Sonotherapeutic device	0.5–3.2 MHz	sinusoidal	applicator and its supply cable	the operator holds in the palm the applicator, which attaches to the patient's body; the cable is usually at a distance of a several centimeters from the operator and patient

* Generators/main units of devices mentioned in the table may also be a source of strong EMF, but usually only if they have technical dysfunctions; usually even workers who remain some distance from them are not affected by EMF.

Table 3. Common sources of strong electromagnetic fields (EMF)* applicable in industrial production, covered by these investigations [4,49–54]

Devices emitting EMF	Dominant frequencies in emitted EMF	Wave-form	Dominant source of EMF in particular devices	Typical tasks nearby particular devices
Arc welding devices	0 Hz–3 MHz	non-sinusoidal	cables connecting electrodes and generator, welding electrode	the operator holds the head of the welding electrode in the palm; cables connecting welding electrodes and the generator are usually at a distance of a several centimeters from the operator's body – but may even be in contact or 50 cm away
Dielectric sealers	27.12 MHz	sinusoidal	powered electrode	the operator of dielectric sealers (which is manually managed) usually stays over the sealing time in front of a powered electrode, at a distance of approximately 30–60 cm; in the case of partly automated devices, this distance may be significantly longer
Induction heaters	0.1–40 kHz	sinusoidal	inductive applicator (coil)	during the heating process the operator stays at a distance of approximately 50 cm from the inductor – when device is manually managed, or at a longer distance when manually managing is not required

Resistance welding devices	50–300 Hz	sinusoidal or rectified	powered electrodes	in the case of the manually managed welding process, during the welding process the operator stays at a distance from several to several dozen cm from the electrodes of a stationary device, or may even touch the electrodes of suspended welding guns; when welding is automated, the distance may be significantly longer
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* Generators/main units of devices mentioned in the table may also be a source of strong EMF, but usually only if they have technical dysfunctions; usually even workers who remain some distance from them are not affected by EMF.

That approach respects the need for equal rights for every worker in the labour market and for the elimination of administrative barriers in employment. Based on that approach, an obligation has been developed to label the locations where EMF influence may be potentially disturbing for AIMD, and where an individual assessment of EMF hazards based on the implant and exposure properties is required [55,56].

The data presented in the Figure 1 may help to identify where warning signs may be necessary and if the need for individual evaluations of EMF hazards to AIMD user is applicable. The data discussed in this paper covers a variety of typical devices, though it needs to be pointed out that stronger EMF emitters may also be used, especially in an industrial environment where even longer SSD may exist near EMF source. The following circumstances indicate the possibility of stronger EMF influence near the devices: many sources used simultaneously (when electric or magnetic components of exposure create combined influence on the AIMD), large dimensions of EMF sources (enlarging the exposed volume of the AIMD user's body) and high power consumption of EMF sources (increasing the probability of strong EMF exposure near the source during regular use or during some specific phases of its maintenance, such as the control of internal circuits when the cover is removed).

The operating parameters of the investigated devices emitting EMF were typical for technological processes used in factories and in medical interventions. The worst case of SSD near investigated medical sources generating EMF of frequencies in the range of 0.3–27.12 MHz was found for the electric field. So, the presented research suggests that an individual risk assessment for users of AIMD should be based primarily on the results of an electric field survey. Whereas, the worst case of SSD near industrial sources was found for the magnetic field and this component needs attention in that respect (Figure 1). However it needs to be pointed out that the level of expo-

sure of AIMD users depends on the organization of the workplace near the EMF source and the pattern of user's activity, and may not be correlated with the level of EMF emitted by the source.

Near to industrial sources of EMF, much longer SSD were identified than near medical devices. So, adverse effects in AIMD users who are involved in any type of activities in the vicinity of EMF sources are more probable there. It is important to recall that the EMF influence on AIMD is assessed by immediate exposure level (non-averaged in time). The affected person may just walk nearby, without expecting to be EMF exposed with any dangerous consequence. Because of that, the places where the level of EMF is strong enough to be able to cause AIMD dysfunctions should be clearly labelled. Labelling the areas of strong EMF plays a very important role in the system of protecting AIMD users against electromagnetic hazards. It also needs to be pointed out that such labelling may be noticed by anyone present near EMF sources, not only to the operators of the devices.

It also needs to be pointed out that in medical and industrial environments other devices may also be found to emit EMF strong enough to cause AIMD malfunctions, even at a distance from the source longer than presented in the Figure 1 (for example MRI scanners), or devices similar to those discussed in this paper, though emitting significantly stronger EMF. Each particular case needs an individual evaluation at the workplace. Electromagnetic fields related AIMD malfunctions need to be considered to be possible up to several meters from EMF sources, but the "individual safety distance" that is sufficient to ensure the safety to a particular AIMD user may be significantly shorter than discussed SSD, unfortunately it needs to be considered in the context of detailed safety data from the manufacturer of particular AIMD (which may be not easily accessible or not accessible at all). In the evaluation of the individual risk to the particular AIMD user, to improve our understanding of hazards caused by EMF more

detailed data on the pattern of exposure may be necessary, as well as the results of numerical calculations regarding the effects of exposure on a particular type of implant or study involving humans – always performed with attention to the bioethical requirements and safety [57]. Some cases may also be analyzed by using physical phantoms or equivalent electronic circuits that mimic sensitivity to EMF exposure and allow for evaluation of exposure effects.

Additionally, it needs to be pointed out that the discussed evaluation of hazards from EMF exposure to AIMD users is applicable only for the exposure situation where the person is not in the galvanic contact with EMF source. In the case of galvanic contact, another kind of hazard that may be caused by contact currents needs to be also analyzed.

CONCLUSIONS

By analyzing the typical operating procedures with the use of the medical or industrial devices characterized in the Tables 2 and 3 and the results of the measurements presented in the Figure 1, it is possible to identify whether workers who are AIMD users may be exposed to EMF at levels which may be strong enough to make malfunctions in the medical implants, caused by electromagnetic interferences. Such hazards are most probable where the AIMD user's body is in direct proximity to an element that is an EMF source (e.g., electrosurgery or welding cables). However, the presented survey has shown that AIMD malfunctions need to be considered and labelled at a distance up to a several dozen cm (up to 1.5 m) from medical devices (such as physiotherapeutic devices and electrosurgery units), and up to several meters from the industrial devices (such as resistance welding devices, dielectric sealers and induction heaters). Fortunately, based on the published reports, it is expected that the individual safety evaluation may show that a particular AIMD user is safe from hazards triggered by EMF even at significantly shorter distances from the EMF source. However only detailed safety data from the manufacturer of the used AIMD may

allow for such individual considerations. This makes it necessary to keep detailed records regarding AIMD used by anyone being still a worker as well as proper labelling of EMF hazards at the workplace.

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