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EXPOSURE OF ACTIVE MEDICAL IMPLANTS BEARERS TO ELECTROMAGNETIC EMISSIONS FROM WIRELESS POWER TRANSFER SYSTEMS

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Keywords: Active implantable medical Devices; Wireless power transfer; Electromagnetic field; Electromagnetic interference; Intermediate frequency; Magnetic leakage field.

People with active implantable medical devices today are a growing category, due to the increase of health care interventions that replace or remedy physiological deficiencies with intelligent artificial medical solutions. These devices are built with electronic circuits, susceptible to electromagnetic interference that could affect their proper operation and could cause discomfort or even health damage to the patient. Manufacture of medical devices has been regulated for decades by international technical standards (such as IEC 60601-1-2 or ANSI / AAMI PC69 series), including immunity conditions; however, attention must always be paid to the continuous assessment of the electromagnetic environment enriched with new technologies, to harmonize the sensitivity of health care devices and the possible conditions of uncontrolled human exposure. In this context, the authors present an attempt to evaluate the current protection offered to bearers of implantable devices in the electromagnetic environment specific to modern electric vehicles and especially to those using wireless power transfer systems for battery charging, due to the magnetic leakage field. These specific exposure conditions and particular regulations are investigated and compared with some assessments performed on the Dacia *Electron* electric vehicle.

1. INTRODUCTION

The electromagnetic environment, in which the population is present for daily life and professional activities, is characterized by increasing levels of emissions, due to the continuous evolution of electrical and electronic devices and technologies that bring unquestionable progress and comfort to our civilized existence. The variety of electromagnetic field sources and power levels involved in applications is constantly growing, making it increasingly difficult to identify features associated with a particular emission source, while people are constantly exposed to this complex environment. Under such circumstances, electromagnetic interference (EMI) issues are addressed as a matter of priority by device manufacturers and by their users, especially when a potential risk to human health is involved. That is the case with active implantable medical devices (AIMDs), which typically provide their bearers with the proper support needed to continue their lives in conditions that are as similar as possible to those of healthy people, including exposure to electromagnetic fields (EMFs) at common levels, in their living environment [1–3].

Among various EMF emitters that surround us with high amplitude emissions and/or operate close to our body, one could identify several important categories of EMF sources, which are inherently tied with modern life conditions:

- high amplitude electrostatic and magnetostatic sources (such as the MRI used for medical diagnosis),
- the electric power system, working at 50 or 60 Hz at electric and magnetic field intensities dependent on the application (high voltage transport lines, medium and low voltage distribution networks and the multitude of household appliances, various electric tools, and commercial services working in the vicinity of the body),
- intermediate frequency applications, including induction heating devices, parts of urban and long-distance electrical traction systems, and, recently, the electric automobiles with all their components and associated equipment, as the battery charger system – wireless power transfer (WPT) charger and, of course,
- high-frequency emissions fill the living space shared between communications, IT applications, broadcasting, radar, security, and many other wireless applications.

Within this conglomeration of man-made EMF emissions, the risks associated with EMI phenomena among different EMF sources and between the EMF environment and sensitive electronic equipment are inevitably present and increasing. This danger occurs in the case of implantable devices, usually built of metal components, when the bearer stands in high-intensity magnetic fields; the phenomenon of electromagnetic induction could generate induced currents in some sensible parts of the implant. For passive implants, such as those used in orthopedic or dental procedures, the induced electric field could cause the implant to heat up [4], but when an AIMD is involved, EMI effects could also affect its accuracy in operation [1,2,5,6].

During the last decade, the automotive industry upgraded massively to electric vehicles (EVs), especially cars for personal and family transportation. In such conditions, the exposure of the general population to EMF inside the EV, including the most vulnerable, became quite common [7]. From the viewpoint of the health potential risk, a comprehensive study is performed by [8], where several designs of vehicles and exposure scenarios are analyzed; different types of measurement conditions were provided – either in the controlled setting of an EMC laboratory or in the road, where a mannequin served as the exposed body. Measurements were performed on the EV, in proximity of the highest power electrical sources (batteries, electric motors and electronic circuitry) covering a frequency

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spectrum from 0 to 10 MHz. The highest magnetic field densities were found close to the electronic inverter, rising to approx. 60 nT at frequencies in the MHz range, but they are far below the acceptable limits given by ICNIRP and by IEEE for the public [9,10].

At the same time, WPT technologies cover both a new fashion in electrical applications and an increase in localized electricity consumption through systems embedded in our living environment, like the battery charging system of an EV [7].

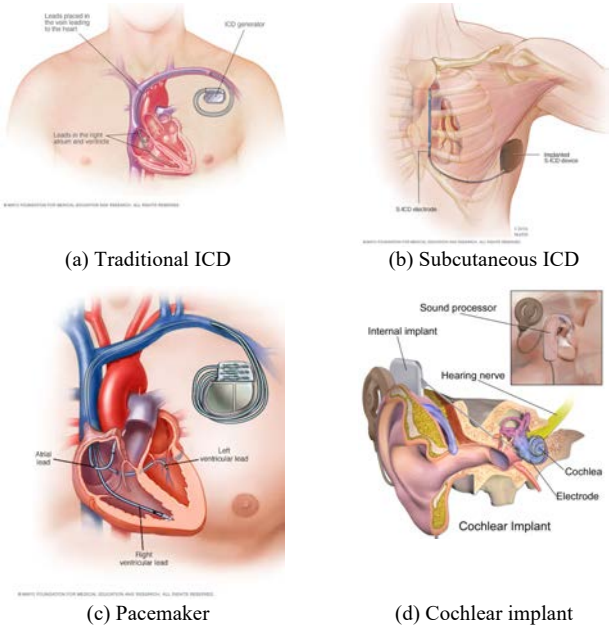
Fig. 1 – Illustrative of an inductive battery charging system by WPT, as an environmental magnetic field source [7].

The study mentioned above shows no assessment in the areas covered by the magnetic field scattered around any wireless battery charging system (see Fig. 1), operating usually within the 20 – 100 kHz range, and reported by other publications as possibly reaching higher levels than inside the EV [11]. The work [12] suggests that supplementary shielding was necessary to lower the magnetic field levels outside an EV, during the battery charging process, to comply with the ICNIRP limit of 27 μT acceptable for the public [9] (as further shown in Fig. 3).

So, this is the reason for opening here a discussion on the assessment of health risks on AIMDs bearers, a category that is not covered by the general guidelines and standards of human protection to EMF. This issue concerns the AIMD manufacturers and medical practitioners who are using them, aiming to better design solutions able to minimize EMI interactions, it also concerns the EV automotive industry to find efficient shielding solutions for the WPT systems, and finally, the matter is of interest for the international standardization bodies, because it is expected that adequate provisions should be issued for the protection of people with any vulnerable condition in circumstances that occur in their daily life.

2. ACTIVE IMPLANTABLE MEDICAL DEVICES

Medical evolution brought solutions for a lot of health conditions through artificial interventions, by filling the deficiencies in the stimulation functions. This is mainly the therapeutic role of an entire class of AIMD, among the best known being the implantable cardiac stimulators (either pacemaker, implantable cardioverter-defibrillators – ICD or cardiac resynchronization therapy devices), the nerve stimulators, or the cochlear implants. They are located inside the body, close to sensitive organs, in vulnerable regions like the head or the torso, and operate based on low-power electronic circuitry (see Fig. 2 for several illustrations from Mayo clinic, showing the positioning of electronic implantable devices).



(a) Traditional ICD (b) Subcutaneous ICD

(c) Pacemaker (d) Cochlear implant

Fig. 2 – AIMD design and positioning as presented by Mayo clinic [13]

Electric signals emitted or received by these circuits are susceptible to EMI phenomena from environmental EMF sources. This risk has been observed by their manufacturers, who have attached technical warnings to the product documentation, addressed to physicians and patients. Avoiding such conditions and keeping a proper distance from various magnetic field sources, especially those based on wireless operation, are always the main protection measures. Most critical health threats would result from impaired cardiac implant operation (like the transmission of false signals or inhibition of stimulatory functions, going up to the crash of the electronic device), which could have dramatic consequences, such as arrhythmia or heart attack and requires emergency medical care [5]. Current documents warning about the effects of EMI on AIMD bearers give priority to cardiac implantable electronic devices (CIEDs), as considered the most unfavorable in terms of their critical reliability.

The demand for AIMD is expanding today, due to the aging population and the focus of Western medical systems on preventing acute conditions and improving the quality of life [14]. It is expected that precautions will be reviewed in the future and that new specific exposure limits and restrictions will be imposed on medical devices.

3. ELECTROMAGNETIC INTERFERENCE RISK AND PROTECTION

3.1. INVESTIGATIONS ON THE HEALTH RISKS OF AIMDS BEARERS DUE TO EFFECTS OF EMI

Even from de beginning of the AIMDs use in medicine, the risk of uncontrolled EMI phenomena was noticed and the technical standards for medical devices introduced provisions (see early editions of IEC 60601 and ISO 14117), but the EMF sources evolved to applications in close proximity to the body, as the antitheft RFID applications, or with strong emissions close to a certain implant location (like the mobile phone used at the ear, near a cochlear implant or stored in a pocket, on the chest of a pacemaker device bearer). Medical literature shows risk studies and exposure assessments performed on such types

of circumstances, either for the case of workers or for the public [2], [1]. An illustrative study conducted in 2010 and 2011 in France and published by [15] shows the results of a national survey addressed to health professionals in some of the most popular specialties and especially those related to AIMD (cardiology, neurology, endocrinology, urology, otolaryngology). Physicians were asked to provide data on observed health incidents involving their patients, related to the electromagnetic influence on the operation of AIMDs. At that time, possible effects of EMI with AIMD were investigated for the evaluation of a wide range of wireless applications, such as mobile telephony, and security and identification devices (like RFID and metal detectors), which show a spectacular growth tendency. Most of the incidents were related to momentary cardiac implant disorders – defibrillators and pacemakers – and were not considered life-threatening.

The authors of [6], concerned about occupational medical risks, determined the thresholds of failure occurrence for heart stimulators when subjected to EMI from power frequency EMFs; typical exposure conditions simulated the most unfavorable cases and there were identified both technical measures (AIMD sensitivity adjustments) and protection measures (by increasing the distances between the subject and the EMF source) to avoid such perturbations.

When new technologies have been used in the last decade, the interest in the possible risks of EMI on AIMDs has explored new paths, namely the general and professional exposure of active implants bearers to magnetic emissions from electric vehicles (EVs) and accessory systems operating at frequencies lower than 10 MHz; electric fields induced in the body could interact with natural biocurrents and with signals produced by active implants. As the comprehensive study presented by [8] demonstrates, the actual exposure of the driver and passengers to magnetic fields inside several types of EVs is certainly below the limits of ICNIRP for the public [9]. However, that survey did not consider the interference phenomena in the intermediate frequency range (IF includes the 1 kHz up to 1 MHz range), between the AIMDs and the EMFs emitted by some novel appliances closely related to the explosive development of EV applications - their power supply and wireless charging systems. These issues have been investigated and presented by the systematic review [3], focusing on the EMI phenomena on cardiac implants; a large volume of data was analyzed, obtained from direct investigations (in vivo surveys and phantom measurements) and numerical simulation of various exposure scenarios. The results converge to the conclusion that "cardiac implants are susceptible to malfunction induced by EMF in the IF range". The [3] analysis notes, however, that the factors influencing EMI are not sufficiently well characterized and that EMF limit values for bearers of implantable devices do not exist yet. Worst case scenarios should be described and analyzed in relation to real exposure situations of AIMD bearers, considering both the spread of EMF sources in the living environment and the presence of people with implants among the general population.

Survey findings often suggest, as a general method of good practice, that the design of AIMDs be continuously adjusted by reinforcing their immunity with the evolution of EMF technologies and human habits [15], while the medical teams involved in selecting the type and functional settings of the implant would better take into account the electromagnetic environmental conditions common to the subject's lifestyle and work, and to adapt their decisions accordingly [6,16,17]. Proper monitoring of the functionality of implantable devices is also a good measure, especially when new models are introduced into medical practice [14]; regular check-ups and telemedicine provide timely data that could compensate for aggressive interactions with environmental EMFs [18] and could provide control data when new types of devices start to be used regularly, or when new electromagnetic technologies are adopted in human life [1]. EMI checks should be performed following multiple levels of safety to achieve a comprehensive risk assessment; EMI tests on experimental settings including humanoid phantoms and numerical simulations would be preferred. Any new operating conditions (new or improved device, change of EMF environment features, superposition of multiple EMF sources, *etc*.) should be evaluated, while standardized exposure configurations (Helmholtz coils, antenna setting) should be designed and used [3].

3.2. STANDARDIZATION DOCUMENTS

3.2.1. GENERAL NORMATIVES FOR HUMAN PROTECTION

Current international documents, such as ICNIRP guidelines [9] or the IEEE standard C95.1 [10] aim to indicate human exposure restrictions (*i.e*., limitations on acceptable EMF quantities) capable of minimizing risk to public health due to unintended and uncontrolled general exposure to EMF. Figure 3 shows a comparison between the current limits of magnetic field set by the main international normative documents, within the low and intermediate frequency range. In the intermediate frequency range (from tens up to 100 kHz, as adopted by WPT technologies for automotive applications), the reference levels recommended by ICNIRP for the magnetic flux density were upgraded from 6.25 μT (approx. 5 A/m) in the 1998 edition to 27 μT (21.5 A/m) stipulated by the 2010 edition, while the IEEE standard C95.1:2019 states the limit of 205 μT (163 A/m) for the exposure of head and torso (it's the same value as in the former edition of 2005).

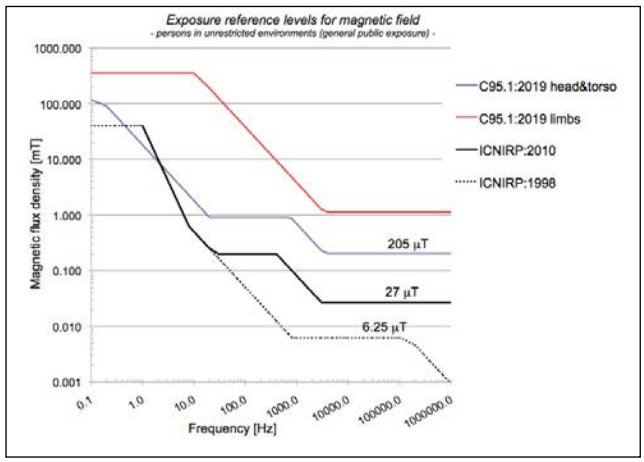


Fig. 3 – Magnetic flux density exposure reference levels for persons in unrestricted environments; comparison between provisions of IEEE std. C95.1:2019 [10] and ICNIRP guidelines (editions 1998 and 2010) [9].

The same tendency of ICNIRP, to increase its recommended reference levels from the 1998 guidelines to

the 2010 version, probably to harmonize with IEEE standards, was observed for human exposure to power-frequency magnetic fields [19], both for unrestricted environments (public exposure) and for occupational environments. However, none of these documents specifies provisions addressed to implanted medical device bearers, although the possibility of interference phenomena occurrence is acknowledged. This position is clearly stated in the ICNIRP guidelines [9]: "Compliance with the present guidelines may not necessarily preclude interference with, or effects on, medical devices such as metallic prostheses, cardiac pacemakers, and implanted defibrillators and cochlear implants. Interference with pacemakers may occur at levels below the recommended reference levels. Advice on avoiding these problems is beyond the scope of the present document but is available elsewhere", and here is referred to the standard IEC 60601-1-2 [20], for electromagnetic compatibility issues of medical devices. A similar assessment is made by the IEEE standard C95.1:2019 [10]: "These exposure limits are intended to apply generally to persons permitted in restricted environments and to the public in unrestricted environments. These exposure limits are not intended to apply to the exposure of patients by or under the direction of physicians and medical professionals, as well as to the exposure of informed volunteers in medical or scientific research studies and might not be protective with respect to the use of medical devices or implants."

Exposure to EMF of AIMD bearers may be restricted especially to the public, but labor safety documents such as Directive 2013/25/EU [21] show more concern for this special category of workers, referred to as a "group at particular risk from EMF" and provides appropriate instructions, as will be seen below.

3.2.2. REGULATIONS FOR PREVENTING INTERFERENCE WITH AIMD

Although international standardization documents recognize the possibility that AIMDs may be affected by EMI phenomena in EMF environments below the recommended levels, it is clearly stated that their provisions do not cover such situations. In [9] it is recommended to look for specific electromagnetic compatibility provisions in the standard IEC 60601-1-2 (at that time, the 3rd edition of 2007 was in force, but now we can refer to the 4.1 edition of 2020), while the IEEE standard C95.1 [10] has a notification in which readers are further directed to technical standards that recommend levels of immunity for implantable medical devices, such as ANSI/AAMI PC69:2007 [22] and ISO/TR 21730:2007 [23].

The European Directive 90/385/EEC named "Active Implantable Medical Devices" came into force in June 2001 and was renewed in May 2021; among other provisions, it basically sets the obligation of manufacturers to provide EMI immunity for the safety of the AIMDs bearers, in compliance with technical requirements of the standard IEC 60601-1-2, mentioned before. First editions (including the 3rd one of 2007) required that essential functions of the electronic medical equipment should not be compromised by exposure to the following immunity limits:

- power frequency magnetic fields of up to 3 A/m (3.8 μT),
- E-fields of up to 3 V/m at frequencies from 80 MHz to 2.5 GHz (typically amplitude modulated at 1 kHz),
- for life support equipment the E-field immunity between 80 MHz and 2.5 GHz is increased to 10 V/m.

Edition 4 (2014), later updated to edition 4.1 (2020) of IEC 60601-1-2 requires the manufacturer of the medical device to increase the immunity levels for devices intended for use in the home healthcare environment [24]. The standard also accepts that achieving these levels of immunity would be difficult for medical equipment to monitor physiological parameters. It, therefore, allows lower immunity for equipment with magnetically sensitive components or circuitry, expecting it to be used in a low field environment.

Under such conditions, IEC 60601-1-2:2020 sets the immunity limit for the power frequency magnetic field to 30 A/m (38 μT), a ten-fold increase compared to the values specified by previous editions (*i.e.,* IEC 60601-1-2:2007). Consistent with new provisions of IEC 60601-1-2:2020, one could also apply an extrapolation technique based on principles used by ICNIRP guidelines [9] (see Fig. 3) to correlate power frequency and intermediate frequency levels for achieving similar electromagnetic induction effects (*i.e.,* electric stimulation); appropriate immunity limit for AIMDs within the intermediate frequency range would be found at approx. 3.2 A/m (4 μT); these are low levels and difficult to achieve in realistic conditions.

European labor legislation, based on the Directive 2013/25/EU [21] gives more precise provisions for human protection against both, direct and indirect effects due to exposure to EMFs; the indirect effects include EMI with AIMDs (such as cardiac pacemakers and defibrillators, cochlear implants, brainstem implants, inner ear prostheses, neurostimulators, retinal encoders, implanted drug infusion pumps) and workers bearing these types of devices form *a labor group at particular risk from EMF*. For this group, *employers should provide additional EMF assessments in workplaces where equipment like inductive or proximity coupling battery chargers are used* [24]. There are no reasons for health-related risks, to consider other protection measures for the public, if the same AIMDs are used for all patients.

3.2.3. REGULATIONS FOR LIMITING ELECTROMAGNETIC EMISSIONS IN EV AND WPT SYSTEMS

Under the technical standard ISO14117 [25] the protocols for EMC testing are presented for implantable cardiovascular devices (cardiac pacemakers, implantable cardioverter defibrillators, and cardiac resynchronization devices), while recent American electromagnetic safety standards IEEE C95.3 [26] and ANSI C63.30 [27] provide recommendations for the assessment, by measurements and computation, of immunity and human safety, from exposure to different environmental EMF sources; the last cited document addresses provisions for WPT emissions. These standards also include provisions for the prevention of EMI effects regarding the electronic devices encountered in a medical environment (hospital) and define the technical documentation (with information on expected levels of immunity) required from the manufacturers of EMF transmitters.

For the same purpose, the company Schmid & Partner Engineering AG [28] provides a special device for EMC testing and validation (according to the mentioned standard ISO14117:2019) of the electric field produced by WPT systems, prior to the assessment of their conformity.

Given that magnetic leakage fields around WPT-based EV charging systems represent the main exposure risk for humans with AIMDs (either from the public, or workers repairing such systems), a few standards have been identified as suitable for the protection of these persons: IEC TS 61980-3 [29], IEC TR 62905 [30], ETSI EN 303 417 [31], the latter being fully experimentally verified in independent laboratories. Two important aspects should be noted: (*) the IEC standards are still being finalized as TS or TR and (**) although different, they are the result of extensive international collaboration.

Fig. 4 shows the four protection zones similarly defined for an EV in all IEC / ISO / SAE standards.

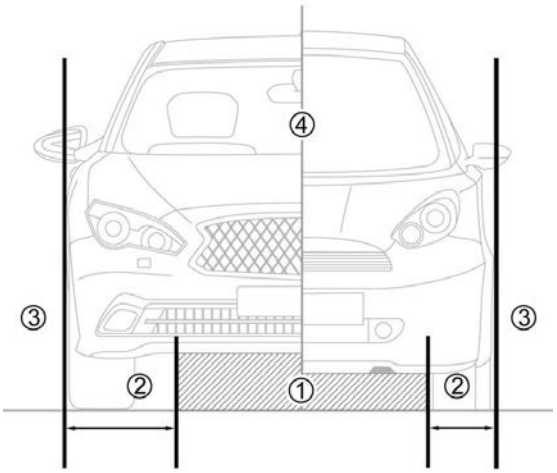


Fig. 4 – Protection zones defined for an EV; 1 - energy transfer zone (lower part of EV - its width is correlated with the dimensions of Tx-Rx in plane), B = Bmax; 2 - lower transition zone, B < Bmax; 3 - outer zone of EV, B < 27 μT (ICNIRP limit for the public); 4 - passenger compartment inside the EV, B < 27 μT.

Except for zones 1 and 2, which are functional areas of the WPT system where human exposure is not permitted, zones 3 and 4 must allow unlimited human access, according to ICNIRP guidelines [9] - the maximum permissible levels of exposure to the electric and magnetic field within the intermediate frequency range are 83 V/m and 27 μT (21 A/m) respectively (Fig. 3). The EMF evaluations should be made at the maximum power of the WPT system in the most unfavorable situation (maximum air gap and offset of the inductive coupling components) [32]. Three-dimensional field probes are used, located at 0.2 m from the EV, and at 0.7 m height from the ground (approximately equal to 1/2 of the EV height). Measurement locations inside the EV (zone 4) are also specified, on the driver and passenger's seat (head, chest, seat cushion, and on the floor) as in Fig. 5.

The maximum permitted electric and magnetic field levels are the same as in outdoor area 3, but measurements are required only if the passenger compartment is occupied during the WPT battery charging process (this is the case for electric buses and taxis). Measurements in area 4 are not usually necessary, because the EV cabin is not normally occupied during wireless charging.

Fig. 5 – Measurement locations in zone 4 (according to [32]).

Protecting the public with cardiac implantable electronic devices (CIED), of which pacemakers are the most widespread, is currently the most important field of EMC in the fabrication and operation of EVs. Documents issued by the American Association of Medical Instrumentation AAMI [33], ISO [34], and ICNIRP [9] agree with the proposal presented by the Society of Automotive Engineers through the SAE J2954 standard [35] as the maximum level for an unobstructed operation of these devices in areas 3 and 4 (as defined in Fig. 4) to be **15 μT** (**11.9 A/m**). For the first time, based on the precautionary principle, this value was included in the "CIED Coexistence Specification" of the SAE together with the following values: maximum 29 μT for temporary operation of the order of minutes and decommissioning of the devices at over 125 μT.

With the expansion of self-driving EV systems for which automatic battery charging will be a default measure, a revision of some of the above values is expected.

4. CASE STUDY - ASSESSMENT OF THE ELECTRIC AND MAGNETIC FIELDS FOR AN EV

4.1. ELECTRIC AND MAGNETIC FIELD EVALUATION BY NUMERICAL ANALYSIS

As a result of a numerical analysis performed on the inductive coupler used for the charging system installed on the electric car Dacia *Electron* [12], the distribution of the electric field was determined [36]. The electric field strength distribution shown in Fig. 6.a is calculated when the inductive coupler is fixed on an EV with a width of 1.8 m. The computed values are lower (36 to 18.5 V/m) than the reference limit level of the electric field strength of 83 V/m set by the ICNIRP guidelines [9] within the intermediate frequency range (3 kHz – 10 MHz), typical for these systems, both at the edge of the vehicle (90 cm from the center) and at a distance of 50 cm from this edge (i.e. at a distance of 140 cm from the center), where passengers or pedestrians supposedly move/walk.

In another FEM study of electromagnetic field on the same couplers, the variation of the magnetic flux density was determined on the surface of the transmitter, from the center up to 300 mm from its edge [37]. The computed values decrease exponentially from 4800 to 4.5 μT (Fig. 6.b); for comparison, the ICNIRP reference level is 27 μT for the public, within the same intermediate frequency range as above. Of course, these results are influenced by the construction of the chassis of the EV, which requires in all cases the experimental verification of these levels.

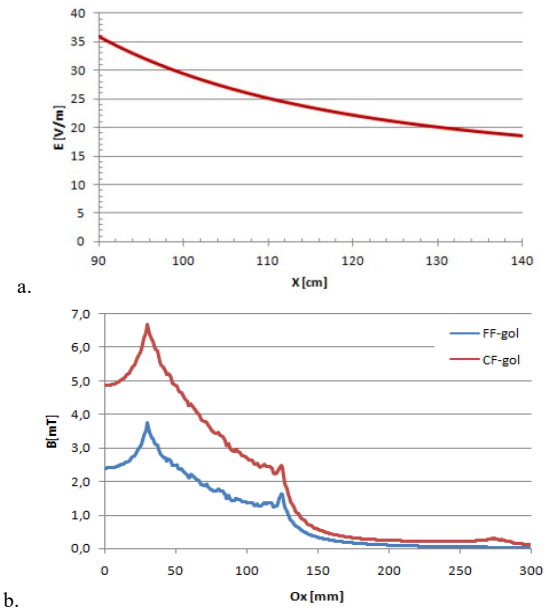


Fig. 6 – Spatial distribution of (a) electric field strength (unperturbed *RMS* values E) [36] and (b) magnetic flux density (unperturbed *RMS* values B) [37], based on the radial distance, measured from the center of the inductive coupler.

4.2. MAGNETIC FIELD MEASUREMENT IN THE LABORATORY AND ON DACIA *ELECTRON* EV

In addition to the attempts to qualify a WPT charging system in which power and energy transfer efficiency is essential for different operating conditions (variable distance and alignment of the transmitter/receiver coils), the magnetic leakage field cannot be neglected when the transferred power is of the order of kW. The measured values of the magnetic flux density vary depending on the distance from the source ($\sim 1/d^3$) and on the three-dimensional nature of this field.

Inductive probes are used for magnetic field measurements; Fig. 7,a shows some models and the isotropic (3D) probe, designed and calibrated by prof. O. Baltag is used for the magnetic field evaluation inside and surrounding an EV [38]; its small dimensions allow the spectrum of the magnetic field to be determined up to the level of the inductive coupler.

Fig. 7 – Magnetic flux density probes; a. Selection of several models: A – 3-D (isotropic) probe achieved by Prof. Baltag – size 10x10x10 mm; 10 turns; sensitivity 5 mV/μT @ 100 kHz; accuracy < 5 %), B – 1D (directional) probe with preamplifier for magnetic flux density harmonics > 100 kHz; C&D - 1D (directional) probes for 1 - 100 kHz; b. Measurements using the 3D probe in the space between the transmitter (Tx) and receiver (Rx) of the WPT inductive coupler [38].

The WPT system was tested to the rated power of 3.7 kW, first in the laboratory, being equipped with structure elements simulating the EV body (Fig. 8): 1.5 mm Al sheet screen and 2 mm steel sheet.

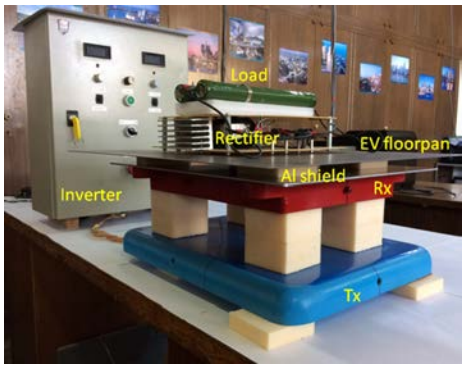


Fig. 8 – Test assembly of the WPT system in the laboratory, with EV body simulation in order to determine the magnetic leakage field.

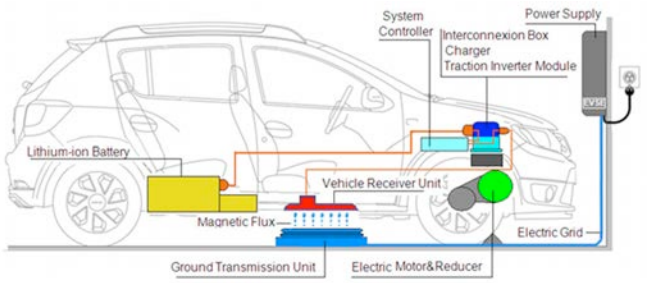


Fig. 9 – The WPT charger implementation on the DACIA *Electron* EV (according to [38])

Further experiments were performed on Dacia *Electron* EV (Fig. 9) fully equipped with the operating WPT system [38]. Fig. 10 gives an example of magnetic leakage field measurement in zone 3 (defined as in previous Fig. 4) made by the authors of [12] on DACIA *Electron* EV, where, if the receiver had been mounted on the longitudinal axis of the EV, all magnetic flux densities values would have been under the limits of 27μT recommended for the general public [9].

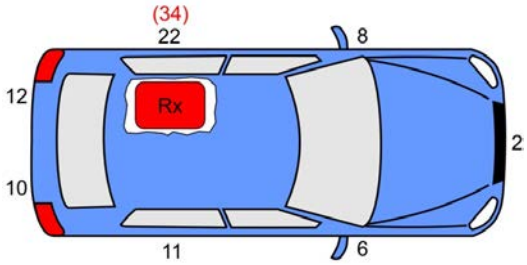


Fig. 10 – Measurements of magnetic leakage field (the *RMS* values of the magnetic flux density B [μT] are marked on the picture) in zone 3 on DACIA *Electron* EV for a transferred power of 3.7 kW [12]

The asymmetrical mounting of the receiver (Rx) was necessary due to the construction of the chassis that was used in the classic vehicle (DACIA Sandero). Initial measurements showed a magnetic flux density of 34 μT (red marking in Fig. 10) close to the Rx coupler. The value exceeds the limits recommended by ICNIRP for the general public, consequently, the additional shielding of the receiver was required; in such conditions, the measured B *RMS* value at the same location was lowered to 22 μT.

5. CONCLUSIONS

The work presented here summarizes some significant topical and interesting information regarding the interference phenomena between active implantable medical devices and electromagnetic emissions of

intermediate frequency. This range nowadays forms a subdomain of the electromagnetic spectrum in growing use in the automotive industry, especially through the inductive couplers used for battery charging systems based on wireless power transfer.

Occurrence conditions, health effects, protective measures, and restrictive standardization are topics of interest that have been revised to establish the current situation and trends. The paper is based on recent scientific literature and normative documents, by correlating the information extracted from technical standards, as well as from protection guidelines and regulations regarding human exposure to electromagnetic fields. Documentary analysis is based on the expertise and interest of authors in the field of compatibility and electromagnetic interference.

Indirect effects of human exposure to EMF include the potential disruption of AIMD by EMI, and in this context, ICNIRP guidelines [9] clearly state in their final section on *protective measures*, that "it is also essential to establish and implement rules that will prevent … interference with medical electronic equipment and devices (including cardiac pacemakers) …". This is an issue that concerns the medical world today (AIMD manufacturers and medical practitioners), the community of patients who bear these devices in various conditions, and, to the same extent, the EV industry in high demand today by all sections of the population. Adequate limits for human exposure to EMF would be the best type of *protection provision*, which could be relevant to all interested parties. Manufacturers of AIMDs may be looking for suitable shielding solutions for increasing their immunity. On the other side, compliance with the current limits set on the leakage magnetic field produced by the installation of WPT on EV requires the development of measurements and certification on EVs as presented in this paper.

There are currently very few data in international regulatory documents expressed as safety limits for the exposure of people with AIMD, to low and intermediate frequency magnetic fields. The reference limits that provide protection to AIMD bearers when exposed to magnetic field emissions from WPT systems used with EV are extracted here from international standards for *RMS* values of B or H (magnetic flux density, magnetic field strength), as follows:

- The standard IEC 60601-1-2:2020 [20] is largely applied for the design, fabrication, and safe performance of medical devices (including the correct functionality of AIMD) and sets the level of *immunity* for these devices at **38 μT** (**30 A/m**) *in power frequency magnetic field*.
- The standard SAE J2954:2020 [35] dedicated to WPT technologies related to EV equipment specifies as reference levels for the normal functionality of CIEDs *the magnetic field limit* of **15 μT** (**11.9 A/m**) *for the frequency range (79 – 90) kHz*. SAE J2954:2020 is also correlated with ISO 19363:2020 [34] and it attempts to harmonize with the ICNIRP guidelines [9] and with the technical standard ANSI/AAMI/ISO 14117:2019 [25] for EMC issues applied to CIED.

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