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The WebNIR platform: a web tool for the risk assessment of workers with active implantable medical devices exposed to electromagnetic fields

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Abstract

Since 2017, the Italian National Institute of Health (ISS) and the Institute of Applied Physics "Nello Carrara" of the National Research Council (CNR-IFAC) have been among the entities involved in a series of Collaborative Research Calls (BRiC) issued by the National Institute for Insurance against Accidents at Work (INAIL) in the context of the protection of workers with active implantable medical devices (AIMDs) exposed to electromagnetic fields. As part of this collaboration, a web portal has been developed and can be accessed at https://webnir.eu. Among the tools made available on the portal, this work will focus in particular on an interactive procedure to help the personnel responsible for assessing the exposure of workers with AIMDs to electromagnetic fields to implement the procedure and follow the steps for risk evaluation reported in the technical standard EN 50527-1:2017 to identify actions to be taken, if any.

1. Introduction

In recent years, the field of medical technology has witnessed remarkable advancements, particularly in the development and utilization of active implantable medical devices (AIMDs). These devices, ranging from pacemakers and defibrillators to neurostimulators and cochlear implants, have revolutionized the treatment and management of various medical conditions. However, alongside these breakthroughs comes the challenge of ensuring the reliable and safe operation of AIMDs in environments where electromagnetic interference (EMI) is prevalent. The presence of EMI can lead to erroneous operation or malfunction of AIMDs, which in turn can have serious consequences for patients relying on these devices for essential medical support. For instance, interference with a cardiac pacemaker or defibrillator could result in improper pacing, failure to deliver necessary therapy, or even the onset of life-threatening arrhythmias.

To minimize these risks, AIMDs - as medical devices - must meet a series of requirements before being placed on the market, including those relating to electromagnetic compatibility [1]. Specifically, AIMDs manufacturers must guarantee adequate levels of immunity to EM fields (EMF). The minimum requirements are based on the recommendations of the International Commission on Non-Ionizing Radiation Protection (ICNIRP) [2], which establish guidelines to provide protection against known adverse health effects for both occupational and public exposure to EMF.

As far as occupational safety is concerned, the EU Directive 2013/35 [3] on the health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) establishes the EMF levels to which healthy workers can be exposed. Such levels are also based on the recommendations of the ICNIRP. According to the ICNIRP approach, more stringent exposure restrictions are adopted for the general public than for the occupationally exposed population. ICNIRP's rationale for this approach is that the occupationally exposed population consists of adults who are generally exposed under known conditions and are trained to be aware of potential risk and to take appropriate precautions. By contrast, the general public comprises individuals of all ages and of varying health status, and it may include particularly susceptible groups or individuals. In many cases, members of the public are unaware of their exposure to EMF. Moreover, individual members of the public cannot reasonably be expected to take precautions to minimize or avoid exposure.

The minimum levels of immunity required for AIMDs are based on the ICNIRP recommendation for the general public (ISO 17114:2019): AIMDs are expected to function unperturbed when exposed to EMF up to the general population reference levels.

Consequently, since the maximum levels of electromagnetic fields allowed for the general population may be exceeded in the workplace, the risk of EMI on AIMDs should be carefully evaluated. Furthermore, the ICNIRP recommendations provide protection against known adverse health effects but explicitly state that meeting the proposed EMF levels may not necessarily preclude interference with medical devices such as AIMDs. Indeed, at the maximum EMF levels allowed by the ICNIRP guidelines for occupational exposure, potential risks for people with an AIMD cannot be excluded. This is the reason workers with AIMD are considered by the occupational health and safety regulation framework as a particularly sensitive risk group that must be protected against the dangers caused by the interference of EMF.

Within European regulations, a family of standards has been developed to provide procedures for risk assessment of this type of sensitive workers. Such procedures, that are grouped within the EN 50527 family standards, shall be

followed to evaluate the risk of employees with an AIMD exposed to EMF. Given the complexity of the topic, the procedures indicated in these standards are not always straightforward. They may involve different areas of expertise (e.g., occupational health and safety experts, occupational physicians, AIMD-employee's responsible physician, AIMD manufacturer), which are not trivial, particularly for small or medium-sized businesses.

To provide support for employers in conducting this assessment, since 2017 the National Institute for Insurance against Accidents at Work (INAIL), the Italian National Institute of Health (ISS) and the Institute of Applied Physics "Nello Carrara" of the National Research Council (CNR-IFAC) have collaborated through the BRiC projects (Collaborative Research Call) to offer operational tools and support documents for conducting an adequate risk analysis within workplaces. One of the outputs of these research collaborations is the web platform WebNIR (Web tools for the assessment of occupational exposure to Non-Ionizing Radiation), an open platform that can be accessed online at a temporary link: https://webnir2.ifac.cnr.it/index.php?lang=gb and that provides to the user various tools and guided procedures for the assessment of occupational exposure to non-ionizing radiation. One of these guided procedures has been specifically implemented to support the employer in carrying out the risk assessment for workers with AIMDs exposed to electromagnetic fields. This procedure follows what is indicated in the technical standard EN 50527-1 [4], which represents the normative reference that, if respected, allows to meet the requirements of the European directive on the safety of workers exposed to magnetic and electromagnetic fields 2013/35.

In this paper, the EU regulatory framework, which addresses the minimum requirements that AIMDs comply with in terms of electromagnetic compatibility (EMC), is first analyzed. Then, the risk assessment procedure indicated in the EN 50527 family standards is described. Finally, the guided procedure for the application of the EN 50527-1 standard that has been implemented on the WebNIR platform is described.

2 The EMC of AIMD

In the EU, the EMC requirements for AIMDs are provided in the standards of the family EN45502. As for pacemaker and implantable cardioverter defibrillators, EMC requirements are provided in the ISO 14117:2019 - Active implantable medical devices — Electromagnetic compatibility — EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators, and cardiac resynchronization devices [5] (which for these devices superseded the EN 45502-1 "Standard Test for Surgical Implants, Active Implantable Medical Devices" [6] and the other product-specific standards of the family EN 45502-2-1 and 45502-2-2).

All these standards have a common background: the immunity levels are determined to protect the AIMD from the foreseeable electromagnetic environment derived from the European Recommendation 1999/519/EC, which was based on the recommendations for the General Public of the ICNIRP Guidelines 1998 [2].

In **Errore. L'origine riferimento non è stata trovata.**, we reported the comparison between the immunity test level adopted by ISO 14117 and ICNIRP 1998 reference level for the general public and occupational exposure, in the frequency range from 10 Hz to 10 MHz. Consequently, the risks for a worker who wears an AIMD could be considered acceptable if he/she is exposed to EMF levels below the ICNIRP reference levels for the General Public. In workplaces, powerful sources of EMF are likely to be encountered, and reference levels for the General Public can be exceeded. Thus, in workplaces, the safety of a worker who wears an AIMD is not guaranteed anymore. In addition, the aforementioned standards take into account only the EMF sources that can be encountered in common-life scenarios (e.g., LTE/4G cellular phones, Wi-Fi transmitters, etc.).

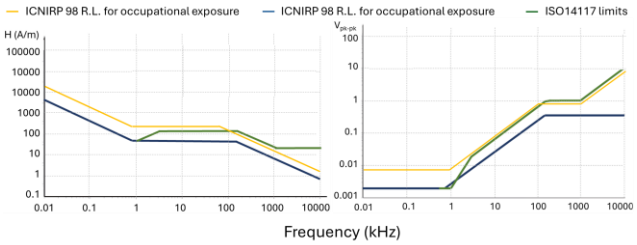

Figure 1. Comparison between the immunity test level adopted by the ISO 14117 and the ICNIRP 1998 reference levels, in the frequency range from 10 Hz to 10 MHz.

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 AIMDs but are not sufficient to protect workers wearing AIMDs. For these reasons, the EU has developed a series of technical standards to support the employers in the risk assessment of workers who wear AIMDs: the general standard EN50527-1 [4] with the particular standards EN50527-2-X for the different AIMD classes.

3. The risk assessment for workers with AIMD

The EN EN50527 family standards 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 AIMD-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 the table, called *whitelist*. A general table, valid for all AIMDs, is reported in EN50527-1. This table is then modified and detailed in the particular standards EN50527-2-X, on the basis of the specific characteristic of the specific class of AIMD considered.

Once all the EMF sources have been identified, the simplified analysis can be considered sufficient if:

- all the EMF sources are listed in the table;

• all the EMF sources are used in accordance with the indication reported in the "exceptions and remarks" column;
• The AIMD employee has not received specific warnings from the responsible physician that the AIMD may be susceptible to EMI from one of the present equipment.

The simplified analysis lies on the assumption that the EMF sources listed in the *whitelist* generate EMF exposure conditions that are below the reference level defined by the 1998 ICNIRP guidelines for the general public. Since the technical standard that addresses the EMC of AIMDs defines the immunity test levels to guarantee the correct behavior of the device up to the ICNIRP 1998 reference level for the general public, workplaces where such limits are not exceeded can be considered reasonably safe for the worker with an AIMD.

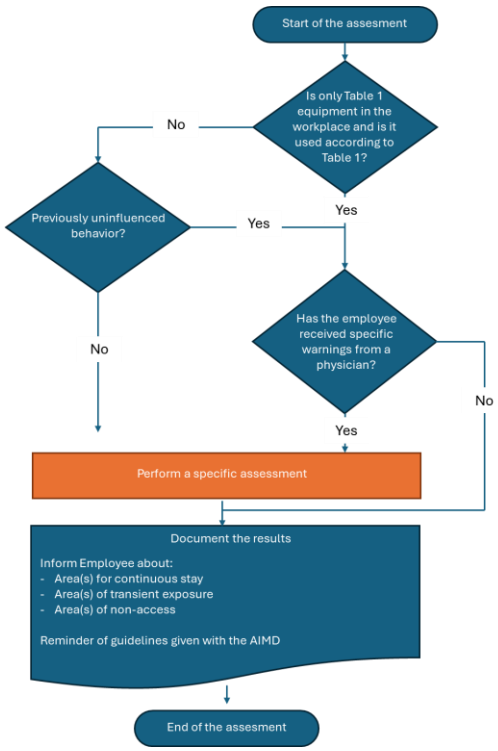

Figure 2. Risk assessment process according to EN 50527-1.

If one of the previously mentioned conditions is not verified, a specific risk assessment shall be carried out, in accordance with the specifications provided in Annex A of the standards. The risk assessment should involve input from: i) the employer and, if applicable, his/her occupational health and safety expert and/or occupational physician; ii) the AIMD employee and his/her responsible physician; and iii) experts (technical and medical), e.g., the 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 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 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.

5. The AIMD section of WebNIR

The guided procedure implemented on the WebNIR platform for risk assessment for workers with AIMDs follows the steps indicated in the technical standard 50527-1, as described in the previous paragraph and schematically represented in Figure 2. As a first step (see Figure 3), after having entered the details of the AIMDs present in the examined worker, the user must indicate whether, in the workplace, there are certain sources of electromagnetic fields, chosen from a pre-established list (i.e., the *whitelist*), indicating for each of these the compliance with the instructions provided in it.

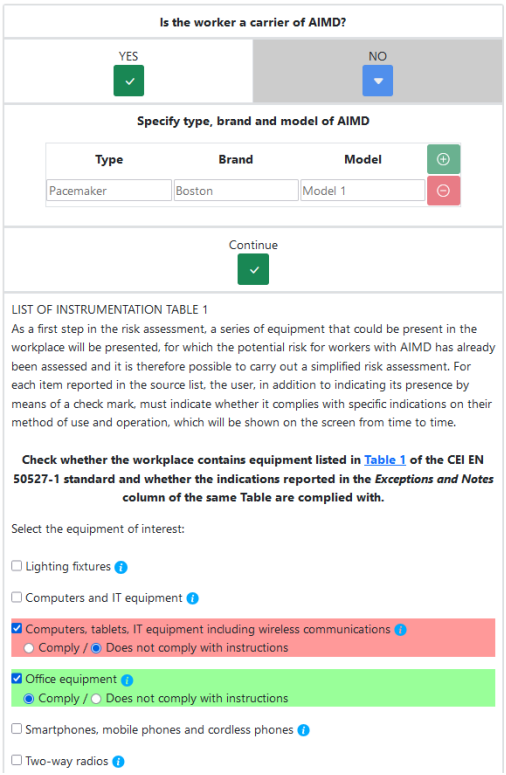

Figure 3. The first part of the online guided procedure.

For such sources, the potential risk for workers with AIMDs has already been assessed, and it is therefore possible to carry out a simplified risk assessment. The user will then be asked to indicate the presence of other sources not listed in the table, and he will finally be presented with a series of questions relating to the work environment and the clinical history of the worker for whom the risk assessment has to be performed. The procedure will conclude with the creation of a report that summarizes the outcome of the risk assessment procedure.

Other advantages related to the use of this tool include:

- the possibility for the operator to modify the route from a specific point without having to repeat the entire procedure from the beginning;
- to export the route followed in PNG format;

- the availability in multiple languages (currently it has been developed in Italian and English).

6. Conclusions

The risk assessment of workers with AIMDs that all the employers shall perform to comply with the EU Directive 2013/35/EU involves an in-depth analysis and a precise characterization of the EMF sources present in the workplace. In this paper, we provided practical indications to help the reader in carrying on this task. The general procedure for the risk assessment should be performed according to the indication of the EN50527 technical standards family, with the assumption that workplaces where ICNIRP 98 reference levels for the general public are not exceeded can be considered reasonably safe for the worker with an AIMD. The guided procedure available online on the WebNIR platform provides practical assistance for employers or those responsible for ensuring workplace safety in conducting a risk assessment that meets the requirements of the European Directive 2013/35 on the safety of workers exposed to magnetic and electromagnetic fields.

7. Acknowledgements

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References

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