14th URSI AT-RASC, Gran Canaria, 19-24 May 2024

Workers with wearable medical devices exposed to electromagnetic fields

Federica Censi[(1)*], Cecilia Vivarelli[(1)], Giovanni Calcagnini[(1)], Rebecca Gasparini[(2)], Fabriziomaria Gobba[(2)], Alberto Modenese[(2)], and Eugenio Mattei[(1)]

(1) Department of Cardiovascular, Endocrine-metabolic Diseases and Aging, Italian National Institute of Health, Rome, Italy

(2) Department of Biomedical, Metabolic and Neural Sciences, University of Modena & Reggio Emilia, Modena, Italy

The diffusion of wearable medical devices (WMD) has grown exponentially in recent years and are widely used among populations of all ages, including workers. The most established and widespread types of WMDs include diagnostic devices such as heart activity trackers and glucose monitors, as well as therapeutic devices like insulin micro-pumps, hearing aids, wearable external defibrillators, devices for improving mobility, and joint prosthetics. In terms of electromagnetic compatibility (EMC), international technical standards require WMDs to be immune to certain electromagnetic field (EMF) levels [1]. These levels are not explicitly based on the guideline published by the International Commission on Non-Ionizing Radiation Protection (ICNIRP 1998 [2]), which provide exposure limits for limiting EMF exposure to ensure protection against known adverse health effects. Indeed, the comparison between the immunity test levels adopted in the WMD technical standards and the exposure limits defined in the ICNIRP guidelines, shows that the electric field immunity test levels at which the medical devices are required to be tested are always below the reference levels for the general population defined in the ICNIRP guideline in the frequency range 80 MHz – 2.7 GHz. In addition, since international guidelines allows for higher exposure limits than those established for the general public, the work environments may introduce additional risks and potential problems for medical devices (including WMD). Workers who use WMDs should be considered at a particular risk from EMF and, in accordance with EU Directive 2013/35/EU, they require an individual risk assessment. Currently, there is no international standard that provides specific guidance on how to perform such a risk assessment. The Italian National Institute of Health has recently published some practical recommendations to employers and/or health physicists for the risk assessment of workers with WMDs [3]. The assessment can be conducted by comparing the field values measured in the workplace with the immunity test levels specified in the technical standards of the WMD. If the measured values are lower than the immunity test levels indicated in the standard, and the distance from the electromagnetic source is greater than the distance used by the manufacturer during the EMC tests (typically 30 cm), the risk for the worker may be considered acceptable. However, if the measured values exceed the immunity test levels or the distance criteria, a specific evaluation based on a case-by-case analysis is required. To perform this evaluation, it could be useful to refer to the series of European technical standards that have been developed to support and guide the employer in the risk assessment of workers who wear active implantable medical devices [4]. Since these standards and these issues are not appropriately and exhaustively known by professionals, it is important to carry out information campaigns that make the professionals involved proactive in the management of these workers. For this reason, the Italian National Institute of Health together with the Italian Association of Medical Radioprotection has started to submit a survey to occupational physicians, in order to estimate the prevalence of workers with WMD and potentially exposed to EMF at the workplace. Such an activity is also supported by the European Joint Action JACARDI (Joint Action on CARdiovascular diseases and Diabetes), which provides a Work-Package dedicated to issues related to workers with these diseases, including workers wearing a MD. The survey will be also distributed to the European partners of the JACARDI project. The survey questions concern the health surveillance visits carried out within occupational physicians' activity and ask for the number of workers exposed to EMF and wearing a medical device (distinguishing among hearing aids, devices to improve mobility, infusion pumps, external defibrillators and others). Preliminary results demonstrate that it is necessary to increase awareness among professionals.

1. International Electrotechnical Commission (IEC). IEC EN 60601-1-2:2015+A1:2021: Medical electrical equipment Part 1: General requirements relating to basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests; 2021
2. International Commission on Non-Ionizing Radiation Protection (ICNIRP). Guidelines for limiting exposure to time-varying electric, magnetic, and electromagnetic fields (up to 300 GHz). Health physics, 74(4), 494–522; 1998.
3. Vivarelli C, Censi F, Calcagnini G, Falsaperla R, Mattei E. Risk assessment for workers with wearable medical devices exposed to electromagnetic fields. Health Physics Journal, in press
4. European standard EN 50527-1: 2016. EMC exposure assessment procedure for workers with active implantable medical devices (DMIA) – Part 1: general requirements; 2016.