TA10 – Non Ionizing Radiations

EVALUATION OF EMF EXPOSURE FROM MEDICAL ELECTRICAL EQUIPMENT

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Abstract – The medical electric and electronic equipment, including electrosurgical devices, short- and microwave diathermy units, and magnetic resonance imaging (MRI) systems, belong to the most hazardous sources of electromagnetic emissions. The electromagnetic emissions can interfere with emissions from other medical equipment located in the same facility (e.g. operation rooms) thus having impact on their work, but more importantly, they can be dangerous to patients, medical personnel operating them and other persons. In the present project, an assessment of EMF intensity was performed for more than 2 000 electrosurgical devices (330 kHz, 440 kHz and 1.76 MHz frequency ranges), 1 200 diathermy units and 45 MRI 0.2 - 1.5 T systems. EMF exposure of medical staff was assessed based on respective national hygienic standards. The actual exposure levels were found to exceed the admissible values in Poland. The recorded EMF intensities were compared with relevant WHO and UE recommendations (e.g. ICNIRP guidelines, 1998, Directive 2004/40/EC). The findings revealed that for 18% of the devices examined, the EMF was higher than the EMF intensity values recommended by UE.

Keywords: electrosurgical devices, diathermy, MRI, EMF exposure, health protection.

1. INTRODUCTION

All electric and electronic systems and installations radiate electromagnetic fields (EMF) to the environment. The EMF emissions may disturb normal functions of other electronic devices but they can also pose a health hazard to the patients, medical personnel operating them and other persons. A modern approach to the problem of ensuring a high level of the protection for humans and for the devices is two-fold. It involves both the technical standardization of the device to ensure proper functioning of the product before it is marketed and used, and the biological and hygienic (biohygienic) standardization to ensure safe and healthy use of the product according to the current state-of-the-art. As laid down in Article 2 of Directive 93/42/EC on medical products [1], EU Member States shall take steps necessary to ensure that medical products can be marketed and used only when, after they have been properly installed, maintained and used according to their intended application, they do not pose hazard to the safety and health of the patients, users and where applicable, of other persons. Another regulation on the safety requirements for medical devices are the EN 60601-2 standards on medical electric equipment [2-3]. As a potential occupational hazard, the EMF of the 0 Hz-300 GHz frequency range are subject to obligatory exposure monitoring. The current admissible occupational exposure limits have been included in the Regulation of the Minister of Labour and Social Policy [4], and for environmental exposure, in the Regulation of the Minister of Environment [5]. In order to protect workers who operate the EMF-emitting devices and systems, periodical measurements of EMF intensity and distribution are performed. According to current national MAI limits, three protective zones: intermediate, dangerous and hazardous, corresponding to the distribution of EMF intensity, have been distinguished. The Polish guidelines on EMF exposure limits (amended in 2001 for occupational exposure and 2003 for environmental exposure) which are based on the biological effects observed at low,

non-thermal EMF intensity levels, differ considerably from those recommended by WHO or ICNIRP (1998) [6] or EU Directive 2004/40/EEC [7]. In ICNIRP guidelines, only the well-documented current effects and thermal effects of EMF exposure have been adopted as the basis for EMF exposure limits. The 1998 Recommendation [8] is the common EU document regarding EMF exposure limits for the general population. However, the Recommendation is more of a guideline than an obligatory provision.

The present paper discusses the outcomes of medical personnel and other persons EMF exposure evaluation for electrosurgical devices, microwave diathermy units and magnetic resonance imaging (MRI) systems. The following exposure parameters were examined: electric and/or magnetic field intensity, effective exposure time, and protective zone extent.

2. ELECTROSURGICAL DEVICES

Recently, the Draft Standard EN 60601-2-2 "Medical Electrical Equipment – Part 2-2: Particular requirements for the safety of high-frequency surgical equipment" [2] has been subject to a general assessment via a questionnaire survey. The standard refers to the devices with output power lower than 50 W. The findings of a comprehensive project carried out by the Nofer Institute of Occupational Medicine (NIOM) in Lodz revealed that the electrosurgical devices are a source of EMF emissions to the environment (Fig. 1) which not only affect the functions of other medical devices but also pose a health hazard to the medical personnel operating them.

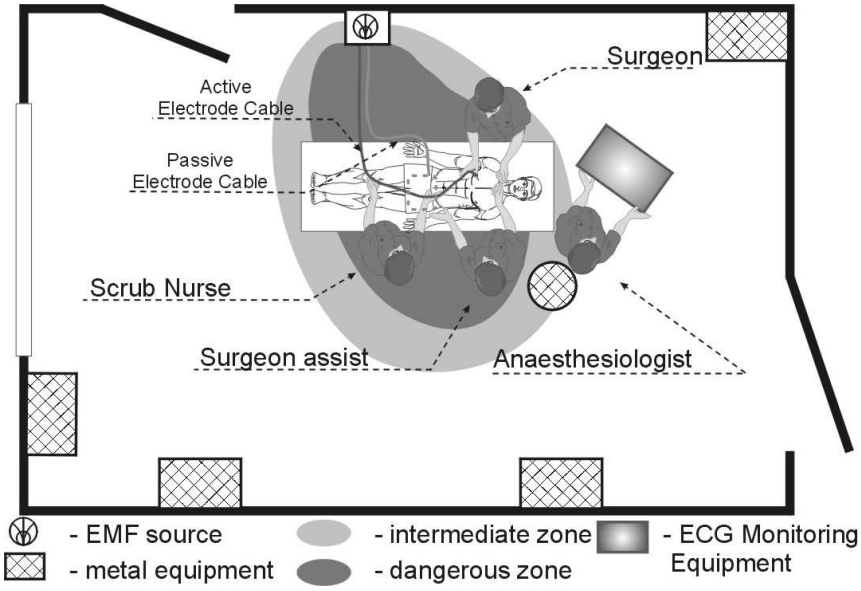

Fig. 1. EMF distribution in particular safety zones, as in relevant Polish regulations.

A total of 2255 electrosurgical devices operating at 330 kHz, 440 kHz and 1.76 MHz frequency ranges were analysed. Three categories of the devices, classified by output power, were distinguished: below 50 W, between 50 W and 300 W, and above 300 W. The electric field intensity in the immediate surrounding to the electrosurgical devices (f = 0.33 MHz, P = 70 W) during a breast resection was 128 V/m for the operating surgeon, 90 V/m for the assisting medical staff, and 11 V/m for the anaesthesiologist. Effective EMF exposure time was about 14 minutes (it can range up to 52 minutes during prostate tumour resection). Detailed measuring results are displayed in tables I and II. Fig. 1 shows EMF intensity in the protective zones around electrosurgical devices, as laid down in respective Polish guidelines.

Operating frequency	Part of device	Output power of device		
		below 50 W	50 – 300 W	above 300 W
f < 1 MHz	Generator	250	700	400
	Quasi-shielded cables	658	1000	1100
	Electrode	700	1000	1000
f > 1 MHz	Generator	125	800	350
	Quasi-shielded cables	350	911	900
	Electrode	820	1000	981

Table I. Highest records of EMF intensity (V/m) measured in the vicinity of an electrosurgical device

Procedure	Duration	Effective working time of electrosurgical device
Quadrantectomy (resection of armpit lymph nodes)	80 min	12 min (15%)
Resection of prostate tumour	120 min	52 min (43%)
Resection of breast tumour	20 min	2 min 14 s (11%)

Table II. Effective exposure time during selected surgical procedures [5]

3. Short- and Microwave Diathermy

The findings of own studies as well as the data recorded at the Central Register of EMF Emission Sources, NIOM, Lodz, Poland, indicate that the maximum values of electric field strength/power density for EMF in workplace range from

- negligible to 235 V/m in the vicinity of short-wave (SW) diathermy, for 540 examined devices (operating frequency 27.12 MHz);
- 0.2 W/m^2 to 22 W/m^2 in the vicinity of microwave (MF) diathermy, for 4 examined devices (operating frequency 2450 MHz).

It was estimated that the dangerous zone around these two types of devices made up 80%, and 75% of workplace area, respectively. During the operation of SW and MF diathermy, EMF was found to penetrate not only the facilities neighbouring the physiotherapy units but also other adjacent facilities such as medical consultancy units, rehabilitation units, or corridors.

4. Magnetic Resonance Imaging Systems

The MRI systems are a source of strong magnetic and electric fields. Superconductive electromagnet generates continuous static magnetic field (the field is present all the time - also in the breaks between the examinations), with induction between 0.2 T and above 3 T; gradient coils emits scanning, low frequency magnetic field of induction (B) changing in time (t), with gradient dB/dt between 10 and 30 mT/s; and a transceiver and sending-receiving coils emits RF field within 20-80 MHz frequency range.

The manufacturer of the device defines the so-called control area around the electromagnet where the static magnetic field induction can be higher than 0.5 mT. The findings of the studies performed at NIOM revealed that the highest values of induction in the working area of medical personnel operating MRI systems ranged from 80 mT to ca. 500 mT. The vertical section of induction in protective zones surrounding MRI system (MAGNETOM Concerto)

with 0.2 T power (the lowest available) is presented in Fig. 2. As one can see, the medical personnel, the patient and other persons staying at MRI facility, they all are within the range of the dangerous zone or even the hazardous zone. The range of each zone category was defined. Worthy of note are the high levels of constant magnetic field induction in the working areas of open MRI systems despite the lowest available induction values of the main electromagnet. The duration of staying at MRI facility ranged from a few to over 20 minutes at a single examination. This applied not only to medical staff of MRI diagnostics unit and the patient but also to the patient's family members, medical staff from other departments, and auxiliary staff (e.g. cleaning service) Fig. 2 presents vertical section of static magnetic field distribution around an open MRI system, 0.2 T.

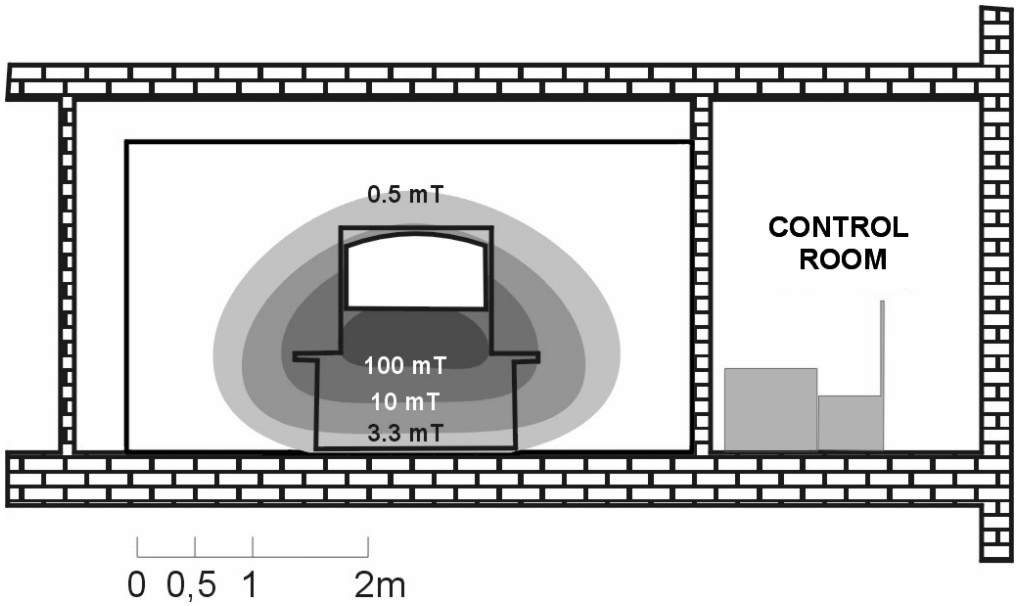

Fig. 2. Vertical section of static magnetic field distribution within protective zones around 0.2 T MRI system (MAGNETOM Concerto, Siemens)

5. Comparative Analysis of WHO, EU and National Regulations on EMF Exposure Conditions for Medical Personnel and Other Persons (Selected Medical Equipment)

The comparison of the project outcomes with EMF exposure levels required by the Directive 2004/40/EC and ICNIRP (WHO) recommendations implies that ca. 18 % of the units examined fail to meet these requirements.

5. 1. Electrosurgical Devices

Fig. 3 displays the results regarding EMF distribution by electric component for electrosurgical devices with output power range from <50 W to >300 W, compared with respective values laid down in national and EU regulations. They revealed that among the devices with output power below 50 W, as much as 7.8% do not comply with EU legislation on admissible EMF levels by electric component. According to the EU Directive mentioned above, another important exposure parameter is the effective exposure time within 6-min. intervals. The measurements of effective exposure time revealed that during major surgeries employing electrosurgical devices (e.g. tumour resection) this parameter ranged from 14 to 52 min for a single surgery, and it means that in case of longer surgeries allowed levels of exposure are exceeded.

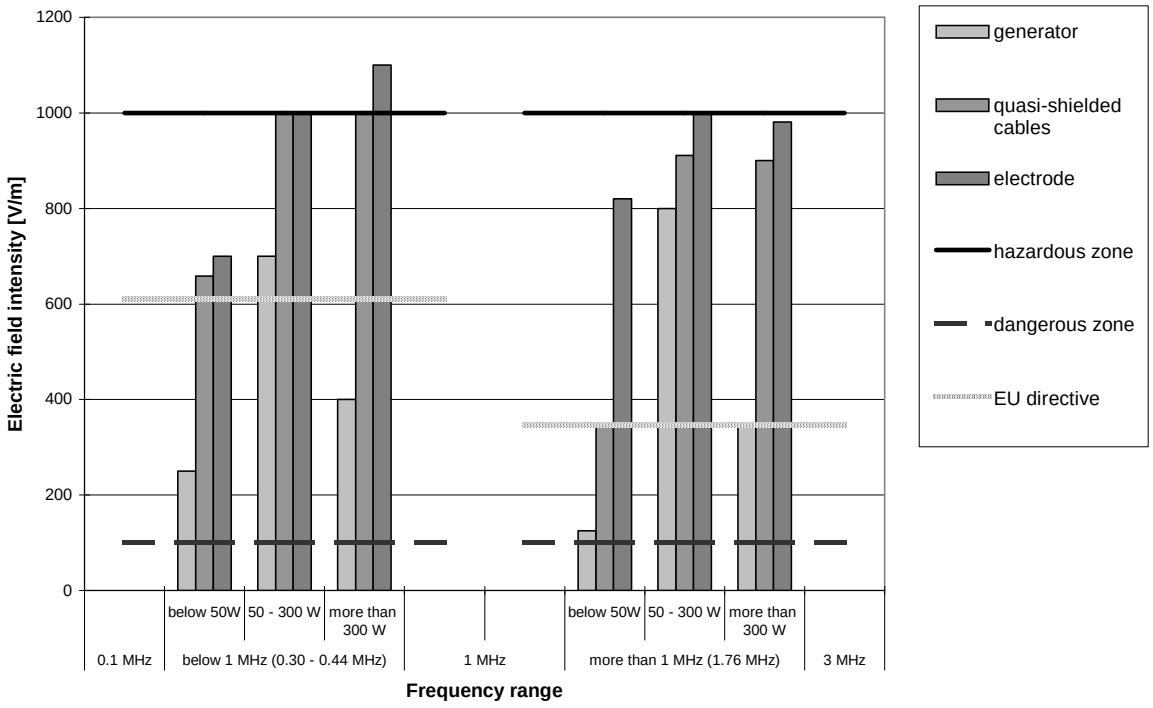

Fig. 3. Electric field intensity around electrosurgical devices: comparative analysis according to the national and EU regulations (Directive 2004/40/EC)

5. 2. SHORT- AND MICROWAVE DIATHERMY

In view of a specific operation procedure in short- and microwave diathermy, namely the very short periods of exposure (up to 1 min, in a series of 2-3 cycles) of medical personnel working close to the electrodes, one may assume that except for emergency conditions, the safety and health requirements of EU Directive 2004/40/EC are generally observed.

5. 3. MRI SYSTEMS

The findings of a comparative analysis of magnetic field induction measurements for 142 MRI systems examined (including 10 covered by own monitoring) and respective national and EU regulations revealed that the values exceeding EU requirements referred mainly to the devices with induction higher than 0.5 T, except for the open MRI systems where excessive values were found for induction levels of 0.2 T, owing to the direct access of medical and other personnel to the main electromagnet.

The monitoring of the duration of exposure to static magnetic field revealed values ranging from a few minutes to 20 minutes for a single examination. The findings indicate that both the national and EU limit values have been exceeded. The results of monitoring static magnetic field intensity in the staff exposure area are displayed in Fig. 4.

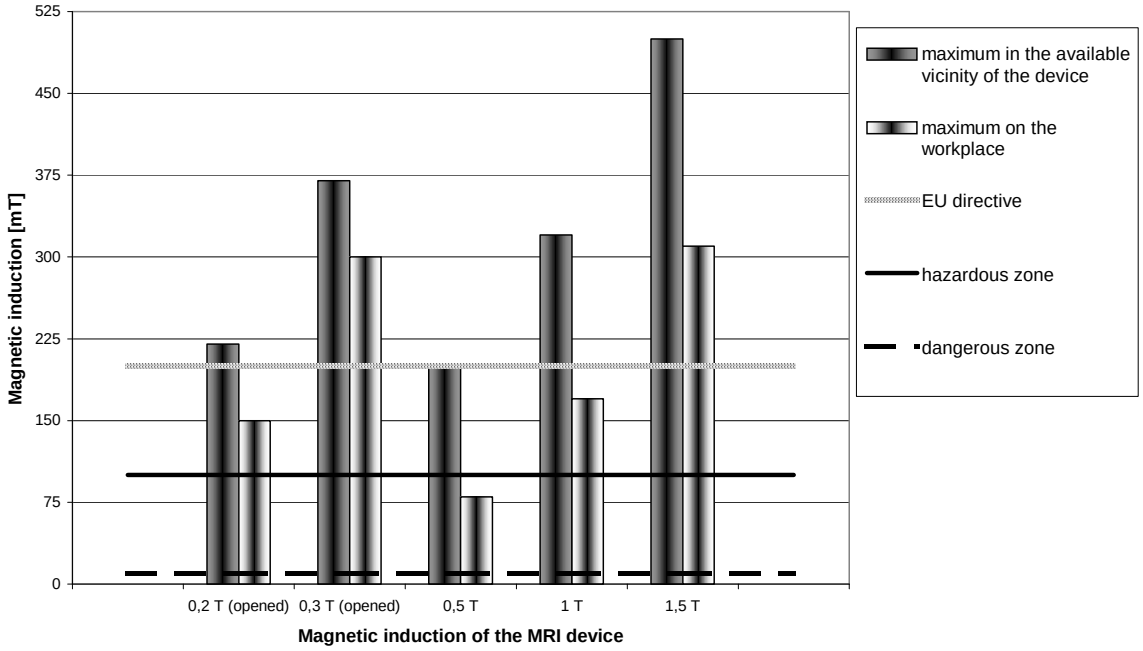

Fig. 4. Static magnetic field in the vicinity of MRI systems: comparative analysis according to the respective national and EU regulations

6. CONCLUSIONS

Considering the technological progress regarding medical electrical devices and the state-of-the-art knowledge on the health and safety of their use, it is necessary to develop close collaboration between the designers and manufacturers and the occupational physicians and hygienists to ensure compliance with the safety and health regulations for medical personnel, the patients and other persons (e.g. the patient's family members). The legal regulations should be applicable also to the technical personnel responsible for the service and maintenance of these devices. The best solution would be to extend the scope of the technical electromagnetic compatibility (EMC) for medical units so that it would also include biohygienic EMC for the protection of human health and environment. The institution responsible for setting respective standards is CENELEC and it would be desirable if it took into account these suggestions while working on the EN 60601-2-… series standards.

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