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ENVIRONMENTAL IMPACT OF THE USE OF RADIOFREQUENCY ELECTROMAGNETIC FIELDS IN PHYSIOTHERAPEUTIC TREATMENT

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ABSTRACT

Background. Electromagnetic fields used in physiotherapeutic treatment affect not only patients, but also physiotherapists, patients not undergoing treatment and electronic medical equipment.

Objective. The aim of the work was to study the parameters of the electromagnetic fields of physiotherapeutic devices with respect to requirements regarding the protection of electronic devices, including medical implants, against electromagnetic interference, and the protection of the general public (patients not undergoing treatment and bystanders), as well as medical personnel, against the health hazards caused by electromagnetic exposure.

Material and methods. The spatial distribution of electric and magnetic field strength was investigated near 3 capacitive short-wave and 3 long-wave diathermies and 3 ultrasound therapy units, as along with the capacitive electric currents caused by electromagnetic field interaction in the upper limbs of the physiotherapists operating these devices.

Results. The physiotherapists' exposure to electromagnetic fields depends on the spatial organisation of the workspace and their location during treatment. Electric fields able to interfere with the function of electronic medical implants and in which anyone not undergoing treatment should not be present were measured up to 150-200 cm away from active applicators of short-wave diathermy, and up to 40-45 cm away from long-wave diathermy ones. Electric fields in which workers should not be present were measured up to 30-40 cm away from the applicators and cables of active short-wave diathermy devices. A capacitive electric current with a strength exceeding many times the international recommendations regarding workers protection was measured in the wrist while touching applicators and cables of active short-wave diathermy devices.

Conclusions. The strongest environmental electromagnetic hazards occur near short-wave diathermy devices, and to a lesser degree near long-wave diathermy devices, but were not found near ultrasound therapy units.

Key words: *electromagnetic hazards, induced current, occupational safety and health, physiotherapeutic diathermies, active implanted medical devices*

STRESZCZENIE

Wstęp. W rehabilitacji fizykoterapeutycznej wykorzystuje się pola elektromagnetyczne, które oddziałują nie tylko na pacjentów, ale także na fizjoterapeutów, pacjentów nie poddawanych tym zabiegom i aparaturę elektroniczną.

Cel badań: Celem pracy była ocena oddziaływania pól elektromagnetycznych urządzeń fizykoterapeutycznych na funkcjonowanie elektronicznych urządzeń medycznych, w tym implantów, w kontekście bezpieczeństwa i zdrowia pracowników, pacjentów nie podlegających zabiegom i osób postronnych.

Materiał i metody. Zbadano rozkład przestrzenny pola elektrycznego i magnetycznego przy 3 pojemnościowych diatermiach krótkofalowych i 3 długofalowych oraz 3 urządzeniach do terapii ultradźwiękami, a także pojemnościowe prądy elektryczne, płynące wskutek oddziaływania pola elektromagnetycznego przez kończyny górne osób obsługujących te urządzenia.

Wyniki. Narażenie fizjoterapeutów na pole elektromagnetyczne zależy od organizacji przestrzennej stanowiska pracy i miejsca ich przebywania w czasie zabiegu. Pole elektryczne, w którym możliwe są zakłócenia w funkcjonowaniu elektronicznych implantów medycznych i nie powinny przebywać w nim osoby nie podlegające zabiegom, stwierdzono w odległości do 150-200 cm od aktywnych diatermii krótkofalowych, a do ok. 40-50 cm od diatermii długofalowych. W odległości do 30-40 cm od kabli i elektrod diatermii krótkofalowych stwierdzono pole elektryczne, w którym nie powinni przebywać pracownicy. Przy dotykaniu do elektrod i kabli aktywnej diatermii krótkofalowej, zmierzono pojemnościowy prąd elektryczny przepływający w ręku wielokrotnie przekraczający zalecenia międzynarodowe dotyczące ochrony pracowników.

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Wnioski. Najsilniejsze środowiskowe zagrożenia elektromagnetyczne występują przy aktywnych diatermiach krótkofalowych, przy diatermiach długofalowych znacznie słabsze, a przy urządzeniach do terapii ultradźwiękami nie stwierdzono takich zagrożeń.

Słowa kluczowe: *zagrożenia elektromagnetyczne, prąd indukowany, prąd kontaktowy, bezpieczeństwo i higiena pracy, diatermie fizykoterapeutyczne, aktywne implanty medyczne*

INTRODUCTION

Posttraumatic rehabilitation and degenerative disease treatment may both involve thermal therapies using electromagnetic energy, such as: infrared, microwave and radiofrequency radiation or ultrasound therapy, in which local exposure to electromagnetic fields (EMF) also occurs [16]. The application of EMF energy causing thermal effects in the body consists in the flow of radiofrequency (RF) capacitive currents (i.e. with a frequency exceeding 0.1 MHz) between two applicators with a high electric potential difference. Such procedures lead to the unintentional dispersion of EMF around the applicators and their supplying cables, being EMF sources (Figure 1). Electric current flows not only through the body of the treated patient, but also through the body of others- the physiotherapist or bystanders, if they find themselves within the EMF, near an active diathermia device (DD), or in direct contact with its EMF-emitting elements [15]. This causes intended effects in the treated patients, but unintended ones in anyone present nearby, such as medical personnel (physiotherapists assisting EMF treatment or other personnel of the medical center, such as physiotherapists doing other therapy or administrative personnel present near by active DD) or bystanders (patients waiting for therapy, being treated by other therapy or their attendants).

Near active DD (being primary EMF sources), even in adjoining rooms, secondary EMF sources may occur, i.e. metal objects emitting induced EMF, such as furniture, water and sewage piping or a central heating installation. The EMF near the secondary sources are usually many times weaker than those from the primary ones.

Because ultrasound emission involves piezoelectric converters supplying time-variable high electric voltage with a frequency of 1÷3 MHz, ultrasound therapy also involves localised exposure to EMF of that frequency near the applicator.

The electric voltage and current in metal objects induced by RF EMF may disturb the work of electronic devices, such as active implantable medical devices (AIMD), (e.g. heart stimulators, cochlear implants and insulin pumps) or diagnostic and therapeutic medical devices (e.g. electrosurgical units) [1]. Such interference may consist in accidentally setting on an alarm in a device, disrupting the sound or image generated by the device, slowing down the pump, stopping or resetting the device or disrupting the transmission between a terminal and its central unit.

Chronic exposure to RF EMF may also be linked with health deterioration, such as the development of cancer (e.g. IARC's classification 2B), and may therefore influence the health of physiotherapists employed for many years near DD [6]. Research on workers exposure

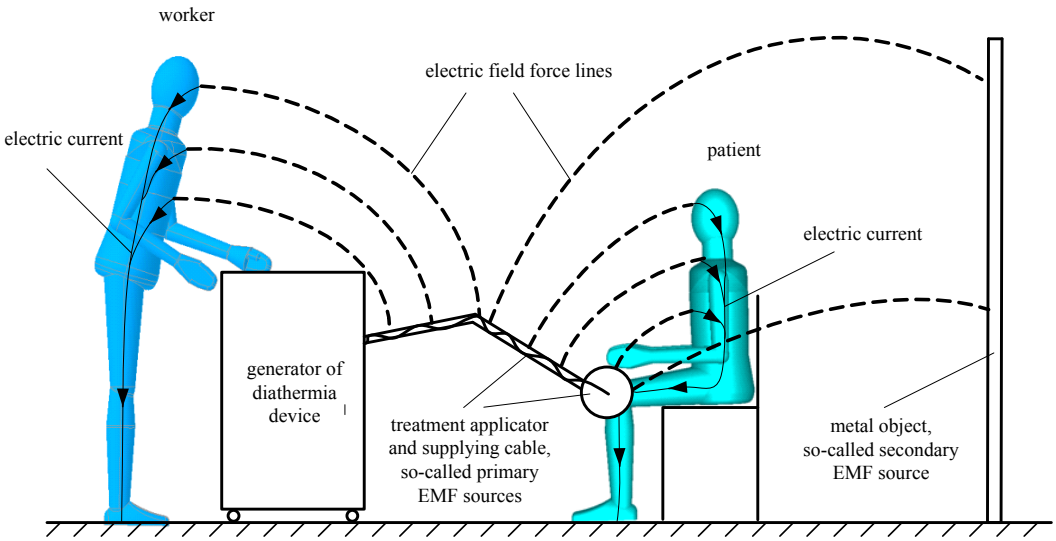

Figure 1. Diagram of impact of electromagnetic fields produced by short-wave diathermy devices (SWDDs) on human and technical infrastructure in treatment room

to RF EMF is among the research priorities of the World Health Organization [19].

The most frequently used parameters characterising the RF EMF impact include electric field strength (*E*) and magnetic field strength (*H*), measured in the environment. They can be used for both an indirect assessment of the hazards arising from thermal effects in humans, as well as the assessment of interference in a device operation. The thermal effects in the body are directly determined using the specific energy absorption ratio – known as SAR – by measuring the temperature increase in the human body phantoms, or by using virtual models [7]. The results of those studies can be used for planning the method of applying EMF to the patient, or for assessing the hazards to the medical personnel or bystanders exposed to EMF dispersed from DD. A SAR assessment cannot be performed in the place of DD use.

Another exposure parameter measured is the electric current flowing through the limbs of a human touching objects affected by the EMF, or staying near an EMF source. It allows the control of the compliance with the limits of the local *SAR* in the limbs, where the strongest thermal effects may occur. Limb current measurements can be performed in laboratory conditions and where DDs are used.

The measurements of electric and magnetic fields strength are routine environmental impact tests performed in the workplace. The current flowing in the limbs is measured sporadically, only by a few research units world-wide.

The results of our survey among 37 members of the physiotherapists indicate that they received insufficient information about EMF hazards at work (39% of responses). In addition, the technical data available to users lack detailed information about the level and range of the EMF around DDs. Information about the environmental impact of the EMF is limited to general warnings about possible adverse effects on AIMD. Consequently, the identification of the scale of EMF hazards to humans and electronic devices may be inappropriate, and therefore the preventive measures applied at physiotherapeutic centres may be inappropriately suited to the actual needs.

The aim of the study was to evaluate the EMF generated by DDs in the context of requirements for protecting electronic devices, including AIMD, against electromagnetic interferences, and protecting the health and safety of the general public (bystanders) and medical personnel.

MATERIAL AND METHODS

The subject of the study included the parameters of EMF present around short-wave and long-wave DDs and ultrasound (sonotherapeutic) devices during the course of therapy. The aim of the study was to evaluate the safety of electronic devices used in the vicinity of active DDs, as well as the safety of anyone not involved in the therapy – medical personnel and bystanders. The EMF exposure to therapeutic patients was not investigated.

The evaluation of the environmental impact of EMF in the vicinity of active DDs included the measurement of electric field strength (*E*), expressed in volts per metre (V/m) and magnetic field strength (*H*), expressed in amperes per metre (A/m). According to the requirements of regulations and standards, the primary field was measured in the absence of humans in the measurement area [3, 7, 14, 17]. When assessing the EMF impact on electronic devices, the maximum value of the signal was accounted for, regardless of its modulation; whereas, when assessing the impact on humans, both the maximum value and the mean value in time (correlated with thermal effects) were taken into account [12].

During the measurements, the tested devices operated with the following settings:

- short-wave diathermia devices (SWDDs, type Curapuls, by Enraf-Nonius) – continuous or modulated wave with a maximum duty cycle and pulse duration, as well as a maximum power output; emitted EMF of 27.12 MHz frequency, used capacitive applicators, output power of 350 W (continuous wave) or 1000 W (pulsed modulated);
- long-wave diathermia devices (LWDDs, type Skanlab Bodywave by Labyrynt Development AS) – continuous or modulated wave with a maximum duty cycle and pulse duration, as well as a maximum power output; emitted EMF of 1 MHz frequency, output power 1 W at 100 ohms load;
- sonotherapeutic units (SU, type Sonicator by Mettler Electronics Corp.) – a modulated wave with a maximum duty cycle and power output, emitted EMF of 1 MHz frequency, output power of 20 W.

In all cases the measurement results were normalised - taking into account the modulation parameters and the metrological parameters of the meters - versus the values corresponding to the maximum value of the electric or magnetic field strength - during the pulse or the continuous wave.

During the SWDDs use, applicators are located near the patient's body without the help of a physiotherapist – their contact with the active SWDDs may happen only sporadically, but in the course of LWDDs or SUs use continuous quasi-massage by the active applicator handled by physiotherapist is performed. An additional assessment regarding the thermal effects in the body was made based on the measurements of currents flowing in the limbs *I*, expressed in milliamps (mA) – Figure 2 [9].

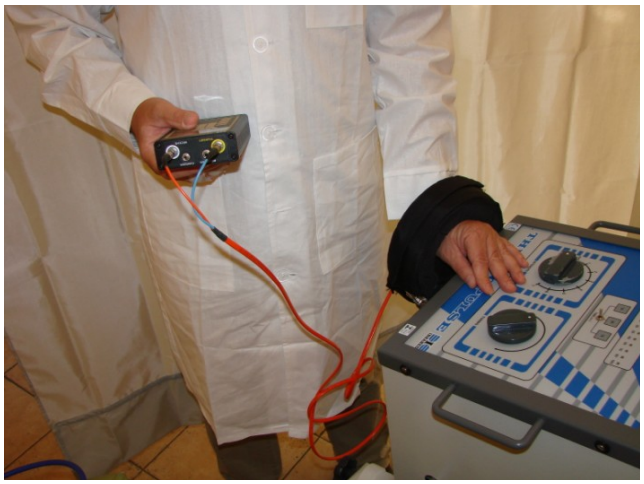

Figure 2. Measurement of electric current in upper limb of worker touching control panel of short-wave diathermy device generator with the use of clamp-on current meter

During the measurements near SWDDs, the patient's body load was simulated by a 1.5 litre container of 1% NaCl solution. Near LWDDs and SUs measurements were carried out during routine physiotherapeutic procedures, using an active applicator touching the patient's hand.

Devices

The EMF measurements were carried out using a broadband meter: Narda EMR-300 (Germany), equipped with isotropic probes for measuring the RMS values of electric and magnetic field strength: type 9.2 with a measuring range of 0.4 to 1,400 V/m, within the frequency band of 0.1 to 3,000 MHz, and type 12 with a measuring range of 0.02 to 16 A/m, within the frequency band of 0.3 to 30 MHz. The current flowing in the arms of the physiotherapists was measured using the RMS value meter type HI-3702 by Holaday (USA), with a measuring range of 1 to 1,000 mA, within the frequency band of 0.009–110 MHz. The sensitivity of the apparatus enabled the performance of a reliable assessment of the environmental impact near the DDs. The measurement uncertainty did not exceed 20%, in accordance with relevant requirements [14]. The accuracy of the meters was tested in an accredited calibration laboratory CIOP-PIB (accreditation certificate from Polish Centre for Accreditation No AP 061).

RESULTS

Measurements in the vicinity of 3 SWDDs with capacitive applicators, 3 LWDDs and 3 SUs were carried out in different physiotherapeutic centres in Poland. The DDs represented typical construction solutions,

Table 1. Measurement results of electric field strength root mean square value near physiotherapeutic devices

Place of measurements near physiotherapeutic devices	Electric field strength E [V/m]		
	Kind of device		
	SWDDs	LWDDs	SUs
Distance from treatment applicators and supplying cables :			
10 cm	760-1160	170-750	4-10
30 cm	200-640	50-180	1-5
50 cm	85-110	20-60	< 2
100 cm	12-30	5-20	< 1
150 cm	5-20	1-5	< 0.4
200 cm	2-15	< 2	< 0.4
Distance from generator in front of control panel. where worker approach:			
10 cm	30-50	10-25	< 2
30 cm	10-30	5-10	< 1
50 cm	7-10	< 5	< 0.4

- 0.4 V/m –sensitivity of measurement device
SWDDs – short-wave diathermy devices; LWDDs – long-wave diathermy devices; SUs – sonotherapy units

Table 2. Measurement results of magnetic field strength root mean square value near physiotherapeutic devices

Place of measurements near physiotherapeutic devices	Magnetic field strength H [A/m]		
	Kind of device		
	SWDDs	LWDDs	SUs
Distance from treatment applicators and supplying cables:			
10 cm	0.70-3.0	0.30-0.40	0.02-0.05
30 cm	0.10-0.50	0.20-0.30	< 0.02
50 cm	0.05-0.30	0.02-0.1	< 0.02
100 cm	0.02-0.10	< 0.02	< 0.02
150 cm	0.02-0.05	< 0.02	< 0.02
200 cm	< 0.02	< 0.02	< 0.02
Distance from generator in front of control panel. where worker approach:			
10 cm	0.20-0.30	0.1-0.2	0.02-0.1
30 cm	0.10-0.20	< 0.02	< 0.02
50 cm	0.02-0.05	< 0.02	< 0.02

- 0.02 A/m – sensitivity of measurement device
SWDDs – short-wave diathermy devices; LWDDs – long-wave diathermy devices; SUs – sonotherapy units

Table 3. Measurements results of current root mean square value flowing in upper limb of workers while operating investigated physiotherapeutic devices

Measurement conditions	Electric current I [mA]		
	Kind of device		
	SWDDs	LWDDs	SUs
Worker touching control panel	3-120	2-4	< 1
Worker touching treatment applicator	23-560	5-6	< 1
Worker touching cable supplying treatment applicator	13-780	4-6	< 1

- lesser values in given ranges were measured while worker standing in longer distance touched particular element of device by straight hand, greater when approach to the investigated device
- 1 mA – sensitivity of measurement device
SWDDs – short-wave diathermy devices; LWDDs – long-wave diathermy devices; SUs – sonotherapy units

Table 4. Requirements regarding protection against undesirable impact of electromagnetic fields of frequency emitted by SWDDs. LWDDs and SUs

Requirements	Parameter characterizing field / Frequency / (kind of device)			
	Electric field strength E [V/m]		Magnetic field strength H [A/m]	
	0.5-3 MHz (LWDDs and SUs)	27.12 MHz (SWDDs)	0.5-3 MHz (LWDDs and SUs)	27.12 MHz (SWDDs)
International guidelines [2, 3, 7] - values averaged over 6 minutes:				
General public exposure limits. according to ER and ICNIRP	87	28	0.73	0.073
Occupational exposure limits. according to ED and ICNIRP	610	61	1.6	0.16
Requirements of legislation established in Poland [16, 17] - maximum values in time:				
General public exposure limit	20-33	6.7-7	0.8-3.3	0.1
Occupational exposure	33-1000	6.7-200	0.8-100	0.3-3
Prohibited exposure limit	> 1000	> 200	> 100 for 0.5 MHz > 26.6 for 3 MHz	> 3

Notes:
SWDDs – short-wave diathermy devices; LWDDs – long-wave diathermy devices; SUs – sonotherapy units
ER – European recommendation [2]
ICNIRP –ICNIRP guidelines [7]
ED – European directive [3]

also produced as models with similar parameters by other manufacturers and under different trade names.

The results of measurements of electric field strength in the vicinity of the applicators, their supplying cables and the DDs generators are given in Table 1, and the results of measurements of magnetic field strength are given in Table 2. The results of measurements using a current clamp-on probe placed on the wrist of workers are summarised in Table 3. The measurements were made without the participation of the medical personnel of physiotherapeutic centres, under regular conditions in which physiotherapeutic procedures are carried out.

DISCUSSION

The principles of evaluating electromagnetic fields around physiotherapeutic devices

In view of possible adverse effects of the EMF on humans and the material environment, requirements and recommendations for the assessment and mitigation of such exposure have been established. Separate requirements apply to the protection of electronic devices, the general public and workers. Those requirements do not apply to patients undergoing treatment under conditions specified by the requirements for medical procedures. According to the European Directive [4]: "*medical devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety."*

The permissible exposure of the general public to the EMF is determined by the non-compulsory European recommendation implementing the guidelines of ICNIRP – International Commission on Non-Ionizing Radiation Protection [2, 7]. ICNIRP guidelines apply only to protection against the immediate effects of EMF occurring during the exposure or immediately afterwards (recognised as short-term effects). In Poland, the rules for permissible exposure of the general public are defined in a Regulation of the Minister of the Environment and also apply to protection against the adverse effects of exposure, but including the chronic ones (recognised as long-term effects) [18].

The technical requirements for 'electromagnetic compatibility' (EMC) apply, among other things, to the immunity of electronic medical devices supporting the human organism (including AIMD) to the interference caused by EMF. In accordance with the IEC EN 60601-1-2 standard, medical devices should be resistant to interference caused by an electric field with a strength of 3 V/m within the frequency range from 80 MHz to 2.5 GHz [8]. The required immunity level for life-supporting devices is higher: 10 V/m. According to the ICNIRP recommendations, within this frequency band the permissible exposure for the general public is 28-61 V/m (frequency dependent), whereas in Poland it is set as 7 V/m (frequency independent). Within those values, AIMDs should work without any interference, provided they meet the requirements of the aforementioned standard, although with exposures nearing the ICNIRP limit some interference may occur.

The hazards arising from interference in the work of AIMD due to the impact of the EMF are important

for patients, medical personnel and bystanders. Concerning workers who are users of AIMD, the standards for assessing exposure to EMF with a frequency of 0 Hz to 300 GHz say that, in the event of exposure exceeding the limits set by ICNIRP for the general public, a detailed assessment of the conditions of such exposure and hazards caused by possible malfunctions to AIMD is required [5]. Because the SWDDs and LWDDs generate strong EMF, their manufacturers recommend that, for safety reasons, patients with AIMD be excluded from treatment. Although the IEC EN 60601-1-2 standard does not refer to EMF of frequencies generated by DDs. Similar recommendations can be found in publications setting out the rules for physiotherapeutic procedures [13].

Therefore, it was assumed that, in order to assess whether hazards for AIMD users exist, the limits of general public exposure, as recommended by ICNIRP, would be used (Table 4).

The ICNIRP recommendations are also the basis for the requirements set out under the European Directive on workers' exposure. They were also taken into account when drafting the Polish labour regulations (Table 4) [3, 7, 17], which stated that EMF exposure exceeding the limit values for the general public is called "occupational exposure"; whereas the highest EMF exposure is recognised as prohibited exposure (where workers should not be present in the highly exposed area). Only workers who have no medical contraindications to be affected by EMF exceeding the general public exposure level may be subjected to "occupational exposure" [11]. Pursuant to international recommendations, the contraindications include the use of AIMDs, such as pacemakers and infusion pumps. Workers not operating the field source should remain in a location with "non-occupational exposure" – i.e. EMF of a level acceptable for the general public, pregnant women and young workers [11].

Thermal effects in the body are subject to additional assessment based on the measurement of the currents flowing in the limbs [3, 7, 9]. Taking into account the anthropometric dimensions and the anatomical structure of humans, the electrical current with a frequency from 0.1 to 110 MHz passing through the wrist, regardless of the conditions under which it occurs, should not exceed 40-50 mA [10].

The assessment of electromagnetic hazards near to physiotherapeutic devices

During the procedure carried out, the strength of electric and magnetic fields near applicators and cables connecting the generator to the SWDDs applicators was found to be exceeding the exposure limits set for the general public (not applicable to the treated patients) as well as the limits of prohibited exposure for workers [2, 3, 7, 17, 18].

Electric fields exceeding the permissible level of general public exposure set in Poland may occur up to 150-200 cm from the applicators and cables, when the highest output power is used for procedures involving SWDDs; however, magnetic fields at such levels may occur up to 30-40 cm. Within this area, there may be interference in the functioning of AIMD, even if they meet the requirements of the EMC standard [8]. On the other hand, taking into account the criteria for the assessment of exposure to workers set out in national and international regulations, an electric field exceeding the level of prohibited exposure may occur up to 30-40 cm, and for the magnetic field – this can go up to 10 cm from applicators and cables. The level of EMF at a distance exceeding 100 cm from the applicators and cables of SWDDs is determined by the previously mentioned configuration of metallic objects nearby the active SWDDs, which may increase the ranges of electric fields of particular levels – in comparison to the empty space. The small size of treatment rooms and cabins where SWDDs are used at physiotherapeutic centres leads to a situation in which those devices may cause hazards to the medical personnel involved in other activities, as well as patients nearby, involved in other procedures or simply waiting, as well as for medical electronic devices, including AIMD used nearby.

In light of the findings, in the case of SWDDs it is necessary to take preventive measures, such as shielding the cabins in order to limit the range of strong EMF, or providing sufficiently spacious rooms to ensure that strong EMF are kept inside the treatment room or cabin. Restrictions on the general public being near to LWDDs are much smaller (for the electric field assessed against the limits set in Poland for general public exposure it is approximately 40-50 cm from the active applicators and their supplying cables). No EMF at levels exceeding the limits for prohibited workers exposure was found. However, exposure by LWDDs requires attention because physiotherapists hold the applicator in their hands during the entire procedure. Exposure by LWDDs operators is decreased (approximately halved) when cables supplying active and passive applicators are close to each other. The manuals of such devices advise that cables do not come into contact with the medical staff or patient.

The SUs do not emit EMF at levels exceeding the exposure limit for the general public set in Poland.

However, it should be noted that the results of the assessment of the level of both the electric and magnetic fields can be unreliable in assessing the risk for humans directly near the EMF source or touching its elements – for example, if physiotherapists are approaching an active SWDDs and touching the cables supplying the

applicators or the applicators, or when they are holding an LWDDs or an SUs applicator during the procedure. Physiotherapists holding an active SWDDs applicator or touching other components of a DD emitting EMF remains in an area of strong EMFs (exceeding the limit set for general public exposure, and even the level of prohibited exposure), and the electric current flowing in his/her hand reaches several hundred mA. The results of our survey indicate that physiotherapists often touch active SWDDs applicators (29% of responses). This indicates that such exposure may apply to a relatively large number of physiotherapists and should be reduced by minimising duration of activities near an active SWDDs.

EMF generated by SWDDs and LWDDs, as well as the conditions of exposure to patients and medical personnel, may always cause interference in AIMD, and the place of the operation of such devices should be marked with warnings for AIMD users.

CONCLUSIONS

1. Among physiotherapeutic devices, SWDDs are the strongest source of radiofrequency EMF impact, both on medical devices as well as on physiotherapists and other people near active devices.
2. EMF with levels exceeding limits provided for in international recommendations and national regulations as regards general public exposure or the undisturbed operation of electronic devices may occur up to 2 m from applicators and supplying cables in the case of SWDDs, and up to 0.5 m in the case of LWDDs; no such EMF was found near SUs.
3. Carrying out procedures with an active SWDDs applicator results in exposing the physiotherapists to EMFs exceeding the permissible limits, both as regards the medical personnel EMF exposure, as well as the electric currents flowing through the body.
4. The level of medical personnel exposure largely depends on the spatial organisation of workplaces and the type of occupational activities, as well as the distance between the physiotherapists and an active DDs during the procedure. With the EMF switched on, touching applicators and their supplying cables should be prohibited.

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Conflict of interest

The authors declare no conflict of interest.

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