

Measurement of electromagnetic characteristics of BIOMAG - medical device for magnetotherapy

Abstract. Magnetotherapy is physical therapeutic method in human medicine based on the application of pulsed magnetic fields. The magnetic flux density and intensity of electric field were measured for 32 programs of the Biomag device and all its applicators and their combinations (solenoid, triangle, light, solenoid + light, triangle + light). Each program was switched on for 5 minutes with intensity set to 100%. The highest value of magnetic flux density 420.98 μT was achieved by the program with the highest frequency 160 Hz. A statistically significant difference in the magnetic flux density was detected during the application of a radiofrequency signal on the control unit (decrease in magnetic flux density on average by 20.42 μT) compared to without the radiofrequency signal. Using Biomag device under laboratory conditions, an average value of 2.13 μT and the highest maximum 56.78 μT were found. The values did not reach the ICNIRP limits but exceeded the EUROPAEM/BioInitiative recommendations. Simulations and measurements with and without a human head phantom confirmed that low frequency magnetic fields are not significantly attenuated in artificial brain tissue. The measured values in the head phantom ranged from 239 μT to 323 μT . The aim of this study was to verify if the tested device can be used not only for supplemental human magnetotherapy but also for the experimental purposes.

Streszczenie. Magnetoterapia to fizykoterapeutyczna metoda w medycynie człowieka oparta na zastosowaniu impulsowych pól magnetycznych. Zmierzono gęstość strumienia magnetycznego i natężenie pola elektrycznego dla 32 programów urządzenia Biomag i wszystkich jego aplikatorów oraz ich kombinacji (elektromagnes, trójkąt, światło, elektromagnes + światło, trójkąt + światło). Każdy program włączano na 5 minut z intensywnością ustawioną na 100%. Największą wartość gęstości strumienia magnetycznego 420,98 μT uzyskał program o najwyższej częstotliwości 160 Hz. Wykryto statystycznie istotną różnicę w gęstości strumienia magnetycznego podczas przykładania sygnału o częstotliwości radiowej do jednostki sterującej (spadek gęstości strumienia magnetycznego średnio o 20,42 μT) w porównaniu z brakiem sygnału o częstotliwości radiowej. Używając urządzenia Biomag w warunkach laboratoryjnych uzyskano średnią wartość 2,13 μT i najwyższe maksimum 56,78 μT . Wartości nie osiągnęły limitów ICNIRP, ale przekroczyły zalecenia EUROPAEM/BioInitiative. Symulacje i pomiary z fantomem ludzkiej głowy i bez niego potwierdziły, że pola magnetyczne o niskiej częstotliwości nie są znacząco osłabiane w sztucznej tkance mózgowej. Zmierzono wartości w fantomie głowy mieściły się w zakresie od 239 μT do 323 μT . Celem pracy było sprawdzenie, czy badane urządzenie może być wykorzystywane nie tylko do uzupełniającej magnetoterapii człowieka, ale również do celów eksperymentalnych. (**Pomiar właściwości elektromagnetycznych BIOMAG - urządzenia medycznego do magnetoterapii**)

Keywords: Biomag Lumina Clinic device, low frequency magnetic field, pulsed magnetotherapy, CST simulation.

Słowa kluczowe: magnetoterapia, BIOMAG

Introduction

Electric and magnetic fields are widely used for diagnostics and therapy in medical practice. Low frequency electromagnetic fields (LF EMFs) usually do not cause any significant tissue heating, or thermal heating that is lower than the natural temperature fluctuations in the tissue [1]. The effects caused by LF EMFs in the frequency range below 100 kHz are mainly electrostimulating [2].

Magnetotherapy as a therapeutic method uses a pulsed LF magnetic fields (MFs). It could affect biochemical reactions within and between the cells, as well as higher permeability of the cell membranes [3]. The MFs affect the magnetomechanical effect in biological tissues, which is caused by changes in the orientation of RNA and DNA macromolecules [4]. Physical effect originates in the principle of electromagnetic induction phenomena, result of which are eddy currents. The magnitude of these currents depends on a magnetic flux density, frequency and length of the object [5, 6]. Pulsed MFs may increase the rate of metabolism [7], blood flow and oxygenation of the body part [8] where MFs are applied, thereby speeding up the healing and regeneration process. Magnetotherapy is used mainly to treat pain, improving musculoskeletal disorders, post-traumatic conditions and damaged tissues [9]. It also can be applied to treat diseases of the nervous system such as multiple sclerosis [10], for supportive treatment of osteoporosis [11] and joint replacement (because magnetotherapy does not overheat the osteosynthetic material). LF MFs can inhibit tumour growth and are

effective in combination therapy with chemotherapeutic drugs [12, 13].

The Biomag Lumina Clinic device (Czech Republic, Biomag) works as a source of LF MFs as part of treatment, preventative care or rehabilitation. It can be applied at the surface of any part of the human body. Biomag defines 6 basic treatment effects according to the frequency range: analgesic (dominant for frequencies 1-10 Hz), muscle relaxant (3-12 Hz), anti-edema (7-22 Hz), vasodilating (10-44 Hz), detoxifying (11-160 Hz) and anti-inflammatory effect (17-160 Hz) [14]. Two applicators for Biomag are constructed as air coils made from a copper conductor with leatherette coverage. Third applicator contains the coil together with a light source, which is used for phototherapy using polarized light. Thus, in combination with a pulsed MF it can increase the healing effect. The manual describes combinations of frequencies for given programs, however, the parameters for the intensity of electric field (E-field) and magnetic flux density (B-field) are missing. Therefore, we decided to perform measurements in order to complete the factory data, as we will utilize the Biomag not only for medical human therapy, but also for scientific (experimental) purposes on animals.

Thus, our study included 4 measurement routines: (I.) determination of B-field and E-field generated by Biomag applicators at particular frequencies, (II.) B-field measurement of Biomag during EM interference by a radiofrequency (RF) signal simulating a mobile phone, (III.) detection of MF levels in the laboratory where the device is

used and their comparison with ICNIRP limits [15], (IV.) measurement of MF attenuation in the artificial brain tissue of the head phantom, and comparison of the values with results obtained from numerical simulations.

Materials and methods

In this study, the pulse medical magnetotherapy device Biomag was used as the source of LF EMF. Three applicators of the device were used: solenoid, triangle and light. According to the datasheet [14] the 3D field solenoid has MF with maximum B-field of 4 mT. The triangle is basically a flat type applicator folded into triangle shape generating the B-field up to 4 mT. The light applicator produces polarized light with the same frequency as the B-field pulses with maximum B-field of 16 mT.

I.) The first procedure was based on the measurement of B-field and E-field in individual magnetotherapy programs in each applicator. The receiving antenna Narda EHP-50D (Narda Safety Test Solutions, Germany) connected to the Narda NBM-550 EMF analyser (Narda Safety Test Solutions, Germany) via an optical fibre was placed inside of particular applicator 10 cm from the edge (Fig.1.). Each of the 32 available programs have own combination of frequencies which alternate within the range from 1 Hz to 162 Hz. The tested clinic version of Biomag allows user to change MF intensity within the range 50–100%. Fig.2. depicts representative comparison of 100% and 50% MF in program number 21 for B-field (a) and E-field (b). The characteristic pulsed behaviour of the device during 20 minutes shows program number 17 (Fig.2.(c)). Last program number 32 is suitable to set both frequency and MF intensity by the user. In this program, the 14 most often frequencies were selected, thus, 14 new programs with the corresponding frequency were created.

During the measurements, each program was switched on for 5 minutes with intensity set to 100% representing the lowest possible therapy time but maximum possible B-field. The root mean square (RMS) value of B-field, E-field and corresponding frequency were measured every minute. This procedure was repeated for each type of the applicator or their combinations (solenoid, triangle, light, solenoid + light, triangle + light). E-field values for each frequency were measured using the marker function of the EMF analyser. Totally 3250 values were measured for B-field (1625 values) and E-field (1625 values).

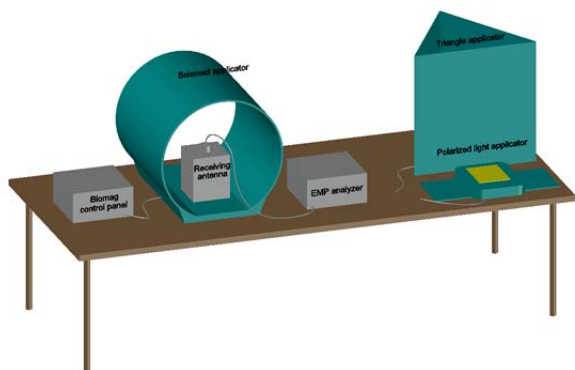


Fig.1. Design of the exposure and analysis system.

II.) The Biomag's interference with mobile phone using RF EMF was tested. According to the Biomag manufacturer, mobile phone should not be used in a vicinity to any part of the device. The RF transmitting antenna GSM/DCS/PCS 900/1800/1900 MHz (Yageo, Taiwan), simulating a mobile phone, was placed 1 cm above the device's control unit. Measurements were performed under three frequencies: 900 MHz, 1800 MHz and 2100 MHz,

corresponding to GSM800, GSM1800 and UMTS2100 standards. Biomag's programs were switched on with the most often frequencies (5.5, 6, 8, 8.5, 9.5, 11, 15, 17, 20, 25, 33, 46, 70, 160 Hz) and for all types of applicator. The receiving antenna remains in the same place as in the measurement routine (part I.). For each type of applicator and their combinations, a comparison was made between the group with and without RF signal exposure. Data were tested for normal distribution and a Wilcoxon signed-rank test and paired Student t test were chosen, using Jamovi statistical software. The results were considered as significant at $p < 0.05$.

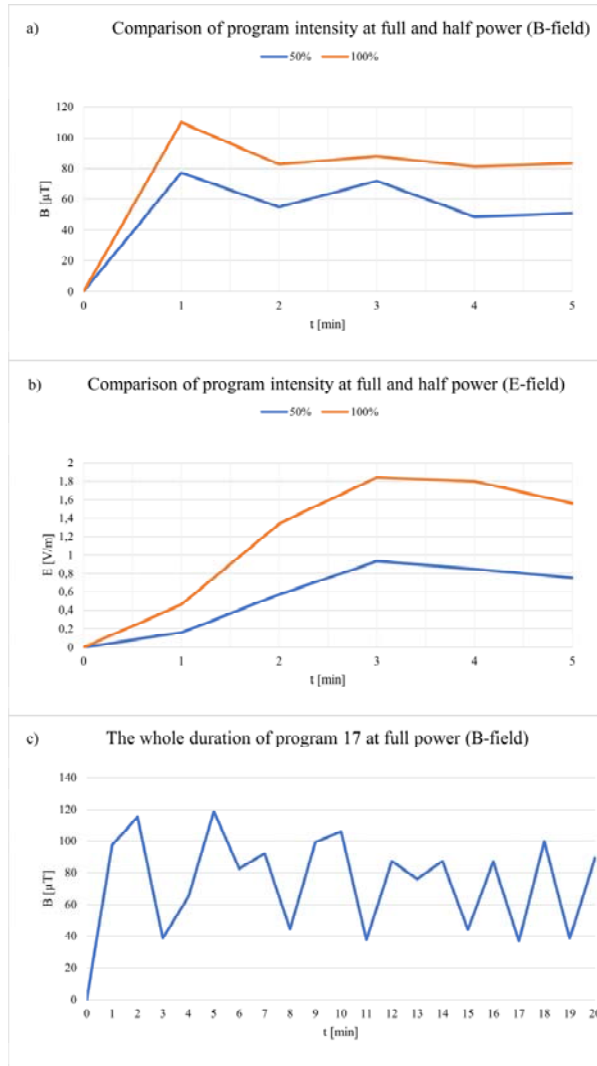


Fig.2. B-field (a) and E-field (b) values during the 5-minute interval at half and full power. (c) Duration of 20-minute program at 100% intensity.

III.) B-field values were measured in the laboratory. All devices inside the laboratory except the Biomag were turned off in the room during the measurement. Biomag programs were switched on with the most often frequencies and for all types of applicators. The receiving antenna was placed within each square meter of the laboratory at a height of 1 m from the floor according to proposals of the Australian Radiation Protection and Nuclear Safety Agency [16]. Thus, 18 measurement points for the laboratory space were obtained.

IV.) In this routine, only one coil of triangle applicator was connected to the control unit. A human head phantom [17] was inserted into the applicator so the active coil was located at the "nose" position in the transverse plane

(Fig.3.). MF inside the phantom was measured with a gaussmeter HGM09s equipped with an axial probe HGM09-AP (MAGSYS magnet system, Germany). For comparison, the same measurement protocol was implemented for the applicator without phantom, where the gaussmeter probe was placed at the same position, but in the free space of the applicator. Exposure to LF MFs from Biomag was numerically simulated in CST Studio Suite (Dassault Systèmes, France). The male phantom Gustav (CST Voxel Family) with a resolution of $2.08 \times 2.08 \times 2.0 \text{ mm}^3$ was used to provide information about the MF distribution in the head. The dielectric properties of the tissues for particular frequency was adjusted according to the database [18]. All information related to the coil and applicator were taken from the Biomag datasheet [14]. According to the following formulas, the number of turns of the coil (1) and the electric current (2) were calculated as input parameters for numerical simulations. Based on the normality test, the Wilcoxon test and the paired Student t test were used in the statistical software Jamovi. Results were considered significant at $p < 0.05$.

$$(1) \quad N = \frac{l}{d}$$

where: N is the number of turns of the coil [-], $l = 27 \text{ mm}$ is the length of the coil and $d = 0.9 \text{ mm}$ is the diameter of the turn.

$$(2) \quad I = \frac{U}{R}$$

where: I is electrical current [A], U is a voltage [V] of coil measured by multimeter Brymen BM257S and R is a resistance [Ω] measured by the same multimeter.

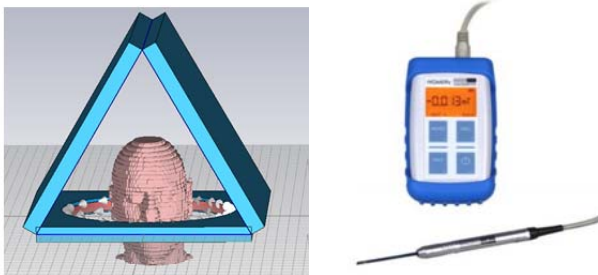


Fig.3. Exposure of human head phantom in CST Studio Suite (left) and gaussmeter HGM09s (right).

Table 1. The most often frequencies and corresponding measured mean values of B-field and E-field.

f [Hz]	Mean \pm SD	
	B-field [μT]	E-field [V/m]
5.5	132.87 ± 54.13	1.01 ± 0.64
6	153.17 ± 71.50	1.98 ± 1.03
8	179.52 ± 89.92	0.54 ± 0.46
8.5	180.38 ± 107.48	4.29 ± 2.89
9.5	189.13 ± 80.70	0.95 ± 0.33
11	205.18 ± 108.09	0.82 ± 0.48
15	217.53 ± 103.51	0.37 ± 0.29
17	238.71 ± 120.83	0.55 ± 0.54
20	247.78 ± 121.81	0.76 ± 0.73
25	234.10 ± 118.60	0.47 ± 0.38
33	284.20 ± 125.48	0.12 ± 0.08
46	335.47 ± 143.43	0.20 ± 0.11
70	393.90 ± 148.42	0.24 ± 0.12
160	420.98 ± 117.87	0.13 ± 0.05

Abbreviations: f – frequency, SD – standard deviation.

Results

I.) The mean RMS values obtained in all tested programs are summarized in Fig.4. Each curve shows RMS values of B-field [μT] and E-field [V/m] of each applicator for

a specific Biomag program. It is evident that the combination of triangle and light applicators produced the highest values of B-field and E-field. According to the whole dataset, the highest value of B-field $134.05 \mu\text{T}$ was found in program 3 (“arthrosis of the joints”), using frequencies of 4-10 Hz and 10-50 Hz. The highest value of E-field 2.88 V/m was found in program 4, which uses the same frequency range as program 3. Table 1 contains the 14 most often frequencies and corresponding mean RMS values of electromagnetic quantities.

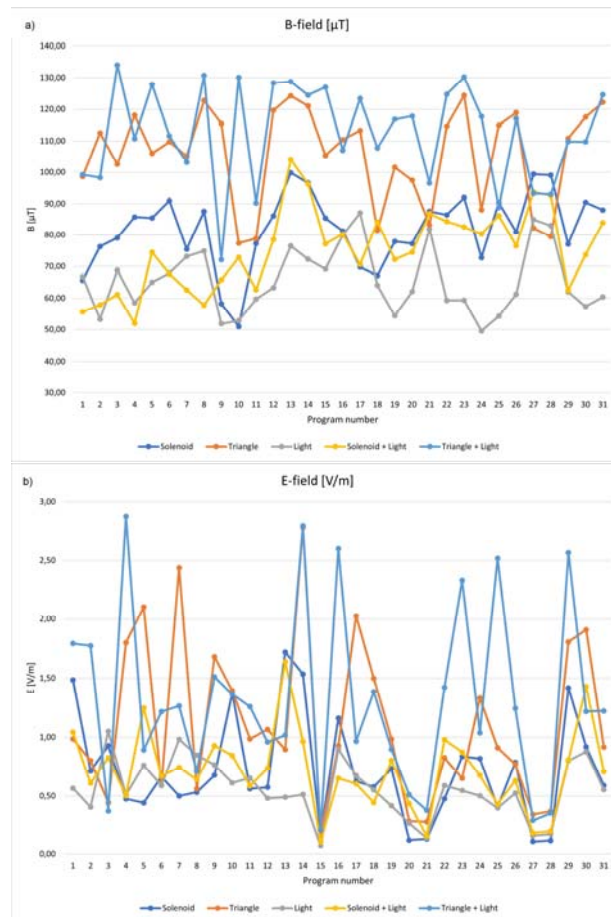


Fig.4. (a) B-field [μT] and (b) E-field [V/m] for individual Biomag programs and relevant applicators.

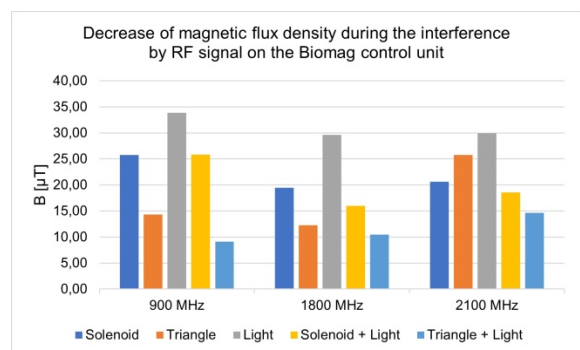


Fig.5. B-field reduction after exposure to RF signal for particular frequencies.

II.) Fig.5. shows the differences in B-fields between the normal Biomag application and combined application using RF signal near the control unit. RF signal reduced B-field in all applicators by an average of $20.42 \mu\text{T}$. The highest decrease was found for the light applicator for frequency 900 MHz ($33.85 \mu\text{T}$; $p = 0.036$). Interesting was, that the

lowest difference occurred in combination triangle and light for the same frequency (9.10 μT ; $p = 0.019$). However, statistically significant differences ($p < 0.05$) were found considering all applicators, and with and without RF signal. III.) The maximum, minimum and mean RMS values of B-field [μT] in laboratory area were evaluated in Table 2. On average B-field level of 2.13 μT was measured. The maximum values were found no further than 1 m from Biomag. The highest value 56.78 μT was measured in the case of the triangle applicator.

Table 2. Levels of MF in the laboratory during operation of the Biomag.

Appl.	B-field [μT]		
	Maximum	Mean	Minimum
S	39.40	2.01	0.04
T	56.78	2.13	0.03
L	54.55	2.06	0.03
S + L	45.20	2.10	0.03
T + L	51.87	2.33	0.03
OFF	0.31	0.07	0.02

Appl. – applicator, S – solenoid, T – triangle, L – light.

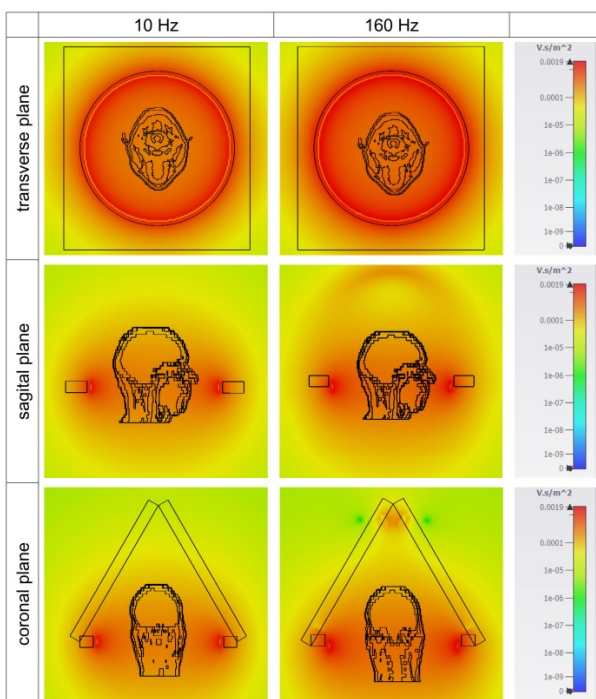


Fig.6. MF penetration through the human head in the transverse, sagittal and coronal plane.

Table 3. Comparison of measured results with simulation results.

f [Hz]	Real measurement B [μT]	Simulation B [μT]	p value
10	239.00 \pm 5.68	235.60 \pm 2.17	0.082
15	250.00 \pm 4.71	247.80 \pm 1.81	0.141
20	260.00 \pm 6.67	259.60 \pm 1.96	1.000
25	271.00 \pm 5.68	272.20 \pm 1.23	0.545
33	283.00 \pm 6.75	286.10 \pm 1.29	0.111
46	302.00 \pm 7.89	307.00 \pm 1.33	0.082
70	311.00 \pm 5.68	321.80 \pm 1.23	0.009*
160	323.00 \pm 4.83	326.20 \pm 1.23	0.069
160 (p)	321.00 \pm 5.68	318.40 \pm 1.07	0.074

f – frequency, p – probe, * $p < 0.05$ (statistically significant difference)

IV.) Fig. 6. shows the simulation results for the lowest (10 Hz) and highest frequency (160 Hz). 10 Hz was considered as lowest, since it was the lowest frequency defined in dielectric properties database. The measured and simulated values of the B-field are shown in Table 3. Measured results reached values in the interval of 239–323

μT . Last representative measurement in Table 3 shows the B-field comparison of simulation with and without the MF probe. In the model with the probe, the B-field was 8 μT lower than the model without the probe and only 2 μT lower compared to the real measurement. Fig. 7. shows conductive current density in MF probe.

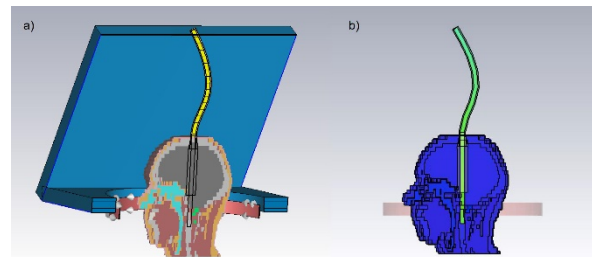


Fig.7. (a) Model with probe and (b) conductive current density in probe.

Discussion

The aim of this study was to measure and analyse the basic electromagnetic parameters of the therapeutic medical device Biomag in different routines. In the first part of the study, the pulsed character of each program was determined. The combination of triangle + light applicators and then the triangle applicator achieved the highest B-field values. In terms of frequencies, the highest B-field values were measured for the highest frequencies of 160 Hz and 70 Hz. According to Murawski et al. [19] it is necessary to know the proper values and differences in parameters (magnetic flux density, frequency, generated course of MF) for magnetostimulation and magnetotherapy. In our study, increased voltage was measured with higher frequency what resulted in the increase in current and higher B-field in the coil. When comparing the pre-set programs and the most often frequencies, the B-field values of the pre-set programs were about three times lower. A study by Poljak et al. [20] found out that B-field values in a close proximity to the magnetotherapy device were measured in the range of 100–500 μT (for 50 Hz, 75 Hz, 100 Hz/15–20 min.). These results are in accordance with our study where B-field values lay in the interval 133–421 μT for the 14 most often frequencies. The measured values of B-field and E-field reached high SD values. We assume that the device purposefully changes the MF level for the purpose of the best possible therapy and thus creates an alternating character of the field in the specified range. We were not able to measure the maximum value of the applicator 4 mT as defined by manufacturer. The measured value 640 μT at the edge of the coil was two times higher compared to the center of the coil 320 μT (distance between the edge and the center of the coil 11.75 cm). However, the manufacturer did not define where the maximum value of the B-field is located. According to the simulation, the B-field at the edge of the coil 1.84 mT was almost six times higher than in the center of the coil 326 μT (distance between the edge and the center of the coil 16.5 cm).

The effect of the RF signal on the B-field value in the applicator was observed. During control unit exposure using RF EMF, B-field decreased in the applicator for all set programs. In one case (900 MHz, triangle applicator), the device automatically turned off during the measurements. In an older study [21], the electromagnetic interference of medical devices by mobile phones was described. About 66% of interfered devices at a distance of 1 m and a mobile phone power of 0.6–0.8 W resulted in the automatic shutdown or restart of the device. Review Mariappan et al. [22] reported that 2G mobile phones caused more interference to medical devices than 3G phones. 4G

phones did not interfere at all. However, the interference can cause even more damage. As showed Badizadegan et al. [23], RF interference caused the failure of hematology equipment (distance 1.22 m for 700-900 MHz and 1700-2000 MHz frequency ranges).

Our results of B-field in the laboratory area reached lower values comparing to the ICNIRP guidelines [15], [24]. The maximum B-field 56.78 μT was measured using triangle applicator. ICNIRP recommends 200 μT for the frequency range 25 – 400 Hz. For lower frequencies of 5.5 – 20 Hz, the limit value is 250 μT – 1.32 mT. However, ICNIRP relies only on the induced current density. However, EUROPAEM or the BioInitiative have defined much lower limits, which are based on the overall scientific knowledge. According to EUROPAEM [25], the average 24-hour exposure to LF EMF should not exceed the value of 0.1 μT . The same limit value was stated by the BioInitiative [26] for children and pregnant women and for the general population the range of 0.2 – 0.4 μT was defined. It should be noted that in the case of the comparison EUROPAEM/BioInitiative and measured values, the average and maximum values in laboratory exceeded the recommended limits.

The same measurement results without and with the phantom head in the center of the applicator confirmed that LF MFs pass through biological tissue with low attenuation. The magnetic flux density depends primarily on the distance from the source. Similar results were also achieved by simulations. The presence of probe in the model did not show a significant effect on B-field distribution. In a study by Tavakoli et al. [27], the circular coil as one of the most common coils in a repetitive transcranial magnetic stimulation device was modelled in CST Studio Suite. The simulation results of B-field and MF intensity (H-field) were in accordance with theoretical calculations. In our study, the input parameters (number of turns, electrical current) in the simulation were obtained by calculation. The simulations were in accordance with the measured values ($p < 0.05$) except one case for 70 Hz where the simulation revealed about 3% higher B-field ($p = 0.009$).

In terms of LF EMFs effects, scientific studies described both positive and detrimental effects. According to the Biomag datasheet [14], analgesic and muscle relaxant effects predominate for the 1 – 10 Hz frequency range. Stimulating and detoxifying effects occur at frequencies up to 25 Hz and the range 25 – 162 Hz has a regenerating and healing effect. Similar effects were confirmed in older studies. For example, in the study by Kanje et al. [28], where treatment increased regeneration of the sciatic nerve in rats, but not all MFs were effective (exposure 60 μT or 300 μT , 15 min/day). In another study [29], pulsed MFs consisting of approximately 100 μT (peak) and exposure to 15 minutes induced analgesia, and increased opioid-induced analgesia in snails. It was also found that exposure to a weak LF EMF significantly improved sleep quality (1 Hz, 0.004 μT , 40 min) [30].

However, it is important to note that in 2002, the IARC classified LF EMF as potentially carcinogenic to humans (group 2B) [31]. According to Manikonda et al. [32] LF MF induces oxidative stress in rat brain (50 Hz, 50 and 100 μT , continuous exposure for 90 days). In another study [33], an increased risk of dementia, motor neurone disease, multiple sclerosis and epilepsy was observed in utility workers at the highest exposure of 1 μT . Radil et al. [34] reported non-thermal effects during the proliferation process of cultured cells by external time-varying LF EMF (1.6, 0.8, 0.4 and 0.2 kHz, 2.39 mT). Our previous study [35] confirmed the inhibitory effect on yeast growth at the given parameters (2.3 mT, 900 Hz, 8 hours).

In addition, there is lack of information about exposure from different EMF sources such as static MF and LF or LF and RF [36, 37]. Superposing RF signal to LF or vice versa may cause different effects to occur. Thus, the combined exposure should also be included to the study interest.

A limitation of this study was the human head phantom, which was originally designed for RF EMF. The authors are also aware of the dimensions of the receiving antenna, which did not allow detailed mapping of MFs in each applicator.

Conclusion

This study focused on the measurements and analysis of the magnetotherapy device. The B-field and E-field parameters for the pre-set programs were detected and the most often frequencies with the corresponding B-field and E-field levels were found. Results showed, that the highest value of B-field (420.98 μT) was achieved at 160 Hz. It was also found that the control unit was affected by RF signal with reduction of the B-field value by 20.42 μT in average. In the laboratory where the device was tested, the B-field reached an average value of 2.13 μT with the highest maximum 56.78 μT . The values were lower comparing to the ICNIRP standards but exceeded the EUROPAEM/BioInitiative recommendations. Simulations and measurements with and without phantom showed low MF attenuation in biological tissue for each frequency.

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