

MAGNETO-THERAPY IN PHYSIOTHERAPY UNITS: INTRODUCTION OF QUALITY CONTROL PROCEDURE DUE TO LACK OF MAINTENANCE

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Rehabilitation practice for many patients consisting of a combined use of magneto therapy resulting emission of low frequency magnetic fields to the patient, elicit concerns about occupational exposure to electromagnetic radiation (EMR) for the operators. The time extended use of the device periodically leads to mechanical failures or troubleshooting of the machine which, in most cases, are not perceived by the operator of the device. All device's efficient functionality have a major impact on the completion of the treatment procedure in a large percentage of specific clinical conditions. If the device's operating condition is technically out of order or in a mode of over-activity, operators are mainly seeking solutions by reviewing the clinical case of the patient. This eliminates their contribution during the primary therapeutic plan or increases the treatment sessions. In this work, an extended survey is presented including 75 physiotherapy centres concerning usability and maintenance issues of magneto therapy devices throughout Greek territory combined with extended measurements of Electromagnetic Radiation in the unit room were performed. Physiotherapists' perceptions revealed lack of technical support, maintenance and safe use of magneto therapy devices that extract auxiliary observations upon their clinical practice routines. Additionally safety measurements have not revealed field strengths over International Reference Levels which could result health risks for users and co-existing patients. The pilot survey that conducted in Attica and Western Greece confirms that magnetic fields strength that are measured are in accordance with the statutory legislation but will, at the same time, revealed lack of maintenance of the devices. Deficiency in topics such as proper equipment function will necessitate the creation of quality safety protocols, concerning the use of magneto-therapy, with the main aim the improvement of treatment procedures for the higher performance of therapeutic rehabilitation services to patients. Finally in this work, the proposal of a QC protocol for magnetotherapy devices is proposed for evaluation.

INTRODUCTION

Physiotherapy attempts to deal with illnesses or injuries that limit a person's ability to move and perform functional activities in his daily life. It usually includes exercises, manipulations, training, physical means through technology including thermotherapy, cryotherapy, electrotherapy, ultrasonic waves, magnetic fields, artificial prostheses, rectangles and other interventions^(1, 7, 10). In the field of physiotherapy, the use of electric and magnetic fields for therapeutic purposes is imperative. Devices such as magneto-therapy are one the main devices emitting low frequency electromagnetic fields^(2, 3).

With regard to the device's therapeutic effects, it is necessary for every health care professional to make reasonable and responsible use of the equipment and observing the necessary health protection measures for both patient and physiotherapist⁽¹⁾. Magneto-therapy, also is called magnetic field therapy and bioenergetic therapy, is an alternative treatment that

uses magnets of various sizes and dynamic strengths that are placed on the body to relieve pain and cure diseases⁽¹⁾. In addition, physiotherapists co-operate with other health care professionals to prevent the loss of mobility before it appears, by developing wellness in their workout programs for healthier and more active lifestyles by providing services to patients to develop, maintain and restore their maximum functional capacity⁽¹⁴⁾.

Physical therapy with the help of natural factors (i.e. temperature) and technology (therapeutical devices) aims at accelerating tissue healing by reducing pain and restoring the patient through these natural physiotherapy tools^(1, 16). Therapy with pulsed magnetic fields (PMF) is a relatively new and very effective form in the physiotherapy field. Magnetic fields are a very effective and simple treatment method. By using generally or locally with a magnetic field emitting pulsed waves, cellular functions can be greatly improved⁽²⁷⁾.

The pulsed magnetic field has high biological efficiency and is used also in the general medical field as a means of treatment and diagnosis^(4, 6). Diseased or damaged cells have variable resting potential. If the ions (electrically charged particles surrounding the cells) move to a region of pulsating magnetic fields, they will be affected by the pulse rate. The resting potential of the cell is proportional to ion exchange occurring in the cell membrane^(17, 23). Pulse magnetic fields can dramatically affect ion-exchange at the cellular level and thus significantly improve the utilisation of oxygen in diseased or damaged tissues.

Degradation of oxygen use is known to be a problem in several areas such as delayed healing and arthritis^(15, 21). From clinical trials, we know that PMF can reduce the sensation of pain almost immediately. This is partly due to the increase in partial oxygen pressure in the tissue and to the increase in local blood perfusion and the rate of capillary blood flow that reduces the production of metabolites due to low vascularisation and blood flow^(8, 23).

In rehabilitation, the magnetic fields result in muscular exercise and strengthening, postoperative restoration, back pain, bone growth, neck pain and low back pain. Other uses are applied in order to recurrent tiredness due to fatigue, relaxation of muscle spasms, prevention or treatment of degenerated muscles, stimulation of local circulation, muscle stimulation after surgery and enhancing by increasing the track gauge of motion⁽¹²⁾. Due to increased blood circulation in the application area, it is also reported slight dizziness in some cases. The body needs some time to get used to increasing blood circulation⁽²¹⁾.

In rare cases, patients report skin rash or redness. Some patients may experience an increase in pain after the magneto-therapy session. The increase in pain is often attributed to the sensitivity to the influence of magnetic fields. This often happens only if people are overly sensitive to magnetic forces. However, in a short time the pain subsides⁽⁶⁾. Magnetic fields should not be used during chemotherapy and radiotherapy⁽⁵⁾.

In some cases, magnet- therapy can cause side effects that lower blood pressure and reduce heart rate⁽¹⁵⁾. In children should not be applied the magnetic field therapy because the safety of this treatment is not proven⁽⁸⁾. People with medical devices or magnetic field implants, such as a pacemaker, should not use magnetic therapy because they could interfere with the implant's operation⁽²⁵⁾.

Having in mind the physiotherapist all contraindications then for patient safety should be aware of the medical history and ask questions about metal implants to avoid the risk of complication in treatment. Furthermore, it will be deducted all the metal object that can be worn by the patient as well as the mobile phone from the point of treatment⁽¹²⁾. Although there are no published quality-control

protocols for magneto-therapy, there are some researches that make it necessary to create certified protocols and to be applied to the specific health sector of physical therapy^(4, 19, 22).

Every time a physiotherapist or his/her assistant applies his therapeutical protocols to a patient in combination with his/her equipment, not only there will be created hypotheses that are related to the occupational exposure from the radiation but also treatments to patients would be affected with danger due to the reduced quality of provided health services^(10, 16).

In this study, we present the results of the first survey concerning magneto-therapy applications in physiotherapy, which took place in Greece during 2018. Additionally, measurements of magnetic field were performed on all magneto-therapies that were installed in physiotherapists and rehabilitation centres that included in the survey. Exposure limits can vary a lot over the full range of the low frequency. But even within the low frequency range, where magneto-therapy operates, there can be differences between 50 Hz and 60 Hz. 50 Hz is used in parts of the world more influenced by British and European practice area, 60 Hz is used in parts of the world more influenced by US practice area^(2, 13).

The results were evaluated in accordance with the European Directive 2013/35/EU which is in accordance with the directives as legislated by International Commission on Non-Ionizing Radiation Protection (ICNIRP 2010) for the World Health Organization (WHO). For both 50 Hz and 60 Hz the occupational exposure limits are 1000 μ T and for the general public exposure limits are 200 μ T. Those limits are concerning the magnetic field reference levels and not the basic restrictions (human head and whole body) as shown in the published guidelines and adopted in Greek legislation^(2, 13).

METHODS

The study was conducted from January 2018 until June 2018. The main measurement equipment and the scientific expertise used for the research needs were provided by the research laboratory Health Physics & Computational Intelligence (HPCI), based in Technological and Educational Institute (TEI) of Western Greece. The research action was carried out after approval by the National Bioethics and Ethics Committee. The lab staff visited 250 physiotherapeutic and rehabilitation centres to conduct the research object. For reasons of clarity, the investigation was divided into two parts.

Assessment of devices with a radiation measurement process

In the 250 physiotherapeutic centres that visited to perform on-site magnetic field measurements, there

were 60 physiotherapeutic centres with 70 magneto-therapy devices that were installed in their physiotherapy rooms. The number of the devices was only 70 due to the current Greek Legislation each physiotherapy unit is obliged to include at least one laser or one magnetotherapy device⁽¹⁾. From them sample of 30 devices was chosen in random order to measure the magnetic field close to the equipment and with no other equipment working.

The measurements based on a patented spectrum analyzer device (Aaronia NF-5020, Germany), connected to a dedicated probe detector operating within the low frequency range (1 Hz to 30 MHz). The analyzer was set up in spectrum analysis mode for magnetic field (H-Field) from 1 pT to 500 μ T with the bandwidth resolution configured from 0.3 Hz to 1 MHz and the detector as peak value. The option for the result type was maximum average mode with lowest sample time 10 ms and typical accuracy at 3%. The expiration date of calibration was until 06 September 2018. All the magneto-therapy devices bed-type were one channel(one single coil) and pre-operated continuously before recording the maximum average power that wanted to be achieved, while the 60 cm diameter cylindrical treatment coil was stable^(3, 11).

Twenty eight magneto-therapy devices installed and operating in 30–70 m² rooms were examined in this study. The overall working status of the tested equipment was also investigated by a certified technician to ensure that the prescribed output levels were achieved. Then field distribution measurements, in μ T, were performed at different output magnetic field treatment power levels with a power density strength of 1–100 gauss (adjustable in steps of one gauss). At each level, a wide range of values were recorded by varying the position of measurement (Figure 1) in terms of the angle between the source and probe

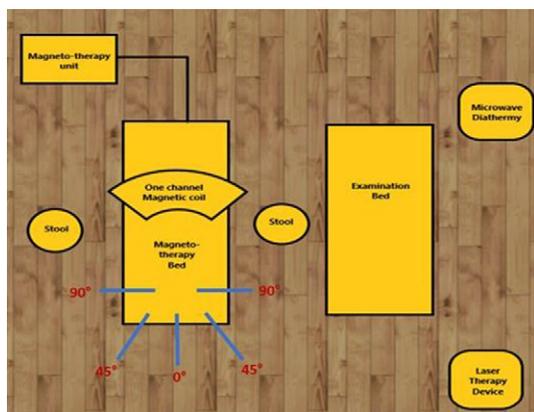


Figure 1. Magneto-therapy in an equipped physiotherapy room (5 m × 14 m/70 m²).

axes (0°, 45° and 90° on each side) and the distance between the magneto-therapy device and the spectrum analyzer (three steps, 1 m–3 m).

Concerning the output power strength value, was at 70 gauss due to the fact that most physiotherapeutic protocols are applied around this rate and time at 20 minutes for the same reason that mentioned before^(4, 12, 24). All measurements were compared to exposure limits in the μ T band which is the field strength (1000 μ T for occupational use and 200 μ T for the general public) proposed by the International Commission on Non-Ionizing Radiation Protection (ICNIRP) and adopted in the European Directive 2013/35/EC^(2, 13). Actual values in this part of the study are presented as mean values \pm uncertainty, which is the standard deviation plus uncertainty of the measuring system (Figure 2).

Questionnaire sharing for appraisal of radiation protection and mechanical inspection

After the measurement procedure the physical therapist proceeded with the completion of the questionnaire that was developed in the laboratory of HPCI. The questionnaire was composed with closed type questions regarding the procedures used by the physiotherapists for the use of magneto-therapy equipment, maintenance issues and acquiring knowledge about technical standards of the equipment. Furthermore provided classified scale questions with only one response from a range of multiple options that related to age, gender, years of professional experience, type of magneto-therapy equipment and rendering of services. In the end, phone directory was used to determine the date of completing the questionnaire by the physiotherapist.



Figure 2. Measurements of the field distribution (actual values in μ T) at all angles for 20 minutes, at different distances (m) and at output level of 70 Gauss, which is a typical choice in treatment protocols. Orange horizontal lines represent the exposure limits of the European Directive 2013/35/EC for occupational use (1000 μ T) and the general public (200 μ T).

RESULTS

Affable radiation device from a safety perspective

Eight out of the 22 magneto-therapy devices surveyed were found to lack working validity because of different mechanical or electronic dysfunctions or even both. The first outcome of the present work was that non-constant output values introducing the need for technical intervention by qualified personnel^(16, 20). The main results concerning the 22 magneto-therapy devices at described angle for 20 minutes and the typical distances of 1 m and 3 m, found to operate properly are presented in Figure 2.

It is clear, as shown in Figure 2, that all of the acquired measurements are way too below the ICNIRP and EU limits for both occupational and general public exposure (1000 μ T for occupational use and 200 μ T for the general public)^(2, 13, 22). For the same reason, there is no more extensive reference to the results from the remaining angles due to there was not any radial burden. In fact, the magnetic field decreased at least 30% as shown in Figure 2.

Maintenance important for effectiveness of treatment protocols

Data from the questionnaire of 60 physiotherapy centres with their magneto-therapy equipment that were evaluated, are presented in Table 1. 78% of the physiotherapists were male and 22% were female. The predominance of the ages practicing the profession shifts from 26–0 years old (2%), 36–40 years old (35%), 41–45 years old (38%) to 46–50 years old (25%).

With reference to the professional experience, it was notable that a 0% had 0–5 years of relevant experience in the field of physical therapy followed by higher rates in other groups (28% had 5–10 years, 68% had 10–15 and only 4% had 15–20 year).

It was remarkable that magneto-therapy accounted for the highest percentages (90% for one device installed in a physiotherapy room, 6% for two devices, 0% for three devices and 4% for three devices). On the subject of the employment of staff such as physiotherapists and assistants, 92% of the interviewees stated that they were self-employed, 7% stated that they employ two health-care professionals (HCP) including themselves and 1% respectively three HCP.

Concerning the offering services by using the magneto-therapy device per day, 90% reported that they offered services with the use of the device from 0 to five patients, 3% for 6–10 patients and 7% for 11–15 patients. Regarding the use of the device per month, 93% reported that they offered services with the use of the device from 11 to 20 patients each month and 7% for 21–30 patients.

As far as is concerned the existence of any certified protocols for standard treatment sessions for

each magneto-therapy device, 77% answered negatively and 23% positively. 42% believed that there is a lack of safety precautions (e.g. shielding, glasses, etc.) for staff and patients during pregnancy and lactation, while 58% supported the opposite. 62% of physiotherapists deemed that there are not certificates of competence and training for staff employed in your area of radiation protection and only a 38% believed that there is such a thing.

As regards the awareness if there are certified protocols for staff to be protected by radiation from magneto-therapy devices, 20% stated that knew something about that, while the rest 80% declared ignorance. 95% of physiotherapists showed insufficiency in having certified magneto-therapy test protocols (e.g. malfunction or damaged cable, observation for operating situation of the device) and 5% claimed to have maintained such a procedure.

Apropos of if the interviewees kept a record for damages of the magneto-therapy devices (e.g. indicating faults, mechanical conversions, repairs and the staff who detected them and those who fixed the damage), 85% answered negatively due to the fact that they were not sure if they were able to observe some of the specialised damages that mentioned above or they had never been able to deal with any damages and 15% handled damages that were obvious.

In the same question but from a standpoint (e.g. quality checklist, periodic technical proofs, control after each physiotherapeutic intervention, etc.) for each magneto-therapy, there was a relative non-uniformity with the previous question, for as much as 85% responded negatively and 15% positively.

Finally, when the physiotherapists were using a magneto-therapy device, 23% replied that they specified the radiation dose for each clinical occasion, 42% answered that they were using the treatment protocols proposed by the device itself (factory settings) and 35% showed us that they were using both of these approaches.

Introduction of QC procedure for magnetotherapy devices

Based on the results of our study it seems to appear a lack of such a need by manufacturers or similar quality guidelines by governmental agencies. As the most important result of the present work and our previous experience on rehabilitation equipment safety procedures, we introduce a quality control protocol for the magneto-therapy devices in physiotherapy units (Table 2)⁽¹⁶⁾.

This includes all appropriate mechanical, electrical, electronic, environmental and radiation exposure guidelines, included in International Quality Procedure Standards adopted by Healthcare

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Table 1. Data from the questionnaire for physiotherapists and assistants included in the analysis ($n = 60$).

Variable		<i>n</i> (%)
I. Gender	Male	47(78)
	Female	13(22)
II. Age (years)	26–30	1(2)
	36–40	21(35)
	41–45	23(38)
	46–50	15(25)
II. Professional experience (years)	5–10	17(28)
	10–15	41(68)
	15–20	2(4)
1. How many magneto-therapy devices do you have in your physiotherapy room?		1(90) – 2(6) – 4(4)
2. How many health professionals/magneto-therapy assistant users are employed in your physiotherapy room, including yourself?	1	55(92)
	2	4(7)
	3	1(1)
3. How many patients do you offer services with magneto-therapy devices per day?	0–5	54(90)
	6–0	2(3)
	11–15	4(7)
4. How many patients do you offer services with magneto-therapy devices per month?	11–20	56(93)
	21–30	4(7)
5. Are there any certified protocols for standard treatment sessions for each magneto-therapy device?	Yes	14(23)
	No	46(77)
6. Is there a safety precaution (e.g. shielding, glasses, etc.) for staff and patients during pregnancy and lactation?	Yes	35(58)
	No	25(42)
7. Is there a certificate of competence and training for staff employed in your area of radiation protection?	Yes	23(38)
	No	37(62)
8. Are you aware if there are certified protocols for staff to be protected by radiation from magneto-therapy devices?	Yes	12(20)
	No	48(80)
9. Does your physiotherapy room has certified magneto-therapy test protocols (e.g. malfunction or damaged cable, observation for operating situation of the device)?	Yes	3(5)
	No	57(95)
10. Do you keep a record for damages of the magneto-therapy devices (indicating faults, mechanical conversions, repairs and the staff who detected them and those who fixed the damage)?	Yes	9(15)
	No	51(85)
11. Do you keep a general record for each magneto-therapy device (quality checklist, periodic technical proofs, control after each physiotherapeutic intervention, etc.)?	Yes	9(15)
	No	51(85)
12. When you're using a magneto-therapy device, do you specify the radiation dose for each clinical occasion or you're using the treatment protocols proposed by the device itself (factory settings)?	Yes	14(23)
	No	25(42)
	Both of them	21(35)

manufacturers and International or National Agencies as IEEE, ICNIRP, FDA, IEC, ETSI, etc^(1, 12, 16, 22). All QC protocols of medical equipment include mechanical, electrical and radiation safety tests⁽¹⁶⁾. Care and use of equipment were inspected before the environmental safety tests as:

Mechanical safety

Proper care of equipment, ensure that no damages exist in mechanical condition (as in case, arms, breaks, electrodes, control panel) that would adversely affect patient or operator safety. All features that must be inspected and acceptable findings are summarised in Table 2⁽¹⁶⁾. For timer accuracy digital stopwatches can be used [DHW 1983].

Output safety tests

Various methods have been suggested for measuring patient dosage but none of these methods, however, necessarily reflects the dose delivered to a patient⁽¹⁶⁾. Thus all available test equipment for measuring output can be used for routine assessment and standardisation to measure the power output linearity, stability, reproducibility and frequency in the power output characteristics that can be tested are summarised in Table 2. Output stability can be measured over a 20 min period, as this is representative of an average treatment session^(1, 16). Analysis of the output waveform can be performed using a digital oscilloscope.

Electrical safety

Magnetotherapy units can be categorised as Class I type LF (low frequency) electrical equipment and are subject to compliance with the relevant IEC 60 601-2-6:2012 that specifies minimum requirements considered to provide for a practical degree of safety in the operation of microwave therapy equipment. This particular standard amends and supplements IEC 60 601-1 (third edition, 2005 and amendment one 2012). The second edition cancels and replaces the first edition of IEC 60 601-2-6, published in 1984⁽¹²⁾. This edition constitutes a technical revision and has been aligned to the third edition of IEC 60 601-1:2005+A1:2012^(12, 16). At this step the electrical safety tester operating in manual mode is necessary as, it must be certified that although the trait switched on when power is supplied, there is no emission until the timer will be activated and the intensity control will be engaged.

As the applied parts are intended to be non-conducting, it is necessary to wrap the electrodes in tin foil to measure the patient leakage currents^(12, 16). After safe care and use of equipment we proceeded for the environmental radiation safety tests further introducing a specific procedure which is best-suited

for the evaluation at hand as here there is mainly magnetic field emitted.

Magnetic field measurements

From radiation protection viewpoint and according a number of studies there have to be recorded values at different distances (1 to 3 m with 1 m step) and angles (0 to +90, -90 degrees) for a 20 min period in the room of the physiotherapy unit when it radiates at maximum average output value^(1, 16). Measurements have to be repeated including objects between transmitting and measuring devices such as other equipment as an environmental survey⁽¹⁾. Usually the devices lack validity as working time passes introducing the need of controls of the device by qualified personnel in order to maintain its' effectiveness in sessions and really withdraws the energy output the therapist asks for (Table 2).

DISCUSSION

Results of this study identified physiotherapists' perception on usability and maintenance issues of magneto-therapy devices. Our findings certainly raise concerns as to how it can affect the clinical routine of the physiotherapists. In Greece the profession of physical therapist has an immediate professional demand, based on the research of at least 21–25 years it is observed that both the physiotherapist and the assistant have already begun to practice the profession.

The fact that the professional is at least 56–60 years old, combined with the data provided by the research in terms of professional experience, the physiotherapist is considered to be active in practicing the profession for at least 20–30 years. In combination with the answers concerning the daily and monthly services to patients by using a magneto-therapy device, either in long or in short terms, the device may be probably malfunctioning from overuse, with the result that the physiotherapists will not properly apply their treatment protocols to patients^(1, 19).

What came up with the query concerning the amount of health care professionals and magneto-therapy devices assistant users that are employed in the physiotherapy room, including the owner of the physiotherapy centre, it seems that in some cases they were employed up to six persons from both specialties in order to cope with a large number of patients who would have to render their services on a daily or on a monthly basis. By combining the data analysed above about the most prevalent type and number of magneto-therapy devices that were installed in physiotherapy rooms with the results that obtained from the last question seems that appears a

Table 2. QC protocol for magneto-therapy units

Qc protocol	Safe use guidelines of operation exposure		Criteria				Reference		
	Test section	Included tests	Control of operation exposure						
			Frequency ^a	Acceptable	Desirable	Units			
Care of equipment	Mechanical Tests	Secure casing	<i>b</i>	All panels in good condition, Access to internal components only with tools			NHMRC (1985)		
		Functioning castors	<i>b</i>	Unit is portable					
		Operating castor breakes	<i>c</i>	Breakes immobilise uints					
		Movable treatment arms	<i>c</i>	Securely attached and freely movable					
		Treatment arms lock	<i>b</i>	Lock in place					
		Interchangable electrodes/coil	<i>c</i>	Lock in place, Range available					
		Condition of electrodes/coil	<i>c</i>	No signs of damage, Air-space adjustable, Rubber on pad electrodes not broken down					
		Functioning control	<i>c</i>	Lamps and controls operational, Dials are fixed and click at correct interval					
		Operation of patient circuit braker	<i>b</i>	Power output stops when operated					
		Timer accuracy	<i>b</i>	Unit only operate with timer Output switches off when timer is zeroed < 5 min: 30 sec 5-10 min: 10% > 10 min: 60 sec		15 sec 5% 30 sec	sec sec sec	IEC 60601-2-3 (1991) DHW (1993)	
Use of equipment	Output tests	Linearity	<i>a</i>	30% Max power output <500 W			IEC 60601-2-3 (2007)		
		Stability	<i>a</i>	20%					
		Reproducibility	<i>a</i>	20%					
		Waveform analysis	<i>a</i>	2445 - 2475 MHz		2455- 2465 MHz	Hz	IEC 60 601-2-6 (2012)	
	Electrical Safety	Visual Inspection	Visual Inspection	<i>c</i>	Pulse Frequency: 30% Pulse width: 30% Physical damage ruled out			IEC 60601-2-3 (2007)	
			Earthing tests	<i>a</i>	200 mΩ		200 mΩ	Ω	
			Insulation Tests	<i>a</i>	> 50 MΩ		Ω 50 MΩ	Ω	
			Leakage current tests	<i>a</i>	Earth: <1000 μA		500 μA	A	IEC 60 601-2-3 (2007)
				<i>a</i>	Enclosure: <500 μA		100 μA	A	
				<i>a</i>	Patient (AC): <500 μA Patient (DC): <50 μA		100 μA 10 μA	A A	
Auxillary current tests	<i>a</i>	AC: <0.1 mA DC: <0.05		0.1 mA 0.01 mA	A A	IEC 60 601-2-3 (2007)			

(Continued)

Table 2. (Continued)

Qc protocol	Safe use guidelines of operation exposure		Criteria				Reference	
	Test section	Included tests	Control of operation exposure					
			Frequency ^a	Acceptable	Desirable	Units		
Enviroment of equipment	Environmental Survey	Furniture	<i>c</i>	Beds and chairs non-metallic			NHMRC (1985), ENRAF NONIUS (1997), DHW (1993), APA (1992), CSP (1992), CSP (1994)	
		Treatment area layout	<i>c</i>	Metal objects >3 m Mains filter present	>5 m	m		DHW (1983), APA (1992)
		Warning Signs	<i>c</i>	No use of mobile phones Danger for patients with pacemakers				IEC 60 601-2-6 (2012)
	LF Field Strength Measurements	Other modalities in area	<i>c</i>	Other electrotherapy units >3 m	>5 m	m	CSP (1992), CSP (1994)	
		Isotropic probe, frequency analysis	<i>a</i>				ICNIRP (2010)	
		Maximum averaging over 20 min Distance: 1 m, 3 m		H-field: 0.16 A/m	1000 μ T	μ T	IEC 61 786 (1998), IEEE Std C95.3 (2002), CEPT Revised ECC/REC/(02) (2004), ETSI EG 202 373 V.1.1.1 (2005)	
	Angle: 0, +90, -90 degrees							

^aa: per 1 year, b: per month, c: per day.

need for establishing quality control (QC) procedure for the magneto-therapy devices.

It is confirmed the fact that even more physiotherapists, including their assistants, serve an overweighted number of patients. As a result, the increasing use of magneto-therapy devices as well as the amount of devices will be an additional radial burden, that would jeopardise the health of the users of micro or short-wave diathermy devices (MWD, SWD) or to be at a high risk the therapeutical protocols of physiotherapists where an eventual malfunction of the device would go unnoticed by its operator, could alter the effectiveness of each therapeutic session that accompanied by the device^(1, 13).

As shown in Table 1 in the middle of the questionnaire to the end (Questions 5–11) there is a series of questions investigating issues such as the safety of personnel from radiation, the existence of certified protocols, the radiation protection training of staff and the maintenance of the functionality of the device. Although there are proposed procedures for the maintenance of the magneto-therapy devices, it is noted that the procedures are not applied in order to make the devices more secure.

Consequently for other types of diathermy devices as magneto-therapy devices, which have mentioned above there are no quality control procedures. If equipment is not calibrated, it impacts the treatment of patients^(1, 3, 11). Additionally, the last question accrues that there is a large proportion of physiotherapists who use and trust mainly the therapeutic protocols proposed by the manufacturers.

This factor supports the risks highlighted above and it could negatively affect future graduates of physiotherapy on issues of clinical knowledge in the field of therapeutic rehabilitation^(3, 9, 15). Finally, analysing topics on performance behaviour of the device due to awkwardly use by the physiotherapist will have a negative impact in patient's treatment.

CONCLUSIONS

The above presented pilot survey confirms that magnetic fields strength that are measured are in accordance with the statutory legislation but at the same time, revealed lack of maintenance of the devices. Deficiency in topics such as proper equipment function will necessitate the creation of quality safety protocols, concerning the use of magneto-therapy, with the main aim the improvement of treatment procedures for the higher performance of therapeutic rehabilitation services to patients.

Finally in this work the proposal of a QC protocol for magnetotherapy devices is proposed. Consequently physiotherapy chambers and state health agencies should organise workshops in order to train users to be aware of the need for preventive maintenance and Quality Controls of their equipment⁽¹⁶⁾.

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