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Interference of Programmed Electromagnetic Stimulation With Pacemakers and Automatic Implantable Cardioverter Defibrillators

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A commercially available magnetic therapy system, designed for clinical application as well as for private use without medical supervision, was examined with respect to its potential for causing electromagnetic interference with implantable pacemakers (PMs) and automatic implantable cardioverter defibrillators (AICDs). A sample of 15 PMs and 5 AICDs were experimentally investigated. Each of the implants was realistically positioned in a homogeneous, electrically passive torso phantom and exposed to the magnetic fields of the system's applicators (whole body mat, cushion, and bar applicator). The detection thresholds of the implants were programmed to maximum sensitivity and both unipolar as well as bipolar electrode configurations were considered. The evaluation of possible interferences was derived from the internal event storages and pacing statistics recorded by the implants during exposure. Any ''heart activity'' recorded by the implants during exposure was interpreted as a potential interference, because the implant obviously misinterpreted the external interference signal as a physiological signal. Only cases without any recorded ''heart activity'' and with nominal pacing rates (as expected from the program parameter settings) of the implants were rated as ''interference-free.'' Exposure to the whole body mat (peak magnetic induction up to 265 μT) did not show an influence on PMs and AICD in any case. The cushion applicator at the highest field intensity (peak magnetic induction up to 360 μT) led to atrial sensing defects in four PM models with unipolar electrode configuration. Under bipolar electrode configuration no disturbances occurred. The bar applicator led to sensing problems and consecutively reduced pacing rates in all tested PM models under unipolar electrode configuration and maximum field intensity (peak magnetic induction up to 980 μT). Bipolar electrode configuration resolved the problem. The investigated AICDs did not show malfunctions under any investigated condition. In conclusion, the examined PEMF therapy system did not interfere with the investigated implantable cardiac devices with bipolar electrode configuration. However, unipolar electrode configuration in pacemakers seems to be potentially hazardous during application of the examined PEMF therapy system. Bioelectromagnetics 27:365–377, 2006.

Key words: magnetic therapy device; pacemaker; defibrillator; interference

INTRODUCTION

The clinical application of pulsed electromagnetic fields (PEMF) or magnetic stimulation systems have become a therapeutic option, especially for the treatment of diseases related to osteoarthritis [Pipitone and Scott, 2001; Hulme et al., 2002], musculoskeletal disorders and wound healing [Trock, 2000]. Beside systems for clinical applications, several PEMF treatment systems for private use, applicable without medical supervision, became commercially available and relatively popular in recent years. Because these systems may produce high peak values of magnetic induction, implantable electronic cardiac devices as pacemakers (PMs), and automatic implantable cardioverter defibrillators (AICDs) have to be considered as contraindications in PEMF therapy.

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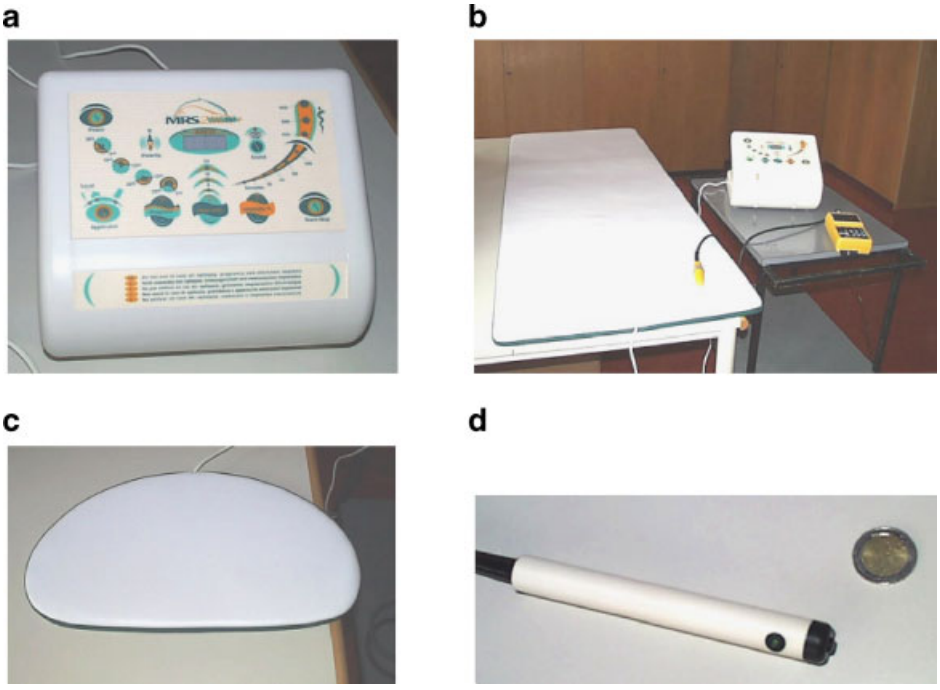

Fig. 1. Components of the investigated magnetic field resonance system MRS 2000+ (**a**) control unit, (**b**) whole body mat and control unit, (**c**) applicator cushion, (**d**) bar applicator. [The color figure for this article is available online at www.interscience.wiley.com.]

Patients with implanted cardiac devices represent a large group. In western countries 1 of 250 to 300 inhabitants has a cardiac pacemaker. The number for AICD patients is estimated to be roughly 20-fold smaller [Irnich, 2002]. Given the high average age of pacemaker patients there is a high incidence of comorbidity. Degenerative and musculoskeletal diseases, arthritis and osteoporosis especially represent a relevant problem in this patient population. Therefore this patient population might benefit from a therapy

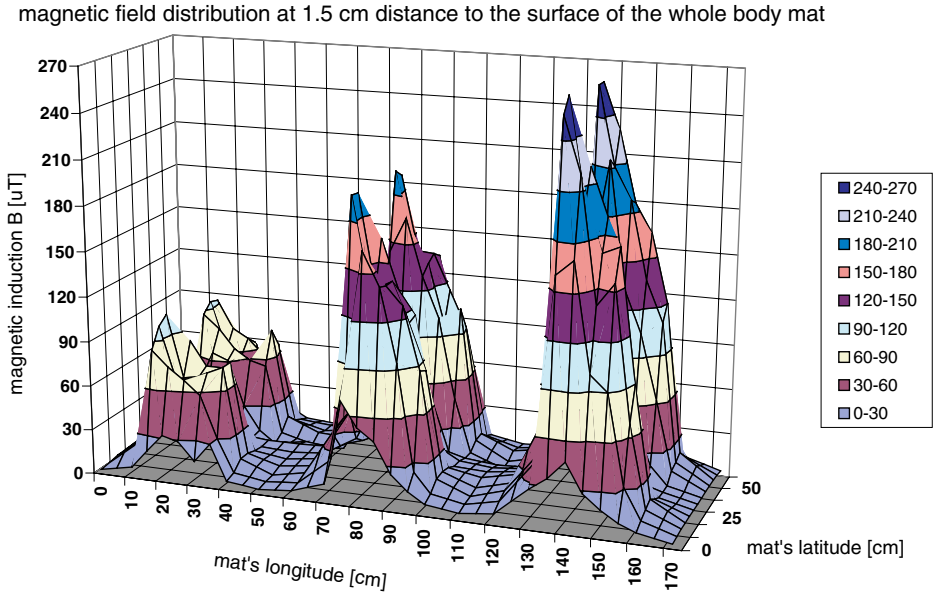

Fig. 2. Distribution of magnetic induction along the whole body mat's surface (peak values) at therapy program "5^{00}–10^{00}." The other available therapy programs show basically the same field distribution (deviations less than ±5%). [The color figure for this article is available online at www.interscience.wiley.com.]

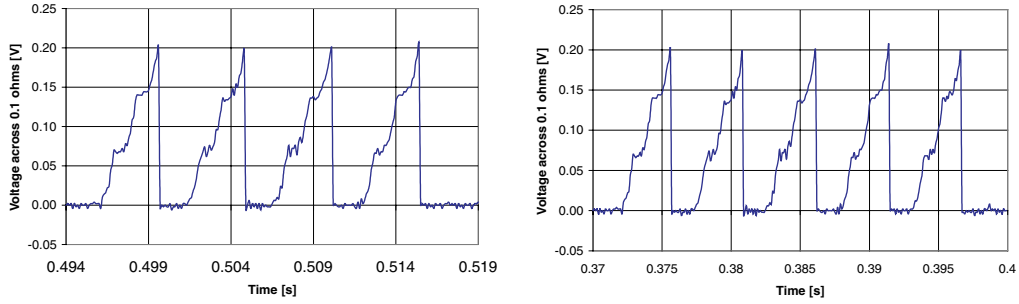

Fig. 3. Elementary bursts of which the therapy programs available for the whole body mat consist (**left**: for programs "5^{00}–10^{00}" and "10^{00}–15^{00}," **right**: for programs "15^{00}–20^{00}" and "20^{00}–5^{00}"). The four available programs differ only with respect to the repetition time of this elementary bursts, leading to different frequency spectra. [The color figure for this article is available online at www.interscience.wiley.com.]

with PEMF. However, since studies investigating the safety of PEMF for PM and AICD patients are missing, PEMF treatment cannot be recommended for this patients group at this point of time. Appropriate sensing of intrinsic cardiac electrical activity is essential for the function of PMs and AICDs. Electromagnetic sources always potentially influence the function of these devices.

Recently, an extensive review discussed the effects of electromagnetic interference (EMI) with implanted cardiac devices [Pinski and Trohman, 2002a,b]. Inappropriate inhibition or triggering of PM stimuli, reversion to asynchronous pacing and spuriously detected AICD tachyarrhythmias resulting in inadequate delivery of shocks are the most frequently observed responses to EMI [Pinski and Trohman, 2002a]. Most commonly the effects of EMI last only as long as the device is within the range of the electromagnetic field, but even permanent damage may occur. The influence of several different types of electric and electronic devices such as mobile phones, metal detectors and antitheft systems on implantable cardiac devices was widely investigated in the past and is well summarized in some review articles [Kainz et al., 2001; Niehaus and Tebbenjohanns, 2001; Pinski and Trohman, 2002a,b]. However, data investigating the possible interference of PEMF on implanted cardiac devices are still missing.

In this study, we investigated the possible influences on PMs and AICDs caused by one specific commercially available PEMF therapy system, which is designed for clinical application as well as for private use without medical supervision. The scope of this study is exclusively on the aspect of EMI for PMs and AICDs. Aspects regarding the therapeutic effectiveness of the investigated PEMF systems are not considered.

TABLE 1. Main Spectral Components of the Magnetic Field Emitted by the Whole Body Mat

Applicator/program	Main frequency components of envelope
Whole body mat/5^{00}–10^{00}	0.3 Hz; 3.0 Hz; 21 Hz;
Whole body mat/10^{00}–15^{00}	0.2 Hz; 3.0 Hz; 18 Hz;
Whole body mat/15^{00}–20^{00}	0.1 Hz; 3.0 Hz; 16 Hz;
Whole body mat/20^{00}–5^{00}	0.1 Hz; 3.0 Hz; 12 Hz;
Cushion	1.7 Hz; 3.4 Hz; 12.5 Hz
Bar	1.7 Hz; 3.4 Hz; 12.5 Hz

MATERIALS AND METHODS

Applied Pulsed Electromagnetic Fields

The magnetic field resonance system MRS 2000 + Med (vita-life, Balzers, Liechtenstein), a low frequency pulsed electromagnetic field system, was used for this study. The control unit of the system can be connected to three different applicators: a whole body mat, an application cushion, and a bar applicator (Fig. 1). The control unit generates time varying electric signals of different shapes, which are converted to corresponding magnetic fields by the applicators. For the whole body mat the control unit provides four different therapy programs (one specific signal shape for each program). The cushion and the bar applicator each have only one program. The intensity of the magnetic field can be adjusted in discrete steps for all available therapy programs.

Because possible interference of electromagnetic fields with PMs and AICDs depend not only on the mean field intensity but also on the peak values and the spectral composition of the interfering signal, the specific signal shape is of importance. Therefore, all signal shapes generated by the system have been analyzed and the magnetic field distribution was measured in close proximity (1.5 cm) to the applicators.

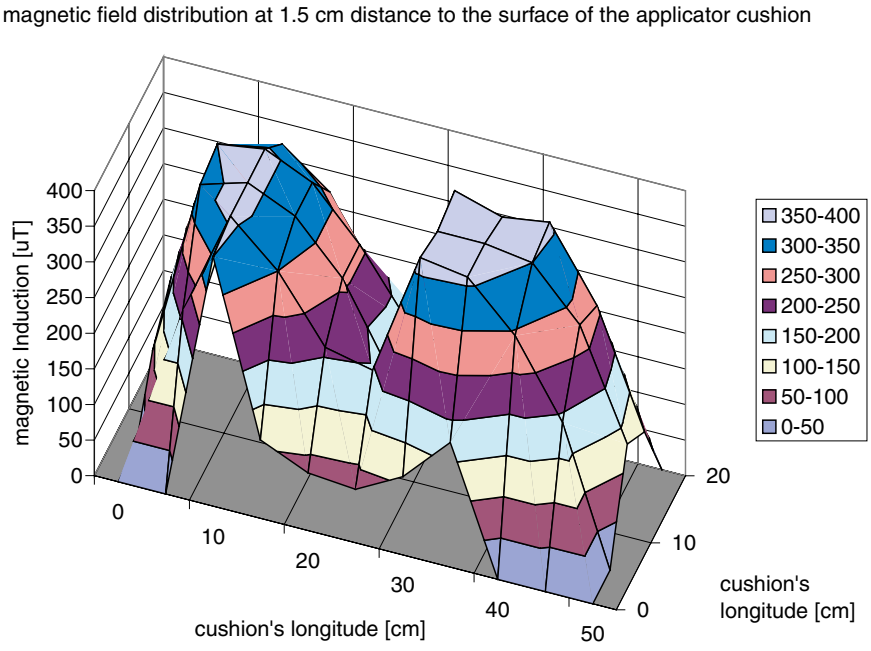

Fig. 4. Distribution of magnetic induction along the application cushion's surface (peak values). [The color figure for this article is available online at www.interscience.wiley.com.]

The qualitative analysis of the signal shapes of the resulting magnetic fields was done by indirect measurement of the electrical current at the applicators' input (voltage across a 0.1 Ω serial resistance) with a digital oscilloscope (TDS 684B, Tektronix, Inc., Beaverton, OR, USA). The resulting magnetic induction in the frequency range from 5 to 30 Hz was measured with an EM field analyzer (EFA 3) connected to the corresponding isotropic magnetic field probe with 3 cm coil diameter (both devices from Wandel and Goltermann GmbH and Co., Eningen, Germany).

In case of the whole body mat the magnetic field is generated by three pairs of coils, leading to a strongly inhomogeneous magnetic field distribution along the mat. Figure 2 depicts the distribution of the magnetic field along the mat, measured on a 5 × 5 cm grid at one of the four therapy programs available for the mat. These four different therapy programs for the whole body mat (referred to as "5^{00}–10^{00}," "10^{00}–15^{00}," "15^{00}–20^{00}," and "20^{00}–5^{00}" according to the manufacturer) differ with respect to the time course of the generated magnetic field.

The basic elements of all four signals are sequences of four or five triangular impulses, referred to as "elementary bursts" depicted in Figure 3. These elementary bursts are repetitively applied with sets of repetition times that are specific for each therapy program. Therefore, the difference between the four therapy programs available for the mat is just the time course of the appearance of these elementary bursts, resulting in different frequency spectra of the generated magnetic field, which have been calculated by FFT

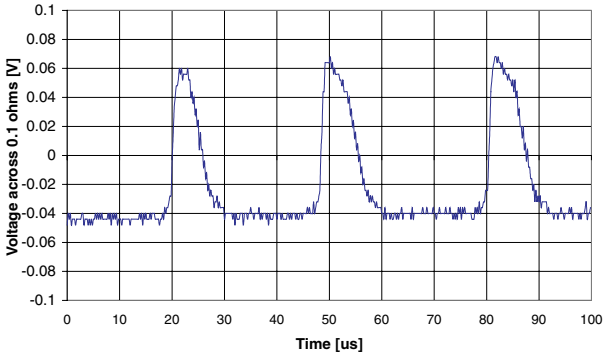

Fig. 5. Periodic signal fed into the bar applicator. [The color figure for this article is available online at www.interscience.wiley.com.]

TABLE 2. Maximum Obtainable Magnetic Induction at the Highest Possible Intensity Level

	Distance to applicator's surface	Maximum obtainable magnetic induction	
Applicator type	(cm)	Peak value (μT)	rms (μT)
Whole body mat[a]	1.5	265	64.1
Whole body mat[a]	4.0	150	36.3
Cushion	1.5	360	83.7
Bar tip	1.5	280	82.0
Bar shaft	1.5	980	287.0

[a]Therapy program "20^{00}–5^{00}."

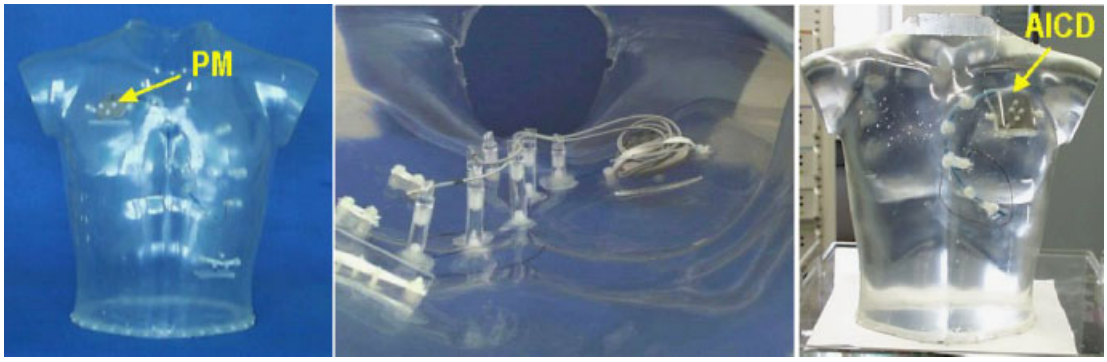

Fig. 6. Torso phantom used for the investigation. **Left**: torso for right pectoral implantation of pacemakers; **Center**: view from the bottom of the torso phantom of right pectoral implantation of pacemakers, the pacemaker and its electrodes—fixed by non metallic mounting pads—can be seen. **Right**: torso for left pectoral implantation of AICDs. [The color figure for this article is available online at www.interscience.wiley.com.]

based on the recordings obtained in the time domain (Table 1). All programs (of all applicators) change the polarity of the magnetic field every 2 min.

The cushion, intended for local application on body parts (shoulder, knee, etc.), contains one pair of coils fed by repetitively occurring bursts of a 31 kHz sinusoidal carrier signal. The resulting inhomogeneous field distribution along the surface of the cushion (measured on a 5×5 cm grid) is shown in Figure 4 and the most relevant spectral components of the signal envelope are listed in Table 1.

The bar applicator for very local treatments consists only of one coil with an iron core located in an aluminum cover and is, very similar to the cushion, fed by repetitively occurring bursts of a nonsinusoidal signal (Fig. 5). The bar applicator provides very local field maxima in front of the tip and along the shaft of the bar. The spectral content of the generated magnetic field is very similar to the cushion (Table 1).

Table 2 summarizes the maximum peak values as well as the root-mean-square (rms) values of magnetic induction obtainable at the highest intensity level at 1.5 and 4 cm distance from the surface of the mat and at 1.5 cm distance form the cushion and the bar applicator. In all cases, a decrease of the magnetic induction with increasing distance d, approximately proportional to $1/d$, could be observed.

Positioning of the Implants in Homogeneous Torso Phantoms

In order to approach physiologic conditions one has to take into account the electrical properties of the human tissue. Therefore, a phantom consisting of a synthetic, electrically nonconductive shell, filled with

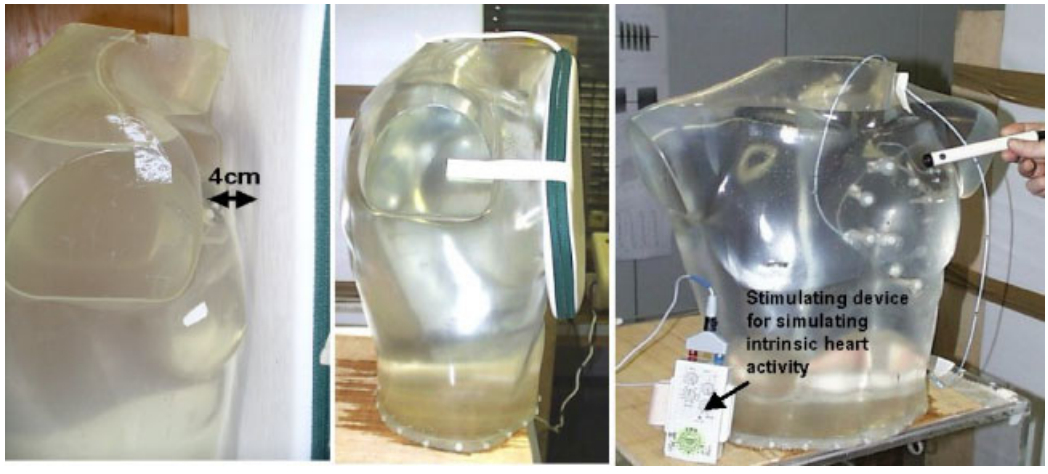

Fig. 7. Illustration of exposure situations using the whole body mat (**left**), the application cushion (**center**) and the bar applicator (**right**). In case of AICDs exposed by the bar applicator additionally proper detection of tachycardia during exposure was checked. [The color figure for this article is available online at www.interscience.wiley.com.]

TABLE 3a. Pacemakers Exposed to Whole Body Mat, Maximum Intensity Level

PM model	Vendor	Year of introduction	NBG mode[a]	Detection sens.[b] (mV)		Electrode configuration (sensing)		Stimulation rate (%)							
								Program "5^{00}–10^{00}"		Program "10^{00}–15^{00}"		Program "15^{00}–20^{00}"		Program "20^{00}–5^{00}"	
				A	V	A	V	A	V	A	V	A	V	A	V
Philos DR-T	Biotronik	2002	DDD	0.1	0.5	Bipolar	Bipolar	100	100	100	100	100	100	100	100
			DDD	1.0	1.0	Unipolar	Unipolar	100	100	100	100	100	100	100	100
Dromos DR	Biotronik	1994	DDD	0.5	0.5	Bipolar	Bipolar	100	100	—	—	—	—	—	—
			DDD	0.5	0.5	Unipolar	Unipolar	100	100	—	—	—	—	—	—
Talent II DR233	ELA Medical	2001	DDD	0.4	1.5	Bipolar	Bipolar	100	100	100	100	100	100	100	100
			DDD	0.4	1.5	Unipolar	Unipolar	100	100	100	100	100	100	100	100
Talent DR213	ELA Medical	1998	DDD	0.4	1.0	Bipolar	Bipolar	100	100	—	—	—	—	—	—
			DDD	0.4	1.0	Unipolar	Unipolar	100	100	—	—	—	—	—	—
Chorum 7334	ELA Medical	1995	DDD	1.0	2.2	Bipolar	Bipolar	100	100	—	—	—	—	—	—
			DDD	1.0	2.2	Unipolar	Unipolar	100	100	—	—	—	—	—	—
Chorus 6244	ELA Medical	1995	DDD	1.2	2.2	Bipolar	Bipolar	100	100	—	—	—	—	—	—
			DDD	1.2	2.2	Unipolar	Unipolar	100	100	—	—	—	—	—	—
Pulsar Max II SR	Guidant	2000	VVI	—	0.25	—	Bipolar	100	100	100	100	100	100	100	100
			VVI	—	0.25	—	Unipolar	100	100	100	100	100	100	100	100
Insignia I Plus	Guidant	2002	DDD	0.15	0.25	Bipolar	Bipolar	100	100	—	—	—	—	—	—
			DDD	0.15	0.25	Unipolar	Unipolar	100	100	—	—	—	—	—	—
Kappa KDR901	Medtronic	2002	DDD	0.18	1.0	Bipolar	Bipolar	100	100	100	100	100	100	100	100
			DDD	0.5	1.0	Unipolar	Unipolar	100	100	100	100	100	100	100	100
Identity DR	St. Jude	2002	DDDR	0.1	0.5	Bipolar	Bipolar	100	100	100	100	100	100	100	100
			DDDR	0.5	0.5	Unipolar	Unipolar	100	100	100	100	100	100	100	100
Integrity AFx DR	St. Jude	2001	DDDR	0.1	0.5	Bipolar	Bipolar	100	100	—	—	—	—	—	—
			DDDR	0.5	0.5	Unipolar	Unipolar	100	100	—	—	—	—	—	—
Clarity DDDR	Vitatron	1999	DDDR	0.25	1.0	Bipolar	Bipolar	100	100	100	100	100	100	100	100
			DDDR	0.5	1.0	Unipolar	Unipolar	100	100	100	100	100	100	100	100
Selection AF 2.0	Vitatron	2000	DDD	0.5	1.0	Bipolar	Bipolar	100	100	—	—	—	—	—	—
			DDD	0.5	1.0	Unipolar	Unipolar	100	100	—	—	—	—	—	—
Diamond 3	Vitatron	1999	DDD	0.25	1.0	Bipolar	Bipolar	100	100	—	—	—	—	—	—
			DDD	0.5	1.0	Unipolar	Unipolar	100	100	—	—	—	—	—	—
Topaz 3	Vitatron	1999	AAI	0.3	—	Bipolar	Bipolar	100	100	—	—	—	—	—	—
			AAI	0.5	—	Unipolar	Unipolar	100	100	—	—	—	—	—	—

[a]NBG mode, mode of pacemaker function according to NASPE/BPEG (North American Society of Pacing and Electrophysiology/British Pacing and Electrophysiology Group); AAI, atrium/atrium/inhibiting; VVI, ventricle/ventricle/inhibiting; DDD, dual/dual/dual; DDDR, dual/dual/dual/rate response.
[b]detection sens., programmed sensing threshold for detection of electrical signals (in mV); A, atrium; V, ventricle.

TABLE 3b. AICDs Exposed to Whole Body Mat, Maximum Intensity Level

AICD-model	Vendor	Year of introduction	NBG mode[a]	Detection sens.[b] (mV)		Electrode configuration (sensing)		Stimulation rate (%)							
								Program "5^{00}–10^{00}"		Program "10^{00}–15^{00}"		Program "15^{00}–20^{00}"		Program "20^{00}–5^{00}"	
				A	V	A	V	A	V	A	V	A	V	A	V
Belos VR	Biotronik	2001	VVI	—	0.5	Bipolar	Bipolar	—	100	—	100	—	100	—	100
GEM 7227	Medtronic	1998	VVI	—	0.15	Bipolar	Bipolar	—	100	—	100	—	100	—	100
GEM DR 7271	Medtronic	1998	DDD	0.15	0.15	Bipolar	Bipolar	100	100	100	100	100	100	100	100
GEM II VR 7229	Medtronic	1999	VVI	—	0.15	Bipolar	Bipolar	—	100	—	100	—	100	—	100
GEM III AT 7276	Medtronic	2001	DDD	0.15	0.15	Bipolar	Bipolar	100	100	100	100	100	100	100	100

[a]NBG mode, mode of pacemaker function according to NASPE/BPEG (North American Society of Pacing and Electrophysiology/British Pacing and Electrophysiology Group); AAI, atrium/atrium/inhibiting; VVI, ventricle/ventricle/inhibiting; DDD, dual/dual/dual; DDDR, dual/dual/dual/rate response.
[b]Detection sens., programmed sensing threshold for detection of electrical signals (in mV); A, atrium; V, ventricle.

0.03 M NaCl solution was used, reflecting the average electric conductivity of muscle tissue. A 0.03 M NaCl solution meets this conductivity value in the considered frequency range within less than ±10% deviation. Because the emitted fields of PEMF are predominately magnetic, electric field components and therefore dielectric permittivity (the dielectric constant) of the liquid plays a minor role and can be neglected. The phantom was equipped with special mounting pads, in order to fix the cardiac devices and electrodes in a realistic right pectoral position for the PMs and left pectoral position for the AICDs (Fig. 6). In order to allow anatomically correct positioning of the PEMF applicators an anatomically shaped phantom shell was used instead of simplified flat phantom shells commonly used for pacemaker immunity testing.

Exposure of the Different PM and AICD Models to PEMF

Fifteen different pacemaker and five different ICD models were exposed to the different applicators of the examined PEMF therapy system, that is, the whole body mat, the cushion and the bar applicator. Prior to each 4 min exposure cycle, chosen in order to have both magnetic field polarities present, the implants were set to their maximum detection sensitivity using the corresponding programming device. The basic pacing rate was set to 60/min and in case of AICDs the threshold frequency for tachycardia detection was set to 100/min. All available sensors (e.g., acceleration sensors) were switched off in order to avoid artifacts due to mechanical manipulations and handling of the phantom. The PM and AICD models and their manufacturers, as well as the programmed sensitivity threshold are listed in Tables 3–5.

After implanting the PM or AICD into the phantom the electrode impedances and the programmed parameters were checked and the implant's event storage and pacing statistics were cleared.

For the exposure cycle the phantom containing the implant was positioned so that the area of the implant was located as close as possible to the field maximum of the applicator. For the whole body mat this resulted in a remaining distance of 4 cm between the implant and the surface of the mat. In case of the cushion and the bar applicator this distance could be reduced to 1 cm due to their local applicability (Fig. 7). Immediately following each 4 min exposure cycle the event storage and the pacing statistics were read out of the implant using the telemetric readout unit connected to the corresponding programming device. The obtained data were reviewed and rated by a cardiologist. Basically, all tests on PMs were performed with unipolar as well as

TABLE 4a. Exposure of the Pacemakers to the Application Cushion

Pacemakers exposed to application cushion											
				Detection sens.[b] (mV)		Electrode configuration (sensing)		Stimulation rate (%)			
								Maximum intensity level		25% of maximum	
PM model	Vendor	Year of introduction	NBG mode[a]	A	V	A	V	A	V	A	V
Philos DR-T	Biotronik	2002	DDD	0.1	0.5	Bipolar	Bipolar	100	100	—	—
			DDD	1.0	1.0	Unipolar	Unipolar	100	100	—	—
Dromos DR	Biotronik	1994	DDD	0.5	0.5	Bipolar	Bipolar	100	100	—	—
			DDD	0.5	0.5	Unipolar	Unipolar	100	100	—	—
Talent II DR233	ELA	2001	DDD	0.4	1.5	Bipolar	Bipolar	100	100	—	—
	Medical		DDD	0.4	1.5	Unipolar	Unipolar	100	100	—	—
Talent DR213	ELA	1998	DDD	0.4	1.0	Bipolar	Bipolar	100	100	—	—
	Medical		DDD	0.4	1.0	Unipolar	Unipolar	100	100	—	—
Chorum 7334	ELA	1995	DDD	1.0	2.2	Bipolar	Bipolar	100	100	—	—
	Medical		DDD	1.0	2.2	Unipolar	Unipolar	100	100	—	—
Chorus 6244	ELA	1995	DDD	1.2	2.2	Bipolar	Bipolar	100	100	—	—
	Medical		DDD	1.2	2.2	Unipolar	Unipolar	100	100	—	—
Pulsar Max II SR	Guidant	2000	VVI	—	0.25	—	Bipolar	—	100	—	—
			VVI	—	0.25	—	Unipolar	—	100	—	—
Insignia I Plus	Guidant	2002	DDD	0.15	0.25	Bipolar	Bipolar	100	100	—	—
			DDD	0.15	0.25	Unipolar	Unipolar	6	100	100	100
Kappa KDR901	Medtronic	2002	DDD	0.18	1.0	Bipolar	Bipolar	100	100	—	—
			DDD	0.5	1.0	Unipolar	Unipolar	100	100	—	—
Identity DR	St. Jude	2002	DDDR	0.1	0.5	Bipolar	Bipolar	100	100	—	—
			DDDR	0.5	0.5	Unipolar	Unipolar	100	100	—	—
Integrity AFx DR	St. Jude	2001	DDDR	0.1	0.5	Bipolar	Bipolar	100	100	—	—
			DDDR	0.5	0.5	Unipolar	Unipolar	100	100	—	—
Clarity DDDR	Vitatron	1999	DDDR	0.25	1.0	Bipolar	Bipolar	100	100	—	—
			DDDR	0.5	1.0	Unipolar	Unipolar	79	100	100	100
Selection AF 2.0	Vitatron	2000	DDD	0.5	1.0	Bipolar	Bipolar	100	100	—	—
			DDD	0.5	1.0	Unipolar	Unipolar	100	100	—	—
Diamond 3	Vitatron	1999	DDD	0.25	1.0	Bipolar	Bipolar	100	100	—	—
			DDD	0.5	1.0	Unipolar	Unipolar	61	100	100	100
Topaz 3	Vitatron	1999	AAI	0.3	—	Bipolar	Bipolar	100	—	—	—
			AAI	0.5	—	Unipolar	Unipolar	47	—	100	—

[a]NBG Mode, mode of pacemaker function according to NASPE/BPEG (North American Society of Pacing and Electrophysiology/British Pacing and Electrophysiology Group); AAI, atrium/atrium/inhibiting; VVI, ventricle/ventricle/inhibiting; DDD, dual/dual/dual; DDDR, dual/dual/dual/rate response.
[b]Detection sens., programmed sensing threshold for detection of electrical signals (in mV); A, atrium; V, ventricle.

TABLE 4b. Exposure of the AICDs to the Application Cushion

AICDs exposed to application cushion, maximum intensity level									
				Detection sens.[b] (mV)		Electrode configuration (sensing)		Stimulation rate (%)	
AICD model	Vendor	Year of introduction	NBG Mode[a]	A	V	A	V	A	V
Belos VR	Biotronik	2001	VVI	—	0.5	Bipolar	Bipolar	—	100
GEM 7227	Medtronic	1998	VVI	—	0.15	Bipolar	Bipolar	—	100
GEM DR 7271	Medtronic	1998	DDD	0.15	0.15	Bipolar	Bipolar	100	100
GEM II VR 7229	Medtronic	1999	VVI	—	0.15	Bipolar	Bipolar	—	100
GEM III AT 7276	Medtronic	2001	DDD	0.15	0.15	Bipolar	Bipolar	100	100

[a]NBG mode, mode of pacemaker function according to NASPE/BPEG (North American Society of Pacing and Electrophysiology/British Pacing and Electrophysiology Group); AAI, atrium/atrium/inhibiting; VVI, ventricle/ventricle/inhibiting; DDD, dual/dual/dual; DDDR, dual/dual/dual/rate response.
[b]Detection sens., programmed sensing threshold for detection of electrical signals (in mV); A, atrium; V, ventricle.

bipolar electrode configuration. In case of AICDs only bipolar detection was possible.

Data Evaluation

The rating whether an exposure cycle caused an influence or not, was entirely based on the event storage and the pacing statistics read out of the implant after each exposure cycle. Per definition, a relative stimulation rate (pacing rate) of 100%, corresponding to a frequency of 60/min reflects no influence on the implanted cardiac devices, leading to an unaffected delivery of electrical stimuli. Any deviations from a 100% stimulation rate indicate the detection of the interfering signal and misinterpretation of it as a natural heart signal and were therefore rated as interference. In the same way any recorded cardiac events, for example, ventricular extra systoles (VES), atrial extra systoles (AES), or high atrial frequency (HAF), were considered as interference. In case of AICDs, falsely detected tachycardia and delivery of defibrillation shocks were additionally considered as effects caused by interference.

Furthermore, in case of exposure of AICDs to the bar applicator it was checked whether the AICD is able to detect intrinsic heart signals during exposure. For this purpose an additional exposure cycle was considered and the intrinsic heart signal was simulated by a commercially available cardiac stimulation device (external pulse generator Model 3074 Siemens, Berlin, Germany). The electrode of the stimulation device was immersed into the phantom with its tip positioned in approximately 3 cm from the tip of the ventricular electrode of the AICD (Fig. 7). If the AICD was able to detect the simulated intrinsic heart activity (90/min) properly during exposure, no interference was assumed.

RESULTS

Exposure to the Whole Body Mat

One PM model of each manufacturer was tested at all available therapy programs at the highest field intensity; all other devices were tested at the therapy program "5^{00}–10^{00}" at the highest intensity only. Therapy program "5^{00}–10^{00}" was chosen because it was assumed to have the highest potential of interference due to its 0.3 Hz frequency component, which is closer to the physiological heart activity than the low-frequency components of the other programs. The AICDs were tested with all available therapy programs.

The whole body mat did not interfere with the proper function of the tested PMs and AICDs (Table 3a,b).

Exposure to the Application Cushion

At the highest field intensity (level "400") four PMs showed severely reduced atrial stimulation rates in unipolar electrode configuration (Table 4). In contrast, the ventricular stimulation rate was not affected. Reducing the intensity to level "100," corresponding to 25% of the highest intensity in terms of magnetic induction, resolved the problem. At bipolar electrode configuration no interference could be observed, even at the highest intensity level (Table 4a).

The proper function of the AICDs remained unaffected by the use of the application cushion (Table 4b).

Exposure to the Bar Applicator

All pacemakers demonstrated significant interference in unipolar electrode configuration at the highest intensity. In contrast to the results observed with the application cushion, not only the atrial, but also

TABLE 5a. Exposure of the Pacemakers to the Bar Applicator

Pacemakers exposed to bar applicator													
								Stimulation rate (%)/detected events[c]					
				Detection sens.[b] (mV)		Electrode configuration (sensing)		Maximum intensity level		25% of Maximum intensity		12.5% of Maximum intensity	
PM model	Vendor	Year of introduction	NBG mode[a]	A	V	A	V	A	V	A	V	A	V
Philos DR-T	Biotronik	2002	DDD	0.1	0.5	Bipolar	Bipolar	100	100	—	—	—	—
			DDD	1.0	1.0	Unipolar	Unipolar	100	89/10 VES	100	100	—	—
Dromos DR	Biotronik	1994	DDD	0.5	0.5	Bipolar	Bipolar	100	100	—	—	—	—
			DDD	0.5	0.5	Unipolar	Unipolar	96	99/2 VES	100	100	—	—
Talent II DR233	ELA medical	2001	DDD	0.4	1.5	Bipolar	Bipolar	100	100	—	—	—	—
			DDD	0.4	1.5	Unipolar	Unipolar	95/2 AES	100	100	100	—	—
Talent DR 213	ELA medical	1998	DDD	0.4	1.0	Bipolar	Bipolar	100	100	—	—	—	—
			DDD	0.4	1.0	Unipolar	Unipolar	98/2 AES	99/1 VES	100	100	—	—
Chorum 7334	ELA medical	1995	DDD	1.0	2.2	Bipolar	Bipolar	100	100	—	—	—	—
			DDD	1.0	2.2	Unipolar	Unipolar	98/ 1AES	100	100	100	—	—
Chorus 6244	ELA medical	1995	DDD	1.2	2.2	Bipolar	Bipolar	100	100	—	—	—	—
			DDD	1.2	2.2	Unipolar	Unipolar	99	100	100	100	—	—
Pulsar Max II SR	Guidant	2000	VVI	—	0.25	—	Bipolar	100	100	—	—	—	—
			VVI	—	0.25	—	Unipolar	—	65	100	100	—	—
Insignia I Plus	Guidant	2002	DDD	0.15	0.25	Bipolar	Bipolar	100	100	—	—	—	—
			DDD	0.15	0.25	Unipolar	Unipolar	31	78	91	100	100	100
Kappa KDR901	Medtronic	2002	DDD	0.18	1.0	Bipolar	Bipolar	100	100	—	—	—	—
			DDD	0.5	1.0	Unipolar	Unipolar	99	100	100	100	—	—
Identity DR[1)]	St. Jude	2002	DDDR	0.1	0.5	Bipolar	Bipolar	100	100	—	—		
			DDDR	0.5	0.5	Unipolar	Unipolar	96/HAF	100	100	100	—	—
Integrity AFx DR	St. Jude	2001	DDDR	0.1	0.5	Bipolar	Bipolar	100	100	—	—		
			DDDR	0.5	0.5	Unipolar	Unipolar	86	86/7 VES	100	100	—	—
Clarity DDDR	Vitatron	1999	DDDR	0.25	1.0	Bipolar	Bipolar	100	100	—	—	—	—
			DDDR	0.5	1.0	Unipolar	Unipolar	91	94/9 VES	100	100	—	—

Selection AF 2.0	Vitatron	2000	DDD	0.5	1.0	Bipolar	Bipolar	100	100	—	—	—	—
			DDD	0.5	1.0	Unipolar	Unipolar	96	98/4 VES	100	100	—	—
Diamond 3	Vitatron	1999	DDD	0.25	1.0	Bipolar	Bipolar	100	100	—	—	—	—
			DDD	0.5	1.0	Unipolar	Unipolar	93	100	100	100	—	—
Topaz 3	Vitatron	1999	AAI	0.3	—	Bipolar	Bipolar	100	—	—	—	—	—
			AAI	0.5	—	Unipolar	Unipolar	74	—	99	—	100	—

[a]NBG Mode, mode of pacemaker function according to NASPE/BPEG (North American Society of Pacing and Electrophysiology/British Pacing and Electrophysiology Group); AAI, atrium/atrium/inhibiting; VVI, ventricle/ventricle/inhibiting; DDD, dual/dual/dual; DDDR, dual/dual/dual/rate response.
[b]detection sens., programmed sensing threshold for detection of electrical signals (in mV); A, atrium; V, ventricle.
[c]AES, detection of atrial extrasystolic beats; VES, detection of ventricular extrasystolic beats; HAF, detected of high atrial frequency.

the ventricular stimulation rate was reduced. In addition, sensing of atrial and ventricular extrasystoles and false detection of high atrial frequencies could be observed. With reduction of the intensity to level ''100'' (corresponding to 25% of the highest intensity) only 2 pacemakers remained affected. After further reduction of the intensity to level ''50'' (corresponding to 12.5% of the highest intensity) no electromagnetic interference could be observed anymore (Table 5a). With bipolar electrode configuration no disturbances of the proper function could be observed in any case.

The stimulation rates of the AICDs were not influenced by the application bar (Table 5b) and no defibrillation shocks were delivered. Furthermore, simulated intrinsic heart activity was properly detected during exposure in any all cases (Table 5c).

DISCUSSION

Although medical devices have to comply strict standards for electromagnetic compatibility, interference cannot be automatically excluded. The risk is especially high if the disturbing signal is similar to heart signals. The pulsed character of the fields generated by magnetic stimulation systems is a priori a potential source of interference for cardiac devices [Irnich, 2002]. This study investigated the possible electromagnetic interference of pulsed electromagnetic fields with cardiac PMs and AICDs. From a physical standpoint every device, which emits electromagnetic fields can interfere with other electronic devices and therefore may be potentially hazardous for patients with implanted cardiac devices [Pinski and Trohman, 2002a,b]. Whether the function of a PM or AICD is impaired depends on a variety of factors such as the configuration of the electrodes, the filter configuration in the detection circuits or the selected sensitivity level [Irnich, 2002]. Since these features vary between the different models a wide variety of PMs and AICDs was investigated.

Application of the whole body mat did not lead to PM or AICD malfunction, even if they are exposed in close proximity (4 cm distance to the mat's surface) to the field maximum at the highest possible intensity level. This statement is valid for unipolar and bipolar electrode configuration and maximum sensitivity of the PM and AICD devices.

During exposure to the application cushion, interference could be observed in four PM models at the highest field intensity level with the unipolar electrode configuration. All disturbances were restricted to the atrial stimulation and could be eliminated by reducing the field intensity to 25% of the maximum. Ventricular pacing was not influenced by

TABLE 5b. Exposure of the AICDs to the Application Bar

AICDs exposed to the bar applicator, maximum intensity level without simulation of intrinsic heart activity									
				Detection sens.[b] (mV)		Electrode configuration (sensing)		Stimulation rate (%)	
AICD model	Vendor	Year of introduction	NBG mode[a]	A	V	A	V	A	V
Belos VR	Biotronik	2001	VVI	—	0.5	Bipolar	Bipolar	—	100
GEM 7227	Medtronic	1998	VVI	—	0.15	Bipolar	Bipolar	—	100
GEM DR 7271	Medtronic	1998	DDD	0.15	0.15	Bipolar	Bipolar	100	100
GEM II VR 7229	Medtronic	1999	VVI	—	0.15	Bipolar	Bipolar	—	100
GEM III AT 7276	Medtronic	2001	DDD	0.15	0.15	Bipolar	Bipolar	100	100

[a]NBG mode, mode of pacemaker function according to NASPE/BPEG (North American Society of Pacing and Electrophysiology/British Pacing and Electrophysiology Group); AAI, atrium/atrium/inhibiting; VVI, ventricle/ventricle/inhibiting; DDD, dual/dual/dual; DDDR, dual/dual/dual/rate response.
[b]Detection sens., programmed sensing threshold for detection of electrical signals (in mV); A, atrium; V, ventricle.

the system. With bipolar electrode configuration no disturbance in PMs was detected. The same was true for the investigated AICDs, which provide bipolar electrode configuration only.

Using the bar applicator at the highest intensity level led to partly severely reduced atrial and/or ventricular stimulation rates in all investigated PMs using unipolar electrode configuration. After reducing the field intensity to 25% of the maximum field level, only two PM models remained affected. At the intensity level corresponding to 12.5% of the maximum intensity no EMI could be detected in any of the PMs. In case of bipolar electrode configuration no interference could be observed even at the highest field intensity. The tested ICD models were not affected in any case.

In an attempt to estimate the risk of pacemakers in the presence of magnetic fields, several risk factors were defined by Irnich [2002]. Left side implantation and unipolar electrode configuration combined with a most sensitive pacemaker input and a pulsed magnetic field is the most unfavorable case. In unipolar pacemaker systems the distance between both electrodes, which can be up to 22 cm, is essential for the antenna effect. Therefore, the unipolar system is by far the most sensitive system. The use of unipolar electrode configuration is low ($<10\%$) in the United States, but is more common in Europe. In Germany, for example, the percentage is around 15%, but in some other European countries it is as high as 50% [Irnich, 2002]. In this study all observed malfunctions occurred with unipolar electrode configurations. In contrast, the pulsed character of the magnetic field seems not to be a risk factor in bipolar systems.

Because AICDs always possess bipolar electrodes for sensing the heart signals, no interference were observed.

A comparison of the magnetic fields emitted by the magnetic field resonance system MRS 2000 + Med with current safety limits for patients with active electronic implants seems to be interesting. The German standard DIN VDE 0848-3-1, version May 2002 [DIN VDE, 2002] is presently one of the most

TABLE 5c. Exposure of the AICDs to the Bar Applicator

AICDs exposed to the bar applicator, maximum intensity level during simulation of heart activity (using stimulation device at 90/min)									
				Detection sens.[b] (mV)		Electrode configuration (sensing)		Detected (%)	
AICD Model	Vandor	Year of introduction	NBG mode[a]	A	V	A	V	A	V
Belos VR	Biotronik	2001	VVI	—	0.5	Bipolar	Bipolar	—	100
GEM 7227	Medtronic	1998	VVI	—	0.15	Bipolar	Bipolar	—	100
GEM DR 7271	Medtronic	1998	DDD	0.15	0.15	Bipolar	Bipolar	100	100
GEM II VR 7229	Medtronic	1999	VVI	—	0.15	Bipolar	Bipolar	—	100
GEM III AT 7276	Medtronic	2001	DDD	0.15	0.15	Bipolar	Bipolar	100	100

The proper detection of simulated tachycardia was checked. Tachycardia was simulated by a commercially available stimulation device.
[a]NBG mode, mode of pacemaker function according to NASPE/BPEG (North American Society of Pacing and Electrophysiology/British Pacing and Electrophysiology Group); AAI, atrium/atrium/inhibiting; VVI, ventricle/ventricle/inhibiting; DDD, dual/dual/dual; DDDR, dual/dual/dual/rate response.
[b]Detection sens., programmed sensing threshold for detection of electrical signals (in mV); A, atrium; V, ventricle.

exhaustive and comprehensive documents of this kind. From this document limit values for electric and magnetic fields can be derived, taking into account different signal shapes and frequencies. The observations in our study are in line with the theoretical considerations of the above-mentioned standard. Comparing corresponding limit values from DIN VDE [2002] with the measured magnetic induction values obtained on the different applicators showed that the measured peak value of magnetic induction at the surface of the mat are below the limit values. In contrast, the peak magnetic induction values on the surface of the cushion and at the shaft of the bar applicator exceeded the limit value by 40 times and up to 110 times, respectively. At a distance of at least 50 cm to the cushion the magnetic induction was below the limit values according to DIN VDE [2002].

CONCLUSION

The pulsed electromagnetic fields emitted by the investigated magnetic field resonance system MRS 2000 + Med seem not to interfere with AICDs and cardiac PMs with bipolar electrode configuration. Application of the whole body mat did not result in interference with pacemakers or AICDs. Therefore, therapy with the tested PEMF seems to be applicable on patients with implantable devices under these conditions. However, electromagnetic interference could be observed with the application cushion and the bar applicator in PMs with unipolar electrode configuration and might be potentially hazardous for patients. Based on the measured magnetic induction at 1.5 cm distance to the cushion's surface and the observed decrease of the magnetic field with increasing distance to the cushion, a safety distance of at least 50 cm between the cushion and the implant is suggested. Due to the generated high magnetic field strength, the bar applicator should not be used on patients with implanted cardiac devices. However, in vivo testing should be performed. It has to be emphasized that the MRS 2000 + Med operates with very specific signal and frequencies. Therefore the results cannot be automatically applied to all PEMF systems.

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