

# Clinically significant magnetic interference of implanted cardiac devices by portable headphones

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**BACKGROUND** Little is known about the magnetic field strength of portable headphones and their potential to cause magnetic interference with implanted pacemakers (PMs) and implantable cardioverter-defibrillators (ICDs).

**OBJECTIVE** The purpose of this study was to evaluate the magnetic field strength of portable headphones and to determine if they can cause clinically relevant magnetic interference.

**METHODS** PM or ICD function was assessed in 100 patients during exposure to eight different models of portable headphones to determine the incidence of clinically relevant magnetic interference. The magnetic field strength of the headphones also was measured *in vitro*.

**RESULTS** Clinically relevant magnetic interference from portable headphones occurred in 30 (30%) of 100 patients and more commonly affected ICD than PM patients (21/55 [38.2%] vs 9/45 [20.0%];  $P = .048$ ). All patients affected by magnetic interference experienced a magnet response, characterized by asynchronous pacing in PM patients and by inhibition of tachyarrhythmia detection in ICD patients. In all but one of the 30 cases of magnetic interference, removal of the headphones

from the patient's chest immediately restored normal device function. Headphones with a measured magnetic field strength  $\geq 10$  gauss at 2 cm were much more likely to cause magnetic interference than were those with lower magnetic field strength (30/100 [30%] patients vs 0/100 [0%] patients;  $P < .0001$ ). Magnetic interference was not observed when headphones were placed  $\geq 3$  cm from the skin surface.

**CONCLUSION** Clinically significant magnetic interference can occur when portable headphones are placed in close proximity to implanted PMs and ICDs. Patients with such a device should be advised to keep portable headphones at least 3 cm from their device.

**KEYWORDS** Pacemaker; Implantable cardioverter-defibrillator; Electromagnetic interference; Electromagnetic field; Gaussmeter; Neodymium; iPod; MP3 player; Headphones; Earphones

**ABBREVIATIONS** EMI = electromagnetic interference; ICD = implantable cardioverter-defibrillator; PM = pacemaker

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## Introduction

Portable digital music devices (MP3 players) such as the iPod (Apple, Inc., Cupertino, CA, USA) have become increasingly common, with more than 100 million units sold.<sup>1</sup> Although some reports have suggested that digital music players may be a potential source of clinically significant electromagnetic interference (EMI) with pacemakers (PMs) and implantable cardioverter-defibrillators (ICDs),<sup>2</sup> reports by the U.S. Food and Drug Administration and others have concluded that clinically significant EMI by MP3 players is very unlikely.<sup>3,4</sup>

Little is known, however, about the potential for interactions between portable headphones, which contain mag-

nets, and implanted cardiac rhythm management devices such as PMs and ICDs. Headphone magnets are used to vibrate the speaker (and thus the air in front of the speaker) to create sound waves that can be heard. Portable headphones typically contain the magnetic substance neodymium, a naturally occurring, powerful, concentrated magnetic substance found in the earth's crust.<sup>5</sup> The potential for magnets to interact with PMs and ICDs is well recognized, as is the potential for other devices, such as cellular telephones, antitheft devices, and airport security wands, to cause clinically meaningful EMI with PMs and ICDs.<sup>6-11</sup>

The ability of portable headphones to cause magnetic interference with implanted PMs and ICDs is uncertain. EMI may potentially cause oversensing, asynchronous pacing, inhibition of ICD therapy, inappropriate shocks, and failure to pace. We sought to investigate whether exposure of patients' cardiac implanted electronic devices to portable headphones could result in clinically important magnetic interference.

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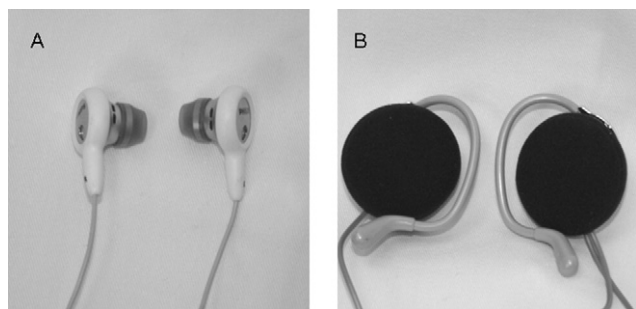
## Methods

### Patients and procedures

This was a prospective, single-blind investigation conducted at a single tertiary-care electrophysiology outpatient clinic at Beth Israel Deaconess Medical Center (BIDMC). The protocol was approved by the BIDMC Institutional Review Board. Patients were considered eligible for enrollment if they (1) had an implanted PM or ICD, (2) were not PM dependent, and (3) were 18 years of age or older. After providing informed consent, patients underwent standard in-office device interrogation and evaluation, which included assessment of intrinsic amplitude, pacing thresholds and impedances, battery function, and evaluation of stored arrhythmias.

Normal device function and all device parameters were verified before patients were exposed to the earphones. Device magnet alarms were confirmed to be “on.” During testing, patients were monitored by continuous single-lead electrocardiographic monitoring. Devices with wireless capability were also monitored via the programmer. Devices without wireless capability were not continuously monitored via the device programmer. Eight different portable headphones (both earbud and clip-on varieties; [Figure 1](#)) were placed one at a time on the patient’s chest in close proximity to the patient’s PM or ICD. In addition to the headphones, two MP3 players (2-GB iPod Nano and second-generation iPod Shuffle, Apple, Inc.) also were tested on each patient. After all testing was completed, devices were re-interrogated to look for any programming changes, and normal device function was verified. If device reprogramming was detected, repeat testing was performed to determine the cause of the reprogramming.

Each iPod player and each headphone was placed in random order on nine prespecified chest locations (typical 12-lead ECG  $V_1$ – $V_6$  precordial lead locations and three locations directly over the implanted generator [top, middle, bottom]). All devices were tested both during 100% pacing and during demand pacing with patients in their native underlying rhythm. Headphone and digital music player testing was performed with the MP3 player in both the POWER ON (with music playing) and POWER OFF mode. Testing also was performed with both the headphone connected and the headphone disconnected to a digital music player. Patients were instructed to report any symptoms that occurred during the study.



**Figure 1** Standard earbud (A) and clip-on (B) headphones.

A device interaction was defined as follows: (1) *pacemaker magnet response*—delivery of asynchronous pacing stimuli without regard to the patient’s underlying heart rhythm; (2) *ICD magnet response*—audible tone from ICD magnet alarm (all ICDs) or suspension of detection displayed on the programmer screen (wireless ICDs only) upon application of headphone or MP3 player; (3) *oversensing*—delay or inhibition of scheduled paced beat during continuous pacing; (4) *undersensing*—failure of the device to detect intrinsic cardiac signals, resulting in an inappropriate paced beat (not due to magnet response); and (5) *device reprogramming*—any other unintended change in device programming.

At the end of the test, all implanted cardiac devices were re-interrogated, and normal device function was verified. If device reprogramming had occurred, repeat testing was performed to determine the cause of the reprogramming.

### In vitro testing

In addition to the clinical study, the magnetic field strength of each headphone was tested *in vitro* using a DC gaussmeter (Gauss max GM-200A, Carlsen Melton, Inc., Sunnyvale, CA, USA). Field strengths at distances of 0, 1, 2, and 3 cm were measured.

### Data collection and statistical analysis

Standardized data collection forms were used to gather baseline information on demographics, device settings, device models, and test results. A prestudy power calculation determined that enrollment of 100 patients would provide 80% power to detect a  $\geq 10\%$  rate of interaction between the headphones and implanted PMs or ICDs (assuming an alpha error of 5%). Statistical comparisons were performed using SAS statistical software (version 9.1, SAS Institute, Cary, NC, USA). Two-sided  $P \leq .05$  was considered significant. Student t-tests were used to compare continuous outcomes, and Chi-square and Fisher exact tests were used to compare discrete outcomes.

## Results

### Baseline characteristics

A total of 100 patients (45 with PM, 55 with ICD) including 26 single-chamber, 62 dual-chamber, and 12 biventricular devices was tested ([Table 1](#)). Mean patient age was  $71.2 \pm 12.7$  years (range 43–97 years). PM patients were significantly older than ICD patients ( $75.8 \pm 12.3$  years vs  $67.4 \pm 11.9$  years;  $P < .001$ ), and 31% of study patients were women. Devices from each of the three major manufacturers (Boston Scientific/Guidant, Inc., Natick, MA, USA; Medtronic, Inc., Minneapolis, MN, USA; St. Jude Medical, Inc., St. Paul, MN, USA) were tested, including 20 PM and 13 ICD models.

### In vitro magnetic field strength measurements

*In vitro* measured magnetic field strengths are given in [Table 2](#). Magnetic field strength decreased markedly with distance. Indeed, highest magnetic field strengths were observed right at the headphone (mean  $189.0 \pm 111.0$  gauss). At 0 cm from the gaussmeter, 7 (87.5%) of 8 tested head-

**Table 1** Baseline patient and device characteristics

Characteristic	PM	ICD	Total
Sex [N (%)]			
Male	25 (55.6)	44 (80.0)	69 (69)
Female	20 (44.4)	11 (20.0)	31 (31)
Age (years) (mean $\pm$ SD)	75.8 $\pm$ 12.3	67.4 $\pm$ 11.9	71.2 $\pm$ 12.7
No. of leads [N (%)]			
Single	5 (11.1)	21 (38.2)	26 (26)
Dual	39 (86.7)	23 (41.8)	62 (62)
Biventricular	1 (2.2)	11 (20.0)	12 (12)
Wireless capability	0 (0)	20 (36.4)	20 (20)
Manufacturer [N (%)]			
Boston Scientific/Guidant	6 (13.3)	3 (5.5)	9 (9)
Medtronic	38 (84.4)	46 (83.6)	84 (84)
St. Jude Medical	1 (2.2)	6 (10.9)	7 (7)
Total [N (%)]	45 (45)	55 (55)	100

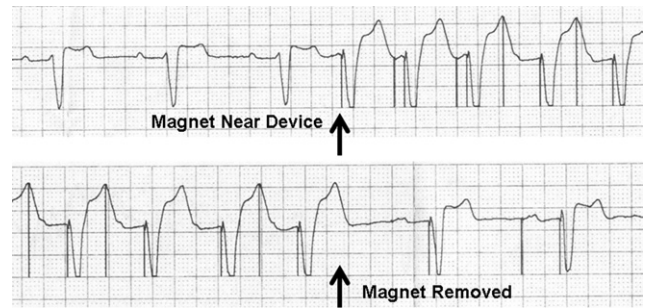
ICD = implantable cardioverter-defibrillator; PM = pacemaker.

phones had maximum magnetic field strengths  $>70$  gauss, and 5 (62.5%) of 8 had field strengths  $>200$  gauss. At a distance of 2 cm, 7 (87.5%) of 8 portable headphones had a magnetic field strength  $>1$  gauss, and 2 (25%) of the 8 headphones had a field strength  $\geq 10$  gauss. Clip-on headphones had higher magnetic field strengths than did in-ear headphones at 0 cm ( $211.5 \pm 187.4$  gauss vs  $181.5 \pm 99.7$  gauss;  $P = .77$ ) and 2 cm ( $15.0 \pm 7.1$  gauss vs  $2.5 \pm 1.5$  gauss,  $P = .24$ ), although this did not reach statistical significance.

## Incidence of clinically significant magnetic interference

### Portable headphones

Clinically significant magnetic interference caused by the headphones was documented in 30 (30%) of 100 patients (Table 2). Magnetic interference more commonly affected ICD patients than PM patients (21/55 [38.2%] vs 9/45 patients;  $P = .048$ ). There was no significant difference in the frequency of magnetic interference based on number of chambers paced (single chamber 26.9%, dual chamber 27.4%, biventricular 50.0%;  $P = .27$ ).



**Figure 2** Example of asynchronous pacing induced when a portable headphone was placed on a patient's chest overlying the pacemaker (top: arrow "Magnet Near Device"). Removal of the headphone (bottom: arrow "Magnet Removed") resulted in an immediate return of normal pacemaker function.

The most commonly observed types of interaction were "magnet responses." All nine PM patients affected by magnetic interference experienced a PM magnet response, characterized by asynchronous pacing (Figure 2). Similarly, all 21 ICD patients affected by magnetic interference experienced an ICD magnet response, characterized by audible sounding of the magnet alarm and inhibition of tachyarrhythmia detection (Figure 3). In all but one of the 30 cases of magnetic interference, removal of the headphones from the patient's chest immediately restored normal device function. One patient, who had a Medtronic Kappa 401 dual-chamber PM, experienced permanent device reprogramming from DDD to DOO mode. However, the device could be reprogrammed to DDD mode with a programmer. This occurrence was reproducible both with reapplication of the headphones and with application of a "doughnut" magnet.

Headphones with a measured magnetic field strength  $\geq 10$  gauss at 2 cm were much more likely to interact with the PM or ICD than were those with a lower magnetic field strength (30/100 [30%] patients vs 0 [0%] 100 patients;  $P < .0001$ ). Magnetic interference was not observed with any PM or ICD when headphones were placed at least 3 cm

**Table 2** Headphone clinical interactions and *in vitro* magnetic field strength

Headphone manufacturer, model, type	Magnetic field strength (gauss)				Clinical interactions*		
	Distance from gaussmeter				PM (N = 45) [n (%)]	ICD (N = 55) [n (%)]	Total (N = 100) [n (%)]
	0 cm	1 cm	2 cm	3 cm			
Sony MDR-Q22LP clip-on	344	75	20	7	9 (20.0)	21 (38.2)	30 (30.0)
Phillips SBC HS430 clip-on	79	27	10	4	4 (8.9)¶	5 (9.1)¶	9 (9.0)¶
Phillips SHE5920 in-ear	215	14	4	1	0 (0)	0 (0)	0 (0)
Bose in-ear‡	111	18	4	1	0 (0)	0 (0)	0 (0)
Sony MDR-E828LP in-ear	260	16	3	1	0 (0)	0 (0)	0 (0)
JVC HA-F130A in-ear	252	12	2	0	0 (0)	0 (0)	0 (0)
Apple in-ear‡	240	10	2	1	0 (0)	0 (0)	0 (0)
JVC HA-FX33A in-ear	11	0	0	0	0 (0)	0 (0)	0 (0)
	Field strength (mean $\pm$ SD)				Total† [N (%)]		
	189.0 $\pm$ 111.0	21.5 $\pm$ 22.9	5.6 $\pm$ 6.5	1.9 $\pm$ 2.4	9 (20.0)	21 (38.2)	30 (30.0)

\*See text for details.

†Number of pacemakers (PMs) or implantable cardioverter-defibrillators (ICDs) experiencing magnetic interference. If a PM or ICD experienced magnetic interference with more than one headphone, it was counted only once.

‡No model number available.

¶All patients who demonstrated a clinical interaction with this headphone also demonstrated an interaction with the Sony MDR-Q22LP clip-on headphone.



**Figure 3** Actual appearance of an implantable cardioverter-defibrillator (ICD) programmer screen. Upon placement of a headphone on a patient's chest overlying the ICD, tachyarrhythmia detection was suspended as indicated by this warning screen displaying "Detection Suspended" (arrow). Removal of the headphone resulted in immediate restoration of normal device function.

from the skin surface. Clinical evidence of magnetic interference was observed more often with clip-on headphones than with earbud headphones (30/100 [30%] patients vs 0/100 [0%] patients;  $P < .0001$ ).

There was no significant difference in the rate of magnetic interference by manufacturer, device model, number of chambers paced, sex, or age. Whether or not the headphones were attached to the digital music player and whether or not the music player was on or off had no impact on the rate of magnetic interference.

### MP3 players

MP3 players were not observed to cause device magnet responses, oversensing, or undersensing.

### Incidence of symptoms

Symptoms due to magnetic interference were rare. Two (2%) patients reported palpitations, and one patient reported lightheadedness and dizziness during asynchronous pacing. No patients reported chest pain, dyspnea, or syncope.

### MP3 player and headphone use

Among the study population, 12% personally owned and used portable headphones on at least a weekly basis. The average frequency of headphone use among these patients was  $3.6 \pm 2.3$  days per week.

### Discussion

Millions of patients have cardiac PMs and ICDs,<sup>12</sup> and the potential for EMI from items such as cell phones and anti-theft devices to affect PM and ICD performance is well documented.<sup>6-11</sup> This study demonstrates that portable headphones, such as those used with portable digital music players (MP3 players) like iPods, generate powerful mag-

netic fields that have the potential to cause clinically relevant magnetic interference in PM and ICD patients.

The most common magnetic substance in portable headphones is neodymium. This substance is found in the earth's crust and has concentrated, powerful magnetic properties.<sup>5</sup> Prior studies with small neodymium magnets demonstrated the potential for magnetic interference on implanted cardiac devices when the magnets were placed within 3 cm of the device.<sup>13</sup> However, detailed data regarding the types of observed interference were not provided.

Importantly, to our knowledge, no adverse events associated with PM or ICD exposure to portable headphones have been reported. Nevertheless, given the millions of PM and ICD patients and the ubiquitous presence of portable headphones, the potential for important clinical interactions exists. For example, placement of portable headphones in a front shirt pocket in close proximity to a patient's ICD could temporarily deactivate the device and inhibit the delivery of a required therapy. Because magnetic field strength falls off quickly with distance, keeping the portable headphones even a short distance from the chest wall can effectively eliminate the potential for magnetic interference. Indeed, evidence of clinically relevant magnetic interference was not observed in this study when headphones were at least 3 cm from the chest wall. Based on these findings, PM and ICD patients should be advised to keep portable headphones at least 3 cm from their chest wall. Specifically, patients should be instructed to avoid draping headphones around their neck over their chest, avoid placing headphones in their front shirt or jacket chest pocket or on an arm band near their chest, and avoid having someone who is wearing headphones from resting his or her head on their chest over their device. PM and ICD patients should not be restricted from using portable headphones in or on their ears because this distance from their implanted cardiac device is sufficient to prevent an interaction.

Only clip-on headphones were noted to interact with implanted PMs and ICDs. This finding appears to relate to the higher magnetic field strengths observed in the two models tested. Although earbud headphones were not noted to cause untoward device interactions, the *in vitro* testing demonstrated that earbud headphone magnetic field strengths are sufficient to interact with implanted cardiac devices. In fact, many earbud headphones had magnetic field strengths  $>200$  gauss, which is more than 20 times that necessary to interact with a PM or ICD.<sup>14</sup> Therefore, the recommendation to keep portable headphones remote from implanted PMs and ICDs applies to these types of headphones as well. Importantly, the magnetic field strength of portable headphones is always "on," whether or not the MP3 player is on or off and whether or not the headphones are even connected to the MP3 player.

A number of factors influence the headphone's magnetic field strength with distance, including the distance of the internal headphone magnet to the headphone surface and the magnet's shape. The magnetic field strength at a distance of 2 cm from the headphone was found to be the strongest

predictor of which headphones would interact; only those with a field strength  $\geq 10$  gauss at 2 cm showed clinical evidence of magnetic interference. Nevertheless, a minority of patients demonstrated any interaction, highlighting that other factors such as the patient's body habitus (and thus the distance from the headphone to the implanted device) and the PM or ICD design contribute to the likelihood of clinically relevant magnetic interference.

PMs and ICDs contain a magnetic switch or sensor that is activated by sufficiently powerful magnetic fields.<sup>15</sup> Generally, this activation leads to temporary asynchronous pacing in PMs and temporary suspension of tachyarrhythmia detection and therapy in ICDs. Normal function resumes as soon as the magnetic field dissipates.<sup>15</sup> The ability to change device functionality noninvasively with an external magnet has important clinical utility and permits remote monitoring of battery function in PM patients and urgent inhibition of therapy in ICD patients receiving inappropriate device therapies. Clinically significant EMI due to other environmental devices, such as cellular telephones or antitheft devices, have led to PM and ICD device design modifications.<sup>16</sup> However, given the important clinical utility of temporary device reprogramming with an external magnet, design modifications in this case are not warranted; patients should simply be instructed to keep portable headphones remote from their implanted PM or ICD. Manufacturers should consider including a warning to this effect in their product labeling.

Concerns about the potential for digital music players to cause EMI with implanted cardiac devices surfaced in 2007 when a report suggested that iPod-PM/ICD interactions may occur.<sup>2</sup> Subsequent studies suggested the interactions were primarily interference with telemetry (communication between the device and device programmer) and not actual interference with the intrinsic function of the implanted device.<sup>3,4,17</sup> Indeed, after bench testing iPods, the Food and Drug Administration announced that the potential for interactions between MP3 players and implanted PMs and ICDs was remote.<sup>3</sup> Our study supports these findings, as not a single episode of clinically relevant EMI was observed despite exposure of 100 PM and ICD patients to two different portable digital music players.

### Study limitations

Although eight different headphone models were tested and these headphones are believed to be representative of commercially available portable headphones, the magnetic field strength of individual headphone models varies. Therefore, the applicability of these results to other headphones is uncertain. Nevertheless, the recommendations to keep all portable headphones at least 3 cm from implanted PMs and ICDs is supported by the study findings. Because continuous device monitoring via the programmer was not possible during headphone testing of some PM and ICD models, it is possible that this study underestimates the true incidence of interaction. Nevertheless, the study was designed to detect potentially meaningful clinical interactions. Although devices from each of the three major PM and ICD manufacturers were tested in this

study, the majority of devices were from one manufacturer. However, no differences in the frequency of headphone-induced magnetic interference were observed among the different brands. In addition, 20 PM models and 13 ICD models were tested. Different devices may be more or less susceptible to magnetic interference from portable headphones. Testing included numerous "modern" current-model devices, suggesting that the results of this study are applicable to most PM and ICD patients.

### Conclusion

Clinically significant magnetic interference can occur when portable headphones are placed in close proximity to implanted PMs and ICDs. The majority of these interactions are typical magnet responses, and in most cases device function returns to normal upon removal of the headphones. *In vitro* measurements of headphone magnetic strength at 2 cm accurately predict headphone clinical interactions with implanted cardiac devices. Patients with an implanted PM or defibrillator should be advised to keep headphones at least 3 cm ( $\sim 1.2$  inches) from their device.

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