APÊNDICE II

Risk Assessment for RAPEX

General Information

Product

Product name:	Portas giratórias detectoras de metais
Product category:	
Description:	Interferência eletromagnética

Risk assessor

First name:	Alexsandro Nogueira Reis
Last name:	Reis
Organisation:	INMETRO
Address:	

Product risks - Overview

Scenario 1 : **Low risk** - Uma pessoa encontra-se perto de uma fonte de CEM, o corpo (sistema nervoso central) fica exposto ao CEM

Scenario 2 : **Low risk** - A pele ou os olhos de uma pessoa são expostos a radiação emitida pelo produto

Overall risk : **Risco baixo**

Scenario 1 : Vulnerable consumers - High intensity electromagnetic field (EMF) source; low frequency or high frequency (microwave)

Product hazard

Hazard Group:	Radiation
Hazard Type:	High intensity electromagnetic field (EMF) source; low frequency or high frequency (microwave)

Consumer

Consumer Type:	Vulnerable consumers - Crianças pequenas. Outras crianças. Outros: pessoas com capacidades físicas, sensoriais ou mentais reduzidas (p. ex. pessoas com deficiência parcial, idosos, incluindo pessoas com mais de 65 anos, com uma certa diminuição das capacidades físicas e mentais), ou com falta de experiência ou conhecimentos.

How the hazard causes an injury to the consumer

Injury scenario:	Uma pessoa encontra-se perto de uma fonte de CEM, o corpo (sistema nervoso central) fica exposto ao CEM

Severity of Injury

Injury:	Long-term damage from contact with substances or from exposure to radiation	
Level:	2	Reversible damage to internal organs, e.g. liver, kidney, slight haemolytic anaemia

Probability of the steps to injury

	Step(s) to Injury	Probability
Step 1:	Probabilidade de desenvolver arritmia cardíaca.	0.05
Step 2:	Probabilidade de o portador de arritmia cardíaca ser usuário de marca-passo.	0.04
Step 3:	Probabilidade de portadores de marca-passo estarem suscepitíveis a interferências eletromagnéticas diversas.	0.016
Step 4:	Probabilidade de um paciente com arritmia e portador de marca-passo submetido a campo magnético sofrer morte súbita.	0.0347

Calculated probability:	0.000001100
Overall probability:	> 1/1,000,000
Risk of this scenario:	Low risk

Scenario 2 : Vulnerable consumers - Ultraviolet radiation

Product hazard

Hazard Group: Radiation
Hazard Type: Ultraviolet radiation

Consumer

Consumer Type: Vulnerable consumers - Crianças pequenas. Outras crianças. Outros: pessoas com capacidades físicas, sensoriais ou mentais reduzidas (p. ex. pessoas com deficiência parcial, idosos, incluindo pessoas com mais de 65 anos, com uma certa diminuição das capacidades físicas e mentais), ou com falta de experiência ou conhecimentos.

How the hazard causes an injury to the consumer

Injury scenario: A pele ou os olhos de uma pessoa são expostos a radiação emitida pelo produto

Severity of Injury

Injury: Long-term damage from contact with substances or from exposure to radiation
Level: 2 Reversible damage to internal organs, e.g. liver, kidney, slight haemolytic anaemia

Probability of the steps to injury

	Step(s) to Injury	Probability
Step 1:	Probabilidade de desenvolver arritmia cardíaca.	0.05
Step 2:	Probabilidade de o portador de arritmia cardíaca ser usuário de marca-passo.	0.04
Step 3:	Probabilidade de portadores de marca-passo estarem suscepitíveis a interferências eletromagnéticas diversas.	0.016
Step 4:	Probabilidade de um paciente com arritmia e portador de marca-passo submetido a campo magnético sofrer morte súbita.	0.0347

Calculated probability: 0.000001100
Overall probability: > 1/1,000,000
Risk of this scenario: Low risk

MATRIZ GUT

Escores					
5	4	3	2	1	0

GRAVIDADE (G)							Nota Atribuída
A)Risco	Extremo	Alto		Moderado	Baixo		
	5	4		2	1		1
B) Similares fora do país			Sim			Não	
			3			0	3
C) Impacto sobre saúde		Sim				Não	
		4				0	4
D)Impacto Meio Ambiente		Sim				Não	
		4				0	0
E) Práticas enganosas		Sim				Não	
		4				0	4
F) Utilização por crianças e/ou idosos		Sim		Não			
		4		2			4
TOTAL (G)							16

URGÊNCIA (U)							Nota Atribuída
A)Pressão Política		Sim				Não	
		4				0	0
B) Pressão do Setor				Sim		Não	
				2		0	0
C) Pressão Sociedade		Sim				Não	
		4				0	0
D) Apelo Midiático		Sim				Não	
		4				0	0
E) Prazo dos impactos			Curto	Médio	Longo		
			3	2	1		3
F) Não tratamento causa impacto econômico		Sim			Não		
		4			1		1
G) Não tratamento causa impacto social		Sim			Não		
		4			1		1
TOTAL (U)							5

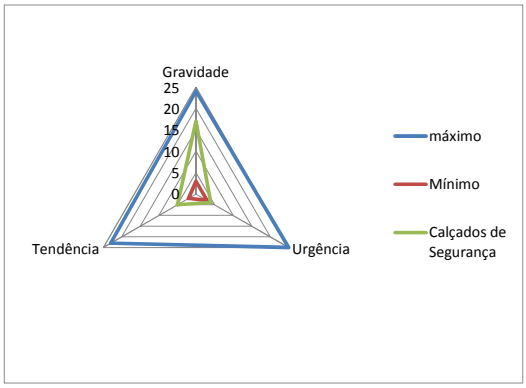
TENDÊNCIA (T)						Nota Atribuída
A)Problema já apresentado antes (recorrente)		Sim		Não		
		4		1		1
B) Acidente nos últimos 12 meses			Sim	Não		
			3	1		1
C) Possível resolução sem Inmetro intervir			Não		Sim	
			3		0	0
D) Inmetro tem competência legal			Sim		Não	
			3		0	3
E) O PAP apontou problemas em relação ao objeto	Sim				Não	
	5				0	0
F) Diretriz Governamental/ Politica Pública	Sim				Não	
	5				0	0
TOTAL (T)						5

PONTUAÇÃO DO PROBLEMA	400

Valor da Pontuação/ Tratamento

Não Ação	< 537
AIR	538 até 5370
Direto Desenvolvimento	5371 até 10800

	Gravidade	Urgência	Tendência
máximo	24	25	23
Mínimo	3	3	2
Calçados de Segurança	17	4	5



APÊNDICE IV

Probabilidade de um campo eletromagnético interferir em marcapasso

PROBABILIDADE	DESCRIÇÃO	MÉMORIA DE CÁLCULO	FONTE DE DADOS	VALOR
P(a)	Probabilidade de desenvolver arritmia cardíaca	Nº de pessoas que apresentam algum tipo de arritmia/população brasileira	Sociedade Brasileira de Arritmia Cardíaca: http://www.sobrac.org/publico-geral/?p=3885	0,05
P(p/a)	Probabilidade de o portador de arritmia cardíaca ser usuário de marcapasso.	Nº de registros de implantes de marca-passo no Brasil/Nº de portadores de arritmia cardíaca	Departamento de Estimulação Cardíaca Artificial: http://www.deca.saude.ws/medica/RBM_DadosglobaisNew.aspx	0,04
P(b/p)	Probabilidade de portadores de marca-passo estarem suscepitíveis a interferências eletromagnéticas diversas.	Resultado observado no estudo do Anexo VI	**Clinical Study of Interference With Cardiac Pacemakers by a Magnetic Field at Power Line Frequencies.** Journal of the American College of Cardiology (Anexo VI)	0,016
P(l/p)	Probabilidade de um paciente com arritmia e portador de marca-passo submetido a campo magnético sofrer morte súbita.	Nº de mortes por doenças cardiovasculares no Brasil*/Nº de portadores de arritmia	Cardiômetro (Sociedade Brasileira de Cardiologia): http://www.cardiometro.com.br/	0,03
			Total:	0,0000011101

* As doenças cardiovasculares abrangem as doenças do sistema circulatório, que inclui o coração. Entre elas está a angina, doenças isquêmicas, infarto agudo do miocárdio, arritmia etc. Sendo assim, podemos inferir que a quantidade real de mortes por arritmia (um dos tipos de doenças do coração) é menor do que o dado utilizado nessa planilha. Utilizamos esse dado por falta de informações mais precisas quanto ao número de mortes dos portadores de arritmias.

Profundida de penetração de onda eletromagnética na pele

Frequência (GHz)	Profundiade de penetração (mm)	Comprimento de onda (λ cm)
1	15,9	30
1,5	11,9	20
1,8	10,0	17
2,5	7,3	12

Propriedades dielétricas do tecido humano

Skin (Wet)

Frequency (Hz)	Human (In vivo-forearm) Current study measurements ε′	ε″	σ (S/m)
1.995E+1	8.045E+4	2.600E+5	2.887E-4
2.239E+1	7.563E+4	2.394E+5	2.981E-4
2.512E+1	7.540E+4	2.133E+5	2.981E-4
2.818E+1	7.352E+4	1.905E+5	2.987E-4
3.162E+1	7.147E+4	1.706E+5	2.999E-4
3.548E+1	6.956E+4	1.526E+5	3.013E-4
3.981E+1	6.808E+4	1.362E+5	3.017E-4
4.467E+1	6.668E+4	1.221E+5	3.034E-4
5.012E+1	6.797E+4	1.107E+5	3.087E-4
5.623E+1	6.300E+4	9.829E+4	3.075E-4
6.310E+1	6.144E+4	8.917E+4	3.130E-4
7.079E+1	6.039E+4	8.030E+4	3.163E-4
7.943E+1	5.889E+4	7.264E+4	3.210E-4
8.913E+1	5.762E+4	6.579E+4	3.262E-4
1.000E+2	5.629E+4	5.969E+4	3.321E-4
1.122E+2	5.524E+4	5.445E+4	3.399E-4
1.259E+2	5.406E+4	4.962E+4	3.475E-4
1.413E+2	5.297E+4	4.533E+4	3.563E-4
1.585E+2	5.192E+4	4.147E+4	3.656E-4
1.778E+2	5.087E+4	3.795E+4	3.754E-4
1.995E+2	4.993E+4	3.478E+4	3.861E-4
2.239E+2	4.898E+4	3.195E+4	3.979E-4
2.512E+2	4.813E+4	2.942E+4	4.112E-4
2.818E+2	4.723E+4	2.709E+4	4.248E-4
3.162E+2	4.642E+4	2.503E+4	4.403E-4
3.548E+2	4.567E+4	2.318E+4	4.575E-4
3.981E+2	4.491E+4	2.147E+4	4.755E-4
4.467E+2	4.420E+4	1.995E+4	4.958E-4
5.012E+2	4.350E+4	1.857E+4	5.178E-4
5.623E+2	4.286E+4	1.735E+4	5.429E-4
6.310E+2	4.223E+4	1.624E+4	5.700E-4
7.079E+2	4.162E+4	1.522E+4	5.996E-4
7.943E+2	4.102E+4	1.432E+4	6.330E-4
8.913E+2	4.043E+4	1.350E+4	6.693E-4
1.000E+3	3.987E+4	1.276E+4	7.096E-4
1.122E+3	3.933E+4	1.208E+4	7.541E-4
1.259E+3	3.880E+4	1.149E+4	8.050E-4
1.413E+3	3.827E+4	1.096E+4	8.609E-4
1.585E+3	3.776E+4	1.048E+4	9.238E-4
1.778E+3	3.726E+4	1.005E+4	9.943E-4
1.995E+3	3.676E+4	9.681E+3	1.075E-3
2.239E+3	3.628E+4	9.348E+3	1.164E-3
2.512E+3	3.580E+4	9.067E+3	1.267E-3
2.818E+3	3.534E+4	8.819E+3	1.383E-3
3.162E+3	3.489E+4	8.587E+3	1.511E-3
3.548E+3	3.441E+4	8.421E+3	1.662E-3
3.981E+3	3.395E+4	8.275E+3	1.833E-3
4.467E+3	3.348E+4	8.157E+3	2.027E-3
5.012E+3	3.301E+4	8.072E+3	2.251E-3
5.623E+3	3.254E+4	8.014E+3	2.507E-3
6.310E+3	3.207E+4	7.989E+3	2.804E-3
7.079E+3	3.159E+4	7.981E+3	3.143E-3
7.943E+3	3.110E+4	7.990E+3	3.531E-3
8.913E+3	3.060E+4	8.021E+3	3.977E-3
1.000E+4	3.010E+4	8.079E+3	4.494E-3
1.122E+4	2.958E+4	8.149E+3	5.087E-3
1.259E+4	2.905E+4	8.233E+3	5.766E-3
1.413E+4	2.851E+4	8.345E+3	6.557E-3
1.585E+4	2.793E+4	8.460E+3	7.459E-3
1.778E+4	2.737E+4	8.592E+3	8.500E-3
1.995E+4	2.678E+4	8.735E+3	9.696E-3
2.239E+4	2.617E+4	8.884E+3	1.107E-2
2.512E+4	2.554E+4	9.049E+3	1.265E-2
2.818E+4	2.489E+4	9.220E+3	1.446E-2
3.162E+4	2.421E+4	9.385E+3	1.651E-2
3.548E+4	2.352E+4	9.554E+3	1.886E-2
3.981E+4	2.283E+4	9.722E+3	2.153E-2
4.467E+4	2.210E+4	9.890E+3	2.458E-2
5.012E+4	2.134E+4	1.005E+4	2.801E-2
5.623E+4	2.055E+4	1.020E+4	3.191E-2
6.310E+4	1.973E+4	1.033E+4	3.626E-2
7.079E+4	1.889E+4	1.044E+4	4.111E-2
7.943E+4	1.803E+4	1.053E+4	4.655E-2
8.913E+4	1.716E+4	1.061E+4	5.260E-2
1.000E+5	1.626E+4	1.065E+4	5.925E-2
1.122E+5	1.535E+4	1.065E+4	6.646E-2
1.259E+5	1.443E+4	1.063E+4	7.444E-2
1.413E+5	1.351E+4	1.056E+4	8.300E-2
1.585E+5	1.259E+4	1.047E+4	9.228E-2
1.778E+5	1.167E+4	1.033E+4	1.022E-1
1.995E+5	1.077E+4	1.015E+4	1.126E-1
2.239E+5	9.885E+3	9.923E+3	1.236E-1
2.512E+5	9.025E+3	9.656E+3	1.349E-1
2.818E+5	8.193E+3	9.352E+3	1.466E-1
3.162E+5	7.400E+3	9.011E+3	1.585E-1
3.548E+5	6.646E+3	8.638E+3	1.705E-1
3.981E+5	5.945E+3	8.242E+3	1.825E-1
4.467E+5	5.289E+3	7.827E+3	1.945E-1
5.012E+5	4.685E+3	7.396E+3	2.062E-1
5.623E+5	4.133E+3	6.961E+3	2.178E-1
6.310E+5	3.634E+3	6.525E+3	2.290E-1
7.079E+5	3.182E+3	6.092E+3	2.399E-1
7.943E+5	2.775E+3	5.668E+3	2.505E-1
8.913E+5	2.416E+3	5.253E+3	2.605E-1
1.000E+6	2.100E+3	4.854E+3	2.700E-1
1.090E+6	2.906E+3	3.379E+3	2.000E-1
1.310E+6	2.444E+3	3.100E+3	2.300E-1
1.570E+6	1.976E+3	2.795E+3	2.400E-1
1.890E+6	1.640E+3	2.583E+3	2.700E-1
2.280E+6	1.330E+3	2.359E+3	3.000E-1
2.740E+6	1.076E+3	2.078E+3	3.200E-1
3.290E+6	8.826E+2	1.848E+3	3.400E-1
3.950E+6	6.814E+2	1.651E+3	3.600E-1
4.750E+6	5.473E+2	1.440E+3	3.800E-1
5.720E+6	4.484E+2	1.240E+3	3.900E-1
6.870E+6	3.825E+2	1.067E+3	4.100E-1
8.260E+6	2.959E+2	9.175E+2	4.200E-1
9.930E+6	2.442E+2	7.824E+2	4.300E-1
1.190E+7	2.052E+2	6.691E+2	4.400E-1
1.440E+7	1.710E+2	5.703E+2	4.600E-1
1.730E+7	1.448E+2	4.847E+2	4.700E-1
2.080E+7	1.251E+2	4.127E+2	4.800E-1
2.500E+7	1.095E+2	3.499E+2	4.900E-1
3.000E+7	9.797E+1	2.972E+2	5.000E-1
3.610E+7	8.841E+1	2.523E+2	5.100E-1
4.340E+7	8.019E+1	2.133E+2	5.100E-1
5.210E+7	7.383E+1	1.804E+2	5.200E-1
6.270E+7	6.874E+1	1.527E+2	5.300E-1
7.540E+7	6.467E+1	1.291E+2	5.400E-1
9.060E+7	6.154E+1	1.092E+2	5.500E-1

Skin (Wet)

Frequency (Hz)	Human (In vivo-forearm) Current study measurements ε′	ε″	σ (S/m)
1.090E+8	6.000E+1	9.257E+1	5.600E-1
1.310E+8	5.900E+1	7.850E+1	5.700E-1
1.570E+8	5.800E+1	6.653E+1	5.800E-1
1.890E+8	5.700E+1	5.649E+1	5.900E-1
1.940E+8	5.750E+1	5.770E+1	6.200E-1
2.150E+8	5.650E+1	5.287E+1	6.300E-1
2.380E+8	5.624E+1	4.844E+1	6.400E-1
2.630E+8	5.530E+1	4.459E+1	6.500E-1
2.910E+8	5.442E+1	4.110E+1	6.700E-1
3.220E+8	5.345E+1	3.783E+1	6.800E-1
3.560E+8	5.269E+1	3.481E+1	6.900E-1
3.940E+8	5.196E+1	3.206E+1	7.000E-1
4.350E+8	5.131E+1	2.966E+1	7.200E-1
4.810E+8	5.072E+1	2.736E+1	7.300E-1
5.330E+8	5.018E+1	2.526E+1	7.500E-1
5.890E+8	4.980E+1	2.346E+1	7.700E-1
6.510E+8	4.943E+1	2.193E+1	7.900E-1
7.200E+8	4.893E+1	2.053E+1	8.200E-1
7.970E+8	4.851E+1	1.918E+1	8.500E-1
8.810E+8	4.818E+1	1.800E+1	8.800E-1
9.740E+8	4.780E+1	1.700E+1	9.200E-1
1.080E+9	4.752E+1	1.613E+1	9.700E-1
1.190E+9	4.722E+1	1.536E+1	1.020E+0
1.320E+9	4.683E+1	1.469E+1	1.080E+0
1.460E+9	4.651E+1	1.414E+1	1.150E+0
1.610E+9	4.619E+1	1.370E+1	1.230E+0
1.780E+9	4.584E+1	1.335E+1	1.320E+0
1.970E+9	4.548E+1	1.305E+1	1.430E+0
2.180E+9	4.505E+1	1.287E+1	1.560E+0
2.410E+9	4.463E+1	1.280E+1	1.720E+0
2.670E+9	4.422E+1	1.278E+1	1.900E+0
2.950E+9	4.377E+1	1.282E+1	2.100E+0
3.260E+9	4.334E+1	1.294E+1	2.350E+0
3.610E+9	4.287E+1	1.313E+1	2.640E+0
3.990E+9	4.236E+1	1.341E+1	2.980E+0
4.410E+9	4.179E+1	1.378E+1	3.380E+0
4.880E+9	4.113E+1	1.421E+1	3.860E+0
5.400E+9	4.030E+1	1.467E+1	4.410E+0
5.970E+9	3.941E+1	1.517E+1	5.040E+0
6.600E+9	3.848E+1	1.569E+1	5.770E+0
7.300E+9	3.747E+1	1.618E+1	6.580E+0
8.080E+9	3.636E+1	1.665E+1	7.480E+0
8.940E+9	3.512E+1	1.712E+1	8.510E+0
9.880E+9	3.380E+1	1.756E+1	9.650E+0
1.090E+10	3.243E+1	1.789E+1	1.088E+1
1.210E+10	3.107E+1	1.819E+1	1.223E+1
1.340E+10	2.970E+1	1.840E+1	1.368E+1
1.480E+10	2.821E+1	1.852E+1	1.523E+1
1.640E+10	2.667E+1	1.863E+1	1.695E+1
1.810E+10	2.515E+1	1.868E+1	1.879E+1
2.000E+10	2.367E+1	1.870E+1	2.081E+1

COMPILATION OF THE DIELECTRIC PROPERTIES OF BODY TISSUES AT RF AND MICROWAVE FREQUENCIES

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ANEXO II

Journal of the American College of Cardiology
© 2005 by the American College of Cardiology Foundation
Published by Elsevier Inc.

Vol. 45, No. 6, 2005
ISSN 0735-1097/05/$30.00
doi:10.1016/j.jacc.2004.10.072

Cardiac Pacemakers

Clinical Study of Interference With Cardiac Pacemakers by a Magnetic Field at Power Line Frequencies

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OBJECTIVES This study examined the risk of interference by high magnetic flux density with permanent pacemakers.

BACKGROUND Several forms of electromagnetic energy may interfere with the functions of implanted pacemakers. No clinical study has reported specific and relevant information pertaining to magnetic fields near power lines or electrical appliances.

METHODS A total of 250 consecutive tests were performed in 245 recipients of permanent pacemakers during 12-lead electrocardiographic monitoring. A dedicated exposure system generated a 50-Hz frequency and maximum 100-μT flux density, while the electrical field was kept at values on the order of 0.10 V/m.

RESULTS A switch to the asynchronous mode was recorded in three patients with devices programmed in the unipolar sensing configuration. A sustained mode switch was followed by symptomatic pacing inhibition in one patient. No effect on devices programmed in bipolar sensing was observed, except for a single interaction with a specific capture monitoring algorithm.

CONCLUSIONS The overall incidence of interaction by a magnetic field was low in patients tested with a wide variety of conventionally programmed pacemaker models. A magnetic field pulsed at power frequency can cause a mode switch and pacing inhibition in patients with devices programmed in the unipolar sensing configuration. The risk of interference appears negligible in patients with bipolar sensing programming. (J Am Coll Cardiol 2005;45:896–900) © 2005 by the American College of Cardiology Foundation

Electromagnetic interference (EMI) with implanted pacemakers has been studied in vitro and in several clinical studies or reported from anecdotal daily life observations. Electromagnetic interference may be observed near high-voltage power lines and plants, transformers, or other structures or may be caused by electrical appliances held close to the chest. Although interference by strong electrical fields has been widely reported, EMI from magnetic fields has not been studied as intensively. Strong magnetic fields are present in industrial or occupational environments and emitted in day-to-day life by household appliances and some electronic surveillance articles. The safe limits of exposure to magnetic flux in recipients of implanted pacemakers remain to be established. Although simulations using a model of the human body have been presented, a single, nondefinitive clinical study has been published on this subject (1–3).

This study was designed to examine, in a large patient population, the behavior of implanted cardiac pacemakers in the presence of magnetic fields at power line frequency and 100-μT flux density, the value retained at 50 Hz in the European recommendations for general public exposure (1999/519/EC) (4). The objectives were to provide clinical data to international organizations responsible for establishing specific limits of exposure for recipients of permanent pacemakers.

METHODS

Patient population. The study design was approved by the Ethical Committee for Human Research of La Pitié-Salpétrière Hospital, University of Paris, France. All patients between 18 and 85 years of age presenting for routine ambulatory pacemaker follow-up during the study period were invited to participate. Written, informed consent was obtained from all patients. Pretesting examination included a 12-lead electrocardiogram (ECG), device interrogation, pacing and sensing threshold measurements, exclusion of myopotential interference, and evaluation of the intrinsic rhythm. The optimal pacing/sensing parameters determined for each patient were programmed and remained unchanged during testing. Pacing dependency was defined as a 2-s period of asystole or an escape rhythm at a rate $\leq$40 beats/min during pacing inhibition or during measurement of the capture threshold.

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Manuscript received August 22, 2004; revised manuscript received September 19, 2004, accepted October 18, 2004.

Abbreviations and Acronyms
AVB = atrioventricular block
ECG = electrocardiogram
EMI = electromagnetic interference

Testing protocol. The exposure system consisted of a pair of rectangular, 120 × 140 cm, Helmholtz coils, 80 cm apart, mounted at the level of the patient's chest. A programmable source of alternative current was connected to the coils (model 6530, Chroma, Taipei-Hsien, Taiwan). Under the control of a computer using a LabView program (National Instruments, Austin, Texas), the source generated a 50-Hz magnetic field with a flux density programmable between 0 and 100 μT. The nominal voltage of the circuit was 16 V. Each coil consisted of 29 wires, 1.53 mm^2 in the cross-sectional area, receiving 5-V tension, generating 3-Amp current. The electrical field between the gates was on the order of 0.10 V/m. Three-dimensional calculation of the flux density with the EFC 400 software (Wandel and Goltermann, Eningen, Germany) confirmed the homogeneity of the magnetic field at the center of the induction volume (Fig. 1). The flux density, calculated as the total flux divided by the cross-sectional area of the volume through which it flows, was monitored through the exposure system by a sensor fixed on one of the gates at the level of the patient's chest. The room flux density was measured by a three-axial detector placed at a distance of 3 m away from the system.

No component of the system under tension was exposed, and the installation of the exposure system was approved by the local electrical safety commission. The patients were instructed to walk through the system at a normal pace, once parallel and once perpendicular to the gates, as well as stand at least 20 s inside the system. Thus, six exposures, three with and three without magnetic field generated, were randomly assigned to each patient, during each test. During the test, the time/density of the continuous signal of the magnetic field in the exposure system was monitored. The data collection included the frequency of the signal, voltage amplitude from the source, root mean square voltage, and current in the coils. The position of the patient, signal

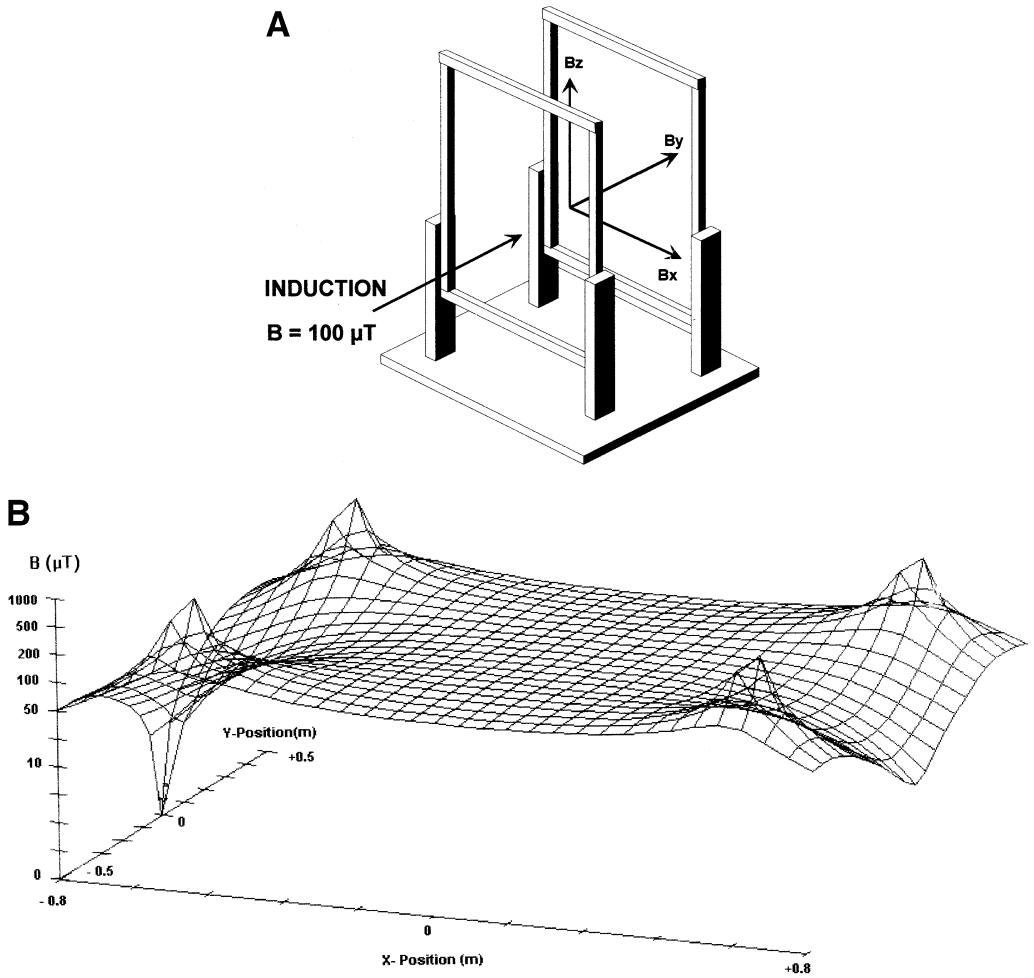

Figure 1. Exposure of the pacing systems and configuration of the magnetic field. The flux density (μT) was calculated along the longitudinal Bx, transversal By, and vertical Bz axes. A homogeneous 100-μT flux density was also measured between the gates at the level of the chest. The flux density was shown in the horizontal plane at Z0 (Helmholtz coils center). The high values correspond to the proximity of the coils.

Table 1. Demographic and Clinical Characteristics of the Patient Population

Men/women, number (%) of tests	151/99 (60.4/39.6)
Age (yrs)	72.2 ± 10.6 (18–85)
Height (cm)	165.8 ± 8.5 (142–188)
Weight (kg)	72.4 ± 15.1 (41–135)
Pacing indications, number (%) of tests	
Sinus node dysfunction	99 (39.6)
Atrioventricular block	134 (53.6)
Sinus node dysfunction and atrioventricular block	11 (4.4)
Other	6 (2.4)
Side of implant, number (%) of tests	
Left	221 (88.4)
Right	29 (11.6)
Years of implant, number (%) of tests	
1984–1994	16 (6.4)
1995–1999	83 (33.2)
2000–2004	151 (60.4)

Unless specified otherwise, data are expressed as the mean value ± SD (range).

frequency, and flux densities in the room and in the gate were recorded every second in an Excel program application (Microsoft Corp., Seattle, Washington). A 12-lead ECG was continuously monitored using an independent computer-based ECG with an optical fiber connection to guarantee complete insulation of the patient from the computer. Attention was paid to select recordings free of motion or 50-Hz artifacts, which might have precluded a detailed analysis of the ECG. All tests were performed at a 100-μT maximum flux density. The test could be interrupted at any time, if necessary, or repeated to study its reproducibility. In case of interference, the control of the flux density between 0 and 100 μT was used to identify the lowest value causing the interference. Interrogation of the pulse generator was repeated after each test.

Table 2. Electrocardiographic and Pacing Variables

Surface electrocardiogram, number (%) of tests	
Atrial and or ventricular pacing	204 (81.6)
Pacing dependency	133 (53)
Spontaneous rhythm	46 (18.4)
Atrial flutter or fibrillation	47 (18.8)
Pacing mode, number (%) of tests	
DDD(R)	164 (65.6)
DDI(R)	25 (10)
AAI(R)	4 (1.6)
VVI(R)	47 (18.8)
VDD(R)	10 (4)
Sensing configuration, number (%) of tests	
Bipolar	153 (61.2)
Unipolar	52 (20.8)
Bipolar combined with unipolar	45 (18)
Atrial sensitivity (mV)	
Bipolar (n = 165)	0.60 ± 0.27 (0.10–3.0)
Unipolar (n = 38)	1.35 ± 0.21 (0.40–1.20)
Ventricular sensitivity (mV)	
Bipolar (n = 163)	2.54 ± 0.75 (1.0–5.6)
Unipolar (n = 83)	2.60 ± 0.83 (1.0–8.0)

Unless specified otherwise, data are expressed as the mean value ± SD (range).

Table 3. Pacemaker Models Tested

Manufacturer	Single-Chamber	n	Dual-Chamber	n
Biotronik (6)			ACTROS DR	1
			AXIOS SLR	3
			DROMOS DR	1
			PHYLOS DR	1
Ela Medical (56)	112	2	213	11
	113	1	230	1
	133	1	233	12
	4621	1	2550	2
			6004	2
			6234	8
			7034	3
			7234	5
			7334	7
Guidant (43)			972	1
			1270	2
			1274	13
			1280	15
			1298	12
Intermedics (4)	291-09	1	292-07	1
			292-09	1
			293-03	1
Medtronic (67)	701 SR	1	303	1
	8423	1	701 VDD	1
	8960	3	706	2
			731	23
			733	3
			906	1
			931	7
			7005	1
			7085	1
			7107	1
			7940	1
			7941	1
			7950	2
			7952	1
			7960	6
			7961	1
			7962	7
			7966	1
			8948	1
Pacesetter (5)	242-6	1	283	1
			2010	2
			2011	1
St. Jude (47)	2400	3	2364	8
	5130	1	5230	1
	5172	1	5330	13
			5346	9
			5376	9
			5430	2
Sorin (5)	MINIOR 100	1	MINISWING DR1	1
			ELECT D	2
			LIVING	1
Telectronics (1)			1256	1
Vitatron (16)	530	1	620	2
	611	1	640	1
			800	1
			900 E	7
			9000	2
			C60	1
Total = 250		20		230

Table 4. Details of the Positive Tests

Test number	94	96	161	180
Pacing indication	AVB	AVB	AVB	AVB
Side of implant	Right	Left	Left	Left
Manufacturer	Medtronic	St. Jude	Guidant	Medtronic
Model	7960	5376	1280	731
Year of implant	1997	2003	2001	2000
Pacing mode	DDD	DDD	DDD	DDD
Permanent ventricular pacing	Yes	No	Yes	Yes
Pacing dependency	Yes	No	Yes	Yes
Atrial sensing polarity	Unipolar	Bipolar	Unipolar	Unipolar
Atrial sensitivity (mV)	0.50	0.75	0.50	0.50
Ventricular sensing polarity	Unipolar	Bipolar	Bipolar	Unipolar
Ventricular sensitivity (mV)	2.80	2.00	2.50	2.80
Electrocardiogram	DOO pacing inhibition	Automatic threshold test*	DOO	DOO

*Interaction with AutoCapture algorithm.

The data are presented as number and percentage of test, with the mean value ± SD and range.

RESULTS

A total of 250 tests were performed in 245 patients, five of whom had a second test after pulse generator replacement for battery depletion. The results are shown in Tables 1, 2, 3, and 4. Interference was observed in four (1.6%) of 250 tests. A mode switch from DDD to DOO pacing was recorded during the test in three patients with unipolar programming. Transient, asymptomatic, asynchronous dual-chamber pacing was recorded in two patients, one with unipolar atrial and ventricular sensing (Medtronic model 731) and the other with atrial unipolar sensing combined with bipolar ventricular sensing (Guidant model 1280). In a third patient, a switch to the asynchronous mode was followed by pacing inhibition (Fig. 2), resulting in complete atrioventricular (AV) block with profound bradycardia and lightheadedness (Medtronic model 7960). The lowest value inducing the mode switch was 45 μT. A mode switch was recorded in none of 153 tests of systems programmed in both atrial and ventricular bipolar sensing configuration, although during one test, transient ventricular pacing with a shorter than programmed AV delay was observed. This effect was caused by an interaction between the extracardiac signals and a specific algorithm used to confirm ventricular capture on a beat-by-beat basis. Bipolar atrial sensing at 0.75 mV was associated with bipolar ventricular sensing at 2 mV (St. Jude Medical, model 5376, AutoCapture). On post-test interrogation, reprogramming of no pulse generator was observed.

DISCUSSION

Interference by electrical appliances generating 50- or 60-Hz electrical or magnetic fields in close or direct contact with cardiac pacemakers is a known potential hazard (5). The main risk factors include device sensitivity, distance from the source of magnetic field, and field strength and orientation. In several clinical studies, the characteristics of the source of interference were poorly detailed or not monitored, and electrical and magnetic fields were often combined. Reprogramming of the sensitivity settings before testing, and variations in the exposure parameters lead to under- or overestimation of risks and consequences of interference. To our knowledge, a single clinical study has previously examined the risk of interference by magnetic fields. The fields were generated by 400-kV outdoor power plant substations located along roads. Interference was

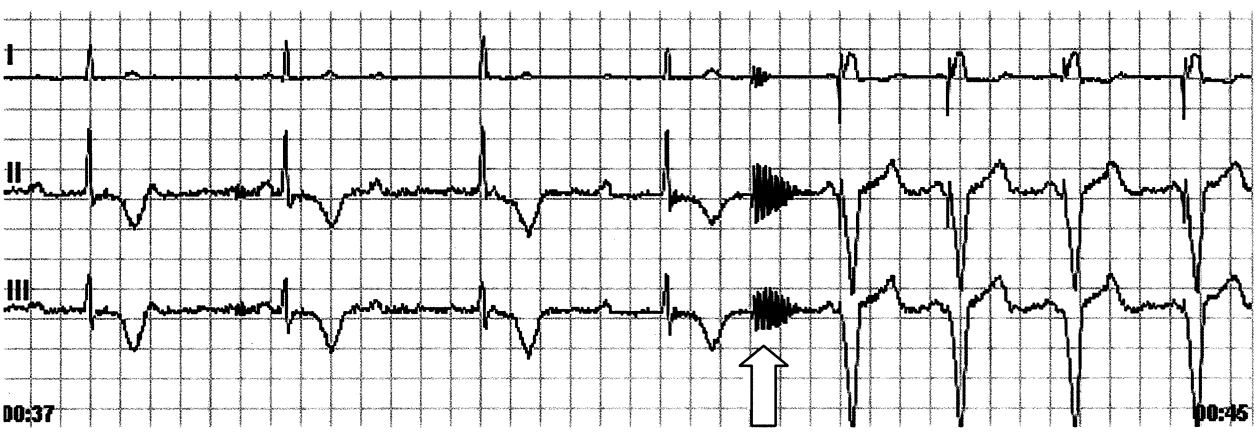

Figure 2. Testing of Medtronic model 7960. Continuous recording showing pacing inhibition and complete atrioventricular block during exposure. Normal DDD pacing resumed when exposure to the magnetic field was interrupted **(arrow).**

observed in one of 15 patients tested at the highest unipolar device sensitivity (3). The exposure system used in our study generated a continuously monitored, pure magnetic field, in the absence of any other electrical field. This system had been evaluated in preliminary tests with a 50-μT magnetic field, at 50- and 60-Hz frequencies (6). In our protocol, the 50-Hz frequency was the same as that of the European distribution of electricity, and the 100-μT flux density was at the recommended safety level for public exposure at 50 Hz (4). The simulation of the geometric effect in the field was included by orienting the device parallel or perpendicular to the gates. Implanted pacing systems form induction loops within which interference voltages may be induced by time-varying magnetic fields. In vitro studies have shown interference thresholds between 552 and 16 μT (root mean square) for magnetic fields at frequencies between 10 and 250 Hz (2).

Numerical simulations in millimeter-resolution, heterogeneous human body models have been performed to study the interference by 60-Hz magnetic fields with implanted unipolar pacemakers. Approximations derived from Faraday's law underscore the complexities of the induced current flowing through the human body, the length and placement of the leads with respect to the direction of the magnetic flow, and the inhomogeneous conductivity. Both the model and the input resistance of the pacemaker amplifier play critical roles in the results of these simulations. Estimated EMI thresholds under "worst case scenarios" were ~40 μT for atrial electrodes at a sensitivity setting of 0.25 mV and 140 μT for ventricular electrodes at a setting of 0.75 mV (1). According to Faraday's law of induction, a left-sided unipolar permanent pacemaker is considered the most sensitive. In this configuration, the lead forms the largest inductive area, a semi-circular area ~225 cm^2, into which a magnetic field can induce a voltage. In bipolar systems, it was estimated that the field must be 17-fold larger to produce the same effect (7). The bipolar sensing configuration is the most protective against EMI. In recent pacemaker models, bipolar sensing is combined with self-adjustments enabling the settings of lower sensitivity levels than usual or nominal.

Our study shows a low incidence of interference by a high-density magnetic field in patients tested during routine follow-up visits, without changes in the programmed sensitivity settings or other pacing parameters made before the test. No interference was shown with bipolar programming, except for a clinically nonsignificant interaction with a specific capture threshold algorithm. In patients with unipolar sensing programming, the interference can cause sustained asynchronous mode reversion and pacing inhibition. Therefore, the risk of interference by a 50-Hz/100-μT magnetic field appears negligible in patients with bipolar sensing programming. AutoCapture function, which may be sensitive to EMI, should be disabled in patients who work in such environments. These clinical observations will help establish the specific limits of exposure to magnetic fields in patients with implanted pacemakers.

Study limitations. Continuous marker channel and intracardiac electrogram recordings allow a more accurate analysis of pacemaker behavior. These recordings were not used, because, in a preliminary study, direct interference by the magnetic field on the telemetry frequently interrupted the data transmission. Therefore, minor abnormalities on the surface ECG may have been missed.

Conclusions. Magnetic fields pulsed at power frequency caused an intermittent mode switch or pacing inhibition in a small percentage of patients with permanent pacemakers programmed in the unipolar sensing configuration. No device reprogramming was observed in this study. The overall incidence of interference was low with typical device programming.

Acknowledgments

We thank Jacques Lambrozo, MD, from the Department of Medical Studies, EDF-Gaz de France, and Robert Frank, MD, Cardiology Institute, Hôpital Pitié Salpétrière, Paris, France.

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