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Implantable Cardioverter Defibrillators in Magnetic Fields of a 400 kV Substation

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Abstract—Workers using an implantable cardioverter defibrillator (ICD) are classified by European Directive 2013/35/EU as being at particular risk because of the potential interference between implanted medical devices and electromagnetic fields. The aim of the study was to investigate ICD function using a human-shaped phantom in high magnetic fields of a shunt reactor at a 400 kV substation. We used the phantom in the following experiment periods: isolated from the ground, grounded by a foot, or grounded by a hand. We performed five ICD tests using five different ICD devices. In experiment place A, the magnetic field was over 1000 μT, and in experiment place B, the exposure was over 600 μT. We did not find any disturbances in the ICDs. However, we conducted only 5 ICD experiments in real exposure situations at 400 kV substations. Although it is not possible to draw a strong conclusion regarding risk level, the risk of such ICD disturbances from magnetic field exposure at 400 kV substations does not appear to be high.

1. INTRODUCTION

The use of active implanted medical devices is quite widespread; for example, about 300,000 persons receive an implantable cardioverter defibrillator (ICD) each year worldwide [1]. In ANSI/AAMI PC69:2007 standards [2], an ICD was defined as an active implantable medical device intended to detect and correct tachycardia and fibrillation by application of cardioversion/defibrillation pulses to the heart created by an implantable pulse generator and leads.

The European Directive 2013/35/EU, which is given by the European Parliament and of the Council on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields), has classified workers with implanted medical devices as being at particular risk because of the potential interference between implanted medical devices and electromagnetic fields (EMFs) [3]. According Directive 2013/35/EU, certain workers may experience interference problems such that EMFs affect the functioning of their medical devices (for example, metallic prostheses, cardiac pacemakers (PMs), ICDs, cochlear implants, and other implants or medical devices in the body). The interference problems (for example, in PMs) may occur at levels below the ALs (action levels), which are as follows (at 50 Hz): (1) for electric fields: low ALs 10 kV/m (rms) and high ALs 20 kV/m (rms); (2) for magnetic fields: low ALs 1,000 μT (rms), high ALs 6,000 μT (rms), and ALs 18 mT (rms) for exposure of limbs to a localized magnetic field (3).

In an earlier study [4], 13 volunteers with an ICD were exposed to sine, pulse, ramp, and square waveform magnetic fields (varied to 300 μT) with frequencies of 2–200 Hz using a Helmholtz coil. They did not determine interference in ICDs [4]. In other ICD studies [5], in vitro tests showed no interference until 3000 μT. However, the researchers tested only 4 devices [5]. In addition, a methodology for

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evaluating the risk of cardiac pacemaker (PM) and ICD dysfunction with occupational exposure to EMF has been developed to help occupational physicians make a decision about fitness for work [6].

Two case reports, where ICDs experienced electromagnetic interference, were published [7, 8]. In the first case report, an ICD user reported receiving 2 ICD shocks while shopping in an automotive center. It happened shortly after stepping away from the counter. The reason behind the ICD shocks could be the electromagnetic interference from electronic article surveillance (EAS) systems [7]. In the second case, the ICD user was on a laptop computer while lying on a bed, and the laptop was positioned on his chest. The ICD user heard a beeping sound from the ICD, indicating magnet mode conversion. The reason for the interference was a relatively high static magnetic field density produced by the laptop's hard disk [8].

We have previously studied the disturbances in PMs and ICDs employing a human-shaped phantom in electric and magnetic fields of 400 kV power lines [9, 10]. We used the phantom in the following manner: isolated from the ground, grounded by a foot, or by a hand. In our 37 ICD tests (10 different devices), when the electric fields were 6.8–7.5 kV/m and the magnetic field was 2.0 μT, one of the ICDs tested recorded 258 ventricular beats/min when a simulated heart signal was applied to ICD electrodes. When the field was 5.1 kV/m and the magnetic field was 3.6 μT, the same ICD had a similar disturbance; however, in a 0.9 kV/m electric field and a 1.4 μT magnetic field, it worked correctly [10].

This new study further investigates the influence of magnetic fields on ICDs because the earlier study [10] found that ICDs could be influenced by electric and magnetic fields near 400 kV power lines. However, in the earlier work, the maximum magnetic field was only 3.6 μT [10]. The aim of the study was to investigate ICD function using a human-shaped phantom in high magnetic fields of a shunt reactor at a 400 kV substation. The objective was to create a test scenario that corresponded to real exposure situations as much as possible. Our objective is also to describe the details of the exposure situation as well as possible. We hypothesize that it is not possible to find disturbances in ICD function when they are exposed to high magnetic fields (over 600 μT) at 400 kV a substation in Finland.

2. MATERIALS AND TEST ENVIRONMENT

During the two measurement days, ICD tests were performed using a human-shaped phantom near the 63 MVAr shunt reactor at the 400 kV substation. We used 5 different ICDs, which were explanted devices and thus available for the study free of cost. The magnetic fields near the reactors were measured earlier, so we knew that it was possible to locate a suitable site (exposure over 1000 μT) for the experiments. We conducted experiments in two places: (day 1) near the fence of the reactors outside (A) and (day 2) inside the substation building (B). On day 2, it rained, forcing us to work inside. Figure 1 shows a

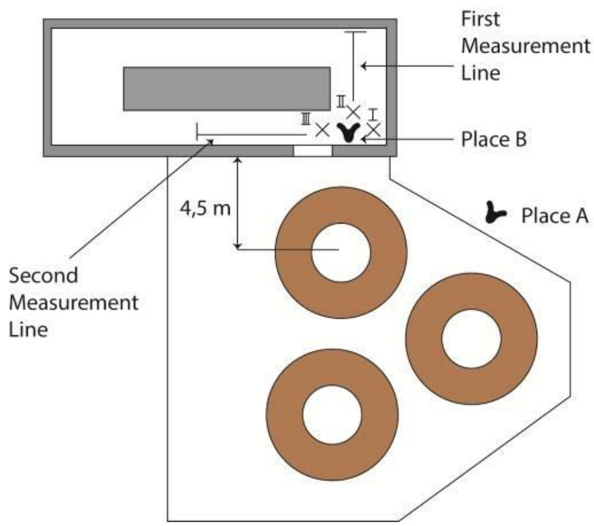

Figure 1. A drawing of the measurement places.

Figure 2. Human-shaped phantom in measurement place A.

Figure 3. Human-shaped phantom in measurement place B.

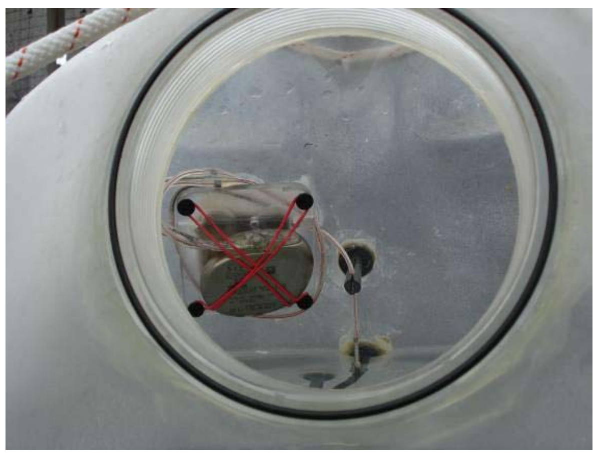

Figure 4. An example of the ICD inside the phantom (in Table 1, ICD: code 2).

drawing of the measurement places. Figure 2 shows the water-tight human-shaped phantom at place A, and Figure 3 shows it at place B.

3. METHODS

We employed the same human-shaped phantom that we used in our earlier PM and ICD tests [9, 10] under 400 kV power lines. We also utilized (as in our earlier ICD tests [10]) a lead from the leg to the ICD so that we could apply a simulated heart-signal to the ICD according to EN 45502-2-1 2003 standards [11]. We used a simulated heart-signal in the ICD tests at a 400 kV substation. We utilized a laptop, Handyscope HS 3 (TiePie engineering, Sneek, Netherlands), and a coaxial cable to input signals into the phantom. The signal was programmed by Matlab version 7.10.0.499 (R2010a; The MathWorks, Natick, MA, USA). Figure 4 shows an example of the ICD inside the phantom. Details of the phantom were described in our previous publication [9, 10].

We implemented the same protocol as in PM and ICD experiments under power lines [9, 10]. However, aluminum paper was not used to shield the electric field exposure. Near the reactor at the substation, the relatively low electric field did not require any shielding to be used. In addition, we had a Boston Scientific programming device at the substation. We switched only one ICD on and off in the Heart Center at Tampere University Hospital (Tampere, Finland). We increased and decreased

Table 1. Measured ICDs (model), function of ICDs, programmed sensing threshold for detection of electrical signals (in mV), and measurement places.

Code (day)	ICD (model, vendor)	Function	Battery	Testing place	Signal	Detection sens.[a], mV, A/V	Detection rate
1 (1)	Guidant, Renewal 4 RF HE H239	VVI¤	EOL, 2.57 V	A	Yes	-/-	200 ppm
2 (1)	Guidant, Prizm VR HE 1852	VVI¤	ERI, 2.65 V	A	Yes	-/-	200 ppm
3 (1)	Guidant, Vitality 1870	VVI¤	EOL, 2.58 V	A	Yes	-/-	200 ppm
4 (2)	Guidant, Vitality 2 EL T177	VVI¤	EOL, 2.62 V	B	Yes	-/-	200 ppm
5 (2)	St. Jude Medical, ATLAS + DR V-243	VVI¤	EOL, 2.20 V	B	Yes	-/0.2	200 ppm

[a]detection sens.: programmed sensing threshold for detection of electrical signals (in mV): A, atrium; V, ventricle, ¤ = Boston Scientific, Endotak Endurance EZ Model 0154 — 64 cm, Detection rate = the ICD recognizes a disturbance when this value exceeded, ERI; Elective Replacement Indicator, EOL; End of Life. In the earlier study [10] during the same summer, the ICD 1 (code 1) was also tested codes 24 and 29, the ICD 2 (code 2) was in tests of codes 25 and 30, the ICD 3 (code 3) was in the test of code 31, the ICD 4 (code 4) was in tests of code 32, the ICD 5 (code 5) was in the tests of codes 26 and 33.

the magnetic field exposure so that Fingrid switched on and off the 63 MVAr shunt reactor. When we changed ICDs, the magnetic field exposure was lower than during experimentation. We chose ICD parameters that were as sensitive as possible. Table 1 shows the ICDs with their parameters. The battery of 4 ICDs were at the end of life, which might affect to the study. However, all ICDs were still working properly. There were the same ICD devices that were used in the earlier study [10].

First, in the measurement places (on both experiment days), we performed magnetic field measurements (the reactor switched on and off) and the electric field measurement. Second, we filled the phantom with saline liquid 0.9 g/l [12] up to the low part of the thorax, and one researcher installed the PM inside the phantom (the reactor was switched off). Next, we filled the phantom completely with saline liquid. Then, the reactor was switched on and the ICD experiment started. We used three experiment periods: (1) phantom isolated from the ground (5 min), (2) one grounded by a foot (5 min), and (3) one grounded by a hand (5 min). To the current measurements between the ground and a foot/hand, we employed a Unitest Hexagon 520 multimeter (BEHAAMPROBE GmbH, Glottertal, Germany).

After the three experiment periods, we measured the temperature inside the head of the phantom with a Yellowspring Industries (YSI) temperature meter containing a thermistor probe (Yellowspring Industries, Yellowsprings, OH, USA) and the conductivity of the liquid using the DiST WP 4 (Hanna Instruments, Ann Arbor, MI, USA).

To measure magnetic fields, we had a Narda ELT-400 meter (L-3 Communications, Narda Safety Test Solutions, Hauppauge, NY, USA; accuracy ±4% RMS) and to measure electric fields, we utilized an EFA-300 meter (Narda Safety Test Solutions GmbH, Pfullingen, Germany) (accuracy ±3%, RMS). Additionally, we controlled our measurements via an EFA-3 field meter (Wandel and Coltermann GmbH, Eningen, France) for measuring the magnetic field (accuracy ±3% ±1 nT, RMS), the x, y, and z components of the field, and the electric field (accuracy ±5%, RMS).

4. RESULTS

4.1. Experiments in Place A (Exposure over 1000 μT)

During the first experiment day, we tested 3 different ICDs in place A (Figure 2). When the reactor was switched on, the measured magnetic field inside the phantom (in the thorax) was 1071 μT (height 1.5 m), and outside the phantom, it was 1170 μT (height 1.5 m). Moreover, when the reactor was switched off, the magnetic field inside the phantom was 17.6 μT (height 1.5 m), and 60 μT (height 1.5 m) was recorded

Table 2. Measured current from the foot (μA) and current from the hand (μA), temperature inside the head of the phantom (°C), resistance inside the head of the phantom (mS/cm), and disturbances of the ICDs (paced, % = the number of impulses correctly delivered by the ICD and sensed, % = the number of beats the ICD missed after detecting an inhibition signal).

Code (day)	ICD (model, vendor)	Current (foot), μA	Current (hand), μA	Temperature in head, °C	Resistance, in head, mS/cm	Paced, %	Sensed, %	Disturbance
1 (1)	Guidant, Renewal 4 RF HE H239	6.4–6.8	6.8–6.9	22	2.0	0	100	No
2 (1)	Guidant, Prizm VR HE 1852	6.6–6.7	6.6–6.7	22	2.1	0	100	No
3 (1)	Guidant, Vitality 1870	6.5–6.7	6.6–6.7	23	2.1	0	100	No
4 (2)	Guidant, Vitality 2 EL T177	1.0–2.0	1.0	20	2.1	0	100	No
5 (2)	St. Jude Medical, ATLAS + DR V-243	0.6	0.6	20	2.1	< 1	> 99	No

Table 3. Measured magnetic fields and x-, y-, and z-components in subsites I and II at different heights (second experiment day).

Height; m	MF, μT (siteI)	X % (siteI)	Y % (siteI)	Z % (siteI)	MF, μT (siteII)	X % (siteII)	Y % (siteII)	Z % (siteII)
0.1	477	8	19	73	503	34	63	3
0.3	580	6	27	67	490	27	72	1
0.5	630	5	39	56	510	36	63	1
0.7	637	6	50	44	530	25	72	3
0.9	610	6	58	36	543	18	81	1
1.1	675	2	68	30	553	11	88	1
1.3	690	4	74	22	582	10	88	2
1.5	690	8	84	8	580	1	92	7
1.7	707	5	90	5	573	6	92	2
1.9	765	6	93	1	576	3	94	3

SiteI (Subsite I): 10 cm from the left hand of the phantom laterally (x-axis sideways from the phantom, y-axis from top to bottom, and z-axis from the face of the phantom to the wall).
SiteII (Subsite II): 10 cm behind the phantom (x-axis from the face of the phantom to the wall, y-axis from top to bottom, and z-axis sideways from the phantom).

outside the phantom. The electric field was 0.9 kV/m (height 1.7 m) when the humidity of air was 65%. The temperature was 19.1°C–21.9°C, and the air humidity was 65%–76%. During the first experiment day, we did not find any disturbances in ICDs in place A. Table 2 shows measured currents, temperatures inside the head of the phantom, and resistances inside the head of the phantom on day 1.

4.2. Experiments in Place B (Exposure over 600 μT)

During the second experiment day, we tested 2 different ICDs in place B (Figure 3). When the reactor was switched on, the magnetic field inside the phantom was 674 μT (meter EFA-3), and outside the phantom, it was 721 μT (height about 1.5 m). When the reactor was switched off, the magnetic field was 70 μT (height 1.5 m). The electric field was 0.2 kV/m (height 1.7 m). The temperature (in place B) was 19.3–19.8°C, and the air humidity was 61–66%. Table 2 also shows measured currents, temperatures inside the head of the phantom, and resistances inside the head of the phantom on day 2.

In place B, we also measured magnetic fields and the x-, y-, and z-components of the magnetic fields at different heights around the phantom and at different distances from the phantom. Tables 3

Table 4. Measured magnetic fields and x-, y-, and z-components in a subsite III at different heights (second experiment day).

Height; m	MF, μT	*X* %	*Y* %	*Z* %
0.1	423	81	13	6
0.3	550	87	10	3
0.5	618	84	15	1
0.7	653	72	27	1
0.9	665	60	39	1
1.1	671	47	52	1
1.3	687	33	66	1
1.5	700	23	76	1
1.7	716	16	83	1
1.9	718	7	91	2

SiteIII (Subsite III): 10 cm from the right hand of the phantom laterally (x-axis from the face of the phantom to the wall, y-axis from top to bottom, and z-axis sideways from the phantom).

Table 5. Measured magnetic fields and x-, y-, and z-components at different distances starting at the subsite II (second experiment day).

Distance; m	MF, μT	*X* %	*Y* %	*Z* %
0.2	685	3	89	8
0.4	630	3	90	7
0.6	560	4	91	5
0.8	517	4	91	5
1.0	467	6	88	6
1.2	415	5	85	10
1.4	379	4	85	11
1.6	344	3	86	11
1.8	315	4	86	10
2.0	292	3	88	9

StartII; first measurement line started from the subsite II (10 cm behind the phantom), so that the line started from the wall in front on the phantom to the behind near the left hand (x-axis sideways from the phantom, y-axis from top to bottom, and z-axis from the face of the phantom to the wall).
Measurement height was 1.5 m.

Table 6. Measured magnetic fields and x-, y-, and z-components at different distances starting at the subsite III (second experiment day).

Distance; m	MF, μT	X %	Y %	Z %
0.3	670	22	76	2
0.4	670	24	75	1
0.6	670	28	71	1
0.8	640	26	73	1
1.0	627	23	76	1
1.2	610	24	75	1
1.4	585	24	76	0
1.6	560	22	76	2
1.8	530	19	80	1
2.0	497	22	77	1

StartIII: Second measurement line started from the subsite III (10 cm from the right hand of the phantom laterally), so that distance to wall was 35 cm. The first point was near the shoulder of the phantom. Other points were positioned every 20 cm from the center point of the phantom. (x-axis from the face of the phantom to the wall, y-axis from top to bottom, and z-axis sideways from the phantom and the corridor). Measurement height was 1.5 m.

and 4 show the magnetic fields and x-, y-, and z-components in subsites I, II, and III (Figure 1) at different heights. Subsite I was 10 cm from the left hand of the phantom laterally, and the heights varied. Subsite II was 10 cm behind the phantom, and the heights varied. Subsite III was 10 cm from the right hand of the phantom with varying heights. Tables 5 and 6 show the magnetic fields and x-, y-, and z-components from different distances starting at subsites II and III (height was 1.5 m). The first measurement line started from subsite II such that the line started from the wall in front of the phantom and extended to just behind the left hand. The second measurement line was from the phantom to the right so that the distance to the wall was 35 cm. The first point was near the shoulder of the phantom. Other points were designated every 20 cm from the center point of the phantom. During the second experiment day, we did not find any disturbances in ICDs in place B.

5. DISCUSSION

When we analyze the results of our study, we need to take into account that we tested only five ICDs, and the battery of four ICDs were in EOL (End of Life); hence, the ICDs were quite old. However, all ICDs still performed well during the experiments. In addition, it is important to note that we used a phantom (and a simulated heart signal), not a human being, which could influence our results. Conversely, the objective was to make the test scenario correspond to real exposure situations as much as possible. In our study, the exposure to magnetic fields was based on a real environment, and the exposure was higher than we can typically find at 400 kV substations. However, it was not very feasible or affordable to organize real experiment places at 400 kV substations and switch the reactor on and off. Therefore, we performed experiments only during two experiment days. Furthermore, we could only find one 400 kV substation where we could examine such high magnetic field exposure in Finland.

When we compare our results to other researchers' results [4, 5], it is easy to understand that we did not obtain any disturbances because our maximum magnetic field was below 1100 μT; the earlier in vitro study [5] did not determine any interference when the exposure was below 3000 μT. On the contrary, we cannot draw strong conclusions, as our material was quite limited. However, our results could confirm the results of other studies [4, 5]. In any case, we can accept our hypothesis that it is not possible to find disturbances in ICD function when exposed to high magnetic fields (over 600 μT) at 400 kV substations in Finland.

At 400 kV substations, there are areas where there is high electric field exposure, which can be higher than electric fields under 400 kV power lines. Therefore, the electric field exposure is also important to take into account when a person with an ICD works at a 400 kV substation. The data of this study acquired is sufficient to use ICDs in areas near substations, but the real upper limit of maximum magnetic field exposure is not possible to say, based on this study. In addition, the entrance-angle of the magnetic field can vary when a person with ICD works and moves at a substation. However, the highest magnetic field source was a shunt reactor; therefore, the highest measured magnetic field components were based on this source.

In the future, it is useful to study this topic further to support the evaluation of the risk of PM and ICD dysfunction with occupational exposure to EMFs. This work also supports the implementation of Directive 2013/35/EU because, again, workers using implanted medical devices are classified by Directive 2013/35/EU as being at particular risk due to the potential interference between implanted medical devices and electromagnetic fields (EMFs) [3].

During the second experiment day, we took several magnetic field measurements. We also measured the x-, y-, and z-components. Tables 3, 4, 5 and 6 show that the magnetic field can vary significantly when we change the measurement points. It is possible to note that in place B, there were also other magnetic field sources, not simply the magnetic field of the reactor. When a worker with a possible a PM or an ICD walks or moves around a substation, exposure to the device can change. Therefore, it is important to develop ICD testing systems, e.g., in laboratories, so that it is feasible to modify the magnetic fields, e.g., x-, y-, and z-components of the field.

It is also important to develop new technology that eliminates electromagnetic interference problems of ICDs. Both cases reports [7, 8] that were published on the electromagnetic interference problems of ICDs were based on public exposure, not on occupational exposure. Therefore, public exposure is also important to take into account in the future.

6. CONCLUSION

In conclusion, it can be stated that in our experiments, the magnetic field exposure (over 600 μT) did not disturb the ICDs. However, we performed only 5 experiments with 5 different ICDs. In any case, if it is possible that ICDs can experience disturbances from magnetic field exposure at 400 kV substations, the risk of such disturbances seems negligible.

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REFERENCES

1. Mond, H. G. and A. Proclemer, "The 11th world survey of cardiac pacing and implantable cardioverter-defibrillators: Calendar Year 2009 — A world society of Arrhythmia's project," *Pacing Clin. Electrophysiol.*, Vol. 34, 1013–1027, 2011.
2. ANSI/AAMI PC69, "Active implantable medical devices — Electromagnetic compatibility — EMC test protocols for implantable cardiac pacemakers and implantable cardioverter defibrillators," 81, American National Standard, Association for the Advancement of Medical Instrumentation, Arlington, 2007.
3. European Parliament and Council of the European Union, "Directive 2013/35/EU of the European Parliament and of the council on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) (20th individual directive within the meaning of Article 16(1) of directive 89/391/EEC) and repealing directive 2004/40/EC," *Official Journal of the European Union*, 21, 2013.
4. Tiikkaja, M., A. L. Aro, T. Alanko, H. Lindholm, H. Sistonen, J. E. K. Hartikainen, L. Toivonen, et al., "Electromagnetic interference with cardiac pacemakers and implantable cardioverter

defibrillators from low-frequency electromagnetic fields in vivo," *Europace*, Vol. 15, No. 3, 388–394, 2013.

5. Katrib, J., M. Nadi, D. Kourtiche, I. Magne, P. Schmitt, M. Souques, and P. Roth, "In vitro assessment of the immunity of implantable cardioverter-defibrillators to magnetic fields of 50/60 Hz," *Physiol. Meas.*, Vol. 34, No. 10, 1281–1292, 2013.
6. Souques, M., I. Magne, and J. Lambrozo, "Implantable cardioverter defibrillator and 50-Hz electric and magnetic fields exposure in the workplace," *Int. Arch. Occup. Environ. Health*, Vol. 84, 1–6, 2011.
7. Gimbel, J. R. and J. W. Cox, "Electronic article surveillance systems and interactions with implantable cardiac devices: Risk of adverse interactions in public and commercial spaces," *Mayo. Clin. Proc.*, Vol. 82, No. 3, 318–322, 2007.
8. Tiikkaja, M., A. Aro, T. Alanko, H. Lindholm, and M. Hietanen, "Inappropriate implantable cardioverter-defibrillator magnet-mode switch induced by a laptop computer," *Pacing Clin. Electrophysiol.*, Vol. 35, e177–e178, 2012.
9. Korpinen, L., H. Kuisti, J. Elovaara, and V. Virtanen, "Cardiac pacemakers in electric and magnetic fields of 400-kV power lines," *Pacing Clin. Electrophysio.*, Vol. l35, 422–430, 2012.
10. Korpinen, L., H. Kuisti, J. Elovaara, and V. Virtanen, "Implantable cardioverter defibrillators in electric and magnetic fields of 400 kV power lines," *Pacing Clin. Electrophysiol.*, Vol. 37, 297–303, 2014.
11. EN 45502-2-1, "Active implantable medical devices — Part 2-1: Particular requirements for active implantable medical devices intended to treat bradyarrhytmia (cardiac pacemakers)," 95s, 2003.
12. CENELEC, "Low profile connector for implantable cardiac pacemakers," EN 50077, 16, Brussels, Belgium, 1993.