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# Implantable Cardiac Rhythm Device at Workplace Electromagnetic Environment

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**Abstract**

The paper presents problems of exposing cardiac pacemaker (CPM) and implantable cardioverter defibrillator (ICD) to electromagnetic field. The authors have focused on work environment EMF source – RF dielectric heaters. To investigate if the basic restrictions were exceeded according to IEC reference levels [8], the interface voltage at the input port of a pacemaker in a full 3D human model and phantom was calculated. The result of calculations was analyzed.

**Keywords**: cardiac pacemakers, implantable cardioverter-defibrillators, interface voltage, safety at workplace, FDTD.

## Implanty regulujące rytm pracy serca w polu elektromagnetycznym wytwarzanym na stanowiskach pracy

**Streszczenie**

Praca prezentuje problemy związane z ekspozycją stymulatora serca i wszczepialnych kardioweterów defibrylatorów na pole elektromagnetyczne w miejscu pracy. Jako źródło pola elektromagnetycznego w środowisku pracy przedstawiono zgrzewarki dielektyczne wysokiej częstotliwości. Przebadano poziom napięcia indukowanego na wejściu urządzenia. W badaniach symulacyjnych wykonanych z wykorzystaniem metody różnic skończonych w dziedzienie czasu (FDTD) zastosowano ograniczenia ekspozycji implantów narzucone przez międzynarodowe standardy [8].

**Słowa kluczowe**: stymulatory serca, wszczepialne kardiowertery-defibrylatory, napięcie indukowane, bezpieczeństwo w środowisku pracy, FDTD.

## 1. Introduction

A person with an implanted defibrillator can safely operate most household and office equipment, provided this person takes a few precautions. Several safeguards built into defibrillator protect it from interference encountered in normal daily living. Such safeguards include electronic filters that separate natural heartbeat signals and interference signals [6, 13].

EMI occurs when electromagnetic waves emitted by one device impede the normal function of another electronic device (ICD, CPM). Some workplace environments contain equipment that may produce large levels of electromagnetic energy and subsequently interfere with the operation of the implanted device. In the paper is described the problem of ICD/cardiac pacemaker malfunction generate by RF dielectric heaters at workplace environment.

Most PCMs/ICDs circuitry uses filters to attenuate electromagnetic interference (EMI) outside the normal intracardiac range and, whereas this design is effective when the interference characteristics are quite different from detected signals associated with cardiac activity, some EMI can produce signals that are similar enough to normal intracardiac activity to cause problems.

## 2. The implantable cardiac rhythm device at workplace environment

The potential for interaction between implanted cardiac rhythm device and source of electromagnetic field has been recognized for fifteen years. It has been shown that EMI can produce significant effects on patients with implanted cardiac rhythm device (CPMs and ICDs). The survey of Medtronic web page and Guidant web page [6, 13] allows make a rough estimation which sources may essentially generate ICDs and CPMs malfunctions. Implantable cardioverter defibrillators and cardiac pacemakers may be sensitive to electromagnetic fields generated by personal items (mobile phone [3, 5, 9, 14, 15, 19, 23, 24, 25]), industrial equipment (arc welding equipment, dielectric heaters, induction heaters for industry, transmission line for electrical power [4, 11, 12, 21]), medical device (Magnetic Resonance Imaging scans [20]).

The electromagnetic field may generate electrical potentials on ICD/CPM sensing electrodes then electromagnetic interference is results in improperly implants function.

While the majority of workplace environments will not adversely affect implantable device operation, EMI of significant strength may impact the performance of the implanted device, and could potentially lead to device responses (Tab. 1).

There are a number of possible ICDs responses to external interference: temporary inhibition of the device (inhibition of pacing) or inappropriate delivery pacing and shocks (inappropriate detection of ventricular tachycardia, inappropriate detection of ventricular fibrillation, failure to sense ventricular tachycardia/ventricular fibrillation, inappropriate pacing). The exposure to electromagnetic environment cardiac pacemaker might be affected by EMI, too. There are a number of possible pacemaker responses to external interference: inhibition of pacemaker output, inappropriate triggering of pacemaker output, asynchronous pacing, reprogramming to different parameters, and damage of the pacemaker circuitry.

The impact to device function is typically temporary; if the worker (with implanted device) moves away from or turns off the EMI source, the implanted device resumes its normal mode of operation. In rare instances, the impact to the device may be permanent such as memory corruption or reversion to Safety Mode operation.

To examine the operation of implantable cardiac rhythm devices exposed to electromagnetic field four approaches are used following methods of examination of isolated cardiac device (in vitro), examination of isolated device in phantom (in vitro in phantom), examination of device implanted in the human body (in vivo) and numerical simulation.

The numerical simulation allows predict the possible implantable cardiac rhythm device responses to external interference from industry equipment generate EMF.

Tab. 1. Device (pacemakers, ICDs) responses to external interferences
Tab. 1. Zaburzenia pracy urządzeń (stymulatorów serca i wszczepialnych kardiowerterów defibrylatorów) generowane przez zewnętrzne pole elektromagnetyczne

| Device response | Pacemakers | ICDs |
|---|---|---|
| Asynchronous pacing [3, 14] | + | + |
| Inhibition of pacing (pacing therapy not provided when needed) [23] | + | + |
| Inhibition of tachyarrhythmia therapy (shock therapy not provided when needed) [2, 4, 5] | - | + |
| Inability to communicate with the device [9, 15] | + | + |
| Inappropriate shocks (shock therapy provided when not needed) [6] | - | + |
| Deactivation of shock therapy [2] | - | + |
| Trigger ventricular pacing at Maximum Tracking Rate [6] | + | + |
| Trigger the End-of-Life indicator [20] | + | - |

## 3. The model

We have used homogenous phantom. As for homogeneous model it can be considered as the torso-simulator completely filled with salt water as specified in the international standards. In our case, the computer model of torso simulator was filled with fluid with parameters being in accordance with Electromagnetic Compatibility Test Protocols [1] - permittivity $\varepsilon_r$=79 F/m, conductivity $\sigma$ = 0.46 S/m, density 1g/cm$^3$ (Fig. 1).

Fig. 1. Homogeneous phantom and implantable cardiac rhythm device
Rys. 1. Fantom homogeniczny i wszczepialne urządzenie monitorujące rytm serca

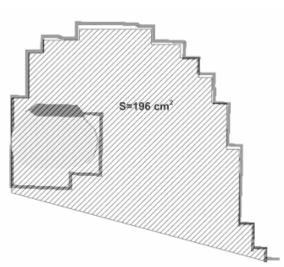


Fig. 2. CAD model of implantable cardiac rhythm device with unipolar electrode
Rys. 2. Model urządzenia z elektrodą jednobiegunową wykorzystany w symulacjach

For the numerical investigation a CAD model of pacemaker was created. The size of the implantable pulse generator is 42x52x6 mm with unipolar electrode 560 mm in length. The projection area of the pacemaker configuration is 196 cm2, and “port1” is the housing port of pacemaker and “port2” is the end of electrode (Fig. 2).

## 4. Results of calculation

The numerical investigation of coupling model i.e. field-to-voltage transfer function is based on FDTD (Finite Difference Time Domain) method [22]. The numerical procedure has been described elsewhere [7].

In this paper the numerical model has to represent the dielectric heater (sealer) which works with the frequency 27.12 MHz. Using method of scaling [7], the distribution of electromagnetic field has been established for the case of plane wave.

In the case of the frontal magnetic field exposure (H=1 A/m) the interference voltage was calculated using Faraday’s law of induction (Eq. 1), where A is the projection area, f is frequency, $\mu_0$ is permeability of free space, H is magnetic field strength.

$$U = 2\pi f \mu_0 H A \qquad (1)$$

The interference voltage U amounts:

$$U = 5.8\ V \qquad (2)$$

In the case of vertical electric field exposure (E=1 V/m) the interference voltage was calculated using the expression (Eq. 3):

$$U = \int_{port1}^{port2} E ds \qquad (3)$$

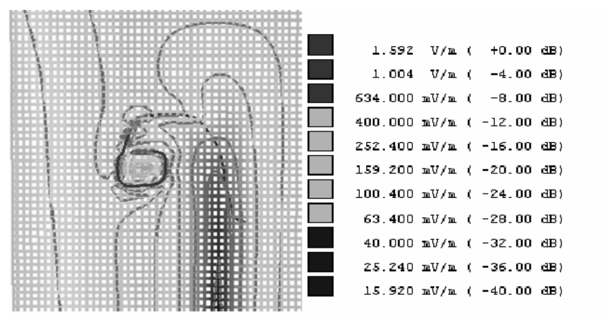


Fig. 3. Implantable cardiac rhythm device and electric field distribution, plane wave
Rys. 3. Rozkład pola elektrycznego wokół urządzenia regulującego rytm pracy serca, fala płaska

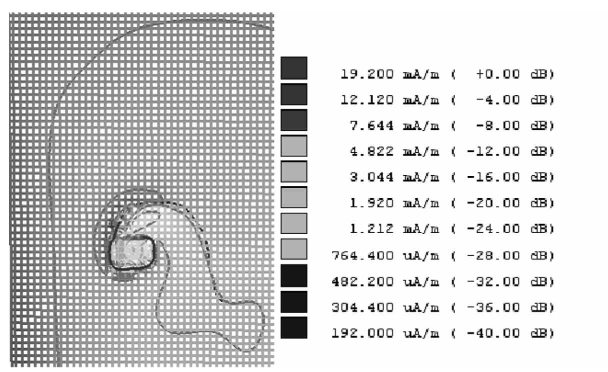


Fig. 4. Implantable cardiac rhythm device and magnetic field distribution plane wave
Rys. 4. Rozkład pola magnetycznego wokół urządzenia regulującego rytm pracy serca, fala płaska

The interferences voltages are big enough not to be accepted for normal operation of cardiac implants. However, the case we considered is the worst as the projection area and the length of wire are extremely big. Taking into account the possibility of generating electromagnetic interferences, the recent procedure of implanting tends to bipolar connection. Our calculations confirm this tendency.

Tab. 2 presented results of numerical calculation in comparison with two other sources of electromagnetic fields, wireless telecommunication device and overhead power lines. Gustrau et al. [7] presented numerical calculation as far as wireless telecommunication device are concerned. Wireless telecommunication generates electromagnetic field of 100 MHz – 2 GHz and this is documented source of electromagnetic field at workplace environment. Scientist from Germany presented numerical calculations of the field-to-voltage transfer unction, i.e. the coupling between GSM and UMTS mobile phones and the base station antenna and the voltage induced the sensing input of cardiac pacemakers. The source of impedance of an unipolar electrode was determined numerically. For the numerical investigation they generated a CAD model of single chamber pacemaker with an unipolar electrode. The authors did numerical calculation for overhead power lines [16]. We have used a full 3D human model with 3 mm resolution. This model is obtained from Brooks Air Force Laboratory, USA. It is based on anatomical slices from a male cadaver (1.8 m tall and 105 kg weight). For the numerical investigation a CAD model of pacemaker was generated, the same model we used at presented calculation (Fig. 2).

Tab. 2. Results of presented calculation in comparison with two others workplace sources of electromagnetic fields
Tab. 2. Prezentowane wyniki symulacji w zestawieniu z wynikami symulacji dla dwóch innych źródeł pola elektromagnetycznego występujących w środowisku pracy

| *Authors, source of EMF/ The results of calculation for plane wave exposure* | Voltage induced the sensing input of cardiac pacemaker (*E=1 V/m*) | Voltage induced the sensing input of cardiac pacemaker (*H=1 A/m*) |
|---|---|---|
| Gustrau et al, *Mobile phone*, **950MHz** [7] | U = 2.9 mV | U = 17.7 μV |
| Pławiak et al., *overhead power lines*, **50Hz** [16] | U = 0.042 μV | U = 21.3 μV |
| The results of calculation presented in the paper, *dielectric heaters*, **27.12MHz** | *U = 1.512 V* | *U =5.8 V* |

## 5. Summary and future research

Return to work for people with implanted cardiac stimulators can be expected even in industries where power-frequency electric and magnetic field environment.

The workers who wear cardiac implants and their employers are interested in estimation of risk and they want to know the relation between the level of risk and technical parameters of exposure is a prevalent aspect of the work

The paper shows the possibility of cardiac stimulators examination at the workplaces. The results of numerical simulation give prediction of possible hazards before implanting cardiac rhythm device.

Our future plans will be focused on examination of dielectric heaters and cardiac stimulators using in vitro method. The result of numerical calculations will be then verified.

## 6. Bibliography


[1] Active Implantable Medical Devices, Electromagnetic Compatibility Test Protocos for Implantable Cardioverters', ANSJ/AAMI PC69:200, Association for the Advancement of Medical Instrumentation

[2] Barbaro V. et al.: Electromagnetic interference of digital and analog cellular telephones with implantable cardioverter defibrillators: In vitro and in vivo studies, PACE, 1999, n. 22, s. 626-634

[3] Barbaro V. et al.: Electromagnetic interference of analog cellular telephones with pacemakers, PACE, n.19, 1996, s.1410

[4] Fetter JG., Beneditt DG., Stanton MS.: Electromagnetic interference from welding and motors on implantable cardioverter-defibrillators as tested in the electrically hostile work site, J Am Coll Cardiol., 1996, Aug;28(2), s.423-7

[5] FetterJG. et al., Digital cellular telephone interaction with implantable cardioverter-defibrillators, J Am Coll Cardiol., 1998, n. 1, s. 623-628

[6] Guidant web page, http:// www.guidant.com

[7] Gustrau F., Bahr A., Goltz S., et al.: Active medical implants and occupational safety - measurement and numerical calculation of interference voltage, Biomedizinische Technik. Biomedical engineering, January 1, 2002, Vol. 47 Suppl 1 Pt 2, s. 656-659.

[8] International Electrotechnical Commission, Medical Electrical Equipment, Part I: General Requirements for Safety, IEC Standard 601-1-2, 2001

[9] Jimenez F. et al.: Electomagnetic interference between automatic defibrillators and digital and analog cellular telephones, Rev Esp Cardiol, 1998, n. 51, s. 375-382

[10] Kainz W., Neubauer G., Alesch F., Schmid G., Jahn O.: Electromagnetic compatibility of electronic implants--review of the literature., Wien Klin Wochenschr., 2001, 113(23-24), s. 903-14

[11] Kolb C., Zrenner B, Schmitt C.: Incidence of electromagnetic interference in implantable cardioverter defibrillators, PACE, 2001, Apr, 24, s. 465-8

[12] Marco D, Eisinger G, Hayes DL.: Testing work environments for electromagnetic interference, PACE, 1992; n. 15, s. 2016-2022.

[13] Medtronic web page, www.medtronic.com

[14] Naegeli B. et al.: Intermittent pacemaker dysfunction caused by digital mobile telephones, Journal of American College Cardiology, 1996, Vol.27, s. 1471-1477

[15] Occhetta E. et al.: Implantable cardioverter defibrillators and cellular phones: Is there any interference?, PACE, 1999, n.22, s. 983-989

[16] Pławiak-Mowna A., Miaskowski A., Krawczyk A., Ishihara J.: Infulence of electromagnetic field on cardiac pacemakers at workplace, Pomiary Automatyka Kontrola, 2006, nr 6, wyd. spec., s. 68-70

[17] Pławiak-Mowna A., Krawczyk A.: Interference of base station antenna with cardiac pacemakers – preliminar research results, XII International Symposium on Electromagnetic Fields in Mechatronics, Electrical and Electronic Engineering - ISEF 2005. Baiona, Hiszpania, 2005 - Vigo, 2005, s. [6] CD-ROM

[18] Pławiak-Mowna A., Kubacki R., Zyss T.: Interferencje elektromegnatyczne w kardiostymulatorach, Pole elektromagnetyczne w biosferze/ red. i oprac. A. Krawczyk, J. Wyszkowska, Warszawa: Polskie Towarzystwo Zastosowań Elektromagnetyzmu, 2005, s. 109 – 123.

[19] Pławiak-Mowna A., Zyss T., Koźluk E., Krawczyk A., Kubacki R.: Kardiostymulatory w polu elektromagnetycznym emitowanym przez telefony komórkowe, Telefonia komórkowa a ochrona zdrowia i środowiska : najnowsze przepisy i wyniki badań: fakty, Warszawa, 2003, s. 27 – 37.

[20] Roguin A. et al.: Modern pacemaker and implantable cardioverter/defibrillator systems can be magnetic resonance imaging safe in vitro and in vivo assessment of safety and function at 1.5T, Circulation, 2004, n.110, s. 475-482

[21] Scholten A., Silny J.: The interference threshold of unipolar cardiac pacemakers in extremely low frequency magnetic fields, Journal of Medical Engineering and Technology, 2001 Sep-Oct,25(5),s. 185-94.

[22] Taflove A.: Computational Electrodynamics – The Finite Difference Time Domain Method, Artech House, 1995.

[23] Vlasinova J, Novotny T.: Pacemaker dysfunction during use of a mobile telephone, Vnitr Lek, 2000, n.46, s.119-121

[24] Yesil, M. et al.: Pacemaker inhibition and asystole in a pacemaker dependent patient, PACE, 1995, n.18, s. 1963

[25] Zyss T., Roman A., Krawczyk A., Koźluk E., Pławiak-Mowna A.: Badania eksperymentalne nad wpływem impulsowego pola magnetycznego o indukcji 2 T na pracę serca u szczura, Kompatybilność elektromagnetyczna w biologii i medycynie/ red.A Krawczyk, A. Pławiak-Mowna, Warszawa: Instytut Naukowo-Badawczy ZTUREK, 2003, s. 69 – 78.


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