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Influence of Electromagnetic Field on Cardiac Pacemakers at Workplace Environment

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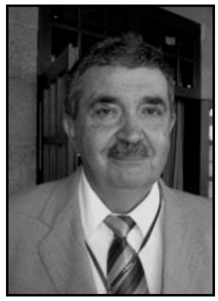

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Abstract

The paper presents problems connected with cardiac pacemaker exposed to electromagnetic field at workplace. The authors have focused on two kinds of sources: 50/60 Hz (overhead power lines) and 100 MHz – 2 GHz (wireless tele-communication). To investigate if the basic restrictions were exceeded accord-ing to IEC reference levels, the interface voltage at the input port of a pace-maker in a full 3D human model was calculated. The numerical investigation of the coupling model i.e. field-to-voltage transfer function, was carried out using FDTD (Finite-Difference Time-Domain) method. The paper presents result of investigation with patient volunteers exposed to electromagnetic field generated by base station antenna.

Keywords: cardiac pacemakers, interface voltage, safety at workplace, FDTD.

Oddziaływanie pola elektromagnetycznego na stymulator serca w środowisku pracy

Streszczenie

Praca prezentuje problemy związane z ekspozycją stymulatora serca na pole elektromagnetyczne w miejscu pracy. Autorzy skupiają się na dwóch rodzajch źródeł: 50/60Hz (napowietrzne linie przesyłowe) oraz 100 MHz – 2 GHz (telefonia komórkowa). Przebadano poziom napięcia indukowanego na .wejściu stymulatora. Badania symulacyjne zostały wykonane z wykorzystaniem metody różnic skończonych w dziedzinie czasu (FDTD). Praca prezentuje wyniki badań przeprowadzonych z udziałem pacjentów ochotników posiadających wszczepione stymulatory serca. Badania te przeprowadzono dla źródła pola elektromagnetycznego w postaci anteny stacji bazowej.

Słowa kluczowe: stymulatory serca, napięcie indukowane, bezpieczeństwo w środowisku pracy, FDTD.

1. Introduction

Manufacturers design medical devices to be immune to electromagnetic fields up to 10 V/m for life-support medical electrical equipment and 3 V/m for non-life-support medical electrical equipment, as proposed in international standards [2, 6]. Meeting these standards would reduce the potential hazards of EMI. Specific EMC standards for implantable cardiac pacemakers and defibrillators are currently being drafted by ISO. Low frequency electromagnetic field can interfere with implants such as cardiac pacemakers. The problem becomes even more serious if the worker with implanted cardiac pacemaker is exposure to constant electromagnetic field at workplace – then higher levels of EF are allowed by standards. In order to access the safety of workers in the vicinity of industrial devices the interference voltage at the input port of cardiac pacemaker is needed [17, 19, 20].

Most pacemaker 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 cardiac pacemaker at workplace environment

The range of responses from the pacemaker system to EMI and other forms of interference is wide and largely depends on the interference signal characteristics.

Although in general desirable, the return of the patient with an implanted cardiac device to a work environment suspected of high level EMI can be challenging. The potential EMI sources do not only emit energy in the radiofrequency spectrum, their associated magnetic fields could potentially induce pacemakers malfunctions.

The documented sources of electromagnetic field at workplace environment are:

- devices generate magnetostatic fields - magnetic resonance image scanners and direct current transmission installations,
- transmission lines of different voltage, including multivoltage lines being serviced by technicians, electrical devices – electromagnetic field of 50/60 Hz,

- dielectric welders, electromedic devices, radio/television transmitters – electromagnetic field of 10 - 100 MHz,
- high frequency electromedic devices, wireless telecommunication – electromagnetic field of 100 MHz – 2 GHz.

EMI from electric power can occur if patients come in proximity to high voltage overhead powerlines (accidentally or by occupation) or it may be caused by electrical appliances held close or in direct contact with the chest. Implanted devices are susceptible to interference signals of 50–60 Hz, frequencies that lie within the bandwidth sampled for detection of intracardiac signals.

3. The methods of examination

To examine the operation of cardiac pacemakers exposed to electromagnetic field four approaches are used:
1. examination of isolated pacemaker (in vitro),
2. examination of isolated pacemaker in phantom (in vitro in phantom),
3. examination of pacemaker implanted in the human body (in vivo),
4. numerical simulation.

All these groups are very important in this kind of research, and all of them lie in the area of the authors' interest but recently the last is of special interest as it allows to predict the possible hazards (pacemaker malfunctions) at the pre-implanting time. Therefore, in the paper the method of numerical simulation is described more detailed.

4. The model

We have used a full 3D human model with 3 mm resolution, fig. 1.

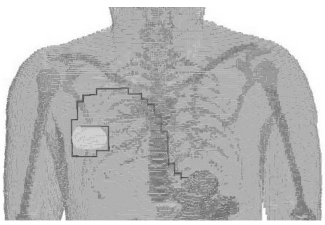

Fig. 1. Human model and implanted cardiac pacemaker
Rys. 1. Model człowieka z implnatowanym stymulatorem serca

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).

In order to model the tissue response by relaxation theory, the electrical properties of human tissues are modelled using the 4 Cole-Cole approximation. In this model the complex permittivity ε_c is varying in time at an angular frequency ω and is modelled as follows:

$$\varepsilon_c(\omega) = \varepsilon_\infty + \sum_{n=1}^{4} \frac{\Delta\varepsilon_n}{1+\left[j(\omega/2\pi)\tau_n\right]^{\alpha_n}} + \frac{\sigma_i}{j\omega\varepsilon_0} \qquad (1)$$

where the ε_∞ is the permittivity in the high frequency, σ_i the ionic conductivity, τ_n the relaxation time in the dispersive region n, and $\Delta\varepsilon_n$, the drop in permittivity in the frequency range in which the time period $2\pi/\omega$ is either much smaller or larger compared to the relaxation time, are obtained by fitting to experimental measurements. The tissue parameters obtained from this model were used in the present article.

For the numerical investigation a CAD model of pacemaker was generated. 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 cm^2, and "port1" is the housing port of pacemaker and "port2" is the end of electrode.

5. Method of calculation

The numerical investigation of coupling model i.e. field-to-voltage transfer function was carried out using the commercial electromagnetic software EMPIRE from IMST GmbH [3]. The software is based on FDTD (Finite Difference Time Domain) method [18].

For the investigation of field-to-voltage function homogeneous electric and magnetic fields were used. These fields were generated by superposing two plane waves travelling in opposite directions. Two standard configuration, that provide maximum interference voltages were investigated: an external frontal orientated magnetic field and an external vertical orientated electric field. The interference voltage U was calculated by scalling the interference voltage U_{FDTD} of the simulation at the f_{FDTD} by the following formula:

$$U=(f/f_{FDTD})U_{FDTD} \qquad (2)$$

where the f is frequency of interests (in our case 50/60 Hz).

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. 3), where A is the projection area, f is frequency, μ_0 is permeability of free space, H is magnetic field strength. The magnetic field distributions in the planes of each port are shown in fig. 2.

$$U = 2\pi f\mu_0 HA \qquad (3)$$

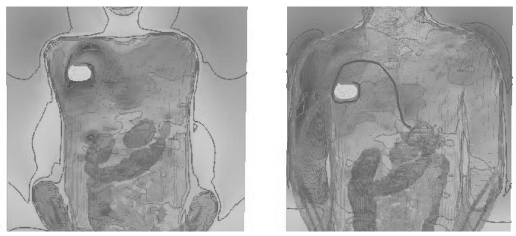

Fig. 2. The magnetic field strength in the plane of port1 (left) and port2 (right)
Rys. 2. Natężenie pola magnetycznego przy wejściu1 (z lewej) i wejściu2

In this case the value of the interference voltage U at frequency 50 Hz was:

$$U = 21.3\ \mu V \qquad (4)$$

In the case of vertical electric field exposure (E = 1 V/m) the interference voltage was calculated using the expression (Eq. 4):

$$U = \int_{port1}^{port2} E ds \qquad (5)$$

where E is electric field strength. The electric field distributions in the plane of "port1" and in the plane of "port2" are shown in fig. 3. In this case the value of the interference voltage U at frequency 50 Hz was U = 0.042 µV.

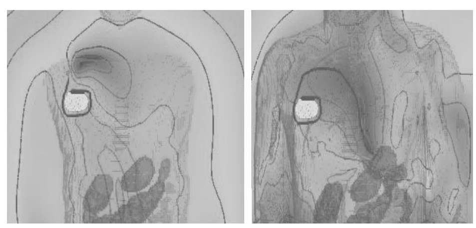

Fig. 3. The electric field strength in the plane of port1 (left) and port2 (right)
Rys. 3. Natężenie pola elektrycznego przy wejściu1 (z lewej) i wejściu2

Gustrau et al. [4] 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 a unipolar electrode was determined numerically. German investigator used software EMPIRE like we did. For the numerical investigation they generated a CAD model of single chamber pacemaker with a unipolar electrode. The maximum amplitudes of the interference voltage ranged from 420 mV at 900 MHz for mobile phone used in front of the chest and 2.9 mV at 950 MHz for plane wave exposure (E = 1 V/m).

6. Summary and future plans of investigation

Workers wear implanted pacemaker who working in close proximity to sources if electromagnetic field may suffer EMI.

Workers wear implanted cardiac pacemakers are interested in estimation of risk taking into account exposure condition at the workplace, type of implanted cardiac pacemaker and position of the implanted device inside human body. Possibility of analysis of the safety of worker with implanted cardiac pacemaker in electric and magnetic fields enable to reduce risk of failure before pacemaker implantation.

The paper shows the possibility of cardiac pacemaker examination at the workplaces. The particular attention is on the method of numerical simulation, giving pre-implanting prediction as to possible hazards.

This numerical calculation will be a framework to realize next part of polish scientists research project "Electromagnetic interferences of cardiac pacemaker" [13].

The investigations are grouped by sources of disturbance:

1. mobile phones and base stations (GSM operated);
2. devices including the power frequencies of 50 Hz,
3. medical devices.

The aims of the work are:

- to develop effective methods to identify the electromagnetic disturbances in cardiac pacemakers,
- to identify malfunction of cardiac pacemaker exposed on electromagnetic field,
- to determine the health effect of these interaction.

The research project including the following examinations:

1. cardiac pacemaker in human body,
2. cardiac pacemaker in phantom which simulated the human tissue,
3. cardiac pacemaker outside the body
4. numerical simulation.

The research project is realizing in cooperation with scientific society – Polish Society of Electromagnetic Applied, University of Zielona Góra, GSM operators and Military Institute in Warsaw, the medical environment - Collegium Medicum UJ and physicians of Medical Academy in Warsaw and Japanese scientists from Doshiha University [12, 15, 21, 22].

At present is realizing first part of project – investigation with base station antenna (GSM operated). The study comprise 230 patients, till now we tested 53 patients yet (37 males, 16 females) with a mean age 67,2 years (range 22-91 years). The average time from pacemaker implantation is 5,13 years (range 1,3 – 15 years). Seventeen (32%) were dual chamber and the remaining were single chamber pacemakers. The following companies manufactured were tested (Table 2): Biotronik (n=32), Medtronik (n=12), St. Jude Medical (n=7), Siemens (n=2).

All the patients were tested in the same place of investigations situated in hallway of Medical Academy hospital in Warsaw (Banacha Street). Place of investigation is marked at special place, where intensity EMF is equal: 7 V/m, 20 V/m, 30 V/m, 40 V/m, 100 V/m. These values correspond to European standards. Patient takes part at two tests. Base station antenna is switched off during one of test – passive test. Base station antenna is switched on only during one test (active test). Tests are executed in random order. The signal is recorded by Holter recorder during 24 hour from the beginning of investigation. We are analyzed 53 recorded electrocardiograms, till now. We have no observed any disturb of pacemaker function relevant with exposing pacemakers to electromagnetic field generated by base station antenna.

Our plans will be focus on examination devices including the power frequencies of 50 Hz using in vitro method. The result of numerical calculations will be verified.

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