Marek PENHAKER[1], Radovan HAJOVSKY[1], David KORPAS[2]

VSB-Technical University of Ostrava (1), Silesian University (2)

Measurement and analysis EMC parameters of implantable pacemaker

Abstract. *This paper deals with problematic of Electromagnetic Compatibility of Implantable Pacemaker. The ambient electromagnetic field can negatively influence the pacemaker functionality and also the wireless communication between its programmer and device. Electromagnetic compatibility parameters are tested by direct induction of interference signal to the inputs of cardiac pacemaker according to technical specification. The experimental tests were also made by generating of interference radio frequency signals to disturb the wireless telemetry communication.*

Streszczenie. *Przeanalizowano problem kompatybilności elektromagnetycznej przy pracy stymulatora serca. Zewnętrzne pole elektromagnetyczne może negatywnie wpływać na pracę stymulatora i na komunikację bezprzewodową z programatorem. Przeprowadzono eksperymenty z bez[pośrednim zakłóceniem pracy zewnętrzną falą elektromagnetyczną. (**Pomiary i analiza kompatybilności elektromagnetycznej stymulatora serca**).*

Keywords: Measurement, Implantable Pacemaker, Electromagnetic Compatibility, Disturbing Signal.
Słowa kluczowe: stymulator serca, kompatybilność elektromagnetyczna

Introduction

In recent years the number of patients with implanted cardiostimulator has increased significantly. This is mainly caused by downgraded lifestyle, aging population, and improving the healthcare and constantly developing top-class medical techniques. However, at the same time there's increasing number of electronic devices and systems which can negatively affect the function of cardio stimulator and may lead to complication threatening a patient's life if the requirements for electromagnetic compatibility aren't followed properly.

The ever increasing number of electronic devices, appliances and systems brings large problems related to electromagnetic disturbance and resistance regarding these and other objects against disturbance. The level of the disturbing signals grows in the frequency range 0 Hz up to hundreds of GHz. Electronic devices can contain signal generators working on several different frequencies, whereas each device or its particular part can be the source as well the receiver of the disturbance.

Electromagnetic compatibility is the ability of the device, system or appliance, to function properly even in an environment, where there are other sources of electromagnetic signals (natural or artificial) operating, at the same time, they must not affect their environment in an illegal way, and thus may not produce signals, which would illegally disturb other appliances and other living beings.

In medical facilities, mainly MRI, CT and the appliance for magneto- and HF- therapy are considered to be the sources of dangerous disturbance. When the requirements of electromagnetic compatibility are not met during the production and testing of the devices, they can adversely affect the function of the cardiac pacemaker and lead to complications endangering the patient's life. The papert describes and offers results of experimental measurements, realized in order to verify the electromagnetic compatibility of the parameters of the pacemaker and the communication with the programmer

Implantable Pacemakers

A pacemaker is a small, battery-powered device that sends out small electrical impulses to make the heart muscle to contract. The pacemaker itself is a waterproof object about the size of a silver dollar. A pacemaker consists of a pulse generator and battery that create the electrical impulses, and wires (leads) that transmit electricity to the heart.

Pacemakers help your heart beat in a regular rhythm and at a normal speed. They are inserted to treat a heart rate that is too slow, too fast, or irregular.

Pacemakers are typically placed under the skin of the chest. These pacemakers are permanent. But sometimes, pacemakers are needed for only a short time to help a person in the hospital with heart rhythm problems. A temporary pacemaker is not surgically inserted but is worn outside the body. Temporary pacemakers are used only while a person is in the hospital.

Modern multi-ventricular pacemakers today are highly integrated electronic devices with many pacing modes and circuits to enhance the quality of the heart pulse rate regulation during the patient's physical activity.

Signals measured by the pacemakers from the heart are usually within the range of 0.1 – 30 mV. The pacemaker on the contrary stimulates the heart muscle using electrical discharge of 1 - 10V if needed, using implanted lead. Additional circuits for measuring the infrasound of the skeletal muscles, vibration sensors, eventually other sensors used for the heart frequency regulation during stress can also be affected by the surrounding electromagnetic disturbance and therewith endangering the correct activity of the devices.

Fig.1. The guidant INSIGNIATM I Entra 1294 DDDR pacemaker - left and Cognis 100-D Pacemaker -right

Pacing modes VVI, AAI, DDD, and rarely also the VDD mode are used with cardiac pacemakers today. Using one lead, a dual chamber pacemaker reads the P wave from the right heart atrium, the detection of which is followed by an adjustable AV delay interval, usually about 120 ms long, and then a pacing impulse is sent into the right ventricle through another lead. During unipolar pacing, the metal case of the pacemaker forms the indifferent electrode for scanning and stimulation. During a bipolar pacing, two electrodes are placed on both leads. The DDD mode basically substitutes the disrupted transfer system, thereby retaining the synchronous activity of the atrium, and ventricle. When the activity of the heart decreases under

the set limit, the pacemaker works at the set speed of the atrium and ventricle stimulation.

Experimental Measurements and Testing

The goal of experimental measurements was to verify the basic parameters of two chosen types of cardio stimulators. Course of the measurement was a subject to recommended procedures introduced in the standard CSN-EN 45502.

A set of two types of measurement were carried out within the testing of the EMC parameters of pacemakers. First of them dealt with the issue of measuring the effect of the electromagnetic non-ionizing radiation on the pacemaker activity itself and the second measurement was carried out with the aim to analyze the effect of the electromagnetic RF radiation on the communication between the pacemaker and the programmer.

A. Electromagnetic Non-Ionizing Radiation Effect of the Pacemaker Activity

The CSN EN 45502-2-1 standard (furthermore "standard") was used as the theoretical base, which describes in detail, how the pacemakers should be build to ensure their correct operation and, at the same time, the safety of the patients and users - it defines the tests, which the appliances have to pass in order to conform to this standard.

The testing method of the EMC pacemaker was selected in accordance with the standard - to find out, if the pacemaker is not likely to change its therapeutical behavior during the common mode induction of the moduled electromagnetic field, i.e. to bring testing signals with the course, frequencies and amplitudes as defined below, to the circuit of the artificial tissue with the connected pacemaker. The pacemaker shall be in the synchronized mode set by a signal from an operating generator.

B. The circuit of Artificial Tissue

In order to follow the measuring procedures defined in the above mentioned standard, it was necessary to design a circuit using artificial tissue. Substitutive electric tissue circuit simulate an life tissue for simulating measurement without testing on humans at all. The basic scheme is shown in Figure 2.

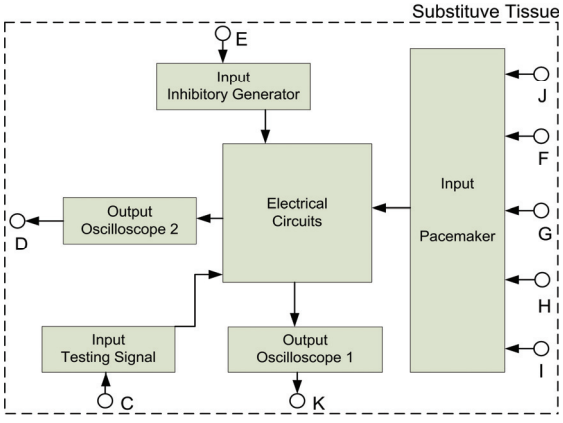

Fig. 2. The Artificial tissue circuit module

A measuring chain was created for the measurement, and the following devices were used in it. The measurement was perform on the Guidant INSIGNIATM I Entra 1294 DDDR pacemaker programmed to Guidant ZOOM® LATITUDETM 3120 Programming System. Furthermore, the digital oscilloscope Tektronix TPS 2014 (Figure.3 oscilloscope 1) and digital oscilloscope Tektronix TPS 2024 (Figure.3 oscilloscope 2) were used in the measuring circuit. Two functional generators Agilent 33220A (Figure.3 generator 1 and 2) were used as the functional generators. The main element of the measuring circuit was the Artificial Tissue Module specified and defined in the standard, where all the above mentioned devices were connected.

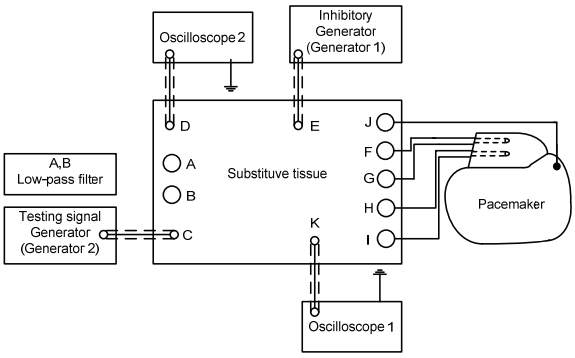

Fig. 3. The experimental measurement chain

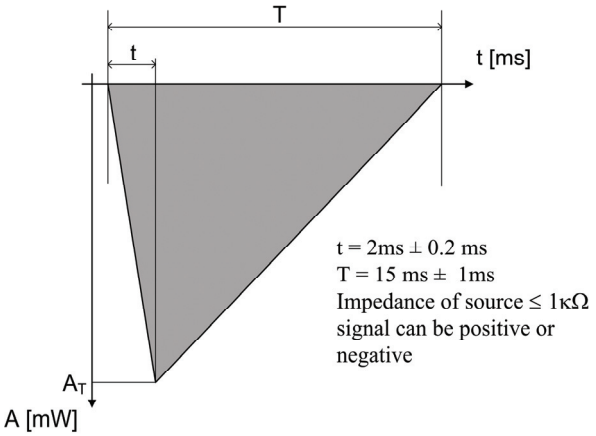

Fig. 4. Inhibitory pulse signal

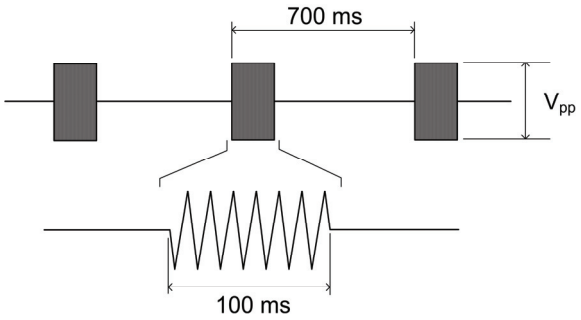

Fig. 5. Examinational signal form

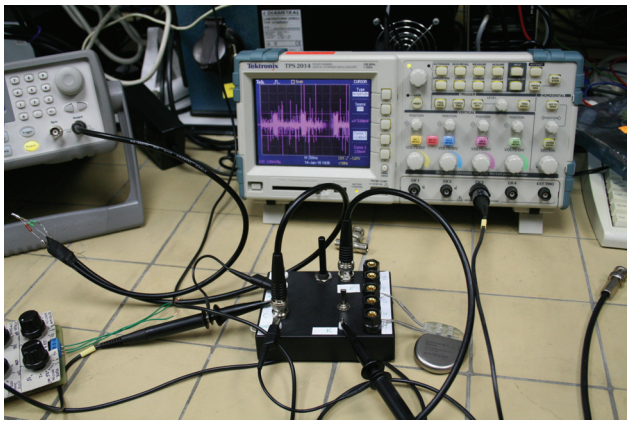

Fig. 6. Measuring workplace for electromagnetic radiation influence

The pacemaker was connected to the programmer through a telemetry wand and it was set to the AAI mode and to the lowest sensitivity. The signal process was set on the inhibitor generator and the test signal generator according to requirements stated in the ČSN EN 45502-2-1 standard. Figure. 6 show the view of the measurement area. Generators 1 and 2 were attached to substitute tissue, the oscilloscope 1 to point D and oscilloscope 2 to the outlet of the S potentiometer.

Firstly, the sensitivity threshold of the pacemaker was measured and the required amplitude of inhibitory impulses was set for the pacemaker to change into the inhibited mod. The oscilloscope 2 was then switched over to point K and the processes at both points were measured with the test signal generator set with a carrier frequency of 20 Hz, 200 Hz, 2 kHz, 20 kHz and 150 kHz and the amplitudes according to Table 1.

Table 1. The parameters of testing signals

Measurement No.	Carrier frequency [kHz]	Amplitude generator 1 [mVpp]	Amplitude generator 2 [Vpp]
1	-	40	off
2	-	80	off
3	-	160	off
4	0.02	160	0.9
5	0.2	160	0.9
6	2	160	5.7
7	20	160	1.3
8	150	160	8.8

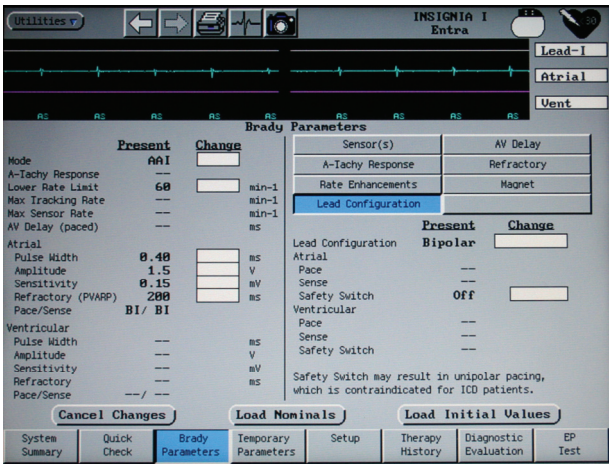

Fig. 7. The example of tested carrier frequency with 150 kHz frequency on the programer's screen

C. The effect of the electromagnetic RF disturbing signals on the communication between the pacemaker and the programmer

The wireless telemetry among the programmer and the patient devices was developed by the Boston Scientific Corporation to have the possibility to program patient devices at longer distances, to decrease the risk of disturbing the operative field sterility during the implantation, as well as to maximize the patient's comfort, e.g. during follow-ups or during the device re-setting, contrary to induction telemetry with the help of a circular probe.

The presetting of the patient's device is secured through acknowledgement signals after a successful transfer of the programmed data as it works in a no-license ISM zone SRD on the frequency of 869.85 MHz, which is not reserved only for the communication between these devices, and practically anybody including the often used mobile phone GSM technology can use it for radiation (when meeting the transmission performance and other transmission parameters), thus causing a communication failure. An incomplete or incorrect device setting is therefore out of the question.

No methodology for this kind of measurement has been cited in the literature. Therefore, the following procedure was selected. A half-wave of a dipole aerial was created and a disturbing signal with the frequency, which is used for the wireless telemetry communication, i.e. 869.85 MHz and the signal shape of a clear unmodulated sines with the help of an RF signal generator. Furthermore, the relation of the radiated output of the aerial in the moment of the failure of telemetric connection (when raising the transceiver output) as well as when the connection was restored (when reducing the transceiver output) was measured at the distance of the aerial placed:

1) on a straight line, formed by the pacemaker and the programmer (position a: aerial-pacemaker-programmer, position b: aerial-programmer-pacemaker)
2) on a vertical line, which passes through the centre of the join of the pacemaker and programmer

Fig. 8. Measuring workplace for electromagnetic RF disturbing signals influence

The pacemaker was connected with the programmer using the wireless telemetry, and it was left in a default setting - to measure the disturbance effect on the telemetry connection, the pacemaker had to only transmit the signal (noise in this case) from the electrodes into the programmer - when the transmission was interrupted, the noise disappeared from the programmer monitor as well. In order to express the total effective radiated output of ERP, the total inhibition of the lead and the aerial was taken into account.

Measurement in placement 1

For the a) and b) position, the pacemaker and the programmer was placed at the distance of 2.5 m. The aerial was placed on a straight line at the distance of 1 to 5.5 m after 0.5 m steps. The output of the generator was set and recorded from the minimum to the telemetric connection failure and again from the maximum till restoring the connection during each placement of the aerial.

Measurement in placement 2

The pacemaker and programmer were placed at a distance of 3 m. The aerial was placed on a vertical line, which goes through the centre of the pacemaker and programmer join at the distance of 1 to 8 m after 1 m steps. The output of the generator was set and recorded from the minimum to the telemetric connection failure and again from the maximum till restoring the connection during each placement of the aerial.

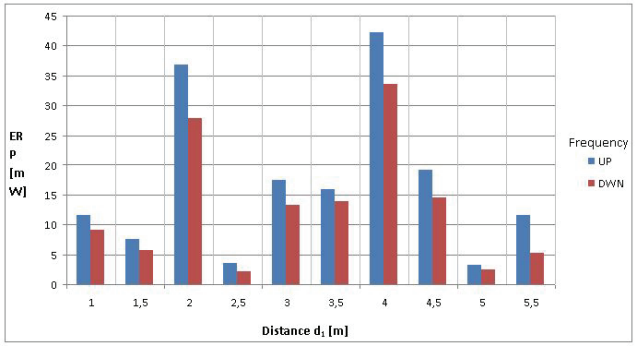

Fig. 9. ERP to antenna distance dependence placement a)

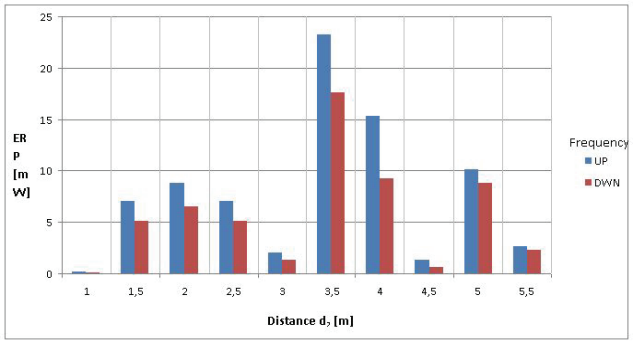

Fig. 10. ERP to antenna distance dependence placement b)

Conclusion

The result of the test measurement shows, that the pacemaker complies with the standard except for the carrier frequency of the test signal of 150 kHz, when the pacemaker stayed inhibited, however on the monitor of the programming device could be seen the fact that the oscillation burst of the test signal detected the activity of the heart chamber to be spontaneous. Practically, this could mean, that the pacemaker would inhibit through the interfering signal, however, if the patient's heart did not produce spontaneous pulses, the pacemaker would not generate pacing pulses and its main function would thus not be fulfilled, which is unacceptable. This false detection was nevertheless probably caused by inaccuracies of measurements and the measuring devices as well as by the noise on the circuit parts.

The wireless telemetry connection failed to work at ERP values in units up to tens of mW. These are relatively low values, which show, that this telemetry can tend to fail when there is a device near the pacemaker, working on this or a close frequency with relatively poor performance, such as wireless phones, headsets, patients' monitors, electrosurgical devices and other devices working in the UHF range.

ACKNOWLEDGMENT

The work and the contribution were supported by the project Grant Agency of Czech Republic – GAČR 102/08/1429 "Safety and security of networked embedded system applications". Also supported by the Ministry of Education of the Czech Republic under Project 1M0567. Students Grant Agency SGS SV450021" Biomedical Engineering Systems VII"

REFERENCES

[1] Bax JJ, Abraham T, Barold SS, Breithardt OA, Fung JW, Garrigue S, Gorcsan J 3rd, Hayes DL, Kass DA, Knuuti J, Leclercq C, Linde C, Mark DB, Monaghan MJ, Nihoyannopoulos P, Schalij MJ, Stellbrink C, Yu CM. Cardiac resynchronization therapy: Part 1--issues before device implantation. J Am Coll Cardiol. 2005 Dec 20;46(12):2153-67.

[2] Augustynek, M., Penhaker, M., Korpas, D. Controlling Peacemakers by Accelerometers. In 2010 The 2nd International Conference on Telecom Technology and Applications, ICTTA 2010. March 19-21, 2010, Bali Island, Indonesia, Volume2 NJ. IEEE Conference Publishing Services, 2010, p. 161–163. ISBN 978-0-7695-3982-9, DOI: 10.1109/ICCEA.2010.288

[3] Ector H, Rickards AF, Kappenberger L, et al. The world survey of cardiac pacing and implantable cardioverter defibrillators: calendar year 1997 – Europe. Pacing Clin Electrophysiol 2001;24(5):863–8.

[4] Guidant Corporation Cardiac Rhythm Management Technical Services. Impact of Therapeutic Radiation and Guidant ICD/CRTD/CRT-P/Pacing systems. St. Paul, MN, Guidant Corporation, 2004, Revision; pp. 1–6.

[5] Labza, Z., Penhaker, M., Augustynek, M., Korpas, D. Verification of Set Up Dual-Chamber Pacemaker Electrical Parameters. In 2010 The 2nd International Conference on Telecom Technology and Applications, ICTTA 2010. March 19-21, 2010, Bali Island, Indonesia, Volume 2NJ. IEEE Conference Publishing Services 2010, p. 168–172. ISBN 978-0-7695-3982-9., DOI: 10.1109/ICCEA.2010.187

[6] Korpas, D., Psychological Intolerance to Implantable Cardioverter Defibrillator, In Biomedical Papers-Olomouc, Volume 152, Issue: 1 p.: 147-149 , June 2008 , ISSN: 1213-8118

[7] Palan, B., Roubik, K., Husak, M., Courtois, B., CMOS ISFET-based structures for biomedical applications, In Proceedings Medicine & Biology at 1st Annual International IEEE-Embs Special Topic Conference on Microtechnologies, Pages: 502-506 Published: 2000, ISBN: 0-7803-6603-4

***Authors**: Ing Marek Penhaker, Ph.D., Ing. Radovan Hájovský, Ph.D., VSB-Technical University of Ostrava, Department of Measurement and Control, Faculty of Electrical Engineering and Computer Science, 17. listopadu 15, 708 33 Ostrava-Poruba, Czech Republic, E-mail: marek.penhaker@vsb.cz, radovan.hajovsky@vsb.cz, Ing.David Korpas, Ph.D., Institute of Nursing Faculty of Public Policies Silesian University Hauerova 4 746 01 Opava Czech Republic, E-mail: david.korpas@seznam.cz.*