# Methods for Ensuring the Sustainability of Pacemakers

Anna V. Busygina
*Department of Television and Control*
*Tomsk State University of Control Systems and Radioelectronics, TUSUR*
Tomsk, Russian Federation
bav-tusur@mail.ru

***Abstract*—The paper describes the main disturbance in the pacemakers operation and existing methods of protecting pacemakers from exposure to electromagnetic fields emitted by electronic devices for various purposes. Methods such as shielding enclosures and layout of electronic components inside a pacemaker, using filters to isolate interference and heartbeat signals, as well as improving stimulation control are considered. The necessity of developing new approaches to testing critical electronic devices, such as a pacemaker, at the development stage is described.**

***Keywords— pacemaker; pacemaker stability; electromagnetic field; protection methods***

## I. Introduction

Currently, there is widespread use of various electronic equipment, devices, household appliances, mobile phones, industrial sources of electromagnetic radiation, medical therapy and diagnostic equipment, for example, magnetic resonance imaging (MRI), as well as radio frequency identification systems, etc. This fact makes more stringent requirements for electromagnetic compatibility (EMC) of electronic equipment, including equipment of critical purpose, ensuring the maintenance of human life, for example, pacemaker. A pacemaker is a device that reads the patient's pulse and, if necessary, stimulates the heart muscle, which helps to overcome a number of diseases, such as atrioventricular block, two-beam and three-beam blocks, sinus node dysfunction, tachycardia, etc. [1]. Disturbance of the operation of such devices can lead to serious consequences up to death. That is why it is necessary to increase the noise immunity of individual components and the noise immunity of the pacemaker as a whole. To date, there are a number of studies devoted to the effects of electromagnetic fields (EMFs) of various sources on the pacemaker, as well as methods of pacemaker protecting from EMF.

When the EMF acts on a pacemaker, the following device malfunctions are distinguished [2]: hyper detection, which can cause a short termination of the stimulating function of the pacemaker, asynchronous stimulation, triggering ventricular stimulation mode with loss of atrioventricular synchronization, increase or decrease of the implanted device impulse, and erroneous recognition of arrhythmia. In addition, EMF can heat the electrodes, followed by thermal damage to body tissues. Despite numerous research and development in the field of implantable electronic devices, the restrictions on patients with such devices are still extensive.

The purpose of this paper is to analyze the methods of protection and ensuring the stability of the pacemaker work.

When solving the pacemaker EMC problem, design and circuit methods are used. When designing the EMC, it is necessary to determine the parameters of the excited radiated interference, the intensity and direction, evaluate the sensitivity of the blocks and units to this effect, and then perform the layout of the electronic inside the pacemaker in such a way as to minimize the effect of the radiated interference. If EMC is not provided with a rational arrangement, shielding of functional units and blocks (receptors) sensitive to electromagnetic interference, or shielding of field sources (interference sources) should be used. In the case of interference penetrating the conductive path and interference, circuitry methods are used. For example, in [3], a method was proposed for protection against magnetic fields generated by MRI, which includes a magnetic field sensor for detecting the presence of a relatively weak static magnetic field level equivalent to the level of a permanent magnet in the immediate vicinity of the device. The device switches from the standard operating mode, in which the nominal functions of the device are active, to a specific protected MRI mode in the presence of a magnetic static field of a level corresponding to the level emitted by MRI equipment.

## II. Shielding and Layout

The results of using various shielding materials to protect the pacemaker from EMF were presented [4 – 6]. So in [7], the shielding properties of two materials (a rubber sheet and a resistive film) were studied. It is established that the shielding properties of the resistive film are higher than that of a rubber sheet. Moreover, their size may vary within the area exceeding the area of the pacemaker itself, without changing the shielding properties. It is also noted that the shielding material should provide shielding effectiveness of about 10-20 dB with a distance of less than 6 cm between the antenna and the human body.

It was shown that the rate of change of the level and the power level itself are the reasons for the failure of the pacemaker. In [8], five different commercial pacemakers in 22 complete configurations were used. The RC circuit is modeled for two different input signals (linear and constant), for a capacitance of 0.01 μF and a resistance of 376 Ohms, which gives $\tau = 3.62$ μs. The maximum voltage applied to the RC circuit is 8.3 V. The power of the 10 W RF source, transmitting at 13.56 MHz, induces 8.3 V on the pacemaker. The distance between the antenna and the pacemaker is 15 cm. If reduction technology is not used, the maximum output voltage of the RC circuit exceeds 30 mV (much more than the sensitivity of heart rate sensors). When using the attenuation method with a slope of 80 W/s, the maximum output current of the RC circuit is approximately 0.25 mV (equal to the sensitivity of heart rate monitoring

The research was carried out at the expense of Russian Science Foundation grant 19-79-10162 in TUSUR University.

devices). When the attenuation method is applied with a slope of 50 W/s, the maximum output current of the RC circuit is approximately 0.15 mV (less than the sensitivity of the cardiac rhythmic control devices). Also, to confirm the simulation, a series of experiments was carried out in which 200 test cases were investigated. Using the proposed interference mitigation technique, the interference was successfully eliminated in all cases. Maximum power consumption ranges from 0.001 W to 10 W. The experiments were conducted for different frequencies using a commercial pacemaker and a human torso model. Typically, the sensitivity of the pacemaker may vary from 0.1 to 2.5 mV. It was experimentally established that the time constant for the pacemaker is from 2 to 27 μs. The carrier wave signal, which increases and decreases with speed as a function of power, does not interfere with the operation of the pacemaker.

The applicability of the EMF registration function for identifying interference sources was evaluated [9]. The pacemaker was exposed to a wide range of magnetic fields. In cases where the pacemaker experienced interference, the time of failure was compared with a graph of the effect of a magnetic field. The study showed that the source of interference can be identified by combining failure times and diary records of patient activity. To investigate this, a Helmholtz coil setup was created to create magnetic fields that were measured with an oscilloscope. A model was placed between Helmholtz coils and measured in three orthogonal directions. You can select the waveform (sine wave, pulse, and so on) and the characteristics of certain waveforms (for example, rise time), frequency (1 Hz - 200 kHz), amplitude, exposure duration and rest time between influences. The magnetic field strength can be accurately calculated from the analytical formula for Helmholtz coils. By comparing the protocol schedule and the data of the pacemaker, it was possible to identify the conditions that caused the interference.

## III. USING FILTERS

A number of studies are aimed to study the use of filters to isolate electromagnetic interference. For example, the design and installation of a broadband ceramic capacitive filter to protect the pacemaker from the electromagnetic field of handheld wireless devices and other RF transmitters. Studies have shown that in the presence of a developed filter, the pacemaker is resistant to electromagnetic fields from telephones operating at 950 MHz and 1.8 GHz [10]. It is not practical every time to determine the modulation frequencies, pulse repetition rate or power levels of all emitters that can affect the pacemaker, therefore, a broadband EMF filter is required. This filter assumes significant (> 40 dB) attenuation over a wide frequency range (from 30 MHz to 10 GHz) [11].

In [12], a pass-through filter of electromagnetic interference with capacitive grounding for a pacemaker was described. The filter offers the developer the ability to limit the number of capacitance circuits to ground, while providing an effective common mode and differential mode of EMF attenuation. The filter becomes part of the continuous electromagnetic shield in which the electronic device is located.

Butterworth bandpass filter using a stepped Gm-C structure to detect heart rate was proposed. The designed filter provides a wide passband covering the range from 80 MHz to 105 MHz with a center frequency of 94.45 MHz, and the quality factor is -3.5 dB. Total power consumption is 42.25 mW [13].

The fourth-order low-power bandpass filter with a switched capacitor for the pacemaker was implemented on a standard 0.18-micron CMOS processor [14]. The sampling frequency of the developed filter is 5 kHz, and the passband is between 80 Hz and 120 Hz. The total power consumption is only 200 nW when using a 1.2 V power supply. The maximum free dynamic range is 72 dB.

Development and implementation of an adjustable bandwidth amplifier designed for ultra low power biomedical implants at 65 nm nm CMOS, providing a tunable gain band in three modes: 0.9 MHz, 1.7 MHz and 2.3 MHz with constant DC gain 56 dB was presented. [15] the amplifier consumes a constant power of 180 nW in low-bandwidth mode and 315 nW in full-bandwidth mode with a load of 8 pF from a supply voltage of 0.9 V.

Pacemaker electrodes constantly monitor the patient's heart signals, so they should always stay on. As a result, it is very important that the system consumes less energy, therefore, a continuous Gm-C filter is presented, which implements the identical function of transmitting a smoothing filter for the pacemaker in a fully integrated form without external capacitors. In addition, since current consumption is a critical performance parameter for the pacemaker, each filter is designed to consume less than 20 nA. In [16], the effects of nonideality of the amplifier, such as linearity, noise, displacement, and leakage in the filter, are eliminated. The filter can be made for any signal on a 0.18 micron CMOS processor.

In [17], a preamplifier with a programmable gain and a filter for detecting spontaneous cardiac activity in a pacemaker were presented. The system is fully integrated in standard 0.35-micron CMOS technology, including all auxiliary circuits. The implemented system can operate up to 1.8 V of the supply voltage and consunes no more than 1.8 μA, with a tolerance of 47 dB dynamic range. According to the measurement results, both channels show the expected programmed gain and realize a biquad filter with a quality factor of about 2 and a central frequency of 105 and 72 Hz for the atrial and ventricular channels, respectively.

## IV. PACEMAKER CONTROL

In modern pacemakers, the onset of the reaction is from 2.5 to 26, and the resynchronization time is from 3.4 to 143. Therefore, a beating detection algorithm was proposed based on the amplitude difference between the maximum and minimum to accurately determine the frequency of atrial contractions, providing faster switching modes [18]. The result showed a sensitivity of 96.64% and a positive prognostic value of an average of 95.5%.

Several approaches to detecting hidden pulses of a pacemaker in an electrocardiogram were described [19]. There were used the wavelet transform, the Hilbert-Huang transform, linear and nonlinear filters. It was shown that they can be used to determine the signal and detect hidden impulses. The results will also be useful to extend the life of the pacemaker and reduce pain in patients.

A 1.8 V analog input signal heart rate detector was presented, which includes a preamplifier cascade and a filter designed to reduce the flicker noise of the device in the electrocardiogram band [20]. A special feedback mechanism has been applied to increase the signal-to-noise ratio. The amplifier will achieve 87.5 dB dynamic range free of spurious frequencies with a total power consumption of 0.354 mW in combination with a filter.

A two-phase pulse pacemaker was also developed and implemented, low-energy treatment was applied during atrial stimulation, and the traditional stimulation mode was replaced, which has potential dangers and disadvantages [21]. Based on keyboard input, the microcontroller system adjusts the initial value of the timer and issues a regular pulse shape. Compared to the traditional shock stimulation regime, this system is characterized by a high degree of safety, low risk, controllability and economy.

An improvement in the design of the control system for the effective regulation of the heart rate of a pacemaker was presented [22]. In the proposed method, controller performance is improved through a performance improvement cycle. The simulation results were obtained on the developed human cardiovascular system, and they showed that the proposed PID-regulator provides excellent control characteristics compared to a conventional regulator.

An advanced intelligent control for the pacemaker using a fuzzy PID controller was introduced [23]. The FPID controller provides a good adaptation of the heart rate to the physiological needs of the patient in three different conditions (rest, walking and exercise). Based on dual sensors, a combination of fuzzy logic and conventional PID control approaches is used to create the controller. Compared to a conventional fuzzy logic control algorithm, FPID provides a more suitable control strategy for determining the frequency of stimulation. Based on the Ziegler-Nichols tuning method, a reliable proportional integral controller with fractional order has been developed [24]. The robust controller of proportional integral derivative of fractional order was superior to controllers with proportional integral derivatives with various tuning methods, as well as controllers with fuzzy logic with respect to rise time, settling time and percentage of overshoot. The fractional order proportional integral derivative controller also demonstrated adaptive speed stimulation. However, the developed controller is not optimal and is limited by the setup procedure. More effective may be a development that provides optimal control of the pacemaker using a genetic algorithm.

The design and analysis of an intelligent control system for regulating heart rate was presented [25]. To achieve optimality, a genetic algorithm is used. The controllability and observability of the entire system is verified and recognized as the best for the proposed system.

A specialized integrated circuit (IC) for three-chamber pacemaker was presented [26]. ICs are manufactured using BCD technology of 0.35 μm with a crystal area of 3.8 × 3.8 $mm^2$. The measurement results show that the magnitude of the stimulation pulses can be programmed from 0.1 to 7.4 V in increments of 0.1 V. Close to a linear measurement of cardiac resistance is achieved in the resistance range from 250 to 4000 Ohm. The average current consumption is 4 μA from a 2.8 V power supply.

Extending the time of use of a pacemaker was considered [27]. The processor is considered as the main device because it controls all peripheral devices. Therefore, creating a low power processor architecture would be a good approach. In addition, the power shutter technology has been found to be excellent for reducing power consumption. Power gating is a method of saving leakage energy by turning off the power of the idling units using power switches. Power switches, usually transistors, are used to connect or disconnect a function block to a power source. As a result, energy consumption is reduced to 25%.

## V. Conclusion

The main problems in the work of the pacemaker and the existing ways to overcome these problems are highlighted. Unfortunately, despite numerous research and development in the field of implantable electronic devices, for patients this is still associated with many limitations. These restrictions are caused by the influence of electromagnetic fields of various sources found in the everyday life of any person, such as radiation from mobile phones, radio frequency identification systems, frames, wireless communication systems, magnetic resonance imaging.

All this makes it necessary to develop new approaches to the design of implantable electronic devices that provide greater noise immunity and durability of such devices. In particular, it is necessary to apply new approaches to testing electronic devices and analyzing risks for the human body when using them.

## References


[1] Yu.V. Shubik, M.M. Medvedev, P.G. Platonov, S.M. Yashin. Indications for implantation of pacemakers and anti-arrhythmic devices // Bulletin of Arrhythmology, No. 38, 2004, pp. 59- 67. (in Russian)

[2] E. Güler, F. Kızılırmak, G.B Güler, F. Kılıçaslan. Interference of biventricular ICD with radiofrequency application during ventricular tachycardia ablation in a pacemaker-dependent patient // International Journal of Heart and Vascular Diseases vol. 2, No. 4, November 2014, pp. 44- 47. (in Russian)

[3] T. Legay et al. System and method for protecting against magnetic fields produced by MRI. Patent US 2019 / 0083802 A1, Mar. 21 , 2019.

[4] Y. Tarusawa et al. Attenuation characteristics of electromagnetic shield materials for microwave near-field EMI // Proc. of Commun. Society Conf. of IEICE, B-296, Sept. 1996.

[5] S. Nishizawa, O. Hashimoto. Near field shielding effect for oval human model using high loss magnetic and dielectric materials // Tech. Rept. of IEICE, EMCJ99-14, June 1999.

[6] S. Kurohwa et al. Effect of various shielding on mobile phone field intensity in human body // Proc. of Commun. Society Conf. of IEICE, B-4-27, Sept. 1999.

[7] J. Wang, T. Ohshima, O. Fujiwara. Effectiveness evaluation of shielding material for reducing electromagnetic interference of cardiac pacemaker by portable information terminals // Proc. of 2001 IEEE Int. Symp. on Electromagnetic Comp., August 13-17, Montreal, Que., Canada. 2001. – pp. 1054-1057.

[8] A. Ogirala et al. Electromagnetic Interference of Cardiac Rhythmic Monitoring Devices to Radio Frequency Identification: Analytical Analysis and Mitigation Methodology // IEEE trans. on inform. Techn. in biomed., vol. 15, no. 6, November 2011, P. 848–853.

[9] T.Alanko et al. EMF interference detection utilizing the recording feature of cardiac pacemakers // 2011 URSI General Assembly and Scientific Symp., pp. 1- 4.

[10] R. Carrillo et al. Electromagnetic Filters Impede Adverse Interference of Pacemakers by Digital Cellular Phones // Paper presented at: Meeting of the College of Cardiologists, 1996.

[11] R. A. Stevenson. Design and application of broadband ceramic feed through capacitor EMI filters to cardiac pacemakers and implantable

defibrillators // Proc.19th Int. Conf. - IEEE/EMBS 1997, pp. 2558–2562.

[12] R. A. Stevenson. Feed through EMI filter with ground isolation for cardiac pacemakers and implantable cardioverter defibrillators // Proc. of the 20th Annual Int. Conf. of the IEEE Engin. in Med. and Biol. Soc., 1998, pp. 3319–3323.

[13] W. C. Lai. A Band Pass Filter to Near Infrared Charging for Implantable Cardiac Pacemaker and ECG Micro-Stimulator Application // 2015 IEEE MTT-S 2015 Int. Microwave Workshop Series on IMWS-BIO, pp. 51 – 52.

[14] M. Hammad et al. A 1.2-V 200nW Fourth Order Switched Capacitor Band Pass Filter for Implantable Cardiac Pacemaker // 2010 Int. Biomedical Engineering Conference, PP. 142 – 145.

[15] A. F. Yeknami et al. A Variable Bandwidth Amplifier for a Dual-Mode Low-Power ΔΣ Modulator in Cardiac Pacemaker System // 2013 IEEE Int. Symp. on ISCAS, pp. 1918 – 1921.

[16] A. E. Zadeh. Fully-Integrated Gm-C Anti-Aliasing Filter For Sense System of Implantable Cardiac Devices // 2012 IEEE Int. Symp. on MWSCAS, pp. 190 – 193.

[17] A. Gerosa et al. A Fully Integrated Dual-Channel Log-Domain Programmable Preamplifier and Filter for an Implantable Cardiac Pacemaker // IEEE Trans. on circuits and systems, vol. 51, No. 10, 2004, pp. 1916 – 1925.

[18] Seung Hwan Lee et al. Amplitude Based Beat Detection for Atrial Fibrillation in Pacemaker // 2016 IEEE Int. Conf. of the EMBC, pp. 2757 – 2759.

[19] M.Stork et al. Hidden Pacemaker Pulses Detection Based on Wavelet and Hilbert-Huang Transform // 2014 Int. Conf. on AE, pp. 1 – 4.

[20] D. Basak et al. A Low Noise Preamplifier and Switched Capacitor Filter for Heart-rate Detection // Proc. of Int. Conf. on Advanced Electronic Systems (ICAES 2013), 21-23 September 2013, Pilani, India, pp. 184 – 188.

[21] L. Xu et al. The Analysis and Design of Diphasic Pacemaker Pulse System Based on Microcontroller // Proc. of the 10th World Congress on Intelligent Control and Automation, 2012, pp. 1192 – 1195.

[22] K.R.A. Govind et al. Design of a Novel PID Controller for Cardiac Pacemaker // Proc. of Int. Conf. on Advances in Green Energy (ICAGE 2014), 17-18 December 2014, Thiruvananthapuram, India, pp. 82 – 87.

[23] W.V. Shi. Advanced Intelligent Control of Cardiac Pacemaker Systems Using a Fuzzy PID Controller // Int.l journal of intelligent control and systems, vol. 18, No. 2, 2013, pp. 28 – 34.

[24] S.P. Arunachalam et al. Intelligent Fractional-Order PID (FOPID) Heart Rate Controller for Cardiac Pacemaker // 2016 IEEE HI-POCT, pp. 105 – 108.

[25] H.O. Bansal et al. Design of an Intelligent PD Controller for Artificial Pacemaker // 2012 Int. Conf. on Power, Control and Embedded Systems, pp. 1 – 4.

[26] J. Zhang et al. A Mixed-Signal ASIC for Triple-Chamber Cardiac Pacemakers with Heart Resistance Measurement // IEEE Asian Solid-State Circuits Conf., 2015, pp. 1 – 4.

[27] H. Trang et al. Power gating technique in pacemaker design on FPGA // 2012 Int. Conf. on ATC, pp. 14 – 18.