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Electrical parameters measurement and testing of implantable cardioverters – defibrillators

***Abstract**. The aim of the work was measurement and testing of implantable cardioverter - defibrillator (ICDs) device. There was realised electronic measuring circuit which substitutes human body tissue during the device accuracy testing. This circuit enables to measure defibrillation shock discharge in the whole energy range (0.1- 41J). The presented measuring and testing procedures can easy check-up precision of parameters and functionality of embedded electronic device circuit's part of the ICDs. Presented suggestion and results of this work can be implemented as verification procedure in various types of ICDs and also pacemakers before their implantation as well.*

***Streszczenie.** Celem pracy było zbadanie właściwości elektrycznych rozrusznika serca. Zaproponowano procedure testowania tego typu urzadzeń. (**Pomiar parametrów elektrycznych i testowanie implantowanych cardio-stymulatorów**)*

Keywords: Implantable Cardioverter - Defibrillator, Defibrillation Shock, Energy, Measurement, Programmer
Słowa kluczowe: defibrylator, kardiostymulatory.

Introduction

Technique in biomedicine has been continuously developing. Steps that lead to new technological applications and searching of new procedures how to improve these applications have been related to it. The heart is one from the most important organum of the human body. Therefore also cardiology does not stay behind in development of these applications. Modern methods especially in care for patients with atrial fibrillation require not only difficult diagnostic procedures but also treatment by means of cardiostimulator implantation or by implantation of cardioverter-defibrillator. Therefore it is important to improve continuously these therapeutic devices in order that they make better quality of life possible, respectively they make immediate rescue of endangered people possible. The target of this project is to measure features of defibrillation discharges by means of a created appliance, to analyse obtained data, and to evaluate results and energetic losses.

Implantable defibrillators

Electronic equipment capable to generate electric pulses that have a task to replace heart's own control system in the case of cardiac insufficiency is called a cardiostimulator. The equipment tends to be implanted into a human organism in the case of important bradypragia of cardiac frequency, respectively in the case of burning creation or conduction of cardiac pulses (bradycardia) out. By means of stimulation electrodes the implantable cardiostimulator not only monitors but also stimulates function of the heart. The implantable defibrillators philosophy comes from a hypothesis that not always it is possible to prevent from continued ventricular tachycardia or from ventricular fibrillation. If such arrhythmia already occurs in a patient, it is practically always fatal if it is not cured. Hemodynamic manifestations of the disease, blood circulation collapse and patient's dead come about quickly. It was proved that by far the most effective and practically the only reliable method is immediate end of arrhythmia by means of defibrillation. This fact has been known for long time from CCUs (coronary care units). By using of external defibrillations this method prevents from Mors subita in first hours after a cardiac infarct. Thanks to technical possibilities the implantable cardioverters-defibrillators - ICD were gradually developed. In fact they are combination of a cardiostimulator and actual defibrillator. Such appliance is able to detect ventricular tachycardia or ventricular fibrillation with a help of very complicated internal algorithm and it is able to suppress this arrhythmia by electric discharge usually by energy of 20 J. After this discharge a brachycardia might come next and here cardiostimulator function is applied.

Fig.1. Implantable defibrillator COGNIS 100-D

Newer ICD generation is able not only to make a detection and discharge but according to setting during detection of ventricular tachycardia it might apply also antitachycardia program (ATP) when it suppresses arrhythmia by means of quick stimulation. The discharge is applied by the appliance no sooner than in the situation when ATP fails. By that the appliance energy is saved and the patient is not exposed to the discharge that is sometimes perceived unpleasantly.

The whole system consists of the appliance and from one or two flexible electrodes conducted through the subclavian vein in to the heart. Inside the appliance there are a battery, a microprocessor processing all the information and appropriate electric circuits (see Fig. 1). ICD monitors continuously electric activity of the heart. In the case of slow rhythm of the heartbeat it operates as a cardiostimulator and keeps the hearts action regular with preset frequency. In the case of creation of a quick life-threatening rhythm of the heartbeat, it starts the appropriate care during a few seconds.

Measurement of implantable defibrillator parameters

For function verification and designation of discharges features of the implantable defibrillators a specific metering application was created.

Measuring chain

For measuring purposes we use PRM programmer, model 3120 by means of which we will program ICD. PRM programmer task is to set individual discharges in the range (0.1 - 41J). For defibrillation discharges measurement

Cognis 100-D Model P107 ICD was used. Because an amplitude of such discharge achieves at maximal discharge not less than a few hundreds Volts, it is important to reduce this voltage, respectively to reduce it on measurable values (0-10V) by means of a developed gauging fixture.

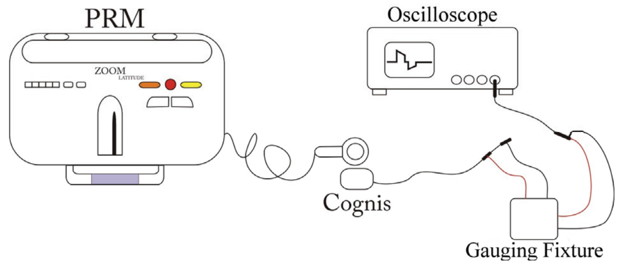

Fig.2. Defibrillation discharge measurement engagement

For recording and evaluation of the measured discharges TEKTRONIX TPS 2024 oscilloscope was used. A working place layout for discharges measurement is stated in Fig. 2.

Gauging fixture for defibrillation discharges measurement

The main function of this fixture is to substitute natural impedance load of the defibrillator which is human texture on current conditions and further to decrease the amplitude of defibrillation discharge on measurable values (0- 10V) with possibility of digitalization. The circuit is solved as a resistor divider. It is equipped with protective elements for the case of failure. The input voltage is decreased, that is in the ratio of the voltage divider. The circuit is equipped with protective elements from the safety reason and reduction of high input voltage break down risks to JP3 output. One from these protective elements is a varistor that serves as a protection in the case of R1, respectively R2 resistor damage. Another protective element is a revertible fuse "Polyswitch" that serves as the current protection.

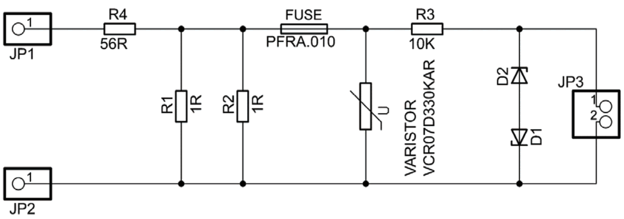

Fig.3. Gauging Fixture Electric Diagram

Fig.4. Gauging fixture

Because it is necessary to rectify a biphasic discharge, two Zener diodes are required. The output is stabilised on the voltage (0-10V). The circuit diagram of the gauging fixture is stated in (Fig.3) and its real construction in (Fig.4).

Measuring of defibrillation discharges

For measuring of defibrillation discharges it is necessary to connect individual elements according to the circuit diagram (Fig.2). A telemetric programming head is attached to ICD. Consequently the electrodes are connected to individual ports of the pulse generator. Input connector of the fixture with conductors and testing hooks designated on the gauging fixture "defib" are connected to the electrode on coils (RV, RA Coils). Connect a test tip with the hook (black) to RV Coil. Connect a test tip with the hook (red) to RA Coil. Connect the output connector of the gauging fixture designated as "Card" to the oscilloscope then. Resulting interconnection is showed in (Fig.5). Further, it is suitable to execute an automatic identification and interrogation of ICD by Quick Start button. PRM identifies ICD automatically, it starts a correct application and automatically tests data transfer.

It is necessary to set ICD on these parameters by means of the programmer SW environment:

- Tachy-Mode: "Monitor + Therapy".
- SETTINGS – VENTRICULAR TACHY THERAPY SETUP : RV Coil to RA Coil
- Lead Polarity: Initial.
- After setting the parameters, it is possible to invoke a discharge: TESTS – EP TESTS - COMMANDED SHOCK - tick off.
- Coupling interval and energy in the range of (0.1-41J)
- Enable
- Deliver
- Defibrillation discharge waveform is consequently recorded on the oscilloscope

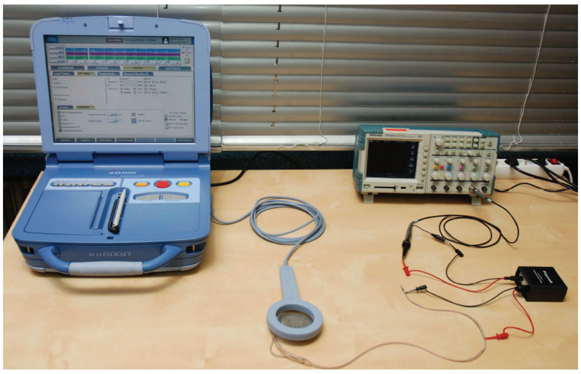

Fig.5. Measurement photo documentation

Measuring of discharge electrode impedance

Impedance of the discharge electrode is an important measurable parameter that states the input impedance of textures from the point of view of the defibrillator terminals. Generally, this figure is important for correct location of the electrodes in the heart. It is measured for verification of the correct electric connection of electrodes connectors to the appliance and further for avoidance of incorrect location of stimulating electrodes in the regioni cordis. Impedance of the discharge electrode is an indicator of cardiostimulating parameters stability and also it is an important indicator of the electrodes failure states (high impedance might signify an electrode conductor breakage, low impedance might be an evidence of an electrode insulation damage). Defibrillation discharge poles have the impedance value in tens of Ohms (30-90 Ohms). The impedance measurement of the discharge electrode does not require a change of measuring chain connection.

The real value of impedance was measured by means of ESCORT 3146A multimeter. It deals basically with the input resistance of the gauging fixture. The appliance measured the value of 59R. PRM programmer measured the value of 66R.

Measurement Results

Defibrillation discharges were set and measured in the range of (0.1-41J) step by step. During discharges measurement the data were recorded dealing with individual amplitudes level values and with individual pulses width values (see Fig. 6).

Enumeration of Defibrillation Discharge Real Value

For purposes of the defibrillation biphasic discharge measurement it was necessary to decrease its voltage level on the values measurable by an ordinary oscilloscope.

Real value of the defibrillation discharge voltage amplitude ranges in hundreds of Volts. Accordingly during the highest discharge of 41J it amounts to 706.8V. The measured waveform of defibrillation discharge voltage in time is displayed in Fig. 8.

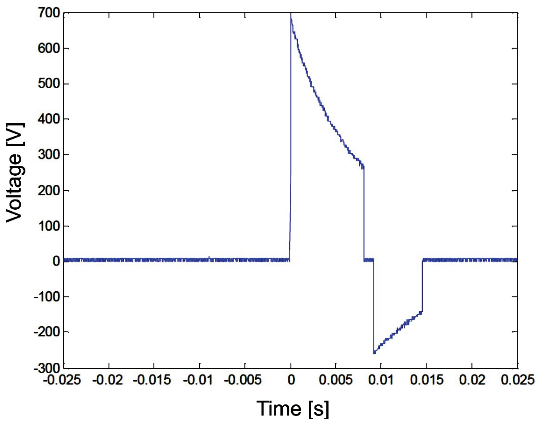

Fig.6. Defibrillation discharge at 41J processed in MATLAB

Considering the way of gauging fixture connection by means of the voltage divider, the input voltage amplitude value can be calculated by multiplication of the measured amplitude value from Table 2 by the dividing ratio D. The voltage divider dividing ratio is designated according to the formula (1).

$$D = \frac{U_{in}}{U_{out}} \quad (1)$$

where: U_{in} – measured voltage on the gauging fixture input, U_{out} – measured voltage on the gauging fixture output.

The dividing ratio must be designated from the immediate voltage values after the input voltage Uin connection because the gauging fixture is getting warmer quickly and the dividing ratio changes depending on it. Obtained results of the real discharge amplitude value are stated in Table 1.

It results from the obtained data that the highest value of A1 amplitude for the discharge energy of 41J is 706.8V. On contrary, the lowest A1 value at the discharge energy of 0.1J reaches 33.48V. All the other levels of real amplitude can be read easily from Table 1. The parameters importance again comes from Fig. 6. For purposes of signal analysis, the measured data of defibrillation discharge from the oscilloscope were gradually transferred firstly from CSV format to Excel program and further they were imported to Matlab program. Figure 8 shows the result of imported data for the defibrillation discharge of 41J energy to Matlab program.

Table 1. Measured Amplitude of Bi Phased Discharge

Discharge energy [J]	A1 [V]	A2 [V]	A2 [V]	A2 [V]	Atotal, [V]
0,1	33,48	18,04	17,11	11,90	50,59
0,3	58,03	28,27	26,78	16,36	84,07
0,6	81,84	37,2	35,34	22,32	117,1
0,9	100,4	42,78	42,78	26,04	145,0
1,1	111,6	44,64	44,64	26,04	158,1
1,7	139,5	59,52	57,66	35,34	197,1
2	146,9	65,1	61,38	37,2	206,4
3	182,2	74,4	74,4	40,92	252,9
5	238,0	93,0	93,0	52,08	331,0
6	256,6	104,1	104,1	63,24	357,1
7	275,2	115,3	111,6	66,96	386,8
9	316,2	130,2	130,2	74,4	442,6
11	357,1	148,8	133,9	81,84	483,6
14	386,8	163,6	156,2	81,84	550,5
17	438,9	178,5	163,6	89,28	595,2
21	483,6	200,8	186,0	104,1	662,1
23	513,3	200,8	200,8	111,6	699,3
26	550,5	215,7	215,7	126,4	751,4
29	572,8	223,2	223,2	133,9	781,2
31	587,7	230,6	230,6	133,9	810,9
36	639,8	245,5	245,5	148,8	870,4
41	706,8	279	260,4	148,8	930,0

It ensues from the graph in Fig. 9 that in the course of too low energy of the defibrillation discharge (0.1J and 0.3J), RPM programmer delivered higher energy than the set one was, respectively approximately by 16.9% higher for 0.1J energy and by 4.47% higher for 0.3J energy.

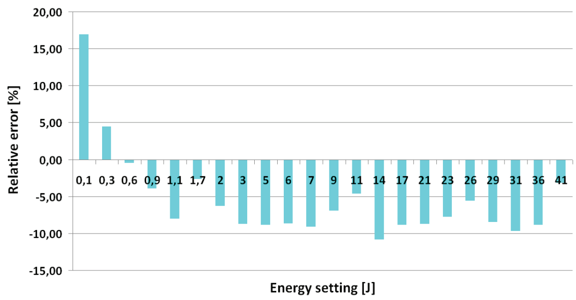

Fig.7. Abnormalities in energy supplied by defibrillator

For the other set energies of the discharges only losses were found out, respectively the set energy was higher than the delivered one.

A. Evaluation of measured amplitude, pulse width and discharge impedance

The obtained measured data of the individual amplitude values and defibrillation discharge correspond to requirements that were put on the gauging fixture. The lowest measured value was on the level of A4 amplitude in the course of discharge energy of 0.1J that is 0.128V. On contrary the highest measured value was on the level of A1 amplitude in the course of discharge energy of 41J that is 7.6V.

As regards the discharge impedance the difference between the real impedance value and the measured impedance value is 7.114 Ohms then. This difference might be caused by the electrode that might have low impedance.

Conclusion

Before the actual measurement proposal and realisation, the know-how of used implantable devices had to be analyzed especially as regards Cognis 100-D cardioverter-defibrillator.

The problem of defibrillation discharge measurement consisted in high voltage that had to be reduced for measuring purposes by appropriate digital equipment. At first a circuit with operation amplifiers was designed. This circuit did not meet with demands of the high voltage pulses. The requirement to measure and reduce this discharge to measurable values was met only with the circuit solved as a voltage divider. During work with these high voltage pulses, the circuit had to meet with both the demands of operators' safety and safety of the gauging fixtures connected to this circuit. It meant to add protective elements to the circuit for the case of failure.

The other step was a proposal of a measuring chain by which it would be possible to ensure quality measuring of the defibrillation discharges and from which it would be possible to evaluate the measured discharges. The measuring chain for defibrillation discharges measurement consisted of four main parts. That is RPM programmer, model 3120, the cardioverter-defibrillator (ICD), the gauging fixture for defibrillation discharges measurement and TEKTRONIX TPS 2024 oscilloscope.

The last step was the appropriate measuring of defibrillation discharges according to the measuring chain, a consequent analysis and evaluation of the obtained data. The results were evaluated and processed in MATLAB program. The gauging fixture meets requirements for defibrillation discharges measurement at Cognis 100-D cardioverter-defibrillator. In spite of that it is important to keep maximal safety especially while setting parameters for defibrillation discharge vector at RPM programmer and correct connection of the gauging fixture to a cardioverter-defibrillator (ICD) electrode. The gauging fixture output is standardised on voltage ±10V and by it for measuring of discharges' parameters it makes usage of measuring card for PC possible.

In future the used gauging fixture will be completed with A/D and D/A converters that make direct semi automated measuring and evaluation with usage of computer technology or with independently working built-in device possible.

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