Detection of AV Impulse Frequency and Verification of Pacemaker Battery Status

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***Abstract* — Pacemaker therapy has irreplaceable position in therapy of many cardiac diseases. The lifetime of implantable devices is several years and functionality depends on the battery condition. The verification of pacemaker battery is possible using portable pacemaker programmers manufactured for specific pacemakers. This option is costly for the general public. An alternative approach is to analyze the patient's electrocardiogram. This article deals with possibilities and methods of pacemaker battery state verifying using stimulation pulse width detection. Future plans include the construction of a small and embedded device, enabling general physicians and patients to obtain on-demand information about the battery status of the pacemaker.**

Keywords - electrocardiography; single chamber pacemaker; dual chamber pacemaker; pulse width; battery.

I. INTRODUCTION

Pacemakers play an important role in the treatment of cardiac diseases. This is especially true in cases where medication is no longer sufficient and patients require a pacemaker while waiting for a heart transplant. The other group of patients includes less severe heart-related problems which can be satisfactorily solved by implanted pacemakers and thus preserving patient vital functions. The lifetime of such devices is several years. Guaranteed operation is currently limited by the battery life of the device. When the battery capacity decreases, the device must be replaced. This end, manufacturer-specific portable pacemaker programmers must be used to verify battery properties. These are however expensive and usually available only to cardiologists or internal physicians performing invasive cardiology. An alternative approach is to evaluate the state of the pacemaker battery by analyzing the patient electrocardiogram (ECG) recording. This article discusses the possibilities and means to verify the battery status of implantable stimulation devices and it proposes future plans for the construction of a small and embedded device, enabling general physicians and patients to obtain on-demand information about the battery status of the pacemaker [1][2][3][4].

Section 2 deals with lifetime of the power source according to norm EN 45502-2-2:2008. Section 3 describes a system for measurement and analysis of simulated ECG signal. This section describes the steps of algorithm for distance detection between the AV impulses that stimulate the atria and ventricles. In Section 4, we test the proposed algorithm. Testing is realized on simulated data with different kinds of noises and on real patient data. After AV impulse detection, the algorithm evaluates battery state. Section 5 deals with conclusion and future work.

II. PACEMAKER BATTERY STATES

According to standard EN 45502-2-2:2008, active implantable medical devices must include means to warn in advance of low battery state. The warning interval (during normal use of the device) must be comparable to regular patient checks at the ambulance. The conditions of replacement are model and manufacturer specific. In Figure 1, the following device lifetime phases are defined based on the residual battery capacity of implantable medical devices:

- Beginning of life (BOL) - implantable device is first approved by the manufacturer and certified for marketing,
- Elective replacement time (ERT) - the power supply reaches a pre-determined threshold capacity of the manufacturer, in which case the device replacement is recommended. This indicates the beginning stages of prolonged service period,
- Prolonged service period (PSP) - time period for the recommended replacement, during which the device continues to operate as specified by the manufacturer,
- End of life (EOL) - expiration of the extended service life, which is the end of the original manufacturer's specified functionality of the device, power saving mode until complete failure.

More frequent patient monitoring is recommended after crossing the elective replacement near (ERN) threshold [1][9].

 ISBN: 978-1-61208-335-3

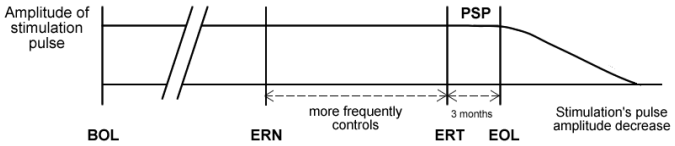

Figure 1. Lifetime of the power source.

The mentioned norm does not define dependence of the device lifetime phases on frequency or on magnitude, but most of the manufacturers especially indicate the dependence on frequency (see Table I). The frequency is measured in asynchronous mode which is activeted by permanent magnet with induction of more than 1 mT [1][9].

TABLE I. THE PACING PULSE FREQUENCIES IN ASYNRONOUS MODE FOR BOL AND ERT STAGES

Manufacturer	BOL [1/min]	ERT [1/min]
Biotronik	90	80
Boston Scientific	100	85
ELA	96	80
Medtronic	85	65
MEDICO	100	70
St. Jude Medical	98.6	86.3
Vitatron	100	86

A. *Low battery*

Figure 2 shows that the battery status of a single chamber pacemaker is determined by measuring the frequency (f = 1/T, f – frequency, T – period) and pacing pulse width (label - d) in asynchronous mode. In general the pacing pulse width can be from 0.05 ms to 2 ms [1].

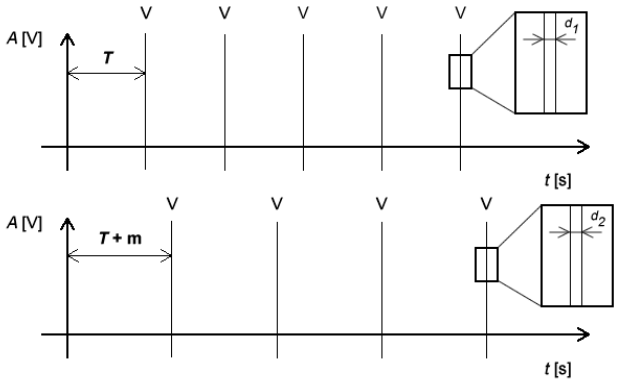

Figure 2. The frequency of single chamber pacemaker stimulation in asynchronous mode: a) the proper function, b) low battery condition.

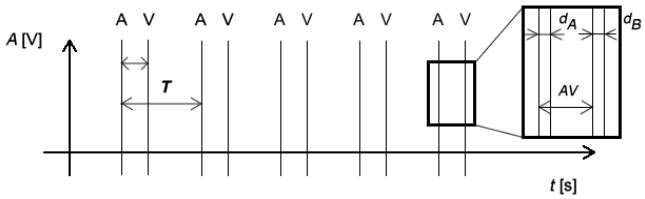

Figure 3. The stimulation frequency in asynchronous mode during correct functioning of a dual chamber pacemaker.

Figure 3 shows that dual chamber pacemakers can also determine the distance between the AV impulses that stimulate the atria and ventricles [1].

III. CONSTRUCTION OF SYSTEM FOR SENSING AND EVALUATION OF THE BATTERY STATUS

To evaluate the pacemaker battery, we must first use a permanent magnet to switch the pacemaker into asynchronous mode and then record the ECG signal. To capture the signal, we used the MP36 unit manufactured by Biopac which we connected to the patient simulator FLUKE MPS450. In Figure 4 we can see the mentioned test system.

Using the simulator, we tested asynchronous mode of single chamber (Figure 5) as well as of dual chamber (Figure 6) pacemaker. The pacemaker in the mentioned mode generates periodic pacing pulses regardless of the actual heart electrical activity. The recorded signal enables us to obtain information about the frequency and pulse width of the stimulus, or the duration of AV delay in dual chamber pacemaker. Based on the measured parameters, it is possible to evaluate the condition of the battery. Stimulation frequency decreases in time and the pacing pulse widens. The proposed algorithm is designed only for these conditions (frequency, pulse width and AV delay) and it does not give a solution for the dependence of the device lifetime phases on magnitude. The future work will be focused on the solution for this problem.

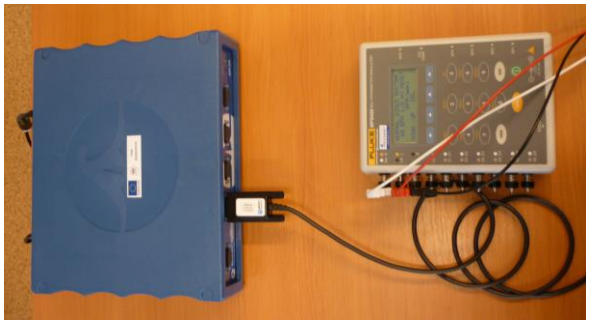

Figure 4. The Test system (measuring unit and MP36 patient simulator MPS450).

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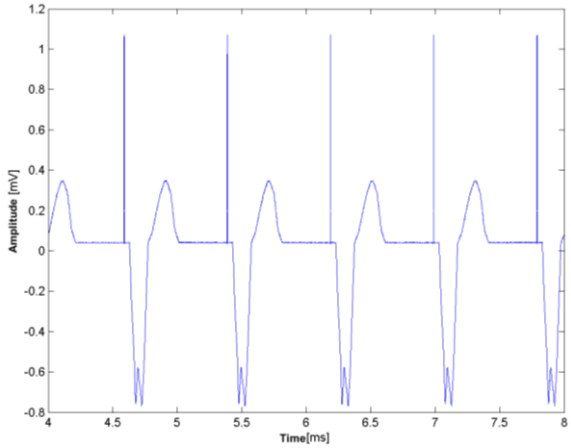

Figure 5. The simulated ECG signal of a patient with a single chamber pacemaker in asynchronous mode.

The design and implementation of the algorithm was carried out in MATLAB. The algorithm development was divided into several steps, each addressing possible drawbacks so as to achieve the desired accuracy and speed of the proposed algorithm. The first step consisted in the analysis and evaluation of the original recording without any modification. The algorithm takes into account only samples above the pre-selected threshold (red line, Figure 7). By comparing the distance between successive samples and known pacing pulse width (information obtained from the simulator), pacing pulses were detected and the required parameters were calculated.

However, detection was not accurate because the signal contained undesired artifacts. To eliminate these artifacts, different filter types were applied (differential filter, averaging filter, band-stop filter) [5][8]. However, after their application, the processed signal lost the information necessary to determine the pulse width (after applying the differential filter) and the evaluation time significantly increased (due to the averaging filter). In the end, we decided to use simple mathematical operations, as one of the main criteria was to design a fast and simple algorithm to enable use thereof in a microcontroller.

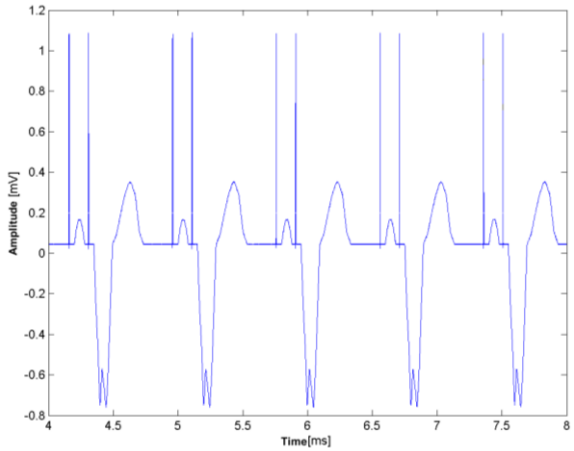

Figure 6. The simulated ECG signal of a patient with a dual chamber pacemaker in asynchronous mode.

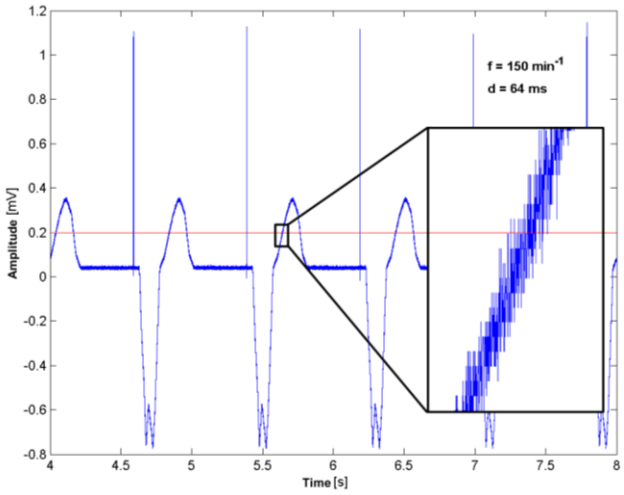

Figure 7. Noisy simulated ECG of a patient with a single chamber pacemaker in asynchronous mode and detail of noisy signal at the boundary (f - frequency of 75 min^{-1}, d - 2 ms pulse width).

Each recorded sample was amplified by its square in order to "smooth out" the recording (amplify the stimulation pulses). Boundaries for pacing pulse detection were first determined intuitively (empirically). At later stages the algorithm has then been modified so as to determine these boundaries based on individual recordings. Subsequent analysis of samples exceeding the threshold value enabled the evaluation of the pulse width, frequency and, in case of dual chamber pacemaker, the duration of the AV delay.

Figure 7 shows that the search for local maxima was performed in order to confirm the correct identification of stimulation pulses and to discard possible noise-related artifacts [6][7].

IV. TESTING OF THE PROPOSED ALGORITHM

The proposed algorithm has been tested on several simulated signals. Individual signals were degraded by different types of artifacts (AC 50 or 60 Hz noise and various breathing motion artifacts). The following section details the individual signals along with the detection and indication of stimulation pulses. Figure 8 shows a sample signal heavily degraded by noise from muscle activity and Figure 9 shows the same signal after processing. In Figure 10, it is shown the detected pacing pulses of a dual chamber pacemaker.

 ISBN: 978-1-61208-335-3

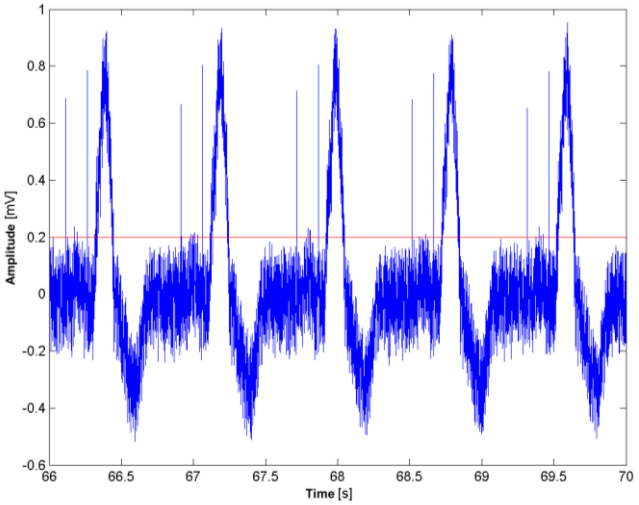

Figure 8. The captured signal containg noise from muscle activity.

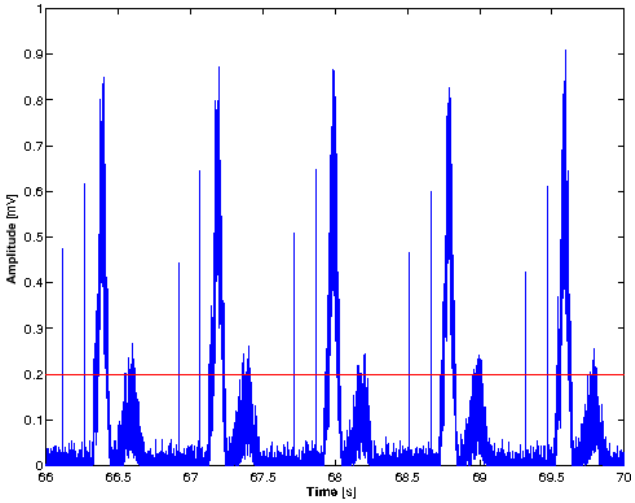

Figure 9. Signal after amplification.

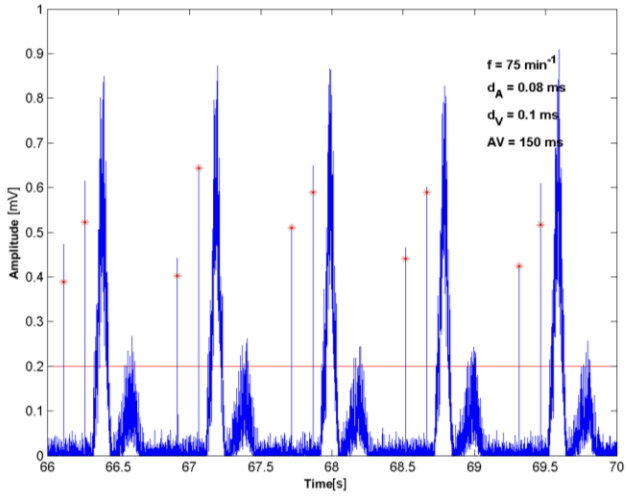

Figure 10. Detection of stimulus pulses (red points).

The developed algorithm was tested with multiple one hour long recordings and the reliability of pacing pulse detection was above 98%. We also tested real-life patient recordings obtained from the Faculty hospital in Zilina. The recording was measured from the first "standard" bipolar limb lead. The patient pacemakers were manufactured by Medtronic. The algorithm efficiency was once again confirmed and the results were discussed with a cardiologist (Dr. Jan Lehotsky) and compared with those obtained from portable pacemaker programmers manufactured by Medtronic. In Figure 11, it is shown the final evaluations of battery status obtained from real patient data. Figure 11a represents the single chamber pacemaker and Figure 11b the dual chamber pacemaker.

V. CONCLUSION AND FUTURE WORK

The algorithm has been tested on real life data from patients with implanted pacemakers (Faculty Hospital Zilina) as well as on simulated recordings containing different types of artifacts (50 Hz, 60 Hz, breathing activity, muscular activity and random noise) and the success rate was above 98%. Current development is focused on hardware design of a small and portable ECG logger to measure and consequently evaluate the status of the battery pacemaker.

The mentioned algorithm is designed only for detection of frequency, pulse width and AV delay and it does not solve the dependence of the device lifetime phases on magnitude. The future work will be therefore focused on solution of this question.

ACKNOWLEDGMENT

This paper is supported by the following project: University Science Park of the University of Zilina (ITMS: 26220220184) supported by the Research & Development Operational Program funded by the European Regional Development Fund.

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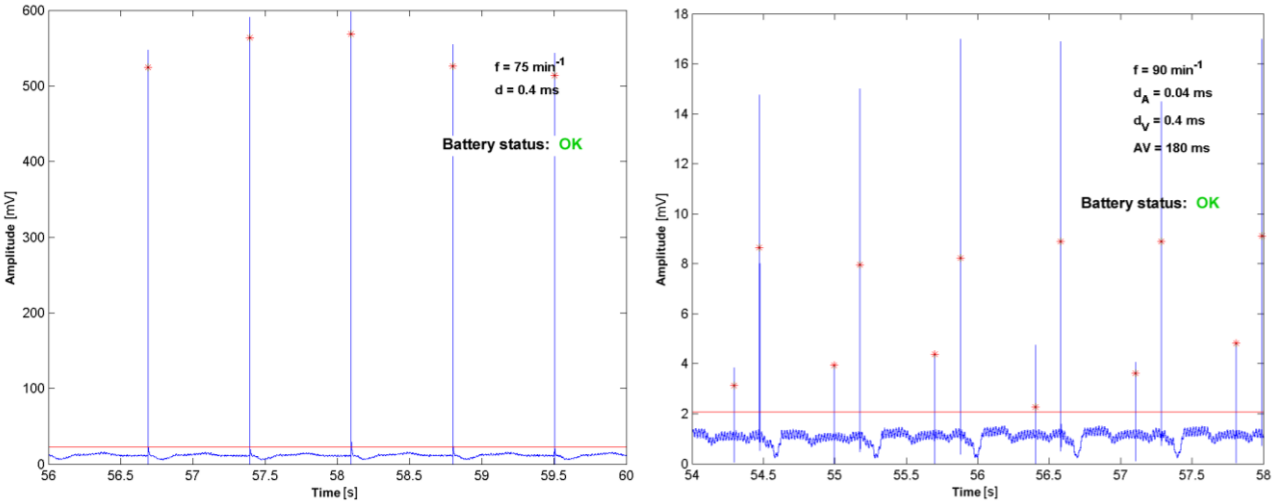

Figure 11. Data analysis of patient with: a) single chamber pacemaker, b) dual chamber pacemaker.