detector of the QRS complexes,
field programmable analog arrays (FPAA),
artificial heart (ventricular assist device - VAD)

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QRS COMPLEXES DETECTOR FOR SYNCHRONIZATION OF VENTRICULAR ASSIST DEVICE

Synchronization of operation of an artificial chamber supporting the sick heart of a patient has a crucial meaning for the effectiveness of support. To make the synchronized operation possible, the information on patient's heart activity should be fed to a controller of the supporting chamber. To this end, the QRS complex detector operating on ECG signal is necessary. The signal must be acquired from a patient's heart. Appropriate signal quality at long-term support may be assured only in a case the signal is acquired with epicardial electrodes. In the paper, the concept of hardware construction of a QRS complex detector has been presented, based on a field programmable analog array FPAA. The results of verification of the developed detector include the correct operation while using the epicardial signals recorded from patients which undergone the cardiosurgical operations.

1. INTRODUCTION

Extensive research on an artificial chamber intended to assist natural heart operation have been continued for many years by The Foundation of Cardiac Surgery Development in memoriam of prof. Zbigniew Religa. At the current stage of the efforts covered by the National Program for the Polish Artificial Heart several innovative measurement methods have been proposed with the aim to improve operational efficiency of the artificial chamber. The important information that is crucial to control the operation of an external assisting chamber is the knowledge about the exact moment in time when the natural ventricle of the patient's heart shrinks. This is the information which enables the synchronization between the external assisting chamber and the natural patient's heart. When the operation of the heart and the assisting chamber becomes asynchronous, the ejection stream from the assisting chamber may prevent the aortic valve from opening in accordance with the natural cycle. It is obvious that pressure waveforms for the peripheral circulatory system are closer to physiological ones and efficiency of the aid is much better when ejections from the natural heart are closely followed by ejections from the assisting chamber.

Contractions of heart ventricles are reflected by the QRS waves in the electrocardiograms [10]. Therefore, the detection of the QRS complex is sufficient to achieve the synchronization between the assisting chamber and the natural heart. On the other hand, the detection of the QRS complex is associated with some technical aspects, including the method employed to measure the electrocardiographic signal. The practice of ambulatory examinations serves as a proof that the quality of the ECG signal recorded with use of external ECG electrodes is far insufficient. Every move of the patient's body and respiratory artefacts may lead to erroneous detections or even missing of the ECG signals, which results in incorrect control of the assisting chamber. As the patients need to support their circulatory system during prolonged periods from several days up to few years, the solution with external electrodes would be troublesome and associated with the risk of repeated breaks in the ECG signal reception.

The problem may be remedied when the electrocardiographic signal is obtained from epicardial electrodes permanently fixed to the pericardial sac. The signal acquired in this way is free from the predominant portion of high amplitude and steep ramp interferences. It guarantees steady conditions for operation of the detector of QRS complexes.

Among various technical aspects which must be resolved upon design of the detector of QRS complexes there is the detection delay. Due to the delay which is contributed by the entire path that

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controls ejections of the assisting chamber the delay of the detector pulse with regard to the QRS complex must be as low as possible. For the needs of this development it was assumed that the detector pulse should never appear later than 20 ms after the *R* wave. It is the requirement which practically eliminates software detectors where the delay time is usually as high as hundreds of milliseconds due to the applied algorithms based on digital filtering [7]. Another assumption was the insensitivity of the detector to pulses generated by already implanted pacemakers.

The hardware detectors have also some drawbacks as they usually represent large and sophisticated circuits which, in turn, entail substantial dimensions of the appliances. Due to the requirement that the measuring part along with the QRS detector should fit inside the assisting chamber it was necessary to miniaturize the dimensions of the hardware structure as much as possible.

2. HARDWARE DETECTOR OF QRS COMPLEXES

2.1. FPAA CIRCUITS

In order to make the dimensions of the detector of QRS complexes as small as possible the Field Programmable Analog Array (FPAA) offered by Anadigm was applied [1]. Internal structure of the FPAA modules is based on circuits with switched capacitances (SC) [9]. Detailed information on design features and performance of FPAA modules can be found in data sheets of their manufacturer [1]. FPAA modules need to have their configuration downloaded after power voltage is switched on where the configuration is written via the SPI serial interface. The configuration process can be carried out with use of a microcontroller which initiates the transmission of the appropriate configuration data stream to the FPAA after power on. Use of a microcontroller makes it also possible to dynamically reconfigure the module during its operation. Partial dynamic reconfiguration means that a part of the module is subject to alterations whilst the remaining part is still running. It is worth emphasizing that the dynamic reconfiguration of the FPAA structure keeps the currently reconfigured module safe from any downtimes. More detailed description of the mechanisms applicable to dynamic reconfiguration of FPAA modules is included in [8]. Two types of FPAA modules are offered where either static or dynamic reconfiguration is possible. For static reconfiguration it is necessary to stop operation of the entire module and it remains halted until the reconfiguration of the entire structure is completed, whilst dynamic reconfiguration amends a part of the module resources on-the-fly.

Unfortunately, Field Programmable Analog Arrays (FPAA) are incapable to provide very large resources and top performances. Operational parameters offered by the modules make them unsuitable for measurement applications where high accuracy is required, chiefly due to the substantial level of offset voltage that appears at their outputs. It is the disadvantage that directly results from their operation principle, i.e. application of circuits with switched capacitances.

During the design process an analog circuit is compiled of library components referred to as Configurable Analog Modules (CAMs) provided by the manufacturer. The compiling process is executed in the AnalogDesigner2 software environment [2]. CAM modules are considered as elementary analog cells (e.g. inversing or non-inversing amplifiers, circuits of the second order active filters, active rectifiers, peak detectors, etc.). Each CAM has its own set of available functions which make it possible to define the configuration of the module when its parameters are altered (e.g. change of the filter cut-off frequency). These functions can be implemented in the software that runs on the microcontroller provided to collaborate with the FPAA module and then used to redefine a partial configuration of the module if the mechanism for partial dynamic reconfiguration is available.

The FPAA modules offer two reconfiguration approaches: the state-driven method and the algorithm method. More detailed information on methods for dynamic reconfiguration is omitted in this paper as it can be found in data sheets provided by the manufacturer [1, 2] as well as in [8].

Designers may select between chips with the power voltage of 5 V (the Anadigmvortex family) or 3.3V (the Anadigmapex family). The low-voltage modules are of the more recent generation and offer better performance [1]. Practical verification of performance and operation parameters demonstrated by FPAA modules of the earlier design with 5 V of power voltage can be found in [6]. Power voltage to

FPAA modules is delivered in asymmetrical manner although all inputs and outputs are of the differential type and need to supply initial offset voltage to the inputs. This offset is 1.5 V for modules with the power voltage of 3.3 V. Such implementation of the module inputs and outputs presents a substantial constraint to the variation ranges and ramps of both input and output signals. Practical tests demonstrated that the modules behavior was satisfying only for input voltages above 50 mV. For lower input voltages the own noise of the module adds on too much interference to the input signals and disables correct processing thereof.

In spite of numerous drawbacks and incompletely satisfying performance, the FPAA modules are perfectly suitable to design a detector of QRS complexes as they enable to incorporate nearly the entire module into a single integrated circuit with really tiny overall dimensions. The FPAA module that was used for this application is available in the QFN package with overall dimensions 7x7 mm [1].

2.2. DESIGN OF THE QRS DETECTOR

The concept that a detector of QRS complexes can be build with the use of field programmable analog arrays is not a new idea. The related information can be found in [7]. Operation principle of most hardware detectors of QRS complexes is based on the detection of peak signals with further comparison of the signal from the detector output against the input waveforms. More details on the operation of such a detector are disclosed in the already mentioned reference paper [7]. Similarly, operation of the detector presented in this study is also based on the same principle of peak detection, although some design details make it different from the reference solutions described in former papers. The detector design benefits from long-term experience gained on development and perfecting detectors of QRS complexes and embedded into MIP-801 pacemakers manufactured by ITAM [5].

The block diagram of the newly developed detector is shown in Fig. 1. The drawing (dotted line) shows components that were implemented within the structures of the FPAA module. Some external parts were also attached aside the programmable array.

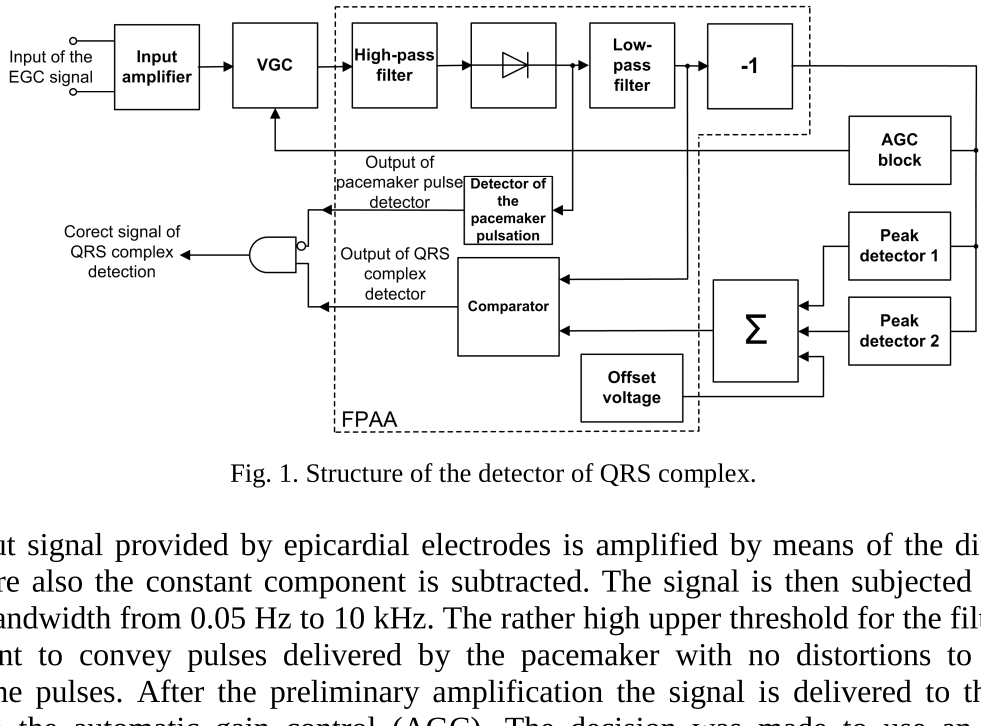

Fig. 1. Structure of the detector of QRS complex.

The input signal provided by epicardial electrodes is amplified by means of the differential input amplifier where also the constant component is subtracted. The signal is then subjected to a band-pass filter for the bandwidth from 0.05 Hz to 10 kHz. The rather high upper threshold for the filter results from the requirement to convey pulses delivered by the pacemaker with no distortions to enable further detection of the pulses. After the preliminary amplification the signal is delivered to the input of the amplifier with the automatic gain control (AGC). The decision was made to use an external AGC amplifier although it was also possible to implement such a subassembly within the FPAA structures and possible diagrams to design an amplifier with the automatic gain control are also included in the application note provided by manufacturers of FPAA modules [3]. The choice for the presented solution results from limited dynamic features of the signal that is delivered to the input of the FPAA module. The minimum amplitude of the input signal (when the differential input of the amplifier is used as a single input) that guarantees correct operation of he FPAA module is 50 mV, whilst the maximum input is 1.375

V [1], which makes it possible to achieve the input dynamics at the theoretical level of 28.8 dB. No literature references were found for electrocardiographic solutions that use input signals delivered directly from the patient's heart so the related knowledge in that field was acquired from post-surgery clinical examinations. On the basis of collected results it could be then assumed that the detector should guarantee reliable and undisturbed operation for variations of the input signal from 1 to 30 mV. For such requirements the dynamics of the input signal should be as high as 30 dB and is unachievable when the amplifier with the automatic gain control is implemented exclusively with use of internal structures within FPAA modules. However, under the assumption that the input signal typical for external ECG electrodes varies from 0.5 to 5 mV (20 dB) it is possible to design an AGC module that bases exclusively on performances and internal structures of the FPAA module, where typical solutions are described in the relevant application notes [3]. The designed detector of QRS complexes offers operation with the input signal at the level of 34 dB (for the ECG signal) which exceeds a lot, with sufficient overhead, the design requirements.

Internal resources of the FPAA module were used to implement an additional high-pass filter, an active full-wave rectifier as well as a low-pass filter. In addition, the detector for the pacemaker pulses was also implemented within the FPAA structures. Principle of operation of the detector is quite typical, and is based on a differentiator circuit and a comparator. After the low-pass filtering, the signal is used by the automatic gain controller, which is designed on the basis of an amplifier with the voltage gain control (VGC). Peak detectors were provided as separate modules, external to the FPAA circuit. Two peak detectors were applied, with different time constants for charging and discharging the detectors. This made it possible to achieve error-free detection for the wider range of the heart pulse variations as well for pathological shapes of waves on the ECG curves. The peak detectors were implemented as external circuits chiefly due to limited resources of the FPAA module, but another advantage of the adopted solution was the possibility to avoid unsteady operation of the detectors observed when the attempts to implement them within the FPAA structures were undertaken.

Subsequently, signals from outputs of peak detectors are combined and added on with a slight constant offset voltage with the value that is associated with the detection threshold. The exact value of that constant voltage is adjusted during calibration of the QRS detector. This is why the mechanism of dynamic reconfiguration of the circuit was implemented in the proposed solution. Dynamic reconfiguration allows to avoid mechanical controls, e.g. potentiometers. Comparison of the input signal against the reference level, i.e. the sum of peak detector outputs and the offset voltage, is also implemented within the FPAA structures. The detector described here provides two detection signals: the signal for detection of the pacemaker pulsation as well as the signal for detection of the QRS complex which can also comprise additional 'intruded' pulses that result from detection of the stimulator pulsation. The both output signals enable digital calculation of the output waveform that unambiguously corresponds to the QRS complex and reproduces it practically with no delay (Fig. 1).

For the presented solution the analog programmable array collaborates with the MSP430 microcontroller from Texas Instruments [4]. The microcontroller is responsible for initial configuration of the programmable device as well as its further reconfiguration as needed. Although the functions that are used to determine partial reconfiguration streams base on floating point arithmetic, the applied microcontroller performs quite well as the reconfiguration procedures are carried out not very often and computation time consumed by these function is not critical for the operation of the detector device. If the dynamic reconfiguration were used to other purposes, e.g. to incorporate the amplifier with the automatic gain control into the FPAA module, it would be associated with the need to use a more powerful microcontroller, because the reconfiguration stream for the input amplifier (to change its gain) would have to be determined during every period of the input signal [3].

3. VERIFICATION OF THE DETECTOR PERFORMANCE

The initial verification of the newly designed detector of QRS complexes was carried out on the basis of test waveforms as defined by the PN-EN 60601-2-27 standard [11]. The test waveform is intended to verify the operability of the detector of QRS complexes when the stimulator pulsation is 'intruded' into the input signal. The test signal amplitude is selected in such a way that a pulse from the stimulator should lead to saturation of the measuring path whilst the amplitude of the usable ECG signal should vary within the presumed range of input amplitudes. The obtained detection results are shown in Fig. 2.

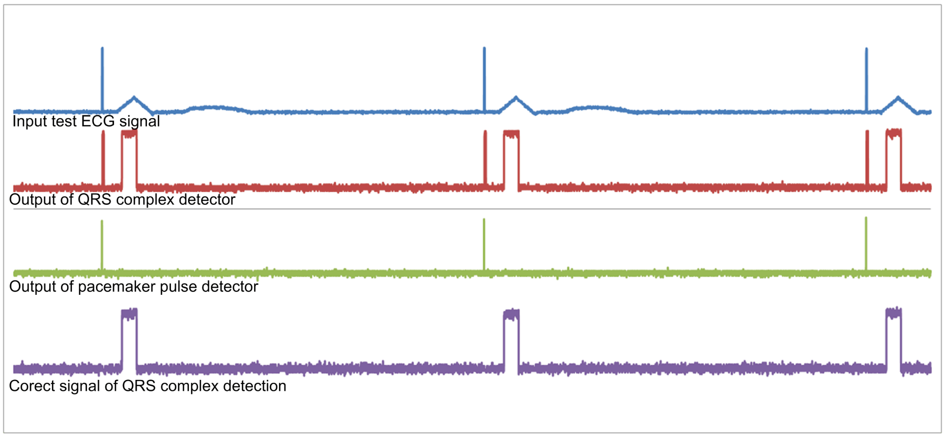

Fig. 2. The detection signal after delivery of an artificial ECG waveform meeting requirements of the PN-EN 60601-2-27 standard to the detector input.

When the detector was examined by means of test waveforms, no erroneous detections were recorded over the entire range of the input signal variation. The detector worked correctly for the range of heart rates (HR) from 30 to 180 bpm, which was absolutely in line with the design assumptions.

The final verification of the detector operability was carried out with the use of eleven signals recorded from epicardial electrodes implanted in patients after cardiac surgeries. The records were made from epicardial electrodes which were left as a safeguarding measure for the need of short-term heart stimulation. Electrodes of that type are usually implanted in patients after cardiac surgery operations. The recorded timings were stored as a set of samples with the sampling period of 1 ms and resolution of 2.36 μV/LSB. Then the recorded timings were restored and supplied to the input of the newly designed detector.

The tests confirmed the correct operation of the detector under conditions when the heart rate or amplitude of the input signal was changed. No erroneous detections were recorded in terms of either omissions or undesired detection of non-existing waves.

Fig. 3 presents the detection of a premature ventricular contraction. Correct detection of such a contraction was confirmed.

However, if a premature contraction occurs right after the QRS complex and has a relatively low amplitude it may happen to be omitted. However, when the contraction, even of low amplitude, is clearly delayed after the QRS complex, it is correctly detected (Fig. 4).

One peculiar effect was observed during experiments, namely the QRS complex immediately following the premature contraction was detected twice in the timing obtained directly from the detector output. This results from the fact that the peak detector is additionally charged and the sensitivity threshold of the detector is set to another level. In practice, the microcontroller which collaborates with the detector very easily resolves the problem of ‘doubled’ detection.

Fig. 3. Correct detection of a premature ventricular contraction.

Fig. 4. Missing detection of a premature contraction.

Fig. 5 presents the waveforms obtained when the circuit of measuring electrodes was disrupted or disconnected. In this case the device fails to work correctly after the input signal disappears. When the signal with undefined amplitude is delivered to the detector input the device responds with detection signals to edges of the input waveform. After the input signal is restored to its 'normal' waveform the detector needs some time to return to its regular operation (detection). This time interval results from the time constants of the RC circuits that are incorporated into the input amplifier with the automatic gain control mechanism and the detector itself. It is assumed that the use of epicardial electrodes practically eliminates any breaks in delivery of the ECG signal to the detector input.

Fig. 5. Response of the detector to disruption of the electrode circuit.

4. CONCLUSIONS

The paper presents a unique design of the detector of QRS complexes which works with the ECG signal delivered to the detector input directly from epicardial electrodes. Eventually, the detector shall be subjected to necessary miniaturization and used to synchronize the artificial chamber intended to assist heart beating during experiments with animals. The research works that are currently in progress are intended to extend the database of physical epicardial signals. Bigger database shall make it possible to tune up the detector more precisely and verify operation with satisfying reliability.

At the current stage of the developments one can state that all the presumed design parameters were successfully achieved. Applicability of Field Programmable Analog Arrays for the construction of a miniaturised detector of QRS complexes was also proved.

Further studies on the newly designed detector shall consist in verification of its immunity to electromagnetic disturbances. In particular, the experiments shall be focused on testing whether and to which degree the Field Programmable Analog Arrays (FPAA) are sensitive to electromagnetic and electrostatic disturbances and how the mechanism of dynamic reconfiguration can be used to increase the detector immunity to electromagnetic disturbances.

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