Configurable External Defibrillator Devoted to Education and Clinical Trials

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Abstract: External defibrillators are recognized effective to revert ventricular fibrillation and pulseless ventricular tachycardia. This paper presents a new settable defibrillator, designed to assess the effectiveness of the following defibrillation waveforms during clinical trials: monophasic damped sinusoidal (MDS); biphasic truncated exponential (BTE) and rectilinear biphasic waveform (RBW). The device flexibility allows the setting of the defibrillation waveforms most relevant parameters, namely energy and pulses duration. The device usage is also relevant in biomedical engineer and medical staff education and training programs.

1 INTRODUCTION

Cardiovascular diseases take a leading role in the morbidity and mortality of the Western countries populations. International experience shows that the use of an automated external defibrillator (AED), outside the hospitals, by non-medical personnel, significantly increases the probability of survival of the victims. However, only the existence of an efficient survival chain, makes AED an effective way to improve survival after cardiorespiratory arrest.

AED is a device capable of automatically identifying defibrillating heart rhythms, alerting to safety conditions, and complete the steps of the approved algorithm on cardiopulmonary resuscitation to produce electric discharges automatically or under the command of an external operator, according to predefined energy values. It also records the data from the electrocardiographic to support later auditing.

Patient's defibrillation is obtained by the delivery of a suitable electrical current through their myocardium, able to depolarize a critical myocardial mass and thereby re-establish a coordinated electrical activity that leads to an organized sinus rhythm and spontaneous circulation.

Several studies have demonstrated that biphasic waveform shocks are superior to monophasic shocks to revert cardiac arrest caused by ventricular fibrillation (Keener et all., 1999; Zhang et all., 2003). This arises from the fact that in biphasic waveforms the current flows in a predefined direction during a time period and thereafter reverses the current flow to the opposite direction for the remaining pulse duration. These type of pulses improve defibrillation efficiency by diminishing the defibrillation threshold value and the underling associated hazards.

Further studies (Zhang et all., 2003), performed in animal's, indicate that the benefits of biphasic waveform could be further enhanced by using of a triphasic waveform composed of three pulses with reversed polarities i.e. the polarity of the second pulse is opposite to that used on the first and third pulses.

Recent published studies (Mittal et all., 1999), patents (Dascoli et all., 2017) and commercial devices (Zoll, 2018) point to rectilinear biphasic waveform (RBW). Those devices deliver an approximately constant current during the first phase of a pulse, independent of the patient's transthoracic impedance (TTI). The optimal current for ventricular defibrillation appears to be 30 to 40 A (Tavakoli et all., 2017). In the pulse second phase the current

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decays according with a first order RC circuit transient, negative exponential pulse, being its polarity opposite regarding the first one.

This paper presents a novel programmable defibrillator device devoted to either clinical studies and educational purposes. The assessment of the therapeutic efficiency of different defibrillation waveforms is only possible by means of the pulses characteristics definition: waveform, amplitude, energy and individual pulses duration time periods.

The implemented device comprises a micro controlled electronic unit connected with a Labview application that performs the pulse configuration and the acquired ECG signals processing. The device allows the implementation of different defibrillation waveforms. The monophasic damped sinusoidal (MDS) is obtained from the Lown circuit being the biphasic truncated exponential (BTE) and the triphasic waveforms implemented using a H bridge. The current based defibrillation waveform includes a set of low value resistances that are electronically bypassed as the capacitor voltage drops, keeping the current value almost constant in the initial pulse phase. Moreover, the implemented defibrillator has an ECG signal acquisition unit, able to identify defibrillable heart rhythms. The acquired signal is later processed to synchronize the location of the defibrillation pulse with respect to the QRS complex.

The paper is organized as follows. Section 2, describes and analyses the waveforms typically used on defibrillators, the underlying theoretical concepts and the employed electronic circuits. Moreover, the results retrieved from each particular circuits are also presented. Section 3, presents the design and implementation issues of the defibrillator. Section 4 covers the implementation and tests on the novel defibrillator in the biomedical engineers courses education in the Institute Polytechnic of Coimbra (IPC). Finally, Section 5 presents the main conclusions and future work.

2 DEFIBRILLATION WAVEFORMS

The developed defibrillator is capable to generate different defibrillation pulses: MDS, BTE or RBW by selecting one of the implemented circuits, explained in detail in the following sections. The circuit analysis is added to explain the waveform generation process and its parameterization.

2.1 Origin and Evolution of the Defibrillators

Defibrillation was first demonstrated in 1899 by Prevost and Batelli. They discovered that small electric shocks could induce ventricular fibrillation in dogs, and that larger charges would reverse that condition. The defibrillator was invented in 1932 by Dr. William B. Kouwenhoven and its first use on a human was conducted in 1947 by Claude Beck (Akselrod et all., 2009; Tavakoli et all., 2017).

Until the early 1950s, defibrillation of the heart was possible only when the chest cavity was open during surgery. The technique used an alternating current (AC) delivered to the sides of the exposed heart by paddle electrodes. During his PhD work Gurvich discovered that direct current (DC) shocks were significantly more efficient and less damaging than AC in defibrillation.

In 1959 Bernard Lown began to investigate the use of monophasic DC shocks resultant from the discharge of capacitors over patients. The designed method assumes that a capacitor or a bank of capacitors is kept at a high voltage (Akselrod et all., 2009). The energy stored in the capacitors is then delivered to the patient's chest through an additional inductor, in order to produce a classical MDS waveform of finite duration. This approach follows previous work performed in human patients reported by both Gurvich and Peleska (Akselrod et all., 2009).

The Lown waveform was the standard for defibrillation until the late 1980s when research showed that a BTE waveform with both positive and negative pulses could provide equal or even better results requiring lower energy levels, thereby increasing patient safety and reducing burden on the power supply system and batteries (Akselrod et all., 2009, Tavakoli et all., 2017).

2.2 Lown Defibrillator

The Lown defibrillator is based on the RLC series circuit depicted in Fig. 1.

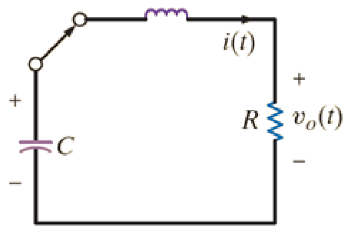

Figure 1: Lown defibrillator circuit. (Irwin, 2015).

The analysis of the circuit assumes that the capacitor was previously charged at a high voltage level, being then connected in series to an inductor and resistor at instant $t = 0$ s. The defibrillation pulse applied to the patient (resistor) is the solution of the second-order differential equation obtained by the application of KVL around the circuit loop.

$$\frac{d^2 i(t)}{dt^2} + \frac{R}{L} \cdot \frac{di(t)}{dt} + \frac{i(t)}{LC} = 0 \qquad (1)$$

The solution of (1) must be a function whose first and second derivatives have the same form as the original function in order to the left side of the equation becoming zero (Irwin, 2015). The solution $i(t) = K \cdot e^{st}$ is then replaced in (1) resulting in

$$K \cdot e^{st} \cdot \left(s^2 + \frac{R}{L} \cdot s + \frac{1}{LC} \right) = 0 \qquad (2)$$

Since $K \cdot e^{st}$ is the assumed solution, the expression in parentheses will have to be zero. That quadratic equation is known as the characteristic equation of the second-order differential equation (1), since the roots of that equation dictate the behaviour of $i(t)$. Using the quadratic formula, two roots of (2) can be found:

$$s_1 = -\alpha + \sqrt{\alpha^2 - \omega_0^2}; \quad s_2 = -\alpha - \sqrt{\alpha^2 - \omega_0^2} \qquad (3)$$

assuming that

$$\alpha = \frac{R}{2L} \text{ and } \omega_0 = \frac{1}{\sqrt{LC}} \qquad (4)$$

The roots s_1 and s_2 are associated with the natural response of the circuit; ω_0 is known as the undamped natural frequency, expressed in radians per second (rad/s); and α is the damping factor, expressed in nepers per second.

If $\alpha > \omega_0$ both roots s_1 and s_2 are negative and real (overdamped case) (Alexander, 2012). Thus, the current decays and approaches zero as t increases.

$$i(t) = \frac{V_C}{2 \cdot L \cdot \omega_d} \cdot \left[e^{-(\alpha - \omega_d) \cdot t} - e^{-(\alpha + \omega_d) \cdot t} \right] \qquad (5)$$

with $\omega_d = \sqrt{\alpha^2 - \omega_0^2}$.

If $\alpha < \omega_0$ the roots s_1 and s_2 are complex conjugate being the electric current given by (underdamped case) (Irwin, 2015; Alexander, 2012)

$$i(t) = \frac{V_C}{L \cdot \omega_d} \cdot e^{-\alpha t} \cdot \sin(\omega_d \cdot t) \qquad (6)$$

with $\omega_d = \sqrt{\omega_0^2 - \alpha^2}$. In (5) and (6) the constant factor was obtained from two initial conditions: the initial value of the current and its first derivative.

Fig. 2 presents the simulated MDS waveforms for patients with resistance values equal to 25 Ω; 50 Ω and 150 Ω. The results were obtained assuming the usage of a 47 µF capacitor and a 33 mH inductor and an initial voltage level in the capacitor, of 4.2 kV.

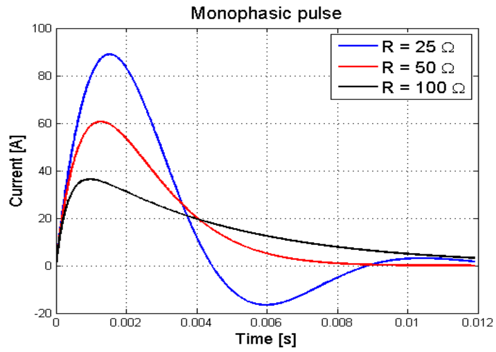

Figure 2: Lown waveform in function of the impedance.

Fig. 3 shows the MDS waveform acquired in the lab using the above components and a $R = 25$ Ω. In this case the system is underdamped with α = 378.78, ω_0 = 802.96 rad/s and ω_d = 708 rad/s.

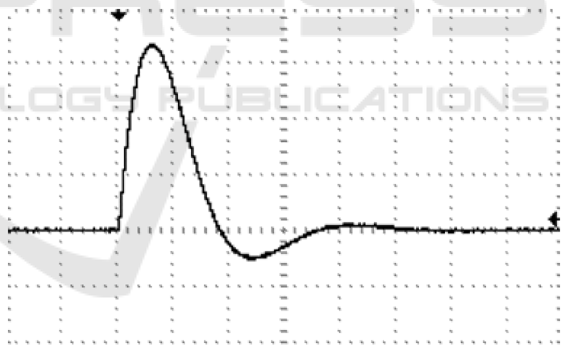

Figure 3: Lown waveform in function of the impedance.

In Fig. 3 the signal was acquired setting the TIME/DIV control of the oscilloscope to 1 ms/DIV.

2.3 BTE Defibrillators

In order to generate a BTE waveform defibrillation pulses a new circuit, represented in Fig. 4 is needed. It uses a high-voltage capacitor and a H bridge. The capacitor is charged with a high DC voltage value that meets the selected energy value to be applied. After charging the capacitor with the desired voltage value, the energy stored in it is then delivered to the patient as a defibrillation pulse. The H-bridge is used to control transfer of energy from the capacitor to the patient. It includes four electronic switches (placed on the H-bridge legs), that are used to define the polarity applied to the load (patient).

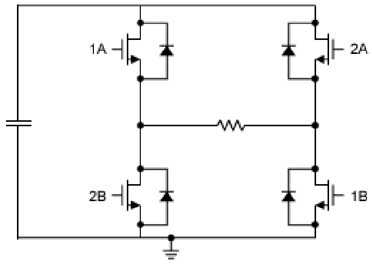

Figure 4: BTE waveform defibrillator circuit.

During the first phase of the waveform, the H bridge connects the capacitors' two terminals with the defibrillator paddles placed on the patient. At the end of the pulse first phase that connection is opened and the terminals of the capacitor are switched to connect in the reverse polarity to the mentioned paddles. It is advisable to have a small guard time interval between phases in order to avoid the simultaneous connection of the switch in the same side of the H-bridge (Sullivan, 1997).

The didactic version of the configurable external defibrillator device uses the TB6612FNG H bridge to control de discharge of the capacitor over the load (patient). This driver IC is devoted to perform the control of up two DC motors. The mentioned device requires three input signals, IN1, IN2 and STBY to select the four modes of operation corresponding to the normal operation CW, in one direction, and CCW; in the opposite direction; the high impedance mode and the short brake mode.

The mentioned control signals are obtained from a ATmega328P microcontroller according with the patient impedance value.

Table 1: BTE parameters for adults (Philips, 1997).

Load resistance (Ω)	Phase II duration (ms)	Phase II duration (ms)
25	2.8	2.8
50	4.5	4.5
75	6.25	5.0
100	8.0	5.3
125	9.64	6.4
150	11.5	7.7

Fig. 5 depicts the simulated BTE waveform delivered to patients with resistance values equal to 25 Ω; 50 Ω and 150 Ω. The presented results assume a 100 µF capacitor and an initial voltage of 1.8 kV. The pulse phases durations of the BTE waveform are presented in table I.

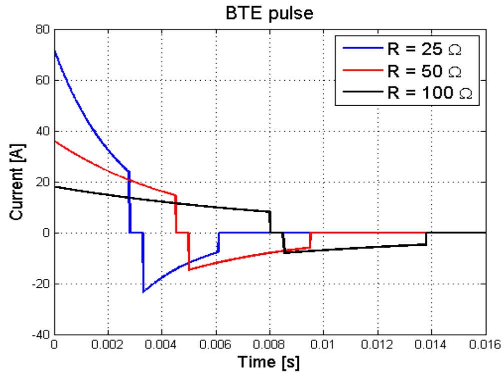

Figure 5: BTE waveform in function of the impedance.

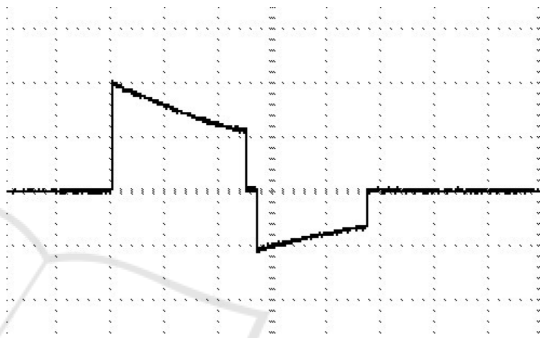

Figure 6: BTE waveform.

Fig. 6 shows the BTE waveform obtained in the laboratory, from the developed device using the following components C = 100 uF and R = 50 Ω and the H-bridge. The signal was acquired setting the TIME/DIV control of the oscilloscope to 1 ms/DIV.

2.4 Rectilinear Biphasic Waveform Defibrillators

The RBW implementation is based on the circuit used for the BTE waveforms. In order to achieve an approximately constant current during the first pulse, as the capacitor discharges across the patient chest, is needed to decrease the circuit impedance accordingly.

The underlying idea of a RBW defibrillator operation comprises the inclusion of several series-connected resistors, in the current path, in series with the patient impedance. Each one of those additional resistors is connected in parallel with a shorting switch controlled by a micro-controller providing an extremely low resistance path to the current (Fig. 7). The resistors should have different resistance values to tune the current with a high accuracy to a nearly constant value.

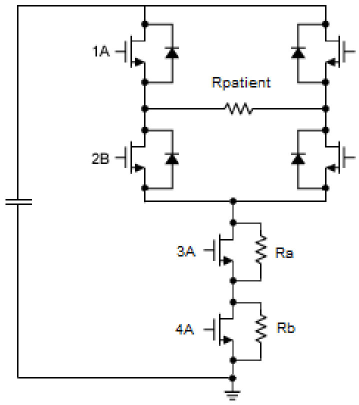

Figure 7: RBW defibrillator circuit.

When the H-bridge switches, of opposite legs, are closed, in the beginning of the pulse, all the resistor-shorting switches are open, to force the current to passes through each one of the mentioned added resistors.

As the voltage in the capacitor decays, with a time constant R·C, the additional resistors in series with the patient are successively shorted out. Each time that one of the resistors is bypassed, the current increases instantaneously, taking into account that the capacitor voltage remains the same, as the event happens. Thus, it can be observed significant ripple, in the positive phase of the RBW (Fig. 8), matching the repeated activation of the resistor-shorting switches. The ripple magnitude is larger at the end of the rectilinear phase because the time constant value is smaller at the end of the phase than at the beginning.

At the end of the positive phase all the H-bridge switches legs are open to ensure a safety guard time period before invert the direction of the current flow. The polarity of the waveform is reversed by closing the H-bridge switches that were open in first positive phase and vice versa.

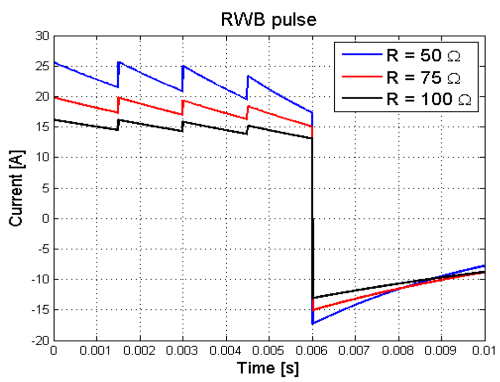

Figure 8: RBW waveform in function of the impedance.

Fig. 8 shows the RBW obtained by simulation. In the conducted simulations was assumed impedances equals to 50 Ω; 75 Ω and 100 Ω. Moreover, it was assumed the usage of a 100 µF capacitor, three 10 Ω additional resistor's and an initial voltage value of 2.3 kV.

The device that generates the RBW defibrillator is based on the TB6612FNG H bridge and on the earlier mentioned ATMEL microcontroller. However, additional control signals must be generated in order to manage each one of the bypass transistors. The signals are defined to turn on each transistor at particular time instants. The transistors sequence of operation is always the same and starts with the transistor connected to the ground and ends with the transistor connected with the H bridge.

3 DEFIBRILLATION DESIGN ISSUES

The implemented novel defibrillator, is expected to be comparable to the existent commercial devices including all its features, being also compliant with international standards. The prototype consists of a hardware part that implements the mentioned waveforms and performs the conditioning and acquisition of the patient's ECG signals and the TTI evaluation. The device includes a power supply unit, a micro-controller unit, and several electronic components. The power source can come either from a battery or from the main supply using an electronic rectifier.

As mentioned earlier the capacitor is the vital element of the defibrillator, it stores a large amount of energy in its electric field, then releases it on a patient's chest accordingly with the system configuration and TTI value. The capacitor charging circuit includes a series-resistor to limit the current value and two electronic sensors to measure, in real time basis, the absorbed /delivered current (Hall effect sensor) to/from the capacitor and the voltage value across its terminals.

A signal conditioning circuit was also implemented, depicted in Fig. 9, in order to perform the mentioned ECG signal acquisition. That circuit employs the low cost AD620 instrumentation amplifier and the LM358N operational amplifier, a band pass filter and right leg reference circuit.

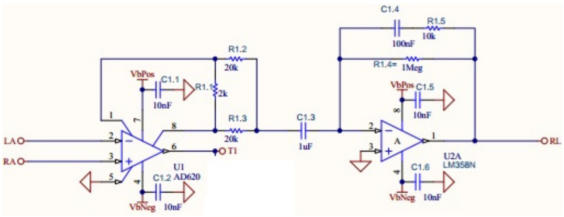

Figure 9: ECG signal conditioning circuit.

The amplified ECG signal is thereafter acquired by a National Instruments low-cost, multifunction DAQ. Fig. 10 presents the acquired ECG signal of a healthy patient, in the test bed, using the conditioning circuit of Fig 9.

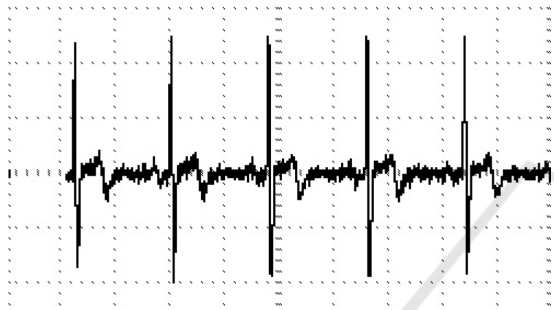

Figure 10: Acquired ECG signal from a patient.

The described circuits are controlled by a software component (LabView) which implements a state machine underlying the operation of the external defibrillator as well as all the signal processing operations.

The procedures related with the defibrillator capacitor are controlled by a state machine that ensure the correct: charging state; charge maintenance, discharge, safety discharge. The state machine also controls other events that take place in a logical order in order to avoid the occurrence of conditions that compromise the device and/or the user safety.

The following features were implemented in the software:

- Defibrillator state machine;
- Charging and discharging circuits monitoring;
- ECG signal acquisition, filtering, processing and representation;
- QRS complex identification;
- Patient impedance value assessment;
- H bridge and control timing signals generation;
- Data storage.

To avoid the hazard of ventricular fibrillation resultant from the application of the DC pulse, the discharge should be synchronized with the electrocardiogram. The defibrillation pulse must be applied during or immediately after the downward slope of the R wave (Zoll, 2018). The synchronization avoids the delivery of the shock during the T wave that corresponds to a partially refractory vulnerable period during which ventricular fibrillation could occur in the presence of an external electric stimulus.

4 LIFE SUPPORT SYSTEMS EDUCATION

The Coimbra Institute of Engineering (ISEC) is a Portuguese higher education Polytechnic school, integrated in the Coimbra Polytechnic Institute. Its formative offer includes, among others, the biomedical engineering and biomedical instrumentation, first and second cycles whose curricula have been designed accordingly to the Bologna process.

The presented external defibrillator was designed and implemented on the Life Support Systems (LSS) curricular unit of the second semester of the biomedical instrumentation master course. This unit is relevant taken into account that in Portugal, cardiovascular diseases are one of the most serious health problems of the population (Santos, 2019).

This curricular unit aims to provide skills and knowledge regarding the existent basic and advanced life support equipment. Furthermore, it is intended that students acquire fundamental knowledge, in the electrical engineering area regarding the design, implementation and maintenance of such equipment. Additionally, R&D activities are encouraged on students, which result on the proposal of new approaches and circuits in compliance with the international standards.

Students that successfully complete the unit should be able to understand RC and RLC transients in order to design Lown BTE and RBW defibrillators'; to understand, pacemakers' and AEDs devices' operation and functionalities. To understand the underling theory and sensor technology needed to obtain the vital signals monitoring and finally to understand the operation principles of the most common ventilators.

5 CONCLUSIONS

This paper describes a novel defibrillator capable to implement different defibrillation pulses, namely: the MDS, BTE and RBW waveforms, using different electrical and electronic components and circuits.

With respect to the Lown defibrillator is only possible to define the energy delivered to the patient. The generated MDS waveforms in the test bed, were validated using the results obtained from simulation of the RLC circuit under the same assumptions. The defibrillator settings allow BTE and RBW waveforms provision by means of the H bridge circuit usage. An external micro-controller is responsible for the pulses different phases timings accordingly with the measured patient impedance value. The retrieved laboratory results, from the defibrillator, were compared and validated with the ones obtained by the circuits simulation.

Additionally, more advanced features were also employed and implemented in order to evaluate the effectiveness of different defibrillation waveforms and parameters during clinical trials.

Moreover, the design, implementation and test of the developed configurable defibrillator in the LSS curricular unit has engaged students on R&D activities; promoted the academic success, the students' motivation facing a real practice problem and the improvement of students' skills teamwork, communication and leadership.

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