In-Vitro Investigation of Very Long Defibrillation Shocks: Design and Testing of a Capacitor-Free Defibrillator

M Triventi[1], E Mattei[1,3], A Delogu[1], F Censi[1], G Calcagnini[1], P Bartolini[1], F Aguel[2], J Stohlman[2], V Krauthamer[2]

[1]Italian Institute of Health, Rome, Italy
[2]Center for Device and Radiological Health, FDA, Silver Spring, MD, USA
[3]"La Sapienza" University of Rome, Rome, Italy

Abstract

The aim of this paper is to describe a defibrillator that allows the delivery of arbitrary waveform shocks, with energy up to 10J and duration up to 100ms. In addition, data from shocks delivered to isolated rabbit's hearts are presented. The solutions adopted in the design and realization of the defibrillator were: rechargeable battery power; linear AB class power amplifier output in bridge configuration; optical isolation of analog and digital lines to and from the PC and earth ground; measure of the actual voltage, current and energy delivered to the load. Laboratory testing showed that the defibrillator is capable to deliver shocks with a rising time less than 150 us, no tilting also for very long waveforms (100ms), peak current up to 10 A. The system was then used on rabbit hearts to define a protocol to investigate the effect of waveform duration on defibrillation threshold. We demonstrate the feasibility of an experimental defibrillator for the generation and delivery of true arbitrary waveforms.

1. Introduction

Research to understand and improve defibrillation waveforms has, so far, suffered from the intrinsic limitation of the capacitor discharge approach. The use of biphasic waveforms has allowed for the reduction of the defibrillation threshold and thus has gained popularity [1][2]. For practical reasons, most of the defibrillation studies are conducted using relatively short falling exponential voltage waveforms. Both monophasic and biphasic waveforms, when delivered by capacitor discharge have a load-dependent exponential decay which allows for few changes in the basic morphologies. The major advantage in the capacitor-discharge approach is that it relies in the high voltage / high current which are easily obtainable with such a design. In addition, data on the current and voltage characteristics during the shock are scarce. In-vitro research, however requires relatively lower energies and thus a greater flexibility in the defibrillator design. A research defibrillator capable of delivering arbitrary waveforms is useful to compare the performance of standard *vs* experimental waveforms [3], as well as to understand the basic mechanisms involved in the defibrillation. Researches to improve cardioverter-defibrillator waveforms and to investigate the mechanisms underlying electrical cardioversion / defibrillation are carried out in several laboratories [1][2][4-6], because reduction in the energy for successful defibrillation potentially leads to less damage to cardiac tissue, less discomfort for the patient and to smaller and cheaper devices. We present a new defibrillator design based on linear power amplifiers, which can generate arbitrary waveforms up to 10 J on loads up to 25 ohms.

2. Methods

In order to be used in in-vitro electrophysiological investigations we set the following design goals for the defibrillator: arbitrary waveforms floating output from DC to 100KHz, PC controlled, isolation from ground, output energy up to 10 J, and pulse duration from 6 to 100 msec, through a load of 10 ohm impedance. Given these parameters we designed the various components of the defibrillator. Figure 1 shows the main blocks, which are discussed in details below.

Power Supply

In order to obtain an isolated power supply we used a series of rechargeable sealed lead-acid batteries. A limitation of lead-acid batteries is the maximum rated battery power. We overcame this problem with the use of lead-acid batteries that can deliver high surge current over few seconds, and compensated for the voltage drop that occurs incorporating a robust voltage regulator. A drawback of relying on the surge current from the batteries is the significant voltage drop occurring. In 12V lead-acid batteries, this voltage drop can be as high as 2V for 10 A current. We thus designed a robust voltage regulator, connected to the output of a series of 8 12V batteries. Such an assembly produces a regulated output of 70V, with a peak current capacity of 10 A.

On the basis of empirical measures of surge currents and voltage drops, we found that batteries with a nominal capacity of 1.2 Ah provided an acceptable tradeoff between surge current, voltage drop, weight and size of the final assembly.

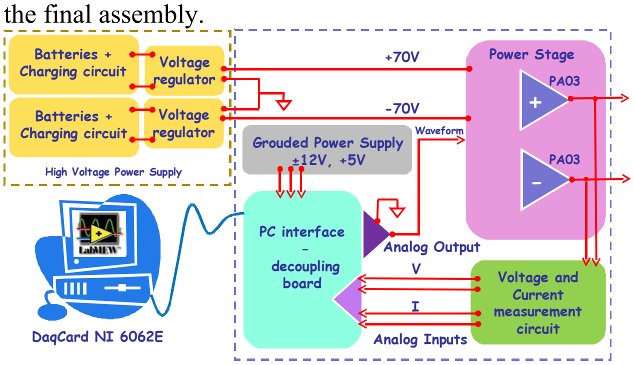


Figure 1. Major components of the defibrillator and their connections.

Battery charging was obtained using a series of DC/DC converters, so that the batteries can be charged in parallel, without disconnecting them from their serial connections to the output circuits. Because the amplifiers can safely operate only with a dual power supply, additional circuitry was added to guarantee that both supplies are available and fall into a proper range. This circuit is based on four comparators with hysteresis (LM 358, with positive feedback network): two comparators continuously check whether the positive supply is within the minimum (68V) and maximum (72V) allowed ratings; the same is done for the negative supply (allowed rating range -68V to -72V). The outputs of the comparators are used as inputs of a 4-AND logic ports which drives two relays, to disconnect the amplifiers from the supply, if the supply voltage is out of range.

PC interface and decoupling board

Arbitrary defibrillation waveforms are generated using a PCMCIA digital-to-analog converter board (DaqCard 6062E, National Instruments, Austin, TX), with 10us temporal resolution, using LabVIEW. The analog waveform is optically isolated and then injected into the amplifiers of the defibrillator output stage. In addition, the actual voltage and current delivered are measured, optically isolated and acquired by the A/D channels of the same converter board (figure 2).

The power for the floating section of the optical isolation board is supplied by DC-DC converters. Note that the measure of voltage and current requires its own floating power supply. For measuring the delivered current, the input of an optoisolated differential amplifier (HCPL-7800) is connected directly to a current sensing resistor (0.02 ohm). Voltage is measured from a voltage divider.

Output stage

As depicted in figure 3, we configured two power amplifiers (PA03, Apex Microtechnology Corporation, US) in a bridge circuit. In this configuration, the amplifiers supply an output-voltage swing twice that of a single op amp. In addition, this configuration doubles the slew rate and any nonlinearities become symmetrical, reducing second harmonic distortion compared to a single amplifier circuit. The PA03 is a high current, MOSFET operational amplifier designed for driving continuous output currents up to 14A and pulse currents up to 30A.

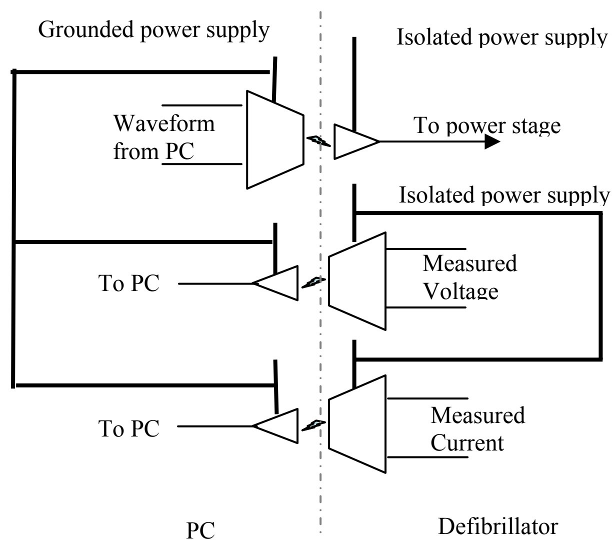


Figure 2. Scheme of the coupling board. Note the two isolated power supplies (bold lines) in the defibrillator output side.

Safe operating area protection circuit

In order to protect the whole system from software faults that could lead the system to work out of the PA03 safe operating area, a hardware-temporized enable circuit was designed. This circuit keeps the amplifier in the "sleep" mode unless the user requests a shock (by a user-operated button): in this case a wake up signal lasting 100 ms is sent to the amplifiers and triggers the waveform generation from the PC. This circuit also increases the safety of the system, since it prevents unexpected shocks originated by software crash/malfunctions.

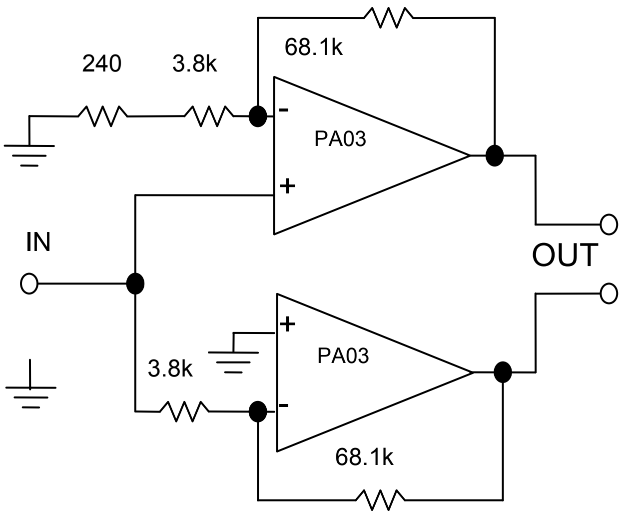


Figure 3. Bridge configuration of the PA03 power amplifiers.

3. Results

The defibrillator was tested on known loads to analyze the output features and then used at the Electrophysiology Laboratory of the Center for Devices and Radiological Health of the FDA. Figure 4 shows a biphasic rectangular voltage waveform (panel A) on 25 ohm load, delivering 2J: the rising front is detailed in panel B (less than 150 µs) for a voltage swing of 70V.

To test the defibrillation in the electrophysiology lab it was designed for, shocks were delivered to a perfused rabbit heart, as depicted in figure 5. An example of the voltage and current waveforms delivered by the defibrillator are illustrated in figure 6.

4. Discussion and conclusions

We designed and realized a research defibrillator able to test a wide variety of waveforms, suitable for in-vitro electrophysiological investigations. The defibrillator is able to deliver up to 10J, obtained with arbitrary shaped waveforms, with duration up to 100ms. The output stage can be connected to loads from 10 to 25 ohms. The possibility of delivering very long shocks (up to 100ms) is a unique for device. The combined use of linear AB amplifier and software generation of input waveforms allows the user to design any waveform, with the only

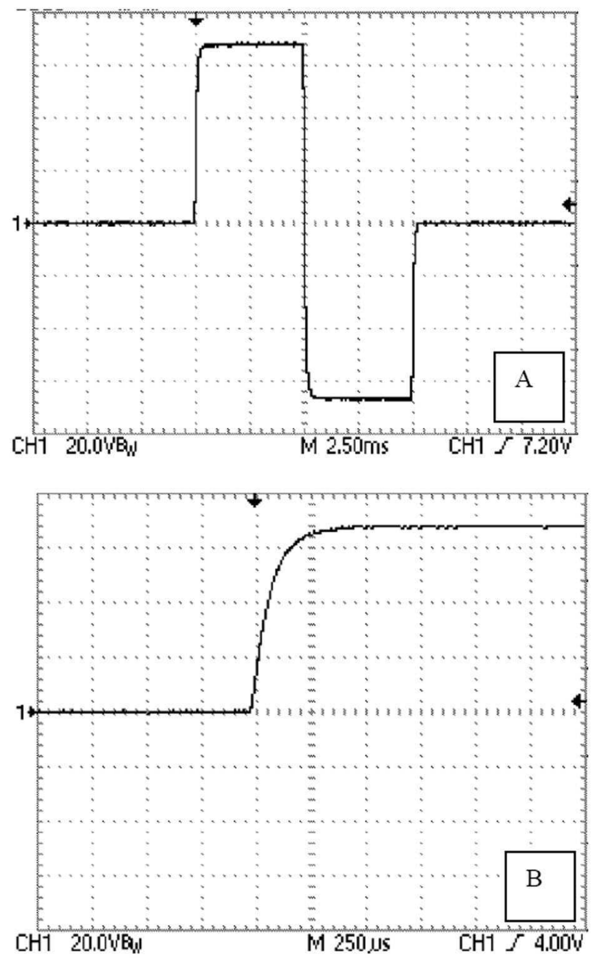


Figure 4. A biphasic rectangular waveform (panel A) on 25 ohm load. Panel B shows the rising front (zoomed from panel A)

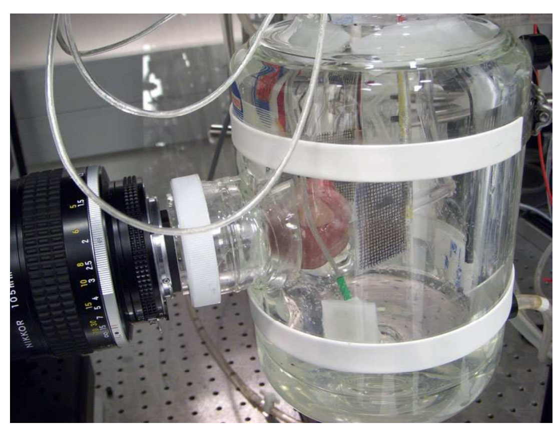
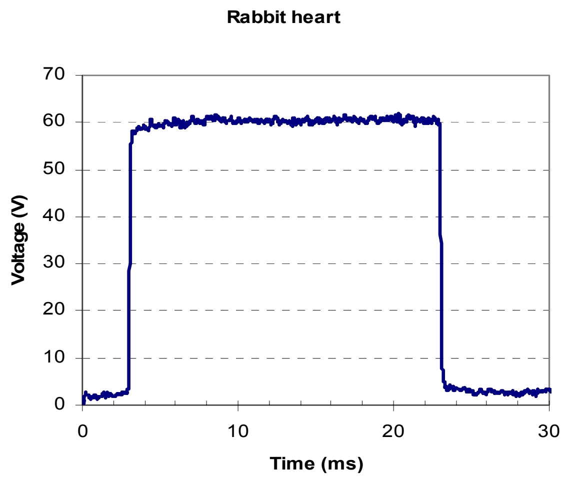


Figure 5. Set-up for the defibrillator testing on a perfused rabbit heart.

constraints given by the internal power dissipation and bandwidth of the amplifiers. To test the defibrillator performance, a preliminary series of tests on known loads were conducted. The system was further successfully tested in electrophysiological experiments on isolated rabbit hearts.

A similar approach has been previously used by Malkin *et al* [7], who developed a defibrillator able to deliver arbitrary waveforms up to a remarkable 700V peak amplitude, with a maximum duration of about 20msec. Since we aimed at studying longer defibrillation waveforms (up to 100 msec), with an experimental set-up having low impedance and requiring high currents, we needed to trade-off peak-voltage to current and shock duration. This required a different choice of the power amplifiers and a different approach to the power supply.



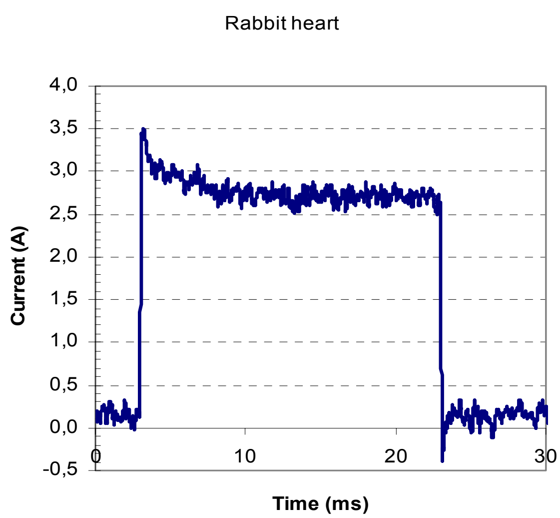


Figure 6. Voltage (upper panel) and Current (lower panel) waveforms delivered to a rabbit heart.

In conclusion, we presented a new approach to experimental defibrillator design, based on linear output stages. It overcomes the major limitations of the capacitor discharge approach and allows the generation and delivery of true arbitrary waveforms.

Disclaimer

The mention of commercial products, their sources, or their use in connection with material reported herein is not to be construed as either an actual or implied endorsement of such products by the U.S. Department of Health and Human Services.

References

[1] Szili-Torok T, Theuns D, Verblaauw T, Scholten M, Kimman GJ, Res J, Jordaens L. Transthoracic defibrillation of short-lasting ventricular fibrillation: a randomised trial for comparison of the efficacy of low-energy biphasic rectilinear and monophasic damped sine shocks. Acta Cardiol. 2002 Oct;57(5):329-34.

[2] Clark CB, Zhang Y, Davies LR, Karlsson G, Kerber RE. Transthoracic biphasic waveform defibrillation at very high and very low energies: a comparison with monophasic waveforms in an animal model of ventricular fibrillation. Resuscitation. 2002 Aug;54(2):183-6.

[3] Dosdall D, Rothe D, Sweeney J. Programmable arbitrary waveform generator for internal defibrillation research. Conf Proc IEEE Eng Med Biol Soc. 2004;6:3971-4.

[4] Seidl K, Denman RA, Moulder JC, Mouchawar G, Stoeppler C, Becker T, Weise U, Anskey EJ, Burnett HE, Kroll MW. Stepped defibrillation waveform is substantially more efficient than the 50/50% tilt biphasic. Heart Rhythm. 2006 Dec;3(12):1406-11. Epub 2006 Aug 25.

[5] Shorofsky SR, Rashba E, Havel W, Belk P, Degroot P, Swerdlow C, Gold MR. Improved defibrillation efficacy with an ascending ramp waveform in humans. Heart Rhythm. 2005 Apr;2(4):388-94.

[6] White RD. New concepts in transthoracic defibrillation. Emerg Med Clin North Am. 2002 Nov;20(4):785-807.

[7] Malkin RA, Jackson SR, Nguyen J, Yang Z, Guan D. Experimental verification of theoretical predictions concerning the optimum defibrillation waveform. IEEE Trans Biomed Eng. 2006 Aug;53(8):1492-8.

Address for correspondence

Michele Triventi
Dept. of Technologies and Health –
Istituto Superiore di Sanità
Viale Regina Elena 299, 00161 Roma – Italy
Tel. +390649902099 Fax. +390649387079
michele.triventi@iss.it