Proposal of a Low Cost Prototype Energy Measurement of Defibrillators with Impedance Variator

S. O. Rodríguez[1] N. G. Gama[2] J. C. Bauza[3]
[1]Biomedex, León, Gto., México [2]Autonomous University of Aguascalientes, Ags., México
[3]University of La Salle Bajío, León, Gto., México

Abstract— In the following work an alternative prototype was developed to measure the energy discharge in external defibrillators, unlike the conventional defibrillator analyzers where the energy discharge is performed with a fixed impedance of 50 Ω, this prototype proposes to perform the energy discharges of any external defibrillator and will have a variable impedance module at an affordable price. To verify that the prototype makes precise measurements, two external defibrillators of the same model were evaluated, and compared with a gold standard Phase 3, making five discharges of each defibrillator in three different energy intervals, and thus validate the proposed prototype, and according to the obtained results it was demonstrated that this prototype is reliable since by means of the Bland-Altman method it was proved that the prototype is accurate and that there is agreement between the two measuring instruments used. This prototype seeks to be an alternative measurement of cardiac resuscitation equipment, for health institutions that do not have the resources to purchase expensive equipment.
Key words: Calibration of Medical Equipment, Defibrillator Analyzer, Biomedical Metrology, Transthoracic Impedance

I. INTRODUCTION

External defibrillators are medical devices that apply an electrical shock to the heart to set a normal heart rhythm in patients who are suffering from ventricular fibrillation or an arrhythmia that requires restoring the heart rhythm through an electric shock. Defibrillators have three basic modes of operation: external defibrillation, internal defibrillation and synchronized cardioversion. The electrical energy discharged on the patient in each mode of operation is provided by a capacitor, which is charged through rechargeable batteries or alternating current (CENETEC, 2005).

Such medical equipment requires maintenance, calibration, repair and withdrawal of service; these activities are managed by biomedical engineers (CENETEC, 2016). The calibration is defined as: "operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication"(JCGM, 2008).

Medical equipment must be periodically calibrated to ensure accuracy and precision in accordance with its corresponding standards and norms, if there are significant discrepancies between the indicated value of a medical equipment and the magnitude that is supplied to a patient, an adjustment should be made (OMS, 2012). The official Mexican standard NOM-240-SSA1-2012 defines that the function of the technovigilance is: to guarantee that the medical devices that are available in the market work in the indicated way according to the intention of use of the manufacturer.

Calibrations of external defibrillators require special measuring instrument known as defibrillator analyzer. It has features such as compatibility with any type of wave (biphasic or monophasic), it has simulation of normal ECG and arrhythmias, flexible configurations of different heart rates, among others. Therefore, a defibrillator analyzer with these characteristics means that these devices present high acquisition costs, so that it represents a limitation for some health centers with a limited budget.

Standard IEC60601-2-4 (specific requirements for basic safety and essential performance requirements for cardiac defibrillators) suggests that defibrillators are tested with different resistance values of 25 Ω, 50 Ω, 75 Ω, 100 Ω, 125 Ω, 150 Ω and 175 Ω, to guarantee the current that is delivered to patients with different transthoracic impedances.

In Mexico, the analyzers that are available in the market for purchase are: Fluke Impulse 6000d-7000dp (Fluke Biomedical, Cleveland), Phase 3 (Datrend systems, Richmond), DA-2006P (BC Biomedical, Nevada), among others, which acquisition cost more than $ 5,000 USD. (Administrative staff, personal communication, November 29, 2017).

Defibrillator analyzers that are on the market perform energy measurements with a transthoracic resistance of 50 Ω. In addition, these analyzers have variable resistor modules that are sold separately and therefore their costs are increased even more. In Mexico, there are no certified laboratories with the calibration service of these equipment, they must be sent directly to the factories that are abroad, consequently, the delivery times is long and expensive.

The proposed prototype has the ability to receive a shock from the defibrillator, analyze the wave type and measure the energy delivered. Said prototype is of low cost, with variable impedance modules and easy to access calibration services from accredited laboratories with ISO/IEC 17025.

II. METHODOLOGY

The next proposed prototype is a defibrillator analyzer, which in its first stage, has resistance modules to select the test ranges, simulating the transthoracic impedance values of different patients. After the resistance module, a voltage divider continues, which allows obtaining and attenuating the voltage delivered by the defibrillator in an oscilloscope.

To perform the energy measurements in the proposed prototype, five discharges of two Cardiolife TEC-5531e defibrillators (Nihon Kohden, Tokyo) were performed in three different energy intervals (150 J, 200 J and 270 J) in each of the resistance modules in values from 25 Ω to 175 Ω (See Fig. 1).

The impedance modules consist of five cabinets, four of them contain internally a 50 Ω high-power (100 W) resistor; and the other cabinet with an impedance value of 25 Ω. Each module has four banana connectors to facilitate the defibrillator-analyzer connection. The modules are designed to be connected in series in order to obtain the impedance values: 25 Ω, 50 Ω, 75 Ω, 100 Ω, 125 Ω, 150 Ω and 175 Ω.

The signal conditioning stage consists of a voltage divider using 10 resistors of 2 MΩ with a tolerance of ± 1%, this step has the purpose of attenuating the high voltage signal coming from the impedance modules and analyzing it in the oscilloscope.

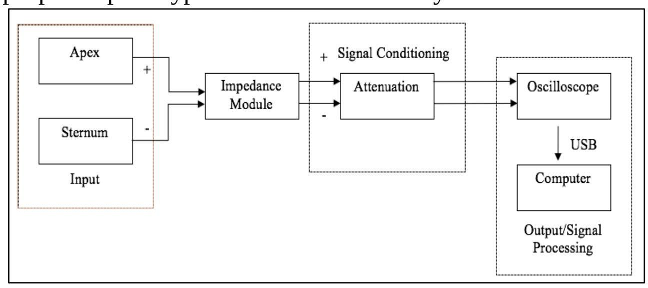
The output signal of the voltage divider was acquired using an Owon SDS 8202V calibrated oscilloscope (OWON, Zhangzhou), with a bandwidth of 200 MHz and a sample rate of 2 GB / s, (OWON, 2010). The numerical data of the output voltage, were obtained using the OWON Oscilloscope processing software through the serial port, this data is exported to an Excel spreadsheet to calculate the area under the curve equivalent to the value of the energy in each discharge, using equation (1).

$$E = \frac{1}{R}\int_0^t v^2(t)dt$$

Where:
E: Supplied energy
v: Supplied voltage
t: Time duration time of the wave
R: Impedance of the analyzer (25 Ω to 175 Ω)

In order to validate the measurements of the proposed prototype, they were compared with the measurements of a Phase 3 defibrillator analyzer (Datrend systems, Richmond), with an energy measurement accuracy of ±1% (Datrend systems, 2009), and with current calibration report traceable to the National Institute of Standards and Technology (NIST). The validation process consisted of performing five discharges in three different energy intervals (150 J, 200 J and 270 J), however, the Phase 3 analyzer has a fixed impedance of 50 Ω, and so the measurements of the proposed prototype were compared in 50 Ω.

The Bland-Altman method was used in order to evaluate the agreement between the results obtained with the proposed prototype and the Phase 3 analyzer.



III. RESULTS

The results presented in Table 1 represent the average of the five measurements in the three energy ranges of the 2 defibrillators Nihon Kohden TEC 5531e using the proposed prototype and the Phase 3 defibrillator analyzer, the measurements were made with an impedance of 50 Ω for both measuring instruments. Column (3) shows the energy values selected in the defibrillators and columns (4) and (5) the average values obtained with the proposed prototype and Phase 3 respectively.

Defibrillator (1)	Impedance (2)	Selected energy defibrillator (3)	Measured value Prototype (4)	Value indicated Phase 3 (5)
1	50 Ω	150 J	148,67 J	148,3 J
1	50 Ω	200 J	197,72 J	197,0 J
1	50 Ω	270 J	266,20 J	266,1 J
2	50 Ω	150 J	147,80 J	148,3 J
2	50 Ω	200 J	196,40 J	197,0 J
2	50 Ω	270 J	264,90 J	266,1 J

Table 1: Comparison of Measurements between Proposed Prototype and Phase 3 Analyzer

To validate the measurements of the proposed prototype with an impedance of 50 Ω, the Bland-Altman method (J.Martin Bland, 1986) was used, for which the average value of the difference between the proposed prototype and the Phase 3 analyzer was plotted.

The Bland-Altman graph is shown (Fig. 2) which was used in order to evaluate the agreement between the measurements of the proposed prototype and the Phase 3 analyzer. The graph shows the average value of each measurement of the instruments used against the average difference of the energy measurements of the proposed prototype and the Phase 3 analyzer.

The width of the limits of agreement has a confidence level of 95.45%, the lower limit has a value of -2.43 J and the upper limit of 2.01 J. The average of the difference in energy measured by the proposed prototype and the Phase 3 analyzer is -0.16 J and a standard deviation of ± 1.11 J. It can be seen that 90% of the measurements are within the limits of agreement and follow a normal distribution, the remaining 10% corresponds to atypical values of the two Nihon Kohden defibrillators model TEC 5531e, however, these values are very close to the lower and upper limits.

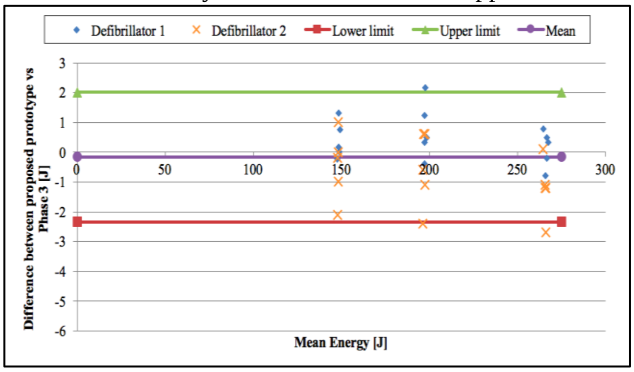


Fig. 2: Bland-Altman graphic. Proposed prototype vs Phase 3

Table 2 presents a comparison of the average of 5 discharges in 3 energy intervals of the two defibrillators TEC 5531e, with the different impedance values that the proposed prototype manages.

150 J		
Ω	Energy Defibrillator 1	Energy Defibrillator 2
25 Ω	125,10 J	127,0 J
50 Ω	149,00 J	148,20 J
75 Ω	154,20 J	155,80 J
100 Ω	158,00 J	160,50 J
125 Ω	159,21 J	159,10 J

150 Ω	159,00 J	161,30 J
175 Ω	159,30 J	161,20 J

Table 2: Measurement of Energy using the Proposed Prototype

In Fig. 3, Fig. 4 y Fig. 5 the waveforms of defibrillator 1 are shown at different impedances and energy intervals obtained by the proposed prototype.

200 J		
Ω	Energy Defibrillator 1	Energy Defibrillator 2
25 Ω	167,40 J	168,25 J
50 Ω	197,50 J	197,10 J
75 Ω	205,60 J	206,10 J
100 Ω	209,20 J	212,80 J
125 Ω	212,30 J	211,50 J
150 Ω	211,90 J	214,10 J
175 Ω	211,10 J	214,80 J
270 J		
Ω	Energy Defibrillator 1	Energy Defibrillator 2
25 Ω	224,30 J	226,20 J
50 Ω	266,10 J	265,00 J
75 Ω	275,40 J	276,00 J
100 Ω	281,00 J	287,00 J
125 Ω	285,00 J	284,50 J
151 Ω	284,60 J	288,00 J
175 Ω	285,10 J	286,30 J

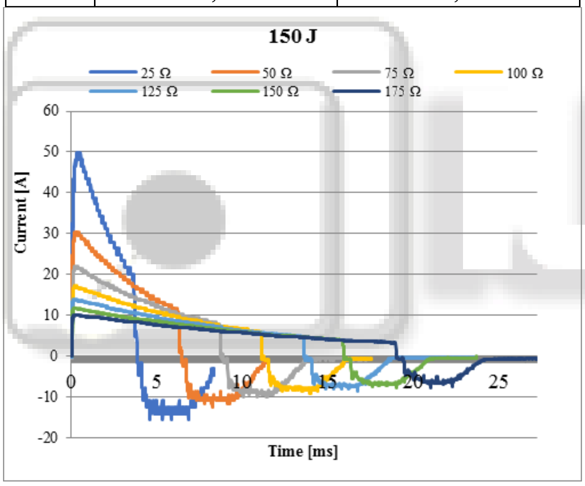


Fig. 3: Comparison of peak currents delivered by the Nihon Kohden TEC 5531e 150 J in the different impedance values of the proposed prototype

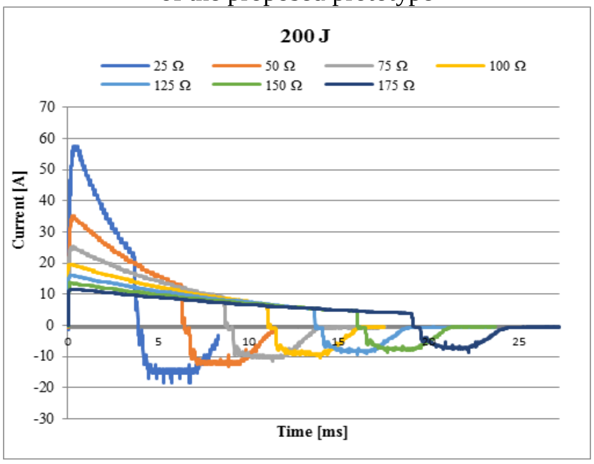


Fig. 4: Comparison of peak currents delivered by the Nihon Kohden TEC 5531e 200 J in the different impedance values of the proposed prototype

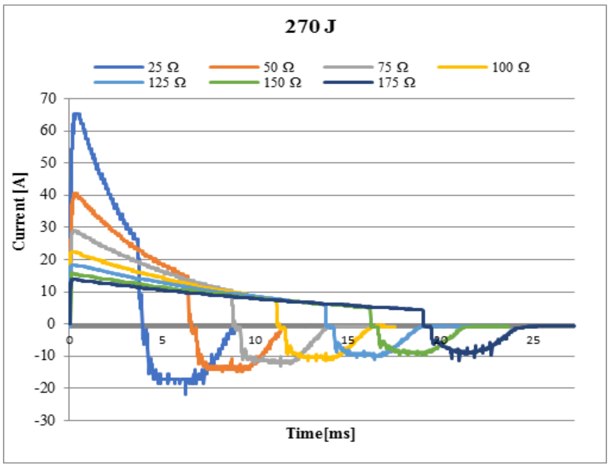


Fig. 5: Comparison of peak currents delivered by the Nihon Kohden 270 J in the different impedance values of the proposed method

IV. Discussion

As the results indicate, the proposed method is valid for the purposes used. It is intended to follow the same methodology in a greater number of defibrillators and different brands to characterize the measurements of the prototype with different waveforms.

The method proposed in the present investigation has as main advantage to be more economical in contrast to the analyzers of defibrillators that exist in the market, the oscilloscope and the proposed prototype can be calibrated by accredited calibration laboratories with ISO/IEC 17025, the delivery times of the calibration are minors as well as the costs. In addition, it has the resistor variator.

However, this method is not portable, since it requires a computer and an oscilloscope. The processing and analysis of the signal is manual and delayed. It does not have pads to perform the discharge using adult or pediatric external paddles.

In order to ensure that the equipment performs with operating specifications, the next step is to develop software that is capable of displaying the waveform of the discharge, measuring the voltage and peak current value, the pulse width, the time of the defibrillator charge, the delay time in cardioversion and include an electrocardiogram simulator with normal rhythms and arrhythmias.

In the absence of a standard equipment with the same range of impedances as the proposed prototype to compare the results, it was decided to perform only the calculation of the energy, it was shown that as the formula of the calculation of the energy indicates, the higher the resistance energy, so that the defibrillator compensates by sending more discharge energy, since the truncated exponential biphasic wave of the Nihon Kohden TEC 5531e compensates for the impedance variations by time and / or voltage. See equation (1).

V. Conclusion

The validation of the results of the proposed prototype can be corroborated in Fig. 2, where it is observed that most of the points corresponding to the values of the measurements with the proposed prototype and the Phase 3 analyzer are within the limits of concordance, it present a standard deviation of ± 1.11 J, so it can be concluded that there is a correlation between the methods and that the measurements obtained with the proposed prototype resemble those obtained with the Phase 3 defibrillator analyzer, thus confirming that the prototype is viable for the objectives established in this work.

It is of vital importance to perform preventive maintenance of defibrillators considering the variations of transthoracic impedances, to guarantee the functioning of the defibrillation equipment in any type of patient.

It was found in Fig. 3, Fig. 4 and Fig. 5 that the pulse width of the negative wave is constant when the impedance is high according to the technical specifications of the Nihon Kohden defibrillator TEC-5531e.

On the other hand, the defibrillator analyzers commonly used in Mexico, such as Phase 3 or Fluke impulse 6000d, require calibration services, which are characterized by being expensive and waiting time is long (approximately 20 days). These equipment has the limitation of being calibrated by laboratories not accredited by the Mexican Accreditation Entity (EMA). The OWON SDS8202V oscilloscope requires a lower cost to be calibrated with a waiting time of less than 3 days and the facility to find national calibration laboratories accredited by the EMA or other entities such as PJLA (Perry Johnson Laboratory Accreditation), A2LA (American Association for Laboratory Accreditation), NVLAP (National Voluntary Laboratory Accreditation Program).

In addition, conventional defibrillator analyzers do not have a variable range of impedances as the prototype includes it. A variable impedance module must be purchased separately. The total cost for the realization of the prototype is less than $ 150 USD.

Finally, the prototype proposed in this research is not intended to replace the methodology implemented by defibrillator analyzers in the market, but is an alternative for those health institutions that do not have sufficient financial resources to purchase expensive equipment.

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