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Experimental paper

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## A R T I C L E I N F O

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#### ABSTRACT

*Aim:* Assessment and comparison of the electrical parameters (energy, current, first and second phase waveform duration) among eighteen AEDs.

*Method:* Engineering bench tests for a descriptive systematic evaluation in commercially available AEDs. AEDs were tested through an ECG simulator, an impedance simulator, an oscilloscope and a measuring device detecting energy delivered, peak and average current, and duration of first and second phase of the biphasic waveforms. All tests were performed at the engineering facility of the Lombardia Regional Emergency Service (AREU).

*Results:* Large variations in the energy delivered at the first shock were observed. The trend of current highlighted a progressive decline concurrent with the increases of impedance. First and second phase duration varied substantially among the AEDs using the exponential biphasic waveform, unlike rectilinear waveform AEDs in which phase duration remained relatively constant.

*Conclusions:* There is a large variability in the electrical features of the AEDs tested. Energy is likely not to be the best indicator for strength dose selection. Current and shock duration should be both considered when approaching the technical features of AEDs. These findings may prompt further investigations to define the optimal current and duration of the shock waves to increase the success rate in the clinical setting.

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#### 1. Introduction

More than thirty years have elapsed since the first report on the use of automated external defibrillation into clinical practice.<sup>1</sup> Since then, automated external defibrillators (AEDs) have been widely spread not only in the emergency medical service setting but also among lay people in public places.<sup>2–7</sup>

Technology has been greatly improved and the AEDs adopt a biphasic waveform strategy, in contrast to the traditional monophasic defibrillators, to promote an increased success of defibrillation by concurrently reducing the myocardial damage due to the shock itself.<sup>8</sup> Biphasic waves exploit less energy than monophasic wave and achieve greater defibrillation efficacy.<sup>9–11</sup>

Corresponding author at: Via Campanini, 6, 20124 Milano, Italy. *E-mail address:* f.kette@areu.lombardia.it (F. Kette). Two main types of biphasic waveforms are available: biphasic truncated exponential (BTE) and rectilinear biphasic (RLB). Among these, some companies developed some variations, like the pulsatile truncated exponential and the rectangular waveform.<sup>12,13</sup>

Based on scientific data, the ILCOR recommendations stated that "...there is no evidence of greater effectiveness of one biphasic waveform or device on another". The guidelines for cardiac arrest and CPR thus recommend that "the initial biphasic shock should be no lower than 150J for BTE and 120J for RLB".<sup>12,13</sup>

Under the clinical point of view, there is as yet no evidence on the best biphasic waveform nor on the best energy to achieve a successful defibrillation.<sup>14</sup> Accordingly, companies have developed their own technology and features based on the international recommendations.

Energy has traditionally been the parameter used to estimate the strength of the shock although it is the current flowing through the heart that defibrillates the myocytes. Biphasic defibrillators modify the delivered current in relationship to trans-thoracic impedance. Thus far, however, the precise amount of current required to achieve a successful defibrillation is still unknown. This







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accounts for the variability of waveforms, peak and average current and of the duration of the first and second phase.

We therefore decided to systematically test several commercially available AEDs sold on Italian land following a large investment from the National Ministry of Health to the Italian Regions for a wide spread diffusion of AEDs in our country.

#### 2. Methods

Overall, eighteen AEDs from twelve different manufactures were tested:

- SaverOne (Ami Italia, Napoli, Italy);
- G3 Pro (Cardiac Science, Bohtell, WA, USA);
- G5 Pro (Cardiac Science, Bohtell, WA, USA);
- Lifeline AED (Defibtech, Guilford, CT, USA);
- Responder AED (General Electric, Schenectady, NY, USA);
- Sam300P (HeartSine, Belfast, Ireland);
- Lifepak 1000 (Physio Control, Redmond, WA, USA);
- Lifepak expess (Physio Control, Redmond, WA, USA);
- Cardiolife 2100 (Nihon Kohden, Shangai, China);
- FR2+ (Philips, Eindhoven, Netherlands);
- FRx (Philips, Eindhoven, Netherlands);
- FR3 (Philips, Eindhoven, Netherlands);
- RescueSAM (Progetti, Trofarello, Italy);
- AED HeartSave (Primedic, Rottweil, Germany);
- FRED Easy (Schiller, Baar, Switzerland);
- FRED Easyport (Schiller, Baar, Switzerland);
- AED Plus (Zoll, Chelmsford, UK);
- AED Pro (Zoll, Chelmsford, UK).

Tests were performed by using a defibrillator analyzer (Impulse 7000D, Fluke Biomedical, Everett). This device allows three different functions: defibrillation, ECG, pacing. Peak and average current (the maximum and average values of current delivered during the shock) and shock duration were measured in defibrillation mode. Each shock was delivered by the AEDs by increasing sequentially the impedance from 25 ohm ( $\Omega$ ) up to 200  $\Omega$  by incremental steps of 25  $\Omega$ . The AED was turned off at every shock and the impedance was changed. Changes of impedance were obtained through an impedance simulator (Impulse 7010D, Fluke Biomedical, Everett). This device allowed variation of impedance since the 7000D model is set at fixed 50  $\Omega$  impedance.

Biphasic waveforms were displayed on a 2 channel oscilloscope (THS720P model, Tektronik, Beaverton) which had a sensitivity from 5 millivolt (mV) to 50 volt per division (V/div) and a 8 bit vertical resolution with a scale of time which can be set from 5 nanoseconds (ns) to 50 second per division (s/div).

Tests were made at the Engineering Laboratory of the Lombardia Regional Emergency Service. In order to avoid bias measurements, all test were made by a single biomedical electronic engineer who consistently performed all evaluations. All but one tests were conducted between January 2012 and May 2012, with the exception of a newly introduced device which came out on the market in summer 2012. Measurements of this device were performed at the end of September 2012. The pads of each model were cut, replaced with suitable plugs and connected to the defibrillator analyzer.

The following parameters were measured at every shock:

- Peak current of first and second impulse phase (*I*<sub>p1</sub>, *I*<sub>p2</sub>), (A) [ampere].
- Average current of first and second impulse phase (*I*<sub>avg1</sub>, *I*<sub>avg2</sub>), (A) [ampere].

- Duration of first and second impulse phase (*T*<sub>1</sub>, *T*<sub>2</sub>) and total duration (*T*<sub>tot</sub>), (ms), [milliseconds].

For measurements we maintained the energy default settings. All tests were repeated three times.

Additional measurements included peak and average voltage, size, weight, time required to analyze the ECG signal and time elapsed between turning on the AED and the ready-to-shock moment. These data, however, are not herein presented as they are part of separate reports. Preliminary results were reported in abstract forms.<sup>15–17</sup>

## 3. Results

Highly consistent data in terms of precision of measurements were registered. Accordingly, due to the negligible standard deviation, the data in the tables reported values without the standard deviation. Overall, there were four types of trends. In the first one, including 6 AEDs, an energy decline ranging from 5 to 36.5% from 25 to 200  $\Omega$  was identified. A second group (two defibrillators) showed a raise in energy in relationship to an impedance increase with, however, a large difference among their percentage energy increase, from 5 to 26.9%. In a third group four AEDs maintained approximately the same energy value at every impedance level. In the fourth group there was an initial increase in energy which then declined steadily. Overall, despite the large energy variation, the majority of the energy delivered was within the range declared by each manufacturer for every given impedance level. The results of energy measurements are shown in Table 1.

The peak current of the first phase showed marked decreases in all eighteen AEDs concurrent with the increases in impedance value (Fig. 1). The greatest variation was seen in FRED Easyport AED that delivered a peak current of 95.5 A at an impedance value of 25  $\Omega$  and ended up with a peak current of 14 A when the impedance was 175  $\Omega$ . Conversely, the AED Pro and AED Plus showed a minor range of variation by maintaining a relatively low peak value. More specifically, the peak current of these two AEDs varied from 25.6 to 8 A from 25 to 200  $\Omega$ . The diversity in peak current among the AEDs was more evident at low impedance values than at high impedance levels. At impedance values greater than 100  $\Omega$ , the peak current was similar for all tested AEDs. The second phase peak current showed a similar trend to that of the first one, but  $I_{p2}$  maintained lower values as compared to those of  $I_{p1}$ .

The first and second phase average current delivered during the shocks showed a similar trend to that described for peak current (Fig. 2).

The first phase, second phase and total wave duration varied among the AEDs in relationship to the impedance (Table 2). The greatest variation in the first phase duration was observed in the Cardiolife AED. This parameter, indeed, increased from 3.9 ms at 25  $\Omega$  to 18.7 ms at an impedance value of 175  $\Omega$ . Instead, the greatest variation in the total duration of the shock was seen in Sam 300P, in which the  $T_{tot}$  varied from 6.5 ms at an impedance value of 25  $\Omega$ to 31.9 ms at an impedance value of 200  $\Omega$ . Fig. 3 represents the FRx waveform showing a larger variation in time duration in contrast to the AED Plus which maintained the same duration regardless of the changes in impedance.

#### 4. Discussion

The Truncated Exponential and the RectiLinear are the most common biphasic waveforms currently available in the automated external defibrillators. The recommendations of both guidelines on CPR, American Heart Association and European Resuscitation Council, however, only relate to the energy that should be

<sup>-</sup> Delivered energy (E), [joule].

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