

# Multicenter Study of the Safety and Efficacy of a Biphasic Impedance-Compensating Waveform for Transthoracic Defibrillation

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## Abstract:

**Background:** An automated external defibrillator (AED) can reduce the time delay in defibrillation. With delivery of fixed amounts of energy, peak leading edge current can be excessive (> 50 amps) if transthoracic impedance is low. These peak currents can produce myocardial dysfunction. At lower energy settings, average current may not be adequate for reliable defibrillation if transthoracic impedance is high. We developed a new AED that uses integrated electronics, 200 $\mu$ F capacitors, and microprocessor-controlled impedance compensation to: (1) reduce the total AED weight to 2.8 lbs. from the 6lbs. of previous AEDs; (2) limit peak leading edge current to 30 amps in patients with low impedance; and (3) deliver an average first phase current of 16 amps in patients with high impedance. Full energy is delivered in these latter patients by extending the pulse duration and utilizing lower tilt enabled by the increased capacitance. We previously showed the benefit of this waveform in animals. This study was designed to test the clinical safety and efficacy of this innovative waveform in humans with ventricular fibrillation.

**Methods and Results:** In this prospective study, 55 patients undergoing ICD implant or testing had ventricular fibrillation induced. Each was defibrillated at the lowest device energy setting (200J). All 55 patients (100%) were successfully defibrillated on the first administered shock. The average transthoracic impedance was 80 ohms (range 42-122). The mean first phase average current was 17 amps (range 12-25) and the mean first phase peak current was 21 amps (range 13-35). No acute ECG or skin changes were observed.

**Conclusions:** This study confirms the safety and high first shock efficacy of the waveform in ventricular fibrillation. This new AED waveform delivers limited peak current in low impedance patients and sufficient average current in high impedance patients for successful defibrillation.

## Background:

- Widespread availability of portable AEDs that can be used by laypersons will reduce time delay to defibrillation and improve survival from Sudden Cardiac Arrest (SCA).
- A 1.3 kg (2.8 lb) AED has been developed to fulfill this need. This AED [Figure 1] has been designed to deliver a safe and effective biphasic waveform.
- Biphasic waveforms have first shock efficacy of 86-100% in the controlled environment of the electrophysiology lab. [1, 2, 3]
- Biphasic waveforms with higher first phase average current and extended pulse duration yield higher first shock efficacy [1, 2, 3].
- The biphasic waveform for this AED was developed to:
  1. deliver average first phase current of 16 amps and extend first phase duration in patients with higher impedance
  2. limit peak current in patients with lower impedance to minimize myocardial injury [4]
  3. maintain charge ratio to lower defibrillation threshold (DFT) [5]
- Initial animal data confirmed that extension of first phase duration in a 100  $\mu$ F capacitor waveform does not lower the DFT current. For a 200  $\mu$ F capacitor waveform, extension of the first phase duration does lower DFT. [6] [TABLE].
- A 200  $\mu$ F capacitor waveform has a lower leading edge current at DFT. [Figure 2]

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Figure 1

TABLE:

	Average Current Threshold (Amps)	Energy Delivered (Joules)	First Phase Duration (msec)
Access (200 $\mu$ F)	13.39 $\pm$ 2.27	55.48 $\pm$ 19.23	8.5
W1 (100 $\mu$ F)	14.26 $\pm$ 1.76	50.13 $\pm$ 16.98	7.5
W2 (100 $\mu$ F)	15.04 $\pm$ 1.41	45.83 $\pm$ 15.72	6.0
p-value* =	< 0.001	0.337	N/A

\* two-way ANOVA analysis

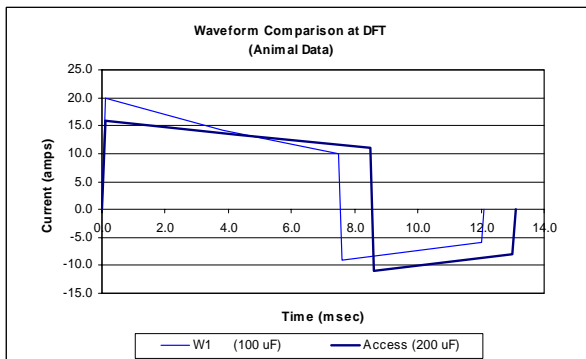


Figure 2

**Hypothesis:**

- The biphasic waveform in this AED will have 100% first shock efficacy in controlled testing in the electrophysiology (EP) lab.
- This waveform will cause no significant skin or ECG changes in the electrophysiology lab.

**Methods:**

Fifty-five (55) patients with ventricular arrhythmias undergoing study in the EP lab, either for initial EP testing, ICD testing, or ICD insertion were studied. Only those patients in whom ventricular fibrillation was induced during the test procedure were included. Patient exclusion criteria were: 1) less than 18 years old, 2) currently enrolled in another pharmaceutical or device trial, 3) pregnancy, 4) history of complicated procedures during previous EP or ICD tests, and 5) uncorrected electrolyte abnormality. Nine (9) patients were excluded for failure to follow the protocol (6), failure to capture data (2), and spontaneous reversion from ventricular tachycardia to a non-shockable rhythm (1). Patients who participated in the study were prepared for testing using local protocol standards. Patients signed informed consent prior to the initiation of the preparation protocol. All testing was performed only for indications that were clinically required.

**Results:**

- All fifty-five (55) patients included in the study were defibrillated successfully on the first shock.
- The average first phase average current was 17.4 amps (range 12-25) and the average patient impedance was 79.6 ohms (range 42- 122). [Figure 3]
- Average energy delivered was 215.0 Joules and the peak current averaged 21.2 amps (range 13-35). Peak current was limited in lower impedance patients. [Figure 3]
- First shock was delivered an average of 10 seconds (range 2-25) after induction of ventricular fibrillation.
- There were no significant post-shock ECG or skin changes.

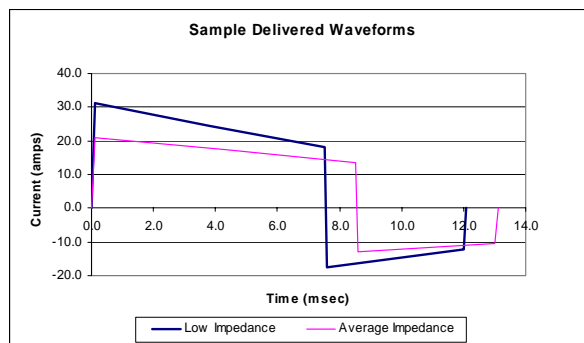


Figure 3

**Conclusions:**

- This study confirms that this AED yields 100% first shock efficacy in the electrophysiology lab for short duration ventricular fibrillation.
- This efficacy is better than or equivalent to that delivered by other currently available AEDs.

**Reference:**

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