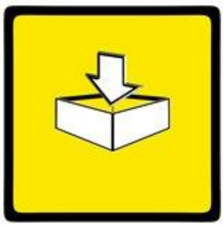
CONSIDERATIONS AND ADVANTAGES OF BIPHASIC WAVEFORM OF 230 JOULES VS THOSE OPERATING AT 360 JOULES



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The current 2005 AHA guidelines have recommended the use of higher energies in old defibrillators which still use monophasic waveforms. However, most modern commercial Automated External Defibrillators (AEDs) use biphasic waveforms [1, 8, 11]. Although there is no consensus on how much energy is required to convert a patient to normal sinus rhythm on the current guidelines they do suggest much lower energy thresholds for both truncated and rectilinear biphasic waveforms i.e. between 150-200 Joules [1]. Most companies quote an optimum or average energy delivered in order to achieve around a 90% success rate of 200 Joules [7-11]. This figure is even quoted by those who manufacture AEDs which have the facility to deliver energies of up to 360 Joules biphasic 16. It is the aim of both industry and academia to strike a balance between increasing shock success whilst minimizing damage to the myocardium post defibrillation and therefore myocardial dysfunction as reported by Jones et al in 1984 [2-3]. There is much literature to confirm the fact that 360 Joules causing significant damage to the myocardium due to the excessive voltages and currents applied to the patient [2, 4, 5-6]. The development of biphasic waveforms was driven by the internal defibrillation market as the components currently used in the original Lown waveform could not be easily applied to implant circuitry and also the requirement for lower energies to minimize post shock cardiac dysfunction and myocardial damage [5-6, 17]. The biphasic waveform at 200 joules is generally accepted to be comparable in terms of overall success rate to the previously used monophasic waveform which uses energies of up to 360 Joules [7-11, 15]. H009-002-020-0 Prior to the development of the biphasic waveforms several studies were completed with the aim of reducing delivered energies. In fact in 1975 Pantridge and colleagues published a paper entitled Electrical Requirements for VF following the group’s successful deployment of the first completely portable defibrillator. The study showed that the delivery of a single low energy monophasic shock succeeded in removing VF in 73 out of 82 episodes. The energy levels used in this study were between approximately 150 and 165 Joules [13-14]. The group then demonstrated in a later study that 200 Joule shocks were successful in 95% of cases following monophasic defibrillation [18]. The development of biphasic waveforms enabled the production of not only implantable defibrillators but also the development of smaller, lightweight Semi-automated and automated defibrillators which could deliver shocks at much lower energies when compared with their DC predecessors. The development of these systems facilitated the implementation of public access defibrillation programmes worldwide to tackle the issue of early access to the patient [17].

> The initial biphasic protocol of 120J-150J-200J for the Rectilinear Biphasic waveform was chosen based on data from a prospective, randomized, clinical trial (Mittal et al JACC 1999 24:1595-1601) which showed 99% first shock efficacy at 120J, and 100% efficacy at 150J. Based on this data, the 200J shock represents a safety margin.

Please check references Annex A

HOW DOES BIPHASIC WAVEFORM DEFIBRILLATE?

For defibrillation to be successful, a sufficient amount of electrical current must be delivered to the heart muscle. How to deliver the electrical current to the heart muscle is the core technique to defibrillate the heart.

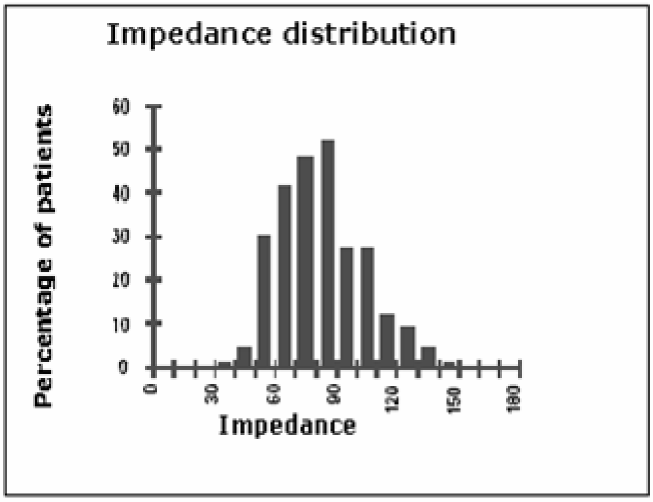
Successful defibrillation would be done when the cell membranes of the heart are “coated” with positive ions on one side and negative ions on the other side, enough to depolarize nearly 100 percent of the cardiac cells at the same instant. Optimal current is determined with the pressure (this means electric Voltage) that controls what an amount of current can be pushed and the duration of time the current flows. This defibrillation current is commonly described in joules of energy. Energy is a measure of the amount of current, voltage, and duration of time the current flows.

$$\text{Energy(joules)} = \text{Current(amps)} \times \text{Voltage(volts)} \times \text{Time(sec)}$$

When the Defibrillation shock is delivered, current flow is affected by transthoracic impedance, the body's resistance from electrode to heart. Impedance is dependent on the anatomy of the chest, skin surface, air in the chest, hair, fat and bone, as well as the size and location of the defibrillation electrodes.

$$\text{Current(amps)} = \frac{\text{Voltage(volts)}}{\text{Resistance(ohms)}}$$

Research has shown that chest resistance can vary significantly from patient to patient. Patients with low impedance are generally easier to defibrillate because the flow of current meets little resistance. Those with higher impedance may be more difficult to defibrillate. According to the International Guidelines 2000 by the American Heart Association (AHA) in collaboration with the International Liaison Committee On Resuscitation (ILCOR), average adult impedance is 70-80 ohms. Defibrillation energy should be designed to optimize the delivery of current over a wide range of patient impedances. Too much current to the myocardial cells can cause damage to the cells and result in an unsuccessful defibrillation. Too little current to the myocardial tissue cells will not depolarize the cells and result in an unsuccessful defibrillation.



The waveform biphasic technology:

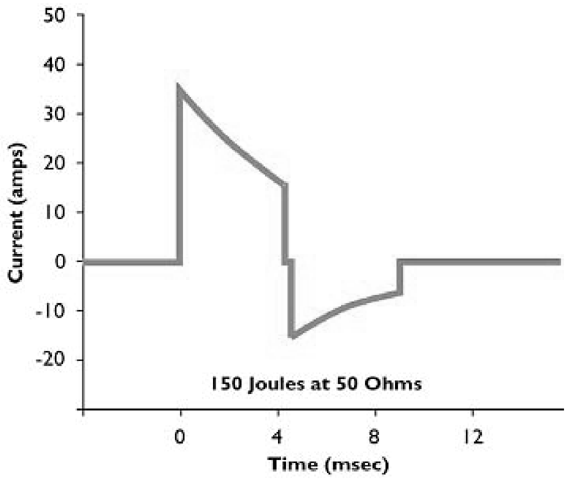
1) Makes it easy to compensate the shock waveform to match the patient impedance,
2) Is more efficient than monophasic technology,
3) Delivers enough energy for restoring heart rhythm.

EASE IN COMPENSATION OF PATIENT IMPEDANCE

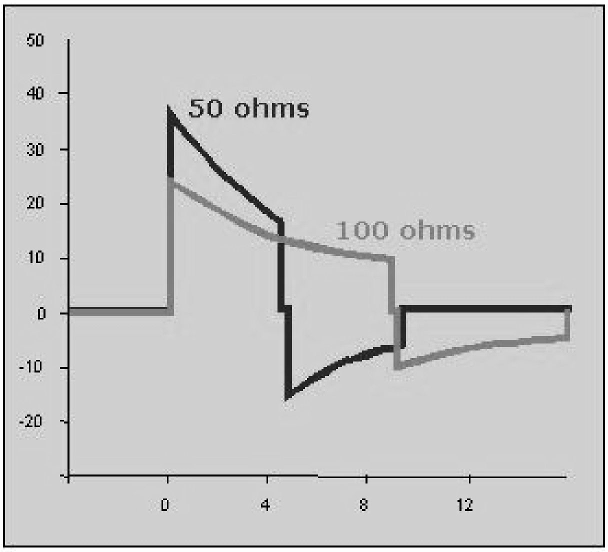
Through Biphasic technology, defibrillation shock delivery is controlled while taking into consideration the patient's impedance. The patient's impedance is measured through the defibrillator electrodes. According to the measured patient's impedance, e-cube Biphasic technology adjusts the duration of current flow to optimize the effectiveness of the shock delivery. **E-cube Biphasic technology** is based on 3 core technologies. 1 The technology for measuring the

patient's impedance. 2 The technology for controlling the voltage level to be delivered. 3 The technology for controlling the duration of current flow.
These technologies can adjust the parameters of the shock waveform to match the transthoracic impedance of the patient. Biphasic technology increases the duration of current flow for patients with high impedance. When escalating energy, for example 150J to 180J, it delivers the electrical energy with higher voltage level if the patient's impedance does not vary.

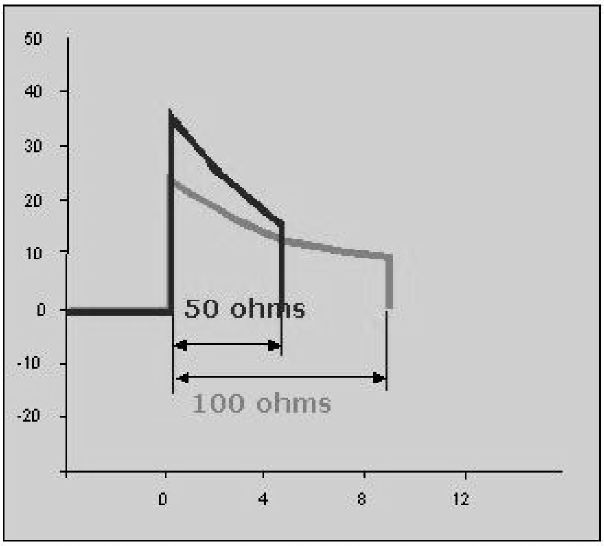
MORE EFFICIENT THAN MONOPHASIC WAVEFORM
The electrical therapy delivered by transthoracic cardiac defibrillators has changed little since the introduction of direct-current defibrillation more than 30 years ago. Throughout this time, the industry-standard shock waveform for external defibrillators has been a monophasic damped sine (MDS) waveform, in which current flows in one direction throughout the shock. Many well-organized emergency medical systems, using monophasic devices for early defibrillation, have documented better than 20% survival to hospital discharge for cardiac arrest patients found in ventricular fibrillation (VF). Attempts to improve this survival rate have adapted proposals to change the waveform and energy level of defibrillation shocks [6].

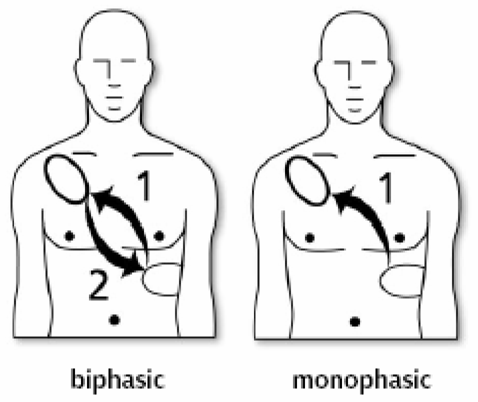


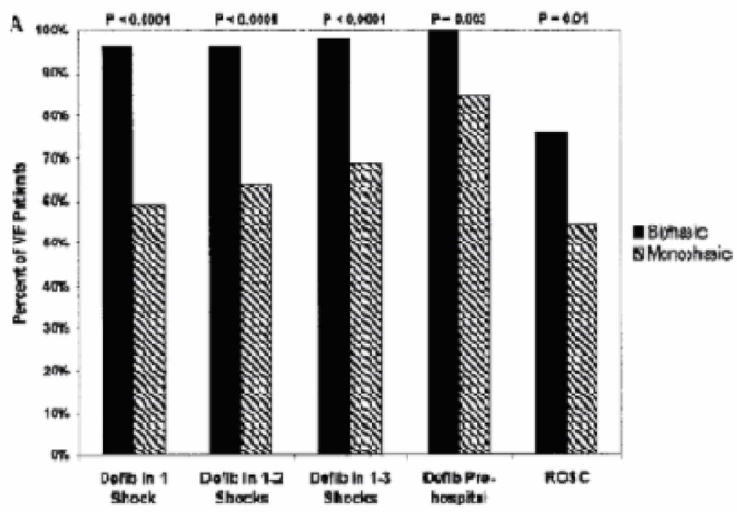
BIPHASIC



MONOPHASIC







Prehospital defibrillation and resuscitation efficacy for 115 patients who presented with VF
Schneider et al. Circulation. 2000; 102:1780-1787

Extensive animal and human data with implanted devices demonstrate that biphasic waveforms offer substantial reductions in defibrillation thresholds and produce less myocardial dysfunction than monophasic waveforms [1], [2], [3], [4].

The defibrillation efficacy of the 150-J biphasic waveform was superior to that of the 200-J to 360-J conventional escalating-energy monophasic waveforms for 115 patients who presented with VF [5].

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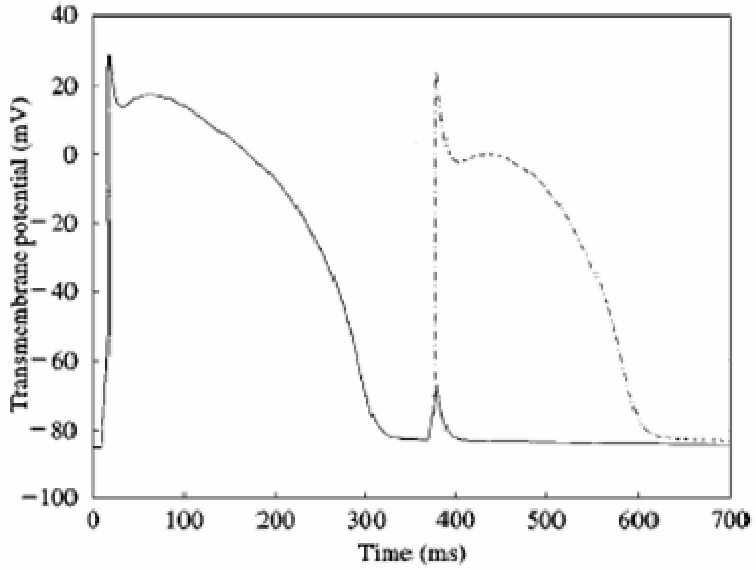
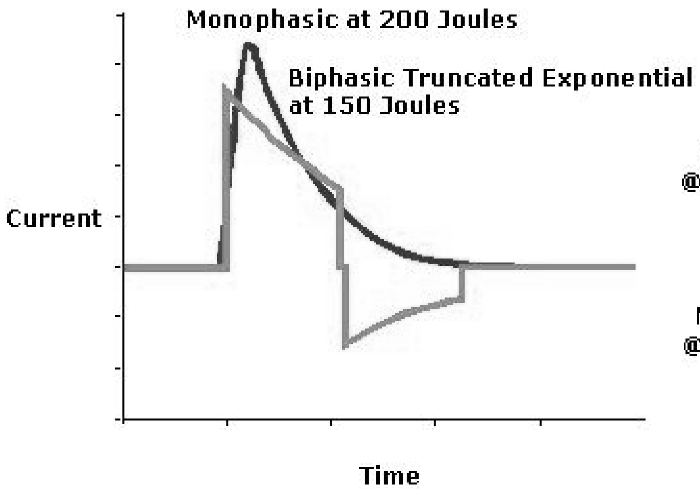


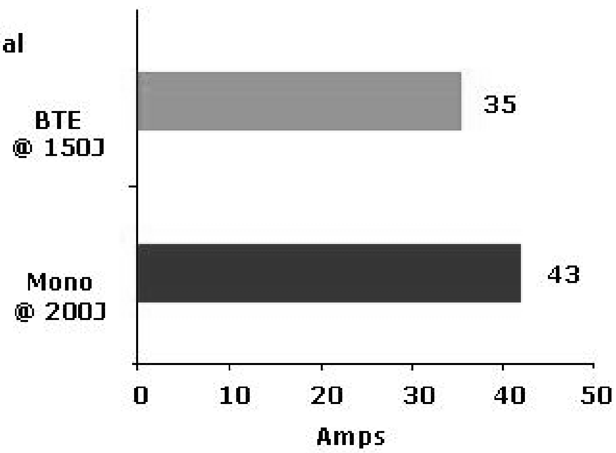
Transmembrane potential for a single Beeler-Reuter cell subject to monophasic and biphasic. Each stimulus amplitude (A) is 17.0 mV, duration is 10 ms and is applied 360 ms after the initial action potential. Notice that for a stimulus of the same amplitude, duration and timing, the biphasic stimulus is successful at activating the cell, whereas the monophasic stimulus fails to activate the cell. Monophasic (———); biphasic (). Keener et al, J. theor. Biol. (1999) 200, 1-17

The difference between monophasic and biphasic waveform is qualitatively similar but varies quantitatively for different parameter values. The fundamental difference is that first phase of the biphasic pulse acts as a pre-pulse to remove inactivation from the heart cell, accelerating its recovery, and thereby lowering the activation threshold for defibrillation prior to second phase of biphasic pulse which is reversed current flow.

ENOUGH ENERGY FOR RESTORING HEART RHYTHM

The Biphasic Truncated Exponential waveform uses lower energy than the Monophasic waveform. But the lower energy of biphasic shock is more efficient than high energy of the monophasic shock for defibrillation to restore heart rhythm.





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In a multicenter, randomized, controlled trial of 150J biphasic waveform compared with 200J and 360J monophasic waveforms done in humans, Schneider et al [5] showed that "the 150-J biphasic waveform defibrillated at higher rates, resulting in more patients who achieved a return of spontaneous circulation. Although survival rates to hospital admission and discharge did not differ, discharged patients who had been resuscitated with biphasic shocks were more likely to have good cerebral performance."
Positive evidence for safety and clinical effectiveness of biphasic truncated exponential waveforms for internal and external use was ascertained by the AHA ECC committee [8], [9].

Please check Annex Reference B

BRANDS WHO CHOOSE TECHNOLOGY DIFFERENT FROM 360J

Here below is reported a scheme with all brands that have chosen to follow the biphasic technology with shock under 360J:

BRAND	MODEL	JOULES
PROGETTI	Rescue Life 7	230J
PROGETTI	Rescue 230	230J
PHILIPS	HeartStart XL+	200J
ZOLL	X Series	200J
PHILIPS	Efficia DFM100	200J
NIHON KOHDEN	TEC-8300K	270J
SCHILLER	Defigard 5000	180J
SCHILLER	Defigard touch 7	200J
CU MEDICAL	Lifegain CU-HD1	200J

ABSTRACT FROM "EUROPEAN RESUSCITATION COUNCIL GUIDELINES FOR RESUSCITATION 2015" REGARDING TO DEFIBRILLATORS' GUIDELINES

Shock Energy

Defibrillation shock energy levels are unchanged from the 2010 guidelines. For biphasic waveforms (rectilinear biphasic or biphasic truncated exponential), deliver the first shock with an energy of at least 150 J. For pulsed biphasic waveforms, begin at120–150 J. The shock energy for a particular defibrillator should be based on the manufacturer's guidance.
There are no high-quality clinical studies to indicate the optimal strategies within any given waveform and between different waveforms. The optimal energy levels may ultimately vary between different manufacturers and associated waveforms. Manufacturers are encouraged to undertake high-quality clinical trials to support their defibrillation strategy recommendations.

Waveforms

Biphasic waveforms are now well established as a safe and effective waveform for defibrillation. Biphasic defibrillators compensate for the wide variations in transthoracic impedance by electronically adjusting the waveform magnitude and duration to ensure optimal current delivery to the myocardium, irrespective of the patient's size (impedance compensation). There are two main types of biphasic waveform: the biphasic truncated exponential (BTE) and rectilinear biphasic (RLB). A pulsed biphasic waveform is also in clinical use, in which the current rapidly oscillates between baseline and a positive value before inverting in a negative pattern. It may have a similar efficacy as other biphasic waveforms, but the single clinical study of this waveform was not performed with an impedance compensating waveform, which is used in the commercially available product.
We recommend that a biphasic waveform is used for cardioversion of both atrial and ventricular arrhythmias in preference to a monophasic waveform.

Energy Level
The optimal energy for defibrillation is that which achieves defibrillation whilst causing the minimum of myocardial damage. Optimal energy levels for defibrillation are unknown. The recommendations for energy levels are based on a consensus following careful review of the current literature.

First Check
There is no evidence that one biphasic waveform or device is more effective than another. First shock efficacy of the BTE waveform using 150–200 J has been reported as 86–98%.
Two studies have suggested equivalence with lower and higher starting energy biphasic defibrillation. Although human studies have not shown harm (raised biomarkers, ECG changes, ejection fraction) from any biphasic waveform up to 360 J, several animal studies have suggested the potential for harm with higher energy levels. The initial biphasic shock should be no lower than 120 J for RLB waveforms and at least 150 J for BTE waveforms
Second and subsequent shocks, the 2010 guidelines recommended either a fixed or escalating energy strategy for defibrillation. There remains no evidence to support either a fixed or escalating energy protocol, although an escalating protocol may be associated with a lower incidence of refibrillation. Both strategies are acceptable; however, if the first shock is not successful and the defibrillator is capable of delivering shocks of higher energy it is reasonable to increase the energy for subsequent shocks.

Refibrillation
Two studies showed termination rates of subsequent refibrillation were unchanged when using fixed120 J or 150 J shock protocols respectively, but a larger study showed termination rates of refibrillation declined when using repeated 200 J shocks, unless an increased energy level (360 J) was selected.
In view of the larger study suggesting benefit from higher sub-sequent energy levels for refibrillation, we recommend that if a shockable rhythm recurs after successful defibrillation with ROSC, and the defibrillator is capable of delivering shocks of higher energy it is reasonable to increase the energy for subsequent shocks.

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