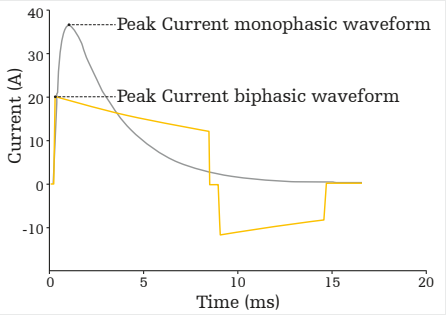
Biphasic Clinical Overview

Full Energy Biphasic 360 Joule Technology
Physio-Control LIFEPAK® monitor/defibrillators

Key definitions

Monophasic waveform (older, single direction energy delivery, higher peak current)



Biphasic waveform (modern, bidirectional energy delivery, less peak current)

- **Biphasic Truncated Exponential- BTE** (dynamic current and duration, fixed shape)
- **Rectilinear Biphasic Waveform- RBW** (dynamic current and shape, short fixed duration)

Energy expressed in joules (combined metric of current and voltage over time)

- **Joule** (unit of energy (J), 1 amp passing through 1 ohm for 1 sec)
- **Current** (flow of electricity measured in amps (A))
- **Voltage** (electromotive push or force measured in volts (V))
- **Duration** (interval of time measured in milliseconds)
- **Impedance** (resistance to flow of current measured in ohms)

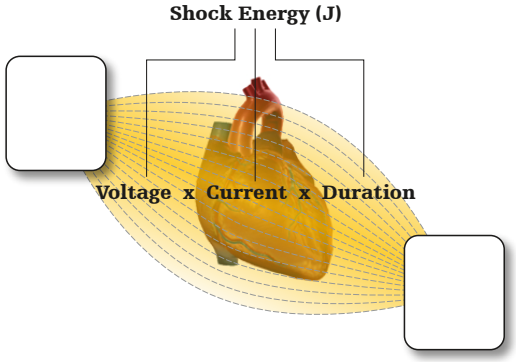
Clinical study (human population)

Experimental study (animal population)

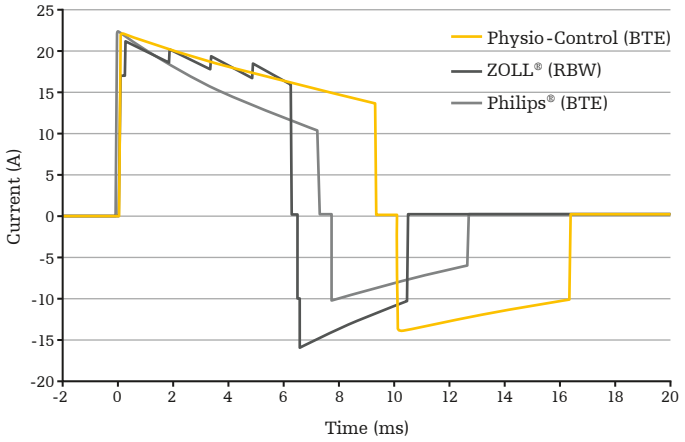
Optimizing conversion rates

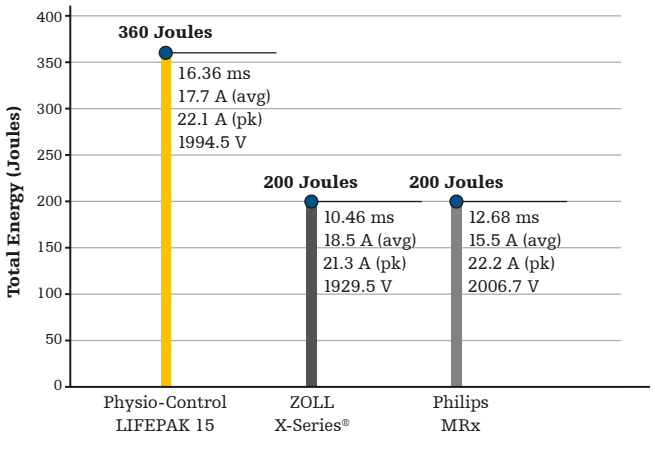
Biphasic research has provided direction on optimizing conversion rates for the 5-11% of cardiac arrest patients who are difficult-to-defibrillate.[1,2] The more efficient biphasic defibrillation waveforms still leave room to improve conversion rates.[13]

- No singular electrical characteristic (current, voltage or duration) of any biphasic waveform determines conversion rate.[5]
- The therapeutic defibrillation dose is a defined set of electrical characteristics over a defined time, measured as energy.[5]
- Published clinical data strongly points to an association between higher biphasic shock energy (joules) and higher conversion rates for VF/pVT and AF.[1-4]



Biphasic waveforms and maximum programmed settings*





*Biphasic measurements testing at 90 ohms with the Physio-Control LIFEPAK 15 Monitor/Defibrillator, ZOLL X-Series Monitor/Defibrillator and Philips MRx Monitor/Defibrillator.[6] Average human impedance range is approximately 70-80 ohms.[6]

Clinical Evidence

1. A large volume of published data now exists on biphasic defibrillation. It should be referenced when evaluating proven performance.
2. The data shows that at the same low energy biphasic shocks, the most widely used defibrillation waveforms (BTE and RBW) have the same conversion rates from 50J to 200J.[8-12]
3. The data also shows that higher energy biphasic waveforms are associated with higher conversion rates for VF/pVT and AF.[1-4,19]
4. The 2010 and 2015 AHA Guidelines state full energy biphasic 360J is safe for patients.[3,7,14-16] High peak current is a primary cause of myocardial injury.[17] Biphasic waveforms use as much as 40% less current than monophasic waveforms.

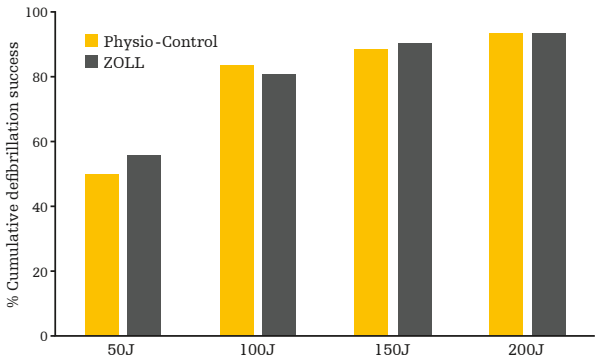
Published clinical performance

- Early manufacturer biphasic studies were done in EP labs on non-critical, short duration VF patients. All showed high conversion rates at lower shock energies. But biphasic performance in real-world cardiac arrest patients matters more.
- The Physio-Control biphasic waveform (BTE) has been studied in nearly 2X as many cardiac arrest patients as all other manufacturers' biphasic waveforms combined, across a wide range of impedances.*

Low energy biphasic 50J to 200J: clinical equivalence

- From 50J to 200J, five clinical cardioversion studies showed that at the same low energies, biphasic waveforms had the same conversion rates.[8-12]
- Three studies compared the Physio-Control BTE (LIFEPAK 12) and ZOLL RBW (M Series®) waveforms.[8-10]
- Two studies compared the Philips BTE (MRx) and ZOLL RBW (M Series and R Series®) waveforms.[11,12]
- For each study; **same low energies = same conversion rates**

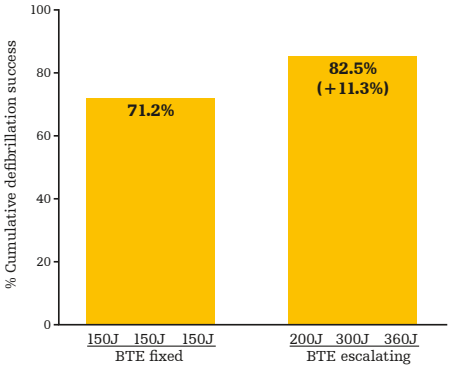
Kim, Neal, Alatawi [9-11]



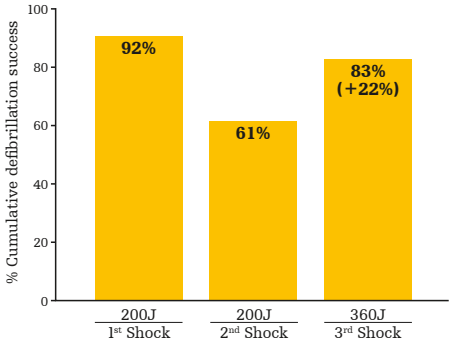
Full energy biphasic 360J: clinical advantage

- Clinical studies (VF and AF) show protocols with escalating energy to full energy 360J improves conversion rates for difficult-to-defibrillate patients.[1-4]
- No clinical (human) evidence exists showing low energy (150J to 200J) from any monitor/defibrillator provides equivalent or superior conversion rates when compared to full energy biphasic 360J.

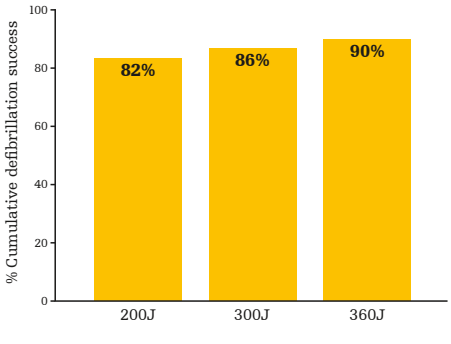
The only randomized, triple-blinded dosing comparison showed higher conversion rate for VF/pVT when escalating to 360J vs. a fixed protocol.[3]



Conversion rate were lower when 200J was repeated for recurrent VF/pVT. All were eventually converted with 360J.[2]



Conversion rate probability increased in a subset of VF/pVT patients who received shocks at each energy dose. 360J had the highest cumulative rate.[1]



*These data represent the cumulative number of cardiac arrest patients in whom the VF termination efficacy (using the established definition of "removal of VF for ≥ 5 seconds") of specific biphasic waveforms and energy levels has been reported in published papers describing either randomized or consecutive case series of OHCA or IHCA patients. Included are papers that report a VF termination rate for at least one of 1) first shocks or 2) all shocks.

Biphasic defibrillation comparison

	LIFEPAK monitor/defibrillators and AEDs	ZOLL E Series® ZOLL M Series monitor/defibrillators	ZOLL X Series ZOLL R Series monitor/defibrillators	Philips monitor/defibrillators and AEDs
Published biphasic data on cardiac arrest patients*	11 studies 2,808 patients	3 studies 441 patients	0 studies 0 patients	8 studies 934 patients
Max programmed setting	360 Joules	200 Joules	200 Joules**	150 Joules - AED 200 Joules - ALS
Biphasic waveform type	BTE	RBW	RBW	BTE
Biphasic waveform duration	13.4 - 18.9 ms[20]	10 ms[21] (fixed)	10 ms[22] (fixed)	8.6 - 17 ms[23]

*These data represent the cumulative number of cardiac arrest patients in whom the VF termination efficacy (using the established definition of "removal of VF for ≥ 5 seconds") of specific biphasic waveforms and energy levels has been reported in published papers describing either randomized or consecutive case series of OHCA or IHCA patients. Included are papers that report a VF termination rate for at least one of 1) first shocks or 2) all shocks. Based on information available in the published literature as of March 2018.

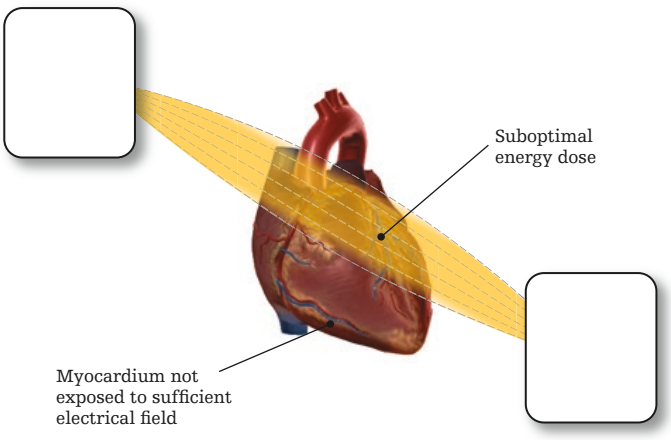
**May deliver more energy than the E Series, M Series and ZOLL AEDs.[21,22] This is less than the maximum energy delivered in LIFEPAK monitor/defibrillators and LIFEPAK AEDs.

Clinical strategies to improve conversion rates

The Critical Mass Theory is a meaningful conceptualization that can help clinicians improve conversion rates.[5] The goal is to depolarize as much of the myocardial tissue as possible at once, placing it into a repolarized, refractory state unable to re-propagate the electrical misfires that cause VF/pVT. Two controllable factors can significantly impact this complex biological interaction.

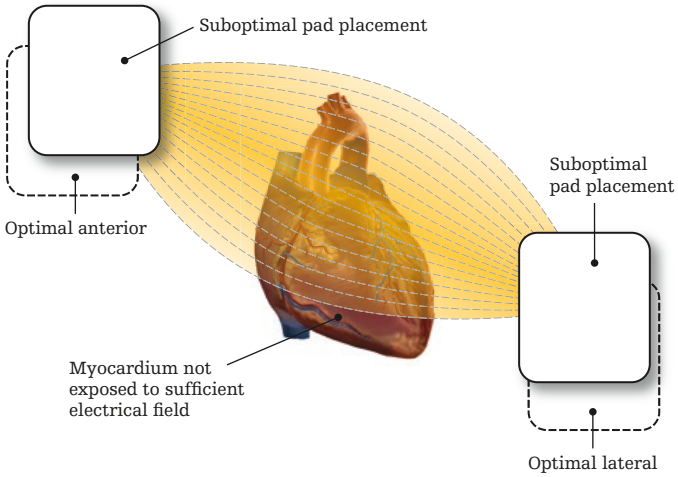
1. Optimize the size of the defibrillation field

Higher energy (J) can increase a shock's myocardial coverage while less energy likely covers less. Data supports escalating to 360J as a mechanism to maximize conversion rates.[1-4,18]



2. Optimize the vector of the defibrillation field

Suboptimal pad placements can also lower conversion rates. Escalating to 360J can compensate for these variations.[19]



Closing points

- Science recognizes that no individual characteristic of a well-designed biphasic waveform determines conversion rate. The combined total of a shock's electrical characteristics (energy expressed in joules), determines conversion rate.
- The data shows that at the same low energy biphasic shocks, the most widely used defibrillation waveforms (BTE and RBW) have the same conversion rates from 50J to 200J.
- Published clinical data demonstrate protocols with escalating energy to 360J improves conversion rates for difficult-to-defibrillate VF and AF patients.
- No commercially available defibrillator on the market offers equivalent strength to full energy biphasic (360J) offered by Physio-Control LIFEPAK defibrillators for both AED and manual defibrillation.

References

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All claims valid as of March 2018.

Physio-Control is now part of Stryker.

For further information, please contact Physio-Control at 800.442.1142 (U.S.), 800.895.5896 (Canada) or visit our website at www.physio-control.com

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