

Why 360 Joules?



Clinical overview

LIFEPAK[®] defibrillators

More power. Fewer "what-ifs."

Energy determines conversion rates, not current.

2

In terms of converting patients, biphasic vs. biphasic studies show that waveforms are equivalent up to 200 joules.

3

Not all patients convert at energy levels up to 200J. Clinicians are now using more targeted strategies for difficultto-defibrillate patients.



Biphasic shocks at 360J have been shown to improve conversion rates when shocks at 200J fail.

*Conversion rate is defined as termination of AF/VT/VF (removal of the tachyarrhythmia for at least 5 seconds).

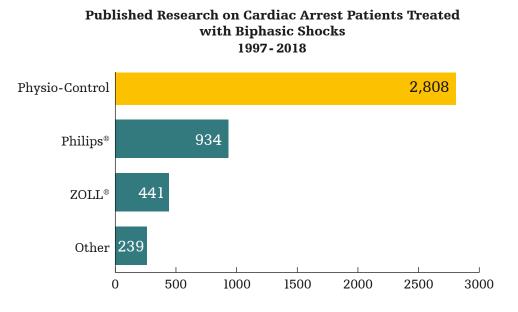




Confidence in our technology

when you need it most

- The Physio-Control waveform has been studied in nearly twice as many patients as all other commercially available waveforms combined.
- This clinical research represents real-world performance in OHCA (out-of-hospital cardiac arrest) and IHCA (in-hospital cardiac arrest) patients.



*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.



Energy determines conversion rates, not just current.

High current alone, or any other singular aspect of the defibrillation shock, does not determine conversion rates. Many factors influence effective defibrillation, including:

- 1. Peak current delivered to the patient
- 2. Current delivery duration
- 3. Maintenance of current level throughout shock duration

Energy includes all three elements and has been shown to best describe the therapeutic dose delivered to the heart.

The evidence: biphasic vs. biphasic studies¹⁻⁵

In five AF studies that compared conversion rates between Physio's BTE waveform and ZOLL's RBW waveform, the same low energy settings resulted in the same conversion rates from 50 to 200 joules. Energy dictated the conversion rates.

Why were AF studies used to compare waveforms? AF studies allow for consistent data collection and pad placement in a controlled research environment. AF and VF share common electrophysiological properties and defibrillation mechanisms.

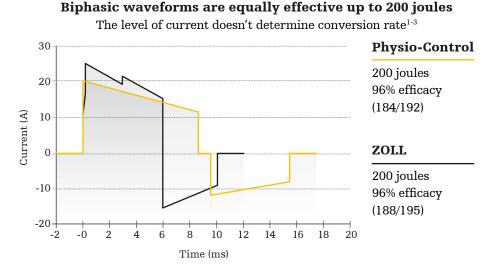




In terms of conversion rates, all **biphasic waveforms** are equivalent up to **200 joules**.

Different levels of current, at the same programmed energies, did not produce different conversion rates. They were statistically equivalent at 100J, 150J and 200 joules.

The evidence



Three biphasic vs. biphasic clinical studies specifically compared waveforms used by Physio-Control and ZOLL in synchronized cardioversion. The cumulative results show that, though ZOLL's waveform delivers higher levels of current, the waveforms are equally effective up to 200 joules.



Not all patients convert at energy levels up to **200 joules**.

Only 8 of the 27 published reports cite first shock success rates greater than 90%. Others report success rates of 70% or less, including other manufacturers' largest published data sets:⁶⁻¹⁷

- Philips (Kramer-Johansen, et al.¹⁷) = 70% conversion rate
- ZOLL (Stothert, et al.¹⁴) = 67% conversion rate.

In addition, recurrent VF is common in cardiac arrest, with studies reporting rates as high as 74%.^{18,19} Later VF episodes can become more challenging to convert.¹⁸

It's no longer controversial: There is a difficult-to-defibrillate patient population, and it's tough to predict who they are.

Clinical trends using 360 joules:

- Some clinicians are now using defibrillation protocols starting with 360J. (i.e. 360J x 360J x 360J)
- Some are using alternate pad placements with 360J after their traditional defibrillation protocol failed.
- Electrophysiologists are using external defibrillators that are capable of escalating to 360 joules biphasic energy. A 2016 hospital survey showed:²⁶
 - $\circ~59\%$ of electrophysiologists now use defibrillators that can escalate to 360J biphasic in their EP labs.
 - 28-29% of electrophysiologists use full energy defibrillators even when their hospitals have standardized on low energy defibrillators in other patient care areas.



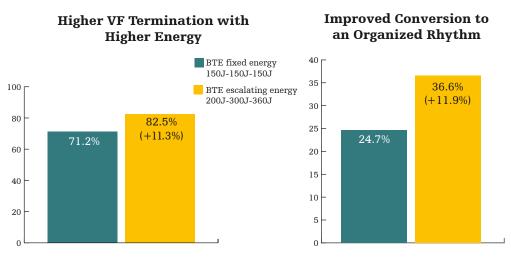
360 joules have been shown to **improve conversion rates**.

When low energy shocks fail, escalating biphasic energy to 360 joules improves conversion rates.

The evidence

The 2010 International Consensus on CPR and ECC Science with Treatment Recommendations (CoSTR) confirms this is supported by high levels of evidence. "Evidence from one well-conducted randomized trial (LOE 1) and one other human study (LOE 2) employing BTE waveforms suggested that higher energy levels are associated with higher shock-success rates."²⁰ Clinical data support full energy in both VF and AF patients.¹⁹⁻²³ In AF studies, looking at variable initial shock energies, a 360 joule shock was recommended when the first 200 joule shock failed, since a second 200 joule shock is rarely effective.^{3, 23}

The 2015 CoSTR did not change statements pertaining to higher energy and higher shock-success rates. It was stated, "There are no major differences between the recommendations made in 2015 and those made in 2010."²⁴



A triple-blinded, multi-center, randomized, controlled trial showed significantly higher rates of VF termination and conversion to an organized rhythm when energy was escalated to 360 joules rather than maintaining the same first shock dose in patients needing more than one shock.²⁰

A defibrillator purchase is an investment that lasts years. **Choosing LIFEPAK defibrillator/monitors with full energy** provides you the flexibility you need as guidelines and protocols evolve to reflect new understanding and research.

References

- Alatawi F, Gurevitz O, White R, et al. Prospective, randomized comparison of two biphasic waveforms for the efficacy and safety of transthoracic biphasic cardioversion of atrial fibrillation. *Heart Rhythm.* 2005;2:382-387.
- Kim M, Kim S, Park D, et al. Comparisonof rectilinear biphasic waveform energy versus truncated exponential biphasicwaveform energy for transthoracic cardioversion of atrial fibrillation. *Am J Cardiol.* 2004;94;1438-1440.
- Neal S, Ngarmukos T, Lessard D, et al. Comparison of the efficacy and safetyof two biphasic defibrillator waveforms for the conversion of atrial fibrillation to sinusrhythm. Am J Cardiol. 2003;92;810-14.
- Deakin C, Connelly S, Wharton R, et al. A comparison of rectilinear and truncatedexponential biphasic waveforms in elective cardioversion of atrial fibrillation: aprospective randomized controlled trial. *Resuscitation*. 2013;84(3)286-91.
- Santomauro M, Borrelli A, Ottaviano L, et al.Transthoracic cardioversion in patients with atrial fibrillation: comparison of threedifferent waveforms. *Ital Heart J Suppl.* 2004;5(1):36-43.
- Hess E, Atkinson E, White R. Increased prevalence of sustained return of spontaneous circulation following transition to biphasic waveform defibrillation. *Resuscitation.* 2008;77:39-45.
- Hess E, White R. Ventricular fibrillation is not provoked by chest compression during post-shock organized rhythms in out-of-hospital cardiac arrest. *Resuscitation*. 2005;66:7-11
- White R, Russell J. Refibrillation, resuscitation and survival in out-of-hospital sudden cardiac arrest victims treated with biphasic automated external defibrillators. *Resuscitation.* 2002;55:17-23.
- 9. Schneider T, Martens P, Paschen H, et al. Multicenter, randomized, controlled trial of 150-J biphasic shocks compared with 200- to 360-J monophasic shocks in the resuscitation of out-of-hospital cardiacarrest victims. *Circulation*. 2000;102:1780-7.
- 10. Koster R, Walker R, Chapman F. Recurrent ventricular fibrillation during advanced life support care of patients with prehospital cardiac arrest. *Resuscitation*. 2008;78:252-7.
- Walker R, Koster R, Sun C, et al. Defibrillation probability and impedance change between shocks during resuscitation from out-of-hospital cardiac arrest. *Resuscitation*. 2009; 80:773-7.
- Whitfield R, Colquhoun M, Chamberlain D, et al. The Department of Health National Defibrillator Programme: analysis of downloads from 250 deployments of public access defibrillators. *Resuscitation*. 2005;64:269-77.
- 13. Van Alem A, Chapman F, Lank P, et al. A prospective, randomised and blinded comparison of first shock success of monophasic and biphasic waveforms in out-of-hospital cardiac arrest. *Resuscitation*. 2003;58:17-24.

- 14. Stothert J, Hatcher T, Gupton C, et al.diac arrest. Prehosp Emerg Care. 2004;8:388-92.
- 15. Edelson DP Abella B, Kramer-Johansen J, et al. Effects of compression depth and pre-shock pauses predict defibrillation failure during cardiac arrest. *Resuscitation*. 2006;71:137-145.
- Walsh S, McClelland A, Owens C, et al. Efficacy of distinct energy delivery protocols comparing two biphasic defibrillators for cardiac arrest. Am J Cardiol. 2004;94:378-380.
- Kramer-Johansen J, Edelson D, Abella B, et al. Pauses in chest compression and inappropriate shocks: a comparison of manual and semiautomatic defibrillation attempts. *Resuscitation*. 2007;73:212-220.
- Koster R, Walker R, Chapman F. Recurrent ventricular fibrillation during advanced life support care of patients with prehospital cardiac arrest. *Resuscitation.* 2008;78:252-257.
- Walker R, Koster R, Sun C, et al. Defibrillation probability and impedance change between shocks during resuscitation from out-ofhospital cardiac arrest. *Resuscitation*. 2009;80:773-777.
- 20.2010 International consensus on cardiopulmonary resuscitation and emergency cardiac care science with treatment recommendations. *Circulation*. 2010;122(suppl 2): S327.
- Stiell I, Walker R, Nesbitt L, et al. The BIPHASIC Trial: A randomized comparison of fixed lower versus escalating higher energy levels for defibrillation in out-of-hospital cardiac arrest. *Circulation*. 2007;115:1511-1517.
- 22. Khaykin Y, Newman D, Kowalewski M, et al. Biphasic versus monophasic cardioversion in shock-resistant atrial fibrillation. J Cardiovasc Electrophysiol. 2003;14:868-72.
- 23. Rashba E, Gold M, Crawford F, et al. Efficacy of transthoracic cardioversion of atrial fibrillation using a biphasic, truncated exponential shock waveform at variable initial shock energies. Am J Cardiol. 2004;94:1572-1574.
- 24.2015 Part 4: Advanced life support. International consensus on cardiopulmonary resuscitation and emergency cardiac care science with treatment recommendations. *Circulation*. 2015;95:e73
- 25.Esibov A, Chapman F, Melnick S, et al. Minor variations in electrode pad placement impact defibrillation success. *Prehospital Emergency Care*. March/April. 2016;20(2):292-298.
- Interviews of 200 U.S. hospitals were conducted by Calo Research Services. September 2015.

Physio-Control is now part of Stryker.

For further information, please contact Physio-Control at 800.442.1142 (U.S.), 800.668.8323 (Canada) or visit our website at www.physio-control.com

Physio-Control Headquarters 11811 Willows Road NE Redmond, WA 98052 www.physio-control.com

Customer Support P. O. Box 97006 Redmond, WA 98073 Toll free 800 442 1142

Fax 800 426 8049

Physio-Control Canada Physio-Control Canada Sales, Ltd. 45 Innovation Drive Hamilton, ON L9H 7L8 Canada Toll free 800 668 8323 Fax 877 247 7925



Physio-Control, Inc., 11811 Willows Road NE, Redmond, WA 98052 USA

@2018 Physio-Control, Inc. All names herein are trademarks or registered trademarks of their respective owners.. GDR 3306561_F