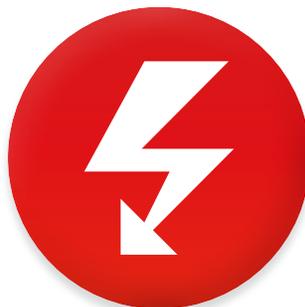


Why 360 Joules?

Clinical Overview

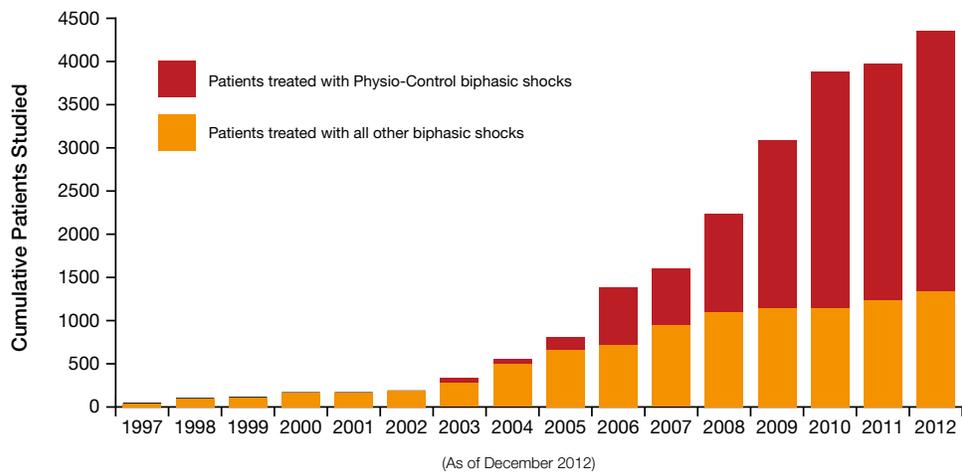


A compelling case for 360 joules.

- 1** When it comes to defibrillation, energy matters more than current.
- 2** In terms of shock efficacy, all biphasic waveforms are equivalent up to 200 joules.
- 3** Not all patients convert at energy levels up to 200 joules.
- 4** Biphasic shocks at 360 joules can improve defibrillation success.

A wealth of clinical data supports biphasic shocks greater than 200 joules, most of which has emerged since the 2005 AHA Guidelines.

Published Research on Cardiac Arrest Patients Treated with Biphasic Shocks



1

When it comes to defibrillation,
energy matters more than current.

Defibrillation technology is complex. Other manufacturers spend a great deal of time discussing the merit of current, but the fact is, current alone does not determine shock efficacy.

Decades of research back this up. And while current does play a role in effectively converting patients, it is simply not the whole story. The evidence shows that many factors influence effective defibrillation, including:

1. Peak current delivered to the patient
2. Shock 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 evidence¹⁻⁵

Independently conducted, peer-reviewed studies prove that the level of current delivered by the shock does not singularly determine shock efficacy.

2

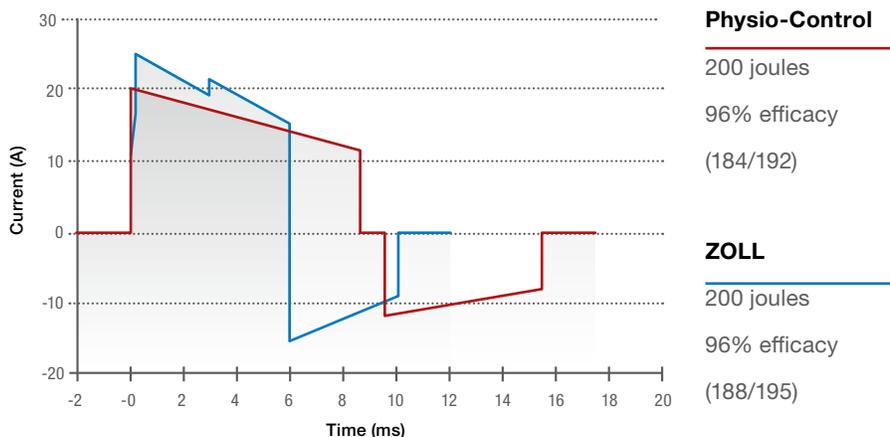
In terms of shock efficacy, all biphasic waveforms are equivalent up to 200 joules.

Biphasic waveforms on the market differ with respect to peak current delivered, shock delivery duration and how the current is maintained throughout the shock. However, five independently conducted, peer-reviewed human clinical studies comparing them show that shocks of the same energy provide the same success rate, even if the level of current is significantly different.¹⁻⁵

The evidence

Biphasic waveforms are equally effective at 200 joules

The level of current doesn't determine shock efficacy^{1,2,3}



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

- The 2005 AHA Guidelines state, "At this time there is no evidence that one biphasic waveform is more outcome-effective than another." (IV-40)
- The 2010 AHA Guidelines state, "There is no clinical evidence for superiority of any specific biphasic waveform over another." (S644)

3

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

There is clearly room for improvement when shocking difficult-to-defibrillate patients. According to published data, biphasic shocks don't always work as well as previously thought, even on the first shock. It is especially important to have full energy capability, up to 360 joules, to give difficult-to-defibrillate patients the best chance of a successful defibrillation.

The evidence

Only 7 of the 26 published reports cite first shock success rates greater than 90%,⁶⁻¹² others report success rates of 70% or less,¹³⁻¹⁶ including our competitors' largest published data sets:

- Philips® (Kramer-Johansen, et al.¹⁶) = 70% efficacy
- ZOLL® (Stothert, et al.¹³) = 67% efficacy

Recurrent VF is common in patients with VF cardiac arrest, with studies reporting rates as high as 74%.^{17,18} VF can become more difficult to terminate in later episodes.¹⁷ A small subset of difficult-to-defibrillate patients accounts for the majority of failed shocks^{17,18} and the data shows us that it's impossible to predict who those patients will be.

The FDA is evaluating the significance of 17 reports of events since 2009 in which a 200 joules biphasic defibrillator was ineffective and a subsequent shock from a different 360 joules biphasic defibrillator resulted in immediate defibrillation/cardioversion.

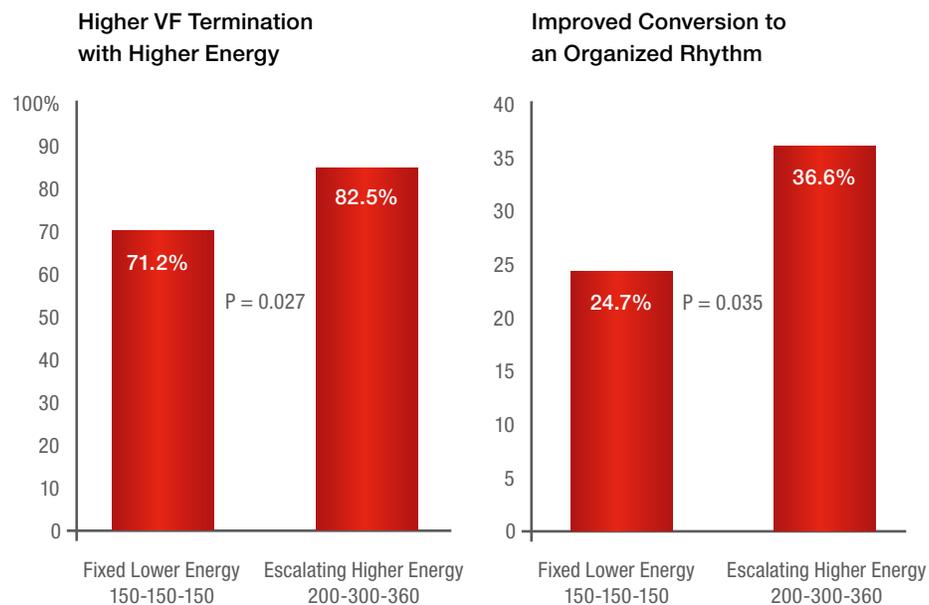
4

Biphasic shocks at 360 joules can improve defibrillation success.

When low energy shocks fail, escalating energy to 360 joules improves shock success.

The evidence

The 2010 international consensus for CPR 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."¹⁹ Clinical data support full energy in both VF^{17,18,20} and AF^{21,22} patients. In AF studies, looking at variable initial shock energies, a 360 joule shock was recommended when the first 200 joule shock failed,²² since a second 200 joule shock is rarely effective.³



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.

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All claims valid as of September 2013.

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