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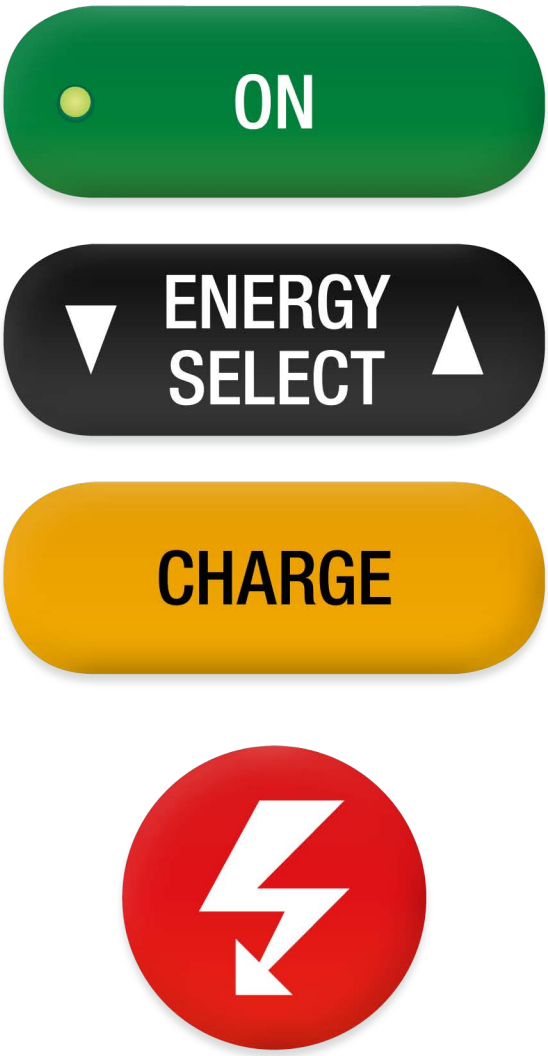
Here to Help!

PHYSIO CONTROL

Why 360 Joules?

Clinical Overview



LIFEPAK® DEFIBRILLATORS

A compelling case for 360 joules.

1. When it comes to defibrillation, energy determines conversion rates*, not current or any single dimension of the shock.

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

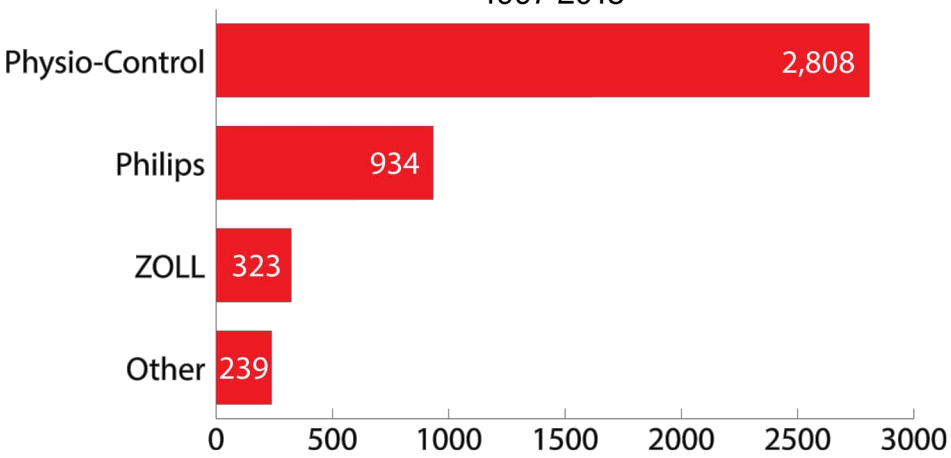
3. Not all patients convert at energy levels up to 200J. Clinicians are now using more targeted strategies for difficult-to-defibrillate patients.

4. Biphasic shocks at 360 joules have been shown to improve conversion rates.

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

Over the last 18 years of biphasic defibrillation research, 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. And this means confidence in technology when you need it most.

Published Research on Cardiac Arrest Patients Treated with Biphasic Shocks
1997-2015



*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.

1

When it comes to defibrillation, energy determines conversion rates, not current or any other single dimension of the shock.

Comparing modern biphasic waveforms to older monophasic waveforms no longer offers valuable clinical insight. What matters is how well your biphasic shocks work today. The fact is, high current alone, or any other singular aspect of the defibrillation shock, does not determine conversion rates. The evidence shows that 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 studies[1-5]

There are five independently conducted, peer-reviewed, clinical atrial fibrillation (AF) studies that compared conversion rates between biphasic truncated exponential waveforms (BTE) and ZOLL's rectelinear biphasic waveform (RBW). The same programmed energy settings resulted in the same conversion rates, regardless of the waveform or the amount of current. 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.

2

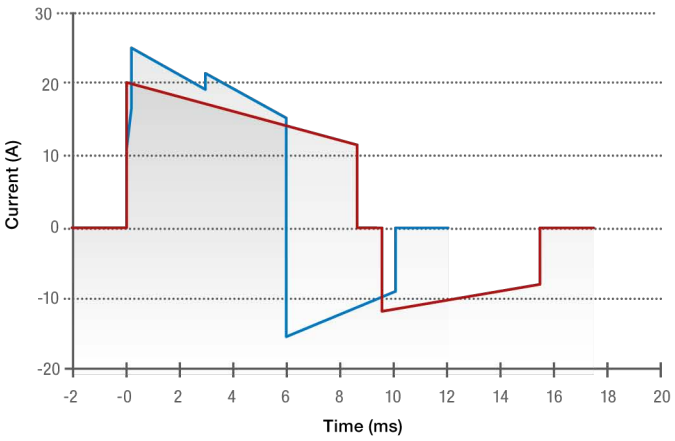
In terms of conversion rates, all biphasic waveforms are equivalent up to 200 joules.

Biphasic waveforms differ with respect to: peak current, how the current is maintained and how long the current is delivered. However, the cumulative output is measured as energy (joules). The same biphasic vs. biphasic studies that compared conversion rates between the biphasic truncated exponential waveform (BTE) and the ZOLL rectilinear biphasic waveform (RBW) showed that different levels of current, at the same programmed energies, did not produce different conversion rates. Rather, they were statistically equivalent at 100J, 150J and at 200 joules.[1-5] (Again), cumulative energy dictated the conversion rates, not peak current.

The evidence

Biphasic waveforms are equally effective at 200 joules

The level of current doesn't determine conversion rate[1, 2, 3]



Physio-Control

200 joules

96% efficacy

(184/192)

ZOLL

200 joules

96% efficacy

(188/195)

Three biphasic vs. biphasic clinical studies specifically compared 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.

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

It's no longer controversial, there is a difficult-to-defibrillate patient population. Clinicians are now using strategies to help patients in refractory VF, such as:

1. Defibrillation protocols starting at maximum energy settings
2. Alternative/additional pad placement using maximum energy settings
3. Taking intra-arrest patients directly to cath lab and bypassing the ED

Recent defibrillation research even shows that lower conversion rates from variations in pad placement can be overcome by using a higher defibrillation energy.[25] And a recent U.S. hospital survey showed that 59% of Electrophysiology Labs are using external defibrillators that can deliver 360J for rescue shocks.[26]

Further evidence

Only 8 of the 27 published reports cite first shock success rates greater than 90%,[6-13] others report success rates of 70% or less,[14-17] including our competitors' largest published data sets:

- Philips® (Kramer-Johansen, et al.[17]) = 70% efficacy
- ZOLL® (Stothert, et al.[14]) = 67% efficacy

Recurrent VF is common in patients with VF cardiac arrest, with studies reporting rates as high as 74%.[18,19] VF can become more difficult to terminate in later episodes.[18] A small subset of difficult-to-defibrillate patients accounts for the majority of failed shocks[18,19] 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

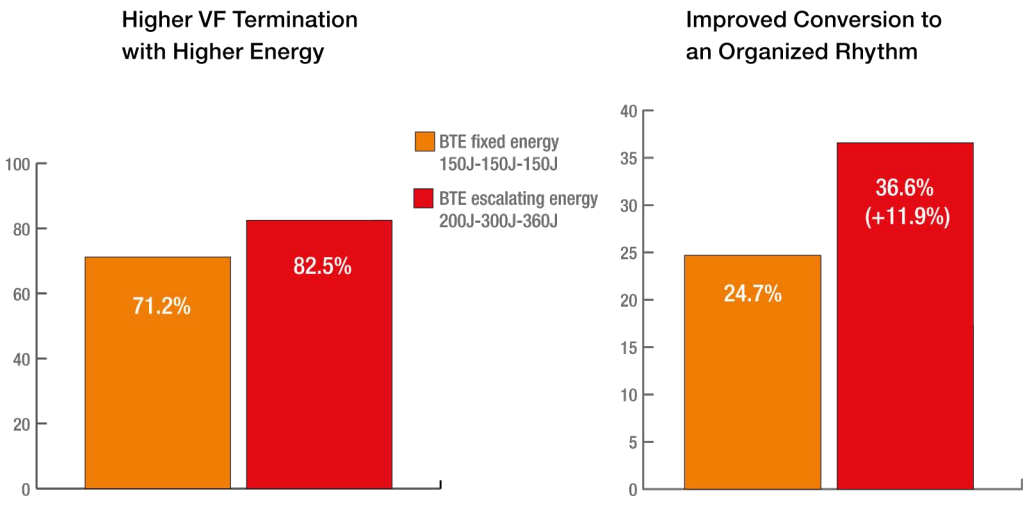
Biphasic shocks at 360 joules have been shown to improve conversion rates.

When low energy shocks fail, escalating 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[19,20,21] and AF[22,23] patients. In AF studies, looking at variable initial shock energies, a 360 joule shock was recommended when the first 200 joule shock failed,[23] since a second 200 joule shock is rarely effective.[3]

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.” (e73) [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.

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All claims valid as of October 2016.

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