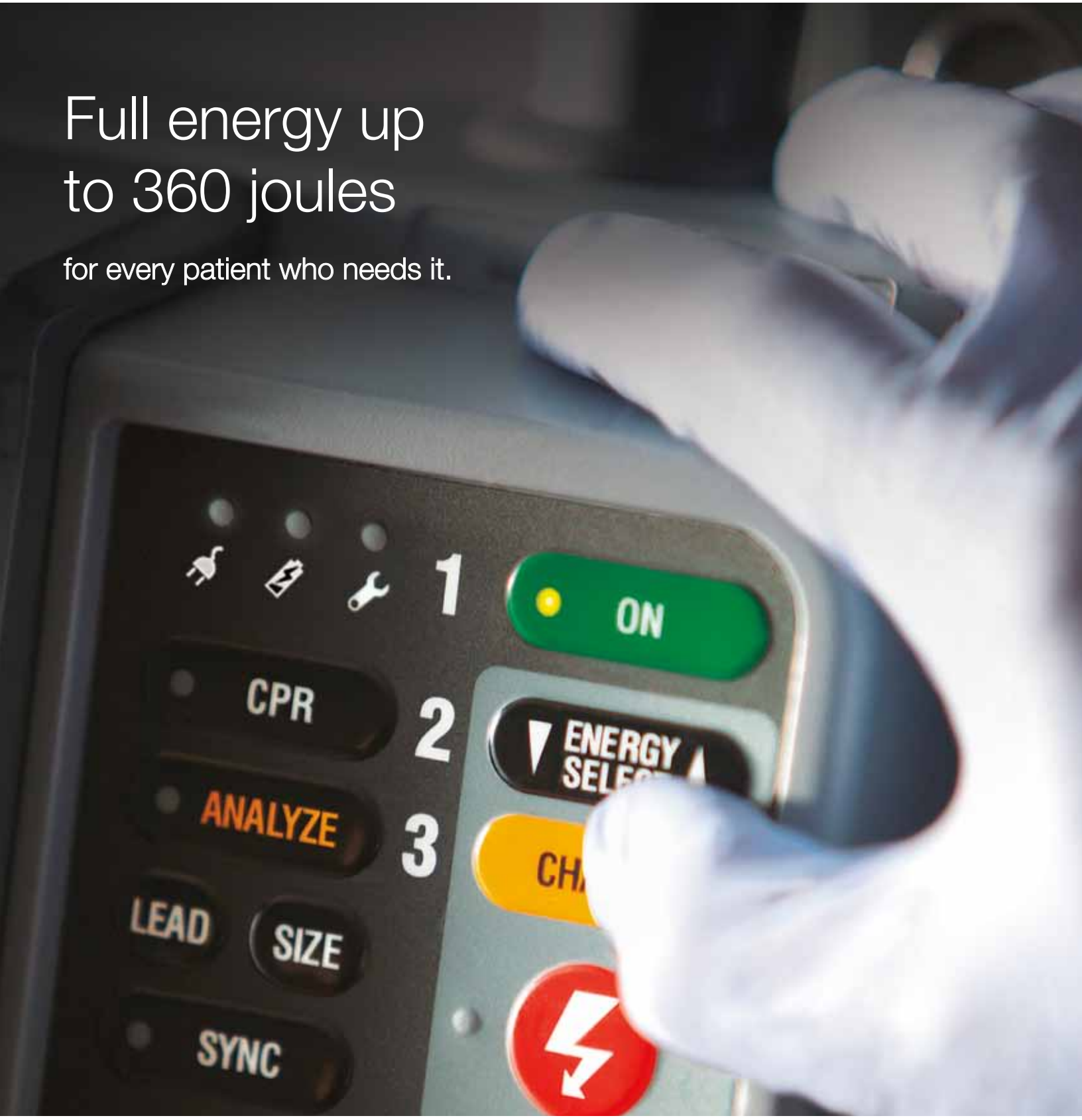
PHYSIO CONTROL

LIFEPAK® DEFIBRILLATORS

Full energy up to 360 joules

for every patient who needs it.

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Full energy up to 360 joules

for every patient who needs it.

All Physio-Control defibrillators deliver a full range of energy up to 360J—whether it's an AED in the hands of a school nurse or a defibrillator/monitor on a hospital crash cart or EMS rescue rig.

We build our defibrillators that way because solid clinical research shows that higher energy can improve shock success for cardiac arrest victims when low-energy shocks fail. No one can identify those hard-to-defibrillate patients ahead of time, so we make sure full energy is there every time you need it.

When transitioning to biphasic waveforms years ago, Physio-Control chose to maintain energy capability up to 360J, as we provided in our monophasic devices. Other manufacturers chose instead to lower the energy capability of their defibrillators. Our LIFEPAK defibrillators leverage both the improved efficacy of biphasic waveforms and their significantly lower risk of shock-related injury compared to monophasic waveforms. We believed then there was a clear clinical upside offered by biphasic defibrillators with extended defibrillation capability, and no clinically meaningful downside. After a decade has passed and extensive clinical research has been done, we believe it even more today.

Solid clinical research shows that higher energy can improve shock success for cardiac arrest victims when low-energy shocks fail.

You can't predict

which patients will be difficult to defibrillate.

Some patients are particularly difficult to defibrillate[1,2] or cardiovert[3,4,5,6]—and it's impossible to predict who they are. A great deal of data has been published during the past several years about patients treated with biphasic shocks, and especially with full energy (up to 360J) biphasic shocks.

A small subset of “difficult-to-defibrillate” patients accounts for the majority of failed shocks.[1,2] For these patients, it is especially important to have full energy capability, with levels up to 360 joules.

The optimal energy for first-shock biphasic waveform defibrillation has not been determined. The current AHA guidelines for CPR and Emergency Cardiovascular Care recommend using 120–200J for the initial biphasic shock, and also recommend that “second and subsequent energy levels should be at least equivalent and higher energy levels may be considered, if available.”[7] The current ERC guidelines state that “…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.”[8]

While some studies do report first shock VF termination rates of 90% or higher, others report rates of less than 75%.[9,10,11,12] Moreover, repeated episodes of VF are common in patients with VF cardiac arrest, with studies reporting rates as high as 74%.[1,2] VF can become more difficult to terminate in later episodes.[1] A small subset of “difficult-to-defibrillate” patients accounts for the majority of failed shocks.[1,2] For these patients, it is especially important to have full energy capability, with levels up to 360 joules.

The current AHA guidelines recommend using 120–200J for the initial biphasic shock, and then the same or higher energy for second and subsequent shocks.[7]

Failed shocks

are costly.

The 2010 AHA Guidelines re-emphasize the importance of quality CPR and minimization of interruptions in chest compressions. When shocks fail to terminate VF, the time patients spend in VF is prolonged, and additional interruptions in CPR are required to re-attempt defibrillation.

Evidence indicates that a greater percentage of time spent doing CPR is associated with a higher survival[13] to hospital discharge. However, the greater the number of failed shocks, the greater the number of interruptions in CPR required, directly reducing the percentage of time spent doing CPR.

Successful resuscitation is associated with higher Coronary Perfusion Pressure (CPP), but CPP drops off quickly when chest compressions are interrupted, whether the interruption is for ventilations as shown below, or to analyze the ECG and deliver a shock.

When compressions are paused it takes several compressions before CPP is restored

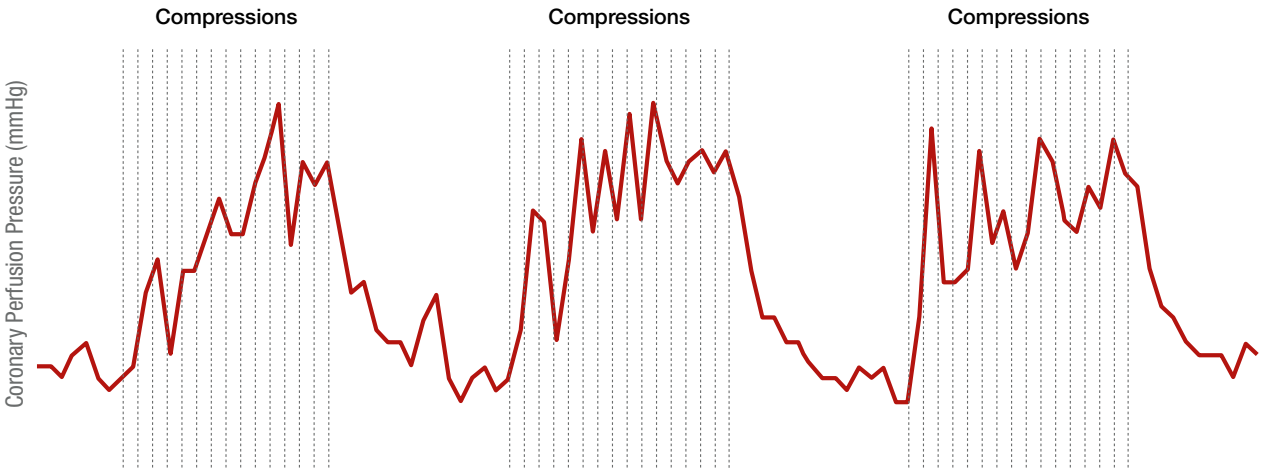


Figure 1. CPP decreases in swine when compressions are paused to deliver ventilations, and it takes several compressions of the next cycle before CPP is restored. Adapted from Berg et al. *Circulation* 2001;104:2465-2470.

Our approach is based

on sound evidence-based medicine.

Here's what it tells us...

Some patients are clearly more difficult to defibrillate[1,2] than others—yet no one can spot them ahead of time. Clinical studies report biphasic shock success in different populations of patients ranging from below 65% to higher than 90%.

Failed shocks carry a high cost, prolonging ventricular fibrillation (VF) and requiring additional interruptions in CPR to deliver additional defibrillation shocks.

Joule-for-joule there is no evidence showing a difference in effectiveness between different biphasic waveforms up to 200J.

Therefore...

Biphasic shocks escalating to 360J can improve shock success.[2,14]

There's hope

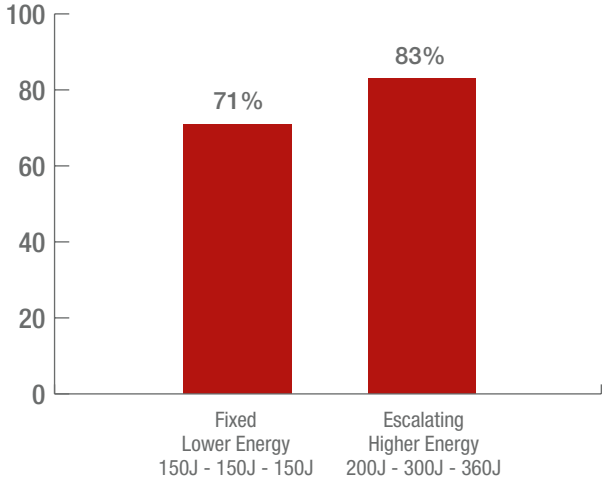
for challenging patients.

When low energy shocks fail, escalating energy to 360J improves shock success. The 2010 international guidelines for CPR and emergency cardiac care science with treatment recommendations 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."[15] Clinical data support full energy in both VF[1,2,14] and AF[3,6] patients. In AF studies looking at variable initial shock energies, a 360J shock was recommended when the first 200J shock failed,[6] since a second 200J shock is rarely effective.[16]

Benefits of escalating energy in multi-shock patients

A triple-blinded,[14] multi-center, randomized, controlled trial showed significantly higher rates of VF termination and conversion to an organized rhythm when energy was escalated to 360J rather than maintaining the same first shock dose in patients needing more than one shock.

Higher VF Termination with Higher Energy



Improved Conversion to an Organized Rhythm

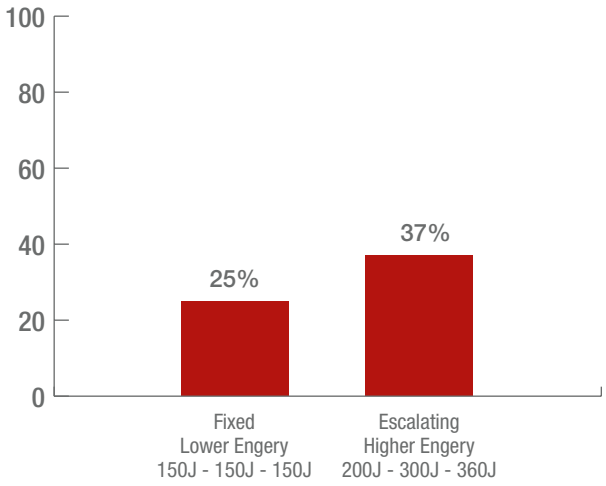


Figure 2. For patients requiring more than one shock, an escalating higher energy protocol provided significantly higher rates of VF termination and return to an organized rhythm, the primary endpoint. Stiell, et al, *Circulation* 2007;115:1511-1517

Repeating the same shock dosage after a failed first shock offers diminishing returns

In a large cohort of prehospital cardiac arrest patients, researchers found a 92% success rate for the first 200J shock vs. a significantly lower success rate (61%) for the second 200J shock.[1]

The effectiveness of energies up to 360J also has been demonstrated in a study of refractory AF,[3] which showed a trend of additional success with each successive escalating shock up to 360J.

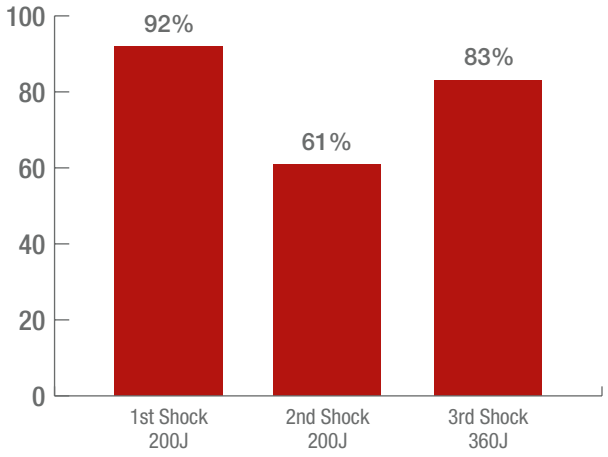


Figure 3. Repeating failed shocks lowers VF termination. Koster et al. *Resuscitation* 2008:78; 252-257.

Two studies of atrial fibrillation patients found that some patients failing to convert at 200J with another manufacturer's device were successfully converted at 360J using a Physio-Control device.[4,5]

The FDA is now evaluating the significance of 14 reports of events since 2006 in which a 200J biphasic defibrillator was ineffective and a subsequent shock from a different 360J biphasic defibrillator resulted in immediate defibrillation/cardioversion.

Claims that 360J is not needed lack firm clinical basis

Though much has been made of proprietary defibrillator waveform technology, no statistically significant clinical data exist to support claims that lower energy biphasic shocks are as effective as Physio-Control 360J biphasic shocks. In fact, two studies of AF patients found that some patients failing to convert at 200J with another manufacturer's device were successfully converted at 360J[4,5] using a Physio-Control device. In those studies, none of the patients who failed to convert at 360J were successfully cardioverted at the 200J maximum of the other device.

The FDA is now evaluating the significance of 14 reports of events since 2006 in which a 200J biphasic defibrillator was ineffective and a subsequent shock from a different 360J biphasic defibrillator resulted in immediate defibrillation/cardioversion. In an Initial Communication, the agency has encouraged healthcare providers to report similar events.[17]

Terminating fibrillation requires exposing enough of the heart to enough current for a long enough period of time. The larger capacitor in our LIFEPAK biphasic defibrillators holds a higher current longer, providing higher average current and delivering more energy compared to other manufacturers' products.[18]

Where joule-for-joule comparisons have been made—such as three independent randomized clinical studies,[4,5,15]— the Physio-Control® ADAPTIV™ biphasic waveform and ZOLL® biphasic waveforms have been shown to be equally effective at equal energy settings up to the 200J maximum of the ZOLL device. Waveforms could not be compared at higher energy levels because other manufacturers' devices have limited energy. (Similar studies have not been conducted to compare the Physio-Control waveforms and those of Philips,® another manufacturer whose devices are limited to 200J.)

Increase defibrillation

probability by increasing energy.

Further support for increasing energy up to 360J comes from a published analysis of the behavior of biphasic shocks from a large set of out-of-hospital cardiac arrest data.[2] The evidence indicates the only way to reliably increase the amount of current delivered to the heart by the next shock is to increase the energy setting. Shocking at the same dose does not move patients up the probability curve.

The study revealed that two common presumptions often invoked to support limited, low-energy defibrillation are not correct. Specifically, researchers found that delivery of a shock does not meaningfully decrease impedance for, or increase the current dose of, the next shock.[2] The study further showed defibrillation probability increased in parallel with each higher energy dose (82% at 200J, 86% at 300J, 90% at 360J) in patients who received shocks at each of the three energy levels. This observation is consistent with the well-established defibrillation dose-response relationship[18] and a wealth of prior clinical data.

Clinical studies of both AF[15] and VF[14] show no evidence of cardiac damage with full energy biphasic shocks, even when researchers specifically looked for it as evidenced by cardiac enzyme levels, heart ejection fractions and ECG ST-segment elevation.

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Defibrillation probability
increases with each energy dose

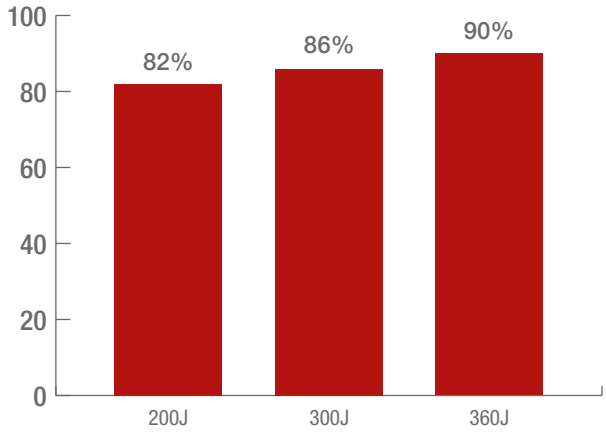

Figure 4. For patients in VF, defibrillation probability increases with each energy dose. Walker, et al, *Resuscitation* 2009;80:773-777.

Are you providing

consistent defibrillation therapy?

All cardiac arrest patients should have access to escalating energy up to 360 joules regardless of where they are in the healthcare system. Imagine a patient that arrests on the street, is transferred to a hospital cardiac cath lab and is resuscitated at 360J. Then he or she is transferred to the ICU and arrests again, where only a 200J defibrillator is available.

We believe there should be 360J energy capability throughout prehospital and hospital environments. And the flexibility to deliver the dose your patient needs.

Clinicians should set the dose—not manufacturers. Physio-Control LIFEPAK defibrillator/monitors give you the flexibility to escalate to full 360J energy wherever it's needed—whether cardiac arrest strikes a high school athlete on the field, an accident victim treated on the scene by paramedics or a hospital patient in surgical recovery.

While our competitors rely on complicated discussions of waveforms to justify their limited energy capability, we stand by the wealth of clinical data on biphasic shocks greater than 200J, most of which has emerged since the Guidelines 2005.

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

Visit www.360-joules.com

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