Current—not energy—defibrillates the heart.

ZOLL delivers the most current to high impedance patients.

Only ZOLL has proven clinical superiority.*
The ZOLL RBW Difference: Real Performance

ZOLL’s Rectilinear Biphasic™ waveform (RBW) was specifically designed for external defibrillation to control for variations in patient impedance. By delivering a constant amount of current, the ZOLL RBW delivers the right “dose” for every patient. At 200 J, the ZOLL RBW delivers more current to high impedance patients than any other biphasic device—even ones that escalate to 360 J.

Don’t Be Fooled by Energy: Current Defibrillates

“The essential requirement for electrical ventricular defibrillation is the attainment of a sufficient current density.”

Tacker WA⁶

“... defibrillation success correlates more strongly with average current than with delivered energy.”

Higgins et al. for the Physio-Control Biphasic Investigators⁷

Energy settings for biphasic waveforms can be confusing. When it comes to defibrillation, it is easy to think 360 J is better than 200 J. However, research has failed to show any clinical benefit from biphasic waveforms delivering more than 200 J of energy.

Why? Because higher energy settings do not necessarily increase current levels; sometimes they merely increase duration. And current—not energy, not duration—is what defibrillates.

So, is 360 J of energy better? Clearly not if it is only an illusion of more capability, created by manipulating waveform durations beyond the clinically-known optimum, without delivering more current.

And subscribing to old-fashioned thinking about energy may decrease effectiveness and increase the risk of myocardial dysfunction and damage.¹⁻³

What if there were a better way? A way to provide the optimal amount of current with less energy? A way to adjust the amount of current based on patient impedance? A way to improve efficacy while decreasing risk to the patient?

These improvements are what ZOLL’s superior Rectilinear Biphasic waveform is all about. The RBW is an exclusive ZOLL innovation that delivers more current than any other biphasic waveform, improving efficacy while reducing the risks associated with high energy.

The facts about the ZOLL RBW tell a compelling story of superior clinical performance.

Biphasic Defibrillation and the AHA/ILCOR Guidelines 2000

Guidelines 2000, developed by AHA, ERC, and ILCOR, are an evidence-based update to global resuscitation standards.

• A Class IIa recommendation is made for biphasic shocks of 200 J or less.
• Energy levels of biphasic shocks, as they apply to the Guidelines, are 200 J or lower.
• Defibrillation protocols vary with specific biphasic waveform employed.
• Biphasic shocks over 200 J are not addressed.

*See reference #14.
Higher energy settings artificially created by increasing waveform duration beyond the optimum are not the answer. . . . The approach runs the risk of a decrease in effectiveness, while at the same time increasing the risk of electroporation and myocardial dysfunction.

Plata EV 13

High Energy Does Not Mean More Current

In the diagram on the right, Waveform “B” has more energy than Waveform “A,” but actually delivers less current. Here's why: Energy (joules) is simply the work required to get current to the heart; it’s the product of three variables:

\[ \text{Joules} = \text{Voltage} \times \text{Current} \times \text{Time} \]

By extending duration (time), as in Waveform “B,” you can deliver more energy. But you only create the illusion of more capability because you have not necessarily delivered more current—or more efficacy.

Once duration extends beyond the optimum, more energy is required to achieve the same efficacy, while risk of post-shock myocardial dysfunction increases.9-11 That's why the ZOLL RBW has a fixed duration of 10 msec. ZOLL doesn't use longer durations to create the illusion of more energy because it does not result in greater efficacy.

The ZOLL RBW always starts with the most amount of voltage for any given energy setting, and then controls the delivery of current through a series of internal resistors. This means low impedance patients are not overdosed, while high impedance patients get the most possible current.

By delivering the right amount of current over the optimal duration, the ZOLL RBW provides superior performance.
The Most Clinical Evidence—The Only Superior Waveform

All biphasic waveforms are not superior to monophasic waveforms. The fact is, only the ZOLL RBW has demonstrated statistical clinical superiority to monophasic waveforms in peer-reviewed, randomized, controlled trials. And now, with data from more than 2,800 patients, you can feel secure in the strength of the RBW evidence.

Superiority for the Conversion of Ventricular Fibrillation

In multicenter, randomized EP lab studies, only the ZOLL RBW showed statistically significant improvement over a Monophasic Damped Sine (MDS) waveform with less energy. Other biphasic waveforms merely showed equivalency.

- 99% of patients were successfully defibrillated at 120 J with the ZOLL RBW on the first shock, as compared with 93% success for monophasic (p=0.05); 100% were defibrillated by a 150 J RBW shock.
- 100% of difficult-to-defibrillate patients (patient impedance > 90Ω) were successfully defibrillated by a 120 J ZOLL RBW shock versus only 63% success with MDS (p=0.02).

Superiority for Long-Duration Ventricular Fibrillation

In the largest retrospective study conducted on patients treated for out-of-hospital cardiac arrest, the superior performance of the ZOLL RBW was again demonstrated over monophasic waveforms.

- 40% increase in first-shock efficacy: 67% at 120 J for the RBW, versus 48% at 200 J for MDS (p<0.0025).
- Significant improvement in Return of Spontaneous Circulation (ROSC) with return to normal sinus rhythm: 25% for RBW versus 15% for MDS (p=0.05).
Superiority for Cardioversion of Atrial Fibrillation

Again, only the ZOLL RBW showed statistically significant improvement over MDS at every incremental energy level and for cumulative efficacy.19-21

- 68% of patients were cardioverted at 70 J with the ZOLL RBW on the first shock, as compared to only 21% of those receiving an MDS shock at 100 J (p=0.0001).
- There was a 19% increase in cumulative efficacy over MDS (94% vs. 79%, p=0.005).
- AF superiority has been confirmed in 4 separate clinical trials representing more than 1,200 patients.22-25

High Energy Offers No Benefit

In the only peer-reviewed randomized trial evaluating biphasic waveforms for AF cardioversion,26 Neal et al. compared a Biphasic Truncated Exponential (BTE) waveform with a maximum setting of 360 J, to the ZOLL RBW with a maximum setting of 200 J.

The trial failed to demonstrate any advantage for the 360 J BTE waveform in a series of 101 patients. At all energy levels tested—50 J, 100 J, and 200 J—the ZOLL RBW was shown to have greater efficacy than the BTE waveform.
Leadership in Defibrillation and Resuscitation

- The performance of ZOLL’s RBW has been confirmed in over a dozen clinical trials involving more than 2,800 patients.
- ZOLL’s RBW has the highest defibrillating current for patient impedance ≥75 ohms of any biphasic waveform, delivered over the optimal duration.
- Only ZOLL’s RBW has the clinical data to support labeling as clinically superior to monophasic waveforms for the cardioversion of AF, and the conversion of VF in high impedance patients.

References
13 Ibid.
27 FDA 510K Clearance 9800762.