# *The Heart of the Matter*

## What Really Defibrillates the Heart?

ZOLL MEDICAL CORPORATION 2015

### Introduction

*There has been a lot of discussion about "low-energy" biphasic defibrillation versus "high-energy" biphasic as well as average current versus peak current. This document is intended to provide clarity around the terminology by reviewing the scientific literature.*

### High Current or High Energy—Which One Matters?

*The term "low energy" has contributed to misunderstandings and has fueled a fear that "low energy" means less efficacy. In the case of the ZOLL Rectilinear Biphasic™ waveform, "low energy" actually means "high current" and "high efficacy."*

*The American Heart Association Scientific Guidelines for Resuscitation clearly state that "Modern defibrillators deliver current based on stored energy. Because it is accepted that defibrillation is accomplished by the passage of sufficient current through the heart, the concept of current-based defibrillation is appealing. Energy is a nonphysiologic descriptor of defibrillation despite its entrenchment in traditional jargon."*[1]

*All ZOLL defibrillators deliver a Rectilinear Biphasic waveform (RBW) that provides more current than the "high-energy" biphasic others use. This capability is particularly important for the difficult-to-defibrillate, high-impedance patient.*

*This "high-current" RBW is the only biphasic waveform that was developed specifically for external defibrillation. It has been studied extensively in over 7,000 patients and shown to be superior to monophasic. Both high- and low-energy biphasic truncated exponential (BTE) waveforms were adapted from internal defibrillation. The high-current ZOLL biphasic waveform is the only one that the FDA has cleared to claim superiority* over monophasic waveforms.*

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## The Scientific Evidence Is Clear

### RBW Is Superior* to Monophasic

The FDA has cleared ZOLL to label its biphasic waveform as superior to monophasic for defibrillation of **high-impedance ventricular fibrillation (VF) and cardioversion of atrial fibrillation (AF):**[2,3]

> "The data also demonstrate the superior efficacy of low-energy [ZOLL RBW] biphasic shocks compared to standard high-energy monophasic shocks in patients with high transthoracic impedance."

RBW has been studied in more than 7,000 patients in over 14 separate clinical trials.

### RBW Is Superior to BTE Biphasic in Pediatrics

"The ZOLL RLB [Rectilinear Biphasic] waveform provided a superior ability to defibrillate a porcine pediatric model in terms of energy dose per body weight (J/kg) and per heart weight (g) when compared to the Medtronic Physio-Control BTE waveform."[4]

### RBW Is Superior in Out-of-Hospital Cardiac Arrest

The ZOLL ORBIT trial represents the largest clinical trial on biphasic waveforms ever conducted for out-of-hospital cardiac arrest (OHCA). The ORBIT trial is the only OHCA study conducted in an ALS (Advanced Life Support) environment and the only biphasic study that included all presenting rhythms (not just VF or VT).[5]

> *The ORBIT results showed ZOLL RBW superior to monophasic in patients with shockable rhythms: 52% to 33.7%, P=0.01*

*The data demonstrate the equivalent efficacy of low-energy (aka, high-current) rectilinear biphasic shocks compared to standard high-energy monophasic shocks for transthoracic defibrillation for all patients at the 95% confidence level. The data also demonstrate the superior efficacy of low-energy rectilinear biphasic shocks compared to standard high-energy monophasic shocks in patients with high transthoracic impedance at the 90% confidence level. There were no unsafe outcomes or adverse events due to the use of the Rectilinear Biphasic waveform.

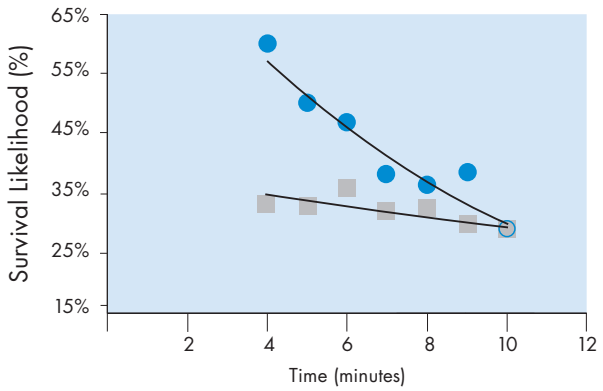

1. Link MS, Atkins DL, et al. Automated external defibrillators, defibrillation, cardioversion, and pacing. 2010 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. *Circulation*. 2010;122(suppl 3):S706 –S719.
2. Mittal, S, Ayati S, et al. Comparison of a rectilinear biphasic waveform with a damped sine wave monophasic waveform for transthoracic conversion of ventricular fibrillation. *J Am Coll Cardiol*. 1999;34(5):1595-601.
3. Mittal S, Ayati S, et al. Transthoracic cardioversion of atrial fibrillation: comparison of rectilinear biphasic versus damped sine wave monophasic shocks. *Circulation*. 2000;101:1282-1287.
4. W Tang, J Wang, C Young. Comparison of rectilinear biphasic defibrillation to biphasic truncated exponential defibrillation for pediatric cardiac life support in a porcine model. Abstract presented at Cardiostim 2004.
5. Morrison I, Dorian P, et al. Out-of-hospital cardiac arrest rectilinear biphasic to monophasic damped sine defibrillation waveforms with advanced life support intervention trial (ORBIT) *Resuscitation*. 2005;66:149-157.
6. Niebauer MJ, Brewer JE, et al. Comparison of rectilinear biphasic waveform with monophasic damped sine waveform for external cardioversion of atrial fibrillation and flutter. *Am J Cardiol*. 2004;93:1495-1499.

## RBW Is Superior for Long-Duration VF[5]

The ORBIT study also shows that ZOLL's RBW demonstrated even greater improvements over monophasic as downtimes decreased. In Figure 1, 24-hour survival is plotted as a function of downtime. The ZOLL biphasic waveform is the upper curve (circles), while the monophasic waveform is the lower curve (squares).

- Nearly double the survival rate at 4 min. downtime
- Relevant especially for AED defibrillation and in-hospital resuscitation

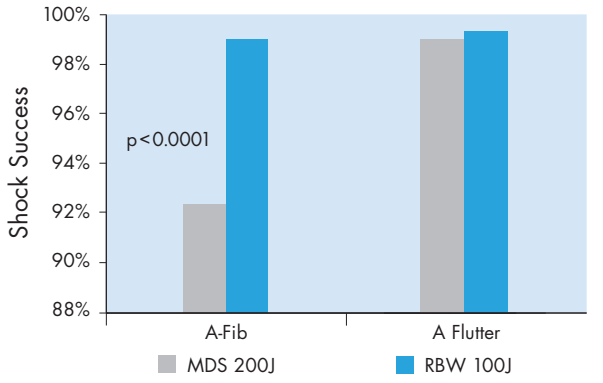
**Figure 1**




## RBW Is Superior for Cardioversion of Atrial Fibrillation[6]

In a study by Niebauer, et al. that included 4,000 external cardioversion procedures, the ZOLL RBW was more effective in terminating atrial fibrillation than a monophasic damped sine (MDS) waveform, 99.1% versus 92.4% (Figure 2). Both waveforms were equally effective in terminating atrial flutter.

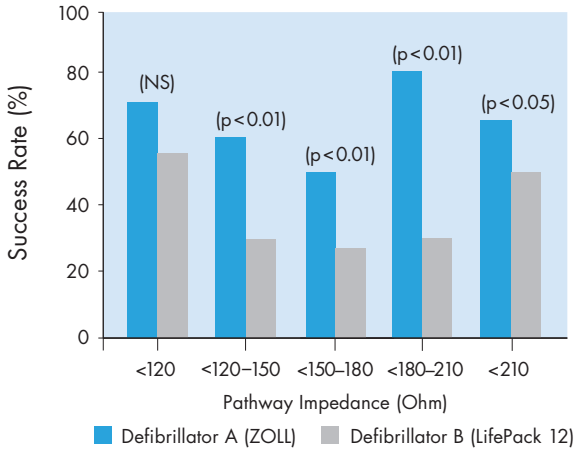
**Figure 2**




## RBW Is Superior for High-Impedance Patients[7]

A 2009 study compared impedance compensation techniques in two defibrillators. Defibrillator A used RBW and controlled current with fixed shock duration, while defibrillator B used a BTE waveform and prolonged the shock duration. The current-based technique was more effective, as shown in Figure 3.

**Figure 3**



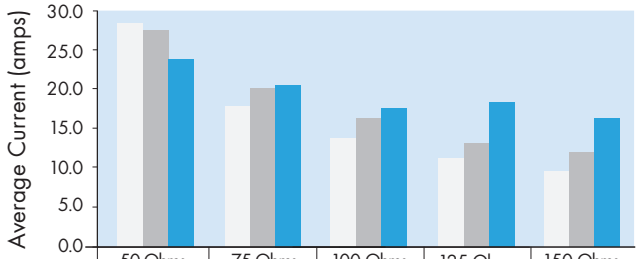

## RBW Is Superior in Obese Patients[8]

In 140 obese patients weighing more than 135 kg (range: 155 kg – 194 kg), all patients were successfully cardioverted and the average energy required was less than 200 joules (J).

## RBW Delivers More Current

Figure 4 shows a comparison of the average current delivered at maximum energy by various defibrillators.

**Figure 4**




| | 50 Ohms | 75 Ohms | 100 Ohms | 125 Ohms | 150 Ohms |
|---|---|---|---|---|---|
| Philips 200J | 28.2 | 17.8 | 13.6 | 10.7 | 9.5 |
| Physio 360J | 27.5 | 20.0 | 15.9 | 13.5 | 11.5 |
| ZOLL R 200J | 24.0 | 20.5 | 17.3 | 18.0 | 16 |


7. Li Y, Ristagno, G et al. A comparison of defibrillation efficacy between different impedance compensation techniques in high impedance porcine model. *Resuscitation*. 2009;80:1312-1317.
8. Niebauer MJ, Brewer JE, et al. Rectilinear biphasic: defibrillation of patients with weight greater than 100 Kg. Abstract from the 7th Congress of the ERC. 2004.
9. Ristagno G, Yu T, et al. Current is better than energy as a predictor of shock success for biphasic defibrillation shocks in a porcine model of ventricular fibrillation. *Resuscitation*. 2013;84:678-683.
10. Chen B, Yu T, et al. Average current is better than peak current as therapeutic dosage for biphasic waveforms in a ventricular fibrillation pig model of cardiac arrest. *Resuscitation*. 2014;85(10:1399-1404.
11. Stiell IG, Walker RJ, et al. BIPHASIC Trial. A Randomized Comparison of Fixed Lower Versus Escalating. *Circulation*. 2007;115(12):1511-7.
12. Koster RW, Walker RD, van Alem AP. Definition of successful defibrillation. *Crit. Care Med*. 2006 Dec;34 (12 Suppl):S423-6.
13. Stothert JC, Hatcher TS, et al. Rectilinear biphasic waveform defibrillation of out of hospital cardiac arrest *Pre-hospital Emergency Care*. 2004;8(4):388-92.
14. Edelson DP, Abella BS, Kramer-Johansen J, et al. Effects of compression depth and pre-shock pauses predict defibrillation failure during cardiac arrest *Resuscitation*. 2006;71:137-145.
15. Kramer-Johansen, J, Myklebust H, et al. Quality of out-of-hospital cardiopulmonary resuscitation with real time automated feedback: A prospective interventional study *Resuscitation*. 2006;71:283-292.

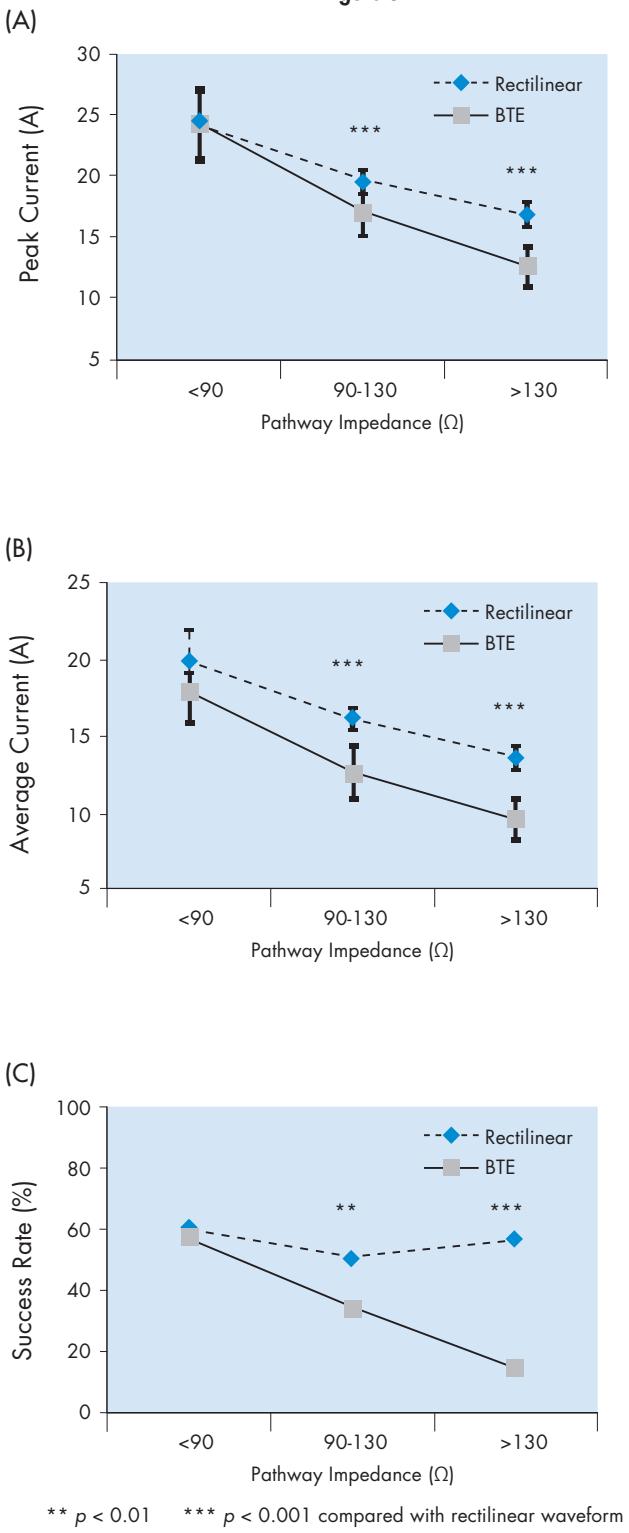
## Average Current Versus Peak Current—Which Matters Most?

Two recent studies, one by Ristagno, et al.[9] and one by Chen, et al.[10] showed that average current is better than peak current as a therapeutic dosage for biphasic waveforms during VF. The Chen paper involved two separate protocols: Study A and Study B. This study compared a defibrillator using RBW to one utilizing the BTE waveform, where impedance levels ranged from 49 to 184 ohms. The RBW delivered more peak current and more average current but less energy, as shown in Figures 5A and 5B. The success rate of converting ventricular fibrillation was significantly higher, at 55% versus 30.7% (Figure 5C).

This paper also reported that the success rate of VF conversion was significantly lower with the BTE waveform when the impedance was over 90 ohms (24% versus 57.1%). Study B was limited to BTE waveforms, and it suggested that extending both a wide and narrow BTE waveform duration to achieve higher energy delivered may contribute to the reduction in shock success due to the decreased average current. Although RBW was not included in this part of the study, it is important to note that RBW does not alter the duration; therefore, it is not a factor when using a defibrillator with RBW.

Because the RBW peak current is very close to the average current in the leading pulse, both can be used to predict shock success. BTE waveforms have an average current that is significantly lower than peak current, especially when the impendance falls below 90 ohms, so only average current can be used as a predictor of shock success.

**Figure 5**




** $p < 0.01$ *** $p < 0.001$ compared with rectilinear waveform

16. White RD, Hankins DG, et al. Patient outcomes following defibrillation with a low energy biphasic truncated exponential waveform in out of hospital cardiac arrest. *Resuscitation*. 2001;49(1):9-14.

17. Schneider T, Maartens PR, 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 cardiac arrest victims. *Circulation*. 2000;102:1780-1787.

18. Koster RW, Walker RG, Chapman FW. Recurrent ventricular fibrillation during advanced life support care of patients with prehospital cardiac arrest. *Resuscitation*. 2008;78:252-257.

19. Walker RG, Koster RW, et al .Defibrillation probability and impedance change between shocks during resuscitation from out-of-hospital cardiac arrest. *Resuscitation*. 2009;80:773-777.

## Some Statements Require a Second Look

### No One Type of Waveform Is More Effective than Another Up to 200 J

ZOLL's RBW delivers significantly more current than high-energy biphasic up to 200 J. ZOLL delivers more current at 200 J than high-energy defibrillators deliver at 360 J.

### A Biphasic Device that Can Reach 360 J Can Increase Rates of VF/VT Termination

A study by Stiell, et al. generally cited as proof of this compares only suboptimal dosing with a high-energy waveform starting at 150 J versus a high-energy waveform at escalating energy beginning at 200 J.[11] The correct adult dose for high-energy biphasic defibrillation is 200 J, 300 J, 360 J.

This study demonstrates that when giving multiple shocks with a high-energy defibrillator, you should to be using a protocol of 200 J, 300 J, and 360 J and should not reduce the dose below effective levels.

### Now that Biphasic Shocks Are More Widely Used, Clinical Data Show that Biphasic Shocks Are Not as Successful as Previously Reported, with Many Systems Reporting Shock Success of <75%[12]

Studies showing first-shock success rates below 75% combine both in-hospital and OHCA data—mixing two very different patient populations—or comparison data against monophasic in a single population.[13, 14, 15]

In addition, studies cited with lower efficacy include patients presenting in asystole and PEA who are returned to a shockable rhythm. Studies showing 92%-plus efficacy are all in OHCA patients presenting in VF.[16, 17, 18]

### Repeating the Same Shock Dosage after a First Shock Failed Offers Diminishing Returns While Escalating Increases Success[11]

The supporting data, which was not statistically significant, only compares a high-energy waveform at 200 J, not a high-current waveform. Two hundred-joule high-energy waveforms deliver significantly less current than the 200-J ZOLL high-current RBW.

### In VF Defibrillation, the Probability of Success Increases with Each Increase in Energy[18, 19]

Defibrillation likelihood increases not because of increased energy, but increased current. A 200-J high-energy waveform delivers an amount of current similar to a ZOLL defibrillator that delivers 120 joules. As you escalate ZOLL's high-current waveform from 120 to 200 J, you are stepping up current in the same fashion, and in the end, delivering more current.

### Independent Studies Show the Efficacy of High-Energy Defibrillation in Atrial Fibrillation

None of the studies typically cited shows a statistically significant difference in outcomes, yet there are definite shock protocol differences:

**Kim:** 4 shocks RBW, 5 shocks BTE on crossover—no reverse crossover data available. Successful cardioversion may only be the next shock away.[20]

**Alatawi:** 6 shocks RBW, 8 shocks BTE before crossover—difference clearly stated as NOT significant.[21]

**Neal:** All patients who received the RBW converted by the first 200-J shock—one patient failed 360 J (fifth shock) and did not convert with 200 J. Conversion required simultaneous 200-J shocks from both defibrillators.[22]

**Khaykin:** This study compares the monophasic waveform to the high-energy biphasic waveform; it does not compare it to low-energy biphasic.[23] It demonstrates that to achieve maximum efficacy with a high-energy defibrillator, you need to go to 360 J.

### BTE Delivers More Peak Current than RBW

The study by Chen, et al. shows that BTE waveforms have a lower average current than peak current—it is average current that is better for therapeutic dosage.[9] RBW has similar average and peak currents.

### Conclusion

Biphasic defibrillators on the market today still use energy as a descriptor for therapeutic doses, despite the fact that it is known that it is current that defibrillates the heart, a fact that is not likely to change in the near future. Therefore, it is important to understand that the RBW used in all ZOLL defibrillators provides the most current available, with peak and average current rates approximately the same values.

20. Kim ML, Kim SG, et al. Comparison of rectilinear biphasic waveform energy versus truncated exponential biphasic waveform energy for transthoracic cardioversion of atrial fibrillation *American Journal of Cardiology*, 2004;94(11):1438-40.

21. Alatawi F, Gurevitz O, 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.

22. Neal S, Ngarmukos T, et al. Comparison of the efficacy and safety of two biphasic defibrillator waveforms for the conversion of atrial fibrillation to sinus rhythm. *Am J Cardiol*. 2003;92:810-814.

23. Khaykin Y, Newman D, et al. Biphasic versus monophasic cardioversion in shock resistant Atrial Fibrillation. *J Cardiovasc Electrophysiology*. 2003;14:862-872.