

# *The Heart of the Matter*

## Current is key for defibrillating the heart

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### 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, including peer-reviewed published articles in reputable journals.

### 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, despite a “lower energy,” a “high current” is delivered, which is the key determinant in ensuring a high shock 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 non-physiologic descriptor of defibrillation despite its entrenchment in traditional jargon.”<sup>1</sup>**

ZOLL defibrillators with a Rectilinear Biphasic waveform (RBW) provide more current than the “high-energy” biphasic waveforms used by others. 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 the monophasic waveform. Both high- and low-energy biphasic truncated exponential (BTE) waveforms were adapted from internal defibrillation devices. The high-current ZOLL biphasic waveform is the only one that the FDA has cleared to claim superiority\* over monophasic waveforms.

### The Scientific Evidence Is Clear

#### RBW is superior\* to monophasic

The FDA has approved ZOLL to label its biphasic waveform as superior to monophasic for defibrillation of **high-impedance ventricular fibrillation (VF) and cardioversion of atrial fibrillation (AF)**.<sup>2,3</sup>

“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 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).<sup>4</sup>

*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. [https://www.accessdata.fda.gov/cdrh\\_docs/pdf16/P160022B.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160022B.pdf)

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.

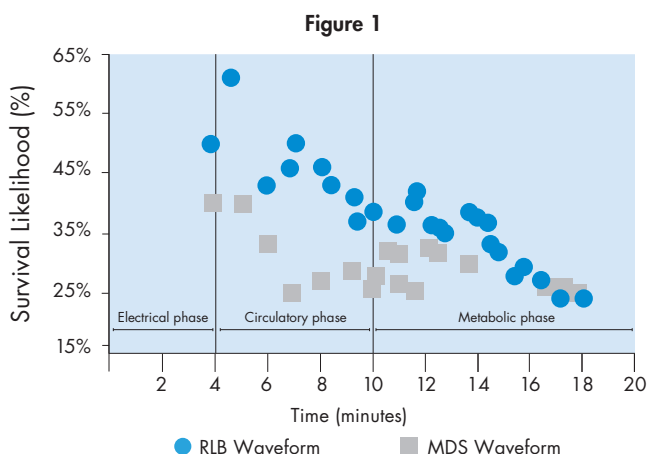
3. Mittal S, Ayati S, et al. Transthoracic cardioversion of atrial fibrillation: comparison of rectilinear biphasic versus damped sine wave monophasic shocks. *Circulation*. 2000;101:1282-1287.

4. 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.

### RBW is superior for long-duration VF<sup>4</sup>

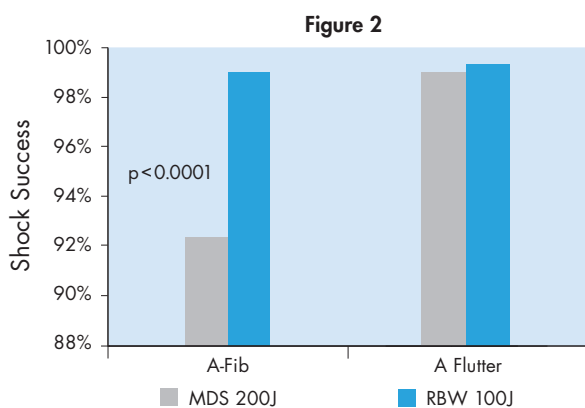
The ORBIT study also shows that ZOLL's RBW demonstrated even greater improvements over monophasic as downtimes decreased. In Figure 1, 24-hour survival (Y axis) is plotted as a function of downtime (X axis), which is the time interval from witnessed collapse to arrival at patient's side. The ZOLL biphasic waveform is the upper curve (circles), while the monophasic waveform is the lower curve (squares).

- RBW is associated with a higher survival rate for up to 10 minutes
- Relevant especially for AED defibrillation and in-hospital resuscitation



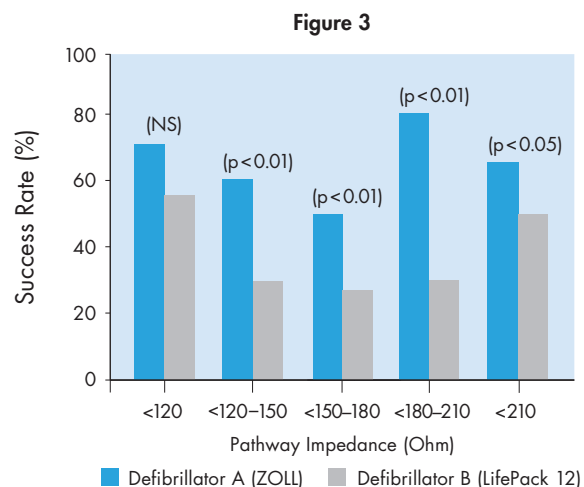
### RBW is superior for cardioversion of atrial fibrillation to monophasic waveform<sup>5</sup>

In a study (Niebauer, et al.<sup>5</sup>) that included ~4,000 external cardioversion procedures in patients, 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.



### RBW is superior for high trans-thoracic impedance<sup>6</sup>

A 2009 experimental study<sup>6</sup> 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 RBW waveform was more effective, as shown in Figure 3.



### RBW is as effective or more effective for cardioversion of atrial fibrillation when compared to other manufacturer waveforms

In 2013, Deakin, et al.<sup>7</sup> published a study where consecutive patients undergoing elective cardioversion for AF were randomized to treatment with ZOLL's RBW or Philips' biphasic truncated exponential waveform (BTEW), using an escalating energy protocol (50 J, 100 J, 150 J, 200 J, 200 J). A median of 2 shocks were required to achieve sinus rhythm with the RBW vs. 3 shocks with the BTEW (p=0.059). In the RBW group, 95.0% of patients achieved sinus rhythm after a maximum of 5 shocks as compared with 90.9% in the BTEW group, although patients in the BTEW group required on average 117.1 J more energy to achieve sinus rhythm compared with the RBW group (p=0.838). For patients whose transthoracic impedance exceeded 115 Ohms, RBW was successful 97.1% in achieving normal sinus rhythm, as compared to 66.7% in the BTEW group.

### RBW delivers more current

Figure 4 shows results from bench tests comparing the average current delivered at the maximum energy by various defibrillators across a wide variety of impedances. The ZOLL RBW delivers more current from 75-150  $\Omega$ , which is representative of a majority of patient trans-thoracic impedances.<sup>4,6</sup>

5. 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.

6. 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.

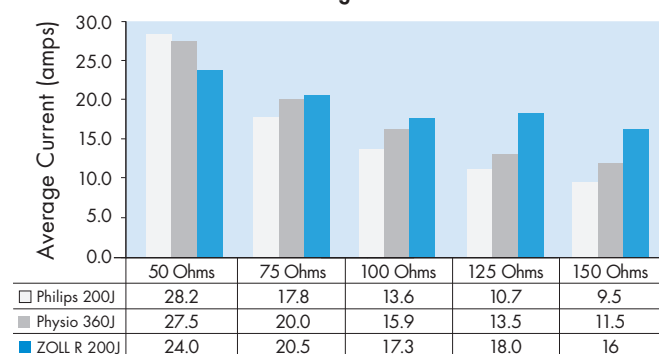
7. Deakin CD, Connolly S, Wharton R, Yuen HM. A comparison of rectilinear and truncated exponential biphasic waveforms in elective cardioversion of atrial fibrillation: a prospective randomized controlled trial. *Resuscitation*. 2013 Mar;84(3):286-91.

8. 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.

9. 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.

10. Stiell IG, Walker RJ, et al. BIPHASIC Trial. A Randomized Comparison of Fixed Lower Versus Escalating. *Circulation*. 2007;115(12):1511-7.

Figure 4



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

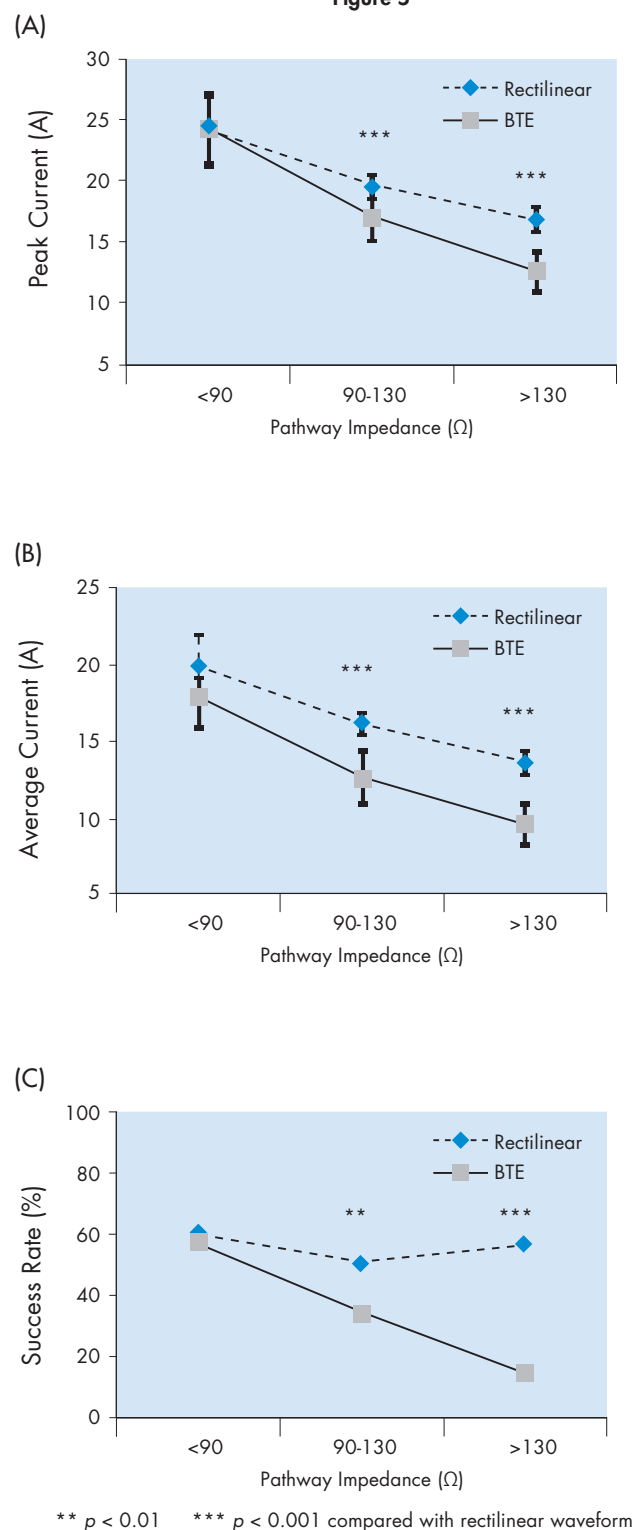
Two recent experimental studies, one by Ristagno, et al.<sup>8</sup> and one by Chen, et al.<sup>9</sup> showed that average current is more effective than peak current as a therapeutic dosage for biphasic waveforms during VF. The Chen paper involved two separate protocols: Study A and Study B. Study A compared a defibrillator using RBVW to one utilizing the BTE waveform, where impedance levels ranged from 49 to 184 ohms. The RBVW delivered more peak current and more average current, as shown in Figures 5A and 5B. The success rate of converting ventricular fibrillation was significantly higher with RBVW, at 55% versus 30.7% ( $p < 0.001$ ) (Figure 5C). Importantly, this was despite the RBVW delivering significantly less energy compared to the BTE waveform ( $77.3 \pm 21.2$  J vs.  $83.3 \pm 31.1$  J,  $p = 0.001$ ). 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 only, and it again showed that extending both a wide and narrow BTE waveform duration to achieve a higher delivered energy ( $188.3 \pm 56.9$  J vs.  $145.3 \pm 42.1$  J,  $p < 0.001$ ) actually contributed to a reduction in shock success (38.8% vs. 67.9%,  $p < 0.001$ ), partly due to the decreased average current associated with the higher energy ( $12.1 \pm 1.5$  A vs.  $13.3 \pm 1.9$  A,  $p < 0.001$ ). Although RBVW was not included in this part of the study, it is important to note that RBVW does not alter the duration of shock; therefore, it is not a factor when using a defibrillator with RBVW.

Because the RBVW 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 impedance falls below 90 ohms, so only average current can be used as a predictor of shock success.

To summarize, an important contribution of both Studies A & B from the Chen paper was to clearly demonstrate that a higher energy does not equate to a higher shock success; in fact, the opposite was true, **that the key variable underlying shock success was the average current delivered.**

Figure 5



11. 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.

12. 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.

13. 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.

14. 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.

15. 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.

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

## 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 up to 200 J than compared to high energy biphasic defibrillators which escalate to 360 J. In fact, the RBW delivers more current at 200 J than other defibrillators do at 360 J. This is demonstrated by the previously mentioned bench test data.

### A biphasic device that can reach 360 J can increase rates of VF/VT termination

A study by Stiell, et al.<sup>10</sup>, generally cited as proof of this, used a high-energy BTE waveform defibrillator and compared a fixed energy dose regimen (150-150-150 J) versus an escalating one (200-300-360 J) for OHCA patients and found the latter to be more efficient. However, it is important to remember that these results are only applicable when using a high-energy BTE waveform defibrillator and are not applicable or comparable to the RBW waveform. **The RBW waveform delivers more current than the other waveforms, and experimental data supports current, not energy, as the key determinant of shock success.**<sup>9</sup>

### In VF defibrillation, the probability of success increases with each increase in energy<sup>11,12</sup>

**Defibrillation likelihood increases not because of increased energy, but increased current.** A 200 J shock from a high-energy, BTE waveform defibrillator delivers an amount of current similar to a ZOLL defibrillator that delivers 120 J. 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, which has been shown to be the key determinant shock success, rather than energy.<sup>9</sup>

### 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.<sup>13</sup>

**Alatawi:** 6 shocks RBW, 8 shocks BTE before crossover—difference clearly stated as NOT significant.<sup>14</sup>

**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.<sup>15</sup>

**Khaykin:** This study compares the monophasic waveform to the high-energy biphasic waveform; it does not compare it to low-energy biphasic.<sup>16</sup> 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.<sup>9</sup> 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 data demonstrating that current is a key determinant in underlying defibrillation success. Therefore, it is important to highlight that the RBW used in all ZOLL defibrillators provides the most current available, with peak and average current having approximately the same values, unlike the competitors' waveforms.