

# ACLS Defibrillation Protocols

## *With the ZOLL® Rectilinear Biphasic Waveform*

### AHA/ERC Guidelines 2005

#### Introduction:

The purpose of this document is to outline the equivalent biphasic protocols specific to the ZOLL Rectilinear Biphasic waveform.

	Monophasic				ZOLL Biphasic				
Defibrillation	200J	300J	360J	360J	120J	150J	200J	200J	
Synchronized Cardioversion	100J	200J	300J	360J	75J** 70J*	120J	150J	200J	
Pediatric Defibrillation	2J/kg				2J/kg				
Internal Defibrillation	Maximum of 50J				5J	10J	20J	30J	50J

\*\* M Series, CCT, R Series

\* E Series

The recommendations for synchronized cardioversion and defibrillation protocols are based upon evidence presented in two prospective randomized clinical trials and the American Heart Association Guidelines 2005.

#### Defibrillation

Historically, defibrillator shocks evolved to a monophasic protocol of 200-300-360J to balance the need for increased ‘strength’ to convert a rhythm from ventricular fibrillation against the potential to damage cardiac tissue with too much current. ZOLL’s Rectilinear Biphasic waveform (RBW) was designed with internal resistors to *control* impedance so that low impedance patients are not ‘overdosed’ (i.e. more equipment resistors are engaged and the amount of current delivered to a low impedance patient is reduced) and high impedance patients get the maximum possible current. The initial biphasic protocol of 120J-150J-200J for the Rectilinear Biphasic waveform was chosen based on data from a prospective, randomized, clinical trial (Mittal et al JACC 1999 24:1595-1601) which showed 99% first shock

efficacy at 120J, and 100% efficacy at 150J. Based on this data, the 200J shock represents a safety margin.

Recent recommendations with ERC and AHA Guidelines suggest that rescue sequences with defibrillation move away from the concept of three stacked shocks to a sequence of single shocks with CPR between each shock. The logic for this recommendation is that stacked shocks result in too much 'hands off' time, during which chest compressions are not performed. Recent experimental data suggests that maximizing the amount of time compressions are performed along with quality of compressions will have the most significant impact on survival. The new Guidelines do not alter the recommended defibrillation protocol for the ZOLL Rectilinear Biphasic waveform. In fact, the efficacy of the ZOLL RBW is specifically incorporated by reference.

### Synchronized Cardioversion

In a randomized multi-center trial<sup>1</sup>, the data demonstrated superior results using the ZOLL Rectilinear Biphasic waveform as compared to the monophasic waveform for both first shock and cumulative efficacy. There was a significant difference between the first shock efficacy of biphasic shocks at 70J of 68% and that of monophasic shocks at 100J of 21% ( $p=0.0001$ , 95% confidence interval of the difference of 34.1% to 60.7%). The results from this clinical trial therefore provide evidence to use 70J-120J-150J-200J for E Series and 75J-120J-150J-200J as the recommended biphasic equivalent for any synchronized cardioversion procedure using the ZOLL Rectilinear Biphasic waveform. Following the publication of this article, additional abstracts have also been presented showing statistically significant improvement over monophasic with energy settings as low as 5J with the ZOLL Rectilinear Biphasic waveform<sup>2, 3, 4</sup>

### Pediatric Defibrillation

The ZOLL Rectilinear Biphasic waveform has also been approved by the FDA for use in pediatric patients and for internal defibrillation. Defibrillation protocols for these uses are based on observational studies and animal testing. Results are summarized below.

FDA approval for the use of ZOLL's RBW technology on pediatrics was based on the results from *A Comparative Biphasic Defibrillation Study for Pediatric Dosing Levels Using a Porcine Model*. This study demonstrates the safety and efficacy of this waveform on pediatric patients, and supports a defibrillation protocol of 2J/kg. Although this is the same protocol as used with monophasic waveforms, pediatric patients will benefit from a reduced possibility of myocardial dysfunction associated with the use of biphasic waveforms, which deliver less peak current than monophasic waveforms.

## Internal Defibrillation

The use of ZOLL's RBW technology for internal defibrillation has also been cleared by the FDA. A shock sequence of 5J, 10J, 20J, 30J and 50J was used in an observational study. First shock success rate was 90% for 5J. In addition to the clinical data, customers should also be made aware that anecdotal stories suggest that internal shocks delivered with the ZOLL RBW do not cause as much movement when the shock is delivered as was seen with monophasic waveforms. This should not be confused with failure to deliver the shock. If the heart does not restart after the initial shock, additional shocks with incremental energy levels should be delivered until conversion is achieved.

## Other Arrhythmias

The use of the ZOLL Rectilinear Biphasic waveform has not been studied in randomized prospective clinical trials for all types of arrhythmias covered by ACLS algorithms. Nonetheless, the following factors support using the biphasic energy equivalents for either Synchronized Cardioversion or Defibrillation as required:

1. All ACLS algorithms which refer to electrical conversion specify either synchronized cardioversion or defibrillation, depending on the specific rhythm, and evidence for the ZOLL Rectilinear Biphasic waveform exists for both synchronized cardioversion and defibrillation.
2. The ZOLL Rectilinear Biphasic waveform has been documented as clinically equivalent or superior (in accordance with the AHA recommendation that the upper boundary of the 90% confidence interval of the difference between standard and alternative waveforms must be  $<0\%^5$ ) to reports of monophasic shock success in two separate prospective randomized clinical trials.

Note: The clinical results for the ZOLL Rectilinear Biphasic waveform are based upon the use of ZOLL Multi-Function electrodes. The combination of RBW waveform, ZOLL electrode properties and gel characteristics achieve efficacy results as described above. There is no data to support equivalent claims with non-ZOLL electrodes.

## Observational Study for Direct Ventricular Defibrillation during Open Heart Surgery

**Overview:** A clinical study was performed to demonstrate the safety and efficacy of the RLB waveform when the waveform was applied directly to hearts in ventricular fibrillation (VF) during open heart surgery. There were 20 patients enrolled in the study. All patients were classified as NYHA class III, had significant coronary artery disease (CAD), and underwent coronary artery bypass graft (CABG) surgery as the method of treatment. One or more RLB waveform shocks were applied directly to the heart if VF occurred. The RLB shock sequence was 5 J, 10 J, 20 J, 30 J, and 50 J. Shock energies were applied in sequence until defibrillation occurred.

**Results:** All patients were successfully defibrillated with a selected shock energy less than or equal to 20 J. The first shock defibrillation success rate at the initial energy selection of 5 J was 90% (18/20) compared to the reported cumulative success rate for the BTE waveform of 50% (25/50) at 5 J<sup>1</sup>. The threshold energy was  $6.0 \pm 3.5$  J, the cumulative energy was  $7.0 \pm 7.0$  J, and the average number of shocks was  $1.2 \pm 0.5$  shocks. No patient experienced abnormal left ventricular wall motion at any time and all patients were defibrillated to normal sinus rhythm.

<sup>1</sup> Schwarz B, Bowdle TA, Jett GK, Mair P, Lindher KH, Aldea GS, Lazzara RG, O'Grady SG, Schmitt PW, Walker RG, Chapman FW Tacker WA, Biphasic shocks compared with monophasic damped sine wave shocks for direct ventricular defibrillation during open heart surgery, *Anesthesiology* 2003; 98: 1063.

## **A Comparative Biphasic Defibrillation Study For Pediatric Dosing Levels Using A Porcine Model**

**Overview.** The safety and efficacy of the ZOLL Rectilinear Biphasic(RLB) waveform was evaluated as the defibrillation shock in an external defibrillator (ZOLL Medical M-Series) to defibrillate young children « 8 years old) presenting in ventricular fibrillation(VF)or hemodynamically unstable ventricular tachyarrhythmias (*VT*). The study compared the ZOLL Medical rectilinear biphasic (RLB) waveform with a biphasic truncated exponential (BTE)waveform.1-3 The study, using an immature porcine model, was a prospective, randomized, controlled, cross-over design to determine the dose response curves for the RIB and BTE defibrillation waveforms. A weight range from 4 to 24 Kg for an animal represented a pediatric patient. The weight ranging from 4 to 8 Kg represented a patient less than 1 year old (infant subgroup), and the weight range from 16 to 24 Kg represented a pediatric patient between the ages of 2 and 8 years (young children subgroup).

**Objectives.** The primary objective of the study was to demonstrate that an RIB shock has superior performance with equivalent safety when compared to a BTE shock in a porcine model for young children. An additional objective was to compare the defibrillation thresholds at a 50% (D50) and 90% (D90) probability of success for the external RLB and BTE defibrillation waveforms.

**Intended Use.** The RLB waveform will be used as the defibrillation shock in external defibrillators manufactured by ZOLL Medical Corporation to defibrillate young children « 8 years old) presenting with VF or *VT*. The RLB waveform defibrillator will be used to defibrillate these children with appropriate dosing levels, as determined from previous work and the present study.

## References

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- <sup>1</sup> Mittal et al Transthoracic cardioversion of atrial fibrillation. *Circulation*. 2000;101:1282-1287
- <sup>2</sup> Niebauer et al Cardioversion thresholds of atrial fibrillation and atrial flutter using an external biphasic waveform defibrillator. Presented at NASPE 2000 (abstract)
- <sup>3</sup> Friedman et al Role of ibutilide and biphasic waveforms for cardioversion of atrial fibrillation in routine clinical practice. *PACE* 2002; 24:634 (abstract)
- <sup>4</sup> Schute et al. Rectilinear biphasic rather than monophasic waveforms for Transthoracic cardioversion of patients with rheumatic heart disease and longstanding atrial fibrillation after corrective mitral valve procedures. *Journal of the American College of Cardiology*. 2002;39:429A (abstract)
- <sup>5</sup> Kerber et al, AHA Scientific Statement. *Circulation* 1997;95:1677-1682.