# stryker

# **Clinical Overview**

Full energy and low energy biphasic waveform performance in published scientific research for termination of ventricular fibrillation (VF), pulseless ventricular tachycardia (pVT) and atrial fibrillation (AF)

## **Key Words**

Out of hospital cardiac arrest (OHCA) In hospital cardiac arrest (IHCA) Basic Life Support (BLS) Advanced Life Support (ALS) Ventricular Fibrillation (VF) Pulseless Ventricular Tachycardia (pVT) Atrial Fibrillation (AF) Defibrillation Threshold (DFT) Biphasic waveform Monophasic waveform Biphasic Truncated Exponential (BTE) Rectilinear Biphasic (RBW/RBL) Joules (J) Amps (A) Voltage (V) Milliseconds (ms) Impedance (Ohms) Clinical study (human data) Experimental study (animal data)

### Summary

Twenty years of biphasic research has provided direction on how to maximize conversion rates, particularly for the cardiac arrest patients who are difficult-to-defibrillate. The published scientific **clinical** and **experimental** research can be summarized in four clinical findings.

- No singular characteristic of any well-designed biphasic waveform determines conversion rate. The level of current (A) used in low energy shocks (≤ 200J) or full energy shocks (360J) is only the therapeutic agent. Shock energy (J) is the therapeutic dose that includes multiple waveform characteristics (current, voltage and duration).
- Clinical comparison data show that at the same low energies (J), the most widely used biphasic waveforms have the same conversion rates from 50J to 200J.
- 3. Clinical and experimental data strongly point to an association between higher shock energy (J) and higher conversion rates for VF/pVT and AF.
- 4. Clinicians can significantly impact conversion rates in two ways:
  - control the size/strength of the shock (selected energy dose)
  - control the vector of the shock (pad placement)

Clinicians are using new strategies with maximum biphasic defibrillation energy for the difficult-to-defibrillate patient cohort:

- protocols starting at 360J biphasic
- alternate pad placement with 360J biphasic

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# Section 1.0: External biphasic defibrillation today

The good news: Since transitioning from monophasic to the biphasic external defibrillation waveforms in 2002, we've learned a lot about biphasic waveform performance and what dictates conversion rates. Monophasic vs. biphasic studies are no longer useful given that monophasic defibrillators are now rarely used. Biphasic technology has proven to be more efficacious, regardless of the waveform; Biphasic Truncated Exponential (BTE) or Rectilinear Biphasic (RBW/RBL). Biphasic defibrillation works well for most patients. However, published clinical data now shows that 5-11% of cardiac arrest patients fall into the difficult-to-defibrillate category.<sup>22,23</sup>

**The bad news:** Understanding the differences between each manufacturer's biphasic waveform technology has become complicated. Confusing claims and inappropriate analogies from some manufacturers have made comparing shock effectiveness among defibrillator/monitors a challenging proposition for most clinicians.

This clinical review describes basic defibrillation principles, biphasic waveform technology, and summarizes the best published clinical and experimental evidence on defibrillation dosing and conversion rates.

### 1.1: External biphasic defibrillation maximums

- Three widely-used, commercially available biphasic waveforms are used in the U.S. (Figure 1)
- Each manufacturer uses a waveform with different delivery characteristics and offers different maximum biphasic energies.



#### Figure 1: Maximum programmed biphasic energy by manufacturer

## Section 2.0: The biphasic waveform

- The therapeutic defibrillation dose (energy) is a defined set of electrical characteristics over a defined time (Energy = voltage x current x duration).<sup>1</sup>
- During a biphasic shock, current and voltage are dynamic.
  (Figure 2) A single metric of current (peak or average) cannot capture the effect of the entire shock. Attempts to do so oversimplify the principles of defibrillation. Duration must also be factored in.<sup>1-5</sup>
- For example, older monophasic waveforms used as much as 40% more peak current than biphasic waveforms, yet decades of research show biphasic waveforms yield higher conversion rates.<sup>40-45</sup> (Figure 2)
- Current, voltage, duration or a combination of these dimensions are further modified by defibrillators based on the patient's impedance (impedance compensation).

#### Figure 2: Monophasic and biphasic waveforms



## Section 3.0: Energy dose response curve

- The **dose response curve** represents the percentage of patients that will be converted by a specific shock energy dose. (Figure 3)
- When using an efficient waveform (see section 4.0), defibrillation probability increases with an increasing energy dose, to a point. This is an established defibrillation dose-response relationship.<sup>1, 21-23</sup>
- The curve shifts to the right for patients who are more difficult-to-defibrillate (Figure 3-Patient B). Lower energy defibrillation, regardless of peak or average current (A), has a lower probability of defibrillation success in these patients.<sup>1, 21-23</sup>
- Recent published clinical data suggests 5-11% of OHCA patients are difficult-to-defibrillate.<sup>22,23</sup>
- Physiological and non-physiological factors may contribute to making a patient difficult-to-defibrillate (see section 10.0).
- These patients are likely to benefit from full defibrillation energy (360J).



#### Figure 3: Dose response curve

### Section 4.0: Strength-duration relationship

- Defibrillation is dependent on the combination of current (A) AND duration (ms). (Figure 4) This is also know as the strength-duration relationship.
- There is a range of shock durations. Some require more current (A) and some require less current (A).
- Shock duration too short or too long (> 24ms) will decrease conversion rates.  $^{\rm 50}$
- Defibrillators with less current output can still generate an effective waveform by increasing the shock's duration.

#### Figure 4: Strength-duration relationship



### Current (A) and duration (ms)

Dosing defibrillation by current (A) alone without duration (ms) is analogous to giving a drug knowing the concentration (i.e. current) but not the volume (i.e. duration). Without duration (ms), current (A) alone cannot describe the total defibrillation dose.

- Physio-Control LIFEPAK shock duration is variable <sup>47</sup> 13.4 18.9 ms (for impedances 50 125 ohms)
- Philips HeartStart shock duration is variable <sup>48</sup> 8.6 17 ms (for impedances 50 125 ohms)
- ZOLL shock duration is fixed  $^{49} \approx 10 \text{ ms}$  (for all impedances)

### Section 5.0: Biphasic waveform comparisons

Before reviewing the published literature on biphasic performance, the fundamental differences among each commercially available biphasic waveform design at maximum energy dosing should be illustrated.\* (Figures 5 and 6)

Figure 6: Physio-Control vs. ZOLL

#### Figure 5: Physio-Control vs. Philips



A recent promotional document states that the Philips low energy biphasic shocks (200J), with initial peak current equivalent to Physio-Control's full energy biphasic shocks (360J), deliver equivalent conversion rates.<sup>6</sup> Published experimental data does not support this (see section 7.0).

<b>Ful</b> Phys defibrill	<b>l energy biph</b> io-Control LIF1 ator max progr setting is 360J	<b>asic</b> EPAK rammed	<b>Low energy biphasic</b> Philips ALS defibrillator max programmed setting is 200J		
	360 Joules	Energy	200 Joules		
	16.36 ms	Duration	12.68 ms		
	17.7 Amps	Avg. current	15.5 Amps		
	22.1 Amps	Peak current	22.2 Amps		
	1994.5 Volts	Voltage	2006.7 Volts		

25 - Average current 20 15 10 Current (A) 5 0 -Full energy to 360J -5 -10 -15 -20<del>|</del> -2 8 10 18 20 12 14 16 6 Ó Time (ms) Physio-Control - ZOLL Full energy BTE waveform Low energy RBW waveform

A recent promotional document states that ZOLL's low energy biphasic shocks (200J), with slightly higher average current due to a short fixed duration, deliver superior conversion rates than Physio-Control's full energy biphasic shocks (360J).<sup>7</sup> Published clinical data does not support this (see section 6.0).



\*Biphasic measurements testing at 90 ohms with the Physio-Control LIFEPAK 15 Monitor/Defibrillator, ZOLL X-Series® Monitor/Defibrillator and Philips MRx Monitor/Defibrillator.<sup>38</sup> Average human impedance range is approximately 70-80 ohms.<sup>19</sup>

# Section 6.0: Low Energy (50 joules to 200 joules) - biphasic comparisons

To compare commercially available BTE and RBW waveforms, we must look at the published, peer-reviewed biphasic vs. biphasic data. Five **clinical** AF conversion studies showed that at the same low energies (J), biphasic waveforms had the same conversion rates from 50J to 200J. Electrophysiologists understand that the mechanism by which a shock terminates fibrillation is the same for AF and VF.<sup>62</sup> Also, AF studies are done in a controlled research environment, thus allowing for greater reproducibility and consistency of results.

### $ZOLL \le 200 \text{ joules} = Physio-Control \le 200 \text{ joules}$

- Three published clinical AF cardioversion studies compared conversion rates between the Physio-Control LIFEPAK 12 (BTE) and the ZOLL M-Series (RBW) waveforms at the same low energy shock settings up to 200J. (n=434)<sup>8-10</sup>
- Kim et al. (2004), Neal et al. (2003) and Alatawi et al. (2005) all found no differences in conversion rates. The slightly higher average current used in the RBW waveform provided no relative advantage in conversion rates from 50J to 200J. (Figure 7)
- Kim stated "At all energy levels tested (50, 100, 150 and 200J), success rates were not significantly different..." <sup>8</sup>
- Neal stated "There was no clinical difference between the BRL and the BTE waveforms."  $^{9}$
- Alatawi stated "No significant difference in efficacy was observed between the BR (RBW) and BTE waveforms."  $^{\rm 10}$

Figure 7: Cumulative conversion rates<sup>24-26</sup> (Kim, Neal, Alatawi)



 Inácio et al. (2016) reached the same conclusions in a recent AF meta-analysis of low energy (J) shock comparisons up to 200J.<sup>11</sup> It was suggested that biphasic defibrillators from Physio-Control (BTE) and ZOLL (RBW) had similar conversion rates at the same low energies (J).

# Section 6.0: Low Energy (50 joules to 200 joules) - biphasic comparisons (continued)

### $ZOLL \le 200$ joules = Philips $\le 200$ joules

- Two published clinical AF studies compared conversion rates between the Philips (BTE) and the ZOLL (RBW) waveforms at the same low energy shock settings up to 200J.
- Deakin et al. (ZOLL R-Series vs. Philips Heartstart XL, 2013) and Santomauro et al. (ZOLL M-Series vs. Philips MRx, 2004) both found no differences in conversion rates up to 200J. (Figures 8 and 9)
  - Deakin et al. stated "No statistically significant difference was shown between the waveforms in either cumulative or step-wise energy delivered" (up to 200J).









 Inácio et al. (2016) reached the same conclusions in a recent AF meta-analysis of low energy shock comparisons up to 200J.<sup>11</sup> Researchers suggested that biphasic defibrillators from Philips (BTE) and ZOLL (RBW) had similar conversion rates at the same low energies.

#### 6.1: Biphasic vs. monophasic comparisons (VF and AF)

The following biphasic vs. monophasic studies have been referenced in promotional materials as evidence for equivalence or superiority of low energy RBW and low energy BTE waveforms vs. full energy BTE waveforms.<sup>6,7</sup> These studies are not applicable for comparing BTE waveforms in currently available defibrillators as they compared biphasic waveforms to the previously used monophasic waveforms. Decades of research show biphasic waveforms yield higher conversion rates than monophasic waveforms.

- Mittal et al. (1999) compared the RBW biphasic to monophasic waveforms for VF conversion.<sup>40</sup>
- Mittal et al. (2000) compared the RBW biphasic to monophasic waveforms for AF conversion.<sup>41</sup>
- Schneider et al. (2000) compared low energy BTE to monophasic waveforms for VF conversion.<sup>42</sup>
- Page et al. (2002) compared low energy BTE to monophasic waveforms for AF conversion.<sup>43</sup>
- Niebauer et al. (2004) compared the RBW biphasic to monophasic waveforms for AF conversion.<sup>44</sup>
- Morrison et al. (2005) compared the RBW biphasic to monophasic waveforms for VF conversion (ORBIT).<sup>45</sup>

# Section 7.0: Full Energy (360 joules) vs low energy (200 joules) - biphasic comparisons

Published **experimental** biphasic comparison studies show that full energy provides superior conversion rates vs. low energy, regardless of commercially available waveform. Experimental studies allow well-controlled protocols and sample sizes to effectively compare different dosing and waveforms.

### 200 joules (Philips or ZOLL) $\neq$ 360 joules (Physio-Control)

- Walker et al. (2003) compared biphasic conversion rates of the Physio-Control LIFEPAK 12 escalating protocol (200J-300J-360J) and the the ZOLL M-Series escalating protocol (120J-150J-200J) in porcine VF using stacked shocks.<sup>14</sup> (Figure 10)
  - Escalating to 360J resulted in higher conversion rates vs escalating to 200J.
  - The average impedance was augmented up to 92 ohms to mimic human impedances.



Figure 10: VF conversion rate

- Esibov et al. (2016) compared biphasic conversion rates of the Physio-Control LIFEPAK 15 360J (BTE) and the Philips MRx 200J (BTE) in porcine VF at three subtly different pad locations.<sup>15</sup> (Figure 11)
  - The full energy BTE shocks (360J) resulted in higher conversion rates at each pad location vs. the low energy BTE shocks (200J). (p<0.01)</li>
  - Using more biphasic energy led to higher conversion rates regardless of pad position.



- Ristagno et al. (2013)<sup>16</sup> and Li et al (2009)<sup>17</sup> compared biphasic conversion rates between the ZOLL R-Series 200J (RBW) and the Physio-Control LIFEPAK 12 360J (BTE) in porcine VF with augmented high impedances.
  - Conversion rates were higher for the RBW waveform vs. the BTE waveform at higher impedances in both studies.
  - However, multiple clinical studies have shown that high impedances are not associated with difficult-todefibrillate patients.<sup>22,23,41</sup>
  - In addition, multiple clinical studies have been done on large numbers of patients which do not support higher conversion rates for the RBW waveform in high impedance patients compared to BTE.<sup>8-10</sup>
- Chen et al. (2014) compared biphasic conversion rates of ZOLL 200J (RBW), Welch Allyn 200J (BTE) and Physio-Control 200J (BTE) or 360J in porcine VF.<sup>18</sup> Researchers hypothesized that average current (A) would be a better predictor of conversion rates than peak current (A).
  - The full energy 360J BTE resulted in higher conversion rates vs. the low energy 200J BTE at each pad location.
  - In addition, the BTE 200J and BTE 360J shock energies were mixed without disclosing the number of each. The ratio of 200J:360J shocks could have confounded the results.

Using biphasic waveforms with more peak or average current (A) have not been shown to improve relative conversion rates at low energies. No singular characteristic of the shock or waveform determines conversion rate. The 2010 American Heart Association (AHA) Guidelines and 2015 AHA Guideline Updates also state that there is no specific biphasic waveform that is superior among commercially available devices.<sup>19, 20</sup>

# Section 8.0: Full energy (360 joules) - biphasic dosing comparisons

No published **clinical** evidence exists showing low energy (150J-200J) from any device provides equivalent or superior conversion rates compared to full biphasic (360J). Published clinical data demonstrate protocols with escalating energy to 360J improves conversion rates for difficult-to-defibrillate VF and AF patients.

- Stiell et al. (2007) compared fixed low energy (150J-150J-150J) vs. escalating energy (200J-300J-360J) with the Physio-Control BTE waveform in BLS treatment for OHCA patients. This is the only randomized, triple-blinded, controlled study comparing energy dosing protocols.  $(n{=}221)^{21}$ 
  - In patients who received multiple shocks (n=106), there was an 11.3% statistically significant improvement in termination of VF (p=0.027) (Figure 12) and nearly 12% significant improvement in conversion to an organized rhythm (p=0.035) when escalating energy dosing to biphasic 360J. (Figure 13)
  - The escalating energy group was also converted with fewer shocks. These patients had fewer interruptions in CPR and thus less potential for long CPR pauses.

- Walker et al. (2009) compared an energy protocol that repeated first shock energy (200J-200J-360J) vs. an escalating energy protocol that did not (200J-300J-360J) with the Physio-Control BTE waveform in OHCA with VF.  $(n=863)^{22}$  (Figure 14)
  - An increased defibrillation probability was observed with increased energy doses in a subset of patients who received shocks at each of the three energy levels. (n=236)
  - Those receiving 360J had the highest cumulative conversion rate.
  - 5% were classified as difficult-to-defibrillate by the researchers.



### Figure 12: VF conversion rate









# Section 8.0: Full energy (360 joules) - biphasic dosing comparisons (continued)

- Koster et al. (2008) compared conversion rates OHCA patients with recurrent VF who received a 200J-200J-360J shock protocol using the Physio-Control BTE waveform. (n=465)<sup>23</sup> (Figure 15)
  - First shock success with 200J was 92%.
  - − 175 had ≥ five VF episodes. Lower conversion rates were observed when shocks at 200J were repeated. (p<0.01)
  - All were eventually defibrillated at 360J, although this was only a statistical trend due to sample size. (p=0.26)
  - 11% were classified as difficult-to-defibrillate by the researchers.



- Khaykin et al. (2003) compared conversion rates with escalating biphasic energy using the Physio-Control BTE waveform in patients with resistant AF.<sup>24</sup>
  - Conversion rates increases with each escalating shock to full energy 360J. (p=0.01)
  - "Cumulative success rates with biphasic shocks of 150J,
    200J and 360J were 22%, 43%, and 69%, respectively."
    (Figure 16)

Figure 16: AF conversion rate with increasing energy doses



# Section 9.0: Full energy (360 joules) - biphasic dosing today

### 9.1: Biphasic dosing: AHA adult recommendations

- The 2010 AHA Guidelines and 2015 AHA Guideline Updates continue to recommend first shock energy (120/150/200J) per manufacturer protocol. Higher energy for second and subsequent shocks (i.e. >200J) may be considered.<sup>19,20</sup>
- The 2010 and 2015 AHA Guidelines also recommend escalating to the maximum manufacturer dose when device energy protocols are unknown.<sup>19,20</sup>
- The 2010 International Consensus on CPR and ECC Science with Treatment Recommendations (CoSTR), which the AHA Guidelines are based on, supported the use of higher energy. "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."<sup>27</sup> The 2015 CoSTR stated "There are no major differences between the recommendations made in 2015 and those made in 2010."<sup>28</sup>

#### 9.2: Biphasic dosing: AHA pediatric recommendations

- The 2010 AHA Guidelines recommend escalating to full energy biphasic for pediatric weight-based defibrillation dosing.<sup>25</sup>
- First shock: 2-4 J/kg, Second shock: 4 J/kg, Subsequent shocks: 4-10 J/kg or the adult maximum dose.
- For example, the minimum second shock dose (4 J/kg) for a 52 kg (115 lbs) child is 208J, not 200J.
- 2015 AHA Guideline Updates made no changes.<sup>26</sup>

### 9.3: Biphasic dosing: AHA myocardial safety

- 2010 AHA Guidelines state "Human studies have not demonstrated evidence of harm from any biphasic waveform defibrillation energy up to 360J, with harm defined as elevated biomarker levels, ECG findings and reduced ejection fraction."<sup>19</sup> Three published clinical studies are referenced by the Guidelines. <sup>21,60,61</sup>
- The 2015 AHA Guideline Updates made no changes to the 2010 statement.  $^{\rm 20}$
- Some promotional documents suggest damage can occur from escalating to higher energy, but these are based on animal data or use of monophasic waveforms.<sup>6,56-58</sup> It is well established that biphasic waveforms are more efficient than monophasic waveforms and use much less peak current. High peak current is a primary cause of myocardial insult.<sup>59</sup>

#### 9.4: Biphasic dosing: clinical trends

- Some clinicians are now using defibrillation protocols starting with full energy biphasic (i.e. 360 x 360 x 360J).\*
- Some are using alternate pad placements with maximum energy output after their traditional defibrillation protocol failed.
- Electrophysiologists prefer external defibrillators that are capable of escalating to full energy (360J).<sup>29</sup> A 2016 hospital survey showed:
  - 59% of Electrophysiologists now use defibrillators that can escalate to 360J biphasic in their EP labs. (Figure 17)
  - 28-29% of Electrophysiologists use full energy defibrillators even when their hospitals have standardized on low energy defibrillators in other patient care areas.
- Electrophysiologists also sometimes implant high energy ICDs and high energy CRT-Ds for potentially difficult-todefibrillate patients. These devices offer approximately 25% more maximum biphasic shock energy than standard ICDs and CRT-Ds.



#### Figure 17: EP lab defibrillator by brand

\*No published, peer reviewed clinical data exists on defibrillation protocols starting with full energy 360J biphasic.

# Section 10.0: Science update: why does a shock succeed or fail?

- Regardless of the cause, multiple clinical studies show that as many as 50% of OHCA patients need more than one shock to terminate  $VF.^{21-23}$
- The same data also shows that 5-11% of these patients are labeled as "difficult-to-defibrillate." But why?
- The science of why a shock succeeds or fails can be categorized by two questions:
  - Is the shock failing to convert due to physiologic factors? (Table 1)
  - Is the shock failing to convert due to factors with the shock delivery? (Table 2)

## Table 1: Shock failure secondary to physiologic factors

Physiologic causes	Difficult-to-defibrillate?	Latest research
Acute myocardial infarction (AMI) size	No	Recurrent VF (re-fibrillation) is much more common in OHCA than Refractory VF. <sup>23,30,31</sup> Data suggests that the majority of non-traumatic OHCA is of ischemic cardiac etiology. <sup>52-55</sup>
Duration of VT/VF (metabolic acidosis)	Probably not	The most recent data in 2010 showed no difference in DFTs between short and long duration $\rm VF.^{32}$
Pre-shock pauses in CPR	No	Recent clinical evidence totaling over 2,200 OHCA patients showed no association between pre-shock pause duration and conversion rate. <sup>33-35</sup> But minimizing pre-shock pauses is still important. Long shock pauses are negatively associated with survival. <sup>33</sup>
Amiodarone (Antiarrhythmic-Class III)	Yes and No	Oral Amiodarone use can raise DFTs due to the active metabolite. Single intravenous use during ACLS care likely has much less of an impact. <sup>51</sup>
Structural heart disease (LV dilatation, CHF, hypertrophic cardiomyopathy)	Possibly	No data on an association between structural heart disease and difficult-to- defibrillate OHCA patients exists. However, EPs sometimes implant high energy ICDs (approx.25% more maximum energy) in patients with these conditions.
Obesity, Body Mass Index (BMI)	Possibly	The published data are mixed. Recent clinical data from the CARES registry found no risk-adjusted relationship between five BMI categories (underweight to obese) and first shock success (100J to 360J). <sup>36</sup>

#### Table 2: Shock failure secondary to shock delivery factors

Problem with the shock	Difficult-to-defibrillate?	Latest research
High shock impedances	No	One of the largest OHCA data sets ever collected showed no association between high impedance and being difficult-to-defibrillate. <sup>22</sup> Other OHCA trials demonstrated similar results. <sup>23,39</sup>
Defibrillation current bypassing the heart (commonly called "shunting")	Yes	As little as 5% of the defibrillation current actually gets to the myocardium. <sup>37</sup> Conditions such as pulmonary edema and third spacing can cause current shunting away from the heart.
Suboptimal defibrillation pad placement	Yes	Minor variations within a chosen pad placement configuration can decrease conversion rates. <sup>15</sup>

# Section 10.0: Science update: why does a shock succeed or fail? (continued)

Multiple mechanistic theories exist on how defibrillation energy terminates fibrillating myocardium. This is a complex biological interaction with evolving theoretical models. Based on Physio-Control's 20 years of biphasic defibrillation research, the Critical Mass Theory is a meaningful conceptualization that can help clinicians improve conversion rates.<sup>1</sup>

- In VF the myocardial cells are misfiring in a continuous, disorganized pattern of depolarization and repolarization.
- Simplified, the goal of defibrillation is to depolarize as much of the myocardial tissue as possible at once, placing them into a repolarized, refractory state that is unable to re-propagate the electrical misfires that cause VF.
- The defibrillation (electrical) field generated by a shock must cover a critical mass of the heart's fibrillating myocardial tissue to successfully terminate VF/pVT. (Figure 18)
- Shock failure likely occurs where the shock's defibrillation field fails to cover a sufficient volume of the heart and depolarize the fibrillating myocardium.
- Two factors that can have a significant impact on conversion rates are:
  - suboptimal shock size<sup>14,15,21-24</sup> (Figure 19)
  - suboptimal shock vector<sup>15</sup> (Figure 20)

#### Figure 18: Optimal defibrillation field via pad location and/or energy dose



# Figure 19: Suboptimal shock size



#### Figure 20: Suboptimal shock vector



# Section 11.0: Mechanisms to increase conversion rates

Clinicians can significantly impact conversion rates in two primary ways.

### 1. Increase the size of the defibrillation field.

• Using a higher defibrillation energy (J) dose will maximize the shock's myocardial coverage. Published clinical and experimental data strongly support escalating to full energy biphasic 360J as a mechanism to maximize conversion rates.<sup>21-24</sup>

### 2. Optimize the vector of the defibrillation field.

- Optimal pad placement will also maximize the shock's myocardial coverage.
- Esibov, et al. (2016) found that suboptimal pad placement significantly lowered VF conversion rates. Using more biphasic shock energy compensated for the poor pad placements.<sup>15</sup>
- However, even with consistent anatomical pad placement, the patient's individual cardiac physiology may place a critical area of the fibrillating heart outside of the defibrillation field.
- Alternate pad configurations that change the shocks vector should be considered.

Some clinicians manually add contact pressure to the defibrillation pads (similar to using paddles) to improve conversion rates. One small study did indicate this may improve conversion rates for difficult-to-defibrillate AF patients by lowering transthoracic impedances or altering the defibrillation current pathway.<sup>46</sup> Clinicians should take precautions to insulate themselves from high shock voltage to prevent a large amount of electrical current from passing through their own body.

Preloading patients with class II or II/III antiarrhythmics may also increase conversion rates but this topic is beyond the scope of this review.

# Section 12.0: Data on biphasic performance

- Cumulative clinical data illustrates biphasic performance for commercially available external defibrillator/monitors.\* (Figure 21)
- This summation of published clinical research represents real-world biphasic waveform performance in OHCA and IHCA patients.
- The Physio-Control BTE waveform has been studied in nearly twice as many patients as all other waveforms combined.

# Figure 21: Published research on cardiac arrest patients treated with biphasic shocks 1997-2016

Physi	o-Control					2,808
Philip	s	934				
ZOLL Other	441 239					
0	500	1000	1500	2000	2500	3000

\*This data represents the cumulative number of cardiac arrest patients in whom the VF termination conversion rate (using the established definition of "removal of VF for  $\geq$  5 seconds") of specific biphasic waveforms and energy levels has been reported in published papers describing either randomized or consecutive case series of OHCA or IHCA patients. Included are papers that report a VF termination rate for at least one of 1) first shocks or 2) all shocks.

# Section 13.0: Biphasic dosing summary

- No commercially available defibrillator on the market offers equivalent strength to full energy biphasic (360J) offered by Physio-Control LIFEPAK defibrillators for both AED and manual defibrillation.
- Published clinical data demonstrate protocols with escalating energy to 360J improves conversion rates for difficult-todefibrillate VF and AF patients.
- The science shows that no individual characteristic of a well-designed biphasic waveform determines conversion rate. The combined total of a shock's characteristics (energy), determines conversion rate. Shock energy (J) is the therapeutic dose that includes multiple waveform characteristics (current, voltage and duration).
- Multiple biphasic vs. biphasic comparison studies show low energy is not equivalent to full energy, regardless of how current (A) alone is managed.

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