Philips SMART Biphasic Therapy

Introduction

Since Philips introduced the first biphasic waveform for an external defibrillator in 1996, biphasic therapy has gained acceptance and is now recognized as the standard of care. However, the various defibrillator manufacturers recommend a wide range of energy (joules) dosages. This is because defibrillator manufacturers have created distinct biphasic waveform "formulations." So each manufacturer recommends energy doses appropriate for their shock formulation. While energy (joules) remains entrenched in defibrillator vocabulary as a descriptor of shock strength, current (amperes) has been shown to be a better predictor. For meaningful shock strength comparisons of biphasic waveforms, it's necessary to look beyond energy levels and compare the current delivered to the patient.

All presently available Philips HeartStart defibrillators incorporate a proprietary biphasic truncated exponential (BTE) waveform formulation employing high current delivered in a low energy dosage. Further, Philips uses real-time impedance compensation to automatically adjust the waveform to deliver shock strength personalized to the needs of each patient, starting with the first shock.

Philips therapy has been rigorously studied and is backed by a substantial body of peer-reviewed, published data demonstrating effectiveness across the full spectrum of patients, including those considered "difficult-to-treat."

While biphasic waveforms effectively terminate arrhythmias, meaningful clinical differences between defibrillators may lie in the amount of energy needed for successful defibrillation and its negative impact on post-resuscitation myocardial function. While high current defibrillates, high energy is associated with negative side effects. So the optimal waveform formulation delivers high current at lower energy doses to help reduce the total energy delivered. Meaningful clinical differences may also lie in how quickly a shock is delivered following the CPR pause, as this may substantially influence shock success.

Biphasic waveforms use distinct formulations

Not all biphasic waveforms are the same. Manufacturers use distinct shock formulations, making their individual energy dosages an invalid comparison tool for evaluating their relative shock strength. This can be likened to pharmaceuticals.

Although different drugs within a class may all be considered safe and effective, each requires its own dosage due to its distinctive molecular structure. For example, statins are proven to lower LDL cholesterol.[1] Yet, the maximum 80mg dose of Lipitor® (atorvastatin calcium) is not necessarily more therapeutic than the 40mg maximum dose of Crestor® (rosuvastatin calcium)[3] simply because it is twice the dose. Because each drug in a class has a unique formulation, the number of milligrams of one drug in a class is not necessarily indicative of therapeutic strength relative to another, and does not lend itself to "apples to apples" comparisons.

Biphasic waveforms as a class have been proven to effectively terminate arrhythmias. They deliver "electric medicine" and, similar to pharmaceutical medications, use distinctive waveform formulations. For biphasic waveforms, the formulation is driven by different device components, waveform shape, and duration, which produce current. According to the American Heart Association and European Resuscitation Council, it's current that defibrillates, not the amount of energy (joules).[2,3] Due to varying waveform formulations, it is possible for the recommended first shock dosage of 150J from one defibrillator manufacturer to deliver higher current levels than a 200J first shock from another defibrillator manufacturer, even though the latter delivers a larger energy dosage.

American Heart Association and European Resuscitation Council positions on current

"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…Transition to current-based description is timely and should be encouraged."

- American Heart Association[2]

"Although energy levels are selected for defibrillation, it is the transmyocardial current flow that achieves defibrillation. Current correlates well with successful defibrillation and cardioversion…Future technology may enable defibrillators to discharge according to transthoracic current: a strategy that may lead to greater consistency in shock success… manufacturers are encouraged to explore further this move from energy-based to current-based defibrillation."

- European Resuscitation Council[3]

A 5-second jolt from the typical 1200V taser used by law enforcement would incapacitate a person, but the person would only absorb a 1/4J shock.

Theoretically, when the connectors of a 9V battery are placed on a conductive surface, such as a person's tongue, the person would eventually absorb 360J.

Current, not energy, determines shock strength

If the connectors of a common 9V battery were placed on a person's tongue, the person would eventually absorb 360J. Of course, no one would consider using a 9V battery to defibrillate a patient as it lacks sufficient voltage and current.

On the other hand, a person incapacitated by the typical 1200V taser used by law enforcement for 5 seconds would only absorb a ¼J shock. After one excruciating minute, just 3J would be absorbed. With sufficient voltage and current, a ¼J shock can be quite strong indeed.

The point of these examples is that while energy (joules) remains entrenched in defibrillator vocabulary as a descriptor of shock strength, published studies have shown that current (amperes) is a better predictor.[4,5] The American Heart Association and the European Resuscitation Council are both advocating a shift to current-based defibrillation.

For effective defibrillation, a defibrillator must generate high voltage in order to drive a sufficiently high current over the duration when the heart cells are physiologically most receptive to defibrillation (See **Table 1** for Waveform formulation key terms). Therefore, for meaningful shock strength comparisons of biphasic waveforms, it is necessary to look beyond energy and compare the current delivered to the patient.

Waveform formulation key terms
Capacitor – A key component of the defibrillator design that stores electrons. Manufacturers have created distinct waveform formulations that use various size capacitors to generate voltage and current for defibrillation. The size of the capacitor impacts the amount of energy (joules) needed to produce voltage and current. Smaller capacitors typically use fewer joules to pack the necessary voltage and current punch for effective defibrillation. Whereas, larger capacitors usually use more joules to achieve comparable levels.
Voltage – The force that pushes the electrons through the patient. The amount of voltage stored on the capacitor drives the amount of current available for defibrillation. The higher the voltage level, the greater the force and amount of current that can be delivered for defibrillation.
Current – The movement of electrons, measured in amperes, which achieves defibrillation. For biphasic waveforms, distinctive formulations driven by different device components, waveform shape, and duration produce current.
Impedance – The resistance of the body to the flow of current, which is measured in ohms. Human impedance levels typically range from 25 ohms to 180 ohms.
Voltage gradient – Reflects the actual intensity of a defibrillation shock in terms of the electric field it generates within the myocardium itself. Accurate measurement of intracardiac voltage gradients requires instrumenting the heart with electrodes to capture the data.
Duration – The period over which the current is delivered to the heart. The goal is to deliver therapy over an optimal time period to increase the chance of defibrillation.

Table 1

The Philips SMART Biphasic waveform formulation

When Philips set out to design the first biphasic waveform for an external defibrillator, the engineers chose a smaller 100 microfarad (µF) capacitor that used fewer joules to pack the necessary voltage and current punch for effective defibrillation. Philips patented the use of a smaller capacitor for external defibrillation, which led other manufacturers to select larger (200 µF) capacitors for their formulations. Larger capacitors typically use more joules to achieve voltage and current, meaning shock strength, comparable to Philips. Using standard protocols, this means that Philips delivers higher shock strength starting with the first shock than other typical biphasic waveforms that escalate their energy levels to reach equivalent shock strength. Escalating potentially wastes time and shocks during an arrest.

The amount of voltage stored on the defibrillator's capacitor determines the amount of current delivered to the patient, which is responsible for defibrillating the heart and considered a more accurate measure of shock strength. **Figure 1** shows that the Philips waveform (using a 100 µF capacitor) at its recommended first shock energy setting can produce significantly higher voltage than another common biphasic waveform (using a 200 µF capacitor) at its recommended first shock setting.[6] Philips distinct waveform formulation uses fewer joules to achieve higher voltage levels.

Higher voltage drives higher current to the patient. Applying basic physics, namely Ohm's Law, **Figure 2** shows how the Philips formulation is able to generate higher current with fewer joules at its recommended first shock energy setting than that of another common biphasic waveform (using a 200 µF capacitor).[7] This biphasic waveform requires more energy to deliver current equivalent to the Philips waveform.

A swine study by Niemann, et al. measured whether energy or peak current measured at the body surface is a better predictor of the actual shock electric-field strength to which the heart is exposed.[8] Porcine hearts were instrumented with electrodes to measure voltage gradients within the heart achieved by various defibrillator brands. **Figure 3** demonstrates that Philips delivers the highest observed peak current and voltage gradients – meaning more defibrillation therapy right to the heart – when comparing each manufacturer's recommended first shock energy setting. The authors concluded that energy descriptors correlate poorly to actual shock intensities and provide an inaccurate measure of relative shock strength among different external defibrillators. The authors also concluded that peak current is a better measure of shock strength.

The Philips SMART Biphasic waveform formulation delivers high voltage to drive high current and generate high voltage gradients at the heart with fewer joules.

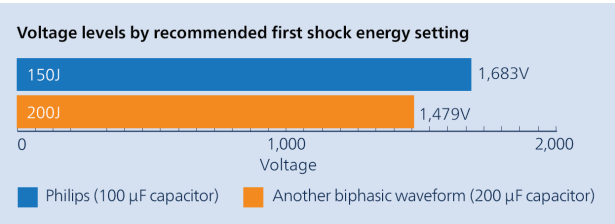

Figure 1 Measurements based on a resistive load of 80 ohms.

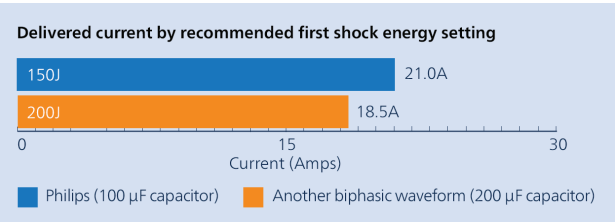

Figure 2 Assumes an average patient impedance of 80 ohms.

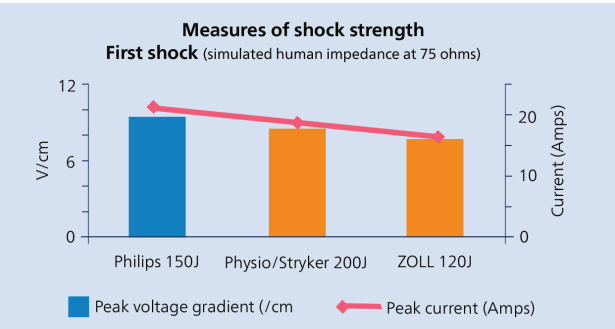

Figure 3

Evidence-based therapy with consistently high efficacy

As the first biphasic waveform in an external defibrillator, the performance of Philips therapy has been rigorously studied and reported in numerous peer-reviewed, published manuscripts. They reflect waveform performance in both animals[9–12] and humans, including the challenging long-duration VF relevant to hospital code teams and responders in out-of-hospital settings.[13–26] These data demonstrate consistently high efficacy, regardless of factors such as: patient size, age, impedance, incidence of refibrillation, or underlying cause of cardiac arrest, including myocardial infarction.

Philips therapy was the first biphasic therapy with sufficient evidence to receive a Class IIa recommendation from the American Heart Association: "Standard of care", "Intervention of choice".[27] In contrast, some biphasic therapies on the market today have limited or no published out-of-hospital clinical data. With no published, peer-reviewed studies in humans directly comparing the performance of various biphasic waveforms in treating VF, the American Heart Association (AHA) advises, "The safety and efficacy data related to specific biphasic waveforms must be evaluated on an individual basis."[27] Accordingly, clinicians are cautioned about generalizing conclusions about one manufacturer's biphasic therapy's performance to other manufacturer's therapy.

With no head-to-head comparison data available, two peer-reviewed, published clinical trials using different biphasic waveforms in out-of-hospital, long-downtime VF patients were of similar size, design, and purpose.[25,28] The observed response conditions for these studies were largely similar in terms of average patient weight, call-to-shock time, percent of witnessed arrest, and percent of bystander CPR. The first study by Schneider, et al. using Philips biphasic therapy (150J fixed-energy protocol) showed a 96% first shock efficacy. Seventy- six (76) percent of patients experienced return of spontaneous circulation (ROSC). Of surviving patients, 94% showed good/moderate neurological function. Survival to discharge was 28%. The second study by van Alem et al. using Stryker/Physio-Control's high-energy biphasic therapy (200-360J escalating energy protocol) also reported a high first shock efficacy of 98%. Sixty-one percent of patients experienced ROSC and 14% survived to discharge. (**Figure 4**)

Another study by Stiell, et al.[29] using Stryker/Physio-Control's high-energy biphasic therapy (200-360J escalating energy protocol) reported first shock efficacy of 89%. Forty nine (49) percent of patients experienced ROSC and 82% of surviving patients showed good/moderate neurological function. Survival to discharge was 16%. This study also included a low-energy (150J non-escalating energy protocol) arm that used a low-current design not comparable to the Philips high-current 150J waveform. Rather, the study compared a manufacturer's standard adult high energy/high current protocol with the same manufacturer's non-standard adult low energy/ low current protocol.

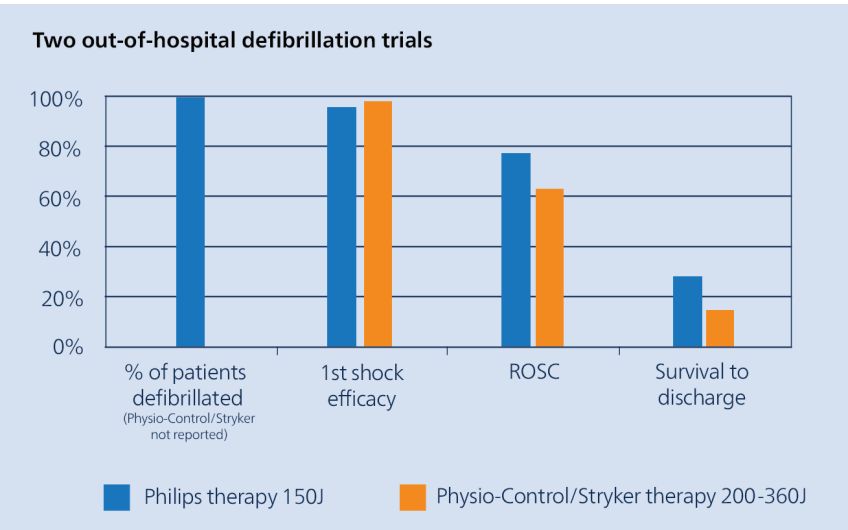

Figure 4

Proven across the full spectrum of patients

Philips therapy has been proven highly effective across the full spectrum of patients, even those considered "difficult-to-treat." [23-26,30,31] The results of some of these published, peer-reviewed studies are summarized in **Table 2**.

Difficult-to-treat patient group	Citation	Study summary
Overweight and obese (BMI > 25) patients	White RD, et al. Critical Care Medicine. 2004.[23]	First shock efficacy and subsequent shock success, resuscitation, and survival were not related to patient body weight. Philips 150J fixed-energy protocol appears effective and appropriate.
High/low impedance patients	White RD, et al. Resuscitation. 2005.[24]	With the Philips 150J fixed-energy protocol, efficacy was high. Impedance had no bearing on defibrillation, ROSC, or survival at discharge.
Refibrillating patients	Hess EP, et al. Resuscitation. 2008.[26]	No significant difference in the frequency of shock success between initial and recurrent episodes of VF using a Philips 150J fixed-energy protocol was observed. VF recurrence is common and does not adversely affect shock success, ROSC or survival.
Myocardial infarction patients Schneider T, et al.	Circulation. 2000.[25]	Over half the patients in this study were diagnosed with acute myocardial infarction, but VF was successfully terminated for all patients using a Philips 150J fixed-energy protocol, with a 96% first shock efficacy.
Atrial fibrillation patients	Santomauro M, et al. Italian Heart Journal. 2004.[30]	Only the Philips biphasic waveform demonstrated 100% cardioversion success for AF compared with patients treated with a monophasic or the Zoll Rectilinear Biphasic™ waveform. The Philips biphasic waveform required less total energy (statistically significant) and fewer shocks per patient (not significant). The Philips waveform appears to achieve a higher success rate at lower energy levels.

Table 2

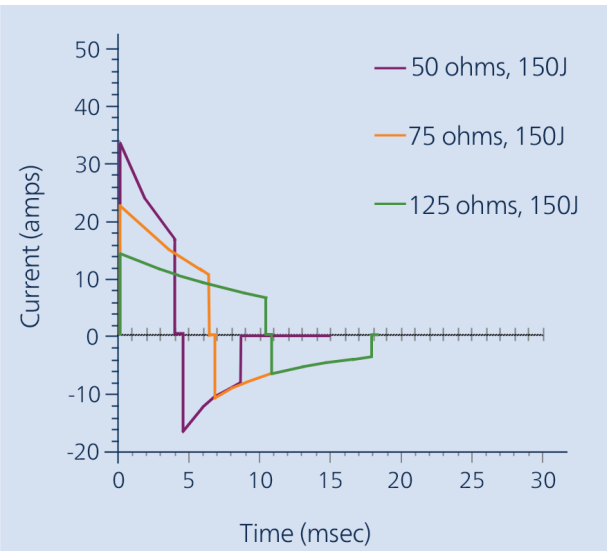

Figure 5

Philips real-time impedance compensation delivers optimized therapy

One major contributor to Philips biphasic therapy's effectiveness across the full spectrum of patients is real-time impedance-compensation technology, which optimizes every shock. Philips defibrillators automatically measure patient impedance and in real time dynamically vary the waveform. Personalized therapy is delivered to each patient, including the difficult-to-treat ones, starting with the first shock for the best chance of success. **Figure 5** shows how the Philips waveform is adjusted to compensate for varying impedance levels.[32]

Meaningful clinical differences among biphasic waveforms

Dysfunction from high energy

When responding to a sudden cardiac arrest emergency, terminating VF quickly is among the highest priorities. However, in the calm of the defibrillator selection process, there is the opportunity to consider the side effects of waveform design, particularly in resuscitation situations that require multiple shocks. Animal studies suggest that electric shocks can have a negative inotropic influence on cardiac function depending on the clinical circumstances, the energy dosage, the number of shocks delivered, and the underlying cardiac function.[10,32,33] Too many shocks can cause transient cardiac injury, such as decreased contractility and reduced cardiac output during the critical period immediately after severe cardiac compromise.[10,33,34] While this type of injury is not permanent, clinical data suggest that during a code this stunning may be significant, complicating subsequent interventions in the emergency department or intensive care unit and potentially impacting patient outcomes.[10,33,35]

Higher-energy defibrillation waveforms, whether monophasic or biphasic, are associated with increased post-shock cardiac dysfunction. Experimental[33,34] and clinical[35] studies suggest that in typical out-of-hospital multi-shock resuscitations, total energy delivered is a negative predictor of myocardial function. An animal study noted a correlation between post-resuscitation myocardial dysfunction and early death after initial successful resuscitation.[33]

Tang, et al.[33] compared the impact of various defibrillation waveforms delivered at different energy settings on post-resuscitation myocardial function using an animal model, which effectively isolated the impact of just the defibrillation shocks. The study showed that for swine in long-duration VF, higher current/lower energy and a higher current/higher energy waveform were equally effective at defibrillating. However, the higher energy waveform was associated with significantly higher levels of harmful cardiac dysfunction.

Group	1	2	3	4
Capacitance	100µF	100µF	200µF	200µF
Energy	150J	200J	200J	360J
Median peak current	34A	40A	24A	37A
Survival (to 72 hours)	100%	100%	40%	100%
Median number of shocks to resuscitate	1	3	5	4
Median CPR duration (seconds)	106	83	909	218
Median total energy required	155J	563J	994J	1440J
Median ejection fraction at 30 minutes (% of baseline)**	95%	75%	62%	53%

Table 3

Table 3 demonstrates that the high energy waveform (200 µF capacitor at 360J) required up to nine times the total energy delivered as the low energy waveform (100 µF capacitor at 150J) to achieve equivalent results.

Table 3 also shows the negative impact of the total delivered energy on ejection fraction, considered a representative measure of dysfunction. Conversely, high peak current was the only positive predictor of increased survival, which reinforces the importance of current in the defibrillation equation.

Tang, et al.[33] concluded that maximizing survival while minimizing myocardial dysfunction may be achieved with a waveform formulation that delivers higher peak current while minimizing total energy delivered. Philips distinct biphasic waveform formulation is able to deliver high peak current at low energy levels. This type of lower energy shock has been shown to have fewer negative inotropic consequences than higher energy shocks. This clinical difference could be particularly meaningful for the long downtime SCA patients, both in and out-of-hospital, who typically require multiple shocks and could help make post-resuscitation interventions in the ED or ICU more successful.

Philips biphasic therapy delivers its strongest therapy from the first shock to maximize effectiveness, yet minimize total energy delivered. In contrast, defibrillators that employ high energy formulations typically start with weaker shocks (lower current delivered at lower energy settings) and escalate to higher energy settings in the event of failure, presumably to balance the trade off between shock strength and potential post-shock dysfunction.

Assuming the Guidelines 2005-recommended protocol[2], it could take up to 6 minutes (including CPR intervals) to reach such an escalating, high energy biphasic waveform's maximum shock strength. Philips does not face this trade off.

Time-to-shock following CPR pause impacts shock success

Animal and clinical studies show that in longer downtime situations (>4 minutes), CPR immediately prior to defibrillation can help restore normal heartbeats in more patients.[36,37] Yet, the beneficial effects of CPR disappear in seconds, making time-to-shock following CPR critical.[38,39] Thus, another key therapy attribute is how quickly the defibrillator delivers a shock following a CPR pause. In fact, a formulation that includes shorter time-to-shock following CPR may substantially influence shock success.[40]

A clinical study evaluating the impact of pre-shock CPR interruptions on shock effectiveness reported that, "…a 5 second decrease in pre-shock pause was associated with an 86% increase in the odds of shock success (p=0.02)." The study concluded that, "… consideration should be given to the use of newer generation AEDs with shorter (<10 seconds) analysis times."[41] **(Figure 6)**

Philips HeartStart AEDs shock as fast as 8-10 seconds (typical) after CPR pause using a technology called "Quick Shock." This unique feature shortens time-to shock after CPR, thereby increasing the chance that a shock will successfully return circulation and, in turn, improve survival.

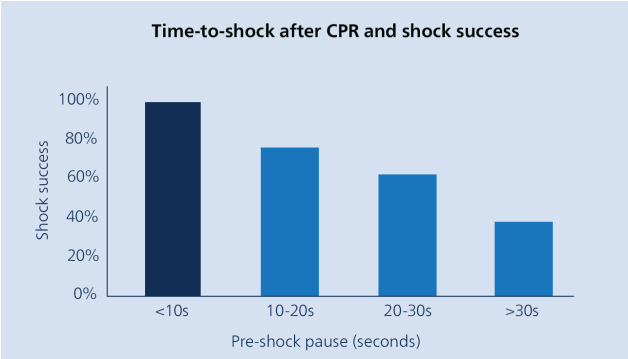

Figure 6

Summary

Biphasic waveforms have become the standard of care for external defibrillation. Manufacturers have created distinctive formulations and recommend energy (joule) dosages appropriate for their waveforms. While energy remains entrenched in defibrillator vocabulary as a descriptor of shock strength, current has been shown to be a better predictor. For meaningful shock strength comparisons of biphasic waveforms, it's necessary to look beyond energy levels and compare the current delivered to the patient.

Philips distinct waveform formulation is able to generate high voltage and deliver high current, which produces high voltage gradients using fewer joules. It's common for other defibrillator manufacturers to use larger capacitors for their formulations and deliver significantly more energy to achieve voltage and current, meaning shock strength, comparable to Philips.

Philips evidence-based therapy has been rigorously studied and is supported by a substantial body of peer-reviewed, published data. It has been clinically proven to deliver high first shock efficacy for long-downtime SCA patients and effectively defibrillate across the full spectrum of patients, including those labeled "difficult-to-treat." In contrast, some biphasic therapies on the market today have limited or no published out-of-hospital clinical data. Philips success across such a broad patient population is due in part to its real-time impedance-compensation technology, which automatically optimizes every shock to deliver personalized therapy to each patient starting with the first shock.

Key waveform design attributes may result in meaningful clinical differences among waveforms. Total delivered energy is a negative predictor of myocardial function and survival. Philips approach reduces the total energy delivered, which minimizes the risk of post-shock myocardial dysfunction. This means Philips can deliver its strongest shock from the outset, without the need to consider trade-offs with dysfunction. In addition, clinical data demonstrate that the sooner a shock is delivered after CPR, the higher the chances of shock success. Only Philips HeartStart AEDs offer Quick Shock technology, which helps shorten time-to-shock after CPR and increase the chance a shock will successfully return circulation, which may improve survival.

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