INTRODUCTION

The 1990s heralded a new era of transthoracic defibrillation in which the rules of conventional practice no longer apply. Seeking waveform designs more efficient than the traditional monophasic defibrillation waveforms, most external defibrillator manufacturers followed the lead of the implantable cardioverter-defibrillator (ICD) industry, which established clear research evidence of superior clinical and engineering performance of low-energy biphasic defibrillation. By 1988, virtually all ICDs employed biphasic defibrillation waveforms, offering manufacturers the ability to design defibrillators that were smaller, more reliable, and superior in clinical performance using lower energies.

As with ICDs, modern day transthoracic biphasic waveform technologies also allow smaller, more reliable devices. However, external waveforms must deal with the effects of varying patient chest impedance. Philips pioneered the first external biphasic defibrillation waveform in an automated external defibrillator. Philips offers a low-energy, impedance-compensating SMART Biphasic truncated exponential (BTE) waveform across its defibrillator product line, and is unique in the defibrillator industry for its leadership in evidence-based design.

Each manufacturer has taken a different approach to defibrillation and impedance compensation. As a result, the notion of one standardized energy protocol for all is no longer warranted or appropriate, and each defibrillation waveform design must be evaluated based on available research.
**Rules of Evidence: Evaluating the Differences Among Biphasic Waveforms**

How does one differentiate the various biphasic designs? Which biphasic is better? The answer is no one knows. While peer-reviewed human research comparing each of the biphasic technologies within one study design is recognized as ideal, the likelihood of establishing performance differences that reach statistical significance using feasible sample sizes is remote. Thus, no manufacturer has undertaken a well-designed, prospective study in humans to answer the question of superiority among biphasic technologies.

The American Heart Association (AHA) has, however, established a clear evidence-based process for evaluating technologies. In 1997, the AHA established a set of recommendations for manufacturers seeking to design "alternative waveforms". These guidelines were followed in 1998 by the first application of the new "evidence-based review" process, in which the AHA evaluated the research available for defibrillation waveforms and provided recommendations for clinical practice. The process resulted in a Class IIb recommendation ("safe, acceptable, and clinically effective") for nonprogressive 150 J biphasic shocks, of which the Philips SMART Biphasic waveform was the first and only example.

Continuing the theme of evidence-based practice in the 2000 Guidelines document, the AHA issued no classification for high-energy defibrillation and a clear recommendation for low-energy biphasic. The following statement appears following a list of studies reflecting performance of the Philips SMART Biphasic waveform:

"Early clinical experience with the 150-J, impedance-compensated BTE waveform for treatment of out-of-hospital long-duration VF was also positive... The growing body of evidence is now considered sufficient to support a Class IIa recommendation for this low-energy, BTE waveform." Page I-63. (Class IIa is defined as having "good to very good evidence", a "standard of care", "intervention of choice").

In addition, the following generic recommendation for low-energy biphasic defibrillation is provided:

"The data indicates that biphasic waveform shocks of relatively low energy (≤ 200 J) are safe and have equivalent or higher efficacy for termination of VF compared with higher-energy escalating monophasic waveform shocks (Class IIa)" Page I-63.

Finally, the need for comprehensive waveform-specific data is emphasized:

"The safety and efficacy data related to specific biphasic waveforms must be evaluated on an individual basis in both in-hospital... and out-of-hospital settings."

As noted earlier, manufacturers of modern day defibrillation waveforms employ different strategies for waveform design. Following the lead of the AHA, it is critical to rigorously review the published waveform performance data before making a product decision. Properly evaluating the differences in waveform designs also requires an understanding of some basic electrical concepts.

**Understanding Electricity**

**A Defibrillator Delivers “Electrical Medicine”**

Think of administering medicine to a patient. The objective is to provide a dose of the correct medicine to quickly and effectively treat a condition. The dose must be properly measured and delivered over a prescribed period of time. The dose must be potent enough to be therapeutic, while minimizing harmful side effects. With too small a dose, therapy may be ineffective; with too large a dose, there are risks of an overdose. In critical situations, it is important to get the dose right the first time without having to first try several experimental doses.

Now think of defibrillation as delivering a dose of electricity, and the waveform as a graphical way of showing how current is delivered to the patient over time. As with traditional medicine, it is crucial to tailor this "electrical medicine", calculating and measuring the correct defibrillation dose the first time, then delivering the dose effectively to optimize chances for success.

**The Defibrillator**

A defibrillator generates and delivers electrical therapy. In portable transthoracic defibrillators, the source of electricity is a battery. Although a battery may contain a huge amount of energy, it is not in a form to generate a defibrillation waveform that can be delivered quickly to the patient. To accomplish this, the defibrillator charging circuit extracts energy from the
battery and stores it in a capacitor, to be released to the patient in a carefully controlled manner.

To illustrate the various electrical terms associated with this process of efficiently storing and delivering electricity to the patient, think of an analogy using a tank of water (see Figure 1). The tank stores energy in the form of water filled to a particular height. Similarly, a defibrillator capacitor stores energy in the form of electrons at a particular voltage. The "capacitance" of the capacitor is measured in microfarads (µF). The larger the capacitance, the more energy must be stored to achieve a desired voltage.

Once the capacitor is charged to a desired voltage, it is ready to deliver a defibrillation waveform.

**Figure 1  Water Tank Analogy**

![Water Tank Analogy](image)

**The Defibrillation Waveform**

When it is time to defibrillate, switching circuitry within the defibrillator connects the charged capacitor to the patient's chest via paddles or electrode pads. Once connected, the voltage on the capacitor causes current to begin flowing through the patient. Just as the height of water in a tank creates pressure, forcing water through an open pipe, voltage is the driving force for electron flow (current) through a defibrillator circuit. It is current that delivers energy to the patient. Current, however, is resisted by the patient’s impedance (measured in "ohms", or Ω) - an effect similar to a restricted water pipe. Contrary to common perceptions, patient impedance is not closely linked to patient size or weight.

Patient size or weight is often believed to be associated with both impedance and energy requirements. It is often considered a factor in defibrillation success. This common misperception exists despite a lack of peer-reviewed evidence, and a statement to the contrary in the American Heart Association 2000 Guidelines recommendations. “There is no definite relationship between body size and energy requirements for defibrillation in adults.”

The influences of body weight and patient impedance were assessed in recent studies utilizing the fixed, low-energy SMART Biphasic waveform (Philips Medical Systems). Results demonstrated no association between either body weight or patient impedance and defibrillation efficacy, return to spontaneous circulation (ROSC) or survival outcomes. These findings are consistent with other studies showing high efficacy of the SMART Biphasic waveform in rigorous out-of-hospital patient populations, including patients with high impedance. Thus, the fixed-energy, impedance-compensating SMART Biphasic waveform has been designed to be effective across a wide range of patient impedances, and with no influence of body weight on shock success.

The current through the patient’s chest must vary during delivery in a specific manner in order to effectively defibrillate. The current delivered to a patient therefore changes during the course of a defibrillation shock. The pattern, or time course, of this current variation is called a waveform. As shown in Figure 2, the current flows in one direction with traditional monophasic waveforms, whereas current in a biphasic waveform flows in both a positive and negative direction. This biphasic two-directional flow of current within the defibrillator is reflected by current going from pad-to-pad in one direction, then reversing to flow in the opposite direction.

**Figure 2  Monophasic vs. Biphasic Waveforms**

![Monophasic vs. Biphasic Waveforms](image)
Understanding Fixed versus Escalating Energy

With substantial patent portfolios protecting various waveform designs, each manufacturer has chosen different approaches to manipulating the waveform. As a result, energy protocols are no longer standardized; some manufacturers have chosen a low-energy approach (either fixed or escalating) while others have adopted the escalating energy standard of the past. It is important to note, however, that the historical method of escalating energy was developed because the early monophasic waveforms performed relatively poorly with high impedance patients. Depending on the type of monophasic waveform, average first shock efficacy was only about 50 to 80 percent. Escalating the energy provided a mechanism to increase the current, overcome the body's impedance, and, thus, increase the probability of success despite inherently inefficient technology.

Historically, there has never been much evidence to support the practice of escalating energy. In fact, there is early evidence that escalation was associated with adverse consequences. The problem with this escalating energy approach, be it with monophasic or biphasic technology, is twofold. First, the myocardium remains in a lethal rhythm state while the device takes the time to ramp up to an effective current dose. Second, while the traditional approach of escalating, high-energy is often assumed to be the appropriate standard for optimizing defibrillation efficacy, use of increasing doses of energy - particularly in the context of biphasic waveforms, whose efficacy has been repeatedly proven using relatively lower energies - must be weighed against a growing body of evidence for toxicity with higher energies.

Energy, in fact, is not the whole story, as it is current that defibrillates, not energy. One recent study comparing a high-energy biphasic waveform with the low-energy SMART Biphasic waveform indicates that high peak current was the only significant predictor of survival (p < 0.001). By contrast, high-energy was associated with cardiac dysfunction, such as impaired ejection fraction and stroke volume. The study concludes that the key to a well-designed waveform is to combine high peak current for efficacy with low-energy for safety. This is the approach that Philips takes.

The defibrillation response curves in Figure 3, from another experimental study, demonstrate graphically how the probability of defibrillation changes with increasing current. Figure 3 also demonstrates the difference between the defibrillation response curves for a typical biphasic truncated exponential (BTE) waveform and the monophasic damped sine (MDS) waveform (the most commonly used monophasic waveform).

With the gradual slope of the MDS waveform, it is apparent that as one increases the current, defibrillation efficacy is also improved. This finding led to the use of escalating energy with the MDS waveform, since peak current is increased with escalating energy, which results in a higher probability of defibrillation. For the monophasic waveform, therefore, increasing the energy can improve defibrillation efficacy. Selecting a fixed energy with the monophasic waveform that would defibrillate all patients could result in dangerously high energy and current levels, another factor supporting the use of escalating energy with traditional monophasic waveforms.

In contrast, the response curve for the biphasic waveform has a steeper slope and the probability of defibrillation changes very little once a certain current level is reached. This means that, if the energy and minimum delivered current levels are chosen appropriately (150 J for defibrillation, in our case), escalating energy is not required to increase efficacy. By selecting a fixed energy dose, the current delivered to the patient can vary as the patient impedance varies (more on this later), and the probability of defibrillation remains high. So, for a well-designed biphasic waveform, increasing the energy does not improve the defibrillation efficacy, and is therefore unnecessary.
**Principles of Effective Waveform Design**

Until recently, essentially all manufacturers used monophasic defibrillation waveforms. Monophasic technology was constrained by the electronic components available during the era in which it originated (1960s), remained largely unchanged over time, and had little research focused on patient outcomes to support its performance. Further, the waveforms used energy inefficiently and were not able to adjust effectively to a patient’s chest impedance.

Without effective defibrillator impedance compensation, high patient impedance degrades the waveform, a key factor in the relatively poor performance of traditional uncompensated monophasic technologies. Low impedance imposes a different set of potential problems. As will be described in greater detail later, low impedance patients may be more likely to shunt current away from the heart.

Today, modern electronics permit much greater control of therapy generation and delivery, including the ability to compensate for the untoward effects of high and low patient impedance. In the next sections, we examine how a well-designed modern defibrillator addresses crucial dosing factors to deliver safe and effective electrical medicine.

**Dosing Factor 1: Seconds Count; Calculate the Correct Dose the First Time**

There is ample evidence that speed to an effective first shock matters; even as little as a minute difference in time to first shock affects patient outcome. The challenge for the defibrillator, then, is to effectively deliver the right amount of current from the very first shock.

It is the pattern of current flow that enables defibrillation. Voltage, current and the time course of waveform delivery all affect energy delivered to the patient. It is now possible for the defibrillator to manipulate any of these electrical characteristics to deliver an effective current pattern while using energy efficiently.

Escalating energy is no longer required. The solution to problems imposed by patient impedance is, instead, to design a defibrillation waveform that effectively measures and compensates for patient impedance, delivering the correct dose of current (and energy) on the first shock. One of the challenges to delivering the correct dose of current, however, is to design a waveform that addresses the issue of shunted current, thought to be particularly an issue in low impedance patients.

A defibrillator delivers current across the chest ("transthoracic current"), but it is the proportion of the transthoracic current crossing the heart ("transcardiac current") that is clinically meaningful. Unfortunately, only a small fraction of the current delivered by the defibrillator flows to the heart. The rest is diverted, or shunted, to the surrounding areas of the chest. To compensate for this current shunting phenomenon, a well-designed defibrillator provides sufficient transthoracic current to supply effective transcardiac current, even in the presence of shunt pathways, as demonstrated in Figure 8.

In summary, by manipulating the defibrillator electronics and optimizing the waveform to address issues such as high impedance and shunting, it is now possible to achieve defibrillation on the first dose using a carefully calibrated fixed low-energy waveform design.

In fact, there is extensive and persuasive evidence that the Philips 150 J BTE waveform performs as well as or, in most studies, far better than the "gold standard" monophasic defibrillation waveform on the first shock, without the need to escalate. In one representative pre-hospital study comparing 150 J SMART Biphasic to monophasic defibrillation, the Philips waveform was associated with superior efficacy (96% on the first shock, 98% by the third shock, and 100% patient efficacy), improved return of spontaneous circulation (ROSC), and better neurological outcomes in survivors, despite long call-to-first shock times averaging 8.9 minutes (see Figures 4, 5, and 6). No other biphasic defibrillator manufacturer has demonstrated superior performance, compared to monophasic defibrillators, in an ischemic sudden cardiac arrest (SCA) patient population.
Another critical factor in achieving effective defibrillation is to deliver an appropriately measured dose of current for the correct amount of time. The engine of this process is a properly sized defibrillator capacitor. The size of the capacitor, ("capacitance", measured in microfarads, or µF) is crucial to effective and efficient defibrillator design.

To prepare for a defibrillator shock, a defibrillator's capacitor must be charged to a voltage high enough to drive appropriate current through the resistance of the patient's chest throughout the time course of the shock. Energy is stored in preparation for defibrillation when the capacitor is charged. The larger the capacitor, the larger the amount of energy that must be stored in order to achieve the voltage necessary to initiate an appropriate dose of defibrillation current.

It is possible, however, to design a system in which energy is used efficiently, not requiring as much energy as has been historically the case with traditional monophasic waveforms. Recognizing this, Philips patented an optimal 100 µF capacitor design for its impedance-compensating SMART Biphasic waveform. The Philips capacitor requires little energy during charging, yet achieves the necessary voltage required to create effective defibrillation currents throughout the 150 J shock.

In contrast, some other modern biphasic defibrillator designs use larger capacitors (200 µF). These designs require twice as much energy in order to achieve the same patient currents available with the Philips low-energy 100 µF design.

Figure 7 contrasts the 150 J SMART Biphasic waveform, using a 100 µF capacitor, with other high-energy waveform designs. The Philips waveform achieves more current delivering 150 J than a 200 µF design delivering 200 Joules. The current of the high-energy biphasic defibrillator becomes comparable to the Philips waveform only when the energy reaches 300 Joules - on the second shock.
It should also be noted from Figure 7 that all modern biphasic waveform designs deliver far less current than some historic monophasic waveform systems. The modern biphasic technologies have been designed to be effective at comparatively lower peak currents. None of the commercially available biphasic defibrillators reaches current levels regarded as potentially dangerous, as is the case with their monophasic predecessors.

In short, the Philips system uses a proprietary low-capacitance design to efficiently generate a waveform personalized to patient impedance. This approach yields consistently favorable results even in challenging long down-time patient populations.

**Dosing Factor 3: Deliver the Current (and Energy) Over the Correct Amount of Time for Each Patient Regardless of Impedance - A Personalized Waveform**

The last critical dosing factor involves the design of the waveform, which delivers a changing pattern of current to the patient throughout the duration of the shock to accommodate variations in patient impedance. Since this current pattern is sometimes adversely affected by patient impedance, a well-designed waveform must measure patient impedance and adjust the waveform shape and duration accordingly, optimizing waveform performance across the range of anticipated impedance values.

A defibrillator waveform should compensate for both high and low chest impedance. Patient impedance in humans has been shown to vary anywhere from 25 to 180 ohms. According to Ohm’s Law (I = V/R), a high impedance patient resists the flow of current and, therefore, the peak current is less; the peak current in a low impedance patient is comparatively higher. This Ohm's Law relationship is illustrated in Figure 8, which shows energy fixed at 150 J and the Philips SMART Biphasic waveform shape and duration adjusting actively based on patient impedance.

**Figure 8 SMART Biphasic Impedance Compensation**

The shape and duration variations shown in Figure 8 have been carefully designed based on peer-reviewed evidence specific to the Philips waveform. Through this research, the “sweet spot” for waveform shape and duration was determined for the SMART Biphasic waveform using a fixed, 150 J adult defibrillation protocol.

Based on this research, the SMART Biphasic waveform is designed to perform across the whole range of anticipated patient impedance values. In the case of high impedance patients, the waveform lengthens to deliver adequate energy. For low impedance patients, the defibrillator delivers somewhat higher peak currents to compensate for the possible effects of shunting.

Because Philips measures impedance and dynamically varies these waveform attributes accordingly on every shock, it is simply not necessary to increase the energy on successive shocks. The optimal therapy is delivered with the first shock, as with every shock.
The performance of the Philips SMART Biphasic waveform has been tested in numerous peer-reviewed manuscripts, the number and breadth of which far exceeds that of any other manufacturer. These published studies reflect waveform performance both in animals and in humans.

Of the 17 published human studies, to date, three report on experience with in-hospital induced, short-duration ventricular fibrillation (VF) and 14 address performance with the challenging long duration VF relevant to out-of-hospital and other delayed defibrillation settings. These data reflect performance consistently equal or superior to that of high-energy escalating therapies, regardless of factors such as: patient size, age, impedance, or underlying cause of SCA, including myocardial infarction.

Comparing the Transthoracic Biphasic Waveforms

Now that we have highlighted the key elements of effective biphasic waveform design, we turn to a brief overview of other external biphasic waveform technologies on the market. The SMART Biphasic waveform was introduced in 1996 with substantial patent protections. There are also patent restrictions on various other technologies. Consequently, the biphasic technologies are all different, as are the associated energy protocols.

Because of these design differences, the energy protocol for each manufacturer’s defibrillator should be individualized. The need for product-specific energy protocols is confirmed by ECRI, a non-profit organization whose mandate it is to objectively evaluate biomedical equipment: "...a waveform designed for low-energy defibrillation may result in an overdose if applied at high energies, while another waveform designed for high-energy may not defibrillate at lower energies."31

Most importantly, compared to the Philips SMART Biphasic waveform, other manufacturers have relatively few published, peer-reviewed studies to demonstrate the performance of their waveforms. Some manufacturers have no data at all, and others rely heavily upon animal data to demonstrate waveform performance. Collectively, the amount and breadth of published SMART Biphasic clinical research exceeds that of all other manufacturers’ waveforms.

The Low-Energy Rectilinear Biphasic Waveform Alternative

The Rectilinear Biphasic waveform (ZOLL Medical Corporation) shares with SMART Biphasic a low-energy, low-capacitance design, but there are significant differences. Most importantly, the Rectilinear waveform offers only limited peer-reviewed evidence to support its performance. As of this writing, we are aware of no published, peer-reviewed data reflecting performance with the challenging long down-time patient population most difficult to treat effectively.

The Rectilinear waveform does little to adjust current in response to the problem of shunt current pathways within the chest. The waveform utilizes what company literature describes as a "constant current" approach in the first phase of the waveform. In contrast to SMART Biphasic, which modifies peak current, waveform shape and duration based on patient impedance, the Rectilinear approach is to hold the overall waveform duration and ratio between the two phases constant regardless of patient impedance (see Figure 9).

Figure 9  SMART Biphasic vs. Rectilinear Biphasic

The published adult energy protocol for the Rectilinear Biphasic waveform device starts at 120 J and escalates to 200 Joules. As noted earlier, escalating energy was employed historically to increase peak current with inherently inefficient monophasic waveforms, but is not necessary with biphasic when the first shock is adequately dosed, as is the case with SMART Biphasic.
For any selected energy setting, the actual delivered Rectilinear waveform energy varies widely across the range of patient impedance. Further, the Rectilinear Biphasic waveform loses the constant current profile, essentially becoming a BTE waveform very similar to SMART Biphasic (Figure 10), when patient impedance values exceed 100 ohms and 200J of energy is selected.

In summary, the Rectilinear waveform, marketed as a "constant current" waveform, does little to adjust current in response to current shunting in the patient’s chest. The manufacturer abandons the hallmark "constant current" approach for some high impedance patients and, perhaps most importantly, has only limited published data on which to measure its waveform’s performance, none of which reflects performance with the ischemic SCA patient.

The High-Energy Biphasic Waveform

Alternatives

There are several escalating high-energy biphasic waveforms currently on the market. It is beyond the scope of this paper to describe in detail each of the designs. Instead, we offer a high level summary of technology issues to consider with high-energy waveforms as a class.

The specific methods of impedance compensation vary with the manufacturer. Figure 11 illustrates the SMART Biphasic waveform compared to one of the common high-energy biphasic waveforms on the market. It is evident that the two waveforms modify peak current, waveform shape and duration similarly in response to patient impedance. The big difference is that the high-energy waveforms require high-energy to deliver adequate current to the patient because of their large capacitors, while the Philips low-energy BTE waveform delivers adequate current on the first shock without the need to escalate.

Most importantly, as of this writing there is only one published, peer-reviewed study reflecting waveform performance of one high-energy biphasic waveform with the ischemic, long downtime SCA patient population. This study compared the high-energy ADAPTIV biphasic waveform (Metronic Physio-Control) with a conventional monophasic damped sine (MDS) waveform. While first shock efficacy for the biphasic waveform was high, there was an atypical trend towards better MDS waveform performance compared to the ADAPTIV biphasic waveform for all other outcome variables.

Compare these results to a similar study in which the SMART Biphasic waveform was associated with improved return to spontaneous circulation, improved survival to hospital admission and discharge, and superior neurological outcome for survivors compared to monophasic treatment.

There is no peer-reviewed research in humans to compare the performance of one biphasic waveform to another. A swine study by Walker, et al. is often cited as evidence of high-energy superiority with moderate to high impedance patients. However, the study utilized a disputed animal model that is
inconsistent with the way in which impedance actually occurs in either animal or human populations.

The Walker, et al. study also yields results inconsistent with numerous peer-reviewed studies demonstrating superior efficacy of the low-energy SMART Biphasic waveform defibrillator to high-energy therapies across a diverse human population, including patients with high impedance.

In summary, high-energy biphasic waveforms offer little or no published, peer-reviewed data in comparison to that published for the Philips SMART Biphasic waveform, and only one study reflecting performance with the long down-time SCA patient population.

As pointed out, high biphasic energy has been associated with increased cardiac dysfunction.15

Finally, the AHA has issued no science-based recommendations regarding biphasic defibrillation > 200 Joules.

**Conclusion**

Traditional monophasic waveform technology, while it saved many lives, had serious design limitations. High patient impedance degraded the waveform, resulting in relatively poor performance. So, an empirical strategy of escalating energy developed, without supporting science, in an effort to compensate for monophasic design limitations.

With the advent of modern biphasic waveform technology, however, impedance compensation and other design improvements have led to generally superior clinical and engineering performance characteristics. It is now possible to produce a highly effective, safe waveform without the need to escalate energy. The variety of external biphasic waveforms in the marketplace has prompted complexity and confusion around clinical practice guidelines. Since traditional, empirical rules-of-thumb are no longer sufficient to guide practice, the clinician is best advised to rely on the manufacturer’s recommendations for their specific waveform and on the associated body of supporting peer-reviewed science.

The AHA has recommended an evidence-based process for evaluating defibrillation waveforms, reflecting published research in both in- and out-of-hospital settings. To date, Philips has offered more published data reflecting performance in both in- and out-of-hospital patients than any other manufacturer, establishing a clear leadership position in evidence-based waveform design. Based on published research, the AHA has provided a IIa recommendation for low-energy biphasic defibrillation (≤ 200 J), and no recommendation for higher energy.
References


