



BIPHASIC DEFIBRILLATION

INTRODUCTION

Defibrillation is the only effective treatment for a heart in sudden cardiac arrest (SCA). The choice of a defibrillator waveform is critical for defibrillation efficacy and patient outcome.

Whether evaluating a defibrillator for use in your community, company, hospital, or emergency response unit, the following questions should be of interest:

- How does defibrillation work?
- How have defibrillation waveforms evolved?
- Why is biphasic technology today's standard of care?
- What do studies show about defibrillation of prolonged ventricular fibrillation?
- Is there a relationship between waveform, energy level, and postresuscitation dysfunction?
- Are escalating energies needed to treat SCA?
- Do some waveforms predispose the heart to refrillation?
- Are all biphasic waveforms alike?
- Can all waveforms be used on the entire patient population?
- How does SMART Biphasic compare to other biphasic waveforms?
- Is there a standard for biphasic defibrillation energy levels?

As with ICDs, modern day transthoracic biphasic waveform technologies also allow smaller, more reliable devices, however external waveforms must deal with the potentially adverse effects of varying patient chest impedance. In 1996, the first external biphasic defibrillation waveform in an automated external defibrillator was deployed by Philips Medical Systems. Philips offers the 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.

This Application Note provides straightforward answers to these questions, with supporting data and references. The timeline provided on the next page summarizes key studies on defibrillation waveforms conducted over the last two decades.

KEY STUDIES

waveforms studies	results
1992 low-energy vs. high-energy damped sine monophasic	249 patients (emergency resuscitation). Low-energy and high-energy damped sine monophasic are equally effective. Higher energy is associated with increased incidence of A-V block with repeated shocks. ¹
1994 biphasic vs. damped sine monophasic 1995	19 swine. Biphasic shocks defibrillate at lower energies, and with less post-resuscitation arrhythmia, than monophasic shocks. ² 171 patients (electrophysiology laboratory). First-shock efficacy of biphasic damped sine is superior to high-energy monophasic damped sine. ³
1995 low-energy truncated biphasic vs. high-energy damped sine monophasic	30 patients (electrophysiology laboratory). Low-energy truncated biphasic and high-energy damped sine monophasic equally effective. ⁴
1996 115 and 130 J truncated biphasic vs. 200 J and 360 J damped sine monophasic	294 patients (electrophysiology laboratory). Low-energy truncated biphasic and high-energy damped sine monophasic are equally effective. High-energy monophasic is associated with significantly more post-shock ST-segment changes on ECG. ⁵
1997 SMART Biphasic vs. 1998 standard high-energy 1999 monophasic	18 patients (10 VF, emergency resuscitation). SMART Biphasic terminated VF at higher rates than reported damped sine or truncated exponential monophasic. ⁶ 30 patients (electrophysiology laboratory). High-energy monophasic showed significantly greater post-shock ECG ST-segment changes than SMART Biphasic. ⁷ 286 patients (100 VF, emergency resuscitation). First-shock efficacy of SMART Biphasic was 86% (compared to pooled reported 63% for damped sine monophasic); three or fewer shocks, 97%; 65% of patients had organized rhythm at hand-off to ALS or emergency personnel. ⁸
1999 low-energy (150 J) vs. high-energy (200 J) biphasic	20 swine. Low-energy biphasic shocks increased likelihood of successful defibrillation and minimized post-shock myocardial dysfunction after prolonged arrest. ¹⁰
1999 low-capacitance biphasic vs. high-capacitance biphasic	10 swine. Five of five low-capacitance shock animals were resuscitated, compared to two of five high-capacitance at 200 J. More cumulative energy and longer CPR were required for high-capacitance shock animals that survived. ¹¹
1999 SMART Biphasic vs. 2000 escalating high-energy monophasic	10 swine. Stroke volume and ejection fraction progressively and significantly reduced at 2, 3, and 4 hours post-shock for monophasic animals but improved for biphasic animals. ¹² 338 patients (115 VF, emergency resuscitation). SMART Biphasic defibrillated at higher rates than MTE and MDS, with more patients achieving ROSC. Survivors of SMART Biphasic resuscitation were more likely to have good cerebral performance at discharge, and none had coma (vs. 21% for monophasic survivors). ¹³

DEFIBRILLATION AND SUDDEN CARDIAC ARREST



Normal sinus rhythm (NSR)



Ventricular fibrillation (VF)

How does Defibrillation works?

The pumping rhythm of the healthy heart is normally controlled by electrical stimuli that originate in the heart's natural pacemaker (the sino-atrial node). In normal sinus rhythm (NSR), these electrical impulses travel rapidly through specialized conduction pathways in the heart, producing a coordinated mechanical contraction that pumps blood throughout the body. When a heart suffers sudden cardiac arrest (SCA), it stops pumping.

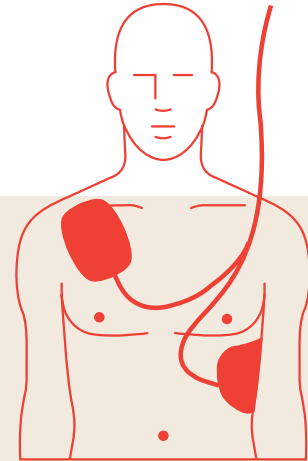
SCA is typically caused by ventricular fibrillation (VF), a life-threatening arrhythmia of uncoordinated, chaotic electrical activity within the heart. The heart muscle quivers rapidly and unproductively, unable to pump blood to the brain and the rest of the body. Unless blood circulation can be restored by defibrillating the heart, death will occur within a matter of minutes. Effective cardiopulmonary resuscitation (CPR) may be able to prolong some degree of circulation, but it cannot stop VF.

The illustrated electrocardiograms (ECGs) at left show the difference between the beating of a heart in NSR, and the unorganized chaos of VF. Unless defibrillated promptly, a heart in VF may degenerate into asystole, a "flat line" on the ECG.

Defibrillation is electrical therapy for the heart in VF. It delivers an electrical shock to stop the chaotic, non-productive activity within the heart muscle.

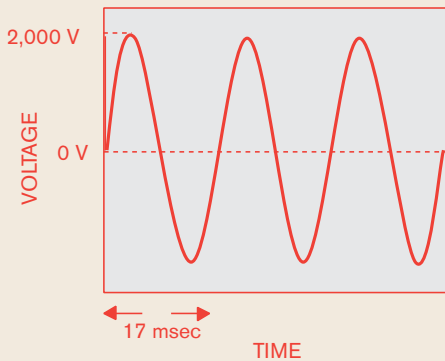
The shock is passed between two disposable adhesive pads that are usually positioned on the chest as shown in the illustration. This placement allows a fast response in an SCA emergency. The shock passes through the heart as it travels from one pad to the other.

Defibrillation stops the chaotic electrical activity of fibrillation and causes the heart to pause, allowing the heart's natural pacemaker to regain control of the rhythm. That is why, immediately after a successful defibrillation shock, it is normal for the heart to briefly experience asystole, a "flat line," before the return of spontaneous rhythm.

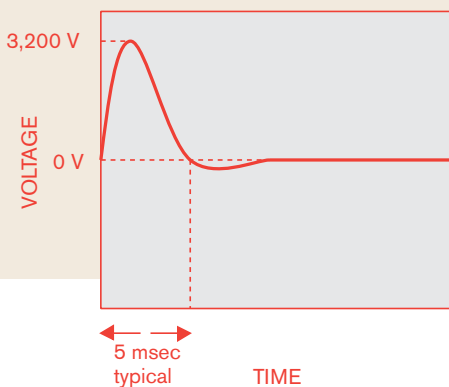


Standard defibrillation pad placement for adults)

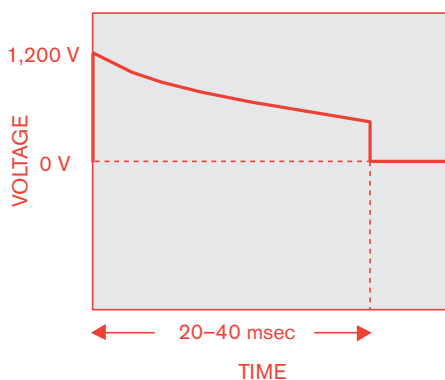
A BRIEF HISTORY OF DEFIBRILLATION



Monophasic damped sine (MDS) waveform



Monophasic damped sine (MDS) waveform



Monophasic truncated exponential (MTE) waveform

How have defibrillation waveforms evolved?

The concept of electrical defibrillation was introduced over a century ago. Early experimental defibrillators used alternating current (AC) 60 Hertz household power with step-up transformers to increase the voltage. The shock was delivered directly to the heart muscle. Transthoracic (through the chest wall) defibrillation was first achieved in the 1950s.

The desire for portability led to the development of direct current (DC) defibrillators in the 1950s. It was also discovered that DC shocks were more effective than AC shocks. The first "portable" defibrillator was developed at Johns Hopkins University. It used a biphasic waveform to deliver 100 joules (J) over 14 milliseconds. The unit weighed only 50 pounds with accessories, at a time when standard defibrillators typically weighed more than 250 pounds and was briefly commercialized for use in the electric utility industry.

Defibrillation therapy gradually gained acceptance over the next two decades. An automated external defibrillator (AED) was introduced in the mid-1970s, shortly before the first automatic internal cardioverter-defibrillator (AICD) was implanted in a human.

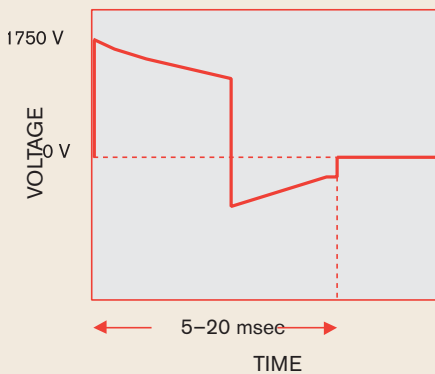
Over most of the last 30 years, defibrillators used one of two types of monophasic waveforms: monophasic damped sine (MDS) or monophasic truncated exponential (MTE). With monophasic waveforms, the heart receives a single burst of electricity that moves from one pad to the other.

The MDS waveform requires high energy levels, up to 360 J, to defibrillate effectively. One reason is that monophasic damped sine waveforms are not designed to compensate for differences in impedance — the resistance of the body to the flow of current — encountered in different patients.

Traditional damped sine monophasic waveform defibrillators assume a patient impedance of 50 ohms, but the average impedance of adult humans is between 80 and 90 ohms. As a result, the energy actually delivered by MDS waveforms is usually higher than the selected energy.

The monophasic truncated exponential (MTE) waveform also uses energy settings of up to 360 J. Because it uses a lower voltage than the MDS waveform, the MTE waveform requires a longer duration to compensate for higher patient impedances. Long-duration (over 20 msec) shocks have been associated with rebrillation.¹⁴

BIPHASIC TECHNOLOGY



SMART Biphasic truncated exponential (BTE) waveform (adult dose)

Why is it today's choice?

Despite the phenomenal advances in the medical and electronics fields during the last 30 years, the waveform technology used for external defibrillation has remained unchanged until very recently. In 1992 research scientists and engineers at Heartstream (now part of Philips Medical Systems) began work on what was to become a significant advancement in external defibrillation waveform technology.

Extensive studies for implantable defibrillators had shown biphasic waveforms to be superior to monophasic waveforms.¹⁵⁻¹⁷ In fact, a biphasic waveform has been the standard waveform for implantable defibrillators for over a decade. With biphasic waveforms, the electricity moves from one pad to the other then reverses direction. The Heartstream team set out to design a biphasic waveform specifically for use in external defibrillation. The result is the SMART Biphasic waveform.

SMART Biphasic is the patented technology now used in all new Philips Medical Systems defibrillators. It is defined as an:

- impedance-compensating
- low-energy
- low-capacitance
- truncated exponential
- biphasic waveform.

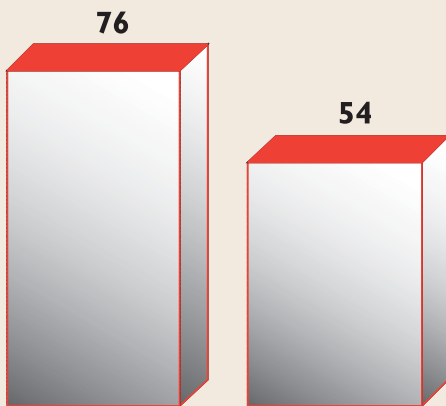
Using a process outlined by the American Heart Association (AHA) in 1995,¹⁸ the Heartstream team put the SMART Biphasic waveform through a rigorous sequence of validation studies. First, animal studies were used to test and fine-tune the waveform parameters to achieve optimal efficacy.

Electrophysiology laboratory studies were then used to validate the waveform on humans in a controlled hospital setting. Finally, after receiving clearance for the new AED, post-market surveillance studies were used to prove the efficacy of the SMART Biphasic waveform in the out-of-hospital, emergency-resuscitation environment.

In the course of these studies, it was shown that defibrillators incorporating the low-energy SMART Biphasic waveform not only defibrillate as well as or better than traditional monophasic waveforms but are associated with better post-shock cardiac function, fewer post-shock arrhythmias, and better neurological outcome for survivors than high-energy monophasic AEDs.⁴⁻¹² In fact, in a randomized clinical trial, SMART Biphasic was shown to be more effective than both MTE and MDS defibrillation.^{13,23}

SMART Biphasic has been used in all Heartstream AEDs – which now bear the HeartStart brand – and is supported by extensive clinical studies. No other waveform has been proven more effective for emergency resuscitation. The success of SMART Biphasic technology has led other manufacturers to follow Philips Medical Systems and move to biphasic waveforms for their external defibrillators.

SCA IN THE REAL WORLD



Return of spontaneous circulation (ROSC) rates are significantly higher for SMART Biphasic patients.

What do studies show about defibrillation of prolonged cardiac arrest?

Current data show most waveforms to have a first-shock efficacy of between 83% and 100% following short-duration VF (less than or equal to 30 seconds), artificially induced in electrophysiology laboratories.^{3-7,24} In this environment, the SMART Biphasic waveform has demonstrated a first-shock efficacy of 97% in one study, and 86% in another (130 J dose).^{4,5}

But what about sudden cardiac arrest in the workplace, at home, in a public area, or healthcare settings? In these settings, VF occurs spontaneously because of cardiac disease, asphyxiation, etc., and is typically untreated for up to 15 minutes. Clinical tests based solely on induced short-duration VF in controlled circumstances do not reflect the rigorous conditions associated with nonlaboratory, emergency resuscitation of long-duration VF in ischemic SCA patients.

In a randomized out-of-hospital study comparing low-energy SMART Biphasic to high-energy escalating monophasic defibrillation, the average call-to-firstshock time was 8.9 minutes. Of the 54 SMART Biphasic patients, 100% were defibrillated – 96% on the first shock, and 98% with three or fewer shocks. Of the 60 patients treated with an escalating energy monophasic device, only 59% were defibrillated on the first shock, and 69% with three or fewer shocks. Of the SMART Biphasic patients, 76% experienced a return of spontaneous circulation (ROSC), versus only 54% of the monophasic escalatingenergy patients.¹³

In a post-market, out-of-hospital study of 100 VF patients defibrillated with the SMART Biphasic waveform, the authors concluded that “Higher energy is not clinically warranted with this waveform.”⁸

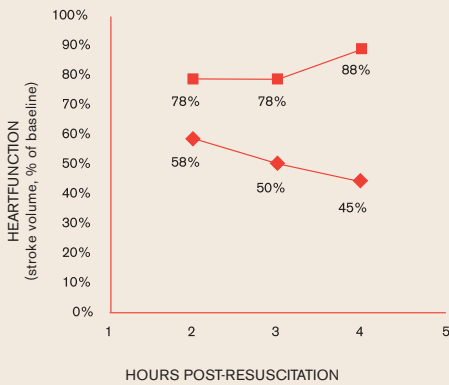
SMART Biphasic is the only biphasic waveform to have extensive emergency resuscitation data for long-duration VF.

DEFIBRILLATION AND DYSFUNCTION

Is there a relationship between waveform, energy level, and post-shock dysfunction?

Yes. Higher-energy defibrillation waveforms – whether monophasic or biphasic – are associated with increased post-resuscitation myocardial dysfunction.

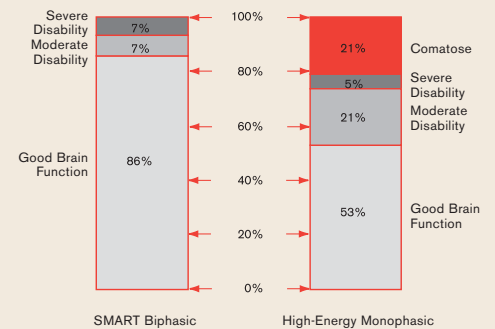
There is a difference between damage and dysfunction. In the context of postshock cardiac assessment, "damage" can be defined as irreversible cell death, as measured by various enzyme tests. "Dysfunction" is reflected in reduced cardiac output as a result of reversible myocardial stunning. Dysfunction can result in significantly reduced cardiac output for many hours postresuscitation. Waveforms that do not cause damage can cause dysfunction.



Post-resuscitation cardiac function as measured by stroke volume is superior with SMART Biphasic therapy and improves over time.

Evidence of this dysfunction includes electrocardiogram (ECG) abnormalities.^{5,7} An animal study of monophasic waveforms found that increased levels of delivered energy were associated with increased evidence of impaired myocardial contractility, perfusion failure, and decreased duration of survival. The authors conclude: "The severity of postresuscitation myocardial dysfunction is related, at least in part, to the magnitude of electrical energy of the delivered shock."¹⁹ Several other studies also provide data to support this conclusion for biphasic as well as monophasic waveforms.^{10,21,22,25}

Post-resuscitation brain dysfunction is another important area that warrants further study. In a randomized study of 115 out-of-hospital SCA patients with VF, 54 were shocked with the SMART Biphasic waveform and the remainder with escalating high-energy monophasic devices. While there was no difference in overall survival, 87% of SMART Biphasic survivors had good brain function at hospital discharge, as opposed to only 53% of monophasic escalating-energy survivors. None of the SMART Biphasic patients experienced post-shock coma, while 21% of monophasic survivors did.¹³



Neurological outcomes for SCA survivors treated with SMART Biphasic are significantly better than for those treated with monophasic AEDs.

ENERGY LEVELS FOR TREATMENT OF SCA

Are escalating energies needed?

Not with SMART Biphasic. Waveform shape counts. Different waveforms require different amounts of energy to be delivered in order to successfully defibrillate the heart. And how the energy is delivered to the heart is as important as how much energy is delivered.

Time is the most critical element in treating SCA. When a defibrillator must escalate its energy delivery in order to find an effective dose, patient defibrillation is unnecessarily delayed.

The SMART Biphasic waveform has been optimized for ventricular defibrillation efficacy at 150 J. SMART Biphasic defibrillators are designed to deliver the full-dose, 150 J shock the first time, and every time.

In a variety of emergency resuscitation settings, the low-energy SMART Biphasic has been used to treat a wide cross section of patient impedance, size, weight, gender, underlying cause of SCA, and pad placements. Yet its performance has remained consistently equal or superior to that of high-energy escalating monophasic therapies.

Following are some specific examples:

• **High-impedance and heavy patients.**

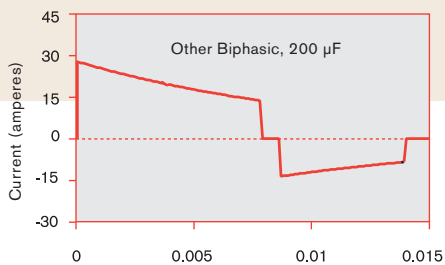
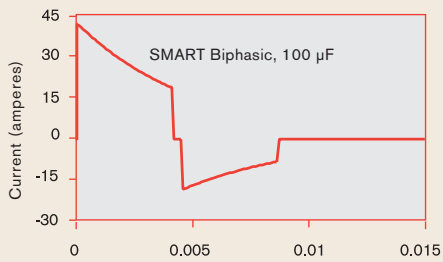
Heavy patients sometimes have a high shock impedance, and high shock impedance presents a challenge to traditional defibrillation therapies. Using a patented method, SMART Biphasic technology automatically measures the patient's impedance and adjusts the waveform dynamically during each shock, to optimize the waveform for each shock on each patient.

SMART Biphasic has been shown to defibrillate patients with high impedance (greater than 100 ohms) as effectively as low-impedance patients, with a first-shock efficacy of 93%.¹³

• **Heart-attack victims.**

In a randomized resuscitation trial of SCA patients, a total of 54 VF patients were treated with the SMART Biphasic waveform. Of those with an identified cause of SCA, 51 % were heart attack victims with documented myocardial infarction (MI). These patients did not require escalating protocols when treated with the 150 J SMART Biphasic waveform. One hundred percent of SMART Biphasic patients were defibrillated, 96% on the first shock. It is clear that MI patients did not require energy escalation beyond 150 J with the SMART Biphasic waveform.¹³

WAVEFORMS AND ENERGY



Waveform shape and efficacy change with capacitance (adult dose).

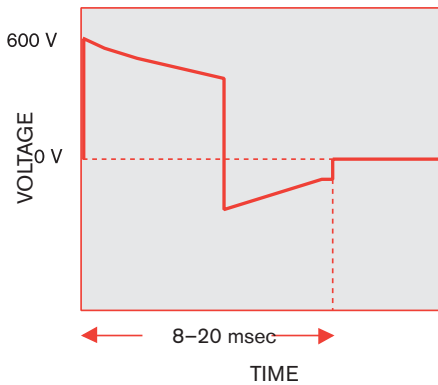
Are all biphasic waveforms alike?

No. Different waveforms perform differently, depending on shape, duration, capacitance, voltage, current, and response to impedance. Each waveform needs to be carefully validated by studies. No other biphasic waveform has been so extensively studied as the low-energy SMART Biphasic waveform, particularly in non-laboratory situations involving long-duration VF.^{6,8,9,13,20,23,32} Its patented design is based on solid scientific research and has accumulated years of impressive data in the field.

The illustrations at right show the SMART Biphasic waveform and another biphasic waveform with a higher capacitance, similar to that used by another AED manufacturer. The low capacitance used by the patented SMART Biphasic waveform delivers energy more efficiently. In an animal study using these two waveforms, the SMART Biphasic waveform successfully resuscitated all animals and required less cumulative energy and shorter CPR time than the other biphasic waveform, which resuscitated only 40% of the animals.¹¹

SMART Biphasic delivers a proven adult defibrillation energy dose of 150 J. Most other biphasic devices still use escalating high-energy protocols originally designed for monophasic devices, with the attendant drawbacks of increased device and protocol complexity, as well as potential postresuscitation myocardial dysfunction.

PROTECTING OUR CHILDREN



SMART Biphasic truncated exponential (BTE) waveform (pediatric dose).

Can all waveforms be used on the entire patient population?

No. Due to concerns about an AED's ability to correctly distinguish between shockable and non-shockable pediatric heart rhythms, and about the safety of shocking small children with waveforms and energies intended for adults, patients under eight years old have traditionally been excluded from treatment with an AED and thus from the early defibrillation standard of care. While VF is not common in small children, studies reveal that it is not rare, and may be under-reported.³³⁻³⁵

But recently the Philips FR2 AED became the first AED cleared by the U.S. Food and Drug Administration for use on cardiac arrest patients of any age, including infants and small children. The FR2 AED, with its outstandingly accurate heart rhythm analysis system – SMART Analysis – and special FR2 infant/child defibrillator pads that reduce the SMART Biphasic shock to 50 J, is now available for use on infants and small children under the age of 8 years or 55 pounds.

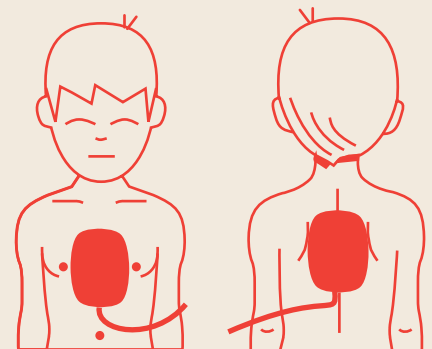
In an animal study by Tang et al., reduced-energy (50 J) SMART Biphasic safely and effectively resuscitated piglets with long-downtime VF.³⁶ These pigs were of various sizes corresponding to infant through eight-year-old humans. The animals were in VF for seven minutes prior to the resuscitation attempt. When treated with 50 J SMART Biphasic therapy, 100% of the pigs experienced return of spontaneous circulation and were successfully resuscitated. They were neurologically intact, and they quickly returned to their baseline cardiac performance without lasting compromise of post-resuscitation myocardial function.

Is 50 J too strong for infants? Compared to the results of studies on older animals, even the smallest pigs in the Tang study demonstrated remarkably rapid recovery.

Is 50 J too weak for seven year olds? The largest pigs, corresponding to 8 year old humans, were all successfully resuscitated, allaying concerns about effectiveness. All animals received at least 2 J/kg, the recommended minimum dose for monophasic waveforms.

When connected to the pediatric pads, the FR2 AED performs rhythm analysis and impedance compensation in a manner similar to that used for adult patients. During shock delivery, the pads simply reduce the adult 150 J SMART Biphasic shock dose to 50 J, an energy that is appropriate for infants and small children.

So SMART Biphasic is the right biphasic for any patient of any age.



Special FR2 pediatric pads – placed on the front and back of the chest – allow the FR2 AED to be used on infants and children under 8 years or 55 pounds.

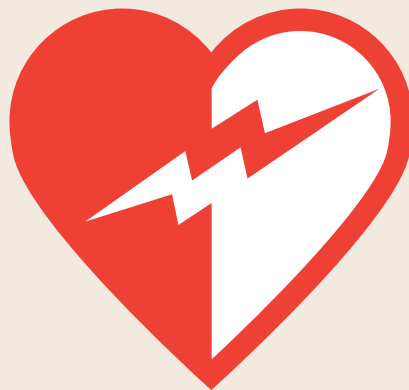
GUIDELINES FOR DEFIBRILLATION

Is there a standard for biphasic energy levels?

No.

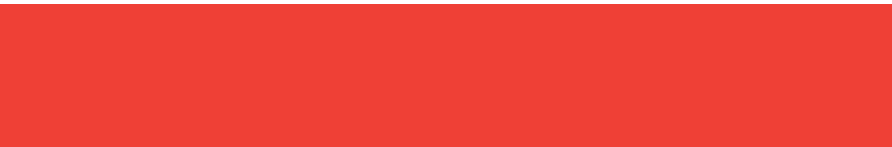
Each biphasic waveform is unique in its design and required energy levels to achieve optimal shock efficacy. The most important factor in judging among biphasic waveforms is the peer-reviewed published data on their performance.

The data supporting low-energy biphasic defibrillation has been reviewed by the American Heart Association (AHA), which found the therapy to be "safe, effective, and clinically acceptable." As stated by the AHA, "A review of previous AHA guidelines for the [monophasic] energy sequence 200 J–300 J–360 J reveals that the evidence supporting this reputed 'gold standard' is largely speculative and is based largely on common sense extrapolation ... Multiple high energy shocks could easily result in more harm than good."³⁷



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