CARDIAC SCIENCE

STAR®
BIPHASIC

STAR®
BIPHASIC

THE STAR™ BIPHASIC WAVEFORM

OPTIMIZED ENERGY DELIVERY FOR SUCCESSFUL DEFIBRILLATION

INTRODUCTION

Automated external defibrillators (AED) and Cardiac Rhythm Module™ (CRM™) devices from Cardiac Science incorporate a number of innovations in automatic, external defibrillation, thanks in part to its STAR™ (Self-Tracking Active Response) Biphasic waveform technology. The STAR Biphasic waveform customizes defibrillation energy to deliver the most effective therapy possible. Validated at leading medical research institutes, the STAR Biphasic waveform was successful in 100% of defibrillation attempts.

Cardiac Science's STAR Biphasic waveform was designed with one principle in mind: optimized energy delivery. When a person experiences cardiac arrest - the sudden onset of chaotic and unproductive heart activity - defibrillation is the only definitive treatment for restoring the heart to a normal rhythm. The STAR Biphasic

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waveform technology quickly assesses the unique characteristics of a patient and customizes the defibrillation energy they receive. It measures a patient's impedance and customizes the waveform to deliver the most effective defibrillation energy to the patient. This customization occurs for all patients, even those with high-impedance levels.

FACTORS THAT INFLUENCE DEFIBRILLATION

The STAR Biphasic waveform treats cardiac arrest patients individually, based on three important characteristics: impedance, defibrillation threshold and cellular response.

IMPEDANCE

Impedance is defined as the opposition to the flow of electrical current. The number one difficulty in delivering current (or energy) through the heart in external defibrillation is the patient's impedance. The body's tissues such as the skin, the fat under the skin, the muscles, and the lungs surrounding the heart all "impede" the flow of electrical current to the heart. The higher a patient's impedance, the greater the opposition to defibrillation energy. Impedance varies from patient to patient based on many factors, such as skin condition, electrode size, electrode to skin contact, and the number and timing of previous shocks[1,2]. In order to optimize energy delivery, adjustments must be made for a patient's impedance. In the past, external defibrillators had no capability to measure and respond to a patient's impedance. If a defibrillation shock was unsuccessful, the energy was simply increased in order to deliver a higher current. This method, while attempting to adjust for a patient's impedance level, does not provide optimized energy delivery.

" ... the longer the heart fibrillates, the lower the chance of patient survival. "

DEFIBRILLATION THRESHOLD

Defibrillation threshold (DFT) is defined as the minimum current required to defibrillate the heart[3]. The concept of DFT is well known with implantable cardioverter defibrillators (ICD). DFT varies from person to person, based primarily on the patient's anatomy, disease condition and metabolic state of the heart. An individual's exact DFT can only be measured precisely in a hospital electro-physiology lab setting. Failure to exceed a patient's DFT means failure to defibrillate that patient's heart. As a result, standard practice is to escalate energy if the first shock is unsuccessful in order to exceed the patient's DFT. The goal is to exceed the patient's DFT as quickly as possible, because the longer the heart fibrillates, the lower the chance of patient survival.

CELLULAR RESPONSE

The heart is made up of individual cells that respond to defibrillation. When a patient has been defibrillated, their heart can retain excess charge from the shock. If not addressed, this can lead to immediate refibrillation - the heart returning to ventricular fibrillation. According to the principles of cellular response to charge, a defibrillation waveform and its energy should first and foremost be customized based on a patient's impedance level. By doing so, the most appropriate level of energy is delivered initially, reducing the likelihood of the heart retaining excess charge and returning to an abnormal rhythm.

THE STAR BIPHASIC WAVEFORM

Cardiac Science's AED and Cardiac Rhythm Module (CRM) devices were designed with one fundamental principle in mind: Optimized Energy Delivery = Successful Defibrillation. Utilizing the proven concepts of variable energy to compensate for impedance, escalating energy to exceed the defibrillation threshold and address cellular response to reduce the risk of refibrillation, the STAR Biphasic waveform technology is the first to address these issues to achieve successful results in defibrillating a sudden cardiac arrest victim.

OPTIMIZED ENERGY DELIVERY

Cardiac Science's STAR Biphasic waveform technology provides optimized energy delivery by measuring a patient's impedance and customizing a waveform to deliver the most effective defibrillation energy. This customization occurs for even the most difficult high-impedance patients. The STAR Biphasic technology delivers optimal therapy for every patient. No other external defibrillator device offers this total customization.

In addition, Cardiac Science devices escalate energy to ensure that the patient's DFT is exceeded as rapidly as possible. This feature is consistent with the American Heart Association guidelines that call for escalating energy.

THE STAR BIPHASIC WAVEFORM — A MATTER OF BALANCE

The STAR Biphasic technology produces a revolutionary new biphasic waveform, one that introduces the proven concept of charge balancing to the defibrillator industry.

A CELL'S RESPONSE TO ENERGY

During the delivery of any defibrillation shock, the cell membranes of the heart are charged, a process in which the membranes are "coated" with positive ions on one side and negative ions on the other side. The charge on the individual cells is increased until the cell depolarizes. A traditional defibrillation shock must be strong enough to depolarize nearly 100 percent of the cardiac cells[4,5] at the same instant. This allows the normal electrical pathways to reestablish control and produce a coordinated rhythm. If any residual charge is left on the cells, however, refibrillation may occur.[6,7]

CHARGE BALANCING

The charge balancing principle states that an excess or residual charge will remain on the cells after a defibrillation shock unless the charge is balanced. In a charge balanced biphasic waveform, all residual charge on the cardiac cells is neutralized. This neutralization is accomplished with the second phase of the defibrillation waveform, by adjusting the second phase to balance the charge known to be remaining on the cells. The STAR Biphasic waveform is uniquely capable of balancing the charge because it precisely controls the energy delivered in the first phase. This enables the second phase to exactly remove the excess charge. By neutralizing or balancing the residual charge on the cells, the STAR Biphasic waveform minimizes the likelihood of refibrillation and provides the best opportunity to defibrillate the heart.[8]

The STAR Biphasic waveform is the first defibrillation waveform to deliver optimal energy in phase one and to successfully balance the residual charge on the cells in phase two.

Figure 1: A Properly Charged Balanced BTE Waveform

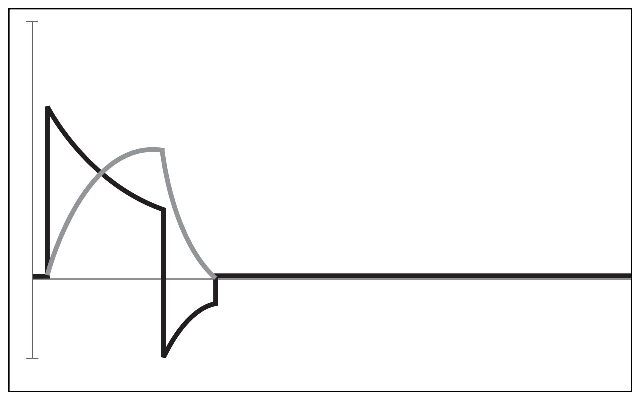
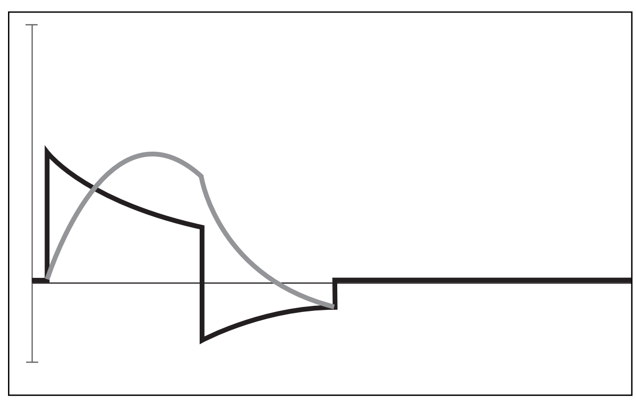


Figure 2: An Unbalanced BTE Waveform



In these figures, the bold line represents the voltage applied to the patient's chest, and the gray line represents the charge on the cardiac cells. When the voltage is applied, the charge on the cells rises until the cells reach their maximum charge. In Figure 1, the first phase is properly halted at the peak of the cellular response curve. Voltage is then reversed, bringing the cells back to zero charge or into balance. In Figure 2, the first-phase voltage continues too long, past the peak of the cell's response, but with no further effect on the cells. When the voltage is reversed belatedly, beginning the second phase, it also continues too long, resulting in overshooting a neutral or charge balanced condition. Both overshooting and undershooting the neutral condition can promote refibrillation.

ESCALATING VARIABLE ENERGY

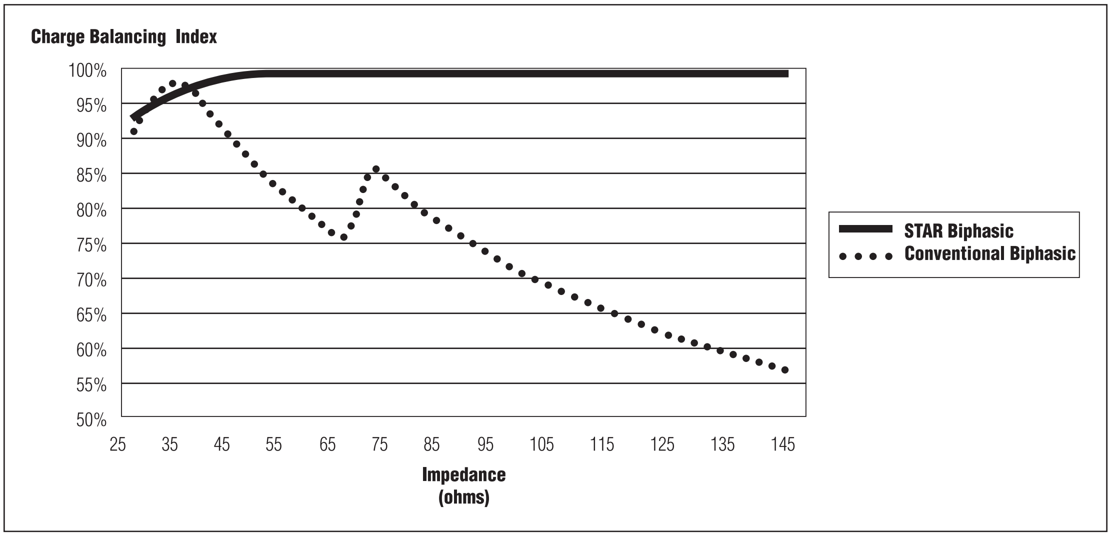
Unlike conventional waveforms, the STAR Biphasic waveform actively compensates for impedance, varying the energy to deliver an optimized defibrillation shock. Devices with the STAR Biphasic waveform are thus able to deliver a customized defibrillation pulse to every patient.

In addition, devices with the STAR Biphasic waveform are consistent with AHA guidelines that call for escalating energy. The exact energy delivered to a patient will depend on the patient's impedance and the programmed energy settings. This variable energy assures that defibrillation shock delivery to all patients will be optimized.

CHARGE BALANCING INDEX

The Charge Balancing Index (CBI) is a measure of a waveform's ability to correctly balance the charge remaining on the cardiac cells. It enables the direct comparison of waveforms over the entire range of a patient's impedance. A waveform with a CBI of 100 percent charge balances more effectively than a waveform with an index of 90 percent. CBI must be evaluated over the entire range of patient impedances. The chart in Figure 3 shows the Charge Balancing Index for the currently available biphasic AEDs. Notice that the Cardiac Science STAR Biphasic waveform achieves a CBI of greater than 99 percent over the vast majority of patient impedances, while the CBI of the other AED waveform falls to 50 – 60 percent.

Figure 3: Charge Balancing Index and Associated Impedance



This graph shows the CBI for the STAR Biphasic and another commercially available AED waveform over the full range of patient impedance. Notice that at low impedance both waveforms have a CBI of over 90 percent. As patient impedance increases, however, the conventional low-energy waveform increasingly fails to balance the charge. The vast majority of patients have an impedance between 60 and 100 ohms, a range in which the STAR Biphasic maintains a CBI of over 99 percent. This graph reveals that only the STAR Biphasic waveform maintains its charge balanced characteristics at these typical impedances, while the conventional low-energy waveform CBI falls to 50 – 60 percent.

CLINICAL RESULTS

The STAR Biphasic waveform was validated in a clinical trial led by researchers at the Cleveland Clinic and Cedars-Sinai Medical Center. This multicenter study enrolled patients in an electrophysiology lab study designed according to FDA guidelines to determine that the STAR Biphasic waveform was safe and effective. The study's high success rates allowed Cardiac Science to achieve statistically significant results with a smaller sample size.

A meta-analysis of these data was done, comparing defibrillation success rates from Cardiac Science's clinical study to those from other published studies. This analysis shows that the overall first-shock defibrillation success rate with the STAR Biphasic waveform is statistically significantly higher than the monophasic damped sine or the 150J non-escalating biphasic waveform.

The chart below compares the overall first-shock success rates of the STAR Biphasic waveform with published data on other commercial external defibrillation waveforms:

Waveform	1st Shock Success Rate	Sample Size	Number of failed 1st shocks	Confidence Interval
STAR Biphasic[9]	100%	115	0	97.5-100%
STAR Monophasic[9]	97.4%	115	3	94.5-100%
Monophasic damped sine[10]	89.6%	223	26	86-93%
150J non-escalating biphasic[10]	87.1%	230	34	83-91%

SUMMARY

Optimizing energy delivery is the key to successful defibrillation, and Cardiac Science's STAR Biphasic waveform technology does just that, compensating for each patient's impedance. Devices with the STAR Biphasic waveform are the first devices in the world to apply these concepts of optimized variable energy delivery to external defibrillation. This unique technology enables Cardiac Science AEDs and Cardiac Rhythm Module (CRM) devices to deliver defibrillation energy that is truly customized for each and every patient.

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