Алматы (7273)495-231
Ангарск (3955)60-70-56
Архангельск (8182)63-90-72
Астрахань (8512)99-46-04
Барнаул (3852)73-04-60
Белгород (4722)40-23-64
Благовещенск (4162)22-76-07
Брянск (4832)59-03-52
Владивосток (423)249-28-31
Владикавказ (8672)28-90-48
Владимир (4922)49-43-18
Волгоград (844)278-03-48
Вологда (8172)26-41-59
Воронеж (473)204-51-73
Екатеринбург (343)384-55-89
Иваново (4932)77-34-06
Ижевск (3412)26-03-58
Иркутск (395)279-98-46
Казань (843)206-01-48
Калининград (4012)72-03-81
Калуга (4842)92-23-67
Кемерово (3842)65-04-62
Киров (8332)68-02-04
Коломна (4966)23-41-49
Кострома (4942)77-07-48
Краснодар (861)203-40-90
Красноярск (391)204-63-61
Курск (4712)77-13-04
Курган (3522)50-90-47
Липецк (4742)52-20-81
Магнитогорск (3519)55-03-13
Москва (495)268-04-70
Мурманск (8152)59-64-93
Набережные Челны (8552)20-53-41
Нижний Новгород (831)429-08-12
Новокузнецк (3843)20-46-81
Ноябрьск (3496)41-32-12
Новосибирск (383)227-86-73
Омск (3812)21-46-40
Орел (4862)44-53-42
Оренбург (3532)37-68-04
Пенза (8412)22-31-16
Петрозаводск (8142)55-98-37
Псков (8112)59-10-37
Пермь (342)205-81-47
Ростов-на-Дону (863)308-18-15
Рязань (4912)46-61-64
Самара (846)206-03-16
Саранск (8342)22-96-24
Санкт-Петербург (812)309-46-40
Саратов (845)249-38-78
Севастополь (8692)22-31-93
Симферополь (3652)67-13-56
Смоленск (4812)29-41-54
Сочи (862)225-72-31
Ставрополь (8652)20-65-13
Сургут (3462)77-98-35
Сыктывкар (8212)25-95-17
Тамбов (4752)50-40-97
Тверь (4822)63-31-35
Тольятти (8482)63-91-07
Томск (3822)98-41-53
Тула (4872)33-79-87
Тюмень (3452)66-21-18
Ульяновск (8422)24-23-59
Улан-Удэ (3012)59-97-51
Уфа (347)229-48-12
Хабаровск (4212)92-98-04
Чебоксары (8352)28-53-07
Челябинск (351)202-03-61
Череповец (8202)49-02-64
Чита (3022)38-34-83
Якутск (4112)23-90-97
Ярославль (4852)69-52-93

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Технические характеристики на автоматические внешние дефибрилляторы Powerheart AED G3 Elite компании ZOLL

6 Technical Data

This section lists the AED parameters and describes the STAR® biphasic waveforms.

Parameters

Table 6-1: Parameters

Parameter	Detail
Operation	Semi-Automatic Automatic
Audible Alerts	Voice Prompt Maintenance Alert
Visible Indicators	Status Indicator Battery Status Indicator Service Indicator Pads Indicator Text Display
Rescue Data Storage	Internal with 60 minutes ECG data with event annotation

Table 6-1: Parameters (continued)

Parameter	Detail
Dimensions	Height: 3.3 in (8 cm) Width: 10.6 in (27 cm) Depth: 12.4 in (31 cm)
Weight (Batteries and Pads)	6.6 lb (3.10 kg)
Operating and Standby Environmental Conditions	Temperature: 32°F to 122°F (0°C to 50°C) Humidity: 5% to 95% (non-condensing) Pressure: 57kPa (+15,000ft) to 103kPa (-500ft)
Pads	Self-adhesive, disposable defibrillation pads Minimum combined surface area: 35.3 in^2 (228 $cm^{2)}$ Extended length of lead wire: 4.27 ft (1.3 m)
9146 Lithium Battery Specifications	Output voltage: 12VDC Batteries are non-rechargeable Lithium content: .32 oz (9.2 g) Check local regulations for disposal information Estimated Shelf Life (from date of manufacture): 5 Years Typical Shocks: 290 shocks **Note:** The battery operating life depends on the type of battery, device settings, actual usage, and environmental factors. Battery was tested with a G3 AED device with Standard prompt set and CPR set to 60 seconds.

Storage and Transport

Configuration	Transport	Storage	Use
Packaged System (packaging, unit, pads, battery)	5 days at -30°C to +65°C	2 years at 0-50°C (pad life)	N/A
Unpackaged System without accessories	5 days at -30°C to +65°C	10 years at 0-50°C	N/A
Unpackaged System with Accessories (batteries and pads)	5 days at -30°C to +65°C	2 years at 0-50°C (pad life)	2 years at 0-50°C (pad life)
Pads (packaged)	5 days at -30°C to +65°C	2 years at 0-50°C (pad life)	N/A
Battery (packaged or unpackaged)	5 days at -30°C to +65°C	5 years at 20-30°C	4 years at 0-50°C

Table 6-1: Parameters (continued)

Parameter	Detail
Batteries and Capacitor Charge Times	A new battery, after the AED has delivered 15 300VE shocks, typically takes 10 seconds to charge the AED to maximum energy. A battery with reduced capacity will take longer to charge the AED.
AED Self test Sequence	Daily: Battery, pads, internal electronics, Shock button, and software. Weekly: Battery, pads, internal electronics, Shock button, software, and partial energy charge cycle. Monthly (every 28 days): Battery under load, pads, internal electronics, full-energy charge cycle, Shock button, and software. Open Lid (when lid is opened): Battery, pads, internal electronics, Shock button, and software. Close Lid (when lid is closed): Battery, pads, internal electronics, Shock button, and software.

Table 6-1: Parameters (continued)

Parameter	Detail
Safety and Performance	Model 9790 The AED has been designed and manufactured to conform to the highest standards of safety and performance including electromagnetic compatibility (EMC). The 9790 and pads conform to the applicable requirements of the following:  C US CSA: Classified by CSA International with respect to electric shock, fire and mechanical hazards only in accordance with CAN/CSA C22.2 No.60601-1:08, EN60601-1 and EN60601-2-4. Certified to CAN/CSA Standard C22.2 No. 60601-1:08. Electrical, Construction, Safety and Performance: IEC 60601-1 IEC 60601-2-4 Electromagnetic Compatibility (EMC): IEC 60601-1-2 IEC 60601-2-4
Emissions	CISPR 11-2016 RTCA DO-160G:2010, Section 20 & Section 21, Category M

Table 6-1: Parameters (continued)

Parameter	Detail
Immunity	EM IEC 61000-4-3, Level X, (20V/m) IEC 60601-2-4 (20V/m) Magnetic IEC 61000-4-8 IEC 60601-2-4 ESD IEC 61000-4-2 IEC 60601-2-4 6kV contact discharge, 8KV air gap discharge
Environmental Conditions	Free Fall Drop: 1 meter per 60068-2-31:2009, Environmental testing – Part 2-31: Tests - Test Ec: Rough handling shocks, primarily for equipment-type specimens. Bump: IEC 60068-2-27:2011, Environmental testing – Part 2-27: Tests Ea and guidance: Shock. Vibration (Random): IEC 60068-2-64:2008, Environmental testing – Part 2-64: Tests – Test Fh: Vibration, broadband random and guidance. Vibration (Sine): IEC 60068-2-6:2007, Environmental testing – Part 2-6: Tests – Test Fc: Vibration (sinusoidal). Enclosure Protection: IEC 60529, IP24 Vibration (random): RTCA DO-160G:2010, Section 8 Airborne use: RTCA DO-160G Sec 8, category U-Airplanes and Helicopters
Shipping and Transportation Conditions	ISTA Procedure 2A

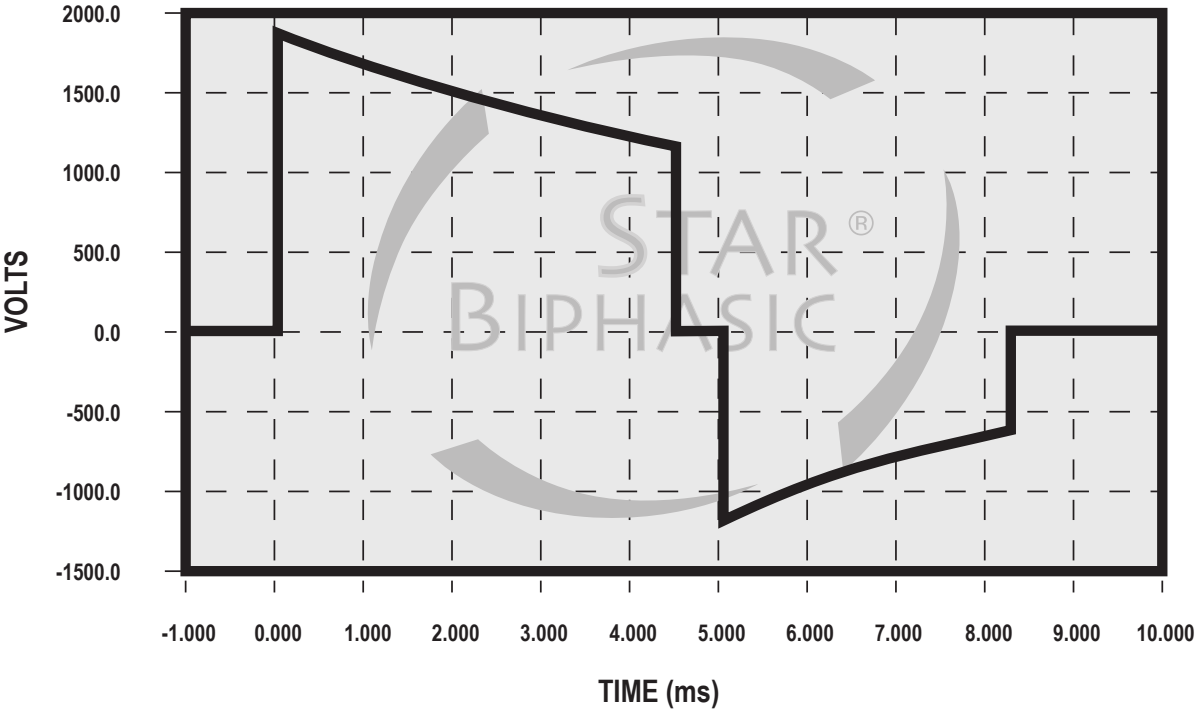
Table 6-1: Parameters (continued)

Parameter	Detail
RHYTHMx® ECG Analysis Performance	The AED RHYTHMx ECG Analysis system analyzes the patient's ECG and advises you when the AED detects a shockable or non-shockable rhythm. This system makes it possible for a person, with no training in the interpretation of ECG rhythms, to offer defibrillation therapy to victims of sudden cardiac arrest. With a new battery, after the AED has delivered 15 300VE shocks, the maximum time from beginning rhythm analysis until the AED is ready to shock is 17 seconds.
Cardiac Rhythms Used to Test the Rhythm Recognition Detection System for Powerheart® G3 AEDs	Shockable Rhythm – VF: Meets IEC 60601-2-4 requirement and AHA recommendation of Sensitivity of >90% Automatic External Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating New Waveforms and Enhancing Safety, AHA AED Task Force and approved by the AHA Science Advisory and Coordinating Committee. Circulation, 1997(95), pp 1677-1682 Shockable Rhythm – VT: Meets IEC 60601-2-4 requirement and AHA recommendation of Sensitivity of >75% Non-shockable Rhythm – NSR: Meets IEC 60601-2-4 requirement (>95%) and AHA recommendation (>99%) of Specificity Non-shockable – Asystole: Meets IEC 60601-2-4 requirement and AHA recommendation of Specificity of >95% Non-shockable: Meets IEC 60601-2-4 requirement and AHA recommendation of Specificity – all other rhythms of >95% For detailed information contact Cardiac Science for white papers: P/N 112-2013-005 (Pediatric Defibrillation Instructions for use) P/N 110-0033-001 (RHYTHMx White Paper) P/N MKT-11081-01 (STAR Biphasic White Paper)

Energy values with Cardiac Science preinstalled (adult) electrodes and STAR® biphasic waveform

The waveform generated by the AED is a Biphasic Truncated Exponential waveform. The following is a graph of the waveform voltage as a function of time when the AED is connected to a 50 Ohm resistive load using preinstalled pads.

High Energy Waveform with 50 Ohm Resistive Load —— High Variable Energy/50 Ohms



The Biphasic Truncated Exponential (BTE) waveform uses variable energy. The actual energy delivered will vary with the patient's impedance and the device will deliver a shock when impedance is between 25-180 Ohms. Energy will be delivered at three different levels referred to as ultra-low variable energy, low variable energy, and high variable energy as shown in the waveform tables on the following pages.

Table 6-2: Ultra-low Variable Energy (150 VE) Powerheart® G3 Waveform

	Phase 1			Phase 2			
Patient's Impedance (Ohms)	Current* (A)	Voltage* (Volts)	Duration* (MS)	Current* (A)	Voltage* (Volts)	Duration* (MS)	Nominal Energy** (J)
25	56	1393	3.3	30	743	3.2	170
50	28	1420	4.5	18	909	3.2	150
75	19	1430	5.8	13	973	3.2	136
100	14	1434	7	10	1007	3.2	127
125	11	1437	8.3	8	1027	3.2	120
150	10	1439	9.5	7	1040	3.2	115
175	8	1441	10.8	6	1049	3.2	111

Table 6-3: Low Variable Energy (200 VE) Powerheart® G3 Waveform

	Phase 1			Phase 2			
Patient's Impedance (Ohms)	Current* (A)	Voltage* (Volts)	Duration* (MS)	Current* (A)	Voltage* (Volts)	Duration* (MS)	Nominal Energy** (J)
25	64	1609	3.3	34	858	3.2	226
50	33	1640	4.5	21	1050	3.2	200
75	22	1651	5.8	15	1124	3.2	182
100	17	1656	7	12	1163	3.2	169
125	13	1660	8.3	9	1186	3.2	160
150	11	1662	9.5	8	1201	3.2	153
175	10	1663	10.8	7	1212	3.2	148

Table 6-4: High Variable Energy Powerheart® G3 Waveform

	Phase 1			Phase 2			
Patient's Impedance (Ohms)	**Current* (A)**	**Voltage* (Volts)**	**Duration* (MS)**	**Current* (A)**	**Voltage* (Volts)**	**Duration* (MS)**	**Nominal Energy** (J)**
25	75	1869	3.3	40	997	3.2	305
50	38	1906	4.5	24	1220	3.2	270
75	26	1918	5.8	17	1306	3.2	246
100	19	1925	7	14	1351	3.2	229
125	15	1928	8.3	11	1378	3.2	216
150	13	1931	9.5	9	1396	3.2	207
175	11	1933	10.8	8	1408	3.2	200

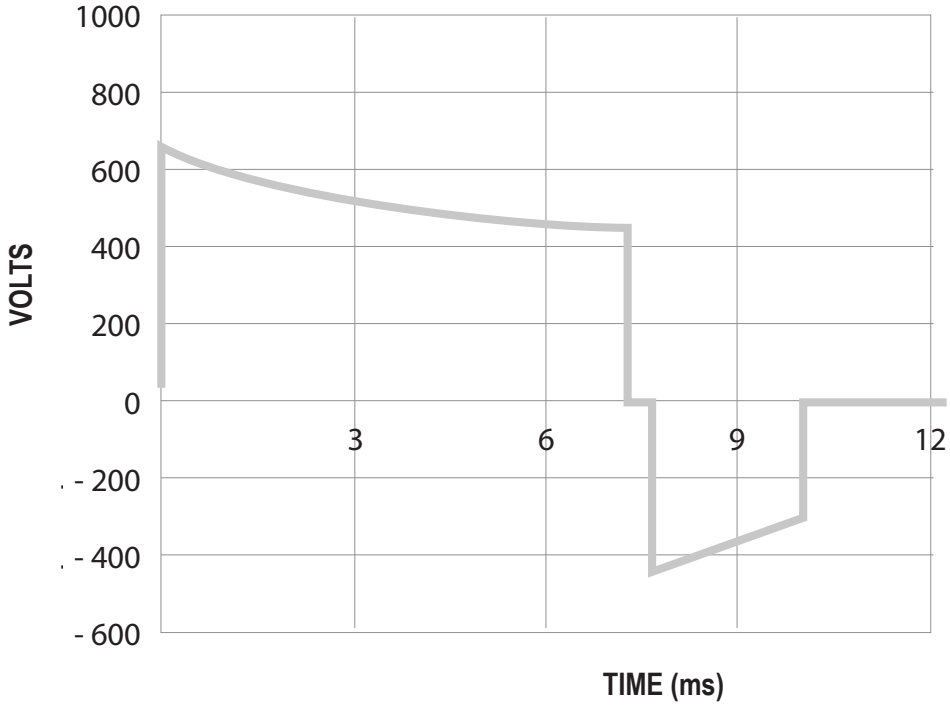
* All values are typical.

**Actual energy delivered +/- 15%.

Attenuated energy values with Cardiac Science pediatric electrodes and STAR® biphasic waveform

The waveform generated by the AED is a Biphasic Truncated Exponential waveform. The following is a graph of the waveform voltage as a function of time when the AED is connected to a 50 Ohm resistive load using pediatric pads.

Typical Pediatric Waveform: Low Energy (200 VE) 50 Ohm Patient Impedance



The Biphasic Truncated Exponential (BTE) waveform uses variable energy. The actual energy delivered will vary with the patient's impedance and the device will deliver a shock when impedance is between 25-180 Ohms. Energy will be delivered at three different levels referred to as ultra-low variable energy, low variable energy, and high variable energy as shown in the waveform tables on the following pages.

Table 6-5: Initial shock – Ultra Low Energy (150 VE) Powerheart® G3 Pediatric Waveform

	Phase 1		Phase 2		
Patient's Impedance (Ohms)	Voltage* (Volts)	Duration* (MS)	Voltage* (Volts)	Duration* (MS)	Nominal Energy** (J)
25	370	6.1	258	3.2	31
50	550	7.3	366	3.2	36
75	640	8.6	417	3.2	37
100	705	9.8	442	3.2	36
125	770	11.1	453	3.2	35

Table 6-6: Initial shock – Low Energy (200 VE) Powerheart® G3 Pediatric Waveform

	Phase 1		Phase 2		
Patient's Impedance (Ohms)	Voltage* (Volts)	Duration* (MS)	Voltage* (Volts)	Duration* (MS)	Nominal Energy** (J)
25	430	6.1	298	3.2	42
50	630	7.3	422	3.2	50
75	745	8.6	482	3.2	51
100	790	9.8	511	3.2	49
125	855	11.1	524	3.2	47

Table 6-7: Second and Subsequent Shocks – Ultra Low Energy (150 VE) Powerheart® G3 Pediatric Waveform

	Phase 1		Phase 2		
Patient's Impedance (Ohms)	Voltage* (Volts)	Duration* (MS)	Voltage* (Volts)	Duration* (MS)	Nominal Energy** (J)
25	370	5.8	270	3.2	31
50	550	6.5	390	3.2	35
75	640	7.0	470	3.2	34
100	705	7.4	510	3.2	32
125	770	7.8	545	3.2	29

Table 6-8: Second and subsequent shocks – Low Energy (200 VE) Powerheart® G3 Pediatric Waveform

	Phase 1		Phase 2		
Patient's Impedance (Ohms)	Voltage* (Volts)	Duration* (MS)	Voltage* (Volts)	Duration* (MS)	Nominal Energy** (J)
25	430	5.8	295	3.2	41
50	630	6.5	425	3.2	47
75	745	7.0	510	3.2	46
100	790	7.4	560	3.2	43
125	855	7.8	610	3.2	39

Table 6-9: Second and subsequent shocks – High Energy (300 VE) Powerheart® G3 Pediatric Waveform

	Phase 1		Phase 2		
Patient's Impedance (Ohms)	Voltage* (Volts)	Duration* (MS)	Voltage* (Volts)	Duration* (MS)	Nominal Energy** (J)
25	500	5.8	380	3.2	56
50	700	6.5	520	3.2	63
75	820	7.0	620	3.2	62
100	920	7.4	680	3.2	58
125	960	7.8	720	3.2	53

* All values are typical.

**Actual energy delivered +/- 15%.

2 Introduction

Contents

This section presents information about the AED, its use, and the training requirements for operation.

AED description

Cardiac Science's Powerheart® G3 Elite AEDs are public access AEDs. They are portable, battery operated, self-testing units used to diagnose and treat life-threatening ventricular arrhythmias in patients who are unresponsive and not breathing normally.

The G3 Powerheart® Elite AED is available with semi-automatic or fully automatic functionality. It includes pre-connected rescue electrode pads, user-paced rescue prompting, and CPR coaching. A patient's electrocardiogram (ECG) is monitored and a defibrillation shock is delivered if necessary. Voice and text prompts provide simple directions to guide the user during a rescue.

AEDs are shipped with defibrillation electrode pads already installed. The Rescue Ready® indicator assures the user that the AED is ready for use.

The AED models employ an impedance compensating, biphasic waveform.

The AED models also automatically perform daily, weekly, and monthly self-tests. Self-test results are communicated by audible alert and via the visual Rescue Ready® indicator.

Batteries

The Powerheart® G3 Elite AED is powered by a user-replaceable, non-rechargeable battery with 4-years of operational performance and an estimated five years of shelf-life from date of manufacturer. Powerheart® G3 Elite AED uses the Intellisense® Lithium Battery (Model 9146). The G3 Elite's automatic self-testing detects when the battery is nearing end of life and signals an alert while the unit still retains enough energy to perform a rescue. All batteries are labeled with an expiration date.

Defibrillation pads

Both adult and pediatric pads are available for use with the Powerheart® G3 Elite AED. The defibrillation electrode pads act as a conductive interface between the AED and the patient's skin.

Indications for use

Powerheart® AED G3 Semi-Automatic and Powerheart® AED G3 Automatic

The Powerheart® G3 Elite AED is indicated for emergency treatment of victims exhibiting symptoms of sudden cardiac arrest who are:

- unresponsive,
- not breathing normally, and
- without pulse.

When the patient is a child or infant up to 8 years of age, or up to 55 lbs. (25kg), the device should be used with the Intellisense™ Defibrillation Pad – Pediatric. The therapy should not be delayed to determine the patient's exact age or weight.

The Powerheart® G3 Elite AED is intended to be used by personnel who have been trained in its operation.

9131 Defibrillation Electrodes

Cardiac Science 9131 Defibrillation Electrodes are single use and intended to be used in conjunction with Cardiac Science automated external defibrillators (AEDs) to monitor and deliver defibrillation energy to the patient.

The electrodes are intended for short term use (<8 hours) and must be used before the expiration date listed on the packaging.

The AED electrodes are used for emergency treatment of cardiac arrest patients over 8 years of age or greater than 55 lbs (25 kg). The user assesses the patient's condition and confirms that the patient is unconscious, pulseless and is not breathing prior to applying the electrodes to the skin.

Contraindications

The Powerheart® G3 Elite AED should not be used on patients that are responsive or breathing normally.

Potential adverse effects of the device on health

Below is a list of the potential adverse effects (e.g., complications) associated with the use of the device and AEDs in general, listed in decreasing order of seriousness:

- Failure to identify shockable arrhythmia;
- Failure to deliver a defibrillation shock in the presence of VF or pulseless VT, which may result in death or permanent injury;
- Inappropriate energy which could cause failed defibrillation or post-shock dysfunction;
- Myocardial damage;
- Fire hazard in the presence of high oxygen concentration or flammable anesthetic agents;
- Electromagnetic interference (EMI) from the defibrillator impacting other devices especially during charge and energy transfers;
- Incorrectly shocking a pulse sustaining rhythm and inducing VF or cardiac arrest;
- Bystander shock from patient contact during defibrillation shock;
- Interaction with pacemakers;
- Skin burns around the electrode placement area;
- Allergic dermatitis due to sensitivity to materials used in electrode construction; and
- Minor skin rash.

Summary of clinical studies

The final order, Effective Date of Requirement for Premarket Approval for Automated External Defibrillator Systems, published on January 29, 2015 and republished on February 3, 2015, states that clinical study information can be leveraged for AEDs from both published studies and clinical data previously submitted to FDA under the 510(k) Premarket Notification process. Cardiac Science submitted the following clinical studies for the original FDA Clearance of the Cardiac Science AEDs.

The RhythmX® ECG Analysis and STAR® Biphasic defibrillation waveform were tested during two (2) separate clinical studies, IDE G920078 and IDE G970230.

The RhythmX® ECG Analysis and STAR® Biphasic defibrillation waveform, IDE G920078

Study objective: To prove the efficacy of the RhythmX ECG analysis using the Powerheart® Automated External Cardioverter Defibrillator (AECD) device, which uses the exact same RhythmX technology as Cardiac Science's current AEDs.

Method: The study was divided into two (2) phases: Phase I and Phase II. Phase I was further divided into two (2) sub-phases. In Phase I, the Powerheart® AED operated as an arrhythmia detector only, and did not deliver shock therapy. Phase I was not randomized. In Phase II, the Powerheart® AED operated as an arrhythmia detector and optionally delivered shock therapy. Phase II was a blind, randomized trial.

Results: A total of 156 patients were enrolled in the trials. Data from the first 15 patients was excluded because the arrhythmia detection algorithm changed after they were studied. The remaining 141 patients experienced 92 shockable episodes, with 117 patients attached to the Powerheart® AED, and the remaining 24 randomized to the standard of care only. The sensitivity of the Powerheart® AED was 100.0%, the positive predictivity was 93.3%, and the specificity was 99.4%. Table 2-1 shows the clinical data of all patients with 95% lower confidence limit scores when attached to the Powerheart® AED.

Conclusion: These data support the conclusion that Powerheart® AEDs accurately detect ventricular tachyarrhythmias and provide appropriate therapy according to physician selected parameters.

The data collected demonstrated sensitivity of 100.0%, positive predictivity as 93.9%, and specificity as 99.4%. The initial sample size calculations assumed an expected sensitivity of 90%. The actual sensitivity of 100% calculated in this trial allowed a smaller number of patients to be entered in the study while still providing the necessary high confidence limits. The Powerheart® AED's arrhythmia detection and therapeutic capabilities, as well as its safety and efficacy have been demonstrated with a high confidence level.

STAR® Biphasic Waveform IDE G970230

Study objective: To evaluate the first shock efficacy of monophasic and STAR® Biphasic Waveforms for external defibrillation.

Methods: A prospective, randomized, blinded, multi-center study of 118 patients undergoing electrophysiologic testing or receiving an implantable defibrillator was conducted. Ventricular fibrillation was induced, and defibrillation was attempted in each patient with a biphasic and a monophasic waveform. Patients were randomly placed into two (2) groups: Group 1 received shocks of escalating energy, and Group 2 received only high energy shocks.

Results: The STAR® Biphasic Waveform achieved a first-shock success rate of 100% in Group 1 (95% confidence interval [CI] 95.1% to 100%) and Group 2 (95% CI 94.6% to 100%), with average delivered energies of 201±17 J and 295±28 J, respectively. The monophasic waveform demonstrated a 96.7% (95% CI 89.1% to 100%) first-shock success rate and average delivered energy of 215±12 J for Group 1, and a 98.2% (95% CI 91.7% to 100%) first-shock success rate and average delivered energy of 352±13 J for Group 2.

Conclusion: The STAR® Biphasic Waveform was validated in a multicenter clinical trial led by researchers at the Cleveland Clinic and Cedars-Sinai Medical Center. The analysis showed that the overall first-shock defibrillation success rate with the STAR® Biphasic Waveform is statistically higher than the monophasic damped sine or the 150J non-escalating biphasic waveform.

RHYTHMx AED ECG analysis algorithm

The RHYTHMx™ AED ECG analysis algorithm provides ECG detection capabilities. The features available with the AED include the following:

- Detection Rate
- Asystole Threshold
- Noise Detection
- Non-Committed Shock
- Synchronized Shock
- Pacemaker Pulse Rejection
- SVT Discriminators
- Supraventricular Tachycardia (SVT) Rate

Detection rate

All ventricular fibrillation (VF) and ventricular tachycardia (VT) rhythms at or above this rate will be classified as shockable. All rhythms below this rate will be classified as non-shockable. This rate is programmable from 120 bpm (beats per minute) to 240 bpm via MDLink Software by the Medical Director. The default Detection Rate is 160 bpm.

Asystole threshold

The asystole baseline-to-peak threshold is set at 0.08 mV. ECG rhythms at or below 0.08 mV will be classified as asystole and will not be shockable.

Noise detection

The AED will detect noise artifacts in the ECG. Noise could be introduced by excessive moving of the patient or electronic noise from external sources like cellular and radiotelephones. When noise is detected, the AED will issue the prompt "ANALYSIS INTERRUPTED. STOP PATIENT MOTION" to warn the operator. The AED will then proceed to reanalyze the rhythm and continue with the rescue.

Non-committed shock

After the AED advises a shock, it continues to monitor the patient ECG rhythm. If the patient's rhythm changes to a non-shockable rhythm before the actual shock is delivered, the AED will advise that the rhythm has changed and issue the prompt "RHYTHM CHANGED. SHOCK CANCELLED." The AED will override the charge.

Synchronized shock

The AED is designed to automatically attempt to synchronize shock delivery on the R-wave if one is present. If delivery cannot be synchronized within one second, a non-synchronized shock will be delivered.

Pacemaker pulse detection

The AED contains pacemaker pulse detection circuitry to detect pulses from an implanted pacemaker.

SVT discriminators

The AED is supplied with the SVT Discriminator enabled and with the default setting "NO THERAPY FOR SVT". With the factory default setting of "NO THERAPY FOR SVT", the AED will not shock an SVT rhythm.

SVT Discriminators are sophisticated filters that analyze the morphology of the ECG waveforms and distinguish VF/VT from SVT and Normal Sinus Rhythms (NSR). The SVT Discriminator will only be applied to rhythms that fall between the Detection Rate and the SVT Rate. The factory default setting for this feature is "NO THERAPY FOR SVT", however the Medical Director can enable this feature using MDLink® on the Powerheart AED.

SVT rate

All rhythms with rates between the Detection Rate and SVT Rate will be screened through a number of SVT Discriminators to classify them into VF/VT or SVT. Rhythms classified as SVT between the two set rates are not shockable. All SVT rhythms above the rates will be classified as shockable. The SVT Rate must be greater than the Detection Rate and is selectable between 160 to 300 bpm or, "NO THERAPY FOR SVT" can be selected via MDLink Software by the Medical Director.

Rescue protocol

The AED rescue protocol is consistent with the guidelines recommended by the AHA/ERC 2015 Guidelines for Resuscitation and Emergency Cardiac Care.

Upon detecting a shockable cardiac rhythm, the AED advises the operator to press the SHOCK button (9790E only) to deliver a defibrillation shock followed by directions to perform 2 minutes of CPR.

For the Powerheart® AED G3 Automatic, upon detecting a shockable rhythm, the AED will automatically deliver a defibrillation shock followed by directions to perform 2 minutes of CPR.

STAR® biphasic waveform

The STAR Biphasic Waveform is designed to measure the patient's impedance and deliver a customized shock. This allows the delivery of an optimized energy level to each patient. The energy levels for the Powerheart® G3 AED are available in three different defibrillation shock levels.

The Ultra-Low Energy (150 VE), Low Energy (200 VE), and High Energy (300 VE) shocks are variable energy. The actual energy is determined by the patient's impedance. See Table 2-2 on page 2-10, Table 6-2 on page 6-8, Table 6-3 on page 6-8, and Table 6-4 on page 6-9 for additional information. For pediatric patients, see Table 6-5 on page 6-11, Table 6-6 on page 6-11, Table 6-7 on page 6-11, Table 6-8 on page 6-12, and Table 6-9 on page 6-12.

STAR® biphasic energy protocols for Powerheart® G3 AEDs

The STAR Biphasic defibrillation waveform will deliver variable escalating energy that is customized to each patient's needs based upon a patient's thoracic impedance. This customization adjusts for the unique physical differences between patients. The Powerheart® G3 AED comes equipped with five different biphasic energy protocols.

The operator, with guidance, direction, and implementation from the designated AED program Medical Director, may select from one of these five protocols when placing the Powerheart® G3 AED into service. The Powerheart® G3 AED's factory default energy protocol is 200-300-300 Joule (J) escalating Variable Energy (VE). The first shock is delivered within the range of 126J-260J. Subsequent shocks are delivered within a range of 170J-351J.

These protocols are selected by using the MDLink software program. The five biphasic energy protocols available are as follows:

Table 2-2: Biphasic Energy Protocols

Energy Protocols	Shock Sequence[1]	Energy Level (VE)	Energy Range[2] (J)
Factory Default	1	200	126-260
	2	300	170-351
	3	300	170-351
Protocol #2	1	200	126-260
	2	200	126-260
	3	300	170-351
Protocol #3	1	150	95-196
	2	200	126-260
	3	200	126-260

Table 2-2: Biphasic Energy Protocols (continued)

Energy Protocols	Shock Sequence[1]	Energy Level (VE)	Energy Range[2] (J)
Protocol #4	1	150	95-196
	2	150	95-196
	3	200	126-260
Protocol #5	1	200	126-260
	2	200	126-260
	3	200	126-260

[1]The Ultra-Low Energy (150 VE), Low Energy(200 VE) and High Energy(300 VE) shocks are variable energy. The actual energy is determined by the patient's impedance.

[2] Allowable energy range.

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