Operator and Service Manual

Powerheart® AED

G3 Pro 9300P

70-00968-01 G

CARDIAC science

AT THE HEART OF SAVING LIVES®

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This device is covered by the following U.S. and foreign patents. For a list of patents, visit www.cardiacscience.com/patents

Other U.S. and foreign patents pending.

CAUTION. Restricted use

U. S. Federal law restricts this device to be sold by or on the order of a physician or practitioner licensed by state law in which he/she practices to use or order the use of the device.

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1 Product Information and Safety

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Before operating the Powerheart® G3 Pro AED:

- Become familiar with the various safety alerts in this section.
- Safety alerts identify potential hazards using symbols and words to explain what could potentially harm you, the patient, or the Powerheart® G3 Pro AED.

Contact information

Inside the United States:

To order additional Powerheart® G3 AEDs or accessories, contact Cardiac Science Customer Care:

- Toll Free (USA): 1.800.426.0337 (option 2)
- Telephone: +1.262.953.3500 (option 2)
- Fax: +1.262.953.3499
- Email: care@cardiacscience.com

Contact information (continued)

Cardiac Science provides 24-hour telephone technical support. You can also contact Technical Support through fax or email.

There is no charge to the customer for a technical support call. Please have the serial and model numbers available when contacting Technical Support. (The serial and model numbers are located on the underside of the AED.)

- Toll Free (USA): 1.800.426.0337 (option 1)
- Telephone: +1.262.953.3500 (option 1)
- Fax: +1.262.798.5236
- Email: techsupport@cardiacscience.com
- Web site: www.cardiacscience.com

Outside the United States:
Contact your local Cardiac Science representative to order devices or accessories and to receive technical support for your AED products.

Defibrillator tracking

Defibrillator manufacturers and distributors are required, under the Safe Medical Devices Act of 1990, to track the location of defibrillators they sell. Please notify Cardiac Science Technical Support in the event that your defibrillator is sold, donated, lost, stolen, exported, destroyed or if it was not purchased directly from Cardiac Science or an authorized dealer.

Product models

This manual is for Powerheart® G3 Pro model 9300P.

Indications for use

Powerheart® AED G3 Pro

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

Contraindications

Cardiac Science AEDs should not be used on patients that are responsive or breathing normally.

9131 Defibrillation Electrodes

Cardiac Science 9131 Defibrillation Electrodes are single use and intended to be used in conjunction with Cardiac Science automatic external defibrillators (AED) 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.

9660 Defibrillation Electrodes

Cardiac Science 9660 Defibrillation Electrodes are single use and intended to be used in conjunction with Cardiac Science G3 Pro automated external defibrillators (AED) to monitor and deliver defibrillation energy to the patient.

9660 Defibrillation Electrodes (continued)

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 pounds. 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.

Warranty information

The Limited Warranty provided by Cardiac Science serves as the sole and exclusive warranty for the Powerheart® AED and its accessories. To obtain a limited warranty statement, contact your local Cardiac Science representative or go to www.cardiacscience.com.

Safety terms and definitions

The symbols shown below identify potential hazard categories. The definition of each category is as follows:

DANGER
This alert identifies hazards that will cause serious personal injury or death.

WARNING
This alert identifies hazards that may cause serious personal injury or death.

Caution
This alert identifies hazards that may cause minor personal injury, product damage, or property damage.

Safety alert descriptions

The following is a list of Powerheart® G3 Pro AED safety alerts that appear in this section and throughout this manual.

Read and understand these safety alerts before operating the AED.

Caution: Read this Operator and Service Manual carefully.

It contains information about your safety and the safety of others. Become familiar with the controls and how to use the AED properly before operating the product.

DANGER! Fire and Explosion Hazard

To avoid possible fire or explosion hazard, do not operate the AED:

- In the presence of flammable gases
- In the presence of concentrated oxygen
- In a hyperbaric chamber

WARNING! Shock Hazard and Possible Equipment Damage

Defibrillation shock current flowing through unwanted pathways is potentially a serious electrical shock hazard and potential damage to the equipment. To avoid this hazard during defibrillation abide by all of the following:

- Do not use in standing water or rain. Move patient to dry area
- Do not touch the patient, unless performance of CPR is indicated
- Do not touch metal objects in contact with the patient
- Keep defibrillation pads clear of other pads or metal parts in contact with patient
- Disconnect all non-defibrillator proof equipment from the patient before defibrillation

WARNING! Battery model 9145 is Not Rechargeable.

Do not attempt to recharge the battery. Any attempt to recharge the battery may result in an explosion or fire hazard.

WARNING! Possible Radio Frequency (RF) Susceptibility.

Radio-frequency (RF) interference from devices such as cellular phones and two-way radios can cause improper AED operation. The AED should be used at least 6 feet (2 meters) away from RF devices, as stated in accordance with EN 61000-4-3:2002.

WARNING! Possible Interference with Implanted Pacemaker.

Therapy should not be delayed for patients with implanted pacemakers and a defibrillation attempt should be made if the patient is unconscious and not breathing. The AED has pacemaker detection and rejection. However, with some pacemakers the AED may not advise a defibrillation shock. (Cummins, R., ed., Advanced Cardiac Life Support; AHA (1994): Ch. 4)

When placing pads:

- Do not place the pads directly over an implanted device.
- Place the pad at least one inch from any implanted device.

WARNING! Electromagnetic Compatibility.

Use of accessories or cables other than those specified, with the exception of accessories and cables sold by Cardiac Science Corporation as replacement parts for internal components, may result in increased emissions or decreased immunity of the AED.

WARNING! Improper Equipment Placement.

Position the AED away from other equipment. If it is necessary to use the AED adjacent to or stacked with other equipment, then observe the AED to verify normal operations.

Caution: Restricted Use.

Federal law restricts this device for sale by or on the order of a physician or practitioner licensed by law of the state in which he/she practices.

Caution: Lithium Sulfur Dioxide Battery (model 9145).

Pressurized contents: never recharge, short circuit, puncture, deform, or expose to temperatures above 149°F (65°C). Remove the battery when discharged.

Caution: Battery Disposal.

Recycle or dispose of the lithium battery in accordance with all federal, state and local laws. To avoid fire and explosion hazard, do not burn or incinerate the battery.

Caution: Use only Cardiac Science Approved Equipment.

Using batteries, pads, cables, or optional equipment other than those approved by Cardiac Science may cause the AED to function improperly during a rescue.

Caution: Possible Improper AED Performance.

Using pads that are damaged or expired may result in improper AED performance.

Caution: Moving the Patient During a Rescue.

During a rescue attempt, excessive jostling or moving of the patient may cause AEDs to improperly analyze the patient's cardiac rhythm. Stop all motion or vibration before attempting a rescue.

Caution: Systems Statement.

Equipment connected to the analog and digital interfaces must be certified to the respective IEC standards (i.e. IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment).

Furthermore, all configurations shall comply with the system standard IEC 60601-1-1. Anybody who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore, responsible that the system complies with the requirements of the system standard IEC 60601-1-1.

Caution: Equipment Malfunction.

Portable and RF communications equipment may affect the AED. Always observe the recommended separation distances as defined in the EMC declaration tables.

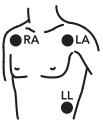
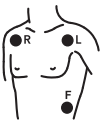
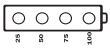
Caution: Equipment Malfunction.

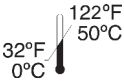
The AED requires special precautions regarding EMC. Use the AED according to the guidelines of the EMC declaration tables.

Symbol descriptions

The following symbols may appear in this manual, on the AED, or on its optional components. Some of the symbols represent standards and compliances associated with the AED and its use.

Symbol	Description	Symbol	Description
	Caution. Consult accompanying documentation.		Additional information is is provided in the accompanying documentation.
	Dangerous Voltage: The defibrillator output has high voltage and can present a shock hazard. Please read and understand all safety alerts in this manual before attempting to operate the AED.		Defibrillator Proof Type BF Equipment: The AED, when connected to the patient's chest by the pads, can withstand the effects of an externally applied defibrillation shock.
	The AED is protected against the effects of splashing water in accordance with IEC 60529.		Do not recharge battery.
	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.		Defibrillation proof type CF applied part.
	When the SHOCK indicator is lit, press this button to deliver a defibrillation shock.		Indicates the AED battery status. The illuminated areas indicate the remaining battery capacity.

Symbol	Description	Symbol	Description
	The Z-Bar provides a relative visual indicator of the total transthoracic impedance between the two defibrillation pads.		Indicates AED requires maintenance by authorized service personnel.
	A red indicator with a BLACK X means the AED requires operator attention or maintenance, and is not Rescue Ready.		A green indicator without a BLACK X means the AED is Rescue Ready.
	Indicates placement of ECG leads and electrodes (AHA).		Indicates placement of ECG leads and electrodes (IEC).
	When pressed and confirmed, activates manual mode.		Indicates that the manual override function has been disabled.
	Symbol for ON. to power on the AED.		Test button: Press to view battery capacity.
	Charge LED: Solid yellow indicates battery charging. Blinking yellow indicates charging error.		Battery capacity: indicates the AED battery status. The illuminated areas indicate the remaining battery capacity when the test button is pressed.
	Date of manufacture: year and month.		Date of factory recertification (R): year and month.

Symbol	Description	Symbol	Description
	Latex free. Not made with natural rubber latex.		Disposable. Single patient use only.
	Tear here to open.		- Position of defibrillation pads on the chest of patient. - When pads on screen are flashing, check defibrillation pads. The defibrillation pads are missing, not connected, or have compromised functionality.
	For use by or on the order of a Physician, or persons licensed by state law.		Separate one pad from blue liner by peeling from the tabbed corner.
	Do not incinerate or expose to open flame.		MR Unsafe - keep away from magnetic resonance imaging (MRI) equipment.
	Upper and lower operating temperature limits.		Use pads by this date.
	Serial Number		Device model number; battery model number
	Option number		Lot number
	Lithium ion		Rechargeable battery

Symbol	Description	Symbol	Description
	Lithium sulfur dioxide		Authorized representative in the European Community
	CE Mark: This equipment conforms to essential requirements of the Medical Device Directive 93/42/EEC.		Manufacturer
	Waste Electronic Electrical Equipment (WEEE). Separate collection for waste electrical and electronic equipment.		Waste Electronic Electrical Equipment (WEEE) containing lead. Separate collection for waste electrical and electronic equipment.
	Recycle cardboard according to local law.		Dispose of properly in accordance with all state, province, and country regulations.

Electromagnetic emissions standards compliance

Guidance and manufacturer's declaration—electromagnetic emissions

The AED is intended for use in the electromagnetic environment specified below. The customer or the user of the AED should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment—guidance
RF emissions CISPR 11	Group 1	The AED uses RF energy only for its internal function. Therefore its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

Emissions test	Compliance	Electromagnetic environment—guidance
RF emissions CISPR 11	Class B	The AED is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration—electromagnetic immunity

The AED is intended for use in the electromagnetic environment specified below. The customer or the user of the AED should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment—guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable	
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Not applicable	

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic enviroment — guidance
Voltage dips, short interruptions and voltage variations on power supply input lines 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec.	Not applicable	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	80 A/m	Power frequency magnetic fields should be at levels no higher than those characteristic of a typical location in typical heavy industrial and power plants and the control rooms of H.V. sub-stations.

Note: U_T is the a.c. mains voltage prior to application of the test level.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic enviroment — guidance
Conducted RF	3 Vrms	Not Applicable	
IEC 61000-4-6	150 kHz to 80 MHz outside ISM bands[a] 10 Vrms 150 kHz to 80 MHz in ISM bands[a]	Not Applicable	

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic enviroment — guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the AED, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	**Recommended separation distance** $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m)[b].

Immunity test	IEC 60601 test level	
		Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[c] should be less than the compliance level in each frequency range.[d] Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 to 40.70 MHz.

[b] The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

[c] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the AED is used exceeds the applicable RF compliance level above, the AED should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the AED.

[d] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 1 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the AED

The AED is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the AED can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the AED as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter	**Separation distance according to frequency of transmitter** **m**			
W	150 kHz to 80 MHz outside ISM bands	150 kHz to 80 MHz in ISM bands	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = 1.2 \sqrt{P}$	**$d = 1.2 \sqrt{P}$**	**$d = 1.2 \sqrt{P}$**	**$d = 2.3 \sqrt{P}$**
0.01	0.12	0.12	0.12	0.23
0.1	0.38	0.38	0.38	0.73
1	1.2	1.2	1.2	2.3
10	3.8	3.8	3.8	7.3
100	12	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 to 40.70 MHz.

Note 3: An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

Note 4: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

2 Introduction

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

AED description

The AED is a self-testing, battery-operated automated external defibrillator (AED). After applying the AED's defibrillation pads to the patient's bare chest, the AED automatically analyzes the patient's electrocardiogram (ECG) and advises the operator to press the button and deliver a shock if needed. The AED guides the operator through the rescue using a combination of voice prompts, audible alerts, and visible indicators. At the discretion of Advanced Life Support (ALS) personnel, the AED can be converted to manual override mode, and deliver a shock by pressing the SHOCK button to deliver therapy. The AED can also provide non-diagnostic ECG monitoring.

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 between 120 bpm (beats per minute) and 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 and 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 2010 Guidelines for Resuscitation and Emergency Cardiac Care.

Upon detecting a shockable cardiac rhythm, the AED advises the operator to press the SHOCK button to 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 Pro 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 2-1 on page 2-5, Table 6-2 on page 6-9, Table 6-3 on page 6-9, and Table 6-4 on page 6-10 for additional information.

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. Powerheart® G3 AEDs come 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 2-1: 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
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.

Operator training requirements

Persons authorized to operate the AED must have all of the following minimum training:

- Defibrillation training and other training as required by state, province, or country regulations
- Training on operation and use of the AED
- Additional training as required by the physician or Medical Director
- A thorough understanding of the procedures in this manual

Note: Keep valid certificates of training and certification as required by state, province, or country regulations.

3 Getting Started

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AED indicators

The following indicators are located on the AED.

Rescue Ready® status indicator

The status indicator is located on the Powerheart® G3 AED handle.

When this indicator is green, the AED is Rescue Ready. This means the AED self-tests have verified the following:

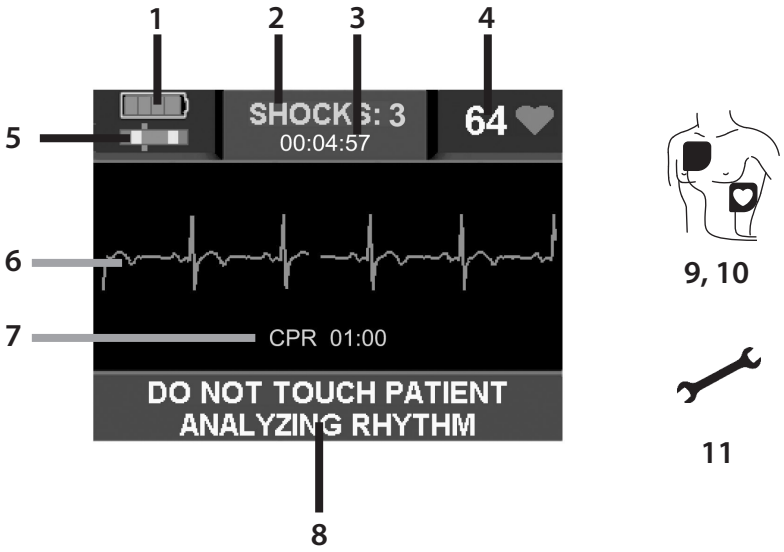
- Battery has an adequate charge
- Pads are properly connected to the AED and functioning
- Integrity of the internal circuitry is good.

When the status indicator is red, attention is required.

1. Open the lid of the AED to troubleshoot the issue.
2. The AED may become Rescue Ready (the indicator turns green) after it runs further tests.
3. If the indicator remains red, contact Cardiac Science Technical Support (see *Contact information* on page 1-2) or outside the U.S., your local Cardiac Science representative.

Note: When the status indicator shows not Rescue Ready (the indicator is red) you might hear an intermittent beep. See *Audible maintenance indicator* below for troubleshooting information.

Diagnostic panel



	Indicator	Description
1	Smartgauge™ battery	Displays the battery capacity. At maximum charge, the battery is GREEN. With use, the GREEN level will gradually go out from right to left as the battery capacity decreases. Once the battery level is depleted, the battery indicator will turn to RED, and the battery should be replaced. **Note:** When the battery indicator is initially RED—upon lid opening or at any time during a rescue—a **BATTERY LOW** prompt will be issued at once. However, the AED is capable of delivering at least nine more defibrillation shocks after the first time a **BATTERY LOW** prompt appears.
2	Number of shocks delivered	Counts and displays the number of shocks delivered.
3	Elapsed rescue time	Times and displays the elapsed rescue time.
4	Heart rate	Displays the patient's heart rate.
5	Z-Bar	Provides a relative visual graphical indicator of the total transthoracic impedance between the two defibrillation pads. The Z-Bar is used in the assessment of: • Adequate pad placement • Pad quality and integrity • Pad adhesion to the patient's skin • Proper pad connection to the AED • Provides for quick assessment between pads off and pads shorted For more information, see *Z-Bar Indicator* on page 3-4.
6	ECG display	Displays 4.5 seconds of the patient's ECG.
7	CPR counter	During CPR, displays a count-down timer.

	Indicator	Description
8	Text display	With 2 lines of text, it provides the operator with information regarding system initialization, text version of the voice prompts and data during a rescue, and diagnostics.
9	Pad placement	Visually assists the rescuer with pad placement with the directions for use. Appropriate text prompts are also displayed.
10	Pad	When flashing with voice and text prompt indicating "Check Pads", indicates to check pads when pads are: • not properly connected to the AED • not within operational specifications (cold, dried, damaged) • disconnected from the patient during a rescue.
11	Service	Indicates that service is required that can only be performed by qualified service personnel.

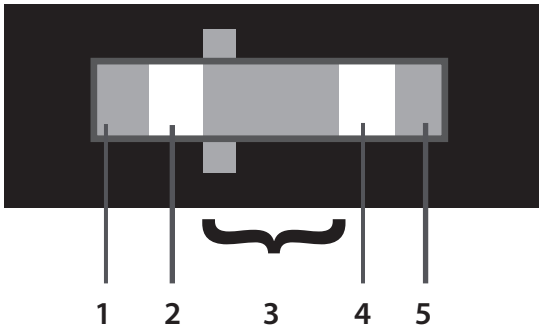
Z-Bar Indicator

The Z-Bar provides a relative visual graphical indicator of the total transthoracic impedance between the two defibrillation pads. The Z-Bar is used in the assessment of:

- Adequate Pad placement
- Pad quality and integrity
- Pad adhesion to the patient's skin
- Proper Pad connection to the AED
- Provides for quick assessment between PADS OFF and PADS SHORTED

Note: The Z-Bar is displayed on all therapy screens with the exception of the ECG MONITORING screen. On the ECG MONITORING screen the Z-Bar will be displayed only if the detection lead is set to Pads.

The Z-Bar is divided into 5 sections. The ideal operating range is section 3 (impedance range from 30 to <150).



Section	Measured Impedance range (ohms)	Description	Color fill
1	<20	Lower Limit Alarm—Non-operational range.	Red
2	20-30	Lower marginala operating range. Indicates potential issue with pad position.	Yellow
3	30-150	Normal operating range.	Green
4	150-180	Upper marginal operating range. Indicates potential Pad degradation in Pad quality or position.	Yellow
5	180	Upper Limit Alarm–Non-operational range.	Red

Audible maintenance indicator

When the daily, weekly, or monthly self-test determines attention is required, a beep sounds every 30 seconds until the lid is opened or the battery power is depleted. Opening and closing the lid may deactivate the beep. If the error is not corrected by the next automatic self-test, the beep will be reactivated.

Because the beep is a general indicator that the AED is not Rescue Ready, always open the lid first and allow the AED to perform its self test. If the AED provides a voice prompt but does not change the Rescue Ready indicator to green, note the prompt and contact Cardiac Science Technical Support (see *Contact information* on page 1-1) or outside the U.S., your local Cardiac Science representative.

Control buttons

The AED has two buttons.

Shock button

The SHOCK button is located at the far right of the control panel.

Pressing this button delivers a defibrillation shock. The word SHOCK and the shock button indicator LED illuminate RED when the AED is ready to deliver a defibrillation shock to the patient. Note modification to behavior below when in manual mode.

Manual override button

The Manual Override button is located at the far left of the control panel and converts the device from automated mode to manual. This feature should only be used by ALS personnel. The factory default setting for Manual Override functionality is enabled, however the Medical Director can disable/enable this feature via MDLink.

- Lift the cover to access the button.
- Pressing this button converts to manual standby mode when pushed once, a voice prompt “Entering manual mode. Press button again to confirm”, will be heard. Converts to manual mode when MANUAL button is pressed again.
- If the rescuer does not confirm within 30 seconds of the capacitors charging, the AED will revert back to AED Mode.
- If the Medical Director has disabled this feature in MDLink, an icon indicating No MANUAL MODE will appear in the bottom left of the display.

Setting the AED internal clock

For US models, the internal clock is preset to Central Standard Time. You can reset it to your local date and time. To set the clock, you need a Windows 7 or newer computer with RescueLink software installed.

To set the clock:

1. Ensure that the computer is set at the correct local time and date.
2. Run the RescueLink software on the computer.
3. Connect the communications cable to the computer.
4. Align the infra-red (IR) port on the AED with the IR port on the communications cable.
5. Open the lid of the AED.
6. In RescueLink:
   a. From the **Communications** menu, select **AED Date and Time**.
   b. Click **Get** to review the current time in the AED. The AED prompts, "Communications Mode."
   c. If the time and date is incorrect, click **Set** to set a new time and date.

   The AED date and time updates to the computer's time and date.
7. Close the lid of the AED.

Note: Use only the IR communications cable available separately from Cardiac Science. Other IR products may interfere with the transmission and are not for use with the AED.

Voice prompts and text display

The voice prompts activate when the AED lid is opened and help guide the operator through the rescue. The AED text display provides a visual display of most of the audible voice prompts.

The following tables list the voice and text prompts and a description of when the prompts are issued.

Table 3-1: Standard prompts

Voice Prompt	Text display	Situation
Note: The AED is shipped from the factory with Traditional CPR defaulted ON. The Medical Director may modify the CPR options in MDLink. Traditional CPR prompts are listed in this table. Except where noted, prompts apply both to compressions-only CPR and traditional CPR (compressions and breaths).		
Tear open package and remove pads.	TEAR OPEN PACKAGE REMOVE PADS	When the lid is opened, this phrase is repeated twice to initiate the rescue sequence.
Peel one pade from plastic liner.	PEEL ONE PAD ON FROM PLASTIC LINER	Repeats until one pad is peeled off of the liner.
Place one pad on bare upper chest.	PLACE ONE PAD ON BARE UPPER CHEST	Repeats twice while one pad is placed.
Peel second pad and place on bare lower chest as shown.	PEEL SECOND PAD PLACE ON LOWER CHEST	Repeats until both pads are placed on the patient.

Table 3-1: Standard prompts (continued)

Voice Prompt	Text display	Situation
Press pads firmly to patient's bare skin.	PRESS PADS TO PATIENT'S BARE SKIN	When better connectivity is required because impedance is too high.
Do not touch patient! Analyzing rythym.	DO NOT TOUCH PATIENT ANALYZING RHYTHM	When the AED is analyzing the cardiac rhythm of the patient.
Shock advised.	SHOCK ADVISED	When the AED is preparing to deliver a defibrillation shock.
Charging.	CHARGING	Repeats while AED is charging.
Stand clear! Push flashing button to deliver shock	STAND CLEAR PUSH BUTTON TO SHOCK	After the AED is fully charged and ready to deliver the. defibrillation shock. The RED SHOCK indicator flashes and the phrase repeats for 30 seconds or until the SHOCK button is pushed.
Plug in pads connector.	PLUG IN PADS CONNECTOR	When the pad socket does not have defibrillation pads or ECG electrodes connected.
Shock delivered.	SHOCK DELIVERED	After the AED delivers a defibrillation shock.
Start CPR.	START CPR	After the AED delivers a defibrillation shock. After the AED detects a non-shockable rhythm.
Give 30 compressions. Then give two breaths.	30 COMPRESSIONS 2 BREATHS	Perform CPR for 2 minutes **Note**: Prompt for traditional CPR only.

Table 3-1: Standard prompts (continued)

Voice Prompt	Text display	Situation
Battery low.	BATTERY LOW	Occurs once when the battery voltage becomes low, although a rescue can continue for approximately 9 more shocks. When the battery is too low to perform a rescue, the device halts operation and displays "Battery Low" on the Display, the NVI will turn to RED and the Sonalert will beep. No voice prompt is issued. If completely depleted, all AED activity will terminate.
Analysis interrupted. Stop patient motion.	ANALYSIS INTERRUPTED STOP PATIENT MOTION	When the AED detects ECG noise artifact, stop moving or touching the patient.
Open lid to continue rescue.	OPEN LID TO CONTINUE RESCUE	When the lid is inadvertently closed during a resce, this prompt will repeat for 15 seconds.
Rhythm changed. Shock cancelled.	RHYTHM CHANGED SHOCK CANCELLED	When the device is prepared to shock then detects a change in rhythm and therefore cancels the shock.
ECG monitoring mode	ECG MONITORING MODE	When ECG Patient Cable is inserted into the pad socket. When the Manual Mode button is pressed when in ECG Monitoring Mode.
Communications mode	COMMUNICATIONS MODE	When the lid is open and IR is transmitting the AED.

Table 3-1: Standard prompts (continued)

Voice Prompt	Text display	Situation
(Beep) (or) Metronome (30 times at 100/ minute) **Note:** Option is selected in MDLink software.	Not applicable	One "Beep" occurs in 30-second intervals during CPR when enabled by the MDLink software program. "Beep" also occurs when the AED requires maintenance.
Continue CPR	CONTINUE CPR	During CPR mode when enabled, or when a rescue is resumed in CPR mode after being interrupted by the lid closing.
Service required	SERVICE REQUIRED	Occurs after a self-test determines that the AED is not functioning properly. The prompt "SERVICE REQUIRED" will be heard when the lid is opened.

Table 3-2: Advanced prompts

Voice Prompt	Text display	Situation
Entering manual mode. Press button again to confirm	MANUAL MODE PRESS BUTTON TO CONFIRM	After ALS presses the MANUAL button once to initiate the manual model
Manual mode. charging	CHARGING	After ALS presses the MANUAL button again to confirm.

Table 3-2: Advanced prompts (continued)

Voice Prompt	Text display	Situation
Manual mode not confirmed	MANUAL MODE NOT CONFIRMED	When the MANUAL button is not pressed a second time within five seconds, the device stays in AED mode.
If rhythm is shockable, press SHOCK button to deliver therapy.	IF SHOCKABLE RJYTHM PRESS SHOCK BUTTON	When in manual mode, prompts ALS personnel to press SHOCK button if ECG indicates a shockable rhythm.
Shockable rhythm. Attach defibrillation pads.	SHOCKABLE RHYTHM ATTACH DEFIBRILLATION PADS	When the dvice is performing ongoing ECG monitoring via the ECG Patient Cable Kit and detects a shockable rhythm.
(none)	DEVICE WILL DISARM IN :30	Should the rescuer go into manual mode and decide that AED mode is more appropriate, the AED will revert back to AED mode 30 seconds after charging is complete. The seconds will count down from 30 on the display. **Note:** When **Remain in manual mode** has been enabled (Using MDLink software). The AED will disarm but remain in Manual Mode.

4 Data Management

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- **Recording rescue data** 4-1
- **Reviewing rescue data** 4-2

The AED is designed for ease of data management and review. The data can be downloaded from the AED and displayed on the PC screen using the Rescuelink software.

Recording rescue data

The AED automatically records RescueLink data and can store up to 60 minutes of ECG monitoring time in its internal memory. Multiple rescues can be stored in the internal memory, allowing the rescuer to administer additional rescues without downloading the data to a PC. Should the internal memory become full, the AED will purge rescues as needed, beginning with the oldest rescue.

When downloading data, RescueLink will enable the user to select which rescue to download. See the RescueLink application HELP files for more information.

Reviewing rescue data

You need a Windows 7 or newer computer with RescueLink software installed.

To retrieve data from internal memory:

1. Run the RescueLink software on the computer.
2. Connect the communications cable to the computer.
3. Align the infra-red (IR) port on the AED with the IR port on the communications cable.
4. Open the lid of the AED.
5. In RescueLink:

   a. From the **Communications** menu, select **Get Rescue** Data.

   b. Select **Internal Memory of AED**, then click **OK**. The AED prompts, "Communications Mode."

   c. Select a rescue by clicking on the date and clicking **OK**.

   d. Wait for the rescue data to appear in RescueLink.
6. Close the lid of the AED.

Note: Use only the IR communications cable available separately from Cardiac Science. Other IR products may interfere with the transmission and are not for use with the AED.

5 Troubleshooting and Maintenance

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- Indicator troubleshooting table 5-3
- Scheduled maintenance 5-4
- Cleaning and care 5-6
- Authorized repair service 5-7
- Frequently Asked Questions 5-8

This section presents information about the AED diagnostics self-tests, maintenance, and service indications.

Self-tests

The AED has a comprehensive self-test system that automatically tests the electronics, battery, pads, and high voltage circuitry. Self-tests are also activated every time you open and close the AED lid.

When performing the self-tests, the AED completes the following steps automatically:

1. Turns itself on, and the Status Indicator changes to red.
2. Performs the self-test.
3. If successful, the Status Indicator reverts to green.
4. Turns itself off if the lid is closed.

There are three types of automatic self-tests:

- The daily self-test checks the battery, pads, and the electronic components.
- The weekly self-test completes a partial charge of the high voltage electronics in addition to the items tested in the daily self-test.
- During the monthly self-test, the high voltage electronics are charged to full energy in addition to the items tested in the daily self test.

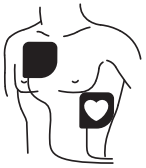
In addition, self-tests will be initiated upon opening the lid and again upon closing the lid.

If the self-test detects an error, the Status Indicator remains red. Upon closing the lid, an audible alert will be issued. The diagnostic panel under the lid indicates the source of the problem according to Table 5-1 on page 5-3.

Indicator troubleshooting table

The following is a troubleshooting table for the AED indicators.

Table 5-1: Indicator Troubleshooting Table

View	Symptom	Solution
	Red Service indicator appears on the screen.	Maintenance by authorized service personnel is required. Contact Cardiac Science Technical Support or, outside the U. S., your local Cardiac Science representative.
	Red Pads indicator (LED) is lit.	Connect the pads or replace with a new pair.
	The last battery indicator (LED) is red and flashing.	The battery is low. Replace with a new battery.
	Rescue Ready Status indicator is red, and no other indicators on the diagnostic panel are lit.	Replace the battery. If the status indicator remains red, contact Cardiac Sciencel Technical Support or, outside the U.S., your local Cardiac Science representative.

Caution: Temperature Extremes

Exposing the AED to extreme environmental conditions outside of its operating parameters may compromise the ability of the AED to function properly. The Rescue Ready® daily self-test verifies the impact of extreme environmental conditions on the AED. If the daily self-test determines environmental conditions outside of the AED's operating parameters, the Rescue Ready indicator could change to red (not Rescue Ready) and the AED may issue a "SERVICE REQUIRED" alert to prompt the user to move the AED to environmental conditions within the acceptable operating parameters at once. See Chapter 6, *Technical Data*, for acceptable environmental conditions and *Rescue Ready status indicator* on page 3-1 for information about the Rescue Ready indicator.

Caution: Not Rescue Ready

Issues other than extreme environmental conditions can cause the AED to become not Rescue Ready. For more information, see *Rescue Ready status indicator* on page 3-1.

Scheduled maintenance

Note: Powerheart® G3 AEDs perform weekly partial energy and monthly full energy charges of the high voltage circuitry as part of their extensive self testing regimens. Consequently, Cardiac Science does not recommend that users perform any additional energy tests.

Perform the following tests per the schedule indicated:

Daily maintenance

Check the Status Indicator to ensure that it is GREEN. When the indicator is GREEN, the AED is ready for a rescue. If the indicator is RED, refer to the troubleshooting table on page 5-3.

Monthly maintenance

Perform the following procedure each month (28 days):

1. Open the AED lid.
2. Wait for the AED to indicate status: observe the change of the STATUS INDICATOR to RED. After approximately 5 seconds, verify that the STATUS INDICATOR returns to GREEN.

3. Check the expiration date on the pads.
4. Check that the battery has adequate charge. If the battery indicator is red, replace the battery.
5. Listen for the voice prompts. Additionally, check the display shows text prompts that correspond to the audio.
6. Close the lid and observe the change of the STATUS INDICATOR to RED. After approximately 5 seconds, verify that the STATUS INDICATOR returns to GREEN.

Annual maintenance

Perform the following tests annually to confirm that the diagnostics are functioning properly and to verify the integrity of the case.

Check the integrity of the pads and circuitry:

1. Open the AED lid.
2. Remove the pads.
3. Close the lid.
4. Confirm that the STATUS INDICATOR turns RED.
5. Open the lid and confirm that the Pad indicator is lit.
6. Reconnect the pads and close the lid.
7. Make sure the expiration date is visible through the clear window of the lid.
8. Check to make sure that the STATUS INDICATOR is GREEN. If the pads are not installed properly, the PAD indicator will illuminate. Contact Cardiac Science Technical Support (see *Contact information* on page 1-2) or outside the U.S., your local Cardiac Science representative.
9. Open the lid and confirm that no diagnostic indicators are lit.
10. Check the expiration date of the pads; if expired, replace them.
11. Check the pads packaging integrity.
12. Close the lid.

Check the Integrity of the Service Indicator (LED) and Circuitry:

1. Immediately after opening the AED lid, press and hold the Shock button and confirm that the Service LED is lit.
2. Release the Shock button.
3. Close the lid.

4. Verify that the STATUS INDICATOR remains RED.
5. Open the lid and confirm that no diagnostic panel indicators are lit.
6. Close the lid.
7. Verify that the STATUS INDICATOR turns GREEN.

Check the integrity of the case:

Examine the molded case of the AED for any visible signs of stress. If the case shows signs of stress, contact Cardiac Science Technical Support (see *Contact information* on page 1-2) or outside the U.S., your local Cardiac Science representative.

Cleaning and care

Use a cloth dampened with an approved cleaning solution to wipe the case. Dry the case with a clean cloth. Do not spray or pour the cleaning solution on the case or submerge the AED.

Approved cleaners

Use one of these solutions to clean the case of the AED: soapy water, ethanol, or 91% isopropyl.

The AED and its accessories cannot be sterilized.

Caution: Equipment Damage

When cleaning the device, use one of the following: Isopropyl Alcohol, Ethanol, a mild soapy water solution, or a 3% hydrogen peroxide solution.

Caution: Equipment Damage

Keep all cleaning solutions and moisture away from the inside of all defibrillation pads and cable connector openings.

Authorized repair service

The AED has no user-serviceable internal components. Try to resolve any maintenance issues with the AED by using the Troubleshooting Table presented in this chapter. If you are unable to resolve the problem, contact Cardiac Science Technical Support (see *Contact information* on page 1-2) or outside the U.S., your local Cardiac Science representative.

WARNING! Shock Hazard

Do not disassemble the AED. Failure to observe this warning can result in personal injury or death. Refer maintenance issues to Cardiac Science authorized service personnel.

Note: The warranty will be void upon unauthorized disassembly or service of the AED.

Frequently Asked Questions

Q: Can I give CPR while the AED is analyzing?

A: No. As with all AEDs, the operator should stop CPR compressions during the analysis phase.

Q: Can I transport the victim while the AED is analyzing?

A: No. Vehicle motion may cause noise artifacts that could interfere with proper cardiac rhythm analysis. Stop the vehicle when cardiac rhythm analysis is necessary.

Q: Is it safe for the AED to provide a shock to a patient lying on a conductive floor, antistatic floor, or a metal surface?

A: Yes, it is safe. Using a Powerheart® AED on a patient lying on a conductive floor, antistatic floor, or a metal surface does not create a safety hazard for either the device user or the patient.

Q: Do I need to prepare the chest prior to pad application?

A: Special preparation is not usually necessary. The chest should be as clean, dry, and as oil free as possible. Follow your Medical Director's instruction.

Q: What happens if the battery is low?

A: There are several Battery Low conditions that the AED will detect:

Battery Low detected - AED not in use: If a low battery condition is detected during a self test, the AED will beep once every 30 seconds. Remove the battery and replace with a fresh battery.

Battery Low detected – AED in use: When the red LED initially lights up—upon lid opening or at any time during a rescue—a BATTERY LOW prompt will be issued at once. However, the AED is capable of delivering at least 9 defibrillation shocks after the first BATTERY LOW prompt is issued.

Battery too low to charge AED during rescue: When the AED is not capable of delivering any more shocks, a BATTERY LOW prompt is displayed until the battery is replaced or AED activity ends.

To continue the rescue attempt, leave the lid open and replace the battery. When the battery replacement takes longer than 60 seconds, the first rescue is terminated and the AED begins to record the events from then on as a separate rescue.

Battery is completely depleted—No AED function: All AED activity stops until the battery is replaced with a fresh battery.

Q: How do I set the AED internal clock?

A: Set the clock by using the RescueLink Software Program and a PC. See *Setting the AED Internal Clock* on page 3-7.

Q: What happens if I close the lid in the middle of a rescue attempt?

A: If you close the lid during a rescue, you must re-open the lid within 15 seconds to continue the rescue. You will hear the prompt, "Open lid to Continue Rescue." If the lid remains closed for more than 15 seconds, a new rescue will initiate when the lid is reopened.

Note: If the lid is closed during a rescue while the pads are connected to the patient, the STATUS INDICATOR remains GREEN. When the lid is reopened, however, the STATUS INDICATOR will turn RED and then back to GREEN. The rescue may be continued.

Q: My AED is sounding an audible alert. Why? How do I stop it?

A: The audible alert indicates that the self-test detected a need for maintenance or corrective action. Open the device lid and view the indicator on the diagnostic panel. Determine the maintenance required by using the troubleshooting table on page 5-3.

Q: The AED did not sound an audible alert when I removed the pads and closed the lid. Why?

Note: Ensure the battery is installed. The AED will never beep while battery is removed.

A: The lid-closed pad self-test only activates the STATUS INDICATOR. The AED allows time for replacement of the pads—as removing pads is a normal procedure after a rescue—or a battery during the post rescue procedure.

Q: What if I have to perform a rescue in an isolated area and at subzero temperatures?

A: When travel to a rescue involves exposing the AED to extremely cold temperatures for an extended period of time, keep the pads and the battery warm.

Q: What should I do if I initiate MANUAL MODE but then decide AED MODE is more appropriate?

A: Momentarily closing the lid and opening the lid will always take the device out of MANUAL mode and into AED MODE. Once charging is complete, wait 30 seconds for the AED to revert back to AED MODE. The seconds will count down on the display. If "REMAIN IN MANUAL MODE" has been enabled, momentarily close the AED lid and reopen. This will revert the AED to AED mode.

6 Technical Data

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

Parameters

Table 6-1: Parameters

Parameter	Detail
Operation	Semi-Automatic (shock advisory) 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
Dimensions	Height: 8 cm (3.3 in) Width: 27 cm (10.6 in) Depth: 31 cm (12.4 in)
Weight (Batteries and Pads)	3.20 kg (7.0 lb)
Environmental Operation and Standby Conditions	Temperature: 0°C to 50°C (32°F to 122°F) Humidity: 5% to 95% (non-condensing) Pressure: 57kPa (+15,000ft) to 103kPa (-500ft)
Shipment and Transport environmental Conditions (for up to 1 week	Temperature: -30°C to 65°C (-22°F to 149°F)) Humidity: 5% to 95% (non-condensing) Pressure: 57kPa (+15,000ft) to 103kPa (-500ft)
Pads	Self-adhesive, disposable defibrillation pads Minimum combined surface area: 228 $cm^{2)}$ Extended length of lead wire: 1.3 m

Table 6-1: Parameters (continued)

Parameter	Detail
9144 Rechargeable Lithium Battery Specifications	Output voltage: 11.1VDC Batteries are non-rechargeable Lithium content: .32 oz (9.2 g) Check local regulations for disposal information Operational life: 2.5 years or 300 battery charge/discharge cycles, whichever comes first Standby: 6 months Capacity: 100 shocks typical (60 shocks minimum) or 3 hours minimum of ECG display (6 hours typical) Charge time: 3 hours for stated capacity; 4.5 hours to fully charge depleted battery **Note:** The battery operating life depends on the type of battery, device settings, actual usage, and environmental factors.
9145 Lithium Battery Specifications	Output voltage: 12VDC Batteries are non-rechargeable Lithium content: 9.2g 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.
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.
Battery charger (for 9144 rechargeable battery)	Power Requirements: 90-132 VAC or 198-264 VAC at 47-63 Hz The charger operates from, and accepts standard IEC mains power cables.

Table 6-1: Parameters (continued)

Parameter	Detail
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 9300P The AED has been designed and manufactured to conform to the highest standards of safety and performance including electromagnetic compatibility (EMC). The 9300P 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	EM: EN 55011/CISPR 11, Group 1, Class B RTCA DO-160D 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: IEC 60068-2-32, 1 meter Bump: IEC 60068-2-29, 40g and 6000 bumps Vibration (Random): IEC 60068-2-64: 10Hz – 2kHz, 0.005 – 0.0012 g^2/Hz Vibration (Sine): IEC 60068-2-6: 10Hz – 60Hz, 0.15 mm and 60Hz – 150Hz, 2g Enclosure Protection: IEC 60529, IP24 Vibration (random): RTCA DO-160D Section 8, category S, curve B Temperature variation: RTCA DO-160D Section 5, category C Temperature/altitude decompression/overpressure: RTCA DO-160D section 4, category A4, operating 0-50° C, ground survival 0-50° C
Shipping and Transportation Conditions	ISTA Procedure 2A
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.

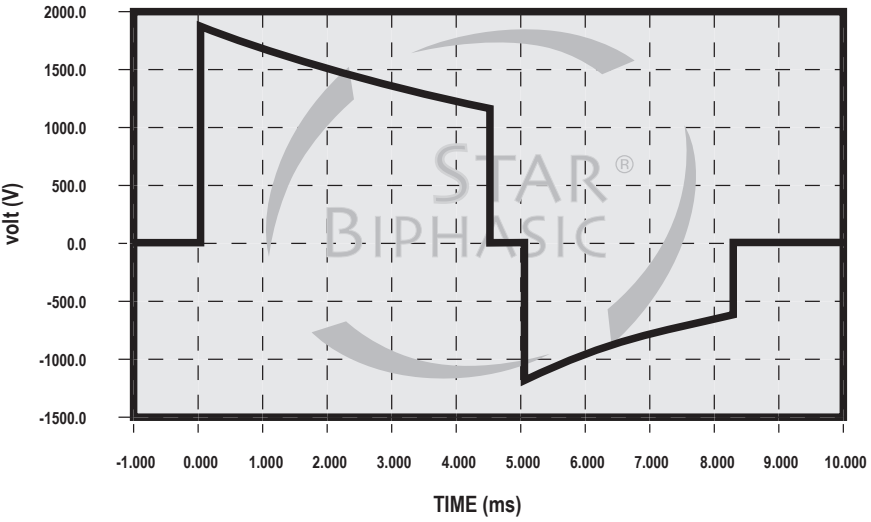
Table 6-1: Parameters (continued)

Parameter	Detail
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)

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

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

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

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

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

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

* All values are typical

**Actual energy delivered ± 15%

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 in support of reasonable safety and effectiveness of the Cardiac Science AEDs.

A. RHYTHMx® ECG Analysis and STAR® Biphasic Defibrillation Waveform

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

1. RHYTHMx® ECG Analysis IDE G920078

Study objective: To prove the effectiveness 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 G3 Pro in this PMA.

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 6-5 shows the clinical data of all patients with 95% lower confidence limit scores when attached to the Powerheart® AED.

Table 6-5: Clinical Data – All Patients Attached to Powerheart® AED

# of Patients	Hours Attached	True Positives	False Positives	True Negatives	False Negatives	Sensitivity	Positive Predictivity	Specificity
117	1138.8	92	6	1065	0	100% (96.8%)	93.9% (88.3%)	99.4% (98.9%)

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 effectiveness have been demonstrated with a high confidence level.

2. Post Market Performance of the RHYTHMx® Analysis Algorithm

Study objective: Post-market, retrospective study evaluating the field performance of the RHYTHMx® Algorithm during field uses.

Method: The rescue data from Cardiac Science AEDs was collected between December 1999 and December 2016 from AEDs deployed in various locations globally. All the rescue files represent actual field use of Cardiac Science AEDs during rescue attempts. All reviews and classifications of the ECG rhythm were consistent with the rhythm classifications outlined in Kerber et al.1997[1].

Results: The Performance Goals and Lower Confidence Limit Goals are from the Kerber recommendation. A total 5,522 AED analysis periods were available for evaluation. Exclusions consisted of 592 rhythm segments from AEDs no longer available or supported and not relevant to the performance of RHYTHMx®. Eight (8) rescues, consisting of 52 separate analysis periods, were rejected due missing or corrupted ECG data. The results of the analysis of the remaining AED records are summarized in Table 6-6.

Table 6-6: RHYTHMx® Results

Rhythms	Goal: Sample Size	Actual: Sample Size	Goal: Performance	Observed: Performance	Goal: 90% One-sided Lower Confidence Limit	Observed: Performance with 90% CI
Shockable						
Coarse VF	200	1035	>90%	>93%	>87%	>93%
Rapid VT	50	58	>75%	>97%	>67%	>91%
Non-Shockable						
NSR	100	428	>99%	100%	>97%	>99%
AF, SB, SVT, heart block, idioventricular, PVCs, other	30	965	>95%	>96%	>88%	>95%
Asystole	100	1969	>95%	>99%	>92%	>99%
Intermediate						
Fine VF	25	229	Report only	56%	N/A	66%
Other VT	25	9	Report only	100%	N/A	75%
Artifact						
Artifact	N/A	185	Report only	94%	N/A	91%

3. Adult Defibrillation Waveform: STAR® Biphasic Waveform IDE G970230

Study objective: To evaluate the first shock effectiveness 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±17J 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±12J for Group 1, and a 98.2% (95% CI 91.7% to 100%) first-shock success rate and average delivered energy of 352±13J for Group 2. Figure 6-7 shows the defibrillation results.

Table 6-7: Defibrillation Results

	Group 1		Group 2		Combined	
Variable	**MTE**	**BTE**	**MTE**	**BTE**	**MTE**	**BTE**
Impedance (Ω)*	64±19	65±18	65±23	64±22	64±21	65±20
E_D (J)*	215±12	201±17	352±13	295±28	NA	NA
Total no. of first shocks	60	60	55	55	115	115
No. of successful first shocks	58	60	54	55	112	115
First-shock success rate (%)	96.7	100	98.2	100	97.4	100
95% CI	89.1–100	95.1–100	91.7–100	94.6–100	92.6–100	97.4–100

E_D, Delivered energy.
*Data are shown as average±SD.

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.

4. Post Market Performance of the STAR® Biphasic Waveform

Study Objective: Post-market, retrospective study evaluating the performance of the Powerheart® STAR® Biphasic Waveform during field uses.

Method: The Cardiac Science data from the FirstSave (subsequently discontinued), G3, G3 Plus, and G3 Pro AEDs used for this study were collected from 584 patients between December 1999 and December 2016. All devices used in this study use the same defibrillation waveform, the STAR® Biphasic Waveform. The AEDs were deployed in various locations throughout the world. The data were captured from electronic files created by Cardiac Science AEDs during rescue attempts. All rescue files included in these data represent actual field use of Cardiac Science AEDs.

The Cardiac Science retrospective data were collected using a method which limits bias by having minimal exclusion criteria. Cardiac Science allowed any data received from a customer to be included into its database, regardless of the variability in the AED deployment model or resuscitation protocols.

Results: Data were divided into two (2) major groupings. The primary group contains the Cardiac Science data sources broadly identified as Retrospective data. A total of 748 shocks met the inclusion criteria and were available for evaluation. These data were split into four (4) identifiable subgroups. The Complaint data set included 394 shocks and showed shock success of 90% (95% lower CI of 88%). The Pittsburgh data set included 97 shocks and showed shock success of 94% (95% lower CI of 88%). The San Diego data set included 93 shocks and showed shock success of 94% with (95% lower CI of 88%).

The other group included two (2) additional data sets: (1) the Netherlands study, and (2) the Health Club data, that were analyzed with the same inclusion criteria. The Netherlands data set included 249 shocks and showed shock success of 93% (95% lower CI of 89%). The Heath Club data set included 65 shocks and showed shock success of 97% (95% lower CI of 91%).

4. Post Market Performance of the STAR® Biphasic Waveform

(continued)

The data were also pooled for a total of 1,062 shocks that met inclusion criteria and were available for evaluation. Overall results showed shock success of the pooled data as 92% (95% lower CI of 90%). The first shock results showed shock success of the pooled data of 584 shocks as 93% (95% lower CI of 91%). Overall restoration of spontaneous circulation (ROSC)/ restoration of an organized rhythm (ROR) was determined for all 584 patient rescue attempts. Overall ROSC/ROR was 75%.

B. Pediatric Defibrillation

Powerheart® Defibrillation Success for Short and Long Duration Ventricular Fibrillation

Study objective: Animal testing was conducted to validate the effectiveness of the Cardiac Science pediatric waveform using the Powerheart® AED with pediatric electrodes. The Powerheart® AED used the same defibrillation waveform, the STAR® Biphasic Waveform as the AED G3 Pro.

Method: Animal testing was performed on a total of seven (7) pigs (domestic crossbreeds) weighing 14 to 24kg. Ventricular fibrillation was induced in the pig and after 15 - 30 seconds of VF, a 200J shock was delivered through the attenuator to the electrode. Two (2) additional shocks of 270J were delivered if required for defibrillation. After a minimum of 30 minutes, a second episode of VF was induced in the pig and sustained for 4 minutes.

Results: For short duration VF, the Powerheart® AED could resuscitate five (5) out of seven (7) pigs on the first shock, and the remaining two (2) pigs with a second shock. The test results for the fibrillation episode of 4 minutes with simulated CPR were that the Powerheart® AED successfully defibrillated all seven (7) pigs with an average of 2.1 shocks ± 1 shock. The average delivered energy was 46.6J ± 3.4J and 59.3J ± 1.2J.

Conclusion: The Powerheart® AED successfully defibrillated all seven (7) pigs for both short and long duration ventricular fibrillation episodes.

C. Pediatric Extrapolation

In this premarket approval application, an animal study was submitted to support the reasonable assurance of safety and effectiveness of the STAR® Biphasic defibrillation waveform in pediatric patients. The pre-clinical study of the STAR® Biphasic defibrillation demonstrated that this waveform successfully defibrillated all animals for both short and long duration ventricular fibrillation episodes in the pediatric model.

D. Human Factors and Usability Studies

Human factors data were collected and analyzed in the Cardiac Science's various usability studies which support the conclusions that the user interfaces for the various AED models, when used by lay users, are safe and effective. The Powerheart® G3 Pro usability study included fifteen (15) participants.

Overall Human Factors Study Approach

The Cardiac Science human factors usability study represents one part of the overall Powerheart® AED validation study plan, which includes the following AED devices:

Intended Users

The Powerheart® G3 Pro AED is intended to be used by:

- **Professional Rescuers/Healthcare Professions (HCPs)**—

Personnel trained and certified in emergency services and CPR, and trained in the use of AEDs (e.g., police, fire-fighter, emergency response team, paramedics, emergency medical technician—EMT, security personnel).

- **Professionally trained healthcare personnel/responders** (e.g., nurse, physician), trained and certified in cardiopulmonary resuscitation (CPR), and trained in the use of AEDs.

Cardiac Science anticipates that the HCPs and Professional Rescuers will be trained in CPR and AEDs.

The Powerheart® G3 Pro AED has been found to be safe and effective for the intended users, uses and use environments. These findings were based of the following results shown in Table 6-8.

Table 6-8: Powerheart® G Pro Usability Study Results

Therapy Function	# of Participants	Shock Delivery Success %	Median time to Shock (seconds)
Adult Mode	14*	100%	53.4
Pediatric Mode	15	100%	65.5
ECG Monitoring Mode	15	100%	65.2

*One participant was eliminated in Adult Mode due to study artifact.

E. Complaint Analysis

To further demonstrate the safety and effectiveness of the Powerheart® G3 Pro AED in clinical use, relevant adverse event data were analyzed over the past three (3) years. The analysis covers January 1, 2015 through March 31, 2018. The results identified two (2) deaths and three (3) malfunctions associated with Powerheart® G3 Pro AED model number 9300P.

For the reported deaths, root cause as determined by Cardiac Science' analysis (regardless if the product was returned or not) and quantity of each cause are: that of the two (2) deaths reported, one (1) was one was related to the battery not being fully seated during use, and one (1) was related to improper handling of pads prior to use.

For the reported malfunctions, the identified root causes and quantities as determined by Cardiac Science are: no fault identified (1), and the device not returned (2).

F. Conclusions

The retrospective analysis of Cardiac Science AEDs in real world use demonstrates efficacy of the STAR® Biphasic waveform consistent with the cited industry studies. STAR® Biphasic performed well across a representative range of deployment environments. In conclusion, the above data, taken together with the other clinical data and preclinical data analyzed are sufficient to demonstrate safety and effectiveness of the performance of the Powerheart® G3 Pro AED.

G. Financial Disclosure

The Financial Disclosure by Clinical Investigators regulation (21 CFR 54) requires applicants who submit a marketing application to include certain information concerning the compensation to, and financial interests and arrangement of, any clinical investigator conducting clinical studies covered by the regulation. The Financial Disclosure by Clinical Investigators regulation was not provided for this file, as the information leveraged was reviewed for the approval of prior IDEs (e.g., G920078, G970230). Other data included post-market data collected and analyzed by the applicant. Overall, the rationale provided in lieu of formal financial disclosure for this file was acceptable and information provided does not raise any questions about the reliability of the data.

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