Operator and Service Manual

Powerheart® AED

G3 9300A and 9300E

70-00966-01 F

CARDIAC science

AT THE HEART OF SAVING LIVES®

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Patents

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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Contents

Troubleshooting and Maintenance 5

Technical Data 6

1 Product Information and Safety

Contents

Before Operating the Powerheart G3 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 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

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.

Indications for use

Powerheart® AED G3 and Powerheart® AED G3 Automatic

The Powerheart AED G3 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 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.

Product models

This guide is for Powerheart G3 model 9300E and Powerheart® G3 Automatic 9300A AED models. They share a basic set of features and differences are noted throughout the manual.

Product references

For purposes of retaining simple, clear instructions in this manual, note the product references used. Features, specifications, operating instructions and maintenance common to product models will be referred to as:

"Powerheart G3 AED", "AED", or "device" refers to both Powerheart G3 model 9300E and Powerheart G3 Automatic model 9300A AEDs unless otherwise noted.

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 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 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.

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: Serial Communication Cable.

The AED will not function during a rescue when the serial communication cable is connected to its serial port. When the serial communication cable is connected to the AED during a rescue, the prompt "Remove Cable to Continue Rescue" will be heard until you remove the serial communication cable.

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. Anyone 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.

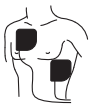
The AED requires special precautions regarding EMC. Use the AED according to the guidelines of the EMC declaration tables.

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 provided in the AED Operation and Service Manual.

Symbol	Description	Symbol	Description
	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.		MR Unsafe. The AED should not be used or stored in an MRI suite.
	Symbol for ON. Open the lid to turn on the AED.		Indicates the AED battery status. The illuminated areas indicate the remaining battery capacity.
	Check pads. The pads are missing, not connected or have compromised functionality.		Indicates AED requires maintenance by authorized service personnel.
	When the SHOCK indicator is lit, press this button to deliver a defibrillation shock.		Serial communication port

Symbol	Description	Symbol	Description
	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.
	Date of manufacture: year and month.		Date of factory recertification (R): year and month.
	Latex free. Not made with natural rubber latex.		Disposable. Single patient use only.
	Tear here to open.		Position of pads on the chest of patient.
	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.		
	Upper and lower operating temperature limits.		Use pads by this date.
	Serial Number		Device model number; battery model number

Symbol	Description	Symbol	Description
MODEL	Device model number; battery model number	LOT	Lot number
$LiSO_2$	Lithium sulfur dioxide	EC REP	Authorized representative in the European Community
CE 0086	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.	 Pb	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. substations.

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]	Not Applicable	
	10 Vrms		
	150 kHz to 80 MHz in ISM bands[a]		

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. 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

Contents

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. For the Powerheart® AED G3 Automatic, the AED automatically delivers a shock if needed.

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 (9300E 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 2-1 on page 2-5, 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.

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 2-1: 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

Table 2-1: 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.

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

Contents

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 ae 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.

Audible maintenance indicator

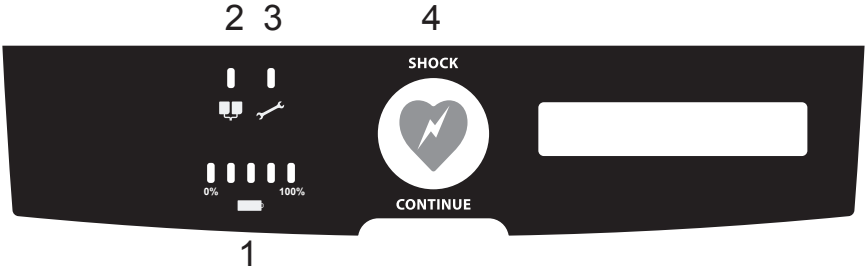
When the daily, weekly, or monthly self-test determines attention is required, a beep sounds every 30 seconds until the lid is opened or the battery power is depleted. Opening and closing the lid may deactivate the beep. If the error is not corrected by the next automatic self-test, the beep will be 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 1-2) or outside the U.S., your local Cardiac Science representative.

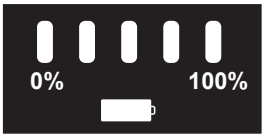
Diagnostic panel

The diagnostic panel has the following indicators:



1. Smartgauge™ battery indicator
2. Pads indicator
3. Service indicator
4. Shock Button (Powerheart G3 model 9300E only)

Smartgauge battery status indicator



The Smartgauge Battery Status Indicator has five LEDs, four green and one red. The right four green LEDs display the remaining capacity of the battery much like a fuel gauge. With use, the green LEDs gradually go out, from right to left, as battery capacity decreases. When the green LEDs go out and the red LED lights up, replace the battery.

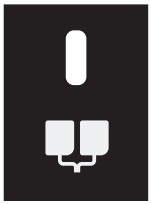
Note: When the red LED initially lights up–upon lid opening or at any time during a rescue–a BATTERY LOW prompt will be issued at once. However, the AED is capable of delivering at least 9 defibrillation shocks after the first BATTERY LOW prompt is issued.

When the AED battery cannot deliver any more shocks, the AED shows BATTERY LOW on the text display, and the red battery LED illuminates. To continue the rescue, leave the lid open, remove the battery, and replace with a fresh battery. If battery replacement takes

longer than 60 seconds, the first rescue will be terminated and a second rescue will begin upon insertion of battery.

Note: When the battery is depleted, neither the LED nor the text display illuminates.

Pads indicator



The Pads LED lights up when the pads are:

- Not properly connected to the AED
- Not within operational specifications (cold, dried, damaged)
- Disconnected from the patient during a rescue.

Service indicator

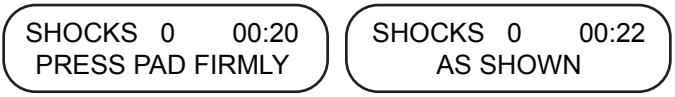
The Service LED lights up when the AED detects an error that cannot be corrected by the self test. Contact Cardiac Science Technical Support (see *Contact information* on page 1-2) or outside the U.S., your local Cardiac Science representative.

Shock button

For the Powerheart G3 model 9300E only: The AED has one button called the Shock button. The word Shock and the shock button LED will illuminate red when the AED is ready to deliver a defibrillation shock to the patient.

Text display

The text display has 2 lines of text. The text display provides the operator with information regarding system initialization, text prompts and data during a rescue, and diagnostics.



System initialization occurs when the lid is first opened. The text display shows the operator the identifiers for the internal code, voice prompts and text prompts versions. The text display also shows the current date and time.

During a rescue, the text display shows the number of shocks delivered and the elapsed time from the beginning of the rescue (when the lid was first opened). During CPR, a countdown timer will be displayed. The text version of the voice prompts will also be displayed.

Note: There is a 3 second delay between the time the AED lid is opened and the start of the rescue. This 3 second delay is not included in the elapsed rescue time.

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 PC is set at the correct local time and date.
2. Open the lid of the AED and run the RescueLink software on the PC.
3. Connect the cable to the serial port on the AED.
4. Verify that the voice prompt states “Communications Mode”.
5. Click Communications on the main menu. Select AED Date and Time.
6. Click on the Get button to review the current time in the AED.
7. If the time and date are incorrect, click Set to set new time and date. The AED date and time will automatically be updated to the PC’s time and date.

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: Preparation

Voice Prompt	Text display	Situation
"Tear open package and remove pads."	TEAR OPEN PACKAGE AND REMOVE PADS	Prompts the rescuer to open the pad package and remove pads.
"Peel one pad from plastic liner."	PEEL ONE PAD FROM PLASTIC LINER	Repeats every 3 seconds until the pads are separated. If a pad has been peeled before the prompt starts, this prompt will be skipped. This prompt will be interrupted when pad is peeled.
"Place one pad on bare upper chest."	PLACE ONE PAD ON BARE UPPER CHEST	Prompts the rescuer to place one pad on the patient.
"Peel second pad and place on bare lower chest as shown."	PEEL SECOND PAD PLACE ON LOWER CHEST	Repeats until second pad placement is sensed. If the pad is placed before prompt starts then this prompt will be skipped. This prompt will be interrupted when second pad is placed.

Table 3-2: Analysis

Voice Prompt	Text display	Situation
"Do not touch patient! Analyzing rhythm."	DO NOT TOUCH PATIENT ANALYZING RHYTHM	Repeats until analysis of the patient's cardiac rhythm is completed. This prompt will be interrupted when ready to shock.
"Shock advised."	SHOCK ADVISED	Repeats while the AED is preparing to deliver a defibrillation shock (charging).
"Charging."	CHARGING	Repeats while the AED is charging.

Table 3-3: Delivering shock - Semi-automatic only

Voice Prompt	Text display	Situation
"Stand clear! Push flashing button to deliver shock."	STAND CLEAR PUSH BUTTON TO SHOCK	Prompts 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.
"Shock delivered."	SHOCK DELIVERED	Prompts when the shock is delivered.

Table 3-4: Delivering shock - Automatic only

Voice Prompt	Text display	Situation
Stand clear! Shock will be delivered in:"	STAND CLEAR SHOCK IN:	After the AED is fully charged and ready to deliver the defibrillation shock. The SHOCK will automatically be administered approximately three seconds after the end of the voice prompt.
"Three"	THREE	Prompts approximately three seconds prior to delivering shock.
"Two"	TWO	Prompts approximately two seconds prior to delivering shock.
"One"	ONE	Prompts approximately one second prior to delivering shock.
"Shock delivered"	SHOCK DELIVERED	Prompts when the shock is delivered.

Table 3-5: CPR prompts

Voice Prompt	Text display	Situation
Note: The Medical Director may modify the CPR options in MDLink. Except where noted, prompts apply both to compressions-only CPR and traditional CPR (compressions and breaths).		
"It is now safe to touch the patient."	IT IS NOW SAFE TO TOUCH THE PATIENT	Advises the rescuer that it is safe to touch the patient: After the AED delivers a shock After the AED detects a non-shockable cardiac rhythm

Table 3-5: CPR prompts (continued)

Voice Prompt	Text display	Situation
"Give 30 compressions then give 2 breaths"	30 COMPRESSIONS 2 BREATHS	This prompt plays at the start of a CPR interval where the AED detects a non-shockable heart rhythm. **Note:** Prompt for traditional CPR only.
"Start CPR"	START CPR	Prompts to start CPR.
(Beep)		One "Beep" occurs in 30-second intervals during CPR when enabled by the MDLink software program, "Beep" occurs when the AED requires maintenance.
"Continue CPR"	CONTINUE CPR	Prompts during the CPR interval enabled in the Standard prompt set. Prompts when lid is reopened during CPR cycle.

Table 3-6: Pad issues

Voice Prompt	Text display	Situation
"Check pads."	CHECK PADS	Occurs when patient impedance is too low or too high.

Table 3-7: Other prompts

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 do a rescue, the following will occur: BATTERY LOW shows on the LCD Smartgauge battery status indicator turns red AED beeps once every 30 seconds while the lid is closed You must replace the battery before continuing with the rescue. If completely depleted, all AED activity will terminate.
(none)	REMOVE BATTERY COMPLETELY	The AED displays this prompt when the battery is partially removed. But when the battery is at the replacement level (displaying BATTERY LOW), REMOVE BATTERY COMPLETELY is not shown, only BATTERY LOW.
"Analysis interrupted. Stop patient motion."	ANALYSIS INTERRUPTED STOP PATIENT MOTION	Prompts the rescuer to press down one third depth of patient's chest. the patient. Remove other electronic devices within a 5 meter radius.
"Open lid to continue rescue."	OPEN LID TO CONTINUE RESCUE	When the lid is inadvertently closed during a rescue, 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.

Table 3-7: Other prompts (continued)

Voice Prompt	Text display	Situation
"Remove cable to continue rescue."	REMOVE CABLE TO CONTINUE RESCUE	Prompts at the end of each CPR round. during a rescue, the phrase repeats until the cable is disconnected.
"Communications mode"	COMMUNICATIONS MODE	When the lid is open and the serial communication cable is plugged into the AED.
"Service required"	SERVICE REQUIRED	Occurs after the self-tests determine that the AED is not functioning properly. The prompt "SERVICE REQUIRED" will be heard when the lid is opened. The red SERVICE indicator will illuminate. After closing the lid, an alarm beep will be heard until the battery is removed or becomes completely depleted.

4 Data Management

Contents

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

To retrieve data from internal memory:

1. Open the AED lid.
2. Connect the serial cable to the PC and to the AED's serial port under the blue rubber data access cover. The voice prompt will say "Communications Mode".
3. Run the RescueLink® software program.
4. From the **Communications** menu, select **Get Rescue Data**.
5. Select I**nternal Memory of AED**, then click **OK**.
6. Select a rescue by clicking on the date, and then press **OK**.

WARNING! Electric Shock and Fire Hazard

Do not connect any telephones or unauthorized connectors to the socket on this equipment.

Caution: Serial Communication Cable

The serial communication cable is only for use with the AED; it is not to be used with a telephone.

5 Troubleshooting and Maintenance

Contents

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.

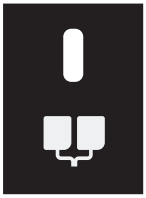
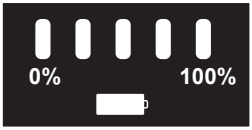
In addition, self-tests will be initiated upon opening the lid and again upon closing the lid.

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 (LED) is lit.	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.	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 Science 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 3-2 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 3-2.

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 (for the Powerheart® G3 model 9300E only).

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.

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* in Chapter 3.

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.

6 Technical Data

Contents

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

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

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)	9300: 6.6 lb (3.10 kg)
Operating 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)
Shipment, Transport, and Storage Environmental Conditions	Temperature: -22°F to 149°F(-30°C to 65°C) (up to 5 days) 68°F to 86°F (20°C to 30°C) (long term) Humidity: 5% to 95% (non-condensing) Pressure: 57kPa (+15,000ft) to 103kPa (-500ft)
Standby Environmental Conditions	Temperature: 32°F to 122°F (0°C to 50°C) (up to 5 days) 68°F to 86°F (20°C to 30°C) (long term) 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 G3 Plus device with Standard prompt set and CPR set to 60 seconds.

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 9300 The AED has been designed and manufactured to conform to the highest standards of safety and performance including electromagnetic compatibility (EMC). The 9300 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)

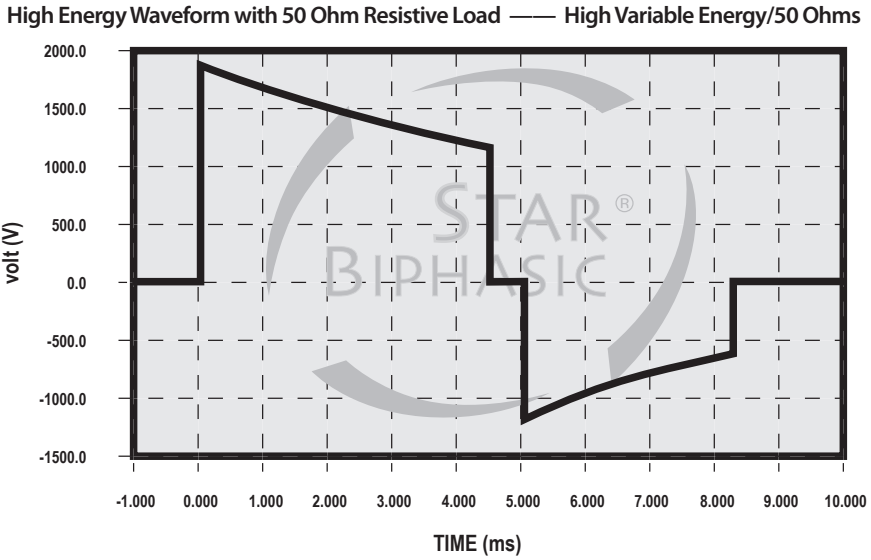
Parameter	Detail
Immunity	EM IEC 61000-4-3, Level X, (20V/m) IEC 60601-2-4 (20V/m) Magnetic IEC 61000-4-8 IEC 60601-2-4 ESD IEC 61000-4-2 IEC 60601-2-4 6kV contact discharge, 8KV air gap discharge
Environmental Conditions	Free Fall Drop: IEC 60068-2-32, 1 meter Bump: IEC 60068-2-29, 40g and 6000 bumps 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 32-122° F (0-50° C), ground survival 32-122° F (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.



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 Defibrillator device (K011901), which uses the exact same RHYTHMx® technology as Cardiac Science's current AEDs (G3, G3 Plus, and G5).

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 on page 6-12 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 (i.e., AED G3, AED G3 Plus, AED G5, and other models with identical RHYTHMx® Analysis Algorithm) during rescue attempts. All reviews and classifications of the ECG rhythm were consistent with the rhythm classifications outlined in Kerber et al.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 on page 6-13.

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 Fort Worth data set included 164 shocks and showed shock success of 90% (95% lower CI of 86%). 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%).

5. 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

1. 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 and AED G3 Plus.

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.

2. Powerheart® G3-G5 Pediatric ROSC

The pediatric defibrillation waveform delivered by the G3 AED and G3 AED Plus is the same. However, the pediatric waveform at different energy levels and impedances is different between the G3 s models and the Powerheart G5 (G5).

Study objective: The purpose of the animal study was to demonstrate that the defibrillation success defined as ROSC of the Powerheart® G5 AED (G5) is not inferior to the G3 AED or G3 AED Plus.

Method: The animals were induced into VF, then remained unsupported for the 30 second-VF duration. The AED under test (G3 AED or G5 AED) was activated such that at 30 seconds a shock energy was delivered. The defibrillation protocol and energy selection was fixed for each induction: 50J, 67J, and 67J in a 3-shock stack. Each successive shock was delivered at 15 second intervals, under the control of the AED analysis protocol. Up to eight (8) VF inductions were performed in each animal at 15-minute intervals between VF inductions.

Results: There were 64 first shocks delivered in the G3 group (of which 44 or 69% had ROSC) and 69 in the G5 group (of which 45 or 65%) had ROSC. There is >99% power with this sample size to detect a noninferiority margin difference between the group proportions of -0.10, where the actual difference detected was 0.0353.

There were 64 stacked shock sets in the G3 group (of which 57 or 89% with ROSC) and 69 in the G5 group (of which 61 or 88% with ROSC). There is >99% power with this sample size to detect a noninferiority margin difference between the groups of -0.10, where the actual difference detected was 0.0065.

Conclusion: The defibrillation rates that resulted in ROSC in the two (2) devices are consistent with the non-inferiority of the G5 relative to the G3, in a porcine animal model of defibrillation. In no case was there any observed damage related to defibrillation.

C. Pediatric Extrapolation

In this premarket approval application, two (2) animal studies were submitted to support the reasonable assurance of safety and effectiveness of the STAR® Biphasic defibrillation waveform in pediatric patients. The pre-clinical studies 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 studies and total number of participants are listed below:

- Human Factors study Powerheart® G3 - 15 participants,
- Human Factors study Powerheart® G3 Plus – 45 participants,
- Human Factor study Powerheart® G5 – 62 participants,
- Supplemental Human Factors study Powerheart® G3 and G5 AEDs – 30 participants.

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

- Powerheart® G3: AED that available in automatic and semi-automatic models.
- Powerheart® G3 Plus: G3 AED with more detailed voice prompting to support untrained users, available in automatic and semi-automatic models.
- Powerheart® G5: AED that available in automatic and semi-automatic models. Includes an optional CPR assistance device (ICPR device) that provides additional feedback for proper CPR technique.

Each device was validated in independent usability studies and included both the automatic and semi-automatic models where applicable. Participants were not allowed to participate in multiple studies to ensure that there was no negative transfer between the models. Unique AED features, such as the manual shock mode and ICPR device attachment, were also tested whenever applicable.

Table 6-8 shows the distribution of user groups across each study. Note that each applicable user group was represented by a minimum of 15 participants. This sample size was chosen to capture the majority of known use errors with the AED devices and is not intended to produce statistically significant results.

Table 6-8: User Group Distribution

	G3	G3 Plus	G5
Professional Rescuers	See G3 Plus	✓	✓
Targeted Responders	See G3 Plus	✓	✓
Lay People	✓	✓	✓

The Powerheart® AEDs have been found to be safe and effective for the intended users, uses, and use environments. Additionally, while not included as Cardiac Science's intended users, untrained lay users were able to deliver a shock despite lack of the training (training is recommended in Cardiac Science's AED Indications for Use). These findings were based of the following results shown in Table 6-9.

Table 6-9: Usability Study Results

AED Model	# of Participants	Shock Delivery Success %	Median time to Shock (seconds)
G3	15	100%	100.3
G3 Plus	45	100%	75.1
G5	62	98%	63.4

E. Complaint Analysis

To further demonstrate the safety and effectiveness of the Powerheart® AEDs in clinical use, relevant adverse event data between January 1,2014 and August 10, 2016. The results identified nineteen (19) deaths and nineteen (19) malfunctions associated with Powerheart® AED model numbers 9300A, 9300E, 9390A, 9390E, and G5A.

For the reported 19 deaths, there were 11 reports in which the device kept prompting users to tear open the pads package after the pads had already been placed on the patients. Cardiac Science evaluated these returned devices and confirmed the user error of improper removal of the pad from liner prior to the placement which caused an insufficient electrical contact between the patients and the pads. Five (5) other reports stated that the AED failed to deliver the shock after analyzing the correct rhythm. Cardiac Science investigated the returned devices and confirmed that the users pressed the shock button before it started flashing, which would result in no shock being delivered. The remaining three (3) of 19 MDRs reported that there were no voice prompts after opening the AED's lid to remove pads as well as no voice prompts for shock advised. Cardiac Science replaced damaged speakers due to mishandling.

For the reported 19 malfunctions, the identified root causes and quantities as determined by Cardiac Science are: device not returned (13), unexpected battery failure (4), user error (2).

F. Conclusions

The retrospective analysis of Cardiac Science AEDs in real world use demonstrates effectiveness of the STAR® Biphasic waveform consistent with the cited industry studies. STAR® Biphasic Waveform 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, G3 Plus, and G5 AEDs.

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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70-00966-01 F

Operator and Service Manual

Powerheart® AED

G3 Plus 9390A and 9390E

70-00914-01 G

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Trademark Information

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Patents

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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Contents

Troubleshooting and Maintenance 5

Technical Data 6

1 Product Information and Safety

Contents

Before Operating the Powerheart G3 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 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

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.

Indications for use

Powerheart® AED G3 and Powerheart® AED G3 Automatic

The Powerheart AED G3 Plus 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 Plus 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.

Product models

This guide is for Powerheart G3 Plus model 9390E and Powerheart® G3 Plus Automatic 9390A AED models. They share a basic set of features and differences are noted throughout the manual.

Product references

For purposes of retaining simple, clear instructions in this manual, note the product references used. Features, specifications, operating instructions and maintenance common to product models will be referred to as:

"Powerheart G3 AED", "AED", or "device" refers to both Powerheart G3 model 9390E and Powerheart G3 Automatic model 9390A AEDs unless otherwise noted.

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 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 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.

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: Serial Communication Cable.

The AED will not function during a rescue when the serial communication cable is connected to its serial port. When the serial communication cable is connected to the AED during a rescue, the prompt "Remove Cable to Continue Rescue" will be heard until you remove the serial communication cable.

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. Anyone 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.

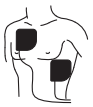
The AED requires special precautions regarding EMC. Use the AED according to the guidelines of the EMC declaration tables.

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 provided in the AED Operation and Service Manual.

Symbol	Description	Symbol	Description
	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.		MR Unsafe. The AED should not be used or stored in an MRI suite.
	Symbol for ON. Open the lid to turn on the AED.		Indicates the AED battery status. The illuminated areas indicate the remaining battery capacity.
	Check pads. The pads are missing, not connected or have compromised functionality.		Indicates AED requires maintenance by authorized service personnel.
	When the SHOCK indicator is lit, press this button to deliver a defibrillation shock.		Serial communication port

Symbol	Description	Symbol	Description
	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.
	Date of manufacture: year and month.		Date of factory recertification (R): year and month.
	Latex free. Not made with natural rubber latex.		Disposable. Single patient use only.
	Tear here to open.		Position of pads on the chest of patient.
	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.		
	Upper and lower operating temperature limits.		Use pads by this date.
	Serial Number		Device model number; battery model number

Symbol	Description	Symbol	Description
REF	Device model number; battery model number	LOT	Lot number
$LiSO_2$	Lithium sulfur dioxide	EC REP	Authorized representative in the European Community
CE 0086	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.	 Pb	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. substations.

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]	Not Applicable	
	10 Vrms		
	150 kHz to 80 MHz in ISM bands[a]		

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. 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

Contents

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. For the Powerheart AED G3 Automatic, the AED automatically delivers a shock if needed.

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 (9390E 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 2-1 on page 2-6, 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.

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 2-1: 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

Table 2-1: 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.

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

Contents

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 ae 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.

Audible maintenance indicator

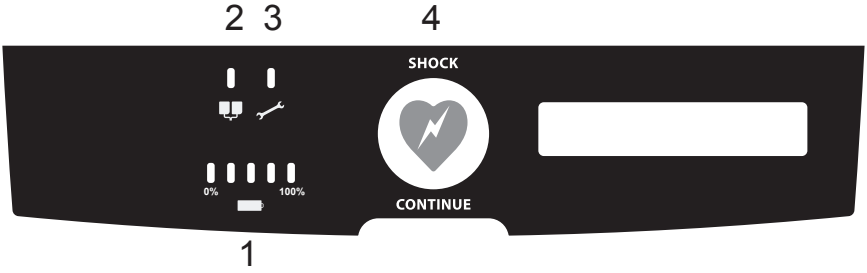
When the daily, weekly, or monthly self-test determines attention is required, a beep sounds every 30 seconds until the lid is opened or the battery power is depleted. Opening and closing the lid may deactivate the beep. If the error is not corrected by the next automatic self-test, the beep will be 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 1-2) or outside the U.S., your local Cardiac Science representative.

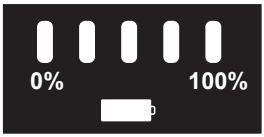
Diagnostic panel

The diagnostic panel has the following indicators:



1. Smartgauge™ battery indicator
2. Pads indicator
3. Service indicator
4. Shock Button (Powerheart G3 model 9390E only)

Smartgauge battery status indicator



The Smartgauge Battery Status Indicator has five LEDs, four green and one red. The right four green LEDs display the remaining capacity of the battery much like a fuel gauge. With use, the green LEDs gradually go out, from right to left, as battery capacity decreases. When the green LEDs go out and the red LED lights up, replace the battery.

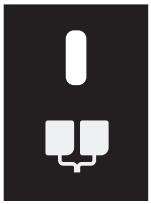
Note: When the red LED initially lights up–upon lid opening or at any time during a rescue–a BATTERY LOW prompt will be issued at once. However, the AED is capable of delivering at least 9 defibrillation shocks after the first BATTERY LOW prompt is issued.

When the AED battery cannot deliver any more shocks, the AED shows BATTERY LOW on the text display, and the red battery LED illuminates. To continue the rescue, leave the lid open, remove the battery, and replace with a fresh battery. If battery replacement takes

longer than 60 seconds, the first rescue will be terminated and a second rescue will begin upon insertion of battery.

Note: When the battery is depleted, neither the LED nor the text display illuminates.

Pads indicator



The Pads LED lights up when the pads are:

- Not properly connected to the AED
- Not within operational specifications (cold, dried, damaged)
- Disconnected from the patient during a rescue.

Service indicator

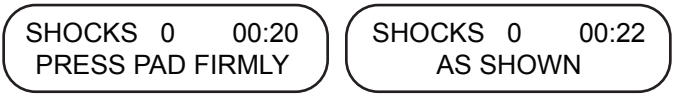
The Service LED lights up when the AED detects an error that cannot be corrected by the self test. Contact Cardiac Science Technical Support (see *Contact information* on page 1-2) or outside the U.S., your local Cardiac Science representative.

Shock button

For the Powerheart G3 model 9390E only: The AED has one button called the Shock button. The word Shock and the shock button LED will illuminate red when the AED is ready to deliver a defibrillation shock to the patient.

Text display

The text display has 2 lines of text. The text display provides the operator with information regarding system initialization, text prompts and data during a rescue, and diagnostics.



System initialization occurs when the lid is first opened. The text display shows the operator the identifiers for the internal code, voice prompts and text prompts versions. The text display also shows the current date and time.

During a rescue, the text display shows the number of shocks delivered and the elapsed time from the beginning of the rescue (when the lid was first opened). During CPR, a countdown timer will be displayed. The text version of the voice prompts will also be displayed.

Note: There is a 3 second delay between the time the AED lid is opened and the start of the rescue. This 3 second delay is not included in the elapsed rescue time.

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 PC is set at the correct local time and date.
2. Open the lid of the AED and run the RescueLink software on the PC.
3. Connect the cable to the serial port on the AED.
4. Verify that the voice prompt states “Communications Mode”.
5. Click Communications on the main menu. Select AED Date and Time.
6. Click on the Get button to review the current time in the AED.
7. If the time and date are incorrect, click Set to set new time and date. The AED date and time will automatically be updated to the PC’s time and date.

RescueCoach™ voice prompts and text display

The RescueCoach 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: Initial instructions

Voice Prompt	Text display	Situation
"Stay calm. Follow these voice instructions. Make sure 911 is called now!"	CALL 911!	Plays after lid opening self test, default ON.
"Stay calm. Follow these voice instructions. Make sure Emergency Services are called now!"	CALL EMERGENCY SERVICES NOW!	Medical Director may use MDLink® to select this prompt instead of "CALL 911!". MDLink also allows the emergency services and 911prompts to be disabled.

Table 3-2: Preparation

Voice Prompt	Text display	Situation
"Begin by exposing patient's bare chest and torso. Remove or cut clothing if needed."	BARE PATIENT'S TORSO REMOVE CLOTHING	Prompts the rescuer to remove patient clothing.

Table 3-2: Preparation (continued)

Voice Prompt	Text display	Situation
"When patient's chest and torso are exposed, remove square foil package from lid of AED."	WHEN CHEST IS BARE REMOVE FOIL PACKAGE	Prompts the rescuer to remove the pads from AED lid.
"Tear open foil package across dotted line and remove pads."	TEAR OPEN PACKAGE REMOVE PADS	Prompts the rescuer to open the pad package and remove. pads.
"Next, separate one of the white pads completely from blue plastic liner. Begin peeling from the tabbed corner."	PEEL ONE PAD FROM BLUE PLASTIC LINER	Repeats every 3 seconds until the pads are separated. If a pad has been peeled before the prompt starts, this prompt will be skipped. This prompt will be interrupted when pad is peeled.
"Firmly place the pad without the liner on the patient, exactly as illustrated. This pad can be placed on either of the two locations shown."	PRESS PAD FIRMLY TO CHEST AS SHOWN	Prompts the rescuer to place one pad on the patient.
"Next, peel the blue plastic liner off of the second white pad."	PEEL SECOND PAD OFF BLUE PLASTIC LINER	Prompts the rescuer to remove the liner from the second pad.
"Firmly place the second pad on the opposite location, exactly as illustrated."	PRESS PAD FIRMLY AS SHOWN	Repeats until second pad placement is sensed. If the pad is placed. before prompt starts then this prompt will be skipped. This prompt will be interrupted when second pad is placed.

Table 3-3: Analysis

Voice Prompt	Text display	Situation
"Do not touch patient! Analyzing heart rhythm. Please wait."	DO NOT TOUCH PATIENT ANALYZING RHYTHM	Repeats until analysis of the patient's cardiac rhythm is completed. This prompt will be interrupted when ready to shock.
"Preparing shock. Move away from the patient!"	NO CONTACT WITH THE PATIENT	Repeats while the AED is preparing to deliver a defibrillation shock (charging).

Table 3-4: Delivering shock - Semi-automatic

Voice Prompt	Text display	Situation
"Press red flashing button to deliver shock."	PRESS BUTTON TO DELIVER SHOCK	Prompts 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.
"Shock delivered"	SHOCK DELIVERED	Prompts when the shock is delivered.

Table 3-5: Delivering shock - Fully automatic

Voice Prompt	Text display	Situation
"Shock will be delivered in"	SHOCK IN:	After the AED is fully charged and ready to deliver the defibrillation shock. The SHOCK will automatically be administered approximately three seconds after the end of the voice prompt.
"Three"	THREE	Prompts approximately three seconds prior to delivering shock.
"Two"	TWO	Prompts approximately two seconds prior to delivering shock.
"One"	ONE	Prompts approximately one second prior to delivering shock.
"Shock delivered"	SHOCK DELIVERED	Prompts when the shock is delivered.

Table 3-6: CPR prompts

Voice Prompt	Text display	Situation
Note: The AED is shipped from the factory with ENHANCED MODE defaulted ON. The Medical Director may modify the CPR options in MDLink®. ENHANCED CPR prompts are listed in this table. Except where noted, prompts apply both to compressions-only CPR and traditional CPR (compressions and breaths).		
"It is now safe to touch the patient."	NOW SAFE TO TOUCH THE PATIENT	Advises the rescuer that it is safe to touch the patient: After the AED delivers a shock After the AED detects a non-shockable cardiac rhythm.

Table 3-6: CPR prompts (continued)

Voice Prompt	Text display	Situation
"When instructed, give patient 30 rapid compressions then give 2 breaths"	30 COMPRESSIONS 2 BREATHS	This prompt plays at the start of a CPR interval where the AED detects a non-shockable heart rhythm. **Note:** Prompt for traditional CPR only.
"Place heel of one hand on center of chest between nipples."	PLACE ONE HAND ON CENTER OF CHEST	Prompts rescuer to correctly place one hand for giving compressions.
"Place heel of other hand directly on top of first hand. Lean over patient with elbows straight."	PLACE OTHER HAND ON TOP OF FIRST HAND	Prompts rescuer to correctly place other hand and body for giving compressions
"Press the patient's chest down rapidly one third depth of chest, then release"	PRESS CHEST DOWN FIRMLY	Prompts the rescuer to press down one third depth of patient's chest.
"Start CPR"	START CPR	Prompts to start CPR.
"Press" (30 times at 100/minute) (or) Metronome (30 times at 100/minute) (or) No Prompt (silence)	{CPR COUNTER}	CPR counter shows the amount of time remaining for the CPR session.
Note: Option is selected in MDLink software.		

Table 3-6: CPR prompts (continued)

Voice Prompt	Text display	Situation
"Stop compressions"	STOP COMPRESSIONS	Prompts at the end of each CPR round. **Note:** Prompt for traditional CPR only, in enhanced mode.
"Give breath, give breath"	GIVE BREATH	Prompts to give two breaths to patient. **Note:** Prompt for traditional CPR only, in enhanced mode.
"Continue with compressions."	CONTINUE WITH COMPRESSIONS	Prompts in subsequent rounds of the same CPR session. **Note:** This prompt is available only in Enhanced Mode. Prompt for traditional CPR only.
"Stop CPR"	STOP CPR	Prompts to stop CPR.
"Continue CPR"	CONTINUE CPR	Prompts during the CPR interval enabled in the Standard prompt set. Prompts when lid is reopened during CPR cycle.

Table 3-7: Pad issues

Voice Prompt	Text display	Situation
"Make sure pad connector is plugged into AED."	CHECK CONNECTOR IS PLUGGED INTO AED	Prompts when defibrillation pads connector is not correctly inserted into pad socket.

Table 3-7: Pad issues

Voice Prompt	Text display	Situation
"Press pads firmly to patient's bare skin."	PRESS PADS FIRMLY TO BARE SKIN	Prompts when better pad connectivity to the patient's skin is required because impedance is too high.

Table 3-8: Other prompts

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 do a rescue, the following will occur: BATTERY LOW shows on the LCD Smartgauge battery status indicator turns red. AED beeps once every 30 seconds while the lid is closed You must replace the battery before continuing with the rescue. 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. Remove other electronic devices within a 5 meter radius.
"Open lid to continue rescue."	OPEN LID TO CONTINUE RESCUE	When the lid is inadvertently closed during a rescue, this prompt will repeat for 15 seconds.

Table 3-8: Other prompts (continued)

Voice Prompt	Text display	Situation
"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.
"Remove cable to continue rescue."	REMOVE CABLE TO CONTINUE RESCUE	When a serial communication cable is connected to the AED during a rescue, the phrase repeats until the cable is disconnected.
"Communications mode"	COMMUNICATIONS MODE	When the lid is open and the serial communication cable is plugged into the AED.
"Service required"	SERVICE REQUIRED	Occurs after the self-tests determine that the AED is not functioning properly. The prompt "SERVICE REQUIRED" will be heard when the lid is opened. The red SERVICE indicator will illuminate. After closing the lid, an alarm beep will be heard until the battery is removed or becomes completely depleted.

4 Data Management

Contents

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

To retrieve data from internal memory:

1. Open the AED lid.
2. Connect the serial cable to the PC and to the AED's serial port under the blue rubber data access cover. The voice prompt will say "Communications Mode".
3. Run the RescueLink® software program.
4. Select Communications. Get Rescue Data.
5. Select Internal Memory of AED, then select OK.
6. Select a rescue by clicking on the date, and press OK.

WARNING! Electric Shock and Fire Hazard

Do not connect any telephones or unauthorized connectors to the socket on this equipment.

Caution: Serial Communication Cable

The serial communication cable is only for use with the AED; it is not to be used with a telephone.

5 Troubleshooting and Maintenance

Contents

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.

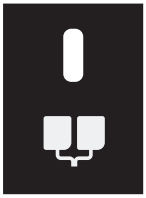
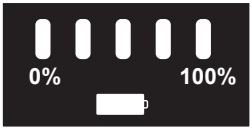
In addition, self-tests will be initiated upon opening the lid and again upon closing the lid.

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 (LED) is lit.	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.	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 Science 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 3-2 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 3-2.

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:

Monthly maintenance

Perform the following procedure each month (28 days):

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 (for the Powerheart G3 model 9390E only).
2. Release the Shock button (for the Powerheart® G3 model 9390E only).
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.

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* in Chapter 3.

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.

6 Technical Data

Contents

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

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

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)	9390: 6.6 lb (3.10 kg)
Operating 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)
Shipment, Transport, and Storage Environmental Conditions	Temperature: -22°F to 149°F(-30°C to 65°C) (up to 5 days) 68°F to 86°F (20°C to 30°C) (long term) Humidity: 5% to 95% (non-condensing) Pressure: 57kPa (+15,000ft) to 103kPa (-500ft)
Standby Environmental Conditions	Temperature: 32°F to 122°F (0°C to 50°C) (up to 5 days) 68°F to 86°F (20°C to 30°C) (long term) 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 G3 Plus device with Standard prompt set and CPR set to 60 seconds.

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 9390 The AED has been designed and manufactured to conform to the highest standards of safety and performance including electromagnetic compatibility (EMC). The 9390 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)

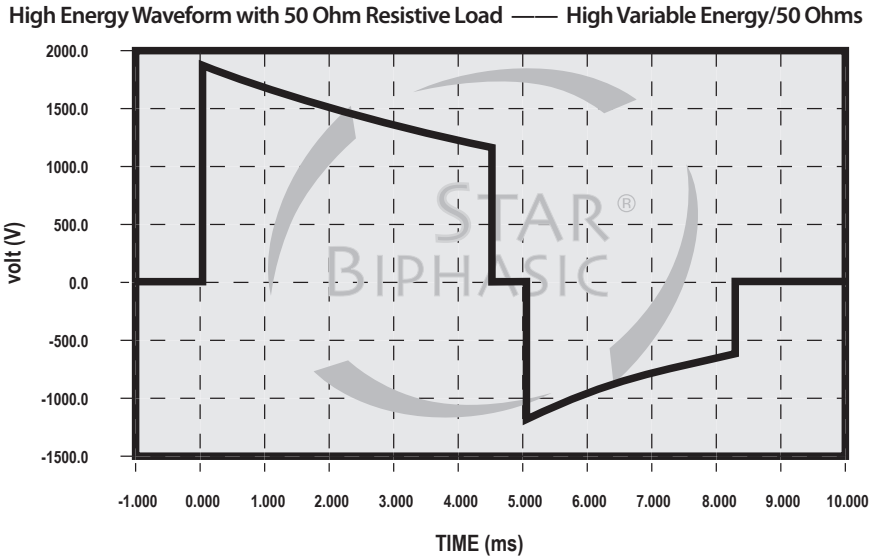
Parameter	Detail
Immunity	EM IEC 61000-4-3, Level X, (20V/m) IEC 60601-2-4 (20V/m) Magnetic IEC 61000-4-8 IEC 60601-2-4 ESD IEC 61000-4-2 IEC 60601-2-4 6kV contact discharge, 8KV air gap discharge
Environmental Conditions	Free Fall Drop: IEC 60068-2-32, 1 meter Bump: IEC 60068-2-29, 40g and 6000 bumps 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 32-122° F (0-50° C), ground survival 32-122° F (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.



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 Defibrillator device (K011901), which uses the exact same RHYTHMx® technology as Cardiac Science's current AEDs (G3, G3 Plus, and G5).

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 on page 6-12 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 (i.e., AED G3, AED G3 Plus, AED G5, and other models with identical RHYTHMx® Analysis Algorithm) during rescue attempts. All reviews and classifications of the ECG rhythm were consistent with the rhythm classifications outlined in Kerber et al.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 on page 6-13.

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 Fort Worth data set included 164 shocks and showed shock success of 90% (95% lower CI of 86%). 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%).

5. 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

1. 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 and AED G3 Plus.

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.

2. Powerheart® G3-G5 Pediatric ROSC

The pediatric defibrillation waveform delivered by the G3 AED and G3 AED Plus is the same. However, the pediatric waveform at different energy levels and impedances is different between the G3 s models and the Powerheart G5 (G5).

Study objective: The purpose of the animal study was to demonstrate that the defibrillation success defined as ROSC of the Powerheart® G5 AED (G5) is not inferior to the G3 AED or G3 AED Plus.

Method: The animals were induced into VF, then remained unsupported for the 30 second-VF duration. The AED under test (G3 AED or G5 AED) was activated such that at 30 seconds a shock energy was delivered. The defibrillation protocol and energy selection was fixed for each induction: 50J, 67J, and 67J in a 3-shock stack. Each successive shock was delivered at 15 second intervals, under the control of the AED analysis protocol. Up to eight (8) VF inductions were performed in each animal at 15-minute intervals between VF inductions.

Results: There were 64 first shocks delivered in the G3 group (of which 44 or 69% had ROSC) and 69 in the G5 group (of which 45 or 65%) had ROSC. There is >99% power with this sample size to detect a noninferiority margin difference between the group proportions of -0.10, where the actual difference detected was 0.0353.

There were 64 stacked shock sets in the G3 group (of which 57 or 89% with ROSC) and 69 in the G5 group (of which 61 or 88% with ROSC). There is >99% power with this sample size to detect a noninferiority margin difference between the groups of -0.10, where the actual difference detected was 0.0065.

Conclusion: The defibrillation rates that resulted in ROSC in the two (2) devices are consistent with the non-inferiority of the G5 relative to the G3, in a porcine animal model of defibrillation. In no case was there any observed damage related to defibrillation.

C. Pediatric Extrapolation

In this premarket approval application, two (2) animal studies were submitted to support the reasonable assurance of safety and effectiveness of the STAR® Biphasic defibrillation waveform in pediatric patients. The pre-clinical studies 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 studies and total number of participants are listed below:

- Human Factors study Powerheart® G3 - 15 participants,
- Human Factors study Powerheart® G3 Plus – 45 participants,
- Human Factor study Powerheart® G5 – 62 participants,
- Supplemental Human Factors study Powerheart® G3 and G5 AEDs – 30 participants.

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

- Powerheart® G3: AED that available in automatic and semi-automatic models.
- Powerheart® G3 Plus: G3 AED with more detailed voice prompting to support untrained users, available in automatic and semi-automatic models.
- Powerheart® G5: AED that available in automatic and semi-automatic models. Includes an optional CPR assistance device (ICPR device) that provides additional feedback for proper CPR technique.

Each device was validated in independent usability studies and included both the automatic and semi-automatic models where applicable. Participants were not allowed to participate in multiple studies to ensure that there was no negative transfer between the models. Unique AED features, such as the manual shock mode and ICPR device attachment, were also tested whenever applicable.

Table 6-8 shows the distribution of user groups across each study. Note that each applicable user group was represented by a minimum of 15 participants. This sample size was chosen to capture the majority of known use errors with the AED devices and is not intended to produce statistically significant results.

Table 6-8: User Group Distribution

	G3	G3 Plus	G5
Professional Rescuers	See G3 Plus	✓	✓
Targeted Responders	See G3 Plus	✓	✓
Lay People	✓	✓	✓

The Powerheart® AEDs have been found to be safe and effective for the intended users, uses, and use environments. Additionally, while not included as Cardiac Science's intended users, untrained lay users were able to deliver a shock despite lack of the training (training is recommended in Cardiac Science's AED Indications for Use). These findings were based of the following results shown in Table 6-9.

Table 6-9: Usability Study Results

AED Model	# of Participants	Shock Delivery Success %	Median time to Shock (seconds)
G3	15	100%	100.3
G3 Plus	45	100%	75.1
G5	62	98%	63.4

E. Complaint Analysis

To further demonstrate the safety and effectiveness of the Powerheart® AEDs in clinical use, relevant adverse event data between January 1,2014 and August 10, 2016. The results identified nineteen (19) deaths and nineteen (19) malfunctions associated with Powerheart® AED model numbers 9300A, 9300E, 9390A, 9390E, and G5A.

For the reported 19 deaths, there were 11 reports in which the device kept prompting users to tear open the pads package after the pads had already been placed on the patients. Cardiac Science evaluated these returned devices and confirmed the user error of improper removal of the pad from liner prior to the placement which caused an insufficient electrical contact between the patients and the pads. Five (5) other reports stated that the AED failed to deliver the shock after analyzing the correct rhythm. Cardiac Science investigated the returned devices and confirmed that the users pressed the shock button before it started flashing, which would result in no shock being delivered. The remaining three (3) of 19 MDRs reported that there were no voice prompts after opening the AED's lid to remove pads as well as no voice prompts for shock advised. Cardiac Science replaced damaged speakers due to mishandling.

For the reported 19 malfunctions, the identified root causes and quantities as determined by Cardiac Science are: device not returned (13), unexpected battery failure (4), user error (2).

F. Conclusions

The retrospective analysis of Cardiac Science AEDs in real world use demonstrates effectiveness of the STAR® Biphasic waveform consistent with the cited industry studies. STAR® Biphasic Waveform 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, G3 Plus, and G5 AEDs.

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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