

User's Guide

Cardiac Science Powerheart®
Automated External Defibrillator



USER'S GUIDE

POWERHEART® G5 AUTOMATED EXTERNAL DEFIBRILLATOR

70-01704-01 C



AT THE HEART OF SAVING
LIVES®

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Patents

U.S. and foreign patents pending. See www.cardiacscience.com/patents for a complete list.

CAUTION. Restricted use

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



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1 About the AED

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This section describes parts of the AED and the optional features for use in rescues.

AED overview

The Powerheart G5 automated external defibrillator (AED) is designed for treating life-threatening heart beat irregularities, such as ventricular fibrillation, that cause Sudden Cardiac Arrest (SCA).

There are two models available—fully automatic and semi-automatic. After the defibrillation pads are applied to the patient, the fully automatic model evaluates the heart rhythm and, if a shockable rhythm is detected, delivers a shock without any rescuer assistance. The semi-automatic model evaluates the heart rhythm and requires the rescuer to press the shock button if a shockable rhythm is detected. Both models have voice and text instructions that guide the rescuer through the entire defibrillation process.

Note: Not all configurations described in this document are available in all areas.

Indications for use

Powerheart® G5

The Powerheart AED G5 is indicated for emergency treatment of victims exhibiting symptoms of sudden cardiac arrest who are:

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

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

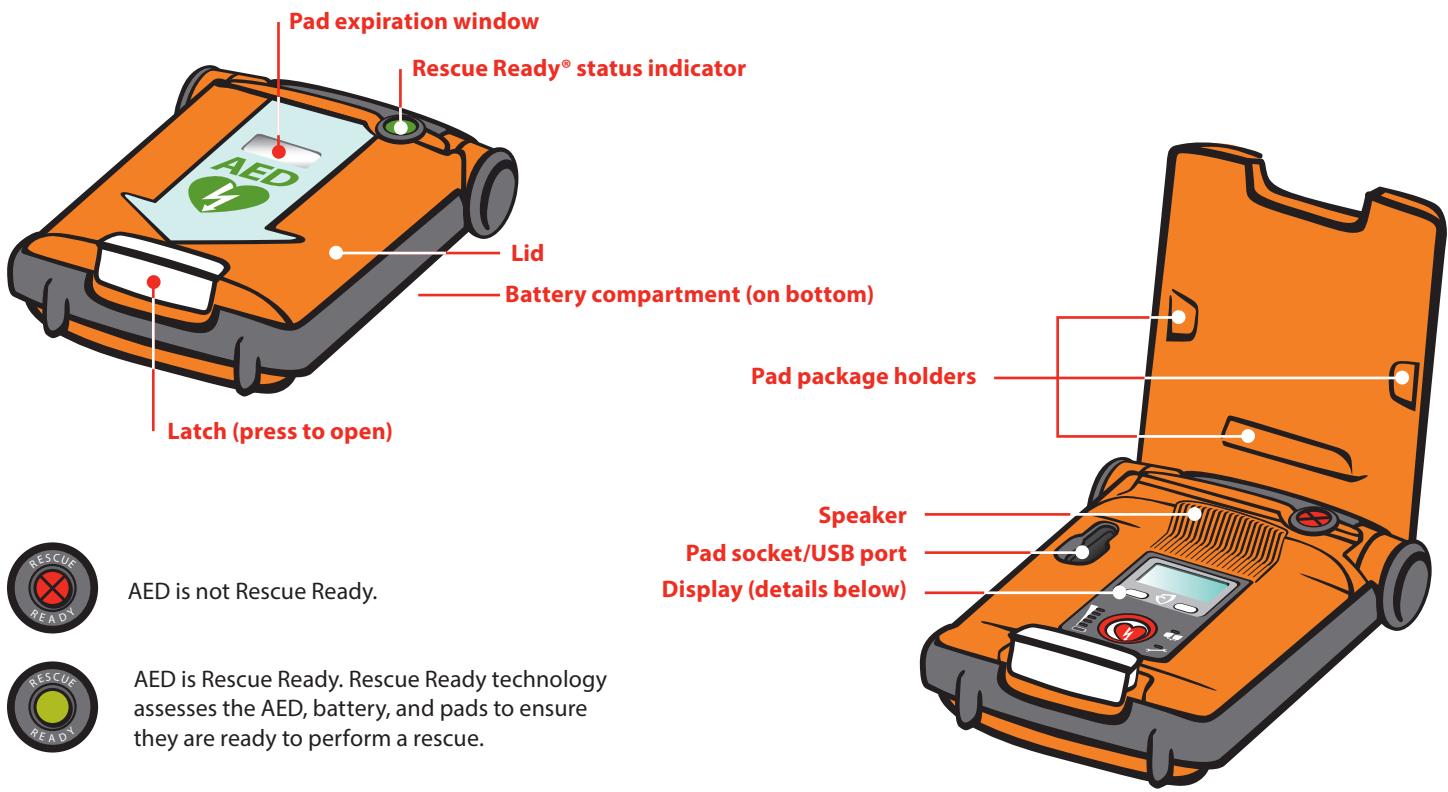
The G5 Automated External Defibrillator (AED) is intended to be used by persons who have been trained in its operation.

When used with the optional Intellisense™ Defibrillation Pad – ICPR, the device offers CPR performance feedback to aid a trained rescuer by providing compression rate and depth performance feedback through audio prompting. The Intellisense™ Defibrillation Pad – ICPR is indicated for use on cardiac arrest patients 8 years of age or older, or who weigh more than 25 kg (55 lbs.).

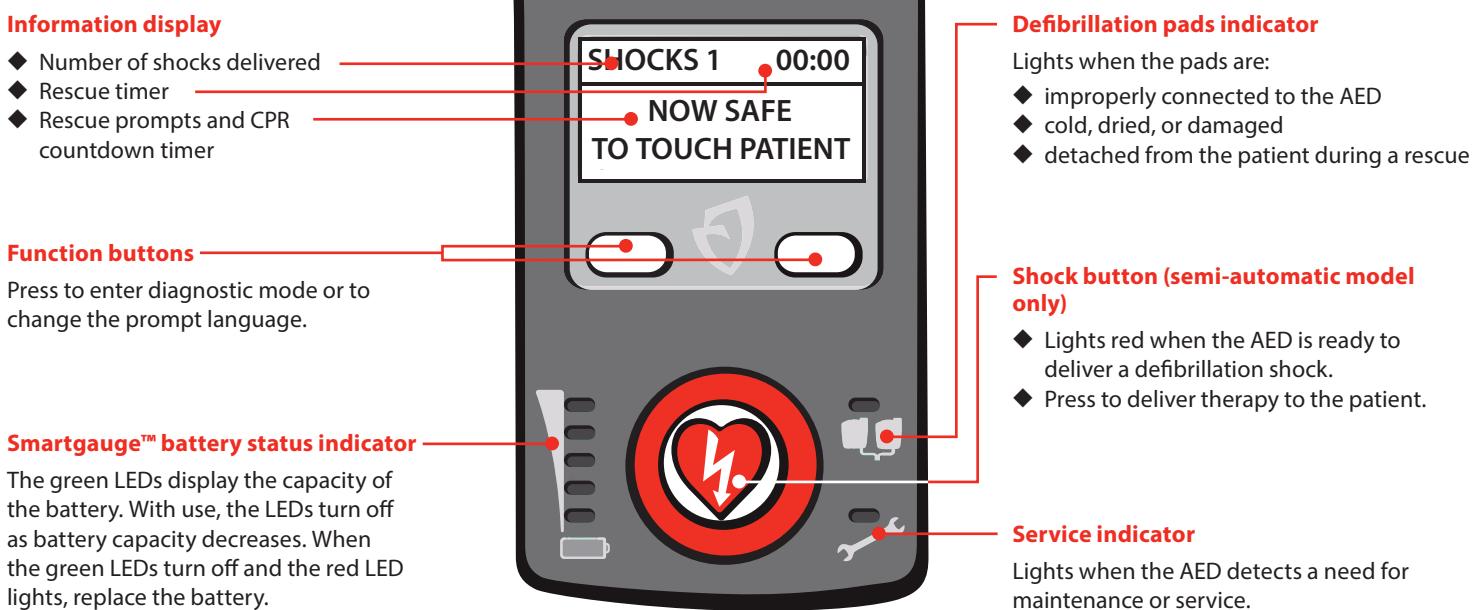
Contraindications

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

AED parts



The display panel



Defibrillation pads

The AED comes with defibrillation pads installed. Pads are stored in a ready-to-use, sealed package. The preinstalled pads are for use with adults and children 8 years and older or over 55lbs. If the child appears younger or lighter do not delay treatment to determine the child's exact age or weight, use the preinstalled pads. Pads are self-adhesive with an attached cable and connector for power and ECG transmission. Pads are disposable; discard after use in a rescue.

The pads have a limited shelf life and should not be used beyond the expiration date. Always keep a fresh, unopened pair of pads plugged into the AED.

The AED can identify the pad type and expiration date. The AED is compatible with these types of pads:

- ◆ XELAED001 defibrillation pads
- ◆ XELAED002 defibrillation pads with CPR feedback device*
- ◆ XELAED003 pediatric defibrillation pads

When the patient is 8 years of age or younger or weighs 25 kg (55 lbs) or less, use the AED with pediatric defibrillation pads, if available. See the instructions for use accompanying pediatric pads to replace preinstalled pads with pediatric pads. DO NOT delay therapy to determine the patient's exact age or weight.

Contact Cardiac Science Customer Care to order replacement pads.

Important: Pediatric pads are not to be pre-connected to the AED. Follow the instructions for use provided with pediatric pads.

See *Warnings and cautions* on page 3-1 for important safety information.



CPR feedback device

The CPR feedback device is about the size of the palm of a hand. Its non-slip surface and shape transfers the rescuer's compressions to the patient's chest. The CPR feedback device (included with optional preinstalled pads with CPR feedback device) measures the depth and rate of chest compressions. The AED uses this information to help guide proper compression rate and compression depth during CPR.

Note: Use of the CPR feedback device is optional.

If the CPR Feedback Device slips during CPR performance, continue chest compressions as trained, without interruption.

If you do not use the CPR feedback device, place it on a surface next to the patient. DO NOT attempt to detach the device from its cable.

Contact Cardiac Science Customer Care to order the preinstalled pads with CPR feedback device.

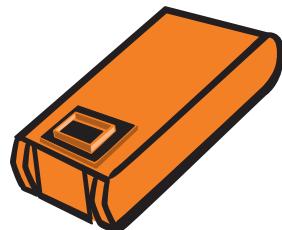
*DO NOT use the CPR feedback device on children under 8 years old or under 55 lbs.

Intellisense® battery

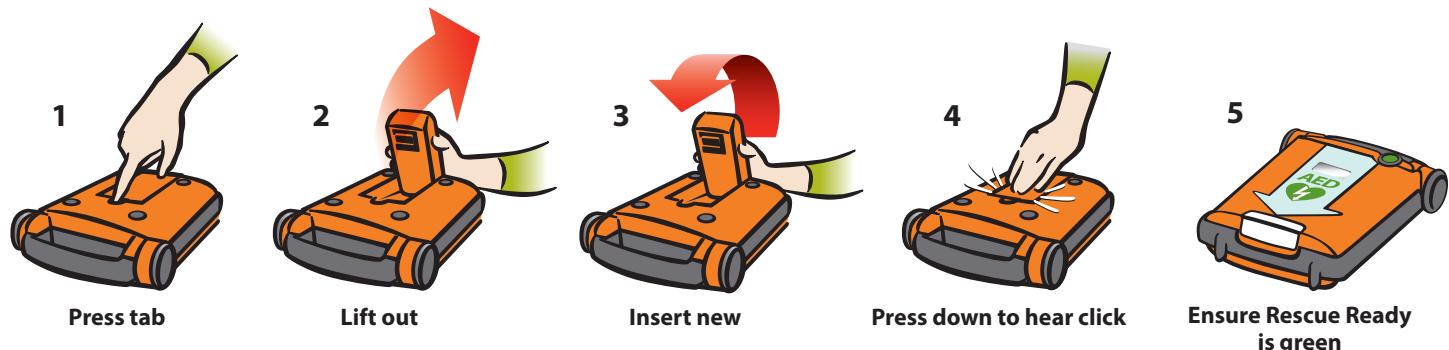
The Intellisense battery (model XBTAED001) automatically stores history of its operating life.

The battery history can be reviewed with *AED Manager* software.

Important: See *Warnings and cautions* on page 3-1 for important safety information.



How to replace the battery:



Note: Ensure that the battery is at room temperature before inserting it into the AED.



www.cardiacscience.com/batteryrecycle

Warranty

The Limited Warranty provided by Cardiac Science serves as the sole and exclusive warranty for the Powerheart G5 AED and its accessories. To obtain a limited warranty statement, contact your local Cardiac Science representative or go to www.cardiacscience.com.

2 Steps to a Rescue

These are the general steps in performing a rescue:



1: Assess the patient (page 2-2)



2: Prepare the patient (page 2-2)



3: Place the defibrillation pads (page 2-2)



4: Analyze the patient's ECG (page 2-3)



5: Deliver a defibrillation shock (page 2-3)



6: Give CPR (page 2-4)



7: Prepare the AED for the next rescue (page 2-4)

1: Assess the patient

Determine that the patient is more than 8 years of age or weighs more than 25 kg (55 lbs) and is both:

- ◆ Unresponsive
- ◆ Not breathing or not breathing normally

DO NOT delay therapy to determine the patient's exact age or weight.

CALL EMERGENCY MEDICAL SERVICES!

Note: When the patient is 8 years of age or younger or weighs 25 kg (55 lbs) or less, use the AED with pediatric defibrillation pads, if available. See the directions for use accompanying pediatric pads to replace preinstalled pads with pediatric pads.



2: Prepare the patient

1. Place the AED next to the patient.

Note: The normal use for the AED is with it lying horizontally.



2. Open the AED lid.
3. Remove clothing from the patient's chest.
4. Ensure that the patient's skin is clean and dry.
5. Dry the patient's chest and shave excessive hair if necessary.

3: Place pads

When the AED prompts...

"Tear open white package across dotted line and remove pads."

Do this...

1. Keeping the pads connected to the AED, tear open the package.
2. Remove the pads from the package.

You can leave the package attached to the pad wires.

"Peel one of the white pads completely from blue plastic."

3. With a firm, steady pull, peel one pad away from the blue plastic liner.
4. You can use either pad.

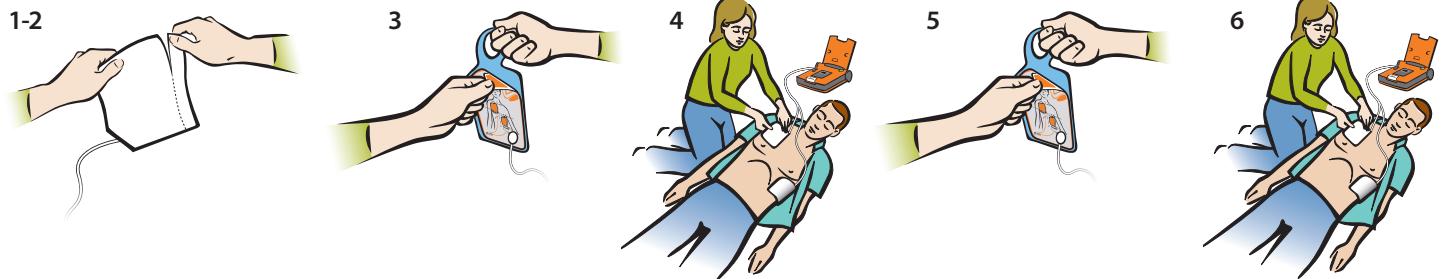
"Firmly place the pad without the blue plastic on patient's bare chest, exactly as shown on pads."

4. Place the pad in either location on the chest.

"Next, peel second white pad from the blue plastic. Firmly place the second pad on the other location exactly as shown on pads."

5. Pull the blue plastic from the second pad.
6. Place the pad on the other location on the chest.

Note: Cardiac Science's standard defibrillation pads are non-polarized and can be placed in either position as shown on the pad package. The package itself can be left attached to the defibrillation pads wires.



4: Analyze the ECG

When the AED prompts...	Do this...
"Do not touch the patient! Analyzing heart rhythm. Please wait."	1. Do not touch the patient. 2. Wait for the next prompt.
The AED begins analyzing the cardiac rhythm of the patient.	



During the analysis phase, you may hear one or more of these prompts:

If the AED prompts...	This is the problem...	Do this...
"Open lid to continue rescue"	The lid of the AED is closed.	Ensure that the lid is fully open.
"Press pads firmly to patient's bare chest"	The pads are not properly placed or are loose.	Ensure that pads are firmly placed on clean, dry skin.
"Make sure pad connector is plugged into AED"	The pads are disconnected from the AED.	Ensure that the connector is plugged properly into the AED.
"Analysis interrupted. Stop patient motion." The AED restarts the analysis.	The patient is excessively jostled or there is strong electromagnetic emitting equipment nearby (within 2 meters).	Remove the electronic device or stop the excessive motion.

5: Deliver a shock

When the AED prompts...	Do this...
"Shock advised. Do not touch the patient"	Ensure that no one is touching the patient.
Automatic model: "Shock will be delivered in 3, 2, 1."	Automatic model: Ensure that no one is touching the patient.
The AED delivers the defibrillation shock automatically.	
Semi-automatic model: When the AED is ready to deliver a defibrillation shock, the Shock button flashes. "Press red flashing button to deliver shock."	Semi-automatic model: Press the Shock button. If you do not press the Shock button within 30 seconds of hearing the prompt, the AED disarms the charge and prompts you to start CPR.
After the AED delivers the defibrillation shock: "Shock delivered."	Wait for the next prompt.
"It is now safe to touch the patient. Give CPR as instructed"	Begin CPR.



When the AED is charged, it continues to analyze the patient's heart rhythm. If the rhythm changes and a shock is no longer needed, the AED prompts, "Rhythm Changed. Shock Cancelled."

6: Give CPR

After the AED delivers a shock or detects a non-shockable rhythm, it enters CPR mode.

When the AED prompts...	Do this...
"If needed, perform CPR as instructed."	Perform CPR according to the prompts. Follow the countdown timer on the text display.

Important: If the AED is not operating as expected, it is preferable to perform CPR without the aid of the AED than to delay providing CPR.

After the CPR time expires, the AED returns to the ECG analysis mode (see 4: *Analyze the ECG* on page 2-3).

If the patient is conscious and breathing normally, leave the pads on the patient's chest and connected to the AED. Make the patient as comfortable as possible and wait for emergency medical services (EMS) personnel to arrive.

Note: If the AED does not provide expected CPR coaching, the rescuer must conduct CPR as appropriate.

After transferring the patient to emergency medical personnel, close the lid of the AED to end the rescue session. Prepare the AED for the next rescue.



7: Prepare the AED for the next rescue

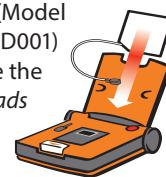
1. Open the lid.



2. Optional: Retrieve the rescue data stored in the internal memory of the AED. See the *AED Manager User's Guide* for details.



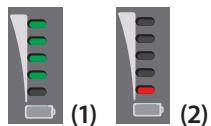
3. Connect a new preinstalled pads package (Model number XELAED001) to the AED. See the *Defibrillation Pads Instructions for Use* for details.



4. Verify that the pad connection indicator is off. If the indicator is on, make sure that the pad connector is properly attached to the AED.



5. Verify that there is adequate charge (1) remaining in the battery. If the battery charge is low (2), replace the battery.



6. Verify that the service indicator is off.



7. Close the lid.



8. Verify that the Rescue Ready indicator is green.



3 Safety

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◆ Warnings and cautions	3-1
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Before operating the 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 AED.

Operator training

Persons authorized to operate the AED should have the following training:

- Appropriate training as required by state, province, or country regulations
- Additional training as required by the 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.

Safety alert descriptions

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.

Warnings and cautions

This section lists general warnings and cautions.



CAUTION. Read these Instructions for Use 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

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

- Do not use in standing water or rain. Move patient to a 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! Shock hazard

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

Note: Unauthorized disassembly, modification, or service of the AED voids the warranty.

**WARNING! Possible radio frequency (RF) susceptibility**

Do not use the AED in locations where large electromagnetic or RF fields can be expected to occur.

Refer to Chapter D: Electromagnetic Emissions Standards Compliance for additional information

**WARNING! Improper equipment placement**

Position the AED away from other equipment in accordance with information in the electromagnetic compliance tables (see Appendix D, *Electromagnetic Emissions Standards Compliance*). If it is necessary to use the AED adjacent to or stacked with other equipment, then observe the AED to verify normal operations.

**WARNING! Possible improper delivery of therapy**

If practical, move the patient to a firm surface before attempting a rescue. We do not recommend that the CPR Feedback Device be used if the patient cannot be moved onto a firm surface.

**WARNING! Patient injury**

Do not place the CPR feedback device on an open wound.

**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! 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 or not breathing normally. 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! Do not reuse pads**

Used pads may not adhere properly to the patient. Improper pad adhesion may result in skin burns. Improper pad adhesion may result in improper AED performance. Used pads may cause patient-to-patient contamination.

**WARNING! AED may not be rescue ready.**

Keep a battery attached to the AED at all times so that the AED is available to perform rescues.

**WARNING! Pediatric pads statement.**

Connect pediatric pads only when attempting a pediatric rescue. Upon completion of the rescue, reconnect the preinstalled pads (Model number XELAED001) prior to placing the AED back into standby mode.

**WARNING! CPR feedback device not for use on children.**

The CPR feedback device used with XELAED002 defibrillation pads must not be used on children under 8 years of age or under 55lbs. The XELAED002 defibrillation pads may be used without the CPR feedback device.

**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.

**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.

**CAUTION. Battery handling and operation**

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

Do not drop the battery.

**CAUTION. Battery disposal**

Recycle or dispose of the lithium battery in accordance with all federal, country, 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; therefore Cardiac Science does not endorse their use. The use of non-approved accessories, if proved to contribute to a device malfunction, shall void any and all support from Cardiac Science.

**CAUTION. Possible improper AED performance**

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

**CAUTION. Moving the patient during a rescue**

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

**CAUTION. Case cleaning solutions**

When disinfecting the case, use a non-oxidizing disinfectant, such as soapy water, denatured ethanol, or 91% isopropyl alcohol to avoid damage to the metal connectors.

**CAUTION. Equipment damage.**

Keep all cleaning solutions and moisture away from the defibrillation pad connectors and cable connector openings.

**CAUTION. Incorrect software version**

The AED is programmed with software that has been tested to work with the version of *AED Manager* software included with the AED. When an older version of *AED Manager* is used to communicate with this AED, there may be features described in this manual that are not available. Also, when communicating with an older AED with the version of *AED Manager* included with this new AED there may be features described in this manual that cannot be used. The software in most cases will give an error message when incompatibilities occur.

Symbols and labels

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

Symbol	Description	Symbol	Description
	Caution. Consult accompanying documentation.	IP55	The AED is protected against access to hazardous parts by dust and the effects of water projected by jets in accordance with IEC 60529.
	Additional information is provided in the accompanying documentation.		Battery capacity indicator LEDs show the remaining battery capacity: 100%, 75%, 50%, 25%, 0% (red only).
	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.		Service Indicator indicates AED requires service by authorized service personnel.
	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.		Defibrillation Pads indicator Indicates that the pads are incorrectly connected or unusable. Check the connection with the AED; check the placement and attachment to the patient. If connections are correct, replace pads.
	CE Mark: This equipment conforms to essential requirements of the Medical Device Directive 93/42/EEC.		Shock button and indicator When the Shock indicator is lit, press this button to deliver a defibrillation shock.
	Classified by CSA 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 and 60601-2-4.		Rescue Ready® indicator A red indicator means the AED requires operator attention or maintenance, and is not Rescue Ready.
	Authorized representative in the European Community.		Rescue Ready® indicator A green indicator means the AED is Rescue Ready.

Symbol	Description	Symbol	Description
	Manufacturer.		Product model number.
	Date of manufacture, year, month and day.		Lot number.
	Use pads by the date shown.		Dispose of properly in accordance with all state, province, and country regulations.
	Latex free. Not made with natural rubber latex.		Recycle cardboard according to local law.
	Disposable. Single patient use only.		Waste Electronic Electrical Equipment (WEEE). Separate collection for waste electrical and electronic equipment. For more information, see <i>Manufacturer's WEEE compliance instructions</i> on page E-1
	Tear here to open.		Waste Electronic Electrical Equipment (WEEE) containing lead. Separate collection for waste electrical and electronic equipment.
	Do not recharge battery.		Box stacking limit.
	Lithium sulfur dioxide.		Fragile: handle with care.
	For use by or on the order of a Physician, or persons licensed by state law.		Keep dry.
	Do not incinerate or expose to open flame.		Relative humidity.
	Upper and lower temperature operating range or storage range limits.		Relative pressure.
	Serial Number.		UN symbol: Packaging is manufactured to conform to United Nations requirements.
			MR Unsafe. The AED should not be used or stored in an MRI suite.

4 AED Features

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The Powerheart AED provides customization for aspects of a rescue—from the amount of assistance given to a rescuer to the CPR protocol used. Additionally, each rescue is recorded.

Note: All configuration is performed by a medical director through the *AED Manager* software supplied with the AED.

Dual languages

The Powerheart G5 provides the option to choose between two languages in selected models. This allows for the user, at any point during the rescue, to change between the two languages. The AED provides all prompts in the chosen language. The prompt language resets to the default when the lid closes.

Prompting levels

The AED provides three selectable levels of prompts.

- ◆ Advanced: The AED provides detailed prompts for performing a rescue.
- ◆ Standard: The AED provides some guiding prompts.
- ◆ Basic: The AED provides minimal prompting for the various stages of a rescue.

Note: The names and descriptions of these prompting levels are provided as suggestions only. Do not construe them as medical guidance. Medical directors must use their professional judgment to determine the proper configuration of the AEDs for which they are responsible.

The following table gives an example of the differences in audio prompting provided for the levels of coaching. See Appendix A, *RescueCoach™ voice and text prompts*, for a complete list of audio and visual prompts.

Table 4-1: Audio prompts for applying pads to a patient

Advanced	Standard	Basic
Firmly place the pad without the blue plastic on patient's bare chest, exactly as shown on pads.	Firmly place the pad without the blue plastic on patient's bare chest, exactly as shown on pads.	Firmly place the pad on the patient.
This pad can be placed on either of the two locations as shown on pads	—	—
Next, peel second white pad from the blue plastic.	Next, peel second white pad from the blue plastic.	Next, peel second white pad from the blue plastic.
Firmly place the second pad on the other location, exactly as shown on pads.	Firmly place the second pad on the other location, exactly as shown on pads.	Firmly place the second pad on the other location.

CPR behavior types

The AED includes optional settings for configuring the style of CPR.

Combining the prompting levels and CPR behavior types, AEDs can be configured in many ways. For example, an AED can be configured to provide rescue instructions with:

- ◆ Advanced prompting and traditional (compressions and breaths) CPR sessions (factory default)

or

- ◆ Basic prompting and timed CPR sessions

or

- ◆ Advanced prompting and compressions-only CPR sessions

Rescue Coach prompts vary for all CPR styles depending on the prompting level chosen.

AED device history and rescue data recording

The AED can store up to 90 minutes of data in its internal memory.

When downloading data, you can select what data to download. See the *AED Manager User's Guide* for more information.

AED Manager software

With AED Manager software you can:

- ◆ Review rescue data and information
- ◆ See the current status of the AED and the status of the AED at the time of a rescue
- ◆ Archive all data for later review
- ◆ Review AED maintenance and diagnostic messages
- ◆ Configure settings and rescue protocol

5 Troubleshooting

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This section presents information about AED diagnostics self-tests, troubleshooting of indicator lights, and descriptions of maintenance and diagnostic messages.

Self-tests

The AED has a comprehensive self-test system that automatically assesses the electronics, battery state, defibrillation pads, and high voltage circuitry.

The AED runs automatic self-tests at regular time intervals:

- ◆ 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 circuitry in addition to the items tested in the daily self test.
- ◆ The monthly self test charges the high voltage electronics to full energy in addition to the items tested in the weekly self-test.

Note: If the AED lid is opened during one of these periodic self-tests, testing stops.

A subset of the self-tests is also run each time the lid of the AED is closed.

When performing a self-test, the AED:

1. Turns the Rescue Ready indicator red.
2. Automatically performs the appropriate self test.
3. Shows the Rescue Ready status.
 - If the test is successful, the Rescue Ready status is green.
 - If the AED detects an error, the Rescue Ready indicator remains red. A beep sounds every 30 seconds.

Note: When the lid of the AED is opened, one or more indicators on the AED display panel may remain lit and service messages may appear on the display. To troubleshoot these conditions, see the sections in this chapter.

Troubleshooting of indicators

Use this table to troubleshoot the AED if an indicator is lit.

Important: Do not delay calling emergency medical services and delivering CPR even if the AED cannot assist with the rescue.

Indicator	Symptom	Resolution
	Rescue Ready status indicator is red and the service indicator is NOT lit.	<p>Close and reopen the lid of the AED. The Rescue Ready indicator may return to green.</p> <p>Enter Diagnostic mode for more information (see <i>Diagnostic mode messages</i> on page 5-4).</p>
	Both the Rescue Ready status indicator and the service indicator are red.	<p>The AED requires service by authorized service personnel.</p> <p>Enter Diagnostic mode for more information (see <i>Diagnostic mode messages</i> on page 5-4). Contact Cardiac Science Technical Support or your local representative.</p>
	Pads indicator is lit.	<p>Ensure that the pads are connected securely to the AED.</p> <p>During a rescue, ensure that the pads connector is securely connected to the AED and the pads are placed properly on the patient's chest.</p>
	The battery indicator is red. Additionally, when the lid is closed, a beep sounds intermittently.	<p>The battery capacity is low. Replace the battery.</p> <p>If the beep continues to sound after the battery is replaced, contact Cardiac Science Technical Support or your local representative.</p>

Maintenance and service messages

These messages may appear during a periodic self-test or during a rescue at any prompt level.

Use the following table to resolve messages that the AED might display.

Voice prompt	Text display		Resolution
	Line 1	Line 2	
Battery Low	BATTERY LOW	The battery charge is low, although a rescue can continue for approximately 9 more shocks.	Replace the battery before the next rescue.
	REPLACE BATTERY NOW	Occurs when the lid is opened to perform a rescue and the battery charge is low. The battery charge is too low to support a rescue. Additionally, the following occur: <ul style="list-style-type: none">• The Rescue Ready indicator turns red• The AED beeps once every 30 seconds	Replace the battery before continuing with the rescue. If the battery charge is completely depleted, all AED activity ends.
Open lid to continue rescue	OPEN LID TO CONTINUE RESCUE	The lid is closed during a rescue. The prompt repeats for 15 seconds.	Ensure that the AED lid is fully open.
Make sure pad connector is plugged into AED	CHECK CONNECTOR IS PLUGGED INTO AED	The defibrillation pads have become disconnected from the AED.	Ensure that the pads are securely plugged in to the AED. Resume the rescue.
Service Required. Contact Technical Support	SERVICE REQUIRED CONTACT TECH SUPPORT	The AED detects a condition that can prevent the AED from continuing a rescue. For example, this condition may occur after a self-test determines that the AED is not functioning properly. This prompt plays when the lid is opened. The red Service indicator illuminates. The prompt repeats until you close the lid. After the lid is closed, an alarm beep sounds until the battery is removed or is depleted.	Contact Cardiac Science Technical Support or your local representative immediately.
Maintenance required, Continue Rescue	MAINTENANCE REQUIRED CONTINUE RESCUE	During a rescue, the AED detects a condition with the defibrillation pads, the internal electronics, or another part of the device. However, the condition has no immediate effect on the ability to continue with a rescue.	Enter Diagnostic mode for more information. If you cannot resolve the issue, contact Cardiac Science Technical Support or your local representative.

Diagnostic mode messages

Diagnostic mode provides detail on the maintenance and service conditions of the AED. For example, if the AED is not Rescue Ready, diagnostic mode displays additional information about the status.

To enter Diagnostic mode:

- ◆ Press and hold both buttons on the AED display panel for three seconds.



The following prompts appear when the AED is in Diagnostic mode. Use the table to resolve the reported conditions.

Voice prompt	Text display Line 1 Line 2	Situation	Resolution
Diagnostic Mode	DIAGNOSTIC MODE	The AED enters Diagnostic mode.	Not applicable
	SERVICE REQUIRED CONTACT TECH SUPPORT	The AED detects a condition that can prevent the AED from continuing a rescue.	Contact Cardiac Science Technical Support or your local representative immediately.
	EXTREMELY LOW BATTERY REPLACE BATTERY	The battery charge is too low to support a rescue.	Replace the battery immediately. If the battery charge is completely depleted, all AED activity ends.
	MAINTENANCE REQUIRED CONTACT TECH SUPPORT	The AED detects a condition that has no negative effect on the ability to perform a rescue. The AED can be used to perform a rescue.	Contact Cardiac Science Technical Support or your local representative.
	TEMP TOO HOT ADJUST STORAGE TEMP	The AED is hotter than its allowable storage temperature. While this condition should be remedied as soon as possible, the AED may be used to perform a rescue.	Move the AED to a cooler location.
	TEMP TOO COLD ADJUST STORAGE TEMP	The AED is cooler than its allowable storage temperature. While this condition should be remedied as soon as possible, the AED may be used to perform a rescue.	Move the AED to a warmer location.
	BATTERY LOW CHECK BATTERY	The battery charge is low, although a rescue can continue for approximately 9 more shocks. While this condition should be remedied as soon as possible, the AED can be used to perform a rescue.	Replace the battery before the next rescue.
	PADS EXPIRED REPLACE PADS	The AED detects that the connected defibrillation pads are older than their "use by" date. CAUTION: Use of pads that are damaged or expired may result in improper AED performance.	Replace the defibrillation pads.
	PADS USED REPLACE PADS	The AED detects that the connected defibrillation pads have been used in a rescue. WARNING! Used pads may not adhere properly to the patient. Improper pad adhesion may result in skin burns. Improper pad adhesion may result in improper AED performance. Used pads may cause patient-to-patient contamination.	Replace the defibrillation pads.
	CHECK PADS	The AED detects an issue with the defibrillation pads.	Ensure the connector is securely plugged into the AED. Replace the pads if necessary.
	NEXT	The AED detects more than one error.	Press the lighted button to view the next error.
	CLEAR	The AED displays a TEMP TOO HOT or TEMP TOO COLD error.	Press the lighted button to remove the error message from the AED.

6 Product Care

Contents

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This section presents information about AED product care and cleaning.

Cardiac Science Corporation provides customer service and technical support.

- ◆ To order additional product or accessories, contact Customer Care.
- ◆ For assistance with product installation or operation, contact Technical Support. Cardiac Science provides 24-hour support by telephone. You can also contact Technical Support through fax or email.

Customer Care

(800) 426 0337 (USA)
(262) 953-3500 (USA and Canada)
care@cardiacscience.com

Technical Support

(800) 426 0337 (USA)
(262) 953-3500 (USA and Canada)
Fax: (262) 798-5236 (USA and Canada)
techsupport@cardiacscience.com
www.cardiacscience.com

Outside the United States and Canada, contact your local representative.

Periodic maintenance

Periodically, perform the following tests.*

Check the color of the Rescue Ready® indicator.

If the color is... Do this...

Green	No action needed. The AED is ready for a rescue.
Red	Refer to <i>Troubleshooting of indicators</i> on page 5-2.

Check that the battery has adequate charge to perform a rescue:

1. Open the AED lid.
2. If the battery indicator is red, replace the battery.
3. Close the lid.

Check that the voice prompts work and the display is readable:

1. Open the AED lid.
2. Listen for the voice prompts.
3. Additionally, the display shows text prompts that correspond to the audio.
4. Close the lid. The voice prompts should stop.
5. Verify that the Rescue Ready indicator returns to green.

If no prompts are heard or they continue after the lid is closed, the display is not readable, or the Rescue Ready indicator remains red, there may be an issue with the AED. Contact Cardiac Science Technical Support, or outside the U.S., your local representative.

Check that the defibrillation pads are ready for use and that the service beep sounds:

1. Open the AED lid.
2. Disconnect the pads connector and remove the pads package.
3. Close the lid.

4. Confirm that the Rescue Ready indicator turns red and the AED beeps at a regular interval. If no sound is heard, contact Cardiac Science Technical Support, or outside the U.S., your local representative.
5. Check the expiration date of the pads; if expired, replace the package.
6. Check that the pads packaging is not ripped or punctured. Replace the package as needed.
7. Open the lid and confirm that the defibrillation pads indicator is lit.
8. Reconnect the pads connector, put the pads back in the pads holder, and close the lid.
9. Make sure the expiration date is visible through the window of the lid.
10. Make sure that the Rescue Ready indicator is green. If the indicator is red, make sure that the pads are installed properly. If the indicator remains red, contact Cardiac Science Technical Support, or outside the U.S., your local representative.
11. Close the lid

 **Check that the LEDs work:**

1. Open the AED lid.
2. Confirm that the device briefly illuminates all indicator LEDs:
 - ✓ 0%, 25%, 50%, 75%, 100% battery LEDs
 - ✓ Pads status LED
 - ✓ Service required LED
 - ✓ Shock button LED
 - ✓ Left function button LED
 - ✓ Right function button LED
3. Close the lid.

 **Check that the buttons work:**

1. Open the AED lid.
2. Within 15 seconds of opening the lid, press the soft buttons and Shock button in turn. The buttons should illuminate. If one does not, contact Cardiac Science Technical Support, or outside the U.S., your local representative.
3. Close the lid.

 **Check the AED case for signs of stress:**

If you find cracks or other signs of stress, contact Cardiac Science Technical Support, or outside the U.S., your local representative.

* At least once each month.

Cleaning and care

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

Approved cleaning solutions

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

The AED and its accessories cannot be sterilized.

Authorized service

The AED has no user-serviceable internal components. The user is responsible for changing batteries and defibrillation pads only.

Try to resolve any maintenance issues with the AED by using the information in Chapter 5, *Troubleshooting*. If you are unable to resolve the problem, contact Cardiac Science Technical Support, or outside the U.S., your local representative.

Return the AED for service if the AED experiences a fall that could cause internal damage.

Note: Unauthorized disassembly, modification, or service of the AED voids the warranty.

A RescueCoach™ Voice and Text Prompts

Contents

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This section describes the prompts the AED provides for rescues and maintenance.

RescueCoach™ voice prompts activate when the AED lid is opened and help guide the rescuer through a rescue. The AED information display provides equivalent text to the voice prompts.

These tables list the voice and text prompts, descriptions of when the prompts are used, and with what prompt level they are used: advanced (Adv), standard (Std), or basic (Bas).

For maintenance and service messages, see *Maintenance and service messages* on page 5-3.

For diagnostic messages, see *Diagnostic mode* messages on page 5-4.

Table A-1: Start up

Voice prompt	Text display		Prompt level			
	Line 1	Line 2	Situation	Adv	Std	Bas
Stay calm. Follow these instructions.	STAY CALM	FOLLOW INSTRUCTIONS	Plays when the lid is opened.		X	
Make sure 911 is called now.	CALL 911	NOW	Plays when the lid is opened.	X	X	
Make sure emergency services are called now.*	CALL EMERGENCY	SERVICES NOW	Plays when the lid is opened.	X	X	

*Alternative start up prompt

Table A-2: Pads placement

Voice prompt	Text display Line 1 Line 2	Situation	Prompt level		
			Adv	Std	Bas
Begin by exposing patient's bare chest.	BARE PATIENT'S CHEST REMOVE ALL CLOTHING	Prompts the rescuer to remove patient clothing.	X	X	
Remove or cut clothing if needed.	BARE PATIENT'S CHEST REMOVE ALL CLOTHING	Prompts the rescuer to remove patient clothing.	X		
When patient's chest is bare, remove the white, square package from lid of AED.	WHEN CHEST IS BARE REMOVE PACKAGE	Prompts the rescuer to remove the pads package from the AED lid.	X		
Remove white square package from lid of AED.	REMOVE WHITE SQUARE PACKAGE	Second prompt to remove pads package from the AED lid.	X	X	
Tear open white package across dotted line and remove pads.	TEAR OPEN PACKAGE REMOVE PADS	Prompts the rescuer to open the pad package and remove pads.	X	X	
Peel one of the white pads completely from blue plastic.	PEEL ONE WHITE PAD FROM BLUE PLASTIC	Prompts rescuer to remove either pad from the blue plastic. 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.	X	X	X
Begin pulling from the tabbed corner.	PULL FROM TABBED CORNER	Prompts rescuer to remove either pad from the blue plastic. 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.	X		
Firmly place the pad without the blue plastic on patient's bare chest exactly as shown on pads.	PRESS PAD FIRMLY TO CHEST AS SHOWN	Prompts the rescuer to place one pad on the patient.	X	X	
Firmly place the pad on the patient.	PRESS PAD FIRMLY TO CHEST	Prompts the rescuer to place one pad on the patient.			X
This pad can be placed on either of the two locations as shown on pads.	PLACE PAD ON EITHER LOCATION	Prompts the rescuer to place one pad on the patient.	X		
Next, peel second white pad from the blue plastic.	PEEL SECOND PAD FROM BLUE PLASTIC	Prompts the rescuer to remove second pad from the blue plastic.	X	X	X
Firmly place the second pad on the other location exactly as shown on pads.	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.	X	X	
Firmly place the second pad on the other location.	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.			X

Table A-3: Pads prompts

Voice prompt	Text display Line 1 Line 2	Situation	Prompt level		
			Adv	Std	Bas
Pediatric Pads Connected	PEDIATRIC PADS	Notifies rescuer that the pediatric pads are connected to the AED.	X	X	X
Make sure pad connector is plugged into AED	CHECK CONNECTOR IS PLUGGED INTO AED	Prompts when defibrillation pads connector is not inserted into the pad socket.	X	X	X
Press pads firmly to patient's bare chest	PRESS PADS FIRMLY TO CHEST	Prompts when better pad contact to the patient's skin is required.	X	X	X

Table A-4: Analysis

Voice prompt	Text display Line 1 Line 2	Situation	Prompt level		
			Adv	Std	Bas
Do not touch the 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 if the AED is ready to shock.	X	X	
Do not touch the 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 if the AED is ready to shock.			X
Shock advised. Do not touch the patient.	SHOCK ADVISED DO NOT TOUCH PATIENT	Notifies the rescuer that a shockable rhythm has been detected and is preparing to deliver a defibrillation shock (charging).	X	X	X
Shock not advised	SHOCK NOT ADVISED	Notifies the rescuer when the AED detects a non-shockable rhythm.	X	X	X
Analysis interrupted. Stop patient motion.	ANALYSIS INTERRUPTED STOP PATIENT MOTION	If the AED detects ECG noise artifacts, stop moving or touching the patient. Remove other electronic devices from the vicinity.	X	X	X

Table A-5: Delivering therapy - G5 semi-automatic

Voice prompt	Text display Line 1 Line 2	Situation	Prompt level		
			Adv	Std	Bas
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 button flashes and the phrase repeats for 30 seconds or until the SHOCK button is pressed.	X	X	X
Shock delivered.	SHOCK DELIVERED	Prompts when the shock is delivered.	X	X	X
Rhythm Changed. Shock Cancelled.	RHYTHM CHANGED SHOCK CANCELLED	Notifies the rescuer when the AED detects a rhythm change and cancels the shock.	X	X	X

Table A-5: Delivering therapy - G5 semi-automatic (continued)

Voice prompt	Text display Line 1 Line 2	Situation	Prompt level		
			Adv	Std	Bas
Shock not delivered.	SHOCK NOT DELIVERED	Plays for either of these situations: <ul style="list-style-type: none"> The SHOCK button is not pressed within 30 seconds of the AED giving the "Press red flashing button..." prompt. The AED is unable to deliver a shock because of a fault condition. 	X	X	X
It is now safe to touch the patient.	NOW SAFE TO TOUCH PATIENT	Advises the rescuer that it is safe to touch the patient: <ul style="list-style-type: none"> After the AED delivers a shock After the AED detects a nonshockable rhythm 	X	X	

Table A-6: Delivering therapy - G5 automatic

Voice prompt	Text display Line 1 Line 2	Situation	Prompt level		
			Adv	Std	Bas
Shock will be delivered in	SHOCK IN:	Notifies the rescuer after the AED is fully charged and ready to deliver the shock.	X	X	X
Three	THREE	Prompts approximately three seconds prior to delivering shock.	X	X	X
Two	TWO	Prompts approximately two seconds prior to delivering shock.	X	X	X
One	ONE	Prompts approximately one second prior to delivering shock.	X	X	X
Shock delivered.	SHOCK DELIVERED	Prompts when the shock is delivered.	X	X	X
Shock not delivered.	SHOCK NOT DELIVERED	Plays if the AED is unable to deliver a shock because of a fault condition.	X	X	X
It is now safe to touch the patient.	NOW SAFE TO TOUCH PATIENT	Advises the rescuer that it is safe to touch the patient: <ul style="list-style-type: none"> After the AED delivers a shock After the AED detects a nonshockable rhythm 	X	X	

Table A-7: CPR

Voice prompt	Text display		Prompt level			
	Line 1	Line 2	Situation	Adv	Std	Bas
If needed, perform compressions as instructed.	IF NEEDED	GIVE COMPRESSIONS	If the AED detects a nonshockable rhythm, prompts rescuer to prepare to provide compressions-only CPR.	X	X	
Give compressions as instructed	GIVE COMPRESSIONS		Prompts rescuer to prepare to provide compressions-only CPR.	X	X	
If needed, perform CPR as instructed.	IF NEEDED	PERFORM CPR	Prompts rescuer to prepare to provide compressions and breaths CPR.	X	X	
Give CPR as instructed.	GIVE COMPRESSIONS AND BREATHS		Prompts rescuer to prepare to provide compressions and breaths CPR.	X	X	
Place heel of one hand on center of chest between nipples.	PLACE ONE HAND ON CENTER OF CHEST		Prompts rescuer to put one hand in the correct place for giving compressions.	X	X	
Place heel of other hand directly on top of first hand. Lean over patient with elbows straight.	PLACE OTHER HAND ELBOWS STRAIGHT		Prompts rescuer to position the other hand for giving compressions.	X	X	
Press the patient's chest down rapidly one third the depth of chest, then release.	PRESS CHEST DOWN FIRMLY		Prompts the rescuer to press down one-third the depth of the patient's chest.	X		
Give patient 30 rapid compressions and 2 breaths	30 COMPRESSIONS 2 BREATHS		Prompts rescuer to give compressions and breaths.	X	X	
Start CPR	START CPR		Prompts the rescuer to start CPR.	X	X	X
Start Compressions	START COMPRESSIONS		Prompts the rescuer to start compressions-only CPR.	X	X	X
"Press" (or) Metronome (or) No prompt (silence)	{CPR countdown timer}		The CPR countdown timer on the display shows the amount of time remaining for a CPR session. The voice prompt or metronome paces the speed of compressions given by the rescuer.	X	X	
Stop Compressions.	STOP COMPRESSIONS		Prompts at the end of each CPR set.	X	X	X
Give breath.	GIVE BREATH		Prompts the rescuer to give breath to the patient.	X	X	X
Continue with Compressions.	CONTINUE WITH COMPRESSIONS		Prompts in subsequent sets of the same CPR session.	X	X	X
Stop CPR.	STOP CPR		Prompts the rescuer to stop CPR.	X	X	X
Continue with CPR.	CONTINUE CPR		Prompts the rescuer to continue CPR.	X	X	X

Table A-8: CPR feedback device (optional)

Voice prompt	Text display		Prompt level			
	Line 1	Line 2	Situation	Adv	Std	Bas
Remove green square package from lid of AED.	REMOVE GREEN SQUARE PACKAGE FROM AED LID		Prompts at the beginning of a CPR session. The green package contains the CPR device.	X	X	
Tear open green package and remove CPR device.	TEAR OPEN PACKAGE REMOVE CPR DEVICE		Prompts to remove the CPR device.	X	X	
Place CPR device on center of patient's chest, between nipples	PLACE DEVICE ON CENTER OF CHEST		Prompts rescuer to put the CPR device in the correct place for giving compressions.	X	X	
Place heel of one hand on CPR device.	PLACE ONE HAND ON CPR DEVICE		Prompts rescuer to place one hand on the CPR device.	X	X	
Press Slower	PRESS SLOWER		If the rescuer is giving compressions too fast, prompts to slow the rate.	X	X	X
Press Faster	PRESS FASTER		If the rescuer is giving compressions too slowly, prompts to quicken the rate.	X	X	X
Press Softer	PRESS SOFTER		If the rescuer is giving compressions that are too deep, prompts to lessen the depth.	X	X	X
Press Harder and fully release	PRESS HARDER FULLY RELEASE		If the rescuer is giving compressions that are too shallow, prompts to use more effort and release all pressure when moving hands up.	X	X	X

Table A-9: Data transfer

Voice prompt	Text display Line 1 Line 2	Situation	Prompt level		
			Adv	Std	Bas
Communications mode	COMMUNICATIONS MODE	Played when AED enters Communications mode.	X	X	X
	DO NOT DISCONNECT USB	Prompts when data is transferred between the AED and the flash drive. Disconnecting the flash drive can corrupt the data being transferred.	X	X	X
	SAFE TO REMOVE USB	Prompts after the data transfer completes. Remove the flash drive.	X	X	X
	UPDATING LANGUAGE	Updating the text and audio prompts as part of a software upgrade using the flash drive.	X	X	X
	VERIFYING LANGUAGE	The AED is verifying that the text and audio prompts in the flash drive are valid or that they are installed properly.	X	X	X
	UPDATING SOFTWARE	Updating the operating software.	X	X	X
	VERIFYING SOFTWARE	The AED is verifying that the operating software is installed properly.	X	X	X
	PROMPT/TEXT UPDATE FAILED	After a language update, the AED determines that the update was not installed properly. Contact Technical Support or your local representative for help.	X	X	X
	SOFTWARE UPDATE FAILED	After a software update, the AED determines that the update was not installed properly. Contact Technical Support or your local representative for help.	X	X	X
	UPGRADE ERROR	There is a problem with the software upgrade. Contact Technical Support or your local representative for help.	X	X	X
	CLOSE THE LID	After a data transfer is complete and the flash drive is removed from the AED, re-connect the pads and close the lid of the AED.	X	X	X
	USB DATA ERROR	A problem occurred with the data transfer. Check the connection with the flash drive and retry the transfer.	X	X	X
	DOWNLOADING DATA	The data transfer to the flash drive is in progress.	X	X	X
	SOFTWARE ERROR	There is a problem with the data transfer to the flash drive. Contact Technical Support or your local representative for help.	X	X	X
	REMOVE USB CLOSE THE LID	The data transfer is complete. It is safe to remove the flash drive, reconnect the defibrillation pads, and close the lid of the AED.	X	X	X
	RESETTING DEVICE	After a software upgrade, the AED restarts itself.	X	X	X
	CONTROL CODE UPDATE	Updating the control software.	X	X	X

Table A-10: Language selection

Voice prompt	Text display Line 1 Line 2	Situation	Prompt level		
			Adv	Std	Bas
	ENGLISH	On multi-lingual AED models only: appears above a button on the display panel. Press the button to switch the prompting language (both audio and text) to this language.	X	X	X
	SPANISH	On multi-lingual AED models only: appears above a button on the display panel. Press the button to switch the prompting language (both audio and text) to this language.	X	X	X

B Technical Data

Contents

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◆ Defibrillation pads	B-3
◆ Intellisense® battery (model XBTaed001)	B-3

This section lists the physical, operating, standby, and storage parameters of the AED, and the physical parameters of the defibrillation pads and AED battery.

Powerheart G5 parameters

Table 1: Physical parameters

Parameter	Detail
Operation	<ul style="list-style-type: none">AutomaticSemi-automaticMulti-language (in specified combinations only)
Dimensions	<ul style="list-style-type: none">Height: 9 cm (3.4 in)Width: 23 cm (9.0 in)Depth: 30 cm (11.8 in)
Weight (with battery and pads)	2.6 kg (5.7 lb)

Table 2: Environmental information

Parameter	Detail
Operating*	<ul style="list-style-type: none">Temperature: 0°C to 50°C (32°F to 122°F)Humidity: 10% to 95% (non-condensing)
Standby**	<ul style="list-style-type: none">Short-term (5 days) temperature: 0°C to 50°C (32°F to 122°F)Long-term temperature****: 20°C to 30°C (68°F to 86°F)Humidity: 10% to 95% (non-condensing)
Storage and transport (up to 3 days)***	<ul style="list-style-type: none">Temperature: -30°C to 65°C (-22°F to 149°F)Humidity: 10% to 95% (non-condensing)
Altitude	<ul style="list-style-type: none">CSA evaluated: -382 m to 3000 mMinimum: -382 m (approximate; calculated from pressure)Maximum: 4594 m (approximate; calculated from pressure)

Table 2: Environmental information (continued)

Parameter	Detail
Pressure	<ul style="list-style-type: none">CSA evaluated: 700 hPa to 1060 hPaMinimum: 570 hPaMaximum: 1060 hPa

* Operating: AED with pads and battery installed and lid open.

** Standby: AED with pads and battery installed and lid closed.

*** Storage and transport: AED with pads optionally connected and battery not installed.

****The defibrillator and its accessories have been tested for long-term standby for 24 months in the temperature range from 20 to 30 °C only. For operation, namely, when the defibrillator lid is open, the operating temperature range is from 0 to 50 °C. Hence, after each rescue attempt, please close the lid, thus bringing the defibrillator back to the standby state, with the associated standby requirement of 20 to 30 °C only. The defibrillator has not been qualified for long term standby in an environment between 30 to 50 °C.

The AED can be stored in long-term standby at temperatures between 0 to 50 °C. However, continuous storage at temperature extremes may reduce the life of the electrodes and / or battery. Rescue Ready technology assesses the AED battery and pads to ensure they are ready to perform a rescue. When the Rescue Ready status is green, the AED is ready for a rescue. Audible and visual indicators will notify when the device requires attention. Deployments in the conditions described above are covered under the Cardiac Science AED warranty, battery performance replacement guarantee, electrode warranty through expiration date and Cardiac Science indemnification agreement. Refer to Section F for complete warranty information.

Technical Data

Table 3: Functionality

Parameter	Detail
RHYTHMx® ECG analysis performance	<p>The AED RHYTHMx ECG Analysis system analyzes the patient's ECG and advises you when the AED detects a shockable or non-shockable rhythm.</p> <p>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.</p>
Waveform	STAR® Biphasic
Impedance	25 Ω to 175 Ω
Energy (preinstalled pads, model number XELAED001)	Escalating energy from 95 J to 354 J
Energy (pediatric pads, model number XELAED003)	Escalating energy from 22 J to 82 J
Shock times	<ul style="list-style-type: none"> Initiation of rhythm analysis to ready to shock: 15 seconds (typical); 45 seconds (maximum) With a fully charged battery Initiation of rhythm analysis to ready to shock, used battery: 15 seconds typical); 45 seconds (maximum) with a battery that has been used for 15 shocks Lid-open to ready to shock: 15 seconds (typical) With a battery that has been used for 15 shocks Post CPR to ready to shock: 10 seconds (typical) With these conditions: "Post CPR" begins after the "Stop CPR" prompt is given; English is the selected language; semi-automatic AED detects persistent VF; new, unused battery is attached to the AED.
Automated self-tests	<ul style="list-style-type: none"> Daily: Battery, pads, internal electronics, buttons. Weekly (every 7 days): Battery, pads, CPR feedback device accelerometer, internal electronics, buttons, high voltage circuit (standard tests, partial energy charge cycle). Monthly (every 28 days): Battery under load, pads, CPR feedback device accelerometer, internal electronics, buttons, high voltage circuit (advanced tests, full energy charge cycle).
Audible alerts	<ul style="list-style-type: none"> Voice prompts Maintenance alerts
Indicators	<ul style="list-style-type: none"> Battery status Check pads Rescue Ready Service Text display
USB port communication	Event download, device data, configuration, and maintenance

Table 3: Functionality (Continued)

Parameter	Detail
Internal data storage	90 minutes
Table 4: Applicable standards	
Type	Detail
General	<ul style="list-style-type: none"> CE Marked by BSI 0086 per the Medical Device Directive 93/42/EEC. Classified by CSA 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 and 60601-2-4.
Safety and performance	<ul style="list-style-type: none"> IEC 60601-1 IEC 60601-1-2 IEC 60601-2-4 RTCA DO-160G:2010: Section 5 Category C; Section 4, Category A4 EN 1789
Emissions	EM: EN 55011+A1/CISPR 11, Group 1, Class B
Immunity	<ul style="list-style-type: none"> EM IEC 61000-4-3, Level X, (20V/m) IEC 60601-2-4 (20V/m) Magnetic IEC 61000-4-8 IEC 61000-4-8 ESD IEC 61000-4-2 IEC 60601-2-4 6 KV contact discharge, 8 KV air gap discharge
Free fall drop	MIL-STD-810G, Method 516.5, Procedure IV
Shock	MIL-STD-810G 516.5, Procedure 1
Vibration (Random)	MIL-STD-810G, Method 514.5, Procedure 1, Category 24; RTCA DO-160G, Section 8, Category 5, Zone 2 (curve B) and Category U, Zone 2 (curves F and F1)
Vibration (Sine)	MIL-STD-810G, Method 514.5, Procedure 1, Category 24, Helicopter Minimum Integrity
Enclosure protection	IEC 60529, IP55

Table 4: Applicable standards (continued)

Type	Detail
Shipping and transportation	ISTA Procedure 2A
Sensitivity and specificity of Rhythm Detection	<ul style="list-style-type: none"> Shockable Rhythm—VF: Meets IEC 60601-2-4 requirement and AHA recommendation of Sensitivity of >90% 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—all other rhythms: Meets IEC 60601-2-4 requirement and AHA recommendation of Specificity – all other rhythms of >95%

Defibrillation pads

Table 5: Preinstalled defibrillation pads (model XELAED001)

Parameter	Detail
Type	Pre-gelled, self-adhesive, disposable, non-polarized (identical pads, which can be placed in either position) defibrillation pads
Applicable age and weight of patient	Older than 8 years or heavier than 25 kg (55 lb)
Shelf life	24 months
Disposal	Check local regulations for disposal information

Table 6: Preinstalled defibrillation pads with CPR feedback device (model XELAED002)

Parameter	Detail
Type	Pre-gelled, self-adhesive, disposable, non-polarized (identical pads, which can be placed in either position) defibrillation pads with CPR feedback device
Applicable age and weight of patient	Older than 8 years or heavier than 25 kg (55 lb)
Shelf life	24 months
Disposal	Check local regulations for disposal information

Table 7: Pediatric defibrillation pads (model XELAED003)

Parameter	Detail
Type	Pre-gelled, self-adhesive, disposable, non-polarized (identical pads, which can be placed in either position) defibrillation pads
Applicable age and weight of patient	Eight years or younger or 25 kg (55 lb) or lighter
Shelf life	24 months
Disposal	Check local regulations for disposal information.

Intellisense® battery (model XBTaed001)

Table 8: Intellisense battery

Parameter	Detail
Type	Intellisense lithium battery, non-rechargeable
Output voltage	12 VDC (nominal)
Lithium content	9.2 g (approximate)
Disposal	Check local regulations for disposal information
Estimated shelf life*	<ul style="list-style-type: none"> 5 years from date of manufacture Temperature ranges: <ul style="list-style-type: none"> Short term (3 days at either temperature extreme): -30°C to 65°C Long term (5 years at either temperature extreme): 20°C to 30°C
Estimated operating life** (new and fully charged battery)	<ul style="list-style-type: none"> Shocks: 420 (typical), 250 (minimum), or 16 hours of operating time at 20-30°C, or Standby: 4 years

* Shelf life is the length of time a battery can be stored prior to installation into an AED without significantly affecting its operating life.

** The battery operating life depends on the type of battery, device settings, actual usage, and environmental factors. The number of shocks is estimated at a 300 VE energy level with a "three shock stack" followed by 60 seconds of CPR using Basic prompt settings between each set of shocks.

C ECG Analysis Algorithm and Rescue Waveform

Contents

◆ RHYTHMx® AED ECG analysis algorithm	C-1
◆ Rescue protocol	C-1
◆ STAR® biphasic waveform	C-1
◆ Potential adverse effects of the device on health	C-3
◆ Summary of clinical studies	C-3

This section describes the ECG analysis algorithm and Star Biphasic waveform.

RHYTHMx® AED ECG analysis algorithm

The RHYTHMx AED ECG analysis algorithm provides extensive ECG detection capabilities.

- ◆ All ventricular fibrillation (VF) are classified as shockable.
- ◆ Asystole is separated primarily by amplitude. ECG rhythms of low amplitude are classified as asystole and are not shockable.
- ◆ The AED detects noise artifacts in the ECG form, generated from, for example, movement of the patient, adjustment of the defibrillation pads, or electronic noise from external sources. The analysis is delayed or aborted in these cases.
- ◆ The AED can detect or reject pulses from an implanted pacemaker.

In addition, RHYTHMx optionally shocks selected VT and SVT rhythms. Settings for several detection features can be adjusted through AED Manager software:

- ◆ Detection rate—All ventricular tachycardia (VT) rhythms at or above this rate are classified as shockable. All rhythms below this rate are classified as non-shockable.
- ◆ Non-committed shock—if the patient's rhythm changes to a non-shockable rhythm before the actual shock is delivered, the AED cancels the shock.
- ◆ Synchronized shock—The AED automatically attempts to synchronize shock delivery on the R-wave if one is present. If delivery cannot be synchronized within one second, a nonsynchronized shock is delivered.
- ◆ SVT discriminator—The AED is configurable to shock SVT waveforms that are above a threshold rate that can be pre-set, or can be disabled (default setting).

Rescue protocol

The AED rescue protocol is consistent with the guidelines recommended by the AHA/ERC 2010 Guidelines for Resuscitation and Emergency Cardiac Care.

Note: For consistency with AHA/ERC guidelines, the CPR time can be set to allow for 5 cycles of 30 compressions and 2 breaths.

Use AED Manager to change the protocol. For details, see the *AED Manager User's Guide*.

STAR® biphasic waveform

The waveform generated by the Cardiac Science AED is a biphasic truncated exponential waveform. The waveform complies with the IEC 60601-2-4 standard. Figure 1 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 (model number XELAED001).

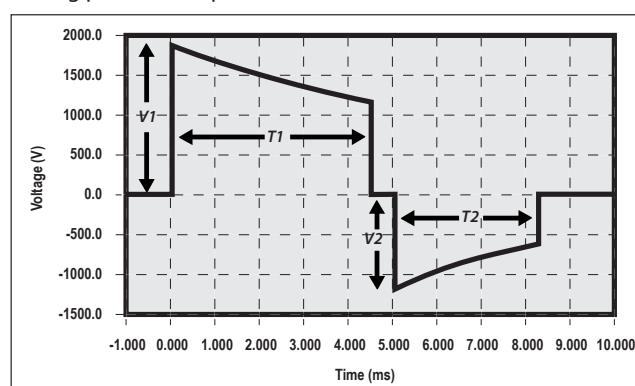


Figure 1: High variable energy waveform with 50 ohm resistive load

Patient impedance

The Cardiac Science Biphasic Truncated Exponential (BTE) waveform uses variable energy. The actual energy delivered varies with the patient's impedance. The device delivers a shock to a patient with an impedance in the range of 25 - 175 ohms. Energy is delivered at up to three different levels: ultra-low variable energy, low variable energy, and high variable energy (see the waveform and energy tables on the following pages).

Waveform and energy levels for preinstalled defibrillation pads (Model number XELAED001)

Table C-1: Ultra-low variable energy 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	1412	30	743	3.25	3.2	171
50	29	1426	18	907	4.5	3.2	150
75	19	1431	13	968	5.75	3.2	136
100	14	1433	10	1000	7	3.2	126
125	11	1435	8	1019	8.25	3.2	119
150	10	1436	7	1031	9.5	3.2	114
175	8	1437	6	1038	10.75	3.2	110

Waveform and energy levels for pediatric defibrillation pads (Model number XELAED002)

Table C-4: Ultra-low variable energy 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	27	682	14	359	3.25	3.2	41
50	14	689	9	438	4.5	3.2	35
75	9	691	6	468	5.75	3.2	32
100	7	692	5	483	7	3.2	29
125	6	693	4	493	8.25	3.2	28
150	5	694	3	498	9.5	3.2	27
175	4	694	5	802	10.75	3.2	26

Table C-2: Low variable energy waveform

Patient's 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	65	1631	34	858	3.25	3.2	229
50	33	1647	21	1047	4.5	3.2	200
75	22	1653	15	1118	5.75	3.2	181
100	17	1655	12	1155	7	3.2	168
125	13	1657	9	1176	8.25	3.2	159
150	11	1658	8	1190	9.5	3.2	152
175	9	1659	7	1199	10.75	3.2	147

Table C-5: Low variable energy waveform

Patient's 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	32	791	17	416	5.8	3.2	54
50	16	798	10	508	6.5	3.2	47
75	11	801	7	542	7	3.2	44
100	8	802	6	560	7.4	3.2	41
125	6	803	5	570	7.8	3.2	37
150	5	804	4	577	9.5	3.2	36
175	5	804	3	581	10.75	3.2	35

Table C-3: High variable energy waveform

Patient's 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)
50	38	1914	24	1216	4.5	3.2	270
75	26	1920	17	1299	5.75	3.2	245
100	19	1923	13	1342	7	3.2	227
125	15	1925	11	1367	8.25	3.2	215
150	13	1926	9	1383	9.5	3.2	205
175	11	1927	8	1393	10.75	3.2	198

Table C-6: High variable energy waveform

Patient's 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	36.6	915	19	481	5.8	3.2	72
50	18	924	12	588	6.5	3.2	63
75	12	927	8	628	7	3.2	57
100	9	929	6	648	7.4	3.2	53
125	7	930	5	660	7.8	3.2	50
150	6	931	5	688	9.5	3.2	48
175	5	931	4	673	10.75	3.2	46

* 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 postshock dysfunction;
- ◆ Myocardial damage;
- ◆ Failure to deliver a defibrillation shock in the presence of VF or pulseless VT, which may result in death or permanent injury;
- ◆ 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 9: Clinical Data – All Patients Attached to Powerheart AED

# of Patients	Hours Attached	True Positives	False Positives	True Negatives	False 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 10.

Table 10: 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 ± 17 J and 295 ± 28 J, respectively. The monophasic waveform demonstrated a 96.7% (95% CI 89.1% to 100%) first-shock success rate and average delivered energy of 215 ± 12 J for Group 1, and a 98.2% (95% CI 91.7% to 100%) first-shock success rate and average delivered energy of 352 ± 13 J for Group 2. Table 11 shows the defibrillation results.

Table 11: Defibrillation Results

Variable	Group 1		Group 2		Combined	
	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 \pm 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.

4. Post Market Performance of the STAR® Biphasic Waveform (continued)

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 Health Club data set included 65 shocks and showed shock success of 97% (95% lower CI of 91%).

- If the test is successful, the Rescue Ready status is green.
- If the AED detects an error, the Rescue Ready indicator remains red. A beep sounds every 30 seconds.

Note: When the lid of the AED is opened, one or more indicators on the AED display panel may remain lit and service messages may appear on the display. To troubleshoot these conditions, see the sections in this chapter.

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 \pm 1 shock. The average delivered energy was $46.6J \pm 3.4J$ and $59.3J \pm 1.2J$.

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 12 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 12: 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 13.

Table 13: 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.

D Electromagnetic Emissions Standards Compliance

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◆ Guidance and manufacturer's declaration—electromagnetic immunity	D-1
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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.
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 Harmonic emissions 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	

Electromagnetic Emissions Standards Compliance

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.			
Conducted RF	3 Vrms	Not Applicable	
IEC 61000-4-6	150 kHz to 80 MHz outside ISM bands ^a 10 Vrms 150 kHz to 80 MHz in ISM bands ^a	Not Applicable	
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	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.
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).			
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.



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 W	Separation distance according to frequency of transmitter m			
	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
			$d = 1.2 \sqrt{P}$	$d = 2.3 \sqrt{P}$
0.01	Not applicable	Not applicable	0.12	0.23
0.1	Not applicable	Not applicable	0.38	0.73
1	Not applicable	Not applicable	1.2	2.3
10	Not applicable	Not applicable	3.8	7.3
100	Not applicable	Not applicable	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 MHz to 40.70 MHz.

Note 3: An additional factor of 10/3 has been incorporated into the formula 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.

E Waste Electrical and Electronic Equipment (WEEE) Directive Compliance

Contents

- ◆ Manufacturer's WEEE compliance instructionsE-1

Manufacturer's WEEE compliance instructions

Pursuant to European Community Directive 2002/96/EC (effective: February 2003), Cardiac Science Corporation is committed to minimizing the disposal of WEEE as unsorted municipal waste.



European Community-based Users of the WEEE medical device contained herein are instructed to contact the following approved service provider for the complimentary / gratis collection and disposal of the subject equipment at the end of its useful life:

WasteCare
Richmond House
Garforth, Leeds
LS25 1NB
Tel: 0800 800 2044
Fax: 01133 854 322
Email: admon@weecare.com

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Cardiac Science Corporation • N7 W22025 Johnson Drive, Waukesha, WI 53186 USA

• 262-953-3500 • US toll-free 800-426-0337 • Fax: 262-953-3499 • care@cardiacscience.com

Technical Support • (US) Fax: 262-798-5236 • techsupport@cardiacscience.com

• (International) internationalservice@cardiacscience.com

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