# User's Guide

Cardiac Science Powerheart® Automated External Defibrillator





### **USER'S GUIDE**

# POWERHEART® G5 AUTOMATED EXTERNAL DEFIBRILLATOR

70-01975-02 A



AT THE HEART OF SAVING LIVES

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#### **Patents**

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



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### 1 About the AED

### **Contents**

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

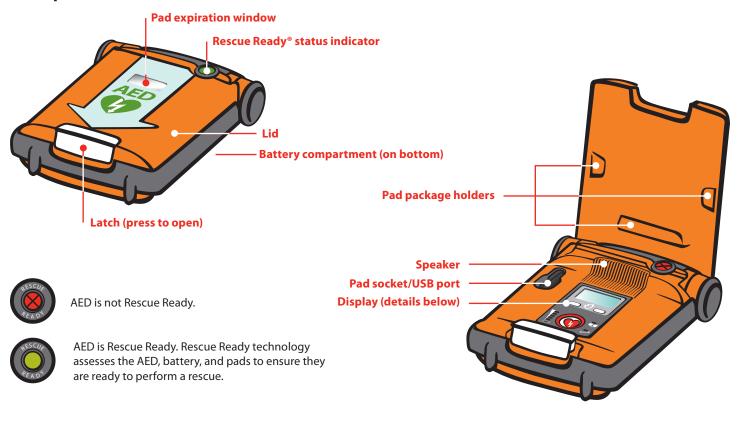
### **AED** overview

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).

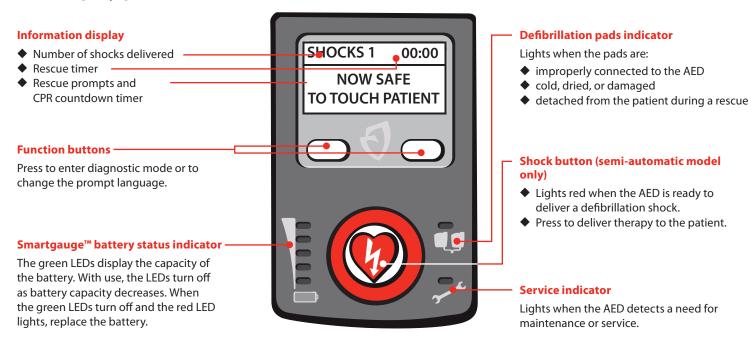
There are two models available—fully automatic and semi-automatic. After the defibrillations pads are applied to the patient, the fully automatic model evaluates the heart rhythm and, if a shockable rhythm is detected, delivers a shock without any rescuer assistance. The semi-automatic model evaluates 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.

### **AED** parts



### The display panel



### **Defibrillation pads**

The AED comes with defibrillation pads installed. Pads are stored in a ready-to-use, sealed package. 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 paediatric defibrillation pads

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

Contact Cardiac Science Customer Care to order replacement pads.

**Important:** Paediatric pads are not to be pre-connected to the AED. Follow the instructions for use provided with paediatric 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 Adult defibrillation 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 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 Adult defibrillation pads with CPR feedback device.

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

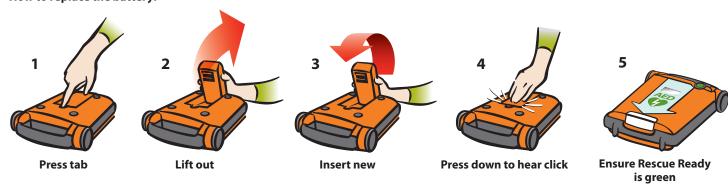
### Intellisense® battery

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.



# 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: Analyse 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 paediatric defibrillation pads, if available. See the directions for use accompanying paediatric pads to replace adult pads with paediatric pads.



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   | Do this  |  |
|--|--|--|
| "Tear open white package across dotted line and remove pads."  | <ol> <li>Keeping the pads connected to the AED, tear open the package.</li> <li>Remove the pads from the package.</li> <li>You can leave the package attached to the pad wires.</li> </ol> |  |
| "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. 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." | <ul><li>5. Pull the blue plastic from the second pad.</li><li>6. Place the pad on the other location on the chest.</li></ul>   |  |

**Note:** Cardiac Science's standard defibrillation pads are non-polarised 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: Analyse the ECG

| When the AED prompts   | Do this  |  |
|--|--|--|
| "Do not touch the patient! Analysing heart rhythm. Please wait." | <ol> <li>Do not touch the patient.</li> <li>Wait for the next prompt.</li> </ol> |  |
| The AED begins analysing 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 metres). | Remove the electronic device or stop the excessive motion.  |

### 5: Deliver a shock

| Do this  |
|--|
| Ensure that no one is touching the patient.  |
| Automatic model: Ensure that no one is touching the patient.   |
|  |
| <b>Semi-automatic model:</b> 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.                                   |
| Wait for the next prompt.  |
|  |
| Begin CPR.   |
|  |



When the AED is charged, it continues to analyse 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: *Analyse 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.



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

### Contents

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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.

### Indications for use

The Powerheart® G5 is indicated for emergency treatment of victims exhibiting symptoms of sudden cardiac arrest who are unresponsive and not breathing or not breathing normally. Postresuscitation, if the patient is breathing, the AED should be left attached to allow for acquisition and detection of the ECG rhythm. If a shockable ventricular tachyarrhythmia recurs, the device will charge automatically and advise the operator to deliver a shock, or for an automatic AED, automatically deliver a shock if needed.

When a patient is a child up to 8 years of age, or up to 25 kg (55 lbs), the Powerheart G5 AED should be used with Paediatric Defibrillation Pads

The therapy should not be delayed to determine the patient's exact age or weight.

### 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 authorised service personnel.

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



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

Radio-frequency (RF) interference from devices such as cellular phones and two-way radios can cause improper AED operation. In accordance with EN 61000-4-3:2002, a distance of at least 6 feet (2 metres) between RF devices and the AED is recommended. 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.



#### **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! Paediatric pads statement.

Connect paediatric pads only when attempting a paediatric rescue. Upon completion of the rescue, reconnect the adult pads 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**

Pressurised 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.  $\label{eq:control} % \begin{subarray}{ll} \end{subarray} % \begi$ 



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

During a rescue attempt, excessive jostling or moving of the patient may cause AEDs to improperly analyse 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-oxidising 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.

| _     |     |
|-------|-----|
| Sym   | hal |
| JVIII | DUI |

#### Description



Caution. Consult accompanying documentation.



Additional information is provided in the accompanying documentation.



Dangerous voltage: The defibrillator output has high voltage and can present a shock hazard.

Please read and understand all safety alerts in this manual before attempting to operate the AED.



Defibrillator Proof Type BF Equipment: The AED, when connected to the patient's chest by the pads, can withstand the effects of an externally applied defibrillation shock.



CE Mark: This equipment conforms to essential requirements of 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.



Authorised representative in the European Community.



#### Description



The AED is protected against access to hazardous parts by dust and the effects of water projected by jets in accordance with IEC 60529.



Battery capacity indicator

LEDs show the remaining battery capacity: 100%, 75%, 50%, 25%, 0% (red only).



Service Indicator indicates

AED requires service by authorised service personnel.



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.



Shock button and indicator

When the Shock indicator is lit, press this button to deliver a defibrillation shock.



Rescue Ready® indicator

A red indicator means the AED requires operator attention or maintenance, and is not Rescue Ready.



Rescue Ready® indicator

A green indicator means the AED is Rescue Ready.

Symbol

Description



Manufacturer.



Date of manufacture, year, month and day.



Use pads by the date shown.



Not made with natural rubber latex.

Not made with natural rubber latex.



Disposable. Single patient use only.



Tear here to open.



Do not recharge battery.



Lithium sulfur dioxide.



For use by or on the order of a Physician, or persons licensed by state law.



Do not incinerate or expose to open flame.



Upper and lower temperature operating range or storage range limits.



Serial Number.



Description



Product model number.



Lot number.



Dispose of properly in accordance with all state, province, and country regulations.



Recycle cardboard according to local law.



Waste Electronic Electrical Equipment (WEEE). Separate collection for waste electrical and electronic equipment. For more information, see *Manufacturer's WEEE compliance instructions* on page E-1



Waste Electronic Electrical Equipment (WEEE) containing lead. Separate collection for waste electrical and electronic equipment.



Box stacking limit.



Fragile: handle with care.



Keep dry.



Relative humidity.



Relative pressure.



UN symbol: Packaging is manufactured to conform to United Nations requirements.

### **4** AED Features

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The Powerheart AED provides customisation 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

◆ 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  |
|---------------------------------|---|---|
| SESCUE CONTRACTOR OF THE SESCUE | Rescue Ready status indicator is red and the service indicator is   | Close and reopen the lid of the AED. The Rescue Ready indicator may return to green.  |
| READY                           | NOT lit.  | Enter Diagnostic mode for more information (see <i>Diagnostic mode messages</i> on page 5-4).   |
|                                 | Both the Rescue Ready status  | The AED requires service by authorised service personnel.   |
|                                 | indicator and the service indicator are red.                        | 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. |
|                                 | Pads indicator is lit.  | Ensure that the pads are connected securely to the AED.   |
|                                 |   | 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.                             |
|                                 | The battery indicator is red.                                       | The battery capacity is low. Replace the battery.   |
|                                 | Additionally, when the lid is closed, a beep sounds intermittently. | If the beep continues to sound after the battery is replaced, contact Cardiac Science Technical Support or your local representative.                                 |

### 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<br>Line 1<br>Line 2       | Situation   | Resolution   |
|--|--|---|--|
| 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.  | Replace the battery before continuing with the rescue. If the battery charge                                   |
|  |  | The battery charge is too low to support a rescue.<br>Additionally, the following occur:  | is completely depleted, all AED activity ends.   |
|  |  | <ul><li>The Rescue Ready indicator turns red</li><li>The AED beeps once every 30 seconds</li></ul>  |  |
| Open lid to<br>continue<br>rescue                    | OPEN LID<br>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<br>connector is<br>plugged into<br>AED | CHECK CONNECTOR<br>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<br>Required.                                 | SERVICE REQUIRED CONTACT TECH SUPPORT  | The AED detects a condition that can prevent the AED from continuing a rescue.  | Contact Cardiac Science Technical<br>Support or your local representative                                      |
| Contact<br>Technical<br>Support                      |  | For example, this condition may occur after a self-test determines that the AED is not functioning properly.  | immediately.   |
| зарроге  |  | 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. |  |
| Maintenance<br>required,<br>Continue                 | 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.   | Enter Diagnostic mode for more information. If you cannot resolve the issue, contact Cardiac Science Technical |
| Rescue   |  | However, the condition has no immediate effect on the ability to continue with a rescue.  | 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<br>prompt    | Text display<br>Line 1<br>Line 2          | Situation  | Resolution  |
|--------------------|---|--|---|
| Diagnostic<br>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<br>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<br>ADJUST STORAGE TEMP       | The AED is hotter than its allowable storage temperature.  | Move the AED to a cooler location.  |
|                    |   | While this condition should be remedied as soon as possible, the AED may be used to perform a rescue.  |   |
|                    | TEMP TOO COLD<br>ADJUST STORAGE TEMP      | The AED is cooler than its allowable storage temperature.  | Move the AED to a warmer location.  |
|                    |   | While this condition should be remedied as soon as possible, the AED may be used to perform a rescue.  |   |
|                    | BATTERY LOW<br>CHECK BATTERY              | The battery charge is low, although a rescue can continue for approximately 9 more shocks.   | Replace the battery before the next rescue.   |
|                    |   | While this condition should be remedied as soon as possible, the AED can be used to perform a rescue.  |   |
|                    | PADS EXPIRED<br>REPLACE PADS              | The AED detects that the connected defibrillation pads are older than their "use by" date.   | Replace the defibrillation pads.  |
|                    |   | CAUTION: Use of pads that are damaged or expired may result in improper AED performance.   |   |
|                    | PADS USED<br>REPLACE PADS                 | The AED detects that the connected defibrillation pads have been used in a rescue.   | Replace the defibrillation pads.  |
|                    |   | 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. |   |
|                    | 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.



| 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

- 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.
- 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.

### 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 sterilised.

### **Authorised 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:** Unauthorised disassembly, modification, or service of the AED voids the warranty.

# **A** RescueCoach<sup>™</sup> Voice and Text Prompts

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

RescueCoach $^{\text{m}}$  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

|   | Text display                     | Prompt level                  |     |     |     |
|---|----------------------------------|-------------------------------|-----|-----|-----|
| Voice prompt                                  | Line 1<br>Line 2                 | Situation                     | Adv | Std | Bas |
| Stay calm. Follow these instructions.         | STAY CALM<br>FOLLOW INSTRUCTIONS | Plays when the lid is opened. | Х   |     |     |
| Make sure 999 is called now.                  | CALL 999<br>NOW                  | Plays when the lid is opened. | Х   | Х   |     |
| Make sure emergency services are called now.* | CALL EMERGENCY<br>SERVICES NOW   | Plays when the lid is opened. | Х   | Х   |     |

<sup>\*</sup> Alternative start up prompt

Table A-2: Pads placement

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

Table A-3: Pads prompts

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

### Table A-4: Analysis

|  | Text display                                |  |     | Prompt le |     |
|--|---|--|-----|-----------|-----|
| Voice prompt   | Line 1<br>Line 2                            | Situation  | Adv | Std       | Bas |
| Do not touch the patient!<br>Analysing heart rhythm. Please<br>wait. | DO NOT TOUCH PATIENT<br>ANALYSING RHYTHM    | Repeats until analysis of the patient's cardiac rhythm is completed. This prompt will be interrupted if the AED is ready to shock. | Х   | Х         |     |
| Do not touch the patient<br>Analysing Rhythm.                        | DO NOT TOUCH PATIENT<br>ANALYSING RHYTHM    | Repeats until analysis of the patient's cardiac rhythm is completed. This prompt will be interrupted if the AED is ready to shock. |     |           | Х   |
| Shock advised. Do not touch the patient.                             | SHOCK ADVISED<br>DO NOT TOUCH PATIENT       | Notifies the rescuer that a shockable rhythm has been detected and is preparing to deliver a defibrillation shock (charging).      | Х   | Х         | X   |
| Shock not advised  | SHOCK NOT ADVISED                           | Notifies the rescuer when the AED detects a non-<br>shockable rhythm.  | Х   | Х         | Х   |
| Analysis interrupted. Stop patient motion.                           | ANALYSIS INTERRUPTED<br>STOP PATIENT MOTION | If the AED detects ECG noise artifacts, stop moving or touching the patient. Remove other electronic devices from the vicinity.    | Х   | Х         | Х   |

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

|   | Text display                      |  |     | Prompt level |     |  |
|---|-----------------------------------|--|-----|--------------|-----|--|
| Voice prompt                                | Line 1<br>Line 2                  | Situation  | Adv | Std          | Bas |  |
| Press red flashing button to deliver shock. | PRESS BUTTON<br>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. | Х   | Х            | Х   |  |
| Shock delivered.                            | SHOCK DELIVERED                   | Prompts when the shock is delivered.   | Х   | Χ            | Χ   |  |
| Rhythm Changed. Shock<br>Cancelled.         | RHYTHM CHANGED<br>SHOCK CANCELLED | Notifies the rescuer when the AED detects a rhythm change and cancels the shock.   | Х   | Х            | Х   |  |

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

|                                      | Text display                 |  | Prompt lev |     |     |
|--------------------------------------|------------------------------|--|------------|-----|-----|
| Voice prompt                         | Line 1<br>Line 2             | Situation  | Adv        | Std | Bas |
| Shock not delivered.                 | SHOCK NOT DELIVERED          | <ul> <li>Plays for either of these situations:</li> <li>The SHOCK button is not pressed within 30 seconds of the AED giving the "Press red flashing button" prompt.</li> <li>The AED is unable to deliver a shock because of a fault condition.</li> </ul> | Х          | Х   | Х   |
| It is now safe to touch the patient. | NOW SAFE<br>TO TOUCH PATIENT | Advises the rescuer that it is safe to touch the patient: <ul><li>After the AED delivers a shock</li><li>After the AED detects a nonshockable rhythm</li></ul>   | Х          | Х   |     |

Table A-6: Delivering therapy - G5 automatic

|   | Text display                 |  | Prompt level |     |     |
|---|------------------------------|--|--------------|-----|-----|
| Voice prompt  | Line 1<br>Line 2             | Situation  | Adv          | Std | Bas |
| Shock will be delivered in SHOCK IN: Notifies the rescuer after the AED is fully char ready to deliver the shock. |                              | Notifies the rescuer after the AED is fully charged and ready to deliver the shock.  | Х            | Х   | Х   |
| Three   | THREE                        | Prompts approximately three seconds prior to delivering shock.   |              | Х   | Х   |
| Two   | TWO                          | Prompts approximately two seconds prior to delivering shock.   | Х            | Х   | Х   |
| One   | ONE                          | Prompts approximately one second prior to delivering shock.  |              | Х   | Х   |
| Shock delivered.  | SHOCK DELIVERED              | Prompts when the shock is delivered.   | Х            | Χ   | Χ   |
| Shock not delivered.  | SHOCK NOT DELIVERED          | Plays if the AED is unable to deliver a shock because of a fault condition.  | Х            | Х   | Х   |
| It is now safe to touch the patient.  | NOW SAFE<br>TO TOUCH PATIENT | Advises the rescuer that it is safe to touch the patient: <ul><li>After the AED delivers a shock</li><li>After the AED detects a nonshockable rhythm</li></ul> | Х            | Х   |     |

Table A-7: CPR

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

Table A-8: CPR feedback device (optional)

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

Table A-9: Data transfer

|                     | Text display                 |  | Pro |     | mpt level |  |
|---------------------|------------------------------|--|-----|-----|-----------|--|
| Voice prompt        | Line 1<br>Line 2             | Situation  | Adv | Std | Bas       |  |
| Communications mode | COMMUNICATIONS MODE          | Played when AED enters Communications mode.  | Х   | Χ   | Х         |  |
|                     | DO NOT DISCONNECT<br>USB     | Prompts when data is transferred between the AED and the flash drive. Disconnecting the flash drive can corrupt the data being transferred.              | Х   | Х   | Х         |  |
|                     | SAFE TO REMOVE<br>USB        | Prompts after the data transfer completes. Remove the flash drive.   | Х   | Х   | Х         |  |
|                     | UPDATING LANGUAGE            | Updating the text and audio prompts as part of a software upgrade using the flash drive.   | Χ   | Χ   | Х         |  |
|                     | 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   | Χ         |  |
|                     | UPDATING SOFTWARE            | Updating the operating software.   | Χ   | Χ   | Χ         |  |
|                     | VERIFYING SOFTWARE           | The AED is verifying that the operating software is installed properly.  | Χ   | Χ   | Χ         |  |
|                     | PROMPT/TEXT UPDATE<br>FAILED | After a language update, the AED determines that the update was not installed properly. Contact Technical Support or your local representative for help. | Х   | Х   | Х         |  |
|                     | SOFTWARE UPDATE<br>FAILED    | After a software update, the AED determines that the update was not installed properly. Contact Technical Support or your local representative for help. | Х   | Х   | Х         |  |
|                     | UPGRADE ERROR                | There is a problem with the software upgrade. Contact Technical Support or your local representative for help.   | Х   | X   | Х         |  |
|                     | 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.                         | Х   | Х   | Х         |  |
|                     | USB DATA ERROR               | A problem occurred with the data transfer. Check the connection with the flash drive and retry the transfer.   | Х   | Х   | Х         |  |
|                     | DOWNLOADING DATA             | The data transfer to the flash drive is in progress.   | Х   | Χ   | Χ         |  |
|                     | SOFTWARE ERROR               | There is a problem with the data transfer to the flash drive. Contact Technical Support or your local representative for help.                           | Х   | Х   | Х         |  |
|                     | REMOVE USB<br>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.                    | Х   | Х   | Х         |  |
|                     | RESETTING DEVICE             | After a software upgrade, the AED restarts itself.   | Х   | Χ   | Χ         |  |
|                     | CONTROL CODE UPDATE          | Updating the control software.   | Х   | Χ   | Χ         |  |

Table A-10: Language selection

|              | Text display     |  |     | Prompt level |     |  |
|--------------|------------------|--|-----|--------------|-----|--|
| Voice prompt | Line 1<br>Line 2 | Situation  | 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. | Х   | Х            | Х   |  |
|              | FRENCH           | 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. | Х   | Х            | Х   |  |
|              | DUTCH            | 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. | Х   | Х            | Х   |  |
|              | ITALIAN          | 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. | Х   | Х            | Х   |  |
|              | GERMAN           | 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. | Х   | Х            | Х   |  |
|              | 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. | Х   | Х            | Х   |  |

### **B** Technical Data

### **Contents**

| <b>♦</b> | Powerheart G5 parameters                | B-1 |
|----------|---|-----|
| <b>♦</b> | Defibrillation pads                     | B-3 |
| <b>♦</b> | 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><li>Automatic</li><li>Semi-automatic</li><li>Multi-language (in specified combinations only)</li></ul> |
| Dimensions                     | <ul><li>Height: 9 cm (3.4 in)</li><li>Width: 23 cm (9.0 in)</li><li>Depth: 30 cm (11.8 in)</li></ul>       |
| Weight (with battery and pads) | 2.6 kg (5.7 lb)  |

**Table 2: Environmental information** 

| Parameter                               | Detail  |
|---|---|
| Operating*                              | <ul> <li>Temperature: 0°C to 50°C (32°F to 122°F)</li> <li>Humidity: 10% to 95% (non-condensing)</li> </ul>   |
| Standby**                               | • Short-term (5 days) temperature: 0° C to 50° C (32° F to 122° F)  |
|   | <ul> <li>Long-term temperature: 20° C to 30° C (68° F to<br/>86° F)</li> </ul>  |
|   | • Humidity: 10% to 95% (non-condensing)   |
| Storage and transport (up to 3 days)*** | <ul> <li>Temperature: -30° C to 65° C (-22° F to 149° F)</li> <li>Humidity: 10% to 95% (non-condensing)</li> </ul>  |
| Altitude                                | <ul> <li>CSA evaluated: -382 m to 3000 m</li> <li>Minimum: -382 m (approximate; calculated from pressure)</li> <li>Maximum: 4594 m (approximate; calculated from pressure)</li> </ul> |
| -                                       |   |

**Table 2: Environmental information** (continued)

| Parameter   | Detail  |  |  |  |  |
|---|---|--|--|--|--|
| Pressure  | <ul> <li>CSA evaluated: 700 hPa to 1060 hPa</li> <li>Minimum: 570 hPa</li> <li>Maximum: 1060 hPa</li> </ul> |  |  |  |  |
| * 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. |   |  |  |  |  |

**Table 3: Functionality** 

| Parameter                               | Detail  |
|---|---|
| RHYTHMx®<br>ECG analysis<br>performance | The AED RHYTHMx ECG Analysis system analyses the patient's ECG and advises you when the AED detects a shockable or non-shockable rhythm.                                |
|   | This system makes it possible for a person, with no training in the interpretation of ECG rhythms, to offer defibrillation therapy to victims of sudden cardiac arrest. |
| Waveform                                | STAR® Biphasic  |
| Impedance                               | 25 Ω to 175 Ω   |
| Energy (adult pads)                     | Escalating energy from 95 J to 354 J  |
| Energy (paediatric pads)                | Escalating energy from 22 J to 82 J   |
|   |   |

**Table 3: Functionality** (continued)

| Parameter             | Detail  | Туре  | Detail  |  |
|-----------------------|---|---|---|--|
| Shock times           | <ul> <li>Initiation of rhythm analysis to ready to shock:<br/>15 seconds (typical); 45 seconds (maximum)</li> <li>With a fully charged battery</li> <li>Initiation of rhythm analysis to ready to shock,</li> </ul>   | to conform to the highest standards of safety and performance including electromagnetic compatibility (EMC). This AED and defibrillation pads conform to the applicable requirements of the |   |  |
|                       | used battery: 15 seconds typical); 45 seconds (maximum) with a battery that has been used for 15 shocks   | General   | • CE Marked by BSI 2797 per the Medic I Device Directive 93/42/EEC.   |  |
|                       | <ul> <li>Lid-open to ready to shock: 15 seconds (typical) With a battery that has been used for 15 shocks</li> <li>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.</li> </ul> |   | <ul> <li>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.</li> <li>Certified to CAN/CSA Standard C22.2 No. 60601-1:08 and 60601-2-4.</li> </ul> |  |
|                       |   | Safety and performance  | <ul> <li>IEC 60601-1</li> <li>IEC 60601-1-2</li> <li>IEC 60601-2-4</li> <li>RTCA DO-160G:2010: Section 5 Category C;<br/>Section 4, Category A4</li> <li>EN 1789</li> </ul>   |  |
|                       | internal electronics, buttons, high voltage<br>circuit (advanced tests, full energy charge<br>cycle).   | Emissions<br>Immunity   | EM: EN 55011+A1/CISPR 11, Group 1, Class B  • EM  |  |
| Audible alerts        | <ul><li> Voice prompts</li><li> Maintenance alerts</li></ul>  |   | <ul> <li>IEC 61000-4-3, Level X, (20V/m)</li> <li>IEC 60601-2-4 (20V/m)</li> <li>Magnetic</li> </ul>  |  |
| Indicators            | <ul><li>Battery status</li><li>Check pads</li><li>Rescue Ready</li><li>Service</li><li>Text display</li></ul>   |   | <ul> <li>IEC 61000-4-8</li> <li>IEC 61000-4-8</li> <li>ESD</li> <li>IEC 61000-4-2</li> <li>IEC 60601-2-4</li> </ul>   |  |
| USB port              | Event download, device data, configuration, and   |   | 6 KV contact discharge, 8 KV air gap discharge  |  |
| communication         | maintenance   | Free fall drop  | MIL-STD-810G, Method 516.5, Procedure IV  |  |
| Internal data storage | 90 minutes  | Shock   | MIL-STD-810G 516.5, Procedure 1   |  |
|                       |   | Vibration<br>(Random)   | MIL-STD-810G, Method 514.5, Procedure 1,<br>Category 24; RTCA DO-160G, Section 8, Category<br>S, Zone 2 (curve B) and Category U, Zone 2<br>(curves F and F1)   |  |
|                       |   | Vibration (Sine)  | MIL-STD-810G, Method 514.5, Procedure 1,<br>Category 24, Helicopter Minimum Integrity   |  |
|                       |   | Enclosure protection  | IEC 60529, IP55   |  |

Table 4: Applicable standards

**Table 4: Applicable standards** (continued)

| Туре  | Detail  |  |  |  |  |
|---|---|--|--|--|--|
| Shipping and transportation                           | ISTA Procedure 2A   |  |  |  |  |
| Sensitivity and<br>specificity of<br>Rhythm Detection | Shockable Rhythm—VF: Meets IEC 60601-2-4<br>requirement and AHA recommendation of<br>Sensitivity of >90%  |  |  |  |  |
|   | <ul> <li>Shockable Rhythm—VT: Meets IEC 60601-2-4<br/>requirement and AHA recommendation of<br/>Sensitivity of &gt;75%</li> </ul>                                     |  |  |  |  |
|   | <ul> <li>Non-shockable Rhythm—NSR: Meets IEC<br/>60601-2-4 requirement (&gt;95%) and AHA<br/>recommendation (&gt;99%) of Specificity</li> </ul>                       |  |  |  |  |
|   | <ul> <li>Non-shockable—Asystole: Meets IEC 60601-<br/>2-4 requirement and AHA recommendation of<br/>Specificity of &gt;95%</li> </ul>                                 |  |  |  |  |
|   | <ul> <li>Non-shockable—all other rhythms: Meets<br/>IEC 60601-2-4 requirement and AHA<br/>recommendation of Specificity – all other<br/>rhythms of &gt;95%</li> </ul> |  |  |  |  |
|   |   |  |  |  |  |

## **Defibrillation pads**

Table 5: Adult defibrillation pads (model XELAED001)

| Dro walled solf adhesive dispessable non   |
|--|
| Pre-gelled, self-adhesive, disposable, non-<br>polarised (identical pads, which can be placed in<br>either position) defibrillation pads |
| Older than 8 years or heavier than 25 kg (55 lb)   |
| 24 months  |
| Check local regulations for disposal information   |
|  |

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

| Parameter                            | Detail   |
|--------------------------------------|--|
| Туре                                 | Pre-gelled, self-adhesive, disposable, non-<br>polarised (identical pads, which can be placed<br>in either position) defibrillation pads with CPR<br>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: Paediatric defibrillation pads (model XELAED003)

| Parameter                            | Detail   |
|--------------------------------------|--|
| Туре                                 | Pre-gelled, self-adhesive, disposable, non-<br>polarised (identical pads, which can be placed in<br>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  |
|---|---|
| Туре  | 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<br>life*  | <ul> <li>5 years from date of manufacture</li> <li>Temperature ranges:         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     </li> </ul> |
| Estimated<br>operating life**<br>(new and fully<br>charged battery) | <ul> <li>Shocks (typical): 420</li> <li>Shocks (minimum): 250 or<br/>16 hours of operating time at 20-30° C or<br/>Standby: 4 years</li> </ul>  |

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

<sup>\*\*</sup> 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**

| <b>♦</b> | RHYTHMx® AED ECG analysis algorithmC | 1          |
|----------|--------------------------------------|------------|
| <b>\</b> | Rescue protocol                      | <u>-</u> 1 |
| <b>♦</b> | STAR® biphasic waveformC             | <u>-</u> 1 |

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.
- ◆ Synchronised shock—The AED automatically attempts to synchronise shock delivery on the R-wave if one is present. If delivery cannot be synchronised within one second, a nonsynchronised 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 adult defibrillation pads.

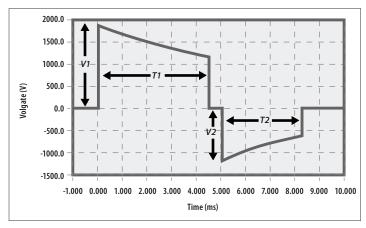


Figure 1: High variable energy waveform with 50 ohm resistive load

#### **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 adult defibrillation pads

Table C-1: Ultra-low variable energy waveform (all values are typical)

|                                  | Phase 1                    |                          | Phase 2                    |                          |                    |
|----------------------------------|----------------------------|--------------------------|----------------------------|--------------------------|--------------------|
| Patient's<br>Impedance<br>(Ohms) | Voltage<br>(Volts)<br>(V1) | Duration<br>(ms)<br>(T1) | Voltage<br>(Volts)<br>(V2) | Duration<br>(ms)<br>(T2) | Energy<br>(Joules) |
| 25                               | 1412                       | 3.25                     | 743                        | 3.2                      | 146-197            |
| 50                               | 1426                       | 4.50                     | 907                        | 3.2                      | 128-172            |
| 75                               | 1431                       | 5.75                     | 968                        | 3.2                      | 116-156            |
| 100                              | 1433                       | 7.00                     | 1000                       | 3.2                      | 108-144            |
| 125                              | 1435                       | 8.25                     | 1019                       | 3.2                      | 102-136            |
| 150                              | 1436                       | 9.50                     | 1031                       | 3.2                      | 97-130             |
| 175                              | 1437                       | 10.75                    | 1038                       | 3.2                      | 94-126             |

Table C-2: Low variable energy waveform (all values are typical)

|                                  | Phase 1                    |                          | Phase 2                    |                          |                    |
|----------------------------------|----------------------------|--------------------------|----------------------------|--------------------------|--------------------|
| Patient's<br>Impedance<br>(Ohms) | Voltage<br>(Volts)<br>(V1) | Duration<br>(ms)<br>(T1) | Voltage<br>(Volts)<br>(V2) | Duration<br>(ms)<br>(T2) | Energy<br>(Joules) |
| 25                               | 1631                       | 3.25                     | 858                        | 3.2                      | 195-263            |
| 50                               | 1647                       | 4.50                     | 1047                       | 3.2                      | 170-230            |
| 75                               | 1653                       | 5.75                     | 1118                       | 3.2                      | 154-208            |
| 100                              | 1655                       | 7.00                     | 1155                       | 3.2                      | 143-193            |
| 125                              | 1657                       | 8.25                     | 1176                       | 3.2                      | 135-182            |
| 150                              | 1658                       | 9.50                     | 1190                       | 3.2                      | 129-174            |
| 175                              | 1659                       | 10.75                    | 1199                       | 3.2                      | 125-168            |

Table C-3: High variable energy waveform (all values are typical)

|                                  | Phase 1                    |                          | Phase 2                    |                          |                    |
|----------------------------------|----------------------------|--------------------------|----------------------------|--------------------------|--------------------|
| Patient's<br>Impedance<br>(Ohms) | Voltage<br>(Volts)<br>(V1) | Duration<br>(ms)<br>(T1) | Voltage<br>(Volts)<br>(V2) | Duration<br>(ms)<br>(T2) | Energy<br>(Joules) |
| 25                               | 1895                       | 3.25                     | 997                        | 3.2                      | 263-355            |
| 50                               | 1914                       | 4.50                     | 1216                       | 3.2                      | 230-310            |
| 75                               | 1920                       | 5.75                     | 1299                       | 3.2                      | 208-280            |
| 100                              | 1923                       | 7.00                     | 1342                       | 3.2                      | 193-260            |
| 125                              | 1925                       | 8.25                     | 1367                       | 3.2                      | 183-246            |
| 150                              | 1926                       | 9.50                     | 1383                       | 3.2                      | 174-235            |
| 175                              | 1927                       | 10.75                    | 1393                       | 3.2                      | 168-226            |

## Waveform and energy levels for paediatric defibrillation pads

Table C-4: Ultra-low variable energy waveform (all values are typical)

|                                  | Phase 1                    |                          | Phase 2                    |                          |                    |
|----------------------------------|----------------------------|--------------------------|----------------------------|--------------------------|--------------------|
| Patient's<br>Impedance<br>(Ohms) | Voltage<br>(Volts)<br>(V1) | Duration<br>(ms)<br>(T1) | Voltage<br>(Volts)<br>(V2) | Duration<br>(ms)<br>(T2) | Energy<br>(Joules) |
| 25                               | 682                        | 3.25                     | 359                        | 3.2                      | 35-46              |
| 50                               | 689                        | 4.50                     | 438                        | 3.2                      | 30-40              |
| 75                               | 691                        | 5.75                     | 468                        | 3.2                      | 27-36              |
| 100                              | 692                        | 7.00                     | 483                        | 3.2                      | 25-33              |
| 125                              | 693                        | 8.25                     | 493                        | 3.2                      | 24-31              |
| 150                              | 694                        | 9.50                     | 498                        | 3.2                      | 23-30              |
| 175                              | 694                        | 10.75                    | 802                        | 3.2                      | 22-29              |

Table C-5: Low variable energy waveform (all values are typical)

|                                  | Phase 1                    |                          | Phase 2                    |                          |                    |
|----------------------------------|----------------------------|--------------------------|----------------------------|--------------------------|--------------------|
| Patient's<br>Impedance<br>(Ohms) | Voltage<br>(Volts)<br>(V1) | Duration<br>(ms)<br>(T1) | Voltage<br>(Volts)<br>(V2) | Duration<br>(ms)<br>(T2) | Energy<br>(Joules) |
| 25                               | 791                        | 3.25                     | 416                        | 3.2                      | 46-61              |
| 50                               | 798                        | 4.50                     | 508                        | 3.2                      | 40-54              |
| 75                               | 801                        | 5.75                     | 542                        | 3.2                      | 37-48              |
| 100                              | 802                        | 7.00                     | 560                        | 3.2                      | 34-45              |
| 125                              | 803                        | 8.25                     | 570                        | 3.2                      | 32-42              |
| 150                              | 804                        | 9.50                     | 577                        | 3.2                      | 31-40              |
| 175                              | 804                        | 10.75                    | 581                        | 3.2                      | 30-39              |

Table C-6: High variable energy waveform (all values are typical)

|                                  | Phase 1                    |                          | Phase 2                    |                          |                    |
|----------------------------------|----------------------------|--------------------------|----------------------------|--------------------------|--------------------|
| Patient's<br>Impedance<br>(Ohms) | Voltage<br>(Volts)<br>(V1) | Duration<br>(ms)<br>(T1) | Voltage<br>(Volts)<br>(V2) | Duration<br>(ms)<br>(T2) | Energy<br>(Joules) |
| 25                               | 915                        | 3.25                     | 481                        | 3.2                      | 62-82              |
| 50                               | 924                        | 4.50                     | 588                        | 3.2                      | 54-72              |
| 75                               | 927                        | 5.75                     | 628                        | 3.2                      | 49-65              |
| 100                              | 929                        | 7.00                     | 648                        | 3.2                      | 46-60              |
| 125                              | 930                        | 8.25                     | 660                        | 3.2                      | 43-57              |
| 150                              | 931                        | 9.50                     | 668                        | 3.2                      | 41-54              |
| 175                              | 931                        | 10.75                    | 673                        | 3.2                      | 40-52              |

# **D** Electromagnetic Emissions Standards Compliance

#### **Contents**

## 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                               | Group 1        | The AED uses RF energy only for its internal function. Therefore its RF emissions are very low and  |  |
| CISPR 11                                   |                | are not likely to cause any interference in nearby electronic equipment.  |  |
| RF emissions                               | Class B        | The AED is suitable for use in all establishments, including domestic establishments and those  |  |
| CISPR 11                                   |                | directly connected to the public low-voltage power supply network that supplies buildings  Harmonic emissions used for domestic purposes. |  |
| Harmonic emissions                         | Not applicable | - Harmonic emissions used for domestic pulposes.  |  |
| IEC 61000-3-2                              |                |   |  |
| Voltage fluctuations/<br>flicker emissions | Not applicable | _   |  |
| IEC 61000-3-3                              |                |   |  |

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

| Immunity test  | IEC 60601 test level  | level          | Electromagnetic<br>enviroment —guidance  |
|--|---|----------------|--|
| Voltage dips, short interruptions and                | $<$ 5% U $_{\rm T}$ ( $>$ 95% dip in U $_{\rm T}$ ) for 0.5 cycle | Not applicable |  |
| voltage variations on<br>power supply input<br>lines | $40\%~U_{_T}$ (60% dip in $U_{_T}$ ) for 5 cycles                 |                |  |
| 61000-4-11   | 70% $U_T$ (30% dip in $U_T$ ) for 25 cycles                       |                |  |
|  | $<$ 5% $U_T$ (>95% dip in $U_T$ ) for 5 sec.                      |                |  |
| Power frequency<br>(50/60 Hz) magnetic<br>field      | 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   |
| IEC 61000-4-8  |   |                | rooms of H.V. substations.   |
| Note: U <sub>T</sub> is the a.c. mai                 | ns 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 <sup>a</sup>                  | Not Applicable |  |
|  | 10 Vrms   |                |  |
|  | 150 kHz to 80 MHz in ISM<br>bands <sup>a</sup>                    |                |  |
| Radiated RF<br>IEC 61000-4-3                         | 10 V/m<br>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  |
|  |   |                | $d = 1.2 \sqrt{P} 80 \text{ MHz}$ 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 metres (m) <sup>b</sup> .   |
|  |   |                | Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.   |
|  |   |                | Interference may occur in the vicinity of equipment $((\bullet))$ marked with the following symbol:  |

Compliance

Electromagnetic

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.

- <sup>a</sup> 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.
- <sup>b</sup> 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.
- <sup>c</sup> 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<br>power of transmitter<br>W | Separation distance according to frequency of transmitter m |                |      |                    |                    |  |
|---|---|----------------|------|--------------------|--------------------|--|
|   |   |                |      |                    |                    |  |
|   |   |                |      | $d = 1.2 \sqrt{P}$ | $d = 2.3 \sqrt{P}$ |  |
| 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 metres (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 instructions ......E-1

# Manufacturer's WEEE compliance instructions

Pursuant to European Community Directive 2002/96/EC (effective: February 2003), Cardiac Science Corporation is committed to minimising 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

# **F** Limited Warranty

#### Contents

| <b>♦</b> | For how long?                       | F-   |
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|          | What we will do:                    |      |
| <b></b>  | Obligations and warranty limits:    | .F-′ |
|          | What this warranty does not cover:  |      |
| <b>\</b> | This limited warranty is void if:   | F-2  |
|          | If the warranty period has expired: |      |

Cardiac Science Corporation ("Cardiac Science") warrants to the original purchaser that its AEDs and stated battery operating life will be free of any defect in material and workmanship according to the terms and conditions of this Limited Warranty ("Limited Warranty"). For purposes of this Limited Warranty, the original purchaser is deemed to be the original end user of the product purchased. This Limited Warranty is NONTRANSFERABLE and UNASSIGNABLE.

#### For how long?

This Limited Warranty covers the following products or parts for the following time periods:

- Eight (8) years from the date of the original shipment to the original purchaser for Powerheart AED automated external defibrillators. Warranty duration for the pads, batteries and accessories are covered below.
- Disposable defibrillation pads shall be warranted until the expiration date.
- Lithium batteries (part number: XBTAED001) have a full operational replacement guarantee of four (4) years from the date of installation into a Powerheart AED.
- One (1) year from the date of original shipment to the original purchaser for Powerheart AED accessories. The terms of the Limited Warranty in effect as of the date of original purchase will apply to any warranty claims.

### What you must do:

Please complete and submit the Product Registration online at www. cardiacscience.com/services-support/product-registration/.

To obtain warranty service for your product:

Inside the US, call us toll free at 800.426.0337 seven days a week, 24 hours a day. Our technical support representative will try to resolve your issue over the phone. If necessary, and at our sole discretion, we will arrange for service or a replacement of our product.

Outside the US, contact your local Cardiac Science representative.

#### What we will do:

If your Cardiac Science product is returned within 30 days of the date it was purchased, at the direction of a technical support representative, we will repair or replace it with a new product of equal value at no charge to you or offer a full refund of the purchase price, provided the warranty applies. Cardiac Science retains the exclusive right to repair or replace the product or offer a full refund of the purchase price at its sole discretion. SUCH REMEDY SHALL BE YOUR SOLE AND EXCLUSIVE REMEDY FOR ANY BREACH OF WARRANTY.

If your Cardiac Science product is returned, at the direction of a technical support representative, after 30 days but within the warranty period, Cardiac Science, at its sole discretion, will repair your product or replace it. The repaired or replacement product will be warranted subject to the terms and conditions of this Limited Warranty for either (a) 90 days or (b) the remainder of the original warranty period, whichever is longer, provided the warranty applies and the warranty period has not expired.

## **Obligations and warranty limits:**

Limited Warranty Obligation: Exclusive Remedy

THE FOREGOING LIMITED WARRANTY IS IN LIEU OF AND SPECIFICALLY EXCLUDES AND REPLACES ALL OTHER EXPRESSED OR IMPLIED WARRANTIES INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

Some states do not allow limitations on how long an implied warranty lasts, so this limitation may not apply to you.

NO PERSON (INCLUDING ANY AGENT, DEALER, OR REPRESENTATIVE OF CARDIAC SCIENCE) IS AUTHORISED TO MAKE ANY REPRESENTATION OR WARRANTY CONCERNING CARDIAC SCIENCE PRODUCTS, EXCEPT TO REFER PURCHASERS TO THIS LIMITED WARRANTY.

YOUR EXCLUSIVE REMEDY WITH RESPECT TO ANY AND ALL LOSSES OR DAMAGES RESULTING FROM ANY CAUSE WHATSOEVER SHALL BE AS SPECIFIED ABOVE. CARDIAC SCIENCE SHALL IN NO EVENT BE LIABLE FOR ANY SPECIAL, PUNITIVE, INDIRECT, CONSEQUENTIAL OR INCIDENTAL DAMAGES OF ANY KIND, INCLUDING, BUT NOT LIMITED TO, EXEMPLARY DAMAGES, COMMERCIAL LOSS FROM ANY CAUSE, BUSINESS INTERRUPTION OF ANY NATURE, LOSS OF PROFITS OR PERSONAL INJURY OR DEATH, EVEN IF CARDIAC SCIENCE HAS BEEN ADVISED OF THE POSSIBILITIES OF SUCH DAMAGES, HOWEVER OCCASIONED, WHETHER BY NEGLIGENCE OR OTHERWISE.

Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you.

#### What this warranty does not cover:

This Limited Warranty does not cover defects or damages of any sort resulting from, but not limited to, accidents, damage while in transit to our service location, product tampering, unauthorised product alterations, unauthorised service, unauthorised product case opening, failure to follow instructions, improper use, abuse, neglect, fire, flood, war or acts of God. Cardiac Science makes no warranty claim as to the compatibility of Cardiac Science products with any non-Cardiac Science products, parts or accessories.

#### This limited warranty is void if:

- 1. Any Cardiac Science product is serviced or repaired by any person or entity other than Cardiac Science unless specifically authorised by Cardiac Science.
- 2. Any Cardiac Science product case is opened by unauthorised personnel or if a product is used for an unauthorised purpose.
- 3. Any Cardiac Science product is used in conjunction with incompatible products, parts or accessories, including but not limited to batteries. Products, parts and accessories are not compatible if they are not Cardiac Science products intended for use with the Powerheart AED.

#### If the warranty period has expired:

If your Cardiac Science product is not covered by our Limited Warranty:

Inside the US, call us toll free at 888.466.8686 for advice as to whether we can repair your Powerheart AED, and for other repair information, including charges. Charges for non-warranty repairs will be assessed and are your responsibility. Upon completion of the repair, the terms and conditions of this Limited Warranty shall apply to such repair or replacement product for a period of 90 days.

Outside the US, contact your local Cardiac Science representative.

This warranty gives you specific legal rights, and you may also have other rights, which vary from state to state.

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• 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

 $\bullet international service@cardiacscience.com \\ \bullet (International) international support@cardiacscience.com$ 

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