CARDIAC SCIENCE AEDS



Instructions for Use

POWER2HEART AED G3

POWER2HEART AED G3
automated external defibrillator
AUT MATIC

FIRSTSAVE AED G3

automated external defibrillator



WARNING: Electric Shock and Fire Hazard. Do not connect any telephones or unauthorized connectors to the socket on this equipment.

AED OVERVIEW

Become familiar with the controls and how to use the AED properly before operating the product.

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AED DESCRIPTION:

The AED is a self-testing, battery-operated automated external defibrillator (AED). After applying the AED's pads to the patient's chest, the AED automatically analyzes the patient's electrocardiogram (ECG) and advises the operator to push the button and deliver a shock if needed. For the Powerheart AED G3 Automatic, the AED automatically delivers a shock if needed. The AED guides the operator through the rescue using a combination of voice prompts and/or text, audible alerts, and visible indicators.

Persons authorized to operate AEDs must have training in accordance to state, province or country regulations.

PRODUCT MODELS

This instruction manual is for multiple, unique Cardiac Science AED models. They share a basic set of features and differences are noted throughout the manual.

The AED warranty for defects in materials or workmanship is 7 years from date of purchase. For the full warranty statement see the warranty paper packaged with your AED or refer to the Operation and Service manual on the Quick Start CD-ROM.

RESCUEREADY® STATUS INDICATOR

The RescueReady STATUS INDICATOR does not apply to AED 9300C.



When this **STATUS INDICATOR** is **GREEN**, the AED is RescueReady. This indicates the AED self-tests have verified the following:

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



When the **STATUS INDICATOR** is **RED**, check AED pads, battery and/or call customer service.

INTELLISENSE® BATTERY



INSTALLATION

- Insert battery as shown.
- Push firmly to snap into place.
- Open the lid for 5 seconds.
- The **STATUS INDICATOR** turns **GREEN** (Does not apply to 9300C).

ABOUT THE INTELLISENSE BATTERY

- When the last battery indicator (LED) is red, the battery is low. Replace the battery right away.
- A new battery typically takes 10 seconds to charge the AED to maximum energy.
- Output voltage: 12VDC (max)
- Batteries are non-rechargeable
- Lithium contents: 9.2g (max)
- Check local regulations for disposal information

MODEL	FULL OPERATIONAL REPLACEMENT GUARANTEE (FROM DATE OF INSTALLATION)	TYPICAL SHOCKS
9146 Lithium	4 Years	up to 290 shocks
9143 Lithium	1 Year	up to 100 shocks

Additionally, batteries are warranted against defects in materials and workmanship for 7 years from date of purchase.

PADS



The pads are already installed in the AED when shipped to you. Confirm that that they are connected. Then, ensure that the expiration date is visible through the clear window of the lid. Make sure the **STATUS INDICATOR** is **GREEN** (does not apply to 9300C).

ABOUT THE PADS

- Self-adhesive, disposable pads
- Minimum combined surface area: 228cm²
- Extended length of lead wire: 1.3m

AUDIBLE MAINTENANCE INDICATOR



For all Cardiac Science AEDs 9300 series:

When the daily, weekly, or monthly self-test determines maintenance is required, an audible beep is sounded every 30 seconds until the lid is opened, or the battery power is depleted. Opening and closing the lid may deactivate the beep. If the next automatic self-test does not correct the error, the beep will be reactivated.

AFTER A RESCUE ATTEMPT



After transferring the patient to Advanced Life Support personnel, prepare the AED for the next rescue:

- 1. Retrieve the rescue data stored in the internal memory of the AED.
- 2. Connect a new pair of pads to the AED.
- 3. Close the lid.



 Verify the STATUS INDICATOR on the AED handle is GREEN. (Does not apply to 9300C).

SYMBOL DESCRIPTIONS

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



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

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



Attention!: Identifies important information in this resource guide, on the AED, or on its component parts regarding the safe and proper use of 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.

IP24 The AED is protected against the effects of splashing water in accordance with IEC 60529.



Classified by ETL Semko with respect to electric shock, fire and mechanical hazards only in accordance with UL 60601-1, CAN/CSA C22.2 No.601.1-M90, EN60601-1 and EN60601-2-4. Conforms to UL Standard UL60601-1. Certified to CAN/CSA Standard C22.2 No. 601.1-M90.



International symbol for ON. Open the lid to turn on the AED.



Open the lid to turn ON the AED.

.....

Indicates the AED battery status. The illuminated areas indicate the remaining battery capacity.



Check pads. The pads are missing, not connected or have compromised functionality.

INSTRUCTIONS FOR USE



Indicates AED requires maintenance by authorized service personnel.



When the **SHOCK** indicator is lit, push this button to deliver a defibrillation shock.



When the **CONTINUE** indicator is lit, push this button to clear the internal memory to allow storage of new rescue data in the AED. (Only for models 9300E and 9300C *not* equipped with Multiple Rescue software)



A red indicator with a BLACK X means the AED requires operator attention or maintenance, and is not RescueReady. (Does not apply to 9300C)



A green indicator without a BLACK X means the AED is RescueReady. (Does not apply to 9300C)



Use pads by this date.



Date of manufacture, year and month.



Date of factory recertification.



Latex free.



Disposable. Single patient use only.



Tear here to open.



Do not recharge battery.



Position of pads on the chest of patient.

R only

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

INSTRUCTIONS FOR USE



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



Do not incinerate or expose to open flame.



Explosion Hazard: Do not use in the presence of a flammable gas, including concentrated oxygen.



Upper and lower temperature limits.



Device model number, battery model number



Lot number



Lithium sulfur dioxide

Serial communication port



Additional information is provided in the AED Operation and Service Manual.



Points to important information regarding the use of the AED.



Lift here



Manufacturer



Authorized European Representative



Symbol for the marking of electrical and electronic equipment that must be recycled.

SAFETY PERFORMANCE STANDARDS

DIMENSIONS

 Measurement
 Dimension

 Height
 8 cm (3.3 in)

 Width
 27 cm (10.6 in)

 Depth
 31 cm (12.4 in)

WEIGHT

Model Weight with Batteries and Pads

9300 3.10 kg (6.6 lb)

ENVIRONMENTAL OPERATION AND STANDBY CONDITIONS

Atmosphere Condition

Temperature 0°C to 50°C (32°F to 122°F)
Humidity 5% to 95% (non-condensing)

Pressure 57kPa (+15,000ft) to 103kPa (-500ft)

SHIPMENT AND TRANSPORT ENVIRONMENTAL CONDITIONS (for up to 1 week)

Atmosphere Condition

Temperature -30°C to 65°C (-22°F to 149°F) Humidity 5% to 95% (non-condensing)

Pressure 57kPa (+15,000ft) to 103kPa (-500ft)

AED MODEL 9300

The AED has been designed and manufactured to conform to the highest standards of safety and performance including electromagnetic compatibility (EMC). The Cardiac Science AED Models 9300 and pads conform to the applicable requirements of the following:



CE

CE Marked by BSI 0086 per the Medical Device Directive 93/42/EEC of European Union.



ETL

Classified by ETL Semko with respect to electric shock, fire and mechanical hazards only in accordance with UL 60601-1, CAN/CSA C22.2 No.601.1-M90, EN60601-1 and EN60601-2-4. Conforms to UL Standard UL60601-1. Certified to CAN/CSA Standard C22.2 No. 601.1-M90.

Electrical, Construction, Safety and Performance

IEC 60601-1 (1998), Amendments 1 (1991) & 2 (1995) IEC 60601-2-4 (2002) ANSI/AAMI DF-39 (1993)

Electromagnetic Compatibility (EMC)

IEC 60601-1-2 (2001) IEC 60601-2-4 Section 36 ANSI/AAMI DF-39 (1993) Section 3.3.21

EMISSIONS

Field	Standard or Compliance
E-M	EN 55011/CISPR 11, Group 1, Class B
Magnetic	ANSI/AAMI DF39, <0.5mT on surface, except for within 5cm of the lid magnet and the speaker

IMMUNITY

Field	Standard or Compliance	
E-M	IEC 61000-4-3, Level X, (20V/m)	
	IEC 60601-2-4, Section 36.202.3 (20V/m)	
	AAMI DF39. Section 3.3.21.2.1	

IMMUNITY (CON'T)

Field	Standard or Compliance				
Magnetic	IEC 61000-4-8 (2001) IEC 60601-2-4 (2002), Section 36.202.8 AAMI DF39, Section 3.3.21.2.3 80A/m, 47.5Hz – 1,320Hz				
ESD	IEC 61000-4-2, Level 3 IEC 60601-2-4 (2002), Section 36.202.2 6KV contact discharge, 8KV air gap discharge				

ENVIRONMENTAL CONDITIONS

Condition	Standard or Compliance
Free Fall Drop	IEC 60068-2-32 (1975) AM 2 (1990), 1 meter
Bump	IEC 60068-2-29 (1987), 40g and 6000 bumps
Vibration (Random)	IEC 60068-2-64 (1993): 10Hz – 2KHz, 0.005 – 0.0012 g ² /Hz
Vibration (Sine)	IEC 60068-2-6 (1995): 10Hz – 60Hz, 0.15 mm and 60Hz – 150Hz, 2g
Enclosure Protection	IEC 60529 (2001), IP24

SHIPPING AND TRANSPORTATION CONDITIONS

ISTA Procedure 2A

HOW TO PERFORM A RESCUE

Step 1: ASSESS



The patient is unresponsive.

AND

The patient is not breathing.

CALL EMERGENCY MEDICAL SERVICES

When the patient is under 8 years of age or weighs less than 55lbs (25kg), the AED should be used with the Pediatric Attenuated Defibrillation Pads. Therapy should not be delayed to determine the patient's exact age or weight. See the directions for use accompanying pediatric pads for procedure on changing adult pads to pediatric and to change energy protocols.

STEP 2: PREPARE



Open the AED lid.

INSTRUCTIONS FOR USE



- Remove clothing from the patient's chest.
- Ensure the skin site is clean and dry.
- Dry the patient's chest and shave excessive hair if necessary.

STEP 3: PLACE PADS



- Tear open pad package and remove pads.
- Peel one pad from plastic liner.



- Place one pad on bare upper chest.
- Peel second pad and place on bare lower chest as shown.

STEP 4: ANALYZE AND SHOCK DELIVERY

(Model 9300C does not have text prompts)

DO NOT TOUCH PATIENT! ANALYZING RHYTHM. (The voice/text prompts will guide you through.)

"DO NOT TOUCH PATIENT! ANALYZING RHYTHM."

SHOCK



If a shockable rhythm is detected, follow these instructions:

- "SHOCK ADVISED CHARGING"
- "STAND CLEAR! PUSH FLASHING BUTTON TO DELIVER SHOCK."

For the Powerheart AED G3 9300E and FirstSave AED G3 9300C and 9300D:

- "SHOCK DELIVERED"
- IT IS NOW SAFE TO TOUCH THE PATIENT"

For the Powerheart AED G3 Automatic 9300A:

DO NOT TOUCH PATIENT! ANALYZING RHYTHM. (The voice/text prompts will guide you through.)

"DO NOT TOUCH PATIENT! ANALYZING RHYTHM."

If a shockable rhythm is detected, follow these instructions:

STAND CLEAR

- "SHOCK ADVISED, CHARGING."
- "STAND CLEAR! SHOCK WILL BE DELIVERED IN"
- "THREE. TWO. ONE."
- "SHOCK DELIVERED."
- "IT IS NOW SAFE TO TOUCH THE PATIENT."

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

STEP 5: CPR



- When instructed, start CPR
- Give 30 compressions followed by 2 breaths.

At the end of the CPR period, the voice prompts will direct you to repeat steps 4 and 5 if required.

SAFETY TERMS AND DEFINITIONS

BEFORE OPERATING THE CARDIAC SCIENCE AED G3

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 Cardiac Science AED G3.

SAFETY TERMS AND DEFINITIONS

The triangle attention symbol shown below, left, identifies the potential hazard categories. The definition of each category is as follows:



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



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



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

SAFETY ALERT DESCRIPTIONS

The following is a list of Cardiac Science AED safety alerts that appear in this section and throughout this resource guide. You must read, understand, and heed these safety alerts before attempting to operate the AED.



DANGER: Fire and Explosion Hazard

Exercise caution when operating the AED close to flammable gases (including concentrated oxygen) to avoid possible explosion or fire hazard.



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 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: Shock and Possible Equipment Damage

Disconnect all non-defibrillator proof equipment from the patient before defibrillation to prevent electrical shock and potential damage to the equipment.



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 the AED! Failure to observe this warning can result in personal injury or death. Refer maintenance issues to Cardiac Science authorized service personnel.



CAUTION: Temperature Extremes

Exposing the AED to extreme environmental conditions outside of its operating parameters may compromise the ability of the AED to function properly. The RescueReady® daily self-test verifies the impact of extreme environmental conditions on the AED. If the daily self-test determines environmental conditions outside of the AEDs operating parameters, a "SERVICE REQUIRED" alert will be issued to prompt the user to move the AED to environmental conditions within the acceptable operating parameters at once.



CAUTION: Lithium Sulfur Dioxide Battery

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



CAUTION: Battery Disposal

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



CAUTION: Use only Manufacturer Approved Equipment

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



CAUTION: Possible Improper AED Performance

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



CAUTION: Serial Communication Cable

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



CAUTION: Possible Radio Frequency (RF) Susceptibility

RF susceptibility from cellular phones, CB radios and FM 2-way radio may cause incorrect rhythm recognition and subsequent shock advisory. When attempting a rescue using the AED, do not operate wireless radiotelephones within 1 meter of the AED – turn power OFF to the radiotelephone and other like equipment near the incident.



CAUTION: Possible Interference with Implanted Pacemaker

Therapy should not be delayed for patients with implanted pacemakers and a defibrillation attempt should be made if the patient is unconscious and not breathing. The AED has pacemaker detection and rejection, however, with some pacemakers the AED may not advise a defibrillation shock.¹

Placing Pads:

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



CAUTION: Moving the Patient During a Rescue

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



CAUTION: Systems Statement

Equipment connected to the analog and digital interfaces must be certified to the respective IEC standards (i.e. IEC 950 for data processing equipment and IEC 601-1 for medical equipment). Furthermore, all configurations shall comply with the system standard IEC 601-1-1. Anybody who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore, responsible that the system complies with the requirements of the system standard IEC 601-1-1.



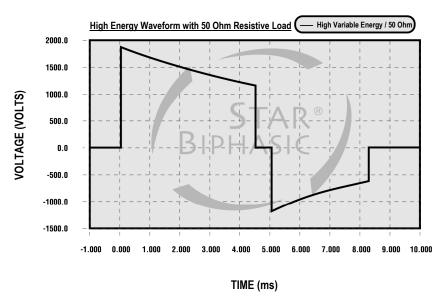
CAUTION: Case Cleaning Solutions

When disinfecting the case, use a non-oxidizing disinfectant, such as ammonium salts or a glutaraldehyde based cleaning solution, to avoid damage to the metal connectors.

¹ Cummins, R., ed., Advanced Cardiac Life Support; AHA (1994): Ch. 4.

STAR BIPHASIC WAVEFORM

The waveform generated by the AED is a Biphasic Truncated Exponential waveform that is compliant with ANSI/AAMI DF2 and DF39. The following is a graph of the waveform voltage as a function of time when the AED is connected to a 50-Ohm resistive load.



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

ENERGY LEVELS

Table A1 - Ultra-Low Variable Energy (150 VE) AED Models 9300 Waveform

	Pha	Phase 1		ise 2	
Patient's Impedance (Ohms)	Voltage* (Volts)	Duration* (ms)	Voltage* (Volts)	Duration* (ms)	Energy** (Joules)
25	1393	3.3	743	3.2	145-196
50	1420	4.5	909	3.2	128-173
75	1430	5.8	973	3.2	116-156
100	1434	7.0	1007	3.2	108-146
125	1437	8.3	1027	3.2	102-138
150	1439	9.5	1040	3.2	98-132
175	1441	10.8	1049	3.2	95-128

Table A2 - Low Variable Energy (200 VE) AED Models 9300 Waveform

	Pha	se 1	Phase 2		
Patient's Impedance (Ohms)	Voltage* (Volts)	Duration* (ms)	Voltage* (Volts)	Duration* (ms)	Energy** (Joules)
25	1609	3.3	858	3.2	193-260
50	1640	4.5	1050	3.2	170-230
75	1651	5.8	1124	3.2	155-209
100	1656	7.0	1163	3.2	144-194
125	1660	8.3	1186	3.2	136-184
150	1662	9.5	1201	3.2	131-176
175	1663	10.8	1212	3.2	126-170

Table A3 - High Variable Energy (300 VE) AED Models 9300 Waveform

	Pha	se 1	Phase 2		
Patient's Impedance (Ohms)	Voltage* (Volts)	Duration* (ms)	Voltage* (Volts)	Duration* (ms)	Energy** (Joules)
25	1869	3.3	997	3.2	260-351
50	1906	4.5	1220	3.2	230-311
75	1918	5.8	1306	3.2	210-283
100	1925	7.0	1351	3.2	195-263
125	1928	8.3	1378	3.2	184-248
150	1931	9.5	1396	3.2	176-238
175	1933	10.8	1408	3.2	170-230

^{*} All values are typical.

^{**} Allowable energy range.

CONTACT INFORMATION



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