POWERHEART® AED

automated external defibrillator

Operation and Service Manual

Cardiac Science

CARDIAC SCIENCE

5 Year Limited Warranty

What is Covered?

Cardiac Science, Inc. (Cardiac Science) warrants to the original purchaser that its products will be free of any defect in material and workmanship according to the terms and conditions of this Five year 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?

Five (5) years from the date of original shipment to original purchaser for all products except those with a date expiration (electrodes and lead acid batteries) and lithium batteries. Products with a date expiration shall be warranted until the expiration date. Lithium batteries shall be warranted a shelf life of Five (5) years from date of shipment. Lithium batteries shall be warranted for an operating life of Two (2) years from the date of installation into a Cardiac Science AED. 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

To qualify for this Limited Warranty, the original purchaser must send the completed Warranty Validation Card within 30 days of original shipment to Cardiac Science, Inc., 5420 Feltl Road, Minneapolis, Minnesota 55343.

To obtain warranty service for your product, call us toll free at (800) 991-5465, or (952) 939-4181 seven days a week, 24 hours a day. Our technical service representative will try to resolve your issue over the phone. If necessary, and in our sole discretion, we will arrange for service or a replacement of our product.

What We Will Do

If your Cardiac Science product contains defects in material or workmanship, and is returned within 30 days of the date it was purchased, at the direction of a technical service representative, we will replace it with a new product of equal value at no charge to you, provided the warranty applies.

If your Cardiac Science product contains defects in material or workmanship and is returned, at the direction of a technical service representative, after 30 days but within the warranty period, Cardiac Science, at its sole discretion, will repair your product or replace it with a new or reconditioned product of the same or similar design. 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 EXPRESS 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 AUTHORIZED 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 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, 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, alterations, unauthorized service, unauthorized product case opening, failure to follow instructions, improper use, abuse, neglect, fire, flood, war or acts of God. Cardiac Science does not warrant your Cardiac Science product to be compatible with any particular other medical device.

This Limited Warranty is Void if…

Any Cardiac Science product is serviced or repaired by any person or entity other than Cardiac Science unless specifically authorized by Cardiac Science;

Any Cardiac Science product case is opened by unauthorized personnel or if a product is used for an unauthorized purpose;

Any Cardiac Science product is used in conjunction with incompatible parts or accessories, including but not limited to batteries. Parts and accessories are not compatible if they are not Cardiac Science products or the functional equivalent.

If The Warranty Period has Expired…

If your Cardiac Science product is not covered by our Limited Warranty, call us toll free at (800) 991-5465, or (952) 939-4181 for advice as to whether we can repair your Cardiac Science product, 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.

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

CARDIAC SCIENCE

5420 Feltl Road
Minneapolis, MN 55343
(800) 991-5465
(952) 939-4181
(952) 939-4191 (FAX)

Limited Warranty Validation Card

Note: This card must be returned in order to validate your limited warranty and to insure traceability.

Prior to usage of this product, we recommend training for your personnel. Please contact the sales representative or dealer from which you purchased this product to arrange training. If you experience difficulty arranging training, please contact Cardiac Science at (952) 939-4181.

Model Number _____ Serial Number _____

Date of Purchase _____ Purchased From _____

Company Name _____

Contact Person _____

Street Address _____

City _____ State _____ Zip Code _____

Telephone Number _____

Extended warranties are available. Please contact your sales representative or dealer or Cardiac Science for the details.

NO POSTAGE
NECESSARY
IF MAILED
IN THE
UNITED STATES

BUSINESS REPLY MAIL
FIRST-CLASS MAIL PERMIT NO. 2135 HOPKINS, MN

POSTAGE WILL BE PAID BY ADDRESSEE

CARDIAC SCIENCE, INC.
5420 FELTL ROAD
HOPKINS MN 55343-9884

Powerheart AED Operation and Service Manual

CAUTION

Powerheart AED is intended for use by or on the order of a Physician or persons licensed by State law.

IMPORTANT

Read this Operation and Service Manual carefully. It contains information about your safety and the safety of others. Become familiar with the controls and their proper use *before* operating the product.

The Powerheart AED Models 9200RD/9210RD are manufactured by:

Corporate Headquarters:
Cardiac Science, Inc.
16931 Millikan Ave.
Irvine, CA 92606 USA

Internet: www.cardiacscience.com
Email: aed@cardiacscience.com

Manufacturer:
Survivalink Corporation (Wholly owned subsidiary of Cardiac Science, Inc.)
5420 Feltl Road
Minneapolis, MN 55343-7982 USA

Authorized European Representive:
Cardiac Science International
Kirke Vaerloesevej 14
3500 Vaerloese Denmark

Trademark Information

Powerheart , ***MDLink***, ***Saving Minutes Saving Lives***, ***SmartGauge, STAR, IntelliSense, RescueReady***, ***RescueLink*** and ***Survivalink*** are trademarks and registered trademarks of Cardiac Science, Inc. ***Microsoft*** and ***Windows*** are registered trademarks of Microsoft Corporation. ***COMPACTFLASH*** is a trademark of SanDisk Corporation.

Limited Warranty

The Powerheart AED Operation and Service Manual and any and all information contained herein does not constitute any warranty as to the Powerheart AED or any related products in any manner whatsoever. The “Limited Warranty” is shipped with the Powerheart AED products and serves as the sole and exclusive warranty provided by Cardiac Science regarding the Powerheart AED.

Customer Service

For Customer Service, call:
(800) 991-5465
(952) 939-4181
(952) 939-2909 (Fax)

Technical Support

For 24-hour service, contact Technical Support at:
(888) 466-8686
(952) 939-4181
(952) 939-4191 (Fax)

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

CE
0123

Notice of Rights

All rights reserved. No part of this documentation may be reproduced or transmitted in any form by any means without the express written permission of Cardiac Science, Inc. Information in this documentation is subject to change without notice. Names and data used in the examples are fictitious unless otherwise noted.

Defibrillator Tracking

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

Table of Contents

Safety
Overview 5
Safety Alert Definitions 6
Safety Alert Descriptions 7
Symbols Descriptions 10

Introduction
Overview 15
Powerheart AED Description 16

Getting Started
Overview 21
Unpacking and Inspecting 22
Powerheart AED 23
Powerheart AED Batteries 25
Electrodes 27
Powerheart AED Indicators 28
Voice Prompt and Text Display Descriptions 32

Instructions for Use
Overview 37
Step 1: Assessment and Electrode Placement 38
Step 2: ECG Analysis 40
Step 3: Shock Delivery and CPR Mode 41
Step 4: Post Rescue 42
Warnings 43

Data Management
Overview 45
Recording Rescue Data 46
Reviewing Rescue Data 47
Transfering Data to a Rescue Data Card 49

 © 2001 Cardiac Science, Inc.

Maintenance & Troubleshooting

Overview 51
Self-Tests 52
Indicator Troubleshooting Table 53
Scheduled Maintenance 55
Authorized Repair Service 57
Frequently Asked Questions 58

Technical Data

Overview 63
Parameters 64
Safety and Peformance Standards 68
Summary of the RHYTHMx Clinical Study 75
Biphasic Clinical Study Summary 78

Accessories

Overview 79
List of Powerheart AED Accessories 80

 © 2001 Cardiac Science, Inc.

Section 1

Safety

Overview

This section presents safety information to guard against injury to persons, and damage to the Powerheart AED.

Topic	Page
Safety Alert Definitions	6
Safety Alert Definitions	7
Symbols Descriptions	10

©2001 Cardiac Science, Inc.

Safety Alert Definitions

Before Operating the Powerheart AED:

Before operating the Powerheart AED, become familiar with the various safety alerts in this section.

Safety alerts identify potential hazards using symbols and words to explain what could potentially harm you, the patient or the Powerheart AED.

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.

The term "Powerheart AED" refers to Models 9200RD/9210RD.

 ©2001 Cardiac Science, Inc.

Safety Alert Descriptions

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

DANGER: Fire and Explosion Hazard

Exercise caution when operating the Powerheart 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 in indicated
- Do not touch metal objects in contact with the patient
- Keep defibrillation electrodes clear of other electrodes or metal parts in contact with the 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.

CAUTION: Possible Radio Frequency (RF) Susceptibility

RF susceptibility from cellular telephones, CB radios, and FM 2-way radio may cause incorrect rhythm recognition and subsequent shock advisory.

When attempting a rescue using the Powerheart AED, do not operate wireless radiotelephones within 1 meter of the Powerheart AED—turn power OFF to the radiotelephone and other like equipment near the incident.

©2001 Cardiac Science, Inc.

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 the rescue.

CAUTION: Use only Cardiac Science Approved Equipment

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

CAUTION: Serial Communications Cable

The Powerheart AED will not perform a rescue when a serial communication cable is connected to its serial connector. The voice prompt will say, "remove cable to continue rescue."

CAUTION: Possible Interference With Implanted Pacemaker

The Powerheart AED may not advise a defibrillation shock when the patient has an implanted pacemaker.[1] However, a defibrillation attempt should be made if the patient:

- Is unconscious and
- Is not breathing a

Placing Electrodes:

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

CAUTION: Lithium Sulfer 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.

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

 ©2001 Cardiac Science, Inc.

CAUTION: Temperature/Humidity/Pressure Extremes

Exposing the Powerheart AED with the battery installed to extremes, outside the following operation and standby conditions, will cause the self-tests to be disabled and could cause the Powerheart AED to function improperly. Storing the Powerheart AED outside the stated temperature conditions for 5 consecutive days will result in a "service required" alert.

- Temperature 0°C to 50°C (32°F to 122°F)
- Humidity 5% to 95% (non-condensing)
- Pressure 57kPa (+15,000 ft) to 170kPa (-15,000 ft)

©2001 Cardiac Science, Inc.

Symbols Descriptions

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

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

Defibrillator Proof Type BF Equipment: The Powerheart AED, when connected to the patient's chest by the electrodes, can withstand the effects of an externally applied defibrillation shock without diverting the shock from the patient or into the Powerheart AED.

CE Mark: This equipment conforms to essential requirements of the Medical Device Directive 93/42/EEC.

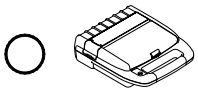
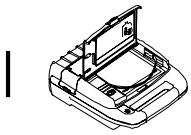
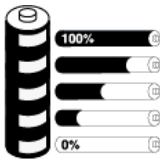
IP23

The Powerheart AED is protected against the effects of splashing water in accordance with IEC 529.

Classified by Underwriters Laboratories Inc. with respect to electric shock, fire and mechanical hazards only in accordance with UL 2601-1 and IEC 601-2-4, IEC SC 62D/WG2 (O'Dowd) and CAN/CSA C22.2 No.601.1-M90.

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

 ©2001 Cardiac Science, Inc.

TSO-C97	FAA TSO marking: This battery conforms to the FAA lithium sulfer dioxide batteries technical standard order, TSO C97.
	International symbol for OFF. Close the lid to turn OFF the Powerheart AED.
	Open the lid to turn ON the Powerheart AED.
	Indicates the Powerheart AED battery status. The shaded areas indicate the remaining battery capacity.
	Check the electrodes. The electrodes are either missing or out of specification. Also, on the electrode packaging, this symbol represents one pair.
	Indicates Powerheart AED requires maintenance by authorized service personnel.
	When lit, push this button to deliver a defibrillation shock.
	When lit: push this button to clear the internal memory to allow storage of new rescue data in the Powerheart AED.

RED with a BLACK **X** means the Powerheart AED requires operator attention or maintenance, and is not RescueReady. For purposes of retaining simple, clear instructions, this symbol will be referred to as RED in the remainder of this manual.

GREEN without a BLACK **X** means the Powerheart AED is RescueReady. For purposes of retaining simple, clear instructions, this symbol will be referred to as GREEN in the remainder of this manual.

Use by or install by date.

Exp. Date

Expiration Date. Replace by this date .

Latex Free.

Disposable. Single patient use only.

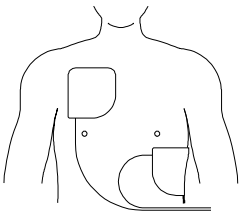
Tear here to open.

Do not recharge battery.

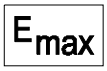
The patient is unresponsive.

 ©2001 Cardiac Science, Inc.

The patient is not breathing.



Place the electrodes on the chest of the patient.



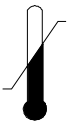
The maximum energy delivered.

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

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.

Serial Number.

©2001 Cardiac Science, Inc.

Lot Number.

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

Points to important information regarding the use of the Powerheart AED.

Lift Here

 ©2001 Cardiac Science, Inc.

Section 2

Introduction

Overview

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

Topic	Page
Powerheart AED Description	16
Indications for Use	16
Contraindications for Use	16
Powerheart AED ECG Analysis Algorithm	17
Powerheart AED Rescue Protocol	19
Powerheart AED STAR Biphasic Waveform	19
Powerheart AED Operator Training Requirements	20

 ©2001 Cardiac Science, Inc.

Powerheart AED Description

The Powerheart AED is a self-testing battery-operated automated external defibrillator (AED). After applying the Powerheart AED's electrodes to the patient's chest, the Powerheart AED automatically analyzes the patient's electrocardiogram (ECG) and advises the user to push the button and deliver a shock if needed. The Powerheart AED uses one button and guides you through the rescue using a combination of voice prompts, audible alerts, and visible indicators.

Indications for Use

The Powerheart AED with STAR Biphasic is intended to be used by personnel who have been trained in its operation. The user should be qualified by training in basic life support or other physician-authorized emergency medical response. The device is indicated for emergency treatment of victims exhibiting symptoms of sudden cardiac arrest who are unresponsive and not breathing. Post-resuscitation, if the victim is breathing, the AED should be left attached to allow for acquisition and detection of the ECG rhythm. If a shockable ventricular tachyarrythmia recurs, the device will charge automatically and advise the operator to deliver therapy. The Powerheart AED with STAR Biphasic is intended to be used on patients older than eight years.

Contraindications for Use

Do not use the Powerheart AED for emergency treatment if the patient is under eight years of age.

 ©2001 Cardiac Science, Inc.

Powerheart AED ECG Analysis Algorithm

The Powerheart AED ECG analysis algorithm, provides superior ECG detection capabilities allowing it to be placed on patients at risk for sudden cardiac arrest. The features available with the Powerheart AED include the following:

- Detection Rate
- Supraventricular Tachycardia (SVT) Rate
- SVT Discriminators
- Asystole Threshold
- Noise Detection
- Continuous Monitoring
- Non-Committed Shock
- Synchronized Shock
- Pacemaker Signal Detection

Detection Rate

All ventricular fibrillation (VF) and ventricular tachycardia (VT) rhythms at or above this rate will be classified as shockable. All rhythms below this rate will be classified as non shockable. The default Detection Rate is 160 bpm (beats per minute). This rate is selectable between 120 bpm and 240 bpm via MDLink Software by the Medical Director.

SVT Rate

All rhythms with rates between the Detection Rate and SVT Rate will be screened through a number of SVT Discriminator to classify them into VF/VT or SVT. Rhythms classified as SVT between the two set rates are not shockable. All rhythms at or above the SVT Rates will be shockable. The default SVT Rate is 200 bpm. The SVT rate must be greater than or equal to the Detection Rate and is selectable between 160 and 240 bpm via MDLink Software by the Medical Director.

SVT Discriminators

These are sophisticated filters that analyze the morphology of the ECG waveforms and distinguish VF/VT from SVT and Normal Sinus Rhythms (NSR). The SVT Discriminator will only be applied to rhythms that fall between the Detection Rate and the SVT Rate.

 ©2001 Cardiac Science, Inc.

Asystole Threshold

The asystole peak to peak threshold is set at 0.08 mV. ECG rhythms at or below 0.08mV will be classified as Asystole and will not be shockable.

Noise Detection

The Powerheart AED will detect noise artifact in the ECG. Noise could be introduced by excessive moving of the patient or electronic noise from external sources like cellular and radio telephones. When noise is detected, the Powerheart AED will issue the prompt "*Analysis interrupted. Stop Patient Motion*" to warn the user. The Powerheart AED will then proceed to reanalyze the rhythm and continue with the rescue.

Continuous Monitoring

Powerheart AED monitors the ECG rhythms continuously throughout the rescue including during Charge and CPR mode. Continuous Monitoring will interrupt CPR if a shockable rhythm is detected. When CPR is interrupted, the prompt "*Do not touch patient. Analyzing rhythm*" will be issued. Only one interruption will be allowed during a single CPR mode. CPR mode will not be interrupted if preceded by three consecutive shocks.

Non-Committed Shock

After the Powerheart AED advises a shock, it continues to monitor the patient ECG rhythm. If the patient's rhythm changes to a non-shockable rhythm before the actual shock is delivered, the Powerheart AED will advise that the rhythm has changed and issue the prompt "*Rhythm changed. Shock cancelled.*" The Powerheart AED will then be disarmed and the ECG reanalyzed.

Synchronized Shock

Powerheart AED is designed to synchronize shock delivery on the R-wave. ***The operator must press and hold the Shock button for one second to deliver a synchronized shock.*** <u>If delivery cannot be synchronized within one second, a non-synchronized shock will be delivered.</u>

 ©2001 Cardiac Science, Inc.

Powerheart AED Rescue Protocol

The Powerheart AED rescue protocol is consistent with the guidelines recommended by the American Heart Association (AHA)[1] and the International Liaison Committee on Resuscitation (ILCOR).

Upon detecting a shockable cardiac rhythm, the Powerheart AED advises you to press the "Shock" button to deliver a series of up to 3 defibrillation shocks followed by performing 1 minute of CPR.

The 3 defibrillation shocks are delivered in a pre-programmed sequence of escalating biphasic energies in the default configuration.

Note: *The CPR protocol can be modified, such that from 1 to 3 minutes, in increments of 5 seconds, of CPR may be administered if the first analysis is non-shockable or following two consecutive non-shockable analysis decisions***.**

Powerheart AED STAR Biphasic Waveform

The Powerheart AED STAR Biphasic Waveform is designed to measure the patient's impedance and deliver a customized shock. This allows the delivery of an optimized energy level to each patient. The energy levels for the Powerheart AED are available in three different defibrillation shock[2] configurations. See table below.

9200RD/9210RD AED Configurations	Defibrillation Shock[2]		
	1st Shock	2nd Shock	3rd Shock
Standard Variable Energy (VE)	Low VE	Low VE or High VE	High VE
Low Variable Energy	Ultra-Low VE	Ultra-Low VE or Low VE	Low VE
Non-escalating Variable Energy	Low VE	Low VE	Low VE

1. "Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care" American Heart Association; 2000. Suppl. Circulation 102(8). August 22, 2000
2. The ultra-low current, low current and high current shocks are variable energy. The actual energy is determined by the patient's impedance.

©2001 Cardiac Science, Inc.

Powerheart AED Operator Training Requirements

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

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

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

 ©2001 Cardiac Science, Inc.

Section 3

Getting Started

Overview

This section presents information on unpacking and setting up the Powerheart AED.

Topic	Page
Unpacking and Inspecting	22
Powerheart AED	23
Batteries	25
Electrodes	27
Powerheart AED Indicators	28
Setting Clock	30
Voice Prompts and Text Display	32

 ©2001 Cardiac Science, Inc.

Unpacking and Inspecting

Every attempt is made to ensure your order is accurate and complete. However, to be sure that your order is correct, verify the contents of the box against your packing slip.

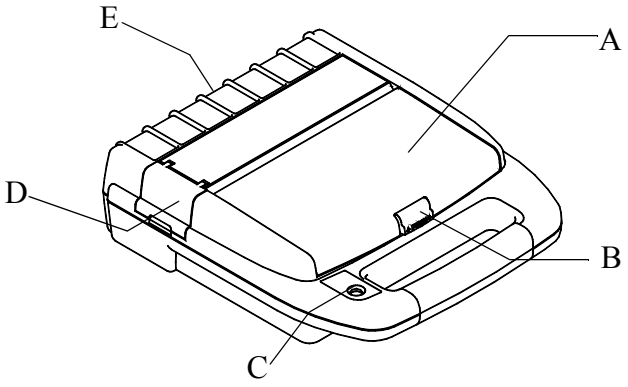
If you have any question about your order, contact our Customer Service Department at: (800) 991-5465 or (952) 939-4181 or your local distributor. For customers from countries outside of the United States, contact your local distributor.

 ©2001 Cardiac Science, Inc.

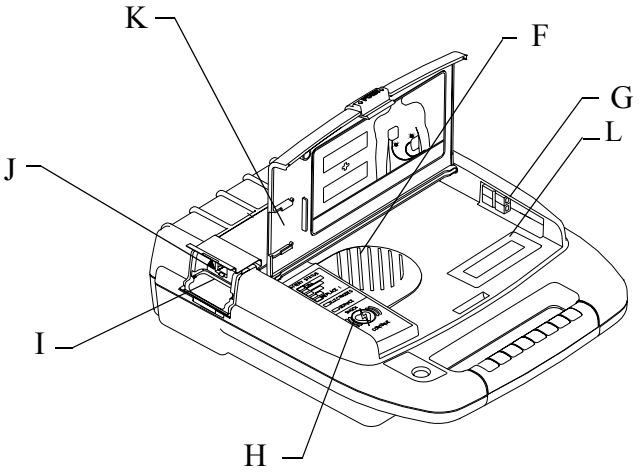
Powerheart AED

The following drawings show the Powerheart AED parts and their locations.

A = Lid
B = Latch (push in and up to open)
C = Status indicator
D = Data access door
E = Battery compartment



F = Speaker
G = Electrode connector
H = Diagnostic panel
I = Card Slot (model 9210RD)
J = Serial communication port
K = Spare flash card storage
L = Text display



The Powerheart AED has three modes of operations:

Operating Mode **-** is defined as having the battery installed and the lid open. This is the mode the Powerheart AED would be in during an actual rescue situation.

 ©2001 Cardiac Science, Inc.

Standby Mode - is when the battery is installed, but the lid is closed. In this mode the Powerheart AED is not being used in a rescue, the device will conduct its routine self-tests to ensure proper operation.

Storage Mode - is when the battery is removed, such as during shipping or transport. With the battery removed, the Powerheart AED is unable to perform self-tests or rescues.

Powerheart AED Operating and Standby Conditions

Temperature	0°C to 50°C (32°F to 122°F)
Humidity	5% to 95% (non-condensing)
Atmospheric Pressure	57kPa to 170kPa

CAUTION: Temperature/Humidity/Pressure Extremes

Exposing the Powerheart AED with the battery installed to extremes, outside the operation and standby conditions, will cause the self-tests to be disabled and could cause the Powerheart AED to function improperly. Storing the Powerheart AED outside these conditions for 5 consecutive days will result in a “service required” alert.

Powerheart AED Shipping and Transport Conditions

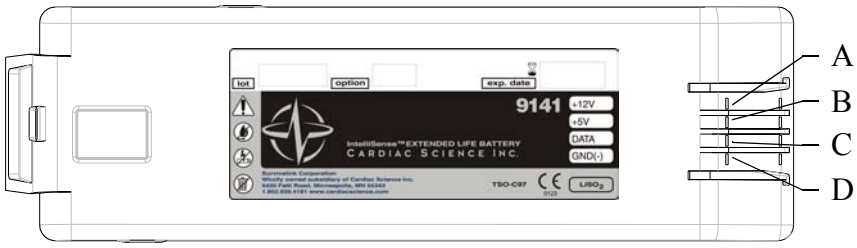
(for up to 1 week)

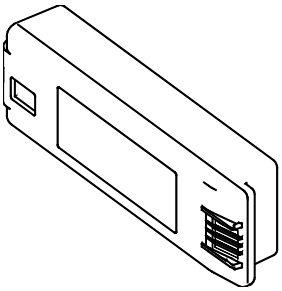
Temperature w/o Display	-40°C to 65°C (-40°F to 149°F)
Temperature w/Display	-30°C to 65°C (-22°F to 149°F)
Humidity	5% to 95% (non-condensing)
Atmospheric Pressure	57kPa to 170kPa

 ©2001 Cardiac Science, Inc.

Powerheart AED Batteries

A = +12V
B = +5V
C = DATA
D = GND (-)





The Cardiac Science IntelliSense battery technology offers your the most advanced battery capabilities available for defibrillators. The Cardiac Science IntelliSense batteries contain an integrated memory chip that automatically stores important usage information, enabling the battery to maintain a complete history of its operation life. The actual battery history can be reviewed using the RescueLink software. This history includes:

- Battery Identification
- Battery Type
- Original Date of Installation in an AED
- Number of Charges Completed
- Time in Operation (hours:minutes)
- Days of Standby Operation
- Battery Capacity Remaining

Battery Operating Life

The expected life of a Cardiac Science battery is defined as the number of years the battery can be expected to last when installed in the Powerheart AED. The expected life will decrease as the Powerheart AED is used in Operating Mode.

The following table represents the expected life of the Powerheart AED when used in Standby Mode.

Model	Estimated Shelf Life	Estimated Operating Life
9141 Extended Life Lithium	5	5 years

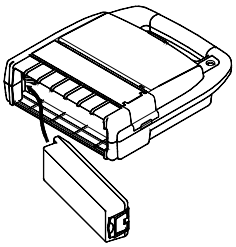
 ©2001 Cardiac Science, Inc.

Battery Shelf-Life

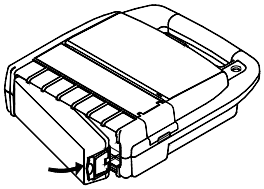
All Cardiac Science batteries have a shelf-life of five years. Shelf-life is defined as the length of time a battery can be stored, prior to installation into the Powerheart AED, without degrading its performance.

Note: Storing the battery outside its specific range (0-50 ^{o}C) will decrease battery life.

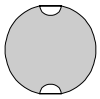
Battery Installation



1. With the label on the battery facing the Powerheart AED battery compartment, insert the battery as shown in the drawing.



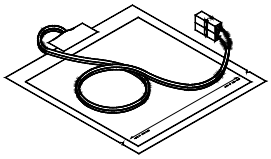
2. Push the latched end of the battery firmly into the Powerheart AED, as shown in the drawing, until the battery snaps into place. The exposed side of the battery should be flush with the outside of the Powerheart AED case.



3. Open the lid for 5 seconds to initiate self test. If the battery is installed properly, the Status indicator will turn GREEN. Close the lid.

 ©2001 Cardiac Science, Inc.

Electrodes



The electrodes come in a ready-to-use sealed package, containing one pair of self-adhesive electrodes with an attached cable and connector. The electrodes are disposable and should be thrown away after one rescue.

The electrodes have a limited shelf-life and should not be used beyond the expiration date. Keep a fresh pair of electrodes plugged into the Powerheart AED at all times. Refer to the electrode package label for operation temperatures.

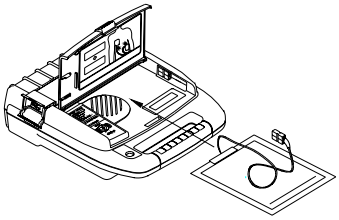
An audible alert will be heard after the daily self-test if the electrodes are missing, damaged, or unplugged.

CAUTION: Possible Improper AED Performance

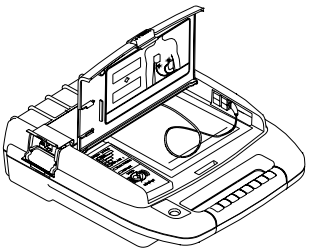
Using electrodes that are damaged or expired may result in improper AED performance. Examine the electrodes before use. The electrode package seal should be intact and the electrode expiration date should not be expired.

Electrode Installation

1. Remove one of the expiration-date stickers from the surface of the electrode package and apply it to the outside of the Powerheart AED. The expiration date of the electrodes will then be readable without opening the lid of the Powerheart AED.



2. Open the lid of the Powerheart AED.
3. Match the color code of the connectors (red to red), then slide the electrode connector along the recess in the Powerheart AED case as shown in the drawing, until the electrode connector fully mates to the connector of the Powerheart AED.
4. Slide the electrode package fully into the Powerheart AED electrode compartment, inserting the cable end first, as shown in the drawing.

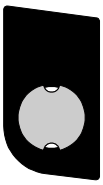


5. Loop the excess cable length as shown in the drawing. With the electrode package completely under the Powerheart AED lid, close the lid.
6. Check to make sure that the Status Indicator is GREEN.

 ©2001 Cardiac Science, Inc.

Powerheart AED Indicators

The following indicators are located on the Powerheart AED.



Status Indicator

The status indicator is located on the Powerheart AED handle. When this indicator is GREEN, the Powerheart AED is RescueReady. This means the Powerheart AED self-tests have verified the following:

- Battery has an adequate charge
- Electrodes are properly connected and in working order
- Integrity of the internal circuitry is good

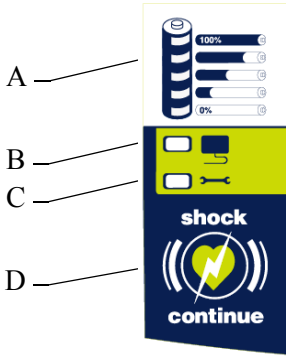
When the “Status indicator” is RED, maintenance is required.

Audible Maintenance Indicator

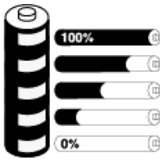
When the daily or monthly self-tests determines maintenance is required, an audible beep is sounded every 30 seconds, until the lid is opened, the battery is removed, or the battery power is depleted. Opening and closing the lid will deactivate the beep. If the error is not corrected by the next automatic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

Diagnostic Panel

A - SmartGauge Battery Status Indicator
B - Electrode Indicator
C - Service Indicator
D - Shock/Continue Button



 ©2001 Cardiac Science, Inc.



SmartGauge Battery Status Indicator

The SmartGauge Battery Status indicator has five (5) LEDs, four (4) GREEN and one (1) RED. The top four GREEN LEDs display the remaining capacity of the battery much like a fuel gauge. With use, the GREEN LEDs gradually go out, from top to bottom, as battery capacity decreases. When the green LEDs go out and the bottom RED LED lights up, replace the battery.

When the bottom RED LED initially lights up, upon lid open or at any time during a rescue, a "*Battery low*" prompt will be issued once. However, the Powerheart AED should still be capable of delivering approximately 9 more defibrillation shocks.

When the Powerheart AED battery cannot deliver any more shocks, it continuously repeats the "*Battery low*" prompt. To continue the rescue, leave the lid "Open", remove the battery and replace with a fresh battery within 60 seconds. If battery replacement is longer than 60 seconds the first rescue will be terminated and a second rescue will begin upon opening the lid.

Electrodes Indicator

The "Electrodes" LED lights up when the electrodes are:

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

Service Indicator

The "Service" LED lights up when the Powerheart AED requires maintenance that can only be performed by qualified service personnel.

Shock/Continue Button

The Powerheart AED has one button called the "Shock/Continue" button; it is used for all operations. This button is located on the diagnostic panel and serves two functions:

- Delivers a defibrillation shock (Shock)
- Clears the internal memory of previous rescue data so that new rescue data can be stored (Continue)

 ©2001 Cardiac Science, Inc.

Shock Indicator

The word “Shock” and the shock button indicator LEDs will illuminate RED when the Powerheart AED is ready to deliver a defibrillation shock to the patient.

Continue Indicator

The word “Continue” will illuminate YELLOW and the continue button indicator LEDs will illuminate RED when the internal and external memory are full at the start of a rescue.

SHOCKS X X:XX
ANALYZING RHYTHM

*Text Display*Text DisplayText DisplayText Display

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

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

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

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

Setting the Clock

Prior to using the Powerheart AED, the internal clock should be set to the correct date and local time. The Powerheart AED will automatically adjust itself for daylight savings time. This feature can be turned off using the Cardiac Science MDLink software. To set the clock, you will need a Windows 95 or newer PC, RescueLink software installed, and Powerheart AED serial cable connected to the PC.

To set the clock settings:

1. Ensure that the PC is set at the correct local time and date.
2. Open the Rescuelink software.

 ©2001 Cardiac Science, Inc.

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

©2001 Cardiac Science, Inc.

Voice Prompt and Text Display Descriptions

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

The following table lists the voice and text prompts and a description of when the prompts are issued.

Voice Prompt	Text Display	Prompt Issued
Place electrodes on patient's bare chest	PLACE ELECTRODES ON BARE CHEST	When the lid is opened the phrase repeats every 5 seconds until the electrodes are placed on the patient
Do not touch patient! Analyzing rhythm	DO NOT TOUCH PATIENT ANALYZING RHYTHM	When the Powerheart AED is analyzing the cardiac rhythm of the patient.
Shock advised. Charging	SHOCK ADVISED CHARGING	When the Powerheart AED is preparing to deliver a defibrillation shock.
Stand clear! Push flashing button to deliver shock	STAND CLEAR PUSH BUTTON TO SHOCK	After the Powerheart AED is fully charged and ready to deliver the defibrillator shock. The RED "Shock" indicator flashes and the phrase repeats for 30 seconds or until you push the "Shock" button.
Check for signs of circulation. If no circulation start CPR	IF NO CIRCULATION START CPR	• After the Powerheart AED delivers 3 consecutive defibrillation shocks • After the Powerheart AED detects a non-shockable cardiac rhythm during cardiac rhythm analysis • When 2 1/2 minutes or more has elapsed since CPR was last administered.

 ©2001 Cardiac Science, Inc.

Voice Prompt	Text Display	Prompt Issued
Check electrodes	CHECK ELECTRODES	If the electrodes become detached from the patient or the Powerheart AED during a rescue. The rescue will continue after you correct the electrode placement problem.
Battery low	BATTERY LOW	Occurs once when the battery voltage becomes low, although a rescue can continue for approximately 9 more shocks. When the battery is too low to do a rescue, the phrase repeats continuously. You must replace the battery before continuing with the rescue. If completely depleted, all Powerheart AED activity will terminate.
Analysis interrupted. Stop patient motion	ANALYSIS INTERRUPTED. STOP PATIENT MOTION	When the Powerheart AED detects ECG noise artifact. Stop moving or touching patient. Remove other electronic devices within a 5 meter radius.
Rhythm changed. Shock cancelled.	SHOCK CANCELLED	When the Powerheart AED detects a change in rhythm when the device is prepared to shock.
Push flashing button to erase data and perform rescue	PUSH BUTTON TO ERASE	When the internal memory and data card are full, the Yellow Continue button will flash and the phrase will repeat. To stop this prompt, push the button or insert a blank Rescue Data Card (for 9210RD).
Data in Memory	DATA IN MEMORY	Data Prompt
Card full! Storing internally	CARD FULL STORING INTERNALLY	When the Rescue Data Card, in the Powerheart AED Model 9210RD, is full. The rescue data will be stored in the internal memory of the Powerheart AED.

 ©2001 Cardiac Science, Inc.

Voice Prompt	Text Display	Prompt Issued
Remove cable to continue rescue	REMOVE CABLE	When a serial communication cable is connected to the Powerheart AED during a rescue, the phrase repeats until the cable is disconnected.
Communications Mode	COMMUNICATIONS MODE	When the lid is open with a serial communications cable plugged into the Powerheart AED.
Program Mode	PROGRAM MODE	• When downloading the rescue-event data from the internal memory of the Powerheart AED to a blank Rescue Data Card (see Data Management section) • When using the MDLink Options Card (see MDLink manual)
Audible alerts		"Two-Tone Beep" occurs after inserting the Rescue datacard or an MDLink option card. Also occurs in 15-second intervals during CPR when enabled by the MDLink software program. "Warble Beep" occurs when the Powerheart AED requires maintenance.
Continue CPR	CONTINUE CPR	During CPR mode when enabled, or when a rescue is resumed in CPR mode after being interrupted by the lid closing.
Service required	SERVICE REQUIRED	Occurs after the self-tests determine that the Powerheart AED is not functioning properly. The prompt "*Service required*" will be heard when the lid is opened. The RED "Service" indicator will illuminate and *"Service required"* will repeat until you close the lid. After closing the lid, an alarm beep will be heard until the battery is removed or becomes completely depleted.

 ©2001 Cardiac Science, Inc.

Section 4

Instructions for Use

Overview

This section presents information about how to use the Powerheart AED to perform a rescue.

Topic	Page
Step 1: Assessment and Electrode Placement	38
Step 2: ECG Analysis	40
Step 3: Shock Delivery and CPR Mode	41
Step 4: Post Rescue	42
Warnings	43

 ©2001 Cardiac Science, Inc.

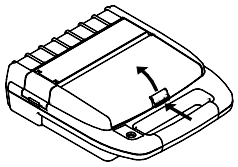
Step 1: Assessment and Electrode Placement

Preparation

Determine that the patient is over 8 years of age and exhibit all of the following:

The patient is unresponsive.

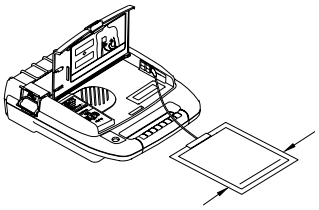
The patient is not breathing.



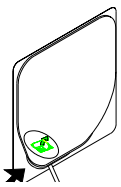
Remove clothing from the patient's chest. Dry the patient chest and shave excessive hair if necessary.

Open the Powerheart AED lid and wait until the LEDs are lit."

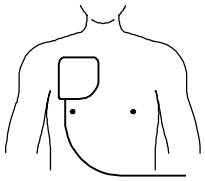
Place Electrodes



The Powerheart AED will issue the prompt "*Place electrodes on patient's bare chest*". Keep the electrodes connected to the Powerheart AED, tear the outer electrode package along the dotted line, and remove the electrodes from the package. Leave the package attached to the electrode wires.



With a firm, steady pull, carefully peel one electrode away from the release liner.



Place the electrode with the sticky side on the patient's skin on the upper right chest, placing the top of the electrode on the collarbone. Avoid placing the electrode directly over the sternum.

With a firm, steady pull, carefully peel the other electrode away from the release liner. Place the other electrode on the lower left chest, below the left breast.

Note: Cardiac Science's standard defibrillation electrodes are not polarized and can be placed in either position as shown on the electrode package. When using pacing/monitoring electrodes, refer to the placement instructions on the pacing/monitoring electrode package.

When the electrodes are placed, the voice prompt will say, *"Do not touch patient. Analyzing rhythm"*. If the electrodes are not properly placed or become disconnected at any time during the rescue, the voice prompt will say, *"Check electrodes"*. When this occurs, ensure that the:

a. Electrodes are firmly placed on clean dry skin.

b. Electrode cable is securely plugged into the Powerheart AED.

©2001 Cardiac Science, Inc.

Step 2: ECG Analysis

As soon as the Powerheart AED detects proper electrode placement, the voice prompt will say, ***"Do not touch patient. Analyzing rhythm."*** The Powerheart AED will begin to analyze the cardiac rhythm of the patient.

If a shock is advised, the voice prompt will say, ***"Shock Advised. Charging".*** Once the AED is armed a tone will be emitted. When the Powerheart AED is ready to deliver a defibrillation shock, the Shock button will flash and the prompt, ***"Stand clear. Push flashing button to deliver shock"*** will be heard. The tone, flashing button, and voice prompt will continue until the shock is delivered or change in rhythm is detected, or 30 seconds elapse.

When the Powerheart AED is charged, it continues to analyze the patients heart rhythm. If the rhythm changes and a shock is no longer needed, the Powerheart AED will issue the prompt "*Rhythm changed. Shock canceled*", disarm and reanalyze.

If no shock is advised, the Powerheart AED will prompt to start CPR with the prompt "*Check for Signs of Circulation. If no Circulation, Start CPR*".

If noise is detected during analysis, the Powerheart AED will warn you with the prompt, "*Analysis interrupted. Stop Patient Motion*" and restart the analysis. This usually occurs if the patient is excessively jostled or there is a strong electromagnetic emitting electronic device nearby (within 5 meters). Remove the electronic device or stop the excessive motion when you hear this prompt.

 ©2001 Cardiac Science, Inc.

Step 3: Shock Delivery and CPR Mode

When the Powerheart AED is ready to deliver a defibrillation shock, the Shock button will flash and the prompt will say, **"***Stand clear. Push flashing button to deliver shock***"**.

Make sure no one is touching the patient and **push the Shock button to deliver the defibrillation shock**. If you do not push the Shock button within 30 seconds of hearing the prompt, the Powerheart AED will disarm and reanalyze the cardiac rhythm.

After the Powerheart AED delivers the first defibrillation shock, it reanalyzes the patients rhythm to determine if the shock is successful. If the Powerheart AED determines that a shockable cardiac rhythm still exists, it will continue to guide you through additional shocks as needed following the AHA and ILCOR protocol.

Note: During a rescue, the text screen displays voice prompts, elapsed time of rescue and number of shocks delivered.

CPR Mode

After delivery of three consecutive defibrillation shocks or detection of a non-shockable rhythm, the Powerheart AED automatically enters CPR mode. The voice prompt will say, *"Check for signs of circulation. If no circulation, start CPR."*. Perform CPR if the patient is not responsive and not breathing.

During this time-out for CPR, the Powerheart AED will continue to monitor the patient's heart rhythm. If the patient's condition changes and the Powerheart AED detects a shockable rhythm during the CPR period, the voice prompt will say "*Rhythm changed. Shock canceled."* followed by *"Do not touch patient. Analyzing rhythm.*"

After delivery of 3 consecutive shocks, the Powerheart AED automatically enters a mandatory CPR timeout period. During this timeout, the PH AED will not interrupt the CPR mode if the patient's condition changes and the PH AED detects a shockable rhythm during the CPR period. After the CPR timeout period has expired, the voice prompt will say, "Do not touch patient. Analyzing rhythm.".

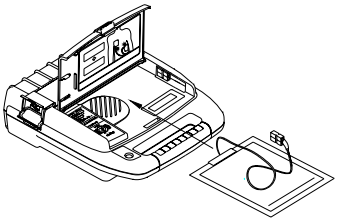
Note: During CPR mode, the text screen displays a count down timer.

If the patient is conscious and breathing normally, leave the electrodes on the patient chest connected to the Powerheart AED. Make the patient as comfortable as possible and wait for Advanced Life Support (ALS) personnel to arrive. Continue to follow the voice prompts until the ALS personnel arrive, or proceed as recommended by the Medical Director

 ©2001 Cardiac Science, Inc.

Step 4: Post Rescue

After transferring the patient to ALS personnel, prepare the Powerheart AED for the next rescue:



1. Retrieve the rescue data stored in the internal memory of the Powerheart AED or from a Rescue Data Card by using RescueLink software installed on a PC (see detailed procedure in the Data Management section).
2. Erase the internal memory of the Powerheart AED or the Rescue Data Card (for Model 9210RD) for a new rescue or insert the blank Rescue Data Card into the Powerheart AED card slot.
3. Connect a new pair of electrodes to the Powerheart AED.
4. Remove one of the electrode expiration date stickers from the electrode package. Place it on the outside surface of the Powerheart AED. where it can be viewed without opening the lid.
5. Close the lid.
6. Verify that the “Status” indicator on the Powerheart AED handle is GREEN.

Warnings

The following cautions must be observed to prevent problems during the rescue.

CAUTION: Fire and Explosion Hazard

Exercise caution when operating the Powerheart AED close to flammable gases to avoid possible explosion or fire hazard.

CAUTION: Possible Radio Frequency (RF) Susceptibility

RF susceptibility from cellular telephones, CB radios, and FM 2-way radio may cause incorrect rhythm recognition and a subsequent shock advisory.

When attempting a rescue using the Powerheart AED, do not operate wireless radiotelephones within one meter of the Powerheart AED—turn power OFF to the radiotelephone and other like equipment near the incident.

CAUTION: Serial Communication Cable

The Powerheart 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 Powerheart AED during a rescue, the prompt will say ***"Remove cable to continue rescue"*** until you remove the serial communication cable from the Powerheart AED.

CAUTION: Possible Interference With Implanted Pacemaker

The Powerheart AED *may not* advise a defibrillation shock when the patient has an unipolar implanted pacemaker.[1] However, a defibrillation attempt should be made with the following precautions:

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

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

Section 5

Data Management

Overview

The Powerheart AED is designed for ease of data management and review. The data stored in the Rescue Data Card or internal memory can be displayed on the PC screen using the RescueLink Software.

Topic	Page
Recording Rescue Data	46
Reviewing Rescue Data	47

 ©2001 Cardiac Science, Inc.

Recording Rescue Data

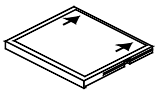
Recording Data in Internal Memory

The Powerheart AED automatically stores up to 20 minutes of rescue data when no external memory source is available.

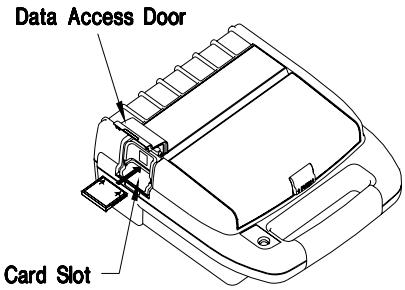
If the internal memory is full when a rescue is attempted, the voice prompt will say "*Data in memory. Push flashing button to erase data and perform rescue*." Pressing the "Continue" button will erase the data and allow the rescue attempt to continue.

Note: Do not press the "Continue" button unless you are sure you want to erase the internal memory in the Powerheart AED.

Recording on a Rescue Data Card



Powerheart AED model 9210RD come equipped with a Rescue Data Card slot. An eight megabyte (8MB) Rescue Data Card can store up to 10 hours of ECG and event data, or up to 40 minutes of ECG, event data and voice recording.



Installing the Rescue Data Card

1. Open the data access door
2. Insert the Rescue Data Card (arrow side up) by sliding it into the card slot with the arrows pointing toward the Powerheart AED.
3. Firmly seat the Rescue Data Card and close the data access door.

Only one rescue at a time can be stored on the Rescue Data Card.

 ©2001 Cardiac Science, Inc.

Reviewing Rescue Data

Retrieving Data from Internal Memory

1. Connect the serial cable (supplied with your RescueLink software) to the PC and to the AED's serial port under the data access door.
2. Open the RescueLink software program.
3. Open the Powerheart AED lid. The voice prompt will say "*Communications Mode.*"
4. Select "Communications, Get Rescue Data."
5. Select "Internal Memory of AED" then select "OK"

Retrieving Data From a Rescue Data Card

There are 3 ways to retrieve data from a Rescue Data Card:

- Inserting the Rescue Data Card into a compact flash card reader on a personal computer.
- Inserting the Rescue Data Card into the Powerheart AED card slot, connecting the Powerheart AED to a PC using the serial communication cable and retrieving the data.
- Inserting the Rescue Data Card into an adapter that fits into the PCMCIA drive in the PC.

To retrieve the data from the Rescue Data Card to the PC for review:

1. Open the RescueLink program.
2. If downloading from the Powerheart AED, connect the serial cable then open the lid. The voice prompt will say "*Communications Mode.*"
3. Select "Communications, Get Rescue Data."
4. Select "PC Card" for the compact flash card reader and the PCMCIA drive or click "Rescue Card in Computer's Card Socket" if downloading via the Powerheart AED.
5. Select "OK."
6. Select "Communications, Clear Rescue Data" to erase the data from the Rescue Data Card in preparation for the next rescue.

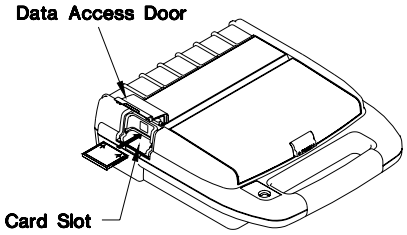
 ©2001 Cardiac Science, Inc.

More information on retrieving and erasing data can be found in the RescueLink Online Help Files.

 ©2001 Cardiac Science, Inc.

Transferring Data to a Rescue Data Card

Rescue data can be transferred from the Powerheart AED's internal memory to a blank Rescue Data Card. To transfer the rescue data from internal memory to a rescue data card:



1. Close the Powerheart AED lid.
2. Open the data access door.
3. Insert a blank Rescue Data Card into the card slot.
4. Open the lid.
5. Hold down the "Shock/Continue" button. When the GREEN "Battery Status" indicators begin to rapidly sequence, the rescue data will transfer the from the Powerheart AED's internal memory to the Rescue Data Card. The voice prompt will say, *"Program mode."*

Note: While transferring data to a rescue card, the Powerheart AED is equipped with the optional text display will display the following: "COPYING DATA TO CARD".

To prevent loss of data, press the "Shock/Continue" button only while the "Battery Status" indicators are sequencing.

6. When the data transfer is complete, the voice prompt will say, **"***Card full. Storing internally."* Remove the Rescue Data Card from the card slot.
7. Close the lid and data access door.

More information on retrieving and erasing data from a Rescue Data Card can be found in the RescueLink Online Help Files.

©2001 Cardiac Science, Inc.

Section 6

Maintenance & Troubleshooting

Overview

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

Topic	Page
Self-Tests	52
Indicator Troubleshooting Table	53
Scheduled Maintenance	55
Authorized Repair Service	58
Frequently Asked Questions	59

 ©2001 Cardiac Science, Inc.

Self-Tests

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

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

- Turns itself ON, and the Status Indicator changes to RED
- Performs the self-test
- If successful, the Status Indicator reverts to GREEN
- Turns itself OFF

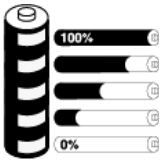
There are two types of automatic self-tests. Both occurr at 03:03 am. The **Daily Self-Test** checks the battery, electrode and the majority of the electronic components. The **Monthly Self-Test** takes place every 28th day in place of the Daily Self-Test. During the Monthly Self-Test, the *high voltage circuitry* is tested in addition to the components tested during the Daily Self-Test.

Self-tests will be initiated upon opening the lid and again upon closing the lid. If the self-test detects an error, the Status Indicator will remain RED. Upon closing the lid, an audible alert will be issued. The Diagnostic Panel under the lid will indicate the source of the problem according to the Indicator Troubleshooting Guide Table below.

The self-tests do not eliminate the need for scheduled maintenance.

Indicator Troubleshooting Table

The following is a troubleshooting table for the Powerheart AED indicators.

	Symptom	Solution
	RED “Service” indicator (LED) is lit.	Maintenance by authorized service personnel is required. Call Cardiac Science Technical Support. (888) 466-8686 or (952) 939-4181 or your local Cardiac Science distributor.
	RED “Electrodes” indicator (LED) is lit.	Connect the electrodes or replace with a new pair.
	The last battery indicator (LED) is RED.	The battery is low. Replace with a new battery.
	Status indicator is RED, and no other indicators on the diagnostic panel are lit.	The battery power is completely depleted. Replace with a new battery. If status indicator remains RED, refer Powerheart AED for maintenance. Call Cardiac Science Technical Support or your local Cardiac Science distributor.

CAUTION: Temperature/Humidity/Pressure Extremes

Exposing the Powerheart AED, with the battery installed, to extremes outside the following operation and standby conditions will cause the self-tests to be disabled and could cause the Powerheart AED to function

 ©2001 Cardiac Science, Inc.

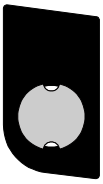
improperly. Storing the Powerheart AED outside these conditions for 5 consecutive days will result in a “service required” alert.

- Temperature 0°C to 50°C (32°F to 122°F)
- Humidity 5% to 95% (non-condensing)
- Pressure 57kPa (+15,000 ft.) to 170kPa (-15,000 ft.)

 ©2001 Cardiac Science, Inc.

Scheduled Maintenance

Daily Maintenance



Check the “Status” indicator to ensure that it is GREEN. When the indicator is GREEN the Powerheart AED is ready for a rescue. If the indicator turns RED, refer to the Troubleshooting Table in this chapter.

Monthly Maintenance

1. Open the Powerheart AED lid.
2. Observe the change of the “Status” indicator to RED.
3. After less than 5 seconds, verify that the “Status” indicator returns to GREEN.
4. Observe the expiration date on the electrodes.
5. Listen for voice prompts.
6. Close lid and confirm the “Status indicator remains GREEN.

Annual Maintenance

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

Check the Integrity of the Electrodes and Circuitry

1. Open the Powerheart AED lid.
2. Remove the electrodes.
3. Close the lid.
4. Confirm that the “Status” indicator turns RED.
5. Open the lid and confirm that the “Electrode” indicator is lit.
6. Reconnect the electrodes and close the lid.
7. Verify that the “Status” indicator turns to GREEN.

©2001 Cardiac Science, Inc.

8. Open the lid and confirm that no diagnostic indicators are lit.
9. Check the expiration date for the electrodes; if expired, replace them.
10. Check the electrode's packaging integrity.
11. Close the lid.

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

1. Immediately after opening the Powerheart AED lid, press and hold the "Shock/Continue" button and confirm that the "Service" LED is lit.
2. Release the "Shock/Continue" button.
3. Close the lid.
4. Verify that the "Status" indicator returns to GREEN.
5. Open the lid and confirm that no diagnostic indicators are lit.
6. Close the lid.

Check the Integrity of the Case

Examine the molded case of the Powerheart AED for any visible signs of stress. If the case shows signs of stress, contact Cardiac Science Technical Support at one of the following telephone numbers:

(888) 466-8686

(952) 939-4181

or contact your local Cardiac Science distributor.

Cleaning the Powerheart AED Case

Gently clean the surface of the Powerheart AED case with a damp sponge or with a cloth and mild soap.

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.

 ©2001 Cardiac Science, Inc.

Check the AED Internal Clock

1. Ensure that the PC is set at the correct local time and date.
2. Open the Rescuelink software.
3. Connect the cable to the serial port on the AED with the AED lid closed.
4. Open the lid of the AED, and verify that the voice prompt states: “Communication Mode”.
5. Click “Options” on the main menu. Select “AED Date/Time”.
6. Click on the “Get” button to review the current time in the AED.
7. If the time and date is incorrect, click “Set” to set new time and date. The the AED date and time will automatically be updated to the PC’s time and date.

©2001 Cardiac Science, Inc.

Authorized Repair Service

The Powerheart AED has no user-serviceable internal components. Try to resolve any maintenance issues with the Powerheart AED by using the Troubleshooting Table presented in this chapter. If you are unable to resolve the problem, contact Cardiac Science Technical Support for repair information at one of the following telephone numbers:

(888) 466-8686

(952) 939-4181

or contact your local Cardiac Science distributor.

Warning: Shock hazard

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

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

 ©2001 Cardiac Science, Inc.

Frequently Asked Questions

		Questions and Answers
1.	Q	Can I give CPR while the Powerheart AED is analyzing?
	A	No. As with all AEDs, the rescuer should stop CPR compressions during the analysis phase.
2.	Q	Can I transport the victim while the Powerheart AED is analyzing?
	A	No. Vehicle motion may cause noise artifacts that could interfere with proper cardiac rhythm analysis. Stop the vehicle when cardiac rhythm analysis is necessary.
3.	Q	Do I need to prepare the chest prior to electrode application?
	A	Special preparation is not usually necessary. The chest should be as clean, dry, and as oil free as practical. Follow your Medical Director's instruction.
4.	Q	What happens if the battery is low when I begin a rescue?
	A	When the battery indicator is RED the Powerheart AED issues the *"Battery low"* prompt *once*; however, the Powerheart AED is still capable of delivering approximately 9 more defibrillation shocks. When the Powerheart AED <u>is not</u> capable of delivering any more shocks, it *continuously repeats* the *"Battery low"* prompt. To continue the rescue attempt, leave the lid open and replace the battery. You must install the replacement battery within 60 seconds to continue the current rescue. When battery replacement takes longer than 60 seconds the first rescue is terminated and the Powerheart AED will begin to record the events from then on as a separate rescue.
5.	Q	How do I set the Powerheart AED internal clock?
	A	Set the clock by using the RescueLink Software Program and a PC. See Setting Clock in Chapter 3.
6.	Q	What happens if I close the lid in the middle of a rescue attempt?
	A	If you close the lid during a rescue, you must re-open the lid within 15 seconds to continue the rescue. If the lid remains closed for more than 15 seconds, a new rescue will initiate when the lid is re-opened. *Note: If the lid is closed during a rescue while the electrodes are connected to the patient, the status indicator may turn RED. When the lid is re-opened, however, the rescue may be continued even though the status indicator remains RED.*

 ©2001 Cardiac Science, Inc.

		Questions and Answers
7.	Q	My Powerheart AED is sounding an audible alert. Why? How do I stop it?
	A	The audible alert indicates that the self-test detected a need for maintenance or corrective action. Determine the maintenance required by using the Troubleshooting Table in this chapter. Opening and closing the lid may turn OFF the audible alert until the next self-test. The" Status" indicator, however, will remain RED.
8.	Q	When I open the lid, why do I get the voice prompt *"Data in memory. Push button to erase data and perform rescue*" How do I get the message to stop occurring?
	A	This message occurs when there is a previously stored rescue in the internal memory of the Powerheart AED AND the Rescue Data Card memory is full or unavailable You can clear the message by: 1. Pressing the "Shock/Continue" button to erase the internally stored rescue data, OR 2. Retrieving the rescue data with RescueLink and erasing the stored rescue data with RescueLink, OR 3. Inserting a blank Rescue Data Card.
9.	Q	When I open the lid, why do I get the voice prompt *"Card full. Storing internally?"*
	A	There is a previous rescue in the optional Rescue Data Card, and the rescue data from the current rescue will be stored in the internal memory of the Powerheart AED. An invalid card (other than the Rescue Data Card) can also cause this prompt.

 ©2001 Cardiac Science, Inc.

		Questions and Answers
10.	Q	The Powerheart AED did not sound an audible alert when I removed the electrodes and closed the lid. Why?
	A	Missing electrodes or a low battery will only trigger the audible maintenance indicator after the Daily Self-Test. The lid-closed self-test only activates the “Status” indicator, providing the rescuer with time to replace the electrodes or battery after a rescue without triggering the audible alert.
11.	Q	What can I do to keep the Powerheart AED warm when a rescue is in an isolated area and at subzero temperatures?
	A	When travel to a rescue involves exposing the Powerheart AED to extremely cold temperatures for an extended period of time, keep the electrodes and the battery warm.

©2001 Cardiac Science, Inc.

Section 7

Technical Data

Overview

This section presents technical data about the Powerheart AED.

Topic	Page
Parameters	64
Safety and Performance Standards	68
Summary of the RHYTHMx Clinical Study	74
Biphasic Clinical Study Summary	79

©2001 Cardiac Science, Inc.

Parameters

Operation

Semi-automatic (shock advisory)

Audible Alerts

Voice prompt
Charged tone
Maintenance alert
Card insert alert

Visible Indicators

Status indicator
Battery status indicators
Service indicator
Electrodes indicator
Optional Text Display

Rescue Data Storage

Storage	Capacity
Internal	20 minutes ECG data with event annotation
External (Removable)	With 8 MB (minimum) Rescue Data Card option: • 40 minutes ECG with voice and event annotation • 10 hours continuous ECG data with event annotation

 ©2001 Cardiac Science, Inc.

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 Electrodes
9200RD	3.50 kg (7.7 lb)
9210RD	3.55 kg (7.8 lb)

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 (+15,000 ft.) to 170kPa (-15,000 ft.)

Shipment and Transport Conditions (for up to 1 week)

Atmosphere	Condition
Temperature w/o Display	-40°C to +65°C (-40°F to +149°F)
Temperature w/Display	-30°C to 65°C (-22°C to 149°F)
Humidity	5% to 95% (non-condensing)
Pressure	58kPa (+15,000 ft.) to 170kPa (-15,000 ft.)

©2001 Cardiac Science, Inc.

Electrodes

ANSI/DF-39 (1993)

- Self-adhesive, disposable defibrillation electrodes
- Minimum combined surface area: 228 cm^2
- Extended length of leadwire: 1.3 m

Lithium Battery Output Voltage and Extended Life

- Output Voltage for standard and extended life: 12VDC (max.)
- Standard and extended life batteries are disposable and non-rechargeable
- Lithium contents: 13.2g (max.)

Battery	Expected Operating Life	Expected Shelf Life	Typical Charges **(at 20°C)**
9141 Extended Life Lithium	5-years	5-years	290

Batteries and Capacitor Charge Times

A fully charged battery typically takes 11 seconds to charge a fully discharged Powerheart AED to its maximum energy.

The Powerheart AED typically takes 11 seconds to charge to its maximum energy after 15 maximum energy charges.

A battery, with reduced capacity that causes the RED LED light to initially turn ON, typically takes 13 seconds to charge a fully discharged Powerheart AED to maximum energy.

The maximum time from “Power On” to “Ready to Shock” is 28 seconds.

The maximum time from “Analyze” to “Ready to Shock” is 22 seconds.

Delivery of Three Defibrillation Shocks

55 seconds (nominal**)**

 ©2001 Cardiac Science, Inc.

Powerheart AED Self-Test Sequence

Frequency of Self-Test	What is Tested
Daily	Battery, electrodes, internal electronics, shock/continue button and software
Monthly (every 28 days)	Battery under load, electrodes, internal electronics, full-energy charge cycle, shock/continue button and software
Open Lid (when lid is opened)	Battery, electrodes, internal electronics, shock/continue button and software
Close Lid (when lid is closed)	Battery, electrodes, internal electronics, shock/continue button and software

©2001 Cardiac Science, Inc.

Safety and Performance Standards

Powerheart AED Models 9200RD/9210RD

The Powerheart AED has been designed and manufactured to conform to the highest standards of safety and performance including electromagnetic compatibility (EMC). The Powerheart AED Models 9200RD/9210RD and electrodes conform to the applicable requirements of the following:

Classification

IEC 601-1, defibrillator-proof type BF patient connection, internally powered only, continuous operation, IP24 & not suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.

The device output has been tested and found to withstand the effects of another defibrillator without damage.

CE

CE Marked by TUV Product Services 0123 per the Medical Device Directive 93/42/EEC of the European Nations

UL and cUL

Classified by Underwriters Laboratories Inc. with respect to electric shock, fire and mechanical hazards only in accordance with UL 2601-1 and IEC 601-2-4, I**EC SC 62D/WG2 (O'Dowd)** and CAN/CSA C22.2 No.601.1-M90 and 45JF

Electrical, Construction, Safety and Performance

IEC 601-1 (1988), Amendments 1 (1991) & 2 (1995)

IEC 601-2-4, 2nd Edition, (**IEC SC 62D/WG2 O'Dowd 97/08**)

ANSI/AAMI DF-39 (1993)

Electromagnetic Compatibility (EMC)

IEC 601-1-2 (1993)

ANSI/AAMI DF-39(1993) Section 3.3.21

 ©2001 Cardiac Science, Inc.

Emissions

Field	Models	Standard or Compliance
E-M	9200RD/ 9210RD	EN 55011/C.I.S.P.R. 11, Group 1, Category B RTCA/DO-160D, Section 21, Category L (Category B during charging) RTCA/DO-199, Section 6.2.2
Magnetic	9200RD/ 9210RD	ANSI/AAMI DF39, < 0.5mT on surface, except for within 5cm of the lid magnet and the speaker RTCA/DO-160D, Section 15, Category Z
	9200RD/ 9210RD	RTCA/DO-199, Section 6.2.1 during analysis only

Immunity

Field	Models	Standard or Compliance
E-M	9200RD/ 9210RD	EN 61000-4-3, Level X, (20V/m) RTCA 160D, section 20, Category U (20V/m)
Magnetics	9200RD/ 9210RD	EN 61000-4-8, 80A/m for 47.5Hz - 1320Hz
ESD	9200RD/ 9210RD	EN 61000-4-2, Level 2

©2001 Cardiac Science, Inc.

Environmental Conditions

Condition	Models	Standard or Compliance
Temperature/ Altitude/ Decompression/Overpressure	9200RD/ 9210RD	RTCA/DO-160D, Section 4, Category A4, Operating: 0°C to 50°C, Ground Survival: 0°C to 50°C
Temperature Variation	9200RD/ 9210RD	RTCA/DO-160D, Section 5, Category C
Free Fall Drop	9200RD/ 9210RD	IEC 68-2-32 (1975), 1 meter
Shock (Bump)	9200RD/ 9210RD	IEC 68-2-29, 40g and 6000 bumps
Vibration (Random)	9200RD/ 9210RD	RTCA/DO-160D, Section 8, Category S
	9200RD/ 9210RD	IEC 68-2-64: 10Hz - 20Hz: 0.05 g^2/Hz; 20Hz -150Hz: 0.05 - 0.0065 g^2/Hz (-3dB/ Oct)
Vibration (Sine)	9200RD/ 9210RD	IEC 68-2-6: 10Hz - 57.6Hz at 0.15 mm and 57.6Hz - 150Hz at 2g
Enclosure Protection	9200RD/ 9210RD	IEC 529, IP24

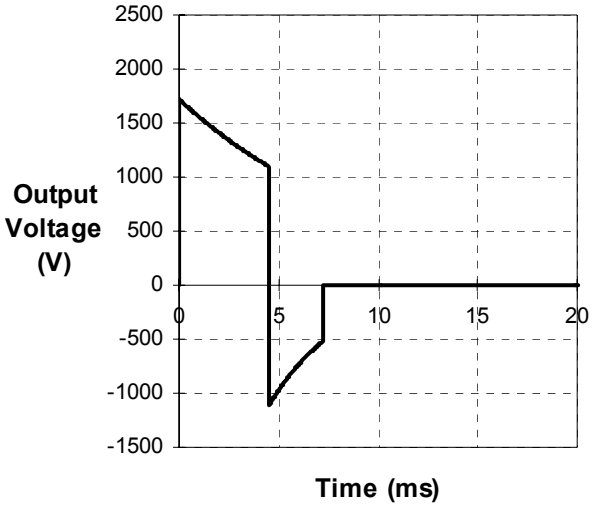
Shipping and Transport Conditions

ASTM D4169-92

 ©2001 Cardiac Science, Inc.

Powerheart AED Models 9200RD/9210RD Waveform

AAMI DF-2 (1996), Section 4.3.4.3, other waveforms



Ultra-Low Current Powerheart AED Models 9200RD/9210RD Waveform (all values are typical)

	Phase 1		Phase 2		
Patient's Impedance (Ohms)	**Voltage** (Volts)	**Duration** (ms)	**Voltage** (Volts)	**Duration** (ms)	**Energy** (Joules)
25	1390	3.3	730	3.2	145-195
50	1420	4.5	915	3.2	130-175
75	1430	5.8	980	3.2	120-160
100	1435	7.0	1020	3.2	110-150
125	1440	8.3	1040	3.2	105-140

©2001 Cardiac Science, Inc.

Low Variable Energy Powerheart AED Models 9200RD/9210RD Waveform (all values are typical)

	Phase 1		Phase 2		
Patient's Impedance (Ohms)	**Voltage** (Volts)	**Duration** (ms)	**Voltage** (Volts)	**Duration** (ms)	**Energy** (Joules)
25	1570	3.3	825	3.2	200-250
50	1600	4.5	1030	3.2	170-210
75	1610	5.8	1105	3.2	160-190
100	1615	7.0	1150	3.2	150-180
125	1620	8.3	1170	3.2	140-170

High Variable Energy Powerheart AED Models 9200RD/9210RD Waveform (all values are typical)

	Phase 1		Phase 2		
Patient's Impedance (Ohms)	**Voltage** (Volts)	**Duration** (ms)	**Voltage** (Volts)	**Duration** (ms)	**Energy** (Joules)
25	1885	3.3	990	3.2	265-360
50	1920	4.5	1240	3.2	235-320
75	1930	5.8	1325	3.2	215-295
100	1940	7.0	1380	3.2	200-270
125	1945	8.3	1405	3.2	190-260

Energy Levels and Patient Impedance

The Cardiac Science Biphasic Truncated Exponential (BTE) waveform utilizes variable energy[1]. The precise energy delivered will vary with the patient's impedance. Energy will be delivered at three different levels referred to as ultra-low variable energy, low variable energy and high variable energy as shown in the preceding Powerheart AED Models 9200RD/9210RD Waveform tables.

1. Powerheart AED Models 9200RD/9210RD: The actual energy of the ultra-low variable energy, low variable energy and high variable energy shocks is determined by the patient's impedance.

 ©2001 Cardiac Science, Inc.

RHYTHMx ECG Analysis Performance

The Powerheart AED RHYTHMx ECG Analysis system analyzes the patient's ECG and advises you when the Powerheart 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.

Cardiac Rhythms Used to Test the Rhythm Recognition Detection System for Powerheart AED

Rhythm Class	Specifications
Shockable Rhythm - VF	Meets AAMI DF 39 requirement and AHA recommendation of Sensitivity[a] of >90%.
Shockable Rhythm - VT	Meets AAMI DF 39 requirement and AHA recommendation of Sensitivity of >75%.
Non-Shockable Rhythm - NSR	Meets AAMI DF 39 requirement (>95%) and AHA recommendation (>99%) of Specificity.
Non-Shockable - Asystole	Meets AAMI DF 39 requirement and AHA recommendation of Specificity of >95%
Non-Shockable - all other rhythms	Meets AAMI DF 39 requirement and AHA recommendation of Specificity of >95%

a. Automatic External Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating New Waveforms and Enhancing Safety, AHA AED Task Force and approved by the AHA Science Advisory and Coordinating Committee. Circulation, 1997(95), pp 1677-1682

 ©2001 Cardiac Science, Inc.

Summary of the RHYTHMx Clinical Study

This section summarizes the results of a clinical trial conducted on the Powerheart Automatic External Cardioverter Defibrillator (AECD) and its arrhythmia detection software (called RHYTHMx ECD software). Although the Powerheart AED utilizes the RHYTHMx ECD software, the clinical data was collected on the Powerheart AECD.

Overview

A clinical trial was conducted between February 1993 and May 1997 on the Powerheart Automated External Cardioverter Defibrillator. The Powerheart AECD analyzes the patient's ECG waveform and determines whether the patient exhibits a shockable or non-shockable rhythm based upon the programmed parameters prescribed by the physician for each patient.

The clinical trial was conducted at four clinical centers including the Arizona Heart Institute, Phoenix, AZ; University of Southern California, Los Angeles, CA; University of California Irvine, Irvine, CA; and Montefiore Medical Center, New York, NY.

Study Objectives

The main purpose of the study was to evaluate the effectiveness (sensitivity) and safety (specificity) of the Powerheart AECD in treating arrhythmias according to the devices's specification. A secondary objective of the clinical trial was to compute the response time of the Powerheart AECD.

The trial was divided into two major phases. Phase I tested the arrhythmia detection algorithm only. Phase II tested the entire system, including both the arrhythmia detection and the shock delivery system. In Phase II, all patients studied in the Electrophysiology Lab (EP Lab) were attached to the Powerheart, and patients studied in other locations of the hospital (Critical Care Unit/ICU/standard hospital bed) were randomized to either control (standard of care) or experimental (Powerheart AECD) groups.

 ©2001 Cardiac Science, Inc.

Clinical Results

A total of 156 patients were enrolled in the Powerheart AECD clinical trial. The mean patient age was 63.4 years. Phase I included 66 patients and Phase II included 90 patients; however, as a result of a change in the arrhythmia detection algorithm after they had been studied, data from the first 15 Phase I patients were excluded. Therefore, data on the remaining 141 patients is included in the final study. The total number of patients connected to the Powerheart AECD was 117 and remaining 24 were in the control group.

The prospectively designed clinical protocol rhythms into two categories for statistical analysis and results reporting. The two rhythm categories were shockable and non-shockable. The Powerheart AECO patients collectively experienced 92 shockable episodes and 1,071 non0shockable episodes. All shockable events, in both Phase I and Phase II, were induced in the EP Lab.

The arrhythmia analysis algorithm successfully identified all 92 shockable episodes (sensitivity of 100.0%). It detected 1,065 of 1,071 non-shockable episodes (specificity of 99.4%) and called the remaining six episodes shockable. All six false events occurred in Phase I of the clinical trial. There were no false positive events in Phase II.

Response Time

The average response time of the Powerheart AECD was 20.9 seconds. The response time is defined as the elapsed time from the onset on the arrhythmia to the delivery of the first shock.

Randomization in Phase II

In Phase II, all patients studied in the EP Lab were attached to the Powerheart AECD. Patients studied in other locations of the hospital (e.g., CCU) were randomized to either control (standard of care) or experimental (Powerheart) groups. Of the 90 phase II patients, 66 were enrolled in the Powerheart AECD group (32 in the EP Lab and 34 in other in-hospital settings) and 24 were in the control group (critical Care Unit/ICU/standard hospital bed).

Study Methods

All patients in the trial were attached to a Holter monitor for the duration of their participation. For analysis, the Holter tape data were classified into episodes. Each episode begins with a rhythm change and ends when the rhythm changes again or when a shock is delivered. Hence, each

 ©2001 Cardiac Science, Inc.

episode was a new challenge to the Powerheart AECD or to the standard of care (as defined on the following page). Each episode was analyzed. For those episodes that should have been shocked according to the specifications of the Powerheart AECD and the parameters programmed per the physician prescription, the outcome was scored as True Positive (TP) if shocked, or False Negative (FN) if not shocked. For those episodes that should not have been shocked per the programmed parameters and the device specifications, the outcome was scored as False Positive (FP) if shocked, or True Negative (TN) if not shocked.

Standard of Care Definition

For this investigation, the standard of care was defined as the care normally available to the patient at the given clinical investigational site. Investigators differed in their preferred ECG monitoring and recording equipment and defibrillators; additionally, availability of this equipment and specific procedures comprising the standard of care varied among investigators' respective institutions. Therefore, the choice of the particular standard of care was left to the discretion of the investigator. However, Cardiac Science specified that the institution use its standard of care during the investigation. In the event of a life-threatening arrhythmia, the standard of care would prompt the appropriate therapy by health care professionals. Therapy could include defibrillation delivered by a defibrillator other then a Powerheart AECD.

Electrode Configuration

In the majority of patients studied, one of two ECG electrode channels was selected as the ECG signal source for detection and analysis. In the Phase II clinical trial, there were five patients for whom the ECG signal from the disposable electrode pads (i.e. Channel 3) was selected as the ECG signal source. During the 32.5 hours for which these five patients were monitored, there was one True Positive and 88 True Negative episodes. The Powerheart AECD did not generate any false episodes using the disposable defibrillation pads. Sensitivity and specificity were 100%, which is consistent with the overall performance of the Powerheart AECD.

Results

All shockable events, in both Phase I and Phase II, were induced in the EP Lab. The calculations were based on multiple shocks (i.e., not first shock) where each shock was considered to be independent. Cardiac Science assumed independence of repeated shocks from the same patient.

 ©2001 Cardiac Science, Inc.

Based upon the data from these patients, who collectively experienced 92 shockable episodes, the sensitivity of the Powerheart AECD was 100%, the positive predictivity was 93.9% and the specificity was 99.4%.

The average response time of the Powerheart AECD was 20.9 seconds. The response time is defined as the elapsed time from the onset of the arrhythmia to the delivery of the first shock. The baseline response times and measurements are not comparable between the experimental (Powerheart AECD) and control (standard of care) groups.

Clinical Study Conclusion

The primary endpoint of this trial was prospectively stated as rejecting the null hypothesis that the sensitivity of the Powerheart AECD is less then 90%. Actual results demonstrated a sensitivity of 100%, positive predictivity of 93.9%, and specificity of 99.4%. The data collected during the clinical trial show that this null hypothesis can be rejected with sufficient statistical power.

 ©2001 Cardiac Science, Inc.

Biphasic Clinical Study Summary

The first shock efficacies of the control Monophasic truncated exponential waveforms were compared to the first shock efficacy of the Biphasic truncated exponential waveforms.

The study was divided into two arms. The first arm was a low energy section comparing a 200J (low energy) Monophasic versus a 200J (low current) Biphasic. The second arm was a high energy arm comparing a 360J (high energy) Monophasic versus a 300J (high current) Biphasic. Each arm was a prospective, randomized, blinded, study designed with an independent group of patients for each arm. All patients undergoing procedures for electrophysiological testing or implantation of ICDs were invited to enroll in the study.

A total of 115 first shocks were delivered for both the Monophasic and Biphasic waveforms. Of the 115 first shock attempts, 60 were in the low energy arm and 55 in the high energy arm. There were no adverse events assocated with any of the treatments.

Defibrillation Rate of Survivalink's Monophasic and Biphasic Waveforms

Waveform Comparison	Monophasic Waveform	Biphasic Waveform	Statistical Analysis
Overall vs. Overall Overall First Shock Success. (95% Confidence Interval)	N = 115 97.4% (92.5% - 100%)	N = 115 100% (96.5% - 100%)	p = 0.0001**
Low Energy vs. Low Energy Low Energy First Shock Success. (95% Confidence Interval)	N = 60 96.7% (88% - 99%)	N = 60 100% (94% - 100%)	p = 0.002**
High Energy vs. High Energy High Energy First Shock Success. (95% Confidence Interval)	N = 55 98.2% (90.2% - 99.5%)	N = 55 100% (93% - 100%)	p = 0.0001**
High Energy (Monophasic) **vs. Low Energy (Biphasic)** **(95% Confidence Interval)**	N = 55 98.2% (90.2% - 99.5%)	N = 60 100% (94% - 100%)	p = 0.001**
Overall (Monophasic) **vs. Low Energy (Biphasic)** (95% Confidence Interval)	N = 115 97.4% (92.5% - 99.5%)	N = 60 100% (94% - 100%)	p = 0.03**

** highly statistically signicant

 ©2001 Cardiac Science, Inc.

Section 8

Accessories

Overview

This section contain a list of parts and software accessories for the Powerheart AED. To place an order, call Cardiac Science customer service at (800) 991-5465 or (952) 939-4181.

Fax: (952) 939-2909.

Topic	Page
AED ACCESSORIES	80
AED DELIVERY SYSTEMSS	80
SOFTWARE ACCESSORIES	81
EDUCATION ACCESSORIES	81

 ©2001 Cardiac Science, Inc.

List of Powerheart AED Accesories

Part Number	Description
	AED ACCESSORIES
9130	Powerheart AED defibrillation electrodes with two year shelf life
9610	Powerheart AED defibrillation/pacing electrodes with one year shelf life
9141	Extended life (5 year) lithium battery for Powerheart AED
9050	Electrode adapter to connect Powerheart AED electrodes to Medtronic Physio-Control defibrillators using FAST-PATCH connector system
9151	Electrode adapter to connect Powerheart AED electrodes to Medtronic Physio-Control defibrillators using QUIK-COMBO connector system
9053	Electrode adapter to connect Powerheart AED electrodes to Zoll defibrillators
9152	Rescue data card
	AED DELIVERY SYSTEMS
9042	Soft-sided carrying case for Powerheart AED
9157	Hard-sided, waterproof carrying case for Powerheart AED
5510	Empty soft-sided backpack carrying case for Powerheart AED, basic life support supplies and oxygen
5530	Insert for empty soft-sided backpack (5510) to hold basic life support supplies
5570	Basic life support supply kit including: B/P cuff, stethoscope, bandages, cold packs and other supplies
5612	Wall mount storage case for Powerheart AED with strobe light alarm
5630	Heart Station Rescue Case, wall mount, connects to security system

 ©2001 Cardiac Science, Inc.

Part Number	Description
5640	Heart Station Rescue Case, recessed wall mount, connects to security system
5501	Heart Station Rescue Case replacement lithium battery
9022	Wall mount rack for Powerheart AED without alarm
5650	Wall mounting sign identifying location of AED
5550	Powerheart AED Ready Kit: includes nitrile gloves, razor, scissors, towel, guaze , alcohol preps, CPR mask
	SOFTWARE ACCESSORIES
9168	SanDisk ImageMate CompactFlash card reader allows reading of Rescue data card in standard desktop PCs.
9155	PCMCIA card adapter for Rescue Data Card allows reading of Rescue data card in PCMCIA card reader.
9154	MDLink Software for Powerheart AED allows PC based programming of the Powerheart AED to the medical director protocol.
9158	MDLink Software Kit and data card (for customers with Rescue Data Cards) allows field programming of the Powerheart AED (for model 9210RD)
	EDUCATION ACCESSORIES
9163R	Powerheart AED training device
9035	Training electrodes for use with Powerheart AED training device
9169	Powerheart AED training video (NTSC format)

©2001 Cardiac Science, Inc.

Shockable

POWERHEART® AED
automated external defibrillator

CARDIAC SCIENCE