

ZOLL
AED PLUS™

Administrator's Guide



ZOLL

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Preface

The ZOLL AED PLUS Administrator's Guide is to be used by responsible medical authorities in conjunction with the ZOLL AED PLUS Operator's Guide.

The ZOLL AED PLUS is to be used by trained rescuers to provide emergency defibrillation. It incorporates a sequence of visual and voice prompts to help rescuers follow established protocols for use of AEDs. It also incorporates recording/memory capabilities to allow medical control authorities to review rescuer's use of the device. Recording includes ECG rhythms, event data, device identification, and optionally, voice recording of rescuer and ambient sounds. This information is available via an upload capability to a personal computer for event review and archiving.

Both the American Heart Association and the European Resuscitation Council publish extensive information regarding the use of automated external defibrillators and their relationship to cardiopulmonary resuscitation. See, for example, the following two publications: "Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Cardiac Care, International Consensus on Science," *Circulation*. 2000;102, 8 and "International Guidelines 2000 for CPR and ECC – A Consensus on Science," *Resuscitation*; 2000; 46, 1-3. Both of these documents provide supplemental material to be used in conjunction with this Guide and the Operating Instructions for the ZOLL AED PLUS.

This guide provides information about the operation and care of the AED unit. The administrator, and user should read each section carefully. Make sure to read the Safety Summary section. This guide is to be used in conjunction with the ZOLL AED PLUS Operator's Guide (ZOLL p/n 9650-0300-01).

This guide is divided into six sections.

Preface - This page.

Safety Summary - Describes General Warnings and Cautions.

Introduction- Provides a general product overview of the AED.

Section 1 - Operation - Describes the functions of all controls and indicator lights of the AED.

Section 2 - Self Test, Maintenance and Troubleshooting- Describes configuration of the unit, data communications, troubleshooting, maintenance and how to order accessories and supplies.

Appendices - Provides the specifications of the AED, characteristics of the ZOLL Rectilinear Biphasic waveform, and information on the ECG Analysis Algorithm Accuracy.

Safety Summary

The following section describes general warnings and safety considerations for administrators, rescuers, and patients.

Warnings

- This device should only be used by properly trained individuals.
- Defibrillation energy delivered to the patient may be conducted through the patient's body and cause a lethal shock to those touching the patient. Always stand clear of patient when delivering treatment.
- DO NOT TOUCH the electrode surfaces, the patient, or any conductive material touching the patient during ECG analysis or defibrillation.
- Move patient away from electrically conductive surfaces prior to use of equipment.
- DO NOT use the unit near or within puddles of water.
- DO NOT use this unit on children less than 8 years of age.
- Keep the patient as motionless as possible during ECG analysis.
- DO NOT use the unit near flammable agents, such as gasoline, oxygen-rich atmospheres or flammable anesthetics.
- Avoid radio frequency interference from high-power sources that might cause the defibrillator to interpret cardiac rhythms incorrectly by turning off cell phones and/or 2 way-radios.
- Disconnect non-defibrillation protected electronic devices or equipment from patient before defibrillation.
- Dry patient's chest, if wet, before attaching electrodes.
- Apply freshly opened and undamaged electrodes within the expiration date to clean and dry skin to minimize burning.
- DO NOT place the electrodes directly over the patient's implanted pacemaker because pacemaker stimuli may degrade the accuracy of ECG rhythm analyses or the pacemaker may be damaged by defibrillator discharges.
- Check labeling inside the ZOLL AED PLUS cover before using the cover as a Passive Airway Support (PASS) device. Ensure it is intended for this use.
- DO NOT use Passive Airway Support System (PASS) if suspected head or neck injury. Place patient on a firm surface before performing CPR.
- DO NOT recharge, disassemble, or dispose of batteries in fire. Batteries may explode, if mistreated.
- The system should not be used adjacent to or stacked with other equipment. If it is, verify proper operation prior to use.

Cautions

- Do not disassemble the unit. A shock hazard exists. Refer all servicing to qualified personnel.
- Use only commercially available type 123A lithium manganese dioxide batteries. Discard batteries properly after removal from unit. Use only batteries from recommended manufacturers.
- Safety and effectiveness data submitted by ZOLL Medical Corporation to the Food and Drug Administration (FDA) under section 510(K) of the Medical Device Act to obtain approval to market are based upon the use of ZOLL accessories such as disposable electrodes. The use of electrodes from sources other than ZOLL is not recommended. ZOLL makes no representations or warranties regarding the performance or effectiveness of its products when used in conjunction with electrodes from other sources. If unit failure is attributable to the use of accessories not manufactured by ZOLL, this may void ZOLL's warranty.

- The CPR-D Padz Electrode can be connected to other ZOLL Defibrillators with Multifunction Cables. Defibrillation can be administered when connected to other ZOLL Defibrillators. The CPR function does not operate with any device other than the AED PLUS.

Indications for Use

Use the AED when a suspected cardiac arrest victim has an apparent LACK OF CIRCULATION as indicated by:

- Unconsciousness and
- Absence of normal breathing; and
- Absence of a pulse or signs of circulation.

Contraindications for Use

Do NOT use the AED when the patient is:

- Conscious; or
- Breathing; or
- Has a detectable pulse or other signs of circulation.

The ZOLL AED PLUS is not indicated for use on patients under 8 years of age (Per AHA Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care, I-64, 2000).

Intended Users of the Device

The ZOLL AED PLUS external defibrillator is intended to be used by personnel who are qualified by training in the use of the AED PLUS, basic life support, or advanced life support, or other physician-authorized emergency medical response to defibrillate victims of cardiac arrest. The CPR monitoring function provides a metronome designed to encourage rescuers to perform chest compressions at the AHA/ERC recommended rate of 100 compressions per minute. Voice and visual prompts encourage a compression depth of 1½ - 2 inches for adult patients.

Tracking Requirements

U.S Federal Law (21 CFR 821) requires the tracking of defibrillators. As an owner of this device, you have the responsibility under this law to notify ZOLL Medical Corporation if this product has been received, lost, stolen or destroyed or has been donated, resold or otherwise distributed to a different organization.

If any of the events described above occur, please contact ZOLL Medical Corporation in writing with the following information:

1. Originator's organization - Company Name, Address, Contact Name and Contact Phone Number.
2. Part Number/Model Number and Serial Number.
3. Disposition of Device (e.g. received, lost, stolen destroyed, distributed to another organization).
4. New Location and/or Organization (if different from #1 above) - Company Name, Address, Contact Name and Contact Phone number.
5. Date change took effect.

Notification of Adverse Events

As a health care provider, you may have responsibilities under the SMDA for reporting to ZOLL and possibly to the FDA, the occurrence of certain events. These events, described in 21 CFR Part 803, include device related death and serious injury or illness. In any event, as part of our Quality Assurance Program, ZOLL should be notified of any device failures or malfunction. This information is required to assure that ZOLL provides only the highest quality products.

Unpacking

- Carefully inspect each packing container for damage.
- Examine the unit for any signs of damage that may have occurred during shipping.
- If the contents are incomplete or damaged or if the unit fails to pass its self-test as indicated by a Red “X” in the status indicator window after battery installation, contact ZOLL Medical Corporation’s Technical Service Department.
- Review the shipping list to insure that all items ordered were received.

Conventions

Throughout this document, voice prompts are indicated by capital italicized letters, such as *CALL FOR HELP*.











WARNING! Warning statements describe conditions or actions that can result in personal injury or death.

CAUTION! Caution statements describe conditions or actions that can result in damage to the unit.

NOTE Notes contain additional information on using the defibrillator.

Symbols

Symbols used in this manual or on the equipment include the following:

	Class II equipment.
	Defibrillation protected Type BF patient connection
	ATTENTION: Refer to manual for more information
	DANGEROUS VOLTAGE
	Not new Battery Cells
	New Battery Cells
	Do Not Push Button
	Push Button
	Do Not use this manufacturer
	Ok to use this manufacturer

Introduction

Using the ZOLL AED PLUS

The ZOLL AED PLUS is an automated external defibrillator that uses voice prompts and visual graphics to guide the rescuer through a resuscitation sequence that may include defibrillation and/or cardiopulmonary resuscitation. It incorporates the ZOLL Rectilinear Biphasic Defibrillation waveform. Following attachment of electrodes to a patient's chest, the defibrillator monitors the electrocardiographic (ECG) rhythm of the patient's heart, analyzes that rhythm, and determines whether the rhythm is shockable or non-shockable. When needed, defibrillation energy is also delivered through these same electrodes. When the unit detects a shockable rhythm, it charges and issues the warning *DON'T TOUCH PATIENT, PRESS TREATMENT BUTTON*. The rescuer presses the Treatment/Shock Button to deliver the shock. If the patient remains in VF or shockable VT, additional shocks can be administered after subsequent analyses of the patient's heart rhythm. The rescuer may be prompted to perform CPR if the initial or subsequent defibrillation attempts are unsuccessful.

Some versions of ZOLL AED PLUS include a cover that can also be used as a PASS (Passive Airway Support System) to support the patient's neck and shoulders in a position that assists in maintaining an open airway. Some versions also contain disposable accessories (razor, barrier mask, scissors, and a towel). The defibrillator is powered by ten commercially available consumer brand lithium-manganese dioxide batteries.

The ZOLL AED PLUS can do the following:

- Perform periodic self tests to ensure its continual readiness.
- Use one piece electrode assembly that facilitates proper electrode placement and that is easy to apply to the patient.
- Analyze heart rhythm and inform the rescuer if the rhythm is shockable or non-shockable.
- Deliver defibrillation treatment to victims of cardiac arrest who exhibit shockable ECG rhythms.
- Provide voice prompts and graphics to guide the rescuer regarding what to do and when to do it during a cardiac emergency, such as calling for help or giving CPR to the patient.
- Provide audible beeps to encourage rescuers to provide CPR compressions at 100 CPM (requires CPR-D padz).
- Monitor the depth of chest compressions during CPR and provide voice prompts, if compression depth is inadequate (requires CPR-D padz).
- Provide a unit cover that functions as a Passive Airway Support System (PASS). (Note the PASS feature is standard with some versions of the product and optional with others.)
- Upload data from the defibrillator to a PC to store events or print event reports.
- Use commercially available batteries.

Using the CPR Function

The CPR-D padz include a sensor that detects the rate and depth of CPR chest compressions. This sensor is placed (as part of the electrodes application) on the patient's chest so that it is located between the rescuer's hands and the patient's lower sternum during chest compressions. When the rescuer performs CPR compressions, the sensor detects their rate and depth and sends the information to the ZOLL AED PLUS unit. When used with ZOLL CPR-D padz the ZOLL AED PLUS monitors the depth and rate of CPR chest compressions. It provides a CPR metronome function designed to encourage rescuers to perform chest compressions at the AHA/ERC recommended rate of 100 compressions per minute (CPM) as well as voice and visual prompts to encourage a compression depth of 1½ - 2 inches for adult patients.

The metronome function is disabled during periods when CPR should not be performed (e.g. during ECG analyses and defibrillation shock sequences). During periods when CPR may be indicated, the metronome begins issuing audible beeps following detection of the rescuer's first few compressions. The beeps continue automatically (at rates described below) until a few seconds after chest compressions are halted by the rescuer or until the recommended "CPR period" ends (1 minute for AHA protocols and 1-3 minutes for ERC protocols). If the rescuer ceases chest compressions during the CPR period, metronome beeps will stop within a few seconds after compressions are halted. Audible beeps will resume during the CPR period following any re-initiation of CPR compressions. If no CPR compressions are detected during "CPR periods", the ZOLL AED PLUS will periodically re-issue *IF NO CIRCULATION, CONTINUE CPR* prompts.

The rate of beeps issued by the ZOLL AED PLUS metronome function adapts to the rescuer's actual chest compression rate. The metronome will beep at 100 CPM when chest compressions are delivered at greater than 80 compressions per minute (CPM). Should the rescuer fail to deliver compressions at 80 CPM or greater, the metronome will beep at a rate that is approximately 15 CPM higher than the rescuer's actual rate. This increased metronome rate is intended to encourage the rescuer to increase his/her chest compression rate until the recommended 100 CPM rate is achieved. The metronome beeps at a minimum rate of 60 CPM in cases where the rescuer's compression rate is substantially below 60 CPM.

During CPR, the ZOLL AED PLUS may issue one or more audible prompts based upon the depth of chest compressions detected. When the CPR monitoring system determines that compression depth is consistently less than 1½ inches, a *PUSH HARDER* prompt will be issued. A *GOOD COMPRESSION* prompt will be issued if the rescuer responds by increasing compression depth to 1½ inches or more.

Operation

Overview

This section describes the following functions:

- Operating Controls and Indicators
- Using the AED Graphics
- Using Voice Prompts
- Using the LCD Display
- Using the Passive Airway Support System (PASS)
- Using Electrodes
- Applying CPR-D padz
- Using the CPR Monitoring Function
- Using the Audio Recording Option

Identifying Operating Controls and Indicators

See *Table 1: Control Functions* for an explanation of each of these controls.

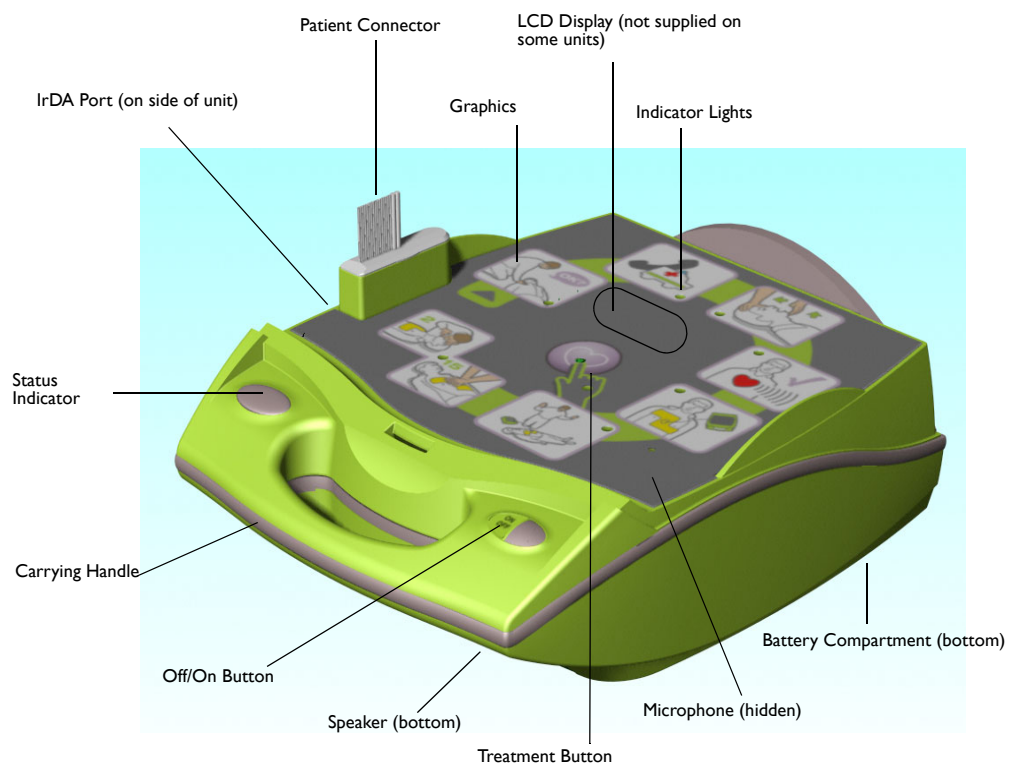




Figure 1: Identifying Operating Controls and Indicators

Table 1: Control Function

Control/Indicator	What it does:
ON/OFF button	Turns power ON or OFF. When held depressed for >5 seconds initiates self test or data communications.
Indicator Lights	Illuminates to indicate which step rescuer must take to treat a patient.
Treatment Button	<ol style="list-style-type: none"> 1. This button illuminates when the AED is charged and ready to deliver treatment to the patient. 2. When pressed, causes the charged and ready defibrillator to discharge its energy into the patient. 3. When defibrillator is not charged the lighted button is extinguished. Pressing this button initiates a voice prompt that indicates the number of defibrillator shocks delivered since the unit was powered on.
Pictograms	Icons that explain the series of steps needed for resuscitation and defibrillation.
Status Indicator	<p>Illuminated check indicates the unit passed its last self test and is ready for use.</p>  <p>Illuminated “X” indicates unit has failed its self test and is not ready for use.</p> 
LCD Display	Displays elapsed time, shock count, user prompts, CPR compression depths and ECG waveforms.
IrDA™ Port	Provides a communications link between the defibrillator and a personal computer or another IrDA™ equipped device.
PASS Cover (optional)	Some ZOLL AED PLUS models include a cover that may be used as a shoulder support to aid patient airway management. The PASS can be ordered separately for other ZOLL AED PLUS models. (See Accessories section.)
Battery Compartment	Holds ten (10) 123A lithium manganese dioxide batteries used to power the unit.
Patient Connector	Connector for attaching electrodes to the AED.
Speaker	Provides audio prompts and metronome beeps that direct rescuers what to do during a resuscitation. It also provides voice prompts to indicate if service is required.
Microphone (optional)	When voice recording option is installed, this microphone picks up and records ambient sounds, including rescuer’s voice.

Using the AED Graphics

The graphical user interface (see Figure 2) is revealed on the top of the unit when the cover is removed. The graphics are reminders of the steps to follow when performing a rescue and to reinforce instructions provided in the form of voice prompts and optional display messages.

The graphics incorporated on the device are each combined with an indicator light (LED) and the listed voice prompts to draw attention to the graphics in a sequence defined by current protocols for use of an AED by the American Heart Association and the European Resuscitation Council.

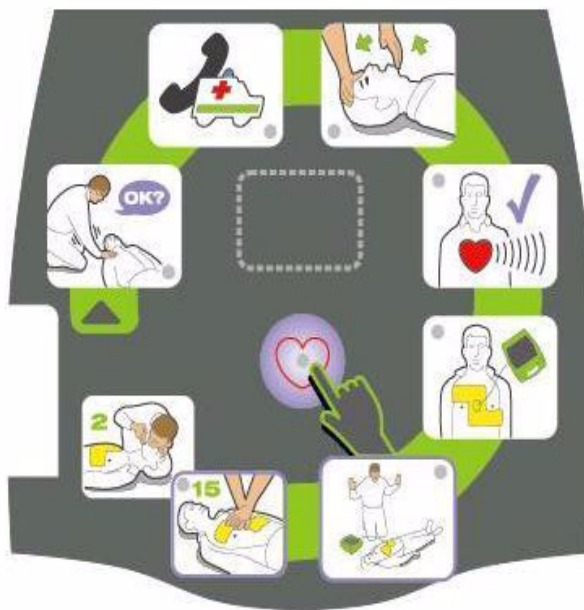


Figure 2: Graphical User Interface

The device contains an LCD display (some special models do not have an LCD) that displays elapsed time, number of shocks delivered, text messages consistent with the voice prompts, depth of CPR compressions, and can be configured to display the acquired ECG signals.

When the device is turned on, the sequence of voice prompts and graphics illuminations are automatically initiated and will continue until the device is turned off or the electrodes are disconnected from the patient for an extended period of time. Analysis of the ECG rhythm will occur after electrodes are attached to the patient and impedance of the connection is verified.

Following the results of this ECG analysis, voice prompts tell the rescuer whether a shockable or non-shockable rhythm has been detected. If a shockable ECG rhythm is present, the graphics illuminate and voice prompts guide the rescuer through the defibrillation sequence. When no shock is advised, the AED issues the following series of audio prompts: *NO SHOCK ADVISED. OPEN AIRWAY. CHECK BREATHING. CHECK CIRCULATION. IF NO CIRCULATION – START CPR* and illuminates the CPR related graphics. A period of 1 – 3 minutes (depending upon device configuration) is then provided for performing rescuer CPR. Following this “CPR period”, the AED automatically re-initiates additional ECG rhythm analyses.

In the continuing presence of a shockable ECG rhythm, the AED is designed to perform up to three ECG analyses and stacked shocks before it prompts the rescuer to initiate CPR. Shocks are delivered by depressing the Treatment Button (indicated by the heart and associated LED) located in the center of the graphic user interface.

Consult the ZOLL AED PLUS Operator’s Guide for more details on the graphics included in the unit’s graphic interface, the audio prompts issued at each step in the treatment protocol and the expected rescuer response to these audio and visual prompts.

Loss of contact between the electrodes and the patient will interrupt ECG analysis and/or shock delivery until the electrodes are re-attached and will result in a *CHECK ELECTRODE PADS* prompt to the operator.

Using Voice Prompts

During clinical use of the ZOLL AED PLUS, you may hear the following voice prompts.

Table 2: Identifying Voice Prompts

Voice Prompt	Definition
<i>UNIT OK.</i>	ZOLL AED PLUS has successfully passed its power up self tests.
<i>UNIT FAILED.</i>	ZOLL AED PLUS has failed its power up self tests and is not usable for patient care.
<i>DATA STORED.</i>	Clinical event data recorded during a prior rescue attempt is still stored in memory and has not been uploaded. This data will be overwritten by data collected during the next clinical use of the ZOLL AED PLUS.
<i>CHANGE BATTERIES.</i>	ZOLL AED PLUS power up self test has detected a low battery condition inconsistent with the device’s use for patient care. Replace batteries immediately.
<i>STAY CALM.</i>	Relax as much as possible and focus on the rescue effort.
<i>CHECK RESPONSIVENESS.</i>	Check patient for responsiveness/consciousness by gently shaking the patient and shouting “Are you all right?”.
<i>CALL FOR HELP.</i>	Activate the EMS system or get a bystander to do it for you.
<i>OPEN AIRWAY.</i>	Place patient in the supine position and perform Head Tilt - Chin Lift or Jaw – Thrust maneuver to open patient’s airway.
<i>CHECK BREATHING. GIVE TWO BREATHS.</i>	Look, listen or feel for the presence of breathing and/or airflow from the patient’s lungs. If patient is not breathing give two rescue breaths.
<i>CHECK CIRCULATION.</i>	Check patient for the presence of a pulse or other signs of circulation such as normal breathing, movement or coughing.
<i>PLUG IN CABLE.</i>	The electrode cable is not properly connected to the AED patient connector.
<i>ATTACH ELECTRODE PADS.</i>	Attach defibrillation electrodes to the patient.
<i>CHECK ELECTRODE PADS.</i>	Previously attached electrodes are not making good contact with the patient’s skin or the electrodes are defective.
<i>DON’T TOUCH PATIENT, ANALYZING.</i>	Don’t touch patient, an ECG rhythm analysis is in progress or about to begin.

Voice Prompt	Definition
<i>TREATMENT ADVISED.</i>	ECG rhythm analysis has detected the presence of VF or shockable VT.
<i>NO TREATMENT ADVISED.</i>	ECG rhythm analysis has detected a rhythm that is not treatable by defibrillation.
<i>ANALYSIS HALTED. KEEP PATIENT STILL.</i>	ECG rhythm analysis has been halted due to the presence of excessive ECG signal artifact. Halt any ongoing CPR and keep the patient as motionless as possible.
<i>DON'T TOUCH PATIENT. PRESS TREATMENT BUTTON.</i>	Warn all persons in attendance of the patient to stand clear and stop touching the patient. Press the Treatment Button to deliver defibrillation therapy.
<i>RELEASE TREATMENT BUTTON.</i>	Treatment Button was depressed before the defibrillator was ready to defibrillate. Release the Treatment Button and press after the ready tone sounds.
<i>TREATMENT DELIVERED.</i>	A defibrillation shock has just been delivered to the patient.
<i>NO TREATMENT DELIVERED.</i>	No treatment (shock) was delivered to the patient because rescuer failed to press Treatment Button or an error condition was detected.
<i>n SHOCKS DELIVERED.</i>	A total of n shocks have been delivered since the AED was turned on.
<i>IF NO CIRCULATION, START CPR.</i>	Check patient for the presence of a pulse or other signs of circulation. If no signs of circulation are detected begin CPR.
<i>IF NO CIRCULATION, CONTINUE CPR.</i>	Continue providing CPR. This prompt may also be issued if the ZOLL AED PLUS CPR monitoring function fails to detect chest compressions at least $\frac{3}{4}$ of an inch deep.
<i>PUSH HARDER.</i>	CPR compressions are consistently less than 1 $\frac{1}{2}$ inches deep.
<i>GOOD COMPRESSIONS.</i>	After prompting to Push Harder, rescuer has succeeded in delivering chest compressions at least 1 $\frac{1}{2}$ inches deep.
<i>STOP CPR.</i>	Stop CPR, the AED is about to begin an ECG rhythm analysis.

Prompts that may be heard during non-clinical use of the ZOLL AED PLUS unit:

Table 2b

Voice Prompt	Definition
<i>IF NEW BATTERIES, PRESS BUTTON.</i>	Press the battery reset button located in the battery compartment after replacing <u>ALL</u> batteries in the device with new batteries.
<i>NON-RESCUE MODE.</i>	ZOLL AED PLUS device has entered the diagnostics/data communications mode.
<i>COMMUNICATIONS ESTABLISHED.</i>	IrDA Communications between the ZOLL AED PLUS and a personal computer or modem have been established.
<i>SENDING.</i>	Data is being sent from the ZOLL AED PLUS to an external computer or IrDA modem.
<i>SENDING FAILED.</i>	Data communications between the ZOLL AED PLUS and personal computer or IrDA modem have failed.

Using the LCD Display

The ZOLL AED PLUS is equipped with a 1.3 x 2.6 inch LCD screen (see Figure 3) that displays the following information:

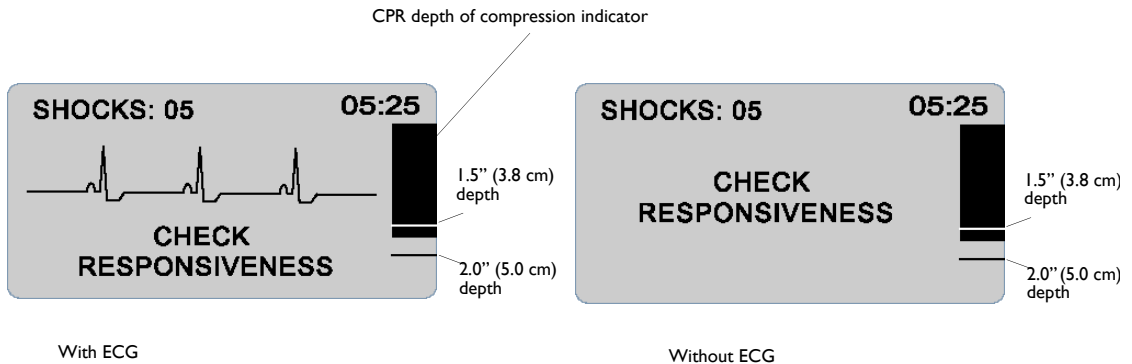


Figure 3: LCD Displays

NOTE Some special models do not have an LCD.

Elapsed Time (Upper right corner of screen): Indicates the total time in minutes and seconds that has elapsed since the ZOLL AED PLUS was last powered on. Elapsed time continues to be counted through brief power off periods (< 5 seconds). When the ZOLL AED PLUS is turned off for more than five (5) seconds, elapsed time is reset to 00:00. When elapsed time exceeds 99 minutes and 59 seconds, the elapse timer wraps around to 00:00 and continues counting.

Shock Count (Upper left corner of screen): Indicates the total number of defibrillation shocks delivered by the ZOLL AED PLUS since it was last powered on. Shock count is saved through brief power off periods (< 5 seconds). When the ZOLL AED PLUS is turned off for more than five (5) seconds, the shock count is reset to 0.

CPR Depth of Compression Indicator (Right side of screen): A bar graph is displayed that shows the depth of chest compressions measured during the delivery of CPR. Indicator lines are displayed in the bar graph area at 1 ½ and 2 inches of compression depth to provide reference points for rescuers performing CPR.

Visual User Prompts (Lower 1/3 of screen): Whenever the ZOLL AED PLUS issues a voice prompt, the text of the voice prompt is simultaneously displayed on the LCD display.

ECG Waveform (Center portion of screen): Although ZOLL AED PLUS units do not display ECG waveforms in their factory default configuration, the device can be specifically set up to continuously display ECG signals as they are acquired.

Using the Passive Airway Support System (PASS)

If there is no evidence of head or neck trauma, the head tilt chin lift method is the recommended maneuver for opening the airway. The PASS may be placed under the patient's shoulders to help maintain head tilt.

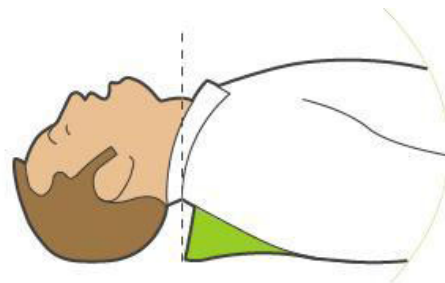
WARNING! DO NOT use Passive Airway Support System (PASS) if suspected head or neck injury. Place patient on a firm surface before performing CPR.

For patients who require airway support after determining there is no evidence of head or neck trauma, the patient should be rolled on his/her side and then rolled back over so that the PASS is under the patient's shoulders causing the head to tilt backwards.

For PASS COVERS only: The shape of the PASS, when placed under the shoulders of the patient, can be used to help maintain an open airway (see Figure 4).



The unit cover also functions as the Passive Airway Support System (PASS).



Place the PASS under the patient to lift his/her shoulders. Do not use the PASS if there is a suspected head or neck injury.

Figure 4: Using the PASS Cover

Using Electrodes

WARNING! DO NOT reuse electrodes.

The ZOLL AED PLUS uses electrode packs that are connected to the unit by a cable. The package will contain electrodes that you attach to the patient.

- Make sure to install a new package of electrodes and connect the electrode cable to the unit after each use to be prepared for future emergencies.
- Check the electrode expiration date regularly to ensure that electrodes are fresh and ready to use in an emergency situation.
- Replace electrodes, if expired.

If the electrodes are not attached properly, you will hear one of the following voice prompts during operation: *CHECK ELECTRODE PADS* or *ATTACH ELECTRODE PADS*. If the electrode cable is not properly attached to the unit, you hear the *PLUG IN CABLE* prompt. Make certain to attach the electrode's cable to the AED and electrodes to the patient properly.

Electrodes are intended to be pre-attached to the device. The electrode package may incorporate:

- Scissors to cut clothing or chest hair.
- Razor to remove excessive hair at the electrode application site, if necessary.
- Small towel to make sure that the patient's skin is dry.
- Gloves.
- Barrier Mask.

NOTE Electrodes contain no hazardous materials and may be disposed of in general trash unless contaminated with pathogens. If contaminated, appropriate precautions should be used in their disposal.

Applying CPR-D padz

Prepare the patient before attaching the electrodes.

To prepare the patient:

1. Remove all clothing covering the patient's chest.
2. Ensure the patient's chest is dry.
3. If the patient has excessive chest hair, clip or shave the hair to help ensure proper adhesion of the electrodes.

To apply the electrodes:

1. Tear open the electrode package and unfold the electrodes. Orient according to graphics (see Figure 5).
2. Hold the CPR sensor and then place the sensor between the nipples and on the middle of the patient's breastbone, using the sensor's cross hairs to guide you.
3. Press the CPR Sensor with your right hand and pull the number 2 tab to peel the protective backing from the electrode. Press the electrode from the center out to make sure it adheres properly to the patient's skin.
4. Press the CPR Sensor with your left hand and pull the number 3 tab to peel the protective backing from the electrode. Press the electrode from the center out to make sure it adheres properly to the patient's skin.

NOTE If the patient is large or there is a need to place the electrode under a breast, you may need to remove the red-centered "pin" (see Figure 5) to extend the pad. Place the pad slightly to the left and below the patient's left breast.

NOTE If the patient has an implanted pacemaker or defibrillator in the upper right chest, angle the electrodes slightly to avoid placing the electrodes over either device. Make certain that the CPR sensor maintains a position over the lower half of the breastbone.

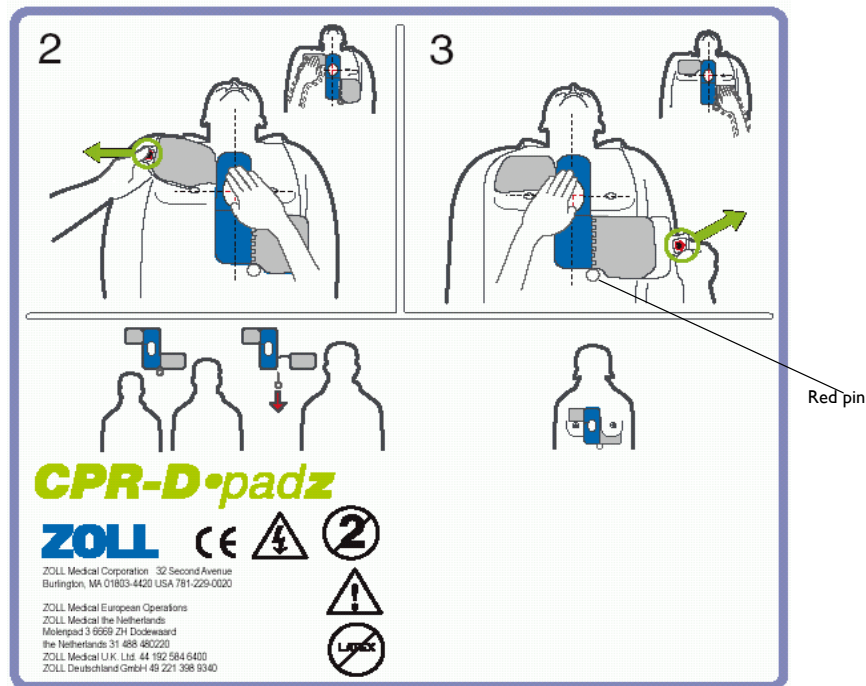


Figure 5: Placement of CPR-D padz

Using the CPR Monitoring Function

When used with ZOLL CPR-D padz, the ZOLL AED PLUS monitors the rate and depth of CPR chest compressions. It provides a CPR metronome function designed to encourage rescuers to perform chest compressions at the AHA/ERC recommended rate of 100 compressions per minute. Voice and visual prompts encourage a compression depth of 1 ½ - 2 inches for adult patients. The CPR monitoring function operates only when CPR-D padz are used.

To use the ZOLL AED PLUS CPR monitoring function you must do the following:

1. Connect CPR-D padz to the ZOLL AED PLUS.
2. Apply the CPR-D padz to the patient as described in the previous section
Ensure that the CPR sensor is centered on the lower half of the patient's sternum.
3. If no signs of circulation are present when the AED issues the *IF NO CIRCULATION – START CPR* prompt, place your hands on top of the CPR sensor and push on the sensor to deliver chest compressions to the patient.
After your first few compressions, the ZOLL AED PLUS metronome will begin issuing timing beeps. Try to maintain synchronization between these beeps and your chest compressions. Shortly after you stop chest compressions to deliver rescue breaths the metronome will stop beeping.

NOTE If the ZOLL AED PLUS prompts you to *PUSH HARDER*, your compressions are less than 1 ½ inches deep. Increase your compression depth to improve CPR performance.

4. Deliver the appropriate number of rescue breaths then resume chest compressions. The metronome will begin to beep again after your first few compressions have been delivered.

Using the Audio Recording Option

If installed and configured, the unit contains an audio recording option that will record and store 20 minutes of continuous audio and data while a rescue is occurring. The audio recording starts at the same time the *STAY CALM* prompt is heard. The recorded data are synchronized to the clinical event data. Therefore, when you playback the recorded audio, the ECG data are synchronized to it. Each time you use the device, the previously stored data (ECG, Audio and Event) are overwritten by the data recorded for the current rescue.

However, if the unit is started in any other mode, such as the mode to configure the unit, then the recorded audio data of the last rescue are retained and may be uploaded. Overwriting of old ECG, audio and event data begins when electrodes are properly connected to the patient.

Self Test, Maintenance and Troubleshooting

Overview

This section describes the following functions to prepare the ZOLL AED PLUS for use:

- Inspection
- Preparing the ZOLL AED PLUS for Use.
- Using Automatic Self-Test.
- Installing or Replacing Batteries.
- Attaching the Electrode Cable to the Device.
- Storing Electrodes and Accessories in Unit.
- Checking for Data Requiring Download.

Inspection

Once unpacked, inspect the device for any signs of damage due to shipping. Check for accessories and any other parts ordered.

Preparing the ZOLL AED PLUS for Use

To ensure that the ZOLL AED PLUS is properly functioning and ready for use in an emergency situation, the following set-up and checkout procedures should be performed prior to putting the device into service and after each clinical use.

1. Inspect all external surfaces of the unit to ensure that they are clean and free of structural damage such as cracks, broken or missing parts.
2. Inspect the patient connector to ensure that there are no broken or missing connector pins.
3. Install new batteries. (See Section *Installing or Replacing Batteries*.)
4. Connect a ZOLL AED PLUS Simulator/Tester (or equivalent) to the AED's patient connector.
5. Power on the simulator and ZOLL AED PLUS unit. Verify that all of the following occur:
 - The Status indicator initially displays a red "X" which changes to a green check within 4 to 5 seconds after the unit is turned on.
 - All top panel user interface lights (LEDs) sequentially illuminate.
 - Within 5 seconds after the ZOLL AED PLUS is turned on, the audible message *UNIT OK* is announced (and displayed if the unit is equipped with a LCD display).
 - If unit is equipped with a LCD display, the message "SHOCKS: 0" appears in the upper left corner and elapsed time is shown in the upper right corner of the screen.

NOTE If the message *DATA STORED* is announced or displayed, ECG and other rescue event data is stored in memory and has not been uploaded to a data storage or archiving system. To avoid overwriting this information, upload the data to a personal computer equipped with ZOLL Data Control or ZOLL Data Review Software before continuing this check out procedure.

6. Using the simulator, input a VF rhythm to the ZOLL AED PLUS, verify that after the AED proceeds through its sequence of patient assessment prompts, it analyzes the ECG rhythm, announces *TREATMENT ADVISED*, charges the defibrillator and announces *DON'T TOUCH PATIENT, PRESS TREATMENT BUTTON*.

7. Verify that the charge ready tone is heard and that the Treatment Button illuminates.
8. Press the Treatment Button and verify that the simulator shows a shock was delivered. Verify that the message “Shocks: 1” displays on LCD screen. (Note: This verification test checks the device’s ability to defibrillate. It does not, however, verify that the correct defibrillation energy was delivered. A defibrillator analyzer must be used in place of the ZOLL AED PLUS simulator/tester to test delivered energy accuracy).
9. Immediately following shock delivery change the simulator input to a normal sinus rhythm (NSR). Verify that the ZOLL AED PLUS performs a new rhythm analysis that results in announcement of a *NO TREATMENT ADVISED* message.
10. Verify that following the *NO SHOCK ADVISED* prompt, the unit issues the following prompts/messages *OPEN AIRWAY – CHECK BREATHING – CHECK CIRCULATION – IF NO CIRCULATION, START CPR*.
11. Activate the simulator’s CPR function and verify that the metronome begins to beep and the following voice prompts/messages are issued during the next 60 seconds: *PUSH HARDER* followed by *GOOD COMPRESSIONS*.
12. After approximately one minute of CPR, verify that the *STOP CPR* prompt is issued. Set the simulator to VF and verify that a new ECG analysis begins.
13. Turn the ZOLL AED PLUS and Simulator off.
14. Verify that new CPR-D padz or stat padz II ® to be used with the ZOLL AED PLUS are well within their expiration date.
15. Follow instructions provided with the new electrodes to pre-connect them to the patient connector on the device and pack them within the ZOLL AED PLUS cover.
16. Close the AED’s top cover then perform a self test by pressing the ZOLL AED PLUS power button. Verify that the voice prompt *UNIT OK* is heard. This prompt indicates that the new batteries and electrodes are properly installed and the unit is ready for service.
17. Turn the ZOLL AED PLUS off.

NOTE If any of the tests described above fail, contact your service provider or ZOLL Technical Service.

Automatic Self-Test

The ZOLL AED PLUS includes a self-test feature that tests the device once every seven (7) days (default configuration) when the unit is stored with batteries installed. This self-test feature verifies the unit’s integrity and readiness for emergency use by testing the following ZOLL AED PLUS functions:

1. Battery Capacity: Verifies that the batteries contain at least 50% of their full capacity;
2. Defibrillation Electrodes Connection: Verifies that defibrillation electrodes are properly pre-connected to the device.
3. ECG Circuitry: Verifies that the ECG signal acquisition and processing electronics are functional.
4. Defibrillator Charge and Discharge Circuitry: Verifies that the device’s defibrillator electronics are functional and can charge and discharge at 2 joules.
5. Microprocessor Hardware/Software Tests: Verify proper function of the ZOLL AED PLUS microprocessor electronics and the integrity of its software.

A manual self test is initiated by pressing and holding down the unit’s On/Off button for 5 seconds. The ZOLL AED PLUS illuminates all graphic indicators and issues voice and LCD display messages to allow user verification of the device’s visual and auditory output functionality.

Following successful completion of all self tests, the AED's status indicator displays a green check (✓) to show that all tests passed and the unit is ready to use.

If a red X is displayed following completion of the unit's self tests, the AED is not ready for use and may be defective. Remove the ZOLL AED PLUS from service and consult the Troubleshooting section of this guide to help determine the problem.

All self tests occur automatically whenever the unit is powered on.

Installing or Replacing Batteries

To power the unit, use ten (10) consumer type 123A Photo Flash lithium manganese dioxide batteries. These batteries:

- Can be purchased at many department, camera, or electronics stores.

CAUTION! Use Duracell, Sanyo or Varta batteries only. **Do not use Panasonic or Rayovac batteries.** Use of Panasonic or Rayovac batteries may result in significantly longer defibrillator charging times than those required during emergency situations.

- Should be used well before their labeled expiration date.
- Should be checked periodically for the expiration date.

Below you will find examples on how to read date codes on Duracell, Sanyo and Varta batteries.

Duracell:

The first digit indicates the year of manufacture:

Example: 7=1997, 6=1996 etc.

The second digit is a letter from A-L which indicates the month of manufacture:

Example: A=January, B=February and so on to L for December.

Sanyo:

The first letter indicates the year of manufacture.

Example: A=1996, B=1997, etc.

The second letter indicates the month of manufacture.

Example: A=January, B=February, etc.

Varta:

The BRAUNSCHWEIG - Code (always two letters) is printed on the side of the can in axial direction to cell height.

The first letter indicates the month of manufacture

Example: B=January, R=February, A=March, etc.

The second letter indicates the year of manufacture

Example: B=2001, R=2002, A=2003, etc.

Batteries produced by all recommended manufacturers have a 10 year from date of manufacture shelf life when not installed in an AED unit.

To install the batteries:

1. Ensure that the unit is turned off. Open the battery compartment by removing the battery cover from the back of the unit.

This is accomplished by inserting a small tool (e.g., flat blade screw driver) into the two slots on the rear of the unit to depress the latches, and then inserting the tool into the groove on the bottom to lift the cover (see Figure 6).

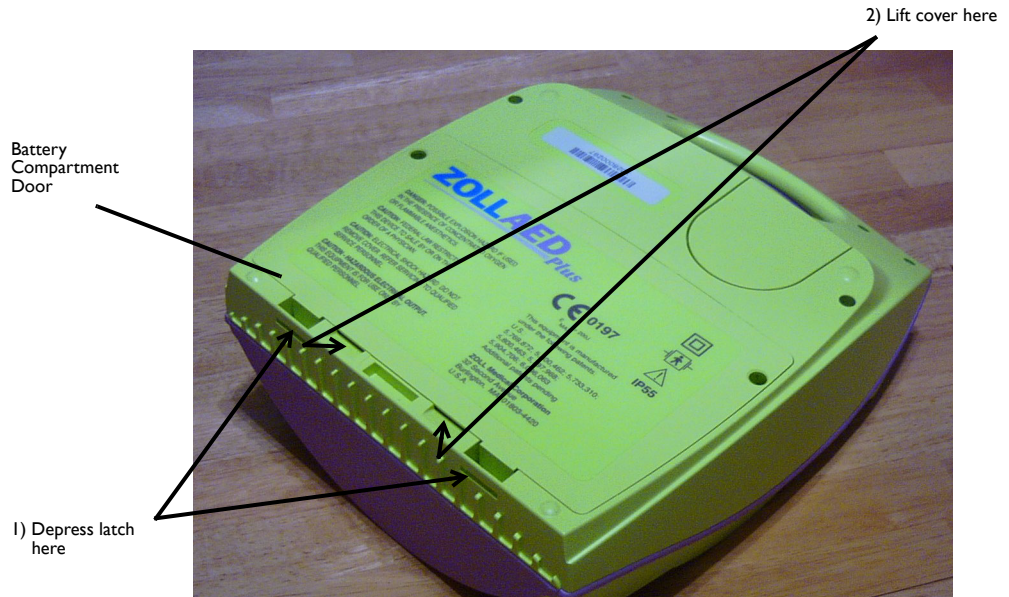


Figure 6: Removing the Battery Compartment Door

2. Remove all batteries at once and discard properly. Place new batteries into the battery bank, observing battery polarity markings and making sure that all batteries are securely seated and oriented properly. After placing the first 5-9 batteries into the battery well, an audio prompt, *INSTALL BATTERY*, reminds you to install the remaining batteries into the battery compartment.

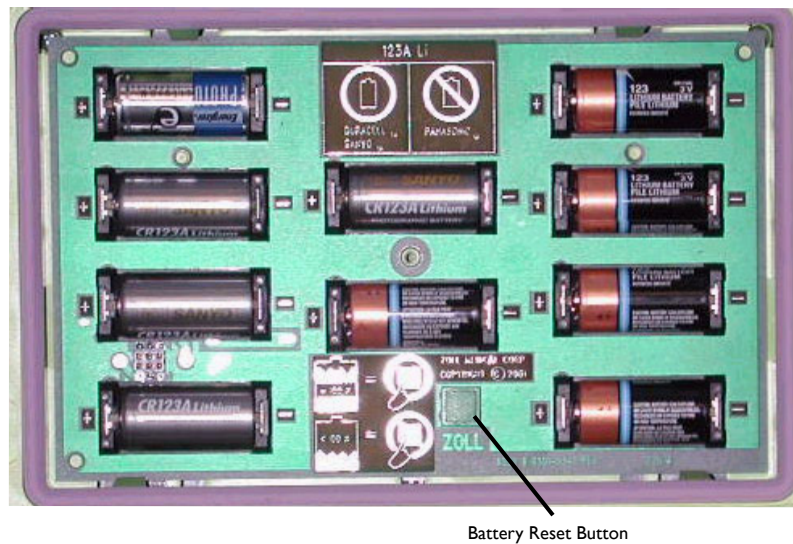


Figure 7: Battery Compartment

- After installing new batteries, press the battery reset button inside the battery compartment when prompted (see Figure 7). Pressing the button resets the battery usage indicator to full charge.

CAUTION! Do not place used batteries into the unit. You **MUST** replace all ten (10) batteries at once. Do not replace individual batteries. The unit cannot detect whether all batteries or only a few batteries have been replaced. **Using less than fully charged batteries can affect the unit when performing a rescue. DO NOT** press the Battery Reset button if all the batteries are not new. The unit then assumes that they are the same batteries that were just removed.

NOTE If you do not press the battery reset button in the battery well within 15 seconds after installing all batteries, the device will assume that the batteries installed in the device were temporarily removed, and are **not fully** charged.

NOTE Because Lithium Manganese Dioxide battery cells do not contain toxic materials they may be disposed of in general trash after discharge or when properly protected against shorting between terminals.

Identifying Battery Condition

Battery capacity depletes during standby operation of the unit, while the unit is operating and as a result of each defibrillation. It also gradually diminishes over a shelf life of years without use. The unit monitors energy remaining in the installed batteries. When battery capacity is low or depleted, the unit will not function to specification. When a low battery condition occurs:

- The unit emits an audible alarm or “beep” once every minute if the unit is off.
- You hear the audio prompt, *CHANGE BATTERIES* if the unit is on.
- Red “X” displays on the status indicator, notifying you that the batteries have less than 50% of the full capacity remaining or that the unit has failed other self tests.

Table 3: Battery Condition

Battery Condition	Indications	Correction
Low Battery with unit off.	Audible beep from unit once every minute.	Replace batteries.
Low Battery during power up self-test.	CHANGE BATTERIES prompt (when unit is powered on)	Replace batteries.
Low Battery or other self test failure with unit powered off or during self-test.	Status Indicator has red “X” indicating failure to operate (when off).	Replace batteries. Check or replace electrodes. If red “X” remains, return to ZOLL Technical Support for service.
Low Battery with unit powered on.	CHANGE BATTERIES prompt (unit powered on).	Replace batteries as soon as possible.
Dead Battery.	Status Indicator has red “X” indicating failure to operate (when off).	Replace batteries. If red “X” remains, return to ZOLL Technical Support for service.

Maintaining the Unit

- Inspect frequently, as necessary.
- Check for the green check showing that the unit is ready to use.
- Test periodically.
- Verify electrodes are within their expiration date.
- Verify the batteries are within their expiration date.
- Verify that electrodes are pre-connected to the input connector.
- Verify supplies are available for use (razor, mask, gloves, extra batteries.)

Cleaning the Unit

- After each use, clean and disinfect the unit with a soft, damp cloth using 90% isopropyl alcohol, or soap and water, or chlorine bleach and water mixture (30 ml/liter water).
- Do not immerse any part of the unit in water.
- Do not use ketones (MEK, acetone, etc.) to clean the unit.
- Avoid using abrasives (e.g., paper towel) on the display window or IrDa port.
- Do not sterilize the device.

Maintenance Checklist

Use the following maintenance checklist when you periodically check your unit.

Table 4: Maintenance Checklist

Check the following	Pass	Fail
Is the unit clean, undamaged, free of excessive wear?	<input type="checkbox"/>	<input type="checkbox"/>
Are there any cracks or loose parts in the housing?	<input type="checkbox"/>	<input type="checkbox"/>
Verify electrodes are connected to the unit and sealed in their package. Replace if expired.	<input type="checkbox"/>	<input type="checkbox"/>
Are all cables free of cracks, cuts and exposed or broken wires?	<input type="checkbox"/>	<input type="checkbox"/>
Periodically test the unit using a simulator. Do three discharges and verify: energy delivery, ECG analysis results, indicators and display illuminate, voice prompts are heard.	<input type="checkbox"/>	<input type="checkbox"/>
Turn the unit on and off and verify the green check indicates ready for use.	<input type="checkbox"/>	<input type="checkbox"/>
Batteries within expiration date. Replace if expired.	<input type="checkbox"/>	<input type="checkbox"/>
Check for presence of supplies.	<input type="checkbox"/>	<input type="checkbox"/>

Troubleshooting

Return the unit to ZOLL's Technical Service Department if the unit is not working properly.

Table 5: Troubleshooting

Technical Problem	Recommended Action
Self test failed.	Manually test by pressing and holding the ON/OFF button for more than 5 seconds. Attempt to repair the device by replacing the batteries or electrodes. If unit fails test again, remove unit from service and contact ZOLL Technical Service.
<i>CHANGE BATTERIES</i> prompt.	Replace all batteries with new ones at the same time. Press the battery button when prompted.
Red "X".	Run manual test. Check to see if cable is attached properly to unit or replace the electrode. Replace batteries with new ones at the same time. Press the battery reset button when prompted. If unit still does not work, remove unit from service and contact ZOLL Technical Service.
Hear beeping noise when unit is off.	Remove unit from service and replace batteries. Replace all batteries with new ones at the same time. Press the battery reset button when prompted. If beeping continues, contact ZOLL Technical Service.
Hear <i>PLUG IN CABLE</i> prompt.	Check cable connection between electrodes and AED.
<i>ANALYSIS HALTED. KEEP PATIENT STILL</i> prompt.	Excessive artifact detected during ECG analysis. A patient must be motionless during ECG analysis. Do not touch the patient during analysis. Keep the patient still. If the rescuer is using the device in an emergency vehicle, bring the vehicle to a halt before performing ECG analyses.
<i>RELEASE TREATMENT BUTTON</i> prompt.	Release Treatment Button, then press and hold Treatment Button until discharge occurs. If voice prompt continues, contact ZOLL Technical Service.

Using ZOLL Administration Software

ZOLL Administration Software helps you perform software maintenance tasks when your defibrillator is connected to your PC. ZOLL Administration Software lets you upload data from a defibrillator to a personal computer (PC), then transmit that data to your main network, or print the data locally from your PC to your printer.

Installing ZOLL Administration Software

Insert the ZOLL Administration Software CD on your PC. The program starts automatically.

If the install program does not start automatically:

- Select RUN from the Start menu.
- In the Open text field, enter X:Setup.exe, substituting X for the correct letter of your CD-ROM drive.
- Click OK.
- Follow the instructions that appear on the screen to complete the installation.

Setting Up Data Communications

You can exchange data between an AED PLUS unit and a personal computer without any cable connection by transferring data using two IrDA (infrared interface standard) ports. One IrDA™ port is located on the side of the ZOLL AED PLUS unit. The second IrDA™ port may be on your personal computer. In some cases, you will be sending data from the IrDA port on your unit to an IrDA port on a modem which then transmits the data to a remote computer.

For best transmission results, IrDA ports must be facing each other and the path between the two devices must be clear of obstacles. Beaming distances between devices may vary but should be at least 10 inches and not more than 18 inches. Power up the PC and have the ZOLL Administration Software and/or ZOLL Data Control software running. Press and hold the ON/OFF button on the AED for at least 5 seconds to establish contact with the computer or modem. Once connected properly, you hear the audio prompt *COMMUNICATIONS ESTABLISHED* and see a message on your computer screen that the connection was successful.

See the online Help for a description on how to use ZOLL Administration Software.

Ordering Accessories

You can order the following accessories from the ZOLL Customer Service Department

Table 6: Ordering Accessories

Item	Part Number
CPR-D padz electrode including accessory kit	8900-0800-01
stat padz II electrode (single)	8900-0801-01
stat padz II electrode (case)	8900-0802-01
Set of 10 Batteries	8000-0807-01
Administrator's Guide	9650-0301-01
Operator's Guide	9650-0300-01
Simulator/Tester	8000-0800-01
Public Safety PASS	8000-0812-01
PASS Cover	8000-0808-01
Low Profile Cover	8000-0803-01
Soft Case	8000-0802-01
Universal Adapter Cable	8000-0804-01
Administration Guide with ZOLL Administration Software CD	9659-0302-01
Mounting Bracket	8000-0809-01
Flush Mount Wall Box	8000-0811
Recess Mount Wall Box	8000-0814
Surface Mount Wall Box	8000-0817
USB IrDA PC Adapter	8000-0815
RS-232 IrDA PC Adapter	8000-0816
ZOLL Data Review Software	8000-0813-01
AEDPlus Trainer	8008-0104-01
Replacement Trainer	1008-0115-01
Replacement Trainer Control	1008-0113-01
Trainer AC Adapter	
	US 9355-0802
	EURO 9355-0803
	UK 9355-0804
	Switzerland 9355-0805
	Australia 9355-0806
Trainer Cord	9355-0801

Contacting Technical Service

If a ZOLL product requires service, contact the ZOLL Technical Service Department:

Telephone: 1-781-229-0020; 1-800-348-9011

Fax 1-781-229-0758

Have the following information available for the Technical Service representative:

- Unit serial number.
- Description of the problem.
- Purchase Order or credit card number to allow tracking of loan equipment.
- Purchase Order or credit card number for a unit with an expired warranty.

If the unit needs to be sent to ZOLL Medical Corporation, obtain a service order request number from the Technical Service representative. Units are available on loan at an additional cost while your unit is being repaired.

Remove all batteries from the unit and return the unit and batteries in its original container or equivalent packaging with the service order request number on it to the following address:

ZOLL Medical Corporation

32 Second Avenue

Burlington, Massachusetts 01803-4420

Attn: Technical Service Department

Contacting Technical Service for International Customers

Customers outside of the United States should remove all batteries from the unit and return the unit and batteries in its original container or equivalent packaging to the nearest authorized ZOLL Medical Corporation Service Center. To locate an authorized service center, contact the nearest ZOLL Sales office or authorized distributor.

Appendix A: Specifications

Table 7: General Specifications

DEVICE	
Size (H x W x D)	5.25"x 9.50" x 11.50"; 13.3 cm x 24.1 cm x 29.2 cm
Weight	6.7 lbs.; 3.1 kg
Power	User Replaceable Batteries. 10 -Type 123A Photo Flash lithium manganese dioxide batteries.
Device Classification	Class II and internally powered per EN60601-1
Design Standards	Meets applicable requirements of UL 2601, AAMI DF-39, IEC 601-2-4, EN60601-1, IEC60601-1-2
ENVIRONMENT	
Operating Temperature	PS Model: 32 °F to 122 °F; 0° to 50°C PA Model: 50° to 104°F; 10° to 40°C
Storage Temperature	PS Model: -22° to 158°F; -30° to 70°C PA Model: 32° to 122°F; 0° to 50°C
Humidity:	10 to 95% relative humidity, non-condensing
Vibration	MIL Std. 810F, Min Helicopter Test
Shock	PS Model: IEC 68-2-27; 100G PA Model: IEC 68-2-27; 50G
Altitude	PS Model: -300 to 15,000 ft.; -91m to 4573m PA Model: -300 to 7,500 ft.; -91m to 2287m
Particle and Water Ingres	IP-55
DEFIBRILLATOR	
Waveform	Rectilinear Biphasic
Defibrillator Charge Hold Time	30 seconds
Energy Selection	Automatic pre-programmed selection (120J, 150J, 200J)
Patient Safety	All patient connections are electrically isolated.
Charge Time	Less than 10 seconds with new batteries.
Electrodes	ZOLL stat padz II or CPR-D padz.
Built in Defibrillator Self Test	Included

DEFIBRILLATOR (cont'd)	
CPR	*Metronome Rate: Variable 60 to 100 CPM Depth: 1/2" to 3"; 1.3 to 7.8 cm.
Defibrillation Advisory	Evaluates electrode connection and patient ECG to determine if defibrillation is required. Shockable Rhythms: Ventricular fibrillation with average amplitude >100 microvolts and wide complex ventricular tachycardia with rates greater than 150 BPM. Refer to ECG Analysis Algorithm Accuracy Section for sensitivity and specificity performance.
Electrode Patient Impedance Measurement Range	0 to 300 ohms
Defibrillator Electrode ECG Circuitry	Protected
ECG Bandwidth	2-30Hz
Display Format	Optional LCD with Moving Bar Size: 2.6" x 1.3"; 6.6 cm x 3.3 cm Viewing Time: 2.6 seconds
Display Sweep Speed	25 mm/sec
Battery Capacity	Typical new (20°C) = 5 years (300 shocks) or 1.5 hours continuous Monitoring/Defibrillation. End of life designated by Red X (typical remaining shocks = 100, 0.5 hours continuous Monitoring/Defibrillation).
PC Minimum Requirements	Windows® 98, Windows® 2000 Windows®NT, Windows® XP IBM-compatible PII with 16550 UART (or higher) computer. 64MB RAM. VGA monitor or better. CD-ROM drive. IrDA™ port 20MB disk space.
<p>*Testing reports validating performance and accuracy of CPR depth measurement capability, metronome feature function and rescuer performance, and the PASS (Passive Airway Support System) cover function are on file with ZOLL Medical and are available for review. Contact ZOLL Technical Support to request a copy of the following report(s) if desired:</p> <ul style="list-style-type: none"> • Using the ZOLL AED PLUS Cover to Aid in Airway Patency • Depth and Compression Rate Response of the AED PLUS CPR System • AED Plus CPR System Test Results. 	

Guidance and Manufacturer's Declaration - Electromagnetic Emissions


Table 8: EMC Specifications

The ZOLL AED PLUS is intended for use in the electromagnetic environment specified below. The customer or the user of the ZOLL AED PLUS should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR11	Group 1	The ZOLL AED PLUS uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	
Harmonic Emission IEC 61000 3-2	Not applicable	
Voltage Fluctuations/Flicker Emission IEC 61000 3-3	Not applicable	
Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to EMC information provided in this document.		

The ZOLL AED PLUS is intended for use in the electromagnetic environment specified below. The customer or the user of the ZOLL AED PLUS should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Not applicable ± 1 kV I/O	
Surge IEC 61000-4-5	± 1 kV differential mode +/- 2 kV common mode	Not applicable Not applicable	

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	<5% U_t (>95% dip in U_t) for 0.5 cycle 40% U_t (60% dip in U_t) for 5 cycles 70% U_t (30% dip in U_t) for 25 cycles <5% U_t (>95% dip in U_t) for 5 sec	Not applicable Not applicable Not applicable Not applicable	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
NOTE U_t is the a.c. mains voltage prior to application of the test level.			

The ZOLL AED PLUS is intended for use in the electromagnetic environment specified below. The customer or the user of the ZOLL AED PLUS should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the ZOLL AED PLUS, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands ^a	3 Vrms	$d = 1.17 \sqrt{P}$
	10 Vrms 150 kHz to 80 MHz in ISM bands ^a	10 Vrms	$d = 1.20 \sqrt{P}$
Radiated RF IEC 61000-4-3	10 Vrms 80 MHz to 2.5 GHz	10 V/m	$d = 1.20 \sqrt{P}$ 80 MHz to 800 MHz

Immunity test (cont'd)	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			$d = 2.30 \sqrt{P}$ 800 MHz to 2.5 GHz
			<p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).^b</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^c should be less than the compliance level in each frequency range.^d</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

NOTE 1 At 80 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

^a The ISM (industrial, scientific and medical) bands between 150 KHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

^b The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

^c Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ZOLL AED PLUS is used exceeds the applicable RF compliance level above, the ZOLL AED PLUS should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ZOLL AED PLUS.

^d Over the frequency range 150 kHz to 80 MHz, field strengths should be less than (V_1) V/m.

Recommended separation distances between portable and mobile RF communications equipment and the ZOLL AED PLUS

The ZOLL AED PLUS is intended for use in an environment in which radiated RF disturbances are controlled. The customer or the user of the ZOLL AED PLUS can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ZOLL AED PLUS as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m			
	150 kHz to 80 MHz outside ISM bands $d = \lceil \frac{3.5}{3} \rceil \sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = \lceil \frac{12}{10} \rceil \sqrt{P}$	80 MHz to 800 MHz $d = \lceil \frac{12}{10} \rceil \sqrt{P}$	800MHz to 2.5 GHz $d = \lceil \frac{23}{10} \rceil \sqrt{P}$
0.01	0.17	0.12	0.12	0.23
0.1	0.37	0.38	0.38	0.73
1	1.17	1.20	1.20	2.3
10	3.69	3.79	3.79	7.27
100	11.70	12.00	12.00	23.00

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

NOTE 3 An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Rectilinear Biphasic Waveform Characteristics

The following table shows the Rectilinear Biphasic waveform's characteristics when discharged into 25 ohm, 50 ohm, 100 ohm, and 125 ohm loads at a maximum energy setting of 200 Joules.

Table 9: Biphasic Waveform

	Discharged into 25 ohm load	Discharged into 50 ohm load	Discharged into 100 ohm load	Discharged into 125 ohm load
First Phase Maximum Initial Current	32 A	26 A	21 A	17 A
First Phase Average Current	28 A	22A	16 A	13 A
First Phase Duration	6 ms	6 ms	6 ms	6 ms
Interphase duration between first and second phases	150 μ sec	150 μ sec	150 μ sec	150 μ sec
Second Phase Maximum Initial Current	33 A	19 A	12 A	11 A
Second Phase Average Current	21 A	14 A	11 A	10 A
Second Phase Duration	4 ms	4 ms	4 ms	4 ms

The efficacy of ZOLL's Rectilinear Biphasic Waveform has been clinically verified during a Ventricular Fibrillation (VF) and Ventricular Tachycardia (VT) defibrillation study. This study (which was conducted using ZOLL M-Series defibrillators) and the findings are described below. Since the AED PLUS's rectilinear biphasic waveform employs the same first and second phase timing, similar first and second phase currents/voltages and essentially the same mechanisms for controlling defibrillation waveshape, the M-Series and AED PLUS defibrillation waveforms are considered substantially equivalent.

Clinical Trial Results for the M Series Biphasic Waveform

The efficacy of ZOLL's Rectilinear Biphasic Waveform has been clinically verified during a study of defibrillation of Ventricular Fibrillation (VF)/Ventricular Tachycardia (VT). A feasibility study was performed initially for defibrillation of VF/VT (n=20) on two separate groups of patients to ensure waveform safety and energy selection. Subsequently a separate, multi-center, randomized clinical trial was performed to verify the waveform's efficacy. A description of this study is provided below. The study was performed using ZOLL defibrillation systems consisting of ZOLL defibrillators, the ZOLL Rectilinear Biphasic Waveform and ZOLL Multi-Function Pads.

Randomized Multi-Center Clinical Trial for Defibrillation of Ventricular Fibrillation (VF) and Ventricular Tachycardia (VT)

Overview: The defibrillation efficacy of ZOLL's Rectilinear Biphasic Waveform was compared to a monophasic damped sine waveform in a prospective, randomized, multi-center study of patients undergoing ventricular defibrillation for VF/VT during electro-physiological studies, ICD implants and test. A total of 194 patients were enrolled in the study. Ten (10) patients who did not satisfy all protocol criteria were excluded from the analysis.

Objectives: The primary goal of this study was to compare the first shock efficacy of the 120J Rectilinear Biphasic Waveform with a 200J monophasic waveform. The secondary goal was to compare all shock (three consecutive 120, 150, 170J) efficacy of the Rectilinear Biphasic Waveform with that of a monophasic waveform (three consecutive 200, 300, 360J). A significance level of $p=0.05$ or less was considered statistically significant using Fischer's Exact test. Also, differences between the two waveforms were considered statistically significant when the customary 95% or AHA recommended 90%* confidence interval between the two waveforms was greater than 0%.

Results: The study population of 184 patients had a mean age of 63 ± 14 years. 143 patients were males. 98 patients were in the biphasic group (ventricular fibrillation/flutter, n=80, ventricular tachycardia, n=18) and 86 patients were in the monophasic group (ventricular fibrillation/flutter, n=76, ventricular tachycardia, n=10). There were no adverse events or injuries related to the study.

The first shock, first induction efficacy of biphasic shocks at 120J was 99% versus 93% for monophasic shocks at 200J ($p=0.0517$, 95% confidence interval of the difference of -2.7% to 16.5% and 90% confidence interval of the difference of -1.01% to 15.3%).

	Monophasic	Biphasic
1st Shock Efficacy	93%	99%
p-value	0.0517	
95% Confidence Interval	-2.7% to 16.5%	
90% Confidence Interval	-1.01% to 15.3%	

Successful defibrillation with rectilinear biphasic shocks was achieved with 58% less delivered current than with monophasic shocks (14 1 vs. 33 ± 7 A, $p=0.0001$).

The difference in efficacy between the rectilinear biphasic and the monophasic shocks was greater in patients with high transthoracic impedance (greater than 90 ohms). The first shock, first induction efficacy of biphasic shocks was 100% versus 63% for monophasic shocks for patients with high impedance (p=0.02, 95% confidence interval of the difference of -0.021% to 0.759% and 90% confidence interval of the difference of 0.037% to 0.706%).

	Monophasic	Biphasic
1st Shock Efficacy (High Impedance Patients)	63%	100%
p-value	0.02	
95% Confidence Interval	-0.021% to 0.759%	
90% Confidence Interval	0.037% to 0.706%	

A single patient required a second biphasic shock at 150J to achieve 100% efficacy versus six patients for whom shocks of up to 360J were required for 100% total defibrillation efficacy.

Conclusion: The data demonstrate the equivalent efficacy of low energy rectilinear biphasic shocks compared to standard high energy monophasic shocks for transthoracic defibrillation for all patients at the 95% confidence level. The data also demonstrate the superior efficacy of low energy rectilinear biphasic shocks compared to standard high energy monophasic shocks in patients with high transthoracic impedance at the 90% confidence level. There were no unsafe outcomes or adverse events due to the use of the rectilinear biphasic waveform.

* Kerber, R., et. al., AHA Scientific Statement, Circulation, 1997; 95: 1677-1682:

“... the task force suggests that to demonstrate superiority of an alternative waveform over standard waveforms, the upper boundary of the 90% confidence interval of the difference between standard and alternative waveforms must be < 0% (i.e., alternative is greater than standard).”

ECG Analysis Algorithm Accuracy

Sensitivity, specificity, false positive rate and positive predictivity are expressions of an ECG analysis system's performance when compared with clinicians or experts. The specifics of computations are detailed below. The accompanying data details the accuracy of the algorithm as tested by independent investigators.

The Algorithm:

- Divides the ECG rhythm into three-second segments.
- Filters and measures noise, artifact, and baseline wander.
- Measures baseline content ('waviness' at the correct frequencies - frequency domain analysis) of signal.
- Measures QRS rate, width, and variability.
- Measures amplitude and temporal regularity ('auto-correlation') of peaks and troughs.
- Determines if multiple 3 second segments are shockable then prompts the user to treat patient. The Algorithm sequence takes approximately 9 seconds.

Table 10: Clinical Performance Results

Rhythms	Sample Size	Performance Goals	Observed Performance	90% One-sided Lower Confidence Limit
Shockable (250 Total min.)	618			
Coarse VF	535	>90% sensitivity	97.38%	95.65%
Rapid VT	83	>75% sensitivity	91.57%	83.39%
Non-shockable (300 Total min.)	3039			
NSR	2205	>99% sensitivity	99.86%	99.60%
AF, SB, SVT, Heart block, idioventricular, PVCs	770	>95% sensitivity	100%	99.52%
Asystole	64	>95% sensitivity	100%	99.40%
Intermediate	88			
Fine VF	64	Report only	93.75% sensitivity	84.76%
Other VT	24	Report only	91.67% specificity	73.00%

1. Arrhythmia Performance is reported according to the article, RE Kerber, LB Becker, JD Bourland, RO Cummins, AP Hallstrom, MB Michos, G Nichol, JP Ornato, WH Thies, RD White, BD Zuckerman, "Automated External Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporation New Waveforms, and Enhancing Safety", Circulation 1997, Vol 95, No 6, 1677-1681

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"CRC Standard Mathematical Tables 28th Edition", William H. Beyer, Ph.D., CRC Press, Inc, Boca Raton, FL., 1981, Percentage Points, F-Distribution Table, pg 573.

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