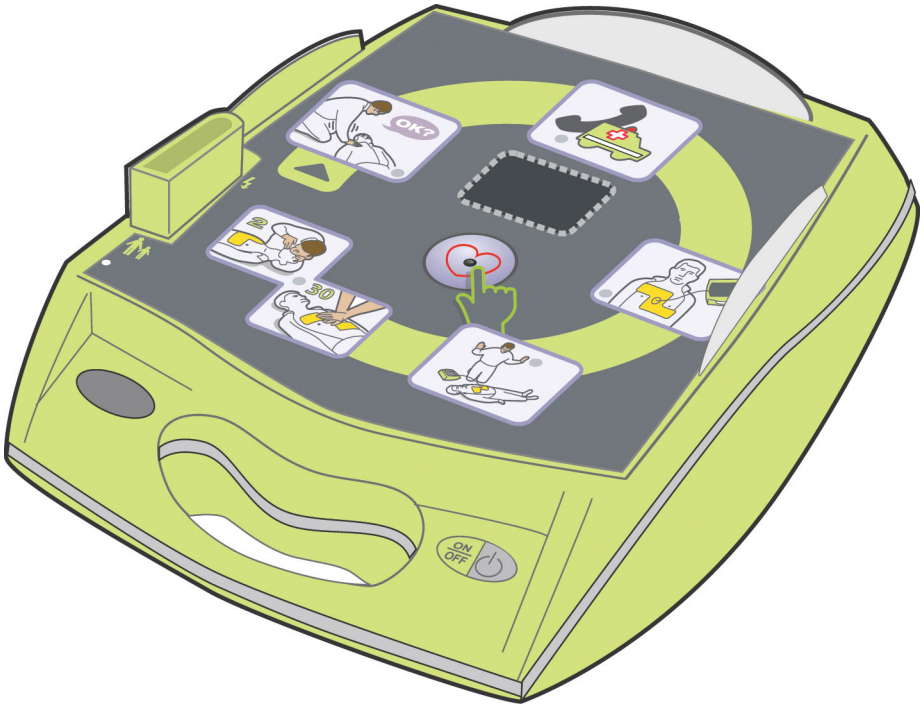
AED Plus®
Administrator's Guide



ZOLL®

9650-0301-06 Rev. F

This issue date for the ZOLL **AED Plus Administrator's Guide**, (**REF** 9650-0301-06 Rev **F**) is **March, 2024.**

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Caution: Federal law restricts this device to sale by or on the order of a licensed practitioner.

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Preface

The AED Plus® *Administrator's Guide* is to be used by responsible medical authorities in conjunction with the *ZOLL AED Plus Operator's Guide* (**REF** 9650-0300-06).

The 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 AHA/ERC Guidelines 2015 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.

This guide provides information about the operation and care of the AED Plus unit. The administrator, and user should read each section carefully. Make sure to read the Safety Summary section.

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 Plus.

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

Section 2 - Installation, 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 Plus, 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.

Summary of Safety and Clinical Performance (SSCP)

The Summary of Safety and Clinical Performance (SSCP) is available in the European database on medical devices (Eudamed) - https://ec.europa.eu/tools/eudamed.

The Basic UDI-DI is 08479460RTF.

Warnings

- Use the AED Plus unit only as described in this manual. Improper use of the device can cause death or injury.
- DO NOT use or place the AED Plus unit in service until you have read the AED Plus Operator's and Administrator's Guides.
- DO NOT use or place the AED Plus unit in service if the unit's status indicator window (located on the left side of the handle) displays a red "X".
- DO NOT use or place the AED Plus unit in service if the unit emits a beeping tone.
- Connect the electrode cable to the AED Plus unit after installing batteries.
- Keep the electrode cable connected to the AED Plus unit at all times.
- This device should only be used by properly trained individuals.

- Only use electrodes labeled “Infant/Child” on children less than 8 years old or weighing less than 55 lbs (25 kg). Use CPR-D-padz® if victim is older than 8 years or weighs more than 55 lbs (25 kg).
- Always stand clear of victim when delivering a shock. Defibrillation energy delivered to the victim may be conducted through the victim’s body and cause a lethal shock to those touching the victim.
- DO NOT TOUCH the electrode surfaces, the victim, or any conductive material touching the victim during ECG analysis or defibrillation.
- Move victim away from electrically conductive surfaces prior to use of equipment.
- DO NOT use this unit near or within puddles of water.
- Keep the victim as motionless as possible during ECG analysis.
- DO NOT use this 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 2 way-radios.
- Disconnect non-defibrillation protected electronic devices or equipment from victim before defibrillation.
- Dry victim’s chest, if wet, before attaching electrodes.
- Apply freshly opened and undamaged electrodes, within the electrode expiration date, to clean and dry skin to minimize burning.
- DO NOT place the electrodes directly over the victim’s implanted pacemaker. Pacemaker stimuli may degrade the accuracy of ECG rhythm analyses or the pacemaker may be damaged by defibrillator discharges.
- Check labeling inside the AED Plus cover before using the cover as a Passive Airway Support System (PASS) device. Ensure it is intended for this use.
- DO NOT use Passive Airway Support System (PASS) if there is a suspected head or neck injury. Place victim on a firm surface before performing cardiopulmonary resuscitation.
- DO NOT recharge, disassemble, or dispose of batteries in fire. Batteries may explode, if mistreated.
- Do not use or stack the AED Plus unit with other equipment. If the unit is used or stacked with other equipment, verify proper operation prior to use.
- Keep the AED Plus unit away from magnetic resonance imaging (MRI) equipment.

Cautions

- Do not disassemble the unit. A shock hazard exists. Refer all servicing to qualified personnel.
- There are no replaceable parts in this unit without the use of tools, and no user replaceable parts while the unit is in clinical operation on a patient.
- Use only commercially available Duracell Coppertop CR123 batteries. Do not use batteries from any other manufacturer. Discard batteries properly after removal from unit.
- If the device is stored outside the recommended environmental conditions, the electrode pads and/or batteries may be damaged or their useful life reduced.
- Safety and effectiveness data submitted by ZOLL Medical Corporation to the Food and Drug Administration (FDA) 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 and AED Pro®.

Intended Purpose

The intended purpose of the ZOLL AED Plus is to help victims of sudden cardiac arrest. Using compatible ZOLL defibrillation electrodes which connect the patient to the ZOLL AED Plus, the AED automatically analyzes the victim's ECG rhythm to determine whether an electrical shock should be delivered. If the AED detects a shockable rhythm (coarse ventricular fibrillation or wide complex ventricular tachycardia), it alerts the rescuer that a shock is advised and then it either issues instructions to press the flashing shock button (semi-automatic model) or it automatically delivers the shock after a 3 second countdown (fully automatic model). The AED then prompts the rescuer to perform CPR for a pre-configured period of time.

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.

This device is intended for use by personnel who have been trained in its operation. Users should receive training in basic life support/AED, advanced life support or a physician-authorized emergency medical response training program.

When the victim is less than 8 years of age or weighs less than 55 lbs (25 kg), the AED Plus should be used with AED Plus pediatric electrodes (Pedi-padz® II). Therapy should not be delayed to determine the victim's exact age or weight.

Contraindications for Use

Do NOT use the AED Plus when the victim:

- Is conscious; or
- Is breathing; or
- Has a detectable pulse or other signs of circulation.

Intended Users of the Device

This device is intended for use by personnel who have been trained in its operation. Users should receive training in basic life support/AED, advanced life support or a physician-authorized emergency medical response training program. The Real CPR Help® 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 minimum compression depth of 2 inches (5 cm) for adult victims. The Real CPR Help function is not intended for use on victims under 8 years of age.

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 Safe Medical Devices Act (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.

Potential adverse effects (e.g. complications) associated with use of AEDs include:

- Failure to identify shockable arrhythmia;
- Failure or delay in delivery of a defibrillation shock in the presence of VF or pulseless VT which may result in death or serious injury;
- Inappropriate energy which could cause failed defibrillation or post-shock dysfunction;
- Myocardial damage;
- Fire hazard in the presence of high oxygen concentration or flammable agents;
- Incorrectly shocking a pulse-sustaining rhythm and inducing VF or cardiac arrest;
- Inadvertent user/bystander shock from patient contact during defibrillation;
- Inadvertent user burn during defibrillation;
- Complications in effective rhythm assessment and shock delivery due to interaction with patient ICDs (pacemakers);
- Patient harmed due to device interference with other critical care equipment;
- Skin burns around defibrillation pad/electrode placement area;
- Allergic dermatitis due to sensitivity to materials used in defibrillation pad/electrode construction;
- Minor skin rash;
- Inadequate and/or delayed delivery of CPR therapy; and
- Broken ribs and/or compression injury due to over aggressive CPR therapy.

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**
	MR unsafe: keep away from magnetic resonance imaging equipment
	Not new battery cells
	New battery cells
	Do Not push button
	Push button
	Do not use this manufacturer
	Ok to use this manufacturer

	Unit equipped to treat adult and pediatric victims
	Manufacturer
	Return to a collection site intended for waste electrical and electronic equipment (WEEE). Do not dispose of in unsorted trash.
EC REP	Authorized representative in the European Community
SN	Serial Number
REF	Catalogue number
	Consult instructions for use
Rx ONLY	Prescription only
UDI	Indicates a carrier that contains Unique Device Identifier information
MD	Indicates the item is a medical device
	Indicates the entity importing the medical device into the locale

Introduction

Using the ZOLL AED Plus

The AED Plus is an automated external defibrillator (AED) that uses voice prompts and visual indicators to guide the rescuer through a resuscitation sequence that may include defibrillation and/or cardiopulmonary resuscitation (CPR). The unit incorporates the ZOLL Rectilinear Biphasic Defibrillation waveform, and operates in either adult or pediatric mode.

The AED Plus supports both adult and pediatric defibrillation electrode pads, and automatically adjusts the defibrillation energy based on the type of electrode pads connected to it. Following attachment of electrodes to a victim's chest, the defibrillator monitors the electrocardiographic (ECG) rhythm of the victim's heart, analyzes that rhythm, and determines whether the rhythm is shockable or non-shockable. When needed, defibrillation energy is delivered through these same electrodes. When the unit detects a shockable rhythm, it charges and issues the warning *PRESS FLASHING SHOCK BUTTON*. The rescuer presses the Shock Button to deliver the shock. The rescuer will then be prompted to perform CPR for a period of 2 minutes, after which the unit automatically initiates a new ECG analysis.

The AED Plus has an optional cover that can be used as a PASS (Passive Airway Support System) to support the victim's neck and shoulders in a position that assists in maintaining an open airway. Some versions may also contain disposable accessories, which can also be purchased separately. The AED Plus is powered by ten commercially available consumer brand lithium-manganese dioxide batteries.

The AED Plus can:

- Perform periodic self tests to ensure its continual readiness.
- Use a one-piece electrode assembly (CPR-D-padz) that facilitates proper electrode placement and that is easy to apply to the victim.
- 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 victim.
- Provide audible beeps to encourage rescuers to provide CPR compressions at 100-120 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 computer to store events or print event reports.
- Use commercially available batteries (Duracell Coppertop CR123 only; see page 17 for more information).

Using Real CPR Help®

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 victim's chest so that it is located between the rescuer's hands and the victim'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 AED Plus unit. When used with CPR-D-padz, the 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 100-120 compressions per minute (CPM) as well as voice and visual prompts to encourage a compression depth of 2-2.4 inches (5-6 cm) for adult victims.

WARNING! Real CPR Help is intended for use on adult victims only; do not use on victims under 8 years of age.

The adaptive metronome function is disabled during periods when CPR should not be performed (for example, 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 (2 minutes for AHA and ERC protocols). If the rescuer ceases chest compressions during the CPR period, metronome beeps stop within a few seconds after compressions are halted. Audible beeps resume during the CPR period following any re-initiation of CPR compressions. If no CPR compressions are detected during "CPR periods", the AED Plus periodically re-issues the *CONTINUE CPR* prompt.

The rate of beeps issued by the AED Plus adaptive 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 AED Plus may issue one or more audible prompts based on the depth of chest compressions detected. When Real CPR Help determines that compression depth is consistently less than 2 inches (5 cm), a *PUSH HARDER* prompt will be issued. A *GOOD COMPRESSION* prompt will be issued if the rescuer responds by increasing compression depth to 2 inches (5 cm) or more.

The AED Plus unit can be configured to display the *FULLY RELEASE* text prompt to remind the user to lift the hands off the chest during CPR. By default, this text prompt is not enabled.

Operation

This section describes the following functions:

- Operating Controls and Indicators
- Using the AED Plus Graphical User Interface
- Voice Prompts
- Using the LCD Display
- Using the Passive Airway Support System (PASS)
- Using Electrodes
- Applying CPR-D-padz
- Applying Pedi-padz II (Infant/Child Electrodes)
- Using the CPR Monitoring Function — Real CPR Help
- Using the Audio Recording Option

Operating Controls and Indicators

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

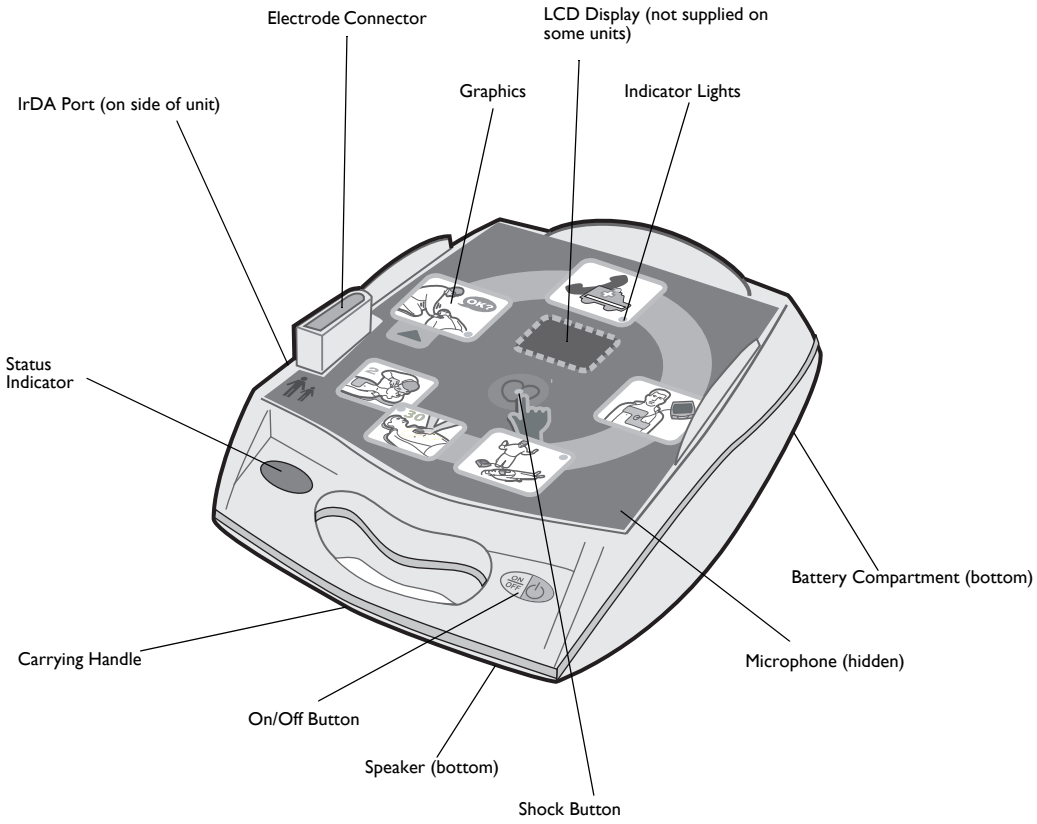


Figure 1: Identifying Operating Controls and Indicators

Table 1: Control Function

Control/Indicator	Description
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 victim.
Shock Button	Illuminates when the AED Plus is charged and ready to deliver a shock to the victim. When pressed, causes the charged and ready AED Plus to discharge its energy into the victim. When the AED Plus 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  	Illuminated check mark indicates the unit passed its last self test and is ready for use. Illuminated “X” indicates unit has failed its self test and is not ready for use
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 AED Plus models include a cover that may be used as a shoulder support to aid victim airway management. The PASS can be ordered separately for other AED Plus models (see “Ordering Accessories” on page 27).
Battery Compartment	Holds 10 123 lithium manganese dioxide batteries used to power the unit.
Electrode Connector	Connector for attaching electrodes to the AED Plus.
Speaker	Provides audio prompts and metronome beeps that direct rescuers on what to do during a rescue; 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 Plus Graphical User Interface

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

Each pictogram on the device is associated with an indicator light (LED) and voice prompts. This combination draws attention to the graphics in a sequence defined by current protocols for use of an Automated External Defibrillator (AED) by the AHA and ERC.

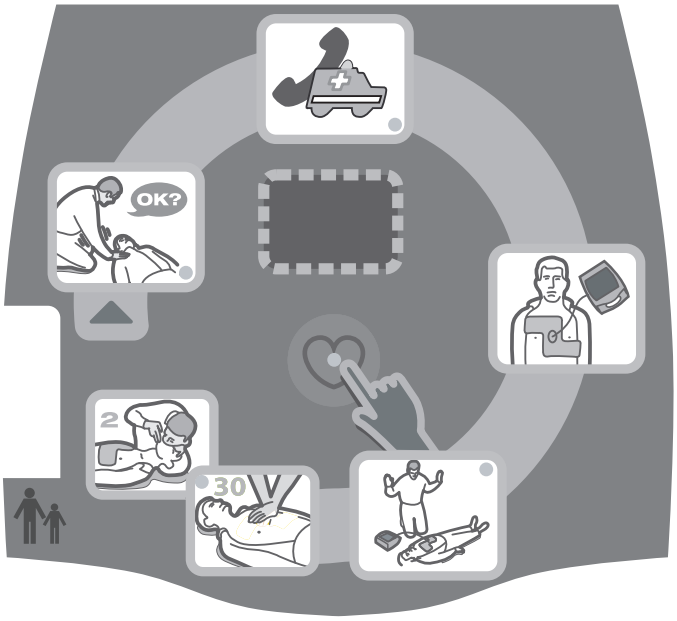


Figure 2: Graphical User Interface

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

When the AED Plus is turned on, the unit automatically initiates the sequence of voice prompts and graphic illuminations for a rescue event. The sequence continues until the AED Plus is turned off or the electrodes are disconnected from the victim for an extended period of time. As soon as electrodes are attached to the victim and impedance of the connection is verified, the unit stops cycling through the above-mentioned voice and graphic illumination sequence and automatically begins analysis of the ECG rhythm.

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 Plus issues the audio prompts, *NO SHOCK ADVISED* and *START CPR,* and illuminates the CPR-related graphics. A period of 2 minutes (depending upon device configuration) is then allowed for rescuer CPR. Following this “CPR period”, the AED Plus automatically re-initiates a new ECG rhythm analysis.

The AED Plus automatically adjusts defibrillation energy to adult or pediatric levels based on the type of electrodes attached to the unit. In its factory default configuration, the unit delivers the first three shocks at 120J, 150J, and 200J respectively in adult mode, and at 50J, 70J, and 85J in pediatric mode. However, the device can be configured to deliver shocks at other energy levels, as long as the setting for each successive shock is the same or greater than the setting for the preceding shock. Shocks are delivered by depressing the Shock Button (indicated by the heart icon and associated LED) located in the center of the graphical user interface.

Consult the 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 rescuer action associated with these audio and visual prompts.

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

Voice Prompts

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

Table 2: Clinical Voice Prompts

Voice Prompt	**Definition**
UNIT OK.	AED Plus has successfully passed its power up self tests.
UNIT FAILED.	AED Plus has failed its power up self tests and is not usable for victim care.
CHANGE BATTERIES.	AED Plus self test has detected a low battery condition that is insufficient for the device's use for victim care. Replace batteries immediately.
STAY CALM.	Relax as much as possible and focus on the rescue effort.
CHECK RESPONSIVENESS.	Check victim for responsiveness/consciousness by gently shaking the victim and shouting "Are you all right?".
CALL FOR HELP.	Activate the EMS system or ask a bystander to do it for you.
OPEN AIRWAY.	Place victim in the supine position and perform Head Tilt – Chin Lift or Jaw – Thrust maneuver to open victim's airway. (This prompt is off by default.)
CHECK BREATHING.	Look, listen or feel for the presence of breathing and/or airflow from the victim's lungs. (This prompt is off by default.)
GIVE TWO BREATHS.	If victim is not breathing, give two rescue breaths. (This prompt is off by default.)
PLUG IN CABLE.	Ensure that the electrode cable is properly connected to the AED Plus electrode connector.
ATTACH DEFIB PADS TO PATIENT'S BARE CHEST.	Attach defibrillation pads to the victim's bare chest.
CHECK ELECTRODE PADS.	Previously attached electrodes are not making good contact with the victim's skin or the electrodes are defective.

Voice Prompt	Definition
ADULT PADS.	AED Plus has detected adult electrode pads connected to it and adjusted defibrillation energy settings to adult levels.
PEDIATRIC PADS.	AED Plus has detected pediatric electrode pads connected to it and adjusted defibrillation energy settings to pediatric levels.
DON'T TOUCH PATIENT, ANALYZING.	Do not touch victim, an ECG rhythm analysis is in progress or about to begin.
SHOCK ADVISED.	ECG rhythm analysis has detected the presence of ventricular fibrillation or shockable ventricular tachycardia.
NO SHOCK ADVISED.	ECG rhythm analysis has detected a rhythm that is not treatable by defibrillation.
ANALYSIS HALTED. KEEP PATIENT STILL.	ECG rhythm analysis has been halted due to excessive ECG signal artifact. Stop any ongoing CPR and keep the victim as motionless as possible.
DON'T TOUCH PATIENT. PRESS FLASHING SHOCK BUTTON.	Warn all persons in attendance of the victim to stand clear and stop touching the victim. Press the Shock Button to deliver defibrillation therapy.
RELEASE SHOCK BUTTON.	Shock Button was depressed before the defibrillator was ready to defibrillate. Release the Shock Button and press again after the ready tone sounds.
SHOCK DELIVERED.	A defibrillation shock has just been delivered to the victim.
NO SHOCK DELIVERED.	No shock was delivered to the victim because rescuer failed to press Shock Button or an error condition was detected.
n SHOCKS DELIVERED.	A total of *n* shocks have been delivered since the AED Plus was turned on.
START CPR.	Begin CPR.
CONTINUE CPR.	Continue providing CPR. This prompt may also be issued if Real CPR Help fails to detect chest compressions at least ¾ of an inch (2 cm) deep.
PUSH HARDER.	CPR compressions are consistently less than 2 inches (5 cm) deep.
GOOD COMPRESSIONS.	After prompting to Push Harder, rescuer has succeeded in delivering chest compressions at least 2 inches (5 cm) deep.
STOP CPR.	Stop CPR, the AED Plus is about to begin an ECG rhythm analysis.

Prompts that may be heard during non-clinical use of the AED Plus unit include:

Table 2b Non-Clinical Voice Prompts

Voice Prompt	Definition
IF NEW BATTERIES, PRESS BUTTON.	Press the Battery Reset Button located in the battery compartment after replacing ALL batteries in the device with new batteries.
NON-RESCUE MODE.	AED Plus device has entered the diagnostics/data communications mode.
COMMUNICATIONS ESTABLISHED.	IrDA Communications between the AED Plus and a personal computer or modem have been established.

Using the LCD Display

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

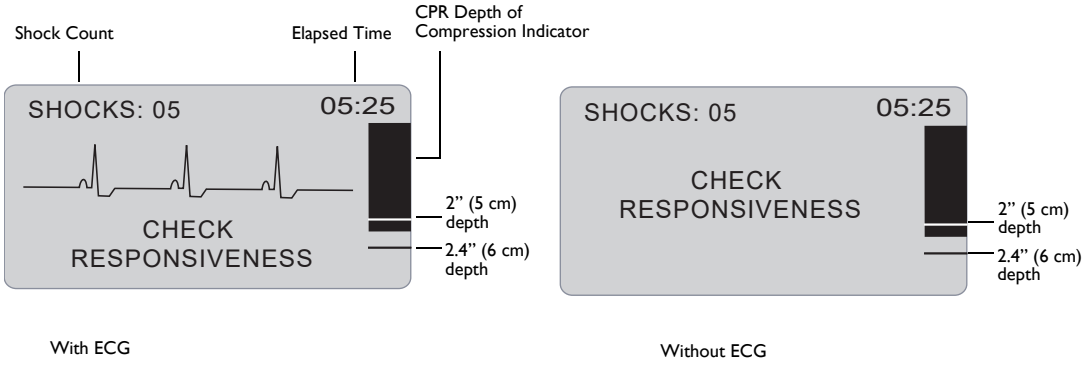


Figure 3: LCD Displays

NOTE Some special AED Plus models do not have an LCD.

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

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

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 2 and 2.4 inches (5 and 6 cm) of compression depth to provide reference points for rescuers performing CPR.

Visual User Prompts (Lower 1/3 of screen): Whenever the 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 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. Devices configured to display the ECG waveform are recommended for environments where the device is used by qualified medical personnel.

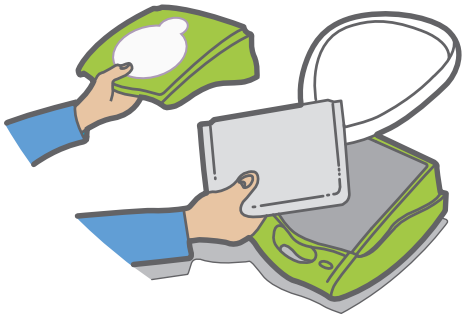
Using the Passive Airway Support System (PASS)

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 victim's shoulders to help maintain head tilt.

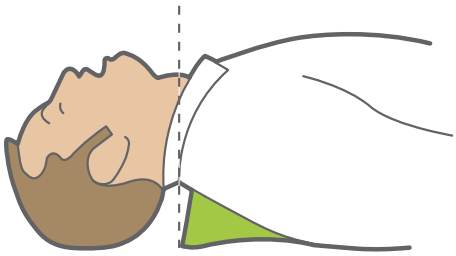
WARNING! DO NOT use PASS if suspected head or neck injury. Place victim on a firm surface before performing CPR.

If the victim requires airway support and there is no evidence of head or neck trauma**,** roll the victim on his/her side and then roll him/her back over so that the PASS is under the victim's shoulders causing the head to tilt backwards.

For PASS COVERS only: The shape of the PASS, when placed under the shoulders of the victim, 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 victim 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 AED Plus supports both adult and pediatric electrode pads. The device automatically adjusts defibrillation energy to adult or pediatric levels depending on the type of electrodes connected to it. Make sure that the electrode pads used are appropriate for the victim.

WARNING! DO NOT use adult electrode pads or *CPR-D-padz* on victims under 8 years of age.

The AED Plus uses electrode packs that are connected to the unit by a cable. The package contains electrodes that you attach to the victim.

- Make sure to install a new package of electrodes and connect the electrode cable to the unit after each use, to prepare 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
- After the AED Plus is powered on and completes its self-test, the unit will issue an "Adult Pads" voice prompt or a "Pediatric Pads" voice prompt to indicate the type of electrodes connected to the unit. Verify that the connected electrode pads are appropriate for the victim being treated. Connect alternate electrode pads if necessary.

If the electrodes are not attached properly, the unit issues the *CHECK ELECTRODE PADS* or the *ATTACH ELECTRODE PADS* voice prompt during operation. If the electrode cable is not properly attached to the unit, the unit issues the *PLUG IN CABLE* prompt. Make certain to connect the electrode cable to the AED Plus unit and attach the electrodes to the victim properly.

WARNING! Electrodes must be pre-attached to the device. Keep the electrode cable connected to the AED Plus unit at all times.

The electrode package may include:

- 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 victim'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.

WARNING! The use of accessories and cables other than those specified in the accessories section of this document may result in increased emissions or decreased immunity of the AED Plus defibrillator.

Applying *CPR-D-padz*

Prepare the victim before attaching the electrodes.

WARNING! ***CPR-D-padz*** **are intended for use on adult victims only; do not use on victims under 8 years of age.**

To prepare the victim:

1. Remove all clothing covering the victim's chest.
2. Ensure the victim's chest is dry.
3. If the victim 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. Place the electrodes on the victim according to the graphics on the package (see Figure 5).
2. Hold the CPR sensor and place the sensor between the nipples and on the middle of the victim'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 victim'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 victim's skin.

NOTE If the victim is large or there is a need to place the electrode under a breast, you may need to tear away the lower pad at the perforated line (see Figure 5) and extend the pad. Place the pad slightly to the victim's left and below the victim's left breast.

NOTE If the victim 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.

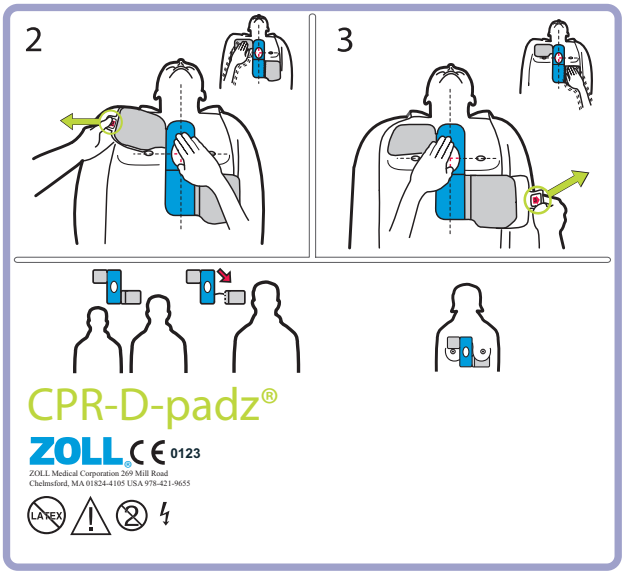


Figure 5: Placement of CPR-D-padz

Applying *Pedi-padz II* (Infant/Child Electrodes)

Prepare the victim before attaching the electrodes.

Important! This symbol indicates that an AED Plus unit is equipped for treating adult and pediatric victims. An AED Plus unit without this symbol is not equipped to treat pediatric victims and will NOT work with the Pedi-padz II pediatric electrodes. To upgrade an AED Plus unit for use with ZOLL Pedi-padz II pediatric electrodes, contact ZOLL Medical Corporation or an authorized ZOLL distributor for information on the ZOLL AED Plus Pediatric Upgrade Kit.

To prepare the victim:

1. Remove all clothing covering the victim's chest.
2. Ensure the victim's chest is dry.

To apply the electrodes:

1. Tear open the electrode package and unfold the inner package to expose the electrodes. Place the electrodes on the victim according to the graphics on the package (see Figure 6).
2. Remove the round electrode from its backing material and place it on the victim's chest (as shown in Figure 6).
3. Place your hand on the electrode edge and, using the other hand, gently roll the electrode onto the victim's chest, pushing any air out from beneath the electrode as you go.
4. Roll the victim onto his/her chest, remove the square electrode from its backing and place it on the victim's back (as shown in Figure 6).
5. Place your hand on the electrode's edge and, using your other hand, roll the electrode onto the victim's skin, pushing any air out from beneath the electrode as you go.
6. Roll the victim onto his/her back and follow the AED Plus prompts.

NOTE The Pedi-padz II (infant/child electrodes) can also be used with ZOLL pacemaker products for up to one hour of pacing (see the *M Series Operator's Guide* for information about pacing).

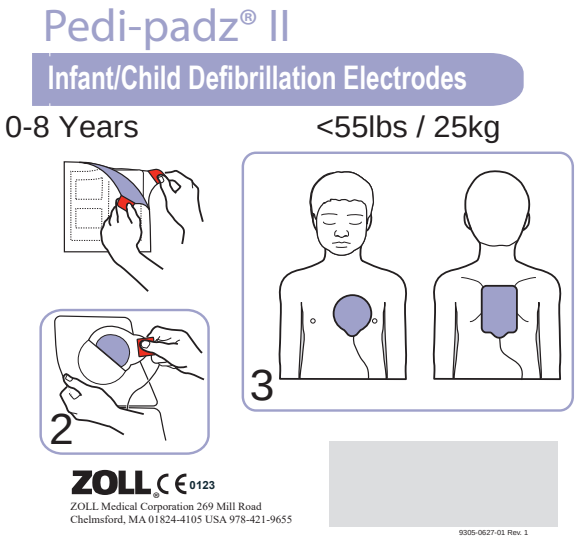


Figure 6: Placement of Pedi-padz II

Using the CPR Monitoring Function — Real CPR Help

When used with ZOLL CPR-D-padz, the AED Plus monitors the rate and depth of CPR chest compressions. The AED Plus provides a CPR adaptive metronome function designed to encourage rescuers to perform chest compressions at the AHA/ERC recommended rate of 100-120 compressions per minute. Voice and visual prompts encourage a compression depth of 2-2.4 inches (5-6 cm) for adult victims. Real CPR Help operates only when CPR-D-padz are used, and is intended for use on adult victims only.

To use Real CPR Help you must do the following:

1. Connect CPR-D-padz to the AED Plus unit.
2. Apply the CPR-D-padz to the victim as described in the previous section
   Ensure that the CPR sensor is centered on the lower half of the victim's sternum.
3. If no signs of circulation are present when the AED Plus issues the *START CPR* prompt, place your hands on top of the CPR sensor and push on the sensor to deliver chest compressions to the victim.
   After your first few compressions, the AED Plus adaptive 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 AED Plus prompts you to *PUSH HARDER*, your compressions are less than 2 inches (5 cm) 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 AED Plus contains an audio recording option that records and stores 20 minutes of continuous audio and clinical event data during a rescue. (The unit records and stores at least 7 hours of clinical event data if the audio recording option is disabled.) The recorded audio data is synchronized to the clinical event data. The audio recording starts when the AED Plus issues the *STAY CALM* prompt.

NOTE The AED Plus allows for up to 3 minutes of audio recording prior to electrode attachment. When you turn the unit off, the first indicator light (LED) on the graphical user interface illuminates and the second indicator light (LED) flashes intermittently while the unit stores the data in memory.

Whenever the device detects a clinical event in rescue mode, the AED Plus deletes previously stored data (ECG, Audio and Event) from memory before data for the current rescue is recorded. Overwriting of old ECG, audio and event data begins 10 seconds after the electrodes are properly connected to the victim. However, if the AED Plus is started in Non-rescue Mode, the recorded data of the last rescue is retained and may be uploaded to a data storage or archiving system.

Installation and Self Test

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

- Inspecting the Unit
- Preparing the AED Plus for Use
- Using the Self Test Feature
- Installing or Replacing Batteries
- Identifying Battery Condition

Inspecting the Unit

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

Preparing the AED Plus for Use

To ensure that the AED Plus is functioning properly and is ready for use in an emergency situation, the following set-up and checkout procedures should be performed before placing 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 electrode connector to ensure that there are no broken or missing connector pins.
3. Verify that new CPR-D-padz, Stat-padz® II or Pedi-padz II to be used with the AED Plus are well within their expiration date.
4. Follow instructions provided with the new electrodes to pre-connect them to the electrode connector on the device and pack them within the AED Plus cover.

NOTE If the electrodes are not connected to the AED Plus unit, the device will fail the self test and display a red “X” in the status indicator window.

5. If the status indicator displays a red X, install new batteries. (See “Installing or Replacing Batteries” on page 17.)
6. Close the top cover of the AED Plus unit and initiate a self test by pressing the Power Button. Verify that the unit issues the *UNIT OK* voice prompt. This prompt indicates that the new batteries and electrodes are properly installed and that the unit is ready for service.
7. Verify that the AED Plus unit issues the appropriate “Adult Pads” or “Pediatric Pads” voice prompt.
8. Turn the AED Plus unit off.
9. Wait 2 minutes. Verify that the green check symbol (✓) appears in the status indicator window and that the unit does not emit a beeping tone.
10. Place the AED Plus unit in service.
11. Check the AED Plus unit periodically to ensure that the green check symbol (✓) appears in the status indicator window.

NOTE If the status indicator displays a red X following completion of the above test, the AED Plus is not ready for use and may be defective. Remove the AED Plus from service and consult the Troubleshooting section on page 23 of this guide to help determine the problem.

Using the Self Test Feature

The AED Plus performs the following self tests to verify unit integrity and its readiness for emergency use:

- Battery Installation Self Test
- Power On Self Test
- Manual Self Test
- Automatic Self Test
- Automatic Monthly Test (software version 5.32 or higher only)

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

If the status indicator displays a red X following completion of any self test, the AED Plus is not ready for use and may be defective. Remove the AED Plus from service and consult the Troubleshooting section of this guide to help determine the problem.

Battery Installation Self Test

The AED Plus performs a self test whenever batteries are installed and verifies the following functions:

1. Defibrillation Electrodes Connection: Verifies that the defibrillation electrodes are properly pre-connected to the device.
2. ECG Circuitry: Verifies that the ECG signal acquisition and processing electronics are functional.
3. Defibrillator Charge and Discharge Circuitry: Verifies that the device's defibrillator electronics are functional and can charge and discharge at 200 joules.
4. Microprocessor Hardware/Software: Verifies proper function of the AED Plus microprocessor electronics and the integrity of its software.
5. CPR Circuitry and Sensor: Verifies that CPR monitoring and compression depth detection are functional.
6. Audio Circuitry: Verifies that voice prompts are functional.

At the end of this self test, the AED Plus prompts the user to press the Battery Reset Button, located inside the battery compartment. Pressing this button resets the unit's battery usage indicator to full charge.

CAUTION! DO NOT press the Battery Reset Button unless all batteries are new. Pressing the Battery Reset Button when used batteries are installed may result in a false high reading of battery capacity. See "Installing or Replacing Batteries" on page 17 for more information.

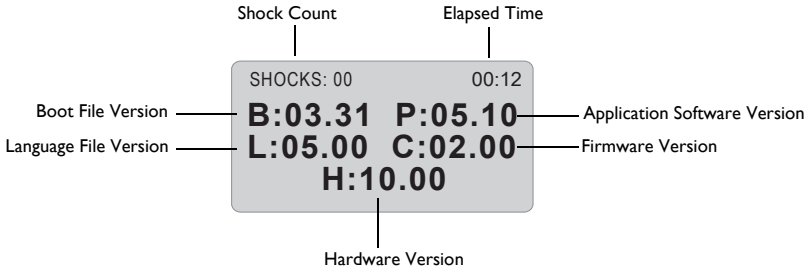
Power On Self Test

The AED Plus performs a self test whenever the unit is turned on and verifies the following functions:

1. Battery Capacity: Verifies that the battery usage indicator shows adequate battery capacity remaining.
2. Defibrillation Electrodes Connection: Verifies that the 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: Verifies proper function of the AED Plus microprocessor electronics and the integrity of its software.
6. CPR Circuitry and Sensor: Verifies that CPR monitoring and compression depth detection are functional.
7. Audio Circuitry: Verifies that voice prompts are functional.

Manual Self Test

You can initiate a manual self test on the AED Plus by pressing and holding the unit's On/Off button for 5 seconds. The 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. In addition, the LCD shows the application software version currently running on the unit.



This self test verifies the following AED Plus functions:

1. Battery Capacity: Verifies that the battery usage indicator shows adequate battery capacity remaining.

NOTE For units with software below version 5.32, batteries must be replaced every 3 years regardless of test results.

2. Defibrillation Electrodes Connection: Verifies that the 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 200 joules.
5. Microprocessor Hardware/Software: Verifies proper function of the AED Plus microprocessor electronics and the integrity of its software.
6. CPR Circuitry and Sensor: Verifies that CPR monitoring and compression depth detection are functional.
7. Audio Circuitry: Verifies that voice prompts are functional.

8. Display: Verifies that visual indicators are functional.

Automatic Self Test

By default, the AED Plus unit performs an automatic self test once every 7 days (this interval can be configured to 1, 2, 3, 4, 5, 6, or 7 days) when the unit is stored with batteries installed. This self test verifies the following AED Plus functions:

1. Battery Capacity: Verifies that the battery usage indicator shows adequate battery capacity remaining.

NOTE For units with software below version 5.32, batteries must be replaced every 3 years regardless of test results.

2. Defibrillation Electrodes Connection: Verifies that the 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: Verifies proper function of the AED Plus microprocessor electronics and the integrity of its software.
6. CPR Circuitry and Sensor: Verifies that CPR monitoring and compression depth detection are functional.
7. Audio Circuitry: Verifies that voice prompts are functional.

Automatic Monthly Test (software version 5.32 or higher only)

By default, the AED Plus unit performs an automatic self test once per month when the unit is stored with batteries installed. This self test verifies the following AED Plus functions:

1. Battery Capacity: Verifies that the battery usage indicator shows adequate battery capacity remaining.
2. Defibrillation Electrodes Connection: Verifies that the 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 200 joules.
5. Microprocessor Hardware/Software: Verifies proper function of the AED Plus microprocessor electronics and the integrity of its software.
6. CPR Circuitry and Sensor: Verifies that CPR monitoring and compression depth detection are functional.

Installing or Replacing Batteries

To power the AED Plus, use 10 Duracell Coppertop CR123 batteries, made in the USA. You can purchase these batteries at many department, camera or electronics stores.

For AED Plus units running software version 5.32 or higher, replace batteries every 5 years or if unit prompts. For earlier software versions, replace batteries every 3 years and place a dated reminder note next to the On/Off button.

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

Batteries should be used within the first year of the manufacturing date. The date of manufacture is located on each individual battery. Format is YYYY/MM, where YYYY = Year and MM = Month. (Example: 2024/04 = April 2024)

To install the batteries:

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

   To remove the battery cover, insert a small tool (e.g., flat blade screw driver) into the two slots on the rear of the unit to depress the latches, then insert the tool into the groove on the bottom to lift the cover (see Figure 7).

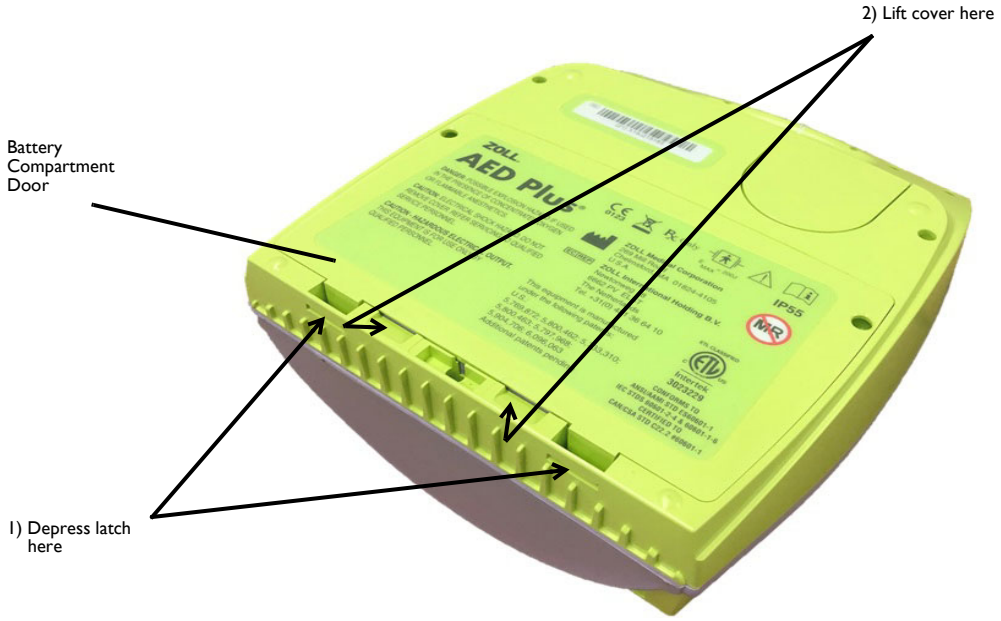


Figure 7: Removing the Battery Compartment Door

2. Remove all batteries at once and dispose of the batteries properly.
3. Insert the eight batteries on the left and right sides first, followed by the two batteries in the center, as shown in Figure 8 below. Observe battery polarity markings and make sure that all batteries are securely seated and properly oriented.

4. After placing the first 5 to 9 batteries in the battery well, the *INSTALL BATTERIES* audio prompt reminds you to install the remaining batteries in the battery compartment.

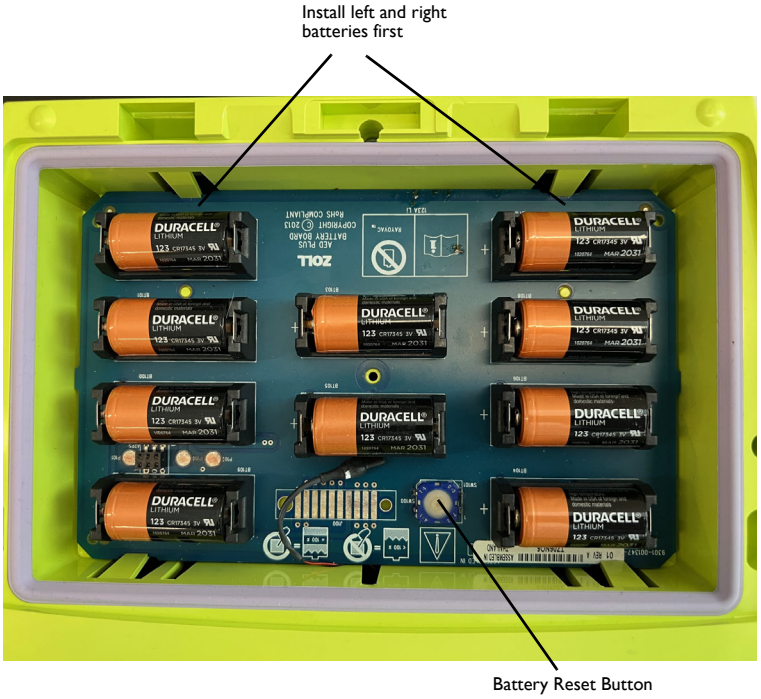


Figure 8: Battery Compartment

5. After installing the new batteries, press the Battery Reset Button inside the battery compartment when prompted (see Figure 8 above). Pressing the button resets the battery usage indicator to full charge.
6. If no *INSTALL BATTERIES* audio prompt is heard, remove all batteries, wait 2 minutes, then reinstall the batteries. Repeat if necessary.

CAUTION! If you do not press the Battery Reset Button in the battery well within 15 seconds after installing all batteries, the AED Plus assumes that the batteries installed in the device were temporarily removed, and are **not fully** charged.

CAUTION! You MUST replace all 10 batteries at once. Do not replace individual batteries. The AED Plus cannot detect whether all batteries or only a few batteries have been replaced. Do not place used batteries into the AED Plus. **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 AED Plus then assumes that they are the same batteries that were just removed.

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. Battery capacity also gradually diminishes over a shelf life of years without use. The AED Plus monitors energy remaining in the installed batteries. When battery capacity is low or depleted, the AED Plus will not function to specification. When a low battery condition occurs, the AED Plus:

- emits an audible alarm or “beep” once every minute, if the AED Plus is off
- issues the *CHANGE BATTERIES* audio prompt, if the AED Plus is on
- displays a red “X” in the status indicator window, indicating that the batteries are at low capacity or that the AED Plus has failed other self tests.

Table 3: Battery Condition

Battery Condition	**Indications**	**Correction**
Low Battery with AED Plus off.	Audible beep from AED Plus once every minute.	Replace batteries.
Low Battery during power up self test.	*CHANGE BATTERIES* prompt (when AED Plus is powered on)	Replace batteries.
Low Battery or other self test failure with AED Plus 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 AED Plus 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.

Maintenance and Troubleshooting

This section describes the following functions to maintain the AED Plus:

- Maintaining the AED Plus
- Cleaning the AED Plus
- Optional Maintenance for Technical Professionals
- Troubleshooting

Maintaining the AED Plus

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

Maintenance Checklist

Use the following maintenance checklist when you periodically check your AED Plus.

Table 4: Maintenance Checklist

Check the following	Pass	Fail
Is the unit clean, undamaged, free of excessive wear?	☐	☐
Are there any cracks or loose parts in the housing?	☐	☐
Verify electrodes are connected to the AED Plus and sealed in their package. Replace if expired.	☐	☐
Are all cables free of cracks, cuts and exposed or broken wires?	☐	☐
Turn the AED Plus on and off and verify the green check indicates ready for use.	☐	☐
Batteries within expiration date. Replace if expired.	☐	☐
Check for adequate supplies.	☐	☐

Cleaning the AED Plus

- After each use, clean and disinfect the AED Plus 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 AED Plus in water.
- Do not use ketones (MEK, acetone, etc.) to clean the AED Plus.
- Avoid using abrasives (e.g., paper towel) on the display window or IrDa port.
- Do not sterilize the AED Plus.

Optional Maintenance for Technical Professionals

The AED Plus automatically performs maintenance testing during periodic self tests. However, if a qualified technical professional wishes to test the AED Plus further, the following checkout procedure can be followed:

1. Connect an AED Plus Simulator/Tester (or equivalent) to the AED Plus electrode connector.
2. Power on the simulator and AED Plus. Verify that all of the following occur:
   - The status indicator (located on the left side of the handle) initially displays a red "X" which changes to a green check (✓) within 4 to 5 seconds after the AED Plus is turned on.
   - All top panel user interface lights (LEDs) illuminate sequentially.
   - The AED Plus issues the *UNIT OK* voice prompt within 5 seconds after power-up (and displays the message if equipped with an LCD).
   - If the AED Plus has an LCD, the message "SHOCKS: 0" appears in the upper left corner and the elapsed time (since power-up) appears in the upper right corner of the screen.
3. Using the simulator, input a VF rhythm to the AED Plus. Verify that after the AED Plus proceeds through its sequence of victim assessment prompts, it:
   - analyzes the ECG rhythm
   - issues the *SHOCK ADVISED* voice prompt
   - charges the defibrillator
   - issues the *DON'T TOUCH PATIENT, PRESS FLASHING SHOCK BUTTON* voice prompt
4. Verify that the charge ready tone is heard and that the Shock Button illuminates.
5. Press the Shock Button and verify that the simulator shows that a shock was delivered. Verify that the message "Shocks: 1" displays on LCD screen.

   NOTE This test checks the device's ability to defibrillate. It does not, however, verify that the correct defibrillation energy was delivered. A defibrillator analyzer should be used in place of the AED Plus simulator/tester to verify the accuracy of the delivered energy.
6. Following shock delivery, verify that the AED Plus issues the *START CPR* messages.
7. Activate the simulator's CPR function. Verify that the adaptive metronome begins to beep and that the following voice prompts/messages are issued within 60 seconds: *PUSH HARDER* followed by *GOOD COMPRESSIONS.*
8. After approximately two minutes of CPR, verify that the *STOP CPR* prompt is issued. Set the simulator to Normal Sinus Rhythm (NSR) and verify that a new ECG analysis begins.
9. Verify that a *NO SHOCK ADVISED* prompt is issued.
10. Turn the AED Plus and Simulator off.

See "Preparing the AED Plus for Use" on page 14 for instructions on placing the AED Plus back into service.

Troubleshooting

The following table summarizes common error indications on the AED Plus, and their associated corrective action. Return the AED Plus to ZOLL's Technical Service Department if the AED Plus is not working properly.

Table 5: Troubleshooting

Technical Problem	**Recommended Action**
Self test failed.	Initiate manual self 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 the AED Plus fails test again, remove the AED Plus from service and contact ZOLL Technical Service.
CHANGE BATTERIES prompt.	Replace all batteries with new batteries at the same time. Press the Battery Reset Button when prompted.
Red "X" in status indicator window.	Initiate manual self test by pressing and holding the ON/OFF Button for more than 5 seconds. Check to see if cable is attached properly to the AED Plus or replace the electrodes. Cycle power on the AED Plus by turning the unit off, then on again. Replace all batteries at the same time with new batteries that are less than 1 year old. Press the Battery Reset Button when prompted. If the AED Plus still does not operate correctly, remove unit from service and contact ZOLL Technical Service.
Beeping noise when AED Plus is off.	Remove AED Plus from service and replace batteries. Replace all batteries at the same time with new batteries. Press the Battery Reset Button when prompted. If beeping continues, contact ZOLL Technical Service.
PLUG IN CABLE prompt.	Check cable connection between electrodes and the AED Plus.
ANALYSIS HALTED. KEEP VICTIM STILL prompt.	Excessive artifact detected during ECG analysis. Victim must be motionless during ECG analysis. Do not touch the victim during analysis. Keep the victim still. If the rescuer is using the AED Plus in an emergency vehicle, bring the vehicle to a halt before performing ECG analysis.
RELEASE SHOCK BUTTON prompt.	Release Shock Button, then press and hold Shock Button until discharge occurs. If voice prompt continues, contact ZOLL Technical Service.

Contacting Technical Service

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

Telephone: 1-978-421-9655
Email: esales@zoll.com
Web: https://www.zoll.com/expertcaresupport

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 you need to send the AED Plus to ZOLL Medical Corporation, obtain a service order request number from the Technical Service representative. AED Plus units are available on loan at an additional cost while your AED Plus is being repaired.

Remove all batteries from the AED Plus 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
269 Mill Road
Chelmsford, MA 01824-4105

Attn: Technical Service Department

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.

ZOLL Administration Software

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

See the online Help for instructions on how to use ZAS.

Installing ZOLL Administration Software

To install ZAS, insert the ZAS CD into the CD-ROM drive on your PC. The installation program starts automatically.

If the installation program does not start automatically:

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

Using RescueNet® EventSummary Software

RescueNet EventSummary software is a PC application that allows you to view or print a PDF of the following resuscitation incident information from the defibrillator:

- Basic Case and Device Information
- Full Disclosure Report, including the ECG waveform, device prompts, and CPR compression bar graph
- CPR Performance Summary report
- Incident Log of all events

ZOLL AED Plus users can set up a ZOLL Online account to enable Wi-Fi file transfers. EventSummary can then open cases in your ZOLL Online account.

Using RescueNet Case Review Software

RescueNet Case Review software is a cloud-based clinical data management and quality reporting system that is hosted in ZOLL Online. Using its Wi-Fi capability, the AED Plus can be configured to transmit clinical event data over Wi-Fi to ZOLL Case Review. When using Case Review software to manage clinical event data, you can perform the following functions:

- Collect clinical files to a single destination.
- Make data easily available to a clinical quality team.
- Review quality of CPR directly from the web.
- View trends in CPR quality and data movement.

Visit www.zollonline.com for more information.

Setting Up Data Communications

You can exchange data between a 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 AED Plus. The second IrDA port may be on your personal computer. In some cases, you will be sending data from the IrDA port on your AED Plus 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 ZAS and/or RescueNet software running. Press and hold the ON/OFF Button on the AED Plus for at least 5 seconds to establish contact with the computer or modem. Once connected properly, you hear the *COMMUNICATIONS ESTABLISHED* audio prompt and see a message on your computer screen that the connection was successful.

Ordering Accessories

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

Table 6: Ordering Accessories

Item	REF
ZOLL products	
CPR-D-padz electrode including accessory kit *	8900-0800-01
Adult Stat-padz II electrode (single) *	8900-0801-01
Adult Stat-padz II electrode (case) *	8900-0802-01
Pedi-padz II electrode (single) *	8900-0810-01
Administrator's Guide	9650-0301-01
Operator's Guide	9650-0300-01
Simulator/Tester	8000-0800-01
Administration Guide with ZOLL Administration Software CD	9659-0302-01
RescueNet Software	Contact customer service
AED Plus Trainer	8008-0104-01
AED Plus Trainer2	8008-0050-01
Replacement Trainer	1008-0115-01
Replacement Trainer Control	1008-0113-01
Trainer AC Adapter US EURO UK Switzerland Australia	 9355-0802 9355-0803 9355-0804 9355-0805 9355-0806
Trainer Cord	9355-0801
Set of 10 Batteries (10 Duracell Coppertop CR123 Batteries)	8000-0807-01
AED Cover (PASS)	8000-0812-01
Graphical Cover (PASS)	8000-0808-01
Low Profile Cover	8000-0803-01
Soft Case	8000-0802-01
Upgrade Kit, Battery Replacement W/Label & Addendum	7771-0100-01
Universal Adapter Cable	8000-0804-01
*** T**he water ingress rating is IPx5 when attached to the AED Plus defibrillator, regardless of the stated rating on individual packaging labels.	
OEM products	
Mounting Bracket	8000-0809-01
Flush Mount Wall Box	8000-0811

Item	REF
Recess Mount Wall Box	8000-0814
Surface Mount Wall Box	8000-0817
Standard Metal Wall Cabinet	8000-0855
Clear AED Plus Wall Cabinet	8000-0856
Brushed Stainless Steel Wall Cabinet	8000-0855-02
USB IrDA PC Adapter	8000-0815
RS-232 IrDA PC Adapter	8000-0816

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 123 Photo Flash lithium manganese dioxide batteries
Device Classification	Class II and internally powered per EN60601-1
Design Standards	Meets applicable requirements of IEC 60601-2-4: 2010 for use in conjunction with IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) + AM1 (2012) or IEC 60601-2: 2014
ENVIRONMENT	
Operating Temperature	PS Model: 32° to 122° F; 0° to 50° C
Storage Temperature	PS Model: -22° to 158° F; -30° to 70° C
Humidity	10 to 95% relative humidity, non-condensing
Vibration	MIL Std. 810F, Min Helicopter Test
Shock	PS Model: IEC 68-2-27; 100G
Altitude	PS Model: -300 to 15,000 ft.; -91m to 4573m
Aircraft	Method RTCA/DO-160G: 2010 Section 20, Category R – all operating modes Section 21, Category M – all operating modes
Particle and Water Ingress	IP-55
DEFIBRILLATOR	
Waveform	Rectilinear Biphasic™
Defibrillator Charge Hold Time	30 seconds
Energy Selection	Automatic pre-programmed selection (Adult mode: 120J, 150J, 200J; Pediatric mode: 50J, 70J, 85J)
Patient Safety	All patient connections are electrically isolated.
Charge Time	Less than 10 seconds with new batteries.
Maximum time from first rhythm analysis to unit charged and ready to shock	With new batteries: 12 seconds With batteries depleted by 15 200J discharges: 13 seconds

DEFIBRILLATOR (cont'd)	
Maximum time from power on to unit charged and ready to shock at 200J	22.6 seconds
Electrodes	ZOLL Stat-padz II, CPR-D-padz or Pedi-padz II
Built in Defibrillator Self Test	Included
CPR	*Metronome Rate: Variable 60 to 100 CPM Depth: ¾" to 3"; 1.9 to 7.6 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 (adult mode) and 200 BPM (pediatric mode). 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 battery at +20° C (68° F): • 5 year stand-by life with batteries installed (weekly self-test), or • 225 ±5 continuous defibrillator discharges at maximum energy (200 joules); or • 13 hours of continuous monitoring (with 2-minute CPR periods). End of life designated by Red X (typical remaining shocks = 9).
*Testing reports validating performance and accuracy of CPR depth measurement capability, adaptive metronome feature function and rescuer performance, and the PASS (Passive Airway Support System) cover function are on file with ZOLL Medical Corporation and are available for review. Contact ZOLL Technical Support to request a copy of the following report(s) if desired: • Using the AED Plus Cover to Aid in Airway Patency • Depth and Compression Rate Response of Real CPR Help • AED Plus Real CPR Help Test Results.	

DEFIBRILLATOR (cont'd)	
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 IrDA™ port 20MB disk space
DATA RECORDING AND STORAGE	
Type	Nonvolatile memory
Capacity	7 hours of ECG and CPR data If audio recording option is installed and enabled: 20 minutes of audio recording, ECG, and CPR data

Guidance and Manufacturer's Declaration - Electromagnetic Compatibility

Table 8: EMC Specifications

The AED Plus is intended for use in the electromagnetic environment specified below. Operation outside of this environment could result in the misinterpretation of the ECG rhythms or CPR signals, interference to the display or audio messages, or the inability to provide defibrillation therapy.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR11	Group 1	The 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	The ZOLL AED Plus is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings for domestic purposes.
Harmonic Emission IEC 61000 3-2 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 AED Plus is intended for use in the electromagnetic environment specified below. Operation outside of this environment could result in the misinterpretation of the ECG rhythms or CPR signals, interference to the display or audio messages, or the inability to provide defibrillation therapy.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	The relative humidity should be at least 5%.
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	30 A/m	30 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 AC mains voltage prior to application of the test level.			

The AED Plus is intended for use in the electromagnetic environment specified below. Operation outside of this environment could result in the misinterpretation of the ECG rhythms or CPR signals, interference to the display or audio messages, or the inability to provide defibrillation therapy.			
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 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] 10 Vrms 150 kHz to 80 MHz in ISM bands[a]	N/A N/A	The AED Plus is battery powered and has no cables longer than 1 meter in length.

Immunity test (cont'd)	IEC 60601 test level (cont'd)	Compliance level (cont'd)	Electromagnetic environment - guidance (cont'd) Recommended separation distance
Radiated RF IEC 60601-1-2, (wireless communications)	28 V/m for GSM 800/900, TETRA 800, iDEN 820, CDMA 850, or LTE Band 5 services (0.3 m separation)	28 V/m	*d* = 0.3 m minimum
	27 V/m for TETRA 400 service	27 V/m	*d* = 0.3 m minimum
	28 V/m for GMRS 460, FRS 460, GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, and 25, UMTS, Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, and LTE Band 7 services	28 V/m	*d* = 0.3 m minimum
	9 V/m for LTE Band 13 and 17, and WLAN 802.11 a/n services	9 V/m	*d* = 0.3 m minimum
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	d = 1.2 $\sqrt{P}$ 80 MHz to 800 MHz d = 2.3 $\sqrt{P}$ 800 MHz to 2.7 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m).[b] 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] Interference may occur in the vicinity of equipment marked with the following symbol: 
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 2.7 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

[c] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the AED Plus is used exceeds the applicable RF compliance level above, the 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 AED Plus.

[d] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

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

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

	Separation distance according to frequency of transmitter m			
Rated maximum output power of transmitter W	150 kHz to 80 MHz outside ISM bands $d = 1.2\sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800MHz to 2.7 GHz $d = 2.3\sqrt{P}$
0.01	0.17	0.12	0.12	0.23
0.1	0.37	0.38	0.38	0.73
1	1.2	1.2	1.2	2.3
10	3.7	3.8	3.8	7.3
100	12	12	12	23

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

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

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

NOTE 3 An additional factor of 10/3 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 2.7 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 µsec	150 µsec	150 µsec	150 µsec
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

Table 10: Delivered Energy at Each Defibrillator Setting into a Range of Loads

	Selected Energy					
Load	**50 J**	**70 J**	**85 J**	**120 J**	**150 J**	**200 J**
25Ω	40 J	61 J	66 J	95 J	111 J	146 J
50Ω	51 J	80 J	85 J	124 J	144 J	183 J
75Ω	64 J	89 J	111 J	148 J	172 J	204 J
100Ω	62 J	86 J	108 J	147 J	171 J	201 J
125Ω	63 J	89 J	110 J	137 J	160 J	184 J
150Ω	67 J	93 J	116 J	127 J	148 J	168 J
175Ω	61 J	86 J	107 J	119 J	138 J	155 J
Accuracy	±15%	±15%	±15%	±15%	±15%	±15%

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.

Figures 9 through 14 show the Rectilinear Biphasic waveforms that the AED Plus defibrillator produces when it discharges into loads of 25, 50, 75, 100, 125, 150, and 175 ohms at each energy setting (200, 150, 120, 85, 70, and 50 joules).

The vertical axis shows the current in amperes (A); the horizontal axis shows the duration in milliseconds (ms).

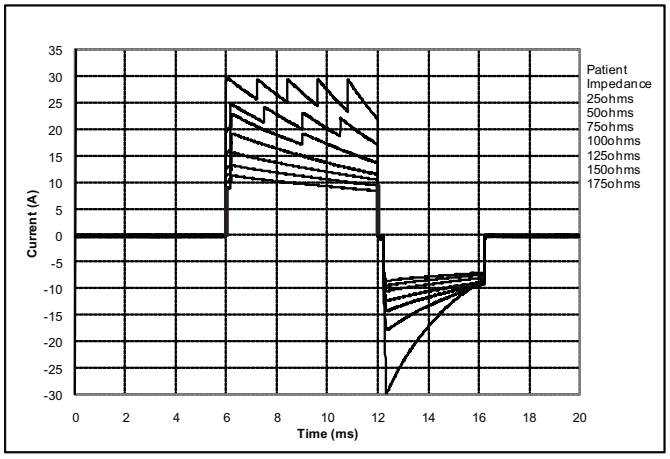


Figure 9: Rectilinear Biphasic Waveforms at 200 joules

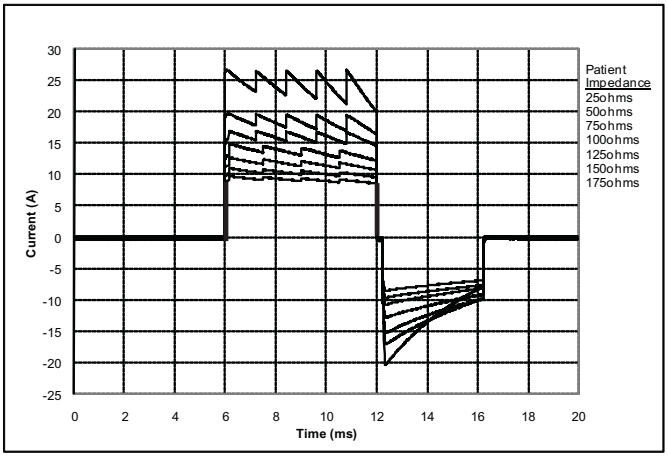


Figure 10: Rectilinear Biphasic Waveforms at 150 joules

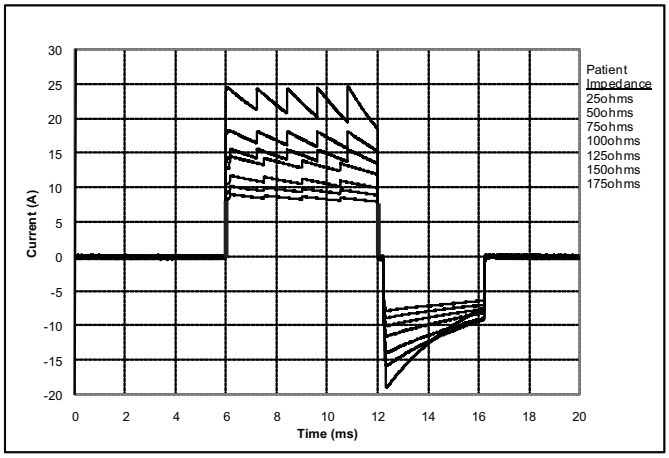


Figure 11: Rectilinear Biphasic Waveforms at 120 joules

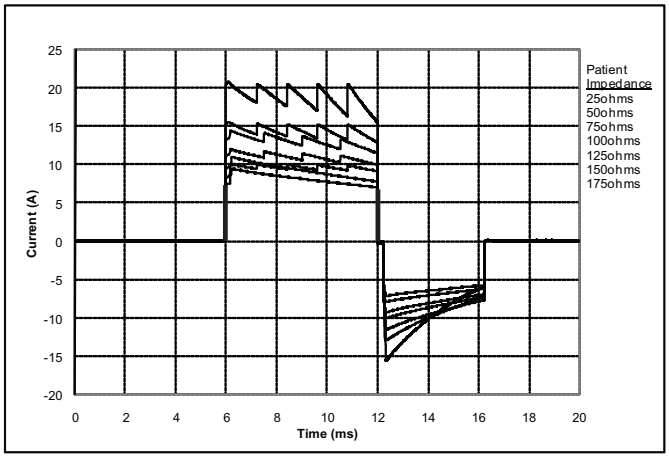


Figure 12: Rectilinear Biphasic Waveforms at 85 joules

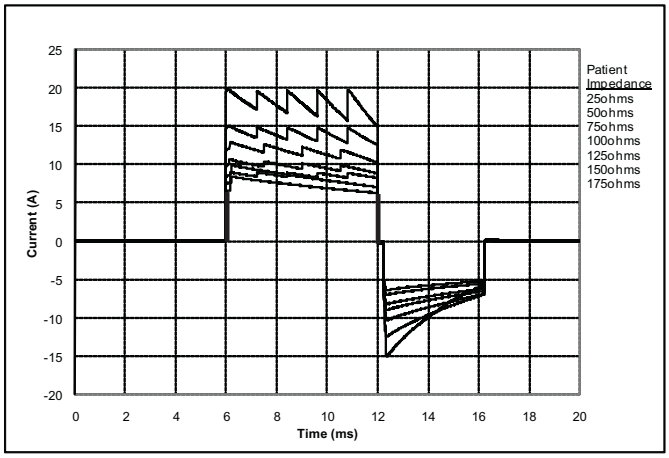


Figure 13: Rectilinear Biphasic Waveforms at 70 joules

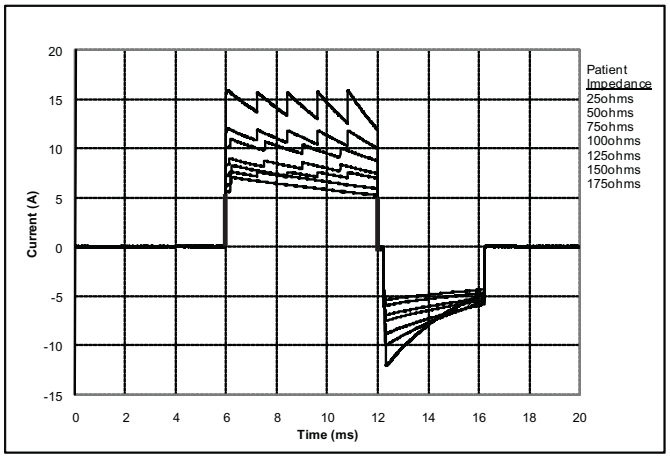


Figure 14: Rectilinear Biphasic Waveforms at 50 joules

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. 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. 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%).

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%).

A single patient required a second biphasic shock at 150J to achieve 100% efficacy versus six patients for whom monophasic 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)."

Pre-Clinical Study

To support pediatric usage for the ZOLL Rectilinear Bi-Phasic Waveform, ZOLL submitted pre-clinical data to the FDA as part of a 510(k) submission for its AED Plus device (cleared by the FDA under K033474). The protocol for this pre-clinical study, along with a summary of the results, have been submitted to FDA under AED Plus PMA application (P160015). A summary of this study is presented below.

To demonstrate the safety and efficacy of our Rectilinear Bi-Phasic Waveform when used to treat pediatric VF patients, ZOLL conducted a study using a porcine model of pediatric patients less than 8 years of age. This study included 18 piglets in three (3) size groups (two (2) animals weighing 4 kg, eight (8) animals weighing 8 kg, and eight (8) animals weighing 16 kg) and compared the defibrillation dose/response curves observed using proposed biphasic waveform with those observed using a standard monophasic damped sine wave (DSW) defibrillator to treat short duration (~ 30 seconds) ventricular fibrillation. The study demonstrated that the biphasic waveform defibrillates pediatric pigs with equal efficacy but lower energy (on a Joules/kg basis) than traditional monophasic damped sine wave defibrillators. To confirm the safety of the proposed biphasic waveform in pediatric patients, we studied and compared measures of cardiac function before and after both DSW and Rectilinear Bi-Phasic Waveform defibrillation shocks over a range of relevant energies. The study demonstrated that the biphasic defibrillation produced equivalent or milder disturbances of cardiac function when compared to traditional DSW defibrillation at the same energies.

Another animal study compared the ZOLL rectilinear biphasic (RLB) waveform to a biphasic truncated exponential (BTE) waveform. The study, using an immature porcine model (n=21), was a prospective, randomized, controlled design to determine the dose response curves for the RLB and BTE defibrillation waveforms. A weight range from 4 to 24 Kg for an animal represented a pediatric patient. The weight ranging from 4 to 8 Kg represented a patient less than 1 year old (infant subgroup), and the weight range from 16 to 24 Kg represented a pediatric patient between the ages of 2 and 8 years (young children subgroup).

The ZOLL RLB waveform demonstrated a superior capability to defibrillate a porcine pediatric model with < 90% of the D50 energy required for a BTE waveform (D50 energy: RLB 25.6 ± 15.7 J, BTE 28.6 ±17.0 J, P = 0.0232; D90 energy: RLB 32.6 ± 19.1 J, BTE 37.8 ± 23.2 J, P = 0.0228).

The ECG ST segment changes (mV) and LV pressure changes (dP/dt) following a defibrillation shock were compared between the RLB waveform to the BTE waveform. The RLB waveform had an average ST segment increase above baseline of 0.138 ± 0.136 mV (N=401 shocks) compared to the BTE waveform's average increase of 0.146 ± 0.148 mV (N=396 shocks). The RLB waveform had an average dP/dt at the 40 mmHg threshold (the point in time when an animal's blood pressure exceeded 40 mmHg spontaneously) of 1987 ± 411 mmHg/s (N=496 shocks) compared to the BTE waveform's average dP/dt of 2034 ± 425 mmHg/s (N=496 shocks).

Published Clinical Data

Additional clinical data was included with PMA application P160015 to support out-of-hospital use of ZOLL's Rectilinear Bi-Phasic defibrillation waveform. The data reported by Hess et al in Resuscitation (82 (2011) 685–689) is considered sufficient to support ZOLL's defibrillation waveform in the out-of-hospital environment. The resulting clinical paper, "Performance of a rectilinear biphasic

waveform in defibrillation of presenting and recurrent ventricular fibrillation: A prospective multicenter study," was included with PMA application P160015. A summary of the study is presented below:

Objectives: The study tested the hypothesis that shock success differs with initial and recurrent episodes of ventricular fibrillation (VF).

Methods: From September 2008 to March 2010 out-of-hospital cardiac arrest patients with VF as the initial rhythm at 9 study sites were defibrillated by paramedics using a rectilinear biphasic waveform. Shock success was defined as termination of VF within 5 s post-shock. The study used generalized estimating equation (GEE) analysis to assess the association between shock type (initial versus defibrillation) and shock success.

Results: Ninety-four patients presented in VF. Mean age was 65.4 years, 78.7% were male, and 80.9% were bystander-witnessed. VF recurred in 75 (79.8%). There were 338 shocks delivered for initial (n = 90) or recurrent (n = 248) VF available for analysis. Initial shocks terminated VF in 79/90 (87.8%) and subsequent shocks in 209/248 (84.3%). GEE odds ratio (OR) for shock type was 1.37 (95% CI 0.68–2.74). After adjusting for potential confounders, the OR for shock type remained insignificant (1.33, 95% CI 0.60–2.53). The study observed no significant difference in ROSC (54.7% versus 52.6%, absolute difference 2.1%, p = 0.87) or neurologically intact survival to hospital discharge (21.9% versus 33.3%, absolute difference 11.4%, p = 0.31) between those with and without VF recurrence.

Conclusions: Presenting VF was terminated with one shock in 87.8% of cases. The study observed no significant difference in the frequency of shock success between initial versus recurrent VF. VF recurred in the majority of patients and did not adversely affect shock success, ROSC, or survival.

ECG Analysis Algorithm Accuracy

Sensitivity and specificity are expressions of ECG analysis algorithm performance when compared to ECG interpretation by a clinician or expert. Sensitivity refers to the algorithm's ability to correctly identify shockable rhythms (as a percentage of the total number of shockable rhythms); specificity refers to the algorithm's ability to correctly identify non-shockable rhythms (as a percentage of the total number of non-shockable rhythms). The data in Table 11 and Table 12 summarizes the accuracy of the ECG analysis algorithm as tested against ZOLL's ECG Rhythm Database.

The algorithm sequence takes approximately 9 seconds and proceeds as follows:

- 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.
- Stops analyzing the ECG after detecting a shockable rhythm and theAED Plus unit is charged and ready to deliver a shock.

Table 11: Clinical Performance Results (Adult Patients)

Rhythms	**Total Segments**	**Correctly Analyzed**	**Incorrectly Analyzed**	**Observed Performance (%)**	**90% One-sided Low Confidence Limit (%)**
Coarse VF	536	536	0	100	99.44
Rapid VT	80	79	1	98.75	99.21
NSR	2210	2209	1	99.95	99.79
AF, SB, SVT, Heart block, idioventricular, PVCs	819	819	0	100	99.63
Asystole	115	115	0	100	97.43
Fine VF	69	85	4	94.20	87.22
Other VT	28	28	0	100	89.85
		No Shock Advised	**Shock Advised**		
Overall Performance	**Non Shockable**	3171	1		
	Shockable	5	680		

Table 12: Clinical Performance Results (Pediatric Patients)

Rhythms	**Total Segments**	**Correctly Analyzed**	**Incorrectly Analyzed**	**Observed Performance (%)**	**90% One-sided Low Confidence Limit (%)**
Coarse VF	49	42	0	100	93.12
Rapid VT	79	79	0	100	96.28
NSR	208	208	0	100	98.57
AF, SB, SVT, Heart block, idioventricular, PVCs	348	346	2	99.43	98.20
Asystole	29	29	0	100	90.19
Fine VF	0	0	0	N/A	N/A
Other VT	44	36	8	81.82	89.58
		No Shock Advised	**Shock Advised**		
Overall Performance	**Non Shockable**	619	10		
	Shockable	0	121		

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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