

Indications for Use

The ZOLL AED 3 system is indicated for use when a suspected cardiac arrest victim has an apparent lack of circulation as indicated by:

- Unconsciousness
- Absence of breathing, and
- Absence of pulse and other signs of circulation.

The AED 3 system is indicated for adult and pediatric patients.

Contraindications for Use

Never use the unit for defibrillation when the patient

- Is conscious
- Is breathing, or
- Has a detectable pulse or other sign of circulation.

General Information

Federal (U.S.A.) law restricts this defibrillator to sale by or on the order of a physician.

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Preface

The ZOLL AED 3™ defibrillator is an Automated External Defibrillator (AED) that is designed to be used for both adult and child victims of sudden cardiac arrest. The defibrillator incorporates a sequence of audio and visual prompts to help rescuers follow established current AHA/ERC/ILCOR Guidelines for use of AEDs. This guide provides information about the operation and care of the ZOLL AED 3 defibrillator. The *ZOLL AED 3 Administrator's Guide* is to be used by trained medical personnel in conjunction with the *ZOLL AED 3 Operator's Manual*.

This guide contains the following sections:

Chapter 1—Overview describes a general product overview of the ZOLL AED 3 defibrillator.

Chapter 2—Data Transfer provides instructions on how to transfer data that is stored on the AED.

Chapter 3—Maintenance provides the recommended procedures for evaluating the condition and performance of the ZOLL AED 3 defibrillator.

Chapter 4—Troubleshooting describes possible problems and solutions and lists the error log messages that indicate the AED requires technical service.

Appendix A—Contains a list of symbols that may be used in this guide or on the ZOLL AED 3 defibrillator.

Appendix B—Contains specification information and the ZOLL® Rectilinear Biphasic™ waveforms that are produced when the ZOLL AED 3 defibrillator is discharged into loads of 25, 50, 75, 100, 125, 150, and 175 ohms at each energy setting (200, 150, 120, 85, 70, and 50 joules).

Appendix C—Contains a list of accessories for the ZOLL AED 3 defibrillator.

Appendix D—Contains definitions of all configuration settings for the ZOLL AED 3 defibrillator and provides instructions for setting up your wireless configuration.

Conventions

Throughout this document, text prompts and 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 defibrillator.

NOTE Notes contain important additional information on using the defibrillator.

ZOLL AED 3 Safety Considerations

Only qualified personnel should service an ZOLL AED 3 defibrillator. Before using this defibrillator, read the *ZOLL AED 3 Operator's Manual*. Before servicing any equipment, review these safety considerations and read this manual carefully.

WARNING! The ZOLL AED 3 defibrillator can generate as much as 2250 volts with sufficient current to cause lethal shocks.

Before discharging the defibrillator, warn everyone near the equipment to *STAND CLEAR*.

Do not recharge, disassemble, or dispose of the battery in fire. The battery might explode if mishandled.

Tracking Requirements

U.S Federal Law (21 CFR 821) requires the tracking of defibrillators. As an owner of this defibrillator, 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 Food and Drug Administration (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 failure or malfunction. This information is required to assure that ZOLL provides only the highest quality products.

Technical Service

If a ZOLL product requires service, contact the ZOLL Technical Service Department or the nearest ZOLL sales office or distributor:

Telephone: 1-978-421-9655

Toll free: 1-800-348-9011

Fax: 1-978-421-0010

Email: techsupport@zoll.com

Have the following information available for the Technical Service representative:

- Serial number
- Description of the problem

If you need to send the ZOLL AED 3 defibrillator to ZOLL Medical Corporation, obtain a service order request number from the Technical Service representative.

NOTE Before sending the defibrillator and battery to ZOLL, check with your local shipping company to see if there are any restrictions on shipping lithium batteries.

Remove the battery pack from the defibrillator and return the AED and battery pack 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 the battery pack from the AED and return the AED and battery pack 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. For a list of ZOLL offices, please visit: <http://www.zoll.com/contact/worldwide-locations/>.

Software Licensing Statement

Certain software components (referred to herein as "Open Source Components") that are used in this product are licensed by ZOLL Medical Corporation (referred to herein as "ZOLL Medical") under various open source license agreements. As required by the terms of these open source license agreements, ZOLL Medical offers to make the source code corresponding to the Open Source Components, and any ZOLL Medical modifications thereof, available upon request.

Chapter 1

Overview

The ZOLL AED 3 defibrillator is an Automated External Defibrillator (AED) that is designed to be used for both adult and child victims of sudden cardiac arrest. The AED uses audio and visual prompts to guide the rescuer through a resuscitation sequence that may include defibrillation and/or cardiopulmonary resuscitation (CPR). The ZOLL AED 3 defibrillator has a liquid crystal display (LCD) touch screen and uses detachable defibrillation pads. The defibrillation pads include an intelligent CPR sensor that allows the AED to monitor chest compressions and provide feedback during CPR.

This guide contains instructions for all ZOLL AED 3 models:

- **ZOLL AED 3** — Operates in Semi-Automatic Mode. Includes lay rescuer prompts and graphics, and Real CPR Help[®] for CPR monitoring and feedback.
- **ZOLL AED 3 *Automatic*** — Operates in Fully Automatic Mode. Includes lay rescuer prompts and graphics, and Real CPR Help for CPR monitoring and feedback.
- **ZOLL AED 3 *BLS*** — Operates in Semi-Automatic Mode. Includes Real CPR Help for CPR monitoring and feedback, optional patient ECG display, CPR Dashboard, optional lay rescuer graphics, and optional audio recording.

When the rescuer attaches defibrillation pads to a patient's chest, the AED monitors and analyzes the electrocardiographic (ECG) rhythm of the patient's heart to determine whether or not the ECG rhythm is shockable. If the AED detects a shockable rhythm, it either issues instructions to deliver the shock (semi-automatic) or automatically delivers the shock (fully automatic). The ZOLL AED 3 defibrillator then prompts the rescuer to perform CPR for a period of time (configured by the AED Administrator), after which the AED automatically initiates a new ECG analysis.

ZOLL AED 3 User Interface

The ZOLL AED 3 defibrillator has a Status Indicator that allows you to quickly see if it has passed its last self test and is ready for use. An LCD screen in the center of the front panel provides text prompts, rescue graphics, and incident information. The AED defibrillator provides audio prompts through a speaker located on the front of the AED. The front panel of the AED has an On/Off button on the top left side of the device and a Shock button beneath the LCD screen. It also has a Child button for patients that are less than 8 years old or weigh less than 55 pounds (25 kg).

The ZOLL AED 3 defibrillator has two operating modes: AED Management Mode and Rescue Mode. In AED Management Mode, the icons on the touch screen allow you to change configuration settings and upload clinical archives, device history, and configuration files. There is also a Supervisor menu for advanced users to make more complex changes to the AED, such as device configuration, shock settings, and CPR settings.

In Rescue Mode, the LCD screen displays graphics that are coordinated with audio prompts to guide the rescuer through the necessary steps to perform a rescue. The steps that include graphics and audio prompts are defined by local protocols for use of an AED.

Child Mode

The ZOLL AED 3 defibrillator has a Child mode that is enabled when the rescuer uses ZOLL Pedi-padz[®] II defibrillation pads. In this mode, the AED uses configured pediatric energy settings that are lower doses of energy than those used for adults. The ZOLL AED 3 defibrillator also uses a pediatric AED analysis algorithm that is specifically designed for a child's ECG. This algorithm accurately distinguishes shockable versus non-shockable rhythms in the pediatric patient.

Real CPR Help

The ZOLL AED 3 adult CPR defibrillation pads include a sensor that detects the rate and depth of chest compressions. This sensor is part of the defibrillation pads that the rescuer places on the patient's chest, and must be located between your hands and the patient's lower sternum. When the rescuer performs CPR compressions, the sensor detects the rate and depth and sends the information

to the AED. The ZOLL AED 3 defibrillator includes a CPR audio metronome function designed to encourage the rescuer to perform chest compressions at the AHA/ERC/ILCOR recommended minimum rate of at least 100 compressions per minute (CPM). The AED performs CPR monitoring, prompts the rescuer, and records chest compressions in the clinical patient file.

WARNING! Real CPR Help audio prompts are not enabled in Child mode.

When performing CPR on adult patients, the ZOLL AED 3 defibrillator may issue one or more audible prompts based on the depth of chest compressions detected. If Real CPR Help determines that compression depth is consistently less than 2 inches, the AED issues a *PUSH HARDER* prompt. The AED issues a *GOOD COMPRESSIONS* prompt if the rescuer responds by increasing compression depth to 2 inches or more.

Using Defibrillation Pads

The ZOLL AED 3 defibrillator is compatible with the following adult and child defibrillation pads:

- CPR-D-padz[®] (for adults only)
- CPR Stat-padz[®] (for adults only)
- Stat-padz II (for adults only)
- Pedi-padz II (for children only)

Make sure that the defibrillation pads used are appropriate for the patient.

NOTE When using Pedi-padz II, the Child button automatically lights up.

The pads package is connected to the AED by a cable. The package contains defibrillation pads that the rescuer attaches to the patient. The pad package includes scissors for cutting clothing or chest hair off the patient.

If the defibrillation pads cable is not attached properly, the AED issues the *PLUG IN PADS CABLE* prompt. Make certain to connect the defibrillation pad cable to the ZOLL AED 3 defibrillator and attach the pads to the patient properly.

WARNING! Defibrillation pads must be pre-attached to the device. Keep the defibrillation pad cable connected to the AED at all times.

NOTE Defibrillation pads 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! DO NOT reuse defibrillation pads.

Data Recording and Storage

All ZOLL AED 3 models can record and store up to 120 minutes of continuous ECG/audio and clinical event data during a rescue or patient case. See “Data and Audio Recording” on page 14 for more detailed information about this function.

Post Event Analysis

All ZOLL AED 3 models automatically store patient clinical data and device history in long-term memory.

- Patient clinical data (clinical archives) — Includes date and time notation that you can view and analyze using ZOLL RescueNet[®] Code Review software or view online with ZOLL RescueNet Case Review (requires ZOLL Online account and ZOLL AED 3 device to transmit clinical event data over Wi-Fi).
- Device history — A log of device status information that you can view and analyze. You can transfer this file over Wi-Fi or upload it using a USB flash drive.

Transferring Files Using a USB Flash Drive

All ZOLL AED 3 models have a USB port that allows you to export and save configuration settings, clinical archives, and device history to a USB flash drive. This feature allows you to easily copy a configuration from one AED to other AEDs. The USB port also allows you to import new system software to quickly upgrade the AED.

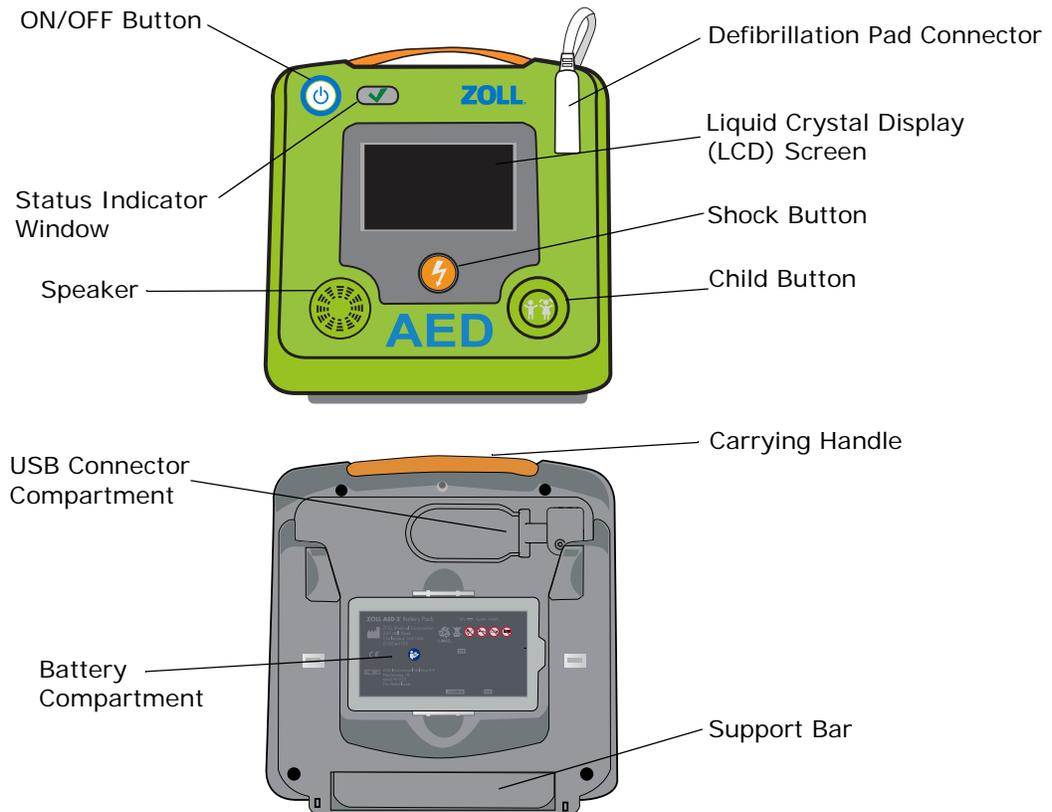
Wi-Fi Communication

All ZOLL AED 3 models have wireless communication that provides automatic upload of self-test reports and on-demand transfer of patient clinical archives and device history information through a wireless access point.

ZOLL AED 3 Operation

Operating Controls and Indicators

This section describes the functions of the controls on the front of the ZOLL AED 3 defibrillator.



ON/OFF Button — Turns power ON or OFF.

When pressed and held for at least 5 seconds, the AED initiates a self test and enters AED Management Mode.



AED Passed
Self Test

Status Indicator Window — Green check indicates that the AED passed its last self test and is ready for use.



AED Failed
Self Test

A blank window indicates that the AED has failed its self test and is not ready for use.

Speaker — Provides audio prompts and metronome beeps that direct rescuers on what to do during a rescue; also provides audio prompts to indicate if service is required.

Defibrillation Pad Connector — This connector is used to attach defibrillation pads to the AED.

Liquid Crystal Display (LCD) Screen — A 5.3 x 9.5 centimeter touch screen for display and user input. During a rescue, it displays graphics and text messages to guide the rescuer.



Shock Button — Illuminates when the AED is charged and ready to deliver a shock to the patient.

When pressed, the charged and ready AED discharges its energy into the patient.



Child Button — Illuminated button indicates the AED is in Child Mode to prepare a rescue for a pediatric patient. Automatically illuminates when using Pedi-padz II.

USB Connector Compartment — Contains a connection for a USB flash drive when importing or exporting files to or from the AED.

Battery Compartment — Holds the battery pack used to power the AED.

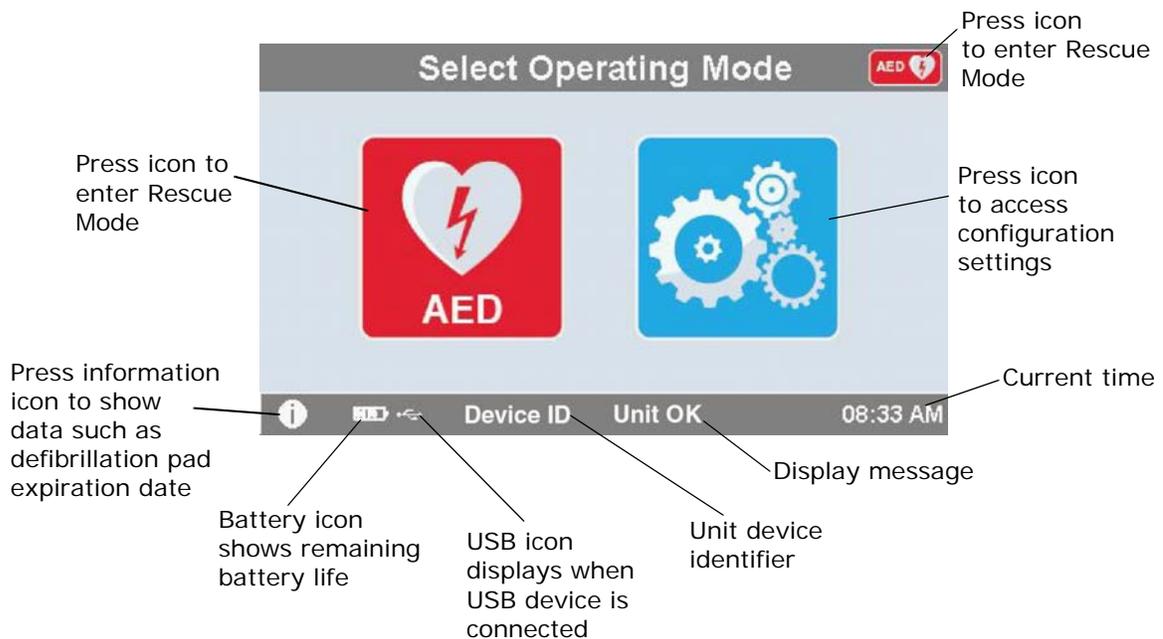
Carrying Handle — The strap designed for carrying the AED.

Support Bar — The brace that opens to hold the AED in an upright position.

Graphical Display Area

The ZOLL AED 3 defibrillator has a 5.3 x 9.5 centimeter LCD screen that displays the following information in the modes in this section: AED Management Mode and Rescue Mode.

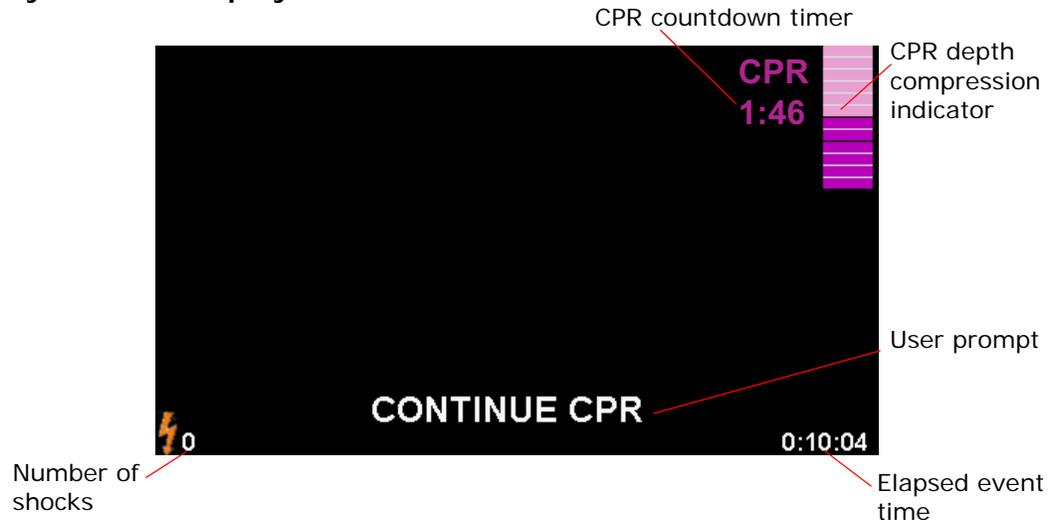
AED Management Mode



Rescue Mode

The ZOLL AED 3 and ZOLL AED 3 *Automatic* models show the Lay Rescuer display, while the ZOLL AED 3 *BLS* model can be configured to show the Lay Rescuer display, CPR only display, or CPR and ECG display.

Lay Rescuer Display



CPR Countdown Timer -- Indicates the amount of time remaining in the CPR interval.

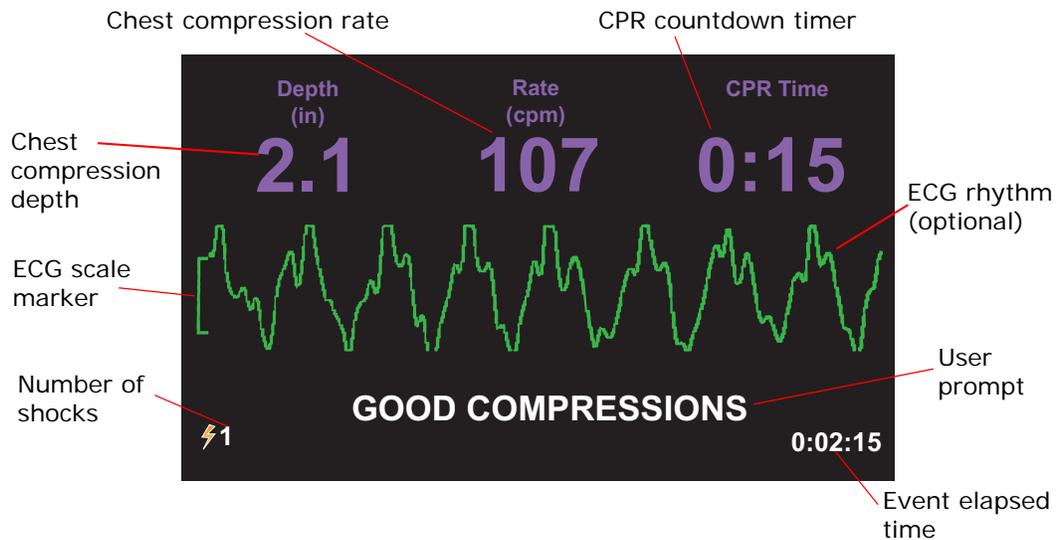
CPR Depth of Compression Indicator -- A bar graph that displays the depth of chest compressions measured while the rescuer is performing CPR. Indicator lines are displayed in the bar graph at 2 and 2.4 inches (5 and 6 centimeters) of compression depth and provide reference points for rescuers performing CPR.

User Prompt -- Displays a visual message on the screen while simultaneously issuing an audio prompt.

Elapsed Event Time -- Indicates the amount of time that has elapsed since the start of the rescue.

Number of Shocks -- Indicates the total number of defibrillation shocks delivered during the rescue.

CPR Only/CPR and ECG Displays (ZOLL AED 3 *BLS* models only)



Chest Compression Depth — Indicates the depth of the current CPR compressions.

NOTE If the chest compression depth is outside of the recommended AHA/ERC range, the AED highlights the depth value inside a red box.

Chest Compression Rate — Indicates the rate of the current CPR compressions.

NOTE If the chest compression rate is outside of the recommended AHA/ERC range, the AED highlights the rate value inside a red box.

CPR Countdown Timer — Indicates the amount of time remaining in the CPR interval.

ECG Rhythm (optional) — Displays the current ECG waveform.

User Prompt — Displays a visual message on the screen while simultaneously issuing an audio prompt.

Event Elapsed Time — Indicates the amount of time that has elapsed since the start of the rescue.

Number of Shocks — Indicates the total number of defibrillation shocks during the rescue.

Audio Prompts

During clinical use of the ZOLL AED 3 defibrillator, you may hear the following audio prompts:

Table 1. Clinical Audio Prompts

| Audio Prompt | Definition/Action |
|----------------------------------|---|
| <i>AUTOMATIC DEFIBRILLATOR</i> | The AED is the fully automatic model that has the capability to automatically shock the patient without the rescuer having to press the Shock button. |
| <i>UNIT OK</i> | The AED has successfully passed its power up self tests. |
| <i>UNIT FAILED</i> | The AED has failed its power up self tests and is not usable for patient care. |
| <i>CHANGE BATTERY</i> | The ZOLL AED 3 self test has detected a low battery condition that is insufficient for the AED's use for patient care. Replace battery pack with a new one as soon as possible. |
| <i>BATTERY HAS BEEN REPLACED</i> | The AED has detected that the battery has been changed. |
| <i>PLUG IN PADS CABLE</i> | Ensure that the defibrillation cable is properly connected to the ZOLL AED 3 defibrillation connector. |
| <i>ATTACH CORRECT DEFIB PADS</i> | Pads that are connected to the AED are not compatible with the ZOLL AED 3 defibrillator. |
| <i>CHECK PADS</i> | Previously attached defibrillation pads are not making good contact with the patient's skin or the pads are defective. |
| <i>REPLACE PADS</i> | There is a problem with the pads connected to the AED. Attach new pads to the AED. |
| <i>ADULT PADS</i> | Adult pads (CPR-D-padz, CPR Stat-padz, Stat-padz II) are attached to the AED. |
| <i>PEDIATRIC PADS</i> | Pedi-padz II are attached to the AED. |
| <i>STAY CALM</i> | Relax as much as possible and focus on the rescue effort. |
| <i>CHECK RESPONSIVENESS</i> | Check patient for responsiveness/consciousness by gently shaking the patient and shouting "Are you all right?" |
| <i>CALL FOR HELP</i> | Call EMS for assistance or ask a bystander to do it for you. |
| <i>OPEN AIRWAY</i> | Place patient in the supine position and perform Head Tilt – Chin Lift or Jaw – Thrust maneuver to open patient's airway. |

| Audio Prompt | Definition/Action |
|--|--|
| <i>CHECK BREATHING</i> | Look, listen, or feel for the presence of breathing and/or airflow from the patient's lungs. |
| <i>REMOVE PAD PACKAGE</i> | Remove the defibrillation pad package from the back of the AED. |
| <i>CUT OR TEAR CLOTHING TO EXPOSE PATIENT'S BARE CHEST</i> | If needed, use scissors to completely remove the patient's shirt. |
| <i>COMPLETELY REMOVE CHILD'S SHIRT, CUTTING OR TEARING IF NEEDED</i> | If needed, use scissors to completely remove child's shirt. |
| <i>OPEN PAD PACKAGE</i> | Tear open the defibrillation pad package to access the defibrillation pads. |
| <i>ATTACH PADS TO PATIENT'S BARE CHEST</i> | Attach defibrillation pads to the patient's bare chest. |
| <i>ATTACH PADS TO CHILD'S BACK AND CHEST</i> | Attach defibrillation pads to child's bare back and chest as shown. |
| <i>DON'T TOUCH PATIENT ANALYZING</i> | Do not touch the patient; an ECG rhythm analysis is in progress or about to begin. |
| <i>NO SHOCK ADVISED</i> | ECG rhythm analysis has detected a rhythm that is not treatable by defibrillation. |
| <i>SHOCK ADVISED</i> | ECG rhythm analysis has detected the presence of ventricular fibrillation or shockable ventricular tachycardia. |
| <i>DON'T TOUCH PATIENT. PRESS THE FLASHING SHOCK BUTTON.</i> | Warn all persons in attendance to stand clear and stop touching the patient. Press the Shock Button to deliver defibrillation therapy. |
| <i>RELEASE SHOCK BUTTON</i> | The Shock Button was pressed before the defibrillator was ready to defibrillate. Release the Shock Button and press again after the ready tone sounds. |
| <i>SHOCK WILL BE DELIVERED IN THREE, TWO, ONE</i> | (ZOLL AED 3 <i>Automatic</i> model only) The AED will automatically deliver shock after the countdown completes. |
| <i>SHOCK DELIVERED</i> | A defibrillation shock has just been delivered to the patient. |
| <i>NO SHOCK DELIVERED</i> | No shock was delivered to the patient because rescuer failed to press Shock Button or an error condition was detected. |
| <i>START CPR</i> | Begin CPR. |
| <i>PUSH TO MATCH THE TONE</i> | Announced at the start of the CPR period. (Adult patients only). |
| <i>PUSH HARDER</i> | CPR compressions are consistently less than 2 inches deep. (Adult patients only) |

| Audio Prompt | Definition/Action |
|---|---|
| <i>GOOD COMPRESSIONS</i> | After prompting to Push Harder, rescuer has succeeded in delivering chest compressions at least 2 inches deep. (Adult patients only) |
| <i>CONTINUE CPR</i> | Continue providing CPR. This prompt may also be issued if Real CPR Help fails to detect chest compressions at least 2 inches deep. (Adult patients only). |
| <i>ANALYSIS HALTED. KEEP PATIENT STILL.</i> | ECG rhythm analysis has been halted due to excessive ECG signal artifact. Stop any ongoing CPR and keep the patient as motionless as possible. |
| <i>GIVE TWO BREATHS</i> | If patient is not breathing, give two rescue breaths. |
| <i>STOP CPR</i> | Stop CPR. The AED is about to begin an ECG rhythm analysis. |
| <i>CPR ONLY MODE</i> | Defibrillation is not working properly; AED will only provide CPR support. |

Prompts that you may hear during non-clinical use of the ZOLL AED 3 defibrillator include:

Table 2. Non-Clinical Audio Prompts

| Audio Prompt | Definition |
|--------------------------|--|
| <i>REPLACE PADS</i> | The ZOLL AED 3 self test has detected that the defibrillation pads have passed their expiration date. Replace the defibrillation pads immediately. |
| <i>CHANGE BATTERY</i> | The ZOLL AED 3 self test has detected that the battery has passed its install by date. Replace the battery pack immediately. |
| <i>UNIT POWERING OFF</i> | The AED is shutting down. |

Chapter 2

Data Transfer

The ZOLL AED 3 defibrillator automatically stores patient clinical data and device history information. You can access this data and transfer it to a remote device (such as a computer) using either a USB flash drive or a wireless access point.

The AED stores the patient clinical event data with the date and time notation. You can view and analyze this information using ZOLL RescueNet Code Review software or ZOLL RescueNet Case Review software through ZOLL Online.

You can transfer information to the AED such as a software upgrade or configuration settings using a USB flash drive. This allows you to quickly and easily update software or copy a configuration to multiple AEDs.



Device
Configuration
Icon

In order to transfer data, the ZOLL AED 3 defibrillator must be in AED Management mode. To enter AED Management Mode, press and hold the On/Off button for at least 5 seconds, then press the Device Configuration icon on the main display screen. While in AED Management mode, you can export data at any time to a USB flash drive or a wireless access point.

NOTE The AED retains device history and clinical event data even when powered off or when the battery pack is removed. When the AED is powered on and defibrillation pads are attached to a new patient, the new clinical data replaces the old clinical data once the AED has stored data for one or two patients (default is two).

Data Storage

The ZOLL AED 3 defibrillator stores the following patient clinical archive and device history data:

Clinical Archive Data (.crd) ***(Clinical Event File)***

- Elapsed time (since power on)
- Continuous ECG Data
- Number of patient shocks
- Selected energy
- Patient impedance
- Audio prompts
- Audio recording (if applicable)
- Power on (date and time)
- Indication of defibrillation pad attachment
- Results of ECG analysis
- CPR data
- Errors

Device History Data (.dhf) ***(Self-Test Report)***

- AED serial number
- Battery status
- Defibrillation pad information
- Hardware revision number
- Software revision number
- Date/time and results of last self test
- Error codes in most recent self test

The ZOLL AED 3 defibrillator generates device history data when it performs a self-test during power up or at a scheduled time during sleep state. When the AED detects system issues it saves these issues in device log files.

Data and Audio Recording

The ZOLL AED 3 *BLS* model has an audio recording option that can be configured on or off. If the audio recording option is on, the ZOLL AED 3 *BLS* model can record and store 60 minutes of continuous audio, ECG, and clinical event data. If the audio recording option is off, the ZOLL AED 3 *BLS* model can record and store 120 minutes of clinical event data and ECG data. The recorded audio data is synchronized to the clinical event data. The audio recording starts when defibrillation pads are attached and the AED completes its automatic self tests.

All ZOLL AED 3 models can be configured to store one or two patient cases containing ECG, audio (*BLS* model), and clinical event data. When the AED is configured to store two cases and a clinical event is detected in rescue mode, the AED deletes the oldest of the two previously stored cases from memory before recording data for the current rescue. If the AED is configured to store one case, it deletes the stored case from memory before recording data for the current rescue. Deleting of old ECG, audio, and event data occurs 15 seconds after the defibrillation pads are properly connected to the patient. If the ZOLL AED 3 defibrillator is started in AED Management Mode, the recorded data of the last rescue is retained and may be transferred using a wireless connection or USB flash drive.

Exporting Files From the AED

You can export the following data from a ZOLL AED 3 defibrillator:

- Clinical Archives (using USB or Wi-Fi)
- Device History (using USB or Wi-Fi)
- Configuration (using USB)

NOTE When transferring files via USB, the USB flash drive must be USB 1.1 or 2.0 compliant.

NOTE You do not need Supervisor access to export data files to a USB flash drive or wireless access point.

Exporting Files

Use the following procedure to transfer files from the AED.

NOTE You cannot transfer configuration files through a wireless connection.

In order to transfer data via a wireless connection, you need to create a wireless profile. If you have not already done so, see .

WARNING! Do not connect the AED to a computer or other device (via the USB port) while the AED's defibrillation pads are still connected to the patient.



Device
Configuration
icon

1. Press and hold the On/Off button for longer than 5 seconds, then press the Device Configuration icon to enter AED Management mode.
2. If you are transferring data:
 - Using a wireless connection, go to step 3.
 - Using a USB flash drive, insert the flash drive into the USB connector on the back of the AED. The USB device icon (•↔) appears in the status bar at the bottom of the display screen.



Export Files
icon

3. Press the Export Files icon and select the following data option(s) to transfer:
 - Clinical Archives (all)
 - Clinical Archives (new)
 - Device History
 - Configuration (USB only)

A green check displays next to the option(s) you have selected.

4. Press **Save (USB)** or **Send (Wi-Fi)**. When the AED has finished transferring data, it issues the prompt, *DATA TRANSFER COMPLETE*.
5. Press **OK** to return to the previous screen.

NOTE If you rename a configuration file with the intention of importing it into another ZOLL AED 3 defibrillator, do not include spaces in the file name.

You can transfer clinical archives (patient data) for use with ZOLL RescueNet Code Review software or Case Review software (over Wi-Fi using ZOLL Online). Once you have transferred a configuration file to a USB flash drive you can copy it to other ZOLL AED 3 defibrillators. See “Importing Files from a USB Flash Drive” on page 16 for more information.

Using RescueNet Code Review Software

RescueNet Code Review software allows you to analyze resuscitation incident information from the AED and perform the following functions:

- Access and review patient event information.
- Add or modify patient information.
- View animated versions of ECG traces.
- Annotate ECG traces.
- Print ECG stripcharts and case reports.

Visit www.zolldata.com/c-r-downloads/ to download the latest version of RescueNet Code Review Software and corresponding documentation.

Using Case Review Software

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 ZOLL AED 3 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.

Importing Files from a USB Flash Drive

You can import a configuration file, a software upgrade, or a wireless configuration to an AED using a USB flash drive. You must have Supervisor access to import data files from a USB flash drive (see “Set Supervisor Passcode” on page 62 for more information).

NOTE When importing files via USB, the USB flash drive must be USB 1.1 or 2.0 compliant.

NOTE The AED does not allow you to perform a software upgrade when the battery is below 30% capacity.

You can import the following file types:

- Configuration— Allows to you import clinical or Wi-Fi configuration files. Before importing a configuration file, make sure the file name (.ini) does not have spaces in it.
- System Software— Allows you to upgrade to the latest software version.
- Root Certificates— Allows you to import Wi-Fi configuration files to validate the identity of the server and different elements in the network.

Importing Files

Follow the steps below to import files from a USB flash drive to an AED.

WARNING! Do not connect the AED to a computer or other device (via the USB port) while the AED's defibrillation pads are still connected to the patient.

1. Insert the USB flash drive into the USB connector on the back of the AED.
2. Press and hold the On/Off button for more than 5 seconds. Once the USB flash drive has been detected, the USB device icon () appears in the status bar at the bottom of the display screen.
3. Press the Device Configuration icon to enter AED Management mode.



Configuration
Device
icon



Supervisor
Access icon



Import Files
icon

4. Press the Supervisor Access icon, enter your supervisor passcode, and press **OK**.
5. Press the Import Files icon and select one the following options to import:
 - Configuration
 - System Software
 - Root Certificates

A green check displays next to the option you have selected.

6. See the table below to determine your next step based on the option you have selected:

| Option | Do the following | Then |
|-------------------|---|---|
| Configuration | Select the following option(s): <ul style="list-style-type: none"> • Clinical Configuration • Wi-Fi Configuration | Press OK . When the ZOLL AED 3 has finished transferring data, it issues the prompt, <i>FILES TRANSFERRED SUCCESSFULLY</i> . |
| System Software | Press OK . The AED issues the prompt: <i>UPON COMPLETION OF THE SOFTWARE UPGRADE THE SYSTEM WILL RESTART. THE SCREEN WILL GO BLANK DURING THIS PROCESS. THIS MAY TAKE UP TO 5 MINUTES. DO NOT POWER OFF DURING THIS TIME.</i> | |
| Root Certificates | Select a root certificate(s). | Press OK . When the AED has finished transferring data, it issues the prompt, <i>SELECTED CERTIFICATES SUCCESSFULLY STORED</i> . |

7. Press **OK** to return to the previous screen.

Troubleshooting Communication Issues

The following table summarizes communication messages that the ZOLL AED 3 defibrillator may issue, and their associated description and/or recommended action. If the AED is not working properly, contact ZOLL's Technical Service Department for assistance. See "Technical Service" on page v for more information.

Table 3. ZOLL AED 3 Communication Error Messages

| Message | Description/Recommended Action |
|--|--|
| <i>DATA TRANSFER COMPLETE</i> | The data transfer through Wi-Fi is complete. |
| <i>UNABLE TO SAVE FILES. PLEASE ENSURE THAT AN EMPTY USB FLASH DRIVE IS SECURELY INSERTED INTO THE DEVICE.</i> | The AED cannot save the files to the USB flash drive. Verify that there is sufficient space to export the file(s) to the USB flash drive, and that the flash drive is inserted properly into the unit. |
| <i>UNABLE TO SAVE FILE TO DEVICE.</i> | The file import was not successful. Make sure there is a configuration file (.ini) on the USB flash drive and try the file import operation again. |
| <i>FILES TRANSFERRED SUCCESSFULLY.</i> | The file(s) has been successfully imported from the USB flash drive. |
| <i>UNABLE TO EXPORT REQUESTED FILE. INTERNAL ERROR.</i> | The file export was not successful. Verify the Wi-Fi configuration and try the export operation again. |
| <i>NO CERTIFICATES FOUND.</i> | There are no root certificates on the USB flash drive available to import. |

| Message | Description/Recommended Action |
|---|--|
| <i>SELECTED CERTIFICATES SUCCESSFULLY STORED.</i> | The root certificates have been imported to the AED. |
| <i>YOU HAVEN'T SELECTED ANY FILES.</i> | You have not selected any files to be imported. Select the file(s) and try the import operation again. |
| <i>CLINICAL ARCHIVE UNAVAILABLE.</i> | There are no clinical archive files (.crd) available to export. |
| <i>DEVICE HISTORY UNAVAILABLE.</i> | There are no device history files (.dhf) available to export. |
| <i>CONFIGURATION FILES UNAVAILABLE.</i> | There are no configuration files (.ini) available to export. |
| <i>THE REQUESTED FILE IS OUT OF DATE. UNABLE TO IMPORT.</i> | The AED cannot import the configuration file (.ini) from the USB flash drive. Verify that the file is a compatible version and try the import operation again. |
| <i>THE REQUESTED FILE CONTAINS INVALID DATA. UNABLE TO IMPORT.</i> | The AED cannot import the file from the USB flash drive. Verify that the file is valid and try the import operation again. |
| <i>THE REQUESTED FILE IS CORRUPTED. UNABLE TO IMPORT.</i> | The AED cannot import the file from the USB flash drive. Verify that the file is valid and try the import operation again. |
| <i>THE REQUESTED FILE CANNOT BE FOUND. VERIFY THAT THE USB FLASH DRIVE CONTAINS THE NECESSARY FILE AND THAT THE USB FLASH DRIVE IS PROPERLY INSERTED IN THE DEVICE.</i> | The AED cannot read the USB flash drive. Verify that the USB flash drive is inserted properly into the unit. |
| <i>CONFIGURATION FILES ARE ONLY SAVED TO USB. THEY ARE NOT TRANSMITTED VIA WI-FI.</i> | The AED cannot transmit configuration files through Wi-Fi. |
| <i>WI-FI CONNECTION NOT ESTABLISHED. CANNOT TRANSMIT REQUESTED DATA.</i> | The AED cannot transmit the data through the Wi-Fi connection. If you have not already done so, see "Setting Up Your Wireless Configuration" on page 65. |
| <i>THE SYSTEM IS UNABLE TO INSTALL THE SELECTED CERTIFICATES. PLEASE ENSURE THAT THE USB FLASH DRIVE IS PROPERLY INSERTED.</i> | The AED cannot save the files to the USB flash drive. Verify that the USB flash drive is inserted properly into the device. |
| <i>UNABLE TO TRANSMIT REQUESTED FILE.</i> | The attempt to export the file to the USB flash drive was unsuccessful. Try the file transfer again. |

| Message | Description/Recommended Action |
|--|---|
| <i>UPON COMPLETION OF THE SOFTWARE UPGRADE THE SYSTEM WILL RESTART. THE SCREEN WILL GO BLANK DURING THIS PROCESS. THIS MAY TAKE UP TO 5 MINUTES. DO NOT POWER OFF DURING THIS TIME.</i> | AED is performing a software upgrade. Wait until the upgrade is complete and the unit restarts. |

Chapter 3

Maintenance

The ZOLL AED 3 defibrillator automatically performs functional testing during periodic self tests. There are also some basic maintenance tests that can be performed on the AED. This section of the guide contains information about functions that are performed with each self test as well as procedures for maintaining the ZOLL AED 3 device.

Self Tests

The ZOLL AED 3 defibrillator performs the following self tests to verify AED integrity and its readiness for emergency use:

- Battery Installation
- Power On
- Manual
- Automatic (daily or weekly, based on configuration)
- Automatic Monthly



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



If the status indicator is blank following completion of any self test, the ZOLL AED 3 defibrillator is not ready for use and may be defective. Remove the AED from service and consult the section, “Chapter 4 Troubleshooting” on page 29, to help determine the problem.

Self Test Functions

The following functions are verified during self tests. Table 4 on page 23 lists the functions that are included in each self test.

- **Battery Capacity:** Verifies that the battery usage indicator shows adequate battery capacity remaining.
- **Defibrillation Pads Connection:** Verifies that the defibrillation pads are properly preconnected to the device.
- **Defibrillation Pads/Battery Expiration:** Verifies that the defibrillation pads and the battery are within their expiration dates.
- **ECG Circuitry:** Tests that the ECG signal acquisition and processing electronics are functional.
- **Defibrillator Charge and Discharge Circuitry:** Verifies that the device’s defibrillator electronics are functional and can charge and discharge at 2 joules. The following tests also include a separate 200 joule charge/discharge test: Battery Installation Self Test, Manual Self Test, Automatic Monthly Test.
- **Microprocessor Hardware/Software:** Verifies proper function of the AED microprocessor electronics and the integrity of its software.
- **CPR Circuitry and Sensor:** Determines that CPR monitoring and compression depth detection are functional (if defibrillation pads with CPR functionality are connected).
- **Audio Circuitry:** Verifies that voice prompts are working.

Automatic Self-Test Transfer

All ZOLL AED 3 defibrillators come standard with Program Management Onboard™ intelligent monitoring technology to transfer self-test data. If configured, the AED can automatically transfer self-test information over Wi-Fi to the ZOLL PlusTrac™ AED program management system or to another AED program management provider.

Table 4. Self Test Functions

| | Battery Installation Self Test | Power On Self Test | Manual Self Test | Automatic Self Test | Automatic Monthly Test |
|--|---------------------------------------|---------------------------|-------------------------|----------------------------|-------------------------------|
| Battery Capacity | ✓ | ✓ | ✓ | ✓ | ✓ |
| Defibrillation Pads Connection | ✓ | ✓ | ✓ | ✓ | ✓ |
| Defibrillation Pads/ Battery Expiration | ✓ | ✓ | ✓ | ✓ | ✓ |
| ECG Circuitry | ✓ | ✓ | ✓ | ✓ | ✓ |
| Defibrillator Charge and Discharge Circuitry (2 Joule Charge/Discharge Test) | ✓ | ✓ | ✓ | ✓ | ✓ |
| Microprocessor Hardware/Software | ✓ | ✓ | ✓ | ✓ | ✓ |
| CPR Circuitry and Sensor (if defibrillation pads with CPR functionality are connected) | ✓ | ✓ | ✓ | ✓ | ✓ |
| Audio Circuitry | ✓ | ✓ | ✓ | ✓ | ✓ |
| 200 Joule Charge/Discharge Test | ✓ | | ✓ | | ✓ |

Optional Maintenance Tests

This section includes a physical inspection of the ZOLL AED 3 defibrillator that you should perform periodically. There is also an optional maintenance test for ZOLL AED 3 models to verify that the AED is working properly and is ready for use. Note that there are two separate optional maintenance tests in this chapter: One for ZOLL AED 3 and ZOLL AED 3 *BLS* models, and one for the ZOLL AED 3 *Automatic* model.

Physical Inspection

| Check the following: | |
|----------------------|---|
| 1. | Is the AED clean, undamaged, free of excessive wear? |
| 2. | Verify that the defibrillation pads are connected to the AED and sealed in their package. Replace defibrillation pads if expired. |
| 3. | Are there any cracks or loose parts in the housing? |
| 4. | Turn on the AED and verify the green check (✓) indicates ready for use; then turn it off. |

Cleaning the ZOLL AED 3 Defibrillator

After each use, clean and disinfect the defibrillator with a soft, damp cloth using either 90% isopropyl alcohol, or soap and water. You can also use a chlorine bleach and water mixture (30 ml/liter water) to clean the defibrillator (except on the contacts and connectors).

NOTE Wipe down the defibrillator with water after using any cleaning solution. Chlorine residue that remains on the LCD screen may damage it.

DO NOT:

- Immerse any part of the defibrillator in water.
- Use chlorine mixture on contacts or connectors; this will degrade the contacts over time.
- Use ketones (MEK, acetone, etc.) to clean the defibrillator.
- Use abrasives (e.g., paper towel) on the display window or graphic screen.
- Sterilize the defibrillator.

Optional Maintenance Test for Technical Professionals

Although the ZOLL AED 3 automatically performs maintenance testing during periodic self tests, you can periodically perform the following manual test to verify that the ZOLL AED 3 is working properly and is ready for use.

This section has two tests: one for ZOLL AED 3 and ZOLL AED 3 *BLS* models, and one for ZOLL AED 3 *Automatic* models.

Test Procedure (ZOLL AED 3 and ZOLL AED 3 *BLS* Models)

NOTE You must use the ZOLL AED Simulator with this test.

1. Connect the ZOLL AED Simulator to the ZOLL AED 3 defibrillation pads connector.
2. Power on the simulator and the ZOLL AED 3 defibrillator. Verify that all of the following occur:
 - The status indicator (located on the top left of the AED) initially changes from blank to a green check (✓) within 4 to 5 seconds after the AED is turned on.
 - The AED issues the *UNIT OK* voice prompt and displays the message within 5 seconds after power-up.
 - The AED displays the number of shocks in the bottom left of the screen and the event elapsed time (since power-up) in the bottom right of the LCD screen.
3. Using the simulator, input a VF rhythm to the AED. Verify that after the AED proceeds through its sequence of victim assessment prompts, it does the following:
 - Analyzes the ECG rhythm.
 - Issues the *SHOCK ADVISED* voice prompt.
 - Charges the defibrillator.
 - Issues the *DON'T TOUCH THE PATIENT; PRESS THE FLASHING SHOCK BUTTON* voice prompt.
4. Verify that the AED emits the charge ready tone 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 number 1 displays next to the shock icon on the bottom left of the LCD screen.
6. Following shock delivery, verify that the AED issues the *START CPR* messages.
7. Activate the simulator's CPR function. Verify that the 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 off the ZOLL AED 3 defibrillator and the simulator.

Test Procedure (ZOLL AED 3 Automatic Models)

NOTE You must use the ZOLL AED Simulator with this test.

1. Connect the ZOLL AED Simulator to the ZOLL AED 3 defibrillation pads connector.
2. Power on the simulator and the ZOLL AED 3 defibrillator. Verify that all of the following occur:
 - The status indicator (located on the top left of the AED) initially changes from blank to a green check (✓) within 4 to 5 seconds after the AED is turned on.
 - The AED issues the *UNIT OK* voice prompt and displays the message within 5 seconds after power-up.
 - The AED displays the number of shocks in the bottom left of the screen and the event elapsed time (since power-up) in the bottom right of the LCD screen.
3. Using the simulator, input a VF rhythm to the AED. Verify that after the AED proceeds through its sequence of victim assessment prompts, it does the following:
 - Analyzes the ECG rhythm.
 - Issues the *SHOCK ADVISED* voice prompt.
 - Charges the defibrillator.
 - Issues the *DON'T TOUCH THE PATIENT; SHOCK WILL BE DELIVERED IN THREE, TWO, ONE* voice prompt.
4. Verify that the AED emits the charge ready tone and the AED automatically delivers a shock.
5. Following shock delivery, verify the following:
 - The AED issues the *SHOCK DELIVERED* message.
 - The simulator shows that a shock was delivered.
 - The number 1 displays next to the shock icon on the bottom left of the AED LCD screen.
 - The AED issues the *START CPR* messages.
6. Activate the simulator's CPR function. Verify that the metronome begins to beep and that the following voice prompts/messages are issued within 60 seconds: *PUSH HARDER* followed by *GOOD COMPRESSIONS*.
7. 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.

8. Verify that a *NO SHOCK ADVISED* prompt is issued.
9. Turn off the ZOLL AED 3 defibrillator and the simulator.

Battery Maintenance

Identifying Battery Conditions

Battery capacity depletes during standby operation of the ZOLL AED 3 defibrillator, while the AED is operating, and as a result of each defibrillation. Battery capacity also gradually diminishes over a shelf life of years without use. The AED monitors energy remaining in the installed battery pack. When battery capacity is low or depleted, the ZOLL AED 3 defibrillator will not function to specification. When a low battery condition occurs, the AED does one of the following things:

- Emits an audible alarm or “beep” once every minute (if the AED is off).
- Issues the *CHANGE BATTERY* voice prompt (if the AED is on).
- Displays a blank status indicator window (no green check), indicating that the battery is at low capacity or that the ZOLL AED 3 defibrillator has failed other self tests.

Table 5. Battery Conditions

| Battery Icon/ Condition | Indications | Correction |
|--|--|--|
| Low Battery with AED off. | Audible beep from AED once every minute. | Replace battery pack. |
| Low Battery during power up self test. | <i>CHANGE BATTERY</i> prompt (when AED is powered on) | Replace battery pack. |
| Low Battery or other self test failure with AED powered off or during self test. | Status Indicator window is blank (no green check) indicating failure to operate (when off). | Replace battery pack. Check or replace defibrillation pads. If blank status indicator window remains, contact ZOLL Technical Service Department for service. |
| Low Battery with AED powered on. | <i>CHANGE BATTERY</i> prompt (AED powered on). | Replace battery pack as soon as possible. |
| Dead Battery. | Status indicator window is blank (no green check) indicating failure to operate when AED is off. | Replace battery pack. If blank status indicator window remains, contact ZOLL Technical Service Department for service. |

Chapter 4

Troubleshooting

This chapter describes technical issues that you may encounter during routine maintenance or after a malfunction of the ZOLL AED 3 defibrillator.

If this chapter does not help you resolve the problem, call the ZOLL Technical Service Department for assistance. For contact information, refer to page v.

Troubleshooting the AED

The following table lists issues that may occur and their solutions. First, try the recommendations listed under “Operator Action.” If these steps do not remedy the problem, follow the suggestions under “Technical Action.”

For information on contacting ZOLL Technical Service, refer to page v.

Table 6. ZOLL AED 3 Troubleshooting

| Problem | Operator Action | Technical Action |
|---|---|---|
| Green check does not appear in status indicator window. | Press and hold the On/Off button for at least 5 seconds to perform a self-test. Verify that the defibrillation pads cable is properly plugged into the patient cable connector. Replace the defibrillation pads. | If the AED continues to fail, remove it from service and contact ZOLL Technical Service. |
| <i>UNIT FAILED</i> | Turn the AED off and then press and hold the On/Off button for at least 5 seconds to perform a self-test. Verify that the defibrillation pads cable is properly plugged into the patient cable connector. Replace the defibrillation pads. | If the AED continues to fail, remove it from service and contact ZOLL Technical Service. |
| Beeping noise when AED is off. | Verify that the defibrillation pads cable is properly plugged into the patient cable connector. Hold the On/Off button for at least 5 seconds to perform a self-test. Verify that a green check appears in the status indicator window. | If the AED continues to beep, remove it from service and contact ZOLL Technical Service. |
| Loss of audio prompts or display. | Cycle power on the defibrillator by turning the AED off, and then on again. | If the AED continues to fail, remove the AED from service and contact ZOLL Technical Service. |
| <i>CHANGE BATTERY</i> | Replace the battery pack. | If the message persists, remove the AED from service and contact ZOLL Technical Service. |
| <i>PLUG IN PADS CABLE</i> | Ensure that the defibrillation pads cable is properly plugged into the patient cable connector. | If the message persists, remove the AED from service and contact ZOLL Technical Service. |
| <i>CHECK PADS</i> | Reattach pads. | If the message persists, attach new pads. |
| <i>ANALYSIS HALTED; KEEP PATIENT STILL</i> | Keep the patient still during ECG analysis. If transporting the patient by stretcher or vehicle, stop all patient movement during analysis. | If the message persists, remove the AED from service and contact ZOLL Technical Service. |

Table 6. ZOLL AED 3 Troubleshooting (Continued)

| Problem | Operator Action | Technical Action |
|----------------------------------|--|--|
| <i>NO SHOCK DELIVERED</i> | The Shock button was not pressed or an internal error occurred. When prompted to press the button, do so within 30 seconds. | If an internal error occurred (no shock was delivered when the Shock button was pressed properly), remove the AED from service and contact ZOLL Technical Service. |
| <i>RELEASE SHOCK BUTTON</i> | (ZOLL AED 3 and ZOLL AED 3 BLS models) Release the Shock button. Do not press the button until the charge-ready tone sounds and the button begins flashing. | If the message persists, remove the AED from service and contact ZOLL Technical Service. |
| <i>ATTACH CORRECT DEFIB PADS</i> | Attach one of the following compatible defibrillation pads to the AED: <ul style="list-style-type: none">• CPR-D padz• CPR Stat padz• Pedi-Padz II (child pads)• Stat-padz II | If the message persists, remove the AED from service and contact ZOLL Technical Service. |
| <i>REPLACE PADS</i> | Attach new defibrillation pads to the AED. | If the message persists, remove the AED from service and contact ZOLL Technical Service. |

Appendix A

Symbols

Symbols

Any or all of the following symbols may be used in this guide or on this equipment:

Table 7: Symbols

| Symbol | Description |
|---|-----------------------------|
|  | Power On/Off. |
|  | Child button. |
|  | Shock button. |
|  | Warning: Dangerous voltage. |
|  | Fragile, handle with care. |
|  | Keep dry. |

| Symbol | Description |
|---|---|
|  | This end up. |
|  | Temperature limitation. |
| Rx ONLY | Federal law restricts this device to sale by or on the order of a physician. |
| CE | Conformité Européenne Complies with medical device directive 93/42/EEC. |
|  | This product has been certified by the Australian Communication and Media Authority. |
| FC | Complies with the Federal Communications Commission. |
|  | Defibrillator-proof type BF equipment. |
|  | Contains lithium. Recycle or dispose of properly. |
|  | Keep away from open flame and high heat. |
|  | Do not open, disassemble, or intentionally damage. |
|  | Do not crush. |
|  | Non-rechargeable battery. |
|  | Return to a collection site intended for waste electrical and electronic equipment (WEEE). Do not dispose of in unsorted trash. |
|  | Use by. |
|  | Latex-free. |

| Symbol | Description |
|---|--|
|  | Do not reuse. |
|  | Not sterile. |
|  | Nonionizing electromagnetic radiation. |
|  | Manufacturer. |
|  | Authorized representative in the European Community. |
|  | Serial Number. |
|  | Catalog number. |
|  | MR Unsafe - keep away from magnetic resonance imaging (MRI) equipment. |
|  | Batch code. |
|  | Consult instructions for use. |
|  | Refer to manual. |
|  | Use by date. |
| IP55 | Protected against dust ingress. Protected against jetting water. |

Appendix B

Specifications

Defibrillator Specifications

This section describes product specifications for the ZOLL AED 3 defibrillator:

| Device | |
|----------------------------|---|
| Size (H x W x D) | 5.0" x 9.3" x 9.7" (12.7 cm x 23.6 cm x 24.7 cm) |
| Weight | 5.5 lbs.; 2.5 kg |
| Power | Battery pack |
| Device Classification | Internally powered per EN60601-1 |
| Design Standards | Meets applicable requirements of EN 60601-1, IEC 60601-1-11, EN 60601-2-4 |
| Environment | |
| Operating Temperature | 32° to 122° F; 0° to 50° C |
| Storage Temperature | -22° to 158° F; -30° to 70° C |
| Humidity | 10 to 95% relative humidity, non-condensing |
| Vibration | IEC 60068-2-64, Random, Spectrum A.4, Table A.8, Cat. 3b; RTCA/DO-160G, Fixed Wing Aircraft, Section 8.6, Test Cat. H, Aircraft Zone 1 and 2; EN 1789, Sweep per EN 60068-2-6 Test Fc |
| Shock | IEC 60068-2-27; 100G |
| Altitude | -1,250 to 15,000 ft.; -381 m to 4573 m |
| Particle and Water Ingress | IP55 |
| Drop | 3.28 ft; 1 m |

| Defibrillator | |
|--|--|
| Waveform | Rectilinear Biphasic™ Refer to “Rectilinear Biphasic Waveform Characteristics” on page 44 and “Clinical Trial Results for the M Series Biphasic Waveform” on page 49. |
| Defibrillator Charge Hold Time | ZOLL AED 3/ZOLL AED 3 <i>BLS</i> models: 30 seconds ZOLL AED 3 <i>Automatic</i> model: 3 seconds prior to automatic shock delivery |
| Energy Selection | Automatic pre-programmed selection (Adult mode: 120J, 150J, 200J; Child mode: 50J, 70J, 85J delivered into a 50 ohm patient) |
| Patient Safety | All patient connections are electrically isolated. |
| Charge Time | Less than 10 seconds with new battery pack. With a depleted battery pack, the charge time is longer. |
| Time from first rhythm analysis to AED charged and ready to shock | With new battery pack: 8 seconds With battery pack depleted by 15 200J discharges: 9 seconds |
| Maximum time from power on to AED charged and ready to shock at 200J | 36 seconds |
| Electrodes | CPR-D padz, CPR Stat-padz, Stat-padz II, or Pedi-padz II |
| Built in Defibrillator Self Test | Included (verifies proper charging and discharging of the defibrillator) |
| Defibrillation Advisory | Evaluates defibrillation pad 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 QRS duration > 120 msec) with rates greater than 150 BPM (adult mode) and 200 BPM (child mode). Refer to “ECG Analysis Algorithm Accuracy” on page 53 for sensitivity and specificity performance. |
| Electrode Patient Impedance Measurement Range | 10 to 300 ohms |
| Defibrillator Electrode ECG Circuitry | Protected |
| ECG | |
| ECG Bandwidth | .67-20Hz |
| Implanted Pacemaker Pulses Detected | The ZOLL AED 3 defibrillator does not reject implanted pacemaker pulses. |

| Display | |
|--------------------------------|--|
| Display type | High resolution liquid crystal display with capacitive touch panel |
| Viewable area (height • width) | 2.12 in • 3.74 in 5.39 cm • 9.5 cm |
| ECG Sweep Speed | 25 mm/sec |
| ECG Viewing time | 3.84 seconds |

| Data Recording and Storage | |
|--|---|
| ZOLL AED 3/ ZOLL AED 3 <i>Automatic</i> | User configurable for 1 or 2 clinical events for a total of 120 minutes. Includes, ECG, patient impedance, audio prompts, and CPR data. |
| ZOLL AED <i>BLS</i> | User configurable for 1 or 2 clinical events for a total for 120 minutes with audio recording disabled, or 60 minutes with audio recording enabled. Includes ECG, patient impedance, audio prompts, CPR data, and optional audio recording. |

| Battery | | | | | | | |
|---|--|------------------------------------|---|-----------------------------------|---|------------------------------------|----|
| Operating Time (Clinical Mode) | <p>Typical new battery running at an ambient temperature of +20° C to +25° C (68° F to 77° F) can provide:</p> <ul style="list-style-type: none"> • 140 defibrillator discharges at maximum energy (200 joules), or • 6 hours of continuous monitoring (with 2-minute CPR periods) <p>Note: CPR periods shorter than 2 minutes can decrease the operating time that can be obtained from a new battery.</p> | | | | | | |
| Standby Life (years) When using a battery stored for up to 2 years at 23° C (73° F) and placed in a ZOLL AED 3 defibrillator. | <p>Auto Self-Test Report OFF</p> <table border="0"> <tr> <td>Self-Test Interval (7 days)</td> <td>5</td> </tr> <tr> <td>Self-Test Interval (1 day)</td> <td>3</td> </tr> </table> <p>Auto Self-Test Report ON</p> <table border="0"> <tr> <td>Self-Test Interval (7 days)</td> <td>3*</td> </tr> </table> | Self-Test Interval (7 days) | 5 | Self-Test Interval (1 day) | 3 | Self-Test Interval (7 days) | 3* |
| Self-Test Interval (7 days) | 5 | | | | | | |
| Self-Test Interval (1 day) | 3 | | | | | | |
| Self-Test Interval (7 days) | 3* | | | | | | |

*Battery standby life will be shorter in areas with low Wi-Fi signal strength and/or more complex Wi-Fi authentication protocols.

| CPR Monitoring | |
|-----------------------|---|
| CPR | Metronome Rate: 105 ±2 CPM |
| Compression Depth | 0.75 to 4 inches ±0.25 inches 1.9 to 10.2 cm ±0.6 cm |
| Compression Rate | 50 to 150 compressions per minute |

Guidance and Manufacturer's Declaration - Electromagnetic Compatibility

The ZOLL AED 3 defibrillator is intended for use in the electromagnetic environment specified below. The customer or the user of the AED should assure that it is used in such an environment.

| Emissions test | Compliance | Electromagnetic environment - guidance |
|--|----------------|---|
| RF emissions CISPR11 | Group 1 | The ZOLL AED 3 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 3 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 used for domestic purposes. |
| Harmonic Emission IEC 61000 3-2 | Not applicable | |
| Voltage Fluctuations/ Flicker Emission IEC 61000 3-3 | Not applicable | |

Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to EMC information provided in this document.

The ZOLL AED 3 defibrillator's essential performance is energy delivery, ECG rhythm analysis, and CPR feedback, as specified on page 37 to page 39. The ZOLL AED 3 defibrillator meets basic safety and essential performance when it is operated in the electromagnetic environment specified in the following tables.

The ZOLL AED 3 defibrillator is intended for use in the electromagnetic environment specified below. The customer or the user of the AED should assure that it is used in such an environment.

| Immunity test | IEC 60601 test level | Compliance 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 Not applicable | |
| Surge IEC 61000-4-5 | ± 1 kV differential mode +/- 2 kV common mode | Not applicable Not applicable | |
| 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. |
| | | | Portable and mobile RF communications equipment should be used no closer to any part of the AED, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter, or 30 cm, whichever is greater. |
| Recommended separation distance | | | |
| Conducted RF IEC 61000-4-6 | 3 Vrms 150 kHz to 80 MHz outside ISM bands ^a | 3 Vrms | $d = 1.2 \sqrt{P}$ outside ISM bands |
| | 10 Vrms 150 kHz to 80 MHz in ISM bands ^a | 10 Vrms | $d = 1.2 \sqrt{P}$ within ISM bands |

| Immunity test (cont'd) | IEC 60601 test level (cont'd) | Compliance level (cont'd) | Electromagnetic environment - guidance (cont'd) |
|------------------------------|--------------------------------|---------------------------|--|
| Radiated RF IEC 61000-4-3 | 10 V/m 80 MHz to 2.5 GHz | 10 V/m | Recommended separation distance |
| | | | $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). ^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:  |

The ZOLL AED 3 defibrillator is suitable for use in all professional and domestic establishments. It is not intended for use near intentional transmitters of radio energy outside the ranges stated in the above table, such as high frequency surgical equipment, radar installations, or radio transmitters. It is also not intended for use in fixed or rotary wing aircraft.

The ZOLL AED 3 defibrillator is MR unsafe. Keep the defibrillator away from magnetic resonance imaging (MRI) equipment.

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.

Adverse effects of ESD may include loss of audio prompts or visual display. See "Chapter 4 Troubleshooting" on page 29 for more information.

NOTE 1: U_T is the a.c. mains voltage prior to application of the test level.

NOTE 2: At 80 MHz, the higher frequency range applies.

NOTE 3: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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

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

^c Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the AED is used exceeds the applicable RF compliance level above, the ZOLL AED 3 defibrillator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the AED.

^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 ZOLL AED 3 defibrillator

The ZOLL AED 3 is intended for use in an environment in which radiated RF disturbances are controlled. The customer or the user of the ZOLL AED 3 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ZOLL AED 3 as recommended below, according to the maximum output power of the communications equipment.

The recommended separation distance should be the distance calculated from one of the equations below, or 30 cm, whichever is greater.

| Rated maximum output power of transmitter in watts (W) | Separation distance in meters (m) according to frequency of transmitter | | | |
|--|---|--|---|---|
| | 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 2.5 GHz $d = 2.3 \sqrt{P}$ |
| 0.01 | 0.12 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.38 | 0.38 | 0.73 |
| 1 | 1.2 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 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 metres (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

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

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

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

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

NOTE The ZOLL AED 3 incorporates RF receivers for Wi-Fi operation (see “Wireless Output Guidance and Manufacturer’s Declaration” on page 56). Other equipment may interfere with ZOLL AED 3 Wi-Fi operations, even if that equipment complies with CISPR emissions requirements.

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.

| | 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 | 29 A | 27 A | 20 A | 16 A |
| First Phase Average Current | 26 A | 24 A | 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 | 30 A | 19 A | 12 A | 11 A |
| Second Phase Average Current | 18 A | 14 A | 10 A | 9 A |
| Second Phase Duration | 4 ms | 4 ms | 4 ms | 4 ms |

Table 8. Delivered Energy at Each Defibrillator Setting into a Range of Loads

| Load | Selected Energy | | | | | |
|----------|-----------------|------|-------|-------|-------|-------|
| | 50 J | 70 J | 85 J | 120 J | 150 J | 200 J |
| 25Ω | 37 J | 54 J | 57 J | 86 J | 109 J | 139 J |
| 50Ω | 50 J | 69 J | 80 J | 118 J | 145 J | 209 J |
| 75Ω | 61 J | 82 J | 97 J | 134 J | 166 J | 196 J |
| 100Ω | 60 J | 84 J | 95 J | 142 J | 165 J | 194 J |
| 125Ω | 57 J | 80 J | 91 J | 133 J | 155 J | 178 J |
| 150Ω | 65 J | 91 J | 103 J | 124 J | 145 J | 192 J |
| 175Ω | 60 J | 84 J | 95 J | 116 J | 135 J | 177 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 ZOLL AED 3 defibrillator'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 ZOLL M Series and ZOLL AED 3 defibrillation waveforms are considered substantially equivalent.

Figures 1 through 6 show the Rectilinear Biphasic waveforms that are produced when the ZOLL AED 3 defibrillator is discharged 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).

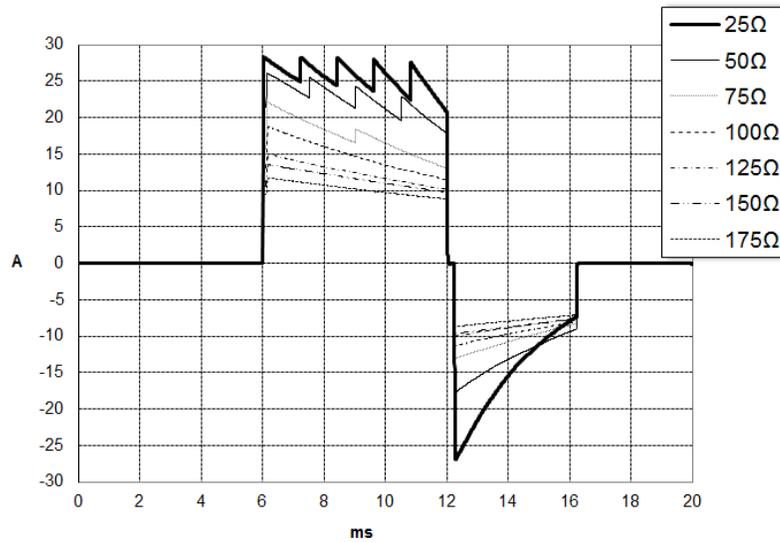


Figure 1. Rectilinear Biphasic Waveforms at 200 Joules

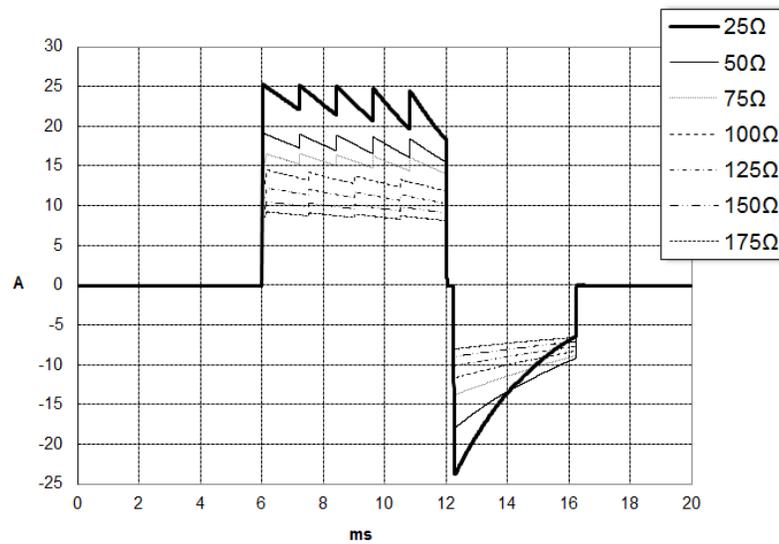


Figure 2. Rectilinear Biphasic Waveforms at 150 Joules

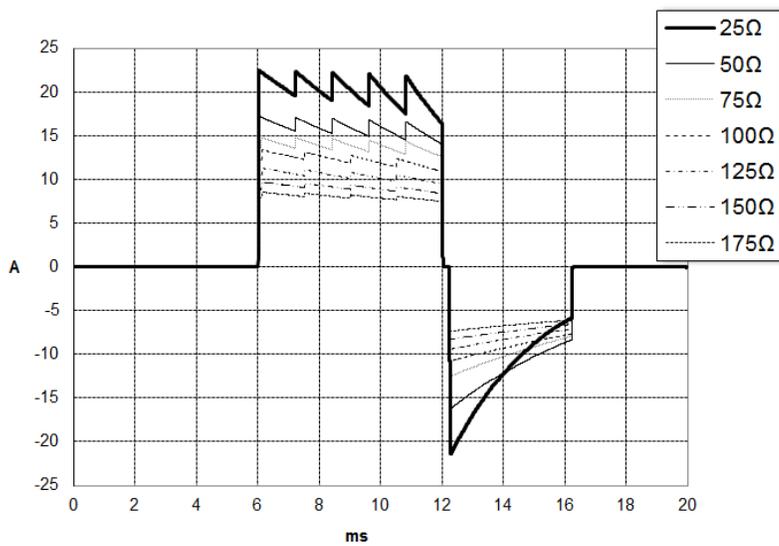


Figure 3. Rectilinear Biphasic Waveforms at 120 Joules

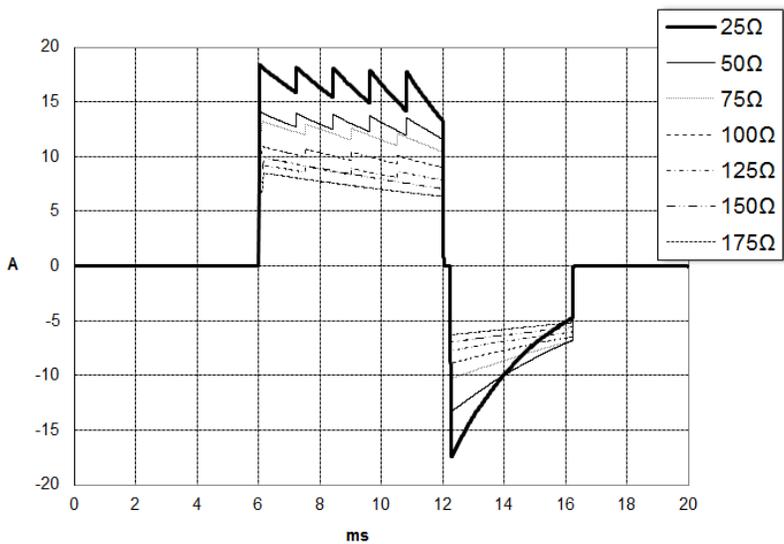


Figure 4. Rectilinear Biphasic Waveforms at 85 Joules

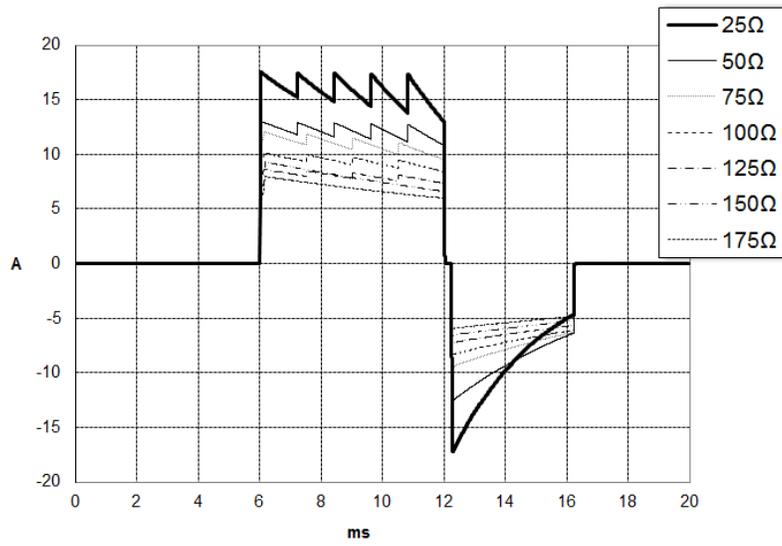


Figure 5. Rectilinear Biphasic Waveforms at 70 Joules

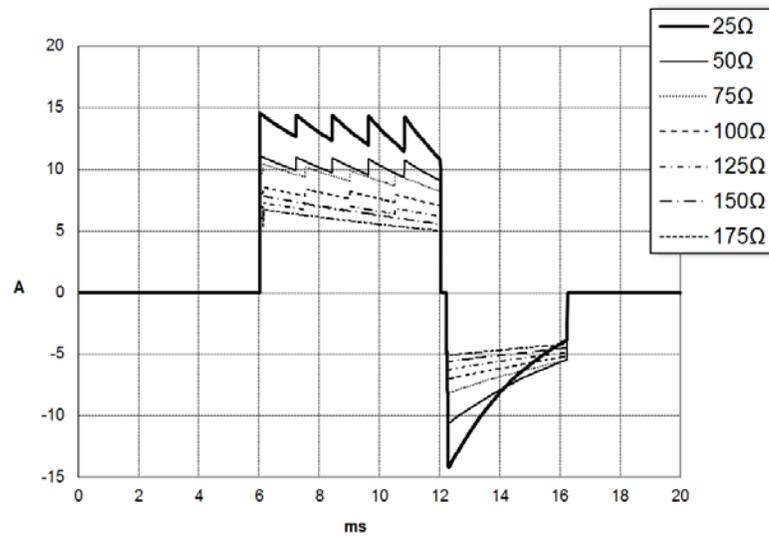


Figure 6. Rectilinear Biphasic Waveforms at 50 Joules

Clinical Trial Results for the M Series Biphasic Waveform

The efficacy of the ZOLL Rectilinear Biphasic waveform has been clinically verified during a study of defibrillation of Ventricular Fibrillation (VF) and 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, multicenter, 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 defibrillation pads.

Randomized Multicenter Clinical Trial for Defibrillation of Ventricular Fibrillation (VF) and Ventricular Tachycardia (VT)

Overview: The defibrillation efficacy of the ZOLL Rectilinear Biphasic waveform was compared to a monophasic damped sine waveform in a prospective, randomized, multicenter study of patients undergoing ventricular defibrillation for VF/VT during electrophysiological studies, ICD implants, and test. A total of 194 patients were enrolled in the study. Ten patients who did not satisfy all protocol criteria were excluded from the analysis, leaving a study population of 184.

Objectives: The primary goal of this study was to compare the first shock efficacy of the 120 J Rectilinear Biphasic waveform with a 200 J monophasic waveform. The secondary goal was to compare all shock (three consecutive 120, 150, and 170 joules) efficacy of the Rectilinear Biphasic waveform with that of a monophasic waveform (three consecutive 200, 300, and 360 joules). 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%¹ 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. Of these, 143 patients were male. 98 patients were in the biphasic group (ventricular fibrillation/flutter, n=80; ventricular tachycardia, n=18) and 86 patients were in the monophasic group (ventricular fibrillation/flutter, n=76; ventricular tachycardia, n=10). There were no adverse events or injuries related to the study.

1. Kerber RE, et al., "Automated External Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating New Waveforms, and Enhancing Safety," *Circ J Am Heart Assoc.* 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 $<0\%$ (ie, alternative is greater than standard)."

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

| | Monophasic | Biphasic |
|-------------------------|-----------------------|----------|
| First shock efficacy | 93% | 99% |
| p-value | 0.0517 | |
| 95% confidence interval | -2.7% to 16.5% | |
| 90% confidence interval | -1.01% to 15.3% | |

Successful defibrillation with Rectilinear Biphasic shocks was achieved with 58% less delivered current than with monophasic shocks (14 ± 1 amperes versus 33 ± 7 amperes, $p=0.0001$).

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 -0.0217% to 0.759% and 90% confidence interval of the difference of 0.037% to 0.706%).

| | Monophasic | Biphasic |
|--|--------------------------|----------|
| First shock efficacy (high impedance patients) | 63% | 100% |
| p-value | 0.02 | |
| 95% confidence interval | -0.0217% to 0.759% | |
| 90% confidence interval | 0.037% to 0.706% | |

A single patient required a second biphasic shock at 150 joules to achieve 100% efficacy versus six patients for whom monophasic shocks of up to 360 joules 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 Rectilinear Biphasic waveform.

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 Pro device (cleared by the FDA under K041892). The protocol for this pre-clinical study, along with a summary of the results, have been submitted to FDA under AED Pro PMA application (P160022). 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 P160022 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 the following tables summarizes the accuracy of the ECG analysis algorithm as tested against ZOLL's ECG Rhythm Database.

The algorithm sequence takes approximately six to nine seconds and proceeds as follows:

- Divides the ECG rhythm into three-second segments.
- Filters and measures noise and artifact.
- Measures baseline content ('waviness' at the correct frequencies) of the signal.
- Measures QRS rate, width, and variability.
- Measures amplitude and temporal regularity ('auto-correlation') of peaks and troughs.
- Determines if two out of three segments are shockable then prompts the user to treat the patient.
- Stops analyzing the ECG after detecting a shockable rhythm and alerts the user that the device is ready to deliver a shock.
- Prompts the user to return to CPR if the ECG rhythm is determined to be non-shockable.

Clinical Performance Results

The following two tables represent clinical performance results of adult and pediatric patients.

Table 9. Clinical Performance Results (Adult Patients)

| Rhythms | Sample Size | Performance Goals | Observed Performance | 90% One-sided Lower Confidence Limit |
|---|-------------|--------------------|----------------------|--------------------------------------|
| Shockable | | | | |
| | | Sensitivity | | |
| Coarse VF | 536 | >90% | >99% | >99% |
| Rapid VT | 80 | >75% | >98% | >94% |
| Non-shockable | | | | |
| | | Specificity | | |
| NSR | 2210 | >99% | >99% | >99% |
| AF, SB, SVT, Heart block, idioventricular, PVCs | 819 | >95% | >99% | >99% |
| Asystole | 115 | >95% | >99% | >97% |
| Intermediate | | | | |
| Fine VF | 69 | Report only | Sensitivity >94% | >87% |
| Other VT | 28 | Report only | >99% | >89% |

Table 10. Clinical Performance Results (Pediatric Patients)

| Rhythms | Sample Size | Performance Goals | Observed Performance | 90% One-sided Lower Confidence Limit |
|---|-------------|--------------------|----------------------|--------------------------------------|
| Shockable | | | | |
| | | Sensitivity | | |
| Coarse VF | 42 | >90% | >99% | >93% |
| Rapid VT | 79 | >75% | >99% | >96% |
| Non-shockable | | | | |
| | | Specificity | | |
| NSR | 208 | >99% | >99% | >98% |
| AF, SB, SVT, Heart block, idioventricular, PVCs | 348 | >95% | >99% | >97% |
| Asystole | 29 | >95% | >99% | >90% |
| Intermediate | | | | |
| Fine VF | 0 | Report only | >NA | >NA |
| Other VT | 44 | Report only | >81% | >69% |

Table 11. Rhythm Recognition Detector Categories (Adult Patients)

| | VF and VT | All Other ECG Rhythms |
|----------------------|------------------|------------------------------|
| Shock | 680 | 1 |
| Non-shockable | 5 | 3171 |

A true positive (680) is a correct classification of a shockable rhythm. A true negative (3171) is a correct classification of all rhythms for which a shock is not indicated. A false positive (1) is an organized or perfusing rhythm or asystole that has been incorrectly classified as a shockable rhythm. A false negative (5) is a VF or VT associated with cardiac arrest that has been incorrectly classified as non-shockable.

Table 12. Rhythm Recognition Detector Categories (Pediatric Patients)

| | VF and VT | All Other ECG Rhythms |
|----------------------|------------------|------------------------------|
| Shock | 121 | 10 |
| Non-shockable | 0 | 619 |

A true positive (121) is a correct classification of a shockable rhythm. A true negative (619) is a correct classification of all rhythms for which a shock is not indicated. A false positive (10) is an organized or perfusing rhythm or asystole that has been incorrectly classified as a shockable rhythm. A false negative (0) is a VF or VT associated with cardiac arrest that has been incorrectly classified as non-shockable.

Wireless Output Guidance and Manufacturer's Declaration

RF Transmission Emitted (IEC 60601-1-2)

The ZOLL AED 3 unit complies with IEC 60601-1-2 for medical electrical equipment and medical electrical systems that include RF transmitters as specified below.

| Standard | Frequency Range | Effective Radiated Power | Modulation Type | Data Rates |
|----------|---|--------------------------|-----------------|--|
| 802.11b | 2412-2472 MHz | 100 mW | DSSS | 1, 2, 5.5, 11 Mbps |
| 802.11g | 2412-2472 MHz | 32 mW | OFDM | 6, 9, 12, 24, 36, 48, 54 Mbps |
| 802.11n | 2412-2472 MHz | 32 mW | OFDM | 6.5, 13, 19.5, 26, 39, 52, 58.5, 65 Mbps |
| 802.11a | 5180-5320 MHz 5500-5700 MHz 5745-5825 MHz | 32 mW | OFDM | 6, 9, 12, 24, 36, 48, 54 Mbps |
| 802.11n | 5180-5320 MHz 5500-5700 MHz 5745-5825 MHz | 32 mW | OFDM | 6.5, 13, 19.5, 26, 39, 52, 58.5, 65 Mbps |

FCC Notice

Contains FCC ID: MCQ-CCi.MX28

ZOLL Medical Corporation has not approved any changes or modifications to this device by the user. Any changes or modifications could void the user's authority to operate the equipment. See 47 CFR Section 15.21.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

NOTE "Harmful interference" is defined by the FCC as follows:

Any emission, radiation, or induction that endangers the functioning of a radio navigation service or other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with FCC rules.

The user is cautioned to maintain 20 cm (8 inches) of space from the product to ensure compliance with FCC requirements.

Canada, Industry Canada (IC) Notices

Contains Model ConnectCard™ for i.MX28 Radio, IC: 1846A-CCi.MX28

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

FCC/IC/EU: This device is limited to indoor use in the 5150 MHz to 5250 MHz band.

Appendix C

Accessories

Accessories

The following accessories are compatible for use with the ZOLL AED 3 defibrillator. To order any of these items, contact your local ZOLL representative.

NOTE The use of accessories other than those specified in this appendix may result in increased emissions or decreased immunity of the ZOLL AED 3 defibrillator.

| Accessory | REF |
|------------------------------|--------------|
| <i>Defibrillation Pads</i> | |
| • CPR-D padz | 8900-0800-01 |
| • CPR Stat-padz | 8900-0402 |
| • Stat-padz II | 8900-0801-01 |
| • Pedi-padz II | 8900-0810-01 |
| <i>Battery</i> | |
| • AED 3 Battery Pack | 8000-000696 |
| <i>Carry Cases</i> | |
| • Battery Case | 8000-001251 |
| • Replacement Shoulder Strap | 8000-001252 |
| • AED 3 Carry Case | 8000-001250 |
| • Small Rigid Plastic Case | 8000-001253 |
| • Large Rigid Plastic Case | 8000-001254 |

| Accessory | REF |
|---|----------------|
| <i>Wall Mounts/Cabinets</i> | |
| • Standard Surface Wall Cabinet | 8000-001256 |
| • Semi-recessed Wall Cabinet | 8000-001257 |
| • Fully-recessed Wall Cabinet | 8000-001258 |
| • Device Wall Mount Bracket | 8000-001255 |
| • Case Wall Mount Bracket | 8000-001266 |
| • Strobe for Standard Surface Wall Cabinet | 8000-001259 |
| • Strobe for Semi/Fully-recessed Wall Cabinet | 8000-001267 |
| <i>Wall Signs</i> | |
| • ILCOR Flush Wall Sign (AED) | 8000-001260 |
| • ILCOR 3D Wall Sign (AED) | 8000-001261 |
| • ILCOR Flush Wall Sign (DAE) | 8000-001262 |
| • ILCOR 3D Wall Sign (DAE) | 8000-001263 |
| • ILCOR Flush Wall Sign (DEA) | 8000-001264 |
| • ILCOR 3D Wall Sign (DEA) | 8000-001265 |
| <i>Simulation/Training</i> | |
| • ZOLL AED Simulator | 8000-000925 |
| <i>Documentation</i> | |
| • ZOLL AED 3 Operator's Manual | 9650-000760-01 |

Appendix D

Configuration Settings

Overview

This section describes the configurable settings for the ZOLL AED 3 defibrillator. The configuration settings can be manually selected through the use of the LCD touch screen, or automatically configured by reading a configuration file directly from a USB flash drive.



Device Configuration icon

Press the Device Configuration icon to access the configuration window. To import a configuration file from a USB flash drive, see “Importing Files from a USB Flash Drive” on page 16.



Supervisor Access icon

There are two levels of configuration settings: user and supervisor. The supervisor settings are indicated by the Supervisor Access icon. You need a pass code to access these advanced settings (the default passcode is listed under “Set Supervisor Passcode” on page 62). Press the icons on the screen to access the configuration settings below. Once you set up your AED to put it into service, ZOLL recommends that you create a new supervisor passcode.

| User/Supervisor Setting | Description | Values |
|---|---|--|
| <p><i>Language</i></p>  <p>Note: This setting is also available to the Supervisor user.</p> | <p>User configurable for one language (up to three possible languages depending on the ordered device configuration).</p> | <ul style="list-style-type: none"> • Language 1 (default) • Language 2 • Language 3 |

| User/Supervisor Setting | Description | Values |
|--|--|--|
| <p><i>Lay Rescuer Prompts</i></p>  <p>Note: This setting is also available to the Supervisor user.</p> | <p>When enabled (ON), the AED issues the following audio and text prompts after completion of the power-on self-test and entry into clinical mode:</p> <p><i>STAY CALM</i> <i>CHECK RESPONSIVENESS</i> <i>CALL FOR HELP</i></p> <p>Note: If defibrillation pads are pre-attached to the patient, these prompts are not issued.</p> | <ul style="list-style-type: none"> • ON (default) • OFF |
| <p><i>Check Breathing Prompts</i></p>  <p>Note: This setting is also available to the Supervisor user.</p> | <p>Allows you to enable the check breathing prompts, “Open Airway and Check Breathing”, based on the guidelines you want to follow.</p> <p>When disabled (OFF), these prompts are not issued.</p> <p>Note: If defibrillation pads are pre-attached to the patient, these prompts are not issued.</p> | <ul style="list-style-type: none"> • ON • OFF (default) |
| <p><i>CPR Depth Measure Units</i></p>  <p>Note: This setting is also available to the Supervisor user.</p> | <p>Allows you to set the CPR depth measurement units to inches or centimeters.</p> | <ul style="list-style-type: none"> • Inches--in • Centimeters--cm <p>Note: The default value depends on the AED's primary language.</p> |
| <p><i>Date</i></p>  <p>Note: This setting is also available to the Supervisor user.</p> | <p>Allows you to manually set the date on the AED.</p> | <p>Month/Day/Year</p> |
| <p><i>Time</i></p>  <p>Note: This setting is also available to the Supervisor user.</p> | <p>Allows you to manually set the time and to specify the time zone.</p> <p>When <i>Auto Adjust for Daylight Savings</i> is enabled (ON), the AED's 24-hour clock automatically adjusts for Daylight Savings Time.</p> <p>Note: You must select a time zone for this setting to work.</p> | <ul style="list-style-type: none"> • 00:00:00 • Dateline • American Samoa • Hawaii • Alaska • N. A. Pacific • N. A. Mountain • N. A. Central • N. A. Eastern (default) • Cuba • Columbia • Venezuela • Atlantic (includes Puerto Rico and Virgin Islands) • Paraguay • Newfoundland |

| User/Supervisor Setting | Description | Values |
|--|-------------|---|
| <p><i>Time (cont'd)</i></p>  <p>Note: This setting is also available to the Supervisor user.</p> | | <ul style="list-style-type: none"> • Chile • Falkland Islands • Greenland • Brazil (São Paulo) • Mid Atlantic (including the east coast of Brazil) • Azores • UTC • Western Europe • Central Europe • Namibia • Algeria • Eastern Europe • Egypt • Lebanon • Syria • Kaliningrad • Iraq • Moscow • Arabia • Iran • Samara • Afghanistan • Western Asia • Yekaterinburg • India • Central Asia • Omsk • Southeast Asia • Krasnoyarsk • Irkutsk • China • W. Australia • Japan (includes Korea) • Yakutsk • Central Australia • E. Australia • Vladivostok • Central Pacific (includes Guam) • Srednekolymsk • New Zealand • Kamchatka |

| Supervisor Setting (Advanced) | Description | Values |
|--|---|---|
| <p><i>Number of Clinical Cases</i></p>  | <p>Sets the number of patient cases that are stored in nonvolatile memory.</p> | <ul style="list-style-type: none"> • 1 • 2 (default) |
| <p><i>Self-Test Interval (Days)</i></p>  | <p>Sets the period of time between automated self-tests in standby state.</p> | <ul style="list-style-type: none"> • 1 day • 7 days (default) |
| <p><i>Auto Self-Test Report</i></p>  | <p>When enabled (ON) and following the completion of a periodic self test, the ZOLL AED 3 will attempt to link to ZOLL PlusTrac via an active Wi-Fi connection.</p> <p>Note: The device history Wi-Fi configuration setup must be completed for this to function (see “Setting Up Device History Wi-Fi Configuration” on page 69).</p> | <ul style="list-style-type: none"> • ON • OFF (default) |
| <p><i>Audio Recording (ZOLL AED 3 BLS model only)</i></p>  | <p>Enables audio recording during Rescue Mode.</p> | <ul style="list-style-type: none"> • ON • OFF (default) |
| <p><i>Device Display (ZOLL AED 3 BLS model only)</i></p>  | <p>Allows you to select information displayed on the LCD screen during clinical use.</p> <p>Lay User -- Displays text prompts and graphics.</p> <p>CPR Only - Displays text prompts and the CPR Dashboard during the CPR cycle.</p> <p>CPR and ECG - Displays text prompts, the patient’s ECG rhythm, and the CPR Dashboard during the CPR cycle.</p> | <ul style="list-style-type: none"> • Lay User • CPR Only • CPR and ECG (default) |
| <p><i>Set Supervisor Passcode</i></p>  | <p>Allows you to change the passcode used to enter Supervisor mode.</p> <p>Note: The AED ships with a default Supervisor passcode of 123456. ZOLL recommends that you change the default passcode as soon as the new device setup is complete.</p> <p>Write the new passcode on the line below and put this document in a secure location for future reference.</p> <p>_____</p> | <ul style="list-style-type: none"> • Six numeric digits |

| Supervisor Setting (Advanced) | Description | Values |
|--|--|--|
| <p><i>Device ID</i></p>  | Allows you to input an alpha-numeric device identifier for RescueNet Code Review. | <ul style="list-style-type: none"> • Eleven alpha-numeric digits |
| User/Supervisor Setting | Description | Values |
| <p><i>Export Files</i></p>  <p>Note: This setting is also available to the general user.</p> | <p>You can upload files from the AED to a USB flash drive or through a wireless connection.</p> <p>Note: You can only upload configuration files to a USB flash drive, not through Wi-Fi.</p> | <ul style="list-style-type: none"> • Clinical Archives (all) • Clinical Archives (new) • Device History • Configuration |
| <p><i>Import Files</i></p>  | You can download files from a USB flash drive to the AED. | <ul style="list-style-type: none"> • Configuration • System Software • Root Certificates |
| Supervisor Setting | Description | Values |
| <p><i>Adult Energy Settings</i></p>  | Sets the energy level in joules for an adult patient for the first, second, and third shocks. | <p>Shock 1</p> <ul style="list-style-type: none"> • 120 J (default) • 150 J • 200 J <p>Shock 2</p> <ul style="list-style-type: none"> • 120 J • 150 J (default) • 200 J <p>Shock 3</p> <ul style="list-style-type: none"> • 120 J • 150 J • 200 J (default) |
| <p><i>Child Energy Settings</i></p>  | Sets the energy level in joules for a child patient for the first, second, and third shocks. | <p>Shock 1</p> <ul style="list-style-type: none"> • 50 J (default) • 70 J • 85 J <p>Shock 2</p> <ul style="list-style-type: none"> • 50 J • 70 J (default) • 85 J <p>Shock 3</p> <ul style="list-style-type: none"> • 50 J • 70 J • 85 J (default) |
| <p><i>Breathe During CPR Prompt</i></p>  | When this option is enabled (ON), the AED prompts <i>Give Two Breaths</i> every 30 recognized compressions. | <ul style="list-style-type: none"> • ON • OFF (default) |

| Supervisor Setting | Description | Values |
|---|--|--|
| <p><i>Continue CPR Prompt</i></p>  | <p>"Continue CPR" prompt will be repeated every "N" seconds (based on the <i>CPR Prompt Interval</i>) if CPR compressions stop during the CPR interval.</p> <p>When this option is disabled (OFF), the "Continue CPR" prompt is not issued during the CPR period.</p> | <ul style="list-style-type: none"> • ON (default) • OFF |
| <p><i>CPR Prompt Interval</i></p>  | <p>This option determines the interval for the following prompts:</p> <ul style="list-style-type: none"> • <i>START CPR</i> • <i>CONTINUE CPR</i> | <ul style="list-style-type: none"> • 10 seconds (default) • 15 seconds |
| <p><i>Start with CPR Period</i></p>  | <p>Sets the duration of the "Start with CPR" period once defibrillation pads are attached to the patient.</p> | <ul style="list-style-type: none"> • Off • 30 seconds • 60 seconds (default) • 90 seconds • 120 seconds • 150 seconds • 180 seconds |
| <p><i>No Shock CPR Period</i></p>  | <p>Sets the duration of the CPR period following a No Shock Advised result from the analysis.</p> | <ul style="list-style-type: none"> • 60 seconds • 90 seconds • 120 seconds (default) • 150 seconds • 180 seconds |
| <p><i>Post Shock CPR Period</i></p>  | <p>Sets the duration of the CPR period following the delivery of a shock.</p> | <ul style="list-style-type: none"> • 60 seconds • 90 seconds • 120 seconds (default) • 150 seconds • 180 seconds |
| <p><i>Wi-Fi Settings</i></p>  | <p>These icons contain the settings to set up your wireless connection. See "<i>Setting Up Your Wireless Configuration</i>" on page 65, for more information.</p> | |

Setting Up Your Wireless Configuration

This section describes how to set up a wireless connection for your AED for uploading both clinical archives and the device history. The wireless settings are accessible when the ZOLL AED 3 defibrillator is in AED Management Mode. The Wi-Fi settings are located in the Supervisor menu for advanced users. You need a six-digit pass code to enter the Supervisor menu (see “Set Supervisor Passcode” on page 62 for more information). The configuration setup has two options for both clinical archives and device history:

- **Quick Setup** - For users with a simple configuration using the default settings.
- **IT Setup** - For users with a more complex configuration using specific wireless settings.

NOTE Prior to setting up your clinical archive configuration, visit zollonline.com to create a ZOLL Case Review account.

NOTE Prior to setting up your device history configuration, refer to the PlusTrac Activation Certificate (in your documentation folder) for instructions on how to register for AED Program Management.

You can also automatically configure the Wi-Fi settings for the AED by downloading a configuration file directly from a USB flash drive. For detailed information on how to do this, see “Importing Files from a USB Flash Drive” on page 16.

For IT Setup Only

Client certificates are needed for the Wi-Fi configuration setup only if you are using the TLS method of Wi-Fi authentication. When you select TLS during the Wi-Fi setup, you will need to select a client certificate as part of the setup process.

Additional root certificates are only needed if you are not using the ZOLL standard Self-Signed (SSL) Certificate. If you are not using an SSL Certificate, you need to import the root SSL certificate to use either before you start the Wi-Fi configuration, or during the process of setting up the configuration. For detailed information on how to import a root certificate, see “Importing Files from a USB Flash Drive” on page 16.

ZOLL supports the following root and client certificates:

| Root Certificates | Client Certificates |
|--------------------------------------|---------------------|
| .pem (b64 encoded) | .pfx (binary) |
| .der (binary) | |
| .p7b (Microsoft Chained Certificate) | |



Device Configuration icon

Entering Supervisor Configuration Mode

To enter configuration mode, follow the steps below:

1. Press and hold down the On/Off button for more than 5 seconds. Then press the Device Configuration icon to access the configuration window.



Supervisor Access icon

2. Press the Supervisor icon, and enter your six-digit passcode. You will need to set up the configuration settings for both the clinical archives as well as the device history. See the following sections for step-by-step instructions on both of these configuration setups.

Setting Up Clinical Archive Wi-Fi Configuration



Clinical Archive Wi-Fi icon

Press the Clinical Archive Wi-Fi icon to access the Select Wi-Fi Setup Level window and make one of the following selections:

- **Quick Setup** - for a simple configuration using the default settings (go to "Quick Setup for Clinical Archives" below).
- **IT Setup** - for a more complex configuration using non-standard wireless setup settings (go to "IT Setup for Clinical Archives" on page 67).

Quick Setup for Clinical Archives

1. Press the Quick Setup button to access the Clinical Archive Quick Settings window and enter the applicable information in the following fields:



Wireless button

- **Network (SSID)**--Press the wireless button to the right of this field to search for available wireless networks. Select a network from the list and press **OK**. Alternately, you can use the alpha-numeric keypad to enter the SSID (Service Set Identifier) name that identifies your wireless network access point. Press **OK**.
- **Password (Pre-Shared Key)** - Use the alpha-numeric keypad to enter the pre-shared key (password) to the wireless access point. Press **OK**.
- **Server Settings** - Press the Server Settings field to display the Server Settings window. Use the alpha-numeric keypad to enter the following server information.

| | |
|----------------|--|
| <i>Address</i> | The default is dxsvc.zollonline.com. If you are using the default server, keep this entry the same. Otherwise, enter the URL address of the host server. Press OK . |
|----------------|--|

| | |
|----------------|---|
| <i>User ID</i> | Use the alpha-numeric keypad to enter the user-name of the host server. Press OK . Note: If you have set up a ZOLL Case Review account on zollonline.com, use the ID you specified for that account. |
|----------------|---|

| | |
|-----------------|---|
| <i>Passcode</i> | Use the alpha-numeric keypad to enter your password of the host server. Press OK . Note: If you have set up a ZOLL Case Review account on zollonline.com, use the passcode you specified for that account. |
|-----------------|---|

-
2. Press the **Test Wi-Fi** button in the Clinical Archive Quick Settings window to test the server connectivity.

NOTE If connectivity is not successful, check your wireless configuration settings.

3. Press **Save** at the bottom right of the screen to save the changes. The AED displays the message *SAVING CONFIGURATION, PLEASE WAIT*. When the AED has saved the configuration, it displays the Advanced Configuration window.

IT Setup for Clinical Archives



Clinical Archive
Wi-Fi icon

1. Press the Clinical Archive Wi-Fi icon.
2. Press the IT Setup button to access the Clinical Archive Wi-Fi Settings window.



Network
Settings icon

3. Press the Network Settings icon. The Network Settings window displays.
4. In the DHCP (Dynamic Host Configuration Protocol) field, select ON or OFF:
 - If you select ON, all necessary information is obtained from the network. Press **OK** and go to step 6.
 - If you select OFF, all of the network setup fields display in the Network Settings window. Go to step 5 to enter the static information.
5. You can either keep all of the displayed default settings and press **OK**, or you can enter information in the following fields:

- *Local IP Address* - Use the numeric keypad to enter your Local IP address (format is xxx.xxx.xxx.xxx where xxx = 000-255). Press **OK**.
- *Gateway IP Address* - Use the numeric keypad to enter your Gateway IP address (format is xxx.xxx.xxx.xxx where xxx = 000-255). Press **OK**.
- *Subnet Mask* - Use the numeric keypad to enter your Subnet Mask (format is xxx.xxx.xxx.xxx where xxx = 000-255). Press **OK**.
- *Primary DNS (Domain Name Server) IP Address* - Use the numeric keypad to enter your Primary DNS IP address (format is xxx.xxx.xxx.xxx where xxx = 000-255). Press **OK**.
- *Secondary DNS IP Address* - Use the numeric keypad to enter your Secondary DNS IP Address (format is xxx.xxx.xxx.xxx where xxx = 000-255). Press **OK**.

6. Press **OK** to save the Network settings.



Server
Settings
icon

7. Press the Server Settings icon to access the Server Settings window and enter information in the following fields:
 - *Mode*: Select URL or IP.

- *Address* - The default is dxsvc.zollonline.com. Use the alpha-numeric keypad to change this default only if your URL/IP is different than the default.

NOTE If you are not using the default value, you need to make an entry in the DNS table for the default value, and you will have to import a new SSL root certificate. For detailed information on how to import a root certificate, see “Importing Files from a USB Flash Drive” on page 16.

- *Port* - The default is 443. Change this default only if your port is different than the default.
- *User ID* - Use the alpha-numeric keypad to enter the User ID. Press **OK**.

NOTE If you have set up a ZOLL Case Review account on zollonline.com, use the ID you specified for that account.

- *Passcode* - Use the alpha-numeric keypad to enter the Passcode. Press **OK**.

NOTE If you have set up a ZOLL Case Review account on zollonline.com, use the Passcode you specified for that account.

8. Press **OK** to save the Server settings.



Profile Settings icon

9. Press the Profile Settings icon and enter information in the following fields in the Profile Settings window:

- *Network (SSID)* - Use the alpha-numeric keypad to enter the SSID (Service Set Identifier) name that identifies your wireless access point.
- *Hidden SSID* - Select ON or OFF.
- *Authentication* - Select the method of Wi-Fi Authentication: PSK (Pre-shared Key), PEAP (Protected Extensible Authentication Protocol), or TLS (Transport Layer Security). See the table below for the next step based on the method you selected.

| Wi-Fi Method | Field(s) to Complete |
|--------------|---|
| PSK | <i>Password (Pre-Shared Key)</i> - Use the alpha-numeric keypad to enter the password to the wireless access point. Press OK . |
| PEAP | <i>Username</i> - Use the alpha-numeric keypad to enter the username. Press OK . <i>Password</i> - Use the alpha-numeric keypad to enter the password to the wireless access point. Press OK . |
| TLS | <i>User Identity</i> - Use the alpha-numeric keypad to enter the user identity. Press OK . <i>Private Key Password</i> - Use the alpha-numeric keypad to enter the password. Press OK . <i>Client Certificate</i> - Choose a client certificate from the list and press OK . |

10. Press **OK** to save the Profile settings.
11. Press the **Test Wi-Fi** button in the Clinical Archive Wi-Fi Settings window to test the server connectivity.

NOTE If connectivity is not successful, check your wireless configuration settings.
12. Press **Save** to save the Wi-Fi settings. The AED displays the message *SAVING CONFIGURATION, PLEASE WAIT*. When the AED has saved the configuration, it displays the Advanced Configuration window.

Setting Up Device History Wi-Fi Configuration



Press the Device History Wi-Fi icon to access the Select Wi-Fi Setup Level window and make one of the following selections:

- **Quick Setup** - for a simple configuration using the default settings (go to "Quick Setup for Device History" below).
- **IT Setup** - for a more complex configuration using non-standard wireless setup settings (go to "IT Setup for Device History" on page 70)

Quick Setup for Device History

1. Press the Device History Wi-Fi icon to access the Device History Quick Settings window and enter the applicable information in the following fields:



- **Network (SSID)**--Press the wireless button to the right of this field to search for available wireless networks. Select a network from the list and press **OK**.
Alternately, you can use the alpha-numeric keypad to enter the SSID (Service Set Identifier) name that identifies your wireless network access point. Press **OK**.
- **Password (Pre-Shared Key)** - Use the alpha-numeric keypad to enter the pre-shared key (password) to the wireless access point. Press **OK**.
- **Server Settings** - Press the Server Settings field to display the Server Settings window. Use the alpha-numeric keypad to enter the following server information.

| | |
|-----------------|--|
| <i>Address</i> | The default is dxsvc.zollonline.com. If you are using the default server, keep this entry the same. Otherwise, enter the URL address of the host server. Press OK . |
| <i>User ID</i> | Use the alpha-numeric keypad to enter the user-name of the host server. Press OK . |
| <i>Passcode</i> | Use the alpha-numeric keypad to enter your password of the host server. Press OK . |

2. Press the **Test Wi-Fi** button in the Device History Quick Settings window to test the server connectivity.

NOTE If connectivity is not successful, check your wireless configuration settings.

-
3. Press **Save** at the bottom right of the screen to save the changes. The AED displays the message *SAVING CONFIGURATION, PLEASE WAIT*. When the AED has saved the configuration, it displays the Advanced Configuration window.

IT Setup for Device History



Device History
Wi-Fi icon

1. Press the Device History Wi-Fi icon.
2. Press the IT Setup button to access the Device History Wi-Fi Settings window.



Network
Settings icon

3. Press the Network Settings icon. The Network Settings window displays.
4. In the DHCP (Dynamic Host Configuration Protocol) field, select ON or OFF:
 - If you select ON, all necessary information is obtained from the network. Press **OK** and go to step 6.
 - If you select OFF, all of the network setup fields display in the Network Settings window. Go to step 5 to enter the static information.
5. You can either keep all of the displayed default settings and press **OK**, or you can enter information in the following fields:

- *Local IP Address* - Use the numeric keypad to enter your Local IP address (format is xxx.xxx.xxx.xxx where xxx = 000-255). Press **OK**.
- *Gateway IP Address* - Use the numeric keypad to enter your Gateway IP address (format is xxx.xxx.xxx.xxx where xxx = 000-255). Press **OK**.
- *Subnet Mask* - Use the numeric keypad to enter your Subnet Mask (format is xxx.xxx.xxx.xxx where xxx = 000-255). Press **OK**.
- *Primary DNS (Domain Name Server) IP Address* - Use the numeric keypad to enter your Primary DNS IP address (format is xxx.xxx.xxx.xxx where xxx = 000-255). Press **OK**.
- *Secondary DNS IP Address* - Use the numeric keypad to enter your Secondary DNS IP Address (format is xxx.xxx.xxx.xxx where xxx = 000-255). Press **OK**.

6. Press **OK** to save the Network settings.



Server
Settings
icon

7. Press the Server Settings icon and enter information in the following fields:
 - *Mode*: Select URL or IP.
 - *Address* - The default is dxsvc.zollonline.com. Use the alpha-numeric keypad to change this default only if your URL/IP is different than the default.

NOTE If you are not using the default value, you need to make an entry in the DNS table for the default value, and you will have to import a new SSL root certificate. For detailed information on how to import a root certificate, see "Importing Files from a USB Flash Drive" on page 16.

- *Port* - The default is 443. Change this default only if your port is different than the default.
- *User ID* - Use the alpha-numeric keypad to enter the User ID. Press **OK**.

NOTE If you are using the default server, this field automatically populates.

- *Passcode* - Use the alpha-numeric keypad to enter the Passcode. Press **OK**.

NOTE If you are using the default server, this field automatically populates.

8. Press **OK** to save the Server settings.



Profile Settings icon

9. Press the Profile Settings icon and enter information in the following fields:

- *Network SSID* - Use the alpha-numeric keypad to enter the SSID (Service Set Identifier) name that identifies your wireless access point.
- *Hidden SSID* - Select ON or OFF.
- *Authentication* - Select the method of Wi-Fi Authentication: PSK (Pre-shared Key), PEAP (Protected Extensible Authentication Protocol), or TLS (Transport Layer Security). See the table below for the next step based on the method you selected.

| Wi-Fi Method | Field(s) to Complete |
|--------------|---|
| PSK | <i>Password (Pre-Shared Key)</i> - Use the alpha-numeric keypad to enter the password to the wireless access point. Press OK . |
| PEAP | <i>Username</i> - Use the alpha-numeric keypad to enter the username. Press OK . <i>Password</i> - Use the alpha-numeric keypad to enter the password to the wireless access point. Press OK . |
| TLS | <i>User Identity</i> - Use the alpha-numeric keypad to enter the user identity. Press OK . <i>Private Key Password</i> - Use the alpha-numeric keypad to enter the password. Press OK . <i>Client Certificate</i> - Choose a client certificate from the list and press OK . |

10. Press **OK** to save the Profile settings.

11. Press the **Test Wi-Fi** button in the Device History Wi-Fi window to test the server connectivity.

NOTE If connectivity is not successful, check your wireless configuration settings.

12. Press **Save** to save the Wi-Fi settings. The AED displays the message *SAVING CONFIGURATION, PLEASE WAIT*. When the AED has saved the configuration, it displays the Advanced Configuration window.

