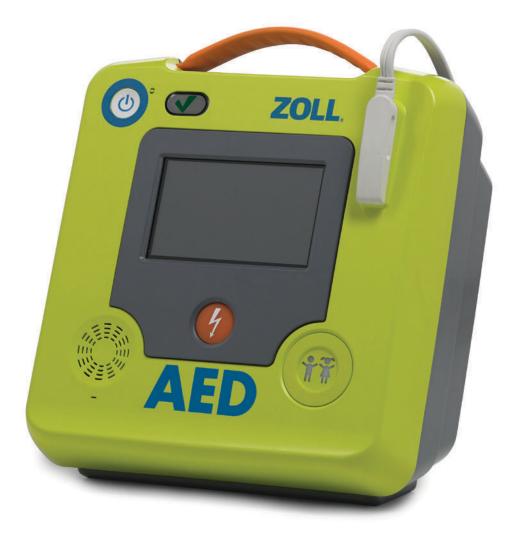
ZOLLAED 3° Operator's Manual





About This Manual

The issue date for the ZOLL AED 3 Operator's Manual (REF 9650-003750-12 Rev. A) is November, 2023.

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Intended Purpose

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

Indications for Use

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 ZOLL AED 3 unit for defibrillation when the patient

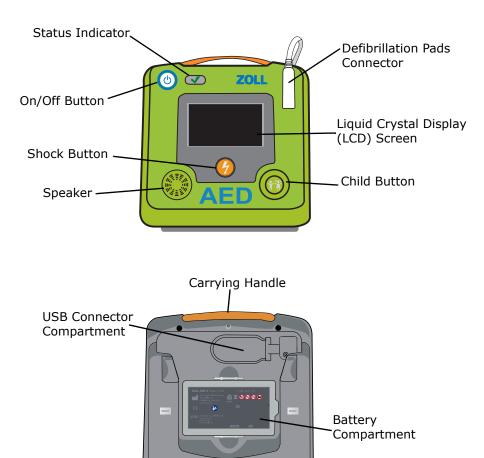
- Is conscious
- Is breathing, or
- Has a detectable pulse or other sign of circulation.

General Information

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

ZOLL AED 3® Controls and Indicators

See "ZOLL AED 3 Control Functions" on the following page for a description of each of these controls.



Support bar

Control/Indicator	Function
Status Indicator AED Passed SelfTest AED Failed Self Test	A green check indicates that the ZOLL AED 3 defibrillator passed its last self test and is ready for use. No green check indicates that the AED has not passed its last self test or a battery has not been installed—see note on page 11 for more information.
On/Off Button	Press to turn power ON or OFF.
Shock Button	Illuminates when the AED is charged and ready to deliver a shock to the patient. When pressed, it causes the AED to discharge its energy into the patient. Note : In <i>Automatic</i> models, the shock button does not illuminate.
Speaker	Provides audio prompts and metronome beeps to guide rescuers during a rescue; also provides audio prompts to indicate when service is required.
Defibrillation Pads Connector	This connector is used to attach the defibrillation pads to the ZOLL AED 3 defibrillator.
Liquid Crystal Display (LCD) Screen	A 2.1 \times 3.7 inch touch screen for display and user input. During a rescue, it displays graphics to guide the rescuer.
Child Button	Illuminated button indicates the ZOLL AED 3 is in Child Mode in preparation for rescuing a pediatric patient. Illuminates when pressed while using CPR Uni-padz [™] ; automatically lights up while using Pedi-padz [®] II.
Carrying Handle	The strap designed to make it easy to carry the AED.
USB Connector Compartment	The area used to connect a USB flash drive when importing/exporting files to or from the ZOLL AED 3 defibrillator.
Battery Compartment	Holds the battery pack used to power the AED.
Support Bar	Opens to hold the AED in an upright position.

Table 1: ZOLL AED 3 Control Functions

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Introduction

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. It uses audio and visual prompts to guide the rescuer through a resuscitation sequence that may include defibrillation and/or cardiopulmonary resuscitation (CPR). The defibrillator provides Real CPR Help[®] corrective rate and depth prompting for adult victims and an active metronome for both adult and child victims. The ZOLL AED 3 defibrillator incorporates the ZOLL[®] Rectilinear Biphasic[™] Defibrillation waveform, and operates in either adult or child mode.

The ZOLL AED 3 defibrillator is available in three models: ZOLL AED 3, ZOLL AED 3 *Automatic*, and ZOLL AED 3 *BLS*. The ZOLL AED 3 and ZOLL AED 3 *BLS* models function in semi-automatic mode where the rescuer initiates the shock. The ZOLL AED 3 *Automatic* model automatically initiates the shock without rescuer intervention.

The defibrillator has two operating modes: Rescue Mode and AED Management Mode. In Rescue Mode, the LCD screen displays graphics that are coordinated with audio prompts to guide you through a rescue. In AED Management Mode, the icons on the touch screen allow you to change configuration settings and upload files.

Intended Users

The ZOLL AED 3 defibrillator is intended to be used by responders who have been trained in CPR and the use of an AED to defibrillate victims of cardiac arrest. The CPR monitoring function provides a metronome designed to encourage rescuers to perform chest compressions at the recommended rate of at least 100 compressions per minute for both adult and child victims. The defibrillator provides voice and visual prompts to encourage a minimum compression depth of 2 inches for adult victims and basic instructions for child victims.

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 device.

NOTE Notes contain important additional information about using the defibrillator.

Safety Summary

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

Summary of Safety and Clinical Performance (SSCP)

The Summary of Safety and Clinical Performance (SSCP) is available in

the European database on medical devices (Eudamed) – https://ec.europa.eu/tools/eudamed. The Basic UDI-DI is 08479460DSK



Warnings

- Use the ZOLL AED 3 defibrillator only as described in this manual. Improper use of the AED can cause death or injury.
- DO NOT use or place the defibrillator in service until you have read the *ZOLL AED 3 Operator's Manual*.
- DO NOT use or place the ZOLL AED 3 defibrillator in service if the green check (✓) is not displayed in the AED's status indicator window (located to the right of the On/Off button). The green check displays when the AED is ready to use.
- DO NOT use or place the ZOLL AED 3 defibrillator in service if the unit emits a beeping tone when it is off.
- DO NOT perform any unauthorized modification to the ZOLL AED 3 defibrillator.
- DO NOT disassemble the unit. A shock hazard exists. Refer all servicing to qualified personnel.
- The ZOLL AED 3 defibrillator is not intended for use in fixed or rotary wing aircraft.
- Connect the defibrillation pads cable to the defibrillator BEFORE installing the battery pack.
- Keep the defibrillation pads cable connected to the defibrillator at all times.
- The ZOLL AED 3 defibrillator should only be used by properly trained individuals.
- Use the ZOLL AED 3 CPR Uni-padz defibrillation pads for both adult and child victims. The ZOLL AED 3 CPR Uni-padz defibrillation pads may be used on children less than 8 years old or weighing less than 55 lbs (25 kg) when the Child button has been pressed.

- The ZOLL AED 3 defibrillator is capable of delivering 200 joules. If necessary, the defibrillator can be completely deactivated by turning it off and removing the battery pack.
- For safety, the semi-automatic version of the ZOLL AED 3 defibrillator automatically disarms a fully charged unit after 30 seconds if the Shock button is not pressed.
- Always stand clear of the victim when delivering a shock. Defibrillation energy delivered to the victim may be conducted through the victim's body and cause a lethal shock to those touching the victim.
- DO NOT TOUCH the defibrillation pad surfaces, the victim, or any conductive material touching the victim during ECG analysis or defibrillation.
- Move the victim away from electrically conductive surfaces prior to use of equipment.
- DO NOT use the ZOLL AED 3 defibrillator near or within puddles of water.
- Keep the victim as motionless as possible during ECG analysis.
- DO NOT use the ZOLL AED 3 defibrillator near flammable agents, such as gasoline, oxygen-rich atmospheres or flammable anesthetics.
- MR Unsafe Keep the ZOLL AED 3 defibrillator away from magnetic resonance imaging (MRI) equipment.
- Turn off cell phones and two-way radios to avoid radio frequency interference from high-power sources that might cause the defibrillator to interpret cardiac rhythms incorrectly.
- Disconnect non-defibrillation protected electronic devices or equipment from victim before defibrillation.
- Dry victim's chest, if wet, before attaching defibrillation pads.
- Apply freshly opened and undamaged defibrillation pads (within the defibrillation pads expiration date) to clean and dry skin to minimize burning.

- DO NOT place the defibrillation pads directly over a victim's implanted pacemaker. Pacemaker stimuli may degrade the accuracy of ECG rhythm analyses, or the pacemaker may be damaged by defibrillator discharges.
- The ZOLL AED 3 defibrillator does not reject implanted pacemaker pulses.
- DO NOT disassemble a battery pack or dispose of it in fire. DO NOT try to recharge the nonrechargeable battery pack. If mishandled, the battery pack may explode.
- DO NOT use or stack the ZOLL AED 3 defibrillator with other equipment. If the defibrillator must be used or stacked with other equipment, verify proper operation prior to use.
- DO NOT connect the ZOLL AED 3 defibrillator to a computer or other device (using the USB port) while the defibrillation pads are still connected to the victim.
- The ZOLL AED 3 USB port is intended for use with a flash drive only. DO NOT insert wireless adapters or other unauthorized devices into the USB port.
- Check the expiration date on the defibrillation pads packaging. DO NOT use defibrillation pads that have passed their expiration date.
- The use of accessories and cables other than those specified in the *ZOLL AED 3 Administrator's Guid*e may result in increased emissions or decreased immunity of the ZOLL AED 3 defibrillator.

• To satisfy FCC RF exposure requirements for mobile transmitting devices, a separation distance of 20 cm or more should be maintained between the antenna of this device and persons during device operations. To ensure compliance, operations at closer than this distance are not recommended. The antenna (located internally in top front of device) used for this transmitter must not be co-located in conjunction with any other antenna or transmitter.



Cautions

- The ZOLL AED 3 defibrillator may not perform to specifications when stored at the upper or lower extreme limits of storage temperature and then immediately put into use.
- Use only the ZOLL AED 3 nonrechargeable, disposable battery pack with the ZOLL AED 3 defibrillator.
- Keep a new spare battery pack with the device at all times.
- When the unit displays the CHANGE BATTERY message, replace the battery pack with a new one as soon as possible.
- Dispose of battery packs in accordance with federal, state, and local regulations. Battery packs should be shipped to a reclamation facility for recovery of metal and plastic compounds as the proper method of waste management.
- ZOLL defibrillation pads contain no hazardous materials and may be disposed of in general trash unless contaminated with pathogens. Use appropriate precautions when disposing of contaminated defibrillation pads.
- If the ZOLL AED 3 defibrillator is stored outside the recommended environmental conditions, the defibrillation pads and/or battery pack may be damaged or their useful life reduced.

- Safety and effectiveness data submitted by ZOLL Medical Corporation to the Food and Drug Administration (FDA) to obtain approval to market are based upon the use of ZOLL accessories such as disposable defibrillation pads and batteries. The use of defibrillation pads and batteries from sources other than ZOLL is not recommended. ZOLL makes no representations or warranties regarding the performance or effectiveness of its products when used in conjunction with defibrillation pads and batteries from other sources. If AED failure is attributable to the use of accessories not manufactured by ZOLL, this may void ZOLL's warranty.
- The ZOLL AED 3 CPR Uni-padz defibrillation pads may be connected to the ZOLL AED Plus[®] or AED Pro[®] defibrillators and function as adult defibrillation pads; however, the device only produces a constant metronome during CPR intervals, it does not provide Real CPR Help.
- When Stat-padz[®] II and Pedi-padz II are connected to the ZOLL AED 3 defibrillator, the device only produces a constant metronome during CPR intervals; it does not provide Real CPR Help.
- Prior to use, assess Wi-Fi performance for possibility of Radio Frequency Interference (RFI) in your environment of use.
- 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 Electromagnetic Compatibility section of the *ZOLL AED 3 Administrator's Guide*, such as high frequency surgical equipment, radar installations, or radio transmitters. It is also not intended for use in fixed or rotary wing aircraft. 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.
- If multiple devices are transmitting simultaneously to the same access point, Wi-Fi data transfer slows down. If the access point is too overloaded, data transmission failures may occur.

Setting Up the ZOLL AED 3 Defibrillator

ZOLL AED 3 Shipping Contents

Check the ZOLL AED 3 shipping container for the following contents:

- 1 ZOLL AED 3 defibrillator
- 1 ZOLL AED 3 battery pack
- 1 package containing CPR Uni-padz defibrillation pads (with scissors attached)
- 1 ZOLL AED 3 documentation packet
- **NOTE** If the contents are incomplete or damaged, contact ZOLL Medical Corporation's Technical Service Department. See "Contacting Technical Service" on page 27 for more information.



AED Failed

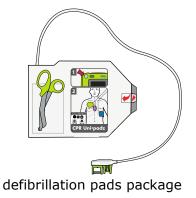
Self Test

NOTE If the ZOLL AED 3 defibrillator fails to pass its self test (indicated by a *UNIT FAILED* prompt or if the green check is not displayed in the status indicator window) after installing a new battery, make sure the defibrillation pads are plugged in properly.

Setting Up the Defibrillator

Follow the steps below to prepare the ZOLL AED 3 defibrillator for use.

1. Remove the defibrillation pads package from the cardboard box in the shipping container.



WARNING! Do not open sealed defibrillation pads until immediately prior to use.

2. Plug the defibrillation pads cable connector into the defibrillation pads port.

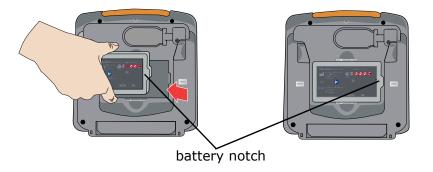


Plug in defibrillation pads cable connector

WARNING! To prepare for an emergency, keep the defibrillation pads cable connected to the AED at all times. Do not reuse defibrillation pads.

- 3. Remove the battery pack from the shipping container.
- 4. Hold the battery pack by the side tabs with the label facing out. Insert the battery pack into the back of the AED until it clicks into place, lining up the notch on the end of the battery to the corresponding recess in the battery well.

The defibrillator runs an automatic self test.



WARNING! To ensure the ZOLL AED 3 defibrillator is ready for use, monitor its status weekly. Verify that the AED has passed its periodic self test by confirming the green check is displayed in the status indicator window.

5. While facing the front of the defibrillator, insert the defibrillation pads package into the back of the AED so that the label on the package is facing you with the defibrillation pads cable on the right.





AED Failed

Self Test

6. Verify that the green check (✓) appears in the status indicator window and that the defibrillator does not emit a beeping tone. This indicates that the new battery pack and defibrillation pads are properly installed and the ZOLL AED 3 defibrillator is ready for use.

- **NOTE** If the defibrillator fails to pass its self test (the green check does not display in the status window or it issues the *UNIT FAILED* audio prompt) after battery installation, remove the battery and unplug the defibrillation pads and repeat steps 2 through 6. If the AED fails to pass its self test a second time, contact ZOLL Medical Corporation's Technical Service Department. See "Contacting Technical Service" on page 27 for more information.
- 7. Place the defibrillator into service in accordance with your local guidelines and hang the rescue poster on the wall near the defibrillator.
 - **NOTE** The ZOLL AED 3 defibrillator ships with a default Supervisor passcode (which is published in the *ZOLL AED 3 Administrator's Guide*). The AED Administrator should change the default passcode after the set up of the device is complete. See www.zoll.com for the latest version of the *ZOLL AED 3 Administrator's Guide*.
 - **NOTE** Defibrillator pads are defibrillation-proof Type BF applied parts.

Important Notes

- Make sure the defibrillation pads are always connected to the defibrillator and the battery is installed.
- To ensure adequate power availability during an emergency, monitor the device status weekly or per local guidelines. Verify that the AED has passed its periodic self test by confirming that the green check is displayed in the status indicator window.
- If you change the battery while the AED is in Rescue Mode (with the defibrillation pads cable connected), the AED automatically powers on displaying the battery icon and then shuts down. Press and release the On/Off button to restart the AED.

Using the ZOLL AED 3 Defibrillator

Overview

Use the ZOLL AED 3 defibrillator when a suspected cardiac arrest victim has an apparent lack of circulation as indicated by ALL of the following symptoms:

- Unconsciousness
- Absence of normal breathing
- Absence of a pulse or signs of circulation

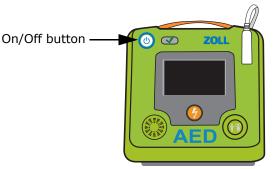
Call for help, retrieve the defibrillator, and bring it to the patient's side. Follow the basic steps on the following pages to treat the suspected cardiac arrest patient:

- 1 Press the On/Off button to turn on the defibrillator and follow the voice prompts.
- 2. Press the Child button (**only** if the patient is a child and you are using CPR Uni-padz).
- 3. Place defibrillation pads on the patient (follow the defibrillator's voice prompts).
- 4. Shock patient, if instructed.
- 5. Start CPR.

STEP 1 Turn on ZOLL AED 3 Defibrillator

Press the On/Off button in the upper left corner of the AED to turn it on.





STEP 2 Press Child button (if needed)

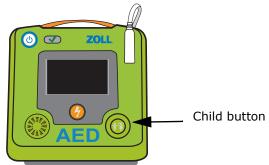
If the patient does not meet the definition of a "Child" (see below), proceed to step 3.



Press the *Child* button on the bottom right side of the defibrillator if you are using CPR Uni-padz and the *patient is less than 8 years old or weighs less than 55 pounds (25 kg)*. The Child button lights up and the AED announces *CHILD PATIENT SELECTED*.

Child Selection button

- **NOTE** If you are using Pedi-padz II, the Child button automatically lights up.
- **NOTE** If you press the Child button while in Child Mode (with CPR Unipadz connected), the Child button light turns off and the defibrillator announces *ADULT PATIENT SELECTED*.

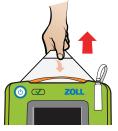


STEP 3 Place defibrillation pads on patient

NOTE If the patient is a child and you are using CPR Uni-padz, press the Child button before placing defibrillation pads on the patient.

The ZOLL AED 3 defibrillator instructs you to:

• Remove the pad package from the back of the defibrillator and open the package as shown in the illustrations below.



Remove pad package

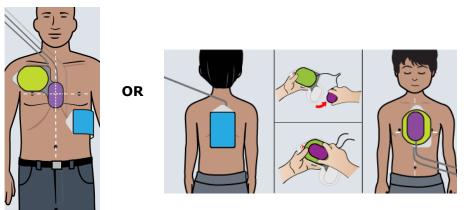


Open pad package

• Remove all clothing from the patient's chest. Use the scissors located on the defibrillation pads package to cut clothing, if needed.

Ensure that the patient's chest is clean and dry. If the patient has excessive chest hair, clip or shave the chest hair.

• Remove the adhesive liner from the purple sensor and green pad and place them according to the illustrations on the pads and pad package. Remove the adhesive liner from the blue defibrillation pad and follow the illustrations to place it in the correct location. The graphics on the display screen also illustrate pad placement.



Adult pad placement

Child pad placement

NOTE If you are using CPR Uni-padz in Child Mode, the AED issues the voice prompts ATTACH BLUE PAD TO CHILD'S BACK, TEAR PURPLE SENSOR AWAY FROM GREEN PAD, PLACE PURPLE SENSOR ON GREEN PAD, and ATTACH GREEN PAD TO CENTER OF CHILD'S CHEST.

WARNING! Poor adherence or air pockets under the defibrillation pads can lead to arcing, skin burns, or reduced energy delivery. To minimize burning, apply freshly opened and undamaged defibrillation pads to clean and dry skin. Do not fold or wrinkle the defibrillation pad gel surface when applying defibrillation pads to the patient.

The AED issues the voice and text prompt, *DON'T TOUCH PATIENT, ANALYZING* and then begins ECG analysis.

STEP 4 Shock the Patient

WARNING! DO NOT touch defibrillation pad surfaces, the patient, or any conductive material touching the patient during ECG analysis or defibrillation.

When a Shock is Needed

ZOLL AED 3/ZOLL AED 3 BLS	ZOLL AED 3 Automatic
You hear: Charge-ready tone DON'T TOUCH PATIENT. PRESS FLASHING SHOCK BUTTON.	You hear: <i>DON'T TOUCH PATIENT. SHOCK WILL</i> <i>BE DELIVERED IN THREE, TWO, ONE.</i>
You see:	You see:
	First screen: 7 3
	Second screen: 7 2
	Third screen: 7 1
Do this: Press flashing shock button.	Do this: Stand clear. (The AED automatically shocks the patient).

AED announces SHOCK DELIVERED.

Once the shock has been delivered, the AED provides CPR guidance and continuing ECG analysis to determine if more shocks are needed.

When a Shock is Not Needed

If the AED determines that a shock is not needed, a voice prompt instructs you to start CPR for a period of time (configured by the AED Administrator), after which the AED automatically initiates a new ECG analysis. If a shock is needed at that time, refer to "When a Shock is Needed" on page 16.

STEP 5 Start CPR

Place your hands on the purple CPR compression sensor as shown on the display screen. Listen to the metronome and follow the AED's instructions. If the patient is an adult, follow the audio prompts that provide feedback on the depth and the metronome rate for CPR chest compressions. The CPR Countdown Timer displays the time left in the current CPR period. Continue to follow the AED's voice instructions until help arrives.

ECG/CPR Dashboard

If configured and using CPR Uni-padz, CPR Stat-padz, or CPR-D-padz[®], the ZOLL AED 3 *BLS* model can display the CPR Dashboard, with or without the ECG waveform. The CPR Dashboard display shows the Chest Compression Rate, the Chest Compression Depth, and the CPR remaining time until the next ECG analysis starts.

NOTE All models of the ZOLL AED 3 defibrillator display the CPR Countdown Timer.



When Emergency Medical Services Arrive

When Emergency Medical Services (EMS) arrive, you can provide the following rescue information:

- Shock delivered count (bottom left of the display screen)
- Elapsed Event time (bottom right of the display screen)

You can transfer the patient event data to a USB flash drive if EMS personnel request the information. See "Exporting Patient Files" on page 28 for more information.

After Using the ZOLL AED 3

See "After Each Use" on page 19 for maintenance instructions to perform after each time the defibrillator is used.

Maintaining the ZOLL AED 3 Defibrillator

Overview

The ZOLL AED 3 defibrillator requires little maintenance. It automatically performs a self test every time you turn on the AED or install a battery, and it also performs a routine self test based on the interval of days that you specify (default is 7 days). The defibrillator collects the self test information in its device history, and performs the following self tests:

- Battery Installation Self Test
- Power On Self Test
- Manual Self Test
- Automatic Self Test
- Automatic Monthly Self Test

This section contains procedures on how to maintain the defibrillator as well as some general information about the self tests. There is also a table containing the most common errors and how to fix them. See the *ZOLL AED 3 Administrator's Guide* for additional maintenance information (intended for qualified technical professionals).

After Each Use

Perform the following steps after each time the AED is used.

 Check that the AED is clean, undamaged, and free of excessive wear. If the AED needs to be cleaned, see "Cleaning the ZOLL AED 3 Defibrillator" on page 20.

- 2. Obtain a new set of defibrillation pads (verify that the expiration date has not passed) and connect the defibrillation pads to the defibrillator. See steps 1 to 3 in the procedure, "Setting Up the Defibrillator" on page 9 for more information.
- 3. Run a manual self test by pressing and holding the defibrillator's On/Off button for at least 5 seconds.

If AED Displays	Then
CHANGE BATTERY message	Replace the battery pack (see "Replacing the Battery Pack" on page 21), then go to step 5.
UNIT OK message	Go to step 4.

- 4. Press the On/Off button to power off the unit.
- 5. Place the defibrillator back into service so that it is ready for use.

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:

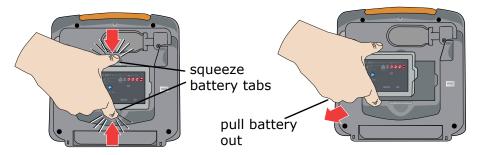
- Immerse any part of the defibrillator in water.
- Use chlorine mixture on contacts or connectors; this will degrade the contacts over time.
- Use ketones (MEK, acetone, etc.) to clean the defibrillator.
- Use abrasives (e.g., paper towel) on the display window or graphic screen.
- Sterilize the defibrillator.

Replacing the Battery Pack

When the defibrillator displays the *CHANGE BATTERY* message, replace the battery with a new battery pack as soon as possible. Before replacing a battery pack, verify that the defibrillator is turned off and the battery pack being installed has not passed its "install by" date.

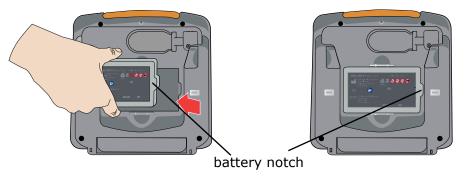
WARNING! To ensure the ZOLL AED 3 defibrillator is ready for use, monitor its status weekly. Verify that the AED has passed its periodic self test by confirming the green check is displayed in the status indicator window.

1. Place your fingers in the wells of the battery compartment and squeeze the battery side tabs to pull out the battery.



NOTE Properly dispose of the old battery.

2. Hold the new battery pack by the side tabs and insert it into the back of the AED, lining up the notch on the end of the battery with the corresponding shape in the battery well until it clicks into place.



The AED issues a *BATTERY REPLACED* prompt and automatically initiates a self test.

3. Verify that the ZOLL AED 3 defibrillator issues the *UNIT OK* voice prompt and that the green check (✓) appears in the status indicator window. This prompt indicates that the new battery pack and defibrillation pads are properly installed and that the AED is ready for service.

Self Tests

The ZOLL AED 3 defibrillator performs the following self tests to verify unit integrity and its readiness for emergency use. See the *ZOLL AED 3 Administrator's Guide* for more detailed information about these tests.

Table 2: ZOLL AED 3 Se	If Tests
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Self Test	When Performed	Functions Performed
Battery Installation	Automatically, after battery pack is installed or replaced.	 Basic functions: Battery Capacity Defibrillation Pads Connection Defibrillation Pads/ Battery Expiration Verification ECG Circuitry Defibrillator Charge and Discharge Circuitry (2 Joule Test) Microprocessor Hardware/Software CPR Circuitry and Sensor (if defibrillation pads with CPR functionality are connected) Audio Circuitry 200 Joule Charge Test
Power On	Automatically, whenever the AED is turned on.	Basic functions: Same as Battery Installation Self Test basic functions.
Manual	By pressing and holding the AED's On/Off button for at least 5 seconds.	Basic functions: Same as Battery Installation Self Test basic functions.

Self Test	When Performed	Functions Performed
Automatic	Once every 7 days (this interval can be configured to once a day) when the AED is stored with battery pack installed.	Basic functions: Same as Battery Installation Self Test basic functions.
Automatic Monthly	Once per month when the AED is stored with battery pack installed.	 Basic functions: Same as Battery Installation Self Test basic functions. Additional function: 200 Joule Charge Test

When the defibrillator successfully completes its automatic self tests, the device displays a green check (\checkmark) in the status indicator window to show that all tests passed and that it is ready to use. If the defibrillator does not display a green check in the status indicator window following the completion of any self test, the ZOLL AED 3 defibrillator is not ready for use and may be defective. Remove the defibrillator from service and consult "Troubleshooting" on page 25 to determine the problem.

Automatic Self-Test Transfer

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

Troubleshooting

The following table lists error indications that may occur on the ZOLL AED 3 defibrillator, and the associated corrective action. For a more extensive list of error messages, see the *ZOLL AED 3 Administrator's Guide*. If the defibrillator is not working properly, contact ZOLL's Technical Service Department for assistance. See "Contacting Technical Service" on page 27 for more information.

Technical Problem	Recommended Action
UNIT FAILED prompt	Initiate manual self test by pressing and holding the On/Off button for more than 5 seconds. Check to see if the defibrillation pads cable is attached properly to the defibrillator or replace the defibrillation pads. Cycle power on the defibrillator by turning the AED off, and then on again. Replace the battery pack. If the defibrillator still does not operate correctly, remove the AED from service and contact ZOLL Technical Service (see "Contacting Technical Service" on page 27).
Beeping noise when AED is off	Check to see if the defibrillation pads cable is attached properly to the defibrillator or replace the defibrillation pads. Remove the defibrillator from service and replace the battery pack. If beeping continues, contact ZOLL Technical Service (see "Contacting Technical Service" on page 27).
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, contact ZOLL Technical Service (see "Contacting Technical Service" on page 27).

Table 3: ZOLL AED 3 Error Messages

Technical Problem	Recommended Action
Green check does not appear in the status indicator window	Initiate manual self test by pressing and holding the On/Off button for more than 5 seconds. Check to see if the defibrillation pads cable is attached properly to the defibrillator or replace the defibrillation pads. Replace the battery pack. If the defibrillator fails the test again, remove the AED from service and contact ZOLL Technical Service (see "Contacting Technical Service" on page 27).
CHANGE BATTERY prompt	Replace the battery pack.
PLUG IN PADS CABLE prompt	Check cable connection between defibrillation pads and the defibrillator.
ATTACH CORRECT DEFIB PADS prompt	 Incompatible defibrillation pads are connected to the AED. Use one of the following pads: CPR Uni-padz CPR-D-padz CPR Stat-padz Stat-padz II Pedi-padz II OneStep Basic Electrodes with Green Connector OneStep CPR A/A Electrodes with Green Connector OneStep Pediatric Electrodes with Green Connector
ANALYSIS HALTED. KEEP PATIENT STILL prompt	Excessive artifact is detected during ECG analysis. The patient must be motionless during ECG analysis. Do not touch the patient during this analysis and keep the patient still. If you are using the defibrillator in an emergency vehicle, bring the vehicle to a halt before performing ECG analysis.
RELEASE SHOCK BUTTON prompt	Release the shock button, then press and hold the shock button (when button is illuminated) until discharge occurs. If the voice prompt continues, contact ZOLL Technical Service (see "Contacting Technical Service" on page 27).

Contacting 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

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.

Transferring Patient Data

Overview



In order to transfer data, the AED 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 the unit is in AED Management Mode, you can export data at any time to a USB flash drive or a wireless access point.

Device Configuration icon

The ZOLL AED 3 defibrillator automatically stores patient clinical data with date and time notation. 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 connection. You can then view and analyze this information using ZOLL's clinical review software products.

NOTE The AED retains the 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, new clinical data replaces the old clinical data if the AED has already stored data for one or two patients (default is two).

Exporting Patient Files

Use the following procedure to transfer patient files (clinical data) from the ZOLL AED 3 defibrillator.

- **NOTE** You do not need Supervisor access to export data files to a USB flash drive or wireless access point.
- **NOTE** When transferring files via USB, the USB flash drive must be USB 2.0 compliant.

In order to transfer data via a wireless connection, you need to create a wireless profile. If you have not already done so, see *Setting up Your Wireless Configuration* in the *ZOLL AED 3 Administrator's Guide.*

WARNING! Do not connect the ZOLL AED 3 defibrillator to a computer or other device (via the USB port) while the 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 icon appears in the status bar at the bottom of the display screen.



Export Files icon

- 3. Press the Export Files icon and select one of the following clinical patient file options:
 - *Clinical Archives (all)* -- includes up to two stored patient files.
 - *Clinical Archives (new)* includes the most recent stored patient file.

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

4. Press **Save (USB)** or **Send (Wi-Fi)**. When the AED has finished transferring data, it displays the prompt, *DATA TRANSFER COMPLETE*.

You can transfer clinical archives (patient data) for use with ZOLL's clinical review software products, using either a USB drive or Wi-Fi transmission to ZOLL Online.

Using ZOLL RescueNet $\ensuremath{\mathbb{R}}$ EventSummary Software

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

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

Using RescueNet 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.

Troubleshooting Communication Issues

The following table summarizes common communication messages you may see when exporting patient data, and their associated description and/or recommended action. If the ZOLL AED 3 defibrillator is not working properly, contact ZOLL's Technical Service Department for assistance. See "Contacting Technical Service" on page 27 for more information.

Message	Description/Recommended Action
CLINICAL ARCHIVE UNAVAILABLE	There are no clinical archive files (.crd) available to export.
DATA TRANSFER COMPLETE	The data transfer through Wi-Fi is finished.
UNABLE TO EXPORT REQUESTED FILE. INTERNAL ERROR.	The file export was not successful. Verify the Wi-Fi configuration and try the export operation again.
UNABLE TO SAVE FILES. PLEASE ENSURE THAT AN EMPTY USB FLASH DRIVE IS SECURELY INSERTED INTO THE DEVICE.	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.
UNABLE TO TRANSMIT REQUESTED FILE	The attempt to export the file to the USB flash drive was unsuccessful. Try the file transfer again.

Table 4: ZOLL AED 3 Patient Data Messages



Symbols

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

Symbol	Description
	Power On/Off.
	Child button.
(I)	Shock button.
4	Warning: Dangerous voltage.
<u>.</u>	General warning.
Ţ	Fragile, handle with care.
`	Keep dry.
	This end up.

Table 5: Symbols

Symbol	Description
	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.
F©	Complies with the Federal Communications Commission.
- ★	Defibrillator-proof type BF equipment.
	Direct current (DC).
LiMnO ₂	Contains lithium. Recycle or dispose of properly.
	Keep away from open flame and high heat.
	Do not open, disassemble, or intentionally damage.
\bigotimes	Do not crush.

Symbol	Description
	Non-rechargeable battery.
X	Return to a collection site intended for waste electrical and electronic equipment (WEEE). Do not dispose of in unsorted trash.
	Use by.
LANEX	Latex-free.
2	Do not reuse.
NON	Not sterile.
(((•)))	Nonionizing electromagnetic radiation.
	Manufacturer.
EC REP	Authorized representative in the European Community.
CH REP	Authorized representative of Switzerland.
SN	Serial Number.

Symbol	Description
REF	Catalog number.
MR	MR Unsafe - keep away from magnetic resonance imaging (MRI) equipment.
LOT	Batch code.
Ĩ	Consult instructions for use.
E	Refer to manual.
INSTALL BY	Use by date.
IP55	Protected against dust ingress. Protected against jetting water.
	Complies with the Conformity Certification System for Radio Equipment in Japan.
C	Complies with the Radio Frequency (RF) requirements in South Korea.
CMIIT	Complies with the China Ministry of Industry and Information Technology.
ZOLL	Contact ZOLL Technical Service.

Symbol	Description
UDI	Indicates a carrier that contains Unique Device Identifier information.
MD	Indicates the item is a medical device.
	Indicates the entity importing the medical device into the locale.

Appendix B

Specifications

This section describes the following product specifications for the ZOLL AED 3 defibrillator.

Table 6: General Specifications

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
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; EN1789, 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 the <i>ZOLL AED 3 Administrator's Guide</i> for the Rectilinear Biphasic Waveform Characteristics and the Clinical Trial Results for the M Series Biphasic Waveform.
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

Defibrillator (cont'd)	
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
Defibrillation pads	CPR Uni-padz, CPR-D padz, CPR Stat-padz, Stat-padz II, Pedi-padz II, OneStep Basic Electrodes with Green Connector, OneStep CPR A/A Electrodes with Green Connnector, or OneStep Pediatric Electrodes with Green Connector
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 the ECG Analysis Algorithm Accuracy Section in the <i>ZOLL AED 3 Administrator's Guide</i> for sensitivity and specificity performance.
Defibrillation Pad Patient Impedance Measurement Range	10 to 300 ohms
Defibrillation Pad ECG Circuitry	Protected

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Defibrillator (cont'd)

ECG	
ECG Bandwidth	.67-20Hz
Implanted Pacemaker Pulses Detected	The ZOLL AED 3 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
Sweep Speed	25 mm/sec
Viewing time	3.84 seconds
Battery	
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.	Auto Self-Test Report OFF (Default Configuration)Self-Test Interval (7 days)5Self-Test Interval (1 day)3Auto Self-Test Report ONSelf-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.

Note: Modifications to default configuration may impact the battery life of the ZOLL AED 3. Consult your local ZOLL representative if you have any questions.

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



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