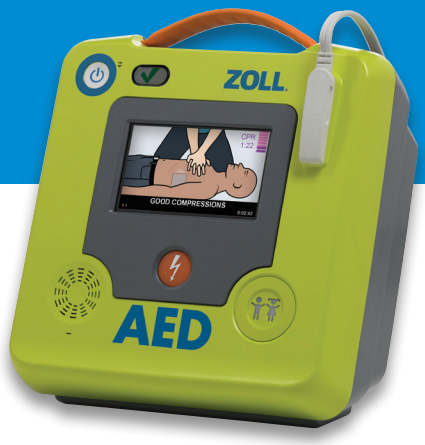
ZOLL AED 3™



Bid Specifications

Defibrillator

- The AED must have a high-resolution liquid crystal display with capacitive touch panel.
- The AED must have an "ON/OFF" button.
- The AED must have a "SHOCK" button that illuminates when the unit is charged and ready to deliver a shock.
- During clinical use, the AED must display the number of shocks and elapsed time since the AED was powered on.
- The AED must display text prompts related to issued voice prompts.
- The AED must utilize a low-energy Rectilinear Biphasic™ waveform.
- The AED and advisory protocols shall comply with the recommendations in the American Heart Association (AHA), European Resuscitation Council (ERC) or International Liaison Committee on Resuscitation (ILCOR) Guidelines 2015 for AEDs.
- The AED and advisory protocols shall comply with the recommendations in the American Heart Association (AHA), European Resuscitation Council (ERC) or International Liaison Committee on Resuscitation (ILCOR) Guidelines 2015 for chest compressions (CPR).
- The AED and advisory protocols shall comply with the recommendations in the American Heart Association (AHA), European Resuscitation Council (ERC) or International Liaison Committee on Resuscitation (ILCOR) Guidelines 2015 for single shocks.
- The energy settings must be user configurable with a maximum energy setting of 200 joules and a minimum of 120 joules for ADULT victims.
- The AED must invoke a specific pediatric algorithm when in pediatric operating mode, with a maximum setting of 85 joules and a minimum of 50 joules.
- The AED must allow the user to manually switch from adult mode to pediatric mode with the press of a button and announce patient type selection once changed.
- In pediatric mode, the AED must:
  - –Perform heart rhythm analysis using a pediatric-specific algorithm
  - –Deliver child/pediatric-specific energy levels
- For a pediatric victim, heart rhythm analysis must detect tachycardia at a heart rate no lower than 200 beats per minute.

ZOLL®

- The AED must be able to deliver a shock within 25 seconds of power on.
- The AED must be able to deliver a shock within 8 seconds of rhythm analysis beginning.
- The AED must record patient impedance and delivered energy shall be adjusted based on patient impedance.
- A version of the AED must be configurable to display a patient ECG.
- A version of the AED must be configurable to turn voice recording ON/OFF.
- The AED must have two operating modes, configurable by the user:
  - Lay rescuer mode with graphical images displayed on the LCD designed to assist a lay responder in the use of the AED
  - Professional/trained rescuer mode with limited graphics and a CPR dashboard displaying compression rate, depth, patient's ECG and a CPR cycle countdown timer
  - For professional rescuer mode, users must be able to configure the ECG display ON/OFF
- The manufacturer of the AED must have a history of at least 20 years' experience providing cardiologic medical devices.

Device Readiness

- The AED shall employ a prominent indicator to signify its state of readiness; simple indicators (i.e., LEDs) are not an acceptable alternative.
- The AED shall perform an automated self-test at least every 7 days depending on user configuration.
- The AED shall allow users to configure the self-test frequency.
- The AED shall perform the following self tests:
  - When a battery is inserted
  - When the AED is powered on
  - When the user performs a manual self-test
  - Automatic weekly
  - Automatic monthly
- The AED self-test shall test/report on the following:
  - Battery Capacity and Status
  - Defibrillation Electrodes Connection
  - Defibrillation Electrode Type
  - Defibrillation Electrode and Battery Expiration Date
  - ECG Circuitry
  - Defibrillator Charge and Discharge Circuitry (2-joule test)
  - Microprocessor Hardware/Software
  - CPR Circuitry and Sensor (if electrodes with CPR functionality are connected)
  - Audio Circuitry
  - 2-joule Charge Test (weekly/daily automatic self-test)
  - 200-joule Charge Test (monthly automatic self-test)
- The AED shall store the results of the most recent self-test in its internal memory.
- The AED shall store all faults or failed self-test results in its internal memory.

- Users shall be able to upload the most recent self-test data onto a USB stick or transmit it over WiFi
- Users shall be able to upload the device history file onto a USB stick or transmit it over WiFi
- The AED shall automatically transmit self-test data following the automatic (weekly/monthly) self-test to a cloud-based AED management solution over a local WiFi network
- When the AED transmits self-test data over a WiFi network the device shall perform an Internal Clock Synchronization with the server's Universal Time Clock

Cardiopulmonary Resuscitation (CPR) Support

- The defibrillator shall have the ability to support the delivery of high-quality chest compressions during CPR efforts
- The AED must provide real-time feedback on a rescuer's CPR quality in adult mode. For lay rescuers, the AED must show the depth of each chest compression visually on the display screen.
- The AED must have a metronome in all patient modes
- In lay responder mode, the AED must provide both audible and visual feedback on compression depth in adult mode
- In professional responder mode, the AED must provide:
  - Visual indication (numeric value) of the rescuer's actual compression rate in compressions per minute (CPM) in both adult and pediatric/child modes
  - In adult mode the AED shall provide a visual indication when compressions are not within the AHA/ERC/ILCOR recommendations for compression rate
  - Visual indication (numeric value) of the rescuer's actual compression depth in both adult and pediatric/child modes
  - In adult mode, the AED shall provide a visual and audible indication when compressions are not within the AHA/ERC/ILCOR recommendations for compression depth
  - The numeric value for compression depth shall be user configurable for inches or centimeters
- The AED must have a CPR cycle countdown timer

Environmental

- The AED must meet water and particle ingress ratings of IP55
- The AED must pass a 1-meter drop test
- The AED must meet the following design standards:
  - Device Classification: Internally powered per EN60601-1
  - Design Standards: Applicable requirements of EN 60601-1, IEC 60601-1-11, EN 60601-2-4
- The AED must meet the following environmental specifications:
  - 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 60608-2-27; 100G
– Altitude: -1,250 to 15,000 ft.; -91 m to 4573 m

Device Settings

- The AED must be capable of operating in semiautomatic mode
- Voice and visual prompts in the AED must be user-configurable
- Device CPR time setting is configurable in 30-second increments up to 180 seconds
- Ability to configure device self-test interval to every one or seven days
- Ability to manage device configuration through the AED's touchscreen
- Ability to export device configuration to a USB stick
- Ability to import device configuration from a USB stick

Battery Options

- The AED shall be designed in a manner such that the battery can be replaced by a typical caregiver in a matter of seconds without the need for tools.
- The AED battery pack shall last five years, in standby mode, once installed in an AED with default configuration
- The AED battery pack shall have an internal processor capable of communicating battery status and expiration date to the AED

Electrodes

- The AED must have pre-connected electrodes for ease of application
- The AED electrode must be designed for use on adult and child patients
- The electrode must have a shelf-life of 5 years
- The electrode must offer an integrated chest compression rate and depth sensor
- Electrode pads must have pre-attached rescue scissors for removing clothing on the front of the electrode packaging
- Electrode pads must be packaged with a rescue accessory pack that provides gloves for rescuer's hands, razor for removing chest hair, paper towel for removing moisture from the chest, and a face-mask for rescue breathing during CPR.

Warranty

- The device shall have a 6-year warranty at minimum

Device Communications

- The AED must be WiFi enabled
- The AED must support both open and protected WiFi networks

- The AED must have a USB port capable of exporting clinical event data, device history files, and device configuration files
- The AED must have a USB port capable of importing device configuration files and/or WiFi network certificates
- The AED must be able to export clinical event files and/or device self-test results over WiFi
- Users must be able to upgrade AED software using a USB drive

Clinical Event Documentation

- The AED must have an internal memory capable of recording up to two (2) clinical events
- A version of the AED must have the ability to record audio if activated by the user when configuring the AED
- The AED must record complete clinical event data including: compression depth, compression rate, patient impedance, all device text and audible prompts, patient ECG data, device serial number, device ID (if configured by user), all shock decisions, and any error codes
- The AED must time-stamp all recorded information
- The internal memory must be configurable by the user to record one or two clinical events
- The AED must offer the ability to export clinical event data via a removable USB key or over a WiFi network

Device Configuration

- The AED must be capable of being configured by a user utilizing the interactive touch screen
- The AED must allow the user to save the device configuration to its internal memory
- The AED must allow the user to export the device configuration file to an USB stick
- The AED must allow the user to import a configuration file from a USB stick onto the AED to update the configuration of the AED
- The AED must allow both "user" and "administrative" configuration options
- The AED must allow the user to input a device identification name/code in configuration mode

The ZOLL AED 3 is not available for sale in the United States or Canada. The product has not received regulatory clearance/approval by the U.S. Food and Drug Administration or Health Canada.

ZOLL®