CARDIAC science

Powerheart® G5 AED – Automatic

RESCUE READY

Bid Specifications

Operation and Use

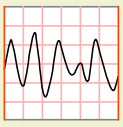
+ The AED shall automatically activate upon lid opening.
+ The AED shall have voice/text prompt and graphical instructions to guide the user through the rescue process in a simple step-by-step manner based on the 2010 Resuscitation Guidelines.
+ The AED shall have RescueCoach™ user–paced voice instructions to guide the user through the rescue process.
+ The AED shall have a backlit LCD text display, which features elapsed rescue time, number of shocks administered, and a CPR countdown.
+ The AED shall have CPR cadence with a metronome sound or verbal prompt, "Press," to guide compression frequency.
+ The AED shall deliver a shock (if required) without requiring the operator to push a button.
+ The AED shall have adult capability with the use of Adult Defibrillation Pads.
+ The AED shall have pediatric capability with the use of Pediatric Defibrillation Pads.
+ The AED shall automatically detect the type of defibrillation pads. Upon detection, the AED shall utilize the appropriate CPR and shock protocols as defined by the configuration, whether for adult or pediatric use.
+ The AED shall have the optional capability to support CPR feedback, providing the rescuer guidance in accordance with the 2010 Resuscitation Guidelines. The AED automatically detects if the CPR Device is present, and provides feedback if it is in use.
+ The AED shall have the optional capability to support dual language. With a single button press, the device shall change the language of the device at any point during a rescue.
+ The AED shall have the ability to inform the user if the defibrillation pads are expired or previously used.
+ The AED shall have the ability to inform the user of the status and capacity of the battery via audible alerts, voice and visual prompts.

Data Recording and Documentation

+ The AED shall provide 90 minutes of internal storage.
+ The AED shall provide multiple rescue functionality.
+ The AED shall store ECG, CPR Device, and essential rescue data, such as time, date, and prompt information.
+ The AED shall store AED data, including information on the battery, defibrillation pads, event history logs, and self-test information.
+ The AED shall permit all AED and rescue information to be downloaded via direct connection to a PC or USB drive.
+ The AED shall automatically begin uploading the AED and rescue information when a USB drive is detected.
+ Data transfer, review, and management software shall be included with each AED.

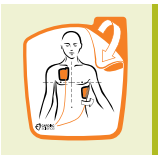
Automated Self-Tests

+ The AED shall assess up to 88 items within the device during self-tests.
+ The AED shall perform a daily automated self-test to confirm presence and function of defibrillation pads, and test the battery, electrical circuitry, and software.
+ The AED shall perform a weekly automated self-test to confirm the presence and function of the defibrillation pads, and test the battery, electrical circuitry, and software, plus conduct a partial charge of the high voltage module.
+ The AED shall perform a monthly automated self-test to confirm the presence and function of the defibrillation pads, and test the battery, electrical circuitry, and software, plus conduct a full energy charge and discharge test to ensure device readiness for full-scale rescue attempts.
+ The AED shall warn the user with an electromechanical visual indicator and audible alerts at a minimum of 70dBA if the system fails any of the automated self-tests and is not ready for use.
+ The audible warning tone will continue to sound every 30 seconds until the lid is opened or battery energy is depleted.
+ The AED mechanical visual status indicator should be visible even when battery is completely discharged.



Therapy / Waveform

+ The AED shall support a waveform that is a Biphasic Truncated Exponential.
+ The AED shall utilize a shock sequence of "variable" escalating energy.
+ The AED waveform shall deliver variable energy levels customized for a broad range of patient impedances (25 Ohms-175 Ohms).
+ The AED shall offer up to 10 separate user selectable energy settings for adult and pediatric protocols separately.
+ The AED shall provide therapy within an adult energy range of 95J-354J depending on programmed energy settings and patient impedance.
+ The AED shall provide therapy within a pediatric energy range of 22J-82J depending on programmed energy settings and patient impedance.
+ The waveform shall compensate for a patient's impedance level.
+ The waveform shall respond to patient's Cellular Response Curve by providing charge balancing, with a waveform that achieves a charge balancing index (CBI) of greater than 99% over most patient impedances.
+ The AED shall not shock a patient inadvertently if the patient does not require a shock.
+ The AED shall automatically synchronize delivery of a defibrillation shock with the patient's electrocardiogram R-wave. If AED is unable to synchronize, it will deliver an unsynchronized shock if a shock is necessary.
+ The AED shall automatically disarm and cancel the shock if the victim converts to a non-shockable heart rhythm after a shock decision is made. The AED shall inform the rescuer that the heart rhythm has changed and enter the CPR mode.
+ The AED shall have 0.08mV asystole threshold, baseline to peak.
+ The AED shall automatically detect noise (artifact) with the ECG rhythm, and alert the rescuer of the condition via a voice prompt.

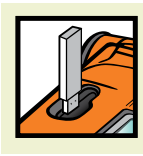


Defibrillation Pads

+ One pair of Adult Defibrillation Pads shall be included with each AED.
+ Adult Defibrillation Pads shall always be installed and ready to use in AED prior to rescue.
+ All defibrillation pads, adult or pediatric, shall be supplied in a ready-to-use, sealed package.
+ All defibrillation pads, adult or pediatric, shall be single-use.
+ All defibrillation pads, adult or pediatric, shall be disposable.
+ All defibrillation pads, adult or pediatric, shall be shipped to the customer with a minimum shelf life of two years.
+ All defibrillation pads, adult or pediatric, shall be non-polarized and interchangeable allowing the user to place either pad in the proper body position.
+ Defibrillation pads wire shall have a nominal length of 1.3 meters.
+ A diagram to assist in proper pad placement shall be available on both pad package and on each individual pad.
+ Designed for ease, all defibrillation pads, adult and pediatric, shall have a clearly identifiable tabbed region to allow for each pad to be easily removed from the blue plastic. The blue plastic shall also have a loop handle to assist in the peeling process.

CPR Feedback

+ The Adult Defibrillation Pads with CPR Device shall be supplied in a ready-to-use, sealed package that contains one pair of self-adhesive defibrillation pads in one pouch, and a CPR Device in a second pouch joined at the connector.
+ The Adult Defibrillation Pads with CPR Device shall be single-use.
+ The Adult Defibrillation Pads with CPR Device shall be disposable.
+ The Adult Defibrillation Pads with CPR Device shall be shipped to the customer with a minimum shelf life of two years.
+ A diagram to assist in proper CPR Device placement shall be available on the CPR Device package and on the CPR Device itself.
+ The AED shall provide the user with voice and text prompt guidance when the CPR Device is in use. The voice and text prompts will advise on rate and depth of compressions.
+ CPR feedback shall be provided every 7.5 seconds, if needed. If the rescuer is performing CPR within the recommended setting, no additional feedback is given.



Configuration Options

+ The AED Manager software shall allow medical directors/administrators or their designees to program devices to meet their protocols for AED use.
+ Parameters can be programmed on the AED via direct connection to a PC or USB drive.
+ The AED shall automatically begin download of the configuration and data when a USB drive is detected.
+ The AED Manager software shall allow the AED default language to be configured if it is a dual language device.
+ The AED default voice prompt level shall be able to be selected. The administrator may choose from three levels: basic, standard, and advanced.
+ The AED default start up prompt shall be user selectable.
+ The administrator shall be able to select if CPR First is enabled. CPR First allows the AED to first provide instructions to perform CPR, and then proceeds to analysis and therapy.
+ The AED Manager software shall allow for up 10 user selectable shock protocols for both adult and pediatric protocols separately.
+ The AED Manager software shall allow for adjustment of the VF/VT rate from 120–240 for both adult and pediatric rhythm detection separately.
+ The AED Manager software shall allow for adjustment of the SVT rate from 160-300 or to turn SVT off for both adult and pediatric rhythm detection separately.
+ The AED Manager software shall allow the configuration of the maximum shocks per sequence between one shock or three shocks.
+ The AED Manager software shall allow the administrator to enable or disable same energy after conversion.
+ The AED Manager software shall allow for CPR style customization for both adult and pediatric protocols independently. This includes determining the number of compressions, breaths, and sets along with timeout style and length.
+ The AED Manager software shall allow for CPR feedback customization. This includes determining the rate and depth ranges for which prompt guidance will be given.
+ The AED clock shall be able to be synchronized to PC clock through direct connection to a PC.

Physical and Environmental

+ The AED weight shall not exceed 2.5 kg (5.5 lbs), which includes AED, battery, and defibrillation pads.
+ The AED shall be water and foreign object resistant to a minimum of IEC 60529, IP55 classification.
+ The AED shall have a solid, integrated carrying handle for easy portability.
+ Dimensions of the AED shall not exceed 30 cm in length by 23 cm in width by 9 cm in thickness (11.8 in x 9.1 in x 3.5 in).
+ The AED shall be capable of operating in temperatures ranging from 0°C to +50°C (32°F to +122°F).
+ The AED shall be capable of operating in relative humidity ranging from 10%-95% (non-condensing).
+ The AED shall be capable of withstanding atmospheric pressure of 106 kPa to 57 kPa (approximately -382 m (-1,253 ft) to 4,594 m (15,073 ft) altitude).
+ The AED shall be able to be stored -30°C to 65°C (-22°F to 149°F) for three consecutive days.
+ The AED shall meet the following classifications per IEC 60601-1: Portable, internally powered equipment with a defibrillator-proof, type BF patient connection, cannot be sterilized, is not suitable for use in presence of flammable mixtures or oxygen, is rated for continuous operation.
+ The AED shall meet the following classification per IEC60601-2-4: A frequent use, Automated External Defibrillator.
+ The AED shall meet ANSI/AAMI/IEC 60601-1: Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance.
+ The AED shall meet CAN/CSA-C22.2 No. 60601-1: Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance.
+ The AED shall meet ANSI/AAMI/IEC 60601-2-4: Medical Electrical Equipment Part 2: Particular Requirements for Basic Safety and Essential Performance of Cardiac Defibrillators.
+ The AED shall meet ANSI/AAMI/IEC 60601-1-2: Medical Electrical Equipment Part 1-2: General Requirements for Basic Safety and Essential Performance Collateral Standard: Electromagnetic Compatibility-Requirements and Tests-Edition 3.0 (per the modifications stated in IEC 60601-2-4).
+ The AED shall meet RTCA/DO-160G: 2010 - Section 5 Category C; Section 4, Category A4.
+ The AED shall meet EN 1789: Medical Vehicles and Their Equipment – Road Ambulances When Installed in a Secured Rack.
+ The AED shall meet MIL-STD-810G, Method 516.6, Procedure IV, for a Free Fall Drop of 1.22 meters.
+ The AED shall meet Shock MIL-STD-810G Method 516.6, Procedure 1 (40g) (1,000 shocks both direction each axis; 6,000 shocks total).
+ The AED shall meet MIL-STD-810G, Method 514.6, Procedure 1, Category 24, Helicopter Minimum Integrity for Sine Vibration.
+ The AED shall meet MIL-STD-810G, Method 514.6, Procedure 1, Category 24, General Minimum Integrity for Random Vibration.
+ The AED shall meet RTCA/DO-160G, Section 8, Category H, Zone 2 (curves B and R) and Category U, Zone 2 (curves F and F1) for Random Vibration.

Battery

+ The AED shall use one non-rechargeable, extended life lithium battery for operation (called Cardiac Science Intellisense® Battery).
+ The battery shall typically provide a minimum of 14 hours of device operating time at 20°C to 30°C.
+ The battery shall typically be capable of providing 420 consecutive shocks at 300VE.
+ The battery shall typically be capable of providing 450 consecutive shocks at 200VE.
+ The battery shall typically be capable of providing 500 consecutive shocks at 150VE.
+ Expected shelf life of a new battery shall be five years from the date of manufacture.
+ The AED shall incorporate a SmartGauge Battery Status Indicator notifying the user of battery capacity during use in quarter life increments.

Service and Warranty

+ The AED shall require no yearly planned service or calibration regardless of frequency of use.
+ The AED shall have a 7-year warranty on defects in materials and workmanship.
+ The Intellisense battery shall have a full replacement operational guarantee for four (4) years from date of installation.

For more information, visit **www.cardiacscience.co.uk** or contact us at:

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