

# Powerheart® AED G3 Pro Automated External Defibrillator With Biphasic Waveform Bid Specifications

AHA/ERC 2005 Guidelines Protocol

## **1 Operation and Use**

- 1.1 AED shall have three operating modes: AED Mode, Manual Mode and ECG Monitoring Mode.
- 1.2 AED shall require an operator to push no more than one shock button during a rescue in AED Mode.
- 1.3 AED shall allow Advanced Life Support rescuers to initiate Manual Override functionality to determine a shockable rhythm and deliver a defibrillation shock if desired.
- 1.4 AED shall have option for manual function, programmable by the medical director
- 1.5 AED shall have voice, visual and text prompts to guide the user through the rescue process in a simple step-by-step manner based on the 2005 AHA/ERC Guidelines for CPR and defibrillation.
- 1.5 AED shall allow Advanced Life Support rescuers to administer ongoing 3-lead ECG monitoring to a conscious and breathing patient via optional ECG cable (Lead II).
- 1.6 Electrodes shall be installed and ready to use in AED prior to rescue.
- 1.7 AED shall have a full color TFT display, which features text prompts, ECG, heart rate, battery capacity, visual impedance indicator, elapsed rescue time, number of shocks administered, and a CPR countdown.
- 1.8 AED shall automatically analyze patient ECG and signal quality using automatic algorithms to determine if a shock is required.
- 1.9 AED shall have pacemaker pulse detection capability.
- 1.10 AED shall have pediatric defibrillation capability.
- 1.11 AED shall have 0.08mV Asystole threshold, baseline to peak.

## **2 Waveform/Algorithm:**

- 2.1 AED shall utilize escalating energy.
- 2.2 AED waveform shall deliver variable energy levels for a broad range of patient impedances (25 Ohms-180 Ohms).
- 2.3 AED shall offer multiple programmable energy settings: 200VE-300VE-300VE, 200VE-200VE-300VE, 150VE-200VE-200VE, 150VE-150VE-200VE, 200VE-200VE-200VE.
- 2.4 AED shall be capable of delivering 105J-360J of energy depending on programmed energy settings and patient impedance.
- 2.4 Waveform shall be Biphasic Truncated Exponential.
- 2.5 Waveform shall actively compensate for a patient's impedance level.
- 2.6 Waveform shall respond to patient's Cellular Response Curve<sup>1</sup>.
- 2.7 AED shall not shock patient inadvertently if the patient does not require a shock.

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<sup>1</sup> "STAR Biphasic Waveform—Optimized Energy Delivery for Successful Defibrillation" White Paper, pp. 3-5, p/n 400781, Rev 03, 2002

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- 2.8 AED shall have the capability to program detection rates for VF/VT (can be programmed by medical directors or their designees using MDLink software).
- 2.9 AED shall have a SVT therapy option (can be programmed by medical director or their designee using MDLink software)
- 2.10 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 necessary.
- 2.11 AED shall automatically disarm if the victim converts to a non-shockable heart rhythm after a shock decision is made (device is charged). AED shall inform the rescuer that the heart rhythm has changed and reanalyze the victim's heart rhythm (non-committed shock feature).
- 2.12 AED shall automatically detect noise (artifact) with the ECG rhythm, and alert the rescuer of the condition via a voice prompt.

## **3 Automated Self Tests:**

- 3.1 AED shall perform a daily automated self-test to confirm presence and function of electrodes and wires, and test the battery, electrical circuitry and software.
- 3.2 AED shall perform a weekly automated self-test with automated self-test to test battery, electrical circuitry and software, plus a partial load capacitor charge of electronics.
- 3.3 AED shall perform a monthly automated self-test to test battery, electrical circuitry and software, plus a full load capacitor charge and discharge test to ensure device readiness for rescue attempts,
- 3.4 AED shall warn user with audible and visual alerts at a minimum of 70 dB if the system fails any of the automated self-tests and is not ready for use.
- 3.5 The audible warning tone will continue to sound every 30 seconds until the lid is opened or the battery energy is low.
- 3.6 AED shall perform an automatic self-test when the lid of the device is opened.
- 3.7 The AED visual status indicator should be visible even when battery is completely discharged.

## **4 Electrodes:**

- 4.1 One pair of electrodes shall be included with each AED.
- 4.2 Electrodes shall be supplied in a ready-to-use, sealed package that contains one pair of self-adhesive electrodes with attached wires and a connector.
- 4.3 Electrodes shall be disposable.
- 4.4 Electrodes shall be shipped to the customer with a minimum shelf life of two years.
- 4.5 A diagram to assist in proper electrode placement shall be available on the electrode package and on each individual electrode.
- 4.6 Electrodes shall have a minimum combined surface area of 228 cm<sup>2</sup>.
- 4.7 Electrode wire shall have a nominal length of 1.3 m.

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## **5 Battery:**

- 5.1 AED shall use one, non-rechargeable lithium battery for operation (called Cardiac Science Intellisense® Lithium Battery).
- 5.2 Typical capacity of a new battery shall be able to provide at least 290 discharges at 20°C.
- 5.3 Expected shelf life of a new battery shall be five years from the date of manufacture.
- 5.4 AED shall incorporate a SmartGuage Battery Status Indicator notifying the end user of battery capacity during use in quarter life increments.
- 5.5 Battery shall incorporate a memory chip giving complete history of battery use (installation date and shocks provided, etc.).
- 5.6 Battery shall be warranted for one (1) year from date of installation into a Powerheart AED G3 Pro or 12 hours of use, whichever is sooner.

## **6 Rechargeable Battery:**

- 6.1 AED shall be compatible with an optional, rechargeable battery.
- 6.2 Rechargeable shall allow a minimum of 60 shocks and 3 hours of ECG display on a full charge.
- 6.3 Rechargeable battery life shall be 2.5 years or 300 charge-discharge cycles, whichever is sooner.
- 6.4 Rechargeable battery will charge to full capacity in three hours (4.5 hours if completely depleted).
- 6.5 Charger for the rechargeable battery shall accept IEC power cables.
- 6.6 The battery shall be based on lithium ion technology.
- 6.7 Must have built in status and remaining capacity indicators

## **7 ECG Monitoring Cable & Electrodes**

- 7.1 ECG electrodes shall indicate position of leads on the patient by labeling L, R, F as well as corresponding color convention.
- 7.2 ECG monitoring cable shall meet AAMI specifications and AHA standards and provide options for IEC specifications.

## **8 ECG Recording and Information Documentation:**

- 8.1 AED shall provide up to 60 minutes of internal event documentation.
- 8.2 AED shall provide multiple rescue functionality.
- 8.3 AED shall permit ECG and event information to be downloaded via a infrared cable to a Windows® based PC after a rescue.
- 8.4 AED clock shall be able to be synchronized to PC clock through direct connection to a PC.
- 8.5 Optional supporting software shall allow medical directors or their designees to program devices to meet their protocols for AED use. Adjustable parameters shall include detection rates for VF/VT & optional SVT therapy, variable energy protocol options, energy level after conversion, etc.
- 8.6 Data transfer, review and management software shall be included with each AED.

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## **9 Color Display Specifications :**

- 9.1 Display shall be full color with a minimum diagonal size of 8.9cm (3.5”), 320x240 pixels (quarter VGA) and Resolution 4.47 dots/mm (113.5 dots/in)
- 9.2 Color display shall show 5 seconds of data with a sweep speed of 1.39 cm/s and ECG bandwidth of 3-33 Hz.

## **10 Visual and Audio Impedance Indicator:**

- 10.1 AED shall display a visual indicator of total transthoracic impedance between the two defibrillation pads.
- 10.2 AED shall assess adequate pad placement, quality and integrity, and assessment between pads off and pads shorted through determining an acceptable patient impedance range after pads are placed on patient.
- 10.3 AED shall prompt “Press pads firmly to patient’s bare skin” if better skin contact is required.

## **11 Physical and Environmental:**

- 11.1 AED weight shall not exceed 7.0 lbs. (includes AED, battery and electrodes).
- 11.2 AED shall have enclosure protection resistant to water and foreign objects to a minimum of IEC 60529, IP24 certification levels.
- 11.3 AED shall have a molded handle formed in the case for easy portability.
- 11.4 AED shall be self contained and does not require a case to in order to function.
- 11.5 The NVI and expiration date of the pre-connected electrodes shall be visible when AED is in case.
- 11.6 Dimensions of AED shall not exceed 3.3 in. (8.4 cm) in height, 10.6 in. (26.9 cm) in width and 12.4 in. (31.5 cm) in length.
- 11.7 AED shall be capable of operating and stand-by in temperatures ranging from 0 degrees Celsius to +50 degrees Celsius (32 degrees Farenheit to +122 degrees Farenheit); relative humidity ranging from 5%-95% (non-condensing); pressure ranging from 57kPa (+15,000ft) to 103kPa (-500ft).
- 11.8 AED without battery and electrodes shall be able to withstand storage at -30 degrees Celsius to +65 degrees Celsius (22 degrees Farenheit to +149 degrees Farenheit).
- 11.9 AED shall meet or exceed IEC 55011/CISPR 11, Group 1, Class B specifications for E-M (radiated).
- 11.10 AED shall meet or exceed ANSI/AAMI DF39 for magnetic emissions, <0.5mT on surface, except within 5cm of the lid magnet and the speaker.
- 11.11 AED shall meet or exceed IEC 61000-4-3, Level X, (20V/m); IEC 60601-2-4, Section 36.202.3 (20-V/m); AAMI DF39, Section 3.3.21.2.1 immunity tests (E-M)
- 11.12 AED shall meet or exceed IEC 61000-4-8, 80 A/M; IEC 60601-2-4, Section 36.202.8; AAMI DF39, Section 3.3.21.2.3 80A/m, 47.5Hz – 1320Hz immunity tests (magnetic)

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- 11.13 AED shall meet or exceed IEC 61000-4-2, Level 3; IEC 60601-2-4, Section 36.202.2; 6KV contact discharge, 8KV air gap discharge for immunity tests (ESD)
- 11.14 AED shall meet or exceed IEC 60068-2-32 one meter free fall drop test
- 11.15 AED shall meet or exceed IEC 60068-2-29 bump test, 40g and 6000 bumps.
- 11.16 AED shall meet or exceed IEC 60068-2-64 vibration (random) test, 10Hz – 2KHz, 0.005 – 0.0012 g<sup>2</sup>/Hz
- 11.17 AED shall meet or exceed IEC 60068-2-6 vibration (sine) test, 10Hz – 60Hz, 0.15 mm and 60Hz – 150 Hz, 2g.

## **12 Training**

- 12.1 Training shall be available with a patient simulator that is separate from the AED that can be used for scenario-based training.
- 12.2 The patient simulator shall be incapable of delivering energy.
- 12.4 Training videos on the AED operation shall be included with each device.

## **13 Technical Service/Warranty**

- 13.1 AED shall require no yearly planned service or calibration regardless of frequency of use.
- 13.2 AED shall have a 7-year warranty on parts and labor (exclusive of battery and electrodes).
- 13.3 Extended Life IntelliSense lithium battery shall be warranted for one (1) year from date of installation into a Powerheart AED G3 Pro or 12 hours of use, whichever is sooner.
- 13.4 Technical service shall be available 24 hours per day, 7 days per week, 365 days per year.