

**HART COUNTY BOARD of COMMISSIONERS  
800 Chandler Street  
HARTWELL, GA 30643**

**DATE: February 25, 2019**

**BID NOTICE**

Sealed bids for 8 new **Portable Defibrillator / Multi-Parameter Monitors for Hart County EMS** subject to the conditions and provisions set forth in the attached bid package will be received at the Hart County Board of Commissioners office until March 22, 2019 at 3:30 PM. The commodities and /or services must be furnished as described and specified in this package.

Bids must be received either by mail or hand delivered in a **sealed envelope**. Faxed bids cannot be accepted.

Please address mailed bids, Fed-Ex, UPS, or hand delivered bids to:

HART COUNTY BOARD OF COMMISSIONERS  
800 CHANDLER STREET  
HARTWELL, GA 30643  
Attn: Lawana Kahn

Also, please show the following on the **OUTSIDE** of the envelope:  
**BID for Portable Defibrillator / Multi-Parameter Monitor Proposal**

**NOTE:** Some "Next Day" deliveries may not get delivered to this office prior to the bid opening. Please be aware of this and make arrangements to have your bid here on time, as late bids will be rejected.

**NOTICE:** If you are downloading this information from a web page, you must register with Hart County Board of Commissioners at the contact information listed on the **Invitation to submit bids page**. This is the only way Hart County Board of Commissioners can be sure that you receive all addendum and relevant information for this bid.

DATE BIDS DUE: Thursday March 22, 2019  
3:30 p.m.

**BID FORM**  
**HART COUNTY BOARD OF COMMISSIONERS**  
**800 CHANDLER ST., HARTWELL, GA 30643**

The (Company)\_\_\_\_\_

submits herewith Bid in response to bid request in this package, and in compliance with the description(s) and/or specification(s) attached hereto:

**NOTE: You must sign and complete the Bid Supplemental Form and Contractor Affidavit.**

**PRICE:**

\_\_\_\_\_  
Price in Numbers

\_\_\_\_\_  
Price in Words

The following Addenda to the Bidding and Contract Documents are acknowledged:

Addendum No: \_\_\_\_\_

Dated: \_\_\_\_\_

OFFICIAL COMPANY ADDRESS\_\_\_\_\_

EMAIL ADDRESS:\_\_\_\_\_

SIGNATURE\_\_\_\_\_

PRINT NAME\_\_\_\_\_

TITLE\_\_\_\_\_ PHONE\_\_\_\_\_

DATE \_\_\_\_\_ FAX\_\_\_\_\_

Corporate Seal (if applicable)

**BID SUPPLEMENTAL FORM  
HART COUNTY BOARD OF COMMISSIONERS**

DATE: \_\_\_\_\_

NOTICE: *Hart County Purchasing Policy prohibits awards to a (1) county employee, (2) employee of a constitutional officer, (3) a Board of Commissioner Member, (4) Constitutional Officer or to a company/business where a county employee/Constitutional Officer holds any interest. These prohibitions also apply to immediate family members of those listed above. By signing below you are confirming that these prohibitions do not apply to your company/bid.*

References: Name Title Organization Phone Number email address

1.

2.

3.

The \_\_\_\_\_ (Bidder) takes the following exceptions to the specification and bid documents:

**(Important: See section IIb)**

SIGNATURE: \_\_\_\_\_

CONTRACTOR AFFIDAVIT AND AGREEMENT OF COMPLIANCE WITH GEORGIA LAW 13-10-91 (1/1/10)

By executing this affidavit, the undersigned contractor verified its compliance with O.C.G.A. 13-10-91, stating affirmatively that the individual, firm or corporation which is contracting with the Hart County Board of Commissioners has registered with and is participating in a federal work authorization program\* [any of the electronic verification of work authorization programs operated by

the United State Department of Homeland Security or any equivalent federal work authorization program operated by the United States Department of Homeland Security to verify information of newly hired employees, pursuant to the Immigration Reform and Control Act of 1986 (IRCA), P.L. 99-603], in accordance with the applicability provisions and deadlines established in O.C.G.A. 13-10-91.

The undersigned further agrees that, should it employ or contract with any subcontractor(s) in connection with the physical performance of services pursuant to this contract with the Hart County Board of Commissioners, contractor will secure from such subcontractor(s) similar verification of compliance with O.C.G.A. 13-10-91 on the Subcontractor Affidavit provided in Rule 300-10-01-.08 or a substantially similar form. Contractor further agrees to maintain records of such compliance and provide a copy of each such verification to the (name of the public employer) at the time the subcontractor(s) is retained to perform such service.

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EEV/Basic Pilot Program\* User Identification Number

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BY: Authorized Officer or Agent

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Date

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Title of Authorized Officer or Agent of Contractor

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Printed Name of Authorized Officer or Agent

SUBSCRIBED AND SWORN  
BEFORE ME ON THIS THE \_\_\_\_\_ DAY OF \_\_, 201\_\_

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Notary Public  
My Commission Expires:

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\* As of the effective date of O.C.G.A. 13-10-91, the applicable federal work authorization program is the "EEV/Basic Pilot Program" operated by the U.S. Citizenship and Immigration Services Bureau of the U.S. Department of Homeland Security, in conjunction with the Social Security Administration (SSA).

***Invitation to Submit Competitive Bids  
For  
Portable Defibrillator / Multi-Parameter Monitors***

DATE: February 25, 2019

Hart County Board of Commissioners is soliciting competitive, sealed bids from qualified vendors for the purchase of Eight (8), Portable Defibrillator / Multi-Parameter Monitors for Hart County Board of Commissioners, 800 Chandler St. Hartwell, Georgia. Hart County Board of Commissioners reserves the right to reject any and/or all bids. Hart County Board of Commissioners also reserves the right to accept the bid most advantageous to Hart County Board of Commissioners.

The attached specification defines the capabilities of the equipment that Hart County is looking to **purchase or lease to purchase Eight (8), Portable Defibrillator / Multi-Parameter Monitors.**

This invitation is extended to all qualified vendors/manufacturers that is specifically in the business of building emergency medical equipment.

This invitation is issued by:  
Hart County Board of Commissioners  
800 Chandler St.  
Hartwell, Georgia 30643  
Email: [tpartain@hartcountyga.gov](mailto:tpartain@hartcountyga.gov)  
Website: [hartcountyga.gov](http://hartcountyga.gov)

Contact Person: Terrell Partain, County Administrator  
Hart County Board of Commissioners  
800 Chandler St.  
Hartwell, Georgia 30643  
Email: [tpartain@hartcountyga.gov](mailto:tpartain@hartcountyga.gov)  
Phone: (706) 376-2024

## Schedule of Events Applying to this Procurement

Origination  
Pre-Bid Conference

### GENERAL CONDITIONS:

### PARTY IDENTIFICATION:

**AGENCY:** "Agency" is hereinafter defined as the customer. The customer is an individual or a group of individuals whom represent the interest of the city, borough, county, parish, state or private enterprise and has been charged with the responsibility of purchasing one or more emergency medical vehicle(s).

Bidder Complies YES \_\_\_\_\_ NO \_\_\_\_\_

**BIDDER:** "Bidder" is hereinafter defined as the equipment manufacturer and/or it's authorized representative. The bidder is an assigned representative who is authorized to commit to a contract with the "Agency".

Bidder Complies YES \_\_\_\_\_ NO \_\_\_\_\_

**VENDOR:** "Vendor" is synonymous with "Bidder".

Bidder Complies YES \_\_\_\_\_ NO \_\_\_\_\_

**NOTICE TO BIDDERS:** Bidders shall thoroughly examine any specifications, schedule, instructions and any other documents supplied as part of this invitation to bid.

Bidders shall make all investigations necessary to thoroughly inform themselves regarding the content of the written specifications, and instructions supplied herein. No pleas of ignorance by the bidder pertaining to the content of the specifications, drawings, schedule or instructions will be considered by the agency once the deadline for bid submission has occurred. Failure or omission on the part of the bidder to make the necessary examinations and investigations into the content of the specifications AND make all clarifications or explanations of exceptions and conditions that exist or that may exist hereafter shall NOT be accepted as a basis for making variations to the **requirements** of the agency or **compensation** to the bidder.

Bidder Complies YES \_\_\_\_\_ NO \_\_\_\_\_

#### **Definitions:**

**CLARIFICATIONS:** Clarifications shall be **written correspondence** between the bidder, the agency and all other qualified bidders. A Clarification shall include the paragraph number, page number, the text with unclear content (as written in the specification) and the definition of the clarification requested. Verbal clarifications shall be documented in writing and distributed to all other qualified bidders at least two business days prior to the deadline for bid submission.

Bidder Complies YES \_\_\_\_\_ NO \_\_\_\_\_

**EXPLANATION OF EXCEPTIONS:** Bidders may take exceptions to any part of the bid contained herein with a written itemized schedule. The schedule shall include the paragraph number(s), the text that the bidder feels he can not comply with an explanation why the bidder feels

that the requirement is not in the best interest of the agency and/or an alternate bidder solution. Alternate bidder solutions may be considered by the agency, if the bidder can show the agency that the alternate solution is, in quality and quantity, equal to OR better than the specified item. This agency will share the exception/alternate solution with all other Qualified Bidders. Explanation of exceptions shall be documented in writing at least two business days prior to the deadline for bid submission.

Bidder Complies YES \_\_\_\_\_ NO \_\_\_\_\_

**CORE DESIGN INTENT:** The core design intent of the specifications supplied herein is to purchase an ambulance with the highest level of engineering excellence. The "Core Design" intent of this equipment shall be centered on the patient's need for pre-hospital care, in conjunction with a safe working environment for the Emergency Medical Personnel.

Bidder Complies YES \_\_\_\_\_ NO \_\_\_\_\_

**BID PACKAGES SHALL NOT TAKE TOTAL EXCEPTIONS:** Bidders are required under this bid invitation to give, for the consideration of the agency, a proposal that will comply with the written specifications, and schedules supplied herein. The specifications supplied represent a compilation of input from all disciplines of users, patients, maintenance and management personnel who are directly affected by the vehicle's performance.

Careful consideration pertaining to safety, configuration, construction, and workmanship are based on working experiences by all the personnel who have direct, working contact with the subject equipment specified herein. The "core design" of this ambulance was created as a result of resolving issues and improvement suggestions that have originated from the personnel most QUALIFIED to make such input.

This agency makes no claim that ALL potential issues or improvements are included in the specifications supplied herein. This agency will consider any VALID concern by any bidder and will consider minor specification exceptions or alternates of equal or better performance, provided that the exception(s) are steered toward meeting the "Core design" intent AND the exception(s) are cleared up not less than two days prior to the bid opening date.

**Caution:**

A bidder who submits a bid that takes "Total Exception" and makes an offering of some "Standard" or "Stock" unit will be viewed by the agency as a bidder who did not make, and is not prepared to make, a valid bid, and is not qualified to manufacture the equipment as specified herein. Alternate bids will NOT be considered.

Bidder Complies YES \_\_\_\_\_ NO \_\_\_\_\_

**EQUIPMENT QUANTITY:** THIS AGENCY is currently seeking to purchase eight Portable Defibrillator / Multi-Parameter Monitors per the specifications set forth in this solicitation for bid. THIS AGENCY AND/OR other government or private agencies that qualify to purchase under this contract will reserve the right to increase the number of equipment purchased without incurring an obligation to obtain bids from other vendors for a period of two years. A contract extension may be provided to the successful, qualified vendor who has performed satisfactorily to the original contract.

Bidder Complies YES \_\_\_\_\_ NO \_\_\_\_\_

**PRODUCT LIABILITY INSURANCE:** Proof of current liability insurance shall be supplied. The proof of insurance shall bear the insurance carrier's name, address and phone number. The proof shall also bear the name and address of the insured. This document shall contain the coverage schedule, explaining the type of insurance, the policy number, the effective date of coverage, the policy expiration date and the individual limits. The **minimum** amount of coverage shall be as follows:

Commercial General Liability - as follows:

Each Occurrence: \$1,000,000

Damage to rented premises, each occurrence: \$1,000,000

Medical Expenses: \$5,000

Personal and Adv Injury: \$1,000,000

General Aggregate: \$2,000,000

Products - Comp/OP Agg: \$2,000,000

Automotive Liability - Combined Single Limit: \$1,000,000

Excess Liability - Umbrella Form

Each occurrence: \$25,000,000

Aggregate: \$25,000,000

Workers Compensation and Employers' Liability

E.L. Each Accident: \$1,000,000

E.L. Disease policy - Each Employee: \$1,000,000

E.L. Disease - Policy Limit: \$1,000,000

Bidder Complies YES \_\_\_\_\_ NO \_\_\_\_\_

**NON-DISCRIMINATION AND EQUAL OPPORTUNITY:** The Bidder/Contractor agrees to comply with all federal statutes relating to non-discrimination. These include but are not limited to:

(a) Title VI of the civil rights act of 1964 (P.L. 88-352) which prohibits discrimination on the basis of race, color or national origin;

(b) Title IX of the Education Amendments of 1972, as amended (20 U.S.C. 1681-1683, and 1685-1686), which prohibits discrimination on the basis of sex;

(c) Section 504 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 794), which prohibits discrimination on the basis of handicaps and the Americans with Disabilities Act of 1990;

(d) The Age Discrimination Act of 1974, as amended (42 U.S.C. 6101-6107), which prohibits discrimination on the basis of age;

(e) The Drug Abuse Office and Treatment Act of 1972 (P.L. 92-255), as amended, relating to nondiscrimination on the basis of drug abuse;

(f) The Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970 (P.L. 91-616), as amended, relating to nondiscrimination on the basis of alcohol abuse or alcoholism;

(g) 523 and 527 of the Public Health Service Act of 1912 (U.S.C. 290 dd-3 and 290 ee-3), as amended, relating to confidentiality of alcohol and drug abuse patient records;

(h) Title VIII of the Civil Rights Act of 1968 (42 U.S.C. 3601 et seq.), as amended, relating to nondiscrimination in the sale, rental or financing of housing;

(i) Any other nondiscrimination provisions in any specific statute(s) applicable to any Federal funding for this Agreement;

(j) The requirements of any other nondiscrimination statute(s) which may apply to this agreement.

Bidder Complies YES\_\_\_\_\_ NO\_\_\_\_\_

**DRUG FREE WORK PLACE:** The Bidder shall conduct business as a Drug Free Workplace. The Bidder/Manufacturer and ALL of its sub-contractors shall provide notice to their employees and sub-contractors as required under the Drug-Free Workplace Act of 1988. A copy of Bidder's Drug-Free Workplace Policy shall be furnished to this agency upon request.

Bidder Complies YES\_\_\_\_\_ NO\_\_\_\_\_

### **Product Specifications for Monitor/Defibrillator**

The following specifications are for a portable multi-parameter monitor/defibrillator.

1. Operating Modes
  - 1.1. AED Mode; the device shall function with automated ECG analysis and a prompted protocol for patients in cardiac arrest.
  - 1.2. Manual Mode; the device shall provide manual defibrillation, synchronized cardioversion, and noninvasive pacing and ECG and vital sign monitoring.
  - 1.3. Archive mode; the device shall automatically store patient data and will allow the operator to access stored patient records.
  - 1.4. Setup Mode; the device shall allow the operator to configure the Setup Options of the device.
  - 1.5. Service Mode; the device shall allow the operator to execute device diagnostic tests and calibrations without the need for physically opening the case.
  - 1.6. Demo Mode; the device shall provide simulated waveforms and trend graphs for demonstration purposes. The device shall immediately revert to normal clinical operation if a therapy cable is connected.

### **OR EQUAL**

2. User Interface
  - 2.1. Controls:
    - 2.1.1. All critical emergency therapy controls shall be grouped together in a logical orientation. Each control is dedicated to a single function to provide for fast, unambiguous access. These controls include Power ON; CPR controls (CPR Metronome), ENERGY SELECT, CHARGE, ANALYZE, SYNC and SHOCK; and pacing controls PACER, RATE, CURRENT and PAUSE.
    - 2.1.2. Critical controls are color coded to enable clear visibility and to help the user distinguish each control for rapid access.
    - 2.1.3. All critical measurement controls are dedicated to single function hard keys to provide for fast, unambiguous access. These controls include LEAD, SIZE, NIBP and 12-LEAD.
    - 2.1.4. Additional operational controls are dedicated to single function hard keys to provide for fast unambiguous access. These controls include TRANSMIT,

PRINT, EVENTS, DISPLAY MODE, CODE SUMMARY and HOME SCREEN.

- 2.1.5. All controls are accessible on the front panel of the device while operating the unit in all typical settings including patient treatment and transport (i.e. equipped with carrying case).
  - 2.1.6. All controls operate with a single press except the ON control, which requires the user to push and hold the ON button for a few seconds to turn the device off to prevent turning off the device inadvertently.
  - 2.1.7. The SYNC control is located separate from the primary defibrillation controls to prevent accidental activation during cardiac arrest.
- 2.2. Audible Prompts
- 2.2.1. While in Manual mode, the monitor allows the operator to enable or disable voice prompts.
  - 2.2.2. Shock tone can be set to ON or OFF when full charge is reached.
  - 2.2.3. Volume settings are adjustable for CPR metronome, alarms, QRS beep, voice prompts and tones; some tones can be silenced with one push of a button.
- 2.3. Patient Connection
- 2.3.1. Patient connections: All patient connections are visible and accessible on the front panel of the device while operating the unit in all typical settings including patient treatment and transport (i.e. equipped with carrying case) or when housed on a closed shelf.
  - 2.3.2. Therapy Cable offers a solid, positive connection to device that is not vulnerable to shock or impact; it is easily inserted or removed with a gloved hand without the need for additional tools for quick replacement during patient use in case it becomes damaged.
  - 2.3.3. ECG cable offers a solid connection and easy removal without side-to-side tension to preserve integrity of cable.
  - 2.3.4. CO<sub>2</sub> connector accepts sensors for intubated and non-intubated patient applications without additional adapters, to maximize clinical functionality. CO<sub>2</sub> monitoring activates automatically when a sensor is connected.
  - 2.3.5. SPO<sub>2</sub>/SpCO all use a common connection and include lock out for incompatible sensors. SPO<sub>2</sub>/SpCO monitoring activates automatically when a proper sensor is connected.
  - 2.3.6. NIBP connector is self-locking and can be easily removed with one hand.
  - 2.3.7. P1/P2 connector(s) are available from the front of the device.
  - 2.3.8. 100mm Printer access is available from the front of the device.

## **OR EQUAL**

- 2.4. Display
- 2.4.1. The device active viewing area is 212 mm (8.4 in) diagonal; 171 mm (6.7 in) wide and 128mm (5.0 in) high.
  - 2.4.2. The device display is dual-mode color backlit display with a resolution of 640 x 480 pixels.
  - 2.4.3. The primary mode is a black background with color waveforms and text data. Waveforms and values are automatically color synchronized to real-time display of patient data to facilitate assessment at a glance (ex. blue pulse oximetry waveform matched with blue pulse oximetry value; green ECG waveform matched with green heart rate).
  - 2.4.4. A secondary mode is black parameter and real time patient data on a white background, for clear viewing in bright sunlight. The user may toggle between primary and secondary viewing modes with each mode available in less than 1 second.
  - 2.4.5. The device displays patient ECG and alphanumeric characters for patient parameter values, device instructions, and prompts.
  - 2.4.6. The device provides the option to display one or two additional waveforms.
  - 2.4.7. The device can be set up for display of up to three simultaneous waveforms.
  - 2.4.8. The device includes a 'home screen' key which, when depressed, returns the display to normal patient monitoring mode without the need to cycle or backtrack through menus.
  - 2.4.9. The display displays status of one or two batteries (including installed, active, low, require replacement, remaining capacities), Bluetooth connections and selected energy.

### **OR EQUAL**

## 3. Defibrillator

- 3.1. The device uses a biphasic truncated exponential waveform with the following characteristics:
  - 3.1.1. Voltage compensation to address varying patient impedance.
  - 3.1.2. Variable duration based on patient impedance.
  - 3.1.3. Escalating energy levels up to 360J to maximize clinical options and treat the widest range of patients. The full range of energy levels are accessible at any time (except internal defibrillation), as limited by pre-determined patient impedance ranges.
- 3.2. The device has the following energy accuracy:
  - 3.2.1.  $\pm 1J$  or 10% of setting, whichever is greater, into 50 ohms.
  - 3.2.2.  $\pm 1J$  or 10% of setting, whichever is greater, into 50 ohm.  $\pm 2J$  or 15% of setting whichever is greater into 25-175 ohms.
- 3.3. The device offers the following paddle options:
  - 3.3.1. Hands-free pacing/defibrillation/ECG electrodes.
  - 3.3.2. Adult Standard Hard Paddles and Pediatric Paddles with standard slip on, conical shaped pediatric paddle attachments with a nominal surface area of 15.4 cm<sup>2</sup>.
  - 3.3.3. Standard paddles with the ability to select energy and charge the defibrillator without having to refer to the defibrillator control panel to facilitate ease of use.
- 3.4. The therapy cable has a length of 2.4m (8 ft), not including electrode assembly.
- 3.5. The charge time to 360 joules does not typically exceed 10 seconds.

- 3.6. The device can monitor the patient ECG for a potentially shockable rhythm and alert the operator, even while in Manual defibrillation mode.

**OR EQUAL**

#### 4. External Defibrillation (AED)

- 4.1. The device is capable of being set up to power on in the AED mode.
- 4.2. The device can be set up to automatically and continuously monitor the patient ECG for a potentially shockable rhythm.
- 4.3. The device allows the operator to configure the output energy delivery sequence to be used during Advisory mode as 200/200/360 or 200/300/360 joules.
- 4.4. During AED mode when a shockable ECG rhythm is detected the device can be ready to  
deliver a shock within 20 seconds with a fully charged battery  
installed.
- 4.5. The device is capable of adjusting the AED protocol by providing the ability to adjust settings for energy protocol, Auto Analyze timing, Motion Detection, Pulse Check, CPR time after a shock, CPR time after No Shock Advised, Initial CPR, Preshock CPR, Metronome  
parameters, and stacked shocks to meet AHA, IEC and local  
protocols.
- 4.6. AED mode is allowed only with a hands-free electrode system.
- 4.7. The device allows switching from AED mode to Manual mode with or without a password or not allowed based on local protocol.
- 4.8. The device allows switching from AED mode to pacing.
- 4.9. The device allows advisory monitoring.
  - 4.9.1. The device allows use of all the monitoring functions without initiating the AED  
prompted protocol when the device is turned on.
  - 4.9.2. When needed, the AED mode prompted protocol can be initiated by pressing ANALYZE.
  - 4.9.3. The device can be set up to restrict access to Manual mode therapies—that is, manual defibrillation, sync cardioversion, or pacing—by unauthorized users.
  - 4.9.4. When in Advisory Monitoring, an ADVISORY MODE-MONITORING message appears continuously.
  - 4.9.5. All configured monitoring functions such as NIBP, SpO2 and 12-lead ECG can be used in Advisory Monitoring.
  - 4.9.6. The uppermost real-time waveform display is reserved for ECG information, Lead II;  
dashes are shown until the patient is connected to an ECG cable or therapy cable.
  - 4.9.7. In Advisory Monitoring, LEAD II and PADDLES lead are the only ECG monitoring leads allowed.
  - 4.9.8. An ECG analysis system is active and automatically evaluates the patient ECG for a potentially shockable rhythm. If a shockable ECG rhythm such as VF is detected, a PUSH ANALYZE prompt occurs. Pressing ANALYZE causes the device to enter AED  
Mode.

#### **OR EQUAL**

5. Manual Defibrillation Mode
  - 5.1. The device operates in manual mode using adult and pediatric hands-free pacing/defibrillation/ECG electrodes, adult standard paddles, or pediatric paddles.
  - 5.2. The device can be set up to operate in Manual mode when it is turned on.
  - 5.3. While in manual mode, the device allows the operator to select the following energy 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 30, 50, 70, 100, 125, 150, 175, 200, 225, 250, 275, and 360 joules or a user configurable sequence of 150-360 (1st shock), 150 - 360 (2nd shock), 150 - 360 joules (3rd shock).
  - 5.4. The device allows the operator to select energy, charge and shock from front panel from controls located on the paddles.

**OR EQUAL**

6. Synchronized Cardioversion
  - 6.1. The device allows for a shock to be automatically delivered that is synchronized to a patient's ECG.
  - 6.2. An indicator is shown on the ECG QRS where the shock will be delivered.
  - 6.3. The device allows adjustment of the shock delivery point by the use of an ECG size
  - 6.4. During synchronous cardioversion, the device begins energy transfer within 60ms of the QRS peak.
  - 6.5. stay in synch mode.
7. Pacer
  - 7.1. The device operates in demand and non-demand modes.
  - 7.2. The device allows the user to program a preferred/default starting mode.
  - 7.3. The device allows the operator to set the default rate and current values.
  - 7.4. The device generates pacing pulses at a rate of 40 to 170ppm.
  - 7.5. The accuracy of the pacing output rate is within +/- 1.5% over the entire range.
  - 7.6. The device generates a monophasic, truncated exponential current pulse (20 +/- 1.5ms).
  - 7.7. The device allows the operator to select the pacing output current from 0 to 200mA.
  - 7.8. The device incorporates a pacing pause function which allows the operator to reduce the
  - 7.9. pacing rate by a factor of 4, to allow assessment of the patient's underlying ECG rhythm. The pacing circuit includes automatic adjustment of the refractory period (function of rate)

from 200 to 300ms +/- 3%, to ensure the delivered rate is consistent with the operator selected rate.

**OR EQUAL**

8. ECG Monitor
  - 8.1. The device monitors patient ECG via the following means:
    - 8.1.1. Three (3) wire cable for 3-lead ECG monitoring.
    - 8.1.2. Five (5) wire cable for 7-lead ECG monitoring.
    - 8.1.3. Ten (10) wire cable for 12-lead ECG acquisition. The cable should be multi-segmented (main trunk, 4-wire section, 6-wire section) to facilitate multiple functionality and minimize replacement costs.
    - 8.1.4. When the 6 chest electrodes are removed, the 10 wire cable functions as a 4-wire cable.
    - 8.1.5. QUIK-COMBO<sup>®</sup> pacing/defibrillation/ECG electrodes for paddles monitoring.
  - 8.2. Lead selection; the device shall provide the following monitoring options:
    - 8.2.1. Leads I, II, III with the 3-wire cable.
    - 8.2.2. Leads I, II, III, AVR, AVL, and AVF with the 4-wire cable (simultaneous acquisition).
    - 8.2.3. Leads I, II, III, AVR, AVL, AVF and C with the 5-wire cable (simultaneous acquisition).
    - 8.2.4. Leads I, II, III, AVR, AVL, AVF, VI, V2, V3, V4, V5, and V6 with the 10-wire cable(simultaneous acquisition).
  - 8.3. The monitor allows the operator to adjust the ECG size using the following settings: 4, 3, 2.5, 2, 1.5, 1, 0.5, 0.25 cm/mV; (fixed at 1 cm/mV for 12-lead).
    - 8.3.1. The monitor digitally displays patient heart rates from 20 to 300 bpm.
    - 8.3.2. The monitor flashes a heart symbol for each patient QRS detected.
  - 8.4. The monitor incorporates a continuous patient surveillance system, which, while in advisory mode or as a VF/VT alarm in manual mode, will monitor the patient via paddles lead or Lead II for potentially shockable ECG rhythms and alert the operator to CHECK PATIENT if a shockable ECG rhythm is detected.
  - 8.5. The device provides a continuous 1V/mV x 1.0 gain analog ECG output.
  - 8.6. The device provides common mode rejection of at least 90dB at 50/60Hz.
  - 8.7. The device offers the following frequency response settings:
    - 8.7.1. Monitoring electrodes: 0.5 to 40Hz or 1.0 to 30Hz (monitoring frequency response);  
0.05 to 40Hz or 0.05 to 150Hz (diagnostic frequency response).
    - 8.7.2. Paddles: 2.5 to 30Hz.
    - 8.7.3. Analog ECG Output: 0.67 to 32Hz (except 2.5 to 30Hz for Paddles ECG).

**OR EQUAL**

9. 12-Lead ECG Algorithm
  - 9.1. The device incorporate University of Glasgow 12-Lead ECG analysis program.
  - 9.2. The analysis program includes interpretative statements to describe the 12-lead ECG including statements such as “Meets ST Elevation MI Criteria”.

- 9.3. The 12-lead ECG provides information related to leads disconnected and noisy ECG and requires user interaction to proceed with acquiring a 12-lead ECG report and interpretation with noisy ECG data.
  - 9.4. The device provides the option of printing the interpretation on the 12-Lead ECG report.
  - 9.5. The device provides the option of printing the 12-Lead ECG report at 25mm/sec or 50mm/sec.
  - 9.6. The 12-lead ECG report shall offer a 3-Channel Standard format with an optional 4-Channel Standard, 3-Channel Cabrera or 4-Channel Cabrera format.
  - 9.7. The device offers the option of printing automatically on the acquisition of a 12-Lead.
  - 9.8. The device includes trending of ST measurement after an initial 12-Lead analysis and automatically generates a 12-Lead ECG to alert the operator if any change in ST elevation or depression is detected.
  - 9.9. The 12-Lead ECG is derived from ten (10) physical ECG leads rather than extrapolated from only five (5) leads to ensure clinical accuracy consistent with the established monitoring standard.
  - 9.10. The 12-Lead ECG algorithm distinguishes between adult and pediatric patients using different algorithms established by user-input age.
  - 9.11. The 12 -Lead ECG algorithm distinguishes between male and female patients using different algorithms established by user-input gender.
10. Pulse Oximetry (SPO<sub>2</sub>), monitoring
- 10.1. The device incorporates SPO<sub>2</sub>, SPCO and SPMet monitoring using <sup>®</sup>Rainbow<sup>®</sup> Masimo technology and compatible sensors.
  - 10.2. Pulse Oximetry (SPO<sub>2</sub>)
    - 10.2.1. The device measures, displays and stores SPO<sub>2</sub> values in the range of 50 to 100%.
    - 10.2.2. The device updates the SPO<sub>2</sub> displayed value (on average) every 4, 8, 12, or 16 seconds.
    - 10.2.3. The saturation accuracy of the SPO<sub>2</sub> circuit shall be 70 to 100%.
    - 10.2.4. The device display saturation rates from the SPO<sub>2</sub> circuit to within  $\pm 2$  digits without motion and  $\pm 3$  with motion.
    - 10.2.5. Historical trended values can be displayed on-screen or on printed trending report.
    - 10.2.6. The device displays pulse rates from 25 to 240 pulses per minute.
    - 10.2.7. The device displays pulse rates from the SPO<sub>2</sub> circuit to within  $\pm 3$  pulses per minute without motion and  $\pm 5$  pulses per minute with motion.
    - 10.2.8. The SPO<sub>2</sub> display section of the monitor shall include a dynamic signal strength bar graph.
    - 10.2.9. The device has user-adjustable sensitivity and averaging time settings to compensate for low perfusion states and patient movement, respectively.
    - 10.2.10. The device emits a pulse tone proportional to the displayed SPO<sub>2</sub> value.
    - 10.2.11. The device can be set up to turn SPO<sub>2</sub> tone to off.
    - 10.2.12. The device is capable of displaying an IR (pleth) waveform.
    - 10.2.13. This waveform is configurable as part of pre-defined lead group with the option to display as a default. SPO<sub>2</sub> waveform has autogain control.
  - 10.3.3. Historical trended values can be displayed on-screen or on printed trending report.

## 10.5. Noninvasive Blood Pressure (NIBP)

- 10.5.1. The device is capable of displaying blood pressure values in mmHg.
- 10.5.2. The device measures Systolic Pressure in range: 30 to 255 mmHg.
- 10.5.3. The device measures Diastolic Pressure in range: 15 to 220 mmHg.
- 10.5.4. The device measures Mean Arterial Pressure (MAP) in range: 20 to 235 mmHg.
- 10.5.5. The device measures BP with accuracy of maximum mean error of  $\pm 5$  mmHg.
- 10.5.6. The device typically performs a blood pressure measurement in 20 seconds.
- 10.5.7. The device measures Pulse rate in range: 30 to 240 PPM.
- 10.5.8. The device measures pulse rate with accuracy  $\pm 2$  PPM or  $\pm 2\%$ , whichever is greater.
- 10.5.9. The device offers a choice of initial cuff inflation pressures.
- 10.5.10. The device can be set to perform automatic recurring measurements at the following set intervals - 2, 3, 5, 10, 15, 30, 60 minutes.
- 10.5.11. The device allows the user to set a pre-defined default setting for NIBP interval.
- 10.5.12. The device allows automatic cuff deflation in case of excessive pressure (greater than 290 Hg) or in case measurement time exceeds 120 seconds.
- 10.5.13. A range of disposable and reusable NIBP cuffs are available, including latex free.
- 10.5.14. NIBP cuffs are single bladder to facilitate placement independent of patient artery for rapid setup.
- 10.5.15. Historical trended values shall be displayed on-screen or on printed report.

### **OR EQUAL**

11. Capnography (EtCO<sub>2</sub> monitoring)
  - 11.1. The device incorporates capnography, using Oridion Microstream<sup>®</sup> technology.
  - 11.2. Capnography monitoring activates automatically upon connecting FilterLine<sup>®</sup> or Smart CapnoLine<sup>®</sup>.
  - 11.3. The device allows monitoring of intubated and non-intubated patients without the need for additional equipment, adapters, or setup.
  - 11.4. The device does not have any CO<sub>2</sub> sensor external to the device due to external sensor vulnerability to damage and high replacement cost.
  - 11.5. The device is capable of displaying CO<sub>2</sub> value in kPa, Vol %, or mmHg.
  - 11.6. The device does not use any separate water traps or filters – these should be integrated into the sensor to facilitate ease of use and setup.
  - 11.7. The device is specific to CO<sub>2</sub> and not adversely affected by the presence of Non-CO<sub>2</sub> gases.
    - There is no requirement for user input to indicate which gases are present.
  - 11.8. The device uses disposable CO<sub>2</sub> intubated and non-intubated sensors to eliminate risk of cross contamination between patients.
  - 11.9. The capnography option is compatible with Oridion FilterLine and Smart CapnoLine CO<sub>2</sub> accessories.
  - 11.10. The device measure CO<sub>2</sub> pressure in range: 0 to 99 mmHg (0 to 13.2kPa). The device shall display CO<sub>2</sub> waveform.
  - 11.11. The device measures CO<sub>2</sub> with the following accuracy:
    - 11.11.1. 0 to 80 bpm: 0 to 38 mmHg ±2 mmHg; 39 to 99 mmHg ±5% of reading plus 0.08% for every 1mmHg above 38 mmHg.
    - 11.11.2. >80 bpm: 0 to 18 mmHg ±2 mmHg; 19 to 99 mmHg: ±4mmHg or ±12% of reading whichever is higher.
  - 11.12. The device measures respiration rate in a range of 0 to 99 breaths/minute.
  - 11.13. The device measures respiration rate with the following accuracy:
    - 11.13.1. 0 to 70 bpm: ±1 bpm
    - 11.13.2. 71 to 99 bpm: ±2 bpm
  - 11.14. The device has a typical initialization time of 30 seconds.
  - 11.15. The initialization time will not exceed 180 seconds.
  - 11.16. The rise time of the CO<sub>2</sub> waveform is less than or equal to 190 msec.
  - 11.17. The response time of CO<sub>2</sub> waveform including the delay time and rise time is 3.3sec.
  - 11.18. This waveform can be set up as part of pre-defined lead group with the option to display as a default.
  - 11.19. The device automatically compensates for ambient pressure changes.
  - 11.20. Historical trended values display on-screen or on printed report.
  - 11.21. The CO<sub>2</sub> system can be easily calibrated by certified technicians through the service menu using standard procedures with known sample gas value.

**OR EQUAL**

## 12. Invasive Pressure (IP)

- 12.1. The device offers two (2) channels of Invasive Pressure monitoring, with both waveform and numerics displayed. Channels will activate automatically once cables are connected. The device allows connection of sensors that are compliant with industry standard AAMI BP22 pressure transducers with  $5\mu\text{V}/\text{V}/\text{mmHG}$  sensitivity.
- 12.2. The device includes a measurement range of  $-30$  to  $+300\text{mmHg}$  in six selectable ranges.
- 12.3. The device is capable of displaying readings in  $\text{mmHg}$  and includes waveform support.
- 12.4. The device offers user-selectable labels of ART, PA, CVP, ICP and LAP for P1 or P2.
- 12.5. The device is compatible with strain-gauge resistive bridge transducers with a  $5\mu\text{V}/\text{V}/\text{mmHg}$  sensitivity.
- 12.6. The device has a bandwidth of DC-30 Hz ( $<-3\text{dB}$ ).
- 12.7. The device has a numeric accuracy of  $\pm 1\text{mmHg}$  or 2% of reading, whichever is greater, plus transducer error.
- 12.8. Historical trended values display on-screen or on printed report.

### **OR EQUAL**

## 13. Alarms

- 13.1. The device incorporates a Quick Set feature which activates default values for parameter and patient alarms. Alarms are established relative to baseline rate and specific to each vital sign.
- 13.2. The user may select a wide or narrow tolerance of alarms around baseline.
- 13.3. The user may select a range of silence periods for the alarms.
- 13.4. The silence function applies only to the specific alarm that has been violated; new alarms will include an audible tone and are silenced separately.
- 13.5. Audible tone is always provided for VF/VT alarm.
- 13.6. The device incorporates a VF/VT alarm which activates continuous patient surveillance of potentially shockable ECG rhythms during manual mode operation with therapy electrodes and through standard ECG electrodes.

### **OR EQUAL**

## 14. Trending

- 14.1. The device offers on-screen trending with choice of HR, PR (SPO<sub>2</sub>), PR (NIBP), SPO<sub>2</sub> (%), SpO (%), CO<sub>2</sub>(ETCO<sub>2</sub>/FiCO<sub>2</sub>), RR (CO<sub>2</sub>), NIBP, IP1, IP2, or ST.
- 14.2. Trending is activated automatically for each vital sign used – no additional user intervention is required other than opting to view the trended data on-screen.
- 14.3. The device includes a timescale of 30 minutes, 1, 2, 4 or 8 hours, or autoscale.
- 14.4. The device includes up to 8 hours of trend data.
- 14.5. The device includes trending of ST measurement after an initial 12-lead analysis. A 12-lead ECG will automatically print to alert the operator following a series of consistent ST elevations or depressions.
- 14.6. A printed trend summary is available either on-demand or at the conclusion of the event summary.

### **OR EQUAL**

15. Printer

- 15.1. The device prints a continuous strip of the displayed patient information.
- 15.2. The device includes a 100mm (3.9 in) thermal recorder that is easily accessible from the front of the device. Paper shall be of standard roll format to facilitate replacement and minimize waste.
- 15.3. The device prints at 25mm/sec or 12.5mm/sec +/- 5% (measured in accordance with AAMI EC-11, 4.2.5.2).
- 15.4. The delay from display to printing is 8 seconds.
- 15.5. The device allows the operator to set up automatic printing of waveform events as they occur, in any combination.
- 15.6. The device offers the following frequency response settings for the printer:
  - 15.6.1. 0.5 to 40Hz (monitoring frequency)
  - 15.6.2. 1 to 30Hz (monitoring frequency)
  - 15.6.3. 0.05 – 40 Hz (diagnostic frequency)
  - 15.6.4. 0.05 to 150 Hz (diagnostic frequency)

**OR EQUAL**

## 16. Data Management

- 16.1. The device captures and stores patient data, events (including waveforms and annotations), continuous ECG waveform and diagnostic 12-Lead ECG reports in internal memory.
- 16.2. The device allows the operator to enter the following patient information:
  - 16.2.1. Last Name
  - 16.2.2. First Name
  - 16.2.3. Incident ID
  - 16.2.4. Patient ID
  - 16.2.5. Age
  - 16.2.6. Sex
- 16.3. If patient age has been previously entered while acquiring a 12-Lead ECG that value is automatically entered in the age field. If the age has been previously entered into the patient information field noted it will be used when acquiring the first 12-Lead ECG without further user intervention.
- 16.4. The device allows stored reports to be retrieved for transmission to a remote location. Transmitted reports must be received by a personal computer (PC) with appropriate software installed.
- 16.5. The device provides a means to manage archived patient records. Access to these records in the device has optional password protection. Options to manage archived records shall include:
  - 16.5.1. Transmit archived patient records
  - 16.5.2. Print archived patient records
  - 16.5.3. Delete archived patient records
  - 16.5.4. Add demographic data to archived patient records
- 16.6. The total memory capacity of the device is at least 400 single waveform events or 360 minutes of continuous ECG. Maximum memory capacity for a single patient includes up to 200 single waveform reports and 90 minutes of continuous ECG.
- 16.7. Memory is internal rather than by removable cards, to eliminate replacement cost issues and to protect data integrity/patient confidentiality.
- 16.8. The device allows the operator to store the following report options:
  - 16.8.1. Short, medium, or long Code Summary
  - 16.8.2. Initial ECG
  - 16.8.3. Auto vital sign measurements every five minutes and whenever alarm limits are exceeded
  - 16.8.4. 3-channel or 4-channel format 12-Lead ECG report
  - 16.8.5. Continuous waveform - 360 minutes continuous ECG record
  - 16.8.6. Trend summary (includes patient information, vital signs data and vital signs graphs).
  - 16.8.7. Vital Signs – includes patient information, event and vital signs log.
  - 16.8.8. Snapshot – includes patient information and 8 seconds of transmitted ECG captured at the time of transmission.
- 16.9. Data Management Architecture
  - 16.9.1. When transferring data, the device outputs data in a format compatible with hospital cardiology information systems such as the Marquette MUSE CV<sup>®</sup> cardiovascular information system.
  - 16.9.2. The data transferred from the device can be transferred and managed using Web- based distribution and management. The data center is managed by the manufacturer on a 7/24 basis.

## **OR EQUAL**

## 17. Communications

- 17.1. The device is capable of transferring data records via a direct connection to a PC.
- 17.2. The device is capable of transferring data records by an internal Bluetooth to other Bluetooth devices.
- 17.3. The device provides the option of transmitting 12-Lead ECG reports to a personal computer installed with appropriate software via a direct cable or wireless connection.
- 17.4. The device and communication system supports the following 12-lead features:
  - 17.4.1. Alert at the receiving end that a 12-lead ECG has arrived
  - 17.4.2. Transmission to multiple locations
  - 17.4.3. Auto forwarding of 12-lead ECG report
  - 17.4.4. Sharing of electronic 12-lead report via email
  - 17.4.5. Acknowledgement of successful transmission at the device

### **OR EQUAL**

## 18. Power

- 18.1. Battery Options; the device operates using Lithium-ion, rechargeable batteries.
- 18.2. The device operates with one or two batteries; it operates from only one battery at a time, monitors the state of each battery and automatically switches to the second battery when a low battery is detected for the first battery, without interruption of functional operation.
- 18.3. Operating Time; two (2) new fully charged Lithium-ion batteries provide the following prior to shutdown at 20 C (68 F):
  - 18.3.1. Monitoring typical 360 minutes, minimum 340 minutes
  - 18.3.2. Pacing typical 340 minutes, minimum 320 minutes
  - 18.3.3. Defibrillation (360 J) typical 420 shocks minimum 400 shocks
- 18.4. Capacity after Low Battery warning
  - 18.4.1. Monitoring typical 21 minutes, minimum 12 minutes
  - 18.4.2. Pacing typical 20 minutes, minimum 10 minutes
  - 18.4.3. Defibrillation (360 J) typical 30 shocks minimum 6 shocks
- 18.5. The device displays battery icons at the top display area for each battery placed in the device. The battery icons indicate the state of battery charge and which of the two batteries is being used to supply power to the device. Low battery status is indicated with a low battery icon, flashing battery icon and a low battery message warning message.
- 18.6. The batteries icons will not be active for any battery pack not provided from the original manufacturer.
- 18.7. The Lithium-ion batteries have four horizontal bars, or battery charge indicators that indicate when the individual battery has: greater than 70% charge (four bars), greater than 50% charge (three bars), greater than 25% charge (two bars), and 25% or less charge (one bar).
- 18.8. When both batteries reach a low battery condition, the device emits an audible voice prompt to replace the battery.
- 18.9. The device retains the operator parameter settings with an inadvertent power loss of less than 30 seconds.
- 18.10. The device displays a service indicator when a fault is detected.

### **OR EQUAL**

## 19. Maintenance

- 19.1. Each time the monitor/defibrillator is powered on, it performs internal self-tests to check that internal electrical components and circuitry work properly.
- 19.2. The defibrillator stores the results of all user-initiated self-tests in a test log.
- 19.3. When the defibrillator is on and a problem is detected that requires immediate service, such as a malfunctioning charging circuit, the Service LED is illuminated.
- 19.4. The defibrillator performs an automatic self-test daily at 03:00 (3:00 A.M.), if not in use.

During the automatic self-test, the defibrillator turns itself on (**ON LED** illuminates) briefly, completes self-test, stores the self-test results in a test log and turns itself off.
- 19.5. The device is capable of a manual user test that includes charging and discharging the defibrillator, and printing a report.
- 19.6. The device has provision to transfer the test log report to a PC by a cable or by wireless means.
- 19.7. The device has provisions to upgrade for future AHA specifications.
- 19.8. The device offers a user replaceable screen protector.
- 19.9. The device offers a removable/Interchangeable shock-absorbing handle.

## **OR EQUAL**

## 20. Physical Characteristics

- 20.1. The device does exceed the following weight limits:
  - 20.1.1. Basic monitor/defibrillator with new roll of paper and two batteries installed  
8.6 kg  
(18.9 lb)
  - 20.1.2. Full featured monitor/defibrillator with new roll of paper and two batteries installed 9.1 kg (20.1 lb)
  - 20.1.3. Lithium-ion battery: 0.59 kg (1.3 lb)
  - 20.1.4. Accessory bags and shoulder strap: 1.77 kg (3.9 lbs)
  - 20.1.5. Standard paddles: 0.95 kg (2.1 lbs)
- 20.2. The device does exceed the following dimensions:
  - 20.2.1. Height: 31.7cm (12.5 in).
  - 20.2.2. Width: 40.1cm (15.8 in).
  - 20.2.3. Depth: 23.1cm (9.1 in).

## **OR EQUAL**

21. Environmental conditions for operation as specified
  - 21.1. The device operates from 0° to 45°C (32° to 113°F). It operates from -20° to 0° C (-4° to 32° F) or 45° to 60°C (113° to 160°F) for 1 hour after storage at room temperature.
  - 21.2. The non-operating temperature range of the device is -30° to +70°C (-22° to 158°F) except therapy electrodes and batteries.
  - 21.3. The device operates in relative humidity from 5 to 95%, non-condensing.
  - 21.4. The device operates from ambient to 429mmHg (-1,253 to 15,000 ft) with NIBP: -152 to 3,048 m (-500 to 10,000 ft).
  - 21.5. The device meets vibration per MIL-STD-810E Method 514.4, Propeller Aircraft - category 4 (figure 514.4-7 spectrum a) Helicopter - category 6 (3.75 Grms), Ground Mobile - category 8 (3.14 Grms) EN 1789: Sinusoidal Sweep, 1 octave/min, 10-150 Hz, ±0.15 mm/2 g.
  - 21.6. The device operates after 5 drops on each side from 18 inches onto a steel surface EN 1789: plus a 30-inch drop onto each of 6 surfaces.
  - 21.7. The device operates after a functional shock per IEC 60068-2-27 and MIL-STD-810E shock requirements 3 shocks per face at 40 g, 6 ms half-sine pulses.
  - 21.8. The device operates after 1000 bumps at 15 g with pulse duration of 6 msec.
  - 21.9. The device can withstand an impact per IEC 60601-1 0.5 + 0.05 joule impact UL 60601-1 6.78 Nm impact with 2-inch diameter steel ball: Meets IEC62262 protection level IK 04.
  - 21.10. The device is dust- and splash-proof (IP44) per IEC 529.
  - 21.11. The device meets EMC emissions standards: EN 60601-1-2:2001 Medical Equipment - General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests, EN 60601-2-4:2003: (Clause 36) Particular Requirements for the Safety of Cardiac Defibrillators and Cardiac Defibrillator-Monitors.
  - 21.12. The device withstands 60 hour exposure to the chemicals: Betadine (10% Povidone-Iodine solution), Coffee, Cola, Dextrose (5% Glucose solution), Electrode Gel/Paste (98% water, 2% Carbopol 940), HCL (0.5% solution, pH=1), Isopropyl Alcohol and NaCl (0.9% solution). Cosmetic discoloration of the paddle well shorting bar shall be allowed following exposure to HCL (0.5% solution).

## **OR EQUAL**

22. Configuration Settings
  - 22.1. To prevent unauthorized access to the setup and service menus, the device requires separate 4 digit numeric security passcodes to be entered.
  - 22.2. General: allows selection of the following:
    - 22.2.1. Language choice.
    - 22.2.2. Code Summary format of short, medium, long.
    - 22.2.3. Trend Summary format of short medium, long.
    - 22.2.4. Site number up to 14 characters.
    - 22.2.5. Device ID up to 14 characters.
    - 22.2.6. Auto Log: automatic recording and storage of vital signs every 5 minutes ON or OFF.
    - 22.2.7. Line filter setting of 50 or 60 Hz.
    - 22.2.8. Screen message timeout value of 5, 10 or 30 seconds.

22.3. Manual Mode: allows selection of the following;

- 22.3.1. Resume sync after shock ON or OFF.
- 22.3.2. Pads default energy setting of 2, 5, 10, 50, 100, 125, 150, 175, 200, 225, 250, 275, 300, 325, 360, or Energy Protocol (Power-on energy setting (joules) for standard paddles and therapy electrodes).
- 22.3.3. Energy protocol allows presetting energy for sequence of 3 shocks: each shock may be preset to a value of 150 J to 360 J with the requirement that energy value for shock 2 cannot be less than shock 1 energy level, and the energy value for shock 3 cannot be less than shock 2 energy value.
- 22.3.4. Voice prompts ON or OFF in manual mode.
- 22.3.5. Shock tone ON or OFF when full charge is reached.
- 22.3.6. Manual Access selection of AED / Confirm Once, AED / Confirm Always, AED / Passcode Once, AED / Passcode Always, AED / Restricted.
- 22.3.7. Set passcode to enter manual access when AED / Passcode Once or AED / Passcode Always are selected for Manual Access.

22.4. AED Mode: allows selection of the following:

- 22.4.1. Energy protocol allows presetting energy for sequence of 3 shocks: each shock may be preset to a value of 150 J to 360 J with the requirement the energy value for shock 2 cannot be less than shock 1 energy level, and the energy value for shock 3 cannot be less than shock 2 energy value.
- 22.4.2. Stacked Shocks Enable consecutive shocks without CPR.
- 22.4.3. Automatically analyzes after each shock ON or OFF.
- 22.4.4. Motion detection ON or OFF.
- 22.4.5. Allow a pulse check prompt choices of Never (Never prompt for Pulse Check), After Second NSA (After every “No Shock Advised” (NSA) except for first analysis NSA result), After Every NSA (Only after “No Shock Advised”), or Always (After every three-shock stack and every NSA).

22.5. CPR Setup

- 22.5.1. CPR Time 1 can set CPR interval after each shock to 15, 30, 45, 60, 90, 120, 180 seconds, 30 minutes.
- 22.5.2. CPR Time 2 can set CPR interval after No Shock Advised decision to 15, 30, 45, 60, 90, 120, 180 seconds, 30 minutes.
- 22.5.3. Initial CPR provides the choice to enable an initial CPR time period immediately after the device is turned on, to Analyze first, or to disable an initial CPR time period.
- 22.5.4. Initial CPR Time can be set to 15, 30, 45, 60, 90, 120 or 180 seconds.
- 22.5.5. Pre-Shock CPR provides the ability to have a CPR interval after shock advised decision of 15 or 30 seconds or to be disabled. Note Pre-Shock CPR applies to the second and all subsequent shocks.

22.6. Metronome

- 22.6.1. Enable provides the metronome during CPR and may be Off or On.
- 22.6.2. The C:V ratio for an Adult with No Airway can be set to 30:2, 16:1, 15:2, 12:1, 10:1 or 100:0.
- 22.6.3. The C:V ratio for an Adult with an Airway can be set to: 30:2, 16:1, 15:2, 12:1, 10:1 or

- 100:0.
- 22.6.4. The C:V ratio for a Youth with No Airway can be set to: 30:2, 16:1, 15:2, 12:1, 10:1 or 100:0.
- 22.6.5. The C:V ratio for a Youth with- Airway can be set to: 30:2, 16:1, 15:2, 12:1, 10:1, or 100:0.
- 22.7. Pacing: allows selection of the following:
  - 22.7.1. Default pacing rate of 40 to 170ppm.
  - 22.7.2. Default output current of 0 to 200mA.
  - 22.7.3. Default mode of DEMAND or NON-DEMAND.
  - 22.7.4. Default internal pacing detection ON or OFF.
- 22.8. Monitoring Setup allows selection of the following;
  - 22.8.1. Channels... Set up to 5 groups of multi-channel waveforms to display as follows:
    - 22.8.1.1.Set 1 Select multi-channel waveforms for Set 1
    - 22.8.1.2.Set 2 Select multi-channel waveforms for Set 2
    - 22.8.1.3.Set 3 Select multi-channel waveforms for Set 3
    - 22.8.1.4.Set 4 Select multi-channel waveforms for Set 4
    - 22.8.1.5.Set 5 Select multi-channel waveforms for Set 5
  - 22.8.2. Channel 1 waveform selections include: Paddles, ECG Lead I, ECG LEAD II, ECG Lead III, aVR, aVL, aVF, V1, V2, V3, V4, V5 or V6. Note 2 When a 3-lead cable is used, Channel 1 displays only ECG leads I, II, or III, even if any other lead (except Paddles lead) is selected in setup. Paddles selection in Channel 1 suppresses ECG lead selections in Channels 2 and 3.
  - 22.8.3. Channel 2 waveform selections include: None, Cascading ECG, ECG Lead I, ECG Lead II, ECG Lead III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6, CO2, P1, P2 or SpO2.
  - 22.8.4. Channel 3 waveform selections include: None, ECG Lead I, ECG Lead, II, ECG Lead III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6, CO2, P1, P2, or SpO2.
  - 22.8.5. Continuous ECG storage of ECG waveform Off or On.
  - 22.8.6. SpO2 Tone SpO2 Pulse tone Off or On.
  - 22.8.7. CO2... Set up CO2 defaults as follows:
    - 22.8.7.1.Set CO2 units of measure to mmHg, kPa or %
    - 22.8.7.2.Set body temperature correction factor for EtCO2 value to Off or On
  - 22.8.8. NIBP... Set up NIBP defaults as follows:
    - 22.8.8.1.Initial cuff pressure to 180, 160, 140, 120, 100, or 80 mmHg.
    - 22.8.8.2.Measurement interval to Off, 60, 30, 15, 10, 5, 3 or 2 minutes.

22.9. 12-lead ECG acquisition. The device uses the University of Glasgow 12-Lead ECG Analysis

Program and provides the following setup choices:

- 22.9.1. Transmit automatically on acquisition Off or On.
  - 22.9.2. Print automatically on acquisition Off or On.
  - 22.9.3. Print speed for 3-Channel 12-Lead report of 25 mm/sec or 50 mm/sec
  - 22.9.4. 12-Lead interpretation Off or On.
  - 22.9.5. Print format for 12-Lead reports of 3-Channel Standard, 4-Channel Standard, 3- Channel Cabrera or 4-Channel Cabrera.
- 22.10. Events: allows selection of the following:
- 22.10.1. Selection of events 2 through 11 from a pre-configured list.
  - 22.10.2. Selection of events 12 through 22 from a pre-configured list.
  - 22.10.3. User customization of up to 18 events to be included in the list.
- 22.11. Alarms: allows selection of the following:
- 22.11.1. Set volume for alarms, tones, and voice prompts.
  - 22.11.2. Enable or disable parameter alarms at power up.
  - 22.11.3. VF/VT alarm enabled or disabled.
- 22.12. Printer: allows selection of the following:
- 22.12.1. Auto print event selection:
    - 22.12.1.1. Print defibrillation events ON or OFF
    - 22.12.1.2. Print pacing events ON or OFF
    - 22.12.1.3. Print CHECK PATIENT events ON or OFF
    - 22.12.1.4. Print SAS events ON or OFF
    - 22.12.1.5. Print patient alarms ON or OFF
    - 22.12.1.6. Print operator annotated events ON or OFF
    - 22.12.1.7. Print initial rhythm ON or OFF
  - 22.12.2. Default ECG frequency response of:
    - 22.12.2.1. Monitor 0.5 - 40Hz
    - 22.12.2.2. Diagnostic 0.05 - 150Hz
  - 22.12.3. Print alarm Waveforms with an alarm events in CODE SUMMARY Off or On.
  - 22.12.4. Print event waveforms with user-entered events in CODE SUMMARY Off or On.
  - 22.12.5. Print waveforms with vital signs in CODE SUMMARY On or Off.

- 22.13. Transmission: allows selection of the following:
  - 22.13.1. Setup 72 data transmission sites
    - 22.13.1.1 Site name up to 14 characters
    - 22.13.1.2. Output port to Bluetooth<sup>®</sup>, Direct Connect or both
    - 22.13.1.3. Clear list of site
    - 22.13.1.4. Select default destination site to None. After sites are defined or select from the list.
    - 22.13.1.5. Select default report for data transmission of Snapshot, All, Code Summary, Trend Summary, Vital Signs, 12-Lead or Continuous ECG.
    - 22.13.1.6. Wireless Enable wireless communication Off or On.
    - 22.13.1.7. Enable filtering of Bluetooth device searches to On or Off.
  - 22.13.2. Clock: allows selection of the following:
    - 22.13.2.1. Set the current date and time.
    - 22.13.2.2. Select real or elapsed time on the display.
    - 22.13.2.3. Daylight Savings Time ON or OFF.
    - 22.13.2.4. Select time zone form non or Universal Time code for 74 time zones
  - 22.13.3. Reset Defaults: allows selection of the following:
    - 22.13.3.1. Cancel and return to Setup Screen.
    - 22.13.3.2. Reset all values to the factory default settings.
  - 22.13.4. Print Defaults: Provides printout of the current device configuration setup.
  - 22.13.5. Send Configuration: Transfer the device setup configuration to another device.
  - 22.13.6. Set Passcode: allows selection of the following:
    - 22.13.6.1.1 Set passcode to enter Setup mode (the current passcode appears 0000). Rotate and press SPEED DIAL to select digits.
    - 22.13.6.1.2. Select passcode access for Archives mode to No Passcode, Archives Only, Delete Only, Archives/Delete.
    - 22.13.6.1.3. Set passcode to enter Archives mode 0000 (Rotate and press SPEED DIAL to select digits).
  - 22.13.7. Delete Records... Set passcode to delete records in Archives mode 0000. (Rotate and press SPEED DIAL to select digits.)
  - 22.13.8. The device allows the entire list of configuration settings to be transferred to other identical devices via the Configuration Setup Tool Software application using a direct connect cable, thereby eliminating the need to configure Setup Options on each device separately.

**OR EQUAL**

**23. Other**

- 23.1. Device is designed to help the operator meet HIPAA (Health Insurance Portability and Accountability Act of 1996) requirements.