



TOWN OF  
**NORTH KINGSTOWN, RHODE ISLAND**

FIRE DEPARTMENT  
PUBLIC SAFETY BUILDING  
8150 POST ROAD  
NORTH KINGSTOWN, R.I. 02852

401-294-3346  
401-294-4180 FAX

**INVITATION FOR BIDS  
HEART MONITOR/ DEFIBRILLATOR**

Sealed proposals for the above will be accepted in the Office of the Purchasing Agent, Town Municipal Offices, 100 Fairway Drive, North Kingstown, RI 02852, until **10:00am on Friday, November 10, 2017**, and will then be publicly opened read aloud.

**NO BIDS WILL BE ACCEPTED AFTER THE FRIDAY, NOVEMBER 10, 2017, 10:00AM DEADLINE.**

**IT IS THE RESPONSIBILITY OF THE PROSPECTIVE BIDDERS TO MONITOR THE TOWN'S WEBSITE FOR ANY SUBSEQUENT BID ADDENDUM. NO ADDENDA WILL BE ISSUED OR POSTED WITHIN FORTY-EIGHT (48) HOURS OF THE BID SUBMISSION DEADLINE.**

The bid will be evaluated as to R.I.G.L. 45-55-5. (2) "Competitive Sealed Bidding" and the award shall be made on the basis of the lowest evaluated or responsive bid price.

Specifications may be obtained at the Purchasing Agent's Office at address listed above.

A certificate of Insurance showing \$1 million General Liability and \$1 million Any Auto, with the Town being named as an additional insured, Worker's Compensation, with a waiver of subrogation will be required of the successful bidder.

The Town of North Kingstown reserves the right to reject any or all proposals or parts thereof; to waive any formality in same, or accept any proposal deemed to be in the best interest of the Town.

The Town of North Kingstown will provide interpreters for the hearing impaired at any pre-bid or bid opening, provided a request is received three (3) days prior to said meeting by calling 294-3331, ext. 142.

**Purchasing Agent**

## SELECTION CRITERIA

**The bid will be evaluated as to R.I.G.L. 45-55-5.(2) “Competitive Sealed Bidding”, and the award shall be made on the basis of the lowest evaluated or responsive bid price.**

The following factors will be considered in determining the lowest evaluated or responsive bid price:

Bid Price;

Meets or exceeds bid specifications;

Delivery date;

Warranty/Guarantee;

Past performance by brand name bid;

**TOWN OF NORTH KINGSTOWN, RHODE ISLAND  
INFORMATION FOR BIDDERS**

**ARTICLE 1. RECEIPT AND OPENING OF BIDS**

Sealed bids must be submitted in SEALED ENVELOPES, addressed to the Purchasing Agent, Town Hall, 100 Fairway Drive, North Kingstown, Rhode Island 02852, and clearly marked with the name of the item bid, and the date and time of opening. Bids will be received by the Purchasing Agent up to the specified time as noted on the Invitation to Bid, and publicly opened and read aloud at the specified time.

It is the bidder's responsibility to see that his bid is delivered within the time and at the place prescribed. Proposals received prior to the time of opening will be securely kept unopened. No responsibility will attach to any officer or person for the premature opening of a proposal not properly addressed and identified.

Any bid received after the time and date specified shall not be considered, by messenger or by mail, even if it is determined by the Town that such non-arrival before the time set for opening was due solely to delay in the mails for which the bidder is not responsible. Conditional or qualified bids will not be accepted.

**ARTICLE 2. PREPARATION OF BID**

Each bid must be submitted on the prescribed form. All blank spaces for bid prices must be filled in, in ink or typewritten, both in words and figures. Erasures or other changes must be explained or noted over the signature of the bidder.

Each bid must be submitted in sealed envelopes, clearly labeled, so as to guard against opening prior to the time set therefore.

The Town may consider any bid not prepared and submitted in accordance with the provisions hereof and reserves the right to reject any or all proposals in whole or in part, toward any item, group of items, or total bid; to waive any technical defect or formality in same, or to accept any proposal deemed to be in the best interest of the Town.

**ARTICLE 3. TELEGRAPHIC MODIFICATION**

Telephonic, telegraphic or oral bids, amendments or withdrawals will not be accepted.

**ARTICLE 4. WITHDRAWAL OF BIDS**

Bids may be withdrawn personally or by written request at any time prior to the time specified for the opening. Bids may be modified in the same manner. Negligence on the part of the bidder in preparing the bid confers no right of withdrawal or modifications of his bid after such bid has been opened.

## **ARTICLE 5. QUALIFICATIONS OF THE BIDDER**

The Town reserves the right to request each bidder to present evidence that he is normally engaged in purveying the type of product or equipment bid on. No bid shall be considered from bidders who are unable to show that they are normally engaged in purveying the type of product or equipment specified in the bid proposal.

To receive full consideration, the bidder must submit literature and necessary details, when applicable, on the material or service he proposes to furnish in order that the Town may have full information available when analyzing the proposals.

## **ARTICLE 6. OBLIGATIONS OF THE BIDDER**

At the time of opening of bids, each bidder will be presumed to have inspected the Specifications and Contract Documents (including all addenda) which has been sent to the address given by such bidder. The failure or omission of any bidder to receive or examine any form, instrument, or document shall in no way relieve any bidder from any obligation in respect to his bid.

Any exceptions or deviations from the provisions contained in this Specification must be explained in detail and attached to proposal. If such deviations do not depart from the intent of this notice and are in the best interest of the Town, the proposal will receive careful consideration.

## **ARTICLE 7. PRICES**

Bidders shall state the proposed price in the manner as designated in the Bid Proposal Form. In the event that there is a discrepancy between unit prices and the extended totals, the unit prices shall govern. In the event that there is a discrepancy between the price written in words and written in figures, the prices written in words shall govern.

The prices in this bid shall be irrevocable for ninety (90) days, or until the bid is awarded by the Town Council. After award by the Town Council, said prices shall then remain firm for the duration of the Contract.

## **ARTICLE 8. TAX EXEMPTIONS**

The Town is exempt from payment of the Rhode Island Sales Tax under the 1956 General Laws of the State of Rhode Island, 44-18-30 Para. I, as amended. The Town is exempt from payment of Federal Excise Taxes. The prices bid must be exclusive of taxes and will be so construed. Exemption certificates will be completed as required by the successful bidder.

## **ARTICLE 9. CONTRACT PERIOD AND TERM OF AGREEMENT *(When Applicable to Bid)***

Contract period: ONE (1) CALENDAR YEAR from date set in the Notice to Proceed, with options for years two and three awarded, contingent upon satisfactory performance by the vendor. If financially advantageous to the Town of North Kingstown, these contracts may be renewed or extended, from time to time, when agreed to, in writing, by both parties.

## **ARTICLE 10. LABOR REGULATIONS** *(When Applicable to Bid)*

The following paragraphs regarding nondiscrimination in employment shall be included and become part of these specifications:

- a. Contractors shall comply with the provisions of the General Laws of Rhode Island and attention is called to Title 37, Chapter 13, Section 1-16, relative to the payment of wages, obligations and charges by Contractors on public works projects.
- b. Non-resident Contractors are subject to Section 44-1-6 of the Rhode Island General Laws, as amended. (OUT OF STATE CONTRACTORS.)
- c. The successful bidder will be required to comply with the Davis-Bacon Act (40USC 2 to a-7) as supplemented by Department of Labor regulations (29CFR Part 5).
- d. The successful bidder will be required to comply with the Contract Works Hours and Safety Standards Act (40 USC 327-330) as supplemented by Dept. of Labor Regulations (29CFR, Part 5).
- e. The successful bidder will be required to comply with Executive Order 11246, entitled Equal Employment Opportunity, as amended, and as supplemented in Department of Labor regulations (41 CFR Part 60).
- f. The successful bidder will be required to comply with the Copeland "Anti-Kickback" Act (18 USC 874) as supplemented in Department of Labor regulations (29 CFR, Part 3).
- g. The successful bidder will be required to comply with the Safety and Health regulations (29 CFR, Part 1926 and all subsequent amendments) as promulgated by the Department of Labor.
- h. The successful bidder will be required to comply with Title VI of the Civil Rights Act of 1964 ( P.L. 88-352).

## **ARTICLE 11. INSURANCE** *(When Applicable to Bid)*

The Vendor shall assume responsibility and liability for all injuries to persons or damages to property, directly or indirectly due to, or arising out of, his operations under the contract and shall be responsible for the proper care and protection of all work performed for the Town.

The Vendor shall also indemnify and save harmless the Town of North Kingstown against any and all claims of whatever kind and nature due to, or arising out of, his breach or failure to perform any of the terms, conditions, or covenants of the contract resulting from acceptance of his bid.

The Vendor shall furnish the Purchasing Agent with certificates of insurance from companies acceptable to the Town of North Kingstown. All insurance companies listed on certificates must be licensed to do business in the State of Rhode Island. The Vendor shall provide a certificate of insurance as specified in the bid specifications. Contracts of insurance (covering all operations under this contract) shall be kept in force until the contractor's work is acceptable by the Town.

The limits of the insurance must be at least in the amounts specified below;\*

1. Commercial General Liability-Occurrence Form \$1,000,000/\$1,000,000.
2. Automobile Liability - \$1,000,000. With both of the above naming the Town as additional insured.

3. Worker's Compensation (if legally allowed and available). Waiver of subrogation applies to Worker's Compensation

The Vendor shall secure, pay for and maintain insurance as necessary to protect himself against loss of owned or rented capital equipment and tools, with provision for waiver of subrogation against the Owner.

## **ARTICLE 12. LAWS, ORDINANCES, AND CODES**

All applicable Federal and State Laws, Ordinances and Codes of the Town of North Kingstown and regulations of all authorities having jurisdiction over this Project shall apply to this contract the same as though written herein in full.

The Town of North Kingstown will not award the Contract to any Contractor who is, at the time, ineligible under the provisions of any applicable regulations issued by the Secretary of Labor, United State Department of Labor, or is not qualified under applicable Ordinances of the Town of North Kingstown, or the laws of the State of Rhode Island.

**TOWN OF NORTH KINGSTOWN, RHODE ISLAND**  
**INSURANCE REQUIREMENTS**  
**(When Applicable to Bid)**

The Town's Insurance requirements are as follows:

One million dollars general liability and one million dollars auto, both naming the Town as additional insured.

Worker's Compensation, with a waiver of subrogation

*(If the vendor does not have worker's comp, they need to fill in an Independent Contractor form which they send to the State of RI and they in turn, will send us a notification that the person/firm is an Independent Contractor. They stay as that until they let the State know that they are no longer that status.)* On the State website is a list of Independent Contractors by Town and by vendor's name  
(See Town Ordinance 08-01 dated 1-14-2008)

**There is also specialized insurance required on certain projects**

Asbestos liability, one million dollars, with the Town named as additional insured for the obvious- Asbestos Removal

Lead Remediation requires \$5,000,000.00 Annual aggregate

Any building projects over \$500,000.00 requires us to notify Colleen Bodziony at The Trust, and Builder's Risk insurance may/shall be required on a building construction project. You may need to call and ask her before the bid specifications are finalized.

Architectural and Engineering projects require one million dollars professional liability, also called Errors and Omission policy.



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401-294-3346  
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**It is the intent of the Fire Department of the Town of North Kingstown to purchase two (2) Heart Monitor/ Defibrillators with this Invitation to Bid.**

**The Fire Department currently has two (2) Physio Control Lifepak 12, approximately ten (10) years old that we would like to offer as trade in towards the purchase. In submitting your bid on the Bid Proposal sheet, please indicate the amount you will be offering for the trade, if any.**

**If you would like to review these units before the bid submission, contact Scott G. Kettelle, Fire Chief at 401-294-3346 extension 7200.**

## Town of North Kingstown - Product Specifications for Heart 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.

### 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/SpMet all use a common connection and include lock out for incompatible sensors. SpO<sub>2</sub>/SpCO/SpMet 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.
- 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.

### 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 Ohms  $\pm 2J$  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.
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, Pre-shock 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, SpO<sub>2</sub> 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.
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 settings; 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 30, 50, 70, 100, 125, 150, 175, 200, 225, 250, 275, 300, 325 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 controls or from controls located on the paddles.

## 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 control.
- 6.4. During synchronous cardioversion, the device begins energy transfer within 60ms of the QRS peak.
- 6.5. The Synch Mode may be set up to return to asynchronous mode after a synchronize shock or 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 +/- 1.5 ms).
- 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 pacing rate by a factor of 4, to allow assessment of the patient's underlying ECG rhythm.
- 7.9. 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.

## 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 300bpm.
  - 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).
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 ( $S_{pO_2}$ ), Carbon Monoxide ( $SpCO$ ) and Methemoglobin ( $SpMet$ ) monitoring
  - 10.1. The device incorporates  $S_{pO_2}$ ,  $SpCO$  and  $SpMet$  monitoring using Masimo<sup>®</sup> Rainbow<sup>®</sup> technology and compatible sensors.
  - 10.2. Pulse Oximetry ( $S_{pO_2}$ )
    - 10.2.1. The device measures, displays and stores  $S_{pO_2}$  values in the range of 50 to 100%.
    - 10.2.2. The device updates the  $S_{pO_2}$  displayed value (on average) every 4, 8, 12, or 16 seconds.
    - 10.2.3. The saturation accuracy of the  $S_{pO_2}$  circuit shall be 70 to 100%.
    - 10.2.4. The device display saturation rates from the  $S_{pO_2}$  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  $S_{pO_2}$  circuit to within  $\pm 3$  pulses per minute without motion and  $\pm 5$  pulses per minute with motion.
    - 10.2.8. The  $S_{pO_2}$  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  $S_{P}O_2$  value.
- 10.2.11. The device can be set up to turn  $S_{P}O_2$  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.  $S_{P}O_2$  waveform has autogain control.
- 10.3. Carbon Monoxide ( $SpCO$ )
  - 10.3.1. The device measures, displays and stores  $SpCO$  values in the range of 0 to 40%.
  - 10.3.2. The device displays  $SpCO$  values to within  $\pm 3$  digits accuracy.
  - 10.3.3. Historical trended values can be displayed on-screen or on printed trending report.
- 10.4. Methemoglobin ( $SpMet$ )
  - 10.4.1. The device measures, displays and stores  $SpMet$  in the range of 0 to 15.0%.
  - 10.4.2. The resolution is 0.1% for  $SpMet$  value from 0 to 10% and 1% for values from 10 to 15%.
  - 10.4.3. The device displays  $SpMet$  circuit to within  $\pm 1$  digits accuracy.
  - 10.4.4. 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.

## 11. Capnography ( $EtCO_2$ 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  $CO_2$  sensor external to the device due to external sensor vulnerability to damage and high replacement cost.
- 11.5. The device is capable of displaying  $CO_2$  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. 0-80 bpm: 0 to 38 mmHg  $\pm 2$  mmHg  
39 to 99 mmHg  $\pm 5\%$  of reading plus 0.08% for every 1 mmHg above 38 mmHg
  - 11.11.2. > 80 bpm: 0 to 18 mmHg  $\pm 2$  mmHg  
19 to 99 mmHg  $\pm 4$  mmHg or  $\pm 12\%$  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:  $\pm 1$ bpm
  - 11.13.2. 71 to 99 bpm:  $\pm 2$ 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. The device automatically compensates for ambient pressure changes.
- 11.19. Historical trended values display on-screen or on printed report.
- 11.20. 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.

## 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 5pVN/mmHG sensitivity.
- 12.2. The device includes a measurement range of -30 to +300mmHg in six selectable ranges.
- 12.3. The device is capable of displaying readings in 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 5pV/V/mmHg sensitivity.
- 12.6. The device has a bandwidth of DC-30 Hz (<-3dB).
- 12.7. The device has a numeric accuracy of  $\pm 1$  mmHg or 2% of reading, whichever is greater, plus transducer error.
- 12.8. Historical trended values display on-screen or on printed report.

## 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 and 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.

#### 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> (%), SpCO (%), SpMet (%), 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.

#### 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. Monitoring frequency: 0.67 to 40 Hz
  - 15.6.2. Monitoring frequency: 1 to 30 Hz
  - 15.6.3. Diagnostic frequency: 0.05 to 40 Hz
  - 15.6.4. Diagnostic frequency: 0.05 to 150 Hz

#### 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™ reports
  - 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® 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.

## 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

## 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 (360J) 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 (360J) 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

## 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.

## 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 lbs)
  - 20.1.2. Full featured monitor/defibrillator with new roll of paper and two batteries installed 9.1 kg (20.1 lbs)
  - 20.1.3. Lithium-ion battery: 0.59 kg (1.3 lbs)
  - 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)

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 3,048m (-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).

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 150J to 360J 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 150J to 360J 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 170 ppm.
  - 22.7.2. Default output current of 0 to 200 mA.
  - 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, CO<sub>2</sub>, P1, P2 or SpO<sub>2</sub>.
  - 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, CO<sub>2</sub>, P1, P2, or SpO<sub>2</sub>.
  - 22.8.5. Continuous ECG storage of ECG waveform Off or On.
  - 22.8.6. SpO<sub>2</sub> Tone SpO<sub>2</sub> Pulse tone Off or On.
  - 22.8.7. CO<sub>2</sub>... Set up CO<sub>2</sub> defaults as follows:
    - 22.8.7.1. Set CO<sub>2</sub> units of measure to mmHg, kPa or %
    - 22.8.7.2. Set body temperature correction factor for EtCO<sub>2</sub> 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 PATIENTS 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 – 40 Hz
      - 22.12.2.2. Diagnostic 0.05 – 150 Hz
    - 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. Set passcode to enter Setup mode (the current passcode appears 0000). Rotate and press SPEED DIAL to select digits.
  - 22.13.6.2. Select passcode access for Archives mode to No Passcode, Archives Only, Delete Only, Archives/Delete.
  - 22.13.6.3. 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.

## 23. Power Adapters

- 23.1. Power Adapters provide operation and battery charging from external AC or DC power
- 23.2. Full functionality with or without batteries when connected to external AC/DC
- 23.3. Typical battery charge time via power adapters is 190 minutes
- 23.4. Auxiliary power indicator on defibrillator illuminated when connected to auxiliary power.
- 23.5. Battery charging indicator illuminated when batteries are fully charged and flashing if either battery is being charged. A means for attaching the power adapter to the device is available.

## 24. Other

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

## 25. Temperature Monitoring

- 25.1. The device offers both invasive temperature and surface temperature monitoring via disposable patient sensors. The temperature measurement will automatically populate on screen when the sensor is placed in/on the patient.
- 25.2. Temperature monitoring range is from 24.8° to 45.2°C (76.6° to 113.4°F)
- 25.3. The Resolution shall be: 0.1°C
- 25.4. The measurement Accuracy shall be : ±0.2°C including sensor
- 25.5. The device must have the following Accessories:
  - 25.5.1. Reusable Temperature Cable: 5 foot or 10 foot
  - 25.5.2. Disposable Sensor Types:
    - 25.5.2.1. Surface for reading Skin temp;
    - 25.5.2.2. Esophageal/Rectal for core monitoring;
    - 25.5.2.3. Foley Catheter for core monitoring.

25.6. The connection point at the monitor must utilize Molex style connectors.

26. Continuous waveforms.

26.1. LIFEPAK 15 captures all the continuous waveforms that are displayed.

26.2. In CODE STAT 9.0 or greater, continuous waveforms can be viewed for post-event review.  
For example, the waveforms for capnography and SpO<sub>2</sub> can be viewed.

27. STEMI Recognition

27.1. Measures the STJ levels and then prints them on a 12-lead.

27.2. The STJ Levels are automatically printed anytime that a 12-lead is printed.

27.3. After the first 12-lead acquisition, if a patient's STJ levels have shifted by 1mm for 2.5 minutes in any lead, the monitor automatically prints another 12-lead ECG and notes the new STJ levels on the printout.

28. Voice Recording

28.1. With the Titan II Wireless Audio Gateway attached to the LIFEPAK 15, the Audio Gateway automatically records audio.

28.2. 270 minute capacity.

28.3. Up to 90 minutes per episode.

28.4. Audio recordings can be heard in versions of CODE-STAT 9.0 software or greater.

**TOWN OF NORTH KINGSTOWN  
HEART MONITOR – DEFIBRILLATOR  
FIRE DEPARTMENT  
BID PROPOSAL**

**To: Town Of North Kingstown  
100 Fairway Drive  
North Kingstown, RI 02852-5762**

**I, (We) the undersigned, agree to furnish to the Town of North Kingstown, TWO (2) Heart Monitor/Defibrillator devices according to the specifications:**

**Make:** \_\_\_\_\_ **Model:** \_\_\_\_\_

\_\_\_\_\_ \$ \_\_\_\_\_  
**(Price in words) (Price in figures)**

**Less Trade-In (if applicable): two (2) Physio Control Lifepak 12**

**TOTAL TRADE-IN** \$ \_\_\_\_\_

**GRAND TOTAL** \$ \_\_\_\_\_

**Warrantee / Guarantee:** \_\_\_\_\_

**DELIVERY DATE:** \_\_\_\_\_

**TERMS:** \_\_\_\_\_

**COMPANY NAME:** \_\_\_\_\_

**ADDRESS:** \_\_\_\_\_

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

\_\_\_\_\_  
**(Please print name and title)**

**TELEPHONE #:** \_\_\_\_\_ **DATE:** \_\_\_\_\_

**EMAIL:** \_\_\_\_\_