# Lake Ozark Fire Protection District

**REQUEST FOR PROPOSALS**
**FOR**

**Cardiac Monitors/Defibrillators**
**Automatic External Defibrillators**
**Cardiac Compression Device**

Address Official Response to:
1767 Bagnell Damn Blvd.
Lake Ozark, MO. 65049

ISSUE DATE: 08/31/18

## SECTION I – GENERAL OVERVIEW

A. PURPOSE

Lake Ozark Fire Protection District is issuing this Request for Proposals (RFP) to solicit **sealed** proposals from qualified Vendors for Cardiac Monitors/Defibrillators, Cardiac Compression Devices, and Automatic External Defibrillators.

B. RFP TIMETABLE

The schedule for the RFP is as follows:

| | |
|---|---|
| Notice of *Request for Proposals* published | 08/31/18 |
| Sealed RFP Responses Due | 8/19/18 by COB, 1600 HRS CST |
| Tentative Award Date | After Comprehensive Review |

Vendors are encouraged to contact Division Chief Tim Dorsey, tdorsey@lofpd.com to clarify any part of the RFP requirements. All questions that arise **prior to** the deadline shall be directed to the contact person in writing via email. Responses to questions will be sent to the email address of record of all proposers who have requested and received a copy of this RFP. Any unauthorized contact shall not be used as a basis for responding to this RFP and also may result in the disqualification of the vendor's submittal.

Vendors may not contact any elected official or other Lake Ozark Fire Protection District employee to discuss the bid process or bid opportunities except: through the contact named herein; or as provided by existing work agreement(s). This policy shall be strictly enforced and the Lake Ozark Fire Protection District reserves the right to reject the submittal of any vendor violating this provision.

C. INSTRUCTIONS FOR RFP RESPONSE:

Bids must be received in sealed envelopes with the words **"Sealed Bid For Cardiac Devices"** and the date that the bids are to be opened must be prominently displayed on the front of the envelope.

Respondents shall include one (1) original and three (3) copies of the entire RFP response.

D. LATE SUBMITTAL AND LATE MODIFICATIONS

Submittals received after **09/19/18 at 1600HRS CST** will not be considered. Modifications received after the opening date will not be considered. Lake Ozark Fire Protection District assumes no responsibility for the premature opening of a proposal not properly addressed and identified, and/or delivered to an improper designation.

E. REJECTION OF PROPOSALS/CANCELLATION

Lake Ozark Fire Protection District reserves the right to reject any and all submittals and reserves the right to waive any irregularities or informalities in any submittal or in the submittal procedure, when to do so would be to the advantage of Lake Ozark Fire Protection District reserves the right to cancel this RFP at any time.

Lake Ozark Fire Protection District shall be the sole judge of the provider's ability to meet the requirements set forth. The decision in determining responsible and responsive provider(s) will be final. Lake Ozark Fire Protection District reserves the right to act in its best interest and choose the **Best** bid for the Fire District in this determinations process, to waive all technicalities, and to select the most responsible and responsive provider providing the **Best** services to the Fire District.

F. MINIMUM RFP ACCEPTANCE PERIOD

Submittals shall be valid and may not be withdrawn for a period of one hundred twenty (120) days from the date specified for receipt of submittals.

All expenses involved with the preparation and submission of the RFP to Lake Ozark Fire Protection District, or any work performed in connection therewith is the responsibility of the vendor(s).

G. OPEN RECORDS

All materials submitted in connection with this RFP will be public documents and subject to the Open Records Act and all other laws of the State of Missouri, and the open records policies of Lake Ozark Fire Protection District. All such materials shall remain the property of Lake Ozark Fire Protection District and will not be returned to the respondent.

## Section II SPECIFICATIONS

## 5 – Cardiac Monitor/Defibrillators

**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.

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.
August 2012 2
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. $CO_2$ connector accepts sensors for intubated and non-intubated patient applications
without additional adapters, to maximize clinical functionality. $CO_2$ monitoring activates automatically when a sensor is connected.
2.3.5. $SpO_2$/SpCO/SpMet all use a common connection and include lock out for incompatible sensors. $SpO_2$/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. ±1J or 10% of setting, whichever is greater, into 50 Ohms.
3.2.2. ±1J or 10% of setting, whichever is greater, into 50 Ohms ±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 $cm_2$.
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.
August 2012 3
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, $SpO_2$ 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 he 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 200 mA.
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® 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, Ill with the 3-wire cable.
8.2.2. Leads I, II, Ill, AVR, AVL, and AVF with the 4-wire cable (simultaneous acquisition).
8.2.3. Leads I, II, Ill, AVR, AVL, AVF and C with the 5-wire cable (simultaneous acquisition).
8.2.4. Leads I, II, Ill, 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).

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 ($SpO_2$), Carbon Monoxide (SpCO) and Methemoglobin (SpMet) monitoring
10.1. The device incorporates $SpO_2$, SpCO and SpMet monitoring using Masimo® Rainbow® technology and compatible sensors.
10.2. Pulse Oximetry ($SpO_2$)
10.2.1. The device measures, displays and stores $SpO_2$ values in the range of 50 to 100%.
10.2.2. The device updates the $SpO_2$ displayed value (on average) every 4, 8, 12, or 16 seconds.
10.2.3. The saturation accuracy of the $SpO_2$ circuit shall be 70 to 100%.
10.2.4. The device display saturation rates from the $SpO_2$ circuit to within ±2 digits without motion and ±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 $SpO_2$ circuit to within ±3 pulses per minute without motion and ±5 pulses per minute with motion.
10.2.8. The $SpO_2$ 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 $SpO_2$ value.
10.2.11. The device can be set up to turn $SpO_2$ 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. $SpO_2$ 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 ±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 ±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 ±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 ±2 PPM or ±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® technology.
11.2. Capnography monitoring activates automatically upon connecting FilterLine® or Smart CapnoLine®.
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 $CO_2$ and not adversely affected by the presence of Non-$CO_2$ gases. There is no requirement for user input to indicate which gases are present.
11.8. The device uses disposable $CO_2$ 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 $CO_2$ accessories.
11.10. The device measure $CO_2$ pressure in range: 0 to 99 mmHg (0 to13.2kPa).The device shall display $CO_2$ waveform.
11.11. The device measures $CO_2$ with the following accuracy:
11.11.1. 0-80 bpm: 0 to 38 mmHg ±2 mmHg
39 to 99 mmHg ±5% of reading plus 0.08% for every 1 mmHg above 38 mmHg
11.11.2. > 80 bpm: 0 to 18 mmHg ±2 mmHg
19 to 99 mmHg ± 4 mmHg 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: ±1bpm
11.13.2. 71 to 99 bpm: ±2bpm

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 $CO_2$ waveform is less than or equal to 190 msec.
11.17. The response time of $CO_2$ 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 $CO_2$ 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 ±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.
August 2012 8
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 ($SpO_2$), PR (NIBP), $SpO_2$ (%), SpCO (%), SpMet (%),$CO_2$($EtCO_2$/$FiCO_2$), RR ($CO_2$), 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 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% Povidonelodine solution), Coffee, Cola, Dextrose (5% Glucose solution), Electrode Gel/Paste (98% water, 2% Carbopol 940), HCL (0.5% solution, pH=1), Isopropyl Alcohol and NaCI (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 orV6. 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, $CO_2$, P1, P2 or $SpO_2$.
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, $CO_2$, P1, P2, or $SpO_2$.
22.8.5. Continuous ECG storage of ECG waveform Off or On.
22.8.6. $SpO_2$ Tone $SpO_2$ Pulse tone Off or On.
22.8.7. $CO_2$... Set up $CO_2$ defaults as follows:
22.8.7.1. Set $CO_2$ units of measure to mmHg, kPa or %
22.8.7.2. Set body temperature correction factor for $EtCO_2$ 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®, 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.
August 2012 15
25.6. The connection point at the monitor must utilize Molex style connectors.
26. Continuous waveforms.
26.1. monitor 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 $SpO_2$ 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 monitor, 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 software.

## 16 – Automatic External Defibrillators

## 4– Automatic External Defibrillator Training Devices

**Defibrillator:**

1.1 Waveform: Device utilizes an escalating ADAPTIV™ biphasic truncated exponential waveform with voltage and duration compensation for patient impedance.

1.2 Output energy accuracy: 10% of the energy setting into 50 ohms. 15 % of the energy settings (150 to 300J) into 25 to 175 ohms. Energy setting at 360J is limited by the amount that can be delivered into 50 ohms.

1.3 Output limit: Device is capable of delivering 360J.

1.4 Energy settings: Device can accommodate three energy levels and be user configurable from 150J to 360J. Device can be deliverable with customer's preferred energy sequence, and can be programmable in setup mode by the customer in the field.

1.5 Operation: Device allows user setup options for analysis

- 1.5.1 Manual initiation of analysis cycles: the operator is required to press an analysis key to initiate every rhythm analysis.
- 1.5.2 The second and third rhythm analysis of each three-shock set is initiated without requiring the operator to press an analyze key.
- 1.5.3 All rhythm analyses are initiated without requiring the operator to press an analyze key.

1.6 Operation: Device guides the operator through operating procedures with

a combination of voice prompts, flashing LEDs, and screen messages on an LCD display.

1.7 Operation: Device prompts the operator to perform CPR after a shock or after no shock advised decision. Device can be configured with the customer's preferred CPR time setting, and the operator will able to change the length of the CPR interval.

1.8 Display: Device displays elapsed time since powered on, number of shocks delivered, remaining CPR time, and messages that support voice prompts.

1.9 Low battery indication: Device alerts operator to low battery condition during use with a combination of icons, screen prompts and voice.

1.10 Self-testing: Device will run a daily self-test, and alert the operator if service is required.

1.11 Device performs a more extensive shelf-test on a monthly basis.

1.12 The battery capacity is checked at every power on, and the device charges as part of the monthly test.

1.13 Charge time: Device will charge with new, non-rechargeable Battery: 200 joules in less than 7 seconds (360J in less than 12 seconds).

1.14 Field upgradeability: Standard with all devices.

1.15 Electrical Protection: Input protected against high voltage defibrillator pulses per IEC 60601-1.

1.16 Safety Classification: Internally powered equipment IEC 60601-1

1.17 Battery capacity: The Readiness Display indicates battery capacity when the device is off.

**Physical Specifications:**

2.1 The dimensions of the device do not exceed 8.7 cm (3.4 in) in height 23.4 cm (9.2in) in width, and 27.7 cm (10.9 in) in depth.

2.2 Device does not exceed 3.2 kg (7.1 lbs) with one set of electrodes and one non-rechargeable battery.

**Shock Advisory Algorithm:**

3.1 ECG analysis: Device completes analysis cycle in 6-9 seconds.

3.2 Device is capable of detecting patient movement. During such motion detection periods, the device delays rhythm analysis for up to 10 seconds, and notifies the operator visually and audibly that motion is detected.

3.3 Device identifies ventricular tachycardia based, in part, on the following criteria:

3.3.1 Minimum heart rate greater than or equal to 120 beats per minute.

3.3.2 No apparent P-waves.

3.3.3 QRS widths greater than 160 milliseconds.

3.4 The device identifies asystole based, in part, on an ECG amplitude of less than 0.08 millivolts.

3.5 The manufacturer can provide clinically relevant evidence of device algorithm sensitivity with the following specifications.

3.5.1 Overall sensitivity for coarse VF in excess of 90%.

3.5.2 Overall specificity for nonshockable rhythms in excess of 95%.

**Environmental and Testing Criteria:**

4.1 One hour Operating Temperature: -20º to 60°C (-4º to 140°F).

4.2 Storage Temperature: -30º to 60ºC (-22º to 140°F) with battery and electrodes, maximum exposure limited to 7 days.

4.3 Atmospheric Pressure: 575 hPa to 1060 hPa (4572 to -382 meters; 15,000 to -1253 ft).

4.4 Relative Humidity: 5% to 95% (non-condensing).

4.5 Dust/Water Resistance: IP55 with battery and REDI-PAK electrodes installed (IEC 60529/EN 60529).

4.6 Bump Test: 15g, 1000 bumps (IEC 60068–2–29).

4.7 Drop: 1 Meter drop on each corner, edge, and surface. (MIL-STD-810F, 516.5, Procedure IV).

4.8 Vibration: Random vibration test - MIL–STD–810F, Method 514.5, Category 20; Ground vehicle 3.15g rms 1 hour per axis.

4.9 Immunity: IEC 60601- 2- 4, IEC 60601-1-2, IEC 61000 - 4 -2, (Level 4), IEC 61000- 4 -3, IEC 61000 -4 -6, IEC 61000 - 4 -8.

4.10 Operating Temperature: 0º to 50º C (32–122ºF).

4.11 Shock: MIL – STD 810F, Method 516.5, Procedure 1, (40 g peak, 15 – 23 ms, 45 Hz crossover frequency).

**Device Settings:**

5.1 Modes:

5.1.1 AED: Displays ECG from QUIK-COMBO® electrodes, graphical and text prompts.

5.1.2 ECG: Displays ECG from the 3-wire cable, graphical and text prompts.

5.1.3 Manual: Provides operating capability for advanced users who may deliver energy at preconfigured energy levels.

5.1.4 Setup: Displays all user configurable setup options; device provides Setup Mode lockout capability.

5.1.5 Data Transfer: Allows users to transfer patient data into CODE-STAT™ post-event review software

5.1.6 Auto Test: Provides daily automatic tests of hardware and software

5.2 Controls: On/Off, Shock, Menu/Manual Override, Two (2) configurable soft keys

5.3 User Defined Options:

5.3.1 Device ID: Assigns unique identifier to particular device.

5.3.2 Energy Range: 150-360 joules; default setting 200-300-360.

5.3.3 Flexible Energy: Increase energy after every shock or when previous energy delivered was unsuccessful.

5.3.4 Auto Analyze: Automatically analyses rhythm initially and after CPR.

5.3.5 CPR Time: Configurable CPR time immediately after each. SHOCK, and after each NO SHOCK advised decision.
5.3.6 Voice Prompt Volume: Changes volume of voice prompts.
5.3.7 ECG Display allows ECG display in AED Mode.
5.3.8 Motion Detection: Allows detection of motion during analysis.
5.3.9 Service Alert: Enables audible tone when device requires attention.
5.3.10 Manual Access: Allows entry to Manual Mode. Devices configured with an ECG display may be set up to allow user to initiate a charge or analysis.

5.4 cprMAX™ Technology settings:
5.4.1 Initial CPR: Setup choice for CPR first or analysis first. Initial CPR time can be set to 15 – 180 seconds.
5.4.2 Preshock CPR: Prompts for CPR after a shockable ECG rhythm is detected. If initial CPR time is set to OFF, then Pre-shock CPR applies to all shock advised decisions (including the first analysis). If initial CPR is enabled,
Pre-shock CPR only applies to the second and subsequent analysis. The defibrillator charges during the Pre-shock CPR period.
5.4.3 Stacked Shocks: Allows delivery of up to three stacked shocks without interposed CPR periods.
5.4.4 Pulse Check: (Always, After Every No Shock Advised, After 2nd No Shock Advised, Never) Allows device to prompt for pulse check either after each shock, after every No Shock Advised, or never prompt for a pulse check.

**Display:**

6.1 Backlit Monochrome LCD displays number of shocks delivered, elapsed time, text and graphics of heart rhythm and optional ECG.
6.2 Size: 120 mm (4.7 in) x 89mm (3.5 in).
6.3 Frequency Response: 0.55 Hz to 21 Hz (–3 dB), nominal.
6.4 ECG Version options:
6.4.1 Waveform Sweep Speed: 25mm/sec for ECG, nominal.
6.4.2 Waveform viewing time: Minimum 4 seconds.
6.4.3 Waveform Amplitude: 1cm/mV, nominal.
6.4.4 Heart Rate: 20 to 300 BPM digital display. Heart symbol flashes for each QRS detection. Display " ---" if heart rate is less than 20 BPM.
6.5 ECG information is received from the adult and Infant/Child electrodes in anterior/lateral position or anterior/posterior position. A 3-wire cable can be used for ECG monitoring (Lead II).

**Event Documentation and Communication:**

7.1 Memory Capacity: Device has the capability of dual patient storage with a minimum of 40 minutes ECG for current patient and summarized data for previous patient.

7.2 Report Types: Continuous ECG, summary (critical resuscitation events and associated ECG waveforms), event log report (report of time stamped markers reflecting operator and device activity), test log report (self-test activity report).
7.3 Capacity: Minimum 100 time-stamped event log entries.
7.4 Data Review: Patient events can be downloaded and reviewed using CODE-STAT post-event review software, LIFENET®
DT EXPRESS reports also include CPR statistics that can be used for process improvement.
7.5 Option to synchronize the device clock to the PC clock.
7.6 Communications: Infrared (IrDA) wireless transfer to personal computer.

**Batteries and Readiness Display:**

8.1 Device operates from 4.5 amp-hour battery.
8.2 Type: Lithium Manganese Dioxide Non-rechargeable (battery gauge indicator on battery): Typical capacity of new battery shall provide 440 200 joule shocks or 1030 minutes of operating time with a new battery (370, 200 joule shocks or 900 minutes of operating time minimum).
8.3 Shelf life: A minimum of 5 years followed by 48 months of standby life.
8.4 Low battery indication: At least 30 shocks at 200J or 75 minutes of operating time remain when low battery is first indicated.
8.5 Device Readiness Display: OK indicator, battery capacity indicator (4 bar), service indicator.
8.6 Standby life (daily tests only): A new battery provides device power for 5 years.

**Electrodes:**

9.1 Performance: Physio-Control electrodes are capable of performing ECG monitoring, pacing and defibrillation. Electrodes can be reconnected to other devices.
9.2 Connection: Device has the capability of being stored with electrodes pre-connected.
9.3 Compatibility: Electrodes are compatible with QUIK-COMBO electrode connection system if used by local advanced life support responders, without requiring purchase of a connectivity solution as with other manufacturer's electrodes.
9.4 Physical: Electrodes have a minimum of conductive adhesive gel contact area of 82 $cm^2$ (12.8 $in^2$).
9.5 Infant/Child Reduced Energy Defibrillation Electrodes: Deliver ¼ selected energy. Intended for use on children up to 8 years of age or 25 kg (55 lbs).

**Technical Service:**

10.1 Device will be covered by a minimum of 5-year warranty on material and workmanship under normal service use.
10.2 Manufacturer certified technicians shall provide technical service on-site.

**Accessories:**

11.1 Available accessories (some are included):
- 11.1.1 Infant-Child reduced energy defibrillation electrodes
- 11.1.2 Battery Replacement Kit
- 11.1.3 Wall mount bracket
- 11.1.4 Wall cabinet with alarm
- 11.1.5 Complete soft shell carrying case (included, installed)
- 11.1.6 Hard shell, watertight carrying case
- 11.1.7 3-wire ECG monitoring cable

**Training Options:**

12.1 Patient Simulator is connected to defibrillator and clip-on training electrodes are attached. These electrodes allow users to practice electrode placement. The simulator connects directly to your device for safe, interactive training without energy transfer to the electrodes.

12.2 Stand-alone training unit that allows potential users to be trained in the use of a defibrillator by simulating corresponding sounds and visual indicators.

12.21 Trainer is capable of demonstrating AED and Manual mode.

12.22 Trainer is fitted with rechargeable Lithium-ion battery. Battery can hold sufficient charge for approximately 4 hours of simulation. Battery can be recharged using AC power.

## 1 – Cardiac Compression Device

Device version • This is the latest version of the LUCAS chest compression system, based on over 15 years of data, over 24,000 devices deployed, and 200+ publications

Type of chest compression

• Piston with suction cup designed to stabilize the compression point
• Suction cup may assist chest recoil
• Factory default settings consistent with AHA and ERC guidelines 2015

Compression rate • Configurable to 102 – 111 – 120 compressions per minute, fixed, or variable during use
• Factory default setting: 102 ± 2 compressions per minute

Compression depth

• Configurable to a fixed value between 1.8 to 2.1 ± 0.1 inches / 45 to 53 ± 2 mm
• Factory default setting: 2.1 ± 0.1 inches / 53 ± 2 mm for nominal patients

Note: 1.5 to 2.1 inches / 40 to 53 mm for chest height < 7.3 inches / 185 mm

Pressure pad during ventilation

• To allow for chest rise during ventilation the pressure pad can be configured to move up 0.4 inch / 10 mm above start position during pauses or during continuous compressions

• Factory default setting: pressure pad remains in start position
Compression
duty cycle
• 50 ± 5%
Compression
modes (operator
selectable)
• ACTIVE 30:2 mode: 30:2 (factory default setting) or 50:2 (setup option)
compression to ventilation ratio
• ACTIVE Continuous mode
Ventilation alerts • ACTIVE 30:2 mode: LED blinks and audible alert signal before ventilation pause
• ACTIVE Continuous mode: LED blink and audible alert. Configurable to 6, 7, 8,
9 or 10 alerts per minute (factory default setting: 10 alerts per minute). Audible
alert configurable ON/OFF (factory default setting: OFF)
Ventilation pause
duration
• ACTIVE 30:2 mode: configurable between 3 to 5 sec.
(factory default setting: 3 sec.)
• ACTIVE Continuous mode: configurable between 0.3 to 2 sec.
(factory default setting: 0.3 sec.)
Suction cup
start position
• Configurable:
-- QuickFit (factory default setting): Manual lowering of the suction cup. Automatic
fine-tuning will occur when locking the start position
-- AutoFit: Automatic lowering of the suction cup from its upper position down to
the chest
-- Manual: Manual lowering of the suction cup to the chest. No automatic finetuning
will occur when locking the start position
Suction cup in
ADJUST mode
• The device can be setup so that the suction cup automatically returns up from the
chest when the operator pushes the ADJUST key coming from PAUSE or ACTIVE
(30:2 or Continuous) modes (factory default setting: OFF)
Audible timers • 1 to 15 minutes, in 1 minute increments (factory default setting: OFF)
• The timer can be setup as either CPR Timer or Continuous Timer
-- CPR Timer: the device only measures the time in uninterrupted ACTIVE (30:2 or
Continuous) modes. Timer starts at first compression
-- Continuous Timer: the device measures the time continuously, independent of
what mode the device is in. Timer starts at first compression

## Bid Specifications

LUCAS® 3 Chest Compression System, version 3.1
Usability • Two part device assembly (back plate and upper part)
• Simple 1-2-3 step user interface
• Device deployment documented as short as 7 sec. (median) in clinical use[1]
• Retains start position during battery change
• Holes in back plate allow for strapping and securing onto transportation device
• Patient and stabilization straps to secure device to patient
• Cath lab compatible as the device is mainly radiotranslucent, except for hood,
piston and metallic screws. Carbon fiber back plate (optional) designed and

optimized for cath lab use
Safety systems
controls
• Automatic self-test at each Power ON
• Advanced control of delivered compression depth, compression rate and duty cycle, with safety alarm
• Soft Start at beginning of compressions
• Automatic adjustment of compression force to reach the set compression depth in individual chests
Patients eligible
for treatment
• 6.7 to 11.9 inches / 17.0 to 30.3 cm chest height
• 17.7 inches / 44.9 cm chest width
• No patient weight limitation
Indications • Adult patients in cardiac arrest where chest compressions are likely to help the patient
• The LUCAS device is intended for use as an adjunct to manual CPR when effective manual CPR is not possible (e.g., during patient transport or extended CPR when fatigue may prohibit the delivery of effective/consistent compressions to the victim, or when insufficient EMS personnel are available to provide effective CPR). (US only)
Contraindications
• Do not use if not possible to position the device safely or correctly on the patient, the patient is too small or too large for the device

Clinical safety
and efficacy data
• Highest level of clinical evidence: a randomized, controlled out-of-hospital trial, showing device is as safe and effective as high-quality manual CPR[3]
• Shown to contribute to over 99% good neurological outcomes at 6 months follow up in out-of-hospital cardiac arrest survivors[3]
• Shown to improve quality of compressions compared to manual CPR
• Shown to reduce interruptions at the scene, during patient movement and transportation compared to manual CPR
• Shown to increase circulation to brain and heart compared to manual CPR
• Documented safe with similar type of side-effects as manual CPR[3,4]
• Shown to increase the opportunities to save patients by serving as a bridge to other lifesaving treatments such as ECMO and PCI
• Shown to improve ROSC and survival chances in resistant cardiac arrest patients
• Shown to create good neurological outcomes despite prolonged CPR of several hours
• Documented high level of operational reliability in multicenter study (>99%)[3]
• Documented 7 sec. (median) application time in real clinical use[1]
• With over 200 scientific publications the device has the largest body of data of any mechanical CPR device. The device is documented to meet the demands throughout the chain of survival.
• Mechanical chest compression devices differ with regards to compression design, application, usability and operational reliability and need to prove and show their own safety and efficacy data. Clinical evidence and usability data from the LUCAS device cannot be transferred to other types of chest compression devices
Settings and
concomitant

therapies
• Tested for EN 1789:2007+ A1:2010 + A2:2014 Medical vehicles and their equipment—Road ambulances
• Tested for EN 13718-1:2014 Medical vehicles and their equipment—Air ambulances Part 1: Requirements for medical devices used in air ambulances
• Catheterization laboratory: documented to allow for oblique fluoroscopy projections, catheterization, angiography and potentially life-saving angioplasty during ongoing compressions
• Defibrillation: defibrillation proof device and documented safe and effective to defibrillate during ongoing device compressions.[3]

Tested against global standards (selected examples)
• EN 1789:2007 +A1:2010 + A2:2014 Medical vehicles and their equipment—Road ambulances
• EN 13718-1:2014 Medical vehicles and their equipment—Air ambulances Part 1: Requirements for medical devices used in air ambulances
• EN 60601-1:2006/A1:2013 (including A11:2011 and A12:2014) (edition 3.1) Medical electrical equipment—Part 1: General requirements for basic safety and essential performance
• EN 60601-1-2:2015 (edition 4) Medical electrical equipment—Part 1-2: General requirements for basic safety and essential performance—Collateral standard: Electromagnetic compatibility—Requirements and tests
• IEC 60601-1-6:2010 + A1:2015 Medical electrical equipment—Part 1-6: General requirements for basic safety and essential performance—Collateral standard: Usability
• EN 60601-1-8:2007 + A1:2013 Medical electrical equipment—Part 1-8: General requirements for basic safety and essential performance—Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
• IEC 60601-1-12:2014 Medical electrical equipment—Part 1-12: General requirements for basic safety and essential performance—Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services
• ANSI/AAMI ES 60601-1:2005(R)2012 Medical electrical equipment—Part 1: General requirements for basic safety and essential performance, with AMD C1: 2009, AMD 2: 2010, AMD 1: 2012
• CSA C22.2 No.60601-1:14 (3rd edition) Medical electrical equipment—Part 1: General requirements for basic safety and essential performance, COR 2: 2011/06/01
• EN 62366:2008 + A1:2015 Medical devices—Application of usability engineering to medical devices
• EN IEC 62133:2012 + CORR 1:2013 Secondary cells and batteries containing alkaline or other non-acid electrolytes—Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications—Edition 2.0

Maintenance and service
• Routine check recommended weekly and after each use
• Fleet management via included software account

• Battery can be charged in device connected to external power (<2 hours), or in external desk-top charger (<4 hours)
• No need for battery reconditioning or written battery administration
• Hard-shell carrying case allows for charge while in bag and check of battery status through top window
• Disposable suction cup
• Yearly service recommended, optional on-site service* with included loaner device
• Platform built for future software upgrades
* May not be available in all geographies.

Training of teams

• Comprehensive train-the-trainer guide and training materials available
• Documented by users as easy or very to learn (> 99%)[2]

Clinical support • Network of experienced users from various settings, sharing of best practice and clinical protocols, support and research

Communication • Wireless connectivity: Device can communicate via Bluetooth™ (factory default setting ON) and connect to configured Wi-Fi® networks (factory default setting OFF) to receive and transmit data when not in clinical use.
• Manual or automatic data transmission: push the TRANSMIT key in range of known networks, or setup option for automatic data transmission whenever the device is off, charging and in range of known networks (configurable)
• Setup options: Device functionality can be configured with setup options via secure, online platform (LIFENET) and be transmitted to the device wirelessly. Single setup profile can be applied to entire fleet or fleet can have different setup options
• Post-Event Reports: Device can transmit Post-Event Reports (PDF) wirelessly and send to any predetermined e-mail addresses
• Device readiness status: Device can transmit device readiness and battery notifications wirelessly to any predetermined e-mail addresses
• Local Bluetooth connection for setting up local Wi-Fi networks, and for Post-Event Report generation and software updates (if Wi-Fi cannot be used)
• Ability to disable Bluetooth and/or Wi-Fi

Post-event device data

Easy to read Post-Event Device (PDF) Report showing:
• Summary of device use: compression time, ratio, rate, count, number of pauses > 10 sec. and duration of longest compression pause
• Visual timeline showing device compressions, rate and pauses
• Event log showing user interactions, battery alerts and alarms
• Full display of device setup for quick reference
• Comprehensive post-event review in CODE-STAT 11 Data Review Software (optional)

Device readiness data

Option to setup automatic e-mail notifications via LIFENET for:
• Battery nearing expiration
• Battery expired
• Failed device self-test

Reporting software over

Bluetooth
• Report Generator software (DTX, included with device purchase for download online) with ability to download, print, save and share device reports of each use (PDF format)
• The Report Generator (DTX) can be downloaded on a pc with Windows® 7, 8.1 or 10
Device data storage
4GB (estimated to store more than two uses per day over the lifetime of the device, 8 years)

Device dimensions when assembled (HxWxD)
22.0 x 20.5 x 9.4 inches / 56 x 52 x 24 cm
Device dimensions while stored in Carrying Case (HxWxD)
22.8 x 13.0 x 10.2 inches / 58 x 33 x 26 cm
Battery dimensions (HxWxD)
5.1 x 3.5 x 2.2 inches / 13.0 × 8.8 × 5.7 cm
Weight of the device with Battery (no straps)
17.7 lbs / 8.0 kg
Battery weight 1.3 lbs / 0.6 kg
Back plate Thin and lightweight back plate (0.6 inches / 15 mm and 2.5 lbs / 1.1 kg)
Device main parts
Included in shipping box
• Device (upper part and back plate)
• Hard shell carrying case
• One battery
• One mounted suction cup and one spare
• Patient straps to secure patient's arms to device
• Stabilization strap to secure device position to patient
• Instructions for use
Optional accessories
• External power supply
• Car cable
• Desktop battery charger
• Spare batteries
• Disposable suction cups
• PCI back plate (carbon fiber version for cath lab)
• Anti-slip tape to slim back plate

Operating
temperature
+32°F to +104°F / +0°C to +40°C
-4°F / -20°C for 1 hour after storage at room temperature
Storage
temperature
-4°F to +158°F / -20°C to +70°C
Relative
humidity
5% to 98%, non-condensing
Device IP
classification
(IEC60529)
IP43
Operating input
voltage
12-28 V DC
Atmospheric
pressure
62-107 kPa
-1253 to 13000 ft (-382 to 4000 m)

Power source Proprietary battery alone or with external power supply or car power cable
Power supply Input: 100-240VAC, 50/60Hz, 2.3A, Class II
Output: 24VDC, 4.2A
Car power cable 12-28VDC/0-10A
Battery type Rechargeable Lithium-ion Polymer (LiPo)
Note: Technical data from LUCAS 3 Chest Compression System, version 3.1, Instructions for Use, 101034-01 Rev E
References:
1. Levy M, Yost D, Walker R, et al. A quality improvement initiative to optimize use of a mechanical chest
compression device within a high-performance CPR approach to out-of-hospital cardiac arrest resuscitation. *Resuscitation.* 2015;92:32-37.
2. Pocock H, Deakin C, Quinn T, et al. Human factors in pre-hospital research: lessons from the PARAMEDIC trial. *Emerg Med J* online Feb 25, 2016.
3. Rubertsson S, Lindgren E, Smekal D, et al. Mechanical chest compressions and simultaneous defibrillation vs conventional cardiopulmonary resuscitation in out-of-hospital cardiac arrest: The LINC Randomized Trial. *JAMA*. 2014;311:53-6.
4. Koster R, Beenen L, van der Boom E. Safety of mechanical chest compression devices AutoPulse and
LUCAS in cardiac arrest: A randomized clinical trial for non-inferiority. *Eur Heart J.* 2017;0:1–8.

GDR 3328501_C
Battery capacity 3300 mAh (typical), 86 Wh
Battery voltage
(nominal)
25.9 V
Battery run time

(nominal patient)
Battery run time 45 minutes (typical)
Extended run time connecting to external power
Maximum
Battery charge
time
Charged in the device using external power supply:
-- Less than two hours at room temperature (+72°F / +22°C)
Charged in the external battery charger:
-- Less than four hours at room temperature (+72°F / +22°C)
Battery service
life (interval for
recommended
replacement)
Recommendation to replace the battery every 3 to 4 years or after 200 uses (of more than 10 minutes each time)
End of Battery service life will be indicated by a constant yellow LED to the far right on the Battery charge indicator
Battery IP
classification
(IEC60529)
IP44
Battery charge
temperature
+32°F to +104°F / +0°C to +40°C
(+68ºF to +77ºF / +20ºC to +25ºC preferred)
Battery storage
temperature
-4ºF to +104ºF / -20ºC to +40ºC
+105ºF to +158ºF / +41ºC to +70ºC ambient for less than a month

## Certification of Response to RFP

The potential Vendor certifies the following by placing his/her initials in all blank spaces:

_____ That this proposal is signed by an authorized representative of the firm.

_____ That the potential Vendor has determined the cost and availability of all materials and supplies associated with performing the services outlined herein.

_____ That all labor costs associated with this project have been determined, including all direct and indirect costs.

_____ That the potential Vendor agrees to the conditions as set forth in this Request for Proposal with no exceptions.

Therefore, in compliance with the foregoing **Request for Proposals**, and subject to all terms and conditions thereof, the undersigned offers and agrees, if this proposal is accepted within one hundred twenty (120) days from the date of the opening, to furnish the services for the prices quoted within the timeframe required.

Business Name: _____

Mailing Address: _____

_____

_____

E-mail Address: _____

Business Phone: _____

_____ _____

Printed Name and Title Authorized Signature Date

**Estimated Delivery Time from Order Placement** _____

**THIS PAGE MUST BE COMPLETED AND SUBMITTED AS A PART OF YOUR PROPOSAL**