

Signed:

Return Bid To:
CITY OF GUNTERSVILLE
341 GUNTER AVENUE
GUNTERSVILLE, ALABAMA 35976
(256) 571-7560

BID OPENING DATE & TIME:
FRIDAY, DECEMBER 22<sup>nd</sup> 2023 at 2:00 P.M.
NO BIDS WILL BE ACCEPTED PAST THIS DATE AND TIME
LOCATION: CONFERENCE ROOM
2ND FLOOR – CITY HALL,
MUNICIPAL BUILDING,
GUNTERSVILLE, ALABAMA

# INVITATION TO BID FOR CARDIAC MONITOR/DEFIBRILLATOR

In accordance with the Laws of Alabama, notice is hereby given that the City of Guntersville, Guntersville, Alabama will receive competitive bids on the above item (s) for the Fire Department, City of Guntersville, and/or any agencies thereof.

The City of Guntersville reserves the right to accept and/or reject any and all bids.

Betty Jones, City Clerk City of Guntersville		
VENDOR'S RESPONSE:		
VENDOR'S NAME		_
		_
FAX NO		_
EMAIL ADDRESS		_
Authorized Representative	Typed or Printed Name	

\*\*\*IF SHEET ISN'T SIGNED, BID IS VOID!!\*\*\*

# $The following \ specifications \ are \ for \ a \ portable, \ multi-parameter \ monitor/defibrill ator:$

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, noninvasive pacing, 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, unambiguou 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 inches) diagonal; 171 mm (6.7 inches) wide and 128 mm (5.0 inches) 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 (e.g., 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 one second.
2.4.5.	The device displays a minimum of five seconds of 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 <sup>®</sup> 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 360 joules 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 percent of setting, whichever is greater, into 50 ohms.	
	3.2.2.	±2 joules or 15 percent of setting, whichever is greater, into 25-175 ohms.	
3.3.	The device	te 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 square centimeters.	
	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 2.4 meters (8 feet), 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. Ext	ernai deiid	rmation (AED)
4.1.	The device	te is capable of being set up to power on in the AED mode.
4.2.	The device rhythm.	ee can be set up to automatically and continuously monitor the patient ECG for a potentially shockable
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.	
0	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	4.9.2.	When needed, the AED mode prompted protocol can be initiated by pressing ANALYZE.
	4.9.3.	The device can be set up to restrict access to manual mode therapies—that is, manual defibrillation, sync cardioversion or pacing—by unauthorized users.
	4.9.4.	When in advisory monitoring, an ADVISORY MODE-MONITORING message appears continuously.
	4.9.5.	All configured monitoring functions such as NIBP, SpO2 and 12-lead ECG can be used in advisory monitoring.
	4.9.6.	The uppermost real-time waveform display is reserved for ECG information, lead II; dashes are shown until the patient is connected to an ECG cable or therapy cable.
	4.9.7.	In advisory monitoring, lead II and paddles lead are the only ECG monitoring leads allowed.
	4.9.8.	An ECG analysis system is active and automatically evaluates the patient ECG for a potentially shockable rhythm. If a shockable ECG rhythm, such as VF, is detected, a push analyze prompt occurs. Pressing ANALYZE causes the device to enter AED mode.

#### 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. 100 - 325 joules, inclusive, in 25 joule steps, and to 360 joules for all 3 shock levels.
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 60 milliseconds 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

The device operates in demand and non-demand modes.
The device allows the user to program a preferred/default starting mode.
The device allows the operator to set the default rate and current values.
The device generates pacing pulses at a rate of 40 to 170 pulses per minute.
The accuracy of the pacing output rate is within +/- 1.5 percent over the entire range.
The device generates a monophasic, truncated exponential current pulse (20 +/- 1 ms).
The device allows the operator to select the pacing output current from 0 to 200 mA.
The device incorporates a pacing pause function which allows the operator to reduce the pacing rate by a factor of four, to allow assessment of the patient's underlying ECG rhythm.
The pacing circuit includes automatic adjustment of the refractory period (function of rate) from 180 to 270 msec, +/- 3 percent, 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 cables for 3-lead ECG monitoring.	
	8.1.2.	Five (5) wire cables for 7-lead ECG monitoring.	
	8.1.3.	Ten (10) wire cables 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 six 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.		itor allows the operator to adjust the ECG size using the following settings: 4, 3, 2.5, 2, 1.5, 1, 0.5, nV; (fixed at 1 cm/mV for 12-lead).
	8.3.1.	The monitor digitally displays patient heart rates from 20 to 300 beats per minute.
	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 90 decibels at 50/60 hertz.	
8.7.	The device offers the following frequency response settings:	
	8.7.1.	Monitoring electrodes: 0.5 to 40 hertz or 1.0 to 30 hertz (monitoring frequency response); 0.05 to 40 hertz or 0.05 to 150 hertz (diagnostic frequency response).
	8.7.2.	Paddles: 2.5 to 30 hertz.
	8.7.3.	Analog ECG output: 0.67 to 32 hertz (except 2.5 to 25 hertz for paddles ECG).

9. 12-lead ECG algorithm

9.1.	The device incorporates 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 25 millimeters per second or 50 millimeters per second.
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.

10.1.	The device incorporates SPO2, SpCO and SpMet monitoring using Masimo <sup>®</sup> Rainbow <sup>®</sup> technology and compatible sensors.  Pulse oximetry (SPO2)		
10.2.			
	10.2.1.	The device measures, displays and stores SPO2 values in the range of 50 to 100 percent.	
PST	10.2.2.	The device updates the SPO2 displayed value (on average) every 4, 8, 12 or 16 seconds.	
	10.2.3.	The saturation accuracy of the SPO2 circuit shall be 70 to 100 percent.	
	10.2.4.	The device display saturation rates from the SPO2 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 SPO2 circuit to within ±3 pulses per minute without motion an ±5 pulses per minute with motion.	
	10.2.8.	The SPO2 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 SPO2 value.	
	10.2.11.	The device can be set up to turn SPO2 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. SPO2 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 percent.	

11/1	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 percent.	
	10.4.2.	The display resolution is 0.1 percent for SpMet value from 0 to 10 percent and 1 percent for values from 10 to 15 percent.	
	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.	

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1. Noninvasive blood pressure (NIBP)		
The device is capable of displaying blood pressure values in mmHg.		
The device measures systolic pressure in range: 30 to 255 mmHg.		
The device measures diastolic pressure in range: 15 to 220 mmHg.		
The device measures mean arterial pressure (MAP) in range: 20 to 235 mmHg.		
The device measures BP with accuracy of maximum mean error of ±5 mmHg.		
The device typically performs a blood pressure measurement in 20 seconds.		
The device measures pulse rate in range: 30 to 240 pulses per minute.		
The device measures pulse rate with accuracy $\pm 2$ pulses per minute or $\pm 2$ percent, whichever is greater.		
The device offers a choice of initial cuff inflation pressures.		
The device can be set to perform automatic recurring measurements at the following set intervals: 2, 3, 5, 10, 15, 30 and 60 minutes.		
The device allows the user to set a pre-defined default setting for NIBP interval.		
The device allows automatic cuff deflation in case of excessive pressure (greater than 290 Hg) or in case measurement time exceeds 120 seconds.		
A range of disposable and reusable NIBP cuffs are available.		
NIBP cuffs are single bladder to facilitate placement independent of patient artery for rapid setup.		
Historical trended values shall be displayed on screen or on printed report.		

12. Capnography (EtCO<sub>2</sub> monitoring) The device incorporates capnography, using Oridion® Microstream® technology. 12.1. Capnography monitoring activates automatically upon connecting FilterLine® or Smart CapnoLine®. 12.2. The device allows monitoring of intubated and non-intubated patients without the need for additional equipment, 12.3. adapters or setup. The device does not have any CO2 sensors external to the device due to external sensor vulnerability to damage 12.4. and high replacement cost. The device is capable of displaying CO2 value in kPa, volume percent or mmHg. 12.5. The device does not use any separate water traps or filters; these should be integrated into the sensor to facilitate 12.6. ease of use and setup. The device is specific to CO2 and not adversely affected by the presence of non-CO2 gases. There is no 12.7. requirement for user input to indicate which gases are present. The device uses disposable CO2 intubated and non-intubated sensors to eliminate risk of cross contamination 12.8. between patients. The capnography option is compatible with Oridion FilterLine and Smart CapnoLine CO2 accessories and 12.9. Medtronic Microstream™ Advance filter lines. The device measures CO2 pressure in range 0 to 99 mmHg (0 to13.2kPa). The device shall display CO2 waveform. 12.10. The device measures CO2 with the following accuracy: 12.11. 0-80 breaths per minute: 0 to 38 mmHg ±2 mmHg, 39 to 99 mmHg ±5 percent of reading plus 0.08 12.11.1. for every 1 mmHg above 38 mmHg > 80 breaths per minute: 0 to 18 mmHg  $\pm$ 2 mmHg, 19 to 99 mmHg  $\pm$  4 mmHg or  $\pm$  12 percent of 12.11.2. reading (whichever is higher) The device measures respiration rate in a range of 0 to 99 breaths per minute. 12.12. The device measures respiration rate with the following accuracy: 12.13. 0 to 70 breaths per minute: ±1 breaths per minute 12.13.1. 12.13.2. 71 to 99 breaths per minute: ±2 breaths per minute 12.14. The device has a typical initialization time of 30 seconds. The initialization time will not exceed 180 seconds. 12.15. The rise time of the CO2 waveform is less than or equal to 190 milliseconds. 12.16. The response time of CO2 waveform, including the delay time and rise time: 12.17. 4.3 seconds max with 200cm FilterLine tubing 12.17.1 5.9 seconds max with 400 cm FilterLine tubing 12.17.2

The device automatically compensates for ambient pressure changes.

Historical trended values display on screen or on printed report.

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12.19.

12.20.	The CO2 system can be easily calibrated by certified technicians through the service menu using standard procedures with known sample gas value.
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13. Invasive pressure (IP)

13.1.	The device offers two 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 5uV/V/mmHg required sensitivity.	
13.2.	The device includes a measurement range of -30 to +300mmHg in six selectable ranges.	
13.3.	The device is capable of displaying readings in mmHg and includes waveform support.	
13.4.	. The device offers user-selectable labels of ART, PA, CVP, ICP and LAP for P1 or P2.	
13.5.	The device is compatible with strain-gauge resistive bridge transducers with a 5uV/V/mmHg sensitivity.	
13.6.	The device has a bandwidth of DC to 30 hertz (<-3 decibels).	
13.7.	The device has a numeric accuracy of ±1 mmHg or 2 percent of reading, whichever is greater, plus transducer error.	
13.8.	Historical trended values display on screen or on printed report.	

# 14. Alarms

	PA AAAU	
14.1.	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.	
14.2.	The user may select a wide or narrow tolerance of alarms around baseline.	
14.3.	The user may select a range of silence periods for the alarms.	
14.4.	The silence function applies only to the specific alarm that has been violated; new alarms will include an audible tone and are silenced separately.	
14.5.	Audible tone is always provided for VF/VT alarm.	
14.6.	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.	

15. Trending

15.1.	The device offers on-screen trending with choice of HR, PR (SpO2), PR (NIBP), SpO2 (percent), SpCO (percent), SpMet (percent), CO2 (EtCO2/FiCO2), RR (CO2), NIBP, IP1, IP2 or ST.
15.2.	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.
15.3.	The device includes a timescale of 30 minutes, 1, 2, 4 or 8 hours or autoscale.
15.4.	The device includes up to eight hours of trend data.

15.5.	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.
15.6.	A printed trend summary is available either on demand or at the conclusion of the event summary.

#### 16. Printer

16.1.	The device prints a continuous strip of the displayed patient information.		
16.2.	The device includes a 100mm (3.9-inch) 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.		
16.3.	The device prints at 25 mm/sec or 12.5mm/sec +/- 5 percent (measured in accordance with AAMI EC-11, 4.2.5.2).		
16.4.	The delay from display to printing is eight seconds.		
16.5.	The device allows the operator to set up automatic printing of waveform events as they occur, in any combination.		
16.6.	The device offers the following frequency response settings for the printer:		
	16.6.1.	Monitoring frequency: 0.67 to 40 hertz	
Į,	16.6.2.	Monitoring frequency: 1 to 30 hertz	
	16.6.3.	Diagnostic frequency: 0.05 to 40 hertz	
	16.6.4.	Diagnostic frequency: 0.05 to 150 hertz	

#### 17. Data management

17.1.	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.			
17.2.	The device allows the operator to enter the following patient information:			
	17.2.1.	Last name		
	17.2.2.	First name		
	17.2.3.	Incident ID		
	17.2.4.	Patient ID		
	17.2.5.	Age		
	17.2.6.	Sex		
17.3.	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, it will be used when acquiring the first 12-lead ECG without further user intervention.			
17.4.	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.			

7.5.	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:					
	17.5.1.	Transmit archived patient records				
a de	17.5.2.	Print archived patient records				
	17.5.3.	Delete archived patient records				
	17.5.4. Add demographic data to archived patient records					
17.6.	ECG. Ma	memory capacity of the device is at least 400 single waveform events or 360 minutes of continuous ximum memory capacity for a single patient includes up to 200 single waveform reports and 90 f continuous ECG.				
17.7.		is internal, rather than by removable cards, to eliminate replacement cost issues and to protect data patient confidentiality.				
17.8.	The device	te allows the operator to store the following report options:				
	17.8.1.	Short, medium or long CODE SUMMARY <sup>TM</sup> critical event record reports				
	17.8.2.	Initial ECG				
	17.8.3.	Auto vital sign measurements every five minutes and whenever alarm limits are exceeded				
	17.8.4.	3-channel or 4-channel format 12-lead ECG report				
	17.8.5.	Continuous waveform: 360 minutes continuous ECG record				
	17.8.6.	Trend summary (includes patient information, vital signs data and vital signs graphs)				
	17.8.7.	Vital signs: includes patient information, event and vital signs log				
	17.8.8.	Snapshot: includes patient information and eight seconds of transmitted ECG captured at the time of transmission				
17.9.	Data man	agement architecture				
	17.9.1.	When transferring data, the device outputs data in a format compatible with hospital cardiology information systems, such as the Marquette MUSE CV <sup>®</sup> cardiovascular information system.				
	17.9.2.	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.				

#### 18. Data transmission

to. Da	ta ti ansimi	30204		
18.1.	The device event rev	ce is capable of transmitting current and archived data records to the LIFENET <sup>®</sup> System or to postiew products such as CODE-STAT <sup>TM</sup> data review software or DT EXPRESS <sup>TM</sup> data transfer software.		
	18.1.1.	The device is capable of transmitting data records via a Bluetooth wireless connection to other Bluetooth devices.		
	18.1.2.	The device is capable of transmitting data records via a direct cable connection to a PC or gateway.		
18.2.	The device Bluetooth	te has a Bluetooth connectivity option that includes a configurable password prompt for protection and a search filter to limit extraneous available external target locations.		
18.3.	The device	ce allows the operator to transmit the following report options:		
	18.3.1.	12-lead ECG report: the diagnostic 12-lead ECG report		
	18.3.2.	CODE SUMMARY: includes patient information, event and vital sign log, and waveforms associated with events		
	18.3.3.	Trend summary: includes patient information, vital signs log and vital signs graphs		
	18.3.4.	Vital signs summary: includes patient information and event and vital signs log		
	18.3.5.	Snapshot report: includes patient information and eight seconds of transmitted ECG captured at the time of transmission		
	18.3.6.	Continuous report: provides real-time waveform data, acquired when the device is powered on and electrodes are connected or other waveform data is displayed in channel two or three		
18.4.	The device appropria	ne device provides the option of transmitting 12-lead ECG reports to a personal computer installed with propriate software via a direct cable or Bluetooth wireless connection.		
18.5.	The device	ce and communication system supports the following 12-lead features:		
	18.5.1.	Alert at the receiving end that a 12-lead ECG has arrived		
	18.5.2.	Transmission to multiple locations		
	18.5.3.	Auto forwarding of 12-lead ECG report		
	18.5.4.	Sharing of electronic 12-lead report via email		
	18.5.5.	Acknowledgement of successful transmission at the device		
The device is capable of streaming continuous, real-time patient data and wavef the LIFENET System using a direct cable connection to a compatible gatew		te is capable of streaming continuous, real-time patient data and waveforms to a remote provider through NET System using a direct cable connection to a compatible gateway.		
	18.6.1.	The device is capable of streaming current patient data during patient monitoring in manual mode.		
7	18.6.2.	The device is capable of streaming current patient data during patient monitoring in advisory monitoring state.		

18.7.	The devic	The device is capable of transmitting reports during an in-progress streaming session.			
18.8.		Continuous patient data streaming has the option to be turned on or off. Default transmission settings can be modified in the device setup mode.			
18.9.	The device has the capacity to stream the following data options:				
	18.9.1. Up to three ECG waveforms in manual mode and advisory monitoring state				
	18.9.2. Heart rate via ECG, SpO2 and NIBP connections				
	18.9.3.	SpO2, SpCO and SpMET data			
	18.9.4.	EtCO2 pressure and respiration rate data			
	18.9.5.	NIBP as combined mean value, systolic value and diastolic value			
1	18.9.6.	Invasive pressure (IP) as combined mean value, systolic value and diastolic value			
	18.9.7.	Temperature in Celsius or Fahrenheit unit options			
18.10.	The device has an available streaming cancel option to discontinue the transmission of data.				
18.11.	The device can display the progress of user-initiated streaming sessions and streaming session success and/or failure prompts.				

19. Power

each battery and automatically switches to the second battery when a low battery is detected for the first battery, without interruption of functional operation.  19.3. Operating time: Two new, fully charged lithium-ion batteries provide the following prior to shutdown at 20°C (68°F):  19.3.1. Monitoring typical 360 minutes, minimum 340 minutes  19.3.2. Pacing typical 340 minutes, minimum 320 minutes  19.3.3. Defibrillation (360 joules) typical 420 shocks, minimum 400 shocks  19.4. Capacity after low battery warning  19.4.1. Monitoring typical 21 minutes, minimum 12 minutes  19.4.2. Pacing typical 20 minutes, minimum 10 minutes  19.4.3. Defibrillation (360 joules) typical 30 shocks, minimum six shocks  The device displays battery icons at the top display area for each battery placed in the device. The battery indicate the state of battery charge and which of the two batteries is being used to supply power to the device.	19. Po	wer				
each battery and automatically switches to the second battery when a low battery is detected for the first battery, without interruption of functional operation.  19.3. Operating time: Two new, fully charged lithium-ion batteries provide the following prior to shutdown at 20°C (68°F):  19.3.1. Monitoring typical 360 minutes, minimum 340 minutes  19.3.2. Pacing typical 340 minutes, minimum 320 minutes  19.3.3. Defibrillation (360 joules) typical 420 shocks, minimum 400 shocks  19.4. Capacity after low battery warning  19.4.1. Monitoring typical 21 minutes, minimum 12 minutes  19.4.2. Pacing typical 20 minutes, minimum 10 minutes  19.4.3. Defibrillation (360 joules) typical 30 shocks, minimum six shocks  The device displays battery icons at the top display area for each battery placed in the device. The battery indicate the state of battery charge and which of the two batteries is being used to supply power to the device.	19.1.	Battery o	Battery options: The device operates using lithium-ion, rechargeable batteries.			
19.3.1. Monitoring typical 360 minutes, minimum 340 minutes  19.3.2. Pacing typical 340 minutes, minimum 320 minutes  19.3.3. Defibrillation (360 joules) typical 420 shocks, minimum 400 shocks  19.4. Capacity after low battery warning  19.4.1. Monitoring typical 21 minutes, minimum 12 minutes  19.4.2. Pacing typical 20 minutes, minimum 10 minutes  19.4.3. Defibrillation (360 joules) typical 30 shocks, minimum six shocks  The device displays battery icons at the top display area for each battery placed in the device. The battery indicate the state of battery charge and which of the two batteries is being used to supply power to the device.	19.2.	each batte				
19.3.2. Pacing typical 340 minutes, minimum 320 minutes  19.3.3. Defibrillation (360 joules) typical 420 shocks, minimum 400 shocks  19.4. Capacity after low battery warning  19.4.1. Monitoring typical 21 minutes, minimum 12 minutes  19.4.2. Pacing typical 20 minutes, minimum 10 minutes  19.4.3. Defibrillation (360 joules) typical 30 shocks, minimum six shocks  The device displays battery icons at the top display area for each battery placed in the device. The battery indicate the state of battery charge and which of the two batteries is being used to supply power to the device.	19.3.					
19.3.3. Defibrillation (360 joules) typical 420 shocks, minimum 400 shocks  19.4. Capacity after low battery warning  19.4.1. Monitoring typical 21 minutes, minimum 12 minutes  19.4.2. Pacing typical 20 minutes, minimum 10 minutes  19.4.3. Defibrillation (360 joules) typical 30 shocks, minimum six shocks  The device displays battery icons at the top display area for each battery placed in the device. The battery indicate the state of battery charge and which of the two batteries is being used to supply power to the device.		19.3.1.	Monitoring typical 360 minutes, minimum 340 minutes			
19.4. Capacity after low battery warning  19.4.1. Monitoring typical 21 minutes, minimum 12 minutes  19.4.2. Pacing typical 20 minutes, minimum 10 minutes  19.4.3. Defibrillation (360 joules) typical 30 shocks, minimum six shocks  The device displays battery icons at the top display area for each battery placed in the device. The battery indicate the state of battery charge and which of the two batteries is being used to supply power to the device.		19.3.2.	Pacing typical 340 minutes, minimum 320 minutes			
19.4.1. Monitoring typical 21 minutes, minimum 12 minutes  19.4.2. Pacing typical 20 minutes, minimum 10 minutes  19.4.3. Defibrillation (360 joules) typical 30 shocks, minimum six shocks  The device displays battery icons at the top display area for each battery placed in the device. The battery indicate the state of battery charge and which of the two batteries is being used to supply power to the device.		19.3.3.	Defibrillation (360 joules) typical 420 shocks, minimum 400 shocks			
19.4.2. Pacing typical 20 minutes, minimum 10 minutes  19.4.3. Defibrillation (360 joules) typical 30 shocks, minimum six shocks  The device displays battery icons at the top display area for each battery placed in the device. The battery indicate the state of battery charge and which of the two batteries is being used to supply power to the device.	19.4.	Capacity	acity after low battery warning			
19.4.3. Defibrillation (360 joules) typical 30 shocks, minimum six shocks  The device displays battery icons at the top display area for each battery placed in the device. The battery indicate the state of battery charge and which of the two batteries is being used to supply power to the device.		19.4.1.	Monitoring typical 21 minutes, minimum 12 minutes			
The device displays battery icons at the top display area for each battery placed in the device. The battery indicate the state of battery charge and which of the two batteries is being used to supply power to the device.		19.4.2.	Pacing typical 20 minutes, minimum 10 minutes			
indicate the state of battery charge and which of the two batteries is being used to supply power to the devi	18	19.4.3.	Defibrillation (360 joules) typical 30 shocks, minimum six shocks			
	19.5.	indicate t	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 warning message.			

19.6.	The batteries icons will not be active for any battery pack not provided from the original manufacturer.
19.7.	The lithium-ion batteries have four horizontal bars or battery charge indicators that indicate when the individual battery has greater than 70 percent charge (four bars), greater than 50 percent charge (three bars), greater than 25 percent charge (two bars), and 25 percent or less charge (one bar).
19.8.	When both batteries reach a low battery condition, the device emits an audible voice prompt to replace the battery.
19.9.	The device retains the operator parameter settings with an inadvertent power loss of less than 30 seconds.
19.10.	The device displays a service indicator when a fault is detected.

# 20. Maintenance

10. 111	intenance			
20.1.	Each time the monitor/defibrillator is powered on, it performs internal self-tests to check that internal electrical components and circuitry work properly.			
20.2.	The defibrillator stores the results of all user-initiated self-tests in a test log.			
20.3.	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.			
20.4.	The defibrillator performs an automatic self-test daily at 3 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.			
20.5.	The device is capable of a manual user test that includes charging and discharging the defibrillator and printing a report.			
20.6.	The device has provision to transfer the test log report to a PC by a cable or by wireless means.			
20.7.	The device has provisions to upgrade for future AHA specifications.			
20.8.	The device offers a user-replaceable screen protector.			
20.9.	The device offers a removable/interchangeable shock-absorbing handle.			

# 21. Physical characteristics

	Basic monitor/defibrillator with new roll of paper and two batteries installed 7.9 kilograms (17.5 pounds)			
	21.1.2.	Full-featured monitor/defibrillator with new roll of paper and two batteries installed 8.4 kilograms (18.5 pounds)		
	21.1.3.	Lithium-ion battery: 0.59 kilograms (1.3 pounds)		
	21.1.4.	Accessory bags and shoulder strap: 1.77 kilograms (3.9 pounds)		
	21.1.5.	Standard paddles: 0.95 kilograms (2.1 pounds)		
21.2.	The device	the does exceed the following dimensions:		

21.2.1.	Height: 31.7 centimeters (12.5 inches)
21.2.2.	Width: 40.1 centimeters (15.8 inches)
21.2.3.	Depth: 23.1 centimeters (9.1 inches)

22.1.	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 one hour after storage at room temperature.		
22.2.	The non-obatteries.	operating temperature range of the device is -30° to +70°C (-22° to 158°F) except therapy electrodes and	
22.3.	The device	ce operates in relative humidity from 5 to 95 percent, non-condensing.	
	22.3.1.	NIBP operates in relative humidity from 15 to 95 percent, non-condensing.	
22.4.		te operates from ambient to -382 to 4,572 meters (-1,253 to 15,000 feet) with NIBP: -152 to 3,048 meters 0,000 feet).	
22.5.	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 hertz, ±0.15 mm/2 grams.		
22.6.	The device operates after five drops on each side from 18 inches onto a steel surface EN 1789: plus a 30-inch drop onto each of six surfaces.		
22.7.	The device operates after a functional shock per IEC 60068-2-27 and MIL-STD-810E shock requirements three shocks per face at 40 g, 6 ms half-sine pulses.		
22.8.	The device operates after 1000 bumps at 15 g with pulse duration of 6 msec.		
22.9.	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.		
22.10.	. The device is dust- and splash-proof (IP44) per IEC 529.		
22.11.	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.		
22.12.	The device withstands 60-hour exposure to the chemicals: betadine (10 percent povidone- iodine cola, dextrose (5 percent glucose solution), electrode gel/paste (98 percent water, 2 percent Car HCL (0.5 percent solution, pH=1), isopropyl alcohol and NaCl (0.9 percent solution). Cosmetic the paddle well shorting bar shall be allowed following exposure to HCL (0.5 percent solution).		

23. Configuration settings To prevent unauthorized access to the setup and service menus, the device requires separate four-digit numeric 23.1. security passcodes to be entered. General: allows selection of the following: 23.2. 23.2.1. Language choice CODE SUMMARY format of short, medium, long 23.2.2. Trend summary format of short, medium, long 23.2.3. Site number up to 14 characters 23.2.4. 23.2.5. Device ID up to 14 characters Auto log: automatic recording and storage of vital signs every five minutes, on or off 23.2.6. 23.2.7. Line filter setting of 50 or 60 hertz Screen message timeout value of 5, 10 or 30 seconds 23.2.8. Manual mode: allows selection of the following: 23.3. Resume sync after shock on or off 23.3.1. Pads default energy setting of 2, 5, 10, 50, 100, 125, 150, 175, 200, 225, 250, 275, 300, 325, 360 or 23.3.2. energy protocol (power-on energy setting in joules for standard paddles and therapy electrodes) Energy protocol allows presetting energy for sequence of three shocks: each shock may be preset to a value of 100 to 360 joules with the requirement that energy value for shock 2 cannot be less than 23.3.3. shock 1 energy level, and the energy value for shock 3 cannot be less than shock 2 energy value. Voice prompts on or off in manual mode 23.3.4. Shock tone on or off when full charge is reached 23.3.5. Manual access selection of AED / confirm once, AED / confirm always, AED / passcode once, AED 23.3.6. / passcode always, AED / restricted Set passcode to enter manual access when AED / passcode once or AED / passcode always are 23.3.7. selected for manual access 23.4. AED mode: allows selection of the following: Energy protocol allows presetting energy for sequence of three shocks: each shock may be preset to a value of 150 joules to 360 joules with the requirement the energy value for shock 2 cannot be less 23.4.1. than shock 1 energy level, and the energy value for shock 3 cannot be less than shock 2 energy value. Stacked shocks enable consecutive shocks without CPR. 23.4.2. Automatically analyzes after each shock on or off 23.4.3.

Motion detection on or off

23.4.4.

	23.4.5.	(after every	Ise check prompt choices of Never (never prompt for pulse check), After second NSA "No Shock Advised" (NSA) except for first analysis NSA result), After Every NSA (only hock Advised"), or Always (after every three-shock stack and every NSA).				
23.5.	CPR setu	p					
	23.5.1.	CPR time 1 can set CPR interval after each shock to 15, 30, 45, 60, 90, 120, 180 seconds, 30 minutes.					
	23.5.2.		2 can set CPR interval after No Shock Advised decision to 15, 30, 45, 60, 90, conds, 30 minutes.				
	23.5.3.	Initial CPR turned on to	provides the choice to enable an initial CPR time period immediately after the device is o analyze first or to disable an initial CPR time period.				
	23.5.4.	Initial CPR	Time can be set to 15, 30, 45, 60, 90, 120 or 180 seconds.				
	23.5.5.	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.					
23.6.	Metronome						
	23.6.1.	Enable prov	vides the metronome during CPR and may be on or off.				
	23.6.2.	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.					
	23.6.3.	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.					
	23.6.4.	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.					
	23.6.5.	The C:V ra	tio for a youth with airway can be set to 30:2, 16:1, 15:2, 12:1, 10:1, or 100:0.				
23.7.	Pacing allows selection of the following:						
11	23.7.1.	Default pacing rate of 40 to 170 pulses per minute					
	23.7.2.	Default output current of 0 to 200 mA					
	23.7.3.	Default mode of demand or non-demand					
	23.7.4.	Default internal pacing detection on or off					
23.8.	Monitoring setup allows selection of the following:						
1 7	23.8.1.	Channels: S	Set up to five groups of multi-channel waveforms to display as follows:				
		23.8.1.1.	Set 1: Select multi-channel waveforms for Set 1				
		23.8.1.2.	Set 2: Select multi-channel waveforms for Set 2				
		23.8.1.3.	Set 3: Select multi-channel waveforms for Set 3				

		23.8.1.4.	Set 4: Select multi-channel waveforms for Set 4				
		23.8.1.5.	Set 5: Select multi-channel waveforms for Set 5				
	23.8.2.	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. 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.					
	23.8.3.		waveform selections include none, cascading ECG, ECG lead I, ECG lead II, ECG 'R, aVL, aVF, V1, V2, V3, V4, V5, V6, CO2, P1, P2 or SpO2.				
	23.8.4.		waveform selections include none, ECG lead I, ECG lead, II, ECG lead III, aVR, V1, V2, V3, V4, V5, V6, CO2, P1, P2 or SpO2.				
4742	23.8.5.	Continuous ECG storage of ECG waveform on or off					
	23.8.6.	SpO2 tone S	SpO2 tone SpO2 pulse tone on or off				
	23.8.7.	CO2: Set uj	p CO2 defaults as follows:				
		23.8.7.1.	Set CO2 units of measure to mmHg, kPa or percent				
		23.8.7.2.	Set body temperature correction factor for EtCO2 value to on or off				
	23.8.8.	NIBP: Set up NIBP defaults as follows:					
		23.8.8.1.	Initial cuff pressure to 180, 160, 140, 120, 100 or 80 mmHg				
		23.8.8.2.	Measurement interval to off, 60, 30, 15, 10, 5, 3 or 2 minutes				
23.9.	12-lead ECG acquisition. The device uses the University of Glasgow 12-lead ECG analysis program and provides the following setup choices:						
	23.9.1.	Transmit automatically on acquisition on or off					
	23.9.2.	Print automatically on acquisition on or off					
	23.9.3.	Print speed for 3-channel 12-lead report of 25 mm/sec or 50 mm/sec					
	23.9.4.	12-lead interpretation on or off					
	23.9.5.	Print format for 12-lead reports of 3-channel standard, 4-channel standard, 3- channel Cabrera or 4-channel Cabrera					
23.10.	Events: allows selection of the following:						
77.5	23.10.1.	Selection of events 2 through 11 from a pre-configured list					
	23.10.2.	Selection of events 12 through 22 from a pre-configured list					
17	23.12.5.	User customization of up to 18 events to be included in the list.					
23.11.	Alarms: a	llows selection	on of the following:				
	23.11.1.	Set volume	for alarms, tones and voice prompts				

	23.11.2.	Enable or d	isable parameter alarms at power up		
	23.11.3.	VF/VT alar	m enabled or disabled		
23.12.	Printer: allows selection of the following:				
	23.12.1.	Auto print e	uto print event selection:		
		23.12.1.1.	Print defibrillation events on or off		
		23.12.1.2.	Print pacing events on or off		
		23.12.1.3.	Print check patient events on or off		
		23.12.1.4.	Print SAS events on or off		
		23.12.1.5.	Print patient alarms on or off		
		23.12.1.6.	Print operator annotated events on or off		
		23.12.1.7.	Print initial rhythm on or off		
	23.12.2.	2. Default ECG frequency response of:			
		23.12.2.1.	Monitor 0.5 – 40 hertz		
		23.12.2.2.	Diagnostic 0.05 – 150 hertz		
	23.12.3.	Print alarm waveforms with an alarm events in CODE SUMMARY on or off			
	23.12.4.	Print event waveforms with user-entered events in CODE SUMMARY on or off			
	23.12.5.	Print waveforms with vital signs in CODE SUMMARY on or off			
23.13.	Transmiss	Transmission: allows selection of the following:			
X.E	23.13.1. Setup 72 data transmission sites		ta transmission sites		
		23.13.1.1.	Site name up to 14 characters		
		23.13.1.2.	Output port to Bluetooth, direct connect or both		
		23.13.1.3.	Clear list of site		
		23.13.1.4.	Select default destination site to none. After sites are defined or select from the list.		
		23.13.1.5.	Select default report for data transmission of snapshot, all, CODE SUMMARY, trend summary, vital signs, 12-lead or continuous ECG.		
		23.13.1.6.	Wireless enable wireless communication on or off		
		23.13.1.7.	Enable filtering of Bluetooth device searches to on or off		
	23.13.2.	. Clock: allows selection of the following:			
		23.13.2.1.	Set the current date and time		

		23.13.2.2.	Select real or elapsed time on the display
		23.13.2.3.	Daylight Savings Time on or off
	-12.0	23.13.2.4.	Select time zone form non or Universal Time code for 74 time zones
2	3.13.3.	Reset defau	lts: allows selection of the following:
		23.13.3.1.	Cancel and return to setup screen
	1.18	23.13.3.2.	Reset all values to the factory default settings
2	3.13.4.	Print defaul	ts: Provides printout of the current device configuration setup
2	3.13.5.	Send config	guration: Transfer the device setup configuration to another device.
2	3.13.6.	Set passcode: allows selection of the following:	
		23.13.6.1.	Set passcode to enter setup mode (the current passcode appears 0000). Rotate and press SPEED DIAL to select digits
		23.13.6.2.	Select passcode access for archives mode to no passcode, archives only, delete only, archives/delete
		23.13.6.3.	Set passcode to enter archives mode 0000 (rotate and press SPEED DIAL to select digits)
2	3.13.7.	Delete records: set passcode to delete records in archives mode 0000 (rotate and press SPEED DIAL select digits)	
2	3.13.8.	via the conf	allows the entire list of configuration settings to be transferred to other identical devices iguration setup tool software application using a direct connect cable, thereby eliminating configure setup options on each device separately.

24. Power adapters

24.1.	Power adapters provide operation and battery charging from external AC or DC power
24.2.	Full functionality with or without batteries when connected to external AC/DC
24.3.	Typical battery charge time via power adapters is 190 minutes
24.4.	Auxiliary power indicator on defibrillator illuminated when connected to auxiliary power
24.5.	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.

### 25. Other

Device is designed to help the operator meet U.S. HIPAA (Health Insurance Portability and Accountability Act of 1996) requirements 25.1.

26. Temperature monitoring

26.1.	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.			
26.2.	Temperature monitoring range is from 24.8° to 45.2°C (76.6° to 113.4°F)			
26.3.	The resolution shall be 0.1°C			
26.4.	The measurement accuracy shall be ±0.2°C, including sensor			
26.5.	The device must have the following accessories:			
	26.5.1.	Reusable te	mperature cable: 5 foot or 10 foot	
	26.5.2.	Disposable	le sensor types:	
		26.5.2.1.	Surface for reading skin temp	
		26.5.2.2.	Esophageal/rectal for core monitoring	
	Min I	26.5.2.3.	Foley catheter for core monitoring	
26.6.	The connection point at the monitor must utilize Molex style connectors.			

#### 27. Continuous waveforms

27.1.	LIFEPAK 15 captures all the continuous waveforms that are displayed.
27.2.	In CODE-STAT 9.0 or greater, continuous waveforms can be viewed for post-event review. For example, the waveforms for capnography and SpO2 can be viewed.

28. STEMI recognition

28.1.	Measures the STJ levels and then prints them on a 12-lead
28.2.	The STJ levels are automatically printed anytime that a 12-lead is printed.
28.3.	After the first 12-lead acquisition, if a patient's STJ levels have shifted by one millimeter for 2.5 minutes in any lead, the monitor automatically prints another 12-lead ECG and notes the new STJ levels on the printout.

29. Voice recording

29.1.	With the Titan II and Titan III Wireless Audio Gateways attached to the LIFEPAK 15, the Audio Gateway automatically records audio.	
29.2.	270-minute capacity	
29.3.	Up to 90 minutes per episode.	
29.4.	Audio recordings can be heard in versions of CODE-STAT 9.0 software or greater.	



# **BID SHEET**

DELIVERY:	F.O.B.
Cardiac Monitor	/Defibrillator
\$	
\$	ADDITIONAL COST IF APPLICABLE
*THE CITY OF ALL BIDS.	GUNTERSVILLE RESERVES THE RIGHT TO ACCEPT AND/OR REJECT ANY AND/OR
BETTY JONES,	CITY CLERK
341 GUNTER A	
GUNTERSVILI	LE AL 35976
256-571-7560	
VENDOR'S RES	SPONSE:
I hereby agree to specifications set	furnish the above-named items on or by the dates requested and hereby certify that all above be met.
Authorized Repr	resentative

\*IF SHEET ISN'T SIGNED, BID IS VOID!!\*\*\*



- 1. The successful bidder shall begin furnishing materials within 16 to 20 weeks lead time. The City of Guntersville reserves the right to negotiate with another bidder for the bid item if not supplied within the 16 to 20 weeks.
- 2. Vendor's bid price shall include the furnishing of all operator manuals, etc.
- 3. It shall be the bidder's responsibility to possess all Proper City, County, State, and Federal license and shall familiarize himself with and shall comply with all Federal, State, and local laws, ordinances, and regulations.
- 4. The City of Guntersville reserves the right to award this contract as a whole or in part, whichever is in the best interest of the City of Guntersville.
- 5. This bid shall be good for 12 months from delivery date of equipment.
- 6. Bids may be submitted either by mail or in person; however, the City of Guntersville will not be responsible for the security of mailed bids. (Also, if mailing bid, please be advised that we do not receive mail before 10:00 A.M. daily, therefore mail early to ensure prompt arrival).
- 7. By signing and submitting of this bid, the vendor certifies that he/she is an equal opportunity employer.
- 8. Bidders are required to use this "Invitation for Bids." Failure to do so will be cause for rejection of bid.
- 9. Bidders shall bid all items, sign, and return <u>all</u> sheets in the "Invitation for Bids". Failure to do so will because for rejection of bid.
- 10. Each individual bid must be submitted in a sealed envelope with the word "BID" and name of item marked on outside of envelope.
- 11. Please be advised that in the event a bid is received from a person, firm, or corporation deemed to be a responsible bidder, having a place of business within the City of Guntersville and the bid is no more than three percent (3%) greater than the bid of the lowest responsible bidder, the Mayor and City Council of the City of Guntersville may award the contract to the resident responsible bidder.
- 12. You are invited to bid on the above specifications. Any substitutes offered, other than the items specified, must include information showing that the substitute is of equal or better quality and equal or better suited for the purported use than the item specified. The right to reject any items or materials not of quality or under any provisions of this act is reserved

#### BIDDER ACKNOWLEDGEMENT

By signing and submitting the above bid, your company acknowledges that the quoted prices cannot be changed during the period of time stated, no can any type of surcharge or escalation charge be assessed without agreement from City Officials. Your company also understands the information set out in the Special Instructions to the Bidders and understands that not following the instructions could lead to bid disqualification.

By signing this contract,	represents and agrees that it is
not currently engaged in, nor will it engage in, any boycott	of a person or entity based on doing business with a
jurisdiction with which the State of Alabama can enjoy ope	
Bidder's Response:	
I hereby understand the information set out in the Special	Instructions to the Bidders and understand that not
following the instructions could lead to bid disqualification	•
Authorized Representative	