

THE UNIVERSITY OF ALABAMA

INVITATION FOR BID

ATTENTION: This is not an order. Read all instructions and terms and conditions carefully.

INVITATION NO.: T052004	RETURN ALL COPIES OF BIDS TO:
Issue Date: 05/14/10	THE UNIVERSITY OF ALABAMA
Title: Lifepak 20 Defibrillators	PURCHASING DEPARTMENT
Buyer: Robin Schmitt	801 University Blvd
Phone: (205) 348-5385	355 Rose Administration Building
Email: rschmitt@fa.ua.edu	Box 870130
	Tuscaloosa, Alabama 35487
	PHONE: (205)348-5230 FAX: (205) 348-8706

Bid Responses may NOT be faxed or emailed.

IMPORTANT: SEALED BIDS MUST BE RECEIVED BY 05/25/10 @ 2:00 P.M. CST TIME

Bid number and opening date must be clearly marked on the outside of all bid packages.

- Pursuant to the provisions of the State of Alabama Competitive Bid Law, Section 41-16-20 and/or 39-2, rules and regulations adopted thereunder sealed bids will be received on the items noted herein by The University of Alabama Purchasing Department until the date and time stated above. In accordance with Alabama State Bid Law Section 41-16-27, where applicable, the University reserves the right to enter into negotiations within thirty (30) days of the bid opening.
- The University's General Terms and Conditions and Instructions to Bidders, viewable at www.purchasing.ua.edu/purchvendinfo.html apply to this Solicitation and shall become a part of any contract issued hereunder.
- For purposes of this Solicitation, the Solicitation documents shall consist of the following components:
 - Invitation for Bid and any Addenda;
 - General Terms and Conditions;
 - Instructions to Bidders
 In the event that any provision of the component parts of the Solicitation conflicts with any provision of any other component parts, the component part first enumerated shall govern.
- This Agreement and any disputes hereunder shall be governed by the laws of the State of Alabama without regard to conflict of law principles.

CERTIFICATION PURSUANT TO ACT NO. 2006-557

Alabama law (section 41-4-116, code of Alabama 1975) provides that every bid submitted and contract executed shall contain a certification that the vendor, contractor, and all of its affiliates that make sales for delivery into Alabama or leases for use in Alabama are registered, collecting, and remitting Alabama state and local sales, use, and/or lease tax on all taxable sales and leases in Alabama. **By submitting a response to this solicitation, the bidder is hereby certifying that they are in full compliance with Act No. 2006-557;** they are not barred from bidding or entering into a contract pursuant to 41-4-116, and acknowledges that The University of Alabama may declare the contract void if the certification is false.

DISCLOSURE STATEMENT

- If you or any owner, officer, partner, board or director member, employee, or holder of more than 5% of the fair market value of your firm or any member of their households is an employee of The University of Alabama, this information must be included in your solicitation response. Failure to disclose this information in your response may result in the elimination of your proposal from evaluation.
- If you or any owner, officer, partner, board or director member, employee, or holder of more than 5% of the fair market value of your firm or any member of their households is an employee of The University of Alabama; and you or your firm is awarded a contract as a result of this solicitation, then within ten (10) days after the contract is entered into, you agree to file a copy of that contract with the State of Alabama Ethics Commission in accordance with Code of Alabama, Section 36-25-11 and upon request by the University furnish evidence of such filing.
- By accepting payments agreed to in any purchase order resulting from this bid, Contractor certifies that to its knowledge no University employee or official, and no family members of a University employee or official, will receive a benefit from these payments, except as has been previously disclosed, in writing, to the University on the Disclosure Statement of Relationship Between Contractors/Grantees and Employees/Officials of The University of Alabama.

AUTHENTICATION OF BID AND STATEMENT OF NON-COLLUSION AND NON-CONFLICT OF INTEREST

- I hereby swear (or affirm) under the penalty for false swearing as provided in Code of Alabama 6-5-180 that
- In accordance with Code of Alabama Section 41-16-25, amended 1975 that the attached response has been arrived at independently and has been submitted without collusion with, and without any agreement, understanding or planned common course of action with, any other vendor of materials, supplies, equipment or services described in the Invitation for Bids, designed to limit independent bidding or competition;
 - The contents of the bid or bids have not been communicated by the bidder or its employees or agents to any person not an employee or agent of the bidder or its surety on any bond furnished with the bid or bids and will not be communicated to any such person prior to the official opening of the bid or bids.
 - The bidder is legally entitled to enter into contracts with The University of Alabama and is not in violation of any prohibited conflict of interest, including those prohibited by the Code of Alabama 13A-10-62, as amended 1975.
 - I have fully informed myself regarding the accuracy of the statement made above.

THIS AREA MUST BE COMPLETED

DELIVERY AFTER RECEIPT OF ORDER:	NAME OF COMPANY:	PHONE:
FEDERAL EMPLOYER ID NO.:	ADDRESS:	FAX:
PAYMENT TERMS:	ADDRESS:	E-MAIL:
SHIPPING TERMS: F.O.B. DESTINATION—PREPAID AND ALLOWED	CITY, STATE & ZIP CODE:	DATE:
QUOTE VALID UNTIL:	SIGNATURE:	Typed/Printed Name of Signor

SIGNATURE REQUIRED: This bid cannot be considered valid unless signed and dated by an authorized agent of the bidder. Type or print the information requested in the spaces provided.

INVITATION FOR BID

The University of Alabama requests sealed bids as per attached general and technical specifications or equal unless otherwise specified in the Special Conditions.

All Bidders submitting a bid must read all specifications carefully and respond accordingly. Failure to do so may eliminate your bid from consideration due to non-compliance.

1.0 GENERAL SPECIFICATIONS

1.1 All bid responses, technical information and any other attachments furnished to The University of Alabama in response to this request for quotation must be submitted in duplicate (THE ORIGINAL BID AND ATTACHMENTS WITH ORIGINAL SIGNATURE AND ONE EXACT COPY OF THE ENTIRE BID RESPONSE). Bidders who fail to follow this format may be disqualified from the evaluation and award phase of this bid.

1.2 The stated requirements appearing elsewhere in this solicitation shall become a part of the terms and conditions of any resulting contract. Any deviations therefrom must be specifically defined. If accepted by the University, the deviations shall become part of the contract, but such deviations must not be in conflict with the basic nature of this solicitation.

Note: Bidders shall not submit their standard terms and conditions or purchase order terms as exceptions to or modification of the terms and conditions of this solicitation. Each exception to or modification of a University term and condition shall be individually listed by the bidder. Failure to follow this instruction may result in the determination that a bid submission is non-responsive to a solicitation and the rejection of that bid.

1.3 The issuance of a University Purchase Order (P#) or a signed Contract document is required to constitute a contract between the successful Bidder and the University which shall bind the successful Bidder to furnish and deliver the commodities ordered at the prices, terms and conditions quoted and in accordance with the specifications of this Solicitation as well as the terms and conditions of the University's Purchase Order or Contract. No shipments are to be made to The University of Alabama without the issuance of a Purchase Order (P#). (Bidders are not to accept or ship items against a requisition number "R" #.)

1.4 Any questions concerning these specifications should be directed to the Buyer listed on the signature page.

1.5 No department, school or office at the University has the authority to solicit or receive official Solicitations nor authorize Solicitation or Contract changes other than the Purchasing Department. All solicitations are issued under the direct supervision of the Associate Director for Purchasing and in complete accordance with the State of Alabama Bid Law, Section 41-16-20 and University policies and procedures.

1.6 The terms and conditions included in this Solicitation along with any addenda, any University contract and/or University purchase order(s) issued referencing this Solicitation, the University's General Terms and Conditions, Instructions to Bidders shall constitute the entire and exclusive Contract between the University and the successful Bidder.

2.0 QUALIFICATIONS AND STANDARDS

Due to the importance of maintaining a safe University environment, it is imperative that the successful bidder meet certain qualifications that will guarantee The University of Alabama the successful Bidder is qualified to furnish and deliver products, equipment and services or furnish, deliver, install, service and/or repair equipment whichever is applicable as required in this Solicitation. In order for Bidders to qualify, the following requirements must be fulfilled:

2.1 The Bidder must provide, in writing, a statement that the Bidder has been regularly engaged in business for a minimum three (3) years engaging in furnishing, delivering, servicing, repairing and installing, equipment, goods, or services required in this Solicitation. In lieu of the minimum number of years in business, a performance bond may be submitted in the amount of one hundred (100 %) per cent of the contract price. This bond will be used to secure the completion of the project should the successful Bidder default for any reason. Failure to comply with this requirement may eliminate your bid response from consideration.

INVITATION FOR BID

- 2.2 Each bidder required to provide a bond, shall submit a letter from a bonding agent licensed to do business in the State of Alabama stating that if the bidding company is the successful bidder, said bonding agent will furnish a 100% performance and payment bond covering and including products and service for the duration of the contract period. Said bond shall be subject to the approval and acceptance of The University of Alabama. The bond must be furnished to the University Purchasing Department within forty-eight (48) hours after receipt of the purchase order. The premium of the bond shall be paid by the successful bidder. Failure to provide the bond letter or bond will eliminate your bid from consideration in the bid award.

3.0 REFERENCES

References must include at least three (3) other universities, institutions or businesses, which the bidder has successfully provided products, services or installation of equipment similar to those required in this Solicitation in terms of manufacturer, size, features, service or type of installation. The references must include company name, address, project/delivery date, contact name, phone number, and email address.

4.0 PRODUCT SPECIFICATIONS

Specify all terms and conditions of the warranties associated with your products with your bid response.

5.0 PRICE QUOTATION

- 5.1 **IMPORTANT:** It is required that the PRICE QUOTATION SHEET(S) furnished with this Request for Price Quotation be completed and submitted with your proposal. **DO NOT** send generated price lists as your bid. Failure to comply with this request may eliminate your bid from consideration in the bid award.
- 5.2 All prices shall be quoted furnish and install (if applicable) FOB The University of Alabama, Tuscaloosa, AL 35487 prepay and allowed. Unit prices quoted must include any and all shipping and handling charges. Any freight claims will be the responsibility of the Bidder. The successful Bidder must transport at the time of set-up, the equipment and supplies necessary for this installation to campus. No direct shipments will be accepted.
- 5.3 It is the Bidder's responsibility to verify any information, measurements and obtain any clarifications prior to submitting the bid response. The University is not liable for any errors or misinterpretations made by the Bidder in response to this Solicitation.
- 5.4 The successful Bidder under the specifications required in this Solicitation shall furnish at its expense all equipment, labor, tools, supplies, transportation, insurance and other expenses necessary to fully perform any phase of the requirements of this Solicitation.
- 5.5 Quote prices firm for a period of ninety (90) days following the bid opening date unless otherwise stated in the Special Conditions. Bids that do not guarantee pricing firm for this period may be eliminated. Failure to quote the term for which your prices will remain firm may eliminate your bid from consideration.
- 5.6 The quoted price must include but not be limited to all cables, wires, connectors, etc. to make a complete functioning unit unless specifically stated in the special conditions.
- 5.7 Include with your bid response complete details of your company's Return Merchandise policy, including, but not limited to, amount of any restocking fee required, procedures, limitations, contact person and phone number. While the University does not enter into any purchase with the intent to return items ordered, we do require this information be included with your bid response. Failure to include this information may be grounds for elimination of your bid from consideration.

6.0 DELIVERY, INSTALLATION AND TRAINING REQUIREMENTS

- 6.1 Proposed delivery dates shall be stated in number of calendar days after receipt of order.
- 6.2 All items must be delivered directly to the University by the successful Bidder and placed according to the instructions supplied by the University.

INVITATION FOR BID

7.0 INSURANCE

- 7.1 See General Terms and Conditions for general Insurance Requirements, Additional Insurance requirements may be listed in the Special Conditions Section.
- 7.2 The successful Bidder shall provide the University Purchasing Department a certificate of insurance listing the required types of insurance and minimum liabilities specified in the General Terms and Conditions unless otherwise modified in the Special Conditions.
- 7.3 The certificate must be received by The University of Alabama Purchasing Department within three (3) days of request. Failure to comply with this request may eliminate your bid from consideration in the bid award.
- 7.4 The University reserves the right to terminate any resulting contract, if the Bidder fails to keep these policies in force for the above amounts or for the duration of the contract period.
- 7.5 In the event of cancellation, material change or any other modifications or intent not to renew any of the insurance requirements specified, thirty (30) days written notice shall be given to the University by the party initiating any revision.
- 7.6 The umbrella policy must be listed on the insurance certificate with an explanation of the coverage.

8.0 RESTRICTIONS ON COMMUNICATIONS WITH UNIVERSITY STAFF

From the issue date of this Solicitation until a Contractor is selected and a contract award is made, Bidders are not allowed to communicate about the subject of the IFB with any University administrator faculty, staff, or members of the Board of Trustees except:

- The Purchasing Department representative, any University Purchasing Official representing the University administration, or others authorized in writing by the Purchasing Office and
- University Representatives during Bidder presentations.

If violation of this provision occurs, the University reserves the right to reject the Bidder's response to this Solicitation.

INVITATION FOR BID

9.0 SPECIAL CONDITIONS

- 9.1 The University of Alabama requests sealed bids to establish a contract upon date of award to Furnish and Deliver LIFEPAK® defibrillator/monitor devices per attached general and technical specifications.
- 9.2 **Do not substitute** the specific defibrillator system requested in this bid due to the compatibility with existing equipment. The area hospitals in which our nursing students do clinical's currently use LifePak 20 defibrillators. Faculty will be orienting students prior to their clinical's to the defibrillators. Most of our students will be working at these institutions after graduation and having the knowledge of the LifePak 20 would lead to increased patient safety as well as patient quality.
- 9.3 Delivery is needed the week of July 20th, 2010.
- 9.4 **Invitation For Bid**
No. 2.0 does not apply to this solicitation
No. 3.0 does not apply to this solicitation
- 9.5 **General Terms and Conditions**
No. 6.0 does not apply to this solicitation

INVITATION FOR BID

10.0 QUOTE SHEET

SCOPE: The University of Alabama requests sealed bids to establish a contract upon date of award to Furnish and Deliver LIFEPAK® defibrillator/monitor devices per attached general and technical specifications **NO SUBSTITUTIONS allowed.**

IMPORTANT: The costs must include the product and the shipping cost. DO NOT LIST SHIPPING COST AS A SEPARATE CHARGE. Quote prices FOB The University of Alabama Prepaid and Allowed delivered and installed unless otherwise noted in the Solicitation.

<u>QTY</u>	<u>ITEM</u>	<u>COST PER UNIT</u>	<u>TOTAL COST</u>
3	LP20E-PKG, AHA 2005, Pacing, English with lithium-ion battery Brand _____ Model _____	_____	_____
3	LIFEPAK 20 defibrillator/monitor Standard Adult Detachable Hard Paddles (1 pair, with built-in pediatric paddles for use with LIFEPAK 20 defibrillator/monitor) Brand _____ Model _____	_____	_____
3	Basic Carry Case/Accessories Organizer (Includes a set of right and left pouches for additional storage of accessories) Brand _____ Model _____	_____	_____
15	Electrode Assembly-Adult, Pre-Connect System (EDGE system™ electrodes with REDI-PAK® preconnect system. Price per pair) Brand _____ Model _____	_____	_____
6	Box of Strip Chart Recorder Paper, 100MM x 22M Paper LP11/LP12 100MM Brand _____ Model _____	_____	_____
		GRAND TOTAL \$	_____

Can you meet the delivery requirement of July 20th, 2010? YES _____ NO _____

If no please explain _____

Please indicate if you can accept ACH payments (direct deposit): YES _____ NO _____

WARRANTY INFORMATION:

UNANTICIPATED ITEMS PURCHASED AT COST PLUS _____%

PORTABLE DEFIBRILLATOR/CRASH CART MONITOR
BID SPECIFICATIONS USA
LIFEPAK® 20 defibrillator/monitor

1. Defibrillator

- a) Device shall be supplied with: Door to automatically convert from AED Mode to Manual Mode, active matrix color LCD screen, built-in AC power supply, built-in battery charger, AC power cord, 3-lead ECG cable, defibrillator therapy pads, therapy cable, therapy cable test plug, ECG adult electrodes, 3 rolls of 50mm ECG printer paper, operating instructions, service manual on CD ROM, in-service video for AED, and Inservice video for manual defibrillation.
- b) Device shall include a removable, breakaway door to provide ease of interaction in AED mode for BLS responders, that, when opened, will automatically convert the display to a manual display with waveform functionality and manual buttons for ALS responders.
- c) Device can be set to any of 74 time zones in real time, as well as, to elapsed time.
- d) Device can be set to the user's choice of identification up to 20 letters or numbers that are displayed in clinical data reports.
- e) Device shall guide the operator through operating procedures with a combination of voice prompts and/or and visual prompts.
- f) Low battery indication: While in use, device shall alert operator to low battery condition with audible tone and visual message on screen.
- g) Device shall prompt the operator to perform CPR for a defined time period following each three-shock set and indication that no shock is advised. Device shall allow the customer to choose the CPR time after first shock and after second shock in increments of:
 - i. OFF (i.e., no CPR time after first or second shock)
 - ii. 15 seconds
 - iii. 30 seconds
 - iv. 45 seconds
 - v. 60 seconds
 - vi. 90 seconds
 - vii. 120 seconds
 - viii. 180 seconds
 - ix. 30 minutes
- h) Device shall have an AC Mains light on front of device to notify user whether device is plugged in, as well as, option of an audible tone to notify the user if device is unplugged. This audible tone needs to be user configurable in increments of:
 - i. Never Alert
 - ii. 5 minutes
 - iii. 15 minutes
 - iv. 30 minutes
- i) Self-testing:
 - i. Device shall be able to automatically run a daily self-test
 - ii. Device shall perform more extensive manually tests

2. Defibrillation Waveform

- a) Device shall utilize a biphasic truncated exponential waveform with voltage and duration compensation for patient impedance and the ability to escalate to 360J.
- b) Output energy accuracy: Output from device shall be accurate to within $\pm 1J$ or $\pm 10\%$ (whichever is greater) into a 50 ohm load, and to within $\pm 2J$ or $\pm 15\%$ into a 25 ohm to 100 ohm load.
- c) Output limit: Device shall be capable of delivering 360J into a 50-ohm load.

3. Physical Specifications

- a) Device shall weigh no more than 12.3 lbs (5.58 kg) Therapy cable shall add no more than .43 lbs (.2 kg) to the device.
- b) Standard hard paddles shall add no more than 1.95 lbs (.88 kg) to the device.
- c) Dimensions of the device shall not exceed 8.4 in (21.3 cm) in height, 10.3 in (26.2 cm) in width, and 10.3 in (26.2 cm) in depth, including handle.
- d) Device shall be available in three versions:
 - i. Without pacing or pulse oximetry
 - ii. With pacing
 - iii. With pacing and pulse oximetry

4. Display

- a) Device display shall have an active viewing area of not less than 4.53 in (115.18mm) wide by 3.4 in (86.38 mm) high.
- b) Device display shall be an active matrix color LCD with a resolution of 320x240 pixels.
- c) Device display when in AED mode shall show visual prompts to provide step-by-step therapy choices and provide the user the option to add a 1-channel ECG waveform while in AED mode.
- d) Device shall display a minimum of 4 seconds ECG and alphanumeric for patient parameter values, device instructions, or prompts.
- e) Device shall be configurable for display of two simultaneous waveforms in Manual mode.
- f) Device shall include a 'home screen' key which when depressed, returns the display to normal patient monitoring mode.
- g) Waveform display sweep speed shall be 25 mm/sec. for ECG.

5. ECG Monitoring

- a) Device shall monitor patient ECG via the following means:
 - i. 3-wire cable for 3-lead ECG monitoring
 - ii. 5-wire cable for 7-lead ECG monitoring
 - iii. Standard paddles
 - iv. QUIK-COMBO™ pacing/defibrillation/ECG electrodes
 - v. FAST-PATCH® disposable defibrillation electrodes
- b) Lead selection; the device shall provide the following monitoring options:
 - i. Leads I, II, III with the 3-wire ECG cable
 - ii. Leads I, II, III, AVR, AVL, AVF and C with the 5-wire ECG cable
 - iii. The monitor shall allow the operator to adjust the ECG size using the following settings; 4, 3, 2.5, 1.5, 1.0, 0.5, 0.25 cm/mV
- c) Monitor shall digitally display patient heart rates from 20 to 300 bpm.
- d) Monitor shall display "—" when the patient heart rate is out of range.
- e) Monitor shall flash a heart symbol for each patient QRS detected.
- f) Monitor shall incorporate a continuous patient surveillance system that will monitor the patient via paddles or Lead II for potentially shockable ECG rhythms, and alert the operator to check patient if a shockable ECG rhythm is detected.
- g) Monitor shall allow the operator to enable or disable voice prompts for selected warnings and alarms.
- h) Device shall provide 1V/mV x 1.0 gain analog ECG output with <30 ms delay.
- i) Device shall provide common mode rejection of at least 90dB at 50/60Hz.

6. Alarms

- a) Device shall incorporate a Quick Set feature that activates alarms for all parameters.
- b) Device shall incorporate a VF/VT alarm, which activates continuous patient surveillance of potentially shockable ECG rhythms during manual mode operation.

7. Printer

- a) Device shall be able to print a continuous strip of the displayed patient information.
- b) Device shall be able to print using 50mm (2.0 in) continuous strip paper.
- c) Printer shall be able to simultaneously print two waveforms on a 50mm (2.0 in) strip paper.
- d) Device shall print at 25mm/Sec +/- 5% (measured in accordance with AAMI EC-11, 4.2.5.2)
- e) Delay from display to printing shall be no more than 8 seconds.
- f) Device shall allow the operator to configure automatic printing of waveform events.
- g) Printer shall have a built-in print head protection to protect the print head when the device is out of paper.

8. Power

- a) Device shall be an AC line operated device with built-in battery.
- b) Device AC power total power draw shall be less than 75 watts.
- c) Device shall have a built-in NiMh (nickel metal hydride) internal battery that can charge while device operates from AC power while device is turned off or while monitoring.
- d) Internal battery recommended replacement is once every 2 years.
- e) Typical battery charge time shall be <2 hours when device is off and AC power is applied.
- f) When device is unplugged from AC power, it shall automatically switch to battery. When battery power falls below a pre-determined level, a low battery message in the status area must show on display and an audible warning tone must occur.
- g) With inadvertent loss of power (<30 seconds) the device must retain settings.
- h) Service LED must illuminate on the front of the device when error detected to notify the user.
- i) A new, fully charged internal battery must provide the following prior to shutdown:
 - i. Monitoring (in minutes): 120 (total) and 5 (after low battery message)
 - ii. Monitoring in device without pulse oximeter (in minutes): 135 (total) and 5 (after low battery message)
 - iii. Defibrillation (360 joule discharges): 90 (total) and 3 (after low battery message)
 - iv. Monitoring and pacing (minutes at 100 mA, 60 ppm): 70 (total) and 2 (after low battery message).

9. Pulse Oximetry (SpO₂)

- a) Device shall incorporate pulse oximetry (SpO₂) monitoring using Masimo sensors.
- b) Device shall measure and display SpO₂ in the saturation range of 1 to 100%.
- c) Saturation accuracy at 70-100% (0-69% unspecified):
 - i. Adults/Pediatrics: +/- 2 digits (during no motion conditions) or +/- 3 digits (during motion conditions)
 - ii. Neonates: +/- 3 digits (during motion or no motion conditions)
- d) Device shall update averaging rate of the SpO₂ is user selectable at 4, 8, 12, or 16 seconds.
- e) Device shall measure, display, and store functional SpO₂ values.
- f) Device shall display pulse rate accuracy (Adults/Pediatrics/Neonates) from the SpO₂ circuit to within +/- 3 digits (during no motion conditions) or +/- 5 digits (during motion conditions).
- g) SpO₂ display section of the monitor shall include a dynamic signal strength bar graph.
- h) Device shall emit a pulse tone at the onset of the pleth waveform.
- i) When defibrillator is turned on, pulse oximeter will automatically turn on and perform a self-test. When the defibrillator is turned off the pulse oximeter also turns off.
- j) Device shall allow the pulse oximeter to go into "sleep mode" when not in use to conserve battery power. Sleep mode is activated within 10 seconds of disconnecting the sensor. The pulse oximeter will return to normal mode after detecting a sensor or a patient signal. The pulse oximeter performs the self-test when it returns from sleep mode to active mode.
- k) SpO₂ waveform shall automatically size itself to provide optimum waveform viewing.
- l) Device shall adjust the SpO₂ pulse tone volume.

10. Non-Invasive Pacer

- a) Device shall operate in demand and non-demand modes.
- b) Device shall allow the operator to set the default rate and current values.
- c) Device shall generate pacing pulses at a rate of 40 to 170ppm.
- d) Accuracy of the pacing output rate shall be within +/- 1.5% over the entire range.
- e) Device shall generate a monophasic output waveform, amplitude stable to +/- 5% relative to leading edge for currents greater than or equal to 40 mA, Duration 20 +/- ms, Rise/Fall time ≤ 1 ms [10-90% levels].
- f) Device shall allow the operator to select the pacing output current from 0 to 200mA.
- g) Device shall incorporate a pacing pause function that allows the operator to reduce the pacing rate by a factor of 4 when activated to assess the patient's underlying ECG rhythm.
- h) Pacing circuit shall include automatic adjustment of the refractory period (function of rate) from 200 to 300 ms +/- 3%, to ensure maintenance of the operator-selected rate.

11. Accessories

- a) The manufacturer shall have device accessories available for day-to-day operation.
- b) Optional accessories shall include the following:
 - i. Docking station – to connect to crash cart.
 - ii. Standard adult hard paddles - with built-in pediatric paddle that includes instructional arrows on how to access pediatric paddles.
 - iii. Accessory pouch to hold therapy cable and set of therapy pads.
 - iv. External sterilizable paddles
 - v. Internal paddle handles with discharge control
 - vi. Internal paddles that come in the following sizes:
 - 1 inch
 - 1.5 inch
 - 2.0 inch
 - 2.5 inch (5.5 inch shaft length)
 - 2.5 inch (8.5 inch shaft length)
 - 3.5 inch
- c) Manufacturer will supply an operator's handbook that fully describes the operation of the device that is included with every device ordered.
- d) Manufacturer will supply a service manual (on CD ROM) with every device ordered.
- e) Manufacturer will supply a test plug to test integrity of therapy cable.

12. Shock Advisory Algorithm

- a) ECG analysis: Device shall complete analysis cycle in less than 9 seconds.
- b) Device shall be capable of detecting patient movement such as that created by excessive patient breathing, CPR or vehicle movement. During such patient motion periods, the device shall stop rhythm analysis, notify the operator audibly that motion is detected, and resume analysis when patient motion subsides.
- c) Device shall identify ventricular tachycardia based, in part, on the following criteria:
 - i. Minimum heart rate greater than or equal to 120 beats per minute
 - ii. No apparent P waves
 - iii. QRS widths greater than 160 ms
- d) Manufacturer shall provide clinically relevant evidence of device algorithm sensitivity with the following specifications:
 - i. Overall sensitivity in excess of 90%
 - ii. Overall specificity in excess of 95%

13. Configuration Settings

- a) To prevent unauthorized access to the setup and service menus, the device shall require separate 4 digit numeric security pass codes to be entered.
- b) Device shall allow the operator to configure specific settings for the following software modules in the setup mode:
 - o **General:** shall allow user to select the following:
 - Language choice (in text)
 - Critical event record format
 - Site number
 - Device number
 - Automatic vital signs event capture every 5 minutes
 - Line filter setting
 - Timeout speed for delay before a menu is dismissed
 - AC loss alert warning (user configurable to be 5, 15, 30 minutes apart, or never to alert)
 - o **Manual Mode:** Shall allow the user to select the following:
 - Sync after shock - On or Off
 - Paddles default energy setting of 2, 5, 10, 50, 100, 125, 150, 175, 200, 300 joules or sequence of defibrillation energy settings full range:
 - o Energy level one: 100, 125, 150, 175, and 200
 - o Energy level two: All of energy level 1 and 225, 250, 275, and 300
 - o Energy level three: All of energy level 2 and 325, 360 joules.
[Energy level 2 cannot be less than Energy level 1. Energy level 3 cannot be less than Energy level 2.]
 - Pediatric range:
 - o Energy level one: 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 30, 50, 70, 100 joules
 - o Energy level two: Same as energy level 1
 - o Energy level three: Same as energy level 1 and 125 and 150 joules.
[Energy 2 cannot be less than Energy level 1. Energy level 3 cannot be less than Energy level 2.]
 - Internal paddles default energy setting of 2, 5, 10, 20 30 or 50 joules
 - Voice prompts in manual mode - On or Off
 - Shock tone when full charge is reached - On or Off
 - Manual access selection of Direct, Confirmed, or Passcode
 - Set passcode to enter manual access of: None - default passcode enabled or NEW - user defined 4-digit passcode enabled.
 - o **AED Mode:** Shall allow the user to select the following:
 - Sequence of defibrillation energy settings 200/200-300/200-360 joules.
[Energy 2 cannot be less than Energy 1. Energy 3 cannot be less than Energy 2.]
 - Voice prompts in AED mode - On or Off
 - Automatically analyzes after shock - On or Off
 - Motion detection - On or Off
 - ECG display - On or Off
 - CPR time interval OFF, 15, 30, 45, 60, 90, 120, or 180 seconds or 30 minutes
 - Continuous patient surveillance system during CPR - On or Off

- **Pacing:** Shall allow the user to select the following:
 - Default pacing rate of 40 to 170ppm
 - Default output current of 0 to 200mA
 - Default mode of Demand or Nondemand
- **Monitoring:** Shall allow the user to select the following:
 - Channel 1: Paddles, ECG Lead I, ECG Lead II, ECG Lead III, (AVR, AVL, AVF, and C)
 - Channel 2: None, Cascading ECG, paddles, ECG Lead I, ECG Lead II, ECG Lead III, (AVR, AVL, AVF, and C), SpO₂
- **Events:** Shall allow the user to select the following:
 - Selection of events 2 through 9 from a preset list
 - Selection of events 10 through 18 from a preset list
 - User customization of up to 16 events to be included in the list
- **Alarms:** Shall allow the user to select the following:
 - Set volume for alarms, tones, and voice prompts
 - Enable or disable parameter alarms at power up
 - VF/VT alarm enabled or disabled.
- **Printer:** Shall allow the user to select the following:
 - Auto print event selection:
 - Print defibrillation events - On or Off
 - Print pacing events - On or Off
 - Print Check Patient events - On or Off
 - Print shock advisory system (SAS) events - On or Off
 - Print patient alarms - On or Off
 - Print operator annotated events - On or Off
 - Print initial rhythm - On or Off
 - Default ECG frequency response of:
 - Monitor
 - Diagnostic
- **Clock:** Shall allow the user to select the following:
 - Set the current date and time
 - Select real or elapsed time on the display
 - Daylight Savings Time - On or Off
 - Time Zone: 74 time zone settings or None
- **Reset Defaults:** Shall allow the user to select the following:
 - Reset all values to the factory default settings.
- **Print Defaults:** Shall allow the user to select the following:
 - Printout the current device configuration setup.
- **Send Config:** Shall allow one device to:
 - Send setup configuration from one device to another using a serial cable.

- **Set Passcode:** Shall allow the user to select the following:
 - Factory default passcode can be changed to a user defined passcode
- **Service Mode:** Shall allow the user to select the following:
 - Defibrillator Calibration
 - Tests
 - Buttons
 - Pixel Test
 - Printer
 - Voice/Tones
 - Status
 - Device Log
 - Device Data
 - Service Log
 - Counters
 - Clear Memory
 - Set Passcode
 - Factory default passcode can be changed to a user defined passcode
 - Maintenance Prompt
 - Interval. Set. Display prompt to complete device maintenance to:
 - Off
 - 3 months
 - 6 months
 - 12 months

14. Communications

- a) Device shall have a serial connection port.
- b) Device shall be EIA/TIA-RS232E compatible at 9,600, 19,200, 38,400, 57,600, and 115,200 bps.

15. Environmental

- a) Device shall operate from 5° to 45°C (41° to 113°F).
- b) Non-operating temperature range of the device shall be -20° to +60°C (-4° to 140°F) except therapy electrodes.
- c) Device shall operate in relative humidity from 5 to 95%, non-condensing except therapy electrodes.
- d) Device shall operate from ambient to 429mmHg (0 to 15,000 ft).
- e) Device (without accessories except for ECG Cable and Hard Paddles) shall be spillage-proof (IPX1) per IEC 60601-1 clause 44.6.
- f) Device shall meet EMC emissions standards; MIL-STD-461D RE101; IEC 60601-1-2 (1993) subclause 36.201.1.
- g) Device shall meet EMC susceptibility standards: MIL-STD-461D CS114, RS101; IEC 60601-1-2 (1993) subclause 36.202.
- h) Device shall operate normally after 1 drop on each side from 18 inches onto a steel surface.
- i) Device shall meet vibration standard MIL-STD-810E Method 514.4 Category 1.



DISCLOSURE STATEMENT

1. Contract/Purchase Order No. _____

2. Name of Contract/Grantee: _____

Address: _____

Telephone: _____

Fax: _____

3. Nature of Contract/Grant: _____

4. Does the contractor/grantee have any relationships with any employee or official of the University, or a family member of such employee or official, that will enable such employee or official, or his/her family member, to benefit from this contract? If so, please state the names, relationships, and nature of the benefit.

(For employees of the University, family members include spouse and dependents. For members of the Board of Trustees (officials), family members include spouse, dependents, adult children and their spouses, parents, in-laws, siblings and their spouses.)

This Disclosure Form will be available for public inspection upon request.

The above information is true and accurate, to the best of my knowledge.

Signature of Authorized Agent of Contractor/Grantee

Date: _____

RETURN FORM TO: The University of Alabama
Purchasing Dept.
Box 870130
Tuscaloosa, AL 35487-0130
Ph: (205) 348-5230
Fax: (205) 348-8706
www.purchasing.ua.edu