

STATEMENT OF WORK

A. DESCRIPTION: Defibrillator

_____Crash cart defibrillators with state of the art biphasic wave forms technology that meets or exceeds American Heart Association 2010 recommendations

_____Four bay battery reconditioning stations

_____Additional batteries

_____Training simulators

MUST MEET OR EXCEED SALIENT CHARACTERISTICS BELOW:

GENERAL REQUIREMENTS:

- Defibrillator with AED option
- The unit shall utilize a biphasic defibrillation waveform in both AED and Manual Mode
- The AED and advisory protocols shall comply with the recommendations in the American Heart Association's Guidelines 2010 for chest compressions (CPR) first
- The AED and advisory protocols shall comply with the recommendations in the American Heart Association's Guidelines 2010 for single shocks
- Defibrillator shall provide for user-configurable fixed and escalating energy capabilities in both manual and advisory modes.
- Time for the defibrillator to charge to maximal energy shall not exceed 7 seconds
- The following information shall be displayed on, and stored with, defibrillation-related ECG recordings: selected energy, delivered energy and patient impedance
- Defibrillator shall provide AED, manual and shock advisory operating modes
- CPR feedback
- AC power shall be a standard, internal feature of the defibrillator; detachable AC modules are not an acceptable alternative
- The defibrillator shall charge its battery when connected to an AC power source (self contained chargers)
- Lithium ion batteries
- Multipurpose pads
- Defibrillator shall have a recorder capable of printing multiple channels when in manual mode

TRANSTHORACIC PACING REQUIREMENTS (Manual Mode):

- Defibrillator shall have an option for transthoracic (external) pacing
- Defibrillator shall employ a 40 msec (+/- 2ms), rectilinear wave form for transthoracic pacing
- Defibrillator shall permit the configuration of an initial pacing rate
- Transthoracic pacing controls shall provide for continuously variable current delivery levels and pacing rates
- Transthoracic pacing shall provide a 4:1 function that permits operators, to examine an underlying rhythm of a paced patient without losing capture
- Transthoracic pacing settings for current delivery and rates shall be maintained when switching between pacing a defibrillation, or pacing and monitoring modes.

- Defibrillator shall have the ability to monitor and display the ECG in multiple vectors while performing transthoracic pacing without requiring the attachment of separate ECG electrodes and leads.
- Transthoracic pacing shall not be interrupted by the loss of an ECG lead.
- Defibrillator shall perform a self test daily
- End tidal carbon dioxide detectors
- Pulse oximetry (capability)
- Non-invasive blood pressure monitoring (capability)
- Pediatric paddles capabilities (capability)
- 3 lead ECG
- Synchronization and pacing capabilities

ECG MONITORING REQUIREMENTS:

- Defibrillator shall be able to acquire an ECG by way of standard ECG electrodes (in a 3 or 5 lead configuration) when in manual mode, paddles when in manual mode, multifunction defibrillation pads, and resuscitation electrodes
- Defibrillator shall have the ability to support the delivery of quality chest compressions during CPR efforts
- Defibrillator shall have an integrated CPR quality indicator that displays how well chest compression delivery meets American Heart Association recommendations
- Defibrillator shall provide a filter that removes chest compression artifact from the ECG signal
- In the Advisory mode for BLS-trained responders, the rate prompting shall be activated at the start of a CPR cycle
- Defibrillator shall have pacemaker detection capability
- Defibrillator shall detect heart rates up to 300 beats per minute (+/-5%)
- Defibrillator shall have the ability to print ECG recordings upon the activation of a heart rate alarm when in manual mode
- Defibrillator shall have a configuration that triggers an alarm and displays a “check patient” message upon the detection of ventricular fibrillation

DISPLAY REQUIREMENTS:

- Defibrillator shall have a color display
- Defibrillator shall have the ability to simultaneously display 3 channels of physiologic information when in manual mode
- Displayed channels shall be able to show ECG leads, physiologic parameters (i.e. pulse oximetry), and chest compression performance
- At least two of the displayed channels shall be user selectable during a code event
- AED mode shall have the ability to display heart rate, waveform, SpO2 and messaging
- The user shall have the ability to configure the AED display

CODE READINESS REQUIREMENTS:

- Defibrillator shall perform a self test at power up
- Defibrillator shall have a code readiness testing function
- Defibrillator code readiness test shall operate in either a manual or automatic mode
- Defibrillator shall employ a prominent, two-state (pass-Fail) indicator to signify its state of code readiness; simple indicators (i.e. LEDs) are not an acceptable alternative
- Defibrillator code readiness test shall evaluate the functional status of the defibrillator, pacer, and ECG capabilities of the unit along with the status of the therapy cables, compatible resuscitation electrodes, and paddles
- Should a defibrillator fail a code readiness test it shall display all causative items

- Defibrillator shall have the ability to automatically print the results of a code readiness test
- Results of each code readiness test, automatic or manual, shall be stored on the defibrillator in nonvolatile memory
- Defibrillator shall have the ability to print a log of all code readiness tests results stored in the defibrillator
- Defibrillator shall have the ability to display and print the detailed results of any code readiness test stored in the defibrillator

BATTERY REQUIREMENTS:

- Defibrillator shall use a rechargeable battery with a minimal capacity of 5.8 amp/hrs
- Battery shall store a history of its use and maintenance
- Defibrillator battery shall have an indicator of runtime; capacity indicators (i.e. 100%, 75%, 50%, etc.) are not an acceptable substitute
- Defibrillator battery shall have separate calibration and fault indicators

PULSE OXIMETRY REQUIREMENTS:

- Defibrillator shall have an option for pulse oximetry
- Pulse oximetry shall employ signal extraction technology
- Pulse oximetry shall have documented minimal sensitivity and specificity levels of 99% and 97%, respectively under motion conditions
- Pulse oximetry shall have a saturation accuracy of +/- 2% in adult and pediatric patients under non-motion conditions
- Pulse oximetry shall have a saturation accuracy of +/-3% in adult and pediatric patients under motion conditions

NON-INVASIVE BLOOD PRESSURE REQUIREMENTS:

- Defibrillator shall have an option for non-invasive blood pressure
- Defibrillator shall have the ability to be programmed to take repeat measurements over a period of time or abort by pressing a single button
- Defibrillators shall have the option to automatically adjust based upon the previously measured systolic value
- Defibrillator shall be able to display at least four hours worth of blood pressure measurements
- Defibrillator shall have alarms that can be configured to alert a clinician when a blood pressure is above or below pre-set values.

END TIDAL CARBON DIOXIDE REQUIREMENTS:

- Defibrillator shall have an End Tidal Carbon Dioxide measurement
- Defibrillator shall have the ability to display both a graphical representation of the concentration or partial pressure of expired carbon dioxide during a respiratory cycle in a capnogram waveform format as well as a numerical display
- Defibrillator shall have mainstream capnography capable of monitoring both intubated and non-intubated patients

STORAGE REQUIREMENTS:

- Defibrillator shall have the ability to store clinical data that includes: a summary of the code, chest compression data, code-related ECG recordings, and a full disclosure file
- Defibrillator shall store defibrillator maintenance data that includes: a troubleshooting log that annotates keystrokes, prompts and warning messages on a first-in first-out basis; a readiness test log that records the results of code readiness tests whether performed manually or automatically; and readiness test log detail that records the pass-fail details of individual readiness tests

COMMUNICATION AND TRANSFER REQUIREMENTS:

- Defibrillator shall be capable of transferring the clinical data files
- Defibrillator shall be capable of transferring maintenance-related files

BATTERY CHARGING AND TEST STATION REQUIREMENTS:

- There shall be a battery charging and test station (battery station) available for the defibrillator battery
- Battery station shall simultaneously charge and test no less than 4 batteries
- Battery station shall automatically calibrate compatible batteries after 500 amp/hrs of use or every 12 months
- Battery station shall minimally provide the following maintenance protocols: Quick Charge, Float Charge, Auto Test and Manual Test
- Battery station shall provide a test button for each battery well
- The well for each battery shall have separate indicators for charging, charging completed, test in progress, and fault
- Battery station shall be able to download the use and maintenance history of compatible batteries
- Battery station shall be able to communicate the use and maintenance history of a battery to a PC running compatible battery management software package

SPECIAL REQUIREMENTS:

Hospital standards will apply to BLS and ACLS training of staff who will be utilizing the AEDs and oversee their training and documentation requirements. The vendor shall provide a full schedule of initial applications training for appropriate staff to include follow-up applications scheduled three to six months after initial training, if required. The vendor shall provide a CD ROM and Operator &/ Service Manual for each facility, Bio-Med training on the maintenance of the defibrillators (include travel and tuition), and a Buy-back program for _____ of defibrillators.