# SPECIFICATION PACKET

# CPR CHEST COMPRESSION SYSTEM

# 2018

The Jessamine County Fiscal Court will be accepting sealed bids on (2) "CPR Chest Compression System(s)" at the County Judge/Executive's Office Jessamine County Courthouse, 101 North Main Street, Nicholasville, KY 40356 until March 19, 2018, at 12:00 p.m. EST. Bids will be opened on March 19, 2018 at 12:00 p.m. EST at the Jessamine County Court House, and be awarded at the Fiscal Court Meeting on March 20, 2018, at 4:00 p.m. Specifications may be picked up from the Division of Emergency Services, Public Safety Center, 101 South Second Street, Ste. B, Nicholasville, KY. 40356, or by calling (859) 887-2987. The Jessamine County Fiscal Court reserves the right to reject any or all bids.

**This needs to be placed in the March 8, 2018, Jessamine Journal and run until March 15, 2018.**

# Reciprocal Preference for Kentucky Resident Bidders

**KRS 45A.490 Definitions for KRS 45A.490 to 45A.494.**
As used in KRS 45A.490 to 45A.494:
(1) "Contract" means any agreement of a public agency, including grants and orders, for the purchase or disposal of supplies, services, construction, or any other item; and
(2) "Public agency" has the same meaning as in KRS 61.805.

**KRS 45A.492 Legislative declarations.**
The General Assembly declares:
(1) A public purpose of the Commonwealth is served by providing preference to Kentucky residents in contracts by public agencies; and
(2) Providing preference to Kentucky residents equalizes the competition with other states that provide preference to their residents.

**KRS 45A.494 Reciprocal preference to be given by public agencies to resident bidders -- List of states -- Administrative regulations.**
(1) Prior to a contract being awarded to the lowest responsible and responsive bidder on a contract by a public agency, a resident bidder of the Commonwealth shall be given a preference against a nonresident bidder registered in any state that gives or requires a preference to bidders from that state. The preference shall be equal to the preference given or required by the state of the nonresident bidder.
(2) A resident bidder is an individual, partnership, association, corporation, or other business entity that, on the date the contract is first advertised or announced as available for bidding:
(a) Is authorized to transact business in the Commonwealth; and
(b) Has for one (1) year prior to and through the date of the advertisement, filed Kentucky corporate income taxes, made payments to the Kentucky unemployment insurance fund established in KRS 341.490, and maintained a Kentucky workers' compensation policy in effect.
(3) A nonresident bidder is an individual, partnership, association, corporation, or other business entity that does not meet the requirements of subsection (2) of this section.
(4) If a procurement determination results in a tie between a resident bidder and a nonresident bidder, preference shall be given to the resident bidder.
(5) This section shall apply to all contracts funded or controlled in whole or in part by a public agency.
(6) The Finance and Administration Cabinet shall maintain a list of states that give to or require a preference for their own resident bidders, including details of the preference given to such bidders, to be used by public agencies in determining resident bidder preferences. The cabinet shall also promulgate administrative regulations in accordance with KRS Chapter 13A establishing the procedure by which the preferences required by this section shall be given.
(7) The preference for resident bidders shall not be given if the preference conflicts with federal law.
(8) Any public agency soliciting or advertising for bids for contracts shall make KRS 45A.490 to 45A.494 part of the solicitation or advertisement for bids.

The reciprocal preference as described in KRS 45A.490-494 above shall be applied in accordance with 200 KAR 5:400.

# REQUIRED AFFIDAVIT FOR BIDDERS, OFFERORS AND CONTRACTORS CLAIMING RESIDENT BIDDER STATUS

**FOR BIDS AND CONTRACTS IN GENERAL:**
The bidder or offeror hereby swears and affirms under penalty of perjury that, in accordance with KRS 45A.494(2), the entity bidding is an individual, partnership, association, corporation, or other business entity that, on the date the contract is first advertised or announced as available for bidding:

1. Is authorized to transact business in the Commonwealth;
2. Has for one year prior to and through the date of advertisement
   a. Filed Kentucky corporate income taxes;
   b. Made payments to the Kentucky unemployment insurance fund established in KRS 341.49; and
   c. Maintained a Kentucky workers' compensation policy in effect.

The BIDDING AGENCY reserves the right to request documentation supporting a bidder's claim of resident bidder status. Failure to provide such documentation upon request shall result in disqualification of the bidder or contract termination.

_____ _____
Signature Printed Name

_____ _____
Title Date

Company Name _____

Address _____

_____

_____

Subscribed and sworn to before me by _____ _____
(Affiant) (Title)

of _____ this _____day of _____,20___.
(Company Name)

_____
Notary Public

[seal of notary] My commission expires: _____

# REQUIRED AFFIDAVIT FOR BIDDERS, OFFERORS AND CONTRACTORS CLAIMING QUALIFIED BIDDER STATUS

**FOR BIDS AND CONTRACTS IN GENERAL:**

I. The bidder or offeror swears and affirms under penalty of perjury that the entity bidding, and all subcontractors therein, meets the requirements to be considered a "qualified bidder" in accordance with 200 KAR 5:410(3); and will continue to comply with such requirements for the duration of any contract awarded. Please identify below the particular "qualified bidder" status claimed by the bidding entity.

_____ A nonprofit corporation that furthers the purposes of KRS Chapter 163

_____ Per KRS 45A.465(3), a "Qualified nonprofit agency for individuals with severe disabilities" means an organization that:
(a) Is organized and operated in the interest of individuals with severe disabilities; and
(b) Complies with any applicable occupational health and safety law of the United States and the Commonwealth; and
(c) In the manufacture or provision of products or services listed or purchased under KRS 45A.470, during the fiscal year employs individuals with severe disabilities for not less than seventy-five percent (75%) of the man hours of direct labor required for the manufacture or provision of the products or services; and
(d) Is registered and in good standing as a nonprofit organization with the Secretary of State.

The BIDDING AGENCY reserves the right to request documentation supporting a bidder's claim of qualified bidder status. Failure to provide such documentation upon request may result in disqualification of the bidder or contract termination.

_____ _____
Signature Printed Name

_____ _____
Title Date

Company Name _____

Address _____

_____

# Method of Award

Best Value – Ranking Approach
**Jessamine County Fiscal Court** intends to award a Contract to the Vendor, whose offer, conforming to the Solicitation, is the most advantageous on the basis of "best value" for all products, services, and requirements contained herein.

An evaluation committee, or a designated individual, will evaluate the information provided by the Vendor in response to the established measurable criteria contained in the Solicitation.

**Measurable Criteria:**

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| **Price** | **95 Points** |
| **Delivery** | **5 Points** |
| **TOTAL POINTS** | **100 Points** |

Each Vendor is responsible for submitting all relevant, factual and correct information with their offer to enable the evaluator(s) to afford each Vendor the maximum score based on the available data submitted by the Vendor. VENDOR SHALL ENTER UNIT PRICE AND TOTAL PRICE ON THE BID SHEET. If adequate space is not available, the Vendor must attach additional information that clearly cross-references the appropriate location in the solicitation (i.e. page number, paragraph, subject, etc.).

Vendors responding with the minimum Best Value requirements in this Solicitation shall not be credited with Best Value points. Vendors responding with greater than the minimum requirements shall receive Best Value points. Failure to provide adequate information will impact the evaluated points awarded to the Vendor.

**Price (95 points)**

The bidder with the lowest Price receives the maximum score. The bidder with the next lowest Price receives points by dividing the lowest Price by the next lowest price and multiplying that percentage by the available points. For example, 95 points is allocated to the lowest Price criteria for this procurement, Bidder "A" bids $3.00 as the lowest bidder and receives the maximum 95 points ($3.00 / $3.00 = 1.00 x 95 = 95). Assume Bidder "B" is the next lowest bidder at $4.00, then "B" receives 71.3 points ($3.00 / $4.00) = .75 x 95 = 71.25).

**Delivery (5 points)**
The bidder with the best delivery time receives the maximum score. The bidder with the next best delivery time receives points by dividing the best delivery by the next best delivery and multiplying that percentage by the available points. For example, 5 points is allocated to the best delivery time for this procurement, Bidder "A" bids 10 days as the best delivery time and receives the maximum 5 points (10 / 10 = 1.00 x 5 = 5). Assume Bidder "B" bids the next best delivery time 15 days, then "B" receives 3.33 points (10 / 15) = ..67 x 5 = 3.33).

Vendor shall enter best delivery time in working days: _____DAYS ARO

The Vendor agrees that when delivery is not made within the contracted due date, one percent (1%) per day shall be deducted from the Vendor's invoice for each day the Vendor fails to meet the contracted delivery date.

Best Value scoring is subject to **Reciprocal preference for Kentucky resident bidders and Preferences for a Qualified Bidder or the Department of Corrections, Division of Prison Industries (KAR 200 5:410). *Vendors not claiming resident bidder or qualified bidder status need not submit the corresponding affidavit.**

Bid Specifications

| Device and Therapy | |
|---|---|
| Device version | • 3rd generation chest compression system, based on 15 years of data, more than 24,000 devices deployed, and 200+ publications. Improved with new slim back plate, a compact hard-shell carrying case, wireless Bluetooth® connectivity, and availability of post-event device reports. |
| Type of chest compression | • Chest compressions consistent with AHA and ERC guidelines, delivered in the middle of the chest<br>• Unique compression using piston with suction cup designed to stabilize the compression point, and which may assist chest recoil back to the start position. |
| Compression rate | • 102 ± 2 compressions per minute |
| Compression depth | • 2.1± 0.1 inches / 53±2 mm for patients with sternum height greater than 7.3 inches / 185 mm<br>• 1.5 to 2.1 inches / 40 to 53 mm for patients with sternum height less than 7.3 inches / 185 mm |
| Chest recoil | • Allows for chest recoil between each compression<br>• Remembers the start position of the suction cup<br>• Suction cup may assist chest recoil |
| Compression duty cycle | • 50±5% |
| Compression modes (operator selectable) | • 30:2 (30 compressions followed by a 3 sec ventilation pause)<br>• Continuous compressions with 10 ventilation alerts per minute |
| Type of system | • Two part device assembly (back plate and upper part)<br>• Simple to use, 1-2-3 step user interface with no complicated programming<br>• Device deployment in less than 20 sec, documented as short as 7 sec (median) in real clinical use[1]<br>• Advanced automatic control of delivered compression depth in the individual patient, compression rate and duty cycle, with safety alarm<br>• Automatic fine-tuning of suction cup's contact to chest when setting the start position (Quick Fit)<br>• Automatic adjustment of compression force and depth to individual chest stiffness (Soft Start)<br>• Remembers the set start position during active and pause modes, and when changing batteries (Smart Restart)<br>• Thin and lightweight back plate (15 mm/0.6 inches and1.1 kg / 2.5 lbs)<br>• Holes in back plate allow for strapping and securing onto transportation device<br>• Patient and stabilization straps to secure device to patient<br>• Cath lab compatible as the device is mainly radiotranslucent, except for hood, piston and metallic screws. Carbon fiber back plate (optional) designed and optimized for cath lab use.<br>• Foldable support legs to minimize size when stored in compact carrying case<br>• Automatic self-test at each Power ON<br>• Extended operation time when connected to external power (wall mains or car cable) (typical, nominal patient), 45 min operation time on battery alone (typical, nominal patient)<br>• Documented fit of ~95% of cardiac arrest patients in U.S. and Europe |

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| Patients eligible for treatment | • 6.7 to 11.9 inches / 17.0 to 30.3 cm sternum height (anterior – posterior)<br>• 17.7 inches / 44.9 cm chest width<br>• No patient weight limitation |
| Indications | • Adult patients in cardiac arrest where chest compressions are likely to help the patient<br>• For use as an adjunct to manual CPR when effective manual CPR is not possible (e.g., patient transport, extended CPR, fatigue, insufficient personnel). |
| Contraindications | • Do not use if not possible to position the device safely or correctly on the patient, the patient is too small or too large for the device |
| Safety and Efficacy documentation | |
| Clinical safety and efficacy data | • Highest level of clinical evidence; a randomized, controlled out-of-hospital trial, showing device is as safe and effective as high-quality manual CPR[3]<br>• Shown to contribute to over 99% good neurological outcomes at 6 months follow up in out-of-hospital cardiac arrest survivors[3]<br>• Shown to improve quality of compressions compared to manual CPR<br>• Shown to reduce interruptions at the scene, during patient movement and transportation compared to manual CPR<br>• Shown to increase circulation to brain and heart compared to manual CPR<br>• Documented similar type of side-effects as manual CPR in autopsy studies<br>• Shown to increase the opportunities to save patients by serving as a bridge to other lifesaving treatments such as ECMO and PCI<br>• Shown to improve ROSC and survival chances in resistant cardiac arrest occurring in the cath lab<br>• Shown to create good neurological outcomes despite prolonged CPR of several hours<br>• Documented high level of operational reliability in multicenter study (>99%)[3]<br>• Documented 7-second median application time in real clinical use[i]<br>• With over 200 scientific publications the device has the largest body of data of any mechanical CPR device. The device is documented to meet the demands throughout the chain of survival. |
| Settings and concomitant therapies | • Tested for EN 1789:2007 + A2:2014 Medical vehicles and their equipment—Road ambulances<br>• Tested for EN 13718-1:2014 Medical vehicles and their equipment—Air ambulances Part 1: Requirements for medical devices used in air ambulances<br>• Catheterization laboratory; documented to allow for oblique fluoroscopy projections, catheterization, angiography and potentially life-saving angioplasty during ongoing compressions<br>• Defibrillation; defibrillation proof device and documented safe and effective to defibrillate during ongoing device compressions.[3]Defibrillation pads can be applied before or after device application.<br>• Ventilation; intubation can be done during ongoing compressions. There are two selectable compression modes of 30:2 (pause for 2 ventilations) or continuous compressions with 10 ventilation alerts. |

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| Tested against global standards (selected examples) | • EN 1789:2007 + A2:2014 Medical vehicles and their equipment— Road ambulances<br>• EN 13718-1:2014 Medical vehicles and their equipment—Air ambulances Part 1: Requirements for medical devices used in air ambulances<br>• EN 60601-1:2006/A1:2013 (including A11:2011 and A12:2014) (edition 3.1) Medical electrical equipment—Part 1: General requirements for basic safety and essential performance<br>• EN 60601-1-2:2007/AC:2010 Medical electrical equipment—Part 1-2: General requirements for basic safety and essential performance—Collateral standard: Electromagnetic compatibility—Requirements and tests<br>• IEC 60601-1-6:2010 + A1:2015 Medical electrical equipment—Part 1-6: General requirements for basic safety and essential performance—Collateral standard: Usability<br>• EN 60601-1-8:2007 + A1:2013 Medical electrical equipment—Part 1-8: General requirements for basic safety and essential performance—Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems<br>• IEC 60601-1-12:2014 Medical electrical equipment—Part 1-12: General requirements for basic safety and essential performance—Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services<br>• ANSI/AAMI ES 60601-1:2005(R)2012 Medical Electrical Equipment—Part 1: General Requirements for Basic Safety and Essential Performance; with AMD C1; 2009, AMD 2; 2010, AMD 1; 2012<br>• CSA C22.2 No.60601-1:14 (3rd edition) Medical electrical equipment—Part 1: General requirements for basic safety and essential performance; COR 2: 2011/06/01<br>• EN 62366:2008 + A1:2015 Medical devices—Application of usability engineering to medical devices<br>• EN IEC 62133:2012 + CORR 1:2013 Secondary cells and batteries containing alkaline or other non-acid electrolytes—Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications—Edition 2.0 |
| **Maintenance and implementation support** | |
| Maintenance and service | • Routine check recommended weekly and after each use<br>• Battery can be charged in device (in bag) connected to external power (<2 hours), or in external desk-top charger (<4 hours)<br>• No need for battery test/reconditioning or written battery administration<br>• Hard-shell carrying case allows for charge while in bag and check of battery status through top window<br>• Disposable suction cup<br>• Yearly service recommended, optional on-site service* with included loaner device |
| Training of teams | • Comprehensive train-the-trainer guide and training materials available<br>• Documented by users as easy or very to learn (>99%)[2] |
| Clinical support | • Network of experienced users from various settings, sharing of best practice and clinical protocols, support and research |
| **Device post-event data and connectivity** | |
| Communication | Bluetooth 2.1 wireless communication built into device to allow for wireless transmission of device data to PC with Bluetooth ability |

* May not be available in all geographies.

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| Types of post-event data | Easy to read post-event reports (PDF) showing:<br>• Compression ratio<br>• Compression rate<br>• Compression count<br>• Pauses over 10 seconds<br>• Longest compression pause<br>• Visual timeline showing device operation and pauses<br>• Event log showing user interactions, battery alerts and alarms |
| Reporting software | • Report Generator software (available online) with ability to print, save and share reports of each use (PDF format)<br>• The report generator can be downloaded on a pc with Windows® 7, 8.1 or 10 |
| Device data storage | 4GB (estimated to store more than two uses per day over the lifetime of the device) |
| **Device physical specifications** | |
| Device dimensions when assembled (HxWxD) | 22.0 x 20.5 x 9.4 inches / 56 x 52 x 24 cm |
| Device dimensions while stored in Carrying Case (HxWxD) | 22.8 x 13.0 x 10.2 inches / 58 x 33 x 26 cm |
| Battery dimensions (HxWxD) | 5.1 x 3.5 x 2.2 inches / 13.0 × 8.8 × 5.7 cm |
| Weight of the device with Battery (no straps) | 17.7 lbs / 8.0 kg |
| Battery weight | 1.3 lbs / 0.6 kg |
| Device main parts | Included in shipping box<br>• Device (upper part and back plate)<br>• Hard shell carrying case<br>• One battery<br>• One mounted suction cup and one spare<br>• Patient straps to secure patient's arms to device<br>• Stabilization strap to secure device position to patient<br>• Instructions for use<br>Optional accessories<br>• External power supply<br>• Car cable<br>• Desktop battery charger<br>• Spare batteries<br>• Disposable suction cups<br>• PCI back plate (carbon fiber version for cath lab)<br>• Anti-slip tape to slim back plate |

| Device environmental specifications | |
|---|---|
| Operating temperature | +32°F to +104°F / +0°C to +40°C<br>-4°F / -20°C for 1 hour after storage at room temperature |
| Storage temperature | -4°F to +158°F / -20°C to +70°C |
| Relative humidity | 5% to 98%, non-condensing |
| Device IP classification (IEC60529) | IP43 |
| Operating input voltage | 12-28 V DC |
| Atmospheric pressure | 62-107 kPa<br>-1253 to 13000 ft (-382 to 4000 m) |
| **Power specifications** | |
| Power source | Proprietary battery alone or with external power supply or car power cable |
| Power supply | Input: 100-240VAC, 50/60Hz, 2.3A, Class II Output: 24VDC, 4.2A |
| Car power cable | 10-28VDC/0-10A |
| Battery type | Rechargeable Lithium-ion Polymer (LiPo) |
| Battery capacity | 3300 mAh (typical), 86 Wh |
| Battery voltage (nominal) | 25.9 V |
| Battery run time (nominal patient) | Battery run time 45 minutes (typical)<br>Extended run time connecting to external power |
| Maximum Battery charge time | Charged in the device using external power supply:<br>• Less than two hours at room temperature (+72°F/+22°C)<br>Charged in the external battery charger:<br>• Less than four hours at room temperature (+72°F/+22°C) |
| Battery service life (interval for recommended replacement) | Recommendation to replace the battery every 3 to 4 years or after 200 uses (of more than 10 minutes each time)<br>End of Battery service life will be indicated by a constant yellow LED to the far right on the Battery charge indicator |
| Battery IP classification (IEC60529) | IP44 |
| Battery charge temperature | +32°F to +104°F / +0°C to +40°C<br>(+68°F to +77°F / +20°C to +25°C preferred) |
| Battery storage temperature | +32°F to +104°F / 0°C to +40°C<br>-4°F to +158°F / -20°C to +70°C ambient for less than a month |

Company Name _____

Contact Person _____

Company Phone Number _____

Company Address _____

Company Email Address _____

Bid _____