

Republic of the Philippines  
Department of Health  
Cagayan Valley Regional Office  
**REGION II TRAUMA AND MEDICAL CENTER**



**BIDS AND AWARDS COMMITTEE**

**SUPPLEMENTAL/BID BULLETIN NO. 1**

***Re-Bidding for the Supply, Delivery, Installation, Testing and Commissioning of various Medical Equipment with Identification No. R2TMC-BAC2-2023-45***

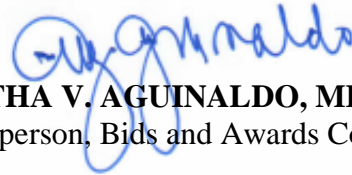
In response to the issues below, this Bid Bulletin is issued to modify or amend the Bid Documents. This shall form an integral part of the Bid Documents.

1. Final delivery period for the medical equipment is **Ninety (90) calendar days** upon receipt of the approved Purchase Order.
2. The following shall form part of the Bid Data Sheet and shall be complied with by all winning bidders:

21.1	<p>Documents to be submitted upon delivery for all the equipment in the list:</p> <ul style="list-style-type: none"><li>• Bank Guarantee or 1% Retention Fee</li><li>• Tax Receipts (BIR/Customs)</li><li>• Certificate of Warranty</li></ul> <p>Other documents (if applicable) or requirements as indicated in the Technical Specifications Form</p> <ul style="list-style-type: none"><li>• Certificate of Preventive Maintenance<ul style="list-style-type: none"><li>○ Schedule of Preventive Maintenance (annually, semi-annually, quarterly)</li></ul></li><li>• Periodic Calibration for 3 years</li><li>• Issuance of Calibration</li><li>• Certificate annually during the warranty period</li><li>• Certificate of Training Program<ul style="list-style-type: none"><li>○ End-User</li><li>○ Bio-Med Engineer</li></ul></li><li>• Certificate of Availability of Spare Parts</li><li>• Declaration of Conformity with ISO/IEC/PNS as issued by the Manufacturer</li><li>• Certificate of Acceptance</li></ul> <p>Manual/s available in English</p> <ol style="list-style-type: none"><li>1. Operational Manual</li><li>2. Service Manual</li></ol>
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	<ol style="list-style-type: none"><li>3. Catalog or Parts List</li><li>4. Schematic and Wiring Diagram</li><li>5. Installation Manual</li><li>6. Certificate of Calibration (Medical Equipment)</li></ol>
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3. See attached document for the *final Technical Specifications* of the **ADVANCED ELECTROSURGICAL DEVICE WITH VESSEL SEALER.**



**EDITHA V. AGUINALDO, MPA, MBA**  
Chairperson, Bids and Awards Committee 2

Posted: August 22, 2023

*EVA/mbbl*

# Technical Specifications

Republic of the Philippines Department of Health Regional Office 02 Region II Trauma and Medical Center			
Item No. 2	<b>ADVANCED ELECTROSURGICAL DEVICE WITH VESSEL SEALER</b>	Quantity ABC	1 unit P3,500,000.00/unit
Name of Manufacturer:		Country of Origin:	
Brand:		Model:	
<b>PURCHASER'S SPECIFICATION</b>		<b>SUPPLIER'S SPECIFICATION</b>	
<p><b>A. Summary Description of the equipment:</b></p> <ul style="list-style-type: none"> <li>- Advanced electrosurgical device with monopolar, bipolar and additional vessel sealing capability for the swift and efficient performance of emergency surgical procedures in trauma and laparoscopy.</li> </ul> <p><b>B. Physical characteristics or attributes, form and design of the equipment:</b></p> <p>Generator Specifications:</p> <ul style="list-style-type: none"> <li>- Weight Generator: maximum 11 kg</li> </ul> <p>Over all dimensions: not more than 36 cm (W) x 36 cm (H) x 140 cm (L)</p> <ul style="list-style-type: none"> <li>- Mounted on a metal trolley with lockable wheels</li> </ul> <p>With the following output plugs:</p> <ul style="list-style-type: none"> <li>1 – bipolar</li> <li>1 – vessel sealing</li> <li>2 - monopolar</li> </ul> <p>Ambient operating conditions: Temperature: 10°C–40°C</p> <p>Transport and storage conditions: Temperature: -10°C–60°C</p> <p>Operation Humidity: 10%–95% non-condensing</p> <p>Operating Atmospheric Pressure: 700-1060 millibars</p> <p>Connector ports must be illuminated</p> <p><b>C. Functionality and Performance:</b></p> <ul style="list-style-type: none"> <li>- Has both bipolar and monopolar electrosurgical and vessel sealing functionality <u>in one (1) device</u></li> </ul>			

- can be used in open and laparoscopic surgery for energy sealing and dissecting with a range of shears
- can simultaneously use both monopolar output
- with upgradable software via USB or WiFi
- automatic instrument recognition
- Has the following monopolar modes: pure cut, blend cut, spray coagulation, soft coagulation, fulgurate coagulation, shared coagulation.
- Must be compatible with monopolar instruments with the following specifications: 4 mm banana pins, A, B and C. distance of A to B is 19.05 mm and distance of A to C is 31.75mm.
- With effect settings up to 6 with maximum of 120
  - 150 volts (watts) for coagulation and 200 watts for cutting at a maximum of 2.4 amps as initial current
- Has the following bipolar effect settings: low (1-15 watts), medium (16-40 watts) and high (45-95 watts) or its equivalent
- Must be compatible with other bipolar connectors with the following specifications: 4mm banana pins, A and B, 28.45 mm apart
- The vessel sealing mode must be capable of tissue fusion on arteries, veins, pulmonary vasculature and lymphatics up to 7mm maximum diameter and tissue bundles for not more than 4 seconds with at least 95% reliability of resistance of burst pressure of 360 mm Hg
- Must have audible alarms for completion of sealing cycle.

**D. Safety Features:**

- Class 1 protection against electric shock
- IP21 – Ingress protection enclosure; IP 68 – Ingress protection footswitch
- With alarm that is activated in case contact of neutral electrode to patient is broken
- With re-grasping alarm on vessel sealers

**E. Convenience Features:**

- high resolution and touchscreen display at least 7 inches
- with back-up power and can retain programmed features even when switched off with recall program from last shutdown

**F. Accessories and Consumables:**

#1 – Trolley that is compatible with the generator set with storage drawer, cord management system, rust resistant and multiple tiers for storage of accessories and with locking wheels

#1 – monopolar cable for laparoscopy

#1 – foot pedal for monopolar use

- Compatible with same brand of machine
- Not less than 4.5 m
- #1 – foot pedal for bipolar use
  - Not less than 4.5 m
  - Compatible with same brand of machine
- #1 – foot pedal for vessel sealing use
  - Not less than 4.5 m
  - Compatible with same brand of machine
- #1 - automatic voltage regulator appropriate for the unit
- # 50 pcs adult pads (electrodes)- same brand with machine
- # 50 pcs pencils
  - same brand with machine
  - Stainless steel electrode
  - Length – at least 3 meters
  - Button switch design
- #2 – Vessel sealing shears -for open procedure
  - Sealer/divider
  - Curved jaw
  - 18-20 cm instrument length
  - 16-20 mm electrode length
  - Hand or foot activation
- #2 – vessel sealing instrument for laparoscopic procedures
  - non stick Maryland Jaw, 37 cm
  - Sealer/ divider
  - Diameter: 5mm
  - 350 degree shaft rotation
  - Activation: one step sealing and foot switching
- #1 – vessel sealing instrument for open procedure
  - Non stick jaw
  - Sealer/divider
  - 20-25 cm instrument length
  - Fine tapered jaw
  - Hand or foot activation

**G. Electrical Requirements**

Main input: 200-240V, 50/60 Hz  
 max VA 950 VA  
 Max Main current – 6 A  
 Max Heat Dissipation – 180 W  
 Fuses – 6 A  
 Power cord – 3-prong hospital-grade connector

**H. Quality Certifications**

- EN (IEC) 60601-1, EN (IEC) 60601-1-2, EN (IEC) 60601-2-2, EN (IEC) 60601-1-8

<p><b>Other Terms and Conditions of Acceptability</b></p> <ul style="list-style-type: none"> <li>- At least 2 years warranty for parts and services inclusions of repair and loaner costs. The supplier shall either repair or replace any item or part in the instruments that is found to be defective in material or in workmanship under normal use. The warranty period shall commence from the date of acceptance by the end-user after testing and commissioning</li> </ul>	
<ul style="list-style-type: none"> <li>- Bids offers in Philippine peso to include taxes and duties</li> <li>- Supplier must provide orientation training for users and maintenance personnel of the hospital</li> <li>- Certificate of sole distributorship from the unit manufacturer mentioning the name of the Philippine representative</li> <li>- The principal will conduct inventory analysis and must have conducted a qualitative and quantitative inventory analysis of surgical instruments in at least three (3) reference hospitals with contact details of the central point person in the hospital</li> </ul> <p><b>Additional Documentary Requirements:</b></p> <ol style="list-style-type: none"> <li>1. Product brochure or technical data sheet(s) of the instruments showing the technical specifications in English language.</li> <li>- 2. Valid and current Certificate of Compliance of manufacturer of the instruments with the latest version ISO 13485: Quality Management System – Requirements for regulatory purposes in the name of the manufacturer. The Certificates must be issued by an independent Certifying Body/Agency.</li> <li>3. Valid Certificate of Distributorship (as first Tier Distributor) issued by the Manufacturer of each instrument authorizing the bidder to sell/distribute the offered instruments.</li> <li>4. Proof (such as sales invoice) that the Brand of the instruments has been sold to other health facilities in the Philippines.</li> <li>5. Notarized Certificate from the bidder:       <ol style="list-style-type: none"> <li>a. That the brand of the instruments has been in the local and/or international market for at least ten (10) years.</li> <li>b. That the instruments and its accessories are brand new, unused, not discontinued models and were not subjected to any product recall.</li> </ol> </li> </ol> <p>Documents to be submitted upon delivery (if applicable):</p> <ul style="list-style-type: none"> <li>· Bank Guarantee or 1% Retention Fee</li> <li>· Tax Receipts (BIR/Customs)</li> </ul>	

<ul style="list-style-type: none"> <li>· Certificate of Warranty</li> <li>· Certificate of Preventive Maintenance  Schedule of Preventive Maintenance  (annually, semi-annually, quarterly)  Periodic Calibration for 3 years  Issuance of Calibration Certificate annually  during the warranty period</li> <li>· Certificate of Training Program  End-User  Bio-Med Engineer</li> <li>· Certificate of Availability of Spare Parts</li> <li>· Declaration of Conformity with ISO/IEC/PNS as  issued by the Manufacturer</li> <li>· Certificate of Acceptance</li> </ul> <p>Manual/s available in English</p> <ol style="list-style-type: none"> <li>1. Operational Manual</li> <li>2. Service Manual</li> <li>3. Catalog or Parts List</li> <li>4. Schematic and Wiring Diagram</li> <li>5. Installation Manual</li> <li>6. Certificate of Calibration (Medical Equipment)</li> </ol>	
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I hereby certify that the statement of compliance to the foregoing technical specifications are true and correct, otherwise, if found to be false either during bid evaluation or post qualification, the same shall give rise to automatic disqualification of our bid.

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Name of Company/Bidder

\_\_\_\_\_  
Signature over Printed Name of  
Authorized Representative

\_\_\_\_\_  
Date