



SUPPLEMENTAL/ BID BULLETIN NO. 1

IB2024 – 079E

PROCUREMENT OF 1 UNIT STATIONARY DIGITAL X-RAY MACHINE (REBID

This Supplemental/Bid Bulletin No. 1 is being issued to revise provisions/specifications in the Bidding Documents for a forecited project:

1. Query during Pre-bidding Conference:		
Technical Specifications	Query	Response of the End User Unit
Power output of at least 40 kilowatts (kW)	Power output: Within 30-50 kilowatts (kW)	Power output: Within 30-50 kilowatts (kW) GRANTED
Exposure time: at least 1 ms to 10 s with at least 20 increments available for exposure time control	Exposure time: at least 1 ms to 10 s or better, with at least 20 increments available for exposure time control or better	Exposure time: at least 1 ms to 10 s or better, with at least 20 increments available for exposure time control or better GRANTED
Total filtration: more than or equal to 2.5mm Aluminum (Al) equivalent	Total filtration: At least 1mm or better Aluminum (Al) equivalent	Total filtration: At least 1mm or better Aluminum (Al) equivalent GRANTED
b. Grid ratio: 10:1	b. Grid ratio: 10:1 or 8:1	b. Grid ratio: 10:1 or 8:1 GRANTED
Table to support patient weight of up to 250kg.	Table to support patient weight of up to 150kg. or better	Table to support patient weight of up to 150kg. or better GRANTED
Table top height: 700 - 730mm	Table top height: Manufacturer Standard	Table top height: Manufacturer Standard GRANTED
Table Type: 6 way Floating Table	Table Type: 4 way Floating Table	Table Type: 4 way Floating Table GRANTED
<ul style="list-style-type: none"> • Equipped with the following patient position immobilizing devices: <ul style="list-style-type: none"> - Foot rest - Shoulder rest - Arm rest - Head rest - Body harness 	Equipped with the following patient position immobilizing devices: <ul style="list-style-type: none"> — Foot rest — — Shoulder rest — — Arm rest — — Head rest — — Body harness — 	Equipped with the following patient position immobilizing devices: <ul style="list-style-type: none"> — Foot rest — — Shoulder rest — — Arm rest — — Head rest — — Body harness — <p>removed GRANTED</p>

Touchscreen image display monitor: at least 5 inch TFT or LCD, at least 3-megapixel resolution, anti-reflective screen with contrast	Touchscreen image display monitor: at least 5 inch TFT or LCD, at least 3-megapixel resolution, anti-reflective screen with contrast	Touchscreen image display monitor: at least 5 inch TFT or LCD, at least 3-megapixel resolution, anti-reflective screen with contrast GRANTED
Export of image files or explorations in JPG, TIF and BMP formats	Export of image files or explorations in JPG or TIF or BMP formats or DICOM	Export of image files or explorations in JPG or TIF or BMP formats or DICOM GRANTED
To include: Civil works to be shouldered by Supplier		

Bidders are advised to use the **following attached forms and submit them together with all required documents for the submission of bids on the 22nd day of August 2024, 9:00 AM:**

This Supplemental/Bid Bulletin No. 1 shall be integral to the Bidding Documents. All other provisions indicated in the bidding documents not affected by this Supplemental/Bid Bulletin No. 1 shall remain in effect.

For guidance and information of all concerned.

Issued this 13th day of August 2024 in MMCHD

Approved by:


JEREMIAS FRANCIS Y. CHAN, MD
 Licensing Officer V / BAC Chairperson

Republic of the Philippines
Department of Health
Metro Manila Center for Health Development

TECHNICAL SPECIFICATIONS

Item No. 1	STATIONARY DIGITAL X-RAY MACHINE	Qty./Unit	1 Unit
Name of Manufacturer:			Country of Origin
Brand:			Model: (if applicable)
ABC: 4,500,000.00			
PURCHASER'S SPECIFICATION		STATEMENT OF COMPLIANCE	
<p>TECHNICAL SPECIFICATIONS:</p> <p>High Tension Generator</p> <ul style="list-style-type: none"> • The generator must be a high frequency inverter system • Power output: <i>Within 30-50 kilowatts (kW)</i> • Kilovoltage Settings <ul style="list-style-type: none"> - Minimum Setting: 40kV - Maximum setting: more than or equal to 125kV - At least 40 increments available for voltage control • Tube current: at least 500 mA • Dose range: at least 0.5 to 500 mAs • <i>Exposure time: at least 1 ms to 10 s or better, with at least 20 increments available for exposure time control or better</i> <p style="text-align: center;">X-ray Tube Assembly</p> <ul style="list-style-type: none"> • Mounting: Floor-mounted • Tube head angulation: at least +/- 90° • Tube stand: Counterbalance enables tube arm movement • Tube arm movement: Lateral, horizontal and vertical • Locking mechanism: Electromagnet or manual • Anode: Rotating • Nominal focal spot size <ul style="list-style-type: none"> - Small focus: less than or equal to 0.8mm - Large focus: more than 0.8mm but less than or equal to 1.5mm • Total filtration: more than or equal to 2.5mm Aluminum (Al) equivalent • Thermal characteristics: <ul style="list-style-type: none"> - Tube more than or equal to 120kHU - Over temperature protection • Collimation system: <ol style="list-style-type: none"> a. Type: Multi-leaf or Rectangular Type b. Manually controlled c. With field lamp and crosshair centering. The lamp must be LED. d. Rotation: minimum of +/- 45° e. With built-in retractable distance measuring device at least 2 meters (indicator) <p>Vertical Image Receptor Stand</p> <ul style="list-style-type: none"> • Bucky Assembly with Grid <ol style="list-style-type: none"> a. Reciprocating grid movement mechanism and adaptive removable grid b. Grid ratio: 10:1 c. Grid frequency: at least 27 lines/cm d. Focal distance: at least 100cm • Movement: Counterbalance enables easy vertical movement. The wall stand is equipped with a Bucky that can be loaded from the left or from the 		<p>Total filtration: At least 1mm or better Aluminum (Al) equivalent</p> <p>b. Grid ratio: 10:1 or 8:1</p> <p>Table to support patient weight of up to 150kg. or better Table top height: Manufacturer Standard Table Type: 4 way Floating Table</p>	

right side.

X-Ray Table

- Table to support patient weight of up to 250kg.
- Table top height: 700 - 730mm
- Table Type: 6 way Floating Table
- Movable bucky assembly with grid
 - Reciprocating grid movement
 - Grid ratio: 10:1
 - Grid frequency: at least 27 lines/cm
 - Focal distance: at least 100 cm
- Equipped with the following patient position immobilizing devices:
 - Foot rest
 - Shoulder rest
 - Arm rest
 - Head rest
 - Body harness

Control Unit

- Microprocessor controlled with control system integrated
- Password protected operation of the equipment
- Technique Selector and Display Indicators for:
 - Anatomically programmed radiography (APR)
 - Kilovoltage (kV)
 - Milliamperage (mA)
 - Time (sec. or msec. and/ or pulse) or milliampere seconds (mAs)
- Remote control connected by retractable cable of at least 4m long or wirelessly
- Radiation Exposure Hand Switch: 2-Phase (ready and expose) and must be dead-man type
- With audio and visual indicator for:
 - Ready and X-ray exposure Ready and x-ray exposure
 - Overload
 - Overheat warning or heat indicator for x-ray tube

Flat Panel Detector

- Detector Material: Cesium Iodide Scintillator coupled thin film transistor made of Amorphous Silicon or other high detective efficiency material
- Detector Size: Imaging area adjustable and capable of acquiring 14 x 17 inch (35 x 43 cm)
- Detector Matrix Size: At least 4 Megapixels
- Image Resolution: At least 2.5 line pairs per millimeter (lp/mm)
- Grayscale level of 12 bits/ pixel or greater
- Geometrical fill factor not less than 65%
- Peak Detective Quantum (DQE) not less than 65% at 0.05 lp/mm
- Spatial resolution greater than or equal to 3.3 pairs of line per millimeter (lp/mm)
- Weight bearing capacity of at least 100 kg
- Protection grade equivalent to IPX3 or better according to standard IEC 60529
- Automatic detection of the detector
- Detector must be capable of sending images at most 3 to 5 seconds after exposure

Image Acquisition

- Touchscreen image display monitor: at least 5 inch TFT or LCD, at least 3-megapixel resolution, anti-reflective screen with contrast and brightness adjustments and must be capable of color and grayscale

~~Equipped with the following patient position immobilizing devices:~~

- ~~Foot rest~~
- ~~Shoulder rest~~
- ~~Arm rest~~
- ~~Head rest~~
- ~~Body harness~~ TO REMOVE

Image Acquisition

- ~~Touchscreen~~ image display monitor: at least 5 inch TFT or LCD, at least 3-megapixel resolution, anti-reflective screen with contrast and brightness adjustments and must be capable of color and grayscale display of at least 10 bits

display of at least 10 bits

- Imaging software capabilities

- Software for patient ID entry, viewing, processing of image, storage, printing and documentation

- Display of exposure indicators

- Display of patient data and actual exposure technique factors used

- Automatic recognition of detectors

- Anatomical programs included

- Allows the pre-visualization of the image in less than 5s

- Measured (not calculated) Patient Dose-Area Product (DAP)

- Image analysis tools (Distance Measurement, ROI, Exposure Index (DDI), Mean Pixel value, PVSD measurement, contrast adjustment, annotations, rotation, zoom, crop, grayscale inversion)

- Image processing functionality (window/ level adjustment, Reverse Contrast mapping, Edge Enhancement, Dynamic range Control

- Image reject folder

- With the respective keys and software installer on CD/DVD/USB.

- Export of image files or explorations in JPG, TIF and BMP formats.

- Interface capability: compliant with DICOM 3 or latest version and must be capable of online (Wifi with PACS) or offline (computed radiography with workstation or film and darkroom)

- Internal database storage of at least 2,000 images

Connectivity

- At least one (1) USB outlet for image storage on external media

- Ethernet connection RJ45 or similar outlet for image transmission

- WiFi IEEE 802.11 connectivity

- DICOM standard connectivity, compatible with radiological image viewing, post-processing, storage and printing software

(Functions: Storage, storage commitment, send/ receive, print, modality worklist management, modality performed procedure step and verification)

- The equipment will have to be connected by the supplier to the hospital PACS (if existent) during the installation phase

- Power Supply: 220V/ 60Hz Mains supply

Accessories

- Radiation Protection Devices

- One lead or lead-free protective apron of at least 0.5 to 0.7mm of Lead (Pb) equivalence

- One lead or lead-free protective thyroid shield of at least 0.5 to 0.7mm of Lead (Pb) equivalence

- One pair of lead or lead-free protective goggles with front and side protection of at least 0.5mm to 0.7mm Lead (Pb) equivalence

- One pair of lead or lead-free protective gloves of at least 0.5 to 0.7mm Lead (Pb) equivalence

- One set lead or lead-free protective gonadal shields of at least 0.5mm Lead (Pb) equivalence

- i. Contact shield for male adult, female adult, infant male, infant female

- i. Upright gonadal shield for chest x-ray examinations

- One piece measuring caliper, sliding double sided, scaled in cm with blunt edges and parallel arm

- Two (2) USB memory sticks with a capacity of 32 GB each to store radiographic images

- All cables, accessories, interconnection devices that allow the assembly

- Export of image files or explorations in JPG or TIF or BMP formats or DICOM

of the system, and that allow the system to function and correctly and safely with all the required functions.

Documentary Requirements

1. Product brochure(s) or technical data sheet(s) showing the technical specifications of the digital x-ray machine, calibration condition of digital image detector and accessories in English Language.

2. Valid and Current Certificate of Compliance with the latest version of ISO 13485: Quality Management System - Requirements for regulatory purposes in the name of the manufacturer of the digital x-ray machine. The certificate must be issued by an independent Certifying Body/Agency.

3. Valid and current Certificate of Compliance and/or Test Report(s) on the following Standards for the brand and model of the digital x-ray machine being offered. The Certificates and/or Test Reports must be issued by independent Certifying Agencies:

a. IEC 60601-1: Medical Electrical Equipment - Part I: General Requirements for Basic Safety and Essential Performance.

b. IEC 60601-1-3: Medical Electrical Equipment - Part 1-3: General Requirements for basic safety and essential performance - Collateral Standard: radiation protection in diagnostic X-ray equipment.

4. Valid Marketing Authorization, Registration Approval or Free Sale Certificate for the digital x-ray machine issued by the Health Authority in the country of origin.

5. Valid Certificate of Distributorship (as First Tier Distributorship) issued by the Manufacturer of the digital x-ray machine authorizing the bidder to sell/distribute the offered equipment.

6. Proof (such as sales invoice) that the Brand of the digital x-ray machine has been sold to other health facilities in the Philippines.

7. Notarized Certificate from the manufacturer:

a. That the brand of the digital x-ray machine has been in the local and/or international market for at least ten (10) years.

b. That the digital x-ray machine and accessories are brand new, unused, not discontinued models and were not subjected to any product recall.

8. Bidder's valid and current License to Operate (LTO) as a medical device distributor issued by the Philippine Food and Drug Administration.

To include: Civil works to be shouldered by Supplier

Requirements if awarded the Contract

1. Completion Period: The delivery, testing, and commissioning, and end-user and maintenance staff training must be completed within **90** calendar days upon receipt of Notice to Proceed.

2. Testing: The digital x-ray machine and accessories must be functioning with no physical damage and/or defect. A Performance Testing on the x-ray machine must be conducted by the Food and Drug Administration (FDA), Common Services Laboratory - Physics Laboratory Support Division or its authorized representative. The bidder shall be the one to apply for the Performance Testing in FDA. Application fees and other expenses for the conduct of Performance

