

Notice Inviting e-Tender

West Bengal Medical Services Corporation Limited Swasthya Sathi GN-29, Salt Lake, Sector-V Kolkata-700091

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Procurement, supply and installation of hand held digital X-ray machines in the Hospital and Medical College of the Government of West Bengal

(Submission of Bid through *online*)

Bid Reference No.: WBMSCL/NIT-246 /2025

Dated-28.03.2025

The following amendment have been made in the tender document,

<u>Amendment –I (Revision of Technical Specification)</u>

The revised technical specifications for the item is given below,

Technical Specifications Ultraportable Handheld Digital X-Ray Kit

Basic Requirements

- 1. Ultra portable handheld digital x-Ray kit must be composed of Handheld X-ray generator, X- ray generator stand, flat panel X-ray detector, X-ray detector stand and acquisition system.
- 2. The System should be capable of taking X-Rays of maximum human anatomies.
- 3. The radiation exposure time should be settable between 0.01 sec to 2.0 sec, with varying setting provision to allow imaging of any anatomy with minimal radiation exposure as per ALARA (as low as reasonably achievable) guidelines.
- 4. System should be able to acquire optimal CXR at 100 & 180 cm.
- 5. The equipment (x-ray device) should be AERB and CDSCO approved as amended under Medical Device Regulation Act 2020 and manufactured at site compliant with the requirements of ISO 13485 Valid certificates in this regard to be provided.
- 6. The detector should be approved by CDSCO as mended under Medical Devices Regulation 2020 and as updated as on date. The valid certificates to be provided.

- 7. The system should be compatible with any CAD approved by CDSCO.
- 8. The complete system must be offered with 3 years of comprehensive onsite warranty followed by 3 years CMC. Details of warranty and CMC are as following. (For details on warranty coverage, the tender terms and conditions must be referred)
 - a. System will be at various locations in the country Onsite warranty and service support to be provided.
 - b. Any Issue should be resolved between 3 to 5 working days from the date of issue reporting.
 - c. In case the device is not resolved within 5 days, standby unit should be provided against the non-functional device.
 - d. For Software related issue: Remote maintenance/intervention should be available within 1 working day.
 - e. For the warranty period, the desired uptime should be 98% of 365 days (24 hour basis). In case the down time exceed 2% limit, the extension of the warranty period will be twice the excess downtime period.
- 9. Free of cost up gradation of software / system for the duration of warranty and CMC.

10. Storage and operating conditions:

- a. Storage and operating condition: ambient temperature range up to +50 degree Celsius at a relative humidity up to 80%.
- b. System should with stand varied and extreme climatic condition in India in terms of storage and operations.
- 11. The total weight of the complete kit should be less than 30 kg.
- 12. The charger with charging cables should be provided for device, detector & laptop.

X-Ray Generator Source:

- 1. The unit must be capable of operating with rechargeable battery. X-ray source must have rechargeable battery which should be capable of doing at least 80+x-rays in one recharge. Any spare batteries needed to achieve this should be supplied along with the system. AC/DC adapter for recharge of battery, Tri-pod stand must be part of the supply.
- 2. X-ray generator and x-ray tube must be integrated in one and must be micro-processor controlled. High frequency. It should have a digital display of mAs and kV and electronic timer.
 - a. kV Range 40kV to 100kV.
 - b. mA range-2 mA to 6 mA
 - c. Exposure time 0.01 s (Minimum) to 2.0 s (Maximum).
 - d. mAS Range- 0.02 to 12 mAS
 - e. Weight up to 5 Kg.
 - f. X-ray Tube: must have a stationary/rotating anode. Focal spot should be 1.3mm or less.
 - g. Inbuilt Collimator must be attached to x-ray exposure device with inbuilt LED /LASER light source for positioning. Beam limiting device must have Pb lining.
- 3. The source should have a digital display to allow different exposure settings and also show critical parameters like battery charge, tube voltage etc.
- 4. Heat storage capacity of the anode must be within 10,000 HU (preferably higher).
- 5. It should have automatic exposure control.

Flat Panel X-Ray Detector System (Wired & Wireless)

1. It should be wireless & wired (must be capable of working as wireless & wired) robust flat panel digital detector with instantaneous image transfer as well as storage capabilities. Wireless Flat Panel Detector system (FPD) of Size 14"x17" or more should be offered.

- 2. The Scintillator material of the detectors should be made up of Cesium Iodide and sensor with Thin Film Transistor (TFT) and Amorphous Silicon technology.
- 3. The detector should be protected from dust and liquid. The IP rating should be IP x6/ IP 67 or better.
- 4. The detectors should be capable of doing out of bucky radiography and Lateral supine Radiography must be possible.
- 5. The detectors should have a minimum spatial resolution of 3.5 lp /mm or more.
- 6. Detector array Size: Should be a minimum of 2.3K x 2.8K pixels or higher.
- 7. Pixel Pitch: 150 microns or less.
- 8. AID Conversion 16 bits.
- 9. Detective Quantum Efficiency (DQE) above 70%.
- 10. The detector should have MTF at 0.5 lp/mm at 60% or more.
- 11. The battery must be of latest Lithium-lon type. Batteries charger should be provided.
- 12. The detectors should have Automatic Exposure Detection as standard feature.
- 13. The detector system should not require frequent calibrations on daily start-up.
- 14. Detector should work on Dual band Antennas (wifi) with minimum 2 antennas and 802.11 n/ac standard ensuring more stable and faster wireless transmission.
- 15. Transmission power: 5Gz 18dbm or better in wireless mode.
- 16. The detector should be capable of placement either in a bucky or directly under the patient if needed and must have load bearing capabilities of at least 200Kg at any single point.
- 17. The detector must be robust, solid, sealed, water resistant, dust resistant and with appropriate certifications for these parameters.
- 18. The detector and/or protective case should withstand drop from 1m. The drop resistance certificate for the quoted model from the manufacturer of the detector or international certification (IEC International Electrical Commission Certificate) should be provided.

Acquisition System

- 1. Operating Console/Modality Workstation should have the facility to enter patient demographics such as patient 10, Name, age, etc. Acquisition console software should have different settings for patient type (adult/ paediatric/ obese) & anatomy (anterior, posterior, oblique, lateral).
- 2. The system should have advanced image-processing algorithm that can show maximum diagnostic details. It should be intelligent to provide best image quality independent of body part.
- 3. Operating Console/Modality Workstation must be LAPTOP (Wireless), 11th Gen or newer processor, with min 14" HD display, Window 11 OS, 64GB RAM, 1 TB SDD for CAD alignment
- 4. Operating Console/Modality Workstation should be DICOM 3.0 ready and should support minimum the following service classes
 - a. Send
 - b. Print
 - c. DICOM Modality Work list.
- 5. Sending images to multiple destinations should be possible. It should be DICOM ready and should be able to send images through PACS system using Bluetooth, Wi-Fi, internet/online, email etc.
- 6. Previews of images should be available in about 10 second or less.
- 7. It should otter capability of local image storage.
- 8. Acquisition software should be compatible with PACS/DICOM servers and DICOM X-ray film printers and provide high-quality jpg / png images, easily transmissible over platforms like WhatsApp / Emails directly from the acquisition station.

9. After image acquisition, the software system should have provision/ function for image adjustment-clip, contrast, brightness, window adjustment, zoom, magnifier, invert, rotate, flip, annotations, measurements, digital collimation, etc.), image view, detail enhancement and noise suppression. Tissue equalization)

Additional Requirements

1. The system should be supplied with solid (hard) travel case for all components which should be suitable for easy and safe transportation of complete system including source, detector, acquisition console, stands for both source and detector by one person / operator.

2. Specification for hard travel case:

- i. Material should be indestructible resin propylene, light weight, provides high quality toughness, resistance and withstand harsh environmental condition
- ii. Standard quality latching system (such as power claw)
- iii. Reinforced metal padlock holes
- iv. Wheels made of Polyurethane to withstand rough surfaces
- v. Stackable
- vi. Waterproof resistance and certified to IP 67 rating
- vii. 2-stage Retractable Handle
- viii. Side mounted spring-loaded handles
- ix. Integrated Lid Stay
- x. Removable Lid
- xi. Top and Bottom Panel Mount
- xii. 100% Stainless Steel Hardware
- xiii. Must have automatic pressure release valve system
- xiv. Multi layered set of customizable inserts made of high-quality polyurethane foam should be provided to store the core and non-core components.
- 3. Stand for x-ray device: Suitable portable light weight tripod stand with vertical movement range (50-150cm) and rotation of 90 degree mound vertical axis.
- 4. Stand with detector frame: Suitable portable light weight tripod stand with vertical movement range (50-150cm).
- 5. The safety accessories at least 2 each 'light-weight lead apron' with at least 0.2mm Pb equivalent and thyroid shield should be provided.
- 6. External charging system: the external power system (power bank) shall be able to charge all electric components (generator, detector and laptop etc.) of the portable digital HH X-ray system with one output AC port. (Specification for power bank-Approx. 85,000 90,000 mAh, 150-Watt. Lithium-Ion, Input 15V/2A, Output AC 220V 50HZ) (Unit- 1 number in each system)
- 7. Radiation hazard stickers and pregnancy warning stickers per device as per AERB guidelines (Pack of 2 each).
- 8. System should be online and offline AI enabled.
- 9. System should be NIKSHAY compatible.
- 10. System should be ICMR validated/approved.

<u>Amendment – II</u>

E. Submission and Opening of Bids

32. The following are to be submitted:

i) Non statutory documents to be submitted under My Document (Each sub-category item should be in multiple page single PDF file)

Guidelines for uploading documents in My Document:

SI. No.	Category Name	Sub - Category Name	Document Name	
1	CERTIFICATES	CERTIFICATES	a) PAN Cardb) 15 – digit Goods and Services TaxpayerIdentification Number (GSTIN)	
2	CREDENTIAL	CREDENTIAL	Performance Statement Form (For the period within last three calendar years ending December 2024) - Form 7 of Section V 1. Submitted document should be supported with Work order / supply order copy 2. Proof of installation (Installation certificate / Service report duly signed by the hospital / healthcare facility) against the work order OR Proof of payment against supply and installation against the work order that the bidder have supplied medical equipment in Hospitals in India within the last 3 (three) calendar Years	
3	DECLARATION	DECLARATION1	Income Tax returns for assessment year (2021-2022, 2022-2023 & 2023-2024)	
		DECLARATION2	Tender Form as per Form 1	
4	EQUIPMENT	MACHINERIES	Manufacturer's Authorization (If applicable) as per Form 5 of Section V	

Amendment - III

Form 2: CHECK-LIST

[Please fill in and include with your Bid]

- **Note 1:** It is essential that all documents in hard copy are to be placed before the Committee and arranged in the same sequence as given in the Check List. All the documents should be appropriately flagged.
- **Note 2:** If any document is written in any language other than English, an English translation of the document duly authenticated is to be submitted.
- **Note 3:** The documents listed at Sl. No. 1,2,3,5,7 & 9 must be submitted online during online bid submission or else the bid would be liable to be summarily rejected.
- **Note 4:** After opening of the technical bids, if it is found that any of the documents required to be submitted with the bids is wanting, WBMSCL shall reserve the right to allow late submission of such document at its discretion within a specified time limit.

	Non statutory documents to be submitted under <u>N</u>	Лу Docume	<u>ent</u>	
SI. No.	Activity		Page No in the Bid	Remark
1	PAN Card			
2	15 – digit Goods and Services Taxpayer Identification Number (GSTIN)			
	Performance Statement Form (For the period, within last three calendar years ending December 2024) - Form 7 of Section V 1. Submitted document should be supported with Work order / supply order copy			
3	2. Proof of installation (Installation certificate / Service report duly signed by the hospital / healthcare facility) against the work order			
	OR			
	Proof of payment against supply and installation against the work order that the bidder have supplied medical equipment in Hospitals in India within the last 3 (three) calendar Years			
4	Income Tax returns for assessment year (2021-2022, 2022- 2023 & 2023-2024)			
5	Tender Form as per Form 1			
6	Manufacturer's Authorization (If applicable) as per Form 5 of Section V			
	BID - A			
SI. No.	Activity	Yes/No /NA	Page No in the Bid	Remark
7	Earnest Money Deposit (EMD) (Copy of receipt of online submission of EMD)			

	BID - B					
SI. No.	Activity	Yes/No/N A	Page No in the Bid	Remark		
8	Model of the equipment offered for (Self Declaration) with					
	Technical Data Sheet					
	Comparative Data Table of the Technical Specifications					
9	(Form No. 4 of Section V)					
10	1 sets of Brochure of the offered product / model.					
11	Standard & safety certification: Valid CDSCO Certificate					
	License for the manufacturer(s) & Registration Certificate					
	from CDSCO for the importer(s) as applicable.					
12	Pre-requisites of installation [Power (KVA, Phase, Hz) and					
	any other requirement, if any]					
13	Average Annual Turnover of the Company in medical					
	equipment division during the last 3 Financial Years (2021-					
	2022, 2022-2023 & 2023-2024) (in INR) - to be certified by					
	practicing Chartered Accountant as per format given in					
	FORM 9					
14	Form 10: Basic information Form					

<u>Amendment – IV</u>

Section IV. Schedule of Requirements

1. List of Consignee

ITEM	Total Quantity (in number)	Consignee List
	01	<mark>Jhargram</mark>
Hand Held Digital X-ray Machines	01	Purulia Purulia
Fland Field Digital X-ray Machines	01	<mark>Malda</mark>
	01	<u>Darjeeling</u>

Please note:

The Consignee Receipt Certificate (CRC) will be issued to the Vendor within 72 hours of the delivery at the Consignee address.