ALL INDIA INSTITUTE OF MEDICAL SCIENCES
ANSARI NAGAR, NEW DELHI - 110029
STORE SECTION (D.O.)

Ref. No. XX-189/SO (DO)/R.D./2024-25/M&E **Dated:29.03.2025**

CORRIGENDUM

It is informed that the tender bearing no. XX-189/SO (DO)/R.D./24-25/M&E and CPP tender I.D No. 2025_AIMSD_845991_1, published through CPP portal has revised technical specification, as per TSEC recommendation and detail given below:

Full Field Tomosynthesis Digital Mammography System against buyback and turnkey basis		
Sl. No.	**DETAIL**	**AMENDED**
1.	Technical Specification	Enclosed revised technical specification. Annexure-I

All other terms & condition of the tender are same.

29/3/25

Sr. STORE OFFICER (D.O)

Department of Radiodiagnosis and Interventional Radiology
AIIMS, New Delhi

Tender Reference Number: : XX-189/SO(DO)/R.D./2024-25/M E: Amended Tender specifications (After Pre-Bid) for Purchase of **Full Field Tomosynthesis Digital Mammography Unit against buy back of existing unit (Selenia Dimension, Prone Biopsy Table, Motorised Mammolux, Mammography chair) on a turnkey basis - 01 unit.** for the Department of Radiodiagnosis & Interventional Radiology, AIIMS, New Delhi

- **The vendor must quote the latest state-of-the-art system and give a declaration from the company (OEM) for supply of the latest released version of the quoted model supported by FDA/CE certification.**

- The offered model should be BIS / European CE with 4 digit notified body number/ US FDA certified. (authentic and legible certificate for the same to be annexed}.

- Also, the vendor will guarantee that the system supplied is not refurbished and the Mammography system quoted is the latest, best available model in the segment quoted, at the time of delivery and should submit an undertaking in this regard.

Technical Specifications

Certifications:

1. The system should be AERB type approved and the copy of E-LORA Listing should be submitted along with the bid. If the quoted model has not yet been installed in India, the vendor should submit NOC from AERB. Regular QA according to AERB norms will be the responsibility of the bidder during warranty and CMC period.

2. Should have import/manufacturing license from Central licensing Authority or State licensing authority of CDSCO for Medical Devices and copy of valid license should be submitted for the quoted model.

3. In case the vendor has not yet obtained import/manufacturing license from CDSCO for the quoted model, proof of application for CDSCO medical device license to be submitted in the bid document and valid CDSCO license to be produced at the time of supply/ NOC for the quoted model.

Full Field Tomosynthesis Digital Mammography Unit against buy back (of existing unit Selenia Dimension, Prone Biopsy Table, Motorised Mammolux, Mammography Chair) on a turnkey basis - 01 unit. (Tender Reference Number: XX-189/SO(DO)/R.D./2024-25/M E)

	Technical Specifications
	State of art, USFDA or European CE or BIS approved Mammography Unit with Tomo Biopsy Facility. The quoted Model should be mentioned in USFDA or European CE or BIS documents. The system should have following features:
1.	**X-ray Generator**
	a. X-ray generator should deliver high frequency constant output with a minimum rating of 5KW with 100 mA or more at 30 kV. b. kV range should be 22 to 5 kV or higher in 1kV increments. c. mAs range should be 4 to 500 mAs or higher. d. Automatic exposure control with manual override facility
2.	**X-ray tube**
	a. Heat storage capacity should be 150 KHU or more. b. Dual focal spots of size 0.3 (large) and 0.1 mm (small). c. There should be two or more nos of Filtration .
3.	**Gantry**
	a. Fully motorized vertical movement and rotational movement b. SID of 65 cm or more. c. Removable patient visor/face shield. d. Fully automated compression mode. e. Single touch positioning of the gantry should be possible for smooth operation(MLO to CC or CC to MLO)
4.	**Digital Flat Panel Detector**
	a. Solid state Direct/indirect conversion type, size 24 cm x29 cm (± 1 cm). b. Pixel size of 100 micron or less with same resolution in both 2D and 3D images c. Specify image matrix (in pixel) and image size (in MB)

5.	**Digital breast Tomosynthesis**
	a. Fully integrated USFDA or European CE approved Tomosynthesis Mammography system to be supplied as the standard component. b. It should be possible to perform a 3D exam in both CC and MLO views. c. It should be possible to obtain both standard views (2D view) and (3D view) without repositioning of the patient or any change in the attachments. d. Specify time taken for tomosynthesis acquisition. e. It should be possible to generate a synthesized mammographic view from Tomo data. f.
6.	**Acquisition workstation**
	a. Diagnostic Grade Monitor of resolution of 3 megapixel or more b. Facility for patient information, work list, scheduled work flow, mammography and Tomo image review, print, storage, query and retrieve c. Storage capacity of 5000 images or more d.
7.	**Reporting workstations: (2 nos.):**
	a. The Image processing as well as reviewing software for both 2D and 3D should be USFDA/CE/BIS approved b. The Image processing as well as reviewing software for contrast enhanced mammography should be USFDA/CE/BIS certified c. 2 Nos. of Medical grade Monitors of minimum 12 Megapixel resolution, capable of at least 1000cd/m² brightness , with Out-of-the-box calibration to the DICOM grayscale display function for luminance. d. There should be automated built-in QA and calibration e. There should be a protective anti-reflective glass panel to prevent accidental damage to the screen. f. Dedicated mammography workflow keypad should be provided. g. Customizable workflow, image layout and image orientation h. It should be ready for multimodality (ultrasound, CT, MRI) viewing i. DICOM storage, query, retrieve, print in ready to use configuration j. Storage capacity of minimum 20,000 images
8.	**Image documentation and transfer**
	a. It should be possible to transfer images to a USB drive in DICOM and PC format from the Acquisition workstation and Reporting workstation. b. The workstation is to be integrated with DICOM compliant network of the institute c. Mammography and tomosynthesis images should be vendor neutral so that viewing at any other workstation and storage in institute PACS server is possible. If these image formats are proprietary, appropriate licenses should be provided to convert them for general viewing. d. DICOM modality worklist (DMWL) and modality pre-procedure setup (MPPS) should be enabled.

9.	**Contrast enhanced mammography**
	a. The system should be capable of dual energy contrast enhanced mammography in 2D acquisition mode. The software and hardware for contrast enhanced mammography should be clinically validated on patients. Proof of validation and any further technical advancement to be submitted b. Dual head pressure injector compatible with mammography system - 01 no (Specify the make of the injector) c. Injector syringes (100) with IV line connectors to be provided.Unit price of consumables to be quoted separately for additional requirement in future.
10.	**Digital Stereotactic breast biopsy facility**
	a. Upright biopsy unit, which should allow biopsy in both CC and ML orientation of the gantry. The biopsy unit should be less than 7 kg in weight. In case more than 7 KG, trolley should be supplied. b. Facility for stereotactic biopsy should be provided. c. Tomo-Biopsy facility should be provided. d. It should be ready to use with standard hookwire needles, 14G core biopsy guns and vacuum assisted biopsy probes. Needle holders, biopsy guides and any other hardware or software required for this purpose should be included with the unit.
11.	**Compression paddles**
	a. Two standard compression paddles of width 15 cm or more and 24 cm or more b. Spot and Magnification paddle and small breast paddles should be supplied c. Stereotactic biopsy paddle with open window, Mag platform d. Wire localization paddle with open window and alpha-numeric markers e. Original (OEM) wall mounted hanger for compact docking of above mentioned f. paddles g. Cross hair localization kit.

12.	**Standard accessories**
	a. ACR approved phantom to be supplied along with the system and the supplier shall provide regular calibration and QA during the warranty and CMC period. b. Specimen localizing grid trays(60 in no) for transporting surgical breast specimens for imaging without losing specimen orientation(ACCuGrid/ KliniTray or equivalent) c. Mammography skin markers for palpable mass, area of concern and scars (30 each) d. Stereotactic core biopsy image and transport containers (30 in no) CoreTainer or equivalent e. Hookwire needle localization wire protectors to stabilize the hookwire during transport from radiology suite to operating theatre f. Latest BI-RADS Atlas (6th Edition) in hardcopy as well as soft copy g. Latest training phantoms for demonstrating stereotactic biopsy and ultrasound guided biopsy (one each) h. Multi Modality viewer for viewing CT, MR, US, CR etc. images. i. Radiation shield with 0.5 mm lead equivalent around acquisition workstation j. The system should be regularly maintained in the latest version of computing software; including software platform updates/upgrades released for the respective system that can prepare it for future enhancements shall be free of cost during warranty and CMC period. k. UPS for 30 minutes back-up for the entire system. l. Two tray online film cameras with dpi 500 or more for printing of mammography films. Required networking of the same shall be done by the vendor. m. Specimen Radiography facility should be inbuilt within the system . The system should have FDA/ CE/BIS approved AI solution. The AI software should be based on Machine learning and deep learning and should be able to categorize and prioritise case reading, depending on the findings. Please specify details of features. n. o. Offline storage server 100 TB, dedicatedly connected to mammography through ethernet network. Facility of viewing mammography images, retrieval of DICOM images to the mammography workstation, CD/DVD writing and DICOM printing.

13	**Optional items**
	a. Facility for contrast biopsy, which has been clinically validated, should be provided, with price to be quoted separately. If currently unavailable, an undertaking to be submitted by the firm that if contrast biopsy facility becomes available during the warranty and CMC period, the system would be upgraded without any additional cost, within 6 months of the global launch of the new product. b. Wireless localization markers should be quoted for marking small, non palpable lesions preoperatively. Magseed/Saviscout/localizer or equivalent (50 in no per year for warranty period) with appropriate compatible reader probe. Unit Price of consumables for markers to be quoted separately for additional requirements in future and fixed for tender validity period.
14	**Other features**
	a. The vendor should assist and facilitate site approval, registration, licensing and b. Certification of the facility by AERB. c. Vendor should have at least Five installation sites in India/abroad of the quoted system (with the quoted detector make/model configuration); performance certificate needs to be submitted along with the supporting documents. d. Onsite Training -The application specialist of the company should stay at the site at -least for 5 days at the time of installation to train all faculty members and technicians in machine operations. This will be followed by similar two visits of 5 days each in the initial 6 months or whenever required. The visits should be scheduled in consultation with the department of Radio-diagnosis. e. The system should have the following safety mechanisms: over voltage protection, short circuit protection and phase sequence corrector (for 3 phase equipment)
15	**After sales, Two years Warranty and Eight years CMC**
	a. The comprehensive onsite warranty of two years and eight years CAMC of the entire system shall commence from the date of issue of installation certificate by the institute. The warranty will include the main unit with all parts including x-ray tube and detector, all accessories and optional items supplied with the unit, all turkey items, including batteries etc. One free software upgrade during warranty and unlimited software updates should be provided. b. Regular maintenance and QA checks as per AERB norms will also be part of warranty and CMC. c. After sales service: a factory trained service engineer should be available and Service call must be attended within 24 hours. d. If the unit is being quoted by Indian agency which is not a direct subsidiary of the principals; an undertaking from the principals must be provided that in case of discontinuation or change of the agency, merger, acquisition or any corporate rearrangement, the principal will arrange for onsite maintenance of the unit and abide by all terms and conditions of the tender.

16	**Turnkey Installation (in consultation with ED, AIIMS, New Delhi:**
	The unit will be installed on Site-modification basis. The vendor should inspect the site before quoting and ensure that the unit and all accessories can be installed in the available space without any functional compromise. Civil modifications (Civil, electrical and AC work) to be done as per the requirement in Machine & Reporting Room.Optimal Radiation safety requirements must be taken into consideration. Air- conditioning for the Mammography Room should be provided. Adequate furniture and fixtures of reputed brands should be provided. It should also include approved quality floor tiles and full height wall tiles. Power supply by the institute will be terminated at desired one point within the Mammography site. All electrical provisions including equipment mains panel, UPS cabling and DB, earthing etc. will be the vendor's responsibility. All Site-modification work must comply with hospital norms.
17	**Instructions to vendors**
	a. All information asked must be provided clearly in the compliance sheet under the same headings. Haphazardly given information will not be considered. b. Original Product Datasheet of main unit and all accessories, including third party items to be provided as a part of the technical bid. Photocopy or computer generated data sheets or emails shall not be accepted. c. Any technical clarification required which is not mentioned in the product data sheet should be clarified by the principals or manufacturer. d. "The equipment should have USA FDA or European CE certified with four digit notified Body number or BIS approved and certificate to be submitted. OR. Should meet IEC 60601-1, IEC60601-1-2 and IEC 60601-2-37 standards and valid test report to be submitted from NABL accredited lab for the quoted model or lab in the country of origin" e. **A demonstration of the product is essential by the firm of the quoted model and must provide preferably a performance certificate of the model quoted.**

General Instructions for the Vendor

1. Suppliers must ensure availability of expertise service and maintenance at site of installation. Uninterrupted availability of spare parts and repair for next ten years must be assured.

2. Two bid system: vendor is required to make separate bids for technical and price components. These should be quoted in two separate sealed envelopes.

3. Please note that all technical features, facilities and accessories mentioned in the tender document are standard requirements and hence, these should be offered as the standard feature. None of these should be offered as optional items.

4. In the price bid, the cost of locally supplied items must be quoted separately in Indian currency.

5. Please respond to each specification in the same format and order as mentioned in the tender document and specify/indicate the verification document from the product data sheet against each column.

6. When required, information other than those in the data sheets should be provided as a separate document from the principals only and should refer to the specific sections being addressed. When the standard vendor data sheet disagrees with the bid response (offer/compliance statement), clarification should accompany in the form of certificate from the principals only. In absence of this, the vendor data sheet will prevail for the purpose of evaluation and the decision of the technical committee shall be final and binding on the supplier.

7. The vendor has to station one application specialist and service engineer at site for a period necessary to familiarize the medical and technical staff to the scanner protocols and enable them to achieve fast and efficient service.

8. Mention the number (with addresses, phone numbers, e-mails) of installations of the quoted unit in the Delhi and India

9. A physical demonstration of the unit offered is a mandatory requirement.