Technical Specifications – (Bid Number: GEM/2026/B/7515593 Dated: 07-05-2026- Kindly omit the earlier point with minor error/ overwriting)

State-of-the-art- USFDA or European CE or BIS approved Mammography Unit with Tomo Biopsy Facility.
All related software should also be USFDA or European CE approved or equivalent Govt of India standard. The quoted Model should be mentioned in the USFDA or European CE or BIS documents.
The system should have the 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 35 kV.
b. kV range should be 22 to 45 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.
e. (Amended after corrigendum)

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. **Direct** conversion type, size 24 cm x29 cm (1 cm). (Amended after corrigendum)
b. Pixel size of 100 micron or less with the same resolution in both 2D and 3D images
c. Specify image matrix (in pixels) and image size (in MB)

5. Digital Breast Tomosynthesis

a. Fully integrated USFDA or European CE or BIS or CDSCO - 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 the time taken for tomosynthesis acquisition.
e. It should be possible to generate a synthesized mammographic view from Tomo data.
f. ***Deleted after corrigendum***

6. Acquisition workstation

a. Diagnostic Grade Monitor of resolution ***of 3 megapixels or more***
b. Facility for patient information, work list, scheduled workflow, mammography, and Tomo image review, print, storage, query, and retrieve
c. Storage capacity of 5000 images or more.
d. There should be height adjustment of the working **Table/Monitor** to facilitate use.**(amended after corrigendum)**

7. Reporting workstations: (2 nos.):

a. The Image processing as well as reviewing software for both 2D and 3D - USFDA or CE or BIS or CSDCO approved.
b. The Image processing as well as reviewing software for contrast-enhanced m should be USFDA or CE or BIS certified.
c. 2 Nos. of Medical grade Monitors **(one of each workstation)** of minimum 12 Megapixel resolution, capable 1000cd/m² brightness, with Out-of-the-box calibration to the DICOM grayscale for luminance.**(amended after corrigendum)**
d. There should be automated built-in QA and calibration.

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e. **(Deleted after corrigendum)**
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 **and if lesser has to be compensated by supplying HDD drives. (amended after corrigendum)**

8. Image documentation and transfer

a. It should be possible to transfer images to a USB drive in DICOM and PC format from 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 workstation and storage in the institute PACS server is possible. If these image proprietary, appropriate licenses should be provided to convert them for general viewing
d. DICOM modality work list (DMWL) and modality pre-procedure setup (MPPS) should be enabled.

9. Additional requirements (amended after corrigendum)

a. Motorized/hydraulic Mammography cum biopsy chair (amended after corrigendum)

b. Contrast enhanced mammography system should be supplied (amended after corrigendum)

c. Dual head pressure injector compatible with mammography system 01 no , similar to Ct scan injector haveing 100ml/ 200 ml syringe capacity with 350 psi or better (Specify the injector offered). Injector syringes (100 of 100 ml with tubing) with IV-line connectors to be provided. Unit price of consumable to be offered as separately for additional requirements in the future. (Amended after corrigendum)

10. Digital Stereotactic Breast Biopsy Facility

a. Upright biopsy unit, which should allow biopsy in both CC and ML orientation of biopsy unit should be less than 7 kg in weight and **if weight is more than 7 kg customized trolley for biopsy module has to be supplied by the vendor (amended after corrigendum)**
b. A facility for stereotactic biopsy should be provided.
c. Tomo-Biopsy facility should be provided.
d. It should be ready to use with standard hook wire needles, 14G core biopsy guns, assisted biopsy probes. Needle holders, biopsy guides, and any other hardware or soft for this purpose should be included with the unit.
e. There should be a facility for the latest arm approach, which should enable needle access the detector from either the lateral left or lateral right position.

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 the above-mentioned paddles.
f. Cross-hair localization kit or equivalent. (Amended after corrigendum)

12. Standard accessories

a. **(Deleted** -Amended after corrigendum, not required by users)
b. 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.
c. **(Deleted** -Amended after corrigendum, not required by users)

d. **(Deleted** -Amended after corrigendum, not required by users)

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e. **(Deleted** -Amended after corrigendum, not required by users)
f. Latest BI-RADS Atlas (6" 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.**Any software update on the equipment has to be done free of cost during the warranty and CAMC period. (amended after corrigendum)**
k. UPS for 30 minutes backup for the entire system.
l. Two tray online film camera with a dpi of 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 provided in the procedure room without any additional X-ray shielding.
n. **(Deleted** -Amended after corrigendum, not required by users)
o. **(Deleted** -Amended after corrigendum, not required by users)

p. **(Deleted** -Amended after corrigendum, not required by users)

q. LED X-ray Film viewer with adjustable brightness; capable of holding 4 films of 14"x17" size, in all rooms as per requirement. (Amended after corrigendum)

r. Cabling of Network (LAN) connectivity for camera system, console system, workstation and computers etc.
s. **(Deleted** -Amended after corrigendum, not required by users)

t. **(Deleted** -Amended after corrigendum, not required by users)

u. **(Deleted** -Amended after corrigendum, not required by users)

v. **(Deleted** -Amended after corrigendum, not required by users)

w. **(Deleted** -Amended after corrigendum, not required by users)

13. Optional accessories
a. **(Deleted** -Amended after corrigendum, not required by users)

b. **(Deleted** -Amended after corrigendum, not required by users)

14. Other features
a. The vendor should assist and facilitate site approval, registration, licensing and Certification of the facility by AERB.
b. Vendor should have at least five installation sites in India of the quoted **model OR five installation sites in India of equivalent system (with the quoted detector make/model configuration). Performance certificate needs to be submitted along with the supporting documents.**
A. Bidder/OEM should have at least one installation sites in India of the quoted system.

OR

B. Bidder/OEM should have at least five installation sites in India/Abroad of the quoted system.

OR

C. Bidder/OEM should have at least five installation sites in of any Mammography system.

OR

D. Bidder/OEM should have at least four installation sites in of any Digital Mammography system.

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c. 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 a 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 Radiology.

d. The system should have the following safety mechanisms: overvoltage protection, short circuit protection, and phase sequence corrector

15. After-sales, Warranty, and CMC

a. The comprehensive onsite warranty of 02 years and CAMC of 08 years of the entire system shall commence from the date of issue of the installation certificate by the institute. The warranty will include the main unit with all parts, including the x-ray tube and detector, all accessories and optional items supplied with the unit, all turkey items, including batteries, etc. **Any Software update on the equipment has to be done free of cost during the warranty and CAMC period.** (Amended after corrigendum)

b. Regular maintenance and QA checks as per AERB norms will also be part of the warranty and CMC.

c. After-sales service: A factory-trained service engineer should be available, and the 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:

The unit will be installed in accordance with an 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 requirements of the Machine site, including the patient preparation room & Reporting Room. Optimal Radiation safety requirements must be taken into consideration and fulfilled. 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 the desired 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 and AERB norms. (Amended after corrigendum)

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 the 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 that is not mentioned in the product data sheet should be clarified by the principals or manufacturer.

d. On-site training of the staff by an application expert should be provided for a period of not less than 2 weeks, as per the convenience of the department.

e. "The equipment should be USA-FDA or European CE certified with a digit notified Body number or BIS approved or CDSCO (Amended after corrigendum) and a certificate to be submitted. OR. Should meet IEC 60601-1, IEC60601-1-2, and IEC 60601-2-37 standards, and a valid test

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report to be submitted from a NABL-accredited lab for the quoted model or lab in the country of origin.

Note:-

1. 02 years comprehensive warranty, inclusive of all parts/components.

2. 08 years CAMC after completion of warranty.

Certification:

The Equipment Should be BIS/US FDA/ European CE with 4 digit notified body number.

Physical demonstration of the quoted model is mandatory,

The comprehensive warranty will be 02 years (including all spares and labor) from the date of satisfactory installation of equipment. Also quote rates for comprehensive CMC (including all spares and labor) for 3rd to 10th year, after expiry of warranty period. Cost of spares, accessories and consumables should also be quoted separately.

95% uptime of the machine. Facility for good after sale & service with trained engineers posted in Delhi. In case the down time exceeds 5% in a calendar year, the comprehensive warranty will be extended beyond 2 years for double the number of days for which the unit is non functioning. Similar clause will apply each year of CMC.

The cost of accessories/ spares/ consumables etc. required to be supplied along with the equipment shall be included in the quoted price. However, the prices of accessories/ spares/consumables etc required for the equipment during lifetime of the equipment shall be quoted separately in pdf format which will be fixed for lifetime of the equipment for future purchases, if needed. If not quoted separately, that/ those accessories/ spares/consumables etc. need to be provided free of cost till lifetime of the equipment.

01 All training and maintenance service should be provided by the vendor.

02 Accessories & Consumable:

The price list of all spares parts, accessories, consumable items (required to use on machine) should be quoted separately in the financial bid section (PDF) and the quoted rates will be valid till the warranty & CAMC period (i.e., 10 years) from the date of installation of equipment. If, the price of any spares, consumables/accessories/parts not quoted by the firm in the price bid and will required in future to run the system, the same has to be supplied by the firm at free of cost without any further term & conditions.

03 Compliance Statement:

The vendor must provide, in tabular form a comparative chart of the required technical specification and technical specification of the quoted product. The vendor must give the relevant page number and paragraph number, in their literature regarding that technical information in the technical bid. Merely stating "complies or meets requirement will lead to assumption that the quoted product does not have the required feature.

04 Important Conditions:

The bidder must quote rates of equipment with 02 (two) years onsite Comprehensive warranty (Including all spares, accessories, 3rd party items, battery, battery of remotes, mattress, wheels, cable of remote control etc. and labour) from the date of Installation of equipment. Further bidder must quote rates for 8 (eight) years (with break-up price on year-to-year basis) Comprehensive Annual Maintenance Contract (CAMC) Including all spares, accessories, 3rd party items, battery, battery of remotes, mattress, wheels, cable of remote control etc. and labour, after expiry of two years comprehensive warranty. In case, bidder not quoted rates for CAMC, it will be treated included and must be provide 10 years comprehensive warranty within quoted rates of equipment. No CAMC proposal will be considered later on. The cost of equipment CAMC (NPV) charges inclusive of GST, will be considered for ranking (L-1) purpose.

The L-1 bidder must submit copies of previous supply order placed by AIIMS, New Delhi or any other Central Govt./Sate Government / reputed Pvt. Hospitals/Organizations within one week of receiving the information for ascertaining the price reasonability of quoted equipment/instruments

(Amended after corrigendum)

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05 All technical bids comparative statement to the tender specifications must be enclosed
long with reference no., paragraph no. from original catalogue of the equipment.

06 The principal firm has to certify that spares, consumables, accessories & support shall be available for next 10 years.

7.If desired by the TSEC, Demonstration of quoted product would be mandatory at AIIMS, New Delhi premises. All bidders are advised to keep ready their quoted product for demonstration. None attending demo meeting/non-demonstration of quoted product, the bid will be summarily rejected. Machine must be provided for demo as per buyer's requirement so that it can be evaluated by all the faculty members, failing which your bid will be disqualify/rejected.

08. Proper training to OT technical staff for the use of the equipment will be provided by the company vendor at free of cost.

Bidders must consider &upload the following documents in the Technical bid & price bid.

1. Tender acceptance Form (as per bid format)
2. Manufacturers Authorization Certificate (As per bid format)
3. Country of origin of quoted product.
4. Product brochure
5. Technical bid (with Make, Model and detailed scope of supply)
6. Technical Compliance Statement (in tabular form)
7. Product Certifications.
8. Complete terms & conditions (Including warranty, CAMC, bank details, mode of shipment, taxes, etc.)
9. Product HSN Code & Sellers GeM ID number must be mentioned in thetechnical bid.
10. Details of Service Centre, (Complete Address)
11. Bidders Registration Certificate, GST certificate, drug license (if applicable).
12. Financial bids should be in the format provided in the CPP portal and no other format is acceptable. If the price bid has been given as a standard BoQ format with the tender document, then the same is to be downloaded and to be filled by all the bidders.
13. Bidders must quote rates of all spares, accessories, consumables (with break-up price of each item) separately (in PDF) and the quoted rates will remain valid for 10 years (warranty & CAMC period) for future purchases as and when required basis.
14. In case any item (spares, accessories, consumables) required to run the system and firm did not quoted rates of those items in their price bid, the same mandatorily will be supplied by the firms at Free of Cost without any condition.

Note: The provision of Public Procurement (Preference to Make in India) order 2017 as amended from time to time is applicable in this tender.

B. GENERAL POINTS

1. Warranty:

a) The bidders must quote for Two years Comprehensive Warranty as per Conditions of Contract of the Tender document for complete equipment (Including all spares, labour and third party items) and Turnkey Work (if required) from the date of satisfactory installation, commissioning, trial run, handing over and acceptance of the goods by the

b) User Department. The warranty charges shall not be quoted separately.

c) During the Warranty period and CAMC period, desired Uptime of 95% of 365/366 (Leap Year) days (24 hrs), if downtime more than 5%, the warranty period/CAMC period will be extended by double the downtime period. In addition a penalty equal to amount of 0.25% of the total cost of equipment per day will be liveable for the excess downtime period subject to Maximum of 10% of Cost of the Equipment. Complaints should be attended properly, maximum within 8 hrs

d) All software updates should be provided free of cost during Comprehensive Warranty period.

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2. After Sales Service:

After sales service centre should be available at the city of Institution on 24 (hrs) X 7 (days) X 365 (days) basis. Complaints should be attended properly, maximum within 8 hrs. The service should be provided directly by Bidder/Indian Agent. Undertaking by the Principals in the "Manufacturer Authorisation Form that the spares for the equipment shall be available for at least 10 years from the date of supply of equipment.

3. Training:

On Site training to Doctors/ Technicians/ staff is to be provided by Principal/Indian Agents (if they have the requisite know-how) for operation and maintenance of the equipment to the satisfaction of the User Department.

4. Comprehensive Annual Maintenance Contract (CAMC) of subject equipment:

a) The cost of Comprehensive Annual Maintenance Contract (CAMC) which shall include preventive maintenance including testing & calibration as per technical/service /operational manual of the manufacturer, labour and all spares, after satisfactory completion of Warranty period (02 years) may be quoted for next **Eight years** on yearly basis for complete equipment including third party items as per Price Schedule.

b) The cost of CAMC may be quoted along with GST applicable on the date of Bid Opening.

c) Cost of CAMC will be added for Ranking/Evaluation purpose on NPB basis.

d) Before commencement of CAMC period, the suppliers shall furnish a Performance Bank Guarantee for 2.5% of the cost of the equipment (as per Performa given in Tender document) valid till 3 months extra after expiry of entire CAMC period. The Performance Bank Guarantee for CAMC will be applicable in case of equipment cost is more than Rs. 10 lakhs.

e) During the Warranty period and CAMC period, desired Uptime of 95% of 365/366 (Leap Year) days (24 hrs), if downtime more than 5%, the warranty period/CAMC period will be extended by double the downtime period. In addition a penalty equal to amount of 0.25% of the total cost of equipment per day will be liveable for the excess downtime period subject to Maximum of 10% of Cost of the Equipment. Complaints should be attended properly, maximum within 8 hrs.

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