Technical Specifications of Digital Mammography System with Tomo-synthesis and Biopsy Guide

The system should be State of art, advanced high-end digital mammography machine for general screening, diagnostics and interventional applications. It should be a 3D mammography (Digital Breast Tomosynthesis) unit. The system should be compatible with Stereotactic Biopsy, Tomo Biopsy applications, Vacuum Assisted Biopsy, Contrast Enhanced Digital Mammography, Contrast Guided Biopsy and also have certified computer Aided Detection (CAD) & Artificial Intelligence features.

The Full Field Digital Mammography system shall include:

a. Tube head and detector assembly
b. Compression system
c. X-ray Generator and tube
d. Flat panel detectors which work on direct conversion photons principle (X-ray directly to electrons)
e. Acquisition and Review workstations
f. Diagnostic review software
g. Interface and networking _RIS /HIS interface system
h. Accessories and consumables
i. Should have facility to do stereotactic biopsy in both 2D and 3D modes
j. Facility to place Patient for stereotactic biopsy on a couch for patient comfort- (supine or lateral). Couch should be supplied.
k. Should be an advanced high-end digital mammography machine with 3D mammography /Tomo synthesis and CEDM

I. Tube head and detector assembly:

- It should have iso -centric rotation for every positioning
- The iso-centric movements should be motorized and the patient compression device should have automated variable multispeed options.
- Vertical travel of C-arm assembly should be 70-140 cm
- Angular range of C arm assembly should be +180 to -180 degree with +/- 25 degree
- Movement of C-arm angulations and vertical movement should be motorized
- Should support wheel chair access.
- Tube angulations (Tomosynthesis) should be minimum +/- 7.5 degree. Total tomo scan angle of 15 degree or more.
- Mention the line per cm of grid and removable grid preferred

II. Compression system

- Compression devices which are capable of adjusting paddle to the contour of the breast tissue
- Should have automated variable multispeed capabilities
- Magnification devices of ratio>/=1.5 and 1.8
- Range of movement of compression plate in relation to breast support platform>=24cm
- Spot magnification and magnification paddles .
- Digital display of compression –force and thickness should be available on either side of gantry.
- Operator selectable compression modes and manual compression option
- Compression controls manual and foot switch/pedal options should be available.
- Foot switch should preferably have option exposure also.
- Emergency release option for compression in case power failure.
- Emergency stop button should be available.
- The compression should be smooth and there be automatic decompression at the end of each exposure.
- Compression paddle tilt-standard/fast/user selectable models

III. X-ray Generator and tube

1. X-ray generator should be high frequency with the following parameters:

- At least 20-49kv in steps of 1kV
- mAs range 3-400 or more
- Exposure time 0.2-4 sec
- Power output should be 7 KW or above
- Maximum number of exposures/hour>100
- Anode heat storage capacity should be at least 300 KHU

2. The X-ray tube unit should comply with the following parameters:

- Dual focus rotating anode tube
- Anode material should be mono-material (tungsten preferred).
- Focal spot sizes of 0.1 and 0.3mm
- Total inherent filtration of X-ray tube should not be more than 1mm of beryllium
- Should preferably have at least four filters: Ag, Rh, Al, Cu (copper for contrast mammography)
- Filter collimation selection: automatic/manual

IV. Flat panel detector

- Flat panel detector that uses direct conversion method (x-ray photons directly to electrons)
- Detector area 24 cm x29 cm or more.
- Automatic exposure (AEC)control is mandatory.
- Pixel pitch </=85 microns in 2D & 3D tomosynthesis
- Image acquisition –display time <30 seconds
- Image matrix in pixels: large size-3K x 4K or more Small Size: 2K x 3K or more
- No Ghosting or lag effect should be present; image depth should be at least more than 12 bits.
- The detector should be air cooled.
- AEC should have 2 sensors.

V. Specifications for 3D Tomosynthesis

- Total Tomo scan angle of 15 degrees or more
- Total 15 Tomo projections or more with exposure at every degree/angle
- Synthesized Reconstruction of 2D images from 3D tomo
- Image resolution of 85 microns or less for 2D images and 100 micron or less for 3D images
- Kindly mention Tomo acquisition and reconstruction time.
- The time taken for tomo acquisition should be less than 4 sec
- System should be capable of taking tomo and conventional images under the same compression
- Should be able to do Tomosynthesis in multiple views such as CC, MLO, LM, ML, etc.
- System should be capable of reconstructing the tomo slices in minimum 1mm slice
- Should be able to perform a tomo scan /3D Scan for up to 15cm breast thickness

VI. Specifications for Contrast Enhanced Digital Mammography

i. The CEDM option should automatically execute two serial exposures with low and high energy while holding the exposure button. After image processing and subtraction of the two images taken with different energies, the mammary gland will be suppressed and only the areas where the contrast agent is concentrated should be enhanced on the subtraction images.

ii. System should be capable of fusing tomo images with the Contrast enhanced mammo 2D images

iii. System should have an option to capture parameters like contrast agent used, speed of injection, timer, etc.
iv. The system should have contrast guided biopsy facility available as standard.

VII. Acquisition and Review workstations

a) Acquisition workstation

- High performance dual core processor with CPU clock speed 3GHz or more and compatible operating system.
- Minimum 6 GB high sped RAM
- 512 GB/1TB HDD for local storage
- On board video resolution of minimum 1024 grey levels (10 bit)
- Min 20" high brightness flat panel display with minimum resolution of 3 Megapixels with a user interface of 1.2 MP Monitor
- Provision for user customizable hard copy (filming) configurations from acquisition workstation.
- Latest DICOM version {DICOM 3 standard} or newer versions compatible.
- Capability to post process, store print, retrieve, schedule workflow etc.
- User interface including keyboard, mouse, etc

b) Diagnostic Review workstation

- High end quad core processor, windows-based system with CPU clock speed 3 GHz or higher.
- Windows based multisession operating system.
- Minimum 16 GB high speed RAM
- Local image storage on HDD minimum 1 TB using RAID technology
- Additional storage of min 1 TB using external HDD
- Review workstation Monitor Resolution with 12 MP should be supplied for mammography reviewing.
- On board video resolution of minimum 1024 grey levels (10 bit)
- Dedicated mammography workflow keypad.
- User interface devices including mouse, keyboard etc.
- The Reporting workstation software offered should be of the same brand as that of the mammography (no 3rd part application accepted)
- Image display should offer user selectable screen layouts from the available combinations.
- Adjustable window settings (contrast and brightness)
- Image inversion (block/white)
- Annotations (left/right markings), text additions, lines rectangles and circles
- Measurements {distance and angle}
- Image evolution –contrast enhancement display of histogram, length measurements, before /after comparisons, filter

VIII. Diagnostic review software

- Should support display of least 3 Mammograms in less than 1 second during normal workflow
- Should have advanced mammography specific hanging protocols.
- Should have customizable user environment including hanging protocols.
- Should have user login, password protected.
- Should support advanced session scheduling function.
- Should facilitate easy image export to communications graphic format for use in presentations.
- Should support diagnostic orienting of mammographic images.
- Should allow annotations archival and intelligent rooming.
- System should be offered with software to calculate density of breast automatically.
- System should be offered with computer aided detection {CAD} software

IX. Interface and networking

- Support for 10/100/1000 MBit Ethernet networks
- Supports DICOM network communication (DICOM 3 standard or later)- Reception, sending, query/retrieve, grey scale printing
- Compliable with PACS system
- Auto fetching of prior studies
- Demographic data should be automatically retrieved directly from HIS/RIS system
- Provision for manual entry of demographic data as well
- Should support Retrieval of images from CD/DVD/PACS workstations should be fully DICOM compatible (DICOM 3 standard or later versions)

X. Stereotactic biopsy system

- This should be fully compatible with Full Field Digital detector.
- Should have facility to do stereotactic biopsy in 2D and 3Dmodes.
- Fully integrated solution optimized with Tomosynthesis that minimizes procedure steps and simplifies workflow
- Intuitive user interface acquisition workstation for enhanced ease of use; Advanced ergonomic and lightweight design for quick and easy transition from diagnostic to interventional procedures under the same imaging modality
- Should have an accuracy of 1mm in all the three axis
- Facility for needle core biopsy, Fine needle aspiration and wire localization should be available.
- Should be compatible to use with vacuum assisted biopsy.

XI. Vacuum Assisted Biopsy System

The Vacuum Assisted Biopsy System should be fully compatible to Stereotactic, Ultrasound, MRI biopsy system. The VAAB should be compatible even in 3T MR. The VABB should be faster and take only 4 – 5 seconds for excision of per specimen & should offer Single incision and single insertion device for multiple tissue sampling. The VABB system should be quoted as a standard feature and to be supplied with Mammography.

XII. Artificial Intelligence software

The System should have FDA approved Artificial Intelligence software based on machine learning and deep learning which should be able to categorize and prioritize case reading, depending on the findings. The system should have FDA approved AI solution which utilizes AI analytics to uniquely reconstruct 3D data based on Strack imaging to reduce number of tomo slices (without any information loss) reduce reading time, reducing data storage space and network traffic (Stack Imaging or equivalent). It should also give lesion score and case score.

XIII. Standard Accessories

- Single head Pressure Injector for contrast and 200 Compatible syringes
- 20 KVA Online UPS
- Dehumidifier (50 Litres/day capacity)
- Motorized Biopsy Chair
- ACR approved phantom, phantom for weekly calibration, any specific phantom for Tomosynthesis
- Radiation shield with 0.3 mm lead equivalent
- 02 Nos. light weight lead aprons should be provided.
- One LED X-ray film viewer (3 films) should be provided.
- At least one set of BIRADS atlas (latest edition).
- Multi-Modality viewer for viewing CT, MR, US, CR etc. images.
- Two tray online film camera with dpi 500 or more for printing of mammography films.

XIV. Turnkey

- The scope of turnkey to be defined by the user unit. The equipment to 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. Necessary Civil, electrical and environmental (AC works) modifications to be done as per requirement in equipment as well as reporting room. Optimal radiation safety requirements must be taken into consideration. Adequate furniture and fixture of reputed make should be provided. All site modifications must comply with AERB as well as hospital norms.

XV. Others

- Quoted model should have at least 5 installation bases in reputed Govt Hospitals in India and working satisfactorily for a minimum of 3 years after installation
- Availability of spares in-house with trained engineers and service personnel is required
- The model offered should be BIS/ European CE / US FDA certified.
- The system should have a comprehensive warranty of 5 years from the date of installation followed by CMC for next 5 years.
- The system should be AERB type approved.
- On site Training for a period of 2 Weeks in multiple intervals as required by the department
- After sales service: Trained engineers should be available and to be attended within 24 hours
- The vendor should assist and facilitate site approval, licensing, and certification of the facility
- The system should have 95% uptime.