

(A Government of Kerala Undertaking) Thycaud P.O, Thiruvananthapuram - 14, Kerala. Tel: 0471 - 2945600, 2337353, Fax: 0471 - 2945647 Email :ep.kmscl@kerala.gov.in CIN: U24233KL200TSGC021616, PAN : AADCK4029M, GSTIN : 32AADCK4029M1ZK

Running Contract Details				
Equipment Name	Digital Mammography			
Running Contract Valid Till	13-05-2026			
Tender Ref No	KMSCL/EP/T523(R)/305/2024			
Tendered Quantity	7			
Supplier Name	M/s Trivitron Healthcare Pvt Ltd			
GST No	33AAACT9378H1Z1			
Installation & Delivery Period	12 Week(s)			
Up-time / PM vist	95% & 4 Visits per year			
Warranty period	3 Years			

Supplier`s Details						
Address	Contact Details					
No.15	Contact Person	Devdatta Wadekari, R. Balasubramanian				
Abhirmapuram IVth Street Chennai- 600018	Phone					
	Mobile No	08828991101,08291282826				
	Email	devdatta.wadekar@trivitron.com, balasubramanian.r@trivitron.com				

Item-wise Price Details							
#	Item Details	Unit Rate (Incl.all taxes & charges)	Service Charges (Through KMSCL)	Grand Total			
1	Digital Mammography (Except the following items) Model & Make : Selenia Dimensions 3D System/Messrs Hologic, Inc.	21280000 Incl.GST :12%	1569400	22849400			
2	3D Tomosynsthesis	Tomosynsthesis 1120000 Incl.GST :12%		1202600			
3	Acquisition and review workstation	560000 Incl.GST :12%	41300	601300			
4	Diagnostic review workstation	560000 Incl.GST :12%	41300	601300			
5	Diagnostic review software	560000 Incl.GST :12%	41300	601300			
6	Stool with back rest	112000 Incl.GST :12%	8260	120260			
7	Dry Imager	448000 Incl.GST :12%	33040	481040			

Item-wise Price Details										
8	Contact amd magnification compression paddle 10cm			1 Incl.	68000 GST :12%	12390			180390	
9	Small Breast paddle			1 Incl.	68000 GST :12%	12390		180390		
10	Axillary compression paddle				1 Incl.	68000 GST :12%		12390		180390
11	Spot contact and frameless spot paddle 7.5cm				1 Incl.	68000 GST :12%		12390		180390
12	Mammographic computer aided detection software			11 Incl.	20000 GST :12%		82600		1202600	
13	Stereotactic biopsy system			33 Incl.	60000 GST :12%	247800		3607800		
14	Biopsy couch			11 Incl.	20000 GST :12%	82600		1202600		
15	Radiologist training cost			3 Incl.	36000 GST :12%	24780		360780		
16	Radiographer training cost			2 Incl.	24000 GST :12%	16520			240520	
17	Contrast Mammography				11 Incl.	20000 GST :12%	82600			1202600
18	Vaccum assisted Biopsy			28 Incl.	00000 GST :12%		206500		3006500	
19	Hardware and software for Tomo Biopsy			11 Incl.	20000 GST :12%	82600		1202600		
				365	12000	2692760		39204760		
Annual / Comprehensive Maintenance Charges (Exl.Tax)										
Rate 4 <sup>th</sup> Year		4 <sup>th</sup> Year	5 <sup>th</sup> Year	6 <sup>th</sup> Year	7 <sup>th</sup> Year	8	<sup>th</sup> Year 9 <sup>th</sup> Year		10 <sup>th</sup> Year	
	Digital Mammography (Except the following items)									
Labou	r	2,00,000.00	2,10,000.00	2,20,500.0	0 2,31,525	.00	2,68,019.00	2,81,420.00		3,09,562.00
Comprehensi ve		13,00,000.00	13,65,000.00	14,33,250.0	0 15,04,913	.00	15,80,158.00	)0 16,59,166.00		17,42,124.00

# **Other terms & conditions**

1. The supplier shall execute an agreement with the purchaser as per tender conditions (agreement format is given in the tender document).

2. The supplier shall submit performance security amounting to 5.00% of the value of the supply order.

3. The labour & comprehensive charges of equipment after the completion of warranty period is finalized by KMSCL as mentioned above.

4. Since discount rate is not applicable for equipment under Running Contract of KMSCL, purchase/supply order can be issued directly to supplier at the given rate with tax & other charges (exclusive of KMSCL service charges).

5. If purchase/supply order is issued directly to the supplier, KMSCL service charge need not be paid. But the copy of the said order may be forwarded to KMSCL for information.

# **Technical Specification**

## Equipment :Digital Mammography (Except the following items)

#### **Equipment Name: Full Field Digital Mammography**

Availability of spares at regional levels with trained engineers and service personnel is required. The USFDA and CE certification for quoted equipment along with 3D tomosynthesis and all its applications is mandatory.

The complete full field digital mammography system is herein after called the FFDM system.

- I. The FFDM system shall comprise of:
- a. Tube head and detector assembly.
- b. Compression system.
- c. X-ray Generator and tube.
- d. Flat panel detectors which work on direct conversion principle (X-ray photons directly to electrons)
- e. Acquisition and Review workstations
- f. Diagnostic review software
- g. Interface and networking -RIS/HIS interface system
- h. Web based image distribution compatibility
- i. Accessories and consumables
- j. High resolution mammography compatible dry laser image.
- k. UPS for the whole system
- 1. Printer

### II. TRAINING

- 1. Training for a radiologist, when recruited, at a reputed centre. (Cost to be quoted separately)
- 2. Training for a radiographer, when recruited, at reputed centre. (Cost to be quoted separately)
- 3. Two types of onsite training shall be offered:
- a. Application training.
- b. System administration and software training
- 4. The application training shall satisfy the following.
  - a. Comprehensive training at site shall be provided for different applicable categories staff such as radiologist radiographers, technicians etc.
- b. The clinical, technical and safety aspects of the system should be covered in such a training program.
- c. The system administration and software training shall include Comprehensive training at site for our system Administrator(s)

#### **III.** Documentation

The following documents shall be included in the base price of the system

- a. One set of operators manual.
- b. One set of reference manuals, wherever possible.

### IV. Site plans and structural drawing

Available upon request to the hospital

## V. Delivery, installation and testing

a. After installation manufacturer/supplier has to conduct a quality assurance test under intimation to DRS.

## VI. Functional & performance requirements

- i. These specification call for a full field digital mammography system that employs flat panel detectors which work on the principle of direct conversion method, as a replacement for conventional film/screen mammography. The system should be operationally and functionally better than the present film/screen based systems.
- ii. All offers should be complete with full technical specifications. System configuration, pricing details and other details in line with the requirements of this tender, incomplete offers will not be considered, tender compliance documentation should also be included.

# VII. TECHNICAL REQUIREMENTS

The FFDM system shall include:

- a. Tube head and detector assemble
- 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 work stations
- f. Diagnostic review software
- g. Interface and networking \_RIS /HIS interface system
- h. Web based image distribution compatibility
- i. Accessories and consumables
- j. High resolution mammography compatible dry laser imager
- k. Should have facility to do stereotactic biopsy
- 1. Should be an advanced high-end digital mammography machine with 3D mammography /Tomo synthesis.

### VIII. Tube head and detector assembly

- 1. 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.
- 3. Vertical travel of C-arm assembly should be 85-140 cm
- 4. Angular range of C arm assembly should be 180-160.
- 5. Movement of C-arm angulations and vertical movement should be motorized
- 6. Should support wheel chair access.
- 7. Tube angulations should be minimum  $\pm 15^{\circ}$
- 8. Mention the line per cm of grid.
- 9. Offered System should be capable to contrast Mammography and the price to be quoted separately

# **IX.** Compression system

- 1. Compression devices which are capable of sensing the breast density and adjusting the compression forces accordingly.
- 2. Should have automated variable multispeed capabilities
- 3. Magnification devices of ratio>/=1.5
- 4. Range of movement of compression plate in relation to breast support platform>=30cm
- 5. Spot magnification and magnification paddles{mention sizes}
- 6. Digital display of compression -force and thickness should be available on either side of gantry.
- 7. Operator selectable compression modes and manual compression option
- 8. Compression controls manual and foot switch/pedal options should be available.
- 9. Foot switch should preferably have option exposure also.
- 10. Emergency release option for compression in case power failure.
- 11. Emergency stop button should be available.
- 12. The compression should be smooth and there be automatic decompression at the end of each exposure.
- 13. Compression paddle tilt-standard/fast/user selectable models

# X. X-ray Generator and tube

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

- i. At least 23-35kv in steps of 1kV
- ii. mAs range 5-400 or more
- iii. Power output should be 4 KW or above
- iv. Time from completion of exposure to availability of next exposure shall be ? 15 seconds
- v. Anode heat storage capacity should be at least 150 KHU

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

- i. Dual focus rotating anode tube
- ii. Anode material should be mono-material molybdenum or tungsten preferred.
- iii. Focal spot sizes of 0.1 and 0.3mm
- iv. Total inherent filtration of X-ray tube should not be more than 1mm of beryllium
- v. Should preferably have at least two filters
- vi. Filter collimation selection:automatic/manual

## XI. Flat panel detector

- i. Flat panel detector that uses direct conversion method(x-ray photons directly to electrons)
- ii. Detector area 24cm x29cm or more with 2 image formals.
- iii. Automatic exposure (AEC)control is mandatory.
- iv. Pixel pitch </=85 microns in 2D &100 microns in 3D tomosynthesis
- v. Image acquisition –display time <30 seconds
- vi. No Ghosting or lag effect should be present; image depth should be at least more than 12 bits.
- vii. The detector should be air cooled.

# XII. SPECIFICATIONS FOR 3D TOMOSYNTHESIS

- 1. Tomo scan angle of 15 degrees or more with tube moving from +7.5 degree to -7.5 degree.
- 2. Total 15 Tomo projections or more with exposure at every degree/angle
- 3. Reconstruction of 2D images from 3D tomo
- 4. Image resolution of 85 microns or less for 2D images and 100 microns or less for 3D images
- 5. Kindly mention Tomo acquisition and reconstruction time

# XIII. Acquisition and Review workstations

Acquisition workstation

- i. High performance dual core processor with CPU clock speed 3GHz or more and compatible operating system.
- ii. Minimum 6GB high sped RAM
- iii. 1TB HDD for local storage
- iv. On board video resolution of minimum 1024 grey levels(10 bit)
- v. Min 20" high brightness flat panel display with minimum resolution of 2 Megapixels.
- vi. Provision for user customizable hard copy (filming) configurations from acquisition workstation itself.
- vii. Latest DICOM version {DICOM 3 standard} or newer versions compatible.
- viii. Capability to post process, store print, retrieve, schedule workflow etc.
- ix. User interface including keyboard, mouse, etc.

# XIV. Diagnostic Review workstation

- i. High end quad core processor, windows based system with CPU clock speed 3 GHz or higher.
- ii. Windows based multisession operating system.
- iii. Minimum 6 GB high speed RAM
- iv. Local image storage on HDD minimum 1 TB using RAID technology
- v. Additional storage of min 1 TB using external HDD
- vi. Review workstation (twin monitors), LCD / LED displays should have min Resolution of 5 Megapixels, 1000 candela brightness and per pixel calibration. Should supply Barco make only
- vii. On board video resolution of minimum 1024 grey levels(10 bit)
- viii. Dedicated mammography workflow keypad.

- ix. User interface devices including mouse, keyboard etc.
- x. Image display should offer user selectable screen layouts from the available combinations.
- xi. Adjustable window settings(contrast and brightness)
- xii. Image inversion (block/white)
- xiii. Annotations (left/right markings), text additions , lines rectangles and circles
- xiv. Measurements {distance and angle}
- xv. Image evolution -contrast enhancement display of histogram, length measurements, before /after comparisons, filter

## XV. Diagnostic review software

- i. Should have advanced mammography specific hanging protocols.
- ii. Should have customizable user environment including hanging protocols.
- iii. Should have user login, password protected.
- iv. Should support advanced session scheduling function.
- v. Should facilitate easy image export to communications graphic format for use in presentations.
- vi. Should support diagnostic orienting of mammographic images.
- vii. Should allow annotations archival and intelligent rooming.
- viii. System should preferably be upgradable with software to calculate density of breast automatically.
- ix. System should support for computer aided detection {CAD} software

## XVI. Interface and networking

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

### XVII. Web based image distribution compatibility

i. The FFDM system should be compatible with web based image Distribution and should be Tele-radiology compatible.

# XVIII. Accessories and Consumables

- i. The FFDM system including acquisition and diagnostic review workstations should be provided with online UPS backup (30 minutes) in order to facilitate seamless workflow in the event of unexpected power failure.
- ii. Compression and magnification paddles
- a. Standard paddles- size 24x30 cm and 18x24 cm
- b. Spot magnification compression paddle.
- c. Contact and magnification compression paddle(10cm)
- d. Small breast paddle.
- e. Auxiliary compression paddle.
- f. Spot contact and frameless spot paddle(7.5cm)
- g. Comfort package-gel pods/arm slings/foam cushions/pillow etc.{Please mention the numbers that will be provided.}
- h. Dual function footswitch
- i. Stool with backrest.

### XIX. High resolution mammography compatible dry laser image

- i. Should have a resolution of ?500dpi
- ii. Spot size should be 50 microns or better
- iii. Should support 14 bit printing.
- iv. Should support film sizes 14x17,14x14, 11x14, 10x12 and Bx 10.

- v. Minimum throughput of 100 films /hr.
- vi. Compatible with latest DICOM version (DICOM 3 standard or later)

Please quote Mammographic Computer Aided Detection (CAD) software as an optional extra and also provide an option quote along the installed system to a new facility when demanded.

## XX. Stereo tactic biopsy system

- 1. This should be fully compatible with Full Field Digital detector.
- 2. Should have facility to do stereotactic biopsy automated on all the three axis.
- 3. Should have an accuracy of 0.2mm in all the three axis
- 4. Facility for needle core biopsy, Fine needle aspiration and wire localization should be available.
- 5. Should be compatible to use with vacuum assisted biopsy and the rate to be quoted separately.
- 6. Facility to place patient for stereotactic biopsy on a motorized biopsy transport chair for patient comfort during upright biopsy procedure should be provided. The chair should have facility to convert into a couch like position. Should have fold away arm rest and foot support. Individually adjustable backrest segment and arm supports for lateral orientation park bench position. Should be suitable for seated up or laying down procedures. The head rest should be height adjustable and should be able to slide away. Motorized up /down height adjustable. Should have wheel locksUpright stereotactic biopsy positioner kit needs to be supplied along with the biopsy chair as standard. Rate to be offered in line item no 14 of the BOQ "Biopsy couch".
- 7. The rate for the hardware and software for Tomo Biopsy to be quoted separately which will not be taken for evaluation.

# Note:

- 1. If CDSCO (Central Drugs Standard Control Organization) certification is required for the import and marketing of the equipment, then the same shall be submitted along with the technical bid
- 2. Warranty exclusions if any shall be discussed at the time of prebid meeting else the tender condition as per clause 6.31.20 shall prevail