

Schedule No. 07 - Full Field Digital Mammography Unit (Rfx no. 3000002195)

Sl. No	Tender Page & Para	TENDER SPECIFICATION	NAME OF THE FIRM	REPRESENTATION RECEIVED FROM THE FIRMS	COMMITTEE RECOMMENDATION
1	Page 93	State of art, USFDA approved, Full field digital mammography unit with digital breast tomosynthesis and stereotactic biopsy facility.	Fujifilm India Pvt Ltd	Change request: State of art, USFDA /European CE approved, Full field digital mammography unit with digital breast tomosynthesis and stereotactic biopsy facility. Justifications: We intend to quote our USFDA approved Model No. FDR MS 3500 which is marketed by name as "ASPIRE Cristalle" in US and outside of the United States (OUS same is known as "AMULET Innovality". However we request you to provide an option of European CE to avoid any confusion that may arise later due to difference in trade name in US and Outside US in spite of being same model.	no change considered
2	Page 93 Para 1.b	1. X-ray Generator a. X-ray generator should deliver high frequency constant output with minimum rating of 5KW with 100 mA at 35 kV.	Siemens Healthcare	Request you to please amend the specification as "X-ray generator should deliver high frequency constant output with minimum rating of 5KW with 100 mA or more at 35 kV."	1. X-ray Generator a. X-ray generator should deliver high frequency constant output with minimum rating of 5KW with 100 mA or more at 35 kV.
3	Page 93 Para 2.c	2. X-ray tube c. Collimator and cross-hair shadow marker.	Siemens Healthcare	Request you to please delete the specification.	2. X-ray tube c. Collimator
4	Page 93 Para 4.a	4. Digital flat panel detector a. Solid state direct conversion type, size 24x30 cm or more	WIPRO GE HEALTHCARE ADS Diagnostic Limited	GE manufactures its own detectors which are independent conversion type detectors that provide 50% less dose compared to direct conversion detectors. Please amend to include "Direct conversion or indirect conversion" detector The detector size should be : 24x29 cm or more.	4. Digital flat panel detector a. Solid state Direct / Indirect conversion type, size 24 cm x29 cm (± 1 cm).
5	Page 93 Para 5.e	added para : 5. Digital breast Tomosynthesis:			added para : 5. Digital breast Tomosynthesis: 5.e : it should be possible to generate synthesized mammographic view from tomosynthesis data.
6	Page 94 Para 7	7. Reporting workstation a. 10MP or more medical grade monitor approved for mammography and tomosynthesis with in-built calibration.	ADS Diagnostic Limited	The reporting workstation should be from the original manufacturing company, who is supplying the main machine.	Para 7 : REPORTING WORKSTATIONS:1 no.: 7.a.: Medical grade Colour Monitor of minimum 10 Megapixel resolution (configurable as 5 MP x 2), Capable of at least 1000cd/m ² brightness , with Out-of-the-box calibration to the DICOM grayscale display function for luminance. Display should be suitable for digital breast imaging, including breast tomosynthesis.With automated built-in QA and calibration. It should include a protective anti-reflective glass panel to prevent accidental damage to the screen.
	page 94 para 9.	added para. : 9. Digital Stereotactic breast biopsy facility			added para. 9. Digital Stereotactic breast biopsy facility 9.c : It should be able to do tomosynthesis -guided biopsy.

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		<p>7. Reporting workstation</p> <p>b. Dedicated mammography workflow keypad</p> <p>c. Mammography and tomosynthesis viewing and post processing facility</p> <p>d. Customizable workflow, image layout and image orientation</p> <p>e. It should be ready for multimodality (ultrasound, CT, MRI) viewing</p> <p>f. DICOM storage, query, retrieve, print in ready to use configuration</p> <p>g. Storage capacity of minimum 20,000 images</p>			<p>7. Para 7 : REPORTING WORKSTATIONS:</p> <p>7.b. i. The Image processing as well as reviewing software shall be from the principal manufacturing company of Digital Mammography unit.</p> <p>ii. The Image processing as well as reviewing software should be USFDA certified for Digital mammography & Tomosynthesis.</p> <p>iii. Dedicated mammography workflow keypad</p> <p>iv. Mammography and tomosynthesis viewing and post processing facility</p> <p>v. Customizable workflow, image layout and image orientation</p> <p>vi. It should be capable of multimodality (ultrasound, CT, MRI) viewing.</p> <p>vii. DICOM storage, query, retrieve, print in ready to use configuration</p> <p>viii. Storage capacity of minimum 10,000 images.</p>
7	Page 94 Para 10.e	<p>10. Compression paddles</p> <p>e. Cross hair shadow device</p>	Siemens Healthcare	Request you to please delete the specification.	<p>10. Compression paddles</p> <p>e. DELETED.</p>
8	Page 94 Para 11.a	<p>Standard accessories</p> <p>a. USFDA approved vendor neutral, DICOM compatible Breast density software. It should be capable of automatic volumetric computation from both 2D and 3D data. It should be able to display individual breast volumes in cc, volumes of fibroglandular density in cc, percentage density score and ACR BI-RADS (5th edition) density score in tabulated form. It should be possible to calculate mean glandular radiation dose to the breast.</p>	Volpara Solutions Ltd	<p>It is suggested that above item should be reworded so that it is complete and inclusive. USFDA cleared vendor neutral, DICOM compatible Breast density software. It should be capable of automatic volumetric computation from both 2D and 3D data. It should be able to display individual breast volumes in cc, volumes of fibroglandular tissue in cc and percentage density score as per ACR BI-RADS (5th edition) density score in tabulated form. It should be possible to calculate mean glandular dose to the breast in milligray (mGy) and applied compression pressure to breast tissue in Kilopascal (kPa). Software should also be able to provide Data Analytics for comparison of patient population.</p>	no change considered
9			Fujifilm India Pvt Ltd	<p>Change request: We Request you to kindly make it an Optional Item.</p> <p>Justifications: As This is an expensive third party item, further it is an undue advantage to one vendor. This will enable all other leading vendors to be competitive.</p>	

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10	Page 94 Para 11.b	11. Standard accessories b. USFDA approved vendor neutral 2D CAD solution. CAD should identify vascular calcification, lymph nodes, nipple and exclude it from markings. CAD marking should be easily toggled on and off.	Fujifilm India Pvt Ltd	Change request: We Request you to kindly make it an Optional Item. Justifications: As This is an expensive third party item, further it is an undue advantage to one vendor. This will enable all other leading vendors to be competitive.	no change considered
11	Page 95 Para 11.c	c. Complete contrast enhanced mammography package including software and hardware should be provided	Siemens Healthcare	Request you to please delete the specification.	11. Standard accessories c. Complete contrast-enhanced : Spectral / Dual energy Mammography package including software and hardware should be provided . Suitable pressure Injector with at least 20 disposable syringes with patient connector tubes.
12		d. Vacuum assisted breast biopsy system with facility for dual suction and saline irrigation (Mammotome-revolve or Suros or BARD-encore or equivalent). It should be configured ready to use with stereotactic as well as hand held ultrasound guidance. Complete consumable sets for stereotactic, hand held ultrasound guided and MR compatible biopsy guns (20 nos each) and compatible biopsy site marker clips (20 nos each) should also be supplied. Unit Price of consumables for vacuum assisted biopsy to be quoted separately for additional requirement in future.	Siemens Healthcare	Request you to please delete the specification.	no change considered
13	Page 95 Para 11.d		Fujifilm India Pvt Ltd	Change request: We Request you to kindly make it an Optional item. Justifications: As This is an expensive third party item, further it is an undue advantage to one vendor. This will enable all other leading vendors to be competitive.	
14			WIPRO GE HEALTHCARE	The following VAB specification is latest and superior in the market, available with many vendors, please take the advancements in biopsy VAB system. Please remove all vendor names from specification. Vacuum assisted biopsy capable for dual modality ultrasound and mammo stereotactic biopsy should be capable of real time needle rotation and movement of cutting blade on screen. System should have LED light for better view programmable rotation of needle during sampling should have minimum 3 gauges of biopsy needles.	
15	Page 95 Para 11.e	e. Motorized mobile biopsy chair cum couch (Acrus or DBI or equivalent reputed brand) suitable for stereotactic biopsy in sitting and lateral decubitus position. Complete digital mammography QA kit (Radcal or Pehamed or Unfor or equivalent) including kV meter and ACR approved phantom.	Siemens Healthcare	Request you to please amend the specification as "Non-Motorized mobile biopsy chair cum couch (Acrus or DBI or equivalent reputed brand) suitable for stereotactic biopsy in sitting and lateral decubitus position. Complete digital mammography QA kit (Radcal or Pehamed or Unfor or equivalent) including kV meter and ACR approved phantom."	11. Standard accessories e. Motorized or Hydraulic mobile biopsy chair cum couch of reputed brand suitable for stereotactic biopsy in sitting and lateral decubitus position.
16			ADS Diagnostic Limited	The Biopsy Chair should be Hydraulic / Motorized.	Complete digital mammography QA kit including kV meter and ACR approved phantom. The supplier shall provide regular calibration and QA during the warranty and CMC period.
17	Page 95 Para 12.c	12. Other features c. Vendor should not be blacklisted from any govt institution or judicial or semi-judicial authority. An affidavit to this effect should be submitted.	WIPRO GE HEALTHCARE	Please seek vendors with at least 10 digital mammo installations in the country. They should provide performance certificates from at least 3 centers. This will ensure vendors with quality service performance are allowed	12. Other features c. Vendors should have minimum three global installations of the quoted system.

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18	Page 95-96 Para 14	14. Installation: Necessary networking, furniture, fixture and modification to reporting room will be vendor's responsibility. Optimal Radiation safety requirements must be taken into consideration. Air conditioning for the Mammography Room, Console 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 point one point within the Mammography site. All electrical provisions including equipment mains panel, UPS cabling and DB, earthing etc. will be vendor's responsibility. All Site-modification work must comply with hospital norms.	Siemens Healthcare	Request you to please clarify all required furniture. We suggest for following furniture and electrical details to be added in specification 1. GYT floor tiles and full height Vitrified wall tiles of size 600mmx600mm in NS, Tech room and Mammo Room. All turnkey work should comply with specified standards of the hospital. 2. Following furniture to be provided Revolving chairs height adjustable, medium-back with hand-rest – 2 NO.5 Cupboard with laminate door shutters for storage of spare parts and accessories and records (300 x 50x40 cm) requirement – 2 NO.5 Dustbins - 4 NO.5 3. The supplier shall be required to specify the total load requirements for the Mammo area including the load of air conditioning, room lighting and for the accessories if any. The supply line will be provided by the institute up to one point within the Mammo area. The distribution panel for UPS, Mammo Scan area shall be provided by the vendor. 4. The electrical work shall include the following: a. Wiring - All interior electrical wiring- with main distribution panel board, necessary MCBs, DB, joint box, switch box etc. the wires shall be of copper of different capacity as per the load and should be renowned make as listed below. b. Switches light and power points should be of modular type and of standard make as listed below. c. General lights -LED light fittings with minimum 500 Lux Illumination. 5. Total 8 TR (5 TR Working+3 TR Standby) Ductable Split Units / Split Air-conditioning that is required for the Mammography and Tech room areas have to be installed by the vendor. Humidity control should be effective to eliminate moisture condensation on equipment surface. The outdoor units of AC should have grill coverings to prevent theft and damage. 6. Cabling of Network (LAN) connectivity for camera system, console system, workstation and computers etc 7. Fire detection system - Comprises of fire panel, smoke / heat detectors.	ADDED PARA: SITE MODIFICATION - DIGITAL MAMMOGRAPHY UNIT, Details of scope of work to be added to the technical specifications
19		Suggested by Bidder	ADS Diagnostic Limited	Point to be added under Para 6: Acquisition workstation Please ADD the software which is required to synthesize 2D Image from TOMO Views.	
20	PAGE 96 Para 15	15. Instructions:		ADDED PARA	15 Instructions ADDED PARA : 15. e : Original Product Datasheet of main unit and all accessories, including third party items to be provided.
21	PAGE 94 PARA 11.	11. Standard accessories:		ADDED PARA	15 Instructions ADDED PARA : 15. f : There should be at least three installations of the quoted model globally. Satisfactory performance certificate by users on their letterhead must be attached. Accessories : ADDED PARA : Crash cart - 1 no.
22	PAGE 95 Para 14	14. Installation:		Air-conditioning for the Mammography Room, Console Room should be provided.	Air-conditioning for the Mammography Room should be provided.

SITE MODIFICATION- DIGITAL MAMMOGRAPHY

1	<p>The Site drawing of the Institute can be obtained from the Project office of NCI - AIIMS, room no. 161, 1st floor, DBAIRCH, AIIMS campus, New Delhi.</p> <p>The vendor should inspect the site at NCI, Jhajjar, before quoting and ensure that the unit can be installed in the available space without any functional compromise.</p> <p>Complete equipment layout site plan and details of work (BOQ) should be part of technical bid.</p> <p>Provisions should be made for placing the various accessories in console room, work-station and printer locations.</p> <p>It should also include Lead lined door with lead glass peeping window, radiation warning indicators and signage, Aluminium false ceiling, GVT floor tiles and full height wall tiles.</p> <p>All site modification works should comply with specified standards of the hospital.</p>
2	The Digital Mammography site modification shall consist of the following rooms:
a)	Digital Mammography Room with Control panel area & patient change area.
3	Moreover Bidders will have to quote the Unit Rates of the following components of Site Modification work.
a)	Civil works
b)	Electrical work
c)	Air Conditioning (HVAC)
d)	Fire Alarm & Detector
e)	Interior Furnishing & Furniture
	The area considered for Site Modification for item: Digital Mammography System is indicated in the site plan attached below as Annexure 1.
4	Civil work
a)	Civil construction work including construction/ modification/ demolition of brick wall if any, plastering, flooring as per the approved plan and equipment layout plan.
b)	Additional strengthening of floor , ceiling structure for equipment , if required
c)	Platform for unloading and shifting the Digital Mammography should be provided if necessary.
d)	Cable tray, trench & channel – necessary trenches, cable tray and channels at required location would be provided.
e)	All the construction work to be done as per the final plan approved by NCI Jhajjar.
f)	False Ceiling-to-floor ceramic wall tiling
5	Flooring
a.	600 x 600 mm glazed vitrified (GVT) tiles with 100mm tile skirting in Digital Mammography room.
6	False Ceiling
a	Lightweight Aluminium ceiling panels , acoustical-treated, supported on grid or finished seamless with support above ceiling. Powder coated finish (colour to be approved by Institute). Ceiling height to suit the equipment mount and clearances.
7	Electrical work
a)	The supplier shall be required to specify the total load requirements for the Digital Mammography including the load of air conditioning , room lighting and for the accessories if any. The supply line will be provided by the Institute up to one point within the DIGITAL MAMMOGRAPHY area. The distribution panel for UPS , DIGITAL MAMMOGRAPHY shall be provided by the vendor.
b)	The electrical work shall include the following:
c)	Wiring – All interior electrical wiring- with main distribution panel board, necessary MCBs, DB, joint box, switch box etc. the wires shall be of copper of different capacity as per the load and should be renowned make as listed below.
d)	Switches light and power points should be of modular type and of standard make as listed below.

e)	General lights –LED light fittings with minimum 500 Lux Illumination
8)	AIR CONDITIONING: minimum 6 TR (4 TR Working + 2 TR Standby)
a)	Split air conditioners may be used according to room requirement and suitability. Humidity control should be provided to effectively eliminate moisture condensation on equipment surface.
b)	The outdoor units of AC should have grill coverings to prevent theft and damage.
c)	Environment specifications:
i	Relative Humidity range: To be maintained between 60% and 80% in all areas except equipment room which shall be as per requirement of the equipment.
ii	Temperature ranges: $22 \pm 2^{\circ}$ C in all areas except equipment room which shall be as per requirement of the equipment.
iii	Air conditioning load: The heat load calculations and maintaining the desired temperature and humidity shall be the responsibility of the bidder.
8	Furniture:
a.	Revolving chairs height adjustable, medium-back with hand-rest – 4 NO.S
b.	Cupboard with laminate door shutters for storage of spare parts and accessories and records as per requirement. – 2 NO.S
c.	Drug trolleys - 1 NO.S
e.	Patient trolley with rubber foam mattress - 1 NO.S
f.	Name boards for all rooms
g.	Tables for Workstation and Radiologist - 2 NO.S
h.	Dustbins: 4 NO.S
i.	All furniture items should be of standard make as mentioned in the table below.
9	Miscellaneous:
i.	LED X-ray Film viewer with adjustable brightness; capable of holding 3 films of 14"x17" size. – 2 no.s
10	Fire alarm & Detector:
i	(i) Fire alarm (along with new/existing panel) should be provided in all rooms, wherever site modification is being carried out. Fire alarm shall comprise of fire panel, smoke / heat detectors. The vendor should discuss with the engineering section and the department before quoting for Site-Modification
ii	Fire extinguisher Dry CO2 type 5kg as required for the building safety. – One per room
11	LIST OF ITEMS AND SUGGESTED MANUFACTURERS.
	ITEMS
	PREFERRED MAKES
a)	FLOORING VITRIFIED TILES -Somany, Kajaria , H&R Johnson, RAK india
b)	PAINT - Dulux, Asian Paints , Nerolac
c)	PLUMBING - Kohler, Jaguar , Grohe , Roca
d)	ELECTRICAL
e)	CABLES - Finolex, Havells ,V-Guard
f)	SWITCHES - Legrand, L&T, Crabtree , Roma
g)	DISTRIBUTION BOX , MCB - Legrand, L&T, Siemens, Havels
h)	LIGHT FITTINGS - Philips / Crompton / Wipro/Syska
13	AIR CONDINTIONING - Daikin, Hitachi, Blue Star, Voltas,
i.	FURNITURE - Hermen Miller , Godrej , Featherlite,Geeken.

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