

**GOVERNMENT OF ASSAM
OFFICE OF THE DIRECTORATE OF MEDICAL EDUCATION, ASSAM
SIXMILE, KHANAPARA, GUWAHATI-22**

No.DME.E-674645-5

Dated ↓

Corrigendum-1

With reference to the IFB No: AHIDMS/JICA/P&C/Equipment/RAD/2025/07 for Supply, Installation and Commissioning of Diagnostic & Imaging Equipment for AMCH, GMCH, LMCH, DMCH, JMCH, FAAMCH and TMCH in Assam UNDER JICA FUNDED PROJECT under Assam Health System Strengthening Project (AHSSP) certain amendments have been incorporated in the IFB document. Bidders are requested to take the note of these amendments prior to the submission of bid.

The following corrigendum in the subject Tender issued is hereby authorized: -

Lot-1 : SPECIFICATIONS OF DIGITAL RADIOGRAPHY 1000mA	
Existing	Corrigendum
2) Generator should be of high frequency of 450 kHz or more.	2) Generator should be of high frequency of 300 kHz or more.
B. TUBE:	
1) Dual Focus Rotating Anode X-ray tube having focal spot 0.6mm ² and 1.5mm ² or less.	Refer Bid Document
2) Multi leaf collimator having halogen lamp / bright light source and auto shut provision of the light.	Multi leaf/layered collimator having halogen lamp / bright light source and auto shut provision of the light.
D. Tube Stand (Floor Mount):	
d. Should have motorized up/down and motorized horizontal travel of tube head.	Should have up/down and horizontal travel of tube head.
E. Table:	
1) Should have 4 way floating tabletop type Horizontal Table with waterproof, stain free & low radiation absorption paper phenolic white laminated radiolucent material or carbon fibre.	Should have 4 way floating tabletop type Horizontal Table with waterproof, stain free & low radiation absorption paper phenolic white laminated radiolucent material or carbon fibre.
F. Vertical Bucky Stand:	
a. Should be Floor Mounted Vertical bucky stand with motorized vertical travel upto 1200mm or more.	Should be Floor Mounted Vertical bucky stand with motorized/manual vertical travel upto 1200mm or more.
G. Digital X-ray Flat Panel Detector:	
5) It should have a minimum spatial resolution of 4lp/mm or more.	It should have a minimum spatial resolution of 3.5lp/mm or more.
J. Product & Manufacturer Quality Standards:	

b Should meet Electrical safety standard EN 60601-1-2: 2015, EN 60601-1-54: 2009 and EMI/EMC standards ETSI EN 301489-1: V2.2.0: 2017, ETSI EN 301489-17: V3.2.0: 2017, EN 55011: 2009 +A1: 2020 (Group 1, Class A) & should be certified by reputed Lab with 4 digit notified body No. Please enclose copy of certification.	BIS/EN 60601-1-2:2015 to allow compliance with the Indian BIS equivalent standard.
d. Should be Class C (BIS-3) medical device under the Medical Devices Rules, 2017/CDSCO/USFDA/CE certified. The bidder must provide valid certification in support of the same.	Should be BIS medical device under the Medical Devices Rules, 2017/CDSCO/USFDA/CE certified. The bidder must provide valid certification in support of the same.
K. Accessories – To be offered as standard:	
2) Dry Laser printer with single online trays offering 14x17, 11x14, 10x12 & 8 x10 film sizes.	Dry printer with single online trays offering 14x17, 10x12 & 8 x10 film sizes.

Lot-2 : SPECIFICATIONS OF DIGITAL MAMMOGRAPHY	
Existing	Corrigendum
- Maximum mA output should be 150mA	Maximum mA output should be 150mA or more
B) <u>X-RAY TUBE</u>	
- Target Material: Molybdenum	Target Material: Molybdenum/Tungsten Molybdenum doped
- Collimation for both side should be available	Collimation should be available
Operating modes:	
<ul style="list-style-type: none"> Automatic selection of Exposure parameters (KV & mAs) as per Fatty, Normal & Dense breasts with manual override to select parameters manually. 	Automatic selection of Exposure parameters (KV & mA/ mAs) as per Fatty, Normal & Dense breasts with manual override to select parameters manually.
<ul style="list-style-type: none"> Mode (Dual shot) for automatic selection of exposure parameters. Automatic density selection as per breast anatomy for optimum Image quality. 	Automatic selection of exposure parameters. Automatic density selection as per breast anatomy for optimum Image quality.
<ul style="list-style-type: none"> mAs 	mA / mAs
<ul style="list-style-type: none"> mAS Selection Switch 	<ul style="list-style-type: none"> mAs/mA Selection Switch
<ul style="list-style-type: none"> Work book feature required to view the image statistics, rejected image information 	feature required to view the image statistics, rejected image information
X-ray generator control:-	
<ul style="list-style-type: none"> KV & mAS increase/ decrease switches 	KV & mAS/mA increase/ decrease switches
Workstation	
<ul style="list-style-type: none"> Dedicated mammography workflow key pad to be provided 	Deleted
F) <u>STAND ASSEMBLY</u>	

- Anti scatter grid: motorized movement, grid ratio 5:1, 31lp/cm with Carbon fiber interspaced material.	Anti-scatter grid: motorized movement, grid ratio 5:1, 35lp/cm or more with Carbon fiber interspaced material or equivalent technology
G) Compression	
<ul style="list-style-type: none"> Digital display of applied Compression Force (In Newton) with range up to 20KG 	Digital display of applied Compression Force (In Newton) with range up to 200N/20KG
<u>SPECIFICATIONS OF FLAT PANEL DETECTOR:</u>	
Size: 24cm x 30 cm.	Size: 24cm x 30 cm +/- 1 cm on either side
Photodiode: amorphous silicon (a-si)	Photodiode: amorphous silicon (a-si) or Amorphos selenium/ equivalent
Pixel pitch should be 85µm or less	Pixel pitch should be 100 µm or less
<u>H) POWER SUPPLY REQUIREMENT</u>	
<u>H) OTHER REQUIREMENTS:</u>	
Generator, Detector and software should be from same principle manufacturer of mammography system.	Generator, Detector and software should be from reputed manufacturers.
The company should be ICMED 13485 and ISO 13485. Company should be ISO 9001 certified with model of detector should be mentioned in it and 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.	The company should be ICMED 13485 and ISO 13485. Company should be ISO 9001 certified with model of detector should be mentioned in it and 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.
Should be Class C (BIS-3) medical device under the Medical Devices Rules, 2017/CDSCO/USFDA/CE certified. The bidder must provide valid certification in support of the same.	Should be BIS approved under the Medical Devices Rules/ 2017/CDSCO/USFDA/CE certified. The bidder must provide valid certification in support of the same.

Lot-3: TECHNICAL SPECIFICATIONS OF DIGITAL Radio-Fluoroscopy System	
Existing	Corrigendum
<ul style="list-style-type: none"> The offered detector should be ISO 9001:2018 certified, and the make and model of Detector should be mentioned. 	The offered detector should be ISO certified, and the make and model of Detector should be mentioned.

Lot-4: Technical Specification of Bone Densitometer	
Exixsting	Corrigendum
3. Detector:	
Material Solid State CdTe (Cadmium Telluride 1 mm) or GADOX	Material Solid State CdTe (Cadmium Telluride 1 mm) or GADOX or equivalent
4. Scan Time: A/P Spine = 30 Secs or less (normal mode); Femur = 25 Secs or less (normal mode)	Scan Time: A/P Spine = 30 Secs or less (normal mode); Femur = 25 Secs or less (normal mode)
10. Patient Weight Limits: min. 200 Kgs	Patient Weight Limits: min. 150 Kgs

All other terms and conditions of the Bid Document shall remain unchanged.

Director of Medical Education, Assam