Z-28016/35/2024-PMSSY-IV (8285627) Government of India Ministry of Health & Family Welfare (PMSSY-IV Section)

Room No. 745-A, Nirman Bhawan, New Delhi Dated the 21-08-2024

Office Order

Subject : Circulation of approved Technical Specifications of 10 Medical Equipment-reg.

In continuation of the office order dated 02-08-2024, please find enclosed herewith the Technical Specifications of following 10 High End Medical Equipment as submitted by the Committee set up by MoHFW under the Chairpersonship of Dr. Raju Sharma, Professor & Head, Department of Radiodiagnosis & Interventional Radiology, AIIMS New Delhi.

2. The above specifications have the approval of Secretary (HFW) and shall be valid for two years. All AIIMS/ INIs/ Institutes/ Hospitals/ Procurement Support Agency (HITES) of the Ministry are advised to adhere to the approved specifications (enclosed) while undertaking procurement of these equipment:

- i. Specifications for Flat Panel based Digital Under couch Fluoroscopy Systemwith Ceiling Mounted Radiography unit on turn key basis
- ii. Digital Radiography system (1000 MA) with Wireless Dual Flat Panel Detector (mid end)
- iii. Specifications of High-frequency over the couch Digital R/F System
- iv. Specifications for Digital Mobile Digital Radiography unit (mid end)
- v. Technical specification of Mobile DR (low end)
- vi. Technical specifications for AI enabled Digital Flat Panel Dual Detector 1000MA X-ray unit (high end)
- vii. Technical specifications for Digital Flat Panel Dual Detector 630 MA X-ray unit(low end)
- viii. Specifications for High end Digital Mobile Digital Radiography unit (high end)
- ix. Specification for Mobile Flat Panel Detector C-Arm unit (high end)
- X. Specification for Low end Mobile Flat Panel Detector C-Arm unit (low end)

Asr

(Arun Kumar Biswas) Under Secretary to the Govt. of India Tel:011-23061730 ak.biswas57@nic.in Encl (2):

i. Technical Specifications of 10 Medical Equipment

ii. Office Order No. Z-28016/35/2024-PMSSY- PMSSY-IV,dated 02-08-2024To

- i. All Additional Secretaries/ Joint Secretaries, MoHFW with a request to circulate the above specifications to all the Institutes/ Hospitals/ INIs/ Autonomous Bodies under their administrative control, for compliance.
- ii. Director General of Health Services, MoHFW, Gol

Copy to :

- i. Director, AIIMS New Delhi
- ii. Director, PGIMER, Chandigarh,
- iii. Director, JIPMER, Puducherry
- iv. Director, NIMHNAS, Bengaluru
- v. The Directors/ Executive Directors of new AIIMS under PMSSY
- vi. The Directors of Central Government Hospitals in Delhi/ North East Hospitals
- vii. CEO, HITES (via email at ceo@hllhites.com)

Copy for information to :

- i. PSO to Secretary(HFW)
- ii. PPS to Joint Secretary (PMSSY)



Circulation of approved Technical Specifications of 10 Medical Equipment- reg.

1 message

pmssysection iv <pmssysectioniv@gmail.com>

Wed, Aug 21, 2024 at 5:52 PM

To: Asfa-mhfw@nic.in, j_mishra@gov.in, asfr-mohfw@gov.in, Roli Singh <roli.singh@ias.nic.in>, ash-mohfw@nic.in, Zhimomiv@ias.nic.in, Dgoffice@naco.gov.in, Ischangsan@nic.in, asmd-mohfw@nic.in, jstraining-mohfw@gov.in, Pushpendra.r@nic.in, Vandana.jain@nic.in, Robert.elangbam@gov.in, Sinha.vijay@nic.in, Ea-mohfw@nic.in, kk.tripathy@nic.in, r.wadhawan15@nic.in, jsrch-mohfw@gov.in, cca-mohfw@nic.in, anoopk.puri@nic.in, Ddgtb@rntcp.org, pradeep.khasnobis@gov.in, js-pmssy-mohfw@gov.in, js-publichealth@gov.in, Ankita.edu@nic.in, dghs@nic.in Cc: Director AIIMS Bhopal <director@aiimsbhopal.edu.in>, director bhubaneswar <director@aiimsbhubaneswar.edu.in>, Director AIIMS Jodhpur <director@aiimsjodhpur.edu.in>, Director Patna <director@aiimspatna.org>, Director AIIMS Raipur <director@aiimsraipur.edu.in>, Director AIIMS Rishikesh <director@aiimsrishikesh.edu.in>, Director Mangalagiri <director@aiimsmangalagiri.edu.in>, Director AIIMS Nagpur <directoraiimsnagpur@gmail.com>, edaiimsrbl@gmail.com, rajwanshiarvind@hotmail.com, ED AIIMS Kalyani <ed@aiimskalyani.edu.in>, Executive Director Gorakhpur <executivedirector@aiimsgorakhpur.edu.in>, "Prof. Dr. D.K. Singh, Director" <director@aiimsbathinda.in>, Director AIIMS Deoghar <director@aiimsdeoghar.edu.in>, Bibinagar <director@aiimsbibinagar.edu.in>, Executive Director AIIMS BILASPUR <director@aiimsbilaspur.edu.in>, shakti810505@gmail.com, cdskatoch@gmail.com, Executive Director AIIMS Raikot <ed.aiimsrajkot@gmail.com>, HanumanthaRao Mangu <drmhraosvims1957@gmail.com>, Director AIIMS Guwahati <director@aiimsquwahati.ac.in>, madhabananda@gmail.com, sachimohanty@rediffmail.in, Dr Vivek Lal <dpgi@pgimer.edu.in>, director@jipmer.ac.in, director@aiims.gov.in, Director Neigrihms <director-neigrihms@gov.in>, nalinaiims.mehta@gmail.com, eigasunil@gmail.com, director@ripans.ac.in, MS OFFICE SJH <msoffice@vmmc-sjh.nic.in>, "Dr. Sunita Sharma" <director-lhmc@gov.in>, minakshi Bhardwaj <med.sup@rmlh.nic.in>, ceo@hllhites.com, secyhfw@nic.in, Praveen.batra@gov.in, "Cc:" <Dinesh.kumar14@nic.in>, ":" <ak.biswas57@nic.in>, sankar.garg@gov.in, Amit Batra <amit.batra@gov.in>

Sir/ Madam

Please find the attachment.

Note: In case this email requires you to reply, you are requested to reply to all the officials of PMSSY-IV Section at - dinesh.kumar14@nic.in; ak.biswas57@nic.in; sankar.garg@gov.in; amit.batra@gov.in Regards PMSSY-IV Section Ministry of Health and Family Welfare

3 attachments

- Circulation.pdf
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Sp	ecifications for Flat Panel based Digital Under couch Fluoroscopy System with ceiling mounted radiography unit on turn key basis
High unit	powered X-Ray unit with digital flat panel for various fluoroscopy examinations and radiography using ceiling mounted radiography
	init should be a completely integrated system (integrated X ray generator and image acquisition control console) having the following fications.
Gene	rator
1.	1000mA unit with microprocessor controlled high frequency X-ray generator with power output of 80 kW or more.
2.	Exposure kV range should be 40-150.
3.	System should have a facility for pulsed fluoroscopy.
4.	Generator should have a minimum exposure time of at least 1ms.
5.	System should have multiple user defined programmes (vendor defined programmes).
6.	There should be provision for automatic exposure control (AEC). It should be possible to override AEC if required.
TABL	1E
1.	Floor mounted table with radiolucent composite material or carbon fiber table top, scratch resistant surface.
2.	System should have motor driven longitudinal, and horizontal table top movements.Please specify the range of movements.
3.	Table should have angulations from longitudinal to head down positions. (Vertical +90 degrees to Trendelenburg -20 degrees)
4.	Table should support a patient weight 185 kgs or more.
5.	System should have a well designed foot switch for releasing fluoroscopy and acquisition.
6.	System should have provision for collision protection.
7.	Table should have an integrated bucky unit for flat panel general radiography and fluoroscopy.
X-Ray	y TUBE
Total	of two numbers X Ray tubes, one is under couch and second ceiling mounted

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•	The X-Ray tube should have dual focal spots.			
•	X-Ray tube rating should be compatible with X-ray generator output.			
 Small focal spot power rating should be in the range 20-50 Kw. Large focal spot power rating should be in the range 50-80 kW. 				
•	Anode heat storage capacity should be 700 KHU or more.			
•	Mention the heat dissipation rate.			
Integ	rated Direct Digital Imaging system for Fluoroscopy:			
1.	Field of view of at least 40 cms or more.			
2.	Collimator may be rectangular or iris type. Radiation free collimation should be possible.			
3.	System should have real time optimization techniques to maintain constant brightness at the lowest allowances dose to the patient.			
4.	Should have Cine loop facility and last image hold facility during fluoroscopy.			
5.	System should be capable of acquiring images in the 2Kx2K matrix.			
6.	The pulsed fluoroscopy mode - it should be at least 30 frames per second; and series exposures should be at least 6 frames per second.			
Imagi	ing Tower : Following are expected specifications for imaging tower. Please specify details in the quoted model :			
a)	Source-image distance (SID): min 89cms, max125 cm.			
b)	Motor-assisted, 22 cm transverse travel, 14 cm to the front and back.			
c)	Grip handle: Ergonomically shaped handle for one-handed control of main functions, Including force sensor-control of motorized			
	tower movement, 8-way tabletop travel, table tilt, collimation control, acquisition trigger and fluoroscopy release.			
	tower movement, o-way tabletop traver, table tilt, commation control, acquisition trigger and hubroscopy release.			
d)	System should have provision for collision protection			
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-	System should have provision for collision protection			
Bucky	System should have provision for collision protection y wall stand :			

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d)	Hand-held control: Tube tracking on/off and other important functions on user interface should be available.		
e)	Tube automatically tracks wall Bucky height adjustments with detector tray height adjustments with detector at 0°, 90° or		
	intermediate tilt angles.		
f)	Suitable Grid of ratio 12:1 or better to be provided.		
Deteo	ctor System:		
a)	Wireless Digital flat panel detector over the table of size at least 43x43 cms or more.		
1.	Image matrix size 2k X 2K pixels or more.		
2.	Pixels size should be 150 micron or less.		
3.	Should allow centered/de-centered collimation.		
4.	DQE 70% or more.		
5.	Tabletop to imaging tower distance adjustable in order to minimize radiation dose to the patient.		
6.	Imaging tower movement should be motorized.		
Image	e display system		
•	Flat medical grade monitors of 19" or more (four in number) to be provided of 1 Megapixel or more, two each in examination and		
	console room.		
•	Post acquisition image processing, viewing, reprocessing, hard copy documentation and onward transmission should be possible.		
Contr	rol Console		
1.	All system movements of the table shall be controlled by the operator at the table in the examination room.		
2.	The system should have facilities for edge enhancement, positive/negative image display, windowing, contrast/brightness, electronic		
	shuttering, vertical and horizontal image reversal, and zoom functions.		
3.	The system should have fast and direct access to all series, single images, in both examination (Remote controlled) and console		
	room.		
4.	System should have angle/distance measurement, image labeling and patient positioning facilities.		
5.	System should have anon line dosimeter on the console to display actual radiation dose.		
Image	e storage and Transmission		
•	Image storage capacity of at least 30,000 images in 1024 x 1024 matrix at 10/12 bits on the main system disk.		
•	The system should be DICOM 3.0 (or higher version) ready (like send, receive, print, record on CD/DVD, acknowledge etc.) for		
	connectivity to any network, computer/PC etc. in DICOM format.		
•	Vendor should connect this with existing PACS system and other laser cameras already existing in the department without any extra		

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	cost		
•	Integration and networking will be done by the vendor free of cost with any other existing/future networking including other modalities, HIS and RIS and PACS.		
Acces	ssories		
1.	One Dry Chemistry, Multiport, multiple films (14"x 17", 11"X 14" and 8"X 10") camera with resolution of 500 DPI or more, DICOM ready and online. At least three size film trays should be active. The vendor should connect this camera with other existing cameras in department of Radiodiagnosis.		
	Lead glass 100 x 150 cm for the console room.		
3.	Five lightweight 'zero lead' aprons with integrated thyroid collar, pediatric gonadal shields (All sizes both for male and female). Stand to keep these aprons.		
4.	Suitable UPS with complete backup for the computer system for at least 30 minutes.		
5.	A voltage stabilizer of 120 KV or better for the entire unit.		
6.	Minimum necessary furniture: chairs (rotating type computer chairs of reputed brand like Godrej) - 8 in number, table, shelves for storage space etc.		
7.	Fire extinguisher alarm system to be connected to the nearest central system of the hospital by vendor.		
8.	Hand grip		
9.	Foot step.		
10.	Patient fixing belts and compression device (for performing excretory urography).		
11.	Integration with existing RIS & PACS to be done by the vendor free of cost.		
Essen	tial requirement :		
	The company should be ISO 13485 /CDESCO / FDA / European CE certified.		
	The unit should be approved by AERB.		
	The company should have a proven track record in the Govt. sector.		
	At least two of the three components (generator, detector & X ray tube) should be from the same principal manufacturer of the X-ray system.		
	During the CMC period, the QA for the unit must be done by the supplier as per AERB requirements.		
	The company is to give an undertaking that the detector will be replaced with the same detector that was quoted during the initial offer for the entire warranty period and the CMC period. No change in the detector company is acceptable in case of replacement during the warranty /CMC period.		

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DIGITAL RADIOGRAPHY SYSTEM (1000 mA) WITH WIRELESS DUAL FLAT PANEL **DETECTOR (MID END)**

The system should be capable of performing exposure in vertical, horizontal, and oblique positions to perform all skeleton body (upright and lying down) radiographs.

The unit should be completely integrated (integrated generator and Image acquisition). It should be possible to do all the general radiological imaging like abdomen, musculoskeletal, PNS, Skull, Spine, etc. with the movement of tube assembly with auto-positioning and auto-tracking.

The unit should be of High-frequency Digital Radiography system with a rotating anode. 3D ceiling suspended stand with Auto-tracking & 2 separate wireless detectors each in table bucky and vertical bucky.

The system should have the following features.

A. HIGH-FREQUENCY GENERATOR:

The generator should be of the latest technology with a high frequency.

Power output of 80KW.

KV range should be 40 to 150 KV in 1KV/step.

mA output: up to 1000 mA.

mAs range should be from 1 to 200 mAs.

It should have a solid-state automatic exposure control device on the table & vertical bucky stand with 3 AEC field sensors each on the table and wall stand.

B. X-RAY TUBE:

A Dual focus High-speed Rotating anode X-ray tube. The focal spots of the tube should be:

- Small focus: 0.6
- Large focus: 1.2

Anode Heat storage capacity 300 KHU.

Collimator: Automatic Multileaf collimator with LED light source with high lux output. Rotation +/-90 degrees.

A DAP meter should be provided to display the dose given to the patient on the monitor.

C. TUBE STAND:

- Ceiling-mounted tube assembly with 3-dimensional motorized movements of the tube head covering a large area.
- Motorized movements in longitudinal, vertical, and transverse directions with control from panel mounted on Tube collimator assembly.
- Tube stands with actuator based/ telescopic noiseless swift motorized up/down • movement.
- Manual Override of Longitudinal & Transverse direction movements with electromagnet locks

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- Touch screen Console panel is provided for Exposure parameters display, tube inclination angle & SID display.
- A Smart Anti-collision software system is provided to avoid any collision.

Movements of the stand should be:

- Motorized Longitudinal movement: more than 2500 mm
- Motorized Transverse movement: more than 1500mm
- Motorized Vertical up/down movement: more than 1000mm
- Tube head Rotation (along the vertical axis): $\pm 180^{\circ}$.
- Tube head Rotation (along the horizontal axis): $\pm 135^{\circ}$.

• Tube assembly should have 3D auto-tracking and auto-positioning on its control for synchronization with the detector fitted inside the vertical bucky stand & table.

• Image stitching facility should be available in both vertical stand and table

D. <u>TABLE</u>:

- A horizontal 6-way table with a floating tabletop and adjustable height should be provided. Table-top should have three-dimensional movement, which is easy for patients as it lowers down to a comfortable position.
- The table should be provided with a motorized Bucky which can house the removable wireless detector
- Transverse and longitudinal movements of the tabletop should be locked by electromagnetic locks.
- A table should have up/ down motorized movement and it should be controlled by two up & down foot switches.
- Movements of table: Transverse movements 18cm or more, longitudinal movements 50cm or more. A height adjustment facility should be available.
- The maximum weight carrying capacity for the table during up/down movement should be more than 200 Kg.
- •___AEC mode with the use of ion chambers should be provided which enables auto selection of radiographic factors, saves time, eliminates retake, increases diagnostic capability and lowers radiation dose, calibrated to multiple exposure classes/densities.
- Removable grid of min 10:1 ratio with focal distance of 100 cm /110cms to be provided. •

E. VERTICAL BUCKY (VB) STAND:

The floor-mounted Motorized Vertical bucky stand should house the removable wireless detector. It should have a user-friendly design and handling.

- VB stand should have provision to do chest radiography with and without a grid.
- Motorized Tilting should be -30 degrees to + 90 degrees.
- Vertical up & Down Movement range should be 1500mm or more.
- The vertical travel range of the detector should minimum 300 mm and maximum 1800 mm above floor (measured at the detector center).
- AEC mode with use of ion chambers should be provided which enables auto selection of radiographic factors, saves time, eliminates retake, increases diagnostic capability and lowers radiation dose, calibrated to multiple exposure classes/densities.
- Removable grid of min 10:1 ratio with focal distance of 100cm /110cms to be provided.

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F. FLAT PANEL DETECTOR (One NO. EACH FOR TABLE BUCKY AND VERTICAL **BUCKY):**

The wireless detector should be a flat panel type with A-Si (amorphous silicon) and CSi as scintillator.

- The size of the detector must be 43cm x 43cm.
- Active Image matrix 3K x 3K.
- Image depth should be 14 bits or more.
- Pixel size should be less than 150 um (Smaller pixel size is preferred)
- Detector resolution should be 3.6lp/mm or better.
- DQE (Detector Quantum Efficiency) should be more than 70%.

G: OPERATING STATION/WORKSTATION:

a. X-RAY/IMAGE CONTROL CONSOLE

Fully integrated system with the following features:

- Digital Display of KV & mAs.
- KV & mAs increase and decrease control on GUI
- Ready and X-Ray ON indication on GUI
- Self-diagnostic Program which can diagnose and display error messages such as Earth fault error, KV error, Filament error & Tube's Thermal Overload.
- Anatomical Programming Radiography (i.e. APR): Preprogrammed parameters of human Anatomy which helps the user to select exposure parameters based on body part, examination view and size of the patient should be available. Since it is a computer-based system (full system integration) so any number of Organ programming combinations should be possible. The user can define his own Organ parameters and can edit the existing parameters to his satisfaction and comfort level.
- APR programs: should be more than 1000 programs. (Expandable as per user's requirement).
- Hand switch with retractable cord for initiating the exposure for performing radiography procedures.
- H. Workstation along with monitor: 2 No. 19" or more high-resolution LCD monitor should be provided with the specifications below.

Hardware Detail of Acquisition /Memory software:

- Compatible computer processor (i5 processor or Xeon Processor) of branded make •
- 1TB Hard disk
- Window OS
- 64 Bit operating system
- CD/DVD writer.
- Wired keyboard & mouse. •
- Operating system Windows 10 Pro operating system. Should be the latest version of • Windows that the system can support. Any updates/upgrades/patches to the OS and the application should be provided free of cost for the entire period of warranty and CAMC.
- It is the vendors responsibility to connect the system to the closest network switch in the hospital network and to configure the system with HIS/RIS/PACS.



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- It is the responsibility of the vendor to install a fire alarm system and connect it to the • nearest available fire alarm panel, if such a system is available in the hospital. Else, the vendor has to install a standalone fire alarm and fighting system.
- Facility to transfer DICOM images in bulk to external hard disk is to be provided •
- The workstation should have a DVD writer for burning images •
- I. POWER SUPPLY REQUIREMENT: 3 Phase, 400 Volts AC 50Hz with line resist 0.2 Ohms. Line Regulation $\pm 10\%$.

J. Accessories: -

- 1. Four nos lead aprons of 0.5 mm lead equivalence.
- 2. Three-panel lead protection barrier.
- 3. Support stand for Image stitching radiography.
- 4. 3 KVA UPS for the console workstation with 30-minute backup to be provided
- 5. 3 tray Dry laser Printer to be supplied (at least 500 dpi)
- 6. Adequate thickness lead glass should be provided between the console room and the examination room

K. Other Requirements:

- The company should be ISO/ CDESCO/European CE/ FDA certified. •
- The unit should be approved by AERB. •
- The company should have a proven track record in the Govt. sector.
- During the CMC period, the QA for the unit must be done by the supplier as per AERB requirements.
- The company is to give an undertaking that the detector will be replaced with the same detector that was quoted during the initial offer for the entire warranty period and the CMC period. No change in the detector company is acceptable in case of replacement during the warranty /CMC period.
- Detector batteries, UPS and its batteries and all accessories supplied with the unit should be covered under warranty and CAMC

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SPECIFICATIONS OF HIGH-FREQUENCY OVER THE COUCH DIGITAL R/F SYSTEM

Digital Radiography/Fluoroscopy System with Wireless Flat Panel Detector in remote-controlled RF table. The unit should be capable of doing all types of Fluoroscopic examinations like GI examination, ERCP, and barium studies, along with all radiography procedures.

X-RAY GENERATOR:

- A High-Frequency X-ray generator of frequency should be provided.
- The power output of the generator should be 80KW.
- KV Range should be:
 - Radiographic KV: 40 to 150 KV.
 - Fluoroscopic KV: 40 to 120 KV.
- mA Range (Rad.): 1000mA.
- mA Range (Fluoroscopy): Normal Flr. Mode: up to 50mA

HD/Boost Flouro/Cine mode: - up to 70mA.

- Exposure time (Rad.): 1 ms to 5 sec or more.
- Cumulative flouro. timer to cut off exposure.
- mAs Range (Rad.): up to 350mAs or more.

CONTROL:

Fully integrated system with the following features:

- Digital Display kV, mA & mAs for radiography & kV & mA for fluoroscopy mode, Cine kV & mA, Spot kV and mAs.
- Integrated touch panel TFT display for various X-ray functions and indications.
- Exposure parameters (eg. kV, mA, mAs) can be controlled from Acquisition software as well as from Touch Panel Display.
- Manual and Automatic brightness stabilization (ABS) in fluoroscopic Modes.
- Exposure indication on Acquisition Software.
- Self-diagnostic Program with Indicators for Earth fault error, kV error, Filament error & Tube's Thermal Overload, Rotor fault, and Phase failure indications.
- Anatomical Programming Radiography (i.e. APR) Preprogrammed parameters of human Anatomy > 150 programs which help the user to select exposure parameters based on the body part, examination view, and size of the patient.
- Hand switch with retractable cord for initiating the exposure for performing radiography procedures.
- 2-Point mode and 3-point mode exposure technique in Radiography mode.

X-RAY TUBE (01No.):

- A Dual focus Rotating Anode X-ray tube thermally protected having focal spots of 0.6 & 1.2mm.
- Anode rotation speed should be a minimum of 9000 RPM.
- The anode heat storage capacity of the tube should be min 1000KHU.
- One Pair of H.V. Cable of suitable length should be provided.

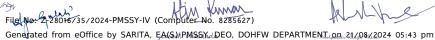
COLLIMATOR:

- 1No. Motorized Square/ Rectangular collimator having a bright light source and auto shut provision of the light.

TABLE:

Remote controlled, motorized RF Table should be provided. The table should have an integrated console. The table should have a scratch-resistant tabletop.

- The table should have a soft start and stop movement with the following minimum features.
- Motorized Tilt: Vertical +90° to -21° or more for Trendelenberg.





- The table should have an automatic stop at Horizontal & Vertical positions during tilt movement.
- Motorized Transverse movement of tabletop: 34cm or more •
- Table with height adjustment facility
- Motorized Longitudinal movements of imaging unit i.e. Tube column detector movement: 100cm or more with auto tracking facility
- Tube Oblique movement. •
- Integrated bucky for wireless flat panel detector for general radiography and fluoroscopy.
- Remotely operated compression device.
- Footswitch for releasing fluoroscopy and acquisition.
- Patient weight carrying capacity: 200kg.
- Intercom system to communicate with the patients.
- The table and tube should be capable of performing chest radiography at an appropriate SID •
- Table accessories: 1No. Each Handgrip, compression band, and footrest. •

BUCKY WALL STAND:

- Travel range (central beam to floor) From 30 cm to 173 cm.
- Detector unit Tiltable from -20° to $+90^{\circ}$
- Alignment with X-ray tube Autotracking facility.
- Hand-held control: Tube tracking and other important functions on the user interface should be available.
- Tube automatically tracks wall Bucky height adjustments with detector tray height adjustments with the detector at 0° , 90° , or intermediate tilt angles.
- Suitable Grid of ratio 12:1 or better to be provided.
- The vertical travel range of the detector should be 1500 mm, minimum 300 mm and maximum 1800 mm above floor (measured at the detector center).

DYNAMIC FLAT PANEL DETECTOR (FPD) (2 No, one for table bucky and another for wall stand bucky

A complete imaging solution with cutting edge performance integrated with our X-ray systems.

FPD should have the following specifications or better.

- Receptor type: Amorphous Silicon
- Scintillator: Cesium iodide (CsI)
- Size of detector: 43 x 43cm or more
- Image matrix size: 3K x 3K or more
- A/D conversion: 16bits
- Pixel size:150µm or less.
- Detector resolution should be 3.6lp/mm.
- DQE: 70% or more at 0 lp/mm.

IMAGE ACQUISITION SOFTWARE should have the following features available.

Exposure Mode

Software Module

- RF (For Fluoro, Cine and Spot)
- DX (For Radiography)

• RF: 1536×1536 (1.5K×1.5K Image resolution) Up-to 18 FPS Pulsed X-Ray

- DX: 3072×3072 (3K×3K Image resolution)
- Patient Entry Module: MWL, Manual, Emergency
- Examination Module: -

□ RF Module

Image Size/ Frame Rate

DX Module



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Generator Controls feature in the software

Examination Layout

Live Parameters

DICOM Compatibility

WL/WW Adjustment

Post-processing Parameters

- Viewing Module
- Print Module
- kVp
- mAs
- ABS ON/OFF
- Filament Selection
- Heat Unit Display
- 3Point (KV, mA, mAs) / 2Point (KV, mAs)
- 1x1 (Live)
- 1x2 (1st: Live, 2nd: Reference)
- WW/WL
- Auto WW/WL
- Dynamic Zoom
- PAN
- Horizontal Flip
- Vertical Flip
- Frame Rate
- Image Invert
- Image Rotation +90°
- Image Rotation -90°
- Software Shuttering/Live Image Masking
- DICOM 3.0 compatible:
- DICOM Send
- DICOM Print
- DICOM MWL
- DICOM MPPS
- Automatic WW/WL adjustment for Radiography.
- Automatic WW/WL adjustment for Fluoro, Cine, and Spot according to the selected procedures
- Manual WL/WW adjustment
- WW/WL
- Zoom
- Magnify
- Invert
- Flip Horizontal
- Flip Vertical
- Annotations
- Image Layouts
- Series Layout
- Image Cropping
- Play DICOM Loops
- Frame by Frame Image View
- Software Shutter
- Tagging of Images
- Angle and Length measurement.
- Image Reset

MONITORS: 2 Nos. medical grade monitors. of the size of 19" or more, one in the examination room integrated on the trolley and one in the console room with a resolution of 1280 x 1024 pixels or more should be provided

Should be provided.

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Additional reporting workstation with a 19" Medical display monitor with the below feature should be provided.

- Operating system Windows 10 Pro operating system. Should be the latest version of Windows that the system can support. Any updates/upgrades/patches to the OS and the application should be provided free of cost for the entire period of warranty and CAMC.
- It is the vendor's responsibility to connect the system to the closest network switch in the hospital network and to configure the system with HIS/RIS/PACS.
- Facility to transfer DICOM images in bulk to external hard disk is to be provided
- The workstation should have a DVD writer for burning images

Advance Features: -

- o DICOM Store
- DICOM Print
- o Job Queue

POWER REQUIREMENT: The unit should be operable on 400V AC, 50 HZ 3 Phase - Max. Allowable line Regulation $\pm 10\%$.

ACCESSORY:

- A servo voltage stabilizer of suitable rating for the complete unit.
- 30-minute UPS backup for the entire system including the x-ray tube, generator, table, and console to be provided
- 1 no dry laser printer of 500 DPI or more.
- 1 no. ceiling suspended lead protection shield.
- Lead glass should be provided for the console
- It is the responsibility of the vendor to install a fire alarm system and connect it to the nearest available fire alarm panel if such a system is available in the hospital. Else, the vendor has to install a standalone fire alarm and fighting system.

OTHER REQUIREMENTS:

- The company should be ISO 13485 / CDESCO / FDA / European CE certified. •
- The unit should be approved by AERB.
- The company should have a proven track record in the Govt. sector. •
- Out of the three components (generator, detector & x-ray tube) two should be from the same principal • manufacturer of the X-ray system.
- During the CMC period, the QA for the unit must be done by the supplier as per AERB requirements. •
- The company is to give an undertaking that the detector will be replaced with the same detector that was quoted during the initial offer for the entire warranty period and the CMC period. No change in detector company is acceptable in case of replacement during the warranty /CMC period.
- Detector batteries, UPS and its batteries and all accessories supplied with the unit should be covered under warranty and CAMC

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SPECIFICATIONS FOR DIGITAL MOBILE DIGITAL RADIOGRAPHY UNIT (MID END)

A High-powered motorized battery-powered mobile Digital X-ray unit with a collapsible column and Telescopic Cross Arm suitable for bedside X-rays in Wards, ICUs, and operation theaters with a digital flat panel detector for image acquisition and should operate on single phase power supply. The quoted unit should have the following minimum specifications and items as mentioned below

The unit should comprise of the following:

- I. High-Frequency Generator built into the mobile unit
- II. X-Ray Tube
- III. Collimator
- IV. Flat Panel Detectors- 1no
- V. Build in Workstation
- VI. Integrated Mobile Cart

A. High Frequency Generator

- 1. It should be a microprocessor-controlled high-frequency X-ray generator
- 2. The power output of the generator should be 30KW or more to give at least 300mA@100kvP or more.
- 3. The radiographic KV range should be 40 KV to 125 KV or more with an increment of 1KV per step
- 4. mA Range: 10- 300 mA or more.
- 5. mAs Range: 0.1 to 300mAs
- 6. Exposure time 1 ms to 10 Sec.
- 7. It should have a digital display of kVp, mA, and mAs
- 8. Individual settings of kVp, mA, mAs, and sec must be possible.
- 9. Wired as well as Wireless Exposure Switch to be provided

B. X-Ray Tube:

- 10. X-ray tube must have a rotating anode type with 3000 rpm or more.
- 11. Dual Focal Spot X-ray tube with 0.6mm for small focus and 1.5mm for large focus.
- 12. Tube Output should match the output of the Generator.
- 13. The anode heat storage capacity should be 200 KHU or more.

C. Collimator

- 14. The Tube unit should be fitted with a manual collimator with 2-axis blade control.
- 15. Should have the capability to select the additional copper filters of 0.1,0.2 and 0.3mm
- 16. Should have bright light preferably LED with minimum luminance of 160 lux or more
- 17. The collimator must be capable of rotating from -90 degrees to 180 degrees
- 18. Measuring tape to be provided

D. Flat Panel Detector:

- 19. The Wireless flat panel detector with Csl scintillator and amorphous Silicon of size at least 14" x 17"
- 20. The Scintillator must be on the exposure side facing the X-ray tube
- 21. The detector pixel matrix should be 2.5K x 3K or more
- 22. Pixel size should be 150 µm or Less
- 23. DQE of the detector must be 65% or more at 0 lp/mm
- 24. The image processing time after exposure should not be more than 7 sec.
- 25. The weight of the detector should not be more than 4kg.
- 26. The detector battery should be removable Li-Ion rechargeable type and least One additional Battery to be provided and provision of charging the battery within the unit.

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- 27. The detector should be able to do a minimum of 200 X-rays on full charge.
- 28. The detector should be dust and waterproof with an IP54 rating

E. Integrated workstation and Control Panel:

29. The machine should have an integrated console with a touchscreen of size of min 21 inches or more

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- 30. The processor should be i3 or better with min 16GB RAM and the latest Solid State Hard Disk of 500GB capacity.
- 31. The monitor should have a minimum 1.3 Mega Pixel resolution with full HD
- 32. The following Features should be available on the Control Panel
 - a. Machine ON / OFF switch
 - b. Digital Display of KV, mA, mAs and Sec
 - c. kV, mA, and mAs increase and decrease switches
 - d. Anatomical Programming should be provided in which kV and mAs are automatically selected depending upon the part of the body to be X-rayed
 - e. Should be capable of storing user-defined APR setting
- 33. A detachable exposure switch with a cord of at least 5 m in length should be provided in addition to the exposure switch in the console. A remote-controlled exposure switch with a range of 5 m or more should also be provided
- 34. The console should be able to view the image and provide post-processing features using the touch screen.
- 35. The post-processing features should have zoom contrast and brightness adjustment, window, Level, etc.
- 36. The workstation should have image storage memory of at least 6000 images or more
- 37. The unit should have a facility for pediatric exposure management
- 38. The workstation software should support the following
 - a. Patient List with the capability of DICOM worklist Query / Search on a variety of patient demographics
 - b. Connectivity to DICOM printers with multi-format options for printing and to external storage devices and the DICOM network
 - c. The machine should be fully network-ready and it should be possible to transfer images and patient data from and to the hospital network using LAN connectivity or Wireless LAN.

F. Mobile Cart Unit:

- 39. The entire system including the X-ray Generator, Tube, workstation console, Battery unit, and Column must be integrated as one single unit mounted on wheels on a mobile cart.
- 40. The Unit must have a collapsible column with a telescopic cross-arm
- 41. The Unit should be powered by a single Lithium Ion/ Polymer Battery for both movement and Exposure
- 42. The battery should provide power for the motor to move the machine with a driving speed of 5km/hr and capable of being moved along a slope of 5 degrees or more.
- 43. The machine should be able to do a minimum of 200 X-rays or more per full battery charge and also capable of moving a minimum of 15 km.
- 44. The Mobile unit must have a detector storage compartment with padded lining with a locking facility
- 45. The unit must have collision sensors and an effective braking system for parking, transport, and emergency braking
- 46. The tube unit must be mounted on a telescopic cross arm with a collapsible fully counterbalanced Column unit with the following specs for maximum positioning flexibility in any patient position
 - a. The column rotation is +/- 300 degrees.
 - b. Tube Reach from the center of the column should be min 80 and max 135 cm
 - c. Tube rotation along the arm axis must be +/- 180 degrees
 - d. Tube rotation along the tube axis must be +90 to -30 degrees
- 47. All cables should be concealed in the arm system.
- 48. The total weight of the Machine should not be more than 400 Kgs
- 49. The Cart battery should be charged from a normal 15A, 220-240V single phase socket in less than 5 hours
- 50. Operating system Windows 10 Pro operating system. Should be the latest version of Windows that the system can support. Any updates/upgrades/patches to the OS and the application should be provided free of cost for the entire period of warranty and CAMC.
- 51. It is the vendor's responsibility to connect the system to the closest network switch in the hospital network and to configure the system with HIS/RIS/PACS.
- 52. Facility to transfer DICOM images in bulk to external hard disk is to be provided

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- 53. The workstation should have a DVD writer for burning images
- 54. Lead Aprons:- 0.5 mm Lead equivalence-2 nos
- 55. Optional item: 3 tray Dry laser Printer to be supplied (at least 500 dpi)

G. Power Line Connection:

The unit should be able to operate on single phase power supply with a plug-in facility to any standard wall outlet with a line voltage of 150 to 240V, 15AMP plug

Regulatory and Other Requirements

- 1. The whole unit should meet European CE / US FDA / CDESCO / BIS-approved
- 2. The unit guoted must have valid AERB type approval and NOC not accepted.
- 3. All Technical information in the tender document must be supported by original product data sheets.
- 4. Compliance sheets must strictly mention the reference pages of the datasheet
- 5. The company is to give an undertaking that the detector will be replaced with the same detector that was quoted during the initial offer for the entire warranty period and the CMC period. No change in detector company is acceptable in case of replacement during the warranty /CMC period.
- 6. Detector batteries, UPS and its batteries and all accessories supplied with the unit should be covered under warranty and CAMC

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TECHNICAL SPECIFICATION OF MOBILE DR (LOW END)

High-frequency Mobile Digital Radiography machine with a touch screen tablet & a portable WI-FI flat panel detector of size 35 cm X 43 cm (14" X 17")

- It should be a lightweight machine that allows the user easy maneuverability in congested areas of wards, ICU, or • hospital/clinic. It should have an ergonomic articulated spring balanced tube stand allowing the operator to position the tube to acquire the images of desired views in patients positioned on standard ICU cots.
- Integrated Touch screen control panel for instant review of image, the size of the LCD/LED touch control panel ٠ should be more than 18".
- X-ray exposure parameter to be controlled from a touch screen control panel/workstation. The exposure parameters • should be selected from the software and the details of radiographic parameters like KV and mAS should be tagged in the final image output.
- Single foot lock for wheel locking while movement.

GENERATOR & TUBE

X-Ray Generator Type	High-frequency microprocessor-controlled
Power Output	4 KW or more
Generator Frequency	110 Khz
KV Range	40 to 120 KV in 1 KV/step.
Maximum mA	110 mA.
mAs Range	1-320 mAs

Dual action hand switch & IR remote for ready & Exposure should be provided in addition to the console exposure switch. An emergency switch should be provided.

X-Ray Tube Head:-

Mono-block version x-ray tube head should be provided. The mono-block should consist of an X-ray tube, H.V. transformer, filament transformer, H.V. rectifiers, and capacitors, all immersed in high-grade oil with high dielectric strength. Mono-block Tube Head should be Protected from thermal overload.

Anode type	Stationary Anode
Focal Spot	1.8 mm
Heat Storage Capacity	42 KHU

FLAT PANEL DETECTOR (Wi fi)

Conversion screen/ Scintillator Photodiode Size Active Image Matrix	Cesium Iodide (CsI) amorphous silicon (a-si) 43cm x 35cm 3000x2400 or better	NGU -		
Pixel pitch	Less than $150\mu m$			
DQE	DQE @ 0lp/mm -70.%,	\rightarrow 1	Atim Kuman	
Grey Scale resolution, bits/pixel	14 bit	Dmt	ATW MINING	Alpe
Weight of the detector Image storage in FPD	Less than 3.2 kgs up to 100 Images 16	jineesh valakada	L'anfam	Africanda March
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Image Acquisition Software:

Integrated Image Software should provide complete control of all image capture functions & Exposure parameters control within the examination room. It should enhance the entire workflow by delivering diagnostic images instantly. It should allow the user to transfer X-Ray images electronically to remote workstations, image archives, and printers, also should have features such as:-

Software Features

1. Main features

- Patient Entry (Manual Emergency and MWL)
- Patient Search Based On PID, NAME, DAYS
- Exam window
- Process window
- View Window
- Print Window
- 2. Post-processing features:-
- WW/WL
- Rotate
- Zoom
- Flip
- Invert
- Annotations
- Measurements
- 3. DICOM Compatible features:-
- DICOM MWL
- DICOM print
- DICOM Send
- Operating system Windows 10 Pro operating system. Should be the latest version of Windows that the system can support. Any updates/upgrades/patches to the OS and the application should be provided free of cost for the entire period of warranty and CAMC.
- It is the vendor's responsibility to connect the system to the closest network switch in the hospital network and to configure the system with HIS/RIS/PACS.
- Facility to transfer DICOM images in bulk to external hard disk is to be provided
- The workstation should have a DVD writer for burning images

The mobile stand offered should be a Spring balanced stand design which should fulfill stringent requirements of mobility, light in weight & easy maneuverability, and ease of operation. Mobile stand should be made to withstand all jerks while in use. Stand should be easily moved on the floor and a lock should be provided to lock the movement on the floor with the following details

- Vertical Travel of >1200mm
- Tube Head rotation of +/-90° along horizontal axis & +90° to -30° along tube axis
- The weight of the machine should be 150kgs or less
- Height should be 150 cm or less
- Accessories

Tube Stand

- Lead Aprons:- 0.5 mm Lead equivalence-2 nos.
 - Inbuilt lead hiped Detector storage box with padded lining ,with Lock and key facility for Detector safety.

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Power Supply:-

- Optional item- 3 tray Dry laser Printer to be supplied (at least 500 dpi)
- 1-Phase 230V (AC-supply) 50/60 Hz, $\pm 10\%$ with automatic compensation
- 15 Ampere wall socket.
- The system should have an inbuilt battery for x-ray exposure in case of • power failure. It should do a minimum of 50 X-rays per charge.

OTHER REQUIREMENTS:-

- The company should be ISO / EN-ISO / CDESCO/European CE / FDA certified. •
- The unit should be approved by AERB.
- The system should be a fully integrated solution, retrofit type solution is not accepted. •
- The company is to give an undertaking that the detector will be replaced with the same detector that was • quoted during the initial offer for the entire warranty period and the CMC period. No change in detector company is acceptable in case of replacement during the warranty /CMC period.
- Detector batteries, UPS and its batteries and all accessories supplied with the unit should be covered under • warranty and CAMC

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TECHNICAL SPECIFICATIONS FOR AI ENABLED DIGITAL FLAT PANEL DUAL DETECTOR 1000 MA X-RAY UNIT (HIGH END)

A high powered High-frequency Inverter technology, X-ray unit for general radiography with 2 nos wireless digital flat panels one in the vertical Bucky and the other in the table Bucky, having the capability to perform all the radiographic examination on both erect and supine positions with facility for Auto stitching on both the vertical and Table bucky and Auto Positioning facility. All software and stitching functionality should be from the OEM.

The unit should comprise of the following with the minimum specs as listed below:

- I. Dual Flat Panel wireless detectors one for vertical and one for table exposures
- II. High Frequency 80KW, 1000mA Generator
- III. X-ray tube with Automatic Collimator
- IV. Ceiling suspended unit with auto tracking and auto-positioning
- V. Diagnostic X-ray table with auto-tracking
- VI. Vertical Bucky Stand with auto-tracking
- VII. Stitching Hardware for the vertical stitching.
- VIII. Removable Grids for Vertical Bucky and Table Bucky
- IX. Integrated X-Ray and DR console
- X. Regulatory requirements

Wireless Flat Panel Detector (One on the wall stand and the other on the table): Ι.

The detectors should be able to perform all routine radiographic examinations. It should have the following features. The flat panel detector should be a proven technology with an amorphous silicon photodiode and CsI scintillator.

- a) Wireless Flat Panel Detector with Tethering option with size of at least 43 cms x 43 cm for wall stand and table bucky
- b) The detector should have a non-tiled CsI scintillator on the tube side and an amorphous silicon photodiode array behind it.
- c) Image matrix size at least 3k x 3k
- d) The minimum pixel size should be 150 microns or less.
- e) Grey scale of 14 bits.
- f) A/D conversion must be 14 bits minimum
- g) Preview time after exposure 3 sec or less.
- h) DQE at 0.0 lp/mm should be at least 70%
- i) Spatial Resolution of 3.5 lp/mm or better
- j) MTF of 80% @0.5 lp/mm
- k) The detector should be dust and water-resistant with IP54 rating
- Should have an inbuilt shock logging mechanism and data to be logged in the main console SW
- m) The detector should be capable of swapping between vertical Bucky and Table Bucky
- n) Modality workstation software with a direct registration facility for the CPU to be attached to the main console for the availability of multiple patient entries.

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II. High-Frequency Generator

Microprocessor-controlled high-frequency X-ray Generator should be of the latest technology with constant output with low ripple frequency

- a. Generator capacity must be 80 KW or more
- b. KVP range 40 KV-150 KV
- c. mA Output Should be 800mA @100 KV ; 1000 mA @80Kv or more
- d. The generator frequency should be 450kHz or more
- e. Exposure time should be 1 ms or 10 Sec.
- f. The Generator capacity must be capable of giving 500mAs or more.
- g. Automatic exposure control should be available with 3 AEC field sensors on the table and wall stand each.
- h. Anatomical Protocol (APR) must be available and the user must be able to add any protocol that is needed
- i. The generator must be completely integrated with the console workstation and it should be possible to control all exposure parameters from the software console.
- j. Hand switch with retractable cord for initiating the exposure for performing radiography procedures.

III. X-Ray Tube & Collimator

The X-ray tube should be a high-speed rotating anode with dual focus, compatible with the generator capacity.

- a. The Focal spot should be as below with the tube loading of
 - i. Large Focal Spot 1.2mm x 1.2mm or less with loading of 96 Kw or more
 - ii. Small Focal spot 0.6mm x 0.6mm or less with loading of 36 Kw or more
- b. Anode heat storage capacity of 600 KHU or more.
- c. Tube protection against overload should be available.
- d. A high-speed rotor accelerator (starter) minimum 8000 rpm
- e. The collimator must be automatic with a manual override facility
- f. It should be controllable by exam preset and control from the software
- g. Collimator must be capable of rotation of +/- 45 deg or more
- h. Must have laser centering and fitted with High luminance lamp
- i. Blade control must be a 4-way motorized type with individual blade control
- j. Should have motorized auto filter programmed with APR
- k. Patient Dose Measurement should be possible using a DAP meter

IV. Ceiling Suspended 3D Column Stand with Display

- a. Ceiling suspended tube with motorized adjustment should be provided with Horizontal and vertical auto-tracking of the tube and detector.
- b. All movements should have electromagnetic brakes with fully counterbalanced mechanisms and should have sensors for collision protection
- c. The tube should be capable of Auto Positioning based on the protocol setting
- d. Movement in all directions should be easily possible.
- e. Vertical telescopic movement should be at least 1500 mm.

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- f. The tube rotation must be $\pm 120^{\circ}$ or more.
- g. The Tube Arm Rotation should be -150° to $+180^{\circ}$ or more.
- h. The Unit should have an LED /LCD display unit of a minimum of 9" size mounted on the tube side to display Positioning details such as SID, tube angle, etc. Additional information if displayed will be an added advantage.
- i. Preview of the image to be displayed on the Tube Head Unit
- j. Position of the detector angle to be displayed for correction of tube angle when the detector is out of the bucky
- k. Should also be able to select the exposure parameters from the Tube head Unit
- I. Motorized trans lateral movement using a remote control should be possible

V. X-Ray Table

- a. 6 Way Fixed Table that has a motorized vertical Height adjustable and four-way floating table top fitted with a Flat detector of size at least 43x43cms with specification as mentioned in point 1., and has provision to rotate from landscape to portrait function without removing the detector.
- b. Footswitch to be provided for all the movements.
- c. The Table-top material should be made of low attenuation and durable to take the required patient weight.
- d. The table should support a patient weight of at least 250 Kg.
- e. It should be possible to synchronize detector movement with the movement of the X-ray tube. (Auto tracking)
- f. Please specify the dimensions of the Table-top length and width
- g. The table top movement should be (minimum) longitudinal movement: ± 40 cm, cross movement: ± 12 cm.
- h. Longitudinal patient coverage should be 200cm or more without patient repositioning
- i. It should have automatic grid sensing capability to avoid exposure with the wrong grid for patient safety.
- j. A removable grid of min 10:1 ratio with a focal distance of 100 cm /110cms to be provided.
- k. Auto stitching facility must be possible on the table bucky

VI. Vertical Bucky stand (wall Stand)

- a. Motorized, counterbalanced, height adjustable vertical Bucky with a digital flat panel detector of size minimum 43 cms x 43 cms to be provided
- b. It should be possible to synchronize detector movement with the movement of the X-Ray Tube. (Auto tracking)
- c. Removable grid with grid of min 10:1 ratio and focus distance of 180cm to be provided
- d. It should have automatic grid sensing capability to avoid exposure with the wrong grid for patient safety.
- e. It should be possible to tilt the detector on the wall stand within a range of -20 to +90 degrees.
- f. The detector holder must be possible to rotate by 45 degrees
- g. The vertical travel range of the detector should be 1500 mm, a minimum of 300 mm, and a maximum of 1800 mm above the floor (measured center to center).
- h. The Vertical Auto stitching must be available with the necessary stitching stand and accessories

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7. Operating Station and Console

The operating console/workstation must be an integrated system to manage the patient information such as adding, editing, and deleting the patient information, Capturing and acquiring images, setting of the X-ray exposure parameters, managing and post-processing of the image using the software tools, and archiving of the images. The system also should be fully DICOM 3.0 compliant or above having the below specifications

- a. Latest PC-based workstation of reputed brands like DELL or HP with latest intel based processor.
- b. It should have SSD 256GB + HDD 1TB or more.
- c. RAM of 16 GB or more to be provided
- d. HDD encryption and cyber security protection are to be provided
- e. 19-inch latest High-Quality LED monitor must be provided along with the console.
- f. The console software must be able to manage the patient information and be capable of connecting to the RIS / HIS and PACS network.

X-ray parameters such as KVP, mA, mAs, X-ray procedure and protocol, AEC, Grid type, focal spot, etc. g.

selection should be possible from the single console.

- The console should display the wireless signal strength and the battery charge condition. h.
- Should be able to show the image on the screen in less than 3 seconds after exposure for the preview i.

of the image

- j. The console software must provide a full range of post-processing features like Geometric Corrections, Window / Level, Algorithms, Annotations such as markers, predefined texts, drawing lines and geometrical shapes, measuring distances and angles, Cobb's Angle, Shuttering, histograms, Zoom, Grey Scale Reversal.
- k. There should be a provision to display the virtual drawing of the receptor boundary and AEC chambers on the patient using a real-time camera should be possible.
- I. Collimator shutters should be adjusted from the console software using a real-time camera function
- m. There should be a provision to get the patient motion alarm in the console SW
- n. Automatic Source tilting method Image Stitching Software up to 3 or 4 images must be provided for performing full leg full spine / long body imaging in both vertical bucky and table bucky
- o. Scoliosis measurement and leg length difference measurement tools must be provided.
- p. The console should also have the functionality/tool to correct radiographic magnification on the image
- q. Al-based Scatter Reduction tool to be provided for removal of scatter Radiation in the image without the need for a physical grid
- The Console system must be capable of advanced AI features such as Bone suppression imaging, r. identifying Lung nodules automatically in single exposure only and not multiple exposures. Also, the Post-processing to be part of the console software
- s. The console should have an automatic program to indicate over /under exposure visually in the preview screen
- t. The console system should have the functionality to automatically detect and correct the detector line artifact and can be accessed by the user.
- u. The system should be fully DICOM 3.0 Ready
- v. It should get the DICOM worklist from HIS/RIS, store images through the PACS network system, and support DICOM image print and DICOM MPPS functions.
- 8. Independent image viewing, Post Processing dicom workstation 1 Nos.

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- a. A post-processing workstation with a high-resolution medical-grade color monitor should be provided with the system
- b. Graphics card: NVIDIA GeForce GTX 1050 Ti or better or better with 4GB DDR4 memory
- c. Display 19" or more FHD medical-grade monitor
- d. Processor intel i7 10th generation or better
- e. RAM 16GB expandable up to 32GB
- f. Storage Dual drives with 256GB Solid State Drive +1TB Hard Drive
- g. Operating system Windows 10 Pro operating system. Should be the latest version of Windows that the system can support. Any updates/upgrades/patches to the OS and the application should be provided free of cost for the entire period of warranty and CAMC.
- h. It is the vendor's responsibility to connect the system to the closest network switch in the hospital network and to configure the system with HIS/RIS/PACS.
- i. It is the responsibility of the vendor to install a fire alarm system and connect it to the nearest available fire alarm panel if such a system is available in the hospital. Else, the vendor has to install a standalone fire alarm and fighting system.
- j. Facility to transfer DICOM images in bulk to external hard disk is to be provided
- k. The workstation should have a DVD writer for burning images
- I. The workstation software should support the following:
 - i. Patient List with the capability to query /search based on various criteria such as name, ID number, date of examination, etc.
 - ii. Features such as DICOM Viewing, windowing, zoom Pan magnify Annotate, mark < measure, Reporting
 - iii. Connectivity to DICOM printers with multi-format options to be provided
 - iv. The workstation should be Dicom ready and have provision to connect to external storage devices and DICOM servers

Accessories

- a. Voltage Stabilized of Suitable capacity for the entire system must be provided
- b. 3 KVA UPS for the console workstation with 30-minute backup to be provided
- c. Compression Belt and Patient Hand Grips are to be provided
- d. 3 tray Dry laser Printer to be supplied (at least 500 dpi)
- e. Adequate thickness lead glass should be provided between the console room and the examination room

a. Regulatory Approval and other requirements:

The Digital Radiography System offered should have the following:

- I. The complete system should have US FDA/CDESCO/BIS/European CE approval
- II. Valid AERB Type approval of the system quoted for installing the unit in India. NOC is not acceptable.
- b. Room for installation to be inspected by the prospective bidders.
- c. Two out of three components (tube, generator and detector) should be from the OEM
- d. During the CMC period, the QA for the unit must be done by the supplier as per AERB requirements.

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- e. The company is to give an undertaking that the detector will be replaced with the same detector that was quoted during the initial offer for the entire warranty period and the CMC period. No change in the detector company is acceptable in case of replacement during the warranty /CMC period.
- f. Detector batteries, UPS and its batteries and all accessories supplied with the unit should be covered under warranty and CAMC

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TECHNICAL SPECIFICATIONS FOR DIGITAL FLAT PANEL DUAL DETECTOR 630 MA X-RAY UNIT (LOW END)

A High powered with High frequency Inverter technology, X-Ray Unit for general radiography with 2 nos wireless digital flat panels one in the vertical Bucky and the other in the table Bucky, having the capability to perform all the radiographic examination on both erect and supine position. The unit should comprise of the following with the minimum specs as listed below:

- I. Dual Flat Panel wireless detectors one for vertical stand and one for table Bucky
- II. High Frequency 50KW, 630mA Generator
- III. X-Ray Tube with automatic Collimator
- IV. Floor mounted unit
- V. Diagnostic X-Ray Table
- VI. Vertical Bucky Stand
- VII. Removable Grids for Vertical Bucky and Table Bucky
- VIII. Integrated X-Ray and DR console
- IX. Regulatory requirements

I. Wireless Flat Panel Detector (One on the wall stand and the other on the table):

The detectors should be able to do all routine Radiographic examinations. It should have the following features. The flat panel detector should be of proven technology with amorphous silicon photodiode and CsI scintillator.

- a) Wireless Flat Panel Detector with size of at least 43cm x 43cm for wall stand and table bucky
- b) The detector should have a non-tiled CsI scintillator on the tube side and amorphous silicon photodiode array behind it.
- c) Image matrix size at least 3k x 3k
- d) Minimum pixel size should be 150 microns or less.
- e) Grey scale of 14 bit.
- f) A/D conversion must be 16 bits minimum
- g) Preview time after exposure 5 sec or less.
- h) DQE at 0.0 lp/mm should be at least 70%
- i) Spatial Resolution of 3.5 lp/mm
- j) MTF of 80% @0.5 lp/mm and above
- k) Detector should be dust and water resistance with IP54 rating
- I) Should have inbuilt shock logging mechanism and data to be logged in the main console
- m) Detector should be capable of swapping between vertical Bucky and Table Bucky
- n) Modality workstation software with direct registration facility to be attached to the main console for availability of multiple patient entries.

II. High Frequency Generator

Microprocessor controlled high frequency X-Ray Generator should be of latest technology with constant output with low ripple frequency

- a. Generator capacity must be 50 KW or more
- b. KVP range 40 KV-150 KV
- c. Generator should be of high frequency
- d. Exposure time should be 1 ms or 10 Sec.
- e. Hand switch with retractable cord for initiating the exposure for performing radiography procedures.

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- f. Automatic exposure control should be available with 3 AEC field sensors each on table and wall stand.
- g. Anatomical Protocol (APR) must be available and user must be able to add any protocol which is needed
- h. The generator must be completely integrated with the console workstation and it should be possible to control all exposure parameters from the software console.

III. X-Ray Tube & Collimator

The X-Ray Tube should be High speed rotating anode with dual focus, compatible with the generator capacity.

- a. The Focal spot should be as below
 - i. Large Focal Spot 1.2mm
 - ii. Small Focal spot 0.6mm
- b. Anode heat storage capacity of 300 KHU or more.
- c. Tube protection against overload should be available.
- d. Collimator must be automatic with manual override facility
- e. Should be controllable by exam preset and control from the software
- f. Collimator must be capable of rotation of +/- 45 deg or more
- g. Must have laser centering and fitted with High luminance lamp
- h. Blade control must be 4 way motorized type mapped with APR
- i. Should have motorized auto filter programmed with APR
- j. Patient Dose Measurement should be possible using DAP meter

IV. Floor mounted Column stand

- a. Movement in all directions should be easily possible.
- b. Vertical telescopic movement should be at least 1500 mm.
- c. The tube rotation must be $\pm 120^{\circ}$ or more.
- d. The Tube Arm Rotation should be -150° to $+180^{\circ}$ or more

V. X-Ray Table

- a. 6 Way Fixed Table which has motorized vertical Height adjustable and with four way floating table top fitted with Flat panel detector of size at least 43x43cms with specification as mentioned in point 1
- b. Footswitch to be provided for all the movements.
- c. The Table top material should be made of low attenuation and durable to take the required patient weight.
- d. Table should support patient weight of at least 200 Kg.
- e. Please specify the dimensions of Table top length and width
- f. The table top movement in longitudinal direction (minimum) ± 40 cm, cross movement: ± 12 cm.
- g. Longitudinal patient coverage should be 200cm or more without patient repositioning
- h. Removable grid of min 10:1 ratio with focal distance of 100 cm /110cms to be provided.

VI. Vertical Bucky stand (wall Stand)

- a. Motorized, counter balanced, height adjustable vertical Bucky with a digital flat panel detector of size minimum 43 cms x 43 cms to be provided
- b. Removable grid with grid of min 10:1 ratio and focus distance of 180cm to be provided
- c. The vertical travel range of the detector should be 1500 mm, minimum 300 mm and maximum 1800 mm above floor (measured at the detector center).





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7. Operating Station/ Console (2 sets)

The operating console / workstation must be an integrated system to manage the patient information such as adding, editing and deleting the patient information, Capturing and acquiring images, setting of the X-ray exposure parameters, managing and post processing of the image using the software tools and archiving of the images. The system also should be fully DICOM 3.0 compliant or above having the below specifications

- a. Latest PC Based workstation of reputed brands like DELL or HP with latest intel based processor.
- b. It should have the SSD storage of 256GB + HDD storage of 1TB or more.
- c. RAM of 16 GB or more to be provided
- d. HDD encryption and cyber security protection to be provided
- e. 19 inches latest High Quality LED monitor must be provided along with the console.
- f. The console software must be able to manage the patient information and capable of connecting to the RIS / HIS and PACS network.
- The console should display the detector's wireless signal strength and the battery charge condition. g.
- h. Should be able to show the image on the screen in less than 3 sec after exposure for the preview of

the image

- The console software must provide full range of post processing features like Geometric Corrections, i. Window / Level, Algorithms, Annotations such as markers, predefined texts, drawing lines and geometrical shapes, measuring distances and angles, cobb's Angle, Shuttering, Zoom, Grey Scale Reversal.
- System should be fully DICOM 3.0 Ready j.
- <u>k.</u> It should get DICOM worklist from HIS/RIS, store images through the PACS network system and should support DICOM image print and DICOM MPPS functions.
- I. Operating system should be Windows 10 Pro. Should be the latest version of Windows that the system can support. Any updates/upgrades/patches to the OS and the application should be provided free of cost for the entire period of warranty and CAMC.
- m. It is the vendors responsibility to connect the system to the closest network switch in the hospital network and to configure the system with HIS/RIS/PACS.
- n. It is the responsibility of the vendor to install a fire alarm system and connect it to the nearest available fire alarm panel, if such a system is available in the hospital. Else, the vendor has to install a standalone fire alarm and fighting system.
- o. Facility to transfer DICOM images in bulk to external hard disk is to be provided
- p. The workstation should have a DVD writer for burning images
- q. 3 KVA UPS for the console workstation with 30-minute backup to be provided
- r. 3 tray Dry laser Printer to be supplied (at least 500 dpi)
- s. Adequate thickness lead glass should be provided between the console room and the examination room

Regulatory Approval and other requirements: a.

The Digital Radiography System offered should have the following:

- a. The complete system should have US FDA/ European CE/CDESCO/BIS approved
- b. Room for installation to be inspected by the prospective bidders.
- c. During the CMC period, the QA for the unit must be done by the supplier as per AERB requirements.
- d. The company to give undertaking that the detector will be replaced with the same detector that was quoted during the initial offer for the entire warranty period and the CMC period. No change in detector company is acceptable in case of replacement during warranty /CAMC period.

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e. Detector batteries, UPS and its batteries and all accessories supplied with the unit should be covered under warranty and CAMC

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SPECIFICATIONS FOR HIGH END DIGITAL MOBILE DIGITAL RADIOGRAPHY UNIT (HIGH END)

A High-powered motorized battery-powered mobile Digital X-ray unit with a collapsible column and Telescopic Cross Arm suitable for bedside X-rays in Wards, ICUs, and operation theaters with a digital flat panel for image acquisition and should operate on a single-phase power supply. All software functionality should be from the OEM.

The quoted unit should have the following minimum specifications and items as mentioned below

- The unit should comprise of the following:
- I. A High-Frequency Generator built into the mobile unit
- II. X-Ray Tube
- III. Collimator with Display Tube unit
- IV. Flat Panel Detectors- 1no
- V. Build in Workstation
- VI. Integrated Mobile Cart

A. High Frequency Generator

- 1. It should be a microprocessor-controlled high-frequency X-ray generator
- 2. The power output of the generator should be 40KW or more to give at least 400mA@100kvP or more.
- 3. The radiographic KV range should be 40 KV to 150 KV or more with an increment of 1KV per step
- 4. mA Range: 10- 500 mA or more.
- 5. mAs Range: 0.1 to 500mAs
- 6. Exposure time 1 ms to 10 Sec.
- 7. It should have a digital display of kVp, mA, and mAs
- 8. Individual settings of kVp, mA, mAs, and sec must be possible.
- 9. Wired as well as Wireless Exposure Switch to be provided in addition to the exposure switch in the console

B. X-Ray Tube:

- 10. X-ray tube must be with a rotating anode type with 3000 rpm or more.
- 11. Dual Focal Spot X-ray tube with 0.6mm for small focus and 1.2mm for large focus.
- 12. Tube Output should match the output of the Generator.
- 13. The anode heat storage capacity should be 300 KHU or more.

C. Collimator and display unit

- 14. The Tube unit should be fitted with Automatic collimator with individual Blade control and manual override
- 15. Should have the capability to select the additional filters automatically based on the APR
- 16. Copper filters of 0.1, 0.2, and 0.3 mm are to be provided
- 17. Should have bright light preferably LED with minimum luminance of 160 lux or more
- 18. The collimator must be capable of rotating from -90 degrees to 180 degrees
- 19. Measuring tape to be provided
- 20. At the tube side, there should be a 7" or more color touch panel which gives the details of tube angulation, X-ray selected parameters, distance, and all other vital information such as patient details.
- 21. Should also be able to select the Exposure parameters from the tube head unit
- 22. Preview of the image to be displayed in the Tube head unit
- 23. The position of the detector angle to be displayed for correction of the tube angle

D. Flat Panel Detector:

- 24. The Wireless flat panel detector with Csl scintillator and amorphous Silicon of size at least 14" x 17"
- 25. The Scintillator must be on the exposure side facing the X-ray tube
- 26. The detector pixel matrix should be 2.5K x 3K or more
- 27. Pixel size should be 150 μm or Less
- 28. DQE of the detector must be 70% or more at 0 lp/mm

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- 29. The image processing time after exposure should not be more than 5 sec.
- 30. The weight of the detector should not be more than 3kg.
- 31. The Detector battery must be capable of getting charged in the storage compartment.
- 32. The detector battery should be removable Li-Ion rechargeable type and least One additional Battery to be provided and provision of charging the battery within the unit.
- 33. The detector should be able to do a minimum of 500 X-rays on a full charge.
- 34. The detector should be dust and water-resistant with an IP54 rating
- 35. The detector should have a minimum distributed weight-bearing capacity of 350kg and should have a minimum bend capacity of 100 kg.
- 36. Should have an inbuilt shock logging mechanism and data to be logged in the main console SW

E. Integrated workstation and Control Panel:

- 37. The machine should have an integrated console with a touchscreen of size of min 21 inches or more
- 38. The latest processor with min 16GB RAM and the latest Solid State Hard Disk of 1TB capacity.
- 39. The monitor should have a minimum 1.3 Mega Pixel resolution with full HD
- 40. The following Features should be available on the Control Panel
 - a. Machine ON / OFF switch
 - b. Digital Display of KV, mA, mAs and Sec
 - c. kV, mA, and mAs increase and decrease switches
 - d. Anatomical Programming should be provided in which kV and mAs are automatically selected depending upon the part of the body to be X-rayed
 - e. Should be capable of storing user-defined APR setting
- 41. A detachable exposure switch with a cord of at least 5 m in length should be provided in addition to the exposure switch on the console. A remote-controlled exposure switch with a range of 5 m or more should also be provided
- 42. The console should be able to view the image and provide post-processing features using the touch screen.
- 43. The post-processing features should have zoom contrast and brightness adjustment, window, Level, etc.
- 44. Workstation should have image storage memory of at least 10000 images.
- 45. The unit should have a facility for pediatric exposure management
- 46. Al-based Scatter Radiation tool to be provided for removal of scatter Radiation in the image without the need for a physical grid and should be a part of main console software and can be mapped with APR
- 47. Dose measurement to be provided and also to be sent as a DICOM image to the PACS.
- 48. The Console system must be capable of advanced AI features such as Bone suppression imaging, identifying Lung nodules, Pneumothorax, and Pleural effusion automatically in single exposure only and not in multiple exposures. Also, the Post-processing should be part of the console software and can generate the findings automatically post-acquisition.
- 49. HDD encryption and cyber security protection are to be provided
- 50. Interactive Tube head unit with the function of minor adjustments to the motorized movement of the machine from the tube side must be possible
- 51. A laser-centering device for the accurate positioning of SID is to be provided and should be APR-based.
- 52. The workstation software should support the following
 - a. Patient List with the capability of DICOM worklist Query / Search on a variety of patient demographics
 - b. Connectivity to DICOM printers with multi-format options for printing and to external storage devices and the DICOM network
 - c. The machine should be fully network-ready and it should be possible to transfer images and patient data from and to the hospital network using LAN connectivity or Wireless LAN.
 - d. There should be a provision to access the RIS/PACS browser within the console SW

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- 53. Operating system Windows 10 Pro operating system. Should be the latest version of Windows that the system can support. Any updates/upgrades/patches to the OS and the application should be provided free of cost for the entire period of warranty and CAMC.
- 54. It is the vendor's responsibility to connect the system to the closest network switch in the hospital network and to configure the system with HIS/RIS/PACS.
- 55. Facility to transfer DICOM images in bulk to external hard disk is to be provided
- 56. The workstation should have a DVD writer for burning images

F. Mobile Cart Unit:

- 57. The entire system including the X-ray Generator, Tube, workstation console, Battery unit, and Column must be integrated as one single unit mounted on wheels on a mobile cart.
- 58. The Unit must have a collapsible column with a telescopic cross-arm
- 59. The Unit should be powered by a single Lithium Ion/ Polymer Battery for both movement and Exposure
- 60. The battery should provide power for the motor to move the machine with a driving speed of 5km/hr and capable of being moved along a slope of 5 degrees or more.
- 61. The machine should be able to do a minimum of 300 X-rays or more per full battery charge and also capable of moving a minimum of 30 km.
- 62. The Mobile unit must have a detector storage compartment with a charging facility and detector locking facility, unlocking of the Detector lock should be password protected, and a physical key is not accepted
- 63. The unit must have collision sensors and an effective braking system for parking, transport, and emergency braking
- 64. The tube unit must be mounted on a telescopic cross arm with a collapsible fully counterbalanced Column unit with the following specs for maximum positioning flexibility in any patient position
 - The column rotation is +/- 300 degrees. a.
 - b. Tube Reach from the center of the column should be min 80 and max 135 cm
 - Tube rotation along the arm axis must be +/- 180 degrees c.
 - d. Tube rotation along the tube axis must be +90 to -30degree
- 65. All cables should be concealed in the arm system.
- 66. The detector should be capable of charging automatically in the cabinet during movement.
- 67. The total weight of the Machine should not be more than 360 Kgs
- 68. The Cart battery should be charged from a normal 15A, 220-240V single phase socket in less than 5 hours
- 69. Lead Aprons:- 0.5 mm Lead equivalence-2 nos
- 70. Optional item 3 tray Dry laser Printer to be supplied (at least 500 dpi)

G. Power Line Connection:

The unit should be able to operate on single phase power supply with a plug-in facility to any standard wall outlet with a line voltage of 150 to 240V, 15AMP plug

Regulatory and Other Requirements

- 1. The whole unit should meet European CE / US FDA /CDESCO /BIS-approved
- 2. The unit quoted must have valid AERB type approval and NOC not accepted.
- 3. All Technical information in the tender document must be supported by original product data sheets.
- Compliance sheets must strictly mention the reference pages of the datasheet 4.

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- 5. The company is to give an undertaking that the detector will be replaced with the same detector that was quoted during the initial offer for the entire warranty period and the CMC period. No change in detector company is acceptable in case of replacement during the warranty /CMC period.
- 6. Detector batteries, UPS and its batteries and all accessories supplied with the unit should be covered under warranty and CAMC

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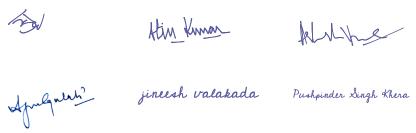


r	Specification for Mobile Flat Panel Detector C-Arm Unit (High end)				
	Mobile C-Arm with Flat Panel system with true counterbalanced C arm for fluoroscopic and X-ray operation				
Α.					
	Fully counterbalanced C-arm with side-to-side (wig-wag) and horizontal travel movements, and the following				
	features:				
1	Motorized Angulations movement: at least 140 degrees or more.				
2	Motorized longitudinal movement: at least 200 mm or more				
3	Motorized Orbital Rotational Movement: at least 140 degrees or more				
4	Motorized Vertical movement: at least 485 mm or more				
5	Swivel range: ±10 degrees				
6	Depth of immersion: 73 cm or more				
7	source to image distance: 990 mm or more				
8	Free space within the C-arm: at least 77 cm				
9	Field of view: square field of view for better ROI coverage.				
10	Touch-based panel for control of C-Arm functions mounted on the C-arm stand itself.				
11	The collision prevention sensors help support patient safety by stopping the C-Arm Movement when an				
_	object is sensed/detected within the periphery of the detector.				
В	Generator & X-Ray Tube				
1	The generator should be a microprocessor-controlled converter & type with an output of at least 15 KW.				
2	Modes: continuous, digital pulse fluoroscopy and digital radiography.				
3	Fluoroscopic KVp range: 40-120kV, minimum 60 mA.				
4	Radiographic kVp range: 40-120kVp, minimum 125 mA or more.				
5	The X-ray tube should have a rotating anode.				
6	Anode heat storage capacity should be 300 KHU or higher.				
7	Anode cooling capacity should be 75 KHU /minute or higher.				
8	Tube housing heat storage capacity should be a minimum of 2000 KHU.				
9	The generator should provide digital pulse fluoroscopy with pulse rates of at least 15 frames/second.				
10	Additional safety size filtration for the safety of scattered radiation				
11	The focal spot size should be 0.3mm & 0.6mm dual focal spots.				
12	Automatic dose rate control.				
13	Integrated laser high localizer, radiation-free collimation				
14	Multifunction foot switch to control all operating modes and single image storage out of the sterile field.				
15	Inbuilt heat management capabilities for long interventional procedures.				
16	Integrated dose monitoring chamber.				
17	Metal Artifact reduction/metal correction should be available.				
18	Additional safety size filtration should be 4 mm or more AI Equivalent				
19	The system should have the Software facility to allow free positioning of the anatomy, even at the edge of the image detector. It automatically detects anatomy and adjusts parameters to produce high-quality image				
с					
1	Flat Panel Detector System Flat detector of CSI (Cesium Iodide) with amorphous Silicon doping.				
2	Size of detector: at least 30 X 30 cm or more				
3	The pixel size should be 155 microns or less.				
3 4	The resolution of the detector must be 1.5 K x 1.5 K.				
4 5	Image inversion: right to left top to down				
5	Provide a last image hold capability that the last image is displayed on the active monitor after the				
6	termination of evenesure				
Ŭ	termination of exposure. 33				

7	Cable-free rear side and 180-degree rotatable monitors.			
	Equipped with two high-resolution 19" HD LED/LCD/TFT monitors with Diagnostic Image quality with an			
8	image matrix of 1024 x 1024 or more in the exam room.			
9	Vertically and horizontally adjustable monitor for specific needs.			
10	Viewing angle of at least 150 degrees with the ergonomic mounting of the monitors on the mobile view			
10	station.			
	The system shall allow the user to change the image orientation on the display screen during a live exposure			
11	or using the last image hold. Those functions include image rotation, left-to-right, and top-bottom image			
	reversals.			
D	Digital System & Image Management			
1	Multipatient database for handling large quantities of images, including dose management reports.			
2	Automatically select proper Imaging parameters, kVp, and mA during an image, but also allow the user to			
2	override these settings manually.			
3	Real-time and automatic brightness and contrast should be provided to optimize the displayed image.			
	Provide a real-time post-processing edge enhancement capability to get better image quality according to			
4	the density of the tissue. An electronic zoom function, an automatic save function to hard disk, Mosaic			
	Display.			
5	The system should save more than 1 lac image to the internal hard disk and retrieve stored images later.			
6	It should have a facility to record online fluoroscopy.			
7	Should have facility for image and Fluoro sequences retrieval on a CD/DVD/Pen drive and print Images on			
	paper/ firm.			
	The system should have a facility for DICOM connectivity and DICOM ready (HIS compatible DICOM modality			
8	worklist, DICOM send/ receive, DICOM print, DICOM query retrieve). All DICOM functions should be offered			
	and installed when needed at no additional cost.			
9	Facility for wireless data transfer.			
10	The System should be equipped with a touch control panel on the patient table side with a Preview image.			
11	Position memory & position tracking.			
12	The system must have a Sensor inside the Detector and non-touch Collision protection. It must have an			
	automatic position Control Feature for C-arm positioning. Operating system Windows 10 Pro operating system. Should be the latest version of Windows that the			
13	system can support. Any updates/upgrades/patches to the OS and the application should be provided free of			
15	cost for the entire period of warranty and CAMC			
	It is the vendor's responsibility to connect the system to the closest network switch in the hospital network			
14	and to configure the system with HIS/RIS/PACS			
	Optional Items:			
15	• 3 tray Dry laser Printer to be supplied (at least 500 dpi)			
	 Software and hardware capability of performing digital subtraction angiography 			
Ε	Essential Accessories.			
1	Suitable U.P.S online to run the entire system for at least 15 minutes of Backup time.			
2	APRON ultra-lightweight: - 4 No.			
3	Thyroid Shield - 04 nos., lead goggles 2			
4	Sterile covers for C-Arm, X-ray tube, and flat panel detector (disposable):100 for each			
6	Lead Apron Stand: - 01 nos.			
7	Patient Table: Compatible, Free-floating, transparent to X-rays with motorized table movement			
	(Cranio-caudal, left-right, up-down). Control Switch for table movement on the table itself.			
н	Terms & Conditions:			
1	The company should be ISO 13485 / ICMED / FDA / European CE certified.			
2	During the CMC period, the QA for the unit must be done by the supplier as per AERB requirements.			
3	The unit should be approved by AERB.			
4	The company should have a proven track record in the Govt. sector.			
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5		Out of the three components (generator, detector & x-ray tube), two should be from the same principal
	manufacturer of the X-ray system	
		The company is to give an undertaking that the detector will be replaced with the same detector that was
6	quoted during the initial offer for the entire warranty period and the CMC period. No change in detector	
	company is acceptable in case of replacement during the warranty /CMC period	

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Spe	Specification for Low end Mobile Flat Panel Detector C-Arm Unit (Low end)				
	Mobile C-Arm with Flat Panel system with true counterbalanced C arm for fluoroscopic and X-ray operation.				
Α.	Gantry / C-Arm				
	Fully counterbalanced C-arm with side-to-side (wig-wag) and horizontal travel movements, and the following				
	features:				
1	Orbital rotation movement: +/- 200 deg or more				
2	Angulation: at least:155° or more				
3	Horizontal movement: more than 195 mm				
4	Vertical movement: at least 49 cm motorized movement				
5	Swivel range: ±10 degrees				
6	Depth of immersion: 73 cm or more				
7	Free space within the C-arm: at least 76 cm				
8	Remote control (touch-based) for control of C-Arm functions.				
9	Touch-based panel for control of C-Arm functions mounted on C-arm stand itself				
10	The operator should be able to have control on his side				
11	The system should have the capability of an electromagnetic locking system				
12	The system should come with uniform reference for the operator and the physician to be used during the				
_	positioning of the C arm				
B 1	Generator & X-Ray Tube The generator should be a microprocessor-controlled converter & type with an output of at least 4 KW or more.				
2	Modes: continuous, digital pulse fluoroscopy and digital radiography.				
2	Fluoroscopy: 40-110 Kv; Minimum 7.2 MA @ 110 KV				
4	Digital exposures with a minimum tube current of 19 Ma @ 110 kv				
5	X-ray tube should be monoblock with active oil circulation				
	The system should operate at full capacity on 220 volts AC, 15amp.				
6					
7	The generator should provide digital pulse fluoroscopy with pulse rates of at least 15 frames/second.				
8	The system should offer a filtration of 5.5 mm which should include copper filtration for pediatric cases				
9	The focal spot size should be 0.6 mm & 1.2 mm dual focal spots.				
10	Automatic dose rate control				
11	Integrated laser high localizer, radiation-free collimation				
12	Multifunction foot switch to control all operating modes and single image storage out of the sterile field.				
13	Inbuilt heat management capabilities for long interventional procedures.				
15	Metal Artifact reduction/metal correction should be available in fluoroscopy and not as post-processing				
С	Flat Panel Detector System				
1	Flat detector of Csl (Cesium Iodide) with amorphous Silicon doping.				
2	Size of detector: min 20 X 20 cm.				
3	The pixel size should be 200 microns or less with 1-bit A/D conversion.				
4	The resolution of the detector must be 1K x 1K.				
5	Image inversion: right to left top to down				
6	Provide a last image hold capability that the last image is displayed on the active monitor after the termination of exposure.				
7	Equipped with two high-resolution 19" HD LED/TFT medical grade monitors with an image matrix of 1024 x 1024 or more.				
8	Vertically and horizontally adjustable monitor for specific needs.				
10	Viewing angle of at least 178 degrees with the ergonomic mounting of the monitors on the mobile view station.				
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11	The system should be equipped with a touchscreen control panel. On the patient table side with preview images.
12	The system shall allow the user to change the image orientation on the display screen during a live exposure or
12	using the last image hold. Those functions include image rotation, left-to-right, and top-bottom image reversals.
D	Digital System & Image Management
1	Multi-patient database for handling large quantities of images, including dose management reports.
2	Automatically select proper Imaging parameters, kVp, and mA during an image, but also allow the user to override these settings manually.
3	Real-time and automatic brightness and contrast should be provided to optimize the displayed image.
4	The system should save at least 140000 images to the internal hard disk and retrieve stored images later
5	The system should be equipped with a touch-screen control panel on the patient table side with a facility to preview images
6	Two high-resolution 19" HD LED/LCD/TFT monitors with Diagnostic Image quality with an image matrix of 1024 x 1024 or more in the exam room.
7	Provide a real-time post-processing edge enhancement capability to get better image quality according to the density of the tissue. An electronic zoom function, an automatic save function to hard disk, Mosaic Display.
8	It should have a facility to record online fluoroscopy.
9	Should have facility for image and Fluoro sequences retrieval on a CD/DVD/Pen drive and print Images on paper/ firm.
10	The system should have a facility for DICOM connectivity and DICOM ready (HIS compatible, DICOM modality worklist, DICOM send/ receive, DICOM print, DICOM query retrieve). All DICOM functions should be offered and installed when needed at no additional cost.
11	Operating system Windows 10 Pro operating system. Should be the latest version of Windows that the system can support. Any updates/upgrades/patches to the OS and the application should be provided free of cost for the entire period of warranty and CAMC
12	It is the vendor's responsibility to connect the system to the closest network switch in the hospital network and to configure the system with HIS/RIS/PACS
13	Optional item: 3 tray Dry laser Printer to be supplied (at least 500 dpi)
Ε	Essential Accessories.
1	Zero Lead Aprons - 02 nos
2	Thyroid Shield - 02 nos.
3	Sterile covers for C-Arm, X-ray tube, and flat panel detector (disposable):100 for each
4	Lead goggles: 2 nos.
н	Terms & Conditions:
1	The company should be ISO 13485 / CDESCO / FDA / European CE certified.
2	During the CMC period, the QA for the unit must be done by the supplier as per AERB requirements.
3	The unit should be approved by AERB.
4	The company should have a proven track record in the Govt. sector.
5	The company is to give an undertaking that the detector will be replaced with the same detector that was quoted during the initial offer for the entire warranty period and the CMC period. No change in detector company is acceptable in case of replacement during the warranty /CMC period

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Government of India

Ministry of Health & Family Welfare

Room No. 201-D, Nirman Bhawan, New Delhi Dated the 02-08-2024

Office Order

Subject : Circulation of approved technical specifications of Digital Subtraction Angiography Unit (Biplane) – reg.

In continuation to Office Order of even no dated 11.7.2024, please find enclosed herewith the technical specifications of Digital Subtraction Angiography Unit (Biplane) - as submitted by the Committee set up by the MoHFW under the Chairpersonship of Dr. Raju Sharma, Professor & Head, Department of Radiodiagnosis & Interventional Radiology, AIIMS New Delhi.

2. The above specifications have the approval of Secretary HFW and shall be valid for two years. All AIIMS/ INIs/ Institutes/ Hospitals/ Procurement Support Agency (HITES) of the Ministry are advised to adhere to the approved specifications (enclosed) while undertaking procurement of these equipment.

Signed by Dinesh Kumar Date: 02-08-2024 15:29:30

(Dinesh Kumar) Joint Director, MoHFW, Gol Tel:011-23061730

Encl(2):

- i. Technical specifications of Digital Subtraction Angiography Unit (Biplane)
- ii. Office Order No. Z-28016/35/2024-PMSSY-IV dated 11.7.2024

То

- i. All Additional Secretaries/ Joint Secretaries, MoHFW with a request to circulate the above specifications to all the Institutes/ Hospitals/ Autonomous Bodies under their administrative control, for compliance.
- ii. Director General of Health Services, MoHFW, Gol

Copy to :

- i. Director, AIIMS New Delhi
- ii. Director, PGIMER, Chandigarh,
- iii. Director, JIPMER, Puducherry
- iv. Director, NIMHNAS, Bengaluru
- v. The Directors/ Executive Directors of new AIIMS under PMSSY
- vi. The Directors of Central Government Hospitals in Delhi/ North East Hospitals
- vii. CEO, HITES (via email at ceo@hllhites.com)

Copy for information to :

- i. PSO to Secretary(HFW)
- ii. PPS to Joint Secretary (PMSSY)



pmssysection iv <pmssysectioniv@gmail.com>

Circulation of approved technical specifications of Digital Subtraction Angiography Unit (Biplane) – reg.

1 message

pmssysection iv <pmssysectioniv@gmail.com>

Mon, Aug 5, 2024 at 11:05 AM

To: Asfa-mhfw@nic.in, j mishra@gov.in, asfr-mohfw@gov.in, Roli Singh <roli.singh@ias.nic.in>, ash-mohfw@nic.in, Zhimomiv@ias.nic.in, Dgoffice@naco.gov.in, lschangsan@nic.in, asmd-mohfw@nic.in, jstraining-mohfw@gov.in, Pushpendra.r@nic.in, Vandana.jain@nic.in, Robert.elangbam@gov.in, Sinha.vijay@nic.in, Ea-mohfw@nic.in, kk.tripathy@nic.in, r.wadhawan15@nic.in, jsrch-mohfw@gov.in, cca-mohfw@nic.in, anoopk.puri@nic.in, Ddgtb@rntcp.org, pradeep.khasnobis@gov.in, js-pmssy-mohfw@gov.in, js-publichealth@gov.in, Ankita.edu@nic.in, dghs@nic.in Cc: Director AIIMS Bhopal <director@aiimsbhopal.edu.in>, director bhubaneswar <director@aiimsbhubaneswar.edu.in>, Director AIIMS Jodhpur <director@aiimsjodhpur.edu.in>, Director Patna <director@aiimspatna.org>, Director AIIMS Raipur <director@aiimsraipur.edu.in>, Director AIIMS Rishikesh <director@aiimsrishikesh.edu.in>, Director Mangalagiri <director@aiimsmangalagiri.edu.in>, Director AIIMS Nagpur <directoraiimsnagpur@gmail.com>, edaiimsrbl@gmail.com, rajwanshiarvind@hotmail.com, ED AIIMS Kalyani <ed@aiimskalyani.edu.in>, Executive Director Gorakhpur <executivedirector@aiimsgorakhpur.edu.in>, "Prof. Dr. D.K. Singh, Director" <director@aiimsbathinda.in>, Director AIIMS Deoghar <director@aiimsdeoghar.edu.in>, Bibinagar <director@aiimsbibinagar.edu.in>, Executive Director AIIMS BILASPUR <director@aiimsbilaspur.edu.in>, shakti810505@gmail.com, cdskatoch@gmail.com, Executive Director AIIMS Rajkot <ed.aiimsrajkot@gmail.com>, HanumanthaRao Mangu <drmhraosvims1957@gmail.com>, Director AIIMS Guwahati <director@aiimsquwahati.ac.in>, madhabananda@gmail.com, sachimohanty@rediffmail.in, Dr Vivek Lal <dpgi@pgimer.edu.in>, director@jipmer.ac.in, director@aiims.gov.in, Director Neigrihms <director-neigrihms@gov.in>, nalinaiims.mehta@gmail.com, director.neigrihms.shillong@gmail.com, eigasunil@gmail.com, Guruaribam Sunil Kumar <director@rims.edu.in>, director@ripans.ac.in, MS OFFICE SJH <msoffice@vmmc-sjh.nic.in>, "Dr. Sunita Sharma" <director-</p> Ihmc@gov.in>, NIMHANS <dirstaff@nimhans.ac.in>, minakshi Bhardwaj <med.sup@rmlh.nic.in>, ceo@hllhites.com, secyhfw@nic.in, Praveen.batra@gov.in, "Cc:" <dinesh.kumar14@nic.in>, ":" <ak.biswas57@nic.in>, jalan.raj@gov.in, sankar.garg@gov.in, Amit Batra <amit.batra@gov.in>

Sir/ Madam

Please find the attachment.

Note: In case this email requires you to reply, you are requested to reply to all the officials of PMSSY-IV Section at - dinesh.kumar14@nic.in; ak.biswas57@nic.in; sankar.garg@gov.in; amit.batra@gov.in

Regards PMSSY-IV Section Ministry of Health and Family Welfare

3 attachments

office oder 02.08.2024.pdf 49K

Office Order 11.07.2024.pdf 3102K

Encl_ Technical specifications of Digital.pdf

SPECIFICATIONS FOR DIGITAL SUBTRACTION ANGIOGRAPHY UNIT (BIPLANE)

The manufacturer/bidder must quote the latest 'state of the art' BiPlane Digital subtraction angiography with flat panel detector technology for vascular diagnostic and interventional procedures as per the specifications below.

- The quoted model must be launched in or after the year 2019 onwards.
- The offered model should be BIS / European CE with 4 digit notified body number/ USFDA certified. USFDA approved (authentic and legible certificate for the same to be annexed].
- Also, the vendor will guarantee that the system supplied is not refurbished and the DSA system quoted is the latest best available model in the segment quoted, at the time of delivery and should submit an undertaking in this regard.

Technical Specifications

1. Certifications:

- 1. The system should be AERB type approved and the copy of E-LORA Listing should be submitted along with the bid. If the quoted model has not been yet installed in India, vendor should submit NOC from AERB. Regular QA according to AERB norms will be the responsibility of the bidder during warranty and CMC period.
- 2. 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 guoted model.
- 3. In case the vendor has not yet obtained import/manufacturing license from CDSCO for the quoted model, proof of application for CDSCO medical device license to be submitted in the bid document and valid CDSCO license to be produced at the time of supply/ NOC for the quoted model.

A. Gantry

- The system should have two gantries: one floor mounted and one ceiling suspended providing full body coverage. The lateral plane should have motorized longitudinal Carm movement.
- 2. It should be possible to pre-program the gantries for multiple examination positions.

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- 3. All movements of the gantries should be controlled from the controller on the table side as well as from the control desk.
- 4. The system should have adequate collision protection for the safety of the patient. Both gantry movements should be rapid, motorized & collision proof. Manual override by the operator should be possible.
- Both gantries should have fast speed for angulations and positioning. The frontal system should have a speed of at least 15 degree/sec. for all positions and lateral plane should have a speed of at least 8 degree/sec.
- Gantry angulations in both planes frontal and lateral should be freely user selectable to satisfy clinical imaging needs.
- Both the gantries should have an automatic positioning capability dependent on the reference image being selected.

B. Patient Table

- The table should have motorized Vertical & longitudinal and free floating with electromagnetic locking facility.
- It should have the motorized stepping facility for automatic bolus chase for peripheral angiography.
- It should be possible to swivel the table or should have multiple floating success in case of emergencies.
- 4. Table should have Trendelenburg tilt/cradle facility.
- 5. It should have patient load capacity of 200Kg or more
- 6. Table side touch control panel for 3D reconstruction and C-arm positioning with respect to 3D image & selection of 3D image positioning should be provided

C. X-Ray Generator:

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- 1. System should have Microprocessor-controlled high-frequency (100 kHz) X-ray generator with automatic dose rate control for fluoroscopy and acquisition.
- 2. Generator should be multi-pulse/high frequency for constant output.
- 3. Max generator power output should be 1000 mA at 100 KV equivalent to 100 kW.
- 4. Radiography KVP range should be 40 kV-125 kV in 0.1 kV steps
- It should have an automatic exposure control device for radiographic fluoroscopy and angio mode. Manual Override facility is preferable.
- 6. It should have a digital display of kVp & mAs.
- Tube current should be freely selectable in 0.01 mA steps for continuous fluoroscopy, pulsed fluoroscopy and angiomode
- 8. Anatomical programming radiography should be possible.

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- It should have over loading protection.
- 10. It should have the facility for pulsed fluoroscopy at variable rates for reducing the radiation dose to the patient during intervention procedure.

D. X-Ray Tubes

- 1. Both planes should be provided with rotating anode high speed tubes with Increased contrast during fluoroscopy, especially for examinations on obese patients
- The focal spot should have the following sizes:
 - 1.0 mm or less with load 80 KW or more in minimum one plane.
 - 0.6 mm or less with load 38 KW or more in minimum one plane.
- 3. Anode heat storage capacity should be 3 MHU or more (true value) having liquid bearing technology or metal lubricant
- 4. The system should have adequate cooling facility for the x-ray tubes for uninterrupted performance during procedure.
- 5. Fluoroscopy power (maximum continuous power)-tubes should provide at least 2.4kW continuous output for over 30 minutes.
- 6. Mention the Heat dissipation rate, higher heat dissipation rate is preferable
- 7. Leakage radiation should conform to international standards. Filtration & leakage radiation dose should be indicated in the offer.
- 8. The lateral plane tube should be mounted on the far side (left of the patient) of the ceiling suspended C-arm to reduce scatter radiation to the operator.
- 9. System should be quoted with the latest dose reduction technique for better image quality with less dose.
- E. Collimator
- 1. One collimator for each plane is to be provided.
- 2. The collimator should have facility for automatic /pre-program / suitable alternative technology copper pre-filtration for reducing the X-ray dose.
- 3. The collimator leaf should have IRIS/rectangular/ wedge shaped type arrangement with Independent rotation and shift of filter blades
- 4. The collimator should have the facility for the dose measurement chamber in order to display the skin dose on the monitors in the lab.
- 5. The collimator should have facility for automatic copper pre-filtration for reducing xray dose as per patient thickness. Additional filters with multiple leaf's should be provided & it should be possible to position these filters & collimator leaf's without live fluoroscopy & independent of each other (clearly mention in the offer).
- 6. Automated exposure control with at least 3-level motorized Cu-filters

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- 7. Independent rotation and shift of filter blades
- Automatic synchronous rotation of the detector and collimator unit to compensate for image rotation at different examination positions.

F. Biplane Digital System

- Dynamic flat detector system with high spatial and 14 bit contrast resolution with 1.5k matrix resolution with Integrated collision sensor, Removable grid and active detector cooling facility
- 2. Size of the detector
 - Size of frontal plane should be at least 43 cm diagonal
 - Size of lateral plane should be at least 39 cm diagonal
- Detector rotation in portrait to landscape mode and Vice versa, should be possible at detector level, examination console and control console at least in frontal plane
- 4. Standard AAPM phantoms for resolution measurement to be provided.
- 5. It should have multiple input format / field with minimum of 4 field zoom sizes,
- Spatial resolution should be at least 2.5 LP/mm in the frontal plane and 2.5 LP/mm in the lateral plane.
- 7. Mention the Pixel pitch and detective quantum efficiency (DQE)

G. Imaging Display System

1. Examination Room Monitor

- Medical grade large high definition display (minimum 55 inches) to display live, reference, 3D CT /MRI images of any patient, Hemodynamic and EP waveforms with layout selection from integrated tableside control in the exam room.
- II. Another Two medical grade (2kX2k) monitors (one for live, another for review) mounted on a movable trolley should be provided as a standard, for radiographer viewing while doing procedure.

2. Console Room

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- Control room shall have at least 4 (QTY) of wide screen (19" or more each), Medical grade monitors for display of live, playback, reference images of each plane.
- II. Gantry, collimator, table & injector operations should be possible from control room console without interrupting image review, hard copying, and archiving or image transfer functions.
- III. Separate/inbuilt Monitor for patient data registration.

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IV. Integrated Two-Way communication system with integrated mic & speaker to allow duplex communication between Console & Exam room.

H. Digital Imaging System

- Should be possible for Fast, direct access to all series, single images and reference images, store monitor images, in both the examination room and the control room
- Should be Possible for display of USG/CT/MR images as static reference image on the examination room monitor
- Post processing software facilities with Changing window values, real time edge enhancement, positive/negative image display, electronic shuttering, roaming, image reversal, zooming/panning, annotation, Distance, angle measurements image labelling, text functions, drawing lines, arrows and circles
- 4. It should have the capability to acquire images in 1024 x 1024 matrix with a maximum speed of 6 frames or more per second on-line subtraction. Specify the maximum image acquisition rate without subtraction.
- It should have a minimum image storage capacity of 50,000 or more images in the 1024 x 1024/12 bit.

6. Operating modes

A. Fluoroscopy mode should have following functions

- Biplane Dual Fluoroscopy mode to allow side-by-side display of digitally processed non-subtracted fluoroscopy and trace-subtract fluoroscopy for visualization and catheter guidance during complex procedures.
- Digital pulsed fluoroscopy with 7.5, 10, 15, 30 p/s
- Road mapping with automatic pixel shift
- Overlay fade (online superimposing of active fluoro and reference image)
- Store Monitor and Store Reference (even during online fluoroscopy)

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- Store Fluoro: Last 1024 image of last performed fluoro
- Last Image Hold (LIH)
- B. DSA mode should have following functions
- Digital subtraction angiography with digital real-time filtering with frame rates from 0.5 f/s to 7.5 f/s in 1K/14-bit matrix or better
- Remask/move mask/Replace mask, peak opacification for iodine contrast (MaxOpac) and CO2 contrast (MinOpac), display of anatomical background (Landmark) from 0 to 100 %
- Pixel shift: Manual pixel shift, automatic pixel shift, flexible pixel shift
- 7. A separate workstation for 3D reconstruction of the rotational angiography images should be provided. The 3D image measurement and slicing should be possible. Facility to display reconstructed images in the procedure room should be provided. The same workstation should have the capability to query, retrieve images from existing PACS system and also should have 3D post processing capability and the same should be displayed on one of examination room monitor for viewing during interventional procedures
- 8. It should be possible to fuse the 3D CT data with 3D Angio to combine high resolution vessel information with soft tissue information.
- 9. The complete digital system along with the workstation should be networked and connected to a DICOM compatible laser camera. Entire networking and necessary switches should be borne by the vendor.
- 10. The digital system should have software for vascular analysis and quantification including stenosis %. All measurements should be possible from the patient table side.
- 11. DVD reader and CD/DVD recorder should be provided with a workstation and main console Computer system.

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- The system should be able to Query, receive DICOM format CT/MRI/USG from PACS or other modality network nodes and display images on reference monitor,
- 13. DICOM print facility should be made available. Also compliant with HIS/RIS/PACS
- 14. It should have a facility to measure dose during the procedures.
- 15. The system should have latest radiation safety package like Clarity IQ/CARE & CLEAR MAX/Blueprint/ Autoright / equivalent
- 16. All software updates should be provided in warranty & CMC period.

I. Essential Applications And Softwares

- Dyna CT or equivalent for acquisition of 3D high contrast reconstruction based on digital rotational angiography (2D/3D) at a speed of 40 degree/sec and acquisition frame rate of atleast 50/sec. Automatic image data transfer to the advanced workstation while all parameters needed for the 3D reconstruction are already included in the exam set to generate cross sectional CT like images.
- Road mapping facility (Real time 2D & 3D) should be available with possibility of superimposing fluoro image on reference image. 3D road mapping facility directly from CT/MR 3D image without rotational angio 3D image to save contrast and radiation.
- Smart mask road mapping procedures by overlaying fluoroscopy with a selected reference image on the live monitor. The reference and fluoro images can be faded to taste on the monitors.
- Peristepping/Bolus chase software (Stepping of the table with a single contrastmedium injection performed while observing the contrast medium bolus should be provided like Peristepping or equivalent /Bolus chase software) should be provided.
- 5. Real time stent enhancement,

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 Needle guidance to plan needle-based procedure in a 3D volume by specifying a target and multiple trajectories

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7. Embolisation Guidance for planning and performing embolizations

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- Rotational angiography facility (2D & 3D) at a speed of at least 40 degree/sec. with acquisition frame rate of at least 25 frames/sec. in 1k matrix with facility for online display of subtracted images should be available. Rotational data acquisition with an output of cross sectional CT like images should be possible.
- 9. System should have CT/MR/PET fusion application.
- 10. Facility of CO2 angiography with supportive software should be provided

Optional Softwares:

- 3D CT/DSA perfusion imaging. contrast-enhanced blood volume distribution of the whole brain in 3D cross-sectional images based on a steady-state contrast injection
- 2. Dyna 4D or equivalent software to see flow patterns in 3D
- 3. TAVR Assist Software or equivalent
- J. Essential accessories:

The following essential accessories to be provided with the unit

- Broadband connection and LAN for the operation of SRS System is responsibility of the vendor and all the recurring cost of same should be borne by the vendor
- Complete hemodynamic Multiparameter patient monitor (Specifications Annexure 1)
- 3. State of the art Anaesthesia equipment (Qty 1 No) (Specifications Annexure 2)
- Suitable UPS of at least 120 kVA with complete back up for the entire system including generator, digital system all essential accessories to continue angio acquisition for 30 minutes.
- 5. Lead glass 100 x 150 cm for the console room.
- 6. Single Head Pressure injector of reputed make should be coupled with DSA system. 100 Nos. disposable syringes sets and 500 Nos. of tubings should be supplied along with the system. Unit price for syringes and tubings should be quoted separately and the same should be valid during warranty and CMC period.
- 7. Dry Chemistry Laser Imager with resolution of 500 DPI or more with two tray. Printer should be DICOM ready and online for printing films of all variable sizes
- Ceiling suspended radiation protection system 0F 0.5 Lead equivalence and table side protection system.
- 9. Focused ceiling mounted high luminous light with a handle for positioning the light. Ater Kugrar Herry De La Depresed valaeada Raju Sharma Hir.

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- Activated Clotting Time (ACT) machine and 30 no's cartridges / tubes. Unit price for cartridges and tubes should be quoted separately and the same should be valid during warranty and CMC period.
- 11. Ultra-light weight ,double sided Lead Gown with lead equivalent of 0.5 mm: 10 Nos
- 12. Thyroid Guards 10 Nos
- 13. Lead spectacles 10 Nos.
- Fully ergonomic foot switch for fluoro/acquisition control with both cordless and with cord should be provided.
- 15. Wooden/Metal household staircase
- 16. Lead protected viewing glass as per AERB norms (Size: 150cm X 100 cm)
- 17. Bi-Phasic Defibrillator (Latest and best in the market)
- 18. Lead Apron Hanger 4 No's
- 19. Lead Apron Stand 1 No
- 20. Accessories for the table should include: (Supply of 2 nos. each)
 - a. Head fixing aids
 - b. Chin support
 - c. Carbon fiber radiolucent arm support for brachial approach
 - d. Body straps
 - e. Shoulder harness
 - f. Easy to clean suitable soft mattress
 - g. Drip stands
 - h. Arm support
 - i. Sand bags for thickness compensation for the head adult & pediatric
- 21. Dehumidifier of 110 Litre 2 Nos.
- 22. Environmental friendly sterile plastic covers for ultrasound probe, flat panel Detectors and control touch panel in console room QTY: 1000 each. Unit price for each of these covers should be quoted separately for future purchase and the same should be valid during warranty and CMC period.
- Vendor should provide LED X-ray Film viewer with adjustable brightness; capable of holding 3 films of 14"x17" size. Qty 2 no.s (one in each Console room and Examination room)

Terms and Conditions to the Vendors

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- Original Product Datasheet of main unit and all accessories, including third party items to be provided.
- All agreements should be binding on the Principal. The principals should be responsible for any lacuna or deficit in service or supply.

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- All items in the supply order should be supplied during the time of installation. No exceptions will be allowed.
- Items under Research Agreement should be finalized well in advance after receipt of supply order), so that there is no delay in delivery of software or coil or any other accessories.
- Software upgrades/ updates (where hardware upgrades are not required) like new application packages. etc, should be provided within one month after release.
- In case, the same is not provided in time, the parent company should undertake the responsibility to implement the same.
- Vendor should provide on site Training for radiologists and Technicians for a period of 4 Weeks

WARRANTY AND COMPREHENSIVE MAINTENANCE CONTRACT

- · The warranty period of the system commences from the date of handing over (from the date of issue of Inspection Note) the fully functional unit of all essential parts and the accessories supplied (such as UPS including batteries replacement as when Required, AC etc.)including third party items such as patient monitor system, with probes, anesthesia machine, against Manufacturing defects of material and workmanship.
- UPS batteries and Anesthesia machine related accessories repairs (including replacement, if needed) should be included in the warranty and CMC period.
- The post-warranty (after 5 years) CMC should be comprehensive and should include (repair and / or replacement) + labour + spares for the complete system which includes all the accessories supplied such as UPS AC, etc. (including all consumables like batteries for UPS, and maintenance for another 5 years.
- If a particular part is not working for more than 5 days and due to which patient work suffers, the firm will be asked to pay penalty of half-a-day beyond 5 days for each day that it is not working.

Buy Back Option: As per need of Consignee Buy Back option may be exercised. It will be the responsibility of the seller/vendor to check on site the existing equipment and calculate offer price. Offer price will be used for calculation of L1

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Annexure 1

Specifications for Portable Multi-parameter Vital Sign Monitor

- 1. It should be a fully portable patient monitoring solution, designed to be small, easy to use and lightweight, to be fixed to the patient table without taking any extra space
- 2. The unit should come with Wireless vital signs 3/5 lead ECG module with trusted artifact free spO2 technology.
- 3. Clinical Features: Standard
 - SpO2 with perfusion Indicator: Wireless
 - ECG:3/5 Lead: Wireless
 - Non- Invasive Blood Pressure
 - Dynamic Trend Indicators
 - Tri-Colored alarm light
 - Full gas module with ETCO2 Sidestream
 - Invasive Blood Pressure
 - Accessories Laryngoscope (Pediatric and adult)
 - Vendor should provide the Pediatric & Adult SPO2 probes-10 Qty each
 - Vendor should provide the Pediatric & Adult BP Cuff-10 Qty each
 - IBP transducer : 20 Qty
 - ECG leads : 5 Qty

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- Vendor should also quote the price for SPO2 probe and BP Cuff, IBP transducers (Pediatric & Adult), ECG leads separately for the further purchase if required and the same should be valid during warranty and CMC period.
- Should be European CE marked/FDA marked
- All the probe and accessories both for Adult & Pediatrics age groups should be provided for 10 years.

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Annexure 2

ANESTHESIA WORKSTATION WITH ANESTHESIA MODULAR MONITOR : Qty

Anesthesia workstation is used for delivering anesthesia agent to the patient during Interventional procedure

- A. It should be integrated anesthesia workstation
- B. It should offer ICU quality ventilator, suitable for adult, children & neonates.
- C. Single user interface should control and display all parameter including control of modes, display of cylinder pressures etc.
- A. The machine should be suitable for low and minimal flow anesthesia application
- B. The machine should have automatic calculations and presetting of patient specific ventilation settings
- C. It should have configurable screen layouts for individual screen set ups.
- D. It should have Nitrous oxide free operation configurable
- A. The anesthesia machine and vaporizer should be manufactured by same company.
- The Anesthesia Machine capable of providing anesthesia to Adult, Paediatric and Neonatal patient should have the following:
 - a. Should have pipelines attachment for oxygen, nitrous oxide and compressed air.
 - b. Should have yoke assembly for oxygen and nitrous oxide with pin index system.
 - c. Durable main switch to put the machine in the on or off position.
 - d. There should be digital control and display for oxygen
 - e. There should be electronic gas mixing.
- 2. Should have safety features like :
 - a. Should be provided with" pneumatic/electronic" hypoxic guard.
 - b. Should provide 25% or more of oxygen when an anesthetic gaseous mixture is in used.
 - c. Should have extra flow meters for oxygen only.
 - d. Should have digital display of pressure value of Cylinders and Central pipeline
- 3. Should have oxygen flush with a flow rate of more than 35L/min.
- 4. Vaporizer New generation
 - a. Should be able to hold two vaporizers (Isoflurane, Sevoflurane & Desflurane) simultaneously.
 - b. Cost of vaporizers to be quoted separately.
 - c. Quantity of vaporizer to be purchased will be as per requirement.
 - d. Temperature / pressure compensated and flow independent vaporizer.
 - e. The vaporizer design should be maintenance free.
 - f. Should have illumination of vaporizer setting and filling level
 - g. Should preferably have electronic monitoring of vaporizer setting and filling level
- 5. CO2 absorber system with the following features :-

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a. Single/Double canister b. Autoclavable c. Canister capacity of 0.8 kg or more. d. It should be possible to bypass the canister if removed during clinical cases to change soda lime. 6. APL valve assembly and Bag mount should be conveniently placed. 7. Independent port for open circuit. 8. Should be provided with drawers for storage space Machine should have a good quality handle and castors to move the machine with locking system. 10. The ventilator of the machine should have the following features:a. Should be electronically controlled. b. Should be suitable for new born, pediatric and adult c. It should have colored screen with minimum 12" screen size. d. Volume and pressure control mode of ventilations. e. Electronic PEEP f. Various ventilator modes: SIMV, pressure support, VCV, PCV modes etc g. Tidal volume range from 20 ml to 1200 ml h. Respiratory rate from 4 to 80 or more i. I:E ratio 2:1 - 1:5 j. Display: Respiratory rate, peak airway pressure and PEEP k. There should be no collection of water in the breathing system 11. Should have independent paramagnetic oxygen sensor for FiO2 monitor and flow sensor for spirometry loops. 12. Should be able to display a. Pressure Vs time b. Volume/ Flow Vs time 13. The work station should be capable of delivery of low and minimal flow anesthesia even at 350 ml of total fresh gas to reduce patient consumption 14. It should have alternate O2 supply mode in case electronic gas mixture failure. 15. Should have a battery backup of at least 60 minutes 16. A demonstration of the product is essential by the firm of the model quoted 17. Monitor should have the following a. A modular configurable patient monitor for adult, pediatric and neonatal patient b. Should have at least 19" or more TFT color display with a minimum of 8 waveforms at a time. c. Should be touch screen 18. Should be able to measure the following parameters: a. 3 and 5 lead ECG with electrocautery & defibrillator filter with ST Segment & arrhythmia detection with analysis, b. Respiration, SpO2 (SpO2 technology to prevent motion artifact), temperature c.SpO2 with Masimo technology to prevent motion artifact d. NIBP, IBP, ETCO2 Hen Kugear Wild Vore Dif La Pour pareed volasada mander duge eine Raju Sharma Hiv.

- e. Multi-Gas analysis with auto detection of all anesthetic agents
- f. Integrated BIS/entropy Monitoring.
- 19. Should be able to automatically detect and calculate MAC of all anesthetic gases. There should be no electrical RF interference.
- 20. Should be able to calculate and display FiO2.
- 21. Intelligent cooling system to keeps the unit running quiet during use.
- 22. Separate indicator lights for technical and physiological alarms.
- 23. Maximum BEEP tone should be loud enough to be audible from at least a distance of 12 feet
- 24. Should have graded audio and visual alarms for the following parameters:
 - a. Blood pressure High and Low
 - b. SpO2 High and Low
 - c. Heart rate High and Low
 - d. Respiration High and Low
 - e. FiO2 High and Low
- 25. Trends Upto 48 Hours or more
- 26. Display of Anesthesia ventilator data like wave forms for flow, pressure, agent and loops, and trends on patient monitors.
- 27. It should be ready to run Web based application like PACS, HIS, RIS, LIS, Cath lab Report, X-Ray as standard on the patient monitor
- 28. All the components like anesthesia ventilator, vaporizer, and patient monitor should be preferably from same manufacturer.
- 29. The quoted model should be European CE or US FDA approved
- 30. The machine should be supplied with the following accessories:
 - a. ECG Cable 10 Nos
 - b. Reusable SpO2 Sensors: 5 each for Adult, Pediatric & Neonatal.
 - c. NIBP Cuff: 10 each for Adult, 5 each for Pediatric & 5 Neonate.
 - e. IBP Cable: 10 nos
 - f. BIS / Entropy Electrode 50 to be given against staggered demand
 - g. ETCO2 Sample Line: 50 nos with each machine
 - h. Water trap 50 nos. with each machine
 - i. Reusable autoclavable Breathing circuit: 25 nos each for Adult & 5 pediatric
 - j. Temperature Probe 1Paed, 4 Adult (skin)
 - k. Isoflurane, Sevoflurane & Desflurane Vaporizers. Cost of vaporizers to be quoted separately.
- 31. Disposable breathing circuit including water trap- 50 each for adult and pediatric. Reusable anesthesia mask 10 set for adult, 5 pediatric and 5 neonate.
- 32. System should have facility and required accessories for suction and active AGSS (Anesthesia gas Scavenging System)(From same OEM)
- 33. Please provide Accessories which would last for one year.
- 34. Demonstration is must.
- 35. System should have Web based Anesthesia Charting facility. Prices to be quoted separately along with Server and complete wiring.

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36. Scope of Supply :

- a. Trolley with drawer
- b. Writing surface
- c. Pin Index yokes for O2 & N2O
- d. Pipeline connections for all three gases
- e. Integrated Ventilator & monitor
- f. Semi closed breathing system
- g. Adult & pediatric autoclavable patient tubings- as asked above
- h. Anesthetic mask (silicon) size Adult & child- As asked above
- i. Vaporizers for Isoflourane, Sevoflourane, Desflurane- (f As asked above one machine ly)
- j. Central gas supply hoses (Color coded)
- k. Instruction for use
- 37. Should be European CE marked/FDA marked
- 38. Vendors should also quote the price for SPO2 probe and BP Cuff, IBP transducers (Pediatric & Adult), ECG leads separately for the further purchase if required and the same should be valid during warranty and CMC period.

All the probes and accessories both for Adult & Pediatrics age groups should be provided for

10 years.

A demonstration of the product is essential by the firm of the quoted model and must provide preferably a performance certificate of the model quoted.

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Z-28016/35/2024-PMSSY-IV (8285627) Government of India Ministry of Health & Family Welfare (PMSSY-IV) Boom No. 745-A Nirma

Room No. 745-A, Nirman Bhawan, New Delhi Dated: 11thJuly, 2024

Office Order

Subject : Circulation of technical specifications of Digital Subtraction Angiography Unit (Biplane) – reg.

With the approval of Competent Authority in the Ministry of Health & Family Welfare, the technical specifications of Digital Subtraction Angiography Unit (Biplane) - as submitted by the Committee set up by the Ministry under the Chairperson-ship of Dr. Raju Sharma, Professor & head Department of Radiodiagnosis & Interventional Radiology, AIIMS New Delhi – are hereby circulated for reference while procuring the above equipment.

107/2029

(Raj Kumar Jalan) Under Secretary to the Government of India Tel:011-23061343

Encl(1): Technical specifications of Digital Subtraction Angiography Unit (Biplane).

To,

1. All Additional Secretaries/ Joint Secretaries, MoHFW – with a request to circulate the above specifications to all the Institutes/ Hospitals/ Autonomous Bodies under their administrative control, for compliance.

Copy to :

- 1. Director, AIIMS New Delhi
- 2. Director, PGIMER, Chandigarh,
- 3. Director, JIPMER, Puducherry
- 4. Director, NIMHNAS, Bengaluru
- 5. The Directors/ Executive Directors of New AIIMS under PMSSY
- 6. The Directors of Central Government Hospitals in Delhi/ North East Hospitals
- 7. CEO, HITES (via email at ceo@hllhites.com)

Copy for information to :

- 1. PSO to Secretary(HFW)
- 2. PPS to Joint Secretary (PMSSY)
- 3. PPS to Joint Director, PMSSY