23.05.2023

TAMILNADU MEDICAL SERVICES CORPORATION LTD.,

SUPPLY AND INSTALLATION OF ANGIOGRAPHY BIPLANE PLANE SYSTEM WITH STEREOTACTIC FRAME (WITH FUNCTIONAL) & SKULL CLAMP FOR NEURO HYBRID OR FOR TERTIARY CARE HOSPITALS AT GOVT. RAJAJI HOSPITAL, MADURAI, GOVT. KILPAUK MEDICAL COLLEGE HOSPITAL, CHENNAI AND GOVT. COIMBATORE MEDICAL COLLEGE HOSPITAL, COIMBATORE IN TAMIL NADU

TENDER REF.: PKG61/C1.2/P2/ICB/TNUHP/ JICA/TNMSC/ENGG/2023, dated 09.03.2023

CORRIGENDUM

a) The following corrigendum is issued:-

Sl. No.	Tender document reference	Instead	Read as
2.	Page No.96 Section VI: Schedule of Requirements 3. Technical Specifications **Technical Specification for Angiography Biplane Plane System with Stereotactic Frame (With Functional) & Skull Clamp for Neuro Hybrid OR**	Existing technical specification	Revised technical specification at **Annexure – A**

b) The following clarification is issued:-

Sl. No.	Tender document reference	Point raised	Clarification Furnished
1	Page No.96 **Section VI: Schedule of Requirements** 3. Technical Specification for Angiography Biplane Plane System with Stereotactic Frame (With Functional) & Skull Clamp for Neuro Hybrid OR **1. Bi Plane Gantry system** 1.3 All movements of the gantries should be controlled from the joystick on the table- side and as well as console room	Request to amend as All movements of the gantries should be controlled from the joystick on the table- side.	No Change. Hence, published specification prevails.
2	Page No.96 **Section VI: Schedule of Requirements** 3. Technical Specification for	Request to amend as Gantry Collimator & table operations must be possible from control room.	No Change. Hence, published specification prevails.

Sl. No.	Tender document reference	Point raised	Clarification Furnished
	Angiography Biplane Plane System with Stereotactic Frame (With Functional) & Skull Clamp for Neuro Hybrid OR 2.6 Gantry Collimator & table operations must be possible from control room as well as exam room.		
3	Page No.96 **Section VI: Schedule of Requirements** 3. Technical Specification for Angiography Biplane Plane System with Stereotactic Frame (With Functional) & Skull Clamp for Neuro Hybrid OR 2.7 System should have foot switch for releasing fluoroscopy, acquisition and table breaks.	Request to amend as System should have foot switch for releasing fluoroscopy, acquisition	No Change. Hence, published specification prevails.
4	Page No.96 **Section VI: Schedule of Requirements** 3. Technical Specification for Angiography Biplane Plane System with Stereotactic Frame (With Functional) & Skull Clamp for Neuro Hybrid OR 3.4 Radiography KVP range should be between 40-125 KV.	Request to amend as Radiography KVP range should be between 50-125 KV.	No Change. Hence, published specification prevails.
5	Page No.97 **Section VI: Schedule of Requirements** 3. Technical Specification for Angiography Biplane Plane System with Stereotactic Frame (With Functional) & Skull Clamp for Neuro Hybrid OR **6. Digital Imaging System:-** Both planes should have flat panel detectors with diagonal size of at least 42 cm for the frontal plane and 42 cm for the lateral plane. Please mention pixel size. The smaller pixel size will be preferred.	Request to amend as Both planes should have flat panel detectors with diagonal size of at least 42 cm for the frontal plane and 42 cm for the lateral plane. Please mention pixel size. The smaller pixel size will be preferred.	No Change. Hence, published specification prevails.
6	Page No.101-106 **Section VI: Schedule of Requirements** 3. Technical Specification for	Request to amend as the Following equipments are required to Sub Package / tendered seperately 1. Skull Clamp with Brain Retractor System.	The Corrigendum will be updated once the confirmation

Sl. No.	Tender document reference	Point raised	Clarification Furnished
	Angiography Biplane Plane System with Stereotactic Frame (With Functional) & Skull Clamp for Neuro Hybrid OR **Neuro Accessories**	2. Stereotactic Frame System 3. Stereotactic Planning Software 4. RF Leision Generator Specification 5. MICRODRIVE For DBS PROCEDURE Since all these equipment's are standalone system and used for Neurosurgery procedures.	received from the Project.
7	**<u>Section VI: Schedule of Requirements</u>** **Page no. 93** **1. List of goods & delivery schedule** Shortest Delivery Period (calculated from the Contract Effective Date) – 90 days Longest Delivery Period (calculated from the Contract Effective Date) – 120 days	Request to amend as Delivery Timeline 150 to 180 days from: a) Issuance of Supply order, b) Opening of Letter of Credit for 90% of Imported Order c) Release of 10% advance payment, d) Site handover along with Permanent Power & statutory approvals whichever is later.	No Change. Hence, published terms prevail.
8	**<u>Section VI: Schedule of Requirements</u>** **Page no. 94** **2. List of Related Services and Completion Schedule** The date of Completion for Services (calculated from the Contract Effective Date) - 120 days from Contract Effective Date	Request to amend as Delivery Timeline 150 to 180 days from: a) Issuance of Supply order, b) Opening of Letter of Credit for 90% of Imported Order c) Release of 10% advance payment, d) Site handover along with Permanent Power & statutory approvals whichever is later.	No Change. Hence, published terms prevail.
9	**<u>Section VIII: Particular Conditions (PC)</u>** **Page no.134** **Point no. GC 18.1** Performance Security to the Purchaser shall be Required. Performance Security to the Purchaser shall be for an amount of 5% of the contract value, valid upto 28 days after the date of completion of performance obligations including warranty obligations. In the event of any correction of defects or replacement of defective material during the warranty period, the warranty for the corrected / replaced material shall be extended to a further period of	Request to amend as Chain Warranty Page no.140 Point no. GC 18.1 Performance Security to the Purchaser shall be Required. Performance Security to the Purchaser shall be for an amount of 5% of the contract value, valid upto 28 days after the date of completion of performance obligations including warranty obligations. Kindly delete this clause.	No Change. Hence, published terms prevail.

Sl. No.	Tender document reference	Point raised	Clarification Furnished
	12 months and the Performance Bank guarantee for proportionate value shall be extended 28 days over and above the extended warranty period.		
10	**Section I. Instructions to Bidders (ITB)** **16. Documents Establishing the** **Conformity of the Goods and Related Services** **Page no. 19 Cl 16.2** The documentary evidence may be in the form of literature, drawings or data, and shall consist of a detailed item by item description of the essential technical and performance characteristics of the Goods and Related Services, demonstrating substantial responsiveness of the Goods and Related Services to the technical specification, and if applicable, a statement of deviations and exceptions to the provisions of the Schedule of Requirements.	Request to amend as The documentary evidence may be in the form of literature, data, and shall consist of a detailed item by item description of the essential technical and performance characteristics of the Goods and Related Services, demonstrating substantial responsiveness of the Goods and Related Services to the technical specification, and if applicable, a statement of deviations and exceptions to the provisions of the Schedule of Requirements.	No Change. Hence, published terms prevail.
11	**Section VII. General Conditions (GC)** **Page no. 121 Cl 26.2 Subject to GC Sub-Clause 26.3**, if conducted on the premises of the Supplier or its Subcontractor, allreasonable facilities and assistance,including access to drawings and production data, shall be furnished by the Supplier at no charge to the Purchaser.	Request to amend as Subject to GC Sub-Clause 26.3, if conducted on the premises of the Supplier or its Subcontractor, all reasonable facilities and assistance, includingaccess to basic drawings and production data relevant to the inspection and not containingconfidential and proprietary information, shall be furnished by the Supplier at no charge to thePurchaser.	No Change. Hence, published terms prevail.
12	**<u>Section VIII: Particular Conditions (PC)</u>** **Page no.132** **Point no. GC 11.3** During the maintenance period the unit must be made functional within 4 working days (including response time) from the time a defect is reported to the contractor. In case, a replacement of defective	Request to amend as During the maintenance period the unit must be made functional within 5 working days (including response time) from the time a defect is reported to the contractor. During Comprehensive Maintenance Contract (CMC) period in case of non-compliance of the above beyond 15 days in a year, then liquidated damages (LD) is levied at 0.075% of the CAMC price per non-functional unit per day	No Change. Hence, published terms prevail.

Sl. No.	Tender document reference	Point raised	Clarification Furnished
	goods needs more than 7 working days, as an interim solution the bidder must make available a service Goods / part for complete functioning of the goods within the same specified time frame as mentioned above. However, the defective goods must be replaced within 15 days.	beyond 20 days in a year subject to a maximum of 10% of the CAMC contract value and equivalent amount shall be deducted from the CMC payment.	
13	**Section VIII. Particular Conditions (PC)** Page no. 135 GC 25.1 The Supplier is required under the Contract to transport the Goods duly insured to the specified final destination, and all related costs shall be included in the Contract Price. The clarifications to customs for appraisal, payment of customs duty and clearance are the responsibility of the supplier only and charges for such requirement are also to be included in the contract price	Request to amend as The Supplier is required under the Contract to transport the Goods duly insured to the specified final destination, and all related costs shall be included in the Contract Price. The Purchaser shall provide all necessary documents including CDEC certificate (if applicable) for timely clearance of shipment. The clarifications to customs for appraisal, payment of customs duty and clearance are to be coordinated by supplier only and charges for such requirement are to be claimed by supplier at actuals.	No Change. Hence, published terms prevail.
14	**Section IV. Bidding Forms** **Form MAN: Manufacturer's Authorization** Page. No. 67 We hereby extend our full guarantee and warranty in accordance with the Contract, with respect to the goods offered by the above firm.	Request to amend as We hereby authorise our Indian Affiliate to extend warranty and after sales services in accordance with the Contract, with respect to the goods offered by the above.	No Change. Hence, published terms prevail.
15	Page No. 106 **<u>Section VI: Schedule of Requirements</u>** 3. Technical Specification for Angiography Biplane Plane System with Stereotactic Frame (With Functional) & Skull Clamp for Neuro Hybrid OR 16. Specification of Turnkey Works: **point 1(c)** Flooring - Shall provide and lay Anti-static flooring of 2 mm thick,	Request to clarify as is it for Cathlab room only or for the entire suite of Biplane.	It is for the entire suite of BiPlane Cathlab.

Sl. No.	Tender document reference	Point raised	Clarification Furnished
	manufactured by reputed standard manufacturers as per BS 2050-1978. Colour as per Purchaser's requirement.		
16	Page No. 106 **Section VI: Schedule of Requirements** 3. Technical Specification for Angiography Biplane Plane System with Stereotactic Frame (With Functional) & Skull Clamp for Neuro Hybrid OR 16. Specification of Turnkey Works: **point 1(f)** Scrub area with an Automatic Surgical scrub sink (Double) and catheter wash area. (Lump sum)	Request to clarify as Inlet and Outlet for Supply and drain will be in the scope of PWD or the facility team	Scrub Area work to be quoted is excluding Inlet and Outlet for Supply and drain.
17	Page No. 106 **Section VI: Schedule of Requirements** 3. Technical Specification for Angiography Biplane Plane System with Stereotactic Frame (With Functional) & Skull Clamp for Neuro Hybrid OR 16. Specification of Turnkey Works: Point 2(a) The power required for the operation of equipment will be provided by the hospital near the site.	Request to clarify as The power required for the operation of equipment will be provided by the hospital near the site to be terminated in the UPS room.	Bidder may visit the site to confirm the Termination of power cabling. It will be provided near the site.
18	Page No. 61 **Price Schedule** Price Schedules as given in Tender	Request to clarify as Line item in the price schedule to capture the prices for the Local bought outs as required in the specifications.	Price breakup for the local accessories may be indicated in the price bid separately.

All other terms and conditions of the tender remain unaltered.

The above forms part of the bidding documents. The bidder shall attach the copy of this corrigendum duly signed by their authorized signatory, in their bid.

S/d
General Manager (E)

Annexure – A

3. Technical Specifications (Revised)

1. Technical Specification for Angiography Biplane Plane System with Stereotactic Frame (With Functional) & Skull Clamp for Neuro Hybrid OR

Technical Specification for Biplane Neuro angiography System with DSA
Latest state of the art, bi plane floor and ceiling mounted C-arm/G-arm Cardiovascular & Neuro-angiography system with flat detector technology digital imaging system for adult and pediatric diagnostic and interventional cardiovascular procedures, including valvuloplasty and vascular angiography and neurovascular applications and online DSA.
1 Bi Plane Gantry system
1.1 The system should have two arm gantries: one floor mounted and one ceiling suspended providing full body coverage. Both gantry movements should be rapid, motorized & collision proof Manual override by the operator should be possible.
1.2 It should be possible to pre-programme the gantry positions, angulations & rotations for at least 50 user defined examination positions.
1.3 All movements of the gantries should be controlled from the joystick on the table- side and as well as console room
1.4 Both gantries should have fast speed for angulations and positioning. The frontal system should have a speed of at least **10-18 degree/sec** for all positions and lateral plane should have a speed of at least **8-10 degree/sec**
1.5 Gantry angulations & rotations in both planes, frontal and lateral should be freely user selectable to satisfy clinical imaging needs
1.6 Both gantries should have an automatic positioning capability as projected from relevant reference image.
1.7 Head to toe coverage with Single plane without repositioning the patient **minimum 180cm.**
1.8 The gantry and detector placement for oblique angulations should be possible without any compromise, systems with uniform & better oblique angulations along the side of detector will be preferred
1.9 The lateral C-arm should have wide view angle and true projections in the extreme lateral arc positions.
2 Table
2.1 The table should be ergonomically designed, made of radiolucent carbon fibre, contoured for all Neuro Radiological examinations & Interventional procedures. Suitable soft mattress, easy to clean & to last long should be provided.
2.2 It should adequately support patients who are tall & heavy weight atleast 200 kg
2.3 The table should have motorized, longitudinal, vertical travel, **Trendelenburg facility** and floating table top for longitudinal and transverse movements with electromagnetic locking facility. It should have full range of applications without restriction on position during CPR.
2.4 Table side controls for 3D reconstruction and C Arm positioning with respect to 3D image & selection of 3D image with respect to C arm positioning should be provided.
2.5 It should have the facility for automatic bolus chase for peripheral angiography
2.6 Gantry Collimator & table operations must be possible from control room as well as exam room.
2.7 System should have foot switch for releasing fluoroscopy, acquisition and table breaks.
2.8 All patient positioning accessories to be supplied.
2.9 Companies to quote Integrated Neuro OR Table with all necessary Neuro attachments. The OR table should be fully compatible with Cathlab and should be operatable from the cath lab controls.
2.10 The table should have the head up/down Tilt and lateral tilt / Cradle for using

during the Neuro procedures.
2.11 It should be possible to Store and recall stand-related positions. It should be possible to recall the Frontal, Lateral, Table, Mag, Shutter, Wedges, SID.
3 X-Ray Generator
3.1 100 KW or more compatible with high resolution imaging.
3.2 The generator should be high frequency **from 2500W** for constant output for radiography fluoroscopy.
3.3 Atleast 100KW at 100 KV or more
3.4 Radiography KVP range should be between 40-125 KV.
3.5 Generator should have automatic exposure control device for radiography, fluoroscopy and angiography mode.
3.6 Generator should have tube overload protection.
3.7 It should have digital display for KVP & mas.
3.8 Pulsed fluoroscopy at variable rates for reducing the X-ray dose to the patient during interventional procedures should be possible without image drag during pulsing intervals.
4 X-Ray Tube
4.1 X-Ray tube should be with fine focal spot (**micro,** small & large) with high cooling rate to ensure continuous operation, capable of pulsed fluoroscopy on both focal spots.The large focus power output should be **80 KW** or more. The Pulsed Fluoroscopy should be offered with pulse rate of 7.5 Frames/sec to 30 frames/sec.
4.2 The X-Ray tube should have Anode heat storage capacity **from** 3.0 MHU or more to run continuously for 6-8 hours without shutting off.
4.3 The system should have cooling rate from 500KHU/min for the X-ray tubes for uninterrupted performance.
4.4 Companies to offer the latest dose saving features like Clarity IQ, OPTIQ, Autoright
5 Radiation protection:
5.1 The system should have integrated computer controlled **automatic** X-Ray Beam filtering with copper filters of various sizes from 0.2 mm to 0.9 mm in fluoro and acquisition mode. Please list the special filters available.
5.2 The system should have positioning of collimator blades without radiation.
5.3 The system should have monitoring and display of X-ray dose during the patient examination. It should be possible to create a DICOM based dose report of the patient.
5.4 One collimator for each plane with motorized transverse, transverse, rectangular/ hexagonal leaves to be provided. The collimator leaf should have IRIS type arrangement.
5.5 Ceiling suspended radiation protection system and tableside protection system for the operator
5.6 Lead glass uppershield shield mounted on a movable stand one on each side of the angiography table to protect the angiographer from the radiation source to be provided preferably form the branded well known radiation protection device supplying company be quoted.
6 Digital imaging System:
6.1 Both planes should have flat panel detectors with diagonal size of at least 45 cm for the frontal plane and **45 cm** for the lateral plane. Please mention pixel size. The smaller pixel size will be preferred.
6.2 Digital system with acquisition and processing in 1024x1024 matrix upto 25/30 fps with 10/12 bit. Digitization with latest image processing software & hardware
6.3 Cine loop replay facility & last image hold facility during fluoroscopy.
6.4 Image storage capacity of at least 100,000 images in 1024x1024 matrix at 10/12 bits on the main system disk.
6.5 System should have facility for ECG / auto-triggered fluoroscopy, display and archive.
6.6 System should have on-line & off-line validated coronary analysis and ventricle analysis programme. The software should have Auto calibration facility for stenosis measurement with geometrical and densitometry calculation. The analysis should be possible from table side in the

examination room and from the control room.
6.7 The full system should have table side control operation with complete acquisition and post processing capabilities.
6.8 The system should have on-line DSA capabilities in 1024x1024 matrix with acquisition frame rate of 1 frame rate of 1 frame/sec to 6 frames/sec or more 2D road mapping capabilities.
6.9 The system should have facility of rotational angiography with online rotational DSA facility. The facility should allow **3D reconstruction of brain**.
6.10 The system should have facility for storage of fluoro loop scene of at least 10 seconds.
6.11 The system should have patient collision protection facility with software & hardware **where the C-arm should not touch the patient at all.**
6.12 The system should be quoted with 3D modeling/analysis of coronary arteries.
6.13 The latest complete software and hardware for visualizing stent with extra high- resolution from table side control. **Appropriate Software should be included to measure the vascular Flow**
6.14 Real time image processing software and overlay of road map on fluoroscopy image for vascular interventions.
6.15 The system should contain functionality to be able to instantly post process images of the same or a different patient in the control room while (or: at the same time) images are acquired in the exam room. Interact with the current patient data/images with no delay in parallel.
7 Monitors / Display:
7.1 The monitor display should be offered with single TFT monitor of 55" or more minimum 8-megapixel resolution. Facility of simultaneously display of at least 8 images source inputs (analog/digital) should be available to display reference image, patient hemodynamic monitoring, 3D acquisition imaging and images from other sources like CT/MR. The monitor display system should be ceiling suspended and should allow flexibility in having different image layouts of desired / different format sizes.
7.2 A standby high resolution TFT/LCD monitor of at least 19 inches along with large display to be offered.- 2 No.s
7.3 Control room shall have at least 2 no.s of widescreen Medical grade monitors for display of live, playback, reference images of each plane.
7.4 High resolution 18/19 inch medical grade monitor for post-processing and reporting in the control room with main console.-1 No.s
7.5 Integrated two way communication system between control room and examination room.
7.6 All post processing functions for images including fusion of CT, MR and angio images with 3D display & 3D volume measurement.. Immediate background transfer of all images as soon as they are acquired, to the PACS.
8 Digital Archiving
8.1 Dynamic viewing of CD/DVD images at frame rate of 0-25 frames/sec, single frame step by step, fast forward & fast rewing.
8.3 Image transfer from digital system in background mode without affecting the system operation.
8.4 USB interface to copy images to **CD/DVD/**memory disk / external hard disk.
8.5 The system should have complete DICOM send, DICOM storage commitment, DICOM query retrieve, DICOM worklist, DICOM MPPS, DICOM print and other DICOM protocols and interfaces of PACS, HIS/RIS
8.6 The patient images from the main system to be transferred to a server of at least 10 terabytes capacity with patient data management system with RAIDS.
9 3D Acquisition and Cross-Sectional Imaging:
9.1 The 3D Acquisition should offer:
a 3D Reconstruction and visualization in real time of a volume in volume rendering technique.
b Multiplanar reconstruction (MPR) & Maximum intensity projection (MIP)
c This should include the accessories for 3D reconstruction like calibration phantoms, phantoms and test plates for image quality measurements.

d 3D Road Mapping with overlay facility of 3D Roadmap over live fluoroscopy.
e 3D Road Mapping with automatic updation of 3D Roadmap with change of C-arm position, zoom and source to image distance. Roadmap should have presets application wise (Abdomen, Peripheral & Neuro). Should also be able to select the Procedures like Navigation, Coil, stent, Glue, Particle in the Roadmap to visualize different materials.
9.2 The system should have cross-sectional CT like imaging based on rotational Angiography for visualization of bleeding, ventricular system of the brain and micro stent placement.
a The acquisition should preferably be ECG gated/angle triggered method to plan and complete ablations is visualizing the actual state of cardiac anatomy and physiology e.g. coronary signs etc. Capability to merge/fade live images with 3D segmentation should be available on the 3D workstation in the control room and a parallel display in the exam room. The cross-sectional & 3D images should have processing capabilities in the examination room.
b The system must have latest generation software/ hardware packages for radiation safety of officer and patient with documentation of radiation per fluoroscopy / cinetime.
c Protocol for viewing the vasculature beyond the clot thru bolus injection using the retrograde filling. Should have the feature to display vessel structure. Before and After Occlusions in ischemic stroke Intra – venous injection protocol using High Resolution soft tissue CT imaging inside Cath lab.
d For visualization of lower peripheral vessel structures wherein the contrast bolus is followed interactively by a motorized table scan movement.
10 Hemodynamic Monitor
10.1 Hemodynamic Monitor with 10" or more for examination with BP, Pulse, Temp., Respiratory rate, NIBP, IBP-2 nos, SpO2 measurement, display with slaving in console room.
10.2 Necessary interface and viewing facility with the large 55" display monitor in the examination room and console room.
11 UPS
11.1 Suitable online UPS of at least 160 KVA capacities with 15 min. battery backup for complete Cath lab including cine and fluoroscopy. Emergency lighting in Exam room should also be on UPS.
12 Accessories to be supplied:
12.1 Dual Head Pressure injector of stand-alone type desirable.
High pressure injector for contrast delivery.
Feasibility of reusable and disposable syringes.
50 reusable syringes to be provided.
Syringes of at least 150 ml capacity with min 500 disposable syringes
All accessories including rubber pushes – 10 extra numbers
Make and model of the reputed injector to be mentioned in the offer along with the brochure.
12.2 Lead Glass 150 x 200 cms or bigger with lead equivalent as prescribed by ICRP or BARC / AERB recommendations (for controls room window) to be fixed between console room and gantry room for radiation protection.
12.3 Lead aprons should be of standard state of the art make, lightweight, should be double sided. 8 of which should be two-piece and remaining 8 should be single piece. Design should be wrap around. It should have lead equivalent of 0.5 mm.
12.4 Thyroid shield of 8 nos. should have lead equivalent of 0.5 mm.
Radiation protection Visors / Light weight lead goggles (for operator use) 8nos.
Trolley stands to hold the 16 lead aprons.
12.5 Laser Network Printer of high resolution (at least 1200 dots per inch) with minimum 128 MB memory and 1200 dpi should also be offered for high quality image printing on A4 paper – 5 reams of glossy printing papers to be supplied-1 Nos
12.6 Set of arm supports with adjustable Cath arm support – 2.
12.7 Multi arm drip stand mounted and adjustable on the table – 2.

12.8 Patient straps – 2.
12.9 Head support – 1.
13 Certifications:
a The system should be AERB type approved and the copy of E-LORA Listing should be submitted.
b Regular QA according to AERB norms will be responsibility of bidder during warranty and CMC period.
c Product should have European CE with 4 digit notifying body no./USFDA Approved certificate to be provided.
14 The Site modification Work – Biplane D.S.A
14.1 The supplier should inspect the proposed site offered by the Consignee Institute in which the Cath Lab system has to be installed and they are required to submit the plan to the Modular OT supplier for the complete Cath Lab Centre. The scope of work includes preparing the drawings considering the OT lights and Pendants which are part of MOT tender.
14.2 **Turnkey works**
Bi Plane Cath lab Equipment located in hybrid OT. Since work order for hybrid OT package is placed already, It is important that the works for hybrid OT room and Biplane Cath lab work are completed simultaneously.
PWD being the tendering authority for main building hybrid OT, Biplane Cath lab vendor is expected to complete the installation work for Biplane Cath lab.
A site visit in close coordination with PWD officials by before bidding by prospective bidding of Biplane Cath lab is highly recommended.
14.3 While preparing the plan, the following aspects have to be addressed:
a) Care should be taken to provide easy negotiation of the patient stretchers/ trolleys through corridors and doors.
b) Radiation shielding for doors, walls, windows etc.
c) Furniture like desk, chairs, shelves etc.
d) Patient stretcher and other furniture/ accessory to make the Cath Lab centre functional.
15 Scope of Planning for Site modification Biplane D.S.A system:
15.1 The Biplane D.S.A site shall consist of the following rooms:
A Biplane D.S.A / Gantry Room
B Console room
C Equipment room
E Electrical / UPS Room
F Concrete bed at Biplane DSA equipment area.
G Platform for unloading and shining the Biplane DSA should be provided if necessary.
H Cable tray, trench & channel — necessary trenches, cable tray and channels at required location would be provided.
I The supplier shall be required to specify the total load requirements for the Biplane DSA centre including the load of air conditioning , room lighting and for the accessories if any. The supply line will be provided by the Institute up to one point within the Biplane DSA centre. The distribution panel shall be provided by the vendor. Few lights in each room shall be connected to the UPS to provide emergency lighting.
15.2 **Environment specifications:**
a) Relative Humidity range: To be maintained between 60% and 80% in all areas except equipment room which shall be as per requirement of the equipment.
b) Temperature ranges: 22 ± 2° C in all areas except equipment room which shall be as per requirement of the equipment.
c) Air conditioning load: The heat load calculations and maintaining the desired temperature and humidity shall be the responsibility of the bidder.
16 Furniture:
a) Revolving chairs height adjustable, medium-back with hand-rest in the Control room, Radiologist room and viewing area. — 4 NO. S

b) Wall mounted shelves for catheter and other procedural hardware — 2 Nos.

c) Cupboard with laminate door shutters for storage of spare parts and accessories and records as per requirement. — 1 NO.S

d) Drug trolley for patient preparation area.-1 No

e) Patient trolley with rubber foam mattress to be kept in the patient preparation room.

f) Name boards for all rooms

g) Tables for Workstation - 2 No.S

h) Dustbins-10 No.s

All furniture items should be of standard make as mentioned in the table below.

17 LIST OF ITEMS AND SUGGESTED MANUFACTURERS.

SL. NO	ITEMS	PREFERRED MAKES
1.	Cables	Finolex, havells, V- Guard
2.	Switches	Legrand, L&T, siemens, Havels
3.	Distribution Box, MCB	Legrand, L&T, Siemens, Havels
4.	Light fittings	Philips / Crompton I wipro / syska
5.	Furniture	Hermen miller, godrej, featherlite, geeken

18 Miscellaneous:

S. No	BOQ	QTY
1	Biplane & Neuro angiography system with DSA, as specified.	1 no.
2	Standby high resolution TFT/LCD monitor of at least 19 inches	2 nos.
3	Wide screen Medical grade control room Monitor	2 Nos.
4	Post Processing monitor	1 no
5	Hemodynamic Monitor	1 no
6	Laser Network printer	1 no
7	ECG cables	10 Nos.
8	Reusable pressure transducers	10 Nos.
9	Online UPS	1 No
10	Pressure injector	1 No
11	Lead Glass	1 No
12	Lead Aprons with hangers	8 Nos.
13	Thyroid Guard	8 Nos.
14	Radiation protection glasses	8 Nos.
15	Ceiling suspended radiation protection	1 no
16	Table mounted radiation protection	1 no
17	Laser Network Printer	1 no
18	Glossy printing papers	5 Reams

	Miscellaneous items	1 set
	Furniture:	
1	Revolving chairs	4 Nos
2	Cupboard with laminate door shutters	1 no
3	Drug trolley for patient preparation area	1 no.
4	Patient trolley with rubber foam mattress	1 no
5	Tables for Workstation	1 no
6	Wall mounted shelves for catheter and other procedural hardware	2 Nos
7	Dustbins	10 Nos
8	Name boards for all rooms	As required
	Miscellaneous:	
1	Cabling of Network (LAN) connectivity for camera system, console	LS

	system, workstation and computers etc	

1. Technical Specification for Skull Clamp with Brain Retractor System

Description:

a) It is for rigid fixation of skull during surgery so that there should not be any movement during using microscope.

b) The items should be manufactured by firms of international repute and must have European CE, ISO, and US-FDA approval.

c) The firms quoting should supply all the Instruments and accessories of single make, No mix and match will be entertained.

d) The firm must quote part number of each and every instruments and accessories in price and technical bid without which the tender will be rejected.

e) All the items and accessories must have USFDA approval. It would have supplied it in prime institutions of India.

Technical specifications:

A. Skull Clamp System:

1. It is for rigid 3 pin fixation of skull during surgery so that there should not be any movement during using microscope and High speed Drill.
2. Fixation pins of adult and pediatric sizes
3. Locking-unlocking mechanism of pin-attachments on side of the frame.
4. Frame lock-unlock by rachet with pull mechanism.
5. The System must be able to mix and match with future Radiolucent skull clamp/Radiolucent Base unit and Radiolucent Swivel Adaptor.
6. The System must have Quick rail technology identifiable even under multiple layers of sterile drape, for attaching retractor systems and accessories at any position on the Quick-Rail.
7. Stainless steel starbursts on both sides of the Skull Clamp provide direct and secure attachment of movement-sensitive navigation tracking devices (Stryker, Brainlab and Medtronic navigation systems directly applicable, should alleviate the need for additional adaptors). No play between arch-holder and Skull Clamp Base when locked
8. Should have frame which can attach to existing OT table.

Each unit/set should have

1. Support/Mount device for base unit to any OT table (Original) - 1 No.
2. Ultra-adjustable Base Unit- 1 No
3. Ball Socket Swivel adaptor- 1 No.
4. Swivel Adaptor – 1Nos.
5. Skull Clamp- 1 No.
6. Adult Reusable Pins in SS - 04 in No.
7. Pediatric Reusable Pins in SS - 04 in No.
8. Adult Horseshoe Head Rest with Extension bar for traction - 1 No.
9. Pediatric Horseshoe Head Rest- 1 No.
10. Cervical Spine Support for Anterior spine surgery - 1 No.
11. Crossbar Adaptor (Original) for sitting position - 1 No.
12. Universal Side Rail (Original) - 2 Nos.

Navigation Attachments for skull clamp which must be compatible with first line navigation systems (Stryker, Medtronics, Brainlab). = 01

14. Base Unit Park-bench = 01
15. Armrest Park-bench = 01
16. Side Rail OR Table Adaptor = 01

2. Technical Specification for Stereotactic Frame System

1. The principal components of the stereotactic system shall include a Cartesian frame and a semicircular arc, suitable even pediatric stereotaxic (for children over 2 years of age and

compatible with X ray, CT and 1.5T and 3T MRI.
2. The semicircular arc shall incorporate a sliding instrument carrier for use with needles, electrodes, and other micro surgical instruments.
3. Sterilization trays tailored for the frame and arc system gas sterilization (ETO), steam sterilization (autoclaving) and gas plasma sterilization should be included.
4. The stereotactic system should be arc centered with a 190 mm radius, and be based on Cartesian coordinate system conforming to the X, Y and Z nomenclature used in CT and MR Scanning.
5. Numeric coordinate values (in millimeters) should be engraved on the frame and arc on both sides to ensure highest possible accuracy.
6. The posterior post should be adjustable in length.
7. The guide and Stop inserts should be able to split to enable effective cleaning.
8. The instrument carrier shall have separate adjustable instrument guide and stop to optimize proximity to skull and thereby accuracy.
9. CT and MR adapters should be included in the system secure and support the patient's head and should be adjustable to ensure a parallel scan plan without having to manipulate the gantry of the scanner
10. The total accuracy of the frame should be minimum 0.2 mm.
11. The system should allow for trans oral or trans nasal intubation at any time during the procedure.
12. It should allow for an approach inferior to the frame for posterior fossa and trans sphenoidal trajectories.
13. It should provide pins or positioning aid for utilization as positioners and stabilizers for frame placement on the patient. (Head ring screws preferably reusable).
14. It should allow arc fixation in both the lateral and sagittal orientation.
15. The stereotactic system should have a dedicated CT & MRI, PET, Angio, X-Ray table fixation with CT and MRI, PET, Angio, X-Ray adaptors. These should however not limit how low the frame may be mounted.
16. The Stereotactic System should have an option for testing its accuracy of the complete frame and arc with the target stimulator.
17. The company should provide a tool to test the straightness of the needles and electrodes.
18. The Stereotactic system should provide tools for intra-operative image verification of the placement of clinical probes in relation the target.
19. Should be ideal to use with DBS, SEEG and Brachy therapy
20. Stereotactic frame should be calibrated for Micro Electrode Recording system
21. The Stereotactic Frame should offer a rigid and accurate fixation to the operation table headrest with three-point fixation even if the patient is shaking and should have a proper space which provides access to the patient's airways.
22. The coordinate frame should have a reusable insertion cannula and hematoma evacuator (2 each) designed to obtain safe guidance of implants, electrodes or catheters using stereotactic technique and hematoma evacuation using single burr hole.
23. The system should have the vaccum/Sedan biopsy needle with window with stop and guide of diameter respectively- (Reusable 3). Rates of reusable components should be quoted separately.
3. Technical Specification of Stereotactic Planning Software
1. Should have standalone stereotactic Planning software for Biopsy, DBS, and brain lesioning procedures.
2. The system has to be compatible with Computer Tomography Scan (CT), Magnetic Resonance Imaging (MRI) and Angiography so that entry and target points can be virtually placed. The system has to be compatible with our hospital CT/MR units.
3. The system should be able to directly import relevant images (CT/MRIPET/Angiograms) from hospital PACS/ CD/USB drive.

4. The system should allow surgical target and trajectory decided on one image modality (e.g. CT) to be extrapolated to all other imaging modalities (like MR/Angio/PET etc.) available with the patient.
5. The system should be compatible with different views (axial, sagittal,coronal) of given imaging modality across all imaging modalities like CT/MRI /PET /Angio.
6. The system should allow planning of unlimited numbers of targets.
7. The System shall provide the operator, in real time, the necessary stereotactic coordinates like ring and arc angle for navigation throughout the procedure allowing for reorientation of arc position like right to left, left to right, anterior to posterior and posterior to anterior.
8. The system should allow pre-planning of the procedure on the work station much in advance of the proposed date of surgery.
9. The system should have a workspace with display of more than 4 images or more preferable at the same time. The system should allow definition of AC-PC line from uploaded images, reorient patient images with respect to this line and allow localization of functional targets based on AC-PC line.
10. Should have provision to upgrade Brachytherapy module for Radiosurgeries and Epilepsy lesioning.
General Requirements:
1. The system should include 3 years warranty, 5 years CMC.
2. Details of the cost of frame reusable/disposable components should be provided separately.
3. Clinical Training program should be provided by the certified personnel from the manufacturer.
4. Valid USFDA and 4 Digit European CE & ISO certificates should be provided.
4. Technical Specification of RF Leision Generator
Basic device functionality
1. Should Support both types of Thermocouple electrodes,
2. used for Monopolar and Bipolar applications for pain management in Brain and Spine.
3. Two direct nerve stimulation modes: constant current
4. control, constant voltage control; to be used for motor and sensory nerve localization
5. Continuous Thermal RF mode: Standard temperature controlled, and pre-set temperature-profile
6. Pulsed RF mode: voltage-controlled mode, stimulation time-controlled mode, and temperature-controlled mode
7. Permanent temperature measurement
8. Continuous Impedance measurement
9. Neutral Electrode Contact Quality Monitoring (NEM) with a split Electrode
10. Digital LCD display with clearly arranged set of temperature graph, measurement values and setting parameter
11. LCD touchscreen allows an intuitive workflow
12. Remote control for ease of use
13. Saving of up to 25 pre-set application profiles
14. Compact and light weight system design
15. Easy to press START & STOP buttons
16. Easy adjusting parameter values with rotary knob
17. Hand controller for remote control including 3m long cable
18. Export function for patient data archiving on USB storage
Features of RF generator
Provides two output channels for simultaneous treatment of two separate targets in the same patient, whereby depending on the application they can be used separately or combined in different ways or modes:
1. Single electrode monopolar against neutral surface electrode,
2. Two electrodes monopolar against neutral surface electrode,

3. Two electrodes monopolar Ch l electrode against Ch2 electrode,
4. Single electrode bipolar,
5. Two electrodes bipolar.
6. Provides different continuous Thermal RF modes:
7. standard temperature controlled,
8. Step programmable mode.
Impedance Measuring Range:
30 Ω - 2 kΩ with Resolution of 1 Ω for 30 Ω - 1 kΩ and 100 Ω for 1kΩ - 2kΩ
Direct Nerve Stimulation Should have the following:
1. Motoric Stimulation Frequency 1 Hz – 49 Hz with Resolution: 1 Hz
2. Sensory Stimulation Frequency 50 Hz – 200 Hz with Resolution: 1 Hz
3. Pulse Duration 50 μs – 3 ms with Min. Resolution: 50 μs
4. Voltage Range should be 50 mV - 10 V with Min. Resolution of 50 mV
5. Current Range should be 50 μA – 8 mA with Min. Resolution: 50 μA
6. Auto Ramp should be of rising edge in steps 0.5s/1S/2S with Min. Resolution range
7. 50 mV [50 mV – 10 V] and 50 μA [50 μA – 8 mA]
8. Should have Unipolar – Square Waveform
9. Colour identification for Neutral Split Electrode Contact (Green, Yellow, Red)
Continuous RF mode should have the following.
1. Maximum Lesion Temperature should be at least 95^0 C
2. Lesioning Time should be in the range of 0 – 10 min with a Resolution of 10 Sec
3. Monitored Temperature Accuracy should be ± 2^0 C
4. Maximum Monitored Temperature should be at least 105^0 C
5. Continuous Frequency should be 488 kHz (Sinewave)
6. Load Impedance Range should be 50 Ω - 2Ω
7. Should have Max. Output Voltage of 100 Vrms and Max. Output Current 800 mA
8. Max. Nominal RF Output Power 50 W per Channel if one Channel is active and 50 W split into 2 Channel if CH I + Ch2 are active
Pulsed RF mode should have the following:
1. Voltage should be in the range of 20 V - 70 V with Resolution of 1 V.
2. Pulse Duration should be in the range of 3 ms - 40 ms with Resolution of 1 ms
3. Temperature should be in the range of 30 °C - 95 °C with Resolution of 1 °C
4. Lesion Time should be in the range of 30 sec - 30 min with Resolution of 30 sec
5. Frequency should be in the range of 1 Hz - 10 Hz with Resolution of 1 Hz
Accessories
1. Reusable TC-Electrodes for Pain and Brain application Bipolar and monopolar electrodes available
2. TC-Electrodes adaptable with 7-pole Lemosa Plug or Opole Superlight Connector Brain electrodes in different length available, compatible with following Stereotactic Systems:
○ Riechert Mundinger
○ Zamorano-Duchovny
○ Leksell
3. Electrode Lengths for Pain application:
○ 50mm
○ 100mm
○ 115mm
○ 150mm
4. Diameter of cannulas for Pain application:
○ 22G
○ 20G

- 18G
- 17G

5.Length of the active Tip of the cannula available for Pain

Application: 2mm, 5mm, 7mm, 10mm, 15mm

5. TECHNICAL, SPECIFICATION OF MICRODRIVE For DBS PROCEDURE

1. It should be capable of recording simultaneously from at least 5 electrodes
2. Should have a measuring range upto 35mm with a resolution of 0.05mm.
3. Should be compatible with major brands of Stereo-tactic frame like !named RM, Inomed ZD, Leksell G-Frame, Radionics CRW, Micromar Aim system, MHT Koch, Zeppelin.
4. There should be a "Haptic feedback" from the drive for the user to get control over the depth which in turn prevent a wrong usage of the depth.
5. The Microdrive should be completely sterilizable in autoclave.
6. Optional depth sensor could be mounted on the Microdrive which provides depth information for MER software.
7. Should have an option to switch the orientation of electrodes between + and x orientation.

Note: ***Modular OR, OT Pendants, OT Surgical Light, Anaesthesia Pendants, Laminar Airflow etc which are required for the OR part has to in the customer scope.***

Specification of Turn Key Works: The turnkey works shall include the following for a floor area of 1500 sq. ft.

1. Civil Works.

a. Minor civil works related to installation of the equipment like Platform, Pedestals, finishing works etc., (lump sum)
b. False ceiling in all the areas shall be provided of **Armstrong** make with necessary fixing arrangements as per manufacturers specifications. Colour as per Purchaser's requirement.
c. Flooring -Shall provide and lay Anti-static flooring of 2 mm thick, manufactured by reputed standard manufacturers as per BS 2050-1978. Colour as per Purchaser's requirement.
d. Wall tiles upto ceiling with vitrified tiles 60 cm X 60 cm. Colour as per purchaser's requirement.
e. Radiation shielding of walls, doors etc., as per AERB and BARC regulations.

The area of 1500 sq. ft. will be considered for price evaluation purpose. However the payment will be for the actual area of work done as per site measurement.

f. Scrub area with an Automatic Surgical scrub sink (Double) and catheter wash area. (Lump sum)

2. Electrical Works: (Lump Sum)

a. The power required for the operation of equipment will be provided by the hospital near the site.
b. Electrical wiring of the equipment and its accessories, with separate wiring for light and power circuits through MCBs of suitable capacity. Adequate safety, measures in the electrical power supply system as per standards. Dedicated isolated earthling as per standards.
c. Floor trenches with wooden / concrete covers in blocks for the cables in the Equipment room, necessary concealment with wire mesh / sheet metal at the cable entry / exit points, various openings in the equipment and electrical panels etc., to make the system rodent / pest proof.
d. LED Backlighted Sky ceiling screen should be provided in Cathlab Gantry room for patient comfort.

3. Air conditioning system

Air conditioning system **(Split/Ductable)**: minimum 6 ton capacity AC (3x2ton capacity) for gantry and 4 ton capacity AC (2x2 ton capacity) for console room, maintained throughout the warranty period of the cath lab & subsequently through the AMC period. The CAMC should be quoted along with the CAMC for main equipment.

Note: To quote the prices separately for Spilt Ac and Ductable AC in the price bid.

4. Lead lined Door of required size and thickness and size as per AERB standards: