SPECIALIZED HEALTHCARE & MEDICAL EDUCATION DEPARTMENT
GOVERNMENT OF THE PUNJAB

PROCUREMENT WING
Dated Lahore 20th October, 2025

NOTIFICATION

NO. SO (STAND) 1-30/2020; In pursuance of the recommendations of the notified PVMS Committees and subsequent approval of **Departmental Standardization Committee (DSC)**, the Competent Authority has been pleased to approve the **PVMS specifications of ANGIOGRAPHY SYSTEMS** pertaining to the **CARDIOLOGY SPECIALTY** for all the Procuring Agencies under the administrative control of SHC & ME Department.

2 The procurement process shall be carried out strictly in accordance with Punjab Procurement Rules-2014 and other relevant rules / regulations / policies.

3 Need of the Procuring Agency for items (main / optional) must be reasonably justified.

4 All the Procuring Agencies (Hospitals, Medical Colleges, Universities and Institutions) under administrative control of SHC&ME Department are bound to follow these PVMS Specifications. The already notified PVMS Specifications of aforementioned specialties are hereby repealed with immediate effect.

SECRETARY
SPECIALIZED HEALTHCARE AND
MEDICAL EDUCATION DEPARTMENT

No & Date Even: -

A Copy is forwarded for information & necessary action to;

1. All VCs & Principals of Medical Health Institutions, SHC&ME Department.
2. All Superintendents of Teaching Hospitals, SHC&ME Department
3. All Head of Special Medical Institutions, SHC&ME Department
4. Director ICT Cell, SHC&ME Department, with the request to upload these PVMS Specification on the Departmental website.
5. PSO to Secretary SHC & ME Department, Lahore.
6. P.S to Special Secretary (D&R), SHC&ME Department.
7. P.A to Additional Secretary (Procurement), SHC&ME Department.

Ateeb 20-10-25

(ENGR. MUHAMMAD ATEEB)
SECTION OFFICER (STANDARDIZATION)

Clinical Specialty	**Cardiology**
Generic Name	**Monoplane Angiography Machine**
Clinical Purpose	Latest model AI Powered/Automated Advance Function, Angiography Machine is intended to perform diagnostic and complicated therapeutic procedures at maximum available image acquisition and display capabilities for adult and Pediatric national leading institutes. This equipment must have ability for extended acquisition duration without compromising quality.

TECHNICAL SPECIFICATIONS

A fully digital flat Single Plane Cardiac Angiography / Cardiac Catheterization System dedicated for Pediatric and Adult diagnostic as well as interventional cardiac procedures. Capable of head-to-toe coverage without repositioning of patient. Companies shall offer their latest and top of the line internationally available systems and applications at the time of tender with best resolution and minimum possible radiation dose. This equipment has to be best possible manufacturing standards in all categories by that company. No justification of any less is acceptable.

Positioning Arm:

1. The positioning placement of the arm (Floor/Ceiling) reflects on the capacity and capability of the equipment (End User to specify).

Geometry:

2. Motorized digital flat panel system with smart collision detector
3. Rotation Range (Degrees): ROA / LAO +/- 105° or more
4. Cranial / Caudal: Minimum +/- 45°
5. Rotational Angiography Speed: 40° / sec or more in LAO to RAO or vice versa; 18° / sec or more for AP Cranial to AP Caudal or vice versa (The manufacturer must supply the best possible, currently available options.)
6. Source to Image Distance (SID) Range: 95 – 105 cm or wider (PA / Lateral)
7. Iso-Centric Height: Variable / Fixed
8. Auto Positioning: Programmable auto positioning of selected angulations, (45 or more) programmable positions
9. All rotational angles should be digitally displayed on the monitor
10. Motorized / manual parking & rotation of the positioning arm, capable of head-to-toe coverage without patient repositioning

Digital Flat Panel Detector:

Detector must be latest version or model from the Manufacturer at the time of procurement. (It is mandatory for the bidder to mention detector model in technical offer)

11. Detector size 30x30 or 30x40cm, as per manufacturer production and if both are available with any manufacturer, then the smallest amongst these two sizes without compromising cardiac positions including steep angulation with close positioning of detector to patient body or smaller detector size 20x20cm (End user to specify)

Further Detector Specifications:

12. ASi / CsI / aSe Type
13. Image matrix of 1024 x 1024 pixels or higher at minimum 14-bits depth for detector. Firms will offer their highest available pixels and bits at the time of procurement.
14. Standard Cardiology Field of View (FOV) sizes: Three formats or more
15. Built in temperature stabilizer
16. Integrated Collision Protection / Collision Detection Technology
17. All other standard accessories according to this digital flat panel

18. Minimum Spatial Resolution: 2.5 lp / mm or more.
19. Minimum Pixel Size: 200 µm or less
20. Removable grid for Pediatric applications
21. Minimum Detector / Detective Quantum Efficiency (DQE): More than 75 % or better

Patient Support Table

22. Floor mounted, 8 – ways horizontal floating top catheterization table with up / down, vertical, longitudinal, and transverse movements capability and pivoting

Further Table Specifications:

23. Minimum table length 280 cm
24. Longitudinal Travel: 1100 mm with tabletop movement or more
25. Lateral/Transverse Travel: 280 mm (± 140mm) or more
26. Vertical/Horizontal Travel: 90 – 105 cm from the floor or more
27. Motorized longitudinal and lateral/Transverse travel of patient support table / Stepping DSA feature
28. CPR should be possible in any table position
29. C Arm Controls should be available as table mounted controls in procedure room.
30. Tabletop should be able to accept patients' weight of up to 200 kg plus 100 kg for resuscitation
31. Tabletop should be metal free (X – ray density < 2mm AI equivalent or better)
32. Complete accessories including arm holders, hand grips, arm supports / arm rests and positioning aids,
32a. Patient head stabilizer, Arm and leg restraining belts/straps for neuro interventions.

X-Rays Generator:

Microprocessor based high frequency using fiber optics for data communication between each imaging system (The bidder will mention the models in their technical offer)

33. Dedicated X-Rays generator of 100 KW
34. Radiographic mA up to 1,000
35. Radiographic kV 40 / 50 – 125 kVp
36. Serial filming exposures with shortest exposure of 1 ms with automatic KV and mA control for optimum image quality/High Pulse Fluoro
37. Capability of digital radiography and fluoroscopy
38. Capability of doing multiple rate digital pulsed fluoroscopy and cine at range of 3.75 to 30 fps
39. Capability to change frame rate during the same study

X-Rays Tube:

Tube must be of highest performance, latest version, model and series from the manufacturer offering actual anode heat storage capacity of 3.7 MHU or more. (The bidder shall submit undertaking from the manufacturer in this regard). The bidder will mention the X-Ray Tube Model in their Technical Offer. Minimum 05year unconditional warranty on the X – Ray Tube.

40. Tube (Liquid / Metal Bearing Technology)
41. Double / Triple focus with actual Anode Heat Storage Capacity of 3.7 MHU or more for un-interruptive long procedures
42. Anode Maximum Continuous Heat Dissipation: best maximum available cooling rate during serial exposure but not less than 500 KHU/min or 6.50 KW or better
43. Anode Small Focal Point: 0.3 – 0.5 or lower

44. Anode Large Focal Point: 0.8 – 1.0 mm or lower

45. Dose management with Fluoro filters range of 0.1 / 0.2 mm and 0.6 / 1.0 mm Cu or Real Time Automatic Filter selection based on patient body weight

46. State of art cooling system (As per Manufacturer's Design / Recommendations)

Radiation Reduction and Monitoring Systems:

47. AI Based Advanced radiation dose reduction & Image Enhancement features are mandatory like Alpha Evolve and DoseRite or Smart IQ/Clarity IQ or Optiq or Score Opera or AutoRight intelligent image chain. Latest technology being produced by each manufacturer in this category, at the time of tender should be quoted. Dose management and reduction / optimization to be done without image quality compromise. All parameter that are provided in hardware and software must be of latest version preferably with AI powered dose prediction capabilities.

48. Grid Pulsed / Physical Radiation Reduction System / Flat Emitter Technology / similar technology tubes with radiation dose management and with auto adjusting Fluoro filters

49. Dedicated X-Rays radiation dose monitoring and dose reduction software features of the latest variety provided by the manufacturer

50. Angulation dependent automatic exposure control including KV, mA, pulse width & focal spot adjustments

51. Automatic calculation and optimization of exposure data based on fluoroscopic data

52. Radiation free patient positioning without active Fluoro

53. Active radiation dose monitoring based on actual C-arm angulations and table positions

54. Radiation Free Collimation

55. Real-time displays on main examination room monitor as well as control room monitor including cumulative Air Kerma display, cumulative Dose Area Product and Fluoro time

56. DAP threshold intimation / warning system

57. DICOM structured report containing patient, procedure, and dose data

High Resolution Digital Imaging and Acquisition / Fluoroscopy System with Real Time Image Processing:

58. Acquisition and Processing at 14 bits or more

59. Parallel processing capability / multitasking facility

60. Real time filtering and roadmap function

61. Magnetic disk capacity for storage of minimum 50,000 images in 1024 x 1024 x 12 bit or highest at the time of tender on the magnetic disk of main console

62. Minimum Cine Length: 10 seconds in 1024 matrix @ minimum 30 fps

63. Images storage and retrieval from archive disk for possible manipulation and quantification using available software packages (compatible format / bits)

Monitoring System:

64. Medical grade large display monitor in examination room, minimum 55" diagonal in size (Make: Eizo or Barco), 8 Mega Pixels resolution along with two or three 19" or larger medical grade monitors for backup to display live image, reference image and pressure tracing and ECG

65. Large Primary Monitor mentioned above should at least be ceiling mounted with original ceiling suspension system

66. Three LCD / LED medical grade monitors for live images, road mapping and hemodynamic system control in the control room, minimum 19" inch diagonal or larger size

67. All 19" or larger Monitors should be Medical Graded, complied with International Standards for medical monitors as recommended by Manufacturer and all with the same brand

Controls:

68. Integrated table side touch screen/Touch Panel (Original from OEM of Angiography Machine) console to adjust system parameters, display setting of 55" monitor, frame rates, Hemodynamic system controls (Additional touch Screen console if required), quantitative analysis, stent enhancement soft-wares, Digital Subtraction Angiography (DSA), Mask- Unmask (Road-mapping) and Rotational Angiography

69. All controls of digital imaging system, measurements, post processing & quantifications analysis shall be in the control room as well as the examination room

70. Table side and Control room panels must have quantification and processing capabilities.

71. The control panel can be mounted at any side of the Patient Table

Recording / Archiving & Communication System:

72. Recording / archiving system should be DICOM – 3 Compatible

73. Digital images should be stored as backup on CDs / DVDs with incorporated original DICOM handling software / DICOM player from original manufacturer

74. DICOM (Send / store, commitment, retrieve / query)

75. PACS compatibility / integration

76. Ethernet connection to connect with other terminals

77. Integrated bi-directional intercom system for Cath lab to control room (From Original Manufacturer).

Software Packages:

The bidders should quote their licensed software with part number in their principal offer. Complete analysis package for following cardiac applications should be included:

78. Dynamic pre and post PTCA / Valvotomy comparison with one image live and other reference

79. Automatic loops replay after acquisition or fluoroscopy

80. Dynamic real time pan / zoom

81. Dynamic real time digital imaging processing like edge enhancement or gamma correction, noise reduction (spatial filtration)

82. Online image density (gray scale) correction

85. Simultaneous display of fluoroscopy and reference images

86. Standard quantification packages for Left Ventricular Analysis

87. Facility to review previous studies in the examination room from the patients' old CD

88. Quantitative Coronary Analysis Software

87. Automatic positioning of the c-arm corresponding to reference image

88. Store Fluoro facility to store last fluoroscopy run

89. Co-registration / Integration of Intra-Vascular Ultrasound (IVUS)

Dedicated Adult Features:

90. Digital subtraction angiography package with manual / real time pixel shift for compensation of patient movement during acquisition

91. Image masking with real-time overlay of live Fluro

92. Latest stent enhancement technology, being produced by each manufacturer in this category, at the time of tender, like, Dynamic device stabilizer (DDS) or PCI Assist 2 including Stent Viz or Stent boost Live or Stent View/ Score View Live or clear stent live with real time image enhancement with integrated table side control with touch panel are mandatory to quote.

Physiological Hemodynamic Monitoring System: (FDA 510k approved)

93. Integrated Hemodynamic System with full table side control having bi-directional communication with the machine for automatic / synchronized acquisition, transfer and display of patient Hemodynamic parameters and demographic data.

94. Multichannel (16 channels or more) to record at least 4 channels IBP, Cardiac output with thermo dilution method, Surface ECG in any configuration and simultaneous 12 lead ECG, NIBP and SpO_2 measurement

Hemodynamic System Features:

95. Live Waveforms display on main monitor in the examination room

96. Digital display of all the parameters like IBP, Heart rate, cardiac output parameters

97. Possibility to print the waveforms simultaneously while acquiring the data in the Background.

98. Capability to store the waveforms on the hard disk of the physiological recording system

99. Two Monitors in the control room, one for live waveforms and the other for control and data entry

100. Facility for freezing Hemodynamic data and simultaneous recovery of recent data/ compare stored data with current waveform

Dedicated Branded Workstation:

Hardware must be as per Manufacturer's Recommendations & Software should be from Original Manufacturer of Angiography System. Online workstation to review studies directly and the facility to review studies with lossless compression and original image quality as on console.

101. DICOM – 3 Compatible. Capable of universal DICOM support

102. Original DICOM handling software from the manufacturer with permanent license

103. Edge enhancement, adjustable view speeds & post processing capabilities

104. High-Definition Medical Graded LCD / LED monitor of minimum 19 inches size

105. CD / DVD writer and CD / DVD ROM Drive

106. Image storage capacity as per Manufacturer's approved hardware

107. SCSI or equivalent controller as per Manufacturer's approved hardware

108. Black & white laser printer

109. 3D reconstruction software package for congenital heart defects including aorta, pulmonary artery and RVOT supplied by the principal manufacturer. (End-user to specify the need.)

Review Stations for Auditorium / Classroom/ Doctor Office:

110. Branded review station with connectivity to main angiography machine including all necessary cabling / hardware for connectivity

111. LED Display (60" inch) and high-resolution multimedia projector for view of live imaging

Radiation Protection Equipment / Accessories:

Must be FDA / MHLW/ CE approved.

112. Ceiling suspended tilt table lead glass (Should be supplied by the same manufacturer) for radiation protection of operator's head & neck regions and upper body parts

113. Table mounted adjustable lower body radiation shields and flaps (front and side coverage both) on both sides

114. Lead glass window size 4 x 1 meter or larger lead equivalent 2.0 mm or better

115. Lead aprons (vest and skirt), double side with different sizes, light weight (4.5 kg or less in total), lead equivalent front 0.5 mm and back 0.35 mm with belts (FDA / CE approved) (Brand & sizes (End-User to specify), Quantity: 05 or more to be specified by the end-user)

116. Lead aprons (single piece), double side with different sizes, light weight, lead equivalent front 0.5 mm and back 0.35 mm with belts. (FDA / CE approved) (Brand & Sizes (End-User to specify), Quantity: 05 or more.

117. Wall Mounted / Trolley mounted hangers of S.S 304L for 5-10 lead aprons (To be supplied Locally) (Quantity: End-User To Specify)

118. Thyroid shields with lead caps. (FDA / CE approved) (Brand & sizes (End-User to specify), Quantity: 08 or more)

119. Lead Goggles: Light Weight (FDA / CE approved) (Brand & sizes (End-User to specify), Quantity: 05 or more)

120. Patient Protection Lead Sheet: Light weight having 30 inches in size

121. Personal Digital Dosimeters (Quantity: 05 or more)

Quality and Safety Standards:

122. For Angiography and Hemodynamics System, US FDA minimum 510k requirement is as under:

a. US FDA minimum 510k approved (For Angiography Machine and Hemodynamic System for Adult)
b. The Equipment / Instrument / Applied parts shall conform to IEC – 60601 – 1 standard general requirement for basic safety and essential performance of medical electrical equipment
c. The System must comply with IEC – 60601 – 1 – 2 Electromagnetic Compatibility (EMC) collateral standard or equivalent for basic safety and essential performance in the presence of electromagnetic disturbances and electromagnetic disturbances emitted by that equipment and systems
d. Medical Graded Displays and Power Supplies

Operating Requirements:

123. Three phases with line voltage of 440 V & 50 Hz

124. Cabling for electrical power supply, generator & UPS connections

125. Cabling for proper earthing

126. Brand New and Latest Version 160 KVA or more true online sine wave Double conversion UPS for whole system with a minimum back up time of 10 minutes including room lights, microprocessor based IGBT technology. Display and alarms of parameters.

Three phase line voltage of 220 50 Hz with all necessary standard parts including dry batteries, unconditional 5 years warranty for UPS and UPS batteries

127. Brand New and Latest Version 250 KVA or more (Stand by) Electric Power Generator with ATS penal power cables and soundproof canopy (imported) set with automatic change over for complete load of Angiography Suite including Air conditioners, lights, and another load of Angiography suite (Engine: Perkins / Cummins / Caterpillar / Volvo)

128. Installation:

a. Room preparations and Lead Shielding of the scan room (2-3mm) and doors (3-4mm) as per PNRA requirements with radiation/exposure indications
b. Vinyl Flooring: Complete vinyl flooring (Inside the rooms and corridors) including Self levelling (2-3mm) of Gerflor/ Tarket/Forbo
c. Wall Finishes: ACP Panels/ UV sheet/Polycarbonate on cement board/UPVC Panels on cement board and Printed Glass Panel on one wall
d. False Ceiling: Airtight suspended ceiling with specified durable material, antimicrobial coating, sealed joints to prevent air leaks and maintain pressure difference. Ceiling panels should be made of galvanized steel sheet 0.60mm-0. 80mm thick or better material. (Country of Manufacturer USA/Europe/Japan)
e. Peripheral Lights: Recessed type LED lights 65 W of Osaka/ Philips or equivalent brands
f. Power Cabling: Supplying, installation, and termination of cables between the Isolator/ DB (provided by GC) and Equipment DB (provided by Vendor), as well as from the Equipment DB to UPS. and to all internal equipment/ services

g. Equipment DB with individual breakers for all equipment protection.
h. Installation of UPS, Cable trays/ trenches, Dedicated Earthing & Power outlets
i. Provision and installation of X-Ray Viewer. Recessed/ built in type, LED X-Ray viewer for 03 X-ray films. (Country of Manufacturer: USA/Europe/Japan)
j. Provision and installation of 1 x Automatic Sliding door with 3-4 mm lead shielding as per PNRA requirements. Size: 1500mm x 2100 mm approx. Door should be automatically hermetically sealed with electronic privacy glass and without contact buttons. Thickness 0.8mm or more stainless steel AISI-304/ AISI-301. Brushed finish or powder coated outer skin. 2 set of photocells in door frame along with infrared sensor at door drive level on inner and outer side of the door. (Country of Manufacturer USA/ Europe/Japan
k. Provision and installation of 2 x Single Hinged Doors with 3-4 mm lead shielding as per PNRA requirements. Size: 1000mm x 2100 mm approx. Stainless Steel/ Galvanized Steel Door fame and door panels (Country of Manufacturer USA/Europe/Japan)
l. Cooling requirements and air conditioning as per manufacturer recommendation
m. Provision and installation of medical gases outlets
n. 2 x Medical Cabinets having 4-5 adjustable shelves. Cabinets should be sealed with a hermetic removable silicone seal and provided with tempered glass. The doors should be made of double steel plates with glazing. Safe Glass, set in double steel sheet window frame. Imported/ Local (Subject to sample approval)
o. Provision and installation of Operator Console
p. Provision and installation of Scrub Sinks with Infrared Hand Free Operation and the provision of hot & cold faucet with mixer for temperature control with front wall mirror as per site requirement. Infrared Operated Soap and Disinfection Agent Dispenser for disinfecting agent, lotion, liquid soap, etc. (Country of Manufacturer: Imported)
q. Any other modification/ requirement and manufacturers recommendations in the existing site will be the responsibility of the firm.

Trainings:

129. One doctor's foreign attachment / training for one week (The Procuring Agency to specify)

130. One hospital Bio-Medical Engineer's comprehensive service training / attachment at manufacturer site for at least one week.

(Note: The Bio-Medical Engineer must be trained appropriately, so that at the time of verification and replacement of part / equipment, he / she can fully endorse without any ambiguity the need to replace the said part. For this the supplier will request the manufacturer to provide dongle to the Bio-Medical Engineer during training at manufacturer's site and later on access to it for needful.)

131. Two technician's local training for two weeks

132. Three visits of application specialist with the last visit after commissioning of machine (Each visit of one-week duration)

Warranty:

133. The warranty period shall be for Five Years (Comprehensive) unconditional for all essential components /equipment to keep the machine functional including x-rays tube and flat panel detector, monitors, machine cables and connecting leads, diesel generator, UPS with batteries, Hemodynamic system, all consumables, all accessories (including probes etc.), non-proprietary items supplied with the machine with all specified parameters that shall cover labor and parts for all equipment

134. During the period of machine functioning before formal signing of installation report, rectification of errors or replacement of faulty parts shall be the responsibility of supplying firm without any financial implications or liabilities at the institute or End-users

135. The warranty shall start from the date of installation report signing and handing over to end-User.

136. Manufacturer will submit undertaking to ensure availability of all spare parts and consumables over minimum of 10 years.

Post Warranty Service & Maintenance Contract:

The supplying firm shall be bound to enter into a comprehensive service contract with the institute for 05 years after the warranty period at a rate not more than 6% of C & F purchase value including all essential components / equipment to keep the machine functional such as x-rays tube and flat panel detector, monitors, machine cables and connecting leads, diesel generator, UPS with batteries, Hemodynamic system, all consumables, non-proprietary items supplied with the machine with all specified parameters that shall cover labor and parts for all equipment (C & F).

137. Financial impact of post warranty service contract should be considered by the bidder while quoting the financial bid

Accessories:

Hemodynamic System Accessories:

- Complete 12 lead ECG Cables (Quantity to be specified by the End-user)
- NIBP cuffs (Neonate, Infant, Pediatric, Small Adult, Large Adult) (Quantity to be specified by the End-user)
- Thermo dilution catheters 5F 4 lumens (Quantity to be specified by the End-user)
- IBP Pressure Transducers (Quantity to be specified by the End-user)
- IBP Transducer Cables (Quantity to be specified by the End-user)
- Holder for mounting the IBP Transducer alongside patient table (Quantity to be specified by the End-user)
- DVD / CD writer for archiving of study data and waveform stored on hard disk independent of live Fluoro
- Portable Pulse Oximeter with probes (I.e., Pediatric, Adult Probes and Infant Probes) (Qty: 02)

Other Accessories:

- Crash Cart (Country of Origin: USA, EU & JAPAN) (The Procuring Agency to specify)
- Patient Shifting Trolley (Country of Origin: USA, EU & JAPAN) (Quantity to be specified by the End-user)
- Steel tray trolley for disposables, 6 x 3.5 feet 40 cm height (Quantity & Size to be specified by the End-user)
- ACT Machine (As per approved PVMS) (Quantity: 01 or more)
- Temporary Pacemaker (Single Chamber) (Quantity = 03) (As per approved PVMS) (More Quantity to be specified by the End-user)
- Programmable Portable Contrast Media Power Injector (Medrad, Angiomat, Medtrone, Nemoto, Guerbet) with disposable syringes (Quantity to be specified by the End-user)
- Bi-directional audio communication between Cath Lab and Auditorium / Office / Remote Place
- Portable Non-Invasive Hemodynamic (As per approved PVMS) / BP Monitor with built- in batteries
- Writeable CDs / DVDs (Quantity to be specified by the End-user)
- Defibrillator (Quantity to be specified by the End-user) (As per approved PVMS)
- ECG Machine (Quantity to be specified by the End-user) (As per approved PVMS)
- Dehumidifier
- Air Purifier (Specially for Air Sulphur) (It is strongly recommended that the Air Sulphur content, bacterial content, and other issues regarding the equipment which are essential for its better and long-term performance must be evaluated prior to installation by the winner of the bid.)
- Smoke Detector with Fire Extinguisher
- Ceiling Suspended Shadow-Less Light

Optional (If any):

Optional Equipment:

- Integrated Complete Licensed Pediatric Catheterization Reporting Software with Image Illustrator based on standard atlas tailored according to congenital heart defects (It should be able to import data and images from main Angiography System and overlay SpO_2 and pressures over images automatically. It should also have a complete Hemodynamics Calculation Module. For Dedicated Pediatric setup the integrated hemodynamic feature of angiography from original manufacturer will be FDA approved (510k, bare minimum).
- Complete software for all Pediatric (if required by the End-User) & adult, right / left heart, Angio / Valvular Hemodynamic calculations such as gradients, valve areas, shunts including annotations and 12 channels ECG
- Double Dome Surgical Light (Shadow Less) (As per approved PVMS)
- Operational & Service Manual
- Rampart/ CATHPAX Radiation Protection System
- CPAC interfaced (Images cross into reporting system with voice assistance capability)
- Voice assisted software for Reporting Purpose
- Intra-Aortic Balloon Pump Machine (As per approved PVMS) (Quantity to specified by the End-user)
- Dedicated Echocardiography System (As per approved PVMS) (Quantity to be specified by the End-user)
- Ventilator with compressor and humidifier (As per approved PVMS) (Quantity to be specified by the End-user)
- Hemodynamic System compatible with EP functionality (Quantity to be specified by the End-user)
- Auto Injector
- Whole Blood Oximeter with cartridges / without cartridges
- Co-registration / Integration of FFR/IFR

Optional Features:

- High resolution Cone Beam CT (CBCT) capability integrated into angiography system for neuroimaging.

General Instructions

"Optional Items / Features" may be included in the tender specifications as per requirements of procuring institute. Specifications of items mentioned under headings "Optional Items" and "Allied accessories" will be as per approved PVMS if available, whereas certifications (FDA, CE & MHLW) will be decided by Procuring Agency. Bidders may quote against respective items, however, non-quoting or not meeting the required specifications for these items would not be a reason to reject / disqualify a bid. The Procuring Agency / Institute may procure optional items if sufficient funds are available post financial bid.

- Bidder will be bound to provide undertaking from the manufacturer that in case the local distributor gets changed during the mentioned warranty or service contract period, the new authorized distributor on behalf of the Principal Manufacturer or Principal manufacturer himself will own the warranty, backup services, replacement of parts and all pending liabilities.
- Bidder will be bound to provide undertaking from the manufacturer to ensure availability of all spare parts and consumables over minimum of 10 years.

Safety Standard:

- Must conform to the requirements of ISO 13485:2016 version or above.

Clinical Specialty	**Cardiology**
Generic Name	**Bi – Plane Angiography Machine**
Clinical Purpose	Bi – Plane, Latest model AI powered / Automated Advance Function, Angiography Machine is intended to perform diagnostic and complicated therapeutic procedures at maximum available image acquisition and display capabilities for adult and Pediatric national leading institutes. This equipment must have ability for extended acquisition duration without compromising quality. This system may also be procured with hybrid configurations.

TECHNICAL SPECIFICATIONS

A fully digital flat Bi-Plane Cardiac Angiography / Cardiac Catheterization System dedicated for Pediatric and Adult diagnostic as well as interventional cardiac procedures. Capable of head-to-toe coverage without repositioning of patient and acquisition of image in Two Plane minimizing contrast exposure and Fluoro Time. Companies shall offer their latest and top of the line internationally available systems and applications at the time of tender with best resolution and minimum possible radiation dose. This equipment has to be best possible manufacturing standards in all categories by that company. No justification of any less is acceptable.

Positioning Arm:

1. Frontal / Lateral Arm Stand (The system should be Ceiling / Floor Mounted with maximum head side free space with possibility of positioning frontal C – Arm to left during biplane mode for free head access). (End-User to specify)

Geometry:

2. Motorized biplane digital flat panel system with smart collision detector
3. Rotation Range (degrees): ROA / LAO ± 105° or more
4. Cranial / Caudal: Minimum ± 45°
5. Rotation Speed: 40° / sec or more in LAO / RAO or vice versa; 18° / sec or more for AP Cranial to AP Caudal or vice versa (The manufacturer must supply the best possible, currently available options.)
6. Source to Image Distance (SID) range 95 – 105 cm or wider range (PA / Lateral)
7. Iso-centric height: Variable / Fixed in biplane mode
8. Auto Positioning: Programmable auto positioning of selected angulations, (45 or more) programmable positions
9. All rotational angles should be digitally displayed on the monitor
10. Motorized / manual parking & rotation of the positioning arm, capable of head-to-toe coverage without patient repositioning

Digital Flat Panel Detector:

Both detectors must be of latest versions or models from the Manufacturer under the required specifications at the time of procurement. (It is mandatory for the bidder to mention detector model in Technical Offer.)

11. Both detectors sizes 30x30 or 30x40cm, as per manufacturer production and if both are available with any manufacturer, then the smallest amongst these two sizes without compromising cardiac positions including steep angulation with close positioning of detector to patient body or smaller detector size 20x20cm (end user to specify).

Further Detector Specifications:

13. ASi / CsI / aSe Type (Bi – Plane)
12. Image matrix of 1024 x 1024 pixels or higher at minimum 14-bits depth for both detectors. Firms will offer their highest available pixels and bits at the time of procurement.
14. Standard cardiology Field of View (FOV) sizes: Three formats or more

16. Built in Temperature Stabilizer
17. Integrated Collision Protection / Collision Detection Technology
18. All other standard accessories according to this digital flat panel
19. Real time automatic filter selection based on patient body weight
20. Minimum spatial resolution 2.5 lp / mm
21. Minimum Pixel size of 200 um
22. Removable grid for Pediatric applications
23. Minimum DQE: More than 75% or better

Patient Support Table

24. Floor mounted, 8–ways horizontal floating top catheterization table with up/down, vertical, longitudinal, and transverse movements along with head tilt (Trendelenburg / reverse Trendelenburg) capability and pivoting

Further Table Specifications:

25. Minimum table length 280 cm with unobstructed image coverage
26. Longitudinal travel up to 1250 mm with tabletop movement
27. Lateral/Transverse Travel: 280 mm (± 140mm) or more
28. Vertical Travel/Horizontal: 90 – 105 cm from the floor or more
29. Motorized longitudinal and lateral/Transverse travel of patient support table/Stepping DSA feature
30. CPR should be possible in any table position
31. Touch Panel C Arm Controls should be available as table mounted controls in procedure room and in Control room as well.
32. Tabletop should be able to accept patients' weight of up to 200 kg plus 100 kg for resuscitation
33. Tabletop should be metal free (X – ray density < 2mm AI equivalent or better)
34. Complete accessories including arm holders, hand grips, arm supports / arm rests and positioning aids
34a. Patient head stabilizer, Arm and leg restraining belts/straps for neuro interventions.

X-Rays Generator:

Microprocessor based high frequency using fiber optics for data communication between each imaging system. (The bidder will mention the models in their Technical Offer.)

35. Dedicated X-Rays generator of 100 KW
36. Radiographic mA up to 1000
37. Radiographic kV 40 / 50 – 125 kVp
38. Serial filming exposures with shortest exposure of 1 ms with automatic KV and mA control for optimum image quality / high pulse Fluoro technology
39. Capability of digital radiography and fluoroscopy
40. Capability of doing multiple rate digital pulsed fluoroscopy and cine minimum 3.75 up to 30 fps
41. Capability to change frame rate during the same study

X-Rays Tube:

Tube must be of highest performance, latest version, model and series from the manufacturer, offering actual anode heat storage capacity of 3.7 MHU or more. (The bidder shall submit undertaking from the manufacturer in this regard). The bidder will mention the X-Ray Tube Model in their Technical Offer. Minimum 05-year unconditional warranty on the X – Ray Tube.

42. Two Tubes (One per plane, both with Liquid / Metal Bearing Technology)

34. Double / Triple focus with actual Anode Heat Storage Capacity of 3.7 MHU or more for un-interruptive long procedures

43. Anode Maximum Continuous Heat Dissipation: best maximum available cooling rate during serial exposure but not less than 500 KHU/min or 6.50 KW or better

44. Anode Small Focal Point: 0.3 – 0.5 or lower

45. Anode Large Focal Point: 0.8 – 1.0 mm or lower

46. Dose management with Fluoro filters range of 0.1 / 0.2 mm and 0.6 / 1.0 mm Cu or Real Time Automatic Filter selection based on patient body weight

47. State of art cooling system (As per Manufacturer's Design / Recommendations)

Radiation Reduction and Monitoring Systems:

35. AI Based Advanced radiation dose reduction & Image Enhancement features are mandatory like Alpha Evolve and DoseRite or Smart IQ/Clarity IQ or Optiq or Score Opera or AutoRight intelligent image chain. Latest technology being produced by each manufacturer in this category, at the time of tender should be quoted. Dose management and reduction / optimization to be done without image quality compromise. All parameter that are provided in hardware and software must be of latest version preferably with AI powered dose prediction capabilities.

48. Grid Pulsed / Physical Radiation Reduction System / Flat Emitter Technology / similar technology tubes with radiation dose management and with auto adjusting Fluoro filters

49. Dedicated X-Rays radiation dose monitoring and dose reduction software features of the latest variety provided by the manufacturer

50. Angulation dependent automatic exposure control including KV, mA, pulse width & focal spot adjustments

51. Automatic calculation and optimization of exposure data based on fluoroscopic data

52. Radiation free patient positioning without active Fluoro

53. Active radiation dose monitoring based on actual C – Arm angulations and table positions

54. Radiation Free Collimation

55. Real-time displays on main examination room monitor as well as control room monitor including cumulative Air Kerma display, cumulative Dose Area Product and Fluoro time

56. DAP threshold intimation / warning system

57. DICOM structured report containing patient, procedure, and dose data

High Resolution Digital Imaging and Acquisition / Fluoroscopy System with Real Time Image Processing:

36. Acquisition and Processing at 14 bits or more

37. Parallel processing capability / multitasking facility

58. Real time filtering and roadmap function

59. Magnetic disk capacity for storage of minimum 50,000 images in 1024 x 1024 x 12 bit or higher at the time of procurement on the magnetic disk of main console

60. Minimum scene length 10 seconds in 1024 matrix @ minimum 30 fps

61. Images storage and retrieval from archive disk for possible manipulation and quantification using available software packages (compatible format / bits)

Monitoring System:

62. Medical grade large display monitor in examination room, minimum 55" diagonal in size (Eizo or Barco), 8 Mega Pixels resolution along with Five 19" or larger medical grade monitors for backup to display live image, reference image, pressure tracing and ECG.

63. Large Primary Monitor mentioned above should at least be ceiling mounted with original ceiling suspension system

64. Four LCD / LED medical grade monitors for live images and road mapping in the control room, minimum 19" inch size

65. All 19" or larger Monitors should be Medical Graded, complied with International Standards for medical monitors as recommended by Manufacturer and all with the same brand

Controls:

66. Integrated table side touch screen/Touch Panel (Original from OEM of Angiography Machine) console to adjust system parameters, display setting of 55" monitor, frame rates, Hemodynamic system controls (Additional touch Screen console if required), quantitative analysis, stent enhancement soft-wares, Digital Subtraction Angiography (DSA), Mask- Unmask (Road-mapping) and Rotational Angiography

67. All controls of digital imaging system, measurements, post processing & quantifications analysis shall be in the control room as well as the examination room

68. Table side and Control room panels must have quantification and processing capabilities

69. The control panel can be mounted at any side of the Patient Table

Recording / Archiving & Communication System:

74. Recording / Archiving System should be DICOM – 3 Compatible

75. Digital images should be stored as backup on CDs / DVDs with incorporated original DICOM handling software / DICOM player from Original Manufacturer

76. DICOM (Send/store, commitment, retrieve / query)

77. PACS compatibility / integration

78. Compatibility to display of doppler ultrasound / echocardiography system images

79. Ethernet connection to connect with other terminals.

80. Integrated bi-directional intercom system for Cath Lab to Control Room (From Original Manufacturer)

Software Packages:

The bidders should quote their licensed software with part number in their Principal Offer. Complete analysis package for following cardiac applications should be included:

81. Dynamic pre and post PTCA / Valvotomy comparison with one image live and other reference

82. Automatic loops replay after acquisition or fluoroscopy

83. Dynamic real time pan / zoom

84. Dynamic real time digital imaging processing like edge enhancement or gamma correction, noise reduction (Spatial Filtration)

85. Online image density (Gray Scale) correction

86. Simultaneous display of fluoroscopy and reference images

87. Quantitative Coronary Analysis Software

88. Standard quantification packages for Left and right Ventricular Analysis

89. Facility to review previous studies in the examination room from the patients' old CD

90. Automatic positioning of the c-arm corresponding to reference image

91. Store Fluoro facility to store fluoroscopy

Dedicated Pediatric Features: (End-user to specify if needed)

92. Integrated Complete Licensed Pediatric Catheterization Reporting Software with Image Illustrator based on standard atlas tailored according to congenital heart defects (It should be able to import data and images from main Angiography System and overlay SpO2 and pressures over images automatically. It should also have a complete Hemodynamics Calculation Module.

93. Fusion software for 3D structure of CT / MRI image overlaying on 2D live Fluoro without cone beam CT

94. 3D reconstruction software for pulmonary arteries, coarctation of aorta and right ventricular outflow tract

95. Removable Grid on FPD.

96. Integrated power injector system.

Dedicated Adult Features:

97. Digital subtraction angiography package with manual / real time pixel shift for compensation of patient movement during acquisition

86. Image masking with real-time overlay of live Fluro along with Automatic System repositioning according to vessel mask location

98. Latest stent enhancement technology, being produced by each manufacturer in this category, at the time of tender, like, Dynamic device stabilizer (DDS) or PCI Assist 2 with Stent Viz or Stent boost Live or Stent View/ Score View Live or clear stent live with real time image enhancement with integrated table side control with touch panel are mandatory to quote.

Physiological Hemodynamic Monitoring System: (FDA 510K APPROVED)

99. Integrated Hemodynamic System from original manufacturer with full table side control having bi-directional communication with the machine for automatic / synchronized acquisition, transfer and display of patient Hemodynamic parameters and demographic data

100. Multichannel (16 channels or more) to record at least 4 channels IBP, Cardiac output with thermo dilution method, Surface ECG in any configuration and simultaneous 12 lead ECG, NIBP and SpO_2 measurements

Hemodynamic System Features:

101. Complete software for all Pediatric (if required by the end-user) & adult hemodynamic work including but not limited to right / left heart, Angio / Valvular Hemodynamic calculations such as gradients, valve areas, shunts including annotations and 12 channels ECG

102. Live Waveforms display on main 55" large monitor in the examination room

103. Digital display of all the parameters like IBP, Heart rate, cardiac output parameters

104. It should be possible to print the waveforms simultaneously while acquiring the data in the background

105. Capability to store the waveforms on the hard disk of the physiological recording system

106. Two Monitors in the control room, one for live waveforms and the other for control and data entry

107. Facility for freezing Hemodynamic data and simultaneous recovery of recent data / compare stored data with current waveform

108. Comprehensive Hemodynamics reporting including congenital heart chamber images

Dedicated Branded Workstation:

Hardware must be as per Original Manufacturer's Recommendations and Software should be from Original Manufacturer of Angiography System. Online workstation to review studies directly and the facility to review studies with lossless compression and original image quality as on console.

109. DICOM – 3 Compatible

110. Capable of universal DICOM support

111. Original DICOM handling software from the manufacturer with permanent license

112. Edge enhancement, adjustable view speeds & post processing capabilities

113. High-Definition Medical Grade LCD / LED monitor of minimum 19 inches size
114. CD / DVD writer and CD / DVD ROM Drive
115. Image storage capacity as per Manufacturer's approved hardware
116. SCSI or equivalent controller as per Manufacturer's approved hardware
117. Black & White Laser Printer
118. 3D reconstruction software package for congenital heart defects including aorta, pulmonary artery and RVOT supplied by the Principal Manufacturer. (End-user to specify the need.)

Review Stations for Auditorium/ Classroom / Doctor Office:

119. Branded review station with connectivity to main angiography machine including all necessary cabling / hardware for connectivity
120. LED Display (60" inch or End-user to specify) and high-resolution multimedia projector for view of live imaging

Radiation Protection Equipment / Accessories:

Must be FDA/MHLW/ CE approved.

121. Ceiling suspended tilt table lead glass(Should be supplied by the same manufacturer) for radiation protection of operator's head & neck regions and upper body parts
122. Table mounted adjustable lower body radiation shields / flaps on both sides
123. Lead glass window size 4 x 1 meter or larger lead equivalent 2.0 mm or better
124. Lead aprons (vest and skirt), double side with different sizes, light weight (4.5 kg or less in total), lead equivalent front 0.5 mm and back 0.35 mm with belts (FDA / CE approved) (Brand & sizes (End-User to specify), Quantity: 5 or more to be specified by the end user)
125. Lead aprons (single piece), double side with different sizes, light weight, lead equivalent front 0.5 mm and back 0.35 mm with belts. (FDA / CE approved) (Brand & sizes (End-User to specify), Quantity: 3 or more to be specified by the end user)
126. Wall Mounted / Trolley mounted hangers of S.S 304L for 5-10 lead aprons (To be supplied Locally) (Quantity: End-User To Specify)
127. Thyroid shields with lead caps. (FDA / CE approved) (Brand & sizes (End-User to specify), Quantity: 8 or more to be specified by the end user)
128. Lead Goggles: Light Weight (FDA / CE approved) (Brand & sizes (End-User to specify), Quantity: 5 or more to be specified by the end user)
129. Patient Protection Lead Sheet: Light weight having 30 inches in size
130. Personal Digital Dosimeters (Quantity: 5 or more to be specified by the end user)

Quality and Safety Standards:

131. For Angiography and Hemodynamics System, US FDA minimum 510K requirement is as under:

a) US FDA minimum 510k approved (Angiography Machine and Hemodynamic System for Adult)
b) The Equipment / Instrument / Applied parts shall conform to IEC – 60601 – 1 standard general requirement for basic safety and essential performance of medical electrical equipment
c) The System must comply with IEC – 60601 – 1 – 2 Electromagnetic Compatibility (EMC) collateral standard or equivalent for basic safety and essential performance in the presence of electromagnetic disturbances and electromagnetic disturbances emitted by that equipment and systems
d) Medical Graded Displays and Power Supplies

Operating Requirement:

132. Three phases with line voltage of 440 V & 50 Hz
133. Cabling for electrical power supply, generator & UPS connections
134. Cabling for proper earthing
135. Brand New and Latest Version 250 KVA or more true online sine wave Double conversion UPS for whole system with a minimum back up time of 10 minutes including room lights, microprocessor based IGBT technology. Display and alarms of parameters. Three phase line voltage of 220 50Hz with all necessary standard parts including dry batteries, unconditional 5 years warranty for UPS and UPS batteries

136. Brand New and Latest Version 320 KVA (Stand by) Electric Power Generator with ATS penal power cables and soundproof canopy (imported) set with automatic change over for complete load of Angiography Suite including Air conditioners, lights, and another load of Angiography suite (Engine: Perkins / Cummins, / Caterpillar / Volvo)

137. <u>Installation:</u>

a. Room preparations and Lead Shielding of the scan room (2-3mm) and doors (3-4mm) as per PNRA requirements with radiation/exposure indications
b. Vinyl Flooring: Complete vinyl flooring (Inside the rooms and corridors) including Self levelling (2-3mm) of Gerflor/ Tarket/Forbo
c. Wall Finishes: ACP Panels/ UV sheet/Polycarbonate on cement board/UPVC Panels on cement board and Printed Glass Panel on one wall
d. False Ceiling: Airtight suspended ceiling with specified durable material, antimicrobial coating, sealed joints to prevent air leaks and maintain pressure difference. Ceiling panels should be made of galvanized steel sheet 0.60mm-0. 80mm thick or better material. (Country of Manufacturer USA/Europe/Japan)
e. Peripheral Lights: Recessed type LED lights 65 W of Osaka/ Philips or equivalent brands
f. Power Cabling: Supplying, installation, and termination of cables between the Isolator/DB (provided by GC) and Equipment DB (provided by Vendor), as well as from the Equipment DB to UPS. and to all internal equipment/ services
g. Equipment DB with individual breakers for all equipment protection.
h. Installation of UPS, Cable trays/ trenches, Dedicated Earthing & Power outlets
i. Provision and installation of X-Ray Viewer. Recessed/ built in type, LED X-Ray viewer for 03 X-ray films. (Country of Manufacturer: USA/Europe/Japan)
j. Provision and installation of 1 x Automatic Sliding door with 3-4 mm lead shielding as per PNRA requirements. Size: 1500mm x 2100 mm approx. Door should be automatically hermetically sealed with electronic privacy glass and without contact buttons. Thickness 0.8mm or more stainless steel AISI-304/ AISI-301. Brushed finish or powder coated outer skin. 2 set of photocells in door frame along with infrared sensor at door drive level on inner and outer side of the door. (Country of Manufacturer USA/Europe/Japan)
k. Provision and installation of 2 x Single Hinged Doors with 3-4 mm lead shielding as per PNRA requirements. Size: 1000mm x 2100 mm approx. Stainless Steel/ Galvanized Steel Door fame and door panels (Country of Manufacturer USA/Europe/Japan)
l. Cooling requirements and air conditioning as per manufacturer recommendation
m. Provision and installation of medical gases outlets
n. 2 x Medical Cabinets having 4-5 adjustable shelves. Cabinets should be sealed with a hermetic removable silicone seal and provided with tempered glass. The doors should be made of double steel plates with glazing. Safe Glass, set in double steel sheet window frame. Imported/ Local (Subject to sample approval)
o. Provision and installation of Operator Console
p. Provision and installation of Scrub Sinks with Infrared Hand Free Operation and the provision of hot & cold faucet with mixer for temperature control with front wall mirror as per site requirement. Infrared Operated Soap and Disinfection Agent Dispenser for disinfecting agent, lotion, liquid soap, etc. (Country of Manufacturer: Imported)
q. Any other modification/ requirement and manufacturers recommendations in the existing site will be the responsibility of the firm.

Trainings:

138. One doctor's foreign attachment / training for one week (The Procuring Agency to specify)

139. One hospital Bio-Medical Engineer's comprehensive service training / attachment At manufacturer site for at least two weeks.

(Note: The Bio-Medical Engineer must be trained appropriately, so that at the time of verification and replacement of part / equipment, he / she can fully endorse without any ambiguity the need to replace the said part. For this the supplier will request the manufacturer to provide dongle to the Bio-Medical Engineer during training at manufacturer's site and later on access to it for needful.)

140. Company is bound to arrange foreign attachment of Doctor (if required) within 3 months after signing of contract

141. Company is bound to arrange foreign attachment of Bio-Medical Engineer within 3 months after signing of contract

142. Two technician's local training for two weeks

143. Three visits of application specialist with the last visit after commissioning of machine (Each visit of one-week duration)

Warranty:

144. The warranty period shall be for Five Years (Comprehensive) unconditional for all essential components /equipment to keep the machine functional including x-rays tube and flat panel detector, monitors, machine cables and connecting leads, diesel generator, UPS with batteries, Hemodynamic system, all consumables, all accessories (including probes etc.), non-proprietary items supplied with the machine with all specified parameters that shall cover labor and parts for all equipment

145. During the period of machine functioning before formal signing of installation report, rectification of errors or replacement of faulty parts shall be the responsibility of supplying firm without any financial implications or liabilities at the institute or End-users.

146. The warranty shall start from the date of installation report signing and handing over to end-User.

147. Manufacturer will submit undertaking to ensure availability of all spare parts and consumables over minimum of 10 years.

Post Warranty Service & Maintenance Contract:

148. The supplying firm shall be bound to enter into a comprehensive service contract with the institute for 05 years after the warranty period at a rate not more than 6% of C & F purchase value including all essential components / equipment to keep the machine functional such as x-rays tube and flat panel detector, monitors, machine cables and connecting leads, diesel generator, UPS with batteries, Hemodynamic system, all consumables, non-proprietary items supplied with the machine with all specified parameters that shall cover labor and parts for all equipment

149. Financial impact of post warranty service contract should be considered by the bidder while quoting the financial bid

Accessories:

Hemodynamic System Accessories:

- Complete 12 lead ECG Cables (Quantity to be specified by the End-user)
- NIBP cuffs (Neonate, Infant, Pediatric, Small Adult, Large Adult) (Quantity to be specified by the End-user)
- Thermo dilution catheters 5F 4 lumens (Quantity to be specified by the End-user)
- IBP Pressure Transducers (Quantity to be specified by the End-user)
- IBP Transducer Cables (Quantity to be specified by the End-user)
- Holder for mounting the IBP Transducer alongside patient table (Quantity to be specified by the End-user)
- DVD / CD writer for archiving of study data and waveform stored on hard disk independent of live Fluoro
- Portable Pulse Oximeter with probes (I.e., Pediatric, Adult Probes and Infant Probes) (Qty: 02)

Other Accessories:

- Crash Cart (Country of Origin: USA, EU & JAPAN) (The Procuring Agency to specify)
- Patient Shifting Trolley (Country of Origin: USA, EU & JAPAN) (Quantity to be specified by the End-user)
- Steel tray trolley for disposables, 6 x 3.5 feet 40 cm height (Quantity & Size to be specified by the End-user)
- ACT Machine (As per approved PVMS) (Quantity: 01 or more)
- Temporary Pacemaker (Single Chamber) (Quantity = 03) (As per approved PVMS) (More Quantity to be specified by the End-user)
- Programmable Portable Contrast Media Power Injector (Medrad, Angiomat, Medtrone, Nemoto, Guerbet) with disposable syringes (Quantity to be specified by the End-user)
- Bi-directional audio communication between Cath Lab and Auditorium / Office / Remote Place
- Portable Non-Invasive Hemodynamic (As per approved PVMS) / BP Monitor with built- in batteries
- Writeable CDs / DVDs (Quantity to be specified by the End-user)
- Defibrillator (Quantity to be specified by the End-user) (As per approved PVMS)
- ECG Machine (Quantity to be specified by the End-user) (As per approved PVMS)
- Dehumidifier
- Air Purifier (Specially for Air Sulphur) (It is strongly recommended that the Air Sulphur content, bacterial content, and other issues regarding the equipment which are essential for its better and long-term performance must be evaluated prior to installation by the winner of the bid.)
- Smoke Detector with Fire Extinguisher
- Intra-Aortic Balloon Pump Machine (As per approved PVMS) (Quantity to be specified by the End-user)
- Double Dome Surgical Light (Shadow Less) (As per approved PVMS)
- Operational & Service Manual

Optional (If any):

- For Dedicated Pediatric setup hemodynamic feature of angiography will be FDA approved (510k, bare minimum).

Optional Equipment:

- Intra-Aortic Balloon Pump Machine (As per approved PVMS) (Quantity to be specified by the End-user)
- CPAC interfaced (Images cross into reporting system with voice assistance capability)
- Wireless chargeable foot paddle
- Voice assisted software for reporting Purpose
- Dedicated Echocardiography System by the same manufacturer (As per approved PVMS) (Quantity to be specified by the End-user)
- Ventilator with compressor and humidifier (As per approved PVMS) (Quantity to be specified by the End-user)
- Hemodynamic System compatible with EP functionality (Quantity to be specified by the End-user)
- Auto Injector set-up (FDA or CE mark or as specified by end-user)
- Whole Blood Oximeter with cartridges / without cartridges
- Co-registration / Integration of Cardiac CT
- Co-registration / Integration of Intra-Vascular Ultrasound (IVUS)

Optional Features:

- High resolution Cone Beam CT (CBCT) capability integrated into angiography system for neuroimaging.

General Instructions

- "Optional Items / Features" may be included in the tender specifications as per requirements of procuring institute. Specifications of items mentioned under headings "Optional Items" and "Allied accessories" will be as per approved PVMS if available, whereas certifications (FDA, CE & MHLW) will be decided by Procuring Agency. Bidders may quote against respective items, however, non-quoting or not meeting the required specifications for these items would not be a reason to reject / disqualify a bid. The Procuring Agency / Institute may procure optional items if sufficient funds are available post financial bid.
- Bidder will be bound to provide undertaking from the manufacturer that in case the local distributor gets changed during the mentioned warranty or service contract period, the new authorized distributor on behalf of the Principal Manufacturer or Principal manufacturer himself will own the warranty, backup services, replacement of parts and all pending liabilities. Bidder will be bound to provide undertaking from the manufacturer to ensure availability of all spare parts and consumables over minimum of 10 years.

Safety Standard:

Must conform to the requirements of ISO 13485:2016 version or above.

Clinical Specialty	**Cardiology**
Generic Name	**MONOPLANE ANGIOGRAPHY MACHINE WITH HYBRID OR**
Clinical Purpose	High Performance, Latest model AI Powered/ Automated Advance Function, Angiography Machine is intended to perform diagnostic, Structural, Endo Vascular and complicated therapeutic procedures at maximum available image acquisition and display capabilities for adult and Pediatric national leading institutes. This equipment must have ability for extended acquisition duration without compromising quality and able to be converted into Operation Room to perform Hybrid Procedures and open-heart surgery in case of complications or other indications.

TECHNICAL SPECIFICATIONS

A fully digital flat Single Plane Cardiac Angiography / Cardiac Catheterization System dedicated for Pediatric and Adult diagnostic as well as interventional cardiac procedures. Capable of head-to-toe coverage without repositioning of patient. Companies shall offer their latest and top of the line internationally available systems and applications at the time of tender with best resolution and minimum possible radiation dose. This equipment has to be according to best possible manufacturing standards in all categories by that company. No justification of any less is acceptable.

Positioning Arm:

1. The positioning placement of the arm (Floor/Ceiling) (End User to specify) reflects on the capacity and capability of the equipment

Geometry:

2. Motorized digital flat panel system with smart collision detector
3. Rotation Range (Degrees): ROA / LAO +/- 105° or more
4. Cranial / Caudal: Minimum +/- 45°
5. Rotational Angiography Speed: 40° / sec or more in LAO to RAO or vice versa; 18° / sec or more for AP Cranial to AP Caudal or vice versa (The manufacturer must supply the best possible, currently available options.)
6. Source to Image Distance (SID) Range: 95 – 105 cm or wider (PA / Lateral)
7. Iso-Centric Height: Variable / Fixed
8. Auto Positioning: Programmable auto positioning of selected angulations, (45 or more) programmable positions
9. All rotational angles should be digitally displayed on the monitor
10. Motorized / manual parking & rotation of the positioning arm, capable of head-to-toe coverage without patient repositioning

Digital Flat Panel Detector:

Detector must be latest version or model from the Manufacturer at the time of procurement. (It is mandatory for the bidder to mention detector model in technical offer)

11. Detector size 30x30 or 30x40cm, as per manufacturer production and if both are available with any manufacturer, then the smallest amongst these two sizes without compromising cardiac positions including steep angulation with close positioning of detector to patient body or smaller detector size 20x20cm (end user to specify).

Further Detector Specifications:

12. ASi / CsI / aSe Type
13. Image matrix of 1024 x 1024 pixels or higher at minimum 14-bits depth for detector. Firms will offer their highest available pixels and bits at the time of procurement.
14. Standard Cardiology Field of View (FOV) sizes: Three formats or more
15. Built in temperature stabilizer
16. Integrated Collision Protection / Collision Detection Technology

17. All other standard accessories according to this digital flat panel
18. Minimum Spatial Resolution: 2.5 lp / mm or more.
19. Minimum Pixel Size: 200 µm or less
20. Removable grid for Pediatric applications
21. Minimum Detector / Detective Quantum Efficiency (DQE): More than 75 % or better

Patient Support Table:

22. Floor mounted, 8 – ways horizontal floating top catheterization table with up / down, vertical, longitudinal, and transverse movements along with head tilt (Trendelenburg / reverse Trendelenburg) capability and pivoting.

Further Table Specifications:

23. Minimum table length 280 cm
24. Longitudinal Travel: 1100 mm with tabletop movement or more
25. Lateral/Transverse Travel: 280 mm (± 140mm) or more
26. Vertical Travel/Horizontal: 90 – 105 cm from the floor or more
27. Motorized longitudinal and lateral/Transverse travel of patient support table/Stepping DSA feature
28. CPR should be possible in any table position
29. Touch Panel C Arm Controls should be available as table mounted controls in procedure room and in Control room as well.
30. Tabletop should be able to accept patients' weight of up to 200 kg plus 100 kg for resuscitation
31. Tabletop should be metal free (X – ray density < 2mm AI equivalent or better)
32. Complete accessories including arm holders, hand grips, arm supports / arm rests and positioning aids
32a.Patient head stabilizer, Arm and leg restraining belts/straps for neuro interventions.

X-Rays Generator:

Microprocessor based high frequency using fiber optics for data communication between each imaging system (The bidder will mention the models in their technical offer)

33. Dedicated X-Rays generator of 100 KW
34. Radiographic mA up to 1,000
35. Radiographic kV 40 / 50 – 125 kVp
36. Serial filming exposures with shortest exposure of 1 ms with automatic KV and mA control for optimum image quality/High Pulse Fluoro
37. Capability of digital radiography and fluoroscopy
38. Capability of doing multiple rate digital pulsed fluoroscopy and cine at range of 3.75 to 30 fps
39. Capability to change frame rate during the same study

X-Rays Tube:

Tube must be of highest performance, latest version, model and series from the manufacturer offering actual anode heat storage capacity of 3.7 MHU or more. (The bidder shall submit undertaking from the manufacturer in this regard). The bidder will mention the X-Ray Tube Model in their Technical Offer. Minimum 05year unconditional warranty on the X – Ray Tube.

40. Tube (Liquid / Metal Bearing Technology)
41. Double / Triple focus with actual Anode Heat Storage Capacity of 3.7 MHU or more for un-interruptive long procedures
42. Anode Maximum Continuous Heat Dissipation: best maximum available cooling rate during serial exposure but not less than 500 KHU/min or 6.50 KW or better
43. Anode Small Focal Point: 0.3 – 0.5 or lower

44. Anode Large Focal Point: 0.8 – 1.0 mm or lower

45. Dose management with Fluoro filters range of 0.1 / 0.2 mm and 0.6 / 1.0 mm Cu or Real Time Automatic Filter selection based on patient body weight

46. State of art cooling system (As per Manufacturer's Design / Recommendations)

Radiation Reduction and Monitoring Systems:

47. AI Based Advanced radiation dose reduction & Image Enhancement features are mandatory like Alpha Evolve and DoseRite or Smart IQ/Clarity IQ or Optiq or Score Opera or AutoRight intelligent image chain. Latest technology being produced by each manufacturer in this category, at the time of tender should be quoted. Dose management and reduction / optimization to be done without image quality compromise. All parameter that are provided in hardware and software must be of latest version preferably with AI powered dose prediction capabilities.

48. Grid Pulsed / Physical Radiation Reduction System / Flat Emitter Technology / similar technology tubes with radiation dose management and with auto adjusting Fluoro filters

49. Dedicated X-Rays radiation dose monitoring and dose reduction software features of the latest variety provided by the manufacturer

50. Angulation dependent automatic exposure control including KV, mA, pulse width & focal spot adjustments

51. Automatic calculation and optimization of exposure data based on fluoroscopic data

52. Radiation free patient positioning without active Fluoro

53. Active radiation dose monitoring based on actual C-arm angulations and table positions

54. Radiation Free Collimation

55. Real-time displays on main examination room monitor as well as control room monitor including cumulative Air Kerma display, cumulative Dose Area Product and Fluoro time

56. DAP threshold intimation / warning system

57. DICOM structured report containing patient, procedure, and dose data

High Resolution Digital Imaging and Acquisition / Fluoroscopy System with Real Time Image Processing:

58. Acquisition and Processing at 14 bits or more.

59. Parallel processing capability / multitasking facility

60. Real time filtering and roadmap function

61. Magnetic disk capacity for storage of minimum 50,000 images in 1024 x 1024 x 12 bit on the magnetic disk of main console or highest at the time of tender

62. Minimum Cine Length: 10 seconds in 1024 matrix @ minimum 30 fps

63. Images storage and retrieval from archive disk for possible manipulation and quantification using available software packages (compatible format / bits)

Monitoring System:

64. Medical grade large display monitor in examination room, minimum 55" diagonal in size (Make: Eizo or Barco), 8 Mega Pixels resolution along with two or three 19" or larger medical grade monitors for backup to display live image, reference image and pressure tracing and ECG

65. Large Primary Monitor mentioned above should at least be ceiling mounted with original ceiling suspension system

66. Three LCD / LED medical grade monitors for live images, road mapping and hemodynamic system control in the control room, minimum 19" inch diagonal or larger size

67. All 19" or larger Monitors should be Medical Graded, complied with International Standards for medical monitors as recommended by Manufacturer and all with the same brand

Controls:

68. Integrated table side touch screen/Touch Panel (Original from OEM of Angiography Machine) console to adjust system parameters, display setting of 55" monitor, frame rates, Hemodynamic system controls (Additional touch Screen console if required), quantitative analysis, stent enhancement soft-wares, Digital Subtraction Angiography (DSA), Mask- Unmask (Road-mapping) and Rotational Angiography

69. All controls of digital imaging system, measurements, post processing & quantifications analysis shall be in the control room as well as the examination room

70. Table side and Control room panels must have quantification and processing capabilities. C-Arm and table Movement can be controlled from control room.

71. The control panel can be mounted at any side of the Patient Table

Recording / Archiving & Communication System:

72. Recording / archiving system should be DICOM – 3Compatible

73. Digital images should be stored as backup on CDs / DVDs with incorporated original DICOM handling software / DICOM player from original manufacturer

74. DICOM (Send / store, commitment, retrieve / query)

75. PACS compatibility / integration

76. Ethernet connection to connect with other terminals

77. Integrated bi-directional intercom system for Cath lab to control room (From Original Manufacturer).

Software Packages:

The bidders should quote their licensed software with part number in their principal offer.
Complete analysis package for following cardiac applications should be included:

78. Dynamic pre and post PTCA / Valvotomy comparison with one image live and other reference

79. Automatic loops replay after acquisition or fluoroscopy

80. Dynamic real time pan / zoom

81. Dynamic real time digital imaging processing like edge enhancement or gamma correction, noise reduction (spatial filtration)

82. Online image density (gray scale) correction

84. Simultaneous display of fluoroscopy and reference images

85. Standard quantification packages for Left Ventricular Analysis

86. Facility to review previous studies in the examination room from the patients' old CD

87. Automatic positioning of the c-arm corresponding to reference image

88. Quantitative Coronary Analysis Software

89. Store Fluoro facility to store last fluoroscopy run

90. Integrated Complete Licensed Pediatric Catheterization Reporting Software with Image Illustrator based on standard atlas tailored according to congenital heart defects (It should be able to import data and images from main Angiography System and overlay SpO_2 and pressures over images automatically. It should also have a complete Hemodynamics Calculation Module.

Dedicated Adult Features:

91. Digital subtraction angiography package with manual / real time pixel shift for compensation of patient movement during acquisition

92. Image masking with real-time overlay of live Fluro along with Automatic System repositioning according to vessel mask location

93. Latest stent enhancement technology, being produced by each manufacturer in this category, at the time of tender, like, Dynamic device stabilizer (DDS) or PCI Assist 2 including Stent Viz or Stent boost Live or Stent View/ Score View Live or clear stent live with real time image enhancement with integrated table side control with touch panel are mandatory to quote.

94. Integrated power injector

Dedicated Pediatric Features: (End-user to specify if needed)

95. Fusion software for 3D structure of CT image overlaying on 2D live Fluoro without cone beam CT

96. 3D reconstruction software for pulmonary arteries, coarctation of aorta and right ventricular outflow tract Angiography machine need integrated inbuilt hemodynamic system with sustainable mean pressure

97. Physiological Hemodynamic Monitoring System: (FDA 510K approved)

98. Integrated Hemodynamic System from the original manufacturer with full table side control having bi-directional communication with the machine for automatic / synchronized acquisition, transfer and display of patient Hemodynamic parameters and demographic data.

99. Multichannel (16 channels or more) to record at least 4 channels IBP, Cardiac output with thermo dilution method, Surface ECG in any configuration and simultaneous 12 lead ECG, NIBP and SpO_2 measurements

OR

Electrophysiology compatible Multichannel (64 – channels or more) Hemodynamic System (End-user to specify the need)

Hemodynamic System Features:

100. Complete software for all Pediatric & adult hemodynamic work including but not limited to right / left heart, Angio / Valvular Hemodynamic calculations such as gradients, valve areas, shunts including annotations and 12 channels ECG

101. Live Waveforms display on main monitor in the examination room

102. Digital display of all the parameters like IBP, Heart rate, cardiac output parameters

103. Possibility to print the waveforms simultaneously while acquiring the data in the background

104. Capability to store the waveforms on the hard disk of the physiological recording system

105. Two Monitors in the control room, one for live waveforms and the other for control and data entry

106. Facility for freezing Hemodynamic data and simultaneous recovery of recent data/ compare stored data with current waveform

Dedicated Branded Workstation:

Hardware must be as per Manufacturer's Recommendations & Software should be from Original Manufacturer of Angiography System. Online workstation to review studies directly and the facility to review studies with lossless compression and original image quality as on console.

107. DICOM – 3 Compatible

108. Capable of universal DICOM support

109. Original DICOM handling software from the manufacturer with permanent license

110. Edge enhancement, adjustable view speeds & post processing capabilities

111. High-Definition Medical Graded LCD / LED monitor of minimum 19 inches size
112. CD / DVD writer and CD / DVD ROM Drive
113. Image storage capacity as per Manufacturer's approved hardware
114. SCSI or equivalent controller as per Manufacturer's approved hardware
115. Black & white laser printer
116. 3D reconstruction software package for congenital heart defects including aorta, pulmonary artery and RVOT supplied by the principal manufacturer. (End-user to specify the need.)

Review Stations for Auditorium / Classroom/ Doctor Office:

117. Branded review station with connectivity to main angiography machine including all necessary cabling / hardware for connectivity
118. LED Display (60" inch) and high-resolution multimedia projector for view of live imaging

Radiation Protection Equipment / Accessories:

Must be FDA / MHLW/ CE approved.

119. Ceiling suspended tilt table lead glass (Should be supplied by the same manufacturer) for radiation protection of operator's head & neck regions and upper body parts.
120. Table mounted adjustable lower body radiation shields / flaps on both sides
121. Lead glass window size 4 x 1 meter or larger lead equivalent 2.0 mm or better
122. Lead aprons (vest and skirt), double side with different sizes, light weight (4.5 kg or less in total), lead equivalent front 0.5 mm and back 0.35 mm with belts (FDA / CE approved) (Brand & sizes (End-User to specify), Quantity: 7 or more to be specified by the end-user)
123. Lead aprons (single piece), double side with different sizes, light weight, lead equivalent front 0.5 mm and back 0.35 mm with belts. (FDA / CE approved) (Brand & sizes (End-User to specify), Quantity: 7 or more to be specified by the end-user)
124. Wall Mounted / Trolley mounted hangers of S.S 304L for 5-10 lead aprons (To be supplied Locally) (Quantity: End-User To Specify)
125. Thyroid shields with lead caps. (FDA / CE approved) (Brand & sizes (End-User to specify), Quantity: 08 or more to be specified by the end-user)
126. Lead Goggles: Light Weight (FDA / CE approved) (Brand & sizes (End-User to specify), Quantity: 08 or more to be specified by the end-user)
127. Patient Protection Lead Sheet: Light weight having 30 inches in size
128. Digital Dosimeters (Quantity: 05 or more to be specified by the end-user)

Quality and Safety Standards:

129. For Angiography and Hemodynamics System, US FDA minimum 510K requirement is as under:

a) US FDA minimum 510K approved (Adult Angiography and Hemodynamic System for both Adult and Pediatric)
b) The Equipment / Instrument / Applied parts shall conform to IEC – 60601 – 1 standard general requirement for basic safety and essential performance of medical electrical equipment
c) The System must comply with IEC – 60601 – 1 – 2 Electromagnetic Compatibility (EMC) collateral standard or equivalent for basic safety and essential performance in the presence of electromagnetic disturbances and electromagnetic disturbances emitted by that equipment and systems
d) Medical Graded Displays and Power Supplies

Operating Requirements:

130. Three phases with line voltage of 440 V & 50 Hz
131. Cabling for electrical power supply, generator & UPS connections

132. Cabling for proper earthing

133. Minimum two cameras, one at foot end of patient and one in-front of operators with 32 Inch LED screen for display in cath lab. Port should be given for transmission online and to conference room

134. Brand New and Latest Version 250 KVA or more true online sine wave Double conversion UPS for whole system with a minimum back up time of 10 minutes including room lights, microprocessor based IGBT technology. Display and alarms of parameters.

Three phase line voltage of 220 50 Hz with all necessary standard parts including dry batteries, unconditional 5 years warranty for UPS and UPS batteries

135. Brand New and Latest Version 320 KVA (Stand by) Electric Power Generator with ATS penal power cables and soundproof canopy (imported) set with automatic change over for complete load of Angiography Suite including Air conditioners, lights, and another load of Angiography suite (Engine: Perkins / Cummins / Caterpillar / Volvo)

136. Installation:

a. Room preparations and Lead Shielding of the scan room (2-3mm) and doors (3-4mm) as per PNRA requirements with radiation/exposure indications
b. Vinyl Flooring: Complete vinyl flooring (Inside the rooms and corridors) including Self levelling (2-3mm) of Gerflor/ Tarket/Forbo
c. Wall Finishes: ACP Panels/ UV sheet/Polycarbonate on cement board/UPVC Panels on cement board and Printed Glass Panel on one wall
d. False Ceiling: Airtight suspended ceiling with specified durable material, antimicrobial coating, sealed joints to prevent air leaks and maintain pressure difference. Ceiling panels should be made of galvanized steel sheet 0.60mm-0. 80mm thick or better material. (Country of Manufacturer USA/Europe/Japan)
e. Peripheral Lights: Recessed type LED lights 65 W of Osaka/ Philips or equivalent Brands Power Cabling: Supplying, installation, and termination of cables between the Isolator/DB (provided by GC) and Equipment DB (provided by Vendor), as well as from the Equipment DB to UPS. and to all internal equipment/ services
g. Equipment DB with individual breakers for all equipment protection.
h. Installation of UPS, Cable trays/ trenches, Dedicated Earthing & Power outlets
i. Provision and installation of X-Ray Viewer. Recessed/ built in type, LED X-Ray viewer for 03 X-ray films. (Country of Manufacturer: USA/Europe/Japan)
j. Provision and installation of 1 x Automatic Sliding door with 3-4 mm lead shielding as per PNRA requirements. Size: 1500mm x 2100 mm approx. Door should be automatically hermetically sealed with electronic privacy glass and without contact buttons. Thickness 0.8mm or more stainless steel AISI-304/ AISI-301. Brushed finish or powder coated outer skin. 2 set of photocells in door frame along with infrared sensor at door drive level on inner and outer side of the door.(Country of Manufacturer USA/Europe/Japan)
k. Provision and installation of 2 x Single Hinged Doors with 3-4 mm lead shielding as per PNRA requirements. Size: 1000mm x 2100 mm approx. Stainless Steel/ Galvanized Steel Door fame and door panels (Country of Manufacturer USA/Europe/Japan)
l. Cooling requirements and air conditioning as per manufacturer recommendation
m. Provision and installation of medical gases outlets
n. 2 x Medical Cabinets having 4-5 adjustable shelves. Cabinets should be sealed with a hermetic removable silicone seal and provided with tempered glass. The doors should be made of double steel plates with glazing. Safe Glass, set in double steel sheet window frame. Imported/ Local (Subject to sample approval)
o. Provision and installation of Operator Console
p. Provision and installation of Scrub Sinks with Infrared Hand Free Operation and the provision of hot & cold faucet with mixer for temperature control with front wall mirror as per site requirement. Infrared Operated Soap and Disinfection Agent Dispenser for disinfecting agent, lotion, liquid soap, etc. (Country of Manufacturer: Imported)

q. Any other modification/ requirement and manufacturers recommendations in the existing site will be the responsibility of the firm.

Trainings:

137. One doctor's foreign attachment / training for one week (The Procuring Agency to specify)

138. One hospital Bio-Medical Engineer's comprehensive service training / attachment at manufacturer site for at least one week.

(Note: The Bio-Medical Engineer must be trained appropriately, so that at the time of verification and replacement of part / equipment, he / she can fully endorse without any ambiguity the need to replace the said part. For this the supplier will request the manufacturer to provide dongle to the Bio-Medical Engineer during training at manufacturer's site and later on access to it for needful.)

139. Two technician's local training for two weeks

140. Three visits of application specialist with the last visit after commissioning of machine (Each visit of one-week duration)

Warranty:

141. The warranty period shall be for Five Years (Comprehensive) unconditional for all essential components /equipment to keep the machine functional including x-rays tube and flat panel detector, monitors, machine cables and connecting leads, diesel generator, UPS with batteries, Hemodynamic system, all consumables, all accessories (including probes etc.), non-proprietary items supplied with the machine with all specified parameters that shall cover labor and parts for all equipment

142. During the period of machine functioning before formal signing of installation report, rectification of errors or replacement of faulty parts shall be the responsibility of supplying firm without any financial implications or liabilities at the institute or End-users.

143. The warranty shall start from the date of installation report signing and handing over to end-User.

Post Warranty Service & Maintenance Contract:

144. The supplying firm shall be bound to enter into a comprehensive service contract with the institute for 05 years after the warranty period at a rate not more than 6% of C & F purchase value including all essential components / equipment to keep the machine functional such as x-rays tube and flat panel detector, monitors, machine cables and connecting leads, diesel generator, UPS with batteries, Hemodynamic system, all consumables, non-proprietary items supplied with the machine with all specified parameters that shall cover labor and parts for all equipment (C & F)

145. Financial impact of post warranty service contract should be considered by the bidder while quoting the financial bid

Accessories:

Hemodynamic System Accessories:

- Complete 12 lead ECG Cables (Quantity: 05)
- NIBP cuffs (Neonate,Infant, Pediatric, Small Adult, Large Adult) (Quantity to be specified by the End-user)
- Thermo dilution catheters 5F 4 lumens (Quantity to be specified by the End-user)
- IBP Pressure Transducers (Quantity to be specified by the End-user)
- IBP Transducer Cables (Quantity to be specified by the End-user)
- Holder for mounting the IBP Transducer alongside patient table (Quantity to be specified by the End-user)
- DVD / CD writer for archiving of study data and waveform stored on hard disk independent of live Fluoro
- Portable Pulse Oximeter with probes (I.e., Pediatric, Adult Probes and Infant Probes) (Qty: 02)

Other Accessories:

- Crash Cart (Country of Origin: USA, EU & JAPAN) (The Procuring Agency to specify)
- Patient Shifting Trolley (Country of Origin: USA, EU & JAPAN) (Quantity to be specified by the End-user)
- Steel tray trolley for disposables, 6 x 3.5 feet 40 cm height(Quantity & Size to be specified by the End-user)
- ACT Machine (As per approved PVMS) (Quantity: 02 or more)
- Temporary Pacemaker (Single Chamber) (Quantity = 03) (As per approved PVMS) (More Quantity to be specified by the End-user)
- Programmable Portable Contrast Media auto Power Injector (Medrad, Angiomat, Medtrone, Nemoto, Guerbet) with disposable syringes (Quantity to be specified by the End-user)
- Auto-injecor set-up(FDA or CE marked or as specified by enduser)
- Bi-directional audio communication between Cath Lab and Auditorium / Office / Remote Place
- Portable Non-Invasive Hemodynamic (As per approved PVMS) / BP Monitor with built-in batteries
- Writeable CDs / DVDs (Quantity to be specified by the End-user)
- Defibrillator (Quantity to be specified by the End-user) (As per approved PVMS)
- ECG Machine (Quantity to be specified by the End-user) (As per approved PVMS)
- Dehumidifier
- Air Purifier (Specially for Air Sulphur) (It is strongly recommended that the Air Sulphur content, bacterial content, and other issues regarding the equipment which are essential for its better and long-term performance must be evaluated prior to installation by the winner of the bid.)
- Smoke Detector with Fire Extinguisher
- Intra-Aortic Balloon Pump Machine (As per approved PVMS) (Quantity to be specified by the End-user)
- Double Dome Surgical Light (Shadow-Less) (As per approved PVMS)
- Dedicated High-End Echocardiography System by the same manufacturer (As per approved PVMS) (Quantity to be specified by the End-user)
- Ventilator with compressor and humidifier (As per approved PVMS) (Quantity to be specified by the End-user)
- Anesthesia Machine built-in ventilator with one Vaporizer and Non-Invasive Cardiac Monitor / Invasive Cardiac Monitor (As per approved PVMS) (Quantity to be specified by the End-user)
- Heart Lung Machine with complete accessories (As per approved PVMS) (Quantity to be specified by the End-user).
- Operational & Service Manual

Mandatory Equipment's/Features:

- Co-registration / Integration of Cardiac CT
- Co-registration / Integration of Echocardiography
- Co-registration / Integration of Intra-Vascular Ultrasound (IVUS)
- Dedicated application for planning and performing structural heart procedures including TAVI

Optional (If any):

Optional Equipment:

- Co-registration / Integration of OCT
- Co-registration / Integration of FFR
- Rampart/Cathpax Radiation Protection System
- CPAC interfaced (Images cross into reporting system with voice assistance capability)
- Wireless chargeable foot paddle
- Hemodynamic System compatible with EP functionality (Quantity to be specified by the End-user)
- Head Up Tilt Table (HUTT) System for autonomic functions (As per approved PVMS) (Quantity to be specified by the End-user)

- Whole Blood Oximeter with cartridges / without cartridges
- Voice Assisted Software for reporting Purpose

Optional Features:

- 3D Rotational Angiography System (Latest software version by the company)
- High resolution Cone Beam CT (CBCT) capability integrated into angiography system for neuroimaging.

General Instructions

- "Optional Items / Features" may be included in the tender specifications as per requirements of procuring institute. Specifications of items mentioned under headings "Optional Items" and "Allied accessories" will be as per approved PVMS if available, whereas certifications (FDA, CE & MHLW) will be decided by Procuring Agency. Bidders may quote against respective items, however, non-quoting or not meeting the required specifications for these items would not be a reason to reject / disqualify a bid. The Procuring Agency / Institute may procure optional items if sufficient funds are available post financial bid.
- Bidder will be bound to provide undertaking from the manufacturer that in case the local distributor gets changed during the mentioned warranty or service contract period, the new authorized distributor on behalf of the Principal Manufacturer or Principal manufacturer himself will own the warranty, backup services, replacement of parts and all pending liabilities.
- Bidder will be bound to provide undertaking from the manufacturer to ensure availability of all spare parts and consumables over minimum of 10 years.

Safety Standard:

- Must conform to the requirements of ISO 13485:2016 version or above

Clinical Specialty	**Cardiology**
Generic Name	**Monoplane Angiography Machine with Additional Features**
Clinical Purpose	High Performance, Latest model AI powered/ Automated Advance Function, Angiography Machine is intended to perform diagnostic and complicated therapeutic procedures including CHIP PCIs, endovascular interventions at maximum available image acquisition and display capabilities for adult and Pediatric national leading institutes. This equipment must have ability for extended acquisition duration without compromising quality.

TECHNICAL SPECIFICATIONS

A fully digital flat Single Plane Cardiac Angiography / Cardiac Catheterization System dedicated for Pediatric and Adult diagnostic as well as interventional cardiac procedures. Capable of head-to-toe coverage without repositioning of patient. Companies shall offer their latest and top of the line internationally available systems and applications at the time of tender, with best resolution and minimum possible radiation dose. This equipment has to be best possible manufacturing standards in all categories by that company. No justification of any less is acceptable.

Positioning Arm:

1. The positioning placement of the arm (Floor/Ceiling) reflects on the capacity and capability of the equipment (End User to specify).

Geometry:

2. Motorized digital flat panel system with smart collision detector
3. Rotation Range (Degrees): ROA / LAO +/- 105° or more
4. Cranial / Caudal: Minimum +/- 45°
5. Rotational Angiography Speed: 40° / sec or more in LAO to RAO or vice versa; 18° / sec or more for AP Cranial to AP Caudal or vice versa (The manufacturer must supply the best possible, currently available options.)
6. Source to Image Distance (SID) Range: 95 – 105 cm or wider (PA / Lateral)
7. Iso-Centric Height: Variable / Fixed
8. Auto Positioning: Programmable auto positioning of selected angulations.
9. All rotational angles should be digitally displayed on the monitor
10. Motorized / manual parking & rotation of the positioning arm, capable of head-to-toe coverage without patient repositioning

Digital Flat Panel Detector:

Detector must be latest version or model from the Manufacturer at the time of procurement. (It is mandatory for the bidder to mention detector model in technical offer)

11. Detector size 30x30 or 30x40cm, as per manufacturer production and if both are available with any manufacturer, then the smallest amongst these two sizes without compromising cardiac positions including steep angulation with close positioning of detector to patient body or smaller detector size 20x20cm (end user to specify).

Further Detector Specifications:

12. ASi / CsI / aSe Type
13. Image matrix of 1024 x 1024 pixels or higher at minimum 14-bits depth for detector. Firms will offer their highest available pixels and bits at the time of procurement.
14. Standard Cardiology Field of View (FOV) sizes: Three formats or more
15. Built in temperature stabilizer
16. Integrated Collision Protection / Collision Detection Technology
17. All other standard accessories according to this digital flat panel

18. Minimum Spatial Resolution: 2.5 lp / mm or more.
19. Minimum Pixel Size: 200 µm or less
20. Removable grid for Pediatric applications
21. Minimum Detector / Detective Quantum Efficiency (DQE): More than 75 % or better

Patient Support Table:

22. Floor mounted, 8 – ways horizontal floating top catheterization table with up / down, vertical, longitudinal and transverse movements along with head tilt (Trendelenburg / reverse Trendelenburg) capability and pivoting

Further Table Specifications:

23. Minimum table length 280 cm or more
24. Longitudinal Travel: 1100 mm with tabletop movement or more
25. Lateral/Transverse Travel: 280 mm (± 140mm) or more
26. Vertical/Horizontal Travel: 90 – 105 cm from the floor or more
27. Motorized longitudinal and lateral/Transverse travel of patient support table / Stepping DSA feature
28. CPR should be possible in any table position
29. Touch Panel C Arm Controls should be available as table mounted controls in procedure room and in Control room as well.
30. Tabletop should be able to accept patients' weight of up to 200 kg plus 100 kg for resuscitation
31. Tabletop should be metal free (X – ray density < 2mm AI equivalent or better)
32. Complete accessories including arm holders, hand grips, arm supports / arm rests and positioning aids
32a. Patient head stabilizer, Arm and leg restraining belts/straps for neuro interventions.

X-Rays Generator:

Microprocessor based high frequency using fiber optics for data communication between each imaging system (The bidder will mention the models in their technical offer)

33. Dedicated X-Rays generator of 100 KW
34. Radiographic mA up to 1,000
35. Radiographic kV 40 / 50 – 125 kVp
36. Serial filming exposures with shortest exposure of 1 ms with automatic KV and mA control for optimum image quality/High Pulse Fluoro Technology
37. Capability of digital radiography and fluoroscopy
38. Capability of doing multiple rate digital pulsed fluoroscopy and cine at range of 3.75 to 30 fps
39. Capability to change frame rate during the same study

X-Rays Tube:

Tube must be of highest performance, latest version, model and series from the manufacturer offering actual anode heat storage capacity of 5 MHU or more. (The bidder shall submit undertaking from the manufacturer in this regard). The bidder will mention the X-Ray Tube Model in their Technical Offer. Minimum 05year unconditional warranty on the X – Ray Tube.

40. Tube (Liquid / Metal Bearing Technology)
41. Double / Triple focus with actual Anode Heat Storage Capacity of 5 MHU or more for un-interruptive long procedures
42. Anode Maximum Continuous Heat Dissipation: best maximum available cooling rate during serial exposure but not less than 500 KHU/min or 6.50 KW or better
43. Anode Small Focal Point: 0.3 – 0.5 or lower
44. Anode Large Focal Point: 0.8 – 1.0 mm or lower

45. Dose management with Fluoro filters range of 0.1 / 0.2 mm and 0.6 / 1.0 mm Cu or Real Time Automatic Filter selection based on patient body weight

46. State of art cooling system (As per Manufacturer's Design / Recommendations)

Radiation Reduction and Monitoring Systems:

47. AI Based Advanced radiation dose reduction & Image Enhancement features are mandatory like Alpha Evolve and DoseRite or Smart IQ/Clarity IQ or Optiq or Score Opera or AutoRight intelligent image chain. Latest technology being produced by each manufacturer in this category, at the time of tender should be quoted. Dose management and reduction / optimization to be done without image quality compromise. All parameter that are provided in hardware and software must be of latest version preferably with AI powered dose prediction capabilities.

48. Grid Pulsed / Physical Radiation Reduction System / Flat Emitter Technology / similar technology tubes with radiation dose management and with auto adjusting Fluoro filters

49. Dedicated X-Rays radiation dose monitoring and dose reduction software features of the latest variety provided by the manufacturer

50. Angulation dependent automatic exposure control including KV, mA, pulse width & focal spot adjustments

51. Automatic calculation and optimization of exposure data based on fluoroscopic data

52. Radiation free patient positioning without active Fluoro

53. Active radiation dose monitoring based on actual C-arm angulations and table positions

54. Radiation Free Collimation

55. Real-time displays on main examination room monitor as well as control room monitor including cumulative Air Kerma display, cumulative Dose Area Product and Fluoro time

56. DAP threshold intimation / warning system

57. DICOM structured report containing patient, procedure, and dose data

High Resolution Digital Imaging and Acquisition / Fluoroscopy System with Real Time Image Processing:

58. Acquisition and Processing at 14 bits or more.

59. Parallel processing capability / multitasking facility

60. Real time filtering and roadmap function

61. Magnetic disk capacity for storage of minimum 50,000 images in 1024 x 1024 x 12 bit or highest at the time of procurement on the magnetic disk of main console

62. Minimum Cine Length: 10 seconds in 1024 matrix @ minimum 30 fps

63. Images storage and retrieval from archive disk for possible manipulation and quantification using available software packages (compatible format / bits)

Monitoring System:

64. Medical grade large display monitor in examination room, minimum 55" diagonal in size (Make: Eizo or Barco), 8 Mega Pixels resolution along with two or three 19" or larger medical grade monitors for backup to display live image, reference image and pressure tracing and ECG

65. Large Primary Monitor mentioned above should at least be ceiling mounted with original ceiling suspension system

66. Three LCD / LED medical grade monitors for live images, road mapping and hemodynamic system control in the control room, minimum 19" inch diagonal or larger size.

67. All 19" or larger Monitors should be Medical Graded, complied with International Standards for medical monitors as recommended by Manufacturer and all with the same brand

Controls:

68. Integrated table side touch screen/Touch Panel (Original from OEM of Angiography Machine) console to adjust system parameters, display setting of 55" monitor, frame rates, Hemodynamic system controls (Additional touch Screen console if required), quantitative analysis, stent enhancement soft-wares, Digital Subtraction Angiography (DSA), Mask- Unmask (Road-mapping) and Rotational Angiography

69. All controls of digital imaging system, measurements, post processing & quantifications analysis shall be in the control room as well as the examination room

70. Table side and Control room panels must have quantification and processing capabilities.

71. The control panel can be mounted at any side of the Patient Table

Recording / Archiving & Communication System:

72. Recording / archiving system should be DICOM – 3 Compatible

73. Digital images should be stored as backup on CDs / DVDs with incorporated original DICOM handling software / DICOM player from original manufacturer

74. DICOM (Send / store, commitment, retrieve / query)

75. PACS compatibility / integration

76. Compatibility to display of doppler ultrasound/ echocardiography system images on main screen

77. Ethernet connection to connect with other terminals

78. Integrated bi-directional intercom system for Cath lab to control room (From Original Manufacturer).

Software Packages:

The bidders should quote their licensed software with part number in their principal offer.

Complete analysis package for following cardiac applications should be included:

79. Dynamic pre and post PTCA / Valvotomy comparison with one image live and other reference

80. Automatic loops replay after acquisition or fluoroscopy

81. Dynamic real time pan / zoom

82. Dynamic real time digital imaging processing like edge enhancement or gamma correction, noise reduction (spatial filtration)

83. Online image density (gray scale) correction

84. Simultaneous display of fluoroscopy and reference images

85. Standard quantification packages for Left Ventricular Analysis

86. Facility to review previous studies in the examination room from the patients' old CD

87. Automatic positioning of the c-arm corresponding to reference image

88. Quantitative Coronary Analysis Software

89. Store Fluoro facility to store last fluoroscopy run

90. Integrated Complete Licensed Pediatric Catheterization Reporting Software with Image Illustrator based on standard atlas tailored according to congenital heart defects (It should be able to import data and images from main Angiography System and overlay SpO_2 and pressures over images automatically. It should also have a complete Hemodynamics Calculation Module.

Dedicated Adult Features:

91. Digital subtraction angiography package with manual / real time pixel shift for compensation of patient movement during acquisition

92. Image masking with real-time overlay of live Fluro along with Automatic System repositioning according to vessel mask location

93. Latest stent enhancement technology, being produced by each manufacturer in this category, at the time of tender, like, Dynamic device stabilizer (DDS) or PCI Assist 2 including Stent Viz or Stent boost Live or Stent View/ Score View Live or clear stent live with real time image enhancement with integrated table side control with touch panel are mandatory to quote.

94. Integrated power injector system.

Dedicated Pediatric Features: (End-user to specify)

95. Fusion software for 3D structure of CT / MRI image overlaying on 2D live Fluoro without cone beam CT

96. 3D reconstruction software for pulmonary arteries, coarctation of aorta and right ventricular outflow tract Angiography machine need integrated inbuilt hemodynamic system with sustainable mean pressure and other parameters

Physiological Hemodynamic Monitoring System: (FDA 510K approved)

97. Integrated Hemodynamic System from the original manufacturer with full table side control having bi-directional communication with the machine for automatic / synchronized acquisition, transfer and display of patient Hemodynamic parameters and demographic data.

98. Multichannel (16 channels or more) to record at least 4 channels IBP, Cardiac output with thermo dilution method, Surface ECG in any configuration and simultaneous 12 lead ECG, NIBP and SpO_2 measurements

OR

Electrophysiology compatible Multichannel (64 – channels or more) Hemodynamic System (End-user to specify the need)

Hemodynamic System Features:

99. Complete software for all Pediatric & adult, right / left heart, Angio / Valvular Hemodynamic calculations such as gradients, valve areas, shunts including annotations and 12 channels ECG

100. Live Waveforms display on main monitor in the examination room

101. Digital display of all the parameters like IBP, Heart rate, cardiac output parameters

102. Possibility to print the waveforms simultaneously while acquiring the data in the background

103. Capability to store the waveforms on the hard disk of the physiological recording system

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105. Facility for freezing Hemodynamic data and simultaneous recovery of recent data/ compare stored data with current waveform

Dedicated Branded Workstation:

Hardware must be as per Manufacturer's Recommendations & Software should be from Original Manufacturer of Angiography System. Online workstation to review studies directly and the facility to review studies with lossless compression and original image quality as on console.

106. DICOM – 3 Compatible

107. Capable of universal DICOM support

108. Original DICOM handling software from the manufacturer with permanent license

109. Edge enhancement, adjustable view speeds & post processing capabilities

110. High-Definition Medical Graded LCD / LED monitor of minimum 19 inches size

111. CD / DVD writer and CD / DVD ROM Drive
112. Image storage capacity as per Manufacturer's approved hardware
113. SCSI or equivalent controller as per Manufacturer's approved hardware
114. Black & white laser printer
115. 3D reconstruction software package for congenital heart defects including aorta, pulmonary artery and RVOT supplied by the principal manufacturer. (End-user to specify the need.)

Review Stations for Auditorium / Classroom/ Doctor Office:

116. Branded review station with connectivity to main angiography machine including all necessary cabling / hardware for connectivity
117. Minimum two cameras, one at foot end of patient and one in-front of operators with 32 Inch LED screen for display in cath lab.Port should be given for transmission online and to conference room
118. LED Display (60" inch) and high-resolution multimedia projector for view of live imaging

Radiation Protection Equipment / Accessories:

Must be FDA / MHLW/ CE approved.

119. Ceiling suspended tilt table lead glass (Should be supplied by the same manufacturer) for radiation protection of operator's head & neck regions and upper body parts
120. Table mounted adjustable lower body radiation shields flaps on both sides
121. Lead glass window size 4 x 1 meter or larger lead equivalent 2.0 mm or better
122. Lead aprons (vest and skirt), double side with different sizes, light weight (4.5 kg or less in total), lead equivalent front 0.5 mm and back 0.35 mm with belts (FDA / CE approved) (Brand & sizes (End-User to specify), (Quantity: 7 or more to be specify by the End-User)
123. Lead aprons (single piece), double side with different sizes, light weight, lead equivalent front 0.5 mm and back 0.35 mm with belts. (FDA / CE approved) (Brand & sizes (End-User to specify), (Quantity: 7 or more to be specified by the End-User)
124. Wall Mounted / Trolley mounted hangers of S.S 304L for 5-10 lead aprons (To be supplied Locally) (Quantity: End-User To Specify)
125. Thyroid shields with lead caps. (FDA / CE approved) (Brand & sizes (End-User to specify), (Quantity: 08 or more to be specified by the End-User)
126. Lead Goggles: Light Weight (FDA / CE approved) (Brand & sizes (End-User to specify), (Quantity: 08 or more to be specified by the End-User)
127. Patient Protection Lead Sheet: Light weight having 30 inches in size
128. Personal Digital Dosimeters (Quantity: 05 or more to be specified by the End-User)

Quality and Safety Standards:

129. For Angiography and Hemodynamics System, US FDA minimum 510K requirement is as under:
a) US FDA minimum 510k approved (Adult Angiography and Hemodynamic System for both Adult and Pediatric)
b) The Equipment / Instrument / Applied parts shall conform to IEC – 60601 – 1 standard general requirement for basic safety and essential performance of medical electrical equipment
c) The System must comply with IEC – 60601 – 1 – 2 Electromagnetic Compatibility (EMC) collateral standard or equivalent for basic safety and essential performance in the presence of electromagnetic disturbances and electromagnetic disturbances emitted by that equipment and systems
d) Medical Graded Displays and Power Supplies

Operating Requirements:

130. Three phases with line voltage of 440 V & 50 Hz
131. Cabling for electrical power supply, generator & UPS connections
132. Cabling for proper earthing

133. Brand New and Latest Version 160 KVA or more true online sine wave Double conversion UPS for whole system with a minimum back up time of 10 minutes including room lights, microprocessor based IGBT technology. Display and alarms of parameters. Three phase line voltage of 220 50 Hz with all necessary standard parts including dry batteries, unconditional 5 years warranty for UPS and UPS batteries

134. Brand New and Latest Version 250 KVA or more (Stand by) Electric Power Generator with ATS penal power cables and soundproof canopy (imported) set with automatic change over for complete load of Angiography Suite including Air conditioners, lights, and another load of Angiography suite (Engine: Perkins / Cummins / Caterpillar / Volvo)

135. Installation:

a. Room preparations and Lead Shielding of the scan room (2-3mm) and doors (3-4mm) as per PNRA requirements with radiation/exposure indications
b. Vinyl Flooring: Complete vinyl flooring (Inside the rooms and corridors) including Self levelling (2-3mm) of Gerflor/ Tarket/Forbo
c. Wall Finishes: ACP Panels/ UV sheet/Polycarbonate on cement board/UPVC Panels on cement board and Printed Glass Panel on one wall
d. False Ceiling: Airtight suspended ceiling with specified durable material, antimicrobial coating, sealed joints to prevent air leaks and maintain pressure difference. Ceiling panels should be made of galvanized steel sheet 0.60mm-0. 80mm thick or better material. (Country of Manufacturer USA/Europe/Japan)
e. Peripheral Lights: Recessed type LED lights 65 W of Osaka/ Philips or equivalent brands
f. Power Cabling: Supplying, installation, and termination of cables between the Isolator/ DB (provided by GC) and Equipment DB (provided by Vendor), as well as from the Equipment DB to UPS. and to all internal equipment/ services
g. Equipment DB with individual breakers for all equipment protection.
h. Installation of UPS, Cable trays/ trenches, Dedicated Earthing & Power outlets
i. Provision and installation of X-Ray Viewer. Recessed/ built in type, LED X-Ray viewer for 03 X-ray films. (Country of Manufacturer: USA/Europe/Japan)
j. Provision and installation of 1 x Automatic Sliding door with 3-4 mm lead shielding as per PNRA requirements. Size: 1500mm x 2100 mm approx. Door should be automatically hermetically sealed with electronic privacy glass and without contact buttons. Thickness 0.8mm or more stainless steel AISI-304/ AISI-301. Brushed finish or powder coated outer skin. 2 set of photocells in door frame along with infrared sensor at door drive level on inner and outer side of the door. (Country of Manufacturer USA/ Europe/Japan)
k. Provision and installation of 2 x Single Hinged Doors with 3-4 mm lead shielding as per PNRA requirements. Size: 1000mm x 2100 mm approx. Stainless Steel/ Galvanized Steel Door fame and door panels (Country of Manufacturer USA/Europe/Japan)
l. Cooling requirements and air conditioning as per manufacturer recommendation
m. Provision and installation of medical gases outlets
n. 2 x Medical Cabinets having 4-5 adjustable shelves. Cabinets should be sealed with a hermetic removable silicone seal and provided with tempered glass. The doors should be made of double steel plates with glazing. Safe Glass, set in double steel sheet window frame. Imported/ Local (Subject to sample approval)
o. Provision and installation of Operator Console
p. Provision and installation of Scrub Sinks with Infrared Hand Free Operation and the provision of hot & cold faucet with mixer for temperature control with front wall mirror as per site requirement. Infrared Operated Soap and Disinfection Agent Dispenser for disinfecting agent, lotion, liquid soap, etc. (Country of Manufacturer: Imported)
q. Any other modification/ requirement and manufacturers recommendations in the existing site will be the responsibility of the firm.

Trainings:

136. One doctor's foreign attachment / training for one week (The Procuring Agency to specify)

137. One hospital Bio-Medical Engineer's comprehensive service training / attachment at manufacturer site for at least one week.

(Note: The Bio-Medical Engineer must be trained appropriately, so that at the time of verification and replacement of part / equipment, he / she can fully endorse without any ambiguity the need to replace the said part. For this the supplier will request the manufacturer to provide dongle to the Bio-Medical Engineer during training at manufacturer's site and later on access to it for needful.)

138. Two technician's local training for two weeks

139. Three visits of application specialist with the last visit after commissioning of machine (Each visit of one-week duration)

Warranty:

140. The warranty period shall be for Five Years (Comprehensive) unconditional for all essential components /equipment to keep the machine functional including x-rays tube and flat panel detector, monitors, machine cables and connecting leads, diesel generator, UPS with batteries, Hemodynamic system, all consumables, all accessories (including probes etc.), non-proprietary items supplied with the machine with all specified parameters that shall cover labor and parts for all equipment

141. During the period of machine functioning before formal signing of installation report, rectification of errors or replacement of faulty parts shall be the responsibility of supplying firm without any financial implications or liabilities at the institute or End-users.

142. The warranty shall start from the date of installation report signing and handing over to end-User.

143. Manufacturer will submit undertaking to ensure availability of all spare parts and consumables over minimum of 10 years.

Post Warranty Service & Maintenance Contract:

144. The supplying firm shall be bound to enter into a comprehensive service contract with the institute for 05 years after the warranty period at a rate not more than 6% of C & F purchase value including all essential components / equipment to keep the machine functional such as x-rays tube and flat panel detector, monitors, machine cables and connecting leads, diesel generator, UPS with batteries, Hemodynamic system, all consumables, non-proprietary items supplied with the machine with all specified parameters that shall cover labor and parts for all equipment (C & F)

145. Financial impact of post warranty service contract should be considered by the bidder while quoting the financial bid.

Accessories:

Hemodynamic System Accessories:

- Complete 12 lead ECG Cables (Quantity to be specified by the End-user)
- NIBP cuffs (Neonate,Infant, Pediatric, Small Adult, Large Adult) (Quantity to be specified by the End-user)
- Thermo dilution catheters 5F 4 lumens (Quantity to be specified by the End-user)
- IBP Pressure Transducers (Quantity to be specified by the End-user)
- IBP Transducer Cables (Quantity to be specified by the End-user)
- Holder for mounting the IBP Transducer alongside patient table (Quantity to be specified by the End-user)

- Portable Pulse Oximeter with probes (i.e., Pediatric, Adult Probes and Infant Probes) (Qty: 02)

Other Accessories:

- Crash Cart (Country of Origin: USA, EU & JAPAN) (The Procuring Agency to specify)
- Patient Shifting Trolley (Country of Origin: USA, EU & JAPAN) (Quantity to be specified by the End-user)
- Steel tray trolley for disposables, 6 x 3.5 feet 40 cm height (Quantity & Size to be specified by the End-user)
- ACT Machine (As per approved PVMS) (Quantity: 01 or more)
- Temporary Pacemaker (Single Chamber) (Quantity = 03) (As per approved PVMS) (More Quantity to be specified by the End-user)
- Programmable Portable Contrast Media Power Injector (Medrad, Angiomat, Medtrone, Nemoto, Guerbet) with disposable syringes (Quantity to be specified by the End-user)
- Auto injector set-up(FDA or CE mark or as specified by end-user)
- Bi-directional audio communication between Cath Lab and Auditorium / Office / Remote Place
- Portable Non-Invasive Hemodynamic (As per approved PVMS) / BP Monitor with built-in batteries
- Writeable CDs / DVDs (Quantity to be specified by the End-user)
- Defibrillator (Quantity to be specified by the End-user) (As per approved PVMS)
- ECG Machine (Quantity to be specified by the End-user) (As per approved PVMS)
- Dehumidifier
- Air Purifier (Specially for Air Sulphur) (It is strongly recommended that the Air Sulphur content, bacterial content, and other issues regarding the equipment which are essential for its better and long-term performance must be evaluated prior to installation by the winner of the bid.)
- Smoke Detector with Fire Extinguisher
- Voice assistant software for Reporting Purpose
- Intra-Aortic Balloon Pump Machine (As per approved PVMS) (Quantity to be specified by the End-user)
- Double Dome Surgical Light (Shadow Less) (As per approved PVMS)
- Operational & Service Manual
- Co-registration / Integration of FFR
- Co-registration / Integration of Intra-Vascular Ultrasound (IVUS)
- Dedicated application for planning and performing structural heart procedures including TAVI (This application if purchased as an essential item at the time contract versus purchased later or as an accessory will be costly for the Procuring Agency, in view of this, this option if needed at time of tender may be placed in standard specifications).

Optional (If any):

Optional Equipment:

- Co-registration / Integration of Cardiac CT
- Co-registration / Integration of OCT
- Zero Gravity System
- CPAC interfaced (Images cross into reporting system with voice assistance capability)
- Wireless chargeable foot paddle
- High End Dedicated Echocardiography System by the same manufacturer (As per approved PVMS) (Quantity to be specified by the End-user)
- Ventilator with compressor and humidifier (As per approved PVMS) (Quantity to be specified by the End-user)
- Whole Blood Oximeter with cartridges / without cartridges

Optional Features:

- High resolution Cone Beam CT (CBCT) capability integrated into angiography system for neuroimaging.

General Instructions

- "Optional Items / Features" may be included in the tender specifications as per requirements of procuring institute. Specifications of items mentioned under headings "Optional Items" and "Allied accessories" will be as per approved PVMS if available, whereas certifications (FDA, CE & MHLW) will be decided by Procuring Agency. Bidders may quote against respective items, however, non-quoting or not meeting the required specifications for these items would not be a reason to reject / disqualify a bid. The Procuring Agency / Institute may procure optional items if sufficient funds are available post financial bid.
- Bidder will be bound to provide undertaking from the manufacturer that in case the local distributor gets changed during the mentioned warranty or service contract period, the new authorized distributor on behalf of the Principal Manufacturer or Principal manufacturer himself will own the warranty, backup services, replacement of parts and all pending liabilities.

  Bidder will be bound to provide undertaking from the manufacturer to ensure availability of all spare parts and consumables over minimum of 10 years.

Safety Standard:

Must conform to the requirements of ISO 13485:2016 version or above