**Section IV: Specifications And Performance Requirements**

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| **Ministry of Health & Social Services** | | | |
| **Supply, delivery, installation, and commissioning of Cardiac Bi-plane for Cath lab at Windhoek Central Hospital** | | | |  |
| **Item Description:** | | **Cardiac Bi-plane** | |
| **Price:** | |  | |
| **Brand/Model:** | |  | |
| **Manufacturer:** | |  | |
| **Country of Manufacture:** | |  | |
| **Year of Manufacture:** | |  | |
| **Year of model launch:** | |  |
| **Item NO** | **PURCHASER'S SPECIFICATIONS** | **SUPPLIER'S SPECIFICATIONS (Reply to all, do not indicate comply only but specify your specification per item failure to do so will lead to dis-qualification)** | |
| **1.** | **GENERAL** |  | |
| 1.1 | Either capable of peripheral digital stepping angiography with online subtraction display in an examination procedure with only one single contrast medium injection under visual control for the bolus flow or capable of visually controlled stepless bolus chase technique which means more accurate bolus chase of the peripheral flow can be achieved |  |
| 1.2 | Capable of real time Digital Angiography (DA) and Digital Subtraction (DSA) acquisition |  |
| 1.3 | Minimum pulse rate available shall be 10 frames or pulses per second or less. The maximum pulse rate shall not be less than 30 frames or pulses per second. |  |
| 1.4 | Rotational angiography capability. |  |
| 1.5 | Road mapping with REAL TIME zoom, freeze-frame and advanced facilities. |  |
| 1.6 | Capable of fluoro grabbing of fluoroscopic image for documentation |  |
| 1.7 | Clinically validated cardiac and vascular quantification software program |  |
| 1.8 | Excellent patient access from all sides for various techniques and procedures including cardiac device implants and vascular procedures. No need to reposition patients for these procedures |  |
| 1.9 | Easy to use and full control of all functionality whether in the examination or control room |  |
| 1.10 | Interventional tool to improve accuracy for coronary stent placement in real time |  |
| 1.11 | Interventional tool for 3D modelling of coronary, thoracic, abdominal and peripheral and neurologic examinations. Rotational angiography possibility with 3D reconstruction |  |
| **Item NO** | **PURCHASER'S SPECIFICATIONS** |  |
| 1.12 | Capable of 3D roadmap with CT or MR scan overlay on live fluoroscopy images. Road mapping or aid to be used in PCI examination with real time live dynamic overlay of the coronary tree on fluoroscopy or Please specify equivalent technology for the reduction of radiation. |  |
| 1.13 | Should be capable of registration of pre-acquired 3D data from various modalities such as CT, MR, PET to the angio information |  |
| 1.14 | Automatic stand and table positioning program with unlimited stand projection that can be saved and recalled in a single procedure |  |
| 1.15 | Should have a minimum image storage capacity of 100,000 images in 1k/12- bit matrix |  |
| 1.16 | Should have bi-directional communication with the physiologic/hemodynamic system for the exchange of patient data, X-ray shots and dose information to ensure optimized workflow: |  |
| **2** | **GENERATOR** |  |
| 2.1 | Multipulse Microprocessor-controlled, high frequency X-ray generators |  |
| 2.2 | Generator with fully integrated system control and automatic regulation of radiation power for all fluoroscopy and imaging modes |  |
| 2.3 | Modes required for all cardiovascular and interventional application such as DSA, rotational DSA, pulsed fluoroscopy, single exposure, and kV reduction technology are supported without limitations |  |
| 2.4 | Radiographic kV/Tube Voltage range of 40 kV to 125 kV. Wider range is acceptable but should include the range of acceptable value |  |
| 2.5 | Power Rating of at least 100 KW at 1000 mA |  |
| 2.6 | Maximum Radiographic Tube Current up to 1000 mA in acquisition mode. |  |
| 2.7 | Maximum Fluoroscopic Tube Current of at least 50 mA for continuous and of at least 150 mA for pulsed fluoroscopy. |  |
| 2.8 | Must have variable pulse frequency of at least 60 pulse/second |  |
| 2.9 | Number of programmable protocol must not be less than 200. Each acquisition protocol shall be able to programme the right x-ray parameters, processing, frame speed including pre-filtration settings, image appearance, etc. based on type of procedures and type of patients. Shall be able to programme different protocols based on individual users’ personal preferences. |  |
| 2.10 | The fields of view can be controlled automatically - without the user having to make any changes |  |
| 2.11 | Integrated automatic kV, mA, and pulse width control |  |
| 2.13 | **PURCHASER'S SPECIFICATIONS** |  |
| **3** | **X-RAY TUBE** |  |
| 3.1 | Dual or triple focus X-ray tubes for biplane system. It should be Grid Switch tube technology with continuous rotating anode with instant x-ray on/off |  |
| 3.2 | Must have different levels of adaptive Copper (Cu) pre-filtration for reduction of skin dose. |  |
| 3.3 | Automatic selection control based on the absorption of the object. The extra Cu pre-filtration should remained in position in function of body absorption and should not be auto-removed depending of c-arm projection at any time |  |
| **3.2** | **The focal spot of the x-ray tubes must be compliance with the following:** |  |
| 3.2.1 | Small focus shall not be more than 0.5 mm |  |
| 3.2.2 | Large focus shall not be more than 0.9 mm |  |
| 3.2.3 | The high tube power should provide brilliant image quality even with heavier/obese patient |  |
| 3.2.4 | The high tube power should provide brilliant image quality even with heavier/obese patients |  |
| 3.2.5 | Maximum anode heat storage capacity/maximum anode heat content at 5 MHU or more |  |
| 3.2.6 | Maximum X-ray tube heat storage capacity of at least 7.0 MHU |  |
| 3.2.7 | Anode heat dissipation not less than 1,500 KHU/min Oil and/or water-cooled X-ray tube with thermal safety switch |  |
| **3.3** | **C-arm For Both Planes** |  |
| 3.3.1 | There should be free space at the head end and both sides of the patient for access during emergencies and for cardiac device implantations |  |
| 3.3.2 | Should be configurable to the room for optimal transfer positions to allow free access to the table from all sides during patient preparation |  |
| 3.3.3 | Positioning is automatic/motorized with option to move it manually |  |
| 3.3.4 | There is a collision protection or a safety system for the C-arm movements with either non-contact sensors or touch sensors on the tube, detector, Carm and stand |  |
| 3.3.5 | Patient coverage: At least 180 cm |  |
| 3.3.6 | Focus to iso-center: Should not be less than 75 cm |  |
| 3.3.7 | Iso-center to floor distance: Should not be less than 105 cm |  |
| 3.3.8 | Variable focal spot-to-detector distance |  |
| 3.3.9 | Automatic Positioning Stand Program |  |
| 3.3.10 | No. of pre-program stand position: at least 50 user definable positions can be stored |  |
| 3.3.11 | Programmable parameters: Must include at least the rotation, angulation and SID |  |
| 3.3.12 | Roadmap-driven positioning: Able to automatically position the stand to the original stand parameter setting based on the roadmap image selected. The stand parameter shall include at least the rotation, angulation and SID |  |
| 3.3.13 | Selection of automatic positioning program must be simple and easy from the patient tableside |  |
| **3.4** | **Floor Mounted C-Arm** |  |
| 3.4.1 | Maximum possible angulation ranges for projections depending on selected working positions. Arm rotation must be both motorized & manual, to position left, head and right side of the patient over at least 180°. |  |
| 3.4.2 | LAO and RAO: (up to 120° LAO, up to to 120° RAO) at head-end position, (90° LAO, 90° RAO at both side of C-arm position) |  |
| 3.4.3 | Cranial: (In head-end position: 0 to 90° cranial. In both side position: 0 to 185° cranial) |  |
| 3.4.4 | Rotation speed and horizontal swivel speed of the C-arm: up to 25 degrees/sec and for 3D applications: 45 degrees/sec or higher |  |
| 3.4.5 | Angulation speed and sliding speed: up to 18 degrees/sec or higher |  |
| **3.5** | **Ceiling Mounted C-Arm** |  |
| 3.5.1 | Ceiling suspended counterbalanced with a single or double C-Arm design LAO and RAO: 0 to 90 degrees or higher |  |
| 3.5.2 | Cranial: 0 to 45 degrees or higher, possible at any rotation angle as stated above |  |
| 3.5.3 | Caudal: 0 to - 45 degrees or higher, possible at any rotation angle as stated above |  |
| 3.5.4 | Angulation speed and sliding speed of the C-arm of at least 8°/s |  |
| **3.6** | **Patient Table** |  |
| 3.6.1 | Type: Floor-mounted carbon fibre radio translucent floating top with tilt function |  |
| 3.6.2 | Dimensions of the table: a. Table Length of at least 280 cm b. Table width of at least 45 cm |  |
| 3.6.3 | Transverse travel: at least 35 cm |  |
| 3.6.4 | Longitudinal travel: at least 120 cm |  |
| 3.6.5 | The height of the patient table-top can be set using a motorized telescopic foot/column or using the control module. |  |
| 3.6.6 | The height adjustment range of the patient table-top: Lowest should be less than 85 cm, Highest up to 110 cm or better |  |
| 3.6.7 | The table load capacity of at least 300 kg. (Inclusive of at least 500 N additional force for emergency CPR). Emergency CPR can be performed at any table position. |  |
| 3.6.8 | Table-top pivot/range of rotation: at least 240 degrees or -180° to +90° |  |
| 3.6.9 | Tilt angle (Head down/Head up): At least +/-15 degrees |  |
| 3.6.10 | With the durable visco-elastic medical grade, body shape conforming mattress with latex free cover at least 7 cm thick |  |
| 3.6.11 | Arm support board to be used to support the patient’s arm during brachio-cephalic catheterization procedures. |  |
| 3.6.12 | Set of elbow supports for patients |  |
| **3.7** | **Flat Detector Image Acquisition System** |  |
| 3.7.1 | High-resolution, dynamic flat detector for a fully digital imaging chain Max. field of view for frontal : at least 30 cm diagonal |  |
| 3.7.2 | Max. field of view for Lateral : at least 30 cm diagonal |  |
| 3.7.3 | Pixel size not more than 160 μm At least 4-6 detector field of views. Please state the FOV sizes. |  |
| 3.7.4 | High resolution image matrix: at least one of the detector must be 2480 x 1920 pixels at 16 bits depth. |  |
| 3.7.5 | Detector quantum efficiency at 0 lp/mm: At least 70% both frontal and lateral |  |
| 3.7.6 | With either passive or active detector cooling mechanism |  |
| 3.7.7 | With removable grid |  |
| 3.7.8 | With integrated non-touch collision protection system |  |
| **3.8** | **Image Display for the Examination Room** |  |
| 3.8.1 | At least six (6) medical grade monitors be installed in the examination room including hemodynamic system, with capabilities where a number of Full HD (1920x1080) monitors, all internal and external video sources can be displayed. |  |
| 3.8.2 | Ceiling-mounted, longitudinally mobile, swivelling, rotating, and height-adjustable display suspension system with six (6) color flat screens display, and hidden cabling, at least four (4) 19” (Medical grade at least 2 MP) |  |
| 3.8.3 | Motorized height adjustment and Swivel range (max. system rotation): 300° ±10° |  |
| 3.8.4 | Color flat display: Flicker-free and distortion-free and can receive different external video signals and process this information for display |  |
| 3.8.5 | All changes can be performed during the procedure by using the touch screen panel at table side. Data such as live and reference images, workplace, recording systems, PACS, HIS/RIS, ultrasound, ECG, external video, endoscope, mapping systems, device and table geometry, system messages and dose indications, can be individually positioned and displayed. All this changes can be performed during the procedure by using the control or screen panel at table side. |  |
| 3.8.6 | Safety measure to secure against a power supply failure: four (4) or more separate power supplies. |  |
| **4** | **CONTROL ROOM** |  |
| 4.1 | Provided with one (1) monitor for live frontal and live lateral in split display of at least 19” monitor with image matrix of at least 1280 x 1024 another one (1) monitor for patient data and review display of at least 19”monitor with image matrix of at least 1280 x 1024 |  |
| 4.2 | Must be able to view images of previous patients in the console while a  current procedure in on-going |  |
| 4.3 | Two (2) units of at least 21” monitor for hemodynamic waveform and  procedure charting |  |
| 4.4 | One (1) unit TFT-LCD color monitor for 3D post-processing and other advanced applications of at least 19” with image matrix of at least 1280 x 1024 |  |
| 4.5 | At least one (1) unit TFT-LCD (minimum 21”) monitor for workstation  (DICOM) and Report editing terminal/ workstation |  |
| 4.6 | Provide the Doctors with workstation complete with UPS and one (1) unit  Medical grade 3 MP monitor of at least 19” for reporting and editing. |  |
| **5** | **DIGITAL IMAGING SYSTEM** |  |
| **5.1** | **Fluoroscopy** |  |
| 5.1.1 | Must have variable frame rate from 0.5 fps to not lower than 30 fps for monoplane and biplane mode |  |
| 5.1.2 | Acquisition Matrix: - highest image matrix of at least 2480 x 1920 pixels at 16 bits depth |  |
| 5.1.3 | Capable of superimposing active fluoro and reference image |  |
| **5.2** | **Pulsed fluoroscopy** |  |
| 5.2.1 | Must have variable pulse rate of up to 30 fps |  |
| 5.2.2 | On-the-fly fluoroscopy mode of at least 3 selections at the table side of different pre-programmed dose rate and copper pre-filtration combinations for optimal balance between dose and image quality |  |
| 5.2.3 | Storage of a fluoroscopic run of at least 20 sec shall be possible and reviewable in cine loop |  |
| 5.2.4 | Real-time on-line image harmonization and edge-enhancement processing  algorithm applicable for both fluoroscopy and acquisition mode |  |
| 5.2.5 | Real-time temporal noise reduction algorithm with vessel motion compensation applicable to reduce noise, produce sharper and better contrast image in fluoroscopy and acquisition runs using very low detector dose and low X-ray tube power settings |  |
| **5.3** | **DSA functions shall include the following:** |  |
| 5.3.1 | Real-time subtraction at frame rates up to 30 fps |  |
| 5.3.2 | Storage of a fluoroscopic run of at least 20 sec shall be possible and reviewable in cine loop |  |
| 5.3.3 | Real-time on-line image harmonization/filtering and edge-enhancement  processing algorithm applicable for both fluoroscopy and acquisition mode |  |
| 5.3.4 | DSA functions shall include the following and must be selectable and operable inside the examination from the tableside: |  |
| 5.3.5 | Real-time subtraction |  |
| 5.3.6 | Subtracted fluoro capability |  |
| 5.3.7 | Mask selection |  |
| 5.3.8 | Land marking |  |
| 5.3.9 | MO pacification for iodine and CO2 contrastanual, automatic and flexible pixel shift |  |
| **5.4** | **Digital Angiography** |  |
| 5.4.1 | Frame rates are available for acquiring digital real-time images: minimum of 7.5 fps or less and can be set up to 30 fps or higher |  |
| 5.4.2 | Can be acquired both as individual and series acquisitions with 1k matrix and bit depth of at least 10 bits for acquisition, display and storage |  |
| 5.4.3 | Over and underexposed areas of native series and individual images can be harmonized online to ensure a homogenous view of the image |  |
| **5.5** | **Roadmap** |  |
| 5.5.1 | Able to store up at least 100 roadmap image of runs. Cine loop must be  possible |  |
| 5.5.2 | Able to create a vessel map from a DSA-scene to enhance image quality over conventional Roadmap to reduce X-ray dose and contrast media at the same time |  |
| 5.5.3 | The system must have an automatic pixel shift processing during Roadmap and DSA based on real time movement detection and image compensation to ensure a perfect image match |  |
| 5.5.4 | Shall have the ability to store up to at least 1 physiological data and display at least one real time physion data with acquired images simultaneously |  |
| 5.5.5 | ECG triggered fluoro and acquisition facility |  |
| **5.6** | **Peripheral DSA** |  |
| 5.6.1 | Native and subtracted peripheral digital angiography with stepping can be  performed using only a single contrast-medium injection or using a digital  stepless bolus technique. |  |
| **5.6.2** | **Shall support the following DICOM protocols:** |  |
| 5.6.2.1 | DICOM Store |  |
| 5.6.2.2 | DICOM WLM |  |
| 5.6.2.3 | DICOM MPPS |  |
| 5.6.2.4 | DICOM Query and Retrieve |  |
| 5.6.2.5 | DICOM Print |  |
| 5.6.2.6 | DICOM SR |  |
| **6** | **SYSTEM CONTROLS AND USER INTERFACE** |  |
| 6.1 | All system movements of the C-arm, table, image display, image review, image processing, and analysis must be operable from table-side |  |
| **6.2** | **The following control elements/control options positioned at table-side:** |  |
| 6.2.1 | Console and controls for stand movements |  |
| 6.2.2 | A handle for table movement |  |
| 6.2.3 | Exposure switch and handswitch table controller for special procedures, if any, such as peripheral stepping or bolus chase and rotational angiography |  |
| 6.2.4 | For detector lift control |  |
| 6.2.5 | For C-arm, table, and collimator movements |  |
| 6.2.6 | A wireless foot pedal for radiation release, acquisition and table break. With configurable setting to switch on/off the room light |  |
| 6.2.7 | Should the wireless foot pedal run out of battery, it should be possible to  just connect a cable and use like a regular foot pedal or there should be  another wired foot pedal as a backup |  |
| 6.2.8 | Images can be digitally magnified from table side control |  |
| **6.3** | **Touchscreen or table side control panel must be able to select and choose live images for display on large display:** |  |
| 6.3.1 | For all fluoroscopy and acquisition modes |  |
| 6.3.2 | For fluoroscopy storage |  |
| 6.3.3 | For image/scene replay and monitor display |  |
| 6.3.4 | For image post-processing |  |
| 6.3.5 | For quantitative analysis |  |
| 6.3.6 | The archived images can be shown on the live monitor in the examination  room |  |
| 6.3.7 | The device and table positions, system messages and dose values can be  displayed in both the examination room and the control room |  |
| **6.4** | **Interventional Packages** |  |
| **6.4.1** | **Provide the following Quantitative Evaluation Software:** |  |
| 6.4.1.1 | Full neuro package 3D software: Optional |  |
| 6.4.1.2 | 3D Rotational Angiography (3D RA) acquisition allow for the creation, assessment, 3D reconstruction, and overlay guidance of rotational angiography of vascular anatomy. |  |
| 6.4.1.3 | Live 3D Roadmap that overlays a 3D reconstruction of the vessel tree, acquired with 3D RA acquisition mode on your interventional x-ray system, with live flouro images. |  |
| 6.4.1.4 | Software to enhance stent visualization in the coronary arteries. |  |
| 6.4.1.5 | Quantification results can be quickly and easily stored I the patient folder for documentation and demonstration purposes |  |
| **6.4.2** | **Must include the following clinically validated quantification software:** |  |
| 6.4.2.1 | Left ventricular analysis, coronary analysis and vascular analysis |  |
| 6.4.2.2 | Automatic contour recognition |  |
| 6.4.2.3 | Automatic stenosis quantification |  |
| 6.4.2.4 | Automatic and manual determination of reference diameter |  |
| 6.4.2.5 | Automatic and manual calibration methods |  |
| 6.4.2.6 | Distance and angle measurement |  |
| 6.4.2.7 | Automated left ventricular analysis including manual Ejection Fraction,  Regional Wall Motion, Centerline Wall Motion, Slager Wall Motion,  Calibration routines |  |
| **6.5** | **Rotational Angiography** |  |
| 6.5.1 | Angle-triggered native and subtracted digital rotational angiography can be performed for optimized 2D image display with 3D effect  Acquisitions with frame rates in 1k matrix from 0.5 to 7.5, 10, 15, 30 f/s  (standard) and 60 f/s with reduced spatial resolution can be selected |  |
| 6.5.2 | 3D Image Acquisition and Generation |  |
| 6.5.3 | A graphic display of 3D protocol menu must be available for easy selection of the appropriate 3D acquisition protocol |  |
| 6.5.4 | Injection recommendations and other important notes for the staff can be  incorporated into the displayed 3D protocol, for consistency in imaging  results and standardization |  |
| 6.5.5 | Acquisition of 3D images be completed at table side if necessary |  |
| 6.5.6 | Angle-triggered native and subtracted digital rotational angiography (if  available) be optimally reconstructed to allow three-dimensional imaging  and review |  |
| 6.5.7 | The selected 3D program already contain all the parameters for 3D  reconstruction |  |
| 6.5.8 | The reconstruction can be performed automatically without need for control room assistance |  |
| 6.5.9 | The default reconstruction parameters and viewing presets can be  configured according to user preferred result |  |
| 6.5.10 | Reconstructions be repeated with different reconstruction parameters |  |
| 6.5.11 | Generation of 3D Volumes with High Contrast Resolution Software. Must  Fulfil the Following Requirements |  |
| 6.5.12 | Acquisition of angiographic images using a fast-rotating C-arm around the isocentre at an angle range of at least 150° |  |
| 6.5.13 | Parameterizable exposure programs must be available that enable situation dependent acquisition parameters |  |
| 6.5.14 | Start positions of the C-arm must be able to be saved, retrieved and  protected against changes |  |
| 6.5.15 | Acquisition of images must be possible using native and subtracted  technology. For native acquisitions, dose reduction must be possible without an additional run |  |
| 6.5.16 | It must be possible to transfer images to the 3D workstation in the  background via a high-speed interface without affecting the work on the  acquisition system and without actions on the acquisition system slowing  down the transfer |  |
| 6.5.17 | The 3D workstation must have processing software that can create back  projections from the images received from the acquisition system |  |
| 6.5.18 | The system will allow both subtracted and native reconstructions |  |
| 6.5.19 | Specific desired working positions can be automatically transferred from  the 3D volume to the C arm |  |
| 6.5.20 | The 3D volume can be set to automatically and simultaneously adjust to any change in C arm geometry and zoom format performed in the system |  |
| 6.5.21 | Specific working projections can be planned in the 3D volume and saved for later use |  |
| 6.5.22 | Specific working projections can be planned in the 3D volume and saved for later use |  |
| 6.5.23 | The 3D workstation must offer functions for the display and editing of 3D  images |  |
| 6.5.24 | Images from CT, MR and PET must be usable and capable for image fusion |  |
| 6.5.25 | There should be a software for reconstructing slices with CT-like soft tissue resolution from the projection images of rotational angiography: Optional |  |
| 6.5.26 | There should be different acquisition programs for the heart, neuro and  abdomen |  |
| 6.5.27 | Should be capable of double volume display, e.g., for simultaneous display of mask and fill run for optimal differentiation of calcification and contrast-filled vessel |  |
| **6.6** | **Three Dimensional (3D) ROADMAP** |  |
| 6.6.1 | Must be possible for any projection, zoom, SID and table position, with  automatic adjustment in the overlaid 3D image should there be any  changes to these parameters |  |
| 6.6.2 | Can be overlaid in both regular or subtracted fluoro. Patient movements can be compensated either manually or automatically to achieve optimal overlay of fluoroscopy |  |
| **6.7** | **Registration of Pre-Acquired 3D Data from Various Modalities to the**  **Angiography System** |  |
| 6.7.1 | Datasets from different modalities such as CT, MR, or PET should be  Supported. |  |
| 6.7.2 | Registration of pre-acquired 3D datasets to the current patient geometry can be performed using fluoroscopy, with or without a current new 3D  acquisition |  |
| 6.7.3 | Fusion of loaded pre-acquired 3D information can be completely performed from table side, without the need to step out to the control room |  |
| 6.7.4 | The module should have automatic registration functions, and  Should have an application dedicated to support TAVI procedures |  |
| 6.7.5 | It should be possible to do a segmentation of the aortic root based on a 3D  dataset generated intra-operatively. Automatic segmentation of tissue,  anatomical structures, landmarks, calcium, anatomical planes and viewing  angles within the cardiac CT data for TAVI/TAVR |  |
| 6.7.6 | Overlay should be possible even without a pre-operative CT. |  |
| 6.7.7 | Automatic distance, diameter, area and perimeter measurements for  TAVI/ It should be capable of having the segmentation of the aortic root take place immediately during the procedure TAVR |  |
| 6.7.8 | Automatic Free centreline measurement along the ascending aorta for  TAVI/TAVR |  |
| 6.7.9 | Automatic or manual segmentation should be possible. Segmentation,  measurements and viewing angles for other SHD procedures, e.g. mitral  valve replacement and left atrial appendage closure |  |
| 6.7.10 | Intra-operative editing of the 3D dataset should be possible or allow pp to  date virtual device library for TAVI/TAVR procedures |  |
| 6.7.11 | Should also have a software that would enable the creation of cross-sectional  3D images of the beating heart/the left atrium by rotational angiography |  |
| **6.8** | **Dose Saving Measures** |  |
| 6.8.1 | There should be fluoroscopy modes with different system doses per image  directly selectable by the user |  |
| 6.8.2 | A measurement chamber is available for the display and documentation of  equivalent skin dose and dose area product |  |
| 6.8.3 | Pulse frequencies can be adapted using additional reduced pulse frequencies  to the requirements of each application to significantly reduce exposure to  radiation in fluoroscopy, particularly during interventions |  |
| 6.8.4 | Different fluoroscopy programs are always available for instant selection at tableside, even under sterile conditions |  |
| 6.8.5 | Dose values of the fluoroscopy programs can be changed simply and quickly without any change in the temporal resolution (constant pulse rate) |  |
| 6.8.6 | There should be radiation-free positioning of the primary and semi-transparent collimators by means of graphic display in the LIH (Last Image Hold) |  |
| 6.8.7 | It should be possible to reposition an object under visual control without  radiation |  |
| 6.8.8 | The measured dose-area product and the calculated patient entry dose  must be shown on the monitor |  |
| **6.9** | **Dose reporting** |  |
| 6.9.1 | The dose information can be displayed in DICOM format after each  examination |  |
| 6.9.2 | The dose information in an integrated DICOM data set consisting of images and dose information can be sent together to a DICOM archive |  |
| 6.9.3 | The dose information in text format can be evaluated flexibly and processed further via an analysis software/database and exported, for example to Excel |  |
| 6.9.4 | Over- and under-exposed images can be harmonized to guarantee a  homogeneous image impression |  |
| 6.9.5 | No need for manual correction via windowing |  |
| 6.9.6 | Image noise can be suppressed efficiently through dose-dependent filtering of image data |  |
| 6.9.7 | Vessel edges can be displayed in high contrast using a real time analysis of pixels without increasing image noise |  |
| 6.9.8 | Small moving vessels and guide wires can be made more clearly visible in  fluoroscopy |  |
| 6.9.9 | Image quality can be customized to the preferences of the user |  |
| **7** | **HEMODYNAMICS SYSTEM / Cardiac Physio monitoring System** |  |
| 7.1 | Should have bi-directional communication with the Angiography system |  |
| 7.2 | Control box in the examination room should be mounted on the tableside rail and not on the floor |  |
| 7.3 | With a built-in database for storage of patient examinations including  measurements, waveforms, event log and hemodynamic flow sheet |  |
| 7.4 | With Hemodynamic software for monitoring paediatric and adult patients |  |
| 7.5 | Able to do annotations, event log, hemodynamic calculations (e.g. gradients, valve areas, shunts, systolic area index) |  |
| 7.6 | 12-channel ECG and four (4) invasive BP pressure channels, Cables for ECG should be radiolucent |  |
| 7.7 | Color waveforms with programmable layout and digital monitoring |  |
| 7.8 | Should display the coronary tree as well as graphical picture of the heart with an extensive menu of congenital heart defects: Optional |  |
| 7.9 | Capable of virtual pullback: calculation of pressure measurements from two separate pressure measurements |  |
| 7.10 | Integrated measurement of vital signs, paediatric and adult (heart rate, non-invasive blood, SpO2) |  |
| 7.11 | At least two (2) Pressure transducer cables compatible with existing  consumables at the hospital with a starter pack of at least 20 disposable  pressure monitoring kits |  |
| 7.12 | Hermodilution Cardiac Output (CO) measurements: Optional |  |
| 7.13 | Integrated FFR and IFR capable with rotablator. |  |
| 7.14 | Congenital Cardiology advance 3D software package, containing tools to provide 3D planning and live guidance for congenital heart disease interventions (CHD). |  |
| 7.15 | Should have a software application for graphical documentation of the  patient’s coronary tree including coronary dominance, collaterals, grafts, etc |  |
| 7.16 | Output / documentation can be customized to conform with the approved  forms of the hospital (e.g. nurses’ narrative notes, Cath lab reports) |  |
| 7.17 | Able to design individually configured narrative and medical reports using document templates containing events, data groups, tables, and fields for the examinations carried out in the catheterization laboratory |  |
| 7.18 | It should be possible to retrieve data on statistics of procedures done at the  Cath lab and be able to retrieve data on the utilization of the system such as: exam durations, patient turnaround time, dose events, to name a few |  |
| 7.19 | With an uninterruptible power supply for the hemodynamic system capable of ≥5 min operating time |  |
| **8** | **ACCESSORIES. The supplier must provide the following accessories** |  |
| 8.1 | Cardiac output catheter and thermistor cable |  |
| 8.2 | Neonatal, paediatric and adult NIBP accessories |  |
| 8.3 | ECG cable clips (10) ten pieces for securing ECG cable to the table top |  |
| 8.4 | Unilateral armrest |  |
| 8.5 | Instrument tray/trolley, stainless steel |  |
| 8.6 | Arm holder (1 pair) |  |
| 8.7 | Head- holder |  |
| 8.8 | Intercom with 2way communication |  |
| 8.9 | LED OR Examination light appropriate for the Cath lab system. |  |
| **8.10** | **11. Radiation Protection:** |  |
| 8.10.1 | Ten (10) pcs. Wrap around Lead gown with thickness of 0.25 mm lead equivalence. Full overlap in front for total protection, flexible belt to release load on back and shoulder, smart side closure to prevent accidental exposure |  |
| 8.10.2 | Six (6) pcs. Lead gown (vest and skirt) with thickness of 0.25 mm lead equivalence Complete overlap on the front opening as well as the vest as well as the vest overlap of the skirt for added protection, optimized weight distribution to reduce load on back and shoulders, full overlap on skirt circumference for added lower body protection |  |
| 8.10.3 | Six (6) pcs. Radiation protective cap |  |
| 8.10.4 | Ten (10) pcs. Thyroid Collar |  |
| 8.10.5 | Six (6) pcs. Lead eye Goggles |  |
| 8.10.6 | Five (5) pcs. Gonadal shield |  |
| 8.10.7 | Two (2) units Apron rack |  |
| 8.10.8 | One (1) unit Lead viewing glass in between control and exam room: Optional |  |
| 8.10.9 | One (1) unit Laser printer for documentation of hemodynamic data |  |
| 8.11 | One (1) unit Headlight Wireless High Performance Led Headlight powered by Li-batteries or rechargeable batteries |  |
| 8.12 | Transparent ceiling mounted Radiation shield for Physician. |  |
| 8.13 | Table mounted shield for Physician and staff. |  |
| 8.14 | Please provide the radiation protection technology available with your system: List all available features and include quote accordingly. |  |
| **9** | **CONFORMITY** |  |
| 9.1 | Must be FDA and or CE marked attach proof |  |
| **10** | **Uninterruptible Power Supply UPS** |  |
| 10.1 | 160 kVA (144kW) Three phase in, three phase out online double conversion static transformer-based UPS system with integrated static and manual bypass. |  |
| **11** | **TRAINING** |  |
| 11.1 | An operator’s manual shall be provided for each installed system component |  |
| 11.2 | Service manuals shall be provided for each installed component type. |  |
| 11.3 | Manuals covering the operation, installation and maintenance of all system components and explaining the operational concept of the system as a whole shall be provided. |  |
| 11.4 | On-site training for users and operators of the system is essential. Training programs shall be instituted for Radiographers, doctors, nursing staff. Bidders to state the duration of training for each group. The cost of this training shall form part of the tender. |  |
| 11.5 | Full Cath lab application training (5x full working days per week for 2 weeks for Radiographers & Doctors as super-users.  Follow-up trainings must be offered after one (1) month and another one after four (4) to six (6) months after initial training and commissioning. Follow up training must be included in schedule |  |
| 11.6 | Technical training for two (2) Bio-engineers must be included in the final offer |  |
| 11.7 | QC Test support Training for Chief Radiographers for three (3) full working days. |  |
| **12** | **MAINTINANCE** |  |
| 12.1 | Tenders must be officially accredited to perform the maintenance by the equipment manufacturer. |  |
| 12.2 | Tenderer must be able to supply new, original spare parts directly from the equipment manufacturer within a reasonable time. Please provide proof and state delivery times of spare parts. |  |
| 12.3 | **In order to evaluate the life-cycle cost of the equipment, a suggested planned maintenance cost, estimated on a year by year basis for five years MUST be quoted for as OPTIONAL. Bidders to supply a quote for:** |  |
| 12.3.1 | A full, all-inclusive maintenance contract including breakdowns spare parts, software and hardware updates |  |
| 12.3.2 | A quote for all-inclusive maintenance contract including yearly preventative maintenance and software/hardware updates, excluding breakdowns and spare parts |  |
| 12.3.3 | A quote for preventative maintenance only should be provided |  |
| 12.3.4 | Timely maintenance and support time is crucial. It is expected that a call to the field engineer will result in a return call within 60 minutes. All problems will be aggressively handled with timely progress communication with departmental staff. The vendor will describe the method and time frame of problem resolution. Complete system failure will receive highest priority, and will result in a service person actively working on the problem within 24 hours. Please include a proposal/action plan for maintenance/breakdown response. |  |
| 12.3.5 | Remote maintenance is highly recommended due to the remote location of this site. Network connection (ADSL) to site to be provided by the hospital. |  |
| **13** | **QC TEST TOOLS AND PHANTOMS** |  |
| 13.1 | **Quality control kit:** Please indicate what the kit contains |  |
| **14** | **AIR CONDITIONER (AC)** |  |
| 14.1 | Bidder must include air conditioning for optimal functioning of the unit. Such air conditioning must be covered by the guarantee bided for on the unit and servicing of the air conditioning units for the guarantee period and must be included in the bid price. The air conditioners must also be included in the 5-year maintenance. |  |
| 14.2 | State details on the air conditioners to be supplied according to the room size and machine requirements. |  |
| 14.3 | The Successful bidder must install an outlet-plumbing pipe for water overflow from air conditioner to be re-directed to a drainage system. |  |
| **15** | **ROOM ALTERATIONS** |  |
| 15.1 | Site Visit compulsory |  |
| 15.2 | List and Quote accordingly |  |