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| --- | --- | --- |
| **Item 1** | **Bi-Plane For Cardiovascular &Interventional Imaging** | **Qty. (1)** |

***IMPORTANT NOTE:***

***Vendors are required to fill out the product details, compliance information, and brochure reference page number in the columns below***

***TECHNICAL SPECIFICATIONS:***

**The unit must meet or exceed the requirements listed in the table below.**

|  |  |
| --- | --- |
| **Product Details** | |
| Name of Manufacturer |  |
| Model/ catalogue number |  |
| Country of Origin for the offered model |  |
| Country where the manufacturer is based |  |
| Delivery time |  |
| Full warranty period |  |
| FDA clearance |  |

|  | **Minimum Requirements** | **Compliance )Y/N) , Notes** | **Brochure Page No*.*** |
| --- | --- | --- | --- |
| **A** | **Bi-plane cardiac imaging .** |  |  |
| **1** | Latest and top of the line model of state of the art Biplane Flat panel Detector Cardiac Angiography system that shall be compatible with all diagnostic and therapeutic intervention of Cardiac adult, pediatric and procedures. Providing superb image quality at lowest possible patient dose. |  |  |
| **2** | System should be of ergonomic design for easy of use. |  |  |
| **3** | Cardiac rotational angiography in a dual axis rotation |  |  |
| **4** | System shall have the ability to manage dose while maintaining high image resolution quality. |  |  |
| **5** | System expansion and upgradeability must be possible |  |  |
| **6** | Shall be able to be programed for different protocols based on individual user personal preferences, for automatic projection sequence for every cardiologists, image quality settings, program selection per clinical domain |  |  |
| **7** | Networking capabilities (Dicom. Latest version) |  |  |
| **B** | **Biplane System :** |  |  |
| **B.1** | **Gantry floor mounted** |  |  |
| **1** | To be consisted of Floor mounted stand easy to use (C or G shapes) |  |  |
| **2** | The gantry can easily be parked away from the patient table during patient transfer and in case of emergency |  |  |
| **3** | The patient access / transfer to the patient table is available from both sides of the table |  |  |
| **4** | parking motorized and manual |  |  |
| **5** | The inner radius of the C-arm is more than 92 cm, to allow easy access for imaging the patient, without the need to move the gantry |  |  |
| **6** | Anti-collision protection at all times. Technique used should be explained |  |  |
| **7** | Projections :LAO projections; 0° to 120°, RAO projections, 0° to 120°, Cranial projections, 0° to 45°,Caudal projections, 0° to 45° |  |  |
| **8** | The rotation speed is minimal 25° / sec |  |  |
| **9** | The angulation speed is minimal 18° / sec |  |  |
| **10** | The floor to isocenter distance should be between 103 and 108 cm |  |  |
| **11** | The source to isocenter distance ≥ 75 cm |  |  |
| **12** | The (SID) range should be minimal between 89 approximately - 123 approximately cm |  |  |
| **B.2** | **Gantry Ceiling mounted** |  |  |
| **1** | To be consisted of ceiling suspended C arm system |  |  |
| **2** | The gantry can be parked away from the patient table so as to free space at the head end and on both sides of the patient for access during emergencies |  |  |
| **3** | maximum patient cardiac coverage: please specify |  |  |
| **4** | The parking is motorized and manual |  |  |
| **5** | rotation speed degrees/s not less than 8°/sec |  |  |
| **6** | source-image distance (SID): 89 approximately - 123 approximately cm |  |  |
| 7 | The patient image always appears with "head up" on the monitor regardless of the position of the gantry |  |  |
| 8 | Motorize angulation of the c arm to allow best and unlimited cardiovascular projection and vessel profiling.  Automatic anti-collision system. |  |  |
| **C** | **X-Ray Generator** |  |  |
| **1** | High Power, grid controlled either from the X-Ray Tube or Generator |  |  |
| **2** | Multi-phase power unit for grid-pulsed fluoroscopy with acquisition console and high frequency converter. |  |  |
| **3** | High power output of not less than 100 kw approximately |  |  |
| **4** | Maximum voltage of not less than 125 kv |  |  |
| **5** | Maximum current of not less than 1000 m A |  |  |
| **6** | Automatic adjustment of kV and mA in radiography and automatic optimization of mA during fluoroscopy |  |  |
| **7** | All system messages shall be displayed |  |  |
| **8** | Maximum current of not less than 160 mA in fluoroscopy mode. |  |  |
| **D** | **X-ray tube Frontal and Lateral** |  |  |
| **1** | the tube must have grid switch & should be grid switch controlled |  |  |
| **2** | Maximum tube voltage of not less than 125 kV |  |  |
| **3** | Anode storage heat capacity not less than 5 MHU |  |  |
| **4** | Continuous heat dissipation of not less than 1500 KHU/m |  |  |
| **5** | two physical focal spots(small, large) |  |  |
| **6** | Silent tube |  |  |
| **7** | wedge-shaped, semi-transparent collimation blades be positioned without any X-ray |  |  |
| **E** | **Patient Table** |  |  |
| **1** | Floor standing and free floating table top. |  |  |
| **2** | Movements: (Longitudinal, Transversal, Vertical, Pivoting, Tilting). |  |  |
| **3** | Capable of supporting at least 250 kg patient CPR can be done in any position of the table top. |  |  |
| **4** | **All table accessories** should be provided, including |  |  |
| **5** | Soft mattress |  |  |
| **6** | Rail Clamps |  |  |
| **7** | Two arm supports |  |  |
| **8** | Infusion stand |  |  |
| **9** | Table rotation of at least +/-90 deg |  |  |
| **10** | Minimum table height is 79 cm or less for easy patient transfer |  |  |
| **11** | Table length at least 280 cm **please specify radiolucent over hang** |  |  |
| **12** | Radiation Shielded &Table mount radiation shielded to be included. |  |  |
| **F** | **Flat panel detector image acquisition system frontal size 20x20 cm approximately and lateral 20x20 cm approximately** |  |  |
| **1** | Detector of the latest design and technology, with high contrast ratio and automatic gain control for improved patient penetration |  |  |
| **2** | Pixel Pitch 184Micron or below |  |  |
| **3** | The largest useful field of view of the detector (in diagonal) shall be 28 cm or higher |  |  |
| **4** | Spatial resolution for frontal detector 2.7 line per millimeter or above |  |  |
| **5** | DQE (detector Quantum Efficiency) 75 or higher |  |  |
| **6** | Number of Acquisition Zoom / FOVs ( diagonal) should be more than 4, specify the sizes |  |  |
| **G** | **Image Processing and Display** |  |  |
| **1** | Monitors: |  |  |
|  | 1. Minimum Qty (6),Size 19" or more high resolution flicker free progressive display LCD monitors in the examination room or equivalent |  |  |
|  | b. Minimum Qty (3) 19” Inch or more high resolution, flicker free progressive display monitors in the control room |  |  |
|  | 1. Optionally quote 58" medical grade flat display monitor to be positioned at both sides of the patient support instead of the small monitors mentioned above |  |  |
| **H** | **Advance Software’s** |  |  |
| **1** | Roadmap in parallel with un-subtracted digital fluoroscopy for both planes . |  |  |
| **2** | Coronary Roadmap (live flouro and angiogram image in the same time) |  |  |
| **3** | stent enhancement software |  |  |
| **4** | Fluoro roadmap |  |  |
| **5** | Live Stent Enhancements |  |  |
| **6** | rotational angiography to view RCA and LCA |  |  |
| **7** | Real-time pixel shifting to compensate for patient movement during DSA and Roadmap |  |  |
| **8** | Road mapping by overlaying fluoroscopy with a selected reference image on the live monitor. |  |  |
| **9** | Distance measurement |  |  |
| **10** | Color-coded cross-sectional blood volume maps to indicates the distribution and amount of blood in lesions and surrounding tissue |  |  |
| **11** | Left ventricular analysis |  |  |
| 12 | Stenotic lesion sizing, stent boost |  |  |
| 13 | Quantitative Coronary Analysis |  |  |
| 14 | Quantitative Vascular Analysis (QVA) |  |  |
| 15 | Vessel evaluation |  |  |
| 16 | Automatic Stenosis degree detection |  |  |
| 17 | FD Dual Fluoroscopy |  |  |
| 18 | Rotation Angio |  |  |
| 19 | Electrophysiology(EP)  -Advanced in imaging and mapping technology  -Shows real time HD imaging delivering true anatomy and creates voltage and activation map.  -EP navigation and 3D software  -Pulmonary vein isolation (PVI)  -Arrhythmias |  |  |
| **I** | **Dose Saving** |  |  |
| 1 | Dose reduction technique to be included hardware and software |  |  |
| 2 | Dedicated programs for dose saving without image quality drop. |  |  |
| 3 | Dose monitoring and dose reporting features should all be included. Please explain features. |  |  |
| 4 | DAP (Dose Area Product) measurement via an ionization chamber (diameter) and displayed on the exam room monitor. |  |  |
| 5 | DICOM structured report containing patient procedure and dose data |  |  |
| 6 | Dose information transfer to a PC for statistical analysis |  |  |
| 7 | Image Gallery for customer selection to customize IQ preferences |  |  |
| 8 | Radiation Free positioning |  |  |
| J | **Dicom Networking** |  |  |
| 1 | Latest technology in DICOM for network interface and fast image access. |  |  |
| 2 | Image storage capacity Not less than 50000 images per plane |  |  |
| K | **Post Processing Workstation** |  |  |
| 1 | Able to make all the post processing procedures |  |  |
| 2 | Automatic background archiving on DVD |  |  |
| L | **Contrast Injector** single head (**from well-known manufacturing)** |  |  |
| 1 | Floor, mobile microprocessor controlled, programmable, high capacity, power contrast medium injector. |  |  |
| 2 | ECG triggering and accessories to include syringe assembly of 150ml (disposable) with one spare kit of at least 100 disposable syringes 150ml and auditable for dual injections . |  |  |
| M | **Hemodynamics** |  |  |
| 1 | State of the Art Embedded Hemodynamic System |  |  |
| 2 | The system should be made from the same manufacturing company |  |  |
| 3 | Capable of measuring and displaying NBP, IBP, ECG(12 Leads+6 Leads), FFR |  |  |
| 4 | Pressure calculations features |  |  |
| 5 | Full Dicom Capabilities |  |  |
| N | **Intravascular ultrasound**  IVUS and physiological measurement system preferably from same manufacturer as the Biplane cathlab system |  |  |
| 1 | IVUS & Physiology data must be visible on Cathlab system's exam room ceiling suspended Monitor |  |  |
| 2 | Supplied with CPU, DVD Burner |  |  |
| 3 | Supplied with user interface ,Preferred to have this Integrated on Cathlab system's table side touch screen console |  |  |
| 4 | Dicom Network Connection Compatibility |  |  |
| 5 | Equipped with IVUS PIM (coronary & Peripheral Procedures) |  |  |
| 6 | Ability to work by both electronic solid state & mechanical rotational catheter |  |  |
| 7 | Equipped with preferably IVUS, FFR and IFR in the same device |  |  |
| 8 | Function of coloring the blood for easy assessment of stent apposition |  |  |
| 9 | Equipped with valid Virtual Histology Option (Colorized Tissue map of Plaque Composition-for complete Lesion Assessment) |  |  |
| 10 | Assessment of diffused or Tandem lesions for example IFR SCOUT |  |  |
| 11 | Availability of IVUS &Fractional flow **reserve** FFR/ The instantaneous wave-free ratio IFR co-registration |  |  |
| O | **Examination light:** designed to provide high intensity illumination at 70,000 Lux or better of the entire treatment area.   * + Provides high intensity illumination of treatment area   Handgrip can be sterilized and used with a disposable cover |  |  |
| P | The Offer must include free local training for 3 technician and free service training for one biomedical engineer in (authorized training center) |  |  |
| Q | The Offer must include the price for a comprehensive service -contract (including all replacement parts and x-ray tubes and resident engineer) valid for a period of (8) years starting at the end of the 24 month warranty period with resident engineer. |  |  |
| R | All available standard & optional features, packages, & accessories must be listed and priced separately |  |  |

**تضاف المواصفات التالية الى المواصفات اعلاه:**

1. ***Advanced imaging and mapping technology.***
2. ***Shows real-time HD imaging delivering true anatomy and creates voltage and activation map.***
3. ***EP navigator and 3D.***
4. ***Pulmonary vein isolation (PVI).***
5. ***EP ablation system (RF generator).***
6. ***EP recording with stimulator.***

***SPECIAL TERMS***

* ***Offers not complying with any of the special terms or the technical specifications shall be considered non-conforming with tender requirements.***
* ***Any vendor providing FORGED documents shall be disqualified from the current tender and banned from participating in any future RMS tenders.***

1. ***All equipment must be the most recently released model/version which is equal to or higher than the range of the specifications of the required system (low, mid or high) and equal to or higher than the level of technology and required options mentioned in the technical specifications.***
2. ***Required certificates:***
3. ***For equipment of US origin, a copy of a certificate of FDA approval & the relevant 510K clearance for selling to US healthcare facilities for the offered model must be submitted with the technical offer.***
4. ***For equipment of other origins, a copy of either a CE certificate with the relevant CE number (MDD)/TÜV/BSI/UL OR a certificate of FDA approval & the relevant 510K clearance for selling to US healthcare facilities for the offered model must be submitted with the technical offer.***
5. ***Only for class Ι medical equipment, submission of a copy of Declaration of Conformity certificate (MDD) for the offered model shall be accepted.***
6. ***With each offer, bidders must provide a formally endorsed document issued by the manufacturer stating that the bidder is the sole certified agent / distributor for the offered item.***
7. ***In all of the above cases (except 2.4) certificates must be formally endorsed by JFDA.***
8. ***Country of origin:***
   1. ***The country of origin of the main part (s) of the system must be one of the following:***

***USA, Canada, Japan, UK, Sweden, Finland, Denmark, Switzerland, Belgium, Germany, France, Netherlands, Spain, Norway, Italy, Ireland, Austria, New Zealand, Australia &Czech Republic.***

* 1. ***Accessories and consumables may be manufactured in other countries and/or by different manufacturers.***
  2. ***All offered items must be approved for sale in the same country of origin. An original and officially endorsed free-sale certificate from an authorised body must be included in the offer.***
  3. ***Vendors must specify the origin of all offered items and accessories in the technical offer.***
  4. ***Except for equipment mentioned in (3.6) below, equipment manufactured by reputable companies based in any of the countries mentioned in (3.1) will be taken into consideration regardless of the manufacturing site only::***
  5. ***If they are approved for sale in the same county of origin (an original and officially endorsed free-sale certificate from an authorised body must be included in the offer.***

***OR***

* 1. ***If they are approved for sale in at least three of the countries mentioned in (3.1) (an original and officially endorsed free-sale certificate from an authorised body in those countries must be included in the offer).***
  2. ***For X-ray based equipment, MRI, and nuclear medicine systems, the following parts must be manufactured in one of the countries mentioned in 3.1 above:***
     1. ***X-ray tubes***
     2. ***X-ray generators***
     3. ***Flat panel detectors***
     4. ***Gantries (including detectors)***
     5. ***Image intensifiers***
     6. ***MRI magnets***
     7. ***Gamma camera heads***
  3. ***Bidders must submit their reservations/queries regarding tender specifications and/or special terms within the first third of the tender closing period starting from the tender announcement date. Reservations/queries submitted after the end of this period shall be rejected.***

1. ***Warranty:*** 
   1. ***Offers must include a full warranty including spare parts and labour for a period of a minimum of 24 months from the date of installation.***
   2. ***If at any time during the warranty period the item becomes inoperative due to a technical fault the item must then be repaired by the supplier /local agent within a period of fourteen days from written notification, otherwise the supplier must replace the item with a new identical functioning one and will endure a penalty determined by the Royal Medical Services for each day of the downtime of the system. In case the item was replaced by a new one, the warranty period mentioned in (4.i) above will start from the installation and commissioning date of the new item.***
2. ***One set of operation manual(s) and one set of service manual(s) including schematics and a spare-part list must be delivered with each unit, CD/DVD is acceptable. For large tenders, a certain agreed percentage of manuals per item may be agreed upon.***
3. ***Where applicable, pre-installation shall be the sole responsibility of the supplier. Pre-installation shall include removal of old system(s), any civil work, electrical work or site modification(s) necessary to accommodate the new system(s) according to manufacturers’ specifications and safety standards in addition to the work required for bringing back the site to the same working conditions as before installing the new system(s).***
4. ***Power requirements: where applicable either single phase 220V, 50Hz or 3-phase 380V. Systems with external transformers are considered conforming only if clearly stated in the technical specifications.***
5. ***Technical offers must include clear original technical brochures/catalogues for all offered items.***
6. ***Offers must include fully detailed technical offers and compliance sheets as a soft copy ( either Microsoft office or Microsoft excel format) in addition to a hard copy, mentioning the exact model/catalogue number and country of origin of the offered item(s), full technical description/specifications and any accessories or options included in the offer.***
7. ***Compliance sheets must be as per the tabular format of the technical specifications in the tender documents, listing the required specifications on one column and a Yes or NO response to each point in the adjacent column, with reference to page and line numbers in the relevant technical brochure. Offers not complying with this term shall be rejected.***
8. ***Accessories and consumables:***
   1. ***Any accessories and consumable items necessary to operate the offered system must be clearly identified and priced separately.***
   2. ***Technical offers must include a priced list for accessories and consumables as a hard copy in addition to a soft copy (either Microsoft office or Microsoft excel format) with prices fixed for a period of five years from the date of installation and commissioning with a maximum annual increase of 2%, any essential item not listed will be considered free of charge.***
   3. ***Accessories and consumables must be priced according to their delivery destination either to Queen Alia International Airport or to RMS Main Medical Stores.***
   4. ***Where applicable, a start-up kit of accessories and consumable items must be provided with each system on a free-of-charge basis.***
9. ***Spare Parts:***
   1. ***Technical offers must include a comprehensive and priced spare parts list as a hard copy in addition to a soft copy (either Microsoft office or Microsoft excel format) valid for a minimum period of five years with a maximum annual increase of 2%, commencing at the end date of the warranty period, any essential item not listed will be considered free of charge.***
   2. ***Spare parts must be priced according to their delivery destination either to Queen Alia International Airport or to RMS Main Medical Stores.***
10. ***Spare parts, consumables and accessories availability must be guaranteed for a minimum period of ten years starting from the date of installation and commissioning.***
11. ***Tender Awards:***
    1. ***For the final list of offers having a chance of winning the award, the awarding process shall be based on the accumulative value of both the offered item and its’ running cost (Total Cost of Ownership) over a period of seven years from the date of installation and commissioning. Only offers with the lowest total cost of ownership over a period of seven years from the date of installation and commissioning shall qualify for the award.***
    2. ***Running cost includes the value of consumables, accessories needed to operate the system over the same period as well as the cost of any service contract (where applicable).***
12. ***For PC/Laptop based systems:***
    1. ***Complete restoration medium(CD/DVD/etc.) of the operating system and the application software must be supplied.***
    2. ***Where locally supplied computers or laptops are offered, only computers/laptops from Apple, hp/Compaq, Lenovo, Dell, fujtisu or Toshiba will be accepted, offered models must be the latest available version upon delivery.***
    3. ***Where locally supplied printers are offered only the following types and brands are accepted: HP, SAMSUNG, OKI, CANON, EPSON.***
13. ***Pricing must include services of sale, shipment, transportation, delivery from port to site or to Main Medical Stores, installation, pre-installation (if needed), training, commissioning, warranty and bringing the equipment into service.***
14. ***Custom clearance of goods shall be the responsibility of the Jordanian Armed Forces (JAF), however, suppliers shall bear all costs incurred by handling charges and any demurrage charges or extra expenses incurred by the port’s corporation (including expenses caused by delay in presenting the necessary shipment documents for either clearing or transporting the goods to the required location mentioned in the final order, delivery note issuing charges, unloading charges, local shipping charges etc.). The supplier is also responsible for providing of all relevant shipping documents, together with the delivery order(s).***
15. ***DRMS has the right to increase or decrease the awarded quantities by a percentage not exceeding 30% after the final order notification with the same prices, terms and conditions of the original contract upon DRMS request and approval of the awarded party.***
16. ***The supplier must furnish DRMS with a guarantee stamped and legalized by the Notary Public equals to (115%) of the total value of the awarded equipment valid for twelvemonths from the date of final acceptance of the equipment by DRMS.***
17. ***Training: onsite user and service training***

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