ANGIOGRAPHY & HYBRID THEATRE EQUIPMENT AND RELATED SERVICES

LOT 1 - ANGIOGRAPHY IMAGING, HYBRID OPERATING THEATRES, CARDIAC CATHETERISATION MONITORING & RELATED EQUIPMENT

In all cases this specification relates to the purchase and provision of equipment relating to the below three categories, installation and commissioning of said equipment involving any associated building works or turnkey provision, software, AI & IT Integration, user training, disposal & replacement of assets, detailed reporting to enable maximum value from the service & any project planning and financing opportunities for the following: including, but not limited to:

Subcategory 1 - Angiography Imaging Systems,

Subcategory 2 - Cardiac Catheterisation Physiological & Haemodynamic Monitoring Systems and,

Subcategory 3 - Hybrid Operating Theatres and Associated Options & Related Services

The following requirements apply only to equipment in SUBCATEGORY 1 – ANGIOGRAPHY IMAGING SYSTEMS

The scope of this subcategory covers the following modalities;

Single Plane, Flat Panel Detector Vascular Angiography Imaging System

Single Plane, Flat Panel Detector Cardiac Angiography Imaging System

Bi-Plane, Flat Panel Detector Cardiac Angiography Imaging System

Bi-Plane, Flat Panel Detector Neuro-Angiography System

This scope of this specification includes but is not limited to; X-Ray Generators, C-arm positioners with Flat Panel Detector (inc. with FPD) and X-Ray tube, Patient Tables (Including Cardiac & Neuro Profile), In room monitors with ceiling support, Control area monitor(s) for review and post processing, Capable of Contrast Injector Interface & Radiation Protection Shields

To meet the minimum requirement of this subcategory ALL systems **must** meet the below minimum requirements;

1. As a minimum requirement X-Ray Generators (including tubes and housings) **must** meet the below minimum requirement;
   - 1.1. The X-Ray generator **must** be high frequency and provide a minimum of 100 kW
   - 1.2. The kVp range **must** be at least 50 to 125 kVp
   - 1.3. The X-Ray Generator and/or X-Ray tube **must** be capable to provide pulsed fluoroscopy with selectable options
   - 1.4. The angiography X-Ray system **must** have automatic dose rate control
   - 1.5. Full control of the X-Ray angiography system **must** be available from the patient tableside, mobile trolly or in room
   - 1.6. The in-room display **must** show all generator operating parameters for both X-Ray tubes
   - 1.7. Each X-Ray tube rating **must** match the X-Ray generator
   - 1.8. The total tube filtration **must** be the equivalent of at least 2.5 mm Al
   - 1.9. Any additional patient specific filtration specifically designed to reduce unnecessary radiation exposure **must** be automatically adjusted
   - 1.10. Each X-Ray tube **must** have at least 2 automatically selected focal spots. The smaller focal spot **must** be no larger than 0.5 mm
   - 1.11. The anode heat storage capacity **must** be at least 2.0 MHU
   - 1.12. The anode heat dissipation rate **must** be at least 300,000 HU/minute
   - 1.13. The angiography X-Ray system **must** have linear collimation with virtual control and automatically selected filtration

2. As a minimum requirement the C-arm positioner with Flat Panel Detector and X-Ray tube **must** meet the below minimum requirement;
    - 2.1. **Must** be Ceiling or Floor Mountable
    - 2.2. The image field of the frontal Flat Panel Detector **must** be at least 20 cm x 20 cm
    - 2.3. All movements **must** be motorised and controlled from the tableside and in-room
    - 2.4. The focus to detector distance (FDD) **must** be adjustable
    - 2.5. The left/right anterior oblique (LAO/RAO) angulations **must** be at least 100°/ 100°
    - 2.6. The cranial/caudal (CRA/CAU) angulations **must** be at least+/-45°
    - 2.7. It **must** be possible to park the positioner away from the patient table
    - 2.8. The positioner **must** include anti-collision protection
    - 2.9. It **must** be possible to manually move the positioner in the event of equipment failure
    - 2.10. The detector **must** have an anti-scatter grid
    - 2.11. The collimation **must** automatically adjust to the focus to detector distance
    - 2.12. The pixel size **must** be no greater than 0.2 mm
    - 2.13. The maximum DQE **must** be at least 70%
    - 2.14. The detector **must** be able to support full resolution acquisition at up to 30 frames per second
    - 2.15. The detector **must** be able to support reduced resolution acquisition and fluoroscopy at up to 7.5 frames per second
    - 2.16. The Flat Panel Detector **must** acquire data with a minimum of 14-bit resolution

3. As a minimum requirement the Patient Table **must** meet the below minimum requirement;
    - 3.1. The table dimensions (fully extended) **must** be at least a minimum of 45 cm wide by 200 cm long
    - 3.2. The tabletop **must** have an X-Ray absorption equivalent to no more than 1.5 mm Al
    - 3.3. The tabletop vertical travel range **must** be at least 80 to 100 cm from the floor
    - 3.4. The vertical movement **must** be motorised
    - 3.5. The table **must** have a four-way floating top
    - 3.6. The lateral coverage using the tabletop and/or detector movement **must** give a combined total coverage of at least 20cm
    - 3.7. The table **must** be capable of supporting a 200 kg (reduced to 180kg for Hybrid Operating Theatres) patient without deflection at maximum tabletop extension. The tabletop **must** be capable of all performance features at this maximum weight
    - 3.8. The table **must** be capable of supporting an additional 25 kg of equipment
    - 3.9. The table **must** be capable of supporting an additional 50 kg for CPR without the need for a CPR support stand
    - 3.10. The patient table **must** be designed with a view to patient transfer by hoist, PATSLIDE or similar device

4. As a minimum requirement the in-Room Monitor(s) with ceiling support **must** meet the below minimum requirement;

    4.1. In room image display (including post processing) **must** be provided on at least one diagnostic quality, high brightness, greyscale, ceiling suspended monitor (additional monitors to be supplied in accordance with individual Participating Authority requirements) Image display features **must** include:

        4.1.1. Contrast and brightness adjustment

        4.1.2. Zoom and pan

        4.1.3. Basic image measurement tools

    4.2. Where required by the contracting authority Multi-modality viewing (viewing pertinent images from other modalities) **must** be available

        4.2.1. Live fluoroscopy and last image hold (including fluoroscopy free collimation adjustment)

        4.2.2. Dose monitoring (dose area product, cumulative dose rate / area product, and cumulative fluoroscopy time)

        4.2.3. Last 10 seconds of fluoroscopy must be available for review

5. As a minimum requirement the Control Area Monitor(s) & Review workstations **must** meet the below minimum requirement;

    5.1. Control room image display **must** be provided via at least one diagnostic quality monitor (additional monitors to be supplied in accordance with individual Participating Authority requirements)

    5.2. Image display **must** have a minimum screen size of 19" (measured diagonally, corner to corner)

    5.3. Features of Images displayed (including post processing) **must** include:

        5.3.1. Contrast and brightness adjustment

        5.3.2. Zoom and pan

        5.3.3. Distance measurement

        5.3.4. Multi-modality viewing (viewing pertinent images from other modalities)

6. All Systems **must** be capable of supporting a contrast injector interface.

7. The Applicant **must** be able to supply lead shielding as required by medical staff, in accordance to RPA recommendations.

8. As a minimum any system **must** meet the below minimum Safety requirements given within Appendix 5

9. The radiation beam **must** be confined to within the image reception area with a maximum overlap not greater than 15% of the image reception area

9.1. The entrance dose levels **must** not exceed those set out in Medical and Dental guidance notes (A good practice guide to implementing ionising radiation legislation in the clinical environment, IPEM 2002)

9.2. The absorbed dose at the skin of a patient (20cm water) **must** not exceed 100 mGy min^{-1} for all available field sizes in fluoroscopy mode

9.3. The angiography X-Ray system **must** have automatic brightness control and variable dose selection

9.4. The table top **must** comply with a minimum of IPX2 Ingress Protection,

9.5. The angiography X-Ray system **must** have an appropriate dose indication and displayed exposure time

9.6. The angiography X-Ray system **must** have the following dose reduction features:

9.6.1.1. Last image hold

9.6.1.2. Automatic skin filters

9.6.1.3. Pulsed fluoroscopy (with at least 15 and 30 pps)

9.6.1.4. Variable image receptor dose levels

9.6.1.5. A range of kV and mA operating characteristics to optimise patient dose

9.7. The angiography X-Ray system **must** be supplied with a dose area product (DAP) (can be calculated or measured) and **must** indicate the DAP rate as well as the accumulated DAP.

9.8. The angiography X-Ray system **must** have software and/or mechanical anti-collision protection.

9.9. The angiography X-Ray system **must** be capable of dynamically detecting and adjusting the dose for optimal imaging.

9.10. The system should conform with the IHE Radiation Exposure Monitoring profile, it should be capable of creating and transferring patient dose information in a DICOM Radiation Dose Structured Report (RDSR) object.

9.11. System should be able to send images to PACS

In Addition, each modality **must** then meet the below specific requirements;

Single Plane, Flat Panel Detector Vascular Angiography Imaging System

10. In Addition to the above requirement the in-Room Monitor(s) **must** perform Digital subtraction angiography

Single Plane, Flat Panel Detector Cardiac Angiography Imaging System

11. In Addition to the above requirement the in-Room Monitor(s) **must** perform Cardiac quantitative analysis software (including ventricular and coronary quantification)

Bi-Plane, Flat Panel Detector Cardiac Angiography Imaging System

12. In Addition to the above requirement the in-Room Monitor(s) **must** perform Cardiac quantitative analysis software (including ventricular and coronary quantification)

<u>The following requirements apply only to equipment in SUBCATEGORY 2 – CARDIAC CATHETERISATION PHYSIOLOGICAL & HAEMODYNAMIC MONITORING SYSTEMS</u>

The scope of this subcategory covers Cardiac Catheterisation Physiological & Haemodynamic Monitoring Systems

13. As a minimum, the monitoring system **must** measure pressures in the chambers of the heart and great vessels, and calculate;
    - 13.1. Pressure gradients,
    - 13.2. Cardiac output,
    - 13.3. Cardiac index and,
    - 13.4. Systemic and pulmonary blood flows and flow ratios

14. To meet the minimum requirement of this subcategory **<u>ALL</u>** systems **must** include the below minimum requirements;
    - 14.1. An operating console with high-resolution colour monitors suitable for display of waveforms and data
    - 14.2. An integrated computer with data processing software and recording system
    - 14.3. Amplifier modules that acquire, amplify, and process physiological and haemodynamic parameters
    - 14.4. A minimum of 12 surface electrocardiogram (SECG) channels
    - 14.5. At least 2 invasive and 1 non-invasive blood pressure monitoring channels
    - 14.6. Integral pulse oximetry (SpO_2) monitoring
    - 14.7. Cardiac output monitoring, Fick, thermal dilution (TDCO) and cardiac output calculations
    - 14.8. Provide data that can be used to determine the presence of shunts, estimate their size, valve areas, and measure pulmonary and systemic vascular resistance
    - 14.9. Measure, track and record all typical patient vital signs and physiological events during catheterisation procedures
    - 14.10. Allow monitoring during catheterisation procedures for both adult and paediatric patients

15. Be able to annotate printouts using a variety of reference lines, grids, or event markers

16. Allow user-configurable parameters and real-time signal analysis through multitasking software capability

17. Be able to event mark and to freeze waveforms for analysis and notations

18. Have an integrated or standalone electrophysiology (EP) capability

19. As a minimum requirement <u>Display Monitors</u> **must** meet the below minimum requirement:

19.1. Provide at least one dedicated monitor for continuous display of patient physiological / haemodynamic parameters

19.2. Provide at least one additional monitor that is capable of displaying procedure notes, measurements, calculations and waveforms independent of continuous patient physiological/haemodynamic monitoring data

19.3. Monitor configurations **must** include a minimum of three displays;

19.3.1.1. 2 at the cardiac catheterisation control station

19.3.1.2. 1 in the catheter lab procedure room

19.4. A minimum display of 12 traces (data channels) simultaneously

19.5. A sweep speed of at least 5 mm/second, with variable increases to at least 400 mm/second for EP 200mm/second

20. As a minimum requirement Printed Pages **must** display the below minimum requirement

20.1. Patient name

20.2. Patient ID

20.3. Date/time marks

20.4. ECG Readings

20.5. Pressure waveforms

20.6. 12 traces simultaneously.

21. As a minimum requirement Software & Integration **must** meet the below minimum requirements;

21.1. Computer software must provide haemodynamic calculations

21.2. Computer software must include a report generator (e.g. Microsoft Word based reports)

21.3. The system **must** have the ability to export monitoring data and reports to external hospital information systems

21.4. The cardiac catheterisation system **must** conform to current DICOM modality work lists (DMWL)

21.5. The cardiac catheterisation system **must** have an ability to interface with Hospital/Cardiac PACS systems

The following requirements apply only to equipment in SUBCATEGORY 3 - HYBRID OPERATING THEATRES AND ASSOCIATED OPTIONS & RELATED SERVICES

The scope of this subcategory is for the supply of Hybrid Operating Theatres including an angiographic or cardiovascular imaging system in a theatre setting. In Additional to the equipment and minimum requirements listed in Subcategory 1 & 2, a Hybrid System can also include the provision of;

Contrast injectors
Ultrasound
Ventricular Assist Pumps
Surgical lights
Pendants & Booms
Physiologic and hemodynamic monitor

Ancillary equipment for minimally invasive and hybrid operating procedures can include but is not limited to the following if requested by the Participating Authority;

Surgical trollies
Catheter trollies
Storage systems (Inc RFID Cabinets)
Radiation Protection Sheilds

22. As a minimum requirement the Integrated Interventional or Integrated Surgical Table **must** meet the below minimum requirement;
    - 22.1. The table **must** have a stationary column
    - 22.2. All X-Ray Imaging table tops **must** be radiolucent
    - 22.3. The positioning control for the table **must** be integrated with the imaging system to optimise imaging workflow and reduce the risk of collision
    - 22.4. The table **must** tilt a minimum 15 degrees for Trendelenburg and Reverse Trendelenburg positioning and **must** tilt a minimum of 15 degrees laterally
    - 22.5. Rotation of the patient table **must** be possible,
    - 22.6. The tabletop **must** comply with a minimum of IPX4 Ingress Protection,
    - 22.7. The table **must** have DIN rails provided for mounting accessories at the table side

23. Where the contracting authority requires lighting, as a minimum the Pendants, Booms & Lights **must** meet the below minimum requirement;
    - 23.1. Lights need to be provided to ensure full coverage of the table
    - 23.2. Light arms **must** enable unrestricted, independent movement and stable positioning of light heads
    - 23.3. The lights **must** not permentantly restrict the movement of a ceiling mounted C-arm

23.4. Lighting **must** be able to be set to fully on for minimal invasive or open surgery and dimmable when using imaging

23.5. A light within the system should be able to take a High Definition Camera for both surgical and training needs if required

23.6. A pendant ceiling mounted system that provides access to gas, electrical and data outlets and must not interfere with the C-arm movement. The pendant will have coverage dependant on local requirements of the room size and imaging equipment to be installed

23.7. Dual LED Surgical Lights **must** be supplied with;

23.7.1. A main light abovef 100k LUX for optimal illumination of multiple surgical fields

23.7.2. A satellite light (if required by the imaging solution) above 100k LUX for optimal llumination of multiple surgical fields

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