ANNEX 1

Specifications

1. Haemodynamic Monitoring System:

Req. Quantity 1 unit

Description:

- Two high resolution TFT (Preferably LED) monitors, 21 inch or more for post-processing and reporting in the control room. One high resolution medical grade TFT/LCD monitor for post-processing and reporting in the workstation. Another monitor in the console room for live scenes. There should be more monitor in console room for live hemodynamic monitoring & Console Monitor for patient registration.
- The monitor display system in examination room should be ceiling suspended and it should be possible to position it on the left or right side of patient table.
- A workstation should be provided with minimum 8 GB ram and upgradable.
- Facility for acquired images to be transferred to the workstation seamlessly without interrupting the procedure; there should be 2-way digital image communication between the workstation and the procedure room.
- Workstation should be able to archive at least 1000 patients' data with easy irretrievability search by name, date of procedure or Cath number
- Monitor should meet at least 21'' screen and 1680*1050 resolution for both operating room and console room.
- The following features of Haemodynamic recording should be available.
    - Maintain Full Patient File Record
    - Automatic store of all analyzed data.
    - Angiography Module.
    - Chronography Module.
    - Intervention module with coronary tree.
    - Report & Archive
    - System Setup
    - Built-in Database (SQL Server)
    - Real Time Calculation of Fraction Flow Reverse.

- Real – Time FFR Values upon onset of hyperemia
- Storage of ECG/pressure recording on CD
- User configuration setup.
- Conversion of homodynamic reports into DICOM Compatible image data format

- Another monitor should be available for use in an adjacent room which can draw case scenes from the workstation and view the scenes, stop/play, zoom in and out.
- All monitors should have the signal acquisition parameters like SPO2, IBP upto 4, 12 - LEAD ECG, Non-Invasive Blood Pressure, ETCO2(Respiration) /Temperature, Thermodilution cardiac output, and pressure wire.
- All monitors should be medical grade having:
  - Flicker free, distortion-free high resolution
  - High contrast
  - Wide viewing angle
  - Brightness at least 600cd / m2
  - Automatic gain, brightness control

Required accessories and consumables:

- ECG cables and reusable pressure transducers
- Software should be provided for offline hemodynamic calculations such as cardiac output, gradients and stunt estimations.
- Haemodynamic monitoring system with all standard accessories for adult, pediatric and neonatal patients.

Standards and Power Requirements:

- USFDA approved product. All other accessories should be USFDA, CE and or ISO certifications or relevant standards certification.
- Electrical safety conforms to standards for electrical safety IEC-60601-General Requirements Shall comply with AERB and BARC guidelines.
- Power requirement:250V, 50Hz.

Additional Remarks or Requirements:

- Complete product details to be enclosed with the original brochure or catalogue (Soft or hard copy).
- Details of the standard accessories, additional accessories, optional items, consumables and minimum supplies to be stated clearly.

2. Ceiling Mounted X-Ray Protective Shield:

Req. Quantity **1 unit**

Description:

- It should be compatible with the existing installed Trump for OT light.
- It should be hand free and movable in any direction.
- It should have a suspension arm to control the appropriate direction.
- Stains of blood, contrast, bile etc., should be easily washable.
- Lead equivalence should be below 1.0 mm (Pb) or 0.50
- Radiation protection apparel should incorporate a high-quality protection sheet of even thickness.
- It should consist of Lead-free protective material manufactured with nontoxic heavy metals.
- It should be compatible with all generations of people – universal size.

Required accessories and consumables:

- ECG cables and reusable pressure transducers
- Software should be provided for offline hemodynamic calculations such as cardiac output, gradients and stunt estimations.

Standards and Power Requirements:

- USFDA approved product. All other accessories should be USFDA, CE and or ISO certifications or relevant standards certification.
- European CE Certified under PPE (Personal Protection Equipment) directive 89/686/EEC. The valid certificate from Notified body of EU with the Notified body no. on the certificate shall be enclosed.

Additional Remarks or Requirements:

- Complete product details to be enclosed with the original brochure or catalogue. (Soft or hard copy).
- Details of the standard accessories, additional accessories, optional items, consumables and minimum supplies to be stated clearly.

3. X-Ray Protective Apron:

Required Numbers:	**Quantity**
• Lead Free Apron Size-XL	05
• Lead Free Apron Size-L	05
• Lead Free Apron Size-M	05

Description:

- Apron should be Ultralight in weight.
- All models should have anti-skid pads resulting in comfort of wearing over shoulders.
- Should be frontal overlap.
- Adjustable in-built elastic belt should be there for reducing back and shoulder stress.
- Should be a slide slit for better mobility
- Should be an anti-skid shoulder pads for added comfort and weight distribution.
- Radiation protection apparel should incorporate high quality protection sheet of even thickness.
- Stains of blood, contrast, bile etc. should be easily washable.
- Apron should consist of Lead-free protective material manufactured with nontoxic heavy metals.
- Core material should be mix of Bilayer (Antimony, Bismuth, Tin, Barium, Titanium and Tungsten) having an Area Density of 2.8 Kg/sqm at 0.25 mm Pb.
- There should be absence of toxic material Lead and it should be Eco friendly.
- The supplier must provide color choice and department/Username on the aprons.
- Should be able to easy wear and remove.
- Should meet the Lead equivalence ranges 0.25mm Pb, 0.35mm Pb,0.50 mm Pb adhesive Backing.
- Should be hook and loop type (Velcro).

Standards and Power Requirements:

- USFDA approved product. All other accessories should be USFDA, CE and or ISO certifications or relevant standards certification.
- European CE Certified under PPE (Personal Protection Equipment) directive 89/686/EEC. The valid certificate from Notified body of EU with the Notified body no. on the certificate shall be enclosed.

Additional Remarks or Requirements:

- Complete product details to be enclosed with the original brochure or catalogue. (Soft or hard copy).
- Details of the standard accessories, additional accessories, optional items, consumables and minimum supplies to be stated clearly.

4. Lead Free Thyroid shield:

Req. Quantity 8 nos

Description:

- Thyroid shield should be Ultralight in weight.
- Adjustable in-built elastic belt should be there for reducing back and shoulder stress.
- Should be a slide slit for better mobility
- Should be an anti-skid shoulder pads for added comfort and weight distribution.
- Radiation protection apparel should incorporate high quality protection sheet of even thickness.
- Stains of blood, contrast, bile etc. should be easily washable.
- Apron should consist of Lead-free protective material manufactured with nontoxic heavy metals.
- Core material should be mix of Bilayer (Antimony, Bismuth, Tin, Barium, Titanium and Tungsten) having an Area Density of 2.8 Kg/sqm at 0.25 mm Pb.
- There should be absence of toxic material Lead and it should be Eco friendly.
- The supplier must provide color choice and department/Username on the aprons.
- Should be able to easy wear and remove.
- Should meet the Lead equivalence ranges 0.25mm Pb, 0.35mm Pb,0.50 mm Pb adhesive Backing.
- Should be hook and loop type (Velcro).
- Thyroid guard should be elegant or slimline.
- Should be easily attachable to all aprons

Standards and Power Requirements:

- USFDA approved product. All other accessories should be USFDA, CE and or ISO certifications or relevant standards certification.
- European CE Certified under PPE (Personal Protection Equipment) directive 89/686/EEC. The valid certificate from Notified body of EU with the Notified body no. on the certificate shall be enclosed.

Additional Remarks or Requirements:

- Complete product details to be enclosed with the original brochure or catalogue. (Soft or hard copy).
- Details of the standard accessories, additional accessories, optional items, consumables and minimum supplies to be stated clearly.

5. Eye Wear/ Lead Goggle:

Req. Quantity 8 nos

Description:

- Should be able to wear over regular spectacles.
- Lead equivalence should be 0.75 mm (Pb).
- It should be light in weight and comes in a size that fits all faces and shapes.
- Should have padding on the temples and bridge of the nose for comfort
- It should be available in different sizes for both adults and children.
- Stains of blood, contrast, bile etc. should be easily washable
- The supplier must provide colour choice.
- It should be lightweight

Standards and Power Requirements:

- USFDA approved product. All other accessories should be USFDA, CE and or ISO certifications or relevant standards certification.
- European CE Certified under PPE (Personal Protection Equipment) directive 89/686/EEC. The valid certificate from Notified body of EU with the Notified body no. on the certificate shall be enclosed.

Additional Remarks or Requirements:

- Complete product details to be enclosed with the original brochure or catalogue. (Soft or hard copy).
- Details of the standard accessories, additional accessories, optional items, consumables and minimum supplies to be stated clearly.

6. X-Ray Protective Apron Storage:

Req. Quantity 3 nos

Description:

- It should be mobile with a caster wheel and sturdy.
- It should accommodate at least 10 Lead Aprons
- Hangers' material should be stainless steel or stain-free and have adequate load-bearing capacity.
- It should be convenient to move with the braking mechanism.
- It should be easily accessible.
- Should be available detachable hooks for more storage options.
- Should be available the compact unit for storing apparel, gloves, and shields.

Standards and Power Requirements:

- USFDA approved product. All other accessories should be USFDA, CE and or ISO certifications or relevant standards certification.
- European CE Certified under PPE (Personal Protection Equipment) directive 89/686/EEC. The valid certificate from Notified body of EU with the Notified body no. on the certificate shall be enclosed.

Additional Remarks or Requirements:

- Complete product details to be enclosed with the original brochure or catalogue. (Soft or hard copy).
- Details of the standard accessories, additional accessories, optional items, consumables and minimum supplies to be stated clearly.

7. UPS with Battery:

Req. Quantity 1 nos

Description:

- It should be suitable with the already purchased machine with at least 30 min battery backup.
- The battery should be available along with the UPS and match the number of batteries for the machine's electrical requirements.
- The minimum requirement should be 120kv or above as per the power requirements of using Cath-lab.
- The UPS panel should be a self-supporting stand-alone panel with a mounting facility to install over the floor.
- Should follow the requirements of output and input voltage as mentioned below.
    - Input

        A. Voltage: - 3 phase 415 V AC Supply
        B. Frequency: 50 Hz

    - Output

        Voltage: - 240 V AC + 5 %
        Frequency: - 50 Hz + 3 %
        Power: - As per the machine requirements
        KW rating – more than 0.7 times of respective 120 KW
        Phase: - 1 phase
        Total Harmonic Distortion < 3 %
        Individual Harmonic Distortion < 5 %
        Line regulation < 5 %
        Load regulation < 5 %
        Startup time < 1 milliseconds
- The environment range should meet the following requirements.: -

    A. Temperature: - 0 to 450 centigrade
    B. Humidity: - 90 % relative
    C. Cooling: - forced cooling
- Efficiency should be more than 90 %
- The controlling unit should be Solid state Control.
- Should have AC-DC converter – Fully controlled bridge rectifier
- Should be DC-AC conversion – MOSFET / IGBT-based inverter (Party must specify the technique)
- Ripple in the regulator circuit output should be 4 V AC Peak to Peak maximum.
- DC battery charging voltage should be user selectable by utilizing a potentiometer on the card (not on the front panel).
- All the indicators are of solid-state LED type; lamp type indicators are not acceptable.

- Should available the following LED indicators: -

  A) AC mains – set of 3 LED for each Phase
  B) Low output voltage
  C) Low DC voltage
  D) Rectifier failure
  E) Inverter failure
  F) Battery overcharge
  G) Battery fully discharge
  H) Boost charging
  I) Float charging
  J) Extended charging
  K) Bypass mode on

- Protections should follow the below-mentioned conditions.

  A) Low output voltage
  B) Low DC voltage
  C) Rectifier failure
  D) Inverter failure
  E) Battery current limit
  F) Incorrect phase sequence (rectifier shall trip)

- Meters should have the following parameters

  A) Input AC voltage
  B) Output AC Voltage
  C) Output AC
  D) Battery/DC voltage
  E) Battery / DC current

- Controls switch should be available such as: -

  A) AC mains ON / OFF
  B) Inverter ON/ OFF
  C) Battery Connect/ Disconnect
  D) Load ON/OFF
  E) Indicator test
  F) Alarm acknowledgement
  G) Alarm Reset
  H) Battery charging auto /manual /boost mode

- A cooling fan should be available for power circuits.
- An exhaust fan should be available for cooling the overall equipment.
- Auto-detection should be available of battery charging option float /boost/ extended.

Standards and Power Requirements:

- USFDA, CE and or ISO certifications Security (EN50091-1) / EMC (EN50091-2) / IP Class (IP 20) / VFI Class (IEC62040-3) or relevant standards certification.
- Complete product details to be enclosed with the original brochure or catalogue (Soft or hard copy).
- Details of the standard accessories, additional accessories, optional items, Consumables and minimum supplies are to be stated clearly.