

**Indira Gandhi Memorial Hospital
Male', Republic of Maldives
Electrical Engineering Department**

Technical Specification for Equipment

Technical Specification for Portable Digital X-Ray Machine

1. General Description

- The system shall be a **non-motorized, lightweight, portable digital X-ray unit** suitable for use in wards, ICUs, operating theatres, and emergency departments.
- The system shall include an **integrated X-ray generator and digital imaging (DX) system** with an onboard image acquisition workstation and wireless image transfer capability.
- The design shall allow **easy maneuverability** and **stable positioning** during imaging procedures.

2. System Configuration

- **X-Ray Generator:** High-frequency, compact type.
- **Output Power:** Minimum 2–40 kW.
- **kVp Range:** 40 – 125 kVp (continuously variable).
- **mA Range:** Minimum 10 – 400 mA.
- **Exposure Time:** 1 ms – 10 s.
- **mAs Range:** 0.1 – 400 mAs or better.
- **X-Ray Tube:**
 - Stationary anode or rotating anode tube.
 - Focal spot size: Small ≤ 0.6 mm, Large ≤ 1.2 mm.
 - Tube heat capacity: ≥ 100 kHU.
- **Collimator:**
 - Manual light-beam collimator with adjustable shutters.
 - Integrated field light with timer and laser alignment.

3. Digital Imaging System

- **Detector Type:** Wireless flat panel detector (FPD), integrated with the X-ray unit, IPX6 or above protection
 - **Active Area:** Minimum 35 × 43 cm.
 - **Pixel Matrix:** $\geq 3k \times 3k$.
 - **Pixel Size:** ≤ 150 μ m.
 - **A/D Conversion:** Minimum 16-bit.
 - **Wireless Connectivity:** Wi-Fi / DICOM 3.0 compliant transfer to PACS or workstation.
 - **Image Processing:** Integrated console with patient data entry, image preview, enhancement, annotation, and measurement tools.
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4. Display and Workstation

- **Display Monitor:**
 - High-resolution medical-grade monitor.
 - Touchscreen preferred for ease of operation.
 - **Software Features:**
 - Patient data management and image archiving. (HIS, PACs and MWL)
 - DICOM compatibility (Store, Print, Worklist, Query/Retrieve).
 - Image rotation, magnification, contrast adjustment, and measurement tools.
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5. Mobility and Ergonomics

- **System Type:** Manual, non-motorized.
 - **Weight:** Lightweight and portable (preferably < 150 kg total system weight).
 - **Wheels:** Large, lockable, anti-static wheels for easy movement.
 - **Handles:** Ergonomically designed handles for manual transport and positioning.
 - **Tube Arm:** Counterbalanced, rotatable arm for flexible positioning at bedside or trolley.
 - **Hanger:** Lead aprons hanger should be available in the machine.
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6. Power Requirements

- **Input Power:** 230V \pm 10%, 50/60 Hz, single phase with overload protection.
 - **Adaptation:** Plug in facility to standard wall outlet with automatic adaptation to line voltage 200 to 240 with 13-Amp BS plug.
 - **Power Backup:** Internal battery backup or UPS support for image acquisition continuity.
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7. Safety and Standards

- The system shall comply with:
 - IEC 60601-1 (General Safety Requirements).
 - IEC 60601-1-2 (Electromagnetic Compatibility).
 - IEC 60601-2-54 (Particular Requirements for X-ray Equipment).
 - DICOM 3.0 standards.
 - Radiation protection and leakage compliance as per IEC/ISO standards.
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8. Environmental Conditions

- **Operating Temperature:** 10°C to 40°C.
 - **Storage Temperature:** -10°C to 50°C.
 - **Humidity:** 30% – 85% RH (non-condensing).
 - **Altitude:** Up to 2,000 meters.
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9. Consumables and Accessories

- All required consumables and accessories must be included:
 - X-ray protection gear (2-lead apron, 2-thyroid shield).
 - Detector protective cover.
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10. Documentation and Training

- The vendor must supply the following documents in both **soft and hard copies**:
 - User Operation Manual.
 - Service and Technical Manual.
 - Installation and Commissioning Report.
 - Preventive Maintenance Schedule.
 - Technical Schematics and Circuit Diagrams.
 - Test and Calibration Certificates.
 - Training Materials for both users and biomedical staff.
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11. Warranty and Support

- **Warranty:** Minimum 2 years (extendable preferred).
 - **Service Support:**
 - Local technical support and maintenance capability.
 - 24x7 technical support until system decommission.
 - **Training:**
 - On-site training for clinical and biomedical staff after installation.
 - Technical training to biomedical staff by a **certified trainer** covering system operations, good practices, preventive maintenance, and error handling.
 - **Installation:**
 - Vendor must carry out installation and commissioning.
 - Vendor must provide a detailed installation and commissioning report upon completion.
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12. Compliance and Quality Assurance

- The system shall be CE and/or FDA approved.
 - The vendor must ensure radiation leakage is within permissible limits.
 - The system shall undergo full performance and safety verification before acceptance.
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End of Specification