



SPECIFICATION

Digital Radiographic Mobile X-ray System

1. Scope

This Specification describes the requirements for a Digital Radiographic Mobile X-ray System (hereinafter referred to as “the System”) to be used as a complete standalone solution for acquisition, review, presentation, display, storage, transfer of radiographic images in a limited resource setting. The System will be located and used at a hospital site.

2. Applicable Documents

The following documents shall be applicable for this Specification to the extent specified hereinafter:

- 2.1. International Electrotechnical Commission, Medical Electrical Equipment, Part 1: General requirements for basic safety and essential performance, Rep. IEC 60601-1, IEC, Geneva (2000);
- 2.2. International Electrotechnical Commission, Medical electrical equipment - X-ray tube assemblies for medical diagnosis - Focal spot dimensions and related characteristics; IEC 60336 (2020)
- 2.3. International Electrotechnical Commission, High-voltage cable plug and socket connections for medical X-ray equipment, IEC 60526 ed2.0 (1978-01);
- 2.4. International Electrotechnical Commission, Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment. IEC 60601-1-3:2008+AMD1:2013+AMD2:2021
- 2.5. International Electrotechnical Commission, Electrical and loading characteristics of X-ray tube assemblies for medical diagnosis, IEC 60613 ed3.0 (2010-01);
- 2.6. International Electrotechnical Commission, Medical electrical equipment - Exposure index of digital X-ray Imaging Systems - Part 1: Definitions and requirements for general radiography, IEC 62494-1 ed1.0 (2008-08); and
- 2.7. EUROPEAN COMMISSION, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, UNITED NATIONS ENVIRONMENT PROGRAMME, WORLD HEALTH ORGANIZATION, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, IAEA Safety Standards Series No. GSR Part 3, IAEA, Vienna (2014). (<https://www.iaea.org/publications/8930/radiation-protection-and-safety-of-radiation-sources-international-basic-safety-standards>).

In the event of conflict between the documents listed above and the content of this Specification, the content of this Specification shall take precedence to the extent of the conflict.

3. Definitions, Acronyms, and Abbreviations

- 3.1. The following definitions, acronyms, and abbreviations shall apply throughout this Specification unless defined otherwise hereinafter:

DICOM: Digital Imaging and Communications in Medicine
DR: Digital Radiography
TPS: Treatment Planning System
kHU: kilo Heat Unit
kV: kilo Volts
mA: milli Ampere



User: The Counterpart in the destination territory, as defined in the Purchase Order

4. Requirements

4.1. The Contractor shall provide a complete mobile radiography system, intended for the planar X ray imaging in hospital consisting of:

- Mobile digital radiography X ray unit;
 - Image processing, acquisition and review;
 - Associated safety equipment;
- to be delivered FCA supplier's warehouse incoterms 2010
- and optionally: installed at the End-User's site by the Contractor and subject of full acceptance testing based on technical and functional requirements.

4.2. The System shall meet the following performance and functional requirements:

- 4.2.1. Be easy to assemble/install/set-up and be fully functional and operational as a complete standalone solution for acquisition, review, presentation, display, storage, transfer of radiographic images in a limited resource setting;
- 4.2.2. Capable of imaging all current portable exams on a DR panel. Operate as a conventional mobile unit in case the DR panel becomes inoperable;
- 4.2.3. Be mobile, motorized, battery operated and AC power operated (AC mandatory for charging and, preferably, for standard working operations too).
- 4.2.4. Have capability of sending images through existing network port and have wireless transfer of images through hospital wireless network. Wireless and cable connections shall be provided;

4.3. Technical Requirements:

The System shall include the following components:

4.3.1.	General technical requirements	<p>Digital Imaging and Communications in Medicine (DICOM) 3.0 compatible image storage and transfer required.</p> <p>The system should be capable of storing at least 2000 images with comprehensive post-processing options</p> <p>Capacity for removable media storage, to transfer data through different options (CD, DVD and/or USB), to send images through existing network port, and, preferably, to have wireless transfer of images through hospital wireless network (wireless and cable connections shall be provided).</p> <p>Integrated Ethernet connectivity required.</p> <p>At least 20 anatomical programmes shall be available.</p> <p>An integrated image review monitor included in the configuration.</p> <p>Equipment provided with DAP (Dose Area Product) device/capability to record the patient dose.</p>
4.3.2	Detailed technical requirements	<p>kVp range at least 40–120 kVp, digitally displayed.</p> <p>mAs range at least 0.5–200 mAs or more.</p> <p>Exposure time range not less than 8.0 msec. to 4 sec and minimum exposure time not higher than 8.0 msec.</p> <p>Automatic exposure control facility (preferable) (if available).</p> <p>Tube power rating at least 20 kW (measured at 100 kVp).</p> <p>Rotating anode with dual focal spots and the maximum focal spot not higher than 1.3 mm (equivalent output/technology could be considered).</p> <p>Heat storage capacity of the anode at least 120000 HU.</p> <p>Cooling rate not less than 14000 HU/min.</p> <p>Total filtration at least of 2.5 mm aluminium equivalent.</p> <p>An integrated/paired DR two (2) flat-panel detectors: wireless and/or with cable (wireless flat detector preferable); sub mm pixel size, active detector area not less than 35 x 43 cm.</p> <p>Capability for alphanumeric annotation of images.</p> <p>Equipment total weight in the range 100–500 kg.</p>
4.3.3	Digital detector	<p>Image quality: spatial resolution better than 3 lp/mm.</p> <p>Pixel pitch: < 150 x 150 µm.</p> <p>Grayscale: at least 4096 (12-bit).</p> <p>Preview image access time: less than 10 sec after X-ray exposure.</p>



4.3.4	Displayed and user-adjustable parameters and settings	<p>Image to be displayed immediately after exposure. Digital display of mAs and kV, KAP/DAP and an electronic timer. Low battery indicator/alarm. Exposure status lights on main control and/or collimator (standby, ready up, exposure). Image display to be contrast- and brightness-adjustable, at least 18 inches diagonal size. Exposures by remote control should also be possible, with operating distance higher than approximately 10 m. The exposure release switch should be detachable, with a cord of at least 5 m.</p>
4.3.5	System components and other physical characteristics	<p>An X-ray tube support with telescopic arm. The tube stand must be fully counter-balanced for rotation in all directions. Articulated arm for imaging with any patient position. Source to image receptor distance (SID) range not less than 100–200 cm. Frame with column/arm rotation range not less than +/- 180 degrees. Adjustable multi-leaf collimator, rotatable ± 90 degrees, with patient centring light. All cables shall be concealed in the arm system. Collimation light to confirm the radiation field size. Unit base wheels must be easily accessible for cleaning.</p>
4.3.6	Mobility portability and	<p>When motor or battery is non-functional, free movement by pushing must be possible. Equipment speed capacity not less than approximately 1.5 km/h. Motorized movement capable of ascending slope of up to at least 7 degrees from horizontal. The unit must have an effective system for parking, transport and emergency braking.</p>
4.3.7	Power supply	<p>AC power input to be 120 and/or 220 V +/-10%, 50–60 Hz, single phase, fitted with compatible mains plug. X ray exposures without power supply (battery mode exposure) is preferable (if available). Motor battery to be sealed lead-acid type, recharged by main unit power connection and recharging time not higher than 8 hours. Battery total energy capacity up to at least 20 000 mAs. Resettable overcurrent breaker to be fitted on both live and neutral supply lines. Voltage corrector/stabilizer to allow safe and stable operations at $\pm 20\%$ of local rated voltage (if necessary).</p>
4.3.8	Accessories spare parts and	<p>Must be supplied with protective dust cover at least for control panel. To be supplied with at least 1 adult-size protective lead apron and 1 thyroid shield. Portable radiation hazard warning signs to be supplied with unit. List of important spares and accessories to be provided with their part numbers and cost. Spare parts availability for the equipment lifespan (not less than 7 years). Equipment provided with image quality phantom.</p>



5. Marking

The System shall have all safety markings in English language. Labelling on the primary packaging to include:

- Name and/or trademark of the manufacturer.
- Production year.
- Model or product reference.
- Information for particular storage conditions (temperature, pressure, light, humidity).

6. Packing

The System, for the shipment by air to the End-Users, shall be packed in accordance with international standards that are applicable for the shipment by air of this kind of equipment. It shall be capable of being stored continuously in ambient temperature of 0–50 °C and relative humidity (RH) of 15–90%. It shall be capable of operating continuously in ambient temperature of 10–40 °C and RH 15–90%

7. Quality Requirements

- 7.1. The System shall be manufactured, shipped (and optionally installed if required by IAEA) in accordance with the Contractor's ISO quality assurance system or an equivalent quality assurance system.
- 7.2. The Contractor shall document the compliance with this quality assurance system.

8. Testing and Acceptance

8.1. Factory Acceptance Test (FAT)

The System, prior to shipment, shall be tested for conformance of the System with manufacturer's performance specifications and the minimum requirements specified herein. Prior to shipment, a certificate of FAT shall be sent to the end-user as well as to the Technical Officer from the Dosimetry and Medical Radiation Physics Section.

8.2. On-site Acceptance Test (SAT) (only if onsite installation is required at the time of the PO by IAEA).

The System shall be tested by the End-User and Contractor to demonstrate that the performance meets the manufacturer's performance specifications and the minimum requirements specified herein as determined by the IAEA and the User.

8.3. The results of the SAT testing shall be documented by the Contractor in an acceptance protocol that shall be signed and dated by both the Contractor and the End-user.

9. Delivery and online Tutorials/Training

- 9.1. The Contractor shall deliver the system as per incoterms 2010 FCA supplier's warehouse.
- 9.2. The Contractor shall provide online tutorials and/or provide online training for staff of the User in operation and maintenance of System.

10. Deliverable Data Items

The Contractor shall provide two (2) complete sets in the English language of:

- 10.1. Operation and servicing manuals and technical drawings.
- 10.2. FAT Report and SAT report (if installation is required).
- 10.3. A plan for preventative maintenance and the name and contacts of a service representative/office for on-call maintenance intervention.



11. WARRANTY

- 11.1. The System shall be covered by one (1) year warranty that includes parts and labour, from the date of proof of delivery (POD) signed by the end-user or date of on-site acceptance (SAT).
- 11.2. Warranty shall include all necessary spare parts, shipment to site, cost of replacement, disposal of faulty parts, and all upgrades and updates to hardware and software.

12. MAINTENANCE SERVICES

- 12.1. The Contractor shall provide on-site full maintenance services during the warranty period for the proper functioning of the system.
- 12.2. Full maintenance services during the warranty period shall include:
 - 12.2.1. Preventive maintenance;
 - 12.2.2. On-call interventions;
 - 12.2.3. Any safety, software and hardware update and upgrade for the system that shall become available; and
 - 12.2.4. All necessary replacement and spare parts.
- 12.3. The Contractor shall provide the End-User with a plan for preventative maintenance and the name and contacts of a service representative/office for on-call maintenance intervention.
- 12.4. The Contractor shall provide evidence of the capability to adequately provide technical support for the System on this site, in a timely manner, stating the network of official representatives in the country and in the region.
- 12.5. The Contractor shall ensure that a suitable qualified person shall be available online within forty-eight (48) hours and within 2 weeks onsite following an unexpected breakdown and shall investigate the problem within the next twenty-four (24) hours during the warranty period.

13. UPTIME AND PENALTIES

- 13.1. The Contractor guarantees that the system shall have an uptime of at least ninety-five percent (95%) excluding outages for scheduled maintenance or causes external to the System.
- 13.2. Uptime is calculated on a basis of two hundred and fifty (250) operating days per year (weekly working days) cumulative on a six months basis (i.e. summing up the hours), then the warranty and/or maintenance (as applicable) shall be extended for a corresponding period. The records of downtime of the system shall be kept by a representative of the End-User at the Site. The Contractor shall have the right to request copies of such records.

14. OPTIONS

- 14.1. At the request of the IAEA, on exceptional basis, the Contractor should install the equipment on-site.
- 14.2. At the request of the IAEA or the End-User, the Contractor shall provide to the End-User an additional three (3) years of full maintenance services (as defined in Section 12 above), following the same terms and conditions. This maintenance shall be at the End-User's expenses.