Portable digital radiography system

Technical specifications

World Health Organization

IAEA
International Atomic Energy Agency
Atoms for Peace and Development

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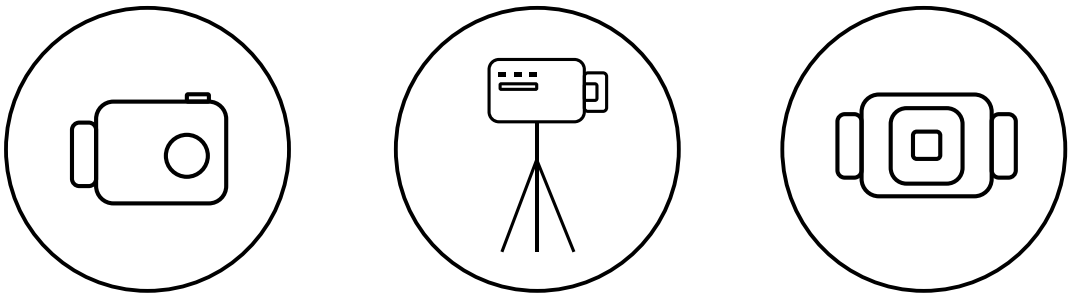

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Portable digital radiography system: technical specifications

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Contents

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The publication was developed under the leadership of Mariangela Simao, Assistant Director General, Access to Medicines and Health Products, WHO; Ren Minghui, Assistant Director General, Universal Health Coverage/Communicable and Noncommunicable Diseases, WHO; and Najat Mokhtar, Deputy Director General, Head of the Department of Nuclear Sciences and Applications, IAEA.

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Abbreviations

AC	alternating current
Al	Aluminium
BS	British Standard
CAD	computer assisted detection
CE	Conformité Européenne
CSA	Canadian Standards Association
DAP	dose area product
DDR	direct digital radiography
DICOM	Digital Imaging and Communications in Medicine
DITTA	Global Diagnostics Imaging Healthcare IT & Radiation Therapy Trade Association
DLP	Dose Length Product
EU	European Union
FAT	factory acceptance test
FDA	Food and Drug Administration (USA)
FSC	free sales certificate
GB	gigabytes
GMP	good manufacturing practice
HD	high definition
HDMI	high-definition multimedia interface
HIS	hospital information system
HU	heat unit
IAEA	International Atomic Energy Agency
IEC	International Electrotechnical Commission
IFMBE	International Federation of Medical and Biological Engineering
IOMP	International Organization of Medical Physics
IMDRF	International Medical Device Regulators Forum
ISR	International Society of Radiology
ISRRT	International Society of Radiographers & Radiological Technologists
IPC	infection prevention and control
IQC	internal quality control
IR	infrared
ISO	International Organization for Standardization
kHU	kilo heat unit
kV	kilovolt
kVA	kilovolt-ampere
kVp	kilovoltage peak
kW	kilowatt
LAN	local area network

LCD	liquid crystal display
LDT	low dose tip
LED	light-emitting diode
lp	line pairs
mA	milliampere
mAs	milliampere seconds
MHz	megahertz
MRI	magnetic resonance imaging
MSK	musculoskeletal
NIST	National Institute of Standards and Technology (USA)
PACS	picture archiving and communication system
POC	point-of-care
psi	pounds per square inch absolute
RH	relative humidity
RIS	radiology information system
s/sec	second(s)
SARI	severe acute respiratory infection
SAT	site acceptance test (on-site)
SID	source to image receptor distance
SOPs	standard operating procedures
SPR	scan projection radiograph
TFT	LCD thin-film transistor liquid-crystal display
UPS	uninterruptible power supply
USB	universal serial bus
W	watt(s)
WHO	World Health Organization

1. Introduction and objective

In June 2020, WHO published a rapid advice guide on the use of medical imaging in the context of the COVID-19 pandemic (1). The guide makes recommendations for the use of chest imaging in the acute care of adult patients with suspected, probable or confirmed COVID-19, based on available evidence. The imaging modalities considered are ultrasound, radiography and computed tomography (CT), for use within the care pathway.

In view of the urgency to produce a complementary document of technical specifications for equipment to support the rapid advice guide, a working group was established with staff and consultants on imaging technologies from different departments of WHO and the IAEA. The technical requirements specific for the 3 types of imaging equipment and systems were published in November 2020, as the chapter 8 of the interim guidance called Priority medical devices for the COVID-19 response and associated technical specifications (2), to support the clinical management for COVID-19 patients(3)

In March 2020, WHO published the operational handbook (4) and the consolidated guidelines (5) on tuberculosis, module 3: diagnosis: rapid diagnostics for tuberculosis detection.

Then, in March 2021, the WHO consolidated guidelines (6) and handbook (7) on tuberculosis: module 2: screening: systematic screening for tuberculosis disease and its annexes, were published. These guidelines call for the use of imaging technologies to screen. The imaging technologies described in the rapid advice guide and the associated technical specifications for imaging technologies for COVID-19: ultrasound, mobile X-ray and CT (2) can be used also for imaging tuberculosis. Nevertheless, for outreach activities in very low resource settings, there is a substantial increase need from Member States, donor agencies and NGOs for using "portable" digital radiography. " "Portable" radiographic systems are a subset of "mobile" radiographic equipment, with specific physical and technological characteristics which mainly, but not exclusively, impact the system portability, management and clinical applications (for details see the section 2 of this document and in particular the paragraph 2.3)". Therefore, WHO convened again the same WHO-IAEA working group who had developed the 2020 technical specifications for imaging technologies to develop additional minimum technical specifications for this portable system.

It is anticipated that the portable diagnostic imaging technology covered by this document will serve not only the pressing demands for tuberculosis screening and triage but also other diseases. Therefore, the requirements, accessories, hardware and software packages listed in these specifications are described in detail in order to serve also other pathologies and conditions, like trauma and pneumonia.

It should be noted that the imaging device to be procured or used is made considering clinical, technical and radiation protection perspectives and depends on the resources available in a specific setting: human, technical, infrastructure and financial. Use is dependent on the clinical judgement of medical professionals and the condition of individual patients.

The imaging device described in the following sections requires a trained health care workforce, specialized care and maintenance activities. Accessories can be procured in the future to further enhance functionality.

The references and resources sections provide further guidance and specific information for the selection, protection and use of this imaging technology.

1.1 Target audience

This document is recommended to support decision-making regarding the selection, incorporation, allocation and use of portable X-ray systems and is intended for health care providers, managers of imaging departments, procurement and regulatory agencies, policymakers and planning officers in ministries of health. It also informs biomedical engineering professionals, medical physicists, the private health sector, medical device industry and intergovernmental and international agencies on the minimum requirements of the product requested.

WHO recommends involving biomedical or clinical engineers, medical physicists, along with clinical doctors, physician assistants, nurses, diagnostic technicians and radiographers in the selection of the medical devices requested, according to clinical needs and local infrastructure, and for verification of operation of the equipment and to ensure training of the health care workforce.

1.2 Methodology

Technical characteristics have been developed to define the minimum requirements for the product to ensure good quality, safety and efficacy. The process to develop these specifications included:

- a review of recent publications of WHO technical specifications for medical devices; analysis of the technologies required to perform the clinical management of COVID-19 (3) and Tuberculosis (4);
- analysis of existing products in the market, based on approval from the regulatory agencies;
- analysis of international, regional and country standards; device overviews, specifications and comparative data published by ECRI (8), an evidence-based practice center, which is a non-profit, independent organization that conducts independent medical device evaluations;
- Review of new products in the market, described in the FIND publication "Digital chest radiography and Computer-Aided Detection (CAD) solutions for Tuberculosis Diagnostics. Technology landscape analysis" (9);

The development of the technical specifications was done jointly between WHO related units on: TB, radiation and medical devices, from headquarters and regional offices, along with the IAEA Division of Human Health: Nuclear Medicine and Diagnostic Imaging and Dosimetry and Medical Radiation Physics sections, and experts from FIND. The draft document was then reviewed and discussed with specialized professional organizations in official relations with WHO, including: International Society of Radiology (ISR), International Society of Radiographers & Radiological Technologists (ISRRT), International Organization for Medical Physics (IOMP), International Federation of Medical and Biological Engineering (IFMBE), International Electrotechnical Commission (IEC) and the Global Diagnostics Imaging Healthcare IT & Radiation Therapy Trade Association (DITTA).

2. Portable digital radiography system

2.1 Context and considerations

This section describes the requirements for an portable radiographic digital system to be used as a complete standalone solution for acquisition, review, presentation, display, storage and transfer of radiographic images in a resource-limited setting. It aims to define the minimum technical characteristics of an portable digital radiography system (also called: Portable X-ray unit/system; Portable digital radiography; Ultra-portable radiographic (or X-ray) system; General portable radiographic X-ray equipment; Radiographic unit, portable; portable X-ray).

The decision of which fixed, mobile or portable equipment should be purchased should take into account many variables as for example, but not exclusively, the local epidemiological situation and health needs, the geographic context, the local health infrastructure, the trained and available health care workforce, as well as the characteristics of the health system (e.g. decentralization of health services).

Portable radiographic digital equipment encompasses medical imaging devices that use X-ray technology to permit users to collect information on normal and abnormal features of different body sections. General-purpose portable diagnostic X-ray system is used in a variety of X-ray imaging applications and to support out-of-hospital infrastructure screening, diagnostic and monitoring interventions, applications and campaigns (e.g. "chest X-ray" for pneumonia or tuberculosis; skeletal radiography for road traffic accidents and other trauma). At times, the radiography systems may be deployed for a specific purpose, in those cases the priority characteristics of the equipment could vary. For example, if a system will be used in a prison or an immigration center primarily for TB screening or in the acute trauma service of an emergency service the minimal product requirements may differ. These requirements could represent trade-offs in voltage ranges, radiation levels or other technical specifications when deciding which equipment to purchase.

Portable X-ray systems are designed to be used mainly, but not exclusively, when the planned diagnostic and/or screening activities are located far from health structures or in any case when multiple outreach interventions are socially or economically convenient and considered an advantage.

Portable radiographic digital systems should not be used for patients whose location, clinical condition and/or isolation status would permit the transport to hospital radiology departments. As per IAEA Safety Standards Series No. SSG-46 (10), these units should only be used for examinations where it is impractical or not medically acceptable to transfer patients to a fixed unit. These devices are commonly used for general 2-D radiographic studies (predominantly for chest X-rays) as well as for orthopedic imaging of small body parts and for other specific clinical diagnostic investigations.

The equipment composing the system are, when electrically operated, battery-powered with a battery provided with charging system. The main AC line voltage is used to charge the batteries and, in some models, to power the equipment during standard operations (this dual power supply reduces the unit's downtime by permitting the equipment to operate while recharging the batteries).

The system components described in these specifications cover: X-ray Generator; X-ray Generator stand; X-ray Detector; X-ray Detector stand; Portable workstation or PC-console and/or portable remote control-station; Software and Hardware for data management and communication; case, bag or specifically designed trolley for packing and transportation; and accessories. It does not cover computer-aided detection software, for which separate guidance should be sought in disease specific normative documentation (e.g. for TB).

2.2 Definitions and intended use

The decision as to the appropriate clinical use of these devices is always reserved to medical staff. With regards to, for example, Tuberculosis and pneumonia related lung damage and connected complications, portable radiographic digital technology offers benefits in chest imaging and assessing levels of diseases probability and severity.

The "user" is defined as the counterpart in the destination territory. The portable X-ray digital system is primarily used in: Health-Care Centers; temporary and emergency Health-Centers (also established in Pandemic circumstances); outreach and field interventions (i.e.: mobile clinics/ vans, screening campaigns, home care); tele-radiology solutions in remote areas.

The main users of the system are expected to be radiographers, radiological technologists and medical professionals trained on safety, radiation protection and image management.

With regard to Tuberculosis infection prevention and control (IPC) precautions, the level of decontamination (cleaning and disinfection protocols) of the X-ray system components included depends on the clinical procedures used and on the brand or model indications provided together with the user and technical manuals.

The use of the system in combination with compatible AI (Artificial Intelligence)-powered Computer-Aided Detection (CAD) software solutions could significantly increase the diagnostic capacities of the system, efficacy and efficiency, and its appropriateness and advantages of use.

2.3 Technical specifications for procurement

Portable digital radiographic system		
i	Version No.	1
ii	Date of initial version	22/02/2021
iii	Date of last modification	
iv	Date of publication	10/07/2021
v	Completed / submitted by	WHO and IAEA working groups
Name, category and coding		
1	WHO Category / Code	(under development)
2	Generic name	Portable X-ray system
3	Specific type or variation	Ultra-portable, digital
4	UNSPS code (optional)	N.A.
5	EMDN name	Mobile Radiographic Units
6	EMDN code	Z11039016
7	Alternative name/s	Ultra-portable radiographic system, digital and Ultra-portable X-ray digital system Portable digital radiography; General portable radiographic X-ray equipment; Radiographic unit, mobile.
8	Alternative code/s	MS 34281; MS 34239; MS 13272; MS 36119
9	Keywords	portable, ultra-portable, imaging, radiography, radiology, digital radiography
Purpose of use		
10	Clinical or other purpose	General-purpose portable diagnostic X-ray system used in a variety of X-ray imaging applications and to support out of hospital infrastructure screening/diagnostic/monitoring interventions, applications and/or campaigns (i.e.: “chest X-ray" for pneumonia and/or TB screening / diagnosis, trauma patients/road accidents, etc.). Adult and paediatric applications/ interventions, as appropriate.
11	Level of use	Healthcare Centers, temporary and/or Emergency Health-Centers (also established in Pandemic circumstances), outreach and field interventions (mobile clinics/vans, screening campaigns, home care) and/or teleradiology solutions in remote areas. User of the equipment: radiographers/radiological technologists and medical professionals trained on safety, radiation protection (including national regulations) and image management. The decision of which equipment should be purchased must take into account the local epidemiological situation and all health needs and not just a particular disease, as well as the characteristics of the health system. The system can be carried by an operator.
12	Clinical department/ward	Not relevant
13	Overview of general functional requirements	Battery operated digital portable Radiographic system (preferably with the possibility to be re-charged during operations). Provides X-ray images of parts of the body (particularly, but not exclusively, on chest imaging) using digital portable technology. X-ray generator and flat panel detector can be positioned to image required body part.

Technical characteristics and minimum requirements		
14	System composition requirement	Core system should be composed at least by the following devices/elements: - X-ray Generator - X-ray Generator Stand / Frame - X-ray Detector - X-ray Detector Stand/ Frame - Portable workstation/PC-console and/or portable remote control-station - Software/Hardware for data management and communication - Case/bag for packing and transportation - Accessories, including radiation protection devices
15	X-ray Generator	High frequency X-ray generator: - Voltage range must include the range from 50kV to not less than 90kV (better with minimum range at least: from 50 kV up to 110 kV), preferably digitally displayed - X-ray generator current-time range must include the range from 0.5 to 2.5 mAs (better with minimum range at least: from 0.3 up to 100 mAs) and preferably digitally displayed - Maximum current: at least 5mA @ 90kV (or calculated on the product voltage available) (better: up to at least 20 mA) - X-ray Generator to be supplied with all needed cables and connectors X-ray tube and collimator: - Stationary or rotating (better) anode with focal spot size less than 1.3mm - Heat storage capacity of the anode at least 10,000 HU (preferably higher) and/or Nominal Radiographic anode input power (IEC 60613, ed 3) at least: 0.45 kW (=90 kV * 2.5 mAs / 0.5 s), preferably 22 kW (=110 kV * 100 mAs/0.5s) - Preferably, high anode temperature alarm and automatic blockage/alarm for high tube temperature. - Multileaf collimator with patient centering light. Total filtration with collimator not lower than 2.5 mm @70kV (or calculated on the product voltage available) Al equivalent (10). Exposure features: - Time range must include the range from 0.04 to at least 0.5 s (better with minimum range at least: from 0.01 to 4.0 s), preferably with at least 20 steps - Preferably: Automatic Exposure Control facility - Exposure release switch, preferably detachable, cordless remote control even more preferable. - Maximum exposure switch operating distance to be specified as well as the optimal source-image distance (SID) - Exposure capacity when fully charged (battery autonomy time) greater than 100 exposures. - Preferably: detachable/replaceable battery (at least 1 extra battery / back up batteries would be preferable, if applicable) - Preferably: DAP display to record/display patient examination dose or alternatively software to calculated dose.
16	X-ray Generator Stand / Frame	Stand/frame with at least the following main characteristics: - Lightweight - Vertical movements range must include the range from 50 to 150 cm from ground - The stand/frame shall be capable to set the best Generator's position for all the clinical applications/uses/interventions requested and available - Preferably, with rotation of 90 degrees around vertical axis - Preferably, fully counterbalanced for safe and easy movement (if necessary). The counterbalanced system to be specified, if any.

17	X-ray Detector	Dimension: - Active detector area not less than 35*43cm Main features: - Time to display image after exposure no longer than 10 sec - Preferably, pixel pitch not greater than approximately 150µm. - Spatial resolution not less than 3 lp/mm (better: at least 3.5 lp/mm. - Preferably, DQE, detective quantum efficiency @ RQA5 at least 70% (better: at least 80%) - Dynamic range of A/D converter at least 14 bit (preferably 16 bit) or at least 10 pixels resolution - Exposure capacity when fully charged (battery autonomy time) at least 100 chest X-ray @ 90KV (or calculated on the product voltage available) - Detector connectivity to workstation capabilities (wireless feature/option preferably included) - To be supplied with all needed cables and connectors, if any - Preferably: Automatic Exposure Detection feature available
18	X-ray Detector Stand / Frame	Stand/frame with at least the following main characteristics: - Lightweight - Vertical movements range must include the range from 50 to 150 cm from ground (better up to 200 cm)
19	Workstation	Workstation / Console with the following minimum requirements: - One Led or LCD colour display, at least 13", at least 2 Mpixel (system integrated or external) - Two or more Microprocessors, each of at least 1.7 GHz - RAM at least 6 GB - Hard drive not less than 500 GB SSD - Ability for high-resolution (at least 1440*1440) images to be retrieved, reproduced and stored without loss of quality - Capacity to store and to transfer data to other workstations / PC-consoles / networks - Display languages should include at least English (preferably with French and Spanish options. National language/s of the user/s will be an asset) - Additional generator-integrated console/monitor/viewer are an advantage - Wireless feature shall be included.
20	Software	Dedicated software for calibration and image management, with at least all the following functions to be included, and DICOM 3.0 compatible (image storage and transfer): - Patient registration/data - Exposure parameter regulation; exposure parameter registration/ recording - Image processing (clip, zoom, magnifier, invert, rotate, flip, annotations, measurements, digital collimation, etc.), image view, detail enhancement and noise suppression, tissue equalization - Alphanumeric annotation of images required - Chest X-ray programme by default with patient thickness range including at least the range from 14 to 40 cm - Last image hold facility required, displayed on clear screen - Storage capacity of at least 2000 images, with capacity for removable media storage - Interoperability with local and/or national Picture Archiving and Communication System (PACS) where available - Preferably: interoperability with other Software - Demonstrated integration with AI-powered Computer-Aided Detection (CAD) solutions - To be supplied with original necessary licenses (CAD, PACS, etc.) in final beneficiary name. - If Computer Aided diagnostics/AI is included in the equipment offered, it has to be approved by WHO, or a stringent regulatory agency for "software as medical device" (i.e. EC, FDA, TGA. Etc.) and compliance must be demonstrated. Moreover, the manufacturers shall state the intended purpose of the CAD (diseases/ conditions covered, screening, diagnostics and standards approved). - If CAD available, preferably provided with ability to analyze multiple diseases - Preferably: open source software that can be adapted to local needs.

Physical/Chemical characteristics		
21	Components (if relevant)	X-ray Generator total weight (with battery) less than 20 kg. X-ray Detector total weight (with battery) less than 5 kg.
22	Mobility, portability (if relevant)	System designed to be fully and easily portable. Total weight of the complete system not higher than 30 kg, including at least: generator, detector, stands (for both detector and generator), PC/workstation and preferably including also the transport case/bag and the external charging system (if any).
23	Raw Materials (if relevant)	N.A.
Utility requirements		
24	Electrical supply	X-ray Generator and Detector powered by rechargeable batteries (preferably with the capability for both devices to be charged during operations). Recharge power source: AC power input to be 120 or 220 VAC +/-10%, 50/60Hz, single phase, fitted with compatible mains plug (if applicable: appropriate transformer /condenser array to be included). Battery recharging time less than 6 hours (both for Generator and Detector). Low battery alarms (preferable). The battery back-up related to the whole system (Generator, detector and workstation) allow at least 100 chest X-ray exposures @90KV with imaging transmission/storage. Voltage corrector / stabilizer to allow safe and stable operations at ± 20% of local rated voltage (when necessary/specified by the user). Detector preferably provided with a separate, removable Lithium-ion battery (where applicable) Alternative energy sources for battery recharge will be an asset (i.e. solar, etc.)
Accessories, consumables, spare parts, other components		
25	Accessories (if relevant)	Must be supplied with at least the following accessories: - Transport Case/Bag which shall allow an easy and safe transportation of the entire portable digital X-ray system (including Generator and Detector) and accessories provided (including workstation/PC/console) - External charging system: the external power system (e.g., solar system, power bank, charging dock, etc.) shall be able to charge all electric components (generator, detector and workstation) of the portable digital X-ray system - At least no.2 protective aprons with the following characteristics: • shoulder to knee length; • material should be as light as possible (i.e. lead-based composite or lead-free materials with high atomic numbers and low densities); • at least 0.25 mm Pb protection equivalence (measured @ 90 kVp at least); • adult size / adjustable front lead apron with Velcro / buckle; • weight of each apron provided less than 4 kg; • to be supplied with at least no.1 thyroid shield/collar. - Based on a workload assessment, a mobile protective shield could be considered preferable in addition to previously mentioned aprons. - At least no.1 set/pack of radiation hazard and pregnancy warning signs which can be installed outside the screening rooms to keep workers and visitors informed of X-ray areas; warning signs shall be made of durable, outdoor-rated materials. - At least no.10 highly visible impact detection stickers ("Shock Stickers") or adhesive labels with tamperproof shock sensors mechanically activated in case of mishandling.
26	Sterilization process for accessories	N.A.
27	Consumables / reagents	N.A.
28	Spare parts	List to be provided of important spares and accessories, with their part numbers and cost. Spare parts availability for the equipment lifespan, not less than 7 years.

29	Other components	N.A.
Packaging		
30	Sterility status on delivery	N.A.
31	Shelf life	N.A.
32	Transportation and storage	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
33	Labelling	Labelling on the primary packaging to include: - Name and/or trademark of the manufacturer. - Model or product's reference. - Information for storage conditions (temperature, pressure, light, humidity).
Environmental requirements		
34	Context-dependent requirements	Capable of being stored in ambient temperature range from +10° to +50°C (preferable from + 5° up to at least +60°C) at a relative humidity range from 15 to 80%. - Capable of operating continuously in ambient temperature from +15° to at least +35°C (preferable from +10° up-to at least +40°C) at a relative humidity from at least 15 to 80% (preferable up to 95%). - Storage and operating conditions of the system provided to be clearly stated. - Both Generator and Detector compliant with IPX standards ("Ingress Protection"), preferably, not less than IPX5.
Training, installation and utilization		
35	Pre-installation requirements	N.A.
36	Requirements for commissioning	Supplier to perform installation, safety, calibration and operation checks before handover; based on user's request, additional "Acceptance Tests" shall be performed before full handover approval. Local clinical staff to affirm completion of installation, inclusive of commissioning and a plan for regular quality control testing.
37	Training of users	On-site theoretical and practical training of at least six (6) operators on safety, utilization, transportation and maintenance, delivered in English or language to be agreed with beneficiaries. Provision of at least one (1) hard and one (1) digital copy of training materials for each trainee. Specific cleaning and disinfection instructions for IPC (Infection Prevention and Control) included (preferable). Training of users in operation (including key principles of basic radiation protection and safety for patients, workers and the public), the use of quality assurance/control tools provided for testing), justification and management of radiation dose to patient (optimization and the use of diagnostic reference levels - DRLs) and training for maintenance, cleaning and disinfection shall be provided. Both maintenance and use training should be, preferably, also available in an online/remote format. Contact details of manufacturer, supplier and lists of local service agents to be provided together with the documentation.
38	User care	Unit layout to enable easy cleaning and sterilization/decontamination of all surfaces

Warranty and maintenance		
39	Warranty	The whole system (Generator, Detector, etc.) shall be covered by a warranty of at least 1 year, including all spare parts and labour, starting as of the date of successful on-site acceptance, as per testing and acceptance. Warranty shall include all necessary spare parts (i.e. batteries when applicable, etc.), shipment to site, cost of replacement work, personnel, disposal of faulty parts, and software (patches, upgrades and updates). Specific warranty inclusions and exclusions shall be clearly listed. At least one service visit per year shall be made under warranty. Visits for preventive and corrective maintenance as required, including spare parts to be replaced, shipment to site, disposal of faulty parts, cost of replacement work, personnel transport and arrangements. Corrective maintenance: issue resolution within five (5) working days maximum from the date of issue reporting. For Software related issues, remote maintenance/intervention should be available, and the first intervention should, preferably, not take more than 24 hours. Contact details of manufacturer, supplier and local service agent to be provided. The manufacturer/ supplier should have a wide network of service centres to fulfill the warranty requirements.
40	Maintenance tasks	List of equipment and procedures required for local calibration and routine maintenance shall be provided. Advanced maintenance tasks required shall be documented.
41	Type of service contract	Costs and types of post-warranty service contract available shall be described.
42	Spare parts availability post-warranty	Guaranteed time period of availability of spare parts post-warranty shall be described (not less than 7 years).
43	Software / Hardware upgrade availability	Guaranteed time period of support and software/hardware upgrade (if relevant) availability post-warranty shall be described.
Documentation		
44	Documentation requirements	User, technical and maintenance manuals, hard and soft copies, to be supplied in English language (provision of versions in other UN languages, if available, will be an asset). Supplier to describe any materials contained in the device that are classified as hazardous under local regulations. Specific cleaning and disinfection instructions for Infection Prevention and Control are preferable.
Decommissioning		
45	Estimated Life Span	Supplier to describe estimated lifetime of fully maintained device
Safety and standards		
46	Standards, for the manufacturer and the equipment	The following certificates shall be available for each of the elements of the whole system: Certified quality management system for medical devices (e.g. ISO 13485:2016 – Medical devices – Quality management systems – Requirements for regulatory purposes). General quality management (e.g. ISO 9001:2015 – Quality management systems – Requirements). Application of risk management to medical devices (e.g. ISO 14971:2019 – Medical devices – Application of risk management to medical devices), as appropriate to the intended use.
47	Regulatory approval/ certification	Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country. Proof of regulatory compliance per the product's risk classification, as appropriate to the intended use (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]), and compliance with the national radiation protection regulations.

48	Standards, for product performance	Compliance of the whole system to the following international standards, when they are applicable, or to regional or national equivalent, as applicable (including the technical tests for safety and performance from accredited laboratory or third party). Reference to the last available version is recommended but compliance to previous standards versions could be considered (as/when applicable). - IEC 60601-1:2005+AMD1:2012 +AMD2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance; - IEC 60601-1-2:2014 +AMD1:2020 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests; - IEC 60336:2020 X-ray tube assemblies for medical diagnosis – Characteristics of focal spots. - IEC 60601-1-3:2008+AMD1:2013 +AMD2:2021 Part 1-3: General requirements for basic safety and essential performance – Collateral standard: Radiation protection in diagnostic X-ray equipment; - IEC 60601-2-28:2017 Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis; - IEC 60601-2-54:2009+AMD1:2015+AMD2:2018 Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and fluoroscopy (when applicable).
Any variation to be indicated in the offer		

2.4 Additional services required

Testing and acceptance

- Factory acceptance test (FAT): the system, prior to shipment, shall be tested for conformity of the system with the manufacturer's performance specifications and the minimum requirements specified. The FAT report shall be provided by the supplier.
- Supplier shall perform, when applicable: installation, calibration, safety and operation checks before handover.
- On-site acceptance test (SAT): the system, after delivery, shall be tested by the contractor together with the user to demonstrate that the performance meets the manufacturer's performance specifications and the minimum requirements specified as determined by WHO, IAEA and users. The results of the SAT shall be documented in an acceptance test protocol that shall be signed by the end user (after consultation with the hospital medical physicist) and the manufacturer.
- The results of the testing of the system shall be documented by the contractor in an acceptance protocol that shall be signed and dated by the user.

Training and manuals (for details see sections from 35 to 38 and 44 of the technical specifications)

- User, technical and maintenance manuals, hard and soft copies, to be supplied in English language (provision of versions in other UN and local languages, if available, will be an asset). Supplier should describe any materials contained in the device that are classified as hazardous under local regulations.
- Specific cleaning and disinfection instructions for IPC included (preferable).
- Training of users in operation (including basic radiation protection topics and the use of quality assurance/control tools provided for testing), and training to technicians for basic maintenance shall be provided (provided also in an online format, if available).
- Contact details of manufacturer, supplier and lists of local service agents to be provided together with the documentation.

3. References and Resources

3.1 References

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3.2 Resources for further reading

- ECRI. Device Overviews & Specifications – Comparative data - Radiographic units, mobile. 1 August 2018 (https://www.ecri.org/components/HPCS/Pages/Radiographic-Units,-Mobile.aspx, accessed 18 April 2021).
- IAEA. Radiation protection and safety of radiation sources: international basic safety standards. Vienna: International Atomic Energy Agency; 2014 (https://www.iaea.org/publications/8930/radiation-protection-and-safety-of-radiation-sources-international-basic-safety-standards, accessed 18 April 2021).
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- IEC. Medical electrical equipment – X-ray tube assemblies for medical diagnosis – Characteristics of focal spots. IEC 60336. Geneva: International Electrotechnical Commission; 2005.
- IEC. Medical electrical equipment – Exposure index of digital X-ray imaging systems Part 1: Definitions and requirements for general radiography. IEC 62494-1. Geneva: International Electrotechnical Commission; 2008.
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