PEOPLE TO PEOPLE HEALTH FOUNDATION
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Annexure – 02 Specifications for Ultraportable Xray with AI

INTRODUCTION

Digital Ultraportable Radiographic system to capture X-ray images of the chest, using digital portable technology and AI based CAD for triaging. An ultraportable X-ray machine with complete Generator Source, detector, stand, acquisition system, accessories and AI based triaging for chest X-ray should be available.

1. MANDATORY SPECIFICATIONS AND REQUIREMENTS

- Should be a firm registered in India- "Made in India Solution"
- The company/OEM offering the solution should be a "Made in India" Class 1 manufacturer of general radiology x-ray systems and should have a minimum of 10 years of experience in manufacturing and deploying General Radiology x-ray systems across India.
- The company/OEM should be ISO 13485 certified for manufacturing and service support for x-ray devices throughout India.
- Live demonstration of Dashboard and Analytics of deployed TB system, to the
- government administrators should be possible.
- Seamless data integration, DICOM, EMR, and AI should be available.
- f.Integration into the national repositories such as the NIKSAY database should be available
- The solution offered should be a seamless End – to – End integrated solution with EMR, Digital X-ray, AI and WHO Approved Rapid Molecular Diagnostic platforms used by the NTEP program at CHC/PHC level. The platform should be able to auto-initiate required tests across the integrated solution, as required. This should be demonstrated to the technical committee during evaluation.

2. CERTIFICATION

- The quoted digital x-ray system should be a Category 1 - Made in India, Ultraportable type and should have AERB Type approval certificate.
- X-Ray device should be BIS IS 7620 (Part 1): 1986 approval for the product.
- The manufacturer of Digital x-ray system should be EN ISO 13485 / NABCB ISO 13485 certified company.
- The company should have CDSCO registration and manufacturing license.
- The AI software should have national and international accreditation such as US FDA / CE / WHO / CDSCO approvals
- ICMR validation report with recommendation for TB screening at peripheral facilities in India

3. SYSTEM DESCRIPTION

Digital X-Ray system

- The System should be capable of taking Chest X-Rays with minimal radiation exposure to

patient / operator / attendants.

- The X-Ray device should be lightweight, less than 3.0 kg including batteries.
- External dimensions of x-ray source should be within 350 (W) x 300 (D) x 200 (H)mm.
- The radiation exposure time should be settable between 0.01 sec to 2.0 sec, with varying setting provision to allow imaging of any anatomy with minimal radiation exposure as per ALARA guidelines.
- X-Ray Generator / tube voltage should be at least 70 kV
- Tube current at most 2mA to ensure lower dose exposure
- Focal spot: 0.4 or more with target angle 12 or more Minimum heat capacity 4000- 6000 or more
- Device should have X-Ray beam limiting and centering arrangement to avoid scatter radiation and FOV centering.
- The X-Ray device should have digital touch screen display of size 3.5 inch or more with APR based exposure settings and should show critical parameters like kV, mA, and exposure time, battery charge indicator with Low battery exposure cutoff and error messages etc.
- The system should come with a large detector of at least 350 X 400 mm for taking images of all body parts.
- The detectors should have a minimum spatial resolution of 3.5 lp /mm or more.
- The detector must be high resolution of at least 2500 X 3000 pixels and 140 microns pixel pitch with A to D conversion 16 bits or more
- The detector must be robust, sealed, water resistant, dust resistant and drop resistant (non-glass) with appropriate certifications for these parameters
- Non-Glass - Drop resistance certification for the quoted model from the manufacturer of the detector or international certification should be provided
- The DR Console should be offered on a laptop with 14" screen of reputed make. (Minimum specifications: 11th Gen processor with >8GB RAM & 1 TB SDD)
- Suitable portable light weight Tripod Stand with vertical movement range (50-150cm), rotation of 90 degree around vertical axis
- Remote control enabled X-Ray acquisition (wired / wireless) should be provided
- Solid carrying case for all components which should be suitable for carriage of complete system including source, detector, acquisition console and stands for both source by one person / operator.
- System should be ICMR approved for TB screening at peripheral facilities in India

AI Software for TB Screening

- AI-triaged study list
- Affected areas should be marked by different pathology with outlines.
- Filtering of the study list based on various parameters like patient ID, name, pathologies, and dates.
- Functionality to manage study list (delete, refresh etc.)

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- All in one single hardware addressing functions of EMR based patient registration, visit management, order management, image acquisition, AI reporting and integration with WHO endorsed Rapid Molecular Diagnostic platforms used by the NTEP program at CHC/PHC level
- Offline / Online EMR with smart sync with secure cloud database - feature should be available
- EMR should consist of analytics and dashboard for different stake holders
- EMR solution should be customizable to some extent
- Explainable AI Results
- Pathology prediction results are displayed in an easy-to-understand mode using Heatmaps and Outlines. Heatmaps and Outlines can be enabled / disabled as per user preference.
- Probability score for the AI predicted pathology (in percentages)
- AI Processing Type
- Offline (without the need of Internet)
- AI Processing Time
- Max. 3 min without any additional dedicated hardware for AI
- Scan Volume Capacity
- Can support up to 80 Studies / hour
- Chest Pathologies covered.
- Tuberculosis
- Normal-Abnormal (Pathologies)

General

- The system should be capable of integration with Nikshay Database.
- AI software should have national and internation accreditation such as US FDA / CE / WHO / CDSCO approvals.