AI based CAD software for Tuberculosis screening

S.N.	Purchaser's Specifications	Yes/No	Page no in catalogue	Remarks
	AI based CAD software for Tuberculosis screening			
	Manufacturer			
	Brand			
	Type / Model			
	Country of Origin			
1	**Description of Function**			
1.1	AI-based Computer-Aided Detection (CAD) software for automated analysis of digital chest X-ray (CXR) images to identify abnormalities suggestive of pulmonary tuberculosis for screening and triage with target population of individuals aged 15 years and older			
2	**Operational Requirements**			
2.1	AI based CAD Software and license package compatible with the existing X-ray DR systems.			
2.2	The bidder shall provide the complete software, license, installation, configuration, interfaces and any hardware/network components required for a fully functional system.			
3	**System Configuration**			
3.1	CAD Software and license package compatible with the existing X-ray DR systems having details: a.X-ray(Mobile): Huestis Medical Corporation (Model:MX40) Detector: Varian 4343 b.X-ray(Fixed): Professional Imaging Inc (Model: PX-500) Detector: Careview 1500Cwe			
3.2	Bidder shall confirm compatibility with the above systems, including acquisition software/version, image output format, DICOM conformance, network/interface requirements and transfer workflow.			
4	**Technical Specifications**			
4.1	Shall support digital chest X-ray images from the existing X-ray systems.			
4.2	Shall support standard DICOM images (DICOM 3.0 or compatible), including images generated by the existing X-ray systems.			
4.3	Shall automatically analyse uploaded/acquired chest X-ray images without requiring manual image processing or image conversion by the user.			
4.4	Shall provide automated assessment of abnormalities suggestive of TB and generate a CAD/TB abnormality score for each image.			

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4.5	Shall provide a configurable screening threshold to classify images as screen-positive or screen-negative. The bidder shall describe the score scale, threshold-setting method and limitations if any.			
4.6	Shall display the original chest X-ray with AI-generated abnormality localization/heat map or equivalent visual representation of detected abnormalities, where supported by the software.			
4.7	Shall generate a report containing patient/image identification, AI score, screening classification, date/time of analysis and software identification/version.			
4.8	Shall allow retrieval, viewing, storage and export of previous analysis results.			
4.9	Shall support integration with existing X-ray image acquisition systems and/or hospital PACS/RIS, where available.			
4.10	Shall support automated image transfer from X-ray systems or PACS.			
4.11	The software shall support both online and offline operation. During offline operation, functionality such as image analysis, report generation, data storage and synchronization should be available. Internet connectivity shall not be mandatory for performing CAD analysis during offline operation.			
4.12	The software shall provide local image storage and buffering to allow image processing and operation during internet connectivity interruptions.			
4.13	The vendor shall provide secure cloud-based storage of 1TB or more, image retrieval, reporting and centralized monitoring/dashboard functionality.			
4.14	The vendor shall specify the cloud storage capacity, retention period, backup mechanism, data ownership, data hosting location, access control and security measures.			
4.15	The software shall automatically synchronize acquired X-ray images, CAD analysis results and associated data with the designated secure cloud server once internet connectivity is restored.			
4.16	The licensed software shall be valid for a period of two (2) years.			
4.17	The proposed software shall be one of the CAD products meeting the WHO 2025 performance standards for TB screening in individuals aged 15 years and older. The bidder shall provide documentary evidence of the WHO evaluation/recommendation for the exact product and version offered. If a newer version is offered, the bidder shall submit evidence of its performance and regulatory status.			
5	**Accessories, spares and consumables**			

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5.1	All interfaces, accessories, hardware components, networking equipment, storage and other items required for the complete and functional operation of the CAD software shall be included in the offer.			
6	**Operating Environment**			
6.1	The product offered shall be designed to be stored and to operate normally under the conditions of the purchaser's country. The conditions include Power Supply, Climate, Temperature, Humidity, etc.			
6.2	Any additional hardware supplied shall be compatible with 220–240 V AC, 50 Hz, single-phase power supply and shall be provided with appropriate power cables and plugs.			
7	**Standards and Safety Requirements**			
7.1	The proposed CAD software shall be medical device software with applicable regulatory authorization/clearance for its intended use in TB screening. The bidder shall submit documentary evidence of applicable regulatory approval/clearance, including CE marking under the applicable European regulatory framework, where applicable, and a valid ISO 13485 certificate for the manufacturer, where available. Submitted certificates shall be valid and applicable to the manufacturer and product offered.			
7.2	The bidder shall also submit documentary evidence that the specific software product and version offered meets the WHO 2025 performance standards for TB screening in individuals aged 15 years and older.			
8	**User Training**			
8.1	Training shall be provided to radiographers, clinicians and other designated users on image uploading, interpretation of CAD results, threshold selection and workflow.			
9	**Warranty**			
9.1	Technical support, troubleshooting, software updates and maintenance shall be provided throughout the license period i.e. for 2 years.			
10	**Maintenance Service during Warranty Period**			
10.1	The supplier shall provide preventive maintenance, software health checks, troubleshooting and corrective maintenance throughout the license period.			
11	**Installation and Commissioning**			
11.1	Installation, configuration, integration and commissioning at the hospital shall be included.			
12	**Documentation**			
12.1	The bidder shall submit evidence of the applicable WHO evaluation/recommendation and regulatory approval or clearance.			
12.2	User manual, installation documentation, license documentation, regulatory certificates and compatibility confirmation shall be provided.			

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12.3	Must submit the manufacturer's authorization letter.			
12.4	Must submit user manual.			

Note: - The bidder shall verify and confirm compatibility of the proposed TB CAD software with both existing mobile and fixed general-purpose digital X-ray systems installed at the hospital. The bidder shall provide a compatibility statement specifying the X-ray manufacturer, model, image acquisition software/version, supported DICOM format, image transfer mechanism and any additional hardware, software, networking or interface requirements. Any additional hardware, interfaces, installation, configuration and integration necessary to make the software fully operational with both X-ray systems shall be included in the quoted price.

Submission Requirements:

Interested firms are required to submit the following documents.

- A duly completed and signed copy of above-mentioned Technical Specification Form (TSF).
- Copy of VAT Registration
- Company Registration
- Latest Tax Clerance Certificate
- The CAD software will be installed in selected two hospitals in Madesh Province.
- CARE Nepal shall be responsible for bearing the vendor's travel and accommodation expenses incurred during field travel, in accordance with CARE Nepal's prevailing policies, procedures.