Health Technology Review

Technology Ref.:	HTA-23074
Technology Name/Version/Model:	QXR - Chest X-Ray-V3.2
Approvals by International Bodies:	EU Quality Management System Certificate (MDR) EU MDD
Company name:	Qure.ai Technologies Private Limited
Agent in UAE:	The Pulse Townhouses
Email:	bhargava.reddy@qure.ai

Short Description of the Technology:	The qXR v3.2 hereby referred to as qXR is a deep learning technology that helps detect and highlight abnormalities in chest radiographs. qXR software is a chest X-ray interpretation software which analyses chest radiographs. qXR is a post processing image analysis software application, used during the review of digital chest radiographic images. The device integrates with the radiology workflow, using image viewing and reporting tools. The software can detect and localize suspected abnormalities and provides results as clinically relevant tags. Additionally, the software has the capability to provide the position of the suspected abnormalities, if relevant. The results produced by qXR are intended to be used as a support tool to assist clinician (radiologist) decision making, to improve efficiency, accuracy and turnaround time. It is not intended to be used as a source of medical advice or determine treatment plan or recommend a course of action for the patient. qXR is compatible with all Radiology IT systems (vendor neutral) including but not limited to PACS, Viewer, RIS systems. qXR (Chest Xray AI solution) is CE-MDR cleared and FDA 510(k) pending AI model that can detect nodules defined as rounded opacity ranging from 6mm to 30mm diameter and masses above 30mm diameter. It can further help clinicians differentiate benign and malignant nodules by computing proprietary Qure Lung Nodule Malignancy Risk. This is done by analysing the nodule characteristics including size, spiculation, calcification, homogeneity and solitary nodules.

Health Technology Assessment Team Recommendation:	**Approve**
Summary of Review:	

Qxr- v3.2 depends on AI technique to reduce the frequency of errors in detection and side-labelling of radiographic findings in chesk x-rays. Moreover, early detection and timely treatment also present a direct revenue opportunity for healthcare facilities.

Advantages	Disadvantages
qXR is compatible with all Radiology IT systems (vendor neutral) including but not limited to PACS, Viewer, RIS systems	Not to be used as a source of medical advice or determine treatment plan or recommend a course of action for the patient
Highlights the abnormal region(s) and generates a fully automated, comprehensive report if required with Instant results.	Limited only for chest radiographs
Technology has EU Quality Management System Certificate (MDR).	Requires validations to ensure the accuracy of the AI before use
Good false positive value in a study is zero and the false negative values are comparatively less.	

We recommend an **approval this technology** for Market entry with the following conditions:
1. Approval of QXR - Chest X-Ray-V3.2
2. It should be used by licensed medical practitioner/ radiologist.
3. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
4. Provision of regular updates and reports about the product to DOH upon request.

Moreover, DOH has the right to stop the product at any stage if deemed necessary, initial conditions and any subsequent conditions must be satisfied before obtaining final approval. Failure to do so will reflect in provoking the approval.

Technology Image
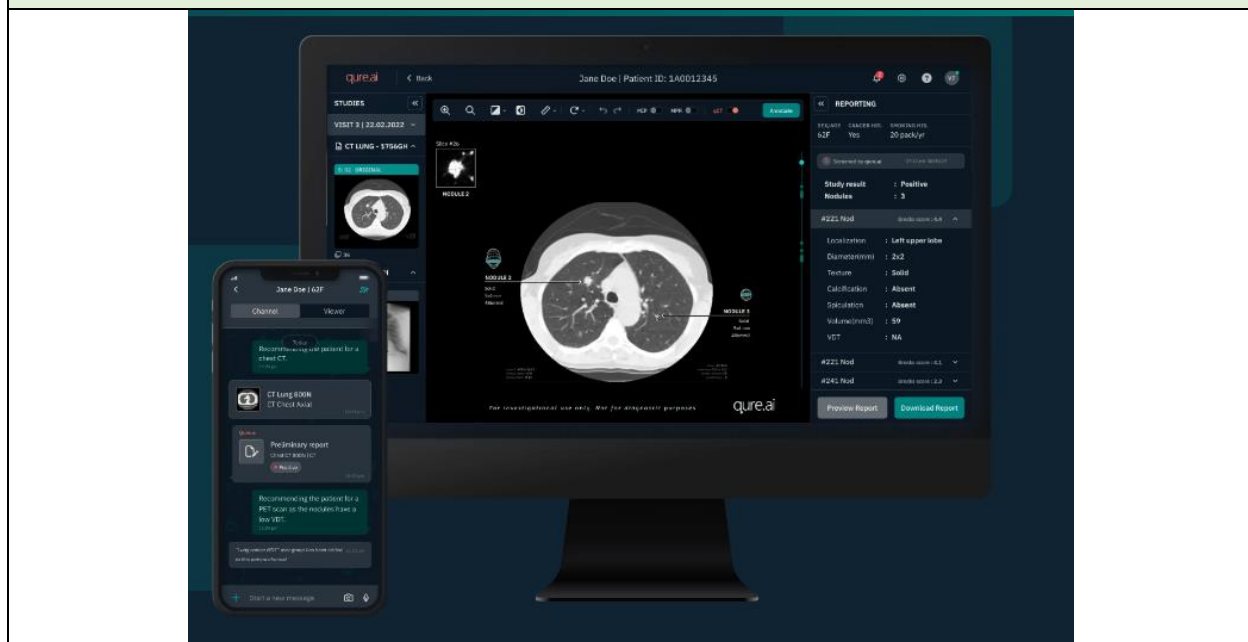
Population, setting and intended user for Technology "Qxr"

Population/ Intended User;

qXR can identify upto 29 abnormalities :
– Atelectasis
– Blunted Costophrenic angle
– Calcification
– Cardiomegaly
– Cavity
– Consolidation
– Degenerative Spine Changes
– Hyperinflation
– Fibrosis
– Opacities
– Pleural Effusion
– Hilar Prominence
– Reticulo Nodular Pattern
– Scoliosis
– Tracheal Shift
– Tuberculosis
– Nodules
– Pneumothorax
– Covid-19 risk
– Elevated Hemidiaphragm
– Pneumoperitoneum
– Rib Fractures
– Mediastinal Widening
– Linear Opacities
– Presence of Tracheal Tube
– Presence of Gastric Tube
– Placement of Tracheal Tube
– Placement of Gastric Tube
– Lung Nodule Malignancy

To be performed by:
– for use by licensed medical practitioner/ radiologist.

Clinical Setting:
– Hospitals

Condition of use:
– 6 years and above who have a chest X-ray as part of their clinical workup

Exclusion criteria:
– Lateral X-rays
– X-rays that do not contain the entire lung field.
– X-rays of other body parts.
– X-rays of patients below 6 years of age.