

Qure.ai receives 510(k) FDA clearance for chest X-ray solution for Pneumothorax and Pleural Effusion

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A monumental step towards getting healthcare AI to augment critical care and emergency care

Qure.ai has announced a pivotal 510(k) FDA clearance for its artificial intelligence (AI)-enabled chest X-ray solution – qXR, under two critical findings. Qure’s qXR has now been cleared to triage pneumothorax (PTX) and pleural effusion (PE), which present severe challenges in emergency rooms and intensive care units (ICUs).

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The newest clearance is an addition to Qure’s existing FDA-cleared product portfolio that includes qXR-BT for breathing tube placement, qER for emergency room head CT scans, and qER-Quant for head CT quantification software.

qXR has shown exemplary clinical accuracy in triaging pneumothorax (PTX), a condition where air collects in the pleural space, causing the lung to collapse. On the other hand, Pleura Effusion (PE) is where fluid accumulates in the pleural cavity.

Performance evaluations reveal that qXR-PTX-PE excels in providing rapid passive notifications, taking an average of 10 seconds to alert healthcare professionals. This impressive speed positions qXR-PTX-PE as an indispensable medical tool designed to inform specialists promptly, especially in critical settings like ICUs and emergency rooms, and to complement the expertise of our trained medical professionals. Utilising a globally sourced training dataset, qXR integrates into the existing standard of care workflow and serves as a passive notification system for worklist prioritisation.