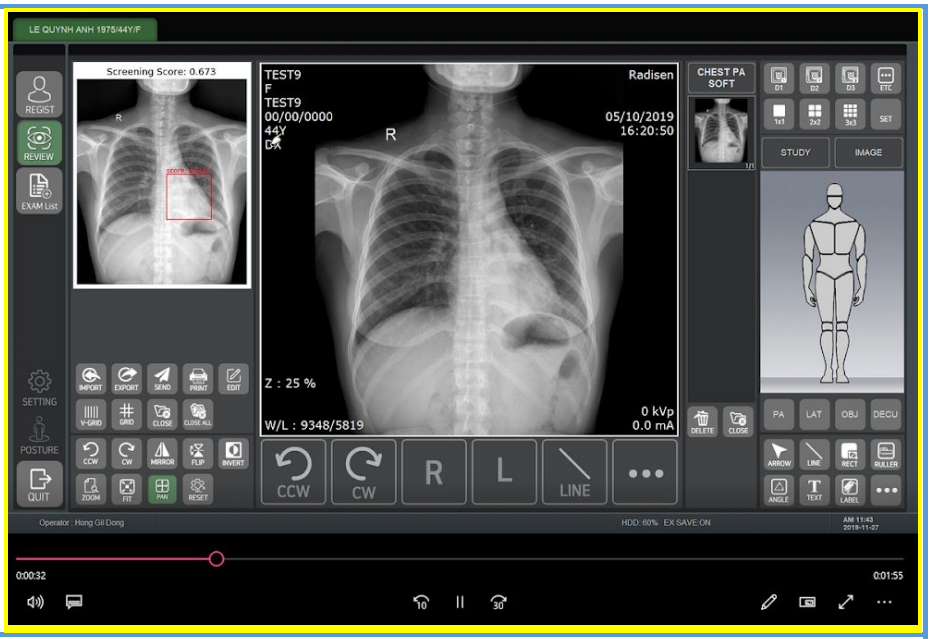
Product Profile: Radisen Co. Ltd.

Product	AXIR
Company	Radisen Co. Ltd.
Company HQ	Seoul, Korea
Version	1.1.2.2
Website	http://www.radisentech.com
Demo	Available upon request
Last updated	March 31, 2020
Description	AXIR is a screening and triaging tool to help clinicians identify abnormalities on chest x-ray. It is also a prioritization tool for radiologists/tele-radiologists. Currently, AXIR is an integrated software which is recommended to be used with Radisen's proprietary chest x-rays detector and viewer / system.
Certification	Stage of development: Validation (recommended to use in combination with Radisen's chest X-rays detector and viewer). Certification: Pending. Clinical evaluation under progress (KFDA, ISO13485, CE Documentation).
Intended Age Group	16+ years
Target Setting	Primary health centers, Teleradiology companies, Government/public sector, e.g. national TB program
Current Market	Currently not on the market.
Input	Can be used to read images from any kind of chest X-rays machine (vendor neutral), however it works best with the Radisen's chest X-rays system. Chest X-ray image format: DICOM Chest X-ray type: Posterior-anterior chest X-ray Other requirements: None
Output	Structured report that includes: ● Bounding boxes or Heat map ● Probability score for TB as well as dichotomous output indicating whether TB is likely present or likely absent. Default threshold probability score for TB if dichotomous: 0.5, but is adjustable. Other non-TB abnormalities detected by the product for which a separate abnormality score is given include: nodule, mass, cavity, integration, exudation, pneumothorax and reticular opacity.

	
Deployment	Offline only. Online service scheduled from June, 2020.
Hardware	A Radisen's proprietary box will be provided with the AI software. This box needs to be connected to the x-ray detector and computer. A port to transfer DICOM images is required.
Xray Machine Validation	None
Software	Image viewer provided by Radisen.
Server	Not applicable
Integration	It is possible to integrate the product with the client's legacy Picture Archiving and Communication System (PACS).
Processing Time	less than 20 seconds
Data Sharing & Privacy	
Server location (for online product)	Not applicable
Data shared with manufacturer?	No
De-identification (option to deidentify?)	Yes
Software Updates	
Frequency	Quarterly
Cost	Annual maintenance charge cover updates.
Price	AXIR is currently only used in combination with Radisen's DR detector. The installation and setup of AXIR is then free of charge. In the future, AXIR may be offered as an online service for settings that are using another DR detector. In those instances, additional setup charges will be applicable. Please contact Ryan Lee (jhlee@radisentech.com) for a quote.

Product Development	
Method (used to develop product)	Supervised deep learning (CNN)
Training	The product was trained on 150,000 chest X-rays.
Reference Standard	Human reader
Publications	Peer-reviewed publications are not yet available.