

# Artificial intelligence in radiology: 173 commercially available products and their scientific evidence

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## More than 300 radiological AI products available!



Products Companies News Contact Login

### Products

Find the artificial intelligence based software for radiology that you are looking for. All products listed are available for the European market (CE marked).

Compare products

Search

Search...

Filters

Modality

CT (134)

MR (81)

Mammography (20)

PET (9)

SPECT (2)

Show More

308/308 products

Sort by: Last Modified

UNITED IMAGING Intelligence

Subspecialty: MSK

Modality: CT

Source: Vendor

uAI-Discover-Chest CT Rib Fracture Detection

CE

Fracture detection list, Multiple fractures warning, Reconstructed images (MPR/MIP), Rib...

The CT Rib Fracture Detection application is intended to detect suspicious rib fractures in chest CT images of adult patients. It detects rib fractures and provides rib labels of the detected fractures. The application also provides 3D...

UNITED IMAGING Intelligence

Subspecialty: MSK

Modality: CT

Source: Vendor

uAI-Discover-Chest CT Lung Nodule Analysis

CE

Benign-malignant prediction, Follow-up analysis, Graphic diagnostic reports, Lung-RADS...

The CT Lung Nodule Analysis application is intended to detect and analyze...

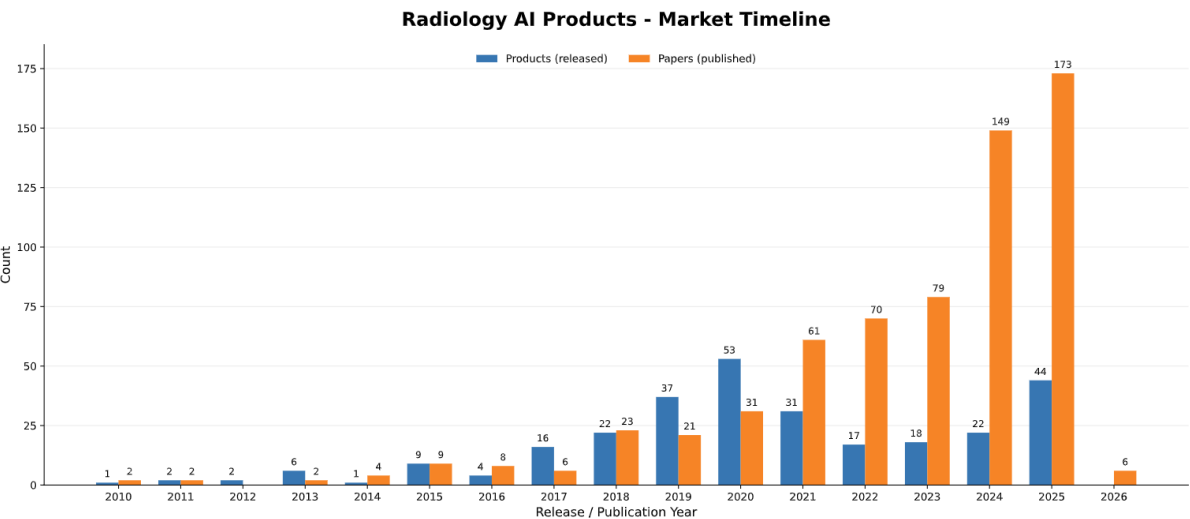
<https://radiology.healthairegister.com/> , extracted 2026-04-08

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# Number of solutions is still slowly growing..

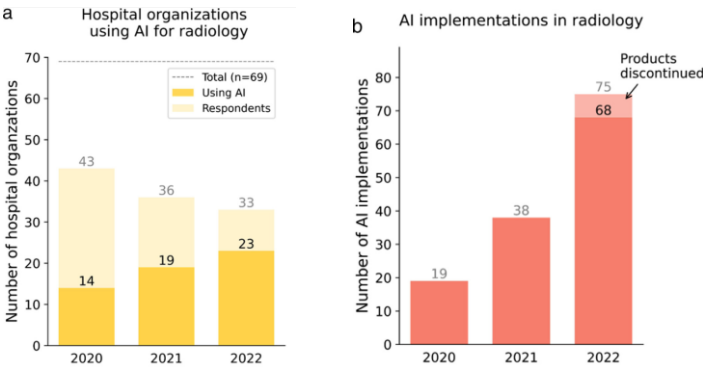


Adapted from a blog post written by Kicky van Leeuwen, posted on [www.healthregister.com](http://www.healthregister.com) "Playtime is over: radiology AI in 2026"

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# Adoption is increasing, but large-scale deployment is still relatively slow



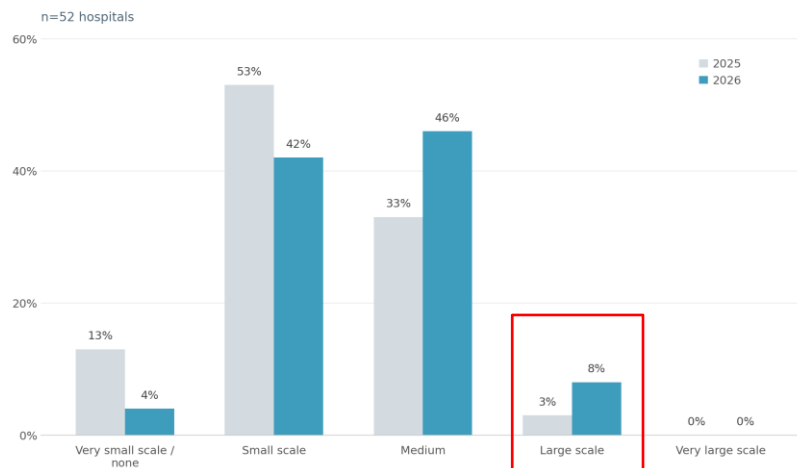
van Leeuwen et al. "Clinical use of artificial intelligence products for radiology in the Netherlands between 2020 and 2022." *European radiology* (2024)

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## Adoption is increasing, but large-scale deployment is still relatively slow

At what scale is AI applied within your hospital?



Adapted and translated to English from AI Monitor Ziekenhuizen 2026, M&I/Partners, 2026

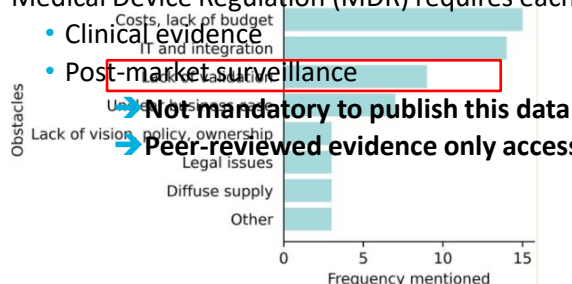
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## Adoption is increasing, but large-scale deployment is still relatively slow

Medical Device Regulation (MDR) requires each vendor to provide:

- Clinical evidence
- Post-market surveillance



→ Not mandatory to publish this data

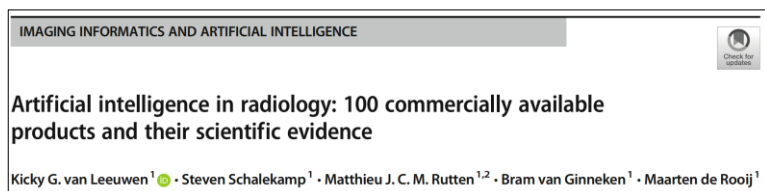
→ Peer-reviewed evidence only accessible source for product evaluation

van Leeuwen et al. "Clinical use of artificial intelligence products for radiology in the Netherlands between 2020 and 2022." European radiology (2024)

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## Lack of validation



### Available evidence

- 36 products were backed by 237 peer-reviewed studies
- 64 products had no publicly available evidence

### Relevance

- Evidence focused on standalone diagnostic accuracy (65%)
- Only 2% on high-level efficacy (clinical or socio-economic impact)

### Design

- Majority of studies were retrospective (81%)
- Half of the evidence (51%) was independent from vendor

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## Did the market significantly change in 3 years?



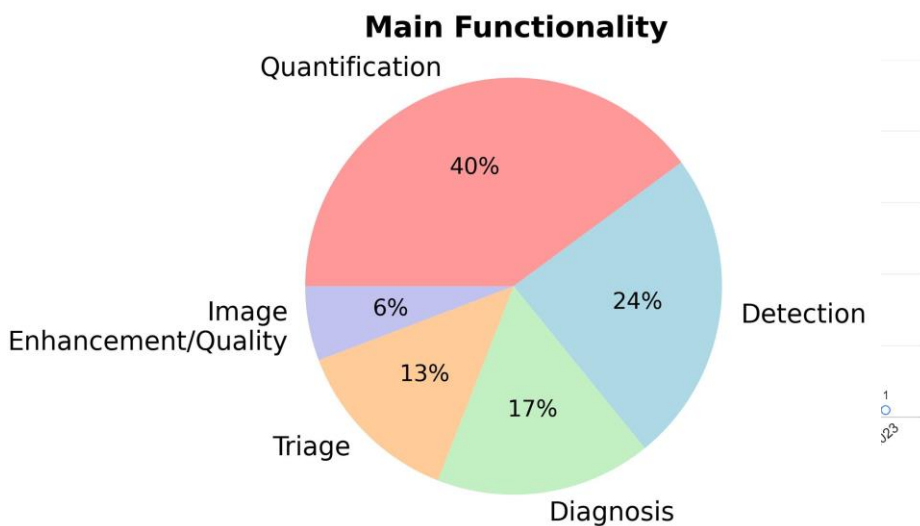
- 173 commercially available AI products and evidence (up to March 2023):
  - Collected peer-reviewed evidence
  - Assessed the level of efficacy per paper
  - Study design, data used, vendor independence

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## Product selection

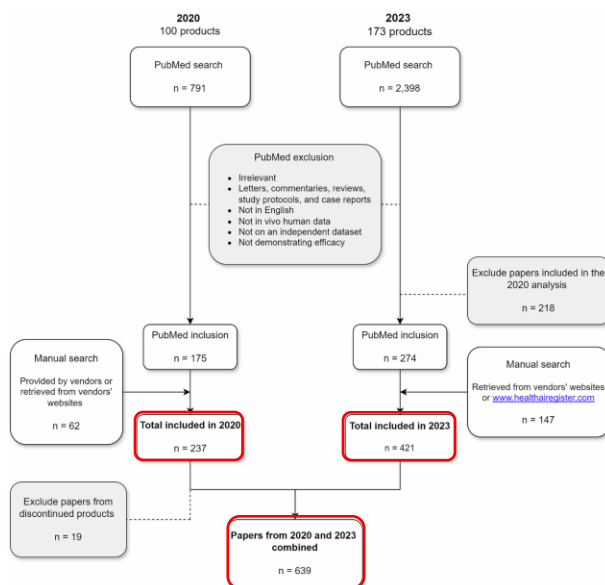
- Available on [www.healthairegister.com](http://www.healthairegister.com) as of March 31, 2023
- 173 products from 90 vendors



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## Peer-reviewed evidence collection



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## Levels of efficacy

Level	Explanation	Typical measures
Level 1t	<b>Technical efficacy</b> Article demonstrates the technical feasibility of the software.	Reproducibility, inter-software agreement, error rate.
Level 1c	<b>Potential clinical efficacy</b> Article demonstrates the feasibility of the software to be clinically applied.	Correlation to alternative methods, potential predictive value, biomarker studies.
Level 2	<b>Diagnostic accuracy efficacy</b> Article demonstrates the stand-alone performance of the software.	Standalone sensitivity, specificity, area under the ROC curve, or Dice score.
Level 3	<b>Diagnostic thinking efficacy</b> Article demonstrates the added value to the diagnosis.	Radiologist performance with/without AI, change in radiological judgement.
Level 4	<b>Therapeutic efficacy</b> Article demonstrates the impact of the software on the patient management decisions.	Effect on treatment or follow-up examinations.
Level 5	<b>Patient outcome efficacy</b> Article demonstrates the impact of the software on patient outcomes.	Effect on quality of life, morbidity or survival.
Level 6	<b>Societal efficacy</b> Article demonstrates the impact of the software on society by performing an economic analysis.	Effect on costs and quality adjusted life years, incremental costs per quality adjusted life year.

Low efficacy evidence

- Technical
- Diagnostic accuracy

Shows whether AI works

High efficacy evidence

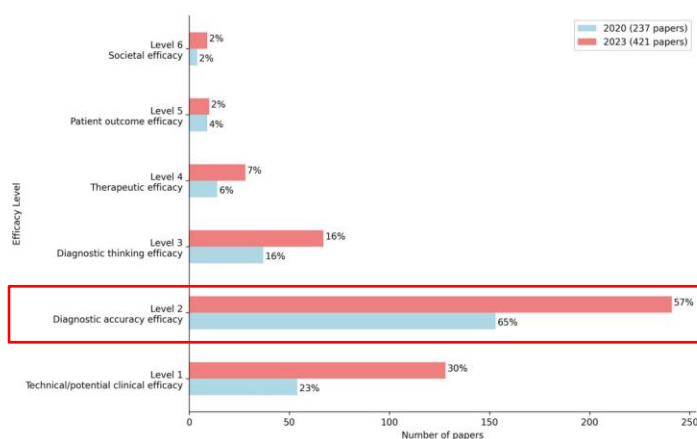
- Impact on patient management and outcomes
- Impact on socio-economic factors

Shows whether AI adds real world value

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## Levels of efficacy assessed per paper by 2023



- Level 1 23% to 30% ( $p < 0.04$ )
- Level 2 65% to 57% ( $ns$ )
- Level 3-6 22% to 24% ( $ns$ )

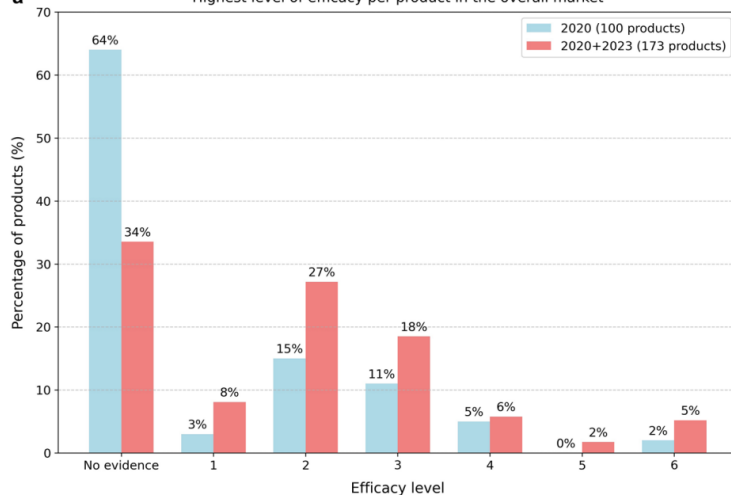
Limited progress in evaluating real world value

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## Highest level of efficacy per product by 2023

**a** Highest level of efficacy per product in the overall market



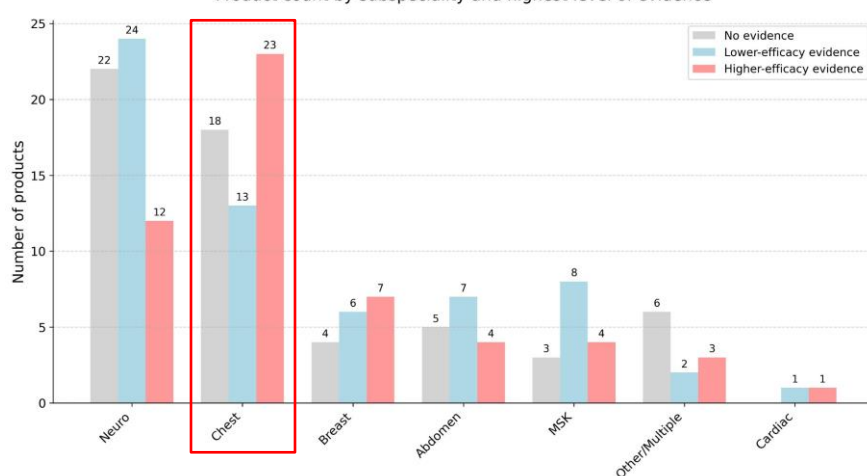
- Products with evidence 36% to 66%
- Level 1-2 18% to 35%
- Level 3-6 18% to 31%

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## Product count by subspecialty and level of evidence by 2023

Product count by subspecialty and highest level of evidence



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## Change in study characteristics by 2023

**Table 2** Comparative analysis of research study characteristics across the 2020 and 2023 analyses

Metric	2020	2023	% Difference [95% CI]	p-value*
Total studies	237 (100%)	421 (100%)	N/A	N/A
Independent of the vendor	116 (48.9%)	188 (44.7%)	−4.29 [−12.23, 3.65]	0.29
Prospective design	45 (19.0%)	66 (15.7%)	−3.31 [−9.39, 2.77]	0.28
Multicentre data	71 (30.0%)	172 (40.9%)	10.90 [3.41, 18.38]	< 0.01
Multinational data	35 (14.8%)	44 (10.5%)	−4.32 [−9.70, 1.06]	0.10
Data acquired from multiple manufacturers	59 (24.9%)	142 (33.7%)	8.83 [1.71, 15.96]	0.02

N/A not applicable  
\* p-values are based on chi-square tests without continuity correction

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## Did the Radiology AI market change by 2023?

- **Increase** in AI products with peer-reviewed evidence (36% to 66%)
- **Increase** in peer-reviewed studies (237 to 639), but:
  - Remain concentrated at **lower** efficacy levels (57%)
  - Are mainly **retrospective** in design (84%) and **very low** quality (5%)
- **Conclusion:** A positive trend is emerging in peer-reviewed evidence, yet robust evidence of real-world clinical impact and health outcomes is still lacking

**Regulatory approval does not guarantee clinical effectiveness!**

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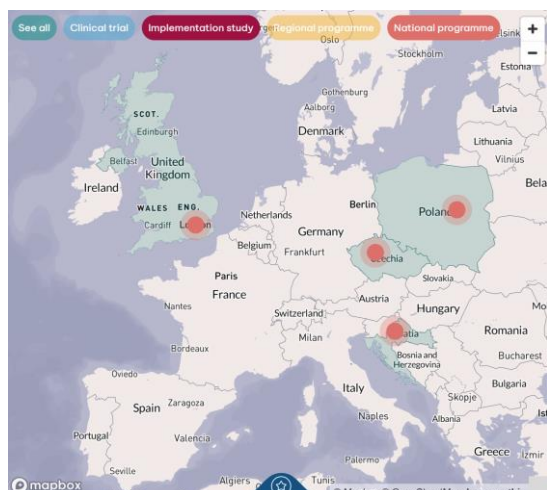
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## Specific use case: AI for lung cancer screening

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## Lung cancer screening is being increasingly implemented across the EU



<https://www.lungcancerpolicynetwork.com/interactive-map-of-lung-cancer-screening/>



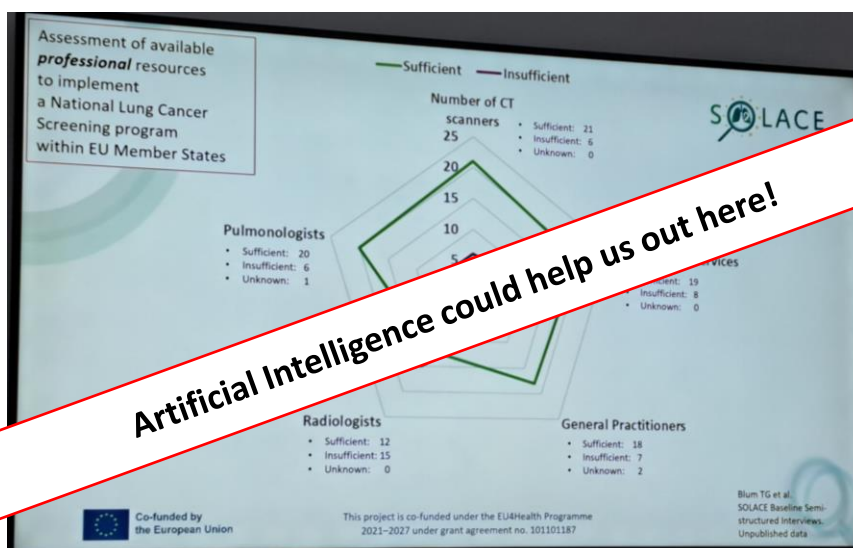
Building on the most recent evidence and methods, the recommendation extends organised screening to three additional cancers:

- **Lung cancer** testing for current heavy and ex-smokers aged 50-75.
- **Prostate cancer** testing in men up to 70 on the basis of prostate specific antigen testing, and magnetic resonance imaging (MRI) scanning as follow-up.
- Screening for *Helicobacter pylori* and surveillance of precancerous stomach lesions in places with **high gastric cancer incidence** and death rates.

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## Radiology resources insufficient in 15 out of 27 EU countries



Slide courtesy Torsten Blum, SOLACE project, presented at ECR2024

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# Germany screening regulation mandates use of AI for detection and volumetry



Federal Ministry  
of Justice and  
Consumer Protection

Federal Office  
of Justice

## Section 5 Diagnostic review of the examination

(1) The radiation protection executive must ensure that a person fulfilling the requirements of section 6 (1) reviews the computed tomography scan first without and then making use of software for computer-assisted detection (first reviewer).

(2) If the first reviewer concludes that the result constitutes a result in need of monitoring or in need of diagnosis, then the radiation protection executive must ensure that an additional person who fulfils the requirements of section 6 (2) reviews the computed tomography scan independently of the first reviewer first without and then making use of software for computer-assisted detection (second reviewer).

(3) The radiation protection executive must ensure that following the diagnostic review in accordance with subsection (2) a final joint assessment of the computed tomography scan is provided by the first and second reviewers. If the joint assessment concludes that the result constitutes a result in need of monitoring, a joint recommendation is to be made on the timing of the next lung cancer screening examination.

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[https://www.gesetze-im-internet.de/englisch\\_lukrfr\\_herkv/englisch\\_lukrfr\\_herkv.html#p0051](https://www.gesetze-im-internet.de/englisch_lukrfr_herkv/englisch_lukrfr_herkv.html#p0051)

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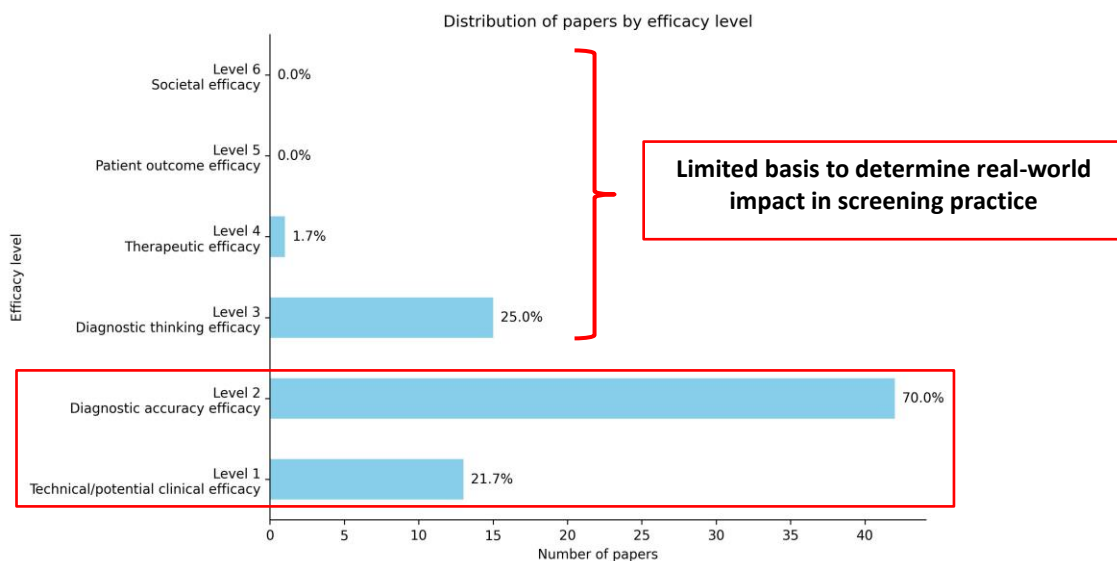
<p><b>contextflow</b></p> <p><b>contextflow ADVANCE Chest CT</b></p> <p>Lung nodule detection, localization and quantification; lung nodule analysis; visualization.</p> <p>contextflow ADVANCE Chest CT offers comprehensive computer-aided detection support for L2, COPD screening cases. It offers lung nodule detection and tracking of changes over time, quantification and...</p> <p><a href="#">Read more</a></p> <p>Subsidiarity Chest Modality: CT</p>	<p>CE: Class IIa - MDR FDA: Class II - MDR</p> <p>Information source: Certification verified</p> <p>Vendor: Yes</p> <p>Subsidiarity Chest Modality: CT</p>	<p><b>InferVision</b></p> <p><b>InferRead CT Lung</b></p> <p>Lung nodule detection, report generation, multi-fragment analysis.</p> <p>InferRead CT Lung is a processing solution for lung cancer screening. It recognizes the size, location and shape of nodules, estimates the characteristics of suspected lung nodules in different images.</p> <p><a href="#">Read more</a></p> <p>Class IIa</p> <p>Information source: Certification verified</p> <p>Vendor: Yes</p> <p>Subsidiarity Chest Modality: CT</p>	<p>CE: Class IIa - MDR FDA: Class II - MDR</p> <p>Information source: Certification verified</p> <p>Vendor: Yes</p> <p>Subsidiarity Chest Modality: CT</p>	<p><b>core:line</b></p> <p><b>AVIEW LCS+</b></p> <p>Nodule detection, nodule classification, nodule volume quantification, VQV, LungRADS scoring.</p> <p>The LCS+ software from Coreline-Soft provides information on the 3 main lung diseases: lung cancer, COPD and primary artery calcification based on a low-flow, non-contrast, non-gated CT scan.</p> <p><a href="#">Read more</a></p> <p>Subsidiarity Chest Modality: CT</p>	<p>CE: Class IIa - MDR FDA: Class II - MDR</p> <p>Information source: Certification verified</p> <p>Vendor: Yes</p> <p>Subsidiarity Chest Modality: CT</p>	<p><b>deephealth</b></p> <p><b>Saige Lung (Veye Lung Nodules)</b></p> <p>Nodule detection, nodule classification, volume quantification, growth calculation (prior study).</p> <p>The AI-assisted software intelligently with detecting, classifying and tracking the growth of pulmonary nodules. Saige Lung previously Veye Lung features by Ascentage integrates into the PACS and is...</p> <p><a href="#">Read more</a></p> <p>Subsidiarity Chest Modality: CT</p>	<p>CE: Class IIa - MDR FDA: Class II - MDR</p> <p>Information source: Certification verified</p> <p>Vendor: Yes</p> <p>Subsidiarity Chest Modality: CT</p>	<p><b>Merix Medical Solutions AG</b></p> <p><b>Veolity</b></p> <p>Nodule detection, segmentation and quantification, temporal registration and nodule comparison.</p> <p>Veolity LungCheck is a reading solution dedicated to lung screening programs as well as incidental pulmonary nodule management. It contains lung CAD or not, non-solid, part-solid, and solid...</p> <p><a href="#">Read more</a></p> <p>Subsidiarity Chest Modality: CT</p>	<p>CE: Class IIa - MDR FDA: Class II - MDR</p> <p>Information source: Certification verified</p> <p>Vendor: Yes</p> <p>Subsidiarity Chest Modality: CT</p>	<p><b>Siemens Healthineers</b></p> <p><b>AI-Rad Companion Chest CT</b></p> <p>Segmentation and volume quantification of lungs, lung lobe, lung lesions, heart, thoracic aorta.</p> <p>The AI-Rad Companion Chest CT solution offers a multi-step approach with pulmonary, cardiovascular and musculoskeletal functionalities. Major functionalities: lung lobe segmentation, lung lesion...</p> <p><a href="#">Read more</a></p> <p>Subsidiarity Chest Modality: CT</p>	<p>CE: Class IIa - MDR FDA: Class II - MDR</p> <p>Information source: Certification verified</p> <p>Vendor: Yes</p> <p>Subsidiarity Chest Modality: CT</p>	<p><b>HY 汇医慧影</b></p> <p><b>CT AI-assisted Lung Nodule Detection</b></p> <p>Lung nodule detection, localization and volume quantification, malignancy score.</p> <p>The AI tool is capable of detecting lung nodules in CT scans. Classification (benign, cancer risk, ground glass, calcification) and risk prediction (benign, malignant) on each nodule are provided.</p> <p><a href="#">Read more</a></p> <p>Subsidiarity Chest Modality: CT</p>	<p>CE: Class IIa - MDR FDA: Class II - MDR</p> <p>Information source: Certification verified</p> <p>Vendor: Yes</p> <p>Subsidiarity Chest Modality: CT</p>	<p><b>RAYSCAPE</b></p> <p><b>Lung CT</b></p> <p>Nodule detection, nodules localization, nodules measurements, volume quantification, detection.</p> <p>RAYSCAPE Lung CT solution helps radiologists identify lung nodules that have a diameter between 3-30 mm. The algorithms highlight the presence of nodules on each slice and, separately, measure the...</p> <p><a href="#">Read more</a></p> <p>Subsidiarity Chest Modality: CT</p>	<p>CE: Class II - MDR FDA: Class II - MDR</p> <p>Information source: Certification verified</p> <p>Vendor: Yes</p> <p>Subsidiarity Chest Modality: CT</p>	<p><b>monitor</b></p> <p><b>LucAS-Plus</b></p> <p>Nodule detection and localization, nodule characterization, nodule classification, segmentation and...</p> <p>LucAS-plus can automatically detect and segment nodules through its AI algorithms. The main aim of the solution is to carry out an automated and interconnected medical diagnosis process to minimize...</p> <p><a href="#">Read more</a></p> <p>Subsidiarity Chest Modality: CT</p>	<p>CE: Class IIa - MDR FDA: Class II - MDR</p> <p>Information source: Certification verified</p> <p>Vendor: Yes</p> <p>Subsidiarity Chest Modality: CT</p>	<p><b>core:line</b></p> <p><b>SenseCare-Lung Pro</b></p> <p>Lung nodule detection, nodule type classification (solid, GGO, etc.), pneumonia detection, lung...</p> <p>SenseCare Lung CT automatically detects pulmonary nodules and pneumonia including COVID-19 lesions and provides analysis such as non-identification, risk evaluation, quantification, and...</p> <p><a href="#">Read more</a></p> <p>Subsidiarity Chest Modality: CT</p>	<p>CE: Class IIa - MDR FDA: Class II - MDR</p> <p>Information source: Certification verified</p> <p>Vendor: No</p> <p>Subsidiarity Chest Modality: CT</p>	<p><b>VUNO</b></p> <p><b>VUNO Med8-LungCT AI™</b></p> <p>Nodule detection, Nodule measurement, Nodule classification, Lung-RADS reporting.</p> <p>It detects and quantifies pulmonary nodules, providing size, volume, nodule type, location, calcification, and spiculation. An automatic report based on the calculated Lung-RADS category is provided.</p> <p><a href="#">Read more</a></p> <p>Subsidiarity Chest Modality: CT</p>	<p>CE: Class IIa - MDR FDA: Class II - MDR</p> <p>Information source: Certification verified</p> <p>Vendor: Yes</p> <p>Subsidiarity Chest Modality: CT</p>	<p><b>JLK</b></p> <p><b>JLD-51K</b></p> <p>Lung nodule detection and quantification, LungRADS categorization, Vancouver Risk calculator.</p> <p>JLD-51K is based on the Convolutional Neural Network (CNN), a type of deep learning model that detects nodules in pulmonary CT images. Measure the diameter and volume of the nodules found, proceed...</p> <p><a href="#">Read more</a></p> <p>Subsidiarity Chest Modality: CT</p>	<p>CE: Class II - MDR FDA: Class II - MDR</p> <p>Information source: Certification verified</p> <p>Vendor: Yes</p> <p>Subsidiarity Chest Modality: CT</p>
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<https://radiology.healthairegister.com>, extracted 2024-04-23, ordered by last modified

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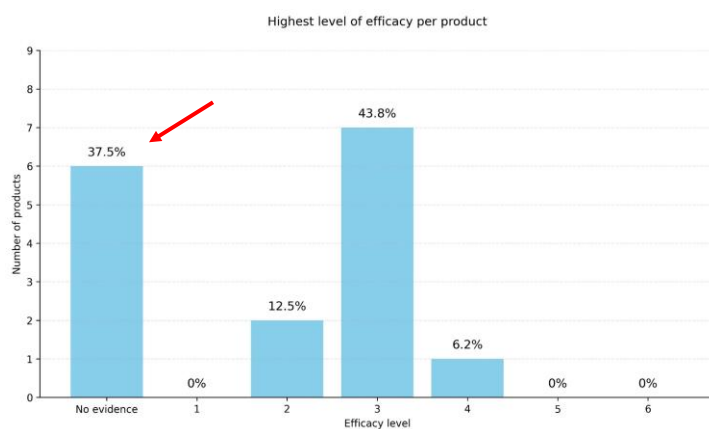
## Efficacy levels accessed in peer-reviewed papers



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## Highest level applicable per product



- 6/16 products had no peer-reviewed evidence

- Almost half of the products had at least a study with efficacy level 3 (*impact on clinical decision making*)

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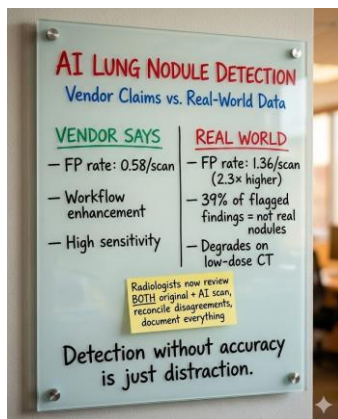
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## Is AI ready to aid radiologists in LCS practice?



**Kirill Lopatin** • 1e  
Helping U.S. radiology groups scale with ready-to-sign AI repo  
[Mijn website bezoeken](#)  
2 w •

39% of AI-flagged lung nodules aren't real.  
And the real-world numbers are twice as bad as vendors claim.



**Bruno Hochhegger** • 2e  
Thoracic radiologist and Clinical Professor of Radiology - Vice Chair of Resea...

1 w •

This is not a prevalence problem! The main problem is that most of softwares are fda approved with poor data that include small samples! Then it is impossible to have reasonable results in external validation! <https://pmc.ncbi.nlm.nih.gov/articles/PMC12140231/>

### The illusion of safety: A report to the FDA on AI healthcare product approvals

Artificial intelligence is rapidly transforming healthcare, offering promising advancements in diagnosis, treatment, and patient outcomes. However, concerns...

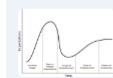


**Grayson L. B.** • 2e  
Vice Chair of Research, Associate Professor, Radiology, Brown U...

(bijgewerkt) 1 w •

This is not really about accuracy. It is about precision, which is massively influence by prevalence. This is called the "accuracy" or "false positive" paradox. And the increase in false positives is the false discovery rate (FDR), not the false positive rate (FPR).

<https://link.springer.com/article/10.1007/s00330-024-11332-z>



### Implementing an AI algorithm in the clinical setting: a case study for the accuracy paradox - European...

Objectives We report our experience implementing an algorithm for the detection of large vessel occlusion (LVO) for suspected...

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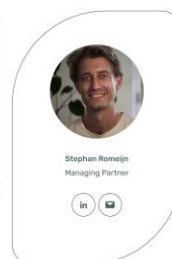
## Conclusion

- A positive trend is emerging in peer-reviewed evidence, but ....
- Robust evidence of real-world clinical impact is still lacking
- Limited high-level clinical evidence complicates integrating AI into guidelines, securing reimbursement, and formulating recommendations for its use
- Future perspective:
  - Research should shift to prospective studies to reflect real-world clinical settings, patient populations, and healthcare systems.
  - Funding agencies should prioritize not just AI *development* but also independent validation, implementation, and long-term monitoring
  - Vendors already collect post-market surveillance data under the MDR → publish these results!

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# Thank you for your attention!



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[Colin.Jacobs@radboudumc.nl](mailto:Colin.Jacobs@radboudumc.nl)



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