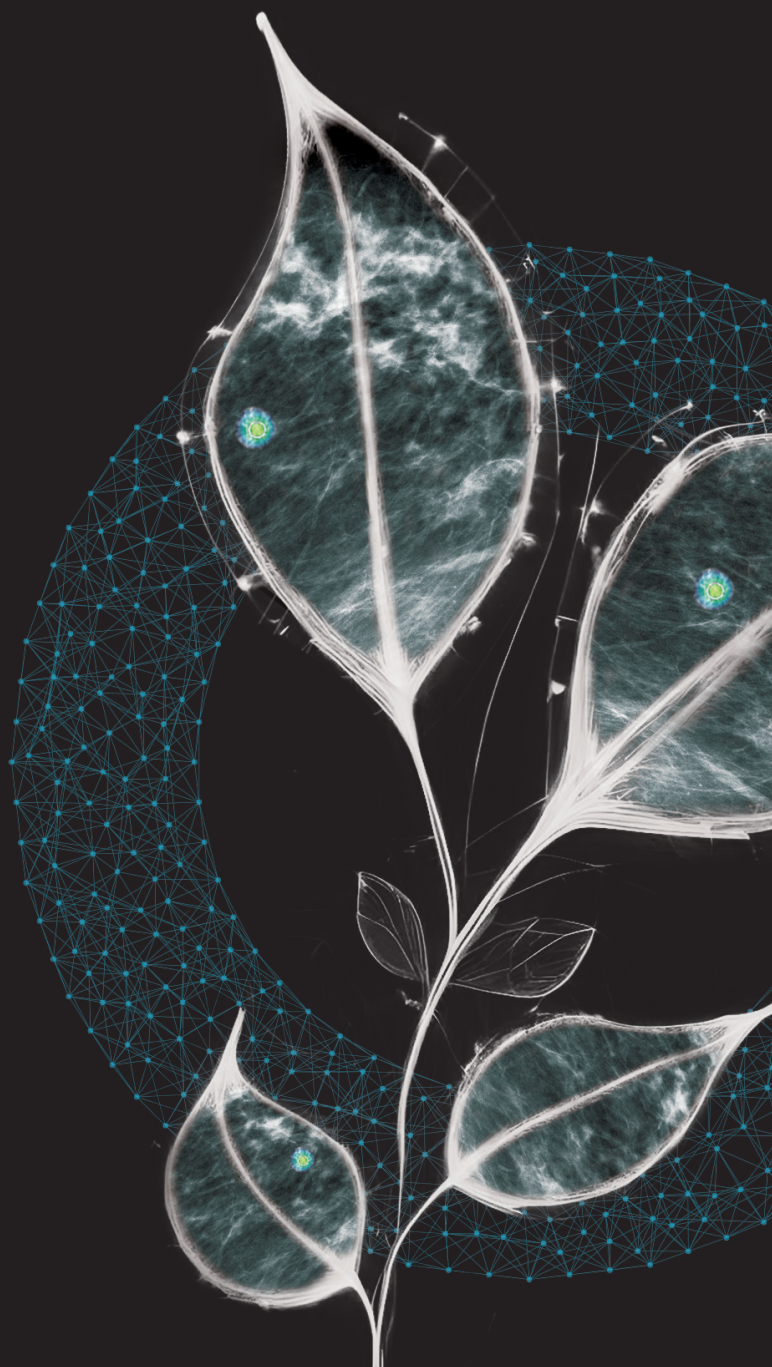
RESEARCH STUDIES

Lunit INSIGHT for Breast: Improve operational efficiency and cancer detection with superior, proven accuracy

Our acquisition by Lunit means we're bringing their technology, Lunit INSIGHT for Breast, to the United States market.

While Lunit INSIGHT for Breast is new to the United States, the technology has a well-documented history across Europe, Asia, and Australia.

Its power, efficacy, and accuracy have been demonstrated via many published studies. Let's explore a few to showcase the exciting opportunities ahead for the United States.



Volpara HEALTH x Lunit

Changes in cancer detection and false-positive recall in mammography using artificial intelligence: a retrospective, multi-reader study

Published in: *Lancet Digital Health*

Details

This study explored whether or not an AI algorithm for diagnosing breast cancer in mammography could benefit radiologists by improving diagnostic accuracy.

The study used 170,230 mammography examinations from five institutions in South Korea, the USA, and the UK. The data set included 36,468 cancer-positive cases confirmed by biopsy, 59,544 benign cases (8,827 confirmed by biopsy and 50,717 by follow-up imaging), and 74,218 normal cases.

A multicenter, observer-blinded, reader study was conducted with 320 mammograms (160 cancer-positive, 64 benign, 96 normal) and independently assessed by 14 radiologists. Each radiologist evaluated the likelihood of malignancy (LOM), the location of malignancy, and the necessity to recall the patient, both without and with AI assistance.

Performance was measured using the LOM-based area under the receiver operating characteristic curve (AUROC), recall-based sensitivity, and specificity.

Results

AI standalone performance:

- **Overall AUROC:** 0.959
- **South Korea dataset:** AUROC 0.970
- **USA dataset:** AUROC 0.953
- **UK dataset:** AUROC 0.938

Reader study:

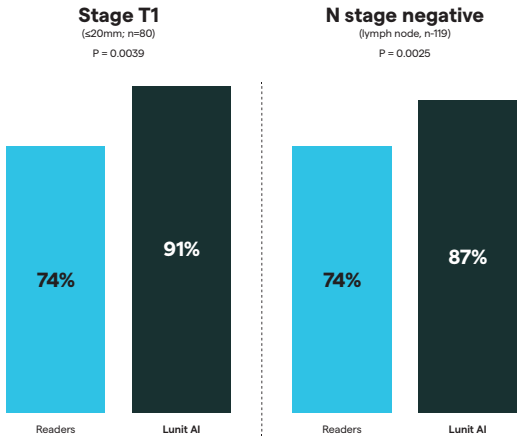
- **AI performance:** AUROC 0.940
- **Radiologists without AI:** AUROC 0.810
- **Radiologists with AI:** AUROC 0.881

Stage of cancer detected comparisons:

- **T1 cancer detection:** AI 91% vs Radiologists 74%
- **Node-negative cancer detection:** AI 87% vs Radiologists 74%

Overall impact

- Demonstrates radiologist performance increases with the assistance of AI
- Increases detection rates for early-stage cancers, such as T1 and node-negative cases
- Supports confident identification of challenging findings, particularly among general radiologists



Impact of AI for digital breast tomosynthesis on breast cancer detection and interpretation time

Published in: *Radiology: Artificial Intelligence*

Details

This study aimed to develop an AI model for diagnosing breast cancer using digital breast tomosynthesis (DBT) and investigate its potential to enhance diagnostic accuracy and reduce the reading time of radiologists.

The AI algorithm was developed and validated with data collected from 14 United States and South Korean institutions between January 2010 and December 2021. A multicenter reader study involving 15 US radiologists (7 breast specialists and 8 general radiologists) was conducted to compare performance in interpreting DBT exams from 258 women, including 65 cancer cases, both with and without the use of AI.

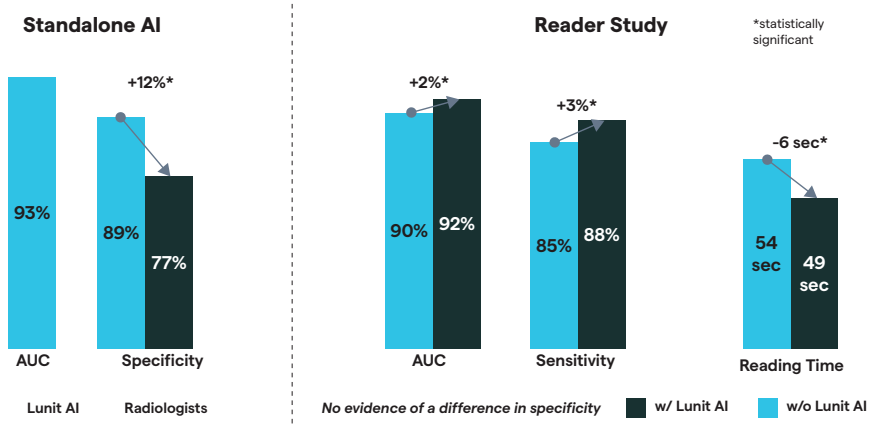
Results

- **AI performance:** Standalone AUC of 0.93
- **Radiologists' AUC improvement:** Increased from 0.90 to 0.92 with AI
- **AI showed higher specificity than radiologists:**
  - **AI:** 89.64%
  - **Radiologists:** 77.34%
- **When reading with AI, radiologists' sensitivity increased:**
  - **Without AI:** 85.44%
  - **With AI:** 87.69%
- **Reading time decreased:** From 54.41 seconds without AI to 48.52 seconds with AI

Overall impact

- Streamline radiologists' workflows by cutting reading time per case by nearly 6 seconds
- Spend 13% less time on reading normal cases
- Reduce false positives and increase cancers found (1 more cancer for every 10 detected)

Lunit AI improved radiologists performance and shortened time in interpreting DBT exams.



Effect of artificial intelligence-based triaging of breast cancer screening mammograms on cancer detection and radiologist workload

Published in: *Lancet Digital Health*

Details

This study investigated the potential of AI cancer-detection software to triage certain screening mammograms into a "no radiologist" workstream and an "enhanced assessment" workstream.

The purpose of the "enhanced assessment" was to simulate the selection of women for more sensitive screening and to promote early detection of cancers that would otherwise be diagnosed as interval cancers or as next-round screen-detected cancers.

The study included samples from 7,364 women—547 diagnosed with breast cancer, 6817 healthy controls. All women diagnosed with breast cancer attended two consecutive screening rounds. Healthy women were randomly sampled to mimic a 0.7% incident cancer frequency per screening interval. Various AI prediction score cutoffs were examined to determine their impact on missed and additionally detected cancers.

The ultimate goal was to examine how AI could be used to reduce radiologist workload and increase early cancer detection. Using the detection rates from the population above, this was done in a simulated screening population of over 75,000 women.

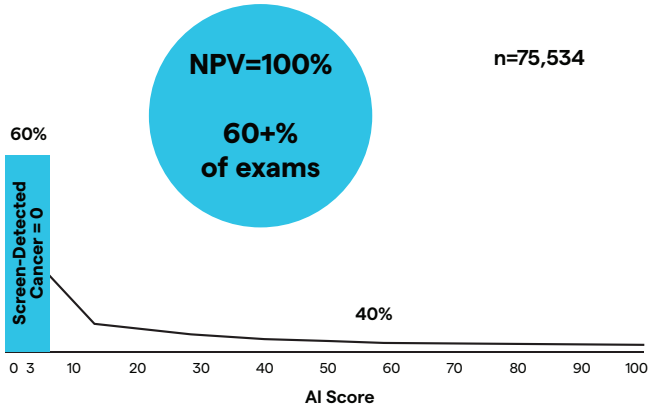
Results

No radiologist stream:

- When including 60% of women by AI score, the proportion of screen-detected cancers that would have been missed was 0%
- When including 70% of women by AI score, the proportion of screen-detected cancers that would have been missed was 0.3%
- When including 80% of women by AI score, the proportion of screen-detected cancers that would have been missed was 2.6%

Enhanced assessment stream:

- **When including 1% of women with the highest AI scores:**
  - 12% additional detection of 200 subsequent interval cancers
  - 14% additional detection of 347 next-round screen-detected cancers
- **When including 5% of women with the highest AI scores:**
  - 27% additional detection of 200 subsequent interval cancers
  - 35% additional detection of 347 next-round screen-detected cancers



Overall impact

- Potential to reduce radiologist workload by more than half without missing screen-detected cancers
- AI triage enables clinics to pre-emptively detect a substantial proportion of cancers otherwise diagnosed later

External evaluation of 3 commercial artificial intelligence algorithms for independent assessment of screening mammograms

Published in: *JAMA Oncology*

Details

This study externally evaluated 3 commercially available artificial intelligence (AI) computer-aided detection (CAD) algorithms as independent mammography readers and assessed the screening performance when combined with radiologists.

The three AI computer-aided detection algorithms, AI-1 (Lunit INSIGHT for Breast), AI-2, and AI-3, yielded a continuous score for the suspicion of cancer in each mammography examination.

Positive follow-up findings were determined by pathology-verified diagnosis at screening or within 12 months thereafter. Negative follow-up findings were determined by a 2-year cancer-free follow-up.

The study included 8805 women aged 40 to 74 years who underwent mammography screening and who did not have implants or prior breast cancer. The study sample included 739 women who were diagnosed as having breast cancer (positive) and a random sample of 8066 healthy controls (negative for breast cancer).

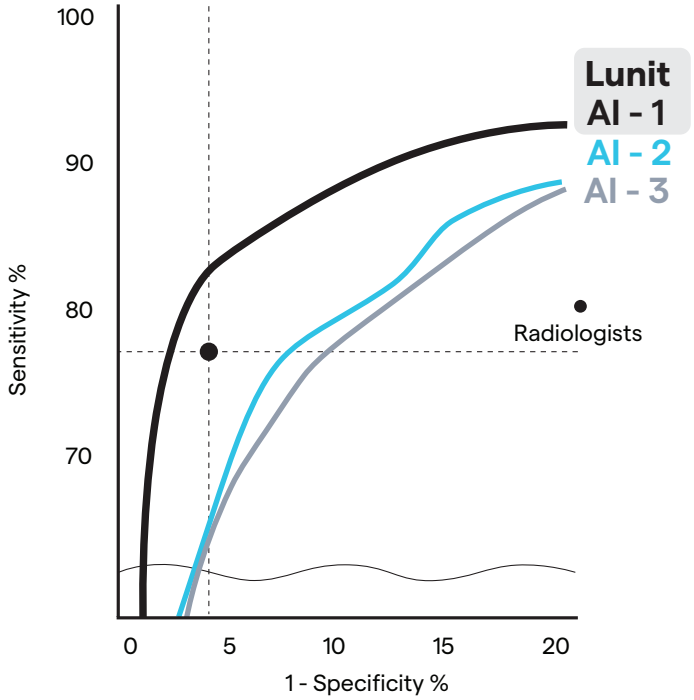
Results

Area under the receiver operating curve (AUC) for cancer detection:

- **AI-1 (Lunit INSIGHT for Breast):** 0.956
- **AI-2:** 0.922
- **AI-3:** 0.920

Combining AI-1 (Lunit INSIGHT for Breast) with first-reader radiologists achieved 88.6% sensitivity at 93.0% specificity (abnormal defined by either of the 2 making an abnormal assessment).

No other examined combination of AI algorithms and radiologists surpassed this sensitivity level.



Overall impact

- Outperforms other AI and radiologist combinations in sensitivity in a head-to-head comparison of the same data
- Sets a new standard for accuracy in mammography screening

Performance of an AI system for breast cancer detection on screening mammograms from BreastScreen Norway

Published in: *Radiology: Artificial Intelligence*

Details

Researchers from Norway's national breast screening program tested Lunit INSIGHT in a study with data obtained from 662k women.

They tested the AI with different specificity and sensitivity settings based on AI risk scores. In one scenario, 50% of the highest risk scores were classified as positive for cancer, while in another, the threshold was set to 10%.

Results

- At the 50% cutoff, AI correctly identified 99% of screen-detected cancers and 85% of interval cancers.
- At the 10% cutoff, AI correctly detected 92% of screen-detected cancers and 45% of interval cancers
- AI performed better in identifying false-positive cases as negative at the 10% threshold than 50% (69% vs. 17%)
- AI had a higher AUC than double-reading for screen-detected cancers (0.97 vs. 0.88)

Overall impact

- Improves identification of false positives
- Minimizes unnecessary follow-ups
- Outperforms traditional double-reading

What does this mean for radiologists in the United States?

Decreased reading time with higher accuracy underscores AI's potential as a valuable partner for radiologists in interpreting DBT images.

Trusted and proven AI, such as Lunit INSIGHT for Breast, can analyze large volumes of imaging data quickly and identify concerning patterns and anomalies before they reach the radiologist.

By providing a way to triage cases by how likely they are to contain a suspicious finding, AI reduces the burden on busy radiologists and allows them to swiftly review and verify findings with higher accuracy.

Curious how this technology could benefit you and your patients? Let us show you how.