

AI-STREAM

World's first **prospective** multicenter cohort study for **single reading** settings

ScreenTrustCAD

Groundbreaking **prospective**, population-based, paired-reader, non-inferiority study replacing one human reader in Europe's **double reading** environment

Lunit's AI is uniquely backed by real-world, prospective studies in both single- and double-reading environments – reflecting our commitment to solving real-world challenges with evidence that matters.

Our solutions empower healthcare providers to make more confident diagnostic decisions, streamline workflows, and optimize reading strategies based on proven clinical outcomes.

AI-Stream

This study explores how AI-CAD impacts diagnostic accuracy when used by breast radiologists in a real-world, single-reading setting — within the framework of South Korea's national breast cancer screening program.



24,543 mammograms

Women aged 40 and above who underwent routine biennial mammography from February 2021 to December 2022, with 140 (0.57%) screen-detected breast cancers. Of all the participants, 67.5% had dense breasts, and 80.7% of diagnosed breast cancer had dense breasts.

ScreenTrustCAD

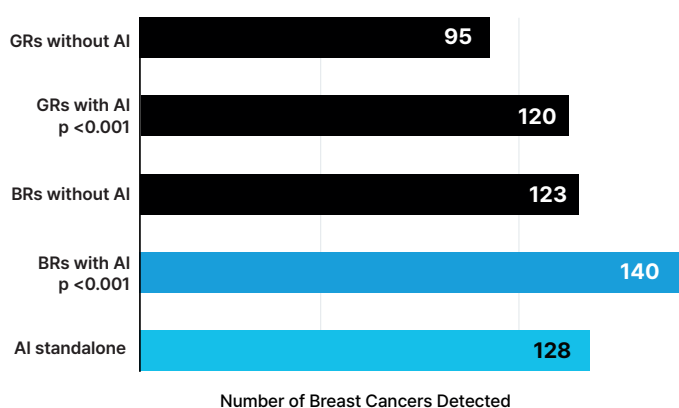
This study represents a shift in breast cancer screening — focusing on how AI supports radiologists in real-world decisions to reduce recalls and improve screening precision.



55,581 mammograms

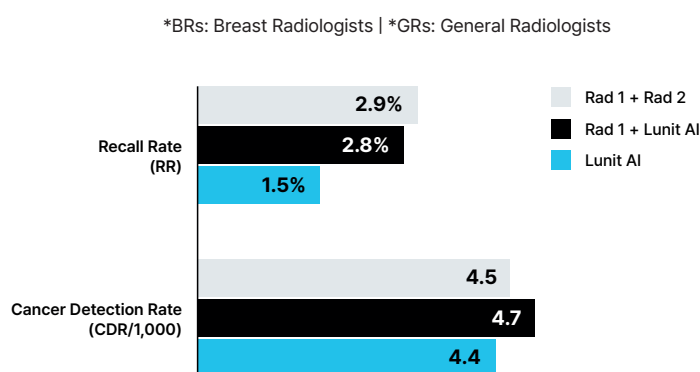
Consecutive women without breast implants aged 40–74 years participating in population-based screening in the geographical uptake area of the study hospital were included from April 1, 2021 to June 9, 2022.

Key results



In the AI-Stream study, Breast Radiologists and Lunit AI showed higher cancer detection rates, as did General Radiologists and Lunit AI.

Lunit AI as a standalone reader detected more breast cancers than Breast Radiologists without AI and General Radiologists with AI.



In the ScreenTrustCAD study, the combination of Radiologist 1 and Lunit AI showed higher cancer detection rates (CDR) and lower recall rates (RR), in comparison with two Radiologists.

From study to practice: Implementing AI to revolutionize screening

In 2023, following the groundbreaking results of ScreenTrustCAD, Capio S:t Göran Hospital became the first in Europe to implement Lunit AI as a second reader within their double-blind breast cancer screening workflow.

Serving approximately 78,000 screening exams annually, the hospital put in place a new AI-augmented workflow.

- 1. Independent initial reads:** Every mammogram is independently assessed by one human radiologist and the Lunit AI, which operates at the same threshold validated in ScreenTrustCAD.
- 2. Consensus discussions:** Two human radiologists then review cases flagged by either the AI, the first reader, or both to make final decisions, now guided by AI insights.

Improved diagnostic performance:

15%

more cancers detected

31%

increase in PPV

11%

fewer recalls, reducing stress for patients



Less time on routine screenings

Streamlining routine mammogram reads and supporting faster turnaround without compromising quality.



More time for complex cases

By easing the load of routine tasks, radiologists have more capacity to focus their expertise where it adds the most value.

Why do these studies matter?

Lunit AI is proving its ability to transform breast cancer screening worldwide. With robust prospective evidence from both single and double reading settings, Lunit AI can enhance efficiency, maintain accuracy, and even replace one human reader in double reading workflows. These advancements are paving the way for more scalable, high-quality screening programs, ensuring earlier detection and improved patient outcomes.

Dr Karin Dembrower, Head Physician of the Department of Breast Radiology at St Goran Hospital and lead of the ScreenTrustCAD study, shared her team's experience over one year post-implementation of the Lunit AI:

"By replacing one radiologist, we've reduced workloads while maintaining consistent cancer detection rates and fewer unnecessary recalls. This shift has eliminated overtime on evenings and weekends, allowing radiologists to focus on complex cases—the work we are trained for. For patients, it means faster and more accurate care; previously, the waiting time for a clinical mammogram was five to six weeks. Now, with AI it's down to zero."

Reference:

Chang, YW, Ryu, JK, An, JK, et al. Artificial intelligence for breast cancer screening in mammography (AI-STREAM): preliminary analysis of a prospective multicenter cohort study. *Nat Commun* 16, 2248 (2025)

Dembrower K, Crippa A, Colón E, Eklund M, Strand F; ScreenTrustCAD Trial Consortium. Artificial intelligence for breast cancer detection in screening mammography in Sweden: a prospective, population-based, paired-reader, non-inferiority study. *Lancet Digit Health*. 2023 Oct;5(10):e703–e711. doi: 10.1016/S2589-7500(23)00153-X. Epub 2023 Sep 8. Erratum in: *Lancet Digit Health*. 2023 Oct;5(10):e646. doi: 10.1016/S2589-7500(23)00181-4. PMID: 37690911.

Dembrower K, Crippa A, Eklund M, Strand F; Human-AI Interaction in the ScreenTrustCAD Trial: Recall Proportion and Positive Predictive Value Related to Screening Mammograms Flagged by AI CAD versus a Human Reader. *Radiology*. March 2025.

Indications for use: Lunit INSIGHT MMG is a radiological Computer-Assisted Detection and Diagnosis (CADe/x) software device based on an artificial intelligence algorithm intended to aid in the detection, localization, and characterization of suspicious areas for breast cancer on mammograms from compatible FFDM systems. As an adjunctive tool, the device is intended to be viewed by interpreting physicians after completing their initial read. It is not intended as a replacement for a complete physician's review or their clinical judgement that takes into account other relevant information from the image or patient history. Lunit INSIGHT MMG uses screening mammograms of the female population.

Disclaimer: The product described is CE-marked and complies with the EU Medical Device Regulation (MDR) 2017/745 and applicable EU standards. It is also FDA-cleared, with the exception of certain features. Please contact your local Lunit representative for more details.

Lunit INSIGHT MMG is a Computer-Assisted Detection/Diagnosis (CADe/x) software intended to aid in the detection, localization, and characterization of suspicious breast cancer in mammograms. The device is an adjunctive tool, supporting readings for interpreting physicians and should be used only after the first reading by interpreting physicians.

This document is for use by healthcare professionals only. The radiologist should always rely on his or her own clinical and professional opinion when deciding whether to use a certain product to diagnose or treat a patient. Availability of Lunit products may vary by market, depending on local medical and/or regulatory requirements. Please contact your Lunit representative if you have questions about the availability of the Lunit products in your area.

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Interested in Lunit INSIGHT MMG?

Contact your Lunit representative, or reach out to us: insight@lunit.io

