

A Step Change for **Cancer** Screening?

By enabling physicians to interpret opaque mammograms, MICA aims to save lives and money

Executive Summary

Effective screening for breast cancer - the most common cancer among women worldwide - requires considerable resources, which many healthcare systems don't have. In particular, dense tissue can make it difficult for a physician to identify a lesion in a standard mammogram, leading to expensive and time-consuming subsequent scans.

To address this challenge, four-year old start-up MICA has developed an artificial intelligence (AI) system that can clarify mammogram images that are clouded by dense tissue. As the system learns from more and more data, it is getting better and better at producing clear images that enable physicians to spot lesions and other potentially malignant abnormalities. Now approved for use in more than 40 countries, MICA's AI is already being employed by clinics in Israel and Argentina. The company believes it will win regulatory approval in the US and the EU during 2025.

Over time, MICA hopes to save the world's healthcare systems a lot of money by removing the need for mammograms to be supplemented by further screening. It anticipates charging customers an annual subscription to use the system, which could translate into fees as low as US\$10 to US\$25 per check-up. By lowering overall screening costs, the system could save many lives, particularly in developing countries where individuals and healthcare systems can't afford follow-up scans.

MICA is aiming to have its technology embedded inside mammogram machines from many different equipment makers. To that end, the start-up, which has raised US\$4 million in funding to date, has already signed letters of intent or memorandums of understanding with about 20 partners.



MICA AI Clears 2D Image of Dense Breast Mammo and calculates the Risk of Cancer

As breast cancer is the most common cancer among women all over the world, healthcare systems regularly screen for the disease. In most countries, physicians use mammography - an x-ray imaging method – to try and detect lesions and other suspicious abnormalities, with the goal of being able to treat cancer in the early stages, when the chances of a recovery are highest.

However, of the 250 million screenings that take place every year, 100 million require a further screening, using either contrast-enhanced mammography, an MRI or ultrasound scan, according to World Health Organization (WHO). That's because dense breast tissue can result in a mammogram that is too opaque for a physician to evaluate properly. The additional medical exams cost healthcare services US\$50 billion globally, according to US Preventive Services, as well as soaking up radiologists' valuable time.

In some cases, either the patient or the healthcare system (depending on the local funding model) can't afford further investigations, potentially leading to unnecessary loss of life, and perhaps lawsuits, in cases where a disease is missed.

But advances in artificial intelligence (AI) are now making it possible to interpret mammograms that are undecipherable to the naked eye. Building on initial research by the Sheba Medical Center Israel, (the largest medical centre in the Middle East) and Tel Aviv University, start-up MICA has developed an AI-based system that is able to detect subtle patterns in otherwise opaque mammography scans that indicate the presence of a lesion or another malignant abnormality. Four-year-old MICA says its system has been deployed commercially in Israel and in Argentina, following regulatory approvals.

In a proof of concept (PoC) study, conducted in 2023, MICA's AI detected 93% of the lesions that were identified by a physician using a contrastenhanced mammogram. MICA says that result indicates that its system is already highly effective in the interpretation of cloudy mammography images. The AI should also get even more accurate as it learns from more data.

Learning from diverse datasets

MICA is collecting data from all over the world to ensure its AI is trained on all kinds of machines, and all kinds of technical definitions. "We train the platform from a huge amount of data that contains the clear images and the unclear images, to realise what is behind that layer of dense tissue," explains Lior Wayn, CEO and co-founder of MICA. "We can help the radiologist from the first simple screening to see what they couldn't see with the naked eye and they do not need to use ultrasound or MRI or whatever."

MICA's AI has learnt to detect small variations in the layers of white and layers of the grey and black in an unclear image, from which it can extrapolate to create a clear image. Advances in generative AI are helping to further improve the quality of this kind of extrapolation.

"We have trained the platform with tens of thousands images to complete the image based on previous cases," adds Lior Wayn. "We are using machine learning to train the platform on a daily basis. We learn from our mistakes and improve based on the new data and we learn also from success and the PoCs we did can improve the accuracy of the platform."

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Lior Wayn - CEO and co-founder of MICA

Lior Wayn claims that MICA is unique in being able to clean an image in this way. He attributes its leadership to a combination of data collection and the use of advanced computer vision techniques, derived from technologies used for military and intelligence gathering applications, such as detecting the presence of enemy units through dense cloud cover.

MICA has also developed software that can scan a clear (or clarified) image and assess the risk of cancer. In a PoC conducted between 2021 and 2024, this system achieved sensitivity¹ of 87% and specificity² of 88% across about 5,000 mammograms, according to MICA, which says that translates into a 24% increase in the accuracy rate and 40% fewer unnecessary biopsies.

MICA's systems are designed to support decisions, rather than make them - physicians use both a clarified image and the risk assessment to help them decide whether there is a need for a biopsy, another screening, or a further check-up six months into the future. As the outcomes are fed back into it MICA's machine learning platform, the accuracy of the risk assessments should improve over time.

Meanwhile, MICA is working with equipment makers to deploy APIs (application programing interfaces) to ensure it AI system can interact with all the different

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mammography machines in use around the world. A breast screening generally requires four mammograms, each about 16 MB in size. These images can be transmitted (using a fixed or mobile broadband network) to MICA's AI system, which runs on GPUs (graphics processing units) in the cloud. That makes the system accessible to both large hospitals and small clinics that lack their own IT infrastructure.

To help it tap more data, MICA is also looking to work with companies that are digitising medical records and making them available to patients and clinicians on smartphones and other devices. Collaborating with these kinds of companies will "reduce the time it takes to get data from hospitals and get more variability of data because any patient that will approve the use of anonymised data will help us to be more data and be more accurate," explains Lior Wayn.

MICA's system has already been approved for use in Israel, and under a regulatory system, called CFS, which is accepted in about 40 countries around the globe, including much of Latin America and Eastern Europe. MICA has also made a pre-submission for regulatory approval as a decision support platform from both the FDA in the US and under the EU's CE and MDR systems³. "We will complete the US FDA by the first half of 2025, and the CE at the end of 2025," predicts Lior Wayn.

These regulatory applications are based on a qualified physician making the actual decision on what should be the next steps following a screening for breast cancer. "All AI platforms in the medical area are running for decision support," Lior Wayn adds. "I don't think that the world is ready for decision making." He predicts that AI won't be used to make decisions in healthcare until at least two years after autonomous cars are in widespread use - as a very high profile manifestation of AI, successful self-driving vehicles will help build public confidence in the technology.

¹ the ability to correctly identify patients with a disease

the ability to correctly identify people without the disease

³ In the EU, CE marking demonstrates that products meet the region's requirements for safety, health and environmental protection, meaning it can be freely traded in the European Economic Area without restrictions. Medical devices are also subject to the EU Medical Device Regulation, or MDR.

2D standard mammo MICA M2C Before After MICA M2C MICA M2C A STEP CHANGE FOR CANCER SCREENING?

MICA M2C Clears 2D Image of Dense Breast Mammo



Pursuing partnerships and building an ecosystem

With its first customers in Israel and Argentina, MICA has entered into agreements that they can use its AI in exchange for giving the company access to more data. "Data is the big barrier for most companies doing AI in the medical field," explains Lior Wayn. "Since data is important and expensive, we prefer to get data instead of getting paid from the first customers. We have also started that kind of agreements with customers from Europe, and from the States, which means that we are getting more and more data."

In the longer-term, MICA's business case rests on saving the healthcare industry a lot of money by removing the need for mammograms to be supplemented by further screening using expensive equipment, such as MRI systems. It anticipates charging customers an annual subscription to use its system, which could translate into fees as low as US\$10 to US\$25 per check-up. As well as saving money, the system could save many lives, particularly in developing countries where individuals and healthcare systems can't afford follow-up scans.

To date, MICA has raised about US\$4 million from a venture capitalist and angel investors, as well as a grant from Israeli Innovation Authority. But it may raise more funds to support distribution and partnership agreements it is looking to strike with other players in this space. The company says it is in the process of signing letters of intent or memorandums of understanding with about 20 partners.

For Lior Wayn, the ideal business model would be to have MICA's technology embedded inside mammogram machines from many different suppliers, just as Intel chips run inside PCs from many different computer makers. Ideally, the technology will be automatically applied to each mammogram. MICA is also exploring how to make its system available through specialist app stores that help distribute AI and other software to healthcare providers. These platforms are designed to make it straightforward for clinics to access this advanced technology without having to perform complex systems integration.

Telecoms operators could play a key role in ensuring that medical facilities have reliable access to AI systems, which generally need to run on powerful GPUs in the cloud. Lior Wayn anticipates that some major telcos will follow in the footsteps of the big tech companies and build out specialised cloud-based solutions and systems that will help people use AI running on their smartphones and other connected devices to monitor their health and wellness. With respect to breast cancer, telcos could play a key role in prompting and reminding women to be screened.

The technology that MICA has developed could be applied for other medical applications, beyond breast cancer screening. "We can eliminate the use of contrast materials to any other body organ screening," explains Lior Wayn. "I think that our next step will be to deliver better CT screening⁴, since the use of contrast materials in CT is very high and I think it can be very efficient as well. But we will need three things: data, data, and data."

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⁴ A CT (computed tomography) scan is a medical imaging technique used to obtain detailed internal images of the body

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GSMA Foundry

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MICA Artificial Intelligence Ltd.

MICA is developing an automatic decision support system, based on AI and ML that supports radiologists and oncologists for breast cancer prevention. Headquartered in Tel Aviv and collaborating with The Sheba Medical Center and ARC (one of the 10 bests hospitals in the world)' MICA aims to become the world leader in the mammography- breast cancer detection field, to make every yearly checkup and follow-up less challenging and set the Platform as the standard practice for mammography analysis.

MICA was founded in 2020 by Lior Wayn(serial entrepreneur with 25 years of experience in the worlds of medical startups as an entrepreneur and CEO of private and public companies), Lilia Shwartsman (serial entrepreneur, a background in leading large development teams), Dr. Dov Tamarkin (serial entrepreneur, with extensive experience in leading companies public and private and IPO in NASDAQ), and Dr. Roni Weitzen (senior oncologist at Sheba, director of the Sarcoma Institute).

MICA won 2 grants from the Israeli Innovation Authority for the development of technology and another grant from the Ministry of Economy for the marketing of technology in the USA. MICA was also named the best new startup in the Middle East, as the best startup in Israel, and received credit from Google and Amazon.

https://youtu.be/wR8aQTL-ty4

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