RESPONSE TO THE ABSI–BISI JOINT POSITION STATEMENT OF 24 AUGUST 2026

What's best for the Women of India?

On 24 August 2026 the **Association of Breast Surgeons of India (ABSI)** and the **Breast Imaging Society, India (BISI)** published a joint position statement advising India's health system to avoid **iBreastExam** — a handheld, radiation-free screening device used by trained health workers in community settings. The statement cites no evidence. This page sets out what the device is, what the published evidence says, and where each of its claims stands against the public record. **Every source below is linked, so you can check it yourself.**

Published by **UE LifeSciences**, the developer of iBreastExam Last updated **18 September 2026**

START HERE

The gap this device was built for

India's national policy has named clinical breast examination as its population screening method since 2016. Mammography has never been the national screening modality. In practice, almost no woman receives either.

1.3%

of Indian women aged 45 and above have ever had a mammogram — 1.7% at 45–59, 0.9% at 60 and above

Peer-reviewed prevalence estimate, 2025

<1%

receive clinical breast examination at national level — the method the statement calls the gold standard

Peer-reviewed estimate, 2024

~3,000

mammography units in the whole country, fewer than 10% of them full-field digital

NAMS Task Force, 2025

~20,500

radiologists in all of India across every subspecialty — against roughly 21,000 needed each year to read a national mammography programme

Workforce figures and capacity arithmetic

India's own National Academy of Medical Sciences put it plainly in 2025: there is *"no structured population-based mammography screening program in the country and it is unlikely to be feasible in the foreseeable future due to its resource-intensive nature."* The World Health Organization makes a strong recommendation *against* population mammography screening in limited-resource settings at ages 40–49 and 70–75, and against it at all ages where health systems are weak.

Sources. NAMS Task Force Report on Breast Cancer in India, 2025 · WHO Position Paper on Mammography Screening, 2014 · MoHFW Operational Framework: Management of Common Cancers, 2016

Population-Based Mammographic Screening in India

Our assessment of the clinical performance, health-system feasibility and cost-effectiveness of a national mammography programme — the trial evidence, the capacity arithmetic, the Government of India's own cost-effectiveness ranking, and the strongest counter-arguments. Twenty-nine cited sources. Assessment is attached below.

IN PLAIN LANGUAGE

What iBreastExam is — and what it is not

iBreastExam is a handheld device a trained health worker moves across the breast. Its sensors measure stiffness, because tumours are typically harder than the tissue around them — the same physical principle as the manual breast examination a doctor performs. It is battery-powered, uses no radiation, and takes a few minutes.

WHAT IT IS

- A **screening and triage tool**, used where women already are — health sub-centres, camps, workplaces — rather than where imaging equipment happens to be
- Operable by **nurses and community health workers** after short training, not only by doctors or radiologists. In a 2026 Memorial Sloan Kettering study, technologists with no prior experience of the device — one virtual session and

WHAT IT IS NOT

- × It is **not a mammogram**, and UE LifeSciences has never marketed it as a replacement for one
- × It is **not a diagnosis**. It cannot tell a woman whether she has cancer — only a biopsy can do that
- × It is **not a replacement for the imaging pathway**. In the programmes where it runs, it feeds that pathway rather than standing in for it

ten supervised exams — performed comparably to nurse practitioners with 15 and 25 years of clinical experience doing the manual examination

- **Radiation-free and painless**, with a recorded, standardised output rather than a subjective manual judgement
- A step that ends in a **referral**: women with findings go into the existing pathway for mammography, ultrasound, biopsy and specialist care
- A device with **US FDA 510(k) clearance K190575 (2019), CE Mark, India's CDSCO approval, regulatory approvals in an additional 12 countries**, and manufactured under ISO 13485

- × It is **not thermography**, the modality the statement groups it with. See claim 3

CLAIM BY CLAIM

Six statements, and where each stands against the record

The ABSI–BISI joint position statement of 24 August 2026 makes six distinct assertions bearing on this device. It is an image-only PDF. It carries no references, no methodology, no declaration of interests, and no DOI; it was not peer-reviewed, and the manufacturer was never contacted before publication. It also does not state the product's name correctly — it refers throughout to “iBreast”. Each assertion is set out below in its own words, with the public record beside it.

CLAIM 1 ON PATIENT HARM

“Risk of false reassurance, delayed diagnosis and adverse treatment outcomes.”

No report, no safety signal and no published case is cited in support of this.

This is an assertion of fact about a regulator-cleared device in active clinical use — that it has caused, or will cause, harm to women. The statement cites nothing for it: no adverse event report, no signal under the Materiovigilance Programme of India,

no complaint, and no documented case. No such material was published with the statement, and none appears in the public record.

No modality or technology can claim to be 100% accurate for breast cancer detection. Mammography has significant limitations in identifying lesions in heterogeneously dense breasts, a condition highly prevalent among Indian women. Mammograms do not detect all breast cancers: invasive breast cancer is present but undetected by mammography in 6% to 46% of examinations. Conversely, mammography can detect clinically insignificant, slow-growing cancers or ductal carcinoma in situ (DCIS) that would never have caused symptoms or threatened the patient's life. Because doctors cannot reliably distinguish between harmful and harmless early-stage tumours, the current standard is to treat all of them. This exposes patients to the adverse side effects, complications and psychological burdens of unnecessary surgery, radiation or chemotherapy.

The specific harm alleged — false reassurance, meaning a missed cancer — is a question of **sensitivity**. On sensitivity, measured directly against clinical breast examination in the same women, the published head-to-head studies run the other way. Those comparisons are set out under claim 2.

On mammography's limits. Sensitivity falls from 85.7% in fatty breasts to 61.0% in extremely dense breasts, with interval cancers rising six-fold — Wanders et al., *Breast Cancer Research and Treatment* 2017;162:95–103. Overdiagnosis is estimated at 11–22% within trials — Nelson et al., AHRQ Evidence Synthesis No. 124, 2016 — and the UK Independent Panel's figures imply roughly three overdiagnosed cancers for every death prevented — Marmot et al., *The Lancet* 2012;380:1778–1786. All three are set out in the attached assessment, references 10, 14 and 6.

CLAIM 2 ON PERFORMANCE AGAINST CBE

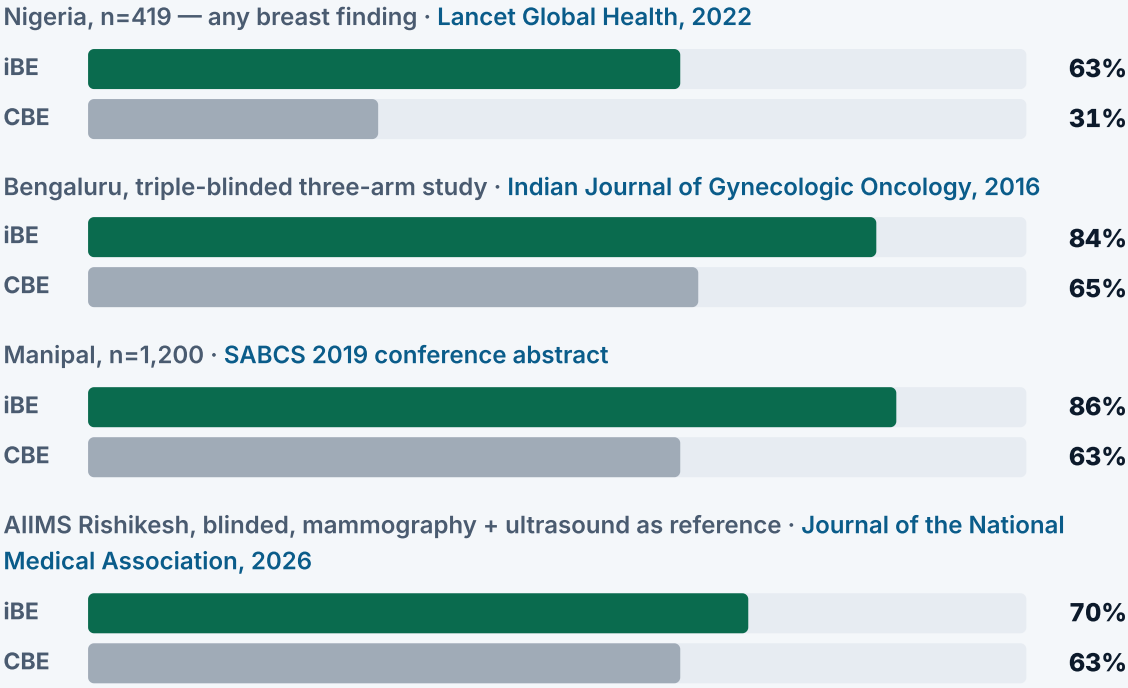
"Do not demonstrate equivalent value to CBE or mammography."

In four prospective studies comparing the two in the same women, the device detected more findings than unaided clinical breast examination — and in the newest, it was the more specific test as well.

Clinical breast examination is the method the statement names as the gold standard for population screening in India. Where the two have been compared directly — same women, same study — these are the published sensitivity figures.

Sensitivity: iBreastExam versus clinical breast examination

Four prospective head-to-head studies. Higher is better — it means fewer findings missed.



The 2022 Nigeria comparison was funded by the US National Cancer Institute (P30 CA008748) and the Prevent Cancer Foundation and conducted with Memorial Sloan Kettering Cancer Center; its comparator was surgeon-performed examination, not community-level examination. Difference $p<0.0001$; negative predictive value 98%. The 2019 Manipal figures come from a conference abstract, which is not peer-reviewed in the way a full paper is. The 2026 AIIMS Rishikesh study was conducted to STARD standards with every examiner blinded to the others' results and all tests completed the same day.

On specificity — the criticism most often made of the device — the two studies published in 2026 answer it directly. The 2022 Nigeria study, which the page cites above for sensitivity, also reported lower specificity for the device than for surgeon-performed examination. The device has since been modified; the Memorial Sloan Kettering team that ran the Nigeria study notes in its 2026 paper that “the iBE device has undergone modifications to improve specificity.” Both 2026 studies measured it against imaging.

AIIMS RISHIKESH · BLINDED, STARD-COMPLIANT · 3D MAMMOGRAPHY AND ULTRASOUND AS THE REFERENCE STANDARD

Sensitivity **70.37%** vs CBE 62.96% Specificity **74.67%** vs CBE 60.81%

Overall accuracy **73.53%** vs CBE 61.39%

Every examiner was blinded to the others' results and all tests were completed the same day. **iBreastExam was the more accurate test on all three measures**, and the authors report that “ROC analysis confirmed iBE outperformed CBE in diagnostic accuracy.” Used together with CBE in parallel, sensitivity rose to

88.9%. The nurses and technicians who ran it described it as time-efficient, acceptable and comfortable for patients; one noted that “hands-on ten cases were sufficient to learn iBE… while CBE is very subjective.”

Khapre M, Anjali M, Huda F, Syed A. *Diagnostic accuracy of iBreastExam and clinical breast examination using mammography and ultrasonography as standards: a single-centre study in North India.* Journal of the National Medical Association 2026. doi:10.1016/j.jnma.2026.09.006. Tertiary breast clinic, January 2024 – January 2025; 106 participants. Figures are per participant. The authors state their endpoint was imaging-based suspicious findings rather than histopathology, and call for large-scale community validation with complete diagnostic follow-up. UE LifeSciences provided the device; the study was designed, conducted and reported by AIIMS Rishikesh.

MEMORIAL SLOAN KETTERING, HARLEM · 300 ASYMPTOMATIC WOMEN · EVERY WOMAN RECEIVED CBE, IBREASTEXAM AND MAMMOGRAPHY ON THE SAME DAY

Specificity **1.000** (95% CI 0.987–1.000) PPV **1.000** vs CBE 0.500 NPV **0.973**

The comparison here is not only of the two tests but of who performs them. The clinical breast examinations were done by nurse practitioners with **25 and 15 years** of clinical experience. The iBreastExam scans were done by radiology technologists with **no prior experience of the device**, after one virtual training session and ten supervised exams. On this cohort the two performed similarly, with no statistically significant difference in negative or positive predictive value. The authors conclude that training to perform iBreastExam is “minimal… much less than required to establish CBE proficiency,” that its output “does not require expertise for interpretation, limiting human subjectivity, and provides real-time results,” and that this “supports the potential for this device to be used in low resource settings by individuals with minimal training.”

Mango VL, Sales M, Ortiz C, Moreta J, Jimenez J, Sevilimedu V, Kingham TP, Keating D. *Detection of breast lesions utilizing iBreast Exam: a pilot study comparison with clinical breast exam.* Cancers 2026;18(2):281. doi:10.3390/cancers18020281. Open access. In this cohort mammography detected all three cancers and the authors state it remains the standard of care; iBreastExam and CBE each detected one of the three, both missing lesions under 2 cm. The study is a pilot, sized by funding rather than by power calculation, and the authors call for further investigation.

There is also a question of what “equivalent value” means for a method that is not delivered. Clinical breast examination has been India's stated national screening modality since 2016, and fewer than 1% of Indian women receive it. A test with good properties that almost no one gets produces almost no detection.

One piece of history worth knowing. The 2016 Bengaluru study was judged the best research paper at ABSICON 2016 — the Association of Breast Surgeons of India's own annual congress — selected from 120 submissions by a 12-member jury of Indian breast specialists, on stated criteria of research rigour and scientific merit. We cite this as ABSI's own institutional assessment of the evidence, not as a personal endorsement by any individual; the paper's first author was at that time an office-bearer of the Association.

CLAIM 3 ON GROUPING WITH THERMOGRAPHY

"Accordingly, neither thermography nor iBreast should be used for population-based breast cancer screening in India..."

Thermography and iBreastExam are in different regulatory positions, and work on entirely different principles.

The statement places the two under a single prohibition, in a single graphic, with a single shared conclusion. In February 2019 the US FDA issued a warning letter and a public safety communication about thermography for breast cancer detection. iBreastExam holds two FDA clearances. The two are not interchangeable, and readers of the statement were given no basis on which they were assessed as one class.

	BREAST THERMOGRAPHY	IBREASTEXAM
How it works	Infrared mapping of skin surface temperature; infers blood-vessel activity indirectly.	Capacitive tactile sensors measure tissue stiffness directly — the same physical principle as the clinical brea examination the statement recommends.
US FDA position	Warning letter and public safety communication, 25 February 2019: "no valid scientific data to show that thermographic devices are an effective screening tool for any medical condition."	Two 510(k) clearances — K142926 (April 2015) and K190575 (16 July 201 under 21 CFR 884.2990.
Manufacturing and distribution in India	—	Manufactured under ISO 13485. Distributed in India by HLL Lifecare Limited, a Government of India publi sector undertaking, and by Molbio Diagnostics.

	BREAST THERMOGRAPHY	IBREASTEXAM
Use in an Indian public programme	—	In use in the Government of Goa's st screening programme since Octobe 2021 — see the Goa record.

CLAIM 4 ON USE IN INDIA

"...should not be used for population-based breast cancer screening in India."

It has been in use in various Indian State Government programmes for nearly a decade.

This is not a proposed or theoretical use. The Government of Goa launched *Swasth Mahila, Swasth Goa* on **26 October 2021**, putting iBreastExam devices into health centres across both districts, operated by nurses and community health workers, with women who screened positive referred on to Goa Medical College and district hospitals. The programme's figures are set out under the Goa record below.

India's Department of Health Research has also modelled the device directly. Its Health Technology Assessment of Strategies for Breast Cancer Screening in India (Policy Brief No. 64, 7 March 2024) compared five screening strategies at three intervals. **iBreastExam produced the highest modelled number of breast-cancer deaths averted at every interval studied** — 59.57 at three years, 44.03 at five, 21.47 at ten — and the lowest modelled number of incident cases at the three-year interval. The same assessment recommends clinical breast examination on cost-effectiveness grounds; it is a public document and readers should consult it directly.

Read the primary documents. National Health Mission Goa programme note · HTAIn Policy Brief No. 64 (PDF)

GOVERNMENT MEDICAL COLLEGE, NAGPUR · 19,583 WOMEN SCREENED, JUNE 2016 – NOVEMBER 2018

Sensitivity **87.98%** Specificity **93.79%** PPV **84.39%** NPV **95.34%**

Diagnostic accuracy **92.18%**

> "The present study concludes that iBreastExam ... shows significantly better sensitivity and higher specificity and was found to be a promising effective tool for younger women with dense breast.
>
> In the developing country like India, where 70% of the population lives in rural and underserved areas, women have no access for breast cancer screening. The iBE is a potential powerful screening tool for use in the third world countries with limited resources, where mammography and clinical breast exam by a trained physician is not readily available.
>
> Performed by trained lay workers and with high specificity of the device, iBE is highly cost-effective in terms of maintenance of the device, transport of females to tertiary center, reducing patient load for surgeons & radiologists, and workload for machines — ultrasound and mammography. Further, more studies and clinical trial needs to be conducted in different regions to establish the iBreast Exam as a standard screening modality."

Jahagirdar D, Gajbhiye R, Ramteke S, Tirpude B, Upganlawar P, Mangam N. *Study of accuracy of iBreast Exam as a screening modality to detect breast lump — experience of a tertiary care centre in Central India.* International Journal of Current Innovation Research 2019;5(2A):1462–1466. Department of General Surgery, Government Medical College, Nagpur. Prospective observational study; 19,583 women screened, a systematic random sample of 934 evaluated against the Triple Test as gold standard. Open access; conflict of interest: none declared.

CLAIM 5 ON REPLACING EXISTING PATHWAYS

"...or as a replacement for CBE or established breast-imaging pathways."

"iBreastExam has never been marketed by UE LifeSciences as a replacement for mammography or for established imaging pathways."

It was built for the women those pathways do not reach, and its function is to move the ones who need imaging *into* them.

The Goa programme is the working example. A trained health worker screens in a community setting. Women with findings are referred to Goa Medical College, district and sub-district hospitals for mammography, ultrasound, biopsy and specialist management. The diagnostic pathway is unchanged; what changes is how many women reach it. By identifying women who need investigation among a population that was previously never examined at all, the device increases demand for diagnostic imaging rather than displacing it.

CLAIM 6 ON THE STANDARD FOR NEW TECHNOLOGY

"Any emerging technology proposed for population-level screening should undergo rigorous, independent evaluation in representative Indian populations, with demonstrated diagnostic performance, safety, feasibility, cost-effectiveness and meaningful clinical benefit before incorporation into a national programme."

"We agree with this, without any reservation."

This is the right standard, and we accept it without reservation. To date, iBreastExam has gone through independent clinical evaluations and publications worldwide in over 25,000 women. UE LifeSciences will continue to work with Public Health professionals and Cancer Researchers, who will take iBreastExam through structured independent evaluations and will publish the results in peer reviewed publications.

The same standard is worth applying to the statement that invokes it. It cites no references; it says references are "enclosed", and none were published with it. It discloses no methodology — no search strategy, no inclusion criteria, no stated threshold for "insufficient evidence". It was not peer-reviewed and carries no DOI. It declares no interests, though one of the two co-signing societies is India's professional body for breast imaging. It did not contact the manufacturer. And it does not name the product correctly.

What has already been independently assessed. The device has been through US FDA review twice (2015, 2019); published in The Lancet Global Health from a US National Cancer Institute–funded study run with Memorial Sloan Kettering Cancer Center; modelled by India's own Health Technology Assessment body; and deployed at scale in a state government programme. The full literature, including studies less favourable to the device, is listed under sources.

THE REAL-WORLD RECORD

Goa: what happened when a state actually ran the programme

Goa is the largest published account of iBreastExam used the way it is meant to be used — in government health services, by frontline staff, with referral into the existing diagnostic system. These are the state's own figures.

2021

Programme launched 26 October, through the state Directorate of Health Services, with 20 devices across 35 health centres

National Health Mission Goa

169,348

women screened, as reported by the state Health Minister in July 2025 — against an original target of 100,000

Reported July 2025

3,429

women identified as suspected cases and referred into the diagnostic pathway for further investigation

Reported July 2025

74

breast cancers confirmed and taken into treatment, in a population where most of these women had never been screened before

Reported July 2025

Step 1 · In the community

A trained nurse or health worker performs the screening examination where the woman already is — no radiation, no referral needed to attend, no radiologist required.

Step 2 · Triage

Findings are identified on the spot. Women with suspected findings enter the referral pathway; the rest continue in routine follow-up.

Step 3 · Established imaging

Referral to Goa Medical College, district and sub-district hospitals for mammography, ultrasound, biopsy and specialist management — the existing pathway, unchanged.

The programme was run with the Government of Goa's Directorate of Health Services alongside the YouWeCan Foundation and SBI Foundation. Screening is free to the woman, as is treatment for those who are diagnosed.

IF YOU ARE READING THIS AS A PATIENT

What this means for you

A statement about screening technology should not leave a woman unsure what to do about her own health. Whatever view anyone takes of the rest of this page, the practical position below is not in question.

THE PRACTICAL POSITION

1. **A new lump or change needs a doctor, not a screening test.** If you have noticed a lump, a change in shape, skin dimpling, or discharge from the nipple, see a clinician now. Screening tests are for women without symptoms. Do not wait for a camp or a programme.

2. **A screening result is not a diagnosis.** If an iBreastExam screening — or a clinical breast examination, or a screening mammogram — flags something, it means you need further investigation, usually a diagnostic ultrasound or mammography and sometimes a biopsy. Most women who are referred do not turn out to have cancer.
3. **A clear screening result is not a guarantee.** No screening test finds every cancer — this is true of mammography too. If something changes in your breast after a normal result, get it looked at anyway. Do not let a past clear result delay you.
4. **If a mammogram is available and affordable to you, that pathway is well established.** iBreastExam was designed for the majority of Indian women for whom it is not. The two are not in competition for the same woman.
5. **If you are offered screening in a government programme, taking it is reasonable.** Being examined is better than not being examined. Make sure you understand what to do if you are referred, and follow the referral up.

CHECK IT YOURSELF

Sources

Everything asserted on this page is linked below, including the studies that are less favourable to the device. Where a document is behind a paywall, the DOI link is given so it can be requested or read through an institution.

POLICY AND HEALTH TECHNOLOGY ASSESSMENT

WHO Position Paper on Mammography Screening (2014)
World Health Organization. Strong recommendation against population mammography screening in limited-resource settings at ages 40–49 and 70–75.

Operational Framework: Management of Common Cancers (2016)
Ministry of Health and Family Welfare, Government of India. Specifies clinical breast examination, women 30–65, five-yearly.

HTAIn Policy Brief No. 64 (7 March 2024)
Health Technology Assessment in India, Department of Health Research. Models five screening strategies including iBreastExam; recommends clinical breast examination on cost-effectiveness grounds.

STUDIES COMPARING IBREASTEXAM AND CBE

The iBreastExam versus clinical breast examination in high risk and symptomatic Nigerian women (2022)
Mango VL, Olasehinde O, Omisore AD, et al. Lancet Glob Health 2022;10(4):e555–e563. NCI-funded, with Memorial Sloan Kettering Cancer Center.

Noninvasive and low-cost technique for early detection of clinically relevant breast lesions (2016)
Somashekhar SP, Vijay R, Ananthasivan R, Prasanna G. Indian J Gynecol Oncol 2016;14:26. Prospective three-arm triple-blinded study.

NAMS Task Force Report on Breast Cancer in India (2025)
Gupta S, Batra A, Prinja S, et al. Ann Natl Acad Med Sci (India) 2025;61(2):132–170.

Clinical efficacy evaluation of a novel palpation imaging device (2019)
Nair S, Kathrikolly T, Saxena PUP. SABCS 2019; Cancer Res 2020;80(4 Suppl):P1-01-01. Conference abstract.

Study of accuracy of iBreast Exam as a screening modality to detect breast lump — experience of a tertiary care centre in Central India (2019)
Jahagirdar D, Gajbhiye R, Ramteke S, et al. Int J Curr Innov Res 2019;5(2A):1462–1466. Government Medical College, Nagpur. 19,583 women screened; sample of 934 against the Triple Test. Sensitivity 87.98%, specificity 93.79%, accuracy 92.18%.

Comparison of iBreastExam with clinical breast examination in community outreach clinics in Pune (2026)
Joshi SN, Dharpawar TS, Kulkarni SR, et al. Int J Cancer 2026;158(5):1204–1214. The largest Indian study, n=9,994; calls for refinement of sensitivity before programme deployment.

Diagnostic accuracy of iBreastExam and clinical breast examination using mammography and ultrasonography as standards (2026)
Khapre M, Anjali M, Huda F, Syed A. J Natl Med Assoc 2026. AIIMS Rishikesh, 106 participants, blinded and STARD-compliant. iBreastExam higher than CBE on sensitivity (70.37% vs 62.96%), specificity (74.67% vs 60.81%) and accuracy (73.53% vs 61.39%). Endpoint is imaging-based, not histopathology; device provided by UE LifeSciences.

Detection of breast lesions utilizing iBreast Exam: a pilot study comparison with clinical breast exam (2026)
Mango VL, Sales M, Ortiz C, et al. Cancers 2026;18(2):281. 300 asymptomatic women, Memorial Sloan Kettering Harlem. iBreastExam specificity 1.000 and PPV 1.000; performed similarly to CBE. Mammography detected all three cancers and remains the standard of care. Open access.

Low clinical efficacy, but good acceptability of a point-of-care electronic palpation device (2022)
Valdez D, Cruz T, Rania S, et al. Med Phys 2022;49(4):2663–2671. Independent evaluation, University of Hawai'i.

Can the clinical utility of iBreastExam aid in optimizing breast cancer diagnosis? A systematic review (2023)
Bhimani F, Zhang J, Shah L, et al. JCO Glob Oncol 2023;9:e2300149. Eleven studies, 16,052 breasts.

REGULATORY

US FDA 510(k) K142926
iBreastExam, UE LifeSciences Inc. Decision 23 April 2015, substantially equivalent. 21 CFR 884.2990.

US FDA 510(k) K190575
iBreastExam, UE LifeSciences Inc. Decision 16 July 2019, substantially equivalent.

FDA warning on breast thermography (25 February 2019)
US Food and Drug Administration press announcement and consumer warning.

THE GOA PROGRAMME

Swasth Mahila, Swasth Goa — programme note
National Health Mission, Government of Goa. Launch 26 October 2021; device description; early programme figures.

Over 1.6 lakh women screened under breast cancer programme (July 2025)
Figures attributed to the Goa Health Minister: 169,348 screened, 3,429 suspected, 74 confirmed cancers.

Goa govt launches initiative for free breast cancer screening (October 2021)
Launch reporting: 20 devices across 35 health centres, target 100,000 women over two years.

EDITORIAL COMMENT

Breast cancer screening: one size does not fit all (2023)
The Lancet Oncology 2023;24(12):1287. An unsigned editorial, not a study or a guideline. It observes that until the required infrastructure and quality control measures are established, breast cancer screening in low- and middle-income countries might require focusing on affordable, easy-to-use alternative solutions, and names iBreastExam as such an example.

ATTACHED

Population-Based Mammographic Screening in India

An assessment of clinical performance, health-system feasibility and cost-effectiveness

Extract · September 2026 · Sections 1–4, the conclusion and the source list of a longer assessment. The complete document is available on request from info@uelifesciences.com.

Scope. This assessment addresses a single question: should India adopt organized, publicly funded, invitation-based mammographic screening of asymptomatic women at population scale? It does not address diagnostic mammography in symptomatic women, which is essential and should be expanded, nor opportunistic mammography chosen by informed individuals in well-resourced urban settings — which is what India's own radiological professional body recommends [1].

Summary judgment. The evidence does not support population-based mammographic screening in India. The conclusion is not that mammography does not work: in high-income systems with complete diagnostic and treatment infrastructure it produces a modest mortality benefit. It is that (a) the benefit is smallest in precisely the age band where most Indian breast cancer occurs; (b) the delivery requirements exceed India's imaging and radiology capacity by more than an order of magnitude; (c) India's own health technology assessment ranks it materially less cost-effective than the modality already in national policy; and (d) the harms of screening scale with the number of women screened, which at Indian population scale is very large. This conclusion aligns with the WHO position paper [2], the Government of India's Operational Framework [3], the Government's own health technology assessment [4], and the 2025 NAMS Task Force Report [5].

1. CLINICAL PERFORMANCE

The evidence base is external and contested. No randomised trial of mammographic screening has been conducted in any low- or middle-income country. The entire mortality evidence derives from trials run in Europe and North America between 1963 and 1997, and their pooled effect is disputed. The UK Independent Panel found a 20% relative reduction in breast-cancer mortality (RR 0.80, 95% CI 0.73–0.89) [6]. The Cochrane review, restricting analysis to the three trials with adequate individual randomisation, found RR 0.90 (95% CI 0.79–1.02) — not statistically significant — and no reduction in all-cause mortality (RR 0.99, 95% CI 0.95–1.03) [7].

The age profile of Indian disease sits where mammography performs worst. Median age at diagnosis in India is 47 years [5]; in published Mumbai data, 52% of cases fall between 40 and 49 [8]. Western screening evidence is strongest at ages 50–69. The one randomised trial designed to test screening from age 40 — the UK Age trial, 160,921 women, 22.8 years of follow-up — was null overall (RR 0.88, 95% CI 0.74–1.03), with benefit confined to the first decade and roughly 1,667 women invited per death prevented [9].

Sensitivity falls as breast density rises, and density rises as age falls. Across 111,898 screening examinations, sensitivity fell from 85.7% in fatty breasts to 61.0% in extremely dense breasts, while interval cancers rose six-fold, from 0.7 to 4.4 per 1,000 [10]; in DMIST,

digital mammography sensitivity in dense breasts was 70% [11]. Most directly: among women aged 40–49, 52.1% of cancers arising within 24 months of a mammogram had not been detected by that mammogram, against 24.7% in women aged 50 and over [12].

Harms scale with the denominator. Over ten years of screening, the cumulative probability of at least one false-positive mammogram is 61% with annual and 42% with biennial screening; 7–9% and 5–6% of women respectively receive a false-positive biopsy recommendation [13]. Overdiagnosis is estimated at 11–22% within trials [14], and the UK Panel's figures imply roughly three overdiagnosed cancers for every death prevented [6]. Radiation harm is real, modest and quantifiable: modelling estimates 125 radiation-induced cancers and 16 deaths per 100,000 women screened annually from 40 to 74 [15]. At a denominator approaching 200 million women, these percentages become programme-defining absolute numbers.

2. HEALTH-SYSTEM FEASIBILITY

Biennial screening of Indian women aged 40–69 — approximately 205–215 million [16] — implies on the order of 105 million mammograms per year.

REQUIREMENT TO SCREEN WOMEN 40–69 BIENNIALLY	NEEDED	INDIA HAS
Mammography units (at ~6,000 exams/unit/year)	**~17,500**	~3,000; <10% full-field digital [5]
Radiologist FTE at the European minimum reading volume of 5,000/year, single reading	**~21,000**	~20,500 radiologists in total, all subspecialties combined [17]
Same, with the double reading European guidance recommends — especially where readers are low-volume [18]	**~42,000**	~2× the entire national radiology workforce

India has roughly 2 mammography units per million population against approximately 81 in the United States [5,19], and roughly 14 radiologists per million against about 146 [17,20]. Meeting even the single-reading requirement would consume the entire national radiology workforce reading nothing else — and would still leave the quality-assurance apparatus unbuilt: annual medical physicist survey, annual medical outcomes audit, facility accreditation and reader-volume floors. India has no statutory equivalent of the US Mammography Quality Standards Act or the European EUREF guidelines [21,22]. Downstream, a recall rate of 8.5%, as observed in an Indian community mammography cohort [23], would generate some 9 million diagnostic work-ups annually, against 954

radiotherapy machines nationally [5] and constrained pathology capacity. The practical test is instructive: the far simpler CBE-based programme already in national policy had reached 0.9% of women aged 30–49 as of NFHS-5 [24].

3. COST-EFFECTIVENESS

The Government of India's own health technology assessment, comparing five modalities in women over 30, found mammography at ₹131,686 per QALY against ₹90,889 for clinical breast examination at five-year intervals — roughly 45% more per QALY — and recommended CBE [4]. The reference modelling study for India reached the same ranking, estimating biennial mammography at approximately Int$3,468 per life-year gained and finding annual CBE nearly as effective at about half the total programme cost [25]. For context, government health expenditure is ₹2,786 per capita per year, or 1.43% of GDP [26]; a single screening mammogram in the Indian private sector lists at ₹2,200–12,700 [27].

4. THE STRONGEST COUNTER-ARGUMENTS, AND WHY THEY DO NOT CHANGE THE CONCLUSION

USPSTF 2024 (Grade B, biennial, ages 40–74) [28]. The extension to age 40 rests on CISNET modelling rather than new trial data, and its own figures give, per 1,000 women, 8.2 deaths averted against 1,376 false positives and 14 overdiagnoses — in a system with complete downstream capacity. It is a recommendation for the United States and presupposes precisely the infrastructure that is the binding constraint in India.

AI-assisted reading. The MASAI trial is the strongest evidence available: in more than 100,000 women, AI support raised sensitivity from 73.8% to 80.5% and cut screen-reading workload by 44% [29]. But it reduced radiologist workload inside an existing double-reading programme rather than replacing radiologists; its interval-cancer reduction was not statistically significant (ratio 0.88, 95% CI 0.65–1.18); and no mammography AI has been prospectively validated on an Indian screening population. Reading is not India's binding cost — units, technologists, quality assurance, biopsy and pathology are.

The Breast Imaging Society, India recommends mammography from age 40 [1]. It does — for opportunistic screening of interested women, and it states plainly that “there are no large credible Indian data to formulate these guidelines.” On the population-programme question this assessment is not in conflict with BISI.

CONCLUSION

Population-based mammographic screening is not clinically indicated, operationally deliverable, or financially justifiable in India at present. The higher-value priorities are closing the diagnosis-and-treatment gap for women who already have symptoms, delivering the CBE-

based pathway that national policy already specifies at genuine population coverage, and expanding diagnostic mammography and ultrasound capacity at district level to serve the women those pathways refer.

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