



# Early Detection. For All.



an innovation from  
UE LifeSciences

Over 650,000 Women Examined Worldwide

Health Equity Innovation Backed by Multiple Publications

Globally Recognized Award-Winning Technology



Global Women's HealthTech Award



2021 Thought Leader



# Global Commercialization, Partnerships & Recognitions

As we develop and scale high-impact innovations, UE LifeSciences has secured major milestones, commercial partnerships, global recognitions and press features

**650,000+**

Women Screened

**800+**

Breast Cx Detected

**500+**

Installations Worldwide

**15+**

Grants & Awards

**10+**

Regulatory Approvals

**2 Million**

Scans Supplied

## Multiple Independent Studies. 25,000 Women Enrolled.

**THE LANCET**  
Global Health

The study shows that with minimal training, inexperienced health-care providers can use the iBreastExam successfully and achieve higher sensitivity than with clinical breast examination

**JCO** Global Oncology  
An American Society of Clinical Oncology Journal

Study demonstrated excellent negative predictive value of iBE

**THE AMERICAN SOCIETY OF**  
Breast Surgeons

iBreastExam helped identify 3 cancers, all were non-palpable lesions



## Regulatory Approvals & Registrations



USA



LatAm, N Africa



HLL Lifecare Limited  
Innovating for Healthy Generations

India



Southeast Asia

### Grants & Awards



**pennsylvania**  
DEPARTMENT OF HEALTH



**ANJANI**  
**MASHELKAR**  
FOUNDATION



**Bayer Cares**  
Foundation



### Recognitions



**International**  
**Finance Corporation**  
WORLD BANK GROUP



**ACOG**  
The American College of  
Obstetricians and Gynecologists



**World Health**  
**Organization**

### The New York Times



**Forbes**

**VOGUE**



# Awards & Recognitions

## 2022 Global Women's HealthTech Award



Innovative Health Technology Recognition  
Compendium of Innovative Technologies for Low-Resource Settings



Thought Leader Recognition  
2021 Annual Meeting

The New York Times

# A New Way to Detect Breast Cancer

**TED**

A new technique to save women's lives from breast cancer





**Ultra Portable Hand-held Breast Exam.** Radiation-Free. Operable by Primary Care Providers with Minimal Training. Wireless. Battery Powered. Cloud Connected. PoC with **Instant Results.**

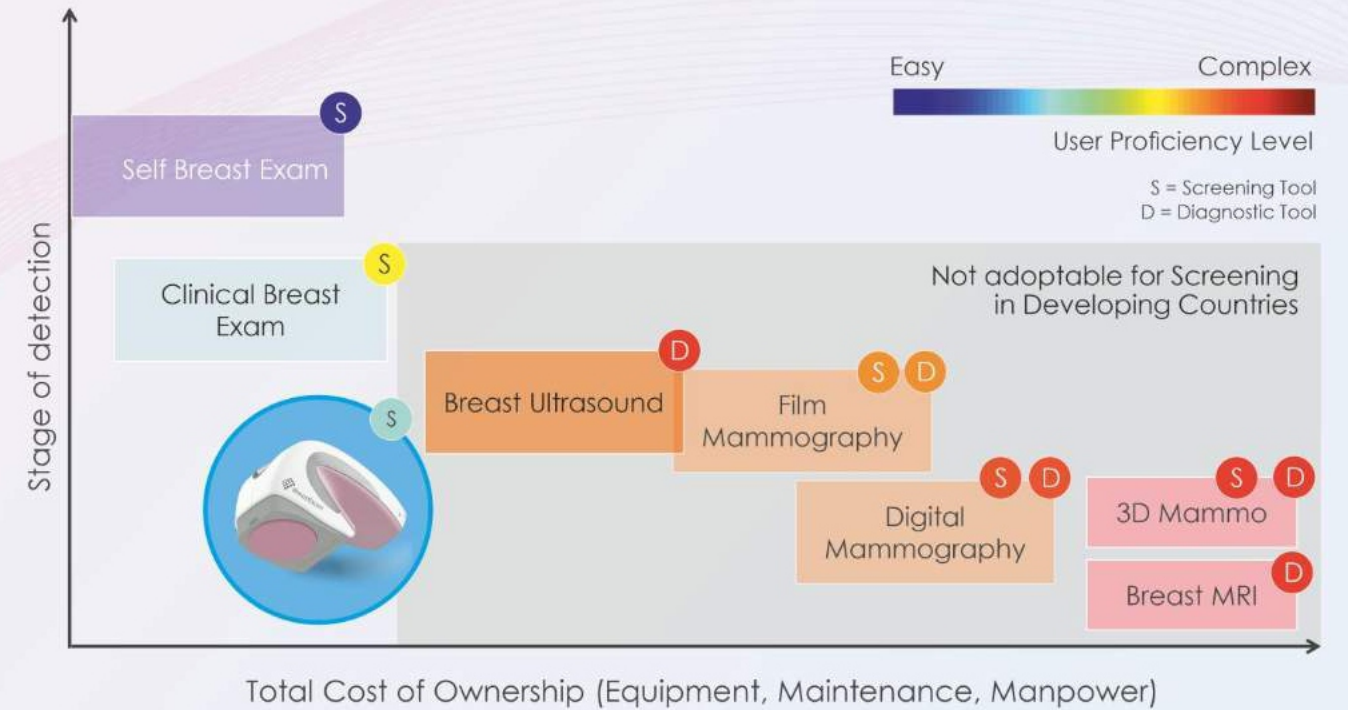


25,000+ Women enrolled across 8 independent, international investigator-initiated publications

**Sensitivity 86%\***  
**Specificity 91%\***  
**NPV 98%\***

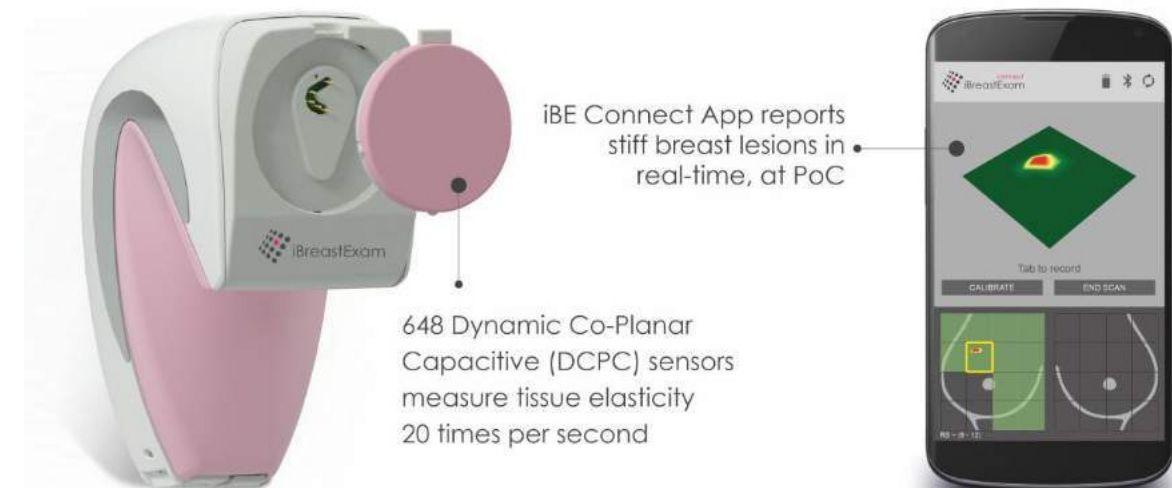
\*Data Presented at 2019 San Antonio Breast Cancer Symposium

Affordable, earlier stage detection with minimal training



## Clinical Validation

| Clinical Study Title, Publication   | Sensitivity | Specificity | NPV | Benchmarked By |
|---|-------------|-------------|-----|----------------|
| Study of Accuracy of iBreastExam as a Screening Modality to Detect Breast Lumps, <b>IJCIR</b>   | 88%         | 94%         | 95% | MMG,CBE        |
| Non-invasive and low-cost technique for early detection of clinically relevant breast lesions, <b>Ann.Oncol.</b>                                  | 84%         | 94%         | 98% | MMG,USG        |
| Clinical efficacy evaluation of a novel palpation imaging device for early detection of breast cancer in the developing world, <b>SABCS</b>       | 86%         | 91%         | 98% | MMG,USG        |
| A cost-effective handheld breast scanner for use in low-resource environments, <b>WJSO</b>  | 86%         | 89%         | 96% | MMG,USG        |
| Breast Tumor Detection using Piezoelectric Fingers: First Clinical Report, <b>J Am Coll</b>   | 83%         | 88%         | 75% | MMG            |
| Diagnostic accuracy of a novel palpation device to improve early detection of breast cancer in low resource settings, <b>SABCS</b>                | 74%         | 88%         | N/A | MMG,USG        |
| Clinical Utility of a Hand-Held Scanner for Breast Cancer Early Detection and Patient Triage, <b>JCO (ASCO)</b>                                   | N/A         | 80%         | 94% | MMG,CBE        |
| The iBreastExam versus clinical breast examination for breast evaluation in high risk and symptomatic Nigerian women, <b>Lancet Global Health</b> | 86%         | 50%         | 98% | MMG,USG,CBE    |





**2 Million+ scans**  
supplied in 12 countries

**iBreastExam  
Global Dashboard™**

Secure, versatile and feature-rich  
cloud-based repository of every scan



The  
New York  
Times

BBC  
WORLD  
NEWS

**TED**

Forbes  
ASIA

Lyfebulb-Helsinn  
Oncology Innovation  
Award 2019

Best Pitch Innov8  
Talks Arab Health  
Award 2019

Bayer Foundation  
Grants 4 Impact  
Award 2018

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✉ info@uelifesciences.com | 🌐 iBreastExam.com | 📘 facebook.com/ibreastexam

# Comprehensive Solution for Breast Cancer Screening



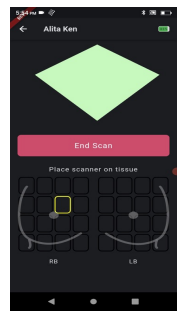
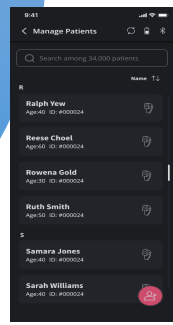
IEC & Mobilization

Innovative, Validated & US FDA cleared Technology



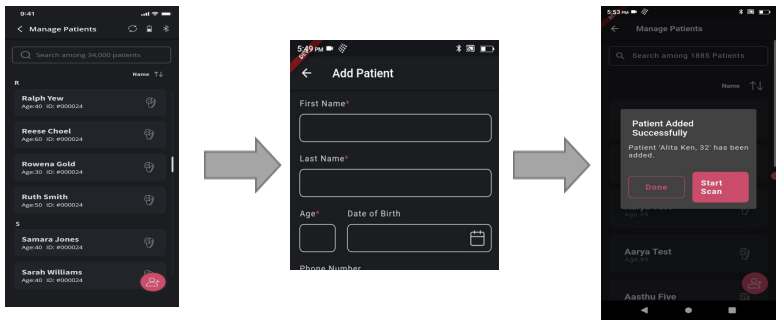
Training, Implementation & Handholding

Mobile App & Data Analytics Platform

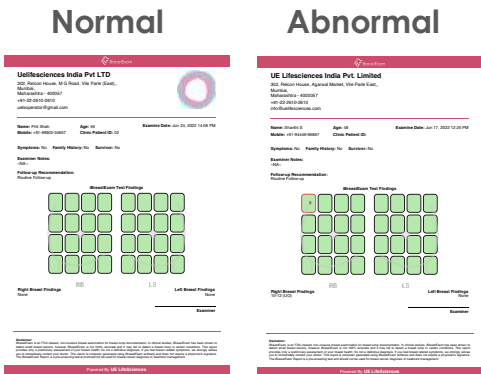


# Mobile App & Cloud Platform with Secured Data Analytics

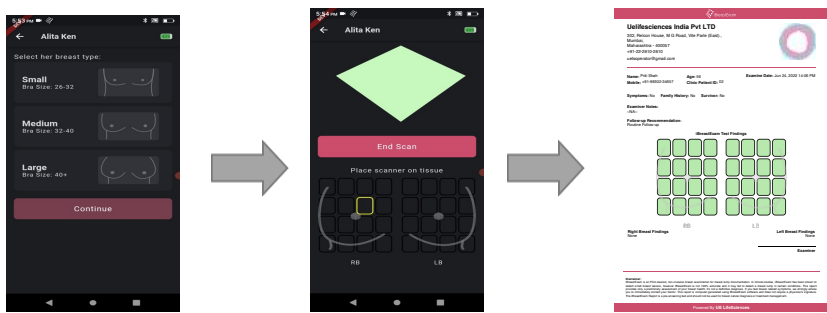
## 1 Patient Data Collection



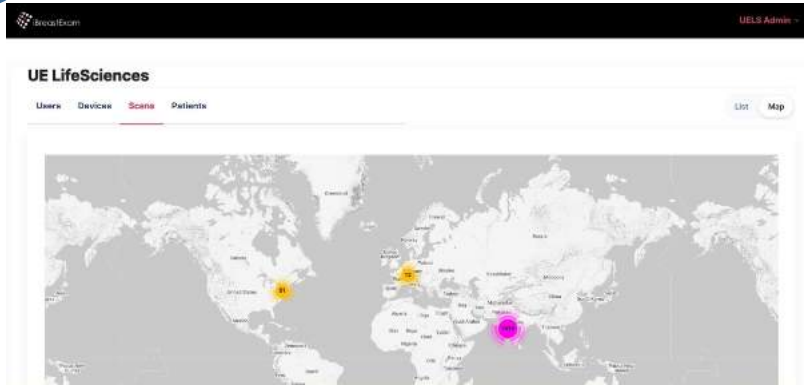
## 3 Patient Reporting



## 2 Patient Screening



## 4 Dashboard & Data Analytics



### Breast cancer screening: one size does not fit all

Mammographic screening for the detection of breast cancer has been the subject of a divisive debate for more than 20 years. Major arguments against screening have been the frequency of false positive scan results and overdiagnosis. However, with breast cancer incidence and mortality due to late diagnosis increasing globally, along with improvements in screening technology, there has been a growing acceptance that screening extends lives. However, questions continue to emerge with respect to screening age, who to screen, and how often to screen, among other issues.

Breast cancer screening in high-income countries includes a large age range and often involves frequent screening. The US Preventive Services Task Force recommends screening for women starting at age 40 years; the Ontario Government in Canada, will permit self-referral for publicly funded mammograms at age 40 years beginning in autumn, 2024; in the UK, all women between the ages of 50 and 70 years are invited for screening every 3 years; and the [European Commission's Initiative on Breast Cancer Guidelines](#) strongly recommends women between the ages of 50 and 69 years have screening every 2 years. However, breast cancer screening rates vary substantially. In the EU, rates are as high as 83% in Denmark and as low as 21% in Bulgaria.

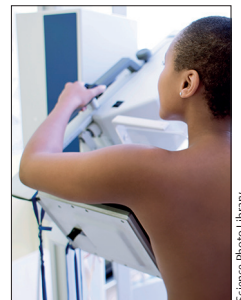
In comparison, breast cancer screening coverage and access in low-income and middle-income countries (LMICs) is alarmingly low. In sub-Saharan Africa, diagnosis of breast cancer is largely based on self or clinical examination, and is often found at an advanced stage of disease, leading to poor treatment outcomes and high mortality. Mammography technology is difficult to adopt and maintain due to availability issues, high costs, and shortage of experienced practitioners. A large proportion of Black women present with aggressive triple-negative breast cancer at a younger age and with high breast tissue density, which makes disease detection by mammography less accurate. Furthermore, poverty, sociocultural and religious beliefs, misconceptions about the disease, stigma, and lack of autonomy make women hesitant to proactively approach the health-care system. Breast cancer awareness campaigns have been somewhat successful at promoting engagement with prevention

and screening strategies, but much more remains to be done. In December, 2001, *The Lancet Oncology* published an Editorial on [poor cancer-screening uptake among ethnic minorities](#); 22 years later, screening awareness, access, and uptake continues to be inadequate.

To achieve the benefit of screening across ethnicities and geographies, it is important to acknowledge that a one-size-fits-all approach will not work. Current screening programmes are predominantly based on an understanding of breast cancer in White women. The genetic and lifestyle modifiers in more diverse populations remain largely unknown. There is an urgent need to design new paradigms of screening that incorporate a greater understanding of the varied risk profiles of diverse populations.

It is time to apply the principles of precision oncology to breast cancer screening strategies. The idea of risk-based screening is not groundbreaking—it is already standard practice to screen women with *BRCA* gene mutations at an earlier age and more frequently than the general population. Breast cancers vary tremendously in their timing of onset, rate of growth, and probability of metastasis, and tailoring screening on the basis of an individual woman's risk would be the ultimate goal. The WISDOM Study is an example of a trial that aims to compare a personalised risk-based approach to traditional annual breast cancer screening strategies. It is important to recognise that programmes that are beneficial in high-income countries might be difficult to implement and unrealistic in low-resource settings. Per the WHO Global Breast Cancer Initiative, early detection strategies will vary based on health-system readiness. Until the required infrastructure and quality control measures are established, breast cancer screening in LMICs might require focusing on affordable, easy-to-use, alternative solutions, such as the iBreastExam.

There is no doubt that timely screening saves lives by enabling treatment at earlier stages when it is more effective, better tolerated, and less expensive than in advanced cancers. We have come a long way from the start of the screening controversy, and by adopting a tailored, region-specific, biology driven, dynamic approach to screening, precision screening of high-risk individuals is within our grasp. ■ *The Lancet Oncology*



Science Photo Library

For the **US Preventive Services Task Force recommendations** see <https://www.uspreventiveservicestaskforce.org/uspstf/draft-recommendation/breast-cancer-screening-adults#bcei-recommendation-title-area>

For the **Ontario Government announcement** see <https://news.ontario.ca/en/release/1003714/ontario-connecting-more-women-to-breast-cancer-screening-earlier>

For the **UK breast screening programme overview** see <https://www.gov.uk/guidance/breast-screening-programme-overview>

For more on the **EU guidelines on breast cancer screening** see [https://healthcare-quality.jrc.ec.europa.eu/en/ecibc/european-breast-cancer-guidelines?topic=84&usertype=59&filter\\_1=78&filter\\_2=79&updatef2=0](https://healthcare-quality.jrc.ec.europa.eu/en/ecibc/european-breast-cancer-guidelines?topic=84&usertype=59&filter_1=78&filter_2=79&updatef2=0)

For more on the **screening rates across the EU** see <https://ec.europa.eu/eurostat/web/products-eurostat-news/w/ddn20231103-2>

For more on **breast cancer screening in LMICs** see *Scientific African* 2023; 21: e01948

For more on **poor cancer-screening uptake among ethnic minorities** see *Lancet Oncol* 2001; 12: 709

For the **WISDOM study** see *npj Breast Cancer* 2017; 3: 1-7

For more on the **WHO Global Breast Cancer Initiative** see <https://www.who.int/initiatives/global-breast-cancer-initiative>

For the **study on iBreastExam** see *Articles Lancet Glob Health* 2022; 10: e555-63



## AVAILABLE PRODUCT

Medical device

WHO compendium of innovative health technologies for low-resource settings

2016-2017

Inclusion in the Compendium does not constitute a warranty by WHO of the fitness of any technology or product for a particular purpose, as no rigorous review for safety, efficacy, quality, applicability or cost acceptability was conducted by WHO. WHO will not be held to endorse nor to recommend any technology or product included in the Compendium. WHO disclaims any and all liability whatsoever for any damage of any kind that may arise in connection with the procurement, distribution and/or use of any such technology or product.

### Breast exam, portable device

Country of origin | United States of America

Primary function | Diagnosis

Health problem addressed

Incidence rates of breast cancer (BC), especially in women older than 50 years old, have nearly doubled in low- and middle-income countries over the past 20 years. Nearly 66% of these women are diagnosed late due to lack of education, awareness and access to affordable, clinically relevant and scalable technology. As a result, women in low- and middle-income countries have a 40%-60% survival rate compared to 90%+ for their USA/UK counterparts. In India alone, over 190 million women between ages 30-65, approximately 35% of the female population, may benefit from access to early detection.

Disease addressed

Neoplasms

Technical descriptions

The device measures the contrast in elastic modulus between normal and abnormal breast tissue. The device contains a novel, low-power, lead zirconate titanate (PZT) piezoelectric material that works by using direct/reverse piezoelectric effects, enabling "electronic palpation" entirely automated, controlled internally and independent of the operator. The device is a FDA cleared, hand-held, battery powered and fully wireless, mobile health (mHealth) solution for clinically effective breast lesion detection.

Developer's claims of products benefits

The 'gold standard' for breast cancer detection, i.e. routine mammography, is unsustainable for low- and middle-income countries, inaccessible to rural areas and requires highly trained radiologists to interpret images. While clinical breast exam (CBE) is affordable, it is subjective and clinically limited in detecting non-palpable lumps at early stages. This breast exam device is objective, affordable, portable, accessible, painless and radiation-free.

Operating steps

Pair the device via Bluetooth with its associated tablet (1 min). Once paired, calibrate the device against air (10 sec). Then calibrate it by placing it on the breast tissue (10 sec). Begin scanning by placing the device gently on one end of the breast tissue. Cover the entire breast tissue by moving the device across smaller quadrants (depending on size of breast), capturing the reading simultaneously on the tablet (4 mins). Repeat procedure on second breast (4 mins).

Regulatory status and standards compliance

United States of America (FDA).

Use and maintenance

User: Trained caregiver (e.g family member), midwife, technician, nurse, general physician, specialised physician, community health workers.

Training: The device requires minimal training. As long as the user is familiar with the use of basic battery powered technology and comfortable using an electronic tablet, they can operate it and perform scans. A user can get fully trained to operate the device after doing approximately 20-30 scans under the supervision of a training instructor, after which the user will receive a certification that they are sufficiently trained to operate it.

Maintenance/Calibration required: Yes

Environment of use

Setting: Rural settings, urban settings, outdoors, indoors, at home, public places (market, library, etc.), primary level (health post, health centre), secondary level (general hospital), tertiary level (specialists hospital), ambulances, anywhere.

Energy requirements: Rechargeable battery.

Product specifications

Weight (kg): 0.2

Dimensions: 120mm x 68mm x 84mm

Accessories: Android Mobile Device, Mobile App, power bank, charger cables, case to carry device and accessories (all included with device).

Lifetime: 5 years

In UN catalog: No

Commercial information

Reference price (USD): 1-5 per scan

Year of commercialization: 2016

Currently sold in: India, Mexico, Botswana, Thailand, Malaysia, Singapore, Myanmar, Philippines, Vietnam, Indonesia, Nepal

Number of units distributed: 0-100

Software requirements: Proprietary

Model: iBreastExam

Other features: Portable, reusable (assuming appropriate decontamination and/or other reprocessing between uses)



Contact Mihir Shah | Telephone +1 631 980 8340 | Web <https://bit.ly/2DcQwca>



# Technology & Clinical Validations

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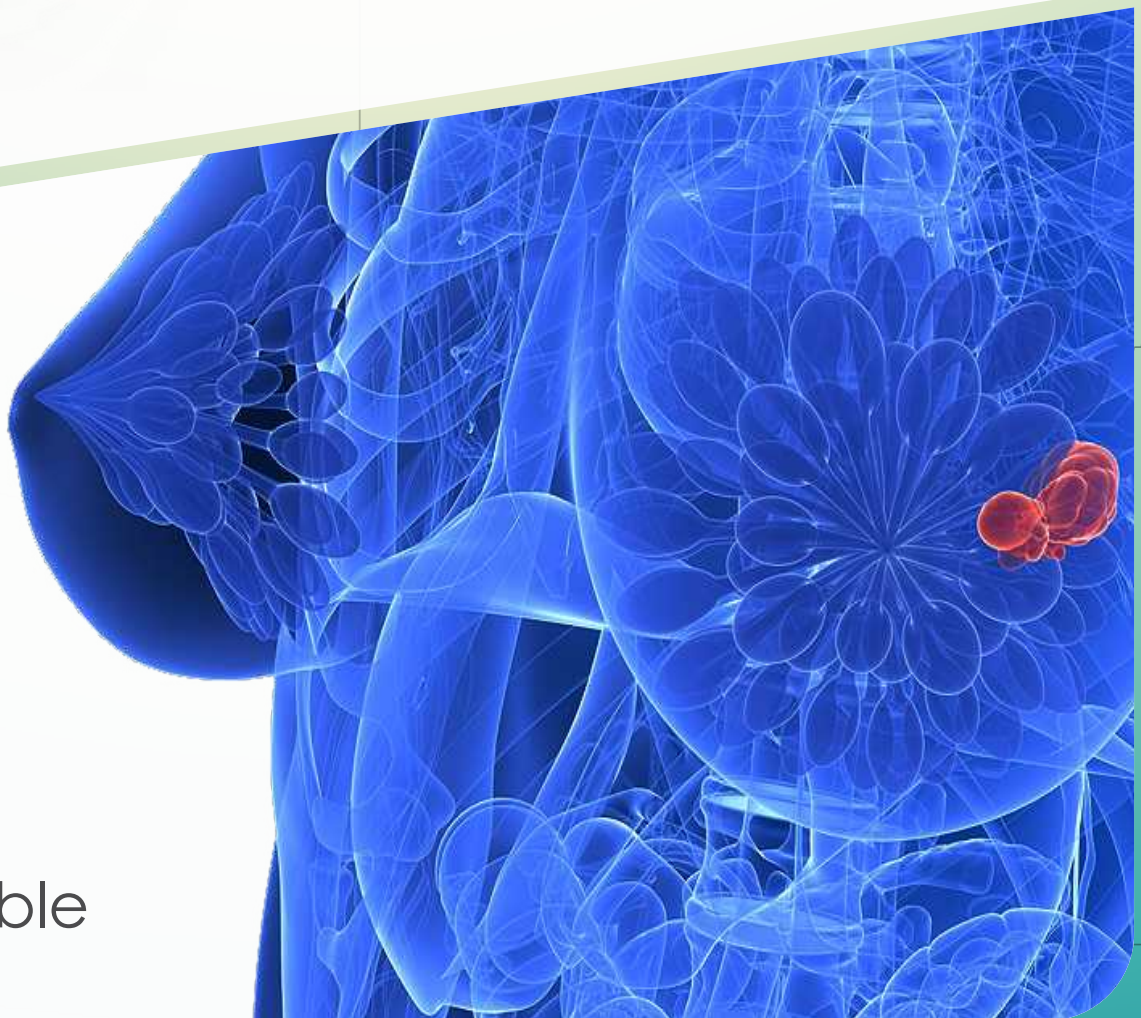
# Dynamic Co-Planar Capacitive (DCPC) Sensors



648 sensors measure tissue stiffness 20 times per second

**Breast lesions are stiffer**

contrast in elastic modulus is measurable



# Our Clinical Studies & Global Advisors

Over 25,000 women enrolled in multiple international investigator-led validations:

- **The Lancet Global Health** (Study: [Lancet Glob. Health 2022](#) and Comment: [Lancet Glob. Health 2022](#))
- **JCO Global Oncology** by the American Society of Clinical Oncology ([ASCO 2020](#))
- **The American Society of Breast Surgeons** ([ASBS 2020](#))
- **San Antonio Breast Cancer Symposium** ([SABCS 2020](#) and [SABCS 2020](#))
- **International Journal of Current Innovation Research** ([IJCIR 2019](#))
- **Annals of Oncology** ([Ann. Oncol. 2019](#))
- **Journal of Cancer Prevention & Current Research** ([JCPCR 2018](#))
- **World Journal of Surgical Oncology** ([WJSO 2016](#))
- **Journal of the American College of Surgeons** ([JAmColl Surg 2013](#))



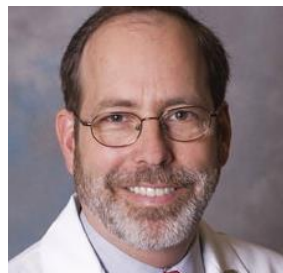
Brian Englander, MD  
Chairman Radiology  
Dept. Penn Hosp.



Ari Brooks, MD, FACS  
Dir. Integrated Breast  
Ctr at Penn Hosp.



Romecio Domingues,  
MD, Chairman DASA  
(Brazil)



Ben Anderson, MD,  
FACS. Founder BHGI,  
BoD UICC



Anne F. Rositch, PhD  
Cancer Researcher  
at Johns Hopkins U.



Mauricio Costa, MD  
President SIS  
(Brazil)

# Summary of Clinical Study Results

| Journal              | Clinical Study (abbreviated)   | Sensitivity | Specificity | NPV | Comp. vs.      |
|----------------------|--|-------------|-------------|-----|----------------|
| IJCIR                | <u>Study of Accuracy of iBreastExam as a Screening Modality to Detect Breast Lumps</u>   | 88%         | 94%         | 95% | MMG, CBE       |
| Ann. Oncol.          | <u>Non-invasive and low-cost technique for early detection of clinically relevant breast lesions</u>                                 | 84%         | 94%         | 98% | MMG or USG     |
| SABCS                | <u>Clinical efficacy evaluation of a novel palpation imaging device for early detection of breast cancer in the developing world</u> | 86%         | 91%         | 98% | MMG, USG       |
| WJSO                 | <u>A cost-effective handheld breast scanner for use in low-resource environments</u>   | 86%         | 89%         | 96% | MMG, USG       |
| J Am Coll Surg       | <u>Breast Tumor Detection using Piezoelectric Fingers: First Clinical Report</u>   | 83%         | 88%         | 75% | MMG            |
| SABCS                | <u>Diagnostic accuracy of a novel palpation device to improve early detection of breast cancer in low-resource settings</u>          | 74%         | 88%         | n/a | MMG, USG       |
| JCO (ASCO)           | <u>Clinical Utility of a Hand-Held Scanner for Breast Cancer Early Detection and Patient Triage</u>                                  | n/a         | 80%         | 94% | MMG, CBE       |
| Lancet Global Health | <u>The iBreastExam versus clinical breast examination for breast evaluation in high risk and symptomatic Nigerian women</u>          | 86%         | 50%         | 98% | MMG, USG & CBE |

# ACCURACY OF iBreastExam AS A SCREENING MODALITY: A TERTIARY CARE CENTRE EXPERIENCE OF CENTRAL INDIA

Dr. Sneha Ramteke<sup>1</sup>; Dr. Raj Gajbhiye<sup>2</sup>; Dr. Deepa Jahagirdar<sup>3</sup>; Dr. Prasad Uppanlawar<sup>4</sup>; Dr. Vipin Kursunge<sup>5</sup>  
(1. Presenter & Junior Resident, 2. Professor & HOD, 3. Associate Professor, 4. Assistant Professor., 5. Junior Resident)

DEPARTMENT OF GENERAL SURGERY, GOVERNMENT MEDICAL COLLEGE, NAGPUR, MAHARASHTRA



## INTRODUCTION

- Breast cancer is the most common malignancy worldwide and incidence is increasing rapidly.
- There is paradigm shift towards its prevention and early detection.
- Early detection improves survival rate, makes treatment less costly and lowers the overall burden of the disease.
- iBreastExam is a handheld, noninvasive and painless breast health test that offers standardized breast examination accurately and easily, at the point-of-care.

## OBJECTIVE

To evaluate the accuracy of iBreastExam as a screening modality in the early detection of breast lump.

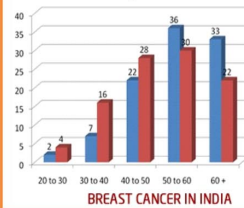
## MATERIALS & METHODS

- This study was conducted in the Department of General Surgery, Government Medical College Nagpur over a period of 2 years from June 2016 to September 2018.
- All females above 18 years of age presenting to OPD with or without symptomatic breast disease were included and considered for I- Breast Exam after informed consent.
- The test was performed with patient in supine position and both the breast were scanned by iBreast exam as well as clinically by palpation.
- The lesion detected were followed by imaging and pathology test.
- Results were compared with the gold standard triple test which include clinical examination, radiological imaging and fine needle aspiration.

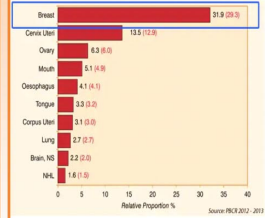


## CURRENT SCENARIO

Since 2008, the incidence of breast cancer has increased by more than 20%, globally



Incidence of breast cancer in Nagpur



- Currently a combination of three tests – (clinical examination, radiological imaging and fine needle aspiration cytology) –triple assessment test is used as gold standard in diagnosing all palpable breast lumps in high risk population.
- Currently aside from palpation and risk assessment questionnaires, there is no prescreening test that can improve the accuracy, safety and cost effectiveness of screening low risk population.

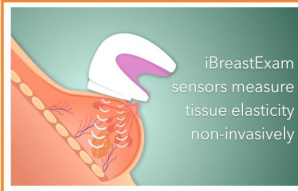


- Considering the solemnity of the problem, this programme was a nationalized & was implemented on large scale.
- Medical health department, Maharashtra State & Empathy Foundation in collaboration, have launched a Breast Health awareness campaign against Breast Cancer across Maharashtra.

## DEVICE - i Breast Exam

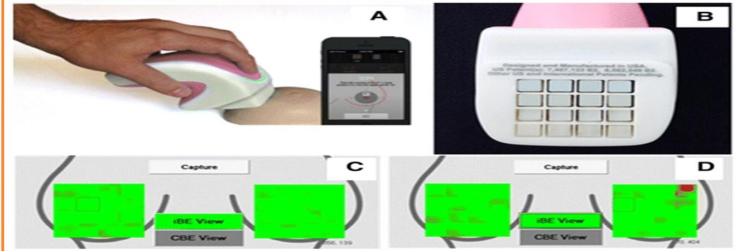


- The iBreastExam consists of a handheld compression probe containing a 4x4 array of piezoelectric tactile pressure sensors, a custom built electronic board and a tablet.
- The patented tactile sensor technology using Piezoelectric Sensor Array (iBreastExam) was invented by doctors and scientists at Drexel university, Philadelphia.



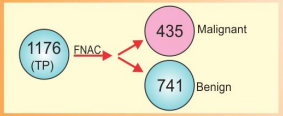
- iBreastExam sensors accurately assess and identify tissue elasticity differences between hard and stiff breast tumours versus normal breast tissue by top down touching of the skin surface and measure the subtle displacements electrically, all within the sensor.

- iBE communicates wirelessly with a mobile device to display and store the findings in real time and no identifiable data are collected or stored by the iBE software.
- The results of the iBE were displayed on the touch screen in a pressure map fashion- green indicates normal breast tissue while red indicates a lesion was detected meaning the iBE is suggesting further testing to characterize the lesion, as the **iBE does not differentiate the type of lesion it detects.**



## RESULTS

A total of 18,366 females were examined both by iBreast and clinical palpation. Out of which 16,154 females were having normal breast without any pathology and 1,942 females were detected positive on iBreast exam.



With the extensive literature search, this is the first compiled data study in central India (Nagpur, Maharashtra) where such a large number of population is screened. When compared with previous studies, iBE is having better sensitivity and high specificity in detecting breast lesions.

|                      | Clinical breast examination positive | Clinical breast examination negative | Measures                        |
|----------------------|--------------------------------------|--------------------------------------|---------------------------------|
| iBreastExam positive | 1176(TP)                             | 766(FP)                              | Positive predictive value=62%   |
| iBreastExam negative | 270(FN)                              | 16,154(TN)                           | Negative predictive value=98.5% |
| Measures             | Sensitivity=81.33%                   | Specificity=95.4%                    | Accuracy =94.6%                 |

## DISCUSSION

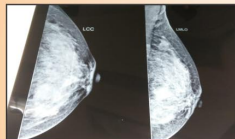
| Clinical study                        | Sensitivity | Specificity | Positive predictive value | Negative predictive value |
|---------------------------------------|-------------|-------------|---------------------------|---------------------------|
| Xu X, et al; Philadelphia, 2013       | 83%         | 88%         | 61%                       | 75%                       |
| Broach RB, et al; Philadelphia, 2015  | 86%         | 89%         | 70%                       | 95%                       |
| Somashekhar SP, et al; Banglore, 2016 | 84%         | 94%         | 60%                       | 98%                       |
| Geha R et al; Pune, 2016              | 77%         | 98%         | -                         | -                         |
| <b>PRESENT STUDY</b>                  | <b>81%</b>  | <b>95%</b>  | <b>62%</b>                | <b>98%</b>                |

## CASE STUDY

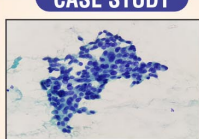
38 yrs/f, came for screening as patient's relative. Histopathology examination - s/o - Ductal carcinoma in situ.



iBreast was positive



Mammography - BIRADS-IV



Proliferative breast disease with atypia



Breast conservative surgery with axillary dissection done

## CONCLUSION

- In the developing county 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 surgery residents and trained staff; iBE is highly cost-effective in terms of maintenance of the device, transport of females to tertiary centre, reducing patient load for physicians and workload for machines and radiologists - ultrasound and mammography.
- iBE is the first modality providing results at point-of-care and making females anxiety free, who came for screening with normal breasts.
- To conclude, iBreastExam shows significantly better sensitivity and higher specificity and was found to be a promising effective tool for younger women with dense breast.

## REFERENCES

- Noninvasive \$ low-cost technique for early detection of clinically relevant breast lesions using a Handheld Point-Of-Care Medical Device (iBreastExam): prospective three-arm Triple-Blinded Comparative study published in IJGO, June 2016.
- "A cost-effective handheld breast scanner for use in low resource environments: a validation study" published in the world journal of surgical oncology on oct 28, 2016.
- Schwartz's principles of surgery ABSITE and board review, 10<sup>th</sup> edition; pg513
- Breast tumour detection using piezoelectric finger, first clinical report, Hahnemann hospital, Philadelphia, USA, 2013.
- Validation of study of iBreast scanner 2015.

## The iBreastExam versus clinical breast examination for breast evaluation in high risk and symptomatic Nigerian women: a prospective study\*\*

Victoria L Mango, MD\*, Olalekan Olasehinde, MD\*, Adeleye D Omisore, MD, Funmilola O Wuraola, MD, Olusola C Famurewa, MD, Varadan Sevilimedu, DrPH, et al.

[The Lancet Global Health, Volume 10, Issue 4, E555-e563, April 01, 2022](#)

**Findings:** [...] 424 Nigerian women were enrolled (151 [36%] at high risk of breast cancer and 273 [64%] symptomatic women). [...]. 419 (99%) women had BI-RADS assessment and were included in the analysis. For any breast finding, the iBreastExam showed significantly better sensitivity than CBE (63%, 95% CI 57–69 vs 31%, 25–37;  $p < 0.0001$ ), and CBE showed significantly better specificity (94%, 90–97 vs 59%, 52–66;  $p < 0.0001$ ). [...] The iBreastExam and CBE showed similar NPVs for any breast finding (56%, 49–63 vs 52%, 46–57;  $p = 0.080$ ) and suspicious findings (98%, 94–99 vs 98%, 96–99;  $p = 0.42$ ), whereas the PPV was significantly higher for CBE in any breast finding (87%, 77–93 vs 66%, 59–72;  $p < 0.0001$ ) and suspicious findings (37%, 26–48 vs 14%, 10–19;  $p = 0.0020$ ). Of 15 biopsy-confirmed cancers, CBE and the iBreastExam detected an ipsilateral breast abnormality in 13 (87%) women and missed the same two cancers (both  $< 2$  cm).

**Interpretation:** The iBreastExam by nurses showed a high sensitivity and NPV, but lower specificity than surgeon's clinical breast examination for identifying suspicious breast lesions. In locations with few experienced practitioners, the iBreastExam might provide a high sensitivity breast evaluation tool. Further research into improved specificity with device updates and cost feasibility in low-resource settings is warranted.

\*Joint first authors. \*\*Following this publication, MSKCC has purchased 5 units of iBreastExam to initiate a community-wide screening study in Nigeria with \$100,000 grant from Pfizer. Breast Imaging Service, Department of Radiology, (V L Mango MD), Department of Epidemiology and Biostatistics (V Sevilimedu DrPH, E Steinberg BS), and Department of Surgery (T P Kingham MD), Memorial Sloan Kettering Cancer Center, New York, NY, USA; Obafemi Awolowo University Teaching Hospital Complex, Ile-Ife, Nigeria (O Olasehinde MD, A D Omisore MD, F O Wuraola MD, O C Famurewa MD, P R Akinmaye RN, B D Adewoyin RN, Prof O Alatise MD); Department of Surgery, Dalhousie University, Halifax, NS, Canada (G C Knapp MD); Department of Global Health, Icahn School of Medicine at Mount Sinai, New York, NY, USA (A Romanoff MD); Division of Cancer Prevention, National Cancer Institute, National Institutes of Health, Bethesda, MD, USA (P E Castle PhD)

## Comment: Breast cancer screening: can the iBreastExam bridge the gap?

Julius Gbenga Olaogun<sup>1</sup>, Olayide Sulaiman Agodirin<sup>2</sup>

[The Lancet Global Health, Volume 10, Issue 4, E461-e462, April 01, 2022](#)

**Findings:** Aside from contributing data to the literature on applicability of the iBreastExam in sub-Saharan Africa, the research was timely and fits well within the context of current research and practice in LMICs, in which there are numerous unresolved challenges of breast cancer screening. The authors were thoughtful to include women at high risk because currently, the most effective strategy for LMICs is the downstaging of breast cancer. [...] The findings show that the iBreastExam has potential to bridge some deficiencies and gaps in the decision-making process, especially for community health-care providers.

In the diagnostic detection algorithm, the iBreastExam will perhaps be well suited as a prescreening device as intended in the study. [...]

**Conclusion:** In conclusion, the study shows that with minimal training, inexperienced health-care providers can use the iBreastExam successfully and achieve higher sensitivity than with clinical breast examination. The iBreastExam can overcome the issue of a shortage of specialists for early detection of breast cancer in Nigerian communities, thus showing the potential to reduce incidence of advanced stage breast cancer and might lead to improvement in survival.

## Clinical Utility of a Hand-Held Scanner for Breast Cancer Early Detection and Patient Triage

Julie M. Clahanan<sup>a</sup>, Sanjana Reddy<sup>b</sup>, Robyn B. Broach<sup>b</sup>, Anne F. Rositch<sup>c</sup>, Benjamin O. Anderson<sup>d</sup>, E. Paul Wileyto<sup>e</sup>, Brian S. Englander<sup>f</sup>, Ari D. Brooks<sup>b</sup>

[JCO Global Oncology, Volume 6, 27-34, 2020](#)

**Methods:** Women presenting for screening or diagnostic workup were enrolled and underwent iBE then CBE, followed by mammography. Mammography was classified as negative (BI-RADS 1 or 2) or positive (BI-RADS 3, 4, or 5). Measures of accuracy and  $\kappa$  score were calculated.

**Results:** Between April 2015 and May 2017, 516 women were enrolled. Of these patients, 486 completed iBE, CBE, and mammography. There were 101 positive iBE results, 66 positive CBE results, and 35 positive mammograms. iBE and CBE demonstrated moderate agreement on categorization ( $\kappa = 0.53$ ), but minimal agreement with mammography ( $\kappa = 0.08$ ). iBE had a specificity of 80.3% and a negative predictive value of 94%. In this cohort, only five of 486 patients had a malignancy; iBE and CBE identified three of these five. The two cancers missed by both modalities were small—a 3-mm retro-areolar and a 1-cm axillary tail.

**Conclusion:** In conclusion, this study demonstrated excellent negative predictive value of iBE and agreement between iBE and CBE as triage tests for the detection of clinically relevant breast lesions. These results support implementation studies of the iBE device as an adjunct to CBE and directed point-of-care ultrasound for triage of breast screening in resource-limited countries.

## Breast Cancer Screening in Rural Area in Kannur District, Kerala, India: “The Kannapuram Model”- A Community Participatory Approach

Neethu Ambali Parambil, B Satheesan, D Adarsh, Maya Padmanabhan, Phinse Philip, TV Satheeshbabu

[ASBS The American Society of Breast Surgeons, Abstract #784629, Volume XXI, 2020 - Virtual Scientific Session, Page 224](#) and [Poster](#)

**Methods:** Continuous community awareness on breast cancer was conducted prior to a screening program in a panchayath in rural Kannur, Kerala, under leadership of local self-government with technical support from a tertiary cancer center. The key objectives of the study were to report on the efficacy and acceptability of iBreastExam, when implemented in rural settings.

**Results:** A total of 3247 women above 30 years of age participated in the camp. There were 203 (6.2%) who were found positive on ibreast exam. All were referred to the tertiary cancer center for further evaluation, of which 137 underwent further investigations. There were 109 (79.6%) who had BIRADS 1 or 2. Ten (7.3%) subjects with BIRADS 3 were advised follow-up at 6 months. Out of 15(11%) with BIRADS 4, 14 underwent wire-guided biopsy, of which 2 were detected to have carcinoma, and none had any palpable abnormality on clinical breast examination. One with BIRADS 5 had early-stage carcinoma. A total of 97% of the participants reported the test as acceptable and recommendable to relatives.

**Conclusion:** iBreastExam is a useful preliminary tool for community-based screening but is not a replacement for established screening modalities. Acceptable screening methods preceded by continuous community sensitization programs on cancer awareness may alleviate apprehensions and improve participation in early detection programs.

# Breast cancer screening in rural area in Kannur district, Kerala, India; "The Kannapuram Model"- a community participatory approach

Dr.Satheesan B, Dr.Neethu A P, Dr. Phinse M Philip, Dr. Satheesh Babu, Dr. Adarsh D, Maya Padmanabhan

Malabar cancer center, Thalassery, Kerala, India



784629

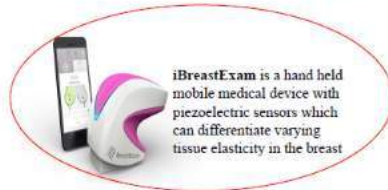
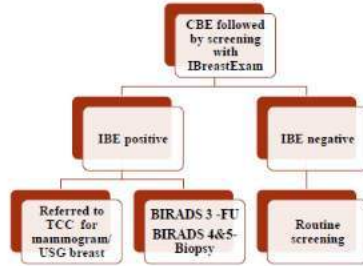
## Background

- Breast cancer accounts for 27% of female cancers in India.
  - Fear and lack of awareness results in late stage presentations and high mortality.
  - Public education about cancer symptoms and importance of early detection can help in improving outcomes
- Aims**
- 1) To assess importance of community participatory approach in success of a screening program
  - 2) Effectiveness of iBreastExam as screening device for breast cancer

## Methods

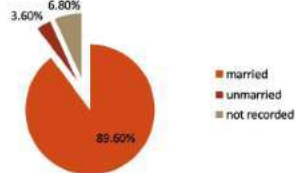
Setting- Kannapuram grama panchayath Kannur, Kerala, India

- Sensitizing workshop
- Awareness activities for representatives of LSG
- Community campaign (posters, meetings, health exhibitions, seminars)
- Visit to 3800 houses and participant recruiting
- Mega camp for 10 days Examination of 250-500 women /day
- Patient navigation to TCC by members of LSG
- Investigation/Treatment of detected cases at Tertiary Cancer Center



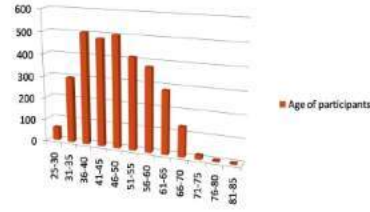
## Results

### Marital status



## Results

### Age of participants



### The flow chart



| Mammo/USG     | Percentage  | Remarks   |
|---------------|-------------|---|
| BIRADS 1 or 2 | 109 (80.7%) | Annual screening                                    |
| BIRADS 3      | 10 (7.4%)   | FU at 6/12  |
| BIRADS 4      | 15 (11%)    | Biopsy done<br>13 benign (87%)<br>2 ca breast (13%) |
| BIRADS 5      | 1 (0.74%)   | Ca breast   |

| BIRADS   | Stage               | Remarks                            |
|----------|---------------------|------------------------------------|
| BIRADS 4 | DCIS                | Post RT on FU                      |
| BIRADS 4 | Stage 11A<br>T2N1M0 | Post OP, Post chemo<br>RT on FU    |
| BIRADS 5 | Stage 1A<br>T1bN0M0 | Post OP, post RT<br>hormones on FU |

### iBreastExam acceptance among women



## Conclusion

- iBreastExam is a useful preliminary tool for community based screening
- Not a replacement for established screening modalities.
- The success of the program was the result of community coalition forged prior to the initiation of camp through sensitization programs popularized as "The Kannapuram Model".
- Acceptable screening methods, continuous community sensitization awareness programs alleviate apprehensions and improve participation

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### Abbreviations

LSG-Local self-government PHC-Primary Health Center FU-Follow up  
TCC-Tertiary Cancer Center CBE -Clinical breast examination  
IRB-IEC No :1617/IRB-IEC/13/MCC/25-4-2018/6

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## Clinical efficacy evaluation of a novel palpation imaging device for early detection of breast cancer in the developing world (Abstract)

S. Nair<sup>1</sup>, T. Kathrikolly<sup>1</sup>, P. Saxena<sup>2</sup>

[SABCS 2019 San Antonio Breast Cancer Symposium Proceedings, Volume 80, Issue 4, Supplement, 2020](#) and [Poster](#)

**Objective:** To evaluate the diagnostic accuracy of a lower cost, non-invasive, portable device called iBreastExam (iBE) in the detection of clinically relevant breast lesions.

**Methods:** Prospective trial enrolled women as part of a community screening program or women seeking. Subjects received an iBreastExam evaluation and a Clinical Breast Examination (CBE), each by a different health-worker, blinded to the other test. Subjects positive on iBE and/or CBE, received follow-up diagnostic imaging.

**Results:** : iBE Vs. Imaging - Sensitivity 86%, Specificity 91%, NPV 98% PPV 57%. CBE Vs. Imaging - Sensitivity 63%, Specificity 82%, NPV 94% PPV 32%. Compared to Clinical Breast Exam, iBreastExam demonstrated significantly (23%) higher sensitivity and moderately (9%) higher specificity to detect breast lesions. iBreastExam may enable community health worker led triaging to detect clinically relevant breast lesions in LMIC settings.

**Conclusion:** iBreastExam demonstrated significantly (23%) higher sensitivity and moderately (9%) higher specificity to detect breast lesions as compared to CBE. Lower FP rates compared to CBE reduces the pool of women requiring further diagnostic follow-up. iBreastExam requires minimal training and provides objective breast examination with digital documentation. iBreastExam may enable community health worker led triaging to detect clinically relevant breast lesions in LMIC settings.

# Clinical Efficacy Evaluation of a Novel Tactile Imaging Device For Early Detection of Breast Cancer in the Developing World

Suma Nair<sup>1</sup>, Thejas Kathrikolly<sup>1</sup>, PU Prakash Saxena<sup>2</sup>

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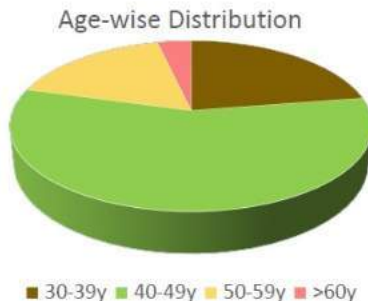
## BACKGROUND

- Breast cancer is the most common cancer in women worldwide, disproportionately affecting low-and-middle income countries (LMICs).
- 52.6% of new breast cancer cases occur in LMICs, and this is expected to grow to 70% by year 2020<sup>1</sup>.
- 5-year survival rate is 40-60% in most LMICs as compared to 80-90% in High Income Countries<sup>2</sup> (HICs).
- Organized screening mammography is expensive and resource intensive.
- iBreastExam (iBE) is a Low-cost, user-friendly technology that can help equip minimally trained community health workers to administer standardized breast exams without any special infrastructure, with the goal to down-stage breast cancer.**
- The aim of this study is to evaluate the clinical efficacy of the lower cost, non-invasive, portable device iBreastExam in the detection of clinically relevant breast lesions.**

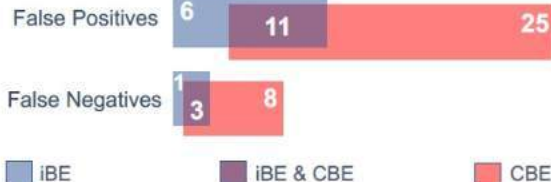
## METHODS

- A prospective non-interventional study** was conducted in Udupi district, Karnataka, India.
- 1200 Non-pregnant Consenting women of Age 30 years and above, seeking routine screening were enrolled.
- Additional 63 women presenting with some breast related symptom, seeking follow-up breast diagnostic evaluation were also enrolled.
- Each woman received an iBE palpation test and Clinical Breast Examination(CBE) blinded to each other. Women detected with any breast lesion on any of these tests were followed up with age appropriate diagnostic imaging.
- Each breast was considered an independent result for the sake of analysis for a total of 222 breasts.
- To assess accuracy of iBE and CBE to detect lesions, the sensitivity and specificity were calculated compared to diagnostic imaging.**
- Standard of truth was established as a positive Mammogram BIRADS 3-5 or a positive Ultrasound(US) as BIRADS 3-5.

## RESULTS



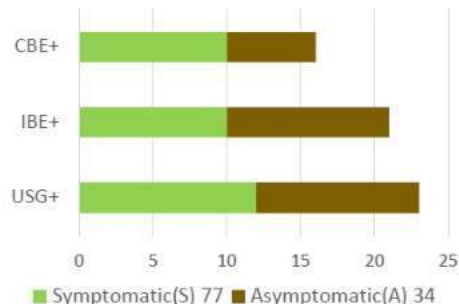
| USG/MAMMO | IBE + | IBE - | TOTAL |
|-----------|-------|-------|-------|
| BIRADS 1  | 9     | 75    | 84    |
| BIRADS 2  | 0     | 3     | 3     |
| BIRADS 3  | 15    | 2     | 17    |
| BIRADS 4  | 5     | 1     | 6     |
| BIRADS 5  | 1     | 0     | 1     |
|           | 30    | 81    | 111   |



|                    |            |
|--------------------|------------|
| <b>Sensitivity</b> | <b>86%</b> |
| <b>Specificity</b> | <b>91%</b> |
| <b>NPV</b>         | <b>98%</b> |
| <b>PPV</b>         | <b>57%</b> |

|                    |            |
|--------------------|------------|
| <b>Sensitivity</b> | <b>63%</b> |
| <b>Specificity</b> | <b>82%</b> |
| <b>NPV</b>         | <b>94%</b> |
| <b>PPV</b>         | <b>32%</b> |

## RESULTS



## CONCLUSIONS

- iBreastExam demonstrated significantly (23%) higher sensitivity and moderately (9%) higher specificity to detect breast lesions as compared to CBE.
- Lower FP rates compared to CBE reduces the pool of women requiring further diagnostic follow-up.
- iBreastExam requires minimal training and provides objective breast examination with digital documentation.
- iBreastExam may enable community health worker led triaging to detect clinically relevant breast lesions in LMIC settings.

## Diagnostic accuracy of a novel palpation device to improve early detection of breast cancer in low-resource settings (Abstract)

M. M. Costa<sup>1</sup>, A. F. Rositch<sup>2</sup>, F. P. A. Pereira<sup>3</sup>, H. C. de Oliveira<sup>4</sup>, C. F. de Oliveira<sup>5</sup>, N. Gomes<sup>6</sup>, F. P. P. L. Lopes<sup>3</sup>

[SABCS 2019 San Antonio Breast Cancer Symposium Proceedings, Volume 80, Issue 4, Supplement, 2020](#)

**Objectives:** To evaluate the diagnostic accuracy of a lower cost, non-invasive, portable device called iBreastExam (iBE) in the detection of clinically relevant breast lesions.

**Methods:** prospective non-randomized trial which enrolled 226 women (449 breasts) seeking routine screening or follow-up breast diagnostic evaluation from two clinics. Each woman received an iBE test and then mammography, ultrasound (US), or both, each by a different blinded clinician.

**Results:** The study enrolled and evaluated 226 women (449 breasts) with iBE, with a median age of 54 years old. Of the 434 breasts scanned by both iBE and mammography, 348 were normal by both and 17 lesions were detected by both. The sensitivity and specificity of iBE compared to mammography were 45.9% and 87.7%, respectively. Compared to the 324 US scans, where 258 normal by both and 20 lesions were detected by both, the sensitivity and specificity of iBE were 66.7% and 87.8%, respectively. Compared to mammography plus US, the sensitivity and specificity were 73.9% and 88.0%.

**Conclusion:** The relatively high specificity highlights the tools' ability to reduce the pool of women warranting further evaluation but the sensitivity of iBE compared to mammography alone was relatively low. Notable, 15 of the 17 cases missed by iBE were classified as BIRADS 0. When these cases underwent US, the net sensitivity increased to 74%. Based on the acceptability survey, iBE shows extreme promise and demonstrates high approval among women. These data highlight the potential for iBE to strengthen breast cancer early detection programs in LMIC's and support the need for next generation sensors with improved sensitivity.

# Diagnostic Accuracy of a Novel Palpation Device to Improve Early Detection of Breast Cancer in Low-Resource Settings

M. M. Costa<sup>1</sup>, A. F. Rositch<sup>2</sup>, F. P. A. Pereira<sup>3</sup>, H. C. de Oliveira<sup>4</sup>, C. F. de Oliveira<sup>5</sup>, N. Gomes<sup>6</sup>, F. P. P. L. Lopes<sup>7</sup>

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## BACKGROUND

- Breast cancer is the most diagnosed cancer in women in both high- and low-resource settings<sup>1</sup>
- The absolute burden of breast cancer and rate of increase is higher in less developed countries and by 2020, over 1 million new cases per year are projected in low- to middle-income countries (LMICs) alone<sup>1,2</sup>
- Mortality rates in LMICs remain disproportionately high due to late-stage presentation
  - Indicating a variety of barriers to early detection and diagnosis of breast cancer as well as scarcity of resources for optimal diagnosis and treatment<sup>3,4</sup>
- iBreastExam (iBE) is a novel, quantitative and low-cost elastic modulus (E) sensor that can measure tissue compression and stiffness by top down touching of the skin surface with patented tactile sensors using Piezoelectric Sensor Array
  - iBreastExams ability to apply a gentle force and measure the subtle displacements electrically, all within the sensor, makes for an ideal 'electronic palpation' sensor for in-vivo breast imaging.

Although incidence continues to increase in low- to middle-income countries, access to early detection in these high burden areas remain limited, in part due to lack of low-cost efficacious tools where mammography isn't feasible. Therefore, the aim of this study is to evaluate the diagnostic accuracy of the lower cost, non-invasive, portable device iBreastExam in the detection of clinically relevant breast lesions.

## METHODS

- A prospective non-randomized trial was conducted in Nova Iguaçu and Rio de Janeiro, Brazil with women seeking routine screening or follow-up breast diagnostic evaluation, respectively.
  - Each woman received an iBE palpation test and then mammography, ultrasound (US), or both, each by a different blinded clinician.
- Each breast was considered an independent result for the sake of analysis for a total of 449 breasts (n=226 women).
- Non-pregnant women aged 18 and older were eligible to enroll after providing informed consent.
- To assess accuracy of iBE to detect lesions, the sensitivity and specificity were calculated compared to mammography alone, ultrasound alone, or mammography plus ultrasound.
- A random subset of women (n=57) were invited to complete a one-minute assessment on the acceptability of iBE after their examination.

## EXAMINATIONS

### iBreastExam

- Trained technicians scanned each breast fully using the iBE in a clock-wise manner.
- The number of required positions to image the whole breast was determined by the patient's breast size and ranged from 4 to 9 scans per breast
- Individual scans took about 3 to 4 minutes and generating an automatic reports

### Mammogram

- In patients in which a mammogram was performed both breasts were imaged in the craniocaudal and mediolateral oblique views by digital mammogram.

### Ultrasound

- US exams were performed by 3 radiologists, one specialized and two nonspecialized in breast imaging.
- Variable ultrasound systems were used equipped with a linear-array transducer with a bandwidth of 7.5–13.5 MHz and interpreted according to the current ACR BI-RADS.

### For the sake of determining true lesion status for calculations:

- A positive mammogram was considered BIRADS 0, 3-6
- A positive US was considered BIRADS 3-6.
- For mammography plus US, the mammographic classification was considered the true status except for BIRADS 0, in which case the US classification was considered the truth.
- 226 women were enrolled for a total of 449 breasts. Median age of participants was 54 years old and all breasts received iBreastExams exams
  - 434 received mammograms
  - 324 received ultrasounds
  - 317 received both

## RESULTS

| Results  | Mammography (n=434) | Ultrasound (n=324) |
|----------|---------------------|--------------------|
| BIRADS 0 | 15                  | 0                  |
| BIRADS 1 | 85                  | 222                |
| BIRADS 2 | 312                 | 73                 |
| BIRADS 3 | 10                  | 13                 |
| BIRADS 4 | 10                  | 13                 |
| BIRADS 5 | 1                   | 2                  |
| BIRADS 6 | 1                   | 1                  |



## RESULTS



## CONCLUSIONS

- The relatively high specificity highlights the tools' ability to reduce the pool of women warranting further evaluation but the sensitivity of iBE compared to mammography alone was relatively low.
- Notable, 15 of the 17 cases missed by iBE were classified as BIRADS 0.
  - When these cases underwent US, the net sensitivity increased to 74%.
- Based on the acceptability survey, iBE shows extreme promise and demonstrates high approval among women
- These data highlight the potential for iBE to strengthen breast cancer early detection programs in LMICs and support the need for next generation sensors with improved sensitivity.



## STUDY OF ACCURACY OF iBREAST EXAM AS A SCREENING MODALITY TO DETECT BREAST LUMP- EXPERIENCE OF A TERTIARY CARE CENTRE IN CENTRAL INDIA

Deepa Jahagirdar., Raj Gajbhiye., Sneha Ramteke., Bhupesh Tirpude Prasad Uppanlawar and Nilesh Mangam

VOLUME & ISSUE: -[HTTP://JOURNALJ CIR.COM/ISSUE/](http://JOURNALJ CIR.COM/ISSUE/)"STUDY-ACCURACY-IBREAST-EXAM-SCREENING-MODALITY-DETECT-BREAST-LUMP-EXPERIENCE-TERTIARY-CARE

Vol. 5, Issue, 02

### Abstract

**Introduction:** Incidence of breast cancer is rising rapidly worldwide. Early detection rate, makes treatment less costly and lowers the overall burden of disease. Currently, there is no prescreening test that improves the accuracy, safety, and cost effectiveness of screening low populations. The piezoelectric finger is a radiation-free, portable, and developed as a prescreening tool to identify all breast lesions and not just cancerous lesions. Study aims to evaluate accuracy of iBreast exam in early detection and diagnosis of breast lump.

**Materials and methods:** This study was conducted in, "Department of General Surgery, Government Medical College, Nagpur" during 2 years from June 2016-November 2018. All presenting to OPD with/without symptomatic breast disease were included, evaluated and results were compared with gold standard Triple test.

**Results:** Overall females screened = 19,583  
A sample of 934, selected by systematic random sampling  
269 were identified with breast lumps by iBreast  
227 were confirmed of breast lumps by clinical examination  
The sensitivity= 87.98% and specificity= 93.79%.

**Conclusions:** Considering sensitivity and specificity, ibreast examination was found to be highly specific to detect breast lump, specifically in younger women with dense breast.

## Non-invasive and low-cost technique for early detection of clinically relevant breast lesions using a handheld point-of-care medical device (iBreast): Prospective three-arm triple-blinded comparative study for breast cancer screening in low resource setting countries

S. P. Somashekhar<sup>1</sup>, Ratna Vijay<sup>1</sup>, Rupa Ananthasivan<sup>1</sup>, Govindarajan Prasanna<sup>1</sup>

[Annals of Oncology, Volume 30, Supplement 3, iiii65, May 01, 2019](#)

**Background:** iBreastExam is a unique portable handheld non-invasive medical device which is developed in India to screen patients in rural and suburban areas. It employs a lead zirconate titanate piezoelectric cantilever sensor and can accurately detect abnormal areas by comparing the degree of deflection. Our tripled blinded study compares it with Clinical Breast Examination and Mammography and breast ultrasound.

**Methods:** 1019 women visiting a tertiary Indian hospital, for annual health check were recruited. Each woman was examined by three independent methods, each blinded to the other two: iBreastExam (iBE), Clinical Breast Examination (CBE) by an expert clinician and Breast Imaging (mammography or breast ultrasound).

**Results:** Out of 916 enrolled participants, 93 were confirmed by imaging to have at least one breast lesion. Clinical Breast Examination in comparison with imaging detected breast lesions with Sn = 65 %, Sp = 94 %, PPV = 52 %, NPV = 96 %, and iBreastExam reported Sn = 84 %, Sp = 94 %, PPV = 60 % and NPV = 98 %. In women below age 40 (314 participants), iBE detected breast lesions with Sn = 85 %, Sp = 93 %. All malignant lesions were identified by iBE, while one non-palpable malignant lesion was missed by clinician CBE.

**Conclusions:** The point-of-care Breast Imaging device (iBreastExam) performed with significantly better sensitivity, by 19 %, than CBE to detect breast lesions while reporting high specificity (94 %) and NPV (98 %). In younger women population under the age of 40 years, where the prevalence of dense breast is high, iBreastExam demonstrated high-performance characteristics. iBreastExam detected all malignant lesions in this study, while the clinician's CBE missed to detect a non-palpable malignant lesion. iBreastExam can be a promising tool to provide clinically effective and standardized breast examinations in low-resource settings to detect breast lesions at early stages. The device can also be an effective screening tool for younger women with dense breasts.

## Health worker led breast examination in rural India using electro-mechanical hand-held breast palpation device

Rohan Khandelwal<sup>1</sup>

[JCPCR Journal of Cancer Prevention & Current Research, Volume 9, Issue 3, 2018](#)

**Introduction:** The study was conducted with the aim to assess the feasibility of iBreastExam (iBE), a radiation free, painless, portable.

**Materials and methods:** 1300 female subjects, above 30 years were enrolled in the study over 6months and underwent both iBE and Clinical Breast Examination.

**Results:** Out of 1420 women who were approached for the study, 1300(91.5%) consented for the study, indicating acceptability rate for the technique. 146(11.2%) women were positive on either or both modalities and underwent breast ultrasonography. 18 patients were found to have significant lesions on USG, for which they underwent breast fine needle aspiration cytology or biopsy and 3 breast cancers were confirmed. All patients who consented for the study, were comfortable taking iBE test due to its radiation free and painless nature.

**Conclusion:** Breast examination by a radiation-free and painless electro-mechanical hand-held breast palpation device (iBreastExam) is socio-culturally acceptable in the rural environment. The device detected all clinically significant lumps. This study highlights the successful implementation of iBE in the community setting and its potential for mass breast cancer screening in rural environment.



## A cost-effective handheld breast scanner for use in low-resource environments: a validation study

Robyn B. Broach<sup>1</sup>, Rula Geha<sup>1</sup>, Brian S. Englander<sup>2</sup>, Lucy DeLaCruz<sup>1</sup>, Holly Thrash<sup>3</sup> and Ari D. Brooks<sup>4\*</sup>

[WJSO World Journal of Surgical Oncology, Volume 14, Issue 277, 2016](#)

**Background:** With the incidence of breast cancer rising worldwide, we are evaluating the iBreastExam (iBE) (UE LifeSciences Inc.), a handheld breast scanning device that can be utilized by community health workers to screen for breast abnormalities. The purpose of this study is to determine the sensitivity of the iBE in a population undergoing diagnostic breast imaging.

**Methods:** Adult patients presenting to a breast imaging center for a diagnostic workup were eligible. Patients underwent an iBE exam performed by a trained ultrasound technician followed by their indicated imaging. Demographic, imaging, and biopsy data were recorded.

**Results:** Seventy-eight iBE exams were completed, 77 females and one male with a mean age of 42 (21–79). All patients were evaluated by ultrasound, 52 had diagnostic mammography and 39 had biopsies. Imaging and/or biopsy confirmed a mass (fibroadenoma, cyst, papilloma, myofibroblastoma, fat necrosis, DCIS, or cancer) in 60 patients. Twelve patients had a cancer diagnosed. In total, 342 quadrants were scanned, 77 quadrants had lesions confirmed on imaging, and iBE correctly identified 66 lesions for a sensitivity of 86 % and specificity of 89 %.

**Conclusions:** This validation study demonstrated excellent sensitivity of iBE for the identification of clinically significant lesions in patients presenting for diagnostic imaging.

## Breast tumor detection using piezoelectric fingers: first clinical report

Xin Xu<sup>1</sup>, Cynthia Gifford-Hollingsworth, Richard Sensenig, Wei-Heng Shih, Wan Y Shih, Ari D Brooks

[Journal of the American College of Surgeons, Volume 216, Issue 6, 1168-73, 2013](#)

**Background:** Mammography is key to detection of breast cancer in high-risk populations. Currently, aside from palpation and risk-assessment questionnaires, there is no prescreening test that can improve the accuracy, safety, and cost effectiveness of screening low-risk populations. The piezoelectric finger (PEF) is a radiation-free, portable, and low-cost breast tumor detector we developed to be used as a prescreening tool.

**Results:** A total of 40 patients were enrolled and 46 lesions were confirmed by imaging or pathology. The PEF reported 55 lesions, with 9 false positives and 2 true positives not originally found on imaging or palpation. The overall sensitivity of the PEF test was 87% (40 of 46). In women 40 years old or younger, overall sensitivity was 100% (19 of 19). In women who had a lesion visible on mammography, PEF had a sensitivity of 83% (24 of 29). Of these, in women aged 40 years or younger, PEF identified all 7 mammographically visible lesions, including 2 malignant lesions. When compared with ultrasound, PEF correctly identified 87% (34 of 39) in this group. Of these, in women aged 40 years or younger, PEF identified 100% (19 of 19) of all ultrasound-visible lesions.

**Conclusions:** The PEF identified abnormalities in all 39 patients who presented with breast abnormalities and did not demonstrate any false negatives that would prevent the patients from additional evaluation, which makes it a good prescreening tool. In addition, PEF demonstrated 100% sensitivity in women aged 40 years or younger, a traditionally low-risk population.



# iBreastExam Implementation Projects

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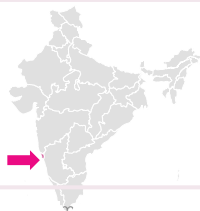


# Swasth Mahila Swasth Goa, Goa, India (ongoing)

📍 **Location:** Goa, India

🕒 **Duration:** October 2021 – ongoing

🎯 **Scanning Target:** 100,000 women



👥 **Partners:** Goa Health Ministry, SBI Foundation, Yuvraj Singh Foundation (YouWeCan)

✉️ **UELS Contact:** Dr Ruhi Agarwala

📰 **News:** [Times of India](#)

Women scanned with iBreastExam:  
**1,00,000** (Across 20 PHCs)

Lesions identified:  
**2000+**

Follow-ups with diagnostic imaging:  
**1400+**

Cancers confirmed:  
**52**



# Breast Cancer Awareness & Screening, Gujarat, India (ongoing)

- 📍 **Location:** Anand, Gujarat, India
- 🕒 **Duration:** March 2022 – ongoing
- 🎯 **Scanning Target:** 250,000 women



- 👥 **Partners:** Gokuldham Nar, Helping Hands for Humanity, Virginia, U.S.A.
- ✉️ **News:** [Video](#)

Women scanned with iBreastExam:  
**26,850**

Lesions identified:  
**240**

Follow-ups with diagnostic imaging:  
**100**

Cancers confirmed:  
**17**



# SEWA Maharashtra, India (Concluded)

📍 **Location:** Maharashtra, India

🕒 **Duration:** 12 months

🎯 **Scanning Target:** ?



👥 **Partners:** ?

✉️ **UELS Contact:** ?

📰 **News:** ?

Women scanned with iBreastExam:  
**101,226**

Lesions identified:  
**4,970 (4.9%)**

Follow-ups with diagnostic imaging:  
**490**

Cancers confirmed:  
**122 (0.1%)**



# Kannapuram model, Kerala, India (concluded)

**Location:** Kannapuram Village  
Kannur District, Kerala, India

**Duration:** 10 days

**Scanning Target:** All age-eligible women in the Kannapuram district



**Partners:** Kannapuram Gram Panchayat & Malabar Cancer Centre

**UELS Contact:** Dr Ruhi Agarwala

**News:** [American Society for Breast Surgeons](#) (Abstract).

Women scanned with iBreastExam:  
**3,247**

Lesions identified:  
**203 (6.3%)**

Follow-ups with diagnostic imaging:  
**137 (67%)**

Cancers confirmed:  
**3 (2.2%)**





# Support Letters & Testimonials

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HLL/HCS/2023-24/NOA/02

06.06.2023

**NOTIFICATION OF EMAPANELMENT**

UE LIFE SCIENCES (INDIA) PVT LTD,  
302 , RELCON HOUSE, M.G. ROAD, VILE PARLE (EAST),  
MUMBAI – 400057, MAHARASHTRA.  
EMAIL : [info@uelifesciences.com](mailto:info@uelifesciences.com)

Sir,

**Sub:** Notification of Empanelment as Technology Partner

**Ref:**

1. EOI for Identification of New Technologies in Emerging Business Areas in Healthcare and Technology Partners (EOI no. HLL/CHO/HCS/NT/2022-23/04 Dated 14-12-2022)
2. Offer submitted by you against ref no.1

With reference to above, we are pleased to inform you that, the expression of interest submitted by you against our invitation for identification of new technologies in emerging business areas in healthcare and technology partners has been accepted and you have been empanelled as a technology partner. Details are as below

| Technology Classification for empanelment         | Sub Classification   |
|---|--|
| Point of care Device with Integrated care Systems | Non invasive Hand held device for Radiation free breast cancer examination |


**Terms and Conditions**

1. This empanelment will be governed by the clauses and stipulations as detailed in the document of EOI no. HLL/CHO/HCS/NT/2022-23/04 Dated 14-12-2022 and its amendments.
2. Period of empanelment will be 60 months from the date of this Notification.
3. During the tenure of empanelment, as and when requirement arises, HLL will float Request for Quote among empanelled vendors

You are hereby requested to sign and stamp copy of this Notification of Empanelment and forward the same to us as a token of acknowledgment and acceptance.

Yours Truly,

For HLL Lifecare Limited



JAYAKUMAR.A  
DEPUTY GENERAL MANAGER (HCS)

**निगमित एवं पंजीकृत कार्यालय :**

एचएलएल भवन, पूजप्पुरा पी.ओ.  
तिरुवनंतपुरम - 695 012.  
केरल, इंडिया  
दूरभाष: +91 471 2354949,  
2350961, 2350959  
वेबसाइट : [www.lifecarehll.com](http://www.lifecarehll.com)  
सीआईएन : यु25193केएल1966जीओआई002621

**Corporate and Registered Office :**

HLL Bhavan, Poojappura P.O.,  
Thiruvananthapuram - 695 012.  
Kerala, India  
Tel : +91 471 2354949,  
2350961, 2350959  
Website : [www.lifecarehll.com](http://www.lifecarehll.com)  
CIN : U25193KL1966GOI002621



**NICPR**  
NATIONAL INSTITUTE OF CANCER  
PREVENTION AND RESEARCH

**NATIONAL INSTITUTE OF CANCER PREVENTION & RESEARCH**

**राष्ट्रीय कैंसर रोकथाम एवं अनुसंधान संस्थान**

(INDIAN COUNCIL OF MEDICAL RESEARCH)

भारतीय आयुर्विज्ञान अनुसंधान परिषद

Department of Health Research

स्वास्थ्य अनुसंधान विभाग

Ministry of Health & Family Welfare, Govt. of India

स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार

**Prof. Ravi Mehrotra**

MD, D.Phil, FRCPATH, FAMS

Director, National Institute of Cancer Prevention & Research

&

WHO FCTC Smokeless Tobacco Global Knowledge Hub

August 4<sup>th</sup>, 2016

To,  
Mihir Shah,  
Founder & CEO  
UE LifeSciences Inc.

**Subject: NICPR support for implementation monitoring and evaluation of breast cancer diagnostic devices.**

Dear Mr. Shah,

Considering the current scenario of breast, cervical and oral cancer in India, National Institute of Cancer Prevention and Research (ICMR) is interested in supporting innovations led initiatives that are bringing access to early detection of these cancers to the people of India. NICPR under ICMR is working with a mandate to "Undertake research for the development of preventive and therapeutic approaches for prevention/diagnosis of cancer in community settings" and "Community intervention studies for major cancers through health system research with emphasis on primary and secondary prevention".

It is my understanding that UE LifeSciences is looking to undertake various projects in public healthcare settings with the support of governmental and non-governmental agencies to implement an innovative breast cancer early detection device in several regions of India. In my view, such devices uniquely enables community health workers to provide standardized breast examinations to identify unsuspecting breast lesions at an early stage. The clinical protocol for using such a cancer device should be in line with the Lancet Review paper "Recommendations for screening and early detection of common cancers in India" authored by global thought leaders in cancer control including our team.

NICPR is supportive of implementation programs that bring this breast health examination device to underserved populations. NICPR is interested in providing support for implementation monitoring and evaluation of such programs. Our support will ensure that outcomes are documented, evaluated and reported to assist and advice future strategies to expand the use of such devices as well as in framing guidelines for secondary prevention of breast cancer at a national scale.

Sincerely,

Prof. Ravi Mehrotra

Director, NICPR

Plot No.1-7, Sector-39, Noida-201301 (UP) India

Tel.: PABX:(0120) - 2446900, Fax:(0120) - 2579473, Clinic:(0120) - 2446938

E-Mail:director@icmr.org.in, rmehrotra@icmr.org.in, director@nicpr@icmr.org.in

Website: www.nicpr.res.in



# DEPARTMENT OF RADIOLOGY

SIR J. J. GROUP OF HOSPITALS & GRANT GOVT. MEDICAL COLLEGE, BYCULLA, MUMBAI- 8.

क्ष-किरणशास्त्र विभाग,

ग्रॅन्ट शासकीय वैद्यकीय महाविद्यालय व सर ज. जी. समुह रुग्णालये, भायखळा, मुंबई - ८.

Tel no. 2373 5555 Extn: 2386 Email id: [radiodiagnosis@gmail.com](mailto:radiodiagnosis@gmail.com)

Date:- 07/10/2021

To,  
Dt. Executive Health Officer,  
NCD. Public Health Department,  
BMC..

Subject: - Regarding iBreastExam of UE LifeSciences  
Reference:- ref, HO/12724/AHOS Dt. 06/09/2022

The department is providing this letter of opinion regarding the use of iBreastExam for large scale screening of population developed by the team at UE LifeSciences for use in public health settings.

The iBreastExam led breast cancer screening program was rolled out in medical colleges across the State as a large scale screening programme was launched by Medical Education Minister of Maharashtra, Hon Shri Girish Mahajan to benefit the women of Maharashtra for breast screening.

The department has conducted screening from Oct 2016 to July 2019 for women visiting the department and at various organized camps. An approximate number of 25000 women were screened. This allowed early detection and treatment of silent cases.

Among Indian women, Breast Cancer is emerging as a significant cause of cancer related deaths. Most cases are diagnosed at late stages and with poor prognosis. A screening program for the early detection of breast cancer can help save thousands of lives and, is necessary for better treatment outcomes. India requires an affordable, accessible and user-friendly tool that can be offered in remote areas as well as in cities. iBreastExam hand held device can be an appropriate solution of utility and usability for Indian population having low resources and poor awareness.

Professor & Head,  
Department of Radiology,  
Sir J.J. Group of Hospitals &  
Grant Government Medical College,  
Mumbai – 400 008.

**Professor & Head**  
**Dept. of Radiology**  
Grant Government Medical College  
& Sir J.J. Group of Hospitals  
Mumbai 400 008



कामा व आल्ब्लेस रुग्णालय, मुंबई  
महापालीका मार्ग, मुंबई ४००००१  
**CAMA & ALBLESS HOSPITALS MUMBAI**  
Mahapalika Marg Mumbai -400001.

Email: - [suptd.camahospital@gmail.com](mailto:suptd.camahospital@gmail.com)

ph no:-022-22620390/2761181

Fax no:-2621197 2611667

Date-16/09/2022

## To Whom It May Concern


It is my great pleasure to provide this letter of support for the large-scale implementation of iBreast Exam, an innovative, non-invasive, hand-held, breast cancer screening, device developed by the team at UE Life-Sciences for use in public health settings. In 2016, Medical Education Minister of Maharashtra, Hon Shri Girish Mahajan, launched a first of its kind large-scale breast cancer screening program to benefit the women of Maharashtra using Breast Exam.

Among Indian women, Breast Cancer is now the leading cause of cancer related deaths. Most cases are diagnosed at late stages and with poor prognosis. A screening program for the early detection of breast cancer can help save thousands of lives and, is necessary for better treatment outcomes. Western solutions for screening are unfortunately not suitable for Indian conditions. In my opinion, what India requires is an affordable, accessible and user-friendly tool like iBreastExam that can be offered in remote areas as well as in cities.

The iBreastExam led breast cancer screening program was rolled out simultaneously in 16 medical colleges across the State to benefit over 2.5 lac women. As a Part of the Program iBreastExam unit was installed at Cama and Albless Hospital, Mumbai in 2016. Under my leadership we have continued screening women for Breast Cancer using iBreastExam. It has helped us screen over 4000 women. Several women have been identified and treated for early malignancies. Treatment of these women is ongoing. Given my experience, iBreastExam is a very adept device to help with primary screening of Breast Cancer.

This gives me great confidence to support the clinical utility and usability of iBreastExam in low-resource government settings.

Sincerely,



Dr. Tushar Palve,  
Medical Superintendent,  
Cama & Albless Hospital, Mumbai.

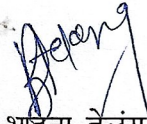
अधिक्षक,  
कामा व आल्ब्लेस रुग्णालय, मुंबई


|   |  |  |
|---|--|--|
|  <p>सत्यमेव जयते</p> | <p style="text-align: center;"><b>महाराष्ट्र शासन</b><br/><b>आरोग्य सेवा</b></p> <p style="text-align: center;">शासकीय प्रसुतीगृह व दवाखाना, उल्हासनगर-४ जि. ठाणे</p> <p>Email ID- <a href="mailto:wh.ulhasnagar-mh@gov.in">wh.ulhasnagar-mh@gov.in</a><br/><a href="mailto:hospitalulhas4@gmail.com">hospitalulhas4@gmail.com</a> / <a href="mailto:hospitalulhas@yahoo.in">hospitalulhas@yahoo.in</a></p> <p style="text-align: center;">दूरध्वनी क्र - 0251-2584903</p> |  <p>सर्वजनिक आरोग्य विभाग<br/>महाराष्ट्र शासन</p> |
|---|--|--|

दिनांक :- १८.०४.२०२३

TO WHOMEVER IT MAY CONCERN:

WE PURCHASED IBREASTEXAM DEVICE ON 1<sup>ST</sup> NOVEMBER 2022  
THE DEVICE HAS BEEN INSTALLED AT GOVERNMENT MATERNITY HOME  
AND DISPENSARY ULHASNAGAR 4 AND MY TEAM HAS BEEN SUCCESSFULLY  
TRAINED BY UE LIFESCIENCES TEAM. BREAST CANCER IS ONE OF LEADING  
CANCERS AMONGST WOMEN IN INDIA. ALMOST FIFTY PERCENT OF WOMEN  
DIE DUE TO BREAST CANCER BECAUSE OF LATE DETECTION. I BELIEVE THAT  
IBREASTEXAM IS A VERY ADEPT DEVICE FOR ITS RADIATION FREE AND  
PAINLESS AND CAN EASILY BE USED BY ANY HEALTHCARE WORKER. THUS,  
IT HAS THE POTENTIAL TO HELP US WITH EARLY DETECTION OF BREAST  
CANCER BOTH, WITHIN THE HOSPITAL AS WELL AS THROUGH CAMPS,  
THEREBY ENABLING US TO SAVE LIVES.


  
(डॉ. भाविना तेलंग)  
वैद्यकीय अधीक्षक,  
शासकीय प्रसुतीगृह व दवाखाना,  
उल्हासनगर-४

|   |   |
|---|---|
| <br>सत्यमेव जयते | (महाराष्ट्र शासन)<br>उपजिल्हा रुग्णालय शहापूर जि.ठाणे<br>फॅक्स - ९५२५२७/२७३४३६ कार्यालय - ९५२५२७/२७२०७४, २७२४६४ |
| आरोग्यसेवा  | जा.क्र.उजिरुश/<br>दिनांक १३.०३.२०२३   |

### To whomever it may concern

We purchased iBreastExam device on 01st Nov 2022

The device has been installed at Shahapur Subdistrict Hospital and my team has been successfully trained by UE LifeSciences team. Breast Cancer is one of leading cancers amongst women in India. Almost fifty percent of women die due to breast cancer because of late detection. I believe that iBreastExam is a very adept device for its radiation free and painless and can easily be used by any healthcare worker. Thus, it has the potential to help us with Early Detection of Breast cancer both, within the hospital as well as through camps, thereby enabling us to save lives.

  
वैद्यकीय अधिकारी  
उपजिल्हा रुग्णालय, शहापूर जि. ठाणे



# THE ASSOCIATION OF BREAST SURGEONS OF INDIA

**President:**

Dr.P.Raghu Ram

**President Elect:**

Dr.Diptendra Sarkar

**Founder President**

Dr.Devendra Patil

**Immediate Past  
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Dr.Chintamani

**Honorary Secretary :**

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**Director, Education &  
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**Director, Education &  
Training, West Zone**

Dr.Sanjay Deshmukh

**Director,Education &  
Training , East Zone**

Dr.S.N.Basak

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Dr.B.C.Ashok  
Dr.Rajshekhara Jaka  
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Dr.V.P.Singh  
Dr.Kumkum Singh  
Dr.Manish Kaushal

**Overseas Co-Ordinator**

Dr.Sankaran Narayanan

**Co-Opted Members**

Dr.Anand Sharma  
Dr.Geeta Kadayaprath



**Dr.P.Raghu Ram**  
President, ABSI



**Dr.Somashekhar S.P.**  
Hon.Secretary, ABSI

Date: August 16<sup>th</sup>, 2016

**Subject: Noninvasive and Low-Cost Technique for Early Detection of Clinically Relevant Breast Lesions Using a Handheld Point-of-Care Medical Device (iBreastExam)**

To Whom It May Concern:

The Association of Breast Surgeons of India (ABSIS) represents General Surgeons, Surgical Oncologists and Plastic Surgeons who treat patients with breast disease. It is committed to improving the art & science of breast surgery by serving as an advocate for surgeons who seek excellence in the care of patients with breast disease. The Association provides a forum for the exchange of ideas by promoting education & research with similar associations across the world.

The Fifth Annual Congress of ABSIS was organized @ ITC Gardenia from 1-3 July 2016 under my leadership (Dr. Somashekhar, Honorary Secretary & Chairman Organising Committee) actively assisted by Dr. Rajashekhar Jaka, Organising Secretary.

120 research papers were submitted and selected for presentation at the conference as poster from around the country. A 12-member evaluation jury panel was established composed of leading breast specialists from India to review these research papers. Criteria for evaluation were based on the excellence in research rigor, scientific merit, quality of execution and impact as well as benefit to the society. In a 3-tier selection process, each poster was evaluated and scored by each of the Jury panel members, leading up to a LIVE presentation by the top 10 posters at the ABSICON 2016 event. The winning paper was offered an Overseas Breast Fellowship in select Centers of excellence in the British Isles and would be badged by the Association of Breast Surgeons of UK.

**I attest and confirm that research paper titled "Noninvasive and Low-Cost Technique for Early Detection of Clinically Relevant Breast Lesions Using a Handheld Point-of-Care Medical Device (iBreastExam): Prospective Three-Arm Triple-Blinded Comparative Study" was selected as the best research paper presentation at the ABSICON 2016 meeting.**

Sincerely,

*Somashekhar S.P.*

Prof.Dr.Somashekhar SP  
MS,MCh(Onco),FRCS.Edinburgh  
Hon. Secretary ABSIS  
Chairman & HOD Surgical Oncology, Manipal Health Enterprise  
Consultant Surgical Oncologist, Manipal Comprehensive Cancer Center,  
Board Member, Business Advisory Board of MHEPL  
Editor-in-chief IJGO springer  
E-mail: absisec@gmail.com; somusp@yahoo.com



**Address:** ABSIS Secretariat, Prof.Dr.Somashekhar S.P., Dept. of Surgical Oncology, Manipal Hospital, Bangalore -17

**Email :** [absisec@gmail.com](mailto:absisec@gmail.com) **Web:** [www.absis.com](http://www.absis.com) **RSVP:** Ms.Suma, Office Secretary **Mobile:** 9731994690



## DIRECTORATE OF MEDICAL EDUCATION & RESEARCH

Govt. Dental College & Hospital Building 4<sup>th</sup> floor, St. George's Hospital Compound, P.D'mello Road, Mumbai - 400 001.  
Tel. No. - +91-22-22620361-65/22652251/57/59. Telegram "MEDUCATNSEARCH" Fax - +91-22-22620562/22652168  
Website : <http://www.dmer.org>

Dr. Suresh Barpande,  
Joint Director.

Date: 18<sup>th</sup> March 2017

### To Whom It May Concern

It is my great pleasure to provide this letter of support for the large-scale implementation of iBreast Exam, an innovative, non-invasive, hand-held, breast cancer screening, device developed by the team at UE Life-Sciences for use in public health settings. In 2016, Medical Education Minister of Maharashtra, Hon Shri Girish Mahajan, launched a first of its kind large-scale breast cancer screening program to benefit the women of Maharashtra using Breast Exam. As Joint Director of DMER, I was entrusted by the Hon. Medical Education Minister to oversee the rollout and implementation of this breast cancer screening program.

Among Indian women, Breast Cancer is now the leading cause of cancer related deaths. Most cases are diagnosed at late stages and with poor prognosis. A screening program for the early detection of breast cancer can help save thousands of lives and, is necessary for better treatment outcomes. Western solutions for screening are unfortunately not suitable for Indian conditions. In my opinion, what India requires is an affordable, accessible and user-friendly tool like iBreastExam that can be offered in remote areas as well as cities.

Under my leadership and with the steadfast commitment of UE Life Sciences team, the iBreastExam led breast cancer screening program was rolled out simultaneously in 16 medical colleges across the State to benefit over 2.5 lac women. The device was installed, hospital health workers are trained and the program was implemented at each hospital by the UE team in just under two weeks. In a short span of 5 months, over 20,000 women have received an iBreastExam test and over 30 early malignancies has been confirmed. Treatment of these women is ongoing. Given my experience, the team at UE Life sciences is very adept at device training, installation, implementation, mobilization and continuous monitoring of the program monitoring of the program progress.

The robust in Maharashtra gives me great confidence to support the clinical utility and usability of iBreastExam in low-resource government settings. I have no doubt that we will complete our stated milestone of 2.5 lac women very soon and will extend the goal to screen every woman in Maharashtra.

Sincerely,

**Dr. Suresh Barpande**  
Joint Director,  
Directorate of Medical Education and Research,  
Government of Maharashtra.



P. O. Moozhikkara, Thalassery,  
Kannur - 670 103, Kerala, S. India

# MALABAR CANCER CENTRE

(an autonomous centre under Government of Kerala)

Tel : +91 490 2355881  
Fax : +91 490 2355880  
E-mail : mcctty@gmail.com  
Website : www.mcctty.org /  
www.mcc.kerala.gov.in

August 9, 2018

## Letter of Recommendation

We have evaluated the usefulness of iBreast Exam in a Community based Breast Cancer Programme for 10 days between May 21-30, 2018. During the camp, our team screened more than three thousand age eligible women at Kannapuram Panchayath in Kannur District, Kerala. The final result is yet to be obtained as persons with abnormalities undergo further evaluation.

iBreastExam system has been found to be an extremely user friendly tool, for Nurses and Community Health workers at Point-of-Care, for the Breast Cancer Screening age eligible women, in large Communities.

We may be able to recommend the use of this device by Primary Care Clinics, Hospitals and NGOs, as a preliminary screening device for the Early Detection of Breast Cancers in age eligible women provided the study result favors.

Dr. Neethu A.P, MBBS, MHSc Public Health  
Head-in-charge,  
Department of Community Oncology



डॉ.एस.के.दास, एम.एस. भा.आ.नि.स्वा.से

वरिष्ठ विशेषज्ञ चिकित्सा अधिकारी (सर्जन)  
चिकित्सा अधिकारी - प्रभारी, एच.वी.एफ.अस्पताल

**Dr. S.K.DAS, M.S., IOFHS,**

Senior Specialist (Surgery)  
Medical Officer I/C, HVF Hospital

भारत सरकार  
रक्षा मंत्रालय  
भारी वाहन निर्माणी चिकित्सालय  
आवड़ी, चेन्नै - 600 054.

GOVERNMENT OF INDIA  
MINISTRY OF DEFENCE  
H.V.F. HOSPITAL  
AVADI, CHENNAI - 600054.

To

UE Lifesciences  
A-102, Universal Paradise,  
Nanda Patkar Road,  
Vile Parle, Mumbai-57

### To whomsoever it may concern

It is my great pleasure to provide this letter of support recommending iBreastExam, an innovative radiation free and ultra-portable handheld device; for early screening of women for breast abnormalities.

We, at Heavy Vehicle Factory, Chennai have been using iBreastExam device for the last 6 months and found it to be extremely useful and convenient in providing routine breast health check up to our staff and their families. It can be used by any trained healthcare worker to perform standardized breast examinations within ten minutes

This mhealth technology has excellent potential to provide painless, safe and affordable breast health check to women across all age group.

Also, I would like to thank you for providing additional support to Heavy Vehicles Factory, Chennai in its breast cancer awareness and screening initiatives.

Avadi,  
13<sup>th</sup> Oct.2018.



*Das*  
13/10/18  
(Dr. S.K. Das)  
Sr.Specialist (Surg)  
MO I/C HVF Hospital

डॉ.एस.के.दास, एम.एस. भा.आ.नि.स्वा.से  
**Dr.S.K.DAS, M.S., IOFHS.**  
वरिष्ठ विशेषज्ञ चिकित्सा अधिकारी (सर्जन) / चिकित्सा अधिकारी-प्रभारी  
Senior Specialist (Surgery) / Medical Officer I/C HVF Hospital  
भारत सरकार / रक्षा मंत्रालय  
GOVERNMENT OF INDIA / Ministry of Defence  
डॉ.एस.के.दास / एम.एस. भा.आ.नि.स्वा.से  
आवड़ी, चेन्नै / Avadi, Chennai - 600054

दूरभाष (का)  
Phone (Office) :  
044 - 2638 2992 / 0026  
044 - 2684 3081 / 3065

निवास  
Phone (Res.) :  
044 - 2684 8730  
044 - 2637 4065

फैक्स  
Fax :  
044 - 26378641  
044 - 26330026

ई.मेल  
E-mail :  
drsantos1@rediffmaili.com



# Regulatory Approvals & Miscellaneous Items

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July 16, 2019

UE LifeSciences Inc.  
Mihir Shah  
CEO  
3401 Market St, Suite 200  
Philadelphia, PA 19104

Re: K190575/S001  
Trade/Device Name: iBreastExam Gen II  
Regulation Number: 21 CFR 884.2990  
Regulation Name: Breast Lesion Documentation System  
Regulatory Class: II  
Product Code: NKA  
Dated: June 11, 2019  
Received: June 12, 2019

Dear Mihir Shah:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.



सत्यमेव जयते

## FORM MD-5

[See sub-rule (4) of rule 20 and sub-rule (6) of rule 20]

Licence to Manufacture for Sale or for Distribution of Class A or Class B medical device

Licence Number: MFG/MD/2023/000375

1. M/s UE LifeSciences (India) Pvt Ltd, A 102 Universal Paradise Nanda Patkar Road Vile Parle East, Mumbai Mumbai, Mumbai City, Maharashtra (India) - 400057 Telephone No.: 02226102610 FAX: 2226102610 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s UE LifeSciences (India) Pvt Ltd, 302 Relcon House MG Road, Vile Parle (East) Mumbai, Mumbai City, Maharashtra (India) - 400057 Telephone No.: 022 26102610 FAX: 022 26102610

2. Details of medical device(s) [Annexed]

3. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

### ANNEXURE

| S.No. | Details Of Device(s)  |
|-------|---|
| 1     | <p>Generic Name:iBreastExam<br/>Model No.:NIL<br/>Intended Use:iBreastExam™ (iBE) device is intended to produce a surface map of the breast as an aid in documenting breast lesions identified in the breast. iBreastExam™ device is intended for use by a qualified healthcare professional trained in its use.<br/>Class of medical device:Class B<br/>Material of construction:ABS material<br/>Dimension(if any):Probe size: 13 x 6.5 x 8.5cm, weight: 0.5kg.<br/>Shelflife:NIL<br/>Sterile or Non sterile:Non-Sterilized<br/>Brand Name(if registered under the Trade Marks Act, 1999):iBreastExam</p> |

Place:

Date:12-Apr-23

State Licensing Authority



# Certificate of Compliance

This is to certify that the technical documentation for the product:

**IBreastExam Medical Device**  
(Product Details as per Annexure 1)

Manufactured by:

**UE LifeSciences (India) Pvt. Ltd.**

302, Trimbak Niwas, Relcon House, M.G. Road, Ville Parle (East), Mumbai - 400057  
(Maharashtra), India.

Complies with the applicable requirements of **Medical Devices Directive 93/42/EEC**  
**Class I Medical Device**

The technical documentation / inspection / test results comply with the requirements of **Medical Devices Directive (MDD)**, hence manufacturer's declaration of conformity according to above directive is accepted. **UE LifeSciences (India) Pvt. Ltd.** can place the CE marking as per laid down regulations on the Products listed in Annexure.

**Certificaat Nummer / Certificate No. : CE-BV-2212-5889**

Date of This Certificate Issue : 22/12/2022  
Vervaldatum / Date of Expiry : 21/12/2025  
Ist Annual surveillance audit due on : 21/10/2023  
IInd Annual surveillance audit due on : 21/10/2024

**Director (Certification)**

**Royal Stancert B.V.**

**Feitelijke Beoordelingen - Wereldwijde Beoordelingen**

**Regd. Office** - Joop Geesinkweg 701, 1114 AB Amsterdam, The Netherlands.  
(KvK-Nummer 71431802 / RSIN 858713159 - Rechtsvorm - Besloten Vennootschap).

This certificate remains the property of **Royal Stancert B.V.** and must be returned whenever demanded. The validity of this certificate can be verified at <http://www.royalstancert.org>. **Royal Stancert B.V.** is an independent system, product and personal assessment body accredited by Global Euro Accreditation Centre, Georgia. (GCIN - 654). Email: [info@royalstancert.org](mailto:info@royalstancert.org)

**CE**

19995



PAC-GEAC-1506-299



# CERTIFICATE

This is to Certify that the Management System of

## UE LifeSciences (India) Pvt. Ltd.

Head Office :- 5th Floor, B/105, Brij Bhoomi, Nehru Road, Vile Parle East,  
Mumbai Suburban, Mumbai - 400057, Maharashtra, India

Site Address :- 302, Trimbak Niwas, Relcon House, M.G. Road,  
Vile Parle (East), Mumbai - 400057, Maharashtra, India

has been audited and found to comply with the requirements of:

## ISO 13485:2016 (Medical Devices – Quality Management System)

For the Scope of activities described below:

Manufacture of Medical Device (iBreastExam, Selfi and cervAlcal)

*Certificate No.:* IN231025003

| <i>Date of initial registration</i> | <i>Date of this Certificate</i> | <i>Surv. audit on or before/ Certificate expiry</i> | <i>Recertification Due</i> |
|-------------------------------------|---------------------------------|---|----------------------------|
| 31 October 2022*                    | 25 October 2023                 | 30 October 2024                                     | 30 October 2025            |

Validity of this certificate is subject to successful completion of surveillance audit on or before due date, in case surveillance audit not conducted this certificate shall be suspended/cancelled.



\*(Note:- Certification Registration is Transferred from LMS Certifications Ltd. So Date of Initial Registration is Subject to previous Registrar. Due to change in Procedural requirements Certificate Numbering has been changed from IN97607H to IN231025003)

*Director*

For verification and updated information concerning the present certificate visit to [www.lmscert.uk/www.lmscert.com](http://www.lmscert.uk/www.lmscert.com)  
This certificate is property of LMS Assessments Limited and remains valid subject to satisfactory surveillance audits and shall be returned immediately when demanded.

### Accreditation



### LMS Assessments Limited

Bartle House, Oxford Court, Manchester,  
M2 3WQ(United Kingdom)  
Phone : +44-7904664589

Visit :- [www.lmscert.uk/www.lmscert.com](http://www.lmscert.uk/www.lmscert.com)

E-mail :- [info@lmscert.uk](mailto:info@lmscert.uk)

(Company Regd. No. 11029176 Registered in England and Wales)



LMS/EGAC/F109Q/19/REV00



# CERTIFICATE

This is to Certify that the Management System of

## UE LifeSciences (India) Pvt. Ltd.

Head Office :- 5th Floor, B/105, Brij Bhoomi, Nehru Road, Vile Parle East,  
Mumbai Suburban, Mumbai - 400057, Maharashtra, India

Site Address :- 302, Trimbak Niwas, Relcon House, M.G. Road,  
Vile Parle (East), Mumbai - 400057, Maharashtra, India

has been audited and found to comply with the requirements of:

### ISO 9001:2015 (Quality Management System)

For the Scope of activities described below:

Manufacture of Medical Device (iBreastExam, Selfi and cervAlcal)

Certificate No.: IN231025002

| <u>Date of initial registration</u> | <u>Date of this Certificate</u> | <u>Surv. audit on or before/ Certificate expiry</u> | <u>Recertification Due</u> |
|-------------------------------------|---------------------------------|---|----------------------------|
| 31 October 2022*                    | 25 October 2023                 | 30 October 2024                                     | 30 October 2025            |

Validity of this certificate is subject to successful completion of surveillance audit on or before due date,  
in case surveillance audit not conducted this certificate shall be suspended/cancelled.



\*(Note:- Certification Registration is Transferred from LMS Certifications Ltd. So Date of Initial Registration is Subject to previous Registrar.  
Due to change in Procedural requirements Certificate Numbering has been changed from IN97607A to IN231025002)

Director

For verification and updated information concerning the present certificate visit to [www.lmscert.uk/www.lmscert.com](http://www.lmscert.uk/www.lmscert.com)  
This certificate is property of LMS Assessments Limited and remains valid subject to satisfactory surveillance audits  
and shall be returned immediately when demanded.

#### Accreditation



LMS Assessments Limited  
Bartle House, Oxford Court, Manchester,  
M2 3WQ(United Kingdom)  
Phone : +44-7904664589  
Visit :- [www.lmscert.uk/www.lmscert.com](http://www.lmscert.uk/www.lmscert.com)  
E-mail :- [info@lmscert.uk](mailto:info@lmscert.uk)

(Company Regd. No. 11029176 Registered in England and Wales)



LMS/EGAC/F109Q/19/REV00



# CERTIFICATE

This is to Certify that the Management System of

## UE LifeSciences (India) Pvt. Ltd.

Head Office :- 5th Floor, B/105, Brij Bhoomi, Nehru Road, Vile Parle East,  
Mumbai Suburban, Mumbai - 400057, Maharashtra, India

Site Address :- 302, Trimbak Niwas, Relcon House, M.G. Road,  
Vile Parle (East), Mumbai - 400057, Maharashtra, India

has been audited and found to comply with the requirements of:

### GMP (Good Manufacturing Practice)

For the Scope of activities described below:

Manufacture of Medical Device (iBreastExam, Selfi and cervAlcal)

*Certificate No.: IN97607U*

| <u>Date of initial registration</u> | <u>Date of this Certificate</u> | <u>Surv. audit on or before/ Certificate expiry</u> | <u>Recertification Due</u> |
|-------------------------------------|---------------------------------|---|----------------------------|
| 31 October 2022                     | 25 October 2023                 | 30 October 2024                                     | 30 October 2025            |

Validity of this certificate is subject to successful completion of surveillance audit on or before due date,  
in case surveillance audit not conducted this certificate shall be suspended/cancelled.



Director

For verification and updated information concerning the present certificate visit to [www.lmscert.com](http://www.lmscert.com)

This Certificate is the property of LMS Certification Limited and shall be returned immediately when demanded.



Membership

**GQNet**

**LMS Certification Limited**

Labrynth Business Centre, 43 Middle Hill Gate, Stockport,

Great Manchester, England-SK1 3DG

Phone :+44 208 935 5094

Company No.: 11029176

Visit :- [www.lmscert.com](http://www.lmscert.com)

E-mail :- [info@lmscert.com](mailto:info@lmscert.com)

LMS/GQNET/F109Comp/17/REV02



## Technical Specifications for iBreastExam

1. **Non-invasive, radiation-free, breast examination**
2. **Ultra-Portable and light-weight probe.** Probe size: 13 x 6.5 x 8.5cm, weight: 0.5kg. Full system with case size: 27 x 26 x 11cm, weight: 2kg.
3. **Operable with rechargeable battery** (1000 to 2000 mAh). Recharging Power: Input 110-220v 50/60Hz at 0.3-0.5A and Output 5v at 2A.
4. **Sensor Technology**
  1. 648 Dynamic Co-Planar Capacitive (DCPC) Sensor
  2. Measurement of tissue elasticity 20 times per second
5. **Wireless operation** using Bluetooth 2.0 standard protocol
6. **Regulatory Clearances & Approvals**
  1. **US FDA cleared Registration# K190575/S001**
  2. **CE Marked Certificate# CE-BV-2212-5889**
  3. **ISO 13485 Certificate# IN97607H**
  4. **GMP Certificate# IN97607U**
7. **Storage capacity** up to 50000 breast examination scans and full reports. \*
8. **Custom Mobile Application for Breast Examination with capabilities to:**
  1. Perform breast examination
  2. Store the breast examination data and
  3. Print the final report
9. **Replay feature** enables the physician to replay a breast examination performed in the past, frame by frame.
10. **Approved for Electromagnetic Compatibility (EMC) Test** 1409-054EA REV. A TEST STANDARDS: IEC 60601-1-2:2007 (3RD EDITION) & IEC 60601-1-2:2014 (4TH EDITION)
11. **Approved for the following Electrical and Mechanical Safety Tests**
  1. IEC 60601-1 Ed.3 (2005) + Am.1 (2012) = IEC 60601-1 Ed.3.1 (2012)
  2. The following National Deviations were included in the evaluation: - AAMI/ANSI ES 60601-1:2005(R) 2012/A1
  3. EN 60601-1 Ed.3 (2007) + Am.1 (2013)
  4. CSA C22.2 No. 60601-1:2014
12. **Clinical study validation performance characteristics: \*\***
  1. Sensitivity is 84%
  2. Specificity is 94%
  3. Negative Predictive Value is 98%
  4. Positive Predictive Value is 60%
13. **Storage, Transport and Operating conditions:**
  1. Temperature range in Use:  
For iBreastExam -10C to 40C  
For Mobile Device 0C to 35C
  2. Maximum relative humidity: 90%
  3. Atmospheric pressure range: 700- 1060 hPa
  4. Store in a dry, cool place away from heat, humidity and direct sunlight

\*Storage capacity can be higher based on mobile device storage.

\*\* Based on 2016 IJGO study.

# Awareness handout for rural area

## Test yourself. By yourself.



When bathing



While looking in the mirror



Before sleeping

If you feel irregular changes in your breasts, contact your doctor right away

For more information:  
**Call 022 2610 2610**

## Some Common Questions...

**Que:** How does iBE detect lumps in the breast?

**Ans:** Lumps in the breast are hard/stiff. iBE is an innovative device that is capable of detecting this hardness/stiffness.

**Que:** How long does an iBE test take?

**Ans:** Approximately 8-10 minutes.

**Que:** Is breast cancer treatable?

**Ans:** Yes. When detected early, breast cancer is highly treatable. Many governmental schemes are available to make treatment cost effective or even free.

**Que:** After what age is it beneficial to get tested by iBE?

**Ans:** Risk for breast cancer increases with age. After age 30, every woman, every year, should get a breast examination.

**Que:** How is iBE test done? Is there pain in the test?

**Ans:** iBE test is done privately and only by a female. There is no pain in this test.

**Que:** Can pregnant women and breast-feeding women get iBE test?

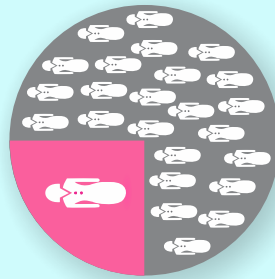
**Ans:** Yes. iBE is a safe test. iBE does not use x-ray radiation and hence there is no possibility of harm.



## Breast Cancer Awareness Campaign



**1 in 25** women are at risk for getting breast cancer



so earlier the detection, better the results



**This Breast Health Screening camp will help you**

**1** Understand primary signs of breast cancer

**2** Learn Breast Self Exam

**3** Receive innovative and private breast exam. for free

iBE is an innovative tool developed in the USA that can detect hidden lumps in the breast.

In the camp, iBE test will be provided to you privately and only by a woman



**90% of breast lumps are not harmful**

but when detected, further testing is necessary

If a lump is detected at the camp by iBE test...

1. Meet your doctor and show the location of the lump
2. Consult your doctor about ultrasound of the breast

# India's Largest Health PSU HLL to Scale iBreastExam Across India

*Alliance with UE LifeSciences Democratizes Women's Health in India*

**HLL Lifecare Limited**, a Government of India Enterprise, has joined hands with **UE LifeSciences** to combat breast cancer in India by providing sales, marketing and distribution support for the **iBreastExam** nationwide.



K. Beji George IRTS, Chairman and Managing Director of HLL expressed happiness in the collaboration, stating *"We are delighted to partner with UE LifeSciences to expand our women's health product portfolio. With iBreastExam, we can provide access to early detection of breast cancer to every woman, right at their doorstep. The collaboration is set to benefit millions of women across India and save numerous lives."*

iBreastExam offers a standardized process for clinical breast exams, eliminating variabilities in the examination process and the training challenges. Given the issues associated with mammogram screening in low resource settings, this device serves as a practical alternative for safe and effective triaging.

Breast lumps are stiffer than normal breast tissue. iBreastExam incorporates Dynamic Co-Planar Capacitive (DCPC) Sensor Technology that measures the differences in tissue elasticity, in real-time, at the point of care and without requiring manual interpretation. It helps in identifying and triaging for clinically relevant breast lumps in healthy, asymptomatic women. Being hand-held, non-invasive, ultra-portable and radiation-free, it helps to bring early detection to women in the community, where they live and work. iBreastExam also facilitates seamless patient follow-up by securely storing data on the cloud.

iBreastExam has undergone over 8 independent clinical studies to validate the accuracy, effectiveness and acceptability in women. These independent studies were conducted by prestigious cancer research centers such as the Malabar Cancer Center (India), The Memorial Sloan Kettering Cancer Center (USA) and others. The results have been published in peer-reviewed high-impact international journals. The device has already obtained regulatory approvals in over 12 countries including US FDA, CE Mark, CDSCO and others.

This cost-effective solution has the potential to bring down the average cost per breast health checkup to approximately Rs 500. UE LifeSciences has supplied 2.5 million iBreastExam scans across South Asia, Southeast Asia and Latin American markets.



**BUSINESSTODAY**

**NEW STRAITS TIMES**

## Malaysia's Leading Pharma Company to Scale iBreastExam across Malaysia

*Collaboration To Make Early Detection Easy & Accessible, Help Save Many Lives*

**KUALA LUMPUR, JULY 20 2023** – Malaysia's top ranking pharma company, Duopharma Biotech Berhad ("Duopharma Biotech") through its wholly-owned subsidiary, Duopharma Marketing Sdn Bhd ("Duopharma Marketing"), has signed a Distribution Agreement to scale iBreastExam in Malaysia with U.S. based women's health innovator company, UE LifeSciences Inc.'s Malaysian wholly-owned subsidiary UE LifeSciences Sdn Bhd ("UE LifeSciences"). The collaboration is set to launch and scale the *iBreastExam* across Malaysia, a breakthrough innovation for radiation-free, clinically effective and accessible breast cancer early detection for women of all ages and demographics.

According to Malaysia's National Cancer Registry 2019, Late-stage cancer presentation is Malaysia's biggest challenge with the NCR reported alarming trends. In 2012-2016 the percentage diagnosed at late stage (Stage III, IV) increased to nearly 48%. This highlights the importance of early detection of breast cancer in increasing the chance of successful treatment and reducing cancer-related mortality. The incidence for breast cancer is highest in age groups 35 – 75 years.

Under the distribution partnership, UE LifeSciences and Duopharma Biotech plan to collaborate with private and governmental healthcare sectors by making iBreastExam available at primary-care clinics across Malaysia to bridge the lack of access to early detection. The collaboration will empower frontline healthcare providers with the mobile tools to drive preliminary screening in the community, where women live and work. The device is designed for use by frontline health workers, nurses, primary care providers and NGOs operating in the women's health areas. It is quick, user friendly and requires minimal training.

[Full Press Release](#)

# 50,000 women screened for Breast Cancer under The 'Swasth Mahila, Swasth Goa' Initiative with iBreastExam

[theprint.in/ani-press-releases/50000-women-screened-for-breast-cancer-under-the-swasth-mahila-swasth-go-initiative-with-ibreastexam/1343416/](https://theprint.in/ani-press-releases/50000-women-screened-for-breast-cancer-under-the-swasth-mahila-swasth-go-initiative-with-ibreastexam/1343416/)

January 30, 2023



'Swasth Mahila, Swasth Goa' Event

Panaji (Goa) [India], January 30 (ANI/PNN): Breast cancer screening of 50,000 women across Goa has been successfully completed under the 'Swasth Mahila, Swasth Goa' initiative, an innovation-led public health initiative of cricketer Yuvraj Singh's YouWeCan Foundation, the Government of Goa, the SBI Foundation and UE LifeSciences. Launched in October 2021, the project aims to screen 1 lakh women in Goa for breast cancer over

two years, ensuring that approximately 50% of the age-eligible female population in the State is screened. The SBI Foundation & the Indian Institute of Banking and Finance have funded the project and UE LifeSciences is the technology partner.

The initiative offers 1,00,000 women free education, awareness, and breast examinations with the help of iBreastExam, an award-winning, US FDA-cleared hand-held medical device. The device allows health workers to identify breast lumps within minutes, instantly at the point of care, without any pain or harmful radiation.

“We now have an excellent technology-led program to win the fight against breast cancer by making early detection reach women right in the community,” said Vishwajeet Rane, Health Minister of Goa. He added, “iBreastExam has a big impact in Goa. It has enabled us to screen 50,000 women quickly and effectively identify early-stage breast lumps before it is too late. We can track every breast exam and navigate the patients to timely treatment. Most of these women had never received a preventive breast exam before.”

Regarding the progress of this project, Yuvraj Singh said, “I am delighted that we have successfully screened over 50,000 women through the Swasth Mahila Swasth Goa Initiative. I thank Vishwajeet Rane, Honourable Health Minister of Goa, for his unconditional support in making this project a success. I also thank our CSR partners, SBI Foundation, and The Indian Institute of Banking and Finance and our technology partner UE LifeSciences. Most importantly I wholeheartedly thank the true heroes, all the doctors, nurses and healthcare professionals from the Directorate of Health Services, Goa Medical College and the YouWeCan team for making this project a great success.”

Dr Anupama Borkar said that “The initiative is working really well. So far 1241 suspected breast tissue anomalies were detected out of which 24 asymptomatic women with early-stage breast cancer were diagnosed and treated. The average age of the population screened is 44 years and that of the diagnosed patients is 43 years.”

The Swasth Mahila, Swasth Goa initiative provides women with Breast Cancer S.E.W.A. – Screening, Education, Wellness, and Awareness for breast cancer. It creates a patient-friendly healthcare ecosystem for referrals and follow-up for free breast cancer diagnosis and treatment. Free-of-cost breast cancer screening is being conducted at 35 Health Centres across Goa, along with multiple outreach camps. 24 asymptomatic women with early-stage breast cancer have been diagnosed and treated. All the suspected cases have been referred to the Goa Medical College & Hospital and district hospitals for further investigations and complete treatment. It is to be noted that free treatment is being provided for all positive cases with the support of the Government of Goa.

As per Sanjay Prakash, Managing Director & CEO, SBI Foundation, “I congratulate all stakeholders on achieving this huge landmark. We must use this momentum to collectively strive harder to reach our target of screening 1 lakh women at the earliest to attain our objective of Swasth Mahila Swasth Goa, thereby making Goa a model state for breast cancer screening.

“Innovations like iBreastExam ultimately depend on last-mile partners to make that life-saving impact in the community. We are thankful to Rane, the entire team of the Goa Government and the health workers who are dedicating their time and effort to bring women life-saving access to early detection. We share the success with YouWeCan Foundation and thank SBI Foundation and IIBF for the CSR support”, said Gauri Godse-Navalkar, UE LifeSciences Country Head – India.

The YouWeCan Foundation is a non-profit organization registered under the Bombay Public Trust Act 1950. Established by international cricketer and cancer survivor Yuvraj Singh in 2012, the Foundation works extensively in the field of cancer control in India, focusing on awareness, screening, patient support, and survivor empowerment. To date, 1,50,000 people have been screened by the Foundation for different types of cancer, 1,25,000 students have been sensitized in anti-tobacco workshops, 30,000 women have been sensitized on self-breast examination, and 24,000 men have been counselled for tobacco cessation. Moreover, 150 cancer survivor students have been supported through the YouWeCan Scholarship, and 15 people have been supported through the YouWeCan Cancer Treatment Fund. [www.youwecan.org](http://www.youwecan.org).

SBI Foundation is the CSR arm of the State Bank of India. True to its tradition of service beyond banking, the foundation currently works in over 27 states and union territories of India on rural development, healthcare, education, livelihood and skill development, youth empowerment, promotion of sports, and more. SBI Foundation believes in reflecting the ethos of the SBI group in running ethical interventions, promoting growth and equality, and creating a positive impact on society. [www.sbifoundation.in](http://www.sbifoundation.in)

UE LifeSciences is an award-winning women’s health company making early detection of leading cancers in women equitable and accessible globally. Its hallmark product, iBreastExam, is an FDA-cleared hand-held device that enables primary health workers to identify breast lumps early, in just a few minutes, without any pain or radiation. Over 2 million breast exams are enabled worldwide. UE LifeSciences is a member of the American Cancer Society and UICC (Union for International Cancer Control). Recently the company has announced a US distribution partnership with Siemens Healthineers and has won the Global Women’s HealthTech award from The World Bank, IFC, and CTA. [www.uelifesciences.com](http://www.uelifesciences.com)



UE LifeSciences wins  
**Global Women's  
HealthTech Award**  
at CES 2022 from:



## Winning Solutions for Women's Health

Jan 5, 2022 – Las Vegas, NV

The Global Women's HealthTech Awards recognizes innovative startups that leverage tech to improve women's health and safety in emerging markets.

UE LifeSciences has developed the iBreastExam, a radiation-free device that is easy to use and requires minimal training for operators. The company has reached almost a half a million women globally, detecting hundreds of breast cancers.

“This prestigious recognition highlights UE LifeSciences’ breakthrough innovations for enabling access to early detection of some of the most common and deadly cancers. This award will help us realize our mission to make early detection of breast and cervical cancers equitably accessible all over the world,” said Mihir Shah, the company’s founder and CEO.



## UE LifeSciences and Siemens Healthineers Launch iBreastExam in the U.S.

Commitment to improving breast cancer outcomes brings two organizations together

**Philadelphia, PA (January 18, 2022)** – [UE LifeSciences](#) has entered into a definitive distribution agreement with [Siemens Healthineers](#), adding its flagship device iBreastExam to Siemens' 360-degree breast care product portfolio for the U.S. market.

The two organizations unite to improve outcomes for a disease that impacts 1 in 8 women (in the U.S.) during their lifetime; a disease that disproportionately affects Black and Hispanic women and one that is [projected to claim the lives of 43,600 women this year](#).



“We’re committed to improving breast cancer-related outcomes by recognizing unmet needs in healthcare delivery, and UE LifeSciences’ iBreastExam clearly addresses a well-defined niche in primary care,” said Niral Patel, Vice President of X-ray Products for Siemens Healthineers. “With iBreastExam we’re making women’s health more equitable and inclusive for all populations.”

In a peer-reviewed study published by the American Society of Clinical Oncology in 2020, [iBreastExam](#) was noted as a solution to the ‘need for additional triage mechanisms’ for reducing the pool of ‘true negatives’. At CES 2022, UE LifeSciences received the [Global Women’s HealthTech Award](#) from The World Bank, IFC and the Consumer Technology Association.

“An objective, quick, and painless documentation of routine breast exams inform and empower care providers and women, especially those younger than 40, with dense breasts, or with family history,” said Dr. Brian Englander, Chairman of the Department of Radiology at Pennsylvania Hospital.

iBreastExam is an FDA cleared, hand-held breast examination device that optimizes the doctor’s routine clinical breast exam, making it objective and traceable with automated digital documentation that can be attached to the patient’s electronic health record. Under the multi-year collaboration with UE LifeSciences, Siemens Healthineers will harness its interdisciplinary national sales team to bring the innovative technology to hospitals, health systems and women’s health providers across the country.

“Siemens Healthineers is an undisputed leader in healthcare innovation, and we’re proud to collaborate with them to accelerate the shared mission of improving access to care for women everywhere,” said Mihir Shah, founder and president of UE LifeSciences. “We have the means of addressing these disparities meaningfully, if we embrace data and technology that can augment existing mechanisms,” Shah added.

UE LifeSciences and Siemens Healthineers will begin co-marketing the iBreastExam in Q4 2021, making it available to healthcare providers by January 2022. For sales inquiries, please contact Jeff Bell at [Jeffrey.t.bell@siemens-healthineers.com](mailto:Jeffrey.t.bell@siemens-healthineers.com).

# The New York Times

## A New Way to Detect Breast Cancer

For poorer people in India and many other countries, a computer engineer has found a way to detect breast cancer without radiation.

By Sophie Cousins

Ms. Cousins writes about health issues and gender inequality in South Asia.

Aug. 28, 2018



Not long before Mihir Shah was to be married in 2007, his soon-to-be mother-in-law got a diagnosis of breast cancer. She underwent chemotherapy and survived, wearing a wig to the wedding.

But while the women in Mr. Shah's family — in both India and the United States — were able to get breast cancer screening, it made him think of the millions who weren't as fortunate.

More than 90 percent of women in the developing world don't have access to early detection of breast cancer. One reason is that mammograms, the gold-standard screening technique, are rarely used because of their high cost and a lack of trained radiologists. India has one radiologist for every 100,000 people; the United States has 12.

Then there are logistical challenges like a lack of electricity and poor roads. Many people are not aware of cancer, and the disease still carries a stigma. As a result, patients turn up for treatment at advanced stages of the disease. Too often, a quick death is inevitable.

In the United States, 90 percent of women with breast cancer survive five years. In India 66 percent do; in Uganda only 46 percent do. Every year more than 70,000 Indian women die of breast cancer, more than anywhere else in the world.

Such poor survival statistics propelled Mr. Shah, a computer engineer, to ask: Is it possible to offer women breast cancer screening that doesn't rely on mammograms?

He knew that whatever device he designed would have to be usable by community



iBreastExam is a very portable battery-operated wireless machine that records variations in breast elasticity. Credit Sophie Cousins

health care workers, the backbone of most developing countries' health systems. It would also have to be portable and battery operated. And screening would have to be affordable and painless.

Using a new ceramic sensor technology developed at Drexel University's School of Biomedical Engineering, Science and Health Systems in Philadelphia to detect subtle variations in breast tissue, Mr. Shah and his colleague Matthew Campisi developed iBreastExam, a battery-operated wireless machine that records variations in breast elasticity. It's hand-held and allows health care workers to perform breast examinations in five minutes, anywhere. Painless and radiation-free, it provides results just a few minutes after the exam through a mobile app, which also records patients' data

In 2015, Mr. Shah asked Dr. Brian Englander,

an associate professor of clinical radiology at the Perelman School of Medicine at the University of Pennsylvania, to lead an evaluation of iBreastExam. Dr. Englander first assumed the technology would fail.

"Mammography is the standard of care," he said. "Anything that deviates from it, we're skeptical."

But his doubts didn't last long. The study, published in the World Journal of Surgical Oncology, concluded that the device demonstrated excellent sensitivity, meaning it was able to correctly detect clinically significant lesions in patients.

"I hope something like the iBreastExam would be accepted in the United States because there's places and groups that don't have access" to breast cancer screening, Dr. Englander said.

Dr. Englander points to the number of women in the United States who refuse mammograms because they fear radiation or lack access to radiologists, and the millions of women who simply choose not to go for mammograms for a host of other reasons. It's this gap where Dr. Englander sees a potential role for iBreastExam in the future. It could be performed by a general practitioner during a routine checkup as a pre-screening, to help identify masses that need to be investigated further, just as it's used in India and other less developed countries.

On a winter afternoon in the southern Indian state of Karnataka, women lined up at their local primary health center in Hennagara village, about an hour and a half's drive from Bengaluru, the capital.

The women had walked from neighboring villages after learning from community health care workers that there would be a free breast and cervical cancer screening camp. It is run by Biocon Foundation, one of the few nongovernment organizations in India that offer free cancer screening for the poor. For many of the women, it's the first time they had heard about cancer and had the opportunity to be screened.

Dressed in a yellow and brown sari, Muniyallamma, 65, laid down on a gurney for an iBreastExam. A health care worker, Veda Kn, held the white and pink scanner in one hand and a cellphone in the other. She went over the four quadrants of each breast with the scanner. The device communicated wirelessly with the cellphone to display and store the findings in real time.

Green would indicate normal breast tissue, and red would mean a lesion was detected, suggesting the need for further testing at a nearby hospital.

Just a few minutes later Muniyallamma, who gave only her first name, got her results: She was in the clear.

"It was fine," she said. "It was no problem. It didn't hurt."

Before Muniyallamma left the primary health center, Veda Kn showed her how to do her own breast examination and explained some of the common symptoms of breast cancer, including nipple discharge and swollen glands.

The device is currently in use in Mexico, Nepal, Myanmar, Indonesia, Oman and Botswana. In the next 12 months, its developers plan to expand its use to more Southeast Asian and African countries.

It takes four to eight hours to train a health care worker to use iBreastExam. Every health care worker undergoes a test before being certified.

In the absence of a nationwide population-based cancer screening program in India, the device is used in some private hospital



The iBreastExam enables painless, radiation-free screenings. Sophie Cousins

chains, medical colleges, nongovernment organizations and state governments, and among community health care workers.

In 2016, the western Indian state of Maharashtra began the country's first campaign to screen over 250,000 women using iBreastExam, with the state government committed to providing free or heavily subsidized follow-up measures when indicated, including ultrasound tests, biopsies and treatment. Mr. Shah is talking to other state governments, hoping the same screening campaign can be replicated across the country.

In Mexico, the country's navy initiated a program to screen 140,000 women with the device. Foundations operated by pharmaceutical companies are also sponsoring iBreastExam. The Pfizer Foundation is supporting a pilot program to screen women in Myanmar, and the Bayer Cares Foundation is supporting screening in Brazil.

Each scan costs between \$1 and \$4, depending on how many scans the provider commits to. A regular mammogram in India costs at least \$20.

But the rollout of iBreastExam in India has not been without problems, the biggest of which has been dealing with bureaucracy.

"In developing countries, if you really want to lower the burden of cancer, you're going to have to work with — and partner with — the government and government institutions," Mr. Shah said. "You don't have a choice."

In the context of India, that meant proving iBreastExam was not an ultrasound device — a highly controversial issue because ultrasound is commonly used to determine the sex of a fetus, and sex-selective abortion and female feticide have given India one of the world's most skewed sex ratios.

While legislation was passed in 1996 banning the determination of a fetus's sex, it has continued to thrive as doctors cash in on the trend. But that means health care professionals go through immense trouble to get an ultrasound device — or something

that looks like one — approved for use.

"Doctors literally placed the iBreastExam on the tummy of a pregnant lady to see if it could pick up the gender of a child," Mr. Shah remembered. "I said, 'This is ridiculous,'" because the iBreastExam device cannot identify the sex of a fetus.

Nevertheless, he said, "People have great fear when a device looks remotely like an ultrasound."

The core objective of a screening program is to improve survival rates. To that end, iBreastExam, like other community-based health screenings, relies on a strong referral system and linkage to care for women whose scans signal a need for further testing. "Any screening without follow-up is useless," said Sumana Y, a doctor with Biocon.

India's public health care system is marked by long waits, poor care and worker shortages. That's why private hospitals, often out of reach for the poor, are so popular. Moreover, most cancer centers are in cities.

Dr. P. Raghu Ram, immediate past president of the Association of Breast Surgeons in India, said breast cancer is also an issue shrouded in stigma. The disapproval is rooted in a widespread belief that cancer is a sign that a woman has done something bad, in fear of death and in a taboo against discussing "women's diseases."

"India is facing a breast cancer tsunami," Dr. Ram said. "The data reported is just the tip of the iceberg. I feel the major barrier in women getting opportunistic screening is it's a taboo closet issue." Nevertheless, Dr. Ram believes that the influence, reach and respect that community health care workers have in India could override the taboos and start to open discussions with women about cancer.

iBreastExam is not a panacea for the detection of breast cancer. Experts agree that a simple blood test is the ultimate goal. But for now, this tool can save lives and revolutionize breast cancer screening in many countries. "It's all about access now," Mr. Shah said. "Innovation is only as good as its reach."



**10+ Countries**  
**600,000+ Women Benefited**





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