



# UE

early detection for all

# LifeSciences



Awards, Recognition & Memberships



Commercial Collaborations



2021 Annual Meeting  
**Thought Leader** Recognition

**TED**      **BBC**  
**VOGUE**      **Forbes**



# WHO compendium of innovative health technologies for low-resource settings

2016- 2017



World Health Organization



## Medical device

### WHO compendium of innovative health technologies for low-resource settings

2016-2017

Inclusion in the Compendium does not constitute a endorsement by WHO of the fitness of any technology for a particular purpose, nor does it represent a recommendation for its adoption. WHO is not responsible for any injury or damage to any person resulting from the use of any 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, charge 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, 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://bitly/2DcQwa>

[www.who.int/medical\\_devices](http://www.who.int/medical_devices)

AVAILABLE PRODUCT





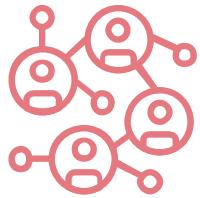
NATIONAL  
**BREAST**  
**CANCER**  
ROUNDTABLE



Proud  
member



# Too Many Women Are Dying From Preventable Cancers



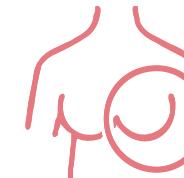
Globally, the lack of trained radiologists and cost of expensive equipment



Women with dense breasts, family history and younger women below age 40 have limited options.

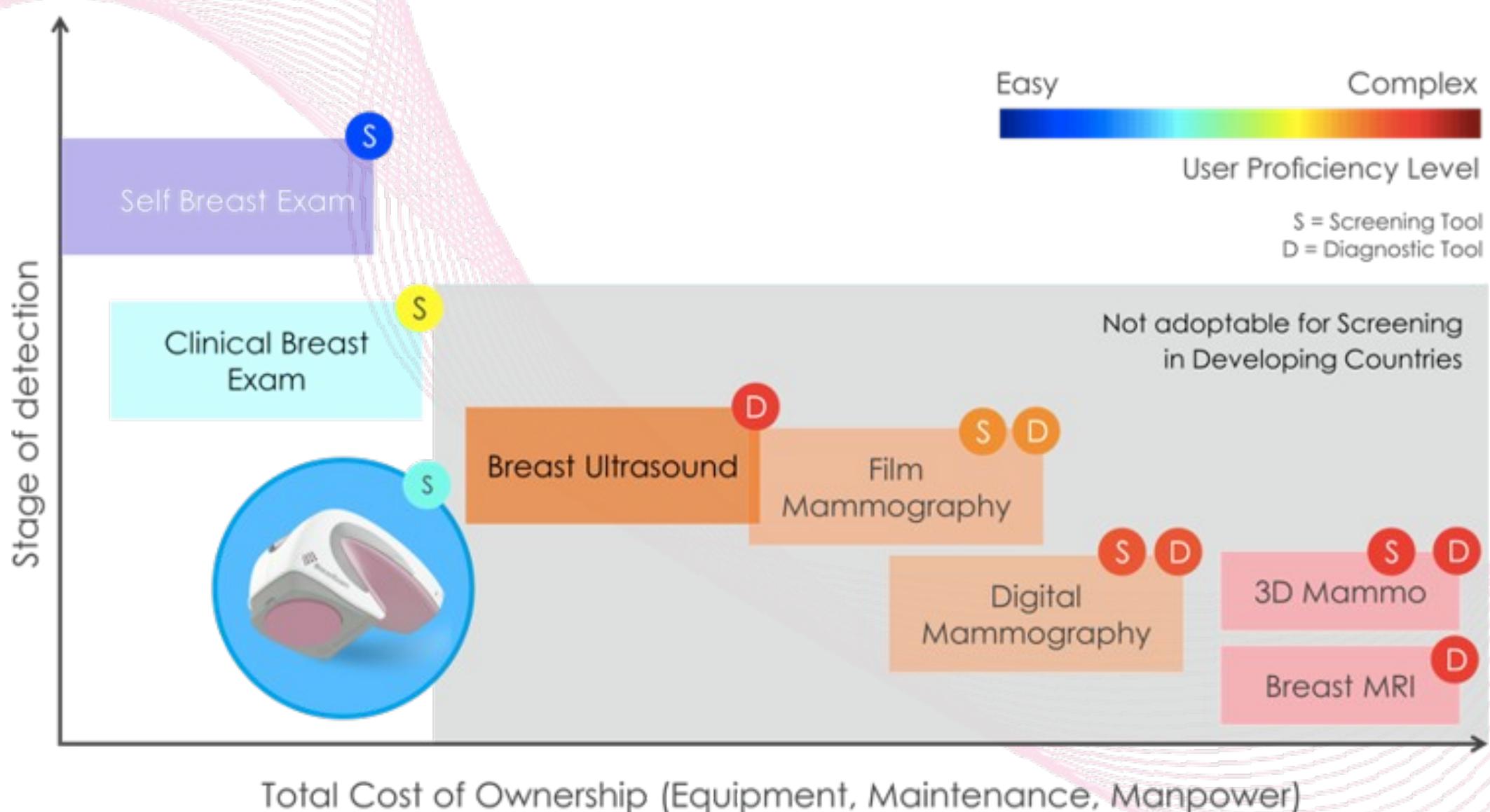


Clinical breast exams are not documented, not tracked over-time and can't be attached to the patient's EHR



There are no digital health solutions to guide or assist women to perform Breast Self-Exams, at home.

# Positioning



# Innovation, Effectiveness, Impact & Ease of Use

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UE LifeSciences  
early detection for all



Painless. Radiation-Free.  
Ultra-portable. Battery Powered.  
Mobile Connected. Cloud Analytics.

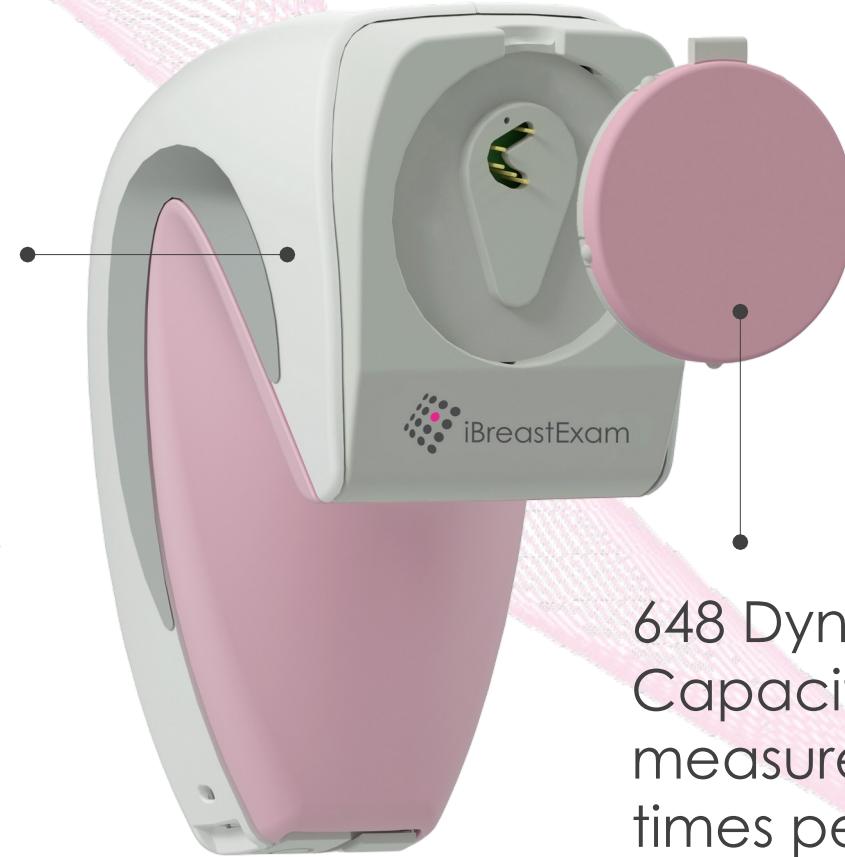
Effective in Younger women,  
Pregnant women & Dense breasts.

Operable by Primary Care Providers.  
Instant Results w/o Manual Interpretation.  
Enables Door-to-Door Testing w/o Special  
Infrastructure.



# The iBreastExam System

Handheld scanner with Bluetooth connectivity and a rechargeable battery



648 Dynamic Co-Planar Capacitive (DCPC) sensors measure tissue elasticity 20 times per second

iBreastExam App reporting stiff breast lesions in real time at the PoC



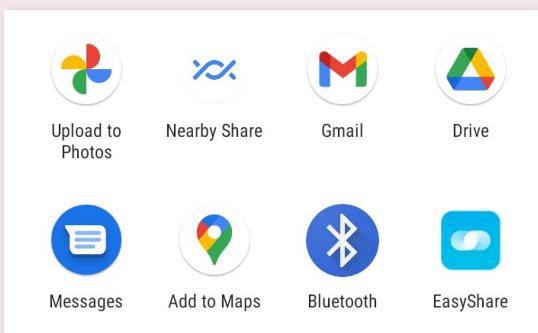
# Sample Report

Clinic info and branding

Patient info, symptoms, history

Physician notes and follow-up recommendation

Documentation of iBreastExam with location details



iBreastExam

**Example Clinic**  
Breast Health Street 100,  
Street Name,  
State - 111111  
+1-234-567-8910  
info@exampleclinic.com

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**Examine Date:** Jul 15, 2022 20:54 PM

**Name:** Example Patient    **Age:** 35

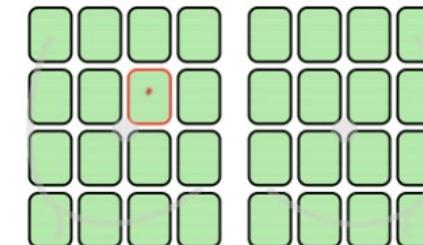
**Mobile:** +1-234-567-8910    **Clinic Patient ID:** 01

**Symptoms:** Yes    **Family History:** No    **Survivor:** Yes

**Examiner Notes:**  
Patient complains of ...  
Nipple discharge in left breast.

**Follow-up Recommendation:**  
Consult doctor

**iBreastExam Test Findings**



**Right Breast Findings**  
1-3 (UI)

**Left Breast Findings**  
None

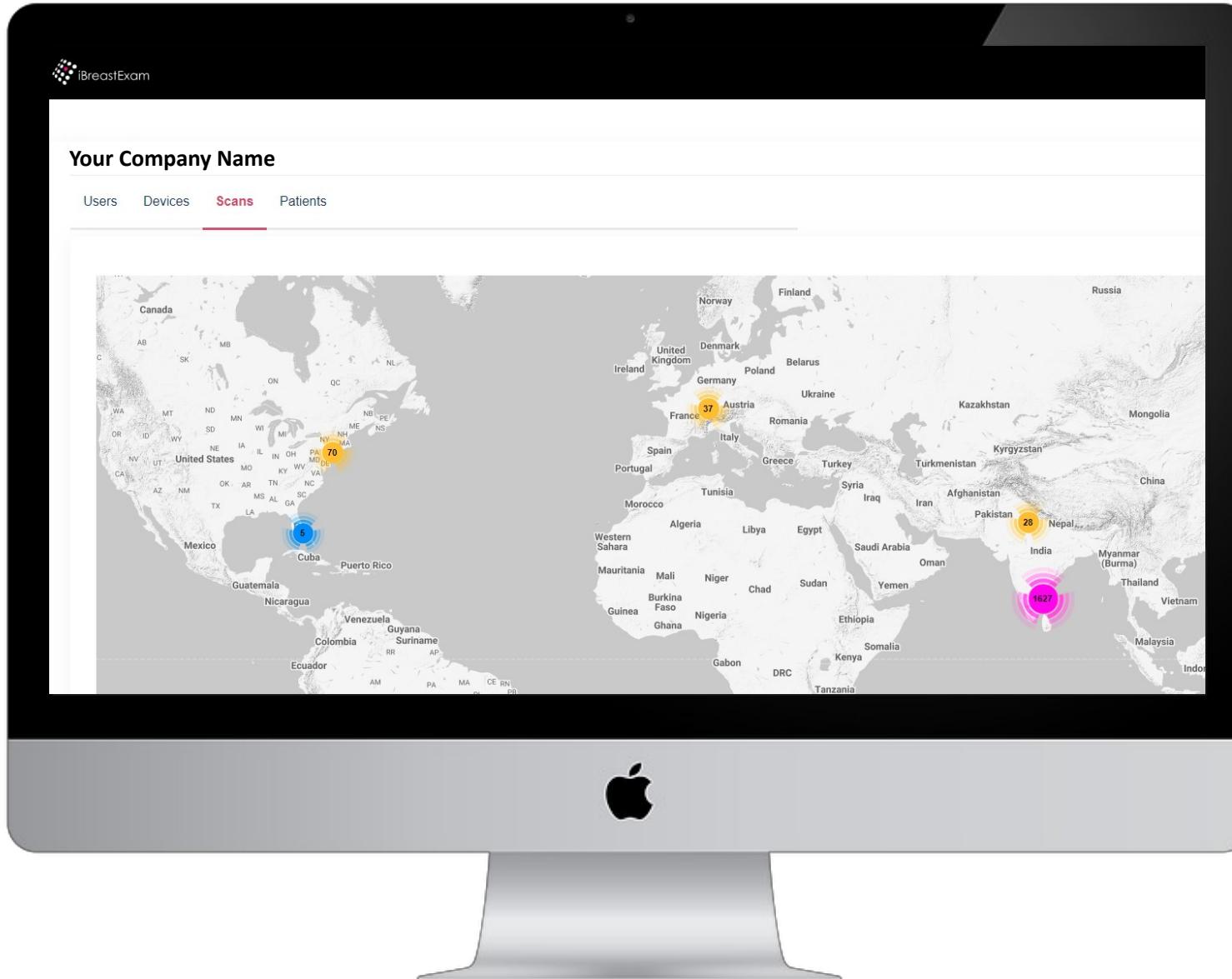
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**Examiner**

**Disclaimer:**  
iBreastExam is an FDA cleared, non-invasive breast examination for breast lump documentation. In clinical studies, iBreastExam has been shown to detect small breast lesions, however iBreastExam is not 100% accurate and it may fail to detect a breast lump in certain conditions. This report provides only a preliminary assessment of your breast health; it's not a definitive diagnosis. If you feel breast related symptoms, we strongly advise you to immediately contact your doctor. This report is computer generated using iBreastExam software and does not require a physician's signature. The iBreastExam Report is a pre-screening test and should not be used for breast cancer diagnosis or treatment management.

Powered By UE LifeSciences

# Remote Scan Repository in the Cloud



- Create and View Technicians and Patients
- Keep overview of total scans, positive findings, location of scans with date and time
- Replay scans remotely
- Aid in Building Mobile Cancer Registry
- HIPAA Compliant



2020



Mays Cancer Center  
UT Health San Antonio MD Anderson Cancer Center



2020



2019



2022



WORLD JOURNAL OF SURGICAL ONCOLOGY

2016



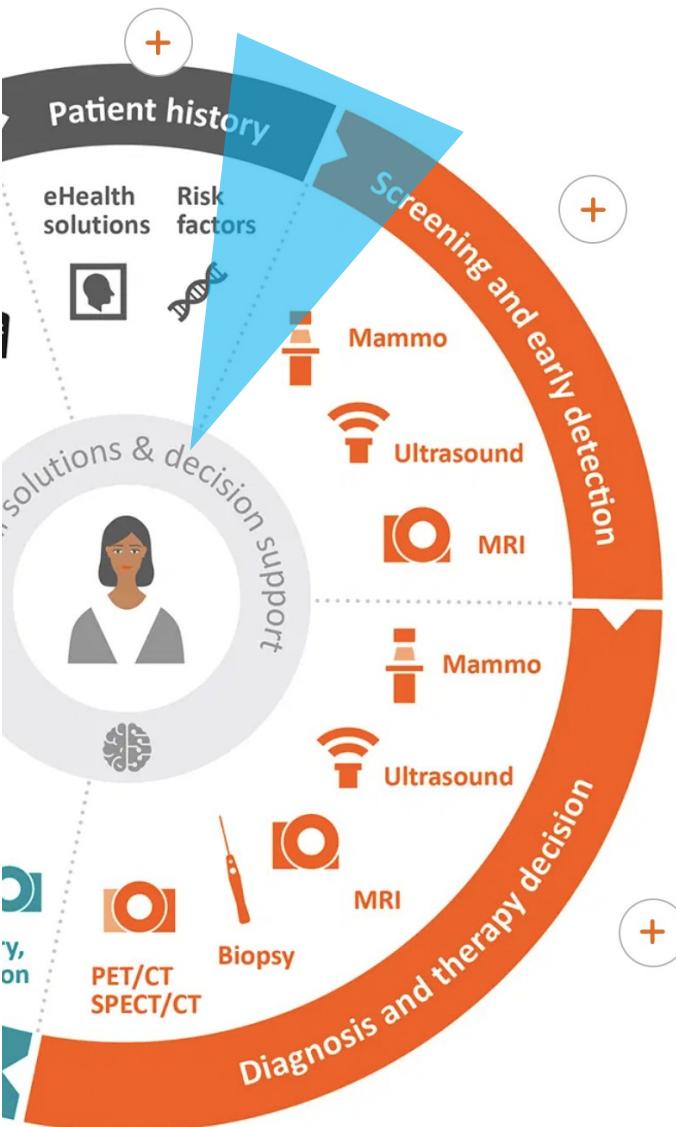
Memorial Sloan Kettering Cancer Center

2022

Multiple Independent Global  
Validation Studies with over  
25,000+ Women Enrolled  
98% NPV, 85% Se. 94% Sp.

US Market

**SIEMENS**  
**Distributor**  
**Healthineers**



**iBreastExam added to  
Siemens' 360-degree  
breast care portfolio to  
address health inequity  
in breast cancer early  
detection**

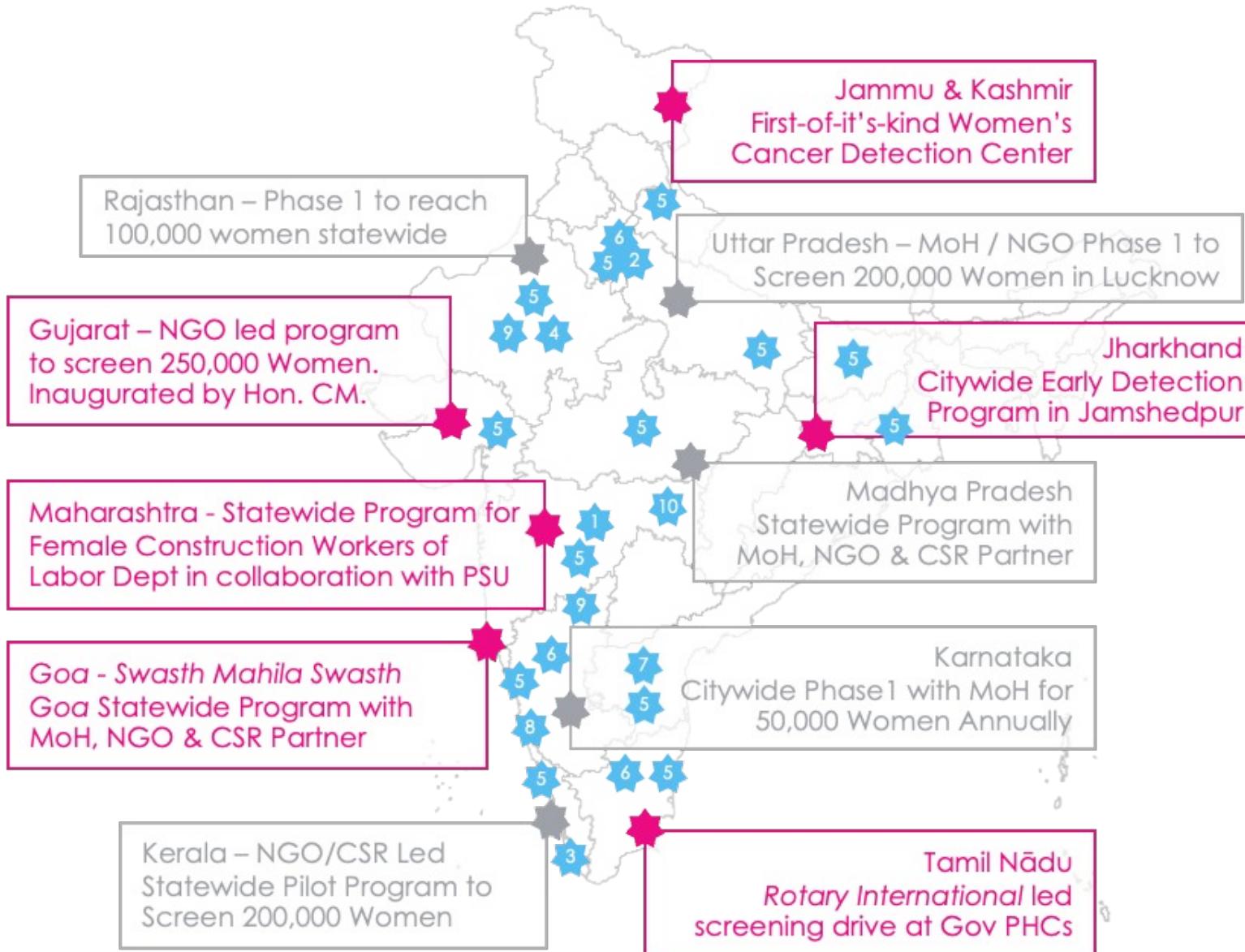
# *Pfizer collaboration to screen 135k women in Middle East & Latin America*



*"iBreastExam is a great example of how advances in connected medtech, novel sensors and the miniaturization of diagnostic devices are increasing access to care.*

***We're proud to partner with UE LifeSciences as they continue to scale and reach more communities"***  
***- Jim Mangione, Pfizer Digital Innovation Lab***

# Projects in India



 **Ongoing**

 **Proposed**

 **Completed**

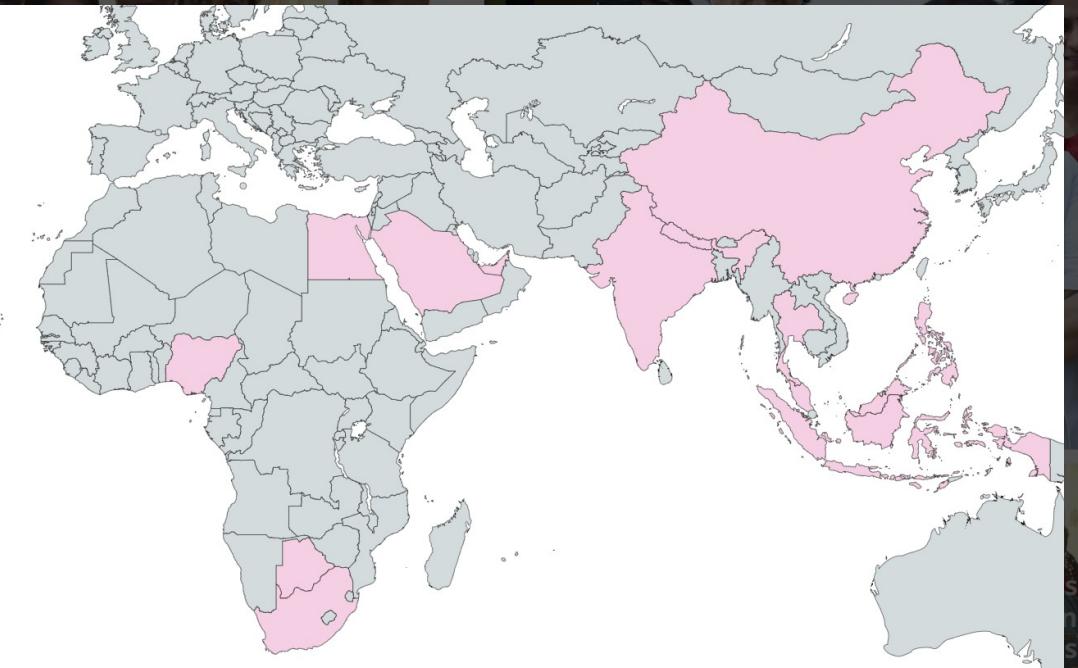
1. Maharashtra State Medical Colleges
2. Delhi Mohalla Clinics
3. Malabar Cancer Center
4. Arogya Rajasthan
5. Bank of Baroda Nationwide
6. Apollo TeleHealth
7. Dr. Reddy's
8. Kasturba Medical College
9. Biocon Foundation
10. Deendayal Foundation

# Diverse Global Team / 35FTEs / USA - India – Malaysia - Colombia



## Notable Angels & Advisors





Americas

LatAm

ME/Africa

APAC

Oceania

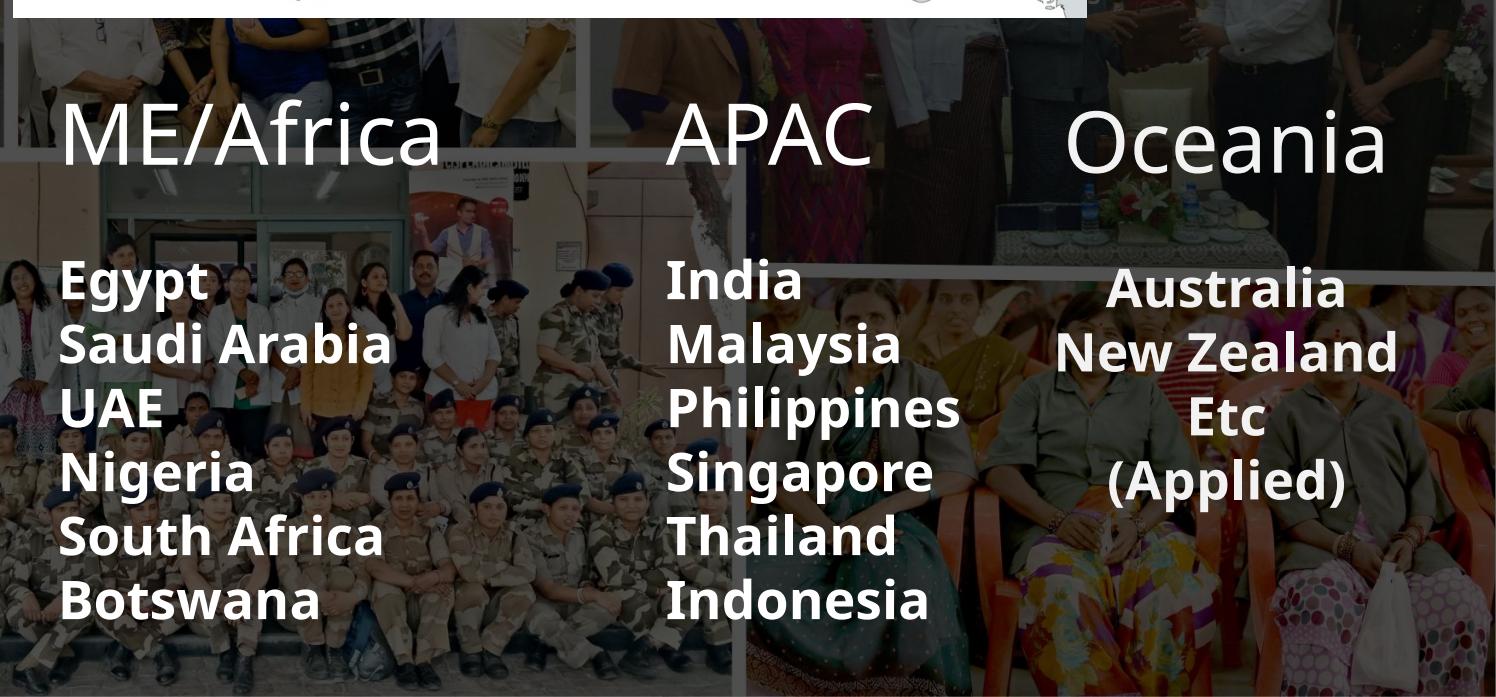
Mexico  
USA

Colombia  
Chile  
Peru  
Ecuador  
Brazil

Egypt  
Saudi Arabia  
UAE  
Nigeria  
South Africa  
Botswana

India  
Malaysia  
Philippines  
Singapore  
Thailand  
Indonesia

Australia  
New Zealand  
Etc  
(Applied)



## Global Accolades



World Health  
Organization



**THE WORLD BANK**  
IBRD • IDA | WORLD BANK GROUP



**International  
Finance Corporation**  
WORLD BANK GROUP



**pennsylvania**  
DEPARTMENT OF HEALTH



Consumer  
Technology  
Association™



**Bayer Cares**  
Foundation



# 2022 Global Women's HealthTech Award



Membership Invitation  
& “Get Screened”  
Thinktank

Membership &  
Spotlight Stage  
Showcase at World  
Cancer Congress,



Proud  
member

# Government Collaborations & Projects

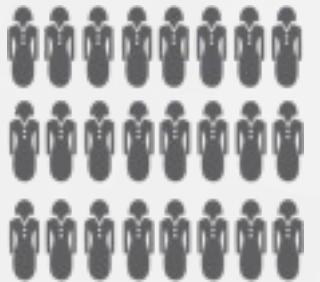
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UE LifeSciences  
early detection for all

**101,226**

Asymptomatic Women at  
Public Health Clinics



**4,970 (4.9%)**

women identified with a  
breast abnormality



**450+**

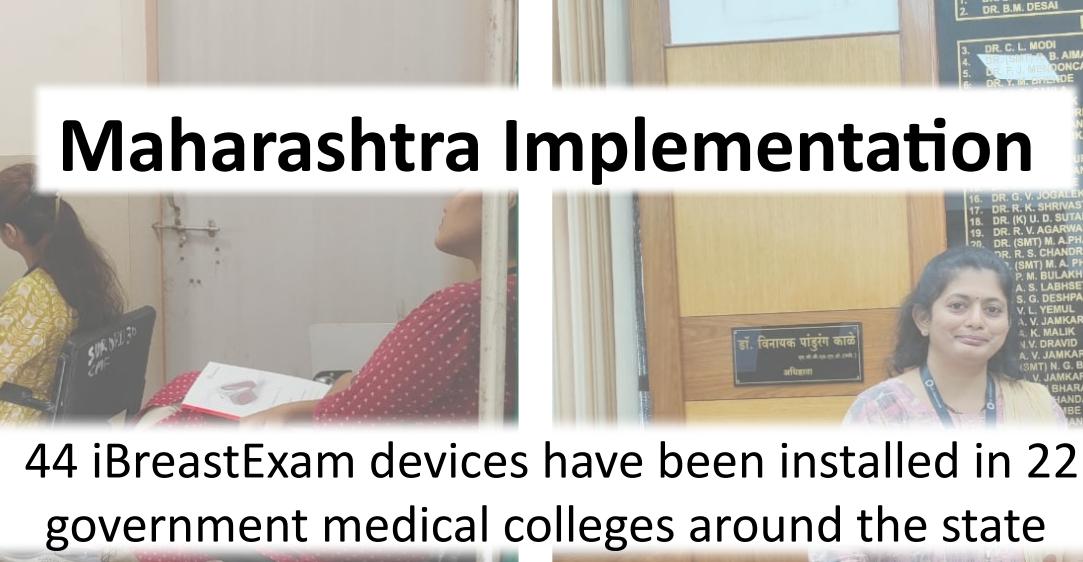
breast cancers  
diagnosed



Maharashtra State  
**India Implementation**  
2 Year Project

# Maharashtra Implementation

44 iBreastExam devices have been installed in 22 government medical colleges around the state





Largest Breast Cancer Initiative in  
India

Launching On World Cancer Day  
2023  
Breast Cancer SEWA

For 8,00,000

Screening Education Wellness

21 Blocks. 12 Months. 8 Lakhs Women



UE LifeSciences





## राष्ट्रीय स्वास्थ्य मिशन, उत्तर प्रदेश

National Programme for Prevention and  
Control of Cancer, Diabetes, Cardiovascular  
Diseases and Stroke (NPCI)

प्रत्येक नियंत्रण गति के लिए विकिता के लिए जो भवित्व प्रतिबद्ध है।

उत्तर प्रदेश में नियंत्रण गति का लिए विकिता के लिए जो भवित्व प्रतिबद्ध है।

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# **Swastha Mahila Swastha Goa**

## **१ लाखात ५५ महिलांना स्तन कर्करोग!**

आता तिशीतही विळखा : २५०० जर्णीमध्ये आढळल्या स्तनात गाठी

| एक लाख महिलाओंची स्क्रिंगिंग करणे गोवा ठरेल पहिले राज्य |                        |
|---|------------------------|
| १,००,०००  | महिलांसाठी स्क्रिंगिंग |
| २५००  | महिलांसाठी चयनक्रम     |

- गारा नवलकर-गांडस, साईजा, यूपी लाइक सोसायन्स



12,000+ women screened in a record time of 45 days

# Chhattisgarh NHM Implementation





# CDSCO

Central Drugs Standard  
Control Organization

**License Number:**  
**MFG/MD/2023/000375**

  **GeM**  
Government  
e Marketplace  
Efficient • Transparent • Inclusive

PRODUCTS    SERVICES    CONTENT    INTERACTIVE TRAINING COURSES NEW

Looking for something on GeM?



# Concluding Thoughts

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UE LifeSciences  
early detection for all

# The New York Times

## A New Way to Detect Breast Cancer

**TED**

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



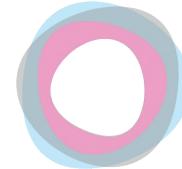
**Equitable access** to early detection of women's cancers can be made affordable, accessible, and scalable.

**Together, we will.**





iBreastExam



Developed and Manufactured by  
UE LifeSciences

## Recognition & Awards



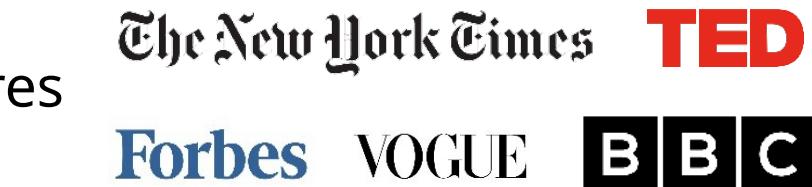
International Finance Corporation  
WORLD BANK GROUP



## Commercial Collaborations



## Features



## Contact

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