Early Detection. For All.
## 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). 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, specialist 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
- **Currenty 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: Mr. Shah | Telephone: +1 631 980 8340 | Web: https://bit.ly/2DcQwca

www.who.int/medicinal_devices
Impact. Innovation.

300,000+ Women Screened
200+ Installations Worldwide
120+ Breast Cx Detected
15+ Grants & Awards
10+ Regulatory Approvals
10+ International Patents

Our Journey

2005 – 2009
Sensor Technology Invented at Drexel University, USA
Bench Test & Ex-vivo Studies with Clinical PoC
UE LifeSciences (UELS) Founded in Philadelphia, USA

2010
UELS Obtains Global Exclusive IP License
Major R&D Grant from Pennsylvania Department of Health
Commercial Prototype Development
First In-vivo Study Published (JACS)

2015
US FDA Clearance
Technology Transfer to India for Production
Investment Made by Ranjan Pai, Unitus Ventures

2016
First Scale Up - 10,000 Women Screened
Anjani Mashelkar Inclusive Innovation Award
Investment Made by Kiran Mazumdar Shaw (Biocon)

2017
CE Mark, ISO 13485 Certification
GE Healthcare Supports UELS under 5.8 Program

2018
150,000+ Women Screened in 12 Countries
Grant Awards from Bayer & Pfizer Foundations
Team of 75+ with Offices in India, Malaysia and USA
300,000+ women benefitted in 12 Countries

USA, Mexico, India, Brazil, Indonesia, Myanmar, Botswana, Nepal & Counting

Global Customers & Partners
iBreastExam enables earlier stage detection at low-cost and minimal training, compared to other options.

Operable & Scalable in Limited Resource Settings

<table>
<thead>
<tr>
<th>&quot;Gold Standard&quot; Modalities</th>
<th>Accessible &amp; Affordable</th>
<th>Easy to Use &amp; Train</th>
<th>Scalable &amp; Connected</th>
<th>Standardized &amp; Objective</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mammography</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>✓</td>
</tr>
<tr>
<td>Breast Ultrasound</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>✓</td>
</tr>
<tr>
<td>Clinical Breast Exam</td>
<td>✓</td>
<td>X</td>
<td>X</td>
<td>x</td>
</tr>
<tr>
<td>iBreastExam</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>
Team of 75+ across USA, India & Malaysia

Advisors & Mentors

Ari Brooks, MD USA
Brian Englander, MD USA
SP Somashekar, MD India
Raghu Ram, MD India
Shekhar Kulkarni, MD India
Shri. RA Mashelkar India
Boman Dhabar, MD India
Mauricio-Costa, MD Brazil
Romeu Domingues, MD Brazil
Enrique Campo, MD Mexico

R&D, Scale-up Grantors & Investors

GE Healthcare
Kiran Mazumdar Shaw
Drexel University
Bayer Healthcare
unitus ventures
Pennsylvania Department of Health
Pfizer
The Pfizer Foundation
Sc21
International Awards & Grants

Best Pitch Innov8 Talks Award
Dubai - 2019

Lexus Design Award
India - 2018

Pfizer Foundation Global Health IG Award
USA - 2018

Bayer Foundation Grants 4 Impact Award
Germany - 2018

Aspirin Social Innovation Award
Berlin - 2017

Accenture Healthcare Innovation Challenge Award
San Francisco, USA - 2017
Sensor Technology
Clinical Studies
Large Scale Implementations
Piezoelectric Tactile Sensors

detect changes in tissue stiffness differences

Breast lesions are stiffer

contrast in elastic modulus is measurable
Diagnostic accuracy of a novel palpation device to improve early detection of breast cancer in low-resource settings


Background and objectives: As the most commonly diagnosed cancer in women, breast cancer is projected to reach 1 million cases per year by 2020 in LMICs alone. 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 a lower cost, non-invasive, portable device called iBreastExam (iBE) in the detection of clinically relevant breast lesions.

Methods: This study was a prospective non-randomized trial which enrolled women seeking routine screening or follow-up breast diagnostic evaluation from Nova Iguaçu and Rio de Janeiro, Brazil, respectively. Non-pregnant women aged 18 and older were eligible to enroll after providing informed consent. Each woman received an iBE palpation test and then mammography, ultrasound (US), or both, each by a different blinded clinician. For the sake of determining true lesion status, a positive mammogram was considered BI-RADS 0, 3-6. A positive US was considered BI-RADS 3-6. To assess accuracy of iBE to detect lesions, the sensitivity and specificity were calculated compared to mammography alone, ultrasound alone, or mammography plus ultrasound. For mammography plus US, the mammographic classification was considered the true status except for BI-RADS 0, in which case the US classification was considered the truth. Each breast was considered an independent result for the sake of analysis.

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%.

Conclusions: Since iBE is being studied as a tool in resource-limited settings to facilitate early detection of suspicious breast lumps that warrant clinical follow-up, we chose other gold-standard diagnostic modalities and classifications, not detection of cancer, as our comparator. 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 BI-RADS 0. When these cases underwent US, the net sensitivity increased to 74%. 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.

Evaluation of a Novel Palpation Imaging Device for Triaging Women in the Developing World for Breast Cancer Early Diagnosis

**Author Block:** S. Nair, T. Kathrikelly, P. Saxena; Kasturba Medical College, Manipal Academy of Higher Education, Manipal, Karnataka, INDIA.

**Background & Objectives:** 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. Two-thirds of the estimated 15,000,000 healthy-life years lost annually to breast cancer globally are from LMICs. The 5-year survival rate is 40-60% in most LMICs as compared to 80-90% in High Income Countries (HICs). Low-cost, user-friendly technology 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.

**Methods:** IRB cleared prospective trial enrolled women as part of a community screening program or women seeking medical advice for breast related symptoms. Consenting women above age 30 were eligible to enroll. 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 (mammogram for women above age 40 years or breast ultrasound for women age 40 years or younger). Standard of truth was established as a positive mammogram BIRADS 3-6 or a positive ultrasound as BIRADS 3-6. To assess accuracy of iBE and CBE to detect lesions, the sensitivity and specificity were calculated compared to diagnostic imaging. For the purposes of analysis, each breast was considered as an independent result. Instead of detection of cancer, standardized diagnostic imaging modalities (mammogram and ultrasound) were used as comparators because the palpation device was evaluated as a tool in LMIC settings to enable early detection of suspicious breast lumps requiring clinical follow-up.

**Results:** 1,200 women (2,400 breasts) with median age of 43 years were examined under this study with both, iBE and CBE. From 2,400 breasts, 96 were identified by iBreastExam, CBE or both to have at least one breast lesion. An additional 63 women (126 breasts) enrolled in the study due to a breast related symptom and were examined with iBE, CBE and age-appropriate diagnostic imaging. Combining both groups, 222 breasts were examined with age-appropriate diagnostic imaging. Compared to diagnostic imaging, the sensitivity, specificity, Negative Predictive Value and Positive Predictive Value of iBE is 86%, 91%, 98%, 57%, respectively. Compared to diagnostic imaging, the sensitivity, specificity, Negative Predictive Value and Positive Predictive Value of CBE is 63%, 82%, 94%, 32%, respectively.

**Conclusions:** Compared to Clinical Breast Exam, iBreastExam demonstrated significantly (23%) higher sensitivity and moderately (9%) higher specificity to detect breast lesions. Given that iBE requires minimal training and provides objective breast examination with digital documentation; better performance than clinical exam highlights the tool’s utility as a triaging tool by identifying women in need for follow-up diagnostics. iBreastExam may enable community health worker led triaging to detect clinically relevant breast lesions in LMIC settings.

Author Disclosure Information: **S. Nair:** None. **T. Kathrikelly:** None. **P. Saxena:** None.
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

S. P. Somashekhar¹  Ratna Vijay¹  Rupa Ananthasivan¹  Govindarajan Prasanna¹

Received: 2 April 2016 / Revised: 11 April 2016 / Accepted: 12 April 2016
© Association of Gynecologic Oncologists of India 2016

Abstract
Context  With limited access to mechanisms of early detection, the vast majority of breast cancer cases present at late stages in developing countries.
Objective  To determine the clinical efficacy of a handheld point-of-care medical device that could potentially assist allied healthcare workers to perform standardized Clinical Breast Examination in low-resource settings.
Design, Setting and Participants  Nine hundred and eighty-nine healthy women visiting Manipal Hospital, Bangalore, for annual health check were recruited for bilateral breast examinations. Additionally, 20 women attending the hospital with breast-related symptoms were also recruited as part of the opportunistic screening program. 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).
Main Outcome Measures  Sensitivity, Specificity, PPV, NPV for iBE and CBE were derived with Breast Imaging tests used as reference standard.
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.
Conclusion  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.

Keywords  iBreastExam · Breast cancer screening · India · Low-cost setting

Introduction

In 2012, 145,000 new cases of breast cancer (BC) and 70,000 deaths were reported in India. BC is the most common cancer in women worldwide, disproportionately affecting low- and middle-income countries (LMICs). 52.6 % of new BC cases occur in LMICs, and this is expected to grow to 70 % by year 2020 [1].

Five-year survival rate is poor 40–60 % in most LMICs as compared to 80–90 % in high-income countries (HICs). Lack of secondary prevention programs (population-based screening) and enhanced treatment are the two major differentiating factors for poorer BC outcomes in LMICs.
A cost-effective handheld breast scanner for use in low-resource environments: a validation study

Robyn B. Broach1, Rula Geha1, Brian S. Englander2, Lucy DeLaCruz1, Holly Thrash3 and Ari D. Brooks4*

Abstract

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 diagnosis. 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.


Background

The incidence of breast cancer is rising rapidly worldwide. Since 2008, the incidence of breast cancer has increased by more than 20% worldwide [1]. Globally, breast cancer now represents one in four of all cancers among women. Early detection improves the survival rate, makes treatment less costly, and lowers the overall burden of the disease. The iBreastExam (iBE) device was developed as a pre-screening tool that could identify women in need of further breast imaging without requiring extensive breast screening infrastructure. This inexpensive handheld device uses piezoelectric palpation to enhance the clinical breast exam (CBE) for detection of breast masses that require further investigation.

The iBE device was built on the principle of the piezoelectric finger (PEF) detector. After their initial development, the PEF was proven in bench-top work on breast phantoms and subsequently in excised human tumors with excellent detection ability and size prediction [2]. A pilot in vivo clinical trial was then completed using a very basic array of four PEFs with excellent detection of breast lesions in women undergoing clinical evaluation [3]. Subsequently, the iBE device was developed as a 16 finger array with a rapid wireless mobile processor algorithm and durable battery powered handheld. The device was developed to be operated by a technician or health care worker and does not require a radiologist for interpretation. This prospective study was designed specifically to validate the ability of the iBE device to detect breast abnormalities worthy of further diagnostic imaging.
Breast tumor detection using piezoelectric fingers: first clinical report.

Xu X, Gifford-Hollingsworth C, Sensenig R, Shih WH, Shih WY, Brooks AD.
School of Biomedical Engineering, Science, and Health Systems, Drexel University, Philadelphia, PA 19102, USA.

Abstract

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.

STUDY DESIGN: Patients presenting with breast abnormalities detected by palpation or imaging were enrolled in this IRB-approved study. The PEF testing was performed with the patient in supine position before undergoing biopsy or surgical excision. The locations of the lesions detected by PEF were compared with those confirmed on imaging or pathology.

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 or 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.

Copyright © 2013 American College of Surgeons. Published by Elsevier Inc. All rights reserved.
Breast Examination in India Using a Portable Handheld Breast Palpation Device is as Effective as an Expert Clinical Breast Exam

Rula Geha, Robyn Broach PhD, Ari D. Brooks, MD, Matthew Campisi, Mihir Shah, Bhaumik Sanghvi, Ojus Wadhwa MSGS, Shekhar R. Kulkarni MSGS

Background:
In 2012, 145,000 new cases of breast cancer and 70,000 deaths were reported in India. The survival rate is poor; over 60% of cases present at advanced stage. Clinical breast exam (CBE) is the mainstay of screening, but is limited by lack of trained medical professionals. Routine mammography screening is virtually impossible due to limited resources. The iBreastExam (iBE) is a portable, handheld piezoelectric pressure sensor that electro-mechanically palpates the breast to differentiate variances in tissue elasticity. The goal of the iBE in India is to enable allied healthcare workers to perform breast exams in 190M women between ages 30-70 in order to find treatable cancers earlier.

Methods:
Thirteen-hundred women from Pune, India were recruited for bilateral breast examinations. A trained allied health care worker would scan each breast using the iBE in a clock-wise manner and then the patient would undergo CBE by a health care worker and then by a doctor. No further investigations were performed if iBE and the CBE were negative. If the iBE and/or the CBE was positive, the subject was asked to undergo a breast ultrasound. If the ultrasound was positive (including cyst, fibroadenoma or suspicious) then the subject was recommended to undergo fine needle aspiration (FNA).

Results:
Out of the 1300 patients, 158 returned with a positive finding by CBE only (22), iBE only (9), or both (127). Fifteen patients declined to obtain a follow-up USG breast exam. A bilateral ultrasound was completed on 143 patients resulting in 94 patients with positive sonographic findings, 17 of which were bilateral positive findings. Eight patients underwent FNA and 3 were found to be malignant. None of these were missed by iBE or physician CBE; one was missed by healthcare worker CBE. The sensitivity and specificity of the iBE when compared to physician CBE is Sn=77.66, Sp=98.96. However, CBE is not the gold standard to determine a true positive so ultrasound was used to determine the sensitivity and specificity of iBE and CBE. The sensitivity using the ultrasonography results for CBE (Sn=95.49 Sp=60.57) and for iBE (Sn=97.29, Sp=69.14) were superior to the sensitivity and specificity of the lay healthworker CBE.

<table>
<thead>
<tr>
<th></th>
<th>Ultrasound positive</th>
<th>Ultrasound negative</th>
<th>No U/S</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expert CBE positive</td>
<td>106</td>
<td>69</td>
<td>14</td>
</tr>
<tr>
<td>Expert CBE negative</td>
<td>5</td>
<td>106</td>
<td>1130</td>
</tr>
<tr>
<td>iBE positive</td>
<td>108</td>
<td>54</td>
<td>12</td>
</tr>
<tr>
<td>iBE negative</td>
<td>3</td>
<td>121</td>
<td>1122</td>
</tr>
</tbody>
</table>

Conclusion:
The iBE is a powerful tool that can be widely used to screen for breast pathology in women who do not have access to routine preventive health care or mammography. Laypeople can be trained on the device and provide access to pre-screening for women in rural and poor communities in developing nations. We have shown that the device is as effective as CBE done by an expert physician. Patients with positive findings can then be referred to medical centers for further evaluation. Since iBE may be more accurate than CBE, a study is currently ongoing to determine the sensitivity and specificity of iBE when mammography screening is used as the gold standard.
Maharashtra State Breast Cancer Screening Initiative
Implementation Progress Report Draft
**Aim:** Program to screen 250,000 women in Maharashtra using iBreastExam (iBE) was initiated by State Government of Maharashtra on 1st October 2016 with support from Empathy Foundation.

**Implementation:** 16 iBreastExam devices were installed at all following Government Medical colleges (GMCs) in Maharashtra:

1. Grant Medical College (Mumbai)
2. Cama & Albless Hospital (Mumbai)
3. B.J. Medical College (Pune)
4. GMC (Nagpur)
5. Indra Gandhi GMC (Nagpur)
6. GMC (Aurangabad)
7. V.M. GMC (Solapur)
8. GMC (Akola)
9. GMC (Chandrapur)
10. Vasantrao Naik GMC (Yevatmal)
11. GMC (Latur)
12. Chatrapati Sivaji GMC (Kolhapur)
13. Shri Bhausaheb Hire GMC (Dhule)
14. GMC (Miraj)
15. GMC (Nanded)
16. Swarni Ramanand Tirth GMC (Ambejogai)
**Screening Protocol**
iBreastExam is being implemented in the gynec OPD of all 16 GMCs and the screening protocol established is as follows:

**Nursing staff responsibilities:**
- 2 nurses are dedicated in each hospital to conduct screening during OPD hours
- Every woman coming into the Gynec OPD is made aware of:
  - breast cancer
  - the importance of routine screening,
  - the benefits of early detection and finally
  - about the free breast health screening program ongoing at that hospital
- Every women screened is immediately provided a report and handed an awareness booklet
- The nurses report total number of women screened daily and women with a positive lump finding to the presiding gynec/radiologist for further follow-up

**Resident Gynecologist/Radiologist responsibilities included:**
- Monitoring the screening process
- Proper documentation of positive finding and their follow up
- Creating a weekly/monthly report of the screening and its finding

**Head of Department**
- Mobilizing women for the screening program
- Coordinating with OPD doctors to create awareness about the screening program among their female patients
- Plan camps in nearby regions/villages
- Collaborate with local NGOs/Foundations to create awareness and encourage women to come forward for screening
Project Progress Summary
Following is the project summary of the breast health screening at GMCs in Maharashtra from October 2016:

- 1,02,685 women screened with iBE across 16 GMCs in Maharashtra
- 5,041 women found positive on iBE were asked for a follow-up targeted ultrasound
- 123 malignancies were confirmed and are undergoing or have undergone treatment
Summary

Women welcomed iBreastExam test and found the breast health check to be pain-less and comfortable

No complaints or adverse events were reported.

A small awareness booklet was given to every women after their screening to help create awareness about Breast Cancer

We appreciate the initiative and support of **Hon. Medical Education Minister, Shri Girish Mahajan**, Maharashtra State Government and **Empathy Foundation** in helping women get access to a standardized early detection test in the tight against breast cancer.
iBreastExam Breast Health Camp
@ Aam Aadmi Mohalla Clinics

Delhi
July - September 2016
Aim: To provide breast health check to 1,000 healthy women at Aam Aadmi Mohalla Clinics (AAMCs) using iBreastExam innovation

Program initiated on July 1st 2016 at the following 7 AAMCs:
- 3 clinics in North - East Delhi (Shahdara, Navin Shahdara)
- 3 clinics in South Delhi (Chhatarpur, Panscheel Vihar, Okhka)
- 1 clinic in East Delhi (Kondli)

UE LifeSciences staff provided awareness, iBreastExam breast health checks and follow-up advise and support to the women visiting AAMCs.

- Normal women with no findings were advised routine follow-up
- Women with positive finding(s) on iBE were recommended a bilateral breast ultrasound, performed by an experienced radiologist.
- For women with findings suspicious of malignancy on breast ultrasound, FNAC/ core needle biopsy gun were performed.
Key Findings

- 1,000 women. Avg. age 33 Yrs.

- 61 women (6.1%) were positive on iBE:
  - 38% below 30 Yrs.
  - 39% between the age of 30-40 Yrs.
  - 23% above 40 Yrs.

- Of these 61 women, 41 received Breast Ultrasound test (USG pending in 20 women)

- Of these 41 women, 35 (85%) tested positive on Breast Ultrasound for clinically relevant breast lesions; 6 women were recommended FNAC/biopsy

- 2 early stage malignancies were detected and treatment is recommended. (One additional case is still pending results)
We conducted a post examination survey to get objective feedback individually from each woman. Below is a summary of results:

- Do you know anyone with breast cancer? 10% replied Yes
- Is Breast Cancer a concern in the community you serve? 96% said Yes
- Was the breast exam you just received comfortable? 100% said Yes
- Would you like a repeat iBE test next year? 100% said Yes
- Would you promote breast exam to your friends/family? 100% said Yes

Survey results show that women overwhelmingly welcomed iBreastExam test and found the breast health check to be pain-less and comfortable. No complaints or adverse events were reported.

We thank you for the opportunity to conduct this demonstration and hope to work closely with Aam Aadmi Mohalla Clinics to bring better access to early detection of breast cancer to the women of Delhi.
Support Letters & Testimonials
To

UE Lifesciences
A-102, Universal Paradise,
Nanda Paikar 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.


(Signed)

Sr. Specialist (Surg)
MO I/C HVF Hospital

Dr. S.K. Das

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

Phone (Res.): 044 - 2684 4730
044 - 2637 4065

Fax: 044 - 2637 8641
044 - 2638 0026

E-mail: drssantoe1@rediffmail.com
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
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 (ABSI) 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 ABSI was organized @ ITC Gardenia from 1-3 July 2016 under my leadership (Dr. Somashekhar, Honorary Secretary & Chairman Organising Committee) actively assisted by Dr. RajashekharJaka, 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 Fellowships 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,

Dr. Somashekhar S.P.

Prof. Dr. Somashekhar SP
MS,MCh(Onco),FRCS.Edinburgh
Hon. Secretary ABSI
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
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 an 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.
Regulatory Approvals & Miscellaneous Items
April 23, 2015

UE LifeSciences, Inc.
Mihir Shah
CEO
3711 Market Street, Suite 800
Philadelphia, PA 19104

Re: K142926
   Trade/Device Name: iBreastExam
   Regulation Number: 21 CFR 884.2990
   Regulation Name: Breast lesion documentation system
   Regulatory Class: II
   Product Code: NKA
   Dated: March 16, 2015
   Received: March 20, 2015

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. 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.

Please be advised that FDA’s issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act’s requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in
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.**

Workshop - 302, Trimabk Niwas, Relcon House, M.G. Road, Ville Parle (East), Mumbai - 400057 (Maharashtra), India.  
Head Office - A-102, Universal Paradise, Nanda Patkar 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.

Datum Van Publicatie / Date of Issue : 21/01/2019
Vervaldatum / Date of Expiry : 20/01/2020

**Royal Stancert B.V.**

Certificate Number / Certificate No. : CE-BV-1901-995
(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.nl](http://www.royalstancert.nl). **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.nl
SECRETARÍA DE SALUD
COMISIÓN FEDERAL PARA LA PROTECCIÓN CONTRA RIESGOS SANITARIOS
COMISIÓN DE AUTORIZACIÓN SANITARIA
DIRECCIÓN EJECUTIVA DE AUTORIZACIÓN DE PRODUCTOS Y ESTABLECIMIENTOS
SUBDIRECCIÓN EJECUTIVA DE SERVICIOS DE SALUD Y DISPOSITIVOS MÉDICOS

MODIFICACIÓN DEL REGISTRO SANITARIO No.
2723E2017 SSA
No. DE SOLICITUD
183300402M0396

Con fundamento en los Artículos 4 párrafo cuarto, 8, 14 y 16 de la Constitución Política de los Estados Unidos Mexicanos; 39 de la Ley Orgánica de la Administración Pública Federal; 1, 3 y 16 fracción X, de la Ley Federal de Procedimiento Administrativo; 3 fracción XXIII, 4 fracción III, 17 bis fracción IV, 194 fracción II, 194 bis, 197, 262, 368, 376, 376 Bis, 378, 380, 391 bis y 393 de la Ley General de Salud; 1 y 2 inciso C fracción X del Reglamento Interior de la Secretaría de Salud; 1, 3 fracción I inciso b, VII, 4 fracción II inciso c y 14 fracción I del Reglamento de la Comisión Federal para la Protección contra Riesgos Sanitarios; 1, 82, 83, 153, 157, 181, 184, 188, 189 y 214 del Reglamento de Insumos para la Salud; Décimo Octavo del Acuerdo por el que se delegan las facultades que se señalan en los Órganos Administrativos que en el mismo se indican de la Comisión Federal para la Protección contra Riesgos Sanitarios, publicado en el Diario Oficial de la Federación el 7 de abril de 2010, así como los relativos y aplicables del Acuerdo por el que se dan a conocer los trámites y servicios, así como los formatos que aplica la Secretaría de Salud, a través de la Comisión Federal para la Protección contra Riesgos Sanitarios, inscritos en el Registro Federal de Trámites y Servicios de la Comisión Federal de Mejora Regulatoria; publicado el 28 de enero de 2011 en el Diario Oficial de la Federación, se otorga la presente Modificación al Registro Sanitario bajo las siguientes condiciones:

Titular del registro: Prevención y Detección Especializada, S.A. de C. V.
R.F.C.: PDE 170522 BE4

CARACTERÍSTICAS DEL PRODUCTO

Denominación Distintiva: iBreastExam™
Denominación Genérica: Sistema de documentación de Lesiones de Pecho
Tipo de Insumo para la Salud Art. 262 LGS: I. Equipo médico
Clasificación del Insumo para la Salud Art. 83 RIS: Clase II

Fabricado por: UE LifeSciences (India) Pvt Ltd
Domicilio: 302, Trimbak Niwas, Relcon House, M.G. Road, Ville Parle (East), Mumbai 400057, Maharashtra, India.

Fabricado para: UE LifeSciences Inc.
Domicilio: 3711 Market St, Suite 800, Philadelphia, PA, 19104, E.U.A.

Este documento no es válido si presenta tachaduras, borraduras o enmendaduras.
Berdasarkan Peraturan Menteri Kesehatan Republik Indonesia Nomor 62 Tahun 2017 Tentang Izin Edar Alat Kesehatan, Alat Kesehatan Diagnostik In Vitro Dan Perbekalan Kesehatan Rumah Tangga dengan ini diberikan persetujuan untuk diedarkan dengan:

**NOMOR IZIN EDAR**

**ALAT KESEHATAN**

**KEMENKES RI AKL 21101810925**

<table>
<thead>
<tr>
<th>Nama Dagang / Merek</th>
<th>UE LIFESCIENCES Hand-held Breast Lesion Detection Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kelompok / Kelas Resiko</td>
<td>Elektromedik Non Radiasi / B</td>
</tr>
<tr>
<td>Kategori Produk</td>
<td>Peralatan Obstetrik dan Ginekologi</td>
</tr>
<tr>
<td>Sub Kategori</td>
<td>Peralatan Obstetrik dan Ginekologi Pemantauan</td>
</tr>
<tr>
<td>Jenis Produk</td>
<td>Breast lesion documentation system.</td>
</tr>
<tr>
<td>Tipe / Ukuran</td>
<td>iBreastExam</td>
</tr>
<tr>
<td>Kemasan</td>
<td>Unit</td>
</tr>
<tr>
<td>Nama Produsen / Pabrikan</td>
<td>UE LIFESCIENCES (INDIA) PVT. LTD., India</td>
</tr>
<tr>
<td>Nama Pendaftar</td>
<td>PT. ANDAMAN MEDICAL INDONESIA, DKI Jakarta</td>
</tr>
<tr>
<td>Atas dasar lisensi dari</td>
<td>-</td>
</tr>
</tbody>
</table>

**Ketentuan**

2. Wajib menyampaikan laporan berkala dan laporan jika ada kejadian yang tidak diinginkan akibat penggunaan Alat Kesehatan tersebut di atas sesuai ketentuan berlaku.
3. Apabila dikemudian hari ada pihak lain yang berhak atas merek dan/atau keagenan produk tersebut, pendaftar bersedia mengembalikan izin edar.
4. Penandaan dan informasi produk yang terlampir merupakan bagian yang tidak terpisahkan dari persetujuan izin edar ini.
5. Apabila di kemudian hari terdapat kekeliruan, maka persetujuan izin edar ini akan ditinjau kembali.

23 Februari 2018

a.n Direktur Jenderal,
Direktur Penilaian Alat Kesehatan dan PKRT

[drg. Arianti Anaya, MKM]
NIP: 19640924 199403 2 001
CERTIFICATE OF REGISTRATION

Universal GmbH

This certificate is granted to the organization,

UE Lifesciences (India) Pvt. Ltd.

A-102, Universal Paradise, Nanda Patkar Road, Vile Parle (East),
Mumbai- 400057, Maharashtra, India.
302, Trimabk Niwas, Reicon House, M.G. Road, Ville Parle (East),
Mumbai 400057, Maharashtra, India.

by review of SEA.020092 numbered report for the scope

The Manufacture of Medical Device (iBreastExam & cervAlcal)

to certify that a management system in accordance with standard’s clauses
is established and being implemented

WHO - GMP

Certificate No : WGMP 0117 020092
Original Certification Date : 2017–01–12
Issue / Revised Date : 2019–05–16
Expiry Date : 2020–01–11
Certification Period : 3 Years (3rd Year)
QUALITY MANAGEMENT SYSTEM CERTIFICATE

Universal GmbH

This certificate is granted to the organization,

UE Lifesciences (India) Pvt. Ltd.

A-102, Universal Paradise, Nanda Patkar Road, Vile Parle (East), Mumbai- 400057, Maharashtra, India.
302, Trimabk Niwas, Relcon House, M.G. Road, Ville Parle (East), Mumbai 400057, Maharashtra, India.

by review of IA2.020092 numbered report for the scope

The Manufacture of Medical Device (iBreastExam & cervAlcal)

to certify that a management system in accordance with standard's clauses is established and being implemented

DIN EN ISO 9001:2015

Certificate No : QMS 1019 020092
Original Certification Date : 2019 - 10 - 24
Issue / Revised Date : 2019 - 10 - 24
Expiry Date : 2020 - 10 - 23
Certification Period : 3 Years (1st Year)
MEDICAL QUALITY MANAGEMENT SYSTEM CERTIFICATE

Universal GmbH

This certificate is granted to the organization,

UE Lifesciences (India) Pvt. Ltd.

A-102, Universal Paradise, Nanda Patkar Road, Vile Parle (East),
Mumbai- 400057, Maharashtra, India.
302, Trimabk Niwas, Relcon House, M.G. Road, Ville Parle (East),
Mumbai 400057, Maharashtra, India.

by review of RA2.020092 numbered report for the scope

The Manufacture of Medical Device (iBreastExam & cervAlcal)

to certify that a management system in accordance with standard’s clauses
is established and being implemented

DIN EN ISO 13485:2016

Certificate No : MDMS 0716 020092
Original Certification Date : 2016 - 11 - 10
Issue / Revised Date : 2019 - 10 - 24
Expiry Date : 2020 - 10 - 23
Certification Period : 3 Years (1st Year)

Universal GmbH
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. **Wireless operation** using Bluetooth 2.0 standard protocol.

5. **Regulatory Clearances & Approvals**
   a. US FDA cleared
   b. CE Marked
   c. ISO 13485 certified
   d. WHO – GMP certified
   e. WHO Compendium recognition as “Innovative Health Technology for Low-Resource Settings”

6. **Storage capacity** for 100,000 breast examination scans and full reports.

7. **Custom Android Application for Breast Examination with capabilities to:**
   a. Perform breast examination
   b. Review the breast examination
   c. Store the breast examination data and
   d. Print the final report

8. **Replay feature** enables the physician to replay a breast examination performed in the past, frame by frame.


10. **Approved for the following Electrical and Mechanical Safety Tests**
    b. The following National Deviations were included in the evaluation: - AAMI/ANSI ES 60601-1:2005(R) 2012/A1
    d. CSA C22.2 No. 60601-1:2014

11. **Clinical study validation performance characteristics:**
    a. Sensitivity is 84%
    b. Specificity is 94%
    c. Negative Predictive Value is 98%
    d. Positive Predictive Value is 60%

12. **Storage, Transport and Operating conditions:**
    a. Temperature range in Use: -10C to 40C
    b. Maximum relative humidity: 90%
    c. Atmospheric pressure range: 700-1060 hPa
Patient Details

Registration# ____________   Name ______________________________________________________   Age _____  Phone# __________________

Family History __________  Pre-Menopausal Y N  Breast Symptoms Y N

Findings on iBreastExam

<table>
<thead>
<tr>
<th>O’Clock ___</th>
<th>R</th>
<th>L</th>
</tr>
</thead>
<tbody>
<tr>
<td>LO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>UI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>UO</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Findings on Clinical Breast Exam

<table>
<thead>
<tr>
<th>O’Clock ___</th>
<th>R</th>
<th>L</th>
</tr>
</thead>
<tbody>
<tr>
<td>LO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>UI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>UO</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Comments ___________________________________________________________________________________________________________________  
____________________________________________________________________________________________________________________________

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 only provides a preliminary assessment of your breast and not a definitive diagnosis. We strongly advise that you immediately contact your doctor if you feel any breast related symptoms.

Participant Signature_____________________    Date______________________   Worker’s Signature______________________   Date______________________
**Some Common Questions...**

**Question:** How does iBE detect lumps in the breast?
**Answer:** Lumps in the breast are hard/stiff. iBE is an innovative device that is capable of detecting this hardness/stiffness.

**Question:** How long does an iBE test take?
**Answer:** Approximately 8-10 minutes.

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

**Question:** Can pregnant women and breast-feeding women get iBE test?
**Answer:** Yes. iBE is a safe test; iBE does not use x-ray radiation and hence there is no possibility of harm.

**Question:** After what age is it beneficial to get tested by iBE?
**Answer:** Risk for breast cancer increases with age. After age 30, every woman, every year, should get a breast examination.

**Question:** How is iBE test done? Is there pain in the test?
**Answer:** iBE test is done privately and only by a female. There is no pain in this test.

**Question:** How does iBE detect lumps in the breast?
**Answer:** Lumps in the breast are hard/stiff. iBE is an innovative device that is capable of detecting this hardness/stiffness.

1 in 25 women are at risk for getting breast cancer

**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

---

**Breast Cancer Awareness Campaign**

**Early detection. for all**

---

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

**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
This Handheld Breast Scan Is Revolutionizing How Indians Detect Cancer

By Suparna Goswami, CONTRIBUTOR
I cover technology and startup trends in India.

Making a Difference in 2018

By Tina Rosenberg
Ms. Rosenberg is a co-founder of the Solutions Journalism Network, which supports rigorous reporting about responses to social problems.

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 Mihir Shah, CONTRIBUTOR
Mihir Shah fights breast cancer.

“There are lots of gizmos out there. Innovation is only one aspect.”

Few women around the world can get a mammogram. They are far from a clinic or lack the money or just don’t battle — and it’s the second part that trips up most entrepreneurs, especially those making products for poor

BBC NEWS

A New Breast Cancer Detection Device Can Identify Tumor Tissue in Under 5 Minutes

Breast cancer is the most common form of cancer in women worldwide with an estimated 1.7 million new diagnoses each year, according to the Breast Cancer Research Foundation. A global health emergency, it’s that much more acute in developing countries where the majority of women are not even screened. Which leads to

FORBES

Asia / #PublicHealth

This Handheld Breast Scan Is Revolutionizing How Indians Detect Cancer

By Suparna Goswami, CONTRIBUTOR

Opinions represented by Forbes Contributors are their own.
iBreastExam presented to India's PM Modi & Ivanka Trump at Global Entrepreneurship Summit

UE LifeSciences' iBreastExam is making early-stage breast cancer detection affordable and accessible