

BREAST-i™



1 IN 8 WOMEN
DIAGNOSED WITH
BREAST CANCER
IN THEIR LIFE



BREAST CANCER IS
THE MOST COMMON
CANCER IN FEMALES
WORLDWIDE

Non-diagnostic Breast Examination Device

Scientifically proven, patented light technology adapted for use in our non-diagnostic breast examination device, based on published research by UK scientists.

The BREAST-i™ uses state-of-the-art light emitting diodes for illumination, allowing you to keep an eye on your breasts and assist in spotting any changes at an early stage, as most screening programmes start over the age of 50 years.

This health screening product can be used for preventative breast cancer examination at home or in a medical setting to offer an aid in the diagnosis of breast lesions at an affordable cost.

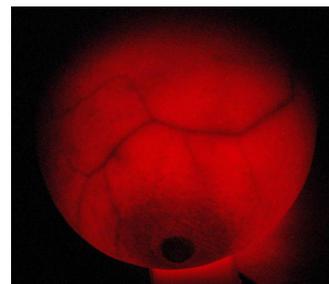
The BREAST-i™ is CE certified and female clinical trials of the product have successfully identified cases of breast cancer that would not have shown up with traditional hand screening examinations.

- » Hand-held & Portable
- » Adjustable Light Intensity
- » No Lubrication
- » Patented Technology
- » Examination in 6mins
- » Light Setting Memory
- » No Tissue Compression
- » Rechargeable Device
- » Advanced Skin Sensors
- » High Intensity LED's
- » Clinically Researched
- » Screening Aid

Screening with the BREAST-i™

BREAST-i™ is a powerful tool in giving an early edge in the ability to monitor blood vessels, identify abnormal tissue and spot potential tumours/lesions. Some small cancers may grow to become life threatening, others may remain dormant or even disappear.

Any cancer detected by BREAST-i™ is likely to be serious since it is detected by associated angiogenesis, implying that it is already in the exponentially growing phase. It must be realised that X-rays and light are monitoring different features of the breast, tissue density and neovascularisation, respectively. Should a shadow or cluster be spotted then medical consultation should be pursued.



A typical lit breast with veins appearing mainly bright throughout*



Breast with a mass, caused by angiogenesis - need for medical opinion*

* Images courtesy of Mammocare Ghana Clinical Screening. Details are available at www.breast-i.com. More images available online

EARLY SCREENING
TESTS CAN HELP
DETECT **BREAST
CANCER**

Over **10,000+**
women have
been examined by
Breast-i and its
predecessors

Examination Sensitivity

87%
benign disease



94%
breast cancer



Key Statistics

Breast cancer is the most common cancer among women, accounting for almost a third of all new cancer cases for females. Cancer Research UK reports how their latest statistics revealed that in 2010, there were 10,000 new cases diagnosed among women aged under the age of 50. This is an 11% increase from 15 years previously in 1995 when there were 7,700 cases of breast cancer diagnosed among women in this age group.

One in five breast cancers (20%) are now diagnosed in women aged under 50. Almost half of breast cancers (48%) are diagnosed in women between the ages of 50 and 69 the age group currently invited for breast cancer screening.

However, the rise in the number of breast cancer cases is not only limited to those aged under 50. Since the 1970's there has been a gradual and steady increase in the number of breast cancer cases. Overall there was an 18% increase in rates between 1995 and 2010.

Source: Cancer Research UK, Web Content Accessed May 2019

New Cases:
55,122

New cases of
invasive breast
cancer, 2015, UK

Survival Rate:
78%

For 10+ years
(females only),
2010-11, Eng & Wales

Preventable:
23%

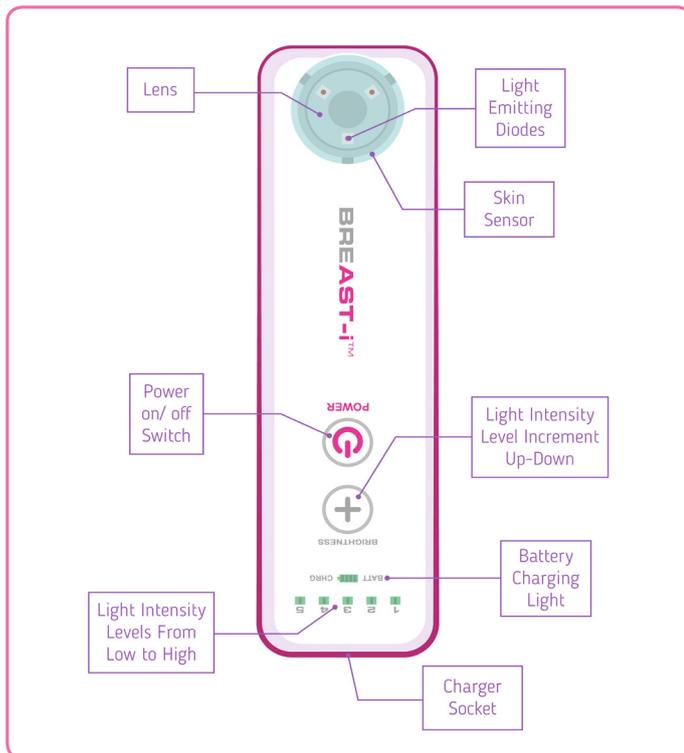
Preventable breast
cancer cases,
2015, UK

Table: Age-specific Probability of Developing Invasive Breast Cancer for US Women

Current age	10-year probability:	or 1 in:
20	0.1%	1,567
30	0.5%	220
40	1.5%	68
50	2.3%	43
60	3.4%	29
70	3.9%	25
Lifetime risk	12.4%	8

Note: Probability is among those free of cancer at beginning of age interval. Based on cases diagnosed 2012-2014. Percentages and "1 in" numbers may not be numerically equivalent due to rounding.

©2017, American Cancer Society, Inc., Surveillance Research



Development of BREAST-i™

Eminent Scottish Scientist and Professor, David Watmough, developed the device following his extensive research and teaching career in the UK, Saudi Arabia and Kuwait. He has over 100 publications which focus on the detection of breast cancers and comparative studies published over 58 years in leading scientific journals.

In 1982, David Watmough showed that absorption of light by red blood cells and specifically presence of new vessels around cancers (angiogenesis or neovascularisation) cause observable shadows when light passes through breast tissues)*

The BREAST-i™ incorporates David's years of study and research to be the only patented, breast cancer self-examination device, built upon pioneering work for optical technology and angiogenesis. This has allowed for the creation of an affordable tool for early breast cancer detection.

* Watmough D.J. [1982]. Diaphanography; Mechanism responsible for the images. *Acta. Radiologica Oncol.* 21, 11-15.



Clinical Screening Research

The BREAST-i™ and its preceding devices have been used in screening studies in Ghana. Over 10,000 women have been examined with clinical breast examination (CBE) and with the BREAST-i™ for comparative analysis. The most recent publication in the International Journal of Breast Cancer (Vol. 2018)* on 2,204 women confirmed the BREAST-i™ as a reliable device which detected 7 cases of angiogenesis that were not detected by CBE due to large breast size. See published abstract to the right.

* Frank Ghartey, David Watmough, Samuel Debrah, Martin Morna, Akwasi Anyanful [2018] International Journal of Breast Cancer – BREAST-i is an effective and reliable adjunct screening tool for detecting early tumour related angiogenesis of breast cancers in low resource sub-Saharan countries

Breast-i is an Effective and Reliable Adjunct Screening Tool for Detecting Early Tumour Related Angiogenesis of Breast Cancers in Low Resource Sub-Saharan Countries

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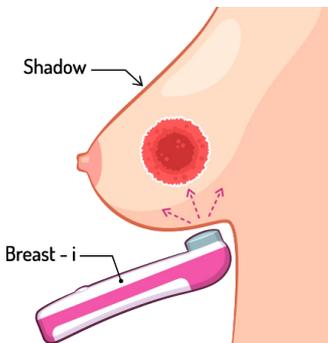
⁴Department of Medical Biochemistry, School of Medical Sciences, University of Cape Coast, Cape Coast, Ghana

Background. What cheaper alternative breast screening procedures are available to younger women in addition to clinical breast examination (CBE) in Sub-Saharan countries? In 2009, we first described BreastLight for screening and reported high sensitivity at detecting breast cancer. Due to its limitations we have, since 2014, been using the more technologically advanced Breast-i to screen 2,204 women to find cheaper screening alternatives. **Methodology.** First, the participant lies down for CBE and then, in a darkened room, Breast-i was placed underneath each breast and trained personnel confirm vein pattern and look for dark spot(s) to ascertain the presence of suspicious angiogenic lesion(s). **Results.** CBE detected 153 palpable breast masses and Breast-i, which detects angiogenesis, confirmed 136. However, Breast-i detected 22 more cases of which 7 had angiogenesis but were not palpable and 15 were missed by CBE due to large breast size. Overall confirmed cases were 26, with Breast-i detecting 7 cases missed by CBE. Breast-i and CBE gave sensitivities of 92.3% and 73%, respectively. **Conclusion.** Breast-i with its high sensitivity to angiogenesis, reliability, and affordability will be an effective adjunct detection device that can be used to increase early detection in younger women, thereby increasing treatment success.

How to use the BREAST-i™

Our simplified guide below, describes use for a breast examinations. The device is easy to use and accurate when used correctly. The device must be used in a darkened room. However, a small red light can help with visibility and ensure the user feels more comfortable. Photographs can also be taken for comparative analysis.

3–4 seconds must be allowed each time you place the device in contact with a breast, this allows for maximum light penetration before changing positions. Doing so will ensure better results and longer battery life. Over illumination can scatter too much light and intensity adjustment is required based on density of breasts.



Light from the high intensity LEDs in BREAST-i™ is scattered through the breast tissues.



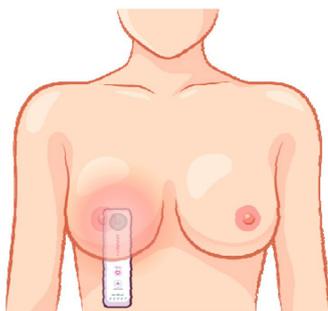
Use the BREAST-i™ whilst sitting or standing, by looking down directly at your breasts.



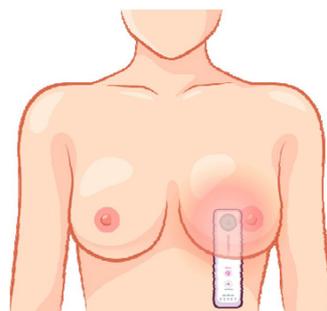
You can also use a mirror. Move the lens around slowly to examine the entire breast.



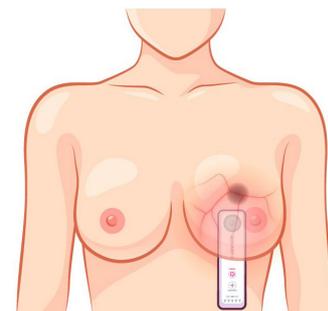
The BREAST-i™ examination can also be carried out by your doctor or a surgeon.



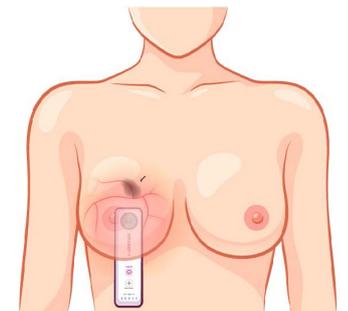
Place the BREAST-i™ under your right breast. Note this appearance, here there are no obvious shadows or clusters to be seen.



Next, place under your left breast. Light is transmitted through the breast and here no shadows/clusters are noticed.



Keep an eye out for any dark areas which weren't there previously. If present, medical consultation should be pursued.



Any enlarged blood vessels and/or small faint dark patches around the vessels should be brought to the attention of your doctor.

The patented BREAST-i™ portable, non-diagnostic device is available for:

£162.50 (excluding VAT)



Our Social Responsibility

In 2017, the World Health Assembly passed the resolution Cancer Prevention and Control through an Integrated Approach (WHA70.12) which was introduced to urge governments and 'WHO' to accelerate action to achieve the targets specified in the Global Action Plan and 2030 UN Agenda for Sustainable Development to reduce premature mortality from cancer.

One of the key areas that the WHO and UN Interagency Task Force are working on is identifying the most cost-effective strategies for cancer prevention and control.

The BREAST-i™ will support these goals and we look forward to working with governments and countries to deliver a solution for improving the screening of breast cancer as part of our social responsibility values.

Our Credentials

- BREAST-i™ CE Compliance Declaration, Oct 2016
- MHRA Registration and Export Sale Certified, Jan 2019
- We have a European Patent, No: **EP1750575B** this covers France, Germany and the United Kingdom. Filed in May 2005, this now covers light suppression features and memory of last light intensity level utilized.
- BREAST-i™ UK Intellectual Property Office Trademark: **UK00003036859**, registered in Jan 2014
- Design renewal registered with UK Intellectual Property Office, No: **4034270**, Feb 2019
- **EN ISO 13485:2016** Registration

Early Screening and Detection

Cancer mortality can be reduced when detected and treated early. When identified early, cancer is more likely to respond positively to treatment with greater survival probability, less morbidity, and less expensive treatment.

Screening aims to identify individuals with abnormalities suggestive of a specific cancer or pre-cancer, who are yet to develop any symptoms and refer them promptly for diagnosis and treatment.

Mammography screening is often only available in countries with stronger health systems. The BREAST-i™ offers a low-cost, portable option for examinations.

- Breast screening uptake in the UK has fallen slightly since 2010/11.
- Less than 1 in 100 screened women in the UK have cancer detected through breast screening, with around 8 in 10 of these are invasive cancers.
- For every breast cancer death prevented through screening, 3 women will be over diagnosed.

Source: Cancer Research UK, Web Content Accessed May 2019



GM INSTRUMENTS

One of the world's leading manufacturers of Medical Technology Solutions, covering Nasal and Respiratory Flow Measurement, Audiometry. Based in the UK, the company was founded in 1992 and has been at the forefront of the development of new medical innovation.

BREAST-i™ is a new area for the company, with its electronic engineering expertise it is well-placed to provide further product innovation. BREAST-i™ originates in Scotland and will remain in close proximity to its origins at the base in Irvine.