

An Introduction

PWB Health Ltd

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www.breastlight.co.uk



Breastlight has been developed as an aid for women's breast awareness. It is a hand held device to be used by women at home. It will be sold to consumers through pharmacy channels and the internet. The retail price will be in the region of £79

Breastlight will add a new dimension to breast awareness and help women spot any changes in their breasts over time. It adds the dimension of "internal sight" to a woman's normal touch and look breast awareness routine

Important Breastlight is not intended to be a substitute for other breast awareness activities. Neither does it not claim to compete with clinical diagnostic / screening techniques such as X-Ray mammography.



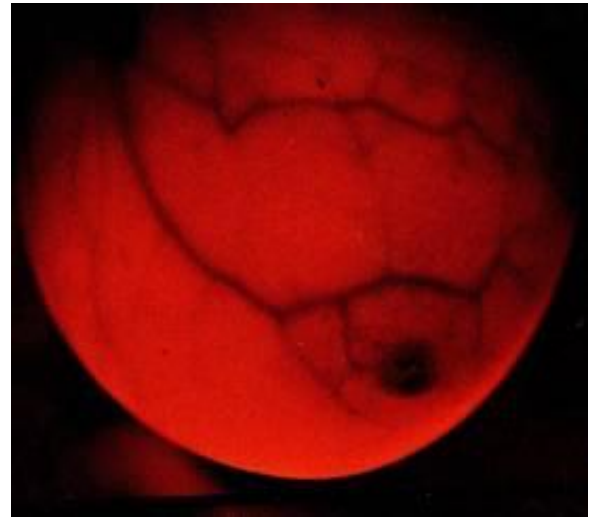
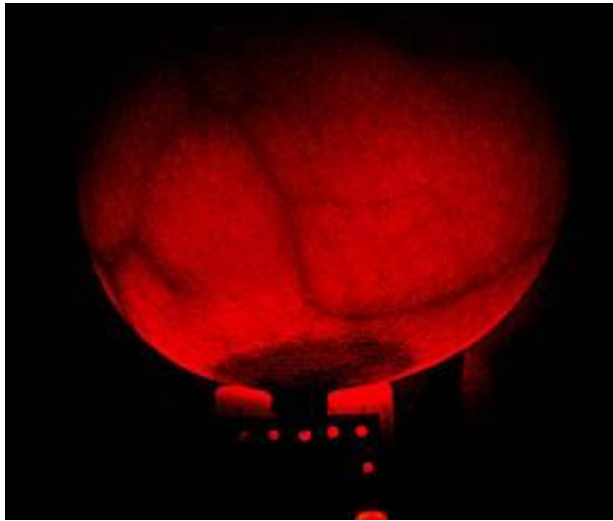
Breastlight emits high intensity light in the red / orange region of the spectrum. The product should be used in a darkened room. Total darkness is best. The transmission of the light from the Breastlight in close contact with the skin illuminates the breast. By looking down or into a suitably positioned mirror a woman is able to get a new view of her breast which may indicate the possible presence of disease.

The light from the Breastlight is strongly absorbed by blood present in the blood vessels. A fraction of the red / orange light passes through normal tissues, non blood filled cysts and some breast implants. A normal healthy breast will appear red and of fairly uniform brightness and usually with a well defined black vein structure.

Where an abnormality has caused a concentration of vessels or an aggregation of blood (e.g. a blood filled cyst, abscess or haematoma) this will usually give rise to a dark area or a shadow. Angiogenesis (formation of a new blood supply) can also give rise to shadows which means that in some cases non palpable cancers can be detected.

- Market Research on 1200 women and a user trial with 100 women showed that Breastlight was seen to be a positive, confidence boost for women who had concerns about self checking for breast cancer.
- Clinical evaluations have shown that the Breastlight is capable of detecting lesions of 15mm and above. There is photographic evidence to substantiate this. A proportion of smaller tumours are also revealed.
- Published clinical trials demonstrate that light based technology can deliver high sensitivity levels (82%) in lesions over 15mm and useful levels (29%) in non palpable lesions.

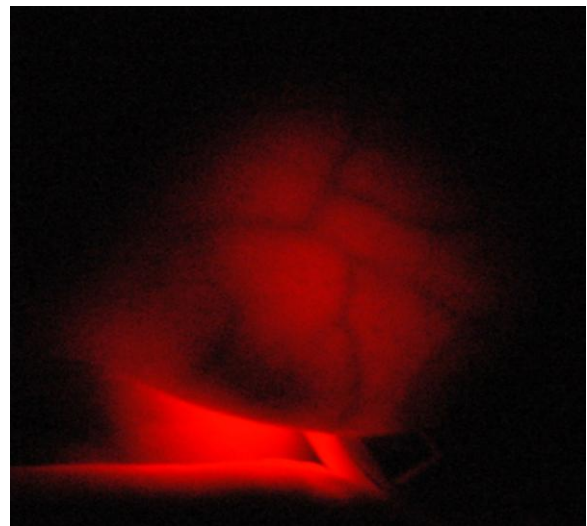
Examples of what is seen in use



Normal breast tissue appears clear with well defined vein structure



1.5 cm tumour 12 o'clock – 61 year old



3 x 7 cm tumour at 9 o'clock – 53 year old

Suspicious lesions show as shadows or darker areas

Background

In 1929 an American Surgeon, Max Cutler, was the first to show that breast cancer could be demonstrated by transmission of light through the tissues.¹

A subsequent study by Dr D J Watmough² showed that the optical images of a cancer of the breast arose principally because of the associated angiogenesis (new blood vessels stimulated to develop by the cancer). The chaotic mass of vessels surrounding the tumour supply oxygen and nutrients to the cancer and permit accelerated tumour growth. Red blood cells strongly absorb light at about 550 nm (the absorption bands of oxyhaemoglobin).

The degree of light absorption is determined by the number of blood cells per unit volume of breast tissue. Cysts generally transmit more light* but blood filled cysts, haematomas and neoplastic tumours produce shadows.

Early studies on the breast illumination method were carried out in the 1980's and 1990's. Clinical results for the technique were very encouraging in terms of detecting carcinomas. However the sensitivity was lower than that achieved with mammography and therefore the technique was not recommended as an alternative to established clinical screening methods.

The consolidated results of the trials were

Malignant tumours	Detected by illumination method	Confirmed by biopsy	
Total	139	169	82%
>2cm	95	106	90%
<2 cm	23	31	74%
Non Palpable	4	14	29%
Not measured	17	18	94%

With the recent advances in LED technology it is now possible to produce an affordable, compact device which can be used by women in the home. This could be a valuable aid to a women's personal breast awareness which is considered to be an important factor in the early detection of breast cancer. In particular it would be of great assistance to women for whom palpation is not an effective way to identify suspicious masses. for example those with lumpy breasts.

Market research studies on over 1200 women and a User Evaluation Trial on 100 women have confirmed that there is a strong interest in such a device.

Results indicate that using a device of this type will increase women's confidence in observing changes to the breasts and therefore have the potential to reduce anxiety as well as potentially leading to early detection of lesions requiring medical follow up.

** This additional transmission can be used to demonstrate cysts as bright areas on the breast surface as the light intensity is reduced.*

¹ Cutler 1929

² Watmough 1982

Summary of the published clinical studies

Edinburgh Royal Infirmary and the Longmore Hospital³

This study included a total of 129 patients, all with palpable lesions in the breast. Of these 74 patients had confirmed tumours and 55 had cysts or other benign disease.

The investigation was carried out with a device which emitted high intensity white light.

Of the 74 patients with a confirmed carcinoma 70 were correctly detected by using the breast illumination method (95%)

In 56 of the patients the size of the lesions was estimated by the use of callipers and the detection rates using the breast illumination method were

- Tumours over 2cm - 38/38 (100%)
- Tumours under 2cm - 15/18 (83.3%)

Results were also recorded by age

- Under 50 years - 22/24 (92%)
- Over 50 years - 31/ 32 (97%)

In cases of a benign lesion the breast illumination method was successful in detecting benign disease in 50 out of the 55 cases. In general a benign lesion will not give rise to a dark shadow due to the fact that there is no associated angiogenesis. The false positives [shadows taken to mean presence of a cancer] were made in those patients with blood filled cysts or abscesses.

2 University of Aberdeen⁴

In the second study 178 patients were investigated without prior knowledge of the mammographic findings. Of the 178 patients 69 had normal mammograms and 109 had abnormalities detected by mammography. Of this latter group 95 had confirmed breast cancer.

The breast illumination method detected 69 of the 95 confirmed carcinomas (73%) Of the cancers that were not detected 8 were ductal carcinomas in situ. The illumination method cannot detect microcalcification associated with some small cancers such as DCIS and excluding these from the sample the detection rate was 79% (69/87). The average size of cancers missed was 1.1cm.

Detection rates were analysed by size of tumour in all cases and the results were

- Tumours over 2 cm - 57 / 68 (83.8%)
- Tumours under 2 cm - 8 / 13 (61.5%)
- Non palpable - 4 / 14 (28.6%)

In 83 of the patients there was no cancer present and this was correctly demonstrated by breast illumination in 68 cases (82%) This was comparable to results from mammography where the corresponding figures were 69 cases and 83%.

³ Bundred et al 1985

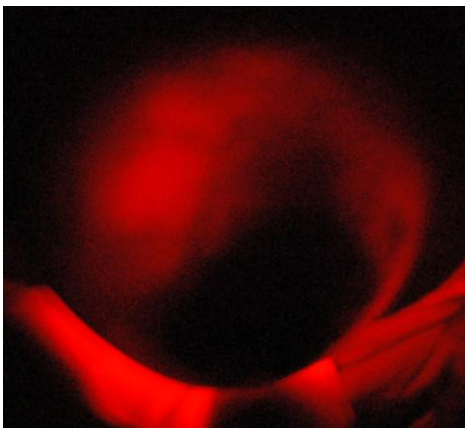
⁴ Brittendon et al 1995

Other clinical experience

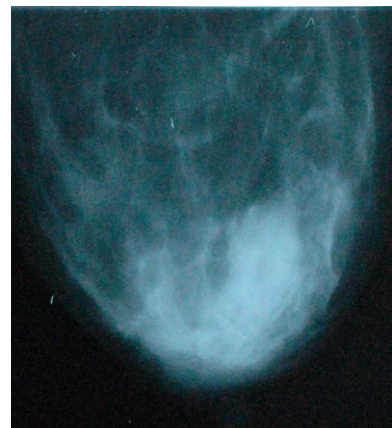
- A nurse at a private well woman clinic used a version of the product over a period of 2 years. In this time she has carried out over 400 examinations on over 250 women. There were no positive identifications in that time. Abnormalities found in two women through palpation were not detected with the Breastlight. Upon subsequent investigation one was found to be cancerous and the other a benign cyst.

In general there was favourable feedback on the product from patients. The women commented that they liked the reassurance of seeing what is going on in their bodies.

- Mammocare, a breast cancer charity operating in Ghana have been using the product as a follow up to their breast screening service. Initial examination is by palpation and women in whom a lump is detected are then invited to attend the clinic for mammography. At the screening centre the Breastlight has been used and results compared with mammography and the pathology report. Detection with the Breastlight conformed to histological / cytological / mammography findings in 16 out of 16 cases. If a shadow was seen during the examination with the Breastlight the patient was asked if they could also see the shadow and in all cases the answer was positive.



Tumour at 8 o'clock showing shadow on upper surface



Mammogram of same tumour - estimated 4cm

In summary

The early clinical studies demonstrated that the breast illumination method is able to detect malignant tumours in women of all ages. Extended use in the well woman clinic shows a low level of false positives whilst the project in Ghana demonstrates that lay women are able to recognise lesions with the Breastlight.

Lay User Evaluation study

This study involved 100 women who were given the product in a simulated post purchase study. Women were provided with the product, an instruction booklet, a quick start guide and a DVD including a filmed demonstration of the product. A nurse help line was available to respondents.

Of the 100 women invited to use the product 98 did actually do so. Of the two who withdrew one did so because of anxiety over the possible results and the other, after viewing the DVD because she felt squeamish about the process.

Out of the 98 women who used the Breastlight, one woman saw something of concern and made an appointment to see her GP. She was subsequently referred for a mammogram investigation which was negative.

The women in the study found the instruction material provided to be comprehensive and adequate in explaining how the device worked, how to use it and what to look out for.

46% of respondents found the Breastlight very easy to use and a further 28% quite easy to use.

82% of women were confident in using the Breastlight for the first time and 78% described themselves as confident in what they were looking for.

When comparing their confidence level with the Breastlight as part of their breast awareness routine compared to their normal routine alone 45% said that they were more confident whilst 14% said they were less confident.

Respondents were asked to keep a diary of their thoughts during the study and the verbatim comments are interesting to analyse.

Before using the product respondents divided into two groups – Confident and Slightly Anxious. The Confident group used words like *"Fine, Confident, Interested"* whilst the other group used terms like *"Nervous, Butterflies, Little scared"*

When asked to record their thoughts on what you saw when using Breastlight the respondents wrote words like *"Amazing, Fascinating, Spectacular, Weird, Surprised, Surreal"*

After use respondents wrote comments such as

- *"A good double check" or "A more thorough check"*
- *"More confident, Put my mind at ease"*
- *"It helps to look inside the breast as well as a hand examination"*
- *"I would be more content between mammograms if I had a Breastlight"*

In summary

The User Evaluation Study demonstrated that the Breastlight is easy and intuitive to use. In the vast majority of users it did not cause any undue concern. Many women found that the Breastlight, when used as part of their normal breast awareness routine, increased their confidence in detecting changes.

Market Research

Two market research studies to test the concept were carried out in summer 2007. In total 716 women, aged 50 to 65, were interviewed - 211 in the UK and 505 in the USA.

The majority of women interviewed (90%) carried out some form of breast awareness (or breast self examination in the USA)

Of these 55% said that they were not confident in self examination for detecting abnormalities.

In the UK there was considerable interest in the Breastlight concept with over 80% of respondents expressing interest and 64% indicating that they would buy the product if the price was right. The corresponding figures for the USA were 78% and 61%.

In the UK 52% of women said that they checked their breasts every month. When asked how frequently they would use the Breastlight 85% said they would use it every month or more frequently. The corresponding figures from the USA were 51% and 88%.

Of the women who currently check their breasts less than once a month over 81% said that they would use the Breastlight more frequently than that.

Respondents were asked to make comments on the product and here are some examples

- *"Having just had breast cancer and it being found through self examination, any device that helps other women must be good"*
- *"Hopefully catch in the early stages. Better than trying to feel something - which is often quite difficult to do".*
- *"Women would feel more assured by using this additional equipment rather than just feeling for lumps, as sometimes lumps aren't easy to feel."*
- *"Peace of mind. As mammograms are only available every 3 years for women over 50 this may be a useful tool to ensure a more thorough examination than is possible by palpation".*

Note - In the verbatim comments a small number (less than 10%) implied that the Breastlight might be considered as a substitute for mammogram screening. This might be expected given that in the UK 9% of the sample had never had a mammogram and 8% had not had one in the last 3 years. However this misconception will be addressed in all product communication.

In summary

Market research indicated a strong interest in a product of this type. The concept was intuitively easy to understand and the majority of women correctly interpreted the role of the device as an additional aid to breast awareness and an adjunct to the breast cancer screening programme. There is evidence that the Breastlight will lead to greater breast awareness and perhaps earlier detection of breast disease.

References:

(1) Cutler M [1929] Transillumination as an aid in the diagnosis of breast lesions. *Surg Gynecol Obstet* 48, 721 – 729.

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

(3) Bundred N., Levack P., Watmough D.J., and Watmough J.A. [1986]. Preliminary results using computerised tele-Diaphanography for the investigation of breast disease. *British J. Hospital Med.* 37, 70-71.

(4)Brittenden J Watmough D.J. Heys S.D. and Eremin O. [1995] Preliminary clinical evaluation of a combined optical Doppler ultrasound instrument for the detection of breast cancer. *Brit. J. Radiol.* 68, 1344 – 1348.

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