



MEDICAL AND CONSUMER MEDIA RELEASE

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New breastlight™ data confirms accuracy in detecting malignant tumours
In a trial of 300 women breastlight™ detected malignancies as small as 7mm
London, June 17th 2010 Data presented today at the European Institute of Oncology's 12th Milan Breast Cancer Conference confirms that breastlight™, a device for women to use at home when carrying out their breast health awareness routine, detects malignant tumours, picking up lesions as small as 7mm.¹

The device was trialled at a breast clinic in Sunderland City Hospital involving 300 women who were referred by their GP for a breast assessment. Patients were examined with breastlight™ before their standard clinical assessment and findings compared to those seen with mammography, ultrasound and biopsy. breastlight™ was highly effective at identifying confirmed malignant disease and benign abnormalities. The device:

- Detected 12 out of 18 malignant tumours¹, confirmed as positive using biopsy (giving a sensitivity of 67%).
- Correctly identified as negative 240 out of 282 breasts¹ (giving a specificity of 85%).
- detected malignant tumours as small as 7mm¹ (it is generally accepted that malignancies below 1.8cm are non-palpable²).
- Detected a number of variants of cancers regardless of age or density of breast tissue or menopausal status of women¹.

“We were impressed with the sensitivity and specificity of the breastlight™ device. To put these figures in perspective, mammography sensitivity tends to be between 60% and 90%. breastlight™ was 67%. The specificity, which indicates the accuracy in confirming a negative result, was 85% with breastlight™. For mammography, specificity ranges between 75% and 95%. This doesn't mean that breastlight™ should in any way replace mammography but it does tell us that breastlight™ can reliably pick up abnormal lumps which can be further investigated to assess whether benign or malignant,” said Mr Matei Dordea, specialist registrar at Sunderland City Hospital.

The study investigators concluded that breastlight™ had a place for women who find palpation difficult: “breastlight™ is very useful for women who have confirmed recurrent benign cysts and find it difficult to examine themselves. Benign cysts often do not have a blood supply so they will not show up with breastlight™. However, if women feel new cysts they should always seek medical advice.”

This latest clinical evidence confirms **breastlight™** place alongside traditional methods of breast awareness: “These trial results are very encouraging and show how **breastlight™**, in conjunction with self-examination, may improve the chance of detecting breast abnormalities. Many women don’t know what is normal for them as they don’t know how to carry out a useful breast examination. A device like **breastlight™** reminds women to get into a good routine, it is easy to use and has been clinically proven to detect non-palpable malignant disease. That has to be a good thing” said This Morning’s Dr Chris Steele.

This study was conducted within a symptomatic breast clinic. However, **breastlight™** usage has been evaluated at-home in a User Study involving over 1,200 women.³ Results showed that **breastlight™** encourages breast examination, at recommended frequency levels, and it gives women confidence in their breast examination:

- 80% of women said they felt more confident when using **breastlight™** in addition to their existing routine³.
- Pre-Breastlight, 34% of women checked their breasts less than once every three months. Post-Breastlight this number was reduced to just 10%³
- once a month checkers, increased from 44% pre-Breastlight to 76% post-Breastlight³.
- Women use **breastlight™** as an addition to their current routine. All women in the study continued with their usual practice including attending mammograms³.

ABOUT BREASTLIGHT:

breastlight™ is a British invention that has been used by over 3,000 women in the UK and 3,500 women worldwide. **breastlight™** works by shining a very bright but harmless red LED light through breast tissue. Veins and other blood vessels show up as dark lines, often referred to as the ‘map’ of the breast. This is normal. If a woman detects other dark spots or shadows, this is generally an indication that there is an abnormality. This could be the stimulation of blood vessels (angiogenesis) that occurs when a tumour is developing or it may be a benign lesion such as a bruise or blood filled cyst.

ENDS

NOTES TO EDITORS:

breastlight™ is available in large Boots stores nationwide. It is also available online at www.breastlight.com and boots.com. Price £86.80.

REFERENCES:

1. Iwuchukwu O, Keaney N, Dordea M: Analysis of **breastlight™** findings in patients with biopsies. City Hospital Sunderland. Presentation given at the European Institute of Oncology’s 12th Milan Breast Cancer Conference
2. Canadian Cancer Society
3. User Study available at www.breastlight.com