

ComfortScan®

OPTICAL SCANNING - A NEW LIGHT IN DIAGNOSTIC BREAST IMAGING

Dynamic Optical Breast Imaging (DOBI) is a low cost, non-invasive optical mammographic technique to obtain physiological information on angiogenesis in breast tissue. Angiogenesis reflects the potential aggressiveness of malignant lesions.

Slight pressure is applied to the breast (10mmHg) and near-infrared light (640nm) from an array of light emitting diodes (LED) is used to illuminate the breast. A camera system records several images per second of the light transmitted through the breast tissue for approximately 45 seconds. Light absorption by the tissue varies according to the haemoglobin/deoxyhaemoglobin ratio. A software application generates colour breast images that map the relative concentrations of deoxyhaemoglobin in the breast tissue and thus permit evaluation of vascularity.

ComfortScan is a DOBI device that can be used in mammography screening procedures, symptomatic breast imaging and follow-up imaging (symptomatic). Its use is particularly recommended for examinations of younger patients.

New, efficient and safe diagnostic breast imaging.

Examination

- Comfortable and quick
- Non-radiographic therefore non-invasive

Scanning

- Real time, high resolution data acquisition
- Using monochromatic red light and a proprietary image processing algorithm

Connectivity or Versatility

- The imaging platform can be enhanced and used in conjunction with other diagnostic systems, including conventional and digital mammography (FFDM), ultrasound and MRI

Unparalleled Advantages

Dynamic Optical Image

- Extremely sensitive to light absorption variations in pressure stimulated blood vessels

Angiogenesis Highlighting

- Visualisation of the abnormal vascular bed. Results in a reduction in diagnostic ambiguity

Gentle Compression

- Sufficient pressure to detect the angiogenesis (only up to 10mmHg)

High Intensity LED's

- A sophisticated optical system optimises the light intensity to the different breast densities creating diagnostic images without ionizing radiation

Rapid Scanning Time

- Images acquired in less than 1 minute

Examinations

- Examinations can be made from the age of 18 to provide very early breast tumour diagnosis

Tumour Angiogenesis Nutrient Supply for Tumour

Highly advanced *vascular* investigation providing a *timely diagnosis* to enable *early treatment*.

History

- In 1994 the Angiogenesis Foundation identified angiogenesis as the "common denominator" in many important diseases, including breast tumour

Research

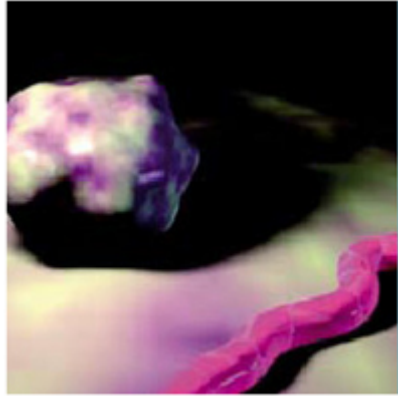
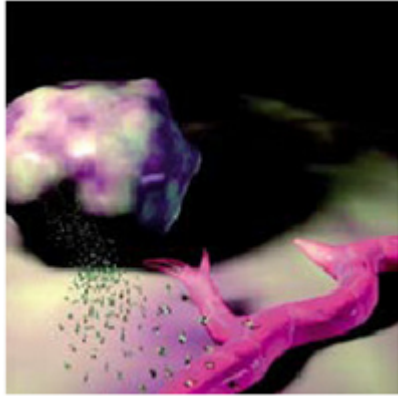
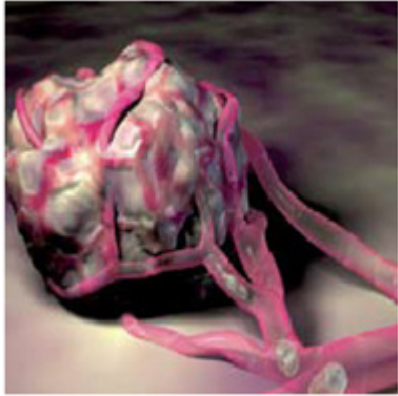
- Proves that a breast tumour becomes clinically relevant once it develops a blood supply vascular network

Early vascular detection

- Subtle vascular changes are often associated with breast cancer in its earliest stages

Advanced Performance Technology

- Detects the vascular changes and defines a unique vascular profile indicating the early development of a tumour angiogenesis

		
Pre-Angiogenesis Tumour	Early Stage Angiogenesis	Advanced Angiogenesis
Needs a blood supply to grow. More nutrient vessels often result in more aggressive growth.	Capillary vessel growth often promotes rapid tumour development	A dense network of blood vessels fuels the tumour growth

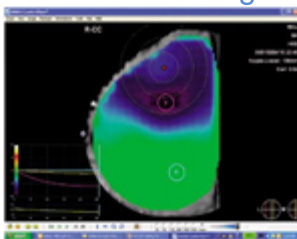
ComfortScan for Improved Diagnostic Analysis

Rapid and Efficient System for periodic patient diagnosis and monitoring



Improved diagnosis of patients with breast cancer symptoms.
Broader patient reach through the continuous monitoring of familial breast cancer in young women.
Periodic monitoring of the pathological changes that X-ray mammography cannot identify.
Ensures regular compliance for post-mammography examination of high risk mastopathy patients.

ComfortView Diagnostic Software

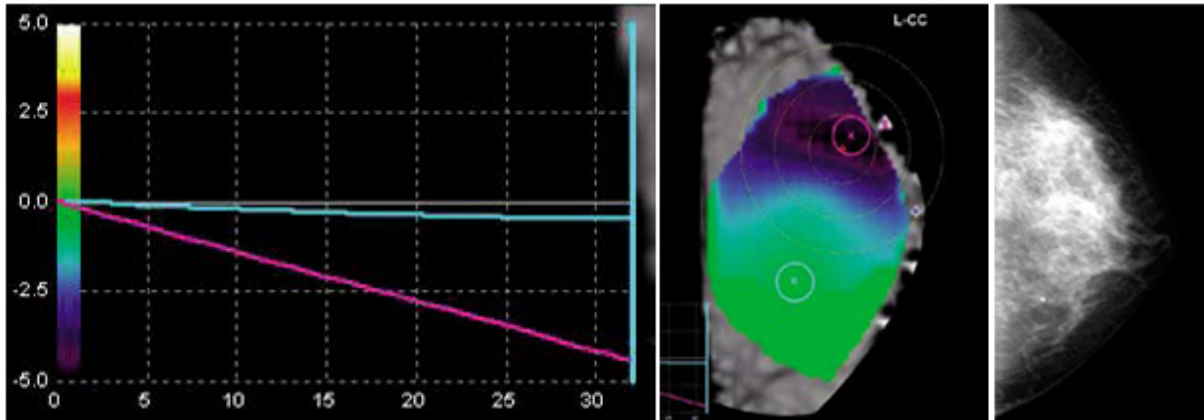


Rapid and dynamic analysis of the images captured by ComfortScan.
Colour images of the breast with chromatic mapping to highlight zones of increased vascularisation.
Real-time graphic measurement of the haemodynamic response to a pressure stimulus of the target zone.
Digital image archiving for post-diagnostic review.

Clinical Case Studies

MALIGNANT LESION

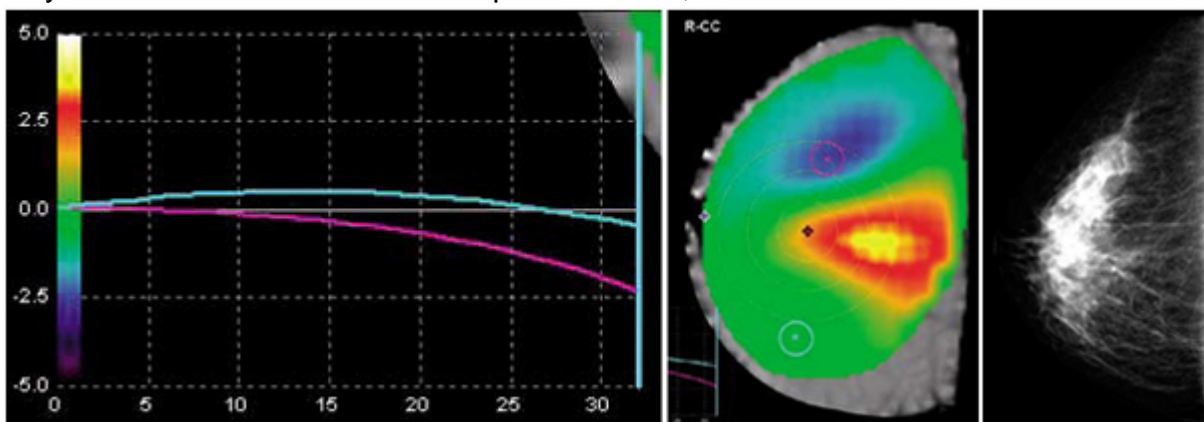
66-year-old woman with 10mm suspected lesion, BI-RADS 3.



Mammography reported “benign and inconclusive” by 2 operators: UNCERTAIN.
ComfortScan revealed the presence of a significant angiogenesis: MALIGNANT.
Biopsy revealed an invasive ductal Stage III carcinoma: CONFIRMED MALIGNANT.

BENIGN LESION

48-year-old woman with 10mm suspected lesion, BI-RADS 3.



Mammography inconclusive: UNCERTAIN.
ComfortScan does not reveal any angiogenesis symptoms: BENIGN.
Biopsy is benign: CONFIRMED BENIGN.

ComfortScan Technical Specifications

General

Patient position	standing
Breast support height	99 cm above floor, min 140 cm above floor, max
Breast support tray	25cm wide; 23cm depth
Breast compression	10mm Hg pressure, typical

Dimensions

Length	145 cm
Width	61 cm
Height	165 cm min to 206 cm max
Weight	295 kg

Illumination

Source	monochromatic red LED
Wavelength	627 nm, typical
Number of LED's	127

Imaging system

CCD Resolution	768 x 512,9 micron pixel
Dynamic Range	4096 (12 bit)
ADC Gray scale	4096 levels
CCD Operating Temp	0°C
System noise	< 70 electrons (RMS)
Lens	8 mm, focal length 3

Power Supply

Input voltage and current 2A - 240V

PC system

CPU	Intel Pentium IV 2GHz
Memory	512MB RAM
Hard Disk	40 GB
CD-R	52x Read/Write
Video Memory	64 MB
Operating system	MS windows XP
Archive CD-R	640MB
Monitor Technology	Flat panel, LCD display
Monitor Size	15" (38cm)

Safety Norms

Electromechanical Safety	UL60601-1
Electromagnetic Compatibility	EN60601-1-2
Electro medical Safety	EN60601-1
System Safety	EN60601-4
Risk Analysis	EN1441
Symbology	EN980