ComfortScan® System Specifications

Overall

Patient Position	Standing
Breast Support Height	39″ (99 cm) above floor, minimum
	55″ (140 cm) above floor, maximum
Breast Support Tray	10″ (25 cm) width
	9″ (23 cm) depth
Breast Compression	10 mm Hg pressure, typical

Dimensions:

Length	<57″ (145 cm)
Width	<24″ (61 cm)
Height	65″ (165 cm) min. to 81″ (206 cm) max.
Overall weight	<650 lb (295 kg)

Electrical

Input Voltage & Current	100-120 VAC 50/60 Hz<4 A
	220-240 VAC 50/60 Hz<2 A

Imaging System

CCD Resolution	768 X 512, 9 micron pixel
Image Binning	5 X 5
Dynamic Range	4096 (12-bit)
ADC Gray Scale	4096 levels (12 bits)
CCD Operating Temperature	32°F (0°C)
System Noise	<70 electrons (RMS)
Lens	8 mm, f1.3

Illumination

Light Source	Red LED, 627 nm (typical)
No. of LEDs	127, computer-controlled

System PC

CPU	Intel Pentium IV, 2.0 GHz
Memory	512 MB RAM
Hard Disk	40 GB
CD-R	52X Read/52X Write
Video Memory	64 MB
Operating System	Microsoft Windows XP
Archive	CD-R – 640 MB

System Display

Type	Flat panel, LCD display
Size	15″ (38 cm)
Resolution	1024 X 768

Environmental

Operational Ambient Temperature	50°F to 95°F (10°C to 35°C)
Operational Relative Humidity	20% to 85% (noncondensing)
Storage Temperature	-4°F to 140°F (-20°C to 60°C)
Storage Relative Humidity	20% to 85% (noncondensing)

Regulatory Safety

Electromechanical Safety	UL 60601-1
Electromagnetic Compatibility	EN 60601-1-2
Electro Medical Safety	EN 60601-1
Programmable System Safety	EN 60601-4
Risk Analysis	EN 1441
Symbology	EN 980

All specifications are subject to change without notice.

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DM805

ComfortScan® System

A New Light in Breast Cancer Diagnosis

DOBI Medical INTERNATIONAL

Tumor Angiogenesis: Fueling Cancer Growth

In 1994, the Angiogenesis Foundation identified angiogenesis as the "common denominator" in many of society's most important diseases, including breast cancer. Research has shown that solid breast tumors become clinically relevant once they develop a blood supply. Recent advances in optical-imaging technology and image processing have focused on identifying the subtle vascular changes often associated with breast cancer in its earliest stages. Once detected, the changes constitute a unique vascular profile that has the potential to indicate the early presence of a vascularized lesion.

The ComfortScan® System—

Advanced Data for Breast Cancer Diagnosis

The DOBI Medical ComfortScan system is an advanced digital-imaging device designed to provide new information that may significantly advance breast cancer diagnosis. The ComfortScan system detects tumor angiogenesis, or abnormal blood vessel growth, which has been associated with aggressive or malignant breast tumors.

A valuable diagnostic tool, the ComfortScan system provides:

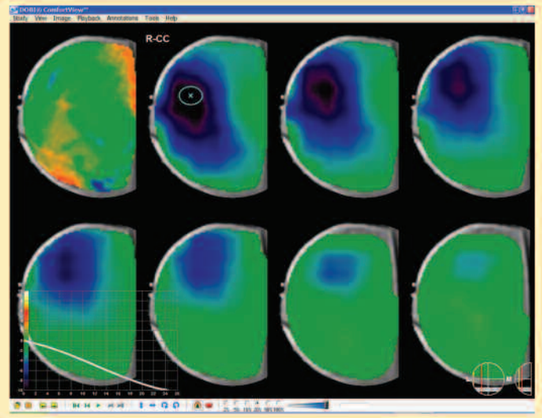
- Gentle, fast, nonradiographic breast examination for angiogenesis
- High-quality, near real-time digital scans using harmless light and proprietary image-processing algorithms
- A platform that can be expanded and used with other diagnostic systems

Unlike X-ray mammography, which provides a singular morphological image (i.e., a static snapshot of physical details at a single point in time), the ComfortScan system is designed to deliver functional, dynamic imaging of changes occurring within the tissue. In combination with mammography and ultrasound, the ComfortScan system should provide physicians with valuable, more complete information to help them determine whether a tumor is malignant or benign.

- UL 60601-1
- CE mark, ISO 9001 and 13485:2003

The DOBI Medical ComfortScan® system has obtained its CE mark and UL certifications. DOBI Medical is a certified ISO 9001:2000 and ISO 13485:2003 company. The ComfortScan system is an adjunct to mammography and is not yet commercially available in the U.S. as it is limited by U.S. law to investigational use until approved by the FDA, which cannot be guaranteed.

Feature Functions	Benefits
Dynamic Optical Breast Imaging (DOBI)	■ Highly sensitive to the differential light-transmission properties of abnormal vascularization after external pressure stimulus ■ Designed to provide new and unique physiological (functional) data currently not readily available to physicians
Targets Angiogenesis	■ Designed to detect key indicators associated with breast cancer ■ Visualizes angiogenesis, reducing ambiguity associated with imaging methods, such as mammography, that provide only morphologic (static) images ■ Targets abnormal vascular bed, a potentially larger target than the tumor itself
Soft Breast Holder	■ Provides comfortable examination with gentle pressure on the breast ■ Enhances attractiveness as a testing method
High-Intensity, Light-Emitting Diodes	■ Noninvasive, no ionizing radiation ■ Designed to overcome certain breast density limitations associated with mammography ■ Can be used for premenopausal women and women on hormone therapy
Fast Exam Time	■ Less than 1-minute image-scanning time ■ High throughput

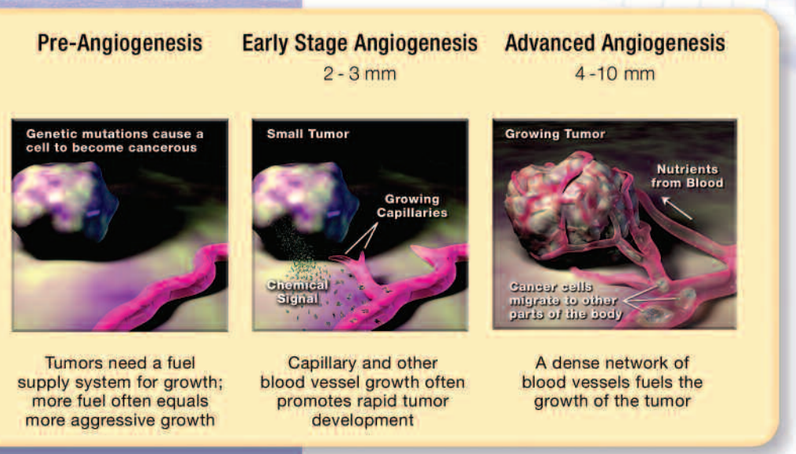


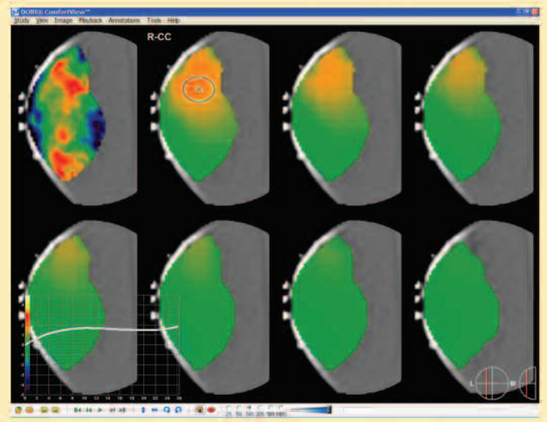
Malignant Case Study

- **63-year-old woman with no prior history.**
- **Suspicious nonpalpable 10 mm mass seen on upper lateral quadrant on mammography. Mammographic findings were indeterminate (BIRADS 0).**
- **ComfortScan image reveals highly suspicious region in upper lateral quadrant.**
- **Case Conclusion: ComfortScan image consistent with core biopsy results revealing invasive ductal carcinoma.**

ComfortView™ Software— the Physician's Interpretation Tool

DOBI Medical's ComfortView software is a simple and intuitive tool for the analysis of angiogenesis and the assessment of breast disease. It enables a quick review and analysis of the dynamic images captured by the ComfortScan system. The Windows®-based software displays color images of the breast, which are color-mapped to indicate areas of increased vascularity. A temporal graph measures the hemodynamic response of the region of interest in the breast to gentle external pressure over time. Images are easily printed or digitally archived for future use and interpretation.





Benign Case Study

- **57-year-old woman with no prior history.**
- **Suspicious nonpalpable 10 mm density seen in upper lateral quadrant on mammography. Mammographic findings were inconclusive (BIRADS 0).**
- **No suspicious areas observed on ComfortScan.**
- **Case Conclusion: ComfortScan image consistent with core biopsy results indicating benign condition.**