

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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ComfortScan®
System

A New Light in
Breast Cancer Diagnosis



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.

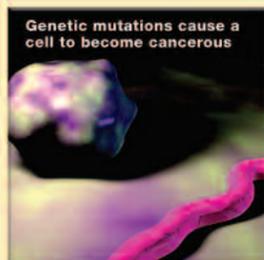


- CE mark, SFDA
- ISO 13485

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.

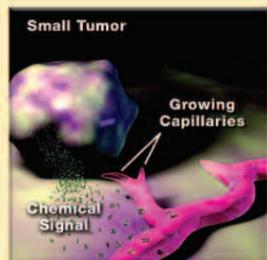
Pre-Angiogenesis



Genetic mutations cause a cell to become cancerous

Tumors need a fuel supply system for growth; more fuel often equals more aggressive growth

Early Stage Angiogenesis 2 - 3 mm



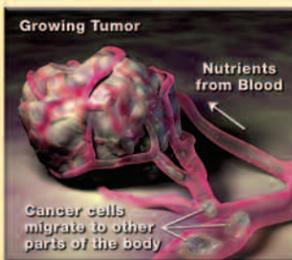
Small Tumor

Chemical Signal

Growing Capillaries

Capillary and other blood vessel growth often promotes rapid tumor development

Advanced Angiogenesis 4 - 10 mm



Growing Tumor

Nutrients from Blood

Cancer cells migrate to other parts of the body

A dense network of blood vessels fuels the growth of the tumor

The DOBI Medical ComfortScan® System has its CE mark and SFDA Approval for international sales, and DOBI Medical is certified ISO 13485 company. The ComfortScan system 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)	<ul style="list-style-type: none"> ■ 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	<ul style="list-style-type: none"> ■ 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	<ul style="list-style-type: none"> ■ Provides comfortable examination with gentle pressure on the breast ■ Enhances attractiveness as a testing method
High-Intensity, Light-Emitting Diodes	<ul style="list-style-type: none"> ■ 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	<ul style="list-style-type: none"> ■ 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.

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.

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.