

ComfortScan[®]
System

A New Light in the
Breast Cancer World

DOBI

Dynamic Optical Breast Imaging



G. John Zhang, Ph.D.

President & CEO

DOBI Global



DOBI Medical
INTERNATIONAL

DOBI ComfortScan[®] System

CCD Camera

Soft Breast Holder

LED Illuminators

Operator Display

Proprietary Software
& Hardware

Mobile, Compact



Present and Future Uses of DOBI Technology



**Diagnostic
Adjunct to
Mammography**



**Broad-based
Breast Cancer
Screening**



**Noninvasive
Therapy
Monitoring**

DOBI Project Contents

- [Background of DOBI Project](#)
- [Clinical Fundamental of DOBI Technology](#)
- [Imaging Principle of DOBI Technology](#)
- [Comparisons of Breast Imaging Modalities](#)
- [DOBI ComfortScan Marketing Development](#)
- [DOBI Screening Device – ComfortScreen](#)
- [DOBI Global Fundraising](#)

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Background *of* DOBI Project



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Five Stages of DOBI Project

- **DOBI Principle Study**
 - DOBI Technique was researched
 - In 1985 at Moscow University
- **DOBI Product Development**
 - DOBI Product, ComfortScan, was developed
 - From 1990 to 2000 by DOBI Medical Systems
- **ComfortScan Marketing Developing**
 - Worldwide Marketing Approvals of ComfortScan were performed
 - From 2001 to 2007 by DOBI Medical International
- **ComfortScan Initial Sales**
 - Over Fifty ComfortScans were sold mostly at Italy and Beijing
 - From 2008 to 2010 by XinAoMDT
- **DOBI Project Reorganization**
 - DOBI ComfortScan is remanufactured
 - Since 2011 by DOBI Global

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DOBI Clinical Fundamental

Tumor Angiogenesis

A Natural Biomarker

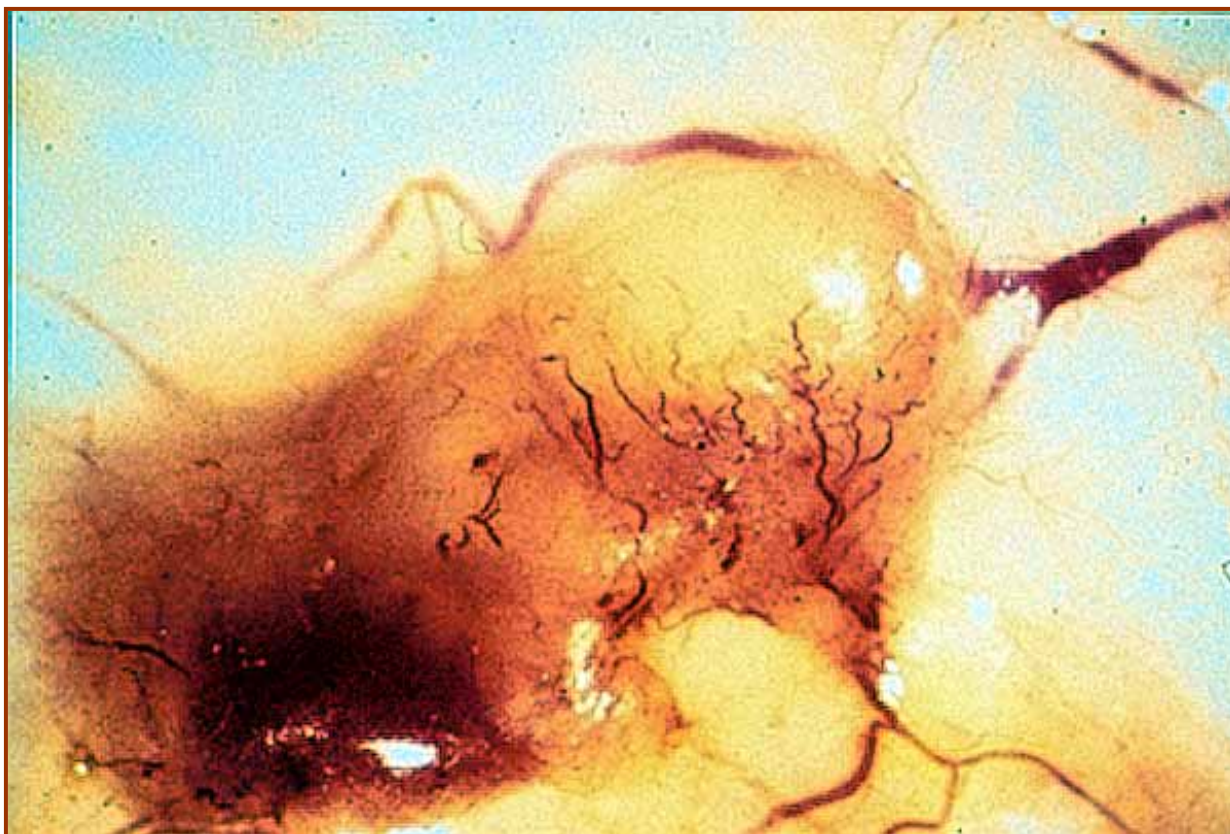
For The Presence Of Breast Cancer



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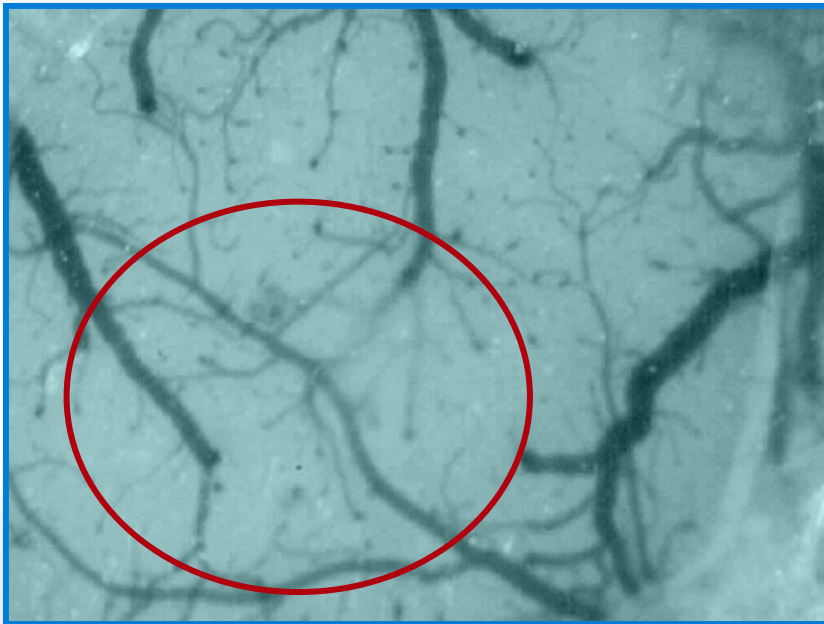
Angiogenesis in the Breast

ComfortScan provides physicians with new, functional physiological information useful for improved clinical decision-making



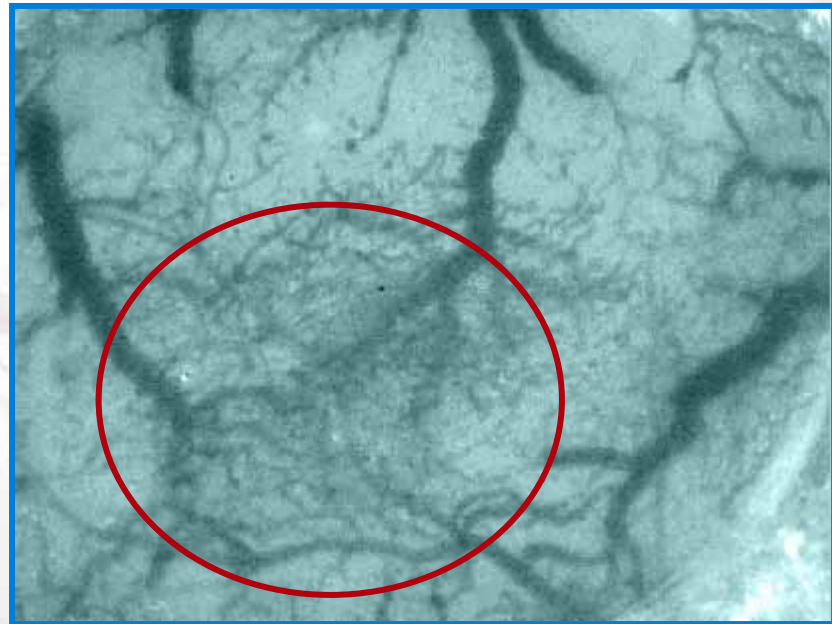
Close-up of a network of angiogenic vessels around a breast cancer lesion

Blood Vessel Growth Surrounding a Tumor



1 day after tumor implantation

- Uniform A-V flow
- Normal permeability
- Vascular hierarchy maintained

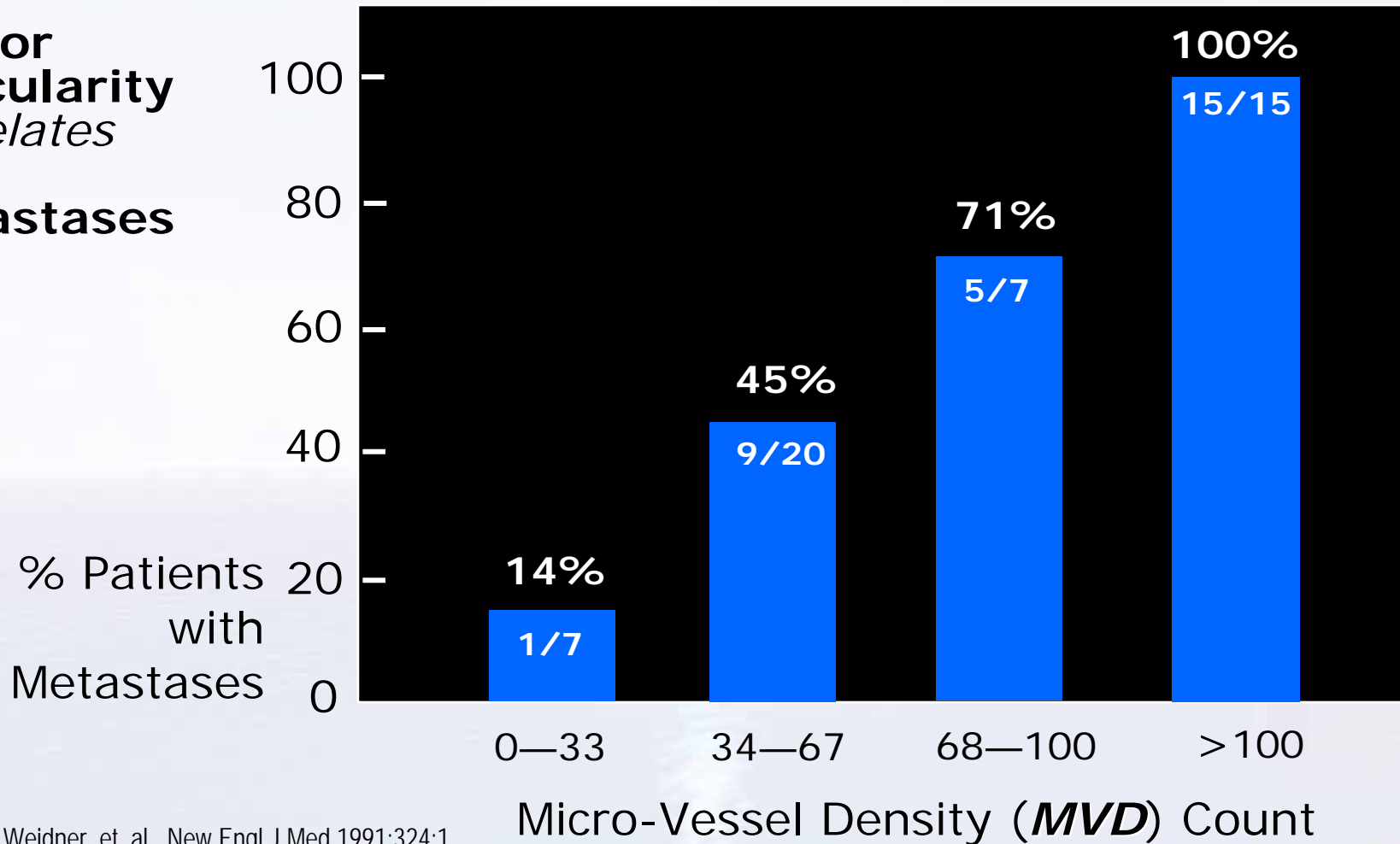


7 days after tumor implantation

- Chaotic to poor flow or regional stasis
- Hyper-permeable and leaky
- Disorganized architecture

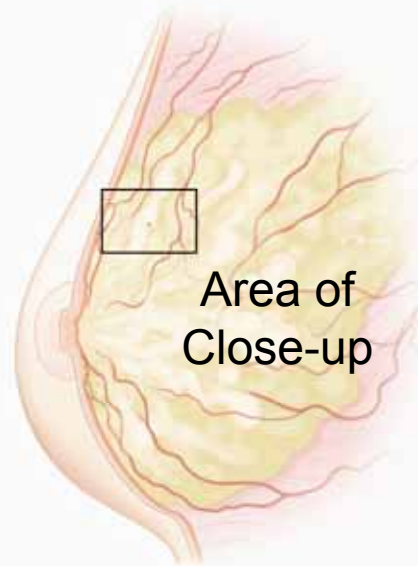
Angiogenesis in the Breast

Tumor Vascularity
correlates with
Metastases



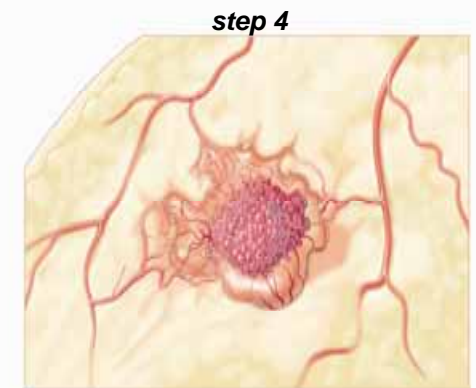
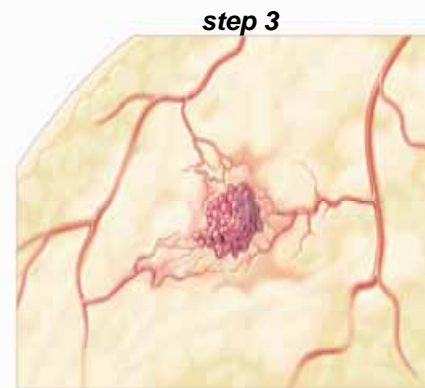
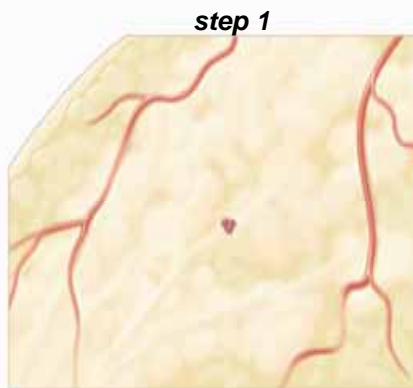
From: N Weidner, et. al., New Engl J Med 1991;324:1

Tumor Angiogenesis in the Breast



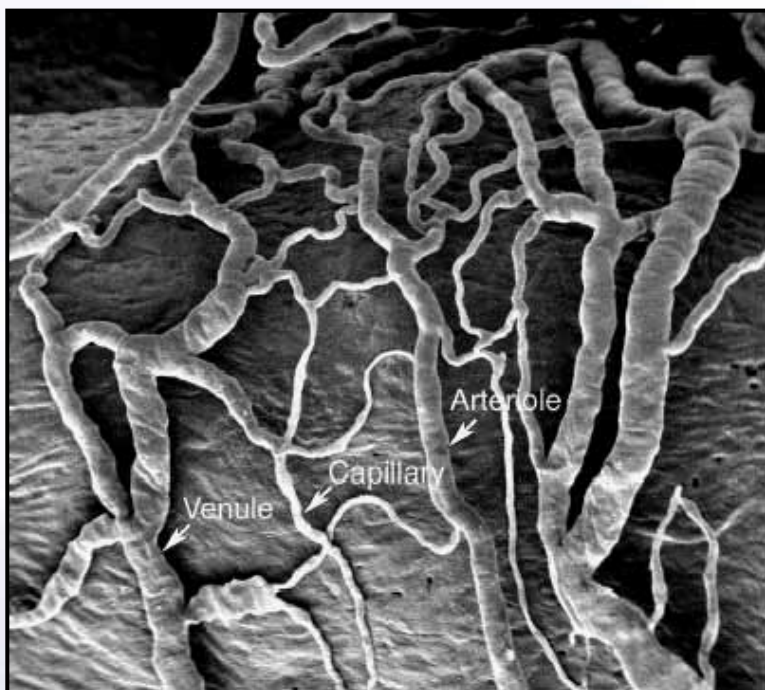
When a malignant tumor starts to grow in the breast (step 1), It usually becomes supported by a complex network of blood microvessels (step 2) That feed it and assist in its local growth and development (steps 3 and 4). This vascularization process is called tumor angiogenesis.

The ComfortScan system has been designed to be able to detect this abnormal network of blood vessels, thereby providing a useful complement to common mammographic images.



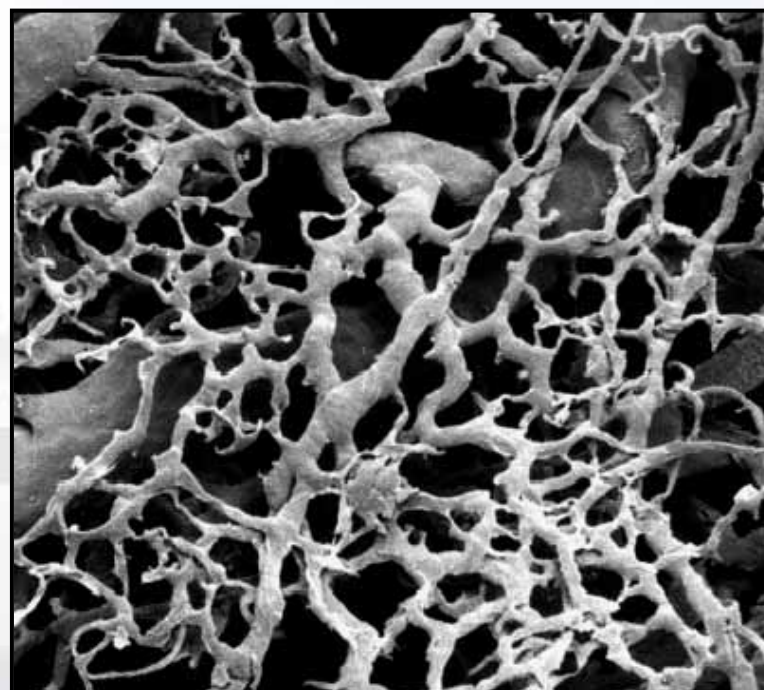
Angiogenesis in the Breast

Normal



- Uniform A-V flow
- Normal permeability
- Vascular hierarchy maintained

Tumor



- Chaotic to poor flow or regional stasis
- Hyper-permeable and leaky
- Disorganized architecture

Source: M Konerding (From: DM McDonald and PL Choyke. Nat Med 2003;9: 7)

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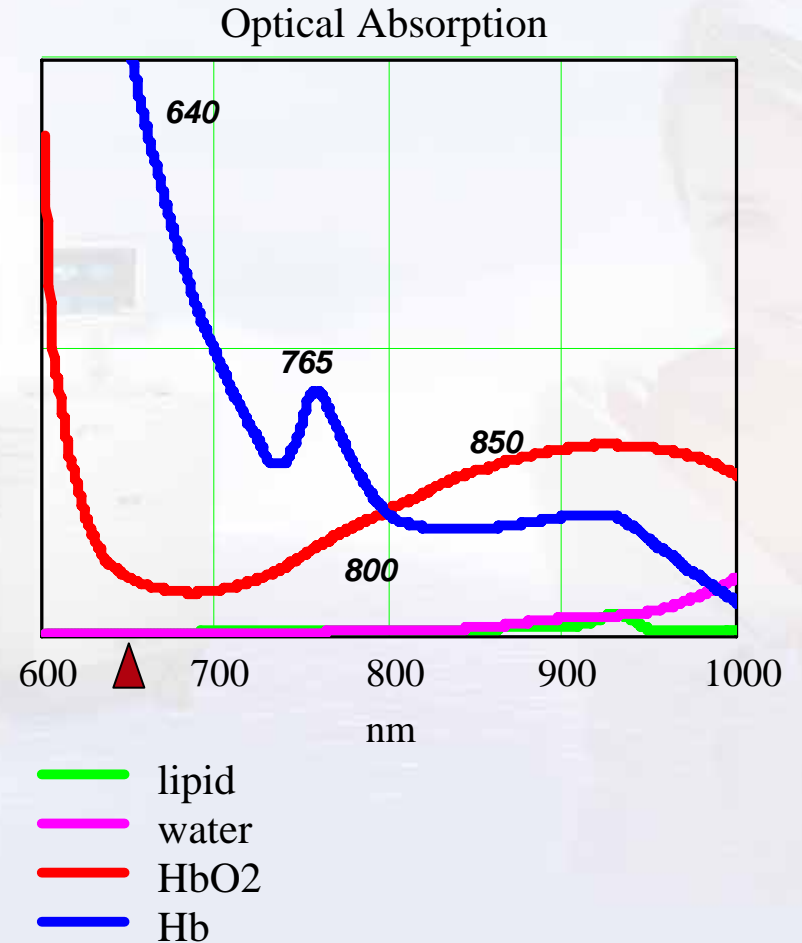
DOBI Imaging Principle

DOBI ComfortScan Overview & Operation

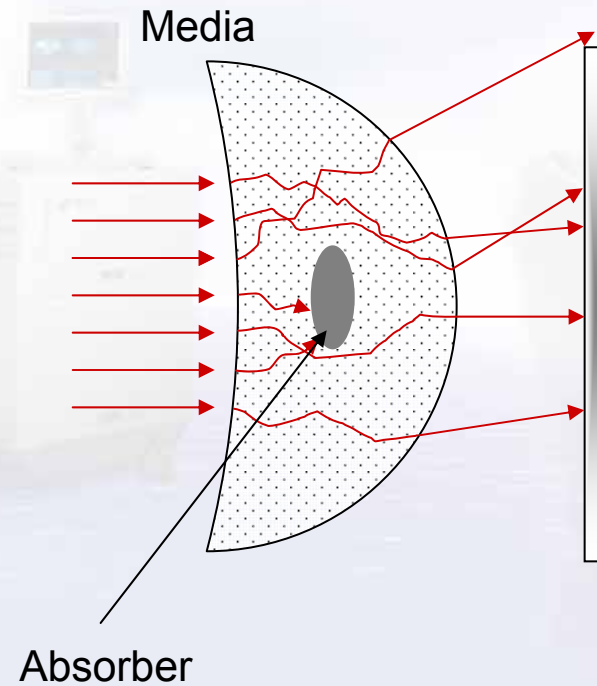
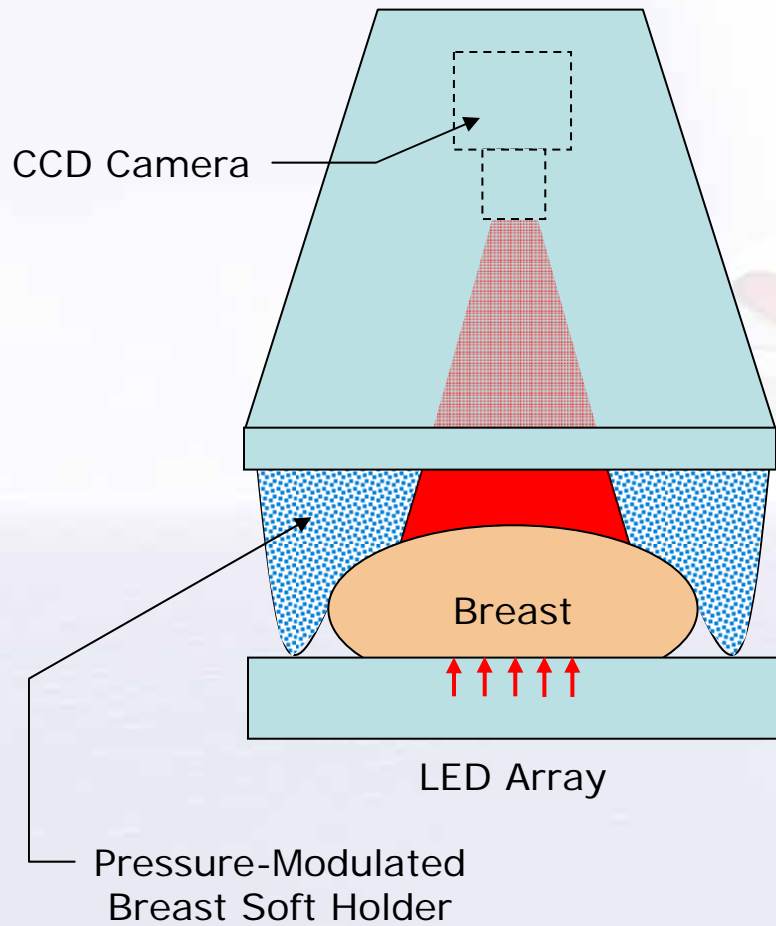


Optical Properties of Tissue

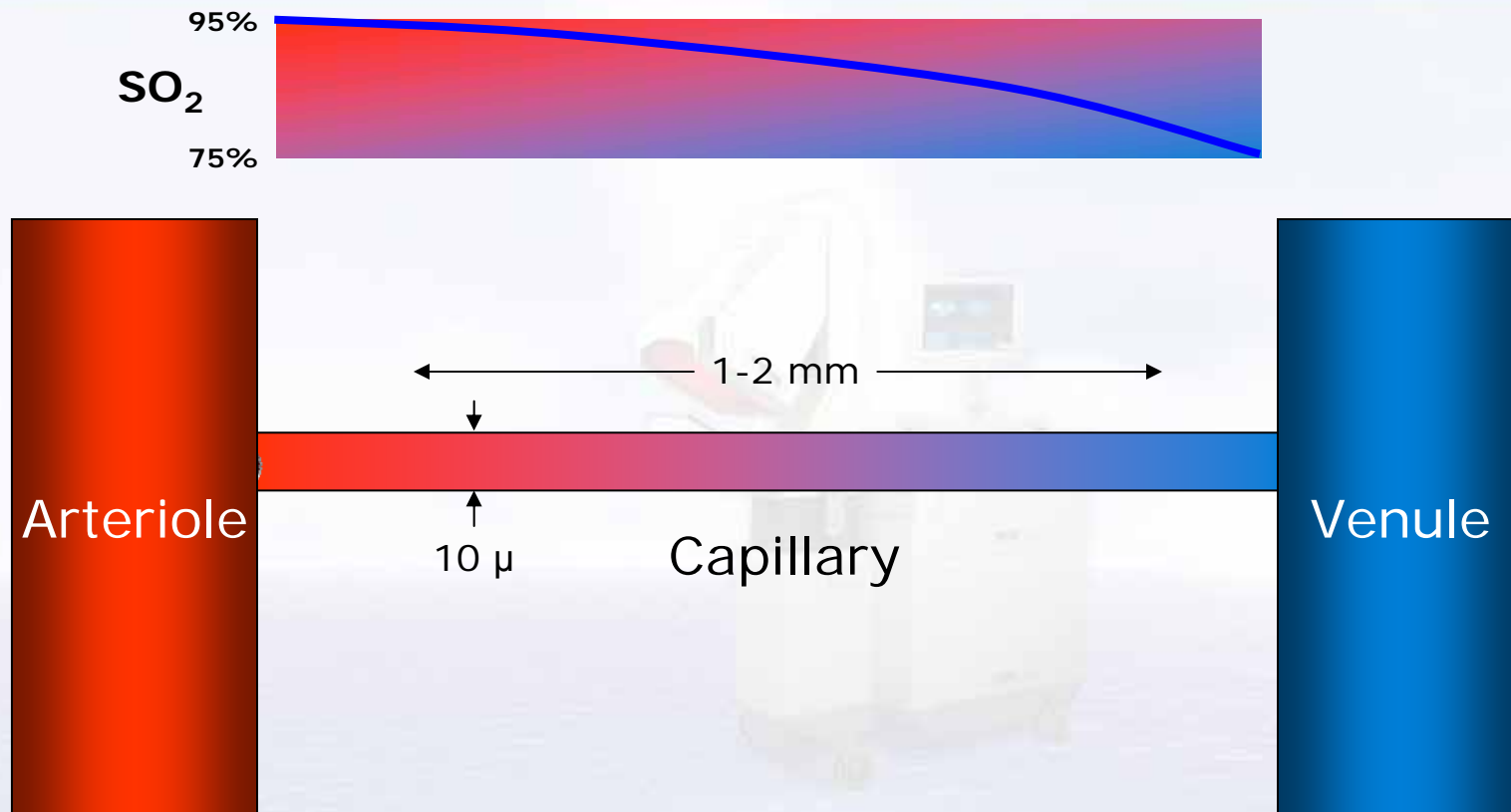
- Highly scattered and diffused
 - Scatter \gg absorption
- 640 nm light is absorbed by blood
 - Absorption greater in de-oxy vs. oxy-hemoglobin
- Light absorption increases with:
 - Blood volume
 - Hypoxia



ComfortScan[®] Imaging Principle

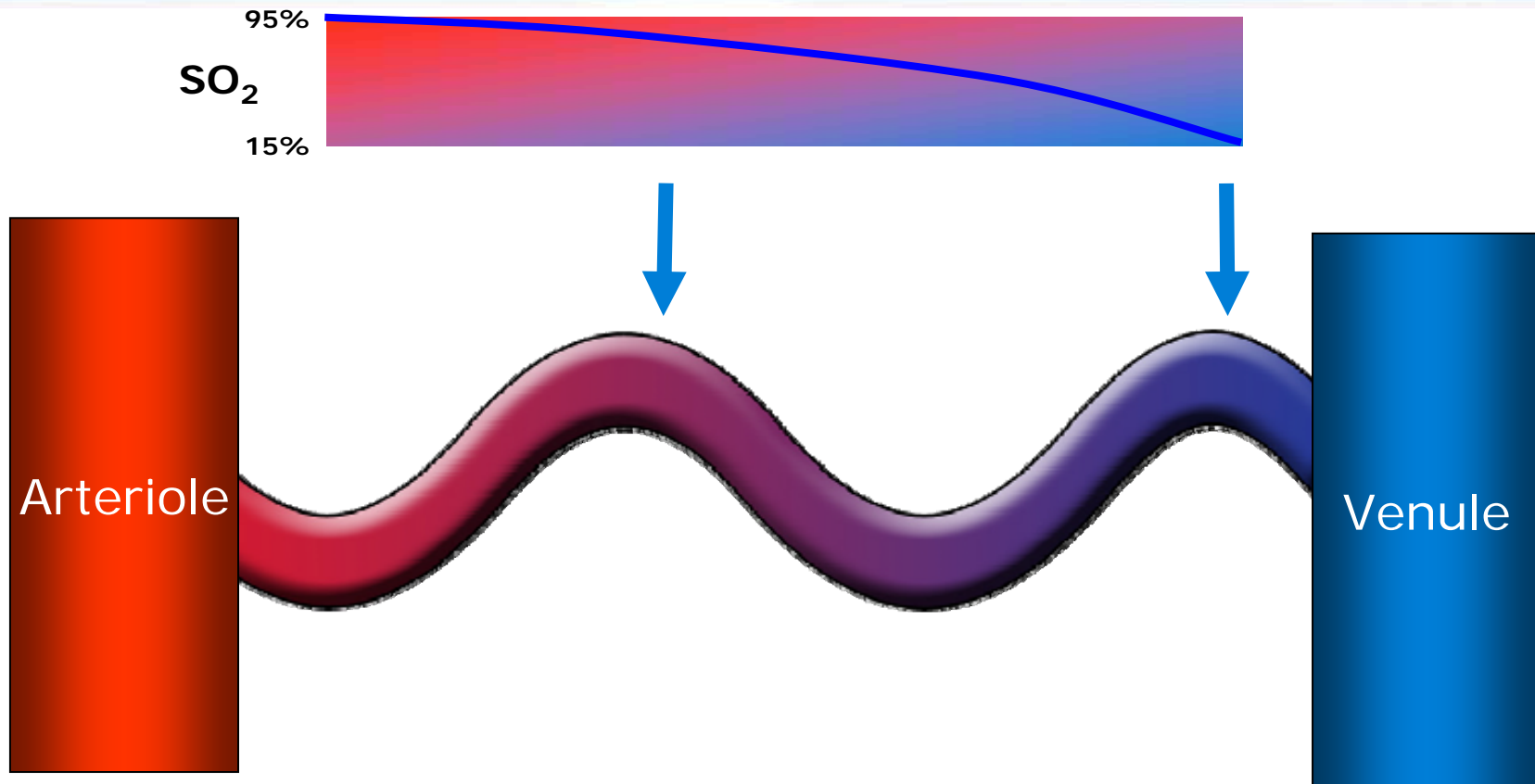


Effect of Pressure on Angiogenic Vessel



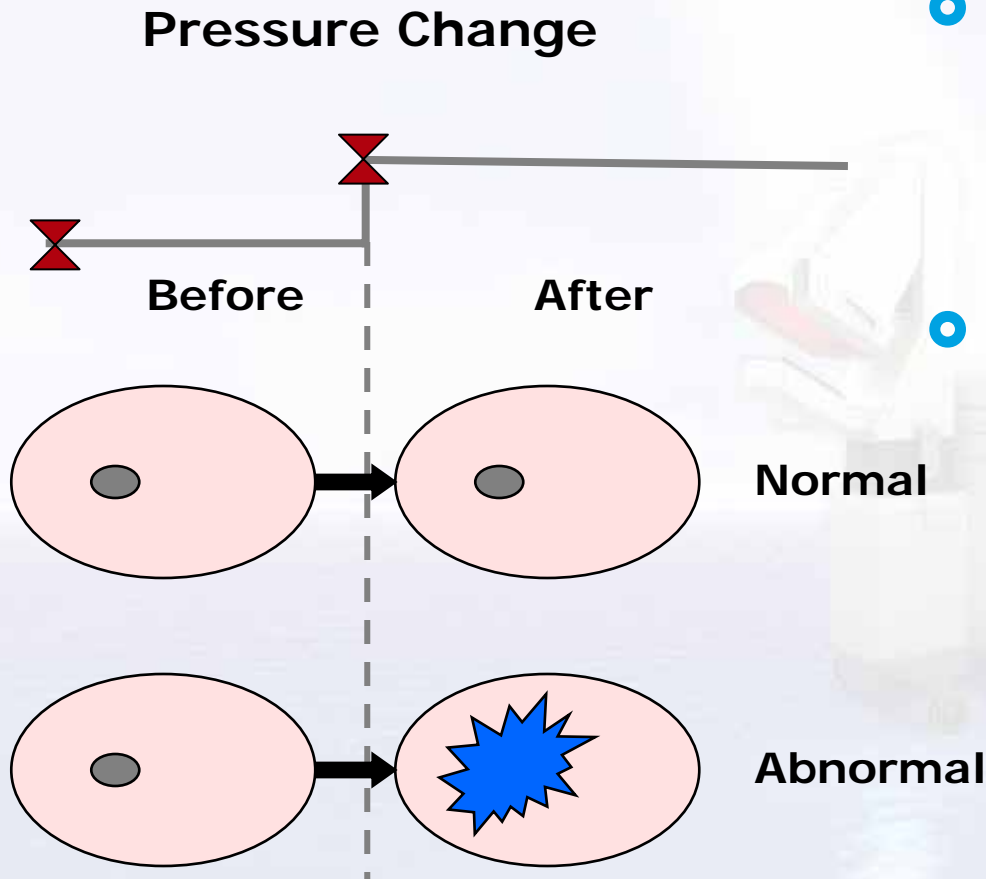
Pressure removes blood from normal Vessel -> No Light Absorption

Effect of Pressure on Angiogenic Vessel



Pressure causes blood block within the Angiogenic Vessel
Tumor Angiogenesis absorbs Light

Dynamic Optical Breast Imaging (DOBI®)



- Use slight pressure stimulus to create contrast between normal and angiogenic areas
- Contrast appears over time in response to pressure
 - Tortuous vessels trap blood
 - High metabolic rate tumor enhances hypoxia
 - ComfortScan is sensitive to changes in blood volume and oxygen saturation

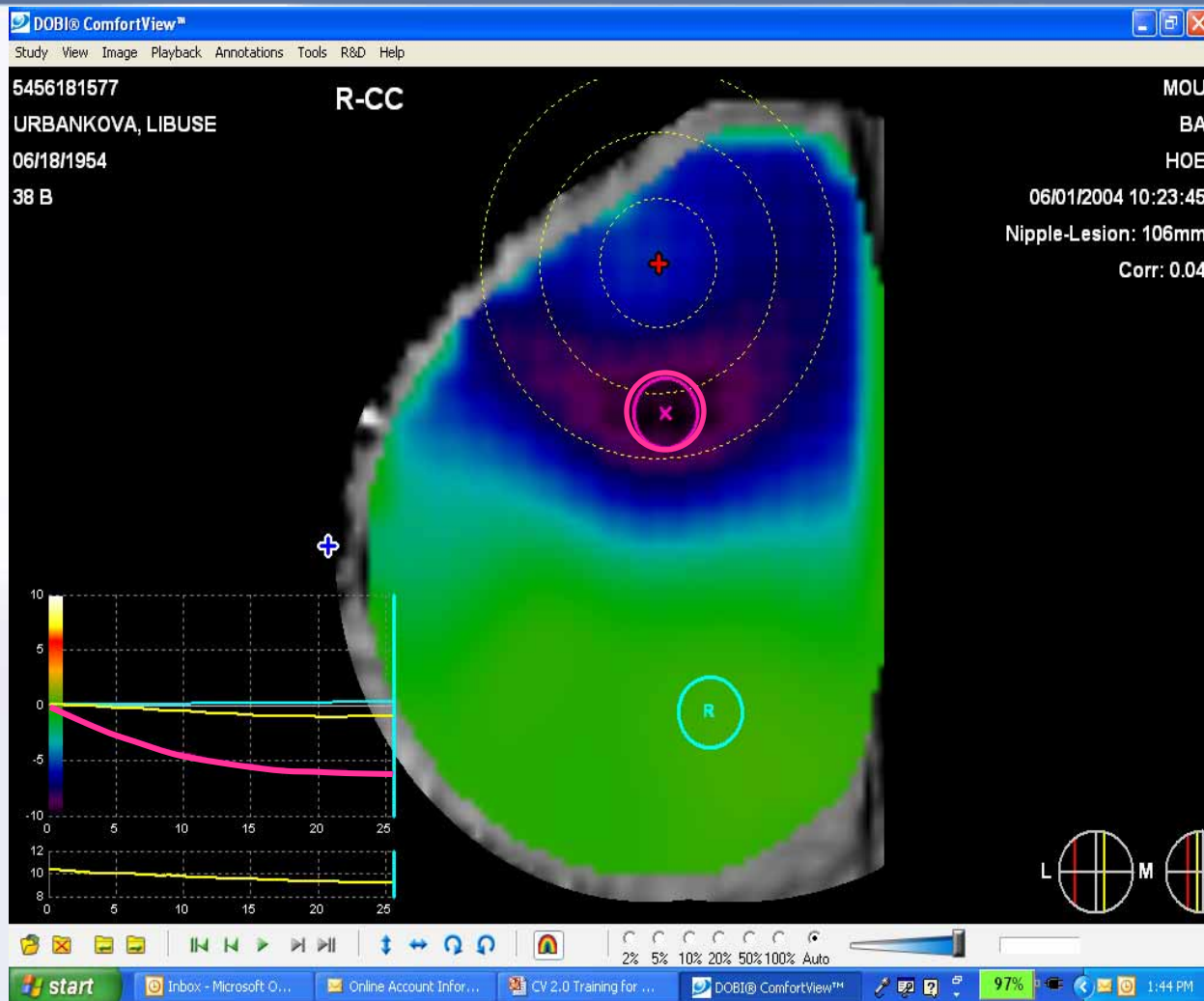
How ComfortScan Works

- Slight, uniform pressure is applied to the breast to capitalize on the properties of tumor angiogenesis
 - *2.5 images per second in < 1 minute*
 - *Pressure change applied to breast (5~10mm Hg)*
 - *Observe provocation induced changes*
- Detect changes in tissue light absorption properties
 - *Pooling → change in blood volume*
 - *High metabolic rate → change in blood oxygen levels*

Thus, the ComfortScan system is sensitive to unique changes in blood volume and metabolic rates associated with angiogenesis in the breast

ComfortView

- Image overview, **spatial** characteristics
- Breast “behavior”—**temporal** characteristics
- Area of **angiogenesis**—spatial/temporal characteristics

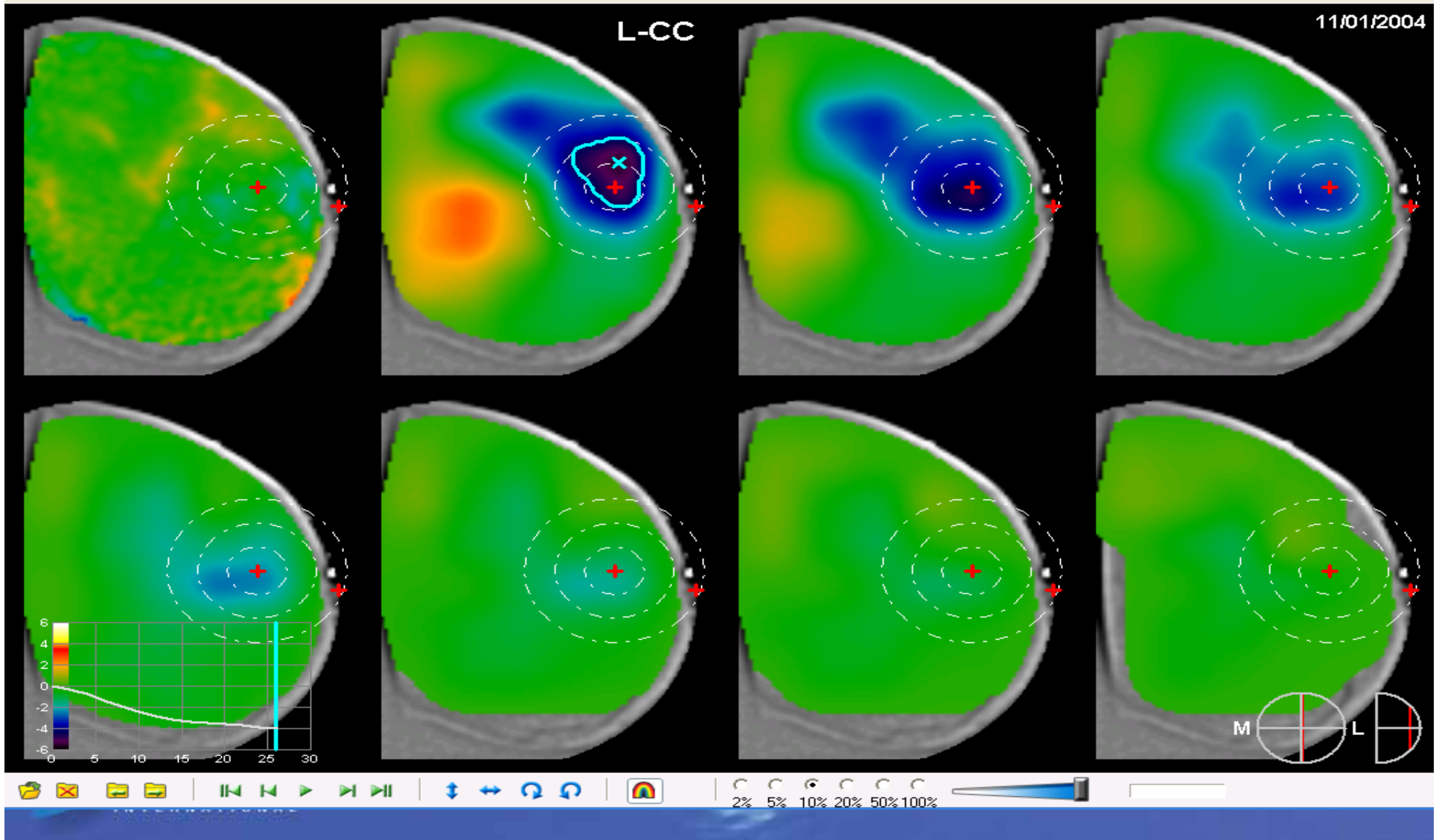


Case Study

60y woman, Non-palpable 22mm mass
Equivocal mammography BIRADS 5 μ calcified
Pathology: Ductal Carcinoma.

DOBI® ComfortView™

Study View Image Playback Annotations Tools Help



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Comparison
with other
Breast Imaging Technologies



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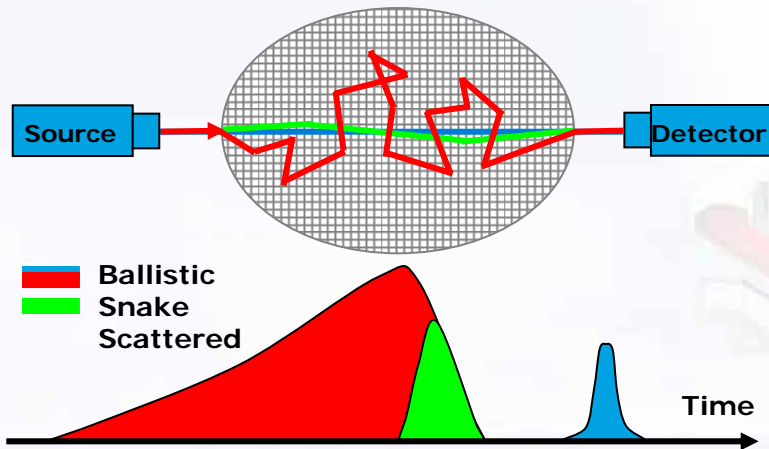
Comparison of Optical Technologies

Factor	DOBI	IMDS	ART
Technology	DOBI	DOT	TOF
Dynamic or static	Dynamic	Static	Static
Intrinsic contrast	Pressure	None	None
Detects unique angiogenic signature	Yes	No	No
Scan Time	1 minute	~15 minutes	~15 minutes
Analysis Time	10 seconds	~10 minutes	~10 minutes
Price	\$	\$\$	\$\$\$

Among optical imaging techniques, the ComfortScan[®] system is unique in that it exploits the properties of angiogenesis to create and detect discernible contrast differences between angiogenesis and normal tissue

Comparison of Optical Technologies

Time Domain Imaging

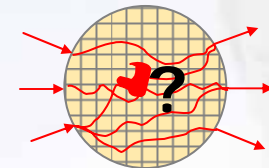
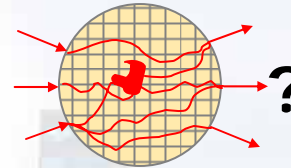


ART



Diffuse Optical Tomography

Forward Problem Easy Inverse Problem Hard



IMDS



Imaging Technologies Comparison

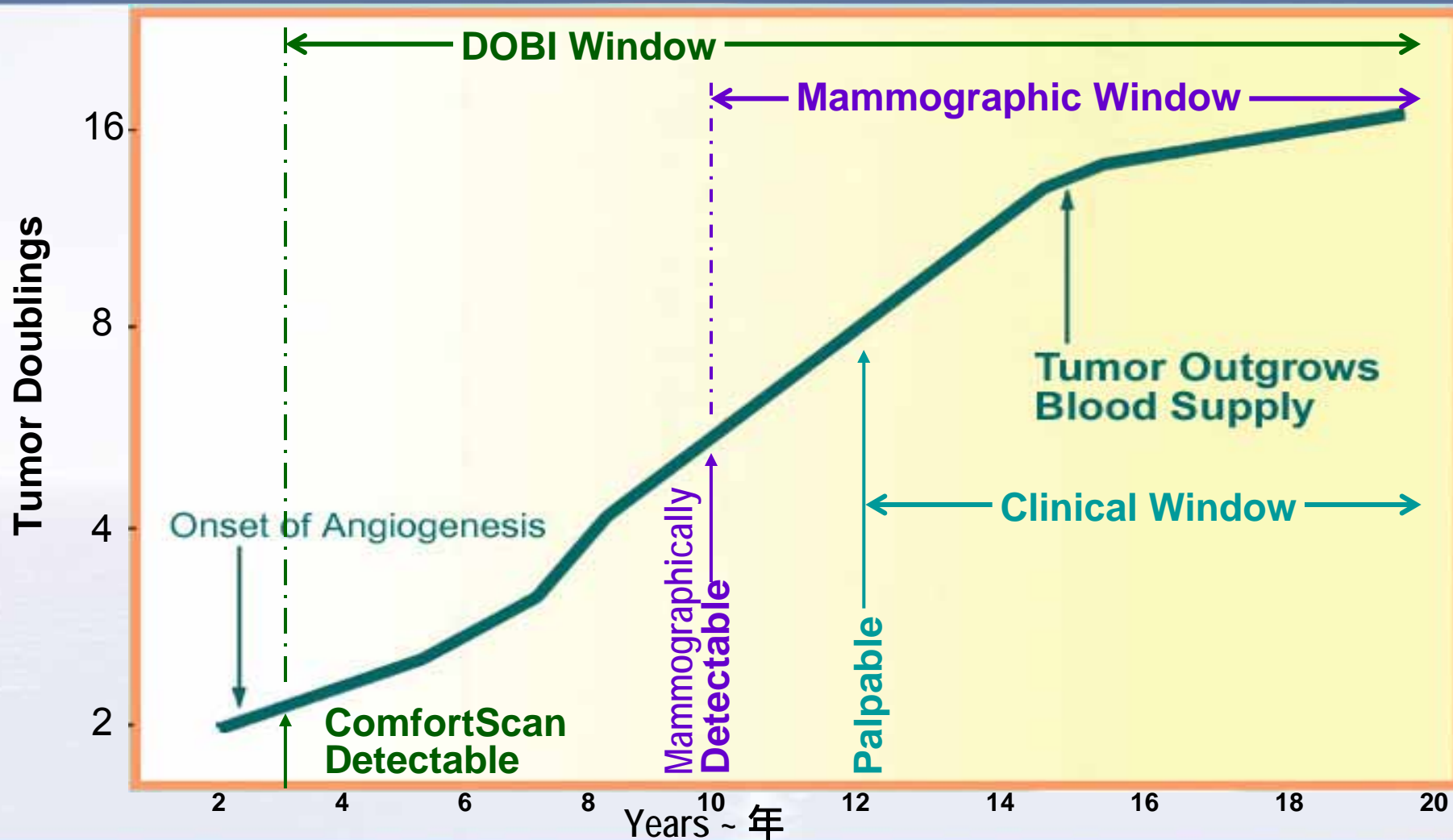
Technology	Sensitivity	Specificity	Imaging Method
Mammography*			
Ages 50 Above	89%	45%	Morphological
Ages 50 & Below	58%	40%	Morphological
Ultrasound *	75%	94%	Morphological
MRI **	96%	69%	Physiological
ComfortScan System ***	92%	67%	Physiological

*T. Kolb, J Lichy, J. Newhouse - Radiology Oct. 2002: "Comparison of the Performance of Screening Mammography Physical Examination, and Breast US and Evaluation of Factors that Influence Them: An Analysis of 27,825 Patient Evaluations"

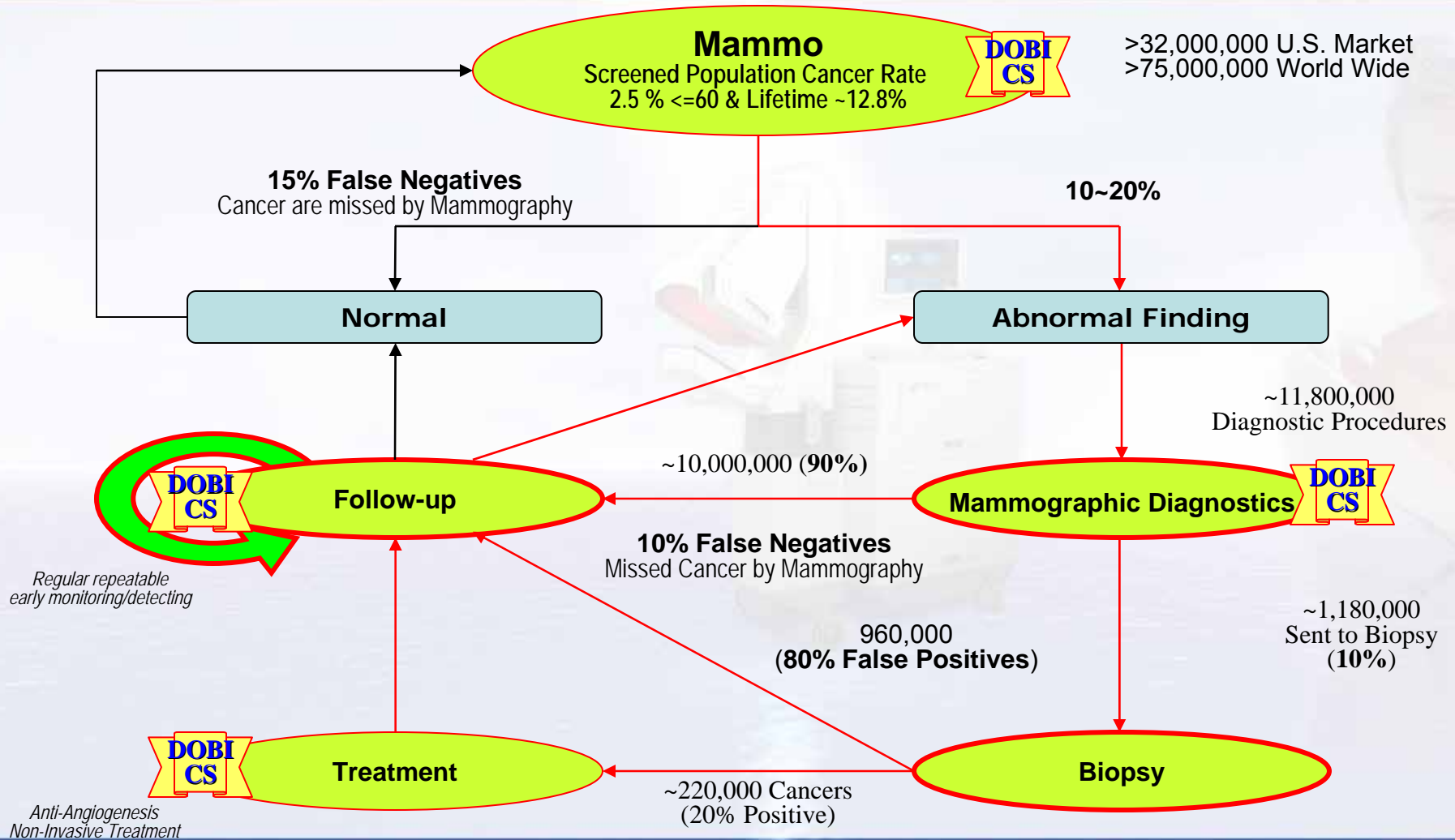
** Kaiser Permanente, Technical Review of MRI 2003

***Internal Validation Study for ComfortView Rev. 1.0. 2002~2004 316 Patients

Life Cycle of Breast Cancer – Different Timing



Mammography Diagnostic Work-up Process



Recent DOBI Clinical Results

	DATE	START	END	MODALITY	DATA	MALIGNANT	SE	SP	PPV	VPN	Accuracy	REGIO N	INSTITUTION	INVESTIGATOR
1	10/3/2011	09/2008	03/2010	ComfortScan	617	269	98%	87%				Italy	Centro Chirurgico Magentino, Centro Medico Monte Rosa Humanitas, Habilita Group-Bergamo	V. Frattinia, L. Ghisoni S. Orefice, PL Vaj
				Ultrasound			74%	70%						
2	2011			ComfortScan	113	74	80%	88%				Italy	Multicenters	DOBI Sough European Distributor Socrate Medical
3	2011			ComfortScan	33	19	83%	67%				Canada	MCMMASTER UNIVERSITY	Kyle J. Wilson, Kavita Dhamanaskar, Terry Minuk, and Gerald R. Moran
				Mammography			94%	13%						
4	2010	06/2009	09/2009	ComfortScan	32	30	72%	92%	93%	61%	79%	Italy	University of Rome Tor Vergata	Rossella Dandolo
5	10/12/2009	06/2008	12/2008	ComfortScan	391	50	95%	78.80%				Italy	Tecnologie Centro Medico Monterosa	di Piercarlo Salari, Oncologia, Tecnologie
				Ultrasound			66%							
6	2009			ComfortScan	46	35	74%	92%	93%	55%	79%	EU	Europa Journal of Radiology 69	Laure S. Fournier, Daniel Vanel, Alexandra Athanasiou, Wolfgang Gatzemeier, I.V. Masuykov, Anwar R. Padhani, Clarisse Dromain, Ken Galetti, Brian Sinal, Alberto Cresta
7	2007	11/2004	11/2005	ComfortScan	72	49	73%	38%					International Cancer Imaging Society 7	Alexandra Athanasiou, Daniel Vanel, Laure Fournier, and Corinne Balleyguier
8	2005			ComfortScan	25							EU	Europa Journal of Radiology 54	Alexandra Athanasiou, Daniel Vanel, Corinne Balleyguier, Laure Fournier, Marie Christine Mathieu, Suzette Delalogue, Clarisse Dromain
				MRI										
9	2006			ComfortScan								EU	Iaso Hospital in Greece in Cancer Imaging 6	Abraham A. Ghiatas, K Pavlaki, I Messini, N Karaglani, D Keramopoulos, V Gaki, D Baltas, and N Bredakis
10	2005			ComfortScan	102	32						EU	Iaso Hospital in Greece	Abraham A. Ghiatas
11		2004	2005	ComfortScan	100	41	71%	64%			76%	Czech Republic	MASARYK MEMORIAL CANCER INSTITUTE	Irena Komorousova, Bartonkova H., Standara M., Schneiderova M.
				Mammography			66%	75%			76%			
12	12/2004	03/2003	2004	ComfortScan	35	30	100%	80%	20%	100%		US	San Antonio Breast Cancer Symposium	Gatzemeier W, Scelsi M, Galetti K, Villani L, Tinterri C, Secci A, and Costa A
13	05/2004	10/01/2000	09/30/2001	ComfortScan	117	15	87%	77%		98%		US	Scientific and Technical Aerospace Reports 42	Suzanne J. Smith
14	09/2004	03/2003	01/2004	ComfortScan	68	49	98%	63%				US		DOBI Medical International
15	2010	05/2007	06/2008	Ultrasound	52	19	73.68%	75.76%				China	301 PLA Hospital	Guojian Tan, Jie Wang, Cui Liu, Chunmian Li, Weiping Wang, John Zhang
				ComfortScan+Ultrasound	25		87.50%	55.56%						
16	2010			ComfortScan	52							China	301 PLA Hospital	Guojian Tan, Jie Wang, Cui Liu, Chunmian Li, John Zhang, Weiping Wang
				ComfortScan(<1cm)			85.70%	80.00%			81.80%			
				Ultrasound(<1cm)			71.40%	40%			50.00%			
17	06/01/2009			ComfortScan(1cm-2cm)	74	33	78.60%	64.10%			71.00%	China	Chinese PLA General Hospital & Postcarduate Medical School	Mei Xu
				Ultrasound(1cm-2cm)			85.70%	76.50%			80.60%			
				ComfortScan(>2cm)			25%	44.40%			33.00%			
				Ultrasound(>2cm)			83.30%	77.80%			81.00%			
				ComfortScan			83.30%	80%			81.50%			
18	2008			Ultrasound	64	30	80.00%	85%			83.10%	China	301 PLA Hospital	Yongfeng Zhang, Junlai Li, Xuejuan Shi, Mei Xu
				ComfortScan+Ultrasound			93.30%	82.90%			87.70%			
				ComfortScan(Overall)			89.62%	68.42%			78.63%			
				ComfortScan(<2cm2)			93.75%	86.49%			88.67%			
19	02/2011	2008	2009	ComfortScan(>=2cm2)	220	131	94.12%	66.67%			84.61%	China	Multicenters	G. Zhang, W. Lin and Wang Yan
				ComfortScan(<1cm)			91.67%	88.24%			89.13%			
				ComfortScan(>=1cm)			95.24%	66.67%			84.84%			
				Non-Palpable			87.67%	58.82%			73.75%			
20	02/2011	2008	2009	ComfortScan+Ultrasound	53	21	90.50%	84.40%			86.60%	China	Multicenters	G. Zhang, W. Lin and Wang Yan
21		2005	2006	ComfortScan	62	31	83.90%	61.30%		79.2%		China	Peking Univisity People Hospital Capital Univisity Chaoyang Hospital	G. Zhang, W. Wang, D. Yang and H. Jiang
DOBI Averaging Statistics					2328	958	83.87%	73.90%	68.67%	78.64%	78.13%			

ComfortScan[®]
System

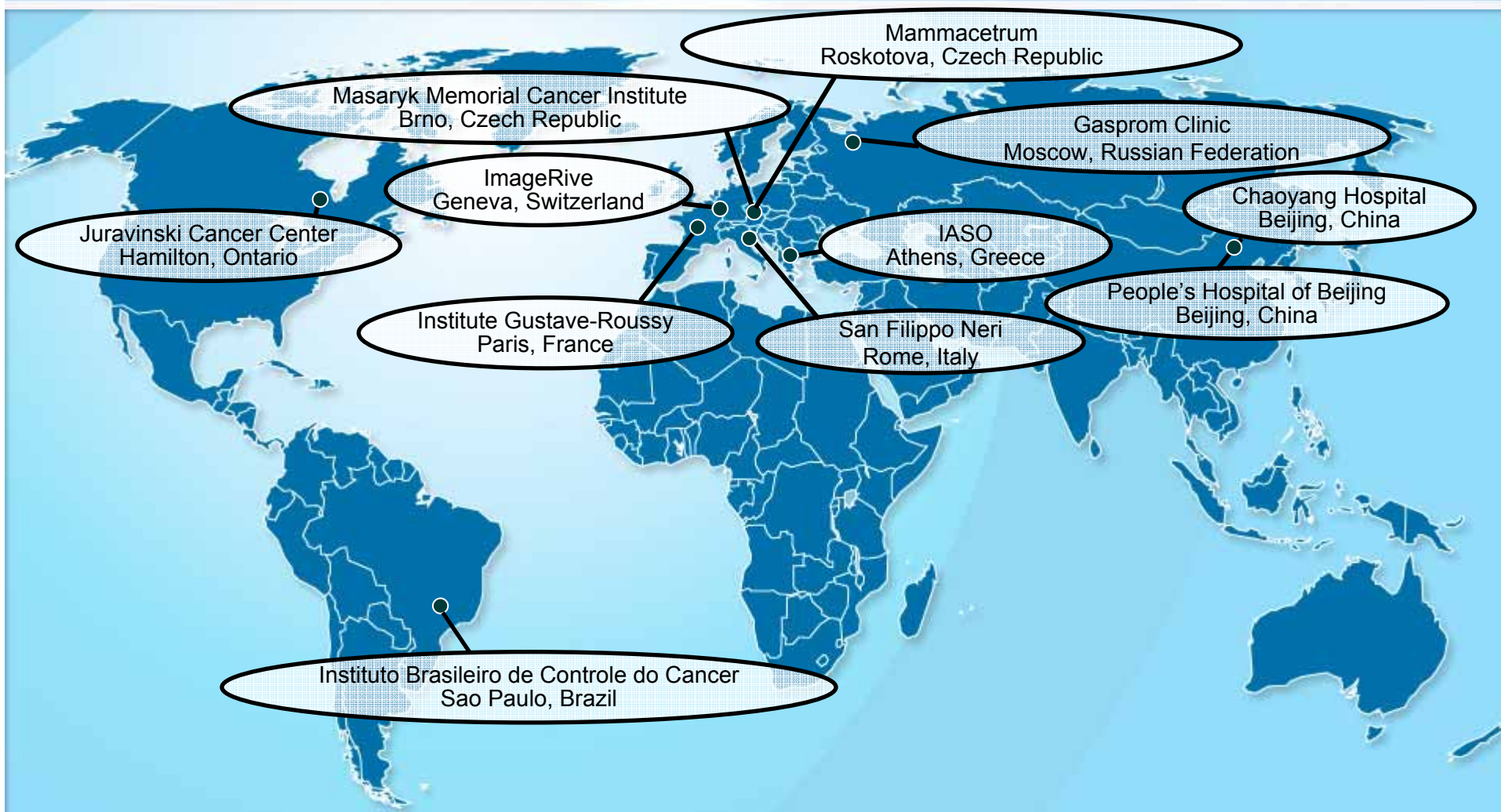
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DOBI Market Approval Development



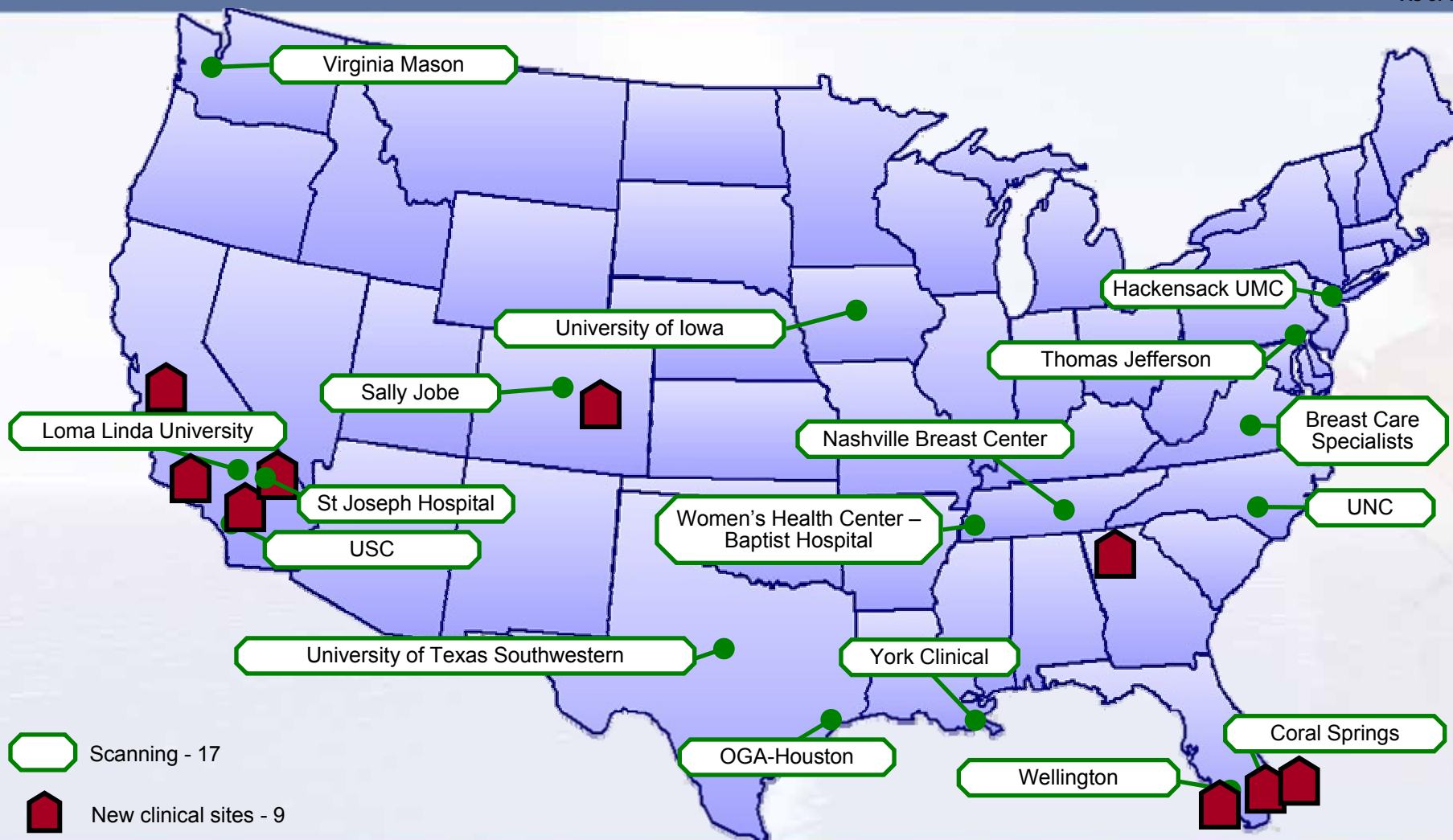
DOBI Medical
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International Clinical/Regulatory Activities



Past PMA Sites Summary (2002~2006)

As of 7/11/05



DOBI Production Quality System

Intertek



Certificate Number
SSC-0113

Initial Certification Date
January 6, 2011

Certificate Issue Date
January 6, 2011

Certificate Expiry Date
January 6, 2014



Certificate of Registration

The following organization's quality management system has been assessed and registered by Intertek Testing Services NA Ltd. as conforming to the requirements of:

ISO 13485:2003

Organization:

DOBI Medical International Inc.

7 Thompson Road, East Windsor, Connecticut, 06088, USA

The Quality Management System is applicable to:

Design, manufacture and distribution of Dynamic Optical Breast Imaging Systems and Accessories.

In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement.

CF105-CA-MED - Issue Date: 01/06/2011

Intertek Testing Services NA Ltd. – Lachine, QC, Canada

China Market Approval



Russia Market Approval



China Initial Sales : 2008~2010



Italy Initial Sales : 2008~2010



Screening Project in Italy

Istituto Nazionale dei Tumori Fondazione G. Pascale
1° European Focus Meeting

24 - 25 June, 2010
Castel dell'Ovo, Naples
www.uwbc.it



UNDERFORTY
WOMEN



BREAST
CARE

Excellence in young women breast care

Chairmen

Giuseppe D' Aiuto, Tonino Pedicini, Aldo Vecchione

Scientific Coordinator
Massimiliano D' Aiuto

Underforty Women Breast Care



Screening Project in China



***National Women
Free Screening Project
from 2011 to 2015***



Screening Potential in America

- U.S. Preventive Services Task Force (USPSTF) recommendation on Nov. 2009
 - Against routine screening mammography in women aged 40 to 49 years
 - Biennial screening mammography for women between the ages of 50 and 74 years.
- The USPSTF recommends against teaching breast self-examination (BSE).
- The USPSTF concludes that the current evidence is insufficient to assess the additional benefits and harms of either digital mammography or MRI instead of film mammography as screening modalities for breast cancer.

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DOBI Screening Product

**ComfortScreen
Development**



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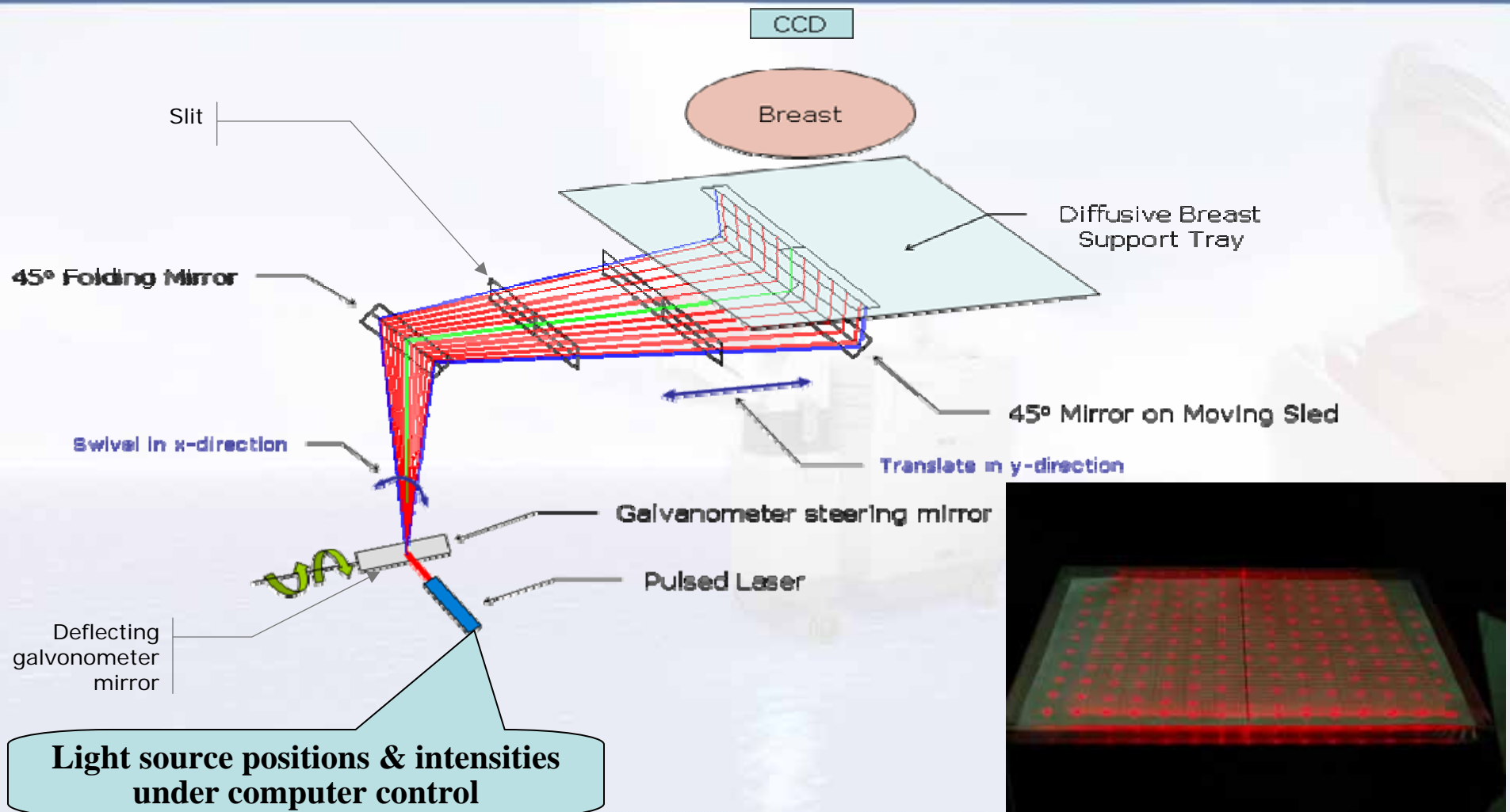
On-going Technological Enhancements

- ✓ Multi-wavelength data acquisition
- ✓ Larger field of view for full breast imaging
- ✓ Variable views of the breast
- ✓ Enhanced small breast imaging
- ✓ 3D imagery
- ✓ Integration of optical capabilities with other imaging modalities such as ultrasound, etc.

ComfortScreen Compared to ComfortScan

	ComfortScreen	ComfortScan
Light Source	Laser	LED
Number of light Sources / Geometry	180 (Slow Mode) ~ Super Cluster (easily reconfigurable)	127 ~ Row
Number of source locations (bottom scan)	~ 4000 (Fast Mode)	--
Max light Sources per scan Number of source locations (voxel model)	180	5
Light Source Spacing	20 mm	12.5 mm
Active Scanning Area	28 x 22 cm²	18 x 12 cm²
Adaptive scanning with breast size	Yes	No
Wavelengths	658 nM, 808 nM and 730 nM, 940 nM	635 nM
CCD Resolution	64 x 64 (~3.8 mm/pixel)	102 x 128 (~1.7 mm /pixel)
CCD Frame Rate	180 Frames/Sec	2.5 Frames/Sec
CCD integration time	~ 5 msec	200 msec
Fast mode photodiode integration time	~ 40 μsec	--
Breast Tray Angle	Horizontal	30 Degrees off Horizontal
C-Arm Rotation	Yes (Not in prototypes)	NO
Scan Time	~ 1 minute	~ 1 minute
Soft Holder Pressure	5 ~ 10 mmHg (max)	5 ~ 10 mmHg (max)
File Size	80+ Mbytes	4+ Mbytes

ComfortScreen Optical Delivery System



Engineering Prototype – W.I.P.



ComfortScreen – System Improvement

- Better to fit small breasts
- Easier to position breasts
 - Multi-wavelength
 - Scan time < 1 minute
 - Adaptive scanning

- Full-field acquisition
- Accommodates large or small breasts
- CC view
- MLO view

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DOBI Global Fundraising

*US Operation
ComfortScreen Developing*



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INTERNATIONAL

DOBI Global Company

• DOBI Global

- Manufacturing
- Marketing, Sales & Services
- Technology & Product R&D

• DOBI Technology and Products

- DOBI Technology Intellectual Property
- DOBI ComfortScan Product
- ComfortScan Production Line : QSR
- DOBI ERP Systems
- ComfortScreen Engineering Prototype

• International Market Reorganization

- Awareness & Acceptance of DOBI ComfortScan through Initial Sales
- Fifty conceptual purchasing orders in 2012

DOBI Global Intellectual Property

DOBI Intellectual Property List with their Values

25 Year Developing	1	ComfortScan Production Line	30,000,000
	2	Quality Management System	10,000,000
	3	ERP System	10,000,000
	4	ComfortScreen Engineering Proto type	5,000,000
10 Year Product Development	5	Clinical Data	20,000,000
	6	Inventory	5,000,000
	7	CS/CV/CN/etc. Software	30,000,000
	8	Patents & Treadmark	5,000,000
	9	Technical Documents & Website	5,000,000
	10	Derivatives / Know How	10,000,000
	11	Certificates: ISO13485/CE/FDA-EOC/SFDA	5,000,000
6 Year Marketing Development	12	Marketing Brand & Materials	10,000,000
	13	Supply/Distribution Channels & Sales Contracts	55,000,000
	<u>TOTAL</u>		<u>200,000,000</u>

DOBI Global Old Patents

International Patent Applications

1. US 5,699,797	Covers a method and apparatus for the investigation of microcirculation functional dynamics of physiological liquids in skin.
2. US 5,730,133	Relates to the invention of an optical mammoscope.
3. US 5,747,789	Covers a method and apparatus for the optical investigation of physiological components in the human body, such as blood hemoglobin.
4. US 5,865,167	Relates to a method and apparatus for living system diagnostics. The subject matter of this application is also covered in a European patent and a Canadian patent application.
5. US 5,865,743	Relates to a method of living organism multimodal functional mapping.
6. US 6,002,958	Covers a method and apparatus for the optical and acoustic diagnosis of internal organs.
7. US 6,192,262 B1	Covers a method of living organism multimodal functional mapping.
8. US 6,243,484 B1	Covers a non-rigid object holder assembly for use in examination of an object having a base.
9. US 6,587,578 B2	Covers the dynamic-functional imaging of biological objects using a non-rigid object holder.
10. Canada No. 2,126,227	Covers method of living system organism diagnosis and apparatus for its realization.
11. European Patent No. 0612500	Covers a method and device for diagnosis of living organisms. Covers: France EP 0612500 U.K. EP0612500 Germany 69 227463 Italy 19487BE/99

1. Canadian Patent Appl. No. 2,303,380	Covers the dynamic-functional imaging of biological objects using a non-rigid object holder; filed 3/20/98.
2. European Patent Appl. No. 02726963.8-1265	Covers the dynamic-functional imaging of biological objects using a non-rigid object holder; filed 6/3/02; to be published in <i>E Patent Bulletin</i> 3/16/05.
3. EP Patent Appl. No. 98914268.2	Covers the dynamic-functional imaging of biological objects using a non-rigid object holder; based on International Appl. No. PCT/US98/05559; filed 3/20/98; international priority date 3/21/97 (US counterpart is Patent No. 6,243,484).
4. EP Patent Appl. No. 0272693.8	Covers the dynamic-functional imaging of biological objects using a non-rigid object holder; EP Publication No. 1514223.
5. Czech Patent Appl. No. PV 2004-6	Covers the dynamic-functional imaging of biological objects using a non-rigid object holder; based on International Appl. No. PCT/US02/17308.
6. Hungary Patent Appl. No. P 04 01966	Covers the dynamic-functional imaging of biological objects using a non-rigid object holder; based on International Appl. No. PCT/US02/17308; filed 6/3/02.
7. Japanese Patent Appl. No. 2003-502770	Covers the dynamic-functional imaging of biological objects using a non-rigid object holder; filed 6/2/02; published 11/18/04.
8. Slovakia Patent Appl. No. PP 0004-2004	Covers the dynamic-functional imaging of biological objects using a non-rigid object holder. Based on International Appl. No. PCT/US02/17308; filed 6/3/02.
9. Hong Kong Patent Appl. No. 05102449.8	Covers the dynamic-functional imaging of biological objects using a non-rigid object holder. Filed in Hong Kong on 3/22/05; international filing date, 6/3/02.

DOBI Global New Patents

To maintain the technology leading position
Ten New Patents will be Applied

- Airless Compression
- Optical Scanner Coupled to Slot Scanning Full Field X-Ray System
- Dynamic Illumination Control
- LED – Multiple Wavelengths in single package for this application
- Two Axis Scanning laser for trans-illumination of breast tissue\
- An optical based palpation device used for the detection of breast abnormalities.
- Inverse geometry – Multiple sources, one detector
- Light Scatter reduction method for optical scanner
- Method for “Auto Selecting” illumination sources to investigate specified region of interest.
- Dual Wavelength image processing algorithms

Market Competition

• Diagnostic

- Method
 - Mammography
 - Ultrasound
 - MRI
- Company
 - GE
 - Siemens

• Screening

- None

• Mammography Market

- 2015 \$0.925 Billion USD world
- 2017 \$1 billion USD US
- 2016 \$1.656 billion USD Europe
- 8.62% Increasing Rate after 2008
\$300 million USD

• Reference

- Screening Market is 60% of the total market
- Market Segmentation:
 - US:40%
 - EU+Japan:40%
 - Rest:20%

Use of Funds

○ Fundraising

- **2012 Three (\$3) million US dollars for US Operation**
 - To continue marketing development of ComfortScan
 - maybe 510(k) in US
 - To develop DOBI ComfortScreen
- **2013 Additional three (\$3) million US dollars**
 - To industrialize the ComfortScreen
 - To develop international market/approval
- *2014~2016 Fifty (\$50) millions US dollars for ComfortScreen FDA PMA if needed*

○ Exit Strategy

- A sale of the Company to a large imaging firm
 - such as GE Medical, Siemens, Kodak or Hitachi
- IPO

Five Year Sales Projection

	2012	2013	2014	2015	2016	Total
ComfortScan	\$ 1,000,000	\$ 2,500,000	\$ 5,000,000	\$ 9,000,000	\$ 18,000,000	\$ 35,500,000
ComfortScreen	\$ -	\$ 500,000	\$ 2,250,000	\$ 10,500,000	\$ 21,875,000	\$ 35,125,000
ComfortCluster	\$ -	\$ 2,450,000	\$ 11,200,000	\$ 22,400,000	\$ 39,200,000	\$ 75,250,000
Annual Revenue	\$ 5,000,000	\$ 22,000,000	\$ 63,000,000	\$ 138,500,000	\$ 245,500,000	\$ 474,000,000
Net Profit	\$ 1,000,000	\$ 5,450,000	\$ 18,450,000	\$ 41,900,000	\$ 79,075,000	\$ 145,875,000
Profit Percentage		445.00%	238.53%	127.10%	88.72%	

DOBI Core Team



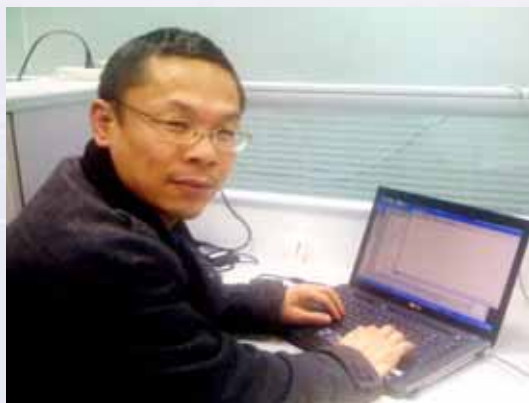
Dr. Lei Zhao
(Clinical Application Advisor)



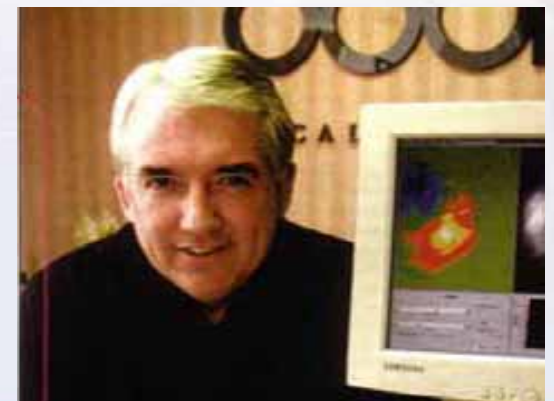
Dr. G John Zhang
(President & CEO)



Dr. Weiping Wang
(Medical Device Advisor)



Dr. Wei Lin
(Algorithm Scientist)



Phillip C Thomas
(Business Adviser)

ComfortScan[®] System

A New Light in the
Breast Cancer World

Thank You!



DOBI Medical
INTERNATIONAL