

# Technical Description

## CT Laser Breast Imaging (CTL<sup>M</sup>) System



**Imaging Diagnostic Systems, Inc.**

**OVERVIEW**

**CTLM IS A REVOLUTIONARY NEW LASER BREAST IMAGING MODALITY, DESIGNED TO IMPROVE BREAST CANCER DETECTION WITHOUT USING X-RAY METHODS, CONTRAST AGENTS OR BREAST COMPRESSION.**

**UNIQUE CTLM DESIGN**

The CT Laser Breast Imaging system is a new modality intended to provide more information about breast abnormalities to aid in the detection of breast cancer.

The CTLM system functions similar to a conventional CT scanner. The x-ray beam has been replaced with an innovative laser source and proprietary computed tomography techniques developed to detect and diagnose cancer. The images created can be viewed in Multiplanar and 3-Dimensional views

The patient lies comfortably in the prone position, with one breast suspended freely in the scanning aperture. The laser beam sweeps 360 degrees around the breast, starting from the chest wall moving forward until the entire breast is scanned. The optical data is collected by an array of specialized detectors from which 3-Dimensional and cross-sectional images are reconstructed.

The CTLM images the angiogenic blood supply by detecting the presence of increased hemoglobin in the imaging field. This increase of hemoglobin (angiogenesis) is used as indication of cancer.

**CLINICAL APPLICATION**

The CT Laser Breast imaging (CTLM<sup>®</sup>) system is intended to provide the physician with physiological and clinical information, obtained non-invasively and without the use of ionizing radiation. The CTLM produces 3-dimensional, coronal, sagittal, and axial cross-sectional images that display the distribution of hemoglobin within the internal structures of the breast. When interpreted by a trained and certified physician, those images provide information that can be useful in diagnostic determination.

**BENEFITS**

- **Leading-edge CT molecular imaging**
- **No ionizing radiation (no X-ray)**
- **Complements other breast imaging modalities**
- **Designed for dense breasts imaging**
- **Non-invasive/harmless**
- **No breast compression/comfortable**
- **Easy and inexpensive to operate**
- **High patient throughput**

**CTLM DESIGN**

The CTLM functions like a conventional CT scanner in that an energy source, a near-infrared (NIR) laser scans the breast; computed algorithms reconstruct cross-sectional images based on measured optical data. The measured optical values are directly related to the optical effective transport coefficient of the breast tissue. Like CT, the images may be viewed as single slices or as 3D volumes.

The patient lies face down in a comfortable position so that the breast to be examined is suspended through the circular aperture within the scanning bed (Figs. 1A and B.) Nothing touches the breast; there is no compression, and there is no radiation because the CTLM system uses a laser as the energy source instead of an X-ray tube. By the chosen wavelength angiogenesis can be detected.

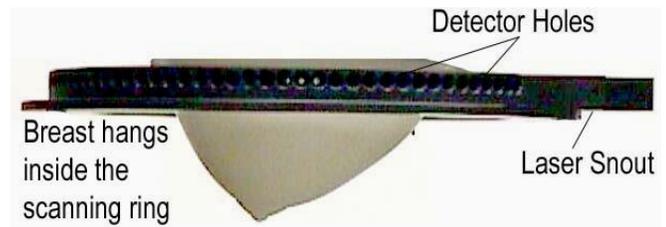


Figure 1A. Breast in scanning position.

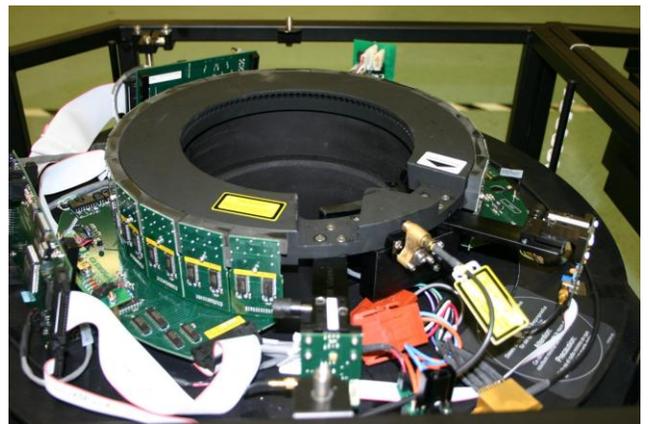


Figure 1B. CT scanning design utilizing special array of detectors.

**THE THEORY OF CT LASER SCANNING**

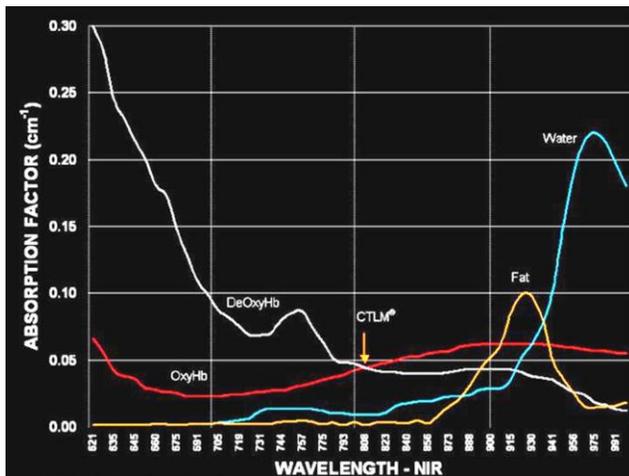
The laser is tuned to a specific near-infrared wavelength of 808 nanometers (nm) to image the blood distribution within the breast. The graph below displays the absorption curves of four different molecules as a function of the wavelength of light passing through. Light in this wavelength range is called near-infrared light (NIR).

The blue line represents the behavior of fat molecules that are almost transparent to the passing of light from 621 to 856nm. As the wavelength increases further, the absorption of light increases; dropping again after reaching the maximum wavelength of 930 nm.

The red line represents the water molecule, which behaves similarly to fat at low wavelengths, but with significantly increasing attenuation at 975 nm.

The cyan and black lines demonstrate the behavior of the molecules of oxy and deoxyhemoglobin. For smaller wavelengths, below 705 nm, fat and water are transparent. Hemoglobin in both forms absorbs NIR light with more absorption in the case of deoxyhemoglobin.

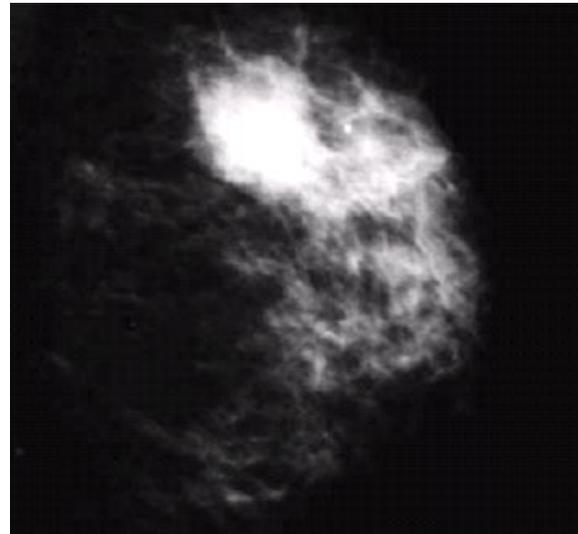
As the wavelength increases, deoxyhemoglobin absorption decreases; at 808 nm the oxy and deoxyhemoglobin lines intersect. The CTL<sup>TM</sup> laser is tuned specifically to this intersection to produce the images showing an attenuation absorption difference between hemoglobin and water or fat molecules. This principle enables the CTL<sup>TM</sup> to produce 3D images of hemoglobin distribution in the breast while tissues rich in fat and water appear transparent.



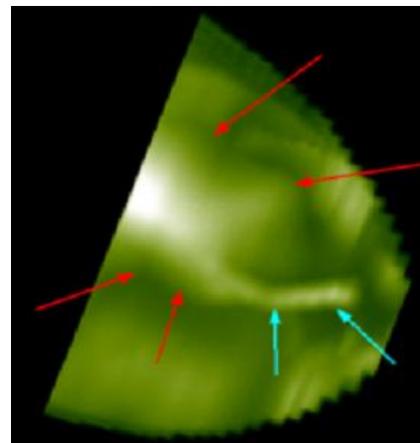
(Adapted from CHANCE, B. 1998. Near-Infrared Images Using Continuous, Phase-Modulated, and Pulsed Light with Quantitation of Blood and Blood Oxygenation. Ann. N.Y. Acad. Sci. 838:29-45.)

**Figure 2: Absorption of light (vertical axis) in hemoglobin, water, and fat, at various wavelengths (horizontal axis). CTL<sup>TM</sup> uses a wavelength of 808 nm, the point at which both oxy and deoxyhemoglobin absorb the near infrared light but water and fat absorb virtually none.**

At the particular wavelength chosen (Fig. 2), blood absorbs most of the light, providing excellent 3D and tomographic images of the entire breast from the chest wall to the nipple. If there is a cancer present, an area of angiogenesis will be seen, which will appear much larger, and therefore easier to see, than the original lesion on the mammogram. In fact, a tumor which is only 3.0 mm in size on the mammogram will usually have an area of angiogenesis which is 4 to 6 cm in size on CTL<sup>TM</sup> image (Figure 3 and 3A below).

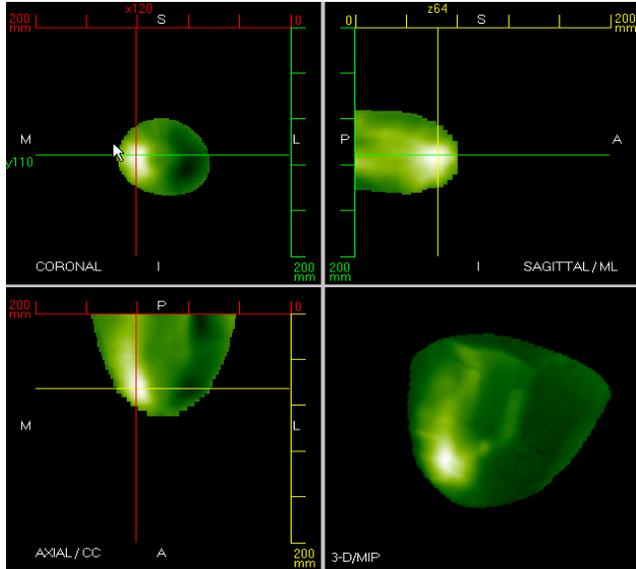


**Figure 3: Medio-lateral mammogram shows an irregular lesion in the upper outer quadrant. BIRADS category 4.**

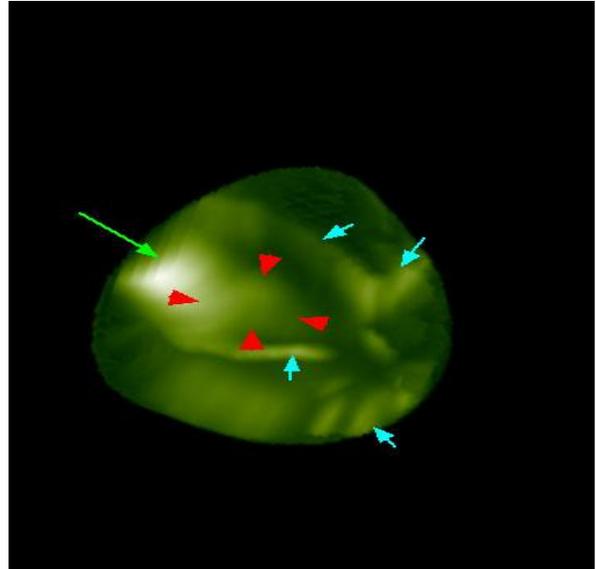


**Figure 3A: Medio-lateral CTL<sup>TM</sup> reveals an area of angiogenesis (red arrows) appearing larger than the actual lesion**

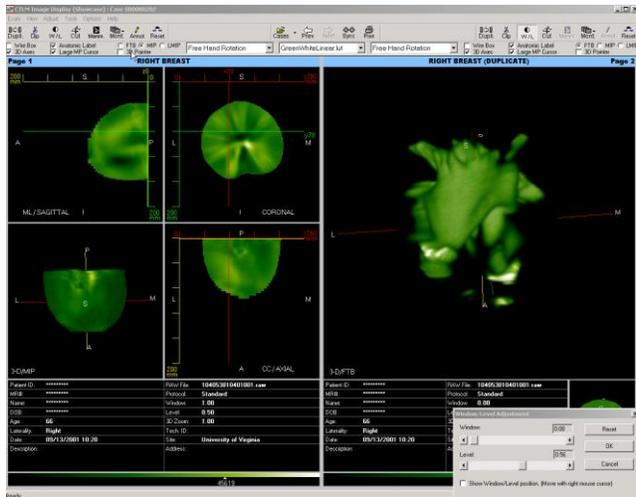
CTLM Images



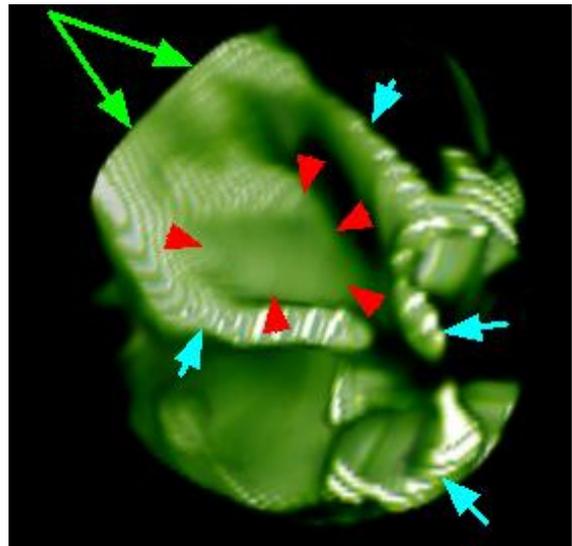
**Figure 4: Sagittal, Coronal, Axial and 3-D images**  
 This is the standard four view image presented on the reading console: the coronal, sagittal, and axial views and the three dimensional image. The white lines indicate intense angiogenesis in an invasive ductal cancer.



**Figure 5: CTLM 3-Dimensional image Maximum Intensity Projection (MIP)**  
 The arrowheads mark a large volume of angiogenesis. The short arrows indicate normal "tubular" veins.



**Figure 4A: Standard 4 views and featuring "Surface rendering Front-to-Back (FTB) projection**



**Figure 6: Enlarged Surface-Rendered FTB projection enlarged**

Clinical Cases

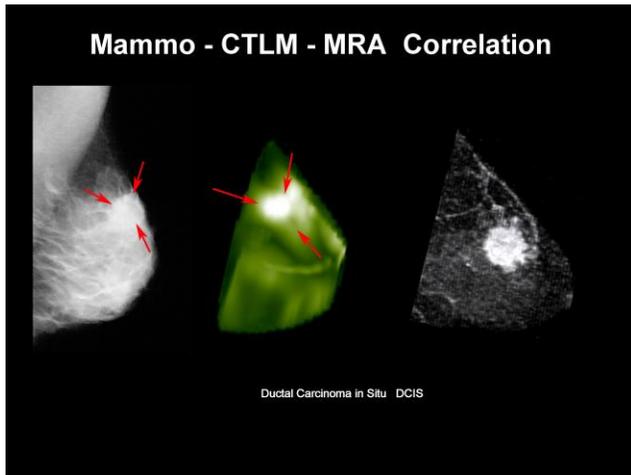


Figure 7: The image sequence displays a mammogram with a nodule lesion, the CTLM 3D revealing the area of angiogenesis and the corresponding MR angiogram of the vasculature of the tumor, which demonstrates the value of CTLM in displaying angiogenesis without the need of contrast agents and expensive equipment like MR.

Biopsy confirms Ductal Carcinoma in Situ (DCIS).

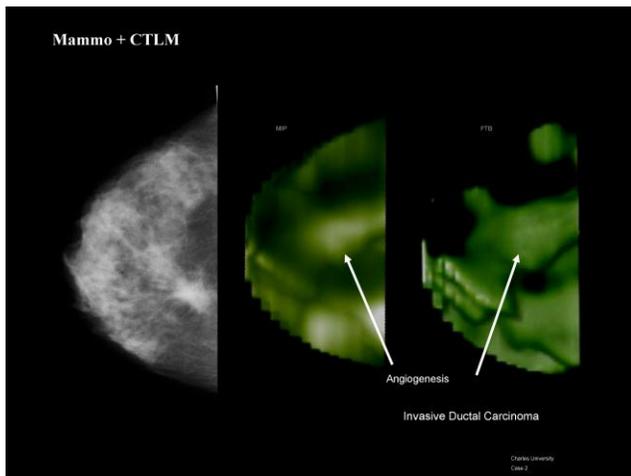


Figure 7A: The image sequence displays a mammogram and corresponding CTLM image revealing the area of angiogenesis.

Biopsy confirms an invasive ductal carcinoma.

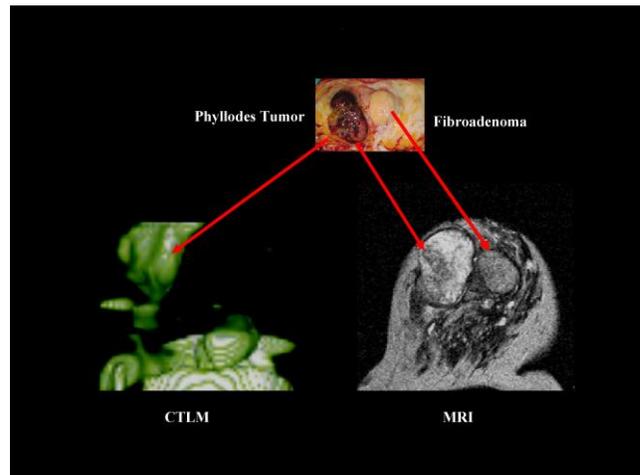


Figure 8: The image sequence shows the imaging of two tumors, a fibroadenoma with no angiogenesis and a vascularized phyllodes tumor. The image on the right is the MRI of the breast showing the contrast enhancement of the phyllodes mass. The corresponding CTLM image reveals the angiogenesis around the phyllodes and the total absence of significant neovascularity around the fibroadenoma without the use of contrast agents.

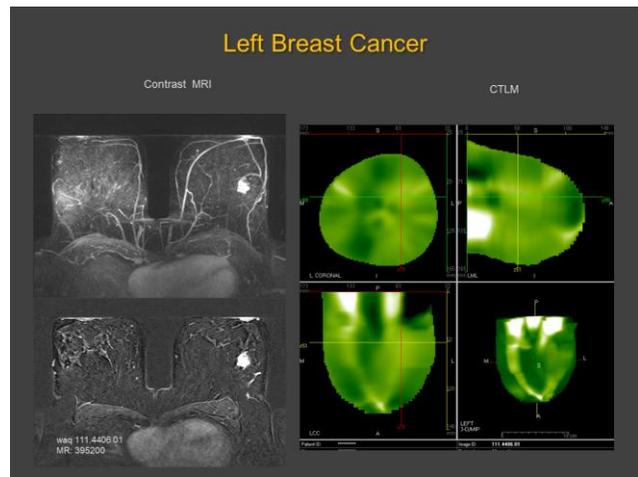


Figure 9: MRI shows an enhancing lesion in the UOQ of the left breast. Note the absence of surrounding vessels contributing to the angiogenesis. The CTLM shows an area of angiogenesis in the corresponding position. Again the area of angiogenesis is larger in the CTLM, image as expected.

Biopsy confirms an invasive ductal carcinoma.

Clinical Cases

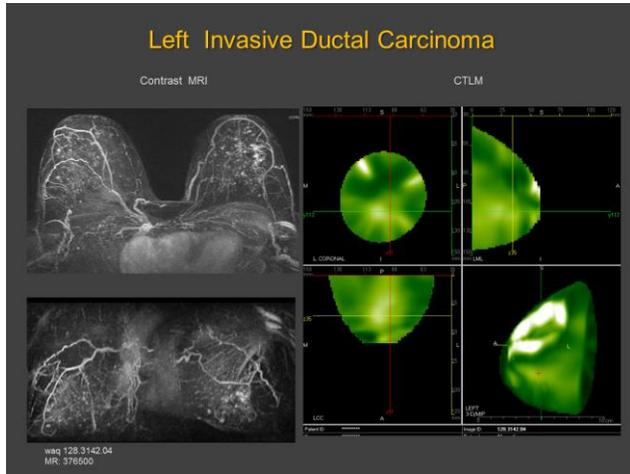


Figure 10: MRI confirms a small area of tumor enhancement in the LOQ of the left breast. There seems to be several small areas of tumor involvement. The CTLM shows a single area of angiogenesis demonstrating the involvement of the entire area in the process.

Biopsy confirms an invasive ductal carcinoma

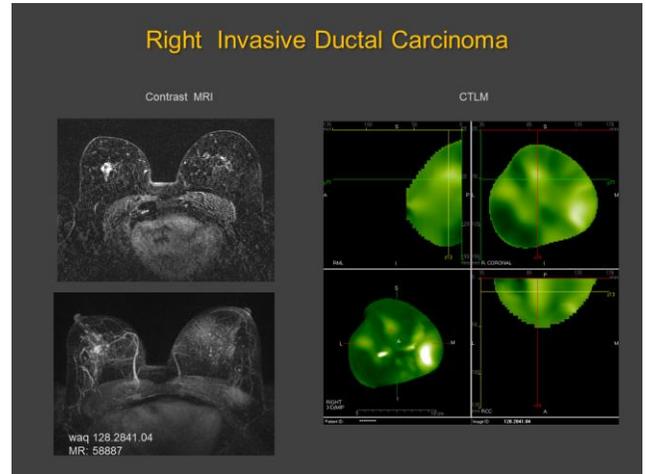


Figure 12: MRI shows an enhancing suspicious lesion in the central upper breast consistent with a carcinoma. Note the marked vascularity of the breast and the irregular path of the vessels. The CTLM is very similar in both size and location of the tumor angiogenesis.

Biopsy confirms an invasive ductal carcinoma.

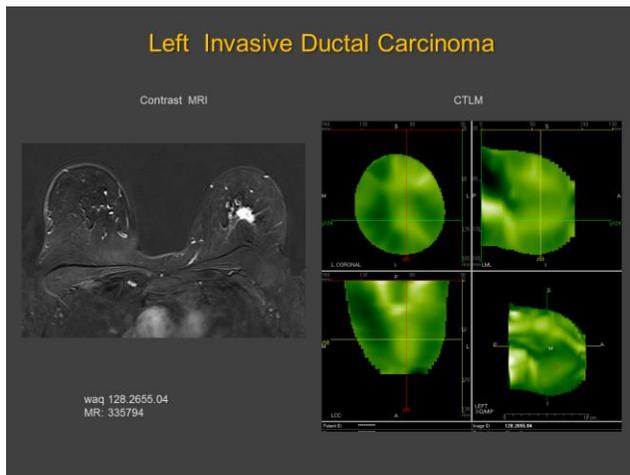


Figure 11: There is a large spiculated area of enhancement on the MRI in the central lower left breast. The CTLM shows a suspicious area of angiogenesis in the same location.

Biopsy confirms an invasive ductal carcinoma.

**IMAGE QUALITY**

In-vitro studies of imaging phantoms provide objective performance quantifications:

**Object Detectability** - The CTLM system clearly resolves a  $2.0 \pm 0.1$  mm spherical opaque inclusion suspended in a 110mm diameter circular phantom of standard IntraLipid solution, with the inclusion 20mm (radially) from the bucket wall.

**Field Uniformity** - The CTLM clearly resolves a  $3.0 \pm 0.2$ mm spherical opaque inclusion suspended in a 110 x 80mm elliptical phantom of standard IntraLipid solution, with the inclusion 10mm (radially) from the bucket wall at the 12:00, 3:00, 6:00 and 9:00 positions.

**SCANNER**

**Scan Field of View** – The scanner acquires data from a 200mm diameter by 200mm tall right cylindrical field of view.

**Laser Beam Characteristics** – The laser source beam diameter is 3mm  $\pm 20\%$  through the scanning well. The average power delivered to the patient does not exceed 500mW. The wavelength is nominally 808 nanometers. Polarization is random.

**Nominal Ocular Hazard Distance** – Per IEC 60825-1, Annex 5, the NOHD is given by:

$$\text{NOHD} = \left( \left( 2.5 * 4 * P_0 / \pi * E_{\text{MPE}} \right)^{1/2} - a \right) / \phi = 69 \text{ meters}$$

**Positioning accuracy**– orbit position is accurate to better than  $\pm 0.1\%$ , relative to the start flag.

**Rotational speed constancy** – orbit speed variations do not exceed  $\pm 3\%$  over the orbit time range of 12 – 45 seconds.

**Elevation accuracy** - elevator position accuracy is better than  $\pm 0.5$ mm.

**Laser Stability** – for the duration of 1 slice (45 seconds max), the laser output power varies no more than  $\pm 0.2\%$  peak-to-peak.

**Perimeter Accuracy** – the measured perimeter lies within  $\pm 0.5$  millimeters of a fitted circle, measured with a centered 110mm diameter, circular IntraLipid-filled phantom.

**ELECTRICAL**

**Earthing** – All devices that receive hazardous voltage with accessible metal parts have less than 0.1 Ohms of resistance between the accessible metal part and the earth ground at the supply connection.

**Residual Power** – a voltage of 60V is not available at the source of the unit 1 sec after the disconnection from the mains.

**Isolation** – The surfaces of the unit that are intended to come in contact with the patient are isolated from the power circuits such that a potential of 1500Vdc is applied between the two points and a breakdown of the insulation does not occur.

**Leakage Current** - The maximum normal condition leakage current does not exceed 500 microamperes. The maximum single fault leakage current does not exceed 1 mA.

**Operator Console** – The Operator Console requires a 220VAC line source (198VAC - 250VAC) at 50/60 Hz with a capacity of 20 Amps.

**System** – The system typically draws 5 Amps at 220VAC, 60 Hz. The heat dissipation is 1100 Watts or 3760 BTUs/hour.

**SCANNING BED AND GANTRY**

The Scanning Bed provides a horizontal surface on which the patient lies in the prone position during the examination. It is 737mm (29”) tall for easy patient access and includes a cushioned pad for patient comfort. The Scanning Bed includes 4 Centering Rings, which are selected for use according to the patient’s breast size. The enclosure of the Scanning Bed is of fiberglass material supported by a metal frame. The power electronics are housed in a steel box in the middle of the Scanning Bed. The Scanning Bed is 88” x 34” (2235mm x 865mm) and weighs 465 lbs (210 kg).



**Weight Rating** – Maximum patient weight is 400 lbs (180 kg).

**OPERATOR’S CONSOLE**



The operator’s Console includes the system PC, a 21” LCD video monitor for image review, a writable DVD-R drive for image archive and an optical mouse and keyboard for operator interaction. The system PC is a Pentium 4 personal computer running the Windows 2000 operating system and CTLM system software. It also includes 1GB of memory, dual 120GB mirrored disk drives for data storage and a 256MB video card. An uninterruptible power supply for immunity to power surges and drawer

space for storage are also included. An optional image printer can connect to the Operator’s Console or to the Physician’s Review Station. The Operator’s Console is 53” x 33” (1345mm x 840mm), weighs 390 lbs (180 kg), and is made of fiberglass.

**Environmental** - The CTLM system operates in a temperature range of +18°C to +27°C (65 to 80°F), a relative humidity of 30% to 75%, and an atmospheric pressure of 700hPa to 1060hPa (altitudes of sea level to 10,000 feet), as long as the dew point does not exceed the laser operating temperature of 19°C.

**Shock and Vibration** - The CTLM system, in its original shipping materials, meets the vibration requirements of MIL-810F, per Annex A, section 2.2.1, Category 4a - Truck transportation over US highways.

**PHYSICIAN’S REVIEW STATION**

The Physician’s Review Station (PRS) is an accessory to the CTLM system that allows simultaneous image review and archiving while scanning. The PRS supports the full display functionality of the CTLM system. It can be used to archive images and to reformat images into axial, sagittal, and 3D projections. The PRS can perform any image metrics supported by the CTLM display software.

The PRS consists of a PC, a 21” LCD video monitor for image review and an uninterruptible power supply for immunity to power surges and dropouts. The PC is a 3.4GHz Pentium 4 personal computer running the Windows 2000 operating system and the CTLM image analysis software. It includes 1GB of memory, a 120GB disk drive, a CDRW to capture images, and a 256MB video card. The Physician’s Review Station connects to the Operator’s Console via a private 100Mbit Ethernet link.

**PRINTERS**

**Codonic Horizon<sup>®</sup> Ci 8”x 10” (20 cm x 25 cm), 14”x 17” (35 cm x 43 cm) or Codonic Horizon<sup>®</sup> SF 8”x 10” (20 cm x 25 cm)** (Recommended)

The Horizon<sup>®</sup> is an intelligent desktop dry film imager that produces superior diagnostic-quality medical films as well as color and grayscale paper images quickly, conveniently and affordably. The imager is compatible with many industry-standard protocols including DICOM and Windows network printing. High-speed image processing, networking and spooling are standard.

Specifications

Print Technology: Dye-diffusion and direct thermal  
 Spatial Resolution: 320 dpi (12.6 pixels/mm)  
 Throughput: Up to 100 films per hour  
 Grayscale Contrast  
 Resolution: 12 bits (4096)

**Epson 1280**

The Epson Stylus Photo 1280 ink jet printer is the ideal large format choice, with BorderFree photo-quality prints of 4" x 6" (10 cm x 15cm), 5" x 7" (13 cm x 18 cm), 8" x 10" (20cm x 25cm), letter (22 cm x 28 cm), 11" x 14" (28 cm x 35 cm) enlargements and 13" x 44" (33 cm x 112 cm) panoramas. The 6-color 2880 x 720 dpi results in continuous tone quality for prints. The 4-picoliter variable-sized ink droplets feature prints 8" x 10" (20 cm x 25 cm) prints in less than two minutes. The Epson Stylus Photo 1280 can produce water-resistant and lightfast media. Water-resistant prints can be printed on Epson Premium Glossy Photo Paper and Epson Photo Paper. Epson Stylus Photo 1280 is Windows and Macintosh compatible.

**Epson Stylus Photo 1290S**

The Epson Stylus Photo 1290S inkjet printer provides lightfast 6-color Photo Reproduction Quality. The Stylus Photo 1290S becomes a desktop photo lab, printing everything from portfolios and proofs to letters and web pages, delivering edge to edge output without the need for cropping. The Stylus Photo 1290S includes support for the Universal Serial Bus, fully supported by Microsoft Windows 98, Windows ME, Windows 2000 and Apple iMac, G3 & G4.

**CLASSIFICATION**

The CTLM<sup>®</sup> system is classified by Underwriter's Laboratories as a class I, type B device ordinary equipment in continuous operation with intermittent loading. The use of flammable anesthetics or oxidizing gases, such as nitrous oxide (N<sub>2</sub>O) and oxygen (O<sub>2</sub>), should be avoided.

**SAFETY (ELECTRICAL/MECHANICAL/LASER)**

<b>EN 60601-1:</b>	Medical Electrical Equipment, Part 1: General requirements for safety.
<b>EN 60601-1-1:</b>	Medical Electrical Equipment, Part 1: General requirements for safety, Collateral standard: Safety requirements for medical electrical systems.
<b>EN 60601-2-22:</b>	Medical Electrical Equipment, Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment.
<b>IEC 60825-1:</b>	Safety of Laser Products, Part 1: Equipment classification, requirements and user's guide.

<b>EN 60950:</b>	Safety of Information Technology Equipment Including Business Equipment.
<b>UL 60601-1:</b>	Standard for Safety of Medical Equipment, Part 1: General requirements for Safety.
<b>EN 540:</b>	Clinical investigation of medical devices for human subjects.
<b>FDA:</b>	21 Code of Federal Regulations, Parts 820, 900, 1010, 1020.10, 1040
<b>Canada:</b>	CAN/CSA-C22.2 No. 601.1-M90: Medical Electrical Equipment, Part 1: General Requirements for Safety.
<b>Europe:</b>	93/42/EEC: Council Directive Concerning Medical Devices

**EMC**

<b>EN 60601-1-2:</b>	Medical electrical equipment. Part 1: General requirements for safety 2. Collateral standard: Electromagnetic compatibility - requirements and tests.
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**QUALITY ASSURANCE SYSTEMS**

<b>ISO 13485:</b>	<b>Quality Systems - Medical devices</b>
<b>ISO 13485:</b>	<b>Canadian Medical Device Conformity Assessment System (CMDCAS) Quality Systems Medical devices</b>
<b>CE Certificate</b>	<b>Annex II, Section 3 of the Directive 93/42/EEC Medical Device</b>

**DISPLAY AND PRINTER SET-UP AND QUALIFICATION**

**SMPTE RP 133-1999**, Specifications for Medical Diagnostic Imaging Test Pattern for Television Monitors and Hard-Copy Recording Cameras (R1999)

**RISK ASSESSMENT**

- ISO 14971:** Medical devices - risk management
- IEC 1025:** Fault tree analysis (FTA)
- IEC 812:** Analysis techniques for System reliability – Procedure for failure modes and effects analysis (FMEA); failure modes and effects criticality analysis (FMECA)

**ADDITIONAL MARKINGS / SYMBOLS / TERMINOLOGY/ DOCUMENTATION**

- EN 980:** Terminology, symbols and information provided with medical devices. Graphical symbols for use in the labeling of medical devices.
- EN 1041:** Medical devices – Information supplied by the manufacturer (FOREIGN STANDARD.)

**LICENSES**

**FDA Certification of Exportability**

**Canada Medical Device License#**

**People’s Republic of China**

Available Model(s): CTL <sup>TM</sup> <sup>®</sup> System 1020 100003	
<i>(Not Yet Available in the United States)</i>	
<b>CTL<sup>TM</sup><sup>®</sup> System</b>	<u>Cat. No.</u>
Scanning Bed Model 1020	100011
Operator’s Console Model 1020	100027
Physician’s Review Station (110VAC)	100032
Physician’s Review Station (220 VAC)	100033
<b>Printer Options</b>	<u>Cat. No.</u>
Codonics Horizon Ci, 14 x 17	160362
Codonics Horizon SF, 8 x 10	160363
Epson Photo 1280, (110VAC)	160360
Epson 1290S, (220VAC)	160361

**CTLM<sup>®</sup>**

# **CT Laser Breast Imaging System**

**CTLM<sup>®</sup> Manufactured by:  
Imaging Diagnostic Systems, Inc. USA**

**Distributed by:**

810041E