

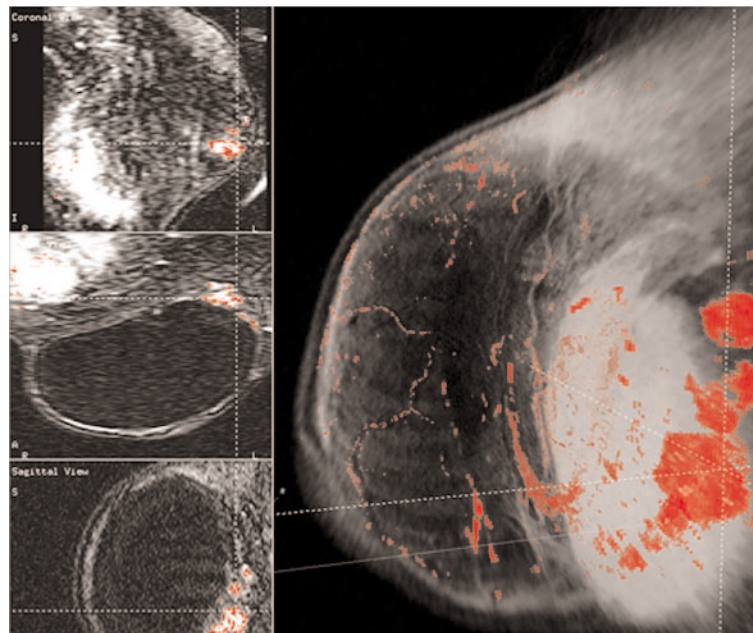
361° SYSTEMS

RELIABLE

ACCURATE

EFFICIENT

BREAST CANCER DETECTION AND DISCRIMINATION SYSTEM



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Breast Cancer Detection and Discrimination System (BCDDS)

A research proven innovative, computerized, medical detection system

An Overview of BCDDS:

361° Systems is a company that provides cutting-edge technology without compromising results. Dedicated to reliability and accuracy, 361° Systems' goal is to produce systems that improve the efficiency, timeliness and precision of MRI interpretations. The Breast Cancer Detection and Discrimination System (BCDDS) has been designed with radiologists for radiologists with optimal ease-of-use in the medical community. 361° Systems BCDDS is a platform that has proven results that work.

The BCDDS is used to help detect breast cancer in three-dimensional space, especially when it is difficult to locate. The system helps to discriminate the kind of malignancy that has been located and whether it is uni-focal or multi-focal, which aids in staging. It gives easy and reliable estimates of each tumor volume to aid in determining whether a tumor is growing, shrinking, or remaining the same size, as might be the case following chemotherapy, radiotherapy, various treatments, or watchful waiting.

The BCDDS medical research system helps:

- 1) Determine the presence or absence of breast cancer
- 2) Determine the three dimensional location of suspicious volumes (malignancies) and other structures within the breast
- 3) Determine whether the suspicious volume is multifocal or unifocal
- 4) Give high indication of the suspicious malignancy type
- 5) Reduce the probability of many false positives associated with MRI of the breast, especially for benign fibroadenomas and cases with earlier wounding of the breast from biopsy or recent surgical reconstruction.

Which patient cases would benefit from using the BCDDS?

The BCDDS system is designed to reduce the time necessary and increase the thoroughness of detection of breast cancer in certain difficult clinical cases. These include:

- 1) mammographically occult, and ultrasonically anomalous cases in which clinical suspicion is high
- 2) women with a family history of breast cancer
- 3) women who carry the BRCA1 or BRCA2 breast cancer gene
- 4) women with dense breasts, especially younger patients
- 5) women who have had breast cancer and have had reconstructive surgery with implants, or women who have had breast augmentation.

Advantages: Reliability, accuracy and efficiency

The BCDDS is easy to use, and can quickly help in breast cancer detection and localization of abnormalities. The system calculates automatically the volumetric extent of the abnormality, and as such may be useful in various questions of staging, treatment course, and case follow-up. The BCDDS training requires less than two days (12 hours or less). It's easy to learn, and follow-up support is available.

The system uses the latest computational technological (mathematical, and visual presentation) solutions to finding, locating, and helping to visualize even very small, very early breast cancers. Ordinary resolution is 1.3 x 1.3 x .65 mm at 1.5T. The BCDDS system is excellent in yielding highly reliable estimates of both the extent and size (volume) of abnormalities.

The BCDDS system automatically calculates the volume of malignant tissues and easily provides (one click) estimates of individual (unifocal vs. multi-focal) or disparate abnormal findings. This can be helpful for reliable measurements of the abnormality by calculating, rather than estimating, whether it is increasing in size and volume, or shrinking.

Unique Features:

The BCDDS system contains these advanced system features:

- ◆ Dynamic MRI 4th dimensional analysis
- ◆ True dynamic 3D visual representation of the entire breast volume simultaneously
- ◆ Three, 2-dimensional cross-referenced views, interactively cross-linked to 3D view, which
- ◆ Cross references in both dimensions
- ◆ Interactive Dynamic Curve Computation (IDCC) for various known malignancies and fibroadenomas

Methods

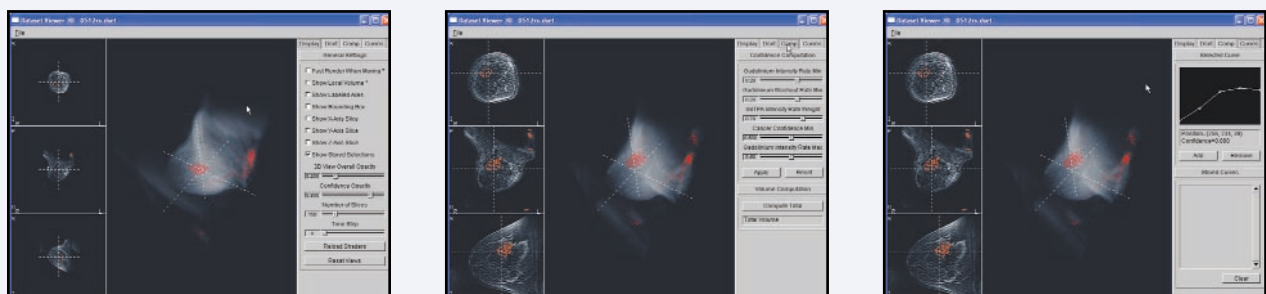
The BCDDS system uses the temporal characteristics of chelated gadolinium to help determine the kind and extent of breast cancers, such as ductal cancer in situ., invasive ductal cancer, lobular cancer, and inflammatory breast cancer.

The BCDDS is very robust, handling very large 3D data sets, including all bilateral data sets (e.g., 1000, 512 x 1024 simultaneous images).

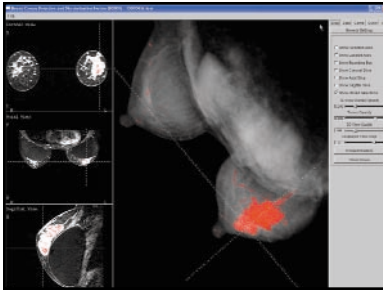
The BCDDS is fully DICOM3 compliant and will work with any suitable MRI scanner equipped with a MRI breast coil. The BCDDS works with unilateral and bilateral breast image acquisition series.

The BCDDS is sold as a research tool for advanced, rapid and thorough detection, discrimination, localization and volume calculation of various kinds of breast abnormalities.

BCDDS is available only from MTC and its affiliate 361° Systems. Price is available upon request. Delivery time is normally 21 to 31 days, from receipt of valid PO, certified check or LLC. Scheduling of 1 and 1/2 days training within ten days of delivery and set-up (location and connection of the system to the radiological/hospital intranet) is suggested.



To find out more about 361° Systems and the BCDDS please contact:
Dr. John P. Brockway at 704-576-1844 or
email at jpbrockway@361systems.com or
write to
361°Systems, P.O. Box 1621, Davidson, NC 28036

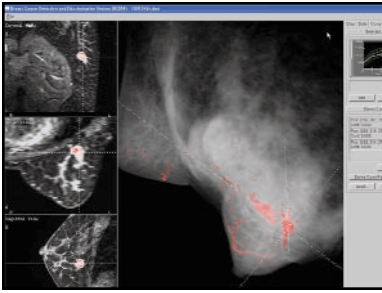


361° System's Unique Properties

The 361° System is a research-driven and research-based tool to aid in the detection, localization, and discrimination of various forms of malignancy, using dynamic-contrast enhanced MRI (DCE- MRI) data as its foundation.

Unique attributes:

- The 361° System enables a true three-dimensional view of 4th dimensional data (allows the viewing of time-dependent data) such as dynamic-contrast enhanced MRI, presented dynamically (it moves). This view is interactive (you can rotate it, pan, zoom, & shift it).
- The three-dimensional view is actively linked to 3, two-dimensional view, giving superior information about each location within the tissue (breast or prostate). You can find where you are specifically, in all three two-dimensional views simultaneously, as well as the three-dimensional view.
- The 361° System accurately measures the volume of tissue (identified as malignant), easily, with one click.
- The features of the 361° System have been developed and tested with more than 388 cases (39 bilateral breast cases, 181 unilateral left breast cases, 166 unilateral right breast cases, 2 prostate cases), and the histopathology results from a significant number of these cases has been used to form the basis for the active seek and search modes.
- The tumor and tissue opacity are manipulable by the user for optimal viewing.
- The 361° System not only uses DCE-MRI time curves to identify possible malignancy, but uses the entire shape of the curve to help reduce false positives and aid in tumor discrimination and it does this interactively. The shape of the curve can be interactively determined by the user to locate other known similar volumes, on the fly.
- The curve characteristics for any particular patient can be easily stored and retrieved for later analysis, or later comparison with differing patients' curves.
- The user may pick several suspicious volumes and the 361° System will interactively determine the commonality of the curve (identifying the shape of those common areas) and allow the user to examine the entire data set for similar "curve-fit" volumes. Any malignant volume may be calculated easily (one click) and stored for future comparison (growing, shrinking, staying the same?).
- The 361° System has several (lobular, DCIS, Invasive Ductal, Infiltrating Lobular) pre-sets for examining data which may be suspicious. It has been useful in identifying mixed-types of suspicious malignancies.



361° System Pricing

The 361° System is a research-driven and research-based tool to aid in the detection, localization, and discrimination of various forms of malignancy, using dynamic-contrast enhanced MRI (DCE- MRI) data as its foundation.

It is sold as an integrated, stand-alone, research hardware/software solution

- The 361° System is DICOM 3 compliant (see Compliance statement).
- The 361° System contains a main application and several sub-systems.
- The 361° System main system displays 4th dimensional datasets in true 3D space and accurately measures the volume of tissue (identified as malignant), easily, with one click.
- The DICOM manager sub-system enables and allows the reading and examination of DICOM datasets.
- The DICOM Converter sub-system converts DICOM 3 data into a computational dataset, stripping headers for examination, computational, and display purposes.
- The 361° System stores it's computed datasets, the parameters, curves, and volumes associated with that dataset, and can retrieve and display those stored datasets
- The hardware contains two high resolution, 19" flat panel LCD displays, CPU Pentium IV, running at 3.4 GHz with 2 GB DDRAM, and high resolution graphics adapter card, Ethernet broadband card network ready, 160 MB 7200 rpm HD, CD Burner, USB & Firewire ports.
- The 361° System is preloaded. Back-up 361° System is provided on CD.
- The 361° System comes with 8 hours of training, included.
- Revisions are included at no charge for updates.
- The 361° System price is available upon request from jpbrockway@361systems.com and delivery is anticipated in 26-31 days from date of valid PO or order.

*Early Adopter Program (EAP) includes all revisions, next version three months prior to all other, data update sharing and curve analyses upgrades, rights to referrals, data accrual.