IZOTROPIC CORPORATION

Summer 2026

Corporate Presentation

Advanced Imaging. Accessible Care.

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Izotropic Corporation holds the exclusive global licensing rights to breast CT technology from the Regents of the University of California. This technology was originally developed at the University of California, Davis, under the Breast Tomography Project led by Company Director Dr. John Boone and his clinical collaborators. Four successive breast CT research devices were developed and evaluated at UC Davis. The clinical data and images referenced by the Company were generated using these research prototypes. IzoView, the commercial breast CT system developed by Izotropic Corporation, is a distinct and separate device designed for commercial use and was not used to generate this data or these images. Accordingly, any clinical performance data or images referenced by the Company should not be interpreted as evidence of IzoView’s abilities, safety or effectiveness. IzoView remains an investigational device and has not been evaluated in clinical trials or studies to support claims of diagnostic performance. No assurances are made that results achieved with earlier breast CT systems will be replicated with IzoView. The Company makes no claims or guarantees regarding the diagnostic capabilities, clinical benefits, or regulatory approval of IzoView at this time. IzoView has not been approved or cleared by any regulatory authority and is not yet available for commercial sale. Any statements regarding potential clinical utility are for informational purposes only.

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All images are for illustrative purposes only.

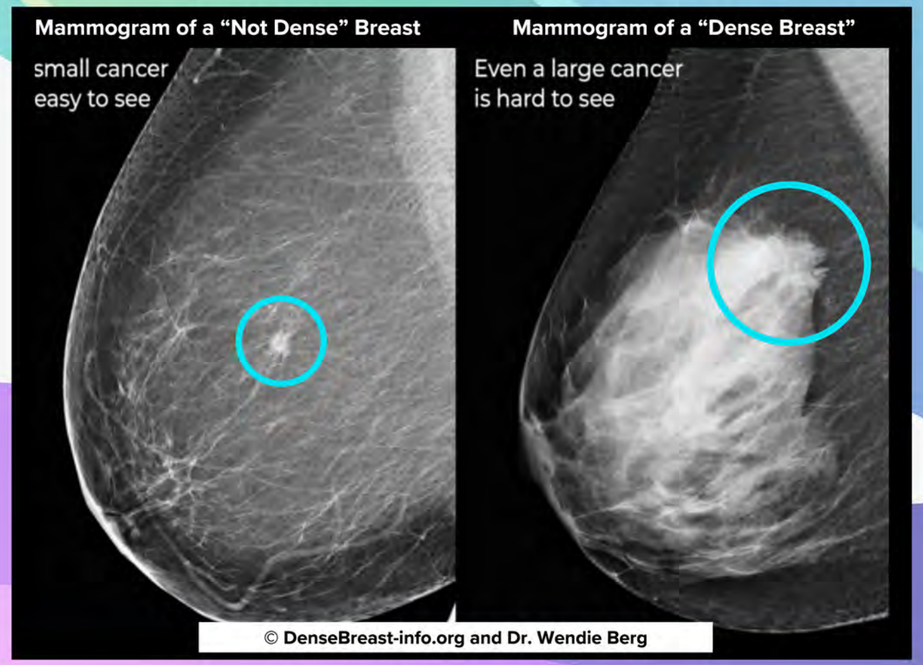
Company Overview

- Izotropic Corporation is a publicly listed medtech company commercializing a dedicated Breast CT imaging system, called IzoView, specifically for adjunctive breast cancer screening in patients with dense breast tissue.
- IzoView delivers true 3D imaging without breast compression, and is purpose-built to address the limitations of mammography, digital breast tomosynthesis (“DBT”), ultrasound, and MRI.
- Izotropic holds the exclusive global rights to breast CT technology and is leading the commercialization of a first-in-class imaging platform designed to become the new standard for breast cancer imaging.
- Izotropic is entering commercialization with a fully engineered system, FDA-aligned clinical study plan for market authorization, and with early adopter interest.

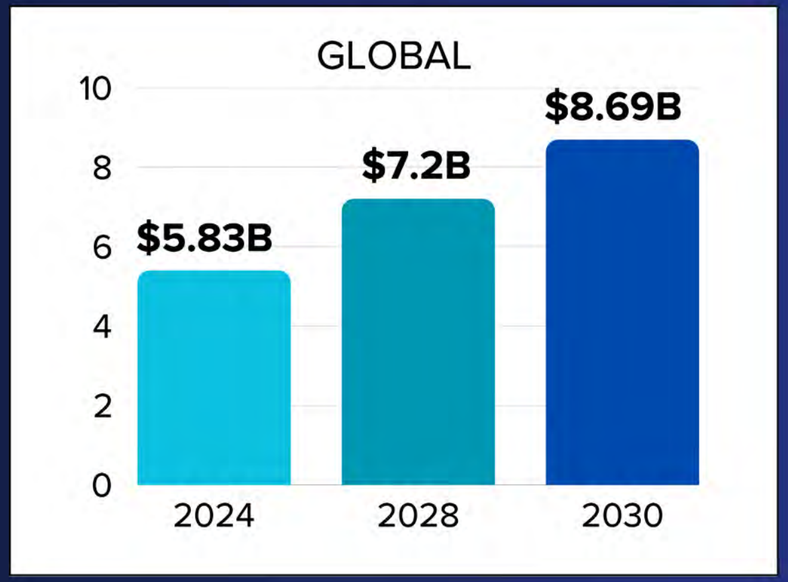
The Market Challenge

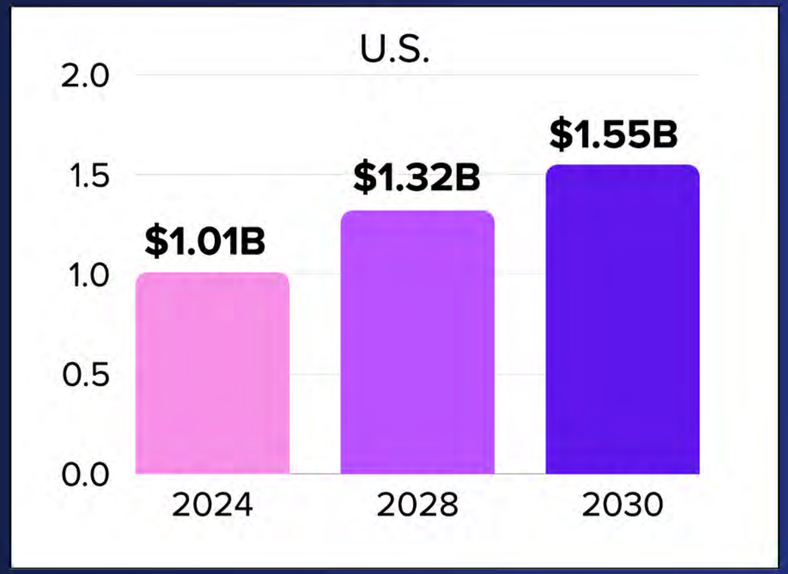
Current Technologies Fail the 50% of Women who have Dense Breasts[1].

- Mammography and DBT are limited by breast compression that causes tissue overlap and breast imaging artifacts.
- Mammography misses ~20% of cancers present at the time of screening[2].
- Dense tissue and lesions and tumors both appear white, reducing visibility.
- Ultrasound has high false positive rates and is highly operator-dependent.
- MRI, the gold standard for 3D imaging, is expensive, time-consuming, has a high-false positive rate, and is resource-limited, with low availability and accessibility issues for routine screening.
- Estimated $8B spent annually in the U.S. on follow-up diagnostic imaging and procedures after initial mammography screening[3] due to inconclusive results and false positives.
- IzoView is positioned to potentially reduce this $8B burden by streamlining workflows and reducing unnecessary follow-ups.



1. (2024, December 9). Dense Breasts: Answers to Commonly Asked Questions. National Cancer Institute. Retrieved July 24, 2025, from https://www.cancer.gov/types/breast/breast-changes/dense-breasts
2. (2023, February 21). Mammograms. National Cancer Institute. Retrieved July 16, 2025, from https://www.cancer.gov/types/breast/mammograms-fact-sheet
3. Vlahiotis A, Griffin B, Stavros AT, Margolis J. Analysis of utilization patterns and associated costs of the breast imaging and diagnostic procedures after screening mammography. Clinicoecon Outcomes Res. 2018;10:157-167 https://doi.org/10.2147/CEOR.S150260





The Global Market Opportunity

Breast Imaging is a High-Growth, High-Need Market.

- Breast cancer is the most diagnosed cancer in women globally, with 2.3M+ new cases/year[1].
- Global breast imaging device market to grow from $5.4B in 2024 to $8.7B in 2030 (CAGR 8.25%)[2].
- U.S. regulatory mandates for breast density disclosure are now in effect[3].
- Insurance coverage for supplemental screening is expanding[4], accelerating demand for advanced imaging technologies.

1. (2024, March 13). Breast cancer. World Health Organization. Retrieved February 1, 2025, from https://www.who.int/news-room/fact-sheets/detail/breast-cancer
2. (2025). Breast Imaging Market Global Forecast 2025-2030. 360i Research.
3. (2023, March 9). FDA Updates Mammography Regulations to Require Reporting of Breast Density Information and Enhance Facility Oversight. U.S. Food and Drug Administration. Retrieved January 7, 2025, from https://www.fda.gov/news-events/press-announcements/fda-updates-mammography-regulations-require-reporting-breast-density-information-and-enhance
4. (2025, June 4). Expanded Breast Imaging Insurance Coverage by State. DenseBreast-Info.org. Retrieved July 30, 2025, from https://densebreast-info.org/wpcontent/uploads/2025/06/DBI-INSURANCE-TABLE060425.pdf

Introducing IzoView

Engineered for Today's Challenges & Tomorrow's Care Models.

IzoView Breast CT

No Compression. No delays. Just Answers.

- IzoView delivers high-resolution, 360° images of the breast in its natural, uncompressed position, with or without contrast enhancement.
- While contrast-enhanced imaging delivers the highest sensitivity, IzoView is also capable of non-contrast exams where appropriate.
- Planned initial Indication for Use is with contrast enhancement adjunctive to DBT in asymptomatic patients with dense breast tissue.
- Follow on Indications for Use are planned.
- Engineered to match or exceed MRI in diagnostic accuracy while dramatically reducing cost, exam time, and patient discomfort.
- Enables detection, characterization, and evaluation of lesions in a single scan, and projected to improve diagnostic confidence and workflow efficiency.

FACT SHEET

IZOTROPIC CORPORATION

Synopsis of Publications from the UC Davis Breast Tomography Project

Introduction

This document summarizes a comprehensive collection of peer-reviewed publications from the UC Davis Breast Tomography Project, led by Dr. John M. Boone and colleagues. Spanning nearly two decades, the work conducted at UC Davis represents the foundational research and clinical evaluation of dedicated breast computed tomography (bCT). The studies included in this synopsis chronicle the technical innovation, system optimization, image processing advancements, and clinical feasibility of bCT as an emerging modality for breast cancer detection and diagnosis. By combining engineering, physics, radiology, and artificial intelligence, this body of work provides the scientific basis for a new standard in breast imaging, one that enables high-resolution, true 3D imaging without compression, and with promising diagnostic accuracy, particularly for women with dense breast tissue. The following summary distills the key findings and contributions from this extensive research program.

Summary of UC Davis Breast CT Publications

The UC Davis Breast Tomography Project's research contributions fall into several major domains: system development and performance optimization, image processing innovations, clinical validation studies, and exploratory applications such as radiation therapy and PET/CT integration. The earliest studies laid the groundwork for characterizing system geometry, scatter properties, spatial resolution, and optimal x-ray spectra. This includes the development of a geometric calibration method for cone-beam systems and quantitative modeling of spatial resolution degradation across the field of view. In parallel, investigators addressed key limitations such as x-ray scatter and cone-beam artifacts, leading to the development of optimized acquisition parameters, including higher tube voltages and filters, and the use of anthropomorphic breast phantoms for reproducible performance testing.

Advanced image processing techniques emerged as a critical focus. Deep learning and maximum likelihood polynomial fitting methods were developed to correct shading artifacts, enabling consistent adipose tissue segmentation and accurate Hounsfield unit representation. Other image enhancement strategies included temporal subtraction of contrast-enhanced datasets and radiomics-driven tumor classification based on shape and local curvature metrics. The group also explored CAD algorithms and segmentation accuracy, emphasizing how image quality directly influences diagnostic performance.

Clinically, early phase patient studies confirmed the advantages of breast CT in mass conspicuity, with higher diagnostic confidence compared to conventional mammography. Contrast-enhanced bCT (CE-bCT) demonstrated promising results in differentiating benign from malignant lesions based on enhancement kinetics, and CE-bCT's accuracy was shown to be comparable to MRI in dense breast tissue, with better spatial resolution and greater patient comfort. Studies also showed how bCT could improve tumor response assessment during neoadjuvant chemotherapy, potentially guiding surgical planning and treatment monitoring.

Journal of Breast Imaging, 2024, Vol. 6, No. 5, 465–475
doi:10.1093/jbi/wbae043
Scientific Review
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Published Online: August 31, 2024

SBI OXFORD

Scientific Review

Dedicated Breast CT: Getting Ready for Prime Time

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Abstract

Dedicated breast CT is an imaging modality that provides true 3D imaging of the breast with many advantages over current conventional breast imaging modalities. The addition of intravascular contrast increases the sensitivity of breast CT substantially. As such, there are immediate potential applications in the clinical workflow. These include using breast CT to replace much of the traditional diagnostic workup when faced with indeterminate breast lesions. Contrast-enhanced breast CT may be appropriate as a supplemental screening tool for women at high risk of breast cancer, similar to breast MRI. In addition, emerging studies are demonstrating the utility of breast CT in neoadjuvant chemotherapy tumor response monitoring as well as planning for surgical treatment options. While short exam times and fully 3D imaging in a noncompressed position are advantages of this modality, limited coverage of chest wall/axilla due to prone positioning and use of ionizing radiation are drawbacks. To date, several studies have reported on the performance characteristics of this promising modality.

Key words: CT; breast imaging; breast CT; breast mass; microcalcifications; screening; diagnostic breast imaging; breast cancer; mammography; cone-beam CT; contrast-enhanced breast CT; noncontrast breast CT.

Introduction

Dedicated breast CT (bCT) provides true 3D imaging of the breast. (The term bCT is used here to describe this technology in general terms; contrast-enhanced bCT [CEbCT] refers specifically to contrast-enhanced studies, and non-CEbCT is specified when needed.)

The advantages of bCT over conventional breast imaging include short exam times, low radiation doses on par with mammography,[1,2] independence of operator skill unlike sonography, noncompressed breast positioning, and minimal susceptibility to the masking effects of breast density. Studies to date have demonstrated superiority to 2D mammography for evaluation of masses[3] as well as increased specificity for detection of malignant microcalcifications when bCT is enhanced with contrast.[4] Enhancement of lesions on intravenous CEbCT reflects tumor vascularity while providing isotropic images and 3D postprocessing capabilities. In addition, preliminary studies have shown the utility of bCT for neoadjuvant treatment monitoring and guiding clinical decisions preoperatively to aid in treatment planning.[5] There is ongoing investigation of bCT radiomics for the prediction of tumor biomarkers and response to therapy. Disadvantages of bCT systems include limited coverage of the chest wall and axilla due to the geometry of prone positioning with the breast in pendant position, limited direct visualization of microcalcifications, and the use of ionizing radiation. While CEbCT has the additional risk of iodinated contrast injection, most MRI protocols also involve gadolinium-based contrast administration. To date, no large studies have been performed to compare bCT with mammography as a screening modality.

Protocols and physics

Breast CT hardware development

The notion of CT imaging of the breast has been considered since the earliest days of CT, dating back to the late 1970s. At the time, General Electric Corporation produced an early

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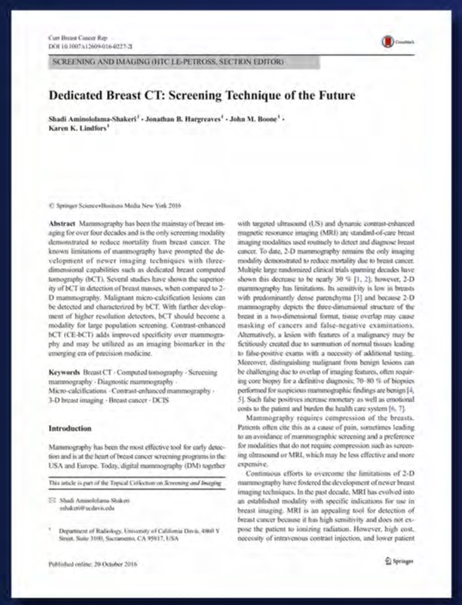

Curr Breast Cancer Rep
DOI 10.1007/s12609-016-0227-2

SCREENING AND IMAGING (HTC LE-PETROSS, SECTION EDITOR)

Dedicated Breast CT: Screening Technique of the Future

Shadi Aminololama-Shakeri[1] · Jonathan B. Hargreaves[1] · John M. Boone[1] · Karen K. Lindfors[1]

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Abstract Mammography has been the mainstay of breast imaging for over four decades and is the only screening modality demonstrated to reduce mortality from breast cancer. The known limitations of mammography have prompted the development of newer imaging techniques with (three-dimensional capabilities such as dedicated breast computed tomography (bCT). Several studies have shown the superiority of bCT in detection of breast masses, when compared to 2-D mammography. Malignant micro-calcification lesions can be detected and characterized by bCT. With further development of higher resolution detectors, bCT should become a modality for large population screening. Contrast-enhanced bCT (CE-bCT) adds improved specificity over mammography and may be utilized as an imaging biomarker in the emerging era of precision medicine.

Keywords Breast CT · Computed tomography · Screening mammography · Diagnostic mammography · Micro-calcifications · Contrast-enhanced mammography · 3-D breast imaging · Breast cancer · DCIS

Introduction

Mammography has been the most effective tool for early detection and is at the heart of breast cancer screening programs in the USA and Europe. Today, digital mammography (DM) together with targeted ultrasound (US) and dynamic contrast-enhanced magnetic resonance imaging (MRI) are standard-of-care breast imaging modalities used routinely to detect and diagnose breast cancer. To date, 2-D mammography remains the only imaging modality demonstrated to reduce mortality due to breast cancer. Multiple large randomized clinical trials spanning decades have shown this decrease to be nearly 30 % [1, 2]; however, 2-D mammography has limitations. Its sensitivity is low in breasts with predominantly dense parenchyma [3] and because 2-D mammography depicts the three-dimensional structure of the breast in a two-dimensional format, tissue overlap may cause masking of cancers and false-negative examinations. Alternatively, a lesion with features of a malignancy may be fictitiously created due to summation of normal tissues leading to false-positive exams with a necessity of additional testing. Moreover, distinguishing malignant from benign lesions can be challenging due to overlap of imaging features, often requiring core biopsy for a definitive diagnosis; 70–80 % of biopsies performed for suspicious mammographic findings are benign [4, 5]. Such false positives increase monetary as well as emotional costs to the patient and burden the health care system [6, 7].

Mammography requires compression of the breasts. Patients often cite this as a cause of pain, sometimes leading to an avoidance of mammographic screening and a preference for modalities that do not require compression such as screening ultrasound or MRI, which may be less effective and more expensive.

Continuous efforts to overcome the limitations of 2-D mammography have fostered the development of newer breast imaging techniques. In the past decade, MRI has evolved into an established modality with specific indications for use in breast imaging. MRI is an appealing tool for detection of breast cancer because it has high sensitivity and does not expose the patient to ionizing radiation. However, high cost, necessity of intravenous contrast injection, and lower patient

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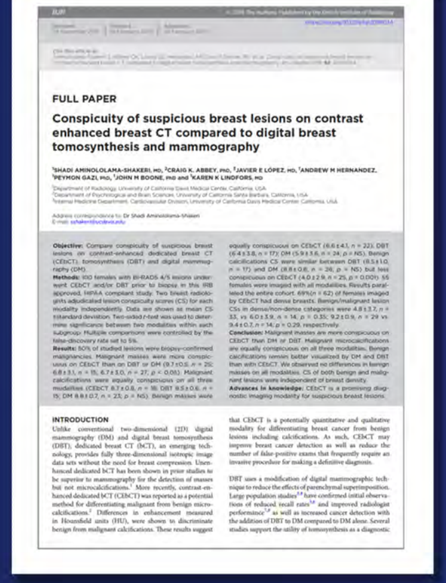

FULL PAPER

Conspicuity of suspicious breast lesions on contrast enhanced breast CT compared to digital breast tomosynthesis and mammography

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Objective: Compare conspicuity of suspicious breast lesions on contrast-enhanced dedicated breast CT (CEbCT), tomosynthesis (DBT) and digital mammography (DM).

Methods: 100 females with BI-RADS 4/5 lesions underwent CEbCT and/or DBT prior to biopsy in this IRB approved, HIPAA compliant study. Two breast radiologists adjudicated lesion conspicuity scores (CS) for each modality independently. Data are shown as mean ± CS standard deviation. Two-sided *t*-test was used to determine significance between two modalities within each subgroup. Multiple comparisons were controlled by the false-discovery rate set to 5%.

Results: 80% of studied lesions were biopsy-confirmed malignancies. Malignant masses were more conspicuous on CEbCT than on DBT or DM (8.7 ± 0.8, *n* = 25; 6.8 ± 3.1, *n* = 15; 6.7 ± 3.0, *n* = 27; $p < 0.05$). Malignant calcifications were equally conspicuous on all three modalities (CEbCT: 8.7 ± 0.8, *n* = 18; DBT: 8.5 ± 0.6, *n* = 19; DM: 8.8 ± 0.7, *n* = 23, $p > NS$). Benign masses were equally conspicuous on CEbCT (6.6 ± 4.1, *n* = 22), DBT (6.4 ± 3.8, *n* = 17) DM (5.9 ± 3.6, *n* = 24, $p > NS$). Benign calcifications CS were similar between DBT (8.5 ± 1.0, *n* = 17) and DM (8.8 ± 0.6, *n* = 36; $p = NS$) but less conspicuous on CEbCT (4.0 ± 2.9, *n* = 25, $p < 0.001$). 55 females were imaged with all modalities. Results paralleled the entire cohort. 69%(*n* = 62) of females imaged by CEbCT had dense breasts. Benign/malignant lesion CSs in dense/non-dense categories were 4.8 ± 3.7, *n* = 33, vs 6.0 ± 3.9, *n* = 14, $p = 0.35$; 9.2 ± 0.9, *n* = 29 vs. 8.4 ± 0.7, *n* = 14, $p = 0.29$, respectively.

Conclusion: Malignant masses are more conspicuous on CEbCT than DM or DBT. Malignant microcalcifications are equally conspicuous on all three modalities. Benign calcifications remain better visualized by DM and DBT than with CEbCT. We observed no differences in benign masses on all modalities. CS of both benign and malignant lesions were independent of breast density.

Advances in knowledge: CEbCT is a promising diagnostic imaging modality for suspicious breast lesions.

INTRODUCTION

Unlike conventional two-dimensional (2D) digital mammography (DM) and digital breast tomosynthesis (DBT), dedicated breast CT (bCT), an emerging technology, provides fully three-dimensional isotropic image data sets without the need for breast compression. Unenhanced dedicated bCT has been shown in prior studies to be superior to mammography for the detection of masses but not microcalcifications.[1] More recently, contrast-enhanced dedicated bCT (CEbCT) was reported as a potential method for differentiating malignant from benign microcalcifications.[2] Differences in enhancement measured in Hounsfield units (HU), were shown to discriminate benign from malignant calcifications. Those results suggest that CEbCT is a potentially quantitative and qualitative modality for differentiating breast cancer from benign lesions including calcifications. As such, CEbCT may improve breast cancer detection as well as reduce the number of false-positive exams that frequently require an invasive procedure for making a definitive diagnosis.

DBT uses a modification of digital mammographic technique to reduce the effects of parenchymal superimposition. Large population studies[3,4] have confirmed initial observations of reduced recall rates[3,4] and improved radiologist performance[3,4] as well as increased cancer detection with the addition of DBT to DM compared to DM alone. Several studies support the utility of tomosynthesis as a diagnostic

Clinical Validation & Performance

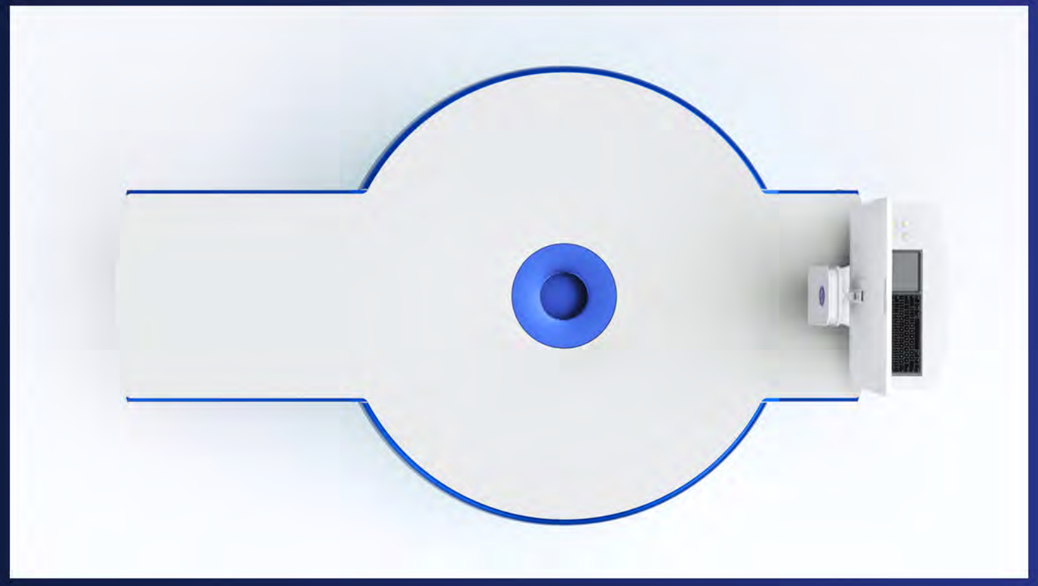
[View more breast CT clinical data here]

- Developed over 2+ decades, over USD $20M spent on building and testing 4 successive breast CT scanners, funded primarily by the NIH.
- UC Davis-based clinical trials using prototype devices for academic research purposes have imaged hundreds of patients and produced 50+ papers.
- Studies have reported that:
  - *Malignant* masses better visualized on contrast-enhanced breast CT than with digital mammography or DBT[1].
  - *Malignant* (cancerous) micro-calcifications are equally conspicuous on all three modalities[2].
  - *Benign* (non-cancerous) calcifications were better visualized by DM and DBT than with contrast-enhanced breast CT[3].
  - No performance differences were found for *benign* (non-cancerous) masses on all three modalities[4].
  - Breast CT would be more practical and cost-effective than breast MRI in a breast imaging clinic[5].

1, 2, 3, 4. Aminololama-Shakeri S, Abbey CK, López JE, Hernandez AM, Gazi P, Boone JM, Lindfors KK. Conspicuity of suspicious breast lesions on contrast enhanced breast CT compared to digital breast tomosynthesis and mammography. Br J Radiol. 2019 May;92(1097):20181034. doi: 10.1259/bjr.20181034. Epub 2019 Apr 3. PMID: 30810339; PMCID: PMC6580915.
5. Boone JM, Kwan AL, Yang K, Burkett GW, Lindfors KK, Nelson TR. Computed tomography for imaging the breast. J Mammary Gland Biol Neoplasia. 2006 Apr;11(2):103-11. doi: 10.1007/s10911-006-9017-1. PMID: 17053979.

Competitive Positioning

- IzoView is the only true 3D breast imaging modality specifically focused on dense tissue screening without breast compression.
- Strategically positioned to address the gap in between DBT and MRI: fast and affordable imaging with high-value imaging data.
- Designed for outpatient clinics, mobile units, and global access- no cranes for installation, no lead-lined rooms, or additional radiation shielding required.
- Competitive target sales price: Up to 67% lower than legacy breast CT devices currently on the market[1], and approximately 83%+ less expensive than MRI[2].



Business Model & Revenue Opportunity

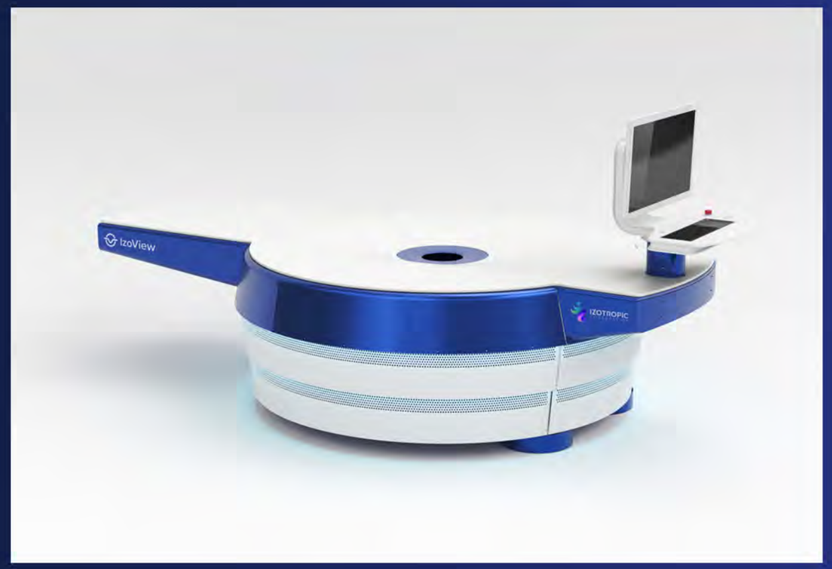
A High-Margin, Platform-Based Model with Recurring Revenue.

- Capital equipment sales model: target sales price of $500K per unit with high gross margin profile, designed for rapid ROI.
- Flexible financing options: Revenue-sharing models and leasing structures support broad market access.
- High clinical throughput: Target cost of USD $250-$500 per scan.
- Additional IzoView uses: Achieved through new clinical studies deliverable via software upgrades for added revenue and incentives for early adopters.
- Pipeline platform leverage: Revenue model expands with each new Indication for Use or companion-platform product released.

Intellectual Property

Strategic IP Portfolio Secures Long-Term Leadership.

- IP protection extending into the 2040s.
- Proprietary AI deep machine-learning reconstruction algorithm held as trade secret.
- Licensed patents and patents held by the Company covering key clinical and commercial uses, spanning platform uses, methods, workflow integration, and more.



Regulatory, Commercial & Market Strategy

- Designed for rapid adoption in outpatient imaging centers, national cancer programs, and underserved regions.
- Aligned with dense breast screening mandates and emerging reimbursement pathways.
- Clinical data from planned U.S.-based 3 site clinical study to be leveraged for CE Mark application in Europe.
- Modular PMA clinical study design in U.S.
- Direct U.S. sales strategy; distributor-led model in Europe and select international markets.
- Distributor partnerships in discussion.

Leadership & Advisors

Izotropic's team includes the original inventors of breast CT, FDA regulatory advisors, and commercialization leaders from GE Healthcare, together mitigating execution and approval risks.

Read Full Bios Online

Download Team Fact Sheets

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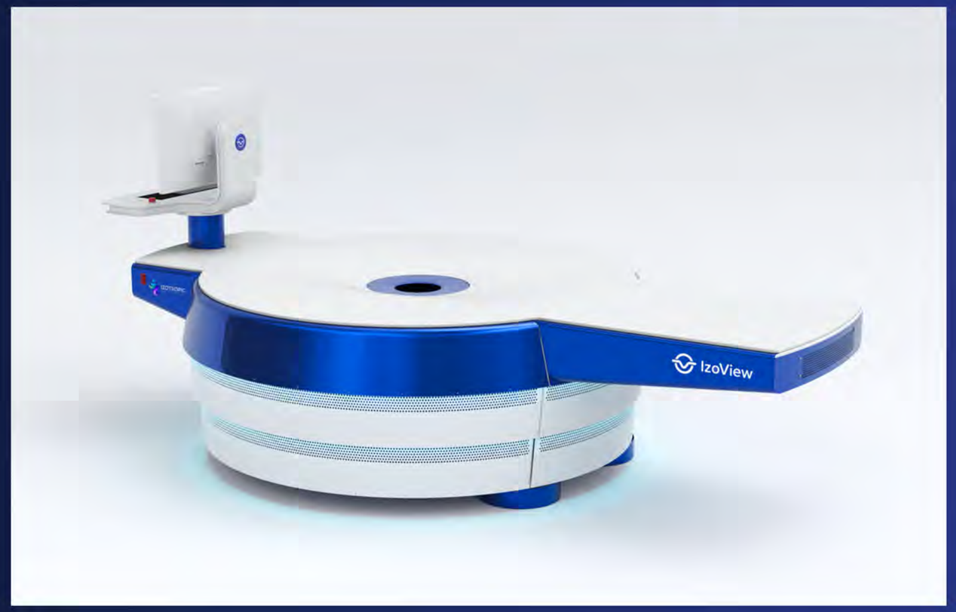

Why Now?

Global breast cancer detection is at an inflection point, driven by regulation, awareness, and innovation.

- FDA breast density mandates are now in effect, standard imaging often fails these patients.
- Global breast imaging device market projected to grow to $8.7B by 2030[1] (CAGR 8.25%).
- 50%+ of women have dense breast tissue; up to 20% of cancers go undetected on mammography[2].
- Only platform with technology projected to offer MRI-comparable performance, modular upgrade path, and AI-readiness.
- Up to 67% lower cost than other legacy breast CT devices, priced for rapid adoption[3].
- Company has a growing list of interested medical facilities and early adopters.
- Izotropic is entering commercialization as breast cancer rates and awareness of breast density is driving demand for new technologies.

1. (2025). Breast Imaging Market Global Forecast 2025-2030. 360i Research.
2. (2023, February 21). Mammograms. National Cancer Institute. Retrieved July 16, 2025, from https://www.cancer.gov/types/breast/mammograms-fact-sheet
3. Izotropic Corporation (August 5, 2025) Izotropic's IzoView Positioned to Capitalize on Key Global Breast Imaging Market Drivers [Press Release]. https://izocorp.com/news-releases/izotropics-izoview-positioned-to-capitalize-on-key-global-breast-imaging-market-drivers/

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