
TRANSFORMING DENSE BREAST SCREENING





SoftVueTM

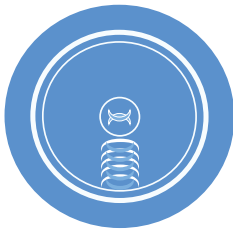


A SYNTHESIS OF INNOVATIONS

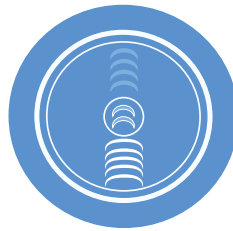
SoftVue™ is an unparalleled 3D whole breast ultrasound tomography system positioned as a breakthrough, first-ever in medical imaging device, delivering a transformational approach to breast cancer detection for individuals with dense breasts.

TriAD™

Utilizing **TRIPLE ACOUSTIC DETECTION**, or **TriAD™**, technology, SoftVue™ offers 3X the imaging power compared to standard ultrasound.



REFLECTION
Tissue Structure



SOUND SPEED
Tissue Characterization



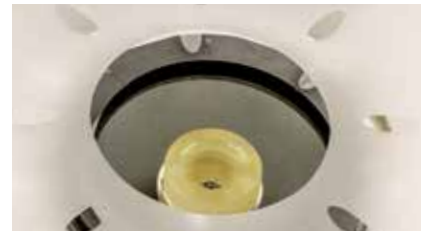
ATTENUATION
Tissue Characterization



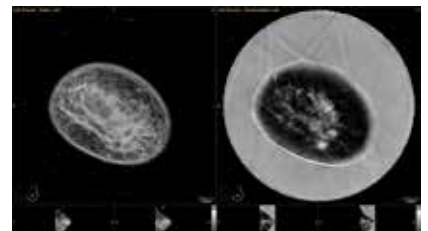
Patented **circular-array transducer** and **Sequor™ Breast Interface** provide the basis for the scanning process and image acquisition



Three sound signals, Reflection, Sound Speed and Attenuation, are collected during the scan and reconstructed into **four image sequences** for interpretation



Presented in the **coronal plane** allowing radiologists to scroll through the entire volume of the breast



UNPARALLELED PATIENT E X P E R I E N C E

The SoftVue™ exam not only increases cancer detection in women with dense breasts, but also offers a spa-like experience that is unmatched by any other breast imaging modality. In fact, **95% of women** who experience a SoftVue™ exam said they would recommend it to other women.

Utilizing a warm water bath, the exam is conducted with **NO COMPRESSION** or **RADIATION**.



PATIENT POSITIONING

- Operator independent
- Warm water coupling agent
- Memory-foam table-top
- Spa-like feel



ENGAGE WITH SEQR™ BREAST INTERFACE

- Acoustically transparent gel
- Engaged with gentle vacuum
- Elongates and stabilizes breasts
- Single use device



CUSTOMIZE & VISUALIZE

- Customizable transducer position
- Dual camera visualization
- Accommodates patient shape
- Nipple to chest wall coverage



SCAN ACTIVATION

- Push-start fully automated operation
- 2048 sequenced elements
- TriAD™ Technology
- Image output to coronal plane

EFFICIENT EXAM WORKFLOW

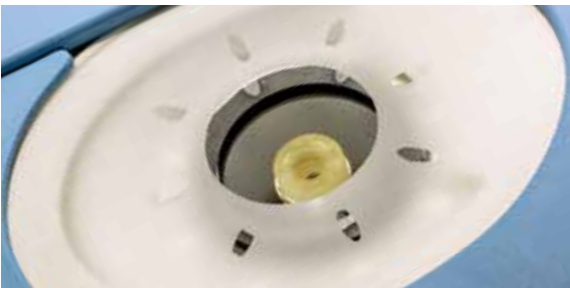
The SoftVue™ exam is private and discreet as the breast is not openly seen during the scanning process, and is faster than standard hand-held ultrasound, with the **scan taking 2-3 minutes** on average per breast.

STEP ONE



The technologist scans a new Sequor™ Breast Interface to initiate the exam process.

STEP THREE



The Sequor™ Breast Interface engages with the front of the breast to center, shape, and steady it during the image acquisition process.

STEP TWO



Patient lies prone on the SoftVue™ table lowering one breast into the warm water imaging chamber.

STEP FOUR



With one touch, the scan is activated and the ring transducer moves along the breast, imaging all levels.

INCREASING CANCER DETECTION

For too long, women with dense breasts have been at a disadvantage with breast cancer screening. In fact, mammography misses almost half of cancers in women with dense breasts and there is a lack of efficient and effective supplementary screening options available. SoftVue's revolutionary imaging power eliminates this disadvantage.

SoftVue™, in combination with mammography, has proven to increase cancer detection and potentially reduce call backs and false positives.

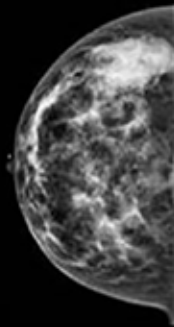
Data analysis following the retrospective reader study in which independent radiologists interpreted dense breast patient mammograms in conjunction with their SoftVue™ exam showed the following:

With the Addition of SoftVue™

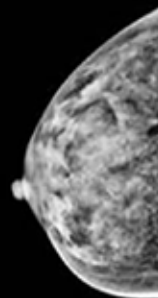


Sensitivity
+20%

Category c



Category d



Specificity
+8%



In women with dense breasts as compared to digital mammography alone

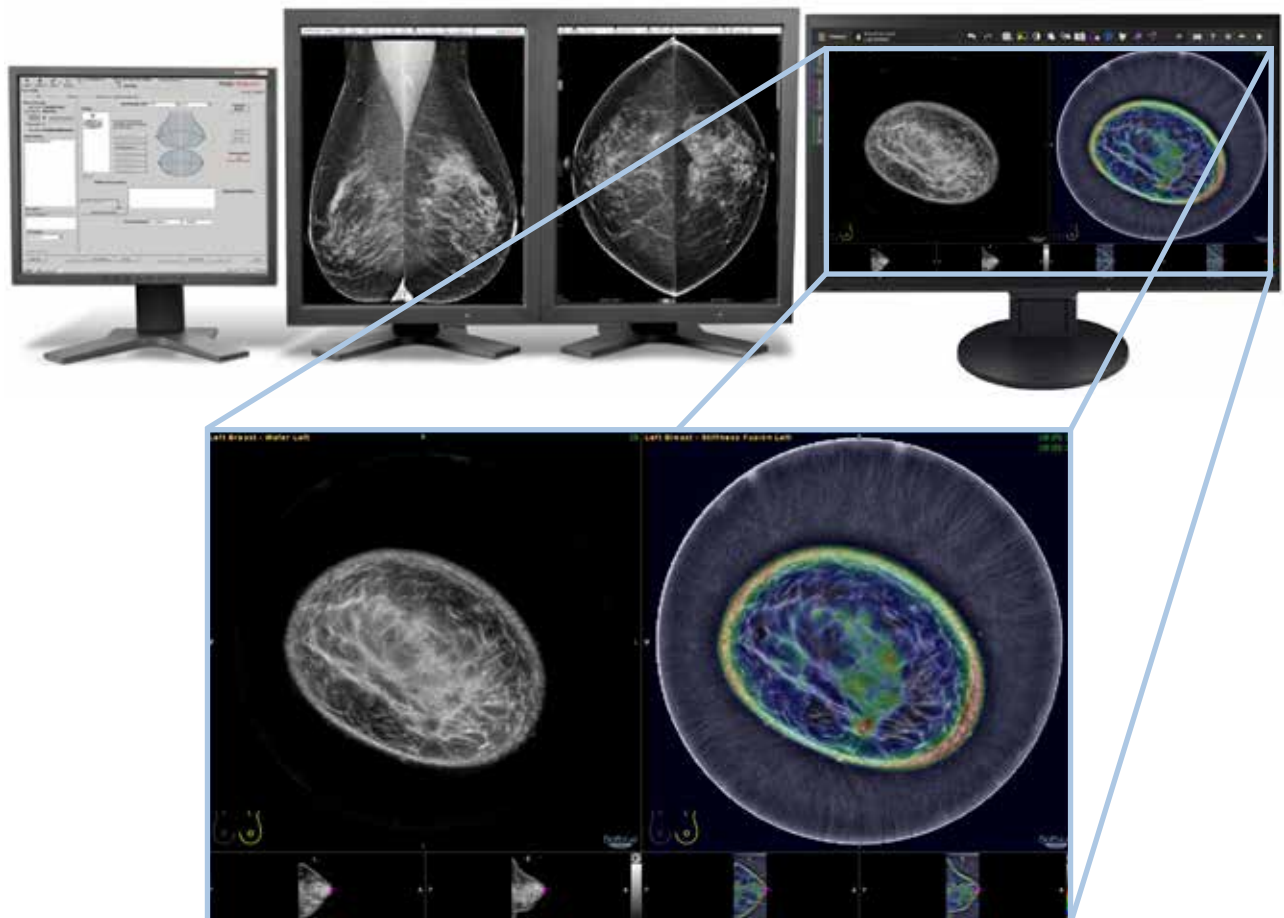
E A S Y T O U S E S O F T W A R E

SoftVue™ Image Review Software

FLEXIBLE, ADAPTABLE, PORTABLE AND EFFICIENT

SoftVue™ offers a secure, user-friendly digital viewing environment offering customizable image view ports and short-cut keys to accommodate radiologist preferences during image interpretation.

- SoftVue™ can utilize existing workstation
- Offers volumetric review of the breast
- Provides for correlation to other imaging modalities
- Presents an efficient reading workflow
- Supports multi-user and multi-location connectivity

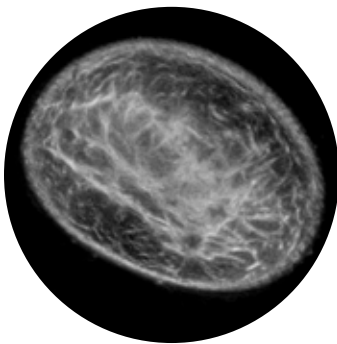


CORONAL PLANE PRESENTATION

Following the SoftVue™ exam, the reflection, sound speed and attenuation signals are reconstructed into four image sequences for radiologist review on the SoftVue™ Image Review Software. The tomographic coronal image presentation delivers an unrivaled view of the structure of breast tissue that assists physicians in distinguishing normal tissue from areas of concern.

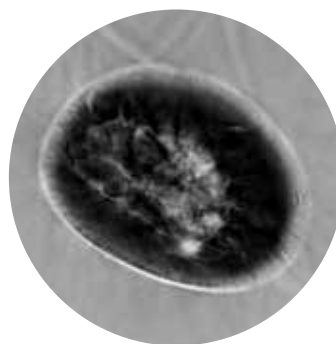
The **Wafer**, **Sound Speed**, **Reflection** and **Stiffness Fusion** volumetric image sequences are presented for interpretation and comparison with an individual's mammogram.

MASS DETECTION SEQUENCES



Wafer

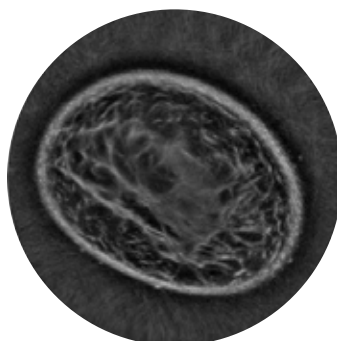
Sound Speed in combination with the Reflection lowers the visibility of fat and to enhance the remaining tissues.



Sound Speed

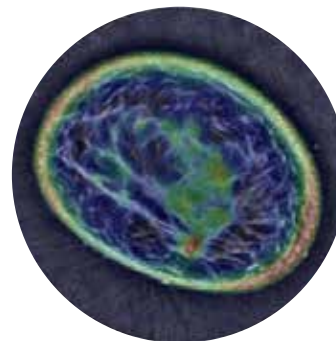
Depicts change in Speed of Sound moving through breast tissue.

MASS CHARACTERIZATION SEQUENCES



Reflection

Dynamic display of breast tissue structure and potential masses.



Stiffness Fusion

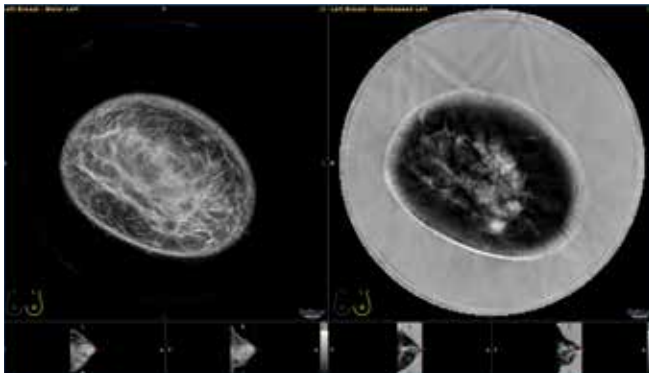
Attenuation in combination with sound speed provides relative differences in tissue stiffness.

COMPREHENSIVE IMAGE INTERPRETATION

SoftVue™ Image Review

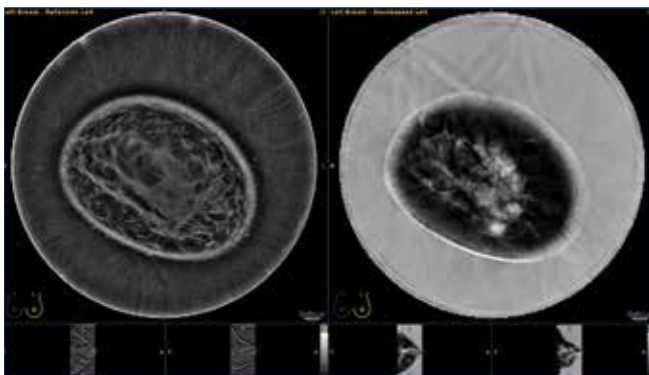
The SoftVue™ Image Review Software offers an efficient reading work flow with the workstation positioned next to the mammography viewing station, allowing physicians to quickly compare areas of concern identified on either modality.

SOFTVUE™ WORKFLOW



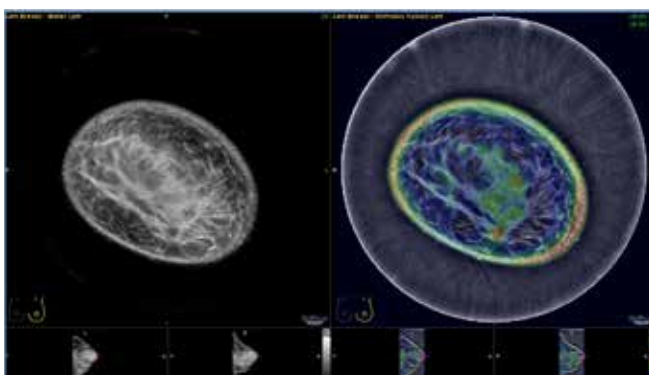
STEP ONE

- Review SoftVue™ Wafer and Sound Speed sequences in conjunction with mammography images
- Look for area of concern on these two sequences



STEP TWO

- Advance to SoftVue™ Reflection and Sound Speed sequences if area of concern is identified on previous sequences



STEP THREE

- If area of concern is confirmed, view Stiffness Fusion sequence to gauge relative stiffness of area

INTEGRATED TRAINING

To ensure confidence in adopting this new technology, Delphinus offers a comprehensive and integrated training program for radiologists learning to interpret SoftVue™ images and technicians responsible for conducting the SoftVue™ scan.

RADIOLOGIST IMAGE INTERPRETATION

Virtual Training

- 9 video modules
- Average 12.5 minutes per module
- Presented by leading breast imaging radiologists
- Training assessment offered after each module to reinforce training concepts

In-Person Training

- 8-hour training session offered at healthcare facility or Delphinus' education facility
- Variety of SoftVue™ cases presented incorporating both group review and prospective review setting
- Offers organic case discussion and one-on-one training opportunities



TECHNOLOGIST TRAINING PROGRAM

Virtual Training

- 2 video modules
- Provides overview of the SoftVue™ scanning procedure, cleaning and maintenance
- Training assessment offered after the modules to reinforce training concepts

In-Person Training

- Conducted over three days with a maximum of two trainees at healthcare facility with newly installed SoftVue™ system
- Training will cover the SoftVue™ Technologist Training Guide and SoftVue™ User Manual
- Each trainee will scan a minimum of 8 volunteers to be recruited by healthcare facility



ASSURANCE AND TECHNICAL SERVICE

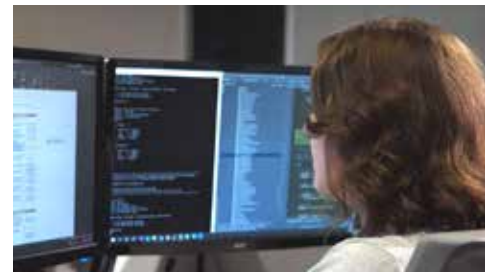
Each SoftVue™ 3D Whole Breast Ultrasound Tomography System is built with the highest quality standards achieving ISO compliance in important areas of quality management, IT security, service quality, and environmental impact.

We offer each client a complimentary one year membership in the **SoftVue™ Assurance Program**. This is our guarantee to provide efficient and professional service and includes:

- Regular system maintenance
- Installation of software and hardware upgrades
- SoftVue™ Image Review Software license
- SoftVue™ system warranty

An extended membership will be offered at the conclusion of your first year in the program to ensure you continue receiving these exclusive benefits:

- Complimentary software upgrades
- Extended coverage hours for all service requests
- Extended Softvue™ system warranty
- Continue preventative maintenance services



REIMBURSEMENT

SoftVue™ is a whole breast ultrasound exam and is covered by **CPT codes 76641** and **76642**. Use modifier 50 to report bilateral procedures performed during the same operative session by the same physician.

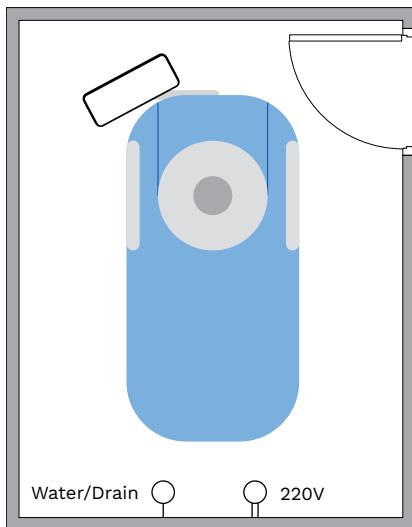
Code	Description
76641	Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; Complete
76642	Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; Limited

SPECIFICATIONS AND INSTALLATION

SoftVue™ System Installation Specifications

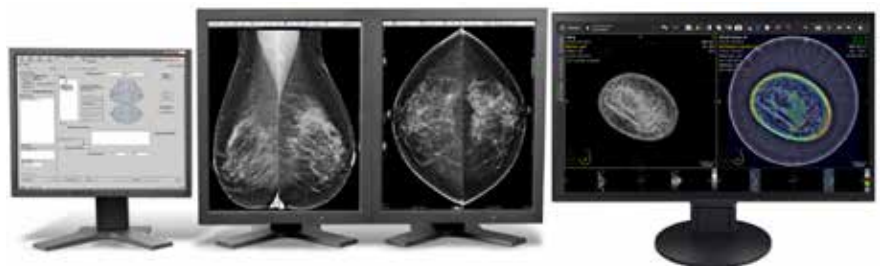
Power Connection	220V split-phase (AKA three-wire single-phase) 50 amp circuit breaker = 208V/230V AC Power Connection
Water Connection	¾" GHT (garden hose thread) cold water connection ¾" GHT or open drain, Water Drain Connection capable of 3 gallons per minute flow rate
Room Requirements	Minimum room size of 8' x 11' System Footprint equals 6.5' x 11'; 3.5' x 8' with 3' clearance around all sides Between 10,000 and 12,000 BTUs of cooling capability Support weight of 1650 lbs.
Internet Connection	Minimum 1 Gigabyte Ethernet Connection

Minimum Size Room (8'x11")



SoftVue™ Image Review Software Requirements

Processor	Intel Core i7 (quad-core) 2.8GHz
RAM	16 = GB
Network	Gigabyte Ethernet
Monitor Resolution	2560 x 1600 px (>= 4MP)
Operating System	Microsoft Windows 10 Pro
Storage Read Speed	>2GB/s



SOFTVUE™ TESTIMONIALS

“The SoftVue™ experience was painless, relaxing and easy!”

*SoftVue™ research participant
Rochester, NY*

“The experience was private and calming and I felt very comfortable.”

*SoftVue™ research participant
Pittsburgh, PA*

“A spa-like experience compared to a mammogram.”

*SoftVue™ research participant
Miami, FL*

“There is no compression, it is very comfortable and relaxing, and not to mention very fast and easy to do.”

*Vivian Linke
Detroit, MI*

“It was less traumatic, less invasive, it was simply laying down on my stomach and allowing myself to float in a small pool of water.”

*Esther Galvez-Dopico
Detroit, MI*

“A much (million times) better experience than the regular mammogram.”

*SoftVue™ research participant
Appleton, WI*

“Could have fallen asleep.”

*SoftVue™ research participant
Rochester, NY*

“So nice to be relaxed and not feel pain.”

*SoftVue™ research participant
Dearborn, MI*

“This was 100 percent more pleasant and much less stressful for me.”

*SoftVue™ research participant
Los Angeles, CA*

“It was by far the best breast health exam ever. I would never skip or postpone a breast exam using SoftVue™.”

*SoftVue™ research participant
Savannah, GA*



“Exactly what is needed in breast cancer screening.”

*SoftVue™ research participant
Dearborn, MI*



“Will recommend to other women.”

*SoftVue™ research participant
Miami, FL*



“Pain-free and no radiation, so I was happy about those two things!”

*Gail Kucinski
Detroit, MI*



“I hope this is the future of breast cancer screening.”

*SoftVue™ research participant
Los Angeles, CA*

TRANSFORMING DENSE BREAST SCREENING



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 **Delphinus**
Medical Technologies