

SoftVue Atlas

Select one of the case examples below to review.

Cancer

1 2 3 4 5

Fibroadenoma

1 2 3 4 5

Cyst

1 2 3 4 5

Dense Tissue

1 2 3 4 5

Cancer 1

View:

PATIENT INFO

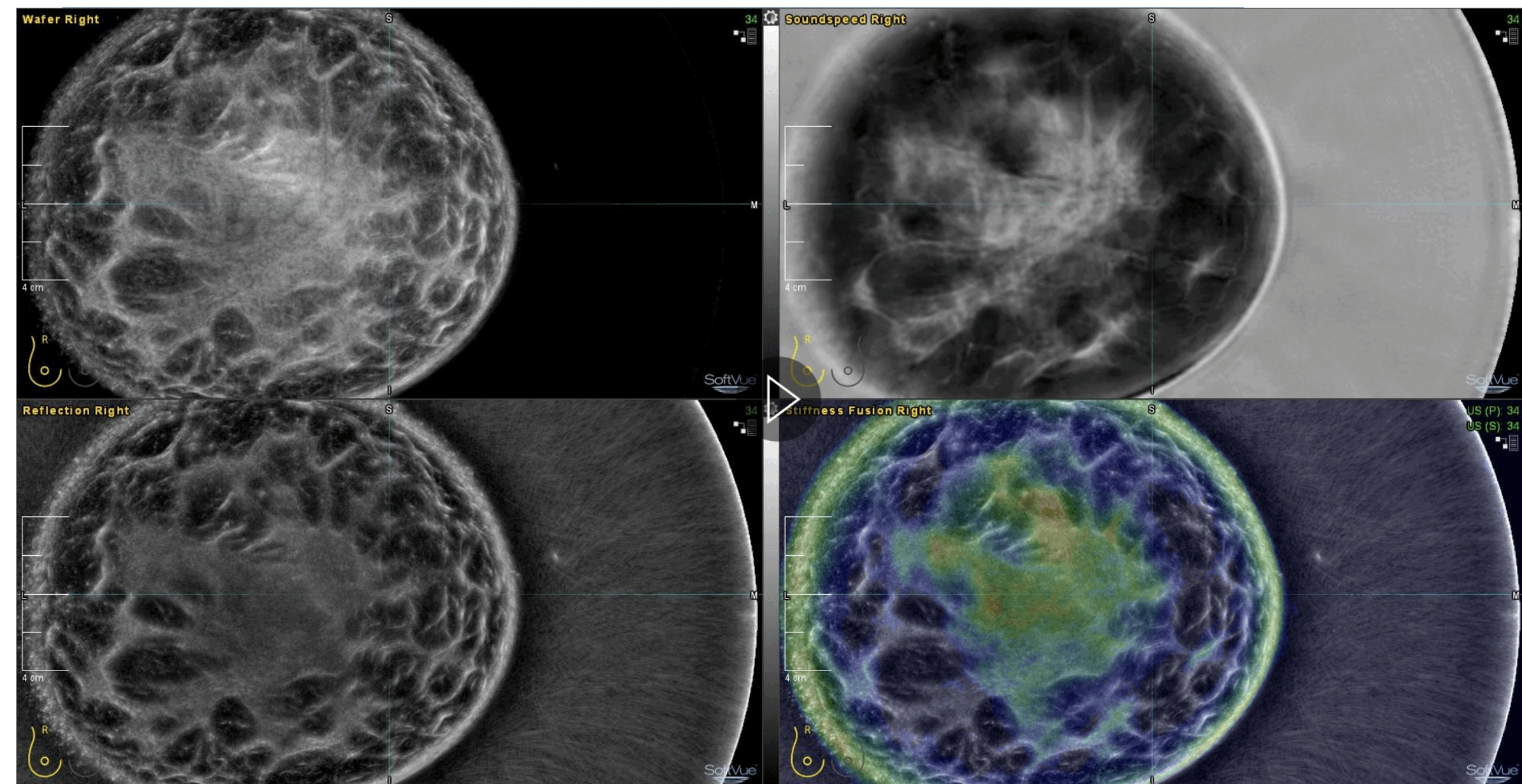
MAMMOGRAM

HHUS

MRI

SHORTCUTS

Review this case using the keyboard shortcuts.



Patient Information

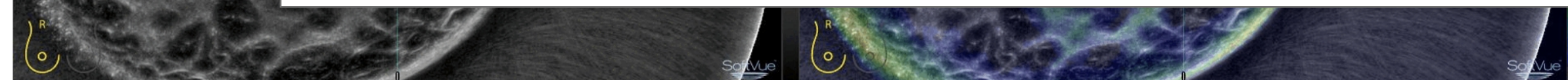
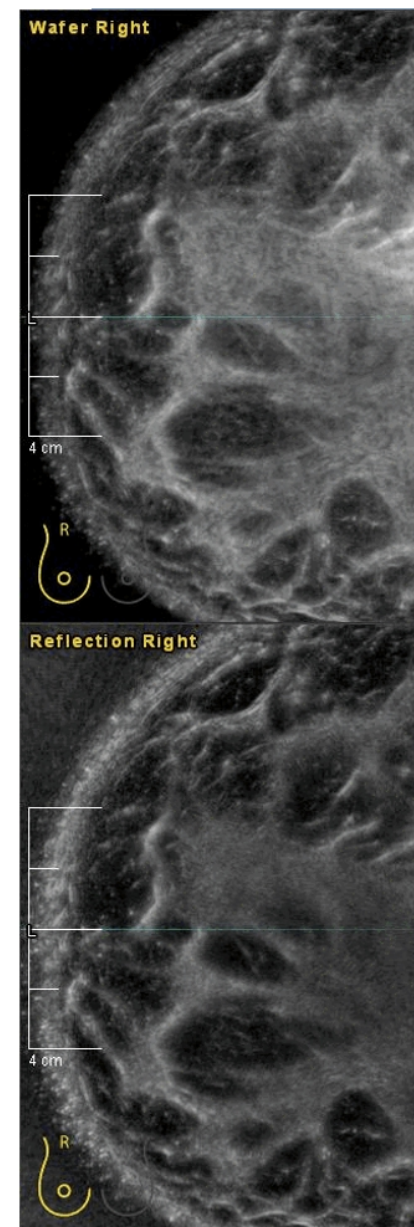
Invasive Ductal Carcinoma at 3:00, measures 1.0 x 0.7 cm. Appears dark on Wafer, bright on Soundspeed, persists on Reflection and contains color on Stiffness Fusion.

« PREVIOUS

NEXT CASE »

Cancer

Review this case u



Case Information

...e Ductal Carcinoma at 3:00, measures
7 cm. Appears dark on Wafer, bright
andspeed, persists on Reflection and
ns color on Stiffness Fusion.

« PREVIOUS

NEXT CASE »

Cancer 1

View:

PATIENT INFO

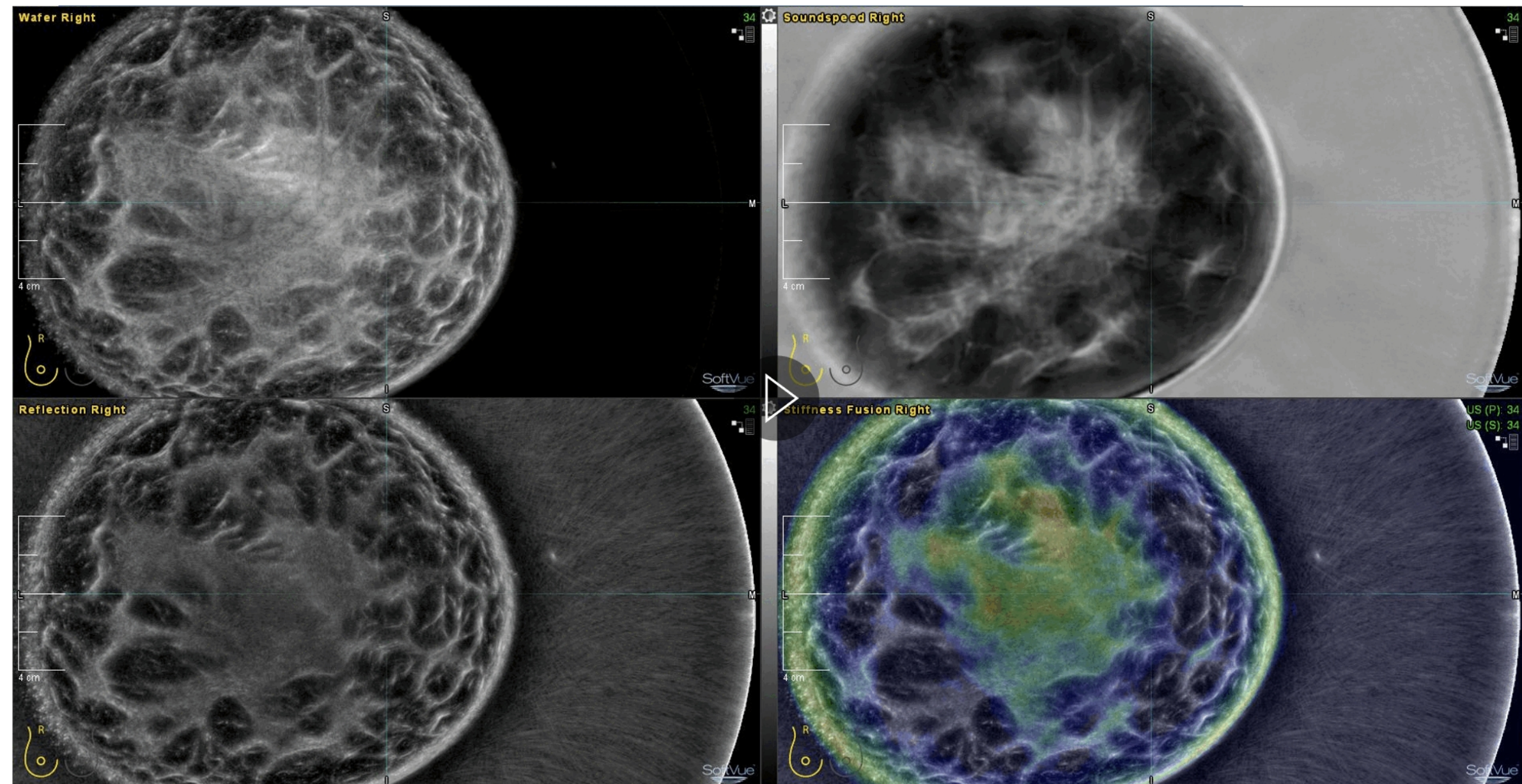
MAMMOGRAM

HHUS

MRI

SHORTCUTS

Review this case using the keyboard shortcuts.



Toggle between full screen case review and questions



Next slice toward chest wall



Next slice toward nipple



Next hanging protocol



Previous hanging protocol



Slice number is shown in upper right corner of the image viewport

« PREVIOUS

NEXT CASE »



SoftVue™

IMAGE INTERPRETATION TRAINING GUIDE

TABLE OF CONTENTS

Why SoftVue™?	Pgs. 3-6
SoftVue™ Image Reconstruction	Pg. 7
SoftVue™ Reading Protocol	Pgs. 8-9
Persistence & Mass Detection	Pg. 10
Focal Color & Mass Detection	Pg. 11
Nipple & Retroareolar Region	Pg. 12
Dense Tissue Characteristics	Pg. 13
Cyst Characteristics	Pg. 14
Fibroadenoma Characteristics	Pg. 15
Cancer Characteristics	Pg. 16
Cancer vs. Focal Dense Tissue	Pg. 17
Lesion Characteristics Matrix	Pg. 18
SoftVue™ BIRADS	Pgs. 19-25
Image Quality Considerations	Pgs. 26-31
SoftVue™ Takeaways	Pg. 32

WHY SOFTVUE™?

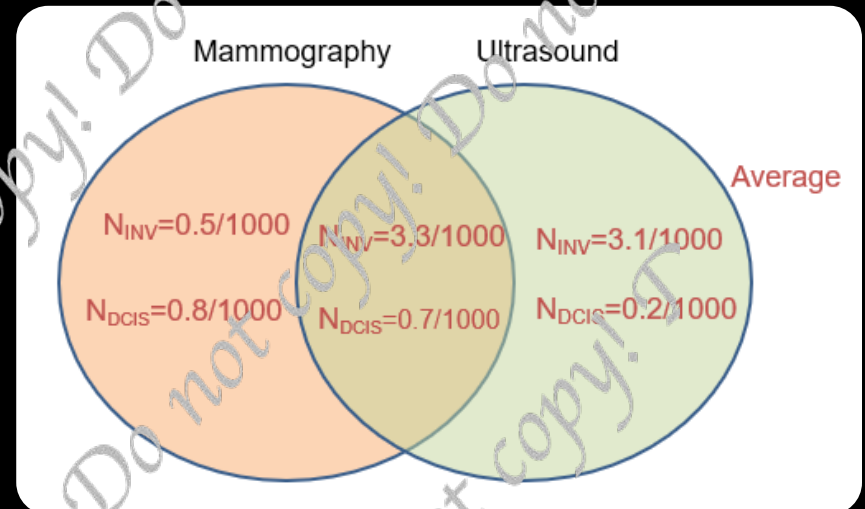
SoftVue™ was designed and developed to address the unmet need for effective breast cancer screening of women with dense breasts.

Mammography is far less sensitive in women with dense breasts. In addition, breast density is an independent risk factor for developing breast cancer.

Women with **BIRADS B density have a 4 fold increased risk of developing breast cancer** when compared with women with BIRADS A density, simply due to the increased density. This occurs in the clinical situation where the sensitivity of mammography is decreased to anywhere between 45-66% in women with dense breasts, as compared to 85% overall sensitivity for mammography.

Numerous studies have demonstrated the effectiveness of ultrasound imaging in detecting mammographically occult breast cancer in women with dense breasts. These studies have shown that **an average of 3 to 4 additional cancers are detected per 1000 screened when ultrasound was added to mammography**. What is even more striking is that the vast majority of the mammographically occult, ultrasound detected breast cancers are predominantly invasive node-negative cancers.

This diagram demonstrates screen detected cancers with mammography and ultrasound.



1. Brem RF et al, *Radiology*. 2015 Mar;274(3):663-73.; 2. Berg WA, et al, *JAMA*. 2012 Apr 4;307(13):1394-404.; 3. Hooley RJ, et al, *Radiology*. 2012 Oct;265(1):59-69.; 4. Kelly KM, et al, *Eur Radiol*. 2010 Mar;20(3):734-42.; 5. Corsetti V, et al, *Eur J Cancer*. 2008 Mar;44(4):539-44.; 6. Crystal P, et al, *AJR Am J Roentgenol*. 2008 Jul;181(1):177-82.; 7. Leconte I, et al, *AJR Am J Roentgenol*. 2003 Jun;180(6):1675-9.; 8. Kolb TM, et al, *Radiology*. 2002 Oct;225(1):165-75.; 9. Kaplan SS, et al, *Radiology*. 2001 Dec;221(3):641-9.; 10. Buchberger et al, *Ultrasound CT MR*. 2000 Aug;21(4):325-36.; 11. Gordon PB, et al, *Cancer*. 1995 Aug 15;76(4):626-30.

WHY SOFTVIEW™?

Ultrasound (US) almost doubles the number of invasive cancers detected. Or stated another way, mammography misses half of the invasive breast cancers.

To that end, automated breast ultrasound (ABUS) has been introduced as a way of overcoming these issues, mainly by reducing operator dependence and uncoupling the acquisition and interpretation of studies.

However, the largest issue for screening breast ultrasound remains the large number of false positive findings. This issue is so significant, with the addition of numerous imaging and biopsies required, that it may preclude effective integration of screening breast ultrasound in clinical practice.

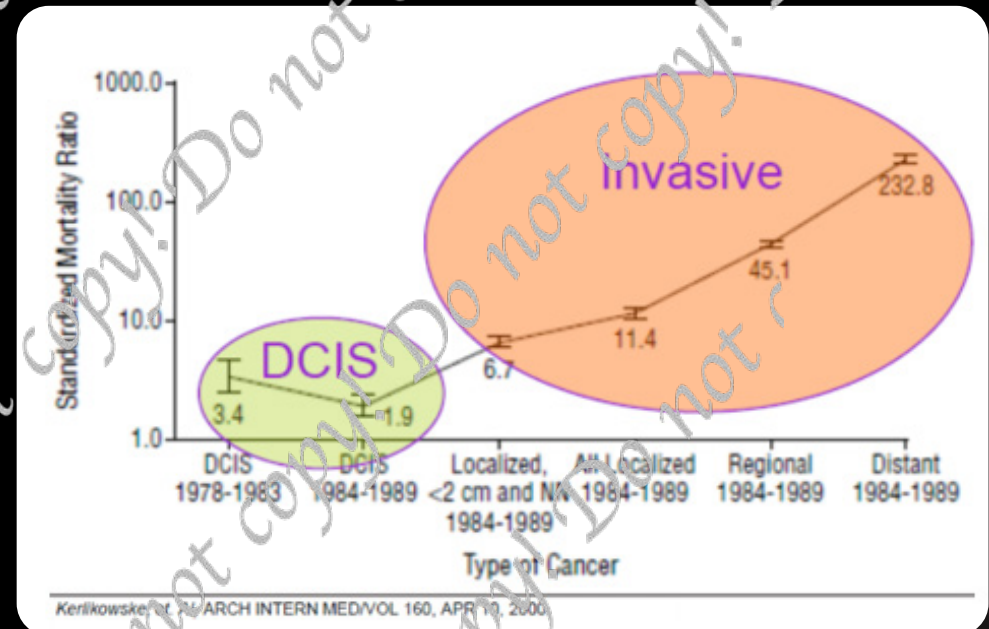
The fundamental quandary of breast screening today is the knowledge that:

1. **Mammography misses cancers in dense breasts**
2. **Automated Breast ultrasound (ABUS) detects cancers that mammography misses and yet**
3. **Screening continues largely with mammography only**

The primary reason this paradox exists today is that ultrasound screening increases call back rates (up to a factor of 2 in case of the SonoInsight study). Technically, with its basic B-mode capability, ABUS has the same issue with false positives as hand-held ultrasound. It is therefore unlikely that screening breast ultrasound, both hand-held and automated, will be widely adopted for screening in the foreseeable future without more tissue-

specific imaging capability. Improved lesion characterization with resultant improvement in specificity, would substantially lower the barriers to adoption of screening breast ultrasound.

This graph shows the relationship between the standardized mortality ratio and the stage of cancer detected. With DCIS, you can see that the mortality ratio is not as large compared to the general population. Whereas mortality ratios increase dramatically for invasive cancers with worsening stage of cancer. These are the cancers we can't afford to miss because these are the ones that lead to much higher mortality ratios compared to DCIS.



WHY SOFTVUE™?

Ultrasound can detect invasive cancers more effectively than mammography and these are the cancers you want to detect to impact a reduction in mortality. This is the motivation for the development of SoftVue, detecting the clinically significant, invasive node-negative breast cancer, while minimizing the false-positive rate of traditional ultrasound by utilizing physiologic parameters to differentiate benign from malignant lesions.

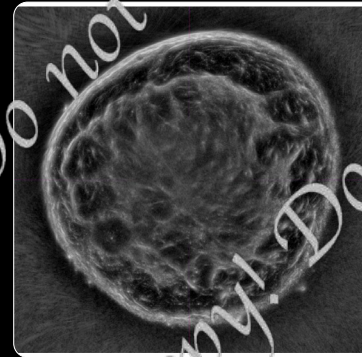
SoftVue™ Answers the Challenge

Unlike regular ultrasound, SoftVue™ is a whole breast tomographic device and has more in common with CT and MR, as the images presented will show.

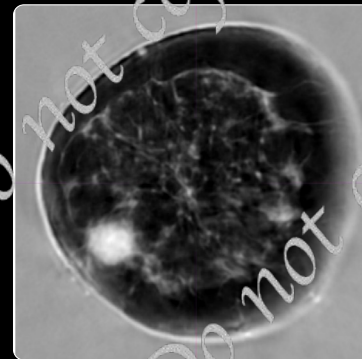
SoftVue™ utilizes traditional ultrasound reflection while improving the clinical information by adding ultrasound transmission to optimize the clinical data.

Ultrasound transmission measures physiologic tissue parameters in sound speed and stiffness, in addition to reflection, a key factor in decreasing the false positive rate. By merging **Reflection** images with images of **Sound speed** and **Attenuation**, SoftVue™ secures anatomical AND physiologic properties of tissue to accurately differentiate cancer from normal tissue or benign disease.

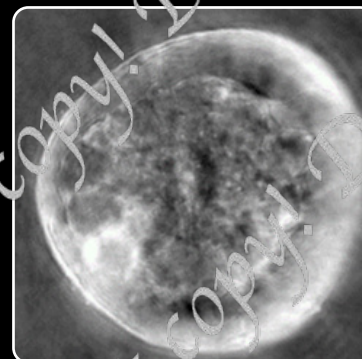
These parameters can be used to characterize lesions in a quantitative manner. This quantitative approach is not available in current breast ultrasound systems. We refer to this as our **TriAd™ (triple acoustic detection)** technology.



Reflection



Sound Speed



Attenuation

WHY SOFTVUE™?

Image acquisition is conducted with a unique closed geometry probe, or circular ring transducer, that surrounds the breast that is immersed in warm water. Each of the 2048 elements emits and receives ultrasound signals in a sequenced 360° circular pattern for each position of the transducer scanning the breast automatically from the nipple to the chest wall. The ring transducer captures not only reflection echoes that define anatomic detail, but also the transmission signals passing through the tissue, quantifying sound speed and attenuation and thereby defining the tissue properties of the breast.

The **Sequir™ breast interface** is a central component of the SoftVue™ system. This **soft anatomically-formed guide** engages the nipple to center, elongate and steady the breast during the imaging procedure. Elongating the breast provides for an increased number of image slices acquired during the imaging process thus offering physicians clarity and detail when reviewing the image stacks.

Unlike mammography and other ABUS systems, multiple positionings are not required. The patient is positioned prone on the memory foam table with one breast at a time submerged in the warm water.



The operator adjusts the transducer level to ensure that imaging of the nipple to the chest wall is acquired. With a press of the start button, the exam is performed automatically without further involvement of the operator.

SoftVue™ scan time is 2-5 minutes per breast (depending on breast size). This scan duration minimizes intra-slice and inter-slice motion artifacts.

A coronal cross-section image set is presented of the entire breast, displayed in volumetric image stacks for interpretation and comparison with other breast imaging studies.



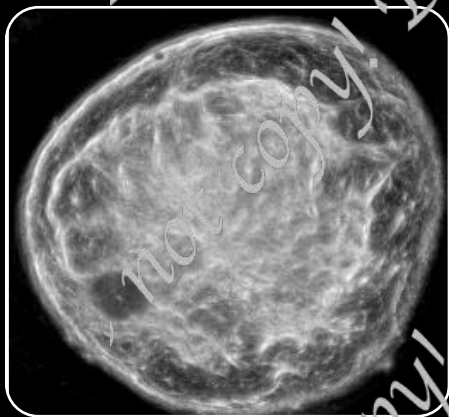
SOFTVUE™ IMAGE RECONSTRUCTION

After SoftVue™ acquires data, its internal computing system performs tomographic reconstructions. The backscattered signals are used to create Reflection images while the transmitted signals are used to create Sound Speed and Attenuation images. Each of the three image outputs represents a separate but complimentary view of the whole breast.

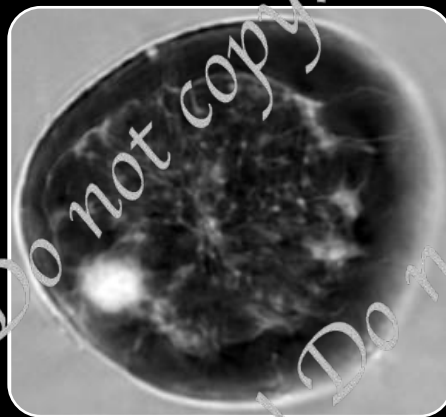
In order to aid in the interpretation two additional steps are performed in post processing. The sound speed image is used to lower the visibility of fat and to enhance the remaining tissues. The resulting image is referred to as Wafer which is a contraction of the words “waveform enhanced reflection”. A combination of Sound Speed and Attenuation images is used to create stiffness images. The resulting images provide relative differences in tissue stiffness. The stiffness image is superimposed on the Reflection image and is referred to as Stiffness Fusion. The final image output for interpretation includes the Reflection images and Sound Speed images as direct outputs of the image acquisition process. The backscatter signal of Reflection and transmitted signal of Sound Speed are used to create the Wafer output image. The Stiffness Fusion image included in the final image out is a combination of the Reflection and Attenuation signals.

The four image outputs are designed to optimize SoftVue™’s tissue specific imaging, that is imaging that represents different tissue properties.

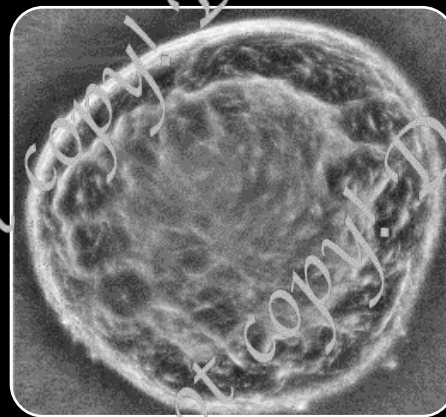
Wafer



Sound Speed



Reflection



Stiffness Fusion



SOFTVUE™ READING PROTOCOL

When reviewing SoftVue™ images, **first scroll quickly through the bilateral Wafer images**. Once the last slice has been reached on the bilateral Wafer sequence **move to the right breast Wafer and Sound Speed sequences**.

Scroll from the nipple to the chest wall through this sequence paying close attention to the Wafer images, reviewing each slice for 1-2 seconds. Pay attention to the fat glandular tissue interface during the review as this is where most cancers are located. Please see the example to the right.

Once you have reached the chest wall, turn to the Sound Speed images and scroll back from the chest wall to the nipple looking for a bright white focal spot that is embedded within the black fatty tissue.

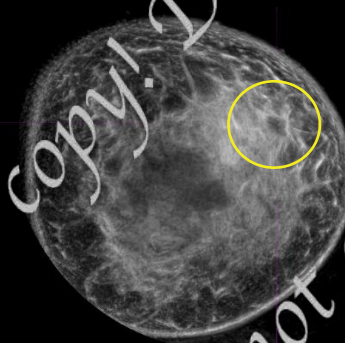
If you do not observe a mass in the right breast on Wafer or Sound Speed move forward to the left breast Wafer and Sound Speed sequences and repeat the same reading protocol.

DO NOT scroll through the entire image sets of Reflection and Stiffness Fusion.

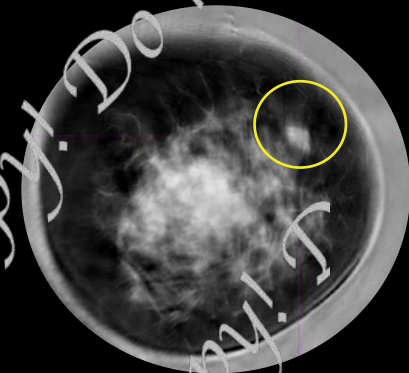
Reflection is used to confirm the presence of a mass by looking to see if an area of concern persists between Wafer and Reflection. Stiffness Fusion images are only to be used to characterize a mass by looking to see if there is focal color associated with an area of concern seen on the Wafer, Sound Speed and Reflection sequences. Scrolling through the entire Reflection and Stiffness Fusion image set could increase false positives and therefore is highly discouraged.

Mass Detection Sequences

Wafer

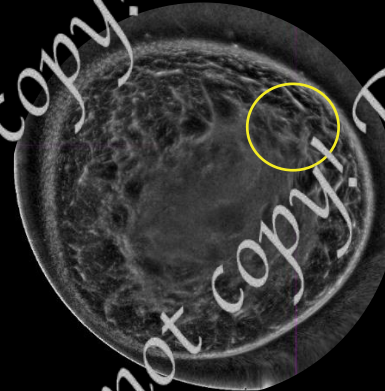


Sound Speed

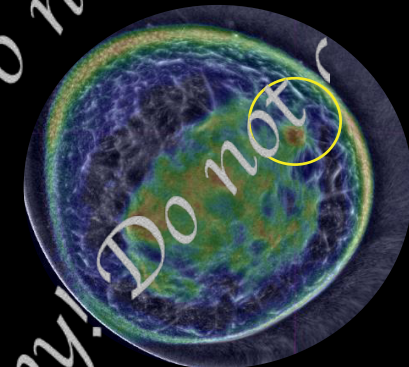


Mass Characterization & Confirmation Sequences

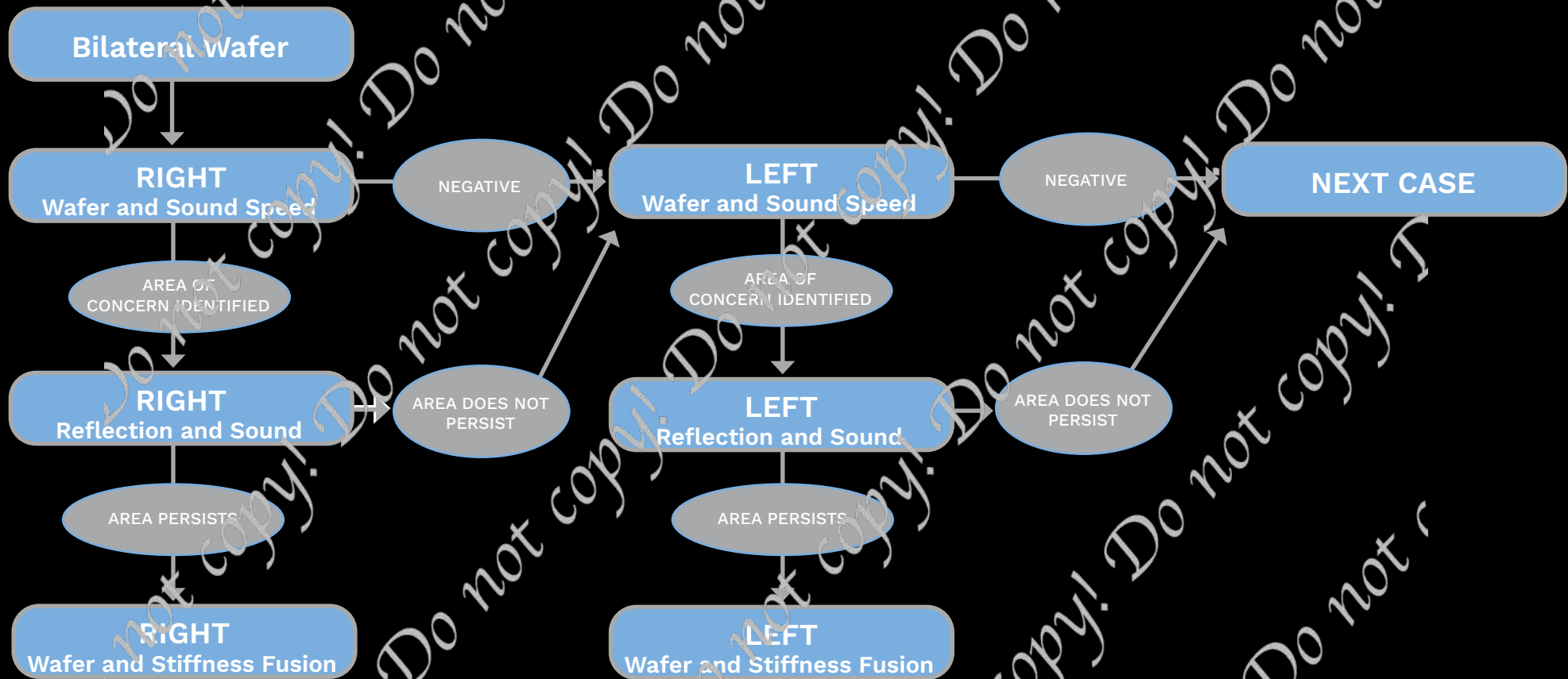
Reflection



Stiffness Fusion



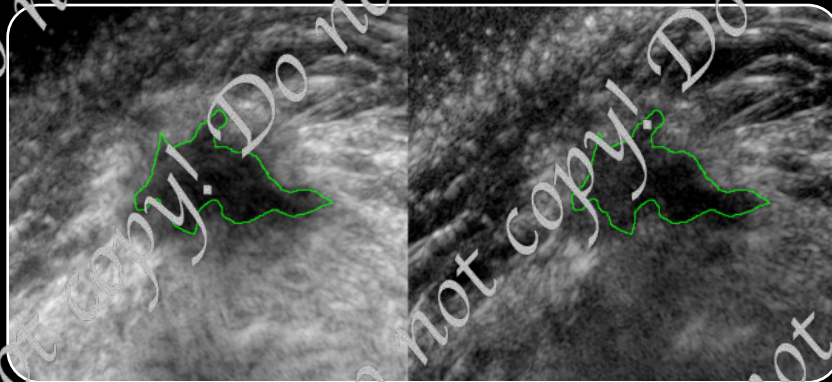
SOFTVUE™ READING PROTOCOL



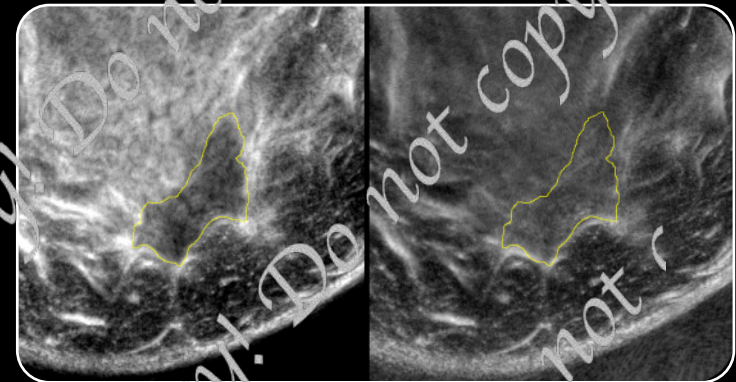
PERSISTENCE & MASS DETECTION

The concept of **persistence** relates to a mass being observed on both **Wafer and Reflection**. If an area of concern does not persist between these image sequences it is not a mass. Wafer will sometimes exhibit dark areas that represent normal tissue, and the areas can be dismissed if they do not persist on Reflection. The two examples presented below demonstrate the difference between a mass that persists between Wafer and Reflection and a pseudo-mass that does not persist on Reflection.

Mass Persists between Wafer & Reflection



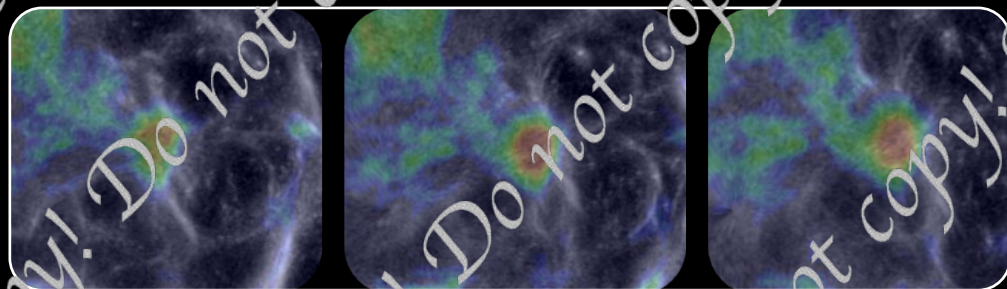
Pseudo-mass DOES NOT Persist between Wafer & Reflection



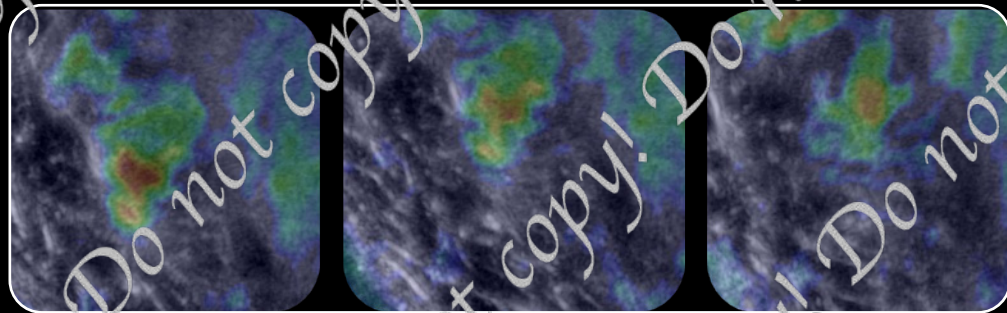
FOCAL COLOR & MASS DETECTION

The concept of focal color, or color staying within the margins of the mass, applies to mass detection on the Stiffness Fusion image sequence. Color associated with dense tissue will not stay focal to the area of concern, but rather will pass over and around an area of concern. However, with a true mass, the color will remain focal and stay within the mass. Below is an example of how color stays with a mass, verses flowing from slice to slice with the dense tissue.

Color stays focal to the mass



Color does not stay focal to the area of concern

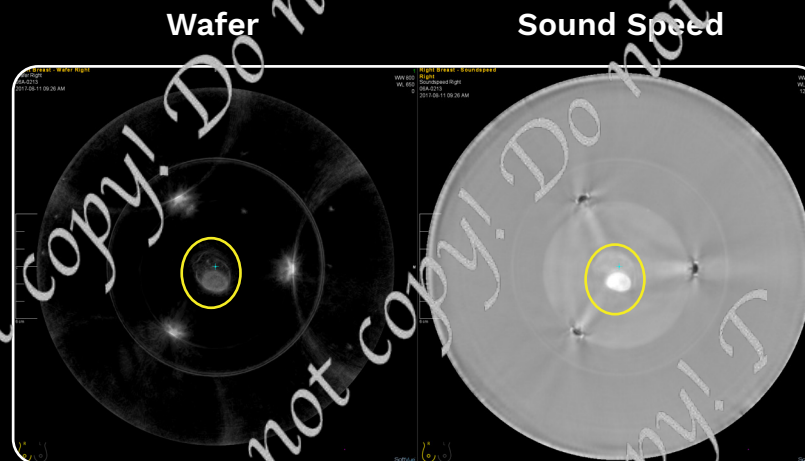


NIPPLE & RETROAREOLAR REGION

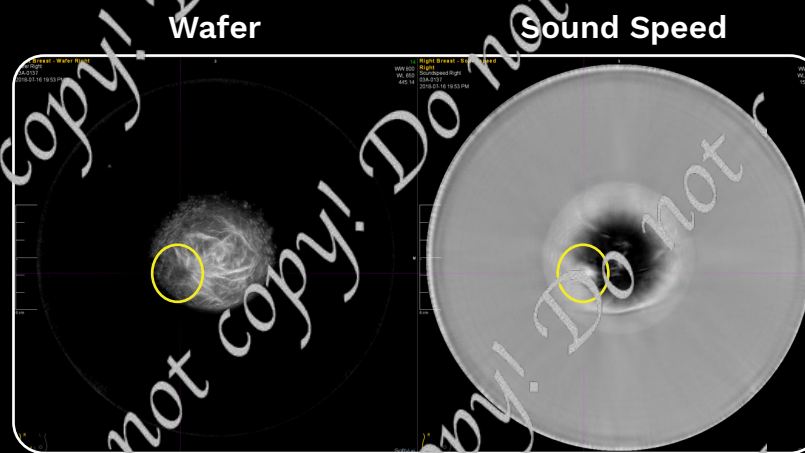
The location and appearance of the nipple may vary from scan to scan due to either individual anatomy or patient positioning. The nipple is not always centered in the Sequi™ gel pad and may not always be visible on the first few slices. In cases where the nipple is not clearly identified on the first slice, during the review pay attention to the periphery of the breast to see if there is a mass like structure protruding out from the edge of the skin as this would indicate the nipple.

Identification of the nipple is important in order to give a correct location of an abnormal finding. It is also important since it can mimic a mass. If a mass like structure is identified near the skin within the first few slices make sure it is not the nipple before calling it a mass. In addition, the retroareolar region will appear dark and patchy and could be falsely identified as an irregular mass. If the area extends to the skin it is just retroareolar glandular tissue.

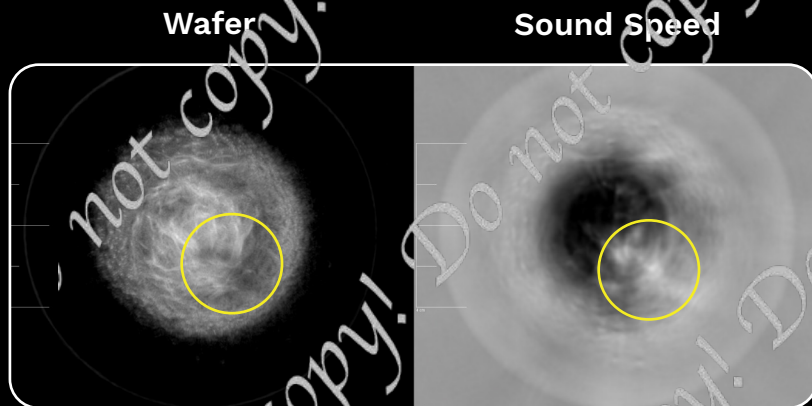
Centered Nipple on First Slice



Uncentered Nipple Several Slices into Review



Retroareolar Glandular Tissue Mimics Mass



DENSE TISSUE CHARACTERISTICS

There are two types of dense tissue. The gray patchy area that has increased water content and the white area that has increased Fibrosis.

On **Wafer** dense tissue will appear **black, gray** or **white** depending on water content or fibrosis, and will have a **patchy appearance**.

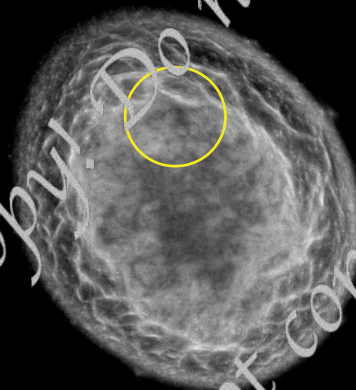
Sometimes focal dense tissue may appear mass like, either as an irregular or circumscribed dark focal area on Wafer as demonstrated in the example to the right.

On **Sound Speed** focal dense tissue appears **bright white** as opposed to fatty tissue which is black. **Any focal area of concern observed on Wafer that is black on Sound Speed is just fat**. If the area of concern is bright on Sound Speed look to Reflection to determine if is a true mass or just dense focal tissue.

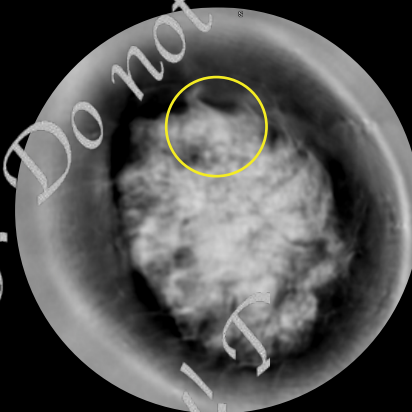
On **Reflection** focal dense tissue observed on Wafer or Sound Speed **may blend in with the surrounding tissue or persist. If the area in question blends in with the surrounding tissue on Reflection it can be dismissed as dense tissue**. If the area in question persists between Wafer and Reflection, meaning the mass morphology remains similar between the two sequences, look at Stiffness Fusion to determine if there is focal stiffness associated with the area of concern.

On **Stiffness Fusion** focal dense tissue will present with a range of colors from **blue to red**. The difference between focal dense tissue and a true mass is the lack of focal color. In other words, the **color associated with an area of focal dense tissue will not stay within the margins of the observed area**, but rather flow in and around the area in question.

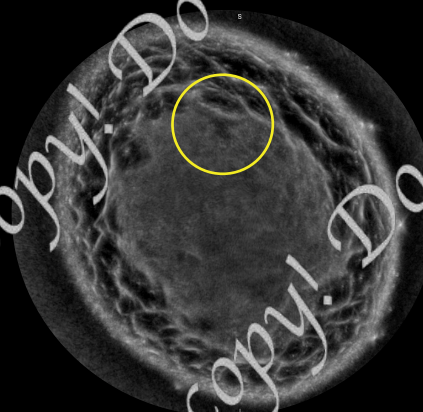
Wafer



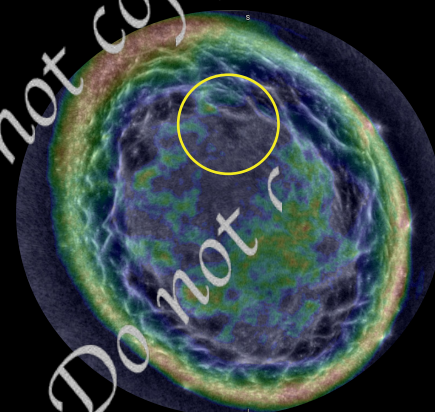
Sound Speed



Reflection



Stiffness Fusion



CYST CHARACTERISTICS

Cysts are fairly easy to identify and characterize on SoftVue™ images. Similar to b-mode ultrasound, cysts will present as **circumscribed round** or **oval** masses.

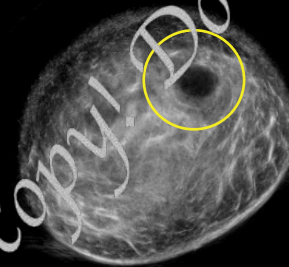
On **Wafer**, cysts will be **dark**.

On **Sound Speed**, they will be **gray**, or similar to the color of the water bath that surrounds the breast during the SoftVue scan.

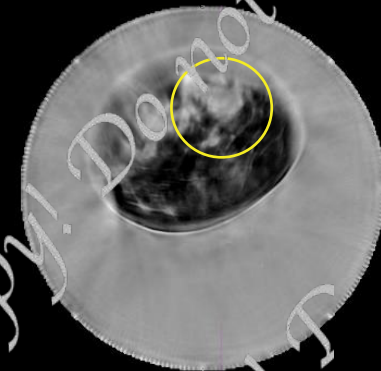
On **Reflection**, cysts will **remain dark** and will **persist** between Wafer and Reflection.

On **Stiffness Fusion**, cysts will be dark blue. As cysts are composed of water primarily, these masses will lack any stiffness properties.

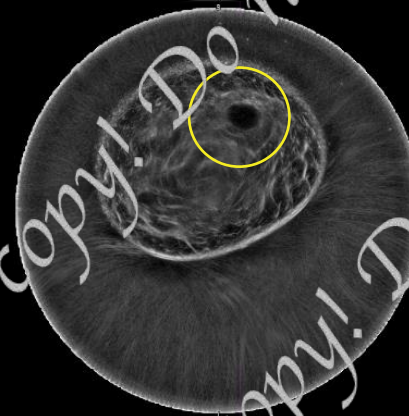
Wafer



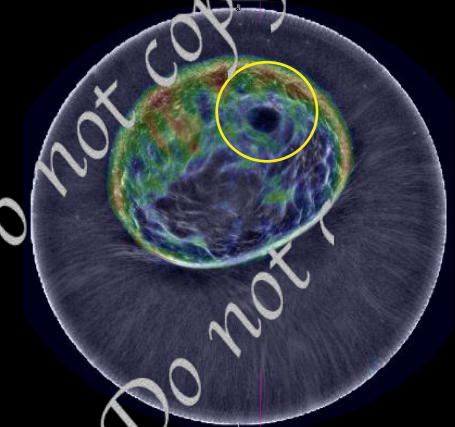
Sound Speed



Reflection



Stiffness Fusion



FIBROADENOMA CHARACTERISTICS

Much like cysts, a Fibroadenoma will present as a **round** or **oval** mass with **circumscribed** margins.

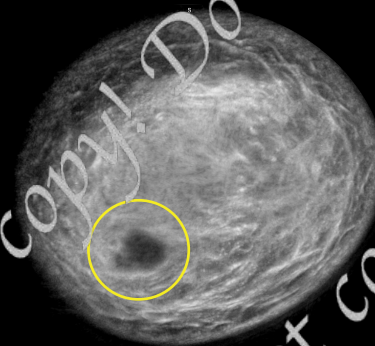
On **Wafer**, fibroadenomas will be **dark**.

On **Sound Speed**, they will be **white**.

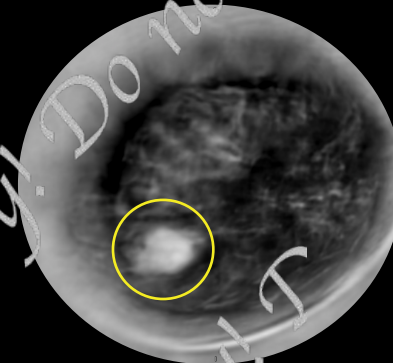
On **Reflection**, fibroadenomas will **persist** and **remain dark**.

On **Stiffness Fusion**, fibroadenomas will range from **blue to green** in color, and the color will **stay within the mass**.

Wafer



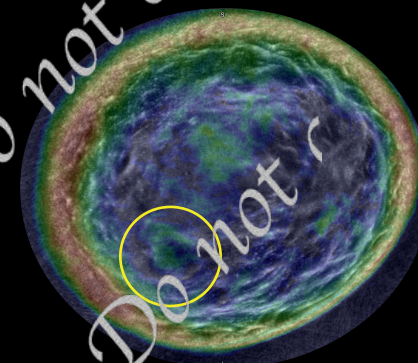
Sound Speed



Reflection



Stiffness Fusion



CANCER CHARACTERISTICS

While the characteristics can vary, cancers are usually **irregular** in shape, They can be associated with **spiculated margins** and/or **architectural distortion**. However, very **small cancers** can be **round** or **oval** masses.

On **Wafer**, cancers will be **dark**.

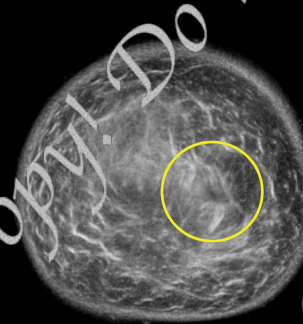
On **Sound Speed**, cancers will be **bright** or white.

On **Reflection**, cancer will **persist and remain dark**.

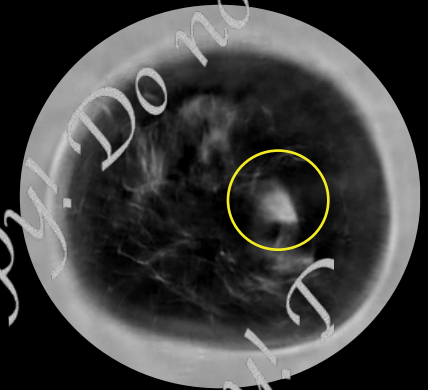
On **Stiffness Fusion**, cancer will range in color from **green to red**. The color associated with cancers will **stay within the margins of the mass**. While cancers will range in color, most cancers will be orange to red.

In particular, the very small round or oval cancers will be red. However, any mass with spiculations or architectural distortion will be cancer regardless of color, as long as it is not blue on Stiffness Fusion.

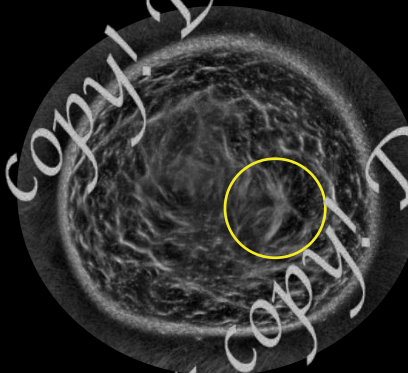
Wafer



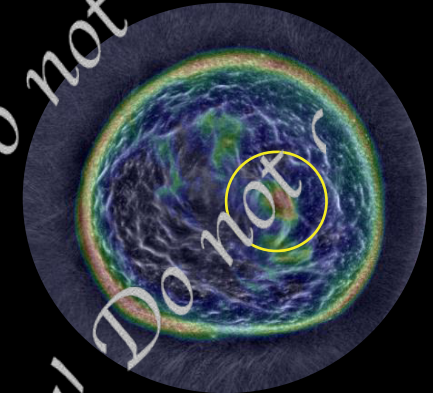
Sound Speed



Reflection



Stiffness Fusion



CANCER VS. DENSE TISSUE

CANCER

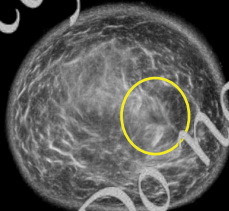
Cancers will always persist on Reflection and have focal stiffness on the Stiffness Fusion sequence.

Cancers will range in stiffness, but are predominantly orange to red in color, with the color staying central to the mass.

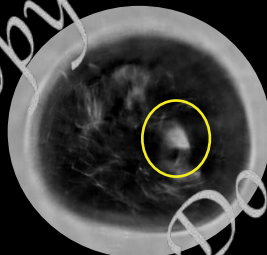
Any mass with spiculations and/or architectural distortion will be cancer, regardless of color.

Cancers are commonly located at the fat-glandular interface (FGI), so pay attention to this area when evaluating the breast.

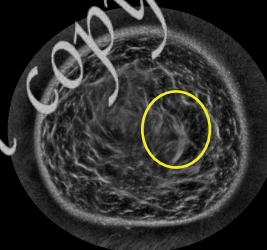
Wafer



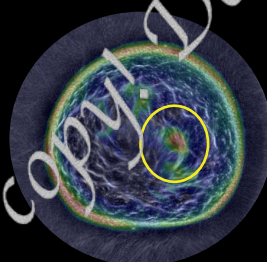
Sound Speed



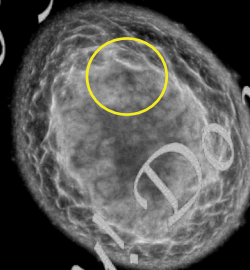
Reflection



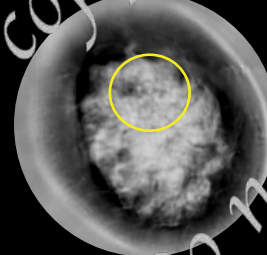
Stiffness Fusion



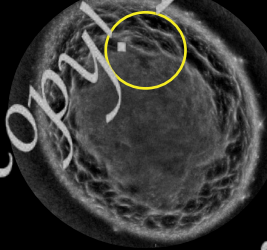
Wafer



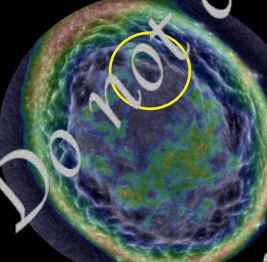
Sound Speed



Reflection



Stiffness Fusion



DENSE TISSUE



If an area is dark on Wafer and white on Sound Speed, but does not persist on Reflection, then you can dismiss it as a focal dense tissue.

If an area is dark on Wafer, white on Sound Speed AND persists on Reflection then look at Stiffness Fusion. If it lacks focal stiffness, then dismiss it as focal dense tissue.

Even if there is red, green, orange or yellow associated with the area of concern, if the colors do not stay within the mass, rather they flow in and around the area, then dismiss it as focal dense tissue.

LESION CHARACTERISTICS MATRIX

The matrix below summarizes the characteristics of masses and dense tissues on SoftVue™. If an area of concern is identified, walk through the matrix identifying the shape and margins, followed by characteristics observed on the four image sequences to help determine the type of mass or tissue in question.

	Shape	Margins	Wafer	Sound Speed	Reflection	Stiffness Fusion
Dense Tissue (Increased water)	* No discernable shape	* No discernable margins	Gray Black	Bright Bright	Blends Persists	* Not applicable  Color Flows
Dense Tissue (Increased fibrosis)	* No discernable shape	* No discernable margins	White	Bright	* Not applicable	* Not applicable
Fatty Lobule	 OR 		Black	Black	Black	* Not applicable
Cyst	 OR 		Black	Gray	Black	
Fibroadenoma	 OR 		Black	Bright Gray	Persists	 Color Stays with Mass
Cancer	 OR  OR 	 OR  OR 	Black	Bright Gray	Persists	 Color Stays with Mass

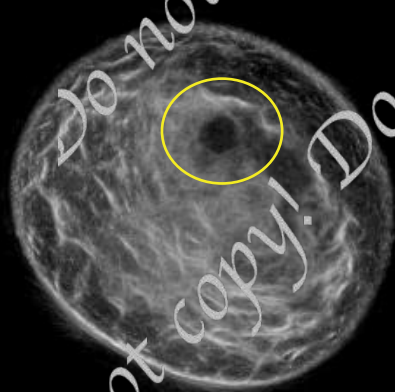
SOFTVUE™ BIRADS

Circumscribed or Indistinct	+ Blue	= BIRADS 2
Circumscribed	+ Green	= BIRADS 3
Circumscribed	+ Red	= BIRADS 4a
Indistinct	+ Green	= BIRADS 4b
Indistinct or Irregular	+ Red	= BIRADS 4c
Spiculations or Architectural Distortion	+ Green to Red	= BIRADS 5

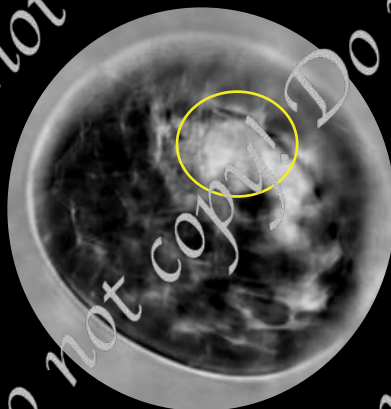
SOFTVUE™ BIRADS 2

Circumscribed or indistinct + Blue = BIRADS 2

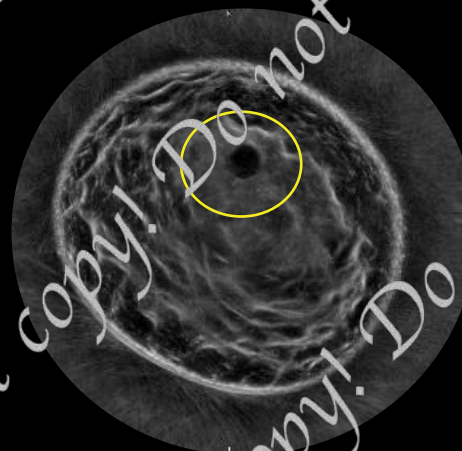
Wafer



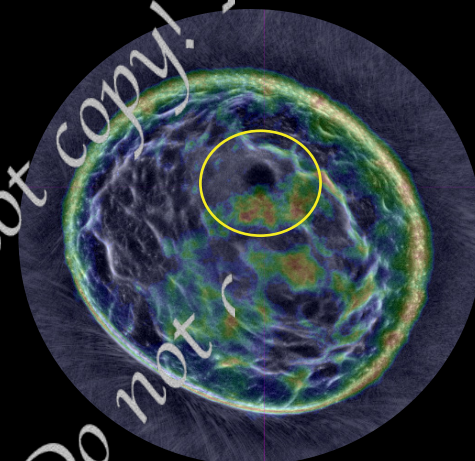
Sound Speed



Reflection



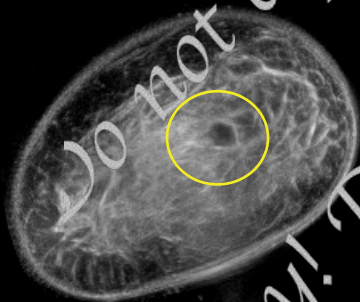
Stiffness Fusion



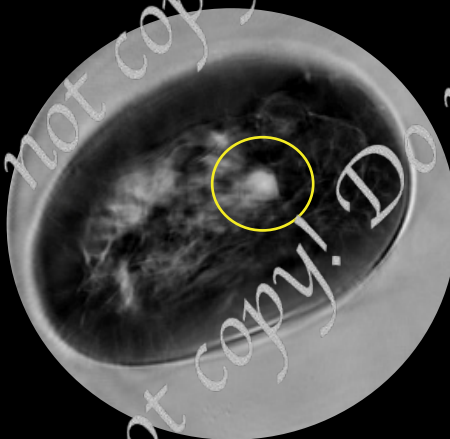
SOFTVUE™ BIRADS 3

Circumscribed + Green = BIRADS 3

Wafer



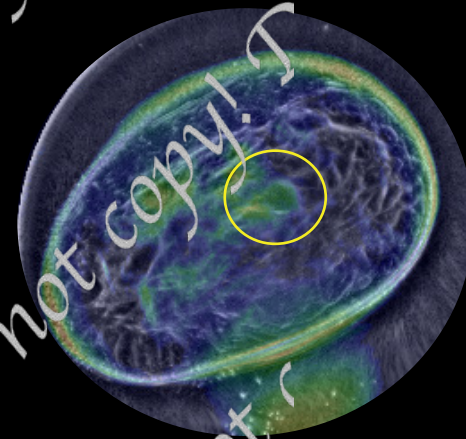
Sound Speed



Reflection



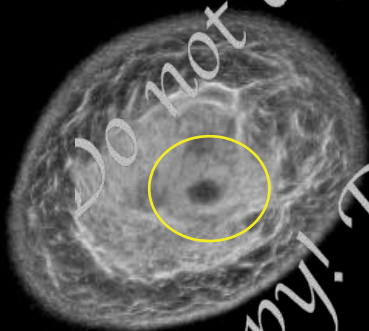
Stiffness Fusion



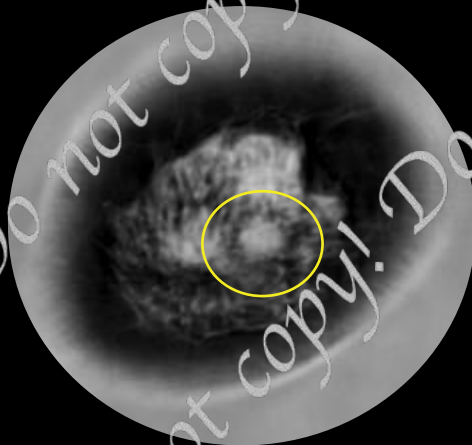
SOFTVUE™ BIRADS 4a

Circumscribed + Red = BIRADS 4a

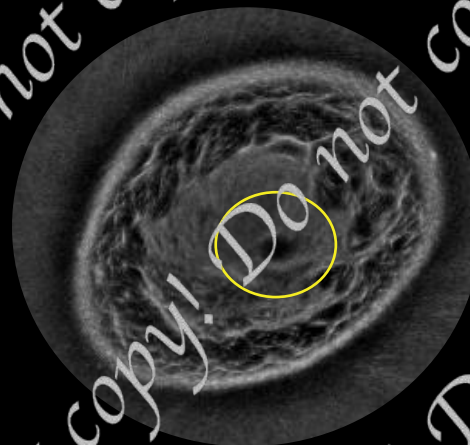
Wafer



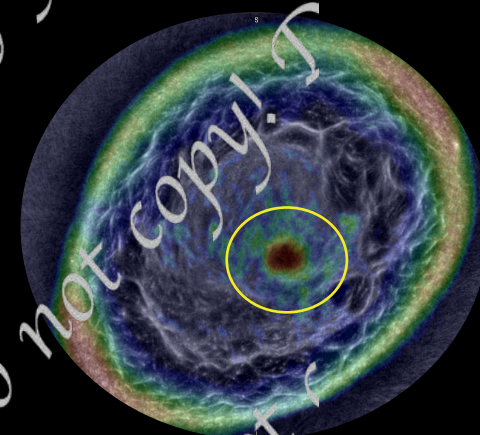
Sound Speed



Reflection



Stiffness Fusion



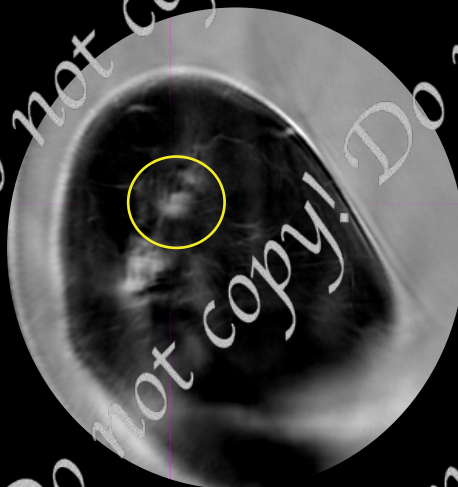
SOFTVUE™ BIRADS 4b

Indistinct + Green = BIRADS 4b

Wafer



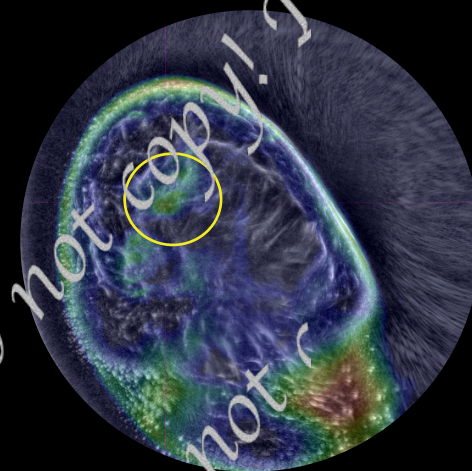
Sound Speed



Reflection



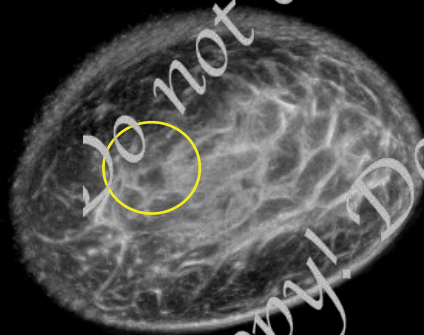
Stiffness Fusion



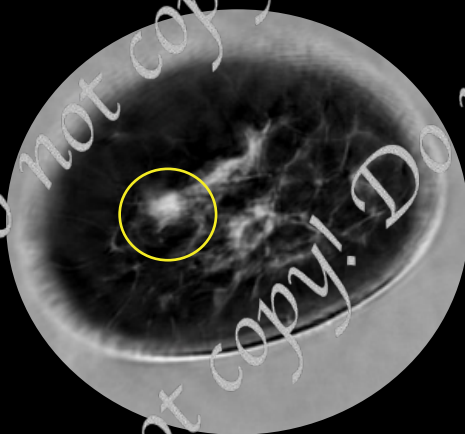
SOFTVUE™ BIRADS 4c

Indistinct or Irregular + Red = BIRADS 4c

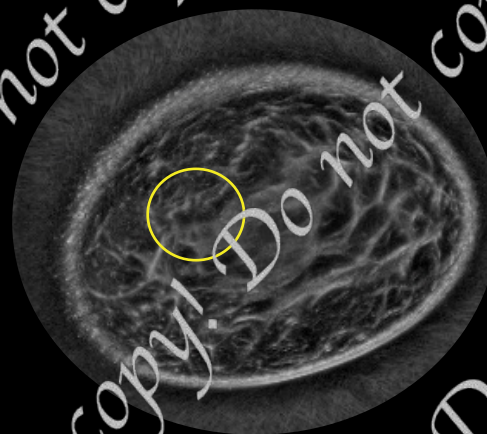
Wafer



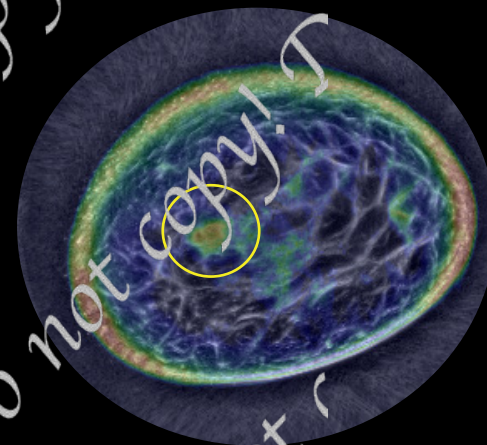
Sound Speed



Reflection



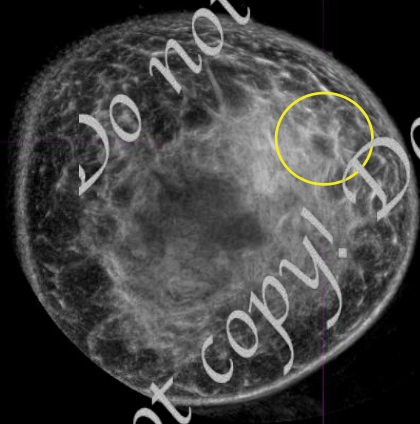
Stiffness Fusion



SOFTVUE™ BIRADS 5

Spiculations or Architectural Distortion + Green to Red = BIRADS 5

Wafer



Sound Speed



Reflection



Stiffness Fusion

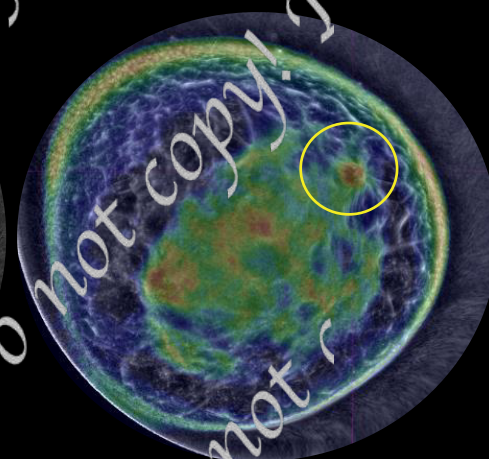


IMAGE QUALITY CONSIDERATIONS

These guidelines were developed to help you confidently identify good quality images and know what corrective actions your operators can take to address quality issues. Patient positioning and breast extension are the most important factors in achieving quality SoftVue™ images. If the breast is not adequately extended, you may notice these factors on SoftVue™ images:

- Inadequate coverage of the pectorals muscle
- Poor resolution at the skin lines on Sound Speed
- Mushrooming of the breast near the Sequur™ gel pad

These factors do not impact mass detection and the ability to interpret SoftVue™ images and can be resolved through additional operator training or a call to the Delphinus service team.

BREAST EXTENSION

Breast extension significantly impacts overall image quality, and an operator can directly observe it during scanning and the radiologist during image review. **Extension of the breast effectively spreads breast tissues and anatomical structures apart from one another**, making the details of masses more prominent.

The greater the extension, the greater the signal penetration, and the more slices of image data can be acquired from the breast volume. This ensures you have optimal images of the breast for interpretation.

The imaging tank is fixed at a maximum depth of 65 slices or 13cm. The optimal extension for patients with similarly sized breasts can be different due to differences in the elasticity of their breast tissue. The Total number of slices is not necessarily indicative of poor vs. good extension in similarly sized breasts.

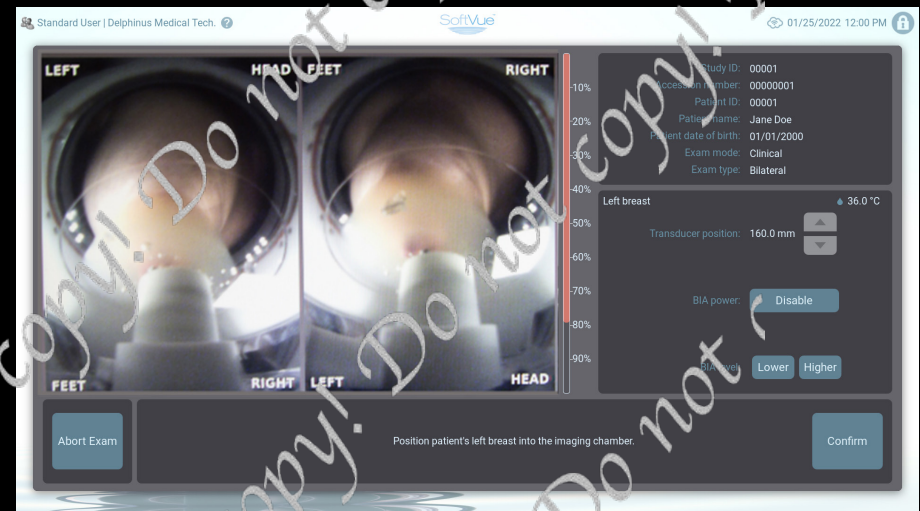


IMAGE QUALITY CONSIDERATIONS

PULSATION

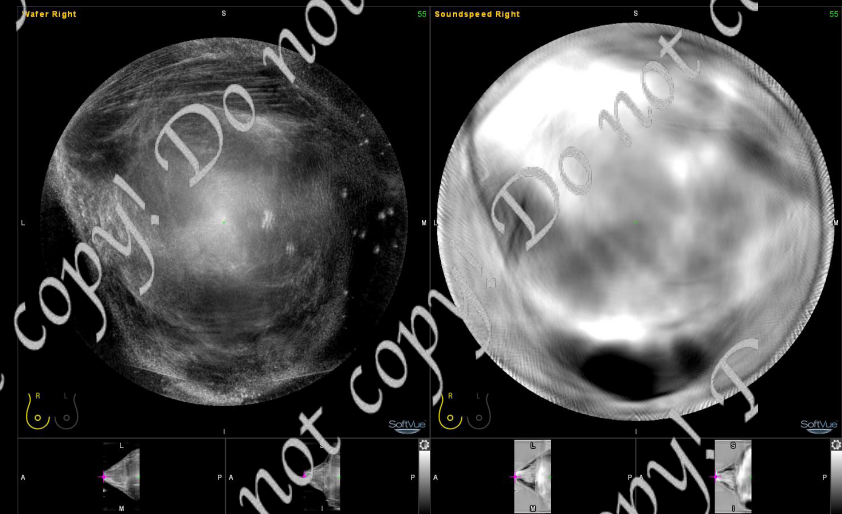
Pulsation, or pulsing, occurs during image acquisition when the vacuum seal repetitively breaks between the areolar region and the Sequor™ gel pad, causing loss of suction and release of the extended breast, then re-engagement with the breast. It is more common in small breasts but can happen with large breasts when off center.

Contributing Factors Include:

- Damaged gel pad
- Poor positioning
- Patient movement, talking, coughing, or heavy breathing
- Suction level is too strong

Pulsation has not been found to cause motion artifact or degrade image quality. However, it can cause sub-optimal breast extension, leading to **inadequate imaging of the pectoralis muscle.** Additional positioning training for operators can help minimize pulsation during image acquisition. To the right are two exams from the same patient, one in which there was pulsing during image acquisition and one where there was no pulsing. Notice the impact on extension and lack of visualization of the pectoralis muscle.

No Pulsing



Pulsing

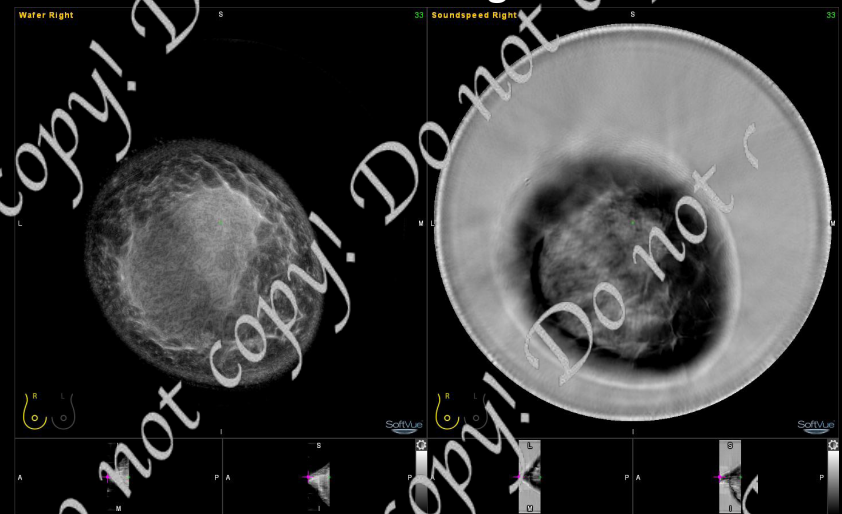


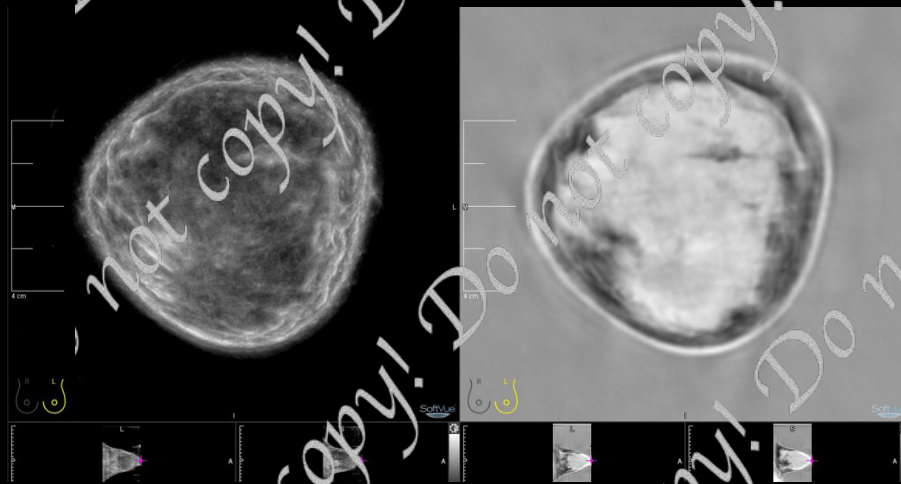
IMAGE QUALITY CONSIDERATIONS

ANGLE OF INCIDENCE

The skin surface of a well-shaped breast is perpendicular (90°) to the transmitted ultrasound beam, allowing the ultrasound beam's energy to be transmitted through the breast without scattering "out-of plane" with the transducer. **The more perpendicular the angle, the less attenuation of that signal at the skin surface. This provides a sharper skin line,** particularly observed on the Sound Speed images.

A **well-shaped breast** will be **cylindrical** rather than cone shaped on the reformatted images at the bottom of the screen. Increasing extension will allow for a more cylindrically shaped breast and sharper skin lines. Additional operator training may be needed if skin lines are fuzzy on a consistent basis.

Good Angle of Incidence



Poor Angle of Incidence

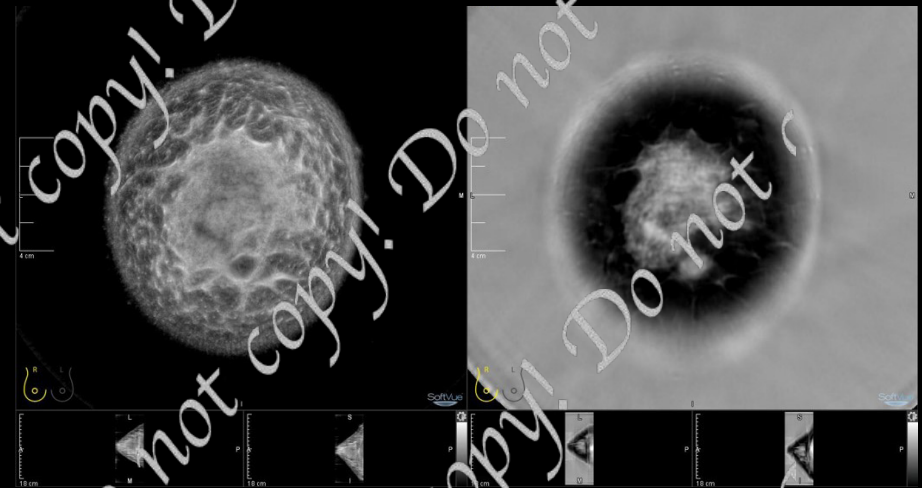


IMAGE QUALITY CONSIDERATIONS

MUSHROOMING

Mushrooming is when there is **overhanging breast tissue** and is typically observed near the Sequor™ gel pad in women with moderate to extremely large breasts. This does not impact image quality or the ability to detect masses. However, in **moderately sized breasts, mushrooming can be addressed through additional positioning training.**

For large to extremely large the only way to increase extension and reduce mushrooming is to position the patient above the table, which sacrifices access to the pectoralis muscle. Therefore, this is not recommended.

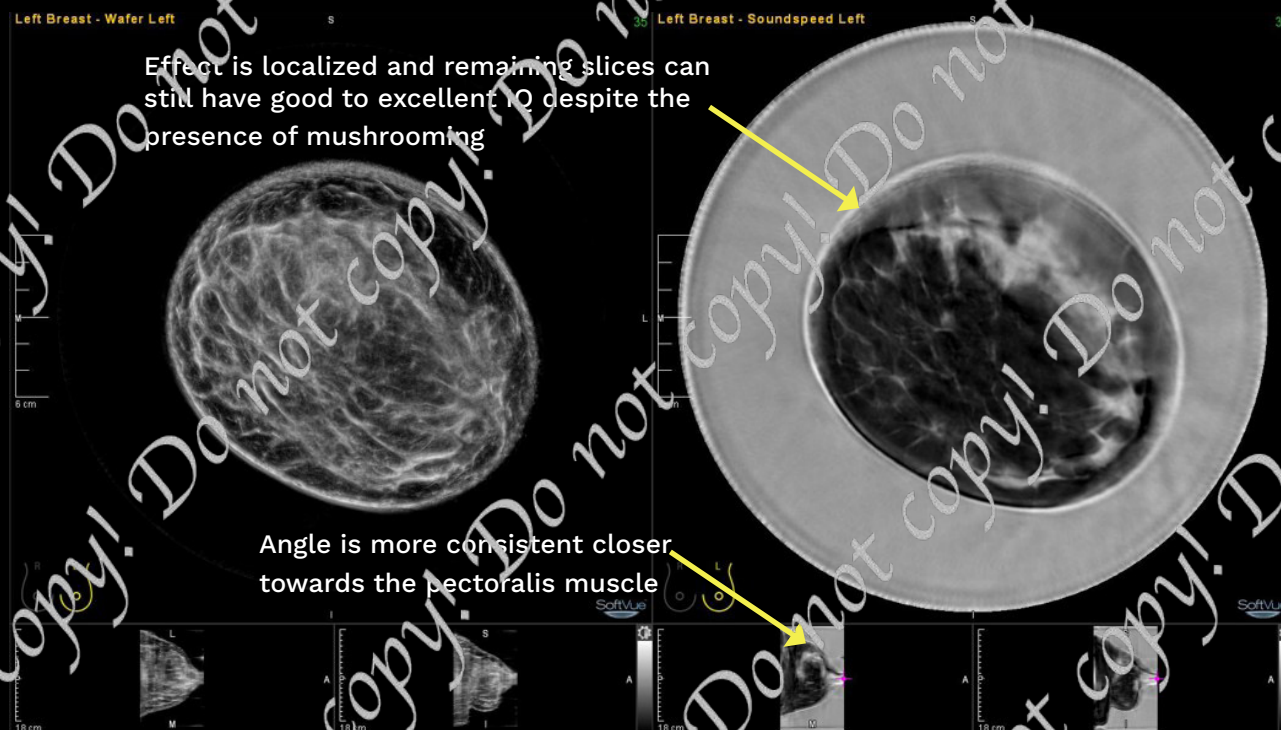


IMAGE QUALITY CONSIDERATIONS

WATER BUBBLES

Water bubbles may be observed within the water bath that surrounds the breast during image interpretation. These artifacts do not impact image interpretation and can be due to two potential factors that are easily resolved:

1. The water in the tank is de-gassed to ensure no air bubbles are present during image acquisition. If **tiny white bubbles** are repeatedly noticed during image review, this could be due to a **SoftVue™ system degasser issue**, and the Delphinus service team should be contacted.
2. Agitation of the water when the chamber is refilled can create bubbles. These **bubbles usually float** to the water surface and disappear, but if a woman is wearing lotion, the bubbles can attach to the skin surface. It is recommended that **lotion is removed prior to a SoftVue™ scan**.



IMAGE QUALITY CONSIDERATIONS

This is a summary of the various imaging factors that may be visualized on SoftVue images and how to best address them by contacting the Delphinus applications specialist for additional training in positioning or the Delphinus service team.

Positioning Training	Delphinus Service Call
Poor Extension	Bubbles in water bath
Blurred skin lines	
Mushrooming	
Pulsation	
Bubbles near skin (lotion)	

SOFTVUE TAKEAWAYS

FATTY & DENSE TISSUE

Patchy dark or grey areas on **Wafer** are dense tissue with increased water content. Dense tissue will flow from slice to slice.

Use **Reflection** to determine if an area of concern is a mass or just dense tissue. If there is a focal dark area of concern on **Wafer** which disappears on **Reflection** (turns grey and blends in with adjacent tissue) then it is focal dense tissue, not a true mass.

Anything dark (black) on **Sound Speed** is fat.

CANCER DETECTION

Focus on the edges of the dense parenchymal tissue at the fat-glandular interface as this is where majority of cancers are found.

Use the zoom feature to gain better clarity on mass margins and shape to help differentiate cancers from benign masses.

Take in to account the shape, margins and characteristics presented on all four sequences (**Wafer, Sound Speed, Reflection & Stiffness Fusion**) to diagnose cancer.

If you see a mass with spiculated margins and/or architectural distortion then it is cancer.

GENERAL READING CONCEPTS

Do not scroll through the entire stack of Reflection and Stiffness Fusion. Only look at the Reflection and Stiffness Fusion images for a targeted area to rule in or rule out a mass.

If there is a mass-like area on the periphery of the breast within the first 15 slices then first identify the nipple to make sure it is not the nipple or retroareolar dense tissue before calling it a mass. In addition, Identifying the nipple helps to determine the location of the abnormality.