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Case Review in the Workflow of Using Live BreastAssist™ and S-Detect™ for Breast

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Introduction

Background

Breast disease is one of the most common diseases among women, and early detection and accurate diagnosis have an important impact on treatment and survival rates. With the recent development of ultrasound and AI technologies, Samsung provides the following two AI solutions for breast ultrasound.

Live BreastAssist™
Based on Deep Learning technology, detects interested areas in during real-time breast scanning and marks the location of lesions to assist healthcare professionals in detection.

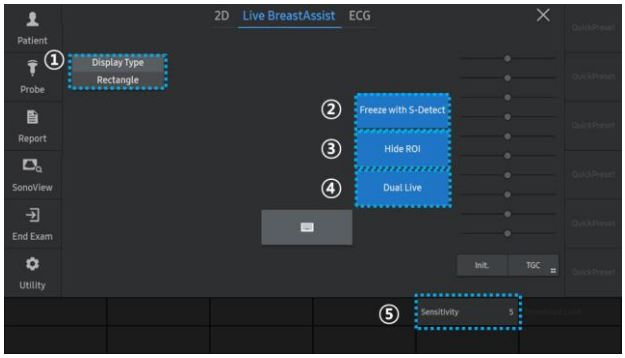
S-Detect™ for Breast
Analyzes the selected area on breast ultrasound and provides differential diagnosis according to the BI-RADS® ATLAS.

Live BreastAssist™ allows lesion detection during real time scanning and can be used as a screening tool that helps minimize human error in that displays suspicious mass in real time to minimize human error.
S-Detect™ for Breast provides BI-RADS® Lexicon Classification and the estimated cancer risk of the lesion that the user is interested in.

How to Apply the Live BreastAssist™ & S-Detect™ for Breast Workflow

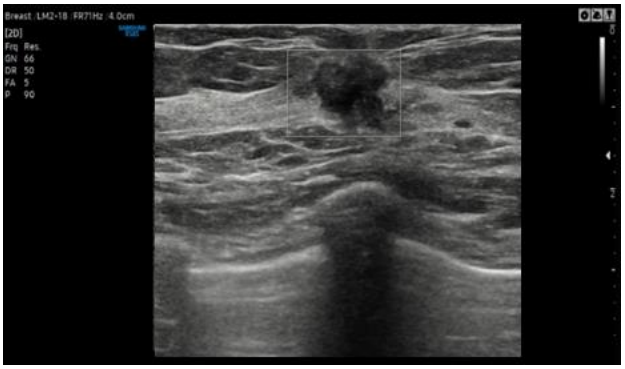
Live BreastAssist™

1. Select a prober transducer, application, and preset
2. Select the Live BreastAssist button on the touch screen.
3. Select a display type, dual live mode, and senstivity.



① User can select the display type (rectangle, color overlay, and edge enhance)
② Freeze with S-Detect: [S-Detect for Breast] will be automatically activated on Freeze.
③ Hide ROI: Select show or hide a target ROI on the monitor screen and then focus on the B-mode image
④ Dual Live: Dual live mode is to display both [2D mode / Color mode] and [Live BreastAssist].
⑤ Sensitivity: Available to select sensitivity Index 1-10 (defaults=5), considering the clinical setting. If you set a higher index, the detection sensitivity will be increased.

4. When a suspicious lesion is found during scanning, the ROI will be shown on it.

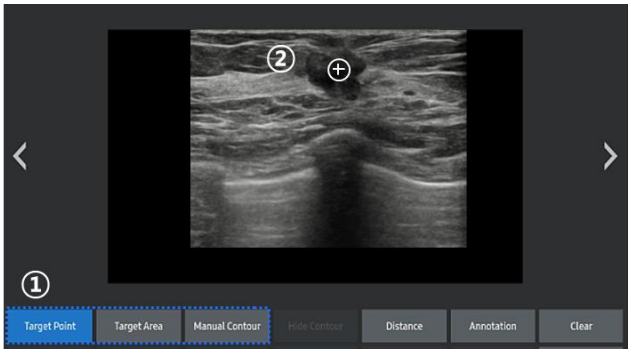


5. Press Freeze button to obtain the desired image and run S-Detect™ for Breast.
(If User select “Freeze with S-Detect” on touch screen, S-Detect for Breast will be automatically activated on Freeze.)

S-Detect™ for Breast

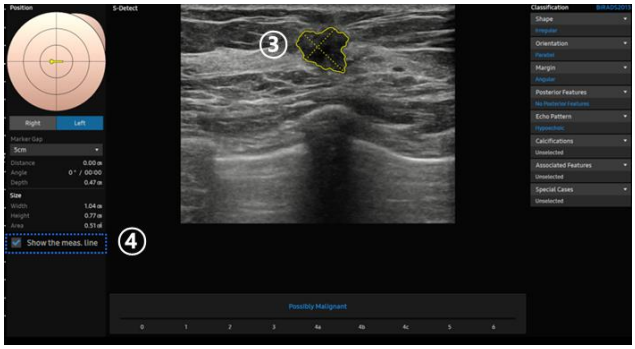
1. Select S-Detect button on the touch screen.

2. Designate the ROI.



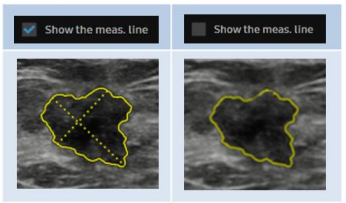
① User can select 3 different type of Detection method: Target Point, Target Area, and Manual Contour.
- Target Point: Analyze the area of the suspected lesion based on the point specified by the user.
- Target Area: Analyzes the area of the suspected lesion based on the area specified by the user.
- Manual Contour: Analyze the area of the suspected lesion by arbitrarily selecting a point.

② (If user select Target Point method,) Touch the center of the lesion on the touchscreen, or locate the cursor on the center of the lesion on the monitor and press the [Set] button.

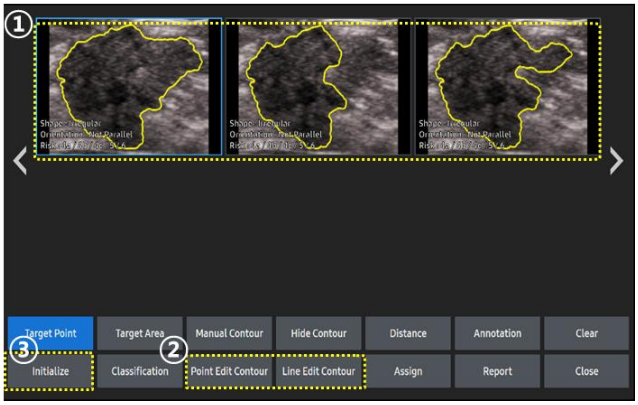


③ Lesion Boundary: automatically detected and displayed as green contour.

④ Show the measurement line: it is to display the measurement line (height, width) of the lesion



3. Select the candidate and edit.

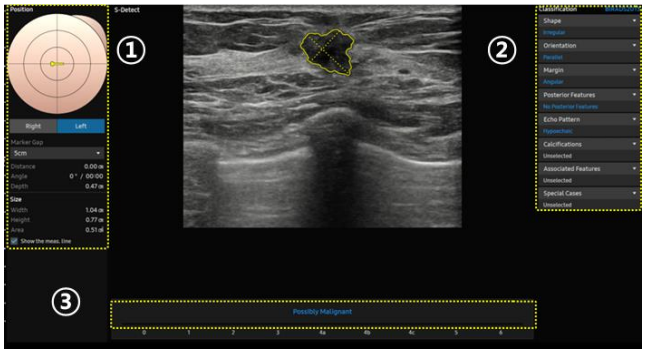


① Candiadates
Candidate images are provided on the touch screen so you can choose the most suitable image. To select, just touch the one.

② Edit Contour
If necessary, you can edit the contour of selected candidate by tap the [Point Edit Contour] or the [Line Edit Contour] on the touch screen.

③ Initialize
To reset all results, tap the [Initialize] button on the touch screen.

4. Results page



① Location Informaton Area
Provides information about the location and the size of lesion.

② BI-RAD® Lexicon Classification Area
Provides the BI-RADS® Lexicon Classification for the lesion that has been finally selected by the user. The auto determination result is displayed in blue, whereas other items are marked 'Unselected' in white.

③ BI-RAD® Assessment Category Score
S-Detect™ for Breast recommends the benignity or malignity of the lesion selected by the user; the user makes a final decision on the BI-RADS® Assessment Category Score.

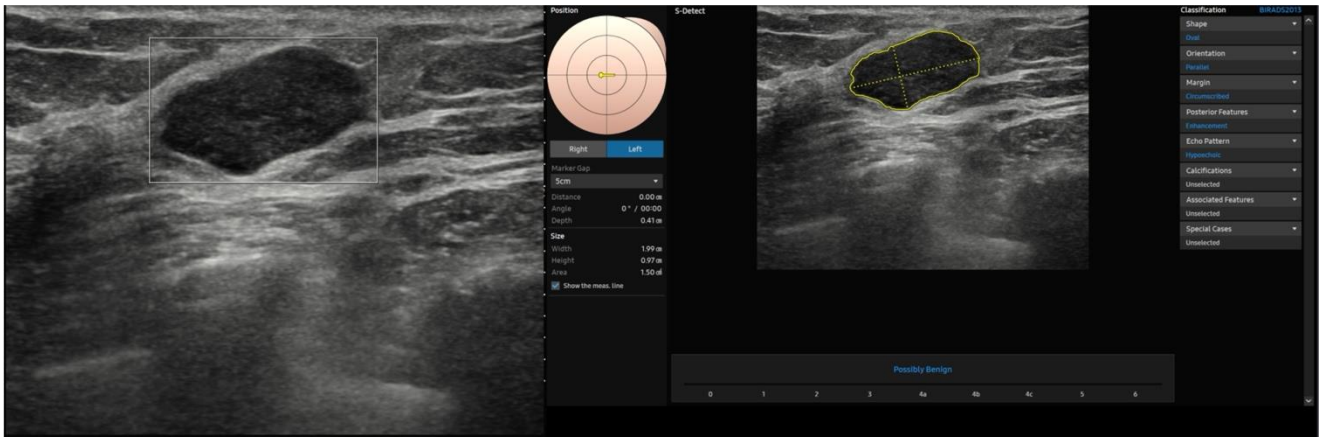
Clinical Cases

This case study was conducted at Severance Hospital, Korea. One experienced breast radiologist (15 years of experience) performed baseline ultrasound examinations applying the Live BreastAssist™ and S-Detect™ for Breast workflow from a dedicated ultrasound machine (RS85 Prestige, Samsung Medison Co., Ltd., Korea) using a 2-18 MHz 1.25D linear transducer (LM2-18, Samsung Medison Co., Ltd., Korea).

CASE #1. F/46, Detection of a benign cyst

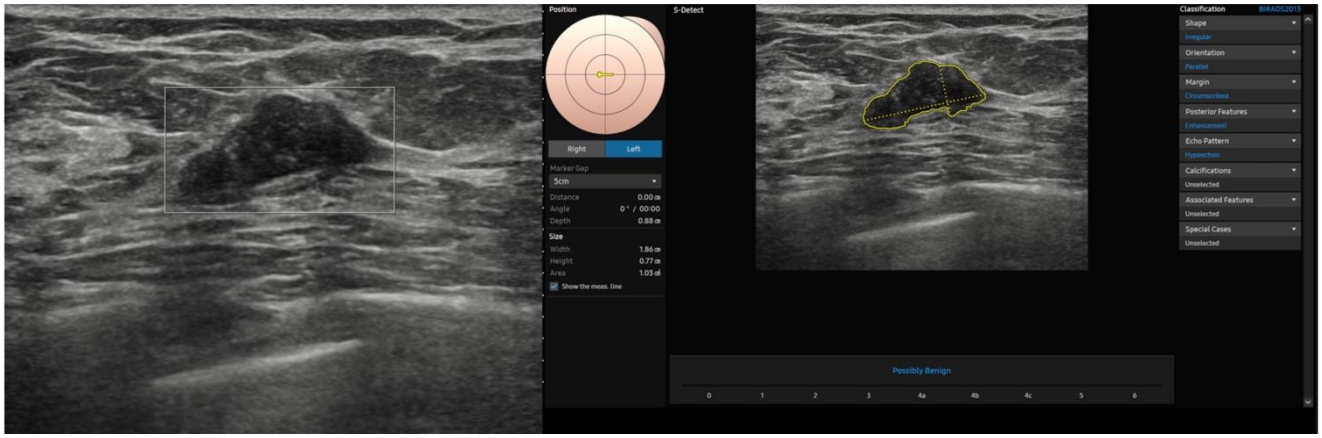
A benign cyst was seen in the breast during US examination, where Live BreastAssist™ detected the lesion, and S-Detect™ for Breast assessed this lesion to be possibly benign.

CASE #2. F/77, Diagnosis of a palpable benign mass



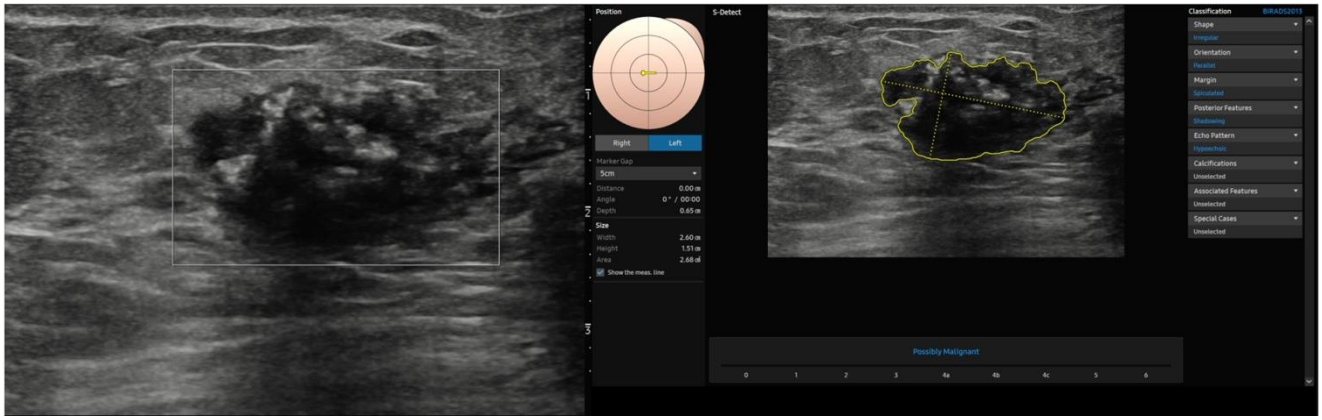
Live BreastAssist™ detects the mass palpated in the breast, which was accuately assessed as benign on S-Detect™ for Breast. Biopsy confirmed this mass to be a benign fibroadenoma.

CASE #3. F/48, Detection and differential diagnosis of a benign mass - Fibroadenoma



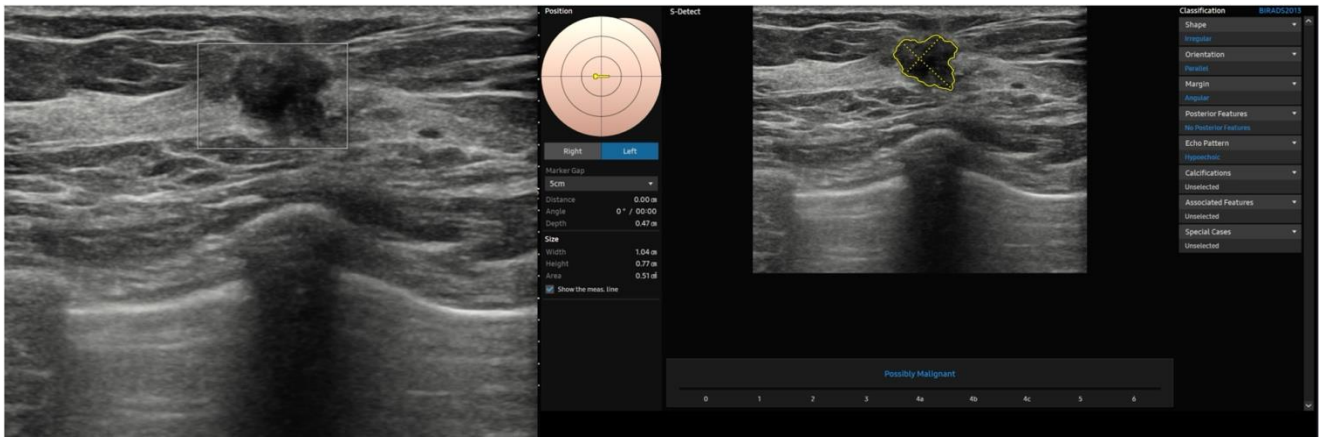
Hypoechoic mass was detected and assessed as BI-RADS 4a by the radiologist and scheduled for biopsy. Live BreastAssist™ detected this mass that was assessed as possibly benign by S-Detect™. Biopsy confirmed this mass to be fibroadenoma.

CASE #4. F/66, Detection and differential diagnosis of a typical cancer - invasive ductal carcinoma



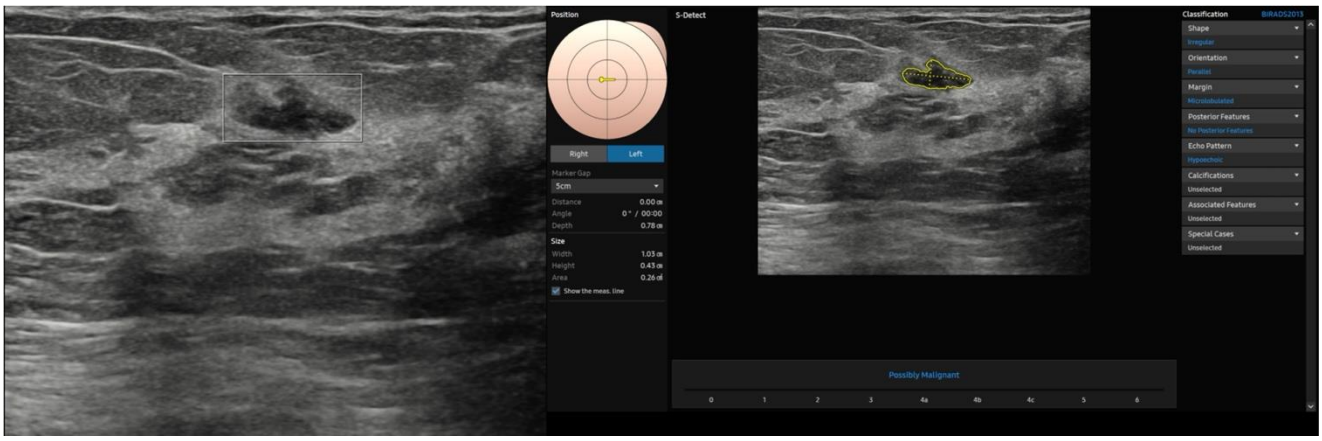
Suspicious mass showing irregular shape, hypoechoic features and calcifications was detected by Live BreastAssist™. This mass was assessed as suspicious malignant by S-Detect™ for Breast. Biopsy confirmed this mass as invasive ductal carcinoma.

CASE #5. Detection and differential diagnosis of asymptomatic, small breast cancers.



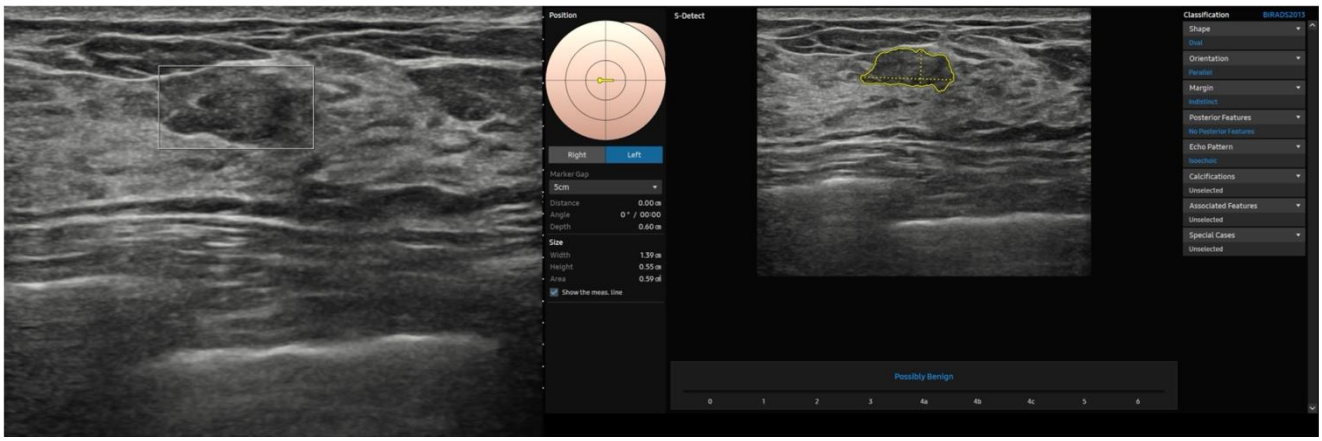
Live BreastAssist™ accurately detects a 8mm sized, small breast cancer. S-Detect™ for Breast assessed this mass as possibly malignant. Biopsy confirmed this mass to be invasive ductal carcinoma.

CASE #6. F/49, Live BreastAssist™ detecting cancer showing subtle suspicious features.



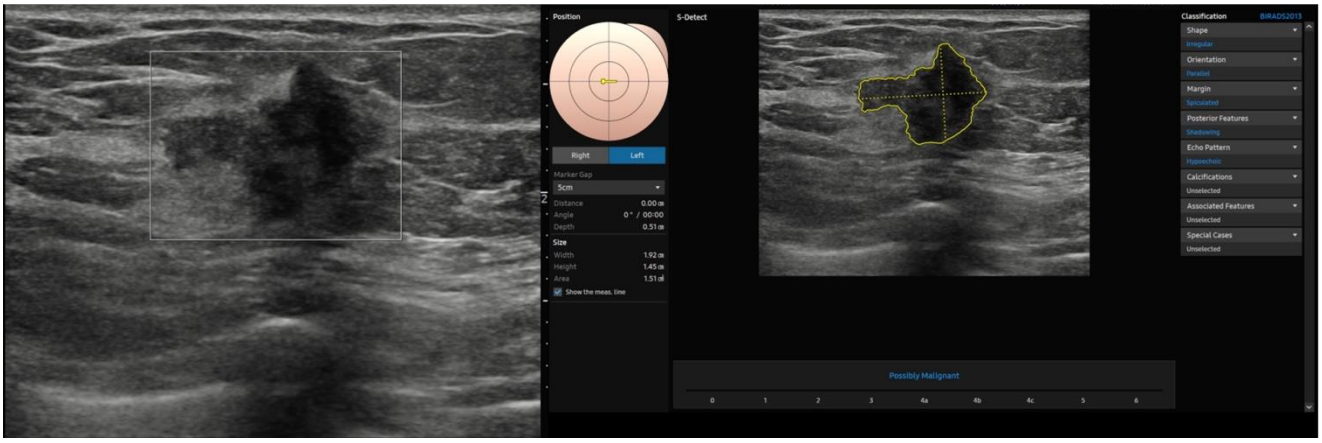
A 9mm sized hypoechoic lesion was detected by Live BreastAssist™, which as assessed as BI-RADS 4a by the radiologist. S-Detect™ assessed this mass to be possibly malignant. Biopsy confirmed this mass to be DCIS.

CASE #7. F/45, Detection of isoechoic masses by Live BreastAssist™.

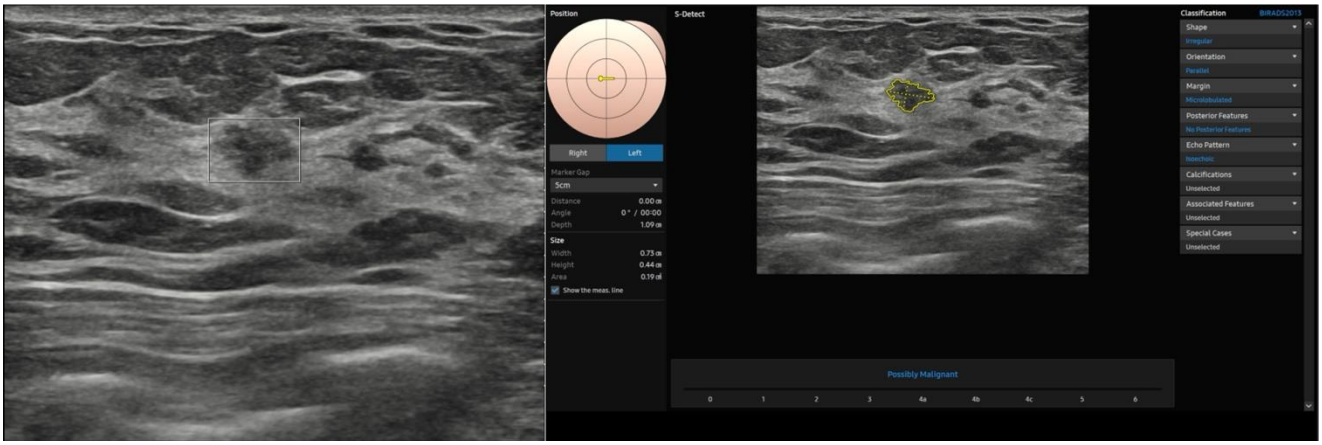


Live BreastAssist™ accurately detects isoechoic breast masses that can be overlooked by users during realtime US scans. Biopsy confirmed this mass as fibroadenoma.

CASE #8. F/44, Live BreastAssist™ used for planning surgery in cancer patients.

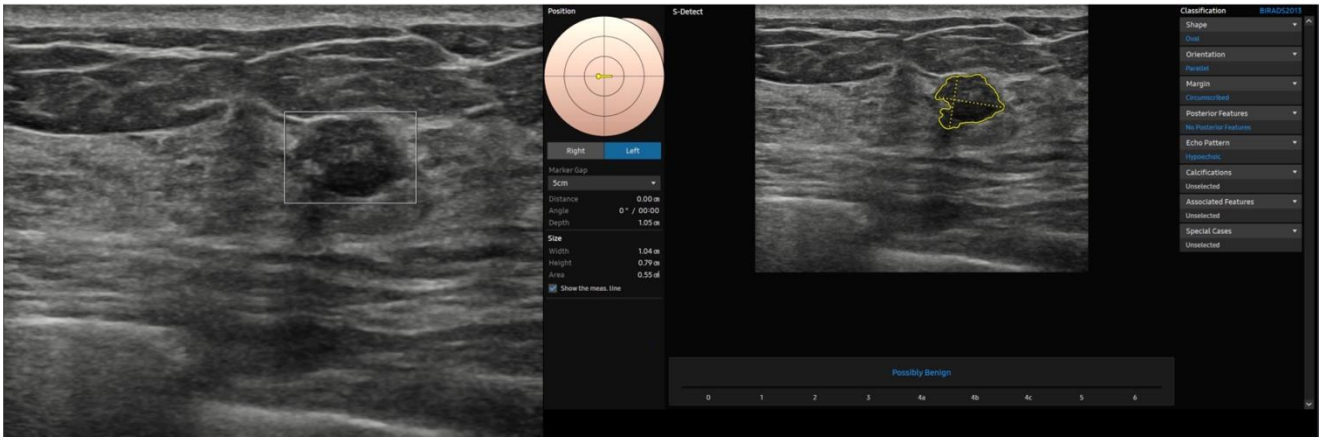


An irregularly shaped, hypoechoic mass was seen in the breast that was confirmed as invasive ductal carcinoma with biopsy.



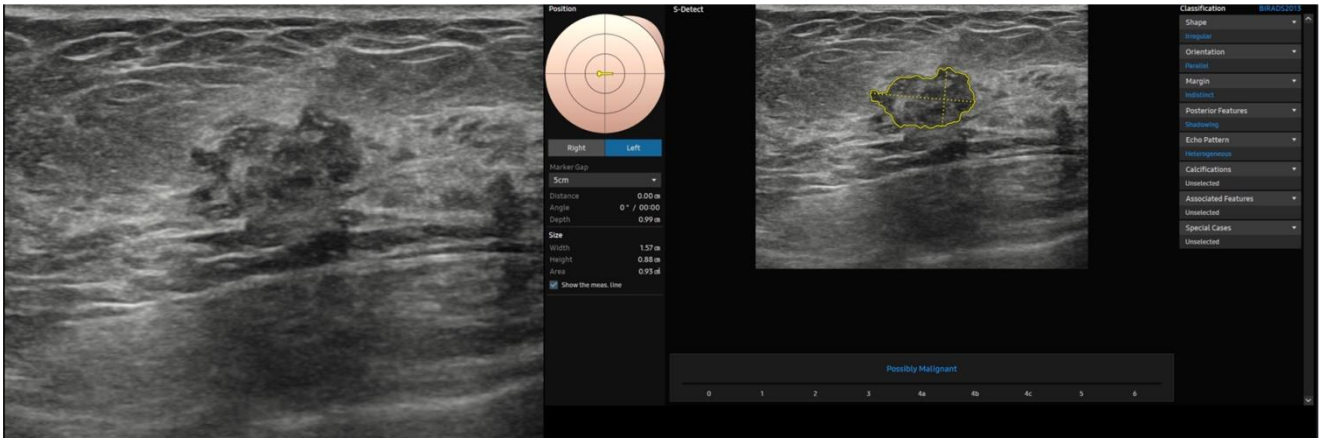
During scanning of the ipsilateral breast, a small, additional lesion was detected by Live BreastAssist™, assessed as possibly malignant by S-Detect™ for Breast. Biopsy confirmed this lesion to be DCIS. Live BreastAssist™ helped in detecting additional cancer in a cancer patient.

CASE #9. F/45, Live BreastAssist™ and S-Detect™ for Breast can provide assistance in patient management



Hypoechoic mass with calcification was assessed as BI-RADS 4c by the radiologist. Live BreastAssist™ detected this lesion that was assessed as possibly benign by S-Detect™. Biopsy confirmed this mass as fibroadenomatoid hyperplasia, but the radiologist considered this result to be discordant to imaging features. Vaccum assisted excision was performed, once again confirming this mass as fibroadenoma.

CASE #10. F/61, DCIS presenting as non-mass with calcifications not detected by Live BreastAssist™.



Suspicious non-mass lesions with calcifications was not detected by Live BreastAssist™ during real-time scanning. When S-Detect™ was manually operated, the non-mass lesion was assessed as possibly malignant. Caution is needed for detection of non-mass lesions when using Live BreastAssist™.

Conclusion

In this case study, we simulated the sequential workflow of using Live BreastAssist™ for lesion detection and S-Detect™ for Breast for classification of the detected regions of interest. In typical benign/malignant cases, Live BreastAssist™ successfully detected the lesions and S-Detect™ for Breast gave accurate assessments of possibly benign/malignant. Also, Live BreastAssist™ accurately detected lesions that are easy to overlook such as isoechoic, small (≤10mm) cancers, and masses showing subtle suspicious features. Caution is needed for applying Live BreastAssist™ on non-mass lesions. To conclude, the sequential workflow of Live BreastAssist™ and S-Detect™ for Breast is feasible and beneficial for both mass detection and classification.

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* This clinical practice review is a result of a personal study conducted by collaboration between Samsung Medison and Prof. Jung Hyun Yoon.

* This review is to aid customers in their understanding, but the objectivity is not secured.

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