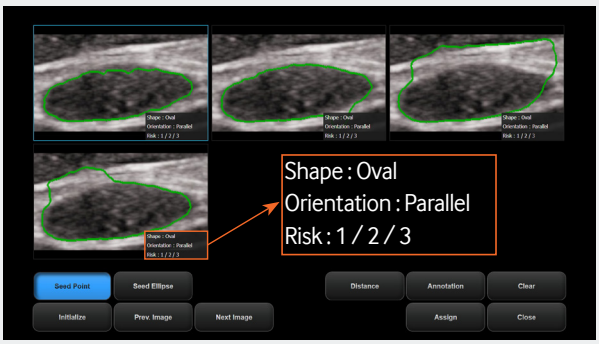
Article # CL201405-S-Detect / Issue Date 1 May, 2014

RS80A

Smart Guidance tool with decision-making support, S-Detect™

Smart-Detect™



Key Advantages

Higher Productivity	Offers streamlined workflow from scanning to reporting
Patient-centered Care	Reduces unnecessary breast biopsies
BI-RADS® Recommendations	Provides higher level of diagnostic confidence

S-Detect™

Ultrasonography (US) is widely used in the detection of breast lesions, evaluation of dense breasts in young patients, and for guidance procedure. The Breast Imaging-Reporting and Data System(BI-RADS®) for ultrasound has promoted clinical efficacy by improving the assessment of masses and providing subsequent management recommendations. This contains a lexicon for standardized terminology as well as standard reporting with final assessment categories and guidelines for follow-up and outcome monitoring.

S-Detect™ is a novel technology to complement your lesion assessment and communication in breast ultrasound which includes functionalities for selecting a lesion, dividing the area of a lesion, describing the characteristics of a lesion, and recommending degree of abnormality. Using **RS80A** with superior image quality, **S-Detect™** brings standardization to diagnostic breast ultrasound, thus ensuring every radiologist in the practice to go through the feature checklist quickly.

The implementation of **S-Detect™** with **RS80A** puts scanning, reading, reporting and finalizing into one system.

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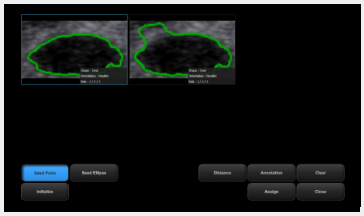
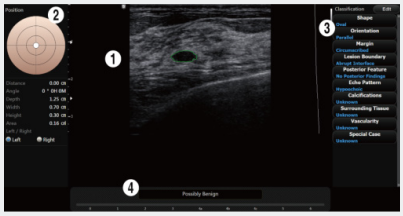
"**S-Detect™** provides multiple options with BI-RADS® categories and lexicon simultaneously, reducing unnecessary biopsies"

Efficient Workflow

- Select Seed Point or Seed Ellipse on region of interest
- Support of BI-RADS® Lexicon Classification
- Recommendations of likelihood of malignancy and BI-RADS® Score
- Report (Patient, Lesion location, BI-RADS®, S-Detect™ image)



Extraction of Suspicious Lesion



S-Detect™ Screen

S-Detect™ Report

❶ Ultrasound Image Area
❷ Location Information Area
❸ BI-RADS® Lexicon Classification Area
❹ BI-RADS® Score Area

Classification (BI-RADS®)

· **S-Detect™** classifies the malignancy of the chosen lesions and the user decides BI-RADS® score. The user has an option to manually modify the classification and score.

· **S-Detect™** identifies the characteristics of the recognized lesion contained in BI-RADS® classification. (Shape, Margin, Lesion Boundary, Posterior features, echo pattern, calcifications, etc.)

Table 1. Concordance Between BI-RADS® Assessment Categories and Management Recommendations.

Assessment	Management	Likelihood of Cancer
Category 0: Incomplete — Need Additional Imaging Evaluation	Recall for additional imaging	N/A
Category 1: Negative	Routine screening	Essentially 0% likelihood of malignancy
Category 2: Benign	Routine screening	Essentially 0% likelihood of malignancy
Category 3: Probably Benign	Short-interval (6-month) follow-up or continued surveillance	> 0% but ≤ 2% likelihood of malignancy
Category 4: Suspicious · Category 4A: Low suspicion for malignancy · Category 4B: Moderate suspicion for malignancy · Category 4C: High suspicion for malignancy	Tissue diagnosis	> 2% but < 95% likelihood of malignancy > 2% to ≤ 10% likelihood of malignancy > 10% to ≤ 50% likelihood of malignancy > 50% to < 95% likelihood of malignancy
Category 5: Highly Suggestive of Malignancy	Tissue diagnosis	≥ 95% likelihood of malignancy
Category 6: Known Biopsy-Proven Malignancy	Surgical excision when clinically appropriate	N/A

Note Subcategories of BI-RADS® Score 4 and some of the classification categories are limited from countries.

Reference

(1) BI-RADS® Ultrasound 2013 American College of Radiology

Supported System

(1) RS80A V1.00

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