

QVCAD™ System User Manual

Federal Law restricts this device to be used by or on the order of a physician.

Software Version 3.0



Manufacturer

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1. Indication for Use

The QVCAD System is indicated for use as an aid to the reader during screening procedures in searching images of female breasts produced by the sono.v Automated Breast Ultrasound System (screening mammography BI-RADS® Assessment Category 1 or 2, and BI-RADS Composition/Density c or d) to detect mammography-occult lesions in regions not known to have suspicious findings. The indicators produced by the QVCAD System are not intended to be used for diagnostic characterization of suspicious findings.

2. About this Manual

This manual is intended for use by qualified and trained users as a reference in their use of the QVCAD System.

3. Definitions

Word or Phrase	Definition
Active Point	The view location under review (i.e. displayed in all 3D images) in the active view. The active point is represented by an X,Y,Z value triplet where X is the distance from the left edge of the scan, Y is the distance from the first ultrasound frame acquired, and Z is the distance below the skin line.
Active View	The view of the currently loaded study that has most recently been under review, either by hovering over it or by reviewing it in one of the Review protocols. Note that there is only one active view in multi-view protocols: the point in that view last actively viewed as described above.
CAD Engine	QVCAD Algorithm and DICOM importer.
CAD Mark	A green circle (or dot) indicating an ROI that has been flagged by the CAD Engine as having properties consistent with those of cancer and should thus be examined more closely by the user. A green dot indicates that the CAD Mark as already been viewed by the user.
CAD Navigator Image	A 2D projection of the ABUS Coronal image data with certain areas of interest highlighted by enhancement of dark areas and/or by enhancement of radial spiculations and retraction patterns. This image is distinguished by a "QV" in the upper left corner.
Case	A grouping of one or more studies of the same patient.
Case ID	An 8 digit number assigned to each case in the clinical database.
Coronal Image	A 2D image reconstructed from a view's 3D volume that is orthogonal to the Transverse images and parallel to the transducer face. It is effectively a view of breast tissue looking from the transducer toward the chest wall.
Hover Image	In the Hover Mode, may refer to either the Coronal or Transverse image that is displayed adjacent to the CAD Navigator Image.
Hover Mode	A configurable feature for quickly reviewing a view from an Overview protocol by displaying the Coronal and Transverse images of the view at the point defined by the X,Y location of the cursor hovering over a CAD Navigator Image and the Z location associated with the CAD Navigator Image at that X,Y point.

Word or Phrase	Definition
Image	A displayed projection of the breast ultrasound data from one of the ABUS Views.
Display Protocol	A display layout specification that defines which views and images are displayed at which locations on the screen. QVCAD uses two types of display protocols: Overview and Review.
Q-Viewer	Main display application of the system.
ROI (Region of Interest)	A subset of a view that has been identified by the CAD Engine as having characteristics that make it a candidate for review by the user.
Sagittal Image	A 2D image reconstructed from a view's 3D volume that is orthogonal to the Transverse and Coronal images. It is effectively a view of breast tissue looking from the patient's right side toward her left side.
Study	A set of 3D ultrasound scans (or views) of a patient's breasts performed in a patient acquisition session.
Survey Mode	A feature used in the Review protocols that allows for review of a view by simply moving the mouse through the image areas of the orthogonal images. For example, moving the mouse through a Coronal or CAD Navigator Image surveys the view from the Transverse and/or Sagittal viewpoints and moving the mouse through the Transverse image surveys the view from the Coronal viewpoint.
Transverse Image	One of the native 2D images acquired by the ABUS ultrasound transducer. The orientation of this image is relative to the ABUS scanner placement on the patient's breast, not necessarily to the transverse plane of the patient's body. It is effectively a view of breast tissue looking from the lower portion of the patient's body toward her head.
View	A 3D ultrasound volume consisting of a set of parallel Transverse images representing one of the ABUS scans of a study acquired as the transducer moves from the inferior toward the superior edge of the breast. There are 6 view types supported by QVCAD System. These Views are named based on the location that the ultrasound scanner is placed on the patient's breast: AP (centered on the nipple), LAT (on the lateral side of the breast), MED (on the medial side of the breast), INF (on the inferior side of the breast), SUP (on the superior side of the breast), UOQ (on the upper outer quadrant, i.e. axillary portion, of the breast).

4. Device Description

4.1. Intended Use

The QView Medical, Inc. QVCAD system is a Computer-Aided Detection and image processing software device intended to aid in the reading of 3D Breast Ultrasound images generated by the Somo.v ABUS (P110006) system ("ABUS"). It is a proprietary software application designed to process and display ABUS images on a computer monitor for review, with certain areas highlighted or marked for attention. The user is instructed to review the ABUS images concurrently with the CAD generated output before making their final assessment of the case.

4.2. Principles of Operation

QVCAD is supplied as a software package consisting of two software components running on a (customer-supplied) workstation computer: i) the QVCAD CAD engine which comprises the CAD and image processing algorithms, and ii) The QVCAD Q-Viewer that formats the ABUS images together with the output of the QView CAD engine for display on the monitor. The QVCAD CAD engine and Q-Viewer are integrated and require each other to operate. See figure 1 below for a schematic of the QVCAD system.

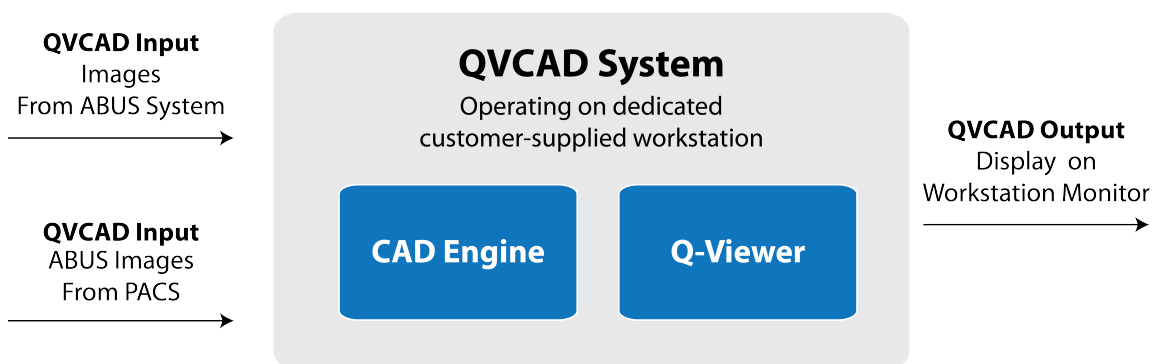


Figure 1 QVCAD System

The QVCAD System receives input images directly from the ABUS acquisition system or from a PACS system, via a standard DICOM interface. The QVCAD System is intended to process 3D Breast Ultrasound images originally acquired by the ABUS system.

The native images from the ABUS system together with the output of the QVCAD CAD Engine are concurrently displayed on the Q-Viewer. The user is instructed to review the ABUS images concurrently with the CAD generated output before making a final assessment of the case.

The QVCAD CAD engine employs several image pattern recognition processes and artificial neural networks to detect suspicious areas of breast tissue 5mm or more in diameter that have characteristics similar to breast lesions. It inspects every tissue location in the 3-D ABUS images it processes with dedicated algorithms that characterize the volumetric region surrounding each location by automatically extracting features that have been determined to represent suspicious signs. These features include typical ultrasound image features described in the radiological literature such as region boundary, margin, echo pattern, orientation, posterior enhancement, architectural distortions, etc. Using those features, the QVCAD CAD engine generates a score for each suspicious area to distinguish potential breast lesions from normal breast tissue.

The training database consists of a large number of cancer, benign and normal cases. All cancers and benign lesions are biopsy proven. Normal cases were confirmed by follow-up exams. The cancers cases include all those encountered during clinical practice without selection. The benign and normal cases are randomly selected from available cases. The training algorithm employs a cross validation technique on this database to achieve optimal performance of the QVCAD CAD engine.

The locations and types of the cancers and benign lesions in the images are annotated as the reference standard by ultrasound experts based on radiology and pathology reports. Using the reference standard and the ultrasound image features extracted from the ABUS images in this training database, the QVCAD CAD engine is trained to distinguish breast lesions from normal breast tissue.

The CAD-generated output from the QVCAD system is presented in two forms:

- i) A QVCAD CAD Navigator image of each ABUS volume or view, which is a modified minimum intensity projection combined with a line texture projection of the coronal image data in areas where CAD has detected possible abnormalities. This is intended to bring attention to certain areas of interest by enhancement of dark areas and/or radial spiculations and retraction patterns. The enhancements may be applied to both malignant and benign lesions.
- ii) CAD marks presented as colored circles around areas of interest and displayed over the CAD Navigator image and over the corresponding original ABUS images. CAD marks are intended to highlight potentially malignant lesions.

The user is instructed to use both the CAD Navigator image and the CAD marks in support of their review of the ABUS case. See figure 2 and figure 3 below for an example of a CAD Navigator image and CAD marks.

The CAD Navigator image is a static roadmap displayed concurrently with the original ABUS images (sagittal, transverse and coronal). The user may select any CAD mark or other area of interest on the CAD Navigator image and the corresponding original ABUS images will be displayed. This is intended to serve as a review and navigation tool, enabling the user to efficiently review the entire ABUS case, focusing on certain areas of interest. It is designed to improve user productivity while preserving the accuracy of diagnosis.

The CAD Navigator and native ABUS images are relative to the orientation of the ABUS scanner as placed on the patient's breast. They roughly correspond to the transverse, coronal and parasagittal planes of the patient's body depending on the exact positioning of the ABUS scanner during image acquisition.

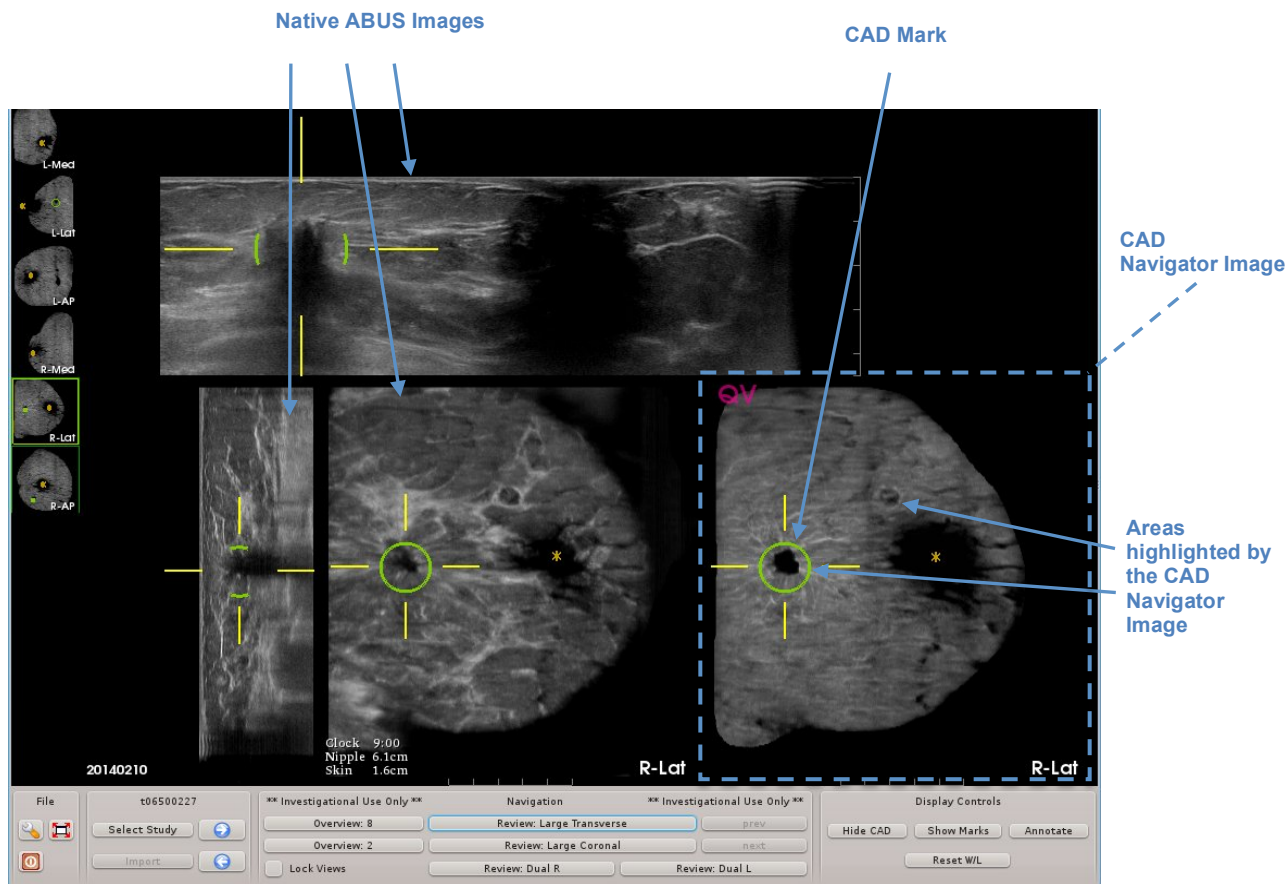


Figure 2 Sample Q-Viewer Display with native ABUS images, the CAD Navigator Image and CAD mark.

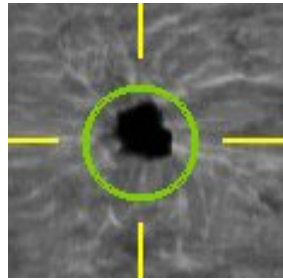


Figure 3 Close-up detail of CAD mark on the CAD Navigator Image

The Q-Viewer is intended to be a comprehensive review platform that displays ABUS images together with the output of the QVCAD CAD Engine. The user is expected to interact with the system primarily via mouse commands as they perform a comprehensive review of the ABUS case.

5. Installation

Installation and commissioning of the QVCAD System is performed by qualified QView Medical, Inc. personnel only. A comprehensive user training program is conducted after installation to instruct the user/s on the operation of the QVCAD System. This training includes modules on system operation, guided case-study, user self-study and a final proficiency assessment. User training is provided by qualified QView Medical, Inc. personnel.

6. Clinical Study Summary

QView Medical, Inc (“QView”) completed a pivotal clinical study (“Study”) to demonstrate the safety and effectiveness of the QView QVCAD System (“QVCAD”) for its proposed indication for use as stated in Section 1 of this User Manual.

QView believes that the QVCAD System will aid in the reading of ABUS images, where productivity improves without any impairment to cancer detection performance. As such, the Study was designed to test a pair of co-primary hypotheses as follows. Both co-primary hypotheses must be successfully tested to declare successfully meeting the primary objectives of the pivotal study.

Co-primary hypothesis 1: Non-inferiority of ROC AUC when radiologists read ABUS images with the aid of QVCAD vs. when they read ABUS images alone

Co-primary hypothesis 2: Improvement (reduction) in average per-case interpretation time when radiologists read ABUS images with the aid of QVCAD vs. when they read ABUS images alone

In the Study, radiologists performed interpretation of Automated Breast Ultrasound (“ABUS”) images with and without the aid of QVCAD, with

- i) area under the receiver operating characteristic (ROC) curve (AUC) used to characterize cancer detection performance, and
- ii) average per case interpretation time used to characterize radiologist productivity.

Although the ABUS system is used as an adjunct to screening mammography, this pivotal study only evaluated performance and interpretation time for the ABUS component of screening. Therefore, the improvement in interpretation time or productivity using QVCAD only applies to the ABUS component and the total productivity improvement will depend on many other factors including those related to interpretation of the screening mammogram.

The clinical protocol was reviewed and approved by an Institutional Review Board and an experienced research team conducted the reader study.

The Study consisted of a highly enriched set of 185 cases (*BI-RADS Composition/Density c or d*), of which 133 were normal and 52 contained cancers (31 mammographic BI-RADS 1 or 2 and 21 mammographic

BI-RADS 0). Eighteen radiologists participated in the Study. They represented a broad spectrum of experience in practice types, breast imaging and ultrasound.

Cases were presented to readers in random order. Each reader interpreted each case twice, once interpreting ABUS images with the aid of QVCAD, and once interpreting ABUS images alone. These two sessions were separated by a washout period of at least four weeks. The combination of case randomization and washout period was intended to compensate for any bias effect of readers recalling individual case/s and any specific findings.

6.1. Clinical Study Primary Analysis Results

The study has two co-primary objectives:

- i) To determine whether radiologists' performance in the detection of breast cancer is non-inferior when they interpret ABUS images with the aid of QVCAD compared with when they interpret ABUS images alone, and,
- ii) To determine whether radiologists' interpretation time is improved (shorter) when they interpret ABUS images with the aid of QVCAD compared with when they interpret ABUS images alone.

Table 1 First co-primary result of the pivotal study: Non-inferiority of trapezoidal AUC.

	AUC	95% CI of AUC	p-value
$AUC_{ABUS + QVCAD}$	0.7353		
$AUC_{ABUS; No QVCAD}$	0.7493		
$AUC_{ABUS + QVCAD} - AUC_{ABUS; No QVCAD}$	-0.0141	[-0.0442, 0.0160]	0.0102

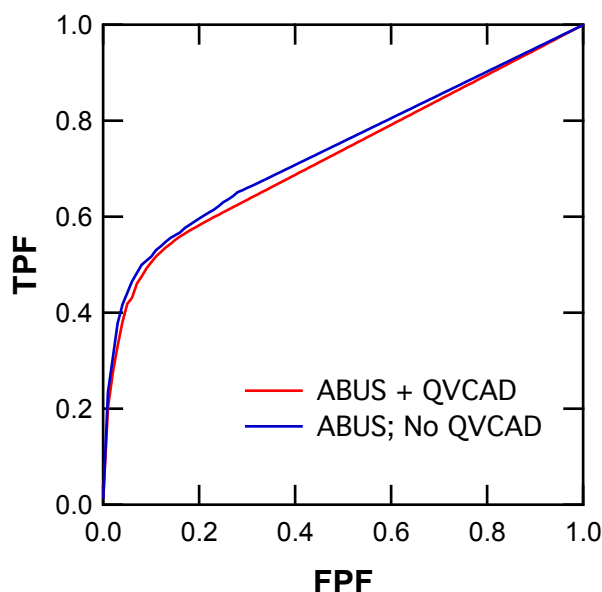


Figure 4 Comparison of "average" trapezoidal ROC curves across the 18 readers between the two interpretation modalities.

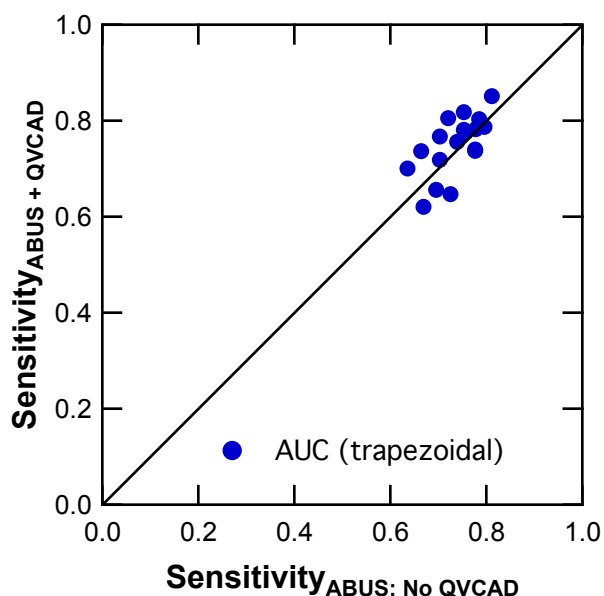


Figure 5 Comparison of trapezoidal AUC estimates of the 18 readers between the two interpretation modalities.

The non-inferiority hypothesis was tested successfully using the 31 mammographic BIRADS 1 or 2 cancer cases and the 133 non-cancer cases (Table 1). The results show that the lower limit of the 95% confidence interval on ΔAUC is approximately -0.0442, which lies above the pre-specified non-inferiority margin of -0.05. Therefore, these results support the conclusion that the average AUC value when radiologists interpret ABUS images with the aid of QVCAD is statistically significantly non-inferior to the average AUC value when they interpret ABUS images alone. The AUC curves and the sensitivity comparison of the two modalities are shown in Figure 4 and Figure 5.

The superiority hypothesis of interpretation time ($\Delta \text{Time} = \text{Time}_{\text{ABUS; No QVCAD}} - \text{Time}_{\text{ABUS + QVCAD}}$) was tested successfully (Table 2). These results show that the estimated ΔTime per case is 71 sec (33% of the average $\text{Time}_{\text{ABUS; No QVCAD}}$), which is statistically significantly greater than zero ($p \ll 0.05$). These results support the conclusion that the average interpretation time when radiologists interpret ABUS images with the aid of QVCAD is statistically superior to (shorter than) the average interpretation time when they interpret ABUS images alone.

Table 2 Second co-primary result of the pivotal study: Superiority of interpretation time (per case).

	Interpretation Time (s)	95% CI of Time (s)	p-value
$\text{Time}_{\text{ABUS; No QVCAD}}$	215		
$\text{Time}_{\text{ABUS + QVCAD}}$	144		
$\text{Time}_{\text{ABUS; No QVCAD}} - \text{Time}_{\text{ABUS + QVCAD}}$	71	[46, 97]	1.6×10^{-5}

These results demonstrate that both co-primary objectives were met, and demonstrate that radiologists who interpret ABUS images with the aid of QVCAD can be expected to produce non-inferior performance of breast cancer detection from ABUS images in a significantly shorter interpretation time than when they interpret ABUS images alone.

6.2. Clinical Study Supplemental (Secondary) Analysis Results

Several supplemental (or secondary) analyses of the pivotal study data were conducted. The purpose of these additional analyses was to assess the strength of the primary conclusion of the pivotal study.

Table 3 and Figure 6 show the average sensitivity and specificity estimates. Table 3 also shows bootstrapping estimates of uncertainty in these estimates. These results show that sensitivity and specificity are similar between the two interpretation modalities. These results support the primary conclusion of the pivotal study.

In Figure 6 top row, short line segments link each reader's sensitivity or specificity at the BI-RADS 3 threshold and the BI-RADS 4 threshold. In Figure 6 bottom row, short line segments link each reader's sensitivity and false-positive fraction in the two interpretation modalities.

Table 3 Supplemental analysis of the pivotal study: Sensitivity and specificity.

BI-RADS Threshold (cancer call)	Interpretation Modality	Sensitivity (%)		Specificity (%)	
		Average*	95% CI	Average*	95% CI
≥ 3	ABUS; No QVCAD	59.0 ± 12.5	[46.2, 72.0]	85.5 ± 8.8	[80.7, 89.9]
	ABUS + QVCAD	54.6 ± 12.1	[40.9, 68.8]	89.0 ± 6.4	[85.1, 92.6]
	Δ	-4.4 ± 8.5	[-11.6, 2.5]	3.5 ± 6.4	[-0.3, 7.7]
≥ 4	ABUS; No QVCAD	57.2 ± 14.2	[43.7, 70.4]	87.4 ± 8.6	[83.0, 91.9]
	ABUS + QVCAD	53.9 ± 12.7	[40.0, 68.1]	89.8 ± 6.8	[85.7, 93.5]
	Δ	-3.3 ± 8.3	[-10.0, 3.2]	2.4 ± 5.4	[-1.1, 5.8]

$$\Delta = (\text{ABUS + QVCAD}) - (\text{ABUS; No QVCAD})$$

*Mean \pm standard deviation

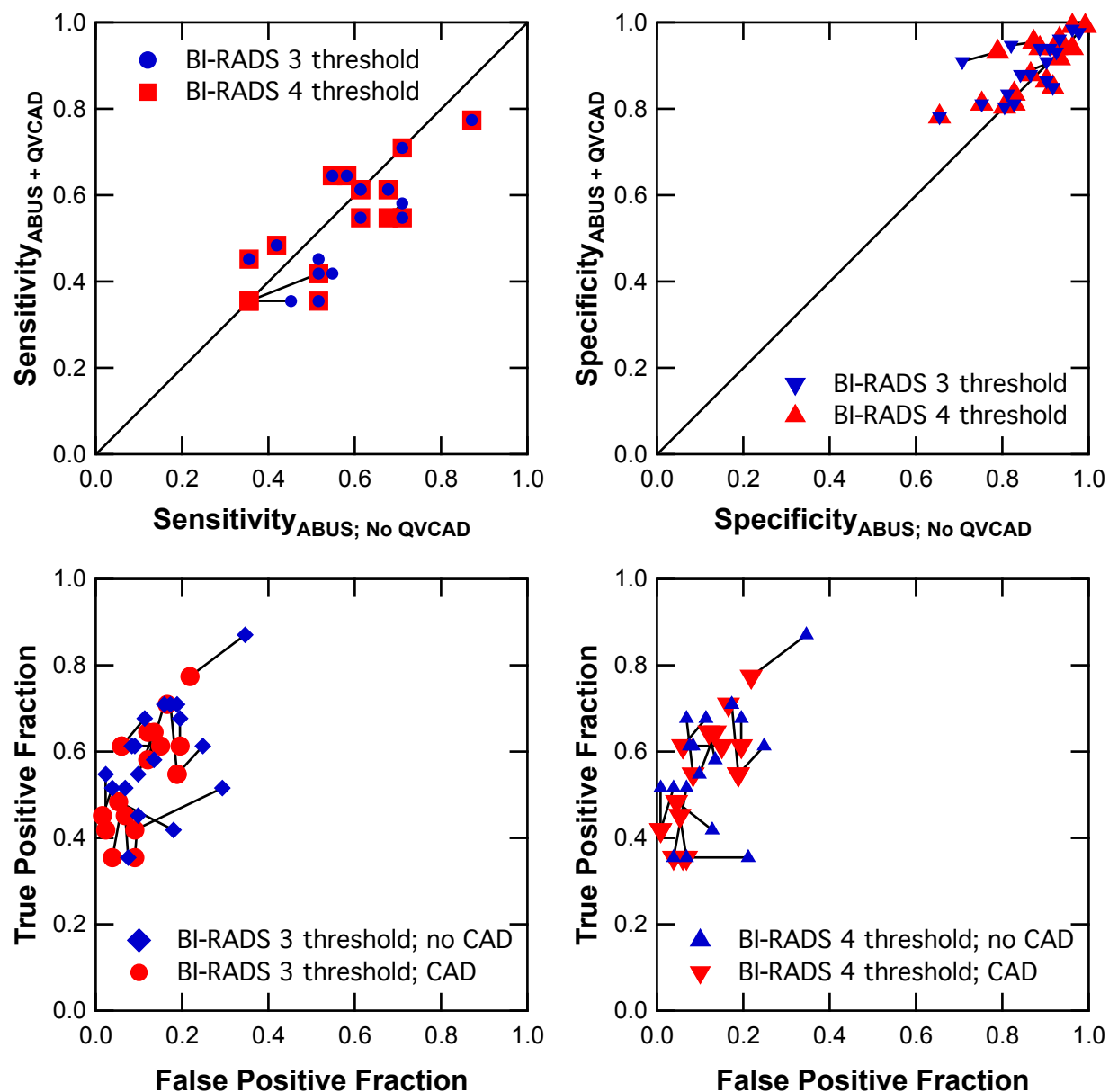


Figure 6 Comparison of sensitivity and specificity estimates of 18 readers between the two interpretation modalities.

Conventional ROC and MRMC analyses do not require correct localization of cancerous lesions. Therefore, additional secondary location-specific analyses were conducted to test whether or not the radiologists in the study found cancers in the correct locations. These analyses required one modification from the conventional MRMC and sensitivity and specificity analyses: for cancer cases, if none of a radiologist's identified lesion(s) matched the location of known cancer(s), then the radiologist's case-level LOS was treated as the lowest possible (1 on the scale of 1–100). Thus, radiologists' scores were penalized in location-specific analyses for identifying non-cancer lesion(s) while missing cancer(s). The criterion for a radiologist-identified lesion to match a known cancer was that the distance between the geometrical centers of the marked lesion and the known cancer must be less than or equal to 15 mm. The MRMC analysis of trapezoidal AUC and analysis of sensitivity and specificity were repeated with location-specific analyses, and these results are shown in Table 4 and Table 5, respectively. These results support the primary conclusion of the pivotal study.

Table 4 . Supplemental analysis of co-primary results of the pivotal study: Non-inferiority of location-specific trapezoidal AUC.

	AUC	95% CI of AUC	p-value
$AUC_{ABUS + QVCAD}$	0.6946		
$AUC_{ABUS; \text{No QVCAD}}$	0.6975		
$AUC_{ABUS + QVCAD} - AUC_{ABUS; \text{No QVCAD}}$	-0.0030	[-0.0412, 0.0353]	0.0082

Table 5 Supplemental analysis of the pivotal study: Location-specific sensitivity and specificity.

BI-RADS Threshold (cancer call)	Interpretation Modality	Sensitivity (%)		Specificity (%)	
		Average*	95% CI	Average*	95% CI
≥ 3	ABUS; No QVCAD	49.0 \pm 12.9	[35.1, 64.2]	85.5 \pm 8.8	[80.7, 89.9]
	ABUS + QVCAD	46.3 \pm 11.0	[31.4, 62.0]	89.0 \pm 6.4	[85.1, 92.6]
	Δ	-2.7 \pm 8.5	[-9.9, 5.9]	3.5 \pm 6.4	[-0.3, 7.7]
≥ 4	ABUS; No QVCAD	48.4 \pm 12.9	[34.6, 63.6]	87.4 \pm 8.6	[83.0, 91.9]
	ABUS + QVCAD	46.1 \pm 11.1	[31.2, 61.6]	89.8 \pm 6.8	[85.7, 93.5]
	Δ	-2.3 \pm 8.3	[-9.7, 5.7]	2.4 \pm 5.4	[-1.1, 5.8]

$$\Delta = (ABUS + QVCAD) - (ABUS; \text{No QVCAD})$$

*Mean \pm standard deviation

The results in Table 1 above compare the readers' performance with and without the aid of the QVCAD System on all 31 mammographic BI-RADS 1 and 2 cancer cases that were included in the study. However, of those 31 cancer cases, 15 were of patients who had prior breast interventions (PBI), for which ABUS is contra-indicated. The remaining 16 were of patients who had no prior breast interventions (no-PBI) and 15 were of patients who had prior breast interventions (PBI). All but one of the 133 normal cases used in the study had no PBI. Thus an additional analysis was performed on the 16 no-PBI cancer cases and the 132 no-PBI non-cancer cases (Table 6). The results of this supplemental analysis are consistent with those of the primary analysis, but statistical significance was not established in this supplemental analysis presumably because, at least in part, of the smaller number of cancer cases in this supplemental analysis.

Table 6. Supplemental analysis of the pivotal study: MRMC analysis of 16 no-PBI cancer cases and 132 no-PBI non-cancer cases

	AUC	95% CI of AUC	p-value
$AUC_{ABUS+QVCAD}$	0.7572		
$AUC_{ABUS; \text{No QVCAD}}$	0.7764		
$AUC_{ABUS+QVCAD} - AUC_{ABUS; \text{No QVCAD}}$	-0.0192	[-0.0637, 0.0252]	0.3931

6.3. CAD standalone performance

The standalone performance of QVCAD System was measured on the dataset with 31 cancer cases and 133 normal cases. As described in Section 4.2 Principles of Operation, the CAD output has two forms of indicators, CAD marks and CAD enhanced dark areas in the CAD Navigator Image.

Tables 7-12 below show the standalone performance for each of the indicator types of the QVCAD System. The sensitivity was measured as the number of cancer cases where at least one CAD indicator is present divided by the total number of cancer cases; the specificity was measured as the number of normal cases without any CAD indicators divided by the total number of normal cases; the false-positive (FP) rate (per volume) was measured twice: 1) for non-cancer cases (NCC) - as the total number of CAD indicators in non-cancer cases divided by the total number of volumes in non-cancer cases; 2) for non-cancer volumes (NCV) - as the total number of CAD indicators in non-cancer volumes in all cases divided by the total number of non-cancer volumes in all cases. The type of indicator used in each of the following tables is defined in the table captions.

Figure 7 below shows the QVCAD System standalone FROC curve.

Table 7 QVCAD standalone test results (CAD marks)

	By-Patient Sensitivity	By-Patient Specificity	FP rate (NCC)	FP rate (NCV)
CAD mark	71.0% [53.7%, 84.6%]	49.6% [41.2%, 58.1%]	0.12 [0.09, 0.14]	0.11 [0.09, 0.14]

Table 8 QVCAD standalone test results (enhanced dark areas)

	By-Patient Sensitivity	By-Patient Specificity	FP rate (NCC)	FP rate (NCV)
CAD Navigator	96.8% [85.9%, 99.7%]	6.0% [2.8%, 11.0%]	0.66 [0.59, 0.74]	0.67 [0.60, 0.74]

Table 9 QVCAD standalone sensitivity by lesion size (CAD marks).

Lesion size	Sensitivity (%)	
	Estimate	95% CI
<10 mm	75.0	[37.9, 91.4]
≥ 10 mm & < 20 mm	70.6	[46.3, 88.2]
≥ 20 mm	87.5	[48.9, 99.0]

Table 10 QVCAD standalone sensitivity by lesion size (enhanced dark areas).

Lesion size	Sensitivity (%)	
	Estimate	95% CI
<10 mm	100.0	[76.2, 99.9]
≥ 10 mm & < 20 mm	94.1	[74.9, 99.4]
≥ 20 mm	100.0	[67.0, 99.9]

Table 11 QVCAD standalone sensitivity, specificity, and false-positive rate by BI-RADS breast density (CAD marks).

Bi-RADS Breast Density	Sensitivity (%)		Specificity (%)		FP rate (NCC)		FP Rate (NCV)	
	Estimate	95% CI	Estimate	95% CI	Estimate	95% CI	Estimate	95% CI
C	70.0	[48.3, 86.4]	49.0	[39.3, 58.8]	0.12	[0.09, 0.15]	0.11	[0.09, 0.14]
D	72.7	[43.5, 91.7]	52.8	[36.4, 68.8]	0.10	[0.06, 0.14]	0.11	[0.07, 0.15]

Table 12 QVCAD standalone sensitivity, specificity, and false-positive rate by BI-RADS breast density (enhanced dark areas).

Bi-RADS Breast Density	Sensitivity (%)		Specificity (%)		FP rate (NCC)		FP Rate (NCV)	
	Estimate	95% CI	Estimate	95% CI	Estimate	95% CI	Estimate	95% CI
C	95.0	[78.9, 99.5]	4.9	[1.9, 10.5]	0.68	[0.60, 0.76]	0.68	[0.61, 0.76]
D	100.0	[80.0, 100.]	11.1	[3.7, 24.8]	0.60	[0.46, 0.75]	0.64	[0.51, 0.78]

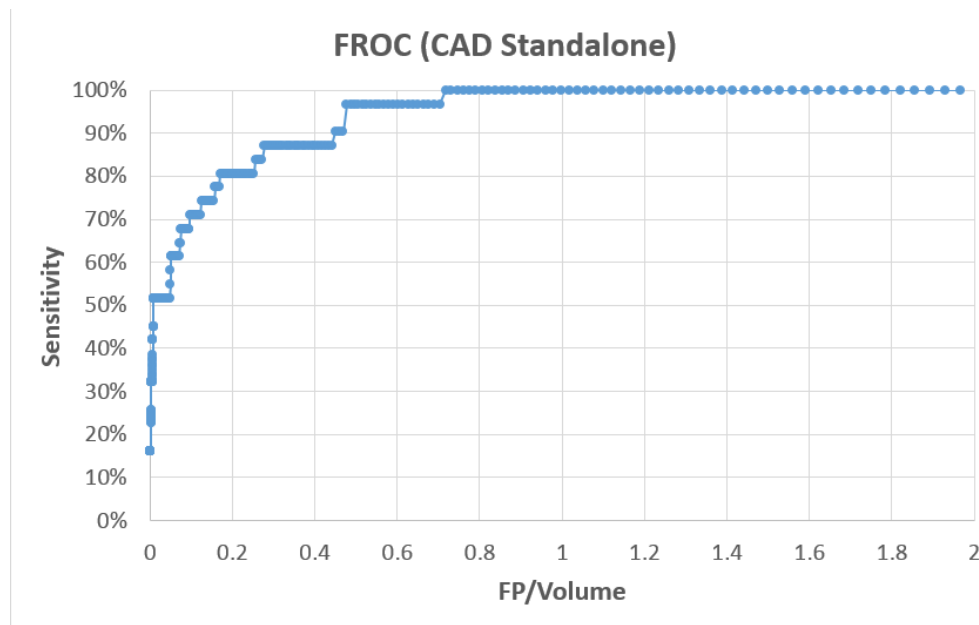





Figure 7: QVCAD System Standalone FROC curve

7. Potential Adverse Effects of Device on Health

There are no known direct safety or health risks caused by or related to use of the QVCAD system. The device has no direct contact with the patient. Indirect risks are that the device may fail to mark or highlight malignant lesions or may mark or highlight some nonmalignant lesions (false positive readings). These possibilities are explained in the Warnings section of the device labeling. Proper use of the information generated by the QVCAD system is explained in the Instructions for use in this manual. The QVCAD output is one of several inputs into physician decision making, and final diagnostic decisions represent physicians' assessments and judgments of these several inputs.

8. Symbols, Contraindications, Warnings and Precautions

8.1. Symbols

 WARNING	This symbol is used to indicate information that may relate to serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur.
 CAUTION	This symbol is used to indicate information regarding any special care to be exercised by practitioner for the safe and effective use of the equipment
	Manufactured by

8.2. Contraindications

There are no contraindications for this device.

8.3. WARNING

- 8.3.1. Federal law restricts this device to be used by, or on the order of a physician.
- 8.3.2. The QVCAD system should be used only after completion of proper training conducted by qualified QView personnel.
- 8.3.3. The QVCAD system is an adjunct to the user. The user must not use the CAD generated output as the primary interpretation
 - a. The QVCAD system may not mark or highlight all regions that are indicative of cancer.
 - b. The QVCAD system may mark or highlight regions that do not contain cancer.
- 8.3.4. The CAD Navigator Images and CAD marks only assist the user in identifying regions of interest. The user should review the ABUS images concurrently with the CAD Navigator Image and CAD marks before making their final assessment of the case.
- 8.3.5. The regions of interest that are marked by the QVCAD system should be reviewed by the user to avoid a potential oversight.
- 8.3.6. The patient history is important to identify prior surgeries or abnormalities, which may be marked by the QVCAD system.
- 8.3.7. The QVCAD system is not intended to analyze views containing an implant.
- 8.3.8. In using the QVCAD system, all parties should take necessary precautions to ensure privacy of patient information.
- 8.3.9. In the event of severely low disk space (<5GB), when a new study is sent to the QVCAD system, the system will delete the oldest reviewed studies from the database one at a time until at least 5GB of space is free. If there are no reviewed studies in the database to be deleted, this may cause failure of the study to be sent. The minimum configuration of the disk is 1 TB, which provides a database capacity of approximately 1200 studies. This deletion function will apply when the database is within 7 studies of capacity. Note that a "Disk Storage Status Warning" will appear several times before this condition occurs (See Section 12).
- 8.3.10. If any studies are deleted from the QVCAD system, images, QVCAD outputs, and annotations will also be permanently deleted.
- 8.3.11. The operator/technologist of the imaging system should assure that all views of a study that were acquired on the ABUS system have been received by the QVCAD System. If not, resend the study to obtain the missing views.
- 8.3.12. The ABUS–QVCAD system is an adjunct to mammography and should only be used for patients with screening mammograms.
- 8.3.13. The majority of the readers in the pivotal study were radiologists with more than 10 years of experience. The benefit of the QVCAD System for non-radiologists with extensive experience and for readers with less experience is not fully demonstrated by the study results.

8.4. CAUTION

- 8.4.1. The QVCAD system user configuration default is set to display "Show QView + CAD" to ensure that CAD marks and CAD Navigator images are displayed.
- 8.4.2. Even though there can be up to 6 views per breast, each study is limited to 10 views. In the unlikely event that more than 10 views need to be acquired in a study - e.g. 6 in each breast or 6 in one breast 5 in other - then split the study into 2 studies, one for each breast.
- 8.4.3. CAD marks corresponding to specific slices are displayed in the transverse/sagittal/coronal images *only* if User Configuration for CAD Marks in 3D Images is set.
- 8.4.4. If Lock Views is checked in the Review Dual protocols, the displayed clock positions of the two views may differ if the active point is outside the extent of one of the views.
- 8.4.5. If the "Disk Storage Status Warning" appears, indicating that the disk is > 90% full, contact QView Customer support for data backup.
- 8.4.6. The user should not change the Case ID of a study until CAD processing is complete for all the views in the study.

9. Conformance to Standards

No performance standards applicable to this device have been established under Section 514 of the FD&C Act.

10. How Supplied

The QVCAD System is supplied as a software package that is installed by qualified QView Medical personnel onto a dedicated customer-supplied workstation that meets the following minimum performance specifications:

- Linux compatible PC
- 16 GB RAM, 2133MHz
- 4 processor cores, each with 3.5 GHz minimum clock speed, with 10MB total cache memory.
- 1 TB, 7200 RPM, hard disk drive
- 17-24" Monitor, 16:10 aspect ratio, with a minimum of 1920x1200 resolution
- EVGA card with at least 1920x1200 resolution and GPU with minimum 2GB RAM
- 1 USB-3.0 or higher port
- 1 high speed Ethernet connection (100/1000 Base-T).
- Standard keyboard and three button optical mouse with scroll wheel.
- DVD drive (built-in **or** external connected to an additional USB-1.0 or higher port)

11. QVCAD System Basic Operation

11.1. Getting Started

11.1.1. **Power On**—Press Power On/Off button on the computer to start the system.

11.1.2. **Logging On**—At the login window, enter User Name and Password*. Press Enter.

After login, the Q-Viewer will be automatically loaded showing the oldest non-reviewed study in the study database. (See section *Study Selection 11.2.4b to load a different study.*)

Note: For security reasons, the password is issued by the system administrator.

11.1.3. System Inactivity

a. Power Saving Mode

After 5 minutes of inactivity, the software will go into power saving mode. Movement of the mouse will wake the system to the Q-Viewer in its prior state.

b. Automatic System Log off

After 10 minutes of inactivity, the software will automatically log the user off the system. Login will be required upon wake-up.

11.2. QVCAD System Overview

11.2.1. Q-Viewer Display Area

Q-Viewer displays the results of the CAD Engine along with the ABUS images. When a study is loaded for review, Q-Viewer shows that study in the chosen display protocol layout as shown in Figure 8 (For more information on display protocols see Q-Viewer Display Protocols Table 18).

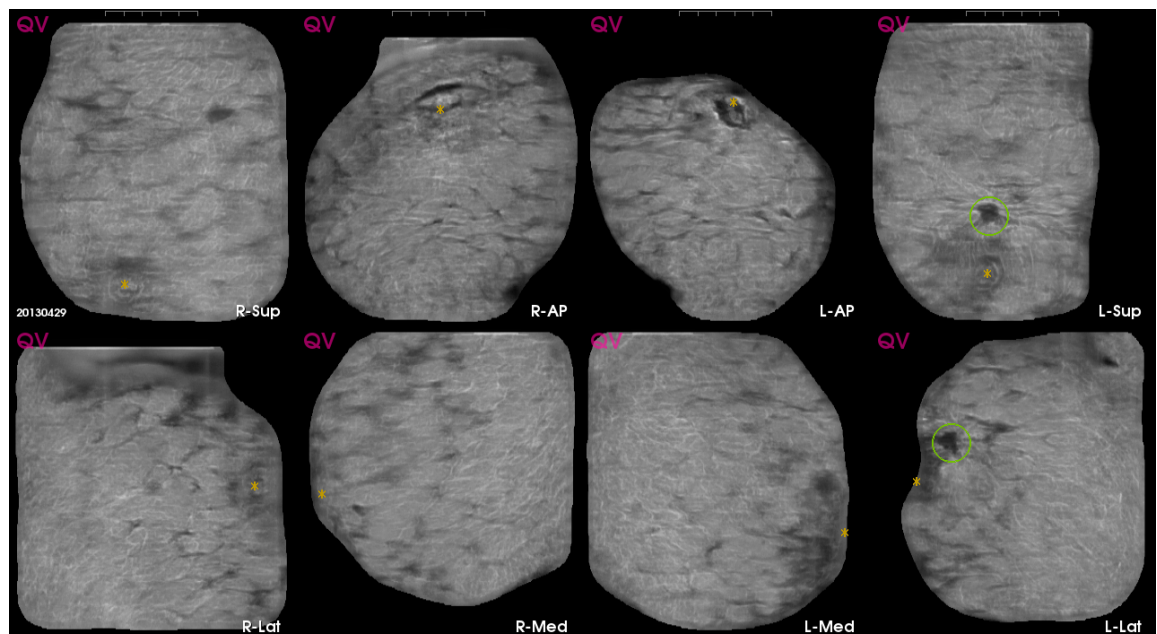


Figure 8 Q-Viewer display area (Overview: 8 display protocol shown)

11.2.2. CAD Navigator Image

One CAD Navigator Image is generated for each acquired view of a study. It is a 2D projection of the Coronal image data of that view. The CAD Navigator Image shows areas of interest indicated by CAD Marks and CAD enhanced dark areas and/or radial spiculations and retraction patterns. The CAD Navigator Image is a roadmap to be used concurrently with the 3D images of the view for review. Each CAD Navigator Image is distinguished by a “QV” in the upper left corner as shown in Figure 9. All CAD marks are displayed on the CAD Navigator image. Two CAD marks may be superimposed on the CAD Navigator image but can be distinguished in the 3D display of the native ABUS images.

Shortcut: Pressing the “Q” key on the keyboard will bring show the CAD Navigator Image to the front.

Note: When the view has been reviewed the first time, the CAD Navigator Image will then be outlined in green.

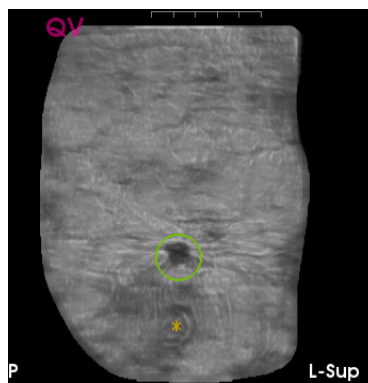


Figure 9 CAD Navigator Image

11.2.3. Cursors, Mouse Control & Scroll Wheel

a. Cursors (Active Point Crosshairs and Green Selection Arrow)

The QVCAD System uses two types of cursors for selection and navigation:

1. Green Selection arrow
2. Yellow crosshairs indicate the active point in all images of any Review Display Protocols (For more information on display protocols see Q-Viewer Display Protocols Table 18).

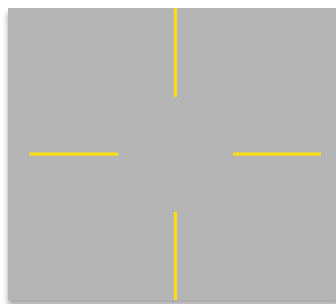


Figure 10 The Active Point Crosshairs

b. Right Click and Hold (Pop-up Menu)

To access any of the contextual pop-up menus in the system, right click and hold button over selected area. This activates a corresponding contextual pop-up menu of available commands (See Table 13). To make a selection, while still holding down the button, move cursor to desired action and release button. To exit the pop-up menu without making a selection, move cursor off the menu and release button.

Table 13 . Pop-up Menu Selections

Display Protocol	View or Image	Location within View or Image	Available Menu Selections
Overview Display Protocols	CAD Navigator Image	Within an Annotation	Edit Annotation Delete Annotation Copy Annotation Paste Annotation* Zoom Reset Zoom*
		All locations outside of any Annotation	Dismiss Annotate Paste Annotation* Zoom Reset Zoom*
Review Display Protocols	Any Image	Within an Annotation or within an Annotated CAD Mark	Start Survey* Terminate Survey* Edit Annotation Delete Annotation Copy Annotation Paste Annotation* Zoom Reset Zoom*
		All locations outside of any Annotation	Start Survey* Terminate Survey* Dismiss Annotate Paste Annotation* Zoom Reset Zoom*
	Coronal or Transverse Image when an Annotation is active	Within an Annotation	Start Survey* Terminate Survey* Edit Annotation Delete Annotation Copy Annotation Paste Annotation* Add Measurement* Delete Measurement* Zoom Reset Zoom*
		All locations outside of any Annotation	Start Survey* Terminate Survey* Dismiss Annotate Paste Annotation* Add Measurement* Delete Measurement* Zoom Reset Zoom*

* **Paste Annotation** is only available where Copy Annotation had previously been executed

Start Survey is only available if Survey mode is inactive

Terminate Survey is only available if Survey mode is active

Reset Zoom is only available when Zoom is active in the selected image

Add Measurement is only available and will be applied to the active Annotation

1) in the Coronal Image if less than two Coronal measurements have been recorded; or

2) in the Transverse Image if no Transverse measurements have been recorded

Delete Measurement is only available when right clicking directly on either of the + ends of a measurement

c. Change Window Width

Increase Window Width – Click and drag Scroll Wheel up

Decrease Window Width – Click and drag Scroll Wheel down

d. Change Window Level

Increase Window Level – Click and drag Scroll Wheel left

Decrease Window Level – Click and drag Scroll Wheel right

e. Hover Mode

The Hover Mode is a feature within the Overview Display Protocols (*For more about the Overview Display Protocols—see Table 8*). Hover Mode enables the user to quickly review a localized area of a view by displaying the corresponding Coronal and Transverse images adjacent to the CAD Navigator Image for the point where the cursor is hovering.

Activating Hover Mode – The Hover Mode activates when the cursor is paused over any area of a CAD Navigator Image (*See 11.2.2 CAD Navigator Image*). When activated, corresponding Transverse and Coronal hover images specific to that cursor position or hover point will appear as separate adjacent windows to the CAD Navigator Image.

Viewing while in Hover Mode – The Coronal slice depth selected for display will correspond to any CAD findings at that location, if any. As the cursor is moved within the CAD Navigator Image, the Transverse image will update accordingly. When the scroll wheel is scrolled, the depth of the Coronal image will update accordingly.

Changing Hover Point – If the cursor is paused over any new point in the CAD Navigator Image more than 1cm away from the previous hover point, the Hover Mode will reset to the new hover point.

Exiting Hover Mode – Moving the cursor off the CAD Navigator Image will deactivate the Hover Mode. The Coronal and Transverse hover images will disappear from the screen.

f. Survey Mode

The Survey Mode is a feature within the Review Display Protocols (*For more about the Review Display Protocols—see Table 8*). Survey enables the user to review an entire breast in a cine-like mode by using the mouse and scroll wheel to navigate within the images without having to hold down a mouse button.

Starting Survey Mode – To activate Survey Mode, right click and hold within the image you would like to survey to display the pop-up menu containing a list of available selections. While still holding down the button, highlight Start Survey, then release the button. This image becomes the surveyed image and enlarged crosshair cursors will appear in that image and the other image updates accordingly.

Reviewing while in Survey Mode – The enlarged crosshairs update as they are moved around the surveyed image. If the crosshair cursor is moved to a different image, then the new image becomes the surveyed image and the other images update accordingly. If the scroll wheel is rolled, the surveyed image will update, moving up or down through each of its 'slices'. By moving systematically through each image, the entire breast can be quickly reviewed.

Note that if the surveyed image is the CAD Navigator or the Coronal image, the enlarged crosshairs are displayed in both of those images. All other operations work identically.

While in Survey Mode in the Review: Dual protocol, moving the enlarged crosshairs to the other view activates Survey Mode on that view. If Lock Views is checked, the enlarged crosshairs are displayed in the same image of both views and both views are surveyed together at the same location relative to the nipple.

Exiting Survey Mode – To terminate a survey, right click and hold to bring up the pop-up menu containing a list of available selections. While still holding down the button highlight Terminate Survey, then release the button.

11.2.4. System Control Panel

The System Control Panel is located at the bottom of the screen below the Q-Viewer display area. There are 4 sections within the System Control Panel. Each section (from left to right) is shown enlarged and described below.



Figure 11 System Control Panel.

a. File (System Settings – User Configuration)

This section of the System Control Panel allows User Settings Configuration and Program Control. (See Figure 12)

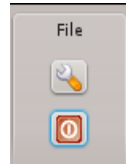


Figure 12 File Section of System Control Toolbar, enlarged.



System Settings Button –displays the User Configuration screen (See Figure 13). The screen displays the current software release in the title bar and enables the user to customize the QVCAD System. The values indicated in Fig.9 are recommended by QView Medical Inc. The values may be changed based on the user's preference. The User Configuration Options are noted in Table 14. Once all changes have been made, the OK button saves the changes or the Cancel button will discard the changes.

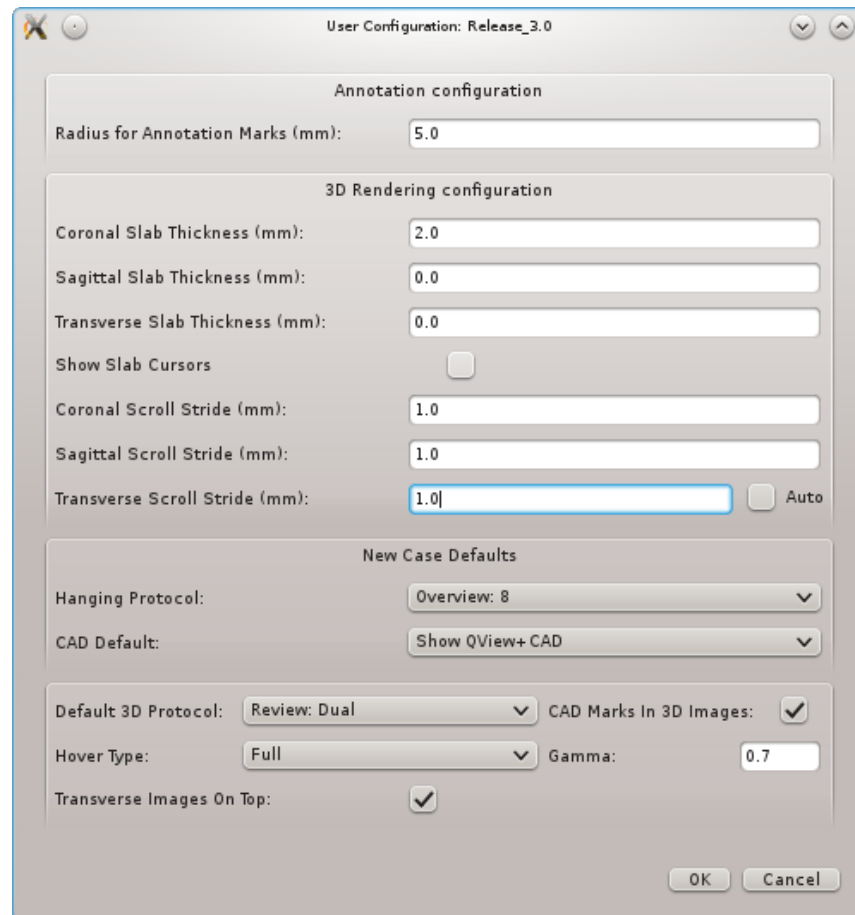


Figure 13 User Configuration Screen

Table 14 System User Configuration Options

Configurable Area	Description	Options
Annotation Configuration	Radius for Annotation Marks	User defined
3D Rendering Configuration	Coronal Slab Thickness (mm)	User defined
	Sagittal Slab Thickness (mm)	User defined
	Transverse Slab Thickness (mm)	User defined
	Slab Cursors	On / Off
	Coronal Scroll Stride (mm)	User defined
	Sagittal Scroll Stride (mm)	User defined
	Transverse Scroll Stride (mm)	User defined
	Auto Transverse Scroll Stride	On / Off (If On, overrides the Transverse Scroll Stride with the actual distance between frames)
New Case Defaults	Hanging Protocol	Overview: 2 Overview: 8 Review: Dual L Review: Dual R Review: Large Coronal Review: Large Transverse
	CAD Default	Suppress QView (CAD Navigator) Hide CAD Show QView (CAD Navigator) + CAD
Miscellaneous Controls	Default 3D Protocol <i>Note: Activated when an image in an Overview protocol is clicked.</i>	Review: Dual Review: Large Coronal Review: Large Transverse
	CAD Marks in 3D images	Show / Hide
	CAD Hover Type	Full / ROI / Off <i>Note: Full sets the Hover Feature to show complete Hover Images adjacent to the CAD Navigator Image. ROI sets the Hover Feature to show 6x6cm zoomed Hover Images adjacent to the CAD Navigator Image. Off turns off the Hover feature.</i>
	Gamma	User defined. (recommended range 0.5 to 2.0)
	Transverse Image On Top <i>Note: This setting only affects Review Protocols.</i>	On / Off

 **Power Button**—Displays the Program Control Screen with options noted in Table 15 below.

Table 15 Program Control Screen Options

Button	Action
Reload	Exits and reloads currently loaded study.
Logout	Logs user out of current session.
Reboot	Reboots the operating system and displays the login screen.
Admin	(No action – feature only available for QView Service personnel)
Cancel	Closes Program Control Screen and returns to Q-Viewer in previously selected protocol display.

b. Study Selection

Select and manage studies on the system. The patient name for the current study being reviewed appears at the top of this section of the System Control Panel.

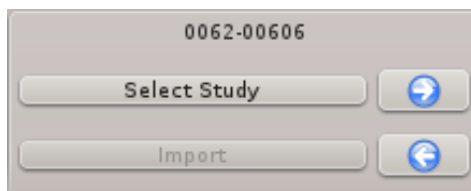




Figure 14 Study Selection Section of System Control Toolbar, enlarged.

Table 16 Study Selection Options

Button	Action
Select Study	Brings up the QView Study Selector Screen (See Figure 15).
	Pulls up the next study in the database or highlighted set in order of study date and time.
	Pulls up previous study in the database or highlighted set in order of study date and time.
Import	(No action – feature only available for QView Service personnel)

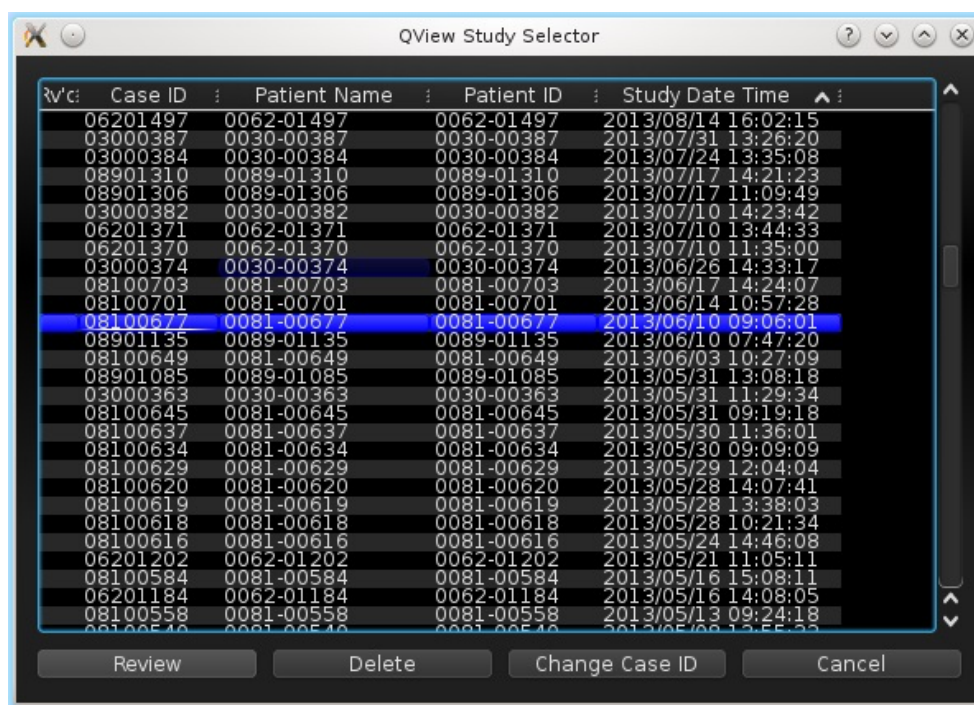


Figure 15 QView Study Selector screen.

Table 17 QView Study Selector Screen Options

Columns	
Rv'd (Reviewed Status)	A check mark (✓) indicates study has been reviewed.
Case ID	QVCAD internal ID of study.
Patient Name	Name of patient
Patient ID	MRID of patient.
Study Date/Time	Start date and time study was acquired.
Actions	
Sorting Studies	Click on any column header to sort
Highlight – Single Study*	Click on a row
Highlight – Multiple Studies (Contiguous Rows)	After clicking on a single study, Shift+Click additional row to select all studies from the first highlight to the current row.
Highlight – Multiple Studies (Non-Contiguous Rows)	After clicking on a single study, Control+Click desired additional rows. Rows do not need to be adjoining.
Buttons	
Review	Pulls up the highlighted study in Q-Viewer. <i>Note: If multiple studies are selected, the oldest study in the highlighted set will be loaded for review. The right/left arrow buttons will select the next/prior study in the highlighted set.</i>
Delete	Removes the highlighted study(ies) from the system. Prompts for confirmation of permanently deleting selected studies.
Change Case ID	Change the system assigned Case ID. The new Case ID must be an 8-digit number.
Cancel	Discards the changes and closes the screen.

* *Note: Double clicking on any column in a row selects and loads that study for review. The screen will automatically be closed.*

c. Navigation (Q-Viewer Display Protocols)

The Navigation section of the System Control Panel allows the user to choose study display protocols to display in Q-Viewer (Figure 16). Q-Viewer uses two types of display protocols, Overview and Review. The options and sample screen shots for each display protocol are noted in Table 18 below.

Please refer to Sec. 3 Definitions and Sec. 11.2.2 CAD Navigator Image above for detailed descriptions of the view and image types referred to in the tables below.



Figure 16 QView navigation section.

Note: The Previous and Next buttons are grayed out (not available in this release).

Table 18 . Q-Viewer Display Protocols

OVERVIEW PROTOCOL: Overview 8											
<div>Overview: 8*</div> <div>Overview: 8</div> <p>Default Display Protocol at startup.</p>		<ul style="list-style-type: none">Displays up to eight CAD Navigator Images for the selected study. The views will be shown in the following locations on the Q-Viewer display. <table><tr><td>Additional View Display Area: R-UOQ, R-SUP or R-INF</td><td>R-AP Display Area</td><td>L-AP Display Area</td><td>Additional View Display Area: L-UOQ, L-SUP or L-INF</td></tr><tr><td>R-LAT Display Area</td><td>R-MED Display Area</td><td>L-MED Display Area</td><td>L-LAT Display Area</td></tr></table> <p><i>Note: If the study has any of the UOQ, SUP INF views, one will be shown in the Additional View Display locations identified above. To see additional views, check the thumbnails in the Overview 2 Display protocol.</i></p> <ul style="list-style-type: none">If there are less than eight CAD Navigator Images, the empty area will display “No Image Available” Any view that has been reviewed is outlined in green.Pressing the “Q” key on the keyboard will bring the CAD Navigator image to the front.		Additional View Display Area: R-UOQ, R-SUP or R-INF	R-AP Display Area	L-AP Display Area	Additional View Display Area: L-UOQ, L-SUP or L-INF	R-LAT Display Area	R-MED Display Area	L-MED Display Area	L-LAT Display Area
Additional View Display Area: R-UOQ, R-SUP or R-INF	R-AP Display Area	L-AP Display Area	Additional View Display Area: L-UOQ, L-SUP or L-INF								
R-LAT Display Area	R-MED Display Area	L-MED Display Area	L-LAT Display Area								
<div>Additional View Display Areas (Right and Left Side)</div>											

REVIEW PROTOCOL: Overview 2

Overview: 2

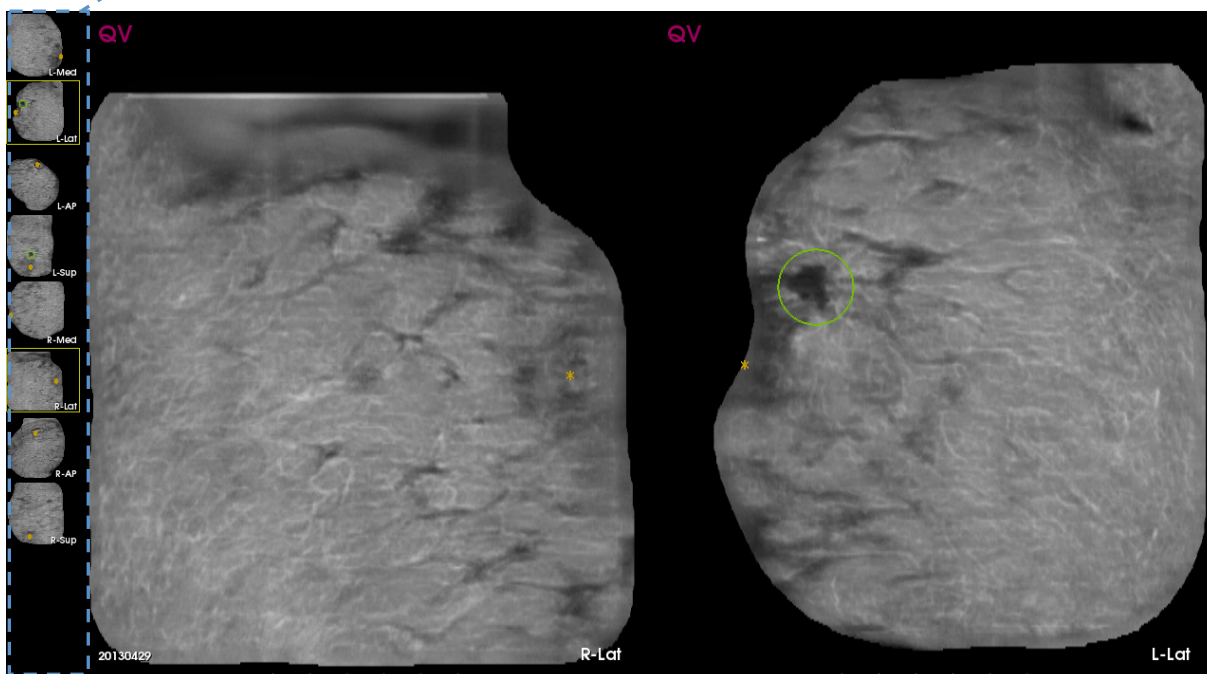
Overview: 2

☐ Lock Views

Note: Selecting Lock Views will synchronize the display and scrolling to the same level.

- Displays two CAD Navigator Images of any two views side-by-side for the selected study.
- Up to ten thumbnails of the available views are displayed on the left side of the screen. The thumbnails of the active views are brightly highlighted.
- Any view that has been reviewed is outlined in green.
- To select a different view, drag the desired thumbnail on top of either CAD Navigator Image and then release mouse button. The display will update with dropped view.
- Pressing the “Q” key on the keyboard will bring the CAD Navigator image to the front.

Thumbnail Area



REVIEW PROTOCOL: Large Transverse

Review: Large Transverse

Review: Large Transverse

- Displays a CAD Navigator Image on the right side of the screen.
- Displays corresponding large transverse image, and smaller sagittal and coronal images.
- Up to ten thumbnails of the available views are displayed on the far left side of the screen. The thumbnail of the active view is brightly highlighted. Any view that has been reviewed is outlined in green.
- To select a different view, click the desired thumbnail. The display will update with selected view.

Thumbnail Area

Large Transverse Image

L-Med

L-Lat

L-AP

L-Sup

R-Med

R-Lat

R-AP

R-Sup

20130429

Clock 5:00

Nipple 6.5cm

Skin 1.5cm

QV

R-AP

R-AP

REVIEW PROTOCOLS: Large Coronal

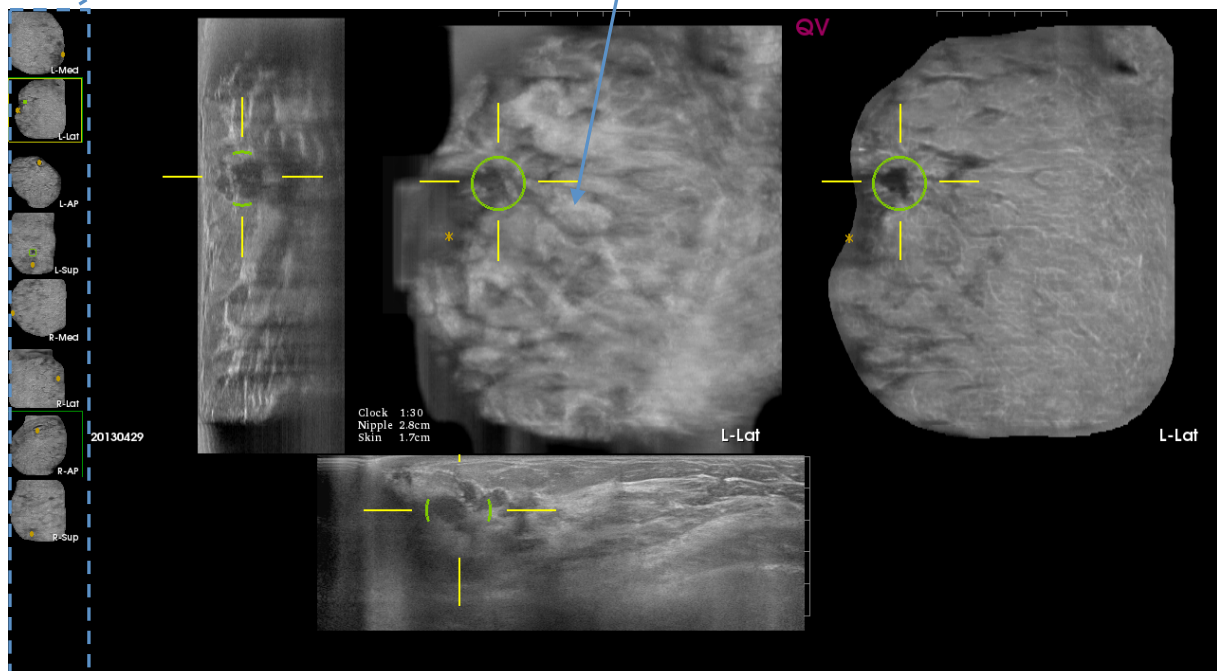
Review: Large Coronal

Review: Large Coronal

- Displays a CAD Navigator Image on the right side of the screen.
- Displays corresponding large coronal image, and smaller sagittal and transverse images.
- Up to ten thumbnails of the available views are displayed on the far left side of the screen. The thumbnail of the active view is brightly highlighted. Any view that has been reviewed is outlined in green.
- To select a different view, click the desired thumbnail. The display will update with selected view.

Thumbnail Area

Large Coronal Image



REVIEW PROTOCOL: Dual (Right or Left)

Review: Dual

Review: Dual R

Review: Dual L

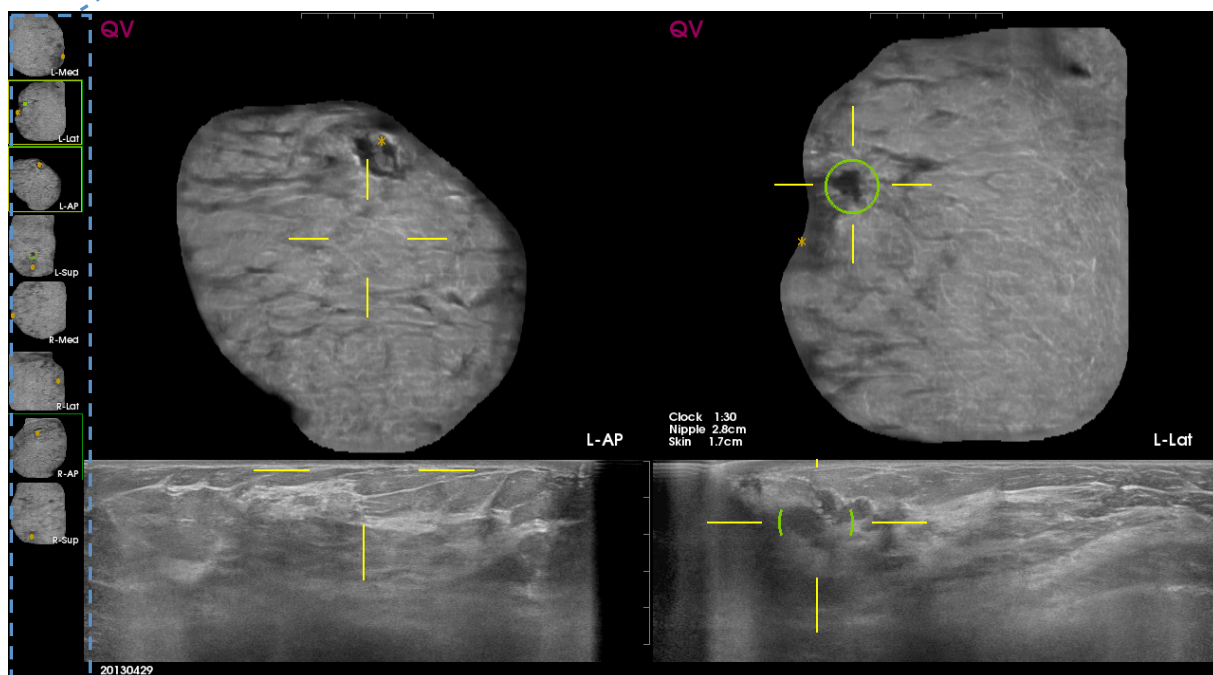
Note: selection is either Dual R or Dual L depending on which breast is being reviewed.

☐ Lock Views

Note: Selecting Lock Views will synchronize the display and scrolling to the same level. If Lock Views is checked while using one of the Review: Dual protocols, the displayed clock positions of the two views may differ if the active point is outside the extent of one of the views.

- Displays two CAD Navigator Images side-by-side of the selected breast.
- Displays corresponding transverse image for each view.
- Up to ten thumbnails of the available views are displayed on the far left side of the screen. The thumbnails of the active views are brightly highlighted. Any view that has been reviewed is outlined in green.
- To select a different view, drag the desired thumbnail on top of either CAD Navigator Image and then release mouse button. The display will update to the selected view.
- Pressing the "Q" key on the keyboard will bring the CAD Navigator image to the front.

Thumbnail Area



d. System Display Controls

Allows user to control the display of CAD Marks, user-made Annotations, and Window/Level (W/L).



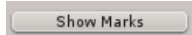
Figure 17 Display Controls Section of System Control Toolbar, enlarged

CAD Marks Display Toggle Button (Hide/Show CAD)



Allows the user to control the display of CAD Marks generated by the QVCAD system. When CAD Marks are displayed, the toggle button will read “Hide CAD”. Clicking the “Hide CAD” button will hide all CAD Marks. When the CAD Marks are hidden, the toggle button will read “Show CAD”. Clicking the “Show CAD” button will show all CAD Marks.

Annotation Marks Display Toggle Button (Hide/Show Marks)



Allows the user to control the display of user-made Annotation Marks. When Annotation Marks are displayed, the toggle button will read “Hide Marks”. Clicking the “Hide Marks” button will hide all Annotations. When Annotation Marks are hidden, the toggle button will read “Show Marks”. Clicking the “Hide Marks” button will hide all Annotation Marks.

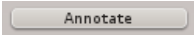
Annotate



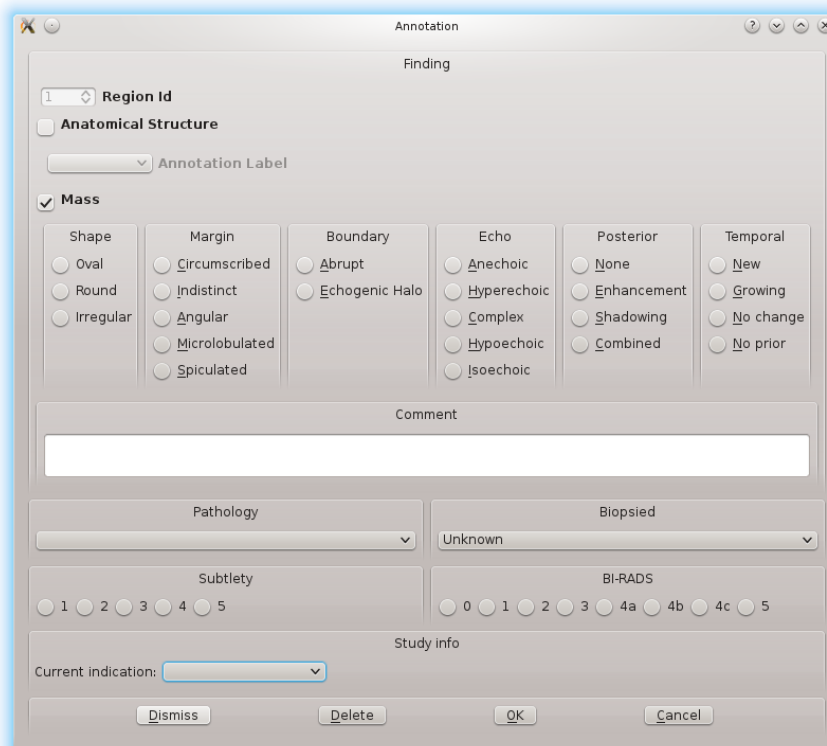
In the Review Display Protocols, the Annotate button pulls up the Annotation screen (See Figure 18). Annotate allows the user to detail or dismiss a region of interest, a dark area on the CAD Navigator Image, or a CAD Mark.

In the Overview Display Protocols, the Annotate button pulls up a Current Indication menu. This menu allows the user to set the indication for all Annotations in the entire study.

Table 19 . Annotation Button Actions

Protocol	Action	Result
Review	Right Click or Annotate Button 	Annotation screen (Figure 18)
Overview	Annotate Button	Current Indication Menu
	Right Click then Annotate from the Pop-up Menu	Annotation Screen (Figure 18)

The choices for the Annotation screen are detailed in Table 20.



The Annotation screen is a window titled "Annotation" with standard macOS window controls. It contains several sections for data entry:

- Finding**: Includes a "Region Id" dropdown set to "1", an unchecked "Anatomical Structure" checkbox, and an "Annotation Label" dropdown.
- Mass**: A checked checkbox followed by six columns of radio button options:
 - Shape**: Oval, Round, Irregular.
 - Margin**: Circumscribed, Indistinct, Angular, Microlobulated, Spiculated.
 - Boundary**: Abrupt, Echogenic Halo.
 - Echo**: Anechoic, Hyperechoic, Complex, Hypoechoic, Isoechoic.
 - Posterior**: None, Enhancement, Shadowing, Combined.
 - Temporal**: New, Growing, No change, No prior.
- Comment**: A large text input field.
- Pathology**: A dropdown menu.
- Biopsied**: A dropdown menu with "Unknown" selected.
- Subtlety**: Radio buttons for 1, 2, 3, 4, 5.
- BI-RADS**: Radio buttons for 0, 1, 2, 3, 4a, 4b, 4c, 5.
- Study info**: A "Current indication:" dropdown.
- Buttons**: Dismiss, Delete, OK, and Cancel at the bottom.




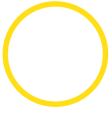



Figure 18 Annotation Screen.


Table 20 Annotation Screen Details

Section	Description	Available Selection(s)
Region ID	System assigned identification of Annotation	None
Type	Anatomical Structure	<ul style="list-style-type: none"> • Ribs • Landmark • Normal • Other structure
	Mass	<p>Shape</p> <ul style="list-style-type: none"> • Oval • Round • Irregular <p>Margin - characteristics of area outside the mass boundary</p> <ul style="list-style-type: none"> • Circumscribed • Indistinct • Angular • Microlobulated • Spiculated <p>Boundary - characteristics of the mass boundary</p> <ul style="list-style-type: none"> • Abrupt • Echogenic Halo <p>Echo - ultrasound echo characteristics of the mass</p> <ul style="list-style-type: none"> • Anechoic • Hyperechoic • Complex • Hypoechoic • Isoechoic <p>Posterior - ultrasound characteristics posterior to the mass</p> <ul style="list-style-type: none"> • None • Enhancement • Shadowing • Combined <p>Temporal - size compared to prior study</p> <ul style="list-style-type: none"> • New • Growing • No Change • No Prior

Section	Description	Available Selection(s)
Pathology	Confirmed or presumed pathology of the mass. Required when "Mass" is the type.	<ul style="list-style-type: none"> • Invasive carcinoma • Ductal carcinoma in situ • Ductal carcinoma, infiltrative • Lobular carcinoma in situ • Lobular carcinoma, infiltrative • Papilloma in situ • Infiltrative papilloma, intracystic carcinoma • Medullar carcinoma • Adenoid-cystic carcinoma • Mucinous/colloid carcinoma • Tubular carcinoma • Plaveiselcel carcinoma • M. Paget • Sarcoma • Non Hodgkin lymphoma • Metastasis from elsewhere • Fibroadenoma • Solitary cyst • Radial scar, complex sclerosing lesion • Phyllodes tumor • Single papilloma • Multiple intraductal papillomatosis • Fibrocystic change • Benign microcalcification • Other benign lesion • Atypical ductal hyperplasia • Normal tissue • Unknown benign • Plasma cell mastitis • Suspicious, unconfirmed • Probably benign, unconfirmed
Biopsied		Yes / No / Unknown
Subtlety		1 / 2 / 3 / 4 / 5 <i>Note: 1 = Obvious and 5 = Extremely difficult to detect.</i>
BI-RADS		0 / 1 / 2 / 3 / 4a / 4b / 4c / 5
Study Info	Current Indication	<ul style="list-style-type: none"> • Screening • High-risk Screening • Control • Recall • Symptomatic • Other • Unknown
Button	Action	
Dismiss	Region of Interest or CAD Mark will be marked as dismissed.	
Delete	Selected Annotation will be deleted.	
OK	Accepts changes.	
Cancel	Discards the changes made on the screen.	

Table 21 Symbols - Marks and Annotations

Symbol	Name	Description
	CAD Mark	<ul style="list-style-type: none"> Bright Green Circle Active (Bright green) or Not Reviewed Cursor located at center
	CAD Mark – Inactive <i>Enlarged to show detail</i>	<ul style="list-style-type: none"> Green Dot Reviewed Not Annotated
	User Annotation - Active	<ul style="list-style-type: none"> Purple Circle with Region ID adjacent Cursor located at center
	User Annotation – Inactive	<ul style="list-style-type: none"> Yellow Circle with Region ID adjacent
	User Dismissed – Active <i>Enlarged to show detail</i>	<ul style="list-style-type: none"> Purple “X” Active User Dismissed Region of Interest
	User Dismissed – Inactive <i>Enlarged to show detail</i>	<ul style="list-style-type: none"> Yellow “X” Inactive User Dismissed Region of Interest
	User Dismissed CAD Mark <i>Enlarged to show detail</i>	<ul style="list-style-type: none"> Green “X” User Dismissed CAD Mark

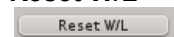
Symbol	Name	Description
	Nipple Marker <i>Enlarged to show detail</i>	<ul style="list-style-type: none"> Yellow Asterisk If nipple location is outside the view, the nipple marker will be displayed in orange at the edge of the image area. If the nipple marker is inadvertently moved, click and drag to the appropriate location.

Annotation Measurements

Adding a measurement—After creating and saving an Annotation Mark, a measurement may be added to an active Annotation Mark. Right click the desired Annotation Mark to access the pop-up menu. Hold button and select Add Measurement from the menu and release button. Green “+” will appear. Click the “+”, drag and release to add the desired measurement. If the Annotation Mark is in the coronal image, up to two measurements may be added. If the Annotation Mark is in the transverse image, one measurement may be added. To reposition or adjust measurements, click and drag the green “+”.

Deleting a measurement—To delete a measurement, right click directly on either of the “+” ends of the measurement to access the pop-up menu. Hold button and select Delete Measurement from the menu and release button.

Reset W/L



Resets the display to the default Window/Level settings.

12. Troubleshooting

QView Medical, Inc.

Customer Support

(844) 643-9527

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The information in this section is intended to provide steps that may be performed by a user to identify basic problems and possible solutions that can be resolved on-site. Any issues determined beyond the scope of the basic user troubleshooting steps provided in this section should be communicated to QView Medical Customer Support.

The steps provided for a particular solution should be followed in sequence. Move to the next sequential step only if the previous step did not resolve the problem as expected.

Area	Problem	Solution
System Operation	CAD Navigator Image not shown as expected.	<ol style="list-style-type: none"> 1. Press the “Q” Key to bring the up the CAD Navigator Image. 2. Check the System Settings – User Configuration. The CAD Default setting should be set to “Show QView + CAD”. 3. Check the System Display Controls – The CAD Display toggle button should read “Hide CAD”. If it does not, click the button to update the display to show CAD Marks. 4. If the study under review has recently been transferred to the QVCAD system, wait for several minutes for the CAD processing to complete. 5. Log off the system. Log back into the system. 6. If the CAD Navigator Image still does not appear after completing all the steps above, contact QView Customer Support.
	CAD Marks not displayed as expected.	<ol style="list-style-type: none"> 1. Check the System Settings – User Configuration. The CAD Default setting should be set to “QView + CAD”. 2. Check the System Display Controls – The CAD Display toggle button should read “Hide CAD”. If it does not, click the button to update the display to show CAD Marks. 3. Log off the system. Log back into the system. 4. Verify that the CAD Navigator Image is displayed. <ol style="list-style-type: none"> a. If the CAD Navigator Image is displayed, no CAD Marks were generated by the system. b. If the CAD Navigator Image does not appear, contact QView Customer Support.
	Disk Storage Status Warning	<p>The disk available for storing new studies is more than 90% full.</p> <ol style="list-style-type: none"> 1. If you wish to archive some of the studies for later review, contact QView Medical Customer Support for data archival and retrieval. 2. Delete studies no longer needed ensuring each study is stored on PACS or some other archival system. 3. If used disk space does not decrease, contact QView Customer Support.

Area	Problem	Solution
	Nipple marker orange at edge of viewing area	The nipple location is outside the viewing area. 1. Verify that the nipple marker hasn't been unintentionally moved outside the viewing area. 2. Reposition nipple marker, if appropriate. If the actual location of the nipple is outside viewing area, estimate placement outside of the view. The nipple marker will remain orange as long as it is outside of the viewing area.
	Thumbnail image Window/Level settings do not reset to defaults.	Load a study 2 or more studies older or newer than the loaded study then reload the study to restore the thumbnail images to their default W/L settings.
	Sometimes the clock position is removed from a view in the Review protocols.	Perform any review action (e.g. click or scroll) in any image of the view to redisplay the clock position.
New studies	Studies do not show up on Study Selector Screen after several minutes when pushed from ABUS.	Request your facility's system administrator to check that the DICOM configuration of the QVCAD system is properly defined on the ABUS system.
	Studies do not show up on Study Selector Screen after several minutes when pushed from PACS.	Request your facility's system administrator to check that the DICOM configuration of the QVCAD system is properly defined on the PACS.
Display of studies	Not all views displayed as expected	1. Verify number of views originally available on ABUS/PACS system. 2. In QVCAD, go to any review protocol and check thumbnails to see if all available views are shown. 3. If any views are still not appearing as expected, re-send study from PACS/ABUS. 4. If the problem persists, contact QView Customer Support.
Review Dual	Clock positions do not match in Review: Dual with Lock Views checked.	If the crosshair cursor is on the edge of the Coronal Images, move the active point to be fully contained in the Coronal Image of both views.
Annotation Measurements	Unable to move one end of an Annotation measurement that is outside of the image area.	1. Right click on the opposite end of the measurement and select Delete Measurement from the Pop-up menu. Recreate measurement. 2. If both ends of the measurement are outside the image area, delete and recreate the annotation and the measurements.
	Unable to add a new Annotation measurement.	1. Ensure that the Annotation is active (i.e. purple in color). 2. Ensure that there are not already the maximum number of measurements defined for the image to which you are adding the measurement. (See <i>3.2.4d System Display Controls—Annotate Measurements</i>)

13. Appendix

13.1. Appendix I – Quick Start Guide

13.1.1. Loading a Study

- a. Click on Select Study button to open the QView Study Selector Screen.
- b. In the QView Study Selector Screen, double-click on study you wish to review.

Note: If reviewing a case sent immediately to QVCAD, it may take time for all views to be processed by the CAD Engine and available for viewing in Q-Viewer. Views that have been processed by the CAD Engine will have a “QV” appear in the upper left corner of the CAD Navigator image of that view.

- c. Study will be loaded into Q-Viewer in the Default Display Protocol, Overview 8.

13.1.2. Study Overview (Overview Display Protocol) – To quickly get an overview of the entire study at a glance.

- a. Review entire study for any regions of interest (ROI) (e.g. dark areas or system generated CAD Marks).
- b. Select desired ROI for further review. Pause mouse over desired area to activate Hover Mode with adjacent Coronal and Transverse images for the localized area.
- c. While remaining within 1 cm of the desired ROI, use Hover Feature to move through the slices of the Coronal and Transverse images. Once finished reviewing ROI, move mouse to next desired ROI and pause to activate Hover Mode for that ROI.
- d. Click on a specific ROI and Q-Viewer will switch to the Default 3D Review Protocol.

13.1.3. Reviewing the ROI (Review Display Protocol)

- a. In the Default 3D Protocol, the detail images will be displayed at the calculated midpoint position of the ROI. Use the thumbnails to select the desired view.
- b. Use Survey Mode for a detailed review of the entire view.
 - Select desired image to survey.
 - Right click then select Start Survey from the pop-up menu.
 - Review each breast in detail.
 - When finished, right click to Terminate Survey.
 - Repeat for each view.
- c. Make an Annotation for a desired ROI.
 - Right click the ROI then select Annotate in the pop-up menu to bring up the Annotation screen.
 - Complete the information on the Annotation Screen.
 - Click Save to exit the Annotation screen.
 - Repeat for each desired ROI.
- d. To copy the information from the completed Annotation for use in another Annotation.
 - Right click the desired completed Annotation.
 - From the pop-up menu, select Copy Annotation.
 - To paste the copied information, right click the desired Annotation or ROI and select Paste Annotation.
- e. Add a measurement to a desired Annotation.
 - Right click the desired completed Annotation.
 - From the pop-up menu, select Add Measurement.
 - Drag the “+” to the desired locations

Note: For detailed information on using any of the above features, refer to QVCAD System Overview section 3.2 of this user manual.



This document defines the curriculum for training and qualifying QVCAD customers in the use of the QVCAD system.

Training materials, content, images, and studies were developed by and with breast imagers who have extensive experience with 3D Breast Ultrasound. The clinical study results are from QVCAD PMA reader study. Images and image studies used in training conform to HIPAA requirements. The materials relative to QVCAD Device and Operations are from the QVCAD System User Manual.

Training objectives: Build the clinical skills in the users to effectively use QVCAD in ABUS breast interpretation. At the completion of the course, the user will be familiar with the use of the system, its the warnings and precautions, the summary of the P150043 clinical study, and have gained the clinical skills to effectively use QVCAD in ABUS breast interpretation. Each attendee will be evaluated at the end of the session as to his/her effectiveness in using the QVCAD system.

Schedule: Training of users of the QVCAD System to be conducted after installation of the system. The training is a combination of presentation material and hands-on interaction. Qualified QView Medical personnel conduct the training program to instruct the users on the operation of the QVCAD system. The hands-on training includes the following modules:

- System operation,
- Guided self-study.
- User self-study, and
- Proficiency assessment.

As a prerequisite for the QVCAD System training program, the user will have completed the certification program for the ABUS workstation. In registering for the training, the attendee will verify that the certification program for ABUS was completed.

The curriculum consists of two sections as follows:

- **Section 1.** Presentation by Qview Medical personnel - a QVCAD system overview, clinical study summary, and review of warnings and precautions in using the QVCAD System.
 - a. **QVCAD System overview**
 - i. Introduction Labeling (following Section I in QVCAD System User Manual)
 - 1. Indication for Use
 - 2. Device Description and Operation
 - 3. Clinical Study Summaries
 - 4. Labeling
 - 5. Contraindications, Warnings and Precautions.
 - 6. Conformance to Standards
 - 7. Training module on risk avoidance or mitigation.



- ii. Review QVCAD software features and functionality. Instructor guided hands-on case review and systems operation. (Following Section II in QVCAD System User Manual – Instructions for Use.
 - 1. Getting Started.
 - 2. Q-Viewer System Overview
 - 3. Q-Viewer Display Area
 - 4. CAD Navigator Image
 - 5. User operations – cursor and mouse control
 - 6. System control panel and options
 - 7. Trouble shooting
- iii. Recommended Review Protocol with emphasis on:
 - 1. Concurrent review
 - 2. CAD Navigator Image
 - 3. Hover Mode
 - 4. Survey Mode

- **Section 2.**

- a. Guided hands-on review of 5 QView supplied ABUS cases.**

Objectives are to introduce the user to the QVCAD system presentation options.

- i. Hands-on usage of the functionality reviewed above.
 - Step by step review of functions described in QVCAD System User manual. Section 11.2
 - ii. Review annotate function described in System Control Panel 11.2.4.d.
 - Step by step review of annotation functions described in QVCAD System User manual. Section 11.2
 - iii. Cases will initially be read by the user in ABUS mode.
 - iv. After the ABUS review, the user will review the same case with the QVCAD system functions of Navigator Overview, CAD Marks displayed for preview of the case. The user will use the Hover function to initially review the CAD mark. The user will then review the case in detail. The user will enter findings using the Annotation function to complete the case review.

- b. Self-study case review of 5 QView supplied ABUS cases.**

Objectives are to observe the user on the use of the QVCAD functions introduced in Section 2 Part a. The outcome will be the user establishing the preferred methods of review with the QVCAD system. Qview personnel will observe the user using the following activities:

- i. User preferences in review with Q-Viewer Display Areas and established user preferences.
 - ii. User capability in CAD Navigator Image review and further examining the CAD marks and CAD enhanced dark areas.



- iii. User protocol in Overall case review
 - 1. Initial review with navigator overview, and hover
 - 2. Review and dismissal of marks and areas,
 - 3. Use of viewing preferences
 - 4. Detail case review and the use of annotations
 - 5. Use of annotate as described in user manual.
 - iv. At the end of this session, Qview Medical personnel will review each user's preferences and operation as observed in i – iii above. Suggestions may be made if there are areas that may be more clearly defined or understood.
- c. Proficiency Assessment on additional 5 Qview supplied ABUS cases.**
- With the user's preferred method of review, Qview personnel will assess the user in effectiveness in case review:
- i. Case Study selection,
 - ii. Initial review using Navigator Images, Hover, and review of CAD marks and enhanced dark areas.
 - iii. Further review of the case with user preferred protocol,
 - iv. Use of annotation screen as described in System Control Panel 11.2.4.d.
 - v. Use of annotations as described in System Control Panel 11.2.4.d. and Table 20. Annotation Screen Details.
 - vi. Understanding and use of symbols for marks and annotations as described in User Manual Table 21 Symbols – Marks and Annotations.
 - vii. At the end of this session the user will be evaluated and the trainer satisfied that the user correctly reviewed the 5 selected cases – initially reviewing the case, annotating appropriately, and completing the case review in an efficient and effective manner.
- d. Optional session where the system is installed.**
- The user can transfer and review 5 cases to get experience with cases that had been previously reviewed with ABUS only. This is intended to give the user confidence in reviewing his/her own cases.