SOFTVUE™ 3D WHOLE BREAST ULTRASOUND TOMOGRAPHY SYSTEM (SOFTVUE™) PHYSICIAN LABELING

1.0 MANUFACTURER CONTACT INFORMATION

Delphinus Medical Technologies, Inc.
45525 Grand River Ave.
Novi, MI 48374
(248) 522-9600

2.0 PRESCRIPTION USE STATEMENT

Federal law restricts this device to sale to or on the order of a physician. The use of this device is restricted to those who receive the appropriate training.

3.0 INDICATION FOR USE STATEMENT

The SoftVue system is indicated as an adjunct to mammography for breast cancer screening in asymptomatic women with dense breast parenchyma after confirmation that the breast density composition is BI-RADS c or d at the time of screening mammography. The device is intended to increase breast cancer detection in the described patient population relative to mammography alone. The device is not intended to be used as a replacement for screening mammography. The device can be used at the same visit as screening mammography and SoftVue images are intended to be interpreted with the mammogram results of enhance screening.

4.0 CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS

4.1 Contraindications

There are no known contraindications for the use of the SoftVue™ System.

4.2 Warning and Precautions

The warnings and precautions for the SoftVue™ System can be found in the User Manual.

5.0 CLINICAL STUDY SUMMARY

The Delphinus Pivotal Retrospective Reader Study (DMT-2019.002) [RRS3] was an analysis of radiologist [Reader] image interpretation performance utilizing prospectively collected patient data obtained from an independent multi-center Prospective Case Collection Registry (DMT-2015.001) [PCC Registry]. The patient data utilized in RRS3 was collected from a total of six (6) PCC Registry clinical sites across the U.S. The retrospective analysis performed is an observational case-controlled, multi-reader, multi case [MRMC] Receiver Operating Characteristic (ROC) study involving 32 Readers who were MQSA qualified radiologists with experience in breast image interpretation. The cases were comprised of bilateral digital mammography [FFDM] and SoftVue (SV) screening imaging acquired from the same patient during the same screening interval. There were one hundred and forty (140) cases sampled for the Pivotal RRS3 study from a pool of 7,439 asymptomatic female volunteers with BI-RADS c or d breast density, of which thirty-six (36) were proven by pathology to have breast cancer, five (5) were biopsy proven benign lesions, and ninety-nine (99) were confirmed non-cancer after one year of follow-up with normal or negative bilateral mammographic imaging.

The primary endpoint analysis was based on a comparison of a Reader's image assessment for a digital screening mammogram alone (FFDM Alone) vs. the same Reader's image assessment for the same digital screening mammogram paired with a screening SoftVue (SV) exam from the same patient (FFDM+SV). Using the area under the ROC (AUC) averaged across Readers, performance with FFDM alone compared to performance with FFDM + SV was evaluated as a primary objective, where calculation of AUC required that the reader identify the correct breast laterality for malignant lesions. As a secondary objective, the sensitivity and specificity for FFDM Alone vs. FFDM+SV was calculated and averaged across readers, also requiring correct breast laterality of malignant lesions for sensitivity and a non-inferiority margin delta = 0.10 for specificity. Additionally, in order to evaluate reader performance within a context relevant to how SoftVue is intended to be used in actual clinical practice, a supportive analysis of both objectives was performed requiring correct lesion localization within 1.5cm of the cancer biopsy site for AUC and sensitivity. The cancer biopsy site was determined as the area encompassing the locations mapped by a panel of three radiologists. The results of the Pivotal RRS3 are summarized below and demonstrate the safety and effectiveness of SoftVue to enhance the screening process in patients with dense breast to identify suspicious lesions that would benefit from further diagnostic assessment for breast cancer.

Prior to participating as Readers in the Pivotal RRS, each reader completed Delphinus' SoftVue Radiologist Training Curriculum. Equivalent training is required for prescription use of the device. Both trainings consist of self-study video training modules with conceptual testing, as well as hands-on case review training delivered by a physician experienced in SV image interpretation. A self-assessment test is administered to provide users

with feedback on their SV interpretation performance after completing the training curriculum. No readers were excluded based upon the self-assessment outcome. All readers scored above 80%.

During the Pivotal RRS3, each reader interpreted each of the one hundred and forty (140) cases in a unique random order, blinded to the ground truth (cancer vs. non-cancer). For each case, a Reader first interpreted the FFDM Alone, without access to the SV images, using commercially available equipment to display the medical images in a setting that simulated standard practice. Suspicious findings (if any) were marked on the FFDM images. A BI-RADS® assessment category was provided and a malignancy score between 1 and 100 was assigned for FFDM Alone. Upon completing the FFDM alone interpretation, the Reader reviewed the SV exam together with FFDM. Suspicious findings (if any) were marked on the FFDM and SV images, a BI-RADS® assessment category was provided and a malignancy score between 1 and 100 was assigned for FFDM+SV. The primary endpoint was the difference in the reader-averaged area under the ROC curve (AUC) between the FFDM Alone reading and the FFDM+SV reading. A secondary endpoint was the Reader-averaged sensitivity and specificity for FFDM+SV reading compared to FFDM Alone reading.

A complete summary of the RRS3 Endpoint Results is provided below.

5.1 Safety Results

Since this is a Retrospective Reader Study, the safety outcomes are restricted to the Interpreting Physicians (Readers) or Principal Investigator (PI). There were no adverse events reported in these individuals in the study.

5.2 Effectiveness Results

The analysis of effectiveness is based primarily on RRS3 which includes 140 cases with 36 cancers and 104 non-cancers. Additional analyses are provided as supportive of the product's Indications for Use.

5.2.1 Primary Endpoint Results

The results were analyzed in accordance with the Statistical Analysis Plan and associated Supplement to the Statistical Analysis Plans. MRMC RRS comparison of AUCs between FFDM only and FFDM + SV was performed using the standard parametric MRMC analysis of variance (ANOVA) method of Obuchowski and Rockette (1995) to ensure generalization of the study results both to the population of readers and the population of cases [5] and also with the non-parametric MRMC analysis. We obtained the average AUC within each modality and its standard error, and the average difference in AUC for (FFDM + SV) – FFDM only and its standard error. These were used to compute corresponding two-sided 95% CIs for the average AUC within each modality and for their difference quantifying precision in these estimates.

The analysis utilized the malignancy score specified by the readers, to develop the ROC curves.

5.3 Results - RRS3

The results for the laterality-based Primary Endpoint analyses were analyzed in accordance with the clinical study protocol and SAP.

The difference in ROC Curves between Mammography and SoftVue are averaged across the 32 Readers and is pictorially shown in **Figure 1** as the average nonparametric ROC curves. These data were used to calculate the difference in the curves using the statistical methods outlined in the SAP. **Figure 2** presents the comparison of AUC for individual readers comparing FFDM alone versus FFDM + SV.

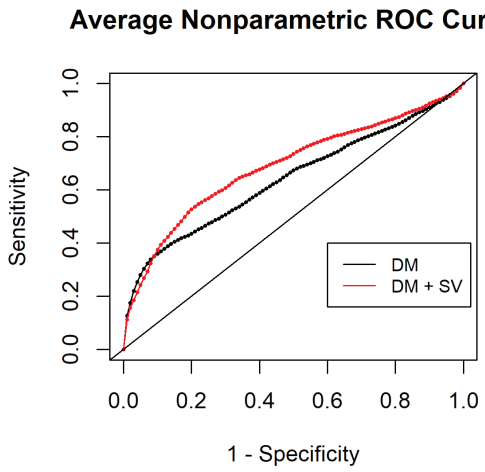

Figure 1: Average Nonparametric ROC Curve for Laterality-Based Analysis

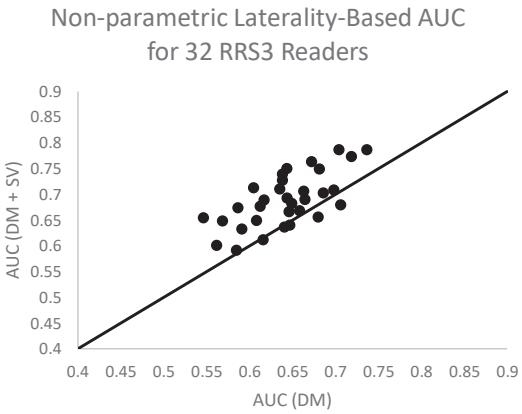

Figure 2: Reader Operating Points for 32 Readers - Nonparametric Laterality-Based Analysis

5.3.1 Primary Endpoint Results – Laterality

The AUC improvement values are shown in **Table 1**. As outlined by the analysis plan, both the non-parametric and parametric results were performed. However, since the ROC plots were so different for the parametric versus non-parametric and the nonparametric ones are unbiased, only the non-parametric analyses are presented here. The p-value did not reach a level of significance for the non-parametric test for this endpoint, however. The sensitivity and specificity results are provided in **Table 2** for completeness. Note that the analysis plan utilized a threshold of BI-RADS4 cases. These analyses were not required however, as the protocol and SAP require that the primary endpoint achieve significance to assess sensitivity and specificity.

Table 1: MRMC Laterality-Based Analysis of AUC using Non-parametric Approach for 32 readers in the RRS3 study and 140 cases (36 cancer, 104 non-cancer)

ROC Model	FFDM (Mean ± Standard Error)	FFDM+SV (Mean ± Standard Error)	Change from FFDM to FFDM+SV		
			ΔAUC (FFDM+SV – FFDM)	95% CI	p-value for test of superiority (two-sided alpha=0.05)
Non-parametric	0.6418 ± 0.0466	0.6897 ± 0.0415	0.0478 ± 0.0257	(-0.0025, 0.0982)	0.0624

Table 2: MRMC Laterality-Based Analysis of Sensitivity and Specificity (BI-RADS 4 Threshold) for 32 readers in the RRS3 study and 140 cases (36 cancer, 104 non-cancer)

	FFDM (Mean ± Standard Error)	FFDM+SV (Mean ± Standard Error)	Change from FFDM to FFDM+SV		
			Δ Sensitivity (FFDM+SV – FFDM)	95% CI	p-value
Sensitivity	0.3837 ± 0.0654	0.4896 ± 0.0621	0.1059 ± 0.0395	(0.0285, 0.1833)	for test of superiority (two-sided alpha=0.05) 0.0073
Specificity	0.8762 ± 0.0214	0.8236 ± 0.0256	-0.0526 ± 0.0180	(-0.0878, -0.0173)	for test of non-inferiority of 10% (one-sided alpha=0.025) 0.0042

5.3.2 Supplemental Analyses Based on Indications for Use and Clinical Utility

Lesion Localization – RRS3

A supplemental analysis of per subject lesion localization is also provided to support the product Indications for Use. The difference in ROC Curves using a non-parametric average across all readers is provided in **Figure 3**. Further, each individual reader performance is provided in **Figure 4,** comparing their lesion localization identification for FFDM vs FFDM + SV.

The result of this analysis, using the same statistical methodology outlined above, ***demonstrated a p-value of 0.0271***; a significant finding (**Table 3**). As such, the sensitivity and specificity are also provided for this per subject analysis. These data provide support for the targeted, proposed indication statement and are believed to provide the relevant outcome.

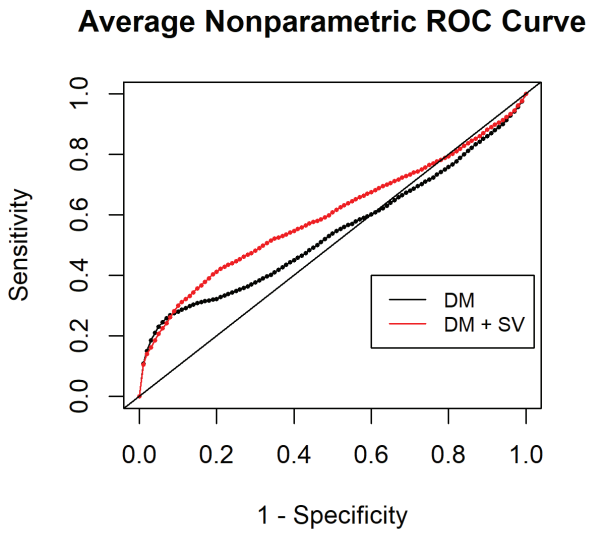

Figure 3: Average Nonparametric ROC Curve for Lesion Localization Analysis

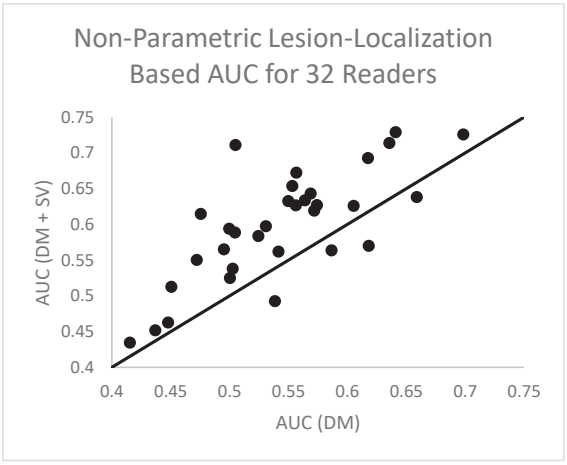

Figure 4: Reader Operating Points for 32 Readers – Nonparametric Based Lesion Localization Analysis

Based upon the significant p-value identified in this supportive endpoint AUC analysis, the sensitivity and specificity were also calculated (**Table 4**) both of which are relevant since the confidence interval for

sensitivity is above zero and p-values < 0.05. The results provide clinically relevant evidence supporting the proposed Indications for Use and clinical utility.

Table 3: MRMC Lesion Localization-Based Analysis of AUC using Non-parametric Approach for 32 readers in the RRS3 study and 140 cases (36 cancer, 104 non-cancer)

ROC Model	FFDM (Mean ± Standard Error)	FFDM+SV (Mean ± Standard Error)	Change from FFDM to FFDM+SV		
			ΔAUC (FFDM+SV – FFDM)	95% CI	p-value for test of superiority (two-sided alpha=0.05)
Non-parametric	0.5436 ± 0.0489	0.5983 ± 0.0459	0.0548 ± 0.0247	(0.0062, 0.1033)	0.0271

Table 4: MRMC Lesion Localization-Based Analysis of Sensitivity and Specificity (BI-RADS 4 Threshold) for 32 readers in the RRS3 study and 140 cases (36 cancer, 104 non-cancer)

	FFDM (Mean ± Standard Error)	FFDM+SV (Mean ± Standard Error)	Change from FFDM to FFDM+SV		
			Δ Sensitivity (FFDM+SV – FFDM)	95% CI	p-value
Sensitivity	0.2977 ± 0.0636	0.3715 ± 0.0630	0.0738 ± 0.0343	(0.0066, 0.1409)	for test of superiority (two-sided alpha=0.05) 0.0314
Specificity	0.8762 ± 0.0214	0.8236 ± 0.0256	-0.0526 ± 0.0180	(-0.0878, -0.0173)	for test of non-inferiority of 10% (one-sided alpha=0.025) 0.0042

Lesion Localization – Partial AUC Analysis

To evaluate the true clinical impact of SoftVue, a partial AUC was assessed based upon the operating point for the Readers. To identify the most appropriate operating point on the AUC curves, the sensitivity and specificity across readers was examined for both BI-RADS3 and BI-RADS4. The points identifying the range for both FFDM and FFDM + SV were used to establish the most clinically relevant operating range of (1-specificity) of 0.1 to 0.6, as shown in **Figure 5**. This range of AUC resulted in a difference of 0.0411, with a corresponding improvement in p-value of 0.0154 (**Table 5**).

Table 5: MRMC Lesion Localization-Based Analysis of Partial AUC using Non-parametric Approach for 32 readers from the RRS3 study and 140 cases (36 cancer, 104 non-cancer) From (1-Specificity) of 0.1 to 0.6

ROC Model	FFDM (Mean ± Standard Error)	FFDM+SV (Mean ± Standard Error)	Change from FFDM to FFDM+SV		
			ΔAUC (FFDM+SV – FFDM)	95% CI	p-value
Non-parametric, partial AUC	0.2134 ± 0.0308	0.2544 ± 0.0294	0.0411 ± 0.0169	(0.0079, 0.0743)	0.0154

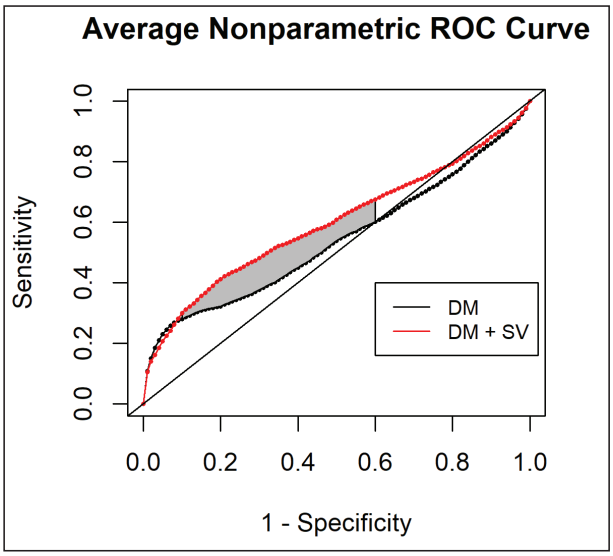

Figure 5: Partial AUC Curve

Additional evaluation of the reader performance based on a threshold of BI-RADS3 is considered as a supplemental analysis in addition to a BI-RADS4 threshold to provide a comprehensive presentation of the study results. **Figure 6** and **Figure 7** show the individual reader performance results as depicted on a scattergram of (1 – Specificity) vs Sensitivity for a BI-RADS3 threshold (**Figure 6**) as well as the BI-RADS4 threshold. **Figure 6** shows that when individual reader performance is evaluated for a threshold of BI-RADS3, sensitivity improves with a trend towards significance and strikingly, specificity improves with a statistical improvement (two-sided p=0.04). This is illustrated by the shift of the FFDM performance (Dark Blue Circle) up and to the left to the SoftVue performance (Dark Orange diamond) to have improved the Sensitivity by 0.066 (two-sided p=0.08) coincident with improved Specificity by 0.058 (two-sided p=0.04). This is a clinically important outcome since BI-RADS 3 patients pose a particularly challenging clinical situation to physicians. The data demonstrate that with BI-RADS 3 lesions, there is both increased sensitivity and increased specificity as the curve moves up and to the left. This is especially helpful in the clinical situation of BIRADS 3 since management of these patients requires a six month wait to see if there is an increase in the size of the lesion and if so, then biopsy is indicated. In BI-RADS 3 lesions, the ability to increase sensitivity with concomitant increase in specificity will allow for improvement in cancer detection without an increase in biopsy rates, particularly critical in these patients for whom the six-month wait can result in later stage diagnosis.

The performance noted for BI-RADS 4 subjects **(Figure 7)** demonstrates an increase in sensitivity by 0.074 (two-sided p=0.03) when SoftVue was combined with mammography, as noted by the shift upwards from the Dark Blue Circle to the Dark Orange Diamond. This improved sensitivity was at a tradeoff in decreased specificity by 0.053 which is not unexpected. Since the BI-RADS4 subjects have a higher likelihood of cancer, the increase in potential biopsies is anticipated and this tradeoff is considered reasonable.

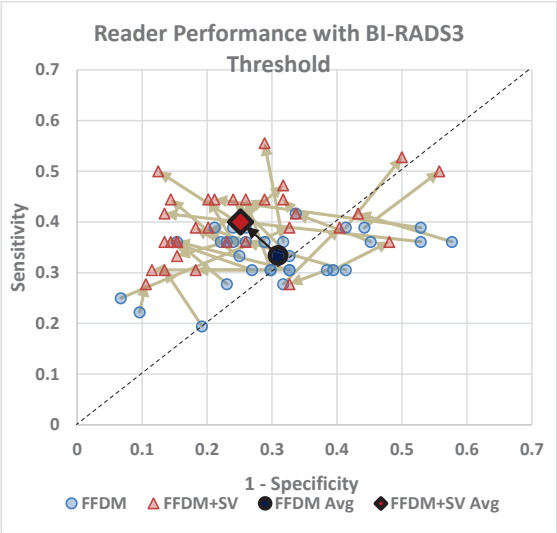

Figure 6: **Individual Reader Performance Threshold BI-RADS 3: Average Reader Performance from FFDM (Dark Blue Circle) to FFDM with SV (Dark Orange Diamond) illustrate the improvement in both Sensitivity (0.066, two-sided p=0.08) and Specificity (0.058, two-sided p=0.04) when BI-RADS3 case threshold are analyzed.**

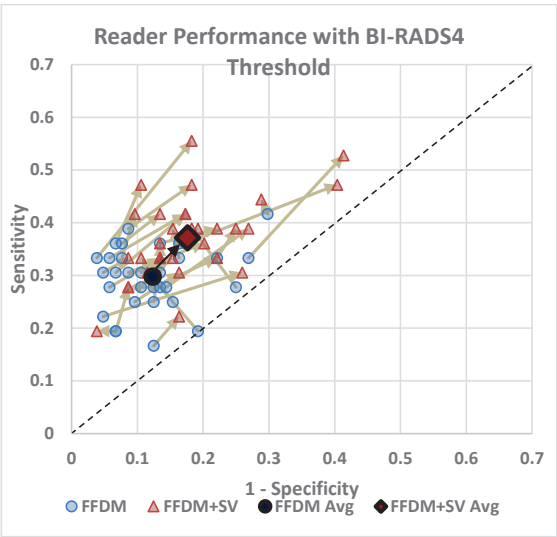

Figure 7: **Individual Reader Performance Threshold BI-RADS 4: Average Reader Performance from FFDM (Dark Blue Circle) to FFDM with SV (Dark Orange Diamond) illustrate the improvement in Sensitivity (0.074, two-sided p=0.03) with a decrease in Specificity (0.053) when BI-RADS4 case threshold are analyzed.**

6.0 SUMMARY OF SUPPLEMENTAL CLINICAL INFORMATION

The RRS3 study provides the pivotal data on AUC improvement, sensitivity and specificity of SoftVue as a screening tool in comparison with digital mammography. Based upon the original SAP, the improvement in AUC was measured as 5.48% absolute improvement over mammography which corresponds to a relative improvement of +10.08% which is statistically significant with a two-sided p-value of 0.0271.

This AUC improvement corresponds with an absolute Sensitivity improved of 7.38% which is associated with a relative improvement of +24.79%. This improvement in sensitivity is balanced by a Specificity decrement of -5.26% which corresponds with a -6.00% relative decrement. In addition, a partial AUC curve targeted around the operating region of the readers was determined based upon the actual reader performance. This result improved the two-sided p-value on SoftVue performance to p=0.0154.

Additional evaluation of the reader performance as a supplemental analysis was performed based on a threshold of BI-RADS 3 in addition to a BI-RADS4 threshold to provide a comprehensive presentation of the study results. When individual reader performance was evaluated for a threshold of BI-RADS3, both sensitivity (+6.66%, two-sided p=0.08) and specificity (+5.77%, two-sided p=0.04) are improved. The average individual performance results with a BI-RADS4 threshold demonstrated an increase in Sensitivity (+7.38%, two-sided p=0.03) with a decrease in Specificity (-5.26%) which is the tradeoff typically noted in AUC performance clinical studies.

The summary of study results is provided in **Table 6** below.

Table 6: RRS3 Clinical Study Results

Study	% Relative Change ([FFDM+SV – FFDM alone]/FFDM alone)	Δ (FFDM+SV – FFDM alone)	95% Confidence Interval
Δ AUC – Laterality			
Primary Analysis	7.45%	0.0478	(-0.0025, 0.0982)
Δ AUC - Lesion Localization			
Supportive Analysis	10.08%	0.0548	(0.0062, 0.1033)
Partial Δ AUC - Lesion Localization			
Supportive Analysis	19.26%	0.0411	(0.0079, 0.0743)
Δ Sensitivity – Laterality (BI-RADS 4 Threshold)			
Primary Analysis of Secondary Endpoint	27.60%	0.1059	(0.0285, 0.1833)
Δ Sensitivity – Lesion Localization (BI-RADS 4 Threshold)			
Supportive Analysis	24.79%	0.0738	(0.0066, 0.1409)
Δ Specificity (BI-RADS 4 Threshold)			
Primary Analysis of Secondary Endpoint	-6.00%	-0.0526	(-0.0878, -0.0173)
Δ Sensitivity – Lesion Localization (BI-RADS 3 Threshold)			
Supportive Analysis	19.75%	0.0660	(-0.0085, 0.1404)
Δ Specificity (BI-RADS 3 Threshold)			
Supportive Analysis of Secondary Endpoint	8.35%	0.0577	(0.0034, 0.1120)

As noted in **Table 6** above, screening mammography with SoftVue can enhance the ability of clinicians to identify suspicious breast lesions in patients with dense breasts. Lesion localization is a key outcome to support the intended use of SoftVue. Based on the results of RRS3, screening mammography with SoftVue provided an increase in sensitivity (lesion localization based) and an increase in specificity for those cases with BI-RADS3, a positive both for sensitivity and specificity, but a decrease for BIRDADS4 which is not unexpected since most modalities require additional biopsies to detect additional cancers. These data support the proposed clinical indication for the product and supports the overall risk to benefit ratio of SoftVue being added to screening mammography to address the limitations of mammography in dense breast patients.

Delphinus Medical Technologies

SoftVue™

User Manual

750-00131 Rev 0.12

Issue Date: 2021-09-28


Delphinus
SoftVue

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Note that the trademark symbol "™" and the registered trademark symbol "®" may or may not be used in this manual.

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Table of Contents

Chapter 1: Introduction

1.1 Preface

This User Manual is written for healthcare professionals who operate the SoftVue™ system. The SoftVue™ system is a product of Delphinus Medical Technologies, Inc.

1.2 About this Guide

This guide describes how to use the SoftVue™ system to conduct a whole breast ultrasound exam.

In order to optimize the system's utilization, users must follow the prescribed clinical procedure for the specific exam to be conducted.

1.3 Indication for Use

The SoftVue system is indicated as an adjunct to mammography for breast cancer screening in asymptomatic women with dense breast parenchyma after confirmation that the breast density composition is BI-RADS c or d at the time of screening mammography. The device is intended to increase breast cancer detection in the described patient population relative to mammography alone. The device is not intended to be used as a replacement for screening mammography. The device can be used at the same visit as screening mammography and SoftVue images are intended to be interpreted with the mammogram results to enhance screening.

1.4 Contraindications

- There are no known contraindications.

1.5 Warnings

- To avoid risk of electric shock, this equipment must only be connected to a mains supply (general purpose AC power) with protective earth (ground).
- Since water is used in the presence of electricity, the user shall take the necessary precautions to avoid electrical shock to the patient and/or user. Discontinue use of the SoftVue™ system where an electrical ground is not established or there is frayed/damaged cable and/or wire insulation.
- Existing diagnostic, monitoring, or therapeutic electronic equipment in the clinical environment may interfere with the operation of the SoftVue™ system . Carefully select equipment that will be used in the vicinity of the system to ensure that electromagnetic interference does not occur.
- As with all electrical medical equipment, this equipment may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take measures such as re-orienting or relocating the SoftVue™ system or shielding the location.
- No modification of this equipment is permitted.
- To ensure the SoftVue™ system images the entire breast and chest wall, only breasts that do not exceed the maximum allowable diameter and/or length should be scanned. Refer to Section 2.4.1 for the maximum allowable diameter and length (when submerged in water).
- To ensure the structural stability of the SoftVue™ system, patients shall not exceed 350 lbs (159 kg) in weight and 6 ft 6 in. (198 cm) in height.
- The user shall ensure drains function properly and spills are cleaned up immediately to prevent a slip and/or fall hazard.

- To prevent falling injuries, patients should use caution while mounting and dismounting the SoftVue™ examination table. A medical grade step stool is provided with SoftVue™.
- Required by the Health Insurance Portability and Accountability Act (HIPAA) of 1996 and the European Union Data Protection Directive (95/46/EC), health care providers who maintain or transmit health information must implement appropriate procedures to ensure the integrity and confidentiality of the information and protect against any reasonably anticipated threats or hazards to the security, integrity, unauthorized uses or disclosures of the information.

1.6 Precautions

- Federal law restricts this device to sale by or on the order of a Physician.
- This equipment is intended for use by healthcare professionals only.
- Only a SoftVue™ trained and certified physician or radiologist shall interpret SoftVue™ images.
- Setup and service of the SoftVue™ system shall be performed by Delphinus representatives.
- Only SoftVue™ trained and certified clinical personnel shall operate the SoftVue™ system. A thorough understanding of the technical principles, clinical applications, and risks associated with the device are necessary for proper use.
- Failure to read and implement the information provided in this manual may affect system use and result in poor image quality, premature wear of the system components, or serious injury to the patient and/or user.
- To maintain optimal performance of the SoftVue™ system, recommended calibration and maintenance schedules of the Transducer and other components must be followed, as specified in this manual.
- To ensure the safety of the patient and user and to prevent potential for injury, do not use an apparently malfunctioning device.
- Lactating patients, patients with nipple discharge, or patients who have breached or compromised skin are not to be scanned using the SoftVue™ system.
- Care should be taken when positioning patients who have pain or limited mobility of the neck, arm, back, hips, legs and/or have balance issues as lying prone on the elevated scan table is required for the SoftVue™ exam.
- Rarely, bruising of skin may occur. The SoftVue™ operator should take care to ensure the appropriate suction level setting is used on each patient to maximize breast extension without causing harm to the patient.
- Female patients who are in the early stages of pregnancy may be scanned by the SoftVue™ system with a physician's recommendation. Patients in the later stages of pregnancy may be scanned at their physician's discretion provided they are comfortable lying prone (i.e. face down on stomach).
- The SoftVue system is an ultrasound system. It is well established that the use of ultrasound in women with implants and with pacemakers is safe. However, the presence of an implant or pacemaker may impact image quality with SoftVue. It is the responsibility of the physician to exercise clinical medical judgement in their determination to scan patients with implanted medical devices in the chest wall region and to assess image quality prior to interpretation.

- All jewelry from the head, neck, and chest areas, must be removed prior to initiating image acquisition.
- To prevent premature damage and inadequate disinfection of the SoftVue™ instruments and materials, use the properly identified cleaning and disinfecting agents as specified in this manual. The imaging chamber and table top should be cleaned between each patient and disinfected periodically according to the guidelines specified in Chapter 4 of this manual.
- While performing system maintenance, the user should take care to avoid contact with the transducer with the brush or brush handle.
- To prevent overheating, do not block the SoftVue™ system's housing air grates. The system must be placed in a well-ventilated, climate-controlled area free from obstruction.
- To prevent disruptions in system operation, the system should not be kept on for extended time periods. If the system happens to be left on for more than 12 hours (e.g., overnight), please reboot the system before using it.
- The SoftVue™ system is intended to remain in one location. If it becomes necessary to move the system, contact a Delphinus Service Representative.
- It is possible that very small suspicious masses or cancers may be missed in the retro-glandular region which extends into the axillary tail.
- SoftVue™ is not guaranteed to improve every reader's performance under normal and customary criteria for deciding between BIRADS 3 and 4.
- The device may not offer improved performance over mammography without reader training to maximize device performance by adjusting the diagnostic threshold of the reader.
- Softvue™ detects and distinguishes between normal (BI-RADS 1 and 2) and abnormal (BI-RADS 3 and higher) lesions with improved specificity and sensitivity, as compared to FFDM alone.
- SoftVue detects and distinguishes between suspicious (BI-RADS 3) and biopsy-indicated (BI-RADS 4 and higher) lesions, with an increase in sensitivity, but a comparable decrease in specificity, as compared to FFDM alone.

1.7 System Requirements

- Single phase 208V/230V power outlet.
- System mains power must be permanently wired to a 50 A circuit breaker with a means of simultaneous isolation from mains on all poles.
- Fresh water source with a minimum pressure of 172 kPa (25 PSI) and minimum flow of 10 L/min (2.7 gal/min).
- Floor drain/Continuous drainage source with a minimum capacity of 3 L/min (0.8 gal/min).
- Networked Picture Archiving and Communication System (PACS) server (not included with the system).
- Digital Imaging and Communications in Medicine (DICOM) compatible viewing source (not included with the system).

1.8 Optional Site Services

The SoftVue™ system has optional communication compatibility with the following network systems:

- Networked Radiology Information System (RIS) server (not included with the system) for patient information retrieval.
- Networked File Transfer Protocol (FTP) server (not included with the system) to transfer raw data.
- Networked Network Time Protocol (NTP) server (not included with the system) for time synchronization of the system with an external source.
- Networked Dynamic Host Configuration Protocol (DHCP) server (not included with the system) for dynamic IP assignment of the SoftVue™ system's external network interface.
- Networked Domain Name System (DNS) server (not included with the system) for domain name resolution of hostnames.

	***NOTE:*** *For proper implementation, network devices require compliance to the SoftVue™ DICOM Conformance Statement (not included in this manual – reference separate documentation for more information).*
	***NOTE:*** *For information on cyber-security precautions in SoftVue™, refer to the SoftVue™ Atlantic Disclosure Statement for Medical Device Security (not included in this manual – reference separate documentation for more information).*

1.9 Image Viewing Recommendations

The SoftVue™ system outputs coronal DICOM images, compatible with standard 2D and 3D DICOM image viewing software.

Delphinus recommends the use of SoftVue™-specific viewing software, which has features and layouts to support efficient review of SoftVue™ exams. Contact Delphinus for more information.

Based on the SoftVue™ reconstructed image/grid size, a monitor resolution of 2560x1600 (4MP) or greater is recommended for optimal viewing.

1.10 Operation Cautions

1.10.1 Installation

Do not attempt to install the system. Delphinus Service Representatives and/or designees will install and setup the system.

1.10.2 Additional Components

The SoftVue™ system has been developed, tested, and approved as a complete system. Use of the system is authorized only in conjunction with related Delphinus equipment described in Chapter 7: Components List.

1.10.3 Maintenance of Electrical Safety

The SoftVue™ system is designed to meet AAMI/NFPA electrical safety requirements. Never attempt to remove or defeat the electrical ground or EMI shielding.

1.10.4 Maintenance of Patient Safety

Verify that all electrical and water connections are in place, secure, and connected to the SoftVue™ system before attempting to operate the system.

1.10.5 Environment

Apart from the water that is required for system operation, and cleaning solutions needed for disinfection, SoftVue™ should not be exposed to moisture or liquids of any kind.

Do not operate the system below sea level or above 1645 m (5400 ft) above sea level.

System operating specifications are between 10 °C (50 °F) to 25 °C (77 °F).

1.10.6 Storage Requirements

The SoftVue™ system does not need to remain connected to mains power when not in use. Store in a cool, dry place. Maintain the following atmospheric conditions:

Temperature	% Relative Humidity	Pressure
5°C (41°F) – 43°C (110°F)	10% – 75% Non-condensing	700 to 1060 hPa (10 to 15 PSI)

1.10.7 Disposal

Collect separately from other household waste. (See European Commission Directive 2002/96/EC (WEEE)). Refer to local regulations for proper disposal.

1.11 Receiving Sequr™ Breast Interface (SBI) Deliveries

Delivery of the SBI will include the reception of a minimum of 1 case of 36 SBI units. The SBI units can be stored in the full case of 36 units, or in the smaller shelf boxes of 6 units each. Both boxes are required to be stored in the orientation indicated on the boxes. An SBI case is shown in Figure 1 below.

Figure 1: SBI Case

The SBI case contains a QR code that must be used to register the case with the SoftVue™ system before using any of the SBI units contained in the case. The QR code must be scanned by navigating to the Sequr™ status screen (section 3.6.5) and scanning the QR code with the reader attached to the display, shown in Figure 2 below.

Figure 2: QR Code Reader

Once the case has been scanned into SoftVue™ and the SBI shelf boxes have been unpacked from the case for storage, the case can be disposed of in regular recycling.

The external case will contain two temperature indicators as shown below in Figure 3.

Figure 3: Temperature indicators

Upon receiving, the indicators should be inspected. In the event that either indicator is activated as shown below in Figure 4, please contact support as indicated in section 8.1.

Figure 4: Activated temperature indicators

The SBI shelf boxes should be stored in a temperature-controlled environment with temperature between 0 °C and 50 °C (32 °F and 122 °F).

Chapter 2: System Overview

2.1 System Description

The SoftVue™ system is a 3D whole breast tomographic ultrasound imaging device that incorporates a circular transducer design, using water as a coupling agent, to examine human breast tissue.

2.2 Principles of Operation

The SoftVue™ system creates medical ultrasound images of the breast from the transmission and reception of mechanical high-frequency waves applied through a circular-array transducer. The ultrasound pulses propagate through the breast, producing reflections when differences in tissue density occur, such as between skin, adipose tissue (fat), and connective tissue. Resulting echoes return to the transducer and are converted to electrical signals, greatly amplified and processed by analog and digital circuits. The high-frequency analog signals, transformed into digital image data stored in memory, are reconstructed into the two-dimensional ultrasound images.

During a patient imaging procedure, the SoftVue™ transducer acquires ultrasound data along a series of positions around the breast. Tomographic image slices are acquired as the transducer indexes up from the nipple to the chest wall in 2.0 mm increments, scanning the entire breast. Resulting image data are temporarily stored in the SoftVue™ system's local memory in a DICOM-conformant format. These images are transferred to external DICOM storage, such as a networked Picture Archiving and Communication System (PACS) server. DICOM viewing software can be used to display the image data sets, providing volumetric interpretation of the entire breast.

All signal transmission, reception, and processing characteristics are optimized and controlled within the system. The user cannot alter any characteristics or features of the system.

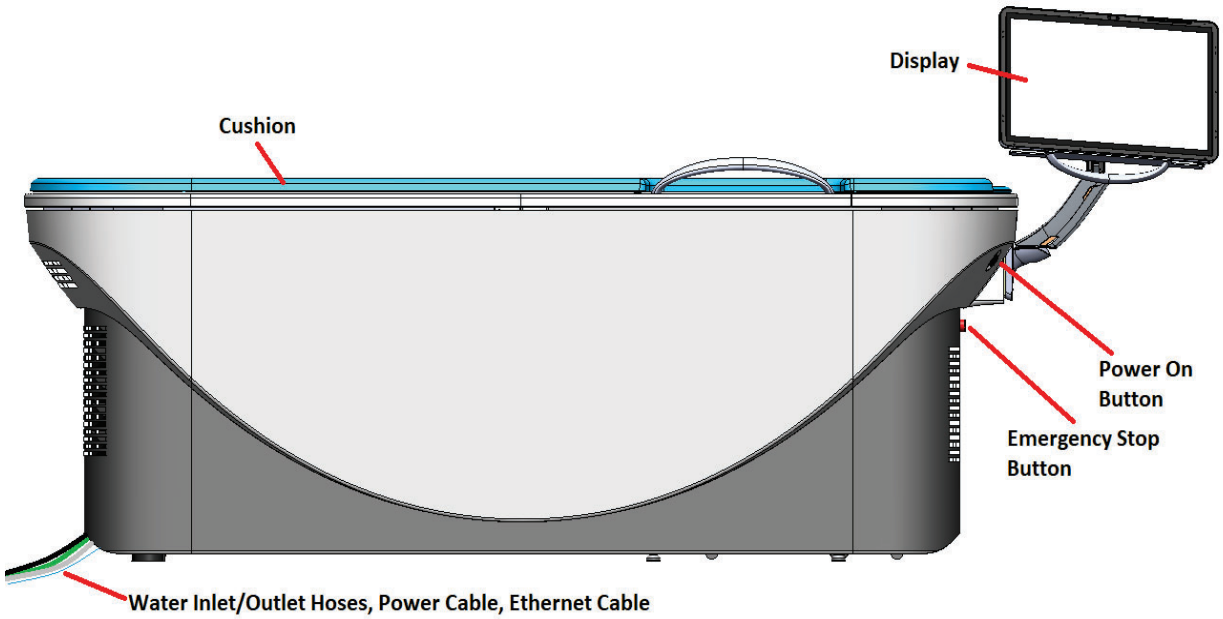
2.3 Applied Parts

The SoftVue™ system includes Type B applied parts. These include the transducer, table top, water in the imaging chamber and Sequr™ Breast Interface.

2.4 Component Overview

The SoftVue™ system is shown in Figure 5 below.

Figure 5: SoftVue™ System



A patient interface membrane is incorporated into the front half of the examination table. The patient's breast is placed through the interface membrane and into an imaging chamber that is filled with warm water. Two live-streaming video cameras located in the base of the imaging chamber aid the user in the positioning of the breast. The video images are displayed on the touchscreen display which is mounted on the swivel arm. The touchscreen display is also used to enter patient information and control the SoftVue™ system.

Under normal operating conditions, the green colored **Power On** button is used to turn the SoftVue™ system "On". In the unlikely event of an emergency, there is a red colored **Emergency Stop** button (see Figure 5 for the exact location of the button) that will immediately shut off the system.

2.4.1 Patient Interface

The patient's breast is placed into the imaging chamber through the center of a latex-free, flexible membrane that contours to the chest wall to maximize imaging of the posterior tissue. The nipple is guided into the center of the Sequr™ Breast Interface. The Sequr™ Breast Interface is a soft, gel interface that engages with the front of the breast to center, shape and steady it during the scan.

The maximum allowable breast diameter is 22 cm (8.66 in.) and the maximum allowable breast length (when submerged in water) is 13 cm (5.12 in.).

The imaging chamber is located directly below the flexible membrane. The water is kept at approximately body temperature (37°C (99°F) to 43°C (110°F)) and is drained and replaced after each patient.

The imaging chamber and table top should be cleaned between each patient and disinfected according to the guidelines specified in Chapter 4: Service and Maintenance of this manual.

2.4.1.1 Imaging Chamber

The SoftVue™ imaging chamber is fully visible when the table top is open. Sensors monitor water temperature and water level in the chamber. A funnel with overflow and drainage channels collect water that may overflow during patient positioning.

2.4.1.2 Transducer

The SoftVue™ transducer consists of a ring-shaped assembly that surrounds the patient's breast. It transmits and receives ultrasound data from transducer elements along the circumference of the ring assembly surface.

2.4.1.3 Sequr™ Breast Interface

The Sequr™ Breast Interface (SBI) is a single-patient use consumable. The SBI rests on the platform of the carriage and is designed to accommodate all breast sizes. When suction is turned on, the carriage height will adjust automatically as the breast comes in contact with the SBI to ensure optimal extension during the imaging.

2.4.2 Display

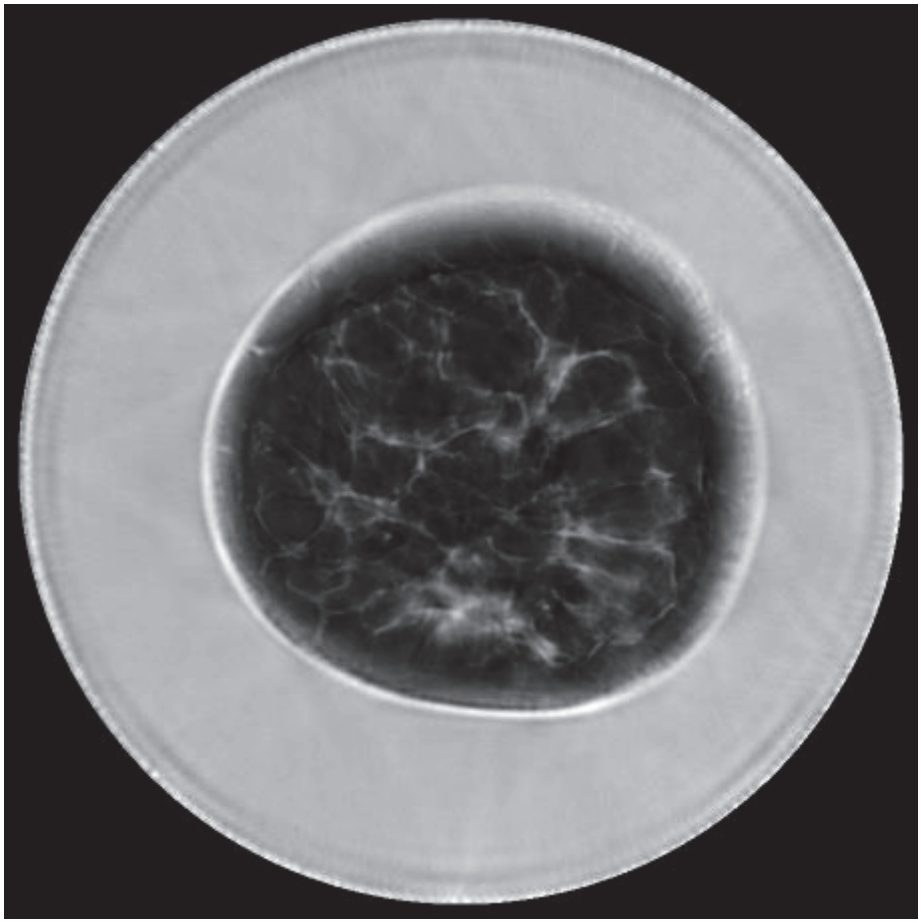
The SoftVue™ display is a single-touch interactive Graphical User Interface (GUI) that presents text and graphical data, allowing the user to control and monitor the system status, enter and review patient data, and observe a live video feed that aids the operator in the positioning of the patient's breast.

Drop-down menus on the GUI require the menu to be pressed and held for one second to open and display the options that can be selected.

2.5 Image Description & Measurements

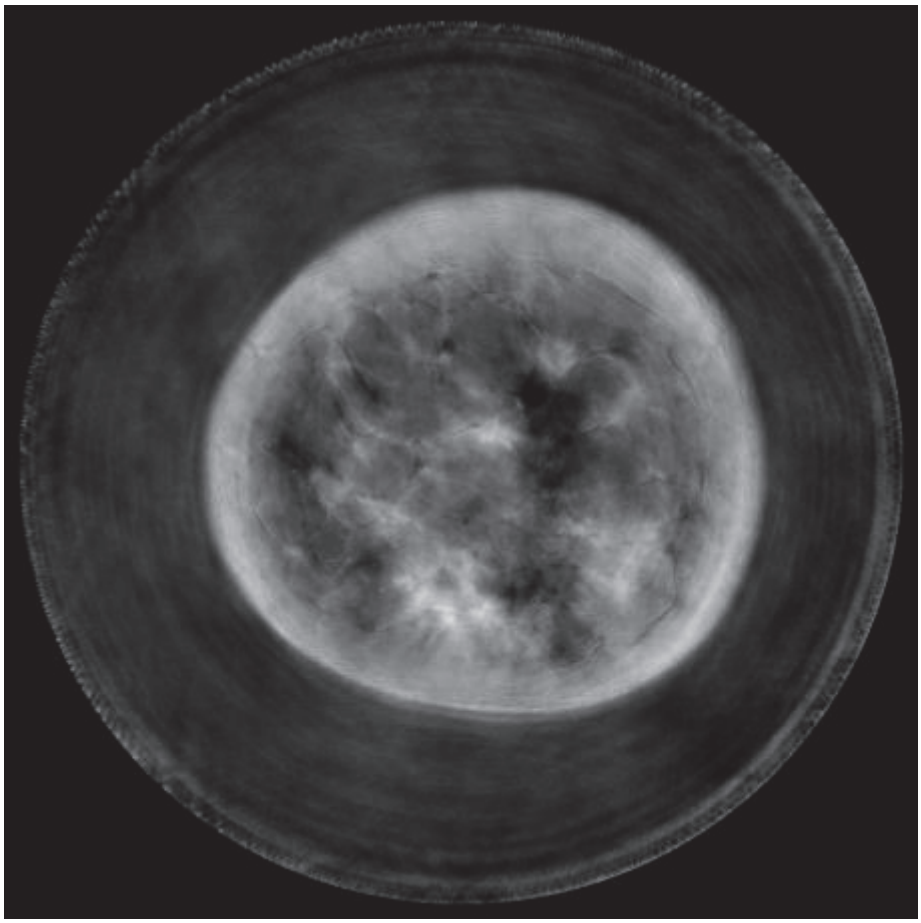
SoftVue™ outputs five image modalities: Sound Speed, Attenuation, Reflection, Relative Stiffness, and Waveform Enhanced Reflection (Wafer). An example and description of each modality follows.

Figure 6: Sound Speed Image



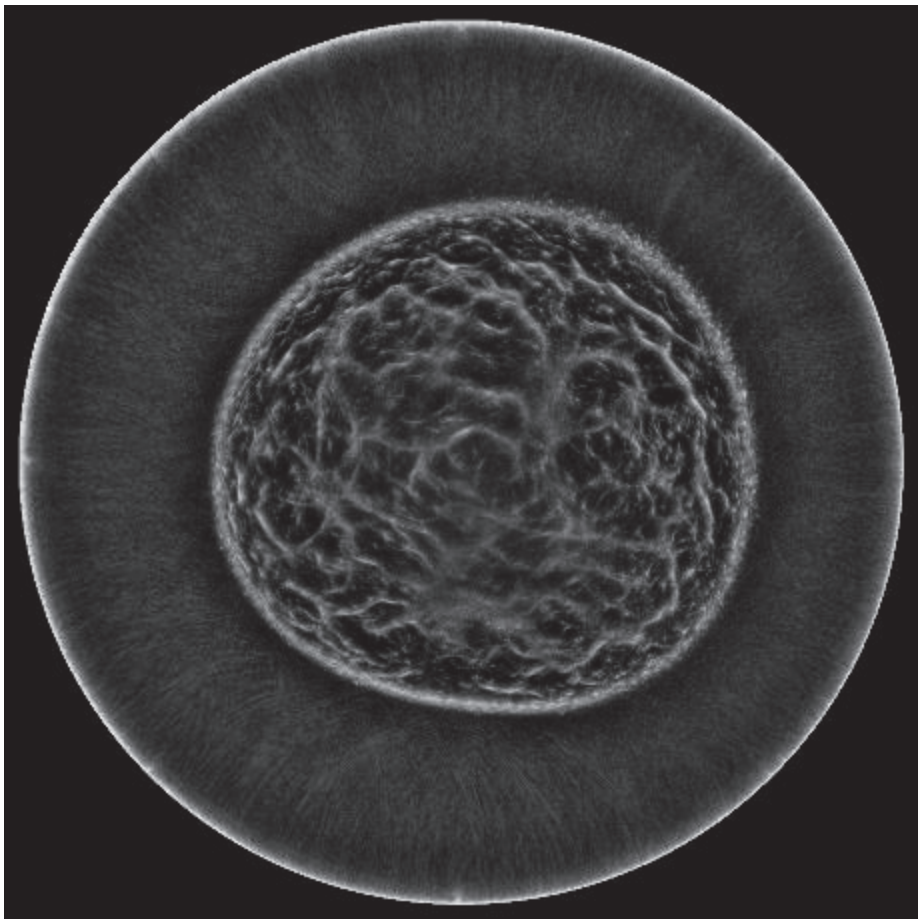
The sound speed image represents the local propagation velocity of ultrasound. The units of this image are meters per second.

Figure 7: Attenuation Image



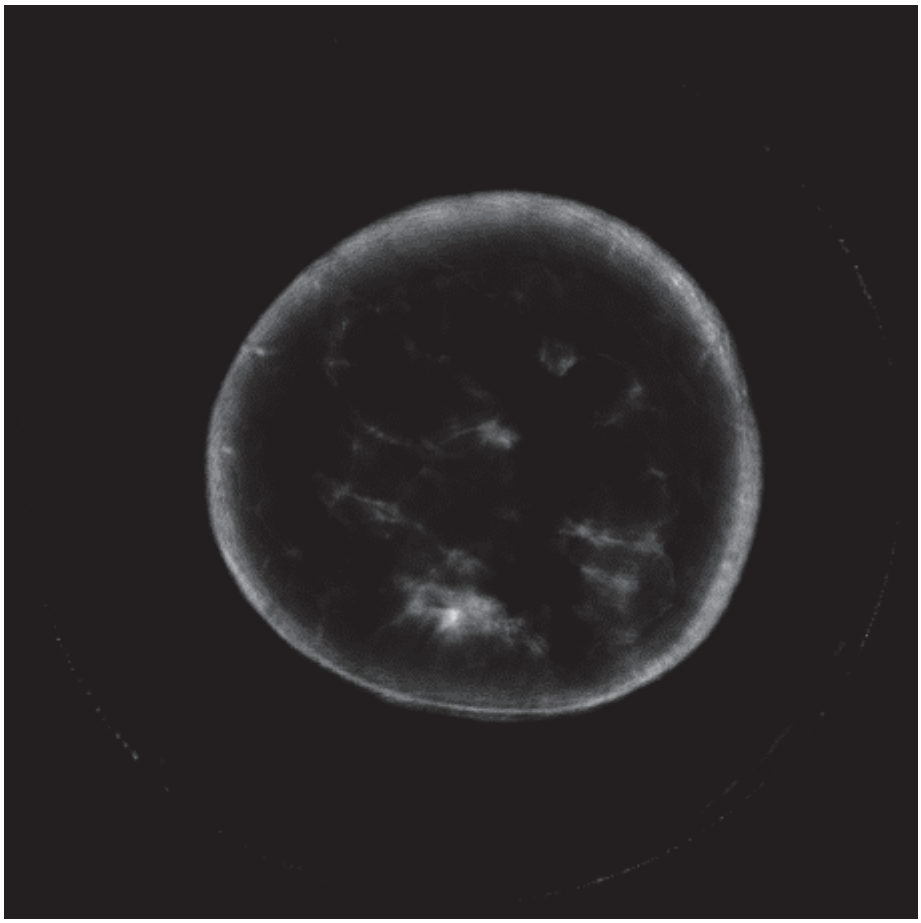
The attenuation image represents the local total attenuation of ultrasound. The units of this image are decibels per meter per megahertz.

Figure 8: Reflection Image



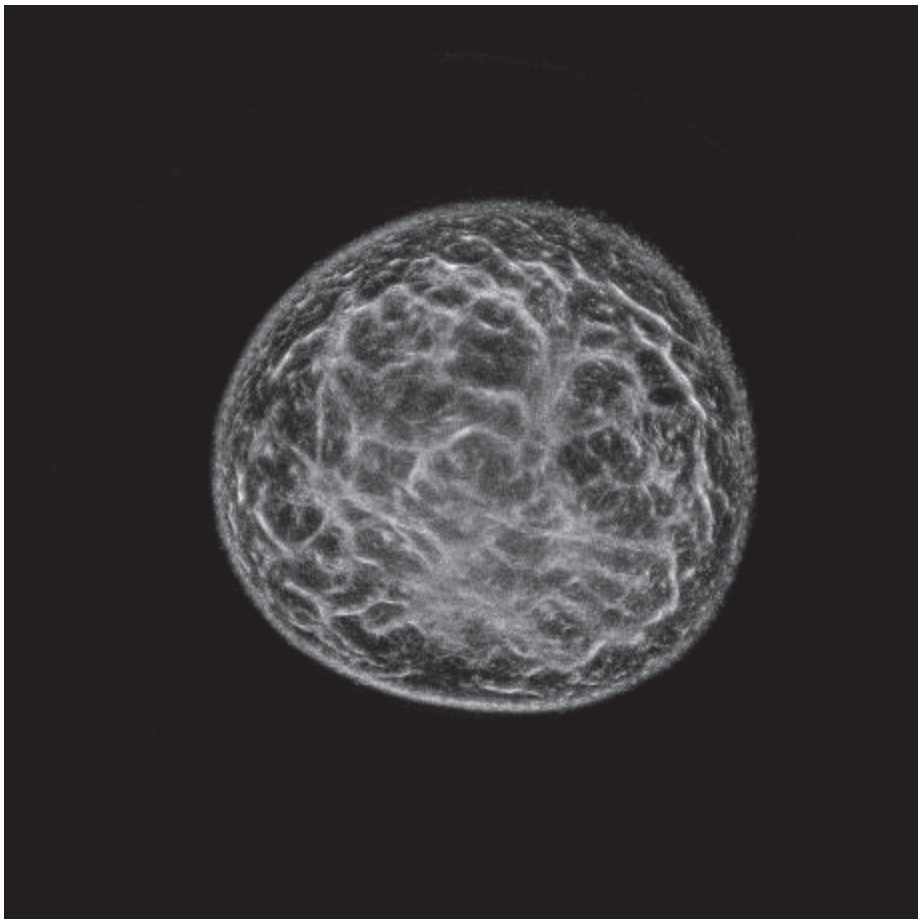
The reflection image represents the relative intensity of reflected ultrasound. This image is unitless.

Figure 9: Relative Stiffness Image



The stiffness image represents the relative stiffness of the imaged medium. This image is unitless.

Figure 10: Wafer Image



The waveform enhanced reflection (wafer) image represents the relative intensity of reflected ultrasound. The wafer image differs from the reflection image in that its contrast has been adjusted by the sound speed image, with areas of higher sound speed being displayed as darker and areas of lower sound speed being displayed as lighter. The wafer image is unit-less.

Table 1 below provides the clinical measurements possible with the output images of the SoftVue™ system and the range over which the measurement accuracy is expected to be maintained.

Table 1: Clinical Measurement Accuracy

Image Modality	Measurement	Accuracy
Attenuation	Distance	< 15% for 1 cm; < 5% for 15 cm
	Pixel Value	± 0.8 dB/cm/Mhz; 0-10 dB/cm/MHz
Reflection	Distance	< 15% for 4 mm; < 5% for 15 cm
Sound speed	Distance	< 15% for 1 cm; < 5% for 15 cm
	Pixel Value	± 10 m/s; 1400-1600 m/s
Relative Stiffness	Distance	< 15% for 1 cm; < 5% for 15 cm
Wafer	Distance	< 15% for 4 mm; < 5% for 15 cm

Chapter 3: Operation

3.1 System Initialization

The main power to the system is enabled by pressing the green **Power On** button located near the touchscreen display on the system housing.

> ***NOTE:*** *The user must ensure that the water supply to the SoftVue™ system is open before system initialization.*

The Delphinus logo will appear on the display screen signifying that the power-on sequence has initiated. Once the applications have properly started, the User Login screen will display (Figure 13) and system initialization will proceed in the background.

System initialization will power on and establish communication between the SoftVue™ subsystems. System initialization will also reset the imaging chamber and start filling the system's internal water reservoir. Do not place hands or any other foreign objects into the imaging chamber during initialization.

Once initialization is complete, the system will run status checks within the subsystems. The Exam and Calibration procedures will be unavailable until these steps are completed successfully. System initialization and system check combined take approximately 20 minutes. During this time the user may hear noise from the system as it prepares itself for the first patient of the day.

Initialization and system check progress and status can be checked in the System Status screen available from the Home screen after the user has logged in (see Section 3.6).

> ***WARNING:*** *The user should never unplug the system while in operation. Use the emergency switch located on the front of the table to power down the system in the event of an emergency.*

3.2 Keyboard

Fields throughout the SoftVue™ graphical user interface (GUI) that permit manual entry can be edited using the soft keyboard incorporated in the touchscreen display (Figure 11).

Figure 11: Keyboard

To display the keyboard, touch any text field on the touchscreen display. The keyboard will appear at the bottom of the screen. The keyboard will disappear when a field is not selected.

NOTE: *Password fields are populated with masking characters instead of clear text characters as they are entered.*

Table 2 identifies the list of special keys and their functions.

Table 2: Special Key Functions

Key	Function
Tab	Continues to the next text field.
Caps Lock	Locks all alphanumeric letters as their capital letter character. Tap again to unlock.
Shift	Displays capital letters and alternate special characters (see Figure 12). Tap again to disable. The shift modification will end after entering any single character. Some fields will automatically enable the shift modification as the default for the first character entry to aid in capitalization of proper nouns.
Clear	Deletes all characters in the field. Disabled if the field is empty.
Backspace	Deletes the previously entered character, or the selected characters if a selection has been made. Disabled if the field is empty.
Enter	Submits the information entered on the screen.
Select	Selects all characters in the field. Replaced with Deselect key when any portion of the field is selected. Disabled if the field is empty.
Deselect	Deselects all characters in the field. Replaced with Select key when no portion of the field is selected.

Figure 12: Shift Enabled Keyboard

3.3 Login Screen

Upon startup, the Login screen will appear (Figure 13).

Figure 13: Login Screen

A registered user can log into the system by entering a secure **Username** and **Password**.

If the user enters invalid credentials, a warning message will appear. The user must acknowledge the invalid entry before attempting to re-enter the username and password. No limit is enforced on the number of failed login attempts.

If login issues persist, or if you are a new user in need of a user profile, an Administrator must be contacted to reset the user password. Refer to Section 3.9.5 for user profile management.

When the **Login** button is tapped, upon successful verification of the user credentials, the Home screen will appear.

3.3.1 Shutdown

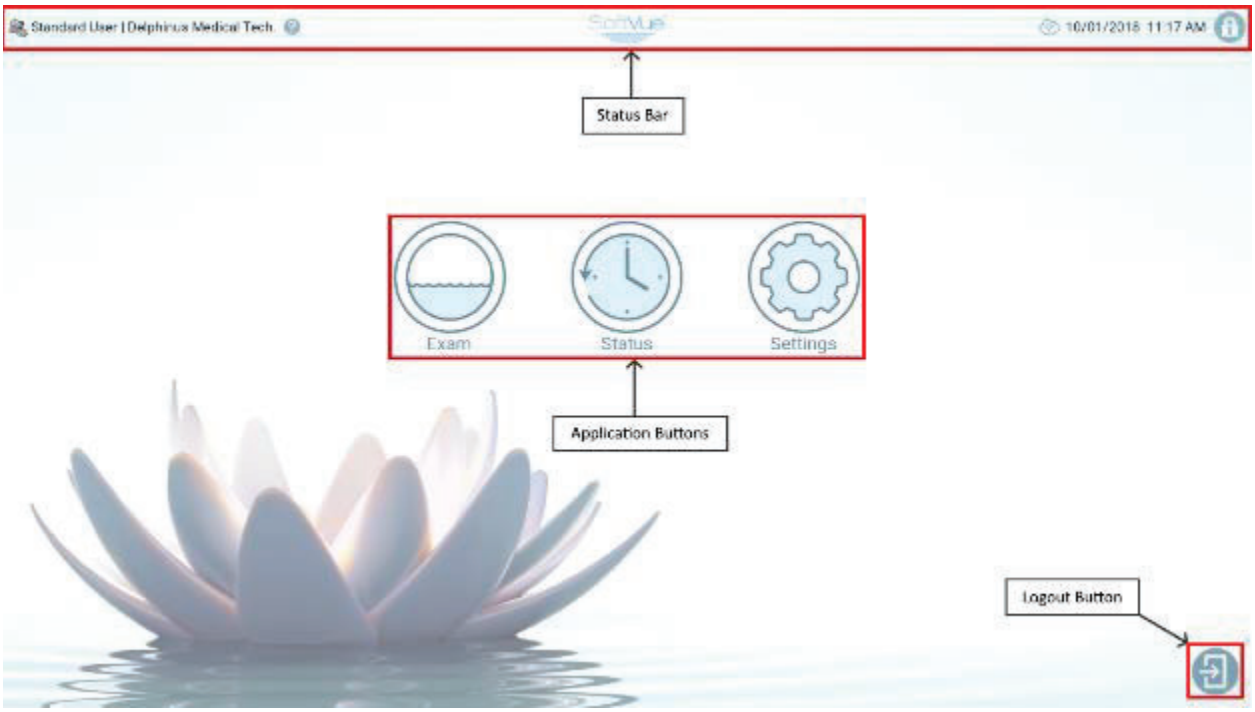
The **Shutdown** button is in the lower right corner of the Login screen. When the **Shutdown** button is tapped, the user will be prompted to confirm the selection.

The shutdown process consists of resetting and draining the imaging chamber and the reservoir and powering off the SoftVue™ subsystems.

3.4 Home Screen

Figure 14 displays the Home screen layout for all users once logged into the SoftVue™ system.

Figure 14: Home Screen Function Locations



3.4.1 User Logout

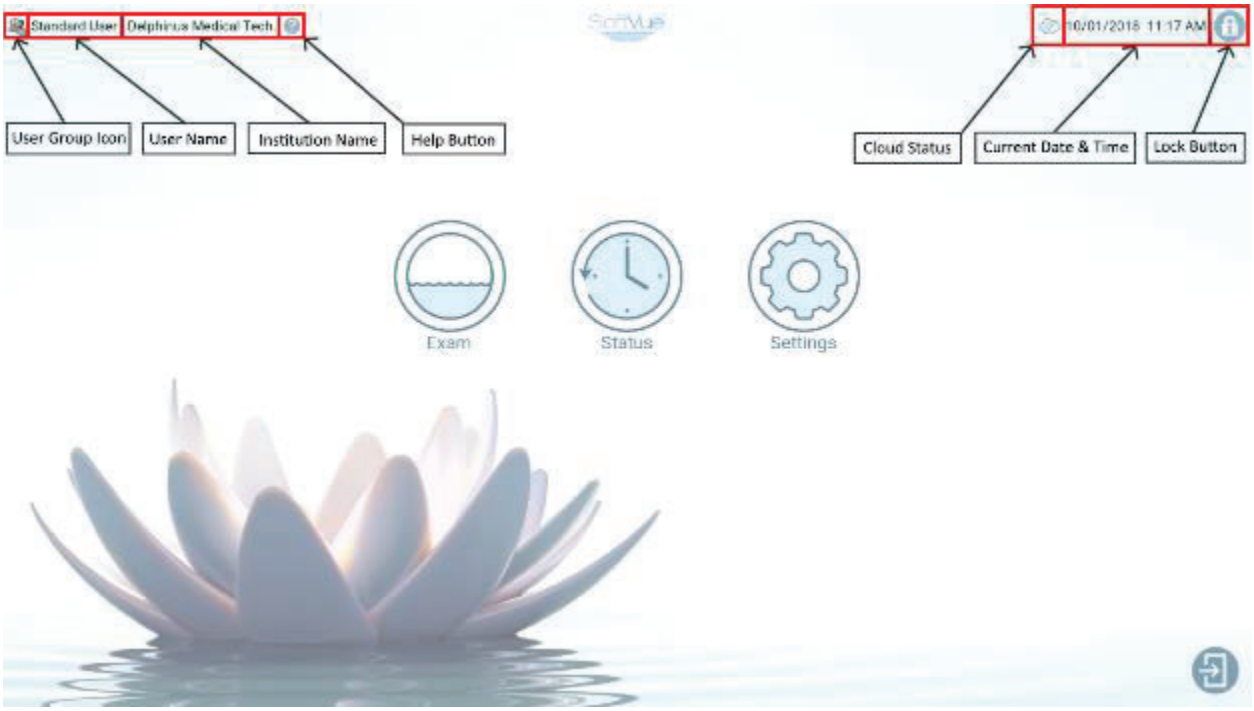
The current user must be logged out before another user can log on to the system. To log out of the system, tap the **Logout** button located in the lower right corner of the Home screen (Figure 14).

NOTE: *If the user who is currently logged into the system fails to log out, the next user should log out the current user before proceeding.*

3.5 Status Bar

The Status Bar is located at the top of the screen and is visible during the operation of the SoftVue™ system. Exceptions to this are on the Login screen, the Lock screen, and when full screen messages are displayed. Figure 15 identifies the content of the Status Bar layout.

Figure 15: Status Bar



3.5.1 User Group Icon

An icon that represents the group of the logged in user is displayed in the upper left corner of the screen in the Status Bar (Figure 15). The user groups and their respective icons are shown in Table 5.

3.5.2 User Name

The username of the user logged into the SoftVue™ system.

3.5.3 Institution Name

Name of the institution configured in the Local Settings (see Section 3.9.3.1). Only displayed if configured.

3.5.4 Help Button

The **Help** button can be tapped to display Delphinus' customer support phone number and email.

3.5.5 Cloud Connectivity Status

The SoftVue™ system connects to the cloud to report Sequr™ Breast Interface inventory information and other usage statistics. This information can be used to schedule a shipment of Sequr™ Breast Interfaces when the system inventory is getting low. An icon that represents the connectivity status is shown to the left of the date and time in the Status Bar (Figure 15). The status icons and their respective meaning are described in Table 3.

Table 3: Cloud Connectivity Status Icons

Icon	Status
	Connected
	Not connected

3.5.6 Date and Time

Current date and time. An Administrator can configure the date and time format using the Display Settings (see Section 3.9.2).

3.5.7 Lock Button

When tapped, the **Lock** button will immediately lock the system and display the Lock screen.

3.5.8 Lock Screen

The user is given the option to lock the screen temporarily to ensure no unauthorized individual can use or shutdown the system.

The Lock screen will display the username and password prompt with the username of the user that is currently logged in (Figure 16).

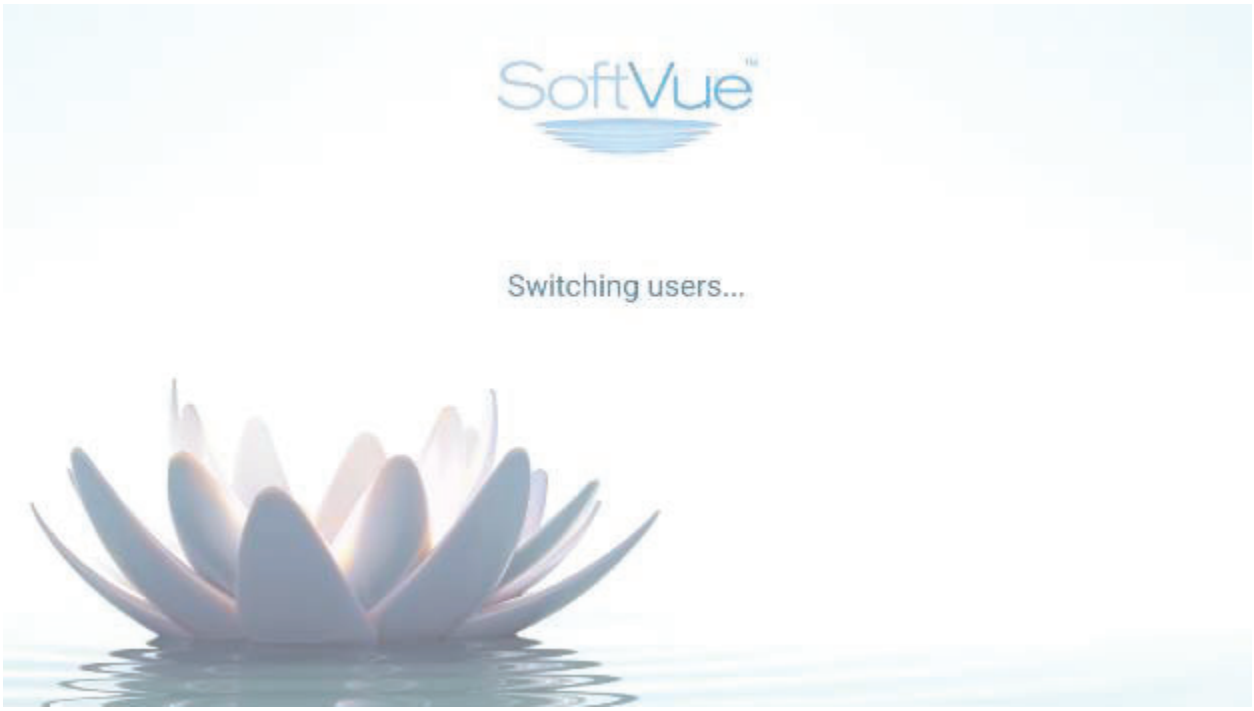
Figure 16: Lock Screen

If the SoftVue™ system is idle for a preconfigured amount of time as set by the Administrator (see Section 3.9.1), the system will return to the Lock screen. To unlock the system, a user must enter valid login credentials and tap the **Unlock** button.

If the current user unlocks the SoftVue™ system, the SoftVue™ system will return to the most recently displayed screen. If a user other than the current user unlocks the system, the user will be prompted to log out the current user. Upon confirmation, all information from the previous session will be lost, and ongoing system operation will be discontinued (e.g., image reconstruction, calibration). A User Switching screen will be displayed (Figure 17) while the

system is being reset. This operation may take several minutes. When complete, the user will be logged in and the Home screen displayed.

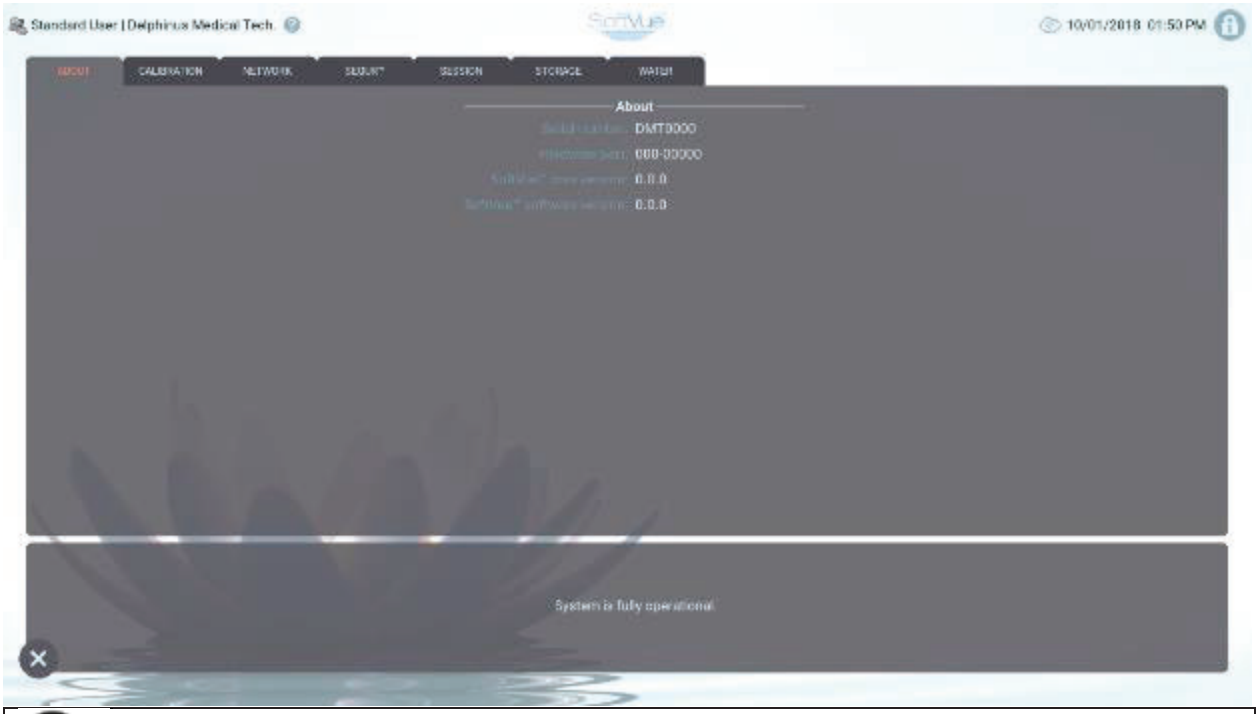
Figure 17: User Switching Screen



3.6 System Status

Tapping the **Status** button located on the Home screen will enter the System Status screen (Figure 18) which displays the SoftVue™ system's current operating statuses within a tab layout. It may take a few seconds for all the information to be populated when a tab is selected. The System Status screen is organized based on categories detailed in the following sections. Tapping the **X** button in the lower left of the screen will return the user to the Home screen.

Figure 18: System Status Screen

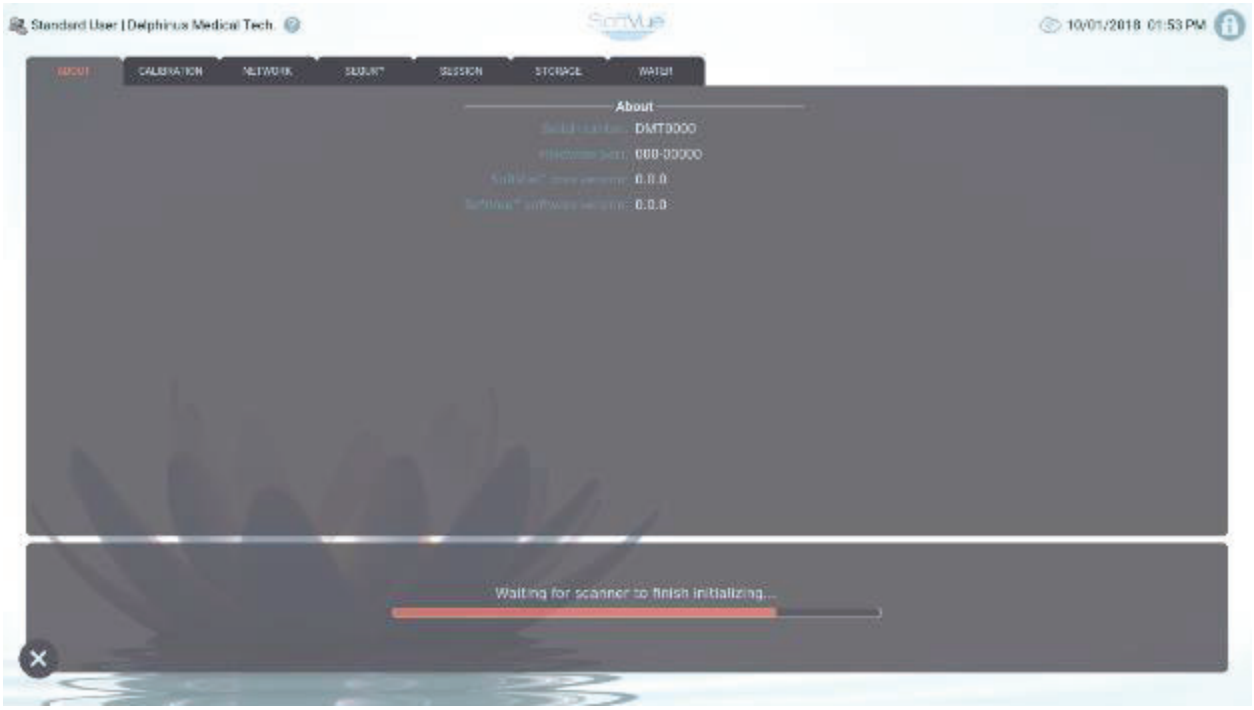


NOTE: *To modify units of measurement, or other settings, refer to Section 3.9.*

3.6.1 Overall Status Box

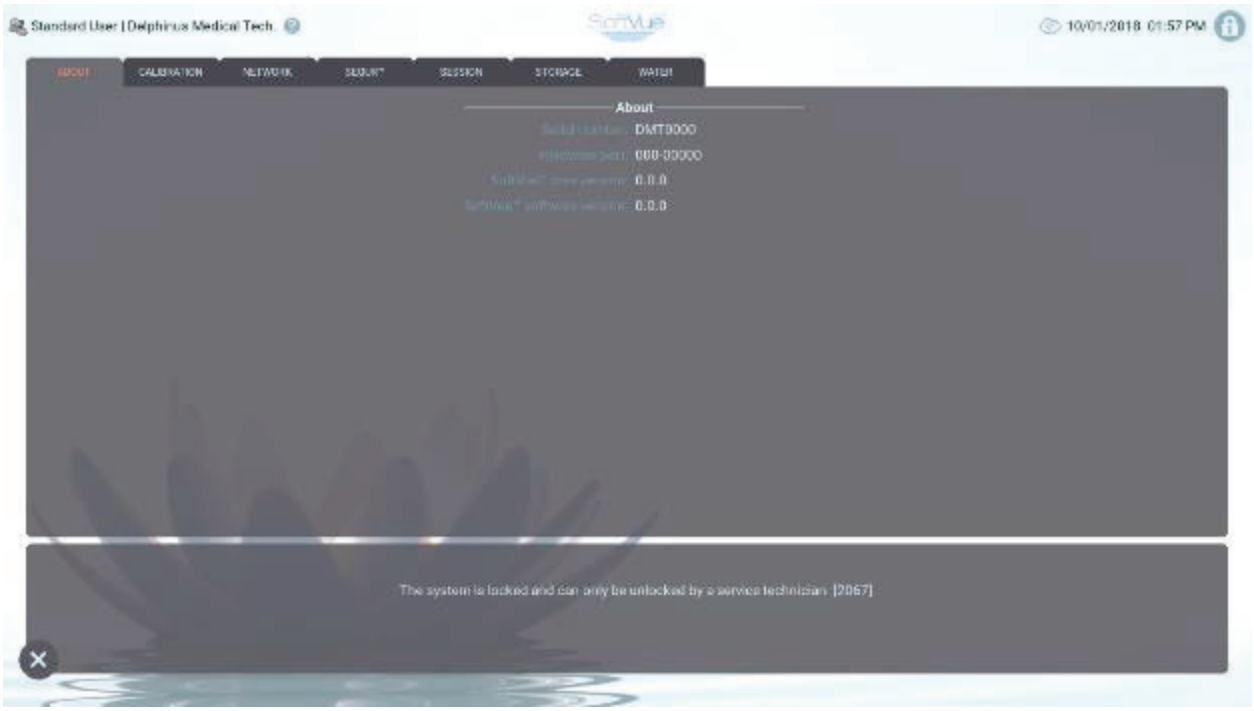
The Overall Status box, positioned below the tabs, shows the overall status of the system. On startup, this box shows the progress of system initialization (Figure 19) and system check. On successful initialization and valid system check, a message will indicate that the system is operational (Figure 18). When a calibration is performed, it will display the progress of the calibration procedure (Figure 37).

Figure 19: System Initialization Progress



If the system encounters an error that causes the system to be locked, the Overall Status box will display a lock message (Figure 20). See Section 8.2 on system lock conditions.

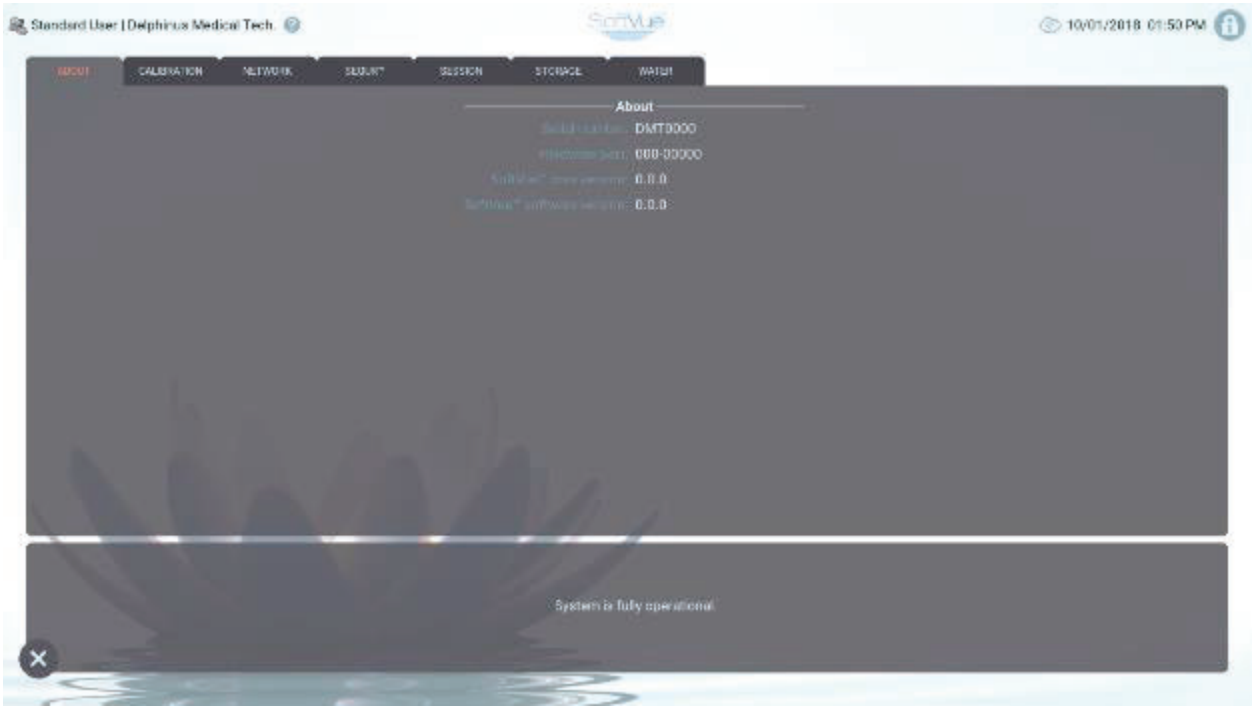
Figure 20: System Locked Status



3.6.2 About Tab

The About tab (Figure 21) displays identification information about the SoftVue™ system parts.

Figure 21: About Status



3.6.2.1 Serial number

The unique serial number of the SoftVue™ system.

3.6.2.2 Hardware part

The reported hardware version of the SoftVue™ system.

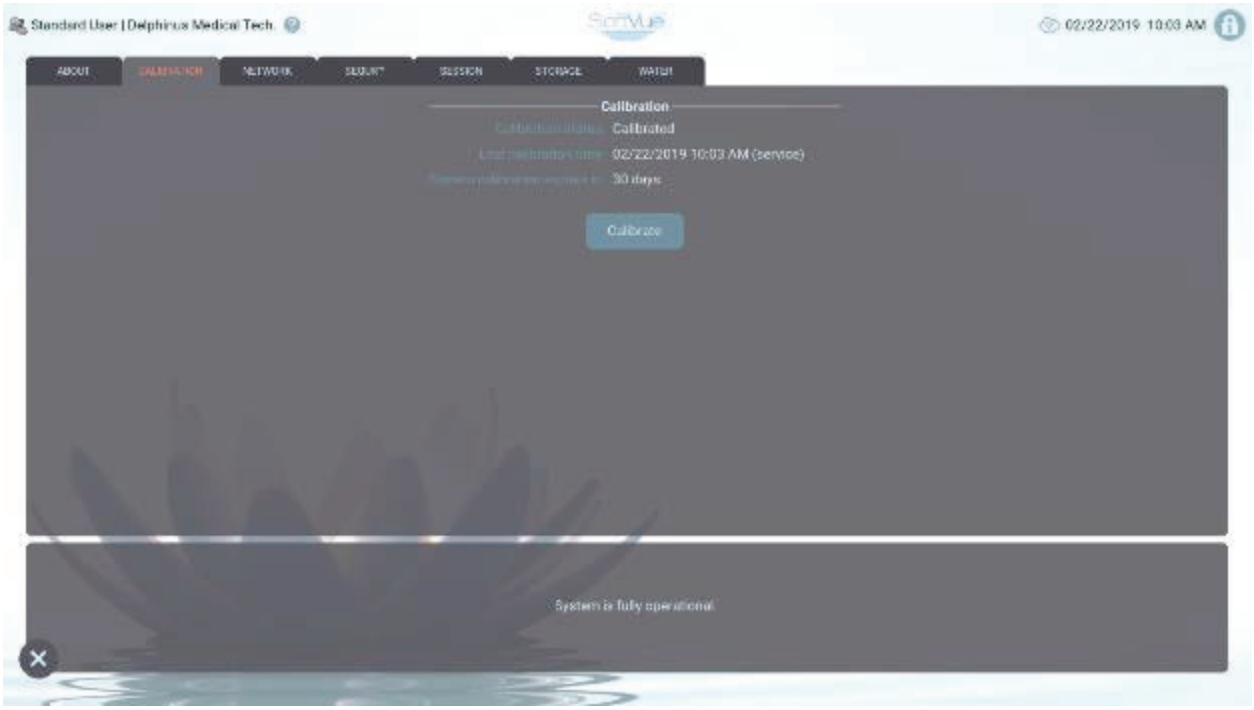
3.6.2.3 SoftVue™ core and SoftVue™ software versions

The reported software release versions of the SoftVue™ system.

3.6.3 Calibration Tab

The Calibration tab (Figure 22) displays status information about calibration, and a **Calibrate** button to start a calibration procedure (see Section 3.7 for details on the calibration procedure).

Figure 22: Calibration Status



3.6.3.1 Calibration status

The current calibration status of the system (Calibrated or Uncalibrated).

3.6.3.2 Last calibration time

The time stamp of the most recent calibration procedure or an indication that the system has never been calibrated.

3.6.3.3 System calibration expires in

The number of days (more than a day) or hours (less than a day) remaining until the calibration of the system expires or an indication that the calibration has expired.

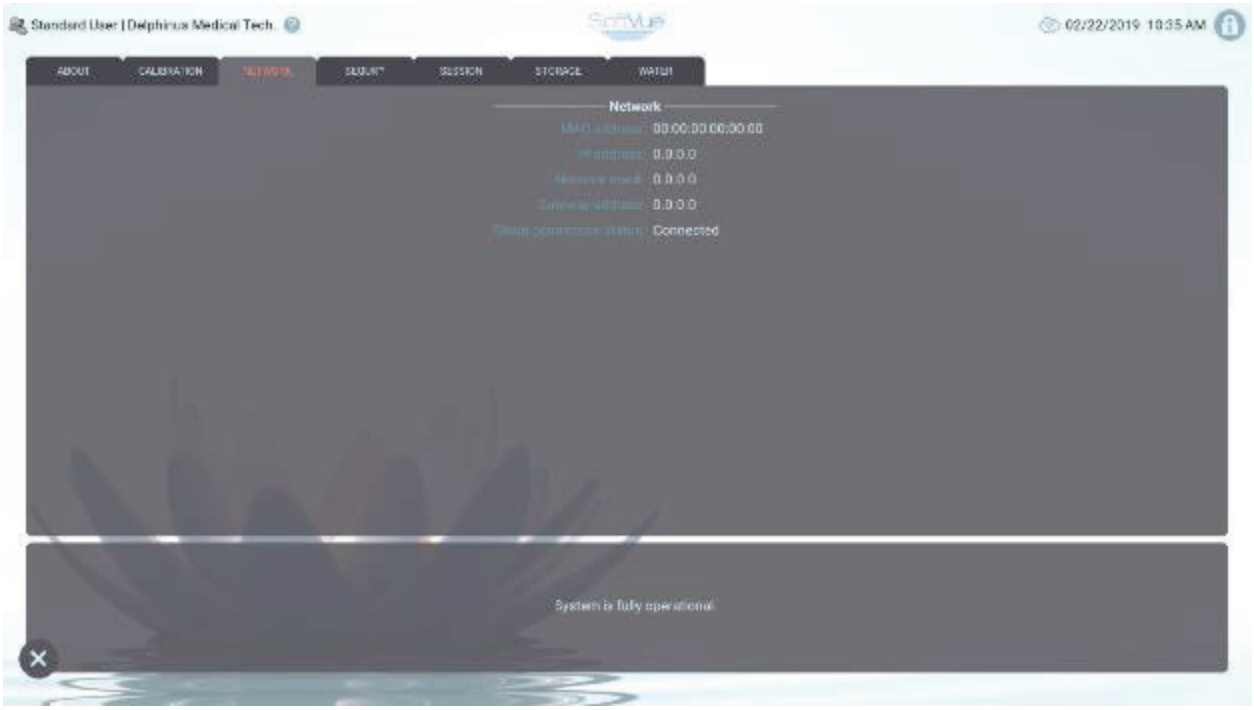
3.6.3.4 Calibrate button

A button to start a calibration procedure (see Section 3.7).

3.6.4 Network Tab

The Network tab (Figure 23) displays information about the current network status of the system.

Figure 23: Network Status



3.6.4.1 MAC address

The 6-byte media access control address of the external network interface of the SoftVue™ system.

3.6.4.2 IP address

The current local Internet Protocol address in dotted-decimal notation assigned to the external network interface of the SoftVue™ system. If an address has not been assigned, the field will show “Not available”.

3.6.4.3 Network mask

The current network mask in dotted-decimal notation assigned to the external network interface of the SoftVue™ system. If an address has not been assigned, the field will show “Not available”.

3.6.4.4 Gateway address

The current gateway address in dotted-decimal notation assigned to the external network interface of the SoftVue™ system. If an address has not been assigned, the field will show “Not available”.

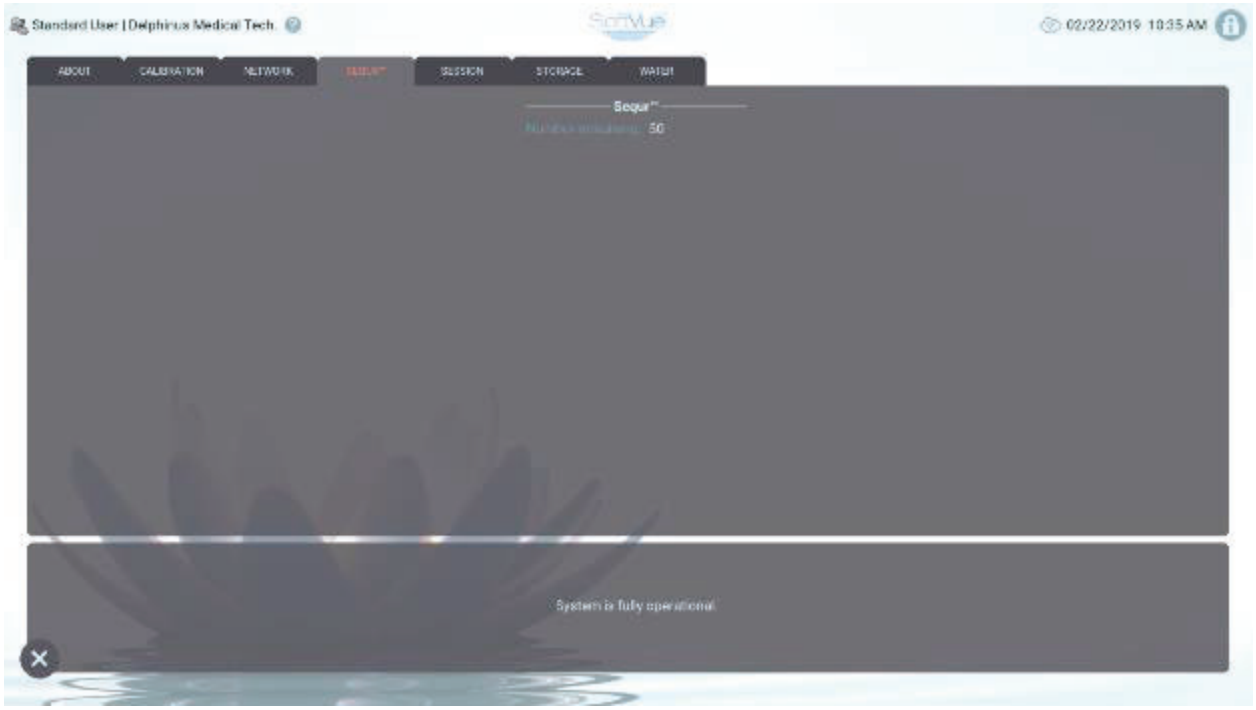
3.6.4.5 Cloud connection status

The cloud connectivity status (Connected / Not connected). This status is also shown on the Status Bar (see Section 3.5.5).

3.6.5 Sequr™ Tab

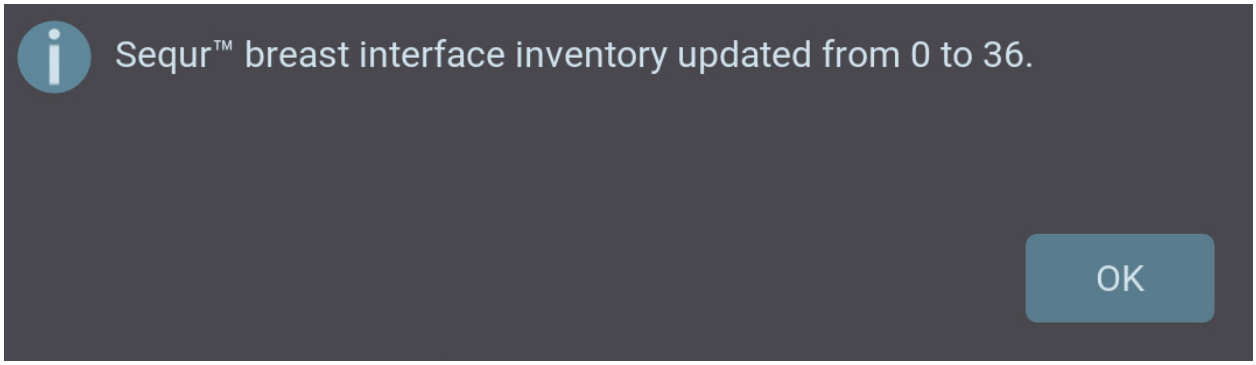
The Sequr™ tab (Figure 24) displays information about the Sequr™ Breast Interface inventory. While the Sequr™ tab is displayed, SBI case barcodes can be scanned to add the SBI units contained within the case to SBI inventory on the system.

Figure 24: Sequr™ Status



Upon successful scan of the SBI case barcode, a message will be displayed indicating that the Sequr™ Breast Interface inventory has been updated (Figure 25).

Figure 25: Case Barcode Scanned



If an unknown barcode is scanned (Figure 26) or the case barcode is scanned for the second time (Figure 27), the GUI will display an error message.

Figure 26: Unknown Case Barcode Scanned

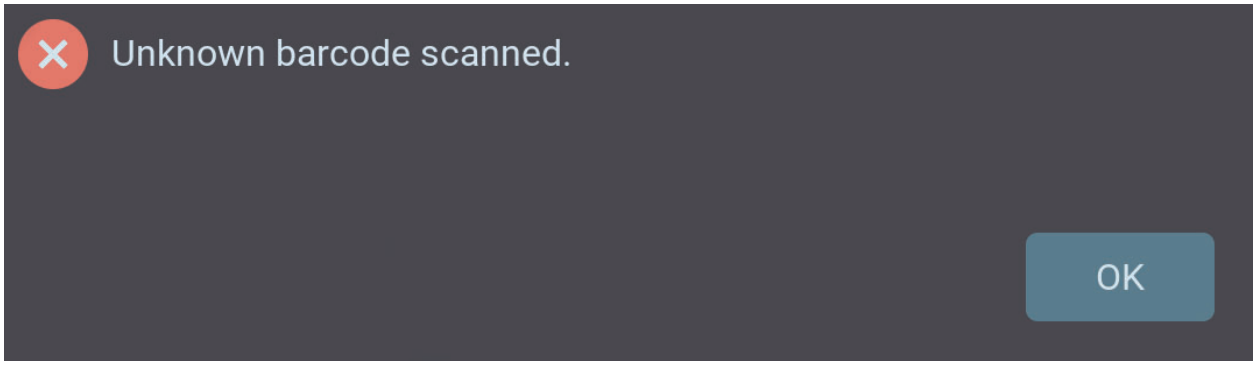
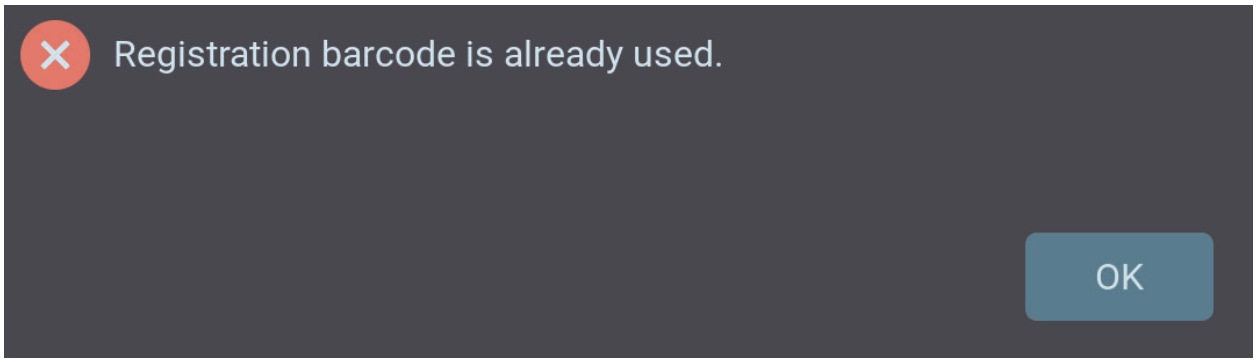


Figure 27: Case Barcode Already Used



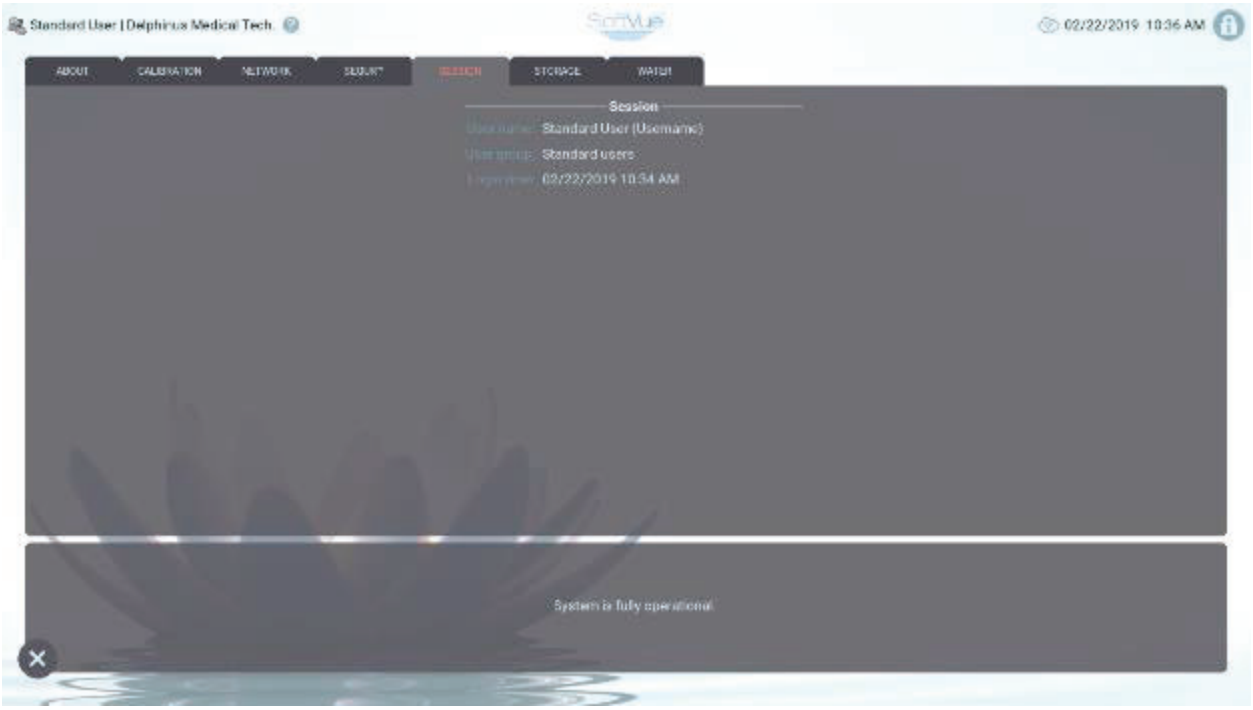
3.6.5.1 Number remaining

The number of unused registered Sequr™ Breast Interfaces remaining in the system inventory. To increase inventory, scan the bar code of a new case of Sequr™ Breast Interfaces and the inventory will automatically update.

3.6.6 Session Tab

The Session tab (Figure 28) displays the login information for the current user.

Figure 28: Session Status



3.6.6.1 User name

The first, middle and last name of the user currently logged into the SoftVue™ system. This field also displays the user's unique username in parentheses.

3.6.6.2 User group

The group the logged in user belongs to.

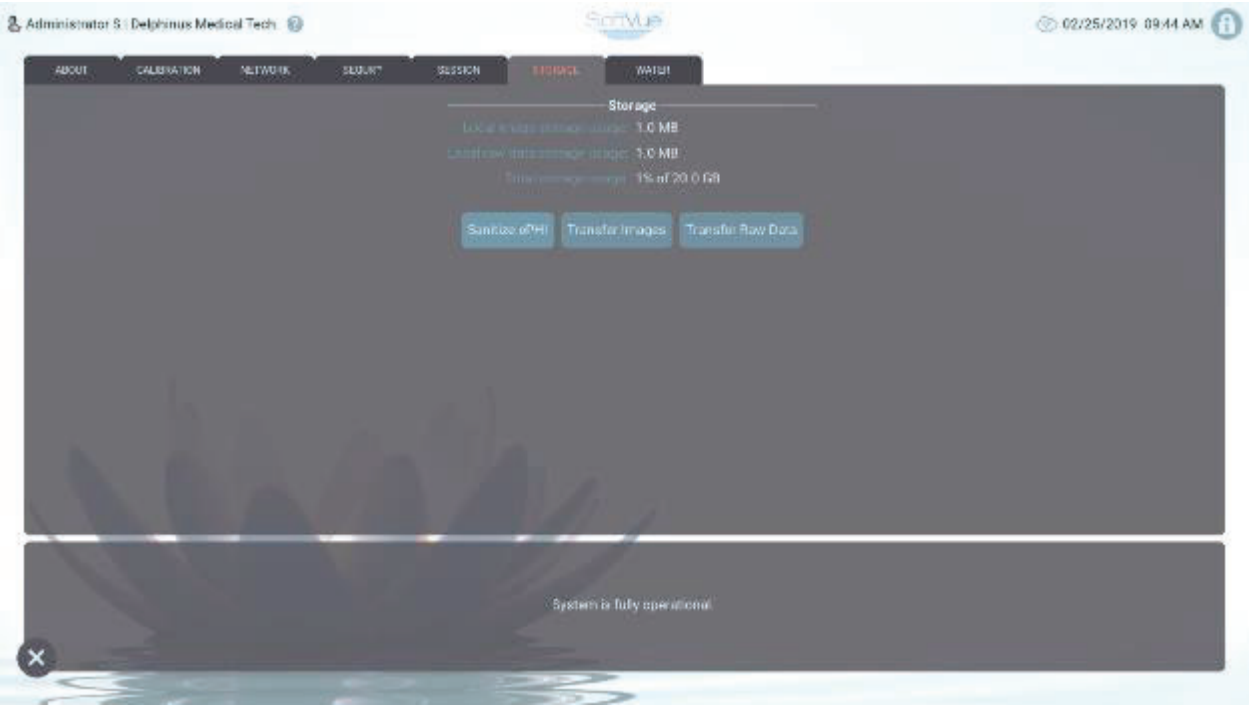
3.6.6.3 Login time

The time stamp of when the current user logged in.

3.6.7 Storage Tab

The Storage tab (Figure 29) displays information about the local storage use, provides the ability to manually transfer the data to external servers and provides an Administrator the ability to sanitize the system from electronic protected health information (ePHI).

Figure 29: Storage Status



3.6.7.1 Local image storage usage

The amount of used image storage inside the SoftVue™ system in megabyte (MB).

3.6.7.2 Local raw data storage usage

The amount of used raw data storage inside the SoftVue™ system in megabyte (MB).

3.6.7.3 Total storage usage

The percent usage (images and raw data) of the total volume expressed in gigabyte (GB) of the SoftVue™ system internal storage.

3.6.7.4 Transfer images button

This button transfers images from the SoftVue™ system's local storage to as many as two external PACS servers (see Section 3.9.4.2 for configuration details). This button is disabled if there are no images to transfer or if no external PACS servers are enabled. When this button is tapped, the Overall Status box will show the progress of the transfer. When the transfer is in progress, it can be aborted. Upon transfer completion, the images are deleted from the SoftVue™ system's local storage only if the transfer to the primary PACS server was successful.

3.6.7.5 Transfer raw data button

This button transfers raw data from the SoftVue™ system's local storage to an external FTP server (see Section 3.9.4.3 for configuration details). This button is disabled if there are no raw data files to transfer or if no external FTP server is enabled. When this button is tapped, the system box shows the progress of the transfer. When the transfer is in

progress, it can be aborted. Upon successful transfer to the FTP server, the raw data is deleted from SoftVue™ system's local storage.

3.6.7.6 Sanitize ePHI button

This button sanitizes the SoftVue™ system's ePHI information. This button is only available to Administrators. When tapped, a confirmation message will be displayed (Figure 30). Upon confirmation, the Overall Status box will show the progress of the procedure. This process takes approximately 3 hours. When complete the user will be prompted to restart the system (Figure 31).

Figure 30: Sanitize ePHI Confirmation

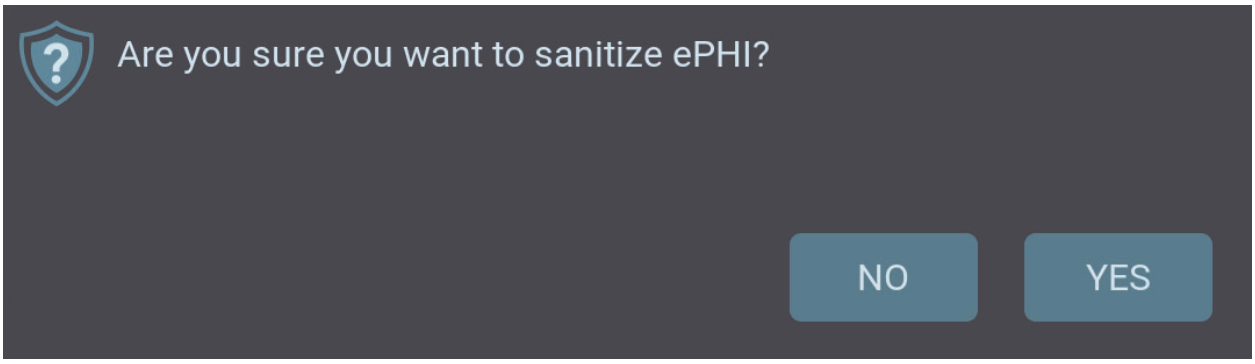
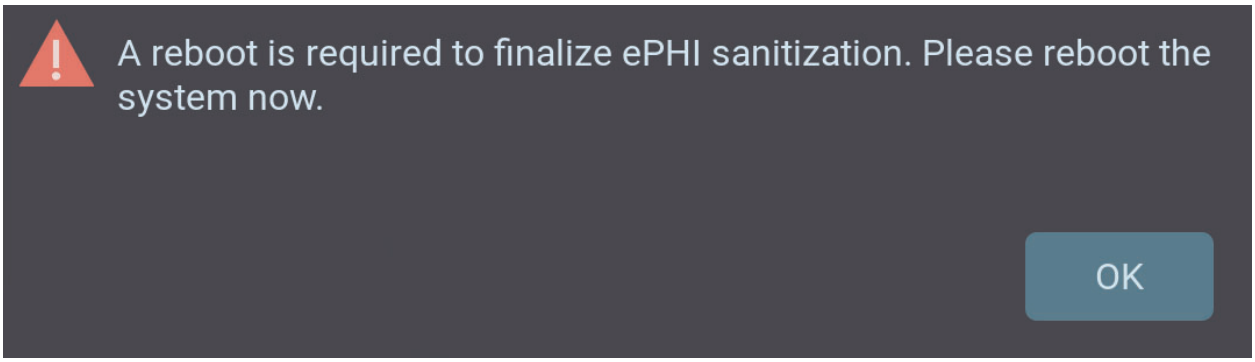


Figure 31: Sanitize ePHI Complete



When the sanitization is in progress, it can be aborted by tapping the **Abort** button. Tapping the **Abort** button will prompt for a confirmation (Figure 32). If the sanitize process is aborted, the GUI will display a message indicating that the sanitization may be incomplete and request the user to reboot the system or retry sanitizing ePHI (Figure 33).

Figure 32: Abort Sanitize ePHI

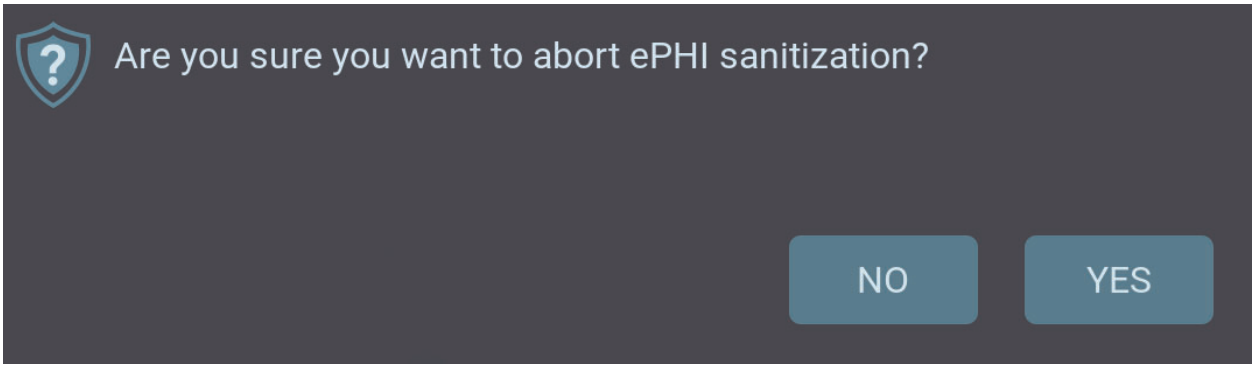
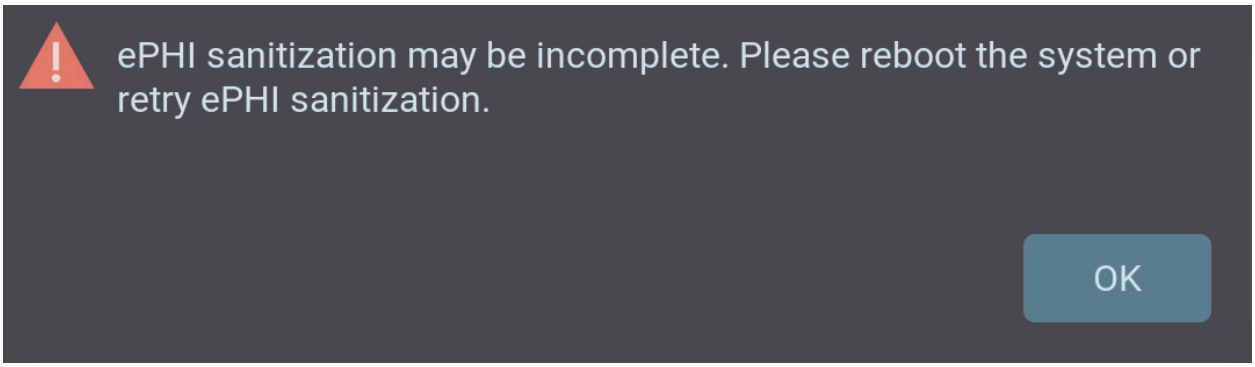


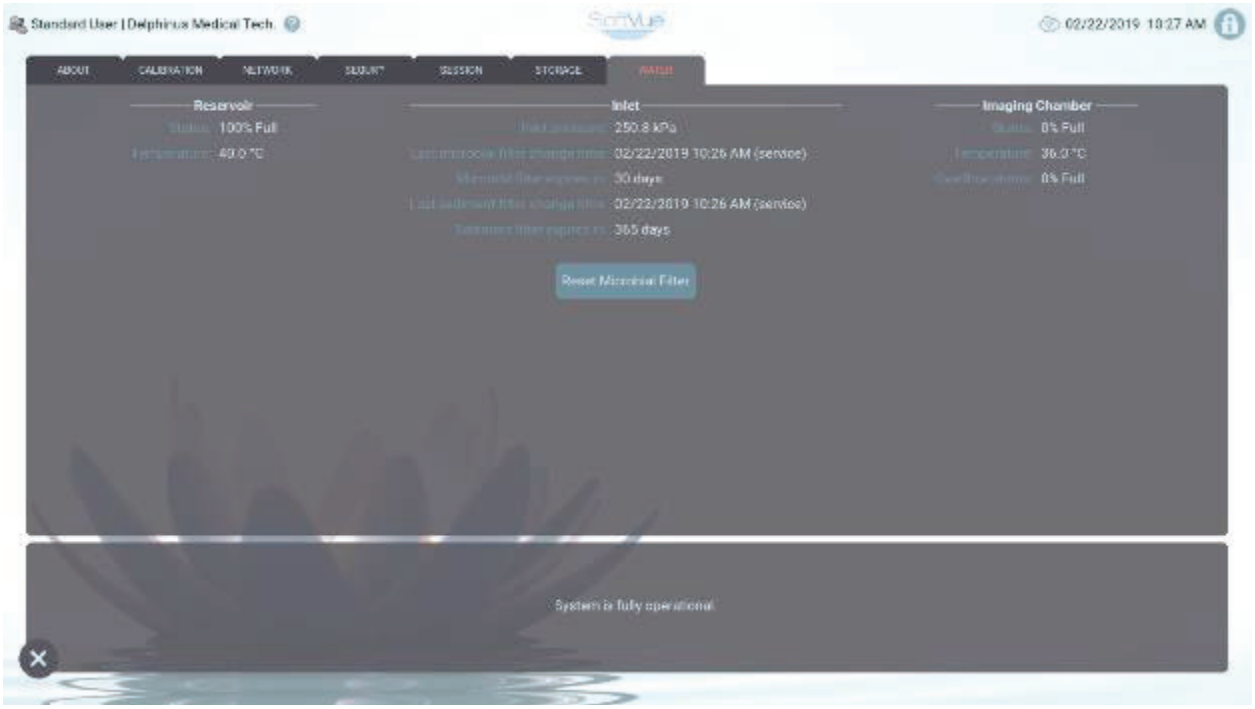
Figure 33: Sanitize ePHI Incomplete



3.6.8 Water Tab

The Water tab (Figure 34) displays information about the SoftVue™ water system and allows a user to reset the microbial filter.

Figure 34: Water Status



3.6.8.1 Reservoir status

The water level in the reservoir, expressed as a percentage.

3.6.8.2 Reservoir temperature

The temperature (expressed as °F or °C) of the water inside the reservoir.

3.6.8.3 Inlet pressure

The measurement of the inline water pressure (expressed as kPa or PSI) from the water source into the SoftVue™ system.

3.6.8.4 Last microbial filter change time

The time when the microbial water filter of the SoftVue™ system was last changed, and the username of the user that reset it.

3.6.8.5 Microbial filter expires in

The number of days remaining until the microbial water filter installed on the system expires, or an indication that the filter has expired.

3.6.8.6 Last sediment filter change time

The time when the sediment water filter of the SoftVue™ system was last changed, and the username of the user that reset it.

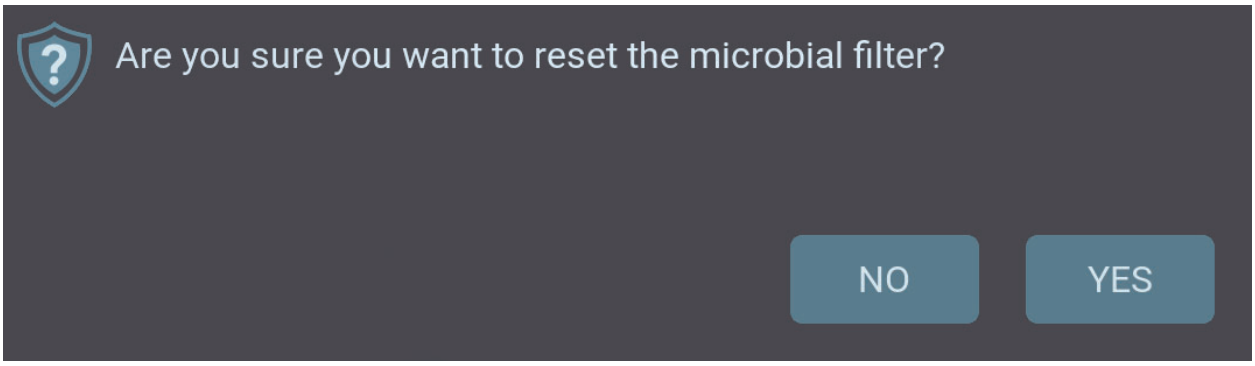
3.6.8.7 Sediment filter expires in

The number of days remaining until the sediment water filter installed on the system expires, or an indication that the filter has expired.

3.6.8.8 Reset Microbial Filter button

Resets the last filter change time to the current date and time and resets the expiration counter for the microbial filter. When tapped will prompt for a user confirmation (Figure 35).

Figure 35: Reset Microbial Filter Confirmation



3.6.8.9 Imaging chamber status

The water level in the imaging chamber, expressed as a percentage.

3.6.8.10 Imaging chamber temperature

The temperature (expressed as °F or °C) of the water inside the imaging chamber.

3.6.8.11 Imaging chamber overflow status

The water level in the imaging chamber overflow, expressed as a percentage.

3.7 Calibration

In order to maintain nominal imaging performance, the SoftVue™ system has a manually activated calibration procedure, approximately 15 to 20 minutes in length, which assesses specific characteristics of the data acquisition electronics. The system will perform several internal checks to ensure the SoftVue™ system is fully operational and suitable for patient procedures. If the calibration procedure fails, the system will prevent the user from performing a new imaging procedure. Repeat the calibration procedure. If the problem persists, contact the Delphinus service organization.

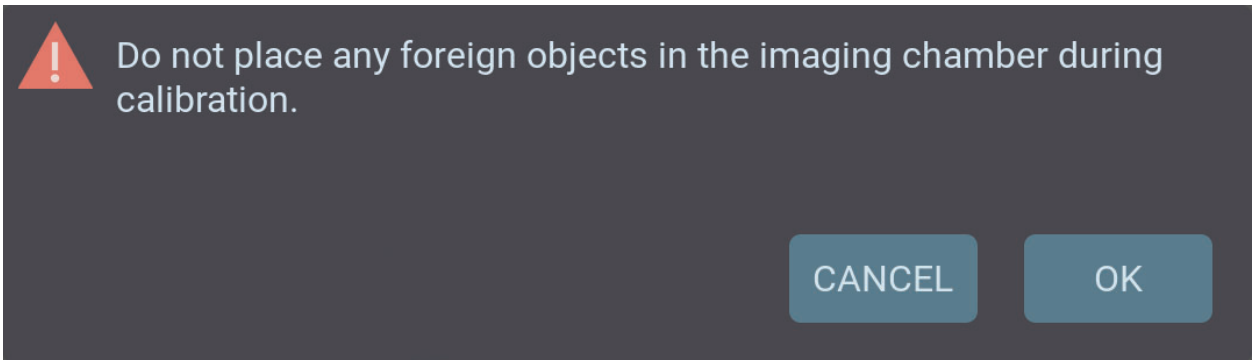
Calibration will be conducted on the SoftVue™ system during installation and regular maintenance checks by a Service Representative. For optimal imaging performance, it is recommended that a calibration schedule for the SoftVue™ system be maintained.

NOTE:	*The SoftVue™ system will prompt the user to perform a calibration at least **once per month**, regardless of usage. In the event that the calibration is expired, the user will not be able to perform an exam until calibration is performed.*

3.7.1 Procedure

Tap the **Calibrate** button from the Calibration tab within the Status menu to initiate a calibration procedure. A warning message will be displayed not to place any foreign objects in the imaging chamber during calibration (Figure 36).

Figure 36: Calibration Warning Message

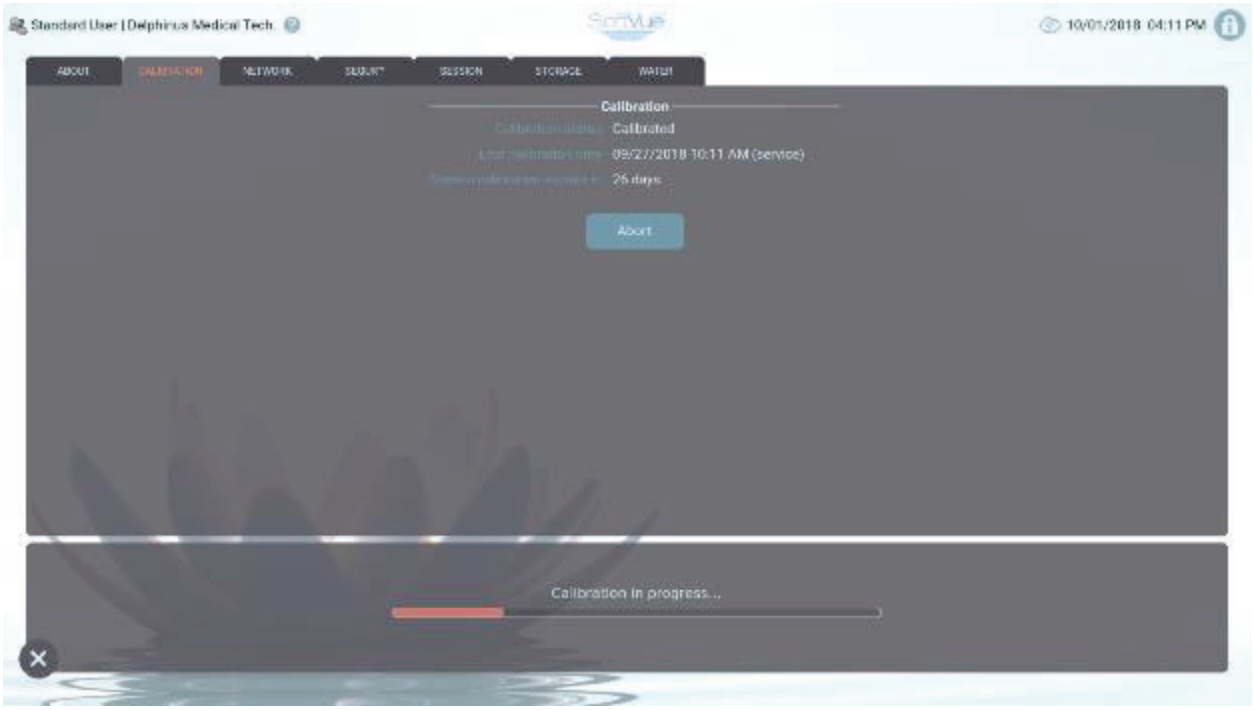


Press the **OK** button to continue through the calibration procedure or the **CANCEL** button to abort.

WARNING:	*The imaging chamber **MUST** remain clear of any foreign objects during calibration. Objects in the imaging chamber could result in poor calibration and/or damage to the system.*

A progress bar in the Overall Status box will display the progress of the calibration that is in progress (Figure 37).

Figure 37: Calibration in Progress Screen

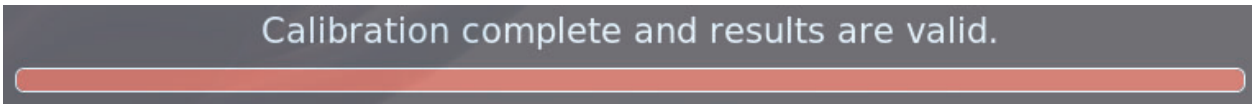


An **Abort** button will be available in the Calibration tab during a calibration. Tapping the **Abort** button will prompt for a confirmation to cancel the current calibration process. Aborting the calibration may take several minutes.

3.7.2 Calibration Results

If the Calibration procedure is successful, a message (Figure 38) will temporarily be displayed above the full progress bar before returning to the report of the overall system status.

Figure 38: Calibration Successful Message



If the Calibration results show a failure (i.e., calibration parameter out of tolerance), the status box will return to the report of the overall system status indicating that the system is uncalibrated (Figure 39). If the system is in an uncalibrated state, the user should initiate a new calibration procedure. If the issue persists, contact Delphinus Service.

Figure 39: System Uncalibrated Status

If the SoftVue™ system is unable to complete a calibration procedure (Figure 40), an error message will be displayed indicating a failure and instructing the user to abort the calibration procedure.

Figure 40: Calibration Failed Message

3.8 Exam

A user can tap the **Exam** button on the Home screen to initiate an exam procedure.

Before beginning an exam, check with the patient to make sure they have no open wounds or sores on the breast tissue or chest wall area.

Ask the patient to remove eye glasses and any jewelry on the head, neck or breasts as they may cause discomfort or may interfere with the scan (i.e. earrings, necklaces, nipple rings, and other jewelry). Ask the patient to remove any powders or lotions from their chest wall area.

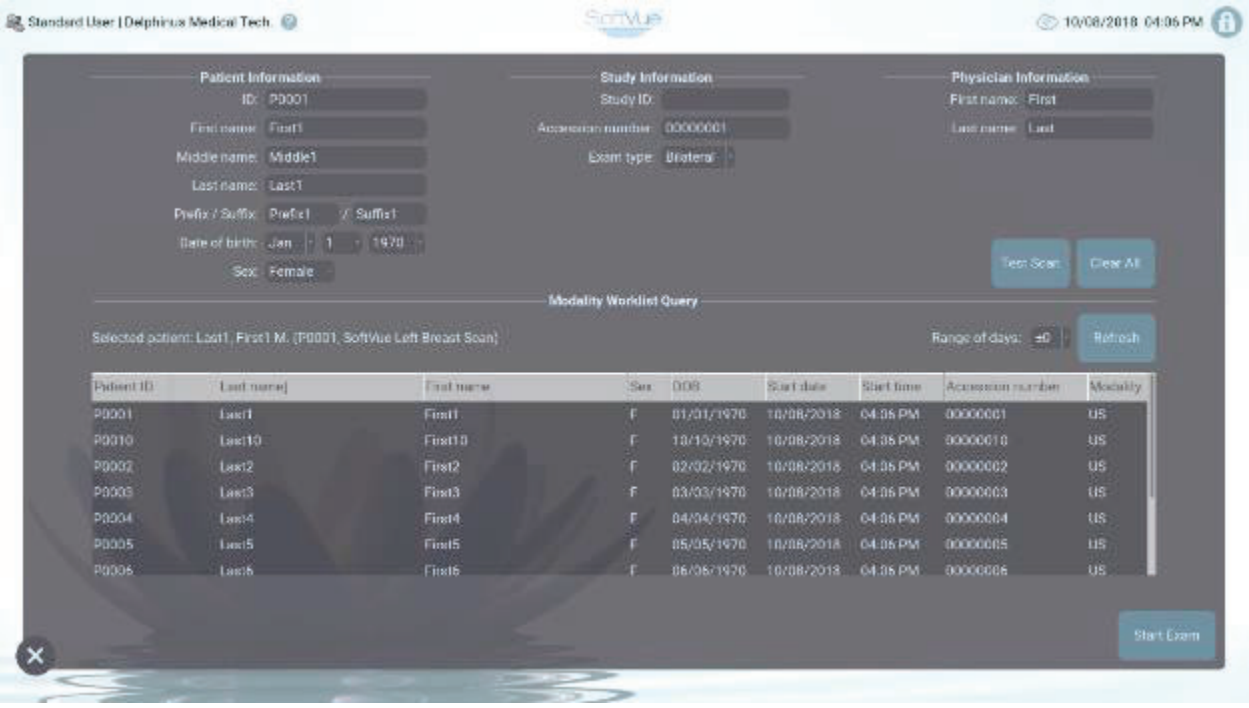
Prior to the exam, please provide the patient with a brief overview of the exam, what to expect, and explain terminology used during the exam.

3.8.1 Exam Information

When the **Exam** button is tapped, an exam information screen is displayed (Figure 41). The user may either enter the exam information manually (if enabled) or populate it automatically from a worklist query (if configured). See Section 3.9.1.1 to enable/disable manual patient entry, and Section 3.9.4.6 to configure the RIS server used for worklist query. If manual patient entry is disabled, and the RIS server is not configured or is unavailable, exam information cannot be entered. Tapping the **X** button in the lower left of the screen will return the user to the Home screen.

NOTE: *The exam information includes several drop-down menus. The drop-down menus must be pressed and held for one second to open the menu and allow the user to select an option.*

Figure 41: Exam Information Screen



3.8.1.1 Patient Information

The patient information section contains patient specific information. All fields except the date of birth are optional. The full name (last, first, middle, prefix, suffix) including separation characters cannot exceed 64 characters.

3.8.1.1.1 ID

The ID should match the patient identification, also known as medical record number (MRN) as provided by the facility's identification system. A valid ID may contain any of the characters from the keyboard except the characters / (slash) and \ (backslash).

3.8.1.1.2 First name

A valid patient first name may contain any of the characters from the keyboard except the characters / (slash), \ (backslash), = (equality), and ^ (caret).

3.8.1.1.3 Middle name

A valid patient middle name may contain any of the characters from the keyboard except the characters / (slash), \ (backslash), = (equality), and ^ (caret).

3.8.1.1.4 Last name

A valid patient last name may contain any of the characters from the keyboard except the characters / (slash), \ (backslash), = (equality), and ^ (caret).

3.8.1.1.5 Prefix / Suffix

A valid prefix / suffix may contain any of the characters from the keyboard except the characters / (slash), \ (backslash), = (equality), and ^ (caret).

3.8.1.1.6 Date of birth

A valid date of birth of the patient will designate a valid date between January 1, 1900 and the current date.

3.8.1.1.7 Sex

The user will be able to select between the following genders: Female (default), Male, Other. The field can also be left blank.

3.8.1.2 Study Information

The Study Information section contains study specific information. An exam type must be selected to start the exam. All other fields are optional.

3.8.1.2.1 Study ID

The study ID is available as a field to be utilized as appropriate by the facility. A valid study ID will contain between 0 and 16 characters, utilizing any of the characters from the keyboard except the characters / (slash) and \ (backslash).

3.8.1.2.2 Accession number

The accession number is a RIS-generated number that identifies the order for the study at the site. A valid accession number will contain between 0 and 16 characters, utilizing any of the characters from the keyboard except the characters / (slash) and \ (backslash).

3.8.1.2.3 Exam type

The user will be able to select one of the following exam types: Bilateral, Left, Right. An exam type must be selected to start the exam.

3.8.1.3 Physician Information

The Physician Information section contains physician specific information. These fields are optional. The full name (last, first) including separation characters cannot exceed 64 characters. The middle name, prefix, and suffix cannot be specified.

3.8.1.3.1 First Name

A valid physician first name may contain any of the characters from the keyboard except the characters / (slash), \ (backslash), = (equality), and ^ (caret).

3.8.1.3.2 Last Name

A valid physician last name may contain any of the characters from the keyboard except the characters / (slash), \ (backslash), = (equality), and ^ (caret).

3.8.1.4 Modality Worklist Query

By default, the configured RIS server will be queried for patients that have been scheduled for a procedure on the specified imaging modality (see Section 3.9.1.4) and falls within a pre-determined date range based on the procedure start date. For example, if the specified modality is “US”, the current date is September 10, 2018, and the range of days is set to ±4 days, all the patients scheduled for an ultrasound with a procedure start date between September 6, 2018 and September 14, 2018 will be queried and pulled into the system patient worklist.

Once the patient worklist has been populated, the results can be further filtered using the exam information fields. The search is not case sensitive. The list will be updated when the keyboard is hidden. Tap the **Refresh** button to trigger a new query using the default filters. The **Clear All** button clears all the Exam Information fields.

To enter patient information using the modality worklist query, select the desired patient from the patient worklist.

Each entry in the list will contain the following information, if available:

- The patient ID
- The last name of the patient
- The first name of the patient
- The sex of the patient
- The patient date of birth (DOB)
- The start date and start time of the procedure
- The accession number
- The scheduled procedure modality

The query results can be sorted by touching the heading of a column. One touch sorts the list in increasing alphabetical order. A second touch sorts the list in decreasing alphabetical order.

When a patient is selected, the patient information fields will be populated. In the event that information obtained through the modality worklist query is erroneous or incomplete, the patient information can be manually edited, if manual patient information entry is enabled (see Section 3.9.1.1). The exam information fields that are not obtained from the modality worklist (e.g., Study ID, Exam type) can always be edited.

Information about the selected patient will be displayed above the patient worklist: the patient ID, patient first name, last name, and middle initial, and Requested Procedure Description.

Refer to Section 3.9.4.6 for details on properly configuring the SoftVue™ system for connection to the facility’s RIS Server.

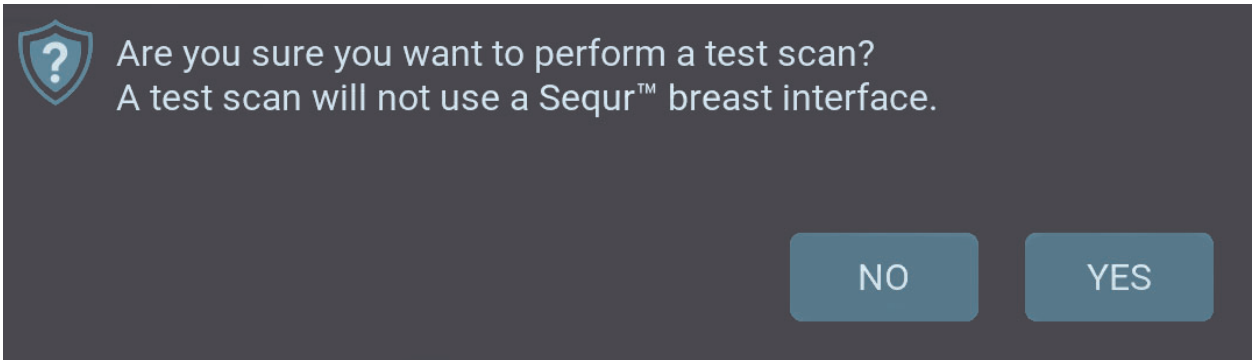
3.8.1.5 Test Scan

A **Test Scan** button is available (Figure 41) to run a non-patient scan using the following pre-defined exam information which cannot be changed:

- Patient first name: Test
- Patient last name: Scan
- Date of birth: January 1, 1900
- Sex: Other

All other text fields are blank. The test scan functionality may be used for testing the system against expected performance metrics, for demonstration purposes, or other tests as directed by a Delphinus representative. During a test scan, a Sequr™ Breast Interface will not be used, and the Breast Interface Assembly controls will be disabled. A confirmation prompt will ask the user to confirm before proceeding to a test scan (Figure 42).

Figure 42: Test Scan Confirmation

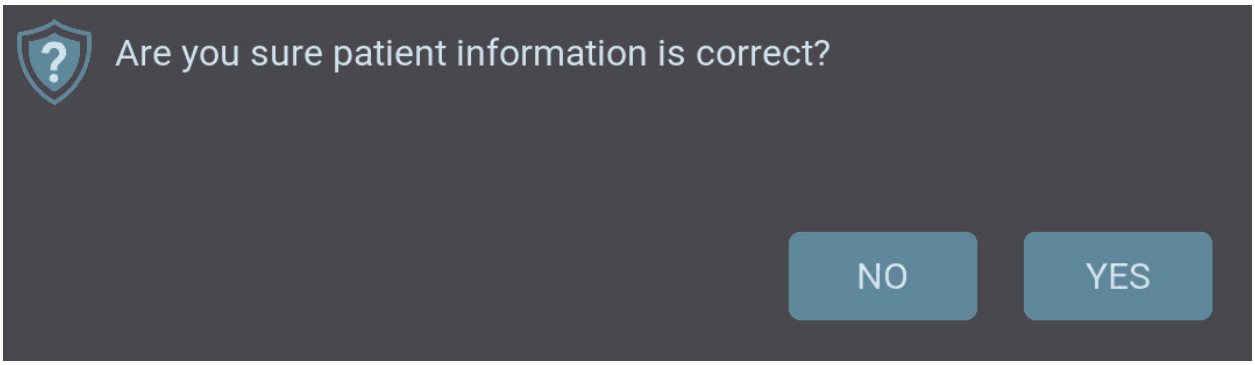


3.8.1.6 Information Confirmation

After the patient information entry fields are completed, the **Start Exam** button can be tapped to proceed. If any information is missing or invalid, an error message will be displayed to prompt the user to complete the information. When the information is complete, a confirmation prompt (Figure 43) will ask the user to confirm that the information is correct before proceeding to the next screen.

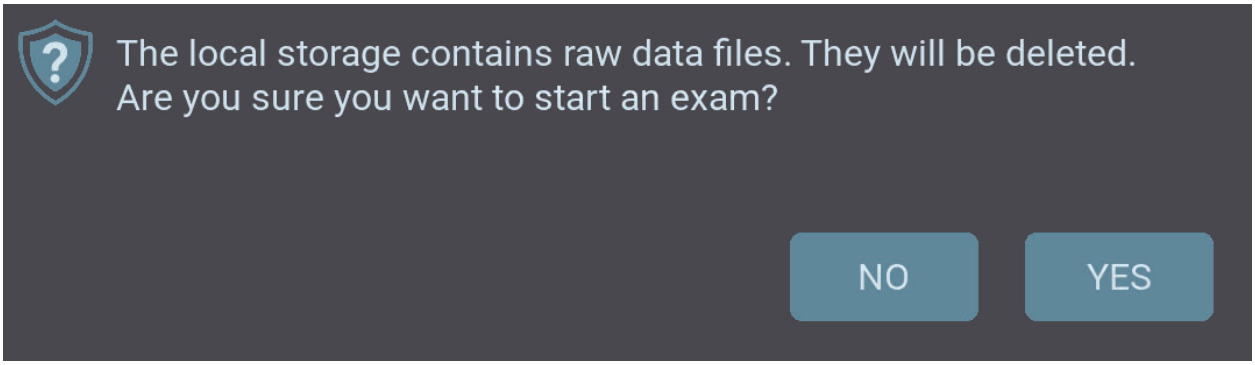
The **Start Exam** button is disabled when initialization, system check, calibration or ePHI sanitization are in progress, if initialization or system check complete unsuccessfully, or if problems occur that prevent an exam procedure from being performed, such as expired filters or water leak errors. If the system is not calibrated, the **Start Exam** button will be disabled until a calibration is completed demonstrating valid results.

Figure 43: Start Exam Confirmation



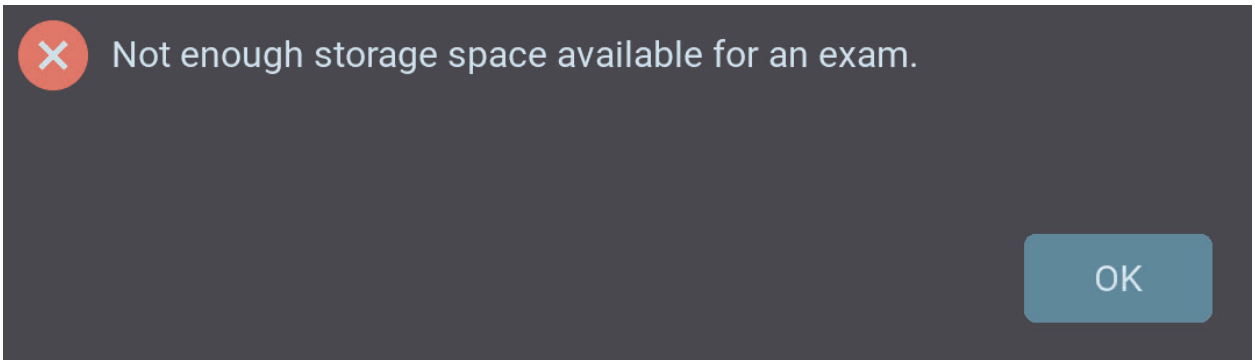
If raw data is on the system from a previous procedure, the confirmation prompt will notify the user that the data will be deleted (Figure 44). Tapping **Yes** will delete the raw data and continue with the exam; tapping **No** will return the user to the Exam Information Screen. To manually transfer the raw data, refer to Section 3.6.7.5.

Figure 44: Start Exam Confirmation with Raw Data Detected



Images that remain on the SoftVue™ system's internal storage from previous exams are not deleted until they are successfully transferred to the primary PACS server. However, if there is not enough free space on the SoftVue™ system's internal storage to store images due to a backup of image data, a notification will be displayed (Figure 45). Refer to Section 3.6.7.4 for a description of how to transfer images.

Figure 45: Start Exam Insufficient Storage Space Notification

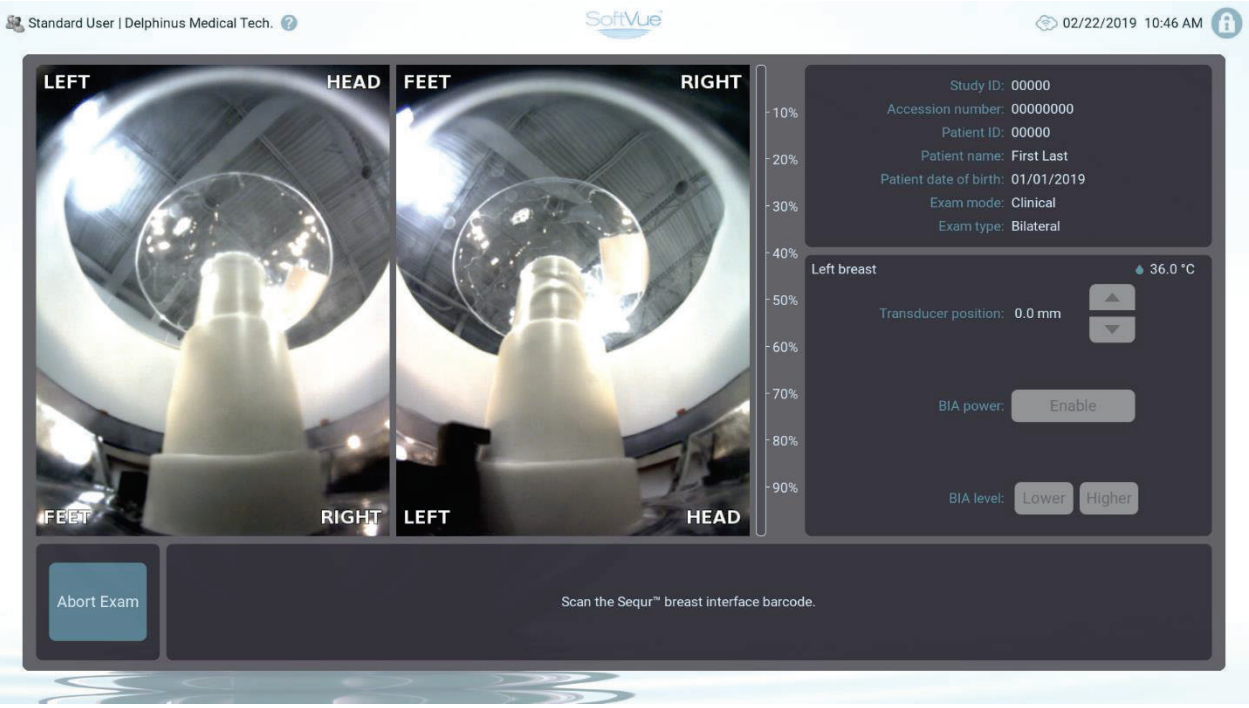


If the **Start Exam** button is tapped and the SBI inventory is empty, a message will be displayed indicating that there is no Sequr™ Breast Interfaces available. The user must scan in a new case of SBIs from inventory before an exam can be initiated. See section 3.6.5 for scanning an SBI case.

3.8.1 Bar Code Scanning and Removal

The GUI will prompt the user to scan a Sequr™ Breast Interface barcode (Figure 46). Obtain one SBI unit from the location where they are stored.

Figure 46: Scan Sequr™ Breast Interface



The SBI barcode is on the side of the SBI packaging, as shown in Figure 47 below.

Figure 47: SBI Barcode

Each exam initiation requires the scan of a new, unused SBI barcode. Sequr™ Breast Interface units cannot be reused as exposure to warm water during imaging degrades their mechanical integrity. If the SBI barcode was previously used (Figure 48), if an invalid barcode is scanned (Figure 49), or if an unknown barcode is scanned (Figure 50), the system will indicate that the barcode is unacceptable, and ask the user to scan a valid SBI barcode before proceeding.

Figure 48: SBI Already Used

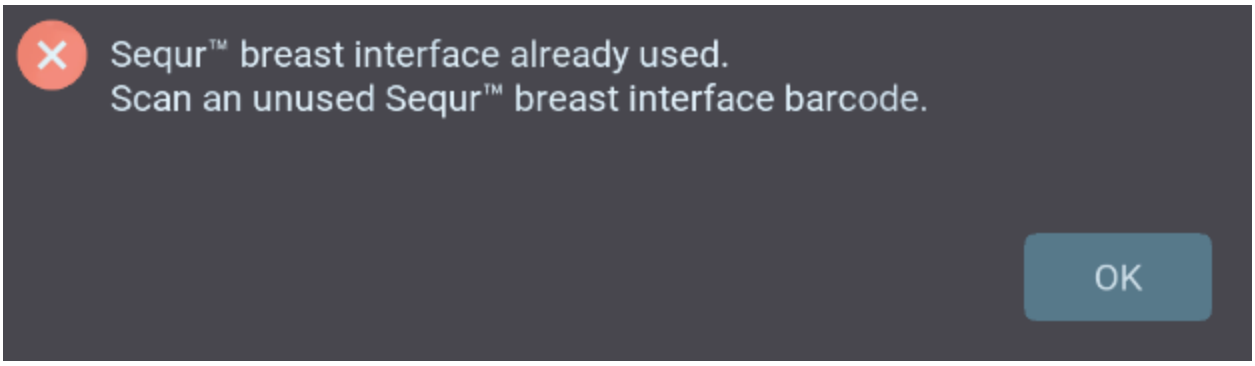


Figure 49: Invalid Barcode Scanned

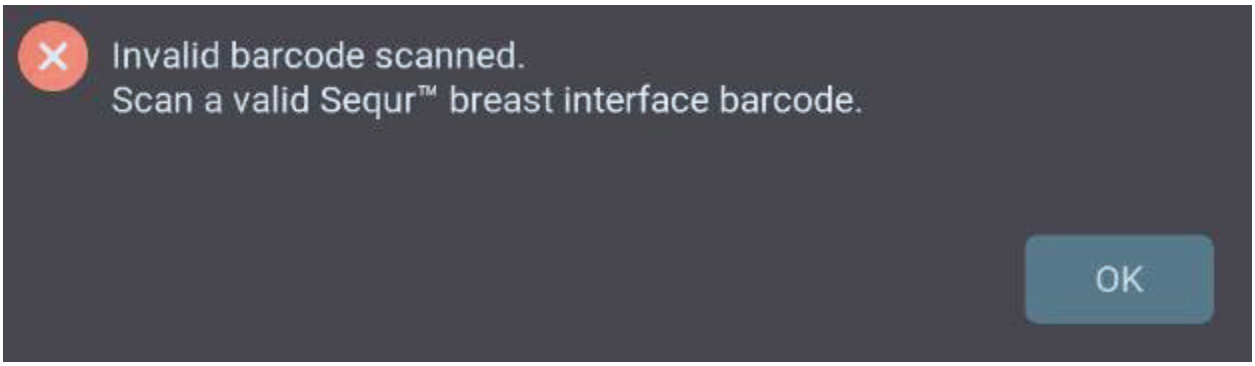
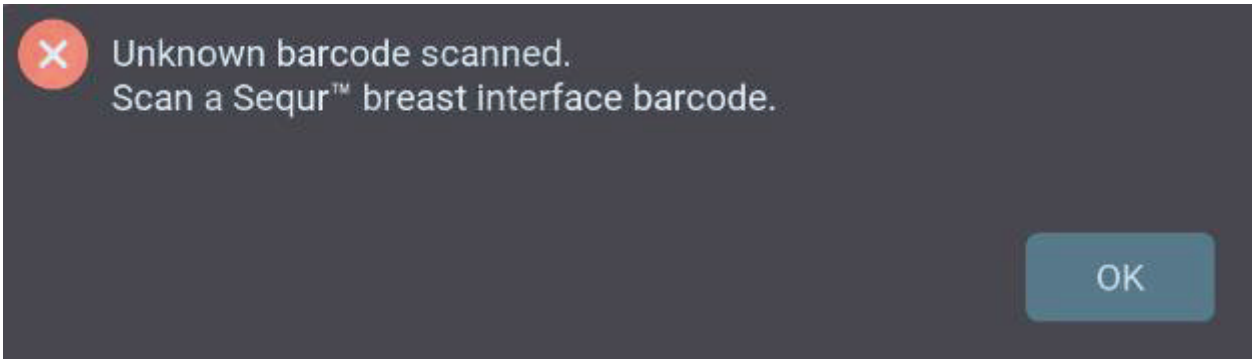


Figure 50: Unknown Barcode Scanned



Once a valid barcode has been scanned, the screen will update with instructions to place the SBI on the platform and provide an option to proceed to prefill of the imaging chamber (Figure 51). The Sequr™ Breast Interface can then be removed from its packaging.

Figure 51: Place Sequr™ Breast Interface

NOTE: *The Sequr™ Breast Interface is delicate. Be careful when handling to prevent damage.*

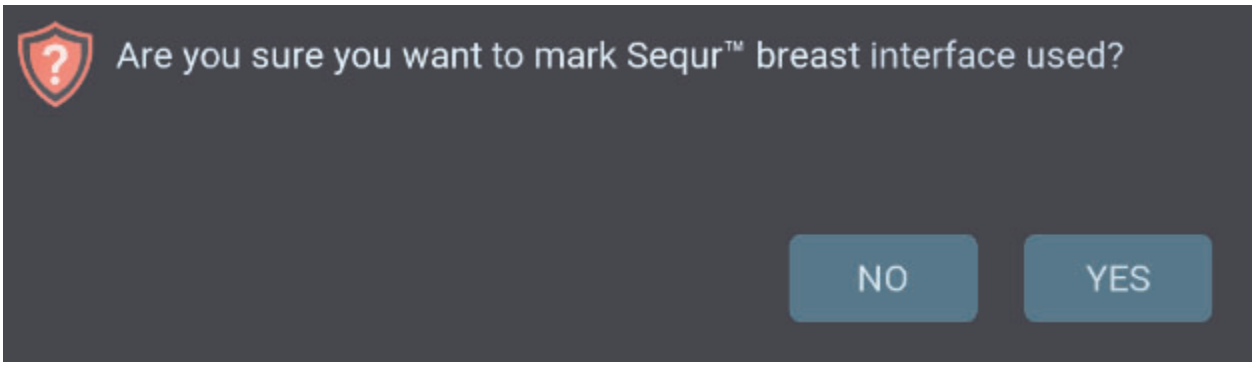
3.8.1.1 Sequr™ Breast Interface Removal: Squeezing Method

To open the Sequr™ Breast Interface, peel off the top of the package, and turn it so that the open side is face down in your hand. Gently squeeze the plastic sides, such that your fingers and thumbs are directly opposite one another, until you observe (feel or hear) a release of suction of the SBI to the package. If necessary, rotate the package 90º and squeeze again until air enters between the SBI and package. The SBI will slide out of the package and into the user's hand. The squeezing method is illustrated in Figure 52 below.

Figure 52: Sequr™ Breast Interface Removal: Squeezing Method

If another SBI must be used at any point in the exam, its barcode must be scanned to update the inventory. When scanned, the user will be prompted to confirm the use of the additional Sequr™ Breast Interface (Figure 53). For a test scan, no SBI should be used and SBI barcode scanning is not required.

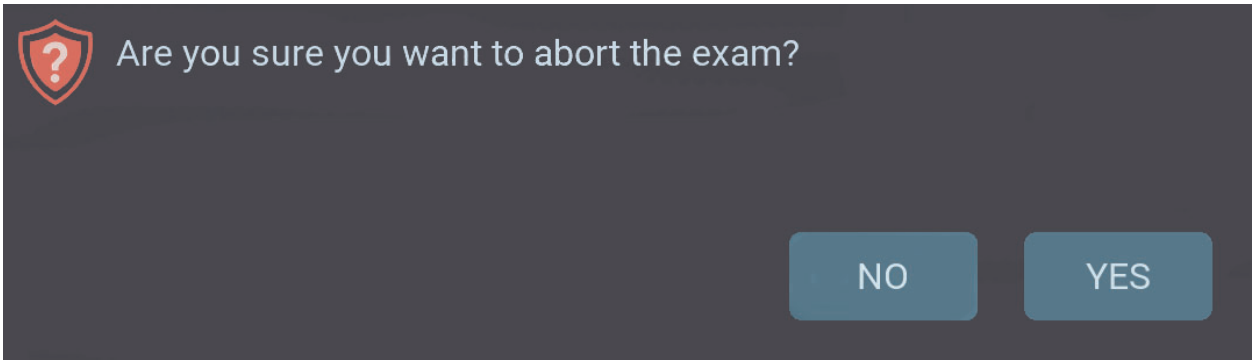
Figure 53: Additional Sequr™ Breast Interface Scanned



The Exam screen is shown in Figure 51. It displays a summary of the exam information in the upper right corner of the screen. A dual camera feed that helps the user position the patient's breast in the imaging chamber is shown in the upper left corner of the screen. The corners of the camera feed are labelled with Head, Feet, Left, Right, to indicate direction to the Head, the Feet, the Left side, and the Right side of the patient, respectively. If a camera feed is lost for any reason at any point during the exam, a button will appear that will allow the user to attempt to restore it.

A bar indicating breast extension is located to the right of the camera feeds. Scan controls including transducer position, BIA power, and BIA level are located in the middle box on the right side of the screen. The **Abort Exam** button is located in the bottom left corner. At any point during the exam, the **Abort Exam** button allows the user to cancel the exam process. When the **Abort Exam** button is tapped it will prompt the user for confirmation (Figure 54). Upon confirmation, all previously entered patient information will be discarded, the imaging chamber will be reset and cleaned, and the user will be returned to the Home screen.

Figure 54: Abort Exam Confirmation



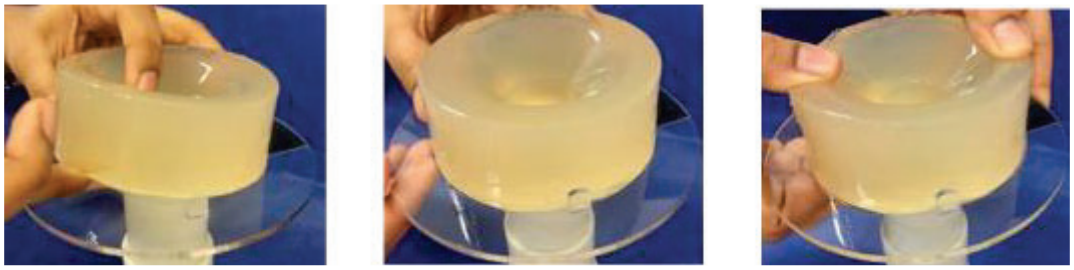
3.8.2 Sequr™ Breast Interface Placement

Lower the Sequr™ Breast Interface onto the platform gently, pressing one side of the SBI against one of the prongs. Be careful not to tear the gel with the prongs. Next, lower an adjacent side and press lightly inward so that the SBI avoids the second pin. Once flat against the platform surface, release the inward pressure on the SBI so that it engages the second pin. Once two of the prongs are engaged, repeat this process for the third pin so that each of the prongs penetrate the SBI securely. Make sure the SBI is resting flat on the platform and secured between the three prongs (Figure 55). If the SBI is not positioned properly, gently press the sides of the SBI together with your fingers to avoid tearing the gel, lift the SBI and start over. Do not slide the SBI across the platform; this can tear the SBI.

In cases where the SBI is torn or damaged, a new SBI will need to be scanned, removed from its packaging, and placed on the carriage platform.

NOTE:	*When the imaging chamber is filled with water, placing the Sequr™ Breast Interface on the carriage platform is more difficult due to the slick surface of a wet Sequr™ Breast Interface.*

Figure 55: Sequr™ Breast Interface Placement



After the SBI is placed on the carriage platform, tap **Proceed** to start filling water in the imaging chamber.

NOTE:	*Wait to fill imaging chamber until patient is seated on the SoftVue™ exam table so the water temperature does not decrease before the exam.*

After the imaging chamber has filled with water, you will be prompted to position the patient's breast. The breast to be positioned first depends on the exam type (left, right, or bilateral) and is indicated on the GUI in the middle section on the right side of the screen as seen in Figure 51.

3.8.3 Patient Positioning

CAUTION:	*Care should be taken when positioning patients who have pain or limited mobility of the neck, arm, back or have balance issues.* *Obtain patient permission before using a hands-on approach to help guide the breast.*
NOTE:	*All bilateral exams are performed with the left breast first, followed by the right breast.* *During positioning, the GUI swivel arm can be carefully moved to allow the user better observation of the patient during the positioning process for the exam. Before positioning the patient, be sure to turn on the power to the Breast Interface Assembly by tapping the **Enable** button.*

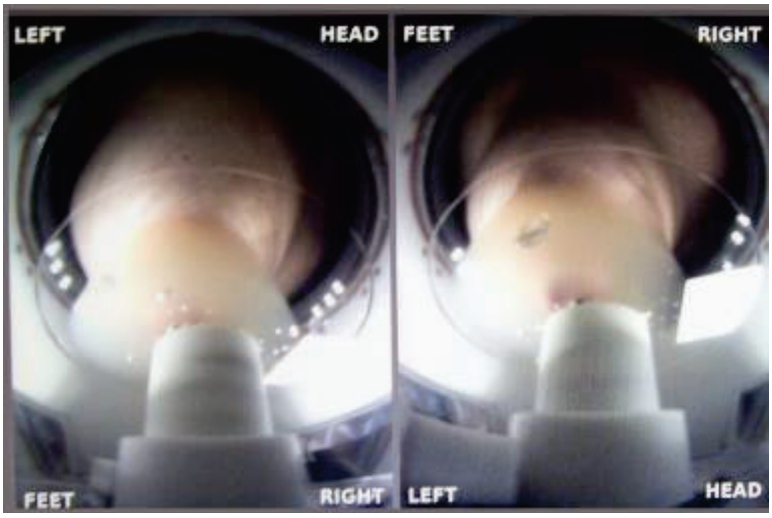
After selecting the **Enable** button to turn on power to the BIA, assist the patient onto the SoftVue™ table using the provided step stool, ensuring stability, and guide the patient toward the imaging chamber.

Instruct the patient to get into the prone position (lying face-down), removing both arms from any gown and/or cape the patient is wearing. Have the patient center the breast being scanned over the imaging chamber. Ensure the patient's upper and lower body are in alignment.

While watching from the head of the SoftVue™ table, instruct the patient to lower the breast into the imaging chamber and have the patient center their nipple in the Sequr™ Breast Interface. The breast should be centered as much as possible (Figure 56); however, if the

patient has an off-centered nipple, this may be challenging, and the operator may need to assist with positioning the breast into the SBI.

Figure 56: Breast Centration



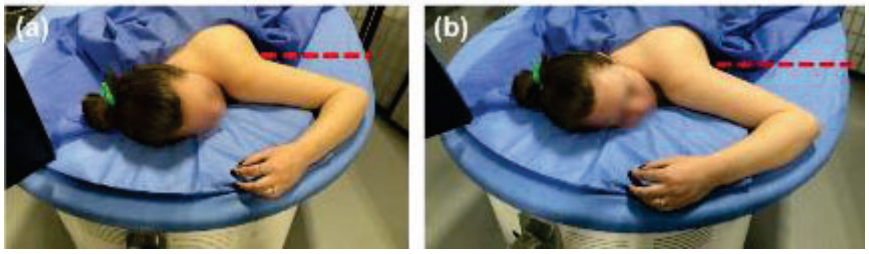
After the breast is lowered into the SBI, the vacuum creates a “seal”, gently pulling the breast downward while the BIA collapses.

As the patient lowers their upper body/breast into the imaging chamber, help guide their ipsilateral arm to their side. Depending on breast size, the arm may be placed loosely at the side of the torso.

Instruct the patient to relax their body into the membrane and have them turn their head to the contralateral side. Position the SoftVue™ head/neck pillow to suit the patient most comfortably, while also ensuring the breast is centered and positioned optimally. Some patients may not desire the pillow.

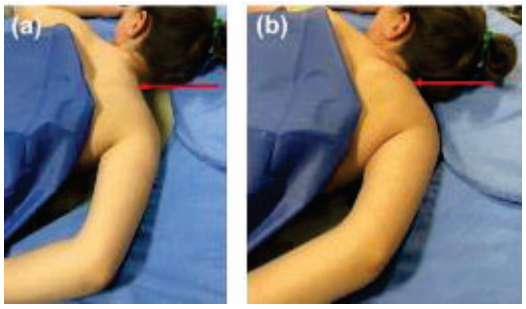
Guide patient’s contralateral arm above their head. The placement of the arm is dependent on patient comfort, breast centration and extension (Figure 57).

Figure 57: Contralateral Arm Placement Options



Ask patient to relax their shoulder and/or use your hand to gently pull the shoulder back, allowing the chest to move further down (Figure 58-a). This may help when the patient is tense or has very rounded shoulders (Figure 58-b). Take especially gentle care when positioning elderly patients who may have more rounding of the back and shoulders. Remind the patient they do not have to hold themselves up and can allow their full weight to rest on the table and imaging chamber.

Figure 58: Relaxed Versus Rounded Shoulder



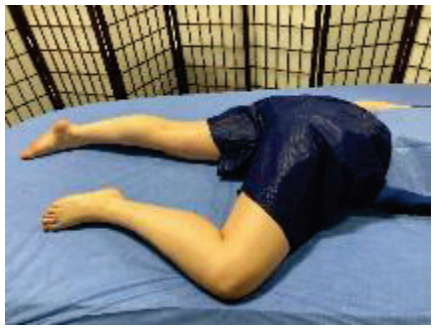
Using the dual camera feed on the GUI with anatomical labeling, verify that the breast is centered in the imaging chamber, the nipple is centered in the Sequr™ Breast Interface, and the SBI is secured and has not shifted on the platform. If the SBI has shifted, check for damage to the SBI and reposition or replace the SBI if necessary.

If the opposite breast is visible in the camera feed, ask the patient to use their hand to gently pull the opposite breast over to the side and out of the imaging chamber, making sure the patient does not raise up out of the SBI. Additionally, a towel can be positioned to keep the opposite breast from falling into the imaging chamber.

Check to make sure the abdominal fold is not in the imaging chamber. The SoftVue™ operator may need to help guide or push back any adjacent tissue rolls along the inframammary and lateral breast margins.

If comfortable and beneficial, have the patient pull the opposite leg up from the side you are scanning to rotate the torso laterally without leaning to the side or moving the body closer to the lateral ring margin (Figure 59). This improves chest wall access and allows the transducer to move into the axillary tail.

Figure 59: Leg Position



Having correct body and breast positioning is instrumental in achieving maximum extension, which is imperative for image quality.

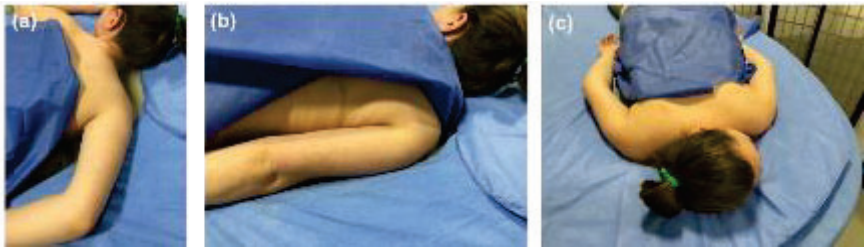
3.8.4 Positioning Tips for Different Habitus

AA/A/B/C Cup

Depending on pendulosity of the patient's breast, maximum extension will vary, and pulsation may not be avoided, especially on smaller breast sizes.

The ipsilateral arm is usually kept relaxed and loose (B and C cups) (Figure 60-a), but on small-breasted patients (A, AA, AAA), tightening the ipsilateral arm closer to the body may help lower the patient's upper body into imaging chamber (Figure 60-b). In unusual circumstances, where a patient is extremely small, bringing both arms by their side will allow their chest area to sink deeper into the imaging chamber (Figure 60-c).

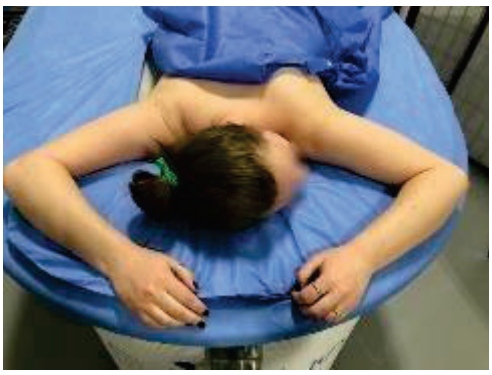
Figure 60: Positioning Tips for Different Habitus



D Cups and Larger

If breasts are pendulous and full, the patient may need to bring both arms above their head to elongate the breast (Figure 61).

Figure 61: Positioning for Large-Breasted Patients



It may be helpful to keep the patient's legs extended instead of raised up from the side you are scanning.

WARNING: *For patients with large breasts where the sides of the breast come into contact with the transducer, or if the patient reports that they can feel the transducer touching the sides of their breast, stop the scan immediately. Such patients are not to have a* SoftVue™ *scan performed, as contact with the moving transducer may create abrasions.*

Challenging Body Habitus/Nipple Position

Large Habitus: Make sure patient's abdominal fold is not in the imaging chamber. You may ask the patient to reach down and pull the tissue out of the imaging chamber or, if the patient is comfortable with being touched, you may help move the tissue away. Also ensure that any lateral adipose tissue is also pulled out of the imaging chamber.

Small Habitus: In patients who are shorter than 5' 3" or have a short torso, it may be difficult to completely remove the patient's inframammary or abdominal tissue from the imaging chamber. For patients with short torsos or necks, repositioning of the table padding or using a towel for head and neck comfort may be necessary.

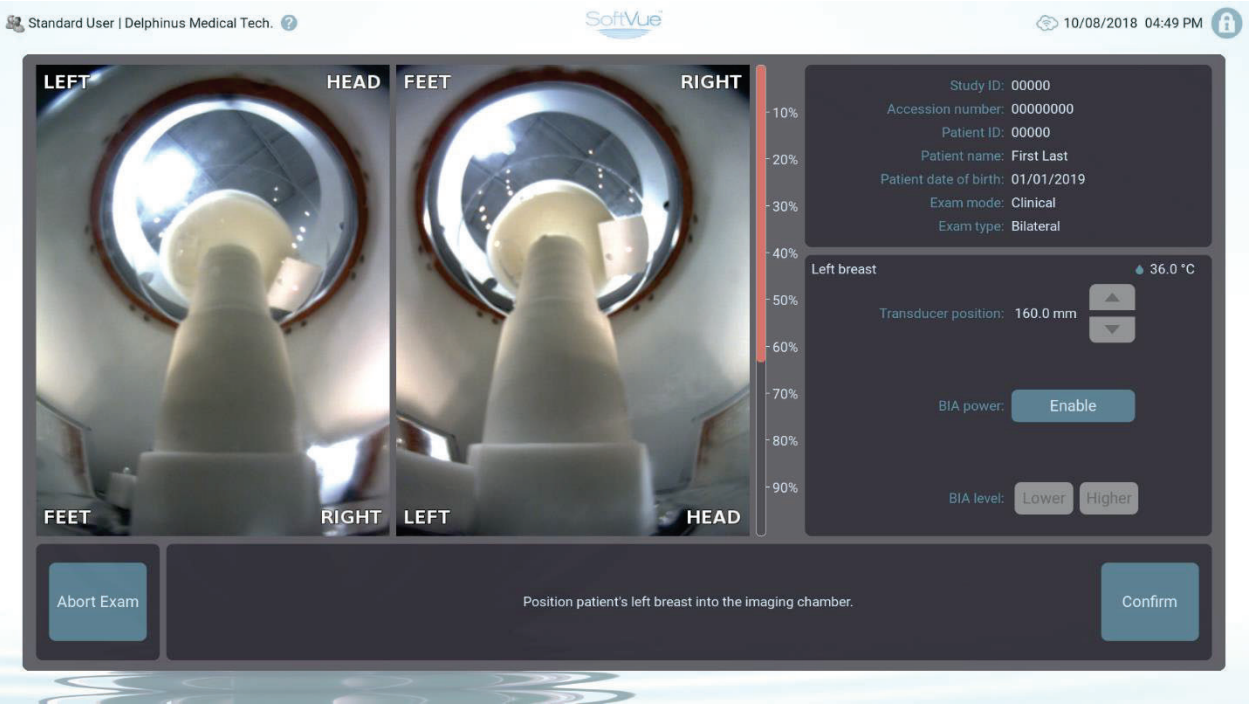
Off-Centered/Inverted Nipple

It may be required to manually guide the patient's off-centered nipple into the Sequr™ Breast Interface, with the patient's permission. Inverted nipples may have more difficulty with creating a proper seal, requiring lower Breast Interface Assembly vacuum level settings to be used.

3.8.5 Adjusting the Breast Interface Assembly Vacuum and Transducer Ring Position

During positioning, the exam screen is displayed (Figure 62).

Figure 62: Exam Screen



The power controlling the vacuum through the Breast Interface Assembly (BIA) is turned off by default. The BIA power can be disabled/enabled using the **Disable/Enable** button. When enabled at the start of patient positioning, it will automatically be set to the highest level setting and can be adjusted using the BIA level buttons. The **Lower** button can be tapped to decrease the BIA vacuum level, the **Higher** button to increase the BIA vacuum level. When the BIA level lower/higher limits have been reached, the respective button is disabled. The relative position of the Breast Interface Assembly platform is shown using the extension gauge displayed to the right of the camera feeds. A display of 0% corresponds to a fully extended assembly and 100% corresponds to a fully compressed assembly. In general, the higher the BIA vacuum level, the more the BIA is compressed.

Optimal breast extension and patient comfort can be modified by changing the BIA vacuum level. In general, the BIA level should be as high as possible to ensure optimal extension of the breast during imaging without causing pulsing of the Breast Interface Assembly or sacrificing patient comfort. This can be achieved by incrementally increasing the BIA level setting while monitoring the extension gauge on the exam screen and continually checking with the patient on their comfort level. If the patient experiences nipple discomfort, or the extension gauge begins to quickly oscillate up and down (“pulsing”), the BIA level should be decreased. For extremely small breasted patients, pulsing may be unavoidable; in that case, the lowest BIA level setting should be used.

Once the patient is properly positioned and comfortable, tap the **Confirm** button. The system will top off the water in the imaging chamber and enable transducer adjustment. Inform the patient that they may feel the water filling in the imaging chamber.

The position of the transducer can be adjusted using the controls displayed in the middle right section of the screen. This section also displays the temperature of the water in the imaging chamber, and the breast to be scanned (left/right). The position of the transducer can be

adjusted using the **Up/Down Arrow** buttons. The transducer will move until the corresponding arrow button is released, or the upper/lower limit of transducer motion has been reached. The position of the transducer is updated as the transducer moves.

Moving the transducer up to the level where a patient can feel it touching their chest wall is critical to image quality. Inform the patient that they may feel the transducer against the chest wall, possibly including a slight lifting sensation. Adjust the transducer position until you see a loss of extension of up to 5% as shown by the extension gauge on the scan screen. Some patients may experience pressure on their rib cage or chest wall when their upper body comes into contact with the transducer; this is expected. Be aware of increased pressure or discomfort to the patient and do not move the transducer too far up into the patient's chest wall; let the patient know that they will only feel the transducer on their rib cage and/or chest wall for a few seconds at the beginning and end of the exam.

The reference position (0.0 millimeters) of the transducer is set at the bottom of its range of motion. The scan length is detected automatically by the system.

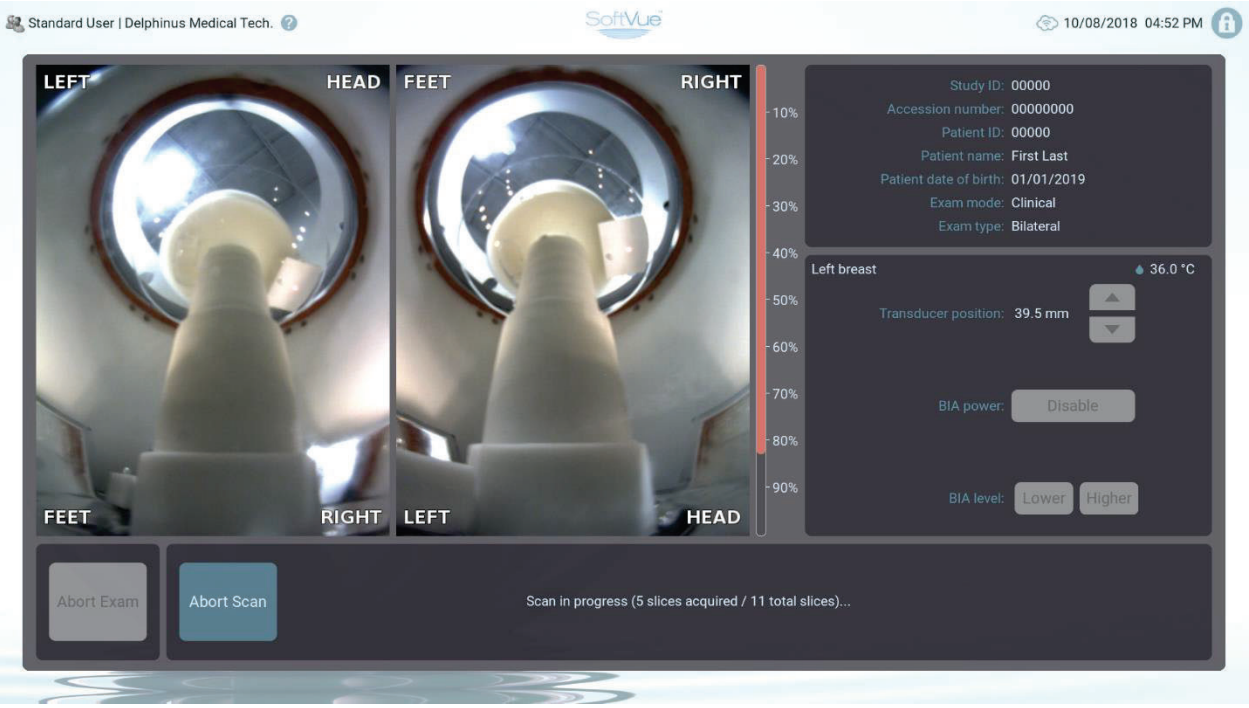
NOTE: *The SoftVue™ system will automatically end the scan once the whole breast has been imaged.*

3.8.6 Starting the Scan

Once the transducer position and BIA level have been set appropriately, the scan can be started. Instruct the patient not to talk or move during the exam, unless they feel any pain, discomfort, or rubbing/scraping of the moving transducer along their breast, in which case the scan can be aborted and retried. Instruct the patient to breathe normally, avoiding deep or irregular breathing. Give the patient an estimate of how long the exam will last. The scan time is dependent on the number of slices being acquired, which varies by breast size, but is approximately two to four minutes.

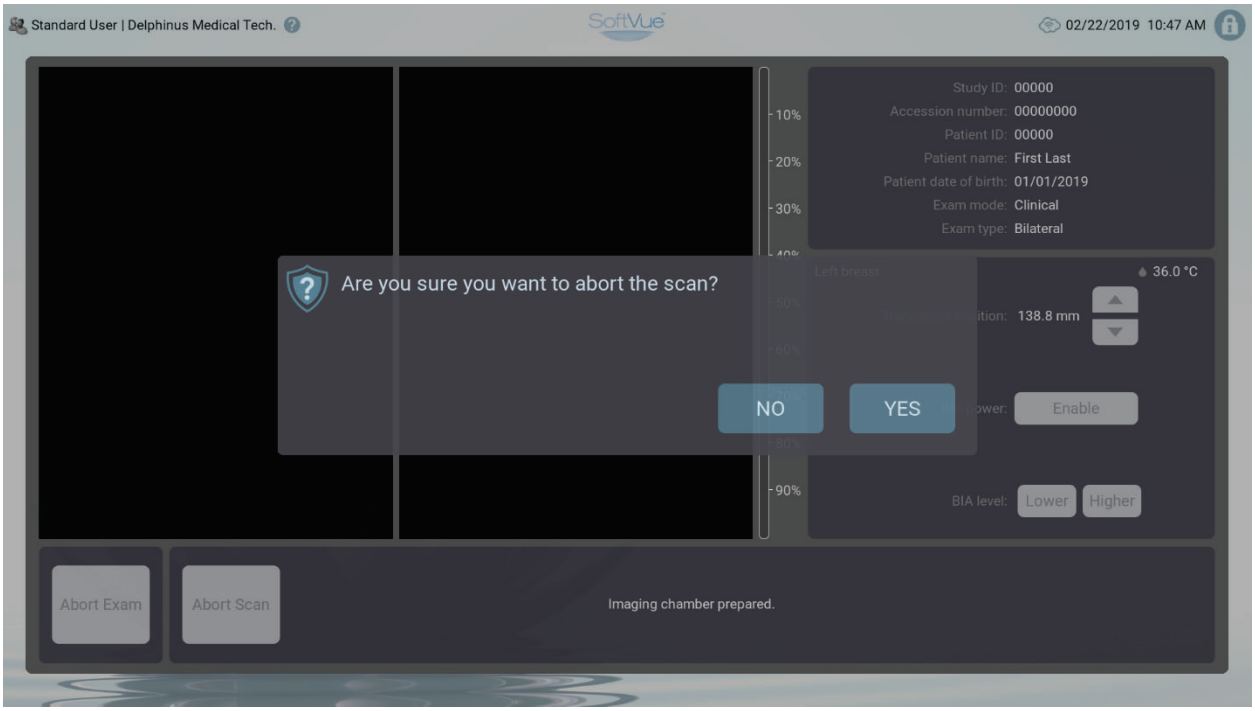
Tap the **Start Scan** button to start the scan. Once the scan has started, "Scan in progress…" will be displayed on the Progress screen and the numbers of slices acquired and total slices in the scan are displayed as the scan progresses (Figure 63). The user should monitor the camera feeds and extension gauge for any excessive patient motion or loss of extension and wait for the scan to complete. In the case of excessive patient motion or loss of extension the scan should be aborted.

Figure 63: Scan in Progress Display



To stop the scan at any time and for any reason, tap the **Abort Scan** button. When the **Abort Scan** button is tapped, a screen will appear prompting the user to confirm the scan is to be aborted (Figure 64).

Figure 64: Abort Scan Confirmation

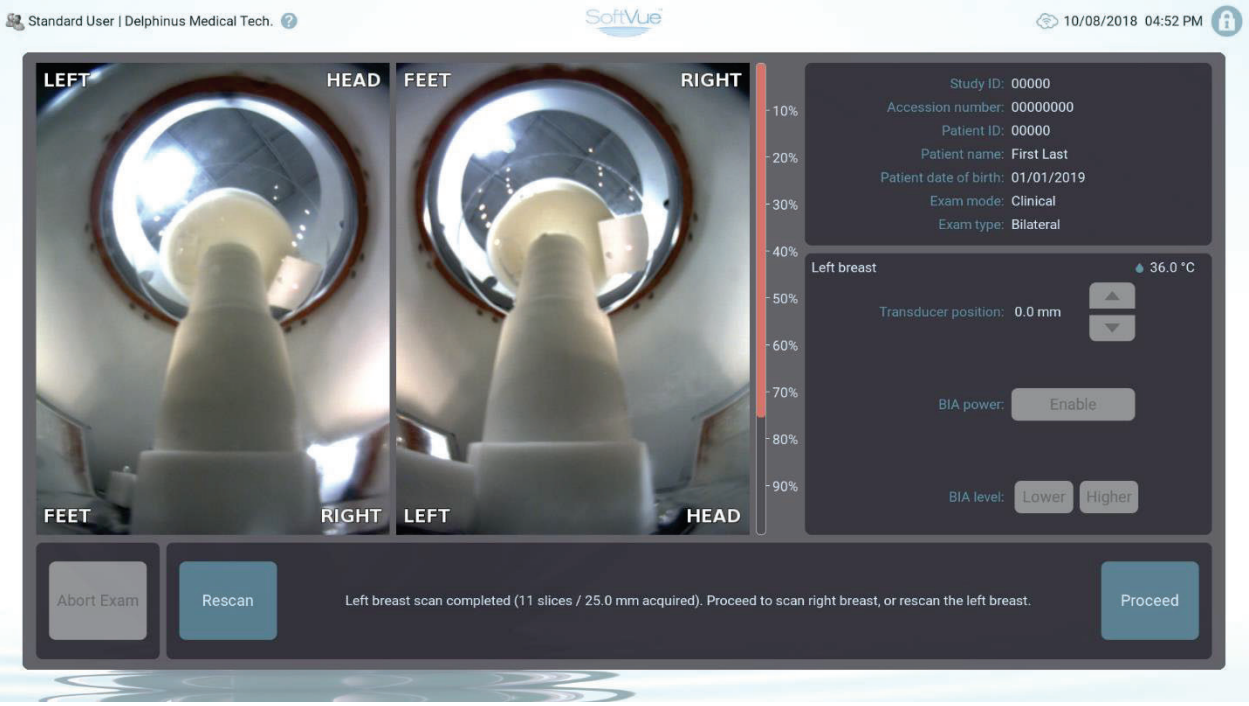


Tapping **No** will return the user to the Scan Progress screen and the scan will continue. Tapping **Yes** will abort the current scan and reset the imaging chamber. The user can then repeat patient positioning and transducer / BIA level adjustment for the breast being scanned.

If the exam must be aborted while a scan is in progress, the scan must be first aborted; the exam can then be aborted.

Once the scan is complete, the BIA power will be turned off and the user will be informed of the total number of imaging slices acquired and the distance the transducer has traveled during the scan (Figure 65).

Figure 65: Scan Complete Display



The breast can be rescanned by tapping the **Rescan** button. The user may wish to rescan the breast if the patient moved during the scan, or the user noted other factors that would lessen the exam quality, such as the Sequr™ Breast Interface slipping off the BIA platform or a loss of extension. If a bilateral exam was selected, the user can proceed to the right breast by tapping the **Proceed** button, which will reset the imaging chamber for the next scan.

The Breast Interface Assembly will release the patient's breast, as shown by the extension gauge moving upward. Once the breast is released, instruct the patient to raise themselves out of the imaging chamber; the patient may wish to dry off the breast that was just scanned with a towel. If only one breast is being scanned, the patient may get dressed and leave the exam room; if a bilateral exam is being performed, the patient positioning, transducer adjustment, and scanning processes will be repeated for the other breast, as indicated on the GUI.

Once the scan is complete, the user should ask the patient to dismount the table. Once the patient dismounts the table, the user should tap the **Proceed** button to reset the transducer position and proceed to cleaning the SoftVue™ system.

3.8.7 Cleaning the SoftVue™ system

After the transducer has been re-set, remove the Sequr™ Breast Interface from the platform as prompted (Figure 66). It can be disposed of in regular trash.

Figure 66: Sequr™ Breast Interface Removal & Cleaning Prompt

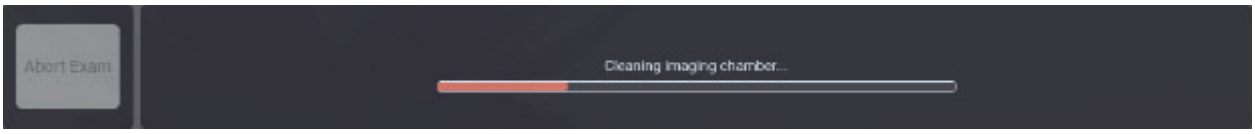
3.8.7.1 Procedure for adding SoftVue cleaning solution:

1. Pour 4 oz. of Protex into the graduated bottle provided by Delphinus (Figure 67).

Figure 67: Cleaning Solution Bottle

2. Add the solution into the SoftVue™ imaging chamber and tap **Confirm** (Figure 66).
3. Rinse the graduated bottle and save for next use.

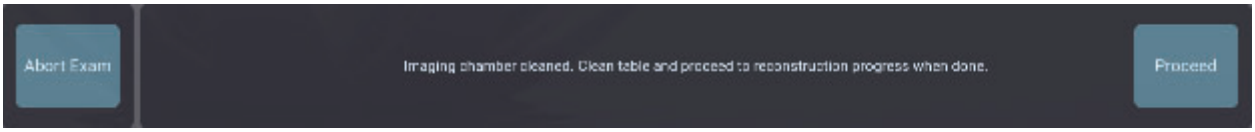
Figure 68: Cleaning Progress Display



Once the **Confirm** button (Figure 66) is tapped, the pump will circulate the water for two minutes and then the imaging chamber will be drained. The cleaning progress is indicated on the display (Figure 68)

After the cleaning cycle is complete, tap the **Proceed** button to display the reconstruction progress (Figure 69).

Figure 69: Clean table and proceed to Reconstruction Display



Clean the table top, membrane and upper and lower funnel with Protex Spray (Figure 70) using disposable lint free cloths (Figure 71) between each patient.

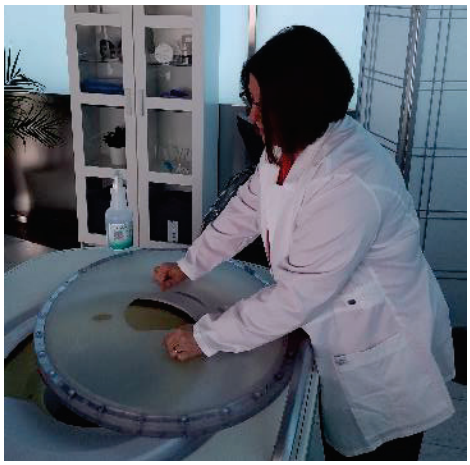
Figure 70: Protex Spray

Figure 71: Lint Free Cloths

Remove the padding from the table. Using the Protex with the spray nozzle attached, spray the front and back of the table padding and the SoftVue™ table surface. Then, wipe dry with TechniCloth Wipes.

Remove the Membrane. Spray the front and back surfaces using Protex and wipe dry using the TechniCloth Wipes (Figure 72).

Figure 72: Clean Membrane



Press the button on the top of the SoftVue™ table, then pull up on the handle to open the hood. It may be necessary to push down on the tabletop while pressing the button (Figure 73).

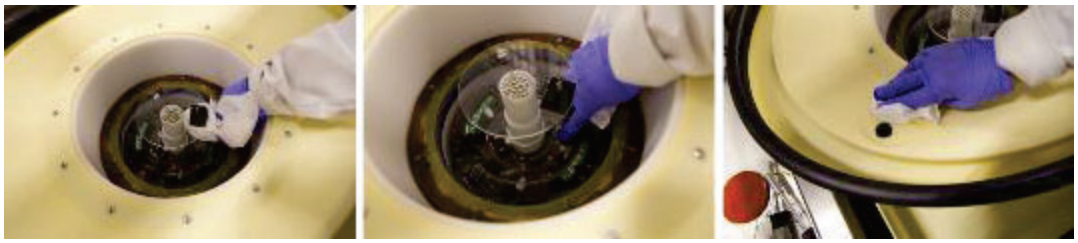
Figure 73: Tabletop Button and Handle

Spray with Protex on the upper and lower funnels (Figure 74).

Figure 74: Funnels

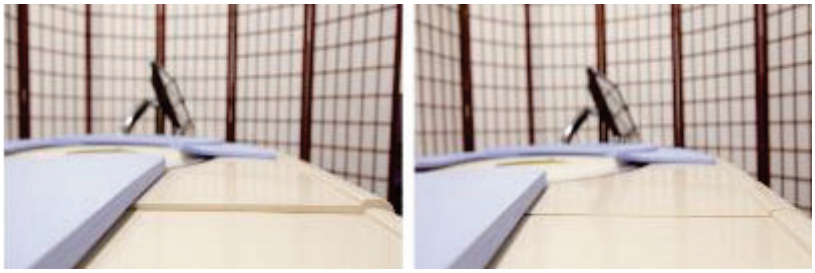
Once the entirety of the upper and lower funnels have been sprayed with Protex, use the TechniCloth Wipes to dry all surfaces. Take special care to wipe dry the cover near the laser and imaging chamber full sensor (Figure 75).

Figure 75: Drying Instructions



Pull the latch down and make sure the latch is secure and the table is seated completely (Figure 76).

Figure 76: Table Edge Alignment



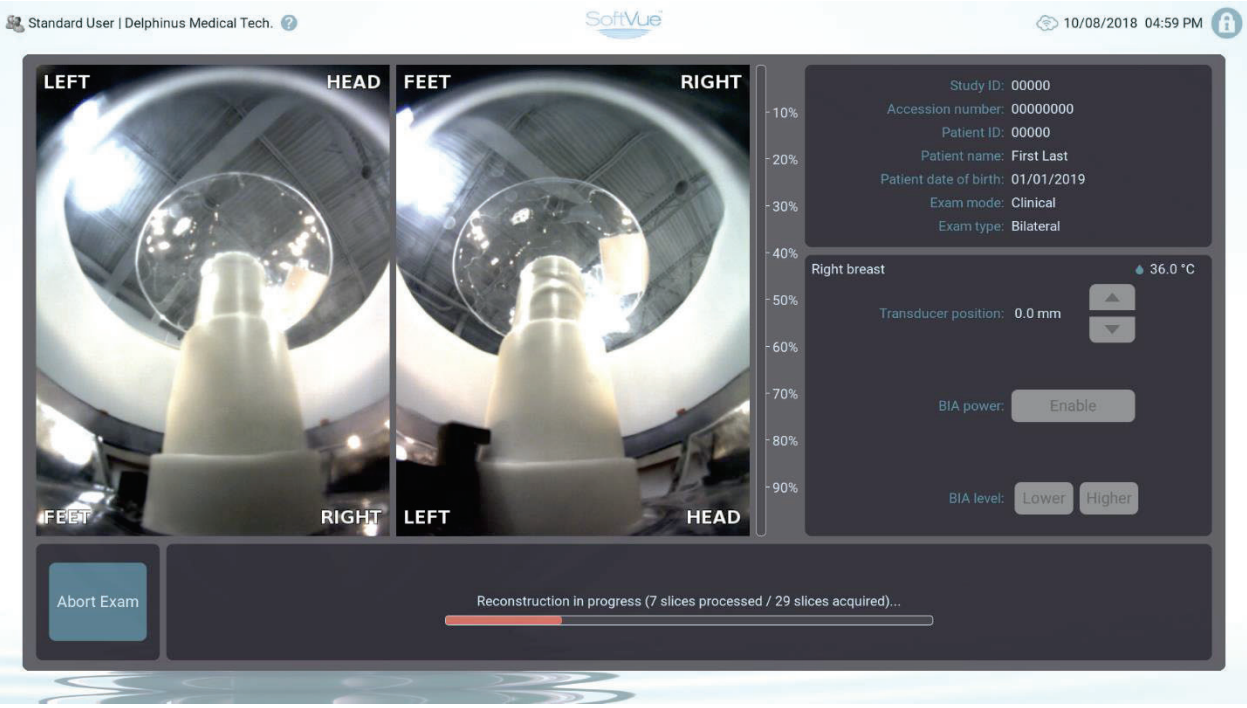
Insert the membrane into the table, making sure the flat cutout is towards the foot-end of the table.

Place the table padding back on the table.

3.8.8 Progress Reporting

A progress bar will appear indicating the progress of image reconstruction (Figure 77). If the image reconstruction and/or image transfer is complete by the time the cleaning process is finalized, no progress bar will be shown.

Figure 77: Reconstruction Progress



3.8.8.1 Reconstruction progress

During image reconstruction, the reservoir is re-filled in preparation for the next exam procedure. Once image reconstruction is complete, the progress of image transfer will be displayed. The image reconstruction process cannot be aborted. If the Exam is aborted using the **Abort Exam** button, all the exam data, including images, will be lost.

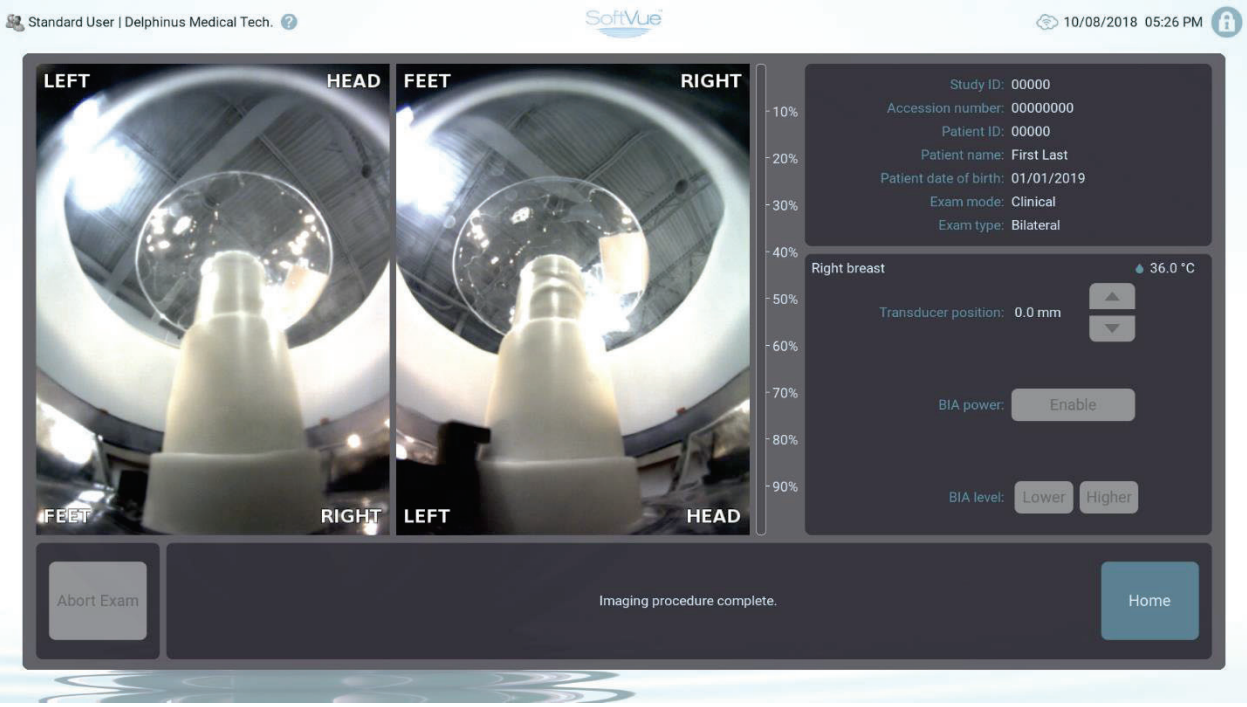
3.8.8.2 Image transfer progress

Once the image reconstruction process is complete, the SoftVue™ system will send the DICOM images to the preconfigured PACS servers for permanent storage at the facility (see Section 3.9.4.2 for PACS configuration details). If the transfer fails or the user chooses to postpone the transfer, the images remain in local storage on the SoftVue™ system. Images remaining in local storage will be transferred automatically at the next image transfer and can include multiple exams. Transfer can be manually triggered at a later point (see Section 3.6.7.4 for instructions on initiating image transfer). If the maximum local image storage capacity is reached, the user will not be allowed to perform further exams.

3.8.8.3 Exam complete

The user will receive a notification message once the data has been reconstructed and the images have been transferred (Figure 78). The user can tap the **Home** button to return to the Home screen as soon as the image reconstruction process is complete and the reservoir is filled. The user can continue to monitor the progress of image transfer through the Overall Status Box (see Section 3.6.1).

Figure 78: Procedure Complete Notification



3.9 System Settings

System settings can be viewed by tapping the **Settings** button from the Home screen. The settings are organized into categories using a tab layout. These categories are detailed in the following sections. Tapping the **X** button in the lower left of the screen will return the user to the Home screen.

When leaving a tab with unsaved modifications, the user is prompted to apply or discard the changes, or to cancel to continue editing the information. If the user does not have sufficient privileges to modify a setting, the corresponding GUI element will be disabled.

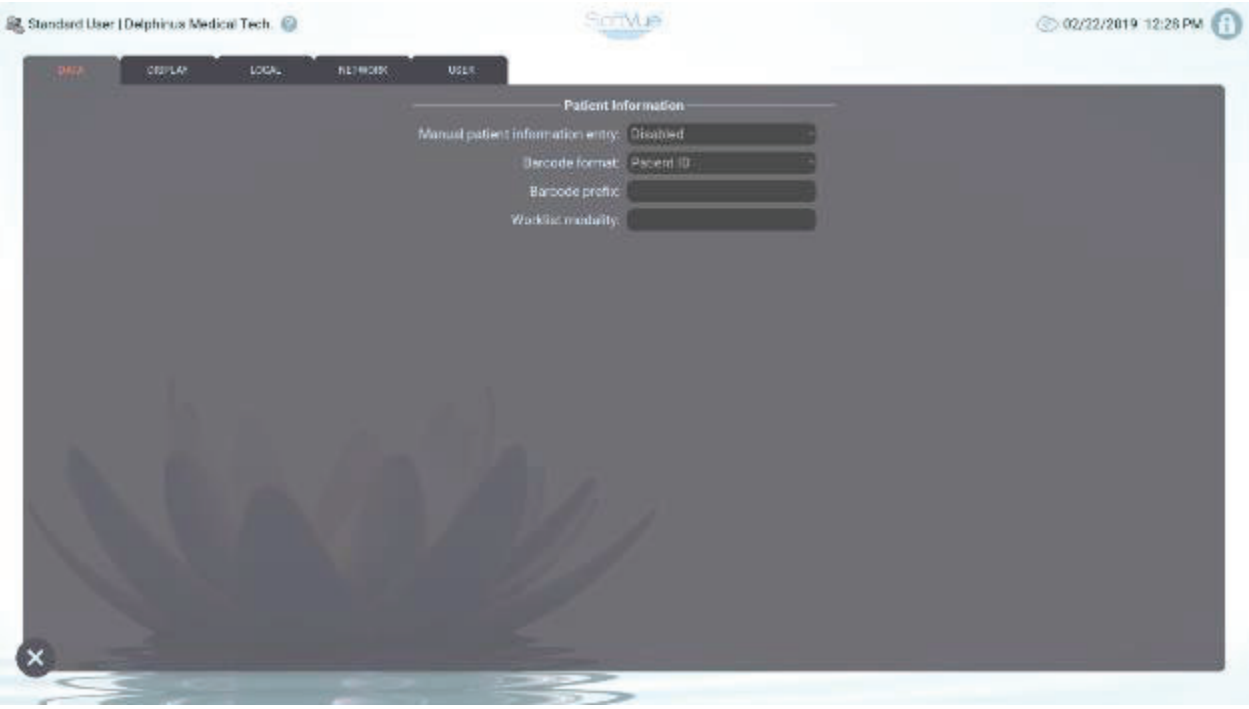
Once changed, settings can be applied by tapping the **Apply Changes** button; the user will be prompted to confirm that the settings will be applied. Changes can be discarded by tapping the **Revert Changes** button. If an invalid entry is made when attempting to apply setting changes, an error message will be displayed and then return to the current settings screen.

NOTE: *The default administrator profile is configured by a Delphinus Service Representative at installation and will be provided to the facility upon completion of the installation process.*

3.9.1 Data Tab

The Data tab allows users associated with the Administrators group to modify settings related to data entry (Figure 79).

Figure 79: Data Tab



3.9.1.1 Manual patient information entry

Used to enable or disable manual patient information entry on the Exam Information screen (see Section 3.8.1). If disabled, users will only be able to modify the study ID and exam type while in the Exam Information screen. The remaining information will need to be provided through the worklist.

3.9.1.2 Barcode format

Used to specify what DICOM tag the string of characters encoded in the patient identification barcode corresponds to.

3.9.1.3 Barcode prefix

Used to specify a prefix encoded in the patient identification barcode. If the prefix does not match what is encoded in the barcode, that barcode is considered not valid and the

worklist will not be filtered. A valid prefix will contain between 0 and 16 characters from the keyboard. If no prefix is provided, prefix matching will not be performed.

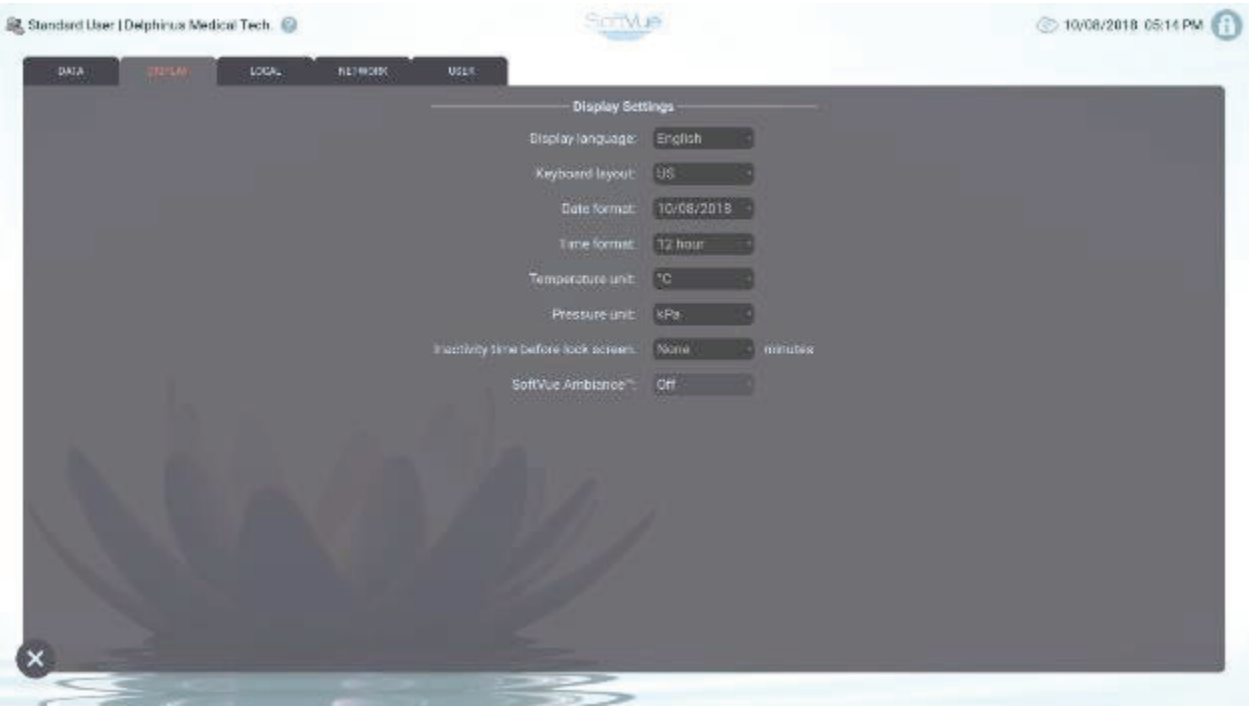
3.9.1.4 Worklist modality

Contains the modality to be used as a filter for worklist queries. A valid modality will contain between 0 and 16 characters from the keyboard, except the character \ (backslash). If no worklist modality is provided, worklist queries will not be filtered by modality. The worklist modality setting is typically used to ensure that only patients that will be scanned on SoftVue™ show up in the worklist; for example, if the site enters all SoftVue™ patients into the RIS server with the modality “SV”, setting the worklist modality to “SV” will ensure that only SoftVue™ patients appear in the worklist.

3.9.2 Display Tab

The Display tab allows the user to choose the way the GUI displays information on the screen (Figure 80). Users associated with the Administrators group can modify all the display settings. Standard users can only modify the SoftVue Ambiance color selection.

Figure 80: Display Tab



The modifications are made by selecting the desired option from the respective drop-down menus. Modifications are directly applied when selected. Table 4 details the available display settings.

Table 4: Display Settings

Setting	Options
Display language	English
Keyboard layout	US
Date format	31/03/2014 Mar 31, 2014 31 Mar 2014 03/31/2014
Time format	24 hour 12 hour
Temperature unit	Celsius (°C) Fahrenheit (°F)
Pressure unit	Kilopascal (kPa) Pounds per square inch (PSI)
Inactivity time before lock screen	None, or a time set in intervals of 5 minutes between 5 and 60 minutes
SoftVue Ambiance (the color of the lighting on the outside of the system)	Off, or one of the following colors: Blue Cyan Green Magenta Red White Yellow

3.9.3 Local Tab

The Local tab (Figure 81) allows Users associated with the Administrators group to modify the local settings of the system.

Figure 81: Local Tab

3.9.3.1 Institution name

Name of the institution where the SoftVue™ system is installed. A valid institution name contains between 0 and 64 characters from the keyboard, except the character \ (backslash).

3.9.3.2 Institution department

Name of the department in the institution where the SoftVue™ system is installed. A valid department name will contain between 0 and 64 characters from the keyboard, except the character \ (backslash).

3.9.3.3 Institution address

Address of the institution where the SoftVue™ system is installed. A valid institution address will contain between 0 and 1024 characters from the keyboard, except the character \ (backslash).

3.9.3.4 Station name

Name assigned to the SoftVue™ system. A valid station name will contain between 0 and 16 characters from the keyboard, except the character \ (backslash).

3.9.3.5 Time Adjustment

The system will use the configured NTP Server for time configuration when the time adjustment method is set to automatic. Refer to section 3.9.4.4 for information on configuring the NTP server. Manual time adjustment can be used to configure the system date and time as selected in the Date and Time fields. SoftVue™ automatically adjusts the time for daylight savings.

3.9.3.6 Date

Sets the date of the system. Disabled when Time adjustment is set to automatic.

3.9.3.7 Time

Sets the time of the system. Disabled when Time adjustment is set to automatic.

3.9.3.8 Time zone

Sets the time zone of the system.

> ***NOTE:*** *Date and time reconfigurations do not apply to the patient data until after the system has been restarted.*

3.9.4 Network Tab

The Network tab allows users associated with the Administrators group to modify network setting for the local host, PACS servers, FTP server, NTP server, DNS server, and RIS server connections (Figure 82).

Figure 82: Network Tab

The SoftVue™ system only supports IPv4 dotted-decimal notation IP addresses.

It is the facility's responsibility to ensure that the PACS, RIS, and FTP servers are configured such that SoftVue™ applications have the required read/write capability to those servers. If the servers are not configured appropriately, patient data may be lost.

3.9.4.1 Local Host

The local host settings configure the SoftVue™ system's interface to the facility's network. If the IP allocation method is set to Dynamic, a network DHCP server will be responsible for the configuration of the SoftVue™ network interface configuration. The Dynamic configuration disables manual configuration of the IP address, Subnet mask, Gateway address, and DNS Server settings. The Subnet mask field must be entered in dotted-decimal IPv4 notation. The local Application Entity (AE) Title of the SoftVue™ system as configured in this section will need to be configured on the network PACS and RIS servers accordingly to allow for proper DICOM communication.

3.9.4.2 PACS Servers

The PACS Servers settings configure the IP addresses/hostnames, ports, and AE titles to be used to connect to the PACS Servers to be used by the SoftVue™ system for DICOM image transfer. Two PACS servers can be configured independently: a primary and a secondary server. If one or both PACS servers are enabled, the images from each exam procedure will be transferred to that PACS server. Each PACS server can be disabled to prevent the SoftVue™ system from transferring images to that server while preserving its configuration parameters.

The PACS Server communication can be tested with the **Connection Verification** button (double monitor icon) in the lower right of the PACS Servers box.

3.9.4.3 FTP Server

The FTP Server settings configure the IP address/hostname, port, file path, username, and password to be used to connect to the FTP Server to be used by the SoftVue™ system for raw data transfer.

The FTP Server communication can be tested with the **Connection Verification** button (double monitor icon) in the lower right of the FTP Server box.

3.9.4.4 NTP Server

The NTP Server settings configure the IP address/hostname of the NTP Server to be used by the SoftVue™ system for automatic network time adjustment.

The NTP Server communication can be tested with the **Connection Verification** button (double monitor icon) in the lower right of the NTP Server box.

3.9.4.5 DNS Server

The DNS Server settings configure the IP addresses of the DNS Servers used by the SoftVue™ system for hostname resolution. When the localhost IP allocation method is set to Dynamic, these fields cannot be modified. When manual DNS Server configurations are used, hostnames used in configuration fields must be fully qualified domain names.

The DNS Server communication can be tested with the **Connection Verification** button (double monitor icon) in the lower right of the DNS Server box.

3.9.4.6 RIS Server

The RIS Server settings configure the IP address/hostname, port, and AE title to be used to connect to the RIS Server to be used by the SoftVue™ system for worklist query.

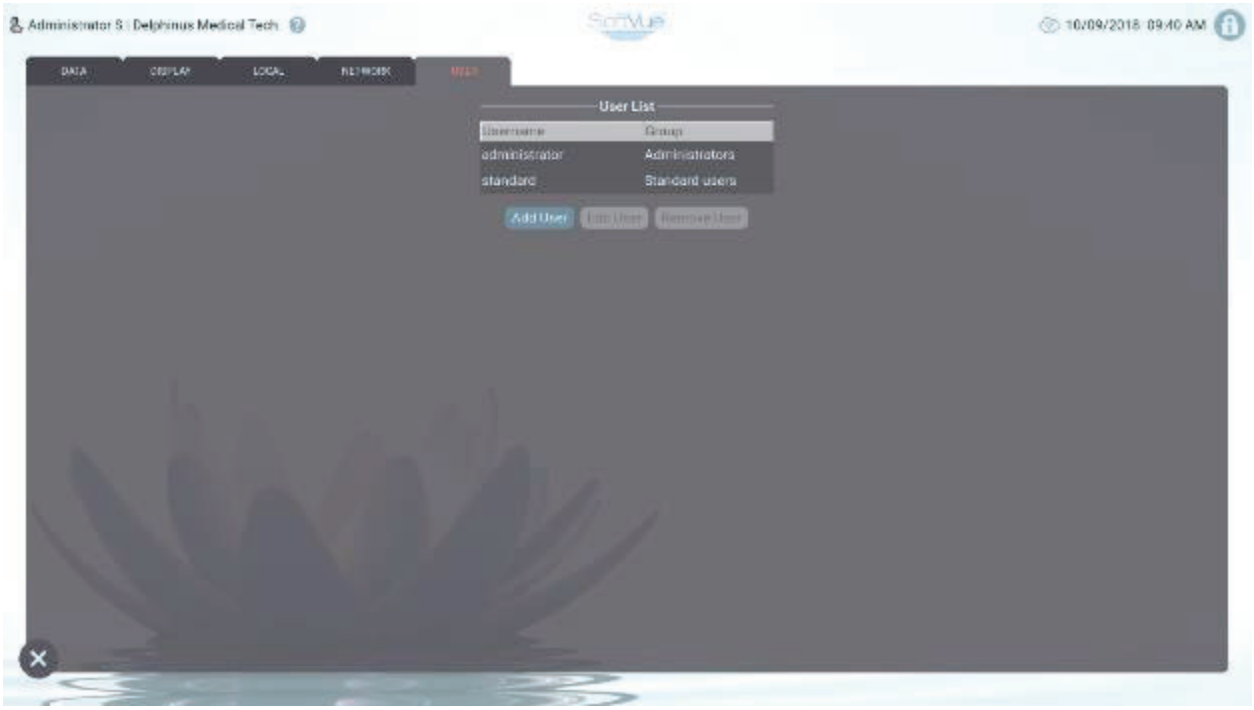
The RIS Server communication can be tested with the **Connection Verification** button (double monitor icon) in the lower right of the RIS Server box.

3.9.5 User Tab

The User tab allows the user to view the list of users registered in the system (Figure 83). The registered users visible in the list will depend on the group the user belongs to.

User profiles can be added, edited, and removed. The permission to use these features is defined by the group associated with the user: standard users can edit their own user profile only; administrators can add, remove, and edit user profiles.

Figure 83: User Tab



3.9.5.1 Add User

When logged in as an Administrator, a new user can be added by tapping the **Add User** button. Tapping the **Add User** button will display the User Profile screen (see Section 3.9.5.4 for details).

3.9.5.2 Edit User

The individual user fields can be edited by selecting the desired user from the list and then selecting the **Edit User** button. This will display the User Profile screen (Section 3.9.5.4) populated with information for the selected user. There will be an **Apply Changes** button instead of the **Add User** button. Users cannot change their own group association or their usernames. If a username requires editing, the profile must be removed and re-created by an administrator.

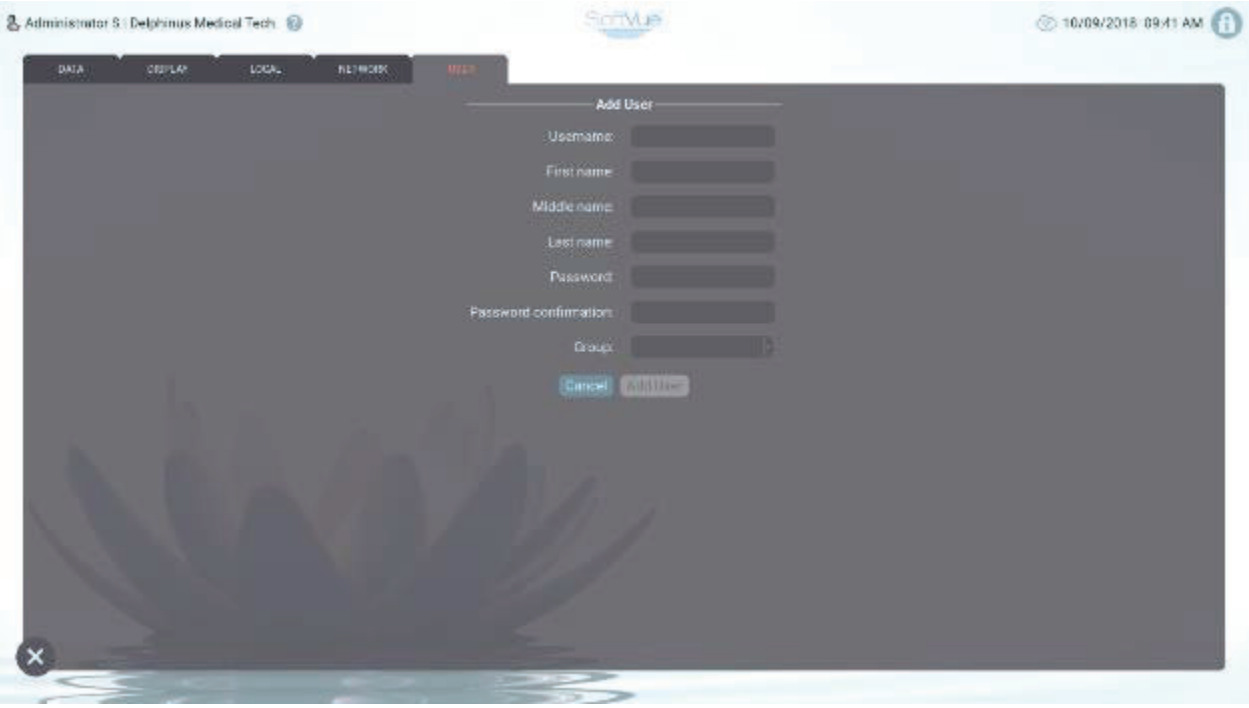
3.9.5.3 Remove User

When logged in as an Administrator, a user can be removed by selecting an existing user from the list and tapping the **Remove User** button. A confirmation prompt will verify the selection. The user account for the active session cannot be removed from the list.

3.9.5.4 User Profiles

When adding or editing user profiles, the User Profile screen (Figure 84) allows the user to modify the fields listed below.

Figure 84: User Profile



Tapping the **Cancel** button will return to the User tab. If any changes were made, the user will be prompted to confirm that the information can be discarded.

Once user information has been entered or modified, the changes can be implemented by tapping the **Add User** button (Add User) or **Apply Changes** button (Edit User). A confirmation prompt will verify the completion of adding/editing the user.

3.9.5.4.1 Username

Unique username assigned to the user. A valid username of the user will contain 3 to 32 characters, utilizing only the alphanumeric characters and the special characters. (dot), _ (underscore), and - (dash).

3.9.5.4.2 First Name

First name of the user. A valid first name of the user will contain 1 to 24 characters, utilizing any of the characters from the keyboard except \ (backslash), = (equality), and ^ (caret).

3.9.5.4.3 Middle Name

Middle name of the user. A valid middle name of the user will contain 0 to 12 characters, utilizing any of the characters from the keyboard except \ (backslash), = (equality), and ^ (caret).

3.9.5.4.4 Last Name

Last name of the user. A valid last name of the user will contain 1 to 24 characters, utilizing any of the characters from the keyboard except \ (backslash), = (equality), and ^ (caret).

3.9.5.4.5 Current Password

Only present when editing your own user profile. Requires the user to enter their current password in order to change the password.

3.9.5.4.6 Password

Password assigned to the user. A valid user password will contain 8 to 32 characters, utilizing any of the characters from the keyboard, except \ (backslash).

3.9.5.4.7 Password Confirmation

Confirmation of the password assigned to the user. The password confirmation must match the password in Section 3.9.5.4.5.

3.9.5.4.8 Group

Group that the user belongs to. The group defines the permissions of the user. See Section 3.9.5.5 for details.

3.9.5.5 Groups

Table 5 shows the group icons as they are displayed in the Status Bar (Section 3.5) for the active user account and the details of the group abilities and privileges.

Table 5: Group Icons and Definitions

Icon	Definition
	**Standard users** A standard user can perform a standard imaging procedure, perform a calibration of the system, view the system status, and edit his/her own user settings.
	**Administrators** An administrator has all the privileges of a standard user. In addition, the user can add, remove, and edit user profiles. Administrators can add standard users as well as other administrators. Administrators can sanitize the system from ePHI information. An administrator can also modify some display parameters of the SoftVue™ graphical user interface and change the SoftVue™ network and scanner configuration parameters.

Table 6 summarizes each user group and their system settings modification privileges.

Table 6: User Group Privileges

Modification Privileges	Standard Users	Administrators
Data Settings	None	All
Display Settings	SoftVue Ambiance color selection only	All
Local Settings	None	All
Network Settings	None	All
User Settings	Edit own First/Middle/Last Name and Password only	All

3.10 Emergency Power Down

In the event of any emergency, the user can immediately remove power from the system by pressing the red **Emergency Stop** button on the front of the system.

When the emergency shutdown is initiated, electrical power is abruptly discontinued to the system and safely shut down. To restore power to the system, rotate the **Emergency Stop** button clockwise and release. The button will return to its original position. Once the **Emergency Stop**

button has been released, press the green colored **Power On** button. The system should now power on.

Chapter 4: Service and Maintenance

In order to ensure the safety of patients, users, and to maximize the lifespan of the SoftVue™ system, recommended and required service and maintenance should be performed by qualified personnel.

Only the in-line water filter specified in this chapter is intended to be serviced by the user. All other components of the SoftVue™ system are to be serviced by a qualified Delphinus Service Representative. Improper installation or modification of components not conducted by qualified personnel can lead to permanent damage to the SoftVue™ system and serious patient or user injury.

Delphinus Medical Technologies will provide circuit diagrams, component part lists, descriptions, and calibration instructions to assist qualified service personnel in parts repair.

4.1 Inspecting the Transducer

Prior to starting the system at the beginning of the day, the user should inspect the transducer ring for cracks or fractures in the housing surface or silicone as well as for any other possible damage to the surface of the transducer that may result in the ingress of water or harm to the patient. If damage is found, contact Delphinus service.

4.2 Cleaning

Cleaning and disinfection should be carried out on a regular schedule. Delphinus Medical Technologies recommends that each user maintain a cleaning/disinfection log to ensure proper cleaning and disinfection of the SoftVue™ system.

4.2.1 Inter-Patient Cleaning of the System

It is recommended that the SoftVue™ examination table top, patient interface membrane, and imaging chamber be cleaned between each patient per the cleaning instructions in section 3.8.7. The user will be prompted to disinfect the table after each patient scan has been completed. The recommended disinfectant for SoftVue™ is Protex™ Disinfectant Spray.

	***CAUTION:***	*It is the user's responsibility to qualify any deviations from the recommended procedure described above. Never use products that contain bleach, glutaraldehyde, or phenol on any component of the SoftVue™ system. Always use lint-free wipes to avoid introducing foreign debris into the imaging chamber.*
	***NOTE:***	*Use of lint-free wipes is required for cleaning.*

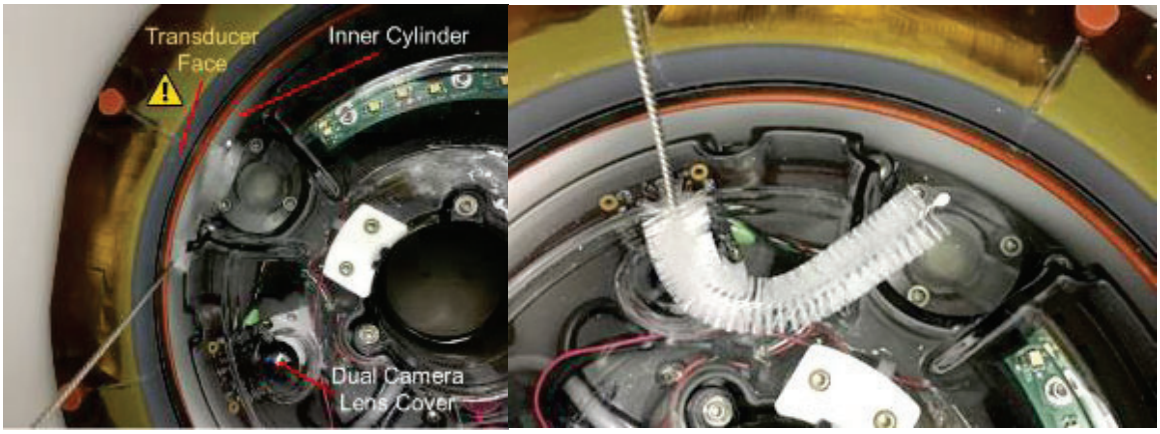
4.2.2 Weekly Cleaning

4.2.2.1 Imaging Chamber Debris Removal

It is recommended that the SoftVue™ imaging chamber is cleaned once per week during shutdown (water-purge) to remove debris from the imaging chamber. This will require the use of a pipe cleaner brush. While the system is purging water, the user should drag the curved section of the brush gently, at an angle through the crevice between the inner cylinder and the dual camera lens cover. The purging water will drain any lifted debris through the drain line. See the figure below for additional detail. Take care not to allow the brush handle to make unreasonable contact with the transducer ring face.

CAUTION: *To prevent potential damage to the transducer, do not touch the transducer face with the brush handle.*

Figure 85: Pipe Cleaner Brush & Imaging Chamber Components



4.2.2.1 Telescope Joint Cleaning

The joints of the telescope can also collect debris and film. Spray the joints liberally with Protex spray and scrub using the brush provided for weekly purge cleaning (Figure 86).

Figure 86: Telescope Cleaning

4.2.2.1 Upper Outer Ring Ridge Cleaning

The ridge between the upper cylinder and the funnel (Figure 87) can collect debris and film as well. This area should be cleaned by pressing a lint free wipe into the crevice and

circling the area. The brush can be used as well if any debris will not come loose with the wipes.

Figure 87: Upper Outer Ridge Cleaning

4.2.3 Cleaning External Components

Follow standard clinical practice for cleaning these types of surfaces.

⚠	***CAUTION:***	*Do not apply any cleaning agents directly to the screen of the touchscreen Display. Apply cleaners with a nonabrasive towel or equivalent.* *Avoid applying cleaning agents directly to labeling.*

4.3 Replacing the Microbial Filter

The user is responsible for the replacement of the Pall Aquasafe™ Water Filter (Pall P/N: AQINA, Figure 88) every 30 days to protect the SoftVue™ water system against waterborne contaminates.

4.3.1 Remove Old Filter

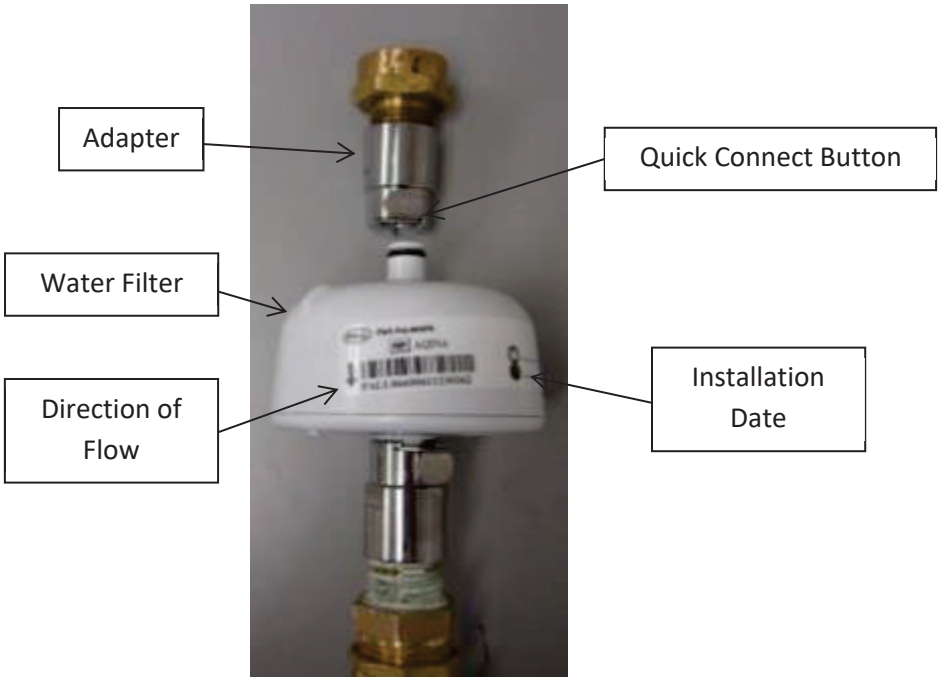
Turn the water source off. Press and hold the quick connect button and pull the filter straight out of the adapter on the side closest to the water source. Repeat this for the adapter closest to the system inlet. The old filter can be disposed of in regular trash.

⚠	***CAUTION:***	*Water pressure inside the hose when the filter is removed may result in spillage. A towel wrapped around the filter is recommended to catch overflow.*

4.3.2 Install New Filter

Prior to installing the new filter, record the installation date on water filter label. To install the new filter, connect the filter with the flow direction arrow pointing toward the hose leading to the SoftVue™ system by pressing the filter into the adapter until an audible snap is heard. Then, connect the adapter from the water source on the incoming water port. Turn the water source on and check for any leaks or faulty connections.

Figure 88: Water Filter



4.3.3 Order New Filters

To order, contact Delphinus Support at: support@delphinusmt.com

If an urgent order, call Delphinus at: +1 (855) 522-9499

4.4 Scheduled Service

Delphinus Medical Technologies, Inc. recommends that the SoftVue™ system undergoes annual servicing. To schedule a service appointment, contact Delphinus Medical Technologies, Inc (see Section 8.1).

Chapter 5: Safety

5.1 Patient Safety

5.1.1 Patient Identification

Proper identification on all patient data is critical. Verify the accuracy of the patient's name and ID numbers when entering data into the SoftVue™ system and ensure correct identification on all recorded data and hard copy prints. Identification errors may result in harm; accurate data entry will increase patient safety and effectiveness.

The SoftVue™ system does not store patient identification information. Upon completion of the exam, the reconstructed DICOM image files containing patient identification information are transferred off of the system.

5.1.2 Diagnostic Information

Equipment malfunction can result in a failure to image, measurement errors, or an inability for the radiologist to interpret the image.

5.1.3 Mechanical Hazard

The use of a damaged transducer ring can result in injury. Inspect the transducer ring daily for sharp, pointed, or rough surface damage that could cause injury.

5.1.4 Electrical Hazard

The use of a damaged transducer ring can also increase the risk of electrical shock if conductive solutions come in contact with internal electrically active parts. A visual inspection of the transducer ring daily for cracks or openings in the housing and holes in and around the acoustic lens or other damage that may allow liquid entry. Additionally, a physical inspection should be performed. By applying light pressure to the top of the 8-white silicone caps the user can confirm that the segments are properly secured to minimize the risk of electrical shock.

5.1.5 ALARA Principle

The SoftVue™ design is based on the As Low as Reasonably Achievable (ALARA) principle. In order to keep the acoustic output ALARA for the shortest time necessary to achieve acceptable diagnostic results, the SoftVue™ system operates at a single acoustic output setting. This ensures that the SoftVue™ system always operates using the minimum energy necessary.

There are no user adjustable parameters that can affect the acoustic output power levels. Because there are no user adjustable parameters and the acoustic output is constant, the mechanical index and the thermal index are also held constant. These values are not displayed to the user since the SoftVue™ system has a fixed acoustic output.

The SoftVue™ system has been designed to ensure that the temperature of the transducer face will not exceed the limits established in *IEC 60601-2-37: Particular requirements for the safety of ultrasound medical diagnostic and monitoring equipment*. In the event of a device malfunction, there are redundant controls in place that limit transducer power.

5.2 Acoustic Output

5.2.1 Acoustic Output Measurement

The acoustic output measurement for the SoftVue™ system has been measured and calculated in accordance with "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers".

5.2.2 Track 1 Acoustic Output Reporting Table (Auto-Scanning Mode):

Operating Mode: B-mode
Transducer Model: 300-01035
Application(s): Breast Imaging

Table 7: Acoustic Output Reporting Table (Auto-Scanning Mode)

Index Label			MI	$I_{SPTA.3}$ (mW/cm^2)	$I_{SPPA.3}$ (W/cm^2)
Global Maximum Value			***0.150***	***0.00591***	***3.23***
Associated Acoustic Parameter	$p_{r.3}$ (MPa)		0.170		
	W_0 (mW)			0.188	0.188
	F_0 (MHz)		3.783	3.783	3.783
	Z_{sp} (cm)		0.300		0.300
	Beam Dimensions	x_{-6} (cm)			0.597
		y_{-6} (cm)			1.07
	PD (µsec)		0.404		0.404
	PRF (HZ)		1110		1110
	EDS	Az. (cm)		69.1	
		Ele. (cm)		1.20	
Operating Control Conditions	Length of Scan: 69.12 cm M-Lines: 1024 Image Rate: 1.085 Hz				

The MI, $I_{SPTA.3}$, and $I_{SPPA.3}$ values in this table are the limit values such that there is a 90% probability that the values for 90% of all transducer elements for the given parameter would be less than the corresponding limit.

The uncertainties in the measurements were ±0.9% for ultrasonic power and intensity, ±0.5% for pressure.

5.2.3 Derated Acoustic Output Exposure

All intensity parameters are measured in water since absorption of ultrasound by water is negligibly small compared to absorption by tissue at these frequencies. The SoftVue™ system uses water as the image acquisition medium and water is used as a worst-case value

during *in situ* testing. The maximum water values and maximum derated values do not always occur at the same operating conditions.

The derated intensity calculations are based on the measured center frequency of the acoustic signal (f_c, MHz) and the distance from the transducer under test to the hydrophone (z, cm) using the derating factor $e^{-0.069 f_c z}$.

5.2.4 System Features that Affect Acoustic Output

There are no interactive system features that affect the acoustic output.

5.3 Safety Standards

5.3.1 Regulatory Standards

The SoftVue™ system conforms to the following regulatory standards:

- IEC 60601-1: Medical electrical equipment - Part 1 – General Requirements for Safety
- IEC 60601-1-2: Medical electrical equipment – Part 1-2 – General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility - requirements and tests
- IEC 60601-1-4: Medical electrical equipment – Part 1-4 – Collateral standard: Programmable electrical medical systems
- IEC 60601-1-6: Medical electrical equipment – Part 1-6 – General requirements for basic safety and essential performance – Collateral standard: Usability
- IEC 60601-2-37: Medical electrical equipment – Part 2-37: Medical electrical equipment – Particular requirements for basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment

5.3.2 Output Display Standard

The SoftVue™ system does not adhere to the Output Display Standard in IEC 60601-2-37 as its acoustic output is fixed.

5.3.3 General Safety Standards

Table 8 lists the required declarations and states the type and degree of protection for listed hazards.

Table 8: Declaration Regarding General Safety Standards

Type	Degree of Protection
Mode of Operation	Continuous
Type of protection against electrical shock	Class I (grounded)
Degree of protection against electric shock	Type B Equipment
Degree of protection against harmful ingress of water and foreign materials	IP1X

5.3.4 Electromagnetic Compatibility (EMC)

The SoftVue™ system has been tested and found to comply with the limits for medical devices to the *IEC 60601-1-2:2014 Medical electrical equipment − Part 1-2: General requirements for safety − Collateral standard: Electromagnetic compatibility*. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. These devices generate, use and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in

the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase separation between equipment.
- Connect equipment into an outlet on a circuit different from that to which other device(s) is/are attached.
- Contact Delphinus Medical Technologies, Inc. for assistance.

All medical equipment may produce electromagnetic interference or be susceptible to electromagnetic interference. The following are guidance and manufacturer's declarations regarding EMC for the SoftVue™ system.

- The SoftVue™ system needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.
- Portable and Mobile RF communications equipment can affect the performance of the SoftVue™ system. Please use the guidelines and recommendations specified in Table 9 and Table 10.
- Other Medical Equipment or Systems can produce electromagnetic emissions and, therefore, can interfere with the functionality of the SoftVue™ system. Care should be used when operating the SoftVue™ system adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the SoftVue™ system should initially be observed to verify normal operation in the configuration in which it will be used.
- The SoftVue™ system is intended for use in the electromagnetic environment specified in Table 9. The customer or user of the device should ensure that it is used in such an environment.

WARNING: *This equipment is intended for use by healthcare professionals only. As with all electrical medical equipment, this equipment may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures such as re-orienting or relocating SoftVue™ or shielding the location.*

Table 9: Guidance and Manufacturer's Declaration - Electromagnetic Emissions

Emissions test	Compliance	Electromagnetic environment - guidance
RF Emissions - CISPR 11 (Radiated & Conducted)	Group 1	The SoftVue™ system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions - CISPR 11 (Radiated & Conducted)	Class A	The emissions characteristics of SoftVue™ make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Harmonic Emissions EN/IEC 61000-3-2	Not Applicable (AC input current exceeds 16A)	
Voltage fluctuations/ Flicker Emissions EN/IEC 61000-3-3	Not Applicable (AC input current exceeds 16A)	

5.3.5 Electromagnetic Immunity

The SoftVue™ system is intended for use in the electromagnetic environment specified in Table 10 below. The customer or user should ensure that they are used in such an environment.

Table 10: Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Immunity Test	EN/IEC 60601 Test Level	Compliance Level	Intended Electromagnetic Environment
Electrostatic Discharge (ESD) EN/IEC 61000-4-2	± 8kV contact ± 2, 4, 8, 15kV air	± 8kV contact ± 2, 4, 8, 15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst EN/IEC 61000-4-4	± 2kV	± 2kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN/IEC 61000-4-5	± 1kV differential mode (line-line) ± 2kV common mode (line-earth)	± 1kV differential mode (line-line) ± 2kV common mode (line-earth)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines EN/IEC 61000-4-11	100% dip for 15 seconds, 3 cycles	Not Applicable (AC input current exceeds 16A)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the system requires continued operation during power mains interruptions, it is recommended that the system be powered from an uninterruptible power supply or a battery.

Immunity Test	EN/IEC 60601 Test Level	Compliance Level	Intended Electromagnetic Environment
Power frequency (50/60Hz) magnetic field EN/IEC 61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity fields from RF wireless communications equipment EN/IEC 61000-4-3	144MHz-2.4GHz	144MHz-2.4GHz	Exposure to RF wireless communications equipment should be that of a typical commercial or hospital environment.

5.3.6 Electromagnetic Immunity for Systems that are Not Life-Supporting

The SoftVue™ system components are intended for use in the electromagnetic environment specified in Table 11 below. The customer or use of the SoftVue™ system should ensure that they are used in such an electromagnetic environment.

Table 11: Guidance and Manufacturer's Declaration - Electromagnetic Immunity for ME Equipment and ME Systems that are Not Life-Supporting

Immunity Test	EN/IEC 60601 Test Level	Compliance Level	Intended Electromagnetic Environment
Conducted RF EN/IEC 61000-4-6	3Vrms 150kHz to 80MHz	3Vrms 150kHz to 80MHz	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of SoftVue, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
Radiated RF EN/IEC 61000-4-3	3V/m 80MHz to 100MHz	3V/m 80MHz to 100MHz	

5.3.7 Laser Component Compliance

The SoftVue™ system's Breast Interface Assembly contains a Class 1 laser component. Class 1 laser products are not considered hazardous. This laser component is certified by the manufacturer to comply with US 21 CFR 1040.10/1040.11 and IEC 60825-1:2007. Laser wavelength = 655nm. Laser Output <0.20mW. Laser Pulse Duration = 7µs to 2ms.

Chapter 6: Symbols

Symbols used in this manual and/or on SoftVue™ labeling are listed in Table 12 below.

Table 12: Symbols Used in SoftVue™ Labeling

Symbol	Symbol Title	Standard or Regulatory Reference / Symbol Ref. #	Description / Explanatory Text
	Manufacturer	ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements ISO 7000 # 3082	Indicates the medical device manufacturer.
	Date of manufacture	ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements ISO 7000 # 2497	Indicates the date when the medical device was manufactured.
	Use-by date	ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements ISO 7000 # 2607	Indicates the date after which the medical device is not to be used.
	Batch code	ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements ISO 7000 # 2492	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Serial number	ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements ISO 7000 # 2498	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Catalogue number	ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements ISO 7000 # 2493	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Follow instructions for use	IEC 60601-1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance ISO 7010 # M002	To signify that the instruction manual/booklet must be read

Symbol	Symbol Title	Standard or Regulatory Reference / Symbol Ref. #	Description / Explanatory Text
	Consult instructions for use	ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements IEC 60601-1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance ISO 7000 # 1641	Indicates the need for the user to consult the instructions for use.
	**Caution:** Federal law restricts this device to sale by or on the order of a physician.	FDA Guidance: Alternative to Certain Prescription Device Labeling Requirements, 21 CFR 801.109 Ref. # N/A	Requires prescription in the United United States.
	Do not re-use	ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements ISO 7000 # 1051	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	Non-sterile	ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements ISO 7000 # 2609	Indicates a medical device that has not been subjected to a sterilization process.
	Do not use if package is damaged	ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements ISO 7000 # 2606	Indicates a medical device that should not be used if the package has been damaged or opened.
	General warning sign	IEC 60601-1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance ISO 7010 # W001	To signify a general warning.
	Warning, electricity	IEC 60601-1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance ISO 7010 # W012	To warn of electricity.

Symbol	Symbol Title	Standard or Regulatory Reference / Symbol Ref. #	Description / Explanatory Text
	Dangerous voltage	IEC 60601-1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC 60417 # 5036	To indicate hazards arising from dangerous voltages.
	Type B Applied Part	IEC 60601-1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC 60417 # 5840	Applied part complying with the specified requirements of IEC 60601-1 to provide protection against electric shock, particularly regarding allowable patient leakage current and patient auxiliary current.
	Alternating Current	IEC 60601-1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC 60417 # 5032	To indicate on the rating plate that the equipment is suitable for alternating current only; to identify relevant terminals.
	Protective earth (ground)	IEC 60601-1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC 60417 # 5019	To identify any terminal which is intended for connection to an external conductor for protection against electric shock in case of a fault, or the terminal of a protective earth (ground) electrode.
	Equipotentiality	IEC 60601-1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC 60417 # 5021	To identify the terminals which, when connected together, bring the various parts of an equipment or of a system to the same potential, not necessarily being the earth (ground) potential, e.g. for local bonding.
	“ON” (power)	IEC 60601-1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC 60417 # 5007	To indicate connection to the mains, at least for mains switches or their positions, and all those cases where safety is involved.

Symbol	Symbol Title	Standard or Regulatory Reference / Symbol Ref. #	Description / Explanatory Text
	Stand-by	IEC 60601-1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC 60417 # 5009	To identify the switch or switch position by means of which part of the equipment is switched on in order to bring it into the stand-by condition, and to identify the control to shift to or to indicate the state of low power consumption.
	Emergency Stop	IEC 60601-1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC 60417 # 5638	To identify an emergency stop control device.
	Collect separately from other household waste.	EN 50419:2006 Marking of Electrical and Electronic Equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE). Ref. # N/A	Electrical equipment, do not throw in trash.
	Fragile, handle with care	ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements ISO 7000 # 0621	Indicates a medical device that can be broken or damaged if not handled carefully.
	Keep away from sunlight	ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements ISO 7000 # 0624	Indicates a medical device that needs protection from light sources.
	Temperature limit	ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements ISO 7000 # 0632	Indicates the temperature limits to which the medical device can be safely exposed.
	Humidity limitation	ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements ISO 7000 # 2620	Indicates the range of humidity to which the medical device can be safely exposed.

Symbol	Symbol Title	Standard or Regulatory Reference / Symbol Ref. #	Description / Explanatory Text
IP1X	International Protection Rating	IEC 60601-1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC 60529 Degrees of Protection Provided by Enclosures (IP Code)	N_1 = 1 Protected against solid foreign objects of 50 mm ø and greater When a characteristic numeral is not required to be specified, it is replaced by the letter "X"
	Notes	N/A	Messages containing useful information that can save time or avoid errors.

Chapter 7: Components List

The SoftVue™ design requires the in-line filter manufactured by Pall Life Sciences, as well as the Sequr™ Breast Interface supplied by Delphinus, listed in Table 13 below. The filter is validated for 31 days of use and needs to be replaced each month. The filter lifespan is tracked on SoftVue™, and if the filter is overdue to be replaced, SoftVue™ will not allow the user to perform an imaging procedure without replacing the filter.

Table 13: Customer Required Components

Product Code	Description	Manufacturer	Quantity
AQINA	31 Day in-line, 0.2µm all microbial filter	Pall Life Sciences	1/month
900-00010	Sequr™ Breast Interface	Delphinus Medical Technologies, Inc.	1/imaging procedure

Chapter 8: Troubleshooting

8.1 Contacting Technical Support

If the user experiences any problems with the SoftVue™ system, please contact Delphinus Technical Support at support@delphinusmt.com. For urgent matters call Delphinus at 1-855-522-9499.

8.2 System Lock

Under error conditions where the system has detected a critical failure that could present harm to the patient or the device, the system will enter a system locked state, notify the user, and attempt to shut down. A system locked state is different from the user Lock screen (see Section 3.5.1 for Lock screen details). In a system locked state, the system will start up the minimal amount of resources to enable user interaction. The status of being in a system locked state is visible in the System Status screen (see Section 3.6.1). The failure that caused the lock status must be investigated and corrected if necessary, by a Delphinus Service Representative. Only a Delphinus Service Representative can unlock the system.

***WARNING**: The system should not be left on in a system locked state. Power and water supplies to the system should be shut off and Delphinus Technical Support should be contacted immediately.*

8.3 Error Codes

Errors that may be displayed for the user and their required responses are listed in Table 14.

***NOTE:** If instructed to restart the SoftVue™ system during an error condition, first attempt to power down the system through the touchscreen display commands as instructed in Chapter 3: Operation. If this is not possible, contact Delphinus Technical Support before any additional action is taken.*

Table 14: Error Messages and Required User Action

Error Code	Error Message	User Response
-1	An unknown error occurred.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2000	Unable to connect to the scanner.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2001	Unable to perform scanner initialization.	Check that the external water source is open and that the filter does not need to be replaced. Attempt to restart the system. If error persists, contact service to resolve the issue.
2002	Unable to request scanner initialization.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2003	Unable to connect to the controller.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2004	Unable to power on the reconstruction engine chassis.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2005	Unable to initialize the controller.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2006	Unable to power on the AE board power supply.	Attempt to restart the system. If error persists, contact service to resolve the issue.

Error Code	Error Message	User Response
2007	Unable to power on the AE transmit power supplies.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2008	Unable to initialize the motors.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2009	Unable to fill the reservoir.	Check that the external water source is open and that the filter does not need to be replaced. Attempt to restart the system. If error persists, contact service to resolve the issue.
2010	Unable to fill the imaging chamber.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2011	Unable to empty the imaging chamber.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2012	Unable to connect to the reconstruction engine chassis.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2013	Unable to initialize the reconstruction engine chassis.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2014	Unable to power on all the blades of the reconstruction engine.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2015	Unable to ping all the blades of the reconstruction engine.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2016	Unable to move the motors to their home position.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2017	Unable to connect to the reconstruction engine.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2018	Unable to initialize the reconstruction engine.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2019	Connection with the scanner lost.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2020	Unable to request a system check procedure.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2021	Unable to perform a system check procedure.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2022	Unable to request a calibration procedure.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2023	Unable to perform a calibration procedure.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2024	Unable to abort the system check procedure.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2025	Unable to abort the calibration procedure.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2026	Unable to request scanner de-initialization.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2027	Unable to perform scanner de-initialization.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2028	Unable to power off the AE board power supply.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2029	Unable to power off the AE transmit power supplies.	Attempt to restart the system. If error persists, contact service to resolve the issue.

Error Code	Error Message	User Response
2030	Unable to de-initialize the reconstruction engine	Attempt to restart the system. If error persists, contact service to resolve the issue.
2031	Unable to disconnect from the reconstruction engine.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2032	Unable to power off all the blades of the reconstruction engine.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2033	Unable to power off the reconstruction engine chassis.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2034	Unable to disconnect from the controller.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2035	Unable to pre-fill the imaging chamber.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2036	Unable to abort the imaging mode on the reconstruction engine.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2037	Unable to abort the exam.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2038	Unable to fill the imaging chamber.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2039	Unable to perform a scan.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2040	Unable to stop the scan.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2041	Unable to scan the patient.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2042	Unable to reset the scan.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2043	Unable to reset the imaging chamber.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2044	Unable to complete image reconstruction.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2045	Unable to abort image transfer to external PACS server.	Verify that the PACS server settings are correct and that the PACS server communication can be established. Attempt to restart the system. If error persists, contact service to resolve the issue.
2046	Unable to perform an imaging procedure.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2047	Unable to transfer images to external PACS server.	Verify that the PACS server settings are correct and that the PACS server communication can be established. Attempt to manually transfer the images through the System Status screen. If unsuccessful, attempt to restart the system. If error persists, contact service to resolve the issue.
2048	Unable to transfer raw data to external FTP server.	Verify that the FTP server settings are correct and that the FTP server communication can be established. Attempt to manually transfer the images through the System Status screen. If unsuccessful, attempt to restart the system. If error persists, contact service to resolve the issue.

Error Code	Error Message	User Response
2049	Unable to abort raw data transfer to FTP server.	Verify that the FTP server settings are correct and that the FTP server communication can be established. Attempt to restart the system. If error persists, contact service to resolve the issue.
2050	A leak has been detected.	Contact service to resolve issue. Do not attempt to use the system.
2051	The reservoir is overheating.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2052	The reconstruction engine is overheating.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2053	The control computer is overheating.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2054	Unable to modify system settings.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2055	Unable to set IP address of external network interface.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2056	Unable to set subnet mask of external network interface.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2057	Unable to set gateway address of external network interface.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2058	Unable to configure external network interface.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2059	Unable to set IP assignment scheme of external network interface.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2060	Unable to set power state of the AE transmit power supplies.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2061	Unable to set power state of the AE board power supply.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2062	Unable to set power state of reconstruction engine chassis.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2063	Unable to set power state of a reconstruction engine blade.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2064	Unable to perform user login.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2065	Unable to perform user logout.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2066	Unable to move ring.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2067	The system is locked and can only be unlocked by a service technician.	Contact service to resolve the issue. Do not attempt to use the system.
2068	The system lost connection to the controller.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2069	Unable to configure domain name server.	Check the validity of the entries for the server connection settings.
2070	Unable to configure PACS server.	Check the validity of the entries for the server connection settings.

Error Code	Error Message	User Response
2071	Unable to configure FTP server.	Check the validity of the entries for the server connection settings.
2072	Unable to configure institution settings.	Check the validity of the entries for the institution settings.
2073	Unable to configure image storage format.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2074	Unable to configure network time protocol server.	Check the validity of the entries for the server connection settings.
2075	Unable to configure RIS server.	Check the validity of the entries for the server connection settings.
2076	Unable to echo desired server.	Verify server connection settings. Verify local host settings and status.
2077	Unable to connect to the PACS server.	Verify server connection settings. Verify local host settings and status.
2078	Unable to connect to the RIS server.	Verify server connection settings. Verify local host settings and status.
2079	Unable to connect to the FTP server.	Verify server connection settings. Verify local host settings and status.
2080	Unable to connect to the NTP server.	Verify server connection settings. Verify local host settings and status.
2081	Unable to connect to the DNS.	Verify server connection settings. Verify local host settings and status.
2082	Unable to configure system clock.	Check the validity of the entries for the date and time settings.
2083	Unable to enable network time protocol server, please check NTP configuration.	Verify server connection settings. Verify local host settings and status.
2084	Unable to disable network time protocol server.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2085	Unable to search modality worklist information.	Verify RIS server connection settings. Verify local host settings and status.
2086	Unable to configure station settings.	Check the validity of the entries for the station settings.
2087	Unable to connect to NTP server, unreachable IP address / hostname.	Verify the IP address entry or hostname. Verify local host settings and status. If using static local host configuration and a hostname verify the hostname is a fully qualified domain name.
2088	Unable to connect to DNS, unreachable IP address / hostname.	Verify the IP address entry or hostname. Verify local host settings and status. If using static local host configuration and a hostname verify the hostname is a fully qualified domain name.
2089	Unable to connect to PACS server, unreachable IP address / hostname.	Verify the IP address entry or hostname. Verify local host settings and status. If using static local host configuration and a hostname verify the hostname is a fully qualified domain name.
2090	Unable to connect to PACS server, invalid port.	Verify the PACS server port number.
2091	Unable to connect to PACS server, DICOM association failed.	Verify the AE Title of the PACS server configuration.
2092	Unable to connect to RIS server, unreachable IP address / hostname.	Verify the IP address entry or hostname. Verify local host settings and status. If using static local host configuration and a hostname verify the hostname is a fully qualified domain name.

Error Code	Error Message	User Response
2093	Unable to connect to RIS server, invalid port.	Verify the RIS server port number.
2094	Unable to connect to RIS server, DICOM association failed.	Verify the AE Title of the RIS server configuration.
2095	Unable to connect to FTP server, invalid port.	Verify the FTP server port number.
2096	Unable to login to FTP server, invalid credentials.	Verify the FTP server credentials.
2097	Unable to connect to FTP server, invalid path.	Verify the FTP server folder path.
2098	Error detected in reconstruction engine.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2099	Lost connection with reconstruction engine.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2100	Unable to connect to FTP server, unreachable IP address / hostname.	Verify the IP address entry or hostname. Verify local host settings and status. If using static local host configuration and a hostname verify the hostname is a fully qualified domain name.
2101	Unable to get system settings.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2102	Data acquisition engine overheating.	Contact service to resolve the issue. Do not attempt to use the system.
2103	Reservoir temperature sensor malfunctioned.	Contact service to resolve the issue. Do not attempt to use the system.
2104	Tank temperature sensor malfunctioned.	Contact service to resolve the issue. Do not attempt to use the system.
2105	Unable to get ring position.	Attempt to restart the system. If error persists, contact service to resolve the issue.
2106	Unable to configure time zone	Attempt to restart the system. If error persists, contact service to resolve the issue.
2109	Unable to set imaging information	Attempt to restart the system. If error persists, contact service to resolve the issue.
2111	Transmit power overcurrent detected	Contact service to resolve the issue. Do not attempt to use the system.
2112	Unable to move ring to the desired location	Attempt to restart the system. If error persists, contact service to resolve the issue.
2113	Unable to seek start scan position with auto termination	Attempt to restart the system. If error persists, contact service to resolve the issue.
2114	Unable to move ring back to start scan position	Attempt to restart the system. If error persists, contact service to resolve the issue.
2115	Unable to disinfect tank	Attempt to restart the system. If error persists, contact service to resolve the issue.
2116	Unable to set patient info settings	Attempt to restart the system. If error persists, contact service to resolve the issue.
2117	Unexpected reset occurred on the controller	Attempt to restart the system. If error persists, contact service to resolve the issue.
2118	Motor error occurred on the controller	Attempt to restart the system. If error persists, contact service to resolve the issue.

Error Code	Error Message	User Response
2119	Unable to perform disinfection	Attempt to restart the system. If error persists, contact service to resolve the issue.
2120	Unable to sanitize ePHI	Attempt to restart the system. If error persists, contact service to resolve the issue.
2121	Unable to abort sanitize ePHI	Attempt to restart the system. If error persists, contact service to resolve the issue.

8.4 Other Issues

Table 15 displays potential problems that may be observed by the user but not detected by the system software as errors or warnings. If the required action is not successful or the user is not comfortable troubleshooting, contact Delphinus Technical Support.

Table 15: Issues and Resolutions

Component Category	Observed Problem	Potential Cause(s)	Required Action
Power On	System does not power on when the green “ON” button is pressed	The emergency stop button may be engaged	Twist the emergency stop button to the right, then release, to disengage it. If the problem is not resolved, contact Delphinus service.
Calibration	Calibration status shows “Not calibrated” when viewing System Status	A status of “Not calibrated” could mean calibration has not been done, or the most recent calibration has failed	Refer to Section 3.7 to calibrate the SoftVue™ system.
Breast Interface Assembly	Breast Interface Assembly carriage does not pull down all the way during imaging	The carriage has become clogged with debris	Execute the preventative maintenance cleaning described in section 4.2.2.1, then compress the carriage by hand and allow it to extend several times.
Reservoir	Reservoir water level remains at the same percentage when the reservoir is filling	The external water source is not filling the reservoir	Check to ensure that the external water source is on and that the microbial filter is not due to be replaced.
Touchscreen Display	No display picture	Disconnected power or video cable; Power button is off.	Check all cable connections in back of display and confirm the display power button is on.
		System was restarted before it completely powered down	Power off the system using the emergency stop button. Let the system sit until all noise stops. Reset the emergency stop button and restart the system.

Component Category	Observed Problem	Potential Cause(s)	Required Action
	Blue LED is illuminated but no display picture	Poor cable connection	Check all cable connections in back of display.
	Display shows lines or strange patterns	Poor cable connection	Check the connection in back of display.
	Image is dim	Poor cable connection; Display color/brightness settings have been modified	Check all cable connections in back of display. Use the local buttons on the touchscreen display to modify color/brightness settings.
	Non-responsive to touch inputs	Single-touch monitor is already sensing input	Ensure no other objects are near or are already in contact with the display, and there are no water drops on the monitor. The display can only respond to a single input at a time and can be sensitive to objects near the screen.
		Drop-down menus not activated correctly	Drop-down menus on the GUI need to be pressed and held for one second to open and display the options that can be selected. If a drop-down menu is not held long enough, it will not activate.
		USB connection issue	Disconnect and reconnect the USB cable connection in the back of the display.

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